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8 UNITED STATES DISTRICT COURT
9 SOUTHERN DISTRICT OF CALIFORNIA
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11 DNA GENOTEK INC., a California
12 Corporation,
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14 Plaintiff,
15 v.
16 SPECTRUM SOLUTIONS L.L.C., a Utah
17 Limited Liability Company,
18 Defendant.
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20

Case No.: 3:21-CV-00516-RSH-DDL

ORDER:

**(1) CLAIM CONSTRUCTION
ORDER; AND**

**(2) DENYING AS MOOT
PLAINTIFF'S MOTION FOR
LEAVE TO FILE A RESPONSE TO
DEFENDANT'S EVIDENTIARY
OBJECTIONS**

[ECF No. 101.]

21 In this case, Plaintiff DNA Genotek ("DNA Genotek") alleges that Spectrum
22 Solutions L.L.C. ("Spectrum") infringes U.S. Patent Nos. 10,619,187 ("the '187 Patent")
23 and 11,002,646 ("the '646 Patent") (collectively "the patents-in-suit"). On January 7, 2022,
24 the Parties filed their Joint Claim Construction Hearing Statement, Chart, and Worksheet
25 in accordance with Patent Local Rule 4.2. ECF No. 74. On February 18, 2022, the Parties
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1 filed their Opening Claim Construction Briefs. ECF Nos. 134, 147.¹ On March 4, 2022,
 2 the Parties filed their Responsive Claim Construction Briefs. ECF Nos. 88, 89. On
 3 November 9, 2022, the Court emailed counsel of record a tentative claim construction
 4 order.

5 The Court held a claim construction hearing on Thursday, November 10, 2022. ECF
 6 No. 176. After considering the parties' briefing and the arguments presented at the hearing,
 7 the Court issues the following claim construction order.

8 **I. BACKGROUND**

9 DNA Genotek is the owner by assignment of the '187 Patent and the '646 Patent.
 10 *See* U.S. Patent No. 10,619,187, at [73] (issued Apr. 14, 2020); U.S. Patent No. 11,002,646,
 11 at [73] (issued May 11, 2021). In the present action, DNA Genotek alleges that Spectrum
 12 infringes the patents-in-suit, either literally or under the doctrine of equivalents, by making,
 13 using, offering for sale, selling and/or importing saliva DNA collection devices, including
 14 Spectrum's SDNA-1000 and SDNA-2000 products. *See* SAC (Aug. 4, 2021), ECF No. 20
 15 ¶¶ 3, 18, 22-27, 35-45, 55-65.

16 The patents-in-suit both generally relate to devices for biological sample collection.
 17 The '187 Patent was issued on April 14, 2020 and is entitled "Compositions and Methods
 18 for Obtaining Nucleic Acids from Sputum." '187 Patent at [54], [45]. The invention
 19 disclosed in the '187 Patent "relates to compositions and methods for preserving nucleic
 20 acids at room temperature for extended periods of time and for simplifying the isolation of
 21 nucleic acids." *Id.* col. 1 ll. 23-26. Specifically, the invention "features a composition for
 22 preserving nucleic acids that includes a chelating agent, and a denaturing agent, where the
 23 pH of the composition is greater than 5.0." *Id.* col. 3 ll. 61-64.

24 Independent claim 1 of the '187 Patent, the only independent claim in the '187
 25 Patent, claims:

26 _____

27 ¹ On July 19, 2022, DNA Genotek filed a Corrected Opening Claim Construction
 28 Brief. ECF No. 134.

1 1. A device for receiving and preserving nucleic acid in a biological sample,
2 said device comprising:

3 a. one or more walls defining a containment vessel having a top having an
4 opening, and a closed bottom having a sample receiving area for holding said
5 biological sample, said opening for receiving a liquid sample and for sealably
6 receiving a sealing cap, said top having an opening for receiving a biological
7 sample from the mouth of a user and further comprising at least one marking
8 on said one or more walls which corresponds to a fluid volume in the sample
9 receiving area;

10 b. a reagent compartment having a barrier, said barrier sealing and containing
11 reagents in said reagent compartment and capable of disestablishment to
12 release said reagents into the sample receiving area;

13 c. reagents in the reagent compartment for preserving nucleic acids potentially
14 present in the sample wherein said reagents comprise a denaturing agent, a
15 chelator and a buffer agent; and,

16 d. the sealing cap, whereby the device is configured such that, when sealably
17 closing said opening with said sealing cap, the barrier mechanically
18 disestablishes to release said reagents to form a mixture of reagents and said
19 biological sample wherein said buffering agent maintains a pH of said mixture
20 equal to or above 5.0 to preserve nucleic acids potentially present in the
21 sample.

22 '187 Patent col. 19 ll. 34-59.

23 The '646 Patent was issued on May 11, 2021 and is entitled "Devices, Solutions and
24 Methods for Sample Collection." '646 Patent at [54], [45]. The invention disclosed in the
25 '646 Patent generally relates to devices, solutions, and methods for collecting samples of
26 bodily fluids containing cells. *Id.* at [57], col. 1 ll. 21-24. The '646 Patent also generally
27 relates to the isolation and preservation of cells from such bodily fluids for cellular analysis.
28 *Id.* at [57], col. 1 ll. 24-29.

1 Independent claim 1 of the '646 Patent, the only independent claim in the '646
2 Patent, claims:

3 1. A kit for collecting and preserving a biological sample, the kit comprising:
4 a sample collection vessel, the sample collection vessel comprising:

5 a sample collection reservoir having an opening configured to receive
6 the biological sample from a user into the sample collection reservoir;

7 a connection member disposed on an exterior portion of the sample
8 collection vessel and adjacent to the opening;

9 a cap, the cap comprising:

10 a reagent chamber configured to store a reagent; and

11 a complementary connection member configured to engage the
12 connection member of the sample collection vessel; and

13 a movable annular valve configured to associate with the cap and with the
14 opening of the sample collection reservoir, the movable annular valve
15 comprising:

16 an inner cylinder in fluid-tight association with the cap and comprising
17 a sidewall, the sidewall comprising a fluid vent; and

18 an outer cylinder in fluid-tight association with the inner cylinder and
19 associated with the opening of the sample collection reservoir, the outer
20 cylinder comprising an aperture defined by an interior sidewall of the
21 outer cylinder,

22 wherein the aperture accommodates at least a portion of the inner
23 cylinder,

24 wherein the interior sidewall obstructs the fluid vent when the movable
25 annular valve is closed, and

26 wherein the interior sidewall does not obstruct the fluid vent when the
27 movable annular valve is open.

28 '646 Patent col. 22 ll. 16-47.

On March 24, 2021, DNA Genotek filed a complaint for patent infringement against Spectrum, alleging infringement of the '187 Patent. *See* Compl. (Mar. 24, 2021), ECF No. 1. On June 8, 2021, DNA Genotek filed its Second Amended Complaint (the "SAC," the operative complaint) against Spectrum, adding a claim for infringement of the '646 Patent. *See* SAC (Aug. 4, 2021), ECF No. 20. On August 18, 2021, Spectrum filed an answer to the SAC along with counterclaims against DNA Genotek for: (1) declaratory judgment of non-infringement of the patents-in-suit; (2) declaratory judgment of invalidity of the patents-in-suit; (3) declaratory judgment of unenforceability of the '187 Patent due to inequitable conduct; (4) monopolization in violation of section 2 of the Sherman Act, 15 U.S.C. § 2; and (5) attempted monopolization in violation of section 2 of the Sherman Act, 15 U.S.C. § 2. *See* Answer & Counterclaims (Aug. 18, 2021), ECF No. 27.

On September 2, 2021, the Court issued a scheduling order for the action. ECF No. 29. On April 1, 2022, the Court denied DNA Genotek's motion to dismiss Spectrum's counterclaims for inequitable conduct, monopolization, and attempted monopolization, and the Court denied DNA Genotek's motion to strike Spectrum's affirmative defenses of inequitable conduct, patent misuse, and unclean hands. ECF No. 111. On May 25, 2022, the Court issued an amended scheduling order. ECF No. 130. By the present claim construction charts, worksheets, and briefs, the Parties agree upon the proper construction for two claim terms, and the Parties request that the Court construe eleven disputed claim terms from the patents-in-suit. ECF Nos. 74-1, 74-2, 88, 89, 134, 147.

II. PLAINTIFF'S MOTION FOR LEAVE TO FILE A RESPONSE TO DEFENDANT'S EVIDENTIARY OBJECTIONS

As an initial matter, the Court addresses DNA Genotek's motion for leave to file a response to Defendant's Evidentiary Objections. Along with its responsive claim construction brief, Spectrum filed a document entitled "Defendant's Evidentiary Objections to the Declaration of Dr. Michael L. Metzker Filed in Support of DNA Genotek's Opening Claim Construction Brief." ECF No. 88-1. In the filing, Spectrum objects to portions of Dr. Metzker's declaration for failure to comply with the Court's

Patent Local Rules, specifically Patent Local Rules 4.1(b), 4.1(d), and 4.2(d)(2).² *Id.* at 1-3.

On March 21, 2022, DNA Genotek filed a motion for leave to file a response to Spectrum's evidentiary objections. ECF No. 101. In the motion, DNA Genotek argues that Spectrum's filing is improper and unauthorized because the filing of separate "evidentiary objections" is a state procedural device that is not envisioned by the Federal Rules of Civil Procedure or the Court's Patent Local Rules. *Id.* at 1.

The Court declines to address Spectrum's evidentiary objections. In the filing, Spectrum objects to certain portions of Dr. Metzker's declaration, specifically, certain statements in paragraphs 18, 25, 34, 60, 63, and 67 of the declaration. *See* ECF No. 88-1 at 3-6. Although the Court is skeptical that these portions of Dr. Metzker's declaration complied with Patent Local Rule 4.2(d)(2), the Court does not rely on or reference any of the statements at issue in reaching the claim constructions set forth below. Thus, because

² Patent Local Rule 4.1(b) provides: "Simultaneously with exchange of the 'Preliminary Claim Constructions[,] . . . [w]ith respect to any such witness, percipient or expert, the parties must also provide a brief description of the substance of that witness's proposed testimony." S.D. Cal. Pat. L.R. 4.1(b). Similarly, Patent Local Rule 4.1(d) provides: "Simultaneously with exchange of the 'Responsive Claim Constructions[,] . . . [w]ith respect to any such witness, percipient or expert, the parties must also provide a brief description of the substance of that witness's proposed testimony." *Id.* 4.1(d). Patent Local Rule 4.2(d)(2) further provides: "The Joint Hearing Statement must include: . . . [w]hether any party proposes to call one or more witnesses, including experts, at the Claim Construction Hearing, the identify of each such witness, and for each expert, a summary of each opinion to be offered in sufficient detail to permit a meaningful deposition of that expert." *Id.* 4.2(d).

"A district court has wide discretion in enforcing the Patent Local Rules." *Finjan, Inc. v. Proofpoint, Inc.*, No. 13-CV-05808-HSG, 2015 WL 9460295, at *1 (N.D. Cal. Dec. 23, 2015). The Federal Circuit has "concluded that the exclusion of evidence is often an appropriate sanction for a party's failure to comply with the patent local rules." *Phigenix, Inc. v. Genentech, Inc.*, 783 F. App'x 1014, 1020 (Fed. Cir. 2019) (citing *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1369 (Fed. Cir. 2006); *Wong v. Regents of Univ. of California*, 410 F.3d 1052, 1060 (9th Cir. 2005)).

the statements at issue from Dr. Metzker’s declaration are not material to the Court’s claim construction rulings, the Court need not rule on Spectrum’s evidentiary objections. *See Elena v. Reliance Standard Life Ins. Co.*, No. 21-CV-00390-GPC, 2022 WL 1174107, at *8 (S.D. Cal. Apr. 20, 2022) (“A court need not rule on evidentiary objections that are not material to its ruling.”); *see, e.g., Williams v. Cnty. of San Diego*, 523 F. Supp. 3d 1183, 1193–94 (S.D. Cal. 2021) (declining to rule on evidentiary objections that were not material to the district court’s ruling); *F.T.C. v. John Beck Amazing Profits, LLC*, 865 F. Supp. 2d 1052, 1062 (C.D. Cal. 2012) (“The Court need not address these objections because the Court did not rely on any portion of the evidence to which Defendants objected.”). Further, because the Court declines to rule on Spectrum’s evidentiary objections, the Court denies as moot DNA Genotek’s motion for leave to file a response to those evidentiary objections.

III. LEGAL STANDARD FOR CLAIM CONSTRUCTION

“A determination of infringement involves a two-step analysis. ‘First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process.’” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1320 (Fed. Cir. 2003) (quoting *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1576 (Fed. Cir. 1993)); *see Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1350 (Fed. Cir. 2022). The first step of the infringement analysis — referred to as claim construction — is now before the Court. Claim construction “is exclusively within the province of the court [to decide],” not the jury. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996); *see Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326 (2015) (holding claim construction is an issue of law for the court to decide).

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). “The purpose of claim

1 construction is to ‘determin[e] the meaning and scope of the patent claims asserted to be
2 infringed.’” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed.
3 Cir. 2008).

4 Claim terms “are generally given their ordinary and customary meaning[,]” which
5 “is the meaning that the term would have to a person of ordinary skill in the art in question
6 at the time of the invention, *i.e.*, as of the effective filing date of the patent application.”
7 *Phillips*, 415 F.3d at 1312-13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576,
8 1582 (Fed. Cir. 1996)). “In some cases, the ordinary meaning of claim language as
9 understood by a person of ordinary skill in the art may be readily apparent even to lay
10 judges, and claim construction in such cases involves little more than the application of the
11 widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314.³
12 “However, in many cases, the meaning of a claim term as understood by persons of skill
13 in the art is not readily apparent.” *O2 Micro*, 521 F.3d at 1360. If the meaning of a term is
14 not readily apparent, a court must objectively look to “those sources available to the public
15 that show what a person of skill in the art would have understood disputed claim language
16 to mean.” *Phillips*, 415 F.3d at 1314 (quoting *Innova*, 381 F.3d at 1116). “Those sources
17 include ‘the words of the claims themselves, the remainder of the specification, the
18 prosecution history, and extrinsic evidence.’” *Id.*; see *Ericsson, Inc. v. D-Link Sys., Inc.*,
19 773 F.3d 1201, 1217-18 (Fed. Cir. 2014).⁴

20 Courts first look to the language and context of the claims themselves. See *Homeland*
21 *Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1375 (Fed. Cir. 2017) (holding that
22 claim construction “begins and ends” with a claim’s actual words); *Source Vagabond Sys.*
23

24
25 ³ “General purpose dictionaries” may be instructive in determining whether the
26 ordinary meaning of claim language as understood by a person of skill in the art is readily
27 apparent. *Phillips*, 415 F.3d. at 1314.

28 ⁴ The specification is the “written description” of the invention which enables one
skilled in the art to make and use the invention and discloses the best mode of carrying out
the invention. See 35 U.S.C. § 112(a).

1 *Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1299 (Fed. Cir. 2014) (“a claim construction
 2 analysis must begin and remain centered on the claim language itself” (quoting *Innova*,
 3 381 F.3d at 1116)). Claims are interpreted subject to the standard canons of claim
 4 construction. *See, e.g., id.* at 1300. For example, because a term that appears in multiple
 5 claims should generally be construed consistently, “[o]ther claims of the patent in question,
 6 both asserted and unasserted . . . [can] be valuable sources of enlightenment as to the
 7 meaning of the [disputed] claim term.” *Phillips*, 415 F.3d at 1314 (citing *Vitronics*, 90 F.3d
 8 at 1582). On the other hand, courts presume the use of different words or phrases in separate
 9 claims “to indicate that the claims have different meanings and scope” under the doctrine
 10 of “claim differentiation.” *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1369
 11 (Fed. Cir. 2007).

12 Furthermore, “the person of ordinary skill is deemed to read the claim term not only
 13 in the context of the particular claim in which the disputed term appears, but [also] in the
 14 context of the entire patent, including the specification.” *Phillips*, 415 F.3d at 1314 (citing
 15 *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). The
 16 specification “is always highly relevant to the claim construction analysis. Usually it is
 17 dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics*, 90 F.3d
 18 at 1582; *accord Phillips*, 415 F.3d at 1317 (“It is entirely appropriate for a court, when
 19 conducting claim construction, to rely heavily on the written description for guidance as to
 20 the meaning of the claims.”). For example, the specification “may reveal a special
 21 definition given to a claim term by the patentee that differs from the [plain and ordinary]
 22 meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.”
 23 *Phillips*, 415 F.3d at 1316. Similarly, “[a] claim construction that excludes a preferred
 24 embodiment is rarely, if ever correct and would require highly persuasive evidentiary
 25 support.” *Kaufman v. Microsoft Corp.*, 34 F.4th 1360, 1372 (Fed. Cir. 2022) (quoting *Epos*
 26 *Tech. Ltd. v. Pegasus Tech. Ltd.*, 766 F.3d 1338, 1347 (Fed. Cir. 2014)). As such, a court
 27 must read claims “in view of the specification, of which they are a part.” *Markman v.*
 28 *Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996);

1 *see* 35 U.S.C. § 112(b) (“The specification shall conclude with one or more claims
2 particularly pointing out and distinctly claiming the subject matter which the inventor or a
3 joint inventor regards as the invention.”).

4 But another principle of claim construction is that “[t]he written description part of
5 the specification does not delimit the right to exclude. That is the function and purpose of
6 claims.” *Markman*, 52 F.3d at 980. As the Federal Circuit in *Phillips* explained, there is a
7 “distinction between using the specification to interpret the meaning of a claim and
8 importing limitations from the specification into the claim.” 415 F.3d at 1323. Therefore,
9 “it is improper to read limitations from a preferred embodiment described in the
10 specification—even if it is the only embodiment—into the claims absent a clear indication
11 in the intrinsic record that the patentee intended the claims to be so limited.” *Dealertrack,*
12 *Inc. v. Huber*, 674 F.3d 1315, 1327 (Fed. Cir. 2012); *accord Openwave Sys., Inc. v. Apple*
13 *Inc.*, 808 F.3d 509, 514 (Fed. Cir. 2015).

14 In addition to the claim and the specification, the patent’s prosecution history may
15 be considered if it is in evidence. *Phillips*, 415 F.3d at 1317. The prosecution history
16 “consists of the complete record of the proceedings before the PTO and includes the prior
17 art cited during the examination of the patent.” *Id.* “Like the specification, the prosecution
18 history provides evidence of how the PTO and the inventor understood the patent.” *Id.* “Yet
19 because the prosecution history represents an ongoing negotiation between the PTO and
20 the applicant, rather than the final product of that negotiation, it often lacks the clarity of
21 the specification and thus is less useful for claim construction purposes.” *Id.*

22 “In most situations, an analysis of the intrinsic evidence alone will resolve any
23 ambiguity in a disputed claim term.” *Vitronics*, 90 F.3d at 1583; *see Seabed Geosolutions*
24 *(US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1287 (Fed. Cir. 2021) (“If the meaning of a
25 claim term is clear from the intrinsic evidence, there is no reason to resort to extrinsic
26 evidence.”). However, “[w]here the intrinsic record is ambiguous, and when necessary,”
27 district courts may “rely on extrinsic evidence, which ‘consists of all evidence external to
28 the patent and prosecution history, including expert and inventor testimony, dictionaries,

1 and learned treatises.’” *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711
 2 F.3d 1348, 1360 (Fed. Cir. 2013) (quoting *Phillips*, 415 F.3d at 1317); *see 24/7 Customer,*
 3 *Inc. v. LivePerson, Inc.*, 235 F. Supp. 3d 1102, 1107 (N.D. Cal. 2016) (“Within the class
 4 of extrinsic evidence, dictionaries, and especially technical dictionaries, ‘can assist the
 5 court in determining the meaning of particular terminology to those of skill in the art’
 6 because they ‘endeavor to collect the accepted meanings of terms used in various fields of
 7 science and technology.’” (quoting *Phillips*, 415 F.3d at 1318)).

8 While sometimes useful, “it is improper to rely on extrinsic evidence” where the
 9 intrinsic evidence alone is sufficient. *Vitronics*, 90 F.3d at 1583. Indeed, a court must
 10 evaluate all extrinsic evidence in light of the intrinsic evidence. *Phillips*, 415 F.3d at 1319.
 11 “[E]xtrinsic evidence is to be used for the court’s understanding of the patent, not for the
 12 purpose of varying or contradicting the terms of the claims.” *Genuine Enabling Tech. LLC*
 13 *v. Nintendo Co.*, 29 F.4th 1365, 1373 (Fed. Cir. 2022) (quoting *Markman*, 52 F.3d at 981);
 14 *see Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1290 (Fed. Cir. 2015) (“Extrinsic
 15 evidence may not be used ‘to contradict claim meaning that is unambiguous in light of the
 16 intrinsic evidence.’” (quoting *Phillips*, 415 F.3d at 1324)). In cases where subsidiary facts
 17 contained in the extrinsic evidence “are in dispute, courts will need to make subsidiary
 18 factual findings about that extrinsic evidence.” *Teva*, 574 U.S. at 332.

19 Nevertheless, “district courts are not (and should not be) required to construe every
 20 limitation present in a patent’s asserted claims.” *O2 Micro*, 521 F.3d at 1362. In some
 21 situations, it is appropriate for a court to determine that a claim term needs no construction
 22 and its plain and ordinary meaning applies. *See id.*; *Phillips*, 415 F.3d at 1314. But “[a]
 23 determination that a claim term ‘needs no construction’ or has the ‘plain and ordinary
 24 meaning’ may be inadequate when a term has more than one ‘ordinary’ meaning or when
 25 reliance on a term’s ‘ordinary’ meaning does not resolve the parties’ dispute.” *O2 Micro*,
 26 521 F.3d at 1361. When the parties present a dispute regarding the scope of a claim term,
 27 it is the court’s duty to resolve the disagreement. *Id.* at 1362; *see Eon Corp. IP Holdings v.*
 28 *Silver Spring Networks*, 815 F.3d 1314, 1318 (Fed. Cir. 2016).

IV. CONSTRUCTION OF THE AGREED UPON CLAIM TERMS FROM THE '187 PATENT

A. “nucleic acid”

DNA Genotek's Proposed Construction	Spectrum's Proposed Construction	Court's Construction
“a chain of nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA)”	“a chain of nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA)”	“a chain of nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA)”

B. “biological sample”

DNA Genotek's Proposed Construction	Spectrum's Proposed Construction	Court's Construction
“any sample containing nucleic acids that has been obtained from or deposited by an animal”	“any sample containing nucleic acids that has been obtained from or deposited by an animal”	“any sample containing nucleic acids that has been obtained from or deposited by an animal”

In their Joint Claim Construction Worksheet, the Parties agree upon the proper construction for the claim terms “nucleic acid” and “biological sample” in the '187 Patent. *See* ECF No. 74-2 at 4-5, 7. These two proposed constructions are well supported by the intrinsic record. The '187 Patent's specification sets forth express definitions for the terms “biological sample” and “nucleic acid.” *See* '187 Patent col. 7 ll. 16-19, col. 7 ll. 28-31. The Parties' joint proposed constructions for these claim terms align with those express definitions set forth in the specification. As such, the Court adopts the Parties' proposed constructions for these two claim terms. *See Phillips*, 415 F.3d at 1316 (“[T]he specification may reveal a special definition given to a claim term by the patentee In such cases, the inventor's lexicography governs.”); *Edwards Lifesciences LLC v. Cook*

Inc., 582 F.3d 1322, 1329 (Fed. Cir. 2009) (explaining that a patentee acts as his own lexicographer when the patentee “‘clearly set[s] forth a definition of the disputed claim term in either the specification or prosecution history.’”); *see, e.g., Biogen MA Inc. v. EMD Serono, Inc.*, 976 F.3d 1326, 1336 (Fed. Cir. 2020). The Court construes the claim term “nucleic acid” as “a chain of nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA),” and the Court construes the claim term “biological sample” as “any sample containing nucleic acids that has been obtained from or deposited by an animal.”

V. CONSTRUCTION OF THE DISPUTED CLAIM TERMS FROM THE '187 PATENT

A. “preserving/preserve”

DNA Genotek’s Proposed Construction	Spectrum’s Proposed Construction	Court’s Construction
The term is definite, does not require construction, and should be accorded plain and ordinary meaning. If construction is required, the term should be construed as “slowing degradation of”/“slows degradation of”	The term is indefinite.	“slowing degradation of nucleic acid[s] at room temperature for extended periods of time”/“slows degradation of nucleic acids at room temperature for extended periods of time”

Spectrum argues that the claim term “preserving/preserve” in the '187 Patent is indefinite. ECF No. 147 at 5-10. In response, DNA Genotek contends that the term is not

1 indefinite and the claim term should be given its plain and ordinary meaning. ECF No. 134
2 at 5-12.

3 “Definiteness is a statutory requirement for patentability.” *Niazi*, 30 F.4th at 1346.
4 Under 35 U.S.C. § 112 ¶ 2, a patent must “conclude with one or more claims particularly
5 pointing out and distinctly claiming the subject matter which the applicant regards as the
6 invention.” 35 U.S.C. § 112 ¶ 2 (pre-AIA).⁵

7 “A claim fails to satisfy this statutory requirement and is thus invalid for
8 indefiniteness if its language, when read in light of the specification and the prosecution
9 history, ‘fail[s] to inform, with reasonable certainty, those skilled in the art about the scope
10 of the invention.’” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1369–70 (Fed. Cir.
11 2014) (quoting *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014)). This
12 “reasonable certainty” standard “reflects a ‘delicate balance’ between ‘the inherent
13 limitations of language’ and providing ‘clear notice of what is claimed.’” *Guangdong
14 Alison Hi-Tech Co. v. Int’l Trade Comm’n*, 936 F.3d 1353, 1359 (Fed. Cir. 2019). “Th[e]
15 standard ‘mandates clarity, while recognizing that absolute precision is unattainable.’”
16 *Nevro Corp. v. Bos. Sci. Corp.*, 955 F.3d 35, 39 (Fed. Cir. 2020) (quoting *Nautilus*, 572
17 U.S. at 910); *see also* *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir.
18 2017) (“‘Reasonable certainty’ does not require ‘absolute or mathematical precision.’”).

19 “General principles of claim construction apply to indefiniteness allegations.”
20 *HZNP Medicines LLC v. Actavis Lab’ys UT, Inc.*, 940 F.3d 680, 688 (Fed. Cir. 2019). The
21 party asserting indefiniteness bears “the burden of proving indefiniteness by clear and
22 convincing evidence.” *BASF*, 875 F.3d at 1365 (citing *Biosig Instruments, Inc. v. Nautilus,
23 Inc.*, 783 F.3d 1374, 1377 (Fed. Cir. 2015)); *see also* *Microsoft Corp. v. i4i Ltd. P’ship*,
24

25
26 ⁵ “Congress amended § 112 when it enacted the Leahy–Smith America Invents Act
27 (‘AIA’).” *In re Durance*, 891 F.3d 991, 1002 n.9 (Fed. Cir. 2018). “However, the amended
28 version of § 112 applies only to patent applications ‘filed on or after’ September 16, 2012.”
Id. Here, the Parties agree that the pre-AIA version of § 112 applies to the ’187 Patent. *See*,
e.g., ECF No. 147 at 5; ECF No. 134 at 19.

564 U.S. 91, 95 (2011) (holding that 35 U.S.C. § 282 “requires an invalidity defense to be proved by clear and convincing evidence”).

The Court begins its analysis of this issue by noting that both the claim language and the specification of the ’187 Patent provide clear guidance on how to achieve the claimed “preserving” of nucleic acids. Independent claim 1 of the ’187 Patent recites a device “for . . . **preserving nucleic acid** in a biological sample” comprising, among other things:

reagents in the reagent compartment for **preserving nucleic acids** potentially present in the sample wherein said reagents comprise a denaturing agent, a chelator and a buffer agent; and,

. . . release said reagents to form a mixture of reagents and said biological sample 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.

’187 Patent col. 19 ll. 34-35, 49-52, 56-59 (emphasis added); *see also id.* col. 3 ll. 61-64 (“[A] first aspect of the invention features a composition for preserving nucleic acids that includes a chelating agent, and a denaturing agent, where the pH of the composition is greater than 5.0.”). Here, the claim language and the specification provide clear guidance to a PHOSITA as to the specific reagents to include in the device for achieving the claimed “preserving” of nucleic acids potentially present in the biological sample. *See* ECF No. 134-1, Metzker Decl. ¶¶ 54-57; ECF No. 134-6, Ex. 1 at 30-35, 39, 40-41, 45-46; *see also BASF*, 875 F.3d at 1368 (rejecting indefiniteness challenge in part because “[b]oth parties’ experts agreed that materials capable of performing the claimed reactions were known in the art at the time of the invention”). Indeed, Spectrum itself asserts: “The [’187] patent includes substantial detail about the reagents that make up the composition of the invention. The patent also demonstrates, with examples, how the composition preserves the nucleic acids for extended periods of time.” ECF No. 147 at 2 (citations omitted).

Despite this guidance, Spectrum argues that the claim term “preserving/preserve” is indefinite because the claim language does not specify a time period (*i.e.*, how long the nucleic acid must be maintained to be considered preserved), and the claim language does

1 not specify the temperature at which the sample is stored. ECF No. 147 at 5, 7 (citing ECF
 2 No. 87, Fischetti Decl. ¶¶ 23, 35-37); *see* ECF No. 88 at 4. But in evaluating indefiniteness,
 3 the Court is not limited to only the claim language. Rather, “in assessing indefiniteness,”
 4 the Court must evaluate the claim language “in light of the specification and the
 5 prosecution history.” *Nautilus*, 572 U.S. at 908; *accord Interval Licensing*, 766 F.3d at
 6 1371.

7 The specification of the ’187 Patent provides guidance to a PHOSITA as to both
 8 time period and temperature. The specification states: “The present invention relates to
 9 compositions and methods for preserving nucleic acids at room temperature for extended
 10 periods of time” ’187 Patent col. 1 ll. 23-25. The specification further states: “The
 11 present inventor has developed a composition, which, when mixed with a mucin-containing
 12 bodily fluid, preserves the nucleic acids at room temperature under ambient conditions for
 13 extended periods of time.” *Id.* col. 3 ll. 48-51; *see also id.* col. 13 ll. 44-47 (“Incubation
 14 can be at room temperature over a relatively long period of time (days or weeks) while
 15 samples are being shipped to a laboratory for analysis.”), col. 16 ll. 19-20 (“The container
 16 can be mailed back to the testing lab at room temperature.”), col. 16 ll. 54-55 (“stabilizes
 17 DNA for longer periods of time”). In these passages, the specification clearly states that
 18 within the meaning of the ’187 Patent, the nucleic acids are able to be preserved at room
 19 temperature and for extended periods of time. As such, contrary to Spectrum’s assertions,
 20 the ’187 Patent’s specification gives guidance to a PHOSITA as to both the time period
 21 and the temperature for the claimed “preserving.”

22 Spectrum’s expert Dr. Fischetti acknowledges these passages in the specification,
 23 but contends that they are insufficient because they do not provide a specific time period
 24 or a specific temperature for the nucleic acid preservation. ECF No. 87, Fischetti Decl. ¶¶
 25 33, 37. The Court rejects this contention. “[A] claim is not indefinite just because it is
 26 broad.” *Niazi*, 30 F.4th at 1347; *see BASF*, 875 F.3d at 1367 (“[B]readth is not
 27 indefiniteness.”). Thus, “a patentee need not define his invention with mathematical
 28 precision in order to comply with the definiteness requirement.” *Guangdong Alison*, 936

F.3d at 1359 (quoting *Sonix Tech. Co. v. Publications Int’l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017)); see *One-E-Way, Inc. v. Int’l Trade Comm’n*, 859 F.3d 1059, 1066 (Fed. Cir. 2017) (holding “[f]or purposes of definiteness, the term is not required to have a technical measure”). “Indeed, patentees often use descriptive words to avoid a strict numerical boundary to the specified parameter.” *Niazi*, 30 F.4th at 1347 (cleaned up); see *Guangdong Alison*, 936 F.3d at 1360. As such, the patentee is free to use broad words to describe the time period and the temperature for the claimed nucleic acid preservation. The patentee did not need to identify specific numerical boundaries as to the time period (*i.e.*, a specific amount of days or weeks) or the temperature (*i.e.*, a specific temperature range) in order to comply with § 112’s definiteness requirement.⁶

Spectrum also argues that the claim term “preserving/preserve” is indefinite because the claims do not specify the type of assay that should be used to determine if the nucleic acid has been preserved. ECF No. 147 at 7 (citing ECF No. 87, Fischetti Decl. ¶¶ 21-22). Again, the specification provides guidance to a PHOSITA on this issue. Spectrum’s expert Dr. Fischetti acknowledges that the specification expressly references both electrophoresis and polymerase chain reaction (“PCR”), and those are both well-known detection techniques for examining the presence or absence of a target nucleotide sequence in a sample. See ECF No. 87, Fischetti Decl. ¶ 21 (citing ’187 Patent col. 16 ll. 56 to col. 18 ll. 8). As such, the ’187 Patent’s specification gives guidance to a PHOSITA as to detection methods that may be used to determine if nucleic acids in the sample have been preserved.

Spectrum also argues that “[t]he term ‘preserving nucleic acids’ does not have a

⁶ The Court notes that in its briefing, Spectrum shows that it understands the meaning of the term “room temperature,” defining it as “(20-25 °C).” ECF No. 147 at 7. In addition, the Court notes that the specification provides additional guidance as to what is meant by the phrase “extended period of time.” Elsewhere, the specification states: “Incubation can be at room temperature over a relatively long period of time (days or weeks) while samples are being shipped to a laboratory for analysis.” ’187 Patent col. 13 ll. 44-47. Here, the specification clarifies that when referring to extended periods of time, the specification is referring to days or weeks.

single meaning to those in the relevant field.” ECF No. 147 at 6 (citing ECF No. 87, Fischetti Decl. ¶ 18 (“[I]n 2002, the term ‘preserving nucleic acid’ did not have just one meaning in the biological sciences.”)). But even assuming this is true, this is insufficient to prove indefiniteness of a patent claim. Under the standard for evaluating indefiniteness set forth by the Supreme Court in *Nautilus*, the Court does not ask whether a PHOSITA examining the claim term by itself in the abstract would possess reasonable certainty as to the scope of the term. Rather, the Court must inquire whether a PHOSITA examining the claim term along with the other claim language, the specification, and the prosecution history, would possess reasonable certainty as to the scope of the claim. *See Nautilus*, 572 U.S. at 901, 908 (“[I]n assessing definiteness, claims are to be read in light of the patent’s specification and prosecution history.”); *Interval Licensing*, 766 F.3d at 1371. As explained above, the specification along with the claim language gives clear guidance to a PHOSITA as to the meaning of the claim term “preserving nucleic acids” within the scope of the ’187 Patent. Moreover, the Court notes that the extrinsic evidence cited by Dr. Fischetti to support his factual assertion that there is not a single meaning for the term “preserving nucleic acid” itself sets forth a common meaning for the term. The cited article states: “[T]he term ‘preservation’ is used by all these fields and refers to the maintenance of chemical and physical integrity of the DNA molecule.” ECF No. 87, Fischetti Decl. ¶ 18. As such, the cited evidence contradicts Dr. Fischetti’s assertion that there is no common meaning for that term.

In addition, that the claim term “preserving/preserve” is definite is supported by evidence that Spectrum presented during IPR proceedings before the PTAB. The Federal Circuit has explained that application of the term at issue by a challenger’s own expert to various references and products without any uncertainty “supports the conclusion that a skilled artisan did understand the term with reasonable certainty.” *Sonix*, 844 F.3d at 1380; *see also Liqwd, Inc. v. L’Oreal USA, Inc.*, 720 F. App’x 623, 631 (Fed. Cir. 2018) (“Evidence of a challenger’s own ability to apply a term without unreasonable uncertainty counts against an indefiniteness contention.”). In IPR proceedings as to a different patent,

U.S. Patent No. 10,767,215 (“the ’215 Patent”), Spectrum submitted a declaration from its expert, Dr. Fischetti, the same expert in this action. *See* ECF No. 134-10, Ex. 5 ¶¶ 53-115. In the declaration, Dr. Fischetti performs an invalidity analysis, opining that the prior art references Birnboim (the invention disclosed in the ’187 Patent) and Stefan render certain claims from the ’215 Patent obvious under 35 U.S.C. § 103. *See id.* ¶¶ 53-115. In that analysis, Dr. Fischetti is able to apply the term “preserving” from the invention disclosed in the ’187 Patent to the relevant elements in the ’215 Patent without any uncertainty. *See id.* ¶¶ 63, 68-70, 75, 79-81; *see also* ECF No. 134-9, Ex. 4 ¶¶ 65, 73, 107 (Spectrum’s expert Dr. Taylor describing and applying the claim term “preserving” to the patent at issue in the IPR without any uncertainty). This supports the conclusion that a skilled artisan did and would understand the claim term “preserving/preserve” with reasonable certainty. *See Sonix*, 844 F.3d at 1380; *see, e.g., Taction Tech., Inc. v. Apple Inc.*, No. 3:21-cv-812-TWR-JLB, ECF No. 141 at 20-22 (S.D. Cal. Sept. 28, 2022) (relying on accused infringer and its expert’s ability to apply claim term without issue during their invalidity analysis in IPR proceedings in rejecting indefiniteness challenge). In sum, Spectrum has failed to demonstrate that the claim term “preserving/preserve” is indefinite.⁷

Turning to construction of the claim term “preserving/preserve,” DNA Genotek

⁷ At the claim construction hearing, Spectrum noted that if the Court rejects its indefiniteness challenge at claim construction, it is not “a dispositive judgment” on its indefiniteness counterclaim and defense in this case, and it is still preserved as an invalidity defense for trial. ECF No. 176 at 4. The Court acknowledges that in rejecting Spectrum’s indefiniteness challenge in this claim construction order, the Court is not entering a judgment against Spectrum on its indefiniteness counterclaim or defense. But, as DNA Genotek correctly noted, indefiniteness is an issue of law for the Court to decide. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341, 1342 (Fed. Cir. 2015) (“The internal coherence and context assessment of the patent, and whether it conveys claim meaning with reasonable certainty, are questions of law.”); *Nature Simulation Sys. Inc. v. Autodesk, Inc.*, 50 F.4th 1358, 1360 (Fed. Cir. 2022) (“Claim indefiniteness is a legal conclusion.”). And the Court has provided a thorough analysis as to the merits of Spectrum’s theory of indefiniteness above.

1 argues that if the claim term must be construed, then it should be construed as “slowing
2 degradation of”/“slows degradation of.” ECF No. 134 at 5. The Court notes that during his
3 deposition, Spectrum’s expert, Dr. Fischetti, described “preservation” as “using a
4 combination of compounds to help slow down the degradation process.” ECF No. 134-6 at
5 46. As such, the Court will include “slowing degradation of” in its construction for this
6 claim term.

7 Moreover, as previously noted, the specification contains a clear disclaimer
8 explaining that “[t]he present invention relates to compositions and methods for preserving
9 nucleic acids at room temperature for extended periods of time” ’187 Patent col. 1 ll.
10 23-25. “When a patentee ‘describes the features of the ‘present invention’ as a whole,’ he
11 implicitly alerts the reader that ‘this description limits the scope of the invention.’”
12 *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016)
13 (quoting *Regents of Univ. of Minnesota v. AGA Med. Corp.*, 717 F.3d 929, 936 (Fed. Cir.
14 2013)); accord *Pacing Techs., LLC v. Garmin Int’l, Inc.*, 778 F.3d 1021, 1025 (Fed. Cir.
15 2015); see, e.g., *Wastow Enterprises, LLC v. Truckmovers.com, Inc.*, 855 F. App’x 748,
16 750–51 (Fed. Cir. 2021); *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318
17 (Fed. Cir. 2006); see also *Poly-Am., L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed.
18 Cir. 2016) (“[A]n inventor may disavow claims lacking a particular feature when the
19 specification describes “the present invention” as having that feature.”). As such, the Court
20 will also include this disclaimer in its construction for this claim term. Accordingly, the
21 Court construes “preserving nucleic acid[s]” as “slowing degradation of nucleic acid[s] at
22 room temperature for extended periods of time,” and the Court construes “preserves nucleic
23 acids” as “slows degradation of nucleic acids at room temperature for extended periods of
24 time.”

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B. “containment vessel”

DNA Genotek’s Proposed Construction	Spectrum’s Proposed Construction	Court’s Construction
No construction required, plain and ordinary meaning	“container”	“container”

Here, the Parties dispute whether the claimed “containment vessel” must be a “container” or something broader. Spectrum contends that the “containment vessel” claimed in the ’187 Patent is simply a container. ECF No. 147 at 10. In response, DNA Genotek argues that the meaning of “containment vessel” would be readily apparent to the Court and a jury by its plain and ordinary meaning, and Spectrum has failed to give a reason for deviating from that plain and ordinary meaning. ECF No. 134 at 15.

The Court begins its analysis of the Parties’ dispute by reviewing the claim language. Independent Claim 1 of the ’187 Patent recites a device comprising, among other things:

a. one or more walls defining a **containment vessel** having a top having an opening, and a closed bottom having a sample receiving area for holding said biological sample, said opening for receiving a liquid sample and for sealably receiving a sealing cap, said top having an opening for receiving a biological sample from the mouth of a user and further comprising at least one marking on said one or more walls which corresponds to a fluid volume in the sample receiving area;

’187 Patent col. 19 ll. 34-44 (emphasis added). Here, the claim language describes the “containment vessel” as a container. First, the claim language uses the word “vessel.” The common meaning of the word “vessel” in this context is a container for holding something. *See* MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/vessel> (defining “vessel” as “a container (such as a cask, bottle, kettle, cup, or bowl) for holding something”); CAMBRIDGE DICTIONARY, <https://dictionary.cambridge.org/>

1 dictionary/english/vessel (defining “vessel” as “a curved container that is used to hold
2 liquid”); *see also Phillips*, 415 F.3d at 1314 (explaining that the use of general purpose
3 dictionaries “may be helpful” in cases that involve “little more than the application of the
4 widely accepted meaning of commonly understood words”). That meaning is consistent
5 with the claim language as claim 1 explains that the “containment vessel” has walls and a
6 closed bottom for holding the biological sample. *See* ’187 Patent col. 18 ll. 36-39. As such,
7 the claim language supports Spectrum’s proposed construction.

8 The specification further supports Spectrum’s proposed construction. Although the
9 specification never uses the specific term “containment vessel,” when the specification
10 describes the component of the claimed invention that holds the biological sample, it refers
11 to that component as a “container.” *See, e.g.,* ’187 Patent col. 6 ll. 8-9 (“placing the bodily
12 fluid into a first region of a container”), col. 6 ll. 28-29 (“The device includes: a container
13 that has a first region for collecting a biological sample . . .”), col. 14 ll. 51-52. As such,
14 Spectrum’s proposed construction is well supported by the intrinsic record.

15 DNA Genotek argues that Spectrum’s proposed construction is improper because
16 the Court should not give a claim term a narrower construction unless it is prescribed by
17 the specification or the prosecution history. ECF No. 134 at 15; ECF No. 89 at 6. DNA
18 Genotek argues that “[a] ‘patentee is free to choose a broad term and expect to obtain the
19 full scope of its plain and ordinary meaning unless the patentee explicitly redefines the
20 term or disavows its full scope.’” ECF No. 89 at 6 (quoting *Thorner v. Sony Computer Ent.*
21 *Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012)). But DNA Genotek fails to articulate
22 precisely how Spectrum’s proposed construction purportedly narrows the scope of the
23 claim term “containment vessel.” And DNA Genotek fails to articulate what it precisely
24 considers to be the proper scope of the claim term “containment vessel.” DNA Genotek
25 itself contends that the meaning of the term “containment vessel” would be readily apparent
26 to the Court and the jury by its plain and ordinary meaning. ECF No. 134 at 15; *see* ECF
27 No. 89 at 6. The readily apparent plain meaning of the word “vessel” is a “container” for
28 holding something. *See* MERRIAM-WEBSTER DICTIONARY, <https://www.merriam->

1 webster.com/dictionary/vessel; CAMBRIDGE DICTIONARY, <https://dictionary.cambridge.org/dictionary/english/vessel>.

3 At the claim construction hearing, DNA Genotek argued that rephrasing the plain
4 language of a claim by substituting synonyms is not the purpose of claim construction.
5 ECF No. 176 at 13 (citing *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 863 (Fed.
6 Cir. 2004)). The Court acknowledges that in *C.R. Bard*, the Federal Circuit explained that
7 courts should forgo detailed dictionary analysis during claim construction if the term is
8 commonplace, and ““merely rephrasing or paraphrasing the plain language of a claim by
9 substituting synonyms does not represent genuine claim construction.”” 388 F.3d at 863;
10 *see also U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (Claim
11 construction “is not an obligatory exercise in redundancy.”); *O2 Micro*, 521 F.3d at 1362
12 (“[D]istrict courts are not (and should not be) required to construe every limitation present
13 in a patent’s asserted claims.”). But the Federal Circuit has also explained in *O2 Micro* and
14 *Eon*, that if the parties present a dispute regarding the scope of a claim term, it is the court’s
15 duty to resolve the dispute. *O2 Micro*, 521 F.3d at 1362; *see Eon*, 815 F.3d at 1318.
16 Although the parties appear to agree that “container” is a synonym for “vessel,” [see ECF
17 No. 176 at 13-14], the parties are unable to represent to the Court that they are in agreement
18 as to the scope of this claim term. As such, the Court construes this claim term in order to
19 resolve the parties’ dispute.

20 In sum, the Court adopts Spectrum’s proposed construction. The Court construes the
21 term “containment vessel” as “container.”

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C. “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”

DNA Genotek’s Proposed Construction	Spectrum’s Proposed Construction	Court’s Construction
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 opening is able to receive a liquid biological sample directly from the mouth of the user”

Here, the Parties’ dispute regarding this claim term is two-part. First, the Parties dispute whether the claimed “opening” is specifically configured for receiving a liquid biological sample directly from the mouth of a user. ECF No. 147 at 11-12. Second, the Parties dispute whether the claimed “opening” must have a diameter of at least 2.0 cm. ECF No. 147 at 13-14. The Court addresses each of these disputes below.

The Court first addresses Spectrum’s contention that the opening be configured so that it can receive a liquid sample directly from the mouth of the user. Beginning with the claim language, independent claim 1 of the ’187 Patent recites a device comprising, among other things:

a. one or more walls defining a containment vessel having a top having an opening, . . . **said opening for receiving a liquid sample and for sealably receiving a sealing cap, said top having an opening for receiving a biological sample from the mouth of a user. . . ;**

1 '187 Patent col. 19 ll. 36-42 (emphasis added). Here, the claim language provides support
 2 for Spectrum's proposed construction. The claim language explains that the containment
 3 vessel has an opening, and one of the purposes of that opening is for receiving a liquid
 4 biological sample from the mouth of a user. *Id.* at col. 19 ll. 36-42. That the claim language
 5 uses the phrase "from the mouth of a user" implies that the liquid sample is sent from the
 6 mouth of the user into the opening. As such, the claim language is consistent with this
 7 portion of Spectrum's proposed construction.

8 Spectrum argues that its proposed construction is additionally supported by a
 9 disclaimer in the prosecution history. ECF No. 147 at 11-12. "Prosecution disclaimer
 10 'preclud[es] patentees from recapturing through claim interpretation specific meanings
 11 disclaimed during prosecution.'" *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1359
 12 (Fed. Cir. 2017) (quoting *Omega*, 334 F.3d at 1323). "[T]he doctrine of prosecution
 13 disclaimer ensures that claims are not 'construed one way in order to obtain their allowance
 14 and in a different way against accused infringers.'" *Id.* at 1360 (quoting *Southwall Techs.,*
 15 *Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995)).

16 "Such disclaimer can occur through amendment or argument." *Id.* at 1359. But "[f]or
 17 a statement during prosecution to qualify as a disavowal of claim scope, it must be 'so clear
 18 as to show reasonable clarity and deliberateness,' and 'so unmistakable as to be
 19 unambiguous evidence of disclaimer.'" *Genuine Enabling Tech. LLC v. Nintendo Co.*, 29
 20 F.4th 1365, 1374 (Fed. Cir. 2022); *see also Aylus*, 856 F.3d at 1361 ("[T]o invoke the
 21 doctrine of prosecution disclaimer, any such statements must 'be both clear and
 22 unmistakable.'"); *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1375 (Fed.
 23 Cir. 2008) ("Prosecution disclaimer does not apply to an ambiguous disavowal."). "Thus,
 24 when the patentee unequivocally and unambiguously disavows a certain meaning to obtain
 25 a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim
 26 consistent with the scope of the claim surrendered." *Biogen Idec, Inc. v. GlaxoSmithKline*
 27 *LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013). "A patentee could do so, for example, by
 28 clearly characterizing the invention in a way to try to overcome rejections based on prior

art.” *Computer Docking Station*, 519 F.3d at 1374. “‘The party seeking to invoke prosecution history disclaimer bears the burden of proving the existence of a clear and unmistakable disclaimer that would have been evident to one skilled in the art.’” *Genuine Enabling Tech.*, 29 F.4th at 1374.

Here, Spectrum specifically relies on statements from the prosecution of U.S. Patent No. 9,523,115 (“the ’115 Patent”) to support its claim of prosecution history disclaimer. See ECF No. 147 at 12. The ’187 Patent is a continuation of the ’115 Patent. ’187 Patent at [63]. “[P]rosecution disclaimer may arise from disavowals made during the prosecution of ancestor patent applications.” *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314 (Fed. Cir. 2007) (quoting *Omega*, 334 F.3d at 1333). “When the application of prosecution disclaimer involves statements from prosecution of a familial patent relating to the same subject matter as the claim language at issue in the patent being construed, those statements in the familial application are relevant in construing the claims at issue.” *Id.*; see *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1070 (Fed. Cir. 2019) (“When a parent application includes statements involving ‘common subject matter’ with the terms at issue, those statements are relevant to construction of the terms in the child patent.”).

During prosecution of the ’115 Patent, the examiner rejected certain claims as obvious under 35 U.S.C. § 103 in light of three prior art references: Baker, Lawrence, and Verscheure. ECF No. 83-5, Ex. 4 at 229-33. In response to these rejections, the patentee amended its claims, including Claim 30,⁸ and argued:

Reconsideration of the present rejection is respectfully requested.

⁸ Claim 30 as amended included the following claim language: “said top having an opening for receiving a biological sample from the mouth of a user.” ECF No. 83-5 at 215 (emphasis in original). This language is identical to the language contained in independent claim 1 of the ’187 Patent. Compare *id.* with ’187 Patent col. 19 ll. 40-42; see also *Regents of Univ. of Minnesota v. AGA Med. Corp.*, 717 F.3d 929, 943 (Fed. Cir. 2013) (“In general, a prosecution disclaimer will only apply to a subsequent patent if that patent contains the same claim limitation as its predecessor.”).

1 Applicant respectfully submits the present rejections totally fail to address key
2 features recited in independent claim 30. The rejections fail to address the
3 **opening for receiving a sample directly from the mouth** and having indicia
4 on the one or more walls that correspond to the desired fluid level of the
5 sample.

6 . . .

7 The device disclosed by Lawrence is not well adapted to receive [a]
8 sample **directly from the mouth**. . . . The samples [disclosed by Lawrence]
9 are not taken **directly from the mouth**. . . . Although sputum is casually
10 mentioned as a sample it is not clear that the sputum would be delivered
11 **directly to the device** which is also engineered to receive an insect, small
12 animal, fungus, plant or animal tissue.

13 *Id.* at 221 (emphasis added). Here, the patentee expressly distinguished the claimed
14 invention from the Lawrence reference on the grounds that Lawrence purportedly did not
15 have an opening for receiving a sample “directly” from the mouth. *Id.* Indeed,
16 subsequently, the examiner acknowledged that in making these arguments, the patentee
17 appeared to be construing the relevant claim term “to mean that the sample is directly
18 transferred from the mouth to the opening (*i.e.*, spitting into the opening).” *Id.* at 195.

19 The patentee further confirmed this understanding of the scope of the term “opening”
20 during the prosecution history. The examiner also rejected certain claim terms as obvious
21 in light of the prior art references: Baker, Lawrence, Verscheure, and Shuber. *Id.* at 200-
22 01; *see also id.* at 233. In response to these additional rejections, the patentee argued:
23 “Applicant respectfully submits Shuber does not address the specialized purpose of the
24 present invention to receive samples directly from the mouth, and therefore fails to remedy
25 the deficiencies of Baker, Lawrence and Verscheure.” *Id.* at 164; *accord id.* at 223. The
26 Court agrees with Spectrum that these statements in the prosecution history constitute clear
27 and unmistakable disavowals requiring that the claimed “opening” be for receiving liquid
28 samples “directly” from the mouth of the user. *See Computer Docking Station*, 519 F.3d at

1 1374 (“A patentee could [make a disclaimer], for example, by clearly characterizing the
 2 invention in a way to try to overcome rejections based on prior art”); *Purdue Pharma L.P.*
 3 *v. Endo Pharms. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006) (Prosecution disclaimer “may
 4 occur, for example, when the patentee explicitly characterizes an aspect of his invention in
 5 a specific manner to overcome prior art.”); *MBO Lab’ys, Inc. v. Becton, Dickinson & Co.*,
 6 474 F.3d 1323, 1330 (Fed. Cir. 2007) (“Prosecution arguments like this one which draw
 7 distinctions between the patented invention and the prior art are useful for determining
 8 whether the patentee intended to surrender territory, since they indicate in the inventor’s
 9 own words what the invention is not.”).⁹

10 In sum, Spectrum’s contention that the claimed “opening” must be configured to
 11 receive a liquid biological sample directly from the mouth of the user is well supported by
 12 the intrinsic record, specifically the disclaimers contained in the prosecution history. As
 13 such, the Court will include the requirement that the claimed “opening” be for receiving a
 14 liquid biological sample directly from the mouth of a user in its construction for this claim
 15 term.

18
 19 ⁹ At the claim construction hearing, DNA Genotek contended that in the prosecution
 20 history at issue, the examiner did not accept its arguments regarding the scope of the
 21 relevant claim term. ECF No. 176 at 54. In response, Spectrum correctly explained that
 22 this is of no consequence because when a patentee makes a disclaimer in the prosecution
 23 history, that particular characterization of the claimed invention need not be accepted by
 24 the examiner in order for prosecution history disclaimer to apply. *Id.* at 55. The Federal
 25 Circuit holds “patentees to distinguishing statements made during prosecution even if they
 26 said more than needed to overcome a prior art rejection.” *Data Engine Techs. LLC v.*
 27 *Google LLC*, 10 F.4th 1375, 1383 (Fed. Cir. 2021); *see, e.g., Tech. Props. Ltd. LLC v.*
 28 *Huawei Techs. Co.*, 849 F.3d 1349, 1358 (Fed. Cir. 2017) (“The patentee’s disclaimer may
 not have been necessary, but its statements made to overcome Magar were clear and
 unmistakable.”); *CliniComp Int’l, Inc. v. Cerner Corp.*, No. 17CV02479GPCDEB, 2022
 WL 3006343, at *8 (S.D. Cal. July 28, 2022) (“Those statements regarding partitioning
 might not have been necessary to distinguish the claimed invention from the prior art.
 Nevertheless, they were clear and unmistakable and constitute prosecution disclaimers.”).

1 Turning to the second part of the Parties' dispute, the Court notes that there is
2 nothing in the claim language requiring that the opening be at least 2.0 cm in diameter. *See*
3 '187 Patent col. 19 ll. 34-44. Indeed, the claim language says nothing at all about the
4 diameter of the opening. *See id.* As such, the claim language does not support Spectrum's
5 contention that the claimed "opening" must be at least 2.0 cm in diameter.

6 Spectrum argues that the specification supports the notion that the "opening" must
7 be at least 2.0 cm. ECF No. 147 at 13. But to support this argument, Spectrum first relies
8 on a passage from the specification explaining that "[t]he collection device of the
9 invention" has "a broad mouth." *See* '187 Patent col. 14 ll. 61, col. 15 ll. 1. The Court
10 acknowledges that, here, the specification is discussing the claimed invention as a whole
11 and not merely a preferred embodiment. *See id.* But a statement that the claimed "opening"
12 has a broad mouth says nothing about the specific diameter of said opening. As such, this
13 is insufficient to support Spectrum's proposed construction.

14 Second, Spectrum relies on the following passage from the specification: "The first
15 region can have an opening of from 2.0 to 7.0 cm, desirably from 2.5 to 3.5 cm, and most
16 desirably 3.0 cm." '187 Patent col. 6 ll. 36-39. But "[a]bsent a clear disavowal or contrary
17 definition in the specification or the prosecution history, the patentee is entitled to the full
18 scope of its claim language." *Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1286 (Fed.
19 Cir. 2011); *see Thorner*, 669 F.3d at 1366. Here, there is no clear disavowal. To the
20 contrary, in the passage at issue, the specification uses permissive language in stating that
21 the first region "can" have an opening of those diameters. '187 Patent col. 6 ll. 37. The
22 specification does not require those diameters. In sum, the specification does not support
23 Spectrum's contention that the claimed "opening" must be at least 2.0 cm in diameter.

24 To support its contention, Spectrum also cites to the prosecution history, specifically
25 statements from U.S. Provisional Patent Application 60/386,398 ("the '398 Provisional").
26 ECF No. 147 at 13. Specifically, Spectrum cites to a passage from the '398 Provisional
27 stating that the sample collection tube "has a wide mouth, approx. 2.5 to 4 cm in diameter
28 to make it easier to spit saliva into it." ECF No. 83-7, Ex. 6 at 216 ll. 17-20. However, the

1 cited passage is in a section called “EXAMPLES” and immediately preceding this section,
 2 the ’398 Provisional states: “The following examples are illustrative but not intended to be
 3 limiting of the embodiment of the invention.” *Id.* at 261 ll. 1-4. As such, the cited language
 4 is insufficient to constitute a disclaimer of claim scope, and the prosecution history does
 5 not support Spectrum’s contention. *See Aylus*, 856 F.3d at 1361 (explaining that a
 6 disclaimer must “‘be both clear and unmistakable’”).

7 Finally, Spectrum cites to extrinsic evidence, specifically DNA Genotek internal
 8 documents. ECF No. 147 at 13-14 (citing ECF No. 147, Ex. 18). This extrinsic evidence is
 9 not persuasive. “If the meaning of a claim term is clear from the intrinsic evidence, there
 10 is no reason to resort to extrinsic evidence.” *Seabed Geosolutions*, 8 F.4th at 1287; *see also*
 11 *Summit 6*, 802 F.3d at 1290 (“Extrinsic evidence may not be used ‘to contradict claim
 12 meaning that is unambiguous in light of the intrinsic evidence.’”). Further, “it is improper
 13 to import a limitation into a claim where the limitation has no basis in the intrinsic record.”
 14 *Seachange Int’l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1376 (Fed. Cir. 2005). As explained
 15 above, a review of the intrinsic record does not support the inclusion of the limitation
 16 proposed by Spectrum that the opening be at least 2.0 cm in diameter. As such, Spectrum
 17 cannot rely on extrinsic evidence alone to support the inclusion of that limitation.¹⁰ *See*
 18
 19

20
 21 ¹⁰ Moreover, even if the Court were to consider the contents of the extrinsic evidence
 22 at issue, it still is not persuasive. Nothing in the documents identify the documents as
 23 specifically discussing the technology claimed in the ’187 Patent. *See* ECF No. 147, Ex.
 24 18. The documents appear to be at most discussing potential commercial embodiments.
 25 *See id.*

26 “Just as claims should not be limited to preferred embodiments described in the
 27 specification, claims should not be limited to commercial embodiments.” *Taction*, No.
 28 3:21-cv-812-TWR-JLB, ECF No. 141 at 16 n.7 (citing *Int’l Visual Corp. v. Crown Metal*
Mfg. Co., 991 F.2d 768, 77172 (Fed. Cir. 1993) (finding district court erred by relying on
 the patentee’s commercial embodiment to limit the scope of the claims during claim
 construction)). “[C]laim construction . . . focuses on the recited limitations of the claims,
 not on the features of a commercial embodiment of the invention.” *Myco Indus., Inc. v.*

Seabed Geosolutions, 8 F.4th at 1287; *Seachange Int'l*, 413 F.3d at 1376.

In sum, the Court adopts in part Spectrum's proposed construction. The Court construes the term "an opening for receiving a biological sample from the mouth of the user"¹¹ as "the opening is able to receive a liquid biological sample directly from the mouth of the user."

D. "reagent compartment"

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

Here, the Parties dispute whether the claimed "reagent compartment" in the '187 Patent must specifically be a region or section of the containment vessel. Spectrum asserts

BlephEx, LLC, 955 F.3d 1, 15 (Fed. Cir. 2020). As such, Spectrum's extrinsic evidence is irrelevant for claim construction purposes.

¹¹ In its claim construction brief, Spectrum specifically requests that the Court construe the claim term "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." See ECF No. 147 at 11. In adopting in part Spectrum's proposed construction, the Court agrees with Spectrum that the prosecution history contains a disclaimer requiring that the sample is received directly from the mouth of the user. But in order to implement that disclaimer, the Court need only construe the specific claim term "an opening for receiving a biological sample from the mouth of the user" rather than the broader claim term proposed by Spectrum. Spectrum has not provided the Court with a sufficient basis for deviating from the plain and ordinary meaning as to the remainder of the claim language Spectrum identifies. Cf. *Eon*, 815 F.3d at 1318 ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))); *U.S. Surgical*, 103 F.3d at 1568 (claim construction "is not an obligatory exercise in redundancy").

1 that the “reagent compartment” must be in the containment vessel because DNA Genotek
 2 has expressly disavowed any claim scope that would cover devices with a reagent
 3 compartment located in the cap. ECF No. 147 at 14. DNA Genotek argues that the term
 4 “reagent compartment” should be given its plain and ordinary meaning, and the claims and
 5 the specification of the ’187 Patent do not require that the reagent compartment be located
 6 within the containment vessel – as opposed to the cap or elsewhere. ECF No. 134 at 16-17.

7 The Court begins with the claim language. Independent claim 1 of the ’187 Patent
 8 in full recites:

9 1. A device for receiving and preserving nucleic acid in a biological sample,
 10 said device comprising:

11 a. one or more walls defining a containment vessel having a top having an
 12 opening, and a closed bottom having a sample receiving area for holding said
 13 biological sample, said opening for receiving a liquid sample and for sealably
 14 receiving a sealing cap, said top having an opening for receiving a biological
 15 sample from the mouth of a user and further comprising at least one marking
 16 on said one or more walls which corresponds to a fluid volume in the sample
 17 receiving area;

18 b. a **reagent compartment** having a barrier, said barrier sealing and
 19 containing reagents in said reagent compartment and capable of
 20 disestablishment to release said reagents into the sample receiving area;

21 c. reagents in the **reagent compartment** for preserving nucleic acids
 22 potentially present in the sample wherein said reagents comprise a denaturing
 23 agent, a chelator and a buffer agent; and,

24 d. the sealing cap, whereby the device is configured such that, when sealably
 25 closing said opening with said sealing cap, the barrier mechanically
 26 disestablishes to release said reagents to form a mixture of reagents and said
 27 biological sample wherein said buffering agent maintains a pH of said mixture
 28

1 equal to or above 5.0 to preserve nucleic acids potentially present in the
2 sample.

3 '187 Patent col. 19 ll. 34-59 (emphasis added). Here, the claim language claims a device
4 comprising: (1) a containment vessel; (2) a sealing cap; (3) a reagent compartment; and (4)
5 reagents. But the claim language is ambiguous as to where precisely the reagent
6 compartment is located within the claimed device – whether it is in the containment vessel
7 or in the sealing cap or whether it can be in either.

8 Turning to the specification, the specification of the '187 Patent provides clear
9 guidance as to the location of the reagent compartment. The specification states:

10 In a sixth aspect, the invention features a device for preserving and/or isolating
11 a nucleic acid obtained from a biological sample. The device includes: a
12 container that has a first region for collecting a biological sample and a second
13 region containing a composition for preserving a nucleic acid, a barrier
14 between the first region the second region that keeps the biological sample
15 and the composition separate, a means for closing the container, and a means
16 for disturbing the integrity of the barrier such that the composition is capable
17 of contacting the biological sample.

18 '187 Patent col. 6 ll. 26-36; *see also id.* col. 6 ll. 6-14, col. 6 ll. 46-56, col. 14 ll. 30-35, col.
19 14 ll. 51-58. Here, the specification expressly and clearly states that the region containing
20 the composition for preserving a nucleic acid (*i.e.*, the reagent compartment) is located
21 within the container (*i.e.*, the collection vessel). *See id.* This strongly supports Spectrum's
22 proposed construction.

23 In response, DNA Genotek argues that it is improper to limit claims to a preferred
24 embodiment. ECF No. 134 at 17. But in the portion of the specification quoted above, the
25 specification is not describing a preferred embodiment. Rather, the specification is
26 describing the invention as a whole. *See* '187 Patent col. 6 ll. 26 (“the invention features .
27 . . .”); *see also id.* at col. 6 ll. 6 (same), col. 6 ll. 46 (same), col. 14 ll. 28 (same), col. 14 ll.
28

49 (same).¹² “When a patentee ‘describes the features of the ‘present invention’ as a whole,’ he implicitly alerts the reader that ‘this description limits the scope of the invention.’” *Luminara*, 814 F.3d at 1353 (quoting *Regents of Univ. of Minnesota*, 717 F.3d at 936); accord *Pacing*, 778 F.3d at 1025; see, e.g., *Wastow*, 855 F. App’x at 750–51; *Honeywell*, 452 F.3d at 1318. “The public is entitled to take the patentee at his word and the word was that the invention is a” device with a reagent compartment in the container. *Honeywell*, 452 F.3d at 1318; see also *Techtronic Indus. Co. v. Int’l Trade Comm’n*, 944 F.3d 901, 907 (Fed. Cir. 2019) (“It is axiomatic that, where the specification ‘describes “the present invention” as having [a] feature,’ that representation may disavow contrary embodiments.”); *Poly-Am.*, 839 F.3d at 1136 (“[A]n inventor may disavow claims lacking a particular feature when the specification describes “the present invention” as having that feature.”).

At the claim construction hearing, DNA Genotek argued that the passage quoted above is insufficient to constitute a disclaimer because it merely describes a “sixth aspect of many” of the invention. ECF No. 176 at 30. But all of the claims in the ’187 Patent claim a “device.” See ’187 Patent col. 19 ll. 34 to col. 21 ll. 17. In the specification, the “sixth aspect” of the invention is the only aspect of the invention that features “a device.” See *id.* col. 3 ll. 66 to col. 6 ll. 65 (describing the seven “aspects” of the invention).¹³ Further, as

¹² Indeed, in the cited portions of the specification, the specification uses express language to distinguish when it is describing “an embodiment” of the invention as opposed to “the invention” itself. Compare ’187 Patent col. 6 ll. 26 (“the invention features”), col. 14 ll. 49 (“the invention features”); with *id.* col. 6 ll. 40 (“In one embodiment of the sixth aspect”); col. 14 ll. 58 (“[i]n one embodiment”).

¹³ The Court notes that in addition to the “sixth aspect” of the invention described in the specification, the only other aspects of the invention described in the specification that disclose “a container” are the “fifth aspect” and the “seventh aspect.” The fifth aspect describes “a method of preserving and/or recovering a nucleic acid” utilizing a container. ’187 Patent col. 6 ll. 6–7. The specification expressly states that the container utilized by the fifth aspect of the invention has a reagent compartment in the container. See *id.* col. 6

DNA Genotek itself explained at the hearing, the “Detailed Description” section of the specification is broken up into three sub-sections: “Compositions of the Invention,” “Methods of the Invention,” and “Collection Devices.” ’187 Patent col. 9 ll. 1, col. 12 ll. 1, col. 14 ll. 39.¹⁴ The “Collection Devices” sub-section contains an almost identical disclaimer to the one quoted above. *See id.* at col. 14 ll. 49-54 (“Desirably, the invention features a device The device 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, [and] a barrier between the first region the second region”). As such, this language in the specification constitutes a clear disclaimer explaining that when the claimed invention is a sample collection device (as opposed to a composition or a method),

ll. 10-11 (“placing a composition of the invention into a second region of the container, which is separated from the first region by a barrier”).

The seventh aspect of the invention is directed to “a method of manufacturing a device” that includes “a container.” *Id.* col. 6 ll. 46-48. The specification expressly states that the container utilized by the seventh aspect of the invention has a reagent compartment in the container. *See id.* col. 6 ll. 10-11 (“providing a container that has a first region and a second region, with the first region suitable for containing a composition of the invention”).

In sum, the fifth, sixth, and seventh aspects of the invention are the only aspects of the invention in the specification that disclose a container (*i.e.*, a containment vessel) and a region for containing a composition of the invention (*i.e.*, a reagent compartment). *See* ’187 Patent col. 6 ll. 6-14, col. 6 ll. 26-36, col. 6 ll. 46-56. And those three aspects of the invention all expressly state that the reagent compartment is in the container. *Id.* There is no explicit disclosure of a reagent compartment that is located anywhere else other than in the container. *See id.*; *see also id.* at figs. 10, 11, col. 8 ll. 46-54, col. 14 ll. 28-35, col. 14 ll. 51-58, col. 15 ll. 17-29, col. 15 ll. 33-49.

¹⁴ “Section 101 [of the Patent Act] specifies four independent categories of inventions or discoveries that are eligible for protection: processes [(*e.g.*, methods)], machines, manufactures [(*e.g.*, devices)], and compositions of matter.” *Bilski v. Kappos*, 561 U.S. 593, 601 (2010). A claimed invention must fit within at least “one of the four statutorily provided categories of patent-eligible subject matter.” *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018) (quoting *Ulramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 713–14 (Fed. Cir. 2014); *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 134850 (Fed. Cir. 2014)).

1 the reagent compartment is in the container of the device and not in alternative locations.
 2 *See, e.g., Techtronic*, 944 F.3d at 908 (“[B]y consistently representing the invention as the
 3 placement of the detector in the wall console, [the specification] has thus effected a
 4 disavowal of alternative locations.”).¹⁵

5 DNA Genotek argues that Spectrum’s proposed construction is improper because it
 6 would read out a disclosed embodiment from the scope of the claims. ECF No. 134 at 17-
 7 18. The ’187 Patent claims priority to and expressly incorporates by reference the ’398
 8 Provisional. ’187 Patent col. 1 ll. 16-19. The Federal Circuit has explained: “provisional
 9 applications incorporated by reference are ‘effectively part of the’ specification as though
 10 it was ‘explicitly contained therein.’” *Trs. of Columbia Univ. in City of New York v.*
 11 *Symantec Corp.*, 811 F.3d 1359, 1366 (Fed. Cir. 2016) (quoting *Advanced Display Sys.,*
 12 *Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000)); *see also MPHJ Tech. Invs.,*
 13 *LLC v. Ricoh Americas Corp.*, 847 F.3d 1363, 1369 (Fed. Cir. 2017) (“[A] provisional
 14 application can contribute to understanding the claims.”).¹⁶ The ’398 Provisional contains
 15

16
 17 ¹⁵ The Court acknowledges that the Federal Circuit has explained that use of the phrase
 18 “present invention” or “this invention” is not always limiting, “such as where the
 19 references . . . are not uniform, or where other portions of the intrinsic evidence do not
 20 support applying the limitation to the entire patent.” *Cont’l Cirs. LLC v. Intel Corp.*, 915
 21 F.3d 788, 798 (Fed. Cir. 2019) (quoting *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659
 22 F.3d 1121, 1136–37 (Fed. Cir. 2011)). But neither of those scenarios is present here. As
 23 explained above, every explicit disclosure of a sample collection device in the specification
 24 is one where the device has a reagent compartment in the container and nowhere else. *See,*
 25 *e.g., ’187 Patent col. 6 ll. 6-14, col. 6 ll. 26-36, col. 6 ll. 46-56, col. 14 ll. 49-54; see also*
 26 *supra* note 13.

27 ¹⁶ Spectrum argues that incorporation by reference of a provisional application is
 28 ineffective because a provisional application is not a U.S. patent or U.S. patent application
 publication, citing 37 C.F.R. § 1.57(d), *ZTE (USA), Inc. v. Cywee Group Ltd.*, No.
 IPR2019-00143, 2021 WL 641742, at *54 (P.T.A.B. Feb. 17, 2021), and *Nomadix, Inc. v.*
Second Rule LLC, No. CV0701946DDPVBKX, 2009 WL 10668158, at *24 (C.D. Cal.
 Jan. 16, 2009). ECF No. 88 at 6-7. 37 C.F.R. § 1.57(d) provides: “‘Essential material’ may
 be incorporated by reference, but only by way of an incorporation by reference to a U.S.
 patent or U.S. patent application publication.” *Accord Droplets, Inc. v. E*TRADE Bank,*

1 an embodiment where the reagent compartment is in the cap. *See* ECF No. 83-7, Ex. 6 at
 2 p. 260 ll. 12-13, p. 262 ll. 4-9, p. 266 fig. 2. DNA Genotek argues that Spectrum’s proposed
 3 construction would exclude this specific embodiment. ECF No. 134 at 17-18. “A claim
 4 construction that excludes a preferred embodiment is rarely, if ever correct and would

5
 6 887 F.3d 1309, 1318 (Fed. Cir. 2018). In *ZTE*, the PTAB explained: “Because a U.S.
 7 provisional application is not a ‘U.S. patent or U.S. patent application publication,’” the
 8 application at issue’s attempt to incorporate by reference a “provisional application was
 ineffective.” 2021 WL 641742, at *54.

9 Although the Court finds that Spectrum’s argument has merit, it is primarily based
 10 on a non-binding PTAB decision and a non-binding district court decision. The Court is
 11 bound by the Federal Circuit’s decision in *Trustees of Columbia University*. *See Panduit*
 12 *Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1573 (Fed. Cir. 1984) (explaining that
 13 district courts are “bound by the substantive patent law of” the Federal Circuit); *see, e.g.,*
 14 *In re Micron Tech., Inc.*, 875 F.3d 1091, 1098 (Fed. Cir. 2017) (“On the patent-specific
 15 issue of the proper interpretation of 28 U.S.C. § 1400(b), the district court was bound by
 this court’s precedent.”); *see also Yong v. I.N.S.*, 208 F.3d 1116, 1119 (9th Cir. 2000)
 (“once a federal circuit court issues a decision, the district courts within that circuit are
 bound to follow it”).

16 At the claim construction hearing, Spectrum noted that in *Trustees of Columbia*
 17 *University*, the Federal Circuit did not expressly address 37 C.F.R. § 1.57(d) in holding
 18 that provisional applications incorporated by reference are effectively part of the
 19 specification. ECF No. 176 at 43-44. This is true. *See Trs. of Columbia Univ.*, 811 F.3d at
 1365–66. And this is an additional reason why Spectrum’s argument has merit. In addition,
 20 the Court notes that in *Trustees of Columbia University*, to support its contention that a
 21 provisional application incorporated by reference effectively becomes part of the
 22 specification, the court cited to the Federal Circuit’s decision in *Advanced Display*. *See*
 23 *Trs. of Columbia Univ.*, 811 F.3d at 1366. In *Advanced Display*, the Federal Circuit
 24 describes the standards for evaluating whether and to what extent material has been
 incorporated by reference into a host document. *See* 212 F.3d at 1282–84. But the
Advanced Display decision never expressly references provisional applications or 37
 C.F.R. § 1.57(d). *See id.*

25 Nevertheless, the Court also notes that the Federal Circuit in at least one subsequent
 26 decision has acknowledged and cited favorably to *Trustees of Columbia University*’s use
 27 of a provisional application for claim construction purposes. *See MPHJ*, 847 F.3d at 1369.
 28 As such, the Court remains bound by the Federal Circuit’s holding in *Trustees of Columbia*
University. *See Panduit*, 744 F.2d at 1573; *Micron*, 875 F.3d at 1098.

1 require highly persuasive evidentiary support.” *Kaufman*, 34 F.4th at 1372. But, here, there
 2 is highly persuasive evidentiary support for Spectrum’s proposed construction and
 3 Spectrum’s contention that the reagent compartment must be in the containment vessel.

4 First, in *Finjan LLC v. ESET, LLC*, the Federal Circuit explained that “the disclosure
 5 of the host patent provides context to determine what impact, if any, a [document]
 6 incorporated by reference will have on construction of the host patent claims.” 51 F.4th
 7 1377, 1382 (Fed. Cir. 2022) (citing *X2Y Attenuators, LLC v. U.S. Int’l Trade Comm’n*, 757
 8 F.3d 1358, 1362–63 (Fed. Cir. 2014)); *see also Advanced Display*, 212 F.3d at 1283
 9 (“Whether and to what extent material has been incorporated by reference into a host
 10 document is a question of law.”). Here, as noted above, the specification as issued contains
 11 several disclaimers of claim scope expressly stating that the disclosed invention features a
 12 device with a reagent compartment that is located in the container. *See* ’187 Patent col. 6
 13 ll. 6-14, col. 6 ll. 26-36, col. 6 ll. 46-56, col. 14 ll. 49-54. In light of this language, the
 14 specification “disavow[s] contrary embodiments,” including those disclosed in the ’398
 15 Provisional. *Techtronic*, 944 F.3d at 907; *see, e.g., Finjan*, 51 F.4th at 1382–83 (declining
 16 to apply definition from patent incorporated through reference into the specifications at
 17 issue based on the context provided by the language in those specifications).

18 Second, as Spectrum correctly notes, when the patentee filed its non-provisional
 19 application, it deleted any explicit disclosure of the reagent compartment being in the
 20 cap/lid.¹⁷ The Federal Circuit in *MPHJ* held that the deletion of material from a provisional
 21

22
 23 ¹⁷ At the claim construction hearing, DNA Genotek challenged the Court’s
 24 characterization of the removal of material from the ’398 Provisional as being a “deletion”
 25 of that material. *See* ECF No. 176 at 17 (“So to say that something was deleted out of that
 26 just isn’t a correct description of how provisional applications work.”). The Court notes
 27 that the Federal Circuit in *MPHJ* referred to certain statements in a provision application
 28 that were omitted from the final application as being a “deletion.” 847 F.3d at 1369.

At the claim construction hearing, DNA Genotek also noted that some components
 of the embodiment at issue in the ’398 Provisional were retained in the ’187 Patent’s
 specification, such as the “septum” and the “piercing member.” *See* ECF No. 176 at 19-21;

1 application can contribute to the understanding of the intended scope of the final
 2 application. 847 F.3d at 1369; *see also Finjan*, 51 F.4th at 1383 (“The use of a restrictive
 3 term in an earlier application does not reinstate that term in a later patent that purposely
 4 deletes the term, even if the earlier patent is incorporated by reference.”).¹⁸ And, notably,
 5 the Federal Circuit in *MPHJ* held this despite the provisional application at issue in that
 6 case being expressly incorporated by reference into the specification. *See* 847 F.3d at 1371.
 7 As such, here, the patentee’s deletion of any explicit disclosure of the reagent compartment
 8 being in is the cap/lid along with the disclaimers in the issued version of the specification

11 *see, e.g.*, ’187 Patent col. 15 ll. 17-20, col. 20 ll. 7-12, col. 21 ll. 13-17. But this is of no
 12 consequence. The issue is not whether the specification as issued retained any components
 13 from the embodiment at issue in the ’398 Provisional. Rather, the issue is whether the
 14 specification retained any explicit disclosure of a reagent compartment that is in the cap/lid.
 15 DNA Genotek has not identified any passage in the specification of the ’187 Patent that
 explicitly discloses a reagent compartment that is located in the cap/lid. *See also supra* note

16 ¹⁸ DNA Genotek argues that the Federal Circuit’s decision in *MPHJ* is irrelevant here
 17 because that case involved the “broadest reasonable interpretation” standard for claim
 18 construction. ECF No. 89 at 8-9. The Court acknowledges that the “broadest reasonable
 19 interpretation” standard that was previously applied by the PTAB during IPR proceedings
 20 is different from the *Phillips* standard for claim construction applied by district courts. *See*
 21 *Seabed Geosolutions*, 8 F.4th at 1287 (recognizing the difference between the two
 22 standards). But DNA Genotek fails to adequately explain how that difference between the
 23 two standards affects the applicability of *MPHJ*’s general holding that deletion of material
 24 from a provisional application can contribute to the “understanding of the intended scope
 25 of the final application.” 847 F.3d at 1369. The Court notes that in reaching that holding,
 26 the panel in *MPHJ* cited to its prior decisions in *Trustees of Columbia University* and
 27 *Vederi*, which are both cases applying the *Phillips* standard of claim construction. *See*
 28 *MPHJ*, 847 F.3d at 1369 (citing *Trustees of Columbia Univ.*, 811 F.3d at 1365; *Vederi*,
LLC v. Google, Inc., 744 F.3d 1376, 1383 (Fed. Cir. 2014)); *see also Trustees of Columbia*
Univ., 811 F.3d at 1362–63 (setting forth the *Phillips* standard for claim construction);
Vederi, 744 F.3d at 1382 (same); *see also, e.g., CXT Sys., Inc. v. Acad., Ltd.*, No.
 218CV00171RWSRSP, 2019 WL 4253841, at *17 n.20 (E.D. Tex. Sept. 6, 2019)
 (rejecting defendants’ argument “that *MPHJ* is distinguishable in that it was applying the
 broadest-reasonable-interpretation standard”).

1 explaining that the reagent compartment is in the container evidence a clear intent to limit
2 the final scope of the invention to a device with the reagent compartment in the containment
3 vessel.¹⁹ *See id.* at 1369.

4 Third, Spectrum has cited to highly persuasive extrinsic evidence supporting the
5 notion that the invention disclosed in the '187 Patent is limited to a device where the
6 reagent compartment is specifically located in the container and not the cap/lid. During
7 IPR proceedings as to a different patent owned by DNA Genotek, U.S. Patent No.
8 8,221,381 ("the '381 Patent"), in an effort to sustain the validity of the '381 Patent, DNA
9 Genotek described the teachings and scope of the invention disclosed in the '187 Patent.
10 DNA Genotek stated (referring to the invention disclosed in the '187 Patent as
11 "Birnbom"):

12 Technically, O'Donovan and Birnbom are very different devices.
13 O'Donovan is a pushed friction fit engagement with spikes in a vial and a
14 reagent in a lid, where the vial includes a shoulder to support the spikes and
15 facilitate rupturing a pierceable membrane in the lid to release the reagent.
16
17

18 ¹⁹ Although the Court finds the Federal Circuit's holding in *MPHJ* to be applicable
19 here, the Court notes that it disagrees with Spectrum's interpretation of *MPHJ*. Spectrum
20 argues that under the Federal Circuit's decision in *MPHJ*, the deletion of material from a
21 provisional application by itself can constitute a disavowal of claim scope. *See* ECF No.
22 147 at 14-17; ECF No. 88 at 6. The Court disagrees. There is nothing in *MPHJ* stating that
23 the mere deletion of material from a provisional application can constitute a disavowal of
24 claim scope. *Cf. Poly-Am.*, 839 F.3d at 1136 ("[T]he standard for disavowal is exacting,
25 requiring clear and unequivocal evidence that the claimed invention includes or does not
26 include a particular feature.").

27 As such, the Court makes clear that it does not find that the deletion of the disclosures
28 at issue from the '398 Provisional alone constitutes a disavowal of claim scope. Rather, the
Court merely finds that the deletion of any disclosure of an embodiment where the reagent
compartment in is the cap/lid is consistent with and supports the disclaimers contained in
the '187 Patent's specification as issued explaining that the reagent compartment is in the
container.

1 Birnboim is a rotated screw cap with a ram in the cap and a reagent below a
 2 plastic cover in a container, where the ram forces a push rod to flip the plastic
 3 and thereby expose a sample to the reagent.

4 ECF No. 83-10, Ex. 9 at 326-27 (citations omitted); *see also* U.S. Patent No. 8,221,381
 5 col. 1, ll. 50-59 (describing the invention claimed in the '187 Patent and stating "[t]h[e]
 6 container has a first region for collecting a biological sample, a second region containing a
 7 composition for preserving a nucleic acid, and a barrier between the first region and the
 8 second region"). Here, DNA Genotek described the scope of its own invention, the
 9 invention disclosed in the '187 Patent, as being a device where the reagent is contained in
 10 the container, and DNA Genotek further stated that the disclosed device is "very different"
 11 from a device where the reagent is in a lid.²⁰ The Court notes that these statements by DNA
 12 Genotek are highly relevant to claim construction as "the statements were 'made in an
 13 official proceeding in which the patentee had every incentive to exercise care in
 14 characterizing the scope of its invention.'" *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286,
 15 1313 (Fed. Cir. 2014), *overruled on other grounds by Williamson v. Citrix Online, LLC*,
 16 792 F.3d 1339 (Fed. Cir. 2015) (quoting *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d
 17 1340, 1350 (Fed. Cir. 2004)).

18 At the claim construction hearing, DNA Genotek argued that its statements during
 19 the IPR proceedings at issue are irrelevant for claim construction purposes because the
 20 patent at issue in the IPR proceedings, the '381 Patent, is unrelated to the '187 Patent. ECF
 21 No. 176 at 25-26 (citing *Apple*, 757 F.3d at 1312). The Court acknowledges that
 22 "statements made in unrelated applications are not relevant to claim construction." *Apple*,
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 25 ²⁰ DNA Genotek argues that the above statement was made in reference to an
 26 embodiment of the '187 Patent. ECF No. 89 at 9. The Court rejects this argument. Although
 27 at times in the response brief, DNA Genotek expressly refers to embodiments of the '187
 28 Patent, *see, e.g.*, ECF No. 83-10, Ex. 9 at 319-20, in the passage cited above, DNA Genotek
 does not use any language explaining that it is merely referring to a preferred embodiment
 of the invention rather than the invention disclosed in the '187 Patent as a whole.

1 757 F.3d at 1312. But the statements at issue are not mere statements made in an unrelated
2 application. Rather, they are statements by the patentee about the scope of its own invention
3 in an official proceeding, represented by counsel, in an effort to preserve the validity of
4 another one of its patents. There are many good reasons why these statements are and
5 should be relevant for claim construction purposes. The Federal Circuit has explained that
6 the public and the Court are “entitled to take the patentee at his word” regarding the scope
7 of its invention. *Microsoft*, 357 F.3d at 1350; *Honeywell*, 452 F.3d at 1318. In addition, the
8 Federal Circuit has explained that competitors should be “entitled to rely on [a patentee’s]
9 representations when determining a course of lawful conduct, such as launching a new
10 product or de-signing-around a patented invention.” *Aylus*, 856 F.3d at 1359. And the
11 Federal Circuit has explained that “one cannot interpret a patent one way for the validity
12 analysis and a different way for the infringement analysis.” *A. G. Design & Assocs. LLC v.*
13 *Trainman Lantern Co.*, 271 F. App’x 995, 999 (Fed. Cir. 2008); *see Data Engine*, 10 F.4th
14 at 1381 (“We have repeatedly rejected efforts to twist claims, like a nose of wax, in one
15 way to avoid [invalidity] and another to find infringement.” (internal quotation marks
16 omitted)); *Aylus*, 856 F.3d at 1360 (explaining that claims should not be “‘construed one
17 way in order to obtain their allowance and in a different way against accused infringers’”).

18 At the claim construction hearing, DNA Genotek also argued that the Court should
19 not give weight to its statements in the IPR proceedings because claim construction of the
20 ’187 Patent was not at issue during the IPR proceedings regarding the ’381 Patent. ECF
21 No. 176 at 26-27. The Court acknowledges that the proper interpretation of the claims of
22 the ’187 Patent was not at issue during the IPR proceedings.²¹ But the scope of the
23 invention disclosed in the ’187 Patent was at issue in the IPR proceedings, and, therefore,
24 DNA Genotek’s statements are probative for claim construction purposes.

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28 ²¹ Indeed, the ’187 Patent had not even issued at the time of the IPR proceedings.

1 During the IPR proceedings, Birnboim (the invention disclosed in the '187 Patent)
2 was being used as a prior art reference in an attempt to render the '381 Patent invalid as
3 obvious under 35 U.S.C. § 103. ECF No. 83-10, Ex. 9 at 288, 314. An obviousness
4 determination requires, among other things, an analysis of “the scope and content of the
5 prior art,” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1047 (Fed. Cir. 2016) (en
6 banc), and, specifically, “requires finding that a person of ordinary skill in the art would
7 have been motivated to combine or modify the teachings in the prior art” *Adapt*
8 *Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1365 (Fed. Cir. 2022).
9 In arguing that Spectrum failed to demonstrate motivation to combine or modify, DNA
10 Genotek made certain statements regarding the differences between the teachings in
11 Birnboim and the teachings in the other prior art reference at issue, O'Donovan. *See* ECF
12 No. 83-10, Ex. 9 at 326-27; *cf. Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir.
13 2020) (“Fundamental differences between the references are central to this motivation to
14 combine inquiry.”). Thus, the scope of the teachings in Birnboim (*i.e.*, the scope of its
15 disclosure) was directly at issue during the relevant IPR proceedings and in the statements
16 made by DNA Genotek. *Cf. Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069
17 (Fed. Cir. 2018) (explaining that in an obviousness analysis a prior art reference “must
18 [be] considered for all it taught” through its “disclosures”) (quoting *Ashland Oil, Inc. v.*
19 *Delta Resins & Refractories, Inc.*, 776 F.2d 281, 296 (Fed. Cir. 1985)). Further, the claims
20 of the '187 Patent may not be broader in scope than that disclosure. *See Gentry Gallery,*
21 *Inc. v. Berkline Corp.*, 134 F.3d 1473, 1480 (Fed. Cir. 1998) (“[C]laims may be no broader
22 than the supporting disclosure, and therefore that a narrow disclosure will limit claim
23 breadth.”); *Indacon, Inc. v. Facebook, Inc.*, 824 F.3d 1352, 1357 (Fed. Cir. 2016) (“[Claim
24 terms] ordinarily cannot be construed broader than the disclosure in the specification.”).
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1 As such, DNA Genotek’s statements even if extrinsic evidence are highly relevant for
2 claim construction purposes here.²²

3 In sum, the specification of the ’187 Patent contains several clear disclaimers
4 explaining that the invention claimed in the ’187 Patent features a device with the reagent
5 compartment in the container (*i.e.*, the containment vessel). Those disclaimers in the
6 specification are supported by the deletion of any explicit disclosure of the reagent
7 compartment being in the cap/lip from the ’398 Provisional and by DNA Genotek’s
8 statements during IPR proceedings describing the scope of the claimed invention. As a
9 result, the Court adopts Spectrum’s proposed construction for this claim term. The Court
10 construes the term “reagent compartment” as “region or section of the containment vessel.”

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26 ²² In briefing, Spectrum expressly states that it does not contend that Genotek’s
27 statements during the IPR proceedings as to the ’381 Patent constitute estoppel. ECF No.
28 147 at 19. The Court agrees with Spectrum that the statements at issue are insufficient to
constitute estoppel. Nevertheless, they are relevant to claim construction, and they support
Spectrum’s proposed construction for the claim term “reagent compartment.”

E. “when sealably closing said opening with said sealing cap, the barrier mechanically disestablishes”

DNA Genotek’s Proposed Construction	Spectrum’s Proposed Construction	Court’s Construction
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”	Plain and ordinary meaning.

Here, the Parties dispute whether the claim term “when sealably closing said opening with said sealing cap, the barrier mechanically disestablishes” is a means-plus-function claim element that is governed by pre-AIA § 112 ¶ 6. Spectrum argues that the claim term at issue is a means-plus-function claim element because the claim language fails to recite sufficient structure for performing the claimed function of disestablishment of the barrier. ECF No. 147 at 22-26. In response, DNA Genotek argues that Spectrum’s arguments are insufficient to rebut the presumption that the claim term at issue is not a means-plus-function claim term. ECF No. 89 at 10-11.

“Means-plus-function claiming occurs when a claim term is drafted in a manner that invokes § 112, para. 6.” *Diebold Nixdorf, Inc. v. Int’l Trade Comm’n*, 899 F.3d 1291, 1297 (Fed. Cir. 2018); *see also Dyfan, LLC v. Target Corp.*, 28 F.4th 1360, 1365 (Fed. Cir. 2022) (“Limitations that invoke § 112 ¶ 6 are generally known as ‘means-plus-function’ or ‘step-plus-function’ limitations.”). Section 112 ¶ 6 of the Patent Act provides:

1 An element in a claim for a combination may be expressed as a means or step
 2 for performing a specified function without the recital of structure, material,
 3 or acts in support thereof, and such claim shall be construed to cover the
 4 corresponding structure, material, or acts described in the specification and
 5 equivalents thereof.

6 35 U.S.C. § 112 ¶ 6 (pre-AIA); *accord* 35 U.S.C. § 112(f) (current).²³ In enacting this
 7 provision, Congress “‘struck a balance in allowing patentees to express a claim limitation
 8 by reciting a function to be performed rather than by reciting structure for performing that
 9 function,’ while ‘placing specific constraints on how such a limitation is to be construed’—
 10 that is, by restricting the ‘scope of coverage to only the structure, materials, or acts
 11 described in the specification as corresponding to the claimed function and equivalents
 12 thereof.’” *Diebold Nixdorf*, 899 F.3d at 1297 (quoting *Williamson v. Citrix Online, LLC*,
 13 792 F.3d 1339, 1347 (Fed. Cir. 2015) (en banc)).

14 “The overall means-plus-function analysis is a two-step process.” *Dyfan*, 28 F.4th at
 15 1365. “The first step is to determine whether a claim limitation is drafted in means-plus-
 16 function format, which requires [the court] to construe the limitation to determine whether
 17 it connotes sufficiently definite structure to a person of ordinary skill in the art.” *Id.* “If the
 18 limitation connotes sufficiently definite structure, it is not drafted in means-plus-function
 19 format, and § 112 ¶ 6 does not apply.” *Id.* If, however, the court concludes that the
 20 limitation is in means-plus-function format, the court performs the second step of
 21 “determining ‘what structure, if any, disclosed in the specification corresponds to the
 22 claimed function.’” *Id.* (quoting *Williamson*, 792 F.3d at 1351).

23 “If the limitation uses the word ‘means,’ there is a rebuttable presumption that § 112
 24 ¶ 6 applies.” *Rain Computing, Inc. v. Samsung Elecs. Am., Inc.*, 989 F.3d 1002, 1005 (Fed.
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 27 ²³ The Court notes that the above language in paragraph 6 of the pre-AIA version of §
 28 112 is identical to the language in current § 112(f). *See* 35 U.S.C. § 112(f).

1 Cir. 2021). “If not, there is a rebuttable presumption that the provision does not apply.” *Id.*
2 But “the presumption can be overcome and § 112, para. 6 will apply if the challenger
3 demonstrates that the claim term fails to ‘recite sufficiently definite structure’ or else recites
4 ‘function without reciting sufficient structure for performing that function.’” *Williamson*,
5 792 F.3d at 1349. “Whether claim language invokes 35 U.S.C. § 112 ¶ 6 is a question of
6 law.” *Rain*, 989 F.3d at 1005.

7 The Court begins with the claim language. The limitation at issue, the claim term
8 “when sealably closing said opening with said sealing cap, the barrier mechanically
9 disestablishes,” does not use the word “means.” *See* ’187 Patent col. 19 ll. 54-55. As such,
10 there is a rebuttable presumption that § 112 ¶ 6 does not apply. *See Rain*, 989 F.3d at 1005.
11 In order to rebut that presumption, Spectrum must demonstrate that claim term fails to
12 recite sufficiently definite structure or else recites function without reciting sufficient
13 structure for performing that function. *See Williamson*, 792 F.3d at 1349; *Rain*, 989 F.3d
14 at 1005.

15 In an effort to rebut the presumption, Spectrum argues that the claim language
16 “recites the function of mechanically disestablishing the barrier to release the reagents, but
17 the claim does not identify any structure for performing that function.” ECF No. 147 at 22.
18 But Spectrum fails to properly view the claim term at issue within the context of the
19 surrounding claim language. The claim term at issue is contained within section “d.” of
20 independent claim 1 which recites: “the sealing cap, whereby the device is configured such
21 that, when sealably closing said opening with said sealing cap, the barrier [of the reagent
22 compartment] mechanically disestablishes to release said reagents to form a mixture of
23 reagents and said biological sample” ’187 Patent col. 19 ll. 53-57. Here, the claim
24 language identifies “the sealing cap” as the structure that performs the function of
25 mechanically disestablishing the barrier. As such, the claim language provides sufficient
26 structure for the claimed function of mechanically disestablishing the barrier.

27 Spectrum argues that the claim language only identifies the “sealing cap” as the
28 structure that performs the function of sealably closing the container’s opening, but there

1 is no structure identified for mechanically disestablishing the barrier. ECF No. 147 at 24.
 2 Spectrum’s contention is based on a misunderstanding of the claim language. The claim
 3 language identifies “the sealing cap” as the structural component of the device that
 4 performs both the function of sealably closing the container’s opening and the function of
 5 mechanically disestablishing the barrier. *See* ’187 Patent col. 19 ll. 53-57.

6 That the sealing cap performs both of these functions is further supported by a review
 7 of the specification. The specification explains: “In one embodiment, the disestablishment
 8 of the barrier is coupled to the closing of the container when a lid is placed on it. In one
 9 example, the barrier is punctured. In a desirable example, the barrier is in the form of a
 10 pivoting sealing disc. In this example, attachment of the lid to the container forces the disc
 11 to pivot” ’187 Patent col. 6 ll. 15-20. Here, the specification describes an embodiment
 12 of the invention where the lid (*i.e.*, the cap) of the device performs both the closing of the
 13 container and the disestablishment of the barrier.²⁴ Additionally, the specification states:
 14 “the means for closing the container may be coupled to the disestablishment of the barrier.”
 15 *Id.* at col. 15 ll. 29-30; *see also id.* col. 15 ll. 11 (“the means for closing the container may
 16 be a cap”). Here, the specification explains that the means for closing the container (*e.g.*, a
 17 cap) can also perform the disestablishment of the barrier. Thus, the specification supports
 18 the notion that by reciting a “sealing cap” the claim language provides sufficient structure
 19 for the claimed function of mechanically disestablishing the barrier.²⁵
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 23 ²⁴ The Court notes that this particular embodiment does not reference “a cap with a
 24 ram and a plunger.” *See generally* ’187 Patent col. 6 ll. 6-24. As such, this contradicts
 25 Spectrum’s contention that the only disclosure in the specification of structure that
 26 mechanically disestablishes the barrier “is ‘a cap having a ram, and a plunger.’” ECF No.
 27 147 at 26.

28 ²⁵ Spectrum argues that the disclosure of a sealing cap is insufficient because:
 “although most collection devices have a sealing cap, these structures do not normally
 include any apparatus to mechanically disestablish a barrier.” ECF No. 147 at 25. Spectrum
 does not support this assertion with a citation to any evidence, intrinsic or extrinsic.

1 A review of the prosecution history also supports the conclusion that the claim term
 2 at issue is not a means-plus-function claim element. As originally drafted claim 1 (formerly
 3 claim 30) recited “**closing means** and **disruptions means**, said **disruption means** for
 4 engaging said barrier whereby when sealably closing said opening with said closing means,
 5 said **disrupting means** mechanically disestablishes said barrier to release said reagents.”
 6 ECF No. 83-4, Ex. 3 at 95 (emphasis added) (deleted material omitted). The Examiner
 7 recognized the claim as invoking means-plus-function claiming and rejected the claim as
 8 indefinite for failing to “clearly link or associate the disclosed structure, material, or acts
 9 to the claimed function such that one of ordinary skill in the art would recognize what
 10 structure, material, or acts perform the claimed function of the ‘disruption means.’” *Id.* at
 11 89. In response, the patentee amended the claim as follows, removing the terms “closing
 12 means” and “disruption means” from the claim language:

13 d. the sealing cap, ~~closing means and disruptions means~~, said ~~disruption~~
 14 ~~means for engaging said barrier~~ whereby the device is configured such that,
 15 when sealably closing said opening with said sealing cap ~~closing means~~, the
 16 barrier ~~said disrupting means~~ mechanically disestablishes ~~said barrier~~ to
 17 release said reagents

18 *Id.* at 71 (new language underlined in original). In addition, patentee stated: “Applicant
 19 amends the claims per the Examiner’s suggestion, so that the claim no longer includes
 20 means plus function limitations.” *Id.* at 84 (underlining in original). The PTO accepted the
 21 claim as amended. *See* ECF No. 134-20, Ex. 15 at 334, 338-41. Here, the patentee’s
 22 amendment of the claims to remove the means-plus-function limitations evidences an
 23 intent for the claim term at issue to avoid the application of § 112, ¶ 6. *See, e.g., TEK Glob.,*
 24 *S.R.L. v. Sealant Sys. Int’l, Inc.*, 920 F.3d 777, 786 (Fed. Cir. 2019) (determining that the
 25 prosecution history establishes that the applicant intended for the claim term at issue to
 26 avoid the application of § 112, ¶ 6).

27 Spectrum argues that the prosecution history actually supports its contention that the
 28 claim term is a means-plus-function claim because when the patentee amended the claim,

1 it only added the “sealing cap” as the structure for performing the function of the “closing
 2 means,” but the patentee did not add any structure for performing the function of the
 3 “disruption means.” ECF No. 147 at 24-25; ECF No. 88 at 9. This argument is based on
 4 Spectrum’s faulty premise that the claimed “sealing cap” can only perform one of the
 5 claimed functions at issue. The specification makes clear that the sealing cap can perform
 6 both the closing of the container and the disestablishment of the barrier.²⁶

7 In sum, a review of the intrinsic record demonstrates that the claimed “sealing cap”
 8 provides sufficient structure for the claimed function of mechanically disestablishing the
 9 barrier. As such, Spectrum has failed to rebut the presumption that the claim term “when
 10 sealably closing said opening with said sealing cap, the barrier mechanically
 11 disestablishes” is not a means-plus-function claim element, and, thus, the Court holds that
 12 the claim term is not a means-plus-function claim element.

13 Spectrum does not provide an alternative proposed construction for this claim term
 14 absent means-plus-function claiming. *See* ECF No. 147 at 20. And DNA Genotek argues
 15 that the Court need not construe the claim term and instead the term should be given its
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 18 ²⁶ At the claim construction hearing, Spectrum also tried to advance a narrative where
 19 DNA Genotek responded to the examiner’s rejection purportedly by amending the claim
 20 language to remove the “closing means” as a means-plus function limitation, retaining the
 21 “disruption means” limitation as means-plus function limitation, and citing corresponding
 22 structure to the examiner to provide support for the “disruption means” as means-plus
 23 function limitation. *See* ECF No. 176 at 55-60. But Spectrum’s narrative is simply not
 24 supported by the record. In the response at issue, DNA Genotek expressly states to the
 25 examiner: “Applicant amends the claims . . . , so that the claim no longer includes means
 26 plus function limitations.” ECF No. 83-4, Ex. 3 at 84 (underlining in original). Here, DNA
 27 Genotek expressly refers to “means plus function limitations” (plural), making it clear that
 28 it was removing both the “closing means” and the “disruption means” and any other means-
 plus-function claim limitations from the claim language. Further, the Court notes that in
 the response at issue, one of the citations made by DNA Genotek to identify corresponding
 structure is to the embodiment in the specification where the lid/cap of the container
 performs the disestablishment of the barrier. *See id.* (citing paragraph “[0029]”); U.S.
 Patent App. No. 2017/0152545, at [0029] (filed Jun. 1, 2017), *available at*
<https://patents.google.com/patent/US20170152545A1/en?q=US+2017%2f0152545>.

plain and ordinary meaning. *See* ECF No. 134 at 18. In light of this, the Court gives the claim term “when sealably closing said opening with said sealing cap, the barrier mechanically disestablishes” its plain and ordinary meaning, and the Court declines to construe the claim term. *See Eon*, 815 F.3d at 1318 (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”).

F. “linear actuator”

DNA Genotek’s Proposed Construction	Spectrum’s Proposed Construction	Court’s Construction
“a device that converts linear motion into rotational motion and/or vice-versa”	Indefinite. In the alternative, “a cap having a ram, and a plunger”	“a device that converts rotational motion into linear motion”

DNA Genotek proposes that the claim term “linear actuator” be construed as “a device that converts linear motion into rotational motion and/or vice-versa.” ECF No. 134 at 12. Spectrum argues that DNA Genotek’s proposed construction would render dependent claims 21 and 26 of the ’187 patent invalid for failure to comply with 35 U.S.C. § 112 ¶ 4 (pre-AIA). ECF No. 147 at 26-27; ECF No. 88 at 10.²⁷ In the alternative,

²⁷ DNA Genotek argues that Spectrum waived this invalidity argument by failing to disclose it in Spectrum’s February 4, 2022 amended invalidity contentions. ECF No. 134 at 12 n.2; ECF No. 89 at 11-12. Patent Local Rule 3.3(d) requires a party’s “Invalidity Contentions” to set forth “[a]ny grounds of invalidity based on indefiniteness under 35 U.S.C. § 112(2) of any of the asserted claims.” S.D. Cal. Pat. L.R. 3.3(d). But, here, Spectrum’s invalidity argument is based on § 112 ¶ 4, not § 112 ¶ 2. *See* ECF No. 147 at 27. As such, Spectrum did not violate the Court’s Patent Local Rules by failing to set forth this particular invalidity argument in its amended invalidity contentions. Moreover, the Court notes that Spectrum set forth its contention that the claim term “linear actuator” is indefinite, rendering dependent claims 21 and 26 invalid, in the Parties’ January 7, 2022 Joint Claim Construction Chart and Worksheet, well in advance of the deadlines in this case for claim construction discovery and claim construction briefing. *See* ECF No. 74-1

1 Spectrum proposes that the claim term “linear actuator” be construed as “a cap having a
2 ram, and a plunger.” ECF No. 147 at 26-28.²⁸

3 Dependent claims 21 and 26 both recite a “linear actuator.” Dependent claim 21
4 recites: “The device of claim 20, wherein the barrier is configured to disestablish when
5 displaced by a **linear actuator**.” ’187 Patent col. 20 ll. 38-39 (emphasis added). Dependent
6 claim 26 recites: “The device of claim 24, wherein a **linear actuator** exerts the force on
7 the barrier.” *Id.* col. 20 ll. 51-52 (emphasis added).

8 DNA Genotek’s proposed construction for the term “linear actuator” is consistent
9 with descriptions in the claims and the specification of the components that perform the
10 disestablishing of the barrier. For example, dependent claim 24 recites: a device “wherein
11 engaging the thread on the sealing cap and the opening comprises exerting a force on the
12 barrier, wherein the force is perpendicular to a direction of rotation of the sealing cap.”
13 ’187 Patent col. 20 ll. 45-48. Additionally, when describing figures 10 and 11, the
14 specification explains:

15 As the cap is twisted on (shown [*sic*] by dotted line and arrow 10, ram 2, which
16 is attached to cap 1, moves downward as shown by dotted line arrow 11. This
17 downward movement forces plunger 4, which is contained in plunger barrel
18 5, downward as indicated by dotted line and arrow 12. The downward
19

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21 at 38-39; ECF No. 74-2 at 22-23. As such, the Court rejects DNA Genotek’s waiver
22 argument.

23 ²⁸ In its responsive claim construction brief, Spectrum argues for the first time that the
24 term “linear actuator” should be construed as a § 112 ¶ 6 means-plus-function claim
25 element. ECF No. 88 at 10. The Court declines to address this new argument as it was not
26 presented in either the Parties’ Joint Claim Construction Chart or Spectrum’s Opening
27 Claim Construction Brief. *See* ECF No. 74-1 at 38-39; ECF No. 147 at 26-28; *see also*
28 *Bazuaye v. I.N.S.*, 79 F.3d 118, 120 (9th Cir. 1996) (“Issues raised for the first time in the
reply brief are waived.”); *Norman v. United States*, 429 F.3d 1081, 1091 (Fed. Cir. 2005)
 (“Arguments raised for the first time in a reply brief are not properly before this court.”
(citing *Novosteel SA v. U.S.*, *Bethlehem Steel Corp.*, 284 F.3d 1261, 1274 (Fed. Cir.
2002))).

1 movement of plunger 4 forces sealing disc 7 to pivot, as shown by dotted line
 2 and arrow 13. Pivoting of disc 7 disestablishes the barrier between regions 8
 3 and 9, thereby permitting contact between the sample and a composition of
 4 the invention, shown as a dotted solution contained in region 9.

5 *Id.* at col. 15 ll. 39-49; *see also id.* figs. 10-11. In both of these examples, the component
 6 of the device that performs the disestablishing of the barrier is described as a component
 7 that converts rotational motion (*i.e.*, the twisting of the cap) into linear motion (*i.e.*,
 8 downward force perpendicular to the barrier). As such, DNA Genotek’s proposed
 9 construction is well supported by the intrinsic record.

10 In addition, DNA Genotek cites to persuasive extrinsic evidence. Specifically, a
 11 technical dictionary defining the term “linear actuator” as “a device that converts some
 12 kind of power into linear motion.” ECF No. Ex. 10, MCGRAW-HILL DICTIONARY OF
 13 ENGINEERING (5th ed. 1997). This definition of the term “linear actuator” is consistent with
 14 the descriptions in the intrinsic record of the components that perform the disestablishing
 15 of the barrier. As such, the Court adopts a slightly modified version of DNA Genotek’s
 16 proposed construction. The Court construes the claim term “linear actuator” as “a device
 17 that converts rotational motion into linear motion.”²⁹

18 Turning to Spectrum’s indefiniteness challenge, Spectrum’s contention that
 19 dependent claims 21 and 26 are invalid for failure to comply with 35 U.S.C. § 112 ¶ 4 and
 20 Spectrum’s alternative proposed construction both rest on the Court accepting Spectrum’s
 21 argument that independent claim 1 contains a means-plus-function claim element. *See* ECF
 22 No. 147 at 27-28. The Court has held that the claim term “when sealably closing said
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 25 ²⁹ The Court modifies DNA Genotek’s proposed construction to better match the ’187
 26 Patent’s descriptions of the components that perform the disestablishing of the barrier. The
 27 claims and the specification consistently describe the linear actuator embodiments as
 28 something that takes rotational motion and turns it into linear motion rather than the other
 way around. *See* ’187 Patent figs. 10-11, col. 15 ll. 39-49, col. 20 ll. 45-48.

opening with said sealing cap, the barrier mechanically disestablishes” is not a means-plus-function claim element. *See supra*. As such, the Court rejects Spectrum’s contention that dependent claims 21 and 26 are invalid for failure to comply with 35 U.S.C. § 112 ¶ 4, and rejects Spectrum’s alternative proposed construction for the claim term “linear actuator.”

G. “associates with”

DNA Genotek’s Proposed Construction	Spectrum’s Proposed Construction	Court’s Construction
The term does not require construction and should be accorded plain and ordinary meaning.	“contacts”	Plain and ordinary meaning.

Here, the Parties’ dispute whether the term “associates with” requires that the relevant components be in “contact” with each other. Spectrum argues that the term “associates with” requires contact between the relevant components. ECF No. 147 at 28. DNA Genotek argues that nothing in the intrinsic record of the ’187 Patent requires “associates with” to be redefined as “contacts.” ECF No. 134 at 21.

The Court begins its analysis of the Parties’ dispute by reviewing the claim language. The term “associates with” is found in dependent claim 34 of the ’187 Patent. Dependent claim 34 recites: “The device of claim 1, wherein the sealing cap associates with the containment vessel to create a fluid-tight seal.” ’187 Patent col. 21 ll. 7-9. The Court acknowledges that the language in claim 34 requires that the sealing cap and the containment vessel “associate[]” in a manner that creates “a fluid-tight seal.” *Id.* But as DNA Genotek correctly notes, this does not necessarily require physical contact between the sealing cap and the containment vessel as there could be an intermediate component between those two specific components that still allows for the creation of a fluid-tight seal. *See* ECF No. 134 at 21-22. Further, the common meaning of the word “associate” in

1 this context is “to join (things) together or connect (one thing) with another: COMBINE,”
2 which does not necessarily require physical contact. WEBSTER’S THIRD NEW
3 INTERNATIONAL DICTIONARY at 132 (1981); *see* MERRIAM-WEBSTER DICTIONARY,
4 <https://www.merriam-webster.com/dictionary/associate> (defining “associate” as “to join or
5 connect together: COMBINE”); *see also Phillips*, 415 F.3d at 1314 (explaining that the use
6 of general purposes dictionaries “may be helpful” in cases that involve “little more than
7 the application of the widely accepted meaning of commonly understood words”). For
8 example, two components could be connected or joined together by a third intermediate
9 component without the two components coming into physical contact with each other. As
10 such, the claim language is insufficient by itself to support adoption of Spectrum’s
11 proposed construction.

12 Turning to the specification, Spectrum argues that the specification supports its
13 proposed construction because the only examples in the specification displaying an
14 association between the cap and the containment vessel require contact between the two
15 components. ECF No. 147 at 28 (citing ’187 Patent figs 10-11). But “it is improper to read
16 limitations from a preferred embodiment described in the specification—even if it is the
17 only embodiment—into the claims absent a clear indication in the intrinsic record that the
18 patentee intended the claims to be so limited.” *Dealertrack*, 674 F.3d at 1327; *accord*
19 *Openwave*, 808 F.3d at 514. Here, there is no clear indication that Claim 34 should be
20 limited to the depiction in the two cited figures.

21 Finally, Spectrum argues that the Court should adopt its proposed construction
22 because the term “associates with” in the ’187 Patent should be construed consistently with
23 the term “associates with” in the ’646 Patent. ECF No. 147 at 28. In response, DNA
24 Genotek argues that Spectrum’s contention should be rejected because the specification of
25 an unrelated patent is not intrinsic evidence. ECF No. 89 at 13. The Court agrees with DNA
26 Genotek. Statements made in an unrelated patent are not relevant to claim construction.
27 *See Apple*, 757 F.3d at 1312 (“[S]tatements made in unrelated applications are not relevant
28 to claim construction.”); *see, e.g., Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167–68

(Fed. Cir. 2004) (finding statements in another patent irrelevant to claim construction “[a]bsent a formal relationship or incorporation during prosecution” of the patent at issue). As such, the Court rejects Spectrum’s contention that the Court should rely on its arguments regarding the ’646 Patent to interpret a claim term in the ’187 Patent.

In sum, the Court rejects Spectrum’s proposed construction for this claim term. The Court gives the claim term “associates with” its plain and ordinary meaning, and the Court declines to construe the claim term.³⁰

³⁰ Spectrum argues that because the parties dispute the scope of this claim term, the Court must construe the claim term. ECF No. 88 at 1, 5, 14 (citing *O2 Micro*, 521 F.3d at 1361–62; *Eon*, 815 F.3d at 1318; *InfoGation Corp. v. Google LLC*, No. 21-CV-00843-H-LL, 2021 WL 5547072, at *5 (S.D. Cal. June 8, 2021)). Spectrum is incorrect and misunderstands the Federal Circuit’s holdings in *O2 Micro* and *Eon*. “When the parties present a fundamental dispute regarding the scope of a claim term, it is the court’s duty to resolve it.” *O2 Micro*, 521 F.3d at 1362; *accord InfoGation*, 2021 WL 5547072, at *5 (“If the parties dispute the scope of a certain claim term, it is the court’s duty to resolve the dispute.”). The Federal Circuit has explained that, in some instances, a determination that a claim term needs no construction or has plain and ordinary meaning may be inadequate, such as when the term’s ordinary meaning does not resolve the parties’ dispute. *See Eon*, 815 F.3d at 1318 (citing *O2 Micro*, 521 F.3d at 1361). But that is not the case here.

Here, the parties’ dispute with respect to this claim term is that Spectrum contends that the claim term “associates with” specifically requires that the components at issue be in contact with each other, and DNA Genotek disagrees and argues that the Court should reject this proposed requirement. By giving the claim term its plain and ordinary meaning, the Court has rejected Spectrum’s proposed requirement and thereby resolved the parties’ dispute with respect to the scope of this claim term in compliance with the Court’s duties under *Eon* and *O2 Micro*. *See, e.g., ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1326 (Fed. Cir. 2012) (finding district court did not violate the principles of *O2 Micro* by giving the claim terms their plain and ordinary meaning and rejecting a proposed construction that erroneously read limitations into the claims); *Summit 6*, 802 F.3d at 1291 (finding district court did not violate the principles of *O2 Micro* by giving claim term its plain and ordinary meaning); *Taction*, No. 3:21-cv-812-TWR-JLB, ECF No. 141 at 17 n.8 (“By giving the claim term its plain and ordinary meaning, the Court has rejected Apple’s proposed limitation and thereby resolved the parties’ dispute . . .”).

VI. CONSTRUCTION OF THE DISPUTED CLAIM TERMS FROM THE '646 PATENT

A. “biological sample”

DNA Genotek's Proposed Construction	Spectrum's Proposed Construction	Court's Construction
The term does not require construction and should be accorded plain and ordinary meaning.	“cells”	“biological sample containing cells”

Here, the Parties dispute whether the claim term “biological sample” must be limited to “cells.” Spectrum argues that the '646 Patent makes clear that the claimed invention is directed to preserving cells. ECF No. 147 at 30-31. In response, DNA Genotek argues that Spectrum's proposed construction seeks to impermissibly narrow the meaning of the claim term “biological sample” in a way that is not supported by the intrinsic record, and argues that the claim term instead should be given its plain and ordinary meaning. ECF No. 134 at 25.³¹

Independent claim 1 of the '646 Patent recites: “A kit for collecting and preserving a **biological sample**, the kit comprising . . . a sample collection reservoir having an opening configured to receive the **biological sample** from a user” '646 Patent col. 22 ll. 16-21

³¹ The term “biological sample” is contained inside the preamble of independent claim 1. *See* '646 Patent col. 22 ll. 16 (“A kit for collecting and preserving a biological sample”). In its briefing, DNA Genotek contends that the preamble of claim 1 is non-limiting and, therefore, the claim term “preserving a biological sample” is not a limitation because that term is contained within the preamble. *See* ECF No. 134 at 25-27. Although DNA Genotek contends that the broader claim term “preserving a biological sample” is not a limitation, DNA Genotek does not appear to contend that the narrower claim term “biological sample” is not a limitation because it is contained within the preamble. *Compare id. with id.* at 25-27.

(emphasis added). Turning to the specification, the Abstract of the '646 Patent states: "The disclosure relates to devices, solutions and methods for collecting and processing samples of bodily fluids containing cells . . . The tube is configured to receive a donor sample of bodily fluid (*e.g.*, saliva, urine), which can then be subjected to processing to extract a plurality of cells." *Id.* at [57]; *see Hill–Rom Co., Inc. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 1341 n.* (Fed. Cir. 2000) (collecting cases) (explaining courts may "look[] to the abstract to determine the scope of the invention"). In addition, the specification states: "The disclosure relates to devices, solutions and methods for collecting samples of bodily fluids or other substances In addition, the disclosure relates generally to functional genomics and to the isolation and preservation of cells from such bodily fluids" '646 Patent col. 1 ll. 21-27; *see also id.* col. 6 ll. 47-48 ("this disclosure also relates to the isolation of cells from bodily fluids, such as saliva and urine, for these studies"), col. 17 ll. 34-36 ("The body fluids can contain a variety of cell types and the cells in the body fluids can be preserved by the solution according to the present disclosure."). In these passages, the specification explains that the invention disclosed in the '646 Patent specifically pertains to samples containing cells. As such, the Court will adopt a construction for this claim explaining that the claimed "biological sample" contains cells.

DNA Genotek argues that the specification distinguishes cells from other biological samples. ECF No. 134 at 25 (citing '646 Patent col. 6 ll. 46-49); ECF No. 89 at 14 (citing '646 Patent col. 6 ll. 46-53). The Court acknowledges that the specification does not equate the term "cells" with the term "samples," and, therefore, Spectrum's proposed construction is improper. Nevertheless, in the passages above and in the passage cited by DNA Genotek, the specification explains that the invention disclosed in the '646 Patent is specifically directed to samples containing cells. *See* '646 Patent at [57], col. 1 ll. 21-27, col. 6 ll. 46-53, col. 6 ll. 61-62.

In addition, DNA Genotek argues that a PHOSITA would understand that a biological sample would include more than just cells in the context of the '646 Patent. ECF No. 134 at 25; ECF No. 89 at 14. But a construction requiring the claimed "biological

sample” contain cells does not mean that the sample can only contain cells as opposed to other biological material. As such, DNA Genotek’s argument is misplaced.

In sum, the Court rejects both Parties’ proposed construction for the claim term “biological sample.” The Court construes “biological sample” as “biological sample containing cells.”

B. “preserving a biological sample”

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

Spectrum argues that within the context of the ’646 Patent, the claim “preserving a biological sample” specifically requires preserving the cells that make up the biological sample. ECF No. 147 at 29-31. In response, DNA Genotek argues that the term “preserving a biological sample” does not require construction because it only appears in the non-limiting preamble, and neither lexicography nor disavowal overturns the term’s plain and ordinary meaning. ECF No. 134 at 25-27.

The Court first addresses DNA Genotek’s contention that independent claim 1 of the ’646 Patent is non-limiting. Independent claim 1 of the ’647 patent contains the following preamble: “A kit for collecting and preserving a biological sample.” ’646 Patent col. 22 ll. 16.

1 “In general, a preamble limits the invention if it recites essential structure or steps,
 2 or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” *Catalina Mktg. Int’l,*
 3 *Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes,*
 4 *Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). “Conversely, a
 5 preamble is not limiting ‘where a patentee defines a structurally complete invention in the
 6 claim body and uses the preamble only to state a purpose or intended use for the
 7 invention.’” *Id.* (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)); *accord Arctic*
 8 *Cat Inc. v. GEP Power Prod., Inc.*, 919 F.3d 1320, 1328 (Fed. Cir. 2019). The Federal
 9 Circuit has explained that “the rule against giving invention-defining effect to intended-
 10 use preamble language reflects a longstanding substantive aspect of the patent statute—
 11 specifically, the ‘well settled’ fundamental principle ‘that the recitation of a new intended
 12 use for an old product does not make a claim to that old product patentable.’” *Arctic Cat*,
 13 919 F.3d at 1328; *see also Catalina*, 289 F.3d at 809 (“[P]reambles describing the use of
 14 an invention generally do not limit the claims because the patentability of apparatus or
 15 composition claims depends on the claimed structure, not on the use or purpose of that
 16 structure.”).

17 “Whether to treat a preamble as a limitation is a determination ‘resolved only on
 18 review of the entire[] . . . patent to gain an understanding of what the inventors actually
 19 invented and intended to encompass by the claim.’” *Catalina*, 289 F.3d at 808 (quoting
 20 *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir.
 21 1989)). “No litmus test defines when a preamble limits claim scope,” but the Federal
 22 Circuit has recognized certain “guideposts” for making that determination. *Id.*

23 One of those guideposts is that: “When limitations in the body of the claim rely upon
 24 and derive antecedent basis from the preamble, then the preamble may act as a necessary
 25 component of the claimed invention.” *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332,
 26 1339 (Fed. Cir. 2003); *accord Pacing*, 778 F.3d at 1024; *see Catalina*, 289 F.3d at 808
 27 (“[D]ependence on a particular disputed preamble phrase for antecedent basis may limit
 28 claim scope because it indicates a reliance on both the preamble and claim body to define

the claimed invention.”); *see also Bell Commc’ns Rsch., Inc. v. Vitalink Commc’ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995) (“[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects.”). This guidepost is present here. The claim term “a biological sample” in the preamble of claim 1 provides the antecedent basis for the claim term “the biological sample” found in the body of claim 1. *See* ’646 Patent col. 22 ll. 20-22 (“a sample collection reservoir having an opening configured to receive the biological sample from a user into the sample collection reservoir”).

The Court acknowledges that the body of claim 1 only includes the specific term “biological sample” and not the broader phrase “preserving a biological sample.” But the Federal Circuit’s decision in *Bio-Rad Laboratories, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353 (Fed. Cir. 2020), is instructive on this point. In *Bio-Rad*, the preamble at issue recited “[a] method for conducting a reaction in plugs in a microfluidic system.” *Id.* at 1370. The terms “reaction” and “microfluidic systems” in the preamble provided antecedent basis for the use of those terms in the body of the claim. *Id.* In light of this, the Federal Circuit found the entire preamble limiting. *See id.* at 1370–72. The Federal Circuit explained: “The language relied upon for antecedent basis in the preamble at issue is intertwined with the rest of the preamble.” *Id.* at 1371. Thus, “[t]he fact that the terms ‘reaction’ and ‘microfluidic systems’ provide antecedent basis for these terms in the body of the claim is a strong indication that the preamble acts ‘as a necessary component of the claimed invention.’” *Id.* (quoting *Eaton*, 323 F.3d at 1339). Similarly, here, the term “biological sample” is intertwined with the broader phrase “collecting and preserving a biological sample” in the preamble. As such, under the Federal Circuit’s decision in *Bio-Rad*, the fact that the term “biological sample” provides antecedent basis for that term in the body of the claim “is a strong indication that the preamble acts ‘as a necessary component of the

1 claimed invention.” *Id.* As such, the Court rejects DNA Genotek’s argument that the
 2 preamble in claim 1 of the ’646 Patent is non-limiting.

3 With that issue resolved, the Court turns to the proper construction of the claim term
 4 “preserving a biological sample.” Independent claim 1 of the ’646 Patent recites: “A kit for
 5 collecting and preserving a biological sample, the kit comprising” ’646 Patent col. 22
 6 ll. 16-17. The Court has construed the claim term a “biological sample” as a “biological
 7 sample containing cells.” *See supra.*

8 The Abstract of the ’646 Patent states:

9 The disclosure relates to devices, solutions and methods for collecting and
 10 processing samples of bodily fluids containing cells (as well as embodiments
 11 for the collection, and processing and/or analysis of other fluids including
 12 toxic and/or hazardous substances/fluids). In addition, the disclosure relates
 13 generally to function genomic studies and to the isolation and preservation of
 14 cells from saliva and other bodily fluids (*e.g.*, urine), for cellular analysis.
 15 With respect to devices for collection of bodily fluids, some embodiments
 16 include two mating bodies, a cap and a tube (for example), where, in some
 17 embodiments, the cap includes a closed interior space for holding a sample
 18 preservative solution and mates with the tube to constitute the (closed) sample
 19 collection device. Upon mating, the preservation solution flows into the
 20 closed interior space to preserve cells in the bodily fluid. The tube is
 21 configured to receive a donor sample of bodily fluid (*e.g.*, saliva, urine), which
 22 can then be subjected to processing to extract a plurality of cells.

23 *Id.* at [57]; *see Hill–Rom*, 209 F.3d at 1341 n.* (explaining courts may “look[] to the
 24 abstract to determine the scope of the invention”).³² Similarly, the specification in a section
 25 entitled “Field of the Disclosure” explains:

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 27
 28 ³² In its briefing, DNA Genotek cites to a portion of the specification stating: “The one
 or more fluids or materials contained in the interior space 20 in the cap 12 may assist in

1 The disclosure relates to devices, solutions and methods for collecting
 2 samples of bodily fluids or other substances, including hazardous and/or toxic
 3 substances, and in particular, a naturally expressed bodily fluid (*e.g.*, saliva,
 4 urine). In addition, the disclosure relates generally to functional genomics and
 5 to the isolation and preservation of cells from such bodily fluids

6 ’646 Patent col. 1 ll. 21-27; *see also id.* col. 4 ll. 53-56 (“Embodiments of the disclosure
 7 provide . . . solutions and methods for preserving cells of samples collected”), col. 4
 8 ll. 47-49 (“there is a need for new solutions and methods that will preserve the antigenicity
 9 and epigenome of cells in other bodily fluids, such as saliva”), col. 17 ll. 34-36 (“[T]he
 10 cells in the body fluids can be preserved by the solution according to the present
 11 disclosure.”).

12 In the above passages, the specification expressly states that the “disclosure” of the
 13 ’646 Patent encompasses preserving cells within that sample. “When a patentee ‘describes
 14 the features of the ‘present invention’ as a whole,’ he implicitly alerts the reader that ‘this
 15 description limits the scope of the invention.’” *Luminara*, 814 F.3d at 1353 (quoting
 16 *Regents of Univ. of Minnesota*, 717 F.3d at 936); *accord Pacing*, 778 F.3d at 1024; *see also*
 17 *Poly-Am.*, 839 F.3d at 1136 (“[A]n inventor may disavow claims lacking a particular
 18 feature when the specification describes “the present invention” as having that feature.”).
 19 The Court acknowledges that in the above quoted passages, the specification does not use
 20 the exact phrase “the present invention” or “the invention.” But the passages at issue use
 21 the similar phrases “the present disclosure” and “the disclosure.” ’646 Patent at [57] (“The
 22 disclosure”), col. 1 ll. 21-27 (“The disclosure”); col. 17 ll. 34-36 (“the present
 23 disclosure”). Claim terms “ordinarily cannot be construed broader than the disclosure in
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25
 26 preserving the sample body fluids contained in the reservoir 40 of the tube 14 during at
 27 least storage and shipping.” ’646 Patent col. 12 ll. 36-40. But the Abstract of the ’646 Patent
 28 explains that the fluid referenced here – the fluid contained in the cap – is a “sample
 preservation fluid” and that fluid is used “to preserve cells in the bodily fluid.” *Id.* at [57].

the specification.” *Indacon*, 824 F.3d at 1357; *see also Gentry Gallery*, 134 F.3d at 1480 (“[C]laims may be no broader than the supporting disclosure, and therefore that a narrow disclosure will limit claim breadth.”). Thus, the specification’s use of the phrases “the present disclosure” and “the disclosure” alerts the reader that invention disclosed in the ’646 Patent is directed to the preservation of cells in samples. *See, e.g., Regents of Univ. of California v. Affymetrix, Inc.*, No. 17-CV-01394-H-NLS, 2018 WL 1466408, at *5 (S.D. Cal. Mar. 26, 2018) (finding that disclaimers in the specification limited the claim term “a sample” specifically to “biological material that is analyzed for a target polynucleotide”). Further, the specification never references any type of preservation other than the preservation of cells. As such, the Court agrees with Spectrum that within the context of the invention disclosed in the ’646 Patent, preservation of a biological sample specifically encompasses preserving cells within that biological sample. *See also, e.g., UltimatePointer, L.L.C. v. Nintendo Co.*, 816 F.3d 816, 823 (Fed. Cir. 2016) (limiting scope of claims based on “[t]he specification repeatedly emphasiz[ing] that the invention is directed to a direct-pointing system”); *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1338 (Fed. Cir. 2011) (limiting scope of claims where broad reading of claim language was “not supported by the specification”); *Tap Pharm. Prod., Inc. v. Owl Pharms., L.L.C.*, 419 F.3d 1346, 1353 (Fed. Cir. 2005) (limiting scope of claims where “all of the 31 examples in the specification describe[d] the use of particles” in a certain manner); *AquaTex Indus., Inc. v. Techniche Sols.*, 419 F.3d 1374, 1381–82 (Fed. Cir. 2005) (limiting scope of claims to synthetic fibers where the specification “describe[d] numerous examples of commercial grade fiberfill, all of which are comprised entirely of synthetic materials”); *Eon*, 815 F.3d at 1320–21 (“A party is . . . ‘not entitled to a claim construction divorced from the context of the written description and prosecution history.’” (quoting *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1144–45 (Fed. Cir. 2005))).

Moreover, the specification of the ’646 Patent provides an express definition for what is meant by preserving cells in a sample. The specification provides: “For purposes of the disclosure, ‘preserving cells’ means preventing the cells from having their antigens

1 degraded, such that they can be purified or enriched based on their antigens, and preventing
2 alterations in the cellular epigenome.” ’646 Patent col. 16 ll. 23-27. Spectrum’s proposed
3 construction aligns with this express definition in the specification, and, thus, is well
4 supported by the intrinsic record. *See Phillips*, 415 F.3d at 1316 (“[T]he specification may
5 reveal a special definition given to a claim term by the patentee In such cases, the
6 inventor’s lexicography governs.”); *Edwards Lifesciences*, 582 F.3d at 1329 (explaining
7 that a patentee acts as his own lexicographer when the patentee “‘clearly set[s] forth a
8 definition of the disputed claim term in either the specification or prosecution history”’);
9 *see, e.g., Biogen*, 976 F.3d at 1336.

10 In an effort to counter Spectrum’s proposed construction and support its own
11 proposed construction, DNA Genotek cites to patent applications filed by Spectrum that
12 contain the phrase “preserving a biological sample.” ECF No. 134 at 26-27 (citing Ex. 17,
13 Ex. 18). The Court rejects DNA Genotek’s reliance on these patent applications.
14 “[S]tatements made in unrelated applications are not relevant to claim construction.” *See*
15 *Apple*, 757 F.3d at 1312; *see also, e.g., Goldenberg*, 373 F.3d at 1167–68 (finding
16 statements in another patent irrelevant to claim construction “[a]bsent a formal relationship
17 or incorporation during prosecution” of the patent at issue).

18 In sum, the Court adopts a slightly modified version of Spectrum’s proposed
19 construction for this claim term. The Court construes “preserving a biological sample” as
20 “preventing cells in the biological sample from having their antigens degraded such that
21 they can be purified or enriched based on their antigens, and preventing alterations in the
22 cellular epigenome.”

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1 **C. “annular valve”**

2 DNA Genotek’s	3 Spectrum’s	4 Court’s
5 Proposed Construction	6 Proposed Construction	7 Construction
8 “valve with two cylinders 9 where the cylinders move 10 relatively to open/close 11 the valve”	12 “ring shaped valve”	13 “ring shaped valve”

14 Here, the Parties dispute whether the claimed “annular valve” must be ring-shaped. DNA Genotek contends that the claimed “annular valve” need only be a valve with two cylinders. ECF No. 134 at 22-23. Spectrum argues that the claimed “annular valve” must be ring-shaped in addition to being a valve with two cylinders (inner and outer). ECF No. 147 at 32-33.

15 The Court begins its analysis of the Parties’ dispute by reviewing the claim language. Independent claim 1 of the ’646 Patent recites a kit comprising, among other things:
16 a movable **annular valve** configured to associate with the cap and with the
17 opening of the sample collection reservoir, the movable **annular valve**
18 comprising:

19 an inner cylinder in fluid-tight association with the cap and comprising
20 a sidewall, the sidewall comprising a fluid vent; and
21 an outer cylinder in fluid-tight association with the inner cylinder and
22 associated with the opening of the sample collection reservoir, the outer
23 cylinder comprising an aperture defined by an interior sidewall of the
24 outer cylinder, ...

25 ’646 Patent col. 22 ll. 31-41 (emphasis added). In claim 1, the claim language uses the
26 adjective “annular” to modify the word “valve.” As Spectrum correctly notes, the common
27 meaning of the word “annular” is ring-shaped. *See* ECF No. 83-14, Ex. 13, THE NEW
28 OXFORD AMERICAN DICTIONARY at 63 (2001) (defining “annular” as “ring-shaped”);

WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY at 88 (1981) (defining “annular” as “of or relating to a ring: forming a ring: shaped like a ring”); THE AMERICAN HERITAGE COLLEGE DICTIONARY at 55 (3d ed. 1997) (defining “annular” as “[s]haped like or forming a ring”); MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/annular> (defining “annular” as “of, relating to, or forming a ring”). As such, the claim language supports Spectrum’s proposed construction.³³ See *Phillips*, 415 F.3d at 1314 (explaining that the use of general purposes dictionaries “may be helpful” in cases that involve “little more than the application of the widely accepted meaning of commonly understood words”).

DNA Genotek argues that the “the claims do not describe the term as ‘ring-shaped,’ let alone mention a ring shape at all.” ECF No. 134 at 23. The Court disagrees. By using the word “annular,” which means “ring-shaped,” the claim language describes the claimed “valve” as being ring-shaped.

In an effort to support its proposed construction, DNA Genotek notes that “Claim 1 describes the claimed ‘annular valve’ as ‘*comprising* . . . an inner cylinder . . . and an outer cylinder.’” ECF No. 134 at 23 (emphasis in original). DNA Genotek argues that this language shows that that the claimed “annular valve” is at least a valve with two cylinders. *Id.* The Court acknowledges that this language requires that the claimed “annular valve” be a valve with at least two cylinders. Indeed, the Parties do not dispute that the claimed “annular valve” includes two cylinders. See ECF No. 147 at 32-33; ECF No. 134 at 23. But under the claim language, the claimed “valve” must not only have two cylinders; it must

³³ DNA Genotek criticizes Spectrum’s proposed construction for relying on a general-purpose dictionary to discern the meaning of the technical term “annular valve.” ECF No. 134 at 23-24. DNA Genotek notes that scientific dictionaries are preferable over non-scientific dictionaries. *Id.* at 24. But DNA Genotek has failed to present the Court with any evidence, intrinsic or extrinsic, showing that the term “annular valve” is a technical term. In addition, DNA Genotek has not provided the Court with any dictionary, technical or non-technical, or other evidence showing that the word “annular” can mean something other than ring-shaped. As such, the Court rejects DNA Genotek’s argument.

1 also be “annular” (*i.e.*, ring-shaped). The Court agrees with Spectrum that DNA Genotek’s
2 proposed construction seeks to improperly read the word “annular” out of the claim
3 language. *See Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1257
4 (Fed. Cir. 2010) (“Claims must be ‘interpreted with an eye toward giving effect to all terms
5 in the claim.’”); *Wasica Fin. GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10
6 (Fed. Cir. 2017) (“It is highly disfavored to construe terms in a way that renders them void,
7 meaningless, or superfluous.”).

8 Turning to the specification, the specification further supports Spectrum’s proposed
9 construction by consistently using the word “annular” to describe something that is ring-
10 shaped. Indeed, the specification uses the words “annular” and “ring” interchangeably.
11 *Compare* ’646 Patent col. 9 ll. 21-28 (referring to the breakaway portion of the “tamper
12 evident” cap displayed in Figures 7A and 7B as “an annular member”); *with* col. 15 ll. 56-
13 62 (referring to the breakaway portion of the “tamper evident” cap displayed in Figures 7A
14 and 7B as “tamper evident feature 160 which may be comprised of a ring”); *see also*
15 *Edwards Lifesciences*, 582 F.3d at 1329 (“The interchangeable use of the two terms is akin
16 to a definition equating the two.”). The specification also refers to an “annular blocking
17 member,” which is displayed in Figures 3A-3C as being ring-shaped. *See id.* figs. 3A-3C,
18 col. 5 ll. 50-55, col. 8 ll. 49-61, col. 14 ll. 37-53. As such, Spectrum’s proposed construction
19 is well supported by the intrinsic evidence.

20 In sum, the Court adopts Spectrum’s proposed construction, and the Court rejects
21 DNA Genotek’s proposed construction. The Court construes the term “annular valve” as
22 “ring-shaped valve.”

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D. “associate with” and variations³⁴

DNA Genotek’s Proposed Construction	Spectrum’s Proposed Construction	Court’s Construction
The term does not require construction and should be accorded plain and ordinary meaning.	“contact”	Plain and ordinary meaning.

Here, the Parties again dispute whether the term “associate with” and variations of that term require that the relevant components be in “contact” with each other. Spectrum argues that the term “associates with” requires contact between the relevant components. ECF No. 147 at 33-34. DNA Genotek argues that nothing in the intrinsic record of the ’646 Patent requires “associates with” to be redefined as “contacts.” ECF No. 134 at 28.

The Court begins its analysis of the Parties’ dispute by reviewing the claim language. Independent claim 1 recites a kit comprising, among other things:

a movable annular valve configured to **associate with** the cap and with the opening of the sample collection reservoir, the movable annular valve comprising:

an inner cylinder in fluid-tight **association with** the cap and comprising a sidewall, the sidewall comprising a fluid vent; and

an outer cylinder in fluid-tight **association with** the inner cylinder and associated with the opening of the sample collection reservoir, the outer cylinder comprising an aperture defined by an interior sidewall of the outer cylinder

³⁴ The variations of the term “associate with” are “associated with,” “association with,” “association of,” and “configured to associate with.” ECF No. 147 at 33.

1 '646 Patent col. 22 ll. 31-41 (emphasis added). Here, there is nothing in the claim language
2 specifically requiring that the relevant components be in physical contact with each other.

3 Spectrum argues that the claim language supports its proposed construction. ECF
4 No. 88 at 15. Specifically, Spectrum contends that because the claim language already
5 recites that the claimed “outer cylinder” is part of the cap that is connected to the opening,
6 there is no reason to recite that the outer cylinder is “associated with” the opening unless
7 “associated with” means in physical contact with. *Id.* The Court disagrees with Spectrum’s
8 contention that a plain meaning construction would render this claim language
9 meaningless. The claim language explains that the claimed kit contains a moveable annular
10 valve that is configured to associate with the cap and the opening. *See* '646 Patent col. 22
11 ll. 31-32. The claim language further explains that the outer cylinder is a component of the
12 annular valve and the outer cylinder associates with the opening. *See id.* at col. 22 ll. 37-
13 38. In so doing, the claim language explains that it is this component of the annular valve
14 that specifically associates with the opening as opposed to a different component of the
15 valve, such as the inner cylinder. As such, a plain meaning construction would not render
16 that claim language meaningless or superfluous.

17 Spectrum also argues that “associate with” must mean contact because contact is
18 required for the invention to work. ECF No. 147 at 34. Specifically, Spectrum argues that
19 the outer cylinder must move to release the contents of the reagent compartment through
20 contact with the opening of the sample collection reservoir. *Id.* The Court does not find this
21 argument persuasive. The claim language states that the claimed “annular valve” is
22 “moveable,” but there is no language in claim 1 expressly stating that the outer cylinder
23 moves via direct contact with the opening. *See* '646 Patent col. 22 ll. 31-47.

24 Turning to the specification, Spectrum argues that the specification supports its
25 proposed construction because the specification reinforces that the components of the
26 claimed device be “associated” with each other via physical contact. ECF No. 147 at 34.
27 To support this contention, Spectrum cites to a portion of the specification discussing
28 Figures 3A-3C and explaining that securely coupling cap 12 onto tube 14 “caus[es] the

1 coupling features 48 of the annular blocking member 62 to engage the coupling member
2 50 of the tube 14.” ’646 Patent fig. 3A-3C, col. 14 ll. 61-65. But “it is improper to read
3 limitations from a preferred embodiment described in the specification—even if it is the
4 only embodiment—into the claims absent a clear indication in the intrinsic record that the
5 patentee intended the claims to be so limited.” *Dealertrack*, 674 F.3d at 1327; *accord*
6 *Openwave*, 808 F.3d at 514. Here, there is no clear indication that the claims should be
7 limited to the cited example. The specification describes Figures 3A-3C as merely
8 displaying “an embodiment of the sample collection device . . . according to some
9 embodiments of the present disclosure.” ’646 Patent col. 8 ll. 49-58. As such, the
10 specification does not support Spectrum’s proposed construction.

11 Turning to the prosecution history, Spectrum notes that DNA Genotek represented
12 to the PTO that claim 1 of the ’646 Patent draws support from Figures 3A and 3B in the
13 patent specification. ECF No. 147 at 33 (citing ECF No. 83-8, Ex. 7). But Spectrum fails
14 to adequately explain why this is of any consequence given that the specification of the
15 ’646 Patent explains that Figures 3A-3C merely represent embodiments of the claimed
16 sample collection device. Spectrum does not argue that these statements constitute
17 prosecution history disclaimer. As such, the Court rejects Spectrum’s reliance on the
18 prosecution history.

19 In sum, the Court rejects Spectrum’s proposed construction. The Court gives the
20 term “associate with” and the related terms their plain and ordinary meaning, and the Court
21 declines to construe the claim terms.

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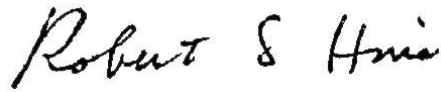
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1 **VII. CONCLUSION**

2 The Court construes the claims as stated in this Order.³⁵

3 **SO ORDERED.**

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5 Dated: November 29, 2022



6 Hon. Robert S. Huie
7 United States District Judge
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27 ³⁵ In addition, the Court denies as moot DNA Genotek's motion for leave to file a
28 response to Spectrum's evidentiary objections.