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UNITED STATES PATENT AND TRADEMARK OFFICE

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**PATENT TRIAL AND APPEAL BOARD**

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SPECTRUM SOLUTIONS LLC

Petitioner

v.

DNA GENOTEK INC.

Patent Owner

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IPR2023-01424  
Patent 11,536,632

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**PETITIONER'S OPPOSITION TO PATENT OWNER'S  
NON-CONTINGENT MOTION TO AMEND**

## TABLE OF CONTENTS

|                                                                                                                                                                          | Page No. |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| I. INTRODUCTION .....                                                                                                                                                    | 1        |
| II. THE CLAIMS REMAIN UNPATENTABLE BASED ON<br>GROUNDS 1 AND 2 IN THE PETITION .....                                                                                     | 2        |
| III. THE SUBSTITUTE CLAIMS DO NOT REQUIRE THE FIRST<br>AND SECOND CYLINDERS TO BE HOUSED ENTIRELY<br>WITHIN THE BOUNDARIES DEFINED BY THE OUTER<br>WALL OF THE CAP ..... | 5        |
| IV. THE SUBSTITUTE CLAIMS ARE UNPATENTABLE UNDER<br>PO’S FLAWED CONSTRUCTION .....                                                                                       | 11       |
| A. Plante and Cho Render Obvious Substitute Claims 21-24,<br>26-36, 48-40 .....                                                                                          | 11       |
| 1. A POSA Would Have Been Motivated to Modify<br>Cho .....                                                                                                               | 13       |
| 2. A POSA Would Have Had a Reasonable Expectation<br>of Success.....                                                                                                     | 16       |
| B. Plante, Cho, and Patterson Render Obvious Substitute<br>Claim 25 .....                                                                                                | 18       |
| C. The Substitute Claims Lack Written Description Support .....                                                                                                          | 19       |

## TABLE OF AUTHORITIES

### Page No(s).

|                                                                                                                |        |
|----------------------------------------------------------------------------------------------------------------|--------|
| <i>Abbott Labs. v. Andrx Pharms., Inc.</i> ,<br>452 F.3d 1331 (Fed. Cir. 2006) .....                           | 18     |
| <i>Acumed LLC v. Stryker Corp.</i> ,<br>483 F.3d 800 (Fed. Cir. 2007) .....                                    | 6      |
| <i>Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.</i> ,<br>340 F.3d 1298 (Fed. Cir. 2003) .....      | 11     |
| <i>Ariad Pharms., Inc. v. Eli Lilly &amp; Co.</i> ,<br>598 F.3d 1336 (Fed. Cir. 2010) ( <i>en banc</i> ) ..... | 21     |
| <i>In re Epstein</i> ,<br>32 F.3d 1559 (Fed. Cir. 1994) .....                                                  | 18     |
| <i>Hockerson-Halberstadt, Inc. v. Avia Group. Int’l, Inc.</i> ,<br>222 F.3d 951 (Fed. Cir. 2000) .....         | 20     |
| <i>KSR Int’l Co. v. Teleflex Inc.</i> ,<br>550 U.S. 398 (2007) .....                                           | 15     |
| <i>Neomagic Corp. v. Trident Microsystems, Inc.</i> ,<br>287 F.3d 1062 (Fed. Cir. 2002) .....                  | 8      |
| <i>Phillips v. AWH Corp.</i> ,<br>415 F.3d 1303 (Fed. Cir. 2005) ( <i>en banc</i> ) .....                      | 6      |
| <i>Seabed Geosolutions (US) Inc. v. Magseis FF LLC</i> ,<br>8 F.4th 1285 (Fed. Cir. 2021) .....                | 10, 20 |
| <i>Smith &amp; Nephew, Inc. v. Rea</i> ,<br>721 F.3d 1371 (Fed. Cir. 2013) .....                               | 18     |
| <i>Trs. of Columbia Univ. in City of New York v. Symantec Corp.</i> ,<br>811 F.3d 1359 (Fed. Cir. 2016) .....  | 8      |

**TABLE OF AUTHORITIES**  
*(cont'd)*

**Page No(s).**

**OTHER AUTHORITIES**

|                          |    |
|--------------------------|----|
| 35 U.S.C. § 112 .....    | 2  |
| 35 U.S.C. § 316 .....    | 19 |
| 37 C.F.R. § 41.121 ..... | 19 |
| 37 C.F.R. § 42.6 .....   | 23 |
| MPEP § 2173.05 .....     | 20 |

## EXHIBIT LIST

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                        |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1001               | U.S. Patent No. 11,536,632 to Biadillah, et al.                                                                                                           |
| 1002               | Declaration of Karl R. Leinsing, MSME, PE                                                                                                                 |
| 1003               | U.S. Patent Pub. No. US 2012/0325721 to Plante, et al. (“Plante”)                                                                                         |
| 1004               | International Patent Publication No. WO 2005/051775 to Cho (“Cho”)                                                                                        |
| 1005               | Certified Translation of Japanese Patent Application Publication No. 2010-213660 to Ueda (“Ueda”)                                                         |
| 1006               | Japanese Patent Application Publication No. 2010-213660 to Ueda                                                                                           |
| 1007               | Claim Construction Order issued in <i>DNA Genotek Inc. v. Spectrum Solutions LLC</i> , C.A. No. 3:21-cv-0516 (S.D. Cal.) (Dkt. 177)                       |
| 1008               | Excerpts of Prosecution History of Application No. 17/510,003                                                                                             |
| 1009               | U.S. Patent No. 4,761,379 to Williams et al. (“Williams”)                                                                                                 |
| 1010               | U.S. Patent Publication No. 2006/0260959 to Patterson, et al. (“Patterson”)                                                                               |
| 1011               | Institution Decision for IPR2022-01347 (’646 Patent IPR)                                                                                                  |
| 1012               | “Needle Stick Safety and Prevention Act” of Nov. 6, 2000, Public Law 106-430, 114 Stat. 1901                                                              |
| 1013               | Workbook for Designing, Implementing and Evaluating a Sharps Injury Prevention Program, Center for Disease Control and Prevention (2008) (“CDC Workbook”) |
| 1014               | Injection Molding Handbook, Ch. 8 (3d ed. 2000)                                                                                                           |
| 1015               | The Complete Part Design Handbook For Injection Molding Of Thermoplastics, Ch. 10 (2006)                                                                  |
| 1016               | Reserved                                                                                                                                                  |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1017               | <i>Curriculum Vitae</i> of Karl R. Leinsing, MSME, PE                                                                                                                                             |
| 1018               | U.S. Patent No. 4,589,548 to Fay (“Fay”)                                                                                                                                                          |
| 1019               | U.S. Patent No. 4,741,346 to Wong (“Wong”)                                                                                                                                                        |
| 1020               | U.S. Patent No. 3,518,164 to Adelin (“Adelin”)                                                                                                                                                    |
| 1021               | 2024-01-17 PTAB Email - RE_ IPR2023-01424 - Request for Reply Briefing                                                                                                                            |
| 1022               | Declaration of Natalia Lehmann [served, not filed]                                                                                                                                                |
| 1023               | Printout of <a href="https://www.osha.gov/bloodborne-pathogens/evaluating-controlling-exposure">https://www.osha.gov/bloodborne-pathogens/evaluating-controlling-exposure</a> [served, not filed] |
| 1024               | Declaration of Benjamin B. Anger [served, not filed]                                                                                                                                              |
| 1025               | FIGS. 3A-3C (annotated) from U.S. Application No. 17/510,003                                                                                                                                      |
| 1026               | FIGS. 3A and 3B (annotated) from U.S. Application No. 61/498,584                                                                                                                                  |
| 1027               | Declaration of Karl R. Leinsing, MSME, PE in support of Petitioner’s Opposition to Patent Owner’s Non-Contingent Motion to Amend                                                                  |
| 1028               | Definition of “Within,” <i>Merriam-Webster Collegiate Dictionary</i> (11th ed., 2004).                                                                                                            |
| 1029               | Definition of “Within,” <i>Random House Unabridged Dictionary</i> (2d ed. 1993)                                                                                                                   |
| 1030               | Definition of “Within,” <i>American Heritage Dictionary</i> (4th ed. 2000)                                                                                                                        |
| 1031               | Definition of “Aperture,” printout of <a href="https://www.dictionary.com/browse/aperture">https://www.dictionary.com/browse/aperture</a>                                                         |
| 1032               | Definition of “Aperture,” printout of <a href="https://dictionary.cambridge.org/us/dictionary/english/aperture">https://dictionary.cambridge.org/us/dictionary/english/aperture</a>               |
| 1033               | Deposition Transcript of Stephen Wereley, Ph.D. (September 10, 2024)                                                                                                                              |
| 1034               | Ex. 1022 of IPR2022-01347 – Deposition Transcript of Stephen Wereley, Ph.D. (July 19, 2023)                                                                                                       |

| <b>Exhibit<br/>No.</b> | <b>Description</b>                                                      |
|------------------------|-------------------------------------------------------------------------|
| 1035                   | U.S. Patent Publication No. 2009/0216213 to Muir et al. (“Muir”)        |
| 1036                   | U.S. Patent Publication No. 2009/0212003 to Gudmundsson (“Gudmundsson”) |
| 1037                   | Patent Owner Response in IPR2022-01347                                  |
| 1038                   | Ex. 2012 of IPR2022-01347 – Declaration of Michael Metzker, Ph.D.       |
| 1039                   | Ex. 2013 of IPR2022-01347 – Declaration of Steven Wereley, Ph.D.        |

## **I. INTRODUCTION**

In substitute claim 21, Patent Owner (“PO”) amended claim 1 of the ’632 patent to add that the cap has “an outer wall” and that the first and second cylinders are “housed within the boundaries of the outer wall of the cap.” Motion to Amend (MTA), 3-5. PO alleges that these new limitations make the substitute claims of the ’632 patent patentable over the prior art. *Id.*, 10-24. They do not.

As an initial matter, PO’s patentability argument rests on a flawed claim interpretation, i.e., that “housed within the boundaries of the outer wall of the cap” in claim 21 means “housed *entirely* within...”<sup>1</sup> But that is not what PO’s new limitation requires. The substitute claims do not require the first and second cylinders to be housed entirely within the boundaries of the outer wall. Under the plain language of the substitute claims, they remain unpatentable under Grounds 1 and 2 as originally set forth in the Petition.

Furthermore, even accepting PO’s flawed claim interpretation, the substitute claims are obvious over the combination of Plante and Cho. Indeed, both parties’ experts agree a POSA would have been motivated to modify Cho’s reagent chamber to meet the new claim limitations, and agree it was easily within the skill of the art to do so.

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<sup>1</sup> Emphasis has been added by Petitioner throughout unless indicated otherwise.

The substitute claims are also unpatentable for failing to satisfy the written description requirement under 35 U.S.C. § 112.

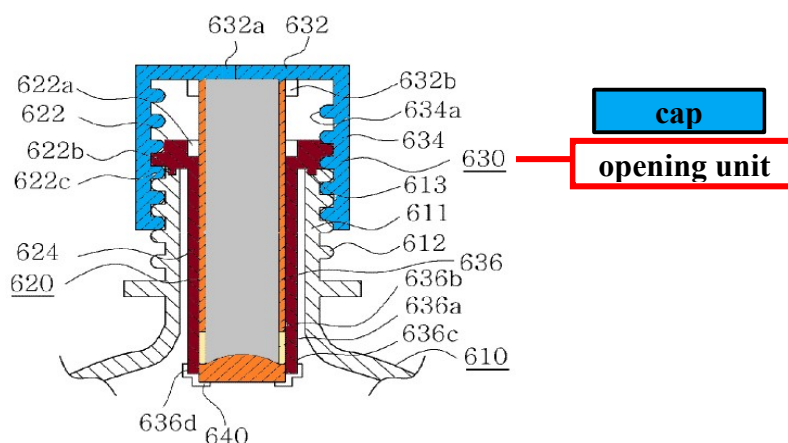
## **II. THE CLAIMS REMAIN UNPATENTABLE BASED ON GROUNDS 1 AND 2 IN THE PETITION**

PO concedes that the original claims of the '632 patent are unpatentable based on the combination of Plante and Cho. Instead, PO has elected to cancel the challenged claims of the '632 patent in favor of its substitute claims. MTA, 1. But even with the newly-added limitations, the substitute claims remain unpatentable over the same prior art in Grounds 1 and 2 of the Petition.

**“a cap comprising an outer wall”**

As set forth in the Petition, the combination of Plante and Cho renders claim 1 unpatentable. Pet., 11-65. Cho also discloses PO's added limitation that the cap "compris[es] an outer wall." For example, Fig. 44 of Cho, shown below, illustrates a cap 630 that includes an outer wall (blue).

Fig.44

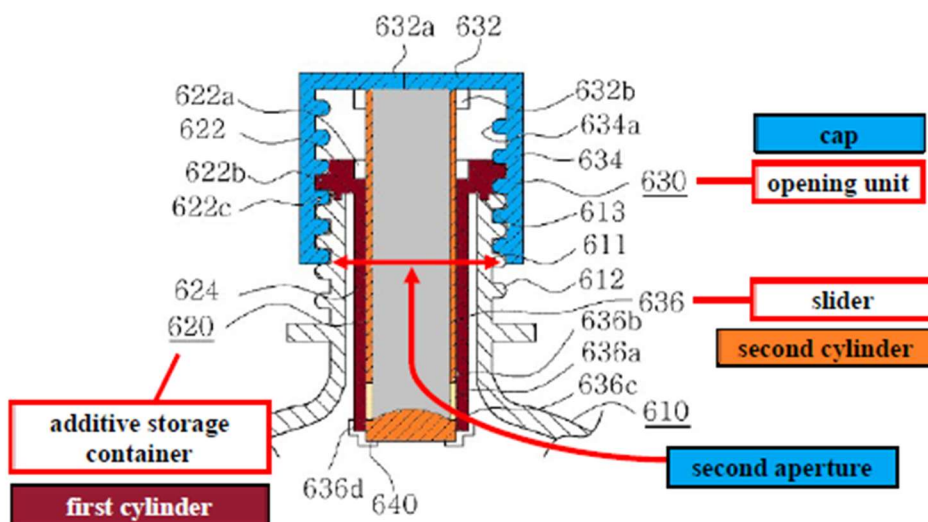


Ex.1004, 48:15-34, Fig. 44 (annotated).<sup>2</sup>

Therefore, Cho discloses a cap comprising an outer wall. Ex. 1027, ¶17.

**“a moveable annular valve positioned in the second aperture”**

As set forth in the Petition, Cho’s valve is in the second aperture, which is the aperture of the cap. Pet., 31-33; Ex.1002, ¶¶ 99–100. Thus, Cho’s annular valve is “positioned in the second aperture,” as recited in substitute claim 21.



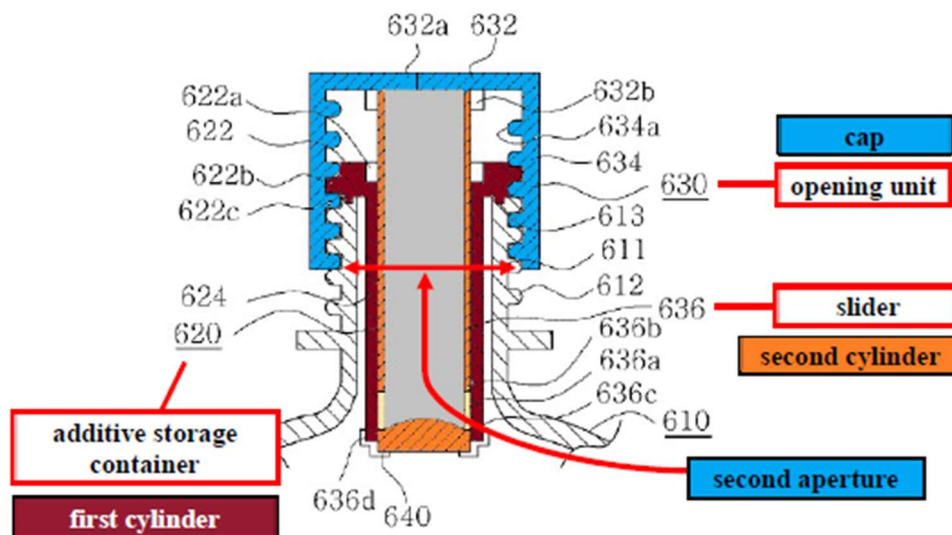
Ex.1004, Fig. 44 (annotated); Ex.1002, ¶¶ 99–100; Ex. 1027, ¶17.

**“the [first/second] cylinder is housed within the boundaries of the outer wall of the cap”**

Cho meets these limitations. As set forth in the Petition, Cho’s annular valve is disposed in the cap and extends into and through the cap’s second aperture. Pet.,

<sup>2</sup> Figures herein have been modified with color highlighting and annotations to illustrate the arguments made herein.

32-33. Cho's annotated Fig. 44, below, illustrates how the inner cylinder (slider 636) and outer cylinder (additive storage container 620) of Cho's annular valve are disposed



Pet., 32-33; Ex.1004, Fig. 44 (annotated); Ex.1002, ¶¶ 99–100; Ex. 1027, ¶¶18-19.

Thus, Cho discloses that the first and second cylinders are “housed within the boundaries of the outer wall of the cap,” as recited in substitute claim 21.

**“relatively moveable within the boundaries of the outer wall of the cap”**

This limitation is also satisfied by Cho, as set forth in the Petition. Pet., 43. As explained above, the first and second cylinders are within the boundaries of the outer wall of the cap. When Cho's cap is tightened on the bottle, the second cylinder (slider 636) “moves downward” through the first cylinder 620 “so that the additive is discharged . . . through the discharge ports 636a.” Ex.1004, 50:8-12; *id.*, Fig. 45A, 49:34-50:12; Ex. 1002, ¶ 121-122. Therefore, relative movement between the first

and second cylinders occurs within the boundaries of the outer wall of the cap. Ex. 1027, ¶¶20-21.

Accordingly, substitute claim 21 is unpatentable under Ground 1 of the Petition as obvious over the combination of Plante and Cho as was claim 1.

Furthermore, the only amendments PO made in substitute claims 22-24, 26-36, and 38-39 was to update the claim dependencies for original claims 2-4, 6-16, and 18-20, to make them depend directly or indirectly back to substitute claim 21. MTA, 28-31. Thus, these claims also remain unpatentable based on the combination of Plante and Cho as set forth in Ground 1 of the Petition. Pet., 45-65.

For the same reasons explained above, substitute claim 25 remains unpatentable as set forth in Ground 2 in the Petition because Cho discloses all the newly added limitations. Accordingly, substitute claim 25 is unpatentable under Ground 2 of the Petition as obvious over the combination of Plante, Cho, and Patterson. Pet., 66-71.

**III. THE SUBSTITUTE CLAIMS DO NOT REQUIRE THE FIRST AND SECOND CYLINDERS TO BE HOUSED ENTIRELY WITHIN THE BOUNDARIES DEFINED BY THE OUTER WALL OF THE CAP**

In its construction proposed in the MTA, PO does no more than restate its amended claim language: “the annular valve comprising the first cylinder, the second cylinder, and the vent are housed within a volume defined by the outer wall 24 of cap 12 (*i.e., within the boundaries of the outer wall of the cap.*)” MTA, 11

(italics in original). In its discussion of the prior art, PO reveals that it contends the limitation “housed within the boundaries of the outer wall of the cap” means “housed *entirely* within the boundaries of the outer wall of the cap.” MTA, 15, 21.

When discussing the combination of Plant and Cho, PO argues that the amended claims are allegedly patentable over the prior art because the first and second cylinders in the prior art are not *entirely* within the volume defined by the boundary of the outer wall of the cap. For example, PO argues that Cho does not satisfy the substitute claims because Cho’s “inner cylindrical component (slider 636)” “extends beyond the boundaries of inner cap 634 and into the mouth of bottle body 610...” MTA, 15. Similarly, PO argues Ueda allegedly does not meet the claim limitations because its components “extend beyond the boundaries of cap 3 and into the opening of container main body 2.” *Id.*, 21. But neither the plain language of the claims, the specification, the prosecution history, nor extrinsic evidence supports PO’s proposed narrowed interpretation of the well-understood term “within.”

Claim construction begins by considering the words of the claim. *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 805 (Fed. Cir. 2007) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*)). The amended claims do not recite that the first and second cylinders are housed “*entirely* within the

boundaries of the outer wall of the cap” and there is nothing in the claim language to suggest such a narrow interpretation.

The plain meaning of “within” encompasses being located entirely in the interior, as well as *extending into* the interior. For example, Merriam-Webster defines “within” as “in or into the interior.” Ex. 1028, 1439; *see also* Ex. 1029, 2183 (“in or into the interior or inner part”); Ex. 1030, 1976 (“in or into the inner part”). The plain and ordinary meaning of “within” is not limited to “entirely within.” Ex. 1027, ¶¶9-10.

The specification does not include any disclosure that supersedes or limits the plain and ordinary meaning of “within.” The plain meaning of the term “within” is broad enough to encompass first and second cylinders that extend into the boundary of the outer wall of the cap. PO cannot point to anything in the intrinsic record or any extrinsic evidence to support its narrowing construction.

PO’s attempt to narrow the meaning of “housed within the boundaries” as “housed entirely within the boundaries” directly contradicts other limitations in substitute claim 21. Claim 21 requires that the cap comprises “a second aperture” and that the “moveable annular valve [is] positioned in the [cap’s] second aperture.” MTA, 4. The parties do not dispute that the “second aperture” is the opening in the claimed cap. Ex.1033, 49:13-51:8 (“[T]here’s an opening in the bottom surface of that Outer Wall 24. And one could call that an aperture.”); Ex. 1027, ¶¶11-12.

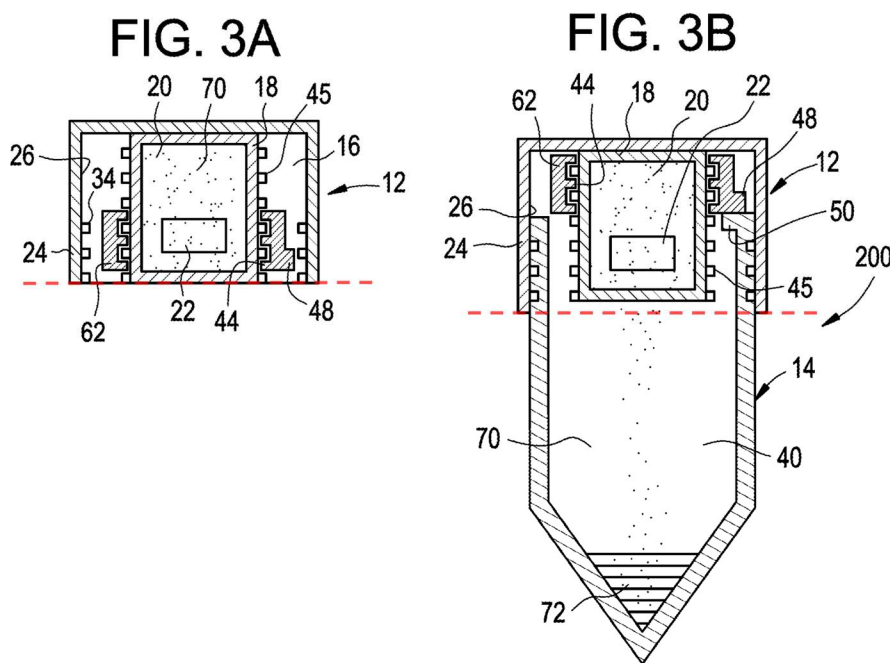
Thus, where substitute claim 21 recites “a movable annular valve positioned in the second aperture,” it means that the first and second cylinders of the moveable annular valve are positioned in the opening of the cap, i.e., extend into the second aperture. If the moveable annular valve—which includes the first and second cylinders—is entirely within the interior space 20 defined by the outer wall of the cap, then the moveable annular valve cannot be within the second aperture defined by the outer wall of the cap. Ex. 1027, ¶13. Therefore, the first and second cylinders cannot be *entirely within* the boundaries of the outer wall of the cap and simultaneously “positioned in the [cap’s] second aperture,” as required by substitute claim 21. “A claim construction that is in disagreement with the plain language of the claim is rarely if ever correct.” *See Neomagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1075 (Fed. Cir. 2002); *Trs. of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1366–67 (Fed. Cir. 2016) (holding that internally contradictory claims were invalid as indefinite).

PO cites only Figs. 3A and 3B of the ’632 patent in support of its implied claim construction. *See* MTA, 11. But Figs. 3A and 3B depict the claimed components inconsistently and without precision,<sup>3</sup> and therefore fail to support PO’s

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<sup>3</sup> Figs. 3A and 3B purport to depict a single embodiment in two states of operation. That the drawings inconsistently show the claimed features highlights that PO’s new

construction of the first and second cylinders being housed *entirely within* the boundaries of the outer wall of the cap. Fig. 3A shows that the second cylinder (“inner wall 18”) extends *into the cap’s aperture*, where the inner wall 18 is equal and in line with the aperture or “boundary” and not entirely within the outer wall or “boundary” of the cap. Fig. 3B, however, shows that the same inner wall 18 is recessed inside the cap.



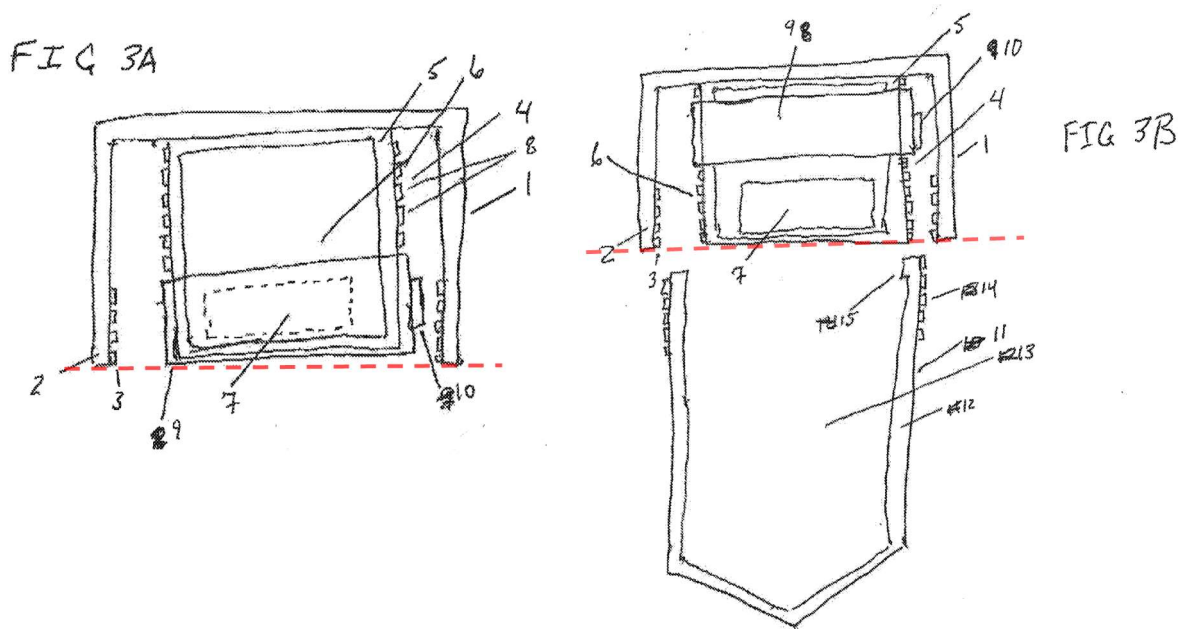
Ex. 2015, Figs. 3A, 3B (annotated); Ex. 1027, ¶15.

Moreover, the hand-drawn drawings in Prov. App. No. 61/498,584 (“584 provisional”) flip flop this arrangement, where Fig. 3A shows a slanted inner

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limitations do not add patentable significance to the claims and, as explained below, that the claims lack written description support if interpreted as PO contends.

cylinder (“inner wall 5”) as slightly recessed and Fig. 3B shows it extending into the aperture of the outer wall 2 of the cap. These drawings are meant to depict the same structure but are internally inconsistent.



Ex. 2022, Figs. 3A, 3B (annotated); *see id.*, 8-9; Ex. 1027, ¶16.

Dr. Wereley agreed that Figs. 3A and 3B in the '584 provisional and the '632 patent are just “meant to be sketches” and “not engineering drawings with tolerances and dimensional lines.” Ex. 1033, 62:18-65:16; *id.*, 63:3-9. Such imprecise and contradictory drawings cannot support PO’s claim construction of requiring the first and second cylinders to be *housed entirely* within the boundaries of the outer wall of the cap. *Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1288-89 (Fed. Cir. 2021) (citing opposing expert’s testimony that “Figure 1 is not a

mechanical drawing” and finding the “rudimentary schematic” does not support a narrowing claim construction); Ex. 1027, ¶14.

However, even if Figs. 3A and 3B provide written support for a first and second cylinder entirely within the boundaries of the outer wall of the cap, they cannot limit the scope of “within.” *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1306–07 (Fed. Cir. 2003) (“[T]he mere fact that the patent drawings depict a particular embodiment of the patent does not operate to limit the claims to that specific configuration.”)

PO’s attempt to narrowly construe its newly-added claim limitation, “housed within the boundaries of the outer wall of the cap,” lacks any support in the claims, specification, or the extrinsic evidence. Moreover, PO had the opportunity to use more precise language in drafting its amendments, but substitute claim 21 is not amended to recite, “*entirely within* the boundaries.” PO did not—and could not—add this express limitation because it is not supported by the specification. PO’s implied construction should be rejected. However, as described below, PO’s substitute claims are unpatentable even under PO’s flawed construction.

#### **IV. THE SUBSTITUTE CLAIMS ARE UNPATENTABLE UNDER PO’S FLAWED CONSTRUCTION**

##### **A. Plante and Cho Render Obvious Substitute Claims 21-24, 26-36, 48-40**

Even if substitute claim 21 required that the first and second cylinders are housed entirely within the boundaries of the outer wall of the cap, substitute claim

21 would still be obvious over Plante and Cho. It would have been obvious to modify Cho's cap to house the cylinders entirely within the boundaries of the outer wall of the cap, and POSA would have had a reasonable expectation of success in doing so. Ex. 1027, ¶¶22-40.

As an initial matter, there is nothing novel or inventive about keeping the first and second cylinders from extending below the opening of the cap, or otherwise having the first and second cylinders housed entirely within, and moveable entirely within, the boundaries of the outer wall of the cap. The volume of inner space 20, and thus the length of the inner wall 18 (defining the claimed first cylinder) is determined by the amount of additive (preservative in the case of the '632 patent) that one desires to add to the container. A POSA could adjust these proportions as he or she saw fit. Ex. 1027, ¶¶23-25.

PO does not, and cannot, point to anything in the '632 patent that even mentions this limitation, let alone describes it as an inventive feature. If this were an inventive feature, one would expect the inventors to have discussed its absence in the Background section when explaining the challenges with "currently available sample collection devices." Ex. 2015, ¶¶14-15. They did not. Similarly, one would expect the inventors to have discussed this concept in the "Summary of the Disclosure" along with the "features [that] may be provided with a sample collection

device.” *Id.*, ¶21. Again, they did not. The specification never describes this concept at all, and certainly never as an inventive feature. Ex. 1027, ¶¶23-25.

**1. A POSA Would Have Been Motivated to Modify Cho**

A POSA would have been motivated for several reasons to modify Cho’s cap to include the first and second cylinders entirely within the boundaries of the outer wall of the cap.

First, a POSA would have been motivated to modify Cho’s cap in order to reduce the potential risk of sample contamination when, for example, the device is handled by an unskilled user. More specifically, a POSA would have been motivated to fully recess Cho’s movable annular valve in the cap to minimize the potential of an unskilled user contacting the reagent reservoir and thus potentially contaminating the biological sample when the preservation reagent is mixed with the biological sample. Ex. 1027, ¶¶26-30.

In the IPR for the related ’646 patent, PO asserted that “Cho’s cap introduces a failure mechanism that increases the risk of sample contamination, which would render a sample defective.” Ex. 1037, 61. PO states the cause of this risk of contamination is that Cho’s first and second cylinders extend below the bottom of the cap, making it more likely for a user to touch the movable annular valve:

Cho’s annular valve extends significantly beyond the bottom of Cho’s cap. This increases the risk that a hand touches the interior of the device. Such a touch could lead to a defective sample. The risk is

heightened because the annular valve resembles a handle (see excerpted portion of Cho Figure 44 below) and naturally suggests itself to be an interaction point for a user.

*Id.* at 64-65.

In the IPR of the '646 patent, PO submitted expert declarations by Dr. Wereley and Dr. Metzker in support of these arguments. *See, e.g.*, Ex.1038 and Ex.1039. Dr. Wereley reiterated these same points in his expert declaration in this case. Ex. 2014, ¶71.

In the '646 patent IPR, PO contrasted Cho's potential for contamination with Plante's low-profile design that minimizes the risk of contamination:

Plante's cap provides minimal risk of contamination....Plante's reservoir protrudes slightly beyond Plante's cap. This significantly reduces the risk that someone would touch the reservoir film, which could render the sample defective.

Ex.1037, 63-64. PO supported this argument with Dr. Wereley's declaration. *Id.* (citing Ex.1039, 90-100). In this case, Dr. Wereley again reiterated that Plante's low-profile design minimizes the risk of contamination. Ex. 2014, ¶70.

Recognizing Cho's risk of contamination, a POSA would have been motivated to modify Cho's moveable annular valve, as Plante suggests, by having a moveable annular valve that is fully recessed past the bottom opening of the cap. Ex. 1027, ¶¶29-30.

Second, a POSA would have recognized there only two options for placement of the moveable annular valve in the cap—either extending into or below the opening of the cap, or housed entirely within the cap. Ex. 1027, ¶31. Thus, with a finite number of identified, predictable solutions—and Cho already disclosing one solution—it would have been obvious to try, with a reasonable expectation of success, positioning Cho’s first and second cylinders entirely within the boundaries of the outer wall of the cap. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Third, a POSA would have been motivated by design choices to modify Cho’s cap to include the first and second cylinders entirely within the boundaries of the outer wall of the cap. Ex. 1027, ¶¶32-34. These design choices can include, e.g., the amount of additive added to the cap and the width of the bottle neck and the reservoir in the cap. For example, when the design calls for a smaller quantity of additive in the cap, a POSA would be motivated to reduce the vertical length of the reagent chamber in Cho’s cap and thereby bring the first and second cylinders entirely within the boundaries of the outer wall of the cap. Similarly, when the design requires a wider neck as part of Cho’s bottle, the cap will also be wider, and a POSA would be motivated to expand the width of the reagent chamber horizontally and reduce the vertical length of the reagent chamber, which brings the first and second cylinders entirely within the boundaries of the outer wall of the cap.

## **2. A POSA Would Have Had a Reasonable Expectation of Success**

A POSA would have reasonably expected success in modifying the dimensions of the Cho's annular valve so that the first and second cylinders are housed entirely within the boundaries of the outer wall of the cap. A POSA understood that Cho's size and volume could be modified based on the intended use of the device. Ex. 1027, ¶¶35-40.

Dr. Wereley agrees, having testified in the '646 patent IPR that a POSA would recognize that Cho's size and volume could be changed based on need. Ex. 1034, 35:10-19 (“[O]ne of skill in the art would recognize that the additive storage container, the size or the volume of the additive storage container could be changed to accommodate some operation....”); *id.*, 35:21-36:14, 38:1-7. He further testified that the volume of the additive storage container could be adjusted by adjusting the axial length of Cho's first and second cylinders (making up the “additive storage container”). *Id.*, 69:13-70:9 (“[A] POSA in 2012 would realize that the axial length of the additive compartment could be changed to some extent” and “[c]hanging the length of the cylinder...would necessarily change its volume.”).

Moreover, the prior art demonstrates a POSA understood that the dimensions of the valve in Cho's lid could be modified, specifically so that the valve is positioned entirely within the boundaries defined by the outer wall of the cap. *See, e.g.*, Ex. 1035, ¶52 (Genotek publication to Muir disclosing that the “size and shape”

of the lid's vertical wall "is dependent upon the intended use of the container system."), ¶51 ("Lid 100 and reservoir 102 can be sized to accommodate a range of volumes of a substance."); Ex. 1036, ¶¶2, 26 (Gudmundsson publication describing uses of cap dispensing system, including "medicine or other chemicals," and disclosing that "[a] person skilled in the art realizes that the exact form and size of the closure and its different parts may be varied due to the form and size of the container and the additive."); Ex. 1027, ¶¶37-39.

Tellingly, the disclosure of the '632 patent does not even specify the position of the movable annular valve and its components (e.g., first and second cylinder), much less teach how to modify the device to achieve any desired position. For example, the '632 patent does not specify whether the inner wall 18 is flush with the outer wall of the cap, is positioned entirely within the inner space 20 defined by the boundaries of the outer wall of the cap, or if it straddles the outer boundary of the outer wall such that it is within the second aperture defined by the outer wall.

Noticeably, the '632 patent does not teach *how* to modify the dimensions of the cap and container. Although the '632 patent discloses that "[t]he dimensions of the device can be modified to suit the specific processing the sample will be subjected to," Ex. 2015, ¶66, there is no teaching of how to make any such modifications. PO argues that the specification need not recite the claimed invention "*haec verba*" and states that it is enough to rely on "the existing knowledge in the

particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.” MTA at 5-6. PO cannot demand exacting disclosure from the prior art when its own patent lacks any such disclosure. *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1341 (Fed. Cir. 2006) (explaining that the patent demonstrates that alleged invention was within scope of the ordinary skill in the art, “and it does so not by what [the patent] discloses but by what it *does not* disclose.”) (emphasis in original); *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994); *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1381 (Fed. Cir. 2013).

As described by the '632 patent and PO's expert and confirmed by Petitioner's expert, Dr. Leinsing, a POSA would have had a reasonable expectation of success in modifying Cho's cap to house the cylinders entirely within the boundaries of the outer wall of the cap. Ex. 1027, ¶¶35-40.

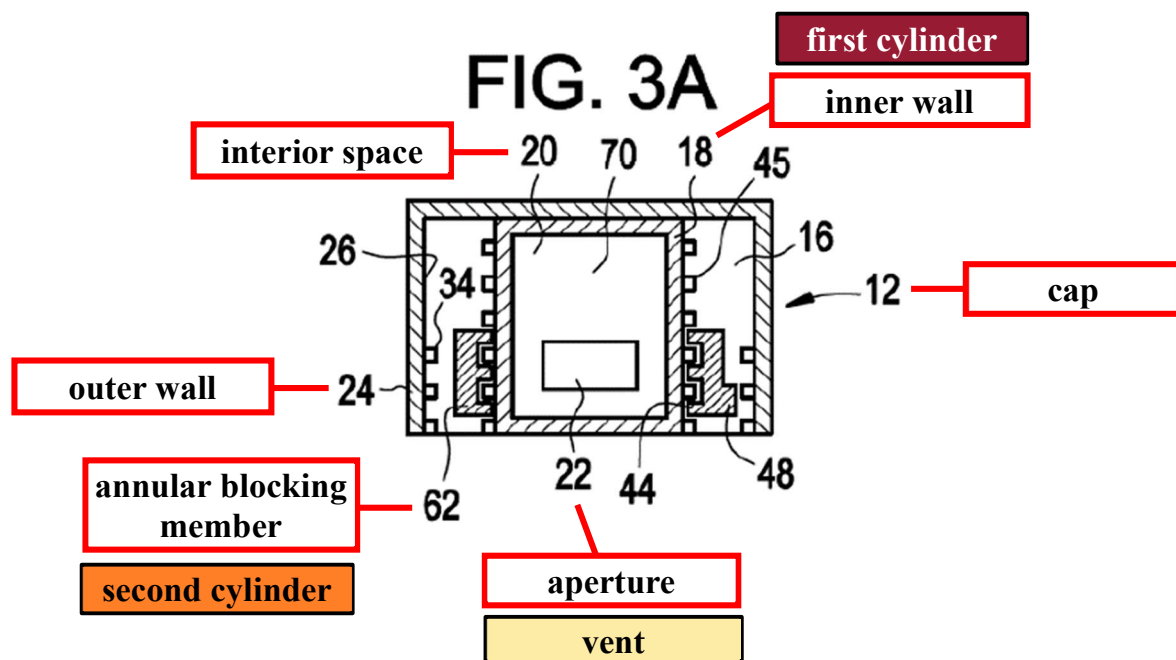
**B. Plante, Cho, and Patterson Render Obvious Substitute Claim 25**

Substitute claim 25 (original claim 5) depends from substitute claim 21 (original claim 1). PO has not substantively amended claim 25. The claim is thus obvious over Plante and Cho (as explained above with respect substitute claim 21) and in view of Patterson as set forth in the Petition under Ground 2. Pet., 66-71; Ex.1002, ¶¶ 165-172.

### C. The Substitute Claims Lack Written Description Support

PO bears the burden to show that the amended claims do not introduce new matter and satisfy the written description requirement. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 41.121(a)(2)(ii). But there is no written description support for the first and second cylinders to be housed *entirely within* the boundaries of the outer wall of the cap and PO cannot meet its burden. Ex. 1027, ¶¶41-47.

The operative application for the MTA is U.S. Application No. 17/510,003 (“’003 application”) (Ex. 2015). The ’003 application describes the cap 12 as having “an outer wall 24,” “an inner wall 18,” and “an annular blocking member 62,” and discloses that “[t]he inner wall 18 may further define an aperture 22.” Ex. 2015, ¶75. For reference, Figure 3A of ’003 application is annotated below with relevant labels from the specification and the substitute claims.



Ex. 2015, Fig. 3A (annotated).

The '003 application is silent regarding the locations of the first and second cylinders relative to the boundaries of the outer wall of the cap. The specification's silence does not constitute disclosure. *Seabed Geosolutions*, 8 F.4th at 1288 (“The specification never mentions gimbaled or non-gimbaled geophones, nor does it provide a reason to exclude gimbals. That silence does not support reading the claims to exclude gimbaled geophones.”) (citations omitted); MPEP § 2173.05(i) (9th ed. Rev. 10.2019, June 2020) (“The mere absence of a positive recitation is not a basis for an exclusion.”).

Given the specification's silence on the issue, the drawings in the '003 application cannot be used for written description support for PO's implied construction that requires the first and second cylinders to be housed ***entirely within*** the boundaries of the outer wall of the cap. *Hockerson-Halberstadt, Inc. v. Avia Group. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000) (“[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.”). Moreover, as set forth above (*supra* Section III), the drawings in the '003 application and the '584 provisional are imprecise and contradictory, providing further evidence that the inventors did not actually invent a cap having the first and second cylinders housed ***entirely within*** the boundaries of the outer wall of the cap.

*Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*) (“[T]he specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.”).

In arguing that the '003 application provides written description support for the claim amendments, PO cites to Ex. 2015, ¶¶43, 44, 75, 76, 78, and Figs. 3A and 3B. *See* MTA at 4, 8-10. But the disclosure that PO cites does not support its amendment. Paragraphs 43 and 44 merely refer to Figs. 3A and 3B under the heading “Brief Description of the Drawings” and explain only that the “movable annular valve” (i.e., the claimed first cylinder) can cover the “aperture” (i.e., the claimed vent) in one instance, and leave it uncovered in another instance. Paragraphs 75, 76, and 78 similarly describe this covering and uncovering process in slightly more detail and do so without ever discussing if the “inner wall 18” or “annular blocking member 62” extend less than, equal to, or further than the bottom opening of the outer wall 24 of the cap 12. Thus, none of the cited paragraphs describes the first and second cylinders as being housed *entirely within* the boundaries of the outer wall of the cap. Ex. 1027, ¶¶45-46.

PO’s citation to Figs. 3A and 3B is equally unavailing. As explained above, the drawings are imprecise and contradictory, and thereby fail to provide written description support to PO’s claim construction requiring the first and second

cylinders to be housed *entirely within* the boundaries of the outer wall of the cap.

*Supra* Section III; Ex. 1027, ¶47.

For the reasons set forth above, the substitute claims are unpatentable as they do not satisfy the written description requirement.

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**CERTIFICATE OF SERVICE**

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e) and with the agreement of counsel for Patent Owner, a true and correct copy of **PETITIONER'S OPPOSITION TO PATENT OWNER'S NON-CONTINGENT MOTION TO AMEND** is being served electronically on September 24, 2024, to the e-mail addresses shown below:

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