

Patent Owner's Demonstratives

Spectrum Solutions L.L.C. v. DNA Genotek Inc.

IPR2023-01424

U.S. Patent No. 11,536,632

January 24, 2025

Roadmap

- **Claim 21 has not been impermissibly broadened**
- **The revised claims are patentable over Plante and Cho**
- **Claim 33 is supported**

Claim 21 (Revised MTA)

21. A biological sample collection system, the system comprising:

a sample collection vessel comprising

a sample collection reservoir,

a first connection member, and

a first aperture for receiving a biological sample;

a cap comprising

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

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

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

a moveable annular valve positioned in the interior volume of the cap~~second aperture~~, the movable annular valve comprising a vent,

a first cylinder comprising a third aperture,

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

a closed configuration, and

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

the first cylinder and second cylinder are relatively moveable to thereby change the annular valve from the closed configuration to the open configuration, wherein the first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve, and

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

RM TA
(Paper 26)

Claim 21 (MTA)

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

a sample collection vessel comprising

a sample collection reservoir,

a first connection member, and

a first aperture for receiving a biological sample;

a cap comprising

an outer wall;

a second aperture,

a reagent chamber storing a reagent therein, and

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

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

comprising

a vent,

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

* * *

* * *

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

a closed configuration, and

an open configuration, wherein

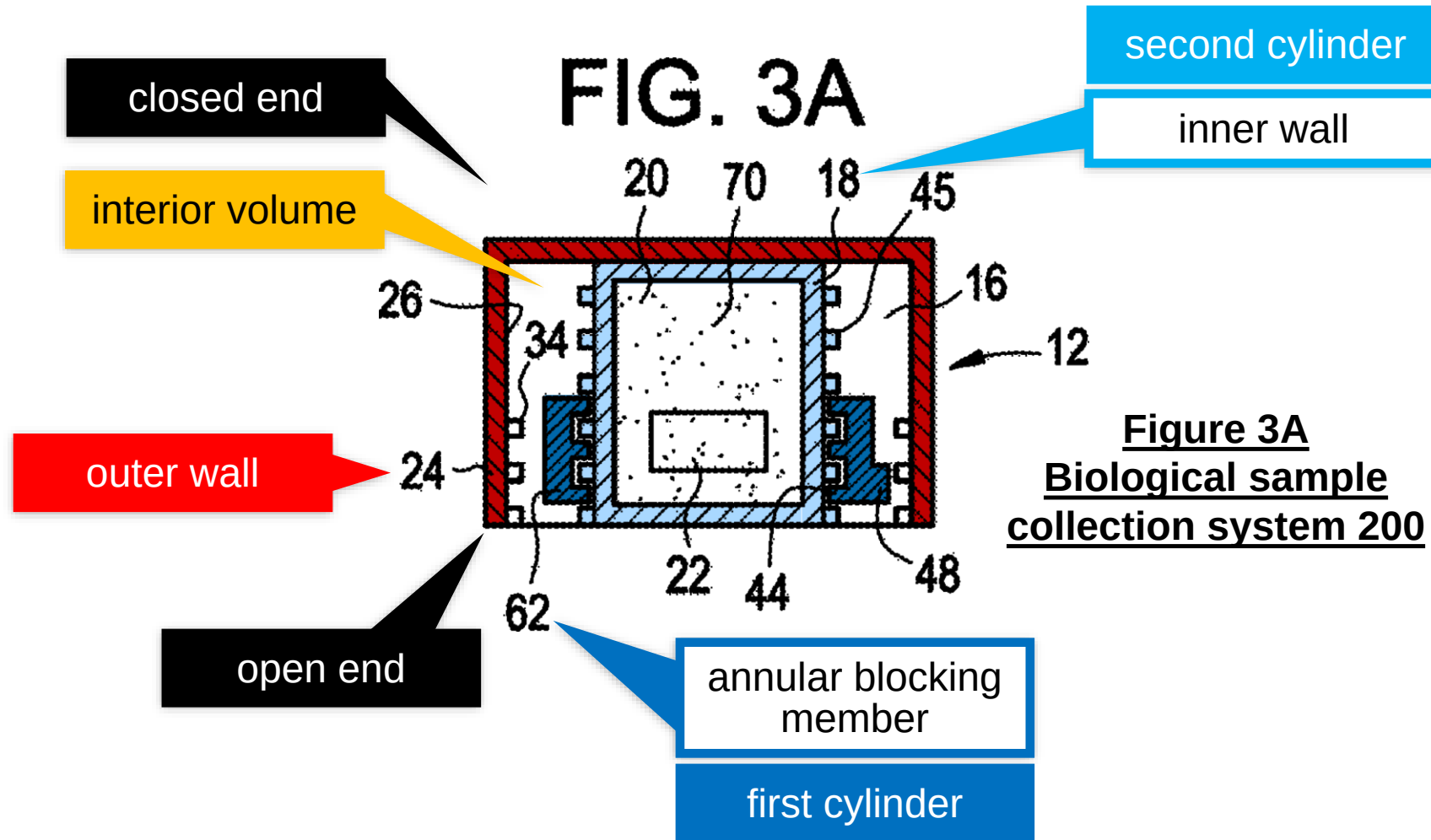
in the moveable annular valve's closed configuration, the first and second cylinders create a fluid-tight seal with the cap and the first cylinder obstructs the vent to retain the reagent in the reagent chamber,

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

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

MTA
(Paper 16)

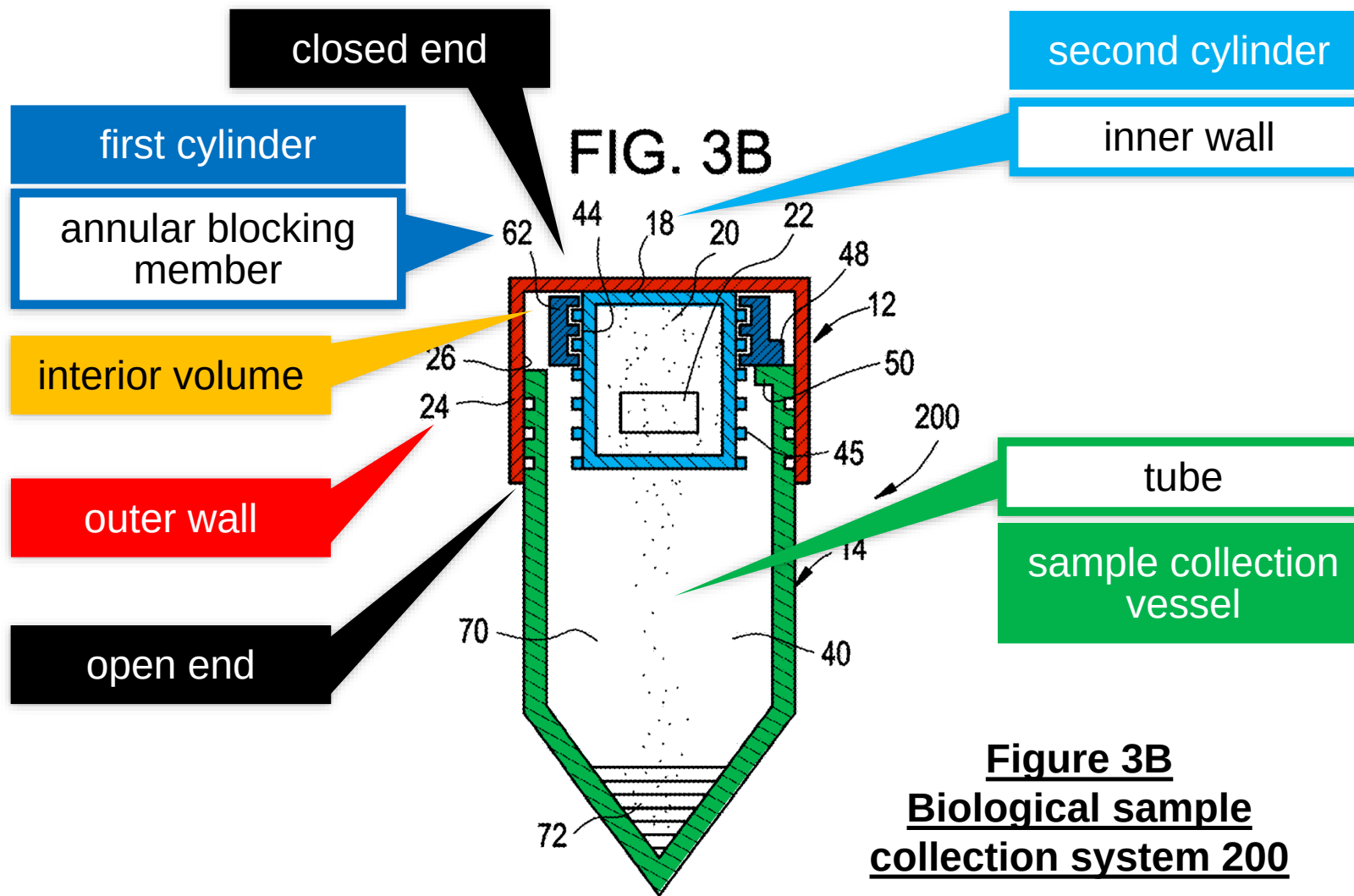
The '632 Patent



RMTA (Paper 26), 7;
Ex. 2025, ¶ 20,
Figs. 3A, 3B

Ex. 1001, Figs. 3A, 3B (annotated)

The '632 Patent



RMTA (Paper 26), 7;
Ex. 2025, ¶ 20,
Figs. 3A, 3B

Ex. 1001, Figs. 3A, 3B (annotated)

Claim 21 – Biological Sample Collection System With Three Main Elements

A biological sample collection system, the system comprising:
a **sample collection vessel** comprising
a sample collection reservoir,
a first connection member, and
a first aperture for receiving a biological sample;

Claim 21 – Biological Sample Collection System With Three Main Elements

a cap comprising

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

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

a second connection member complementary to the first connection member;

Claim 21 – Biological Sample Collection System With Three Main Elements

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

- a vent,

- a first cylinder comprising a third aperture,

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

- a closed configuration, and

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

- the first cylinder and second cylinder are relatively moveable to thereby change the annular valve from the closed configuration to the open configuration, wherein the first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve, and

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

Dependent Claims 29, 33 And 36

Substitute Claim 29	Substitute Claim 33	Substitute Claim 36
The biological sample collection system of claim <u>21</u>, <u>wherein the first cylinder and second cylinder are relatively moveable entirely within the interior volume of the cap to thereby change the moveable annular valve from the closed configuration to the open configuration</u>~~further comprising a funnel attachable to the sample collection vessel.~~	The biological sample collection system of claim ~~1~~<u>32</u>, wherein the annular valve comprises a flange extending from at least one of the first and second cylinders, <u>and wherein initial contact between the flange and a portion of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration, said portion of the sample collection vessel being disposed proximal to the first aperture.</u>	The biological sample collection system of claim <u>21</u>, wherein the sample collection system comprises a separable two-piece sample collection system, the sample collection vessel comprising a first piece of the separable two-piece sample collection system, and the cap with movable annular valve comprising a second piece of the separable two-piece sample collection system.

Claim 21: No Broadening

Claim 21

a cap comprising

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

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

...

a moveable annular valve positioned in the interior volume of the cap~~second aperture~~, the movable annular valve comprising

Petitioner: “Aperture” Is An Infinitely Thin Plane

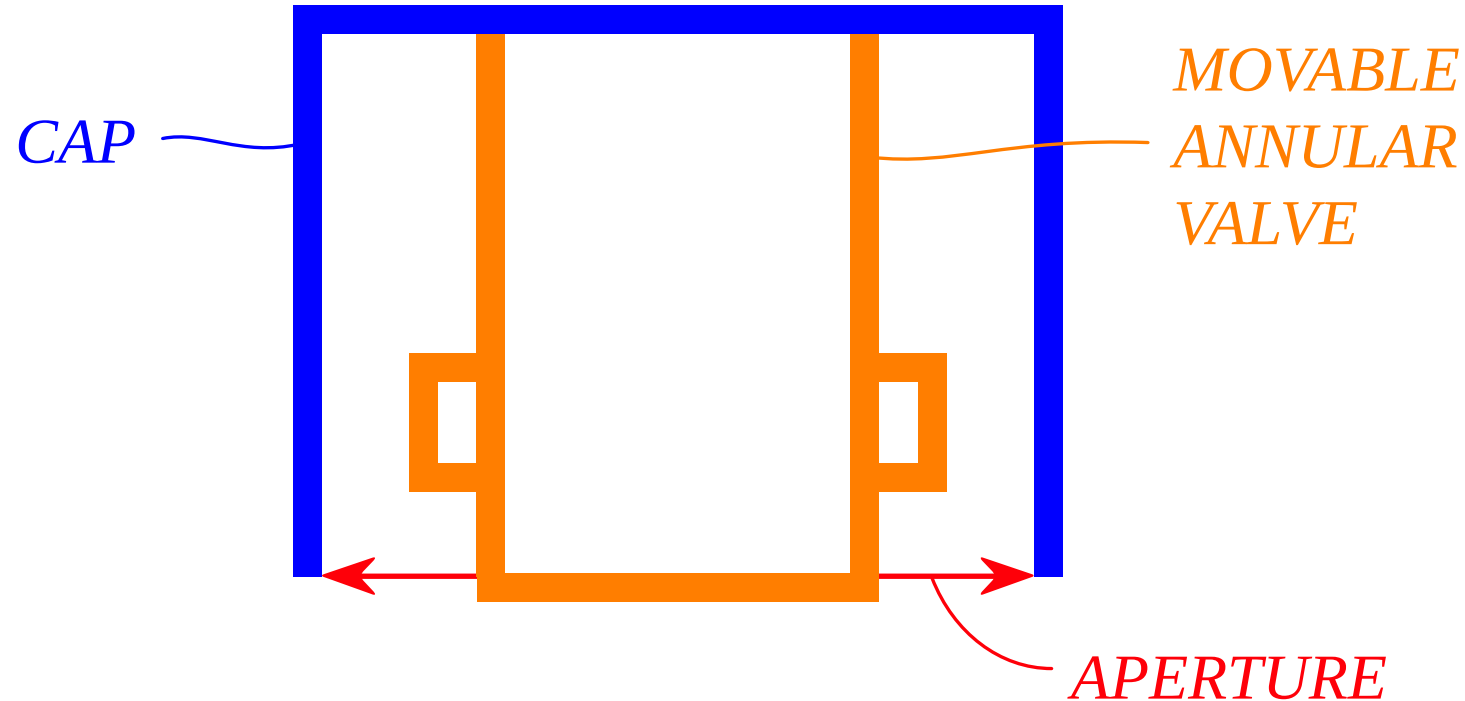


FIG. A

Opposition to RMTA (Paper 32), 4

Reply (Paper 38), 1

Patent Owner: “Aperture” Is A Volumetric Open Space

- ✓ Consistent with POSITA understanding and dictionary definitions
- ✓ Consistent with '632 specification and claims
- ✓ Consistent with relevant caselaw

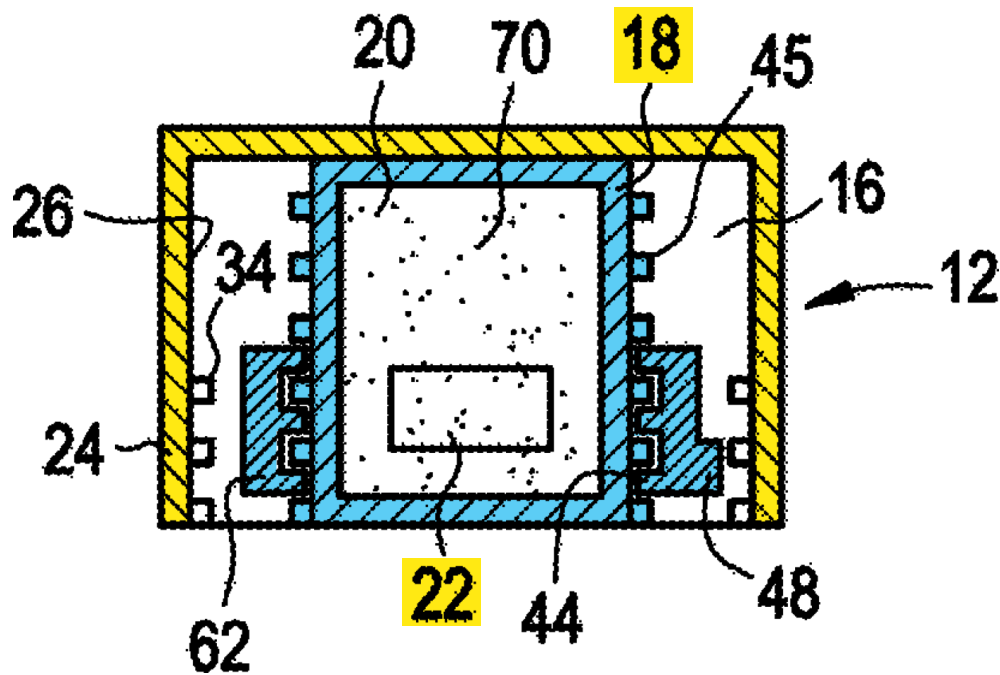
Reply (Paper 38), 1-2

POSITA Understanding & Dictionaries

An Aperture as an Open Space with Volume	
POSITA (Wereley) Declaration, Ex. 2025, ¶ 33	“. . . an ‘aperture’ is not an infinitely thin, planar feature but rather an ‘opening’ or ‘open space’ (e.g., a hole).”
POSITA (Wereley) Testimony, Ex. 1033, 44:16-18	“For instance, an aperture is the hole in a camera that lets light in to -- to the imaging element of a camera.”
<i>American Heritage Dictionary</i> , Ex. 2028	“[a]n opening, such as a hole”
<i>Dictionary.com</i> , Ex. 1031	“an opening, as a hole”
<i>Cambridge Dictionary</i> , Ex. 1032	“a small and often narrow opening, especially one that allows light into a camera”

Reply (Paper 38), 1-2

'632 Specification Supports Patent Owner



Ex. 1001, Fig. 3A (annotated)

“The thickness of the Aperture 22, which I would refer to as the depth in this figure, in this view of 3A, the depth goes from the outside of 18 to the inside of 18, Inner Wall 18”

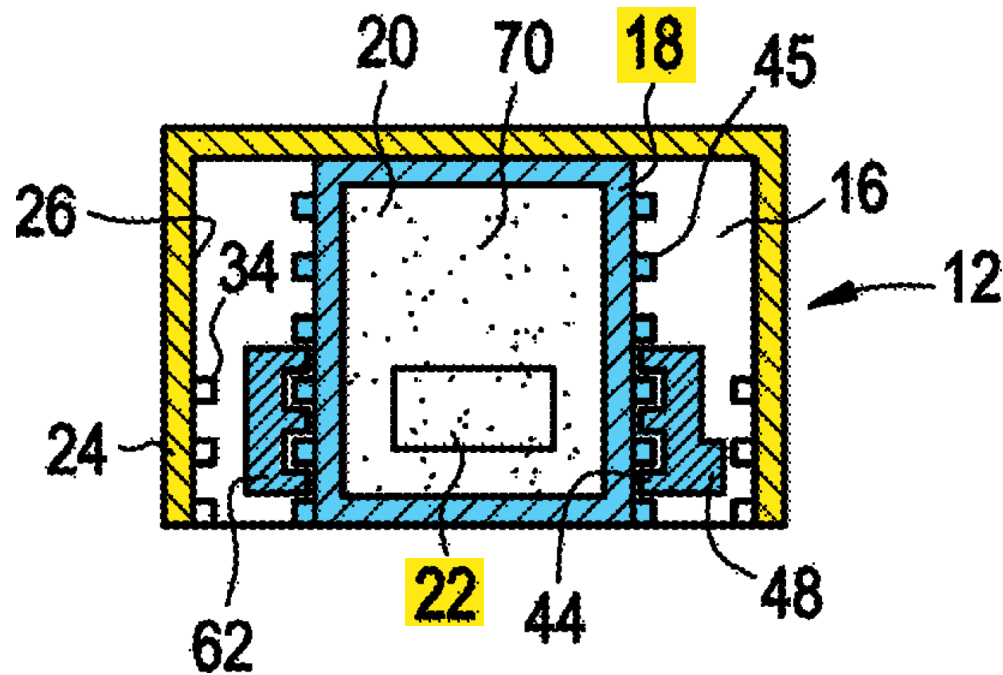
Ex. 1033 (Wereley Deposition), 42:12-16

“[T]he way the sentence in Paragraph 75 that we're looking at reads, the Inner Wall 18 may further define an aperture, which I interpret to mean the removal of or absence of material of the wall 18 in a certain place is, creates the aperture.”

Ex. 1033 (Wereley Deposition), 43:5-11

Reply (Paper 38), 1-2;
MTA (Paper 16), 9

'632 Specification Supports Patent Owner



Ex. 1001, Fig. 3A (annotated)

“The inner wall 18 may further define an aperture 22 which may be open or closed depending on the position of an annular blocking member 62 relative to the aperture 22.”

Ex. 1001, 14:24-27

Reply (Paper 38), 1-2;
MTA (Paper 16), 9

The Revised Claims Are Patentable Over Plante And Cho

Plante

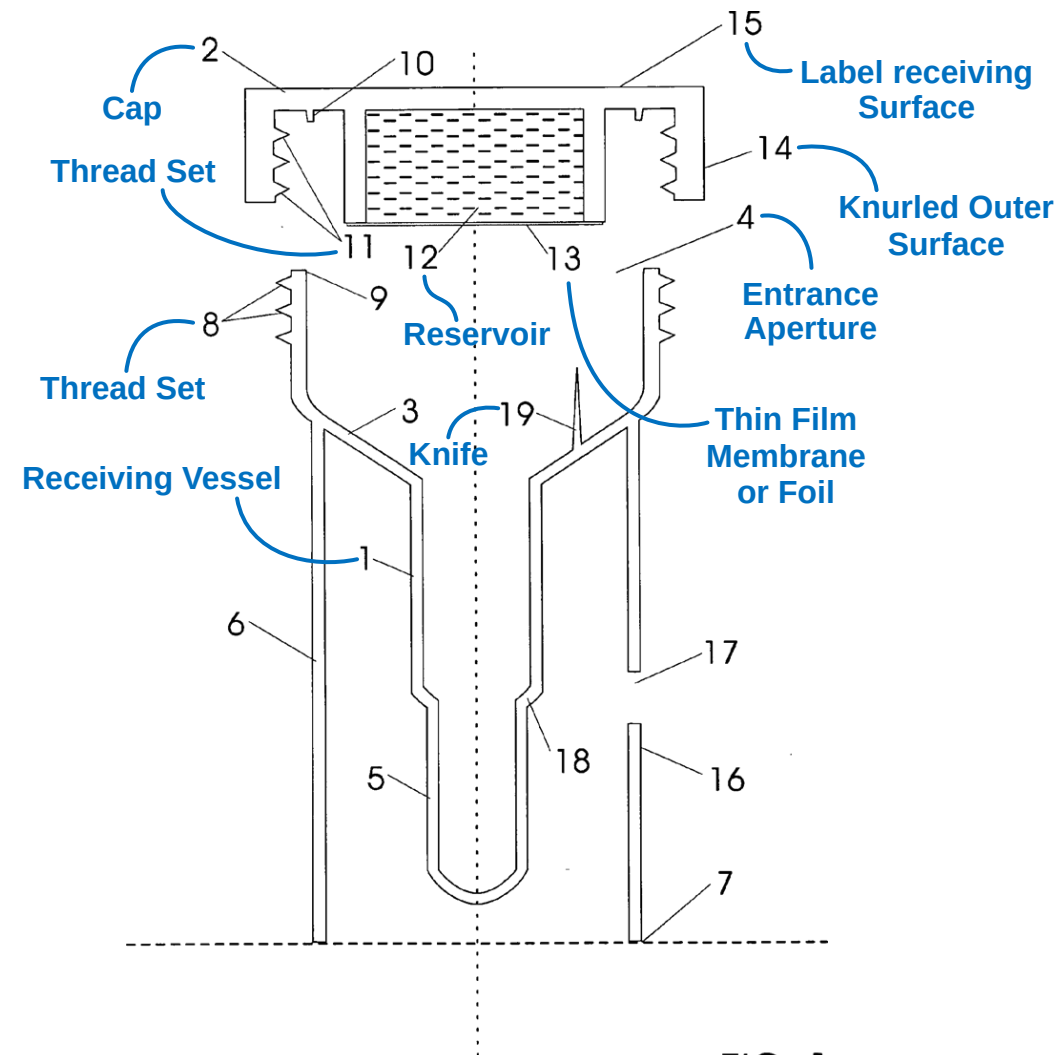
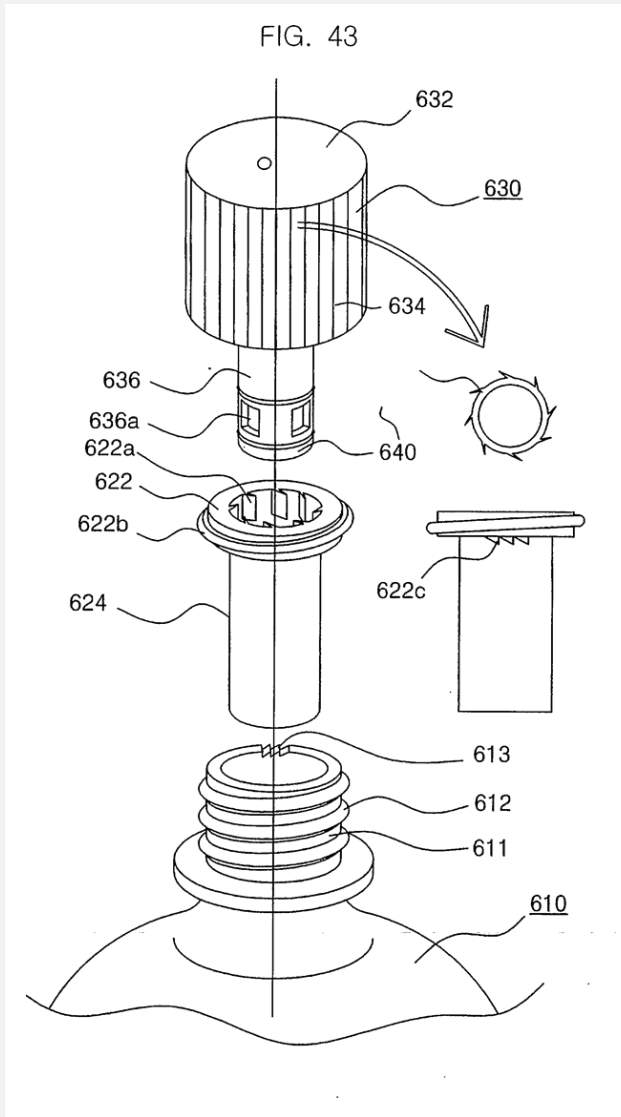
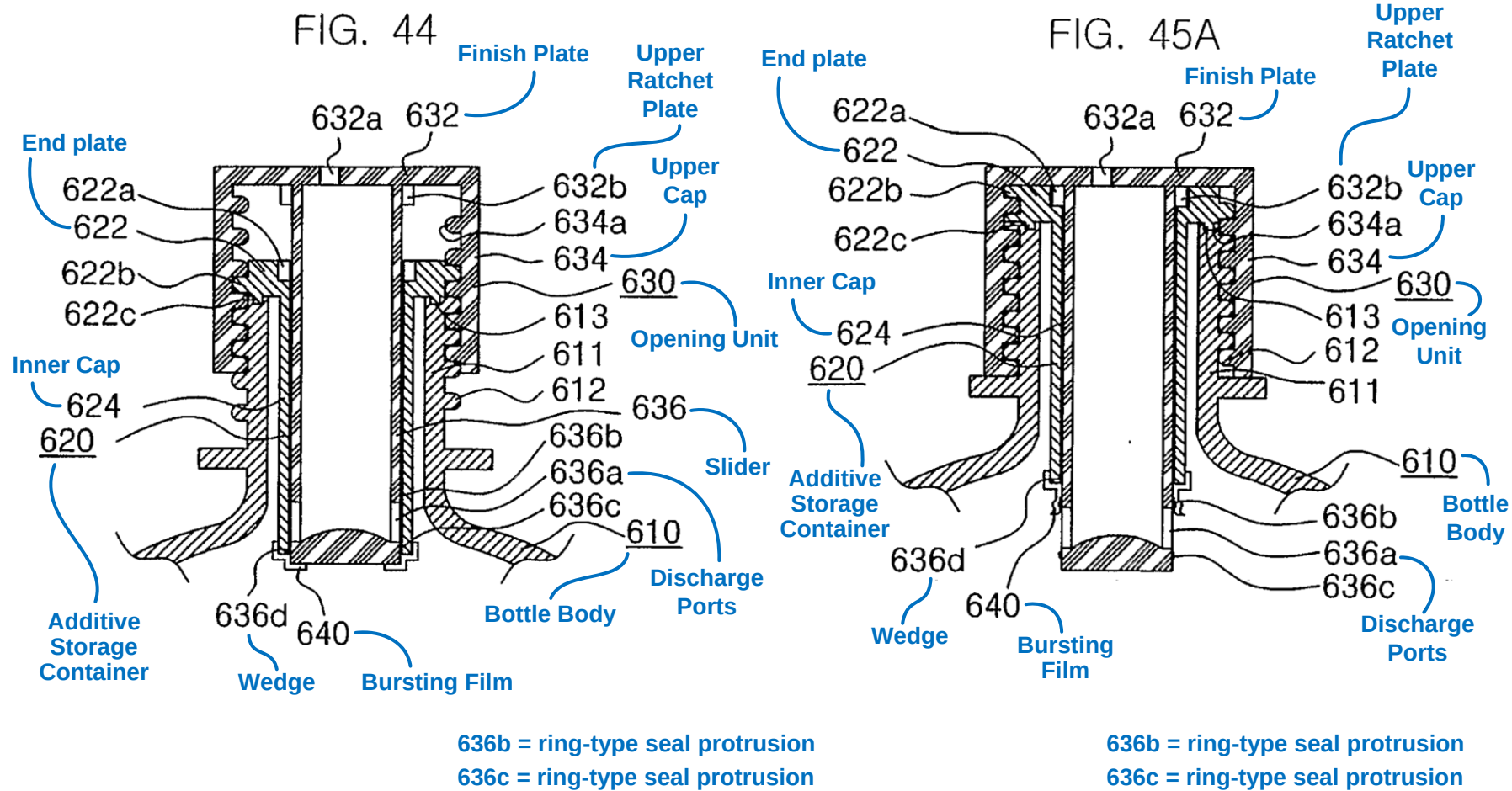


FIG. 1

RMTA (Paper 26), 13;
Ex. 2025, ¶ 41;
Ex. 1003, Fig. 1 (annotated)



Ex. 1004, Fig. 43



Ex. 1004, Figs. 44, 45A (annotated)

Reply (Paper 38), 4; Ex. 2030, ¶ 25

'632 Patent

For example, in some embodiments, the sample collection devices use **a minimum amount of parts** and do not require removal or exchange of a piece or an object thereof.

Ex. 1001, 4:63-66

. . . there is limited to **no risk of exposure to toxic solutions** (e.g., sample preservative solutions).

Ex. 1001, 5:6-8

Reply (Paper 38), 3

The Advantages Of The Claimed Invention

Simple Design Of Biological Sample Collection System

1. **A sample collection vessel**
2. **A cap**
3. **An annular valve positioned in the interior volume of the cap**, where the annular valve further comprises only three sub-components:
 - **A first cylinder** positioned externally to the sample collection vessel during operation
 - **A second cylinder**
 - **A vent**

Reply (Paper 38), 3; RMTA (Paper 26), 3-4

The Advantages Of The Claimed Invention

Simple Design Of Biological Sample Collection System

- ✓ *A minimal number of parts*
- ✓ *Limited or no risk of contamination*
- ✓ *Limited or no risk of exposure to toxic chemicals*

Reply (Paper 38), 3; Ex. 1001, 4:64-65, 5:6-8

Claim 21 Recites Features Not Disclosed In Plante Or Cho

21. A biological sample collection system, the system comprising:

a cap comprising

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

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

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

a moveable annular valve positioned in the interior volume of the cap~~second aperture,~~ the movable annular valve comprising

a vent,

wherein

the first cylinder and second cylinder are relatively moveable to thereby change the annular valve from the closed configuration to the open configuration, wherein the first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve, and

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

RM TA
(Paper 26),
27-29

Claim 21 Recites Features Not Disclosed In Plante Or Cho

Fig. 3A (closed)

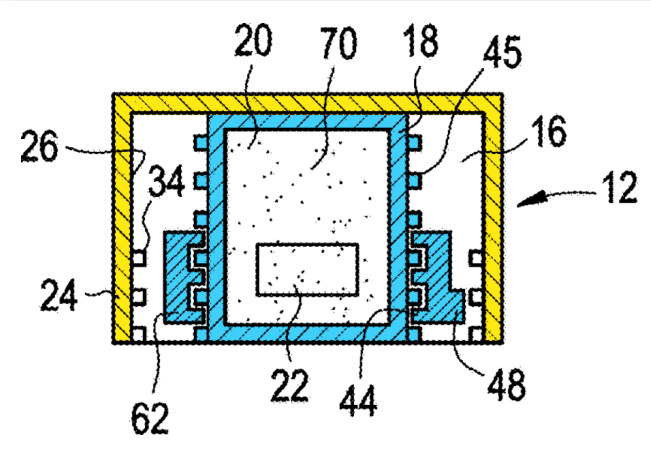
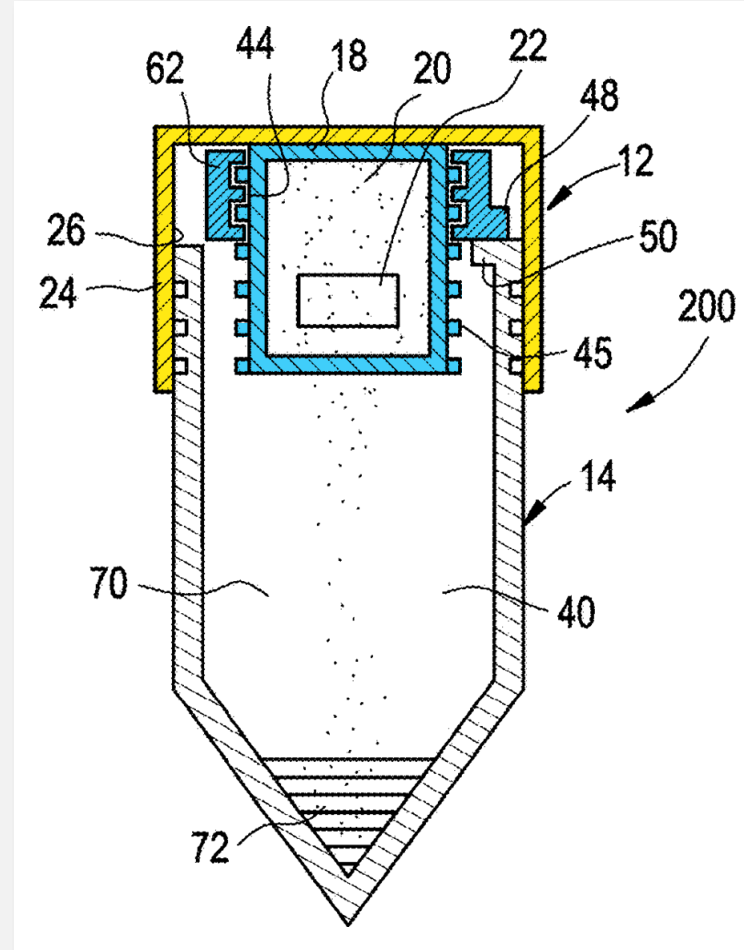


Fig. 3B (open)



Ex. 1001, Figs. 3A-B (annotated)

The “outer cylinder” (annular blocking member 62) **does not enter the sample collection tube 14** in any valve configuration

MTA (Paper 16), 8-9; Ex. 2014, ¶¶ 30-31
RMTA (Paper 26), 13-14; Ex. 2025, ¶¶ 39-45

Claim 21 Recites Features Not Disclosed In Plante Or Cho

Figure 3A
Biological sample collection
system 200

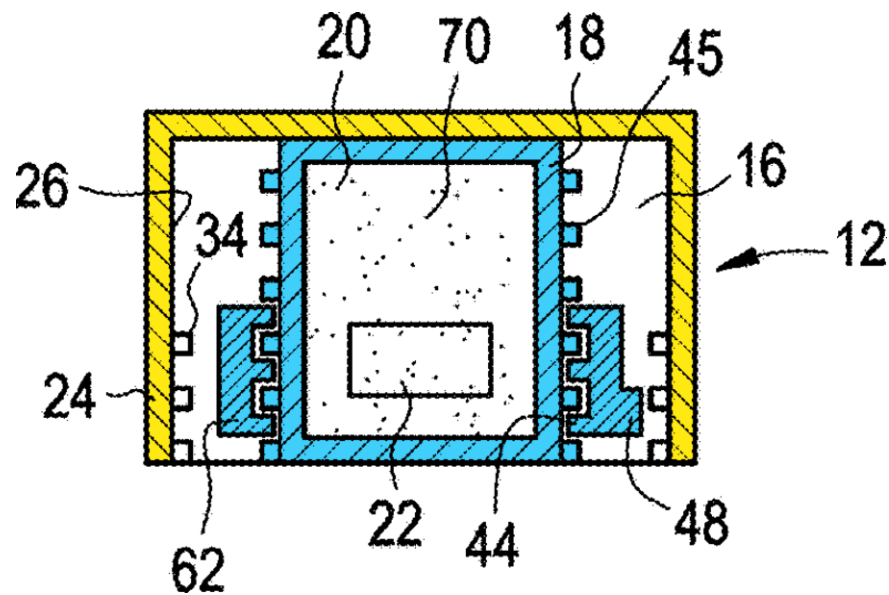
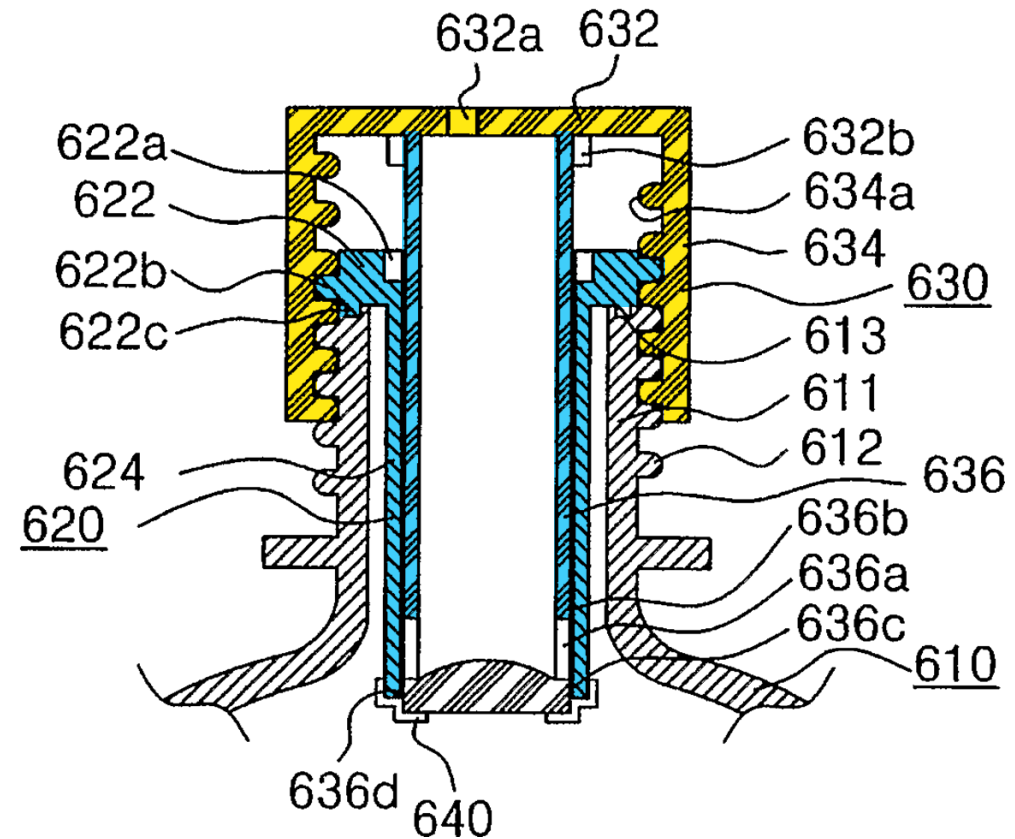


FIG. 44



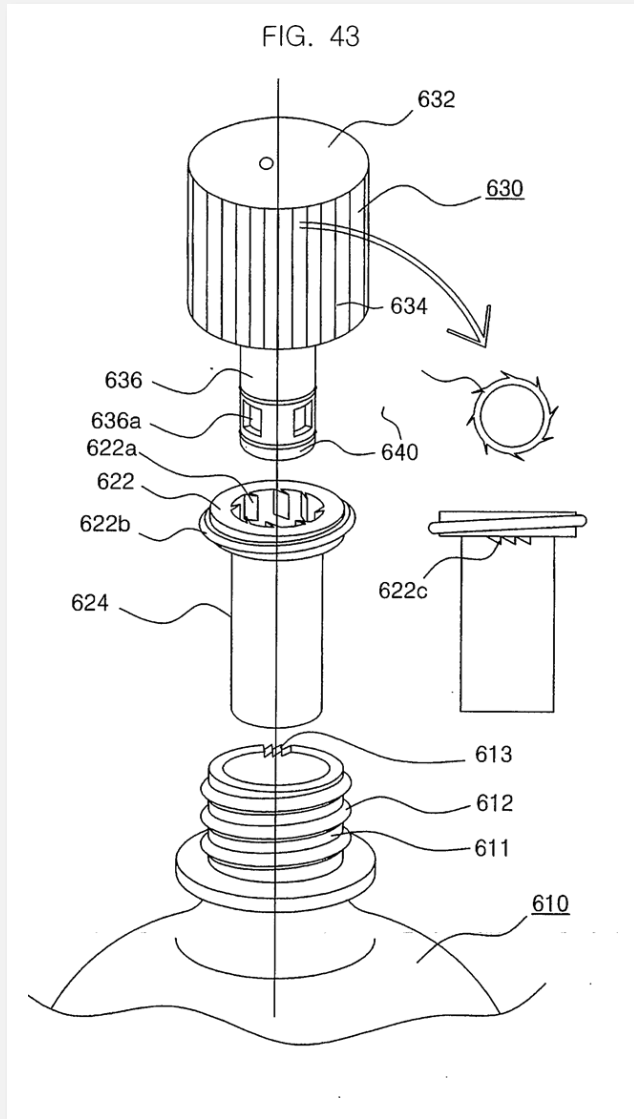
Reply (Paper 38), 4-6

Petitioner Is Factually Wrong

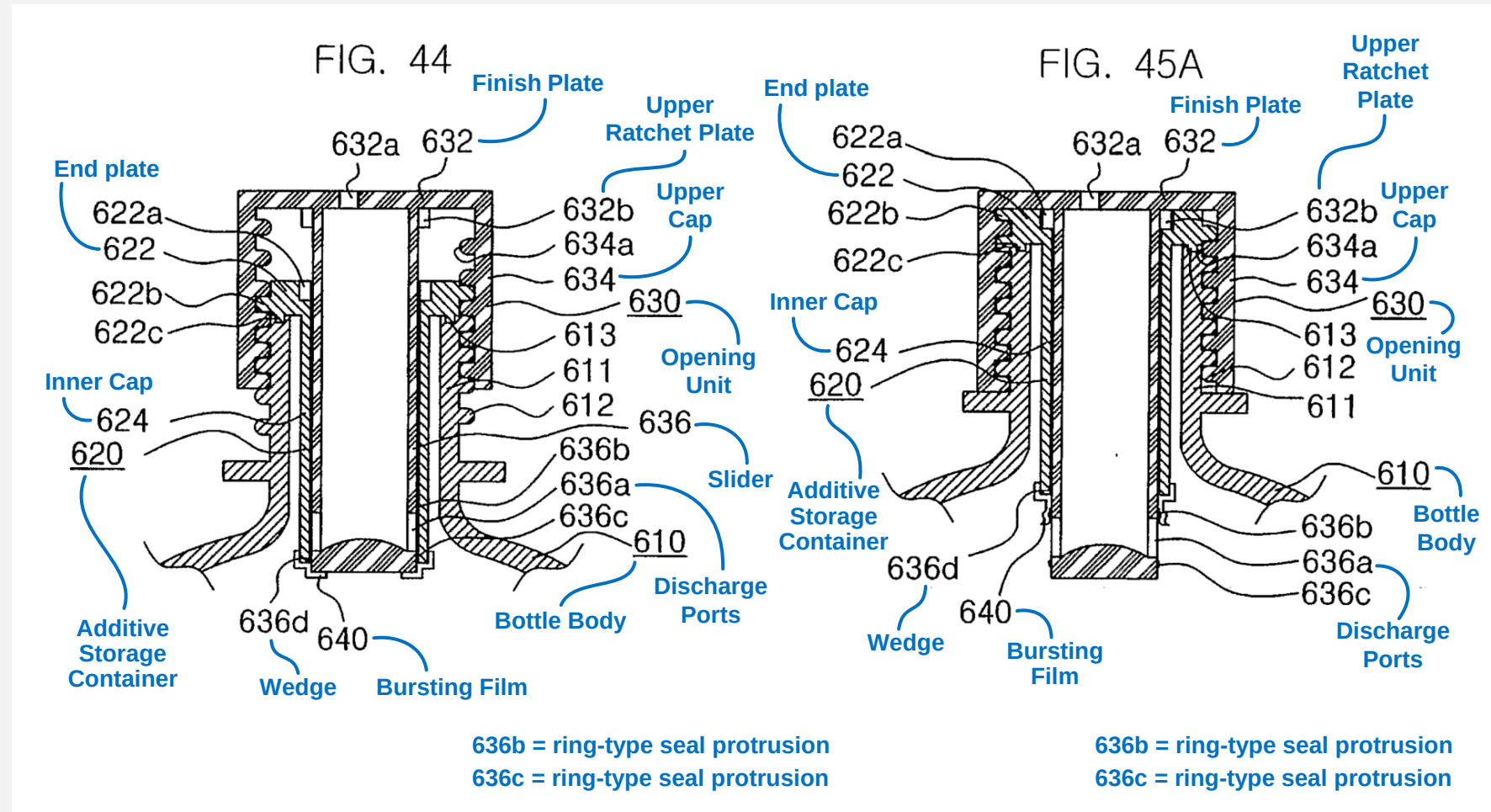
-  Cho's valve is ***essentially identical*** and ***functions identically*** to the claimed invention. Sur-Reply (Paper 40), p. 6; Opp., 8, 14
-  Cho's valve ***includes the same basic parts as the claimed valve and functions in the same way.***
Sur-Reply (Paper 40), p. 5; Ex. 1041, ¶¶ 7-10
-  The combination of Plante and Cho involves the ***simple substitution*** of one known element for another—Plante's cap for Cho's cap.
Sur-Reply (Paper 40), p. 11; Pet., 14-17; Ex. 1002, ¶¶ 62-75

Reply (Paper 38), 6, 11

Cho's Complex Valve Design

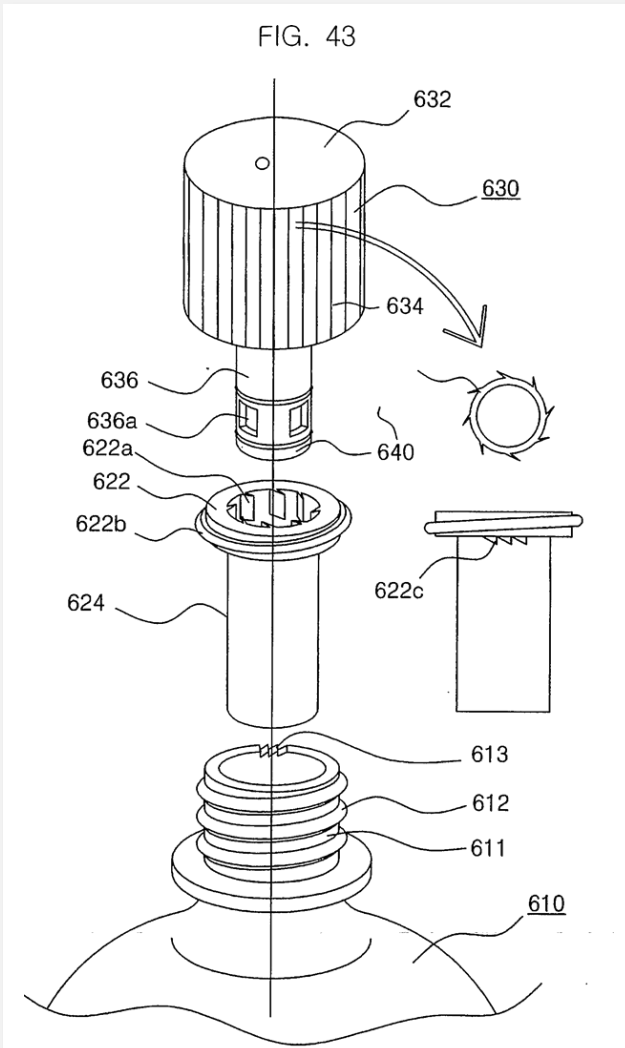


Ex. 1004, Fig. 43



Ex. 1004, Figs. 44, 45A (annotated);
Reply (Paper 38), 4; Ex. 2030, ¶ 25

Cho's Complex Valve Design



Ex. 1004,
Fig. 43

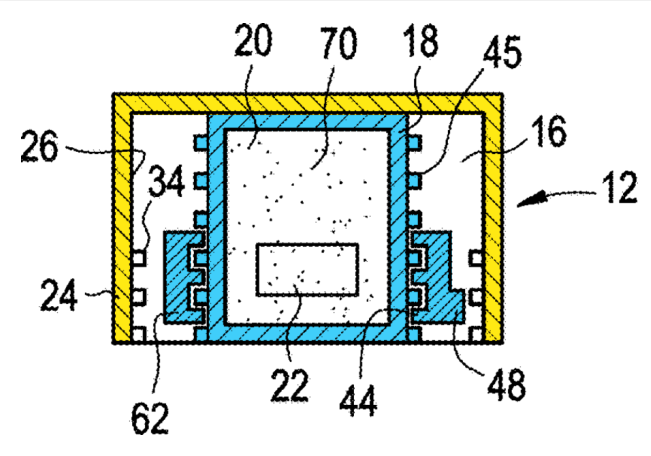
1. Upper cap 634 (including integrated slider 636; inner cylinder)
2. Open port 632a (not labeled)
3. Open port 632a sealing means (not shown; described at Cho, page 49, line 35 through page 50, line 2)
4. Upper ratchet plate 632b
5. Internal thread 634a (not shown)
6. Discharge ports 636a
7. Ring-type seal protrusion 636b (not labeled)
8. Ring-type seal protrusion 636c (not labeled)
9. Wedge 636d (not shown)
10. Inner cap 624 (outer cylinder) which forms part of additive storage container 620 (not labeled), together with:
 11. End plate 622
 12. Lower ratchet plate 622a
 13. External thread 622b
 14. Upper ratchet 622c
15. Bursting film 640
16. Bottle body 610
17. External threads at neck 612

RMTA (Paper 26), 19-22;
Ex. 2025, ¶ 77;
Ex. 1004, 48:27-31;
Ex. 2030, ¶ 25

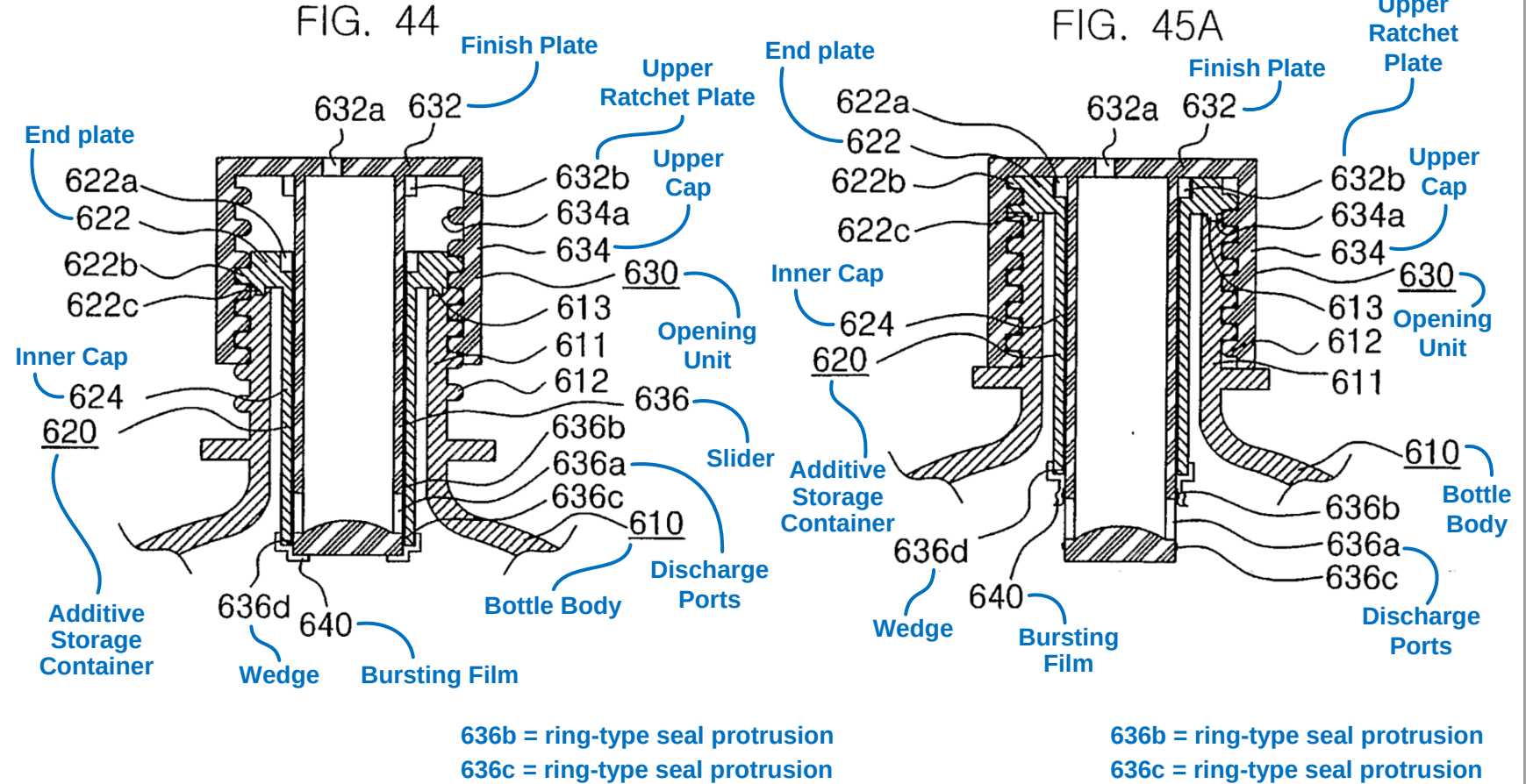
TOTAL = approximately 17 parts / features

Cho's Complex Valve Design Is Different Than Claimed Invention

Fig. 3A



Ex. 1001, Fig. 3A
(annotated)



Ex. 1004, Figs. 44, 45A (annotated);
Reply (Paper 38), 4; Ex. 2030, ¶ 25

'632 Patent: One-Step Operation

Fig. 3A

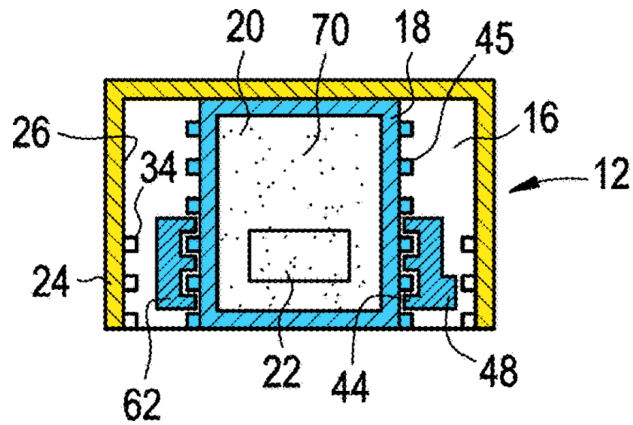
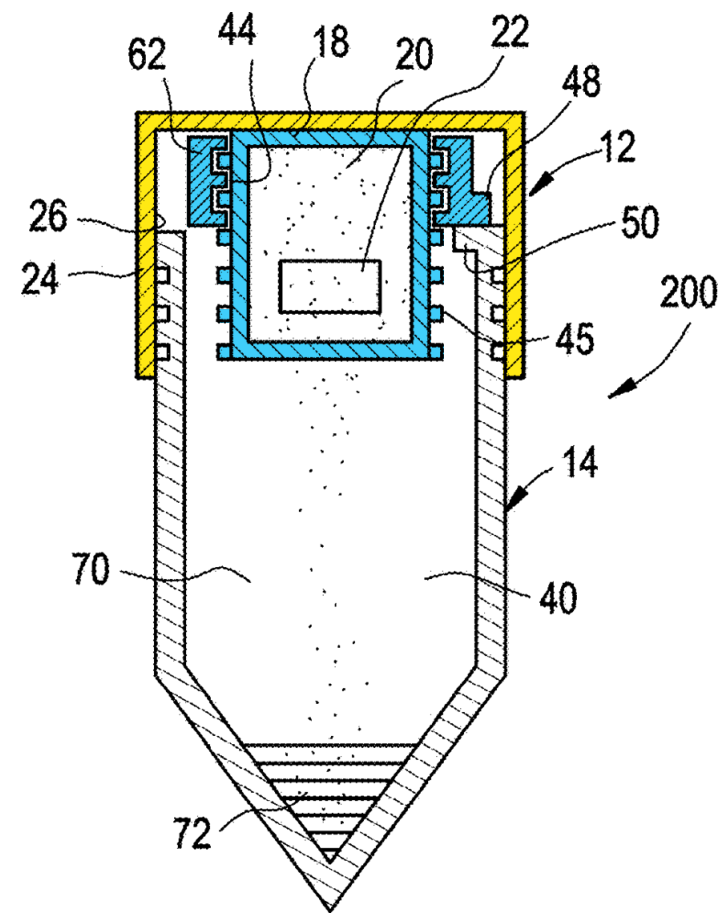


Fig. 3B

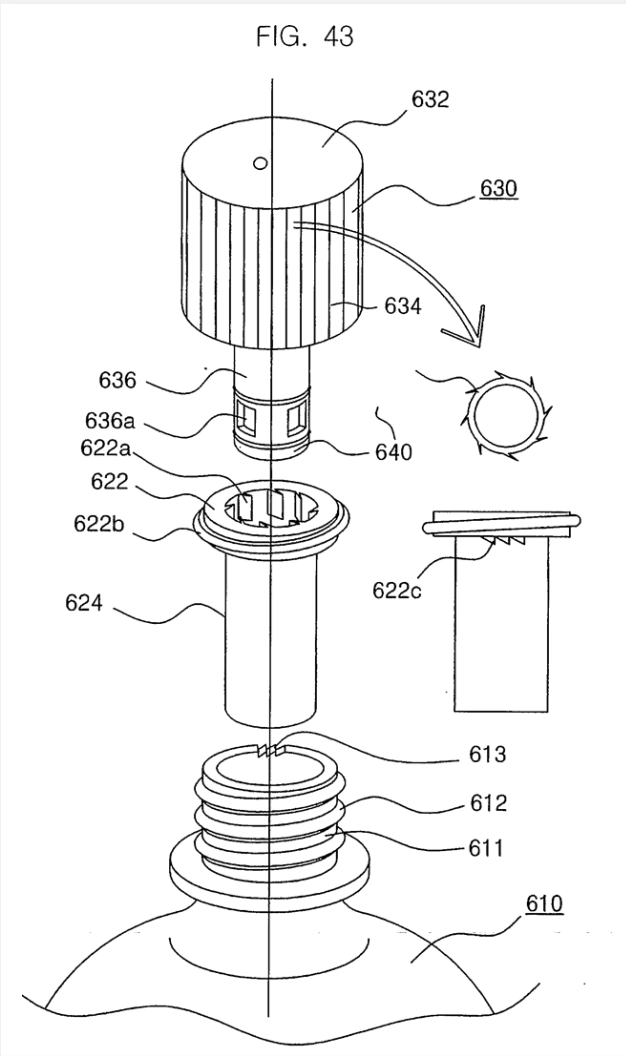


Ex. 1001, Figs. 3A-B (annotated)

“In contrast [to Cho’s cap], the cap of the ’632 patent is shipped *separately* from the empty biological sample collection vessel. When the cap is attached to the biological sample collection vessel, it brings a flange (coupling feature 48) on the outer cylinder (annular blocking member 62) into contact with the rim (coupling member 50) of the biological sample collection vessel, which causes the outer cylinder (annular blocking member 62) to recess further into cap 12 and moves the annular valve from the closed configuration to the open configuration *as the cap is tightened*. (Ex. 2030, ¶¶ 35-36.)”

Reply (Paper 38), 5; Ex. 2030, ¶¶ 35-36;
MTA (Paper 16), 8-9; Ex. 2014, ¶¶ 30-31;
RMTA (Paper 26), 13-14; Ex. 2025, ¶¶ 39-45

Cho's Different Mode Of Operation: Two Steps



Ex. 1004,
Fig. 43

- 1 “This structure reflects a two-step cap attachment process. The cap is attached to the bottle during assembly at the factory and filled to create a fluid tight seal, with the valve remaining in the closed configuration during distribution. (Ex. 1001, 22:41-44.) In this first attachment step, the outer cylinder is fully inserted in bottle 610, abuts the upper edge of the bottle mouth 611, and is engaged with internal threads 634a of upper cap 634. It is only upon further tightening of upper cap 634 by the user that the inner cylinder (slider 636) is further advanced into bottle 610 and the valve changes to the open configuration. (Ex. 2030, ¶¶ 32, 35-36, 40.)”
- 2

Reply (Paper 38), 5;
 RMTA (Paper 26), 19-22; Ex. 2025, ¶¶ 77;
 Ex. 2030, ¶¶ 32, 35-36, 40

TOTAL = approximately 17 parts / features

Dependent Claims 29, 33 And 36

Substitute Claim 29	Substitute Claim 33	Substitute Claim 36
The biological sample collection system of claim <u>21</u>, <u>wherein the first cylinder and second cylinder are relatively moveable entirely within the interior volume of the cap to thereby change the moveable annular valve from the closed configuration to the open configuration</u>~~further comprising a funnel attachable to the sample collection vessel.~~	The biological sample collection system of claim ~~1~~<u>32</u>, wherein the annular valve comprises a flange extending from at least one of the first and second cylinders, <u>and wherein initial contact between the flange and a portion of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration, said portion of the sample collection vessel being disposed proximal to the first aperture.</u>	The biological sample collection system of claim <u>21</u>, 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.

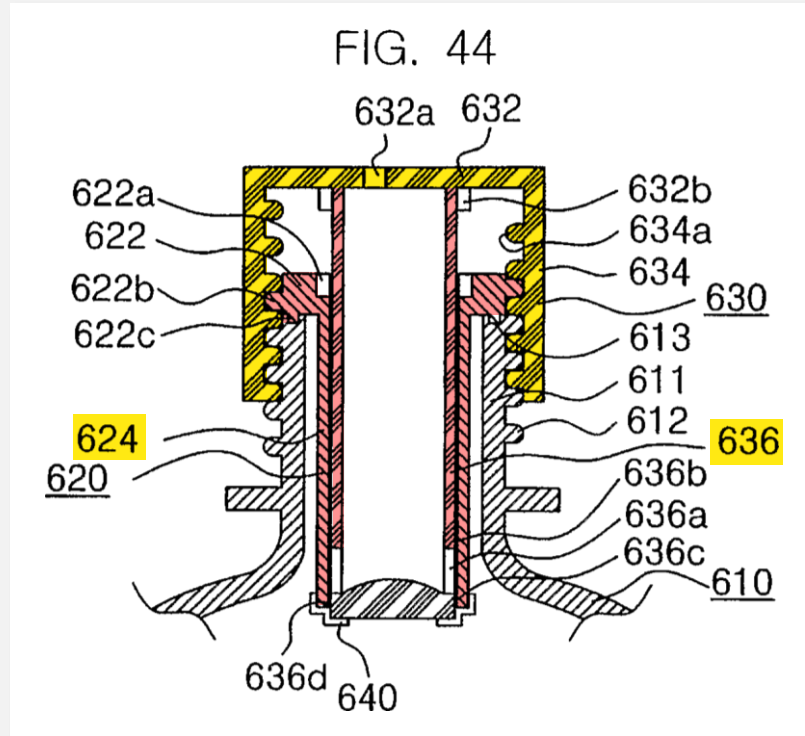
Plante-Cho Combination: No Motivation To Combine / Reasonable Expectation Of Success

-  Complete Structural Redesign of Cho's Annular Valve
-  Molding Complexity Beyond a POSITA's Skill Level
-  Incompatible With Clinical Diagnostics Product Requirements
-  Would Negate the Stated Advantages of Plante

RM TA (Paper 26), 19-24; Ex. 2025, ¶¶ 62-87; Reply (Paper 38), 4-11

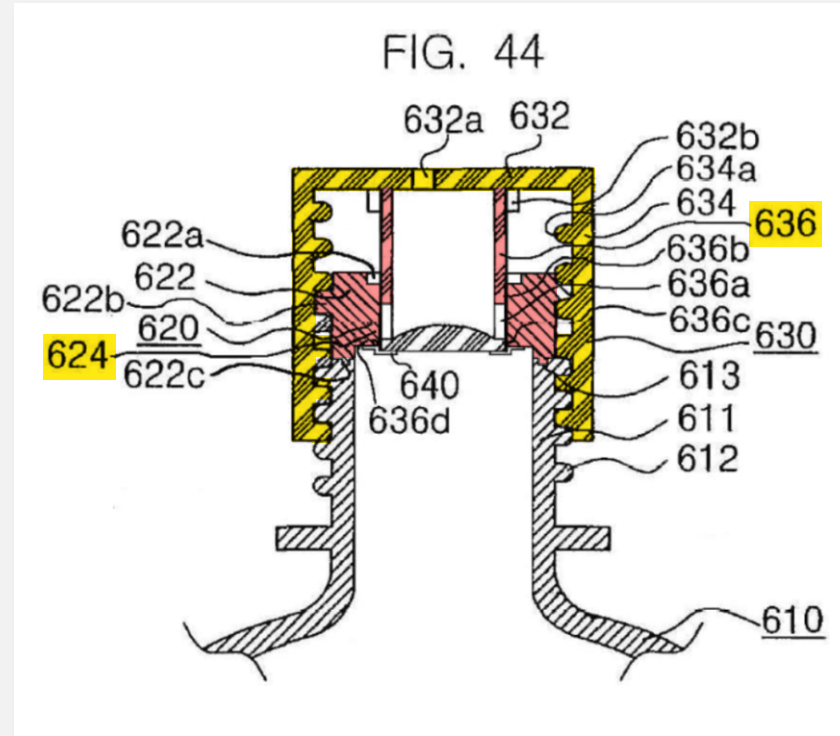
Structural Redesign Of Cho's Valve

Original Cho Figure



Ex. 1004, Fig. 44 (annotated)

Modified Cho Figure



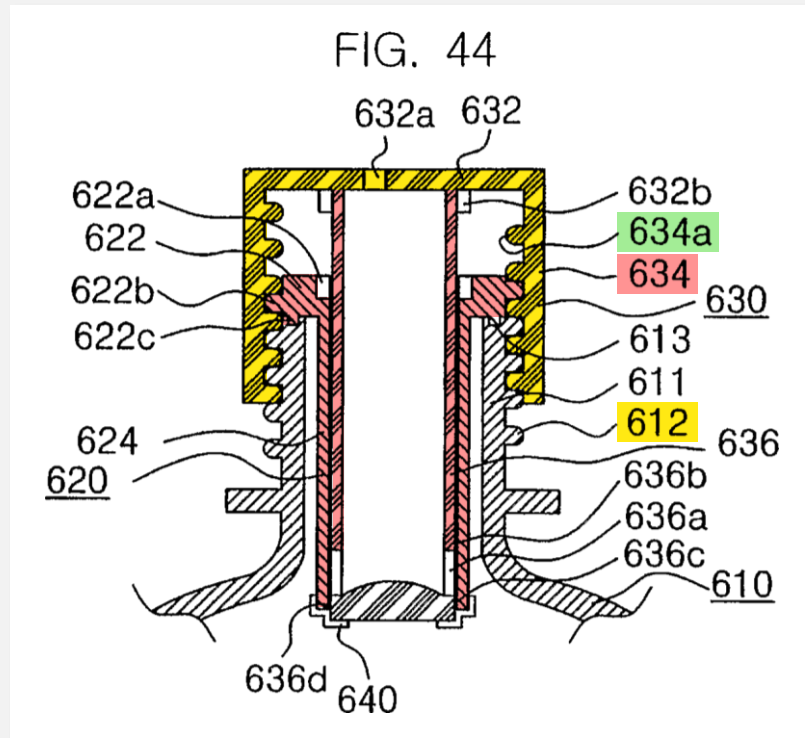
Petitioner has:

- ❌ Modified the length of slider 636
- ❌ **Eliminated** inner cap 624 (reference character 624 now points to the same part as reference character 622 – the end cap)

Reply (Paper 38), 6-7; Opposition to RMTA (Paper 32), 13

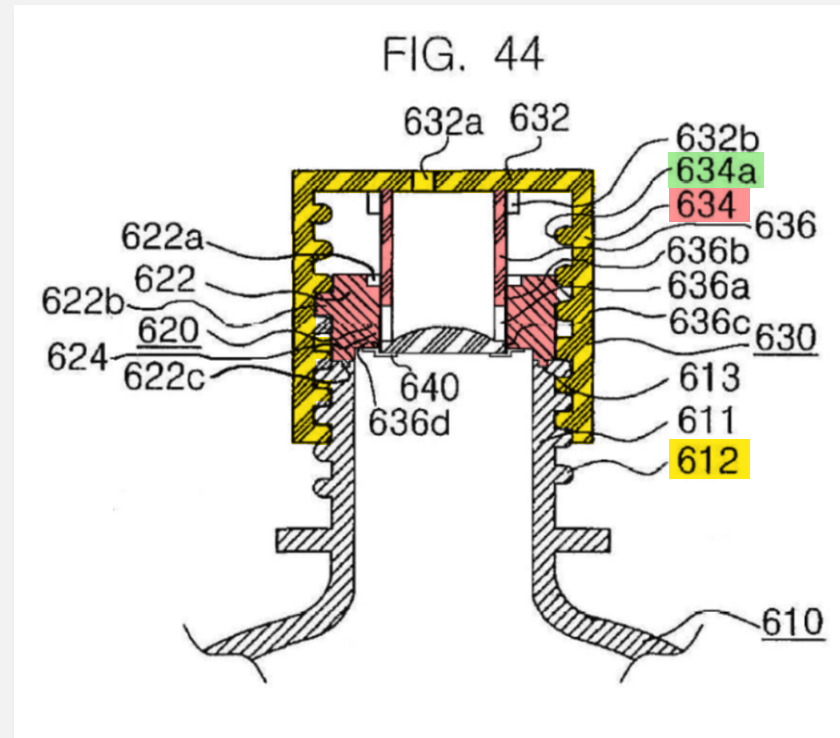
Structural Redesign Of Cho's Valve

Original Cho Figure



Ex. 1004, Fig. 44 (annotated)

Modified Cho Figure



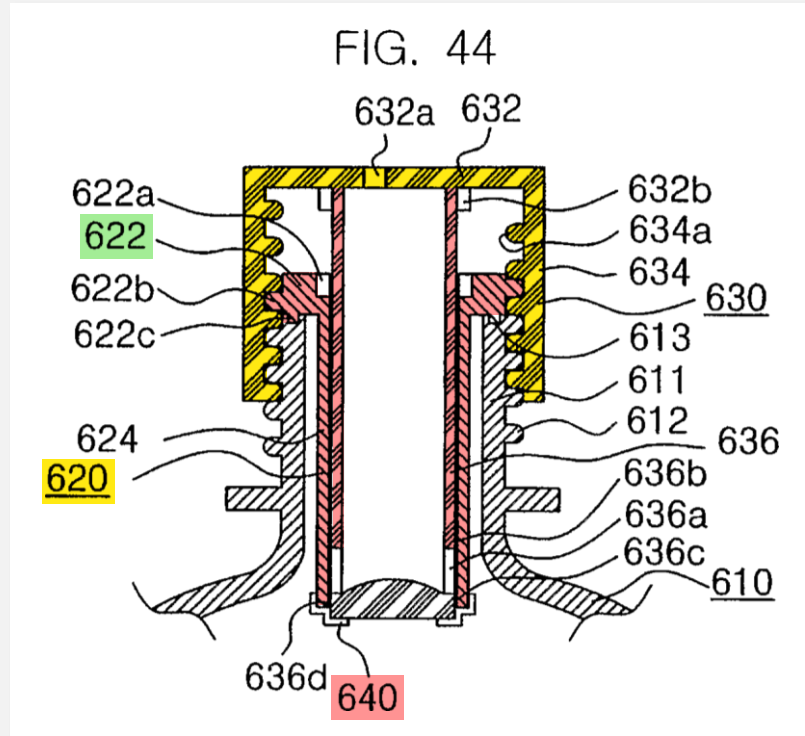
Petitioner has:

- ❌ Modified the vertical dimension of upper cap 634 by extending the outer walls
- ❌ Increased the number of internal threads 634a available to engage with the external threads 612 of the bottle

Reply (Paper 38), 6-7; Opposition to RMTA (Paper 32), 13

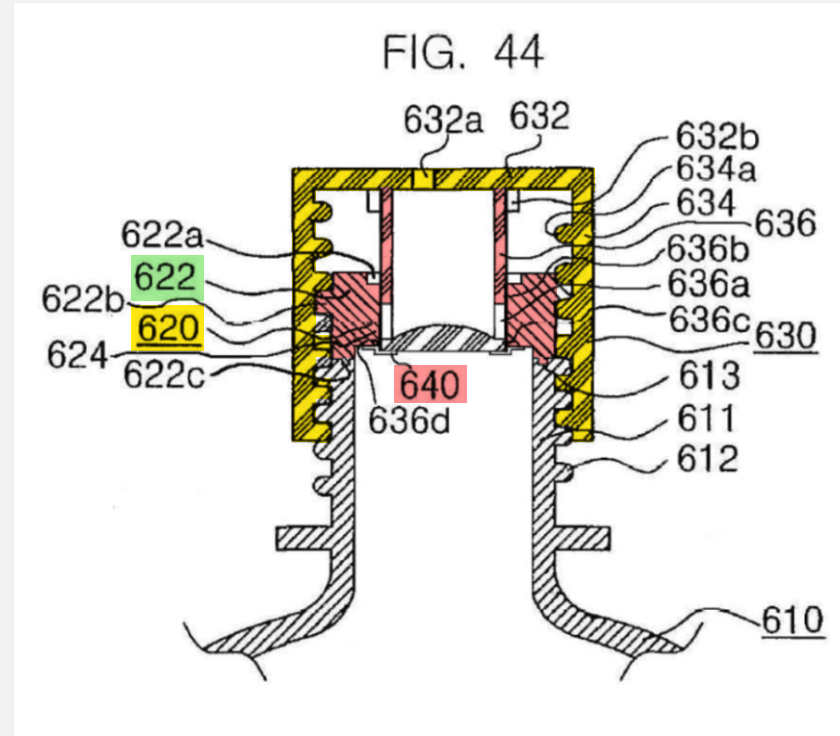
Structural Redesign Of Cho's Valve

Original Cho Figure



Ex. 1004, Fig. 44 (annotated)

Modified Cho Figure

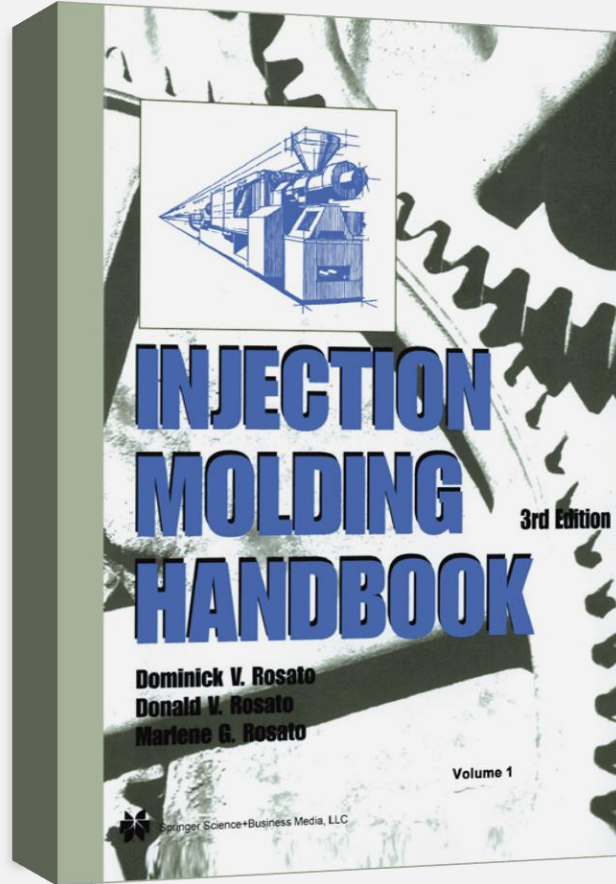


Petitioner has:

- ❌ Significantly enlarged circular end plate 622 of the additive storage container 620
- ❌ Modified bursting film 640

Reply (Paper 38), 6-7; Opposition to RMTA (Paper 32), 13

Injection Molding Handbook

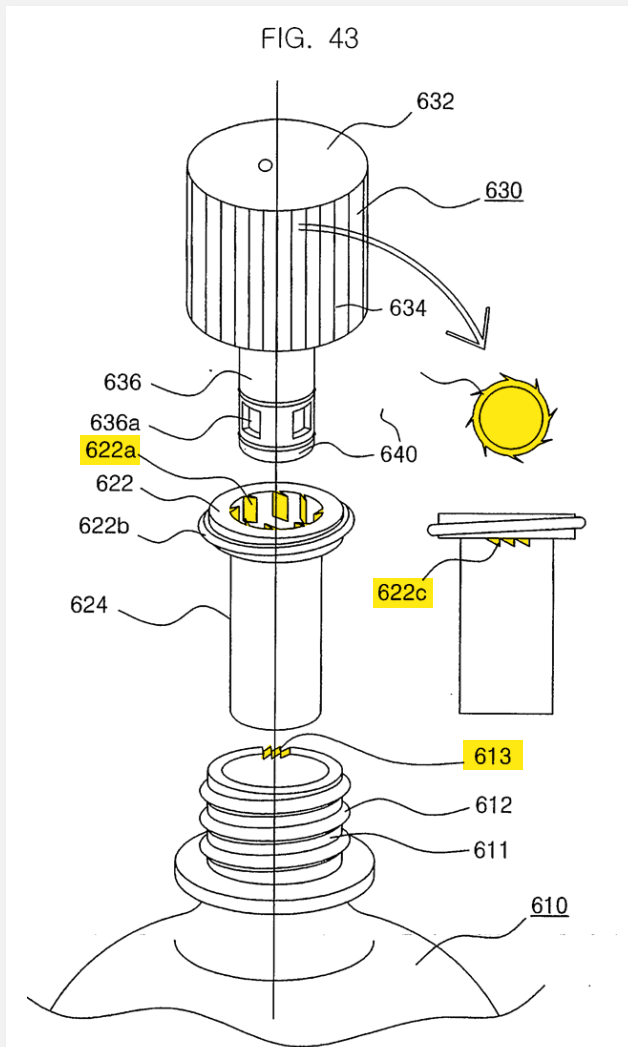


Ex. 2029

73. In discussing design concepts, the Handbook discusses a number of different features that can be problematic to injection mold, including parts comprising thin or thick sections, parts requiring multiple gates and weld lines, parts too thin, parts too thick, living hinges, thread inserts, etc.⁵⁷

Reply (Paper 38), 8; Ex. 2025, ¶¶ 66-85

Cho's Ratchet-Heavy Design



Ex. 1004,
Fig. 43
(annotated)

1. Upper cap 634 (including integrated slider 636; inner cylinder)
2. Open port 632a (not labeled)
3. Open port 632a sealing means (not shown; described at Cho, page 49, line 35 through page 50, line 2)
4. Upper ratchet plate 632b
5. Internal thread 634a (not shown)
6. Discharge ports 636a
7. Ring-type seal protrusion 636b (not labeled)
8. Ring-type seal protrusion 636c (not labeled)
9. Wedge 636d (not shown)
10. Inner cap 624 (outer cylinder) which forms part of additive storage container 620 (not labeled), together with:
 11. End plate 622
 12. Lower ratchet plate 622a
 13. External thread 622b
 14. Upper ratchet 622c
15. Bursting film 640
16. Bottle body 610
17. External threads at neck 612

RMTA (Paper 26), 19-22;
Ex. 2025, ¶ 77;
Ex. 1004, 48:27-31;
Ex. 2030, ¶ 25

TOTAL = approximately 17 parts / features

Dr. Wereley: Molding Complexity

46. Some of the features depicted in FIGS. 43, 44, and 45A of Cho present difficulties for injection molding, for example, those that include sharp edges (e.g., upper ratchet plate 632b, lower ratchet plate 622a, upper ratchet 622c, and lower ratchet 613). Small, sharp features such as the ratchet features in Cho's device are difficult to fill as they often trap gases that prevent the polymer from completely filling the features. . . .

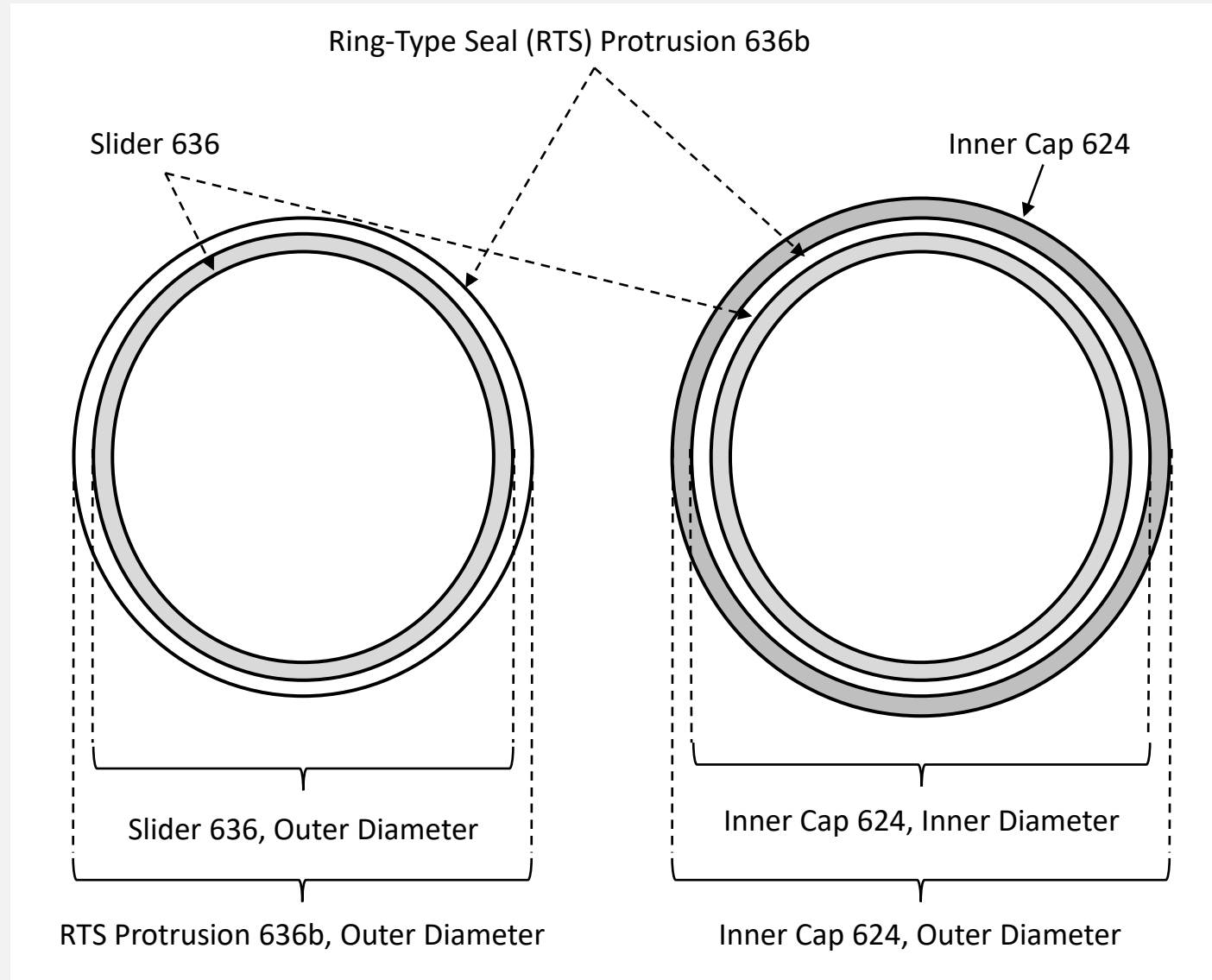
Reply (Paper 38), 8; Ex. 2030, ¶ 46

Dr. Wereley: Molding Complexity

46. . . . Furthermore, some of these features also require precise molding to tight tolerances, e.g., the inner diameter of inner cap 624 and the outer diameter of slider 636 – or of ring-type seal protrusions 636b and 636c – to form a tight seal, and internal thread 634a which engages with both external thread 622b of the additive storage container 620 and with external thread 612 on the mouth 611 of bottle 610 (Ex. 1004, page 49, lines 8 - 10). In general, smaller parts require holding the molding process to tighter tolerances.

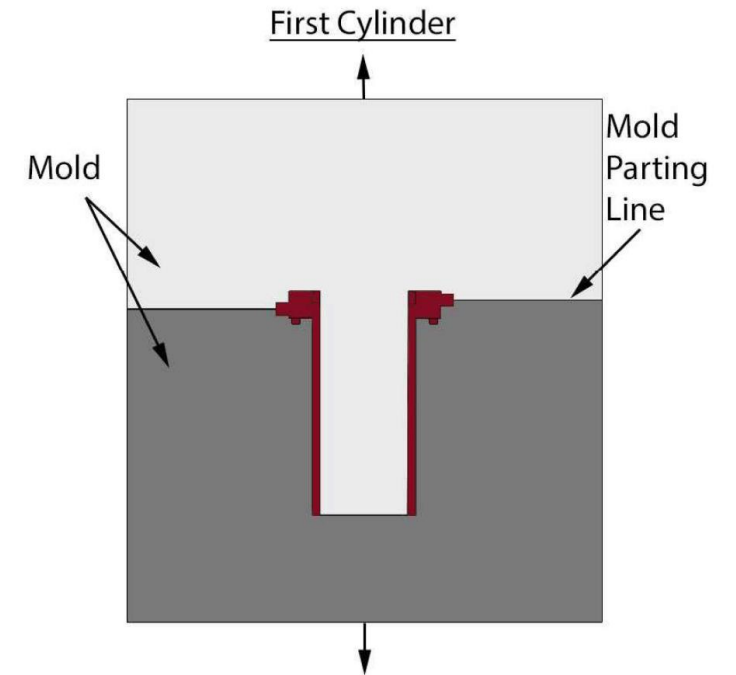
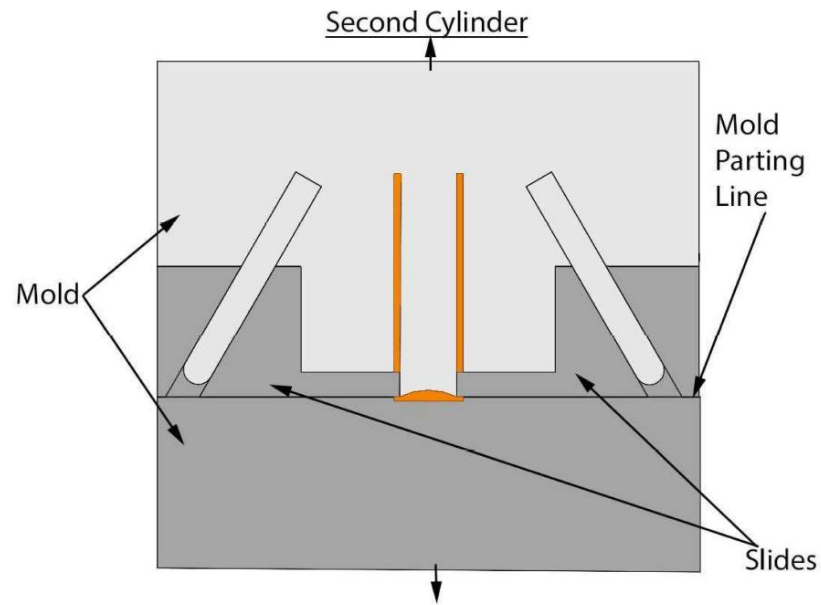
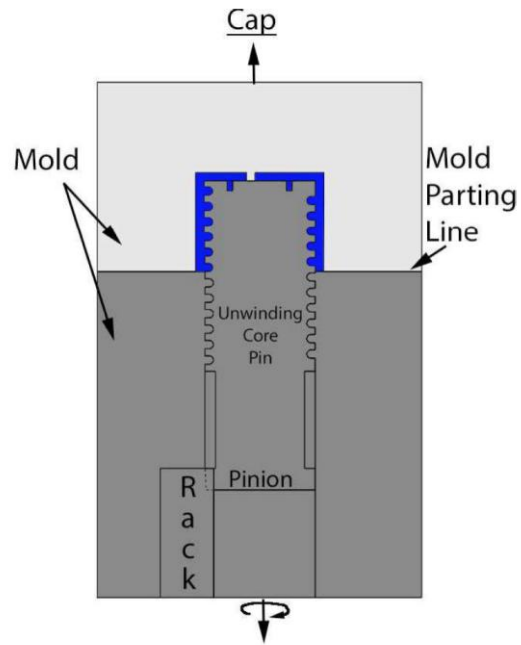
Reply (Paper 38), 8; Ex. 2030, ¶ 46

Dr. Wereley: Tight Tolerances



Reply (Paper 38), 8;
Ex. 2030, ¶ 46

Mr. Leinsing's Mold Designs



Ex. 1041, ¶¶ 18-21

Reply (Paper 38), 8

48. ...In my opinion, the mold designs shown in the figures provided by Mr. Leinsing are oversimplified and appear to leave out some of the features required by Cho, e.g., the lower ratchet 613 formed on the upper rim of bottle 610.

49. For example, in the mold design provided by Mr. Leinsing for fabricating the cap (Ex. 1041, ¶ 18) the protrusions extending downward from the underside of the top of the cap presumably indicate the feature described by Cho as upper ratchet plate 632b. If so, the use of an unwinding core pin, as depicted in the figure, wouldn't work as the molded ratchet features would prevent one from unwinding the core pin. This mold design appears to comprise 4 to 5 separate mold components.

50. As another example, in the mold design provided by Mr. Leinsing for fabricating the second cylinder (Ex. 1041, ¶ 19), the second cylinder (i.e., Cho's slider 636) is fabricated independently of the cap (as suggested in my previous declaration (Ex. 2025, ¶ 82)), while Cho's FIGS. 44 and 45A depict this part as being an integral component of upper cap 634.

50. ...I also note that this design requires the molding of a long, thin part that can be problematic to mold according to the injection molding references (see, e.g., Ex. 1014, p. 728) cited previously by Mr. Leinsing. Furthermore, the illustrated mold design would require the molded cylinder to be withdrawn from the mold by the end that is perforated by the vents (Cho's discharge ports 636a) that are created using the sliders. This would be difficult to do without also incurring increased breakage during fabrication / production of the part.

Finally, the molds for the second cylinder presented by

50. ...Finally, the molds for the second cylinder presented by Mr. Leinsing in his declaration (Ex. 1041, ¶ 19) don't take into account the presence of ring-type seal protrusion 636b. The light gray portion of the proposed mold design is meant to be pulled upwards, but ring-type seal protrusion 636b would prevent that. It would be impossible to extract the part from the mold due to the presence of ring-type seal protrusion 636b. Cho also indicates a ring seal 636c and wedge 636d that must be included in the bottom portion of the mold. These would complicate the extraction of the part from the bottom mold portion, potentially rendering it impossible to remove.

Molding Complexity: Non-Obviousness

Modification and incorporation of Cho's complex, multi-component valve design would have led to a long development time and increased fabrication and assembly costs for the biological sample collection device. (Ex. 2030, ¶¶ 34, 59)

“Mr. Leinsing did not consider the amount of time or resources it would have taken to modify [prior art] Gallo Modifying the device disclosed in Gallo to arrive at the '759 patent device would have required an extensive re-design of the Gallo device”

See Ethicon Endo-Surgery, Inc. v. Covidien LP,
No. 16-12556-LTS, 2020 U.S. Dist. LEXIS 72133, at *12 (D. Mass. Apr. 24, 2020)

Reply (Paper 38), 8, 10; Ex. 2030, ¶¶ 34, 59, 60

Molding Complexity: Non-Obviousness

“... a POSITA would have no motivation to substitute Cho’s complex, redesigned valve for Plante’s simple approach, especially in the field of clinical diagnostics where sensitivity to the cost of goods sold is often a driver in product decision making. *Hulu v. Sound View Innovations*, IPR2018-00582, Paper 34 at 19 (P.T.A.B. Aug. 5, 2019) (finding “costly” databases supported non-obviousness).

Reply (Paper 38), 10

Dr. Wereley's Testimony In 646 IPR

Q. Okay. I'm going to reask my question. Do you agree that one of skill in the art would have understood that the axial length of the cylindrical additive storage space could be adjusted in Cho?

A. The axial length -- so a POSA in 2012 would realize that the axial length of the additive compartment could be **changed to some extent, not any extent**, could be changed to some extent, period.

Q. And that would affect the volume of the additive storage space; correct?

A. Changing the length of the cylinder that comprises the axial or the additive compartment would necessarily change its volume.

Ex. 1034, 69:13-70:9 (objections omitted)

RM TA (Paper 26), 20

Ordinary Level Of Skill In The Art

23. It is my opinion that a POSITA for the '632 patent would have a Bachelor's degree in a scientific field relevant to the mechanical aspects of containers and valves in disposable medical devices and some experience in disposable medical devices. More education may compensate for less experience, and vice-versa. At the time of the '632 patent, I consider myself to have been at least at the level of ordinary skill in the art for the mechanical aspects of the '632 patent.

Ex. 2014, ¶ 23

Reply (Paper 38), 9-10

Ordinary Level Of Skill In The Art

Furthermore, although Mr. Leinsing states that “Molding the parts of the Cho annular valve would be a simple process well within the level of skill of a POSITA” (Ex. 1041, ¶ 17), I believe that the level of skill required to redesign Cho’s device, and to design the associated molds required to fabricate it, would exceed that of a POSITA as defined by Mr. Leinsing (see Ex. 1002, ¶ 52) due, for example, to the difficulties of molding smaller parts and the tighter tolerances required. To the degree that it’s possible to mold such parts, it would be a difficult undertaking well beyond the capabilities of a POSITA at the time. This conclusion is even stronger under my own definition of the applicable level of skill of a POSITA. Mold design engineers, unlike the POSITA here, are highly trained, highly specialized engineers with extensive experience in both mold design and troubleshooting injection molding processes.

Ex. 2030, ¶ 61

Reply (Paper 38), 9-10

Ordinary Level Of Skill In The Art

Ethicon, 2020 U.S. Dist. LEXIS 72133, at *52 n.20 (Mr. Leinsing testified that a “person of ordinary skill in the art would have been motivated to replace Gallo’s straight lever handle But such testimony is not evidence of a motivation to modify—it is only evidence that Mr. Leinsing was able, with the full benefit of hindsight, to articulate how Gallo might have been improved by redesigning it to be more like the device claimed in the ’759 patent.”).

Reply (Paper 38), 9-10

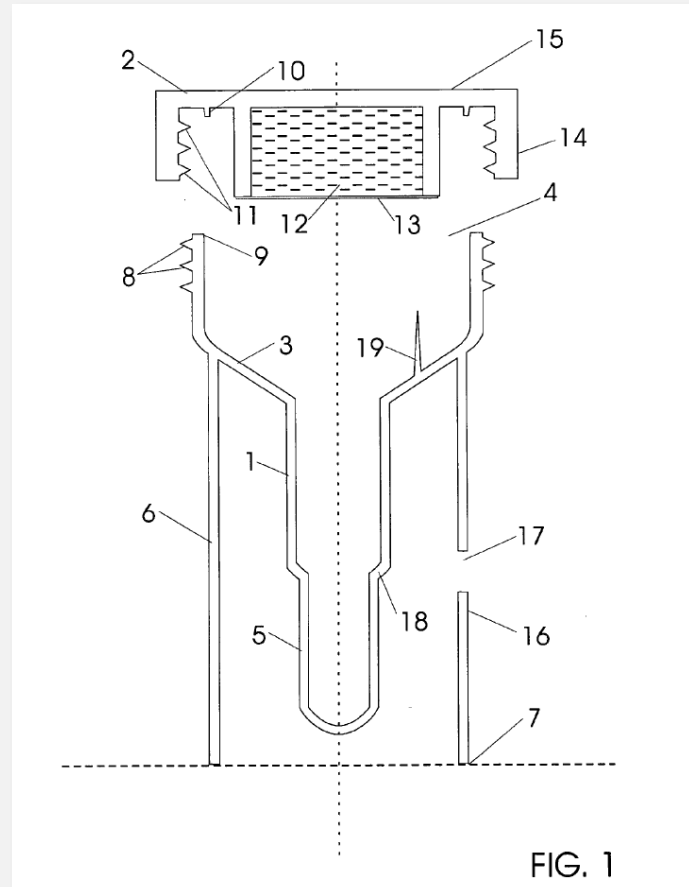
Modification Of Plante

38. . . . In order to arrive at the claimed device, one would also need to modify Plante's device, e.g., by removing knife 19, eliminating the step down in the inner diameter(s) of receiving vessel 1 and cylindrical tubular portion 5, and modifying seating surface 9 to include a ratchet feature if the corresponding feature is not removed in the modified Cho device (see Ex. 1003, FIG. 1, and the description thereof).

Ex. 2030, ¶ 38

Reply (Paper 38), 8

Plante-Cho Combination Negates Advantages Of Plante



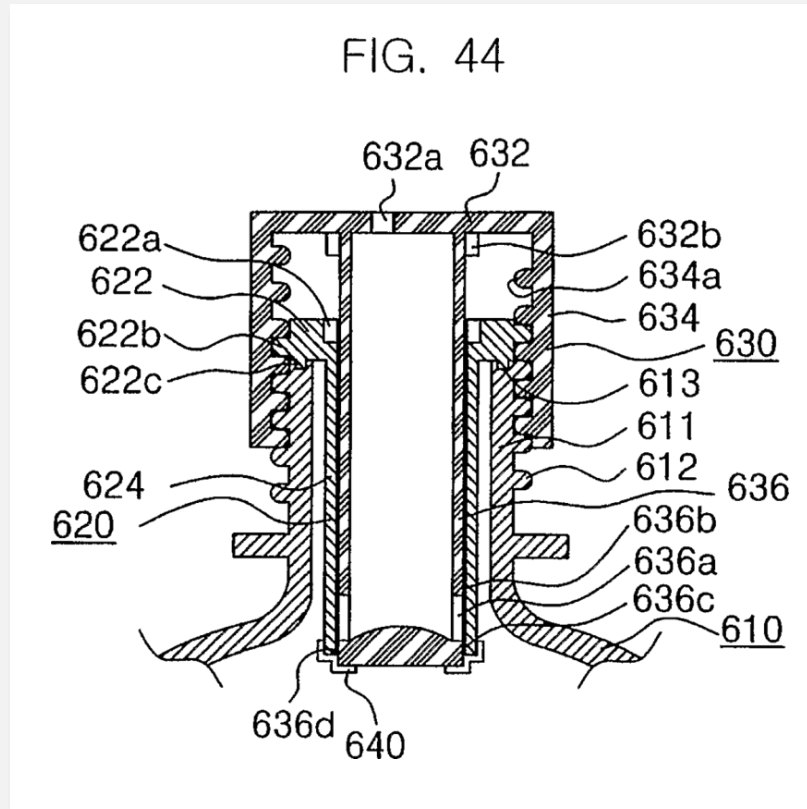
Ex. 1003, Fig. 1

Plante: allows a user to “capture a sample with a **minimal amount of steps** and a **minimal number of parts**.” (Ex. 1003, ¶ 6.)

Reply (Paper 38), 10

Plante-Cho Combination Negates Advantages Of Plante

“... an object of the present invention is to **provide a bottle which stores two kinds of materials separately in a bottle when the bottle is distributed** on the market, thus saving resources, unlike conventional bottles, in which two bottles are required to store two materials therein.” (Ex. 1004, 1:19–24.)



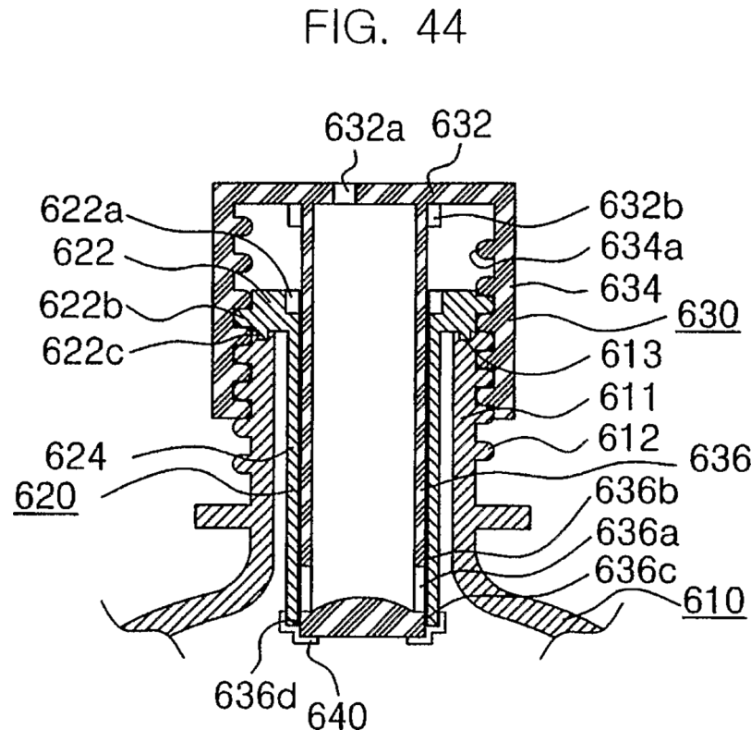
Ex. 1004, Fig. 44

Cho: designed to be attached to a beverage bottle to a **specific predetermined position prior to distribution of the product**

Reply (Paper 38), 10;
RMTA (Paper 26), 16

Plante-Cho Combination Negates Advantages Of Plante

The ratchet features included in Cho's design allow rotation of opening unit 630 (corresponding roughly to Plante's sealing cap 21) and its components in only one direction relative to the mouth 611 of the bottle (Ex. 1004, 49:1-4, 28-33).



Ex. 1004, Fig. 44

Cho: designed to be attached to a beverage bottle to a specific predetermined position prior to distribution of the product

Reply (Paper 38), 10-11;
RMTA (Paper 26), 16

Plante-Cho Combination Negates Advantages Of Plante

Such a combination:

-  Would require the user to *remove the cap from the sample collection vessel prior to depositing a biological sample*
-  Would yield a device *difficult to open* by the user
-  If forced, may *prevent a fluid tight seal* when the cap is replaced after depositing a biological sample

Reply (Paper 38), 10-11;
RMTA (Paper 26), 16

Plante: No Risk Of Injury

57. As noted in my first declaration,⁴¹ I disagree with Mr. Leinsing's assertion that a POSITA would have been motivated to replace Plante's knife because a POSITA would have perceived Plante's knife as creating a risk of injury.⁴² A POSITA would not have recognized that Plante's knife presented a significant risk of injury in the first place, and would have known that the cylindrical wall of Plante's sample collection tube (that defines the entrance aperture 4 of the tube) provides an engineering control to mitigate any risk of injury (*e.g.*, by varying the diameter of the entrance aperture and or the placement of the knife 19 within the sample collection tube). Furthermore, the existence of numerous, long-term commercial devices that are similar to that described in Plante, and that include a puncturable membrane and knife-based design for reagent release, without any indication of injury over the years undermines the argument that a POSITA would have perceived Plante's knife as creating a risk of injury.

Ex. 2025, ¶ 57

RMTA (Paper 26), 17-18

Dependent Claims 29, 33 And 36

Substitute Claim 29	Substitute Claim 33	Substitute Claim 36
The biological sample collection system of claim <u>21</u>, <u>wherein the first cylinder and second cylinder are relatively moveable entirely within the interior volume of the cap to thereby change the moveable annular valve from the closed configuration to the open configuration</u>~~further comprising a funnel attachable to the sample collection vessel.~~	The biological sample collection system of claim ~~1~~<u>32</u>, wherein the annular valve comprises a flange extending from at least one of the first and second cylinders, <u>and wherein initial contact between the flange and a portion of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration, said portion of the sample collection vessel being disposed proximal to the first aperture.</u>	The biological sample collection system of claim <u>21</u>, wherein the sample collection system comprises a separable two-piece sample collection system, the sample collection vessel comprising a first piece of the separable two-piece sample collection system, and the cap with movable annular valve comprising a second piece of the separable two-piece sample collection system.

Claim 33 Is Supported

Claim 33

33. (substitute for claim 13) The biological sample collection system of claim 13, wherein the annular valve comprises a flange extending from at least one of the first and second cylinders, and wherein initial contact between the flange and a portion of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration, said portion of the sample collection vessel being disposed proximal to the first aperture.

Claim 33 Is Supported



Petitioner's Elided Reading:

“initial contact...causes”



Actual Language of Claim 33:

“wherein initial contact between the flange and a portion of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration”

Reply (Paper 38), 11-12

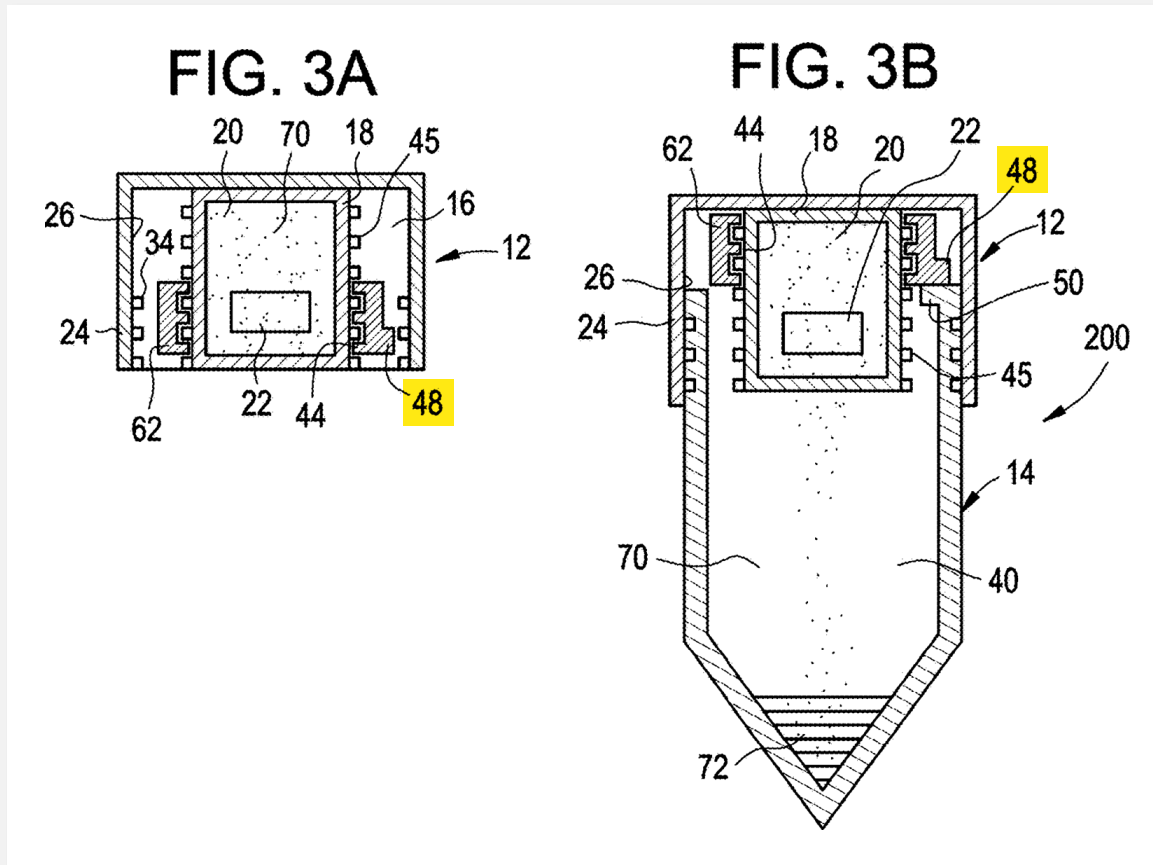
Claim 33 Is Supported

[0076] In the embodiment shown by way of example in FIGS 3A-3C, the annular blocking member 62 may be configured to interact with one or more features, such as a coupling member 50, of the tube 14 such that as the cap 12 is being securely coupled to the tube 14, the one or more features of either the tube 14 or annular blocking member 62 can cause the annular blocking member 62 to move from a position where the annular blocking member 62 is covering the aperture 22 to a position where the annular blocking member 62 is not covering the aperture 22, thus allowing the sample preserving fluid or material 72 to release from the interior space 20 and interact with the sample 72.

Ex. 2015, [0076]

Reply (Paper 38), 11-12; RMTA (Paper 26), 5

Support In FIGS. 3A-3B



Ex. 1001, Fig. 3A, 3B

“... FIGS. 3A-B of the '632 Patent illustrate an embodiment of the claimed device that shows a flange (coupling feature 48) attached to the first (outer) cylinder of the annular valve that contacts a portion of the sample collection vessel (the upper rim of the sample collection vessel) upon engagement of the cap with the sample collection vessel.”

Ex. 2030 (Wereley Declaration), ¶ 19

Reply (Paper 38), 11-12; RMTA (Paper 26), 5, 10-11

Claim 33 Is Supported

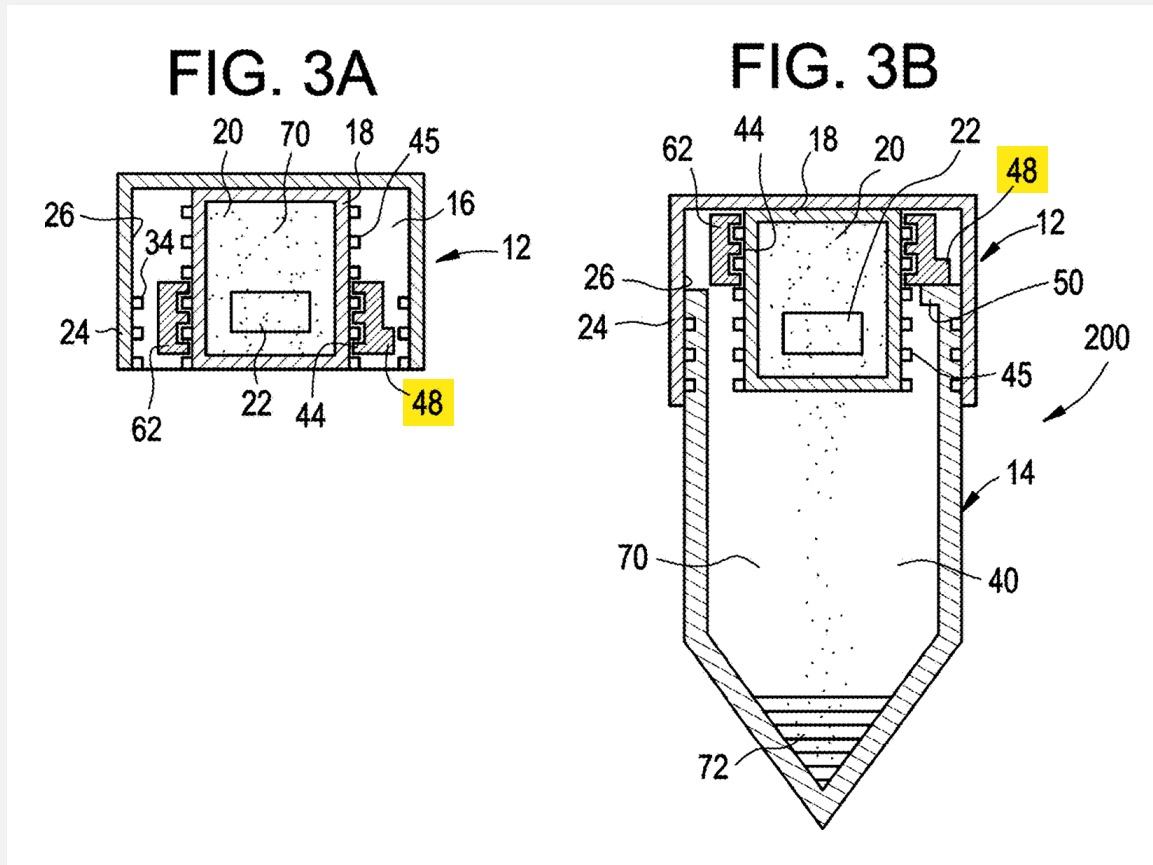


“ . . . there is no categorical rule that a species cannot suffice to claim the genus . . . Here, the supposed genus consists of only two species, a multiplexed and a non-multiplexed bus, and Hynix has failed to make any argument that persons of ordinary skill would not have understood that Rambus possessed a non-multiplexed bus.”

Hynix Semiconductor Inc. v. Rambus Inc., 645 F.3d 1336, 1352 (Fed. Cir. 2011)

Reply (Paper 38), 11-12; RMTA (Paper 26), 5, 10-11

Support In FIGS. 3A-3B



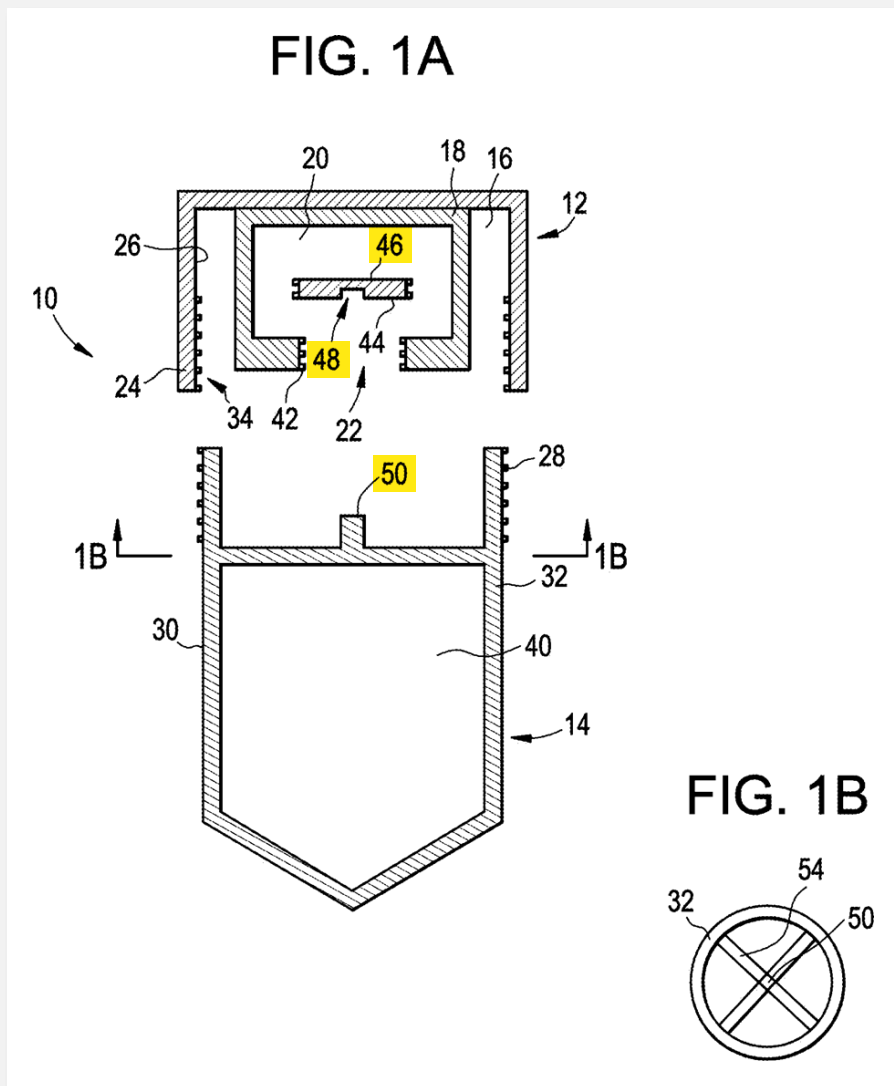
Ex. 1001, Fig. 3A, 3B

“In my opinion, this one instance would provide support for the other option, i.e., having the flange attached to the second (inner) cylinder, because that is the only other option.”

Ex. 2030 (Wereley Declaration), ¶ 19

Reply (Paper 38), 11-12; RMTA (Paper 26), 5, 10-11

Claim 33 Is Supported



Ex. 1001, Fig. 1A, 1B

“ . . . FIGS. 1A-B . . . illustrate a different embodiment in which coupling feature 48 is part of a cylindrical blocking member 46 and is, again, configured to contact a coupling member 50 that is part of the sample collection vessel.”

Ex. 2030 (Wereley Declaration), ¶ 20

Reply (Paper 38), 12; RMTA (Paper 26), 5, 10-11

APPENDIX

Dependent Claims

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

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

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

RMTA (Paper 26)

Dependent Claims

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

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

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

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

Dependent Claims

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

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

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

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

RMTA (Paper 26)

Dependent Claims

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

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

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

Dependent Claims

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

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

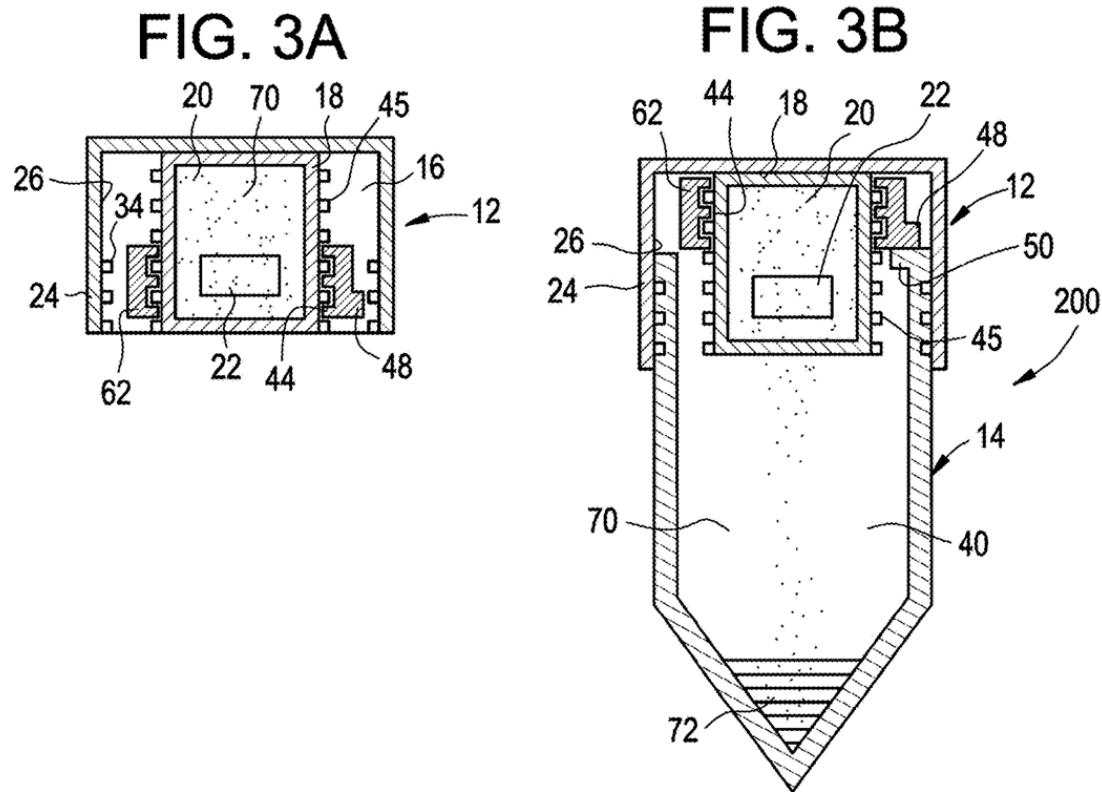
the second cylinder comprises a sidewall and the sidewall comprises the vent, wherein

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

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

RM TA (Paper 26)

Claim 29



Ex. 1001, Fig. 3A-3B

Testimony of Mr. Leinsing:

The cap in FIGS. 3A and 3B “would be generally . . . understood as a generally cylindrical component with one capped end and one opened end” and “cup like.”

Ex. 2026, 43:7-13, 51:21-24

Q: “[i]f you were to take a cup and fill it with sand all the way to its top lip, would that sand be entirely within the volume of the cup”

A: “You could say it was in the entirety of the volume of the cup”

Ex. 2026, 66:19-67:5

RMTA (Paper 26), 7

Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PATENT OWNER'S
DEMONSTRATIVES were served as of the below date via email (by agreement)
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Dated: January 22, 2025

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