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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

Case No. IPR2023-01424
Patent No. 11,536,632

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,536,632**

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LIST OF EXHIBITS

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

Exhibit No.	Description
1017	<i>Curriculum Vitae</i> of Karl R. Leinsing, MSME, PE
1018	U.S. Patent No. 4,589,548 to Fay (“Fay”)
1019	U.S. Patent No. 4,741,346 to Wong (“Wong”)
1020	U.S. Patent No. 3,518,164 to Adelin (“Adelin”)

Spectrum Solutions L.L.C. (“Petitioner”) requests *inter partes* review of claims 1–16 and 18–20 of U.S. Patent 11,536,632 (“the ’632 patent,” Ex.1001).

**I. MANDATORY NOTICES, GROUNDS FOR STANDING,
AND FEE PAYMENT**

Pursuant to 37 C.F.R. §42.8(a)(1), the mandatory notices identified in 37 C.F.R. § 42.8(b) are provided below as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. §42.8(b)(1))

Spectrum Solutions LLC is the real party in interest for Petitioner. The parent company for Spectrum Solutions LLC is Spectrum Holdco LLC. Furthermore, the following entities have a financial interest in, or could be substantially affected by the outcome of, this proceeding: Spectrum Holdco LLC and Spectrum Intermediate LLC.

B. Related Matters (37 C.F.R. §42.8(b)(2))

The parties were recently engaged in district court litigation in the case captioned *DNA Genotek Inc. v. Spectrum Sols. LLC*, C.A. No. 3:21-cv-0516-RSH-DDL (S.D. Cal Nov. 29, 2022.) (“District Court Litigation”). DNA Genotek (“Genotek” or “Patent Owner”) asserted a patent related to the ’632 patent (U.S. Patent No. 11,002,646 (“the ’646 patent”)) against Petitioner in the District Court Litigation. The District Court granted summary judgment of non-infringement and Genotek has appealed.

Inter partes review of the related '646 patent has been instituted in IPR2022-01347 (“'646 Patent IPR”). Ex.1011 ('646 DI). The decision granting institution issued on February 10, 2023. *Id.*

C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Petitioner’s Power of Attorney.

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D. Service Information (37 C.F.R. §42.8(b)(4))

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxSpectrum8@knobbe.com.

E. Grounds for Standing (37 C.F.R. §42.104)

Petitioner certifies that the '632 patent is available for IPR and is not barred or estopped from requesting IPR on the identified grounds.

F. Payment of Fees (37 C.F.R. §42.15(a))

The Office may charge the §42.15(a) fee to Deposit Account No. 11-1410. Review of nineteen claims is requested. Payment for any additional fees due may be charged to the above-referenced Deposit Account.

II. INTRODUCTION

The '632 patent claims are directed to biological sample collection systems with three primary elements:

- a sample collection vessel;
- a cap; and
- a movable annular valve.

These are common elements that were ubiquitous before the alleged invention. Further, collection systems with the same features were used prior to the '632 patent for the same application of collecting biological samples.

Figures 3A and 3B from the '632 patent show a representative collection system.¹ Figure 3A below shows the valve in the **closed position**, with the first cylinder covering the vent on the second (inner) cylinder.

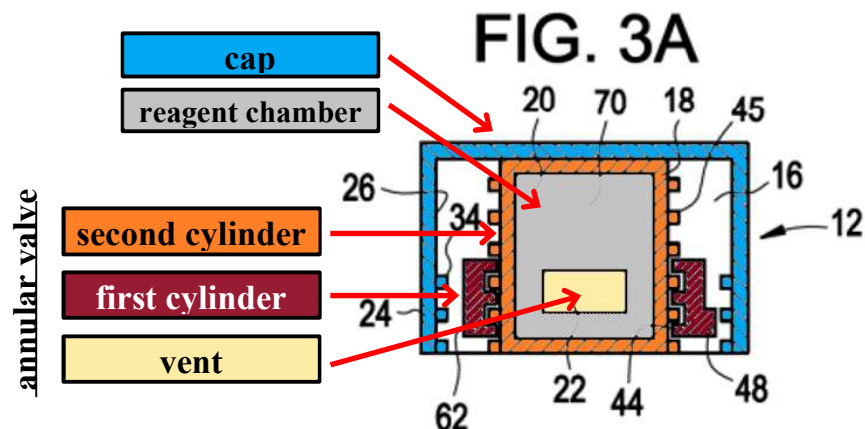
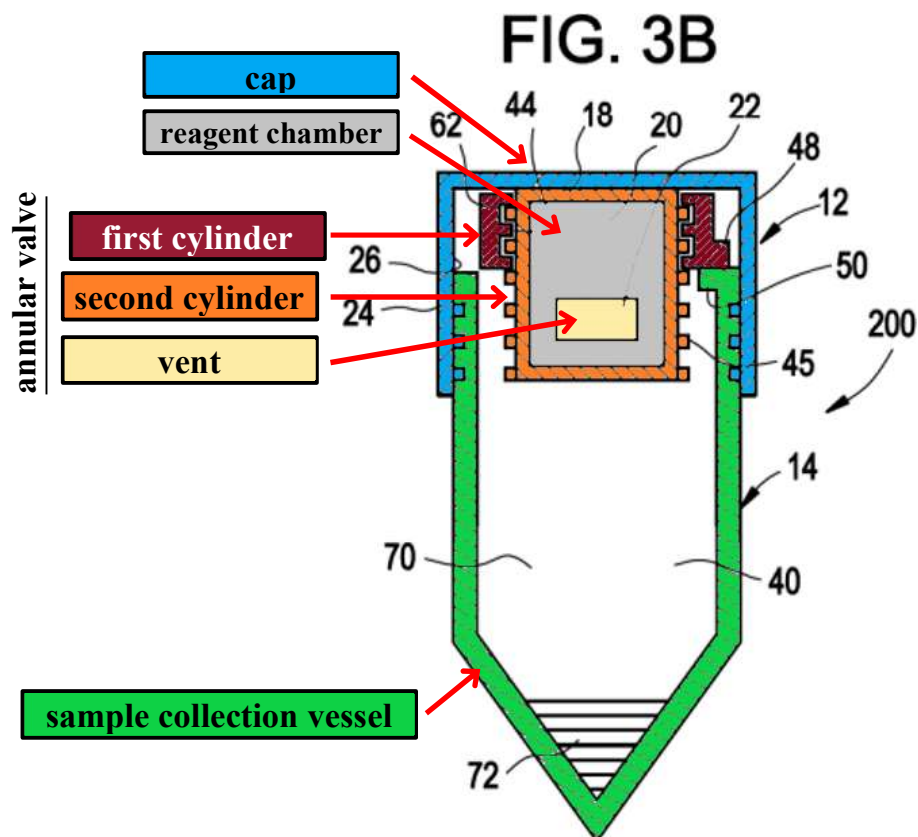


Figure 3B below shows the cap attached to the sample collection vessel and in the **open position**, with the first cylinder no longer blocking the vent on the second cylinder:

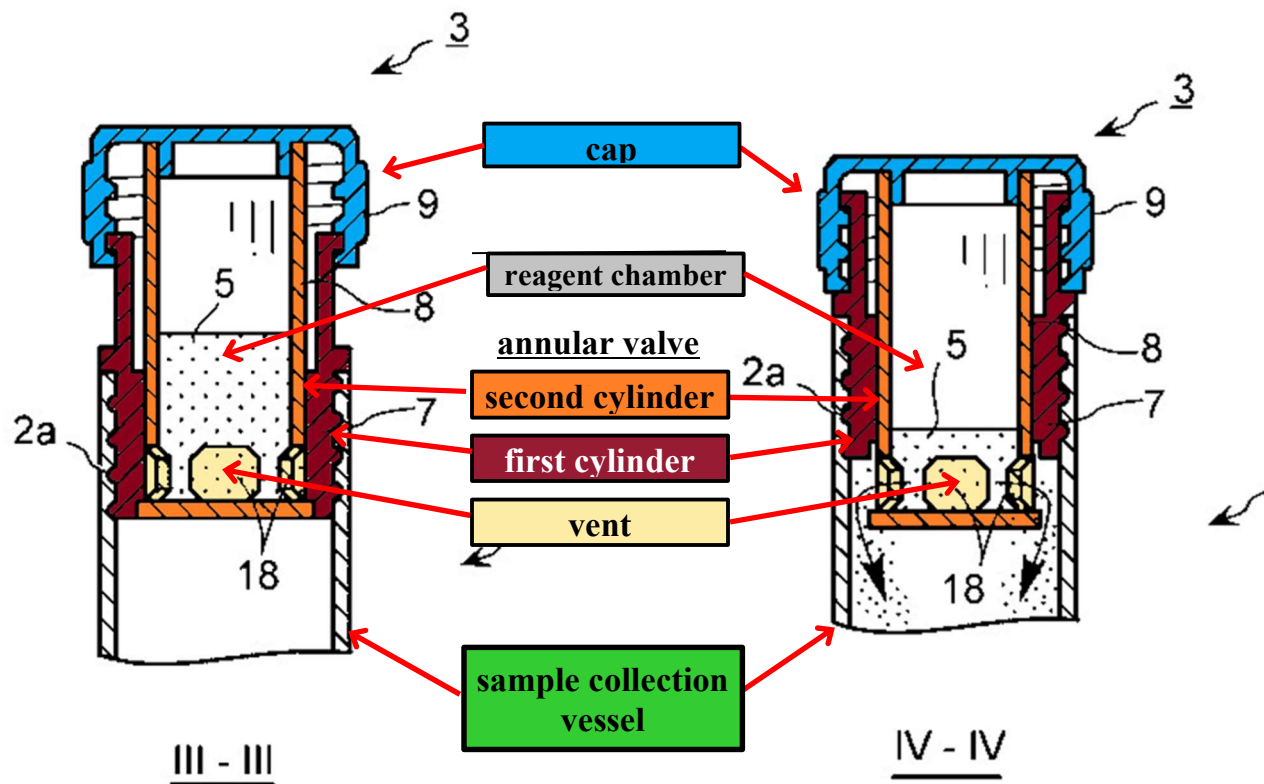
¹ The '632 patent claims use terminology not used in the specification. The Petition provides colored figures from the '632 patent that have been annotated with the claim terminology.



With the valve open, a reagent is released from the reagent chamber into the sample collection vessel. *Id.*

The '632 patent claims would have been obvious in view of Plante and Cho. The IPR on the related '646 Patent was instituted based on this same combination against similar claims. Plante and other prior collection systems include a sample collection vessel and a cap with a reagent chamber. Cho is an example of a movable annular valve that releases the reagent stored in a cap into a container. It would have been obvious to use a well-known annular valve like Cho's in a biological sample collection system like Plante's.

Not only are the challenged claims obvious, but they are also anticipated by Ueda, which discloses a biological sample collection system with an annular valve and all the features of claim 1, as shown below.



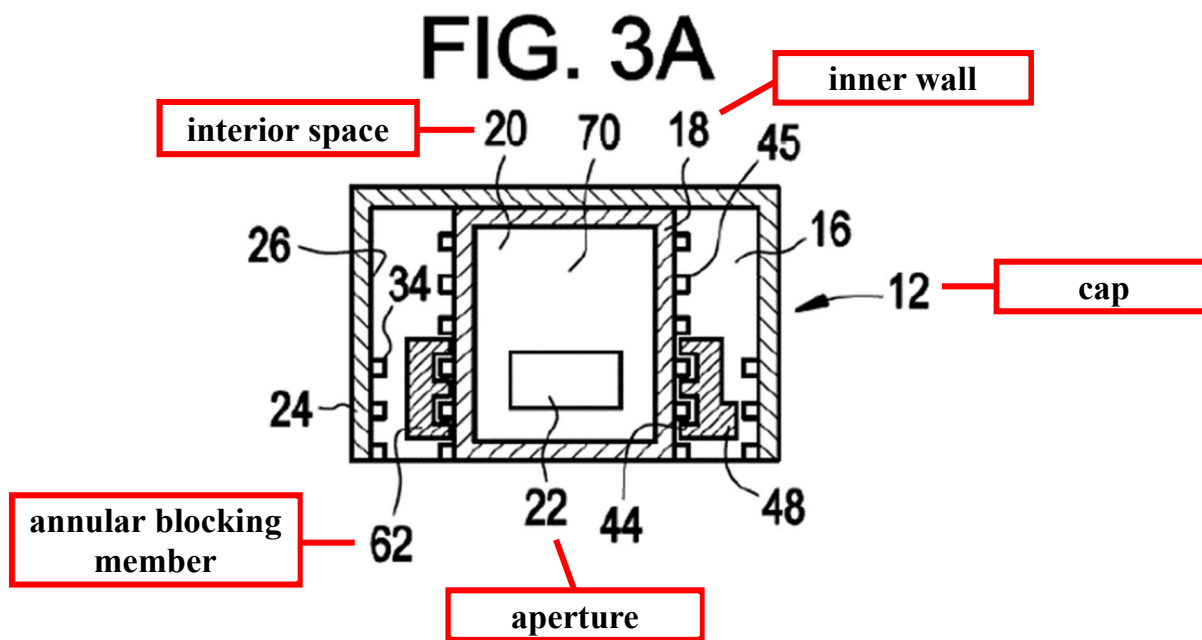
Thus, the prior art anticipates and renders obvious the challenged claims of the '632 patent.

III. THE '632 PATENT

The '632 patent includes embodiments of sample collection devices with a cap that holds a preservation solution and a tube that receives the sample. Ex.1001

at 5:9-19, Figs. 1-7B. When a user closes the cap on the tube, a valve in the cap may “release the preservative solution and allow it to mix with the donor specimen.” *Id.*

Figure 3A of the '632 patent is annotated below with relevant labels from the specification.



Ex.1001, Fig. 3A (annotated). The cap 12 includes an interior space 20, which holds a sample preservation fluid or material 70. *Id.*, 14:15-30. The interior space 20 is defined by an inner wall 18. The inner wall 18 also includes an aperture 22, “which may be open or closed depending on the position of an annular blocking member 62 relative to the aperture 22.” *Id.*, 14:24-32. The patent explains that when “the annular blocking member 62 is not covering the aperture 22, the fluid or material 70 that may be contained in the interior space 20 may be allowed to travel outside of

the interior space 20, such as into the reservoir 40 of the tube 14.” *Id.*, 14:32-37, Fig. 3B.

IV. LEVEL OF ORDINARY SKILL

The invention of the '632 patent relates to devices for collecting samples of bodily fluids. Ex.1001, 1:20-23. The patent therefore includes both mechanical and biological aspects. Ex.1002, ¶52. A hypothetical person of ordinary skill in the art would have a combination of these two skill sets. *Id.*, ¶¶ 51-52. Thus, a hypothetical person of ordinary skill (“POSA”) 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. *Id.* Such a person would have worked as part of a team and collaborated with a person having training and experience in the biological aspects of such systems. *Id.* As to the biological aspects of the disclosure, a person of ordinary skill would have had education and experience relating to the collection of biological samples. *Id.*

This Petition does not turn on this specific definition. The claims are anticipated and would be obvious from the perspective of any reasonable definition of a POSA. *Id.*, ¶ 53

V. CLAIM CONSTRUCTION

The Board construes the claims “using the same claim construction standard that would be used” in district court. 37 C.F.R. § 42.100.

In the district court litigation, the court construed some of the claim terms in the related ’646 patent. As explained herein, the challenged claims are anticipated and obvious under any reasonable constructions.

A. “Biological Sample”

The preamble of claim 1 recites a “*biological sample* collection system . . .” Claim 1 further recites “a first aperture for receiving a *biological sample* . . .” (emphasis added).

In the district court litigation, Patent Owner argued that this term in the related ’646 patent does not require construction and Petitioner argued that it should be construed as “cells.” Ex.1007, 57. The district court construed this term as “biological sample containing cells.” *Id.*

As described herein, the claims are unpatentable as anticipated and obvious regardless of whether the preamble is limiting and under any reasonable construction.

B. “Annular Valve”

Claim 1 recites “a moveable *annular valve* in the second aperture . . .” (emphasis added). The ’632 patent specification does not use the term “annular

valve” or even “valve.” The term was only added in a continuation years after the original application was filed.

In the district court litigation, Patent Owner argued that this term in the related ’646 patent should be construed as “valve with two cylinders where the cylinders move relatively to open/close the valve.” Ex.1007, 66. Petitioner argued that this term should be construed as “ring shaped valve.” *Id.* The district court agreed with Petitioner and construed this term as “ring shaped valve.” *Id.*

As described herein, the claims are unpatentable as anticipated and/or obvious under any reasonable construction of this term.

VI. RELIEF REQUESTED

Petitioner requests that the Board cancel claims 1-16 and 18-20 of the ’632 patent as anticipated and obvious in view of the following prior art references:

Ex.	Reference	Date	Art Type
1003	Plante	Filed: March 25, 2009	§102(e)
1004	Cho	Published: June 9, 2005	§102(b)
1005	Ueda	Published: September 30, 2010	§102(a)
1009	Williams	Published: August 2, 1988	§102(b)
1010	Patterson	Published: November 23, 2006	§102(b)

IPR is requested for the following grounds of unpatentability:

Ground	Reference(s)	Basis	Challenged Claims
1	Plante and Cho	§103(a)	1-4, 6-16, 18-20
2	Plante, Cho and Patterson	§103(a)	5
3	Ueda	§102(a)	1-8, 10-16, 18-20
4	Ueda and Patterson	§103(a)	5
5	Ueda and Williams	§103(a)	9

The petition is supported by the expert declaration of Karl R. Leinsing, MSME, PE, Ex.1002.

**VII. GROUND 1: PLANTE AND CHO RENDER
OBVIOUS CLAIMS 1–4, 6–16 AND 18–20**

A. Disclosure of Plante

Plante discloses a biological sample collection system for “collection of biological matter.” Ex.1003, [0002] and [0017]. The system includes a receiving vessel 1 and a sealing cap 2. *Id.*, [0018]. The cap includes a reservoir 12 that holds a reagent fluid to preserve the sample. *Id.*, [0021], [0041]. The reservoir 12 is sealed with a pierceable membrane or film 13 to protect the preserving fluid until it is mixed with the sample. *Id.* [0041].

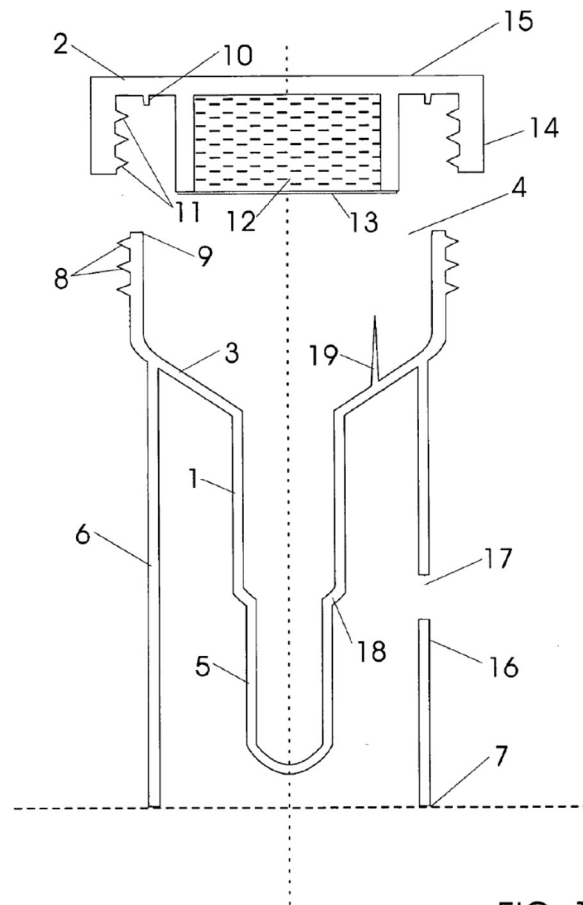


FIG. 1

The vessel and cap include cooperating threads. *Id.*, [0035], Fig. 1. After a sample has been added to the vessel, the cap is screwed onto the vessel. *Id.* Screwing the cap onto the vessel breaches the integrity of the sealed fluid reservoir in the cap as a knife in the vessel pierces a film or membrane of the reservoir to release the preserving fluid. *Id.*, [0022], [0038]; Ex.1002, ¶¶ 29-35.

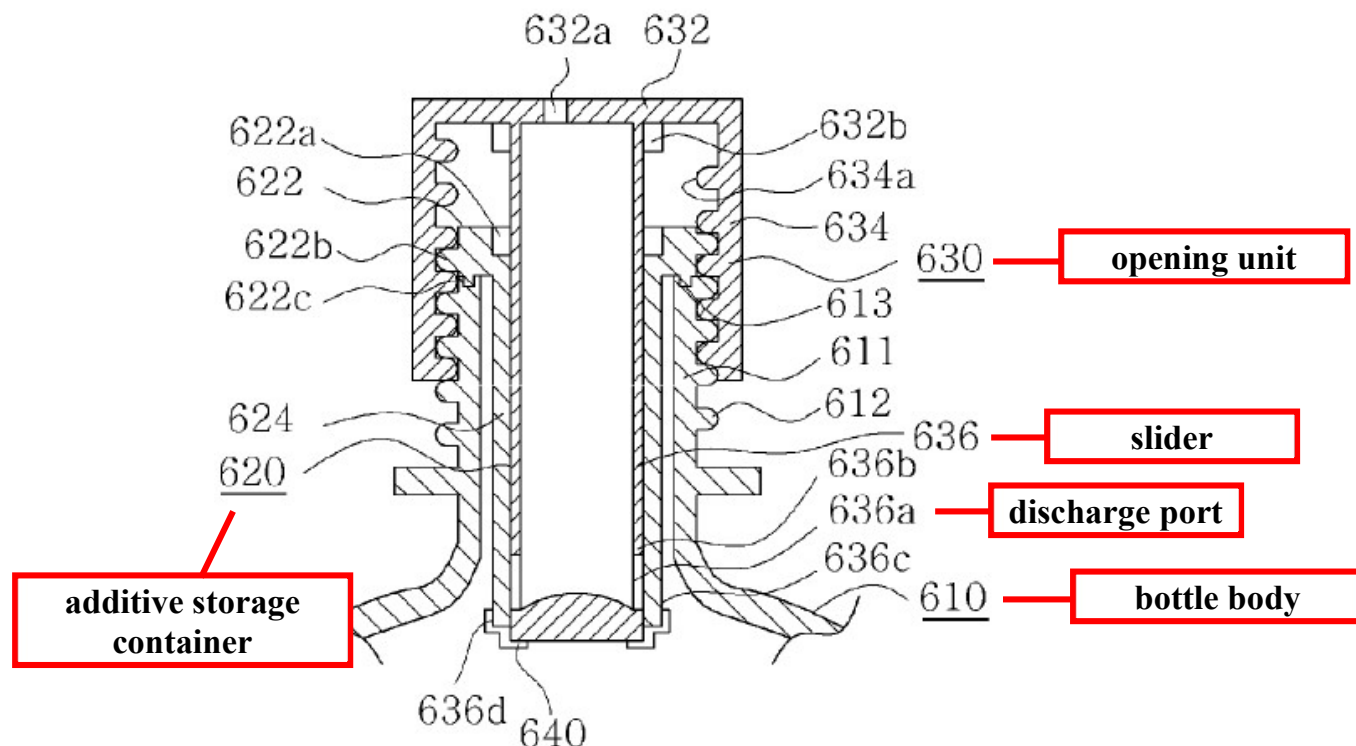
B. Disclosure of Cho

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.

Ex.1004, 1:3-6. The Cho system includes a cap that stores an additive and maintains a “good seal on the interior space . . .” *Id.*, 1:28-2:3; 50:4-12; Ex.1002, ¶¶ 37-39.

Cho discloses mechanisms for releasing the contents of the additive storage container, including a pierceable membrane. *See, e.g., id.*, 40:30-41:10; Figs. 26, 27A. In other embodiments, Cho discloses the use of an annular valve. For example, in Figs. 43-45B, Cho discloses a valve with cooperating inner and outer cylinders that move relative to each other to open/close a vent in the inner cylinder. Ex.1002, ¶¶ 41-43. This embodiment, depicted below, includes a cap (“opening unit 630”) having a valve that is used to release the additive from the additive storage container 620 into the bottle upon tightening the cap on the bottle. Ex.1004, 48:15-50:27. The additive storage container 620 is an outer cylinder, and a “slider 636” is an inner cylinder. *Id.*, 49:10:13; Ex.1002, ¶¶ 41-43. The slider 636 includes “discharge ports 636a” that serve as fluid vents to release the additive into the bottle when the valve is opened. Ex.1004, 50:4-12; Ex.1002, ¶¶ 41-43.

Fig.44



Id., Fig. 44 (annotated).

C. Plante and Cho Render Obvious Claim 1

Plante discloses a biological sample collection system with every element of claim 1 except for the movable annular valve. Cho discloses the claimed movable annular valve. Plante and Cho are in the same field of endeavor as the '632 patent and address the same problem. Ex.1002, ¶¶ 63–66. 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. Ex.1004, 1:28-2:3; Ex.1002, ¶¶ 63–66. A POSA would have been

motivated for multiple reasons to use Cho’s cap with its annular valve in Plante’s sample collection system. Ex.1002, ¶¶ 63–76.

First, a POSA would have been motivated by safety incentives to eliminate Plante’s knife by using Cho’s safer annular valve in the cap. Ex.1002, ¶¶ 67–70. A POSA would have recognized that the knife in Plante’s sample collection system poses a risk of injuring a user or others handling the device. *Id.* It has long been understood in the field of medical devices to avoid sharp objects if possible. *Id.* For example, the adoption of the “Needlestick Safety and Prevention Act” of 2000, provided federal guidance to choose devices without sharps where possible. *Id.*; Ex.1012; Ex.1013. Medical device engineers and designers avoided sharps for many years before this guidance from the government, but this confirmed the importance of safety in design and the avoidance of any potentially unsafe sharp object. Ex.1002, ¶¶ 67-70.

Second, a POSA would have known it is also difficult and more expensive to mold sharp thin features in plastic, like Plante’s knife. *Id.*, ¶¶ 71–72; Ex.1014, 729, 733; Ex.1015, 547. Such sharp features often fail to fully form in the molding process and result in a weakened structure. Ex.1002, ¶¶ 71-72. This increases the failure rate and creates an added expense to visually inspect each sample if it is even possible to mold it consistently. *Id.* Cho describes a container that provides the

same functionality as Plante, but does not require a sharp object to pierce the sealed storage compartment of the cap. *Id.*

Third, using an annular valve like Cho's instead of Plante's knife design would allow the cap to seal onto the vessel before the valve is opened. Ex.1002, ¶ 73. Cho's Figure 44 shows the container in a sealed state in which the cap is attached to the vessel and sealed before the valve is opened to release any reagent. *Id.* On the other hand, the foil in Plante will be pierced by the knife to release the reagent before the cap is fully attached and sealed onto the vessel. *Id.* A POSA would have known that this sealing feature of Cho is beneficial because the vessel containing the sample would be sealed with the cap, protecting the sample, before the reagent is released. *Id.*

Fourth, the combination of Plante and Cho involves the simple substitution of one known element for another—Plante's cap for Cho's cap—to yield predictable results. *Id.*, ¶ 74. A POSA would have readily substituted Plante's cap having the reservoir and the pierceable membrane for Cho's cap having a reservoir and annular valve for releasing material stored in the reservoir. *Id.* Using Cho's cap with Plante's sample collection vessel would no longer require manufacturing the knife in the vessel. *Id.*

A POSA also would have reasonably expected success in combining a cap having an annular valve as disclosed in Cho with the biological sample collection

system of Plante. *Id.*, ¶ 75. For example, a POSA would have readily understood that Cho’s cap could be made to accommodate the sample collection vessel disclosed in Plante. *Id.* The cap disclosed in Cho is used to release a reagent into a bottle when fastened to the bottle, and a POSA would have expected success in using Cho’s cap to perform the same function when connected to Plante’s sample collection vessel. *Id.* Thus, the combination would have involved no more than the routine substitution of one cap (having an annular valve) for another (having a pierceable membrane) that eliminated the need for a sharp knife but provided all the same desired functionality. *Id.*

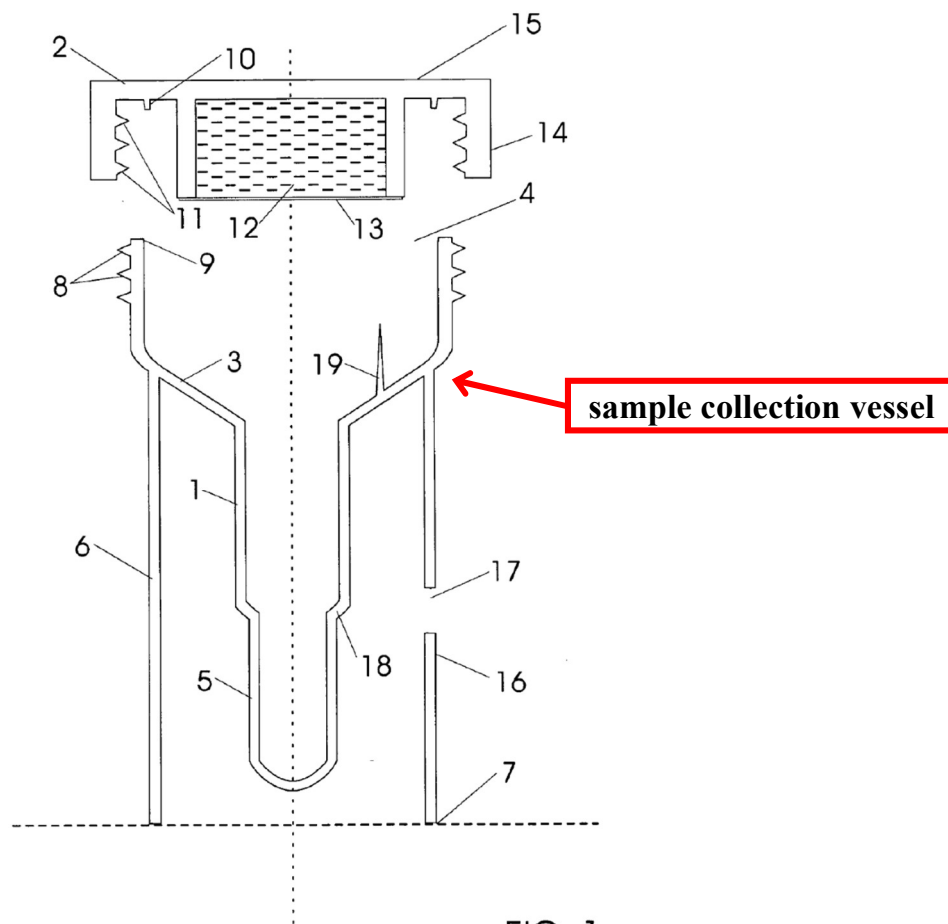
As described below, combining Plante and Cho meets each limitation of claim 1 and the other challenged claims of the ’632 patent.

1. Preamble

The preamble of claim 1 recites: “A biological sample collection system.” To the extent the preamble is limiting, Plante discloses such a collection system. Plante discloses “kits and systems for collection of biological matter and more specifically concerned with saliva collection,” and saliva contains cells. Ex.1003; [0002]; [0018]; Ex.1002, ¶ 77.

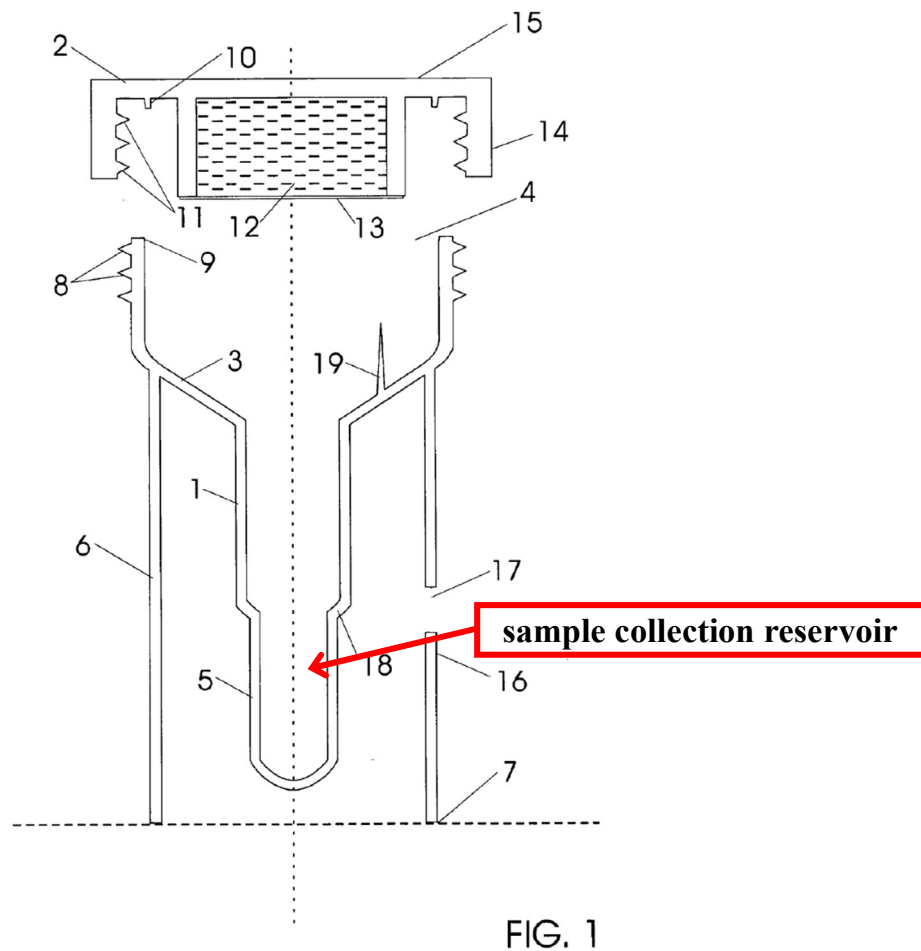
2. Limitation 1[a]: “a sample collection vessel comprising”

Plante discloses this limitation, as shown below in Figure 1 (receiving vessel 1). *See, e.g.*, Ex.1003, [0035], [0018], Fig. 1 (annotated) (“An apparatus for saliva sample collection ... formed of two primary elements ... A *receiving vessel* and sealing cap ...”) (emphasis added); Ex.1002, ¶ 78.



3. Limitation 1[a][i]: “a sample collection reservoir”

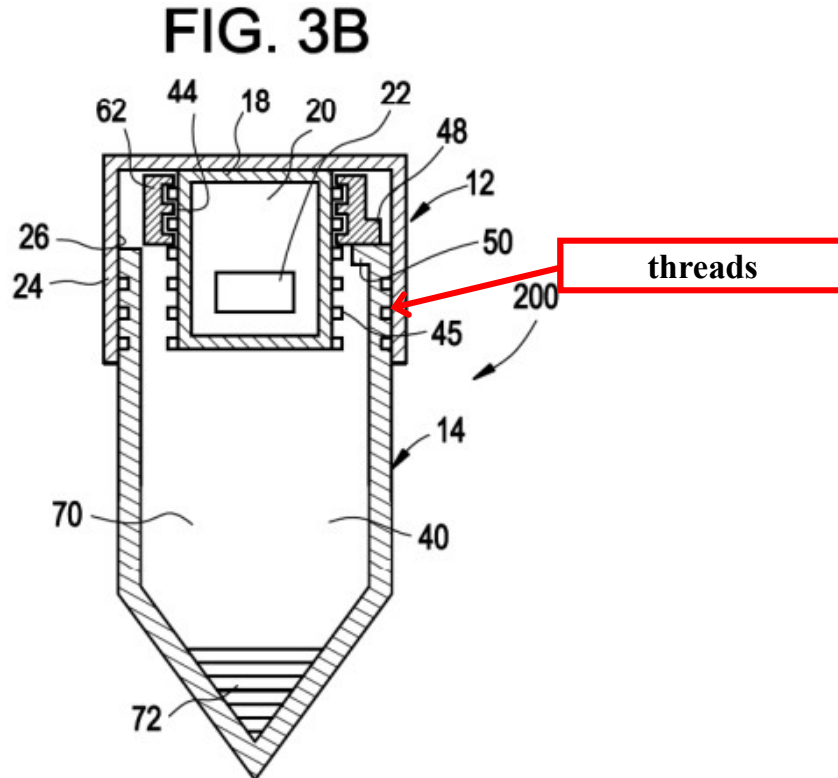
Plante also discloses this limitation, for example the sample collection vessel (receiving vessel 1) has a reservoir that holds the sample once received, as shown below. Ex.1003, [0035], Fig. 1; Ex.1002, ¶ 79.



4. Limitation 1[a]ii: “a first connection member”

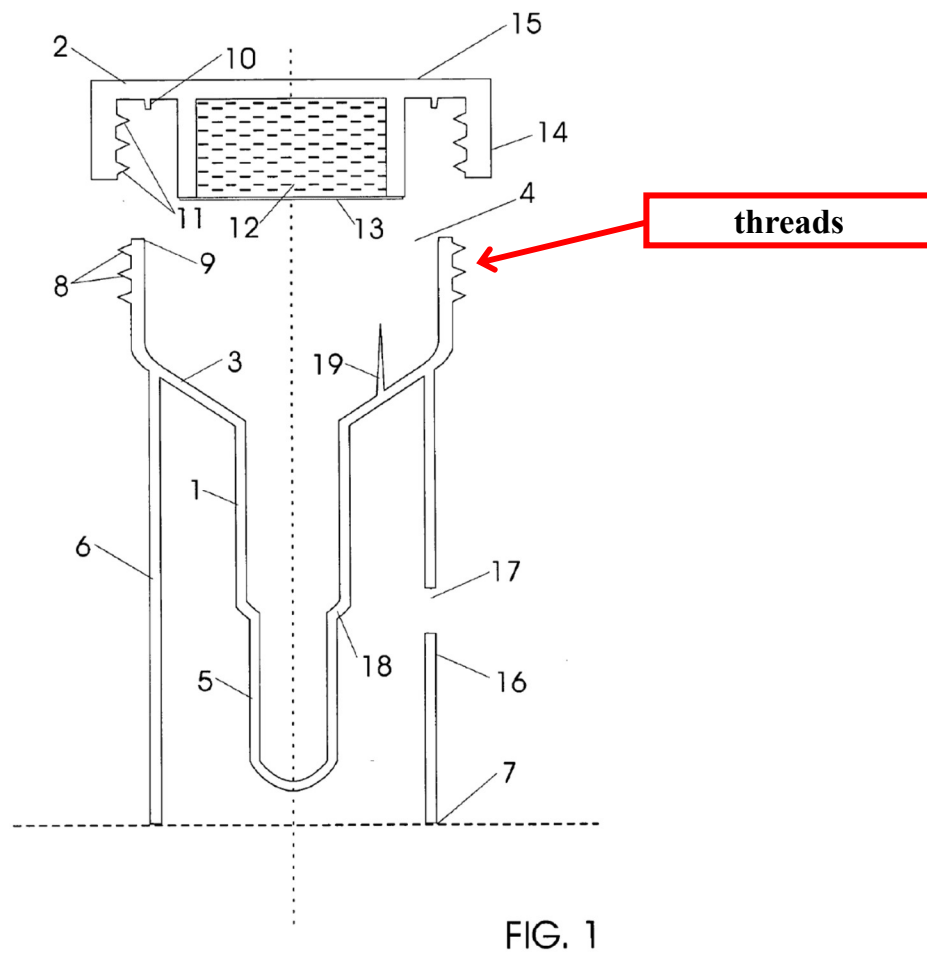
In the '632 patent, the “connection member” is the structure that connects the cap and the bottle. Ex.1001, 10:30-65. The '632 patent lists terms such as “push,

rotate, screw, mate as well as thread” that “correspond to structure (well known to those of skill in the art) for connection” of two components. Ex.1001, 10:58-65. Per claim 14, which depends from claim 1, the connection member can comprise “a threaded connection,” confirming that “connection member” of claim 1 encompasses threads and other well-known means for connection. Ex.1001, claim 14. Figure 3B of the ’632 patent below shows threads on the exterior surface of the sample collection vessel. *Id.*, 15:2-6.



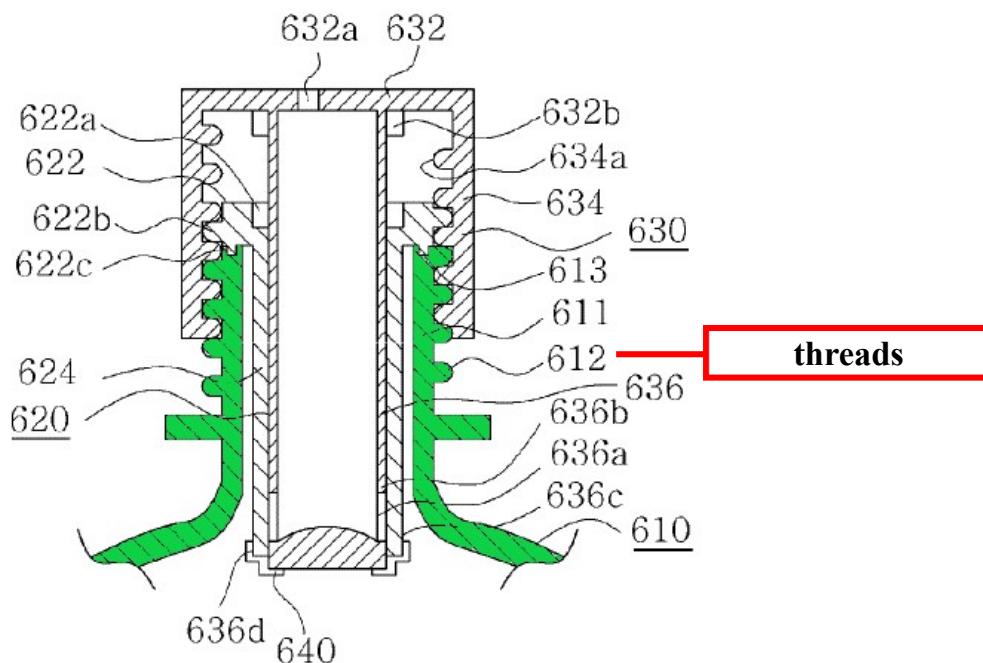
Ex.1001, Fig. 3B (annotated), 14:61-65; Ex.1002, ¶ 80.

Like the '632 patent, Plante discloses a threaded connection of the cap and sample collection vessel: thread set 11 on the cap and corresponding thread set 8 on the collection vessel, as shown in annotated Fig. 1 below. Ex.1003, [0035], Fig. 1.



Cho also discloses a threaded connection on a container with “a mouth provided with an external thread around an outer circumferential surface thereof.” Ex.1004, 2:7-10. The “mouth 611 having an external thread 612,” as shown below in Cho Figure 44. *Id.*, 48:16-19, Figs 43-45B (annotated).

Fig.44



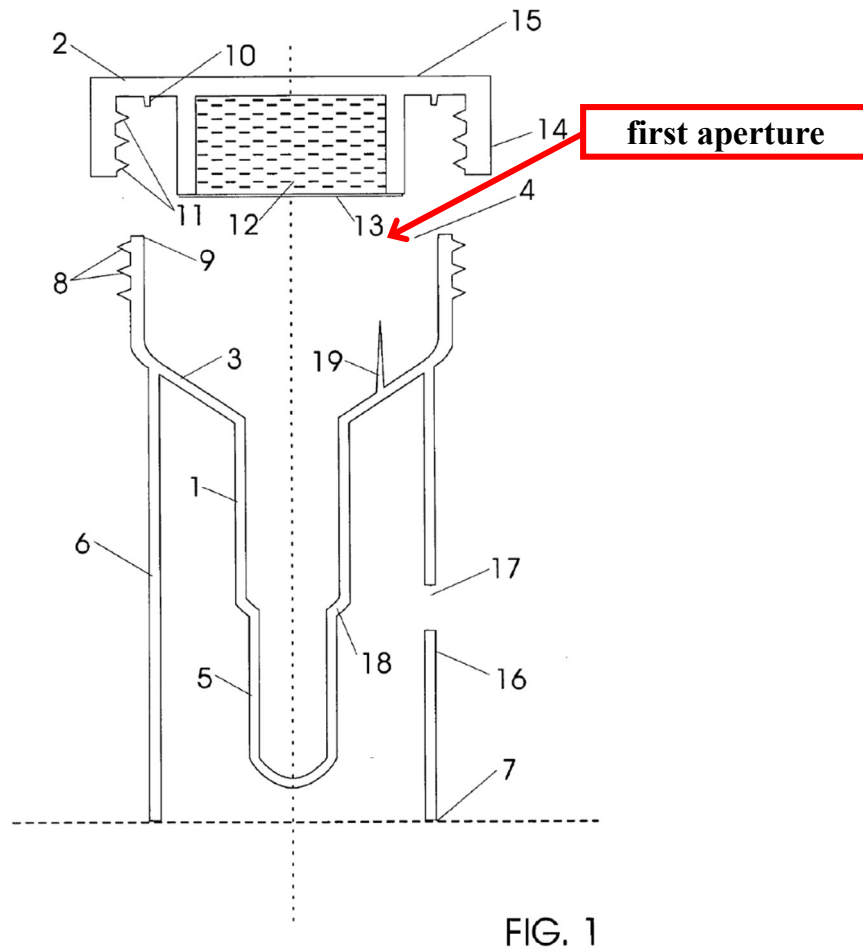
Thus, Plante and Cho each disclose this limitation. Ex.1002, ¶¶ 80–82.

5. Limitation 1[a][iii]: “a first aperture for receiving a biological sample”

Plante discloses this limitation. In the district court litigation, the court construed “biological sample” to mean “biological sample containing cells.” Ex.1007, 57. Plante discloses a vessel with a first aperture that receives a biological sample such as saliva which clearly contains cells. Ex.1002, ¶ 83. For example, Plante discloses a receiving vessel 1 having an “entrance aperture 4” to receive a saliva sample from a user, as shown in annotated Fig. 1 below. Ex.1003, [0035], Fig. 1; Ex.1002, ¶ 83. A POSA would have understood that saliva includes mostly

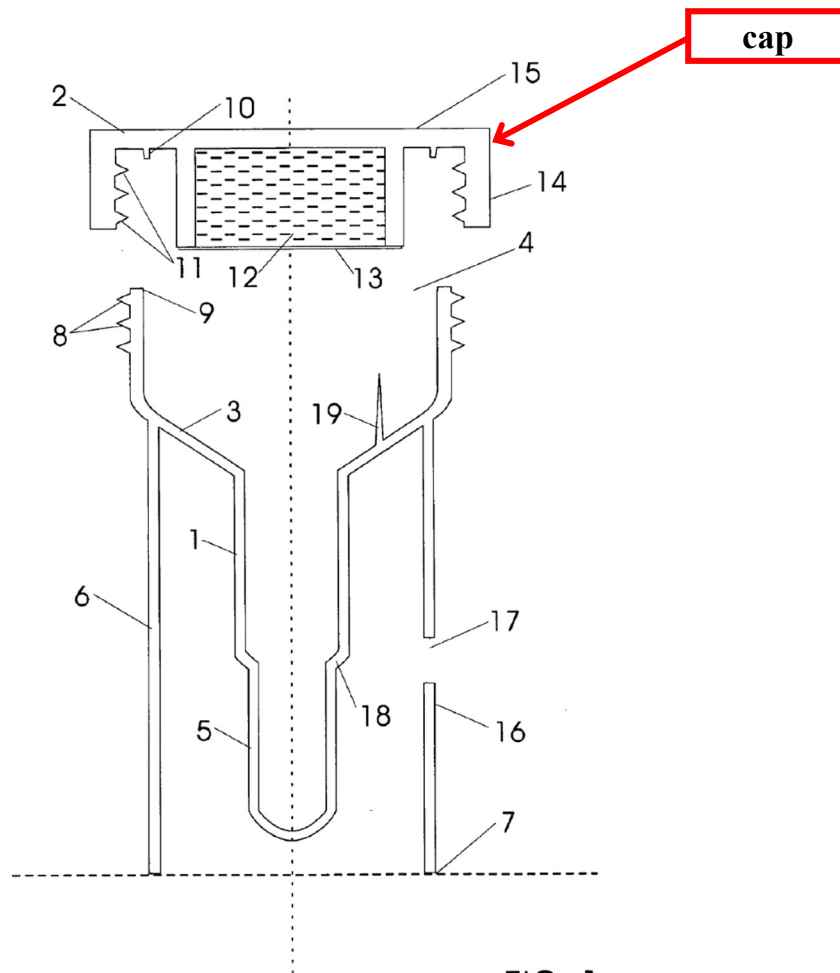
water, but also contains white blood cells, epithelial cells, and other cells. Ex.1002,

¶ 83.



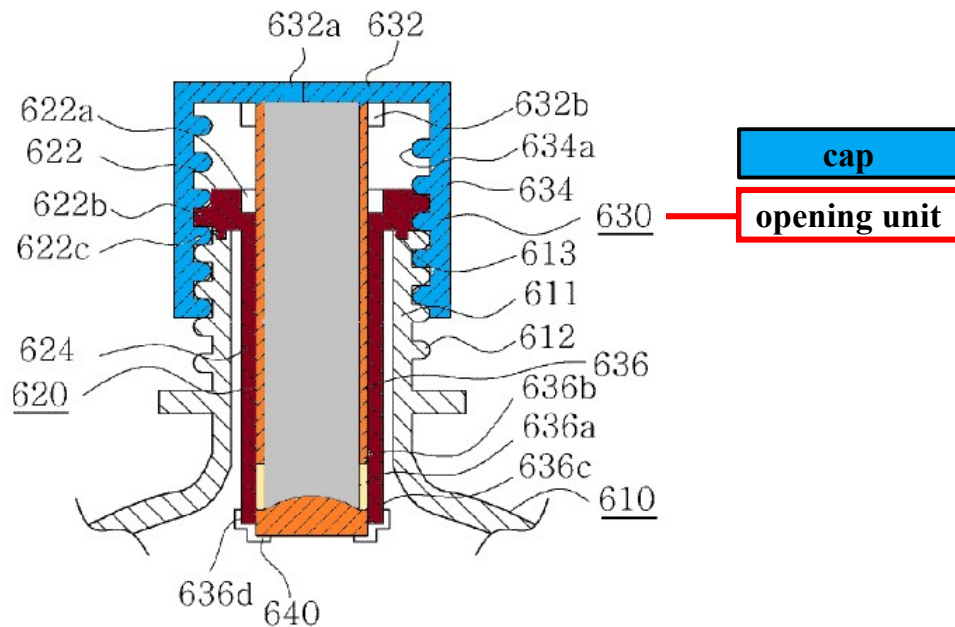
6. Limitation 1[b]: “a cap comprising”

Plante discloses a cap 2 as one of the principal elements of the system, as shown below in Fig. 1. Ex.1003, [0035], Fig. 1 (annotated).



Cho also discloses a cap (opening unit 630), which includes the first and second cylinders forming the annular valve, as shown in Fig. 44 below.

Fig.44

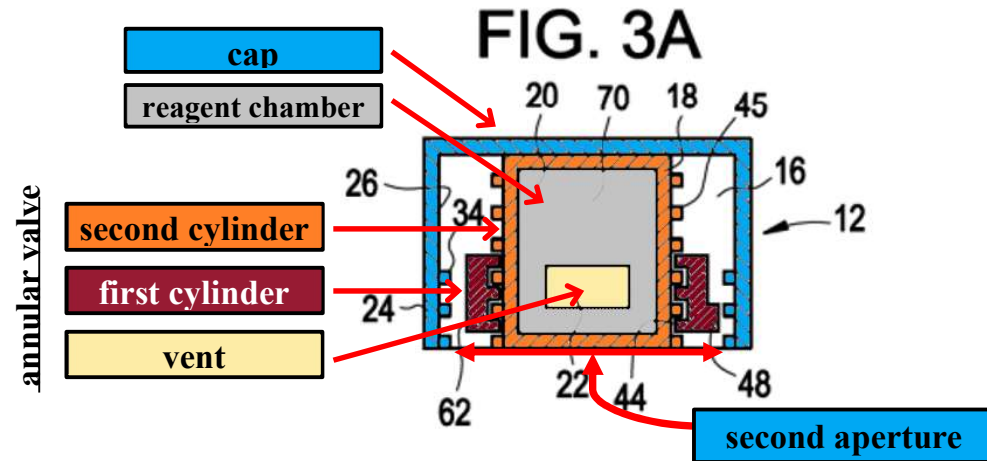


Ex.1004, 48:15-34, Fig. 44 (annotated).

Thus, Plante and Cho each disclose a cap. Ex.1002, ¶¶ 84-85.

7. Limitation 1[b][i]: “a second aperture”

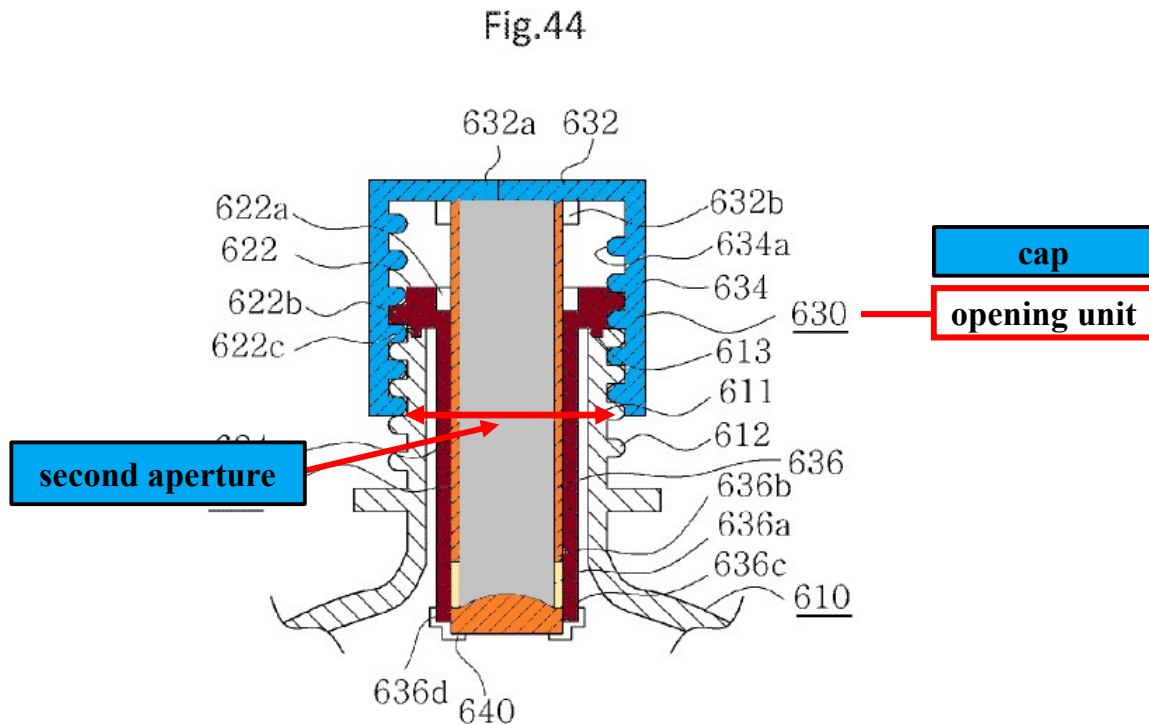
This limitation refers to the cap comprising an aperture, referred to as the second aperture. In the '632 patent, the cap includes an aperture, as shown below in annotated Figure 3A. Although not referred to in the specification as an aperture, this is an aperture defined by the cap. Ex.1002, ¶ 86.



Plante's cap includes a second aperture that receives a threaded portion of the receiving vessel 1. Ex.1003, [0035], Fig. 1.

Cho's cap (opening unit 630) also has an aperture that receives a portion of the container bottle. Ex.1004, 48:15-34, Figs. 43-45B. For example, in Figs. 43-45B Cho's cap (upper cap 634) has an aperture and internal threads 634a that engage

the external threads of the container, as shown below. Ex.1004, 2:7-10, 48:16—
49:10, Figs 43-45B.

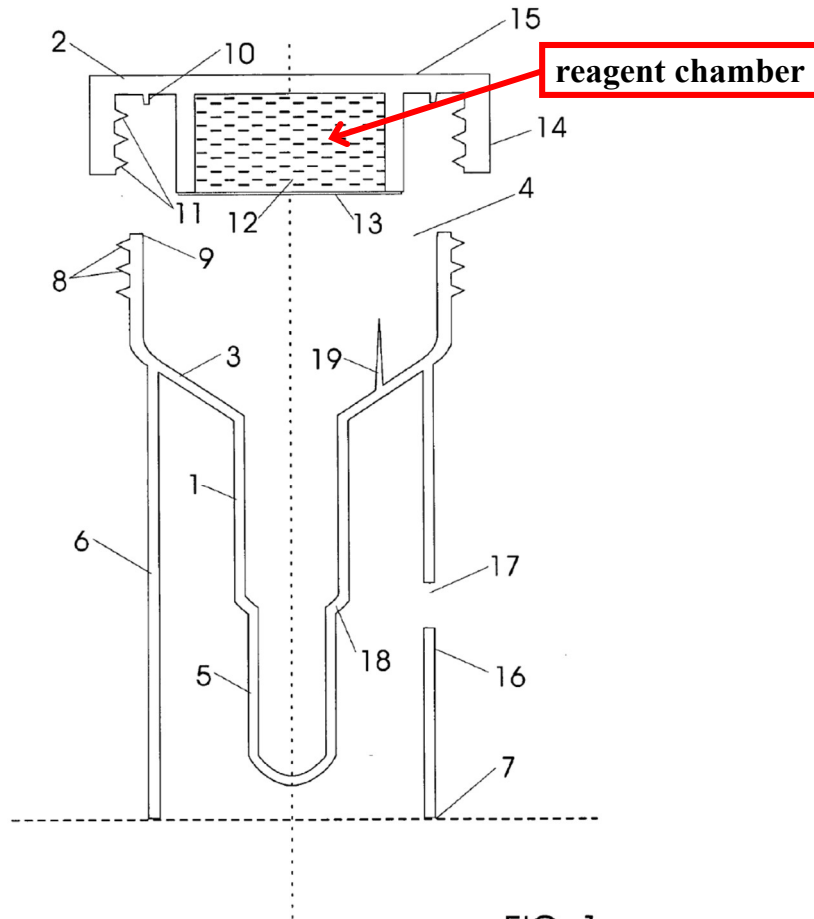


Id., Fig. 44 (annotated).

Thus, Plante and Cho each disclose this limitation. Ex.1002, ¶ 86–87.

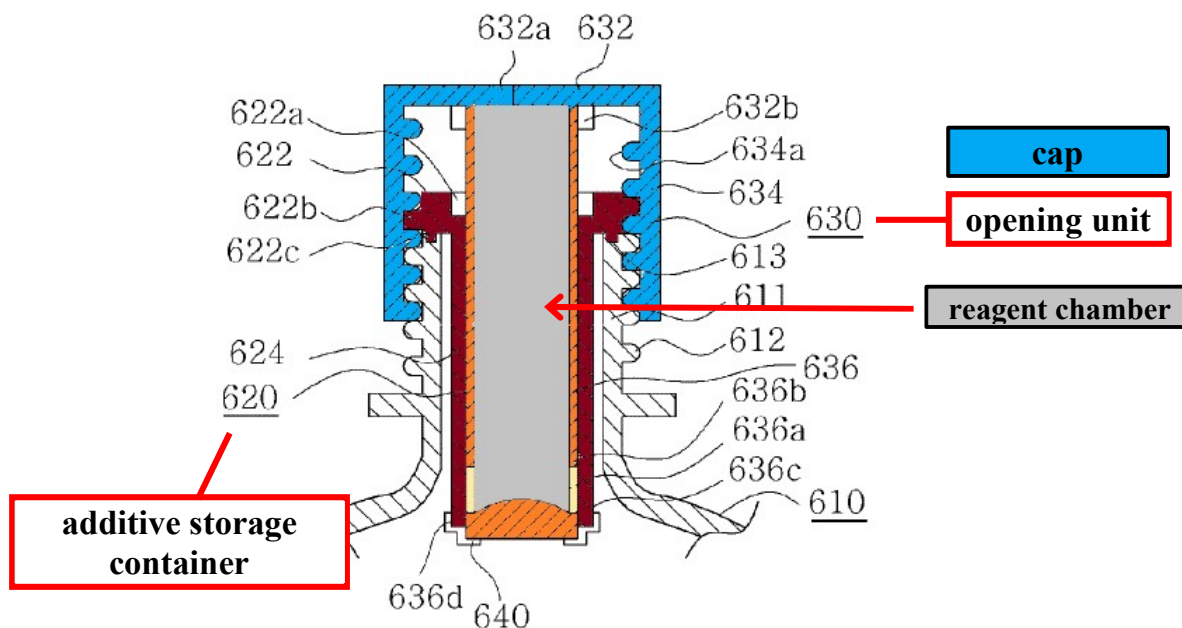
8. Limitation 1[b][ii]: “a reagent chamber storing a reagent therein”

Plante and Cho each disclose a chamber in a cap for storing a reagent. Ex.1002, ¶¶ 88–91. Plante’s cap includes a reagent chamber (reservoir 12) which stores a “preserving fluid,” as shown in annotated Fig. 1 below. Ex.1003, [0035], [0041].



Cho also includes a chamber in the cap for storing an additive until the additive is mixed with the contents of the container. *See, e.g.*, Ex.1004, 1:3-12, 1:28-2:3, 48:16-24, 48:27-31, 49:5-13, 50:5-12, Figs. 43-45B. Cho's chamber, as identified in annotated Figure 44 below, is defined by an inner and outer cylinder and can be used for mixing materials, including medicines and chemicals. Ex.1004, 1:8-24, 55:13-25; Ex.1002, ¶ 90. *Id.*

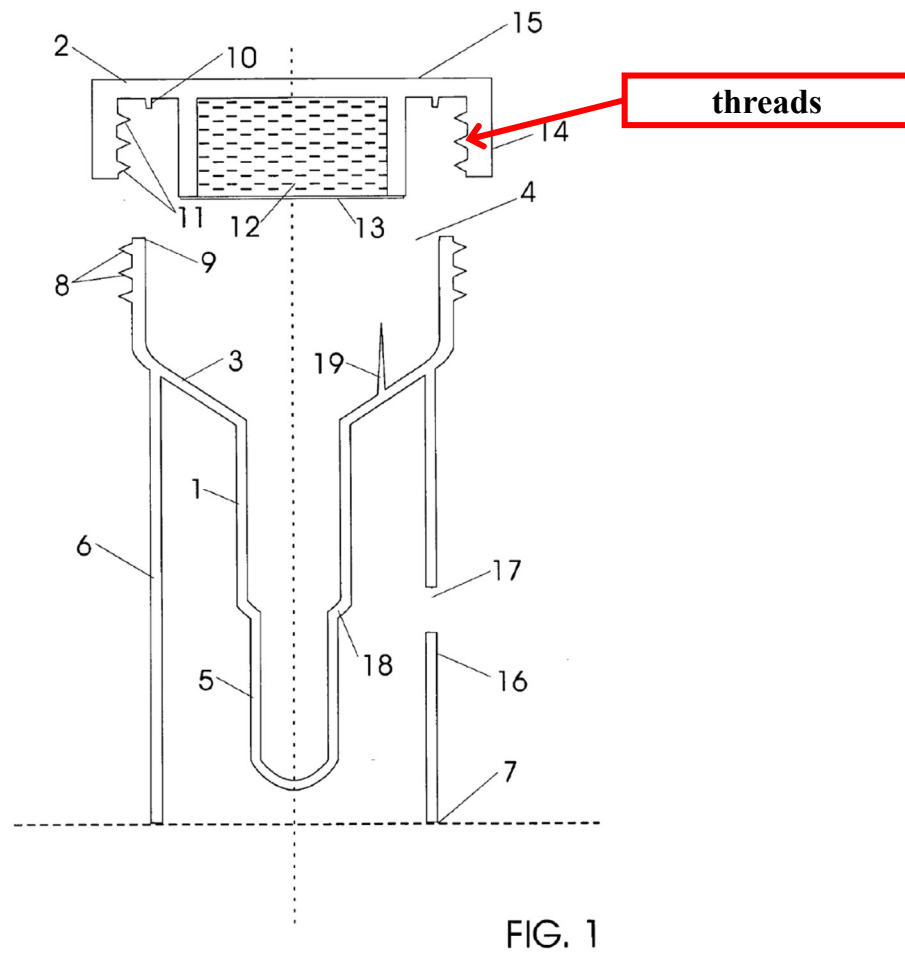
Fig.44



9. **Limitation 1[c]: “a second connection member complementary to the first connection member”**

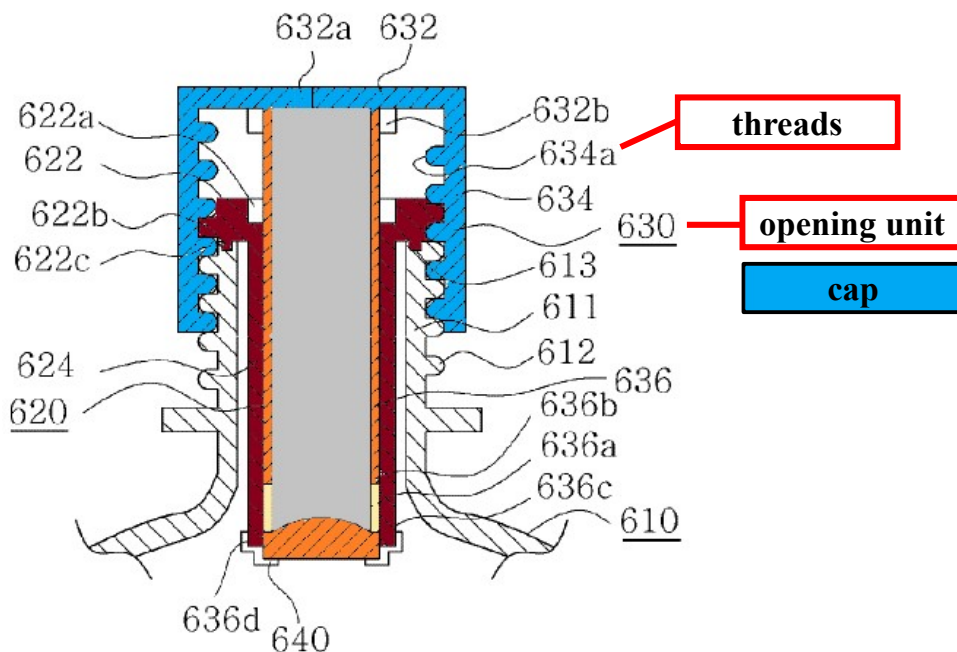
Plante and Cho each disclose this limitation. Ex.1002, ¶¶ 92–96. As explained above, the term “connection member,” as used in the ’632 patent, encompasses threads. *Supra* §VII.C.4; Ex.1001, 10:50-64.

Plante discloses a second connection member (thread set 11) on the cap and a complementary first connection member (thread set 8) on the receiving vessel, as shown below in annotated Fig. 1. Ex.1003, [0035], [0038], Fig. 1.



Cho discloses an “internal thread 634a” on the inside of the cap 630 which engages “the external thread 612” of the bottle container. Ex.1004, 49:5-10, Figs. 43-45B.

Fig.44



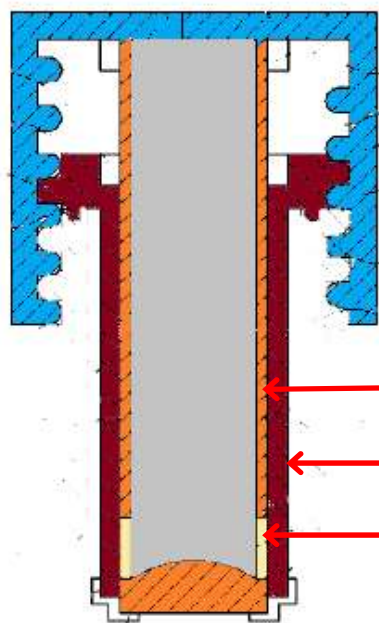
Id., Fig. 44 (annotated).

10. Limitation 1[d]: “a movable annular valve in the second aperture, the movable annular valve comprising”

As described above, the district court construed “annular valve” as a “ring shaped valve” in the related ’646 patent. Ex.1007, 66. Cho’s valve is a movable annular valve under this construction or any other reasonable construction.

Cho’s annular valve is ring shaped with various cylindrical parts. It corresponds identically to the embodiment of the ’632 patent, as illustrated in the comparison below of the Cho Fig. 44 and the ’632 patent Fig. 3A. The ring-shaped cylinders work together to function as a valve that holds and releases the reagent.

Cho, Fig. 44



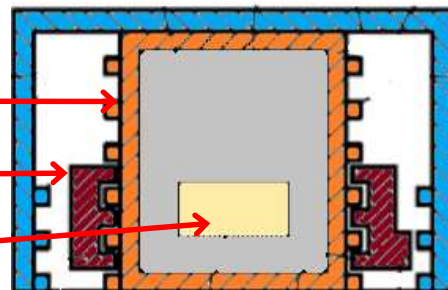
'632 Patent, Fig. 3A

Annular Valve

second cylinder

first cylinder

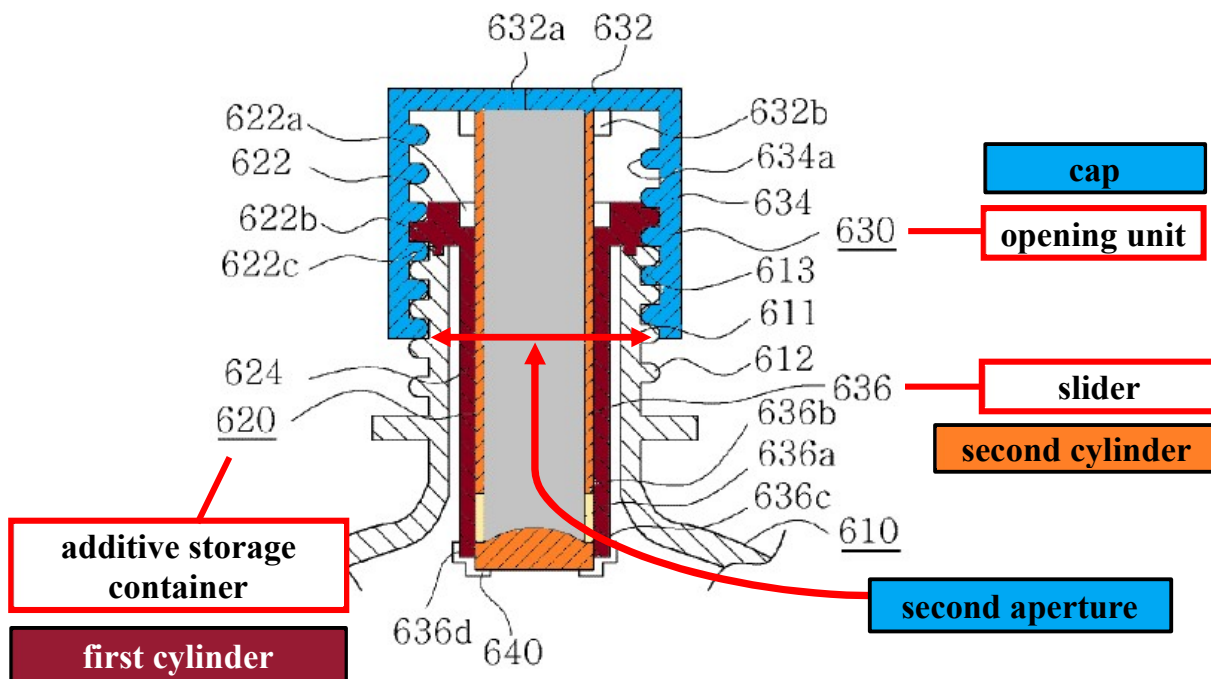
fluid vent



Ex.1004, Fig. 44; Ex.1001, Fig. 3A (annotated); Ex.1002, ¶¶ 97–98.

Limitation 1[d] also recites that the valve is “in the second aperture.” Cho’s valve is in the second aperture, which is the aperture of the cap. Ex.1002, ¶¶ 99–100. Cho’s valve is positioned within the cap and extends within the second aperture in the cap, as shown in annotated Fig. 44 below. Ex.1004, 49:5-13, 50:4-15, Figs. 44-45B. The outer cylinder (additive storage container 620) includes external threads 622b that engage with the internal threads 634a of the cap (opening unit 630). *Id.*, 49:8-10. Cho’s annotated Fig. 44 below illustrates how the inner cylinder (slider 636) and outer cylinder (additive storage container 620) of Cho’s annular valve are in the aperture of the cap (opening unit 630):

Fig.44



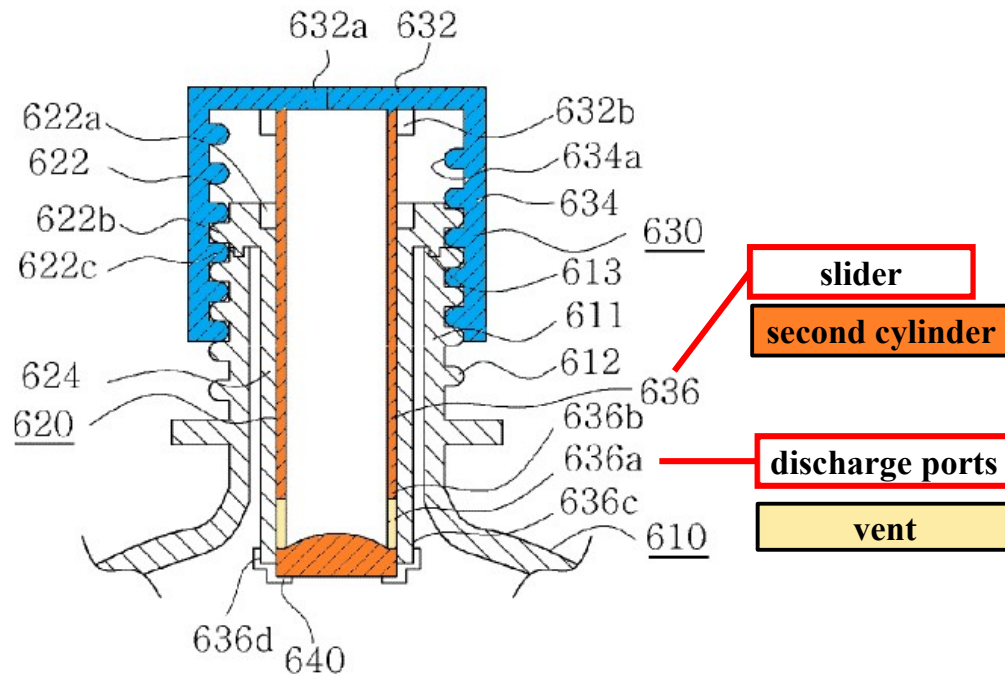
Ex.1004, Fig. 44 (annotated); Ex.1002, ¶¶ 99–100.

Cho’s annular valve is in the cap and extends into the sample collection vessel when the cap is screwed on, thus extending into and through the second aperture in the cap. Thus, Cho discloses this limitation. Ex.1002, ¶¶ 97–100.

11. Limitation 1[d][i]: “a vent”

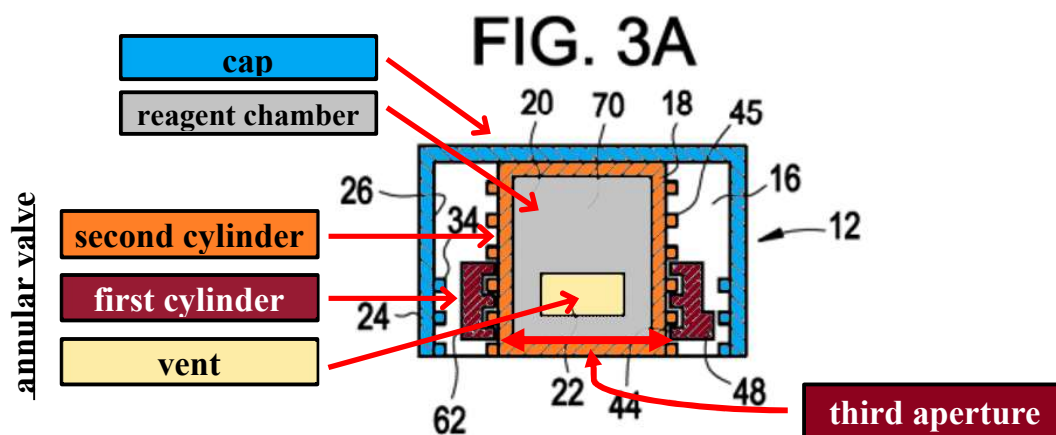
Cho discloses this limitation. Ex.1002, ¶¶ 101–102. Specifically, Cho’s second cylinder (slider 636) includes a vent (discharge ports 636a), as shown below in annotated Fig. 44. Ex.1004, 49:14-21, 50:10-12, Figs. 43-45B.

Fig.44



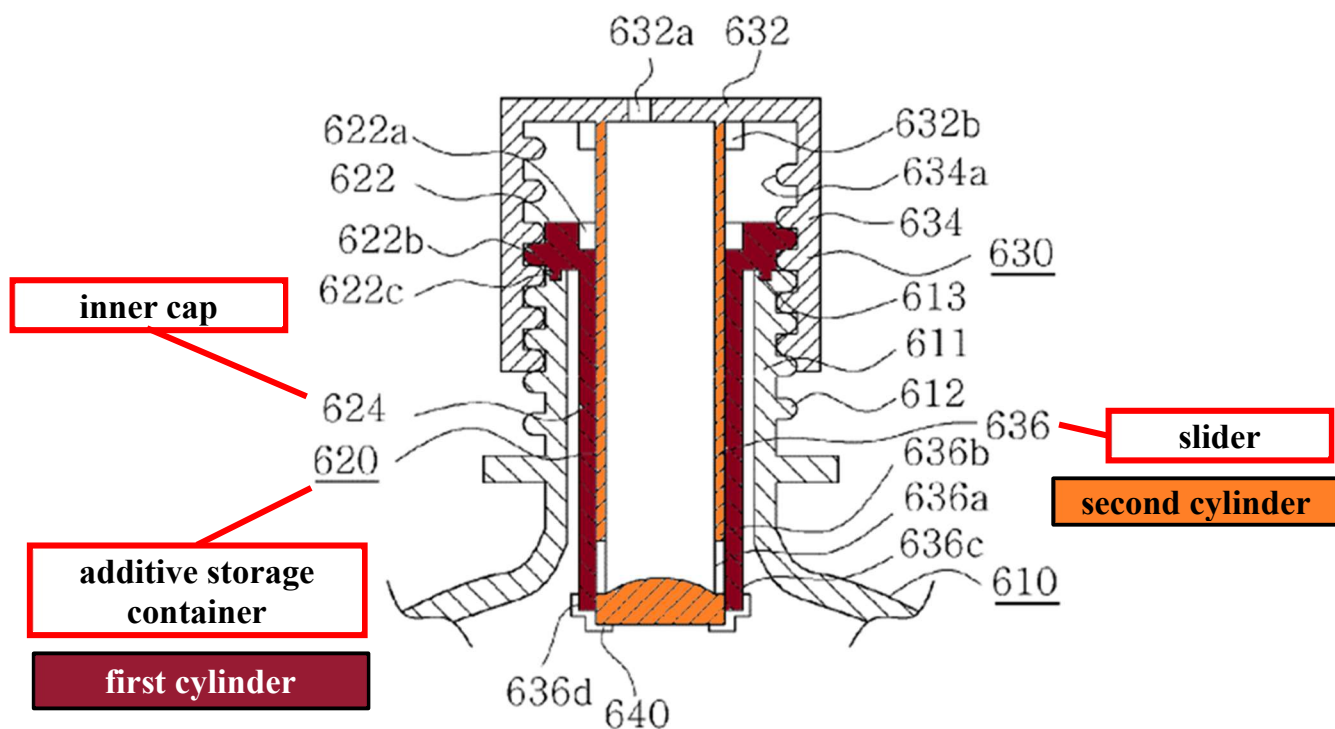
12. Limitation 1 [d][ii]: “a first cylinder comprising a third aperture”

The '632 patent describes an annular valve having a first cylinder defining a third aperture, as shown below in annotated Fig. 3A. Ex.1002, ¶ 103. The annular blocking member 62 is the first cylinder and it defines a third aperture. *Id.*



Similarly, Cho includes this limitation. Ex.1002, ¶¶ 103–108. In Cho’s annular valve, the first cylinder (additive storage container 620) includes a cylindrical portion called the “inner cap 624,” which “extends downward in an axial direction from the inner circumferential edge of the end plate 622.” Ex.1004, 48:18-20, 48:27-31, 49:10-13, 50:4-12, Figs. 43-45B.

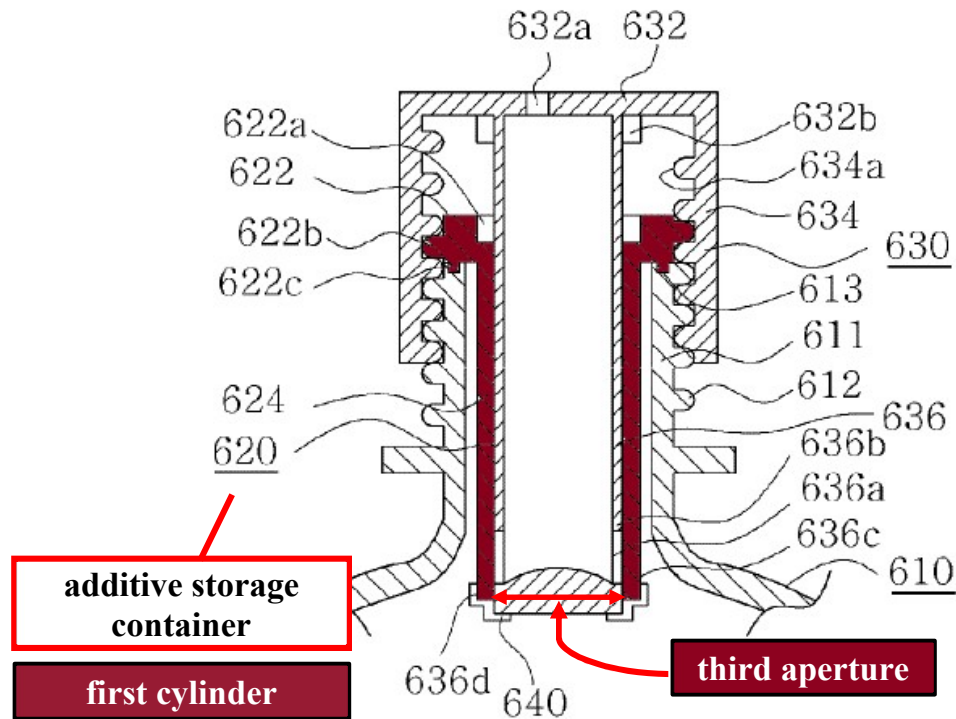
Fig.44



Id., Fig. 44 (annotated).

Cho’s annular valve includes a third aperture defined by the first cylinder 620, as shown below in Figure 44. Ex.1004, 49:5-13, Figs. 43-45B.

Fig.44



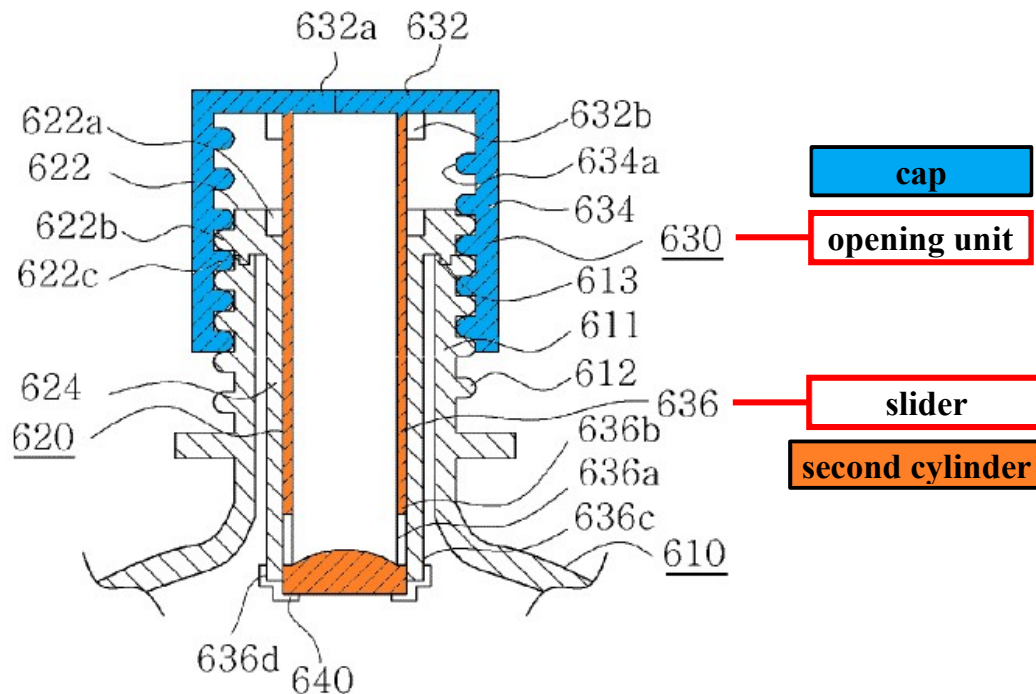
Id., Fig. 44 (annotated).

13. **Limitation 1[d][iii]: “a second cylinder comprising the vent, the second cylinder positioned in the third aperture”**

The '632 patent includes an inner wall 18 that forms a second cylinder positioned within the cap and the first cylinder 62. Ex.1002, ¶ 109. The second cylinder includes a vent 22 and is positioned in the third aperture of the first cylinder 62. *Id.*

Cho discloses this limitation. Cho's slider 636 is the second cylinder, as shown below. Ex.1004, 49:5-13, 50:4-15, Figs. 43-45B; Ex.1002, ¶¶ 110-113.

Fig.44

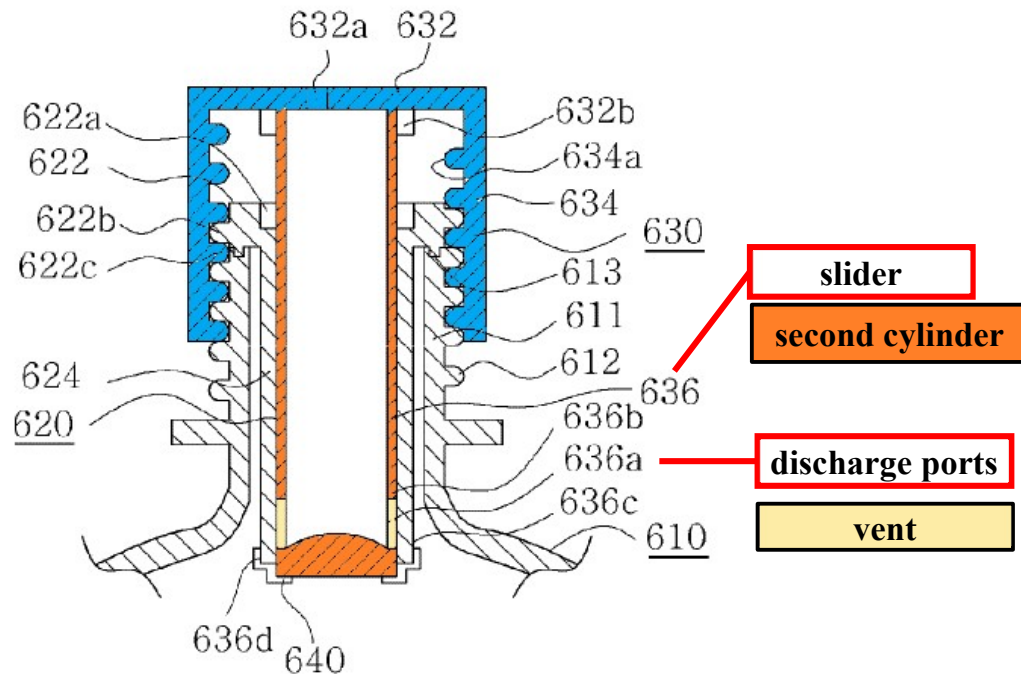


Id., Fig. 44 (annotated); *see also id.*, 49:5-13.

Cho's second cylinder (slider 636) is positioned in the third aperture, which is defined by the first cylinder (620). Ex.1002, ¶¶ 111-113.

Cho's second cylinder (636) also includes a vent (discharge ports 636a), which allows passage of the additive, as shown below in annotated Figure 44. Ex.1004, 49:14-21, 50:10-12, Figs. 43-45B; Ex.1002, ¶104. Thus, Cho discloses this limitation. Ex.1002, ¶¶ 112-113.

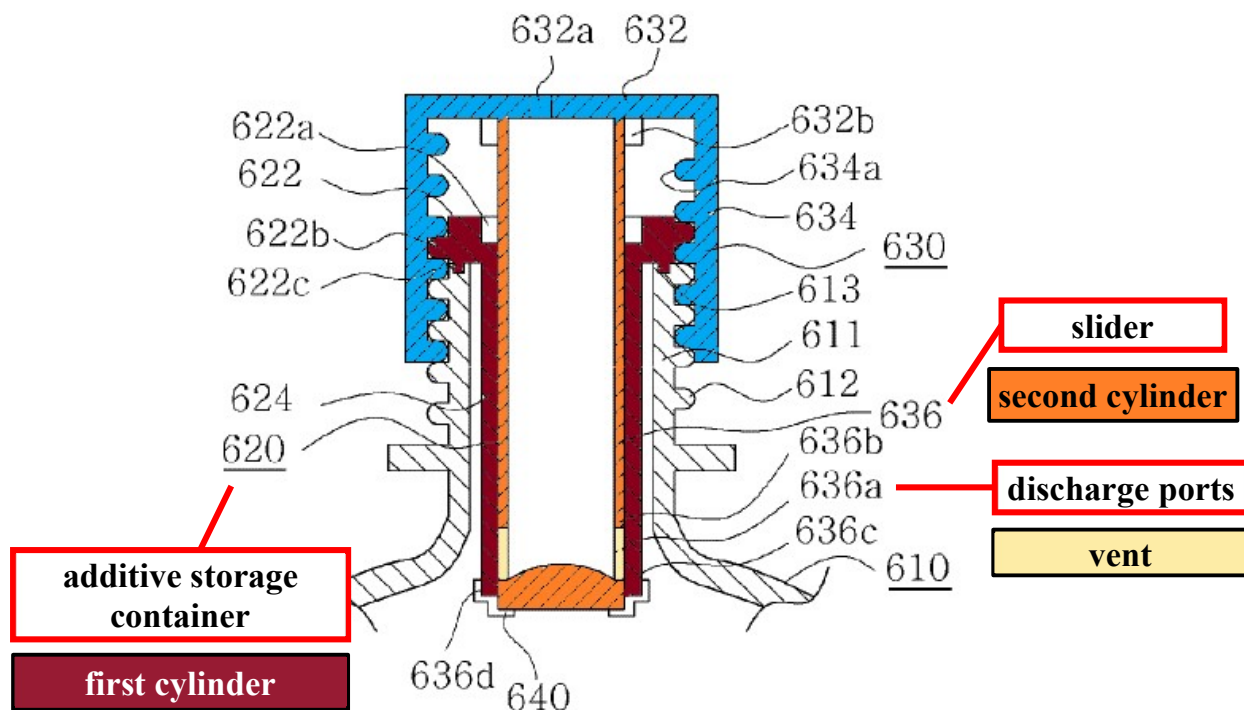
Fig.44



14. Limitation 1[d][iv]: “a closed configuration, and”

Fig. 44 in Cho shows the movable annular valve in a closed configuration, with the interior sidewalls of the first cylinder (additive storage container 620) obstructing the vent (discharge ports 636a) on the second cylinder (slider 636). Ex.1004, 49:10-13; Ex.1002, ¶¶ 114-116. The additive is sealed in the additive storage space in a closed configuration until it is released into the bottle. Ex.1004, 1:28-2:3.

Fig.44

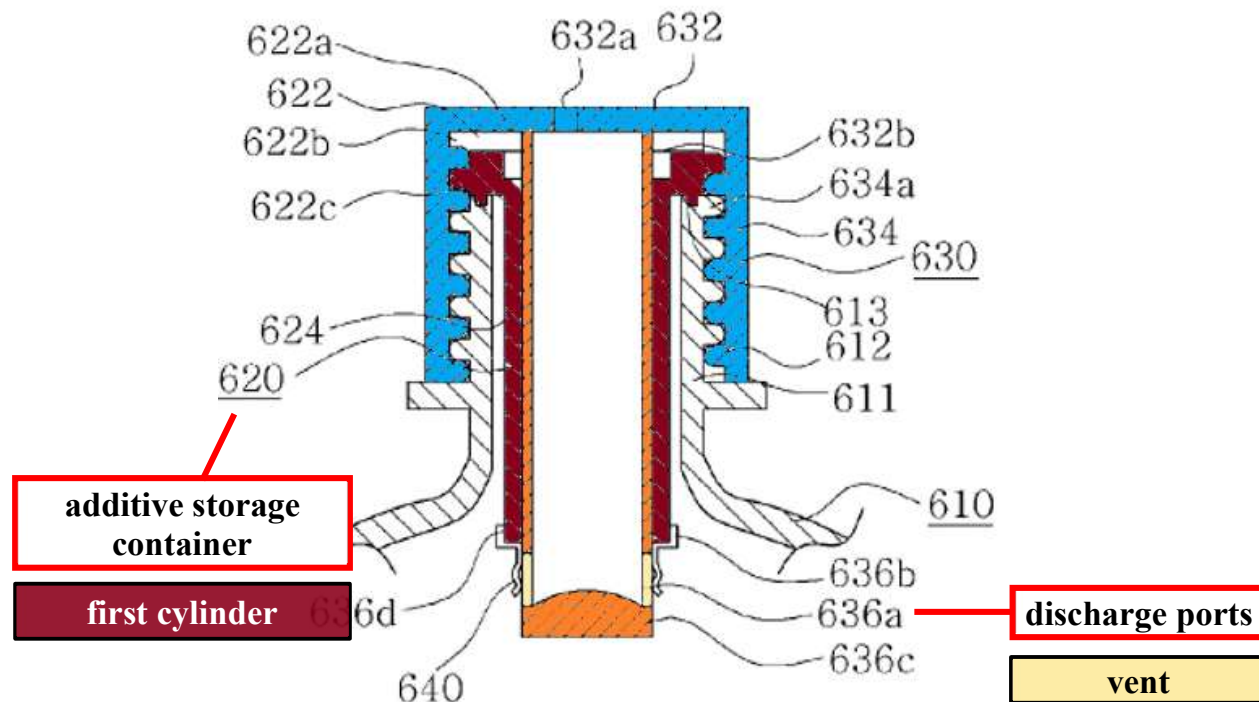


Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21.

15. Limitation 1[d][v]: “an open configuration, wherein”

When Cho's cap is tightened on the bottle, the second cylinder (slider 636) "moves downward" through the first cylinder 620 "so that the additive is discharged from the additive storage container 620 into the bottle body through the discharge ports 636a." Ex.1004, 50:8-12. Cho's Figure 45A shows the movable annular valve in an open configuration, where the interior sidewall of the first cylinder (additive storage container 620) no longer obstructs the fluid vent (discharge ports 636a).

Fig.45A



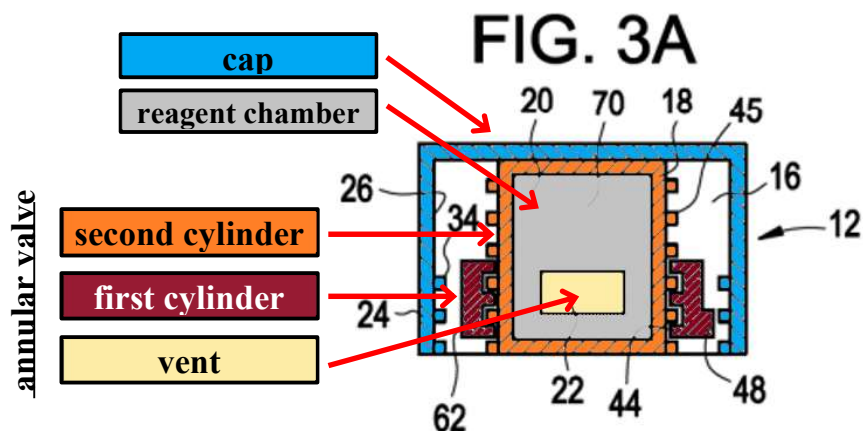
Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12; Ex.1002, ¶¶ 117-118.

16. **Limitation 1[d][vi]: “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 '632 patent discloses an annular valve closed configuration in which the first and second cylinders create a fluid tight seal with the cap by arranging the second cylinder as an inner wall of the cap. Ex.1002, ¶ 119. The specification explains that “[w]hen the aperture 22 is closed such that the annular blocking member 62 is covering the aperture 22, fluid or material . . . [may] be contained in the interior space 20 may not be allowed to travel outside of the interior space 20, as shown in FIG. 3A” below. Ex.1001, 14:20-32. The wall of the second (inner)

cylinder acts as an inner wall of the cap to seal the reagent within the cap. In this manner, 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.

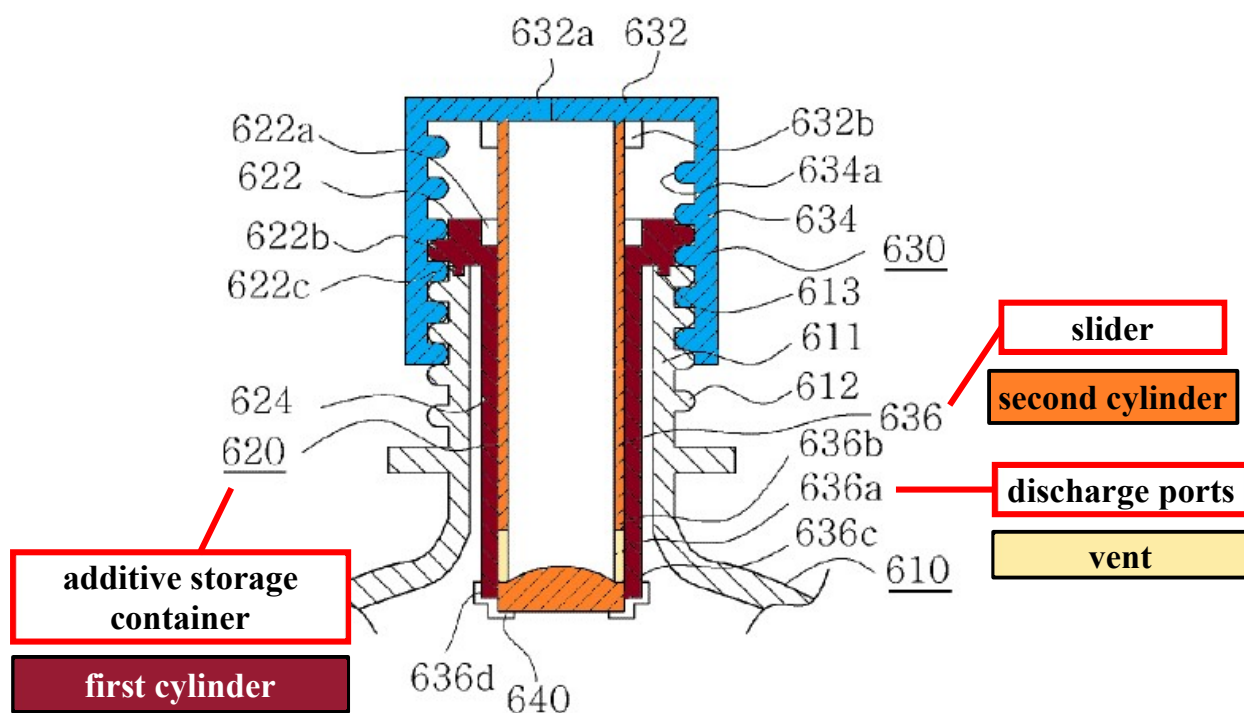
Ex.1002, ¶¶ 119-120.



Cho's annular valve has first and second cylinders that create a fluid tight seal with the cap in the same way as the '632 patent embodiment. Cho's annular valve includes a second cylinder (slider 636) that acts as an inner wall of the cap to seal the reagent within the cap when the first cylinder (additive storage container 620) blocks the vent 636a. Ex.1004, 49:10-13; Ex.1002, ¶ 120. Cho's additive is sealed in the additive storage space as the first and second cylinders create a fluid-tight seal with the cap until the additive is released into the bottle. Ex.1004, 1:28-2:3. Cho discloses that the second cylinder (slider 636) includes "[r]ing-type seal protrusions 636b and 636c," which are "in *close contact* with the inner circumferential surface of the inner cap 624, *thus preventing an additive from leaking through the discharge ports 636a.*" Ex.1004, 49:10-21 (emphasis added). Further, Cho states

that the bottle “maintains a good seal on the interior space of an additive storage container . . .” *Id.*, 1:28-2:3; *id.*, 55:22-25. Fig. 44 below shows Cho’s movable annular valve in a closed position, with the first cylinder (620) obstructing the vent (636a) on the second cylinder (636) to maintain a fluid-tight seal with the cap and retain the additive in the chamber. When combined with Plante, the additive would be the reagent.

Fig.44



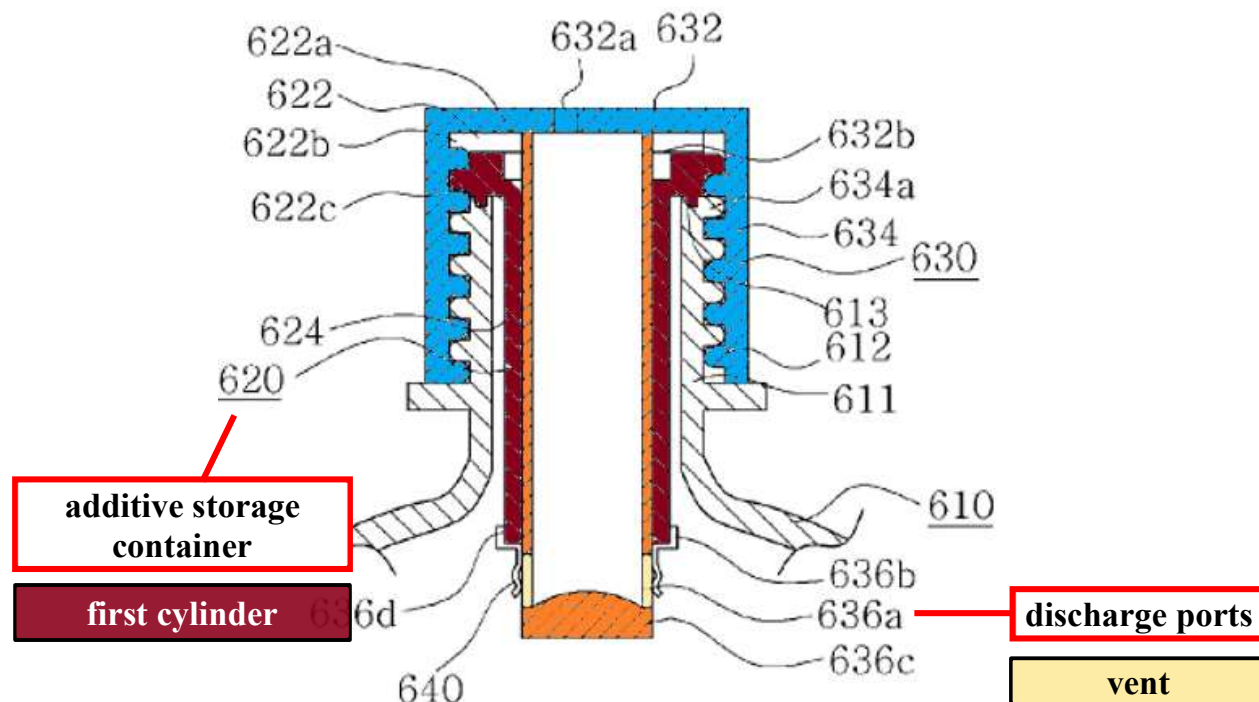
Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21. Thus, Cho discloses this limitation.

Ex.1002, ¶¶ 119-120.

17. **Limitation 1[d][vii]: “the first cylinder and second cylinder are relatively moveable to thereby change the annular valve from the closed configuration to the open configuration, and”**

Cho discloses this limitation. Ex.1002, ¶¶ 121-122. When Cho's cap is tightened on the bottle, the second cylinder (slider 636) "moves downward" through the first cylinder 620 "so that the additive is discharged . . . through the discharge ports 636a." Ex.1004, 50:8-12. As the cap is screwed onto the threads of the bottle, the second cylinder 636 moves relative to the first cylinder 620 from the closed configuration to the open configuration, as shown in Cho's Figs. 44 and 45A.

Fig.45A



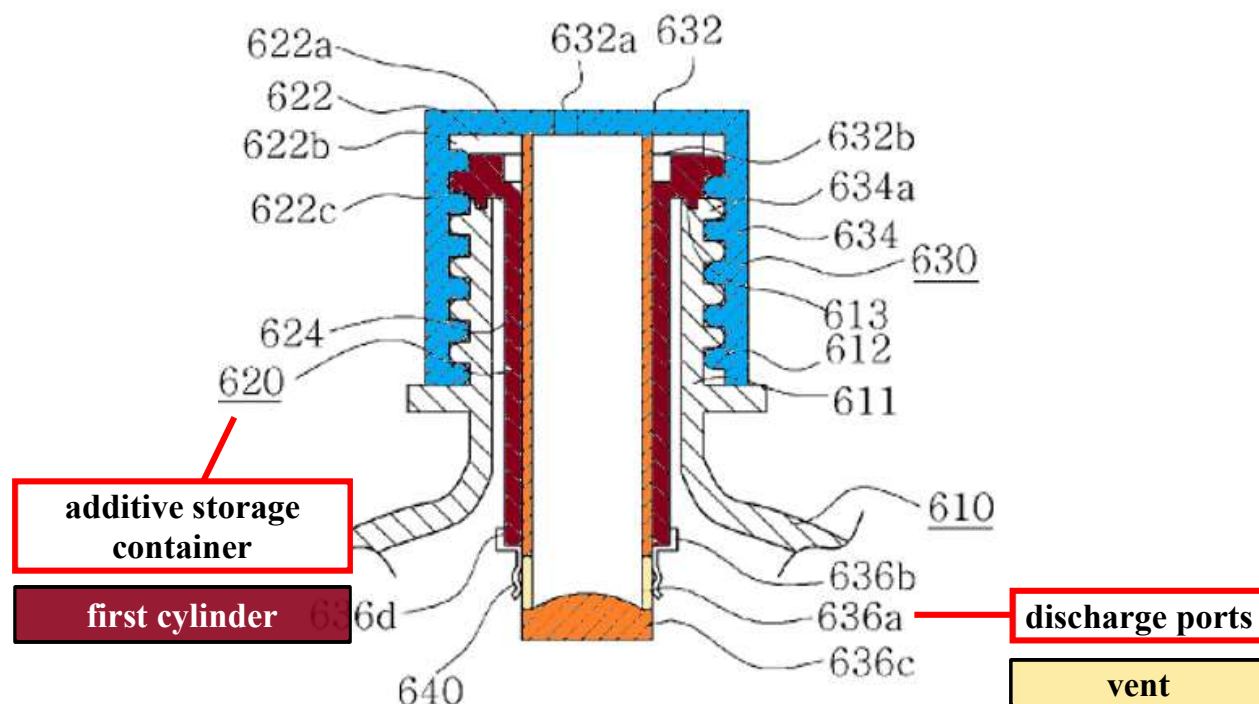
Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12; Ex.1002, ¶ 121-122.

18. Limitation 1[d][viii]: “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.”

Cho also discloses this limitation. Ex.1002, ¶¶ 123-124. When Cho’s cap is tightened on the bottle, the second cylinder (slider 636) “moves downward” through the first cylinder 620 “so that the additive is discharged from the additive storage container 620 into the bottle body through the discharge ports 636a.” Ex.1004, 50:8-12. Cho’s Fig. 45A below shows the movable annular valve in an open position, where the first cylinder (additive storage container 620) does not obstruct the vent (discharge ports 636a) of the second cylinder (slider 636) to allow flow of the additive from the storage chamber, through the vent, and into the bottle/vessel.

Fig.45A



Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12; Ex.1002, ¶ 123-124.

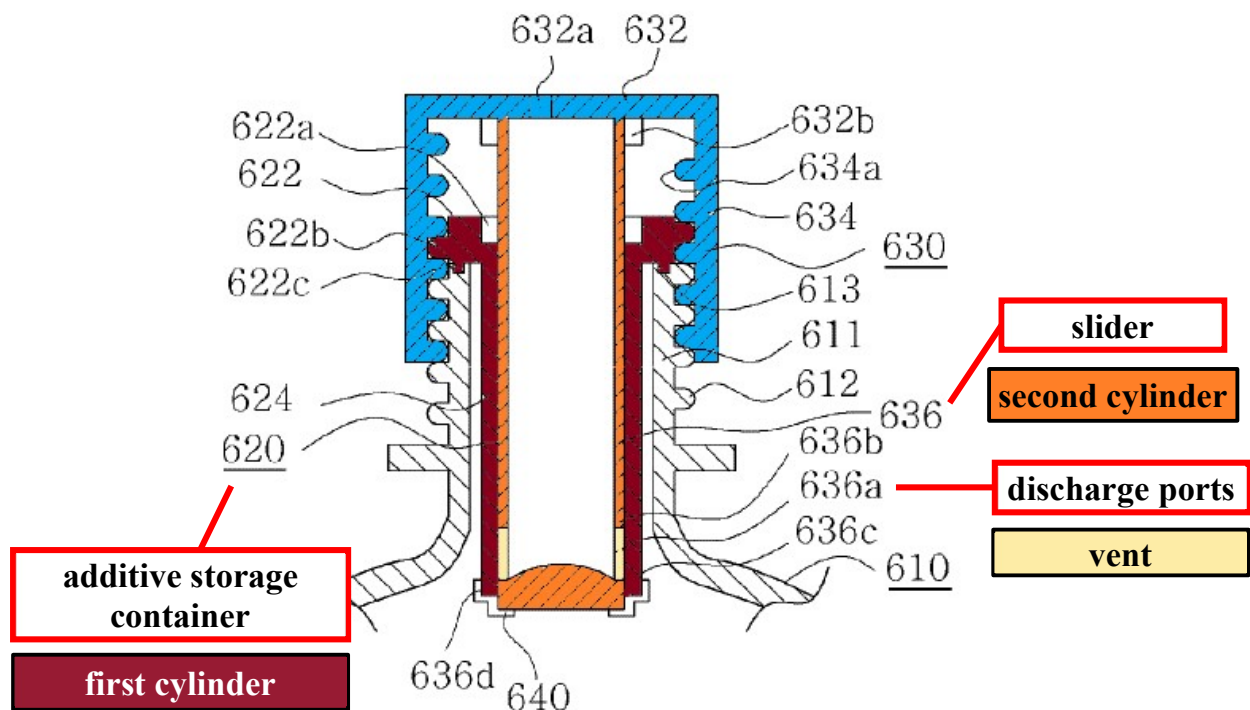
In sum, the combination of Plante and Cho discloses all limitations of claim 1.

D. Plante and Cho Render Obvious Claim 2

Claim 2 depends from claim 1 and recites “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.” Cho’s valve meets this limitation for the reasons provided above in Sections VII.C.11-18. Ex.1002, ¶¶ 125-127.

Cho’s second cylinder (slider 636) includes a sidewall with a vent (discharge ports 636a). Ex.1004, 49:10-15. In the closed configuration, the additive is sealed in the additive storage space as a sidewall of the first cylinder 620 obstructs the vent (discharge ports 636a) until the additive is released into the bottle. *Id.*, 1:28-2:3. Fig. 44 shows the movable annular valve in a closed position, with the sidewall of the first cylinder 620 obstructing the vent 636a:

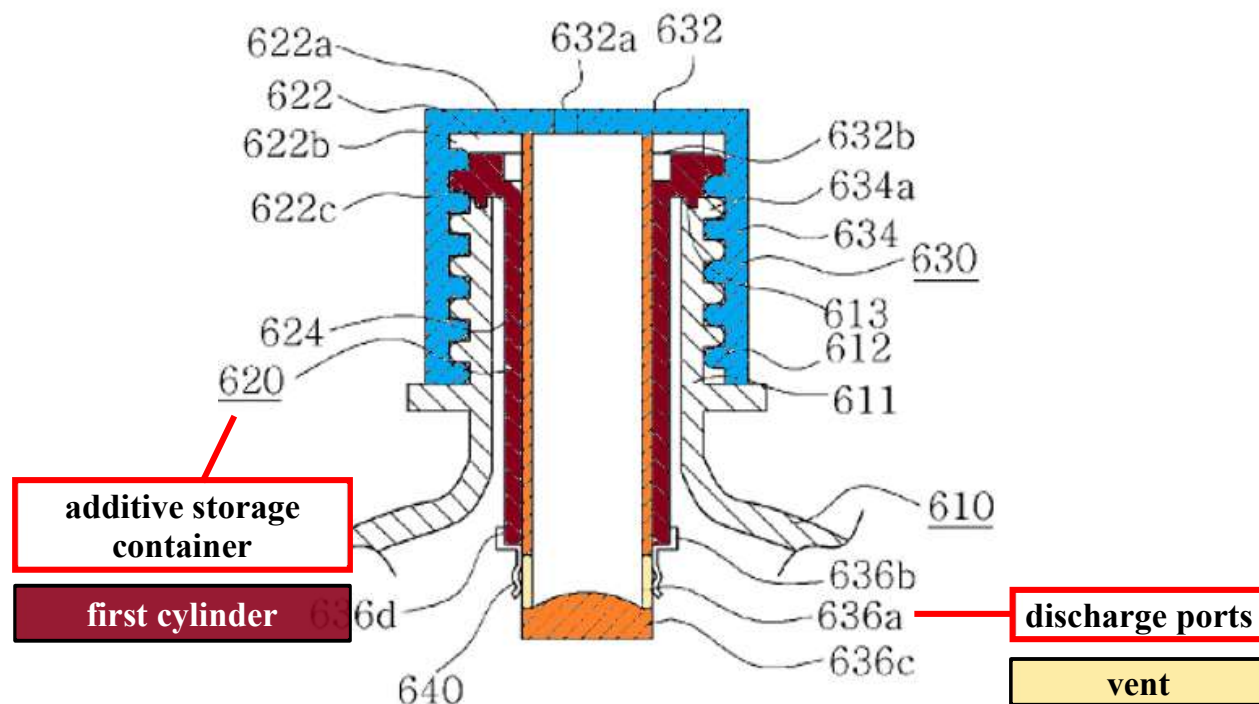
Fig.44



Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21; Ex.1002, ¶115.

In the open configuration, the sidewall of the first cylinder 620 does not obstruct the vent and “the additive is discharged from the additive storage container 620 into the bottle body through the discharge ports 636a,” as shown below.

Fig.45A



Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12; Ex.1002, ¶¶ 126-127.

E. Plante and Cho Render Obvious Claims 3 and 4

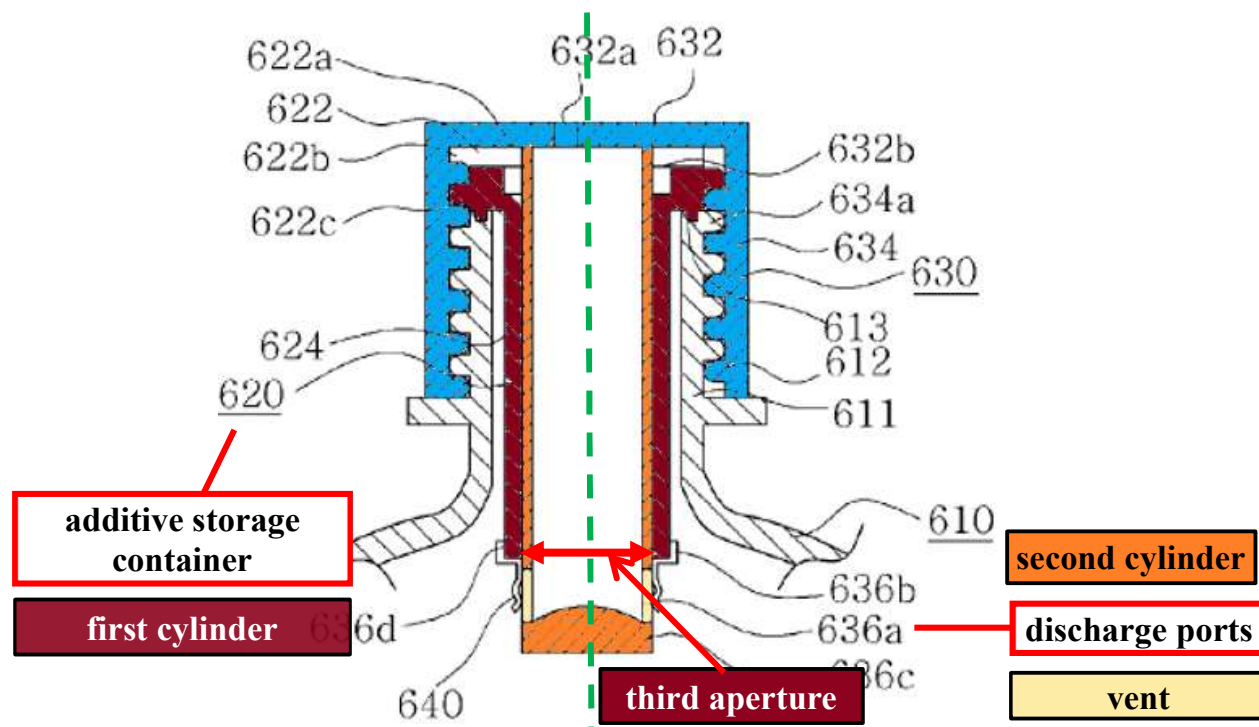
Claim 3 depends from claim 1 and recites “wherein the first and second cylinder's relative movement, from the annular valve's closed configuration to the open configuration, is translational along a longitudinal axis of the cap.”

Claim 4 depends from claim 1 and recites “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.”

Cho discloses these limitations of claims 3 and 4. Ex.1002, ¶¶ 128-130.

When Cho's cap is tightened on the bottle, the second cylinder (slider 636) "moves downward" through the first cylinder 620 in the third aperture "so that the additive is discharged from the additive storage container 620." Ex.1004, 50:8-12. As the cap is screwed onto the threads of the bottle, the second cylinder moves **translationally downward** along a longitudinal axis of the cap to move from the closed configuration to the open configuration. Ex.1002, ¶ 130. This movement from the closed configuration to the open configuration involves the second cylinder moving **in the third aperture** in the first cylinder. *Id.* Cho's Figs. 44 and 45A show the translational movement of the second cylinder in the third aperture.

Fig.45A

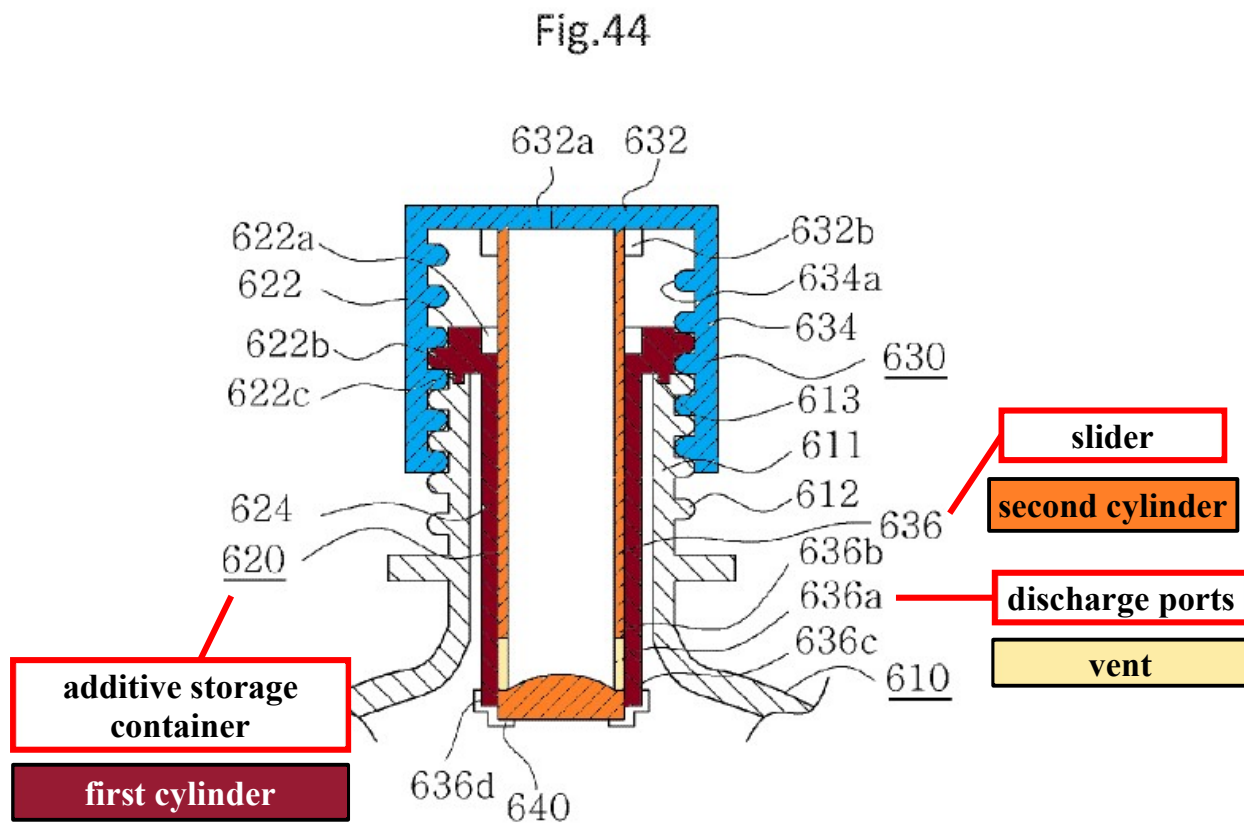


Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12; Ex.1002, ¶ 130.

F. Plante and Cho Render Obvious Claim 6

Claim 6 depends from claim 1 and recites “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.” Cho’s valve meets this limitation for the reasons provided above in Sections VII.C.14-18. Ex.1002, ¶¶ 131-132.

Cho’s second cylinder (slider 636) includes multiple vents (discharge ports 636a). Ex.1004, 49:10-15. In the closed configuration, the additive is sealed in the additive storage space as a sidewall of the first cylinder 620 obstructs the vents (discharge ports 636a), as shown below.

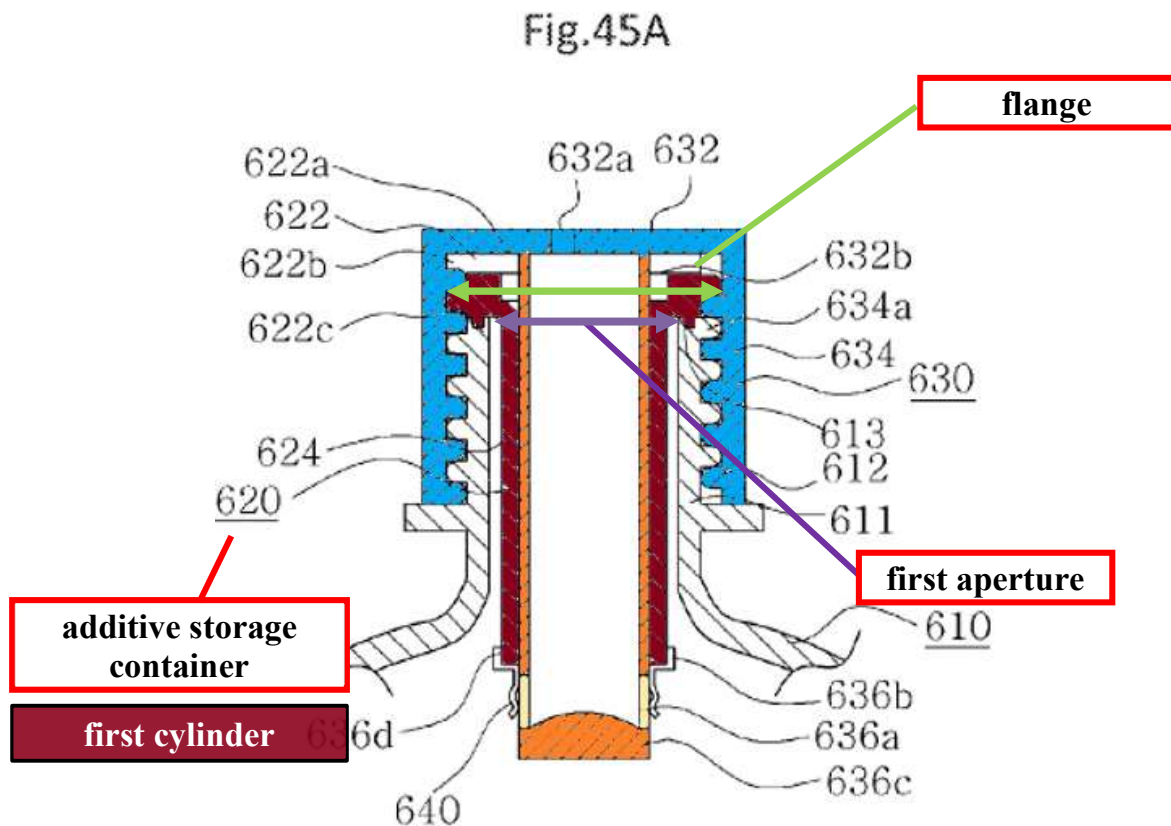


Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21; Ex.1002, ¶ 132.

G. Plante and Cho Render Obvious Claims 7 and 8

Claim 7 depends from claim 1 and recites “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.” Cho discloses this limitation. Ex.1002, ¶¶ 133-134.

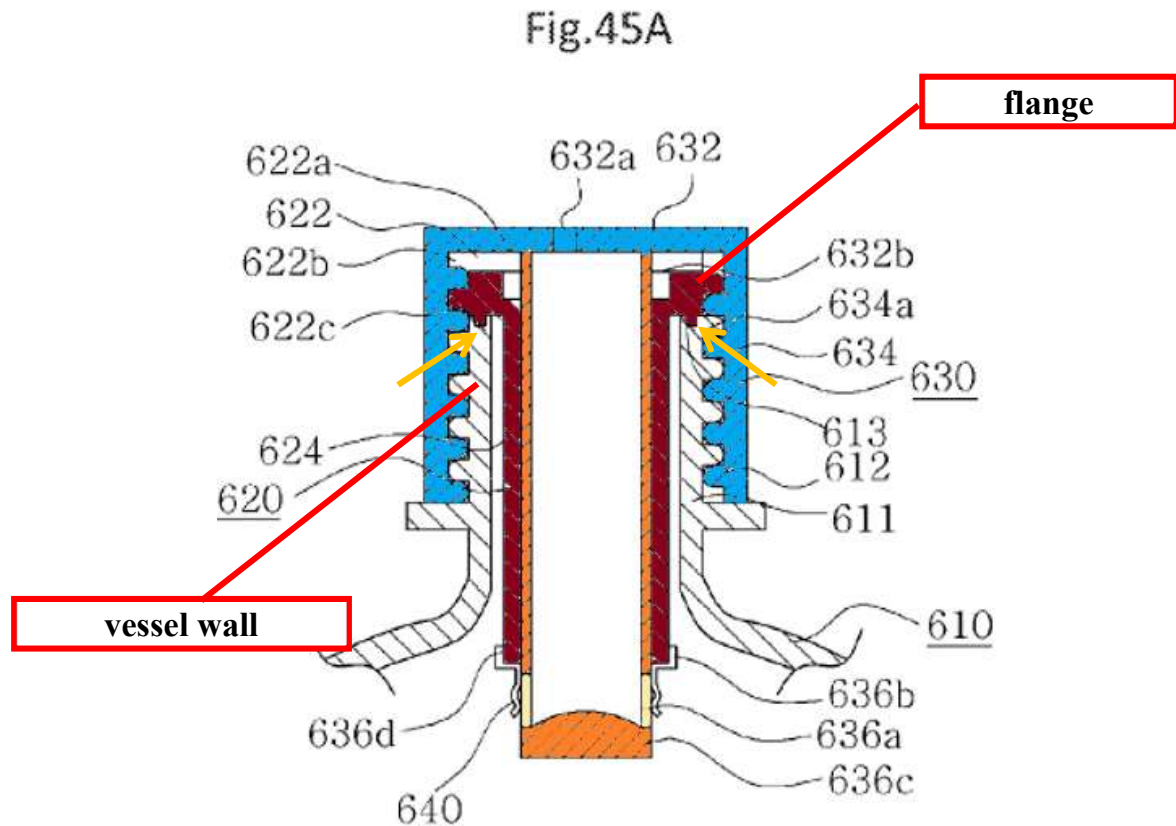
Cho’s first cylinder 620 includes a flange which has a width larger than a width of the first aperture in the sample collection vessel 610, as shown below in annotated Figure 45A. Ex.1004, Fig. 45A; Ex.1002, ¶ 134. The green line below illustrates the width of the flange, and the purple line indicates the width of the first aperture defined by the container. Thus, the flange on the first cylinder has a width that is larger than the width of the first aperture. *Id.*



Claim 8 depends from claim 7 and recites “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.” Cho also discloses this limitation. Ex.1002. ¶¶ 135-136.

As Cho’s cap is screwed onto the vessel 610, the flange of the first cylinder 620 interacts with the top of sample collection vessel 610 which causes the first cylinder to stop moving relative to the vessel 610 while the second cylinder 636 continues to move downward relative to the vessel 610. Ex.1004, 50:4-15. In this manner, the interaction between the flange and the wall of the collection vessel 610 (see yellow arrows below) causes the first and second cylinders to move relatively

and change the annular valve from the closed configuration to the open configuration, as shown in the annotated Fig. 45A below. Ex.1002. ¶ 136.



Ex.1004, Fig. 45A.

H. Plante and Cho Render Obvious Claim 9

Claim 9 depends from claim 1 and recites “further comprising a funnel attachable to the sample collection vessel.” Plante discloses this limitation and also renders it obvious.

In one embodiment, Plante’s sample collection vessel includes an integrated funnel, as shown below in annotated Figure 1.

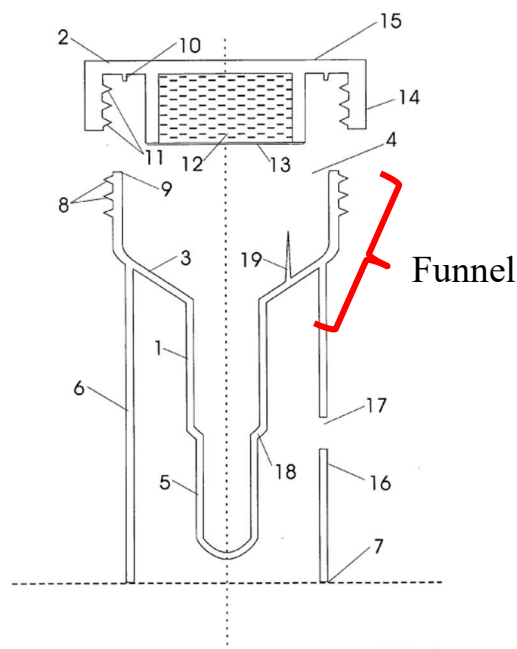


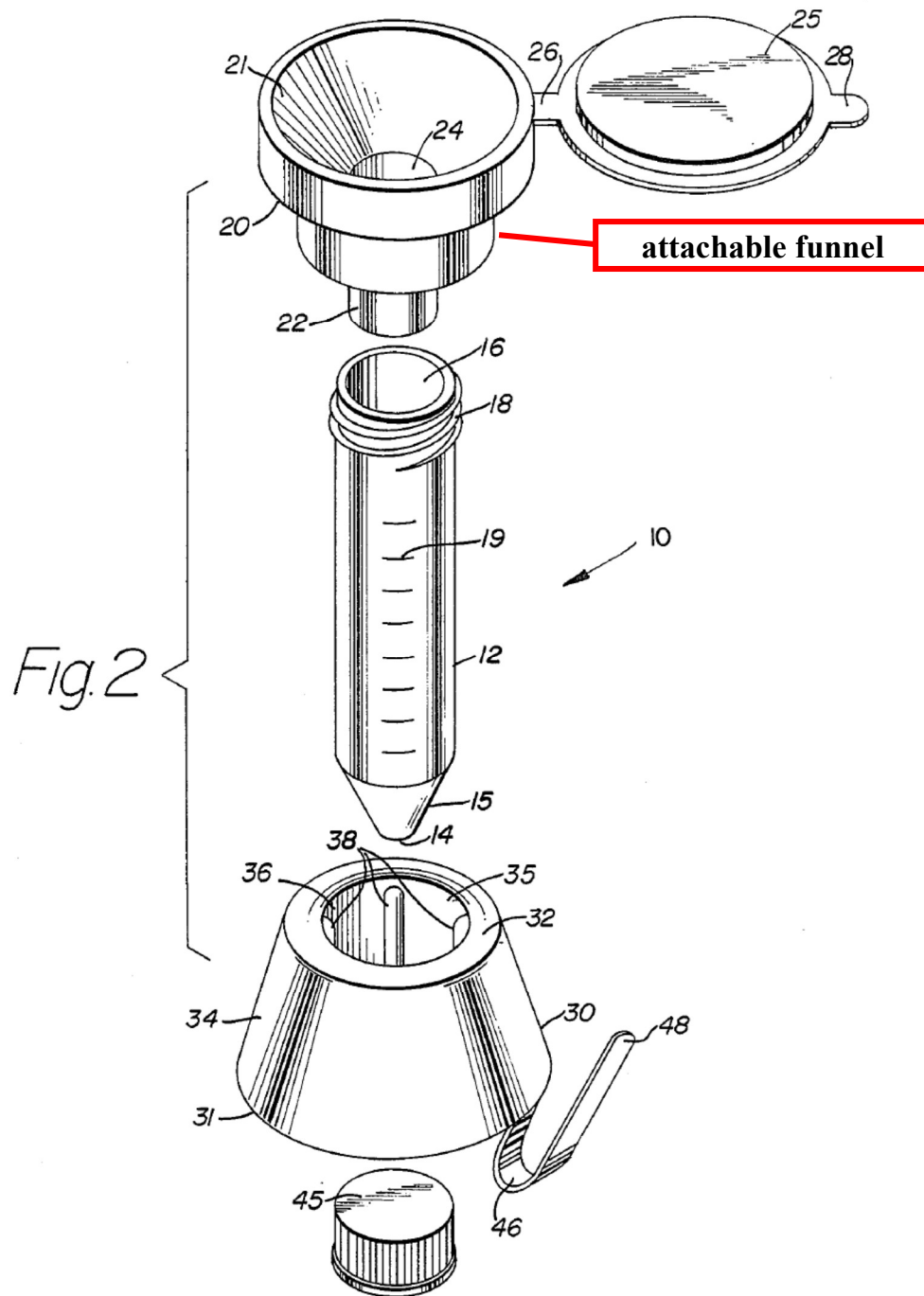
FIG. 1

Ex.1003, Fig. 1, [0019]; Ex.1002, ¶¶ 137-138.

To the extent “attachable” means the funnel must be a separate part that is attached to the vessel, Plante also teaches that using a separate attachable funnel was known in the art. Ex.1003, [0014] and [0015] (“a receiving vessel is coupled by way of a thread set to a funnel element After a sufficient quantity of saliva is received into the vessel, the funnel must be decoupled from the receiving vessel by twisting the funnel about an axis Because the funnel needs to be coupled to and decoupled from the receiving vessel . . .”). Although Plante describes the separate attachable funnel as having some disadvantages compared to the integrated funnel design, such a known design does not become patentable simply because it has been described as somewhat inferior. *In Re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994); *In Re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012). Whether to use a separate

attachable funnel or an integrated funnel would have been a mere design choice from a finite number of options. Ex.1002, ¶ 139.

Using a separate attachable funnel also would have been an obvious and common option in view of the knowledge of a POSA. Ex.1002, ¶¶ 139-142. Williams discloses a biological specimen collection device with a receptacle and a separate attachable funnel, as shown below in Figure 2. Ex.1009, Abstract, 6:9-15, Fig. 2. Williams explains that the funnel is “removably connected” to the receptacle for “ready removal of the funnel after the specimen has been collected.” *Id.*, 2:39-43, 4:11-22.



Ex.1009, Fig. 2.

A POSA would have been motivated to use a separate attachable and detachable funnel to facilitate collection of the sample from the user while allowing

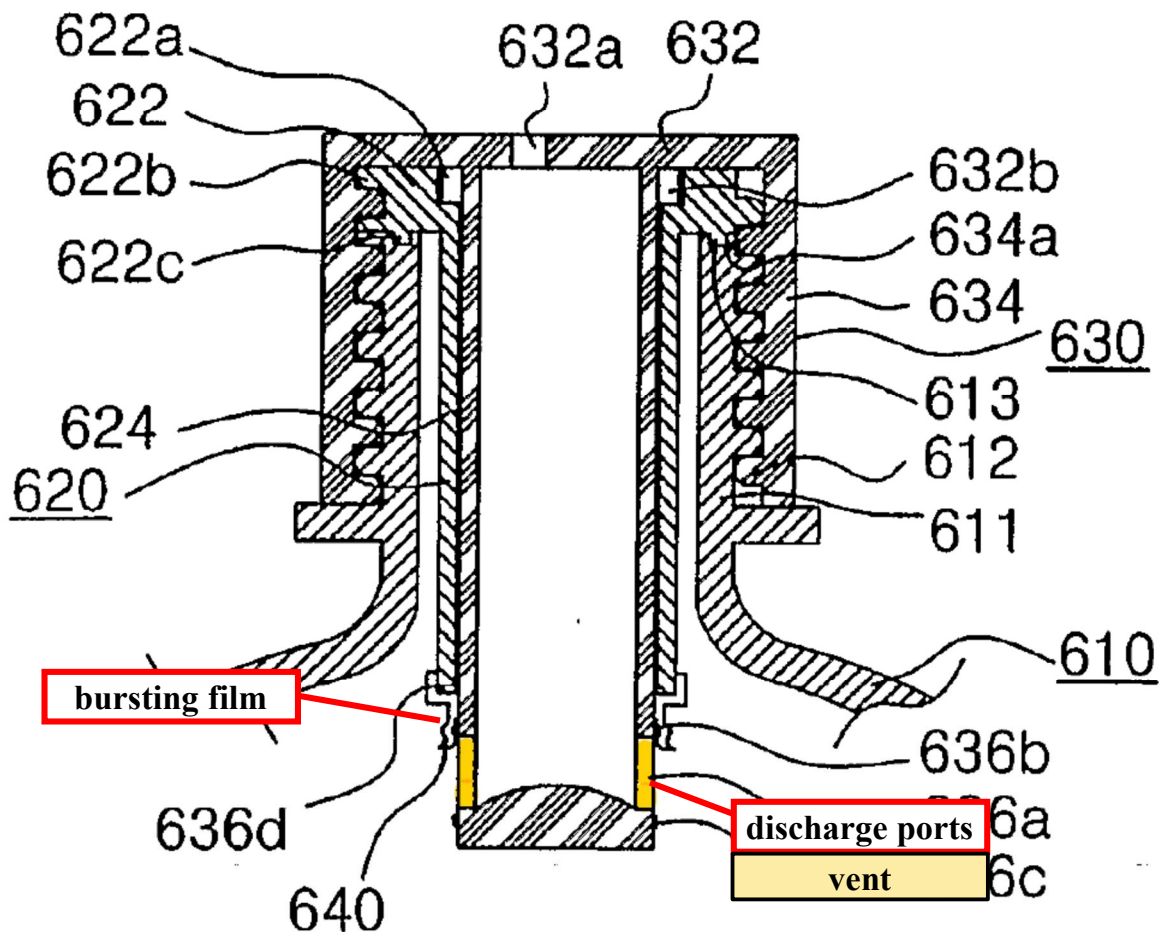
for a smaller cap and container that would require less manufacturing materials. Ex.1002, ¶¶ 141-143. A smaller opening of the vessel and a smaller cap would provide a better sealing interface compared to a much larger diameter integrated funnel to which a larger cap would be attached and sealed. *Id.* In addition, using a separate attachable funnel would also allow for lower profile packaging and a smaller container for shipping the sample to the lab for analysis. *Id.* A POSA would have also understood that a separate attachable funnel would allow for a smaller vessel that would better fit into existing vial racks. *Id.* Thus, claim 9 would have been obvious in view of the combination Plante and Cho. *Id.*, ¶¶ 137-143.

I. Plante and Cho Render Obvious Claims 10 and 11

Claim 10 depends from claim 1 and recites “wherein the vent is at least partially unobstructed in the annular valve's open configuration.” Cho discloses this limitation. Ex.1002, ¶¶ 144-149.

Cho’s cap is tightened to the open configuration “so that the additive is discharged from the additive storage container 620 into the bottle body through the discharge ports 636a.” Ex.1004, 50:8-12. Cho’s Fig. 45A shows the open configuration in which the first cylinder (additive storage container 620) does not obstruct the fluid vent (discharge ports 636a) which is at least partially unobstructed. Ex.1002, ¶ 145.

FIG. 45A



Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:15; Ex.1002, ¶ 145.

Claim 11 depends from claim 1 and recites “wherein the vent is fully unobstructed in the annular valve's open configuration.” Cho’s vent (discharge ports 636a) is fully unobstructed in the valve’s open configuration. Ex.1002, ¶ 146. As shown in Figure 45A above, the second cylinder and vent 636a burst through the

film 640 and the vent is not obstructed by any portion of the first cylinder 620. Ex.1004, 50:4-12. In Figure 45A, the bursting film 640 appears adjacent to the vent 636a, but a POSA would have understood that the bursting film 640, once burst by the second cylinder 636 would “tear off” and not obstruct the vent 636a. *Id.* (“the lower end of the slider 636 tears off the bursting film 640 and moves downward, so that the additive is discharged from the additive storage container 620 into the bottle body through the discharge ports 636a.”). Cho describes the vents as “discharge ports” which further confirms that they are not obstructed in the open position. Ex.1002, ¶¶ 146-148.

In addition, a POSA would have known that Cho’s bursting film 640 is optional and unnecessary because the second cylinder 636 has ring-type protrusions 636b and 636c that prevent any additive from leaking through the discharge ports 636a. Ex.1004, 49:16-21; Ex.1002, ¶ 148.

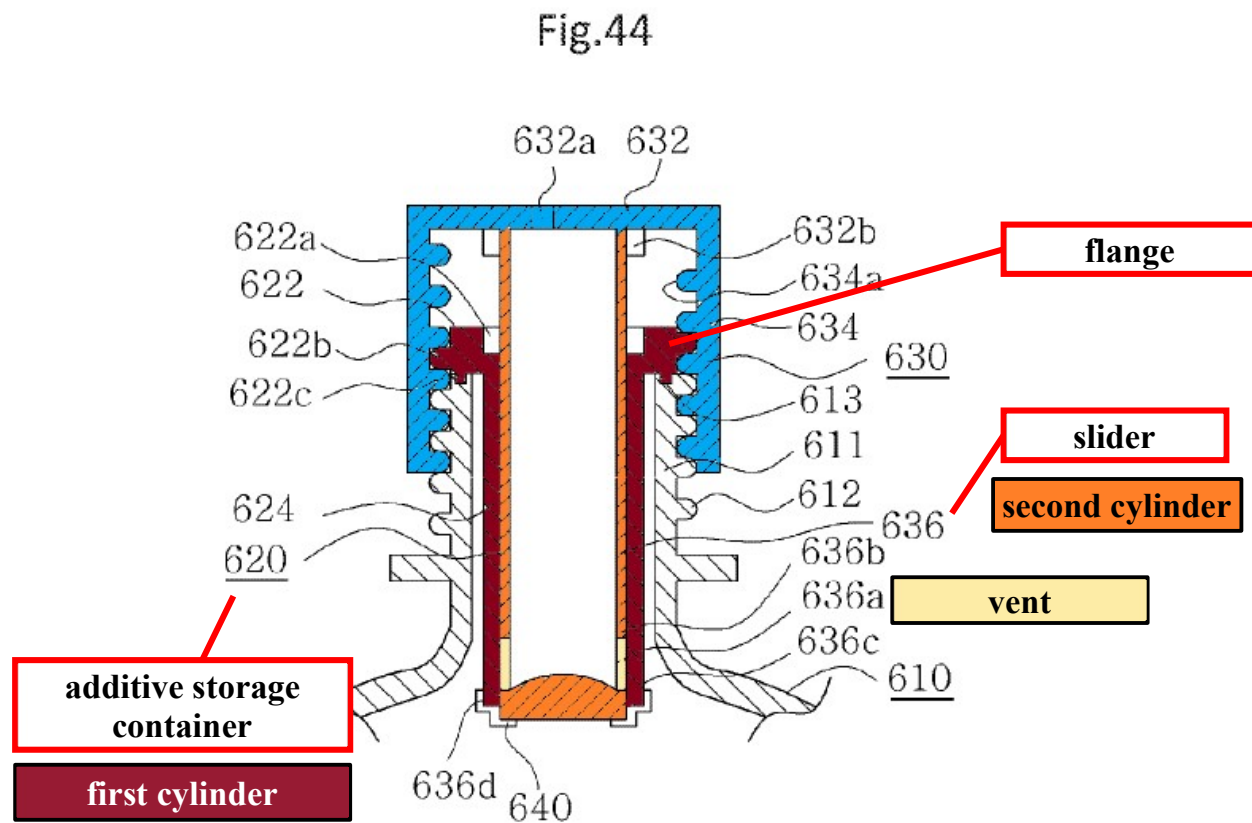
Moreover, to the extent Cho’s vent is somehow partially obstructed by a part of the burst film 640, a POSA would have understood that it would have been obvious to arrange the open configuration such that the vent 636a extends well past any remnant of the bursting film so that the film cannot obstruct any of the vent 636a. Ex.1002, ¶ 147.

Thus, limitations of claims 10 and 11 are rendered obvious by Plante and Cho.

J. Plante and Cho Render Obvious Claims 12 and 13

Claim 12 depends from claim 1 and recites “wherein the first and second cylinders comprise generally constant exterior diameters.” Claim 13 depends from claim 12 and recites “wherein the annular valve comprises a flange extending from at least one of the first and second cylinders.” Cho discloses these limitations. Ex.1002, ¶¶ 150-151.

Figure 44 below shows that the first cylinder (additive storage container 620) and second cylinder (slider 636) have generally constant exterior diameters. Fig. 44 also shows the flange extending from the first cylinder 620. Ex.1002, ¶ 151.



Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21.

K. Plante and Cho Render Obvious Claim 14

Claim 14 depends from claim 1 and recites “wherein the first and second connection members comprise a threaded connection.” Plante and Cho disclose this limitation. Ex.1002, ¶¶ 152-153.

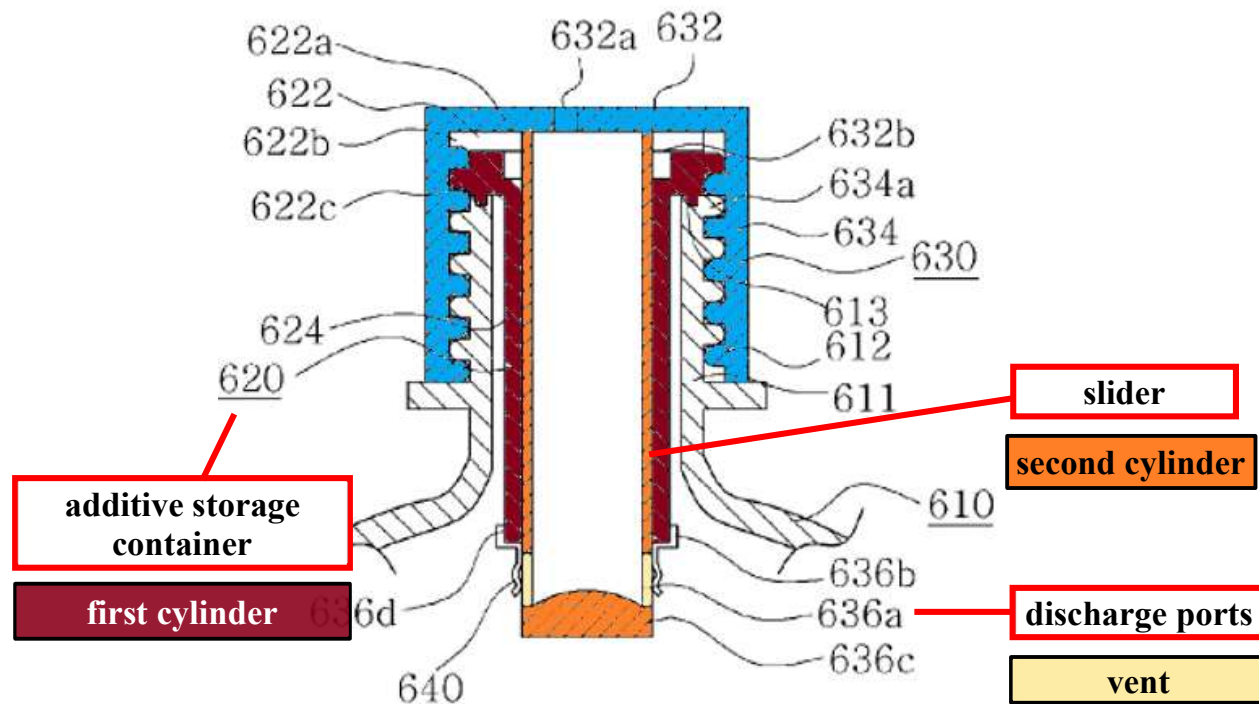
These threaded connections, which the ’632 patent describes as “well known to those of skill in the art” (Ex.1001, 10:58-65), are disclosed in Plante and Cho, which each disclose external threads on a container that mate with internal threads on a cap. *See, e.g.*, Ex.1003, Fig. 1 (thread sets 8 and 11); Ex.1004, Figs. 44, 45 (threads 634a and 612); Ex.1002, ¶ 153.

L. Plante and Cho Render Obvious Claim 15

Claim 15 depends from claim 1 and recites “wherein the annular valve comprises a sliding connection between the first and second cylinders.” The annular valve of Cho includes this limitation. Ex.1002, ¶¶ 154-155.

When Cho’s cap is tightened on the bottle, the slider 636 “moves downward” through the first cylinder. Ex.1004, 50:8-12. Thus, the second cylinder moves relative to the first cylinder in a sliding connection to move from the closed configuration to the open configuration. Cho’s Figures 44 and 45A show the sliding movement between the second cylinder (slider 636) and the first cylinder.

Fig.45A



Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12; Ex.1002, ¶ 155.

M. Plante and Cho Render Obvious Claim 16

Claim 16 depends from claim 1 and 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 and Cho disclose and render obvious these features. Ex.1002 ¶¶ 156-159.

Plante discloses a separable two-piece system. *See, e.g.*, Ex.1003, Figs. 1-4, [0018] (“An apparatus for saliva sample collection ... is formed of *two primary elements*”) (emphasis added); Ex.1002, ¶ 157.

Cho also discloses a separable two-piece system. The vessel bottle body 610 is the first piece. Ex.1004, 1:3-6, 1:25-2:3, 48:16-22, Figs. 43-45B. As discussed above regarding limitations 1[c]-1[c][vii], Cho’s cap, which includes a movable annular valve, is the second piece. Ex.1004, 48:16-50:27; Ex.1002, ¶ 157.

Even if Cho were somehow interpreted to not include a two-piece kit, the disclosure of Plante and Cho would have rendered Claim 8 obvious. Ex. 1002, ¶ 158. Plante discloses a separable two-piece kit where the first piece is the sample collection vessel and the second piece is the cap having a reagent storage container. *Id.* Plante also describes a shipping box for the sample collection container system. *Id.*

It would have been obvious to use Cho’s cap with an annular valve in Plante’s two-piece sample collection system where the cap and vessel are initially separate and then connected after a sample is collected. Ex. 1002, ¶¶ 156-159.

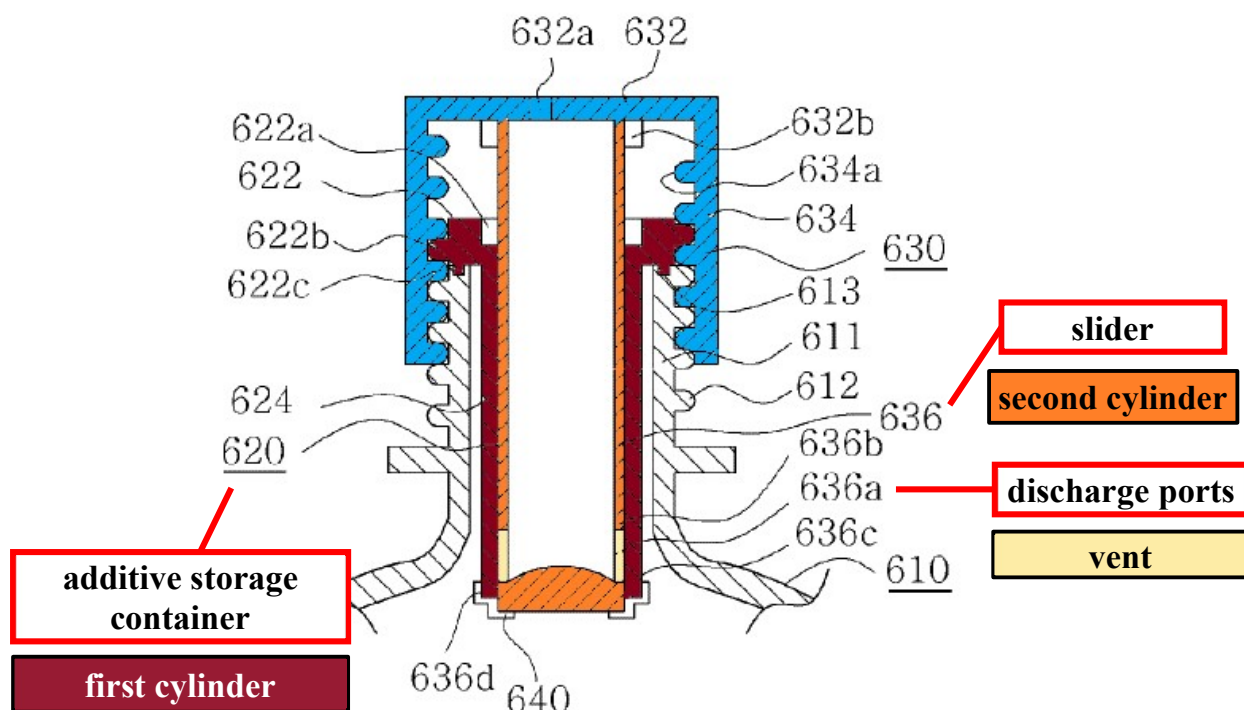
N. Plante and Cho Render Obvious Claim 18

Claim 18 depends from claim 1 and recites “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.” These limitations would have been obvious in view of Plante and Cho.
Ex.1002 ¶¶ 160-161.

Cho’s second cylinder (slider 636) has an outer wall with a diameter that is sufficiently equal to the diameter of the inner wall of the first cylinder (additive storage container 620). Ex.1004, 49:10-13. As can be seen, for example, in Figure 44 below, the outer diameter of Cho’s inner cylinder (slider 636) is substantially equal to the inner diameter of the outer cylinder (additive storage container 620), while allowing for relative vertical movement. Ex.1002, ¶ 161. Cho also describes that the slider 636 (inner cylinder) includes “[r]ing-type seal protrusions 636b and 636c” around the circumferential surface “so that the protrusions 636b and 636c are in close contact with the inner circumferential surface of the inner cap 624 [portion]” of outer cylinder.” Ex.1004, 49:16-20. This fluid-tight connection between the inner and outer cylinders “prevent[s] an additive from leaking through the discharge ports 636a.” *Id.*, 49:20-21; Ex.1002, ¶ 161.

Fig.44



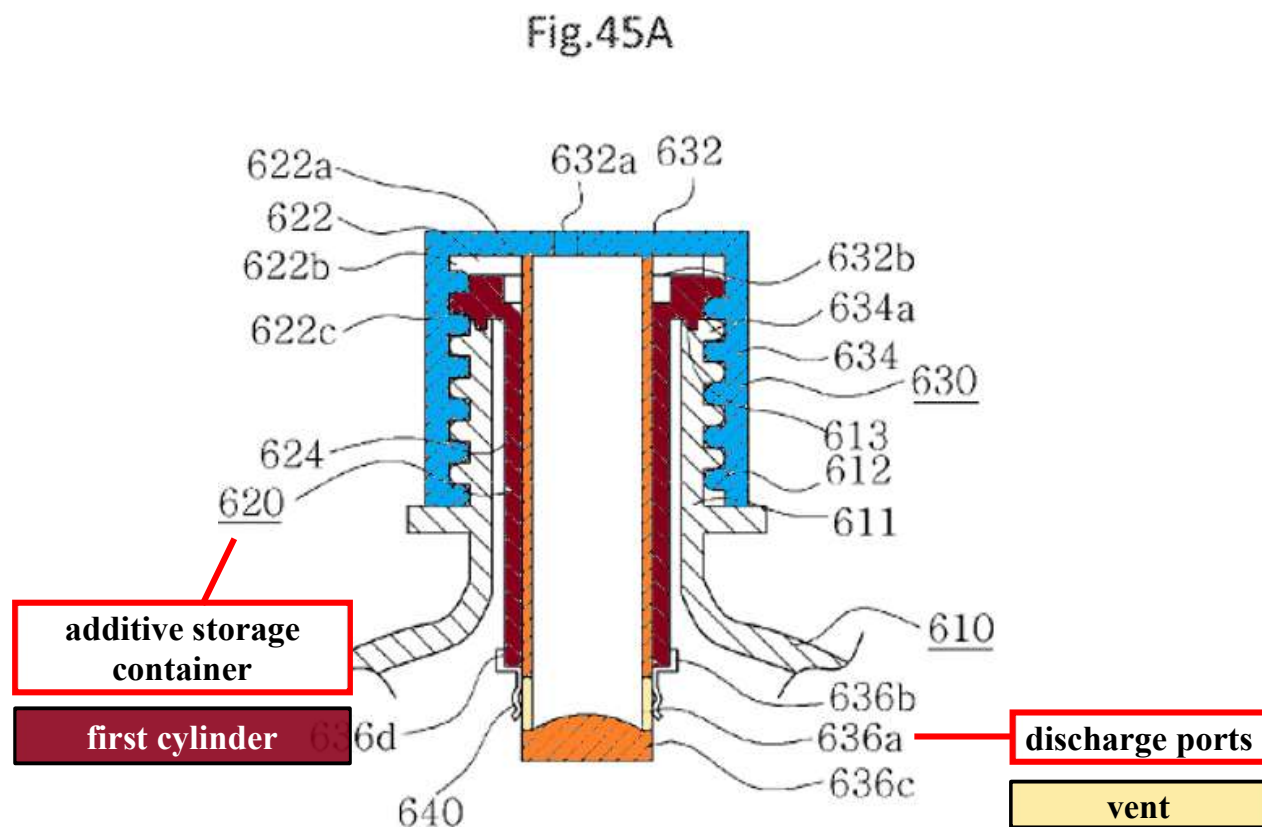
Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21.

O. Plante and Cho Render Obvious Claim 19

Claim 19 depends from claim 1 and recites “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.” This limitation would have been obvious in view of Plante and Cho. Ex.1002, ¶¶ 162-163.

When Cho’s cap is tightened on the bottle/vessel, the slider 636 “moves downward” through the first cylinder “so that the additive is discharged from the additive storage container 620 into the bottle body through the discharge ports 636a.” Ex.1004, 50:8-12. As Cho’s cap is connected by screwing onto the threads

of the bottle/vessel, the second cylinder moves relative to the first cylinder to move the parts of the annular valve from the closed configuration to the open configuration, as shown below.



Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12; Ex.1002, ¶ 163.

P. Plante and Cho Render Obvious Claim 20

Claim 20 depends from claim 1 and recites limitations from claims 2, 3, and 19. As discussed above with regard to claims 2, 3, and 19, Cho discloses these limitations. *See supra* Section VII.D, VII.E and VII.O.

**VIII. GROUND 2: PLANTE, CHO AND PATTERSON RENDER OBVIOUS
CLAIM 5**

Claim 5 depends from claim 1 and recites “wherein the first cylinder comprises a press-fit connection with the cap.” This limitation would have been obvious in view of Plante, Cho and Patterson. Ex.1002, ¶¶ 165-172.

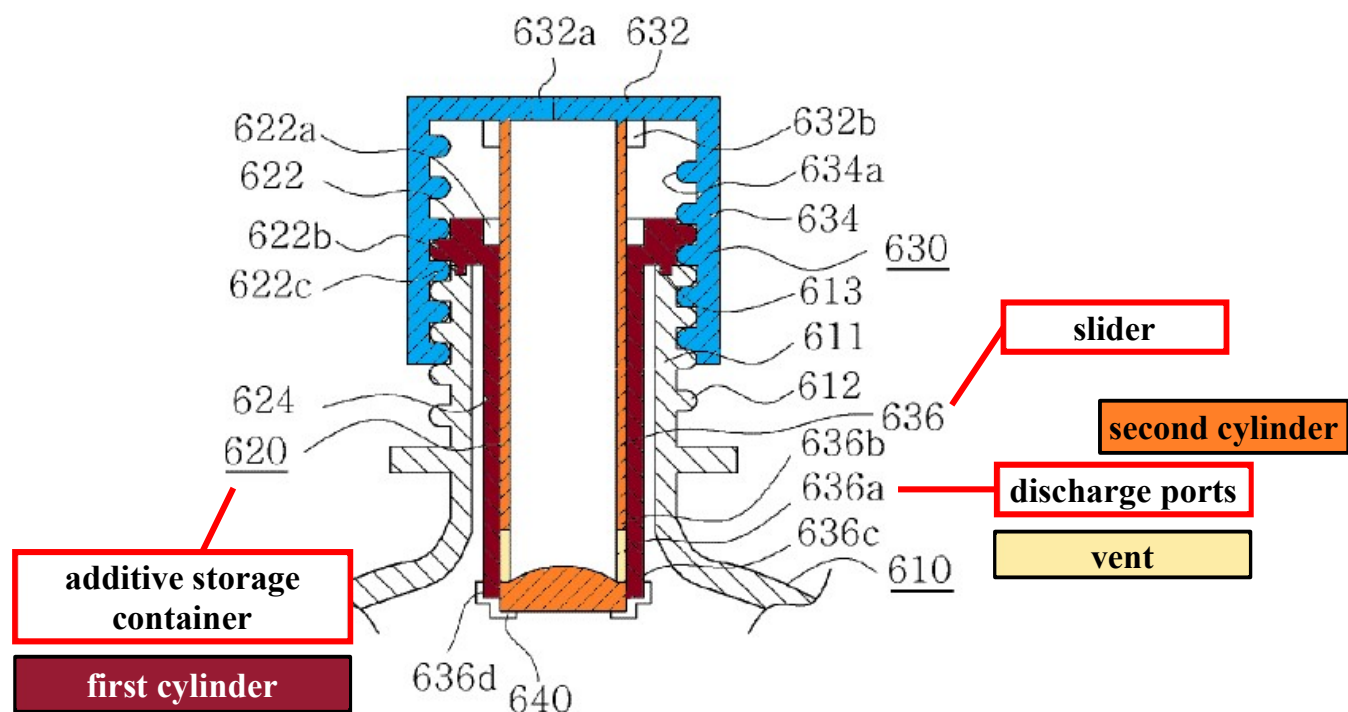
The '632 patent specification never uses the term “press-fit,” nor does it explain whether any of the disclosed connections are press-fits. Rather, the relevant embodiments described in the '632 patent have a first cylinder (annular blocking member 62) that has a *threaded* connection with the cap (*see* thread features 44 and 45 in Figs 3A and 3B). To the extent the '632 patent's disclosed threaded connection is somehow considered a “press-fit” connection, Cho discloses the same type of threaded connection between the first cylinder and the cap (*see* external thread 622b and internal thread 634a in Cho Figs. 44 and 45A). Ex.1002, ¶ 166.

Moreover, based on the lack of disclosure in the '632 patent and in order for the specification to satisfy § 112, use of a press-fit connection in this context must have been familiar to a POSA and easily implemented. Ex.1002, ¶ 167. Rather than expressly describing a press-fit connection, the '632 patent generally identifies various types of “well known” connections. Ex.1001, 10:58-67. Thus, according to the '632 patent, it was unnecessary to expressly describe a press-fit connection. *Id.* In view of these admissions, it would have been obvious to use a press-fit connection

with the cap and a POSA would have a reasonable expectation of success in implementing such a connection in a cap like Cho's. Ex.1002, ¶ 167.

The prior art also confirms that press-fit connections in container caps were well known before the '632 patent. Cho's cap includes a press-fit connection between the first cylinder (additive storage container 620) and the second cylinder (slider 636) which is part of the cap. Ex.1002, ¶ 168. Cho discloses that the second cylinder (slider 636) of the cap is "inserted into the inner cap 624" of the first cylinder 620, and the second cylinder 636 includes "[r]ing-type seal protrusions 636b and 636c," which are "in *close contact* with the inner circumferential surface of the inner cap 624, *thus preventing an additive from leaking through the discharge ports 636a.*" Ex.1004, 49:10-21 (emphasis added), 1:28-2:3, 55:22-25. Cho's Fig. 44 below shows the press-fit connection between the first cylinder (additive storage container 620) and the second cylinder (slider 636). Ex.1002, ¶ 168. A press-fit is used to maintain a seal between the first cylinder 620 and the second cylinder 636 of the cap. *Id.*

Fig.44



Ex.1004, Fig. 44 (annotated).

Patterson also teaches press-fit connections between cylindrical parts of the cap that do not involve threads. Ex.1010, [0032]. Patterson discloses a press-fit connection between a first cylinder and a cap. Ex.1002, ¶ 169. For example, Patterson discloses an outer cylinder (outer housing 20, 22) of the cap 10 that comprises an interference fit with an inner cylinder (inner tube 40) of the cap 10, as shown below in annotated Figs. 2 and 3. Ex.1010, [0032]. The outer cylinder 20 is “depressed or forcefully pushed to downwardly slide neck portion 24 thereof over sidewall 44 of the inner tube 40.” *Id.*, [0035]. By way of a press-fit, specifically an interference-fit or snap-fit, between the two cylinders, the rounded upper flange 48

is pressed passed the rounded inner medial flange 26 of the outer cylinder 20.

Ex.1002, ¶ 169. The '632 patent identifies a “snap-fit” as a type of pushing connection or press-fit. Ex.1001, 10:65-67.

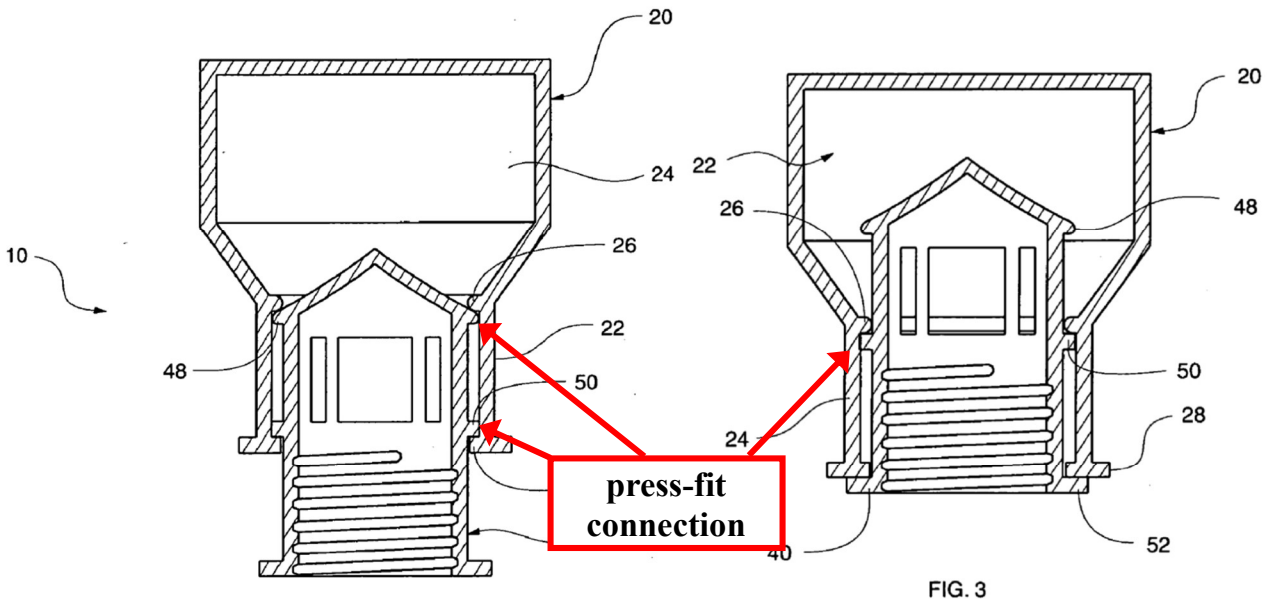


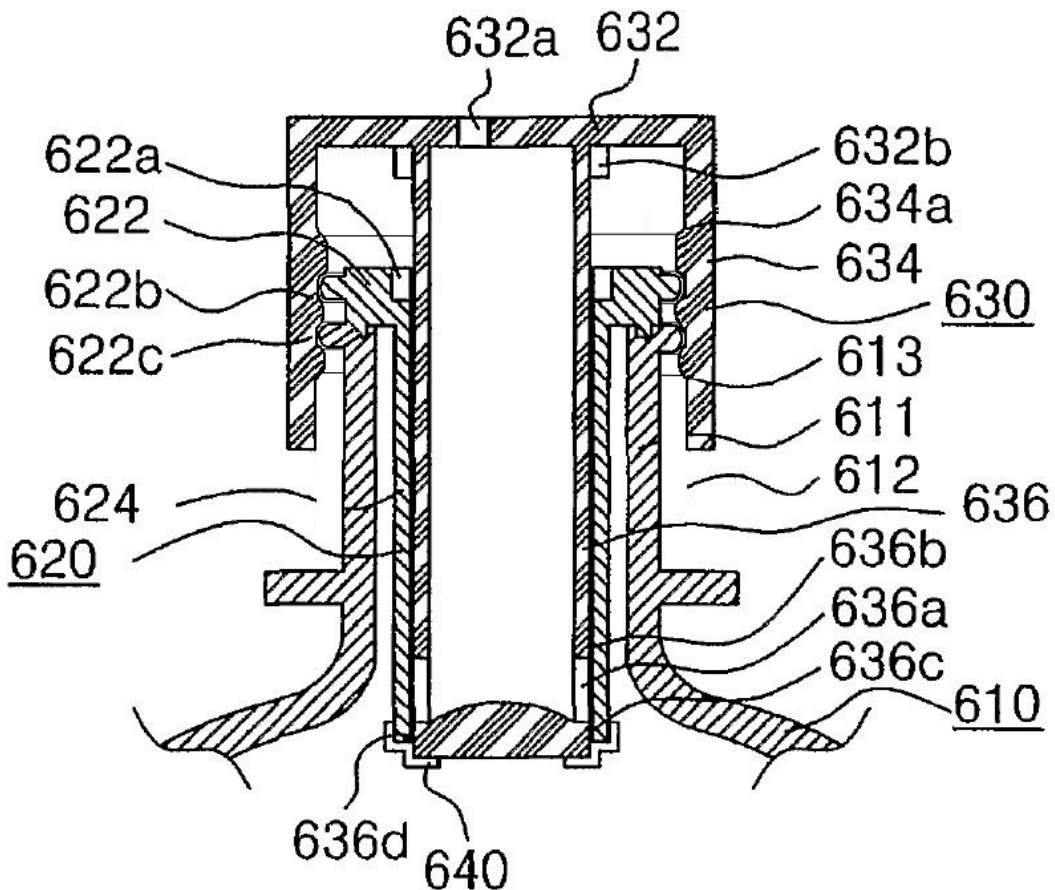
FIG. 2

Ex.1010, Figs. 2 and 3 (annotated).

It would have been obvious for a POSA to modify Cho’s movable annular valve in view of Patterson such that the threaded connection between Cho’s first cylinder 620 and the cap 634 is replaced with a non-threaded press-fit connection like Patterson’s. Ex.1002, ¶ 170. In this modified design, the user would screw the cap assembly 630 onto the container 610, and interaction between the flange 622 of the first cylinder 620 and the wall defining the opening of the container would cause the flange 622 to move upward relative to the cap via an interference-fit, as described in Patterson. *Id.* Alternatively, a POSA could easily implement Patterson’s non-

threaded press-fit in (1) the connection between Cho's cap and container, and (2) the connection between Cho's first cylinder 620 and the cap 634, as shown below in modified Fig. 44. *Id.*

FIG. 44



Patterson's press-fit (snap-fit) could also be designed as a simple press-fit with only an interference-fit and no snap feature. Ex.1002, ¶ 171. Such simple press-fits were common and well-known to a POSA. *Id.*

Using a non-threaded press-fit instead of a threaded connection would have been a mere design choice, and a POSA would have had a reasonable expectation of success implementing such a common connection, as shown in Patterson. Ex.1002, ¶ 172. A POSA would have been motivated to use a threadless press-fit between the first cylinder and the cap because it would simplify the design and manufacturing process by eliminating the threaded portions. *Id.* A POSA would have understood that molding threads on these types of devices can be difficult and requires a more complex manufacturing process. *Id.* Molding a protrusion, bump, or a rib is much easier than helical threads. *Id.* The non-threaded press-fit would also allow for faster and easier engagement of the cap to release the reagent into the vessel because the user could simply press the cap toward the vessel in one movement as opposed to screwing the cap onto the threads. *Id.*

IX. GROUND 3: UEDA ANTICIPATES CLAIMS 1–8, 10–16, AND 18-20

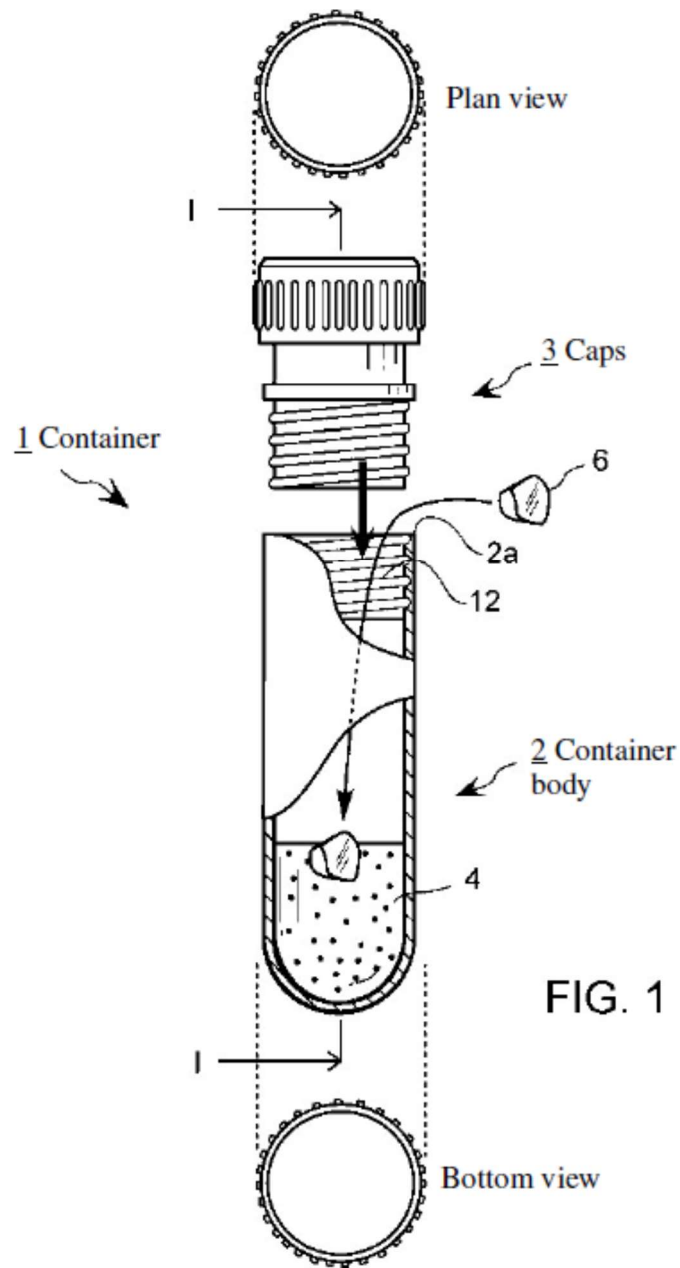
A. Disclosure of Ueda

Ueda discloses a biological sample container. Ex.1005, [Abstract]; Ex.1002, ¶ 173. Ueda’s container “consists of a container body 2 containing a first mixed material 4, and a cap 3 that holds a second mixed material 5 . . . to be mixed with the first mixed material 4, when detachably screwed to the container body 2.” Ex.1005, [0020]. After a biological sample is placed into the container body 2, the container “releases the second mixed material 5 from the cap 3 by screwing the cap 3 onto the

container body 2.” *Id.*, [0021]. The second mixed material in the cap can be “a granular gelling material, where mixing this with the first mixed material 4 gels the first mixed material 4.” *Id.*

Figure 1 of Ueda below illustrates the container 1 before the cap 3 is screwed onto the container body 2.

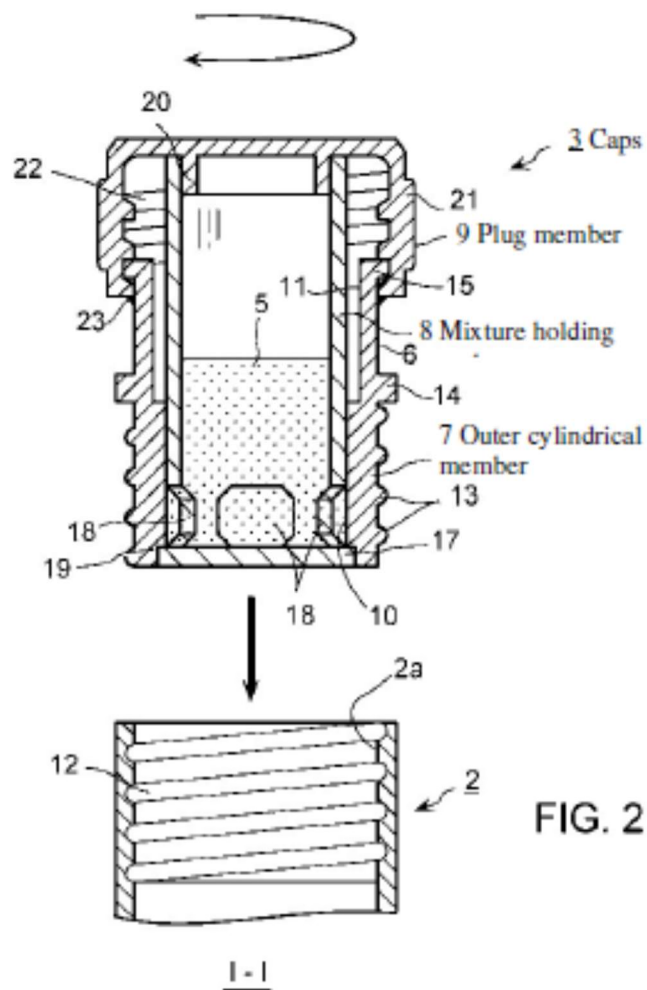
[FIG. 1]



As shown in Figure 2 below, 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.” Ex.1005, [0025], Fig. 2.

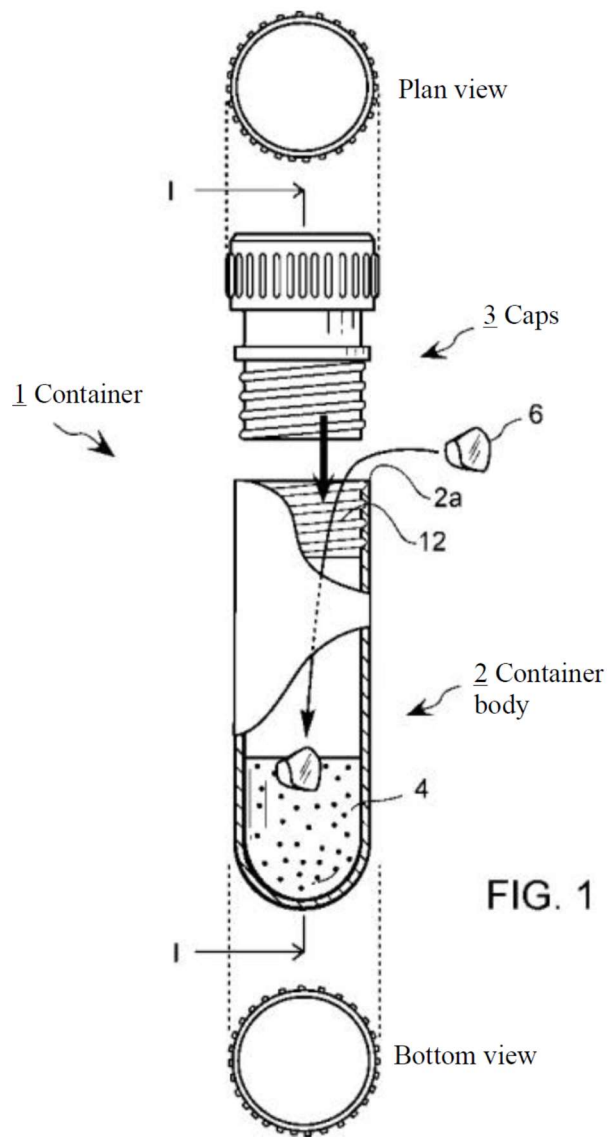
[FIG. 2]



B. Ueda Anticipates Claim 1

1. Preamble

The preamble of claim 1 recites: “A biological sample collection system, the system comprising.” To the extent the preamble is limiting, Ueda meets this limitation. Ueda discloses “containers suitable for storing **biological samples**” that contain cells, as shown below in Fig. 1. Ex.1005, [0001] (emphasis added), [0021], Fig. 1; *see also* Ex.1002, ¶ 176. Ueda confirms that the biological samples contain cells and discloses that the biological samples include “regenerative medicine, cell-containing drugs, and other pathological tests.” Ex.1005, [0002].

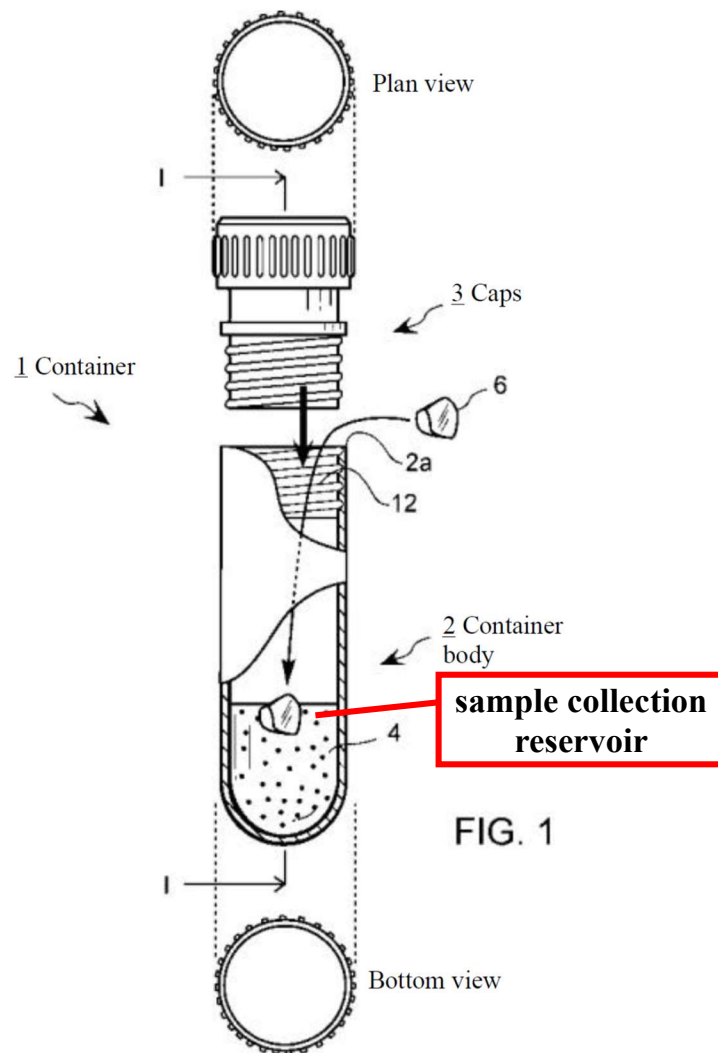


2. Limitation 1[a]: “a sample collection vessel comprising”

Ueda discloses this limitation. *See, e.g.*, Ex.1005, [0001] (“The present invention relates to containers, in particular to containers suitable for storing biological samples.”); Ex.1002, ¶ 177.

3. Limitation 1[a][i]: “a sample collection reservoir”

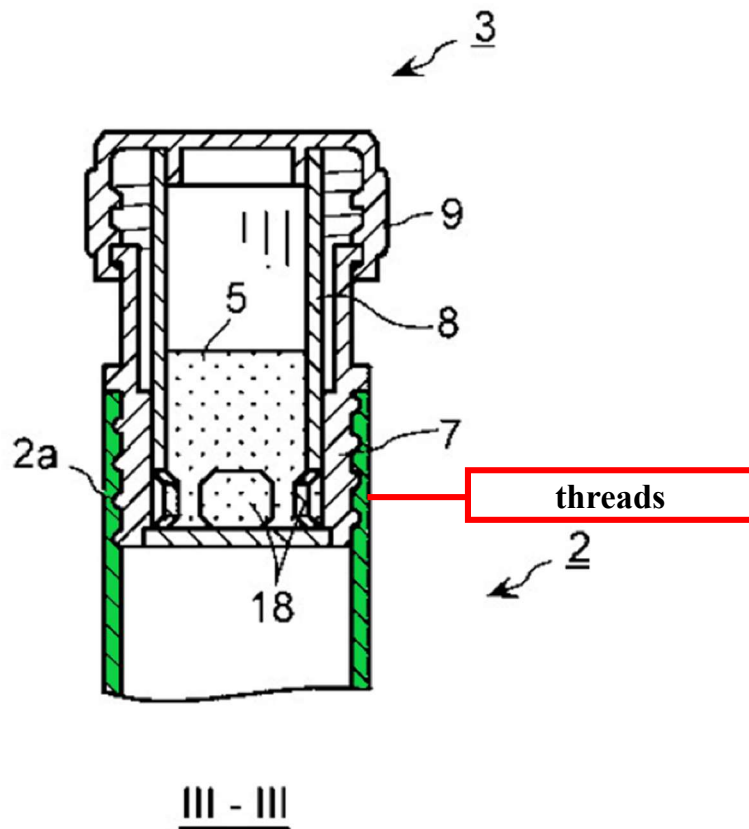
Ueda also discloses this limitation. The sample collection vessel (container body 2) includes a reservoir that receives the biological sample 6, as shown below in Fig. 1. Ex.1005, [0020]-[0021], Figs. 1 and 3A; Ex.1002, ¶ 178.



4. Limitation 1[a][ii]: “a first connection member”

As explained above in Section VII.C.4, the '632 patent discloses threads as a type of connection member.

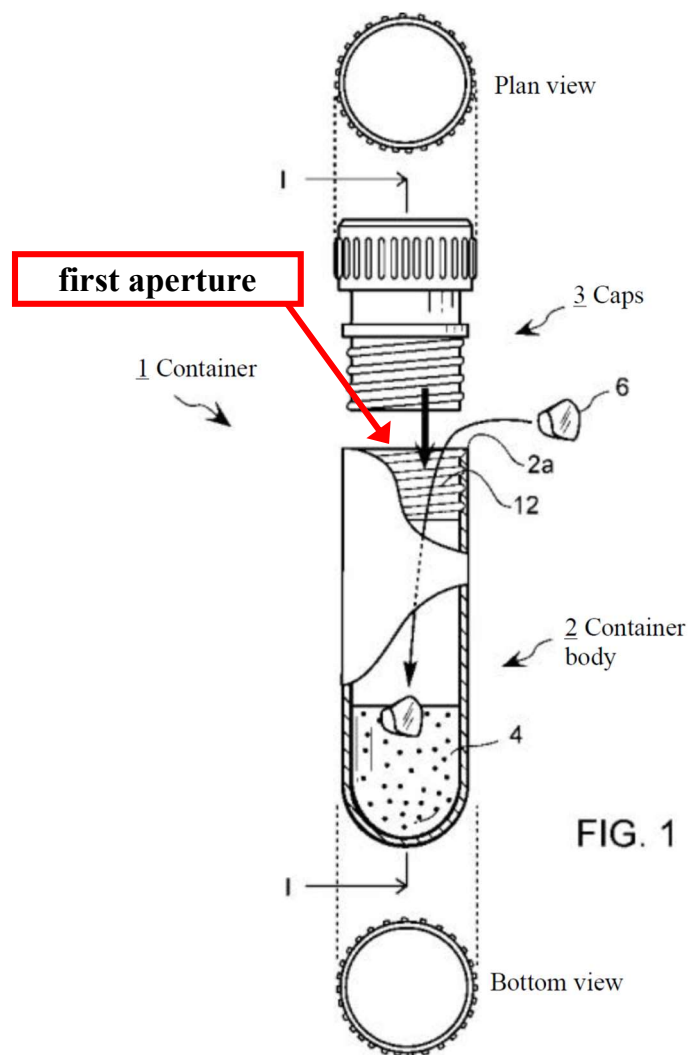
Ueda discloses a threaded connection between the cap and sample receiving container body 2, namely thread set 13 on the cap and corresponding first connection member (thread set 12) on the container body, as shown below. Ex.1005, [0026], Figs. 1 and 2.



Id., Fig. 3B (annotated). Thus, Ueda discloses this limitation. Ex.1002, ¶¶ 179-180.

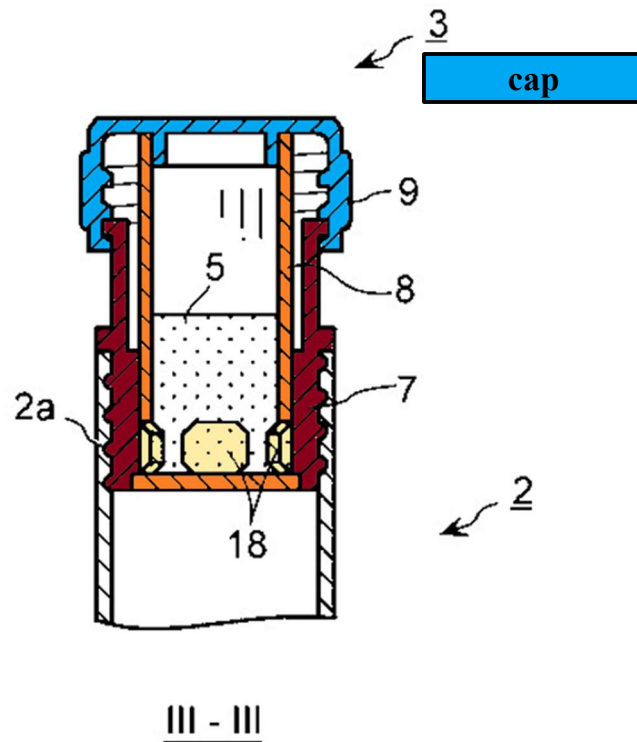
5. **Limitation 1[a][iii]: “a first aperture for receiving a biological sample”**

Ueda also discloses this limitation, namely “upper end opening 2a of the container body 2” which receives the biological sample 6, as shown below. Ex.1005, [0024], Fig. 1; Ex.1002, ¶ 181.



6. Limitation 1[b]: “a cap comprising”

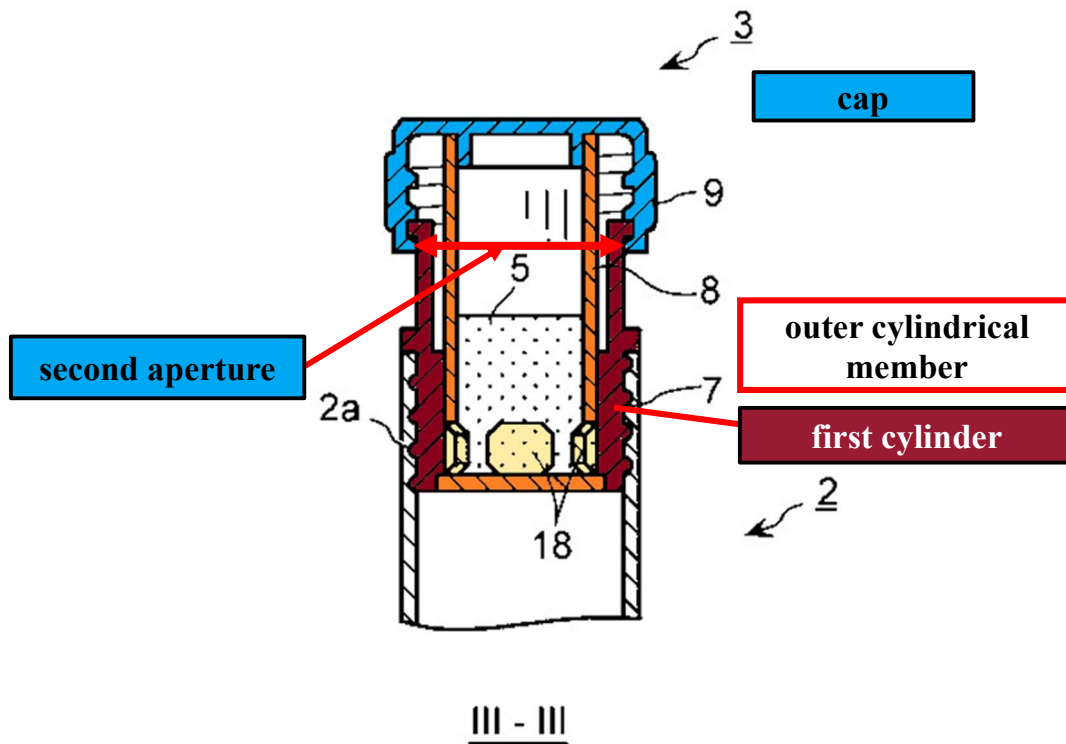
Ueda discloses a “cap” as one of the principal elements of the system, as shown below. Ex.1005, [0020]-[0022], Fig. 1; Ex.1002, ¶ 182.



Id., Fig. 3B (annotated).

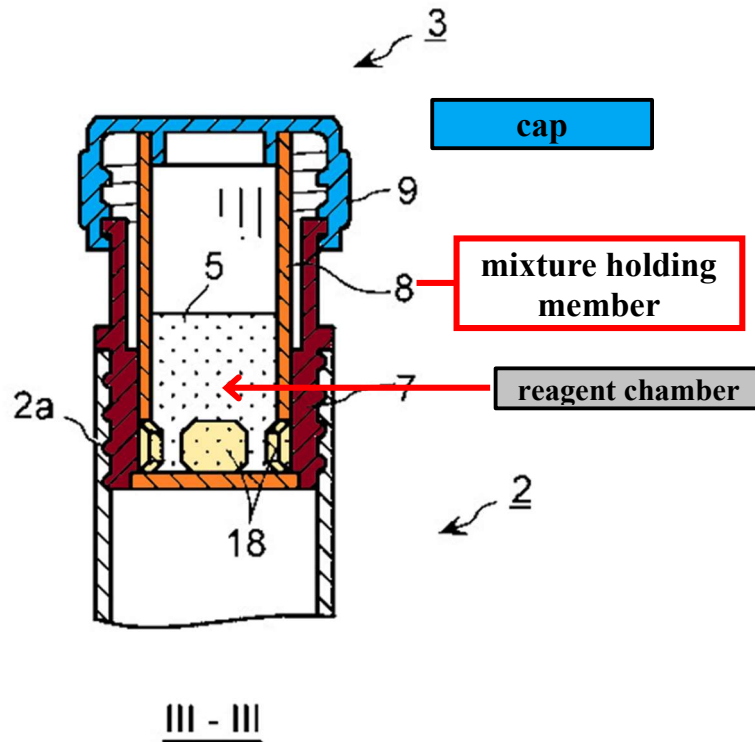
7. Limitation 1[b][i]: “a second aperture”

Ueda’s cap 3 includes a second aperture. Ex.1005, [0025], Fig. 2; Ex.1002, ¶ 183. For example, in the embodiment depicted in Figures 1-4, the cap 3 includes plug member 9 which has an aperture (the second aperture) that receives a portion of the first cylinder (outer cylindrical member 7), as shown below in annotated Figure 3B. Ex.1005, [0029], Figs 2-3B.



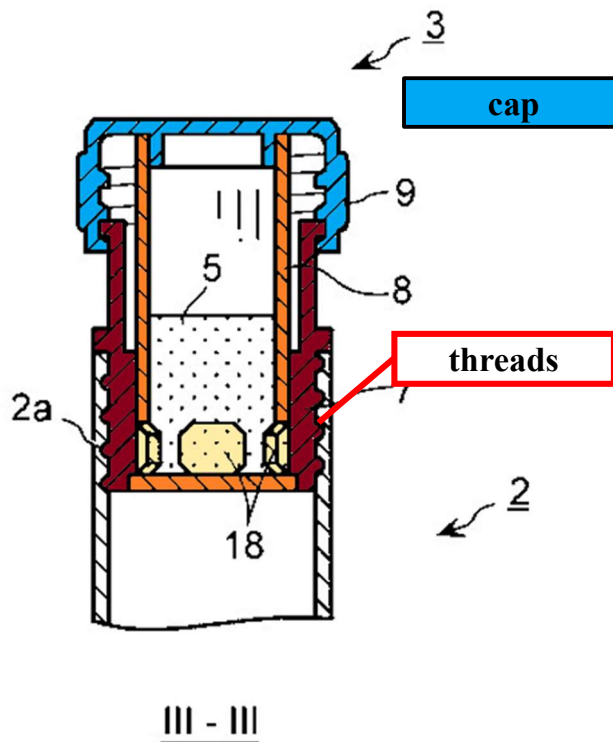
8. Limitation 1[b][ii]: “a reagent chamber storing a reagent therein”

Ueda discloses this limitation. Ex.1002, ¶¶ 184-185. Ueda’s cap includes a reagent chamber defined by mixture holding member 8, which stores a “mixture to be introduced into the interior of the container body.” Ex.1005, [0009]; *see also*, [0023]-[0027]. Ueda’s chamber, as identified in annotated Figure 3B below, is defined by the second cylinder (mixture holding member 8) and the first cylinder (outer cylindrical member 7). Ex.1005, [0025]. Ueda explains that the cap “hold[s] a mixture to be introduced into the interior of the container body.” *Id.*, [0009].



9. **Limitation 1[c]: “a second connection member complementary to the first connection member”**

Ueda discloses this limitation, namely that the cap 3 includes a first cylinder (outer cylindrical member 7) with “a male screw projection 13 that can be screwed into the female screw groove 12 of the container body 2,” as shown below in annotated Figure 3B. Ex.1005, [0026], Figs. 1-3B; Ex.1002, ¶¶ 186–188. The threads 13 are a second connection member. *Id.*

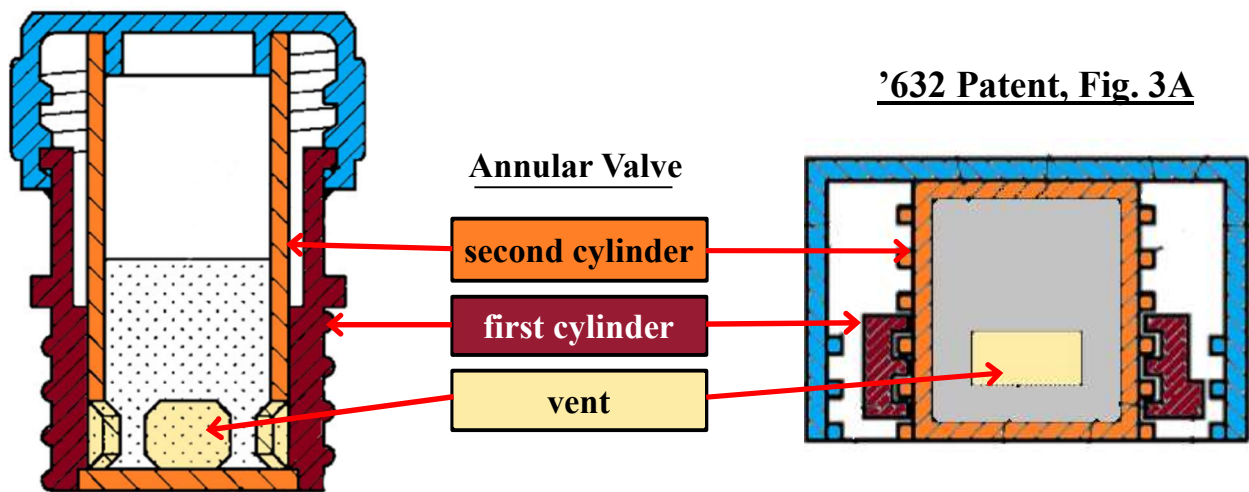


10. **Limitation 1[d]: “a movable annular valve in the second aperture, the movable annular valve comprising”**

Ueda discloses this limitation under any reasonable construction. Ex.1002, ¶¶ 189–192. As described above, the District Court construed “annular valve” in the related ’646 patent to mean “ring shaped valve.” Ex.1007, 66.

Ueda’s annular valve corresponds exactly to the embodiment of Fig. 3A in the ’632 patent, as illustrated in the comparison below. Similar to the ’632 patent embodiment, Ueda’s annular valve is ring shaped and includes first and second cylinders that move relative to one another in order to release the reagent from the vent on the second cylinder. Ex.1002, ¶ 190.

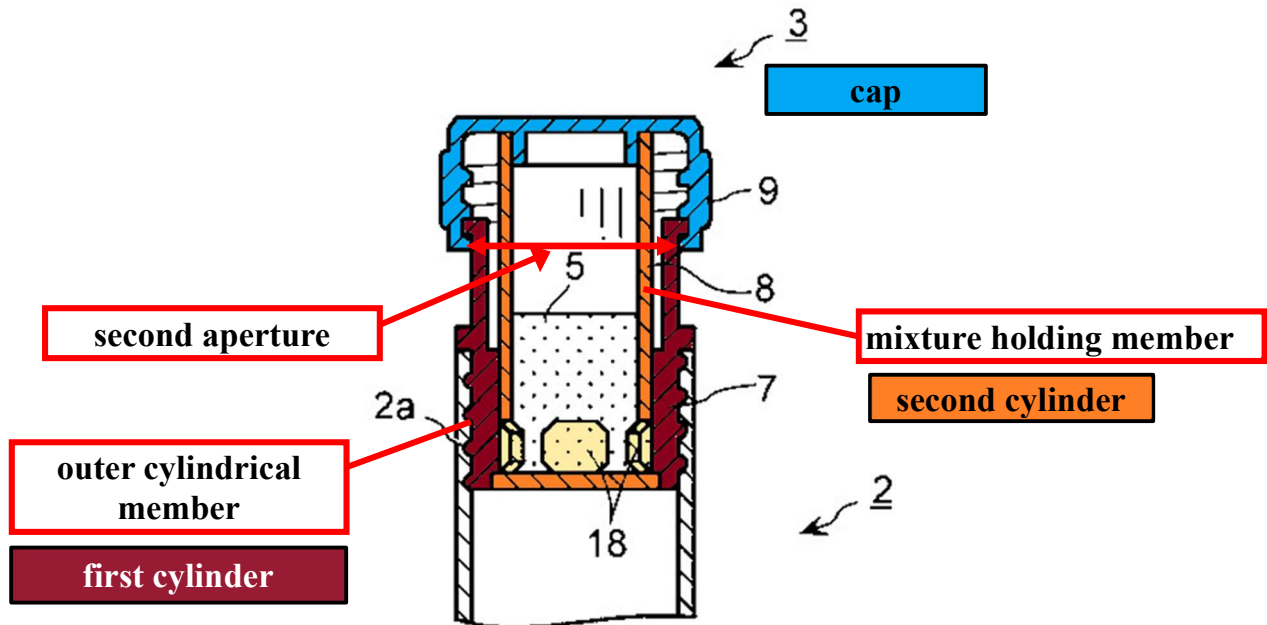
Ueda, Fig. 2



Ex.1005, Fig. 2 (annotated); Ex.1001, Fig. 3A (annotated).

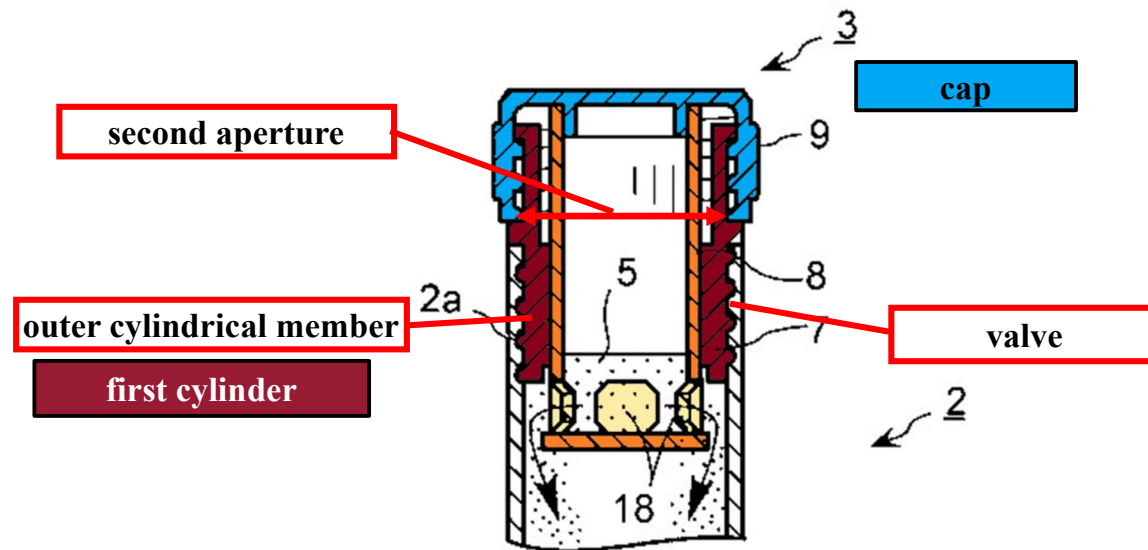
Limitation 1[d] also recites that the valve is “in the second aperture.” Ueda’s valve is in the second aperture, which is the aperture of the cap, as shown below in Figure 3B. Ex.1002, ¶ 191.

First, Ueda’s valve, which includes the first and second cylinders, is positioned within the cap and extends within the second aperture in the cap, as shown below in Figure 3B. Ex.1005, [0025], Figs. 2-3B. The cap’s first cylinder (outer cylindrical member 7) includes a flange portion 15 that engages with the internal threads 22 of the cap (female thread groove 22). Id., [0029]. Ueda’s Fig. 3B is annotated below to illustrate how the second cylinder (mixture holding member 8) and first cylinder (outer cylindrical member 7) in Ueda’s annular valve are held within and extend through the aperture in the cap 2:



Ex.1005, Fig. 3B (annotated); Ex.1002, ¶¶ 190-192.

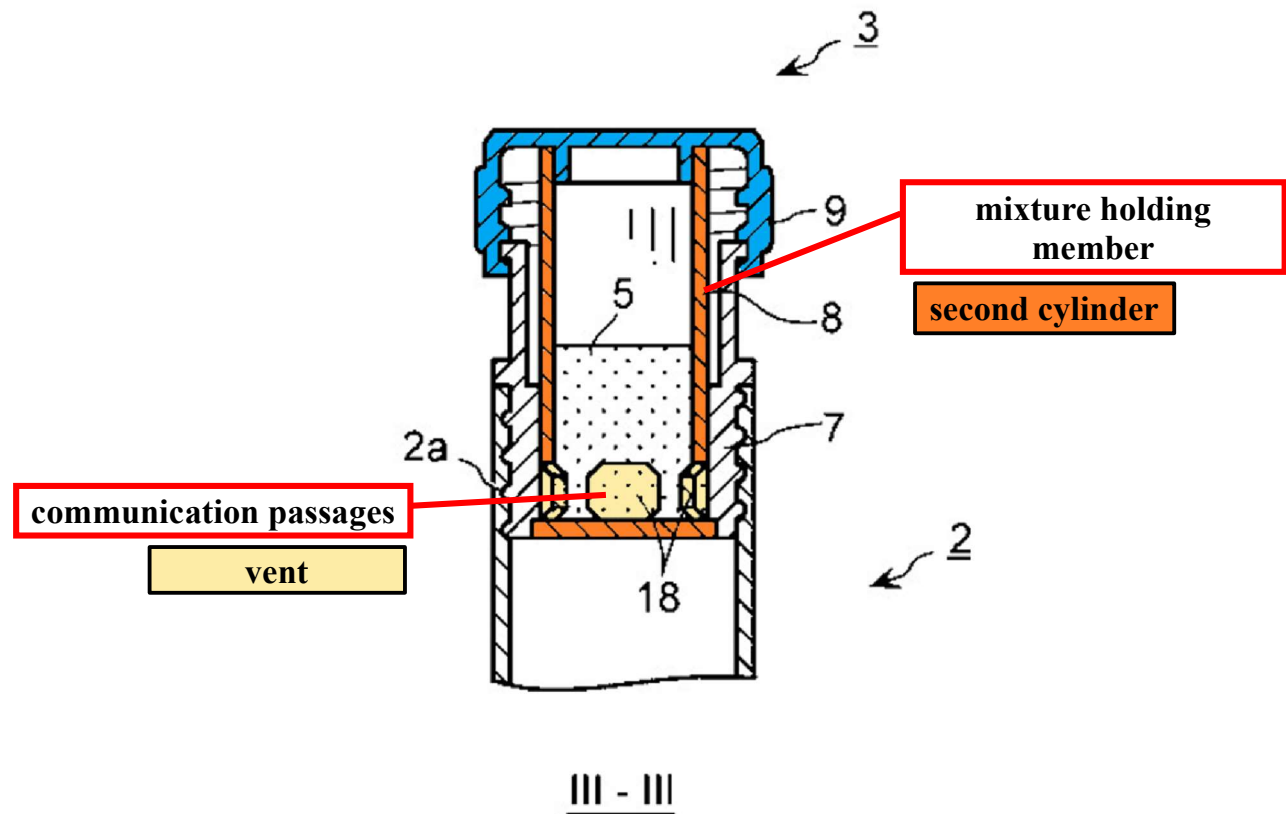
As shown below in annotated Figure 4B, when the Ueda cap 3 is fully screwed onto the container 2, the valve of Ueda is in the cap and also extends into the container body 2, thus being positioned in and extending through the second aperture in the cap 3. Ex.1002, ¶ 192.



Ex.1005, Fig. 4B (annotated).

11. Limitation 1[d][i]: “a vent”

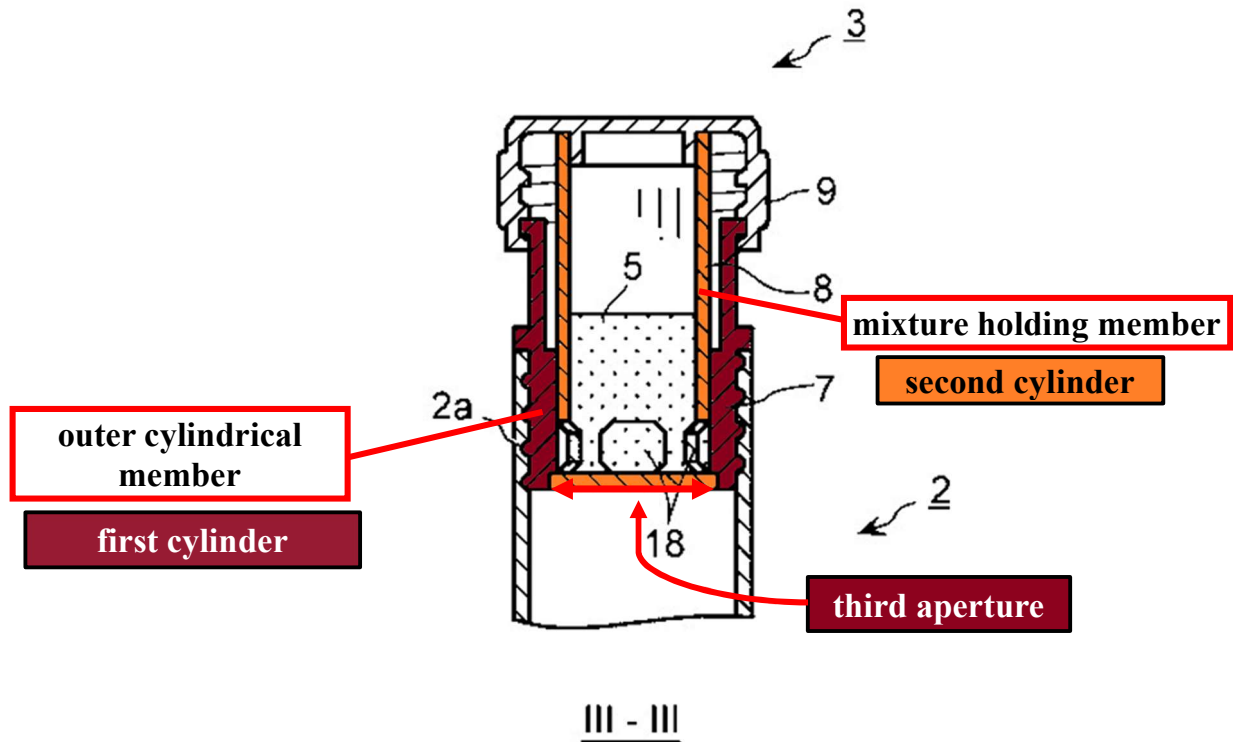
Ueda discloses this limitation. Specifically, Ueda’s second (inner) cylinder 8 includes communication passages 18, which provide a vent. Ex.1005, [0027], Figs. 2-4B; Ex.1002, ¶¶ 193–194. Ueda’s vent 18 is shown in annotated Figure 3B below:



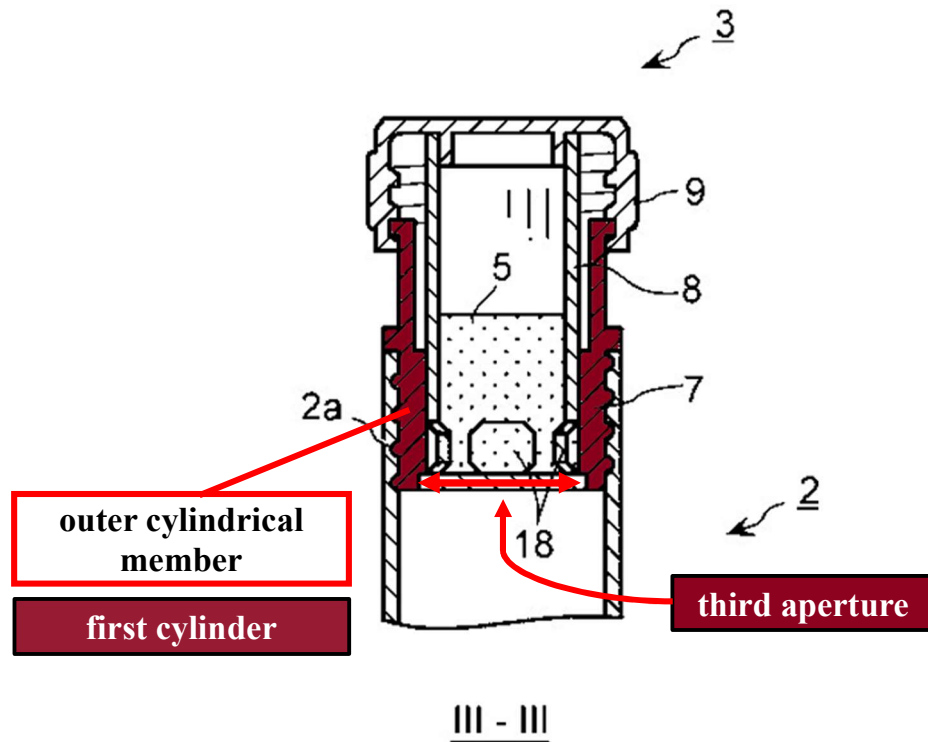
Ex.1005, Fig. 3B (annotated).

12. Limitation 1[d][ii]: “a first cylinder comprising a third aperture”

Ueda discloses this limitation. In Ueda’s annular valve, the outer cylindrical member 7 is the claimed first cylinder. Ex.1005, [0025]-[0028], Figs. 2-4B; Ex. 1002, ¶¶ 195–198. The outer cylindrical member 7 “is a circular outer cylindrical member having a lower end opening 10 and an upper end opening 11.” Ex. 1005, [0026]. Figs. 1-4B. Thus, the first cylinder (outer cylindrical member 7) comprises a third aperture (lower end opening), as shown below in annotated Figure 3B.



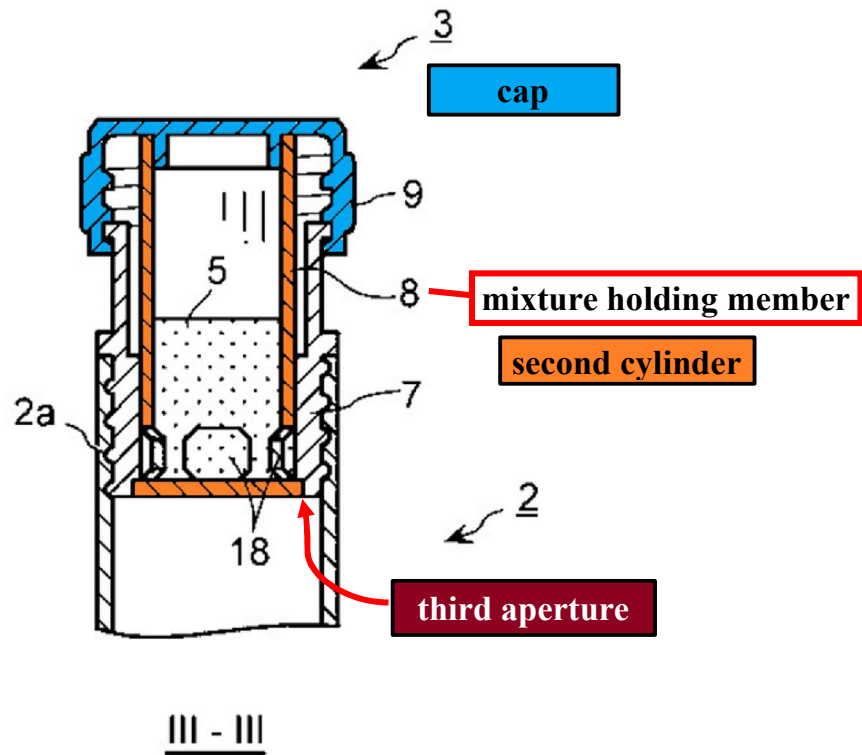
In the '632 patent, the third aperture is defined by the interior sidewall of the first cylinder (annular blocking member 62). *See, e.g.,* Ex.1001, Fig. 3A. Similarly, in Ueda's the third aperture is defined by the first cylinder (outer cylindrical member 7), as shown below. Ex.1005, [0027], Figs. 2-4B; Ex.1002, ¶¶ 195–198.



Ex.1005, Fig. 3B (annotated).

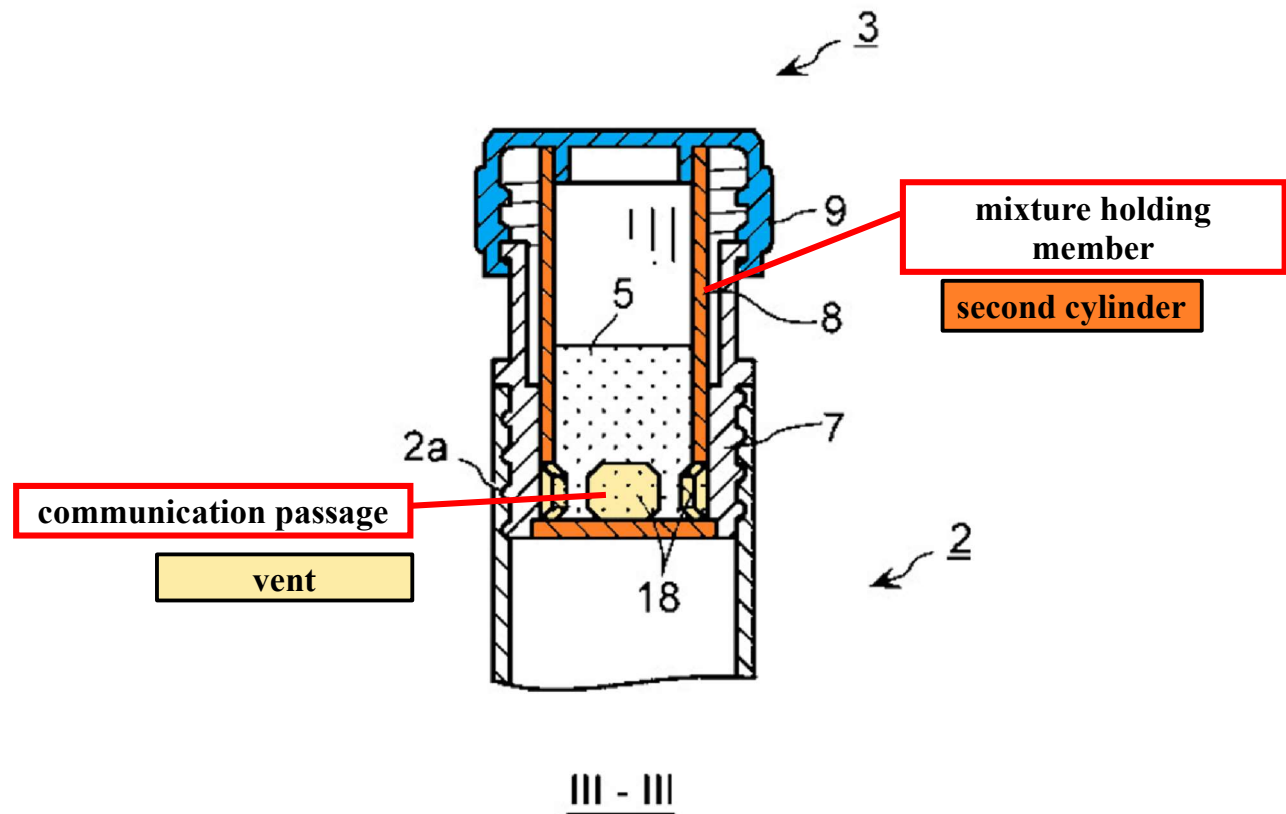
13. Limitation 1[d][iii]: “a second cylinder comprising the vent, the second cylinder positioned in the third aperture”

Ueda discloses this limitation. In Ueda's valve, the mixture holding member 8 is the claimed second cylinder. Ex.1005, [0025], [0027], Figs. 2-4B; Ex.1002, ¶ 199. As shown in annotated Figure 3B below, Ueda's second cylinder (mixture holding member 8) comprises the vent (communication passages 18) and is positioned in the third aperture in the first cylinder 7. *Id.*



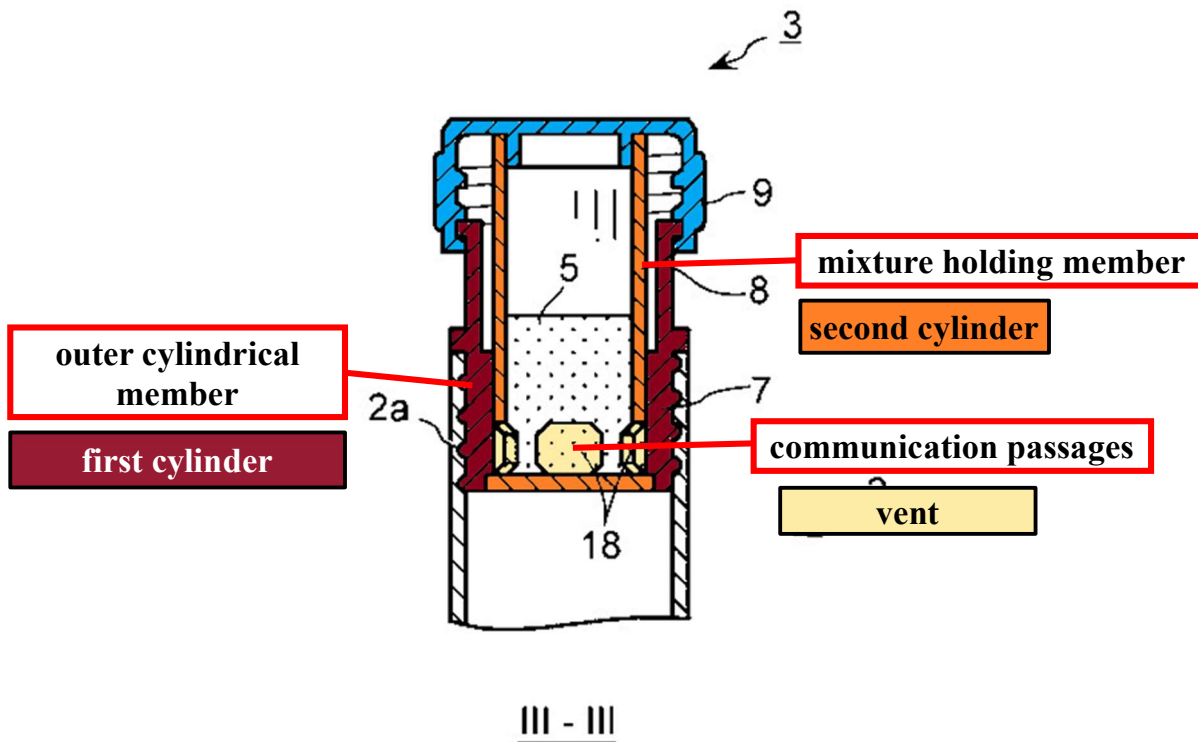
As shown in Figure 3B above, the second cylinder 8 is positioned in and slides within the third aperture in the first cylinder 7. Figure 4B also shows the second cylinder 8 positioned in and extending through the third aperture. Ex.1002, ¶¶ 199–201.

The vent 18 is shown in Fig. 3B below:



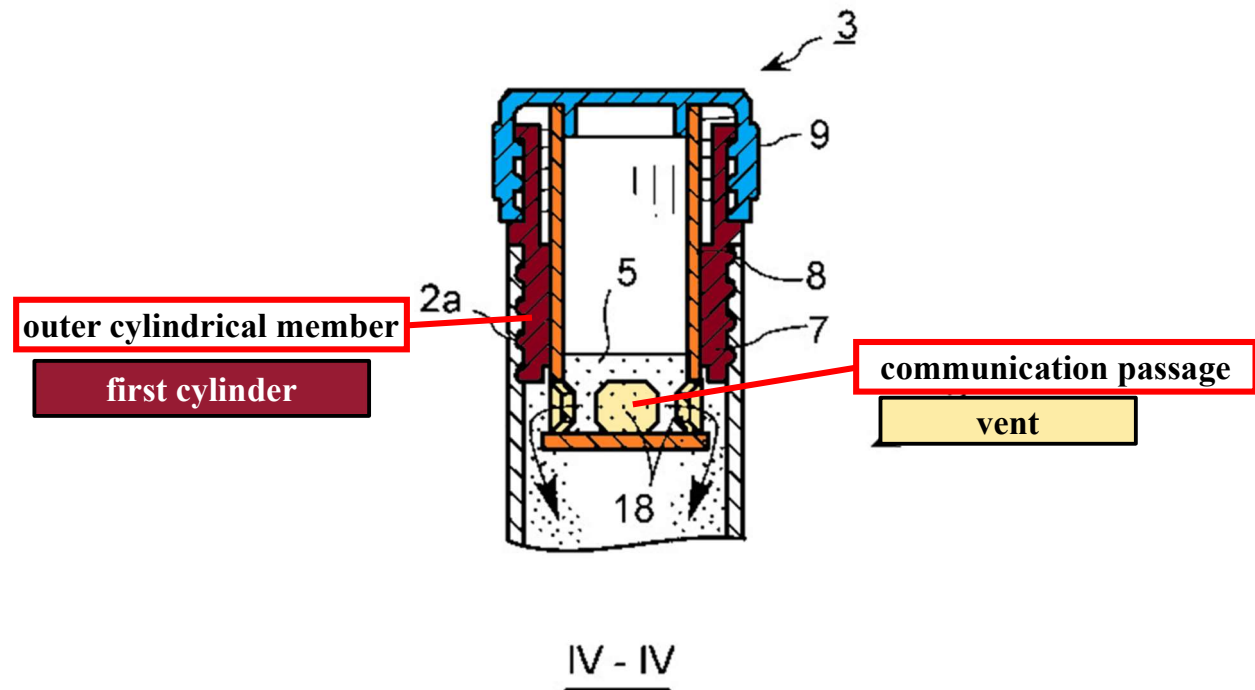
14. Limitation 1[d][iv]: “a closed configuration, and”

Ueda discloses this limitation. Ex.1002, ¶ 202. Ueda discloses that “[w]hen the holding member 8 does not protrude from the lower end opening 10 of the outer cylindrical member 7 . . . the communication passage 18 is **closed** by the inner peripheral surface of the outer cylindrical member 7.” *Id.* (emphasis added). Annotated Figure 3B below shows the closed configuration, with the interior sidewalls of the first cylinder 7 obstructing the vent (communication passage 18) on the second cylinder 8. Ex.1005, [0027]; Ex.1002, ¶ 202.



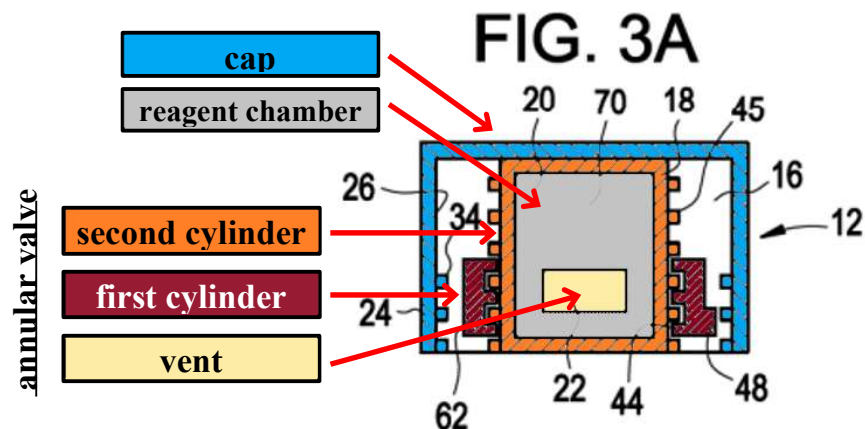
15. Limitation 1[d][v]: “an open configuration, wherein”

Ueda discloses this limitation. Ex.1002, ¶¶ 203–204. When Ueda’s cap 3 is tightened on the container 2, the second cylinder (mixture holding member 8) “slides vertically along its axial direction within the outer cylindrical member 7” so that the “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.” Ex.1005, [0027], Fig. 4B. Ueda’s annotated Figure 4B below shows the movable annular valve in an open configuration, with the first cylinder (outer cylindrical member 7) no longer obstructing the vent (communication passage 18). Ex.1002, ¶ 204.

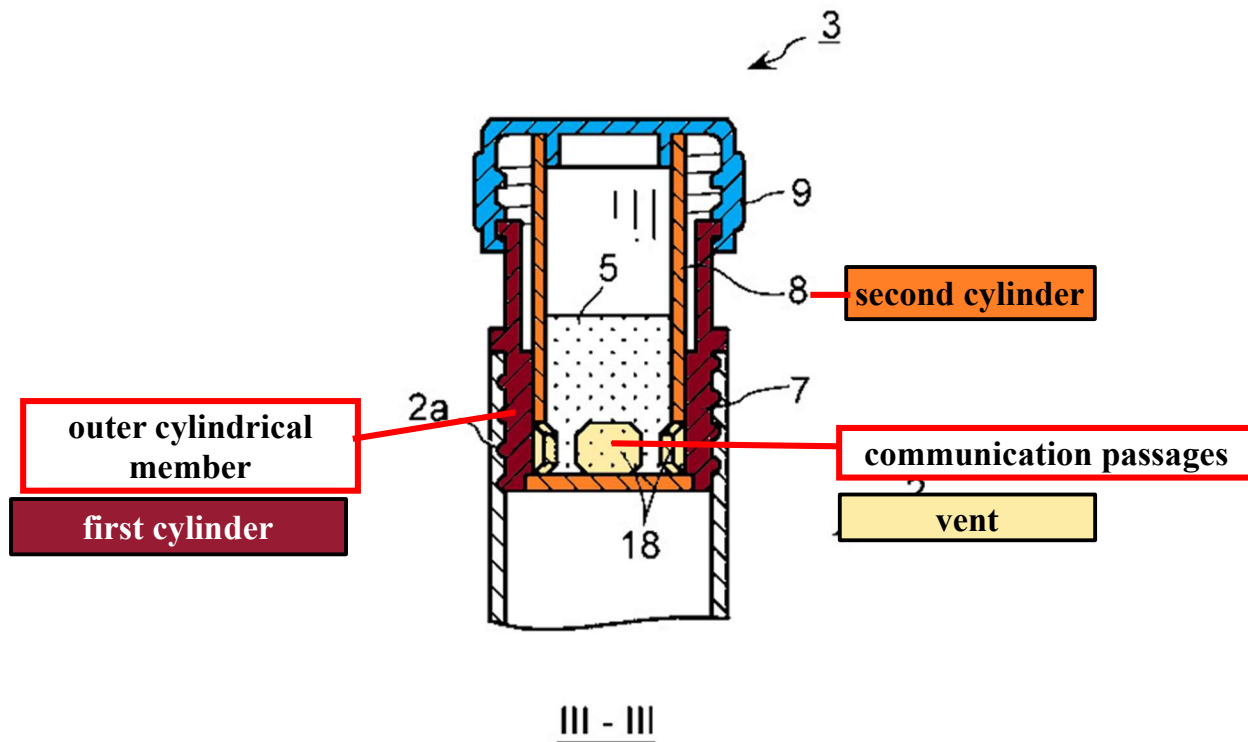


16. **Limitation 1[d][vi]: “in the annular valve’s closed configuration, the first and second cylinders create a fluid-tight seal with the cap and the first cylinder obstructs the vent to retain the reagent in the reagent chamber”**

Ueda discloses this limitation. As described above in Ground 1, the '632 patent discloses an annular valve closed configuration in which the first and second cylinders create a fluid tight seal with the cap by arranging the second cylinder as an inner wall of the cap. Ex.1001, 14:20-32. As shown below in annotated Figure 3A, the first and second cylinders create a fluid-tight seal with and in the cap, and the first cylinder obstructs the vent to retain the reagent in the reagent chamber. Ex.1002, ¶¶ 205–207.

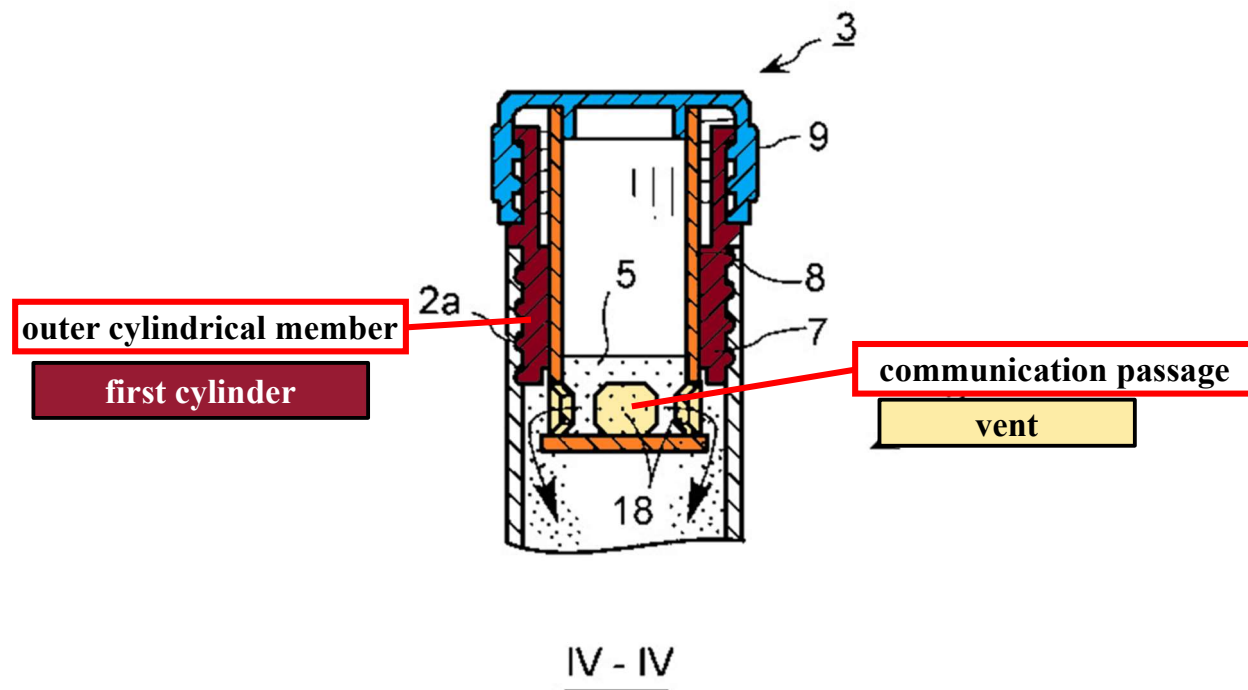


Ueda's annular valve has first and second cylinders that create a fluid tight seal with the cap in the same way as the '632 patent embodiment. Ueda's annular valve includes a second cylinder (mixture holding member 8) that acts as an inner wall of the cap to seal the reagent within the cap when the first cylinder 7 blocks the vent 18. Ex.1005, [0027], Figs. 2-4B; Ex.1002, ¶ 207. Ueda further discloses that "the bottom wall plate is constructed so as to liquid-tightly seal the space between the outer cylindrical member 7 and the mixture holding member 8." Ex.1005, [0028]. In this closed configuration, Ueda's first cylinder 7 overlaps with the second cylinder 8, blocking the vents and creating a fluid-tight seal with the cap to retain the reagent 5 within the second cylinder 8, as shown in annotated Figure 3B below. *Id.*; Ex.1002, ¶ 207.



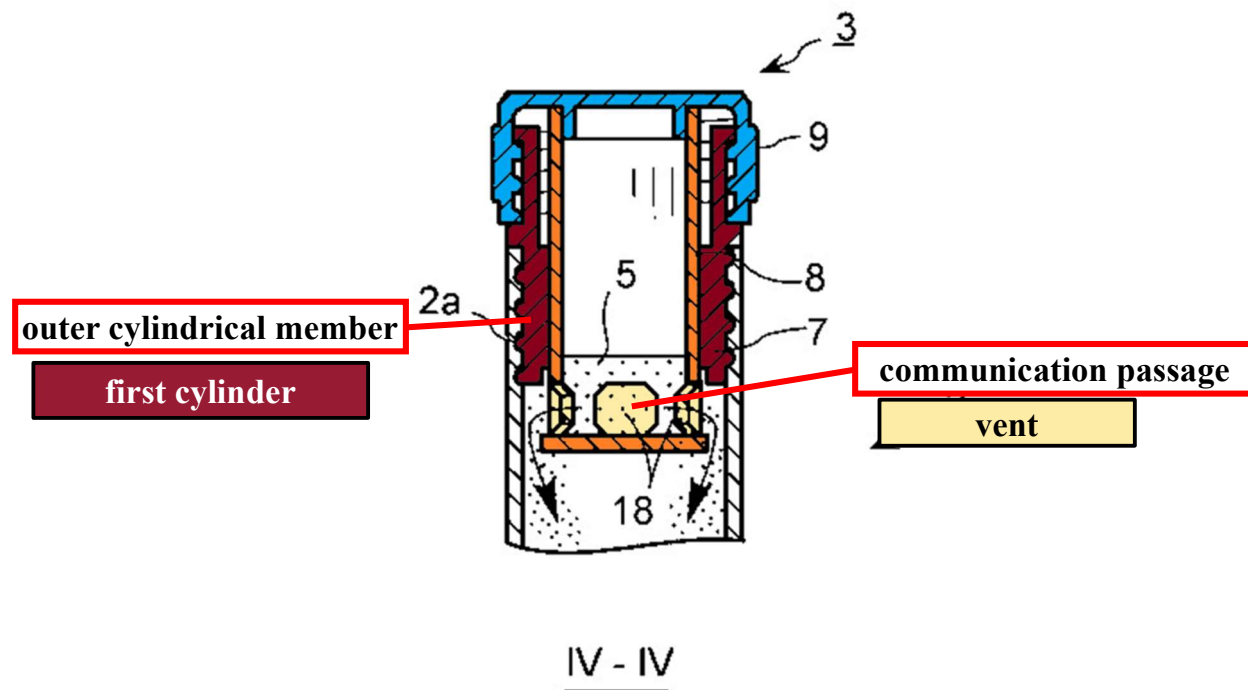
17. **Limitation 1[d][vii]: “the first cylinder and second cylinder are relatively moveable to thereby change the annular valve from the closed configuration to the open configuration, and”**

Ueda discloses this limitation. Ex.1002, ¶ 208. When Ueda’s cap 3 is tightened on the container 2, the second cylinder (mixture holding member 8) “slides vertically along its axial direction within the outer cylindrical member 7” from the closed configuration to the open configuration.” Ex.1005, [0027], Fig. 4B. Ueda’s Figures 3B and 4B show the closed and open configurations, illustrating the movement of the second cylinder (mixture holding member 8) relative to the first cylinder (outer cylindrical member 7). Ex.1002, ¶ 208.



18. **Limitation 1[d][viii]: “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.”**

Ueda also discloses this limitation. Ex.1002, ¶¶ 209–211. When Ueda’s cap 3 is tightened on the container 2, the second cylinder (mixture holding member 8) slides downward relative to the first cylinder 7 so that the vent 18 is unobstructed, allowing flow of the reagent (second mixed material 5) into the sample collection reservoir. Ex.1005, [0027], Fig. 4B. In Ueda’s open configuration, “the second mixed material 5 held in the mixture holding member 8 can be configured to be released into the container body 2,” as shown in annotated Figure 4B below. *Id.*; Ex.1002, ¶¶ 210–211.



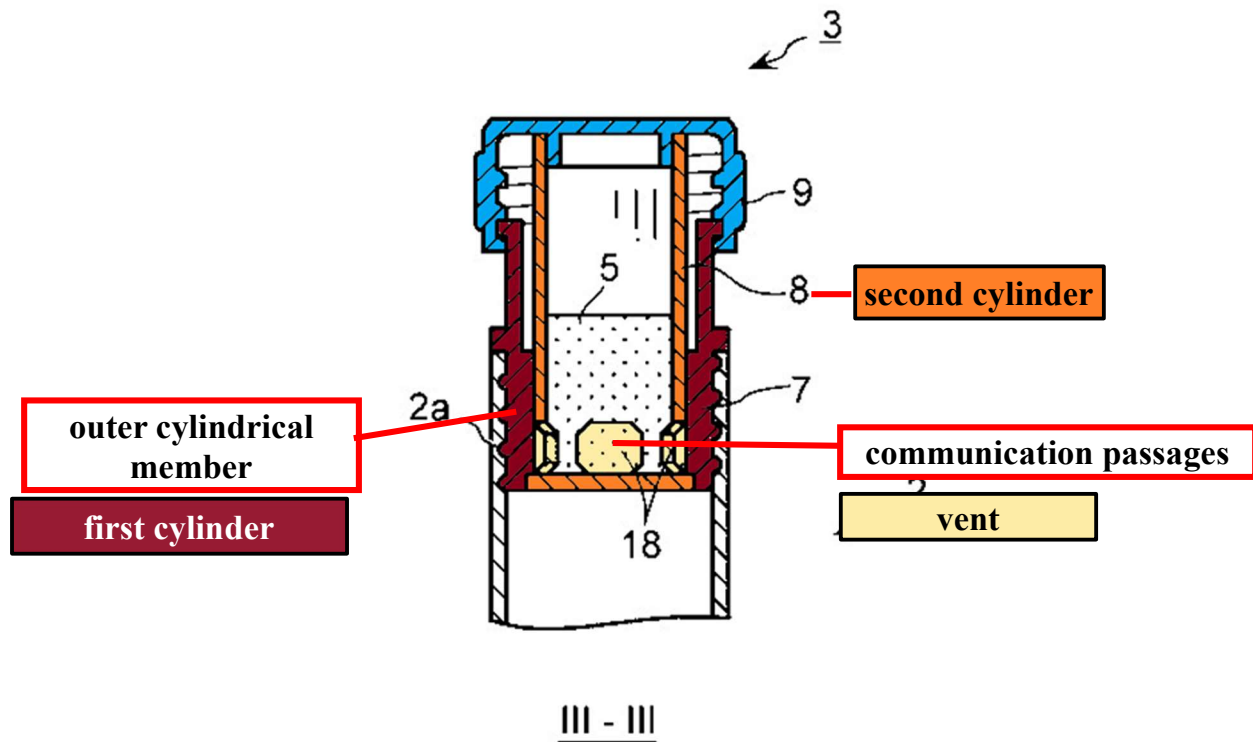
In sum, Ueda discloses all limitations of claim 1.

C. Ueda Anticipates Claim 2

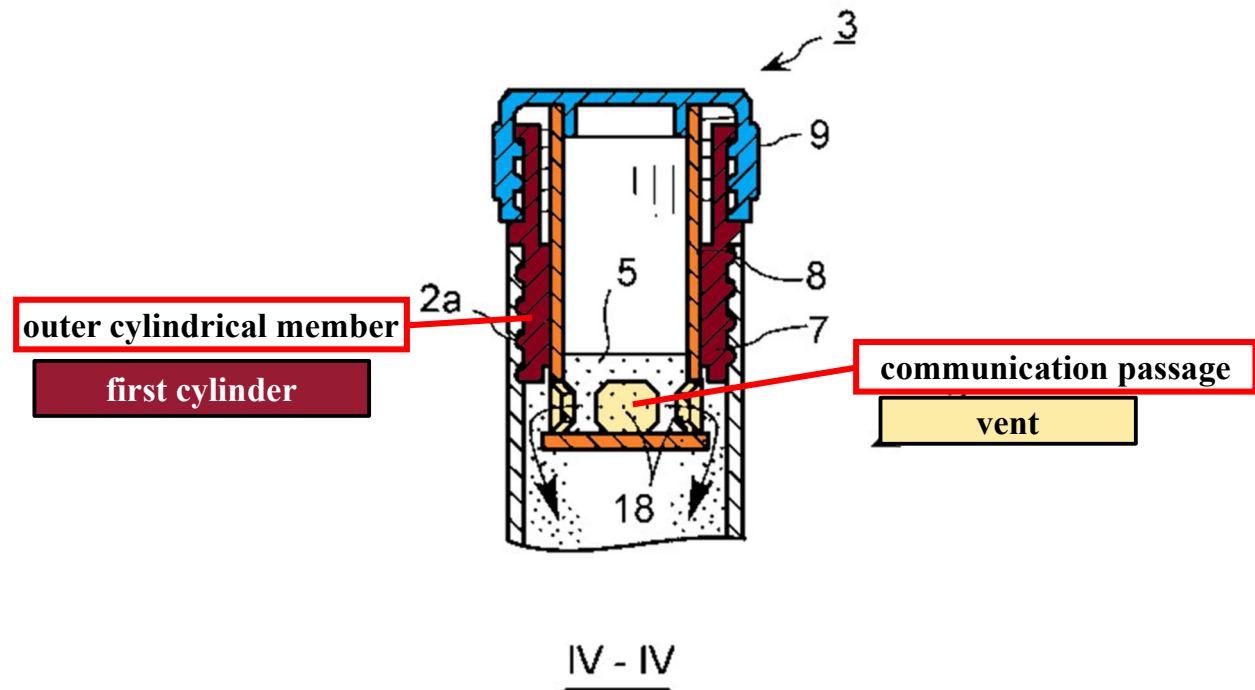
Claim 2 depends from claim 1 and recites “wherein the second cylinder comprises a sidewall and the sidewall comprises the vent, wherein the annular valve's closed configuration comprises a sidewall of the first cylinder obstructing the vent and the annular valve's open configuration comprises the sidewall of the first cylinder not obstructing the vent.” Ueda discloses this limitation. Ex.1002, ¶¶ 212–214.

Ueda’s second cylinder (mixture holding member 8) includes a sidewall with a vent (communication passages 18). Ex.1005, [0027]. In the closed configuration, the reagent is sealed in the mixture holding member as a sidewall of the first cylinder

7 obstructs the vent (passages 18) on the sidewall of the second cylinder to create a seal with the cap until the reagent is released into the container. *Id.* Annotated Figure 3B shows the closed configuration, with the sidewall of the first cylinder obstructing the vent:



In Ueda's open configuration, the sidewall of the first cylinder does not obstruct the vent. Ex.1005, [0027]. Annotated Figure 4B below shows the open configuration, where the sidewall of the first cylinder (outer cylindrical member 7) does not obstruct the vent (passages 18). Ex.1005, [0027]; Ex.1002, ¶¶ 213–214.



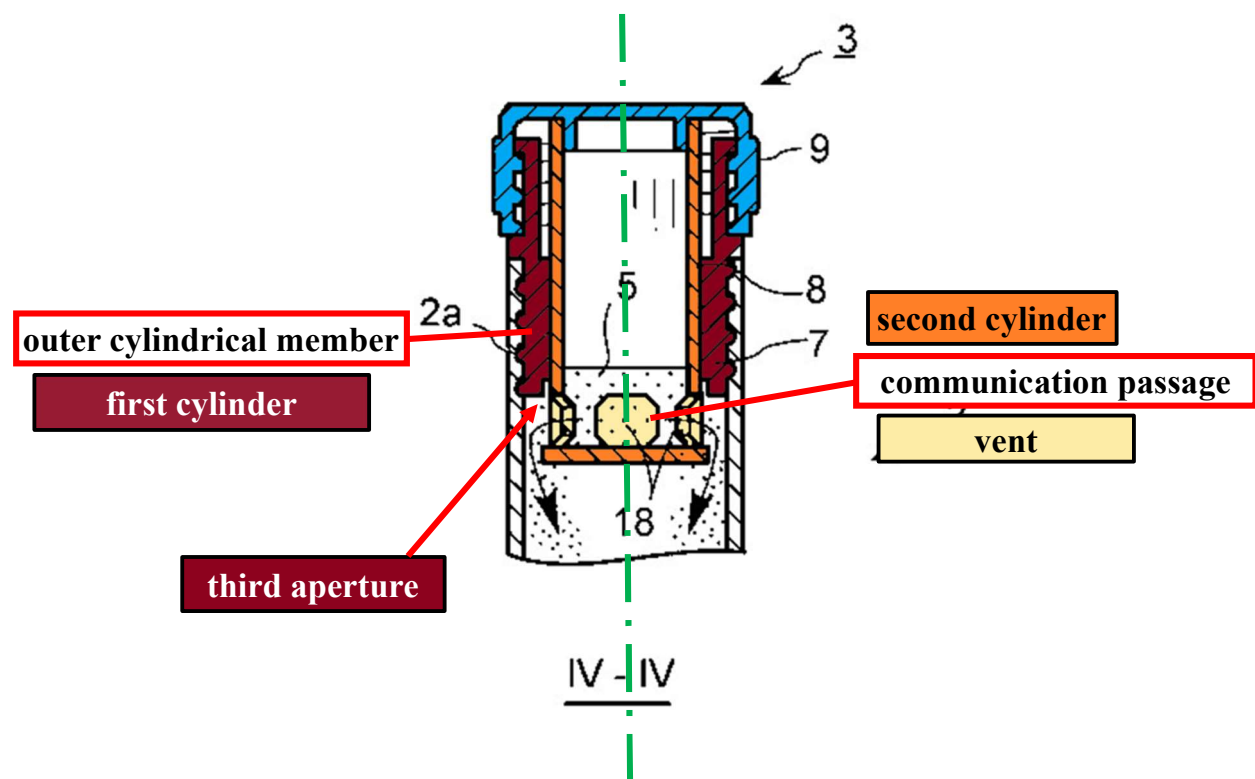
D. Ueda Anticipates Claims 3 and 4

Claim 3 depends from claim 1 and recites “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.”

Claim 4 depends from claim 1 and recites “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.”

Ueda discloses the limitations of claims 3 and 4. Ex.1002, ¶¶ 215–217. As Ueda’s plug member 9 is screwed onto the first cylinder 7 toward the container body 2, the second cylinder 8 “**slides vertically along its axial direction** within the outer

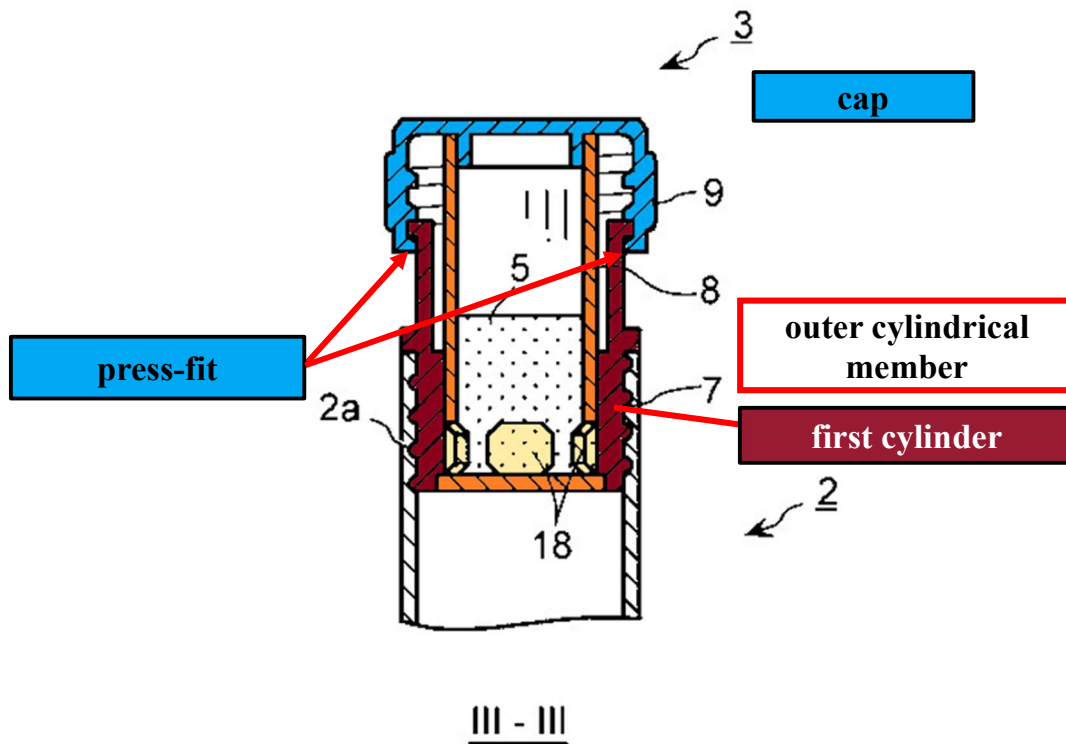
cylindrical member 7” to the open configuration. Ex.1005, [0027], Fig. 4B. As the cap is tightened and further screwed towards the container, the second cylinder 8 moves translationally downward within the aperture in the first cylinder 7 along a longitudinal axis (shown in green below) of the cap 3 until the walls of the first cylinder 7 no longer block the vents, thus moving the annular valve from the closed configuration to the open configuration, as shown in Figure 4B below. Ueda’s Figs. 3B and 4B illustrate the translational movement. Ex.1002, ¶ 217.



E. Ueda Anticipates Claim 5

Claim 5 depends from claim 1 and recites “wherein the first cylinder comprises a press-fit connection with the cap.” Ueda discloses this limitation. Ex.1002, ¶¶ 218–220.

As discussed in Ground 2 (Section VIII) above, the ’632 patent specification does not use the term “press-fit,” nor does it explain what a press-fit is or whether any of the disclosed connections are press-fits. Rather, the ’632 patent discloses a *threaded* connection between the first cylinder and the cap. Ex.1002, ¶ 219. Ueda discloses a press-fit connection between the upper flange 15 of the first cylinder and the cap (*see* second flange portion 15 on the first cylinder and the bottom inner protrusion of the cap in Ueda Figures 2, 3B and 4B). *Id.* This press-fit allows the second flange portion 15 of the first cylinder to be pressed into the threaded portion of the cap such that the cap can be screwed onto the first cylinder, but the cap is not easily removed from the first cylinder. *Id.*



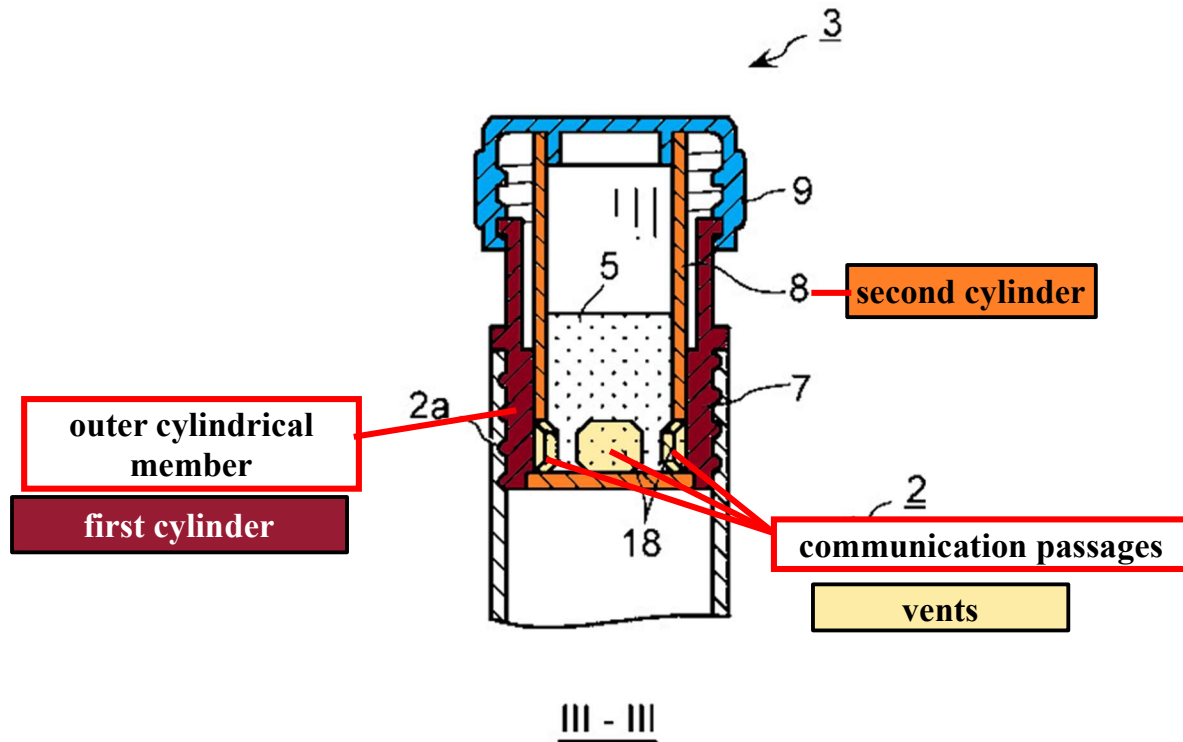
Moreover, Ueda's cap also includes a press-fit connection between the first cylinder (outer cylindrical member 7) and the second cylinder (mixture holding member 8) which is part of the cap. Ex.1002, ¶ 220. Ueda's first cylinder 7 overlaps with the second cylinder 8, blocking the vents and creating a fluid-tight seal with the cap to retain the reagent 5 within the second cylinder 8. Ex.1005, [0028], Figs. 2-4B; Ex.1002, ¶ 220. Ueda further discloses that "the bottom wall plate is constructed so as to liquid-tightly seal the space between the outer cylindrical member 7 and the mixture holding member 8." *Id.*, [0028]. As shown above in Ueda's Figure 3B, the press-fit connection between the first cylinder (outer cylindrical member 7) and the

second cylinder (mixture holding member 8), which is part of the cap. Ex.1002, ¶ 220. A press-fit is used to maintain a seal between the cylinders of the cap. *Id.*

F. Ueda Anticipates Claim 6

Claim 6 depends from claim 1 and recites “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.”

Ueda discloses this limitation. Ex.1002, ¶¶ 221–222. Ueda’s second cylinder (mixture holding member 8) has a plurality of vents (communication passages 18). Ex.1005, [0027], Figs. 2-4B. In the closed configuration, the first cylinder 7 overlaps with the second cylinder 8, obstructing the vents 18, as shown below in annotated Figure 4B. *Id.*



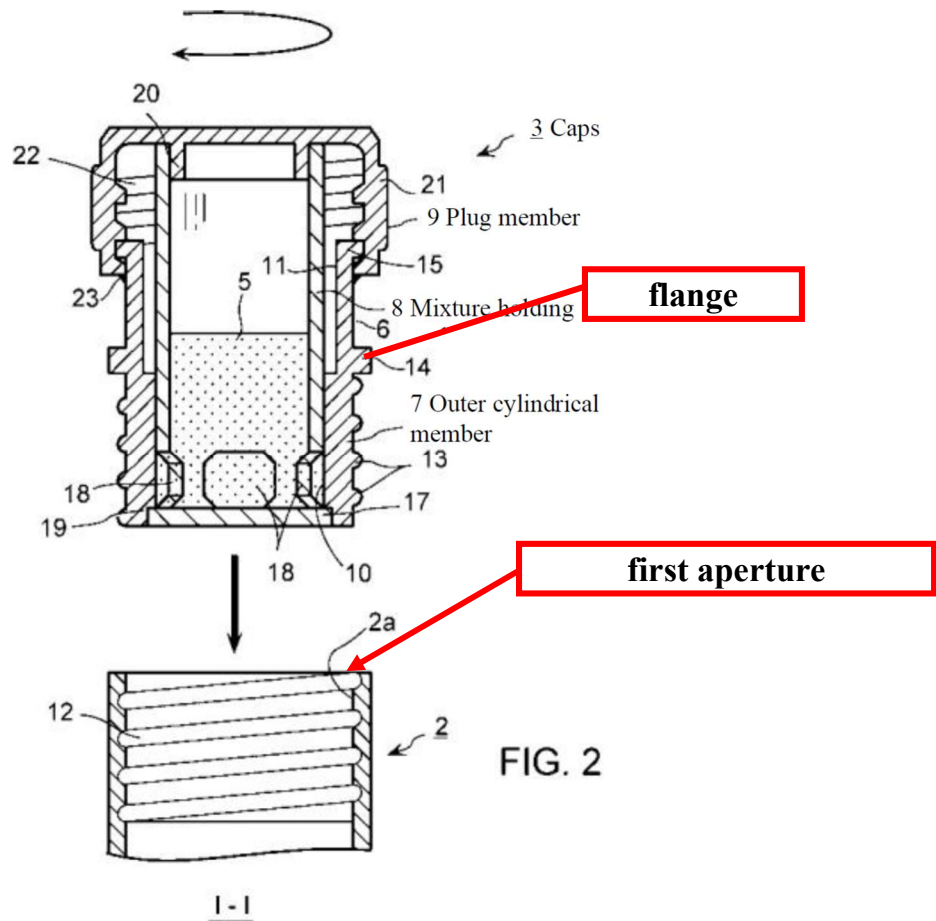
G. Ueda Anticipates Claims 7 and 8

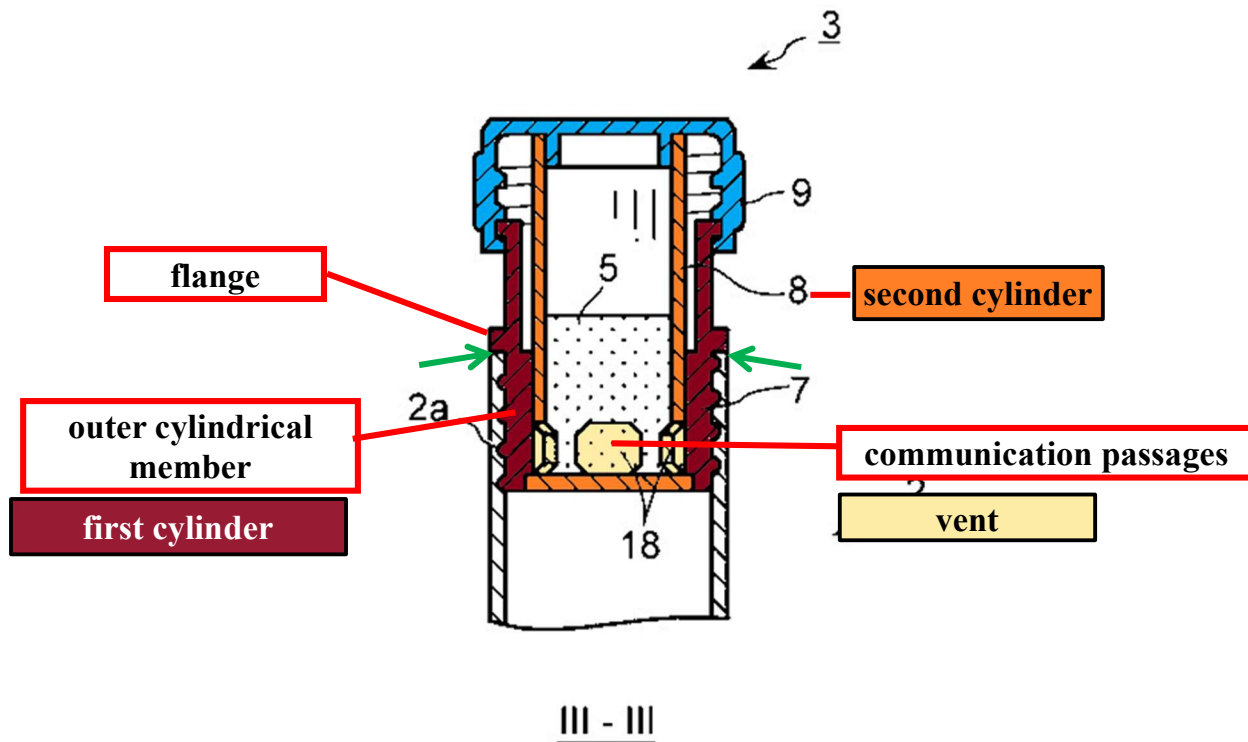
Claim 7 depends from claim 1 and recites “wherein the first cylinder of the annular valve comprises a flange and the annular valve with flange comprises a width larger than a width of the first aperture.”

Claim 8 depends from claim 7 and recites “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.”

Ueda discloses the limitations of claims 7 and 8. Ex.1002, ¶¶ 223–225. Ueda’s first cylinder 7 includes a flange (first flange part 14), which has a width

larger than a width of the first aperture in the sample collection vessel 2, as shown below in annotated Figs. 2 and 3B. Ex.1002, ¶ 225. As Ueda's cap is screwed onto the container/vessel 2, the flange 14 of the first cylinder 7 contacts and interacts with the top of the container body 2 (see green arrows) and causes the first cylinder 7 to stop moving relative to the container body 2 while the second cylinder 8 continues to move downward relative to the container 2. Ex.1005, [0026]-[0029]; Ex.1002. ¶ 225.



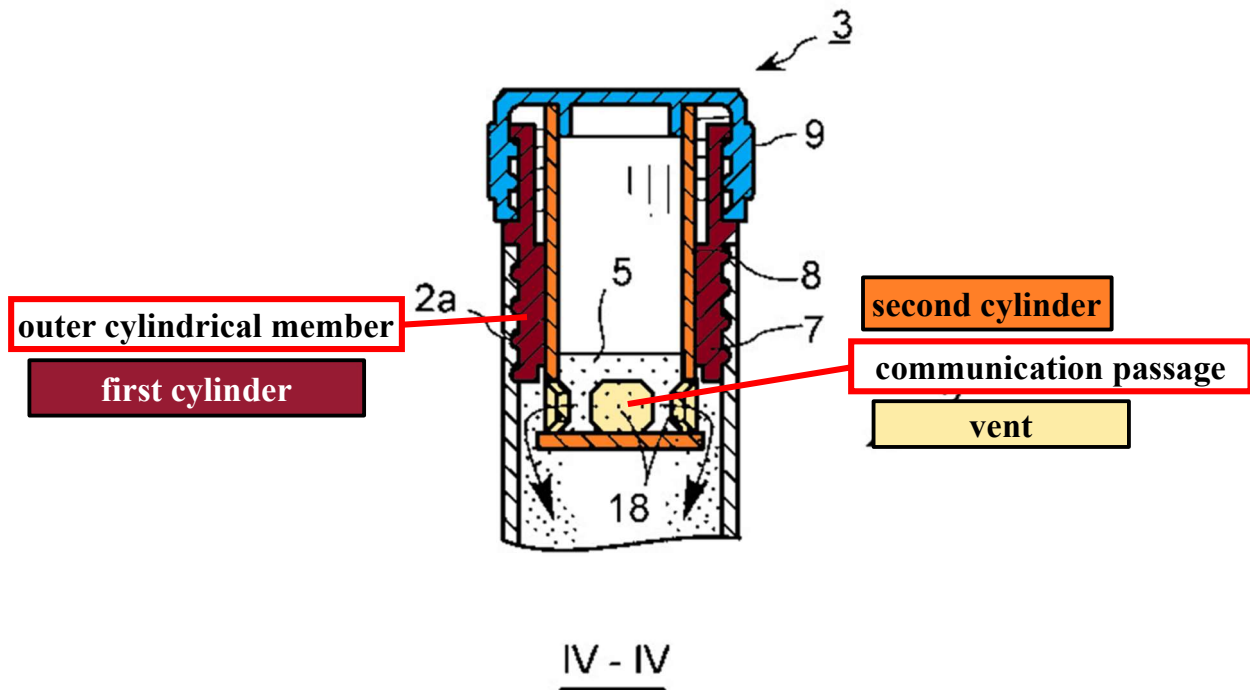


H. Ueda Anticipates Claims 10 and 11

Claim 10 depends from claim 1 and recites “wherein the vent is at least partially unobstructed in the annular valve's open configuration.” Claim 11 depends from claim 1 and recites “wherein the vent is fully unobstructed in the annular valve's open configuration.” Ueda discloses these limitations. Ex.1002, ¶¶ 226–227.

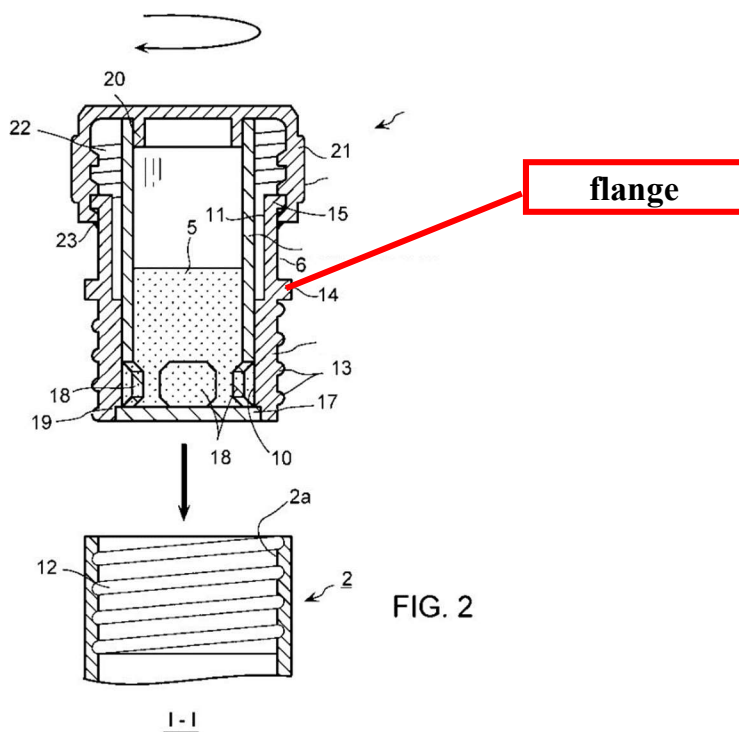
When Ueda's cap 3 is completely tightened on the container 2, the second cylinder (mixture holding member 8) has moved vertically downward so that the vent (passage 18) is open to allow passage of the reagent. Ex.1005, [0027], Fig. 4B. Ueda's annotated Figure 4B below shows the movable annular valve in an open configuration in which the first cylinder (outer cylindrical member 7) no longer

covers or obstructs the vent (communication passage 18) such that the vent is unobstructed in that configuration. *Id.* Thus, the vent is both at least partially unobstructed and fully unobstructed in the open configuration. Ex.1002, ¶ 227.

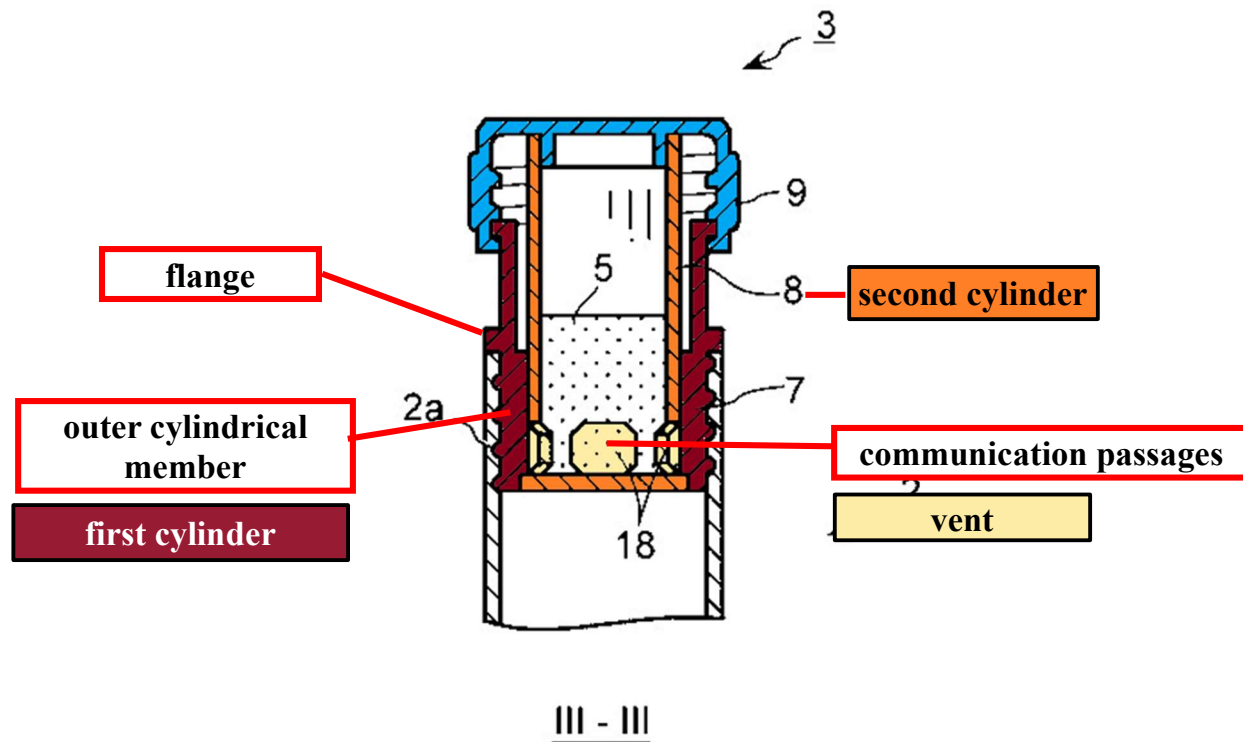


I. Ueda Anticipates Claims 12 and 13

Claim 12 depends from claim 1 and recites “wherein the first and second cylinders comprise generally constant exterior diameters.” Claim 13 depends from claim 12 and recites “wherein the annular valve comprises a flange extending from at least one of the first and second cylinders.” Ueda discloses these limitations. Ex.1002, ¶¶ 228–229.



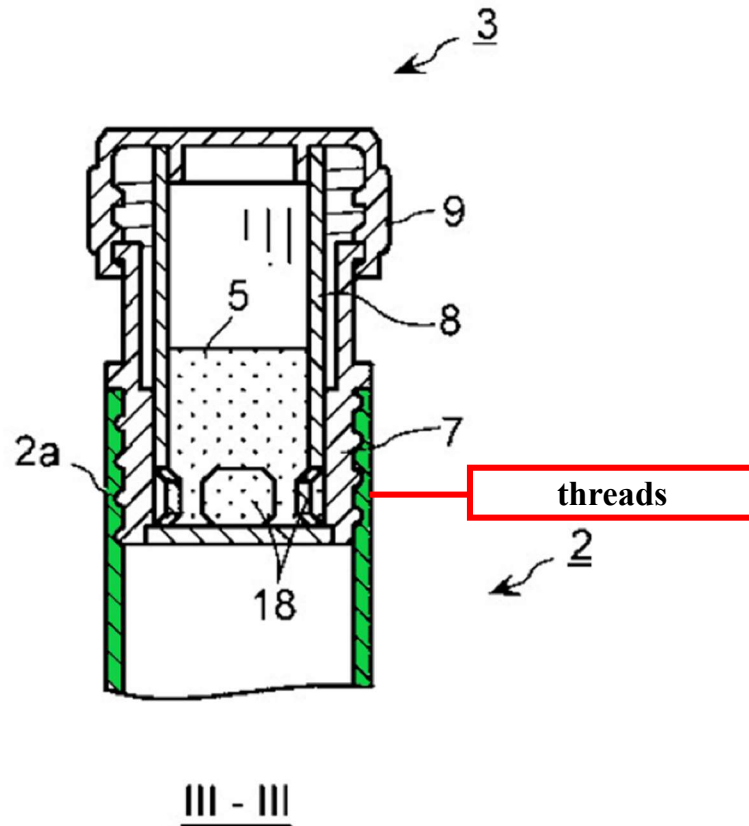
As shown in Figure 2 above and Figure 3B below, Ueda’s first cylinder 7 and second cylinder 8 have generally constant exterior diameters. Ex.1002, ¶ 229. Ueda’s first cylinder 7 also includes a flange (first flange part 14) which extends from the first cylinder. Ex.1002, ¶ 229; Ex.1005, [0026]-[0029].



J. Ueda Anticipates Claim 14

Claim 14 depends from claim 1 and recites “wherein the first and second connection members comprise a threaded connection.” Ueda discloses this limitation. Ex.1002, ¶¶ 230–231.

Like the '632 patent, Ueda discloses a threaded connection between the cap and sample receiving container body 2, namely thread set 13 on the cap (second connection member) and corresponding thread set 12 on the container body (first connection member). Ex.1005, [0026], Figs. 1 and 2. Ueda’s Figure 3B below, shows the container body 2 with internal threads adjacent to the opening that engage with and allow the cap to screw onto the container body.

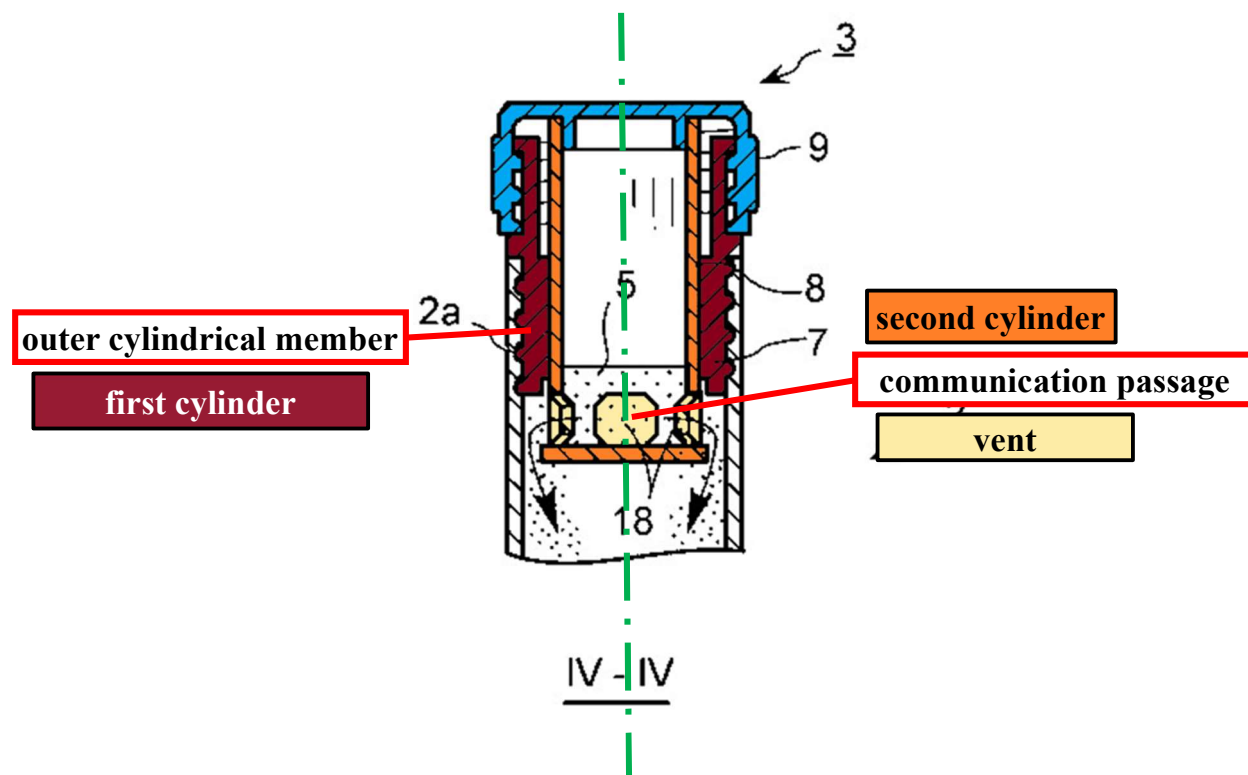


K. Ueda Anticipates Claim 15

Claim 15 depends from claim 1 and recites “wherein the annular valve comprises a sliding connection between the first and second cylinders.” Ueda discloses this limitation. Ex.1002, ¶¶ 232–233.

When Ueda’s plug member 9 is screwed onto the first cylinder 7 toward the container body 2, the second cylinder 8 “*slides* vertically along its axial direction within the outer cylindrical member 7.” Ex.1005, [0027] (emphasis added), Fig. 4B. As the cap is tightened and further screwed towards the container, the second

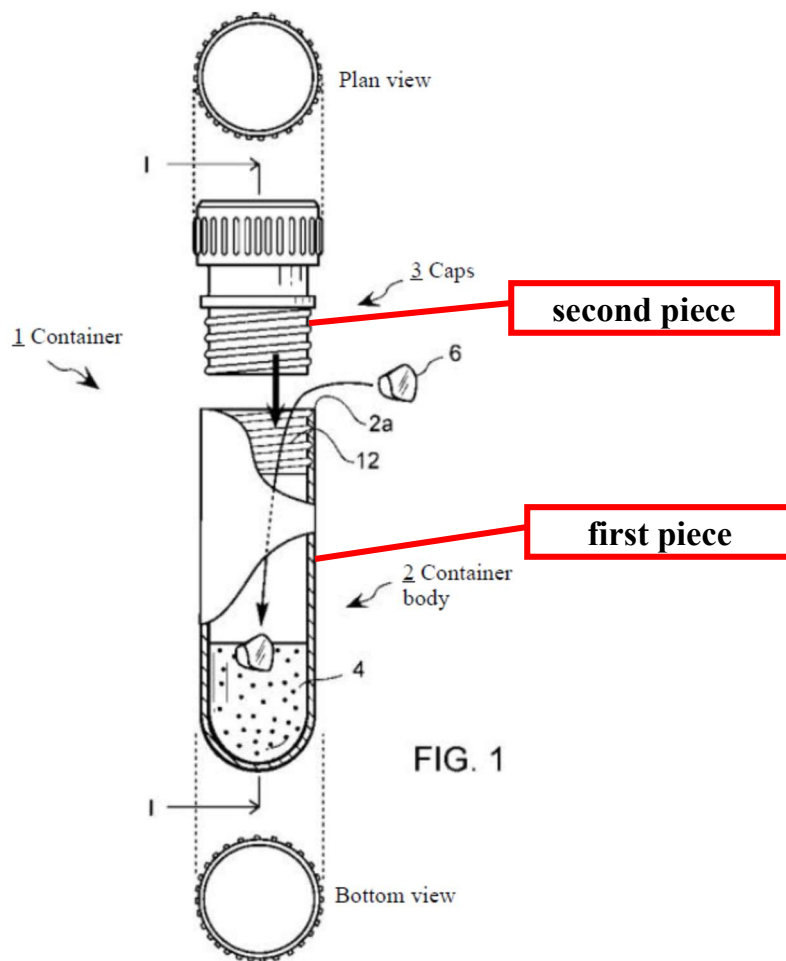
cylinder 8 moves downward in a sliding connection between the first and second cylinders, as shown below in annotated Figure 4B. Ex.1002, ¶ 233.



L. Ueda Anticipates Claim 16

Claim 16 depends from claim 1 and 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.” Ueda discloses this limitation. Ex.1002, ¶¶ 234–235.

Ueda's sample collection system includes two separable pieces. The first piece is the sample collection vessel (container body 2) and the second piece is the cap 3 with its movable annular valve, as shown in Figure 1 below. Ex.1002, ¶ 235. Ueda explains that these two pieces are separable: "this container 1 is preferably supplied with the cap 3 attached to the container body 2 as shown in FIG. 3. Then, the above cap 3 is removed . . . [and] it is reinstalled." Ex.1005, ¶ [0034]. Figure 6 of Ueda includes a locking mechanism 29 between the cap and the container body, but no such locking mechanism exists in the embodiment of Figures 1-4B. Ex.1005, [0031]; Ex.1002, ¶ 235.

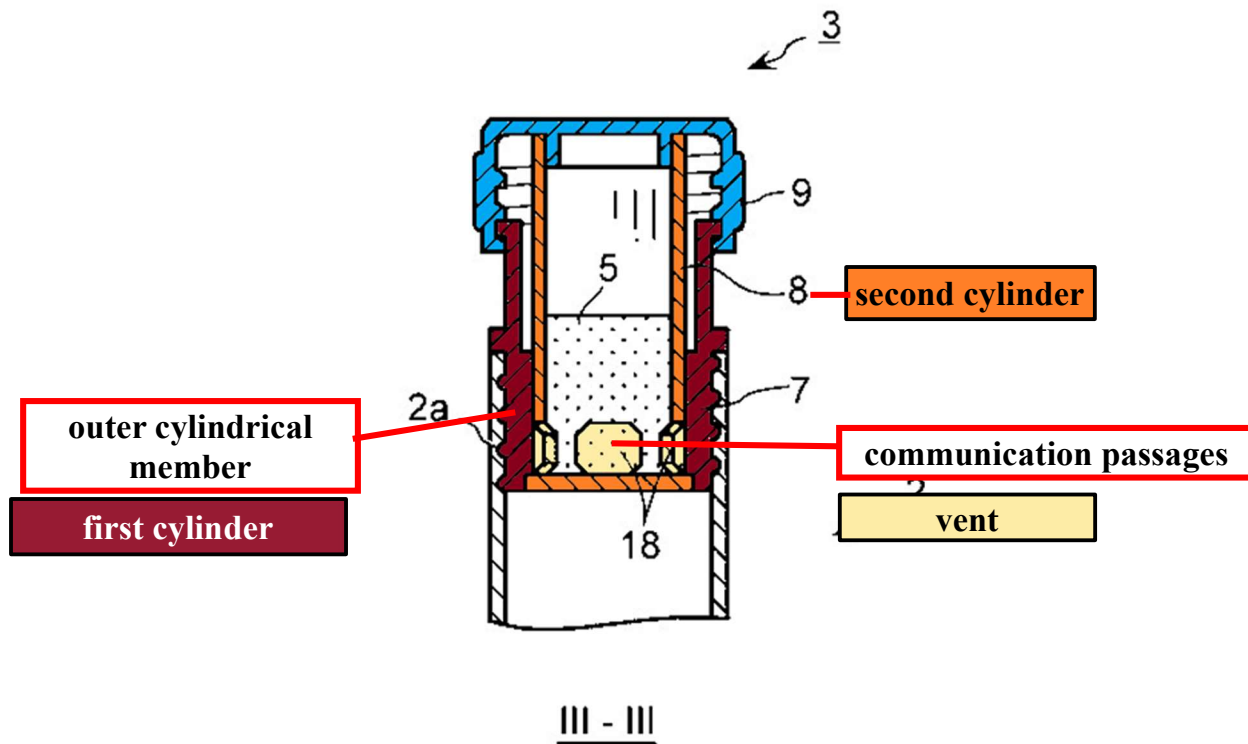


M. Ueda Anticipates Claim 18

Claim 18 depends from claim 1 and recites “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.” Ueda discloses this limitation. Ex.1002, ¶¶ 236–237.

Ueda’s annular valve includes an outer wall of the second cylinder (mixture holding member 8) that is sufficiently equal to the diameter of the inner wall of the

first cylinder (outer cylindrical member 7). Ex.1005, [0027], Figs. 2-4B. Ueda states “the mixture holding member 8 is a cylindrical member . . . and its outer diameter is formed to a dimension such that it slides vertically along its axial direction within the outer cylindrical member 7.” *Id.* In the closed configuration, “the ***communication passage 18 is closed*** by the inner peripheral surface of the outer cylindrical member 7.” *Id.* (emphasis added). Thus, Ueda’s first and second cylinders move relative to one another with inner wall of the first cylinder 7 is sufficiently equal to a diameter of an outer wall of the second cylinder 8 to create a fluid-tight connection therebetween. *Id.*; Ex.1002, ¶ 237; *see also* Section IX.B.16 regarding limitation 1[d][vi]. Annotated Figure 4B below shows the corresponding dimensions of Ueda’s cylinders with the interior sidewalls of the first cylinder 7 obstructing the vent 18 on the second cylinder 8 to retain the reagent mixture 5 in the storage chamber. Ex.1002, ¶ 237.

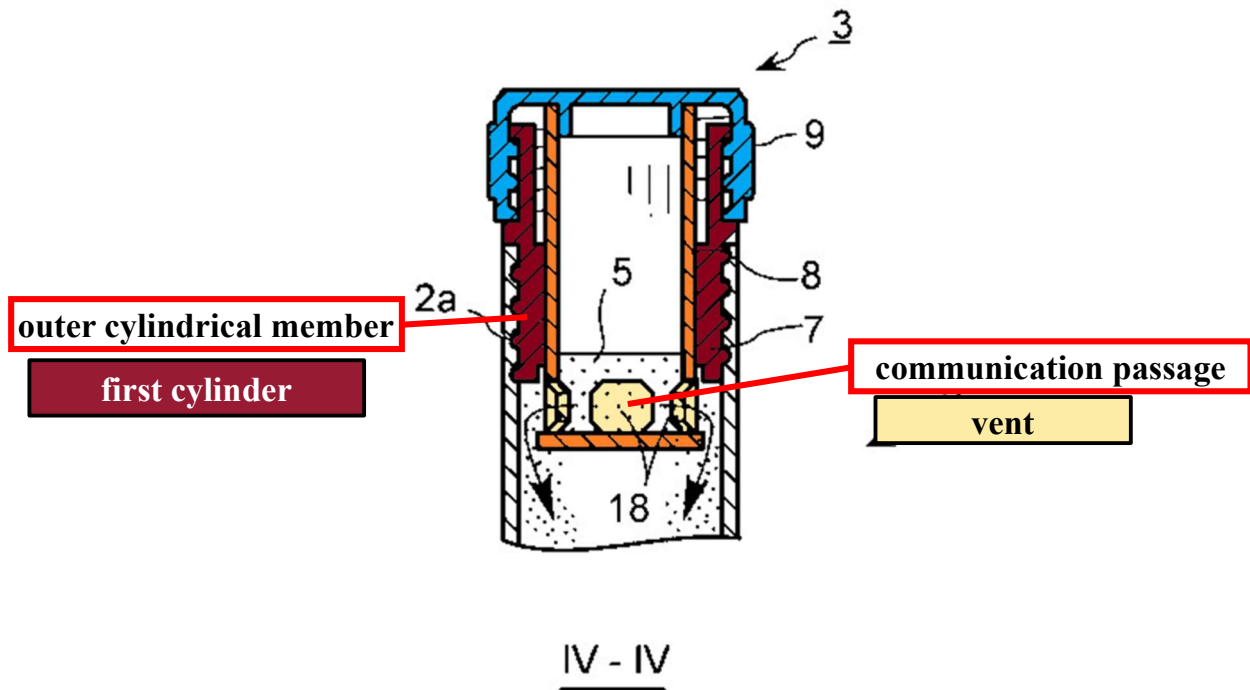


N. Ueda Anticipates Claim 19

Claim 19 depends from claim 1 and recites “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.” Ueda discloses this limitation. Ex.1002, ¶¶ 238–239.

When Ueda’s cap 3 is connected to and tightened on the sample collection vessel 2, the annular valve’s mixture holding member 8 “slides vertically along its axial direction within the outer cylindrical member 7” from the closed configuration to the open configuration. Ex.1005, [0027], Fig. 4B. Annotated Figure 4B shows the result of tightening the cap 3 onto the sample collection vessel 2, namely the

movable annular valve is moved to the open configuration, where the vent (communication passage 18) of the second cylinder (mixture holding member 8) has slid downward past the end of the interior sidewall of the first cylinder (outer cylindrical member 7). Ex.1005, Figs. 3B-4B; Ex.1002, ¶ 239.



O. Ueda Anticipates Claim 20

Claim 20 depends from claim 1 and recites limitations from claims 2, 3, and 19. As discussed above with regard to claims 2, 3, and 19, Ueda discloses these limitations. *See supra* Sections IX.C, IX.D. and IX.N.

X. GROUND 4: UEDA AND PATTERSON RENDER OBVIOUS CLAIM 5

Claim 5 depends from claim 1 and recites “wherein the first cylinder comprises a press-fit connection with the cap.” This limitation would have been obvious in view of Ueda and Patterson. Ex.1002, ¶¶ 241–247.

As discussed in Ground 2 (Section VIII) above, the ’632 patent specification does not use the term “press-fit,” nor does it explain what a press-fit is or whether any of the disclosed connections are press-fits. Rather, the ’632 patent discloses a *threaded* connection between the first cylinder and the cap (*see* thread features 44 and 45 in Figures 3A and 3B). Ex.1002, ¶ 242. As discussed above in Ground 3, Ueda discloses this limitation. This limitation would have also been obvious to a POSA. *Id.*

The lack of disclosure in the ’632 patent suggests that the use of a press-fit connection in this context must have been familiar to a POSA and easily implemented. Ex.1002, ¶ 243. Rather than expressly describing a press-fit connection between the first cylinder and the cap, the ’632 patent generally identifies various types of “well known” connections, including push, rotate, screw, mate, thread, couple, and attach. Ex.1001, 10:58-67. Thus, according to the ’632 patent, it was unnecessary to expressly describe a press-fit connection because such connections were well known. *Id.*; Ex.1002, ¶ 243. Consistent with the ’632 patent disclosure, it would have been obvious to design a first cylinder having a press-fit

connection with the cap and a POSA would have a reasonable expectation of success in implementing such a connection in a cap like Ueda's. Ex.1002, ¶ 243.

The prior art also confirms that press-fit connections in container caps were well known before the '632 patent. For example, Patterson teaches press-fit connections between cylindrical parts of the cap that do not involve threads, as explained above in Ground 2 (Section VIII). Ex.1010, [0032]; Ex.1002, ¶ 244. In Patterson's press-fit (interference fit or snap fit) between the two cylinders, the rounded upper flange 48 is pressed passed the rounded inner medial flange 26 of the outer cylinder 20, facilitating the passage of ingredients from the mixing cap 10 to the container. *Id.*; Ex. 1010, [0031]-[0039] . The '632 patent identifies a "snap-fit" as a type of pushing connection or press-fit. Ex.1001, 10:65-67. Thus, Patterson teaches the use of a non-threaded press-fit connection between cylinders in an annular valve that releases a reagent from a cap into a container. Ex.1002, ¶ 244.

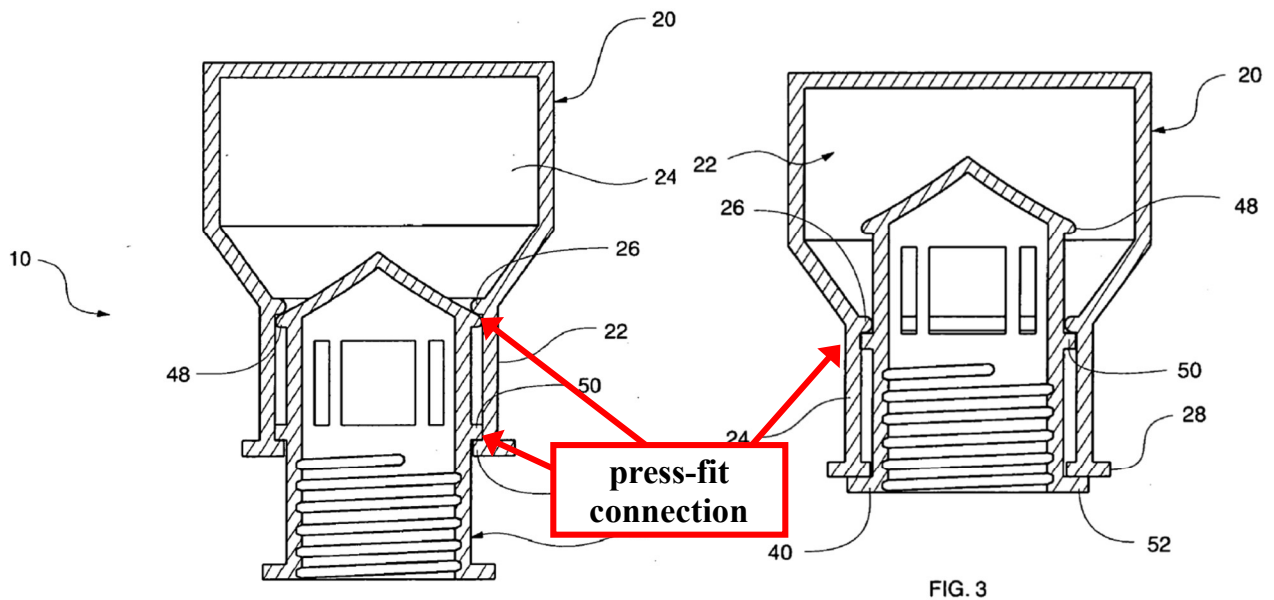


FIG. 2

FIG. 3

It would have been obvious for a POSA to modify Ueda's movable annular valve in view of Patterson such that the threaded connection between the first cylinder 7 and the cap 9 is replaced with a press-fit connection like Patterson's, as illustrated in the modified version of Ueda's Figure 3B below. Ex.1002, ¶ 245. In this modified design, the user would screw the cap assembly 3 onto the container, and then press the cap 9 downward relative to the first cylinder 7 which would push the second cylinder 8 downward relative to the first cylinder 7 and unblock the vent 18. *Id.* Alternatively, a POSA could also implement a connection like Patterson's non-threaded press-fit in the connection between Ueda's first cylinder 7 and the vessel 2 instead of that threaded connection. *Id.*

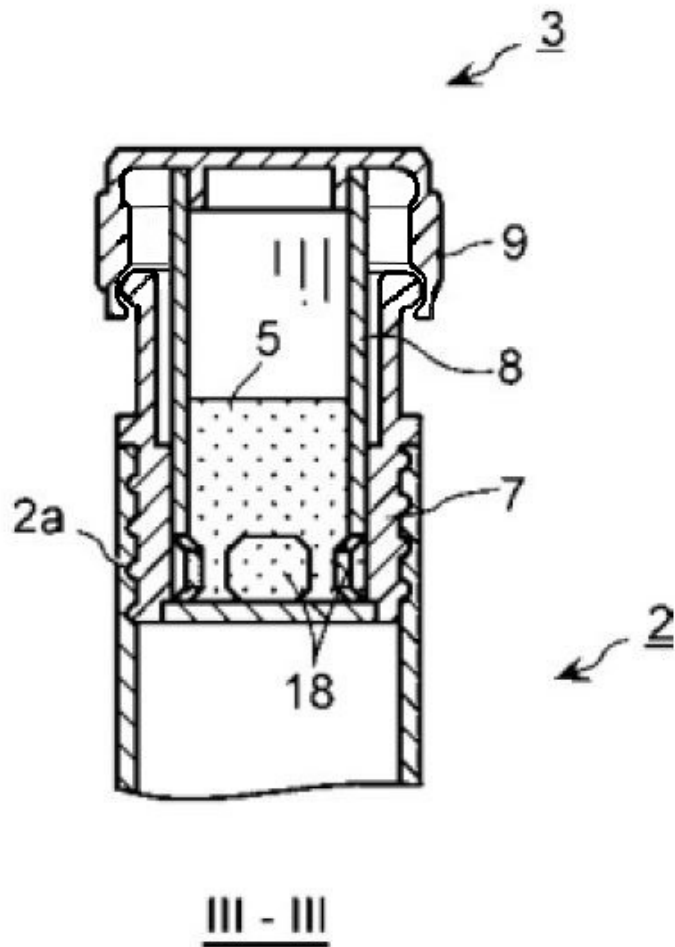


FIG. 3B

Patterson's press-fit, which would have been obvious to incorporate into Ueda's cap, could also be designed as a simple press-fit with only an interference-fit and no snap feature. Ex.1002, ¶ 246. Such simple press-fits were common and well-known to a POSA. *Id.* This is supported by the straight interference fits shown

by Figures 3B and 44 of Ueda and Cho respectively between the two cylinders that form a seal with a lead-in chamfer to facilitate the connection. *Id.*

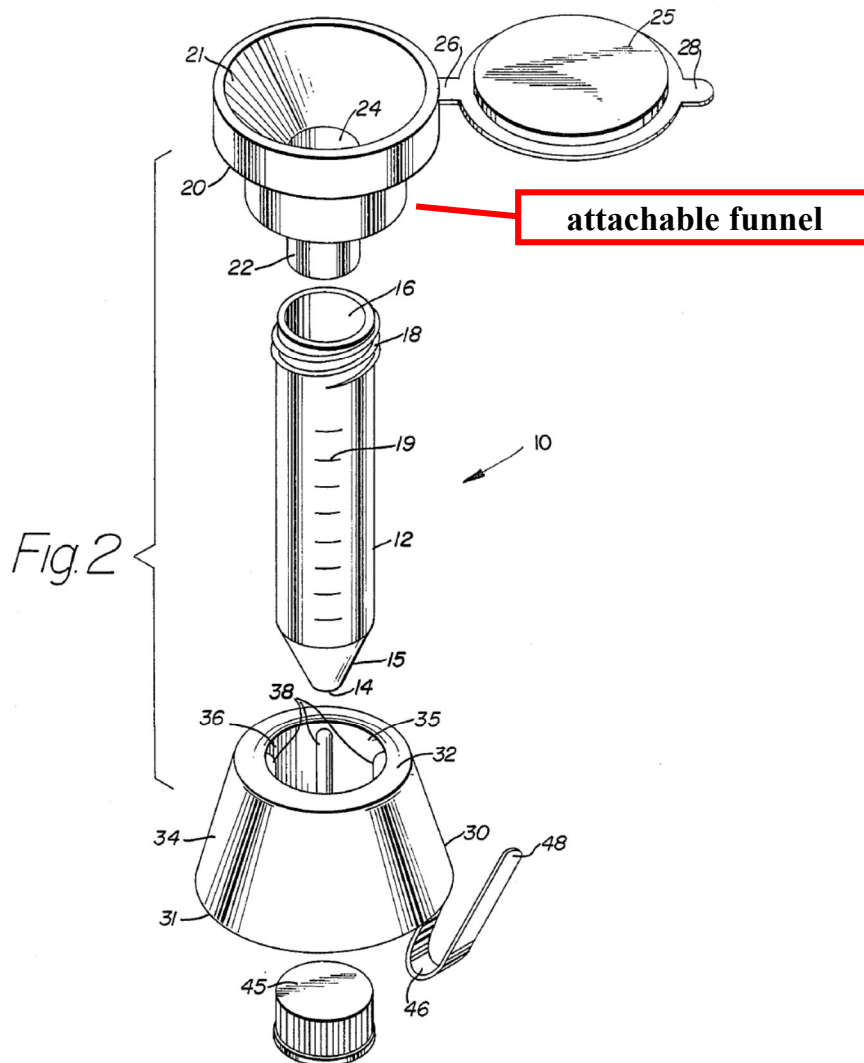
Using a non-threaded press-fit instead of a threaded connection would have been a mere design choice, and a POSA would have had a reasonable expectation of success implementing such a connection, as shown in Patterson. Ex.1002, ¶ 247. A POSA would have been motivated to use a threadless press-fit between the first cylinder and the cap because it would simplify the design and manufacturing process by eliminating the threaded portions. *Id.* A POSA would have understood that molding threads on these types of devices can be difficult and requires a more complex manufacturing process. *Id.* Molding a protrusion, bump, or a rib is much easier than helical threads. *Id.* The non-threaded press-fit would also allow for faster and easier engagement of the cap to release the reagent into the vessel because the user could simply press the cap toward the vessel in one movement as opposed to screwing the cap onto the threads. *Id.*

XI. GROUND 5: UEDA AND WILLIAMS RENDER OBVIOUS CLAIM 9

Claim 9 depends from claim 1 and recites “further comprising a funnel attachable to the sample collection vessel.” This limitation would have been obvious in view of Ueda and Williams. Ex.1002, ¶¶ 248–251.

Using an attachable funnel in the Ueda system would have been obvious in view of Williams, which discloses a biological specimen collection device with a

funnel that removably attaches to a receptacle, as shown in Williams’ Figure 2 below. Ex.1009, Abstract, 2:39-43; 6:9-15. Williams’ design allows for “ready removal of the funnel after the specimen has been collected.” *Id.*, 4:11-22. A POSA would have had a reasonable expectation of success in attaching a funnel to the vessel of Ueda and would have been motivated to use the funnel for the same purpose it had been commonly used in the prior art. Ex.1002, ¶¶ 249–250. A POSA would have been motivated to use an attachable funnel because it was a common way to facilitate obtaining the biological saliva sample from the user while allowing for a smaller cap and sealed container. *Id.* The funnel provides a wider receiving portion that makes it easier for a user to spit saliva into or otherwise deposit bodily fluids. *Id.* Williams’ funnel 20 includes a “relatively wide specimen receiving portion 21 into which the specimen is deposited.” Ex. 1009, 4:11-22. The funnel 20 can be removed after the specimen is collected which helps maintain the cleanliness of the process and the vessel. *Id.*; Ex.1002, ¶ 249.



XII. THE BOARD SHOULD NOT EXERCISE DISCRETION TO DENY INSTITUTION

A. Board Should Not Decline Institution Pursuant to 35 U.S.C. § 325(d)

This is the first petition challenging the '632 patent. Also, the prior art cited herein was not applied by the Examiner during prosecution of the '632 patent.

Moreover, as described above, the Petition makes a strong showing that the challenged claims are unpatentable.

B. Board Should Not Decline Institution Pursuant to 35 U.S.C. § 314(a)

Patent Owner has not asserted the '632 patent against Petitioner and there is no parallel litigation involving the '632 patent. Moreover, this Petition raises a compelling case of unpatentability for the challenged claims of the '632 patent. Thus, none of the *Fintiv* factors support discretionary denial.

XIII. CONCLUSION

Petitioner respectfully requests that the Board institute an IPR and find claims 1-16 and 18-20 of the '632 patent unpatentable.

Dated: September 15, 2023

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APPENDIX 1

Listing of Claims from U.S. 11,536,632	
Claim 1 ²	
Preamble	1. A biological sample collection system, the system comprising:
1[a]	a sample collection vessel comprising
1[a][i]	a sample collection reservoir,
1[a][ii]	a first connection member, and
1[a][iii]	a first aperture for receiving a biological sample;
1[b]	a cap comprising
1[b][i]	a second aperture,
1[b][ii]	a reagent chamber storing a reagent therein, and
1[c]	a second connection member complementary to the first connection member; and
1[d]	a movable annular valve in the second aperture, the movable annular valve comprising
1[d][i]	a vent,
1[d][ii]	a first cylinder comprising a third aperture,
1[d][iii]	a second cylinder comprising the vent, the second cylinder positioned in the third aperture,
1[d][iv]	a closed configuration, and
1[d][v]	an open configuration, wherein

² Bracketed labels have been added for convenient referencing to the claim limitations.

Listing of Claims from U.S. 11,536,632	
1[d][vi]	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,
1[d][vii]	the first cylinder and second cylinder are relatively moveable to thereby change the annular valve from the closed configuration to the open configuration, and
1[d][viii]	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.
Claim 2	
--	2. The biological sample collection system of claim 1, 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.
Claim 3	
--	3. The biological sample collection system of claim 1, 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.
Claim 4	
--	4. The biological sample collection system of claim 1, 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.

Listing of Claims from U.S. 11,536,632	
Claim 5	
--	5. The biological sample collection system of claim 1, wherein the first cylinder comprises a press-fit connection with the cap.
Claim 6	
--	6. The biological sample collection system of claim 1, 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.
Claim 7	
--	7. The biological sample collection system of claim 1, 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.
Claim 8	
--	8. The biological sample collection system of claim 7, 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.
Claim 9	
--	9. The biological sample collection system of claim 1, further comprising a funnel attachable to the sample collection vessel.
Claim 10	

Listing of Claims from U.S. 11,536,632	
--	10. The biological sample collection system of claim 1, wherein the vent is at least partially unobstructed in the annular valve's open configuration.
Claim 11	
--	11. The biological sample collection system of claim 1, wherein the vent is fully unobstructed in the annular valve's open configuration.
Claim 12	
--	12. The biological sample collection system of claim 1, wherein the first and second cylinders comprise generally constant exterior diameters.
Claim 13	
--	13. The biological sample collection system of claim 12, wherein the annular valve comprises a flange extending from at least one of the first and second cylinders.
Claim 14	
--	14. The biological sample collection system of claim 1, wherein the first and second connection members comprise a threaded connection.
Claim 15	
--	15. The biological sample collection system of claim 1, wherein the annular valve comprises a sliding connection between the first and second cylinders.
Claim 16	

Listing of Claims from U.S. 11,536,632	
	16. The biological sample collection system of claim 1, 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.
Claim 17	
--	17. The biological sample collection system of claim 1, wherein the first cylinder comprises threads on an interior sidewall configured to mate with threads on an exterior sidewall of the second cylinder.
Claim 18	
--	18. The biological sample collection system of claim 1, 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.
Claim 19	
--	19. The biological sample collection system of claim 1, 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.
Claim 20	

Listing of Claims from U.S. 11,536,632	
--	20. The biological sample collection system of claim 1, 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 COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,536,632 contains 13,679 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 14,000 word type-volume limit specified by 37 C.F.R. § 42.24(a)(1).

Dated: September 15, 2023

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,536,632, PETITIONER’S POWER OF ATTORNEY, AND EXHIBITS 1001-1015 and 1017-1020, were served by FedEx on the Patent Owner at the correspondence address of record for the subject patent as follows:

58249 - COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
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A courtesy copy has been sent by FedEx on this day to Patent Owner’s counsel of record in the matter identified in Section I.B of the Petition as follows:

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