

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS L.L.C.,
Petitioner,

v.

DNA GENOTEK INC.,
Patent Owner.

Patent No. 11,536,632 B2

Inter Partes Review No. IPR2023-01424

**PATENT OWNER'S REVISED
NON-CONTINGENT MOTION TO AMEND**

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<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	11
<i>Vas-Cath Inc. v. Mahurkar</i> , 935 F.2d 1555 (Fed. Cir. 1991)	6

Other Authorities

37 C.F.R. § 42.121	1
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37 C.F.R. § 42.121(a)(2)(ii)	2
37 C.F.R. §§ 42.121(a)(2)(ii) and (b)(1)	3
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
Second Declaration of Dr. Steven Wereley (Wereley II)	2025
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Definition of “External,” <i>American Heritage Dictionary of the English Language</i> (5th ed. 2011)	2027
Definition of “Aperture,” <i>American Heritage Dictionary of the English Language</i> (5th ed. 2011)	2028
Injection Molding Handbook, Ch. 4-7 (3d ed. 2000)	2029

**Patent Owner’s Exhibits 2001-2024 were previously filed and are listed again here based on 37 C.F.R. § 42.63.*

***Patent Owner’s Exhibits 2025-2029 are newly filed.*

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.121 and the Board’s Order (Paper 10) and in view of Petitioner’s Opposition to Patent Owner’s Motion to Amend (“Opposition”) (Paper 19) and the Board’s Preliminary Guidance (“Preliminary Guidance”) (Paper 21), Patent Owner Genotek submits this revised non-contingent Motion to Amend (“Motion” or “rMTA”) cancelling challenged claims 1–16 and 18–20 of the ’632 patent and substituting claims 21–39. This Motion and Wereley II (Ex. 2025) demonstrate that the substitute claims are patentable over the grounds in this proceeding, even though Genotek does not bear a burden of persuasion to demonstrate the patentability of the substitute claims. *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1327 (Fed. Cir. 2017).

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

A. Reasonable Number Of Substitute Claims

Genotek proposes only one substitute claim for each challenged claim in Appendix A. This Motion is thus consistent with 37 C.F.R. § 42.121(a)(3).

B. The Substitute Claims Are Responsive To The Instituted Grounds, Opposition, And Preliminary Guidance

Substitute claims 21–39 are responsive to all grounds of unpatentability. 37 C.F.R. § 42.121(a)(2)(i). In this Motion, Genotek proposes one revised substitute independent claim—claim 21—with recitations that overcome Ground I as described *infra*. Furthermore, the terms “within” and “boundary”—the recent focus

of Petitioner and the Board—no longer appear in revised substitute claim 21. Revised substitute dependent claims 22–39 are also responsive to one or more instituted grounds, because their amendments are tied to their dependency from claim 21 and provide a basis of patentability over Grounds I–V as described *infra*.

C. The Substitute Claims Do Not Enlarge Scope

Revised substitute independent claim 21 adds further recitations to challenged independent claim 1 as follows: (1) amending the “cap” recitation to also comprise an “outer wall” that defines an “open end” of the cap, an opposing “closed end” of the cap, and an “interior volume” of the cap; (2) clarifying that the “reagent chamber” and the “moveable annular valve” are “positioned in the interior volume of the cap”; and (3) clarifying that “first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve.” Thus, there is no enlargement in claim scope. 37 C.F.R. § 42.121(a)(2)(ii).

D. Support In The Original Disclosure And No 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 and *Wereley II* (Ex. 2025, ¶¶ 15–37), 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)
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 defining an open end of the cap, an opposing closed end of the cap, and an interior volume of the cap, said open end defining a second aperture,</u> - a reagent chamber storing a reagent therein <u>and positioned in the interior volume of the cap,</u> and - a second connection member complementary to the first connection member; and	<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>“an outer wall defining an open end of the cap, an opposing closed end of the cap, and an interior volume of the cap, said open end defining a second aperture”</u> Ex. 2015: [0022], [0060], [0075], FIG. 3A-3B; Ex. 2022: 4-9, FIG. 3A-3B.

¹ The intervening non-provisional applications (Exs. 2016–2018) are identical to the '003 application for the purposes of this Motion. (*See* Ex. 2025, ¶ 9.)

a moveable annular valve <u>positioned in the ~~second aperture~~ interior volume of the cap</u>, the movable annular valve comprising - a vent, - a first cylinder comprising a third aperture, - a second cylinder comprising the vent, the second cylinder positioned in the third aperture, - 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 to thereby change the annular valve from the closed configuration to the open configuration, <u>wherein the first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve</u>, and - in the <u>moveable annular valve's</u> 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.	<u>“reagent chamber” and the “moveable annular valve” are “positioned in the interior volume of the cap”</u> Ex. 2015: [0022], [0043], [0044], [0075], FIG. 3A-3B; Ex. 2022: 4-9, FIG. 3A-3B. <u>“the first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve”</u> Ex. 2015: [0075], [0076], FIG. 3A-3B, <i>see also</i> [0043], [0044], [0078]; Ex. 2022: 4-6, 8-9, FIG. 3A-3B.
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The chart below shows the exemplary support for the substitute dependent claims with additional discussion for claims 29 and 33 *infra*.

Substitute Dependent Claims	Support
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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 (amendment to claim 9)	Ex. 2015: [0022], [0043], [0044], [0060], [0075], [0078], FIGS. 3A, 3B; Ex. 2022: 4-6, 8-9, FIGS. 3A, 3B.
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 (amendment to claim 13)	Ex. 2015: [0043], [0044], [0075]-[0078], FIGS. 3A, 3B, 3C; Ex. 2022: 5, 7-9; FIGS. 1A, 1B; FIGS. 3A, 3B; Claim 13 as originally filed.
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.

Although there is support for the newly added recitations in both the written description as well as the figures, the figures alone can be enough to provide written description support. *See, e.g., Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991) (finding that “drawings alone may be sufficient to provide the ‘written description of the invention’ required by § 112, first paragraph”); *In re Mraz*, 455 F.2d 1069, 1072 (C.C.P.A. 1972).

1. The “outer wall defining an open end of the cap, an opposing closed end of the cap, and an interior volume of the cap, said open end defining a second aperture”

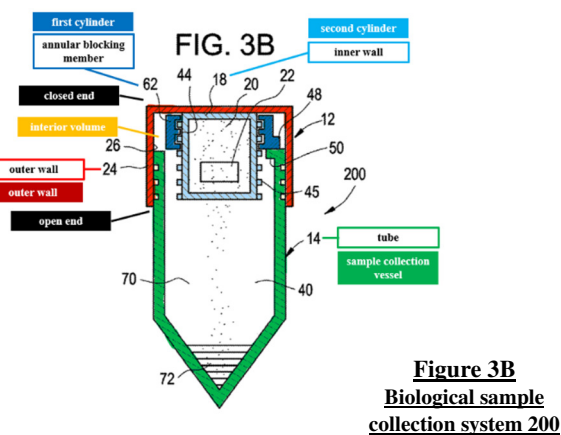
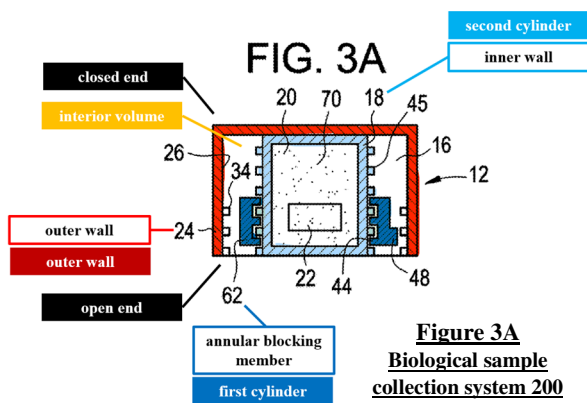
The original disclosure describes a biological sample collection system having a cap that “comprises an *outer wall*.”² (Ex. 2015, [0022].) Petitioner does

² All emphases have been added unless otherwise noted.

not appear to dispute this, and the Board agreed in its Preliminary Guidance.

(Paper 21, 5; Ex. 2025, ¶ 18.)

FIGS. 3A and 3B (below) illustrate a biological sample collection system 200 having a cap 12 with an outer wall 24 (red), which has a closed end and an open end, and an interior volume. (Ex. 2015, [0075]; Ex. 2025, ¶¶ 19–21.) Mr. Leinsing agreed, explaining that the cap in FIGS. 3A and 3B “would be generally . . . understood as a generally cylindrical component with one capped end and one opened end” and “cup like.” (Ex. 2026, 43:7–13; 51:21–24; *see also* 43:15–44:3.) And asked “[i]f you were to take a cup and fill it with sand all the way to its top lip, would that sand be entirely within the volume of the cup,” Mr. Leinsing responded: “You could say it was in the entirety of the volume of the cup” (*Id.*, 66:19–67:5.)



2. The “reagent chamber” and the “moveable annular valve” are “positioned in the interior volume of the cap”

The original disclosure describes a biological sample collection system with “a cap having an *interior chamber*” and an “*interior space*.” (Ex. 2015, [0022].) In the cap, there is “a movable annular member that can cover an aperture in the inner wall.” (*Id.*, [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 . . . may be contained in the interior space 20.” (*Id.*, [0075]; Ex. 2025, ¶ 22.)

FIGS. 3A and 3B (above) illustrate a biological sample collection system 200 having a cap 12 with an outer wall 24 (red) wherein the reagent chamber and moveable annular valve (components 20, 18 (light blue), and 62 (dark blue), at least) are positioned within an interior volume of the cap 12 as defined by the outer wall 24. (Ex. 2015, [0075]; Ex. 2025, ¶¶ 23–24.) Mr. Leinsing similarly testified that the cap comprises an “open volume with other components inside of it like a [cup] shape.” (Ex. 2026, 44:18–25; *see also* 53:12–23.)

3. The “first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve”

The original disclosure describes a biological sample collection system where “the annular blocking member 62 may be configured to interact with . . .

coupling member 50, of the tube 14 such that as the cap 12 is being securely coupled to the tube 14, the one or more features of either the tube 14 or annular blocking member 62 can cause the annular blocking member 62 to move from a position where the annular blocking member 62 is covering the aperture 22 to a position where the annular blocking member 62 is not covering the aperture 22.” (Ex. 2015, [0076].) In other words, the first cylinder (annular blocking member 62) interacts with a feature of the sample collection vessel (tube 14) which causes it to move relative to the second cylinder (inner wall 18), preventing the first cylinder from entering the sample collection reservoir. (Ex. 2025, ¶ 25–26.)

FIGS. 3A and 3B (above) further emphasize this point. They illustrate a biological sample collection system 200 transitioning from the closed configuration to the open configuration. (Ex. 2015, FIGS. 3A–3B.) FIG. 3A demonstrates a “closed configuration” where annular blocking member 62 (dark blue) covers the vent (aperture 22) of the second cylinder (inner wall 18 (light blue)). (*Id.*, [0076].) FIG. 3B demonstrates an “open” configuration wherein a tube 14 (green) has been attached and annular blocking member 62 has been engaged and moved from its “closed” configuration in FIG. 3A. Note that the annular blocking member 62 is pushed up into the cap 12 upon engagement with the tube 14, so when the valve transitions from the “closed” to “open” configuration, the

first cylinder necessarily remains external to the tube 14. (*Id.*, FIGS. 3A–3B; Ex. 2025, ¶¶ 27–28.)

4. Support for substitute dependent claims 29 and 33

Revised substitute dependent claim 29 recites “wherein the first cylinder and second cylinder are relatively moveable entirely within the interior volume of the cap to thereby change the moveable annular valve from the closed configuration to the open configuration.” FIGS. 3A and 3B—whether in Ex. 2015 or Ex. 2022—illustrate a first and second cylinder “entirely within” the interior volume of the cap. (*See also* Ex. 2015, [0075], [0078]; Ex. 2025, ¶¶ 30–35.) Asked “[i]f you were to take a cup and fill it with sand all the way to its top lip, would that sand be *entirely within the volume* of the cup,” Mr. Leinsing responded: “You could say it was in the *entirety of the volume* of the cup” (Ex. 2026, 66:19–67:5.) Thus, the “first cylinder” and “second cylinder” are relatively movable “entirely within the interior volume of the cap.”

Revised substitute dependent claim 33 recites “wherein initial contact between the flange and a portion of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration, said portion of the sample collection vessel being disposed proximal to the first aperture.” The original disclosure describes how initial contact between a coupling member 50 of the end

of the tube 14 (*i.e.*, a flange) and the annular blocking member 62 can cause the annular blocking member 62 to move from the closed position to the open position. (Ex. 2015, [0076]; *see also*, FIGS. 3A, 3B, 3C; Ex. 2025, ¶¶ 36–37.)

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

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

A. Claim Construction

The words in a patent claim “‘are generally given their ordinary and customary meaning’ . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention[.]”

Phillips v. AWH Corp., 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (internal citations omitted). A POSITA would understand “externally” in substitute claim 21 in this context, *i.e.*, to mean that the first cylinder is “outside of” or “exterior to” the sample collection vessel. (Ex. 2025, ¶¶ 11–14.) This is supported by the 2011 dictionary definition of “external” (adjective) as “[r]elating to, existing on, or connected with the outside or outer part; exterior.” (Ex. 2027.) The proposed construction is also consistent with how Cho uses “external” in the 21st embodiment of his device. Cho describes a bottle body 610 with “a mouth 611 having an external thread 612 formed around the outer circumferential surface of the mouth 611” meaning “external” components are on the outside or “outer”

portion of a component. (Ex. 1004, 48:16–18.) Mr. Leinsing agreed with this definition of “external” as he noted that the relevant Cho threads “would be on the exterior or external surface of those particular features.” (Ex. 2026, 115:24–116:8.)

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

As explained in *Wereley II* (Ex. 2025, ¶ 10), a POSITA 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 as Petitioner urges. 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)

1. Claim 21 and dependent claims

In view of the Opposition and Preliminary Guidance, Plante and Cho fail to disclose or suggest the recitations of substitute independent claim 21.

Although Plante’s cap 2 includes an outer wall (corresponding to the wall comprising knurled outer surface 14) that defines “*an outer wall defining an open end of the cap, an opposing closed end of the cap, and an interior volume of the cap, said open end defining a second aperture*” (see, e.g., Plante, FIG. 1), there is clearly no “*moveable annular valve positioned in the interior volume of the cap,*” as is required by substitute claim 21. There is also no “first cylinder” (*i.e.*, a component of a moveable annular valve) that “*is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve*” as required by substitute claim 21. (See Ex. 2025, ¶¶ 38–41.)

As can be seen in Cho’s FIG. 44 (closed configuration) and FIG. 45A (open configuration), Cho’s device includes an upper cap 634, an additive storage container 620 that is positioned within the mouth 611 of bottle body 610, and an opening unit 630 that is combined with the additive storage container 620 through a screw-type engagement. (Ex. 1004, 48:16–22.) It is clear from these figures and the corresponding description that the “first cylinder” (*i.e.*, which Petitioner maps to inner cap 624) extends into the mouth 611 of bottle body 610 in both the closed configuration (FIG. 44) and the open configuration (FIG. 45A) of the “annular valve.” Consequently, Cho’s “annular valve” does not include a “first cylinder” that “*is positioned externally to the sample collection vessel in both the closed*

configuration and the open configuration of the moveable annular valve” as is required by substitute claim 21. (Ex. 2025, ¶¶ 42–44.)

Neither Plante nor Cho, individually or in combination, disclose or suggest substitute claim 21 based on the above recitations, and therefore Patent Owner respectfully submits that substitute claim 21 and the substitute dependent claims are patentable over the combination of Plante and Cho for at least these reasons.

2. Claim 29

Substitute dependent claim 29 recites “wherein the first cylinder and second cylinder are relatively moveable entirely within the interior volume of the cap to thereby change the moveable annular valve from the closed configuration to the open configuration.” Plante’s device does not include an annular valve. As illustrated in FIGS. 43, 44, and 45A of Cho, the inner and outer cylinders of Cho’s “annular valve” (*i.e.*, that Petitioner maps to inner cap 624 and slider 636) clearly are not confined to be “relatively moveable entirely within the interior volume of the cap” as is required by substitute dependent claim 29. Thus, Patent Owner submits that substitute dependent claim 29 is patentable over the combination of Plante and Cho for this additional reason. (Ex. 2025, ¶¶ 45–46.)

3. Claim 33

Substitute dependent claim 33 recites “wherein initial contact between the flange [extending from at least one of the first and second cylinders] and a portion

of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration.” As illustrated in FIGS. 43, 44, and 45A of Cho, a flange (endplate 622) attached to Cho’s first cylinder (inner cap 624) is already in contact with a portion of the mouth of bottle body 610 (*i.e.*, lower ratchet 613) prior to changing the “annular valve” from the closed configuration (FIG. 44) to the open configuration (FIG. 45A) upon tightening of upper cap 634 to the threaded mouth of bottle body 610. Thus, Patent Owner submits that substitute dependent claim 33 is patentable over the combination of Plante and Cho for this additional reason. (Ex. 2025, ¶¶ 45, 47.)

4. Claim 36

Substitute dependent claim 36 recites “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.”

Plante describes a saliva collection device intended for direct-to-consumer use in diagnostic application. (Ex. 1003, [0017].) As described in Plante, the sealing cap comprising the reagent reservoir is provided as a separate component

of the kit that includes the sealing cap (storing a reagent) and the empty sample receiving vessel. (*See, e.g., id.*, [0018]–[0022].)

Cho’s device is intended for commercial sale in a configuration where the cap ***has already been attached*** to the bottle: “Accordingly, the present invention has been made keeping in mind the above problems occurring in the prior art, and an object of the present invention is to provide a bottle which stores two kinds of materials separately in a bottle when the bottle is distributed on the market, thus saving resources, unlike conventional bottles, in which two bottles are required to store two materials therein.” (Ex. 1004, 1:19–24.) As illustrated in FIGS. 43, 44, and 45A, Cho’s opening unit 630 is designed to be attached to bottle body 610 prior to release of the additive stored within the additive storage container 620. Only after upper cap 634 is further tightened is slider 636 pushed past the end of inner cap 624 to open the discharge ports 636a.

Cho’s device thus addresses a different need, *i.e.*, shipment of ***two kinds*** of materials in a ***single bottle*** for subsequent mixing (*e.g.*, a coffee-based beverage to be mixed with sugar or cream powder (Ex. 1004, 1:8–12)) than that addressed by Plante’s device, *i.e.*, the need to ship a sample preservative stored in a container (*e.g.*, a cap) that is separate from the empty sample collection vessel, but configured for reliable and safe release of the preservative when the cap is attached to the sample collection vessel. (Ex. 2025, ¶¶ 45, 48–52.)

Patent Owner thus submits that a POSITA would have had no motivation to combine Cho's valve with Plante's sample collection device, nor would a POSITA have had any motivation to try to modify Cho's device in an attempt to do so. Accordingly, Patent Owner submits that substitute dependent claim 36 is patentable over the combination of Plante and Cho for this additional reason.

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

There is no disclosure in Patterson of “a moveable annular valve positioned in the interior volume of the cap” (the first cylindrical component of Patterson's “annular valve” is integrated with cap 20), as is required by substitute claim 21. (Ex. 2025, ¶ 90.) Thus, Patent Owner respectfully submits that Plante, Cho, and Patterson, either individually or in combination, fail to disclose or suggest the substitute claim 21, and that therefore substitute claim 21 and its dependent claims, including claim 25, are patentable over the combination of Plante, Cho, and Patterson at least for these reasons.

E. There Is No Motivation To Combine Plante And Cho With Reasonable Expectation Of Success In Grounds I and II

1. A POSITA would not recognize Plante's knife as presenting a risk of injury

As discussed in Patent Owner's first MTA (Paper 16, 13–17), a POSITA would not have been motivated to replace Plante's knife because a POSITA would not have perceived Plante's knife as creating a significant risk of injury. Rather, a

POSITA would have recognized that the cylindrical wall of Plante's sample collection tube (that defines the entrance aperture 4 of the tube) provides an engineering control to mitigate any risk of injury (*e.g.*, by varying the diameter of the entrance aperture and/or the placement of the knife 19 within the sample collection tube). Furthermore, the existence of numerous commercial devices that are quite similar to that described in Plante (including a puncturable membrane and knife-based design for reagent release), without any indication of injury over the years, undermines the argument that a POSITA would have perceived Plante's knife as creating a risk of injury. (*See, e.g.*, Ex. 2025, ¶¶ 56–57.)

2. A POSITA would not recognize molding Plante's knife as being unduly difficult

Although sharp corners and other sharp features can be problematic to injection mold (potentially requiring iterative refinements of mold design and/or molding process parameters to achieve a robust manufacturing process), a POSITA would understand that injection molding could be used to create features sufficiently pointed to puncture a thin film membrane, as required in Plante. (Ex. 2025, ¶ 58.)

Furthermore, Petitioner cites Cho's device as a substitution for Plante's knife to avoid having to mold a sharp feature, despite the fact that Cho's device includes a larger number of sharp features. Plante's device comprises a single sharp feature (*i.e.*, knife 19), whereas inspection of Cho's FIG. 43 indicates that the device

comprises at least 22 sharp features. (*See, e.g.*, Ex. 2025, ¶ 59.) Even a POSITA that was concerned about molding a single sharp feature would not be inclined to replace a device comprising a single sharp feature (Plante’s knife) with one that comprises a much larger number of sharp features (*e.g.*, Cho’s design), particularly when, as discussed above, simple modifications to Plante’s device would effectively mitigate risk of injury. (Ex. 2025, ¶¶ 56, 58–60.)

3. Scaling down and/or modifying Cho as a replacement for Plante’s knife would require extensive redesign and testing with an unpredictable outcome

Petitioner has characterized replacement of Plante’s membrane and knife with Cho’s annular valve design as a “simple substitution.” (*See, e.g.*, Pet., 16; Ex. 1002, ¶ 74.) Patent Owner disagrees. Even if a POSITA decided to attempt to modify Cho’s device, despite the considerations outlined above, there would be no *a priori* guarantee of success, *i.e.*, the outcome would be unpredictable.

First, in its Opposition, Petitioner stated that “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.” (Paper 19, 1.) In support, Petitioner quotes from Dr. Wereley’s testimony in IPR2022-01347. (*Id.*, 16.) But Dr. Wereley repeatedly made clear that the changes “could” be made. (*See, e.g.*, 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....”); 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”). That is, an acknowledgement that one of skill in the art would understand that Cho’s design could be modified (*e.g.*, the size or volume of the additive storage container) is not the same as stating that a POSITA would be motivated to do so. Nor is it the same as stating that it would be within the skill in the art to do so. (Ex. 2025, ¶¶ 61–64.)

Second, replacement of Plante’s puncturable membrane and knife-based design with Cho’s valve design would require significant rescaling and redesign, and a number of problems would arise—all directing a POSITA against the combination. As discussed by Dr. Wereley, Cho’s device comprises multiple fabricated parts (*e.g.*, 634 and 624) that collectively include over a dozen distinct features that are difficult to fabricate by injection molding as described in the *Injection Molding Handbook* (Ex. 1014). The Handbook (cited by Mr. Leinsing in his first declaration (Ex. 1002, ¶ 71)) discusses many different features that can be problematic to injection mold, including parts comprising thin or thick sections, parts requiring multiple gates and weld lines, parts too thin, parts too thick, living hinges, thread inserts, etc. (Ex. 1014, 728; Ex. 2025, ¶¶ 65–72.) For example,

some of the features in Cho’s design are ratchet features that are difficult to fill. (Ex. 2025, ¶¶ 76-77.)

Indeed, some of Cho’s features require molding to *tight tolerances*, such as the inner diameter of inner cap 624 and the outer diameter of slider 636 to form a tight seal. As indicated in the Injection Molding Handbook, “a part that has many critical dimensions will be more difficult to mold to tolerance than a part with fewer such dimensions.” (Ex. 2029, 595). And failure to hold such parts to tight tolerances could result in leakage and/or binding, thereby undercutting Petitioner’s assertion of “simple substitution.” (Ex. 2025, ¶¶ 71–73, 76–84.)

Furthermore, Chapters 4–7 of the Injection Molding Handbook (Ex. 2029) discuss in detail the many challenges of injection molding relating to part or feature shape, parts requiring critical dimensions, and part complexity—again all of which are implicated by Cho’s cap given its feature-laden design. (Ex. 2025, ¶¶ 72–73.) For example: “Shorter cycle times and thinner or more complex parts continually increase the need for precise control in injection molding.” (Ex. 2029, 704.) And another reference cited by Mr. Leinsing, *The Complete Part Design Handbook for Injection Molding of Thermoplastics* (Ex. 1015), states that “When designing injection molded thermoplastic parts, the product designer must also be aware of some part configurations that pose potential problems during the injection molding process.” (Ex. 1015, 546.)

Therefore, despite Mr. Leinsing's assertion that to replace Plante's cap with Cho's cap (or a modified version thereof) would be a simple substitution, it is clear that a product design engineer, let alone a POSITA, would not have a reasonable expectation of success in redesigning and/or scaling down Cho's device without having to invest in expensive iterations of redesign, prototyping, and testing with an unpredictable outcome. (Ex. 2025, ¶¶ 74–75.)

4. Petitioner's alleged motivations for a POSITA to modify Cho are meritless

Petitioner and Mr. Leinsing also assert that a POSITA would have been motivated to modify Cho's cap to include the first and second cylinders entirely within the boundaries of the outer wall of the cap. (Paper 19, 13–15.) The alleged motivations for a POSITA to thus modify Cho include: (i) to minimize the likelihood of contact by a user, and thus reduce the risk of contamination; (ii) that there are only two options for placement of the moveable annular valve in the cap ; (iii) that design choices (*e.g.*, the amount of additive stored in the cap and the width of the neck of the bottle) would have motivated a POSITA to modify Cho; and (iv) that a POSITA would also be motivated to modify Cho in order to reduce the likelihood of tampering or purposely or accidentally peeling off or damaging the foil of Plante's device.

With respect to the first and second of these alleged motivating factors, Mr. Leinsing states:

Dr. Wereley has contrasted Cho's potential for contamination with Plante's low-profile design that minimizes the risk of contamination. [Citation omitted.] I agree with Dr. Wereley's assessment that Plante's design positioning the reservoir only slightly below the cap "significantly reduces the risk that an individual could touch the film," which would render the sample defective.

(Ex. 1027, ¶ 29.) This is an argument for *not* trying to combine Cho with Plante in the first place, not an argument to try to modify Cho. There is no reason that a POSITA would embark on an uncertain undertaking as Petitioner proposes when Plante's device already comprises minimal risk of contamination due to a user touching the film. (Ex. 2025, ¶¶ 85–86.)

With respect to the third of these alleged motivating factors, the design choices (*e.g.*, the amount of additive stored in the cap and the width of the neck of the bottle) highlighted by Mr. Leinsing again provide an argument for why a POSITA would *not* be motivated to try to combine Cho's device with that of Plante, *i.e.*, it would require extensive and costly redesign and would raise potential problems, as discussed above. (Ex. 2025, ¶ 87.)

Finally, with respect to the fourth of these alleged motivating factors, a POSITA would not be motivated to undertake a lengthy and costly redesign of Cho's device to reduce the likelihood of tampering or purposely or accidentally peeling off or damaging the foil of Plante's device. Tampering with Plante's device, or accidentally peeling off or damaging the foil of Plante's device, would be

self-evident. A less expensive option to prevent accidental damage would be to simply recess the reagent reservoir 12 of Plante's device a bit so that it is protected by the walls of the cap 2. (*See, e.g.*, Ex. 2025, ¶ 88.)

F. The Substitute Claims Are Patentable Over Ueda, Patterson, and Williams (Grounds III - V)

Petitioner did not raise the grounds based on Ueda in its Opposition. Ueda discloses a cap comprising a reagent chamber and an annular valve, where the annular valve comprises a first cylinder (mapped by the Petitioner to outer cylindrical member 7) and a second cylinder (mapped by Petitioner to sample holding member 8). As indicated in FIGS. 1, 2, and 3A-B of Ueda, and the description thereof, there is no teaching or suggestion of a moveable annular valve wherein “the first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve” as is required by substitute independent claim 21. Patent Owner thus submits that substitute independent claim 21 and all of the substitute claims that depend therefrom are patentable over Ueda. (Ex. 2025, ¶ 91.)

Patterson describes a “pre-loaded” mixing cap 10 for discharging dry or liquid ingredients using an annular valve comprising a first cylinder (mapped by the Petitioner to outer housing 20) and a second cylinder (mapped by the Petitioner to inner tube 40). (*See, e.g.*, Ex. 1010, Abstract, FIGS. 1–3.) However, there is no teaching or suggestion in Patterson of a moveable annular valve wherein “the first

cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve” as is required by substitute claim 21. Patterson fails to cure the deficiencies of Ueda in anticipating or rendering substitute independent claim 21 obvious. Patent Owner thus submits that substitute independent claim 21, and all of the substitute claims that depend therefrom, are patentable over the combination of Ueda and Patterson. (Ex. 2025, ¶ 92.)

Williams (Ex. 1009) also 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, and all of the substitute claims that depend therefrom, are patentable over the combination of Ueda and Williams. (Ex. 2025, ¶ 93.)

IV. CONCLUSION

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

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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 defining an open end of the cap, an opposing closed end of the cap, and an interior volume of the cap, said open end defining a
second aperture,

a reagent chamber storing a reagent therein and positioned in the interior volume of the cap, and

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

a moveable annular valve positioned in the interior volume of the capsecond aperture, the movable annular valve comprising

a vent,

a first cylinder comprising a third aperture,

a second cylinder comprising the vent, the second cylinder positioned in the third aperture,

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 to thereby change the annular valve from the closed configuration to the open configuration, wherein the first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve, 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, wherein the first cylinder and second cylinder are relatively moveable entirely within the interior volume of the cap to thereby change the moveable annular valve from the closed configuration to the open configuration~~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 ~~13~~2, wherein the annular valve comprises a flange extending from at least one of the first and second cylinders, and wherein initial contact between the flange and a portion of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration, said portion of the sample collection vessel being disposed proximal to the first aperture.

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 REVISED NON-CONTINGENT MOTION TO AMEND was served as of the below date on the Petitioner via email (by agreement) to the following counsel of record:

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