

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 PETITIONER'S OPPOSITION TO PATENT OWNER'S
NON-CONTINGENT MOTION TO AMEND**

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I. INTRODUCTION

1. I, Karl R. Leinsing, MSME, PE, submit this declaration on behalf of Petitioner Spectrum Solutions, LLC (“Petitioner” or “Spectrum”) in support of Petitioner’s Opposition to Patent Owner’s Non-Contingent Motion to Amend (“MTA”) in the *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 substitute claims proposed by Patent Owner in the IPR of the ’632 patent. This declaration is provided after my review and analysis of the ’632 patent, the substitute claims, the prior art, relevant background technology, and is also based on my education and experience, as well as additional materials identified herein. I incorporate by reference the declaration I previously submitted in support of Petitioner’s IPR Petition (Ex. 1002).

II. THE SUBSTITUTE CLAIMS

3. The MTA proposes cancelling claim 1 of the ’632 patent and substituting it with claim 21, which amends claim 1 as follows:

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 at 3-5.

III. THE SUBSTITUTE CLAIMS WOULD HAVE BEEN OBVIOUS

4. In substitute claim 21, Patent Owner amended claim 1 of the '632 patent as shown in MTA on pages 3-5. Specifically, Patent Owner is seeking to amend claim 1 to add that the cap has “an outer wall,” that the first and second cylinders are “housed within the boundaries of the outer wall of the cap,” and that the first and second cylinders are “relatively moveable within the boundaries of the outer wall of the cap.” MTA at 3-5. However, these additional limitations are also disclosed in the prior art.

5. A POSA would understand that the term “within the boundaries of the outer wall of the cap” requires the first and second cylinders to be within the boundaries defined by “the outer wall.” Indeed, in its proposed claim construction, Patent Owner merely restates its amended claim language: “the annular valve comprising the first cylinder, the second cylinder, and the vent are housed within a volume defined by the outer wall 24 of cap 12 (i.e., *within the boundaries of the outer wall of the cap.*” MTA at 11 (italics in original).

6. In the context of discussing the combination of Plant and Cho, Patent Owner argues that the amended claims are patentable over the prior art because the first and second cylinders in the prior art are not entirely within the volume defined by the boundaries of the outer wall of the cap. MTA at 15, 21. Patent Owner asserts that Cho’s “inner cylindrical component (slider 636)” “extends beyond the

boundaries of inner cap 634 and into the mouth of bottle body 610...” MTA at 15. Patent Owner also argues that Ueda allegedly does not meet the claim limitations because its components “extend beyond the boundaries of cap 3 and into the opening of container main body 2.” *Id.* at 21.

7. A POSA would not understand the term “within the boundaries of the outer wall of the cap” to mean “entirely within the boundaries of the outer wall of the cap.” Patent Owner’s suggested interpretation is inconsistent with the plain and ordinary meaning of the phrase “within the boundaries.” Also, I am not aware of anything in the claims, the specification, or the prosecution history that supports Patent Owner’s proposed narrowed interpretation of the well-understood term “within.”

8. Substitute claim 21 could have been drafted to recite, “entirely within the boundaries,” but, as written, the claim does not require the first and second cylinders to be entirely within the boundaries defined by the cap’s outer wall.

9. The plain and ordinary meaning of the term “within” is broad enough to encompass an object being located entirely in the interior and also *extending into* the interior. Merriam-Webster defines “within” as “in or into the interior.” Ex. 1028; *see also* Ex. 1029 (“in or into the interior or inner part”); Ex. 1030 (“in or into the inner part”). The specification does not restrict this understanding of the term “within.”

10. Patent Owner's attempt to narrow the meaning of "within the boundaries" as "entirely within the boundaries" is contrary to the language of substitute claim 21. Claim 21 requires that the cap comprises "a second aperture" and that the "moveable annular valve [is] positioned in the [cap's] second aperture." MTA at 4.

11. The plain meaning of "aperture" is an opening. Ex. 1031 ("an opening, as a hole, slit, crack, gap"); Ex. 1032 ("a small and often narrow opening"). The "second aperture," as recited in substitute claim 21, is the opening at the bottom of the cap. The specification uses the term "aperture" consistently with this meaning when describing the opening in the side of the inner wall 18. Ex. 2015 at ¶75 ("The inner wall 18 may further define an aperture 22 which may be open or closed....").

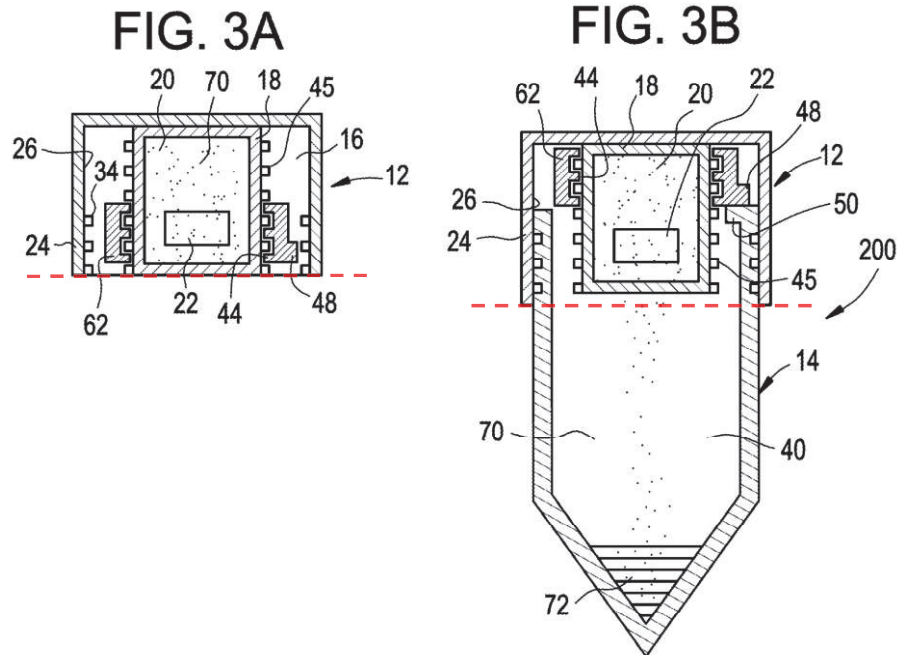
12. I understand that Dr. Wereley referred to the bottom opening in the claimed cap as the cap's aperture: "[T]here's an opening in the bottom surface of that Outer Wall 24. And one could call that an aperture." Ex. 1033 at 49:13-51:8. I agree with Dr. Wereley that the bottom opening of the cap is the cap's aperture.

13. Thus, in my opinion, claim 21's limitation reciting "a movable annular valve positioned in the second aperture" means that the first and second cylinders of the movable annular valve are positioned in the opening of the cap, i.e., extending through the second aperture. The moveable annular valve, which includes the inner and outer cylinders, cannot be entirely within the interior space defined by the outer

wall of the cap and also positioned in the second aperture. In this way, the inner and outer cylinders cannot be entirely within the boundaries of the outer cap and also satisfy the limitation requiring the moveable annular valve to be “positioned in the [cap’s] second aperture,” as recited in substitute claim 21.

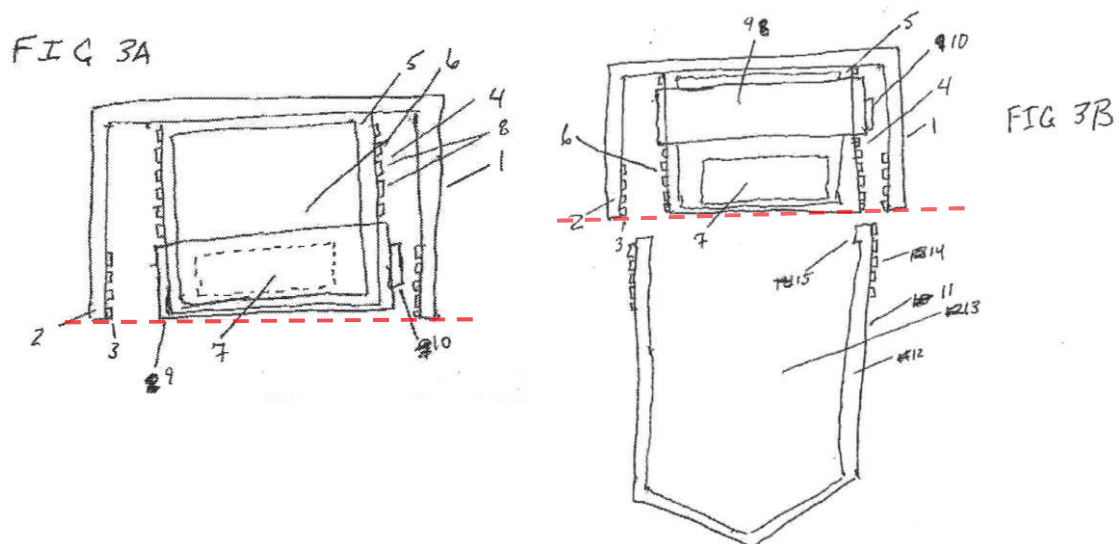
14. Figs. 3A and 3B of the ’632 patent do not support Patent Owner’s implied claim construction that the first and second cylinders are housed **entirely** within the boundaries of the outer wall of the cap. Figs. 3A and 3B depict the claimed components inconsistently and without the precision a POSA would expect to evaluate the component dimensions. I understand that Dr. Wereley testified that Figs. 3A and 3B in the ’632 patent and in Provisional Application No. 61/498,584 (“’584 provisional”) are “meant to be sketches” and “not engineering drawings with tolerances and dimensional lines.” Ex. 1033at 62:18-65:16. These imprecise and inconsistent drawings do not convey to a POSA that the first and second cylinders are housed **entirely** within the boundaries of the outer wall of the cap.

15. Furthermore, Fig. 3A shows that the second cylinder (“inner wall 18”) extends into the cap’s aperture. Fig. 3B, however, shows the same second cylinder, recessed in the cap. This inconsistency in the location of the second cylinder highlights to me that the inventors did not consider its location important to their invention.



Ex. 2015 at Figs. 3A, 3B (annotated).

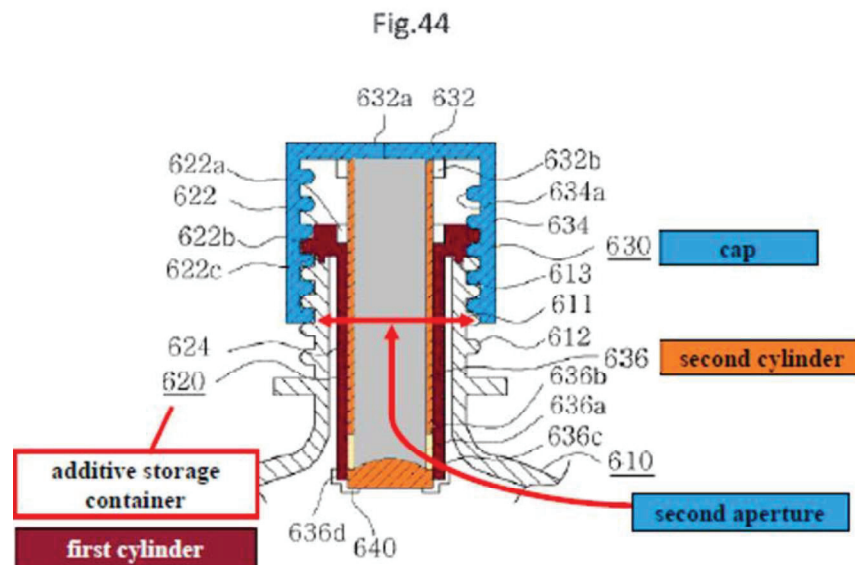
16. The drawings in '584 provisional" are hand drawn and switch this arrangement, such that Fig. 3A presents the inner cylinder ("inner wall 5") as slightly recessed (and slanted) in the cap, and Fig. 3B presents the inner cylinder as extending at least partially through the aperture of the outer wall 2 of the cap.



Ex. 2022 at Figs. 3A, 3B (annotated).

A. **Plante and Cho Disclose “wherein the first cylinder is housed within the boundaries of the outer wall of the cap,” and “wherein the second cylinder is housed within the boundaries of the outer wall of the cap”**

17. Cho discloses a cap comprising an outer wall. As shown, for example, in Fig. 44, Cho discloses a cap 630 that includes an outer wall (annotated in blue).



Ex. 1004 at Fig. 44 (annotated).

18. As I explained previously, Cho discloses that the first and second cylinders extend into the boundaries defined by the outer wall of a cap. Ex. 1002 at ¶¶99-100. Specifically, Fig. 44 of Cho shows a container cap 630 having a valve with cooperating first and second cylinders (annotated in red and orange, respectively). Cho discloses that the second cylinder (slider 636) is integrally connected with the cap (opening unit 630). Ex.1004 at 49:5-13, 50:4-15, Figs. 44-45B. Cho’s annotated Fig. 44 above illustrates how the second cylinder (slider 636)

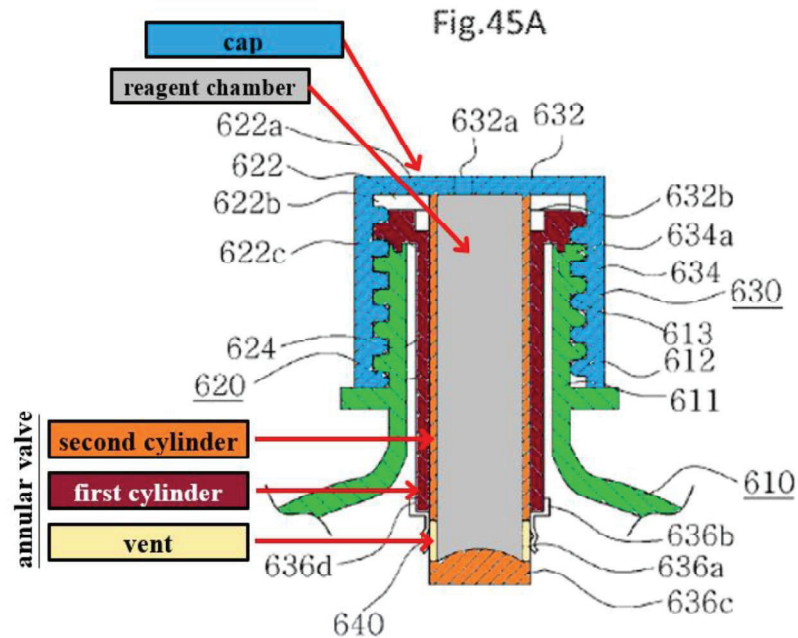
and first cylinder (additive storage container 620) of Cho's annular valve are disposed in the aperture of the cap (opening unit 630) and extend into the boundary defined by the outer wall of the cap.

19. Cho therefore discloses that the first cylinder and second cylinders are positioned in the second aperture and are housed within the boundaries of the outer wall of the cap.

B. Plante and Cho disclose “the first cylinder and second cylinder are relatively moveable within the boundaries of the outer wall of the cap”

20. Cho discloses that the first and second cylinders are moveable relative to one another within an interior space of the cap. Fig. 44 of Cho (shown above) illustrates the cap 630 and the first and second cylinders in a closed configuration. In the closed configuration, the top surface of the inner cylinder is disposed above a top surface of the outer cylinder in the interior space of the cap 636.

21. When the cap is tightened on the container as shown below in Fig. 45A (shown below), the annular valve is opened by the inner cylinder moving downward relative to the outer cylinder within the boundaries defined by the outer wall to expose the fluid vent:



Ex.1004 at Fig. 45A (annotated). Cho therefore discloses that the inner cylinder and the outer cylinder are moveable relative to one another within the boundaries defined by the outer wall of the cap.

C. The Substitute Claims Are Unpatentable Under Patent Owner's Implied Claim Construction

22. Even if the claim required the first and second cylinders to be entirely within the boundary of the outer wall of the cap, substitute claim 21 would still be obvious over Plante and Cho.

23. It would have been obvious to modify Cho's cap to bring the cylinders entirely within the boundaries of the outer wall of the cap, and POSA had a reasonable expectation of success in doing so.

24. There is nothing novel or inventive about keeping the first and second cylinders from extending below the opening of the cap, or otherwise having the first and second cylinders housed entirely within, and moveable entirely within, the boundaries of the outer wall of the cap. It would have been within the knowledge of a POSA at the earliest priority date of '632 patent to modify the dimensions of the device's inner chamber, including the first and second cylinders, to accommodate various design choices, volumes, or purposes.

25. For example, the specification of the '632 patent explains that the device's dimensions can be modified based on need, particularly the device's "inner chamber" can be modified to accommodate a variety of different volumes, and also that it would be equivalent to swap locations of elements between the cap and the tube. Ex. 2015 at ¶ 66. But the specification does not include any specific disclosure teaching a POSA how to make these modifications. This is unsurprising, given that the information was within the knowledge of a POSA as of the earliest priority date of the '632 patent.

1. A POSA Would Have Been Motivated to Modify Cho

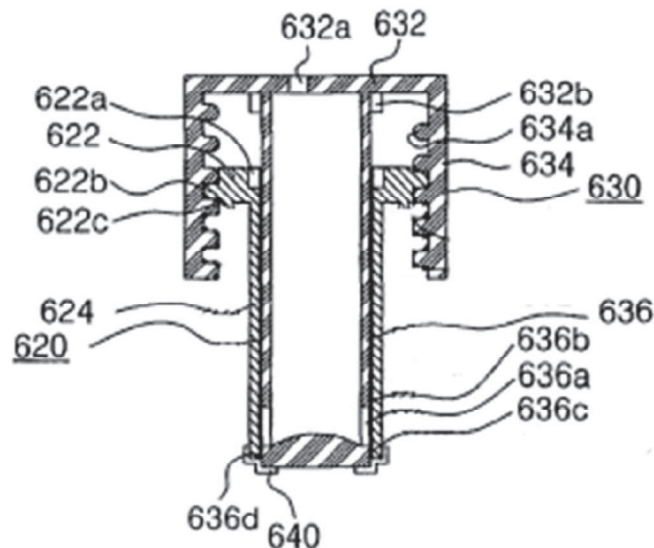
26. As discussed in my declaration supporting the Petition in this IPR, a POSA would have been motivated for multiple reasons to use Cho's cap with a movable annular valve in Plante's biological sample collection system. Ex. 1002 at ¶¶66-74. A POSA would have also been motivated to modify Cho's cap to include

the first and second cylinders entirely within the boundaries of the outer wall of the cap.

27. First, when making such a biological sample collection system for use by an unskilled user, a POSA would have been motivated to reduce the risk of sample contamination.

28. Cho's annular valve extends beyond the bottom of Cho's cap. As Dr. Wereley has asserted, this increases the likelihood that the user touches the fluid reservoir and thus increases the risk of contamination. Ex. 2014, ¶71. Further, the risk of contamination is heightened because the extended portion of the cap resembles a handle that naturally suggests itself to be an interaction point for a user:

FIG. 44



Ex. 1005, Fig. 44.

29. Dr. Wereley has contrasted Cho's potential for contamination with Plante's low-profile design that minimizes the risk of contamination. Ex. 2014, ¶70. I agree with Dr. Wereley's assessment that Plante's design positioning the reservoir only slightly below the cap "significantly reduces the risk that an individual would touch the film," which could render the sample defective. *Id.*

30. Accordingly, 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.

31. Second, a POSA would have recognized there are only two options for placement of the moveable annular valve in the cap: extending into or below the opening of the cap or housed entirely within the cap. With so few options, it would have been obvious for a POSA to try positioning Cho's first and second cylinders entirely within the boundaries of the outer wall of the cap. And as I explain below, a POSA would have reasonably expected to be successful in this endeavor.

32. Third, design choices would have motivated a POSA to modify Cho's cap to include the first and second cylinders entirely within the boundaries of the outer wall of the cap. These design choices include, for example, the amount of the additive stored in the cap and the width of the neck of the bottle. 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. Similarly, when the design calls for a wider neck in Cho's bottle, the cap will naturally be wider also, and a POSA would be motivated to expand the width of the reagent chamber horizontally, which allows the vertical length of the reagent chamber to be reduced to maintain the same volume, which brings the first and second cylinders entirely within the boundaries of the outer wall of the cap.

33. As an example of one such design choice, when medicines or volatile chemicals (which are specifically called out in Cho (Ex. 1004 at 1, 55)) are stored in Cho's reagent chamber, a POSA would have been motivated to size the space to minimize the amount of extra space (and therefore oxygen) that could degrade the contents.

34. Fourth, a POSA would also be motivated to make the chamber entirely within the boundaries of the outer wall of the cap to reduce the likelihood of tampering or purposely or accidentally peeling off or damaging the foil. A POSA would be motivated to use the boundaries of the cap wall to protect the inner chamber and its contents.

2. A POSA Would Have Had a Reasonable Expectation of Success

35. A POSA would have had a reasonable expectation of successfully modifying the dimensions of the Cho's annular valve so that the valve does not

extend below the bottom opening of the cap, and the first and second cylinders are housed entirely within the boundaries of the outer wall of the cap.

36. Dr. Wereley agrees that changing the dimensions of Cho's annular valve was within the skill of the art at the time of the earliest priority date of the '632 patent. In the '646 patent IPR, he testified that "one of skill in the art would recognize that the additive storage container, the size or the volume of the additive storage container could be changed to accommodate some operation." Ex. 1034 at 35:10-19; *id.* at 35:21-36:14, 38:1-7. Dr. Wereley agreed that, based on a POSA's understanding, the volume of the additive storage container could be adjusted by adjusting the axial length of Cho's first and second cylinders (making up the "additive storage container"). *Id.* at 69:13-70:9 ("[A] POSA in 2012 would realize that the axial length of the additive compartment could be changed to some extent" and "[c]hanging the length of the cylinder...would necessarily change its volume.").

37. The prior art also demonstrates that the dimensions of Cho's annular valve could be modified, specifically so that the valve is positioned entirely within the boundaries defined by the outer wall of the cap.

38. U.S. Patent Publication No. 2009/0216213 to Muir et al. ("Muir") discloses a vial 1 and a lid 100. *See, e.g.*, Ex. 1035 at Fig. 1. The lid 100 comprises wall 104 which defines a reservoir 102 that holds a substance. *Id.* at ¶¶ 46-47. Muir discloses that "the shape and size of the w[a]ll 104 is dependent upon the intended

use of the container system.” *Id.* at ¶ 52. For example, the “[l]id 100 and reservoir 102 can be sized to accommodate a range of volumes of a substance.” *Id.* at ¶ 51. Muir suggests that “[i]t may be desirable to keep a substance isolated from a donor until the donor’s biological sample has been collected. This will help prevent the donor from accidentally ingesting or spilling the substance.” *Id.* at ¶ 5.

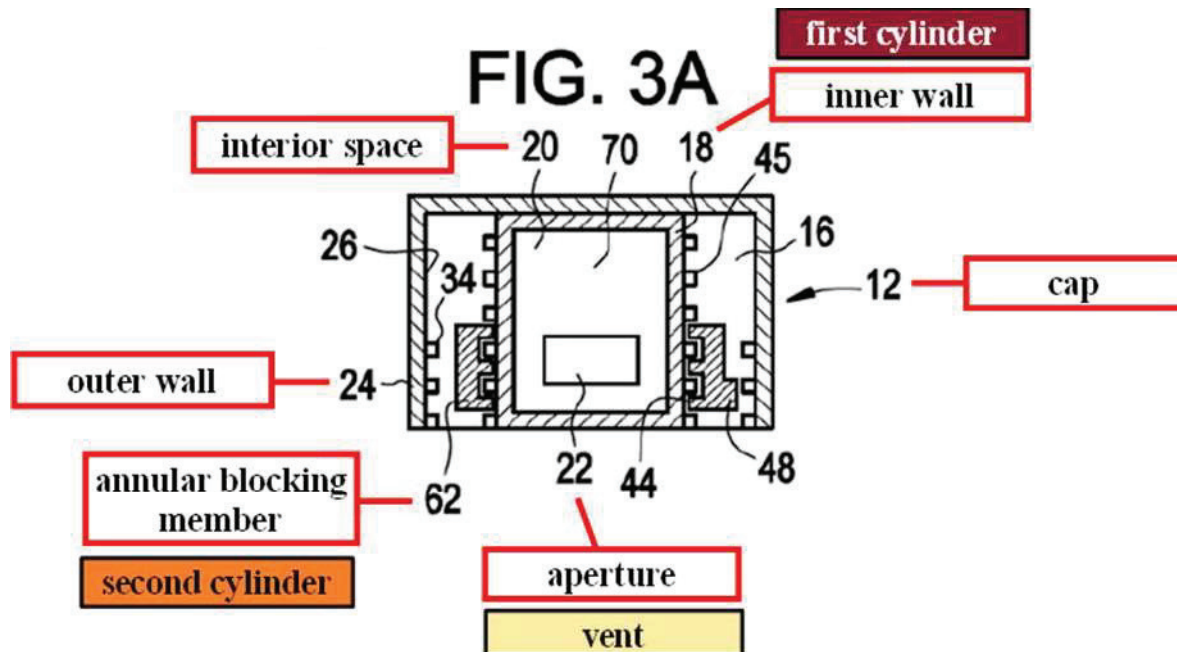
39. U.S. Patent Publication No. 2009/0212003 (“Gudmundsson”) discloses a cap 2 for dispensing an additive into a container 1. *See, e.g.*, Ex. 1036 at Abstract, ¶19, and Fig. 2. Gudmundsson discloses that “[t]he content of the container is normally in a liquid form and may be a drink, a medicine[,] or other chemicals” and that “the additive may have any form.” *Id.* at ¶¶ 2, 23. Gudmundsson recognizes that “[a] person skilled in the art realizes that the exact form and size of the closure and its different parts may be varied due to the form and size of the container and the additive.” *Id.* at ¶ 26.

40. Thus, as of the earliest priority date of the ’632 patent, a POSA would have had a reasonable expectation of success in modifying the dimensions of Cho’s annular valve so that the first and second cylinders are positioned entirely within the boundaries defined by the outer wall of the cap.

IV. THE SUBSTITUTE CLAIMS ARE UNPATENTABLE FOR LACK OF WRITTEN DESCRIPTION SUPPORT

41. It is my opinion that the substitute claims lack written description support if claim 21 is read to require that the first and second cylinders must be housed entirely within the boundaries of the outer wall of the cap.

42. The application that led to the '632 patent is U.S. Application No. 17/510,003 ("003 application") (Ex. 2015). The '003 application describes the cap 12 as having "an outer wall 24," "an inner wall 18," and "an annular blocking member 62," and discloses that "[t]he inner wall 18 may further define an aperture 22." Ex. 2015 at ¶75. For reference, I have included an annotated version of Figure 3A from the '003 application below with relevant labels from the specification and the substitute claims.



Ex. 2015, Fig. 3A (annotated).

43. The '003 application is silent regarding the locations of the first and second cylinders relative to the boundaries of the outer wall of the cap. That is, the specification never describes inner wall 18 as extending less than, equal to, or further than the bottom opening of the outer wall 24 of the cap 12. Also, as I explained above, Figs. 3A and 3B in the '003 application and the '584 provisional are not drawn with any precision or specificity and are internally contradictory, all of which indicates to me that the inventors did not actually invent a cap having the first and second cylinders housed entirely within the boundaries of the outer wall of the cap.

44. I understand Patent Owner has alleged that paragraphs 43, 44, 75, 76, 78, and Figs. 3A and 3B in the '003 application provide written description support for the claim amendments that require the first and second cylinders to be housed entirely within, and moveable entirely within, the boundaries of the outer walls of the cap. MTA at 4, 8-10. I have reviewed these portions of the '003 application and do not believe they provide support for the substitute claims under Patent Owner's interpretation of these limitations.

45. Paragraphs 43 and 44 are under the heading "Brief Description of the Drawings" and correspond to the descriptions of Figs. 3A and 3B. Paragraph 43 explains that the "movable annular valve" (i.e., the claimed first cylinder) can be positioned to cover the "aperture" (i.e., the claimed vent). And paragraph 44

explains that the moveable annular valve can be moved to a position where it does not cover the aperture. Neither paragraph describes the first and second cylinders as being housed entirely within the boundaries of the outer wall of the cap.

46. Paragraphs 75, 76, and 78 describe the process of covering and uncovering the aperture in more detail, but they never discuss whether the “inner wall 18” or “annular blocking member 62” extend less than, equal to, or further than the bottom opening of the outer wall 24 of the cap 12. Thus, none of these paragraphs describes the first and second cylinders as being housed entirely within the boundaries of the outer wall of the cap.

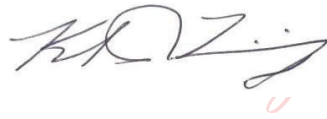
47. Patent Owner’s citation to Figs. 3A and 3B also does not establish written support for the claim amendments. As I explained above, these drawings are imprecise and contradictory such that they do not convey to a POSA that the inventors invented a cap with the first and second cylinders housed entirely within the boundaries of the outer wall of the cap.

V. CONCLUSION

For the reasons above, it is my opinion that substitute claims are unpatentable.

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 24, 2024, in Dover, NH.



Digitally signed by Karl R.
Leinsing
Date: 2024.09.24 19:03:11
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Karl R. Leinsing, MSME, PE