

1 Joseph F. Jennings (SBN 145,920)
joe.jennings@knobbe.com
2 Ali S. Razai (SBN 246,922)
ali.razai@knobbe.com
3 Paul N. Conover (SBN 192,358)
paul.conover@knobbe.com
4 Nicholas M. Zovko (SBN 238,248)
nicholas.zovko@knobbe.com
5 Brandon G. Smith (SBN 307,676)
brandon.smith@knobbe.com
6 KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main St., 14th Floor
7 Irvine, CA 92614
Telephone: (949) 760-0404
8 Facsimile: (949) 760-9502
9 Attorneys for Defendant
SPECTRUM SOLUTIONS L.L.C.

11 **IN THE UNITED STATES DISTRICT COURT**
12 **FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

14 DNA GENOTEK INC., a Canadian
15 Corporation,

16 Plaintiff,

17 v.

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

20 Defendant.

21 AND RELATED COUNTERCLAIM.
22

Case No. 3:21-cv-00516-JO-AGS

**DEFENDANT SPECTRUM
SOLUTIONS, LLC'S OPENING
CLAIM CONSTRUCTION
BRIEF**

JUDGE. Hon. Jinsook Ohta

MAGISTRATE JUDGE:
Hon. Andrew G. Shopler

23 **REDACTED PUBLIC VERSION**
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Opening Claim Construction Brief
Case No. 3:21-cv-00516-JO-AGS

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Opening Claim Construction Brief
Case No. 3:21-cv-00516-JO-AGS

I. INTRODUCTION

The two asserted patents relate to compositions and devices for “preserving” biological samples, albeit very different aspects of the biological sample. U.S. Patent No. 10,619,187 (the “’187 patent” (Ex. 1¹)) is directed to a device having reagents that preserve nucleic acids in the sample. To do this the reagents initially destroy the cells in the sample to liberate the nucleic acids. U.S. Patent No. 11,002,646 (the “’646 patent” (Ex. 2)), in contrast, is directed to a device that preserves the cells in the sample. This allows particular cells to be isolated and later studied.

The parties dispute a number of limitations regarding the claimed devices. Spectrum proposes constructions consistent with the inventions described in the patents. Genotek, on the other hand, generally asserts the claim terms should not be construed and instead be accorded some undefined “plain meaning.” Genotek does so to enable it to later assert a broad reading of the claims untethered to the invention described in the patent so it can try to cover Spectrum’s device, which is very different than its claimed inventions. Genotek largely offers no constructions for the terms in dispute, but instead urges the Court not to construe them. But kicking the can down the road will only lead to future disputes regarding the proper scope of the claims. The Court should resolve the parties’ disputes and construe the claims consistent with the patents’ specifications as Spectrum proposes.

II. THE ASSERTED PATENTS

A. The ’187 Patent

Per the ’187 patent, “[t]he present invention relates to compositions and methods for preserving nucleic acids at room temperature for extended periods of time” Ex. 1 at 1:23-25.² The compositions include reagents that destroy or

¹ All Exhibits are attached the Declaration of Ali S. Razai filed concurrently herewith.

² All citations to the text of the patents are in column:line format. Other

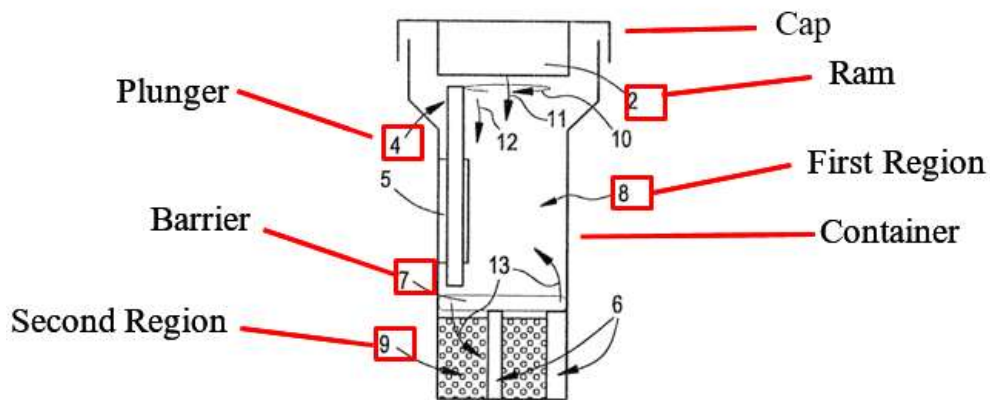
1 lyse the cells contained within a biological sample. The patent describes what
2 happens when the reagent composition contacts the sample: “When sputum is
3 mixed with a composition of the present invention, cells are disrupted, nucleic acids
4 are liberated from the cells, membranous material [i.e., the cell membrane] is
5 solubilized, proteins are stripped from the nucleic acids, and protein digestion
6 begins.” *Id.* at 13:38-42.

7 The patent includes substantial detail about the reagents that make up the
8 composition of the invention. *Id.* at 9:1-11:67. The patent also demonstrates, with
9 examples, how the compositions preserve the nucleic acids for extended periods of
10 time. In each instance where the composition is said to have “preserved” the
11 nucleic acids, the patent specifies a time period. *See, e.g., id.* at Table 1 (64 or 15
12 days); Example 4 (14 days); Example 5 (62 days); Table 3 (various time periods
13 ranging from 3 days to 31 days). The storage temperature is specified when it is
14 not room temperature. *See, e.g., id.* at Table 3. And the patent describes the type
15 of analysis conducted to confirm the nucleic acid (specifically DNA) is still present
16 at the end of the specified time period, *i.e.*, that it was preserved for the specified
17 time period. *See, e.g., id.* at Examples 5 and 6 (polymerase chain reaction (“PCR”);
18 Figs. 1 and 4 (gel electrophoresis).

19 The ’187 patent also describes a device that contains the reagent composition
20 and permits the collection of the biological sample and mixing of the sample with
21 the reagent composition. As depicted below, the device includes a container with
22 a cap. The container portion of the device includes two compartments (regions)
23 that are separated by a barrier, which the patent teaches can be a pierceable
24 membrane or pivoting sealing disc. Ex. 1 at Fig. 11 (annotated below); 15:17-20.

25 ///

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27
28 exhibit citations refer to the exhibit page numbers added per L.R. 5.1, unless
otherwise noted.



The first region of the container is for the biological sample to be collected and the second region contains the reagents. The barrier initially keeps the reagents sealed in the second region of the container. *Id.* at 6:32-33.

The device also includes structures that displace the barrier after the sample is collected to allow the reagents and the sample to mix. Specifically, a ram, which is attached to the cap, moves down when the cap is screwed on. The ram contacts a plunger in the container and causes the plunger to move down. Depending on the embodiment, the plunger then either pierces the membrane or pivots the sealing disc to open the reagent compartment of the container and release the reagent into the container. *Id.* at 15:33-45; Figs. 10-11.

B. The '646 Patent

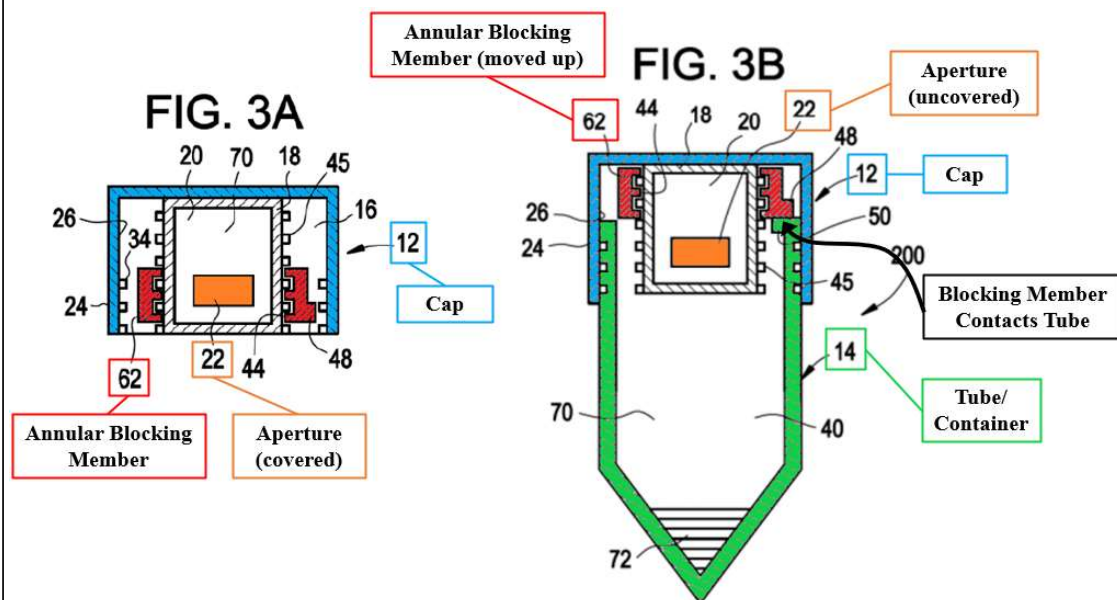
The '646 patent also relates to a device and composition for preserving a biological sample, but it is very different from the '187 patent. Rather than ***destroying*** cells to release the nucleic acids, the '646 patent invention ***preserves*** the cells in the biological sample. The '646 patent addressed the need for a device that enabled a biological sample to be collected and its cells preserved so that particular cells could be isolated and their genetic makeup (epigenome) could be profiled. Ex. 2 at 4:47-49. Consistent with addressing this need, the patent

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specification repeatedly discusses preserving the cells in the biological sample³ and also includes an explicit definition: “For purposes of the disclosure, ‘preserving cells’ means 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.” *Id.* at 16:23-27.

The ’646 patent describes a number of devices. The claims of the ’646 patent are drawn to the device depicted in Figures 3A and 3B. *See* Ex. 7 at 268. The device includes a cap 12 (shown in Fig. 3A), which fits on a container or tube 14 (shown in Fig. 3B).



Ex. 2 at Figs. 3A and 3B.

The cap includes an interior space 20 that contains the preservation solution 70. The space 20 includes an aperture 22, which is initially covered by an annular blocking member 62 (as shown in Figure 3A).⁴ When the cap is placed on the tube,

³ The citations are too numerous to list all of them. Exemplary citations include: Ex. 2 at 1:20-30, 2:34-4:49, 4:53-61, 5:21-25, 6:6-8:24, 9:44-10:15, 13:29-47, 14:54-15:5, 16:9-47, 16:62-17:42, 17:43-18:59, and 18:64-19:40

⁴ The covered arrangement may not be apparent from Figure 3A, which is a cross-section. In three dimensions, however, the annular blocking member 62

the annular blocking member engages or contacts a coupling member 50 of the tube. This causes the blocking member to move upward (to the position shown in Fig. 3B). This uncovers the aperture and releases the preservation solution to mix with the sample 72 in the tube.

III. DISPUTED TERMS OF THE '187 PATENT

A. Preserving/Preserve

Spectrum's Proposed Construction	Genotek's Proposed Construction
The term is indefinite	no construction required, plain and ordinary meaning or, in the alternative, "slow[] degradation of"

The claims of the '187 patent are directed to a "device for receiving and preserving nucleic acid in a biological sample." Ex. 1 at 19:34-35. The device includes "reagents ... for preserving nucleic acids." *Id.* at 19:49-50. The claims, unlike the specification, provide no specificity as to what it means to "preserve" nucleic acids. How much nucleic acid must remain in the sample to be considered "preserved"? Are the reagents able to maintain the nucleic acids for one hour, one day, one month, etc.? At what temperatures are the samples stored? Even assuming a skilled artisan understood how much nucleic acid must remain to be considered preserved, a device with the same reagents may or may not be found to infringe depending on how long and at what temperature the sample is stored.

1. The Patent Statute Requires Claims to be Sufficiently Definite

Section 112, ¶ 2 of the patent statute requires that patent claims "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as [the] invention." The claims, read in light of the specification, must define the scope of the invention with "reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). "Otherwise there would be a zone of uncertainty which enterprise and experimentation may enter only at the risk of

extends around the circumference of space 20 and covers or blocks the aperture 22.

infringement claims.” *Id.* (internal quotations and annotations omitted). A claim is indefinite if a device could infringe or not infringe depending on external factors. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1254-55 (Fed. Cir. 2008).⁵

The term at issue in *Halliburton* was “fragile gel.” *Halliburton*, 514 F.3d at 1246. *Halliburton* argued that a person of ordinary skill in the art would know how to determine what constituted a “fragile gel” by performing certain measurements. *Id.* at 1254. But “[t]he fact that an artisan would know how to perform these measurements and tests, however, says nothing about whether the artisan would also know which fluids” satisfied the claim language. *Id.* The patentee failed to “answer the fundamental question: what quantity, weight, size and/or volume of cuttings must be suspended” to be within the scope of the claim. *Id.* The person of ordinary skill in the art was left to “make a separate infringement determination for every set of circumstances in which the composition may be used, and [because] such determinations [were] likely to result in differing outcomes (sometimes infringing and sometimes not)” the claims were indefinite. *Id.* at 1255.

2. The Claims of the ’187 Patent Are Indefinite

The term “preserving nucleic acids” does not have a single meaning to those in the relevant field. Declaration of Vincent A. Fischetti Ph.D (“Fischetti Decl.”) ¶ 18. This was true as of the filing date of the ’187 patent in 2002 and it is true today. *Id.* For example, several years after the ’187 patent was filed, a review paper in the field acknowledged this lack of a single meaning for the term:

The preservation of DNA is of wide interest to scientists in disparate fields from biorepository management to pharmaceutical sciences.

Although the term “preservation” is used by all these fields and refers

⁵ Though *Halliburton* is pre-*Nautilus*, *Nautilus* lowered the standard for indefiniteness. See *Dow Chem. Co. v. Nova Chem Corp. (CA)*, 803 F.3d 620, 630-31 (Fed. Cir. 2015). Thus, *Halliburton* remains good law.

1 to the maintenance of chemical and physical integrity of the DNA
2 molecule, it should not be surprising that the perspectives of scientists
3 from these distinct fields differ significantly.

4 Ex. 11 at 357.

5 Adding to the uncertainty inherent in the term “preserving nucleic acids,”
6 the claims of the ’187 patent do not provide guidance to those of skill in the art that
7 would allow them to determine with reasonable certainty whether a device
8 infringes. Whether a device preserves nucleic acids or not depends on several
9 external factors not specified in the claims.

10 First, the claims do not specify a time period, *i.e.*, how long must nucleic
11 acids be maintained to be considered “preserved.” To assess whether nucleic acids
12 have been preserved one must know when to test the sample to confirm the nucleic
13 acids are still present. *See* Fischetti Decl. ¶ 23. For example, the amount of nucleic
14 acid remaining in a sample after 60 minutes will be different than the amount of
15 nucleic acid remaining in the sample after, for example, 1 day, 7 days, 14 days, 3
16 months, etc. *See* Fischetti Decl. ¶¶ 25-33.

17 Second, the claims do not specify the temperature at which the sample is
18 stored. Temperature affects whether nucleic acids in a sample are maintained.
19 Fischetti Decl. ¶¶ 34-37. For example, even a twenty-degree difference in
20 temperature will have a drastic difference in how much nucleic acid remains in a
21 sample after just one week of storage. Fischetti Decl. ¶¶ 25-26; *see* Ex. 15 at Fig. 2.
22 Accordingly, the amount of nucleic acid remaining would be different if the sample
23 were stored at room temperature (20-25 °C) or in a typical freezer (-20 °C).

24 Third, the claims do not specify how much nucleic acid must remain at the
25 end of a storage period to be considered “preserved.” This is significant because
26 different assays have different detection thresholds. Fischetti Decl. ¶¶ 21-22. And
27 depending on the selected assay, nucleic acid may be detected or not. But one of
28 skill in the art has no guidance on what type of assay to use. *Id.*

1 The claims of the '187 patent stand in stark contrast to the patent
2 specification. The specification recognizes the need for parameters such as a time
3 period and temperature in assessing preservation. Indeed, the '187 patent discusses
4 storage conditions at various temperatures, including -25, 20, 50, and 70 °C. Ex. 1
5 at Example 7, Table 3, and Fig. 4. Examples 4-6 reflect preservation of DNA at
6 distinct time periods (e.g., 14 days, 62 days, 30 days) using the “nucleic acid-
7 preserving solution” of Example 3. *Id.* at 16:40-18:8. In every instance where the
8 composition is said to have “preserved” the nucleic acids, the patent specifies a
9 time period and a temperature. And the patent describes the type of analysis
10 conducted to confirm the nucleic acid (specifically DNA) is still present at the end
11 of the specified time period, *i.e.*, that it was preserved for the specified time period.
12 *See, e.g., id.* at Examples 5 and 6 (PCR); Figs. 1 and 4 (gel electrophoresis).

13 Though one of skill in the art may know how to perform measurements and
14 tests to determine how much of the nucleic acids remain in the sample, this artisan
15 would not know whether the device is within the scope of the claim. The claims
16 do not recite how much nucleic acid must remain in the sample to be considered
17 preserved, at what temperature the sample is stored, nor how long the sample can
18 be stored before it is tested. Assuming *arguendo*, that preservation of a sample
19 means that 50% of the nucleic acid remains in the sample, a skilled artisan would
20 still not be able to determine whether a device having a particular composition
21 infringes without knowing, for example, the storage temperature and duration. For
22 example, although a sample might achieve such preservation if stored in a typical
23 freezer (-20 °C) for two days, it does not necessarily mean that same sample will
24 also be preserved at room temperature (20-25 °C) for five days. *Halliburton*, 514
25 F.3d at 1246 (holding that the claims were indefinite where a person of ordinary
26 skill in the art was left to “make a separate infringement determination for every
27 set of circumstances in which the composition may be used, and [because] such
28 determinations [were] likely to result in differing outcomes (sometimes infringing

and sometimes not)"). To one skilled in the art it is not reasonably clear at what point and under what conditions nucleic acid preservation must be evaluated. Fischetti Decl. ¶¶ 38-40. It would be difficult, if not impossible, for an accused infringer to reasonably determine whether a device is within the scope of the claims of the '187 patent. *Id.* The claims are therefore indefinite.

3. Genotek's Proposed Construction Fails to Answer Fundamental Questions about what the Claims Mean by "Preserving"

Genotek proposes that "preserving" need not be construed and it "should be accorded plain and ordinary meaning." But Genotek does not say what that meaning is. Genotek cites a dictionary definition as support. Dkt. 74-1 at PageID 1806. The dictionary defines "preserve" as "maintain (something) in its original or existing state." Ex. 14 at 488. But Genotek does not advocate that meaning when it proposes a construction. Genotek instead proposes the construction of "slowing degradation." This term appears nowhere in the '187 patent. Indeed, the patent shows nothing about rates of degradation and includes no figures or data showing degradation as a function of time. Genotek also provides no explanation of what it means by "degradation." And "slowing," of course, is a relative term. Thus, Genotek's construction begs the question: slows degradation relative to what? Genotek offers no answer. And neither does the '187 patent—there is no control condition in the '187 patent, *e.g.*, comparing rates of degradation between preserved and unpreserved samples.

In sum, Genotek's proposals of either (i) an unexplained "plain and ordinary meaning" or (ii) the alternative "slowing degradation" would only add to the uncertainty of the '187 patent claims. Because the claims fail to provide sufficient guidance for one skilled in the art to determine with reasonable certainty what falls within the scope of the claims, the claims should be held indefinite. *See, e.g., Halliburton*, 514 F.3d at 1246; *Panavision Imaging, LLC v. OmniVision Techs., Inc.*, 2012 WL 12952006, at *4 (C.D. Cal. May 25, 2012) ("high impedance" was

indefinite because the same device could infringe or not infringe based solely on the external voltage); *Charleston Med. Therapeutics, Inc. v. AstraZeneca Pharmas. LP*, 2015 WL 12607083, at *3-4 (D.S.C. Nov. 25, 2014) (“elevated inflammation” was indefinite because infringement could depend on “the indicator of inflammation used”); *Advanced Aerospace Techs., Inc. v. U.S.*, 124 Fed. Cl. 282, 304, 308-09 (2015) (“being designed to deflect” was indefinite because it depended on numerous external parameters; “kept clear” indefinite because it depended on an unknown, the pilot’s intended flight path).

B. Containment Vessel

Spectrum’s Proposed Construction	Genotek’s Proposed Construction
container	no construction required, plain and ordinary meaning

The “containment vessel” claimed in the ’187 patent is simply a container. “Containment vessel” is not common parlance, and risks confusing the jury. The term appears nowhere in the specification. The specification refers to and depicts the device as having a “container 3.” Ex. 1 at 6:6-65, 14:28-15:39. In prosecution of a related application, Genotek used the same reference numeral “3” to refer to the containment vessel. Ex. 5 at 240. Thus, even Genotek recognizes the two are the same.

During the parties’ meet and confer, Genotek never explained why it believes that Spectrum’s construction is not the plain and ordinary meaning. To avoid jury confusion and to be faithful to the specification of the ’187 patent, the term “containment vessel” should be construed in accordance with its plain and ordinary meaning as a “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”**

Spectrum’s Proposed Construction	Genotek’s Proposed Construction
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	no construction required, plain and ordinary meaning

Claim 1 recites an opening for: (1) receiving a liquid sample; (2) sealably receiving a sealing cap; and (3) receiving a biological sample from the mouth of the user. Ex. 1 at 19:36-42.

The parties’ dispute focuses on two issues: (1) whether the sample must go directly from the mouth of user to the opening, and (2) the size of opening to accommodate that.

1. Genotek Explicitly Defined “receiving a biological sample from the mouth of the user” to Mean “receiving a biological sample directly from the mouth of the user”

“Explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations because ‘[t]he public has a right to rely on such definitive statements made during prosecution.’” *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319, 1325 (Fed. Cir. 2002). Applying prosecution history disclaimer ensures that “claims are ‘not argued one way in order to maintain their patentability and in a different way against accused infringers.’” *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1364 (Fed. Cir. 2017). Statements made in the prosecution of parent applications apply to continuation applications. *See, e.g., Omega Eng’r, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1333 (Fed. Cir. 2003) (“As long as the same claim limitation is at issue, prosecution disclaimer made on the same limitation in an ancestor application will attach.” (internal quotations omitted)).

1 The '187 patent is a continuation of U.S. Patent No. 9,523,115 (the "'115
 2 patent). Ex. 1 at Cover. During prosecution, the Patent Office rejected claims of
 3 the '115 patent over Lawrence. Ex. 4 at 229-234. In arguing over the rejection,
 4 Genotek focused on the limitation "said top having an opening for receiving a
 5 biological sample from the mouth of a user." *Id.* at 220-224. Genotek argued that
 6 Lawrence is "not well adapted to receive sample **directly** from the mouth [of a user]
 7 Although sputum is casually mentioned as a sample [in Lawrence] it is not
 8 clear that the sputum would be delivered directly to the device which is also
 9 engineered to receive an insect, small animal, fungus, plant or animal tissue." Ex. 4
 10 at 221 (emphasis added). The Examiner recognized that Genotek was narrowing
 11 the scope of the limitation, stating that with respect to the limitation "the top has
 12 an opening for receiving a biological sample from the mouth of a user
 13 ***Applicants appear to be construing this to mean that the sample is directly***
 14 ***transferred from the mouth to the opening*** (i.e., spitting into the opening)." Ex. 4
 15 at 195 (emphasis added). Genotek confirmed its understanding of the claim
 16 limitation when it unequivocally argued that the "***specialized purpose of the***
 17 ***present invention*** [was] to receive samples ***directly from the mouth.***" Ex. 4 at 164
 18 (emphasis added). Genotek's explicit, definitive statements during the prosecution
 19 of the '115 patent constitute prosecution history disclaimer. *Techtronic Indus. Co.*
 20 *v. Int'l Trade Comm'n*, 944 F.3d 901, 907 (Fed. Cir. 2019).

21 The claim limitation at issue in the '187 patent is recited *verbatim* from the
 22 '115 patent. Accordingly, Genotek's prosecution disclaimer in the '115 patent
 23 attaches to the '187 patent. Thus, the claim term "for receiving a biological sample
 24 from the mouth of the user" must mean "for receiving a biological sample *directly*
 25 from the mouth of a user, (i.e., spitting into the opening)." *Omega Eng'r*, 334 F.3d
 26 at 1333.

27 ///

28 ///

1 **2. The Specification Explains that the Opening Must be at Least**
 2 **2.0 cm to Receive Sample Directly from the Mouth of the User**

3 With an understanding that the sample is received *directly* from the mouth
 4 of a user, the parties' second dispute relates to the size of the opening necessary for
 5 receiving the sample directly from the user's mouth. Genotek has defined when an
 6 opening would be configured to receive sample directly from the mouth of a user.
 7 Intrinsic and extrinsic evidence supports that the opening must have a diameter of
 8 at least 2.0 cm to receive sample directly from the mouth of the user.

9 The '187 patent claims priority to U.S. Provisional Patent Application
 10 60/386,398 (the "'398 provisional"), which Genotek filed in 2002. Ex. 1 at Cover.
 11 The '187 patent and its underlying '398 provisional teach that the opening must be
 12 at least 2.0 cm to accommodate receiving sample directly from the mouth of a user.
 13 The '398 provisional describes that "[the tube] has ***a wide mouth, approx. 2.5 to 4***
 14 ***cm in diameter*** to make it easier to spit saliva into it." Ex. 6 at 261 ll. 17-20
 15 (emphasis added). When Genotek filed its non-provisional application, it expanded
 16 the permissible size to an opening of at least 2.0 cm. The '187 patent describes the
 17 container as having "***a broad mouth***" to make it easy for a user to deposit
 18 "expectorated sputum" or "expectorated saliva" into the container. Ex. 1 at 15:1-
 19 4 (emphasis added); *see also* Figs. 10-11 (showing the broad mouth opening on the
 20 container). The '187 patent discloses that the "broad mouth" can have an opening
 21 with lower and upper bounds of 2.0 to 7.0 cm, respectively. Ex. 1 at 6:26-39
 22 (describing "the invention" as having a "first region for collecting a biological
 23 sample" that "***can have an opening of from 2.0 to 7.0 cm***, desirably from 2.5 to
 24 3.5 cm, and most desirably 3.0 cm."). Thus, the '187 patent specifies that the broad
 25 mouth opening has a diameter of at least 2.0 cm for receiving the biological sample
 26 directly from the mouth of the user.

27 The extrinsic evidence supports the same conclusion. Genotek's internal
 28 documents indicate that [REDACTED]

1 [REDACTED]

2 [REDACTED] Ex. 18 at 555.

3 **D. Reagent Compartment**

4 Spectrum's Proposed Construction	5 Genotek's Proposed Construction
6 region or section of the [containment vessel]	7 no construction required, plain and ordinary meaning

8 As drafted, it is ambiguous whether the reagent compartment in claim 1 is in the cap or the containment vessel. In an effort to take advantage of this ambiguity, Genotek urges the Court not to construe this term, so Genotek can argue that the claim covers devices with the reagent compartment located in the cap. However, Genotek clearly disavowed any claim scope with the reagent compartment located in the cap. On numerous occasions, Genotek explicitly represented to the Patent Office that the '187 patent describes only devices where the reagent compartment is in the container, not the cap.

15 It is axiomatic that "where the inventor...has manifested that the invention does *or does not include* a particular aspect, that intention is regarded as dispositive." *Techtronic*, 944 F.3d at 907 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)) (emphasis added). "In [this] circumstance, the inventor has 'disavowed' claim scope." *Id.* The Federal Circuit has held that such a disavowal "need not be explicit," but "may be inferred." *Id.* "[A] provisional application can contribute to understanding the claims" and here "it is the deletion from the [provisional] application that contributes understanding of the intended scope of the final application." *MPHJ Tech. Invs., LLC v. Ricoh Americas Corp.*, 847 F.3d 1363, 1369 (Fed. Cir. 2017).

25 As explained above, the '187 patent claims priority to the '398 provisional. The '398 provisional describes a sample collection device or tube having a reagent compartment. The '398 provisional describes one embodiment where the reagent compartment is in the cap of the device and another embodiment where the reagent

1 compartment is in the container. In the non-provisional application, however,
2 Genotek deleted the embodiment with the reagent compartment in the cap.

3 The '398 provisional extensively describes a first embodiment, where the
4 "compartment is the underside of the cap of the container." Ex. 6 at 260, ll.12-13.
5 The '398 provisional states:

6 **"Figure 2. Tube design 'B'.** In this embodiment, the
7 tube is of design A in which the lid has been modified: It
8 contains a small bag (3) containing about 2 milliliters of
9 DNA preserving composition described above or other
10 desired agent. The cap and bag are designed such that the
11 action of tightening the cap both locks the cap and
12 releases the contents of the bag, allowing the DNA
13 preserving solution to mix with the saliva."

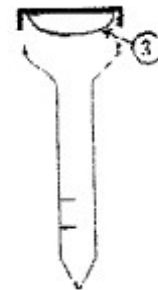


FIGURE 2

14 (*Id.* at p.5, ll.4-9; Figure 2) (emphasis original).

15 The second embodiment described in the '398 provisional is depicted in
16 Figures 3-5, which have the reagent compartment at the bottom of the container.

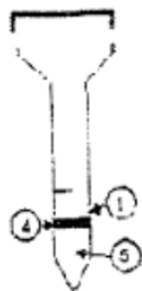


FIGURE 3

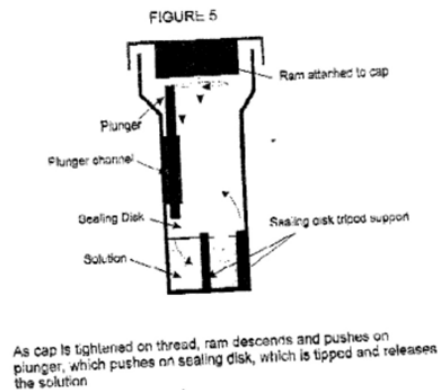
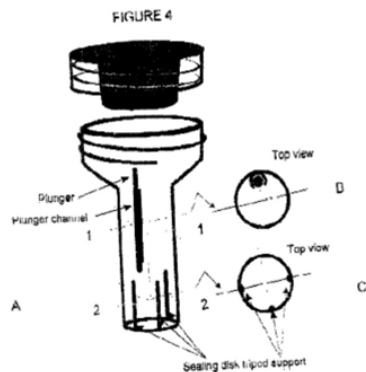
17 **"Figure 3. Tube design 'C'.** This is tube of design
18 A where a septum (4) is introduced into the tube.
19 The septum is made of polyethylene or similar
20 material that can be easily pierced. It is used to seal
21 the DNA preserving composition/solution (5) *in*
22 *the bottom of the tube.* The DNA preserving
23 composition/solution is mixed with the collected
24 saliva and the dried protease (1) by piercing of the
25 septum with a plastic pick, similar to a toothpick."

26 (*Id.* at p.5, ll.11-16, Fig. 3) (first emphasis original; second emphasis added).

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Figures 4 and 5 (reproduced below) also include the reagent compartment in the bottom of the tube but replace the piercable membrane with a sealing cap that pivots on a support.



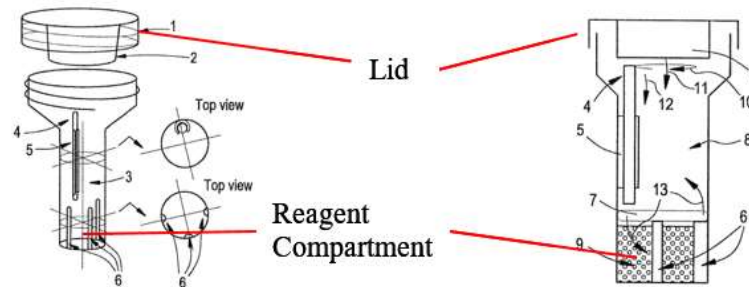
(Ex. 6 at Figs. 4-5).

When Genotek filed its non-provisional application, it deleted all references to the embodiment with the reagent compartment in the cap, including Figure 2 and the associated text quoted above. Genotek included only the embodiments with the reagent compartment in the container, namely the embodiments shown in Figures 3-5 of the '398 provisional.

The '187 patent always describes the reagent compartment (second region) as being in the container, not the lid. Ex. 1 at 6:6-14 (“a second region *of the container*, which is separated from the first region by a barrier” (emphasis added)), 6:26-36 (“The device includes: a container that has a first region ... and a second region containing [reagents], a barrier between the first and second region..., [and] a means for closing the container...”), 6:46-65, 14:49-60, 15:1-13, 15:33-49 (all describing the reagent compartment in the container, and a separate lid). Moreover, Figures 10 and 11 in the '187 patent correspond to Figures 4 and 5 of the '398 provisional, and show the reagent compartment being in the container, not the lid. Compare Ex. 1 at Figs. 10-11 (below), with Ex. 6 at Figs. 4-5.

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In fact, Genotek did not leave a single reference in the '187 patent to an embodiment with the reagent compartment in the cap.

In *MPHJ*, the Federal Circuit found that the patentee's deletion of material from a provisional application directly affected claim construction. 847 F.3d at 1369. There, the patentee sought a narrow construction of a claim term to escape a validity challenge. *Id.* at 1368. The patentee pointed to descriptions and limiting statements in its provisional application to argue that the claim term at issue was narrow in scope. *Id.* The Federal Circuit rejected the patentee's arguments because, like the '187 patent, the disclosure in the provisional application were deleted from the specification of the patent-in-suit. *Id.* The court stated that "the deletion from the '798 Provisional application [] contributes understanding of the final scope of the final application" and relied upon the patentee's deletion of the disclosure from the provisional application in construing the claim term at issue. *Id.* Similarly, the Court should adopt Spectrum's construction because Genotek disavowed a reagent compartment in the cap when it deleted all description of that from the provisional.

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Moreover, consistent with this disavowal, Genotek has repeatedly represented to the public and the Patent Office that the disclosure of the '187 patent is limited to the reagent compartment located in the container. In 2006, Genotek filed U.S. Patent No. 8,221,381 ("381 patent"). The '381 patent listed as an inventor the sole inventor of the '187 patent, Dr. Birnboim. As shown in annotated Figure 24 from the '381 patent, like the '187 patent, Genotek's '381 patent discloses a sample collection device with a reagent chamber for releasably storing a substance. However, the '381 patent was specifically directed to a reagent compartment in the *cap* of the device. Ex. 10 at Fig. 24 (annotations added), 4:24-33 ("Lid 100 releasably stores a substance.... [R]eservoir 102 for holding a substance...").

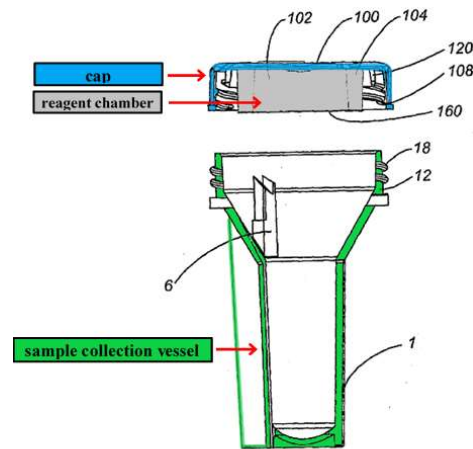


FIG. 24

In the background of the '381 patent, Genotek distinguished the '187 patent by describing the reagent compartment in the container, not the cap as disclosed in the '381 patent. Genotek described the container of the '187 patent as follows: "This *container has* a first region for collecting a biological sample, *a second region containing a composition for preserving nucleic acid*, and a barrier between the first region and a second region." Ex. 10 at 1:50-59 (emphases added). Genotek thus distinguished its own disclosure to obtain a patent specifically directed to a reagent compartment in the cap.

Later, in 2016, during a validity challenge to the '381 patent, Genotek argued that the reagent compartment of the '187 patent cannot be in the lid. There, Ancestry.com DNA, LLC ("Ancestry") petitioned for *inter partes* review ("IPR") of Genotek's '381 patent, relying on the disclosure of the '187 patent family as prior art (referred to as "Birnboim" in the proceedings). See Ex. 9 at 288. Ancestry

1 argued, *inter alia*, that it would have been obvious to modify Birnboim to put the
 2 reagent compartment in the lid. In opposing the IPR, Genotek represented that
 3 Birnboim describes a “very different device[]” than those with a reagent
 4 compartment in the lid because Birnboim has “a reagent below a plastic cover in a
 5 container.” *Id.* at 326-27. The Patent Office denied institution of Ancestry’s IPR
 6 petition based, in part, on this understanding of Birnboim’s disclosure. Ex. 8 at
 7 276-79.

8 The Patent Office explained: “As Patent Owner [Genotek] points out,
 9 Petitioner does not explain sufficiently why one of ordinary skill in the art would
 10 have considered combining the container of Birnboim with certain features of the
 11 container of O’Donovan to arrive at the claimed invention.” Ex. 8 at 277.

12 To be clear, Spectrum is not arguing that Genotek’s subsequent admissions
 13 amount to estoppel. Rather, Genotek’s admissions are probative evidence showing
 14 that Genotek understood its invention in the ’187 patent to be limited to the reagent
 15 compartment in the container. *See Neev v. Alcon Labs., Inc.*, 2016 WL 9051170,
 16 at *8 n.2 (C.D. Cal. Dec. 22, 2016) (inventor’s characterizations of the asserted
 17 patent in his subsequent patents were extrinsic evidence supporting construction).

18 Genotek disavowed any scope to a reagent compartment in the cap when it
 19 deleted specific embodiments from its provisional application. Genotek’s
 20 subsequent representations and arguments characterizing the invention of the ’187
 21 patent confirmed its understanding that the ’187 patent encompassed only a reagent
 22 compartment in the container of the device.

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

Spectrum’s Proposed Construction	Genotek’s Proposed Construction
Means-plus-function under 35 U.S.C. § 112, ¶ 6	no construction required, plain and ordinary meaning

1. **35 U.S.C. § 112, ¶ 6 Applies When a Claim Recites a Function Without Sufficient Structure for Performing that Function**

Historically, patentees used functional claiming to achieve broader patent coverage by claiming the end the invention accomplishes, not the means of getting there.⁶ The following two claims are illustrative: (1) a vehicle comprising a chassis and four wheels, and (2) a means for transporting objects or people at high velocities. *Id.* Although both claims are directed to an automobile, the second claim could potentially cover much broader scope than the first, e.g., a car, a speed boat, a plane. *Id.*

Functional claiming dates back to the beginning of the U.S. patent system, and the Wright Brothers even used it to claim portions of their airplane. *Id.* at 902. However, in 1946, the Supreme Court prohibited the use of functional claiming in an apparatus claim, warning of the “broadness, ambiguity, and overhanging threat of [a] functional claim.” *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 13 (1946). In invalidating the claim at issue, the Court held “a patentee cannot obtain greater coverage by failing to describe his invention than by describing it as the statute commands.” *Id.* The Court reasoned that the claim before it would have been valid had the patentee claimed “the machine he claims to have invented [instead of functionally claiming] broad rights to bar the use of all devices now or hereafter known” that perform the claimed function. *Id.*

⁶ Joel Bradley, *Patent Law and Means-Plus-Function Claim Language: Where It Was, Where It Is (Post Williamson v. Citrix), and Where it Should Go In the Future*, 52 Ga. L. Rev. 897, 899 (2018)

1 In 1952, Congress enacted 35 U.S.C. § 112, ¶ 6, to allow functional claiming,
2 but with express limitations. As the Federal Circuit has explained:

3 Congress, in enacting this provision, ‘struck a balance in allowing
4 patentees to express a claim limitation by reciting a function to be
5 performed rather than by reciting structure for performing that
6 function,’ while ‘placing specific constraints on how such a limitation
7 is to be construed’—that is, by **restricting the ‘scope of coverage to
8 only the structure, materials, or acts described in the specification**
9 as corresponding to the claimed function and equivalents thereof.’

10 *Diebold Nixdorf, Inc. v. Int’l Trade Comm’n*, 899 F.3d 1291, 1297 (Fed. Cir. 2018)
11 (emphasis added) (quoting *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1347
12 (Fed. Cir. 2015) (en banc)).⁷

13 To determine whether a claim invokes § 112, ¶ 6, courts look at the language
14 of the claim. Claims reciting a “means” create a rebuttable presumption that the
15 statute applies, whereas the absence of the word “means” creates a rebuttable
16 presumption that the statute does not apply. *See Williamson*, 792 F.3d at 1348.

17 Under *Williamson*, the threshold test for §112, ¶ 6 is a fact-dependent
18 inquiry. If the claim limitation in dispute lacks the word “means” but recites a
19 function, the court must consider the recited function to determine whether the
20 limitation is subject to §112, ¶ 6. *Synchronoss Techs., Inc. v. Dropbox, Inc.*, 987
21 F.3d 1358, 1367 (Fed. Cir. 2021). “The question is not whether a claim term recites
22 any structure but whether it recites sufficient structure—a claim term is subject to
23 [§ 112, ¶ 6] if it recites ‘**function without reciting sufficient structure for**
24 **performing that function.**’” *Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1374
25 (Fed. Cir. 2020) (emphasis in original) (internal citations omitted).

26
27 ⁷ In 2012, as part of the America Invents Act, Congress reorganized Section
28 112 such that § 112, ¶ 6 became § 112(f) for patent applications filed on or after
September 16, 2012. The language of pre-AIA § 112, ¶ 6 and § 112(f) is identical.

1 If the Court determines that a limitation invokes §112, ¶ 6, “[t]hen, the Court
 2 must determine what structure, if any, disclosed in the specification corresponds to
 3 the claimed function.” *Williamson*, 792 F.3d at 1351. “Structure disclosed in the
 4 specification qualifies as ‘corresponding structure’ if the intrinsic evidence clearly
 5 links or associates that structure to the function recited in the claim.” *Id.* at 1352.
 6 If there are multiple claimed functions, the patentee must disclose adequate
 7 corresponding structure to perform all of the functions. *Id.* at 1351-52.

8 **2. The Claims Do Not Recite Sufficient Structure to Perform the**
 9 **Claimed Function of Disestablishing the Barrier**

10 Claim 1 of the ’187 patent is directed to a “device for receiving and
 11 preserving nucleic acid.” Ex. 1 at 19:34-59. The claim requires, *inter alia*, a
 12 container with an opening for depositing sample, a sealing cap, a reagent
 13 compartment, and a barrier that seals reagents in the reagent compartment. *Id.* The
 14 claim requires that “when sealably closing said opening with said sealing cap, the
 15 barrier mechanically disestablishes to release said reagents” *Id.* In a classic
 16 example of functional claiming, the claim recites the function of mechanically
 17 disestablishing the barrier to release the reagents, but the claim does not identify
 18 any structure for performing that function. The reason is clear. The specification
 19 includes a single structural assembly for disestablishing the barrier, but Genotek
 20 wants to encompass all devices now or hereafter known that perform the claimed
 21 function. This is directly contrary to established precedent.

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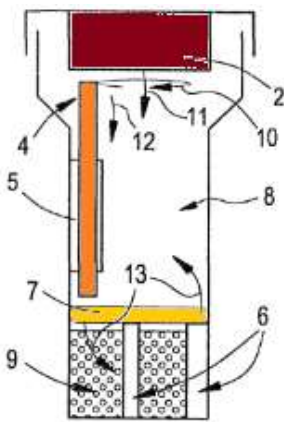
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1 The '187 patent discloses only a crude stick-like projection called a
 2 "plunger" to either puncture a barrier or move a pivoting disc that acts as a barrier,
 3 thereby releasing reagent into the sample collection device. Ex. 1 at 6:17-24, 15:17-
 4 28, 15:33-49. The plunger is shown, for example, in Figure 11, reproduced with



colored annotations. Ex. 1 at Fig. 11. "As the cap is
 twisted on (shown by dotted line and arrow 10[]), ram 2
 [red], which is attached to cap 1, moves downward as
 shown by dotted line arrow 11. This downward
 movement forces plunger 4 [orange], ... downward as
 indicated by dotted line [11] and arrow 12. The
 downward movement of the plunger 4 forces sealing
 disc 7 [yellow] to pivot Pivoting of disc 7
 disestablishes the barrier."

14 *Id.* at 15:39-46; *see also id.* at 6:60-65 ("connecting screw-on lid to a plunger
 15 mechanism").

16 Without invoking § 112, ¶ 6, Genotek's functional claiming would stretch
 17 the scope of the claim to potentially encompass any structure that performs the
 18 claimed function. This is precisely the "broadness, ambiguity, and overhanging
 19 threat" of functional claiming that the Supreme Court warned against in
 20 *Halliburton*. As claim 1 does not recite sufficiently definite structure to perform
 21 the claimed function of mechanically disestablishing the barrier, § 112, ¶ 6 applies
 22 to tether the functional language to the actual structure that the patentee disclosed
 23 in the specification. *See Williamson*, 792 F.3d at 1349-51.

24 The prosecution history also highlights that the "disestablishing" limitation
 25 is a means-plus-function limitation. Originally, claim 1 required "**closing means**
 26 and **disruption means**, said disruption means for engaging said barrier whereby
 27 when sealably closing said opening with said closing means, said **disrupting means**
 28 mechanically disestablishes said barrier to release said reagents" Ex. 3 at 95

(pending claim 30) (emphases added). The Examiner recognized that claim 1 invoked means-plus-function claiming and rejected the claim as indefinite for failing to “clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function of the ‘disruption means.’” Ex. 3 at 89-90.

In response, Genotek submitted the following amendment, removing the presumptive means-plus-function language “closing means” and “disruption means.”

d. ~~the sealing cap, closing means and disruption means, said disruption means for engaging said barrier~~ whereby the device is configured such that, when sealably closing said opening with said sealing cap ~~closing means, the barrier said disrupting means~~ mechanically disestablishes ~~said barrier~~ to 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.

Ex. 3 at 71.⁸ Importantly, Genotek did nothing to identify any structure to perform the claimed function of mechanically disestablishing the barrier. Instead, Genotek merely switched to passive voice, “the barrier mechanically disestablishes,” and avoided identifying any structure for performing that function.

Where there are multiple claimed functions, the patentee must disclose adequate corresponding structure to perform each of those claimed functions. *Williamson*, 792 F.3d at 1351-52. Here, Genotek added “sealing cap” as structure to perform the function of the “closing means,” which is to sealably close the container’s opening. However, Genotek never added any structure in place of the deleted “disruption means” for “mechanically disestablish[ing] the barrier.” Thus, issued claim 1 recites the function of mechanically disestablishing the barrier without reciting sufficient structure for performing that claimed function.

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⁸ Underlines reflecting additions; strikethroughs reflecting deletions

1 The facts are analogous to *Intelligent Auto. Design, LLC v. Zimmer Biomet*
 2 *CMF and Thoracic, LLC.*, 799 Fed. Appx. 847, 850-51 (Fed. Cir 2020). There, the
 3 Federal Circuit analyzed two claims from the same patent to determine whether
 4 § 112, ¶ 6 applies. *Id.* Both claims 1 and 6 included the same functional language,
 5 “determining a time when torque reaches a maximum.” *Id.* Although the plaintiff
 6 did not contest that claim 1 implicated § 112, ¶ 6, it disputed that the same phrase
 7 in claim 6 was also a means-plus-function limitation. In holding that claim 6 also
 8 invoked § 112, ¶ 6, the Federal Circuit held that “the same phrase in different claims
 9 of the same patent should have the same meaning unless it is clear that the same
 10 phrase has different meanings in different claims.” *Id.* at 851 (internal citations
 11 omitted). The court held that although claim 6 added a “control circuit,” that
 12 structure does not change the meaning of the functional limitation, “nor does it
 13 provide enough description of the structure to render the limitation structural, rather
 14 than functional.” *Id.*

15 Here, the claimed function of mechanically disestablishing the barrier has
 16 the same meaning in the original claim and the amended claim. Genotek’s addition
 17 of “sealing cap” does not change the meaning of the functional limitation nor does
 18 it add sufficient structure to perform the claimed function. *Arsus, LLC v. Tesla*
 19 *Motors, Inc.* is illustrative. There, the plaintiff argued that a steering wheel was
 20 sufficient structure to perform the claimed function of “prevent[ing] said vehicle
 21 from being steered beyond a rollover threshold of said vehicle.” *Arsus, LLC v.*
 22 *Tesla Motors, Inc.*, 2021 WL 5889383, *3 (N.D. Cal. Dec. 13, 2021). In rejecting
 23 the argument and applying § 112, ¶ 6, the court reasoned that “[w]hile every
 24 ordinary car has a steering wheel, the vast majority of cars do not have an apparatus
 25 to prevent steering to the point of rollover, through the structure of the steering
 26 wheel or otherwise.” *Id.* Here, although most collection devices have a sealing
 27 cap, these structures do not normally include any apparatus to mechanically
 28 disestablish a barrier. Claim 1 of the ’187 patent does not recite sufficient structure

1 to mechanically disestablish the barrier, and § 112, ¶ 6 applies.

2 **3. The Corresponding Structure**

3 Section 112 ¶ 6 requires looking to the specification to determine the
4 corresponding structure. *Nomos Corp. v. Brainlab USA, Inc.*, 357 F.3d 1364, 1367-
5 68 (Fed. Cir. 2004). The corresponding structure should be limited to “that which
6 is necessary to perform the recited function.” *Id.* Here, as discussed above, the
7 specification describes the necessary structures as a cap having a ram, and a
8 plunger. Each of the cap, ram, and plunger are necessary to perform the claimed
9 function of mechanically disestablishing the barrier. If any is removed, the
10 specification provides no description of how the claimed function of mechanically
11 disestablishing the barrier could be performed. Thus, the corresponding structure
12 is “a cap having a ram, and a plunger.”

13 **F. Linear Actuator**

14 Spectrum’s Proposed Construction	Genotek’s Proposed Construction
15 Indefinite; Alternatively: a cap 16 having a ram, and a plunger	A device that converts linear motion into rotational motion and/or vice versa

17 Asserted dependent claims 21 and 26 recite a “linear actuator.” For example,
18 claim 21 recites: “wherein the barrier is configured to disestablish when displaced
19 by a linear actuator.” Genotek’s proposed construction of “linear actuator”
20 highlights that the mechanically disestablishing limitation of claim 1 is means-plus-
21 function and invokes § 112, ¶ 6. Under Section 112, a dependent claim must
22 necessarily be narrower than the claims from which it depends. 35 U.S.C. § 112,
23 ¶ 4. However, even Genotek’s proposed construction for the narrower limitation
24 “linear actuator” does not include any structure for performing the claimed function
25 of mechanically disestablishing the barrier. Instead, Genotek’s proposed
26 construction is purely functional: “a device that converts linear motion into
27 rotational motion and/or vice versa.” The Federal Circuit has explicitly held that
28 the word “device” does not convey any structure. *Williamson*, 792 F.3d at 1350-

51 (“Generic terms such as ... ‘device,’ and other nonce words that reflect nothing more than verbal constructs may be used in a claim in a manner that is tantamount to using the word ‘means’ because they ‘typically do not connote sufficiently definite structure.”). The only thing disclosed in the ’187 patent that converts rotational motion into linear motion is the ram and plunger discussed above.

As explained above, claim 1 invokes § 112, ¶ 6 and should be limited to the ram and plunger disclosed in the specification. *Supra* Section III.E. If the Court were to accept Genotek’s proposed broad functional construction of linear actuator, it would render claims 21 and 26 invalid for improperly broadening the scope of claim 1 beyond the ram and plunger of claim 1. A dependent claim that fails to narrow the scope of the claim from which it depends is invalid. *Pfizer, Inc. v. Rabaxys Labs. Ltd.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006) (holding dependent claim invalid because it “does not properly narrow the scope” of independent claim); *Amgen Inc. v. Hospira, Inc.*, 2016 WL 7013483, at *4 (D. Del. Nov. 30, 2016) (holding dependent claim invalid “because it contradicts a limitation” of independent claim).

Genotek’s proposed construction of “linear actuator” is broader than “a cap having a ram, and a plunger.” The specification never uses the term “linear actuator,” or even “actuator.” As explained above, the specification only discloses a cap having a ram and plunger for performing the function of mechanically disestablishing the barrier. *Supra* Section III.E. Under any reading, Genotek’s proposed construction of “linear actuator” would be broader than a ram and plunger and would render dependent claims 21 and 26 invalid under 35 U.S.C. § 112, ¶ 4. *Pfizer, Inc.*, 457 F.3d at 1291-92; *Amgen Inc.*, 2016 WL 7013483, at *4.

The term “linear actuator” in asserted claims 21 and 26 cannot broaden the scope of claim 1, from which claims 21 and 26 depend. The only possible construction for the term, which is not found in the specification of the ’187 patent, is “a cap having a ram, and a plunger.” As explained above, this is the only

1 structure the specification discloses for performing the function of mechanically
 2 disestablishing the barrier. *Supra* Section III.E. The '187 patent has no enabling
 3 disclosure for any other structure that performs this function, which weighs against
 4 a broader construction. *Digit. Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344
 5 (Fed. Cir. 1998) (construction that is clearly enabled should be adopted over a
 6 “broader one [that] raises questions of enablement”). The patentee simply did not
 7 invent anything but a ram and a plunger. *Supra* Section III.E. Thus, in view of the
 8 intrinsic evidence, the Court should reject Genotek’s overly broad proposed
 9 construction.

10 **G. Associates With**

11 Spectrum’s Proposed Construction	Genotek’s Proposed Construction
12 contacts	The term does not require construction 13 and should be accorded its plain and ordinary meaning

14 Spectrum has set forth its position for the term “associates with” in
 15 connection with the '646 patent. Spectrum seeks to construe the term in connection
 16 with the '187 patent for consistency in the case. The '187 patent does not use the
 17 word “associates” in relation to mechanical components. Yet, the only examples
 18 in the context of an association between the cap and the containment vessel require
 19 contact. Ex. 1 at Figs. 10-11. Further, Claim 34’s recitation that the association
 20 “create a fluid-tight seal” requires contact between the components.

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1 **IV. DISPUTED TERMS OF THE '646 PATENT**

2 **A. A Biological Sample and Preserving a Biological Sample**

3 “biological sample”

4 Spectrum’s Proposed Construction	Genotek’s Proposed Construction
5 Cells	The term does not require construction and should be accorded its plain and ordinary meaning

6 “Preserving a [biological sample]”

8 Spectrum’s Proposed Construction	Genotek’s Proposed Construction
9 Preventing cells from having their 10 antigens degraded such that they can 11 be purified or enriched based on their 12 antigens, and preventing alterations in 13 the cellular epigenome	The term does not require construction and should be accorded its plain and ordinary meaning. If a construction is required: “slowing degradation of a biological sample”

14 While claim terms are not construed in light of an accused device, a court
15 can appropriately consider the accused device to provide context to a claim
16 construction dispute. *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442
17 F.3d 1322, 1327 (Fed. Cir. 2006); *Pall Corp. v. HemasurrInc.*, 181 F.3d 1305, 1308
18 (Fed. Cir. 1999) (“Although the construction of the claim is independent of the
19 device charged with infringement, it is convenient for the court to concentrate on
20 those aspects of the claim whose relation to the accused device is in dispute.”).
21 Spectrum’s accused product at issue here includes reagents that destroy or lyse the
22 cells in a saliva sample. This provides relevant context for the parties’ claim
23 construction dispute.

24 The clause at issue in Claim 1 of the ’646 patent is “preserving a biological
25 sample.” In the context of the parties’ dispute, the ultimate question to be answered
26 is whether “preserving a biological sample” requires preserving the cells that make
27 up the biological sample or whether the claim term could encompass something

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1 that destroys the cells in the sample. As described below, the '646 patent makes
2 crystal clear that the cells of sample must be preserved.⁹

3 Neither “preserving a biological sample” nor even “biological sample”
4 appears anywhere in the specification of the '646 patent. Similarly, neither term
5 appears in any claim of the parent applications to the '646 patent. This is because
6 Genotek introduced the term in 2018 when it filed proposed claims in a
7 continuation application after it acquired the patents from the inventors who had
8 filed their application in 2012. As described below, this new “preserving a
9 biological sample” terminology cannot properly be construed to encompass
10 something other than what the inventors described as their invention, *i.e.*,
11 “preserving cells.”

12 Looking at what the inventors actually regarded as their invention (*i.e.*, what
13 is described in the patent), “cell” or “cells” appears hundreds of times. And the
14 patent repeatedly discusses preserving cells. One need read no further than the
15 Abstract of the patent to understand the '646 patent is directed to preserving the
16 cells of a biological sample so the cells can be isolated: “devices ... for collecting
17 and processing samples of bodily fluids containing *cells*,” “the disclosure generally
18 relates to ... the isolation and *preservation of cells* from saliva and other bodily
19 fluids,” “processing to extract a plurality of *cells*,” and “isolate one and/or another
20 *cell type* therefrom.” Ex. 2 at Abstract (emphases added).

21 The '646 patent’s Field of the Disclosure explains that the patent relates to
22 the “isolation and preservation of cells” from bodily fluids. *Id.* at 1:25-27. The
23 '646 patent’s Background of the Invention describes the need the invention
24 addressed – a device that enables collecting and preserving cells so they can be
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26 _____
27 ⁹ The parties broke up “preserving a biological sample” into two subparts
28 (“preserving” and “a biological sample”) in the parties’ Joint Claim Construction
Hearing Statement, Chart, and Worksheet. Dkt. 74. Because the subparts are so
interrelated Spectrum addresses them together in this brief.

1 isolated for epigenetic studies. *Id.* at 2:63-67; 3:57-59; 4:37-49. The '646 patent's
 2 Summary of the Disclosure also repeatedly discusses preserving and isolating cells.
 3 *Id.* at 4:56-61, 6:5, 6:31, 6:38, 6:50-51, 6:61-62, 7:7-11, 7:54-55, 8:11-14. And
 4 nowhere does the Summary mention preserving anything other than the cells of a
 5 bodily fluid. The '646 patent's Detailed Description of the Embodiments also
 6 repeatedly describes the preservation and isolation of cells. *Id.* at 9:44-47; 9:63-
 7 65; 16:9-10; 16:11-12; 16:23-24; 16:38-40; 16:44; 16:50; 16:62; 17:15-16; 17:20;
 8 17:30-31; 19:14-15. And finally, the Example of the patent describes "Isolating T-
 9 Cells from a Bodily Fluid (e.g., Saliva)." *Id.* at 18:61-19:40; *see also* Figs. 8-10
 10 (demonstrating yield of isolated T-cells after storage in preservation solution).

11 In view of the '646 patent's repeated and consistent description that the
 12 invention was directed to preserving cells, there can be no legitimate dispute that
 13 "preserving a biological sample" requires preserving the cells in the sample. *See,*
 14 *e.g., Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1338 (Fed. Cir.
 15 2011) (affirming construction of "source" in a car radio patent as appropriately
 16 limited to a fixed source of broadcast on a specified frequency rather than satellite
 17 signals because specification characterized source as radio stations); *Ormco Corp.*
 18 *v. Align Tech., Inc.*, 498 F.3d 1307, 1313-14 (Fed. Cir. 2007) (affirming
 19 construction of orthodontics patent claims to require automatic determination of
 20 finish tooth position where specification indicates a clear emphasis on automatic
 21 determination and described such as a primary objective of the invention);
 22 *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006)
 23 (affirming construction of "fuel injection system component" as limited to a fuel
 24 filter where written description described it as such, e.g., "the invention relates to
 25 a fuel filter").

26 Once it is settled that cells must be preserved, the meaning of "preserving"
 27 is clear in the context of the '646 patent. The patent explicitly defines it:
 28 "'preserving cells' means preventing the cells from having their antigens degraded,

such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome.” Ex. 2 at 16:23-27. And when a patent defines a term, that definition controls. *Biogen MA Inc. v. EMD Serono, Inc.*, 976 F.3d 1326, 1336 (Fed. Cir. 2020).

For these reasons, the Court should adopt Spectrum’s construction of “preserving a biological sample.” Spectrum’s construction is consistent with the description in the patent regarding what is to be preserved (cells) and the explicit definition in the patent as to what preserving the cells means.

B. Annular Valve

Spectrum’s Proposed Construction	Genotek’s Proposed Construction
ring shaped valve	valve with two cylinders where the cylinders move relatively to open/close the valve

Spectrum’s construction adopts the plain meaning of “annular”—ring shaped. *See* Ex. 13. The specification of the ’646 patent uses annular several times, each to describe something that is ring shaped, consistent with that plain meaning. The most common use of “annular” in ’646 patent is to refer to the “annular blocking member” shown in Figure 3A. Ex. 2 at 5:37-55, 8:49-58, 10:65-11:7, 14:7-15:5. The “annular blocking member” is indisputably ring shaped. Similarly, the “tamper evident feature 160,” depicted as ring shaped in Figure 7, is described as both an “annular member” and a “ring.” Ex. 2 at Fig. 7A-7B, 9:21-28, 15:49-67.

The Federal Circuit has cautioned that the construction of a claim limitation should not render other limitations “meaningless.” *E.g., Bicon Inc. v. Straumann Co.*, 441 F.3d 945, 950-51 (Fed. Cir. 2006) (refusing to adopt a construction that would render other limitations “meaningless”). It is also improper to construe “a claim term to include features of that term already recited in the claims.” *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1237-38 (Fed. Cir. 2016). But this is precisely what Genotek’s proposed construction does. For example, Claim 1

1 already requires that the valve include two cylinders (inner and outer). Ex. 2 at
 2 22:23-41. Likewise, the claim already recites relative movement of the cylinders
 3 to open/close the valve because the vent of the inner cylinder is claimed as being
 4 obstructed by the outer cylinder when the valve is closed and not obstructed by the
 5 outer cylinder when the valve is open. Ex. 2 at 22:32-47. Genotek's construction
 6 renders multiple limitations of Claim 1 meaningless and should be rejected. *Bicon*,
 7 441 F.3d at 950-51.

8 C. The Associate Terms

Claim Terms	Spectrum's Proposed Construction	Genotek's Proposed Construction
associate with / associated with / association with / association of / configured to associate with	contact / contacting / contact / contact between / configured to contact	The term does not require construction and should be accorded plain and ordinary meaning.

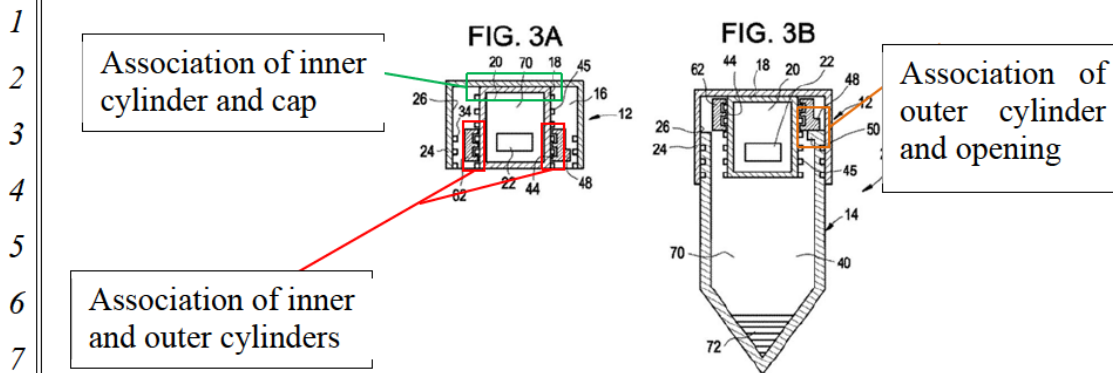
15 Claim 1 of the '646 patent uses "associate" or variations thereof in several
 16 contexts: (1) the inner cylinder of the annular valve is "in fluid-tight **association**
 17 with the cap"; (2) the outer cylinder is "in fluid-tight **association** with the inner
 18 cylinder and **associated** with the opening of the sample collection reservoir;" and
 19 (3) the annular valve is "configured to **associate** with the cap and with the opening
 20 of the sample collection reservoir." However, the word "associate" (or variations
 21 thereof) appears in the specification in only a handful of instances, none of which
 22 describe the uses recited in Claim 1. Ex. 2 at 2:4-7, 5:59-63, 12:10-14, 15:40-45.

23 Genotek represented to the Patent Office that Claim 1 of the '646 patent
 24 draws support from Figures 3A and 3B in the patent specification. Ex. 7 at 268.
 25 These figures are excerpted below, with the associations recited in Claim 1 labeled.

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Ex. 2 at Figs. 3A & 3B. In each instance, the components said to be associated in the claim are in contact. And the patent specification reinforces that the components of the device claimed to be “associated” physically contact. For example, the specification describes how placing the cap onto the tube causes “coupling features 48 of the annular blocking member 62 [the outer cylinder recited in the claims] *to engage* the coupling member 50 of the tube 14 [the opening of the sample collection reservoir recited in the claims].” Ex. 2 at 14:63-65 (emphasis added). If the blocking member does not contact the opening of the tube it would not move up as shown in Figure 3B. The contact is required for the invention to work. The inventors did not describe any invention where an outer cylinder of a valve moves to release the contents of a reagent compartment by anything other than contact with the opening of the sample collection reservoir.

Despite this consistent intrinsic record, Genotek seeks to avoid any interpretation of “associate” (and variations thereof) to enable it to later argue that components of a device that do not contact each other are “associated.” Such an argument would be inconsistent with the invention described in the patent.

Spectrum submits that the Court should adopt a construction that “associate” and variations thereof as used in Claim 1 of the ’646 patent require “contact” between the referenced components of the device consistent with the invention described in the patent.

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Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 18, 2022 By: s/ Ali S. Razai
Joseph F. Jennings
Ali S. Razai
Paul N. Conover
Nicholas M. Zovko
Brandon G. Smith

Attorneys for Defendant
SPECTRUM SOLUTIONS L.L.C.

CERTIFICATE OF SERVICE

I hereby certify that on February 18, 2022, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following person(s):

Brian M. Kramer
BMKramer@mofo.com
John R. Lanham
JLanham@mofo.com
Candice F. Heinze
CHeinze@mofo.com
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
Telephone: 858.720.5100

I certify and declare under penalty of perjury under the laws of the State of California that I am employed in the office of a member of the bar of this Court at whose direction the service was made, and that the foregoing is true and correct.

Executed on February 18, 2022, at Irvine, California.



Claire A. Stoneman

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