

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ARCHERDX, INC. and THE GENERAL )  
HOSPITAL CORPORATION d/b/a )  
MASSACHUSETTS GENERAL )  
HOSPITAL, )  
 )  
Plaintiffs, )  
 )  
v. ) C.A. No. 18-1019 (MN)  
 )  
QIAGEN SCIENCES, LLC, QIAGEN LLC )  
f/k/a QIAGEN INC., QIAGEN BEVERLY, )  
LLC f/k/a QIAGEN BEVERLY, INC., )  
QIAGEN GAITHERBURG, LLC f/k/a )  
QIAGEN GAITHERSBURG, INC., )  
QIAGEN GMBH, QIAGEN N.V. and )  
JONATHAN ARNOLD, )  
 )  
Defendants. )

**MEMORANDUM ORDER**

At Wilmington this 18th day of June 2020:

IT IS HEREBY ORDERED that the agreed-upon construction of the claim term “the same sequence” in U.S. Patent No. 10,450,597 (“the ’597 Patent”) is: “the identical sequence,” (’597 Patent, cl. 1).

Further, as announced at the hearing on May 28, 2020, IT IS HEREBY ORDERED that the disputed claim terms of the ’597 Patent are construed as follows:

1. “double-stranded target nucleic acid” means “a target nucleic acid comprising a first strand and a second strand that are complementary to each other and hybridized to each other but that may have 3’ or 5’ overhangs or tails,” (’597 Patent, cl. 1, 3, 11, 25-27, & 29);
2. “target nucleic acid” means “a nucleic acid molecule of interest (e.g., a nucleic acid to be analyzed),” (’597 Patent, cl. 1, 3, 11, 25-27, & 29);
3. “target-specific primer” means “a primer that has a level of complementarity between the primer and the target such that there exists an annealing temperature at which the primer will anneal to and mediate

amplification of the target nucleic acid and will not anneal to or mediate amplification of non-target sequences present in a sample,” (’597 Patent, cl. 1, 14, 19, & 21);

4. “target-specific hybridization sequence” means “a sequence of the target-specific primer that has sufficient complementarity with a sequence of the double-stranded target nucleic acid to enable hybridization between the target-specific primer and a sequence in/of the double-stranded target nucleic acid,” (’597 Patent, cl. 1, 13, 14, 19, & 20);
5. “plurality of different primers” means “two or more different primers,” (’597 Patent, cl. 1, 5, 24, 25, & 26);
6. “a sequence that is characteristic of the target-specific primer” means “a sequence from one of the strands of the single target nucleic acid recited in step (a),” (’597 Patent, cl. 1);
7. “[contacting a] first nucleic acid template comprising a sequence of a first strand of a double-stranded target nucleic acid [with a complementary target-specific primer that comprises a target-specific hybridization sequence]” needs no construction, (’597 Patent, cl. 1 & 2);
8. “[contacting a] second nucleic acid template comprising a sequence of a second strand that is complementary to the sequence of the first strand of the double-stranded target nucleic acid” needs no construction, (’597 Patent, cl. 1).<sup>1</sup>

The parties briefed the issues (*see* D.I. 226) and submitted a Joint Claim Construction Chart containing intrinsic evidence (*see* D.I. 249, Ex. A<sup>2</sup>). They also submitted an extensive Appendix that included four expert declarations. (D.I. 227.) The Court carefully reviewed all submissions in connection with the parties’ contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 251), and applied the following legal standards in reaching its decision.

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<sup>1</sup> Pursuant to the parties’ request, the Court considered the disputed terms in the order they were argued rather than the order in which they were presented in the final amended claim construction chart. (*See* D.I. 249 at 5; D.I. 251.)

<sup>2</sup> The parties amended their original claim construction chart (D.I. 194) three times. (D.I. 225; D.I. 246, Ex. A; D.I. 249, Ex. A). The Court references the third, and final, amended claim construction chart.

## I. LEGAL STANDARDS

“[T]he ultimate question of the proper construction of the patent [is] a question of law,” although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). “[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Id.* at 1314. “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted).

The patent specification “is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. “Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir.

1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence, . . . consists of the complete record of the proceedings before the [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

In some cases, courts “will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 135 S. Ct. at 841. Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. Expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, although extrinsic evidence “may be useful to the court,” it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

## II. THE COURT'S RULING

The Court's rulings regarding all of the disputed claim terms of the '597 Patent were announced from the bench at the conclusion of the hearing as follows:

Good afternoon again, counsel. Thank you for the arguments today. The Court previously construed seven terms in Plaintiffs' U.S. Patent No. 10,017,810. Today we are addressing their U.S. Patent No. 10,450,597, which has been added to the case. There are another eight terms in dispute in that patent.

I am prepared to rule on all eight of those disputes. As with my earlier constructions, I will not be issuing a written opinion on the constructions of these eight terms, but I will issue an order stating my rulings.

Also, I want to emphasize that, as with my prior ruling, although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the '597 Patent and the portions of the prosecution history submitted. There was full briefing on each of the disputed terms. There was an extensive appendix that included two more expert declarations from Niall Lennon on behalf of Plaintiffs and two more from Michael Metzker on behalf of Defendants. There has been argument here today. All of that has been carefully considered.

I also incorporate the law regarding claim construction set out in my earlier order and will also set it out in the order that I issue on the '597 Patent.

Additionally, I note that as to a person of ordinary skill in the art, the parties appear to agree that any differences in their respective proposals are not relevant to claim construction.<sup>[3]</sup>

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<sup>3</sup> Through Dr. Lennon, Plaintiffs define the person of ordinary skill in the art as someone having “a Ph.D. in Biology, Molecular Biology, Genetics, Biochemistry, Pharmacology, Biomedical Engineering or related fields, with 2 to 5 years of experience in next generation sequencing OR a BSc in Biology, Molecular Biology, Genetics, Biochemistry, Pharmacology, Biomedical Engineering, or related fields and 5 to 6 years of experience in next generation sequencing.” (See D.I. 124-1 ¶ 16 (JA007).) Defendants, through Dr. Metzker, define the person of ordinary skill as one having “either an M.D./Ph.D. or Ph.D. in Molecular Biology, Molecular Genetics, Chemistry, Engineering, or equivalent disciplines with two years of experience, or a Bachelor of Science in such fields with five years of experience, with such experience including library preparation methods, PCR, and next generation sequencing.” (See D.I. 124-2 ¶ 26 (JA211).)

Now as to my rulings. First, we have the term “double-stranded target nucleic acid” in claims 1, 3, 11, 25 through 27, and 29.

Plaintiffs propose the construction “a target nucleic acid comprising a first strand and a second strand that are complementary to each other and that are sufficiently hybridized to maintain a double-stranded nature.” Defendants propose the construction “a target nucleic acid consisting of a first strand and a second strand that are complementary to each other.”

The dispute here appears to be over whether some portion of the molecule may be single-stranded, such as a tail, or whether it must be 100 percent double-stranded.

Here, I mostly agree with Plaintiffs and conclude that the term “double-stranded” does not require that a molecule be entirely or 100 percent double-stranded. And I will construe the term to mean “a target nucleic acid comprising a first strand and a second strand that are complementary to each other and hybridized to each other but that may have 3’ or 5’ overhangs or tails.”

This construction is consistent with the ordinary meaning of the term “double-stranded” as used in references cited by the parties and in a number of Qiagen’s patents.<sup>[4]</sup>

Defendants argue that Plaintiffs, in essence, define “double-stranded” in the intrinsic evidence to mean wholly double-stranded. They point to references cited in the patent, which are incorporated by reference into the patent. Although I agree that those references are part of the intrinsic evidence, I disagree that those references provide a clear definition for the term that alters the ordinary meaning. For example, Defendants cite U.S. Patent No. 7,282,337 [(“the ’337 Patent”)] and the Encyclopedia of Molecular Biology. The ’337 Patent describes nucleic acid molecules as “single-stranded, double-stranded, or double-stranded with single-stranded regions.” [See ’337 Patent, col. 6 ll. 36-38.] I do not read this to clearly redefine the term “double-stranded,” however. Instead, it appears to allow for the term “double-stranded” to be used to encompass molecules that are fully double-stranded as well as those that have some portions that are single-stranded. And nothing in

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<sup>4</sup> See, e.g., The Encyclopedia of Molecular Biology 956, 1036 (John Kendrew et al. eds. 1994) (D.I. 227, Ex. E, Ex. 5); U.S. Patent No. 8,628,914 (D.I. 227, Ex. A, Ex. 2); N.H. Dekker et al., Joining of Long Double-Stranded RNA Molecules Through Controlled Overhangs, 32 Nucleic Acids Research e140, 1, Fig. 1 (2004) (D.I. 227, Ex. A, Ex. 4).

that sentence suggests that a nucleic acid molecule must be 100 percent single-stranded or 100 percent double-stranded, but not both.

Similarly, although the Encyclopedia, in discussing viruses and fill-in reactions, refers to molecules having portions that are single-stranded and portions that are double-stranded, [*see, e.g.*, The Encyclopedia of Molecular Biology 377, 484 (John Kendrew et al. eds. 1994),] it also refers to double-stranded molecules having single-stranded ends. For example, in discussing “sticky ends” it refers to “single-stranded DNA termini protruding from fragments of double-stranded DNA.” [*Id.* at 1036.] And in discussing restriction enzymes, it refers to double-stranded DNA fragments with single-stranded extensions at the ends. [*Id.* at 956.] This, too, allows for use of the term “double-stranded” in connection with molecules having single-stranded termini.

The parties also dispute whether the definition of “portions” and Figure 2A in the patent support Plaintiffs’ or Defendants’ construction. I do not find that either of these parts of the patent clearly define or alter the ordinary meaning of “double-stranded.” For example, with Figure 2A, there is some incongruity between the illustration and the description. The illustration suggests that a double-stranded molecule having a single-stranded end is the “double-stranded” molecule purified in Step 205. Yet the written description suggests that the double-stranded illustration after Step 206 in the Figure is representative of the product of Step 204 because it includes the common sequences. [*See* ’597 Patent, col. 10 l. 63 – 11 l. 15.]

And finally, Defendants argue that the “double-stranded target nucleic acid” of the claims has a first strand and a second strand that are complementary to each other. And then argue that the word “complementary” in the patent means 100 percent complementary and thus the “double-stranded target nucleic acid” must be 100 percent complementary. I do not, however, read the patent to use the word “complementary” on its own to require 100 percent complementarity. Indeed, the patent, at column 38, line 2, refers to varying levels of complementarity[,] including 100 percent. If the word “complementary” on its own meant 100 percent, then the reference to 100 percent [in that sentence] would be redundant.

The second disputed term is “target nucleic acid,” also in claims 1, 3, 11, 25 through 27, and 29. Plaintiffs propose the construction “a nucleic acid molecule of interest (e.g., a nucleic acid to be analyzed).” Defendants’ proposal includes all of Plaintiffs’

proposal and then adds to the end: “which is a genomic nucleic acid molecule or cDNA molecule.”

Here, I agree with Plaintiffs and will construe the term to mean “a nucleic acid molecule of interest (e.g., a nucleic acid to be analyzed).”

It is settled law that when the specification defines a claim term, “the inventor’s lexicography governs.” [*Phillips*, 415 F.3d at 1316.] “To act as its own lexicographer, a patentee must ‘clearly set forth a definition of the disputed claim term’ other than its plain and ordinary meaning.” [*Cont’l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019); accord *Pacing Techs., LLC v. Garmin Int’l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015); *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012); *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).]

The patentee has done so here, stating “[a]s used herein, the term ‘target nucleic acid’ refers to a nucleic acid molecule of interest (e.g., a nucleic acid to be analyzed).” [’597 Patent, col. 15 ll. 30-32.] Neither party disputes that that is the definition.

Instead, Defendants contend that additional limitations must be added to resolve a dispute regarding what it means to be “a nucleic acid molecule of interest” and/or “a nucleic acid to be analyzed” – that is, to resolve their disputes regarding the meaning of certain aspects of the definition provided in the specification.

It is not, however, the Court’s job in claim construction to resolve every derivative dispute between the parties regarding the meaning of the terms.<sup>[5]</sup>

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<sup>5</sup> See *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007) (“[A] sound claim construction need not always purge every shred of ambiguity. The resolution of some line-drawing problems—especially easy ones like this one—is properly left to the trier of fact.” (citing *PPG Indus. V. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) (“[A]fter the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.”))); see also *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1372 (Fed. Cir. 2016) (“Where a district court has resolved the questions about claim scope that were raised by the parties, it is under no obligation to address other potential ambiguities that have no bearing on the operative scope of the claim. . . . This is because ‘[s]uch an endeavor could proceed ad infinitum, as every word—whether a claim term itself, or the words a court uses



And moreover, here, I am not convinced that the disputes raised by Defendants are those of claim construction rather than factual questions relating to infringement – e.g., whether the particular molecule asserted to be a target nucleic acid is “of interest” or “to be analyzed.” Thus, I reject the changes proposed by Defendants to the definition set forth in the specification.

The third disputed term is “target-specific primer” in claims 1, 14, 19, and 21. During the argument today, Plaintiffs agreed that the “target-specific primer” must target the “target nucleic acid” and that Defendants’ construction is correct if “target nucleic acid” is not limited to genomic DNA. In my construction of “target nucleic acid,” I declined to read in the limitation that the target nucleic acid must be “a genomic nucleic acid molecule or cDNA molecule.” Thus, I understand that Plaintiffs agree to the construction advocated by Defendants and I will adopt that.

And to be clear, that construction is “a primer that has a level of complementarity between the primer and the target such that there exists an annealing temperature at which the primer will anneal to and mediate amplification of the target nucleic acid and will not anneal to or mediate amplification of non-target sequences present in a sample.”<sup>[6]</sup>

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to construe a claim term—is susceptible to further definition, elucidation, and explanation.” (internal citations omitted)).

<sup>6</sup> The agreed-upon construction is supported by the intrinsic evidence. The relevant claim language says: “A method of preparing nucleic acids for analysis, the method comprising: (a) contacting a first nucleic acid template comprising a sequence of a first strand of a double-stranded target nucleic acid with a complementary target-specific primer that comprises a target-specific hybridization sequence, under conditions to promote template-specific hybridization and extension of the target specific primer. *See* ’597 Patent, cl. 1. The only thing referred to as a “target” in the claim language is the “double stranded target nucleic acid.” The fact that the nucleic acid template is “contacted” by the target-specific primer does not alter that, as the “double stranded target nucleic acid” is included within the nucleic acid template. The term at issue is “target-specific primer,” not “template-specific primer” or “contact primer.” Thus, based on the language of the claim itself, the Court is inclined to find that the “target” of the “target-specific primer” is the “target nucleic acid.” Additionally, the prosecution history indicates that the applicants intended for the “target-specific primer” to “target” the “target nucleic acid” recited in the claims. During prosecution, the applicants stated that “[t]he present claims . . . relate to two extension reactions to generate an extension product containing ‘a sequence that is characteristic of the target-specific primer’ – that is, an extension product encoding a sequence from the target nucleic acid recited in step (a).” (*See* D.I. 227, Ex. J, Ex. 5 at ADX-000490591.)

The fourth disputed term is “target-specific hybridization sequence” in claims 1, 13, 14, 19, and 20. Plaintiffs offer the construction “a sequence of the target-specific primer, that has sufficient complementarity with a sequence of another nucleic acid (e.g., a template molecule, a target sequence) to enable hybridization between the nucleic acids.” Defendants counter with the construction “a sequence of the target-specific primer that that has sufficient complementarity with a sequence of the double-stranded target nucleic acid to enable hybridization between the target-specific primer and a sequence in/of the double-stranded target nucleic acid.”

The dispute here is essentially the same as the dispute over “target-specific primer” – whether the hybridization sequence must be specific to the target nucleic acid or may enable hybridization to any part of the nucleic acid template.

In the papers, Plaintiffs propose that I adopt the specification’s definition of “hybridization sequence.” Yet that definition is general and does not account for the “target-specific” modifier in the term at issue. Defendants’ proposal, on the other hand, modifies the specification’s “hybridization sequence” definition to match its argument that the “target-specific primer” must target the “double-stranded target nucleic acid.”

As I already stated and the parties agreed, the target of the “target-specific primer” is the “double-stranded target nucleic acid.” As the “target-specific hybridization sequence” is a part of the “target-specific primer,” its target must be the same.

Thus, I will construe “target-specific hybridization sequence” to mean “a sequence of the target-specific primer that has sufficient complementarity with a sequence of the double-stranded target nucleic acid to enable hybridization between the target-specific primer and a sequence in/of the double-stranded target nucleic acid.”<sup>[7]</sup>

The fifth disputed term is “plurality of different primers” in claims 1, 5, 24, 25, and 26. Plaintiffs propose the construction “two or more different primers.” Defendants propose: “two or more different primers that are not target-specific primers.” The dispute

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<sup>7</sup> The Court intentionally uses “that has” rather than “that that has” in its construction. This, however, is solely a grammatical modification. Although “that that has” appears in the specification’s definition of “hybridization sequence,” the repetition of “that” appears to be a typographical error.

is over Defendants' addition of the language "that are not target-specific primers."

Here, I agree with Plaintiffs and will construe the term to mean "two or more different primers."

This construction is supported by the intrinsic evidence, which allows for the "different primers" to be target-specific primers. For example, at column 8, lines 60 through 64, the patent states: "Subsequent rounds of PCR or extension may be performed using different primers (e.g., second tail primers or nested primers or a second target-specific primer) to incorporate different sequences into the resulting products." Similarly, at column 30, lines 23 through 26, the patent states: "In some embodiments, target nucleic acids in a sample, or separate portions of a sample, can be amplified with a plurality of primers (e.g., a plurality of first and second target-specific primers)."

Defendants assert that the specification distinguishes the claimed method from prior art sequencing in which primers were designed based on known sequences at each end of the target molecule. [*See* '597 Patent, col. 6 ll. 26-30.] And thus, they argue, I should except target-specific primers because if the "plurality of different primers" are designed based on known sequences, as the claimed "target-specific primer" is, then the invention is covered by the prior art. Although it is possible that Plaintiffs' construction will allow for more arguments based on the prior art, there is no argument that construing the term as I am will necessarily leave the claims invalid. And I reject Defendants' arguments.

The sixth disputed term is "a sequence that is characteristic of the target-specific primer" in claim 1. During the argument, the parties agreed to the construction "a sequence from one of the strands of the single target nucleic acid recited in step (a)." I will adopt that construction.

Lastly, we have two terms – (1) "contacting a first nucleic acid template comprising a sequence of a first strand of a double-stranded target nucleic acid with a complementary target-specific primer that comprises a target-specific hybridization sequence" as used in claims 1 and 5; and (2) "contacting a second nucleic acid template comprising a sequence of a second strand that is complementary to the sequence of the first strand of the double-stranded target nucleic acid," also as used in claim 1. These terms comprise the bulk of steps (a) and (b), respectively, described in claim 1.

Plaintiffs propose that no construction is necessary for these terms and the Court should leave them as-is. Defendants, however, want me to construe the first of these terms as “contacting a set of nucleotides in/of a first strand of a double-stranded target nucleic acid that make up a first nucleic acid template with a complementary target-specific primer that comprises a target-specific hybridization sequence,” and ask that I construe the second to mean “contacting a set of nucleotides in/of a second strand of the double-stranded target nucleic acid that is complementary to the first strand that make up a second nucleic acid template.”

I will note first that the parties agree that steps (a) and (b) may be interchangeable and sequential. That is not the dispute. [*See also* ’597 Patent, col. 6 l. 64 – col. 7 l. 8 (“In some embodiments, steps (a) and (b) above are performed sequentially.”).]

Instead, the dispute seems to be Defendants’ request that I include language that requires the “nucleic acid template” claimed to be made up only of the “target nucleic acid.” Defendants’ proposed limitations, however, are contradicted by the plain language of the claims, which say that the nucleic acid template comprises a sequence of a first strand of the double-stranded target nucleic acid and not that it is limited to only that sequence.


“Comprising” is a term of art that denotes inclusion but not limitation.<sup>181</sup> And that is also the way “comprising” is defined in the patent, starting at column 38, line 66, where it says: “As used herein the term ‘comprising’ or ‘comprises’ is used in reference to compositions, methods, and respected component(s) thereof, that are essential to method or composition, yet open to the inclusion of unspecified elements, whether essential or not.”

Defendants’ proposed additions are also inconsistent with claim 5, which specifies that “the first nucleic acid template comprises an extension product resulting from the hybridization and extension of the at least one of the plurality of different primers in step (b).”

Thus, I see no reason to limit the first and second strands as proposed by Defendants, and I agree with Plaintiffs that no further construction of the terms are necessary.

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<sup>8</sup> *Waters v. Agilent*, 410 F. Supp. 3d 702, 709-20 (D. Del. Sep. 20, 2019) (citing *Mars, Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004)).

  
The Honorable Maryellen Noreika  
United States District Judge