

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 IPR2023-01424
Patent 11,536,632

**DECLARATION OF KARL R. LEINSING, MSME, PE, IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 11,536,632**

TABLE OF CONTENTS

	Page No.
I. INTRODUCTION	1
II. BACKGROUND AND QUALIFICATIONS	1
III. LEGAL PRINCIPLES	4
A. Prior Art.....	4
B. Anticipation	4
C. Obviousness.....	4
IV. THE '632 PATENT.....	6
A. Specification of the '632 Patent	6
B. Claims of the '632 Patent.....	8
C. Prosecution History of the '632 Patent	11
V. BACKGROUND AND STATE OF THE ART	11
A. Biological Sample Collection Systems With a Reagent Chamber and Annular Valve in a Cap	11
1. Ueda	11
B. Biological Sample Collection Systems Having a Reagent Chamber in a Cap and a Piercing Member	15
1. Plante.....	15
C. Annular Valves in a Container Cap	20
1. Cho	20
2. Patterson.....	23
VI. LEVEL OF ORDINARY SKILL.....	27

TABLE OF CONTENTS
(cont'd)

	Page No.
VII. CLAIM CONSTRUCTION	29
A. “Biological Sample”	29
B. “Annular Valve”	30
VIII. GROUND 1: PLANTE AND CHO RENDER OBVIOUS CLAIMS 1-4, 6-16, AND 18-20	31
A. Plante and Cho Render Obvious Claim 1	31
1. Claim 1 Preamble.....	39
2. Limitation 1[a]: “a sample collection vessel comprising”	39
3. Limitation 1[a][i]: “a sample collection reservoir”	41
4. Limitation 1[a][ii]: “a first connection member”	42
5. Limitation 1[a][iii]: “a first aperture for receiving a biological sample”	44
6. Limitation 1[b]: “a cap comprising”	46
7. Limitation 1[b][i]: “a second aperture”	47
8. Limitation 1[b][ii]: “a reagent chamber storing a reagent therein”	49
9. Limitation 1[c]: “a second connection member complementary to the first connection member”	51
10. Limitation 1[d]: “a movable annular valve in the second aperture, the movable annular valve comprising”	52
11. Limitation 1[d][i]: “a vent”	55

TABLE OF CONTENTS

(*cont'd*)

	Page No.
12. Limitation 1[d][ii]: “a first cylinder comprising a third aperture”	56
13. Limitation 1[d][iii]: “a second cylinder comprising the vent, the second cylinder positioned in the third aperture”	58
14. Limitation 1[d][iv]: “a closed configuration”	61
15. Limitation 1[d][v]: “an open configuration, wherein”	63
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”	64
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”	67
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.”	68
B. Plante and Cho Render Obvious Claim 2	70
C. Plante and Cho Render Obvious Claims 3 and 4	72
D. Plante and Cho Render Obvious Claim 6	74
E. Plante and Cho Render Obvious Claims 7 and 8	75

TABLE OF CONTENTS

(*cont'd*)

	Page No.
F. Plante and Cho Render Obvious Claim 9	77
G. Plante and Cho Render Obvious Claims 10 and 11	83
H. Plante and Cho Render Obvious Claims 12 and 13	86
I. Plante and Cho Render Obvious Claim 14	87
J. Plante and Cho Render Obvious Claim 15	88
K. Plante and Cho Render Obvious Claim 16	89
L. Plante and Cho Render Obvious Claim 18	91
M. Plante and Cho Render Obvious Claim 19	92
N. Plante and Cho Render Obvious Claim 20	94
IX. GROUND 2: PLANTE, CHO, AND PATTERSON RENDER OBVIOUS CLAIM 5.....	94
X. GROUND 3: UEDA ANTICIPATES CLAIMS 1-8, 10-16, AND 18-20	102
A. Ueda Anticipates Claim 1	102
1. Claim 1 Preamble.....	104
2. Limitation 1[a]: “a sample collection vessel comprising”	105
3. Limitation 1[a][i]: “a sample collection reservoir”	106
4. Limitation 1[a][ii]: “a first connection member”.....	107
5. Limitation 1[a][iii]: “a first aperture for receiving a biological sample”	109

TABLE OF CONTENTS (*cont'd*)

	Page No.
6. Limitation 1[b]: “a cap comprising”	110
7. Limitation 1[b][i]: “a second aperture”	111
8. Limitation 1[b][ii]: “a reagent chamber storing a reagent therein”	112
9. Limitation 1[c]: “a second connection member complementary to the first connection member”	114
10. Limitation 1[d]: “a movable annular valve in the second aperture, the movable annular valve comprising”	115
11. Limitation 1[d][i]: “a vent”	118
12. Limitation 1[d][ii]: “a first cylinder comprising a third aperture”	119
13. Limitation 1[d][iii]: “a second cylinder comprising the vent, the second cylinder positioned in the third aperture”	122
14. Limitation 1[d][iv]: “a closed configuration, and”	124
15. Limitation 1[d][v]: “an open configuration, wherein”	126
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”	127
17. Limitation 1[d][vii]: “the first cylinder and second cylinder are relatively moveable to thereby change	

TABLE OF CONTENTS

(*cont'd*)

	Page No.
the annular valve from the closed configuration to the open configuration, and”	130
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.”	132
B. Ueda Anticipates Claim 2	134
C. Ueda Anticipates Claims 3 and 4	136
D. Ueda Anticipates Claim 5	138
E. Ueda Anticipates Claim 6	140
F. Ueda Anticipates Claims 7 and 8	141
G. Ueda Anticipates Claims 10 and 11	143
H. Ueda Anticipates Claims 12 and 13	145
I. Ueda Anticipates Claim 14	146
J. Ueda Anticipates Claim 15	148
K. Ueda Anticipates Claim 16	149
L. Ueda Anticipates Claim 18	151
M. Ueda Anticipates Claim 19	153
N. Ueda Anticipates Claim 20	154
XI. GROUND 4: UEDA AND PATTERSON RENDER OBVIOUS CLAIM 5.....	155

TABLE OF CONTENTS
(cont'd)

	Page No.
XII. GROUND 5: UEDA AND WILLIAMS RENDER OBVIOUS	
CLAIM 9.....	160
XIII. CONCLUSION	164

I. INTRODUCTION

1. I, Karl R. Leinsing, MSME, PE, submit this declaration on behalf of Petitioner Spectrum Solutions, LLC (“Petitioner” or “Spectrum”), regarding a Petition for *Inter Partes* Review of U.S. Patent No. 11,536,632 (“the ’632 patent”).

2. The subject of my declaration is the invalidity of the challenged claims of the ’632 patent. This declaration is provided after my review and analysis of the ’632 patent, the prior art, relevant background technology, and is also based on my education and experience, as well as additional materials identified herein.

II. BACKGROUND AND QUALIFICATIONS

3. I received a Bachelor of Science (B.S.) degree in mechanical engineering from the University of New Hampshire in 1988 and a Master of Science (M.S.) degree in mechanical engineering from North Carolina A&T State University in 1995. I am also licensed as a Registered Professional Engineer in the state of New Hampshire (License#: 11437).

4. I have been a medical device engineer since 1992 and have worked extensively with medical device disposables, including syringes of all types, since that date. I have extensive expertise in the mechanical design and manufacturing of medical devices. My areas of expertise include full-life cycle product development of medical devices, including conception, manufacturing, testing, verification, validation, packaging, bioburden testing, sterility assurance testing, residual testing,

biocompatibility, bacterial contamination testing, labeling, clinical trials, regulatory approval, marketing, and sales training.

5. Since 2006, I have been President of ATech Designs, Inc., where I have worked in the development of various medical devices, including cardiovascular, surgical, intravenous, endoluminal, and percutaneous devices. More specifically, I have consulted in the development of various drug delivery devices, such as auto-injectors, pen injectors, syringes, safety syringes, disinfecting caps, stop-cock valves, urinary catheter kits that include either bags or metered containers, IV valves, and catheter dressing designs that use a burst-type foil pouch that releases an antiseptic, subcutaneous ports, catheters, among others. In many of these applications, vaporized hydrogen peroxide, ethylene oxide (EtO), gamma irradiation, autoclave, or E-beam sterilization methods were used to sterilize the medical devices.

6. Previously, from 2005 to 2006, I worked as a Director of Biomedical Engineering at Mitralign, Inc., developing implants for heart valve repair. From 2002 to 2005, I worked as a Manager of Design Engineering at ONUX Medical, 3 Inc., developing fixation devices for abdominal aortic aneurysm repair as well as laparoscopic devices for stapling and sutures.

7. From 1992 to 2002, I worked as a Senior Principal Design Engineer at IVAC, which was a subsidiary of Eli Lilly & Company. There, I developed a number

of medical drug infusion products, including disposable sets and components, IV and syringe pump systems, injection systems, vial adapters, syringes, solution bags and containers, and needle-free valves for the delivery of drugs. My work involved both the conception and manufacturing of these devices, including both EtO and gamma irradiation sterilization of disposable medical devices such as syringes and male luer caps. During this time, I was the sole inventor of the SmartSite® Needle-Free Valve for intravenous infusion pumps and disposables. I was also involved in the development of a dual-acting pen injector, capable of dispensing both long-term and short-term insulin, for Eli Lilly (parent company of my employer IVAC). In addition to my extensive involvement with the design team for the entire device, my work focused on the development of the disposable needle, valve mechanism, and adapters that attached to the distal end of the device.

8. I am a named inventor of over 39 patents, all of which relate to the medical device field. I have previously lectured on the product design and manufacturing process of medical devices. I was also named Chairman of the Medical Device and Manufacturing Conference in 2014 for the development process of medical devices.

9. A copy of my curriculum vitae, attached as Exhibit A, contains further details concerning my education, experience, publications, patents, awards, recognition, licenses, and other qualifications to render an expert opinion in this

matter.

III. LEGAL PRINCIPLES

10. I am not a lawyer. Therefore, in formulating my opinions and conclusions in this proceeding, I have been provided with an understanding of the relevant aspects of U.S. patent law that govern the issues of patent validity.

A. Prior Art

11. I understand that, in this IPR proceeding, the prior art to the '632 patent includes patents and printed publications in the relevant field(s) that predate the '632 patent's priority date. Prior art for this IPR proceeding does not allow and does not present prior device art.

B. Anticipation

12. I understand that a person cannot obtain a patent if someone else already made the same invention, which is referred to as "anticipation." I understand that to anticipate a claim, each and every element in the claim must be, as properly construed, present in a prior art reference either expressly and/or inherently.

C. Obviousness

13. I understand that a claim of a patent may be obvious to a person of ordinary skill in the art if the differences between the subject matter set forth in the patent claim and the prior art are such that the claimed subject matter as a whole would have been obvious at the time of the invention.

14. I understand that obviousness is a determination of law based on various underlying determinations of fact. In particular, these underlying factual determinations include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art at the time the claimed invention was made; (3) the differences between the claimed invention and the prior art; and (4) the extent of any proffered objective “indicia” of non-obviousness. I understand that the objective indicia, also known as secondary considerations, which may be considered in such an analysis include, among other factors: the commercial success of the patented invention (including evidence of industry recognition or awards), the existence of a long-felt but unmet need in the field satisfied by the invention, the failure of others to arrive at the invention, industry acquiescence and recognition of the invention, initial skepticism of the invention by others in the field, the extent to which the inventors proceeded in a direction contrary to the accepted wisdom of those of ordinary skill in the art, and licensing of the patent.

15. In determining the scope and content of the prior art, I understand a reference is considered prior art for the obviousness analysis if it falls within the inventors’ field of endeavor. Additionally, a reference is prior art for the obviousness analysis, even if from a different field of endeavor, if it is reasonably pertinent to the particular problem for which the invention was made. A reference is reasonably pertinent if it is something a person of ordinary skill in the art would

have looked to when attempting to solve the problem.

16. While multiple prior art references or elements may be combined to render a patent claim obvious, I understand that a patent claim composed of several elements is not proven obvious merely by demonstrating that each of its elements was, independently, known in the prior art. I understand that I should consider whether there is an “apparent reason” or motivation to combine the prior art references or elements in the way the patent claims. It is my further understanding that the law recognizes several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known method or product ready for improvement; and choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.

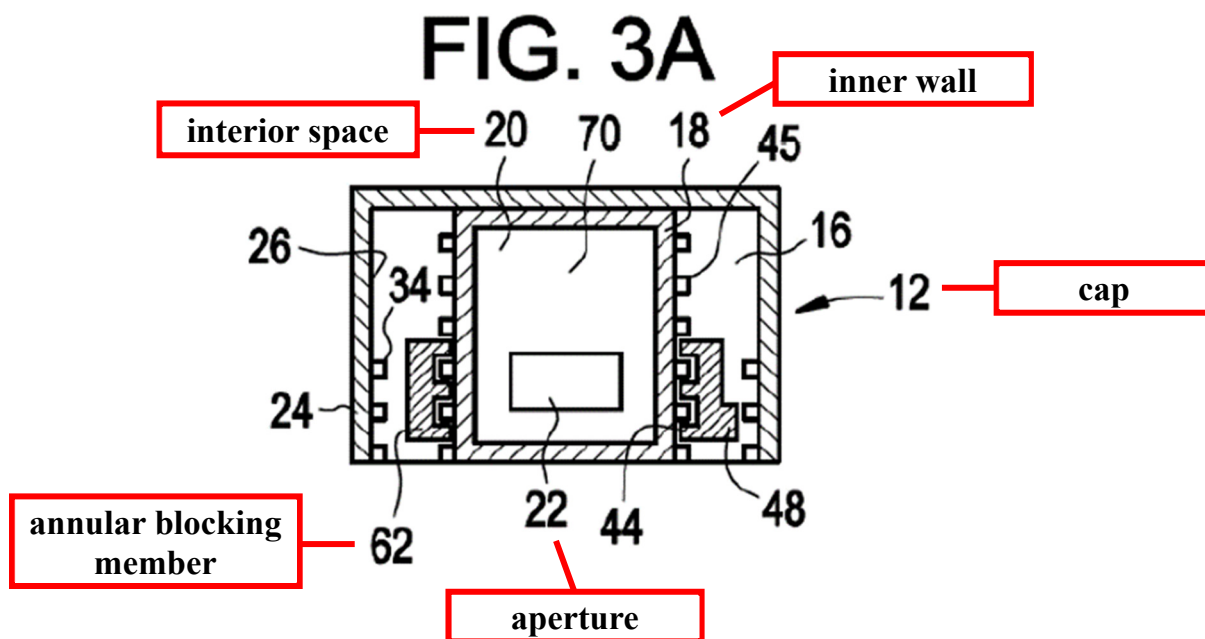
IV. THE '632 PATENT

A. Specification of the '632 Patent

17. The '632 patent is directed to “devices, solutions and methods for collecting samples of bodily fluids or other substances, including hazardous and/or toxic substances, and in particular, a naturally expressed bodily fluid (e.g., saliva,

urine).” Ex.1001, 1:20-24. The ’632 patent includes embodiments of a sample collection device that “have two main mating bodies, a cap and a tube.” *Id.*, 5:9-12; *see id.*, Figs. 1-7B. The cap holds a preservation solution and the tube receives the donor specimen. *Id.*, 5:11-15. When the user closes the cap on the tube, “the cavity holding the preservative solution may be opened to release the preservative solution and allow it to mix with the donor specimen.” *Id.*, 5:14-20.

18. Fig. 3A which illustrates an embodiment related to the claims of the ’632 patent is shown below, annotated with relevant labels from the patent specification.



Id., Fig. 3A (annotated). The described cap 12 includes an interior space 20 that is defined by an inner wall 18 and holds a sample preservation fluid or material 70. *Id.*, 14:10-24. 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 ’632 patent states that “when the aperture 22 is open such that 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, as shown in FIG. 3B.” *Id.*, 14:32-44, Fig. 3B.

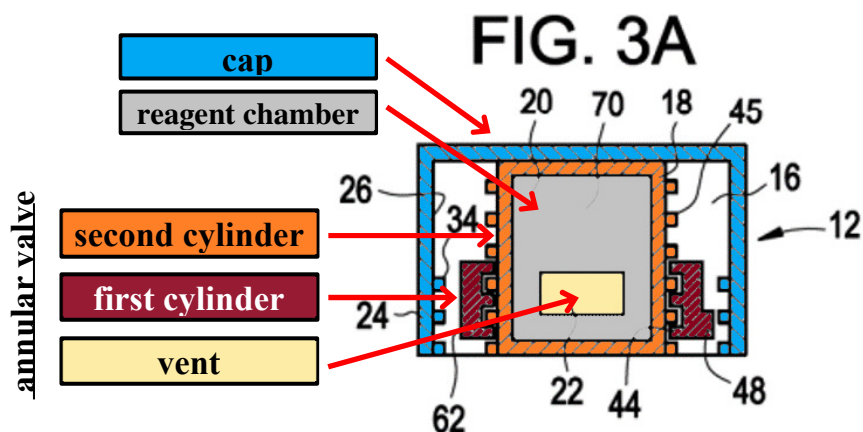
B. Claims of the ’632 Patent

19. Claim 1, the only independent claim of the ’632 patent, is set forth below (with bracketed labels added for convenient referencing to the claim limitations).

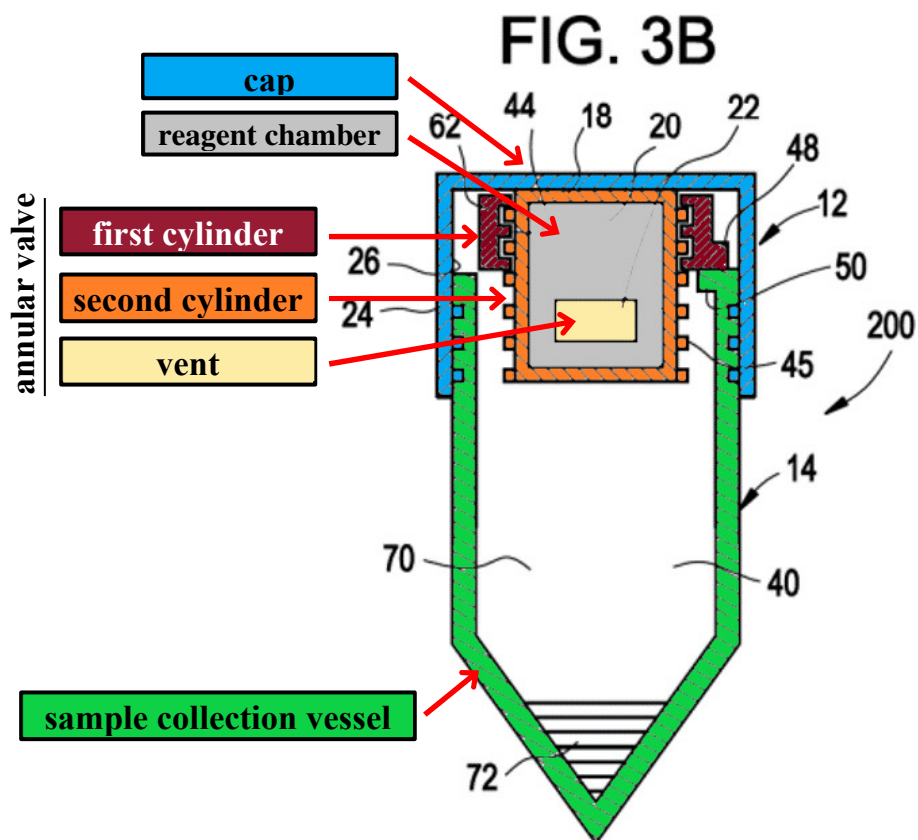
Claim 1	
Preamble	1. A biological sample collection system, the system comprising:
1[a]	a sample collection vessel comprising
1[a][i]	a sample collection reservoir,
1[a][ii]	a first connection member, and
1[a][iii]	a first aperture for receiving a biological sample;
1[b]	a cap comprising
1[b][i]	a second 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

Claim 1	
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
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.

20. The '632 patent claims use terminology that is not used in the patent specification. The relevant figures from the '632 patent have been annotated below with the claim terminology. In Fig. 3A shown below, the movable annular valve is in the *closed* configuration with the first cylinder covering the vent in the second cylinder.



Ex.1001, Fig. 3A (annotated), 14:24-32. Fig. 3B below shows the cap attached to the sample collection vessel. Here the annular valve is in the *open* configuration, with the first cylinder no longer blocking the vent:



Id., Fig. 3B (annotated), 14:32-37.

C. Prosecution History of the '632 Patent

21. I have reviewed the prosecution history of the application that led to the '632 patent. During prosecution of the '632 patent, the PTO issued only one substantive Office Action. Ex.1008, 89-95. In the Office Action, the Examiner rejected all pending claims as being indefinite and lacking written description. *Id.* Patent Owner amended the claims in response to the Examiner's rejections. *Id.*, 97-104.

22. I am not aware of any discussion or rejection of the claims by the Examiner based on the prior art discussed herein.

V. BACKGROUND AND STATE OF THE ART

A. Biological Sample Collection Systems With a Reagent Chamber and Annular Valve in a Cap

23. Biological sample collection systems similar to those disclosed and claimed in the '632 patent were known in the art prior to the '632 patent. These systems include a cap that attaches to a receiving vessel, and the cap includes a reagent chamber and annular valve.

1. Ueda

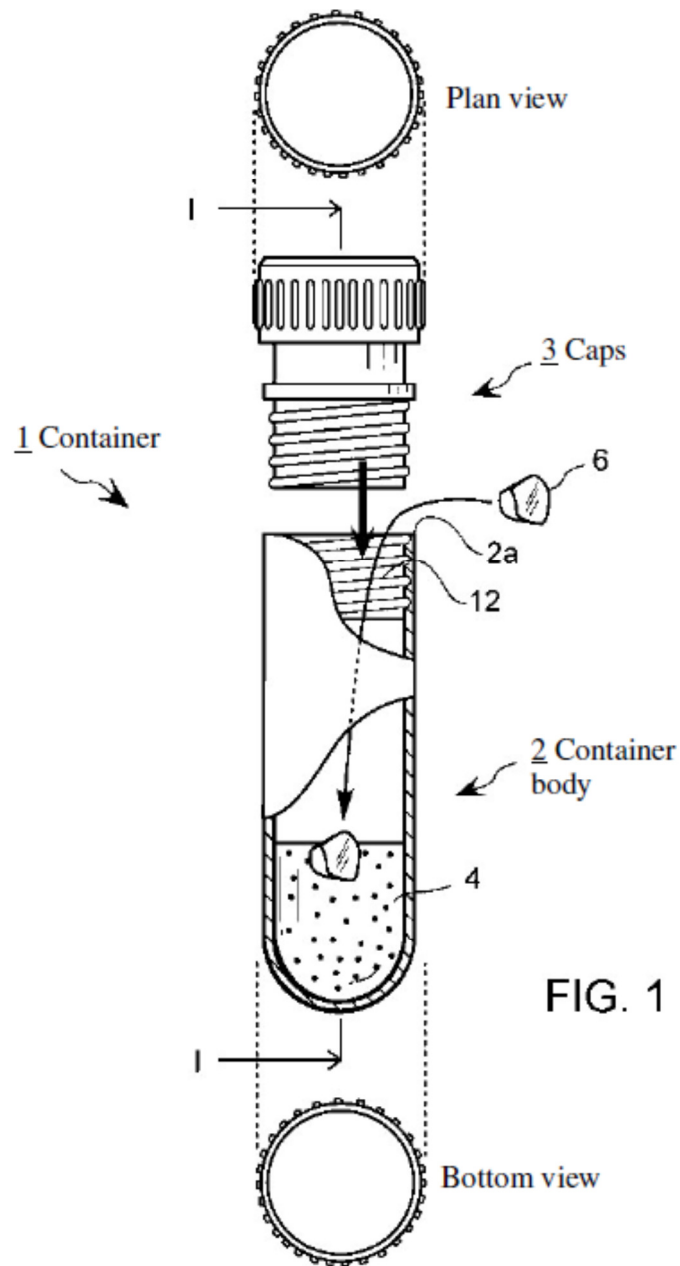
24. Japanese Patent Application Publication No. 2010-213660 ("Ueda", Ex.1005) describes a prior art biological sample collection system with a sample container and a cap having an annular valve. Ex.1005, [0020]. I understand Ueda

is prior art to the '632 patent because it was published on September 30, 2010, which is before the earliest filing date for the '632 patent in 2011. I am not aware of any information suggesting the '632 patent inventors made their invention before September 30, 2010.

25. Ueda's container system "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]. The container receives a biological sample and after the biological sample is placed into the container body 2, the system "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 reagent such as "a granular gelling material, where mixing this with the first mixed material 4 gels the first mixed material 4." *Id.*

26. Figure 1 of Ueda (below) illustrates the system with its container 1 and cap 3 before the cap 3 is screwed onto the container body 2. The biological sample 6 is received into the container body 2 before the cap is screwed onto the container body.

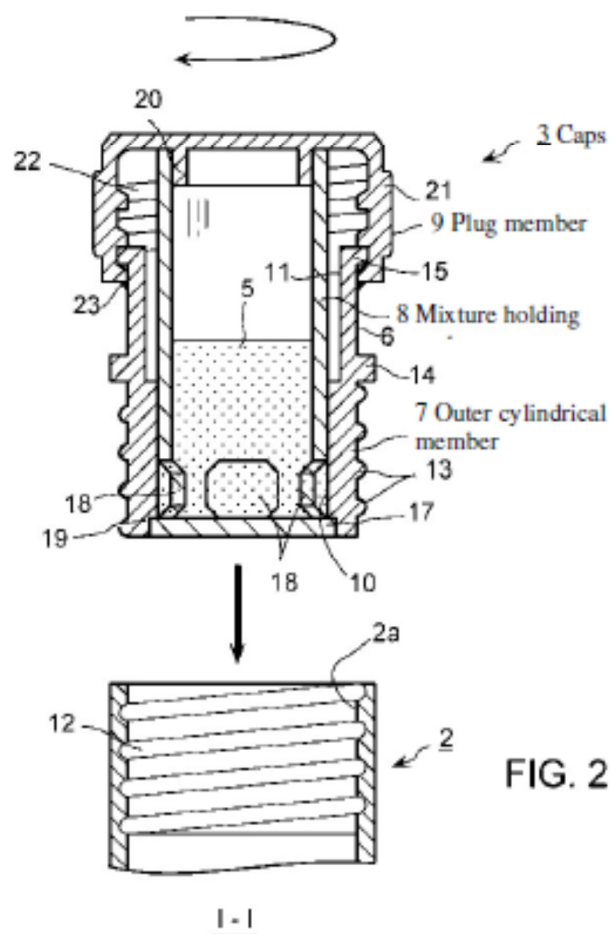
[FIG. 1]



27. As shown in Ueda's Figure 2 below, the 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]. These three members of the cap 3 provide a movable annular valve which releases the reagent from the reagent compartment of the cap 3 into the container body 2 through communication passages 18.

[FIG. 2]



B. Biological Sample Collection Systems Having a Reagent Chamber in a Cap and a Piercing Member

28. Similar biological sample collection systems incorporating a reagent chamber in a cap, but using a piercing member instead of an annular valve, were also known in the art prior to the '632 patent.

1. Plante

29. U.S. Patent Publication No. U.S. 2012/0325721 to Plante, et al ("Plante", Ex.1003) describes a prior art system for receiving and preserving a biological sample which includes a knife that pierces the reagent chamber to release the reagent. I understand Plante is prior art to the '632 patent because it was filed March 25, 2009, which is before the earliest filing date for the '632 patent in 2011. I am not aware of any information suggesting the '632 patent inventors made their invention before March 25, 2009.

30. The Plante system includes a sample collection vessel and a cap with a reagent chamber located in the cap. Fig. 1 of Plante is shown below:

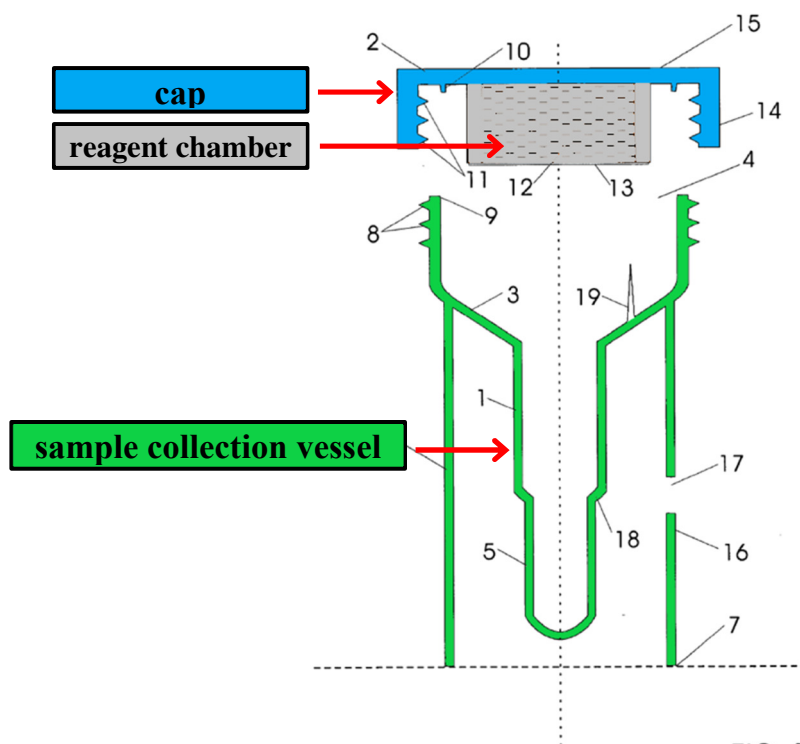


FIG. 1

Ex.1003, Fig. 1 (annotated), [0035]. Upon closing the cap, the reagent is released from the reagent chamber to mix with a biological sample (e.g., saliva) in the sample collection vessel. *Id.*, [0019], [0035], [0039].

31. The sealing cap includes a pierceable liquid reservoir. *Id.*, [0021]. The reservoir includes a preserving fluid to preserve the saliva sample. *Id.*, [0041]. The reservoir is sealed and protects the fluid until it is required for use. *Id.* Plante describes a breakable membrane or foil to seal the reagent chamber within the cap. *See* Ex.1003, [0035] (“The reservoir is comprised in part of one surface which may be pierced or otherwise compromised such as a thin-film membrane or foil 13”). To

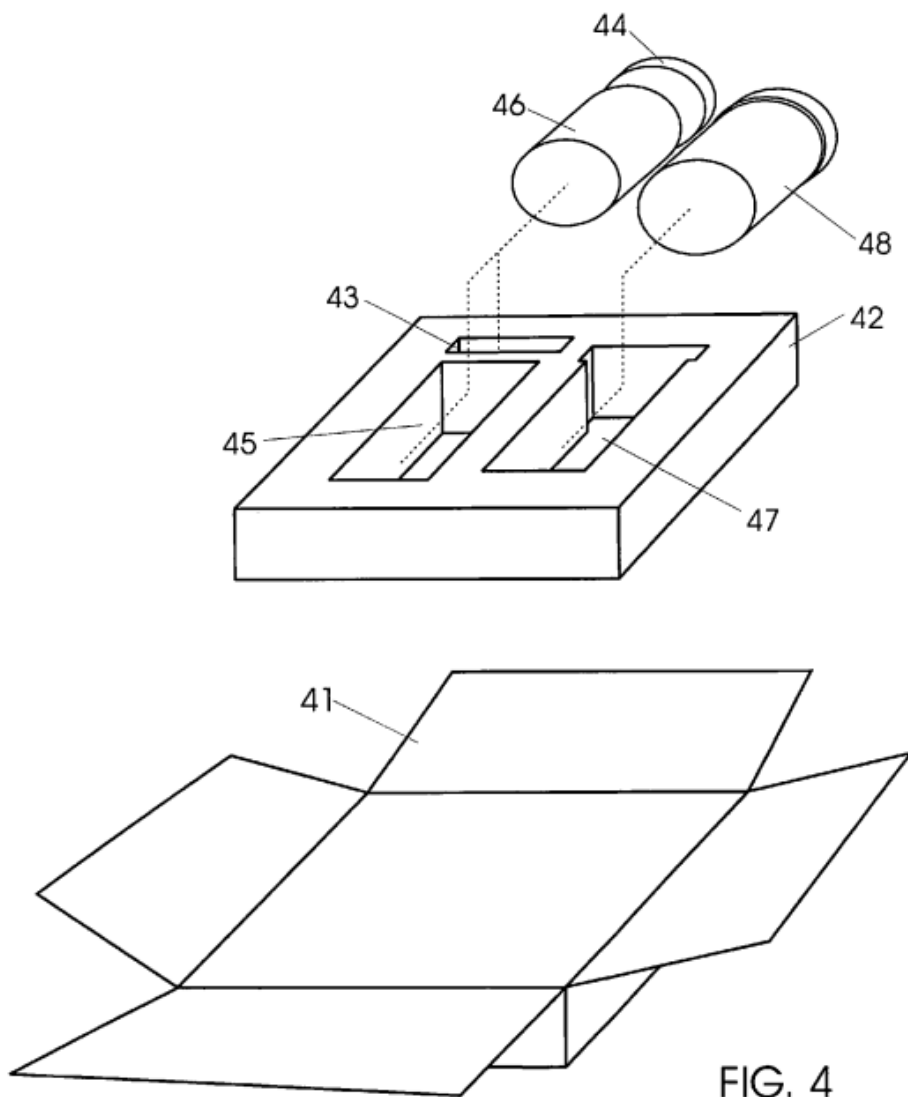
break the membrane or foil, the vessel includes a knife that points toward the opening of the vessel. The knife punctures the membrane or foil when the cap is tightened on the vessel, thereby releasing fluid from the reagent chamber into the vessel. *See* Ex.1005, [0035].

32. Plante explains that sample collection system “configured for ease-of-use by unskilled users and further configured for safe conveyance via standard shipping services.” Ex.1003, [0017]. The system includes a receiving vessel and a sealing cap. *Id.*, [0018]. The receiving vessel includes an integral funnel portion to facilitate a donor providing a saliva sample. *Id.*, [0019].

33. The receiving vessel and sealing cap include cooperating threads. *Id.*, [0035], Fig. 1. After a sample has been added to the receiving vessel the cap is coupled to the receiving vessel. Coupling the cap to the receiving vessel breaches the integrity of the liquid reservoir in the cap and releases the preserving fluid to mix with the sample collected in the receiving vessel. *Id.*, [0022]. Specifically, when the cap is threaded onto the vessel, a knife in the vessel pierces a thin-film or membrane of the reservoir to release the preserving fluid. *Id.*, [0038]. Plante states that the biological sample can be preserved in the sample collection vessel for extended periods of time. *Id.*, [0018] (“suitable for long-term and durable storage of a DNA in a saliva sample”).

34. Plante also describes a shipping box (or sample collection kit) for the

sample collection container system. *Id.*, [0042]. Plante explains that because the system is designed for use by consumers, it is advantageous to provide for two-way shipping in a box suitable for same. The box, depicted in Figure 4 (reproduced below) includes cut-out cavities that support two discrete shipping modes, namely the cap and receiving vessel separate (before the sample is collected) and together (after the sample is collected).



35. When the sample collection device is shipped to a consumer, the cap and receiving vessel are held separate to protect the contents of the fluid reservoir against being released. The box includes cut-out cavities 43 and 45 for each of the cap and receiving vessel. After a user has deposited a sample and placed the cap on receiving vessel (and preserving fluid has been released from its containment in the reservoir), the combined cap and receiving vessel are inserted into another cut-out

cavity 47 provided to return the sample for analysis. *Id.*, [0042].

C. Annular Valves in a Container Cap

36. Containers having a cap with an annular valve to release a material from the cap to mix with the contents of the container were also known in the art. In addition to Ueda which has a cap with an annular valve, I provide two more examples of these container caps with annular valves below.

1. Cho

37. International Patent Publication No. WO 2005/051775 to Cho (Ex.1004), an application published in 2005, discloses a container having a cap with an annular valve to release a material from the cap to mix with the contents of the container. *See* Ex.1004, 48:15-50:27, Figs. 43-45B. I understand that Cho is prior art to the '632 patent because it was published more than a year before the earliest priority date for the '632 patent.

38. 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; *id.*, Abstract. Cho discloses various means to “cause the separate spaces to communicate with each other as necessary so that the two materials can be mixed to be used.” *Id.*

39. Cho explains that the container includes an “additive storage container” that stores an additive in the cap. *Id.*, 1:28-2:3, 50:4-12. The additive storage

container maintains a “good seal on the interior space . . . so that the additive is not oxygenated or spoiled and the additive storage container can be easily applied to the mouth of typical bottles.” *Id.*, 1:28-2:3. Cho recognizes that such a container is needed in “a variety of industrial fields” for mixing different materials together, including for mixing “**medicines and chemicals.**” *Id.*, 1:9-12 (emphasis added). The container “can prevent chemical and physical properties of the materials from being changed or deteriorated.” *Id.*, 55:24-29.

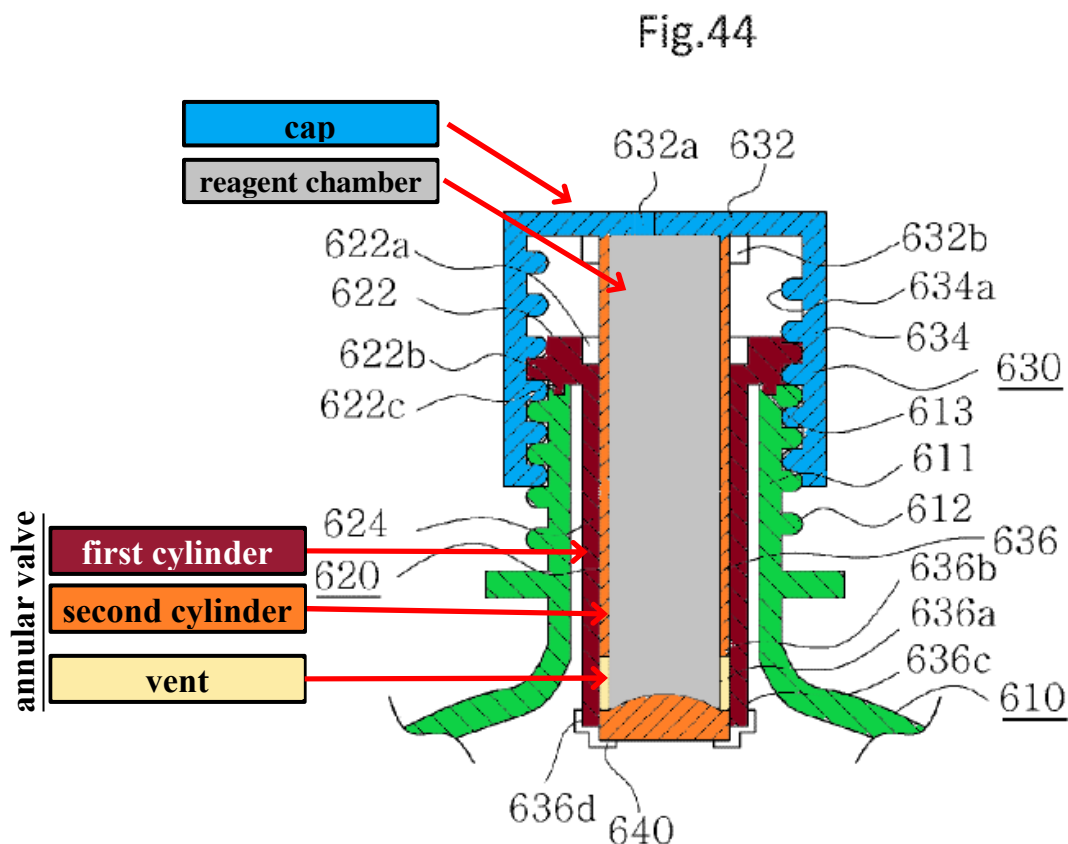
40. Cho discloses the use of various mechanism for releasing the contents of the additive storage container into the bottle. In some embodiments the additive storage container includes a burstable or frangible membrane that is torn by cutting tips when a cap is screwed down. *See, e.g., id.*, 40:30 – 41:10.

41. In other embodiments Cho discloses the use of an annular valve to release the contents of the additive storage container into the bottle. In particular, in the embodiment of Figs. 43-45B, Cho discloses a container cap having a valve with cooperating inner and outer cylinders that move relative to each other to open/close a fluid vent in the inner cylinder.

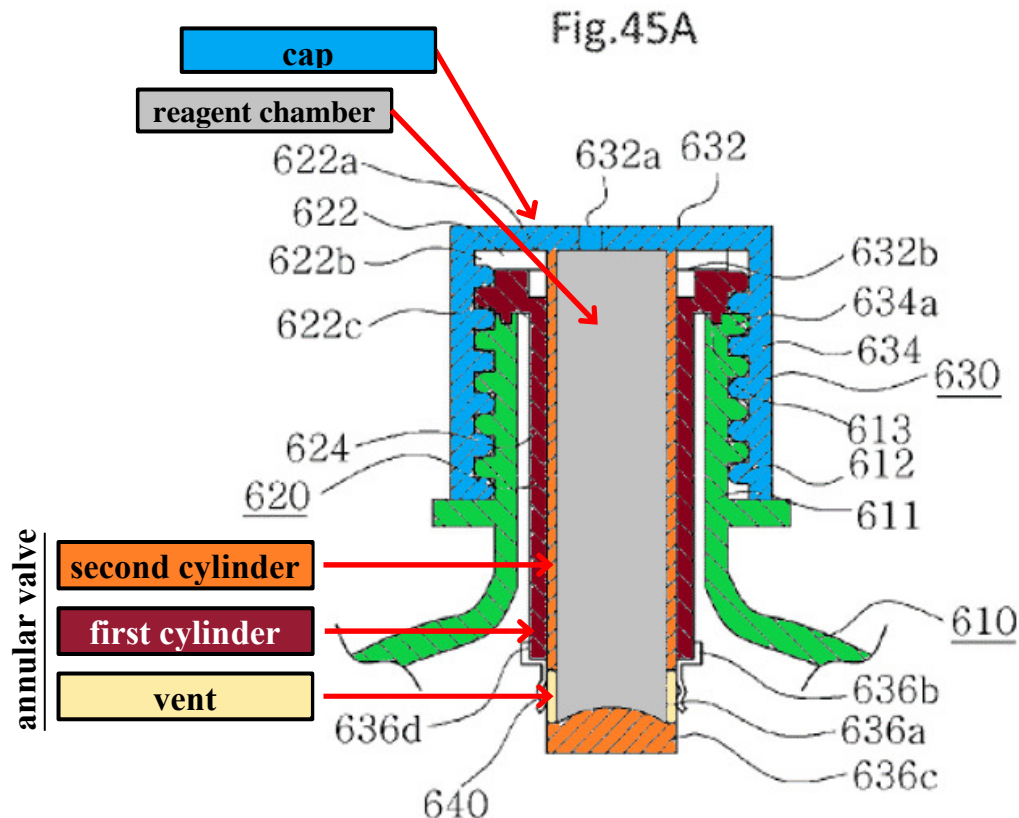
42. The embodiment includes a cap (“opening unit 630”) having a valve system that is used to release the additive from the additive storage container 620 into the bottle upon tightening the cap on the bottle. *Id.*, 48:15-50:27. In Cho’s valve system, the additive storage container 620 is an outer cylinder, and a “slider

636” is an inner cylinder. *Id.*, 49:10-13. The slider 636 includes “discharge ports 636a” in the sidewall that serve as a fluid vent to release the additive into the bottle when the valve is opened upon tightening the cap on the bottle. *Id.*, 50:4-12. Fig. 44 shows the valve system with the valve in a closed state prior to releasing the additive into the bottle.

43. Fig. 44 in Cho (reproduced below with annotations corresponding to the '632 patent claims) shows the movable annular valve with an inner and outer cylinder. The inner cylinder includes a vent. In the closed position the outer cylinder blocks the vent on the inner cylinder to initially seal the additive in the cap's chamber.



Ex.1004, Fig. 44 (annotated). When the cap is tightened on the container as shown below in Fig. 45A, the annular valve is opened by the inner cylinder moving downward to expose the fluid vent:



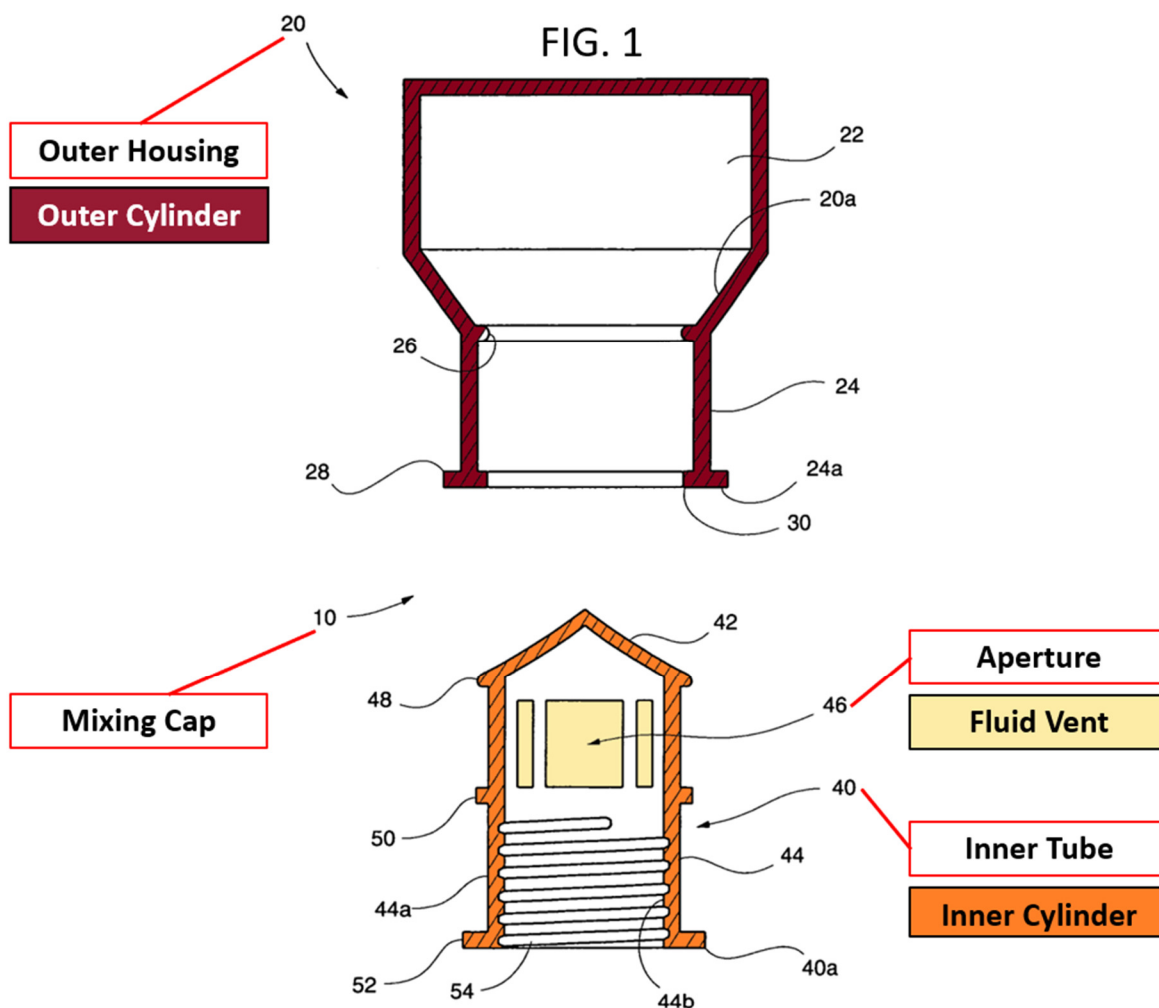
Ex.1004, Fig. 45A (annotated). With the annular valve open, the material in the reagent chamber is released into the container. *Id.*, 50:4-12.

2. Patterson

44. U.S. Patent Publication No. 2006/0260959 to Patterson (Ex.1010), like Cho, discloses cap having movable annular valve to enable mixing of a material stored in the cap with contents of the container vessel. I understand Patterson is

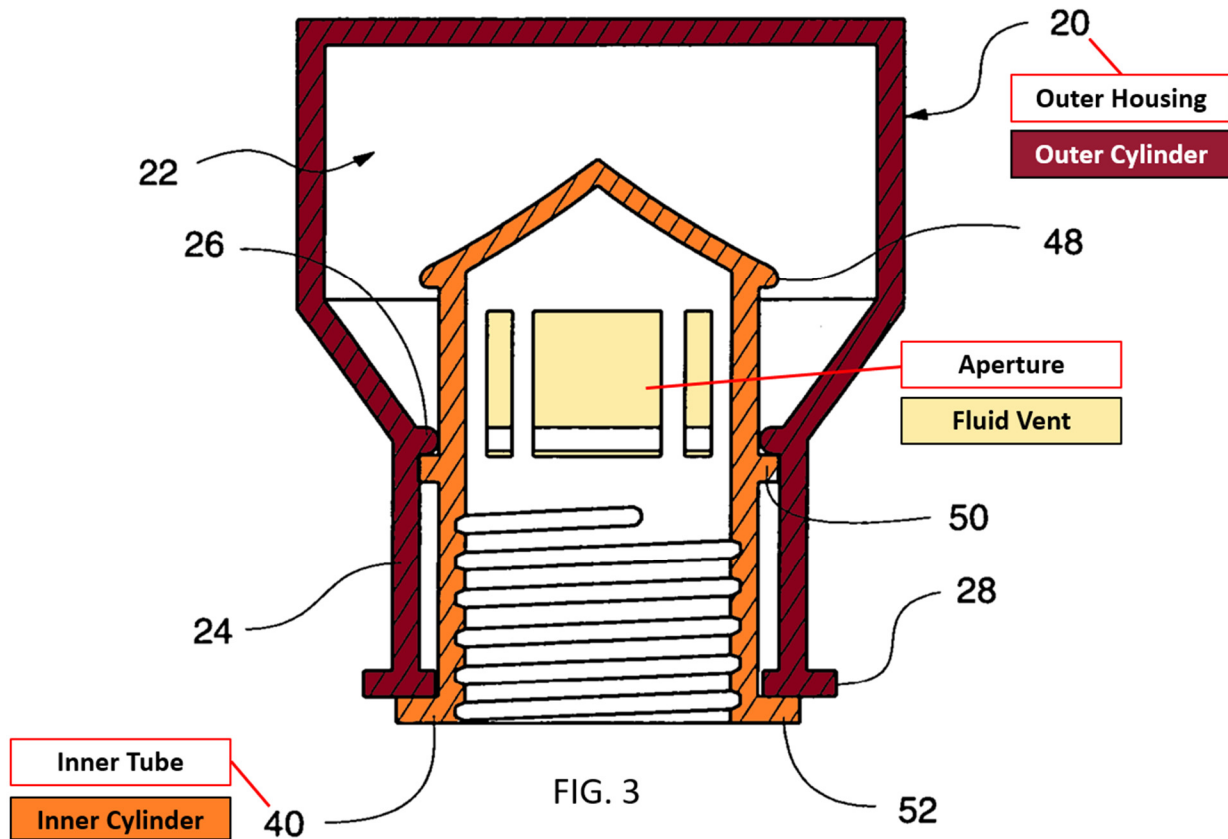
prior art to the '632 patent because it was published in 2006, more than a year before the earliest priority date for the '632 patent.

45. Patterson refers to the cap as a “mixing cap.” Ex.1010, Abstract. The mixing cap includes a storage receptacle for storing a material that can be mixed with the contents of the container to which it is attached. *Id.* [0030]-[0034]. As shown in Figure 1 reproduced below, the mixing cap includes two components: an outer housing 20 and an inner tube 40. The inner tube includes an aperture 46. *Id.*

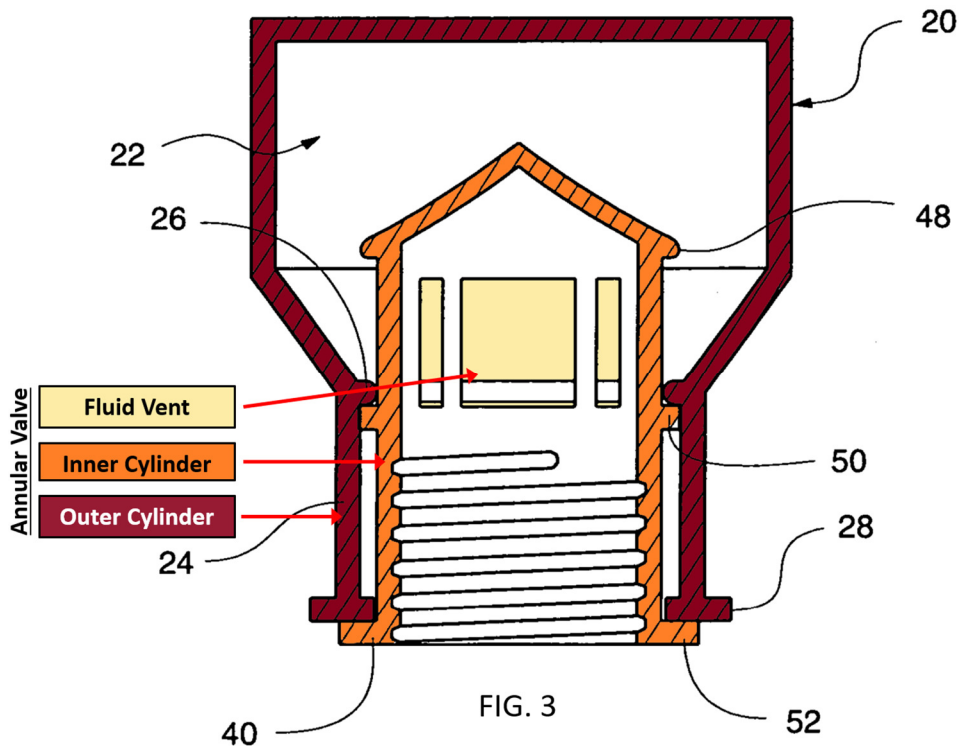


46. The assembled mixing cap is shown in Figure 2 (closed vent) and

Figure 3 (open vent). *Id.* Figure 3 is shown below.



47. The two components of the mixing cap provide a movable annular valve. The outer housing 20 is the first cylinder as claimed in the '632 patent and the inner tube 40 is the second cylinder as claimed. The aperture 46 is the vent of the second cylinder.



48. Patterson discloses that the storage receptacle of the mixing cap can contain various dry or liquid ingredients for introduction into the container. *Id.*, [0029]-[0032]. The preferred use of the mixing cap is for powdered sports drinks, supplements and the like, but, as Patterson explains, it “may be utilized to facilitate the introduction and mixture of any selected ingredient, additive or the like to the contents of a communicating bottle or container.” *Id.*, [0044]. This includes mixing “**medicines, chemicals ...or the like.**” *Id.* (emphasis added).

49. In use, the mixing cap is applied to a container and the outer cylinder (outer housing 20) is moved distally over the inner cylinder (inner tube 40). This exposes the vent (aperture 46), which allows the ingredients stored in the storage receptacle defined by the outer housing to mix with the contents of the bottle as

depicted in Figure 4 reproduced below.

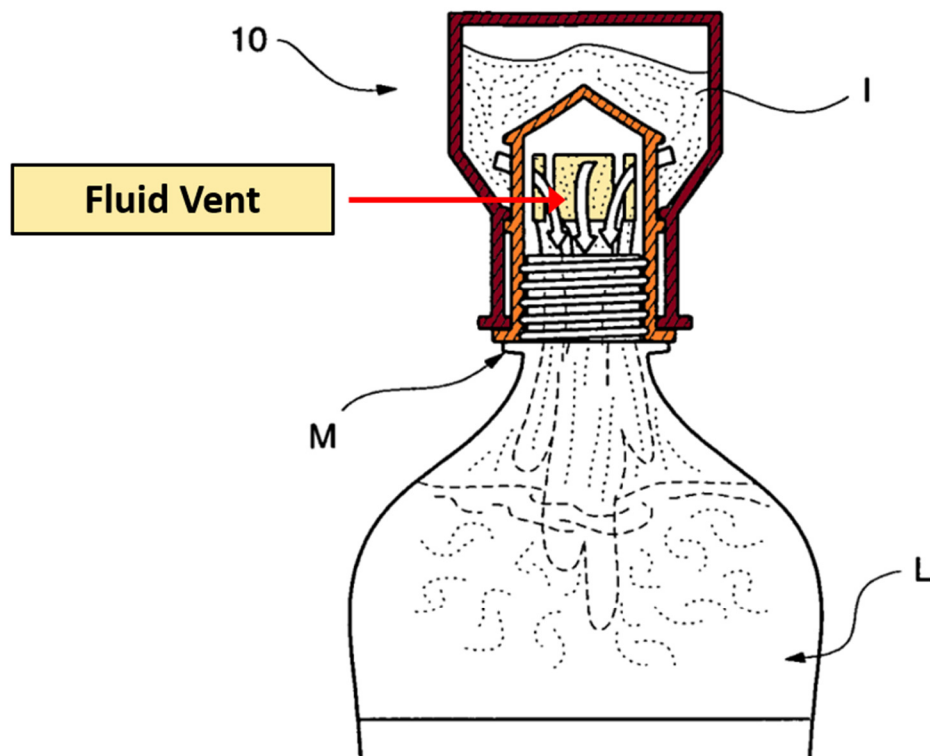


FIG. 4

50. As described in more detail below, the challenged claims of the '632 patent are anticipated by Ueda and would have been obvious in view of the combination of Plante and Cho.

VI. LEVEL OF ORDINARY SKILL

51. I have been informed that for purposes of assessing the obviousness of patent claims, the level of skill possessed by the hypothetical person of ordinary skill in the art is informed by several factors. These factors include the type of problems encountered in the relevant art, the prior art solutions to those problems, the rapidity

with which innovations are made in the relevant art, the sophistication of the relevant technology, and the educational level of active workers in the field.

52. The '632 patent relates to devices for collecting samples of bodily fluids, and particularly naturally expressed bodily fluids, e.g. saliva, urine. Ex.1001, 1:23-28. Aspects of the patent also relate “generally to functional genomics and to the isolation and preservation of cells from such bodily fluids . . .” *Id.*, 1:23-28. The patent therefore includes both mechanical aspects and biological aspects. During my career I have worked in teams where persons with mechanical engineering education and experience, such as myself, have worked with persons have education and experience in the biological, surgical or chemical aspects of medical devices and their use. For example, my U.S. Patent Nos. 8,092,363 is a heart valve repair device that claims methods of modifying heart valve function. The co-inventor, Dr. Jai Raman, is a cardiovascular surgeon. A hypothetical person of ordinary skill in the art would have a combination of these two skill sets. Thus, a 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. 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 the systems described in the '632 patent,

namely the collection of biological samples. As to the biological aspects of the patent disclosure, a person of ordinary skill would have had education and experience relating to the collection of biological samples.

53. As I describe in further detail below, the challenged claims are anticipated and would be obvious from the perspective of any reasonable definition of a POSA.

VII. CLAIM CONSTRUCTION

54. I understand the Board construes the claims using the same claim construction standard that would be used in a district court case.

55. I understand in the district court case, the parties disputed the construction of certain terms from the related '646 patent. I understand the district court issued an order construing these claim terms. Some of the '646 patent terms construed by the district court are also found in the claims of the related '632 patent. I discuss below the parties' proposed constructions and the district courts construction for these terms. As explained herein, the '632 patent claims are anticipated and would have been obvious regardless of which claim construction is adopted for the terms in question.

A. “Biological Sample”

56. Per the preamble of claim 1 of the '632 patent, the claimed invention is directed to a “*biological sample* collection system.” The claimed system also

includes “a first aperture for receiving a *biological sample*” Ex.1001, claim 1.

57. 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.*

58. The construction of “biological sample” does not impact my opinion regarding the patentability of the ’632 patent claims. The claims are unpatentable as anticipated and obvious regardless of whether the term is limiting and how the term is construed if it is limiting.

B. “Annular Valve”

59. Claim 1 includes “a moveable *annular valve* in the second aperture . . .” The specification does not use the term “annular valve” or even “valve.” I understand that this term was added to the patent when Patent Owner filed a continuation application in 2020, years after the original application was filed.

60. 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.*

61. The construction of “annular valve” does not affect my opinion

regarding the patentability of the '632 patent claims. The cited prior art includes ring shaped valves and the claims would have been anticipated and obvious regardless of which construction was adopted.

VIII. GROUND 1: PLANTE AND CHO RENDER OBVIOUS CLAIMS 1-4, 6-16, AND 18-20

A. Plante and Cho Render Obvious Claim 1

62. As described above, Plante discloses a sample collection system made up of a sample collection vessel and a cap, which are used together to collect and preserve a biological sample. As I explain in further detail below, Plante discloses every element of claim 1 except for the movable annular valve, which is disclosed in Cho.

63. A POSA would have understood that Plante and Cho are in the same field of endeavor as the '632 patent and address the same problem. The '632 patent is directed to “safer and easy to use sample collection devices for naturally expressed bodily fluids (for example), as well as solutions and methods for preserving cells of samples collected.” Ex.1001, 4:52-55.

64. Plante is also directed to an easy-to-use sample collection container system for unskilled users. Ex.1003, [0006], [0025]. The container system 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. *Id.* [0013] (“[a] liquid tight reservoir 12 contains therein a special formula which operable to stabilize and

preserve a biological sample such as saliva”); [0041] (“reservoir may be sealed and contain and protect the fluid until it is desired for use”).

65. Cho is similarly directed to an easy-to-use container for mixing two materials. Ex.1004, 1:25-27 (“Another object of the present invention is to provide a bottle which can mix two materials together at an exact mixture ratio using only a simple action.”); 1:1-6 (“Technical Field:” ...[t]he present invention relates, in general, to a bottle, which can not only contain two kinds of materials in two separate spaces in a bottle, but also cause the separate spaces to communicate with each other as necessary so that the two materials can mixed to be used.”) Cho’s container also 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. *See e.g., id.*, Figs. 43-45B. A POSA would thus understand that Cho is in the same filed of endeavor and addresses the same problem as Plante and the ’632 patent.

66. A POSA would have been motivated for multiple reasons to use Cho’s cap with a movable annular valve in Plante’s sample collection system.

67. First, safety design incentives would have motivated a POSA to replace Plante’s approach of using a sharp knife in the vessel, which pointed at the opening into which the saliva sample was delivered, with Cho’s safer design using an annular valve in the cap. A POSA would have recognized that the knife in Plante’s sample collection system created a risk of injuring a user and others who handle the device.

It has long been known in the field of medical devices to avoid sharp objects if possible. In fact, one of my most successful inventions arose from this motivation to choose devices without sharps. The SmartSite Needle-Free Valve that I invented (see, e.g., U.S. Patent Nos. 5,549,577, 5,676,346, 6,706,022, 7,244,249) eliminated the use of sharps in numerous medical devices, including IV sets (except for the catheter insertion needle), vial access devices, heparin locks, solution bags, stopcock bags, stopcock valves.

68. This safety design incentive was made even more significant in 2000 when the federal “Needlestick Safety and Prevention Act” (NSPA) was enacted. *See* Ex.1012. The NSPA had a great impact on myself and others working in the design and manufacture of medical devices. The NSPA reported that “[n]umerous studies have demonstrated that the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, when they are part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries.” *Id.* at 2. The NSPA created official guidance to, among other things, choose devices without sharps where possible. *Id.* (“Modification of the bloodborne pathogens standard is appropriate to set forth in greater detail its requirement that employers identify, evaluate, and make use of effective safer medical devices.”).

69. Furthermore, the Centers for Disease Control and Prevention produced

a workbook in 2008 (“CDC Workbook”) to assist healthcare organizations in preventing injuries from sharps and in satisfying existing regulatory standards, including the NSPA. Ex. 1013, 3. The CDC Workbook describes the hierarchy of controls used to prioritize injury prevention steps and indicates that the top priority is eliminating sharps altogether where possible. *Id.*, 12-13 (“In the hierarchy for sharps injury prevention, the first priority is to eliminate and reduce the use of needles and other sharps where possible.”). If eliminating the sharps is not possible, the next option is to “isolate the hazard, thereby protecting an otherwise exposed sharp, through the use of an engineering control.” *Id.*, 13. 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.

70. A POSA would have recognized that eliminating the sharp from the Plante device would have been beneficial to those manufacturing the device, end users of the device, laboratory technicians who would analyze the sample collected in the device, and those dealing with the disposal of the device after use. 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. A POSA therefore would have been motivated to combine the annular valve of Cho to achieve a predictable improved result with the Plante sample collection system.

71. Second, a POSA would have understood that it is difficult and more expensive to mold sharp thin features, like Plante's knife, in plastics. Such features end up being the last features of the part to fill in the mold. They often fail to fully fill the mold to form the sharp or will stall and try to fill after the rest of the part is filled, which results in a weakened structure. For example, the Injection Molding Handbook states:

[V]arying wall thicknesses from thick and thin sections in a part will lead to problems in molding. Having a uniform wall throughout a part gives it good strength and appearance. Thick and thin sections will have molded-in stresses, different rates of shrinkage (causing warpage), and possibly void formation in the thick portion.

Ex. 1014, 729. The Injection Molding Handbook also explains that "part quality can be considered a direct outcome of a plastic melt's flow behavior in its mold cavity or cavities. Excessive restrictions and obstructions to the flow of material spell trouble in injection molding." *Id.*, 733.

72. A different manual on injection molding similarly states:

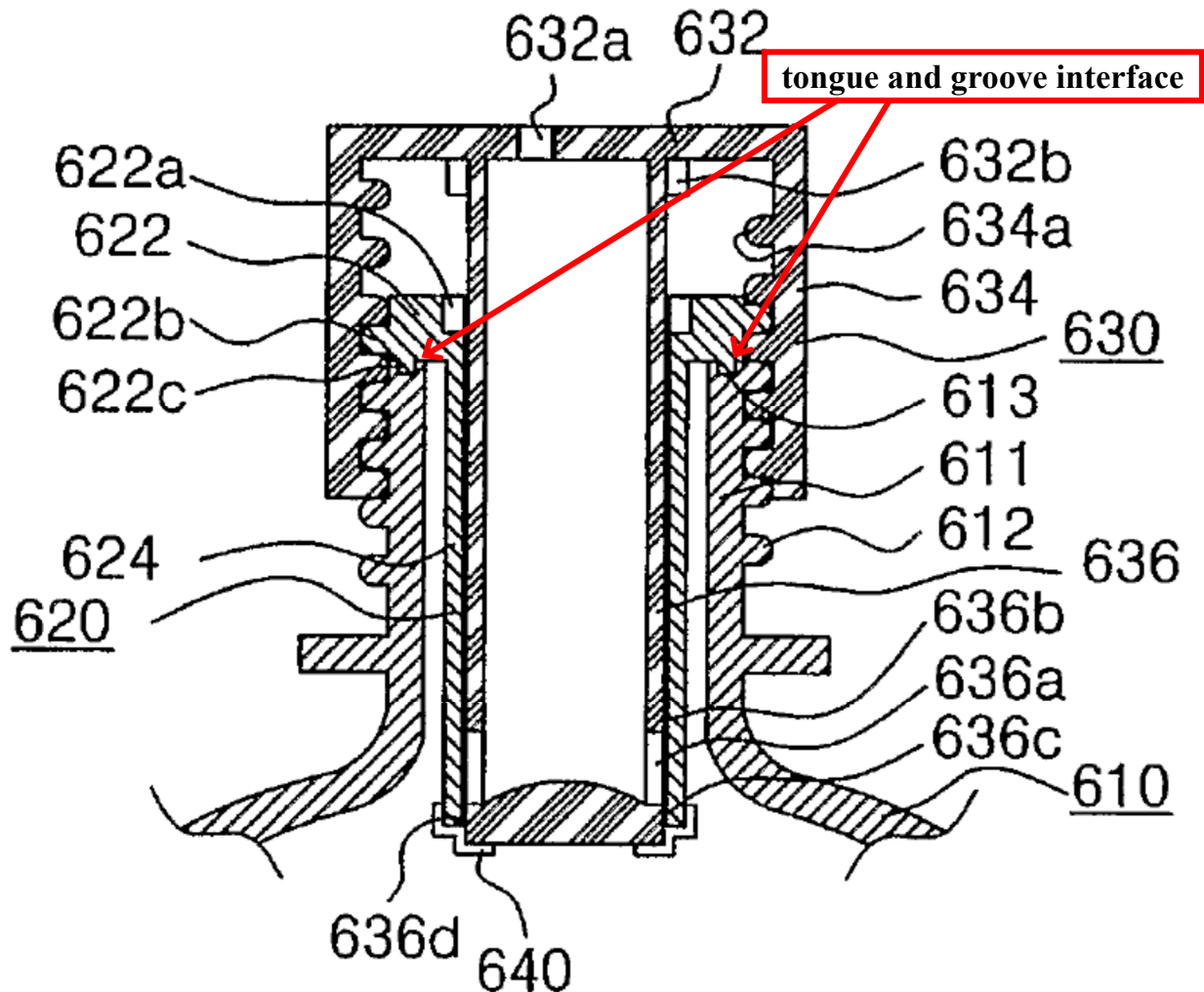
After the thermoplastic melt has been injected, variations in part wall thickness do not allow the walls to cool at consistent rates. Thick walls will shrink more than thin walls, causing part warpage, voids on thicker wall cross sections, poor dimensional control, long cycle times, poor surface finish, and structural defects.

Ex. 1015 [Complete Part Design Handbook for Injection Molding], 547. The

molding challenge increases the failure rate and then creates the added expense to perform extensive mold process validations and then likely requires visual inspection of each part, if it were even possible to mold it consistently in the first place. Plastic parts mold best when wall thickness is uniform throughout the part.

73. Third, a POSA would have understood that using an annular valve like Cho's instead of Plante's knife design would also allow the cap to be sealed onto the vessel before the valve is opened. Cho's Figure 44 below shows the container in a sealed state with the cap attached to the vessel and sealed before the valve is opened to release any reagent. As shown, Cho's cap and annular valve form a tongue and groove interface with the top of the container. In contrast, the foil in Plante is pierced by the knife to release the reagent before the cap is fully attached and sealed onto the vessel. *See, e.g.,* Ex. 1003, Fig. 2. A POSA would have understood that Cho's sealing feature is beneficial because the vessel containing the sample would be sealed with the cap before the reagent is released, thus protecting the user and the reagent.

FIG. 44



74. Fourth, combining the teachings of Plante and Cho involves no more than the simple substitution of one known element for another to yield predictable results, namely substituting Plante's cap for Cho's cap. A POSA would have readily made the substitution of Plante's cap with a reservoir and pierceable membrane for Cho's cap with a reservoir and annular valve to release the reagent stored in the reservoir. Ultimately, combining two containers useful for medical or chemical

solutions such as Plante and Cho would have involved the mere application of a known technique (Cho's annular valve for releasing a material stored in the cap of a container) to a known system ready for improvement (Plante's sample collection container that relied upon a knife to release a material stored in the cap) to yield predictable results.

75. A POSA would have had a reasonable expectation of success in combining a cap with an annular valve as disclosed in Cho with the biological sample collection system of Plante. For example, a POSA would have known that Cho's threaded cap could be made to accommodate the threaded sample collection vessel in the embodiment disclosed in Plante. The cap disclosed in Cho is used for releasing a stored reagent into a bottle when the cap is fastened to the bottle, and a POSA would have expected success in using Cho's cap to perform the same function when the cap was fastened to Plante's sample collection vessel in order to release reagents from the cap into the vessel to mix with the biological sample collected therein. It would have been clear to a POSA that the combination of these references would have involved the routine substitution of one cap with an annular valve for another with a pierceable membrane, which would eliminate the need for a sharp knife but maintain all the same desired functionality.

76. As set forth in the sections below, the combination of Plante and Cho meets each limitation of claim 1 and the other challenged claims of the '632 patent.

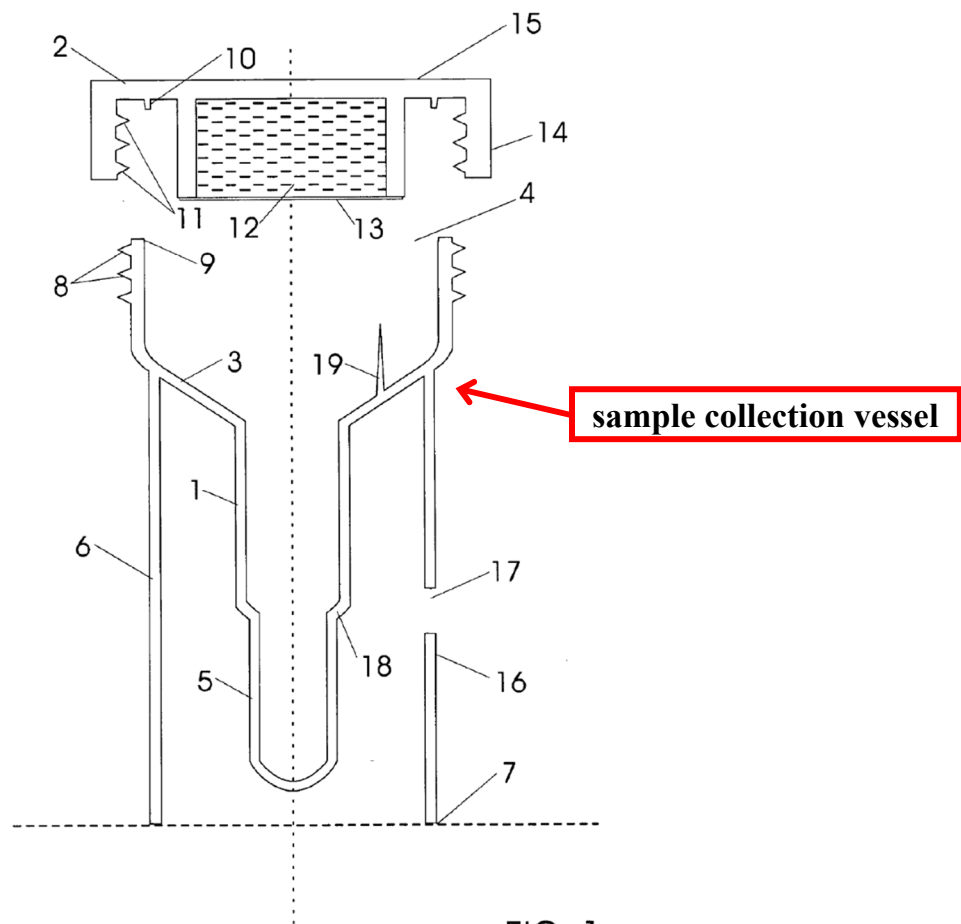
1. Claim 1 Preamble

77. The preamble of claim 1 recites: “A biological sample collection system, the system comprising.” Plante discloses a system for collecting and preserving a biological sample. The disclosed invention of Plante is “for the collection of biological matter and more specifically concerned with saliva collection, storage and transmission systems configured for non-expert use.” Ex.1003, [0002]. The system includes a receiving vessel and a sealing cap, which includes a pierceable liquid reservoir. *Id.*, [0021], [0041]. The reservoir holds a preserving fluid to preserve the sample. *Id.*, [0021], [0041]. Plante states that once mixed with the preserving fluid the biological sample can be preserved in the sample collection vessel for extended periods of time. *Id.*, [0018]. As to the construction of “biological sample” as recited in the preamble of claim 1, it does not impact my opinion regarding the patentability of the ’632 patent claims at least because Plante specifically discloses a collection system for biological matter such as saliva which contains cells. The claims are unpatentable as obvious regardless of whether the preamble is limiting and how it is construed if it is limiting.

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

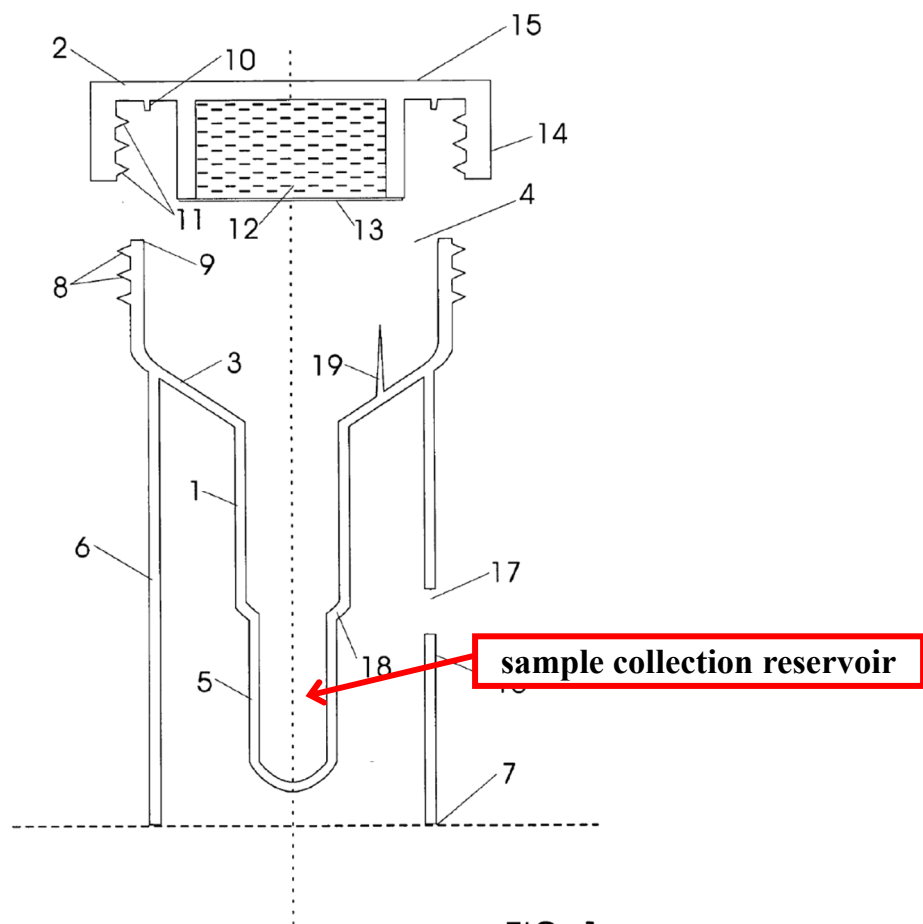
78. Limitation 1[a] recites “a sample collection vessel.” Plante plainly discloses this limitation. *See, e.g.*, Ex.1003, [0018] (“An apparatus for saliva sample collection, temporary storage and conveyance via delivery services is formed of two

primary elements—each of these two elements having a plurality of features integrated therewith. Preferably formed of plastic in molding processes, these two elements cooperate together to provide ‘coupled’ and ‘decoupled’ states. **A receiving vessel** and sealing cap ...”) (emphasis added). Plante’s receiving vessel is a sample collection vessel. As shown below in Fig. 1, the receiving vessel 1 includes an entrance aperture 4 and a cylindrical tubular portion 5. Ex.1003, [0035].



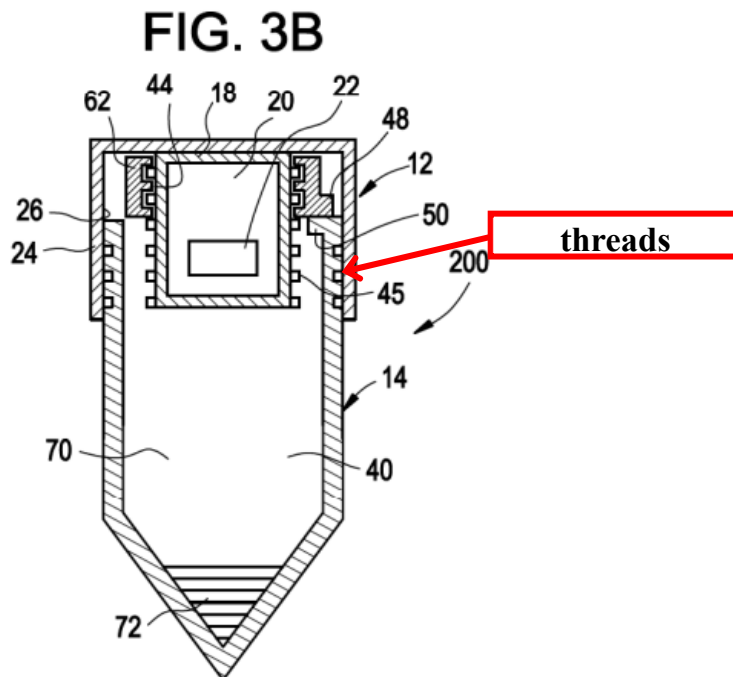
3. Limitation 1[a][i]: “a sample collection reservoir”

79. Limitation 1[a][i] recites that the sample collection vessel comprises “a sample collection reservoir.” Plante also discloses this limitation, namely a “receiving vessel” [1] having an “entrance aperture” [4] to receive a saliva sample from a user. Ex.1003, [0035], Fig. 1. Plante’s vessel 1 collects the sample in a reservoir. Thus, Plante’s sample collection vessel includes a sample collection reservoir.



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

80. Limitation 1[a][ii] recites that the sample collection vessel comprises “a first connection member.” In the ’632 patent, the term “connection member” refers to a structure that connects two items together, e.g., the structure that connects a cap and a bottle. Ex.1001, 10:30-46 and 10:58-65. For example, the ’632 patent specification lists terms such as “push, rotate, screw, mate as well as *thread*” that are intended to “correspond to *structure* (well known to those of skill in the art) *for connection*” of two components. Ex.1001, 10:58-65 (emphasis added). Also, per claim 14, which depends from claim 1, the connection member can comprise “a threaded connection.” Ex.1001, claim 14. This confirms that “connection members” of claim 1 include threaded members and other well-known means for connection. Further, Fig. 3B of the ’632 patent shows threads on the exterior surface of the sample collection vessel, and the corresponding description states the vessel is “threadably engaged” with the cap.

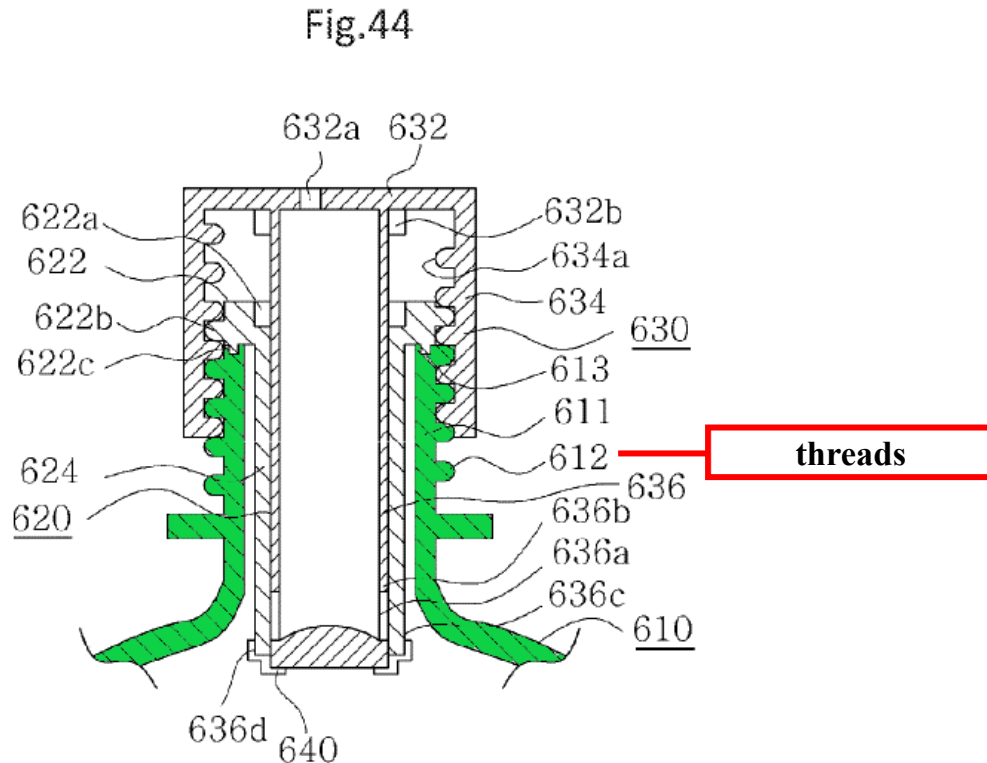


Ex.1001, Fig. 3B, 14:61-65. Thus, a POSA would understand the claim term “a first connection member” to encompass, for example, threads on the interior or exterior of the sample collection vessel.

81. Like the '632 patent, each of Plante and Cho disclose a threaded connection to screw a cap on a vessel. Plante discloses thread set [11] on the cap and corresponding thread set [8] on the receiving vessel. Ex.1003, [0035], Fig. 1.

82. Cho discloses “a bottle, comprising: a bottle body which has a mouth provided with an external thread around an outer circumferential surface thereof.” Ex.1004, 2:7-10. The specific embodiment in Figs. 43-45B of Cho includes “a bottle body 610 that is composed of a mouth 611 having an external thread 612 formed

around the outer circumferential surface of the mouth 611.” *Id.*, 48:16-19, Figs 43-45B. Fig. 44 in Cho, reproduced below, shows the bottle with the external threads adjacent to the opening:



Id., Fig. 44 (annotated). Thus, Plante and Cho each disclose “a first connection member” on the sample collection vessel.

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

83. Limitation 1[a][iii] recites that the sample collection vessel comprises “a first aperture for receiving a biological sample.” Plante discloses this limitation,

namely a “receiving vessel” [1] having an “**entrance aperture**” [4] to receive a saliva sample from a user. Ex.1003, [0035], Fig. 1. 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 contains cells. A POSA would have understood that saliva includes mostly water, but also contains white blood cells, epithelial cells, and other cells.

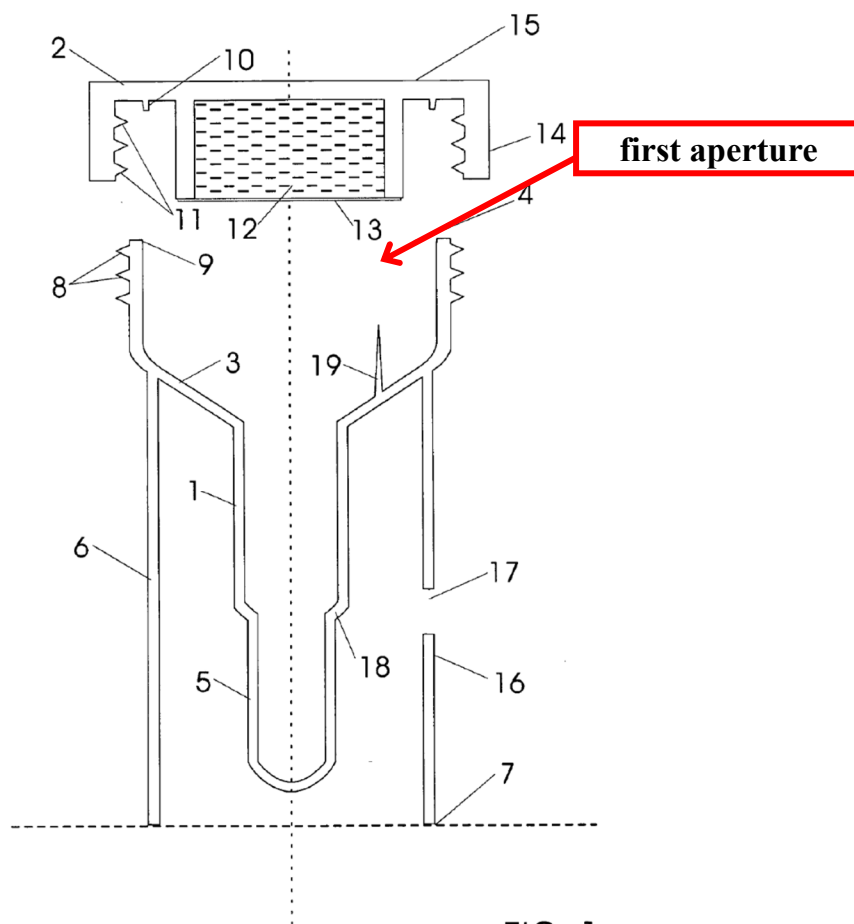
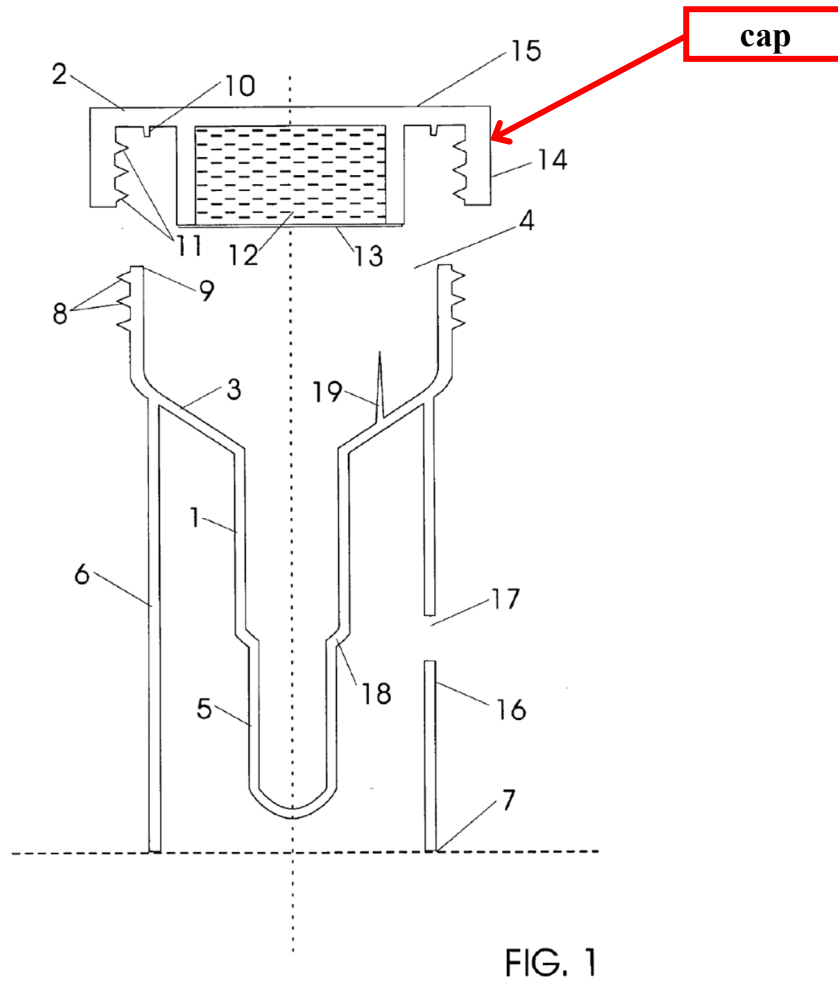


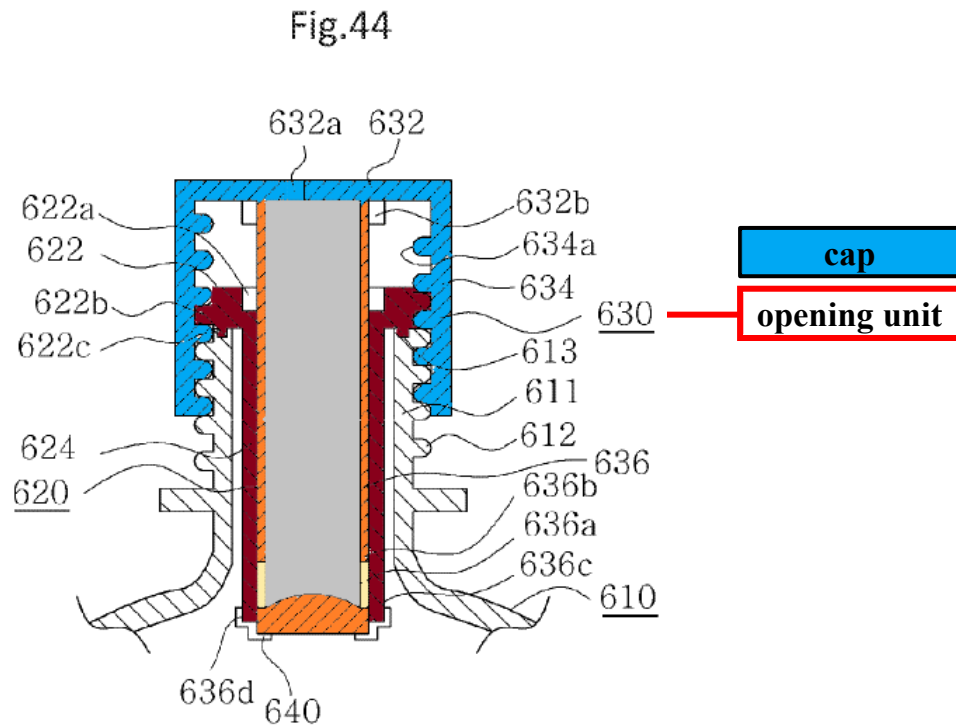
FIG. 1

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

84. Limitation 1[b] recites “a cap.” Plante discloses cap 2 as one of the main elements of the sample collection system, as shown below in Fig. 1. Ex.1003, [0035], Fig. 1.



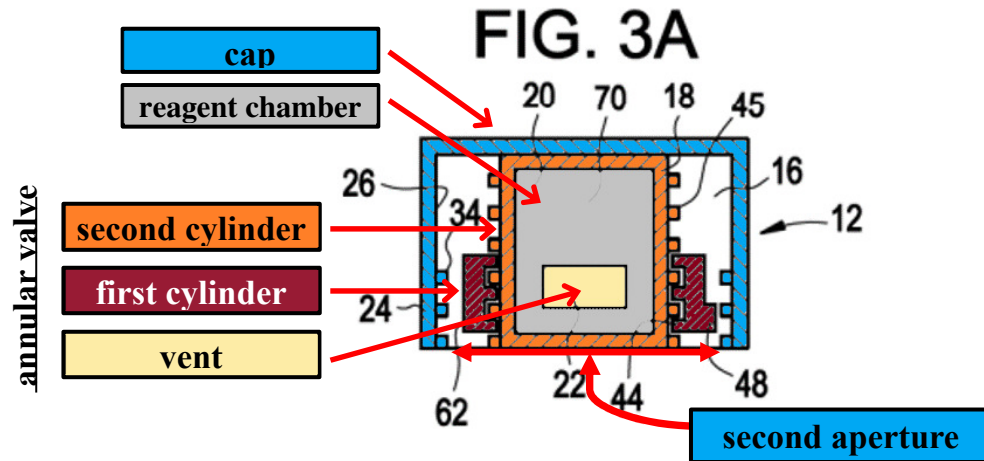
85. Cho also discloses a cap. Cho's "opening unit 630," which includes the inner and outer cylinders forming the annular valve, is a cap. Ex.1004, 48:15-34, Figs. 43-45B. Cho's cap (opening unit 630) is shown in Fig. 44 below:



Id., Fig. 44 (annotated). Thus, Plante and Cho each disclose a cap.

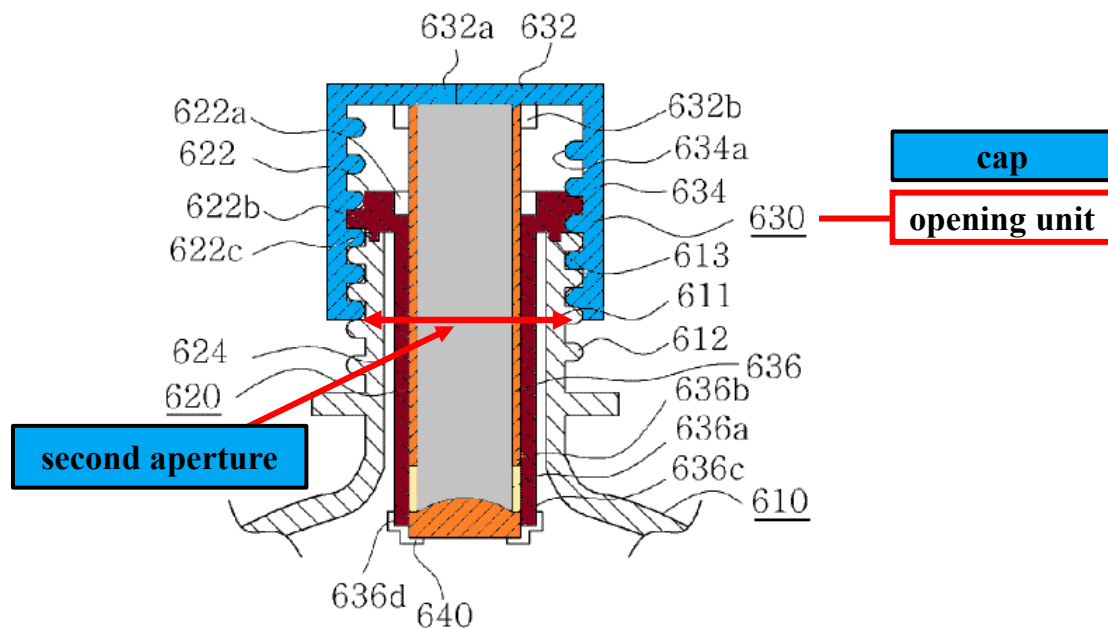
7. Limitation 1[b][i]: "a second aperture"

86. Limitation 1[b][i] recites that the cap comprises "a second aperture." The '632 patent has a cap with 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.



87. Plante’s cap has an aperture that receives a threaded portion of the receiving vessel 1. Ex.1003, [0035], Fig. 1. Also, Cho’s “opening unit 630” is a cap with an aperture that receives a portion of the bottle. Ex.1004, 48:15-34, Figs. 43-45B. For example, in the embodiment depicted in Cho Figs. 43-45B, “bottle body 610” has “a mouth 611 having an external thread 612 formed around the outer circumferential surface of the mouth 611.” Ex.1004, 2:7-10, 48:16-19, Figs 43-45B. And “upper cap 634” has “internal thread 634a engaging with...the external thread 612 of the mouth 611.” *Id.* 49:6-10. Cho’s opening unit 630 (cap), which includes a second aperture, is shown in Fig. 44 below:

Fig.44



Id., Fig. 44 (annotated). Therefore, Plante and Cho each disclose a cap with a second aperture.

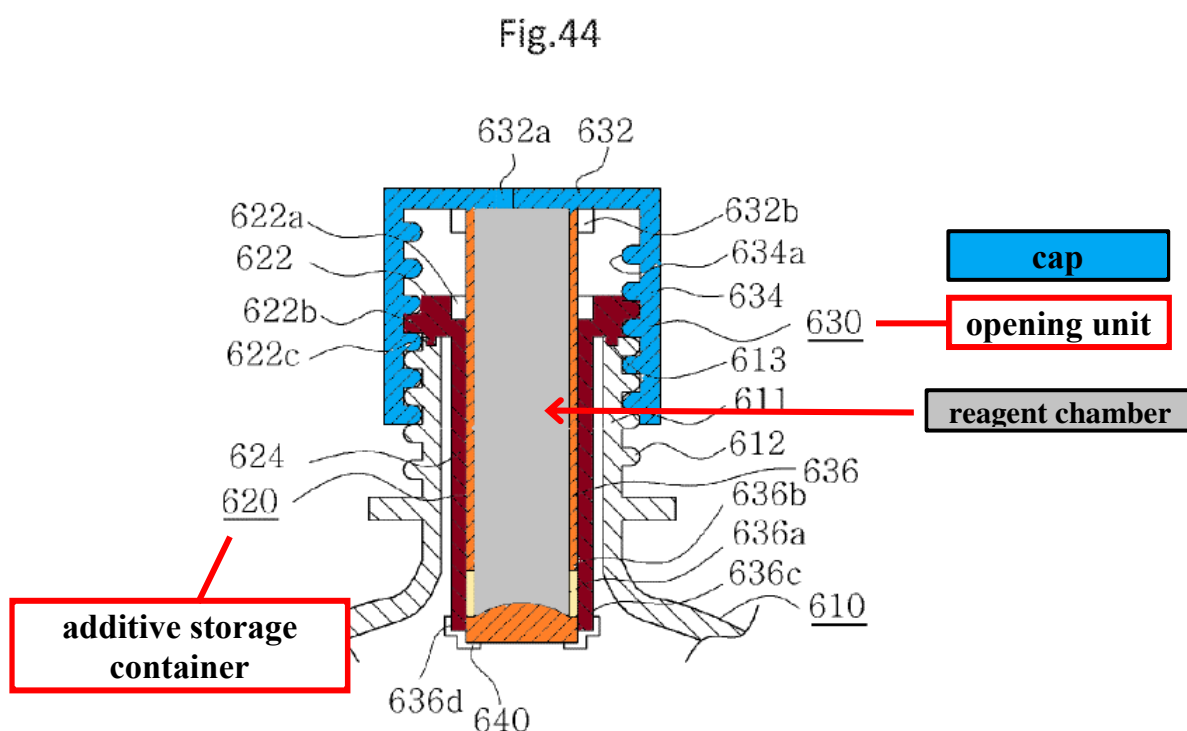
8. Limitation 1[b][ii]: “a reagent chamber storing a reagent therein”

88. Limitation 1[b][ii] recites that the cap comprises “a reagent chamber storing a reagent therein.” Plante and Cho each disclose a reagent chamber in a cap that stores a reagent therein.

89. Plante’s cap includes a reagent chamber storing a reagent, namely reservoir [12], which stores a “preserving fluid.” Ex.1003, [0035], [0041], Fig. 1.

90. Cho similarly includes a chamber in a 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. The chamber, as identified in Figure 44 below, in the Cho cap is defined by an inner and outer cylinder. *Id.*, Fig. 44 (annotated). Cho states that the container can be used for mixing two different kinds of materials, one in the cap and one in the bottle. *Id.*, 1:19-24, 55:13-17.



Cho explains that the container can be used for mixing “medicines and chemicals.” *Id.*, 1:8-12. And Cho explains by storing the additive in the chamber of the cap it prevents the material from “being changed or deteriorated.” *Id.*, 55:22-25.

91. Thus, Plante and Cho each disclose a cap comprising “a reagent chamber storing a reagent therein.”

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

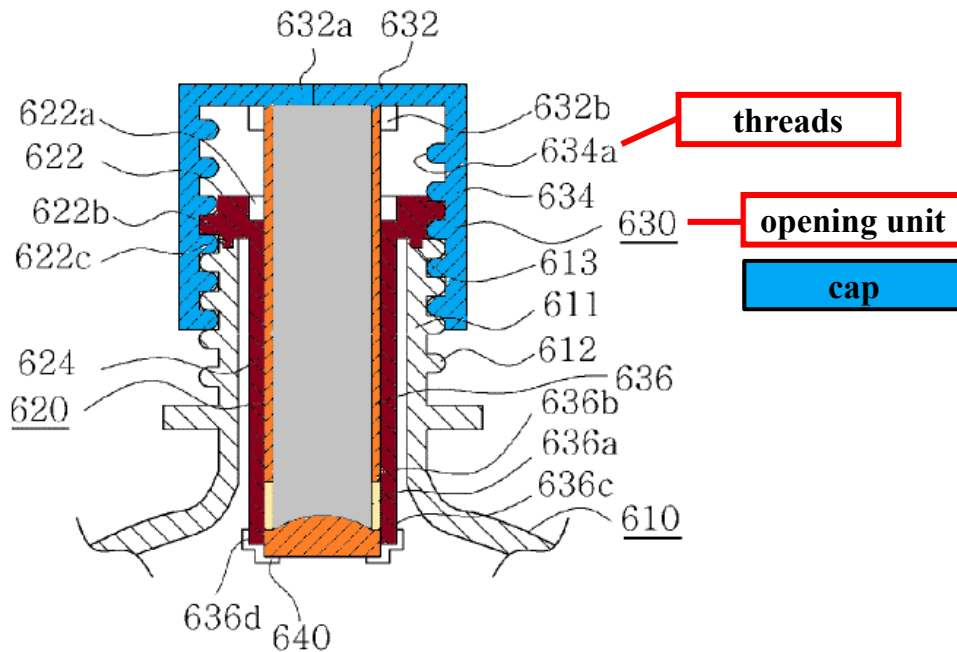
92. Limitation 1[c] recites “a second connection member complementary to the first connection member.” Both Plante and Cho disclose the claimed complementary connection member.

93. As explained above regarding limitation 1[a][ii], the term “connection member,” as used in the ’632 patent, encompasses threads for connecting a cap to a container. Further, claim 14 in the ’632 patent depends from claim 1 and recites that the “second connection member” of claim 1 comprises a threaded connection, confirming that this limitation encompasses at least threads on the cap. Ex.1001, claim 14.

94. Plante discloses a thread set [11] on the cap and a corresponding thread set [8] on the receiving vessel. Ex.1003, [0035], Fig. 1. Plante also includes “rotation indicators” [23] to instruct the user on screwing the cap onto the receiving vessel. *Id.*, ¶[0035], [0038], Fig. 1.

95. Cho also discloses that the cap (i.e., opening unit 630) includes “internal thread 634a,” and the internal threads are used to “engag[e] with both the external thread 622b of the additive storage container 620 and the external thread 612 of the mouth 611.” Ex.1004, 49:5-10, Figs. 43-45B. Fig. 44 shows the internal threads 634 on the opening unit 630 that are complementary to the first connection member threads on the vessel:

Fig.44



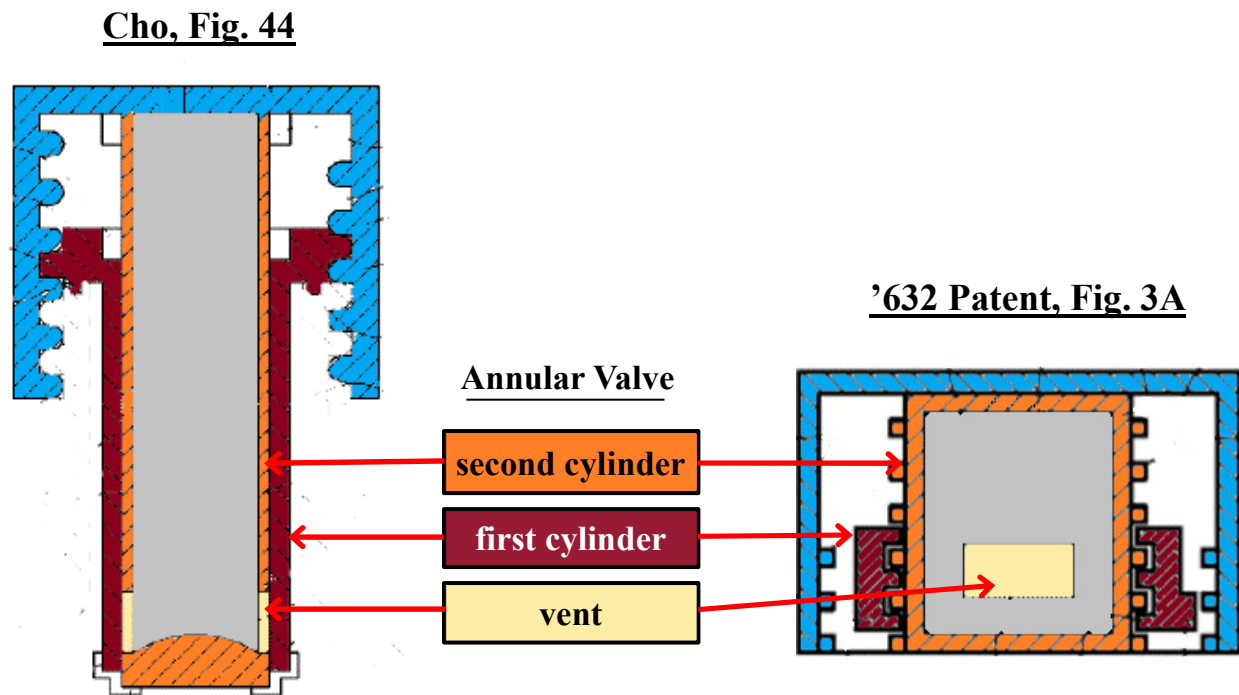
Id., Fig. 44 (annotated).

96. Thus, Plante and Cho each disclose a cap with “a second connection member complementary to the first connection member.”

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

97. Limitation 1[d] recites “a movable annular valve in the second aperture, the movable annular valve comprising.” Cho discloses a movable annular valve under any reasonable construction of the term, including the district court’s construction of this term in the related ’646 patent, namely that an annular valve is a “ring shaped valve.” Ex.1007, 66.

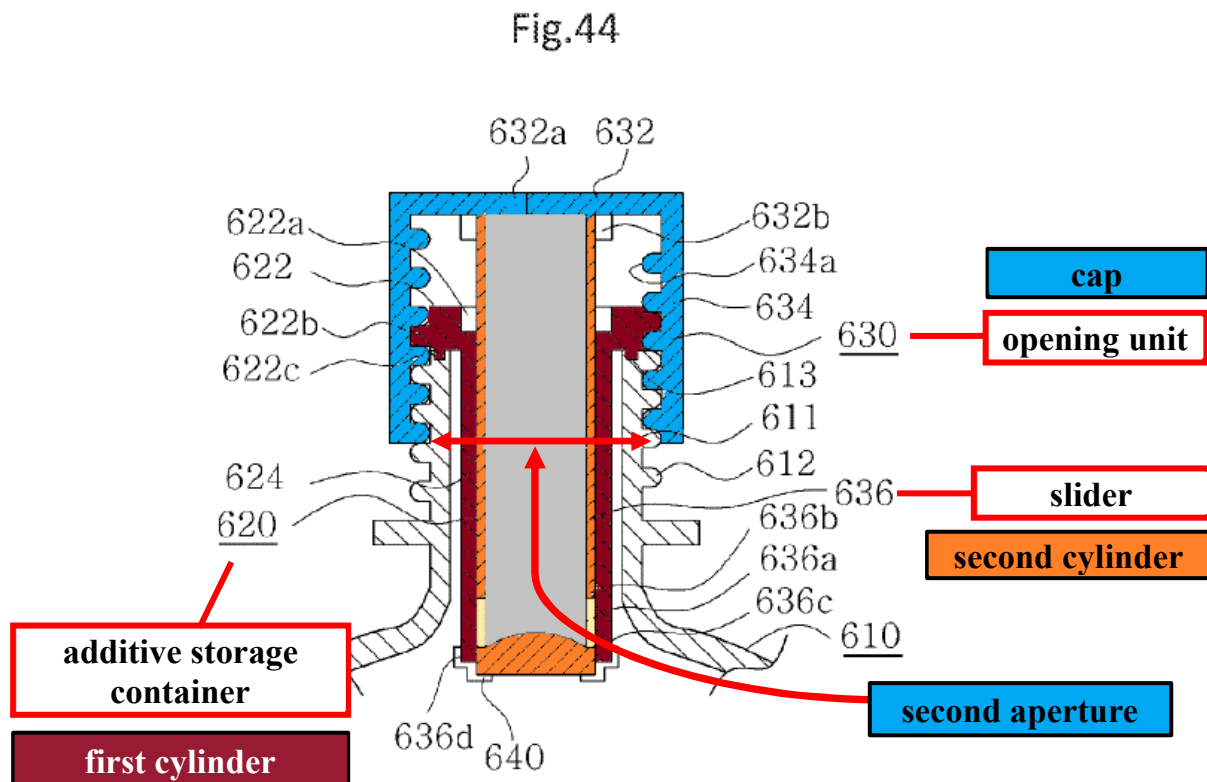
98. Cho's disclosure of the claimed movable annular valve is represented in, for example, Fig. 44, which has been annotated below on the left, alongside Fig. 3A from the '632 patent on the right, to show that Cho's valve includes the same elements recited in claim 1 of the '632 patent. Cho's annular valve is ring shaped and includes the same movable configuration as the embodiment of the '632 patent. The ring shaped cylinder moves over the inner cylinder to function as a valve that holds and then releases the reagent.



Ex.1004, Fig. 44; Ex.1001, Fig. 3A (both figures annotated, with reference numbers removed).

99. Limitation 1[d], in addition to reciting “a movable annular valve,” recites that the valve is “in the second aperture.” Cho's annular valve is positioned

in the second aperture, which is the aperture in the cap. Cho's valve is positioned within the cap and extends within the second aperture in the cap, as shown below. For example, Cho discloses that the inner cylinder (slider 636) is integrally connected with the cap (opening unit 630). 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):

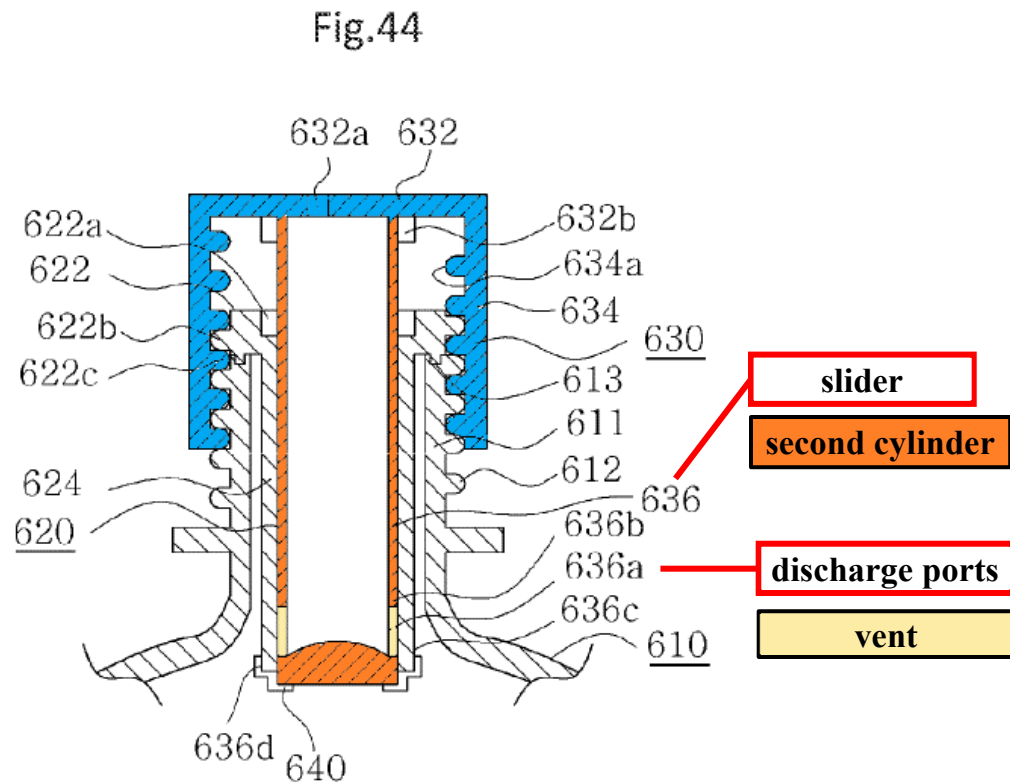


100. The valve of Cho is in the cap and extends into the sample collection

vessel, thus being positioned in and extending through the second aperture in the cap. Thus, Cho discloses “a movable annular valve in the second aperture.”

11. Limitation 1[d][i]: “a vent”

101. Limitation 1[d][i] recites that the movable annular valve comprises “a vent.” Cho discloses this vent limitation. Cho’s second (inner) cylinder includes discharge ports 636a, which provide a vent. Ex.1004, 49:14-21, 50:10-12, Figs. 43-45B. The vent is shown in Fig. 44 below:

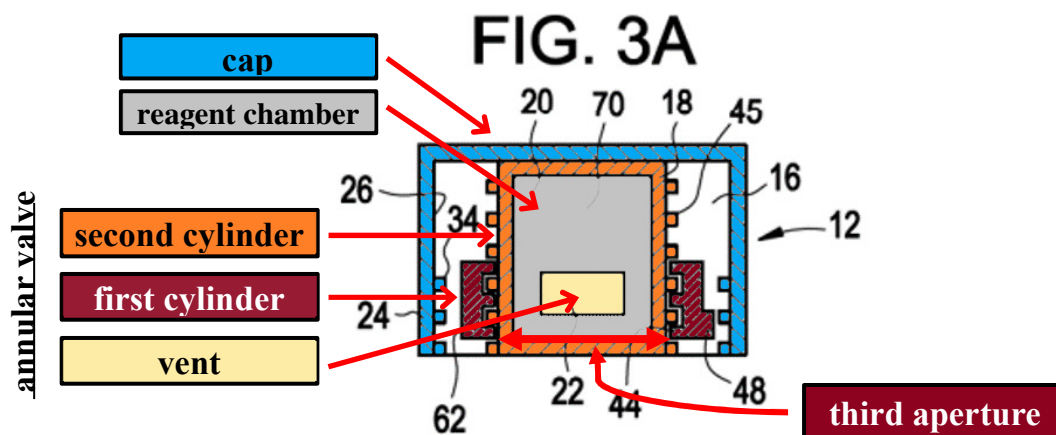


102. When Cho’s cap is tightened on the bottle, the second (inner) cylinder 636 slides past the first (outer) cylinder 624 and additive is released into the bottle through the vent (discharge ports 636a) in the sidewall of the second cylinder. *Id.*,

50:8-12.

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

103. Limitation 1[d][ii] recites that the movable annular valve includes “a first cylinder comprising a third aperture.” Cho discloses this limitation. The ’632 patent describes an annular valve having a first cylinder defining a third aperture, as shown below in annotated Fig. 3A. The annular blocking member 62 is the first cylinder and it defines a third aperture.

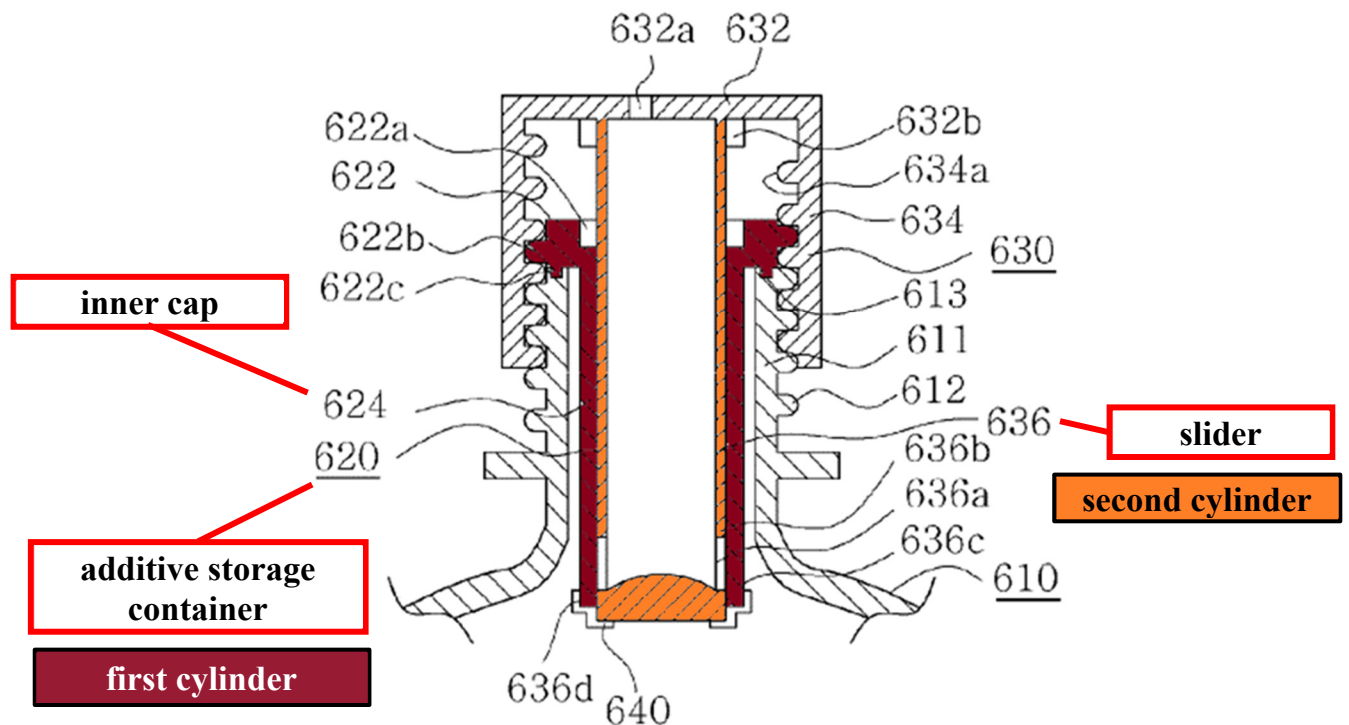


104. In Cho’s movable annular valve, the additive storage container 620 is the claimed first cylinder. Ex.1004, 48:18-20, 48:27-31, 49:10-13, 50:4-12, Figs. 43-45B. The additive storage container 620 includes a cylindrical portion called the “inner cap 624,” which “extends downward in an axial direction from the inner circumferential edge of the end plate 622.” *Id.*, 48:27-31.

105. Cho’s first cylinder (additive storage container 620) is in fluid-tight association with a second cylinder (slider 636). For example, Cho discloses that the inner cylinder (slider 636) is “inserted into the inner cap 624” and the slider 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 that contains the additive therein, so that the additive is not oxygenated or spoiled and the additive storage container can be easily applied to the mouth of typical bottles.” *Id.*, 1:28-2:3; *id.*, 55:22-25. Fig. 44 shows the additive storage container 620 and the inner cap 624:

Fig.44



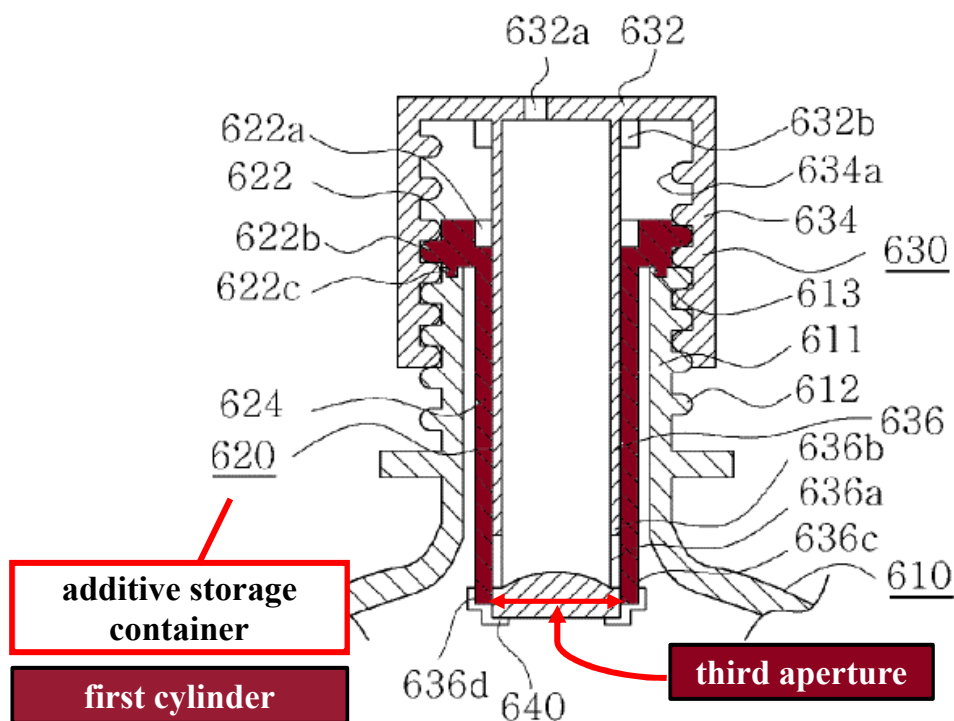
Id., Fig. 44 (annotated).

106. In the '632 patent, the third aperture in the first cylinder is the opening

defined by the annular blocking member 62 (first cylinder). *See, e.g.*, Fig 3A. The aperture permits the inner and outer cylinders to move axially relative to each other.

107. Cho’s annular valve similarly includes an aperture defined by the first cylinder, namely the additive storage container. Ex.1004, 49:5-13, Figs. 43-45B. Fig. 44 from Cho, annotated below, shows the aperture in the additive storage container 620, which is a third aperture.

Fig.44



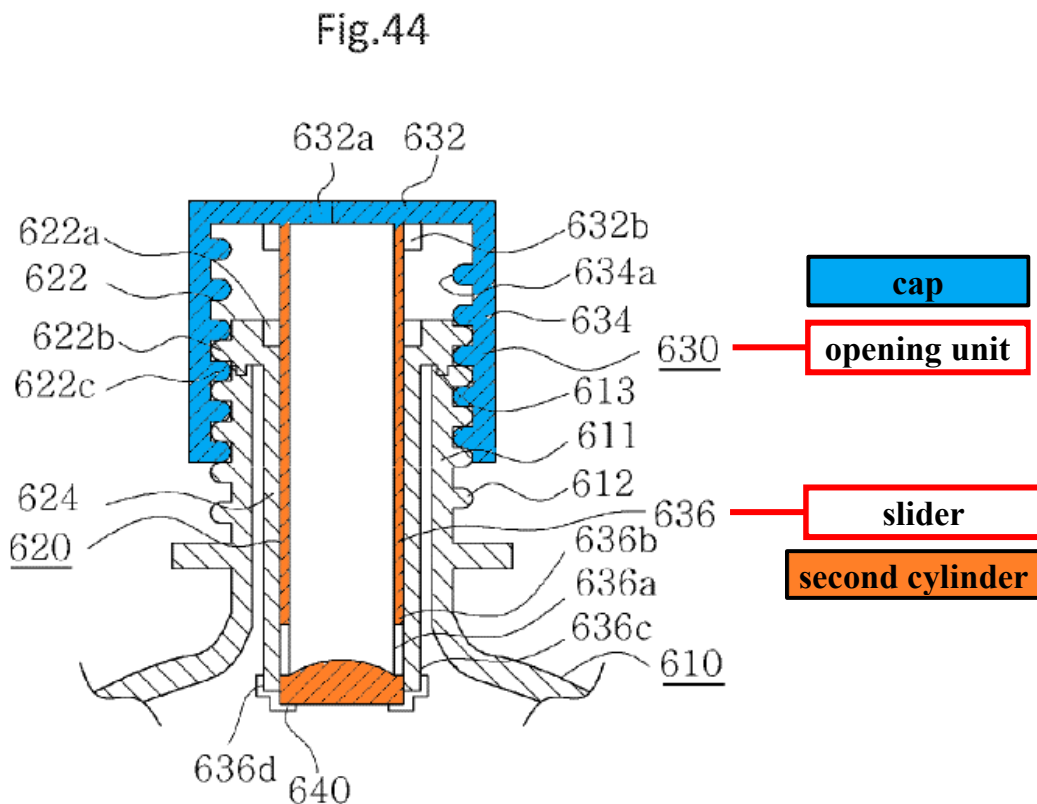
108. Thus, Cho discloses that the movable annular valve comprises “a first cylinder comprising a third aperture” as recited in limitation 1[d][ii].

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

109. Limitation 1[d][iii] recites that the movable annular valve includes “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. The second cylinder includes a vent 22 and is positioned in the third aperture of the first cylinder 62.

110. Cho discloses this limitation. Specifically, in Cho’s annular valve, the slider 636 is the claimed second cylinder. Ex.1004, 49:5-13, 50:4-15, Figs. 43-45B. As shown in Fig. 44 below, slider 636 is integrally connected with the cap (opening unit 630):

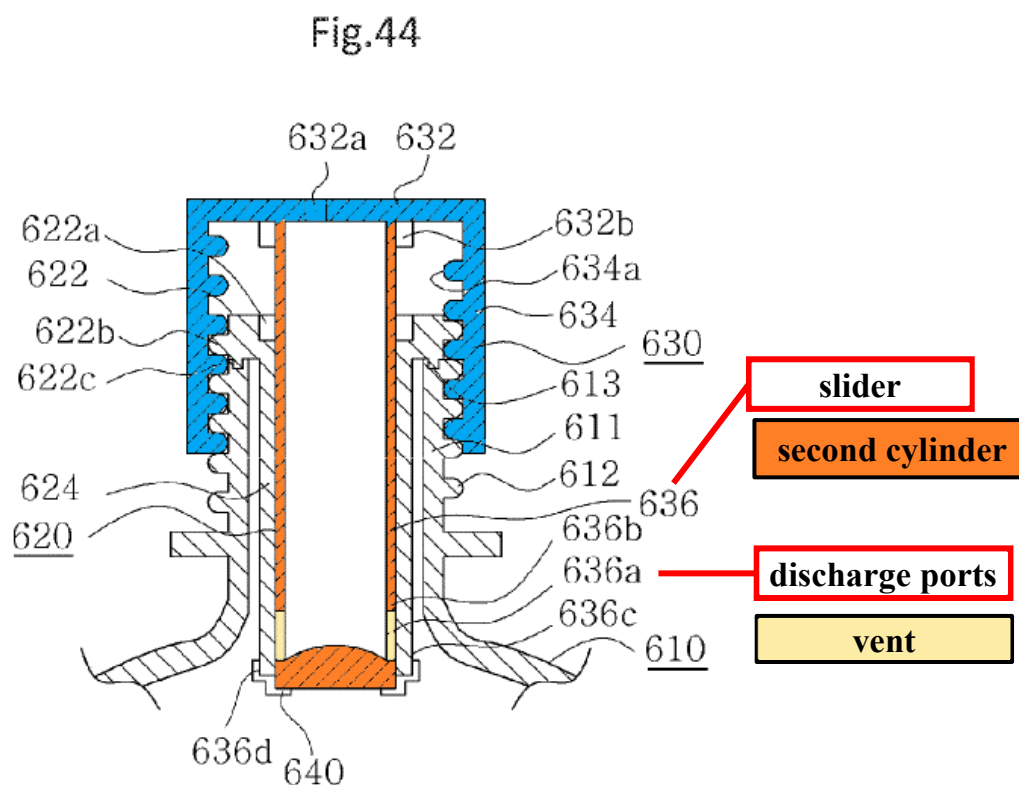


Id., Fig. 44 (annotated); *see also id.*, 49:5-13.

111. Cho’s second cylinder (slider 636) spans the length of the first cylinder

and is positioned in the third aperture, which is defined by the first cylinder (620). Thus, Cho's second cylinder is positioned in the third aperture defined by the first cylinder.

112. Cho's second cylinder includes discharge ports 636a, which provide a vent in the second cylinder. Ex.1004, 49:14-21, 50:10-12, Figs. 43-45B. The vent is shown in Fig. 44 below:



113. In use, when the cap is tightened on the bottle, the inner cylinder slides past the outer cylinder and additive is released into the bottle through the vent (discharge ports 636a) in the sidewall of the inner cylinder. *Id.*, 50:8-12. Thus, Cho discloses “a second cylinder comprising the vent, the second cylinder positioned in

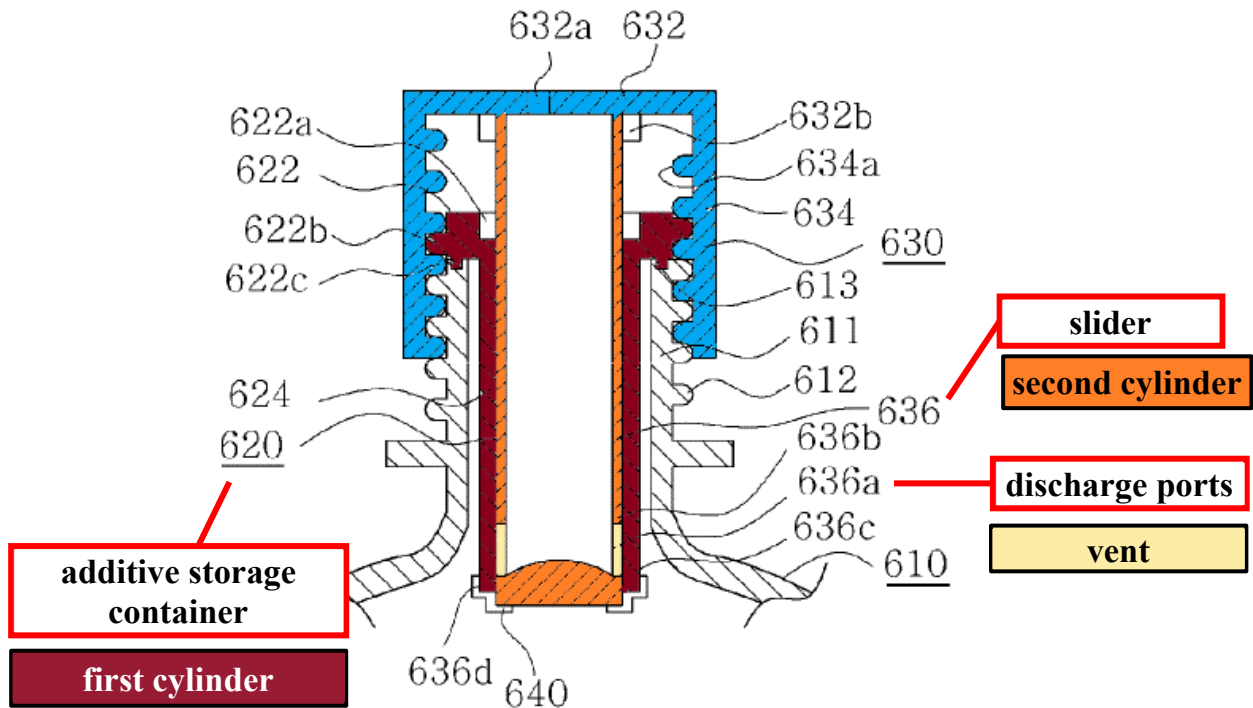
the third aperture.”

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

114. Limitation 1[d][iv] recites the movable annular valve comprises “a closed configuration.” Cho discloses this limitation.

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

Fig.44



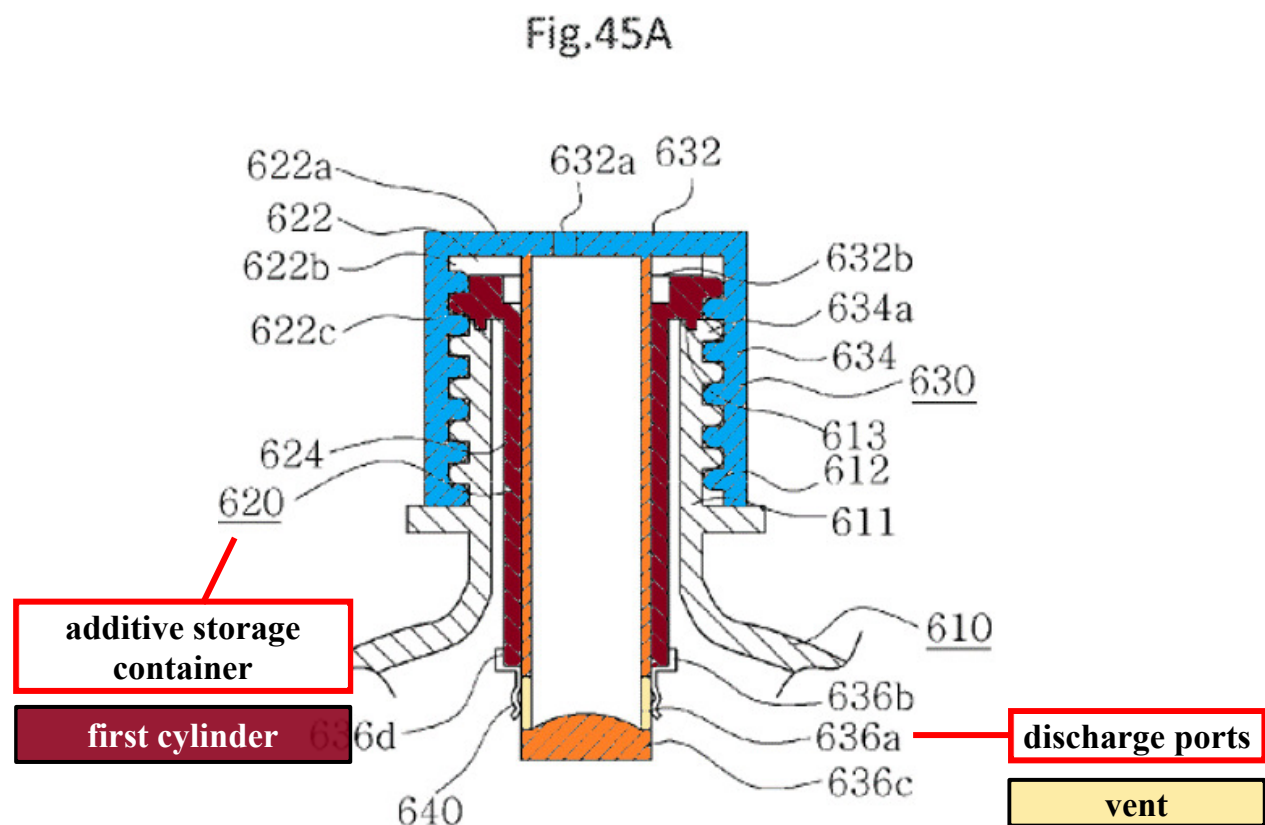
Id., Fig. 44 (annotated), 49:14-21. The opening unit 630 includes a port 632a through which the additive is loaded. Cho further states that the bottle “maintains a good seal on the interior space of an additive storage container that contains the additive therein, so that the additive is not oxygenated or spoiled and the additive storage container can be easily applied to the mouth of typical bottles.” *Id.*, 1:28-2:3; *id.*, 55:22-25.

116. Thus, the movable annular valve disclosed in Cho comprises “a closed configuration.”

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

117. Limitation 1[d][v] recites that the movable annular valve comprises an “open configuration.” Cho discloses this limitation.

118. When Cho’s cap is tightened on the bottle, the slider 636 “moves downward” within 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. Cho’s Fig. 45A shows the movable annular valve in an open configuration, with the interior sidewall of the first cylinder (additive storage container 620) no longer obstructs the fluid vent (discharge ports 636a) of the second cylinder (slider 636) so that the additive is discharged:

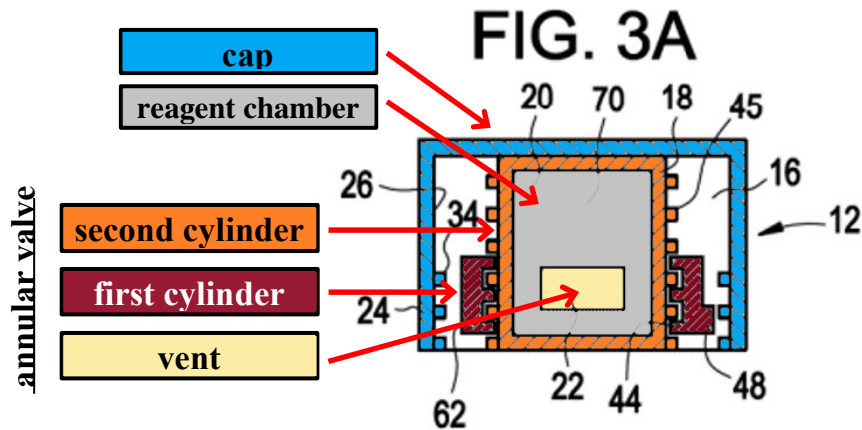


Id., Fig. 44 (annotated); *id.*, 49:34-50:12. Thus, Cho discloses an annular valve comprising an open configuration.

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”

119. Limitation 1[d][vi] recites wherein “in the annular valve’s closed configuration, the first and second cylinders create a fluid-tight seal with the cap and the first cylinder obstructs the vent to retain the reagent in the reagent chamber.” The ’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. The specification explains that the “interior space 20 may be at least partially defined by at least one of an inner wall 18 or outer wall 24 of the cap 12. . . . When the aperture 22 is closed such that the annular blocking member 62 is covering the aperture 22, fluid or material, such as sample preservation fluid or material 70, that me be contained in the interior space 20 may not be allowed to travel outside of the interior space 20, as shown in FIG. 3A.” Ex.1001, 14:20-32. As shown below in annotated Fig. 3A, 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 and in the cap, and the first cylinder obstructs the vent to retain the reagent in the reagent

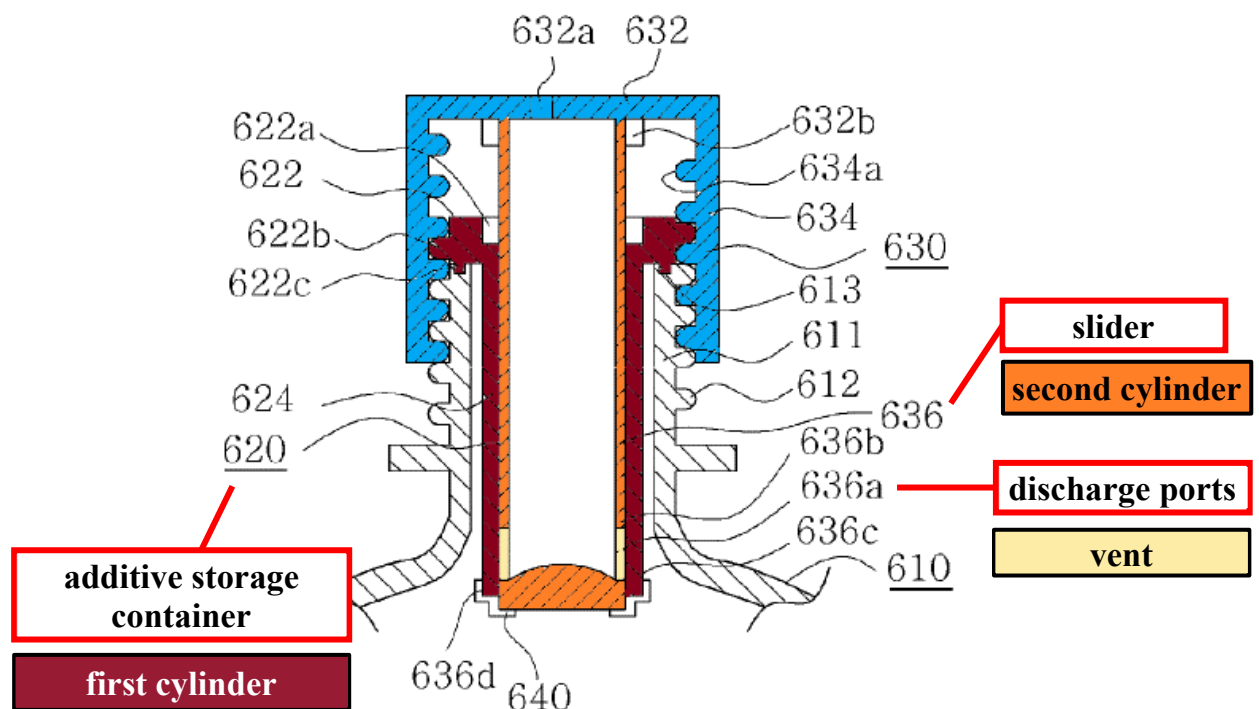
chamber.



120. Cho discloses these limitations. Specifically, 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. 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 inner cylinder (slider 636) is "inserted into the inner cap 624" and the slider 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 that contains the additive therein, so that the additive is not oxygenated or spoiled and the additive storage container can be easily applied to the mouth of typical bottles.” *Id.*, 1:28-2:3; *id.*, 55:22-25. Fig. 44 below shows the movable annular valve in a closed position, with the interior sidewalls of the first cylinder (additive storage container 620) obstructing the vent (discharge ports 636a) on the second cylinder (slider 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 disclosed in Plante.

Fig.44



Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21. Thus, Cho discloses a movable annular

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

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”

121. Limitation 1[d][vii] recites “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.

122. Cho's movable annular valve has an inner cylinder (slider 636) inserted into the outer cylinder (additive storage container 620). Ex.1004, 49:10-13. When Cho's cap is tightened on the bottle, 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 the cap is screwed onto the threads of the bottle, 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. Cho's Figs. 44 and 45A show the movement of the annular valve from a closed position to an open configuration in which the first cylinder no longer obstructs the fluid vent of the second cylinder (slider 636).

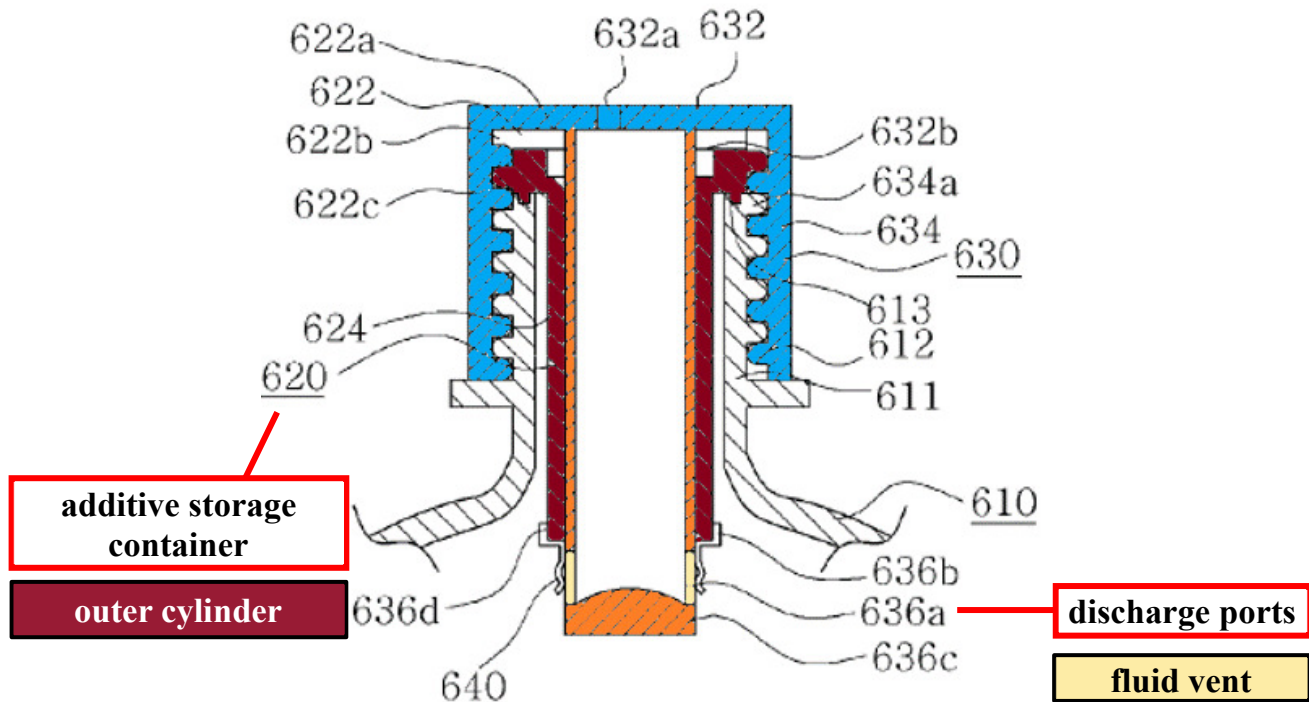
This diagram shows a cross-section of a container with two vertical chambers. The left chamber is labeled 'additive storage container' and contains a dark red substance. The right chamber is labeled 'first cylinder' and contains an orange substance. The container has a central vertical passage (632) and two side passages (634a, 634b) leading to discharge ports (636a, 636b, 636c). The container is surrounded by a vent (640). Various components are labeled with reference numerals: 620, 622, 622a, 622b, 622c, 624, 630, 632, 632a, 632b, 634, 634a, 634b, 636a, 636b, 636c, 640, 610, 611, 612, 613, 620, 624, 630, 632, 632a, 632b, 634, 634a, 634b, 636a, 636b, 636c, 640, 610, 611, 612, 613.

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 discloses this limitation.

124. Cho discloses that when the cap (opening unit 630) is tightened on the bottle, the slider 636 “moves downward” through the fixed-in-place outer cylinder (additive storage container 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 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. Thus, Cho discloses a movable annular valve wherein “in the annular valve's open configuration, the first cylinder

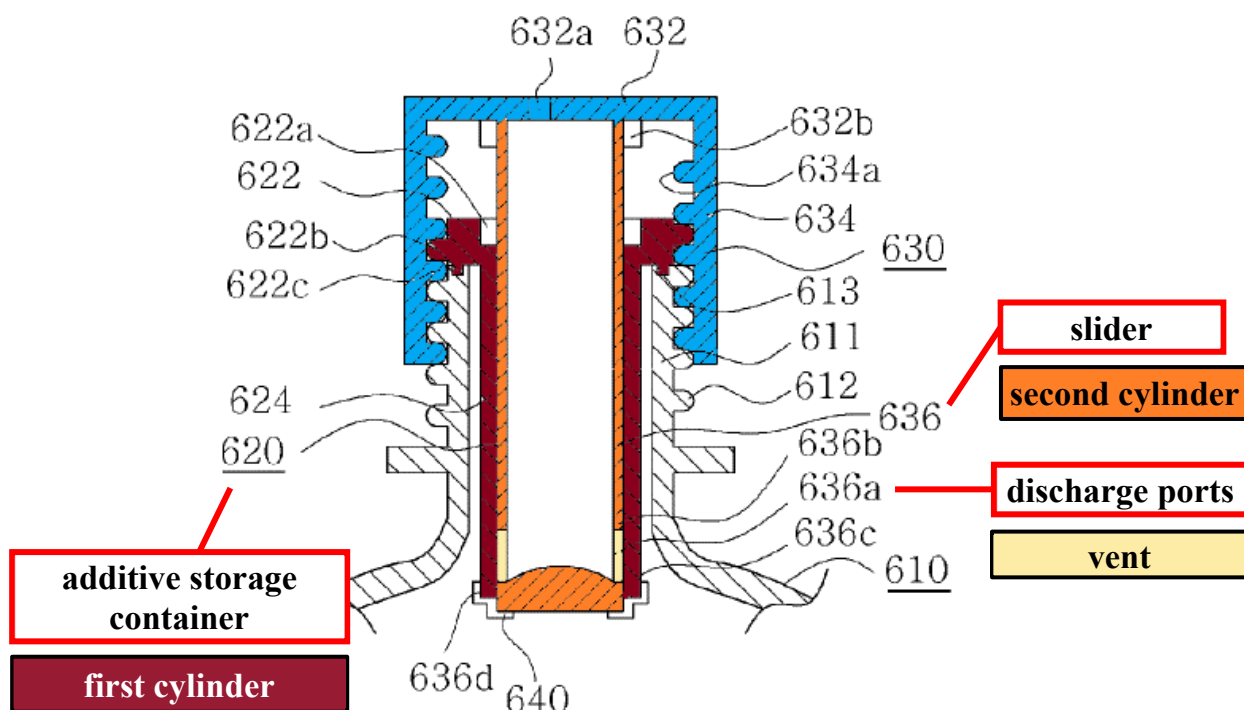
does not obstruct the vent to thereby allow flow of the reagent from the reagent chamber, through the vent, and into the sample collection reservoir.”

B. Plante and Cho Render Obvious Claim 2

125. Claim 2 depends from claim 1 and states: “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 discloses this limitation.

126. Regarding claim 2, Cho’s second cylinder (slider 636) includes a sidewall with a vent (discharge ports 636a). Ex.1004, 49:10-13. In the closed configuration, the additive is sealed in the additive storage space as a sidewall of the first cylinder obstructs the vent (discharge ports 636a) on the sidewall of the second cylinder to create a fluid-tight seal with the cap 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 obstructing the vent:

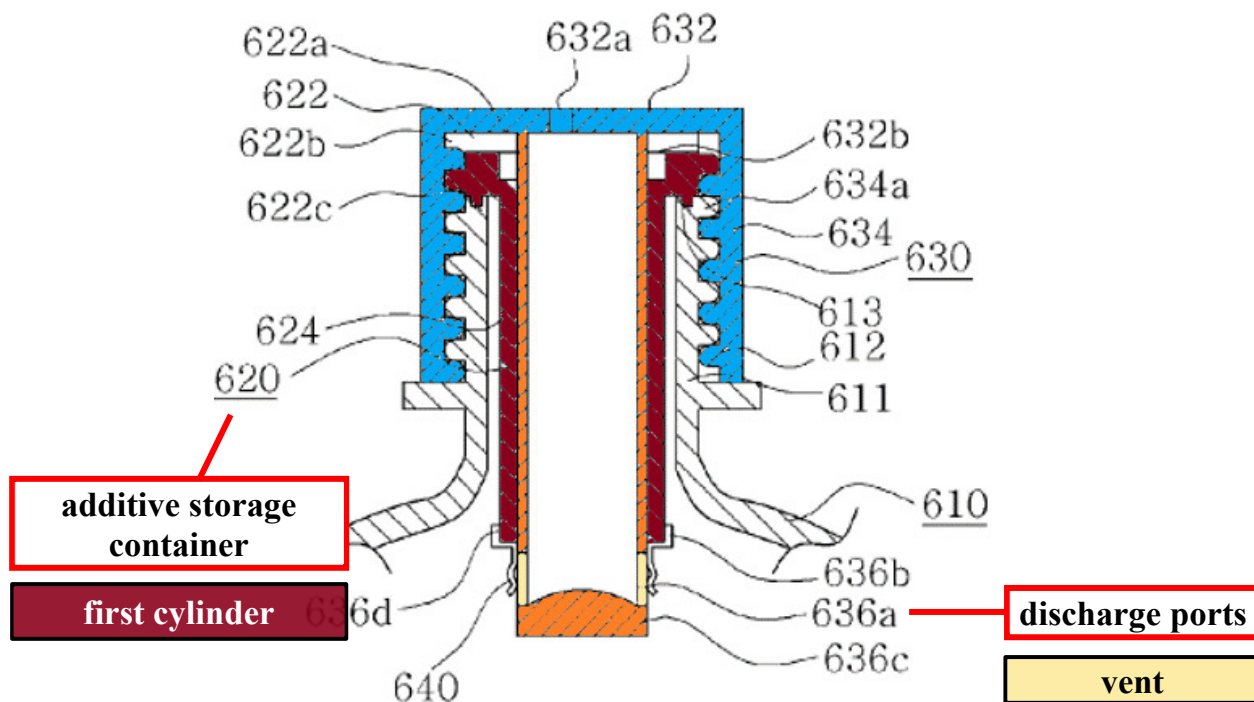
Fig.44



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

127. In the open configuration, the sidewall of the first cylinder 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.” Ex.1004, 50:8-12. Cho’s Fig. 45A shows the movable annular valve in an open configuration, where the sidewall of 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. Thus, Cho discloses the limitations of dependent claim 2.

C. Plante and Cho Render Obvious Claims 3 and 4

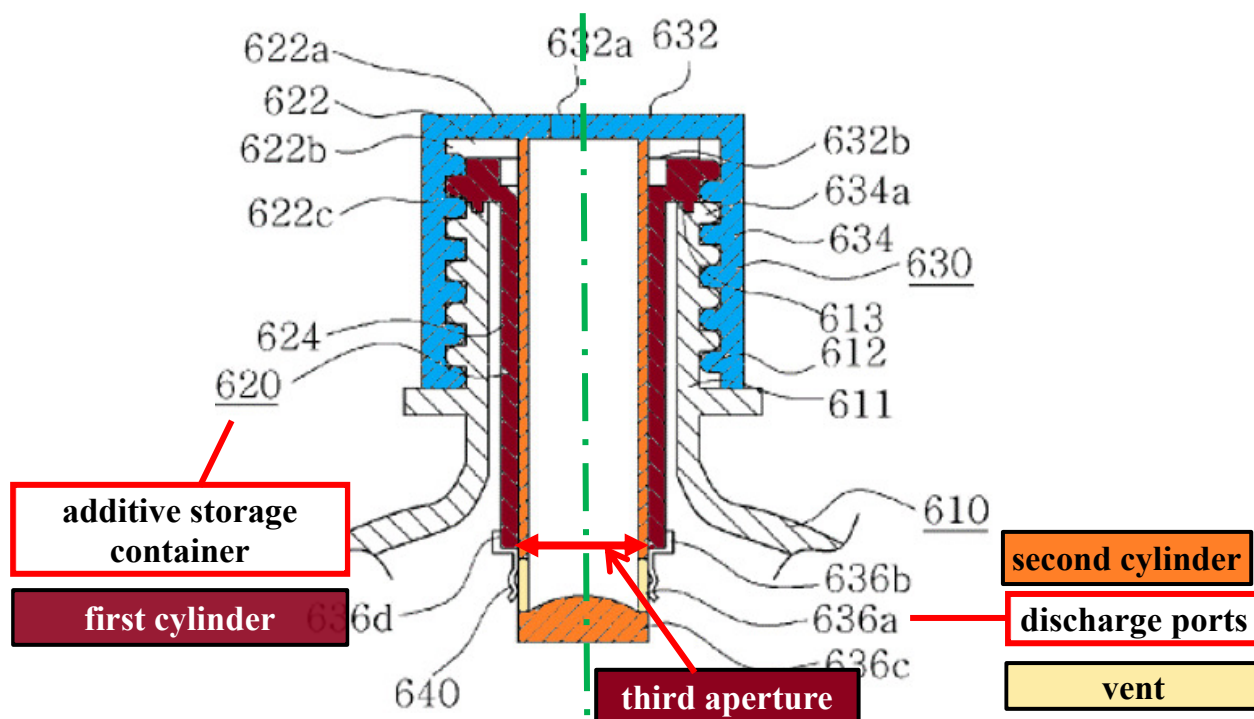
128. Claim 3 depends from claim 1 and recites “wherein the first and second cylinder's relative movement, from the annular valve's closed configuration to the open configuration, is translational along a longitudinal axis of the cap.” Cho’s valve meets this limitation.

129. 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's valve also meets this limitation.

130. As Cho's cap is tightened on the bottle, the slider 636 "moves downward" through the first cylinder in the third aperture "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 the cap is screwed onto the threads of the bottle, the second cylinder moves translationally downward along a longitudinal axis (green dashed line below) of the cap to move the parts of the annular valve from the closed configuration to the open configuration. This movement from the closed configuration to the open configuration involves the second cylinder moving in the third aperture in the first cylinder. Cho's Figs. 44 and 45A show the translational movement of the second cylinder in the third aperture in the first cylinder from a closed position to an open configuration:

Fig.45A



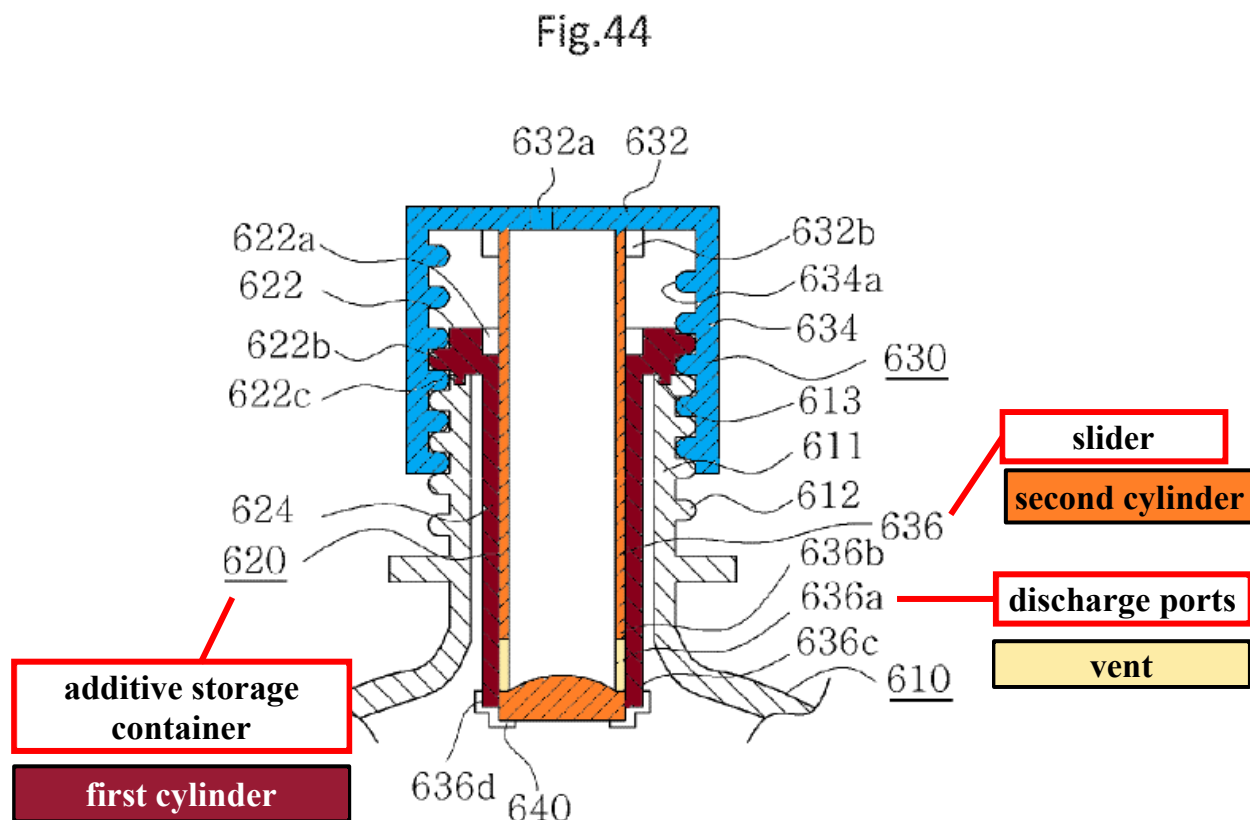
Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12. Thus, Cho discloses these limitations of dependent claims 3 and 4.

D. Plante and Cho Render Obvious Claim 6

131. Claim 6 depends from claim 1 and states: “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.

132. Cho’s second cylinder (slider 636) includes multiple vents (discharge ports 636a). Ex.1004, 49:10-15 (“At least two discharge ports 636a are formed around the circumferential surface of the lower part of slider 636). In the closed configuration, the additive is sealed in the additive storage space as a sidewall of the

first cylinder obstructs the vents (discharge ports 636a). *Id.* Fig. 44 shows the movable annular valve in a closed position, with the sidewall of the first cylinder obstructing the vents:



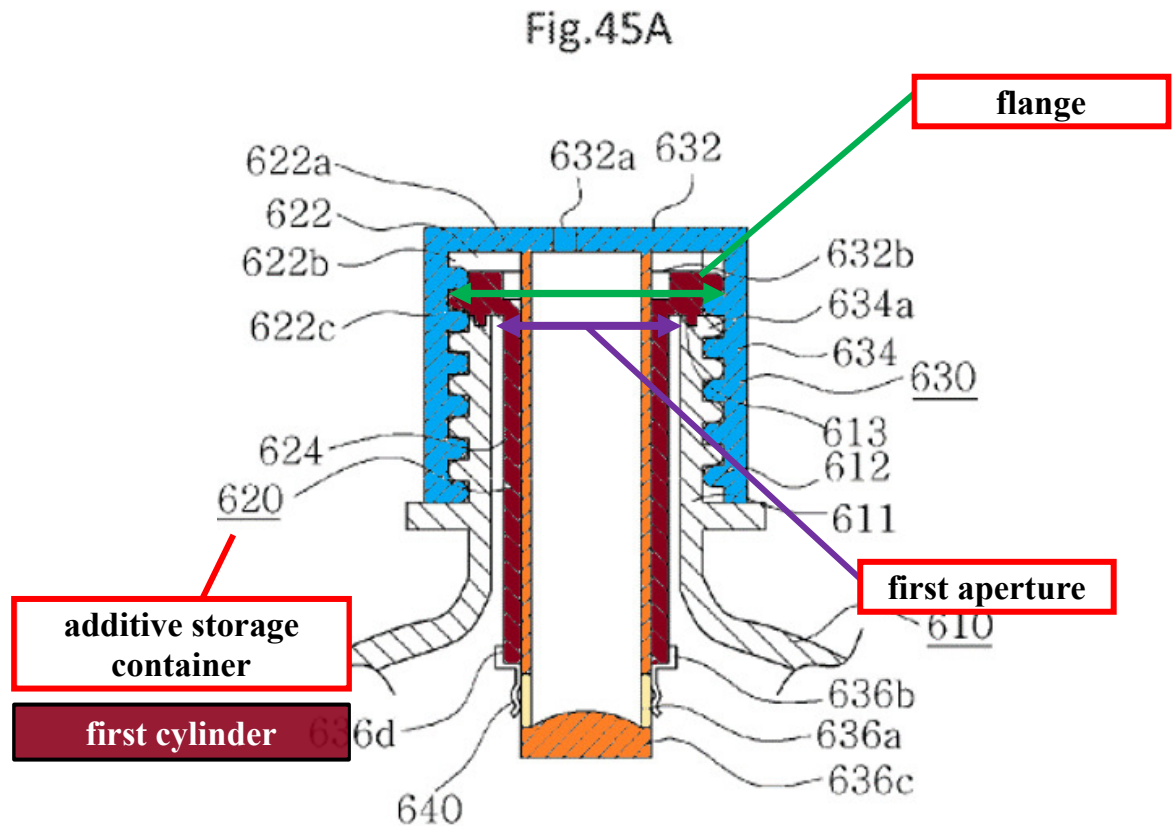
Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21.

E. Plante and Cho Render Obvious Claims 7 and 8

133. Claim 7 depends from claim 1 and states: “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’s valve includes this limitation.

134. Cho’s first cylinder 620 includes a flange having a width larger than a width of the first aperture in the sample collection vessel 610, as shown below in

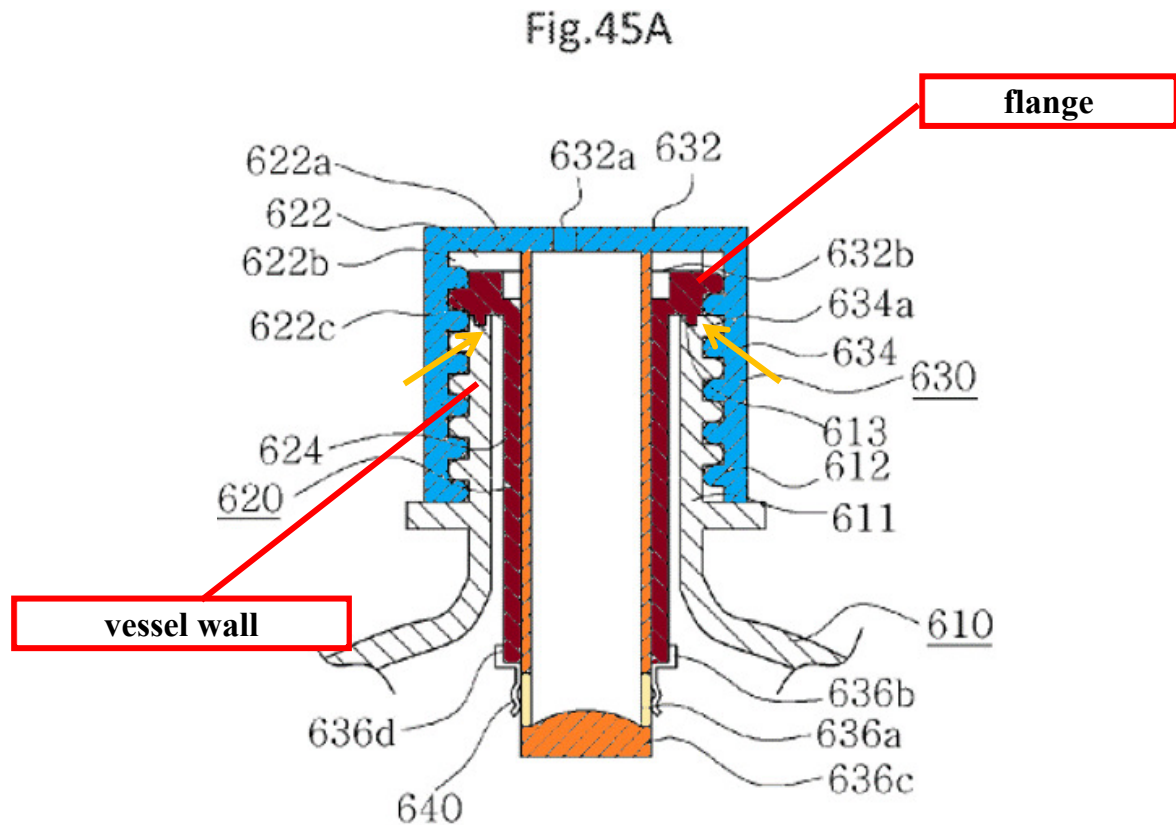
annotated Fig. 45A. The green line below illustrates the width of the flange and the purple line indicates the width of the first aperture defined by the container.



135. Claim 8 depends from claim 7 and states: “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’s valve also meets this limitation.

136. As Cho’s cap is screwed onto the vessel 610, the flange of the first cylinder 620 contacts and 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. Thus, Cho discloses these limitations.

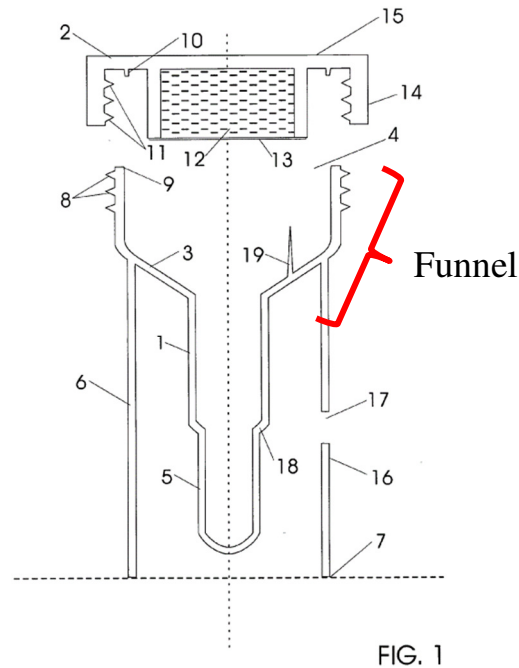


F. Plante and Cho Render Obvious Claim 9

137. Claim 9 depends from claim 1 and states: “further comprising a funnel attachable to the sample collection vessel.” Plante discloses this limitation which also would have been obvious.

138. In one embodiment, Plante’s sample collection vessel includes an

integrated funnel attached to the sample collection vessel, as shown below in Fig. 1.



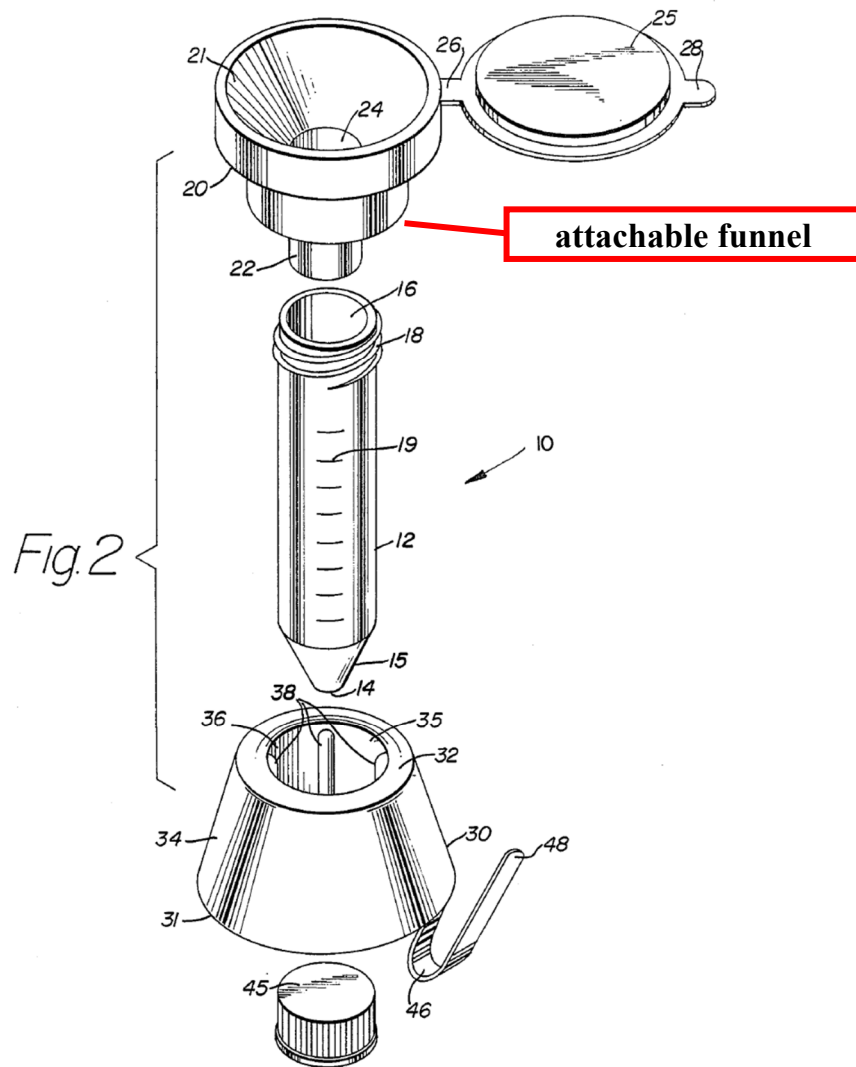
Ex.1003, Fig. 1. The funnel facilitates collection of the biological sample (e.g. saliva. *See, e.g.*, (Abstract: “The receiving vessel has integrated therewith: ... a funnel system ...”); [0019] (“A receiving vessel may be provided include an integrated funnel portion which allows ergonomic cooperation with the human mouth with regard to spitting and efficiently receives saliva from a donor as the donor spits into a large aperture of the funnel at its top end. The funnel terminates at a narrow, generally cylindrical tubular portion suitable for containing liquids received therein.”).

139. To the extent “attachable” means the funnel must be a separate part that is attached to the vessel, a POSA would have also known that it was common to use a separate funnel that can be selectively attached to and/or detached from the sample

collection vessel. Plante itself discloses such a separate attachable and detachable funnel, confirming that using such a funnel was well known in the art. Ex.1003, [0014] and [0015] (a receiving vessel is coupled by way of a thread set to a funnel element. The funnel is provided so that a user can easily spit into the device and the received saliva will be conveyed into the small aperture of the receiving vessel. 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, it is formed with integrated finger grips which are easily engaged and ergonomically cooperative with human finger tips.”) Although Plante describes the separate attachable funnel as having some disadvantages compared to the integrated funnel design, the separate attachable design would have still been a well-known option to a POSA. Whether to use a separate attachable funnel or an integrated funnel would have been a mere design choice from a finite number of options. Thus, Plante discloses the limitation of Claim 9 which would have been obvious in view of the combination of Plante and Cho.

140. References such as Williams (Ex.1009) further confirm that it would have been obvious to use a separate attachable and detachable funnel with the sample collection system of Plante and Cho. This would have been obvious in view of the knowledge of a POSA because it was common to use such a funnel in sample

collection systems. For example, Williams discloses a biological specimen collection device with a receptacle and a separate attachable/detachable funnel, as shown below in Fig. 2. Ex.1009, Abstract, 6:9-15 (“In order to collect the biological specimen, such as sputum, cover 25 is lifted by virtue of finger tab 28 whereupon the specimen is deposited in wide receiving portion 21 of the funnel.”). Williams explains that the “funnel includes a relatively wide sputum receiving portion and a passage tube to which the receptacle is removably connected so that the tube communicates with the inside of the receptacle through its open end.” *Id.*, 2:39-43. Williams’ design allows for “ready removal of the funnel after the specimen has been collected.” *Id.*, 4:11-22.



141. A POSA would have been motivated to use a separate attachable and detachable funnel for several reasons. Such an attachable funnel would be beneficial because it would facilitate obtaining the biological saliva sample from the user while allowing for a smaller cap and container that would require less manufacturing

materials. A funnel must be significantly wider than a typical test tube in order to provide its desired benefits of facilitating collection. A separable funnel allows the container and cap combination to remain small after the funnel is removed, which is very beneficial for post-collection processing. 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. In addition, using a separate attachable funnel would also allow for lower profile packaging and a smaller container for shipping to the lab for analysis. 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 for storage.

142. There are several additional examples of prior art sample collection systems that included separate attachable/detachable funnels. *See e.g.*, Ex.1018 (U.S. 4,589,548 to Fay) at 6:18-26 (“To collect a specimen, tab 38 is grasped and upper lid 34 is opened in the direction of arrow 88. The patient then deposits the sputum sample into the funnel 24 so that it is conducted into container 12. Lid 34 is closed in the direction of arrow 90 so that ridge means 40 are received by funnel mouth 26 and sealably engage the inside surface of the funnel 24 proximate mouth 26. When collection of the specimen has been completed, the funnel is removed from container 12 and discarded.”); Ex.1019 (U.S. 4,741,346 to Wong) at 3:39-44 (“A portion of the funnel 32 can be inserted in the vial open end 61. The

upper surface of the vial 30, contiguous to the open end 61, is formed with threads which are threadably mateable with a threaded vial cap 74.”); Ex.1020 (U.S. 3,518,164 to Adelin) at 2:48-52, 3:24-29 (“The sputum specimen receptacle 1 illustrated in FIGS. 1 and 3 is closed at its bottom end and open at the top so that the annular ring 7 of the funnel 2 may be frictionally seated therein.”).

143. Thus, the limitation of Claim 9 would have been obvious in view of the combination of Plante and Cho.

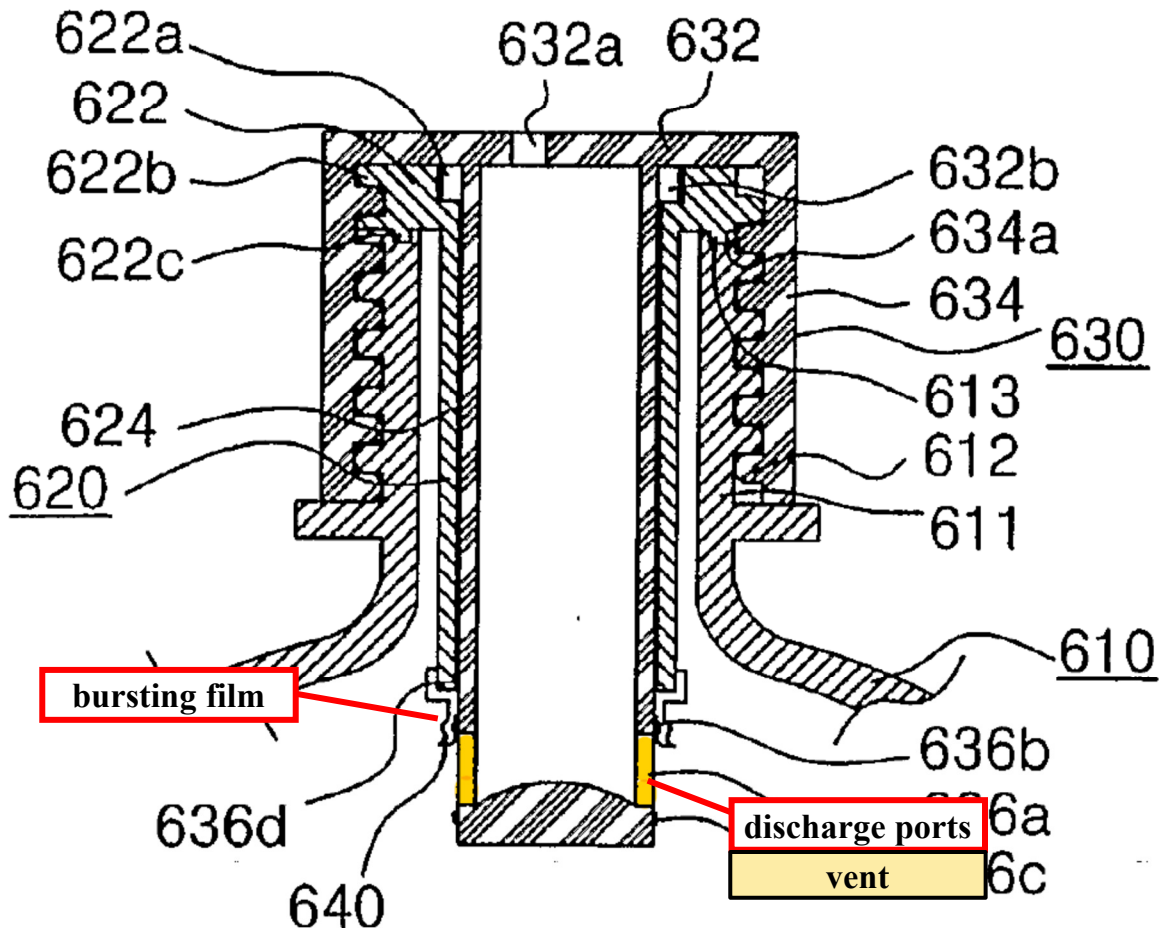
G. Plante and Cho Render Obvious Claims 10 and 11

144. 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.

145. When Cho’s cap is tightened on the bottle, the second cylinder (slider 636) “moves downward” through the first cylinder 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. In the open configuration, the vent is positioned below the first cylinder 620 and thus the vent is not obstructed by the first cylinder 620. Cho’s Fig. 45A shows the movable annular valve in an open configuration, where the first cylinder (additive storage container 620) does not obstruct the fluid 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. In this open configuration, the vent is at least partially unobstructed.

FIG. 45A



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

146. Claim 11 depends from claim 1 and recites “wherein the vent is fully unobstructed in the annular valve's open configuration.” A POSA would have understood that Cho’s vent (discharge ports 636a) is fully unobstructed in the valve’s

open configuration. As shown in Figure 45A above, the second cylinder and vent 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. However, 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. A POSA would also know that the film 640 is optional, so to the extent the film partially blocks the vents the film could be removed.

147. To the extent Cho’s vent is somehow partially obstructed by the burst film, a POSA would have understood that it would have been obvious to arrange Cho’s open configuration such that the vent 636a extends past any remnant of the bursting film so that the film cannot obstruct any of the vent 636a. For example, a POSA could have easily changed the length of the first cylinder 620 so that the second cylinder extends out further when in the fully open position.

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 (“Ring-type seal protrusions 636b and 636c are formed around the outer circumferential surface of the slider 636 at positions above and below the discharge ports 636a, so that the protrusions 636b and 636c 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.”). Thus, a POSA would have known that the bursting film 640 was optional in Cho’s annular valve.

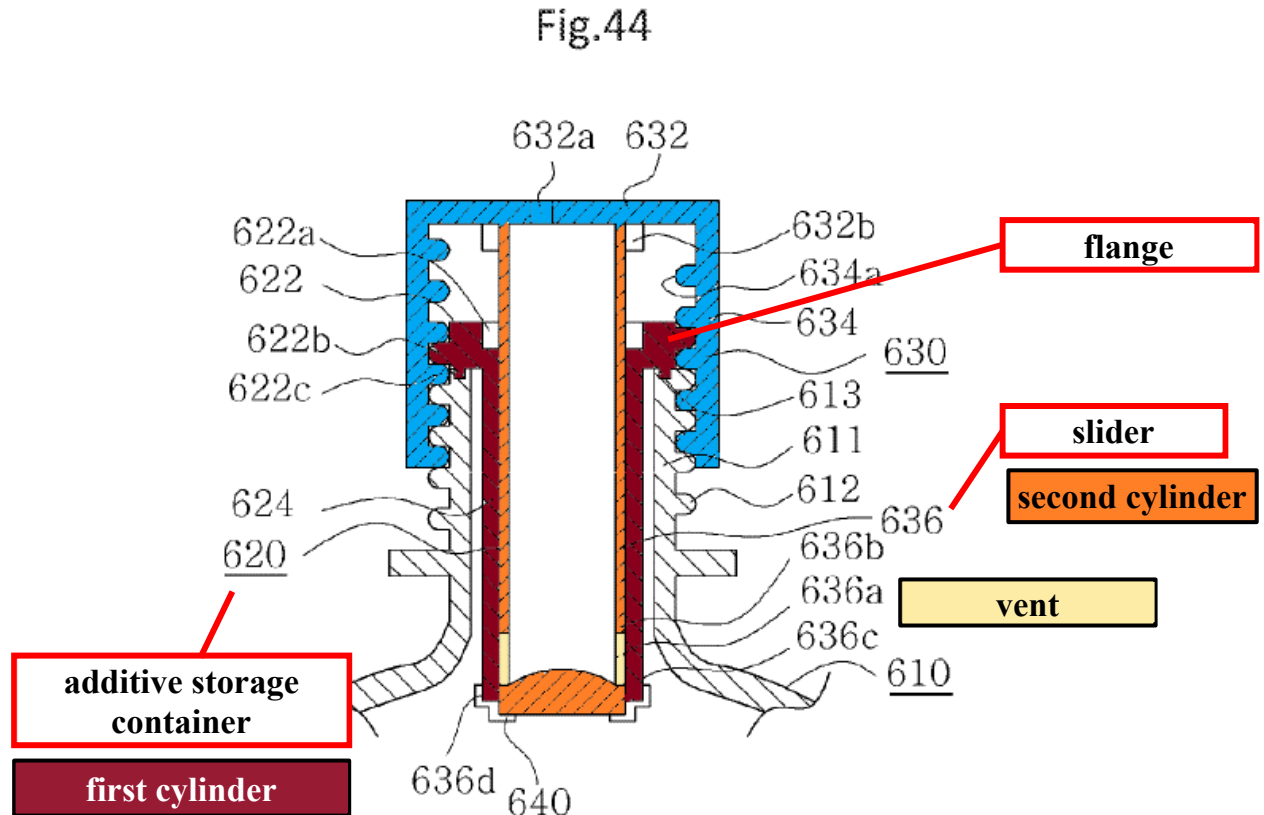
149. Therefore, these limitations of Claims 10 and 11 would have been obvious in view of Plante and Cho.

H. Plante and Cho Render Obvious Claims 12 and 13

150. 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.

151. As shown in Fig. 44 below, Cho’s first cylinder (additive storage container 620) and second cylinder (slider 636) have generally constant exterior diameters. These parts are cylindrical and the second cylinder moves within the first cylinder. A POSA would understand that these cylinders have generally constant exterior diameters such that they can function properly from the closed to open

configuration while maintaining a seal in both configurations. Fig. 44 also shows the flange extending from the first cylinder 620.



Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21. Thus, the annular valve of Cho includes each of the limitations of Claims 12 and 13.

I. Plante and Cho Render Obvious Claim 14

152. 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.

153. Both Plante and Cho disclose threaded connection members. These threaded connections, which the ’632 patent describes as “well known to those of

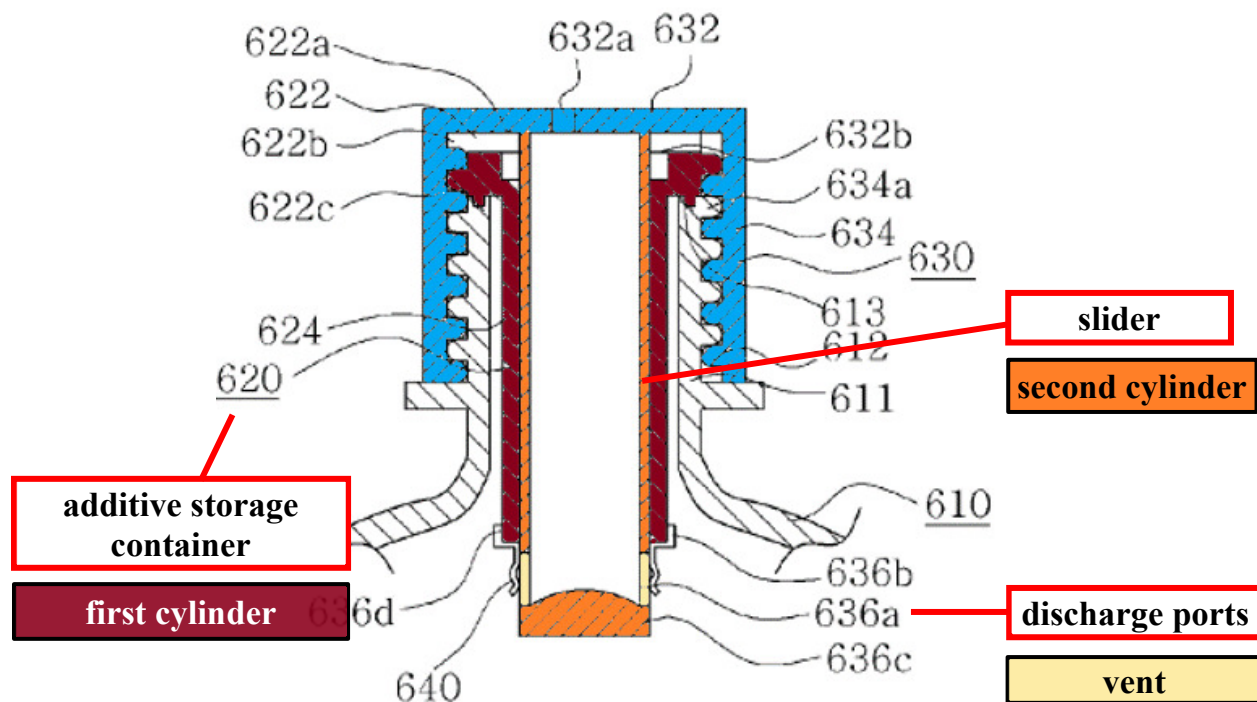
skill in the art” (Ex.1001, 10:58-65), are disclosed in Plante and Cho, which each disclose external threads on a container that mate with internal threads on a cap. *See, e.g.,* Ex.1003, Fig. 1 (thread sets 8 and 11); Ex.1004, Figs. 44, 45 (threads 634a and 612). Thus, claim 14 is disclosed by and would have been obvious based on the combination of Plante and Cho.

J. Plante and Cho Render Obvious Claim 15

154. 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.

155. Cho’s second cylinder slides relative to the first cylinder when the cap is fully screwed onto the bottle. When Cho’s cap is tightened on the bottle, the slider 636 “moves downward” through the first cylinder “so that the additive is discharged from the additive storage container 620.” 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 Figs. 44 and 45A illustrate the sliding movement of the annular valve in which second cylinder (slider 636) slides relative to the first cylinder.

Fig.45A



Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12. Thus, this limitation is rendered obvious by the combination of Plante and Cho.

K. Plante and Cho Render Obvious Claim 16

156. 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 these features.

157. 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). 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.

158. 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. 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.*, [0042]. Plante explains that because the system is designed for use by consumers, it is advantageous to provide for two-way shipping in a box suitable for same. *Id.* The box, depicted in Figure 4, includes cavities that support two discrete shipping modes: the cap and receiving vessel separate (before sample collection) and together (after sample collection). Ex.1003, Fig. 4.

159. 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. Thus, the combination of Plante and Cho renders claim 16 obvious.

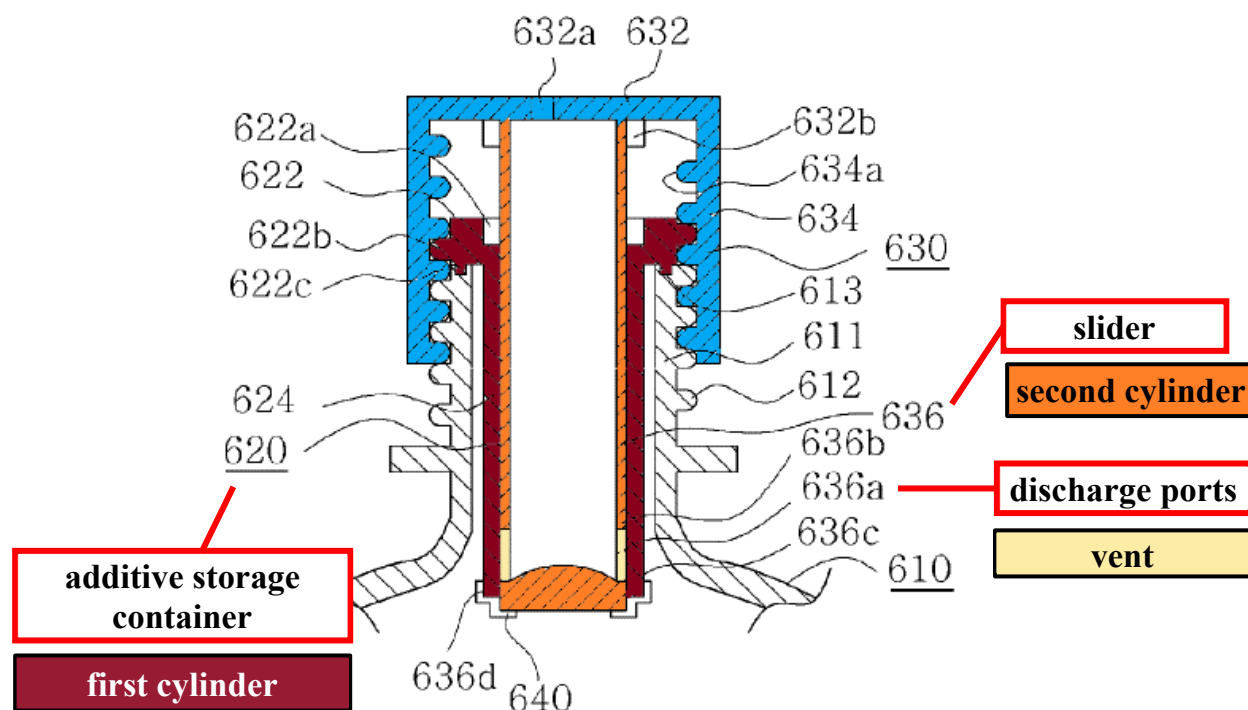
L. Plante and Cho Render Obvious Claim 18

160. Claim 18 depends from claim 1 and states: “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.” Cho discloses this limitation.

161. Cho discloses that the slider 636 “extends downward in an axial direction” and “is inserted into the inner cap 624” of the additive storage container 620. Ex.1004, 49:10-13. Cho discloses that the slider 636 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.” *Id.*, 49:16-20. This fluid-tight connection between the inner cylinder (slider 636) and the outer cylinder (inner cap 624, additive storage container 620) “prevent[s] an additive from leaking through the discharge ports 636a.” *Id.*, 49:20-21. Fig. 44 below shows that the inner cylinder (slider 636) is substantially equal to the diameter of the inner wall of the outer cylinder (additive storage container 620). 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.

Fig.44



Ex.1004, Fig. 44 (annotated), *id.*, 49:14-21. Thus, claim 18 would have been obvious based on the combination of Plante and Cho.

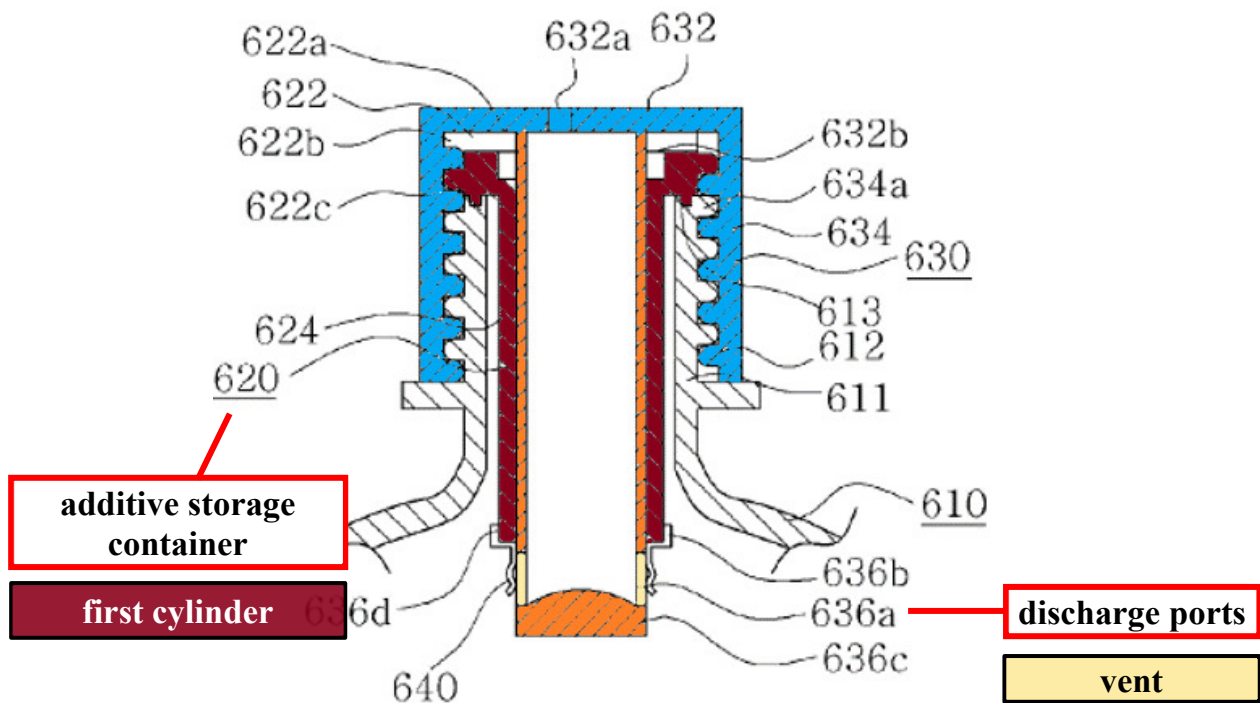
M. Plante and Cho Render Obvious Claim 19

162. Claim 19 depends from claim 1 and states: “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.” The combination of Plante and Cho discloses this limitation.

163. When Cho’s cap is tightened on the bottle/vessel this causes the slider 636 to move 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. Cho’s cap is connected to the bottle by screwing onto the threads of the bottle/vessel, which causes the second cylinder to move relative to the first cylinder to move the parts of the annular valve from the closed configuration to the open configuration. Cho’s Figs. 44 and 45A show the movement of the annular valve from a closed position to an open configuration when the cap is connected to the bottle/vessel.

Fig.45A



Ex.1004, Fig. 45A (annotated); *id.*, 49:34-50:12. Thus, claim 19 would have been obvious based on the combination of Plante and Cho.

N. Plante and Cho Render Obvious Claim 20

164. Claim 20 depends from claim 1 and recites limitations from dependent claims 2, 3, and 19. I have already addressed these limitations above in the corresponding sections. As discussed above with regard to claims 2, 3, and 19, Cho discloses these limitations and these limitations would have been obvious in view of the combination of Plante and Cho. *See supra* Section VIII.B, VIII.C and VIII.M.

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

165. Claim 5 depends from claim 1 and recites “wherein the first cylinder comprises a press-fit connection with the cap.” It would have been obvious to use such a press-fit connection between the first cylinder and the cap in view of Plante, Cho and Patterson.

166. The ’632 patent specification does not use the term “press-fit,” and it fails to explain whether any of the disclosed connections are press-fits. The ’632 patent does not provide any definition of “press-fit” or example of a press-fit connection between the first cylinder and the cap. 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

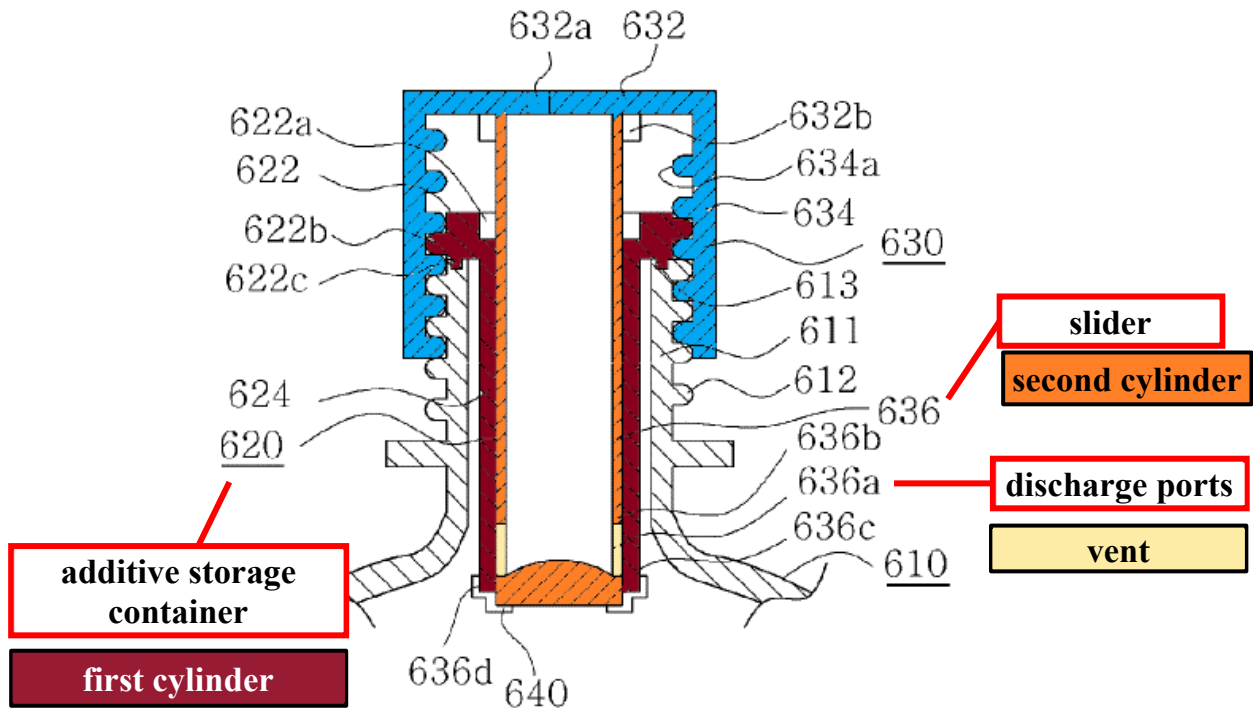
internal thread 634a in Cho Figs. 44 and 45A).

167. Also, the '632 patent's lack of disclosure confirms that the use of a press-fit connection in this context was fundamentally known and familiar to a POSA and easily implemented. A POSA would have been familiar with press-fit connections, which were common in containers and medical devices. Instead of describing a press-fit connection between the first cylinder and the cap, the '632 patent generally identifies various types of "well known" connections. Ex.1001, 10:58-67 ("The terms push, rotate, screw, mate as well as thread, couple, and attach, as well as any corresponding tenses and plurals thereof . . . disclosed herein, correspond to structure (well known to the those of skill in the art) for connection (either permanent or temporary) of two (or more) components."). Thus, according to the '632 patent, it was unnecessary to expressly describe a press-fit connection because such connections were "well known to those of skill in the art." *Id.* As confirmed by 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 Cho's.

168. The prior art also confirms that press-fit connections in container caps were well known prior to the '632 patent. Cho's cap has a press-fit connection between the first cylinder (additive storage container 620) and the second cylinder

(slider 636) which is part of the cap. 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) which is a friction fit that maintains a fluid-tight seal between those parts. In order to maintain a seal between the first cylinder 620 and the second cylinder 636 of the cap, a press-fit providing an interference between the two parts is necessary.

Fig.44



169. Patterson is another example of prior art disclosing press-fit connections between cylindrical parts of the cap that do not involve threads. Ex.1010, [0032] (“mixing cap 10 may be coupled to an unthreaded mouth of a bottle via frictional-fit.”). Patterson discloses a press-fit connection between a first cylinder and a cap. For example, Patterson discloses an outer cylinder (outer housing 20, 22) of the cap 10 that comprises an interference fit (press-fit connection) with an inner cylinder (inner tube 40) of the cap 10, as shown below in annotated Figs. 2 and 3. Ex.1010, [0032]. In Patterson’s embodiment, the inner cylinder 40 includes threads that engage and couple with corresponding threads on the bottle or container.

Id. After the cap 10 is threaded onto the container, 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, facilitating the passage of ingredients from the mixing cap 10 to the container. *Id.* 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.

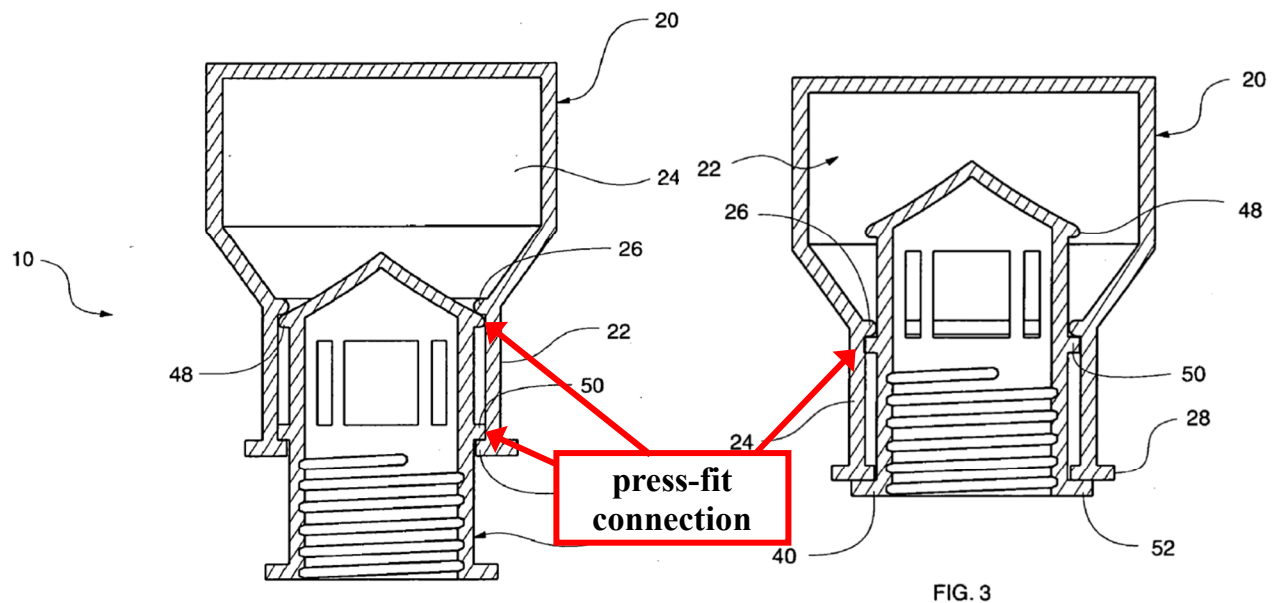


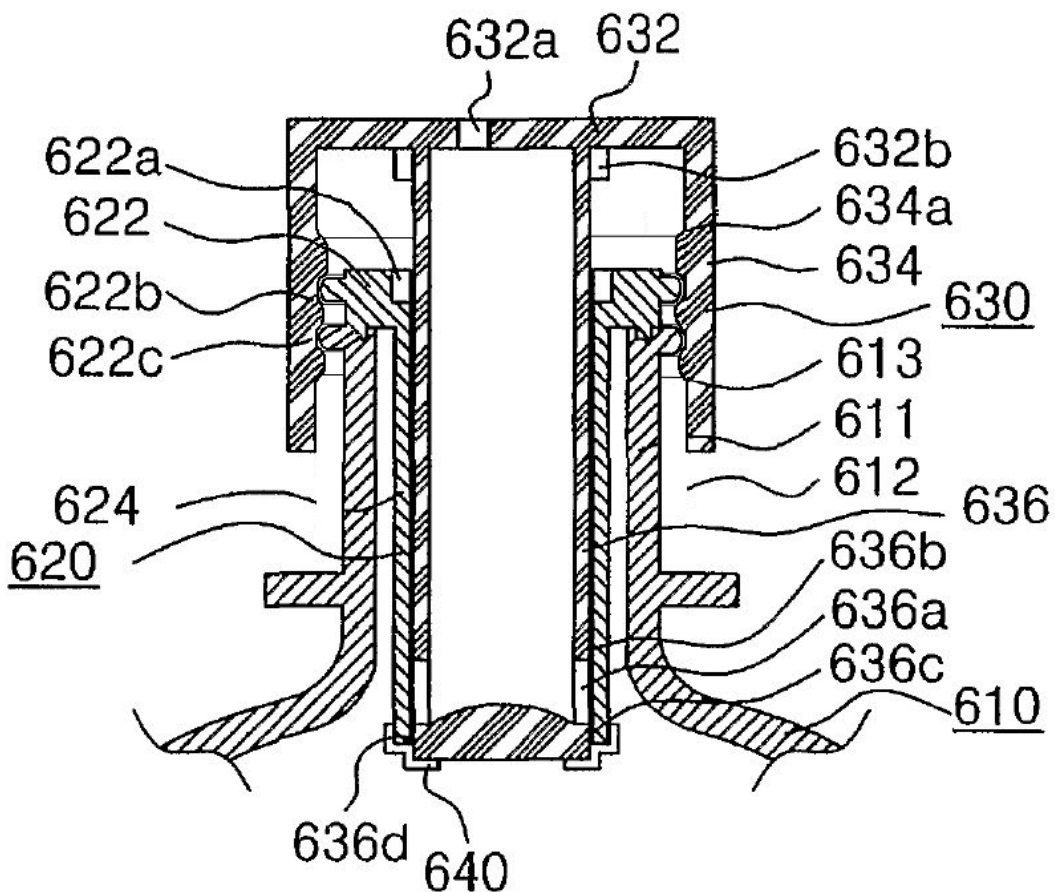
FIG. 2

FIG. 3

170. It would have been obvious for a POSA to modify Cho’s movable

annular valve in view of Patterson to replace the threaded connection between Cho's first cylinder 620 and the cap 634 with a non-threaded press-fit connection like Patterson's. As modified, 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. 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 in modified Fig. 44 below.

FIG. 44



171. Patterson's press-fit (snap-fit), which would have been obvious to incorporate into Cho's cap, could also be designed as a simple press-fit with only an interference-fit and no snap feature. Such simple press-fits were common and well-known to a POSA. This is supported by the straight interference fits shown in 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.

172. Using a non-threaded press-fit instead of a threaded connection in these collection systems 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. 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. A POSA would have understood that molding threads on these types of devices can be difficult and requires a more complex manufacturing process. Molding a protrusion, bump, or a rib is much easier than threads. For example, molding threads can sometimes require a mold with an unwinder core, whereas a protrusion, bump, or rib can be formed by a simple two-sided mold or by merely pulling the tool over the molded part. A POSA could have molded an interference fit with a 0.003 inch or less protrusion that can be molded as an undercut in the tool. On the other hand, threads require unwinding tool or other complex tooling to mold the helical threads. 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.

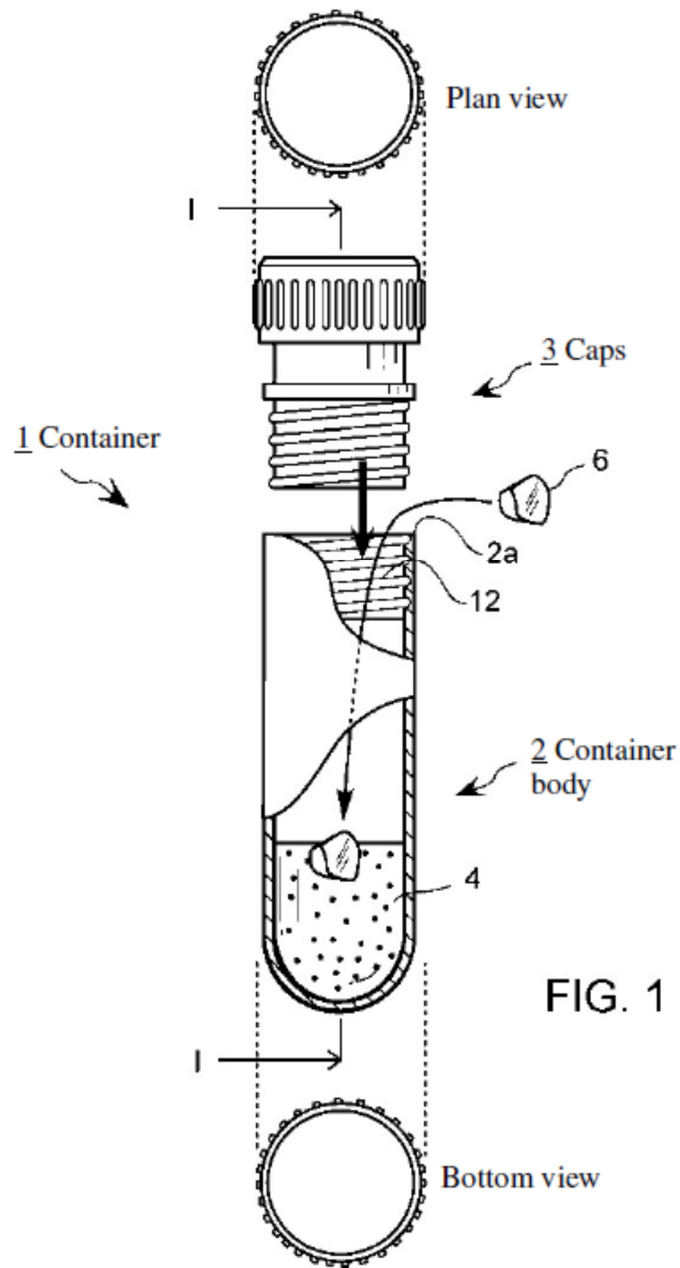
X. GROUND 3: UEDA ANTICIPATES CLAIMS 1-8, 10-16, AND 18-20

A. Ueda Anticipates Claim 1

173. Ueda discloses a biological sample container with all of the features of Claim 1 of the '632 patent. Ex.1005, [Abstract]. 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.* The second mixed material in the cap can be a reagent such as "a granular gelling material, where mixing this with the first mixed material 4 gels the first mixed material 4." *Id.*

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

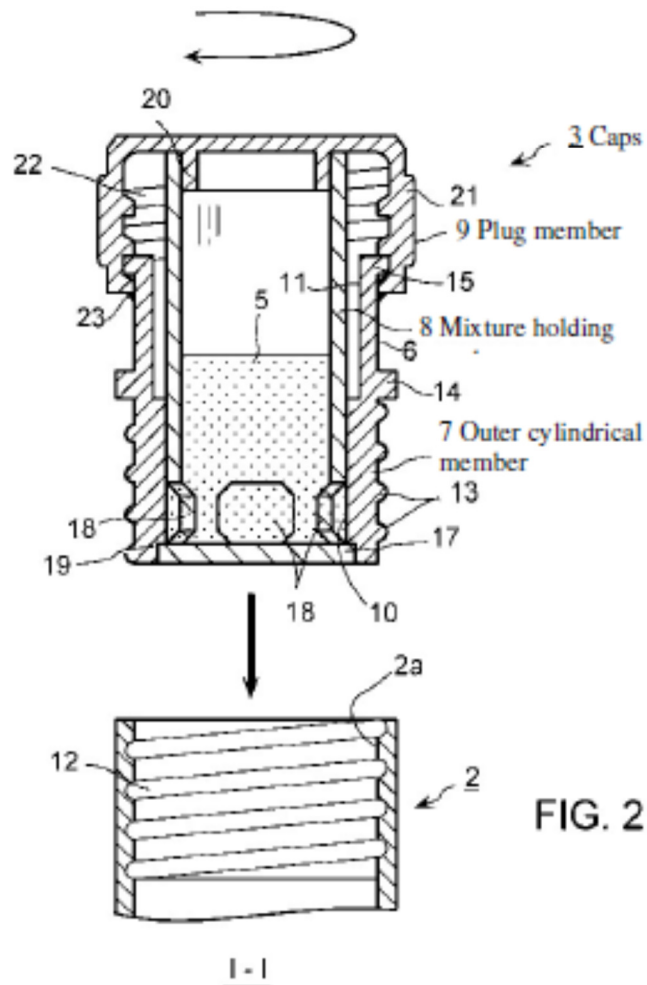
[FIG. 1]



175. 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]



1. Claim 1 Preamble

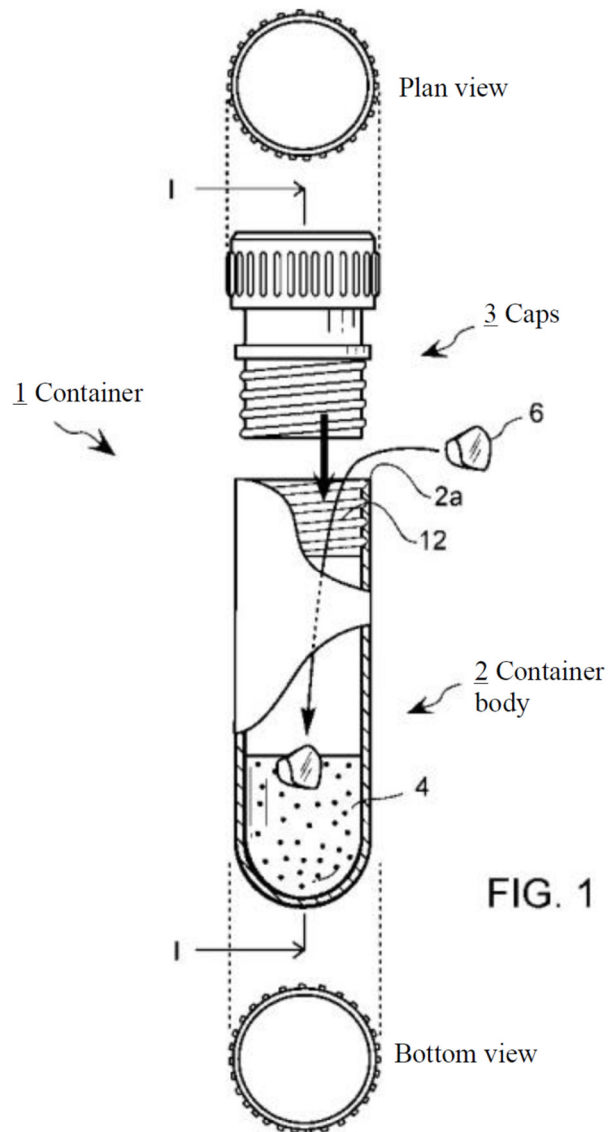
176. The preamble of claim 1 recites: “A biological sample collection

system, the system comprising.” To the extent the preamble is limiting, Ueda meets this limitation. Specifically, Ueda discloses “containers suitable for storing biological samples.” Ex.1005; [0001]. Ueda describes “container 1, after a biological sample (for example, ‘deciduous tooth’) indicated by 6 in the FIG. is placed into the container body 2, releases the second mixed material 5 from the cap 3 by screwing the cap 3 onto the container body 2.” *Id.*, [0021]. As to the construction of “biological sample” as recited in the preamble of claim 1, it does not impact my opinion regarding the patentability of the ’632 patent claims at least because Ueda specifically discloses a collection system for a “biological sample” which contains cells. 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]. The claims are unpatentable in view of Ueda regardless of whether the preamble is limiting and how it is construed if it is limiting.

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

177. Limitation 1[a] recites “a sample collection vessel.” 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.”), [0021] (“container 1, after a biological sample [for example, ‘deciduous tooth’] indicated by 6 in the FIG. is placed into the **container body 2**, releases the second

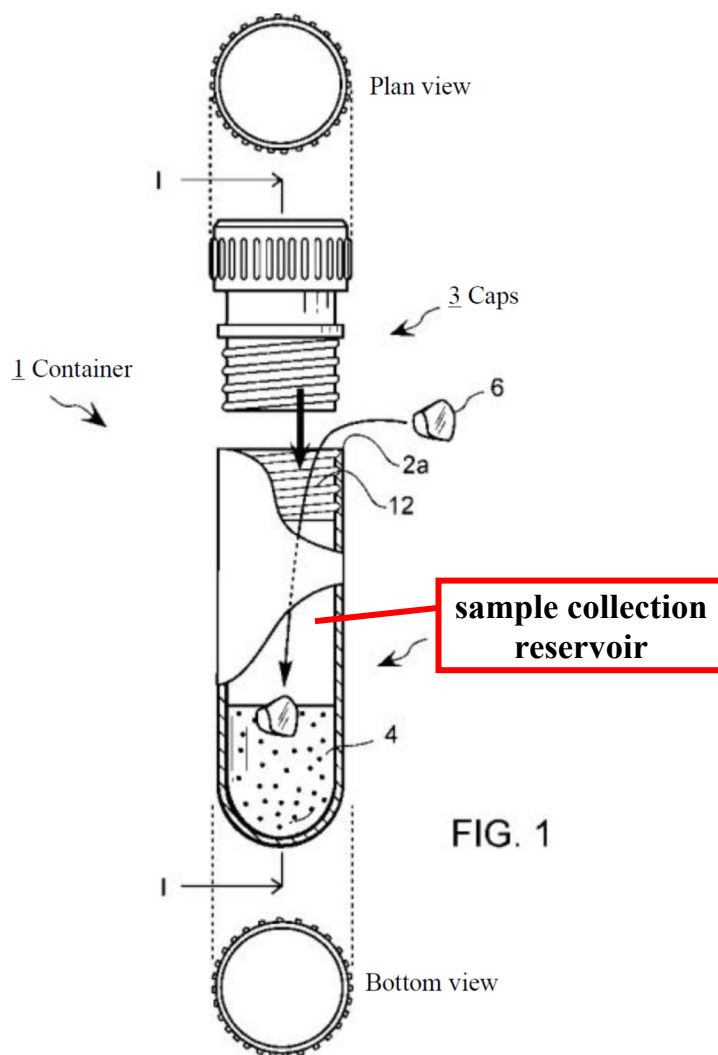
mixed material 5 from the cap 3 by screwing the cap 3 onto the **container body 2.**”) (emphasis added).



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

178. Limitation 1[a][i] recites that the sample collection vessel comprises “a

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



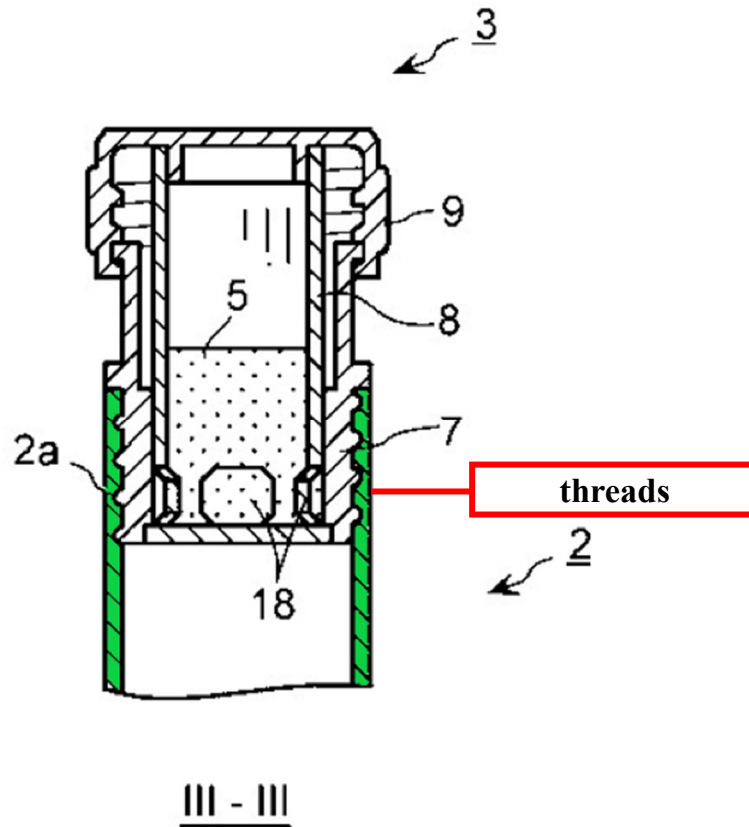
4. Limitation 1[a][ii]: “a first connection member”

179. Limitation 1[a][ii] recites that the sample collection vessel comprises “a first connection member.” In the ’632 patent, the term “connection member” refers to a structure that connects two items together, e.g., the structure that connects

a cap and a bottle. Ex.1001, 10:30-46 and 10:58-65. For example, the specification lists terms such as “push, rotate, screw, mate as well as *thread*” that are intended to “correspond to *structure* (well known to those of skill in the art) *for connection*” of two components. Ex.1001, 10:58-65 (emphasis added). Also, per claim 14, which depends from claim 1, the connection member can comprise “a threaded connection.” Ex.1001, claim 14. This confirms that “connection members” of claim 1 include threaded members and other well-known means for connection. Further, Fig. 3B shows threads on the exterior surface of the sample collection vessel, and the corresponding description states the vessel is “threadably engaged” with the cap. Ex.1001, Fig. 3B, 14:61-65. Thus, a POSA would understand the claim term “a first connection member” to encompass, for example, threads on the exterior of the sample collection vessel.

180. 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 and corresponding thread set 12 on the container body. Ex.1005, [0026], Figs. 1 and 2. Ueda discloses that the cap includes “a male screw projection 13 that can be screwed into a female screw groove 12 of the container body 2 . . . so that the lower end opening 10 can be detachably connected to the upper end opening 2a of the container body 2.” *Id.*, [0026]. Fig. 3B in Ueda, reproduced below, shows the container body 2 with internal threads adjacent to the opening that engage with and allow the cap to

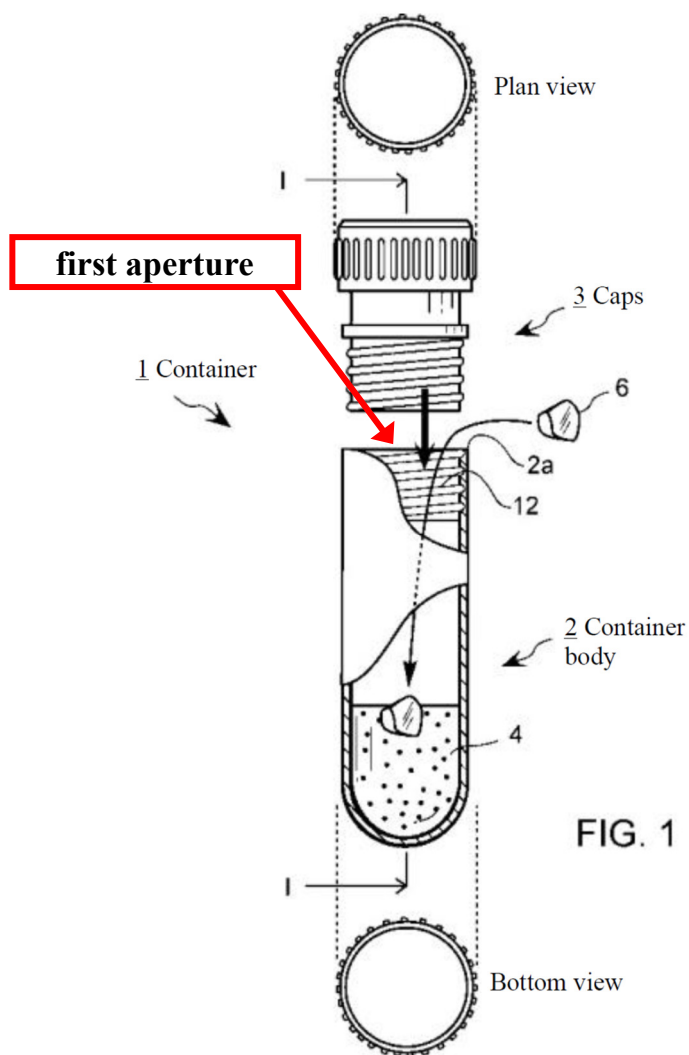
screw onto the container body:



Id., Fig. 3B (annotated). Thus, Ueda discloses “a first connection member” on the sample collection vessel.”

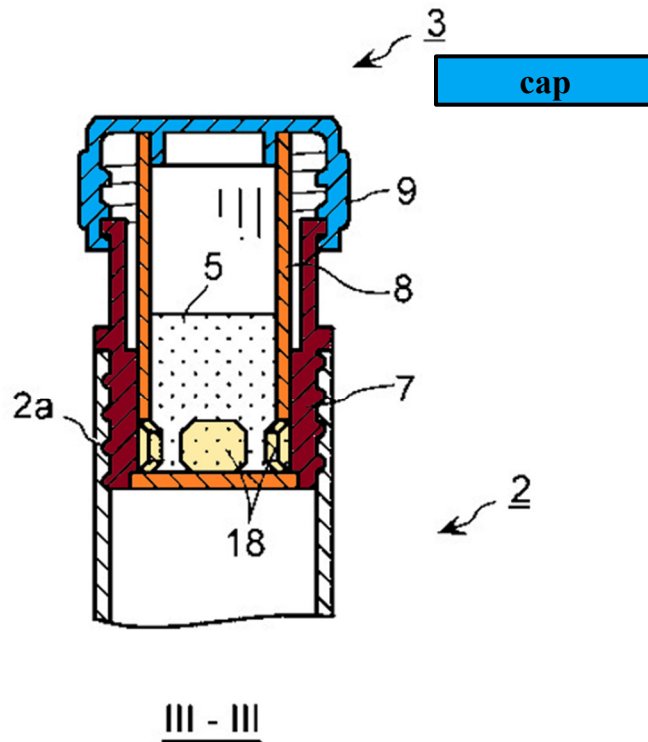
5. Limitation 1[a][iii]: “a first aperture for receiving a biological sample”

181. Limitation 1[a][iii] recites that the sample collection vessel comprises “a first aperture for receiving a biological sample.” Ueda also discloses this limitation, specifically the “upper end opening 2a of the container body 2” which receives the biological sample 6. Ex.1005, [0024], Fig. 1.



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

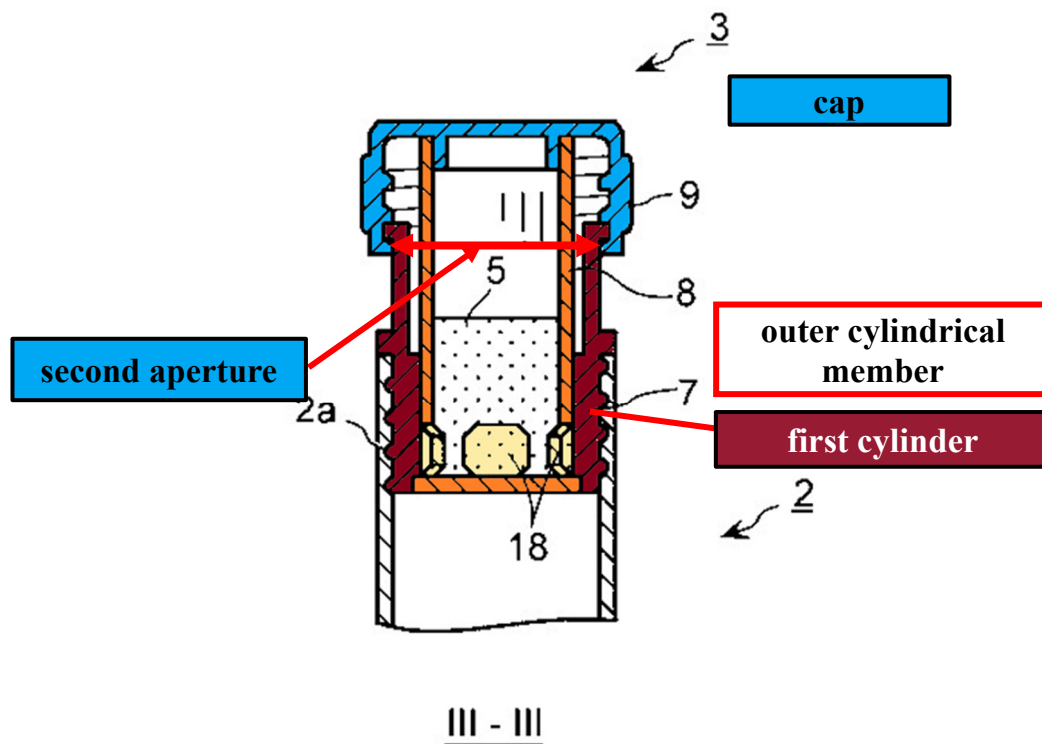
182. Limitation 1[b] recites “a cap” as one of the principal elements of the system. Ueda also discloses a “cap” as one of the principal elements of the system. Ex.1005, [0020]-[0022], Fig. 1. Ueda’s cap 3, which includes the first and second cylinders forming the annular valve, is shown in Fig. 3B below:



Id., Fig. 3B (annotated). Thus, Ueda discloses the claimed cap.

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

183. Limitation 1[b][i] recites that the cap comprises “a second aperture.” Ueda’s cap 3 includes a second aperture. Ex.1005, [0025], Fig. 2. For example, in the embodiment depicted in Figs. 1-4, the cap 3 includes plug member 9 which has an aperture that receives a portion of the outer cylindrical member 7 so that the plug member 9 can be screwed downward onto the outer cylindrical member 7. Ex.1005, [0029], Figs 2-3B. Ueda’s cap 3 with its second aperture (defined by plug member 9) and internal threads that engage the top portion of the outer cylindrical member 7 are shown below in Fig. 3B:



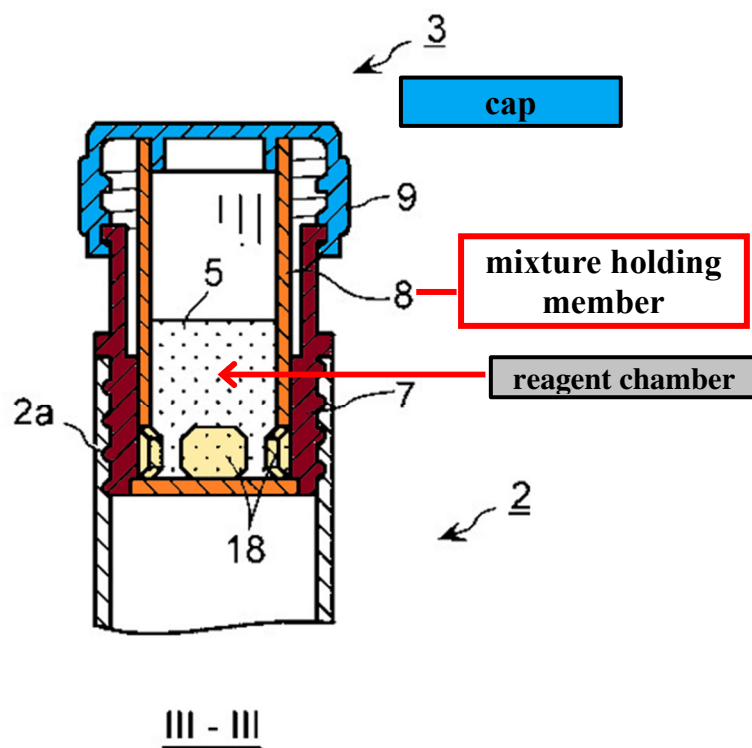
Id., Fig. 3B (annotated). Thus, Ueda discloses a cap with a second aperture.

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

184. Limitation 1[b][ii] recites that the cap comprises “a reagent chamber storing a reagent therein.” Ueda discloses a reagent chamber in a cap that stores a reagent therein.

185. Ueda’s cap includes a reagent chamber, specifically the mixture holding member 8, which stores a “mixture to be introduced into the interior of the container body [second mixed material 5].” Ex.1005, [0009], [0023]-[0027]. Ueda’s chamber, as identified in Figure 3B below, is defined by the mixture holding member 8 and the 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]. Ueda explains that “the second mixed material 5 is a granular gelling material, where mixing these with the first mixed material 4 gels the first mixed material. This action allows the container 1 to secure the above biological sample 6 within the above container body 2.” *Id.*, [0021]. The second mixed material 5 is a reagent that is stored in the mixture holding member chamber and mixes with the first mixed material 4, as shown in Figure 3B:



Id., Fig. 3B (annotated). Thus, Ueda discloses a cap comprising “a reagent chamber

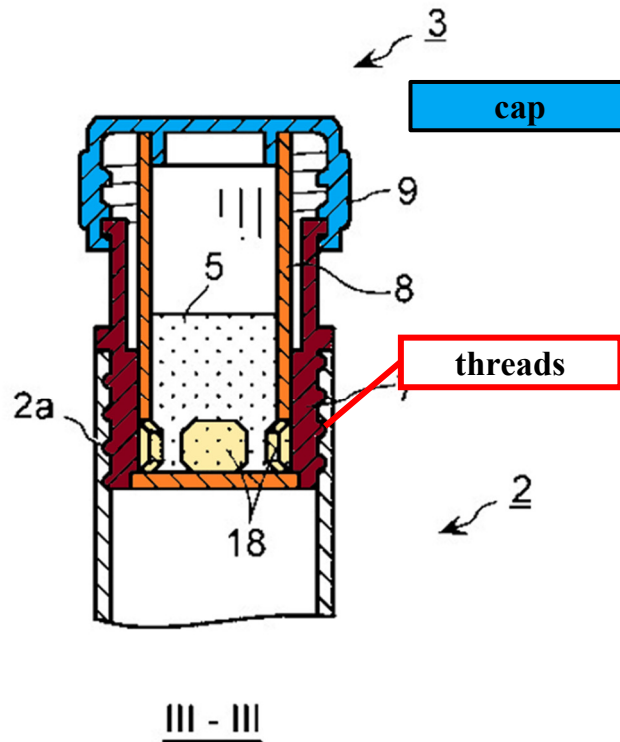
storing a reagent therein.”

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

186. Limitation 1[c] recites “a second connection member complementary to the first connection member.” Ueda discloses the claimed complementary connection member.

187. As explained above in paragraphs regarding limitation 1[a][ii], the term “connection member,” as used in the ’632 patent, encompasses threads for connecting a cap to a container. Further, claim 14 in the ’632 patent depends from claim 1 and recites that the “second connection member” of claim 1 comprises a threaded connection, confirming that this limitation encompasses at least threads on the cap. Ex.1001, claim 14.

188. Ueda discloses that the cap 3 includes outer cylindrical member 7 which includes “a male screw projection 13 that can be screwed into the female screw groove 12 of the container body 2.” Ex.1005, [0026], Figs. 1-3B. Fig. 3B of Ueda below shows the second connection member threads (male screw projection 13) that engage and are complementary to the internal container threads 12:

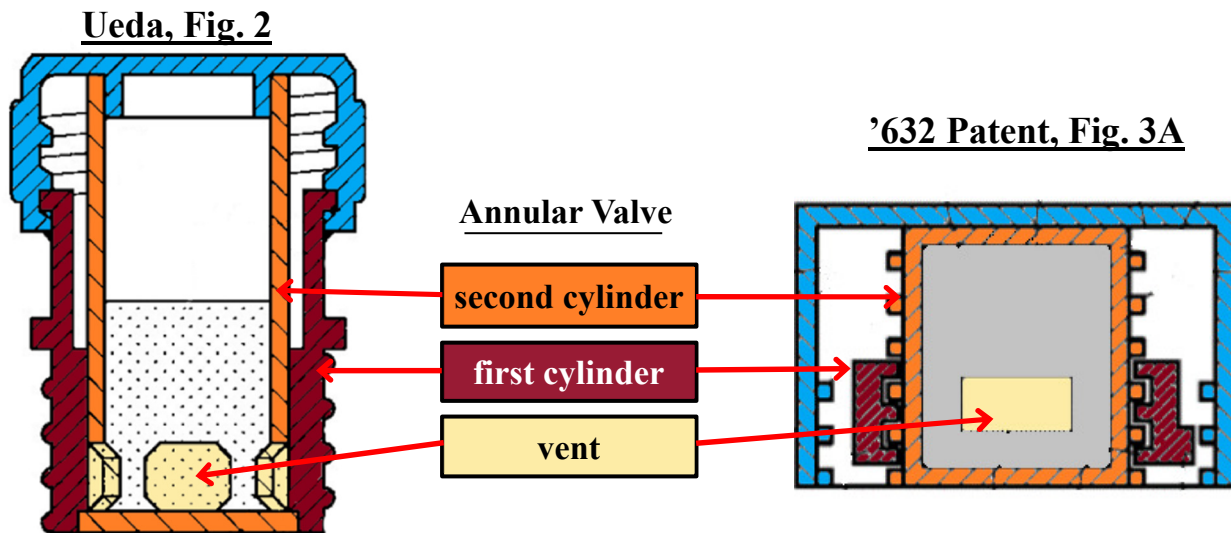


Id., Fig. 3B (annotated). Thus, Ueda discloses a cap comprising “a second connection member complementary to the first connection member.”

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

189. Limitation 1[d] recites “a movable annular valve in the second aperture, the movable annular valve comprising.” Ueda discloses a movable annular valve under any reasonable construction of the term. As described above, the District Court construed “annular valve” in the related ’646 patent to mean “ring shaped valve.” Ex.1007, 66. Under any reasonable construction, Ueda discloses this limitation.

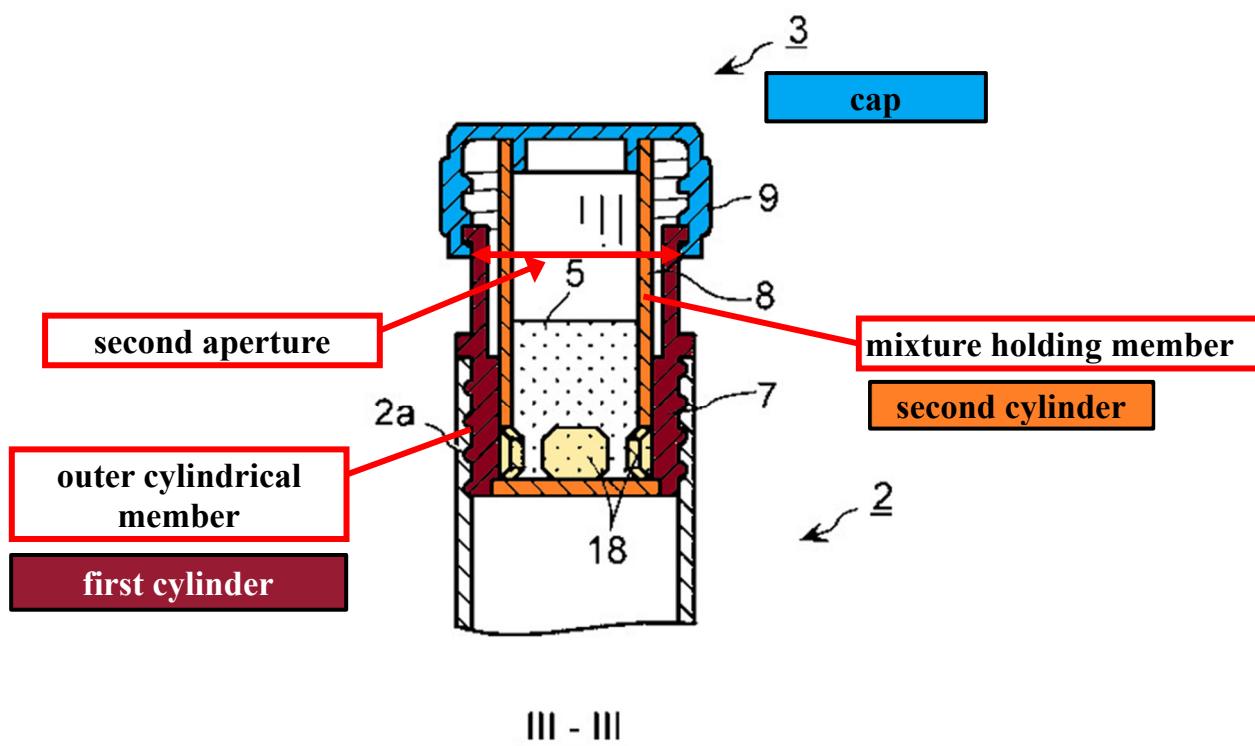
190. Ueda's annular valve corresponds identically to the embodiment of Fig. 3A in the '632 patent, as illustrated in the comparison below of the Ueda Fig. 2 and the '632 patent Fig. 3A. Ueda's annular valve is ring shaped and includes first and second cylinders that move relative to one another in order to release the reagent from the vent on the second cylinder.



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

191. Limitation 1[d] also recites that the valve is “in the second aperture.” Ueda's valve is also in the second aperture, which is the aperture in the cap. First, Ueda's valve, which includes the first and second cylinders, is positioned within the cap and extends in the second aperture in the cap, as shown below. For example, Ueda discloses that the second cylinder (mixture holding member 8) is part of the cap 3. Ex.1005, [0025], Figs. 2-3B. The first cylinder (outer cylindrical member 7)

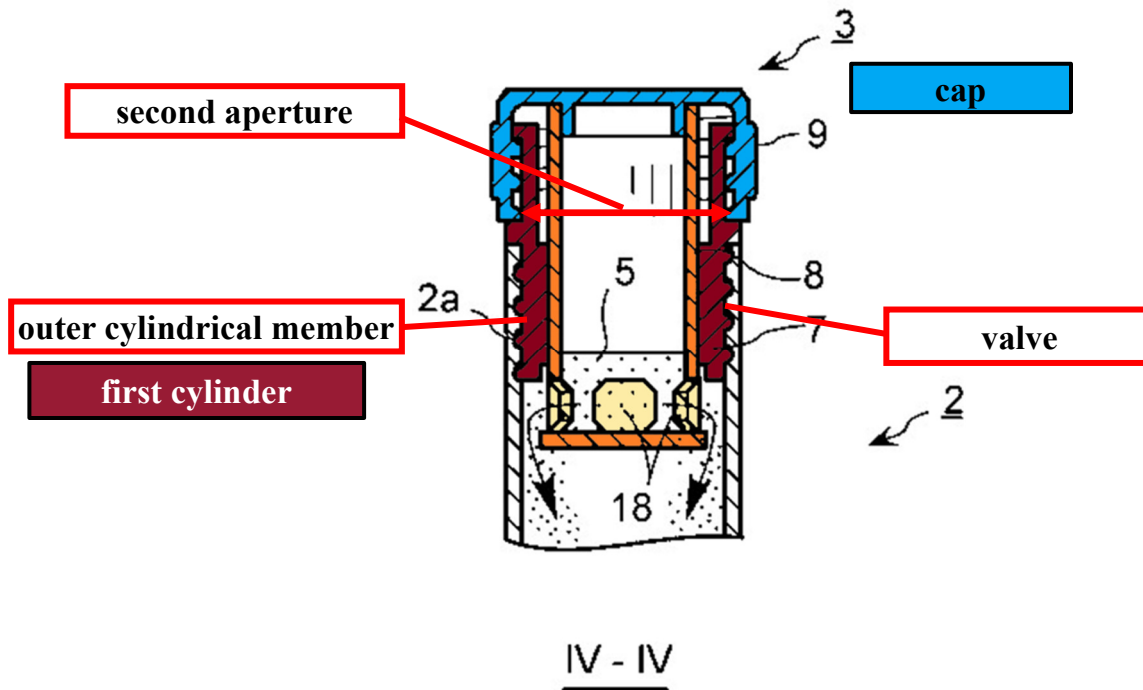
includes a flange portion 15 that engages with the internal threads 22 of the cap (female thread groove 22). *Id.*, [0029]. Ueda's Fig. 3B is annotated below to illustrate how the second cylinder (mixture holding member 8) and first cylinder (outer cylindrical member 7) in Ueda's annular valve are held within and extend through the aperture in the cap 2:



Ex.1005, Fig. 3B (annotated)

192. Also, as shown below in Fig. 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 through the second aperture in the

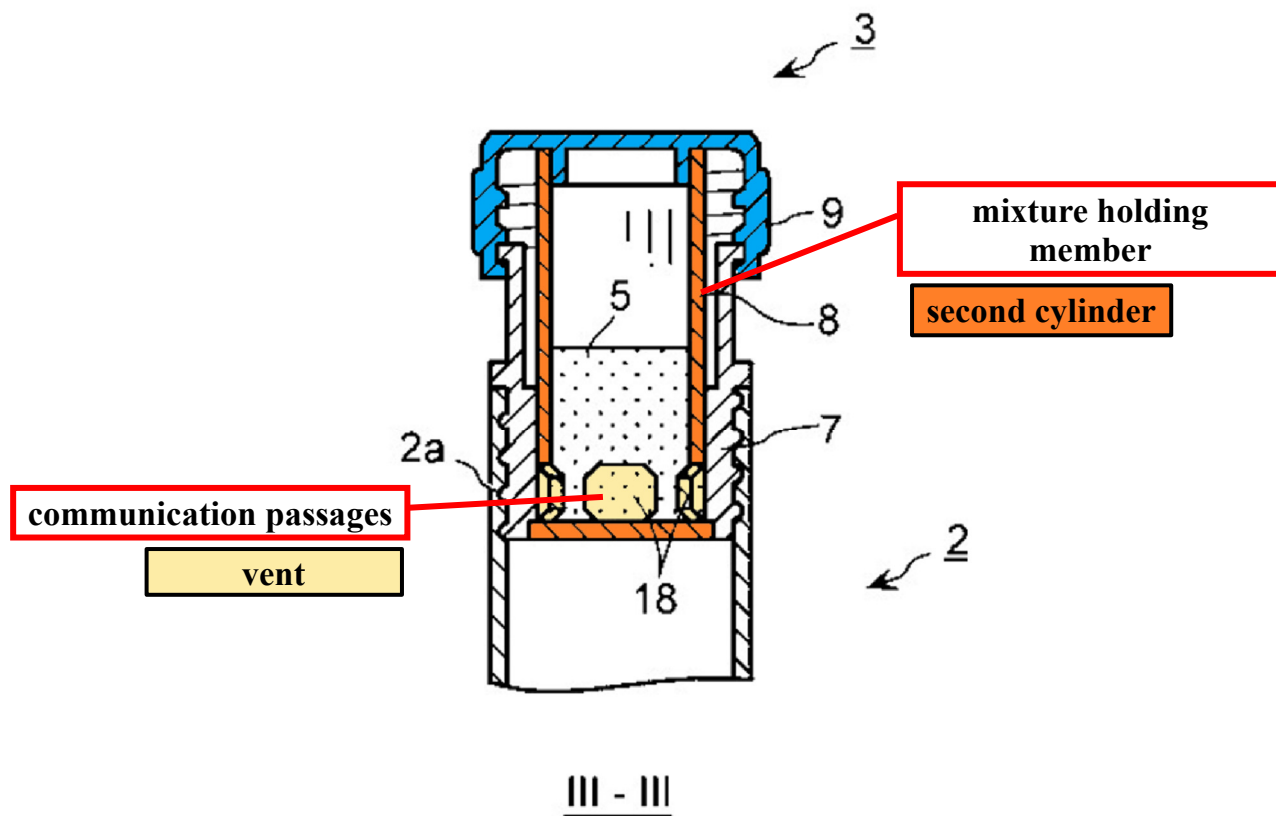
cap 3.



Ex.1005, Fig. 4B (annotated). Thus, Ueda discloses “a movable annular valve in the second aperture.”

11. Limitation 1[d][i]: “a vent”

193. Limitation 1[d][i] recites that the movable annular valve comprises “a vent.” Ueda discloses this limitation. Ueda’s second (inner) cylinder 8 includes communication passages 18, which provide a vent. Ex.1005, [0027], Figs. 2-4B. The vent 18 is shown in Fig. 3B below:



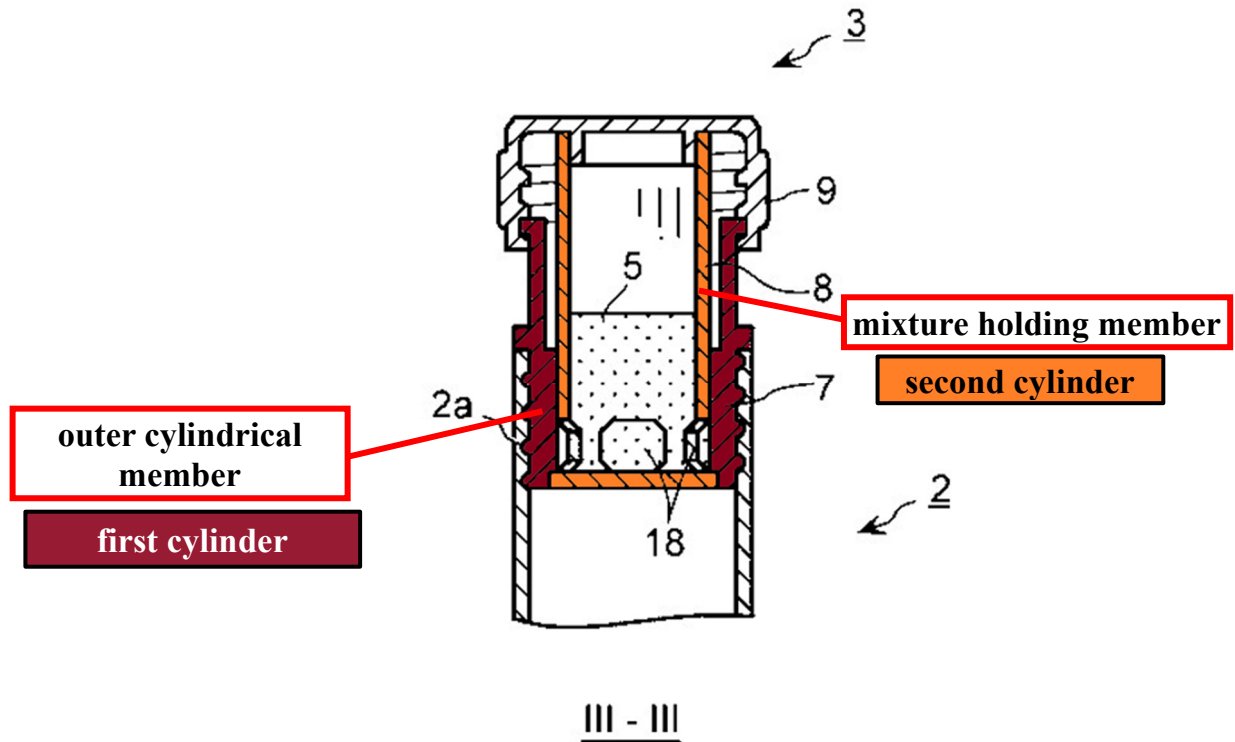
194. In use, when Ueda’s cap is tightened on the bottle and further screwed onto the outer cylindrical member 7, the second (inner) cylinder slides vertically relative to the first cylinder (outer cylindrical member 7) and the passages 18 allow the second mixed material 5 held in the mixture holding member 8 to be released into the container body 2. *Id.*, [0027]. Thus, Ueda discloses “a vent.”

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

195. Limitation 1[d][ii] recites that the movable annular valve includes “a first cylinder comprising a third aperture.” Ueda discloses this limitation.

196. In Ueda’s annular valve, the outer cylindrical member 7 is the claimed

first cylinder. Ex.1005, [0025]-[0028], Figs. 2-4B. The outer cylindrical member 7 “is a circular outer cylindrical member having a lower end opening 10 and an upper end opening 11.” *Id.*, [0026]. Figs. 1-4B. Thus, the first cylinder (outer cylindrical member 7) comprises a third aperture, as shown below in Fig. 3B.

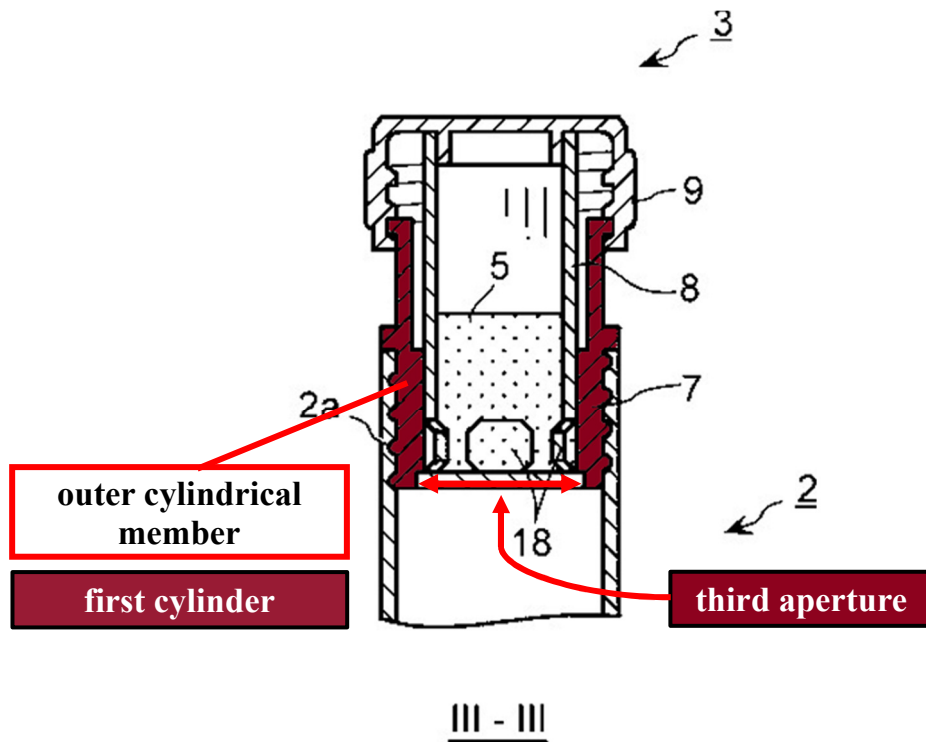


Id., Fig. 3B (annotated). Ueda discloses that the second cylinder (mixture holding member 8) is “formed to a dimension such that it slides vertically along its axial direction within the outer cylindrical member 7.” Ex.1005, [0027]. Further, Ueda states that “[w]hen the holding member 8 does not protrude from the lower end opening 10 of the outer cylindrical member 7 toward the container body 2, so that it does not communicate with the inside of the container body 2 . . . the communication

passage 18 is closed by the inner peripheral surface of the outer cylindrical member 7.” *Id.*

197. In the '632 patent, the aperture defined by the first cylinder, is the aperture defined by an interior sidewall of the annular blocking member 62 (first cylinder). *See, e.g.*, Fig 3A. The aperture permits the inner and outer cylinders to move axially relative to each other.

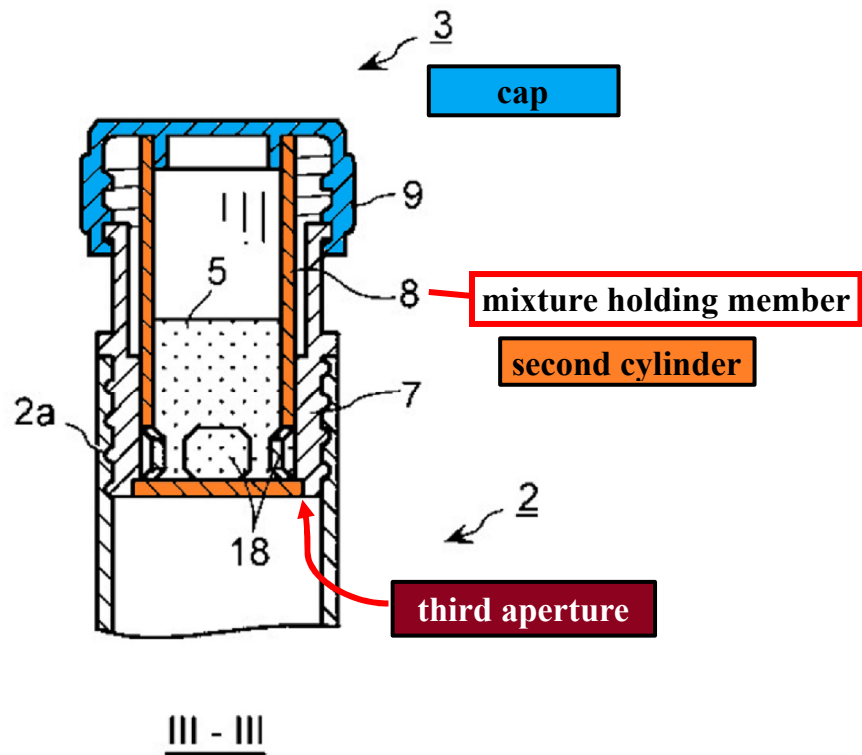
198. Ueda’s annular valve similarly includes a third aperture defined by the inner side wall of a first cylinder, namely the outer cylindrical member 7. Ex.1005, [0027], Figs. 2-4B. Fig. 3B from Ueda, annotated below, shows the third aperture in the first cylinder.



Id., Fig. 3B (annotated). Thus, Ueda discloses an annular valve having “a first cylinder comprising a third aperture.”

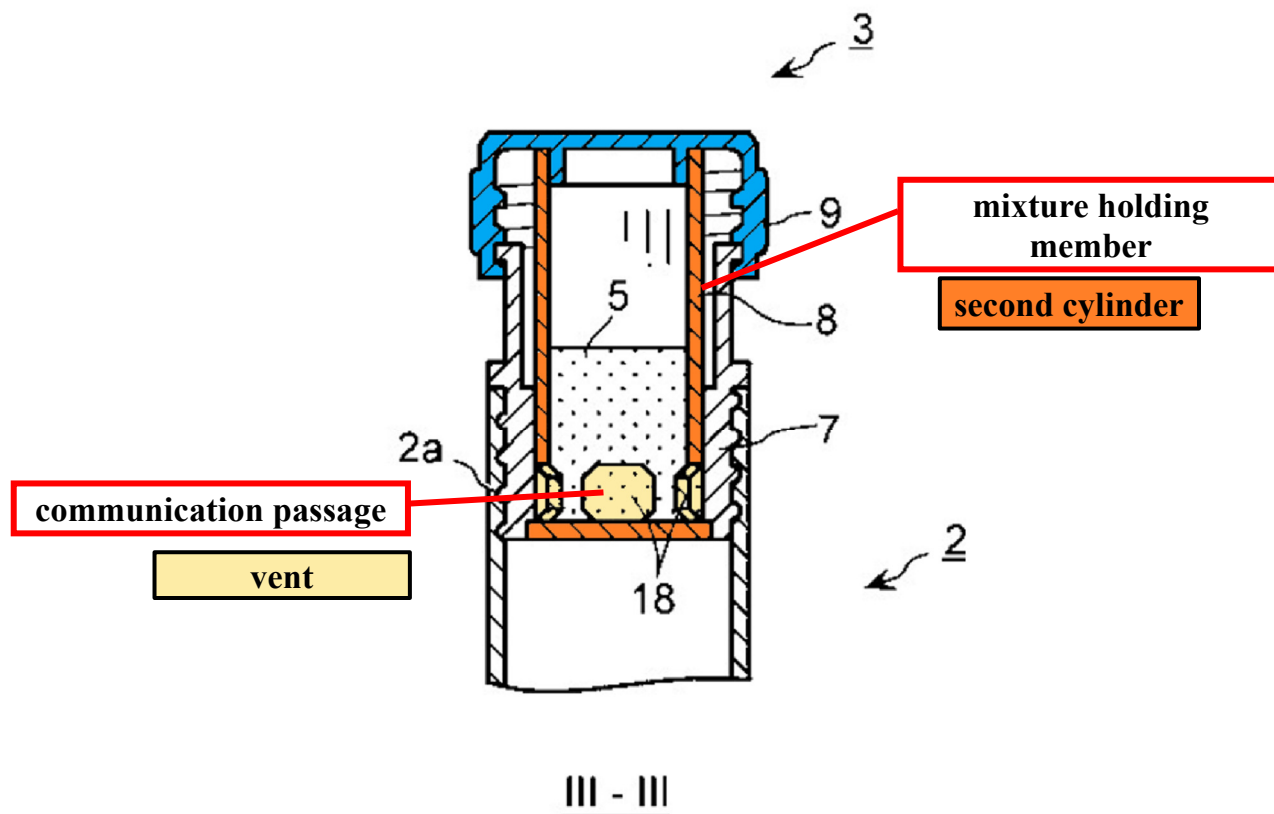
13. Limitation 1[d][iii]: “a second cylinder comprising the vent, the second cylinder positioned in the third aperture”

199. Limitation 1[d][iii] recites that the movable annular valve includes “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, [0027], Figs. 2-4B. As shown in Fig. 3B below, mixture holding member 8 is connected to and held within plug member 9 of cap 3 and is positioned in the third aperture in the first cylinder 7:



Id., Fig. 3B (annotated); *see also id.*, [0025]. The second cylinder (mixture holding member 8) “slides vertically along its axial direction within the outer cylindrical member 7.” *Id.*, [0027]. As shown in Fig. 3B above, the second cylinder of Ueda is positioned in the third aperture in the first cylinder 7. Fig. 4B also shows the second cylinder positioned in and extending through the third aperture. A portion of Ueda’s second cylinder (mixture holding member 8) spans the length of the first cylinder 7 and extends through the third aperture. Thus, Ueda’s second cylinder is positioned in the third aperture defined by the first cylinder.

200. Ueda’s second cylinder also includes communication passages 18, which provide a vent. Ex.1005, [0027], Figs. 2-4B. The vent is shown in Fig. 3B below:

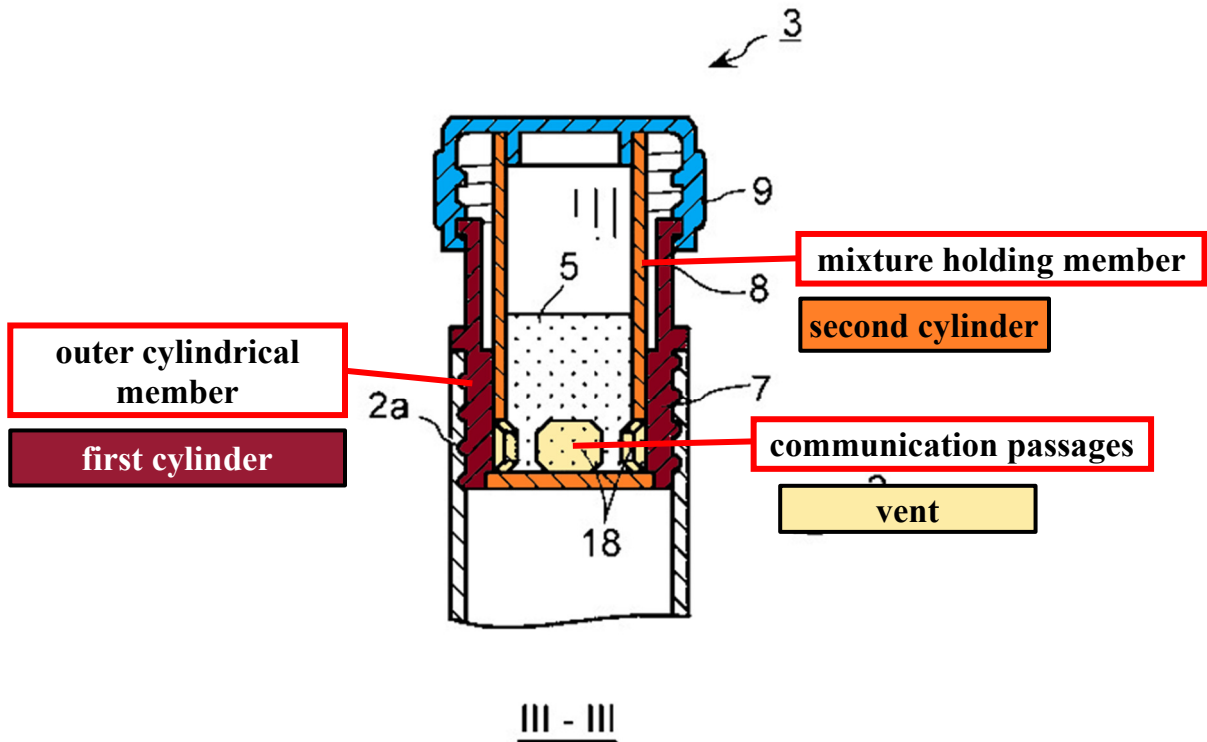


201. In use, when Ueda’s cap is tightened on the container and further screwed onto the outer cylindrical member 7, the second (inner) cylinder slides vertically relative to the first cylinder (outer cylindrical member 7) and the passages 18 allow the second mixed material 5 held in the mixture holding member 8 to be released into the container body 2. *Id.*, [0027]. Thus, Ueda discloses “a second cylinder comprising the vent, the second cylinder positioned in the third aperture.”

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

202. Limitation 1[d][iv] recites the movable annular valve comprises “a closed configuration.” Ueda discloses this limitation. Ueda’s annular valve includes

a second cylinder (mixture holding member 8) that can slide within the first cylinder (outer cylindrical member 7). Ex.1005, [0027]. Ueda discloses that “[w]hen the holding member 8 does not protrude from the lower end opening 10 of the outer cylindrical member 7 toward the container body 2, so that it does not communicate with the inside of the container body 2 (see the first screw-in state shown in FIG. 3), the communication passage 18 is **closed** by the inner peripheral surface of the outer cylindrical member 7.” *Id.* (emphasis added). Fig. 3B below shows the movable annular valve in a closed position, with the interior sidewalls of the first cylinder obstructing the vent (communication passage 18) on the second cylinder.Ex.1005, Fig. 3B (annotated), *id.*, [0027]. Thus, Ueda discloses a movable annular valve comprising a closed configuration.

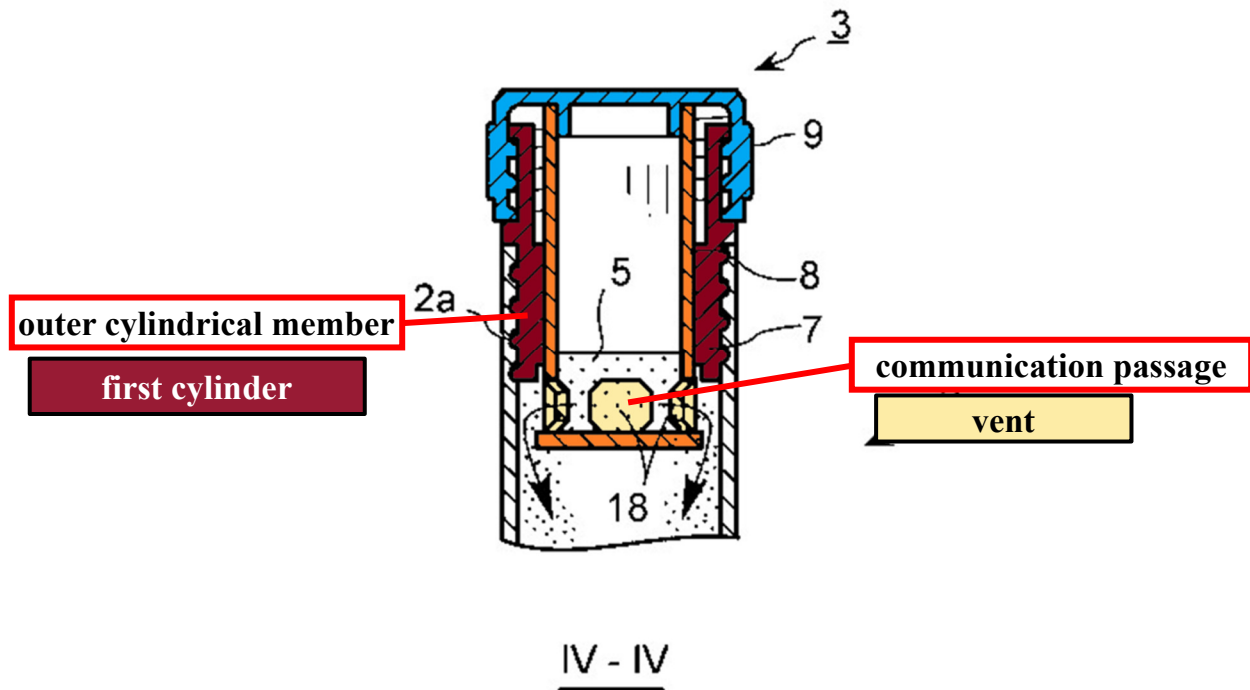


15. Limitation 1[d][v]: “an open configuration, wherein”

203. Limitation 1[d][v] recites that the movable annular valve comprises an “open configuration.” Ueda discloses this limitation.

204. When Ueda’s cap 3 is tightened on the container 2, the 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. In this 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.” *Id.* Ueda’s Fig. 4B shows the movable annular valve in

an open configuration, where the interior sidewall of the first cylinder (outer cylindrical member 7) no longer obstructs the vent (communication passage 18) of the second cylinder (mixture holding member 8) such that the reagent is released into the container 2.



Ex.1005, Fig. 4B (annotated); *id.*, [0027]. Thus, Ueda discloses an annular valve comprising an open configuration.

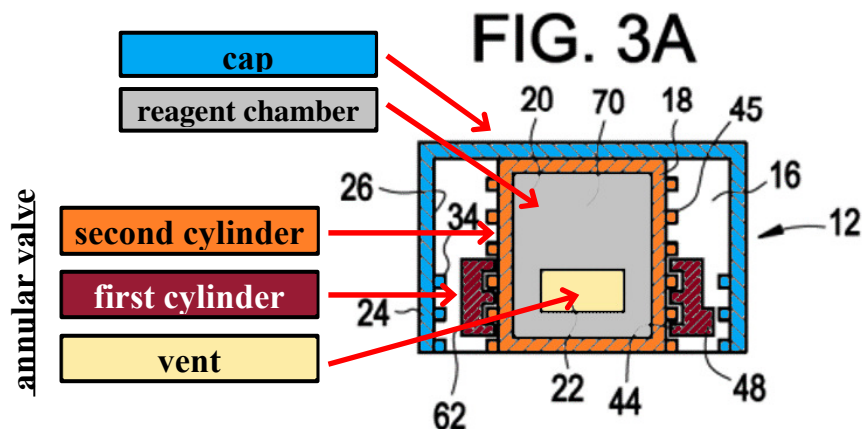
- 16. Limitation 1[d][vi]: “in the annular valve’s closed configuration, the first and second cylinders create a fluid-tight seal with the cap and the first cylinder obstructs the vent to retain the reagent in the reagent chamber”**

205. Limitation 1[d][vi] recites wherein “in the annular valve’s closed configuration, the first and second cylinders create a fluid-tight seal with the cap and

the first cylinder obstructs the vent to retain the reagent in the reagent chamber.”

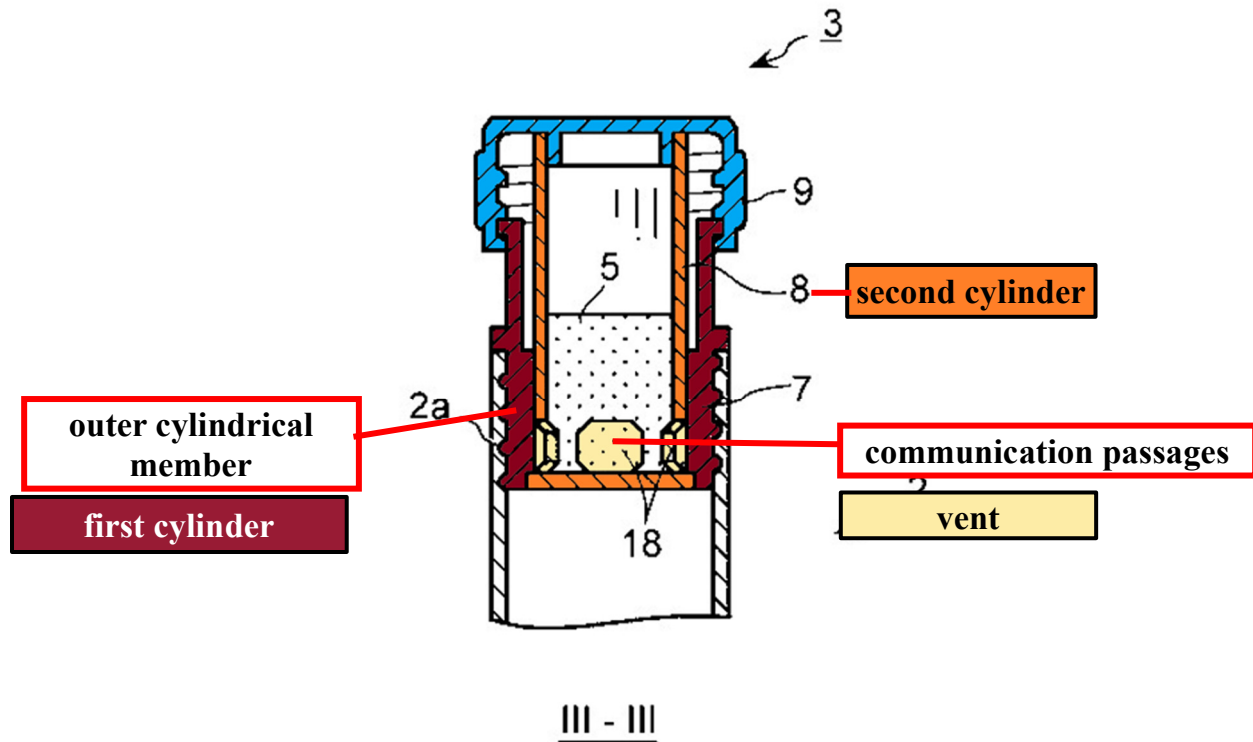
Ueda discloses this limitation.

206. 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. The specification explains that the “interior space 20 may be at least partially defined by at least one of an inner wall 18 or outer wall 24 of the cap 12 When the aperture 22 is closed such that the annular blocking member 62 is covering the aperture 22, fluid or material, such as sample preservation fluid or material 70, that 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.” Ex.1001, 14:20-32. As shown below in annotated Fig. 3A, 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 and in the cap, and the first cylinder obstructs the vent to retain the reagent in the reagent chamber.



207. Ueda's annular valve includes a second cylinder (mixture holding member 8) within the first cylinder (outer cylindrical member 7). Ex.1005, [0027], Figs. 2-4B. "When the holding member 8 does not protrude from the lower end opening 10 of the outer cylindrical member 7 toward the container body 2, so that it **does not communicate** with the inside of the container body 2 (see the first screw-in state shown in FIG. 3), the **communication passage 18 is closed** by the inner peripheral surface of the outer cylindrical member 7." *Id.* (emphasis added). 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. In this state, the outer cylindrical member 7 and the lower end of the mixture holding member 8 (the lower surface of the bottom wall plate 17) are configured to be flush with each other." *Id.*, [0028]. In this closed configuration, the 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. *Id.* Fig. 4B

shows Ueda's movable annular valve in a closed position, 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.

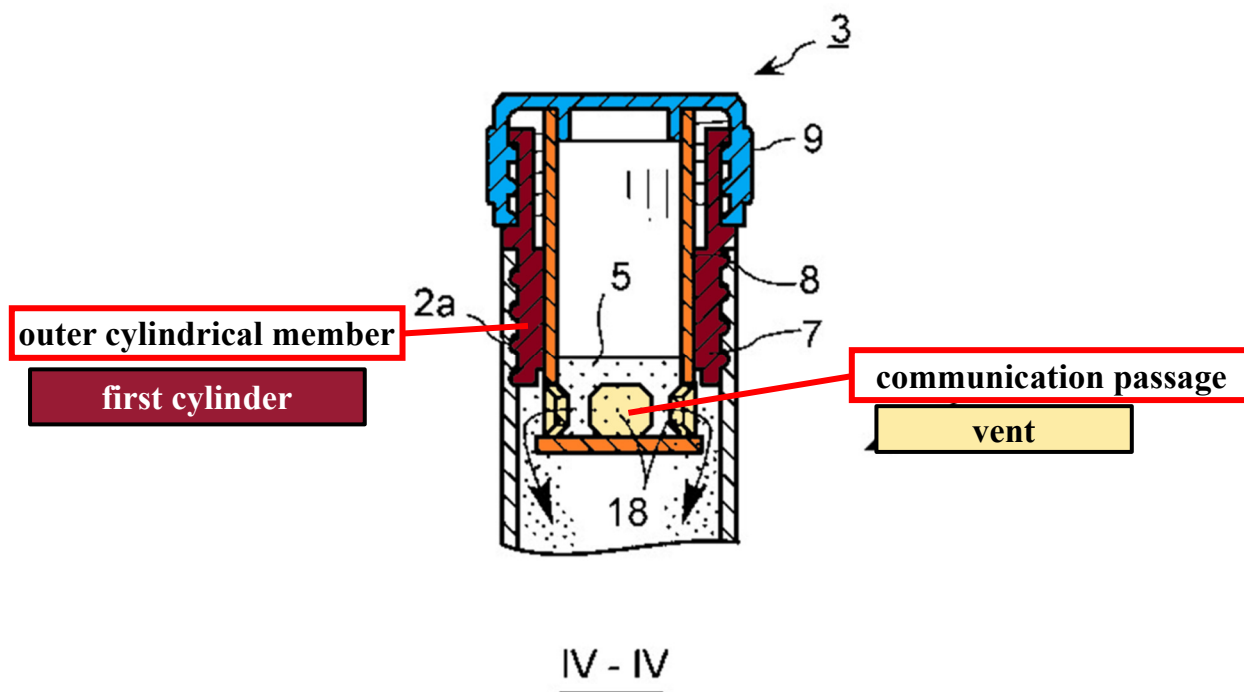


Ex.1005, Fig. 3B (annotated), *id.*, [0027]. Thus, Ueda discloses a movable annular valve closed configuration in which “the first and second cylinders create a fluid-tight seal with the cap and the first cylinder obstructs the vent to retain the reagent in the reagent chamber.”

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”

208. Limitation 1[d][vii] recites “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. When Ueda’s cap 3 is tightened on the container 2, the 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. In this 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.” *Id.* Ueda’s Figs. 3B and 4B show the closed and open configuration, illustrating the relative movement by the first and second cylinders to change from the close to open configuration. Ueda’s Fig. 4B shows the movable annular valve in an 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). In this manner, the second cylinder 8 moves relative to the first cylinder 7 to unblock the vent 18 and enter the open configuration. *Id.*



Ex.1005, Fig. 4B (annotated); *id.*, [0027]. Thus, Ueda discloses that the “first cylinder and second cylinder are relatively moveable to thereby change the annular valve from the closed configuration to the open configuration.”

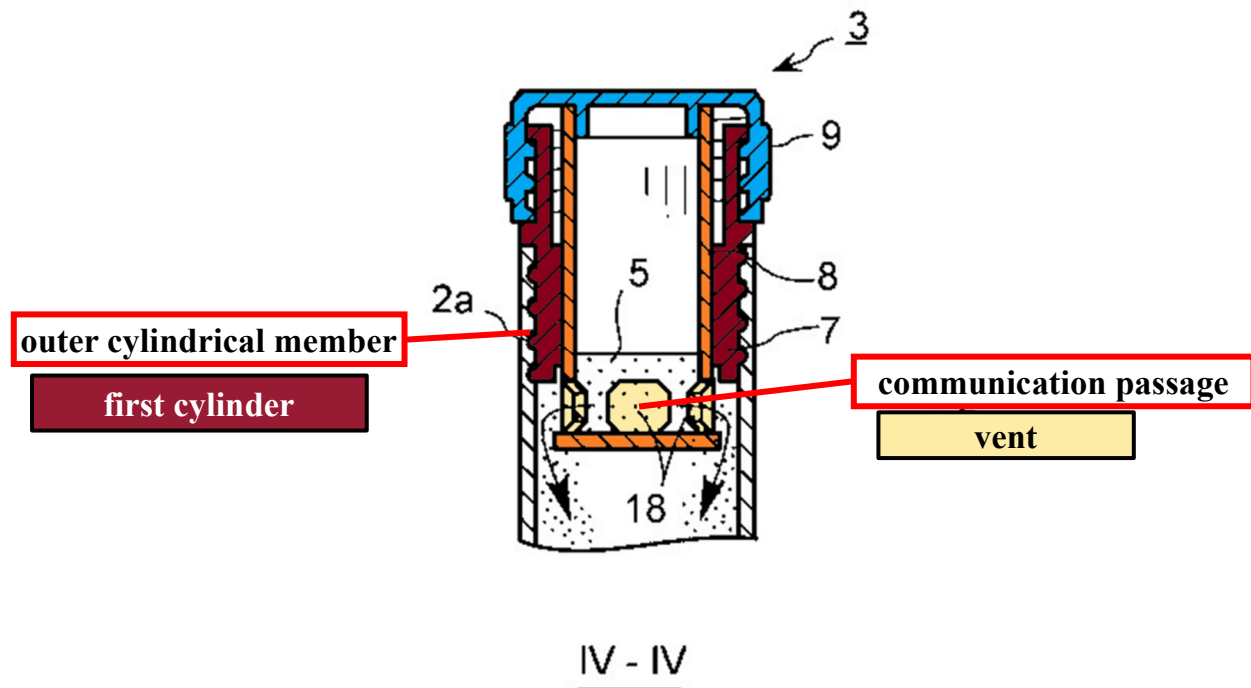
18. Limitation 1[d][viii]: “in the annular valve's open configuration, the first cylinder does not obstruct the vent to thereby allow flow of the reagent from the reagent chamber, through the vent, and into the sample collection reservoir.”

209. Limitation 1[d][viii] recites “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 discloses this limitation.

210. When Ueda’s cap 3 is tightened on the container 2, the 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. In this 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.” *Id.* Ueda’s Fig. 4B shows the movable annular valve in an open configuration, where the interior sidewall of the first cylinder (outer cylindrical member 7) no longer obstructs the vent (communication passage 18) of the second cylinder (mixture holding member 8) to allow flow of the reagent (second mixed material 5) through the vent and into the sample collection reservoir.



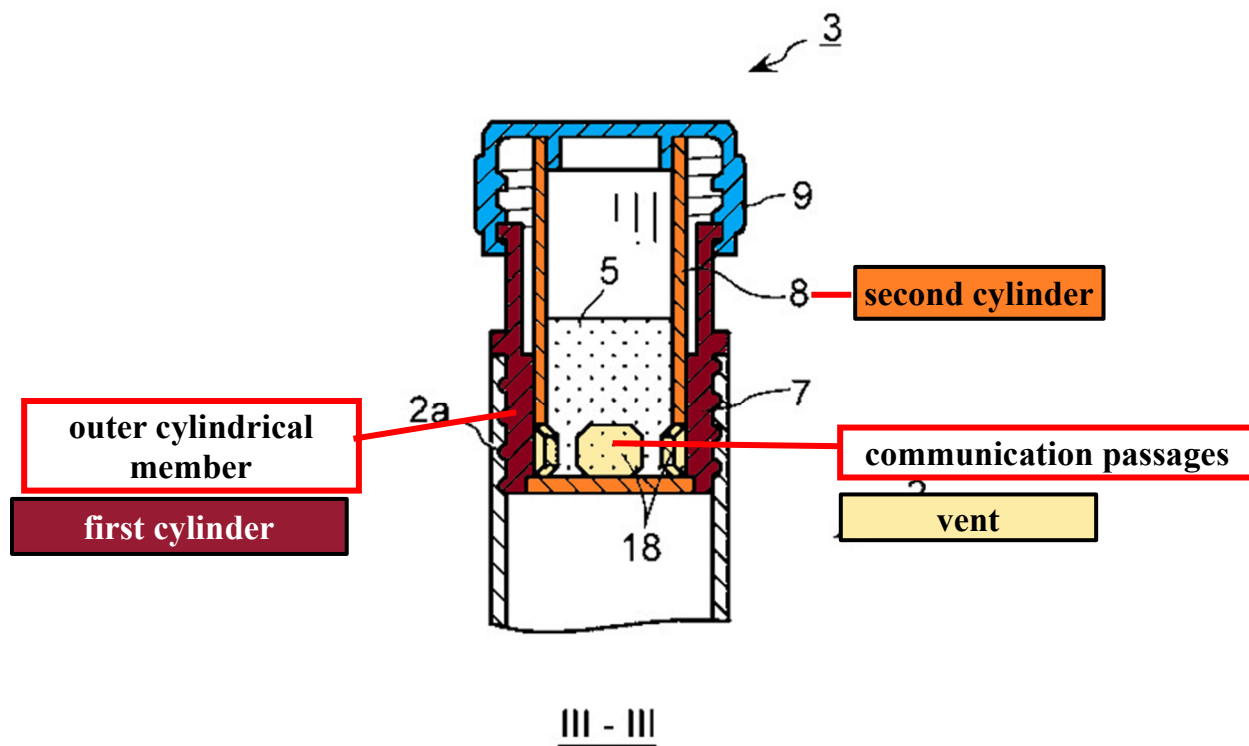
Ex.1005, Fig. 4B (annotated); *id.*, [0027]. Thus, Ueda discloses an annular valve open configuration in which “the first cylinder does not obstruct the vent to thereby allow flow of the reagent from the reagent chamber, through the vent, and into the sample collection reservoir.”

211. Based on my analysis above, Ueda discloses all limitations of claim 1.

B. Ueda Anticipates Claim 2

212. 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.

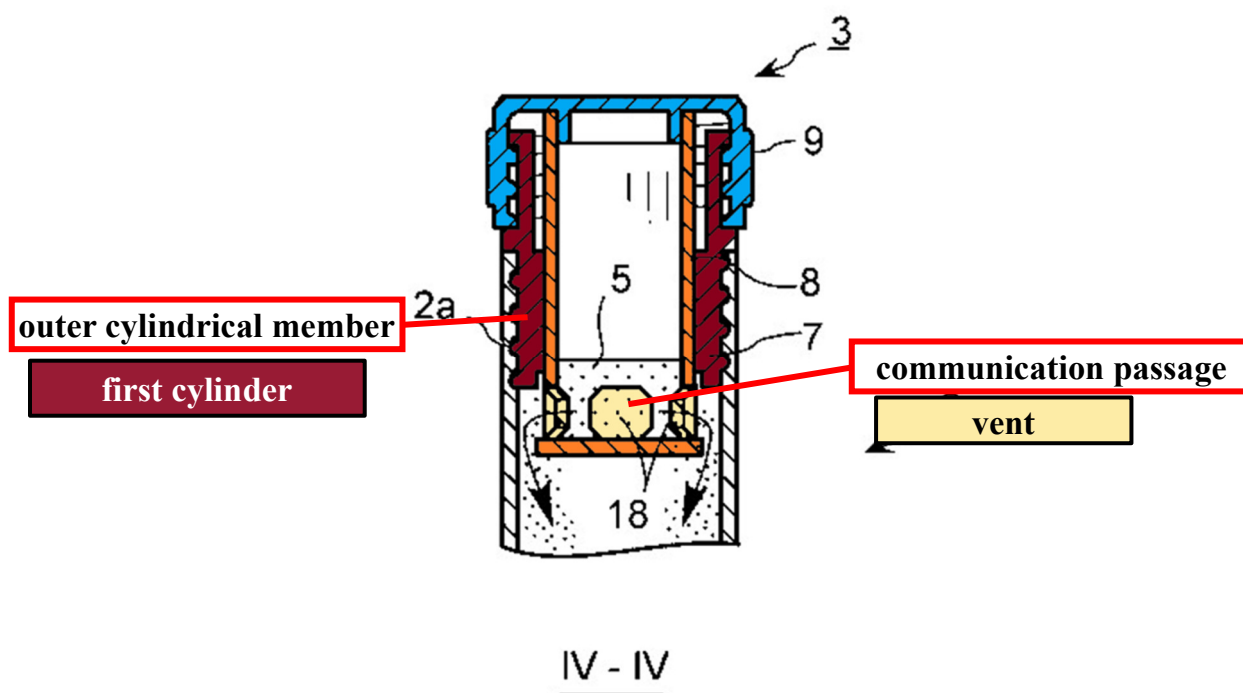
213. Regarding claim 2, Ueda's second cylinder (mixture holding member 8) includes a sidewall with a vent (communication passages 18). Ex.1005, [0027]. In the closed configuration, the reagent is sealed in the mixture holding member as a sidewall of the first cylinder obstructs the vent (passages 18) on the sidewall of the second cylinder to create a seal with the cap until the reagent is released into the container. *Id.* Fig. 3B shows the movable annular valve in a closed position, with the sidewall of the first cylinder obstructing the vent:



Ex.1005, Fig. 3B (annotated), *id.*, [0027].

214. In the open configuration, the sidewall of Ueda's first cylinder does not

obstruct the vent and “the second mixed material 5 held in the mixture holding member 8 can be configured to be released into the container body 2” through the vent. Ex.1005, [0027]. Ueda’s Fig. 4B shows the movable annular valve in an open configuration, where the sidewall of the first cylinder (outer cylindrical member 7) does not obstruct the vent (passages 18) of the second cylinder 8 to allow flow of the reagent from the storage chamber, through the vent, and into the container/vessel.



Ex.1005, Fig. 4B (annotated); *id.*, [0027]. Thus, Ueda discloses the limitations of dependent claim 2.

C. Ueda Anticipates Claims 3 and 4

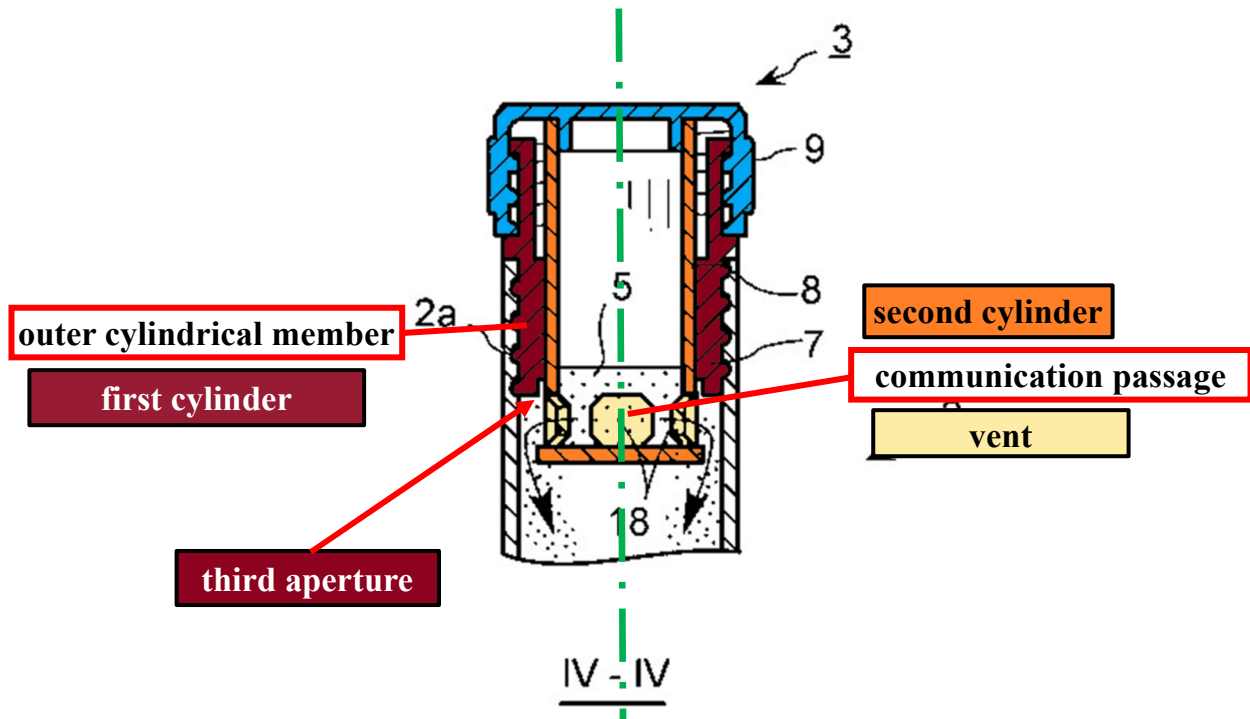
215. Claim 3 depends from claim 1 and recites “wherein the first and second cylinder's relative movement, from the annular valve's closed configuration to the

open configuration, is translational along a longitudinal axis of the cap.” Ueda’s valve meets this limitation.

216. 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’s valve also meets this limitation.

217. A POSA would have understood that 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” 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. In this 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.” *Id.* As the cap is tightened and further screwed towards the container, the second cylinder 8 moves translationally downward along a longitudinal axis (shown in green below) of the cap 3 to move the parts of the annular valve from the closed configuration to the open configuration. Ueda’s Figs. 3B and 4B show the translational movement of the second cylinder in the third aperture from a closed position to an open configuration in which the first cylinder no longer obstructs the vent. The second cylinder 8 is positioned within the first cylinder 7 so its movement

is in the third aperture in the first cylinder 7.



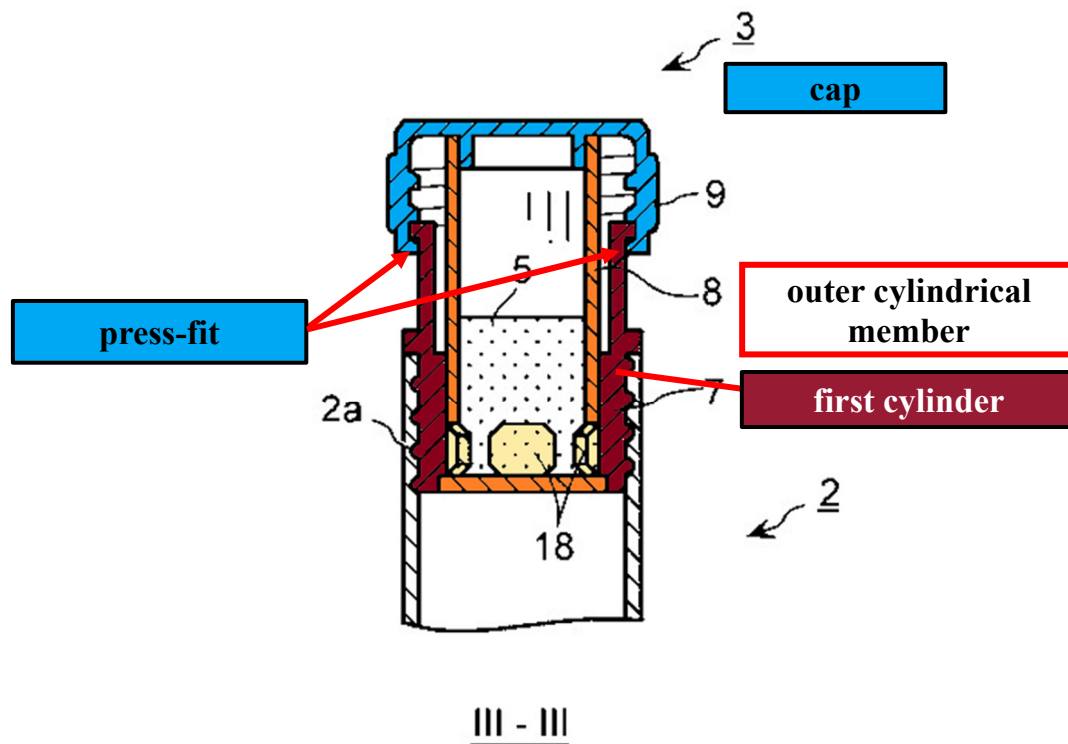
Ex.1005, Fig. 4B (annotated); *id.*, [0027]. Thus, Ueda discloses the limitations of dependent claims 3 and 4.

D. Ueda Anticipates Claim 5

218. Claim 5 depends from claim 1 and states: “wherein the first cylinder comprises a press-fit connection with the cap.” Ueda discloses this limitation.

219. The '632 patent specification does not use the term “press-fit,” and it fails to explain what a press-fit is or whether any of the disclosed connections are press-fits. Instead, the '632 patent discloses a threaded connection between the first cylinder and the cap. Ex.1005, [0029]. 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, while also ensuring that the cap is not easily removed from the first cylinder, as shown below in annotated Figure 3B. *Id.*



220. Ueda's cap also includes a press-fit connection between the first cylinder (7) and the second cylinder (8), which is part of the cap. Ex.1005, [0028], Figs. 2-4B. Ueda's first cylinder 7 overlaps with the second cylinder 8, blocking the

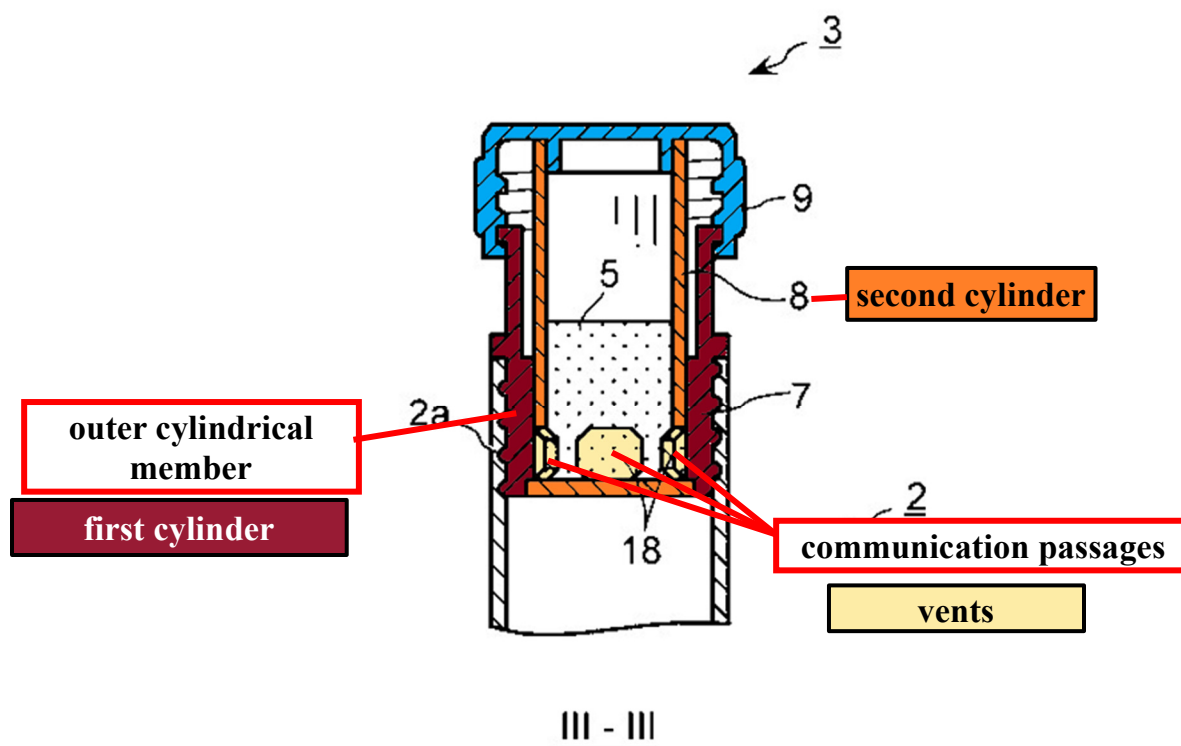
vents and creating a fluid-tight seal with the cap to retain the reagent 5 within the second cylinder 8. *Id.* Ueda explains that “the bottom wall plate is constructed so as to liquid-tightly seal the space between the outer cylindrical member 7 and the mixture holding member 8.” *Id.*, [0028]. Ueda’s Figure 3B above shows the additional 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. A press-fit is used to maintain a seal between the cylinders of the cap.

E. Ueda Anticipates Claim 6

221. 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’s annular valve meets this limitation.

222. As I explained above, Ueda’s annular valve includes a second cylinder (mixture holding member 8) that has a plurality of vents (communication passages 18). Ex.1005, [0027] (“plurality of communication passages 18”), Figs. 2-4B. Ueda further explains that “When the holding member 8 does not protrude from the lower end opening 10 of the outer cylindrical member 7 toward the container body 2, so that it **does not communicate** with the inside of the container body 2 (see the first screw-in state shown in FIG. 3), the **communication passage 18 is closed** by the inner peripheral surface of the outer cylindrical member 7.” *Id.* (emphasis added).

In this closed configuration, the first cylinder 7 overlaps with the second cylinder 8, obstructing the vents and creating a fluid-tight seal with the cap to retain the reagent 5 within the second cylinder 8. *Id.* Fig. 4B shows Ueda's movable annular valve in a closed position with the first cylinder 7 obstructing the plurality of vents 18 on the second cylinder 8 to retain the reagent mixture 5 in the storage chamber.



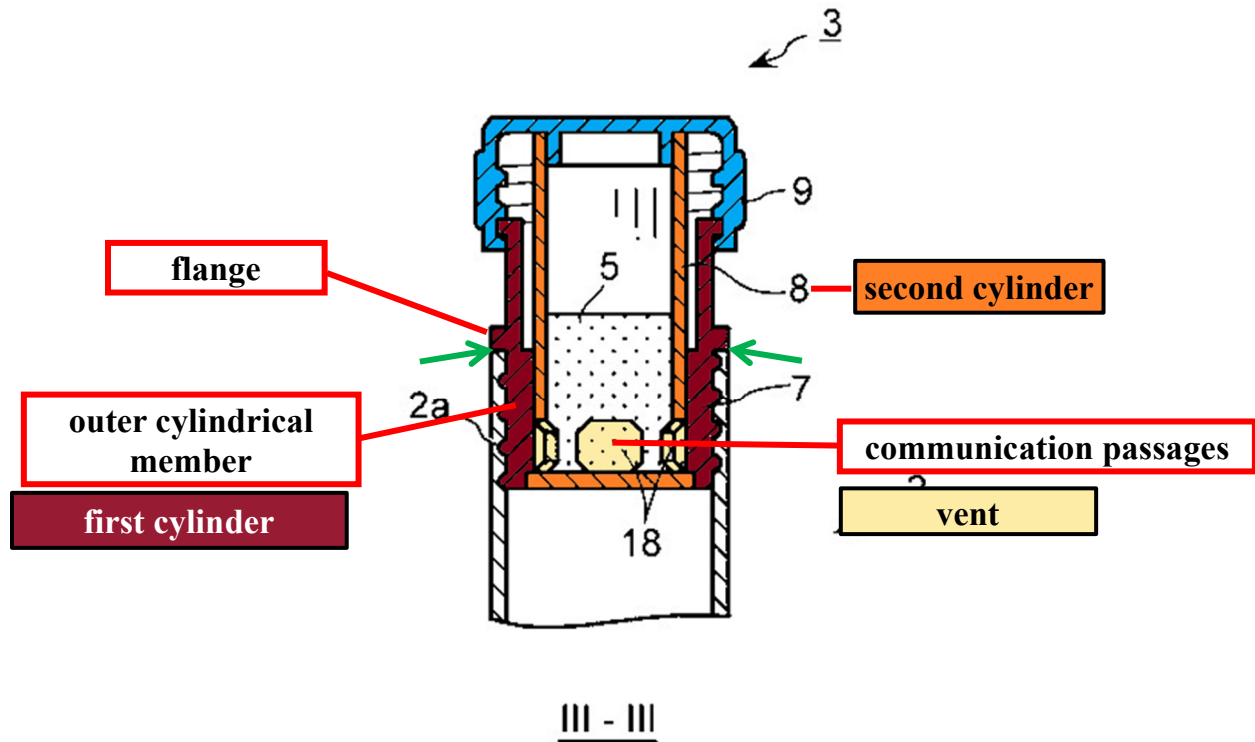
Ex.1005, Fig. 3B (annotated), *id.*, [0027].

F. Ueda Anticipates Claims 7 and 8

223. 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.” Ueda’s valve meets this limitation.

224. 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’s valve also meets this limitation.

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. 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 which 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]. In this manner, the interaction between the flange 14 and the wall of the collection vessel 2 (see green arrows) 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. 3B below. Thus, Ueda discloses these limitations.



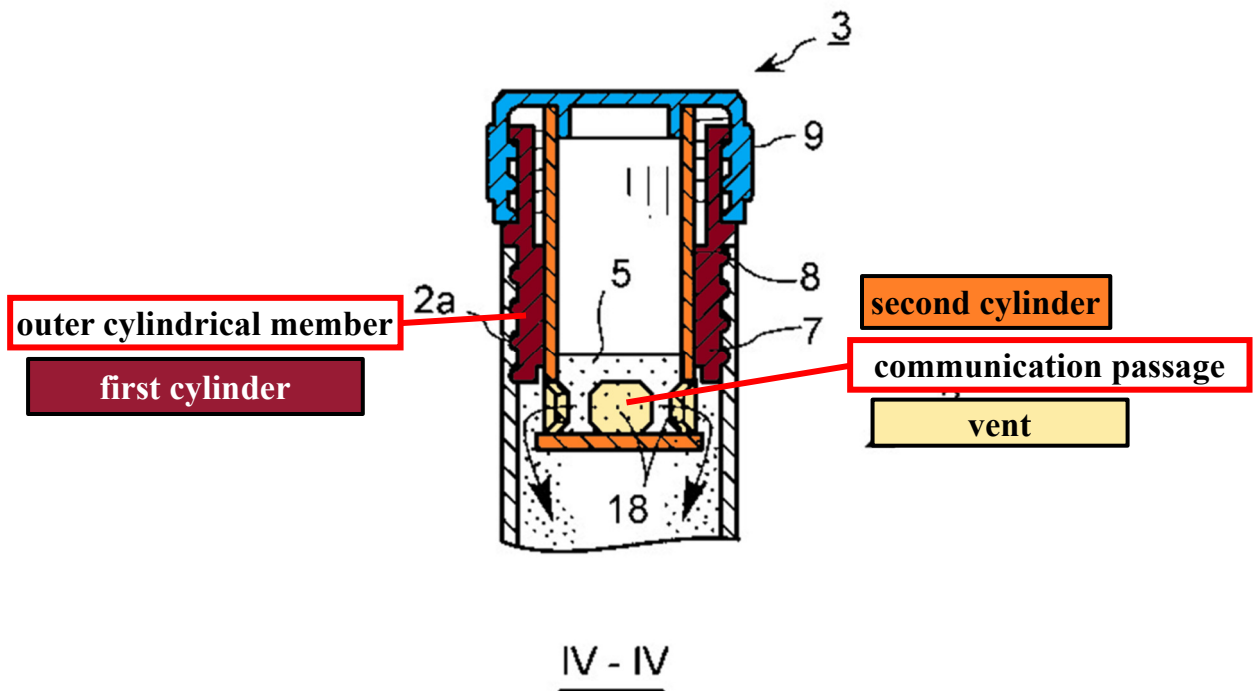
Thus, Ueda discloses the limitations of Claims 7 and 8.

G. Ueda Anticipates Claims 10 and 11

226. 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.

227. When Ueda’s cap 3 is completely tightened on the container 2, the 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

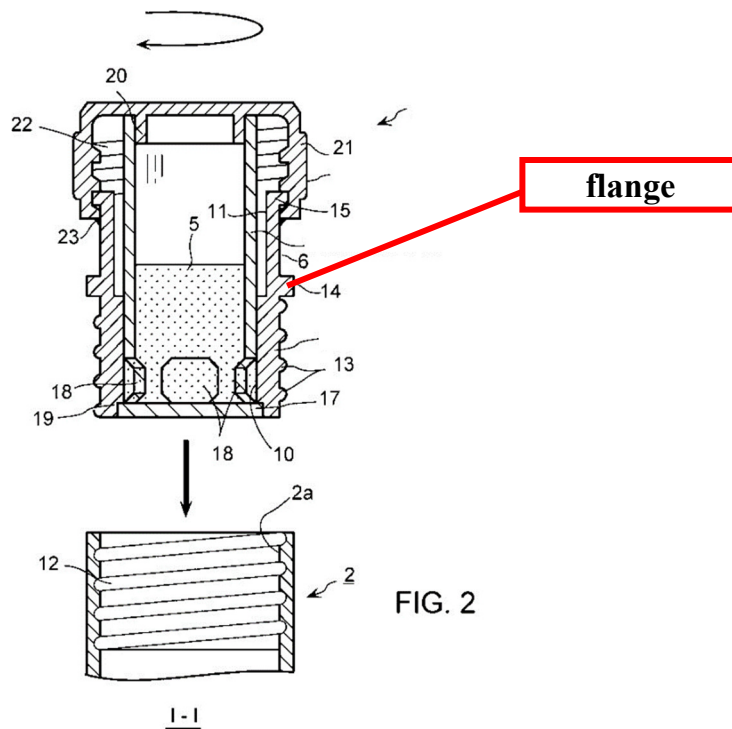
container body 2 and the internal space of the mixture holding member 8 to communicate with each other.” Ex.1005, [0027], Fig. 4B. Ueda’s Fig. 4B shows the movable annular valve in an open configuration, where the interior sidewall of the first cylinder (outer cylindrical member 7) no longer obstructs the vent (communication passage 18) such that the vent is fully unobstructed in the open configuration. Therefore, the vent is both at least partially unobstructed and fully unobstructed in the open configuration.



Ex.1005, Fig. 4B (annotated); *id.*, [0027]. Thus, Ueda’s annular valve includes these limitations of Claims 10 and 11.

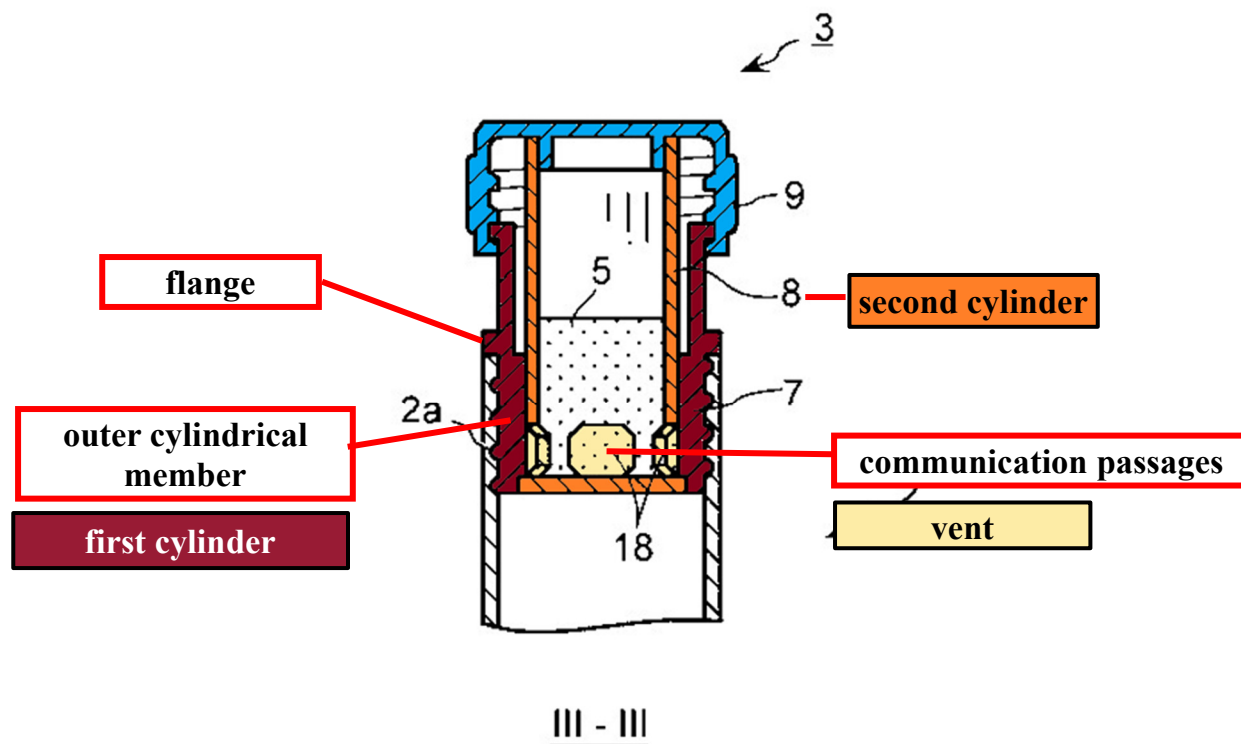
H. Ueda Anticipates Claims 12 and 13

228. 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.



229. As shown in Fig. 2 above and Fig. 3B below, Ueda’s first cylinder 7 and second cylinder 8 have generally constant exterior diameters. A POSA would have understood that both cylinder parts have cylindrical shapes with generally constant outer diameters and inner diameters. Ueda’s first cylinder 7 also includes

a flange (first flange part 14) which extends from the first cylinder. Ex.1005, [0026]-[0029].



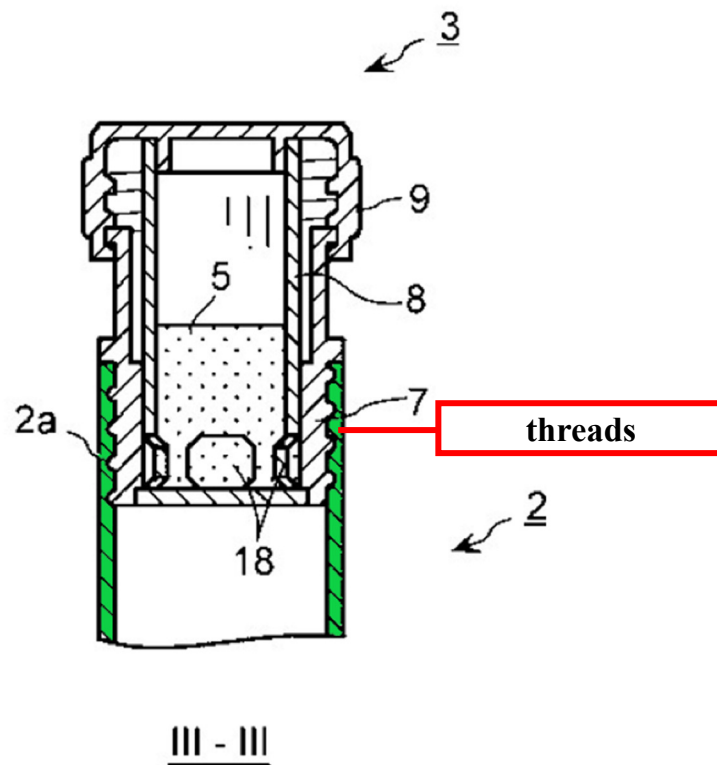
Ex.1005, Fig. 3B (annotated), *id.*, [0026]-[0029]. Thus, the annular valve of Ueda includes each of the limitations of Claims 12 and 13.

I. Ueda Anticipates Claim 14

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

231. Ueda’s device uses common threaded connection members. 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 Ueda and the other prior art references. 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 and corresponding thread set 12 on the container body. Ex.1005, [0026], Figs. 1 and 2. Ueda discloses that the cap includes “a male screw projection 13 that can be screwed into a female screw groove 12 of the container body 2 . . . so that the lower end opening 10 can be detachably connected to the upper end opening 2a of the container body 2.” *Id.*, [0026]. Fig. 3B in Ueda, reproduced 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:

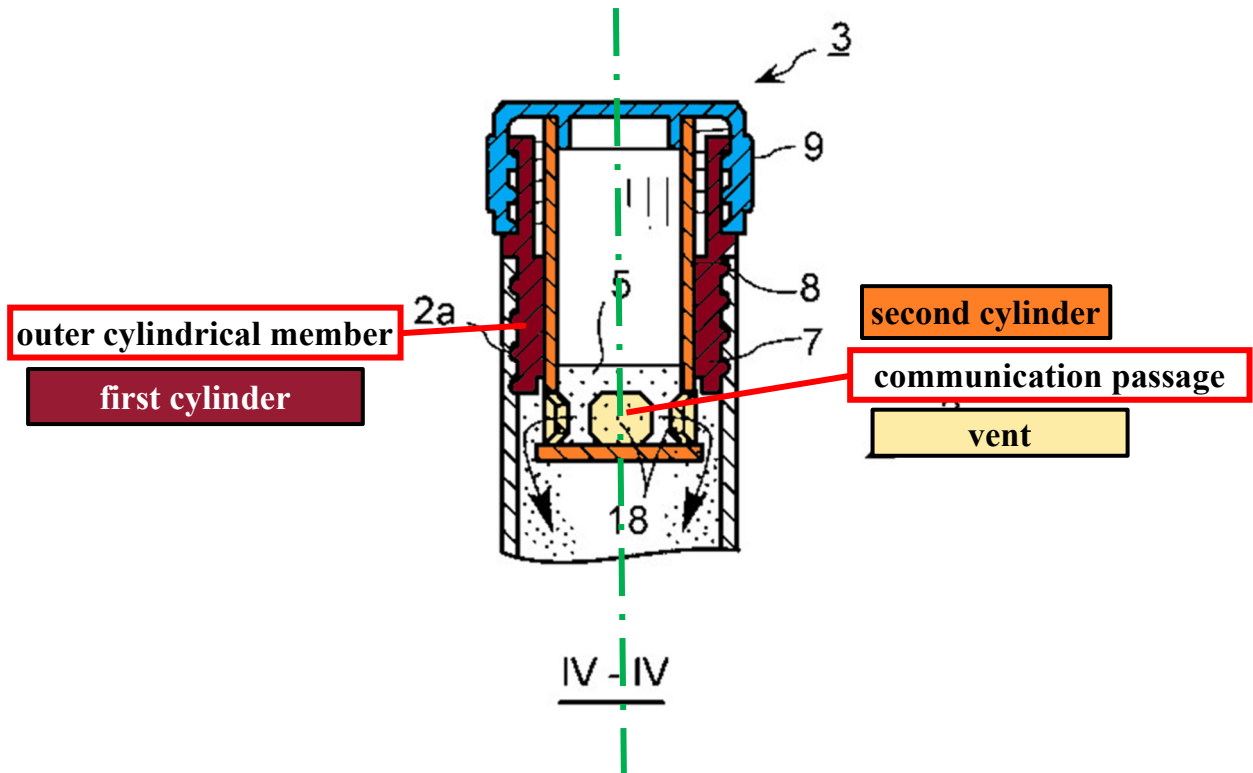


Id., Fig. 3B (annotated). Thus, Ueda discloses this limitation.

J. Ueda Anticipates Claim 15

232. 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 Ueda includes this limitation.

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” 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] (emphasis added), Fig. 4B. A POSA would have understood that, as the cap is tightened and further screwed towards the container, the second cylinder 8 slides downward along a longitudinal axis (shown in green below) of the cap 3 in a sliding connection between the first and second cylinders. Ueda’s Figs. 3B and 4B show the sliding connection.



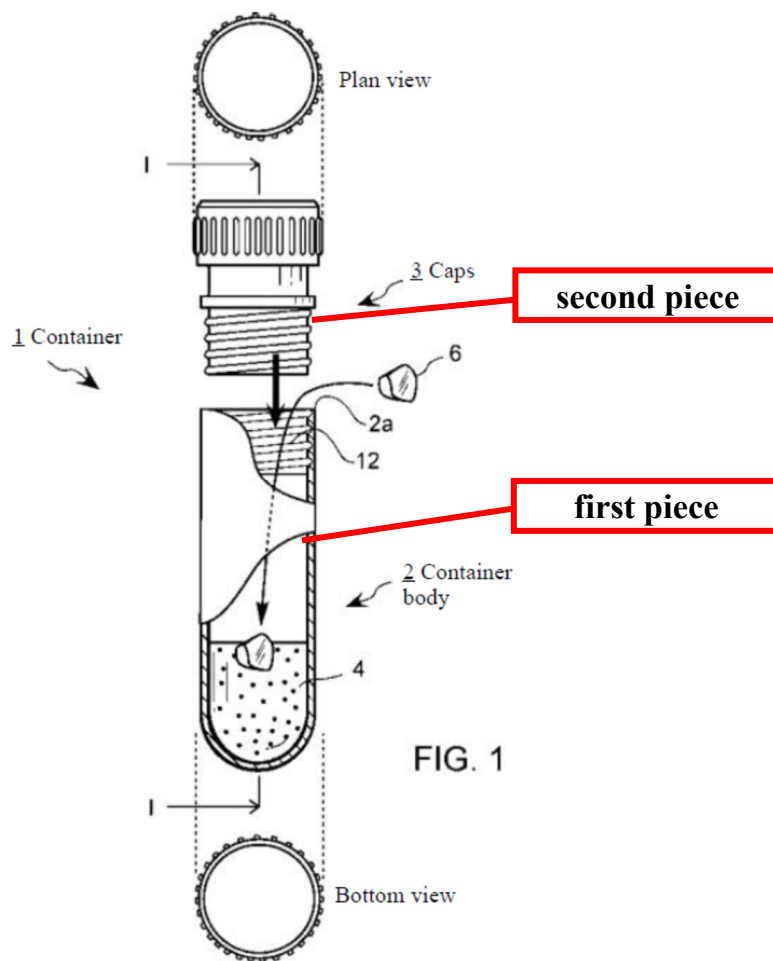
Ex.1005, Fig. 4B (annotated); *id.*, [0027]. Thus, this limitation anticipated by Ueda.

K. Ueda Anticipates Claim 16

234. 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 these features.

235. Ueda’s sample collection system includes two pieces. A POSA would have understood that 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 Fig. 1 below. Ueda explains that these two pieces are also separable, for example “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 once from the container body 2 as shown in FIG. 1, and after the biomaterial 6 is placed into the container body 2, it is reinstalled.” Ex.1005, ¶ [0034]. The embodiment of FIG. 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 which further confirms that these two pieces are separable. Ex.1005, [0031]. Thus, a POSA would have understood that Ueda’s sample collection system includes a separable two-piece sample collection system with a sample collection vessel as the first piece and the cap as the second piece.

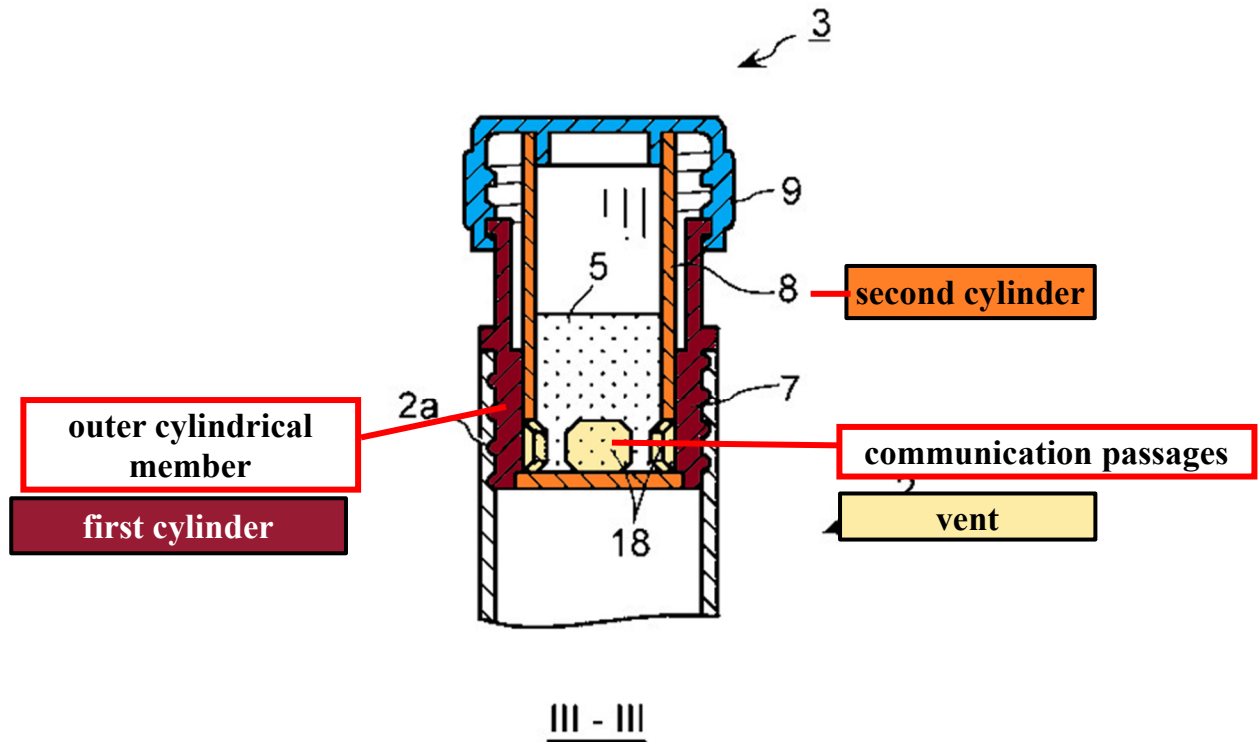


L. Ueda Anticipates Claim 18

236. Claim 18 depends from claim 1 and states: “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.

237. A POSA would have understood that 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 whose lower end is closed with a bottom wall plate 17, and its outer diameter is formed to a dimensions such that it slides vertically along its axial direction within the outer cylindrical member 7.” *Id.* “When the holding member 8 does not protrude from the lower end opening 10 of the outer cylindrical member 7 toward the container body 2, so that it **does not communicate** with the inside of the container body 2 (see the first screw-in state shown in FIG. 3), the **communication passage 18 is closed** by the inner peripheral surface of the outer cylindrical member 7.” *Id.* (emphasis added). Thus, the first and second cylinders move relative to one another while maintaining a fluid-tight connection therebetween in the closed configuration. *Id.* Fig. 4B 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.



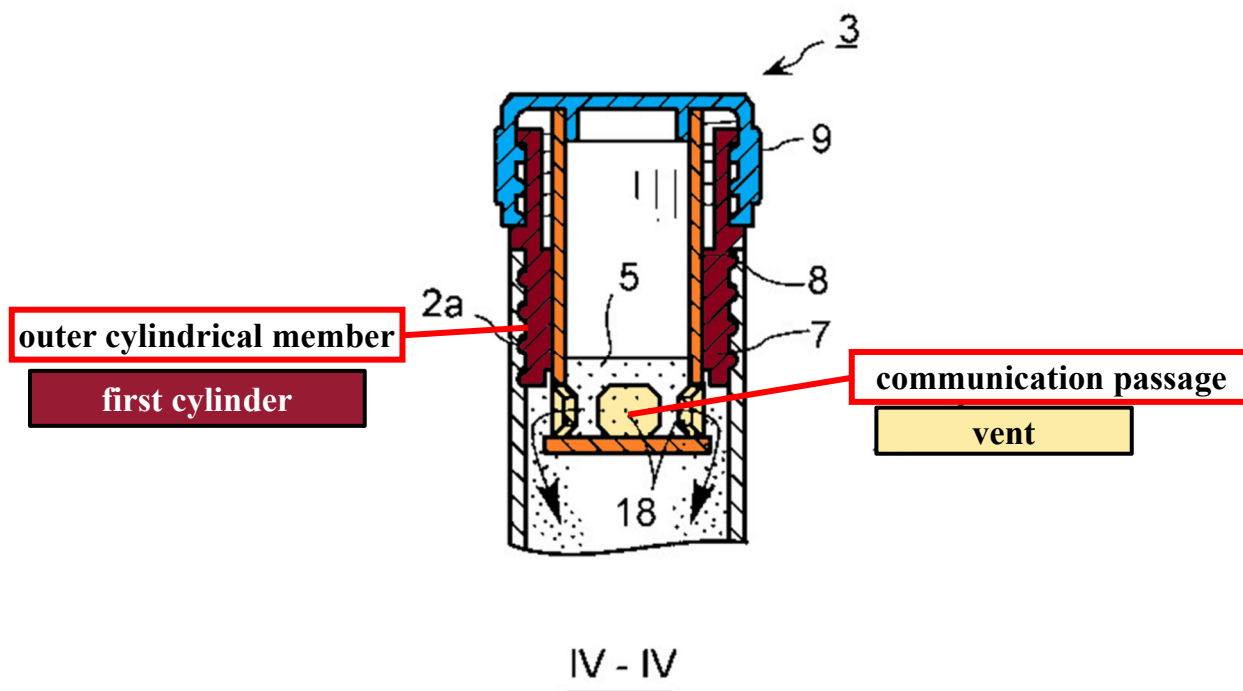
Ex.1005, Fig. 3B (annotated), *id.*, [0027]. Thus, claim 18 is disclosed by Ueda.

M. Ueda Anticipates Claim 19

238. 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.

239. As explained in Ueda, when the 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” 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 Fig. 4B shows the result of tightening the cap 3 onto the sample collection vessel 2, namely the movable annular valve in 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, Fig. 4B (annotated); *id.*, [0027]. Thus, Ueda discloses the limitation of claim 19.

N. Ueda Anticipates Claim 20

240. Claim 20 depends from claim 1 and recites the same limitations from claims 2, 3, and 19. I have already addressed these limitations above in the

corresponding sections. As discussed above with regard to claims 2, 3, and 19, Ueda discloses each of these limitations.

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

241. Claim 5 depends from claim 1 and states: “wherein the first cylinder comprises a press-fit connection with the cap.” This limitation would have been obvious in view of Ueda and Patterson.

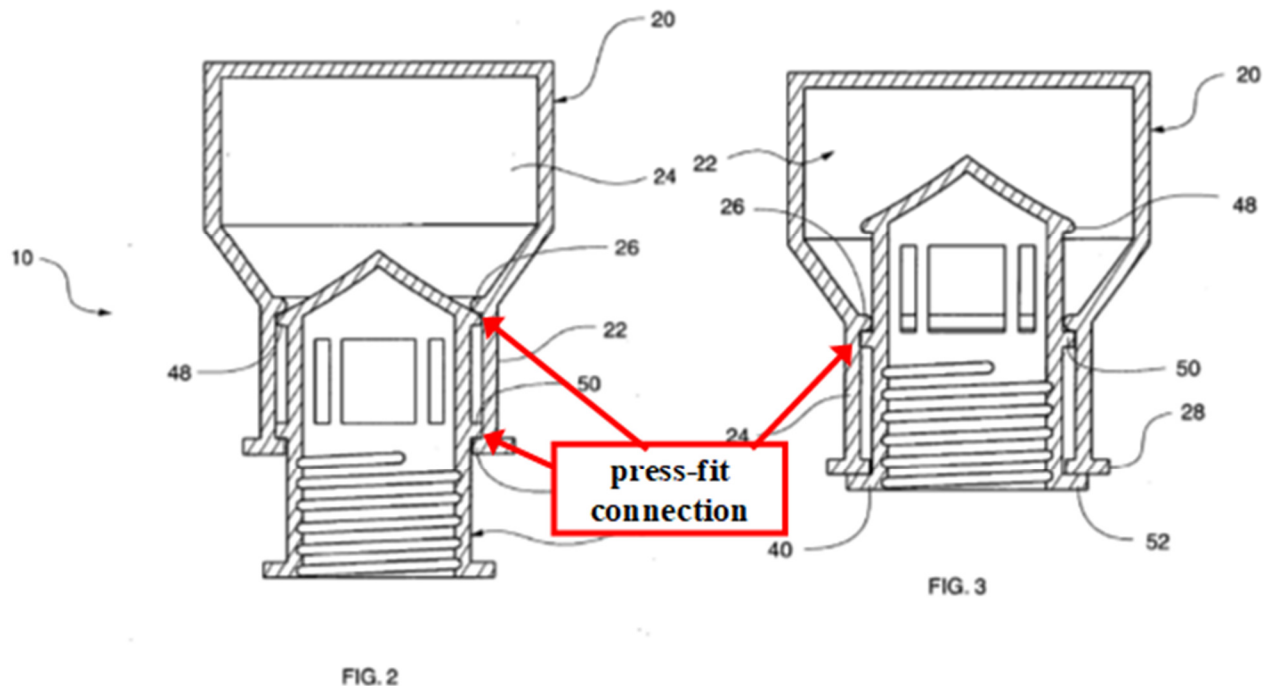
242. As I explained above in Ground 2, the ’632 patent specification does not use the term “press-fit” or explain what a press-fit is or whether any of the disclosed connections are press-fits. Instead, the ’632 patent discloses threaded connections between the first cylinder and the cap, for example the thread features 44 and 45 in Figs 3A and 3B of the ’632 patent. As I explained above in Ground 3, Ueda discloses the claimed press-fit connection. However, using a press-fit connection would have also been an obvious option for connecting the first cylinder and the cap.

243. The lack of disclosure in the ’632 patent confirms that the use of a press-fit connection in this context was familiar to a POSA and easily implemented. A POSA would have used and been familiar with press-fit connections, which were common in containers and medical devices. Instead of describing a press-fit connection generally or specific examples of such a fit 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 to those of skill in the art.” *Id.* 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.

244. The prior art also confirms that press-fit connections in container caps were well known prior to the '632 patent. For example, Patterson teaches press-fit connections between cylindrical parts of the cap that do not involve threads. Ex.1010, [0032] (“mixing cap 10 may be coupled to an unthreaded mouth of a bottle via frictional-fit.”). Patterson discloses a press-fit connection between a first cylinder and a cap. For example, Patterson discloses an outer cylinder (outer housing 20, 22) of the cap 10 that comprises an interference-fit (press-fit connection) with an inner cylinder (inner tube 40) of the cap 10, as shown below in annotated Figs. 2 and 3. Ex.1010, [0032]. In Patterson's embodiment, the inner cylinder 40 includes threads that engage and couple with corresponding threads on the bottle or container. *Id.* After the cap 10 is threaded onto the container, 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, facilitating the passage of ingredients from the mixing cap 10 to the container. *Id.* 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.



245. It would have been obvious for a POSA to modify Ueda’s movable annular valve in view of Patterson to replace the threaded connection between the first cylinder 7 and the cap 9 with a press-fit connection like Patterson’s, as illustrated in the modified version of Ueda’s Figure 3B below. As modified, 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. As another feasible option, 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.

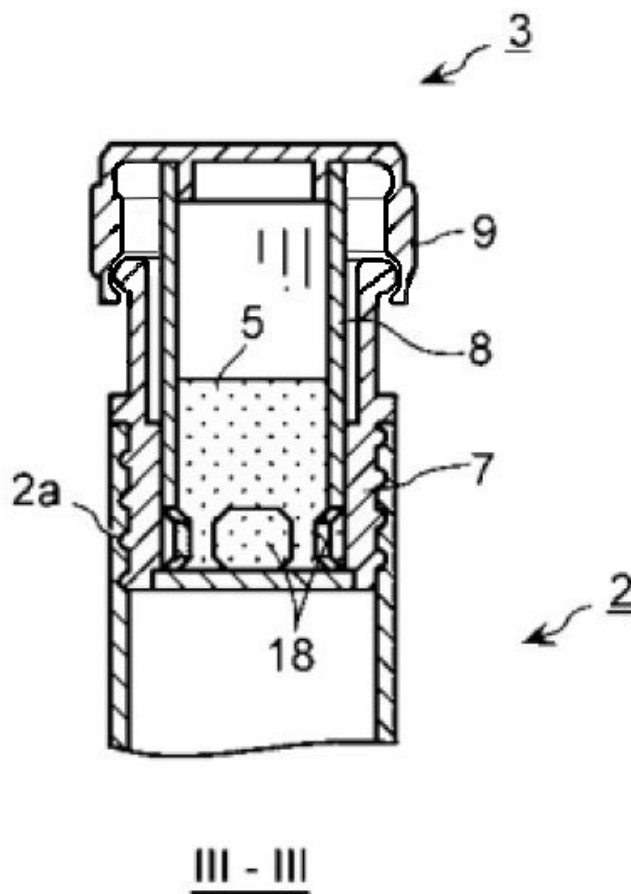


FIG. 3B (MODIFIED)

246. Patterson's press-fit could also be designed as a simple interference-fit with no snap feature. Such simple press-fits were common and well-known to a POSA. 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.

247. Using a non-threaded press-fit instead of a threaded connection in Ueda 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. As I explained above in Ground 2, 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. A POSA would have understood that molding threads on these types of devices can be difficult and requires a more complex manufacturing process. Molding a protrusion, bump, or a rib is much easier than threads. For example, molding threads can sometimes require a mold with an unwinder core, whereas a protrusion, bump, or rib can be formed by a simple two-sided mold or by merely pulling the tool over the molded part. A POSA could have molded an interference fit with a 0.003 inch or less protrusion that can be molded as an undercut in the tool. On the other hand, threads require unwinding tool or other complex tooling to mold the helical threads. 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.

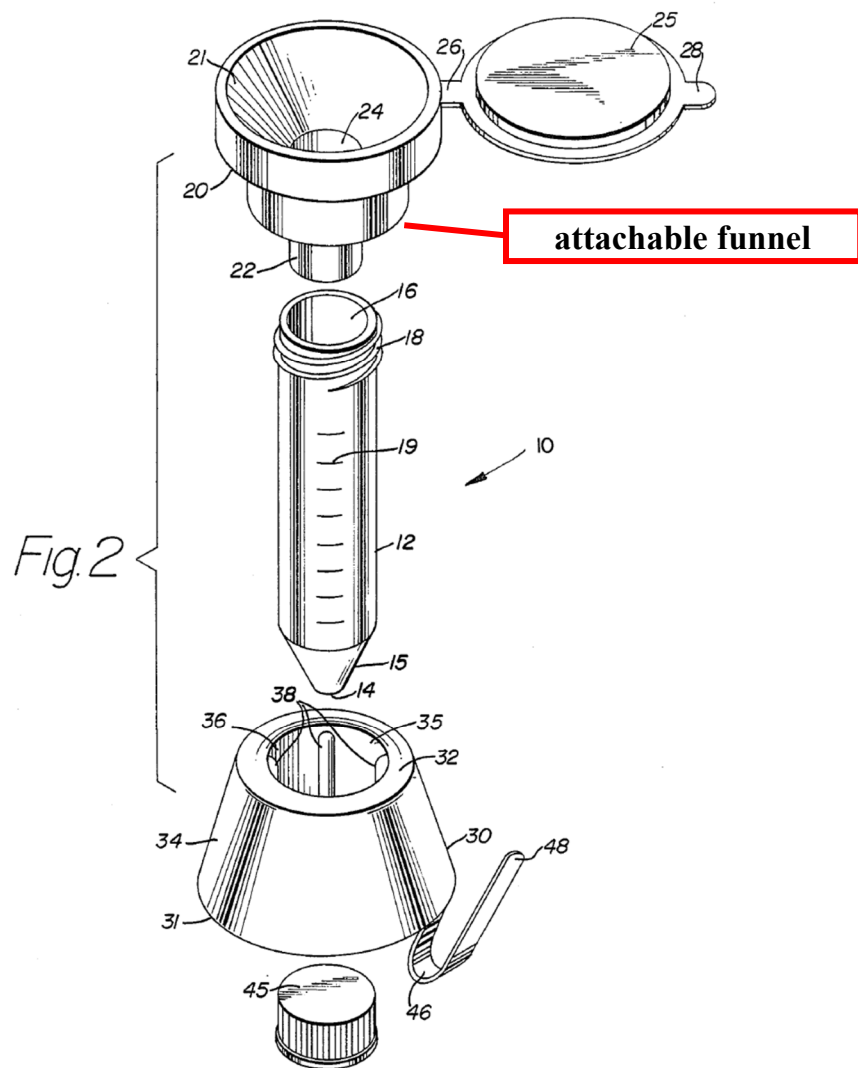
XII. GROUND 5: UEDA AND WILLIAMS RENDER OBVIOUS CLAIM 9

248. Claim 9 depends from claim 1 and states: “further comprising a funnel

attachable to the sample collection vessel.” This limitation would have been obvious in view the combination of Ueda and Williams.

249. It would have been obvious for a POSA to use an attachable funnel in the Ueda system in view of Williams. Williams discloses a biological specimen collection device with a receptacle and an attachable funnel, as shown below in Fig. 2. Ex.1009, Abstract, 6:9-15 (“In order to collect the biological specimen, such as sputum, cover 25 is lifted by virtue of finger tab 28 whereupon the specimen is deposited in wide receiving portion 21 of the funnel.”). Williams explains that the “funnel includes a relatively wide sputum receiving portion and a passage tube to which the receptacle is removably connected so that the tube communicates with the inside of the receptacle through its open end.” *Id.*, 2:39-43. 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. A POSA would have understood that an attachable funnel like Williams’ could easily be implemented in Ueda by using a threaded connection to the vessel or a simple friction fit like the one illustrated in Williams. A POSA would have been motivated to use an attachable funnel because it would facilitate obtaining the biological saliva sample from the user while allowing for a smaller cap and sealed container. The funnel provides a

wider receiving portion that makes it easier for a user to spit saliva into or otherwise deposit bodily fluids. Williams' funnel 20 includes a "relatively wide specimen receiving portion 21 into which the specimen is deposited when being collected from the patient. 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.*



250. As I explained above in the Plant and Cho grounds, there are several

additional examples of prior art sample collection systems that included separate attachable/detachable funnels. *See e.g.*, Ex.1018 (U.S. 4,589,548 to Fay) at 6:18-26 (“To collect a specimen, tab 38 is grasped and upper lid 34 is opened in the direction of arrow 88. The patient then deposits the sputum sample into the funnel 24 so that it is conducted into container 12. Lid 34 is closed in the direction of arrow 90 so that ridge means 40 are received by funnel mouth 26 and sealably engage the inside surface of the funnel 24 proximate mouth 26. When collection of the specimen has been completed, the funnel is removed from container 12 and discarded.”); Ex.1019 (U.S. 4,741,346 to Wong) at 3:39-44 (“A portion of the funnel 32 can be inserted in the vial open end 61. The upper surface of the vial 30, contiguous to the open end 61, is formed with threads which are threadably mateable with a threaded vial cap 74.”); Ex.1020 (U.S. 3,518,164 to Adelin) at 2:48-52, 3:24-29 (“The sputum specimen receptacle 1 illustrated in FIGS. 1 and 3 is closed at its bottom end and open at the top so that the annular ring 7 of the funnel 2 may be frictionally seated therein.”).

251. Thus, Claim 9 would have been obvious in view of the combination of Ueda and Williams.

XIII. CONCLUSION

For these reasons, it is my opinion that challenged claims of the '632 patent are anticipated and/or would have been obvious in view of the prior art.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on September 14, 2023, in Dover, NH.



Digitally signed by Karl R.
Leinsing
Date: 2023.09.14 13:09:08
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Karl R. Leinsing, MSME, PE