

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SPECTRUM SOLUTIONS L.L.C.,  
Petitioner

v.

DNA GENOTEK INC.,  
Patent Owner

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Case IPR2023-01424  
Patent 11,536,632

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**DECLARATION OF KARL R. LEINSING, MSME, PE, IN SUPPORT  
OF PETITIONER'S OPPOSITION TO PATENT OWNER'S  
REVISED 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 Revised 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 Dr. Wereley’s new and recent Supplemental Declaration (Ex. 2025) dated November 5, 2024 and additional materials identified herein. I incorporate by reference the declarations I previously submitted in support of Petitioner’s IPR Petition (Ex. 1002) and in connection with Patent Owner’s original motion to amend (Ex. 1027).

## **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 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 ~~second~~  
~~aperture~~ interior volume of the cap, 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,

rMTA at 3-4.

### **III. THE SUBSTITUTE CLAIMS WOULD HAVE BEEN OBVIOUS**

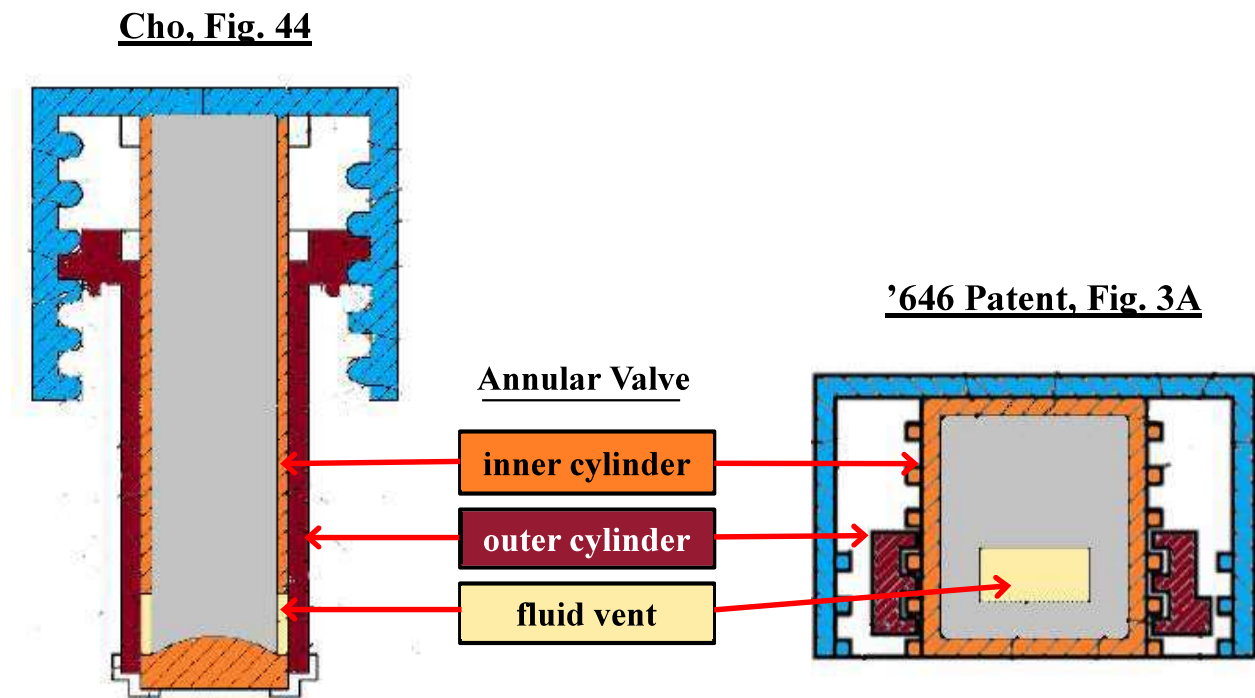
4. In substitute claim 21, Patent Owner amended claim 1 of the '632 patent as shown in rMTA on pages 3-4. The amendments generally provide the following changes: (1) amending language regarding the cap, including the open end of cap defining the second aperture; (2) reciting the reagent chamber is "positioned in the interior volume of the cap;" (3) reciting the movable annular valve is positioned in the interior volume of the cap (and removing the requirement that the movable annular valve is in the second aperture); and (4) and reciting the first cylinder of the movable annular valve is positioned externally of the sample collection vessel in the closed and open configuration. In my opinion, claim 21 remains obvious in view of the prior art.

5. Patent Owner's amendments do not change my opinion regarding the obviousness of the claims. The first three amendments do not at all impact my analysis and opinion that the claims are obvious as reflected in my original

declaration (Ex. 1002) and my declaration in response to the original motion to amend (Ex. 1027). Patent Owner only argues the last of these changes affects the non-obviousness of the claims. I address that in detail below.

6. Patent Owner argues patentability of the amended claims based on the added limitation that the first cylinder of the valve is positioned externally of the sample collection vessel in the closed configuration and the open configuration. Motion at 13. This new limitation relates to the sizing of the movable annular valve.

7. The movable annular valve of Cho is essentially identical to that described in the '632 patent. These are shown below (with reference numerals removed for simplicity).



8. The claims of the '632 patent recite a movable annular valve having first and second cylinders. The claimed movable annular valve was known in the art, including as disclosed in Cho and as I described in my initial declaration. Ex. 1002. Cho refers to what corresponds to the claimed first cylinder as the “additive storage container 120.” For clarity I will refer to this as the first and/or outer cylinder herein. Cho refers to what corresponds to the claimed second cylinder as the “slider 636.” For clarity I will refer to this as the second and/or inner cylinder herein.

9. In each of the annular valves of the '632 patent and Cho, an inner cylinder defines a space for an additive and an outer cylinder or blocking member blocks an aperture in the inner cylinder. When the cap is added to a container, the outer cylinder abuts the upper rim of the container. The outer cylinder then recesses further into the cap as the cap is screwed onto the container. The movement of the outer cylinder relative to the inner cylinder uncovers the aperture and permits the release of the additive stored within the inner cylinder.

10. The axial length of the two cylinders that make up the annular valve of Cho determine the volume of the additive that it will accommodate. And whether the first cylinder extends into the container or not as recited in the amended claim language depends on the amount of additive contained in the valve. For example, for a cap of a given width or diameter, a larger amount of additive would require cylinders of a longer axial length, and a lesser amount of additive would need

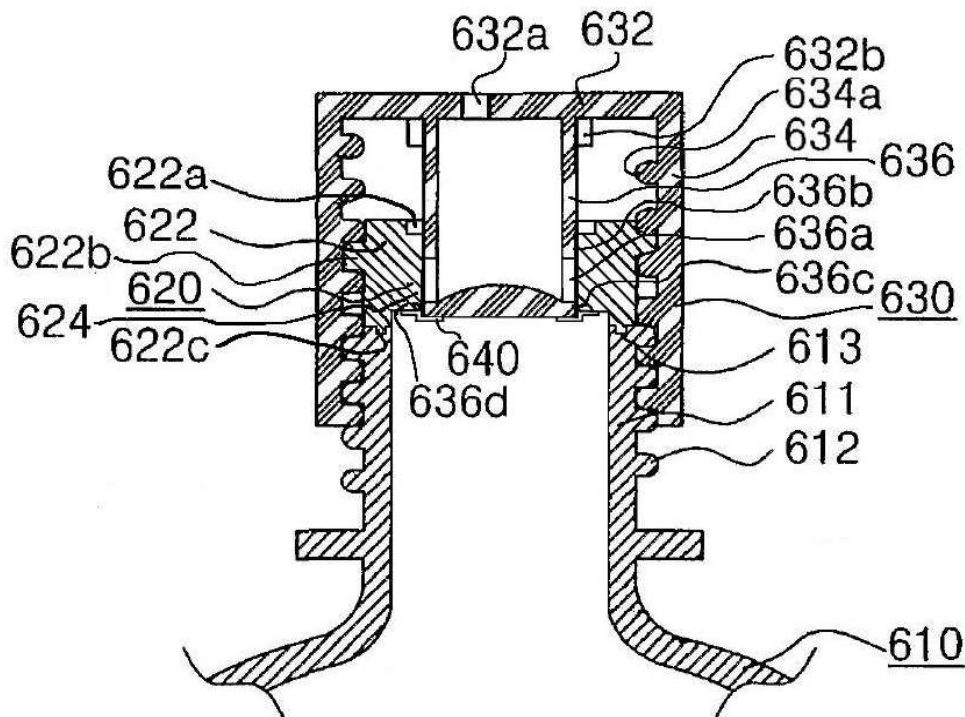
cylinders of a lesser axial length. A POSA would know that the size of the valve could be adjusted depending on how much additive were intended to be used in a particular application. If less additive were needed, a POSA would be motivated to have cylinders with a shorter axial length.

11. 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. I addressed this in my prior declaration in relation to Patent Owner's first amendment. Ex. 1027, ¶¶23-25. These conventional size adjustments include sizing the valve such that the outer, first cylinder does not extend into the container. It would have been obvious to modify the size of Cho's valve such that the resulting smaller size would force the first cylinder to be positioned externally to the sample collection vessel in the closed and open configurations. A POSA would have had no concern regarding the success of modifying the size, and certainly would have had a reasonable expectation of success in doing so.

12. Shown below is a modified version of Cho's Figure 44 where the size of the cylinders making up the annular valve have been adjusted for an application requiring a lesser amount of additive.

Modified

FIG. 44



13. I also note that the '632 patent does not mention this added limitation that Patent Owner now relies on for patentability. If it were an inventive feature, one would expect the inventors to have discussed it in the Background section when they explained the challenges with “currently available sample collection devices.” Ex. 2015, ¶¶14-15. They did not. Similarly, one would expect the inventors to have discussed the concept in the “Summary of the Disclosure” along with the “features [that] may be provided with a sample collection device.” *Id.*, ¶21. Again, they did

not. The specification never describes the concept of “the outer cylinder remaining outside the container” at all. The patent certainly never describes the feature as an inventive feature.

14. In fact, in multiple embodiments of the '632 patent the “blocking member,” what the '632 patent specification calls the element that blocks the aperture of the interior space containing the additive, does extend into the sample collection vessel. This can be seen in Figs. 1A, 2A, 4A, and 5A. Thus, the '632 patent does not suggest maintaining the blocking member external to the container adds any patentable significance to the claimed invention.

15. The motivations addressed in my prior declaration (Ex. 1027) addressed Patent Owner’s initial amendment language, which described the sizing issue with respect to the cap, i.e., Patent Owner’s argument that the prior amended claims required the movable annular valve to be entirely within the cap. Patent Owner’s new amendment goes to the same issue (size), but describes the degree of size adjustment in relation to the outer, first cylinder and the container. A POSA would have recognized that different applications call for different volumes of additive and would size the inner cylinder such that the outer, first cylinder would not extend into the container. The outer cylinder in Cho functions by abutting the upper edge of the container rim. It then recesses into the cap as the cap is screwed onto the container. This is the same as the '632 patent. The degree to which the

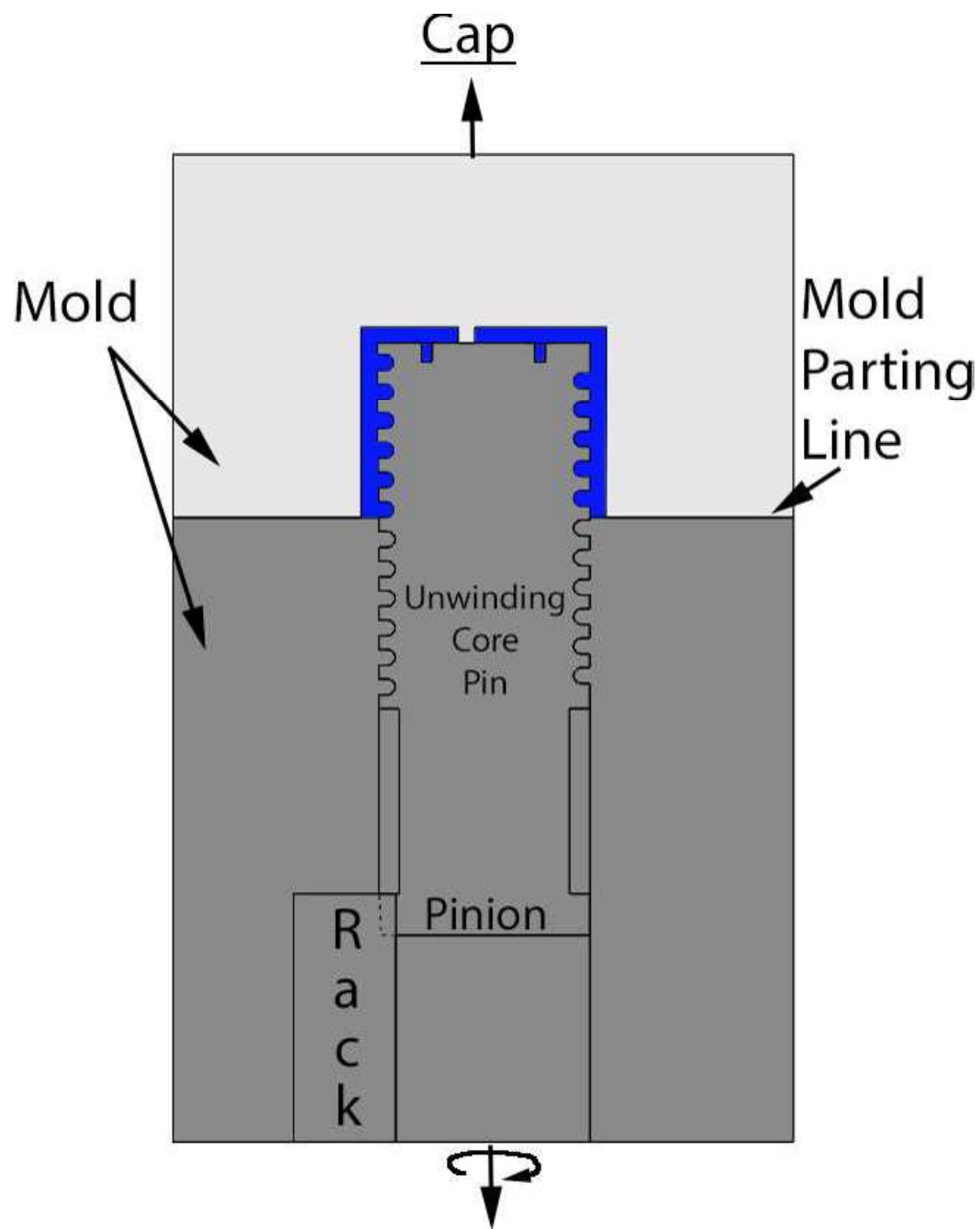
outer cylinder extends down into the container is simply a function of the volume of additive/size of the inner cylinder. In cases where less additive is necessary a POSA would recognize that the inner cylinder would be adjusted accordingly and the aperture would and could be placed above where the outer cylinder abuts the container as shown in the modified Figure 44 above. Such a sizing adjustment would not affect functionality and would have been a simple design alternative well within the skill of a POSA.

16. A POSA would have reasonably expected success in modifying the dimensions of the Cho's annular valve as depicted above.

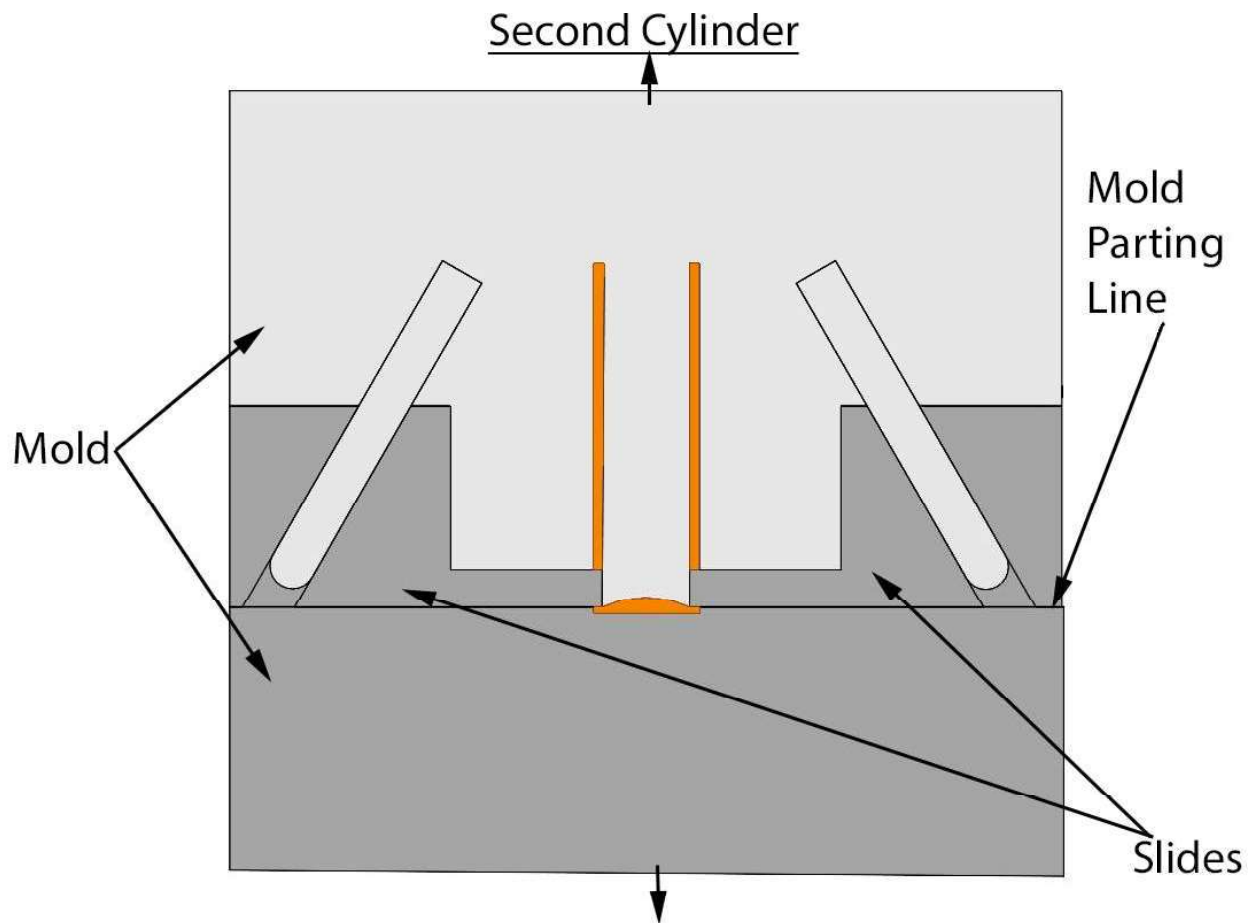
17. I understand Patent owner and Dr. Wereley contend molding the parts of the movable annular valve in Cho would present so many difficulties that a POSA would be motivated to not use it or would not expect to be successful in doing so. I disagree. Molding the parts of the Cho annular valve would be a simple process well within the level of skill of a POSA.

18. A POSA would recognize the cap with annular valve in Cho would be a straightforward component to make. It could be made in a very straightforward manner using three molds and NOT "at least six molds" as suggested by Dr. Wereley. 1027, ¶82. The cap could be made in a single mold as depicted below. The mold is a basic type of mold well within the skill of a POSA. The inner threads of the cap are formed with an unwinding core pin. This type of mold was

conventional at the time of the '632 patent.

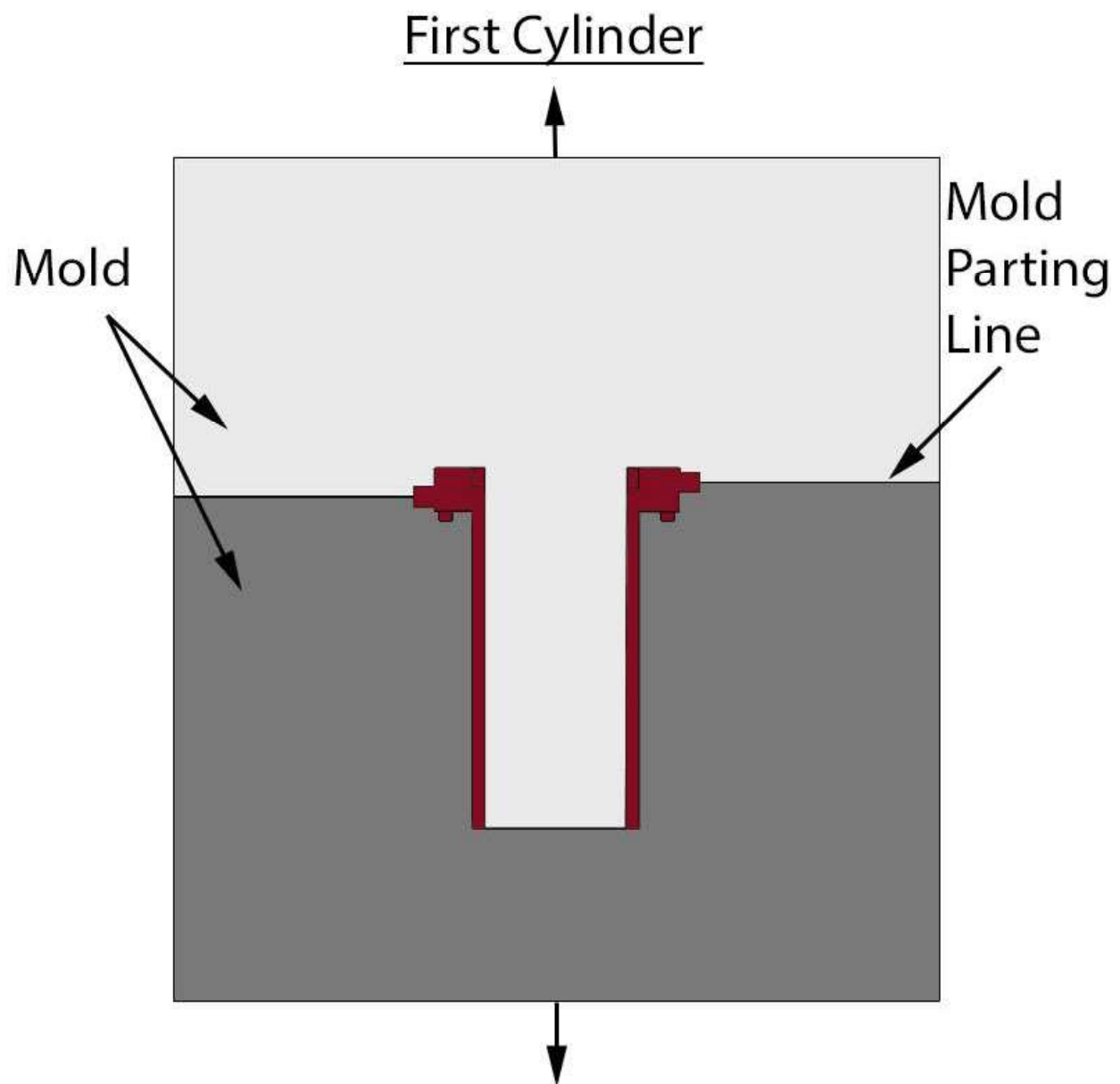


19. The inner cylinder is also a straightforward part to mold and a POSA would have recognized it as such. It could have been molded in a single mold as depicted below. The sliders form the apertures in the inner cylinder. The mold was also conventional at the time of the '632 patent.



20. The inner cylinder would then be connected to the cap via ultrasonic welding, spin welding, bonding or other well-known method of connecting plastic parts at the time of the '632 patent.

21. The outer cylinder is similarly a straightforward component to make a mold for it is shown below.



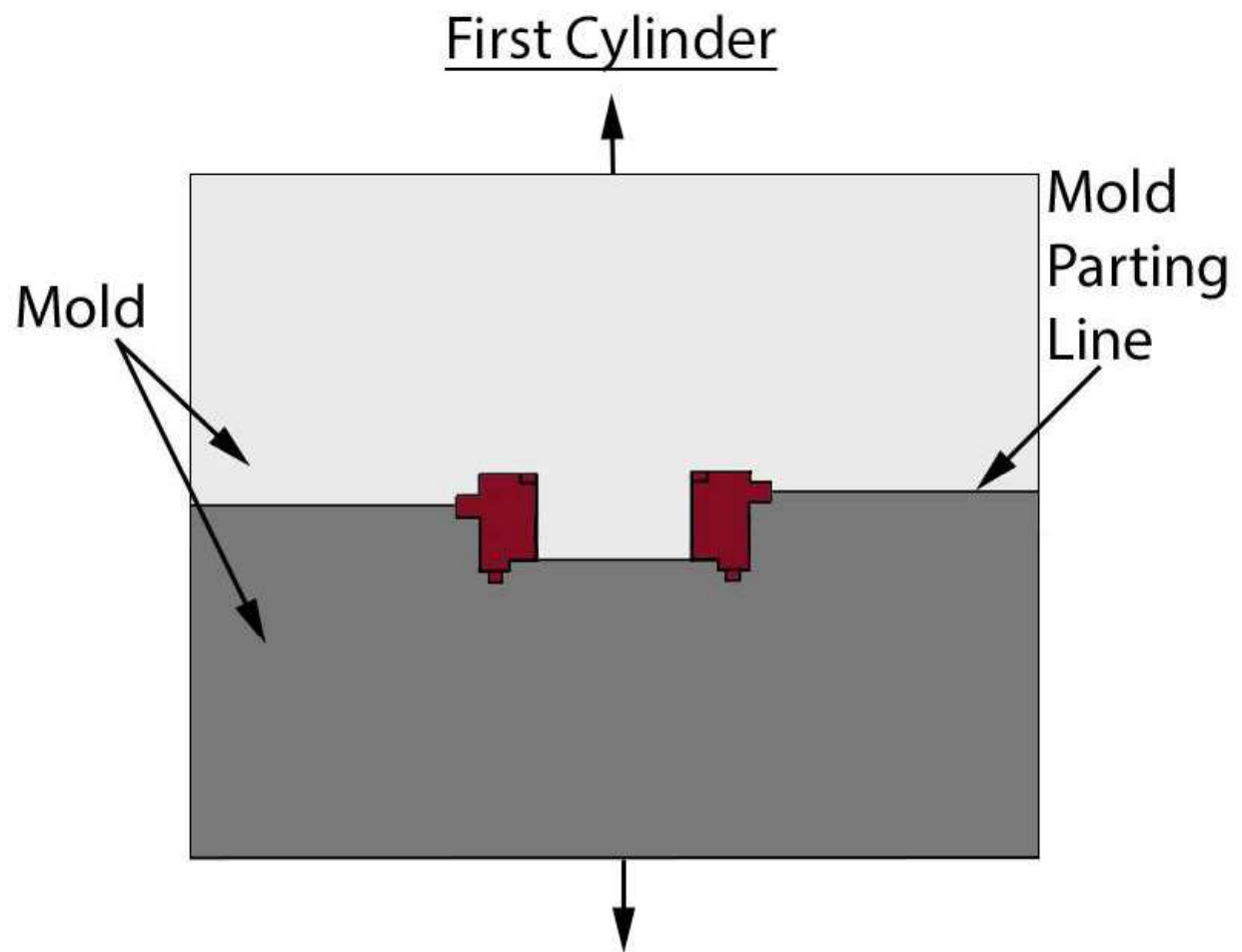
22. The tolerances needed for the components that make up the parts of the Cho annular valve were also conventional and readily attained since long before the '632 patent. Many, many millions of plastic caps that seal containers and plastic valves have been molded since long before the '632 patent.

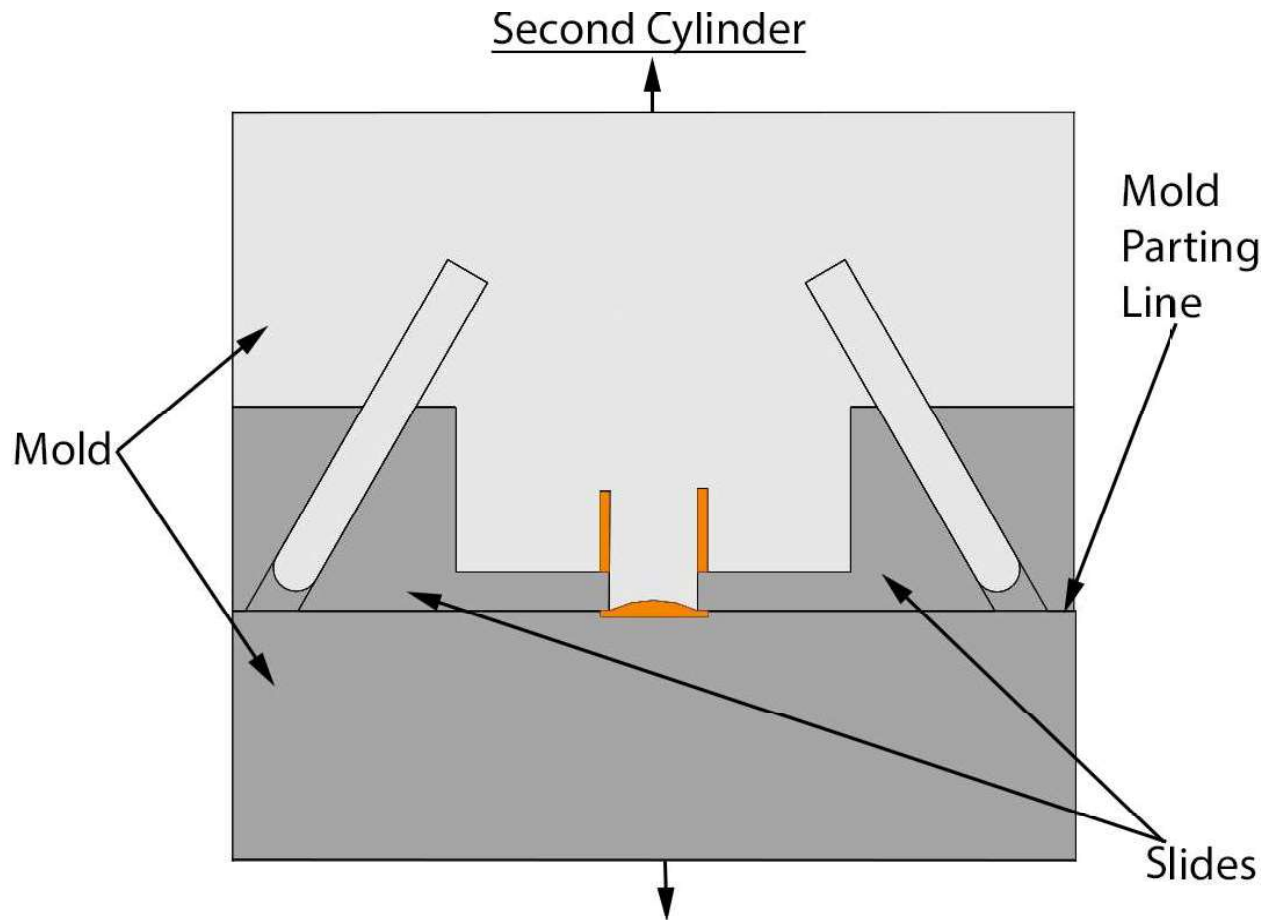
23. For example, plastic medical stop-cock valves that use rotating

cylinders to provide a sealed open – closed configuration have been available long before the '632 patent. Examples of such a valve are depicted in a 2001 Saint Gobain Performance Plastics Brochure (Ex. 1042). Another example of such valve is depicted in U.S. Patent No. 5,578,016 issued November 26, 1996 entitled “Stopcock.” 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.

24. A POSA would have also known that changing the size of the components that make up the Cho annular valve was conventional and straightforward. Changing the size of the components would not change the functionality of the parts or the valve or even change how they are molded. They fit together and seal in the same way. A POSA would correctly expect the valve to function in the same way when sized down.

25. I have shown below molds for sized – down versions of the inner and outer cylinders that would provide a smaller additive chamber. And the outer cylinder for this sized-down version would not extend into the container as depicted in the modified Fig. 44 of Cho above.





26. I disagree with Dr. Wereley’s opinion that scaling down or modifying Cho’s annular valve would require “extensive redesign and testing with an unpredictable outcome.” Ex. 2025, ¶ 62-85. As I describe above, changing the size of Cho’s annular valve for use with a lesser amount of additive would have been straightforward and would not have impacted the manner in which the annular valve works.

27. Dr. Wereley makes many generalities about alleged difficulties in molding the parts that make up the annular valve of Cho, but points to very few specifics, namely ratchet teeth, tolerances, and holes or ports. Ex. 2025, ¶¶ 78-80.

I disagree that molding issues would disincentivize a POSA from using Cho's annular valve in Plante as I have described above and in my prior declarations and depositions. With respect to ratchet teeth, these are common features that have been used on things such as medicine bottles, milk bottles, soda bottles, etc. The ratchet features on these bottles allow the caps to be screwed on the bottle, but when removed the ratchet teeth engage and tear off the tamper lock ring. The tolerances associated with the Cho annular valve are not any different than would be provided in many types of sealed caps and valves and a POSA would readily know how to design interference fits that provided a sealed arrangement of the parts or provide holes or ratchet teeth as necessary. I did not see any description in Cho that the device somehow needed particularly tight or unconventional tolerances. The holes, vents, or apertures in the inner cylinder and the outer cylinder that seals it is again the same arrangement of the two cylinders used in conventional stopcock valves that have been made and sold for decades as discussed above.

28. Patent Owner has separately argued several of the dependent claims. I address these below.

29. 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 14. 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.

30. Substitute dependent claim 33 adds “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.” Motion at 14-15.

31. Initially, the '632 patent specification does not describe an embodiment of the invention having a flange on the second, inner cylinder. The patent specification also does not describe that “*initial contact* between a flange and a portion of the sample collection vessel ... *causes* the annular valve to change from” the closed to open configuration.

32. In the disclosed embodiment that corresponds to the '632 patent claims (figures 3A and 3B), initial contact with a flange of the first cylinder does not cause the valve to change from closed to open. The cap must be rotated after initial contact, this causes the outer cylinder to rotate relative to the inner cylinder. And only after the outer cylinder has been rotated or screwed up the inner cylinder sufficient to pass the aperture, does valve change from closed to open.

33. I reviewed what Dr. Wereley said about claim 33. Not surprisingly, he did not address the “initial contact ...causes” requirement. Ex. 2025, ¶ 37.

34. 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.

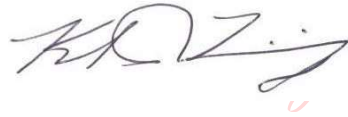
35. Substitute dependent claim 36 is identical to original claim 16 (subject to the amendments to claim 1). Motion at 6. The claim is obvious over Plante and Cho for the reasons described in my original declaration, Ex. 1002, ¶¶ 156-159, and because it would have been obvious to adjust the size of Cho as described above with respect to claim 21.

#### **IV. 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 December 12, 2024, in Dover, NH.



Digitally signed by Karl R.  
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Karl R. Leinsing, MSME, PE

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