

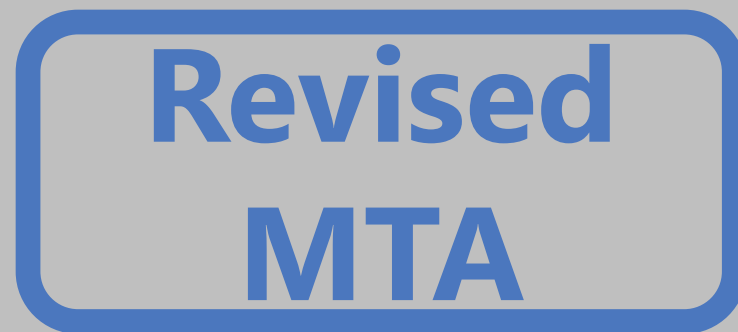
Petitioner Spectrum's Demonstratives For Oral Argument

January 24, 2025

Spectrum Solutions LLC v. DNA Genotek Inc.

IPR2023-01424 (Patent 11,536,632)

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE



Broadened Claims

An Amendment May Not Enlarge Claim Scope

“An amendment [made during IPR] may not enlarge the scope of the claims of the patent or introduce new matter.”

35 U.S.C. § 316(d)(3)

Patent owner has the burden to show “that the proposed amendment complies with relevant regulatory and statutory requirements.”

Sisvel Int'l S.A. v. Sierra Wireless, Inc., 81 F.4th 1238, 1241 (Fed. Cir. 2023), citing 37 C.F.R. § 42.121(d)(1)

Proposed Substitute Claim 21

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

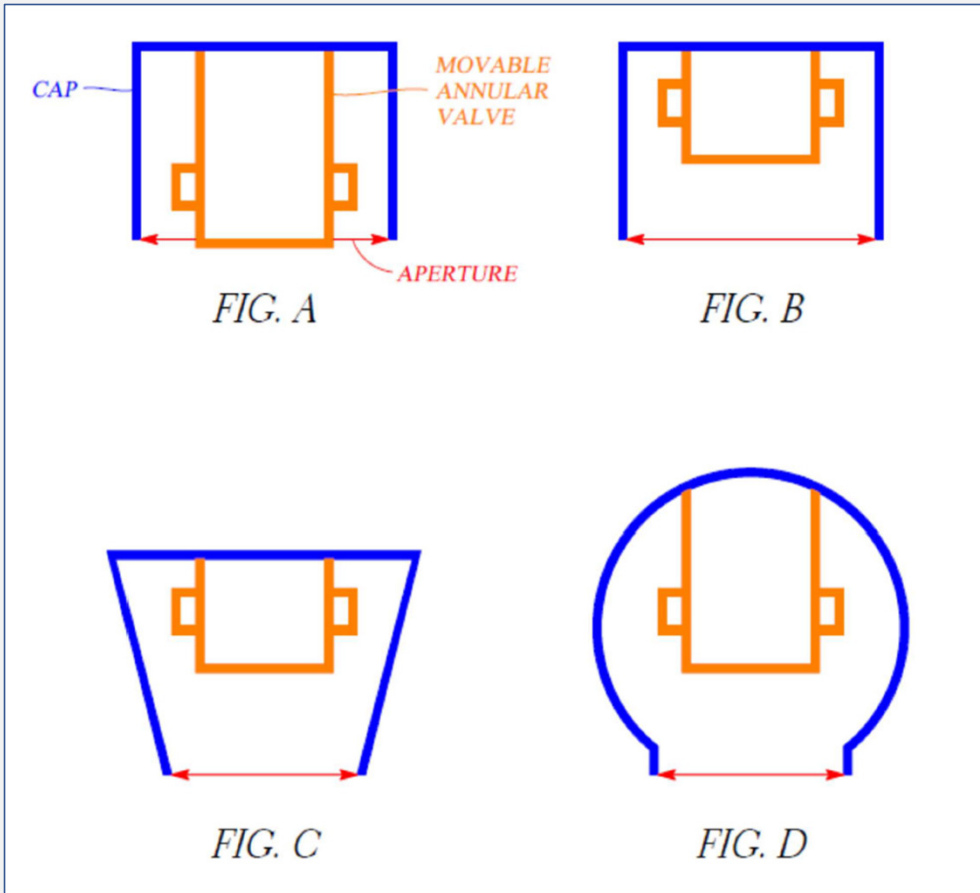
...

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

“If a substitute claim is broader in *any respect* it is considered to be broader than the original claim even though it may be narrower in other respects.”

Sisvel Int'l S.A. v. Sierra Wireless, Inc., 81 F.4th 1231, 1241 (Fed. Cir. 2023) (emphasis in original)

The Amended Claims Cover More than the Original Claims



Examples of embodiments encompassed by new claims, but not original claims, are a “helpful illustration” in determining whether claim scope has been broadened.

Sisvel Int'l S.A. v. Sierra Wireless, Inc., 81 F.4th 1231, 1238 (Fed. Cir. 2023)

An Aperture is Not the Same as the Interior Space/Volume

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

Proposed Substitute Claim 21

An Aperture is Not the Same as the Interior Space/Volume

- ⌚ The '632 specification also distinguishes between an aperture and an interior space/volume:

The chamber may comprise inner walls which define **an interior space** and **an aperture** ...

Ex. 1001, 5:24-25

... the chamber comprises inner walls defining **an interior space** which holds the fluid, and **an aperture** ...

Ex. 1001, 6:14-16

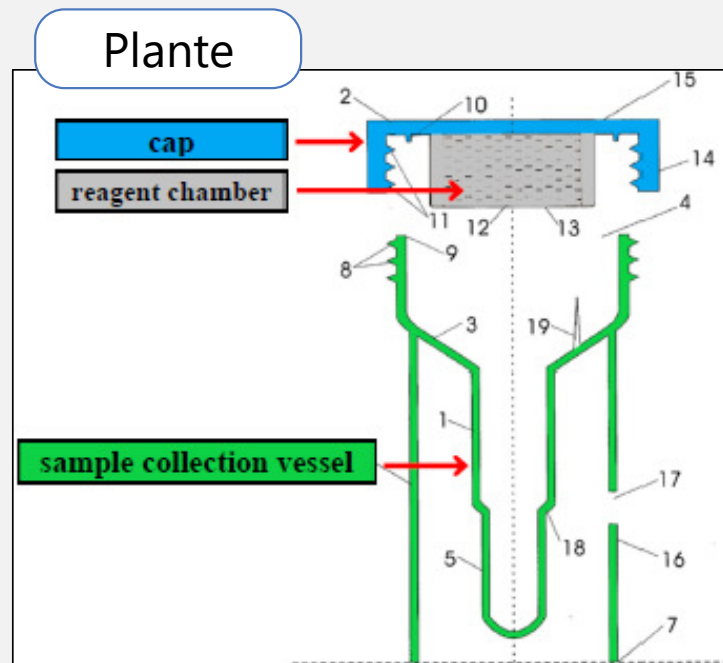
“The **interior space 20** may be at least partially defined by at least one of an interior wall 18 The inner wall 18 may further define an **aperture 22**....”

Ex. 1001, 14:20-22; 24-27

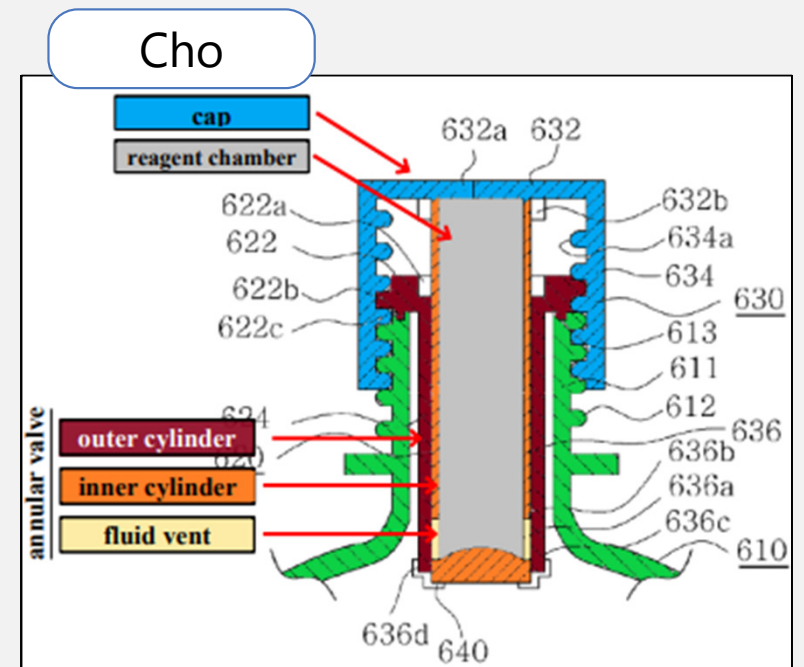
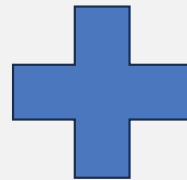
**Revised
MTA**

Plante + Cho

'632 Patent is Obvious In View of Plante and Cho

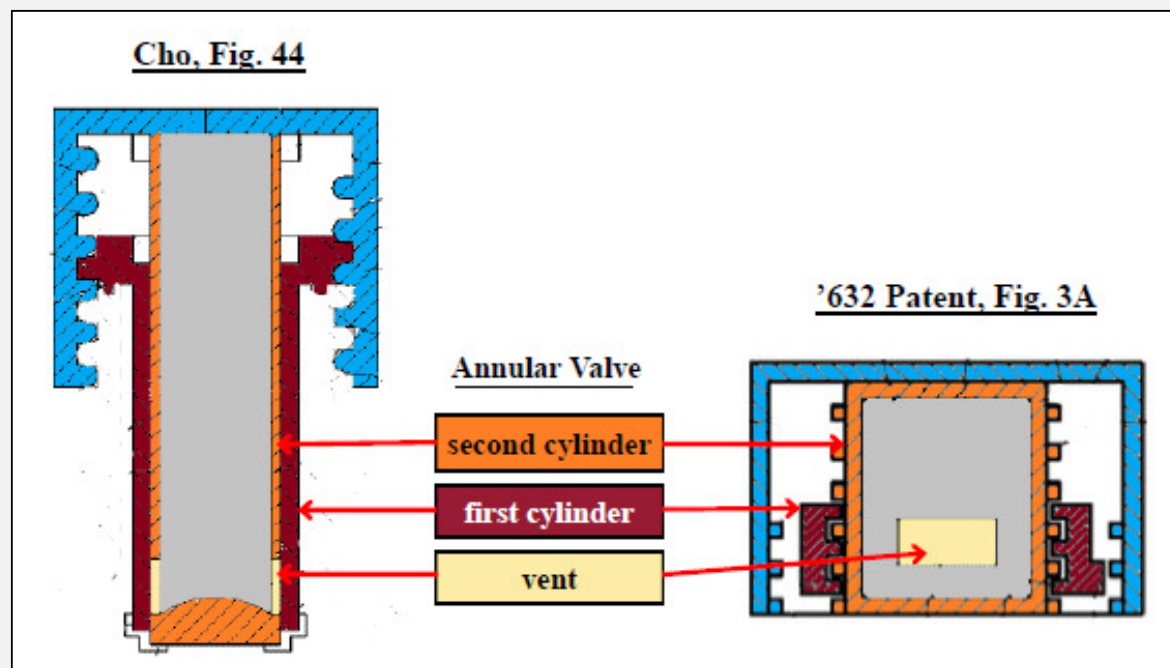


(Ex. 1003, Fig. 1)



(Ex. 1004, Fig. 44)

The Annular Valves of Cho and the '632 Patent are Essentially the Same



Ex. 1002, ¶198; Ex. 1004, Fig. 44; Ex. 1001, Fig. 3A

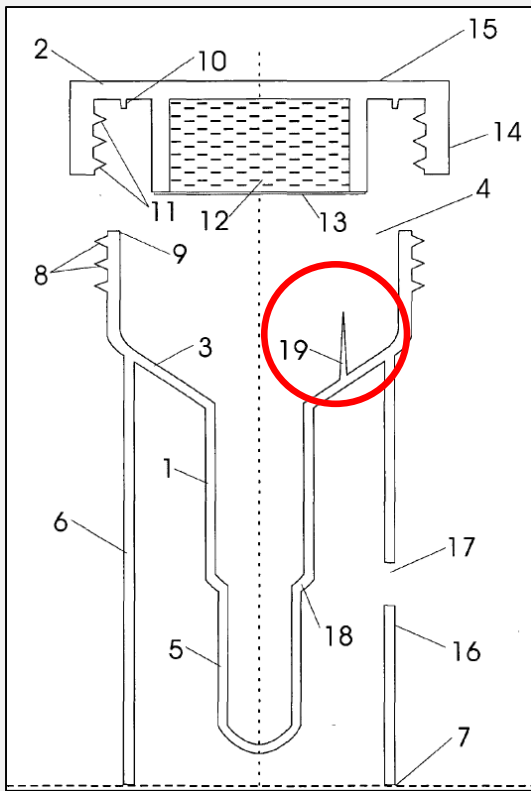
Plante + Cho

Motivation To Combine

A POSA Would Be Motivated to Combine Plante and Cho

- ⌚ Safety design considerations motivate replacement of Plante's sharp knife. Ex. 1002 ¶¶67-70.
- ⌚ It is difficult to mold sharp, thin features such as Plante's knife. Ex. 1002 ¶¶71-72.
- ⌚ Using Cho's annular valve allows the cap to be sealed prior to opening. Ex. 1002 ¶73.
- ⌚ Replacing Plante's cap with Cho's cap is a simple substitution of known elements. Ex. 1002 ¶74.

A POSA Would Have Been Motivated To Replace Plante's Knife



(Ex. 1003, Fig. 1)

Plante:

“When the cap is screwed onto the receiving vessel it advances in an axial direction towards the receiving vessel. A carefully positioned **knife 19** integrated with the receiving vessel is provided to pierce the membrane and cause the liquid therein to leave via gravity.”

(Ex. 1003, ¶[0035])

Mr. Leinsing's testimony re Plante:

“[D]esign incentives would have motivated a POSA to replace Plante's approach of using a 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.”

(Ex. 1002, ¶167)

The '632 Patent Recognizes Sharps Were A Known Safety Risk

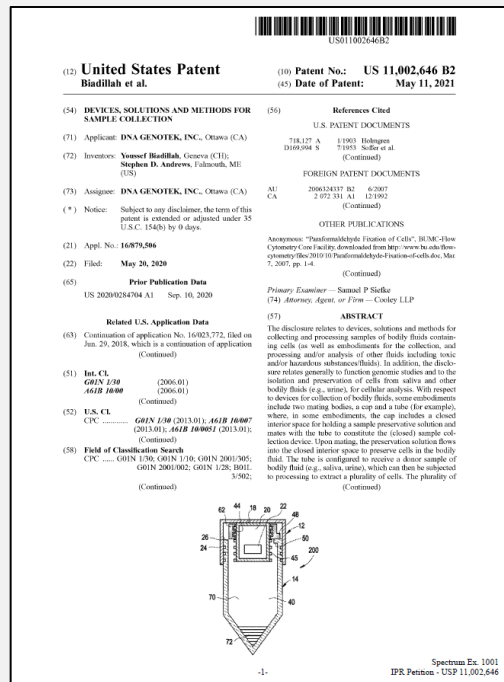
'632 Patent:

“Finally, the sample collection device may further allow a **laboratory technician** to receive the sample collection device and safely open it for processing with generally **no risk of exposure to any hazards.**”

(Ex. 1001, 4:10-14)

“In some embodiments, use of the sample collection devices provide **improved safety for both the sample donor and the end user**, since, for example, **sharp objects are not included** and there is limited to no risk of exposure to toxic solutions (e.g., sample preservative solutions).”

(Ex. 1001, 5:3-8)



The NSPA and CDC Teach Eliminating Sharps

NSPA

PUBLIC LAW 106-430—NOV. 6, 2000 114 STAT. 1901

(4) “Nevertheless, occupational exposure to bloodborne pathogens from accidental sharps injuries in health care settings continues to be a serious problem. In March 2000, the Centers for Disease Control and Prevention estimated that more than 380,000 percutaneous injuries from contaminated sharps occur annually among health care workers in United States hospital settings.

Estimates for all health care settings are that 600,000 to 800,000 needlestick and other percutaneous injuries occur among health care workers annually. Such injuries can involve needles or other sharps contaminated with bloodborne pathogens, such as HIV, HBV, or HCV.”

-1-

Spectrum Ex. 1015
IPR Petition - USP 11,002,646

(Ex. 1012, 1)

CDC

Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program

“In the hierarchy for sharps injury prevention, the first priority is to eliminate and reduce the use of needles and other sharps where possible.”



A workbook designed for:
Infection Control & Occupational Health Personnel •
Healthcare Administrators •
Sharps Injury Prevention Committees •

-1-

Spectrum Ex. 1013
IPR Petition - USP 11,536,632

(Ex. 1013, 18-19)

The CDC Workbook was Publicly Available in 2008

Workbook for Designing, Implementing, and

Welcome to the CDC website on Sharps Safety. Here you will find the Workbook for Designing, Implementing and Evaluating a Sharps Injury Prevention Program, which has been developed by CDC to help healthcare facilities prevent needlesticks and other sharps-related injuries to healthcare personnel. *The Workbook is one part of a package of materials that is being made available on this website.* ... Thank you for visiting this site. CDC hopes that you will find this information helpful and that you will apply it in your healthcare setting.

Sharps Injury Prevention Committees •
Spectrum Ex. 1013
-1- IPR Petition - USP 11,536,632

(Ex. 1013 at 2)

- ⦿ Workbook has a 2008 date
- ⦿ OSHA website cites to the workbook as a 2008 publication
- ⦿ OSHA website shows the Workbook is intended for the public
- ⦿ All references in the workbook pre-date 2008

The Board Already Found Motivation to Combine Plante and Cho

“Eliminating sharp components in Plante’s sample collection system as a reason for modifying Plante with Cho’s system for releasing a component in the cap has a rational un[der]pinning based on this record. *See KSR*, 550 U.S. at 418.”

Ex. 1044, 40

“In sum, the preponderance of the evidence supports the stated rationale [safety considerations] for combining the teachings of Plante and Cho.”

Ex. 1044, 42

Plante + Cho

Reasonable Expectation of Success

A POSA Would Have a Reasonable Expectation of Success

Mr. Leinsing's testimony:

“[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.”

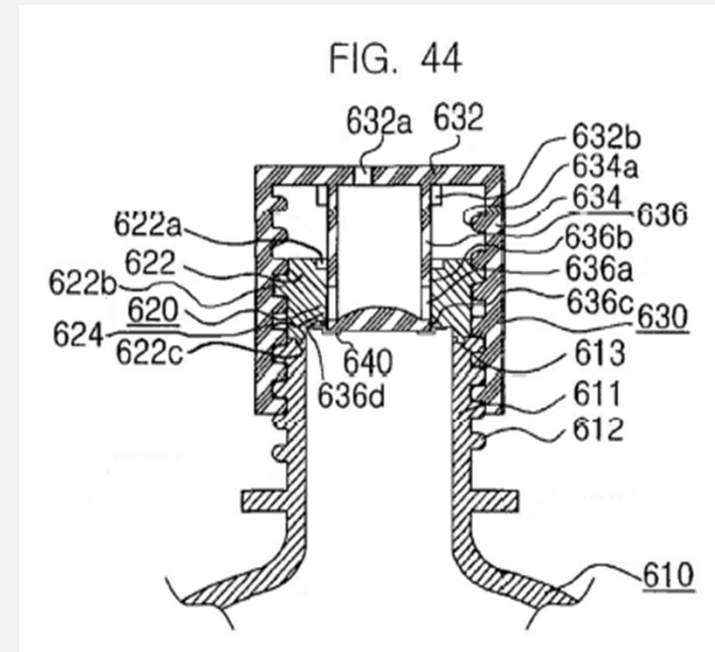
It would have been clear to a POSA that the combination of these references would have involved the routine substitution of one cap with an annular valve for another with a pierceable membrane, which would eliminate the need for a sharp knife but maintain all the same desired functionality.

Plante + Cho

Modifying the Size of Cho

A POSA Would Have Been Motivated to Modify the Size of Cho

- ⦿ Reducing risk of sample contamination. Ex. 1027, ¶¶27-30.
- ⦿ There are two options for placement of the moveable annular valve in Cho's cap. Ex. 1027, ¶31; Ex. 1041, ¶15.
- ⦿ Simple design choices. Ex. 1027, ¶32; Ex. 1041, ¶¶10-15.



(Ex. 1041, 7)

Modifying Cho's Size Reduces Risk of Sample Contamination

Dr. Wereley identifies the risk of contamination with Cho's design:

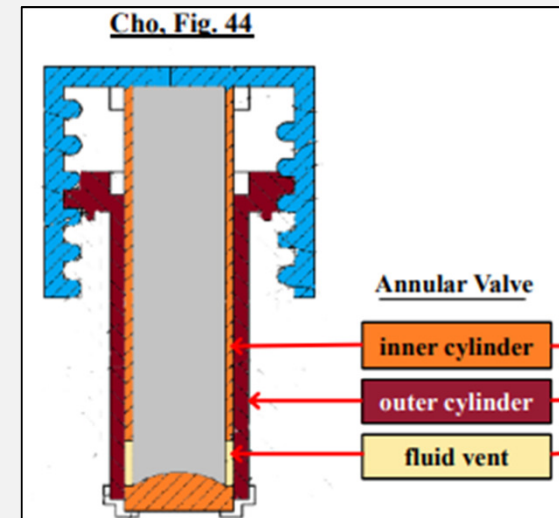
“As seen in Figure 44 below, **Cho's annular valve protrudes significantly beyond the bottom of Cho's cap. This increases the risk that an individual touches the interior of the device**, which I understand from Dr. Metzker could render the sample defective.”

Ex. 2014, ¶174

A POSA would resize Cho to solve this problem:

“[A] POSA would have been motivated to modify Cho's cap to position the first and second cylinders entirely within the boundaries defined by the outer wall of the cap to minimize the likelihood of contact by a user, and thus reduce the risk of contamination.”

Ex. 1027, ¶130

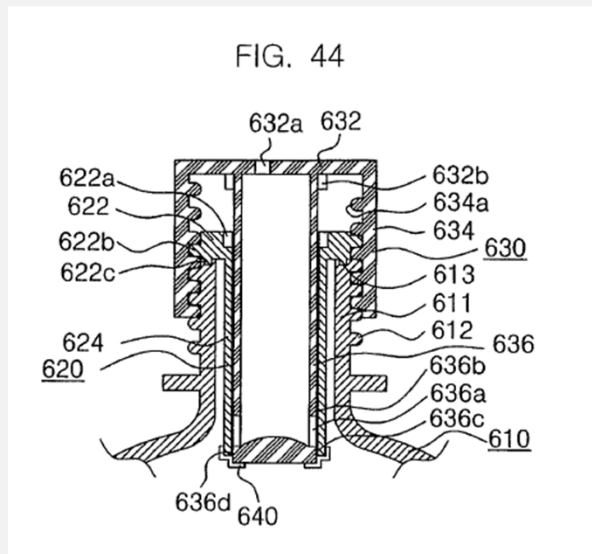


(Ex. 1004, Fig. 44)

Limited Number of Placements for Cho's Annular Valve

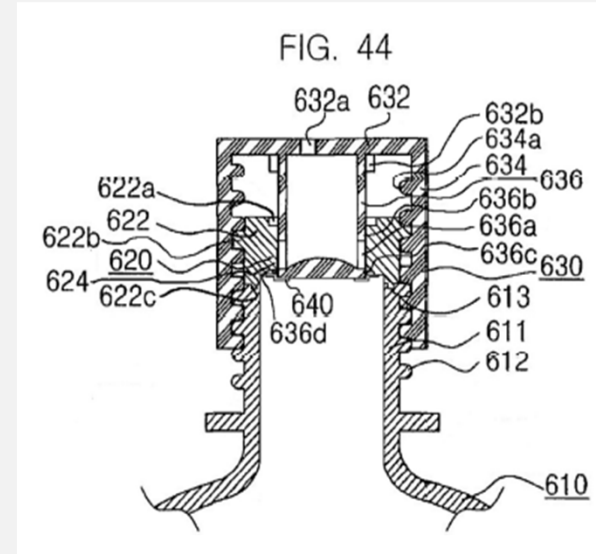
A POSA would recognize two options for placement of Cho's annular valve in the cap:

Inner cylinder aperture located below where outer cylinder abuts container opening:



(Ex. 1004, Fig. 44)

Inner cylinder aperture located above where outer cylinder abuts container opening:



(Ex. 1041, 7)

Design Considerations Motivate Changing Cho's Size

A POSA would modify the size of Cho depending on the amount of additive

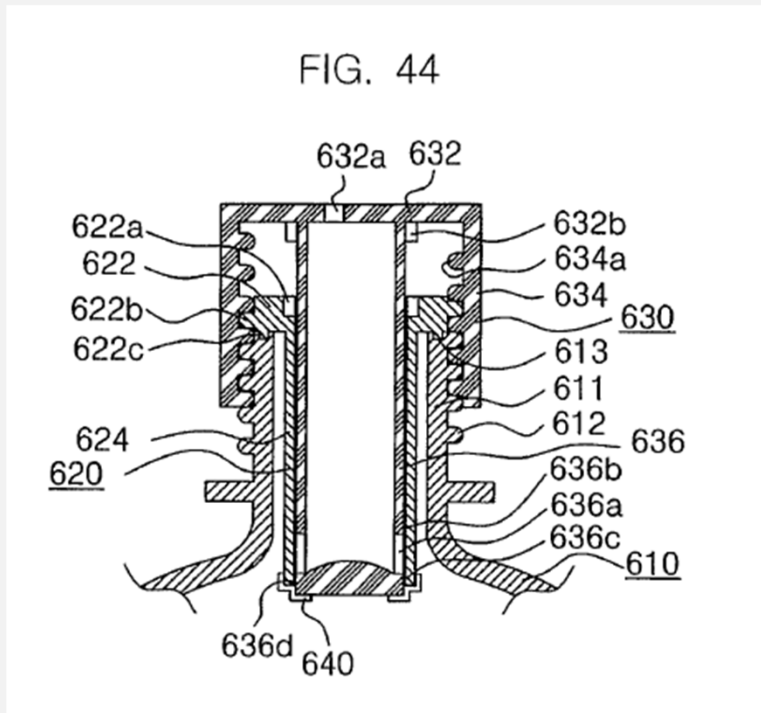
“When the design calls for a smaller amount of additive in the cap, **a POSA would be motivated to reduce the vertical length of the reagent chamber in Cho's cap and thereby bring the first and second cylinders entirely within the boundaries of the outer wall of the cap. ...**”

Ex. 1027, ¶132

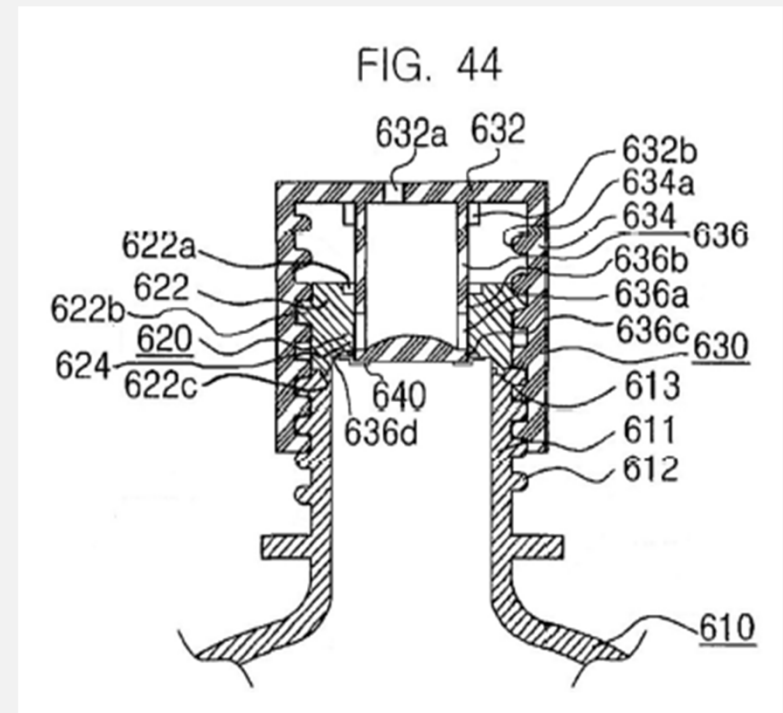
“**A POSA would have been motivated to adjust the size of the movable annular valve and its components depending upon the amount of additive to be added.** A POSA would and could adjust the size of the cylinders that make up the annular valve as he or she saw fit for a given application.”

Ex. 1041, ¶11

Cho's Modification is a Mere Change in Size



(Ex. 1004, Fig. 44)



(Ex. 1041, 7)

Mere Changes in Size are Obvious

“[I]t has generally been held that changes in sizes and shapes of known elements are within the level of skill in the art, especially in the absence of unexpected results or criticality.”

Ex Parte Martin Uram, No. APPEAL 2017-002323, 2018 WL 799041, *6 (P.T.A.B. Jan. 8, 2018)

The Board has already acknowledged a POSA would understand such size changes :

“Precedent has long held that the person having ordinary skill in the art must be regarded as skillful and ordinarily creative, not as a mere literalistic automaton. [citations omitted] **A person having ordinary skill in the art would have understood how to size, scale, and otherwise form the sample collection kit taught by Plante using Cho’s cap**”

Ex. 1044, 43

A POSA Would Have a Reasonable Expectation of Success Changing Cho's Size

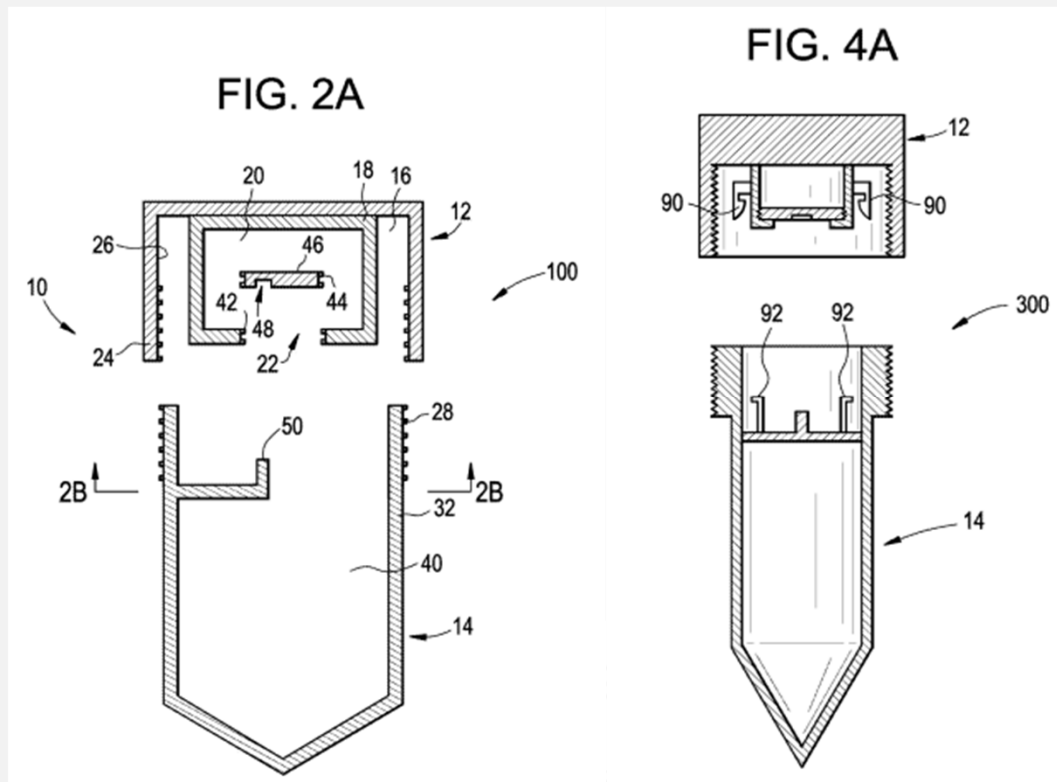
- ⌚ Dr. Wereley testified a POSA would recognize Cho's size could be changed:

15 THE WITNESS: So one of skill in the art
16 would recognize that the additive storage container,
17 the size or the volume of the additive storage
18 container could be changed to accommodate some
19 operation so holding some material.

Ex. 1034, 35:15-19

PO Never Discloses Change in Size as Inventive

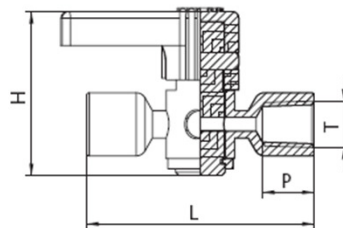
- ⌚ The '632 Patent does not discuss the new sizing limitation at all.
Ex. 1041, ¶13.
- ⌚ Several embodiments in the '632 Patent show the blocking member within the container volume.
Ex. 1041, ¶14.



(Ex. 1001, 7)

These are Simple, Easily Manufactured Devices

V21F 2-Way Stopcock 1/4 Turn Female Threaded PFA HP Valve

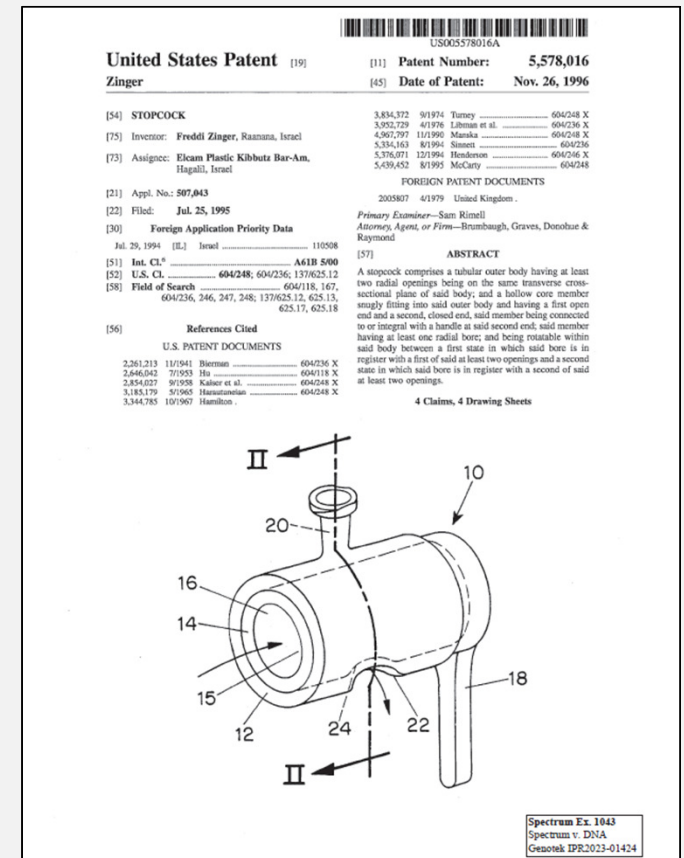


Part Number	Orifice ID mm	H mm	L mm	T NPT	P mm
V21 F4	4	48	67	1/4	15
V21 F6	8	67	79	3/8	15

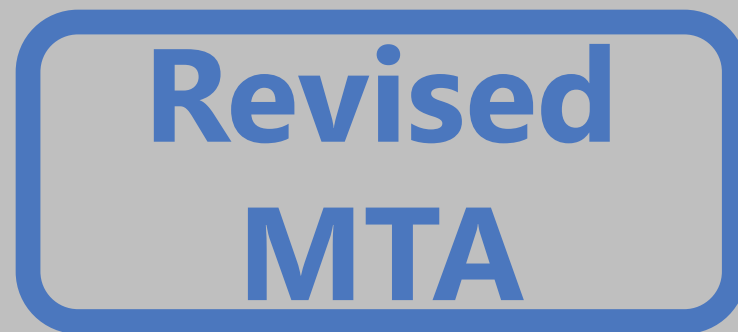
Ex. 1045

“These documents support my conclusion that **it was conventional to mold valves, in high volumes, using two plastic cylinders with an interference fit since well before the '632 patent** and a POSA would not be disinclined to use Cho’s annular valve and would very reasonably expect it to work in Plante’s application.”

Ex. 1041, ¶23



Ex. 1043



Substitute Claim 29

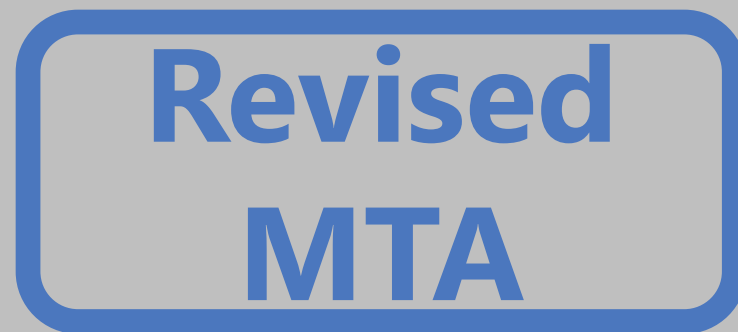
Proposed Substitute Claim 29

29. The biological sample collection system of claim 21, wherein the first cylinder and second cylinder are relatively moveable entirely within the interior volume of the cap to thereby change the moveable annular valve from the closed configuration to the open configuration ~~further comprising a funnel attachable to the sample collection vessel.~~

Substitute Claim 29 Would Have Been Obvious

“Substitute dependent claim 29 adds that the first and second cylinders “are relatively moveable entirely within the interior volume of the cap” to change from the closed to open configuration. Motion at 15. The claim is obvious over Plante and Cho because, as described above, **adjusting the size of the movable annular valve and inner/outer cylinders would have been obvious. Based upon such obvious size adjustments the first and second cylinders would be relatively moveable entirely within the interior volume of the cap.** This is depicted in the modified Cho Figure 44 above.”

Ex. 1041, ¶129



Substitute Claim 36

Proposed Substitute Claim 36

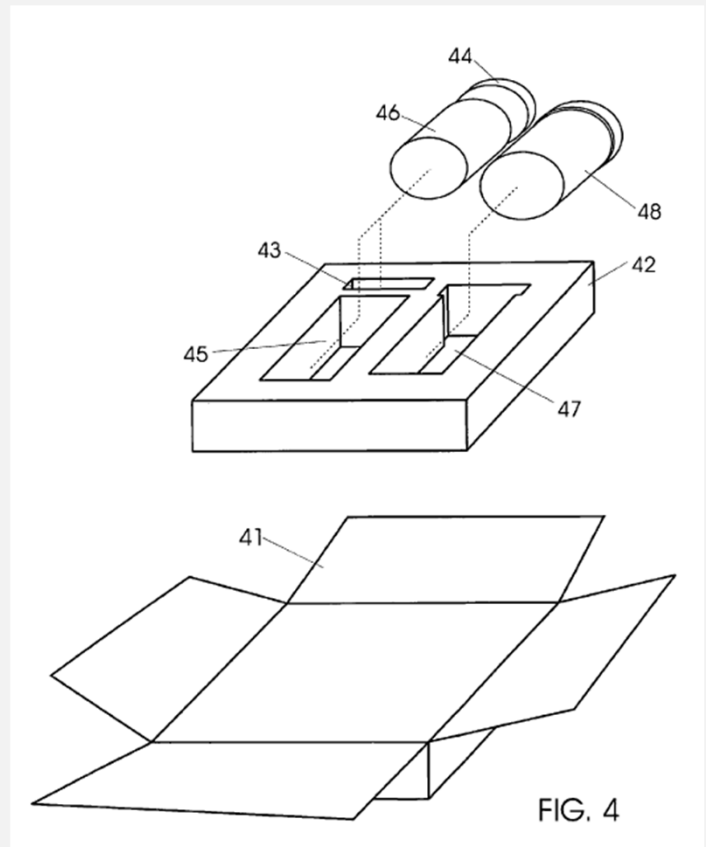
33. The biological sample collection system of claim 21, wherein the sample collection system comprises a separable two-piece sample collection system, the sample collection vessel comprising a first piece of the separable two-piece sample collection system, and the cap with movable annular valve comprising a second piece of the separable two-piece sample collection system.

Substitute Claim 36 Would Have Been Obvious

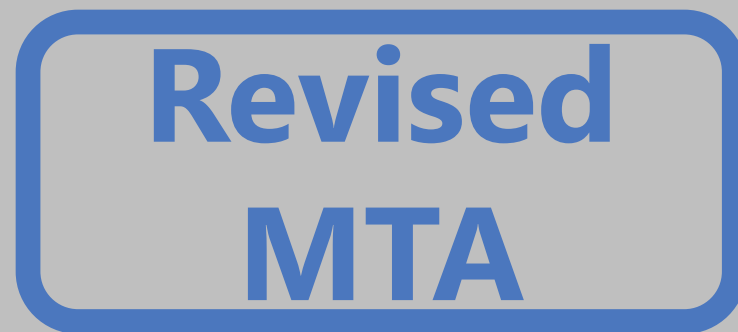
Substitute Claim 36 corresponds to original claim 16

“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.”

Ex. 1002, ¶159



Ex. 1003, Fig. 4



Substitute Claim 33

Proposed Substitute Claim 33

33. The biological sample collection system of claim 432, 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.

Modified Claim 33 Lacks Written Description Support

- ⦿ The '632 Specification does not disclose a flange on the inner cylinder. Ex. 1041, ¶31.
- ⦿ The '632 Specification does not disclose "*initial contact* between the flange and a portion of the sample collection vessel ... *causes* the annular valve to change" from the open to closed position. Ex. 1041, ¶31.

Substitute Claim 33 Would Have Been Obvious

If Claim 33 had written description support, it is obvious:

“As described above, the features of claim 33 are not described in the '632 patent specification. To the extent the claim had support, e.g. if it were to read on the embodiment of Figures 3A and 3B, **the Cho movable annular valve includes an outer, first cylinder with a flange and it functions in the same manner as the '632 patent embodiment of Figures 3A and 3B** as I have described above. Thus, to the extent claim 33 had written description support, the claim would have been obvious in view of Plante and Cho.

Ex. 1041, ¶134