

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS LLC
Petitioner,

v.

DNA GENOTEK INC.,
Patent Owner.

Patent No. 11,536,632 B2

Inter Partes Review No. IPR2023-01424

**PATENT OWNER'S NON-CONTINGENT MOTION TO AMEND AND
REQUEST FOR PRELIMINARY GUIDANCE**

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37 C.F.R. § 42.121(a)(2)(ii)	2
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37 C.F.R. § 42.121(a)(3)	1

EXHIBIT LIST

Exhibit Description	Exhibit #
<i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347 Order (Paper 37) Issued November 16, 2023	2001
Excerpts of Prosecution History of Application No. 16/879,506, filed as Exhibit 1012 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2002
DNA Genotek Inc.’s Opening Claim Construction Brief, <i>DNA Genotek Inc. v. Spectrum Solutions LLC</i> , C.A. No. 21-cv-0516 (S.D. Cal. February 18, 2022) (Dkt. 86), filed as Exhibit 1014 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2003
Deposition Transcript of Karl Leinsing taken on April 6, 2023 in <i>DNA Genotek, Inc. v. Spectrum Solutions, LLC</i> , No. 21-cv-516 (S.D. Cal.), filed as Exhibit 2011 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2004
Declaration of Vincent A. Fischetti, Ph.D. in Support of Petition for Inter Partes Review of U.S. Patent 11,002,646 filed as Exhibit 1011 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347 on July 27, 2022	2005
Spectrum Solutions LLC’s [Redacted] Opening Claim Construction Brief, <i>DNA Genotek Inc. v. Spectrum Solutions LLC</i> , C.A. No. 21-cv-0516 (S.D. Cal. February 18, 2023) (Dkt. 83), filed as Exhibit 1013 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2006
Deposition Transcript of Steven Wereley, Ph.D. taken on July 19, 2023 filed as Exhibit 1022 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2007
Declaration of Steven Wereley filed as Exhibit 2013 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2008

Deposition Transcript of Karl Leinsing taken on August 25, 2023 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347, filed as Exhibit 2057	2009
OraSure Technologies to Acquire DNA Genotek Inc., DNA GENOTEK (July 25, 2011), https://www.dnagenotek.com/us/company/news-events/press-releases/2011/2011-07-25.html , filed as Exhibit 2002 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2010
TIME MAGAZINE, December 12, 2005, filed as Exhibit 2005 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2011
Declaration of Karl R. Leinsing, MSME, PE, in Support of Petitioner's Reply, filed as Exhibit 1019 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2012
Declaration of Dr. Michael Metzker, filed as Exhibit 2012 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2013
Declaration of Dr. Steven Wereley	2014
U.S. Patent Application 17/510,003 (filed Oct. 25, 2021)	2015
U.S. Patent Application 16/023,772 (filed June 29, 2018)	2016
U.S. Patent Application 15/227,693 (filed Aug. 3, 2016)	2017
U.S. Patent Application 14/127,832 (filed as PCT application on June 19, 2012)	2018
U.S. Patent 9,442,046	2019
U.S. Provisional Patent Application 61/598,601 (filed Feb. 14, 2012)	2020
U.S. Provisional Patent Application 61/598,618 (filed Feb. 14, 2012)	2021
U.S. Provisional Patent Application 61/498,584 (filed June 19, 2011)	2022

Patent Owner's Response in <i>Inter Partes</i> Review No. IPR2022-01347	2023
U.S. Provisional Patent Application 61/861,329 (filed Aug. 1, 2013) filed as Exhibit 2028 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2024

**Patent Owner's Exhibits 2001-2013 were previously filed and are listed again here based on 37 C.F.R. § 42.63.*

***Patent Owner's Exhibits 2014-2024 are newly filed.*

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.121 and the Board’s Order (Paper 10), DNA Genotek Inc. (“Genotek” or “Patent Owner”) submits this non-contingent Motion to Amend (“Motion” or “MTA”) with respect to the challenged claims of U.S. Patent No. 11,536,632 (the “’632 patent”). Specifically, Patent Owner proposes cancelling challenged claims 1–16 and 18–20 and substituting claims 21–39. This Motion and the supporting Declaration of Dr. Steven Wereley (Ex. 2014) demonstrate that the substitute claims are patentable over the grounds in this proceeding, even though Patent Owner does not bear a burden of persuasion to demonstrate the patentability of the substitute claims. *Aqua Prod., Inc. v. Matal*, 872 F.3d 1290, 1327 (Fed. Cir. 2017). Finally, Genotek requests that the Board provide preliminary guidance.

II. THE SUBSTITUTE CLAIMS MEET THE REQUIREMENTS OF 37 C.F.R. § 42.121

A. Reasonable Number Of Substitute Claims

As shown in Appendix A, Genotek proposes, at most, only one substitute claim for each challenged claim. This Motion is thus consistent with the general presumption that “only one substitute claim would be needed to replace each challenged claim.” 37 C.F.R. § 42.121(a)(3).

B. The Substitute Claims Are Responsive To The Instituted Grounds

Substitute claims 21–39 are responsive to all grounds of unpatentability in the trial phase of this proceeding. 37 C.F.R. § 42.121(a)(2)(i). Specifically, the Board instituted review of independent claim 1 based on Grounds I and III in the Petition. Genotek proposes one substitute independent claim—claim 21—with recitations that overcome Grounds I and III as described *infra*.

Substitute dependent claims 22–39 are also responsive to one or more instituted grounds, because their amendments are tied to the amendments in the substitute independent claim. The substitute dependent claims correspond to challenged dependent claims 2–16 and 18–20 and thus reflect their dependency from substitute independent claim 21. These substitute dependent claims overcome Grounds I–V as described *infra*.

C. The Substitute Claims Do Not Enlarge The Scope Of The Original Claims

Substitute independent claim 21 adds further recitations to challenged independent claim 1 and thus does not enlarge the scope of the claims. 37 C.F.R. § 42.121(a)(2)(ii). Specifically, Genotek seeks to amend substitute independent claim 21 as follows: (1) amending the description of the “cap” recitation to also comprise an “outer wall”; (2) clarifying that the “first cylinder” and the “second cylinder” of the “annular valve” are “housed within the boundaries of the outer

wall of the cap”; and (3) clarifying that the “first cylinder” and “second cylinder” are relatively movable within the boundaries of the outer wall of the cap.

D. The Substitute Claims Are Supported By The Original Disclosure And Do Not Introduce New Matter

The ’632 patent issued from U.S. app. no. 17/510,003 (the “’003 application”) (Ex. 2015), filed on October 25, 2021. The ’003 application claims priority to U.S. app. no. 61/498,584 (the “’584 application”) (Ex. 2022) filed on June 19, 2011. As set forth in the charts below, Genotek submits that both the ’584 and ’003 applications support each substitute claim and make clear that no new matter has been introduced.¹ 37 C.F.R. §§ 42.121(a)(2)(ii) and (b)(1). The left column of the first chart below shows the substitute independent claim in comparison to the challenged independent claim, with added recitations underlined and any deleted recitations with strikethroughs. The right column shows exemplary support in the original disclosures—first with respect to the recitations of the challenged independent claim and then for the newly added recitations.

Substitute Independent Claim	Support in the ’584 Application (Ex. 2022) and the ’003 Application (Ex. 2015)
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¹ The intervening non-provisional applications (Exs. 2016-2018) are identical to the ’003 application for the purposes of this Motion. (*See* Ex. 2014, ¶ 34.)

A biological sample collection system, the system comprising: - a sample collection vessel comprising - a sample collection reservoir, - a first connection member, and - a first aperture for receiving a biological sample; - a cap comprising <u>an outer wall,</u> - a second aperture, - a reagent chamber storing a reagent therein, and - a second connection member complementary to the first connection member; and - a moveable annular valve <u>positioned in the second aperture, the movable annular valve comprising</u> - a vent, - a first cylinder comprising a third aperture, <u>wherein the first cylinder is housed within the boundaries of the outer wall of the cap,</u> - a second cylinder comprising the vent, the second cylinder positioned in the third aperture, <u>wherein the second cylinder is housed within the boundaries of the outer wall of the cap,</u> - a closed configuration, and - an open configuration, wherein - in the <u>moveable annular valve's</u> closed configuration, the first and second cylinders create a fluid-tight seal with the cap and the first cylinder obstructs the vent to retain the reagent in the reagent chamber, - the first cylinder and second cylinder are relatively moveable <u>within the boundaries of the outer wall of the cap</u> to thereby change the annular valve	<u>'632 patent claim 1</u> Ex. 2015: Abstract, [0022], [0023], [0043], [0044], [0058], [0060], [0063], [0075]-[0078], FIG. 3A-3B; Ex. 2022: 4-9, FIG. 3A-3B. <u>"outer wall"</u> Ex. 2015: [0022], [0060], FIG. 3A-3B, <i>see also</i> [0075]; Ex. 2022: 4-6, 8-9, FIG. 3A-3B. <u>"first cylinder" and the "second cylinder" are "housed within the boundaries of the outer wall"</u> Ex. 2015: [0043], [0044], [0075], FIG. 3A-3B; Ex. 2022: 4-6, 8-9, FIG. 3A-3B. <u>"first cylinder" and "second cylinder" are relatively moveable within the boundaries of the outer wall of the cap</u> Ex. 2015: [0075], FIG. 3A-3B, <i>see also</i> [0043], [0044], [0076], [0078]; Ex. 2022: 4-6, 8-9, FIG. 3A-3B.
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from the closed configuration to the open configuration, and in the <u>moveable</u> annular valve's open configuration, the first cylinder does not obstruct the vent to thereby allow flow of the reagent from the reagent chamber, through the vent, and into the sample collection reservoir.	
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The chart below shows the exemplary support for the substitute dependent claims.

Substitute Dependent Claims	Support
Claim 22 (corresponding to claim 2)	Ex. 2015: [0020]-[0022], [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 4-9, FIGS. 3A, 3B.
Claim 23 (corresponding to claim 3)	Ex. 2015: [0043], [0044], [0075], FIGS. 3A, 3B; Ex. 2022: FIGS. 3A, 3B.
Claim 24 (corresponding to claim 4)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.
Claim 25 (corresponding to claim 5)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.
Claim 26 (corresponding to claim 6)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 7-9, FIGS. 3A, 3B.
Claim 27 (corresponding to claim 7)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 7-9, FIGS. 3A, 3B.
Claim 28 (corresponding to claim 8)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.
Claim 29 (corresponding to claim 9)	Ex. 2015: [0059]; Ex. 2018: [0058].
Claim 30 (corresponding to claim 10)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.

Claim 31 (corresponding to claim 11)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.
Claim 32 (corresponding to claim 12)	Ex. 2015: [0043], [0044], FIGS. 3A, 3B; Ex. 2022: FIGS. 3A, 3B.
Claim 33 (corresponding to claim 13)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B, 3C; Ex. 2022: 5, 7-9, FIGS. 3A, 3B.
Claim 34 (corresponding to claim 14)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.
Claim 35 (corresponding to claim 15)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.
Claim 36 (corresponding to claim 16)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.
Claim 37 (corresponding to claim 18)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.
Claim 38 (corresponding to claim 19)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.
Claim 39 (corresponding to claim 20)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B; Ex. 2022: 5, 8-9, FIGS. 3A, 3B.

Support for the substitute claims is also provided by Dr. Wereley as discussed below. (Ex. 2014, ¶¶ 28-34.)

Genotek provides additional discussion on written description support for the newly added recitations to substitute independent claim 21. As a preliminary matter, the Federal Circuit considers a number of factors in determining written description support, including “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.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Moreover, the “description requirement does not demand any particular form of disclosure” or that the “specification recite the claimed invention in *haec verba*.” *Id.*, at 1352.

1. The “outer wall” of the cap

The original disclosure describes a biological sample collection system having a cap that “comprises an *outer wall* having the first engagement member.” (Ex. 2015, [0022].) The original disclosure repeatedly mentions this outer wall, describing at least an embodiment of an “outer wall with interior threads” and an embodiment with outer wall that may help define an interior chamber of the cap (Ex. 2015, [0060].) Figure 3B (below) illustrates a biological sample collection system 200 having a cap 12 with an outer wall 24 (yellow). (Ex. 2015, [0075].) Thus, the combination of originally filed Figure 3B and its accompanying description establishes written description support for a cap comprising an “outer wall” in substitute independent claim 21. (Ex. 2014, ¶ 29.)

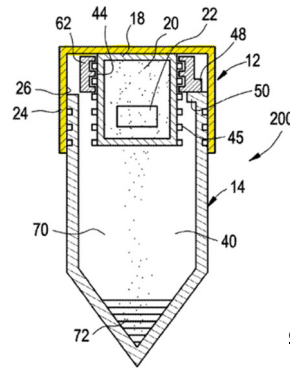


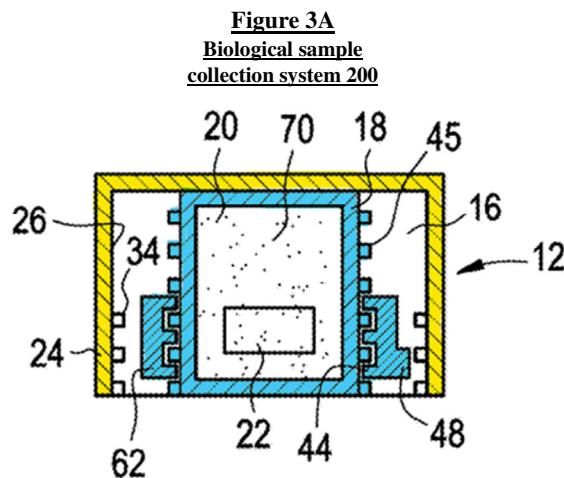
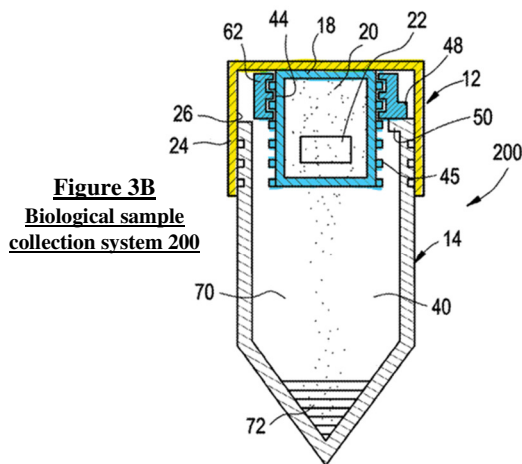
Figure 3B
Biological sample
collection system 200

2. The “first cylinder” and the “second cylinder” of the “annular valve” are “housed within the boundaries of the outer wall of the cap”

The original disclosure describes a biological sample collection system where the “cap 12 can include an outer wall 24” and “interior space 20 [of the cap] may be at least partially defined by at least . . . an outer wall 24 of the cap 12.” (Ex. 2015, [0075].) This “interior space” of the cap has “a movable annular member that can cover an aperture in the inner wall.” (Ex. 2015, [0043].) The “annular member,” also referred to as an “annular blocking member” in some embodiments, may be removably coupled to the aperture 22 such that when “the annular blocking member 62 is covering the aperture 22, fluid or material . . . m[ay] be contained within the interior space 20. . . .” (Ex. 2015, [0075].)

Figures 3A and 3B (below) illustrates a biological sample collection system 200 having a cap 12 with an outer wall 24 (yellow) wherein the components of the annular valve (components 18 and 62 (blue), at least) are positioned within an interior space of the cap 12 as defined by the outer wall 24. (Ex. 2015, [0075].)

Thus, the combination of originally filed Figures 3A and 3B and their accompanying description establishes written description support for an annular valve where the “first cylinder” and the “second cylinder” of the “annular valve” are “housed within the boundaries of the outer wall of the cap.” (Ex. 2014, ¶¶ 30-31.)



3. The “first cylinder” and “second cylinder” are relatively movable “within the boundaries of the outer wall of the cap

The original disclosure describes a biological sample collection system having an annular valve where “the inner wall 18 can include engagement features 60, such as threads, along a surface of the inner wall 18.” (Ex. 2015, [0075].) The “annular blocking member 62 can then threadably engage the engagement features, such as threads, along the side of the inner walls.” (Ex. 2015, [0078].) As explained *supra*, the interior chamber of the cap “may be at least partially defined by at least one of an inner wall 18 or outer wall 24 of the cap 12.” (Ex. 2015,

[0075].) Thus, the “first cylinder” and “second cylinder” are relatively movable “within the boundaries of the outer wall of the cap.”

Figures 3A and 3B (above) further emphasize this point. Figures 3A and 3B illustrate a biological sample collection system 200 having a cap 12 with an outer wall 24 (yellow) wherein the components of the annular valve (components 18 and 62 (blue), at least) are positioned within an interior space of the cap 12 as defined by the outer wall 24. (Ex. 2015, [0075].) Figure 3B demonstrates an “open” configuration wherein annular blocking member 62 has been threadably engaged and moved from its “closed” configuration in Figure 3A. Note that the threads on both components 62 and 18 are within the boundaries of outer wall 24 of the cap, so when the valve transitions from the “closed” to “open” configuration, the annular valve components necessarily move relative to each other only within the boundaries of the outer wall of the cap. Thus, the combination of originally filed Figures 3A and 3B and their accompanying description establishes written description support for an annular valve where the “first cylinder” and “second cylinder” are relatively movable “within the boundaries of the outer wall of the cap.” (Ex. 2014, ¶¶ 32-33.)

III. THE SUBSTITUTE CLAIMS ARE PATENTABLE OVER THE PRIOR ART OF THE INSTITUTED GROUNDS

Substitute independent claim 21, and those claims that depend therefrom, are patentable over the instituted grounds in this trial.

A. Claim Construction

1. “cap”

In the Decision on Institution, the Board determined that “the context of the ’632 patent claim does not support Patent Owner’s position that the term ‘cap’ precludes the cap from being co-extensive with the ‘annular valve.’” (Paper 10, 15–16.) Patent Owner maintains its assertion that *the cap and annular valve are separate components of the claimed sample collection system (i.e., the cap is not co-extensive with the annular valve)* and has amended substitute independent claim 21 to further emphasize this feature.

2. “within the boundaries of the outer wall of the cap”

Patent Owner has amended substitute independent claim 21 to indicate that the annular valve comprising the first cylinder, the second cylinder, and the vent are housed “within the boundaries of the outer wall of the cap.” As illustrated in FIGS. 3A and 3B of the ’632 patent, 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*), regardless of whether the annular valve is in the closed configuration (as illustrated in FIG. 3A) or the open configuration (as illustrated in FIG. 3B).

B. Level Of A Person Of Ordinary Skill In The Art

Petitioner has asserted that a person having ordinary skill in the art (POSITA) “would have had at least a bachelor’s degree in mechanical engineering,

biomedical engineering, or similar technical degree and at least 3 years of experience in the medical device industry, including experience with containers and valves used in disposable medical devices.” (Paper 10, 10 (citing Ex. 1002 ¶¶ 51–52.)) Petitioner further asserted that such a person would have collaborated with a team member having training and experience relating to the collection of biological samples. (*Id.*)

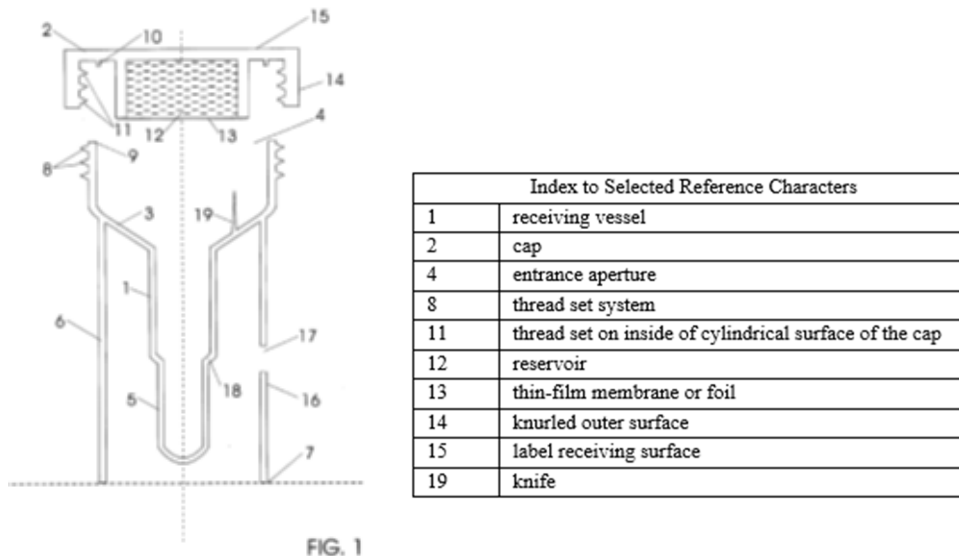
Patent Owner respectfully disagrees. A POSITA for the ’632 patent would have at least a Bachelor’s degree in a scientific field (not necessarily engineering) that is relevant to the mechanical aspects of containers and valves in disposable medical devices, and some experience with the design and fabrication of disposable medical devices. Not all individuals would require at least three years of experience, as more education can compensate for less experience in some cases and *vice versa*. While a POSITA would have some relevant mechanical experience, the person would not always have collaborated with another team member on the chemical/biological aspects of the claimed device. There are many individuals in this field with both mechanical and chemical/biological expertise, such that a POSITA for both the mechanical and chemical aspects of the device claimed in the ’632 patent could be a single person.

C. The Substitute Claims Are Patentable Over Plante And Cho (Ground I)

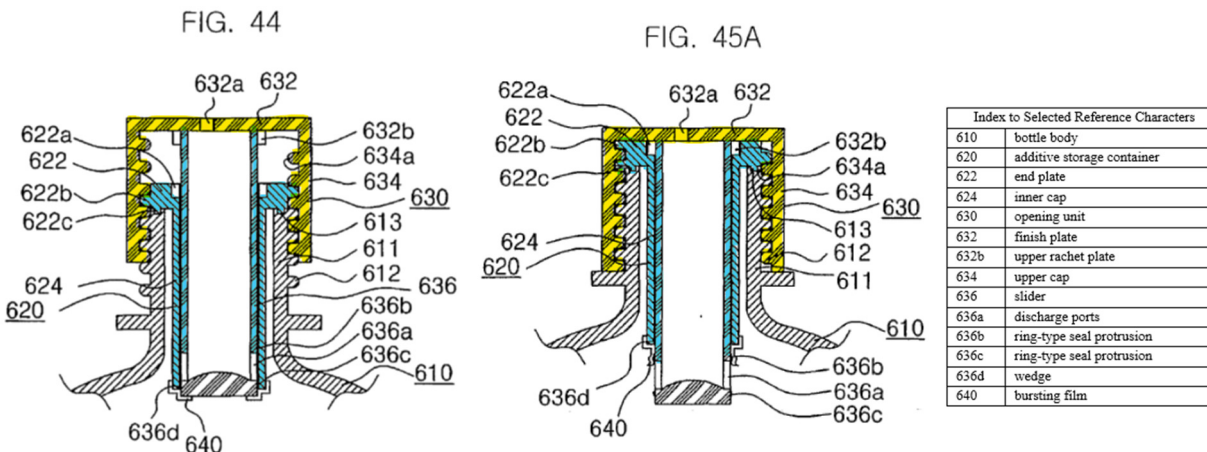
Claims 1–4, 6–16, and 18–20 have been challenged under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Plante and Cho. Plante and Cho fail to disclose or suggest the new recitations of amended substitute independent claim 21.

Plante describes a saliva sample collection system comprising a cap having an integrated reagent reservoir, where a reagent is sealed within the integrated reagent reservoir by means of a pierceable thin-film membrane. (*See, e.g.*, Ex. 1003, Abstract, [0035], FIG. 1.) A knife integrated with the receiving vessel pierces the membrane when the cap is screwed onto the receiving vessel and advances in an axial direction towards the receiving vessel. (*Id.*).

As shown in FIG. 1 in below, Plante’s cap 2 attaches to receiving vessel 1 by means of thread set 11 that is complementary to thread set system 8 on the outside of entrance aperture 4 of receiving vessel 1. A liquid tight reservoir 12 contains a preservative reagent that is held in place by means of a thin-film membrane or foil 13. The sealing cap 2 may include a knurled outer surface 14 and a label receiving surface 15. Thin-film membrane or foil 13 is pierced by knife 19 to release the preservative reagent when cap 2 is screwed onto receiving vessel 1.



Cho describes a bottle that contains two different materials stored in two separate spaces that can be connected in order to allow the two materials to mix. (See, e.g., Ex. 1004, Abstract, FIGS. 43, 44, 45A–B.) As illustrated in FIGS. 43, 44, and 45A–B, Cho’s system comprises an opening unit 630 that includes upper cap 634, an outer cylindrical component (inner cap 624), and an inner cylindrical component (slider 636) which is inserted into the outer cylindrical component (inner cap 624). (Ex. 1004, FIGS. 43, 44, 45A–B.) FIG. 44 of Cho (illustrating the closed configuration of Cho’s valve) and FIG. 45A (illustrating the open configuration) are reproduced below.



When opening unit 630 comprising upper cap 634 is screwed onto bottle body 610 by means of complementary threads, the inner cylindrical component (slider 636)—which extends beyond the boundaries of inner cap 634 and into the mouth of bottle body 610—is pushed through the outer cylindrical component (inner cap 624) in an axial direction to expose vents (discharge ports 636a), and thereby release the material stored in additive storage container 620. (*See, e.g., Ex. 1004, 48:15–24, 48:27–31, 49:10–13.*)

Thus, neither Plante nor Cho teaches or discloses a “moveable annular valve comprising: a vent, a first cylinder comprising a third aperture, wherein *the first cylinder is housed within the boundaries of the outer wall of the cap*, a second cylinder comprising the vent, the second cylinder positioned in the third aperture, wherein *the second cylinder is housed within the boundaries of the outer wall of the cap*, . . . [and wherein] *the first cylinder and second cylinder are relatively moveable within the boundaries of the outer wall of the cap to thereby change the*

annular valve from the closed configuration to the open configuration . . .”

(emphasis added), as is required by substitute independent claim 21. (Ex. 2014, ¶¶ 35-40.) Patent Owner respectfully submits that substitute independent claim 21 is patentable over the combination of Plante and Cho.

Even if Plante and Cho could be modified to meet the recitations of substitute independent claim 21, Patent Owner submits that there would have been no motivation for a POSITA to combine the teachings of the Plante and Cho references for at least the following reasons. First, a POSITA would not recognize that Plante’s knife creates a risk of injury nor molding that knife would be difficult such that he or should be motivated to combine Plante with Cho. (Ex. 2014, ¶¶ 42-54.) Second, whereas the device described by Plante is intended for collection, preservation, and safe transport of saliva samples (*see, e.g.*, Ex. 1003, Abstract, [0038]), the device described by Cho is intended for mixing an additive (*e.g.*, sugar, cream) with a liquid (*e.g.*, coffee) in a bottle (*see, e.g.*, Ex. 1004, Abstract, 1:8–12, 31:34–32:3). (Ex. 2014, ¶¶ 55-57.) Third, the device described by Cho for mixing additives with beverages does not provide the same functionality as that intended for Plante’s saliva sample collection device (*e.g.*, ease-of-use for the unskilled user, and safe transport and delivery by conventional delivery services (*see, e.g.*, Ex. 1003, Abstract)). (Ex. 2014, ¶¶ 55, 58-67.) Fourth, there would have been no reasonable expectation of success in substituting Cho’s cap

(comprising an annular valve mechanism) for Plante’s relatively simple cap (comprising a pierceable thin-film membrane) given the increased complexity and concomitant likelihood of increased manufacturing costs associated with the Cho design, as well as the increased likelihood of accidental release of reagents and/or sample contamination issues during use by an unskilled consumer that are inherent in the Cho device design. (Ex. 2014, ¶¶ 62-72.)

Substitute claims 22–39 depend from and include all elements of substitute claim 21, and recite additional elements of advantage and utility. The asserted combination of Plante and Cho does not teach all elements of substitute independent claim 21, much less the combination of elements in substitute claims 22–39. (Ex. 2014, ¶¶ 40-41.) Patent Owner thus respectfully submits that substitute claims 22–39 are also patentable over the combination of Plante and Cho.

D. The Substitute Claims Are Patentable Over Plante, Cho, And Patterson (Ground II)

Claim 5 has been challenged under 35 U.S.C. § 103(a) as allegedly being unpatentable in view of Plante, Cho and Patterson.

FIG. 2 of Patterson (illustrating the closed configuration) and FIG. 3 (illustrating the open configuration) are reproduced below along with FIG. 1. Patterson describes a “pre-loaded” mixing cap 10 for discharging dry or liquid ingredients from an outer housing 20 through apertures 46 of an inner tube 40,

thereby permitting the ingredients to flow through the apertures 46 of the inner tube 40 and into the liquid contents of a bottle. (*See, e.g.*, Ex. 1010, Abstract, FIGS. 1–3.) In the closed configuration (*see, e.g.*, Ex. 1010, FIG. 2), the preloaded ingredients are maintained within storage receptacle 22 of outer housing 20 (*i.e.*, an integrated outer wall—or outer cylindrical component—of the mixing cap 10) by a seal formed between the peaked or dome-shaped top wall 42 of inner tube 40 (*i.e.*, an inner cylindrical component that extends well beyond the confines of the outer wall—or outer cylindrical component—of mixing cap 10) and neck portion 24 of outer housing 20. (*See, e.g.*, Ex. 1010, [0033]–[0034].)

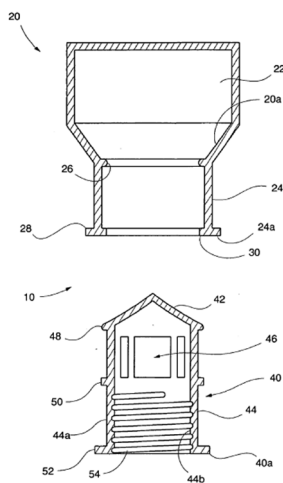
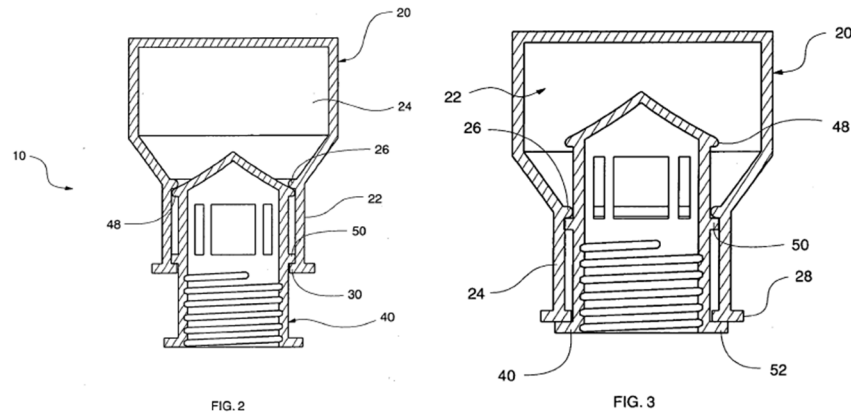


FIG. 1

Index to Selected Reference Characters	
10	mixing cap
20	outer housing
20a	inner wall of neck portion
22	storage receptacle
24	neck portion of outer housing
40	inner tube
42	peaked or dome-shaped top wall
44	sidewall of inner tube
46	apertures



In the closed position, apertures 46 of sidewall 44 of inner tube 40 are also preferably disposed against and covered by inner wall 20a of neck portion 24 of the outer housing 20. (Ex. 1010, [0034], FIG. 2.) In the open configuration (*see, e.g.,* Ex. 1010, FIG. 3), outer housing 20 is pushed downward such that the neck portion 24 of the outer housing 20 slides over sidewall 44 of inner tube 40, thereby introducing the apertures 46 in sidewall 44 of inner tube 40 into storage receptacle 22 of outer housing 20, and enabling the ingredients contained therein to flow through apertures 46 and inner tube 40 into the liquid contents of the bottle. (*See, e.g.,* Ex. 1010, [0035]–[0036].)

However, Patterson does not cure the deficiencies of Plante and Cho in rendering substitute independent claim 21 unpatentable. There is no teaching or disclosure in Patterson of a “moveable annular valve [positioned in an aperture of a cap] comprising: a vent, a first cylinder comprising a third aperture, wherein *the first cylinder is housed within the boundaries of the outer wall of the cap*, a second cylinder comprising the vent, the second cylinder positioned in the third aperture,

wherein the second cylinder is housed within the boundaries of the outer wall of the cap, . . . [and wherein] the first cylinder and second cylinder are relatively moveable within the boundaries of the outer wall of the cap to thereby change the annular valve from the closed configuration to the open configuration . . .”

(emphasis added), as is required by substitute independent claim 21. (Ex. 2014, ¶¶ 74-76.) Patent Owner thus respectfully submits that substitute independent claim 21 is patentable over Patterson.

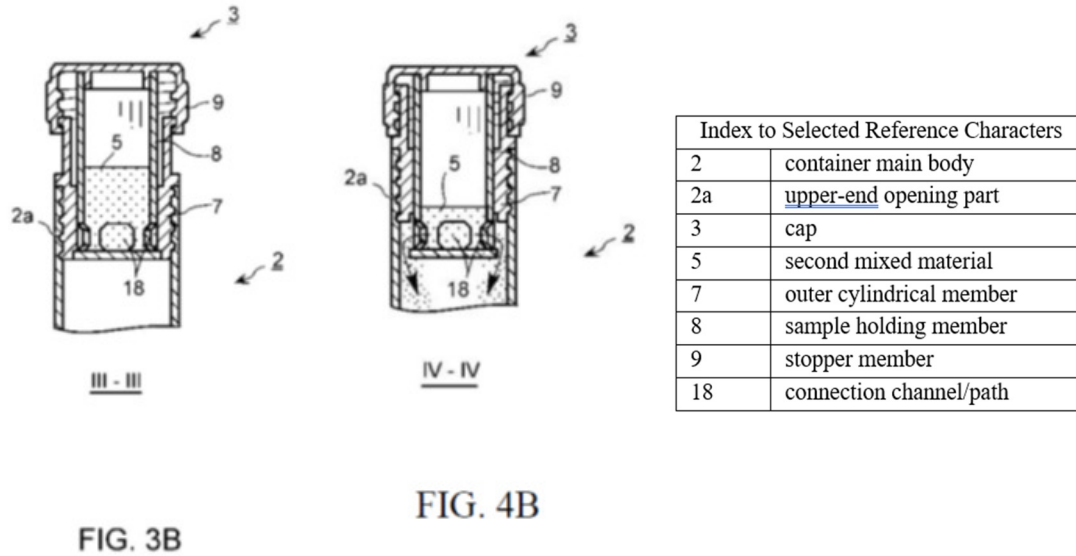
Substitute claims 22–39 depend from and include all elements of substitute claim 21, and recite additional elements of advantage and utility. Patterson does not teach all elements of substitute independent claim 21, much less the combination of elements in substitute claims 22–39. (Ex. 2014, ¶¶ 76-77.) Patent Owner thus respectfully submits that substitute claims 22–39 are also patentable over Patterson.

E. The Substitute Claims Are Patentable Over Ueda (Ground III)

Claims 1–8, 10–16, and 18–20 have been challenged under 35 U.S.C. § 102(a) as allegedly being unpatentable in view of Ueda.

As noted in the Decision on Institution, Ueda describes “containers, in particular . . . containers suitable for storing biological samples.” (Paper 10, 21.) Ueda’s FIG. 3B and FIG. 4B are reproduced below. Ueda’s FIG. 3B (section III–

III) shows a cross-sectional view of a closed configuration of an embodiment of the container device. (Ex. 1005, FIG. 3B.)



Outer cylindrical member 7 of cap 3 is screwed into the threads 2a at the upper-end opening part of container main body 2. (*Id.*) Cap 3 includes sample holding member 8 (*i.e.*, an inner cylindrical component configured to contain a material 5). Both outer cylindrical member 7 and sample holding member 8 extend beyond the boundaries of cap 3 and into the opening of container main body 2. (*Id.*) Sample holding member 8 has an outer diameter that allows it to slide vertically along its axial direction within outer cylindrical member 7. (*Id.*) The lower end of sample holding member 8 is closed with a bottom wall plate, and comprises a plurality of connection channels/paths 18 that open outward in a radial direction. (*Id.*)

In the closed configuration (FIG. 3B), sample holding member 8 is flush with (*i.e.*, does not protrude from) the lower end opening of outer cylindrical member 7, and the plurality of connection channels/paths 18 are sealed by the inner surface of outer cylindrical member 7. (*Id.*) In the open configuration (FIG. 4B, Section IV–IV), sample holding member 8 protrudes from the lower end of the outer cylindrical member 7 and the plurality of communication passages 18 communicate with the internal space of container main body 2 to release material 5 into container main body 2. (Ex. 1005, FIG. 4B.)

However, there is no teaching or disclosure in Ueda of a “moveable annular valve [positioned in an aperture of a cap] comprising: a vent, a first cylinder comprising a third aperture, wherein *the first cylinder is housed within the boundaries of the outer wall of the cap*, a second cylinder comprising the vent, the second cylinder positioned in the third aperture, wherein *the second cylinder is housed within the boundaries of the outer wall of the cap*, . . . [and wherein] *the first cylinder and second cylinder are relatively moveable within the boundaries of the outer wall of the cap to thereby change the annular valve from the closed configuration to the open configuration . . .*” (emphasis added), as is required by substitute independent claim 21. (Ex. 2014, ¶¶ 79-82.) Patent Owner thus respectfully submits that substitute independent claim 21 is patentable over Ueda.

Substitute claims 22–39 depend from and include all elements of substitute claim 21, and recite additional elements of advantage and utility. Ueda does not teach all elements of substitute independent claim 21, much less the combination of elements in substitute claims 22–39. (Ex. 2014, ¶¶ 82-83.) Patent Owner thus respectfully submits that substitute claims 22–39 are also patentable over Ueda.

F. The Substitute Claims Are Patentable Over Ueda And Patterson (Ground IV)

Claim 5 has been challenged under 35 U.S.C. § 103(a) as allegedly being unpatentable in view of Ueda and Patterson.

As noted above, Patterson describes a “pre-loaded” mixing cap 10 for discharging dry or liquid ingredients from an outer housing 20 through apertures 46 of an inner tube 40, thereby permitting the ingredients to flow through the apertures 46 of the inner tube 40 and into the liquid contents of a bottle. (*See, e.g.*, Ex. 1010, Abstract, FIGS. 1–3.)

However, Patterson does not cure the deficiencies of Ueda in anticipating or rendering substitute independent claim 21 obvious. Patent Owner therefore respectfully submits that substitute claim 21 (as well as substitute dependent claims 22–39, which depend from and further limit substitute claim 21) are patentable over the combination of Ueda and Patterson. (Ex. 2014, ¶¶ 85-86.)

G. The Substitute Claims Are Patentable Over Ueda And Williams (Ground V)

Claim 9 has been challenged under 35 U.S.C. § 103(a) as allegedly being unpatentable in view of Ueda and Williams.

Williams describes a biological specimen collection device that comprises a specimen receptacle, where a removable conduit (*e.g.*, a funnel) is provided for introducing a biological specimen into the receptacle, and a base is provided that removably receives the specimen receptacle and supports the receptacle in a substantially vertical position. (*See, e.g.*, Ex. 1009, Abstract.)

However, Williams does not cure the deficiencies of Ueda in anticipating or rendering substitute independent claim 21 obvious. Patent Owner therefore respectfully submits that substitute claim 21 (as well as substitute dependent claims 22–39, which depend from and further limit substitute claim 21) are patentable over the combination of Ueda and Williams. (Ex. 2014, ¶¶ 88-89.)

IV. CONCLUSION

Patent Owner respectfully requests that the Board grant this Motion as to the substitute claims.

IPR2023-01424

Dated: July 2, 2024

Respectfully submitted,

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APPENDIX A – LISTING OF SUBSTITUTE CLAIMS

Patent Owner presents the following substitute claims in marked-up form with underling indicating inserted text and brackets or strikethrough indicating deleted text from the original patent claims.

21. (substitute for claim 1) A biological sample collection system, the system comprising:

a sample collection vessel comprising

a sample collection reservoir,

a first connection member, and

a first aperture for receiving a biological sample;

a cap comprising

an outer wall;

a second aperture,

a reagent chamber storing a reagent therein, and

a second connection member complementary to the first connection member; and

a moveable annular valve positioned in the second aperture, the movable annular valve

comprising

a vent,

a first cylinder comprising a third aperture, wherein the first cylinder is housed within the boundaries of the outer wall of the cap,

a second cylinder comprising the vent, the second cylinder positioned in the third aperture, wherein the second cylinder is housed within the boundaries of the outer wall of the cap,

a closed configuration, and

an open configuration, wherein

in the moveable annular valve's closed configuration, the first and second cylinders create a fluid-tight seal with the cap and the first cylinder obstructs the vent to retain the reagent in the reagent chamber,

the first cylinder and second cylinder are relatively moveable within the boundaries of the outer wall of the cap to thereby change the annular valve from the closed configuration to the open configuration, and

in the moveable annular valve's open configuration, the first cylinder does not obstruct the vent to thereby allow flow of the reagent from the reagent chamber, through the vent, and into the sample collection reservoir.

22. (substitute for claim 2) The biological sample collection system of claim 21, wherein the second cylinder comprises a sidewall and the sidewall comprises the vent, wherein the annular valve's closed configuration comprises a sidewall of the first cylinder obstructing the vent and the annular valve's open configuration comprises the sidewall of the first cylinder not obstructing the vent.

23. (substitute for claim 3) The biological sample collection system of claim 21, wherein the first and second cylinder's relative movement, from the annular valve's closed configuration to the open configuration, is translational along a longitudinal axis of the cap.

24. (substitute for claim 4) The biological sample collection system of claim 21, wherein the first and second cylinder's relative movement, from the annular valve's closed configuration to the open configuration, comprises the second cylinder moving in the third aperture.

25. (substitute for claim 5) The biological sample collection system of claim 21, wherein the first cylinder comprises a press-fit connection with the cap.

26. (substitute for claim 6) The biological sample collection system of claim 21, wherein the second cylinder comprises a plurality of vents and the first cylinder obstructs the plurality of vents in the annular valve's closed configuration.

27. (substitute for claim 7) The biological sample collection system of claim 21, wherein the first cylinder of the annular valve comprises a flange and the

annular valve with flange comprises a width larger than a width of the first aperture.

28. (substitute for claim 8) The biological sample collection system of claim 27, wherein interaction between the flange and a wall of the sample collection vessel causes the first and second cylinders to move relatively and change the annular valve from the closed configuration to the open configuration.

29. (substitute for claim 9) The biological sample collection system of claim 21, further comprising a funnel attachable to the sample collection vessel.

30. (substitute for claim 10) The biological sample collection system of claim 21, wherein the vent is at least partially unobstructed in the annular valve's open configuration.

31. (substitute for claim 11) The biological sample collection system of claim 21, wherein the vent is fully unobstructed in the annular valve's open configuration.

32. (substitute for claim 12) The biological sample collection system of claim 21, wherein the first and second cylinders comprise generally constant exterior diameters.

33. (substitute for claim 13) The biological sample collection system of claim ~~4~~32, wherein the annular valve comprises a flange extending from at least one of the first and second cylinders.

34. (substitute for claim 14) The biological sample collection system of claim 21, wherein the first and second connection members comprise a threaded connection.

35. (substitute for claim 15) The biological sample collection system of claim 21, wherein the annular valve comprises a sliding connection between the first and second cylinders.

36. (substitute for claim 16) The biological sample collection system of claim 21, wherein the sample collection system comprises a separable two-piece sample collection system, the sample collection vessel comprising a first piece of the separable two-piece sample collection system, and the cap with movable annular valve comprising a second piece of the separable two-piece sample collection system.

37. (substitute for claim 18) The biological sample collection system of claim 21, wherein a diameter of an inner wall of the first cylinder is sufficiently equal to a diameter of an outer wall of the second cylinder to create a fluid-tight connection therebetween and allow relative movement.

38. (substitute for claim 19) The biological sample collection system of claim 21, wherein the system is configured such that connecting the cap to the sample collection vessel causes the annular valve to move from the closed configuration to the open configuration.

39. (substitute for claim 20) The biological sample collection system of claim 21, wherein

the system is configured such that connecting the cap to the sample collection vessel causes the annular valve to move from the closed configuration to the open configuration, wherein

the second cylinder comprises a sidewall and the sidewall comprises the vent, wherein

the annular valve's closed configuration comprises a sidewall of the first cylinder obstructing the vent and the annular valve's open configuration comprises the sidewall of the first cylinder not obstructing the vent, and wherein

the first and second cylinder's relative movement, from the annular valve's closed configuration to the open configuration, is translational along a longitudinal axis of the cap.

CERTIFICATE OF SERVICE

I hereby certify that the attached PATENT OWNER'S NON-CONTINGENT MOTION TO AMEND AND REQUEST FOR PRELIMINARY GUIDANCE was served as of the below date on the Petitioner via email (by agreement) to the following counsel of record:

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Dated: July 2, 2024

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