IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COLD SPRING HARBOR LABORATORY, **Plaintiff,** **v.** **GUARDANT HEALTH, INC.,** **Defendant.**	**Court No. 1:25-cv-00263-JCG**

OPINION AND ORDER

[Providing claim construction for the patents in suit.]

Dated: May 27, 2026

Sara M. Metzler and Kelly E. Farnan, Richards, Layton & Finger, P.A., of Wilmington, DE; John M. Desmarais, Brian D. Matty, Kevin Goon, and Ashley DaBiere, Desmarais LLP, of New York, N.Y. Attorneys for Plaintiff Cold Spring Harbor Laboratory.

Brian E. Farnan and Michael J. Farnan, Farnan LLP, of Wilmington, DE; Edward R. Reines and Matthew M. Everts, Jones Day, of Palo Alto, CA; Derek C. Walter, Jones Day, of San Francisco, CA. Attorneys for Defendant Guardant Health, Inc.

Choe-Groves, Judge: This matter is before the Court for claim construction of terms in U.S. Patent Numbers 10,947,589 ("the '589 Patent") and 12,234,510 ("the '510 Patent") (collectively, "Asserted Patents" or "Patents"). See Joint Claim Construction Chart ("Joint Chart") (D.I. 54); Am. Joint Claim Construction Chart ("Am. Joint Chart") (D.I. 67); Joint Chart at Ex. 1 ("'589 Patent") (D.I. 54-1); Joint

Chart at Ex. 2 ("'510 Patent") (D.I. 54-2). The Parties seek construction of the following terms and phrases: "nucleotide sequences that are not known before the tagged nucleic acid molecules are generated" and "random nucleotide sequences" from the '510 Patent, and "location on a [reference] genome" from both the '589 and '510 Patents. Am. Joint Chart at 2–5; see Joint Chart.[1]

Upon consideration of the brief and arguments of counsel, the Court construes the disputed claim terms and phrases as set forth below.

BACKGROUND

Plaintiff Cold Spring Harbor Laboratory ("Plaintiff" or "Cold Spring") filed suit against Defendant Guardant Health, Inc. ("Defendant" or "Guardant") for infringement of the Asserted Patents. Pl.'s First Am. Compl. Patent Infringement ("Am. Compl.") (D.I. 15). This Opinion concerns the first step of the two-step infringement analysis, the construction of claims asserted in the '589 Patent and '510 Patent.

The United States Patent and Trademark Office ("USPTO") issued the '589 Patent on March 16, 2021, and the '510 Patent on February 25, 2025. '510 Patent; '589 Patent. Both Patents are titled "Varietal Counting of Nucleic Acids for

[1] The Parties identified four disputed terms from the Asserted Patents requiring construction in the Joint Claim Construction Chart, but only propose three disputed terms for construction in the Joint Claim Construction Brief and Amended Joint Claim Construction Chart. See Joint Chart; Joint Claim Construction Brief ("Joint Br.") at 3 (D.I. 64).

Obtaining Genomic Copy Number Information" and are continuations of the same application filed in 2011. '510 Patent; '589 Patent. Cold Spring is the owner of all rights, title, and interest in the Asserted Patents. Am. Compl. at ¶¶ 31, 37. Genomic copy information is often obtained through whole genome amplification, which can be a problematic method due to over-sampling of certain regions, leading to a non-uniform amplification of the genome. '589 Patent at 1:37–40; '510 Patent at 1:37–40. The methods claimed in the Asserted Patents provide for obtaining genomic copy number information that is unaffected by amplification distortion. '589 Patent at 2:43–45; '510 Patent at 2:43–45. Cold Spring alleges that the Guardant360 and Guardant360 CDx blood tests infringe the Asserted Patents by practicing the claimed methods, such as obtaining segments of nucleic acid from a sample, tagging the segments with nucleic acid tags, subjecting the plurality of unique tagged nucleic acid molecules to polymerase chain reactions, sequencing amplified copies of tagged nucleic acid molecules, assigning tag associated sequence reads to a location of a reference genome, and obtaining copy number information from the genomic nucleic acids in the sample. Am. Compl. at ¶¶ 44–57.

The Court held a claim construction hearing on April 2, 2026, and the Parties did not call expert witnesses. Sched. Order (May 12, 2025) (D.I. 18).

CLAIM CONSTRUCTION STANDARD

When the meaning of a patent claim's language is disputed, the court must construe the claim as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). "[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman, 517 U.S. at 372. "The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.'" O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed. Cir. 2008) (citing Markman, 52 F.3d at 976).

"The patent is a fully integrated written instrument." Markman, 52 F.3d at 978. For the purpose of claim construction, "[a] court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (emphasis omitted) (citing Markman, 52 F.3d at 979). "The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." Thorner v. Sony Comput. Ent. Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)).

Limitations from dependent claims, the specification, and embodiments will not be read into the claims. "The doctrine of claim differentiation [ ] creates a presumption that [ ] dependent claim limitations are not included in the independent claim." GE Lighting Sols., LLC v. AgiLight, Inc., 750 F.3d 1304, 1310 (Fed. Cir. 2014) (citation omitted). Limitations found in the specification are not imposed into the claims. Phillips, 415 F.3d at 1323–24. In the same vein, "[i]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." GE Lighting Sols., 750 F.3d at 1309 (citation omitted) (discussing a figure as a "depicted embodiment").

DISCUSSION

I. Undisputed Terms

The Court acknowledges that the Parties agree on the construction of one term from Claims 2 and 6 of the '589 Patent, and one term from Claims 35 and 36 of the '510 Patent. Am. Joint Chart at 1. The Parties agree that "region of the reference genome" from Claims 2 and 6 of the '589 Patent shall mean "section of the reference genome comprising multiple discrete locations," and "substantially unique nucleic acid tags" from Claims 35 and 36 of the '510 Patent shall mean "tags in a plurality of tags, wherein at least 50% of the tags of the plurality are

unique to the plurality of tags." Id. The Court accepts and adopts these constructions without further discussion.

II. Disputed Terms

The Parties disagree on two terms in Claims 33 and 34 of the '510 Patent, and one term that appears in Claim 1 of both the '589 Patent and '510 Patent. Am. Joint Chart at 2–5. The Court examines the disputed claim terms and the Parties' proposed constructions in turn.

A. '589 Patent & '510 Patent: "location on a [reference] genome"

Step (e) of Claim 1 of the '589 Patent recites: "assigning each of the amplified tagged nucleic acid molecules to a location on a reference genome from the same species from which the sample has been obtained by mapping each of the tag associated sequence reads of step (d) to a location of the reference genome[.]" '589 Patent at 35:32–36. Step (e) of Claim 1 of the '510 Patent recites: "assigning each of the unique tagged nucleic acid molecules to a location on a genome by mapping each of the tag associated sequence reads of step (d) to a location in the genome[.]" '510 Patent at 35:34–37.

Plaintiff asserts that the phrase "location on a [reference] genome" should be construed as "a locus (e.g., a gene, marker, known sequence) within a given region on a [reference] genome." Joint Br. at 15. Plaintiff notes that the Asserted Patents describe "region in the genome" as "a continuous genomic sequence comprising

multiple discrete locations." Id. at 16 (emphasis in original); '510 Patent at 15:59–61; '589 at 15:59–61. Plaintiff argues that locations on the genome are not limited to a specific type of sequence, but encompass multiple, non-limiting examples to allow for various analyses. Joint Br. at 16–17. Plaintiff's construction accounts for this variety by naming non-limiting examples such as a "gene," "marker," and "known sequence." Id. at 17.

Plaintiff claims that Defendant's construction replaces a four-to-five-word phrase with a thirty-word paragraph that injects additional concepts to limit the claims in a way that is not supported by the specification. Id. at 17, 22. Plaintiff refers to the claim language's use of "a" versus "the" when referring to "a location" to show that the claims do not limit the plurality of locations to the locations mapped earlier, as Defendant argues. Id. at 18; '589 at 35:33–36; '510 at 35:35–37. The specification provides two exemplary methods that Plaintiff claims analyze a flexible plurality of locations, and Plaintiff argues that the specification requires flexibility as to the analyzed locations because different sequence reads may have different sizes. Joint Br. at 19. Plaintiff contends that Defendant's construction is contrary to the specification because it takes away location flexibility and restricts the locations to those substantially identical, or substantially complementary, to the subsequence of a tagged sequence read. Id. at 20–21.

Plaintiff asserts that the prosecution history of the Asserted Patents shows that the patent examiner rejected as indefinite much of the language added in Defendant's construction. Id. at 24–26. Plaintiff scrutinizes the change in Defendant's proposed construction from proceedings before the USPTO to this litigation. Id. at 26–27. Specifically, Plaintiff notes that Defendant interpreted the claimed location as "gene, genetic locus, chromosomal region, or start and stop position" in the Joint Claim Construction Chart and Inter Partes Review petition,[2] but has proposed a narrower construction in the Joint Claim Construction Brief. Id. at 26–28; see Joint Chart at 1. Plaintiff argues that Defendant's construction is not supported by record evidence and narrows the claim unjustifiably. Id. at 27.

Defendant asserts that the phrase "location on a [reference] genome" should be construed as "segment on a [reference] genome that is substantially identical to or substantially fully complementary to the subsequence of a tag associated sequence read corresponding to a species of nucleic acid molecule." Am. Joint Chart at 2.[3] Defendant contends that the Asserted Patent's claim language ties the

[2] Plaintiff claims that Defendant took a broad interpretation of the claimed "location" to support its invalidity arguments in its Inter Partes Review positions before the USPTO and that the Patent Trial and Appeal Board ("PTAB") rejected Defendant's invalidity challenges one week prior to filing the Joint Claim Construction Brief. Id. at 27.

[3] Defendant's proposed construction was "gene, genetic locus, chromosomal region, or start and stop position" in the Joint Claim Construction Chart. Joint

concept of "location" to where a particular sequence is mapped. Id. at 31. Defendant claims that intrinsic evidence confirms that a "location" is tied to mapping and uses the specification's definition of mapping in its proposed construction. Id. at 33 ("'[T]he term 'mapping' refers to identifying a location on a genome or cDNA library that has a sequence which is substantially identical to or substantially fully complementary to the subsequence of a tag associated sequence read corresponding to a species of nucleic acid molecule, and assigning the tag associated sequence read or the tagged nucleic acid molecule generating the tag associated sequence read to the location.'") (quoting '589 Patent at 15:4–11) (emphasis omitted).

Defendant accepts that the claims allow for a plurality of locations, but states that this does not undermine Defendant's construction. Id. at 37–38. Defendant refers to step (f) of Claim 1 of the '589 Patent to show that the "locations" that the claim language considers are the locations that were determined in the mapping step of step (e). Id. at 38. Defendant contends that interpreting "location" differently depending on where it appears in the claims is contrary to the claim language and law. Id. Defendant argues that any scrutiny for changing proposed constructions should be placed on Plaintiff because Plaintiff disclaimed the broad

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Chart at 1. Both Parties reserved the right to amend their positions in the Joint Claim Construction Chart. Id.

construction it now seeks during the Inter Partes Review proceedings. Id. at 34–36. Defendant states that its construction is clear and explicit about how the subsequence of each tag-associated sequence read corresponds to a location of the genome, and that the language the patent examiner rejected as indefinite is not the language in Defendant's proposed construction. Id. at 43.

In response, Plaintiff argues that it never disclaimed or disavowed its proposed construction of the disputed term in prior Inter Partes Review proceedings, and claims that Defendant fails to meet the legal standard to show disavowal. Id. at 43–44. Plaintiff avers that each quote Defendant cites from the Inter Partes Review was limited to the issue of including "chromosomal region" in Guardant's construction. Id. at 44–45. Plaintiff claims that its proposed construction includes examples of locations while stating that these locations must be within a chromosomal region, and argues that the proposed construction is consistent with its Inter Partes Review arguments. Id. at 45. Defendant argues that Plaintiff is wrong in stating that its construction does not include chromosomal regions because "genes," "genetic loci," and "start/stop positions" are chromosomal regions. Id. at 57. Thus, Defendant claims that Plaintiff disclaimed interpreting location to encompass chromosomal regions in prior Inter Partes Review proceedings and should not be permitted an overbroad construction of "location" now in contrast to Plaintiff's prior arguments. Id. at 56–57.

i. Intrinsic Evidence Analysis

While specific terms may be at the center of claim construction, the context provided by the surrounding claim language can inform the ordinary meaning of the terms. ACTV, Inc. v. The Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003). Courts should not construe claims restrictively unless the patentee demonstrated a clear intention to limit the claim scope. Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1117 (Fed. Cir. 2004). Claim scope may be limited when the claims, read in view of the specification, do not permit the broad construction proposed by the patentee or suggest that the patentee has limited the scope of the claims. Profectus Tech. LLC v. Huawei Techs. Co., 823 F.3d 1375, 1381–83 (Fed. Cir. 2016). The prosecution history can also inform the meaning of the claim language when it demonstrates how the inventor understood the invention and whether the inventor narrowed the scope of the claims during prosecution. Phillips, 415 F.3d at 1317.

Where a patentee has unequivocally disavowed a certain meaning to obtain a patent, "the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Omega En'g, Inc, v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003). The alleged disavowing actions or statements made during prosecution must be both clear and unmistakable. Id. at 1325–26. Statements made by a patent owner during an Inter

Partes Review proceeding, whether before or after an institution decision, can be considered for claim construction and relied upon to support a finding of prosecution disclaimer. Aylus Networks, Inc. v. Apple Inc., 856 F.3d 1353, 1362 (Fed. Cir. 2017). The court will not use an ambiguous disclaimer to limit a claim term's ordinary meaning. 01 Communique Lab'y, Inc. v. LogMeIn, Inc. ("01 Communique") 687 F.3d 1292, 1297 (Fed. Cir. 2012) (quoting SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1287 (Fed. Cir. 2005)). "There is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term." Id.

Guardant petitioned for Inter Partes Review of the '589 Patent in 2025.[4] Petition for Inter Partes Review of U.S. Patent No. 10,947,589, Ex. J ("Inter Partes Review Petition") (D.I. 65-10). Guardant argued that the claimed method for determining genomic copy number information in the '589 Patent was obvious and relied on prior art references that disclosed the same method for genetic copy numbering. Id. at 1. In arguing that Claim 1 was unpatentable as obvious over prior art Lo, Guardant discussed steps (e) and (f) of Claim 1. Id. at 23, 37–41. Guardant explained that when counting the number of mapped reads in

[4] As of the filing date of Guardant's Petition for Inter Partes Review, Guardant also had a pending Inter Partes Review of the '510 Patent. Inter Partes Review Petition at 4.

chromosomal regions, "Lo teaches counting nucleic acid molecules that have been assigned the same location at a plurality of locations in the reference genome." Id. at 39. Guardant stated that this mapping to a chromosomal region was consistent with Cold Spring's broad reading of location. Id.

In Cold Spring's preliminary responses to Guardant's petitions, Cold Spring claimed that Guardant was attempting to "pin the broad read of 'location'" on Cold Spring and that it was Guardant rather than Cold Spring "now proposing a construction of 'location' that explicitly encompasses 'chromosomal region' in the co-pending Delaware Litigation." Patent Owner's Preliminary Response, Ex. 11 ("'510 Prelim. Resp.") at 18 (D.I. 65-24); Patent Owner's Preliminary Response, Ex. 10 ("'589 Prelim. Resp.") at 18 (D.I. 65-23). Cold Spring faulted Guardant for not citing a concrete construction that was advanced by Cold Spring in this district court litigation and for failing to identify any specific statement in Cold Spring's Disclosure of Asserted Claims and Infringement Contentions for the Asserted Patents that interprets "location" to mean "chromosomal region(s)" as required to show obviousness. '510 Prelim. Resp. at 18–21; '589 Prelim. Resp. at 18–21. Cold Spring asserted that no statement in the filed infringement contentions that mentions "genes," "genetic locus," or "start/stop positions" suggests an interpretation of "location" as recited in step (f) as being as broad as an entire "chromosomal region" as used in Lo's method. '510 Prelim. Resp. at 23; see '589

Prelim. Resp. at 24. Cold Spring argued that although "genes," "genetic locus," and "start/stop positions" are mentioned in the infringement contentions, the mere mention of these terms does not amount to an interpretation of location as chromosomal region. '510 Prelim. Resp. at 22; see '589 Prelim. Resp. at 24 ("Although 'genetic loci,' 'one or more loci,' and 'genes' are mentioned in the cited portions of [the patent owner's] infringement contentions, there is no mention whatsoever of 'chromosomal region.' Certainly, the mere mention of 'genetic loci,' 'one or more loci,' and 'genes' in the infringement contentions does not amount to an interpretation of 'location' as 'chromosomal region.'") (emphasis omitted). Cold Spring also noted that neither Guardant's petition nor its experts address statements in the Asserted Patents that explain that a "region of the genome" can be "a continuous genomic sequence comprising multiple discrete locations." '510 Prelim. Resp. at 23; '589 Prelim. Resp. at 24.

Cold Spring's proposed construction for the term "location on a [reference] genome" provides several examples of a locus—"a gene, marker, known sequence"—and specifies that these locations are "within a given region on a [reference] genome." Am. Joint Chart at 2. Cold Spring clarifies that these examples of locations must be within a chromosomal region and are not the chromosomal region itself. Joint Br. at 45. Guardant opposes this argument and asserts that claimed locations of "genes," "genetic loci," and "start/stop positions"

are chromosomal regions. Id. at 57. Guardant claims that Cold Spring offers no explanation for how its current construction does not encompass chromosomal regions, nor identifies how to distinguish between "location" and "chromosomal region." Id. at 58.

If Cold Spring's statements during the Inter Partes Review proceedings are subject to more than one reasonable interpretation, there is no clear and unmistakable disclaimer as required by precedent. 01 Communique, 687 F.3d at 1297. In the Inter Partes Review proceedings, Cold Spring made clear its position that the infringement contentions filed in this litigation do not support an interpretation of the word "location" as "chromosomal region." '510 Prelim. Resp. at 22–23; '589 Prelim. Resp. at 24. Cold Spring's proposed construction describes locations within a given region. Am. Joint Chart at 2. The proposed construction differs from Cold Spring's prior statements because it specifies that locations such as a gene, marker, or known sequence are within a region rather than an entire chromosomal region itself. There was no clear disclaimer of the use of the words locus, gene, marker, or known sequence in defining location by Cold Spring. Cold Spring states that it did not disclaim this construction in previous Inter Partes Review proceedings, and the Court agrees. Joint Br. at 46. The Court concludes that Cold Spring did not disavow the proposed construction in previous Inter Partes Review proceedings, and the Court will turn to analyzing the proposed

constructions in relation to the claim language and specifications in the Asserted Patents.

The Court looks to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention. Vitronics Corp. 90 F.3d at 1582 (citing Bell Comm'ns Rsch., Inc. v. Vitalink Comm'ns Corp., 55 F.3d 615, 620 (Fed. Cir.1 995)). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Renishaw PLC v. Marposs Societa' per Azioni ("Renishaw"), 158 F.3d 1243, 1250 (Fed. Cir. 1998) (citing Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc., 112 F.3d 1137, 1142 (Fed. Cir. 1997)). Steps (e) and (f) in Claim 1 in the Asserted Patents both use the disputed term. Claim 1 of the '589 Patent recites:

> e) assigning each of the amplified tagged nucleic acid molecules to a location on a reference genome from the same species from which the sample has been obtained by mapping each of the tag associated sequence reads of step (d) to a location of the reference genome; and
>
> f) at a plurality of locations on the reference genome, counting the number of unique tagged nucleic acid molecules that have been assigned to the same location on the reference genome based on the mapping step to obtain a count for each location of the plurality of locations on the reference genome, thereby obtaining copy number information from genomic nucleic acids in the sample.

'589 Patent at 35:32–44. Claim 1 of the '510 Patent recites:

> e) assigning each of the unique tagged nucleic acid molecules to a location on a genome by mapping each of the tag associated sequence reads of step (d) to a location in the genome; and
>
> f) in a plurality of locations in the genome, obtaining relative copy number information of the genomic nucleic acids from the sample based on the number of unique tagged nucleic acid molecules that have been assigned to each of the plurality of location in the genome.

510 Patent at 35:34–43. The claim language of steps (e) and (f) are related and should be read in conjunction. Step (e) discusses assigning amplified tagged nucleic acid molecules to a location on a reference genome by mapping each of the tag associated sequence reads to a location of the reference genome. '589 Patent at 35:33–37; '510 Patent at 35:34–37. This step of assigning molecules to a location on a reference genome is determined by mapping. Step (f) in the '589 Patent discusses counting the number of unique tagged nucleic acid molecules that have been assigned to the same location on the reference genome based on the mapping completed in the previous step, and step (f) in the '510 Patent discusses obtaining copy number information based on the number of unique tagged nucleic acid molecules that have been assigned to locations in the genome. '589 Patent at 35:37–44; '510 Patent at 35:38–43. This step relates directly, in both Asserted Patents, to what was done in step (e) and indicates that the location of molecules shares a connection to mapping.

While the Asserted Patents do not define location, they define various relevant parts of the claimed language, such as reference genome, region of the

genome, mapping, sequence read, tag, and mapping. '589 Patent at 15:4–61; 16:1–55. "[I]t is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." Vitronics Corp., 90 F.3d at 1582. The specification is usually dispositive and is the "single best guide to the meaning of a disputed term." Id. The specification defines mapping as:

> identifying a location on a genome or cDNA library that has a sequence which is substantially identical to or substantially fully complementary to the subsequence of a tag associated sequence read corresponding to a species of nucleic acid molecule, and assigning the tag associated sequence read or the tagged nucleic acid molecule generating the tag associated sequence read to the location.

'589 Patent at 15:4–11; '510 Patent at 15:4–11. The specification describes the invented method of assigning each tagged nucleic acid molecule to a location on a genome associated with the genomic material by mapping and counting the number of tagged nucleic acid molecules having a different tag that have been assigned to the same location on the genome. '589 Patent at 6:58–65; '510 Patent at 6:58–65. This language shows that locations on the genome for assigning in step (e) are associated with the act of mapping. Id. The claim language shows that mapping is relevant to the disputed term and is an essential part of the location on a reference genome for assigning and counting tagged nucleic acid molecules, and for the invention's goal of obtaining genomic copy number information that is

unaffected by amplification distortion. See '589 Patent at 6:58–67; '510 Patent at 6:58–67.

"[T]he standard construction rule [is] that a term can be defined only in a way that comports with the instrument as a whole." Markman, 517 U.S. at 389. The '589 and '510 Patents teach that the method assigns tagged nucleic acid molecules at locations on the reference genome based on mapping. Defendant's proposed construction takes the specification's own definition of mapping into consideration and uses that to inform the definition of "location on a [reference] genome." See Am. Joint Chart. This accurately reflects how the claim language relates a location on a reference genome to mapping, and aligns with the patent's description of the invention. See Renishaw, 158 F.3d at 1250. As the claim language and specification correlate the location on a reference genome to the act of mapping, a construction of the term should account for this correlation and the process that constitutes mapping as described in the patent. The specification's definition of mapping shows that it involves identifying a location on a genome based upon sequences that share substantial similarities to the subsequence of a tag associated sequence. See '589 Patent at 15:4–11. For purposes of mapping, being "substantially identical" or "substantially fully complementary" is a factor for subsequences when identifying a location on a genome. Id. Thus, because mapping is integral to the term "location on a reference genome," how mapping is

conducted should be factored into a construction of the term. Plaintiff's proposed construction opens "location on a [reference] genome" beyond what the claim language describes, which is that location is determined by mapping.

Accordingly, the Court adopts Defendant's proposed construction and construes "location on a [reference] genome" as "segment on a [reference] genome that is substantially identical to or substantially fully complementary to the subsequence of a tag associated sequence read corresponding to a species of nucleic acid molecule."

B. '510 Patent: "nucleotide sequences that are not known before the tagged nucleic acid molecules are generated" and "random nucleotide sequences"

Claim 33 of the '510 Patent recites "[t]he method of claim 22, wherein the nucleic acid tags comprise nucleotide sequences that are not known before the tagged nucleic acid molecules are generated." '510 Patent at 37:17–19. Claim 34 of the '510 Patent recites "[t]he method of claim 22, wherein the nucleic acid tags comprise random nucleotide sequences." Id. at 37:20–21. For both terms, Plaintiff asserts that the plain language is clear, and the phrases need no construction. Joint Br. at 66. However, if the Court deems construction necessary, Plaintiff requests the following constructions: "nucleotide sequences that are not known before the tagged nucleic acid molecules are generated" as "nucleotide sequences that are unknown before tagging nucleic acid molecules," and "random nucleotide

sequences" as "nucleotide sequences that are randomly generated." Id. at 66–67, 71; Am. Joint Chart at 4–5. Defendant asserts that both "nucleotide sequences that are not known before the tagged nucleic acid molecules are generated" and "random nucleotide sequences" should be construed as "tags with a randomly generated sequence." Joint Br. at 72; Am. Joint Chart at 4–5.

For the disputed term "nucleotide sequences that are not known before the tagged nucleic acid molecules are generated," Plaintiff argues that the Court should decline to construe the limitation because it is straightforward and clear. Joint Br. at 66–67. Plaintiff argues that its proposed construction would clarify that the sequences are not known "before tagging target nucleic acid molecules," which aligns with the specification. Id. at 67. Plaintiff contends that there is no requirement that sequences that are not known be randomly generated, as Defendant argues, and that Defendant's proposal suggests a narrow reading that requires that the entire tag must be a "randomly generated sequence" that is supported by neither the claims nor the specification. Id. at 68–70. For the disputed term "random nucleotide sequences," Plaintiff argues that the plain language is clear but argues that the term be construed as "nucleotide sequences that are randomly generated," should the Court require construction. Id. at 71; Am. Joint Chart at 5. Plaintiff claims that Defendant's proposed construction reads in

randomness for the entire tag which contradicts specification embodiments and should be rejected. Joint Br. at 71.

Defendant supports its proposed constructions by arguing that the specification treats "not known" and "random nucleotide sequences interchangeably." Id. at 73. Defendant admits that the specification does not directly define the term "random" or the phrase "not known prior to tagging," but argues that these are interchangeable concepts because the specification only contemplates random sequences for tags that are unknown prior to sequencing. Id. at 73–74. Defendant also claims that the plain meaning of random is an outcome that is unpredictable or unknown in advance and cites dictionary definitions. Id. at 75. In response, Plaintiff reiterates that Claims 33 and 34 of the '510 Patent use different words that describe different scenarios, and claims that Defendant's proposed constructions would read the two separate claims the same. Id. at 76.

The Court should not depart from the plain meaning of the claims, "absent lexicography or disavowal[.]" Alcon Rsch., Ltd. v. Watson Lab'ys, Inc., No. 16-129-LPS-SRF, 2018 WL 1805530, at *4 (D. Del. Apr. 17, 2018) (quoting Luminara Worldwide, LLC v. Liown Elecs. Co., 814 F.3d 1343, 1353 (Fed. Cir. 2016)). "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term,' and 'clearly express an intent to define the term.'" GE Lighting Sols., 750 F.3d at 1309 (quoting Thorner, 669 F.3d at 1365).

Claims 33 and 34 recite limitations to Claim 22. '510 Patent at 37:17–21. The specification states that "[t]he sequence of individual tags does not need to be known prior to generating tagged nucleic acid molecules," and that "[t]ags may be designed such that the variable portion has a random sequence[,]" indicating that unknown tags and random tags are distinct. Id. at 21:25–26, 21:33–35.

Defendant requests construing Claims 33 and 34 identically because unknown and random nucleotide sequences are interchangeable; however, Claims 33 and 34 are separate claims in the '510 Patent and the plain language of the claims offer two different circumstances. '510 Patent at 37:17–21. By construing both terms to mean "tags with randomly generated sequence," as Defendant proposes, the differentiation between claim language in Claims 33 and 34 is lost. See Comark Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) ("There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant."). Claim terms should be given their ordinary and customary meaning as a person of ordinary skill in the art would understand the terms to mean, and both disputed terms carry a plain meaning that does not need to be construed. See Thorner, 669 F.3d at 1365. Random nucleotide sequences are distinct from

nucleotide sequences that are not known, and construing both terms with the same definition rids the claim language of its intended meaning. Defendant fails to provide evidence of disavowal or intrinsic evidence that explicitly defines the disputed terms. The Court finds no reason to depart from the plain meaning of the terms as argued by Plaintiff. Accordingly, the Court adopts the plain and ordinary meaning of "nucleotide sequences that are not known before the tagged nucleic acid molecules are generated" and "random nucleotide sequences."

CONCLUSION

For the foregoing reasons, the Court construes the disputed claim term from the '510 and '589 Patents as follows:

1. "location on a [reference] genome" as "segment on a [reference] genome that is substantially identical to or substantially fully complementary to the subsequence of a tag associated sequence read corresponding to a species of nucleic acid molecule."

The Court construes the disputed claim terms from the ’510 Patent as follows:

1. “nucleotide sequences that are not known before the tagged nucleic acid molecules are generated” has its plain and ordinary meaning; and
2. “random nucleotide sequences” has its plain and ordinary meaning.

IT IS SO ORDERED this 27th day of May, 2026.

/s/ Jennifer Choe-Groves
Jennifer Choe-Groves
U.S. District Court Judge*

*Judge Jennifer Choe-Groves, of the United States Court of International Trade, sitting by designation.