IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TECAN GENOMICS, INC., Plaintiff, v. QIAGEN SCIENCES, LLC, QIAGEN GAITHERSBURG, LLC f/k/a QIAGEN GAITHERSBURG, INC., QIAGEN GMBH, and QIAGEN N.V., Defendants.	)	C.A. No. 23-1115-GBW **JURY TRIAL DEMANDED**

DEFENDANTS' ANSWER AND DEFENSES

Defendants QIAGEN Sciences, LLC, QIAGEN Gaithersburg, LLC, QIAGEN GmbH, and QIAGEN N.V. (collectively "QIAGEN"), by and through the undersigned attorneys, hereby provides the following answer and defenses in response to the Complaint of Tecan Genomics, Inc. ("Tecan"). To the extent not specifically admitted herein, the allegations of the Complaint are denied. QIAGEN denies any allegations that may be implied by or inferred from the headings of the Complaint.

ANSWER

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"), 11,098,357 ("the '357 patent"), and 11,725,241 ("the '241 patent") (collectively "the Asserted Patents") (attached hereto as Exhibits 1–4 respectively).

RESPONSE: QIAGEN admits that Tecan's Complaint purports to allege claims for past, ongoing, and future acts of infringement of U.S. Patent Nos. 10,036,012 ("the '012 patent"), 10,876,108 ("the '108 patent"), 11,098,357 ("the '357 patent"), and 11,725,241 ("the '241 patent")

(collectively "the Asserted Patents"). QIAGEN denies that it infringes the Asserted Patents. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 1.

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-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.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 2 and on that basis denies them.

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.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 3 and on that basis denies them.

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 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

[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 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.*

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.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 4 and on that basis denies them.

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.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 5 and on that basis denies them.

6. Given the nature, and substantial benefits, of Tecan Genomics' patented technologies, others, including Defendants, have infringed and continue to infringe Tecan Genomics' patents. Defendants 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 NGS target enrichment technology. In reality, however, these products use technologies developed and patented by Tecan Genomics, including those claimed in the '012, '108, '357, and '241 patents.

RESPONSE: QIAGEN denies that it has infringed or continues to infringe Tecan's patents. QIAGEN denies that is uses or continues to use Tecan's patented NGS technology. QIAGEN denies that it provides services and kits that use the enrichment and related technologies that Tecan developed years ago. QIAGEN denies the remaining allegations of Paragraph 6.

7. Defendants knowingly and willfully infringe the Asserted Patents. For example, in 2013, QIAGEN attempted to purchase NuGEN. During its due diligence, QIAGEN became privy to both confidential information relating to the design of NuGEN's proprietary products, as well as its intellectual property (including, but not limited to, the disclosure of patents granted and filed by NuGEN at the time). As part of this due diligence, QIAGEN became aware of the inventions

of the Asserted Patents and NuGEN's patent submissions. Despite extensive diligence, a deal was not finalized. Instead, QIAGEN acquired Enzymatics Inc. ("Enzymatics"), one of NuGEN's competitors, in late 2014, and began commercializing products that made use of Tecan Genomics' proprietary technology, as claimed in the Asserted Patents.

RESPONSE: To the extent Paragraph 7 of the Complaint implicates legal conclusions, no response is required. QIAGEN admits that from time to time it has in the past been involved in business discussions with Tecan. QIAGEN denies that it willfully infringes any Tecan patent or that it has improperly used any Tecan proprietary information.

8. Not only was QIAGEN familiar with the Asserted Patents prior to its commercialization of its infringing products, but, on information and belief, QIAGEN also was made aware of the Asserted Patents through Enzymatics. Specifically, prior to the acquisition by QIAGEN, Enzymatics had acquired ArcherDX, Inc. ("Archer"), a competitor of NuGEN that had long been aware of NuGEN's patented technology and had commercialized its own infringing products. As part of QIAGEN's due diligence on Enzymatics, it would have been made aware of Enzymatics and Archer's knowledge and infringement of NuGEN's proprietary technology and patents. Despite knowing this, as part of the Enzymatics acquisition, QIAGEN partnered with Archer to use its infringing enrichment and sequencing technologies. On information and belief, Archer and QIAGEN knew of the Asserted Patents and their infringement, yet they continued to use NuGEN's proprietary technology without authorization.

RESPONSE: QIAGEN denies that it knew of and willfully infringed Tecan patents or used Tecan proprietary technology without authorization. QIAGEN denies the remaining allegations in paragraph 8.

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 letter.

RESPONSE: QIAGEN admits that Tecan contacted QIAGEN in 2023. QIAGEN denies that its products infringe Tecan's patents. QIAGEN denies the remaining allegations of Paragraph 9.

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.

RESPONSE: To the extent Paragraph 10 of the Complaint implicates legal conclusions, no response is required. QIAGEN denies that it infringes Tecan Genomics patents, including

infringement that is pervasive and willful. QIAGEN admits that Tecan's complaint seeks compensation for alleged patent infringement and an injunction to prevent QIAGEN from further infringing Tecan Genomics' patented technology without permission. QIAGEN denies the remaining allegations of Paragraph 10.

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.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 11 and on that basis denies them.

12. On information and belief, QIAGEN Sciences, LLC ("QIAGEN Sciences") is a Delaware limited liability company having a principal place of business at 19300 Germantown Road, Germantown, MD 20874. On further information and belief, QIAGEN Sciences is a wholly-owned subsidiary of QIAGEN Gaithersburg, Inc. QIAGEN Sciences is responsible for QIAGEN's North American manufacturing, research, and development, including Defendants' QIAseq Targeted DNA Panel, QIAseq Targeted Methyl Panel, QIAseq Targeted RNAscan Panel, and QIAseq Immune Repertoire RNA Library. QIAGEN Sciences can be served with process through its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

RESPONSE: QIAGEN admits that QIAGEN Sciences, LLC is a Delaware limited liability company having a place of business at 19300 Germantown Road, Germantown, MD 20874. QIAGEN admits that QIAGEN Sciences, LLC is a subsidiary of QIAGEN Gaithersburg, LLC. QIAGEN admits that QIAGEN Sciences is involved in QIAGEN's North American manufacturing, research, and development. QIAGEN admits that QIAGEN Sciences' registered agent is Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 12.

13. On information and belief, QIAGEN Gaithersburg, LLC f/k/a QIAGEN Gaithersburg, Inc. ("QIAGEN Gaithersburg") is a Delaware limited liability company having a principal place of business at 19300 Germantown Road, Germantown, MD 20874. QIAGEN Gaithersburg is involved in the research, development, and marketing of QIAGEN products, including Defendants' QIAseq Targeted DNA Panel, QIAseq Targeted Methyl Panel, QIAseq

Targeted RNAscan Panel, and QIAseq Immune Repertoire RNA Library. QIAGEN Gaithersburg can be served with process through its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

RESPONSE: QIAGEN admits that QIAGEN Gaithersburg, LLC is a Delaware limited liability company having a place of business at 19300 Germantown Road, Germantown, MD 20874. QIAGEN admits that QIAGEN Gaithersburg's registered agent is Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 13.

14. On information and belief, QIAGEN GmbH is a German corporation having a principal place of business at Qiagen Strasse 1 40724, Hilden, Germany. On further information and belief, QIAGEN GmbH has directly and through its subsidiaries marketed and helped to sell QIAGEN-branded products, including QIAseq products, in the United States, including in Delaware, and continues to do so. Furthermore, QIAGEN GmbH has admitted that it "controls the Qiagen.com website, which offers products for sale worldwide." *Illumina, Inc. v. Qiagen N.V.*, Case No. 16-cv-02788-WHA (N.D. Cal.) (QIAGEN GmbH's Answer to Complaint for Patent Infringement, at ¶ 2).

RESPONSE: QIAGEN admits that QIAGEN GmbH is a German corporation having a place of business at QIAGEN Strasse 1 40724, Hilden, Germany. QIAGEN admits that QIAGEN GmbH controls the QIAGEN.com website. To the extent Paragraph 14 of the Complaint implicates legal conclusions, no response is required. To the extent that a further response is required, QIAGEN denies the remaining allegations and characterizations contained in Paragraph 14 of the Complaint.

15. On information and belief, QIAGEN N.V. is a Dutch corporation having a principal place of business at Hulsterweg 82, 5912 PL Venlo, The Netherlands. On further information and belief, QIAGEN N.V. is "the ultimate parent of a number of subsidiaries in the United States" including named QIAGEN Sciences and QIAGEN Gaithersburg. *Illumina, Inc. v. Qiagen N.V.*, Case No. 16-cv-02788-WHA (N.D. Cal.) (QIAGEN N.V.'s Answer to Complaint for Patent Infringement, at ¶ 8). QIAGEN N.V. is also the ultimate parent of QIAGEN GmbH. On further information and belief, QIAGEN N.V. has directly and through its subsidiaries marketed and helped to sell QIAGEN-branded products, including the QIAseq products, in the United States, including in Delaware, and continues to do so.

RESPONSE: QIAGEN admits that QIAGEN N.V. is a Dutch corporation having a place of business at Hulsterweg 82, 5912 PL Venlo, The Netherlands. QIAGEN admits that QIAGEN N.V.

is the ultimate parent corporation of QIAGEN Sciences, QIAGEN Gaithersburg, and QIAGEN GmbH. QIAGEN admits that certain subsidiaries of QIAGEN N.V. have marketed and helped to sell certain QIAGEN-branded products, including certain QIAseq products, in the United States. To the extent Paragraph 15 of the Complaint implicates legal conclusions, no response is required. To the extent that a further response is required, QIAGEN denies the remaining allegations and characterizations contained in Paragraph 15 of the Complaint.

JURISDICTION AND VENUE

16. 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.

RESPONSE: QIAGEN admits that the Complaint purports to allege claims arising under federal law, including the Patent Act, 35 U.S.C. § 1 *et seq*., but denies that there is any factual or legal basis for any such action. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 16.

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

RESPONSE: QIAGEN admits that the Court has subject matter jurisdiction over claims arising under these statutes pursuant to 28 U.S.C. §§ 1331 and 1338(a). Except as specifically admitted, QIAGEN denies the allegations in Paragraph 17.

18. This Court has personal jurisdiction over QIAGEN Sciences because QIAGEN Sciences is organized and exists under the laws of the State of Delaware and is a resident of the State of Delaware. QIAGEN Sciences has purposefully availed itself of the benefits and protections of Delaware state law by organizing under Delaware law. Additionally, QIAGEN Sciences has designated Corporation Service Company as its registered agent for service of process in the State of Delaware. On information and belief, QIAGEN Sciences, through or with QIAGEN GmbH, sells and/or offers for sale QIAGEN's infringing products and services through the website QIAGEN.com throughout the United States, including in Delaware.

RESPONSE: To the extent Paragraph 18 of the Complaint implicates legal conclusions, no response is required. QIAGEN does not contest personal jurisdiction over QIAGEN Sciences in

this judicial district solely for purposes of this action. QIAGEN admits QIAGEN Sciences has designated Corporation Service Company as its registered agent for service of process in the State of Delaware. QIAGEN denies that its products infringe. Except as specifically admitted, QIAGEN denies the allegations and characterizations in Paragraph 18.

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

RESPONSE: To the extent Paragraph 19 of the Complaint implicates legal conclusions, no response is required. QIAGEN does not contest personal jurisdiction over QIAGEN Gaithersburg in this judicial district solely for purposes of this action. QIAGEN does not contest personal jurisdiction over QIAGEN Gaithersburg in this judicial district solely for purposes of this action. QIAGEN admits QIAGEN Gaithersburg has designated Corporation Service Company as its registered agent for service of process in the State of Delaware. QIAGEN denies that its products infringe. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 19.

20. This Court has personal jurisdiction over QIAGEN GmbH because of QIAGEN GmbH's tortious acts against Tecan Genomics, including that, on information and belief, QIAGEN GmbH sells and/or offers for sale QIAGEN's infringing products through the website QIAGEN.com throughout the United States, including in Delaware.

RESPONSE: QIAGEN denies that this court has personal jurisdiction over QIAGEN GmbH in this judicial district. QIAGEN denies that its products infringe and denies that it committed tortious acts against Tecan. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 20.

21. This Court has personal jurisdiction over QIAGEN N.V. because of QIAGEN N.V.'s tortious acts against Tecan Genomics, including that, on information and belief, QIAGEN N.V., through or with QIAGEN GmbH, sells and/or offers for sale QIAGEN's infringing products through the website QIAGEN.com throughout the United States, including in Delaware.

RESPONSE: QIAGEN denies that this court has personal jurisdiction over QIAGEN N.V. in this judicial district. QIAGEN denies that its products infringe and denies that it committed tortious acts against Tecan. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 21.

22. QIAGEN GmbH and QIAGEN N.V. are alternatively subject to personal jurisdiction under Fed. R. Civ. P. 4(k)(2). Rule 4(k)(2) allows "'a court to exercise personal jurisdiction over a defendant if (1) the plaintiff's claim arises under federal law, (2) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction, and (3) the exercise of jurisdiction comports with due process.'" *Bos. Sci. Corp. v. Micro-Tech Endoscopy USA Inc.*, No. 18-cv-1869-CFC-CJB, 2020 WL 229993, at *4 (D. Del. Jan. 15, 2020) (quoting *M-I Drilling Fluids UK Ltd. v. Dynamic Air Ltda.*, 890 F.3d 995, 999 (Fed. Cir. 2018)), report and recommendation adopted (Dkt. 66, Feb. 5, 2020).

RESPONSE: Paragraph 22 states legal conclusions to which no response is required. To the extent a response is required, QIAGEN denies that this court has personal jurisdiction over QIAGEN GmbH or QIAGEN N.V. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 22.

23. With regard to the first prong, Plaintiff brings this action to seek relief for Defendants' patent infringement under federal law.

RESPONSE: Paragraph 23 states legal conclusions to which no response is required. QIAGEN admits that Plaintiff purportedly brings this action to seek relief for Defendant's alleged patent infringement under federal law. To the extent further response is required, QIAGEN denies that this court has personal jurisdiction over QIAGEN GmbH or QIAGEN N.V. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 23.

24. With regard to the second prong, on information and belief, QIAGEN GmbH is a German corporation having a principal place of business at Qiagen Strasse 1 40724, Hilden, Germany. On further information and belief, QIAGEN GmbH does not maintain any offices in the United States. To the extent that exercise of personal jurisdiction under the Delaware long-arm statute is not proper, then on information and belief, QIAGEN GmbH is not subject to jurisdiction in any state's courts of general jurisdiction.

RESPONSE: Paragraph 24 states legal conclusions to which no response is required. To the extent a response is required, QIAGEN denies that this court has personal jurisdiction over QIAGEN GmbH or QIAGEN N.V. QIAGEN admits QIAGEN GmbH is a German corporation having a place of business at Qiagen Strasse 1 40724, Hilden, Germany and does not maintain any offices in the United States. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 24.

25. On information and belief, QIAGEN N.V. is a Dutch corporation having a principal place of business at Hulsterweg 82, 5912 PL Venlo, The Netherlands. On further information and belief, QIAGEN N.V. does not maintain any offices in the United States. To the extent that exercise of personal jurisdiction under the Delaware long-arm statute is not proper, then on information and belief, QIAGEN N.V. is not subject to jurisdiction in any state's courts of general jurisdiction.

RESPONSE: Paragraph 25 states legal conclusions to which no response is required. To the extent a response is required, QIAGEN denies that this court has personal jurisdiction over QIAGEN GmbH or QIAGEN N.V. QIAGEN admits QIAGEN N.V. is a Dutch corporation having a place of business at Hulsterweg 82, 5912 PL Venlo, The Netherlands and does not maintain any offices in the United States. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 25.

26. With regard to the third prong, courts consider whether (1) the defendant purposefully directed its activities at residents of the United States, (2) the claim arises out of or relates to the defendant's activities within the United States, and (3) assertion of personal jurisdiction is reasonable and fair. *Bos. Sci. Corp.*, 2020 WL 229993, at *6. QIAGEN N.V., through or with QIAGEN GmbH, sells and/or offers for sale QIAGEN's infringing products through the website QIAGEN.com throughout the United States. QIAGEN GmbH sells and/or offers for sale QIAGEN's infringing products through the website QIAGEN.com throughout the United States. The unlicensed sale or offer for sale of QIAGEN's infringing products serves as the basis for Plaintiff's patent infringement claims.

RESPONSE: Paragraph 26 states legal conclusions to which no response is required. To the extent a response is required, QIAGEN denies that this court has personal jurisdiction over

QIAGEN GmbH or QIAGEN N.V. To the extent further response is required, QIAGEN denies the remaining allegations in Paragraph 26.

27. Assertion of personal jurisdiction over QIAGEN N.V. and QIAGEN GmbH is reasonable and fair. Any burden on QIAGEN N.V. and QIAGEN GmbH is sufficiently outweighed by the interest of the United States in adjudicating Plaintiff's claims, which are based on infringement of U.S. patents and the sale of the Accused Products in the U.S., and by the interests of Plaintiff in obtaining effective and convenient relief. *Bos. Sci. Corp.*, 2020 WL 229993, at *7–8. As such, this Court has personal jurisdiction over QIAGEN N.V. and QIAGEN GmbH pursuant to Fed. R. Civ. P. 4(k)(2).

RESPONSE: Paragraph 27 states legal conclusions to which no response is required. To the extent a response is required, QIAGEN denies that this court has personal jurisdiction over QIAGEN GmbH or QIAGEN N.V. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 27.

28. 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 Defendants' QIAseq Targeted DNA Panel, QIAseq Targeted Methyl Panel, QIAseq Targeted RNAscan Panel, QIAseq Immune Repertoire RNA Library, and all other Defendants' products that make use of Defendants' enrichment technology 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.

RESPONSE: Paragraph 28 states legal conclusions to which no response is required. To the extent a response is required, QIAGEN denies that this court has personal jurisdiction over QIAGEN GmbH or QIAGEN N.V. QIAGEN denies that any Defendants engage in infringing activities in Delaware. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 28.

29. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400. On information and belief, QIAGEN Sciences and QIAGEN Gaithersburg reside in this District, and therefore meet the requirements of 28 U.S.C. § 1400(b). Venue is proper pursuant to 28 U.S.C. § 1391(c)

in any District, including the District of Delaware, for the foreign entities QIAGEN GmbH and QIAGEN N.V.

RESPONSE: Paragraph 29 states legal conclusions to which no response is required. To the extent a response is required, QIAGEN denies that this court venue is proper in this district for Defendant QIAGEN GmbH or Defendant QIAGEN N.V. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 29.

BACKGROUND

Tecan Genomics & NuGEN [Alleged] Innovations

30. 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.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 30 and on that basis denies them.

31. 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]

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 31 and on that basis denies them.

32. 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.

[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.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 32 and on that basis denies them.

33. 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.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 33 and on that basis denies them.

34. 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.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 34 and on that basis denies them.

The Amorese Enrichment Patents – '012 and '108 patents

35. 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.

RESPONSE: QIAGEN admits that United States Patent No. 10,036,012 ("the '012 patent"), on its face is entitled "Compositions and Methods for Targeted Nucleic Acid Sequence Enrichment and High Efficiency Library Generation" and states that it was issued to Doug Amorese, Chris Armour, and Nurith Kurn on July 31, 2018 and assigned to NuGEN Technologies, Inc. QIAGEN admits that a purported copy of the '012 patent is attached to the Complaint as Exhibit 1. QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the

allegation that Tecan is currently 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. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 35.

36. 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.

RESPONSE: QIAGEN admits that United States Patent No. 10,876,108 ("the '108 patent"), on its face is entitled "Compositions and Methods for Targeted Nucleic Acid Sequence Enrichment and High Efficiency Library Generation" and states that it was issued to Doug Amorese, Chris Armour, and Nurith Kurn on December 29, 2020 and assigned to NuGEN Technologies, Inc. QIAGEN admits that a purported copy of the '108 patent is attached to the Complaint as Exhibit 2. QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegation that Tecan is currently 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. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 36.

37. 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 37 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '012 and '108 patents, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope

of the ’012 and ’108 patents. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 37.

38. 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.

RESPONSE: QIAGEN admits that Tecan quoted certain passages from the ’012 and ’108 patents. QIAGEN denies that Tecan properly construed those passages and to the extent that the allegations in Paragraph 38 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’012 and ’108 patents, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’012 and ’108 patents. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 38.

39. 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 39 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '012 patent, those documents are the best source of their full content and context. QIAGEN admits that Tecan quoted certain passages from the '012 patent. QIAGEN denies these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope of the '012 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 39.

40. 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.

RESPONSE: QIAGEN admits that Tecan quoted certain passages from the '012 patent and asserts that, to the extent that the allegations in Paragraph 40 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '012 patent, those documents are the best source of their full content and context. QIAGEN denies

these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope of the '012 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 40.

41. 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.*

RESPONSE: QIAGEN admits that Tecan quoted certain passages from the '012 and '108 patents and asserts that, to the extent that the allegations in Paragraph 41 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '012 and '108 patents, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope of the '012 and '108 patents. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 41.

42. 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.

RESPONSE: QIAGEN admits that Tecan quoted certain passages from the '012 and '108 patents and asserts that, to the extent that the allegations in Paragraph 42 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '012 and '108 patents, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope of the '012 and '108 patents. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 42.

43. 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.

RESPONSE: QIAGEN admits that Tecan quoted certain passages from the ’012 and ’108 patents and asserts that, to the extent that the allegations in Paragraph 43 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’012 and ’108 patents, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’

full content and context, or do not correspond to the proper legal scope of the ’012 and ’108 patents. It does appear that Tecan correctly quoted language from claim 1 of the ‘012 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 43.

44. 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 44 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’012 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’012 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 44.

45. 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 45 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’012 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’012 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 45.

46. 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:
>
> 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 46 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’108 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’108 patent. QIAGEN admits that Tecan appears to have correctly copied the language from claim 1 of the ’108 patent in this paragraph. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 46.

47. 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 47 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’108 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’108 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 47.

48. 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 48 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’108 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’108 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 48.

The Amorese UMI Patents – ’357, and ’241 patents

49. 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 3.

RESPONSE: QIAGEN admits that United States Patent No. 11,098,357 ("the '357 patent"), on its face is entitled "Compositions and Methods for Identification of a Duplicate Sequencing Read" and states that it was issued to Doug Amorese, Jonathan Scolnick, and Ben Schroeder on August 24, 2021 and assigned to Tecan Genomics, Inc. QIAGEN admits that a purported copy of the '357 patent is attached to the Complaint as Exhibit 3. QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegation that Tecan is currently 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. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 49.

50. 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 4.

RESPONSE: QIAGEN admits that United States Patent No. 11,725,241 ("the '241 patent"), on its face is entitled "Compositions and Methods for Identification of a Duplicate Sequencing Read" and states that it was issued to Doug Amorese, Jonathan Scolnick, and Ben Schroeder on August 15, 2023 and assigned to Tecan Genomics, Inc. QIAGEN admits that a purported copy of the '241 patent is attached to the Complaint as Exhibit 4. QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegation that Tecan is currently 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. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 50.

51. The inventions of the ’357 and ’241 patents are directed to “methods, compositions, and kits for detecting duplicate sequencing reads.” Ex. 3 at Abstract. The ’357 and ’241 patents disclose that “[i]n some embodiments, the duplicate reads are removed.” *Id.*

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 51 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’357 and ’241 patents, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’357 and ’241 patents. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 51.

52. As the ’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 ’357 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 1:35–56.

RESPONSE: QIAGEN admits that Tecan appears to have correctly copied excerpts from the ’357 and ’241 patents. QIAGEN asserts that, to the extent that the allegations in Paragraph 52 purport to summarize one or more documents, or otherwise provide a general description directed to the

proper legal scope of the ’357 and ’241 patents, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’357 and ’241 patents. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 52.

53. The ’357 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 1:56–65.

RESPONSE: QIAGEN admits that Tecan appears to have correctly copied excerpts from the ’357 patent. QIAGEN asserts that, to the extent that the allegations in Paragraph 53 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’357 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’357 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 53.

54. However, as the ’357 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 1:65–2:03.

RESPONSE: QIAGEN admits that Tecan appears to have correctly copied excerpts from the '357 patent. QIAGEN asserts that, to the extent that the allegations in Paragraph 54 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '357 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope of the '357 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 54.

55. The inventions of the '357 and '241 patents fulfill that need. As explained by the '357 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 2:03–05.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 55 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '357 and '241 patents, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope of the '357 and '241 patents. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 55.

56. The '357 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 2:15–17.

RESPONSE: QIAGEN admits that Tecan appears to have correctly copied excerpts from the ’357 patent. QIAGEN asserts that, to the extent that the allegations in Paragraph 56 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’357 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’357 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 56.

57. To address this need in the prior art, the ’357 and ’241 patents teach and claim new methods for detecting duplicate sequencing reads. 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.

RESPONSE: QIAGEN admits that Tecan appears to have correctly copied a claim from the ’357 patent. QIAGEN asserts that, to the extent that the allegations in Paragraph 57 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’357 and ’241 patents, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope

of the ’357 and ’241 patents. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 57.

58. 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 58 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’357 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’357 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 58.

59. 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.” *Id.* 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 59 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the ’357 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents’ full content and context, or do not correspond to the proper legal scope of the ’357 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 59.

60. 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.

RESPONSE: QIAGEN admits that Tecan appears to have correctly copied a claim from the '241 patent. QIAGEN asserts that, to the extent that the allegations in Paragraph 60 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '241 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope of the '241 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 60.

61. 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 61 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '241 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope of the '241 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 61.

62. 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. 4 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.

RESPONSE: QIAGEN asserts that, to the extent that the allegations in Paragraph 62 purport to summarize one or more documents, or otherwise provide a general description directed to the proper legal scope of the '241 patent, those documents are the best source of their full content and context. QIAGEN denies these allegations to the extent they do not accurately represent the documents' full content and context, or do not correspond to the proper legal scope of the '241 patent. Except as expressly admitted, QIAGEN denies the remaining allegations of Paragraph 62.

Defendants' Accused Products

63. 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.

RESPONSE: QIAGEN denies that any of its products or services infringe Tecan's patents. QIAGEN denies any remaining allegations in Paragraph 63.

64. Specifically, Defendants have used and continue to use, manufacture and/or commercialize products using infringing technology incorporated in at least Defendants' QIAseq Targeted DNA Panel, QIAseq Targeted Methyl Panel, QIAseq Targeted RNAscan Panel, QIAseq Immune Repertoire RNA Library, and all other Defendants' products that make use of Defendants' enrichment technology (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.

RESPONSE: QIAGEN admits that certain Defendants manufacture and/or commercialize the products: QIAseq Targeted DNA Panel, QIAseq Targeted Methyl Panel, QIAseq Targeted RNAscan Panel, and QIAseq Immune Repertoire RNA Library (collectively, the "Accused

Products"). QIAGEN denies that any of QIAGEN's products, including the Accused Products and associated products, make use of any infringing technology or otherwise infringe Tecan's patents. QIAGEN denies that specific references to a product or service in the Complaint are illustrative of any action(s) by Defendant. Except as specifically admitted, QIAGEN denies the allegations and characterizations in Paragraph 64.

65. On information and belief, in late 2014, QIAGEN acquired Enzymatics (and with it Archer). As part of QIAGEN's acquisition of Enzymatics, Enzymatics became a wholly-owned subsidiary of QIAGEN, and Archer was spun out as a separate entity. As part of the acquisition of Enzymatics, QIAGEN entered into a strategic partnership with Archer, providing QIAGEN with access and distribution rights for unique NGS products based on Archer's infringing AMP technology. Through this partnership, Archer 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 Archer's Board of Directors. As a result of this partnership, QIAGEN began making, using, offering to sell, and selling the Accused Products.

RESPONSE: Paragraph 65 states legal conclusions to which no response is required. To the extent a response is required, QIAGEN admits in late 2014 that it acquired Enzymatics. QIAGEN admits that, after QIAGEN's acquisition of Enzymatics, Archer was a separate entity from QIAGEN and Enzymatics. QIAGEN denies that it entered into an agreement with Archer to distribute some of Archer's NGS products. QIAGEN denies that Archer instructed QIAGEN on its infringing methods or that Archer shared information with QIAGEN employees. QIAGEN admits that a QIAGEN employee sat on Archer's Board of Directors. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 65.

66. On information and belief, QIAGEN and Archer collaborated on the development of products using Archer's infringing technology. Additionally, Archer instructed QIAGEN employees on how to use Archer's infringing technologies while Archer and QIAGEN negotiated a distributorship of Archer's infringing products. Archer and QIAGEN did not reach an agreement on distributing Archer's infringing products, and the collaboration collapsed in 2016.

RESPONSE: QIAGEN denies the allegations in Paragraph 66.

67. Later that year, on information and belief, QIAGEN released its QIAseq products incorporating Archer's infringing technologies.

RESPONSE: QIAGEN denies the allegations in Paragraph 67.

Defendants Have [Allegedly] Known of Their Infringement of the Asserted Patents

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

RESPONSE: QIAGEN admits it was aware of the asserted patents at least a day before the complaint was filed. QIAGEN denies ever infringing the asserted patents and thus has no knowledge of such infringement. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 68.

69. On information and belief, Defendants have known of Tecan Genomics' enrichment technology since 2013. On information and belief, Defendants have regularly monitored Tecan Genomics' patent filings and developments and have been aware of their infringement since the issuance of Tecan's patents. On information and belief, Defendants' monitoring of Tecan Genomics' patent portfolio since 2013 resulted in their learning of U.S. Patent No. 9,546,399 ("the '399 patent")—which shares a common specification with the '357 and '241 patents—and its patent family by at least May 14, 2015, when the application for the '399 patent published.

RESPONSE: QIAGEN denies that its products infringe any asserted patent. The remaining allegations and characterizations are too vague and undefined in for example the claim of "regular monitoring" and "Tecan enrichment technology" for QIAGEN to understand what is being alleged and on that basis denies the allegations.

70. On information and belief, QIAGEN has been aware of Tecan Genomics' proprietary enrichment technology and families of the Asserted Patents since 2013. In December 2013, NuGEN and QIAGEN entered into discussions related to QIAGEN's potential acquisition of NuGEN. As part of these discussions, QIAGEN performed extensive due diligence. As a result of that formal due diligence, QIAGEN spoke to many senior-level employees at NuGEN and reviewed various documents. As part of this due diligence, QIAGEN received unfettered access to confidential information concerning NuGEN's research and development of technologies, its entire IP portfolio, and any other trade secrets that NuGEN possessed.

RESPONSE: QIAGEN admits that NuGEN and QIAGEN entered into discussions related to QIAGEN's potential acquisition of NuGEN. QIAGEN denies that the discussions between

NuGEN related to QIAGEN's potential acquisition of NuGEN began in December 2013. QIAGEN admits that it performed some level of due diligence regarding acquisition of NuGEN. QIAGEN admits that QIAGEN's due diligence involved discussions with QIAGEN employees and reviewing various documents. QIAGEN denies that it received unfettered access to confidential information concerning NuGEN's research and development of technologies, its entire IP portfolio, and any other trade secrets that NuGEN possessed." The remaining allegations and characterizations are too vague and undefined in for example the claim of "families of the Asserted Patents" and "Tecan enrichment technology" for QIAGEN to understand what is being alleged and on that basis denies the allegations.

71. QIAGEN requested detailed information on NuGEN technologies, including a list of all patents and/or patent applications as well as utility models; copies of file histories for all pending, granted, and abandoned patents; the status of all patents that pertain or relate to NuGEN products or technology that are not owned by NuGEN; a list of invention disclosures and reports for any invention for which NuGEN had not yet sought patent protection; any research and development that may be appropriate for future patent protection; opinions regarding the validity of the patents and pending claims of applications; all documents relating to the infringement or alleged infringement of any NuGEN patents; and copies of any documents pertaining to NuGEN's trade secrets. NuGEN provided executives of QIAGEN with access to its sensitive and confidential information about its most coveted technology.

RESPONSE: QIAGEN admits that it received certain detailed information on NuGEN technologies. But at this time QIAGEN is unable to determine if QIAGEN requested from NuGEN a list of all patents and/or patent applications as well as utility models; copies of file histories for all pending, granted, and abandoned patents; the status of all patents that pertain or relate to NuGEN products or technology that are not owned by NuGEN; a list of invention disclosures and reports for any invention for which NuGEN had not yet sought patent protection; any research and development that may be appropriate for future patent protection; opinions regarding the validity of the patents and pending claims of applications; all documents relating to the infringement or alleged infringement of any NuGEN patents; and copies of any documents pertaining to NuGEN's

trade secrets and therefore denies the same. The remaining allegations and characterizations are too vague and undefined in for example the claim of "most coveted technology" for QIAGEN to understand what is being alleged and on that basis denies the allegations.

72. No acquisition occurred. Instead, QIAGEN acquired Enzymatics in December 2014. Notably, Enzymatics had previously acquired Archer, a company that also knew of NuGEN's proprietary technology, including the subject matter of the Asserted Patents.

RESPONSE: QIAGEN admits that it did not acquire NuGEN. QIAGEN admits it acquired Enzymatics in 2014. QIAGEN admits that Enzymatics acquired Archer before QIAGEN acquired Enzymatics. QIAGEN otherwise denies the allegations in this paragraph.

73. With the acquisition of Enzymatics, QIAGEN possessed both the knowledge of NuGEN's technologies that it learned through the due diligence of NuGEN, as well as knowledge specific to Enzymatics and Archer about NuGEN's technologies and their infringement of those technologies through the due diligence process and the retention of numerous high-level employees from the previous Enzymatics/Archer entity. Additionally, the collaboration agreement between QIAGEN and Archer, on information and belief, resulted in considerable information sharing, including how to use Tecan Genomics' patented technologies.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 73 of the Complaint.

74. 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.[5] On information and belief, Enzymatics agents, including one of the founders, were present at the event.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 74 and on that basis denies them.

75. 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 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/Archer approached an employee of NuGEN to tell him that Enzymatics/Archer's management team had informed the employee that they planned to file a

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

lawsuit against NuGEN related to the practice of NuGEN's enrichment technology. The NuGEN employee did not pursue the topic further with the Enzymatics/Archer employee. NuGEN subsequently provided Enzymatics/Archer with a copy of NuGEN's patent application, showing that NuGEN had in fact invented the technology. No lawsuit was ever filed.

RESPONSE: QIAGEN denies that Enzymatics integrated ArcherDX into its company as a business unit in 2014. QIAGEN admits that Enzymatics was a gold sponsor of the AGBT conference in 2014. As to the other allegations, QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 75 and on that basis denies them.

76. On information and belief, from this time onward, Defendants 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. Despite knowing of these patents and their infringement by the Accused Products, Defendants have continued to commercialize the Accused Products.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 76 of the Complaint.

77. On information and belief, several key executives at Enzymatics and Archer remained in leadership positions during QIAGEN's due diligence review, including Enzymatics' co-founders and Archer's founder. Many of these individuals continued working at QIAGEN after QIAGEN's acquisition of Enzymatics, bringing with them and sharing their knowledge of NuGEN's technology. For example, one of Enzymatics' co-founders remained at QIAGEN and served in executive roles including Vice President and Senior Vice President of Reagents for over two years, where on information and belief, he would have been obligated to share his knowledge concerning Archer's prior acts of infringement. Other key executives assumed leadership roles at Archer after the acquisition and spin-off where, on information and belief, these individuals would have imparted their knowledge of NuGEN's technology to Qiagen as part of their partnership to create infringing products.

RESPONSE: QIAGEN admits that certain employees who worked at Enzymatics continued at Enzymatics after QIAGEN acquired Enzymatics. QIAGEN admits that Enzymatics' co-founders remained at QIAGEN and served in executive roles including Vice President and Senior Vice President of Reagents for over two years. QIAGEN denies the other allegations and characterizations contained in Paragraph 77 of the Complaint.

78. Additionally, other key executives who were part of QIAGEN's due diligence review of NuGEN have remained at QIAGEN until present. For example, on information and belief, a senior executive for Corporate Business Development for the Americas at QIAGEN participated extensively in the due diligence review. He has remained at QIAGEN since then and is now the head of QIAGEN's Molecular Diagnostics Business Area. He is also on QIAGEN's Executive Committee. Likewise, on information and belief, the current Vice President for Research and Development—who was also Vice President for Research and Development at the time of the diligence review—also participated extensively in the due diligence review.

RESPONSE: QIAGEN admits that certain employees for QIAGEN were involved in QIAGEN's due diligence review of NuGEN and have remained at QIAGEN until the present. QIAGEN denies that QIAGEN's current Head of the Molecular Diagnostics Business Area participated in due diligence review or was employed at QIAGEN at the time of the due diligence review. QIAGEN admits that QIAGEN's Head of the Molecular Diagnostics Business Area is a member of the executive committee. QIAGEN admits that its Vice President for Research and Development at the time of the diligence review was a member of the team that was involved in the due diligence of NuGEN. QIAGEN denies the other allegations and characterizations contained in Paragraph 78 of the Complaint.

79. On information and belief, because of the post-spinoff partnership between Archer and QIAGEN, QIAGEN also was made aware of NuGEN's patents. Archer and Enzymatics had long been aware of and monitored NuGEN's patent filings. Not only was this information shared between Archer and Enzymatics, which became part of QIAGEN, but QIAGEN worked for years to integrate Archer's infringing technology into its products. On information and belief, Archer, through its prior relationship with Enzymatics and partnership with QIAGEN, made QIAGEN aware of NuGEN's technology and patent filings.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 79 of the Complaint.

80. 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 Defendants knew or should have known of the Asserted Patents. QIAGEN N.V. conducted a rigorous due diligence review before acquiring Archer that would have requested all information about potential IP risks. As subsidiaries under the control of QIAGEN N.V., members of the group with QIAGEN N.V. to make, use, sell, and/or offer to sell the Accused

Products, QIAGEN GmbH, QIAGEN Sciences, and QIAGEN Gaithersburg would also have been privy to the information gathered by QIAGEN N.V., including the Asserted Patents. Each Defendant knew or should have also known of the Asserted Patents given that high-level employees and executives of Archer and Enzymatics joined QIAGEN after its acquisition of Enzymatics and Archer—with many of these high-level employees and executives directing operations associated with Defendants' infringing actions that spanned the various QIAGEN entities.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 80 of the Complaint.

81. 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.[6] For example, the '012 patent has been listed in connection with Tecan Genomics' own genetic enrichment protocols and kits.

RESPONSE: QIAGEN is without information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 81 regarding Tecan's marking practices in general. QIAGEN otherwise denies the allegations in this paragraph.

82. 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 since 2014.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 82 of the Complaint.

83. Defendants were again reminded of the '012, '108, '357, and '241 patents and their infringement of those patents in advance of filing this Complaint. On September 29, 2023, Tecan Genomics sent Defendants a notice letter concerning their continued infringement of Tecan Genomics' patents, which is attached as Exhibit 5. Additionally, copies of the September 29 notice letter were emailed to QIAGEN senior executives on October 2 with one senior executive confirming receipt of the letter that same day.

RESPONSE: QIAGEN admits that on September 29, 2023, Tecan Genomics sent Defendants a notice letter concerning alleged infringement of Tecan patents. QIAGEN admits that copies of the

[6] *See, e.g.*, https://www.tecan.com/intellectual_property/patent_portfolio.

September 29 notice letter were emailed to certain QIAGEN employees on October 2, 2023. To the extent that a further response is required, QIAGEN denies the other allegations and characterizations contained in Paragraph 83 of the Complaint.

84. As of the filing of this Complaint, no further responses or communications have been received from Defendants.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 84 of the Complaint.

85. 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 notice letter, 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 Plaintiff's patent rights. On information and belief, Defendants continue to make, use, sell, and offer to sell the Accused Products that infringe the Asserted Patents.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 85 of the Complaint.

DEFENDANT'S [ALLEGED] INFRINGEMENT OF THE ASSERTED PATENTS

Defendants' [Alleged] Infringement of the '012 patent

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

RESPONSE: QIAGEN denies that it has in the past or currently infringes any claim of the '012 patent including under 35 U.S.C. §§ 271(a)-(c).

87. 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 use the Accused Products, they infringe at least claim 1 of the '012 patent.[7] 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

[7] *See* The QIAseq advantage; QIAseq Targeted DNA Panel Handbook; QIAseq Targeted Methyl Panel Handbook; QIAseq Targeted RNA Panels Handbook; QIAseq Immune Repertoire RNA Library Handbook.

claim 1 of the '012 patent.[8] 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.[9]

RESPONSE: QIAGEN denies that it has ever infringed an asserted patent.

88. Defendants coordinate to infringe Tecan Genomics' patents. For example, on information and belief, the packaging of the Accused Products bears the name of QIAGEN Sciences. On information and belief, QIAGEN Gaithersburg is involved in the research and development of components and reagents in the Accused Products. On information and belief, QIAGEN GmbH operates the QIAGEN.com website, which offers for sale and sells the Accused Products. On information and belief, QIAGEN N.V., as the ultimate parent to these subsidiaries, is directly involved in, responsible for, and benefits from the sales of the Accused Products.

RESPONSE: QIAGEN is unable to understand what is meant by the named entities coordinating to infringe and thereby denies that allegation. QIAGEN admits that QIAGEN GmbH operates the QIAGEN.com website. As specified previously, QIAGEN admits there is a relationship between the various QIAGEN entities. QIAGEN denies that it has ever infringed any of the asserted patents.

89. 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

[8] *See* Qiagen, Next-Generation Sequencing, https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing; QIAseq NGS Brochure, Introducing QIAseq (April 2017).

[9] *See* The QIAseq advantage; QIAseq Targeted DNA Panel Handbook; QIAseq Targeted Methyl Panel Handbook; QIAseq Targeted RNA Panels Handbook; QIAseq Immune Repertoire RNA Library Handbook; Qiagen, Next-Generation Sequencing, https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing; QIAseq NGS Brochure, Introducing QIAseq (April 2017).

combination of gene-specific primers and partial duplex universal adaptors.[10] The kit protocols of the Accused Products state their intended use is to provide enriched sample libraries for NGS.[11]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 89 of the Complaint.

90. 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 fragment of interest to be ligated to a partial duplex adaptor. Specifically, a first adaptor is ligated to the target nucleic acid fragment.[12]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 90 of the Complaint.

91. As shown in the below diagram,[13] the adaptors that are used are partial duplex adaptors: they are double stranded. In addition, one strand is longer than the other, creating a partial overhang shown in color in the below diagram.

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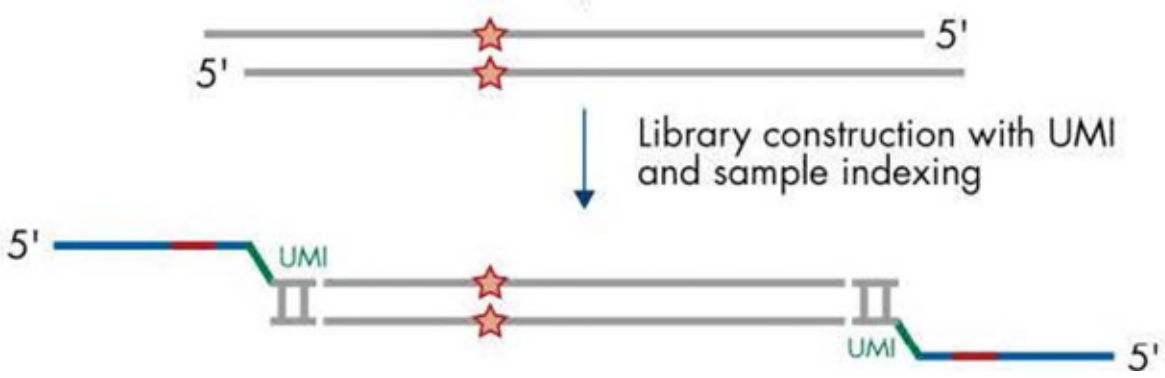
[10] *See* QIAseq Targeted DNA Panel Handbook, pages 11-12 "Introduction" ("The QIAseq Targeted DNA Panels overcome these biases/artifacts by utilizing a highly optimized reaction chemistry whereby UMIs are integrated into a single gene-specific, primer-based targeted enrichment process" at 11); QIAseq Targeted Methyl Panel Handbook, pages 6-8 "Introduction" ("The adapted EpiTect Fast bisulfite conversion chemistry, including the DNA protect reagent, delivers an optimal starting material for target enrichment and library generation since it allows complete conversion of unmethylated cytosines while avoiding fragmentation of the DNA during bisulfite treatment." at 6); QIAseq Targeted RNAscan Panel Handbook, pages 10-12, "Introduction" ("QIAseq Targeted RNAscan Panels rely on highly efficient RNA conversion, gene specific single primer enrichment, and molecular barcoding for sensitive fusion gene detection." at 10); QIAseq Immune Repertoire RNA Library Handbook, pages 10-14 "Introduction" ("The QIAseq Immune Repertoire RNA Library Kit utilizes unique molecular indexing (UMIs) with targeted single primer extension (SPE) enrichment to robustly create targeted RNA-seq libraries for NGS instruments.").

[11] *Id.*

[12] *See* QIAseq Targeted DNA Panel Handbook, pages 29-36 "Protocol: Adaptor Ligation"; QIAseq Targeted Methyl Panel Handbook, pages 24-25 "Adaptor ligation"; QIAseq Targeted RNAscan Panel Handbook, pages 24-28, "Adaptor ligation" QIAseq Immune Repertoire RNA Library Handbook, pages 29-32 "Procedure: Adaptor Ligation."

[13] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 91 of the Complaint.

92. 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 nucleic acid fragments that are ligated to a partial duplex adaptor.[14] The Accused Products anneal oligonucleotides to the sequence of interest in the nucleic acid fragment ligated to the partial duplex adaptor.[15]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 92 of the Complaint.

93. The oligonucleotides (referred to as "GSP," shown in solid yellow and red below)[16] comprise a second adaptor sequence and a 3′ sequence that is complementary to the nucleic acid sequence of interest. These oligonucleotides are annealed to the nucleic acid sequence of interest in the nucleic acid fragment ligated to the partial duplex adaptor. The annealed oligonucleotides contain a 3′ portion that is complementary to the nucleic acid sequence of interest. As shown below,[17] the solid yellow section is the portion complementary to the nucleic acid sequence of interest.

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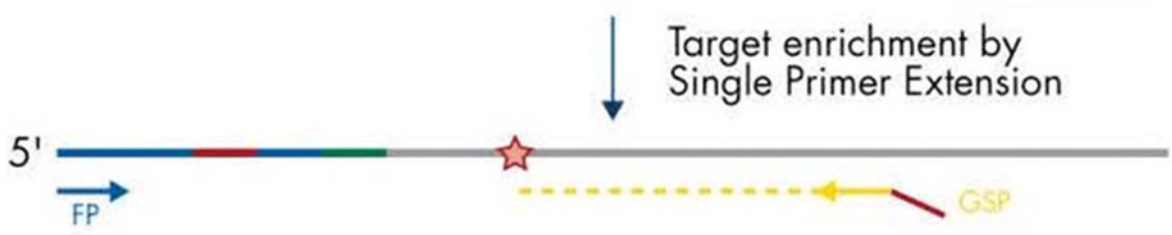
[14] *See supra* ¶ 56.

[15] *See* QIAseq Targeted DNA Panel Handbook, pages 29-36 "Protocol: Adaptor Ligation"; QIAseq Targeted Methyl Panel Handbook, pages 24-25 "Adaptor ligation"; QIAseq Targeted RNAscan Panel Handbook, pages 24-28, "Adaptor ligation" QIAseq Immune Repertoire RNA Library Handbook, pages 29-32 "Procedure: Adaptor Ligation."

[16] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

[17] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 93 of the Complaint.

94. The annealed oligonucleotides also contain a 5′ tail portion comprising a second adaptor sequence that is non-complementary to the nucleic acid sequence of interest (see the red element after the solid yellow sequence above).

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 94 of the Complaint.

95. In the Accused Products, the 3′ portion comprises at least 10 bases complement to the target sequence of interest. 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).[18]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 95 of the Complaint.

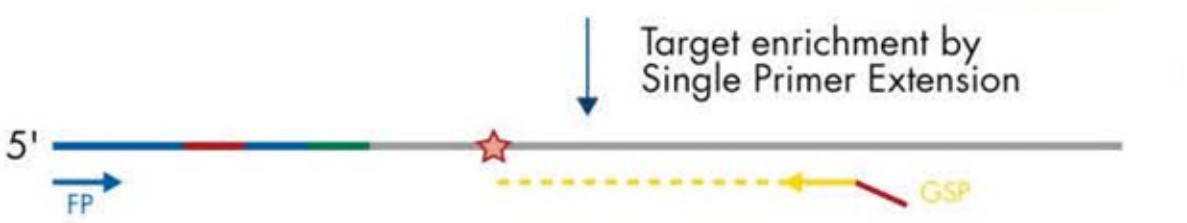
96. Defendants' Accused Products "extend[] one or more oligonucleotides annealed to the nucleic acid sequence of interest in the nucleic acid fragment ligated to the partial duplex adaptor with a polymerase, thereby generating one or more oligonucleotide extension products comprising sequence complementary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

[18] 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; QIAseq Targeted DNA Panel Handbook, pages 37-40 "Protocol: Target Enrichment"; QIAseq Targeted Methyl Panel Handbook, pages 26- 28 "Target enrichment"; QIAseq Targeted RNAscan Panel Handbook, pages 28-29, "SPE target enrichment"; QIAseq Immune Repertoire RNA Library Handbook, pages 35-36 "Protocol: Target enrichment."

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.[19]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 96 of the Complaint.

97. As shown below,[20] the extension occurs through the annealed oligonucleotides comprising a second adaptor sequence (depicted in red below) and a 3′ portion that is complementary to the nucleic acid sequence of interest (depicted in solid yellow region, the extension itself is depicted by the yellow dashed lines).



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 97 of the Complaint.

98. The result after the initial round of PCR is an oligonucleotide extension product comprising a sequence complementary to the first adaptor at one end (shown below,[21] 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).

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 98 of the Complaint.

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[19] *See* QIAseq Targeted DNA Panel Handbook, pages 37-40 "Protocol: Target Enrichment"; QIAseq Targeted Methyl Panel Handbook, pages 26-28 "Target enrichment"; QIAseq Targeted RNAscan Panel Handbook, pages 28-29, "SPE target enrichment"; QIAseq Immune Repertoire RNA Library Handbook, pages 35-36 "Protocol: Target enrichment."

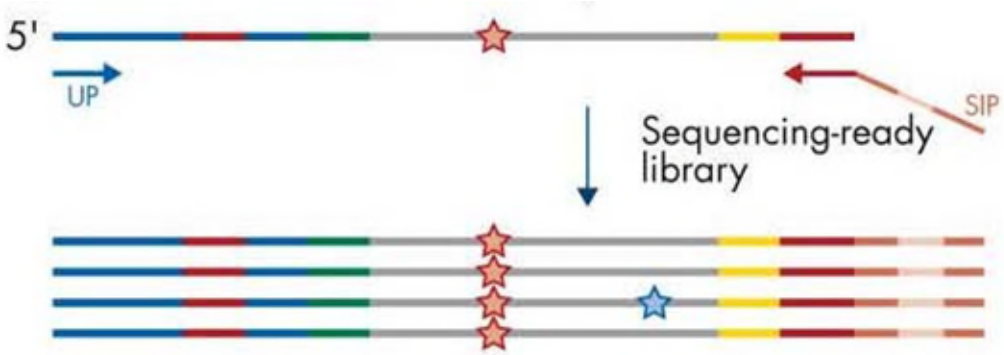
[20] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

[21] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

99. 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 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.[22]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 99 of the Complaint.

100. As shown below,[23] the oligonucleotide extension product is contacted with two primers, a first primer corresponding to the first adaptor sequence (labeled "UP" shown in blue) and a second primer corresponding at its 3′ end to the sequence of the second adaptor (primer labeled "SIP" with the sequence corresponding to the second adaptor sequence shown in red). The result is amplification enriching the nucleic acid of interest (represented by the products shown beneath the downward facing arrow).



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 100 of the Complaint.

101. The Accused Products amplify the one or more oligonucleotide extension products wherein products of the amplifying comprise a 3′ end with sequence complementary to a sequence on a surface. Specifically, incorporation by amplification of the second primer that anneals at its

[22] *See* QIAseq Targeted DNA Panel Handbook, pages 41-47 "Protocol: Universal PCR"; QIAseq Targeted Methyl Panel Handbook, pages 29-31 "Library amplification"; QIAseq Targeted RNAscan Panel Handbook, pages 30-34, "Universal PCR amplification"; QIAseq Immune Repertoire RNA Library Handbook, pages 37-42 "Protocol: Universal PCR."

[23] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

3′ end to a complement of the second adaptor sequence generates an amplification product containing a 3′ end with sequence complementary to a sequence on a surface.[24]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 101 of the Complaint.

102. 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 are designed for use with the Illumina and Ion Torrent next generation sequencing platforms.[25] Specifically, the Accused Products include manuals that direct users towards use of the Accused Products with Illumina or Ion Torrent sequencing platforms.[26]

RESPONSE: QIAGEN admits that certain QIAGEN publications regarding certain Accused Products discuss the Illumina and Ion Torrent sequencing platforms. QIAGEN denies the remaining allegations and characterizations contained in Paragraph 102 of the Complaint.

103. 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 Illumina MiSeq platform employs a flow cell constituting a surface covered with short nucleic acid fragments complementary to both adaptors

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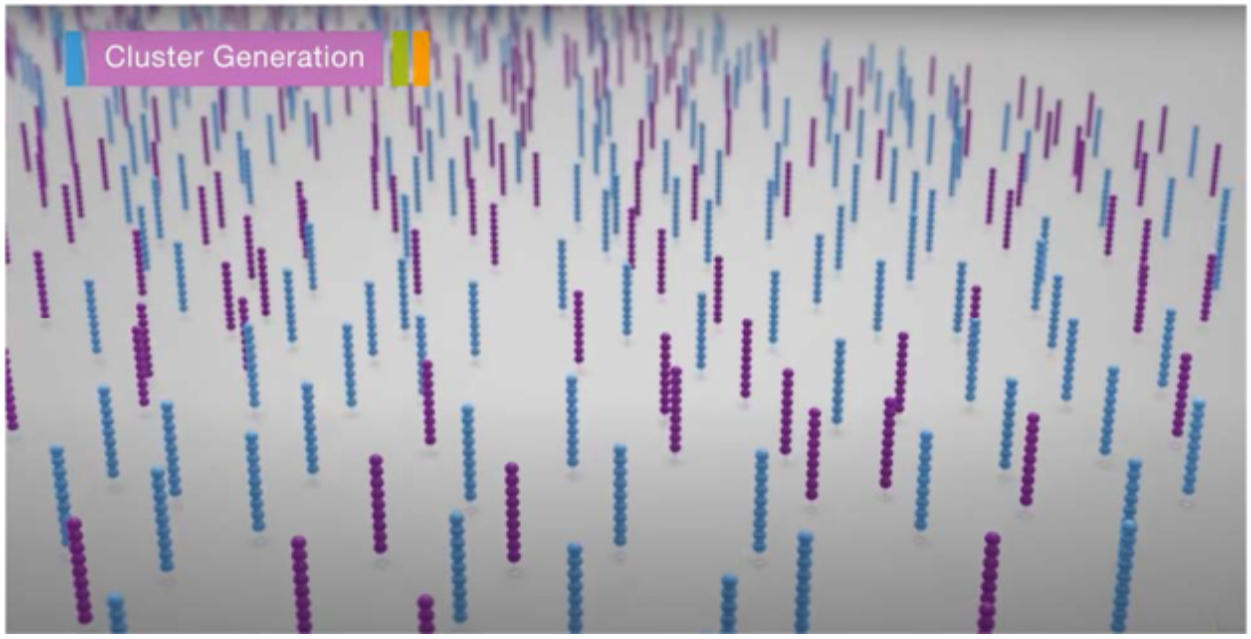
[24] *See* QIAseq Targeted DNA Panel Handbook, page 14 "Target enrichment and final library construction" ("A universal PCR is ultimately carried out to amplify the library and add platform-specific adaptor sequences and additional sample indices." at 14);
QIAseq Targeted Methyl Panel Handbook, pages 8-9 "Principle and procedure" ("A Universal PCR is ultimately carried out to amplify the library and add platform-specific adaptor sequences and additional sample indices." at 9);
QIAseq Targeted RNAscan Panel Handbook, pages 11-12, "Procedure" ("A universal PCR is then carried out to amplify the library and add a second sample index (dual index if needed, platform specific) and other platform-specific required sequences." at 11);
QIAseq Immune Repertoire RNA Library Handbook, page 13 "Target enrichment and final library construction" ("A universal PCR is ultimately carried out to amplify the library and introduce platform-specific adaptor sequences, as well as additional sample indices." at 13).

[25] *See* Introducing QIAseq, page 2 ("Enable biological discoveries with QIAseq NGS on any Illumina or Ion Torrent sequencer." at 5).

[26] *See* QIAseq Targeted DNA Panel Handbook (Illumina), pages 51-61 "Protocol: Sequencing Setup on Illumina MiSeq, NextSeq 500/550, MiniSeq, and NovaSeq"; QIAseq Targeted DNA Panel Handbook (Ion Torrent), pages 40-48 "Protocol: Sequencing Setup for Ion Torrent Instruments" and "QIAseq Targeted DNA Panel Ion Chef and S5 set up."

that serve as anchors (the blue and purple lines depicted below,[27] each color represents a different complementary adaptor sequence).

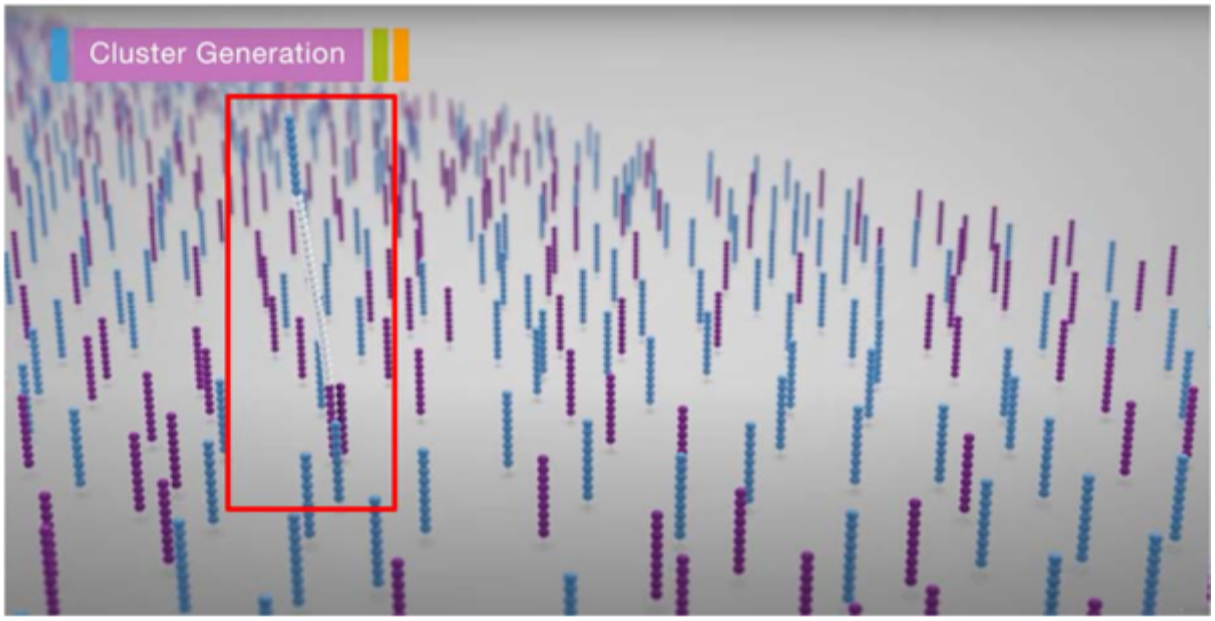


RESPONSE: QIAGEN lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 103 and on that basis denies them.

104. 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,[28] 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.[29]

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

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



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 104 of the Complaint.

105. 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 are designed for use with the Illumina and Ion Torrent next generation sequencing platforms.[30]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 105 of the Complaint.

106. Specifically, the Accused Products include manuals that direct users towards use of the kits with Illumina or Ion Torrent sequencing platforms.[31]

[30] *See* Introducing QIAseq, page 2 ("*Enable biological discoveries with QIAseq NGS on any Illumina or Ion Torrent sequencer*." at 5); Illumina MiSeq System Guide; *see* also MiSeq System Specification Sheet.

[31] *See* QIAseq Targeted DNA Panel Handbook (Illumina), pages 51-61 "Protocol: Sequencing Setup on Illumina MiSeq, NextSeq 500/550, MiniSeq, and NovaSeq"; QIAseq Targeted DNA Panel Handbook (Ion Torrent), pages 40-48 "Protocol: Sequencing Setup for Ion Torrent Instruments" and "QIAseq Targeted DNA Panel Ion Chef and S5 set up."

RESPONSE: QIAGEN admits that certain QIAGEN publications regarding certain Accused Products discuss the Illumina and Ion Torrent sequencing platforms. QIAGEN denies the remaining allegations and characterizations contained in Paragraph 106 of the Complaint.

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

RESPONSE: QIAGEN denies that it infringes any claim of the '012 patent. Except as specifically admitted, QIAGEN denies the allegations in Paragraph 107.

108. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 108 of the Complaint.

109. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 109 of the Complaint.

110. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 110 of the Complaint.

111. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 111 of the Complaint.

112. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 112 of the Complaint.

Defendants' [Alleged] Infringement of the '108 patent

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

RESPONSE: QIAGEN denies that it infringes any claim of the '108 patent including under 35 U.S.C. §§ 271(a)-(c).

114. 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 use the Accused Products, they infringe at least claim 1 of the '108 patent.[32] 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 '108 patent.[33] 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

[32] *See* The QIAseq advantage; QIAseq Targeted DNA Panel Handbook; QIAseq Targeted Methyl Panel Handbook; QIAseq Targeted RNA Panels Handbook; QIAseq Immune Repertoire RNA Library Handbook.

[33] *See* Qiagen, Next-Generation Sequencing, https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing; QIAseq NGS Brochure, Introducing QIAseq (April 2017).

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.[34]

RESPONSE: QIAGEN denies that it has ever infringed an asserted patent.

115. On information and belief, the packaging of the Accused Products bears the name of QIAGEN Sciences. On information and belief, QIAGEN Gaithersburg is involved in the research and development of components and reagents in the Accused Products. On information and belief, QIAGEN GmbH operates the QIAGEN.com website, which offers for sale and sells the Accused Products. On information and belief, QIAGEN N.V., as the ultimate parent to these subsidiaries, is directly involved in, responsible for, and benefits from the sales of the Accused Products.

RESPONSE: To the extent Paragraph 115 of the Complaint implicates legal conclusions, no response is required. QIAGEN admits QIAGEN GmbH operates the QIAGEN.com website. QIAGEN admits that QIAGEN N.V. is the ultimate parent to QIAGEN sciences, QIAGEN Gaithersburg, and QIAGEN GmbH. To the extent that a further response is required, QIAGEN denies the remaining allegations and characterizations contained in Paragraph 115 of the Complaint.

116. 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

[34] *See* The QIAseq advantage; QIAseq Targeted DNA Panel Handbook; QIAseq Targeted Methyl Panel Handbook; QIAseq Targeted RNA Panels Handbook; QIAseq Immune Repertoire RNA Library Handbook; Qiagen, Next-Generation Sequencing, https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing; QIAseq NGS Brochure, Introducing QIAseq (April 2017).

combination of gene-specific primers and partial duplex universal adaptors.[35] The Accused Products' protocols state their intended use is to provide enriched sample libraries for NGS.[36]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 116 of the Complaint.

117. 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 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." For example, in the Accused Products, a first adaptor is ligated to the target nucleic acid fragment.[37]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 117 of the Complaint.

118. As shown in the below diagram,[38] the adaptors are ligated to the nucleic acid fragment of interest (see blue, red, green, and grey addition in the second step of the below).[39]

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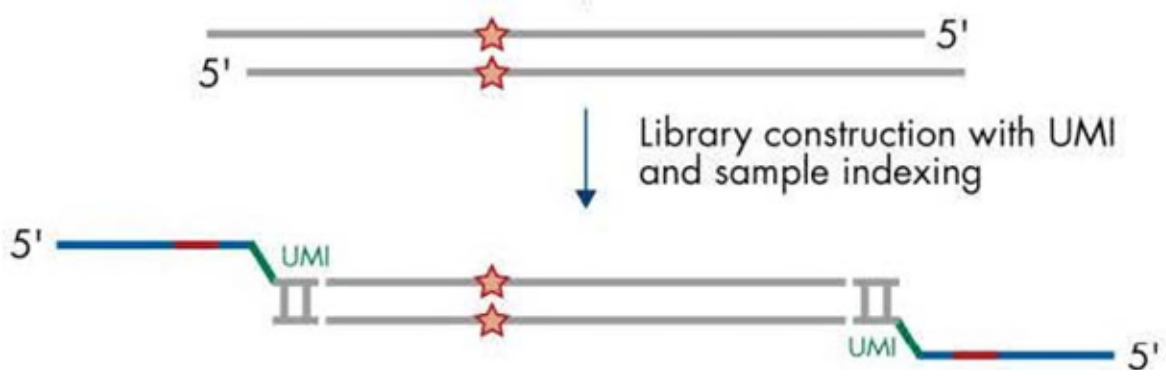
[35] *See* QIAseq Targeted DNA Panel Handbook, pages 11-12 "Introduction" ("The QIAseq Targeted DNA Panels overcome these biases/artifacts by utilizing a highly optimized reaction chemistry whereby UMIs are integrated into a single gene-specific, primer-based targeted enrichment process"); QIAseq Targeted Methyl Panel Handbook, pages 6-8 "Introduction" ("The adapted EpiTect Fast bisulfite conversion chemistry, including the DNA protect reagent, delivers an optimal starting material for target enrichment and library generation since it allows complete conversion of unmethylated cytosines while avoiding fragmentation of the DNA during bisulfite treatment."); QIAseq Targeted RNAscan Panel Handbook, pages 10-12, "Introduction" ("QIAseq Targeted RNAscan Panels rely on highly efficient RNA conversion, gene specific single primer enrichment, and molecular barcoding for sensitive fusion gene detection."); QIAseq Immune Repertoire RNA Library Handbook, pages 10-14 "Introduction" ("The QIAseq Immune Repertoire RNA Library Kit utilizes unique molecular indexing (UMIs) with targeted single primer extension (SPE) enrichment to robustly create targeted RNA-seq libraries for NGS instruments.").

[36] *Id.*

[37] *See* QIAseq Targeted DNA Panel Handbook, pages 29-36 "Protocol: Adaptor Ligation"; QIAseq Targeted Methyl Panel Handbook, pages 24-25 "Adaptor ligation"; QIAseq Targeted RNAscan Panel Handbook, pages 24-28, "Adaptor ligation"; QIAseq Immune Repertoire RNA Library Handbook, pages 29-32 "Procedure: Adaptor Ligation."

[38] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

[39] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 118 of the Complaint.

119. The Accused Products anneal oligonucleotides to the sequence of interest in the nucleic acid fragment ligated to a first adaptor.[40]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 119 of the Complaint.

120. The oligonucleotides (referred to as "GSP," shown in solid yellow and red above)[41] comprise a second adaptor sequence and a 3′ sequence that is complementary to the nucleic acid sequence of interest. These oligonucleotides are annealed to the nucleic acid sequence of interest in the nucleic acid fragment ligated to the partial duplex adaptor. The annealed oligonucleotides contain a 3′ portion that is complementary to the nucleic acid sequence of interest. As shown above,[42] the solid yellow section is the portion complementary to the nucleic acid sequence of interest.

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[40] *See* QIAseq Targeted DNA Panel Handbook, pages 29-36 "Protocol: Adaptor Ligation"; QIAseq Targeted Methyl Panel Handbook, pages 24-25 "Adaptor ligation"; QIAseq Targeted RNAscan Panel Handbook, pages 24-28, "Adaptor ligation" QIAseq Immune Repertoire RNA Library Handbook, pages 29-32 "Procedure: Adaptor Ligation."

[41] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

[42] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 120 of the Complaint.

121. In the Accused Products, the 3′ portion comprises at least 10 bases complement to the target sequence of interest. 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).[43]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 121 of the Complaint.

122. 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." For example, the Accused Products extend the one or more oligonucleotides annealed to the sequence of interest.[44]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 122 of the Complaint.

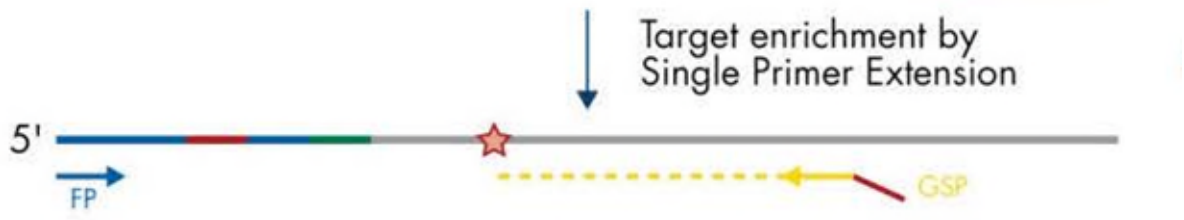
123. As shown below,[45] the extension occurs through the annealed oligonucleotides comprising a second adaptor sequence (depicted in red below) and a 3′ portion that is

[43] 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; QIAseq Targeted DNA Panel Handbook, pages 37-40 "Protocol: Target Enrichment"; QIAseq Targeted Methyl Panel Handbook, pages 26-28 "Target enrichment"; QIAseq Targeted RNAscan Panel Handbook, pages 28-29, "SPE target enrichment"; QIAseq Immune Repertoire RNA Library Handbook, pages 35-36 "Protocol: Target enrichment."

[44] *See* QIAseq Targeted DNA Panel Handbook, pages 37-40 "Protocol: Target Enrichment"; QIAseq Targeted Methyl Panel Handbook, pages 26-28 "Target enrichment"; QIAseq Targeted RNAscan Panel Handbook, pages 28-29, "SPE target enrichment"; QIAseq Immune Repertoire RNA Library Handbook, pages 35-36 "Protocol: Target enrichment."

[45] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

complementary to the nucleic acid sequence of interest (depicted in solid yellow region, the extension itself is depicted by the yellow dashed lines). This extension is accomplished by using a polymerase found in the reaction mixture.



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 123 of the Complaint.

124. This extension anneals one or more oligonucleotides to the fragment with the first adaptor (represented by the grey element (the target fragment) and green, blue, and red elements (the first adaptor step)).

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 124 of the Complaint.

125. The result after the initial round of PCR is an oligonucleotide extension product comprising a sequence complementary to the first adaptor at one end (shown below,[46] 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).

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 125 of the Complaint.

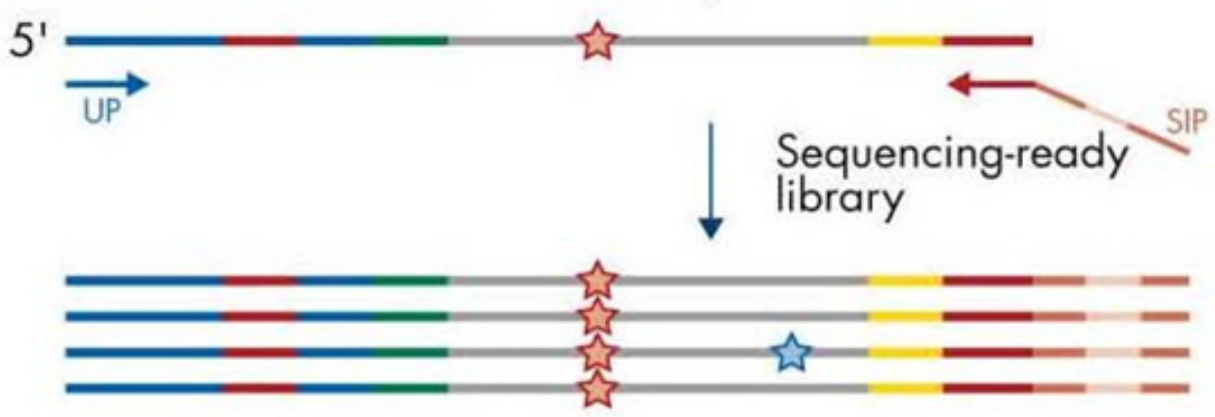
126. Defendants' Accused Products "amplify[] the one or more oligonucleotide extension products, in the reaction mixture, using a first primer that anneals to the complement of the first adaptor sequence and a second primer that anneals at its 3′ end to a complement of the second adaptor sequence, thereby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

[46] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

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.[47]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 126 of the Complaint.

127. As shown below,[48] the oligonucleotide extension product is contacted with two primers, a first primer corresponding to the sequence of the first adaptor (labeled "UP" shown in blue) and a second primer corresponding to at its 3′ end to the sequence of the second adaptor (primer labeled "SIP" with the sequence corresponding to the second adaptor sequence shown in red). The result is amplification enriching the nucleic acid of interest (represented below by the products shown beneath the downward facing arrow) by generating amplified products comprising the enriched nucleic acid sequence of interest.



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 127 of the Complaint.

128. 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 are designed for use with the Illumina and Ion Torrent next

[47] See QIAseq Targeted DNA Panel Handbook, pages 41-47 "Protocol: Universal PCR"; QIAseq Targeted Methyl Panel Handbook, pages 29-31 "Library amplification"; QIAseq Targeted RNAscan Panel Handbook, pages 30-34, "Universal PCR amplification" QIAseq Immune Repertoire RNA Library Handbook, pages 37-42 "Protocol: Universal PCR."

[48] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

generation sequencing platforms.[49] Specifically, the Accused Products include manuals that direct users towards use of the kits with Illumina or Ion Torrent sequencing platforms.[50]

RESPONSE: QIAGEN admits that certain QIAGEN publications regarding certain Accused Products discuss the Illumina and Ion Torrent sequencing platforms. QIAGEN denies the remaining allegations and characterizations contained in Paragraph 128 of the Complaint.

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

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 129 of the Complaint.

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

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 130 of the Complaint.

131. 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.

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[49] *See* Introducing QIAseq, page 2 ("Enable biological discoveries with QIAseq NGS on any Illumina or Ion Torrent sequencer." at 5); Illumina MiSeq System Guide; MiSeq System Specification Sheet.

[50] *See* QIAseq Targeted DNA Panel Handbook (Illumina), pages 51-61 "Protocol: Sequencing Setup on Illumina MiSeq, NextSeq 500/550, MiniSeq, and NovaSeq"; QIAseq Targeted DNA Panel Handbook (Ion Torrent), pages 40-48 "Protocol: Sequencing Setup for Ion Torrent Instruments" and "QIAseq Targeted DNA Panel Ion Chef and S5 set up.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 131 of the Complaint.

132. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 132 of the Complaint.

133. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 133 of the Complaint.

134. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 134 of the Complaint.

Defendants’ [Alleged] Infringement of the ’357 patent

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

RESPONSE: QIAGEN denies that it infringes any claim of the ’357 patent including under 35 U.S.C. §§ 271(a)-(c).

136. 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 use the Accused Products, they infringe at least claim 1 of the ’357

patent.[51] 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 '357 patent.[52] 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.[53]

RESPONSE: QIAGEN denies that it has ever infringed an asserted patent.

137. On information and belief, the packaging of the Accused Products bears the name of QIAGEN Sciences. On information and belief, QIAGEN Gaithersburg is involved in the research and development of components and reagents in the Accused Products. On information and belief, QIAGEN GmbH operates the QIAGEN.com website, which offers for sale and sells the Accused Products. On information and belief, QIAGEN N.V., as the ultimate parent to these subsidiaries, is directly involved in, responsible for, and benefits from the sales of the Accused Products.

RESPONSE: QIAGEN admits QIAGEN GmbH operates the QIAGEN.com website. QIAGEN admits that QIAGEN N.V. is the ultimate parent to QIAGEN sciences, QIAGEN Gaithersburg, and QIAGEN GmbH. To the extent that a further response is required, QIAGEN denies the remaining allegations and characterizations contained in Paragraph 137 of the Complaint.

138. 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

[51] *See* The QIAseq advantage; QIAseq Targeted DNA Panel Handbook; QIAseq Targeted Methyl Panel Handbook; QIAseq Targeted RNA Panels Handbook; QIAseq Immune Repertoire RNA Library Handbook.

[52] *See* Qiagen, Next-Generation Sequencing, https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing; QIAseq NGS Brochure, Introducing QIAseq (April 2017).

[53] *See* The QIAseq advantage; QIAseq Targeted DNA Panel Handbook; QIAseq Targeted Methyl Panel Handbook; QIAseq Targeted RNA Panels Handbook; QIAseq Immune Repertoire RNA Library Handbook; Qiagen, Next-Generation Sequencing, https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing; QIAseq NGS Brochure, Introducing QIAseq (April 2017).

to generate a population of sample sequencing reads.[54] The Accused Products are also used to detect duplicate sequencing reads within this population.[55]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 138 of the Complaint.

139. 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 to about 8 nucleotides, an indexing site unique to a subset of the adaptors, and a primer binding site."

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 139 of the Complaint.

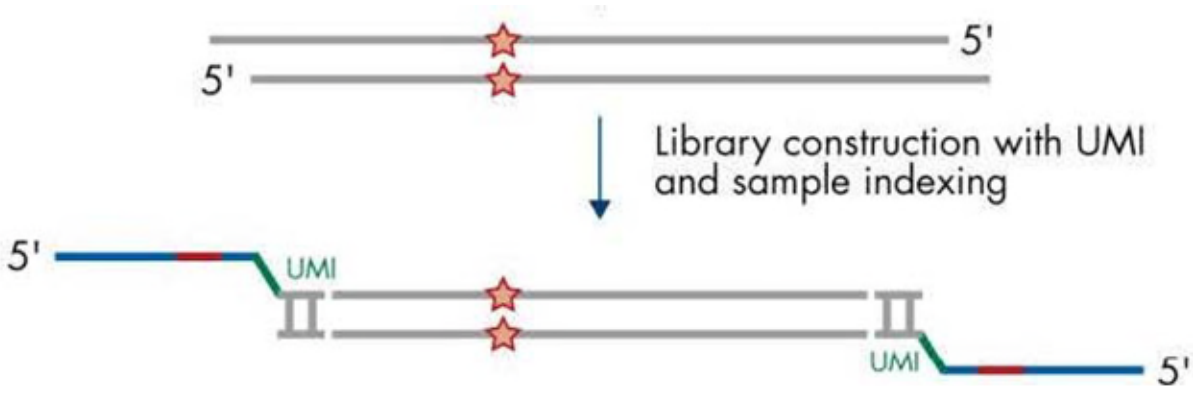
140. For example, in the Accused Products, an adaptor is ligated to each of a plurality of nucleic acid fragments.[56] As shown in the below diagram,[57] the adaptor is ligated to the nucleic acid fragment of interest (see the blue, red, green, and grey addition in the second step of the below).

[54] *See* QIAseq Targeted DNA Panel Handbook, pages 11-12 "Introduction"; QIAseq Targeted Methyl Panel Handbook, pages 6-8 "Introduction"; QIAseq Targeted RNAscan Panel Handbook, pages 10-12, "Introduction" QIAseq Immune Repertoire RNA Library Handbook, pages 10-11 "Introduction."

[55] *See* QIAseq Targeted DNA Extended Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/dna-sequencing/somatic-panels/qiaseq-targeted-dna-extended-panels; QIAseq Targeted RNAscan Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/rna-sequencing/custom-rna-panels/qiaseq-targeted-rnascan-custom-panel; The QIAseq advantage, page 1 "NGS workflow challenges addressed by QIAseq technologies."

[56] *See* QIAseq Targeted DNA Panel Handbook, pages 29-36 "Protocol: Adaptor Ligation"; QIAseq Targeted Methyl Panel Handbook, pages 24-25 "Adaptor ligation"; QIAseq Targeted RNAscan Panel Handbook, pages 24-28, "Adaptor ligation," QIAseq Immune Repertoire RNA Library Handbook, pages 29-32 "Procedure: Adaptor Ligation."

[57] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 140 of the Complaint.

141. As shown in the below diagram[58] (an expanded version of the adaptor shown above), the adaptor comprises a unique identifier having from about 1 to about 8 nucleotides (shown in green), an indexing site unique to a subset of the adaptors (shown in red), and a primer binding site (shown in blue at far left).

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 141 of the Complaint.

142. The adaptor comprises a unique identifier having a fixed number of nucleotides (labeled UMI, shown in red above).[59] On information and belief, these may include up to 12 nucleotides. This is either "about 1 to about 8 nucleotides" or its equivalent. For example, a 12

[58] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

[59] *See* QIAseq Targeted DNA Panel Handbook, page 14 "UMI Assignment" "Prior to target enrichment and library amplification, each original DNA molecule is assigned a unique sequence or index, commonly referred to as a UMI. This assignment is accomplished by ligating fragmented DNA with an adaptor containing a 12-base fully random sequence (i.e., the UMI). Statistically, this process provides 412 possible indices per adaptor, and each DNA molecule in the sample receives a unique UMI sequence. In addition, this ligated adaptor also contains the first sample index."; QIAseq Targeted Methyl Panel Handbook pages 8-9 "Principle and procedure"; QIAseq Targeted RNAscan Panel Handbook, page 10 "Molecular Barcodes"; QIAseq Immune Repertoire RNA Library Handbook, page 13 "UMI Assignment."

nucleotide unique identifier performs the same function (the identifier oligonucleotides are used to identify the nucleic acid fragment and allow for deduplication), in substantially the same manner (oligonucleotides are added to a fragment in an adaptor to identify a nucleic acid fragment), to obtain substantially the same result (identifying different fragments by the makeup of the identifier oligonucleotides).[60]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 142 of the Complaint.

143. The adaptor 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 simultaneously.[61] As such, the sample-specific indexing site represents a unique subset within the population of all adaptors used.[62]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 143 of the Complaint.

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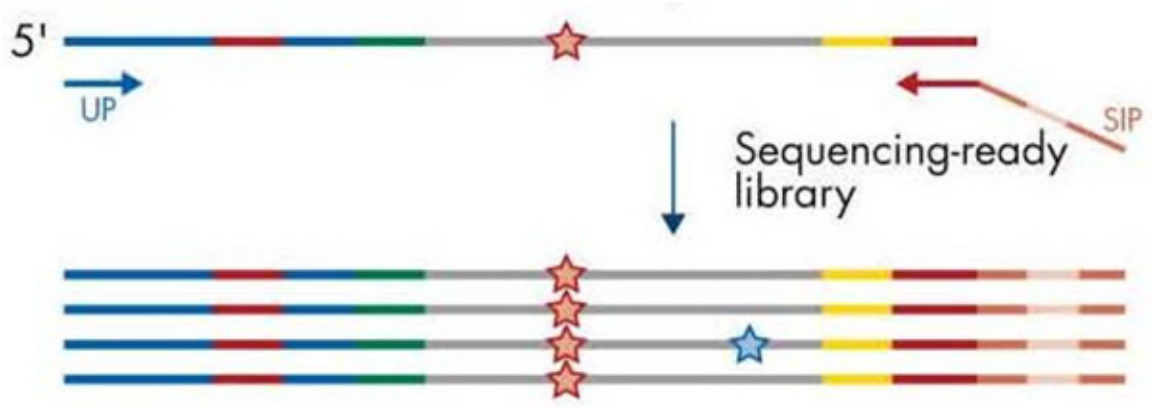
[60] *See* QIAseq Targeted DNA Panel Handbook, page 14 "UMI Assignment" "Prior to target enrichment and library amplification, each original DNA molecule is assigned a unique sequence or index, commonly referred to as a UMI. This assignment is accomplished by ligating fragmented DNA with an adaptor containing a 12-base fully random sequence (i.e., the UMI). Statistically, this process provides 412 possible indices per adaptor, and each DNA molecule in the sample receives a unique UMI sequence. In addition, this ligated adaptor also contains the first sample index."; QIAseq Targeted Methyl Panel Handbook pages 8-9 "Principle and procedure"; QIAseq Targeted RNAscan Panel Handbook, page 10 "Molecular Barcodes"; QIAseq Immune Repertoire RNA Library Handbook, page 13 "UMI Assignment."

[61] *See* QIAseq Targeted DNA Panel Handbook, page 14 "UMI Assignment" "In addition, this ligated adaptor also contains the first sample index."; QIAseq Targeted Methyl Panel Handbook pages 8-9 "Principle and procedure"; QIAseq Targeted RNAscan Panel Handbook, page 10 "Molecular Barcodes"; QIAseq Immune Repertoire RNA Library Handbook, page 13 "UMI Assignment"; QIAseq Targeted DNA Panel Handbook, page 14 "NGS adaptor and index technologies"; QIAseq Targeted Methyl Panel Handbook pages 8-9 "Principle and procedure"; QIAseq Targeted RNAscan Panel Handbook, page 11 "Procedures"; QIAseq Immune Repertoire RNA Library Handbook, page 13 "NGS adaptor and index technologies."

[62] *See* QIAseq Targeted DNA Panel Handbook, page 14 "UMI Assignment" "In addition, this ligated adaptor also contains the first sample index."; QIAseq Targeted Methyl Panel Handbook pages 8-9 "Principle and procedure"; QIAseq Targeted RNAscan Panel Handbook, page 10 "Molecular Barcodes"; QIAseq Immune Repertoire RNA Library Handbook, page 13 "UMI Assignment"; QIAseq Targeted DNA Panel Handbook, page 14 "NGS adaptor and index technologies"; QIAseq Targeted Methyl Panel Handbook pages 8-9 "Principle and procedure"; QIAseq Targeted RNAscan Panel Handbook, page 11 "Procedures"; QIAseq Immune Repertoire RNA Library Handbook, page 13 "NGS adaptor and index technologies."

144. The Accused Products "amplify[] the adaptor-ligated fragments into amplicons." For example, the Accused Products amplify the adaptor-ligated fragments into amplicons by PCR.[63] As shown below,[64] primers (shown, as an example, as the blue and red arrows) are used to amplify the adaptor-ligated fragments by PCR. The result is amplification enriching adaptor-ligated fragments (represented below by the products shown beneath the downward facing arrow) generating amplified products, or amplicons.[65]



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 144 of the Complaint.

145. The Accused Products "sequenc[e] the amplicons to produce sequence reads that include identifier and target sequences." For example, the Accused Products are designed for use with NGS platforms.[66] Specifically, the Accused Products include manuals that direct users towards use of the kits with Illumina or Ion Torrent sequencing platforms.[67]

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[63] *See* QIAseq Targeted DNA Panel Handbook, pages 41-47 "Protocol: Universal PCR"; QIAseq Targeted Methyl Panel Handbook, pages 29-31 "Library amplification"; QIAseq Targeted RNAscan Panel Handbook, pages 30-34, "Universal PCR amplification" QIAseq Immune Repertoire RNA Library Handbook, pages 37-42 "Protocol: Universal PCR."

[64] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

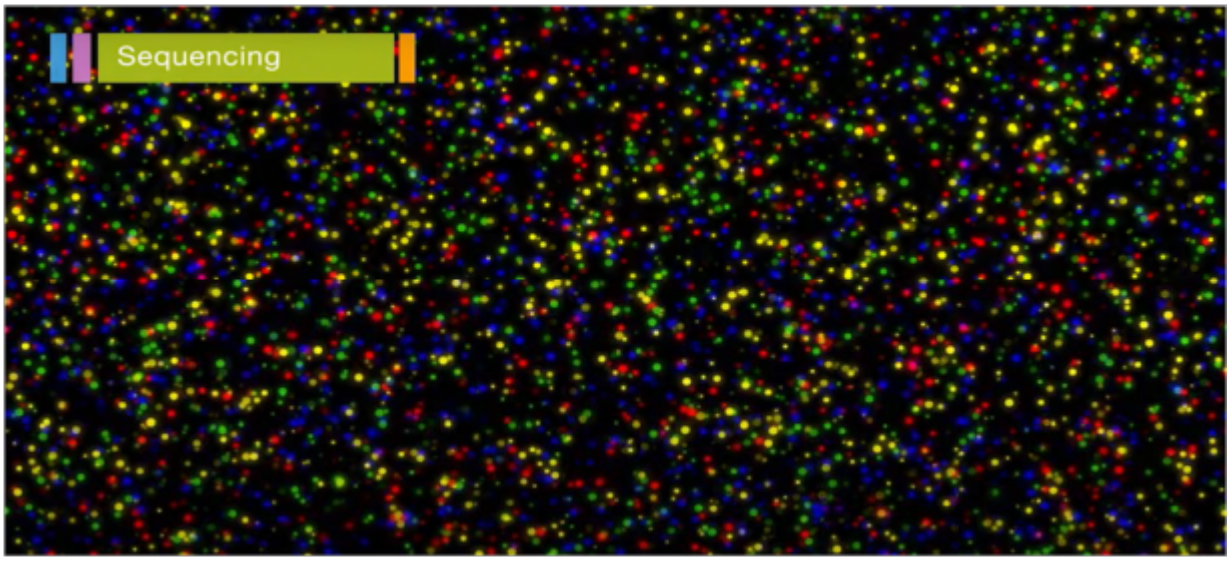
[65] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

[66] *See* Introducing QIAseq, page 2 ("Enable biological discoveries with QIAseq NGS on any Illumina or Ion Torrent sequencer." at 5); Illumina MiSeq System Guide; MiSeq System Specification Sheet; QIAseq Targeted DNA Panel Handbook (Illumina), pages 51-61 "Protocol: Sequencing Setup on Illumina MiSeq, NextSeq 500/550, MiniSeq, and NovaSeq"; QIAseq Targeted DNA Panel Handbook (Ion Torrent), pages 40-48 "Protocol: Sequencing Setup for Ion Torrent Instruments" and "QIAseq Targeted DNA Panel Ion Chef and S5 set up."

[67] *See* Introducing QIAseq, page 2 ("Enable biological discoveries with QIAseq NGS on any Illumina or Ion Torrent sequencer." at 5); Illumina MiSeq System Guide; MiSeq System Specification Sheet; QIAseq Targeted DNA Panel Handbook (Illumina), pages 51-61 "Protocol: Sequencing Setup on Illumina MiSeq, NextSeq 500/550, MiniSeq, and NovaSeq"; QIAseq

RESPONSE: QIAGEN admits that certain QIAGEN publications regarding certain Accused Products discuss the Illumina and Ion Torrent sequencing platforms. QIAGEN denies the remaining allegations and characterizations contained in Paragraph 145 of the Complaint.

146. Sequencing on a massively parallel sequencing platform consists of sequencing the adaptor-ligated fragment products, or amplicons, generated in the amplification step.[68] The fragments are attached to the platform and sequenced simultaneously (pictured below,[69] where each colored dot represents a single nucleotide sequencing event).



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 146 of the Complaint.

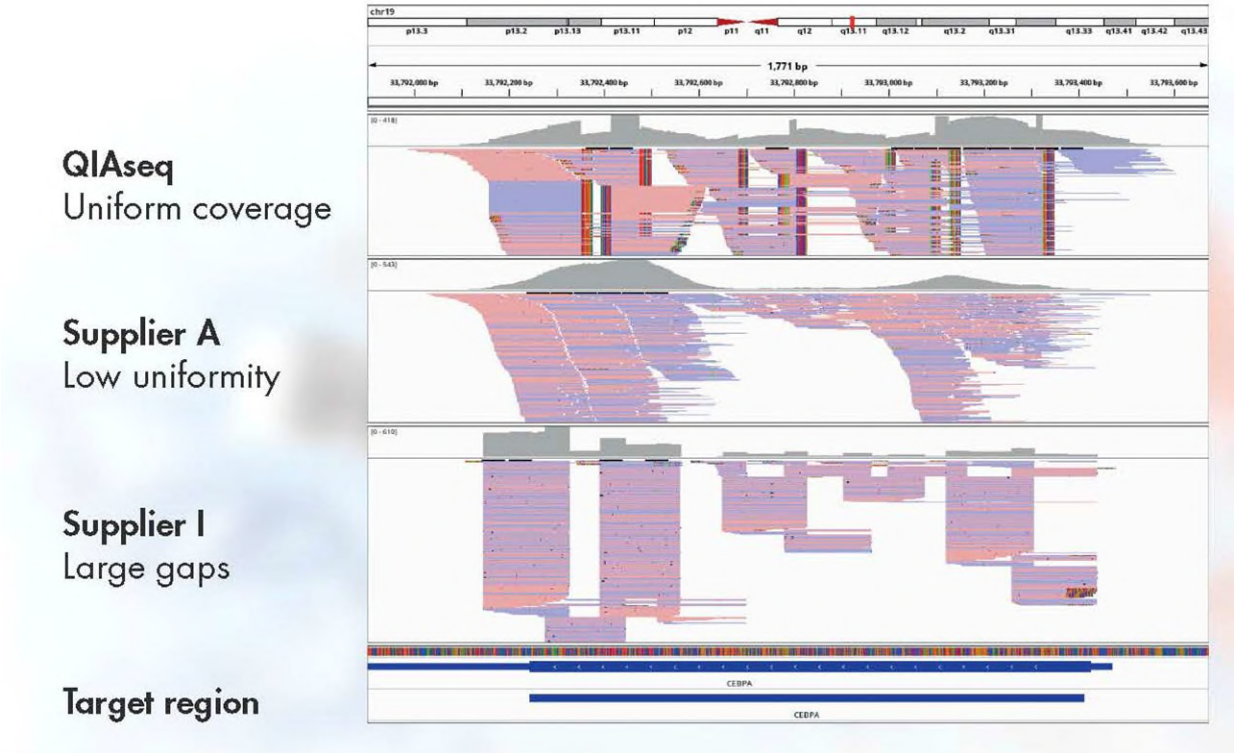
147. The result of sequencing the amplified adaptor-nucleic acid fragment ligated products is a population of sequencing reads generated from the amplified adaptor-nucleic acid fragment ligated products that include the identifier and target sequences (represented below in the

Targeted DNA Panel Handbook (Ion Torrent), pages 40-48 "Protocol: Sequencing Setup for Ion Torrent Instruments" and "QIAseq Targeted DNA Panel Ion Chef and S5 set up."

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

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

top panel "QIAseq Uniform Coverage" in blue and purple, aligned to a reference genomic sequence in blue at bottom).[70]



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 147 of the Complaint.

148. The Accused Products "identify[] sequence reads with identical identifier and target sequences as duplicates." For example, the Accused Products provide for the identification of

[70] *See* The QIAseq advantage, page 8; QIAseq Targeted DNA Panel Handbook, pages 51-61 "Protocol: Sequencing Setup on Illumina MiSeq, NextSeq 500/550, MiniSeq, and NovaSeq"; QIAseq Targeted DNA Panel Handbook (Ion Torrent), pages 40-48 "Protocol: Sequencing Setup for Ion Torrent Instruments"; QIAseq Targeted Methyl Panel Handbook, pages 45-51 "Appendix A: Sequencing Setup on Illumina MiSeq and NextSeq"; QIAseq Targeted RNA Panels Handbook, page 37 "Appendix D: Combine Libraries for Multiplex Sequencing"; QIAseq Immune Repertoire RNA Library Handbook, pages 45-51 "Protocol: Sequencing Setup on Illumina MiSeq and NextSeq"; Illumina MiSeq System Guide; MiSeq System Specification Sheet.

duplicative sequencing reads.[71] These duplicative sequence reads consist of the identifier sites (the Molecular Barcodes) and target sequences.[72]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 148 of the Complaint.

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

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 149 of the Complaint.

150. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 150 of the Complaint.

151. 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

[71] *See* QIAseq Targeted DNA Panel Handbook, page 13; QIAseq Targeted DNA Extended Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/dna-sequencing/somatic-panels/qiaseq-targeted-dna-extended-panels; QIAseq Targeted RNAscan Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/rna-sequencing/custom-rna-panels/qiaseq-targeted-rnascan-custom-panel; the QIAseq advantage.

[72] *See* QIAseq Targeted DNA Panel Handbook, page 13; QIAseq Targeted DNA Extended Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/dna-sequencing/somatic-panels/qiaseq-targeted-dna-extended-panels; QIAseq Targeted RNAscan Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/rna-sequencing/custom-rna-panels/qiaseq-targeted-rnascan-custom-panel; the QIAseq advantage.

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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 151 of the Complaint.

152. 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 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 152 of the Complaint.

153. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 153 of the Complaint.

154. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 154 of the Complaint.

Defendants’ [Alleged] Infringement of the ’241 patent

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

RESPONSE: QIAGEN denies that it infringes any claim of the ’241 patent including under 35 U.S.C. §§ 271(a)-(c).

156. 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 use the Accused Products, they infringe at least claim 1 of the '241 patent.[73] 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 '241 patent.[74] 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.[75]

RESPONSE: QIAGEN denies that it has ever infringed an asserted patent.

157. On information and belief, the packaging of the Accused Products bears the name of QIAGEN Sciences. On information and belief, QIAGEN Gaithersburg is involved in the research and development of components and reagents in the Accused Products. On information and belief, QIAGEN GmbH operates the QIAGEN.com website, which offers for sale and sells the Accused Products. On information and belief, QIAGEN N.V., as the ultimate parent to these subsidiaries, is directly involved in, responsible for, and benefits from the sales of the Accused Products.

RESPONSE: QIAGEN admits QIAGEN GmbH operates the QIAGEN.com website. QIAGEN admits that QIAGEN N.V. is the ultimate parent to QIAGEN sciences, QIAGEN Gaithersburg, and QIAGEN GmbH. To the extent that a further response is required, QIAGEN denies the remaining allegations and characterizations contained in Paragraph 157 of the Complaint.

158. 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

[73] *See* The QIAseq advantage; QIAseq Targeted DNA Panel Handbook; QIAseq Targeted Methyl Panel Handbook; QIAseq Targeted RNA Panels Handbook; QIAseq Immune Repertoire RNA Library Handbook.

[74] *See* Qiagen, Next-Generation Sequencing, https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing; QIAseq NGS Brochure, Introducing QIAseq (April 2017).

[75] *See* The QIAseq advantage; QIAseq Targeted DNA Panel Handbook; QIAseq Targeted Methyl Panel Handbook; QIAseq Targeted RNA Panels Handbook; QIAseq Immune Repertoire RNA Library Handbook; Qiagen, Next-Generation Sequencing, https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing; QIAseq NGS Brochure, Introducing QIAseq (April 2017).

to generate a population of sample sequencing reads.[76] The Accused Products are also used to detect duplicate sequencing reads within this population.[77]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 158 of the Complaint.

159. The 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."

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 159 of the Complaint.

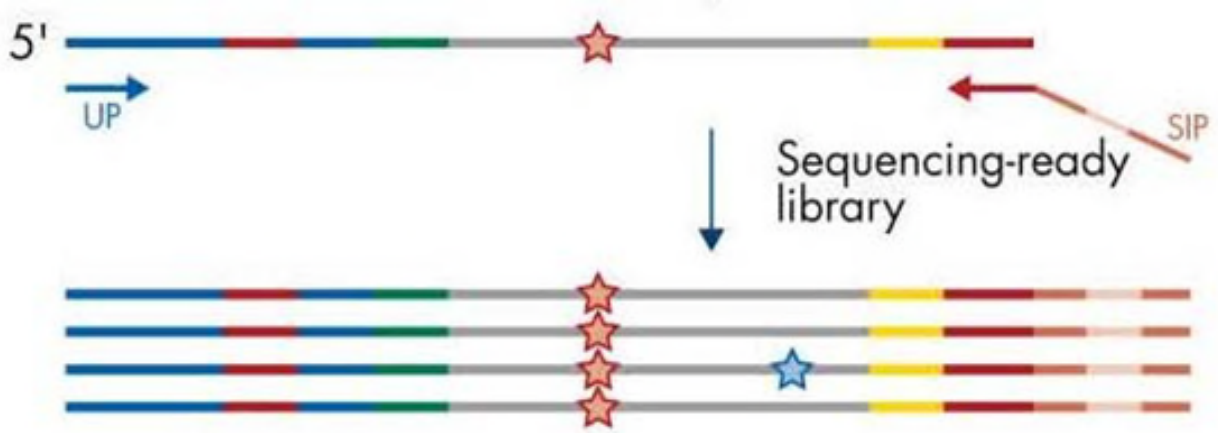
160. The Accused Products requires obtaining amplicons of adaptor-ligated fragments by PCR.[78] As shown below,[79] primers (shown, as an example, as the blue and red arrows) are used to amplify the adaptor-ligated fragments by PCR. The result is amplification of the adaptor-ligated fragments generating amplified products, or amplicons, containing the fragment and an identifier site comprising a plurality of nucleotides unique to the amplified fragment (represented by the products shown beneath the downward facing arrow, with the identifier site shown in green).

[76] *See* QIAseq Targeted DNA Panel Handbook, pages 11-12 "Introduction"; QIAseq Targeted Methyl Panel Handbook, pages 6-8 "Introduction"; QIAseq Targeted RNAscan Panel Handbook, pages 10-12, "Introduction" QIAseq Immune Repertoire RNA Library Handbook, pages 10-11 "Introduction."

[77] *See* QIAseq Targeted DNA Extended Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/dna-sequencing/somatic-panels/qiaseq-targeted-dna-extended-panels; QIAseq Targeted RNAscan Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/rna-sequencing/custom-rna-panels/qiaseq-targeted-rnascan-custom-panel; The QIAseq advantage, page 1 "NGS workflow challenges addressed by QIAseq technologies."

[78] *See* QIAseq Targeted DNA Panel Handbook, pages 41-47 "Protocol: Universal PCR"; QIAseq Targeted Methyl Panel Handbook, pages 29-31 "Library amplification"; QIAseq Targeted RNAscan Panel Handbook, pages 30-34, "Universal PCR amplification" QIAseq Immune Repertoire RNA Library Handbook, pages 37-42 "Protocol: Universal PCR."

[79] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

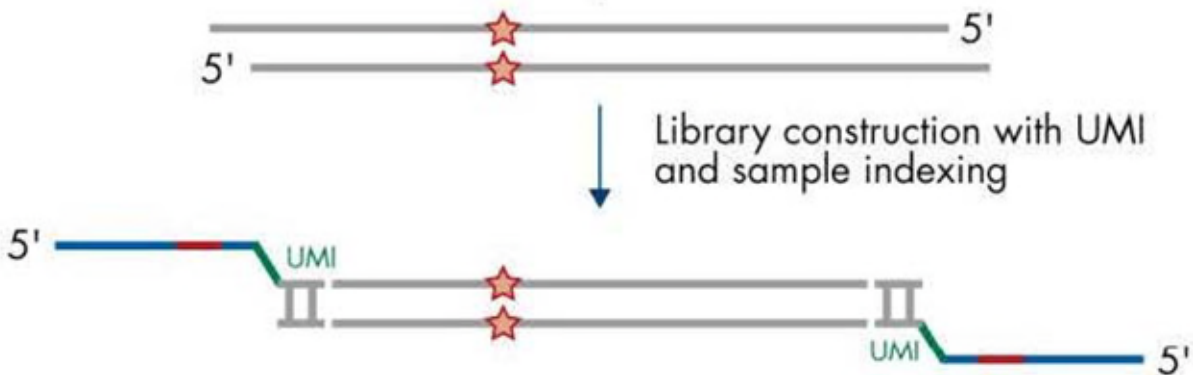


RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 160 of the Complaint.

161. Prior to amplification, an adaptor comprising an identifier site comprising a plurality of nucleotides unique to the amplified fragment is appended to the fragments of nucleic acid.[80]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 161 of the Complaint.

162. As shown in the below diagram,[81] the adaptor is ligated to the nucleic acid fragment of interest (see blue, red, green, and grey addition in the second step of the below).



[80] *See* QIAseq Targeted DNA Panel Handbook, pages 29-36 "Protocol: Adaptor Ligation"; QIAseq Targeted Methyl Panel Handbook, pages 24-25 "Adaptor ligation"; QIAseq Targeted RNAscan Panel Handbook, pages 24-28, "Adaptor ligation" QIAseq Immune Repertoire RNA Library Handbook, pages 29-32 "Procedure: Adaptor Ligation."

[81] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 162 of the Complaint.

163. As shown in the below diagram[82] (an expanded version of the adaptor shown above), the adaptor comprises an identifier site (shown in green) comprising a plurality of nucleotides unique to the fragment.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 163 of the Complaint.

164. The adaptor comprises an identifier site containing a plurality of nucleic acids that are unique to the fragment to which it is ligated.[83] Specifically, each identifier site is unique in sequence content with respect to other identifier sites present in the samples.[84]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 164 of the Complaint.

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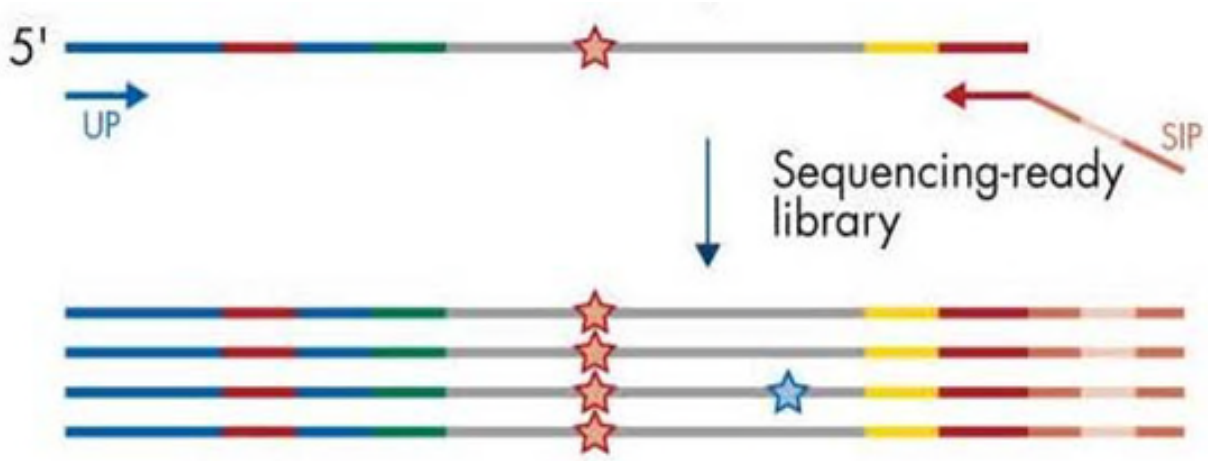
[82] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

[83] *See* QIAseq Targeted DNA Panel Handbook, page 14 "UMI Assignment"; QIAseq Targeted Methyl Panel Handbook pages 8-9 "Principle and procedure"; QIAseq Targeted RNAscan Panel Handbook, page 10 "Molecular Barcodes"; QIAseq Immune Repertoire RNA Library Handbook, page 13 "UMI Assignment."

[84] *See* QIAseq Targeted DNA Panel Handbook, page 14 "UMI Assignment"; QIAseq Targeted Methyl Panel Handbook pages 8-9 "Principle and procedure"; QIAseq Targeted RNAscan Panel Handbook, page 10 "Molecular Barcodes"; QIAseq Immune Repertoire RNA Library Handbook, page 13 "UMI Assignment."

165. The Defendants' Accused Products amplify the adaptor-ligated fragments into amplicons by PCR.[85] As shown below,[86] the Accused Products use primers (shown, as an example, as the blue and red arrows) to amplify the adaptor-ligated fragments by PCR. The result is amplification of the adaptor-ligated fragments generating amplified products, or amplicons, containing the fragment and an identifier site comprising a plurality of nucleotides unique to the amplified fragment (represented below by the products shown beneath the downward facing arrow, with the identifier site shown in green).



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 165 of the Complaint.

166. The Accused Products "sequenc[e] the amplicons to produce sequence reads that include identifier and target sequences." For example, the Accused Products are designed for use

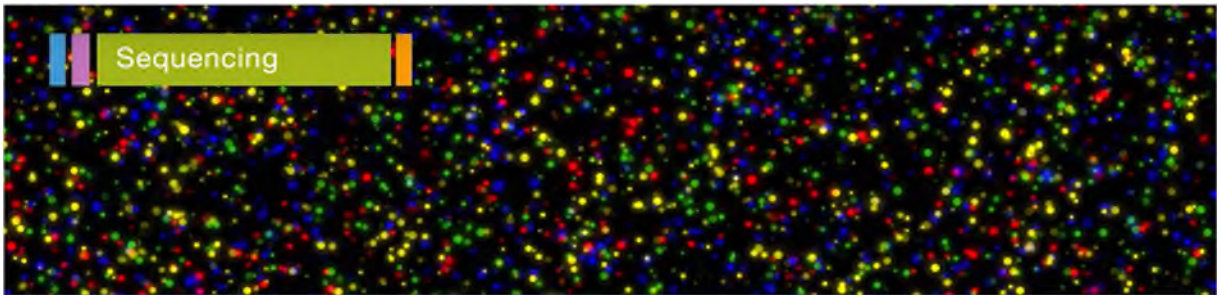
[85] QIAseq Immune Repertoire RNA Library Handbook, page 12 "Figure 1. QIAseq Immune Repertoire RNA Library Kit workflow; see QIAseq Targeted DNA Panel Handbook, pages 41-47 "Protocol: Universal PCR"; QIAseq Targeted Methyl Panel Handbook, pages 29-31 "Library amplification"; QIAseq Targeted RNAscan Panel Handbook, pages 30-34, "Universal PCR amplification" QIAseq Immune Repertoire RNA Library Handbook, pages 37-42 "Protocol: Universal PCR."

[86] Adapted from QIAseq Targeted DNA Panel Handbook, page 11 "Figure 2. QIAseq Targeted DNA Panels workflow."

with next generation sequencing platforms.[87] Specifically, the Accused Products include manuals that direct users towards use of the kits with Illumina or Ion Torrent sequencing platforms.[88]

RESPONSE: QIAGEN admits that certain QIAGEN publications regarding certain Accused Products discuss the Illumina and Ion Torrent sequencing platforms. QIAGEN denies the remaining allegations and characterizations contained in Paragraph 166 of the Complaint.

167. Sequencing on a massively parallel sequencing platform consists of sequencing the adaptor-ligated fragment products, or amplicons, generated in the amplification step.[89] The fragments are attached to the platform and sequenced simultaneously (pictured below,[90] where each colored dot represents a single nucleotide sequencing event).



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 167 of the Complaint.

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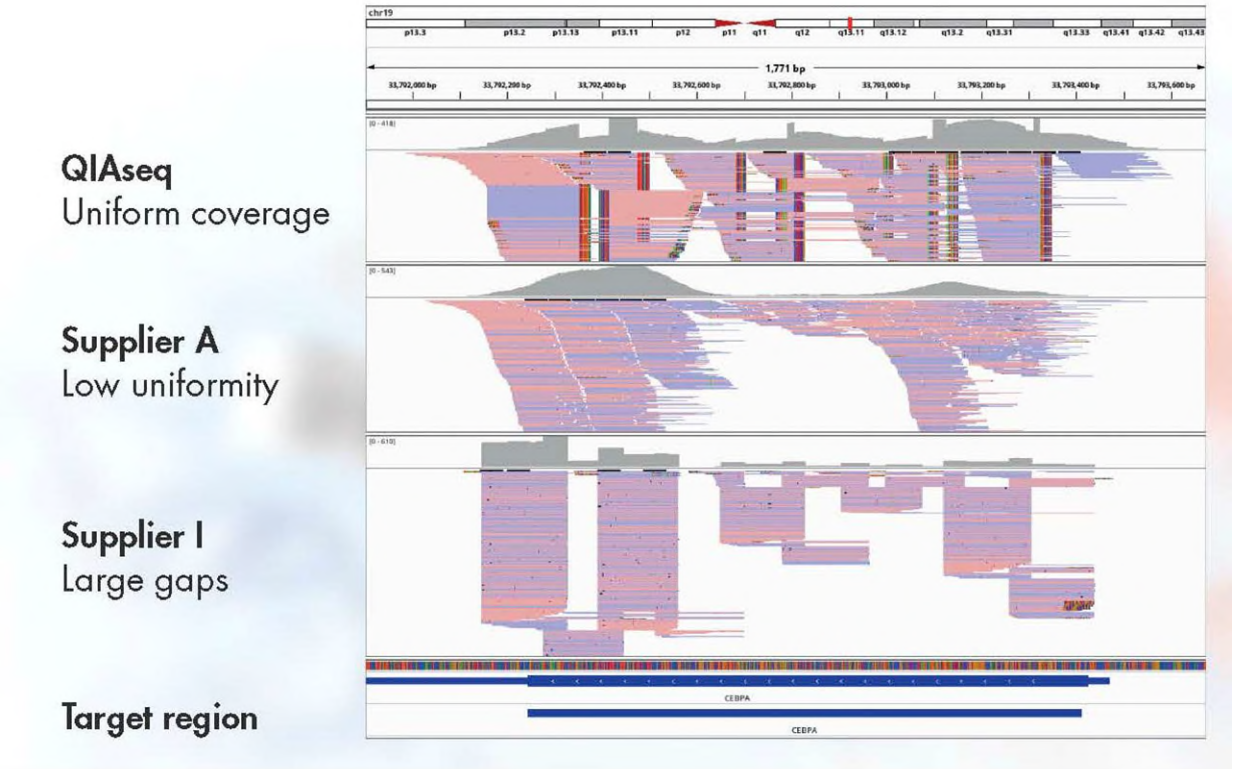
[87] *See* Introducing QIAseq, page 2 ("Enable biological discoveries with QIAseq NGS on any Illumina or Ion Torrent sequencer." at 5); Illumina MiSeq System Guide; MiSeq System Specification Sheet; QIAseq Targeted DNA Panel Handbook (Illumina), pages 51-61 "Protocol: Sequencing Setup on Illumina MiSeq, NextSeq 500/550, MiniSeq, and NovaSeq"; QIAseq Targeted DNA Panel Handbook (Ion Torrent), pages 40-48 "Protocol: Sequencing Setup for Ion Torrent Instruments" and "QIAseq Targeted DNA Panel Ion Chef and S5 set up."

[88] *See* Introducing QIAseq, page 2 ("Enable biological discoveries with QIAseq NGS on any Illumina or Ion Torrent sequencer." at 5); Illumina MiSeq System Guide; MiSeq System Specification Sheet; QIAseq Targeted DNA Panel Handbook (Illumina), pages 51-61 "Protocol: Sequencing Setup on Illumina MiSeq, NextSeq 500/550, MiniSeq, and NovaSeq"; QIAseq Targeted DNA Panel Handbook (Ion Torrent), pages 40-48 "Protocol: Sequencing Setup for Ion Torrent Instruments" and "QIAseq Targeted DNA Panel Ion Chef and S5 set up."

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

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

168. 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 (represented below in the top panel "QIAseq Uniform Coverage" in blue and purple, aligned to a reference genomic sequence in blue at bottom).[91]



RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 168 of the Complaint.

169. The Accused Products "identify[] sequence reads with identical identifier and target sequences as duplicates." For example, the Accused Products provide for the identification of

[91] *See* The QIAseq advantage, page 8; QIAseq Targeted DNA Panel Handbook, pages 51-61 "Protocol: Sequencing Setup on Illumina MiSeq, NextSeq 500/550, MiniSeq, and NovaSeq"; QIAseq Targeted DNA Panel Handbook (Ion Torrent), pages 40-48 "Protocol: Sequencing Setup for Ion Torrent Instruments"; QIAseq Targeted Methyl Panel Handbook, pages 45-51 "Appendix A: Sequencing Setup on Illumina MiSeq and NextSeq"; QIAseq Targeted RNA Panels Handbook, page 37 "Appendix D: Combine Libraries for Multiplex Sequencing"; QIAseq Immune Repertoire RNA Library Handbook, pages 45-51 "Protocol: Sequencing Setup on Illumina MiSeq and NextSeq"; Illumina MiSeq System Guide; MiSeq System Specification Sheet.

duplicative sequencing reads.[92] These duplicative sequence reads consist of the identifier sites (the Molecular Barcodes) and target sequences.[93]

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 169 of the Complaint.

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

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 170 of the Complaint.

171. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 171 of the Complaint.

172. 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

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[92] *See* QIAseq Targeted DNA Panel Handbook, page 13; QIAseq Targeted DNA Extended Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/dna-sequencing/somatic-panels/qiaseq-targeted-dna-extended-panels; QIAseq Targeted RNAscan Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/rna-sequencing/custom-rna-panels/qiaseq-targeted-rnascan-custom-panel; the QIAseq advantage.

[93] *See* QIAseq Targeted DNA Panel Handbook, page 13; QIAseq Targeted DNA Extended Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/dna-sequencing/somatic-panels/qiaseq-targeted-dna-extended-panels; QIAseq Targeted RNAscan Panels, https://www.qiagen.com/us/products/discovery-and-translational-research/next-generation-sequencing/rna-sequencing/custom-rna-panels/qiaseq-targeted-rnascan-custom-panel; the QIAseq advantage.

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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 172 of the Complaint.

173. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 173 of the Complaint.

174. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 174 of the Complaint.

175. 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.

RESPONSE: QIAGEN denies the allegations and characterizations contained in Paragraph 175 of the Complaint.

COUNT I

([Alleged] Infringement of U.S. Patent 10,036,012 by ALL QIAGEN DEFENDANTS)

176. Plaintiff repeats and re-alleges the allegations of paragraphs 1–175 as though fully set forth herein.

RESPONSE: QIAGEN incorporates by reference Paragraphs 1-175 of this Answer as set forth fully herein.

177. Plaintiff Tecan Genomics is the owner of all rights in the ’012 patent.

RESPONSE: QIAGEN lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 177 and on that basis denies them.

178. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 178.

179. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 179.

180. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 180.

181. 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.[94] Defendants also advertise and tout the benefits of the Accused Products to their distributors, customers, and users.[95]

RESPONSE: QIAGEN denies the allegations of Paragraph 181.

182. 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.

RESPONSE: QIAGEN admits that it was aware of the '012 patent at least a day before the filing of this complaint. QIAGEN denies the remaining allegations of Paragraph 182.

183. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 183.

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

RESPONSE: QIAGEN denies the allegations of Paragraph 184.

185. 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

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[94] *See, e.g., Next-Generation Sequencing*, accessible at https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing.

[95] *See, e.g., Next-Generation Sequencing*, accessible at https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing.

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

RESPONSE: QIAGEN admits that it was aware of the '012 patent at least a day before the filing of this complaint. QIAGEN denies the remaining allegations of Paragraph 185.

186. Defendants' infringement of the '012 patent has been and continues to be willful.

RESPONSE: QIAGEN denies the allegations of Paragraph 186.

187. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 187.

188. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 188 and denies that Plaintiffs are entitled to any relief whatsoever.

COUNT II

([Alleged] Infringement of U.S. Patent 10,876,108 by ALL QIAGEN DEFENDANTS)

189. Plaintiff repeats and re-alleges the allegations of paragraphs 1–188 as though fully set forth herein.

RESPONSE: QIAGEN incorporates by reference Paragraphs 1-188 of this Answer as set forth fully herein.

190. Plaintiff Tecan Genomics is the owner of all rights in the '108 patent.

RESPONSE: QIAGEN lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 190 and on that basis denies them.

191. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 191.

192. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 192.

193. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 193.

194. 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.[96] Defendants also advertise and tout the benefits of the Accused Products to their distributors, customers, and users.[97]

RESPONSE: QIAGEN denies the allegations of Paragraph 194.

195. 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 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.

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[96] *See, e.g.*, *Next-Generation Sequencing*, accessible at https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing.

[97] *See, e.g.*, *Next-Generation Sequencing*, accessible at https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing.

RESPONSE: QIAGEN admits that it was aware of the '108 patent at least a day before the filing of this complaint. QIAGEN denies the remaining allegations of Paragraph 195.

196. 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 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 196.

197. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 197.

198. 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.

RESPONSE: QIAGEN admits that it was aware of the '108 patent at least a day before the filing of this complaint. QIAGEN denies the remaining allegations of Paragraph 198.

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

RESPONSE: QIAGEN denies the allegations of Paragraph 199.

200. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 200.

201. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 201 and denies that Plaintiffs are entitled to any relief whatsoever.

COUNT III

([Alleged] Infringement of U.S. Patent 11,098,357 by ALL QIAGEN DEFENDANTS)

202. Plaintiff repeats and re-alleges the allegations of paragraphs 1–201 as though fully set forth herein.

RESPONSE: QIAGEN incorporates by reference Paragraphs 1-201 of this Answer as set forth fully herein.

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

RESPONSE: QIAGEN lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 203 and on that basis denies them.

204. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 204.

205. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 205.

206. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 206.

207. 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.[98] Defendants also advertise and tout the benefits of the Accused Products to their distributors, customers, and users.[99]

RESPONSE: QIAGEN denies the allegations of Paragraph 207.

208. 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.

RESPONSE: QIAGEN admits that it was aware of the '357 patent at least a day before the filing of this complaint. QIAGEN denies the remaining allegations of Paragraph 208.

209. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 209.

210. 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

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[98] *See, e.g., Next-Generation Sequencing*, accessible at https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing.

[99] *See, e.g., Next-Generation Sequencing*, accessible at https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing.

substantial non-infringing uses, and (c) are especially made or adapted for use in infringing one or more claims of the ’357 patent.

RESPONSE: QIAGEN denies the allegations of Paragraph 210.

211. 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.

RESPONSE: QIAGEN admits that it was aware of the ’357 patent at least a day before the filing of this complaint. QIAGEN denies the remaining allegations of Paragraph 211.

212. Defendants’ infringement of the ’357 patent has been and continues to be willful.

RESPONSE: QIAGEN denies the allegations of Paragraph 212.

213. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 213.

214. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 214 and denies that Plaintiffs are entitled to any relief whatsoever.

COUNT IV

([Alleged] Infringement of U.S. Patent 11,725,241 by ALL QIAGEN DEFENDANTS)

215. Plaintiff repeats and re-alleges the allegations of paragraphs 1–214 as though fully set forth herein.

RESPONSE: QIAGEN incorporates by reference Paragraphs 1-214 of this Answer as set forth fully herein.

216. Plaintiff Tecan Genomics is the owner of all rights in the ’241 patent.

RESPONSE: QIAGEN lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 216 and on that basis denies them.

217. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 217.

218. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 218.

219. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 219.

220. 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.[100] Defendants also advertise and tout the benefits of the Accused Products to their distributors, customers, and users.[101]

RESPONSE: QIAGEN denies the allegations of Paragraph 220.

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[100] *See, e.g.*, *Next-Generation Sequencing*, accessible at https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing.

[101] *See, e.g.*, *Next-Generation Sequencing*, accessible at https://www.qiagen.com/us/product-categories/discovery-and-translational-research/next-generation-sequencing.

221. 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.

RESPONSE: QIAGEN admits that it was aware of the '241 patent at least a day before the filing of this complaint. QIAGEN denies the remaining allegations of Paragraph 221.

222. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 222.

223. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 223.

224. 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.

RESPONSE: QIAGEN admits that it was aware of the '241 patent at least a day before the filing of this complaint. QIAGEN denies the remaining allegations of Paragraph 224.

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

RESPONSE: QIAGEN denies the allegations of Paragraph 225.

226. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 226.

227. 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.

RESPONSE: QIAGEN denies the allegations of Paragraph 227 and denies that Plaintiffs are entitled to any relief whatsoever.

DEMAND FOR JURY TRIAL

QIAGEN acknowledges that Tecan demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

These paragraphs of the Complaint set forth the statement of relief requested by Plaintiffs to which no response is required. QIAGEN denies that Plaintiffs are entitled to any of the requested relief and denies any allegations contained therein.

GENERAL DENIAL

To the extent not specifically admitted herein, the allegations of the Complaint are denied. QIAGEN denies any allegations that may be implied by or inferred from the headings of the Complaint.

DEFENSES

QIAGEN has insufficient knowledge or information upon which to form a belief as to whether there may be additional defenses available, and therefore QIAGEN reserves the right to assert such additional defenses based upon subsequently acquired knowledge or information that becomes available through discovery or otherwise. Without assuming the burden of proof on any

matters where that burden rests on Plaintiffs, QIAGEN asserts the following defenses with respect to the Complaint:

FIRST DEFENSE

The Complaint, and each cause of action purportedly alleged therein, fails to state any claim for which relief may be granted.

SECOND DEFENSE

QIAGEN does not infringe and has not infringed, directly or indirectly, literally or under the doctrine of equivalents, is not liable for infringement of any valid and enforceable claim of the '012 patent, '108 patent, '357 patent and '241 patent, including under the doctrine of equivalents, and has not otherwise committed any acts in violation of 35 U.S.C. § 271.

Tecan has not met their burden of proof to show infringement of the '012 patent, '108 patent, '357 patent or '241 patent in its Complaint and will be unable to meet their burden of proof to show infringement of the '012 patent, '108 patent, '357 patent or '241 patent.

THIRD DEFENSE

Plaintiffs' claims are barred in whole or in part because one or more claims of the '012 patent, '108 patent, '357 patent and '241 patent are invalid for failure to comply with one or more of the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 100, et seq., including, but not limited to, §§ 101, 102, 103, and/or 112.

FOURTH DEFENSE

Plaintiffs' claims are barred in whole or in part based on the doctrines of estoppel and/or license.

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FIFTH DEFENSE

Without admitting that Tecan's Complaint states a claim upon which relief can be granted, any remedies are limited to the extent that Plaintiffs seek overlapping or duplicative recovery pursuant to the various claims for any alleged single wrong.

SIXTH DEFENSE

The Court lacks personal jurisdiction over QIAGEN GmbH and QIAGEN N.V. which are limited liability companies organized and existing under the laws of Germany and the Netherlands, respectively.

SEVENTH DEFENSE

The claims of the '012 patent, '108 patent, '357 patent and '241 patent are unenforceable under the doctrine of unclean hands.

PRAYER FOR RELIEF

QIAGEN respectfully requests that this Court enter judgment in its favor and against Tecan, enter judgment that this case is an exceptional case under 35 U.S.C. § 285 and/or other applicable laws, award the costs and expenses of the suit incurred herein, attorneys' fees reasonably expended in this action, and such other and further relief as the Court deems just and appropriate under the circumstances.

DEMAND FOR JURY TRIAL

QIAGEN demands a trial by jury on all issues so triable.

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Respectfully submitted,

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