

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.

IPR2023-01424
Patent 11,536,632 B2

Before DONNA M. PRAISS, CHRISTOPHER M. KAISER, and
JAMIE T. WISZ, *Administrative Patent Judges*.

PRAISS, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Spectrum Solutions, L.L.C. (“Petitioner”)¹ filed a Petition requesting *inter partes* review of claims 1–16 and 18–20 (“the challenged claims”) of U.S. Patent No. 11,536,632 B2 (Ex. 1001, “the ’632 patent”). Paper 1 (“Pet.”). DNA Genotek Inc. (“Patent Owner”)² filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). With our authorization, Petitioner filed a Preliminary Reply Brief (Paper 7, “Prelim. Reply”) and Patent Owner filed a Preliminary Sur-Reply Brief (Paper 9, “Prelim. Sur-Reply”) to address the claim construction of the term “cap.”

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” The following findings of fact and conclusions of law are not final, but are made for the sole purpose of determining whether Petitioner meets the threshold for initiating review. Any final decision shall be based on the full trial record, including any response timely filed by Patent Owner. Any argument not raised by Patent Owner in a timely-filed response may be deemed waived.

For the reasons stated below, we determine that Petitioner has established a reasonable likelihood that it would prevail with respect to at

¹ Petitioner identifies itself as the real party in interest. Pet. 1. In addition, Petitioner notes that Spectrum Holdco LLC is its parent company and that Spectrum Holdco LLC and Spectrum Intermediate LLC “have a financial interest in, or could be substantially affected by the outcome of, this proceeding.” *Id.*

² Patent Owner identifies itself as the real party in interest and notes that it is a wholly owned subsidiary of OraSure Technologies, Inc. Paper 4, 2.

least one claim. We hereby institute an *inter partes* review as to claims 1–16 and 18–20 of the ’632 patent based upon Petitioner’s asserted grounds of unpatentability.

II. BACKGROUND

A. *Related Matters*

The parties indicate that U.S. Patent No. 11,002,646 B2 (“the ’646 patent”), which is related to the ’632 patent, is the subject of *DNA Genotek Inc. v. Spectrum Solutions LLC*, No. 3:21-cv-0516-RSH-DDL (S.D. Cal.), which is currently on appeal. Pet. 1; Paper 4, 2.

The parties also indicate that the ’646 patent is challenged in IPR2022-01347. Pet. 2; Paper 4, 2. We issued a final written decision in IPR2022-01347 on February 7, 2024, determining claims 1, 3–8, 11, and 12 of the ’646 patent are unpatentable. *See Spectrum Solutions, L.L.C. v. DNA Genotek Inc.*, IPR2022-01347, Paper 43 (PTAB Feb. 7, 2024).

B. *The ’632 Patent*

The ’632 patent is titled “Biological Collection System.” Ex. 1001, code (54). The ’632 patent describes the field of disclosure as relating to “devices, solutions and methods for collecting samples of bodily fluids or other substances, including hazardous and/or toxic substances, and in particular, a naturally expressed bodily fluid (e.g., saliva, urine).” *Id.* at 1:20–23. The ’632 patent describes saliva and urine as examples of bodily fluids that “may enable large-scale ‘population-sized’ epigenetic research.” *Id.* at 2:50–52. Specifically, the ’632 patent states that “home-base[d] sample collection . . . may allow for a much wider range of research options available as it can greatly increase participant numbers and samples can be more easily shipped by the subjects from anywhere.” *Id.* at 2:52–57.

The '632 patent describes as beneficial the ability to “securely house a toxic preservative solution in a closed chamber” of the device to preserve specimens from a widely geographically dispersed population without exposing the donor or laboratory technician to the toxic solution. *Id.* at 3:59–4:7. However, the '632 patent states that existing sample collection devices utilize “sharp extruding objects and thin pierceable membranes” that “represent a safety hazard to the sample donor as any wrong manipulation (such as with a finger nail) can lead to piercing of the membrane and release of the solution.” *Id.* at 4:15–30. In addition, the '632 patent describes existing treatments for treating cells to maintain their antigen profiles and epigenomic profiling containing lysine, glycine, and formaldehyde for stabilizing cells from blood, which will not protect cells from proteases found in bodily fluids such as saliva. *Id.* at 4:36–48.

The '632 patent describes the invention as providing a safe and easy to use sample collection device for naturally expressed bodily fluids that uses a minimum amount of parts, does not include sharp objects, and does not require removal or exchange of a piece or object thereof apart from depositing the sample and closing the sample collection device. *Id.* at 4:52–5:8. The '632 patent describes an embodiment as having a tube with a reservoir for collecting sample fluid, a cap being securely coupled to the tube, and an annular blocking member that moves from a position where the annular blocking member is covering an aperture to a position in which the annular blocking member is not covering the aperture, thus allowing sample preserving fluid or material to release from an interior space to interact with the sample. *Id.* at 14:45–61. The '632 patent describes the cap and tube as being threadably engaged and also the annular blocking member being

threadably engaged along the side of the inner walls. *Id.* at 14:62–15:13.

Figure 3B below depicts an embodiment.

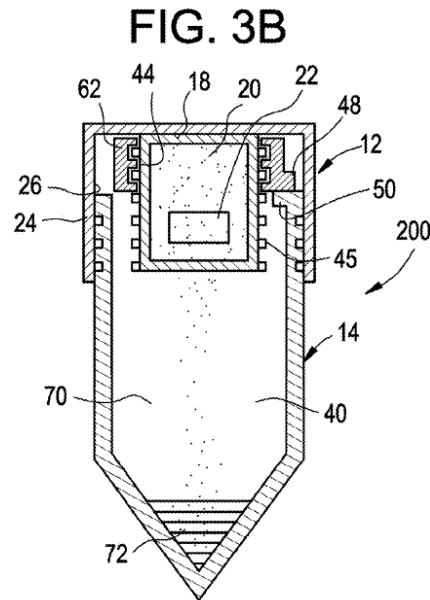


Figure 3B above shows a sample collection device in which cap 12 is coupled to tube 14 and movable annular member 62 is moved to a position where it does not cover aperture 22 in the inner wall, thereby allowing the sample preserving fluid to be released from interior space 20 and to interact with sample 72. Ex. 8:54–58, 14:45–56. The Specification further discloses that “interior space 20 may be at least partially defined by at least one of an inner wall 18 or outer wall 24 of the cap 12.” *Id.* at 14:20–22.

C. Illustrative Claim

Petitioner challenges claims 1–16 and 18–20. Pet. 1. Claim 1 is the sole independent claim. Ex. 1001, 22:21–24:7, 24:12–38. Claims 2–16 and 18–20 directly or indirectly depend from claim 1. *Id.* at 22:54–24:7, 24:12–38.

Claim 1 is reproduced below.

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
 - 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 in the second 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 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, and
 - in the 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.

Id. at 22:21–53.

D. Asserted Grounds of Unpatentability

Petitioner, supported by the declaration of Karl R. Leinsing, MSME, PE (Ex. 1002), asserts the following five grounds of unpatentability (Pet. 10–11):³

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–4, 6–16, 18–20	103(a)	Plante, ⁴ Cho ⁵
5	103(a)	Plante, Cho, Patterson ⁶
1–8, 10–16, 18–20	102(a)	Ueda ⁷
5	103(a)	Ueda, Patterson
9	103(a)	Ueda, Williams ⁸

III. ANALYSIS

A. Legal Standards

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the

³ The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, took effect on March 16, 2013. The ’632 patent claims priority to applications with filing dates before this date. *See* Ex. 1001, code (60), (63). For the purposes of this Decision, pre-AIA versions of the statutes apply.

⁴ US 2012/0325721 A1, published Dec. 27, 2012 (Ex. 1003).

⁵ WO 2005/051775 A2, published June 9, 2005 (Ex. 1004).

⁶ US 2006/0260959 A1, published Nov. 23, 2006 (Ex. 1010).

⁷ JP 2010-213660, published Sep. 30, 2010 (Ex. 1006). Citations herein are to the certified English language translation (Ex. 1005).

⁸ US 4,761,379, issued Aug. 2, 1988 (Ex. 1009).

grounds for the challenge to each claim”)); *see also* 37 C.F.R. § 42.104(b) (requiring a petition for *inter partes* review to identify how the challenged claim is to be construed and where each element of the claim is found in the prior art patents or printed publications relied upon).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). “Inherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.” *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745, (Fed. Cir. 1999)). “[T]he reference must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements arranged as in the claim.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083 (Fed. Cir. 2008) (internal quotation marks omitted). In other words, it is not enough to be able to find all of the pieces of the claimed invention somewhere in a prior art reference; rather, those elements must be set out in the prior art reference in the same way they are in the claimed invention. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (“Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983))).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and “the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).⁹

B. Level of Ordinary Skill in the Art

In order to determine whether an invention would have been obvious at the time the application was filed, we consider the level of ordinary skill in the pertinent art at the critical time. *Graham*, 383 U.S. at 17. The resolution of this question is important because it allows us to “maintain[] objectivity in the obviousness inquiry.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991). In assessing the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (quotation omitted). Generally, it is easier to establish obviousness under a higher level of ordinary skill in the art.

⁹ At this stage of the proceeding, the parties have not provided evidence of objective indicia of nonobviousness.

Innovention Toys, LLC v. MGA Entm't, Inc., 637 F.3d 1314, 1323 (Fed. Cir. 2011) (“A less sophisticated level of skill generally favors a determination of nonobviousness . . . while a higher level of skill favors the reverse.”).

Petitioner asserts 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.” Pet. 8 (citing Ex. 1002 ¶¶ 51–52). Petitioner further asserts that such a person would have collaborated with a team member with training and experience in the biological aspects of the invention and education and experience relating to the collection of biological samples. *Id.* (citing Ex. 1002 ¶¶ 51–52).

Patent Owner does not offer an alternative definition of a person of ordinary skill in the art at this time. *See generally* Prelim. Resp. Accordingly, for the purposes of this Decision, we adopt Petitioner’s proposal regarding the level of one of ordinary skill in the art.

C. Claim Construction

In an *inter partes* review proceeding, we apply the same claim construction standard used by Article III federal courts, which follow *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), and its progeny. Under this standard, the words of a claim are generally given their “ordinary and customary meaning,” which is the meaning the term would have to a person of ordinary skill at the time of the invention, in the context

of the entire patent including the specification. *See Phillips*, 415 F.3d at 1312–13.

1. “*Biological Sample*” and “*Annular Valve*”

Claim 1 of the ’632 patent recites a “biological sample” and an “annular valve.” According to Petitioner, the parties disagreed on the construction of these terms in the district court litigation involving the ’646 patent. Petitioner reports that the district court construed “biological sample” as a “biological sample containing cells” and “annular valve” as a “ring shaped valve.” Pet. 9–10. Petitioner argues the claims of the ’632 patent are unpatentable as anticipated and obvious regardless of whether the preamble is limiting and under any reasonable construction of these terms. *Id.* Patent Owner does not address the construction of “biological sample” or “annular valve” at this time. *See generally* Prelim. Resp.

We determine that it is not necessary for us to construe “biological sample” or “annular valve” at this stage of the proceeding because neither party contends that construing either term is material to deciding whether to institute a trial on the asserted grounds in the Petition. *See Nidec Motor Corp. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

2. “*Cap*”

Claim 1 of the ’632 patent also recites a “cap.” The parties disagree on the construction of the term “cap.” At Petitioner’s request, we authorized briefing on the construction of the term “cap” in this proceeding. Ex. 1021.

We addressed the construction of “cap” in the context of the ’646 patent in the final written decision in IPR2022-01347. *See Spectrum Solutions, L.L.C. v. DNA Genotek Inc.*, IPR2022-01347 (PTAB Feb. 7, 2024) (Paper 43). We determined that “the term ‘cap’ means ‘a cover for the sample collection vessel’ without any negative limitation on the manner and extent to which the reagent-containing portion of the sample collection device is defined by the cap.” *Id.* at 20. We apply the same construction here.

Petitioner asserts that the plain meaning of “cap” in the context of the ’632 patent is “‘a lid or cover’ for the sample collection vessel.” Prelim. Reply 1. Petitioner directs us to the ’632 patent’s disclosure that the sample collection vessel includes “two mating bodies, a cap and a tube” and that the cap “mates with the tube” or “is coupled to the tube.” *Id.* at 1–2 (quoting Ex. 1001, code (57), 5:9–11, 8:54–55, 10:11–16). Petitioner asserts that the context of the claim also supports the plain meaning of cap because the cap comprises “a second connection member [e.g., threads] complementary to the first connection member [on the sample collection vessel]” thus covering or closing the vessel. *Id.* at 2. Petitioner also directs us to claim 1’s identification of the movable annular valve as being part of the cap because the cap comprises the “reagent chamber” and the reagent chamber is part of the valve’s second cylinder. *Id.* at 3 (citing Ex. 1001, 22:27–29, 22:43–44, 22:49–53 (“[A] cap comprising . . . a reagent chamber . . . second cylinder[] create[s] a fluid-tight seal with the cap . . . in the annular valve’s open configuration . . . the vent to thereby allow flow of the reagent from the reagent chamber.”)). Petitioner asserts that the term should not be construed to include the negative limitation of “a cover . . . that is not co-extensive

with the movable annular valve” because such a negative limitation is not consistent with the ’632 patent’s disclosure that the entirety of the cap includes the chamber/valve components such that the reagent chamber “may be at least partially defined by at least one of an inner wall 18 or outer wall 24 of the cap 12.” *Id.* at 3–4 (quoting Ex. 1001, 14:20–22).

Patent Owner submits that the term “cap” means “a cover for the sample collection vessel that is not co-extensive with the movable annular valve.” Prelim. Resp. 11. Patent Owner contends that the text of the claims supports this construction because the valve and cap are distinct components and because it would be “impossible” otherwise for the valve components, i.e., the first and second cylinders, to create a fluid-tight seal with the cap. *Id.* at 12 (citing Ex. 1001, 22:21–53). According to Patent Owner, the Specification supports this construction because Figure 3A and all of the other figures show a cap that is not co-extensive with any depicted valve. *Id.* Patent Owner contends “[w]hether or not the cap may form part of a cavity that holds reagents, the cap is not the valve” and supports this with the description of an embodiment having “an annular member at the base of the cap that is partially secured to the cap.” *Id.* at 13 (quoting Ex. 1001, 11:41–43). Patent Owner also directs us to Examiner statements and expert testimony that refer to the cap and valve independently. *Id.* at 13–14 (citing Ex. 2002, 4–6; Ex. 2004, 28:812, 93:6–13, 99:17–21; Ex. 2005, 9; Ex. 2006, 10).

In the Prelim. Sur-Reply, Patent Owner states that claim 1 requires “[t]he ‘valve’ is ‘in the second aperture’ of the ‘cap.’” Prelim. Sur-Reply 2 (quoting Ex. 1001, 22:32) (emphasis omitted). According to Patent Owner, this precludes the valve from being co-extensive with the cap because the

valve could not be in the opening of the cap if it were co-extensive with the cap. *Id.* Patent Owner asserts that Petitioner’s analysis is flawed because claim 1 does not require the reagent chamber to be within or outside the valve itself. *Id.* at 2–3.

We conclude that the term “cap” means “a cover for the sample collection vessel” without any negative limitation on the manner and extent to which the reagent-containing portion of the sample collection device is defined by the cap. Both Petitioner and Patent Owner direct us to the ’632 patent’s description of the embodiment shown in Figure 3A, shown below, to support their proposed claim constructions.

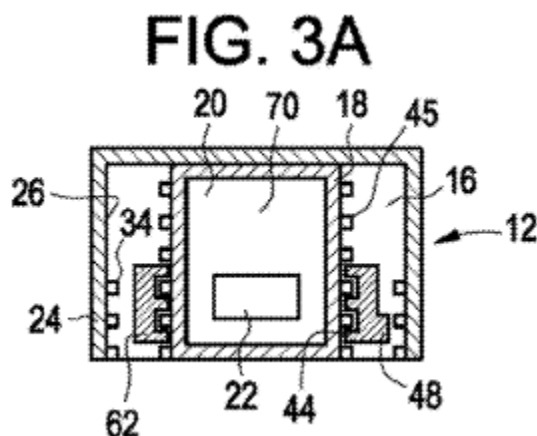


Figure 3A above is a cross-sectional view of the cap prior to being coupled to the tube (which coupling is depicted in Figure 3B reproduced in Section II.B. describing the ’632 patent). Ex. 1001, 8:49–50, 8:54–55, 14:17–18. The ’632 patent describes Figure 3A as an embodiment of the sample collection device in which cap 12 contains inner space 20 (containing sample preservation fluid or material 70) with moveable annular blocking member 62 that can cover an aperture 22 in inner wall 18. Ex. 1001, 8:49–53, 14:17–32. Patent Owner asserts that “whether or not the cap may form part of a cavity that holds reagents, the cap is not the valve”

based on the description of Figure 3A's annular blocking member 62 being "configured to interact with one or more features . . . of the tube." Prelim. Resp. 13 (citing Ex. 1001, 11:41–43, 14:46–49). However, the '632 patent's written description of the cap is expansive rather than limiting in terms of the overlap between structures in the cap section of the cap and tube collection device. Specifically, the '632 patent states "[t]he interior space 20 may be at least partially defined by at least one of an inner wall 18 or outer wall 24 of the cap 12." Ex. 1001, 14:20–22. The disclosure "at least partially" means that the cap may fully define the interior space for holding the reagent and not merely "part of a cavity that hold reagents" as Patent Owner asserts. *Compare* Ex. 1001, 14:20–22, *with* Prelim. Resp. 13.

Regarding Patent Owner's assertion that the context of claim 1 precludes the valve from being co-extensive with the cap (Prelim. Sur-Reply 2), we disagree. Claim 1 recites "a cap comprising a second aperture, a reagent chamber storing a reagent therein" and further recites "a moveable annular valve in the second aperture." Ex. 1001, 22:27–29, 22:32). Thus, claim 1 locates the valve "in" the cap. *Id.* at 22:32 ("a moveable annular valve in the second aperture"). This, however, does not preclude the valve from being co-extensive with the cap it is "in." Indeed, locating both the cap and the valve in the same space would indicate the opposite—that the two are co-extensive because they occupy the same space. Similarly, claim 1 locates both the reagent chamber and the moveable annular valve in the same place, namely "the second aperture" that comprises the "cap." *Id.* at 22:29 ("a cap comprising a second aperture, a reagent chamber storing a reagent therein"), 22:32 ("a moveable annular valve in the second aperture"). Accordingly, 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.”

In the absence of support for the negative limitation that Patent Owner asserts and in view of the “strong presumption against a claim construction that excludes a disclosed embodiment,” we determine that the intrinsic evidence supports the construction of the term “cap” to mean “a cover for the sample collection vessel.” *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1324 (Fed. Cir. 2011).

D. Discretionary Denial

Patent Owner asserts that we should exercise our discretion under 35 U.S.C. § 325(d) for two reasons: (1) “Petitioner puts forth substantially the same arguments” that were presented against the related ’646 patent and (2) “Petitioner still has failed to show that Plante’s plastic design is dangerous or would otherwise motivate a POSA to modify it.” Prelim. Resp. 38.

Petitioner asserts that we should not deny institution under 35 U.S.C. § 325(d) because (1) this is the first petition challenging the ’632 patent; (2) the prior art present in the Petition was not applied during examination of the ’632 patent; and (3) the Petition makes a strong showing that the challenged claims are unpatentable. Pet. 123–24. Petitioner also asserts that we should not exercise our discretion to deny institution under 35 U.S.C. § 314(a) because there is no parallel district court litigation involving the ’632 patent and Petitioner raises a compelling case of unpatentability for the challenged claims of the ’632 patent. *Id.* at 124.

We decline to exercise our discretion here. As pointed out by Petitioner, the same or substantially the same art or arguments were not

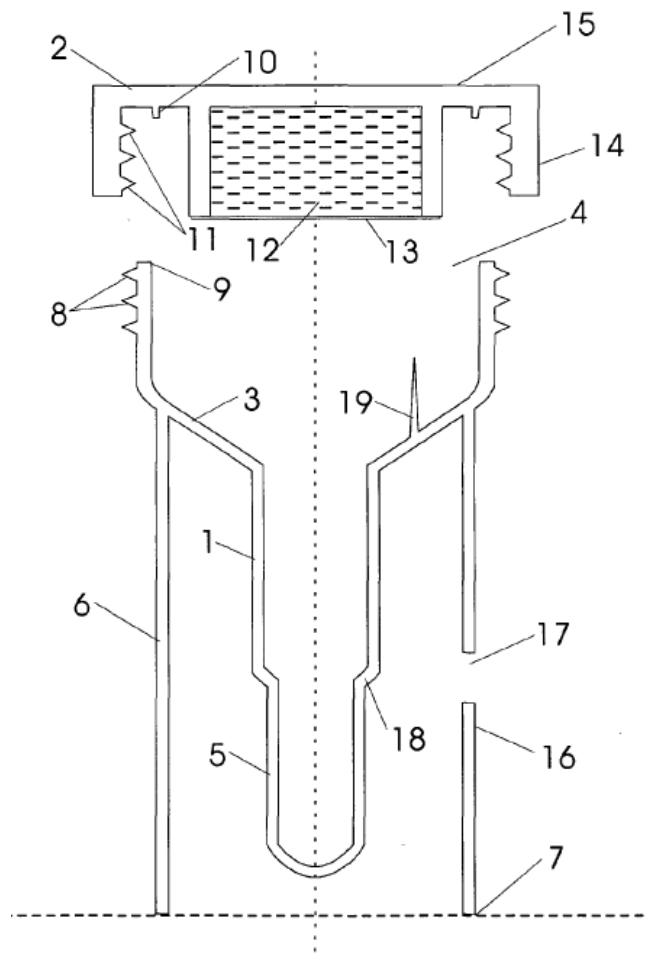
previously presented with respect to the '632 patent. Pet. 123–24. Petitioner challenges the '632 patent on grounds that were not asserted against the '646 patent, namely the grounds based on Ueda. *Id.* at 71–123. In addition, we found Petitioner's arguments based on Plante sufficiently persuasive and determined that the challenged '646 patent claims are unpatentable.

IPR2022-01347, Paper 43 (Feb. 7, 2024). For these reasons, we do not exercise our discretion to deny institution.

E. Overview of the Asserted Art

1. Plante (Exhibit 1003)

Plante is titled “Saliva Sample Collection Systems.” Ex. 1003, code (54). Plante describes a receiving vessel having integrated threads and a complementary cap element including cooperating threads along with a reservoir with pierceable thin-film membrane. *Id.* at code (57). Plante discloses that the reservoir contains a special formula to stabilize and preserve a biological sample such as saliva. *Id.* ¶ 35. Plante describes a carefully positioned knife integrated with the receiving vessel which pierces the membrane when the cap is screwed onto the receiving vessel and advances in an axial direction towards the receiving vessel. *Id.* Plante describes the preserving fluid as passing into the receiving vessel after the film is pierced to mix with the collected saliva, and a liquid-tight seal forming between an annular flange of the sealing cap and an inside surface of the receiving vessel. *Id.* ¶ 38. Plante's Figure 1 is shown below.



Plante's Figure 1 above depicts receiving vessel 1 having entrance aperture 4, cylindrically tubular portion 5, carefully positioned knife 19 integrated within the receiving vessel, and thread set system 8 formed as a part of a coupling means between the receiving vessel and cap portion 2. *Id.* ¶ 35.

Plante's Figure 1 above also shows cooperating thread set 11 formed on an inside cylindrical surface of cap 2 and liquid tight reservoir 12 having a surface which may be pierced or otherwise compromised, such as a thin-film membrane or foil 13. *Id.*

2. *Cho (Exhibit 1004)*¹⁰

Cho is titled “Bottle” and describes “a bottle, which contains two kinds of materials separately in two spaces in a bottle body and communicates the separated spaces with each other as necessary so that the two materials can be mixed together.” Ex. 1004, codes (54), (57). Cho states that “[i]t is . . . often necessary to mix two kinds of different materials together in a variety of industrial fields.” *Id.* at 3:9–10. Cho gives as an example a coffee-based beverage being mixed with sugar or cream powder and states “medicines and chemicals are similar cases.” *Id.* at 3:10–12.

Cho's embodiment shown in Figure 44 is reproduced below.

FIG. 44

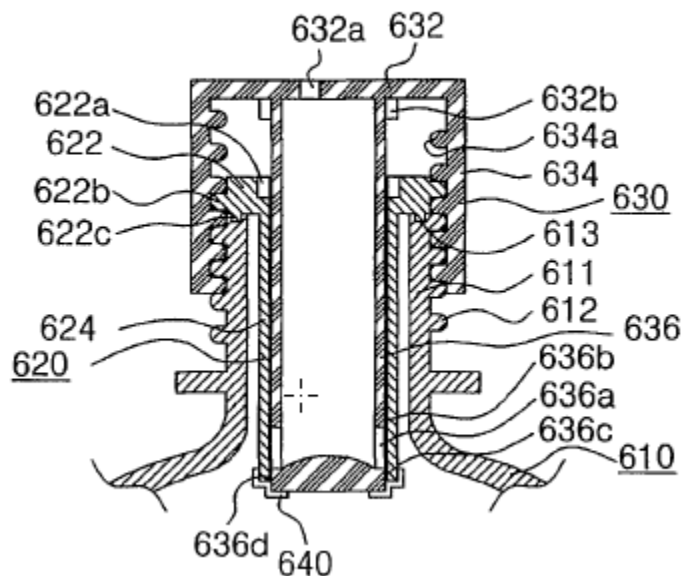


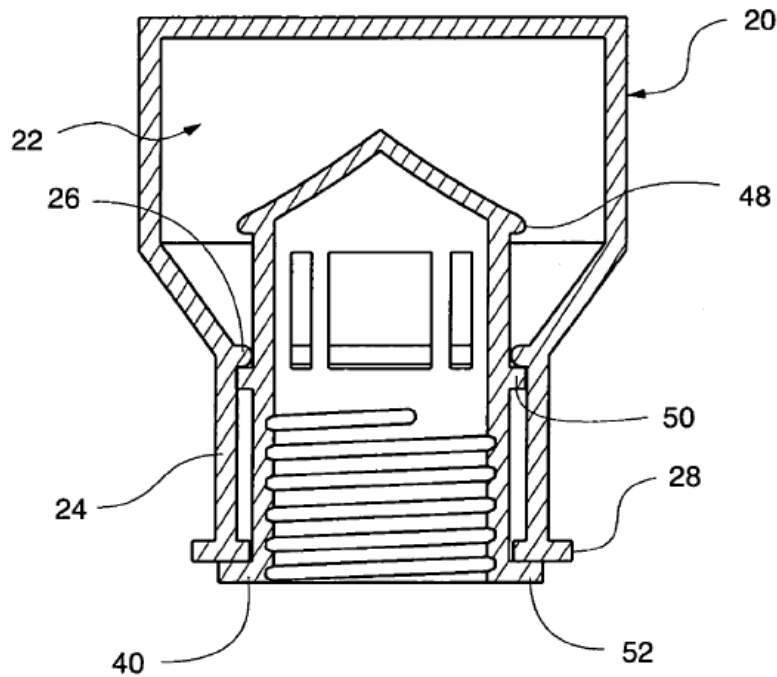
Figure 44 above depicts bottle body 610 having external threads 612 formed around the circumferential surface of mouth 611, which threads interact with internal threads 634a on upper cap 634. *Id.* at 48:15–18, 49:6–10. Cho

¹⁰ Citations herein are to Cho's original pagination.

describes additive storage container 620 as comprising a circular end plate 622 and an inner cap 624 that extends downward in an axial direction and is axially inserted into mouth 611. *Id.* at 48:27–31. Cho describes slider 636 as extending in an axial direction from finish plate 632 at a position spaced apart from upper cap 634 and inserted into inner cap 624. *Id.* at 49:10–13. Cho describes ring-type seal protrusions 636b and 636c as formed around the outer circumferential surface of slider 636 at positions above and below discharge ports 636a to prevent additive from leaking through discharge ports 636a. *Id.* at 49:16–21. Cho describes bursting film 640 preferably made of aluminum film to close the lower ends of both inner cap 624 and slider 636. *Id.* at 49:24–27. Cho describes the bottle cap in operation as being rotated so that the lower end of slider 636 tears off bursting film 640 so that additive discharges from additive storage container 620 through discharge ports 636a into the bottle body. *Id.* at 50:4–12.

3. *Patterson (Ex. 1010)*

Patterson is titled “Mixing Cap and Method for Use Thereof.” Ex. 1010, code (54). Patterson describes a “pre-loaded” mixing cap as discharging selected dry or liquid ingredient from an outer housing through apertures of an inner tube, permitting the ingredients to flow through the apertures of the inner tube and into the liquid contents of a bottle. *Id.* at code (57). Patterson discloses that the mixing cap is for use with “powdered sports drinks, supplements and the like” as well as “any selected ingredient, additive or the like” including “medicines, chemicals, oils, or the like.” *Id.* ¶ 44. Patterson’s Figure 3 is shown below.



Patterson’s Figure 3 above shows an “open position” of a mixing cap after outerhousing 20 is pushed to downwardly slide neck portion 24 over a sidewall of inner tube 40 to introduce the dry/liquid ingredients of storage receptacle 22 through apertures in inner tube 40 and into the liquid contents of a bottle. *Id.* ¶¶ 35–36.

4. *Ueda (Ex. 1005)*

Ueda is titled “Container.” Ex. 1005, code (54). Ueda describes “containers, in particular . . . containers suitable for storing biological samples.” *Id.* ¶ 1. According to Ueda, “there has been increasing demand for containers in the medical field using biological samples, such as regenerative medicine, cell-containing drugs, and other pathological tests, gene therapy, organ transplantation, and autologous transplantation,” and it is very important that biological samples used in such applications are not adversely affected during storage and transportation. *Id.* ¶¶ 2–3. Ueda’s Figure 3B is shown below.

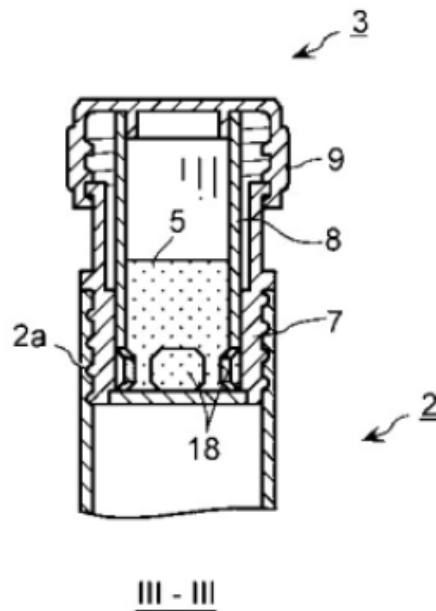


FIG. 3B

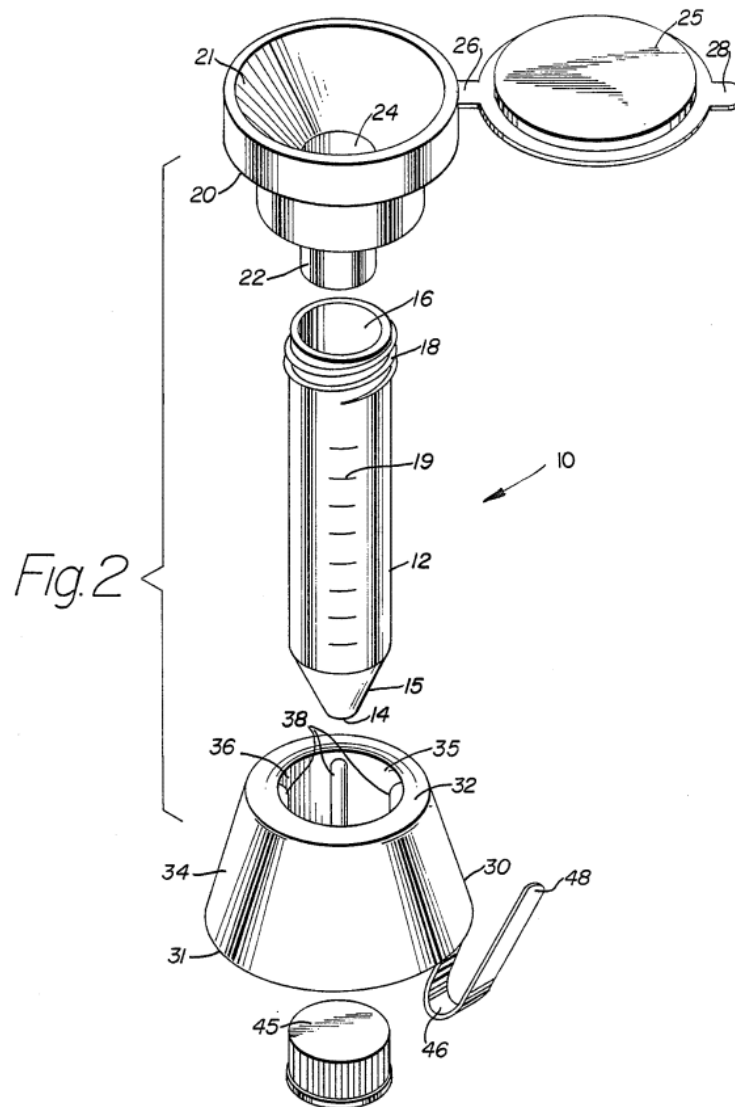
Ueda's Figure 3B above shows a cross-sectional view of a "first screw-in state" of a container according to an embodiment in which outer cylindrical member 7 of cap 3 is screwed onto screw grooves of upper end opening 2a of container body 2 such that second mixed material 5 is not released into container body 2. Ex. 1005 ¶¶ 18, 23, 26–27. Cap 3 includes mixture holding member 8 and plug member 9. *Id.* ¶ 25. Mixture holding member 8 has an outer diameter that allows it to slide vertically along its axial direction within outer cylindrical member 7, a lower end that is closed with a bottom wall plate, and a plurality of communication passages 18 that open radially outwardly at predetermined circumferential intervals. *Id.* ¶ 27.

The plurality of communication passages 18 are closed by the inner peripheral surface of outer cylindrical member 7 when holding member 8 is

flush with (i.e., does not protrude from) the lower end opening of outer cylindrical member 7 and does not communicate with the inside of the container body 2. Ex. 1005 ¶¶ 27–28. The internal spaces of the plurality of communication passages 18 communicate with the internal space of container body 2 and release second mixed material 5 into container body 2 when holding member 8 is configured to protrude from the lower end opening of the outer cylindrical member 7. *Id.* ¶¶ 23, 27.

5. *Williams (Ex. 1009)*

Williams is titled “Biological Specimen Collection Device.” Ex. 1009, code (54). Williams describes “a biological specimen collection device, and more particularly, concerns such a device which may be employed in the collection of sputum.” *Id.* at 1:6–9. According to Williams, the biological specimen collection device “is easy to use, inexpensive to manufacture and may be conveniently handled so as to minimize the spread of infection during and subsequent to the specimen collection procedure.” *Id.* at 6:42–46. Williams’s Figure 2 is shown below.



Williams's Figure 2 is an exploded, perspective view of an embodiment of Williams's biological specimen collection device that is useful for the collection of biological specimens such as urine, sputum, blood, and the like. Ex. 1009, 3:24–26, 3:52–54. The biological specimen collection device 10 includes specimen receptacle 12 with closed end 14 with inwardly tapering side walls 15, a series of graduation marks 19, and opening 16 in communication with the interior of receptacle 12 which includes external thread 18 that facilitates the closure of threaded cap 45. *Id.*

at 3:54–66. Receptacle 12 may be supported vertically by placing it into base 30 that is configured to receive closed end 14. *Id.* at 4:36–40.

Williams’s biological specimen collection device 10 also includes funnel 20 with specimen receiving portion 21 into which a specimen is deposited. Ex. 1009, 4:11–13. Specimen receiving portion 21 is connected to passage tube 22 with passageway 24 that communicates with the inside of receptacle 12 when funnel 20 is positioned on top of receptacle 12. *Id.* at 4:13–19. Funnel 20 also includes cover 25 with finger tab 28 that provides a sealing closure over receiving portion 21 and is connected to funnel 20 by hinge 26. *Id.* at 4:23–35.

F. Unpatentability Grounds

1. Unpatentability over Plante and Cho

Petitioner asserts that claims 1–4, 6–16, and 18–20 are unpatentable under 35 U.S.C. § 103(a) over the combination of Plante and Cho, citing the Declaration of Karl R. Leinsing for support. Pet. 11–65 (citing Ex. 1002 ¶¶ 29–163).

a. Claim 1

Petitioner contends Plante’s system for the collection, storage, and shipping of biological matter, specifically saliva, discloses every element of claim 1 except for the recited “movable annular valve.” Pet. 14. Petitioner contends that it would have been obvious to a POSITA to use Cho’s cap having a movable annular valve in Plante’s sample collection system for the reasons: (1) Cho’s cap with an annular valve is a safer design than Plante’s approach of using a knife in the vessel in view of a federal mandate to choose devices without sharps where possible, (2) Cho’s container provides the same functionality as Plante’s system without the drawbacks of molding

Plante’s sharp, thin knife in plastic, (3) using an annular valve like Cho’s instead of Plante’s knife design would have allowed the cap to seal onto the vessel before the valve is opened, and (4) it would have been a simple substitution of one known element for another—Plante’s cap for Cho’s cap—to avoid the use of a knife in a vessel. *Id.* at 14–16 (citing Ex. 1002 ¶¶ 63–74). According to Petitioner, a POSITA would have expected Cho’s cap to perform successfully the same function of releasing a reagent when connected to Plante’s sample collection vessel because Cho’s cap functions to release a reagent into a bottle when fastened to the bottle. *Id.* at 16–17 (citing Ex. 1002 ¶ 75).

Petitioner maps the preamble to Plante’s disclosure of a system for collecting biological matter, specifically, saliva, and the recited “sample collection vessel” and “sample collection reservoir” to Plante’s receiving vessel 1 and the lower portion of receiving vessel 1 that holds the sample once received. Pet. 17–19. Petitioner maps the recited “first connection member” to Plante’s threaded connection between cap 2 and sample collection vessel 1 (corresponding thread sets 11 and 8) and also identifies a similar threaded connection on Cho’s container. *Id.* at 21–22 (citing Ex. 1003 ¶ 35, Fig. 1; Ex. 1004, 2:7–10, 48:16–19, Figs. 43–45B; Ex. 1002 ¶¶ 80–82). Regarding the recited “second connection member complementary to the first connection member,” Petitioner maps this limitation to Plante’s complementary thread set 11 and Cho’s internal thread 634a, which each engage the recited “first connection member.” *Id.* at 29–31 (citing Ex. 1003 ¶¶ 35, 38, Fig. 1; Ex. 1004, 49:5–10, Figs. 43–45B). Petitioner maps the “first aperture for receiving a biological sample” to the aperture in Plante’s vessel (“entrance aperture 4”) for receiving saliva. *Id.* at

22 (citing Ex. 1003 ¶ 35, Fig. 1; Ex. 1002 ¶ 83). Petitioner maps the recited “cap” to both Plante’s cap 2 and Cho’s “opening unit 630” that has a threaded connection to Cho’s container. *Id.* at 24–25 (citing Ex. 1003 ¶ 35, Fig. 1; Ex. 1005, 48:15–34, Fig. 44). Petitioner maps the recited “second aperture” to the portion of Plante’s cap and Cho’s cap that engages the threaded portion on the receiving vessel and container bottle, respectively. *Id.* at 25–27 (citing Ex. 1003 ¶ 35, Fig. 1; Ex. 1004, 48:15–34, Figs. 43–45B). Petitioner maps the recited “reagent chamber,” which the recited “cap” further comprises, to Plante’s reservoir 12 and Cho’s chamber for holding mixing materials such as chemicals, which is defined by Cho’s inner and outer cylinders. Pet. 27–29 (citing Ex. 1003, Ex. 1004, 1:3–12, 1:28–2:3, 48:16–24, 48:27–31, 49:5–13, 50:5–12, Figs. 43–45B).

Regarding the recited “movable annular valve in the second aperture” and claim 1’s remaining limitations regarding the features of the “moveable annular valve,” Petitioner relies on Cho’s disclosure alone, which is illustrated by Cho’s Figures 43–45B. Pet. 31–44. Petitioner asserts the annular valve is in the second aperture because it is in the aperture of the cap. *Id.* at 32. Petitioner maps the recited “vent” to Cho’s discharge ports 636a in Cho’s second cylinder (slider 636). *Id.* at 33. Petitioner maps the recited “first cylinder comprising a third aperture” to Cho’s first cylinder 620 which defines a third aperture and the recited “second cylinder positioned in the third aperture” to Cho’s slider 636 which includes the recited “vent” (discharge ports 636a). *Id.* at 34–38. Regarding the recited “closed” and “open” configurations, Petitioner directs us to Cho’s disclosure of discharge ports 636a on slider 636 being obstructed by the interior sidewalls of the first cylinder (additive storage container 620) and no longer

obstructed when slider 636 moves downward through the first cylinder. *Id.* at 38–40 (citing Ex. 1004, 49:10–21, 1:28–2:3, 49:34–50:8–12, Figs. 44, 45A).

Regarding the recited “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,” Petitioner directs us to Cho’s disclosure that the reagent is sealed in the additive storage space until released into the bottle and that slider 636 (mapped to the second cylinder) includes “[r]ing-type seal protrusions 636b and 636c . . . preventing an additive from leaking through the discharge ports 636a.” *Id.* at 41 (quoting Ex. 1004, 49:10–21). Regarding the limitations that the “first cylinder and second cylinder are relatively moveable” and that the “first cylinder does not obstruct the vent” in the “open configuration,” Petitioner directs us to Cho’s Figures 44 and 45A in which additive storage container 620 (first cylinder) does not obstruct discharge ports 636a (vent) of the slider 636 (second cylinder) when slider 636 moves downward through container 620. *Id.* at 43–44 (citing Ex. 1004, 49:34–50:12, 50:8–12, Figs. 44, 45A).

Based on the current record, we find Petitioner’s assertions to be persuasive and sufficiently supported.

Patent Owner contends the Petition should be denied because (1) a person of ordinary skill in the art would have had no motivation to combine Plante and Cho, and (2) Cho is not analogous art to the ’632 patent. Prelim. Resp. 14–34.

Patent Owner contends that a POSITA would not have been motivated by the “Needlestick Safety and Prevention Act” to modify Plante’s plastic knife because it is not a “sharp” and Plante’s saliva sample collection system

does not pose a risk of occupational exposure to bloodborne pathogens. *Id.* at 15. Patent Owner asserts that Petitioner presents no evidence of harm due to a “Plante-type device” and that Dr. Werely demonstrated that a commercial embodiment posed no risk of sharps injury. *Id.* at 15–16 (citing Ex. 2007, 81:17–82:12; Ex. 2008 ¶¶ 26–45). Patent Owner contends that injection molding difficulties also would not have motivated a POSITA to modify Plante because a POSITA would have known how to mold a plastic knife that is sharp enough with routine plastic molding. *Id.* at 18–19 (citing Ex. 2008 ¶¶ 34, 53–64; Ex. 2012 ¶ 6). Patent Owner contends that forming Plante’s plastic knife “would have posed fewer plastic molding difficulties than the valves of the cited art” due to the “bending, shear, rolling, and sliding stress on a mechanism . . . to transmit uniform motion and power” that the Injection Molding Handbook refers to as “one of the more complicated areas for designing with plastics.” *Id.* at 19 (citing Ex. 1004, 50:4–27). Patent Owner asserts that the substitution of Cho’s cap would add parts to Plante’s design and increase the number of steps to release the reagent, which would defeat Plante’s objective to reduce parts and increase ease of use. *Id.* at 20–22 (citing Ex. 1003 ¶¶ 28, 41). Patent Owner asserts that Plante’s “plastic pointed member . . . is carefully and safely positioned deep within Plante’s vial.” *Id.* at 23 (citing Ex. 1003, Fig. 1).

Patent Owner asserts that substituting Cho’s cap would introduce interfering contaminants because Cho’s annular valve extends beyond the bottom of Cho’s cap and resembles a handle. *Id.* at 24 (citing Ex. 2008 ¶¶ 91–92). Patent Owner also asserts that substitution is not a sufficient reason to modify Plante because Petitioner has not met its burden to show

predictable results. *Id.* at 25–26 (citing *Johns Mansville Corp. v. Knauf Insulation Inc.*, IPR2018-00827, Paper 9 (PTAB Oct. 16, 2018)).

Patent Owner asserts that Cho is not from the same field of endeavor as the '632 patent because Cho is “directed to mixing water and a flavoring prior to drinking the mixture” whereas the '632 patent is directed to mixing a biological sample with a preservative before shipping the container. *Id.* at 27–29 (citing Ex. 1001, code (54), code (57), 1:21–22, 1:60–61, 2:55–57, 4:52–54, 11:65–12:1, 12:43–47). Patent Owner asserts that the Petition’s characterization of Cho as “an easy-to-use container for mixing two materials” is insufficient to establish Cho is in the same field of endeavor. *Id.* at 29–30. Patent Owner also asserts that Cho is not reasonably pertinent to the problem addressed by the '632 patent because the '632 patent addresses “wrong manipulation” and provides “a minimum number of parts.” *Id.* at 30. Patent Owner asserts that Cho adds complexity that only compounds the problem the '632 patent solves. *Id.* at 31.

Upon review of the parties’ arguments and supporting evidence, we do not find Cho’s device to be limited to beverages and mixtures that are consumed, but, rather, more broadly applicable to containers for mixing two components as Petitioner asserts. Cho broadly defines the “technical field” of invention as a bottle which “contains two kinds of materials in separate spaces” and “cause[s] the separate spaces to communicate with each other as necessary.” Ex. 1004, 1:3–6. Patent Owner’s assertion that Cho is limited to beverages and mixtures to be consumed is not supported by the record because Cho discloses that the “two kinds of material” kept in separate spaces and that can be mixed include “chemicals,” which appears to suggest a non-consumable mixture and a broader field of use. Ex. 1004, 1:3–12. In

addition, Patent Owner implies that Cho's container system is not in the same field of art because it does not adequately retain the contents of the mixture. Prelim. Resp. 27–29. However, the record at this stage of the proceedings shows that Cho's cap and vessel device includes not only the threaded connection between the cap and vessel, but, additionally, the first and second cylinders of Cho's annular valve create a seal that prevents leakage. Pet. 13, 21–22, 40–41; Ex. 1004, 1:28–2:3, 2:7–10, 48:16–19, 49:10–21, 50:4–15, 55:22–25, Figs. 43–45B.

Therefore, the evidence at this stage in the proceeding sufficiently shows that Cho's device is within the same field of endeavor as the '632 patent to provide a device to easily mix a chemical held within a reservoir of a cap with the contents of a vessel. Ex. 1001, 3:67–4:3 (“The sample collection device may also allow easy and safe collection of a donor specimen . . . with no risk of exposure of the donor to the toxic solution.”); Ex. 1004, 1:3–6, 1:25–27 (“a bottle . . . contain[ing] two kinds of materials in two separate spaces . . . caus[ing] the separate spaces to communicate with each other . . . so that the two materials can be mixed . . . using only a simple action”); Pet. 12–13 (“Like the '632 patent and Plante, Cho discloses a container ‘contain[ing] two kinds of materials in two separate spaces’ and subsequent mixing of those materials.”); Pet. 14 (“Like Plante and the '632 patent claims, Cho's container includes a vessel and a cap, with the cap having a sealed reservoir for storing a material until it is mixed with the contents of the container by the user.”).

After determining the Petition meets the threshold inquiry of Plante and Cho being analogous art, we next consider whether a POSITA would have been motivated to modify Plante's sample collection system by

replacing Plante's knife in the interest of avoiding risk of injury to a user. Pet. 15. The Petition further states substituting Cho's cap for Plante's cap would eliminate Plante's knife to release material stored in the reservoir and a POSITA would have had a reasonable expectation of success that such a substitution would provide the same desired functionality. *Id.* at 16–17.

Eliminating sharp components in Plante's sample collection system as a reason for modifying Plante with Cho's system for releasing a component in the cap has a rational underpinning based on this record. *See KSR*, 550 U.S. at 418 (“[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”). Petitioner's expert, Mr. Leinsing, states that it is desirable “to avoid sharp objects if possible” in the medical device field. Ex. 1002 ¶ 67. Mr. Leinsing explains how this incentive applies to Plante's sample collection kit. Mr. Leinsing describes Plante's approach as “using a knife in the vessel, which pointed at the opening into which the saliva sample was delivered.” *Id.* This is supported by the record. Ex. 1003 ¶ 35, Fig. 1 (knife 19 pointing up towards entrance 4 of receiving vessel 1). Aside from the degree of sharpness of Plante's knife or the extent to which Plante's knife positioned inside the vessel may harm a user, there is no dispute that Plante's design includes a knife element that is “sharp enough to rip a foil membrane.” Prelim. Resp. 17 (citing Ex. 2008 ¶ 34 (Dr. Wereley Declaration)). Patent Owner's argument that “a POSA would easily know to mold a plastic knife that was sharp enough to rip a foil membrane but not so sharp as to be dangerous to human skin” underscores that the function of Plante's knife is to be sharp. *Id.*

Mr. Leinsing identifies the NSPA as support for why a POSITA designing a sample collection kit would have had an incentive to eliminate the sharp object completely. Ex. 1002 ¶ 68; Ex. 1012. Mr. Leinsing testifies that the NSPA impacted his own work by designing devices that eliminate or reduce the use of needles (sharps). Ex. 1002 ¶ 68. In addition, the '632 patent itself acknowledges that eliminating sharps is a need in the field of sample collection devices. Ex. 1001, 5:3–6 (“[T]he sample collection devices provide improved safety for both the sample donor and the end user, since, for example, sharp objects are not included.”).

In sum, Petitioner’s stated rationale for combining the teachings of Plante and Cho to eliminate Plante’s sharp is sufficient for purposes of institution. *See KSR*, 550 U.S. at 420 (“[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the matter claimed.”).

Petitioner’s assertion that it would have involved no more than routine substitution to replace Plante’s reservoir containing cap with Cho’s reservoir containing cap, which provides the same desired functionality of releasing a material stored in the cap without the need for a sharp knife, is supported by the record. Pet. 16–17; Ex. 1002 ¶¶ 74–75. Patent Owner’s argument that a POSITA would not have had a reasonable expectation of success in substituting Cho’s cap for Plante’s cap because Cho’s cap “extends significantly beyond the bottom of Cho’s cap” presenting a “contamination risk” that “could lead to a defective sample” is unavailing because it is premised on the bodily incorporation of an embodiment of Cho’s cap coupled to an embodiment of Plante’s vessel. Prelim. Resp. 24. “The test for obviousness is not whether the features of a secondary reference may be

bodily incorporated into the structure of the primary reference Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) (“[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.”); *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973) (“Combining the *teachings* of references does not involve an ability to combine their specific structures.”). “[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR*, 550 U.S. at 417.

Even if Cho’s system is constructed from parts that differ from Plante’s system, i.e., the size of the reservoir in the cap, the Petition identifies a reason for modifying Plante with Cho’s valve, namely, to replace Plante’s knife in the interest of safety to the user. Pet. 15. Precedent has long held that the person having ordinary skill in the art must be regarded as skillful and ordinarily creative, not as a mere literalistic automaton. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1304 (Fed. Cir. 2010); *In re Sovish*, 769 F.2d 738, 742 (Fed. Cir. 1985). A person having ordinary skill in the art, characterized by having a bachelor’s degree in mechanical engineering, biomedical engineering, or similar technical degree and at least 3 years of experience with containers and valves used in disposable medical devices, would have understood how to size, scale, and otherwise form the sample collection kit

taught by Plante using Cho's cap such that components engage each other and do not include Plante's knife. Pet. 8; Ex. 1002 ¶ 52.

Patent Owner's assertion that molding difficulties is not an adequate rationale for modifying Plante's knife with Cho's valve is unavailing because the record supports Petitioner's position that varying thickness is something to be avoided. Prelim. Resp. 18–19; Ex. 1014, 729 (“[V]arying wall thicknesses from thick and thin section in a part will lead to problems in molding.”). Patent Owner directs us to the statement on the same record page that varying thickness can be “unavoidable,” which only reinforces Petitioner's position that varying thickness is something that should be avoided when possible. Prelim. Resp. 19 (citing Ex. 1014, 729). Patent Owner further asserts that “designs with varying thickness . . . are easily made” following the guidance that “the transition should be gradual and coring should be utilized whenever possible.” *Id.* However, the record does not support whether a gradual transition and coring are techniques that can be applied to Plante's sharp.

Based on the foregoing, we determine that Petitioner demonstrates a reasonable likelihood that claim 1 would have been obvious over the combined disclosures of Plante and Cho.

b. *Claims 2–4, 6–16, and 18–20*

Claims 2–4, 6–16, and 18–20 directly or indirectly depend from claim 1. The Petition identifies the further limitations of claims 2–4, 6–16, and 18–20 in the disclosure of Plante and/or Cho. Pet. 45–65.

Patent Owner does not address Petitioner's arguments with respect to claims 2–4, 6–16, and 18–20, beyond the arguments discussed above with respect to independent claim 1. Prelim. Resp. 14–34.

Upon review of the parties' arguments and supporting evidence, we determine that Petitioner demonstrates a reasonable likelihood that dependent claims 2–4, 6–16, and 18–20 would have been obvious over the combined disclosures of Plante and Cho.

2. *Unpatentability over Plante, Cho, and Patterson*

Claim 5 depends from claim 1 and recites “wherein the first cylinder comprises a press-fit connection with the cap.” Ex. 1001, 23:4–6.

Petitioner asserts that claim 5 is unpatentable under 35 U.S.C. § 103(a) over the combination of Plante and Cho as discussed above in further view of Patterson's disclosure of press-fit (e.g., interference fit or snap fit) connections between cylindrical parts of a cap that do not involve threads, citing the Declaration of Karl R. Leinsing for support. Pet. 66–71 (citing Ex. 1002 ¶¶ 165–172). According to Petitioner, the '632 patent does not expressly describe a press-fit connection, but, rather, “generally identifies various types of ‘well-known’ connections.” *Id.* at 66 (citing Ex. 1001, 10:58–67). Petitioner asserts this is an admission that a press-fit connection is “well-known” and would have been obvious to a POSITA to use a press-fit connection in a cap such as Cho's with a reasonable expectation of success. *Id.* at 66–67. Petitioner also asserts that the use of press-fit connections in container caps was well-known prior to the '632 patent, citing both Cho and Patterson. *Id.* at 67–68 (citing Ex. 1004, 1:28–2:3, 55:22–25, Fig. 44; Ex. 1002 ¶¶ 168–169; Ex. 1010 ¶¶ 32, 35).

In addition to the arguments discussed above with respect to the unpatentability of independent claim 1 over Plante and Cho, Patent Owner contends the Petition should be denied because Patterson is not analogous art to the '632 patent. Prelim. Resp. 26–34. Similar to Patent Owner's argument

that Cho is not analogous art, Patterson is asserted to be directed to a different field of endeavor, namely mixing water and a flavoring prior to drinking the mixture. *Id.* at 27. Patent Owner asserts that neither the Petition nor Dr. Leinsing’s declaration argues that Patterson is either in the same field of endeavor or addresses the same problem as the ’632 patent. *Id.* at 30.

Based on the cited record at this stage of the proceeding, we find the Petition provides sufficient evidence for purposes of institution that Cho and Patterson are “container caps” and, for that reason, are within the same field of endeavor as the ’632 patent. Pet. 67–68. The Petition characterizes the ’632 patent, Plante, and Cho as all being directed to “a container ‘contain[ing] two kinds of materials in two separate spaces’ and subsequent mixing of those materials.” *Id.* at 12 (quoting Ex. 1004, 1:3–6) (alteration in original). To the extent that the ’632 patent’s field of use is disputed by the parties, this issue can be addressed in subsequent briefing in the proceeding.

The Petition relies on both Cho and Patterson to show that “press-fit connections in container caps were well known before the ’632 patent.” *Id.* at 67–68. Having determined that Petitioner demonstrates a reasonable likelihood that claim 1 would have been obvious over the combined teachings of Plante and Cho, we further determine that Petitioner demonstrates a reasonable likelihood that claim 5 would have been obvious over Plante and Cho alone or together with Patterson.

3. *Unpatentability over Ueda*

Petitioner asserts that claims 1–8, 10–16, and 18–20 are unpatentable under 35 U.S.C. § 102(a) as anticipated by Ueda because Ueda discloses every element of the claims. Pet. 71–116 (citing the Declaration of Karl R. Leinsing for support, Ex. 1002 ¶¶ 173–239).

a. *Claim 1*

Petitioner contends Ueda discloses a “biological sample collection system” as recited in the claim’s preamble because Ueda explicitly discloses that its containers are “suitable for storing biological samples.” *Id.* at 75 (quoting Ex. 1005 ¶ 1, citing Ex. 1005 ¶¶ 2, 21, Fig. 1) (emphasis omitted). Referring to Ueda’s Figures 1, 2, and 3B, Petitioner identifies Ueda’s container body 2 as the recited “sample collection reservoir” in which biological sample 6 is received, the upper end opening in Ueda’s container body 2 as the recited “first aperture,” and Ueda’s thread set (“male screw projection 13 screwed into female screw groove 12 of the container body 2”) between Ueda’s vessel and cap as the recited “first connection member” and “second connection member complementary to the first connection member.” *Id.* at 77–79, 82 (citing Ex. 1005 ¶¶ 20, 21, 26). According to Petitioner, Ueda’s cap 3 “consists of three members, i.e., an outer cylindrical member indicated by reference numeral 7, a mixture holding member indicated by reference numeral 8, and a plug member indicated by reference numeral 9.” *Id.* at 73–74 (quoting Ex. 1005 ¶ 25, citing Ex. 1005, Fig. 2). Ueda’s Figure 2 is shown below:

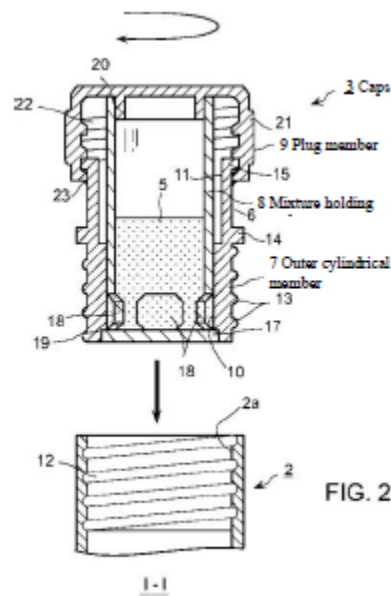
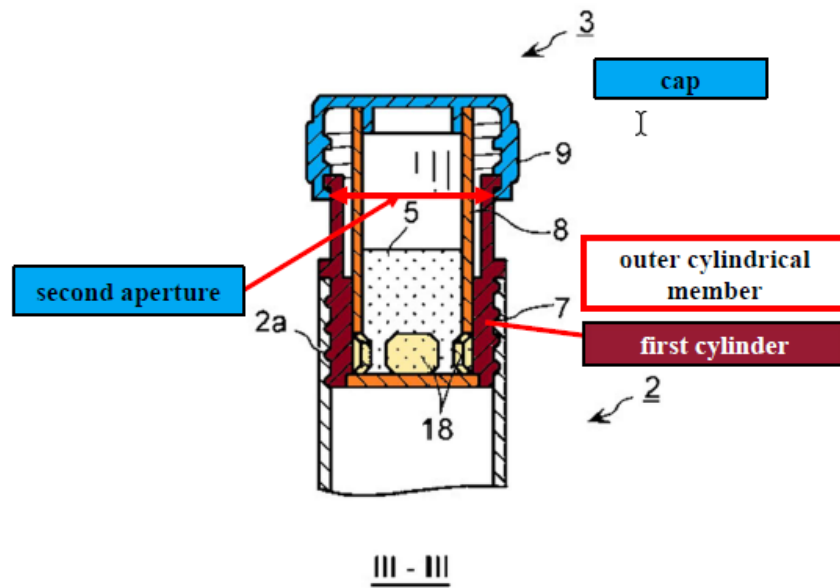


Figure 2 above is a cross-sectional view of a longitudinal section of cap 3 and container body 2. Ex. 1005 ¶¶ 18, 22.

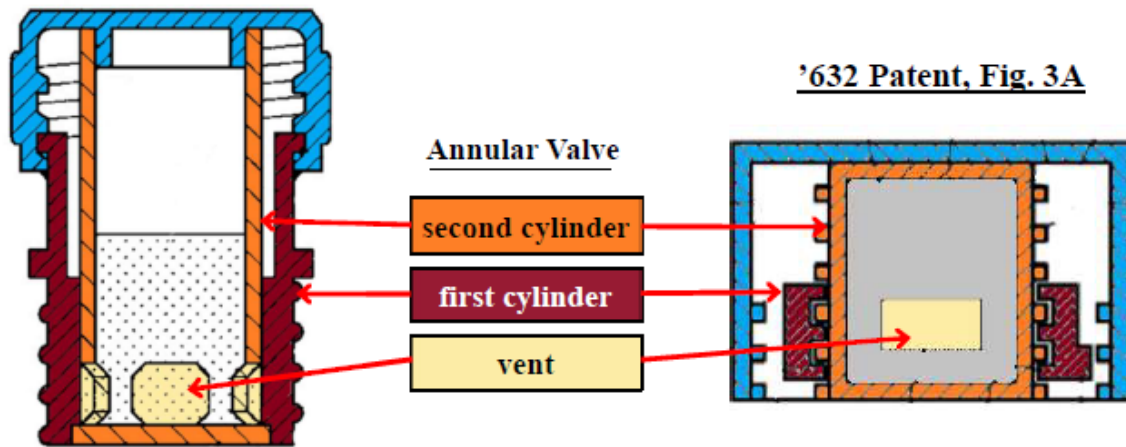
Referring to Ueda’s Figure 3B, Petitioner identifies the recited “cap” and its components, namely the “second aperture” that receives a portion of the recited “first cylinder,” which Petitioner maps to Ueda’s outer cylindrical member 7, and the recited “reagent chamber,” which Petitioner maps to Ueda’s mixture holding member 8. *Id.* at 80–81 (citing Ex. 1005 ¶¶ 9, 23–27, Fig. 3B). Annotated Figure 3B is shown below.



Petitioner's annotated Figure 3B above identifies the second aperture as the space where Ueda's plug member 9 engages Ueda's outer cylinder member 7. Pet. 81.

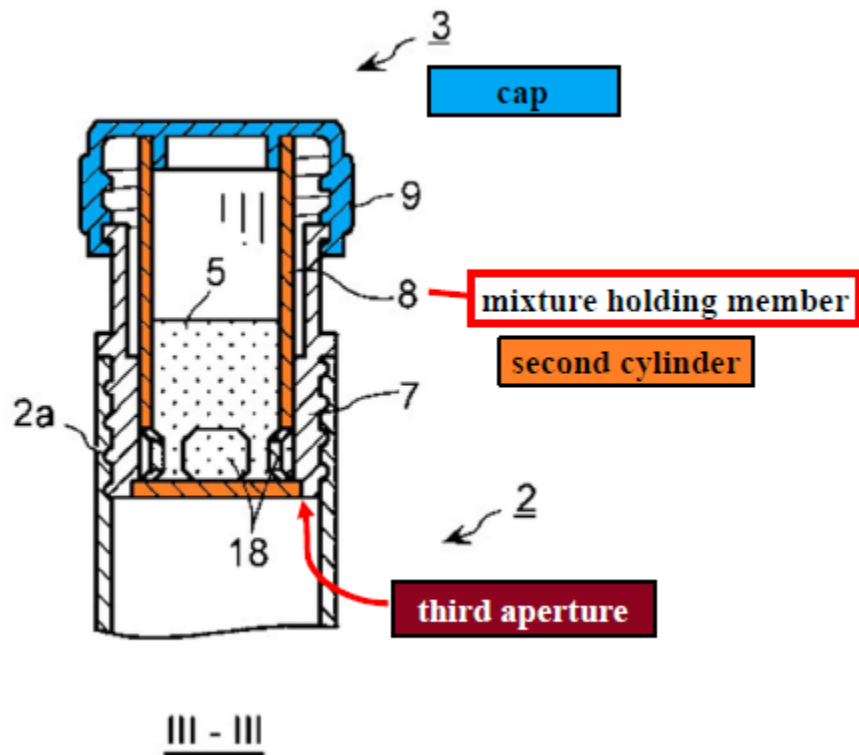
Regarding the recited "moveable annular valve," Petitioner contends Ueda discloses an annular valve having (1) first and second cylinders that move relative to one another and (2) a vent on the second cylinder from which reagent is released similar to the '632 patent's Figure 3A embodiment. Pet. 83–84, 86 (citing Ex. 1005, Fig. 2; Ex. 1001, Fig. 3A). Petitioner's annotated comparison of Ueda's Figure 2 and the '632 patent's Figure 3A is shown below.

Ueda, Fig. 2



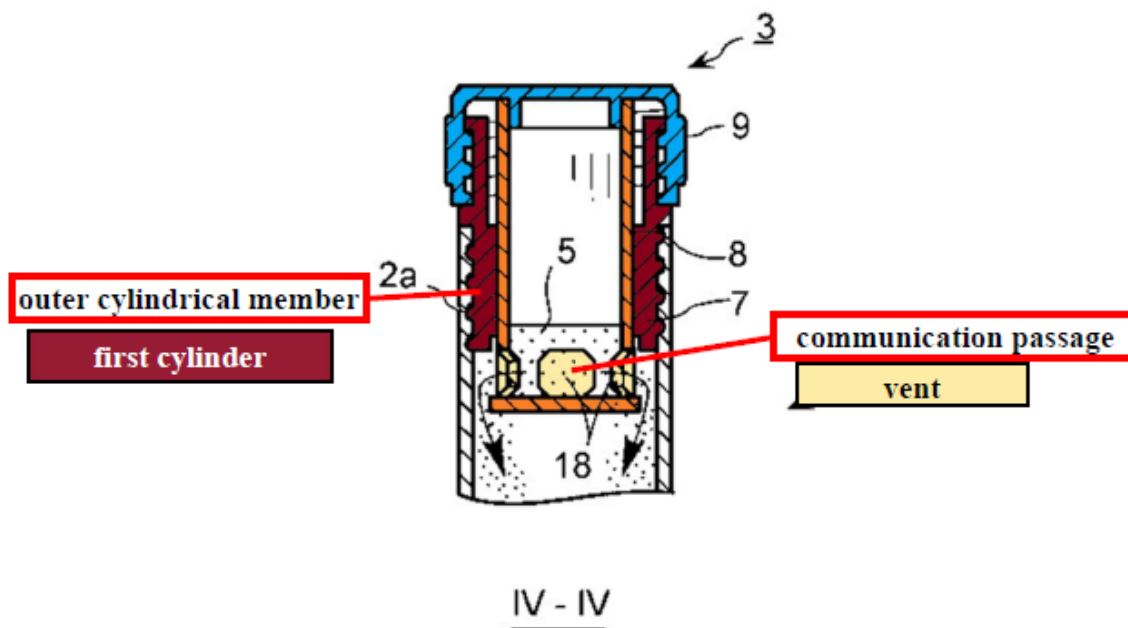
Petitioner's annotated comparison above identifies each of the first cylinder, the second cylinder, and the vent in Ueda's device and the '632 patent's embodiment. *Id.* at 84. Petitioner asserts Ueda's annular valve is "in the second aperture" because the second aperture is the cap aperture depicted with the color blue in each of the annotated figures. *Id.* at 84–85.

Petitioner identifies the recited "first cylinder comprising a third aperture" as Ueda's outer cylindrical member 7 (the first cylinder), and the recited "second cylinder comprising the vent, the second cylinder positioned in the third aperture" as Ueda's mixture holding member 8 (second cylinder) comprising Ueda's communication passages 18 (vent) in the third aperture in first cylinder 7 in Ueda's Figure 3B annotated below. *Id.* at 87–91.



Ueda's annotated Figure 3B above highlights in orange Ueda's mixture holding member and indicates the location of Ueda's mixture holding member in a third aperture.

For Ueda's disclosure of the recited "closed configuration," Petitioner directs us to Ueda's Figure 3B which shows the interior sidewalls of the first cylinder (Ueda's outer cylindrical member 7) obstructing the vent (communication passages 18). *Id.* at 91–92. For Ueda's disclosure of the recited "open configuration," Petitioner directs us to Ueda's Figure 4B which is annotated below.



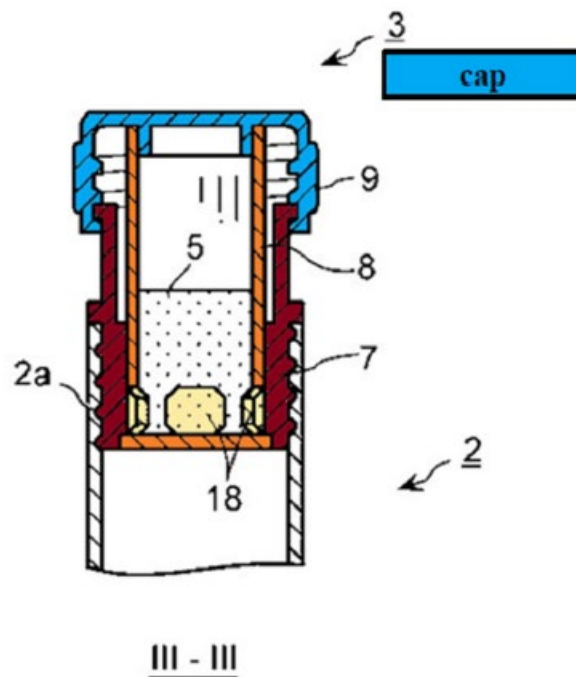
Ueda's Figure 4B annotated above shows outer cylindrical member 7 (first cylinder) no longer obstructing communication passage 18 (vent) and "passage 18 allows the internal space of the container body 2 and the internal space of the mixture holding member 8 to communicate with each other." Pet. 92 (quoting Ex. 1005 ¶ 27). Petitioner asserts that Ueda discloses the recited "first and second cylinders create a fluid-tight seal with the cap and the first cylinder obstructs the vent" in the closed configuration in the same way as the '632 patent embodiment because Ueda's mixture holding member 8 (second cylinder) acts as an inner wall of the cap to seal the reagent within the cap when the outer cylindrical member 7 (first cylinder) blocks the vent (passage 18). *Id.* at 93–95 (citing Ex. 1005 ¶ 27, Figs. 2–4B; Ex. 1001, 14:20–32). Petitioner asserts that Ueda discloses that the first and second cylinders are relatively moveable between the open and closed configurations and that the open configuration allows reagent from the reagent chamber to flow through the vent into the sample collection

reservoir as required by the remainder of the claim limitations. *Id.* at 95–97 (citing Ex. 1005 ¶ 27, Fig. 4B).

Patent Owner contends the Petition should be denied because Ueda does not disclose a cap as recited in claim 1. Prelim. Resp. 34. Patent Owner’s argument that Ueda’s valve shares a surface with plug member 9 is predicated on the Board adopting Patent Owner’s proposed claim construction of cap, namely, that the valve and cap are not co-extensive, which we declined to do on the present record as discussed above.¹¹ *Id.* at 35. Patent Owner also asserts that Ueda’s plug member 9 fails to function as a “cover for the container of Ueda” because “[t]he inner facing threads of the plug member cannot mate with inner facing threads of the tube.” *Id.* at 36. To support the position that Ueda’s plug member 9 does not cover Ueda’s tube, Patent Owner notes that Ueda identifies the cap with the numeral 3 and the plug member with the numeral 9. *Id.* Patent Owner’s argument is unavailing because it likewise is predicated on parts comprising the cap and the parts comprising the valve not being co-extensive. As Petitioner explains, Ueda’s cap 3 includes plug member 9. Pet. 73–74. The record supports Petitioner’s position that plug member 9 functions as a cover or cap to Ueda’s container. Ex. 1005 ¶ 25.

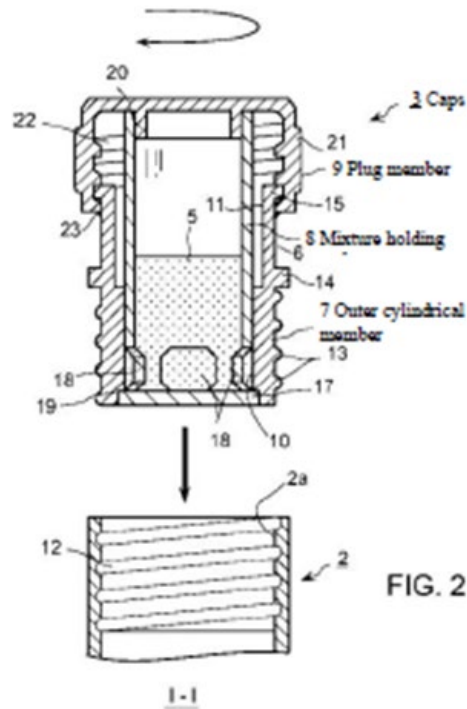
¹¹ Patent Owner directs us to our order requesting briefing on claim construction in related proceeding IPR2022-01347. Prelim. Resp. 35 (citing Ex. 2001, 3). In the related proceeding, we determined that the term “cap” means “a cover for the sample collection vessel” and clarified that this construction was “without any negative limitation on the manner and extent to which the reagent-containing portion of the sample collection device is defined by the cap.” *Spectrum Solutions, L.L.C. v. DNA Genotek Inc.*, IPR2022-01347 at 20 (PTAB Feb. 7, 2024) (Paper 43).

Patent Owner alternatively contends that even if Ueda discloses the cap as recited in claim 1, “the connection member of Ueda’s alleged cap is not complimentary to the connection member of Ueda’s vessel.” Prelim. Resp. 34. Specifically, Patent Owner asserts that “Ueda’s plug member does not have a second connection member complementary to the first connection member of the sample collection vessel.” *Id.* at 37. Patent Owner directs us to Petitioner’s annotated Ueda Figure 3B, shown below.



According to Patent Owner, annotated Ueda Figure 3B above depicts inner facing threads on Ueda's plug member 9 (shown in blue) as not engaged with the internal threads of Ueda's tube 2 and, therefore, these threads not shown as complementary to each other. Prelim. Resp. 37. Patent Owner's argument is based on mapping the inner facing threads on Ueda's plug member 9 to the recited "second connection member" of the cap and mapping the internal threads of Ueda's tube 2 to the recited "first connection

member” of the vessel. *Id.* However, Petitioner maps the recited “second connection member” and “first connection member” to thread sets 13 (located on the outer cylindrical member portion 7 of Ueda’s cap 3) and 12 (located on Ueda’s vessel 2), respectively, shown in Figure 2, reproduced below. Pet. 82.



Petitioner contends that Figure 2, reproduced above, includes a first connection member (thread set 12), a second connection member (threads 13), and discloses that they are complementary as required by claim 1. Pet. 78 (first connection member, thread set 12), 82 (second connection member, threads 13). The record supports Petitioner’s assertion that Ueda’s cap 3 includes outer cylindrical member 7 having “male screw projection 13 that can be screwed into the female screw groove 12 of the container body 2.” Ex. 1005 ¶ 26; Pet. 82. Claim 1 does not require that the recited “second

connection member” to be located in the recited “second aperture” as Patent Owner’s argument implies.

In sum, after review of the parties’ arguments and supporting evidence in the current record, we determine that Petitioner sufficiently identifies where Ueda expressly discloses every limitation of claim 1. As such, Petitioner demonstrates a reasonable likelihood that claim 1 is anticipated by Ueda.

b. Claims 2–8, 10–16, and 18–20

Claims 2–8, 10–16, and 18–20 directly or indirectly depend from claim 1. The Petition identifies the further limitations of claims 2–8, 10–16, and 18–20 in the disclosure of Ueda. Pet. 97–116.

Patent Owner does not address Petitioner’s arguments with respect to claims 2–8, 10–16, and 18–20, beyond the arguments discussed above with respect to independent claim 1. Prelim. Resp. 34–37.

Upon review of the parties’ arguments and supporting evidence, we determine that Petitioner demonstrates a reasonable likelihood that claims 2–8, 10–16, and 18–20 are anticipated by Ueda.

4. Unpatentability over Ueda and Patterson

Petitioner asserts that claim 5 is unpatentable under 35 U.S.C. § 103(a) over Ueda as discussed above in further view of Patterson’s disclosure, namely press-fit (e.g., interference fit or snap fit) connections between cylindrical parts of a cap that do not involve threads, citing the Declaration of Karl R. Leinsing for support. Pet. 117–21 (citing Ex. 1002 ¶¶ 241–247).

Patent Owner does not address Petitioner’s arguments with respect to claim 5, beyond the arguments discussed above with respect to the

unpatentability of independent claim 1 as anticipated by Ueda, and Patterson's status as non-analogous art. Prelim. Resp. 26–38.

Having determined that Petitioner demonstrates a reasonable likelihood that claims 1–8, 10–16, and 18–20 are anticipated by Ueda, we need not consider the further combination with Patterson at this time.

5. *Unpatentability over Ueda and Williams*

Claim 9 depends from claim 1 and recites “further comprising a funnel attachable to the sample collection vessel.” Ex. 1001, 23:20–22.

Petitioner asserts that claim 9 is unpatentable under 35 U.S.C. § 103(a) over Ueda as discussed above in further view of Williams's disclosure, namely to use an attachable funnel with a biological sample container to facilitate obtaining a biological sample from a user, citing the Declaration of Karl R. Leinsing for support. Pet. 121–23 (citing Ex. 1002 ¶¶ 248–251).

Patent Owner does not address Petitioner's arguments with respect to claim 9, beyond the arguments discussed above with respect to the unpatentability of independent claim 1 as anticipated by Ueda. Prelim. Resp. 34–38.

Having determined that Petitioner demonstrates a reasonable likelihood that claims 1–8, 10–16, and 18–20 are anticipated by Ueda, we need not consider the further combination with Williams at this time.

IV. CONCLUSION

For the reasons above, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to challenged claims 1–16 and 18–20 of the '632 patent. Having determined that the record establishes a reasonable likelihood

that the Cho and Patterson prior art references are analogous art to the '632 patent at the institution stage, we invite the parties to address the analogous art issue at trial. At this juncture in the proceeding, we have not made a final determination with respect to the patentability of the challenged claims, or with respect to claim construction.

V. ORDER

For the foregoing reasons, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–16 and 18–20 of the '632 patent is hereby instituted with respect to the grounds of unpatentability set forth in the Petition; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial will commence on the entry date of this Decision.

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