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DNA GENOTEK INC.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DNA GENOTEK INC.,
a Canadian Corporation,

Plaintiff,

v.

SPECTRUM SOLUTIONS L.L.C.,
a Utah Limited Liability Company,

Defendant.

Case No. 3:21-cv-0516-JO-AGS

DNA GENOTEK INC.'S OPENING CLAIM CONSTRUCTION BRIEF

Date: TBD
Judge: Hon. Jinsook Ohta

JURY TRIAL DEMANDED

Spectrum Ex. 1014
IPR Petition - USP 11,002,646
DNA Genotek Inc. - IPR2023-01424
Exhibit 2003 - Page 1 of 36
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I. INTRODUCTION

This case involves two patents: (1) U.S. Patent No. 10,619,187 ("the '187 patent") directed to a device for use in collecting and preserving nucleic acids, and (2) U.S. Patent No. 11,002,646 ("the '646 patent") directed to a kit for collecting and preserving a biological sample (collectively, "Asserted Patents"). The inventor of the '187 patent founded Plaintiff DNA Genotek Inc. ("DNA Genotek") in 1998 in Ottawa, Canada. DNA Genotek has patented and launched dozens of sample collection devices. Defendant Spectrum Solutions LLC ("Spectrum") is a Utah-based company that makes a variety of products including packaging for wine bottles, essential oils, and more recently, the saliva collection devices at issue in this litigation.

The parties disagree over the construction of eleven terms across the two Asserted Patents. DNA Genotek's proposals stay true to plain and ordinary meaning, the claims, specification, and the extrinsic record. Accordingly, no construction is necessary for most terms. Spectrum insisted on proposing fistfuls of terms for construction during the parties' exchanges. The reason for that is now evident: Spectrum's numerous, strategic proposals are a bald attempt to craft a non-infringement or invalidity position if one of its proposals sticks. Spectrum even goes so far as to maintain that the device of claim 1 of the '187 patent is indefinite despite its expert's admission that "[t]he device wouldn't be indefinite." For the reasons set forth below, the Court should adopt DNA Genotek's proposals.

II. LEGAL STANDARDS

A. Plain and Ordinary Meaning Is the Presumed Meaning of a Term

The objective of claim construction is to ascertain the meaning that a person of ordinary skill in the art ("POSA") would give to the claims "at the time of the invention, i.e., as of the effective filing date of the patent application." *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). The words of a claim have their plain and ordinary meaning in the context of the entire patent

unless (1) "a patentee sets out a definition and acts as his own lexicographer"; or (2) "the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). The specification is "highly relevant" to claim construction, and "the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. The prosecution history is also relevant. *Id.* at 1317. Extrinsic evidence, such as experts, articles, and dictionaries, may help a court to "'better understand the underlying technology' and the way in which one of skill in the art might use the claim terms." *Id.* at 1318.

B. A Claim Is Presumed Valid and Cannot Be Held Indefinite Absent Clear and Convincing Evidence

Patents are presumed valid. 35 U.S.C. § 282(a). To render a claim invalid for indefiniteness, the challenger must prove by clear and convincing evidence that a claim, when interpreted in light of the specification and prosecution history, fails to inform a person of ordinary skill in the art about the scope of the invention with reasonable certainty. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The challenging party bears this heavy burden. *See id.* Claim construction principles are relevant to an indefiniteness analysis. *Spansion, Inc. v. ITC*, 629 F.3d 1331, 1344 (Fed. Cir. 2010). Thus, a term must be read in context of the patent as a whole, including the claims and specification, with the aid of extrinsic evidence and not in isolation. *See Cox Commc'ns, Inc. v. Sprint Commc'n Co. LP*, 838 F.3d 1224, 1229-30 (Fed. Cir. 2016). Although the "common practice of training questions of indefiniteness on individual claim terms is a helpful tool," that is not the "ultimate question." *Id.* at 1232 (citing *Nautilus, Inc.*, 572 U.S. at 910).

A claim is not indefinite merely because it is broad. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1366 (Fed. Cir. 2017). Nor is a claim indefinite simply because a term is not defined in the specification or elsewhere. *Nautilus*, 572 U.S. at 906. Absolute or mathematical precision is not required for a claim to

be definite. *Id.* And the fact that there is "some modicum of uncertainty" is not a basis to find a claim indefinite. *Id.*

C. A Means-Plus-Function Construction Has a Very Narrow Application, Which Almost Always Requires the Claim to Recite the Word "Means"

Courts presume that claim terms without the word "means" do not invoke a means-plus-function construction. *See* 35 U.S.C. § 112; *Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1372 (Fed. Cir. 2020). To rebut this presumption, the proponent of a means-plus-function construction must show that the claim (1) fails to "recite sufficiently definite structure" or (2) recites "function without reciting sufficient structure for performing that function." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). Means-plus-function claiming will not apply if the name of the structure has a sufficiently definite meaning. *Id.*

III. THE LEVEL OF ORDINARY SKILL IN THE ART

The Asserted Patents are primarily directed to a mechanical device, and contain chemical limitations only to the extent necessary to provide context for the use of the mechanical device. (Dkt. No. 74-4 at 125-26; Metzker Decl. ¶ 38.) Neither party has put forward an expert with respect to the mechanical aspects of the claimed device and kit. (Metzker Decl. ¶ 38; Dkt. No. 74-4 at 125-26.) This is appropriate because the disputed terms may be understood by their plain and ordinary meaning within the context of the Asserted Patents. Nonetheless, for the purposes of these claim construction briefs only, DNA Genotek accepts Spectrum's definition of a person of ordinary skill with respect to the mechanical aspects of the claimed device and kit. A person of ordinary skill in the art would have more training in mechanical engineering and experience with medical devices than Spectrum suggests. Under Spectrum's definition, with respect to the mechanical aspects, a person of ordinary skill in the art would have "experience or training in mechanical engineering or have access to individual(s) with experience or training in mechanical engineering for the design and development of [sample collection]

containers." (Dkt. No. 74-4 at 125-26.) The choice of the level of ordinary skill in the art will not change the proposed claim constructions.

With respect to the chemical aspects of the claimed device and kit, a person of ordinary skill in the art would be knowledgeable about and familiar with the preservation of biological samples and nucleic acids through relevant education, work experience, or a combination of experience and education in biochemistry, molecular genetics, chemistry, microbiology, immunology, or a related field. (Metzker Decl. ¶ 38.) For example, a person may have a Ph.D. in one of those fields, or a person may have a bachelor's degree in one of these fields with at least 4 years of related practical experience. (*Id.*) Although the parties have proposed slightly different definitions of a person of ordinary skill with respect to the chemistry aspects, neither party contends that the difference is material to the issues before the Court. (*See* Dkt. No. 74-3 at 120; Dkt. No. 74-4 at 126; Declaration of Drew A. Hillier ("Hillier Decl.") Ex. 1 [Fischetti Dep. Tr.] at 141:14-16 ("Essentially, it's the same").)

IV. '187 PATENT: THE COURT SHOULD ADOPT DNA GENOTEK'S PROPOSALS

The asserted claims of the '187 patent are directed to a collection device that contains reagents for preserving nucleic acids potentially present in a biological sample. The parties disagree over the construction of seven terms in asserted claims 1, 2, 4, 8, 20, 21, 23, and 31 of the '187 patent.

A. "Preserving" / "Preserve"

The Court should adopt the plain and ordinary meaning of "preserving" / "preserve." When read in context of the entire patent, the term is definite, and a person of ordinary skill in the art would understand the term's meaning with reasonable certainty. Claim 1 of the '187 patent is directed to a mechanical device that is capable of holding a biological sample and releasing onto that sample "reagents in [a] reagent compartment for preserving nucleic acids potentially

present in the sample, wherein said reagents comprise a denaturing agent, a chelator and a buffer[ing] agent" and "wherein said buffering agent maintains a pH of said mixture equal to or above 5.0 to preserve nucleic acids potentially present in the sample." (Hillier Decl. Ex. 2 ['187 patent] at claim 1.) Claim 1 refers to "reagents in a reagent compartment for preserving nucleic acids *potentially* present." (*Id.*) The limitations of the device in claim 1 do not require the presence of a biological sample, nucleic acids, or that the preservative-reagents have mixed with the biological sample to meet the limitations of the claim. (*Id.*; Metzker Decl. ¶ 48) The disputed term appears in claim 1 of the '187 patent:

Term	DNA Genotek's Position	Spectrum's Position
"preserving" / "preserve"	The terms are definite, do not require construction, and should be accorded plain and ordinary meaning. If a construction is required, the Court should construe "preserving" / "preserve" as "slowing degradation of" / "slows degradation of."	Indefinite.

1. "Preserving" / "Preserve" Should Be Accorded Its Plain and Ordinary Meaning

"Preserving" / "Preserve" should be given its plain and ordinary meaning because the patentee did not (1) act as its own lexicographer, or (2) disavow the full claim scope in the specification or during prosecution. *Thorner*, 669 F.3d at 1365. Nothing in the intrinsic record is to the contrary and Spectrum does not contend otherwise. The extrinsic record also supports the plain and ordinary meaning of "preserving" / "preserve." As DNA Genotek's expert Michael Metzker, Ph.D., testified, "a person of ordinary skill in the art would understand the word preserve or preserving by its plain and ordinary meaning." (Hillier Decl. Ex. 3 [Metzker Dep. Tr.] at 183:5-12; Metzker Decl. ¶¶ 47-49.) Spectrum's expert, Vincent Fischetti, Ph.D., also demonstrated that the term has a plain and ordinary meaning. (Hillier Decl. Ex. 1 at 87:7-14.) The jurors in this case would be familiar with the

concept of preservation, making no further explanation necessary. *See Phillips*, 415 F.3d at 1314. The Court should give the term its plain and ordinary meaning. *Thorner*, 669 F.3d at 1365.

2. Alternatively, "Preserving" / "Preserve" Means "Slowing" / "Slows Degradation Of"

Should the Court require a construction, "preserving" / "preserve" should be construed as "slowing" / "slows degradation of." Both experts agreed in their depositions that in this context preservation refers to slowing the degradation of nucleic acids. (Hillier Decl. Ex. 1 at 29:3-7; *Id.*, Ex. 3 at 183:5-12; Metzker Decl. ¶ 50-51.) As Dr. Fischetti testified, "preservation is a mixture of solutions that is an attempt to slow down the degradation of the nucleic acid." (Hillier Decl. Ex. 1 at 29:3-7.) This construction is consistent with the claims and the specification. In describing the background of the invention, for example, the patent explains that natural conditions "can degrade the quality of the DNA after a period of time." (Hillier Decl. Ex. 2 at 1:60-65.) A preservation solution acts to slow that natural rate of degradation. (*Id.*, Ex. 1 at 148:3-9 ("A. . . . Any biological sample has a rate of degradation based on the composition of that biological sample. Q. And preservation acts to diminish that natural rate of degradation . . . . ? A. Correct."); *see also id.* at 162:8-10.)

A person of ordinary skill would understand that the claimed reagents of the preservation solution—a buffering agent, a denaturing agent, and a chelator—preserve nucleic acids by slowing their degradation. (Metzker Decl. ¶ 50; *see also id.* at ¶¶ 18-34.) Dr. Fischetti admitted, for example, when asked the purpose of the claimed chelator in the preservation solution, that "the chelating agent would remove trace ions in order to . . . slow down the degradation of the nucleic acid." (Hillier Decl. Ex. 1 at 32:12-24.) In fact, Dr. Fischetti admitted that "preserving nucleic acids by slowing the rate of degradation" is "done all the time in [his]

laboratory." (*Id.* at 44:9-19.) Dr. Fischetti has used the same class of reagents claimed in the '187 patent—a buffer, a chelator, and a denaturing agent—"to preserve nucleic acids potentially present in [a] sample" which he testified meant the same thing as "to slow down the degradation process . . . ." (*See id.* at 29:7 – 49:5.)

Accordingly, if a construction is required, the Court should construe the term as "slowing" / "slows degradation of."

3. Spectrum Fails to Prove Indefiniteness With Clear and Convincing Evidence

Spectrum's indefiniteness argument rests on the flawed opinion of its expert Dr. Fischetti, a bacterial pathologist who is not an expert in sample collection devices for the preservation of nucleic acids. (*See id.* at 7:7-9, 17-18; 15:16-19.) Dr. Fischetti offers two reasons why the term is indefinite: (1) the '187 patent does not define how or when to test whether nucleic acids were preserved, and (2) the '187 patent does not define a specific temperature at which nucleic acids are to be preserved. (Dkt. No. 74-4 at 136-37, ¶¶ 38-40; Hillier Decl. Ex. 1 at 191:16-19 ("Q. Does [your Summary of Opinions by Vincent Fischetti, Ph.D.] completely and accurately reflect your opinions in this case? A. Yes").) Those reasons do not withstand scrutiny.

a. A POSA Would Understand "Preserving" / "Preserve" With Reasonable Certainty in the Context of the Device Claim in Which the Term Appears

Definiteness requires only "reasonable certainty" about the scope of the claims. *Cox Commc'ns*, 838 F.3d at 1229. Spectrum's position myopically focuses on the single word, "preserving" / "preserve," without considering whether the "claims . . . fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.*; (Dkt. No. 74-4 at 137). But when confronted with the "ultimate question," *Cox Communications*, 838 F.3d at 1229, about whether the device claims as a whole were indefinite, Dr. Fischetti was crystal-clear: "The

device wouldn't be indefinite . . . ." (Hillier Decl. Ex. 1 at 173:2-7.) And, when asked what the term means in the '187 patent, Dr. Fischetti conceded that it would be understood as "slowing degradation." (*See id.* at 85:21-86:14.)

Whether read in isolation or in context, the term is not indefinite. A person of ordinary skill in the art would understand what "preserving" means and which reagents to include in a device for preserving nucleic acid potentially present in the sample. (Metzker Decl. ¶¶ 47, 52-58.) The claim tells a person of ordinary skill which reagents to use and the specification provides detailed information. (Hillier Decl. Ex. 2 at claim 1 ("said reagents comprise a denaturing agent, a chelator and a buffer agent"); *id.* at 3:36-45, 3:48-65.) Both experts agree that determining which reagents would be suitable for use in the device for preserving nucleic acids potentially present in a sample would be easily understood by a person of ordinary skill. (Hillier Decl. Ex. 1 at 29:9-13, 33:14-17, 34:9-11, 35:2-6, 46:3-8; Metzker Decl. ¶ 56.)

b. Spectrum's Expert Applied the Wrong Legal Standards

Dr. Fischetti's indefiniteness opinion rests on incorrect rules of law. First, Spectrum's expert required the complete absence of a "modicum of uncertainty." But that is not a basis to hold a claim indefinite. *Nautilus*, 572 U.S. at 906. Dr. Fischetti testified that preservation cannot be known absent a test that specifies "certain conditions" and "certain times" because "you need to test it at that period of time to know that the preservation has actually occurred." (Hillier Decl. Ex. 1 at 142:8-143:2.) As he clarified: "if you haven't tested . . . for preservation" then "there's still a modicum of uncertainty." (*See id.* at 143:15-18.)

Second, Dr. Fischetti testified that "preserve" was indefinite because the term is "extremely broad" and "[t]here's no enablement." (*Id.* at 145:10-146:6.) But the definiteness analysis is separate and distinct from the enablement standard. *See Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1341 (Fed. Cir. 2010).

Dr. Fischetti's demand for testing parameters and temperature conditions as the basis for indefiniteness goes to enablement, not the meaning of "preserve." (Dkt. No. 74-4 at 129, 134-36.) In fact, when asked to explain his understanding of the term in claim 1, Dr. Fischetti based his claim construction testimony on enablement standards and expressly applied the Federal Circuit's *enablement standard* set forth in *In re Wands*, specifically the "undue experimentation" test for determining whether a patent claim lacks enablement under 35 U.S.C. § 112. *In re Wands, et al.*, 858 F.2d 731, 733, 737 (Fed. Cir. 1988); (*e.g.*, Hillier Decl. Ex. 1 at 61:22-63:6 ("Q. Is it your contention that the word 'preserving' . . . is a limitation that requires preservation? . . . . A. There's no detail of how that is to be done, how preservation is to occur. . . . They just used the term without giving any details of how preservation is to occur. . . . I could not preserve nucleic acid using that description at all. Not enough detail. It would take too much experimentation to figure it out . . . . It would take undue experimentation")). The question for indefiniteness is whether a person of ordinary skill in the art would understand the device claim with reasonable certainty—not whether a person of ordinary skill in the art would require undue experimentation to practice the claim. *See Ariad Pharms.*, 598 F.3d at 1341. The Federal Circuit has ignored expert testimony about enablement to resolve a challenge to definiteness: "[t]he invention's operability may say nothing about a skilled artisan's understanding of the bounds of the claim." *Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). This Court should do the same. *Id.* (holding that the contention that "the claims do not describe a workable invention" is "irrelevant to definiteness").

Third, Dr. Fischetti testified that, under his view a term would be indefinite if it was "not defined." (Hillier Decl. Ex. 1 at 11:13-18.) Thus, according to his opinion, there can be no understanding of preservation in the context of nucleic acid preservation if "there's no preservation defined." (*Id.* at 51:7-19; 145:10-17 ("It needs to be defined. It's not defined in the '187 [patent]. . . . There's no testing,

there's no specific periodic identification . . . . It's broad . . . It's not defined.").) But "the lack of a technical definition does not render the term indefinite." *One-E-Way, Inc. v. Int'l Trade Comm'n*, 859 F.3d 1059, 1066 (Fed. Cir. 2017) (reversing the district court's finding of indefiniteness). The term in context refers to *reagents located in the device* that are for slowing degradation of nucleic acids potentially present in the sample. (Hillier Decl. Ex. 2 at claim 1.)

There is no dispute that a person of ordinary skill would have a reasonable degree of certainty about which reagents may be used for slowing degradation of nucleic acids and how to identify them. (Metzker Decl. ¶¶ 55-57; Hillier Decl. Ex. 1 at 29:9-13, 33:14-17, 34:9-11, 35:2-6, 46:3-8.) Moreover, claim 1 refers to "reagents in a reagent compartment for preserving nucleic acids *potentially present*." The claim does not require that nucleic acids or a biological sample be present in the device in order to infringe. (Metzker Decl. ¶ 48.) The claims simply contemplate that preservation may occur when the device is used. (*Id.*) Dr. Fischetti is wrong to demand highly specific, technical, chemistry definitions about preservation conditions. *See Source Search Techs., LLC v. LendingTree, LLC*, 588 F.3d 1063, 1076 (Fed. Cir. 2009) ("If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more.").

c. "Preserving" / "Preserve" Is Not Indefinite Because Spectrum Has Used the Same Term in Contexts That Require Reasonable Certainty

A challenger's own use of the allegedly indefinite term undercuts its indefiniteness contention, particularly when it uses the term in a context that requires reasonable certainty. *See BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1368 (Fed. Cir. 2017); *see also Liqwd, Inc. v. L'Oreal USA, Inc.*, 720 F. App'x 623, 631 (Fed. Cir. 2018). In *BASF*, the asserted claims were directed to a

system for performing catalytic conversions in an exhaust gas stream. *BASF*, 875 F.3d at 1362. The court held that the phrase "composition . . . effective to catalyze" was not indefinite in part because the challenging party's expert had agreed that materials capable of performing the claimed reactions were well known in the art. *Id.* at 1368. Similarly, here, Dr. Fischetti agreed that the reagents suitable for use in the device for preserving nucleic acids were well known in the art. (Hillier Decl. Ex. 1 at 29:9-13, 33:14-17, 34:9-11, 35:2-6, 46:3-8.) Moreover, Dr. Fischetti and Dr. Richard Taylor—Spectrum's experts in recent *inter partes* reviews ("IPR[s]")[1]—had no problem using and understanding the allegedly indefinite term in their declarations to the Patent Office. (*E.g.*, Hillier Decl. Ex. 4 [IPR2021-00850, Taylor Decl.] at ¶ 167 ("the composition must *preserve* sufficient quantities of nucleic acids for subsequent analysis"); *id.*, Ex. 5 [IPR2022-00134, Fischetti Decl.] at ¶ 25, ("the method claims of the '215 patent involve performing simple steps using well-known reagents to *preserve* RNA").)

Those statements were not made long ago: Dr. Fischetti used the term in an IPR of a DNA Genotek patent about nucleic acids that Spectrum filed only about ***two weeks before*** it served invalidity contentions in this Court claiming that the term was indefinite. (*See* Hillier Decl. Exs. 4 and 5.) Spectrum also recently used the term in its own patent publication and marketing materials describing the accused products. (*See e.g.*, Hillier Decl. Ex. 6 [U.S. Patent Application Publication No. 2020/0397418] at claim 1; Ex. 7 [Technically-Superior Saliva Collection: SDNA-1000, Spectrum DNA MKTG-Doc-001.4] at 1; Ex. 8 [SDNA-1000 Saliva Collection Kit Used to Track Viral Variants and Successfully Detect Omicron Including Mutations, Making Headlines, https://spectrumsolution.com/sdna-1000-saliva-collection-kit-used-to-track-

[1] *Inter partes* review is an adversarial proceeding for certain validity challenges to a patent before the Unites States Patent & Trademark Office's Patent Trial and Appeal Board.

variants-and-successfully-detects-omicron/ (last visited Dec. 17, 2021)].) Spectrum cannot show that "preserving" / "preserve" is indefinite by clear and convincing evidence when both Spectrum and its experts have used that term's plain and ordinary meaning. *See BASF*, 875 F.3d at 1368; *see also L'Oreal*, 720 F. App'x at 631.

B. "Linear Actuator" Means "A Device That Converts Linear Motion into Rotational Motion and/or Vice-Versa"

Term	DNA Genotek's Proposed Construction	Spectrum's Position
"linear actuator"	"a device that converts linear motion into rotational motion and/or vice-versa"	Indefinite. Alternatively: "a cap having a ram and a plunger"

While a person of ordinary skill would not require a construction of "linear actuator" to understand the term, DNA Genotek had proposed a construction to aid the jury's understanding of the term in response to Spectrum's now withdrawn position that the term is indefinite.[2] The Court can, therefore, give the term its plain and ordinary meaning, which is consistent with DNA Genotek's proposed construction. However, unlike the word "preserve," which may be easily understood by its plain and ordinary meaning, a jury may benefit from a

[2] In the Joint Claim Construction Chart, Spectrum claimed that "linear actuator" was indefinite. (Dkt. No. 74-1 at 39.) Spectrum withdrew its position when it served its in Invalidity Contentions after the close of claim construction discovery on February 4, 2022, in which it contended that the only indefinite term was "preserve" / "preserving." (*See* Hillier Decl. Ex. 9 [Spectrum's Amended Invalidity Contentions] at 23-24); *I-Flow Corp. v. Apex Med. Techs., Inc.*, No. 07CV1200 DMS (NLS), 2008 WL 2899822, at *5 (S.D. Cal. July 25, 2008) (finding defendants waived their argument that a claim term should be construed as a means-plus-function element because they failed to disclose that theory in their invalidity contentions, as required by Patent Local Rule 3.3); *see also Teashot.LLC v. Green Mountain Coffee Roasters, Inc.*, 595 F. App'x. 983, 987 (Fed. Cir. 2015). Spectrum chose not to designate an expert on whether "linear actuator" is definite.

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construction of "linear actuator" because the meaning of "linear actuator" may not be readily apparent to a lay individual. *See Phillips*, 415 F.3d at 1314.

Claim 21 is directed to a device having a barrier, "wherein the barrier is configured to disestablish when displaced by a linear actuator." (Hillier Decl. Ex. 2 at claim 21.) Claim 26 is also directed to a device having a barrier, "wherein a linear actuator exerts the force on the barrier." (*Id.* at claim 26.) The claims and specification further describe how an embodiment of a linear actuator displaces a barrier by converting rotational motion into linear motion, and/or vice versa. (*See e.g.*, *id.* at claim 24 ("where the sealing cap sealably closes, and *where force is exerted perpendicular to a direction of rotation of the sealing cap*").) Figures 10 and 11 also depict an embodiment of a linear actuator that converts linear motion into rotational motion, and/or vice versa. (*Id.* at 14:28-15:57, Figures 10-11 ("[a]s the cap is twisted on . . . [t]he downward movement of plunger 4 forces sealing disc 7 to pivot, as shown by dotted line and arrow 13 . . . pivoting of disc 7 disestablishes the barrier between regions 8 and 9").)

The extrinsic evidence supports DNA Genotek's construction. For example, the specialized McGraw-Hill Dictionary of Engineering defines "linear actuator" as "a device that converts some kind of power . . . into linear motion." (Hillier Decl. Ex. 10 [*Linear actuator*, *McGraw-Hill Dictionary of Engineering*, (5th ed. 1997)].) Although Spectrum has offered lay dictionary definitions for "linear" and "actuate," (Dkt. No. 74-1 at 39), a technical dictionary like DNA Genotek's dictionary takes precedence over non-technical dictionaries. *E.g.*, *L & P Prop. v. JTM, LLC*, 578 F. Supp. 2d 318, 326-327 (D. Mass. 2008) (quoting *Dow Chem. Co. v. Sumitomo Chem. Co., Ltd.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001)). Thus, the Court should construe "linear actuator" as "a device that converts linear motion into rotational motion and/or vice-versa."

Spectrum also improperly limits its construction to a single embodiment of linear actuators in the specification. (Hillier Decl. Ex. 2 at 14:28-38, 19:34-59);

see, e.g., *CCS Fitness, Inc.*, 288 F.3d at 1366 (explaining that the presumption of plain and ordinary meaning cannot be rebutted "simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification"). And Spectrum's proposed dictionary actually supports DNA Genotek's proposal, not Spectrum's tortured "a cap having a ram and plunger." (Hillier Decl. Ex. 11 [*Linear*, *Actuate*, *New Oxford American Dictionary* (2001)] (defining "linear" as "arranged in or extending along a straight or nearly straight line" and "actuate" as "cause (a machine or device) to operate").)

The Court should reject Spectrum's litigation-driven construction. There is no real dispute that Spectrum's devices have linear actuators. (*See* Hillier Decl. Ex. 12 [Am. Infringement Contentions] at 78.) Spectrum is improperly attempting to avoid the consequences of its infringement through claim construction. *See Phillips*, 415 F.3d at 1327-28.

C. The Remaining Terms in the '187 Patent Should Be Accorded Plain and Ordinary Meaning

The remaining seven terms in the '187 patent should be accorded their plain and ordinary meaning because the patentee did not (1) act as its own lexicographer, or (2) disavow the full claim scope in the specification or during prosecution. *Thorner*, 669 F.3d at 1365. The terms are nontechnical, and would be easily understood by a lay juror. *Catheter Connections, Inc. v. Ivera Med. Corp.*, No. 14-CV-2208-H-RBB, 14-cv-2966-H-RBB, 2015 WL 6511545, at *9 (S.D. Cal. May 22, 2015) (declining construction because a term was "unambiguous, [and] easily understandable by a jury"); *Asetek Danmark A/S v. CoolIT Sys. Inc.*, No. 19-CV-00410-EMC, 2020 WL 4207520, at *23 (N.D. Cal. July 22, 2020) (declining construction because "[the term] [was] not technical or complicated, but [was] a 'common' word in the English language"); *see also Phillips*, 415 F.3d at 1314.

1. "Containment Vessel" Should Be Accorded its Plain and Ordinary Meaning

Term	DNA Genotek's Position	Spectrum's Proposed Construction
"containment vessel"	The term does not require construction and should be accorded plain and ordinary meaning.	"container"

The meaning of "containment vessel" would be readily apparent to the Court and jury by its plain and ordinary meaning. In the absence of lexicography or disavowal, the Court should reject Spectrum's proposed construction because courts do not support "prescribing a more particularized meaning unless a narrower construction is required by the specification or prosecution history." *3M Innovative Properties Co. v. Tredegar Corp.*, 725 F.3d 1315, 1329 (Fed. Cir. 2013). Spectrum gives no reason to deviate from plain and ordinary meaning. (Dkt. No. 74 at 22.) As described in more detail below, this unusual construction is step one in Spectrum's two-step manufacture of a non-infringement defense. *See* Part IV.C.3.

2. "Said Opening . . . " Should Be Accorded its Plain and Ordinary Meaning

Term	DNA Genotek's Position	Spectrum's Proposed Construction
"said opening for receiving a liquid sample[,] for sealably receiving a sealing cap, [and] for receiving a biological sample from the mouth of the user"	The term does not require construction and should be accorded plain and ordinary meaning.	"said opening configured to be closed with a sealing cap to prevent leakage and having a diameter of at least 2.0 cm so that it can receive a liquid [biological sample] directly from the mouth of the user"

The Court and jury would readily understand all words in the term by their plain and ordinary meaning. There is no disavowal or lexicography to justify deviating from plain and ordinary meaning of the "said opening . . ." term.

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A party may not rebut the presumption of plain and ordinary meaning "simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history." *CCS Fitness, Inc.*, 288 F.3d at 1366. It is also error in claim construction to import the dimensions of a device component when those dimensions do not appear in the specification. *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1360 (Fed. Cir. 2003). While portions of the specification provide possible dimensions for the opening, the specification does not limit the term to any particular size, nor do the claims. (*E.g.*, Hillier Decl. Ex. 2 at 6:26-39 ("[t]he first region can have an opening of from 2.0 to 7.0 cm, desirably from 2.5 to 3.5 cm, and most desirably 3.0 cm.").) The prosecution history also does not limit the term to certain dimensions. (Ex. 13 [Provisional Application No. 60/386,398, FH, Specification filed 2002-06-07] at 3:1-5 ("[i]n another embodiment, the container comprises an elongated body with a wide opening at one end suitable for such collection").) Spectrum's construction should be rejected.

3. "Reagent Compartment" Should Be Accorded Its Plain and Ordinary Meaning

The Court and jury would easily understand "reagent compartment" by its plain and ordinary meaning. "Reagent compartment" is at issue in claim 1, which is directed to a device, having "a reagent compartment having a barrier, said barrier sealing and containing reagents in said reagent compartment." (Hillier Decl. Ex. 2 at claim 1.)

Term	DNA Genotek's Position	Spectrum's Proposed Construction
"reagent compartment"	The term does not require construction and should be accorded plain and ordinary meaning.	"region or section of the [containment vessel]"

The Court should not adopt Spectrum's proposed construction because there has been no lexicography or disavowal and Spectrum again improperly limits the

claim to language in the specification. As discussed in Part IV.B, it is improper to limit claims to a preferred embodiment. *CCS Fitness, Inc.*, 288 F.3d at 1366.

Again, Spectrum has proposed a construction at odds with plain and ordinary meaning to manufacture a potential non-infringement position. Spectrum argues that "reagent compartment" should be construed as "region or section of the [containment vessel]." (Dkt. No. 74 at 27.) Under Spectrum's view, this would make the claim mean "a ***region or section of the containment vessel*** having a barrier, said barrier sealing and containing reagents in the ***region or section of the containment vessel***." But that construction cannot be correct because the claims and specification do not require that the reagent compartment be located *within* the containment vessel—as opposed to the cap or elsewhere. (Hillier Decl. Ex. 2 at claim 1, 14:49-54 ("*[d]esirably*, the invention features a device . . . [that] includes: a container that has a first region for collecting a biological sample and a second region containing a composition for preserving a nucleic acid").) Indeed, Spectrum's construction violates bedrock law by reading out a disclosed embodiment. "[T]here is a strong presumption against a claim construction that excludes a disclosed embodiment." *In re Katz Interactive Call Processing Pat. Litig.*, 639 F.3d 1303, 1324 (Fed. Cir. 2011).

The specification of Provisional Application No. 60/386,398 ("'398 application")—whose content the '187 patent incorporates expressly by reference—even discloses an embodiment in which *the reagent compartment is outside of the containment vessel*, e.g., as part of the cap. (*Id.*, Ex. 13 at 3 ("[i]n one embodiment the compartment is the underside of the cap of the container. . . another embodiment the compartment is in the tube and can released by an external means for releasing said contents"); *id.*, Ex. 2 at 1:15-19.) There is no basis to overcome this presumption here. There has been, for example, no disclaimer. *See, e.g.*, *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276 (Fed. Cir. 2008) (collecting cases and holding that a district court improperly excluded embodiment in claim construction:

"We normally do not interpret claim terms in a way that excludes embodiments"); *Alliance Packaging LLC v. Smurfit-Stone Container Corp.*, No. C07-112Z, 2008 WL 681843, at *8 (W.D. Wash. Mar. 7, 2008) (finding that a patent in its final form did not exclude an embodiment disclosed in a provisional application because nothing in the prosecution history suggested that particular embodiment had been abandoned). Thus, the Court should reject Spectrum's construction.

4. "When Sealably Closing . . . " Is Not a Means-Plus-Function Term Because It has a Precise Physical Structure, and Should Be Accorded Its Plain and Ordinary Meaning

The device in claim 1 comprises a containment vessel, a reagent compartment, reagents, and a sealing cap. (Hillier Decl. Ex. 2 at claim 1.) Claim 1 further recites: the sealing cap, whereby the device is configured such that, **when sealably closing said opening with said sealing cap, the barrier mechanically disestablishes** to release said reagents to form a mixture of reagents and said biological sample . . . ." (*Id.*) The parties dispute whether the "when sealably closing . . ." term should be given its plain and ordinary meaning or whether the highly particular means-plus-function statutory framework applies. This is not a means-plus-function term.

Term	DNA Genotek's Position	Spectrum's Proposed Construction
"when sealably closing said opening with said sealing cap, the barrier mechanically disestablishes"	The term does not require construction and should be accorded plain and ordinary meaning.	This term is governed by 35 U.S.C. § 112, ¶ 6 (pre-AIA) Corresponding structure: "a cap having a ram and a plunger." Function: "mechanically disestablishing the barrier upon sealably closing the opening of the sample receiving area."

a. Spectrum Cannot Overcome the Presumption Against Means-Plus-Function Claiming

"An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112 (Pre-AIA). Courts presume that means-plus-function claiming does not apply when the claim does not use the word "means" or other "generic terms such as 'mechanism,' 'element,' 'device,' and other nonce words that reflect nothing more than verbal constructs." *Williamson*, 792 F.3d at 1350; *Egenera*, 972 F.3d at 1372. The disputed term does not use the word "means" or any other "nonce" word. And Spectrum has identified none. Therefore, there is a presumption that means-plus-function claiming does not apply to the disputed term.

Thus, Spectrum is left to prove that the "claim term" (1) fails to "recite sufficiently definite structure," or (2) recites "function without reciting sufficient structure for performing that function." *Williamson*, 792 F.3d at 1349. If "*documented in* the prosecution history," a patentee's "intent" to avoid means-plus-function claiming supports the conclusion that the claim is not a means-plus-function claim. *TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 786 (Fed. Cir. 2019). In *TEK Global*, the term at issue "was rewritten to avoid means-for language." *Id.* at 785-86. Likewise, here, during prosecution of the '187 patent the examiner rejected draft claims based on the use of means-plus-function claiming. In response, the patentee rewrote the claims to replace "closing means" with "the sealing cap" and removed the term "disruption means":

Previously Presented	As Amended
closing means and disruption means, whereby when sealably closing said opening with said closing means, said disrupting means mechanically disestablishes	the sealing cap, whereby the device is configured such that, when sealably closing said opening with said sealing cap, the barrier mechanically disestablishes . . . .

(Ex. 14 ['187 patent, FH, Response dated 2019-11-01] at 3.) The Examiner did not afterwards analyze the claims as means-plus-function claims. (*Id.* at 12, 13, 16; *see also* Ex. 15 ['187 patent, Notice of Allowance dated 2020-01-23].) The term is not a means-plus function claim: it does not use the word "means"; it recites a definite structure and does not recite function without reciting sufficient structure; and DNA Genotek rewrote the claims to avoid means-plus function claiming. *TEK Glob., S.R.L.*, 920 F.3d at 785-86.

b. "When Sealably Closing . . ." Has Its Plain and Ordinary Meaning

The plain and ordinary meaning of each word in the term would be readily apparent to the Court and jury. In the absence of lexicography or disavowal, the plain and ordinary meaning of the term "when sealably closing . . ." controls. *Thorner*, 669 F.3d at 1365. Spectrum argues the term should be construed to have a structure of "a cap having a ram and a plunger" and a function of "mechanically disestablishing the barrier upon sealably closing the opening of the sample receiving area." (Dkt. No. 74 at 30.) The portion of the specification on which Spectrum relies represents only one embodiment of the device. (Hillier Decl. Ex. 2 at 15:39-49.) Thus, Spectrum improperly attempts to limit the claim to an embodiment of the specification. *CCS Fitness, Inc.*, 288 F.3d at 1366. The Court should reject Spectrum's ploy for this reason also.

5. "Associates With" Should Be Accorded Its Plain and Ordinary Meaning

There is no dispute that the Court and jury would understand "associates with" by its plain and ordinary meaning. As with the other terms in Part IV.C, the plain and ordinary meaning of "associates with" applies because there is no lexicography or disavowal of claim scope. *Thorner*, 669 F.3d at 1365. The term "associates" appears in claim 34: "wherein the sealing cap associates with the containment vessel to create a fluid-tight seal":

Term	DNA Genotek's Position	Spectrum's Proposed Construction
"associates with"	The term does not require construction and should be accorded plain and ordinary meaning.	"contacts"

Neither the plain language of the claims, the specification, nor the prosecution history require "associates with" to be redefined to mean "contacts." (*See, e.g.*, Hillier Decl. Ex. 2 at 6:15-25, 6:40-45, 6:57-65.) Spectrum hangs its hat on a general-purpose dictionary for the definition of "associate." (Dkt. No. 74-1 at 42.) But that dictionary never uses the word "contacts" to define "associate." (Hillier Decl. Ex. 11 (defining "associate" as "connect (someone or something) with something else in one's mind").) While "associates" can include contacts, there is nothing in the specification to so limit the term. (*See, e.g.*, Hillier Decl. Ex. 2 at 6:15-25, 6:40-45, 6:57-65.) The plain and ordinary meaning of "associates with" includes a conceptual or a configuration connection between two components. (*See id.*, Ex. 2.) Thus, while "associates" can include "contact" between two components, it is not limited to association by contact. For example, there may be an intermediate component between the two associated components, but that does not destroy the association. A gasket in a valve placed between a cap and containment vessel, for instance, could prevent the cap and containment vessel

from coming into contact with each other, but would not destroy the association. The patentee chose to use the term, "associates with," without limiting the meaning of the term to "contacts," and chose to use the term, "contacts," without limiting the meaning of the term to "associates with." (*See, e.g.*, Hillier Decl. Ex. 2 at 6:15-25, 6:40-45, 6:57-65); *Phillips*, 415 F.3d at 1316. Thus, the Court should not adopt Spectrum's proposed construction because a patentee "define[s] precisely what his invention is" and it is "unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." *See Phillips*, 415 F.3d at 1312.

V. '646 PATENT: THE COURT SHOULD ADOPT DNA GENOTEK'S PROPOSALS

The '646 patent is directed to a kit for collecting and preserving a biological sample. (Hillier Decl. Ex. 16 ['646 patent] at claim 1.) Among other things, the kit is directed to a (1) sample collection vessel, (2) cap, and (3) moveable annular valve that is configured to associate with the cap and the opening of the sample collection reservoir. (*Id.*) Like the '187 patent, the '646 patent is directed to a mechanical device, as opposed to a method or composition. (*Id.*, Ex. 19 ['646 patent, FH, Restriction Requirement dated 2020-09-21] at 3, 4.)

A. "Annular Valve" Should Be Construed to Mean "Valve With Two Cylinders Where the Cylinders Move Relatively to Open / Close the Valve" Because the Claim Defines the Term Itself

The term "annular valve" appears in claim 1, which is directed to a kit. The kit includes a moveable annual valve configured to associate with the cap, and with the opening of the sample collection reservoir. (*Id.*, Ex. 16 at claim 1.)

Term	DNA Genotek's Position	Spectrum's Proposed Construction
"annular valve"	"valve with two cylinders where the cylinders move relatively to open/close the valve"	"ring shaped valve"

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The intrinsic evidence supports DNA Genotek's construction of the term. Claim 1 describes an "annular valve" as "*comprising* . . . an inner cylinder . . .and an outer cylinder." (*Id.*, Ex. 16 at claim 1.) Thus, the claimed annular valve is at least a valve with two cylinders. *Lexion Med., LLC v. Northgate Techs., Inc.*, 641 F.3d 1352, 1356-57 (Fed. Cir. 2011) (preferring "a claim interpretation that harmonizes the various elements of the claim to define a workable invention"). Claim 1 further requires that the "aperture of the outer cylinder accommodates at least a portion of the inner cylinder" and that the "interior sidewall of the outer cylinder" moves relatively to the "sidewall" of the interior cylinder having a "fluid vent." (Hillier Decl. Ex. 16 at claim 1.) This shows that the claimed valve is a valve with two cylinders where the cylinders move relatively to open / close the valve. Figures 3A and 3B, for example, also depict an embodiment of the claimed annular valve. (*Id.* at Figures 3A and 3B.) Those figures also show a valve with two cylinders where the cylinders move relatively to open / close the valve. (*Id.*)

Spectrum considers the two words "annular valve" in isolation and argues that the term means a "ring shaped valve," but the claims do not describe the term as "ring shaped," let alone mention a ring shape at all. (*Id.* at claim 1.) The specification only mentions "ring" in relation to embodiments or as possible features that may be added to the kit. (*Id.* at 5:64-67, 6:1-6, 15:49-67.) If the patentee wanted to say "ring"-shaped, it knew how to do so, (*see id.*) and that reference to "ring" is not lexicography. *Thorner*, 669 F.3d at 1365 (explaining that "[i]t is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term").

The Court should also not adopt Spectrum's proposed construction, which relies on a general-purpose dictionary, because that extrinsic evidence is "'less significant than the intrinsic record in determining the 'legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317. Spectrum again relies on a general-

purpose dictionary that defines "annular" as "of, relating to, or forming a ring." But that general dictionary has no definition of "annular valve" and a mash-up of lay definitions cannot be used for the meaning of the technical term "annular valve." (*See Annular*, *New Oxford American Dictionary* (2001)); *L & P Prop.*, 578 F. Supp. 2d at 326-327 (quoting *Dow Chem. Co. v. Sumitomo Chem. Co., Ltd.*, 257 F.3d 1364, 1372) (explaining that scientific dictionaries are preferable over non-scientific dictionaries, "lest dictionary definitions . . . be converted into technical terms of art having legal, not linguistic significance"). The meaning of the term in the claim itself should prevail over any extrinsic evidence. *Phillips*, 415 F.3d at 1317-18 (noting that extrinsic evidence is generally viewed as less significant than intrinsic evidence because "undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims"). The Court should reject Spectrum's position because "rephrasing or paraphrasing . . . by substituting synonyms does not represent genuine claim construction" and "ring-shaped" is not even an accurate rephrasing or paraphrase of "annular valve" under Spectrum's own evidence. *C.R. Bard., Inc. v. United States Surgical Corp.*, 388 F.3d 858, 863 (Fed. Cir. 2004).

B. "Biological Sample" and "Preserving a Biological Sample" Should Be Accorded Their Plain and Ordinary Meaning

1. "Biological Sample" Should Be Accorded Its Plain and Ordinary Meaning

The parties dispute the meaning of "biological sample" in claim 1, which is directed to "an opening configured to receive the biological sample from a user into the sample collection reservoir." (Hillier Decl. Ex. 16 at claim 1.)

Term	DNA Genotek's Position	Spectrum's Proposed Construction
"biological sample"	The term does not require construction and should be accorded plain and ordinary meaning.	"cells"

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The Court and jury would easily understand "biological sample" by its plain and ordinary meaning. Without lexicography or disavowal, "biological sample" should be given its plain and ordinary meaning. The intrinsic evidence supports the plain and ordinary meaning of the term because the specification provides several examples of biological samples. (*Id.* at 6:54-59 ("the collection of 'bodily fluids' generally refers to the collection of naturally expressed bodily fluids . . . although some embodiments can be used for collection of intravenous collection methods—e.g., blood").) The extrinsic evidence also supports the plain and ordinary meaning of the term because expert testimony shows a person of ordinary skill in the art would understand the term to have its plain and ordinary meaning. (Metzker Decl. ¶¶ 59-62.)

The Court should reject Spectrum's proposed construction of "cells" because Spectrum improperly seeks to narrow the meaning of the term in a way that is not supported by the intrinsic or extrinsic record. *3M*, 725 F.3d at 1329. The specification distinguishes cells from other biological samples. (*E.g.*, Hillier Decl. Ex. 16 at 6:46-49 ("this disclosure also relates to the isolation of cells from bodily fluids, such as saliva and urine").) It would be clear to a person of ordinary skill of the art that "biological sample" includes more than just "cells" in the context of the patent. (Metzker Decl. ¶ 63.) The Court should reject Spectrum's construction.

2. "Preserving a Biological Sample" Should Be Accorded Its Plain and Ordinary Meaning

The parties dispute whether "preserving a biological sample" requires construction. The term does not require construction because it appears in the non-limiting preamble and neither lexicography nor disavowal overturns its plain and ordinary meaning.

Term	DNA Genotek's Position	Spectrum's Proposed Construction
"preserving a biological sample"	The term does not require construction and should be accorded plain and ordinary meaning. If a construction of "preserving a biological sample" is required, the Court should construe "preserving a biological sample" as "slowing degradation of a biological sample."	"Preventing the cells from having their antigens degraded such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome"

The term "preserving a biological sample" appears in the preamble; it is not a limitation. A preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). The preamble states that the claimed kit's purpose is "collecting and preserving a biological sample" and then defines a structurally complete invention in the claim body. (Hillier Decl. Ex. 16 at claim 1.) The preamble of claim 1 is not limiting. *Id.* at 808. There is no reason to construe a claim term that is non-limiting. *See Thorner*, 669 F.3d at 1365.

Spectrum will point to a definition of "preserving *cells*" but that clause does not define the meaning of "preserving a biological *sample*." (Metzker Decl. ¶¶ 64, 67.) The term should be given its plain and ordinary meaning because there is no lexicography or disavowal.

Spectrum's own use of the term also demonstrates that the term has its plain and ordinary meaning. Most remarkably, Spectrum has used "preserving a biological sample" as a term in its own sample collection patent applications without defining its meaning. (*See e.g.*, Ex. 17 [U.S. Patent Application Publication No. 2021/0052257 ("'257 patent application")] at claim 14, claim 20, ¶¶ 0007, 0010, 0025, 0026.; Ex. 18 [U.S. Patent Application Publication No. 2021/0177385] at claim 1, claim 16, ¶¶ 0007, 0010, 0025, 0026.) Spectrum even expressly accorded "preserving a biological sample" its plain and ordinary meaning

in one of its patent applications. (Ex. 17 at ¶ 0057 ("Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the present disclosure pertains").) Spectrum's own use of the term in the context of sample collection devices is further evidence that a person of ordinary skill would understand the term by its plain and ordinary meaning.

3. Alternatively, "Preserving a Biological Sample" Means "Slowing Degradation of a Biological Sample"

Should the Court require a construction, the term should be construed to mean "slowing degradation of a biological sample," which is consistent with a person of ordinary skill in the art's understanding of the term when read in the context of the claims.[3] The intrinsic evidence supports this construction because the specification describes how the term prolongs the biological sample. (Hillier Decl. Ex. 16 at 12:36-40 ("[t]he one or more fluids or materials contained in the interior space in the cap may assist in preserving the sample body fluids contained in the reservoir of the tube during at least storage and shipping"); *id.* at 16:23-24 ("'preserving cells' means preventing the cells from having their antigens degraded").)

The extrinsic evidence also supports this construction. Dr. Metzker explained that a person of ordinary skill in the art would understand that the term means "slowing degradation of a biological sample." (Metzker Decl. ¶¶ 65-67.) Moreover, Spectrum's own expert suggested that a person of ordinary skill in the art would understand "preserving" means "slowing degradation of" in the '187 patent. (Hillier Decl. Ex. 1 at 12:23-25, 13:2-3, 44:5-11; Ex. 5 at ¶ 76.)

[3] Adopting either party's construction will not alter that "preserving a biological sample" is functional language within the clause "kit for collecting and preserving," and thus no actual "preserving" is required for a device to infringe.

The Court should reject Spectrum's construction because it is not consistent with the intrinsic and extrinsic record. While the specification defines the phrase "preserving cells," this phrase does not appear in claim 1—"preserving a biological sample" is the term at issue. (Hillier Decl. Ex. 16 at 16:23-27.) A person of ordinary skill in the art would understand that "preserving cells" is not the same as "preserving this biological sample." (Metzker Decl. ¶ 67.) Nor would a person of ordinary skill in the art understand the term to have Spectrum's litigation-motivated construction. (*Id.*)

C. "Associates With" Should Be Accorded Its Plain and Ordinary Meaning

The parties dispute the meaning of the term "associates with" in claim 1, 4, 8, 11, and 12:

Term	DNA Genotek's Position	Spectrum's Proposed Construction
"associates with"	The term does not require construction and should be accorded plain and ordinary meaning.	"contact" / "contacting" / "contact" / "contact between" / "configured to contact"

For substantially the same reasons as with the '187 patent, "associates with" should be given its plain and ordinary meaning. *See* Part IV.C.5. There is no lexicography, disavowal, or extrinsic evidence to justify Spectrum's position. Neither the claims, the specification, nor the prosecution history requires "associates with" to be redefined to "contacts." (*See, e.g.*, Hillier Decl. Ex. 16 at 7:7-11, 8:10-14,15:24-30.) The Court should accord the term its plain and ordinary meaning because the patentee chose to use the term throughout the claims. *See Phillips*, 415 F.3d at 1316.

VI. CONCLUSION

For the reasons above, the Court should adopt DNA Genotek's positions and constructions for the dispute claim terms.

Dated: February 18, 2022 MORRISON & FOERSTER LLP

By: s/ Brian M. Kramer

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CERTIFICATE OF SERVICE

The undersigned hereby certified that, on February 18, 2022, a true and correct copy of the foregoing was transmitted electronically to the Electronic Filing System of the United States District Court for the Southern District of California which, under Local Civil Rule 5.4(b)–(d), is believed to have sent notice of such filing, constituting service of the filed document, on all Filing Users, all of whom are believed to have consented to electronic service.

Executed on February 18, 2022, at San Diego, California.

s/ Brian M. Kramer

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Spectrum Ex. 1014
IPR Petition - USP 11,002,646
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