

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.

Patent No. 11,536,632

Inter Partes Review No. IPR2023-01424

THIRD DECLARATION OF DR. STEVEN WERELEY

I, Dr. Steven Wereley, make this third declaration in connection with the proceeding identified above.

I. INTRODUCTION

1. I have been retained by counsel for DNA Genotek Inc. (“Genotek” or “Patent Owner”) as a technical expert in connection with the proceeding identified above. I submit this third declaration in support of Patent Owner’s Reply to Petitioner’s Opposition To Patent Owner’s Revised Non-Contingent Motion To Amend (hereafter “Petitioner’s Opposition”) for *Inter Partes* Review (“IPR”) of United States Patent No. 11,536,632 (“the ’632 patent”).¹

2. I am being paid at an hourly rate of \$710 for my work on this matter. My compensation does not depend in any way upon the opinions or testimony that I provide or the outcome of this litigation.

3. I am not a legal expert and offer no legal opinion in my report.

II. QUALIFICATIONS

4. I incorporate the description of my background in my first declaration herein.²

¹ Ex. 1001.

² Ex. 2014 at ¶¶ 4–13.

III. MATERIALS CONSIDERED

5. In forming the opinions set forth in this third declaration, I considered and relied upon my experience, knowledge of the field, and education.

6. In preparing this third declaration and earlier declarations, I have reviewed, among other things, the following materials: (a) U.S. Patent No. 11,536,632 (Ex. 1001); (b) Declaration of Karl R. Leinsing, MSME, PE, in Support of Petition for *Inter Partes* Review of U.S. Patent 11,536,632 (Ex. 1002); (c) U.S. Patent Pub. No. US 2012/0325721 to Plante, et al. (“Plante”) (Ex. 1003); (d) International Patent Publication No. WO 2005/051775 to Cho (“Cho”) (Ex. 1004); (e) U.S. Patent Publication No. 2006/0260959 to Patterson, et al. (“Patterson”) (Ex. 1010); (f) JP 2010-213660 to Ueda et al. (“Ueda”) (Ex. 1006) and the certified English language translation thereof (Ex. 1005); (g) U.S. Patent No. 4,761,379 to Williams et al. (“Williams”) (Ex. 1009); (h) the Petition for *Inter Partes* Review of the ’632 patent, (i) Patent Owner’s Non-Contingent Motion to Amend and Request for Preliminary Guidance (“Motion”) (Paper 16), (j) Petitioner’s Opposition Patent Owner’s Non-Contingent Motion to Amend (“Opposition”) (Paper 19), (k) Declaration of Karl R. Leinsing, MSME, PE in Support of Petitioner’s Opposition to Patent Owner’s Non-Contingent Motion to Amend (Ex. 1027), (l) the Preliminary Guidance (“Preliminary Guidance”) (Paper 21) by the Patent Trial and Appeal Board (“PTAB” or “Board”), (m) the

definitions of “external” and “aperture” as set forth in the American Heritage Dictionary of the English Language (Fifth Edition) (Exs. 2027 and 2028); (n) the deposition transcript of Mr. Karl Leinsing dated October 29, 2024 (Ex. 2026); (o) the Injection Molding Handbook, Chapter 8 (3d ed. 2000) (Ex. 1014) and Chapters 4-7 (Ex. 2029), and Declaration of Karl R. Leinsing, MSME, PE in Support of Petitioner’s Opposition to Patent Owner’s Revised Non-Contingent Motion to Amend (Ex. 1041).

IV. DEFINITIONS AND STANDARDS

7. I incorporate the descriptions of the definitions and standards in my first declaration herein.³

8. I understand that whether there is written description support for a claim is governed by 35 U.S.C. 112, first paragraph (pre-AIA). I further understand that courts consider a number of factors in determining written description support, including “the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.”⁴ Moreover, the “description requirement does not demand any

³ Ex. 2014 at ¶¶ 16–18.

⁴ *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

particular form of disclosure” or that the “specification recite the claimed invention in *haec verba*.”⁵ I am not a legal expert, but I understand that drawings and/or figures alone can be enough to show written description support.⁶ I understand that sometimes patent drawings are not “working drawings,” but when the drawings and/or figures show something clearly, one cannot ignore what is clearly shown.⁷

V. THE '632 PATENT

9. I incorporate the description of the '632 patent in my first declaration herein.⁸ I also understand that the intervening non-provisional applications (Exs. 2016–2018) are identical to the '003 application for the purposes of this Declaration.

⁵ *Id.* at 1352.

⁶ *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991) (finding that “drawings alone may be sufficient to provide the ‘written description of the invention’ required by § 112, first paragraph.”).

⁷ *In re Mraz*, 455 F.2d 1069, 1072 (C.C.P.A. 1972).

⁸ Ex. 2014 at ¶¶ 19–21.

VI. LEVEL OF ORDINARY SKILL IN THE ART

10. I incorporate my opinion on the level of ordinary skill in the art as of the earliest priority date of the '646 patent from my first declaration herein.⁹ As I noted in my first declaration, aspects of Mr. Leinsing's definition of the level of ordinary skill in the art are incorrect in my opinion. However, I believe the claims as set forth in this third declaration are patentable even under Mr. Leinsing's definition of the level of ordinary skill in the art.

VII. THE SUBSTITUTE CLAIMS OF THE '632 PATENT ARE SUPPORTED BY THE ORIGINAL DISCLOSURE

A. Substitute claim 21

11. A marked-up copy of revised substitute claim 21 (as submitted by Patent Owner in the Revised Non-Contingent Motion to Amend ("rMTA")) that shows the differences between revised substitute claim 21 and claim 1 of the '632 patent is presented below.

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

A sample collection vessel comprising

a sample collection reservoir,

a first connection member, and

⁹ Ex. 2014 at ¶¶ 22–25.

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.

13. As noted in my second declaration, I believe that revised substitute independent claim 21 is supported by the '003 application (Ex. 2015) – the original disclosure of the application that issued as the '632 patent. I hereby incorporate the detailed description of that support and the reasoning that led me to this conclusion from my second declaration herein (Ex. 2025, ¶¶ 19 - 29).

B. Support for substitute dependent claim 33

14. Patent Owner presented a revised substitute dependent claim 33 in the rMTA.

15. Revised substitute dependent claim 33 recites “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.”

16. As discussed in my second declaration, I believe that substitute claim 33 is supported by is supported by the '003 application (Ex. 2015). I hereby incorporate the detailed description of that support and the reasoning that led me to this conclusion from my second declaration herein (Ex. 2025, ¶¶ 37 - 38).

17. I understand that Mr. Leinsing disagrees, and has asserted that claim 33 lacks written description support. For example, Mr. Leinsing argues that claim 33 does not have written description support because there is allegedly no disclosure that “*initial contact* between a flange and a portion of the sample collection vessel..... *causes* the annular valve to change from” the closed configuration to the open configuration (see, e.g., Ex. 1041, ¶¶ 31-32). He also argues that the '632 Patent specification “does not describe an embodiment of the invention having a flange on the inner cylinder” (Ex. 1041, ¶ 31).

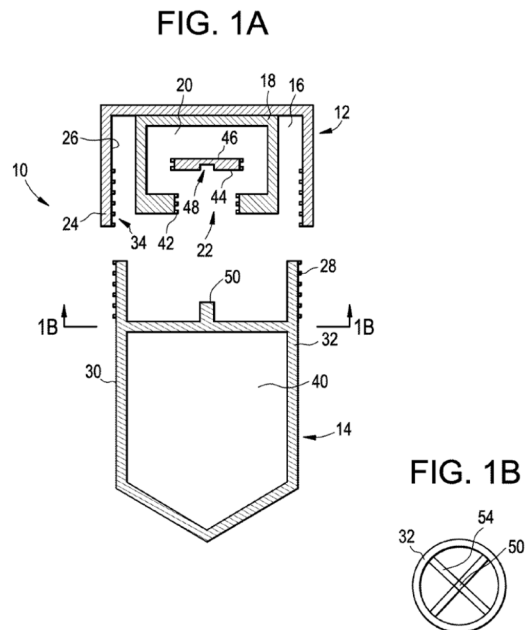
18. I disagree with these statements. As noted above, substitute claim 33 recites “wherein *initial contact* between the flange and a portion of the sample collection vessel *upon engagement of the cap to the sample collection vessel*

causes the annular valve to change from the closed configuration to the open configuration.” It is not the “*initial contact*” alone that causes the annular valve to change from the closed to the open configuration, but rather the initial contact in combination with “*engagement of the cap to the sample collection vessel*”, i.e., the flange is brought into contact with a portion of the sample collection vessel and causes the annular valve to open as the cap is attached (screwed on) to the sample collection vessel. This mechanism is distinctly different from the two-step mechanism by which Cho’s cap is operated (as will be discussed in more detail below), i.e., the cap is first attached to the bottle to create a fluid-tight seal (with the annular valve still in the closed configuration), and subsequently the cap is further tightened to open the valve.

19. Furthermore, 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. 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.

20. Finally, there are other embodiments described in the ’632 Patent. FIGS. 1A-B of the ’003 application (Ex. 2015, ¶ 76, and FIGS. 1A-B (reproduced

below)) 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.



21. In my opinion, therefore, substitute claim 33 is supported by the disclosure in the '632 Patent, and also differentiates the claimed device from one that would result from a combination of Plante and Cho as discussed in my previous declaration and below.

VIII. SUBSTITUTE INDEPENDENT CLAIM 21 IS PATENTABLE OVER PLANTE IN VIEW OF CHO

A. The Combination of Plante and Cho Does Not Teach All Limitations Of Substitute Independent Claim 21

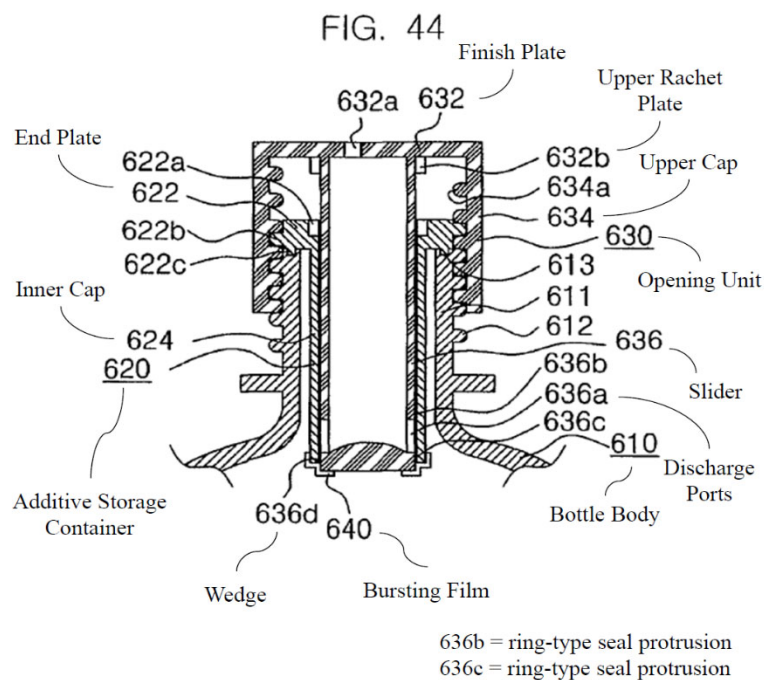
22. I understand that original independent claim 1 has been challenged under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Plante (Ex. 1003) and Cho (Ex. 1004). In my opinion, Plante and Cho fail to disclose or suggest the new limitations recited in amended substitute independent claim 21.

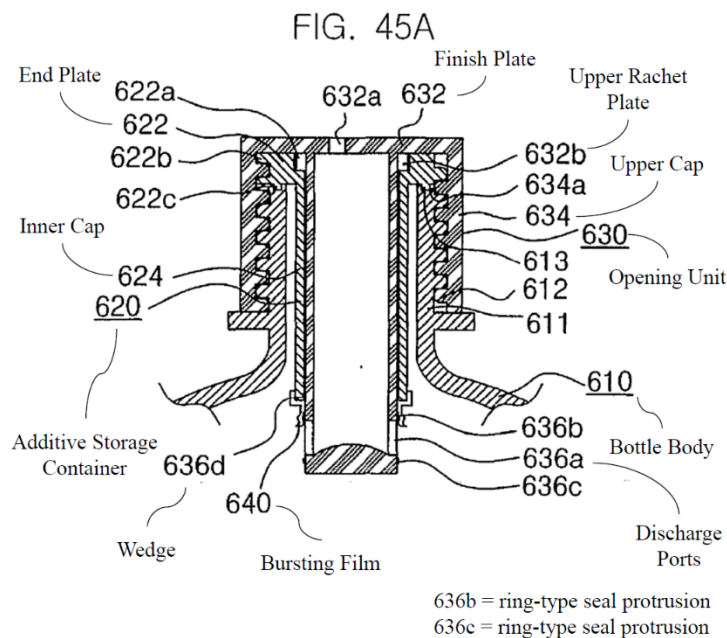
23. I incorporate the description of the Plante and Cho references in my first declaration herein.¹⁰

24. As noted above, revised substitute claim 21 has been amended to clarify the position of the annular valve (e.g., “*positioned in the interior volume of the cap*”) and to recite additional features (e.g., “*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*”) that differentiate the claimed device from that described in Cho when the claim is considered as a whole.

¹⁰ Ex. 2014 at ¶¶ 36–39.

25. Plante's device does not include an annular valve at all, and Cho's annular valve (depicted in the annotated versions of Cho's FIG. 44 (closed configuration) and FIG. 45A (open configuration) reproduced below) includes two cylindrical components that collectively make up the annular valve (i.e., additive storage container 620 (comprising inner cap 624 and end plate 622) and slider 636), and that clearly extend deep within the opening of bottle body 610. As recited in Cho at page 48, lines 27-32: "The additive storage container 620 comprises a circular end plate 622 formed on the open end of the additive storage part 611 [sic], and *an inner cap 624 that extends downward in an axial direction from the inner circumferential edge of the end plate 622 and is axially inserted into the mouth 611 in an axial direction.*" (emphasis added).





26. It is clear from these figures and the description thereof provided in Cho that the “first cylinder” (*i.e.*, which Petitioner maps to additive storage container 620, but which appears to also comprise inner cap 624 and end plate 622) extends into the mouth 611 of bottle body 610 in both the closed configuration (FIG. 44) and the open configuration (FIG. 45A) of the “annular valve”. Consequently, Cho’s “annular valve” does not include a “first cylinder” that *“is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve”* as is required by substitute claim 21.

27. Thus, in my opinion, neither Plante nor Cho, individually or in combination, disclose or suggest the new features recited in substitute claim 21, and therefore substitute claim 21 and its dependent claims are novel over the combination of Plante and Cho for at least the above reasons.

B. The Combination of Plante and Cho Does Not Render Substitute Independent Claim 21 Obvious

28. Throughout this proceeding, Mr. Leinsing has insisted that it would have been obvious to a POSITA to try to combine Plante’s saliva collection device (comprising a reagent compartment sealed by a puncturable membrane) with Cho’s beverage container device (comprising a form of an annular valve used to release a beverage additive) to arrive at the claimed device. I disagree for at least the reasons reiterated below.

1. Cho’s annular valve is not “essentially identical” to, and does not “function identically” to, the device claimed in the ’632 Patent

29. Mr. Leinsing has characterized Cho’s device as being “*essentially identical to that described in the ’632 patent*” (emphasis added; see, e.g., Ex. 1041, ¶¶ 7-9) and has stated that it “*functions in the same manner*” to the device described in the ’632 Patent (emphasis added; see, e.g., Ex. 1041, ¶ 34). Furthermore, he has repeatedly insisted that to modify and combine Cho’s annular valve with Plante’s saliva collection device would be a “*simple substitution of one known element for another*” (emphasis added; see, e.g., Petition, p. 16, third para.;

Ex. 1002, ¶¶ 16, 74) that would require only “*resizing*” of Cho’s device (see, e.g., Ex. 1041, ¶¶ 10-12, 15). These are nonsensical arguments.

30. First, based on an inspection of Cho’s FIGS. 44 and 45A and their accompanying description, a POSITA would recognize that the design of Cho’s annular valve is clearly quite different from that of the device claimed in the ’632 Patent (see, e.g., FIGS. 3A-B of the ’632 Patent). Although they share the feature that turning one cylindrical part relative to another causes a vent to open, the mechanism for opening that vent is very different with regard to how the two cylindrical components are configured, where threads and other features are located, etc.

31. In addition to the fact that both of the cylindrical components of Cho’s annular valve (i.e., additive storage container 620 and slider 636) extend well into the mouth of bottle body 610 (Cho, FIGS. 44 and 45A) - perhaps for improved mixing of an additive released from the cap with a beverage in the bottle (see Ex. 1004, 55:13-25) – other examples of design differences between Cho’s device and that claimed in the ’632 Patent include as follows:

32. The outer cylinder of Cho’s annular valve (mapped to additive storage container 620 by the Petitioner) comprises inner cap 624, end plate 622 (the latter including external threads 622b) and engages directly with the bottle body 610 in both the open and closed valve states, the internal threads 634a of upper cap 634,

and with the inner cylinder (slider 636). The outer cylinder of the embodiment of the claimed device illustrated in FIGS. 3A-B does not engage directly with the interior threads of the cap, and only contacts the rim of the sample collection vessel upon attachment of the cap.

33. Cho's design includes ratchet features, e.g., lower ratchet plate 622a that engages with upper ratchet plate 632b so that the opening unit 630 is allowed to rotate in only one direction relative to the additive storage container 620 (Cho, page 49, lines 28 - 33), and upper ratchet 622c that engages with a lower ratchet 613 formed on the top of the bottle mouth 611 so that the additive storage container 620 is allowed to rotate only in one direction relative to the mouth 611 (Cho, page 49, lines 1 - 4).

34. Other differences between Cho's design and that of the claimed device include Cho's use of ring-type seal protrusions to prevent leakage between inner cap 624 and slider 626, incorporation of the wedge feature 636d, and sealing of the ends of the two cylindrical components with bursting film 640. All of these design differences can result in longer development times and increased manufacturing (fabrication and assembly) complexity and cost (*i.e.*, parts that are more difficult to fabricate and/or to assemble).

35. These differences in design lead to differences between how Cho's device and that claimed in the '632 Patent are operated, despite Mr. Leinsing's

assertions that they function “in the same manner” (see, e.g., Ex. 1041, ¶ 34).

Cho’s design is used to implement a two-step cap attachment process that reflects the difference in requirements for the application for which it was designed. The cap is attached to the bottle to create a fluid tight seal with the annular valve remaining in the closed configuration, e.g., during distribution of a beverage product (Cho, p.1, lines 19 – 24, and FIG. 44). In this first stage of attachment, the outer cylinder (additive storage container 620, comprising inner cap 624, end plate 622, and external threads 622b) is fully inserted into mouth 611 of the bottle body 610, abuts the upper edge of bottle mouth 611, and is engaged with the internal threads 634a of upper cap 634. It is only upon further tightening of the upper cap 634 that the inner cylinder (slider 636) is further advanced into bottle mouth 611 and the annular valve changes to the open configuration to release an additive.

36. In contrast to Cho’s device, attachment of the cap to the sample collection vessel (designed for, e.g., saliva collection, where the cap is shipped separately from the sample collection vessel) in the claimed device (illustrated in FIGS. 3A-B of the ’632 patent) *brings a flange (coupling feature 48) on the outer (first) cylinder (annular blocking member 62) into contact with the rim (coupling member 50) of the sample collection vessel*, which causes the outer (first) cylinder (annular blocking member 62) to recess further into cap 12 and *moves the annular*

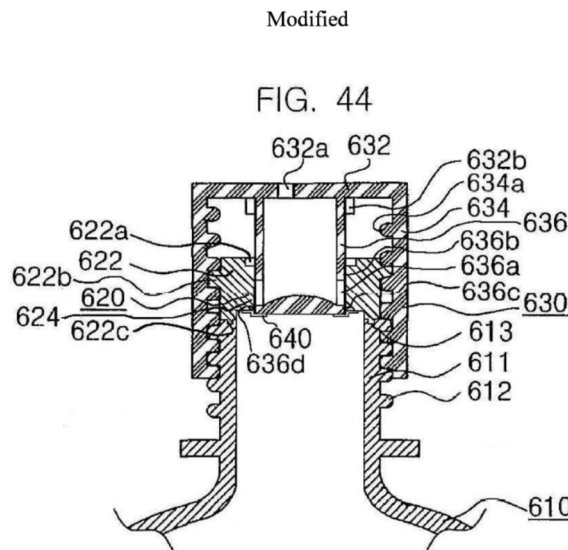
valve from the closed configuration to the open configuration as the cap is tightened. I should note that substitute claim 33 is directed to this subject matter.

37. Again, the differences in design between Cho's device and that claimed in the '632 Patent lead to different mechanisms for operation, which in turn reflect the different functions of these devices in their respective applications (i.e., shipment of beverages and an additive in a container that keeps the **two components** separate (e.g., to prevent deterioration) until mixing is desired) versus collection of a biological sample (e.g., a saliva sample) in a container that requires minimal manipulation by the user, that minimizes the chance of accidental contamination of the sample (e.g., through accidental touching of internal components of the sample collection device by the user after depositing a sample), and that prevents exposure to toxic chemicals (e.g., by accidental release of a sample preservative by the user prior to attaching the cap to the sample collection tube after depositing a sample). The device in the '632 Patent is manufactured with a single biological sample preservative stored in the cap, and the cap is separate from the empty sample collection vessel when the device is shipped to the end user prior to use.

2. The amendments to substitute claim 21 are not directed to a simple resizing of Cho's valve

38. Mr. Leinsing repeatedly argues that the amendments to substitute independent claim 21 are directed to a simple *adjustment of the size* of Cho's valve (see, e.g., Ex. 1041, ¶¶ 6, 11), and that a POSITA would have had a reasonable expectation of success in doing so (see, e.g., Ex. 1041, ¶¶ 15, 24-25). I disagree. Rather, the amendments to substitute claim 21 are directed to features that differentiate the claimed device from one that would result from attempting to combine Plante and Cho, and that cannot be achieved by simply resizing Cho's device. 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).

39. Mr. Leinsing provides a figure which he asserts illustrates that a *simple adjustment of the size* of Cho's device would yield the same device as that claimed in the '632 patent (see, e.g., Ex. 1041, ¶¶ 11-12). In this figure, reproduced below, Mr. Leinsing has: (i) decreased the length of slider 636, (ii) extended the



Leinsing's drawing, reference characters 624 and 622 are both pointed at the same part).

40. Cho describes inner cap 624 as extending “downward in an axial direction from the inner circumferential edge of the end plate 622”, and specifies that it “is axially inserted into the mouth 611 in an axial direction” (Ex. 1004, p. 48, lines 27-31). Beyond the fact that the extended cylinder labeled 624 is missing, Mr. Leinsing's replacement for inner cap 624 (i.e., modified end plate 622) cannot be inserted into the mouth of the bottle axially. Because it's so short, modified slider 636 only enters the mouth of the bottle after the user begins screwing the cap onto the bottle, which means that it enters helically, i.e., in a cork screw motion. In Cho's design, the manufacturer would insert the end of the inner cap 624 into the mouth of the bottle (e.g., after assembly and filling at the factory) until the cap threads engaged with the bottle threads and end plate 622 abuts the upper edge of bottle neck 611. Then the user screws the cap on further to insert slider 636 deeper into bottle 610 and release an additive from the additive storage compartment through discharge ports 636a.

41. Mr. Leinsing's edited figure points to wedge 636d as being located very near the end of modified slider 636. Cho states that the purpose of the wedge is to keep the slider from “rising up over a predetermined position relative to the inner cap 624” (Ex. 1004, p. 49, lines 22-24). Given the indicated proportions of

modified slider 636 and the position of wedge 636d, it appears to serve no purpose since it can't prevent the slider 636 from moving up even further.

42. Finally, the part labeled bursting film 640 has been modified from the way Cho drew it. Cho shows that the bursting film would be wrapped around the end and up the side of the inner cap 624 (Ex. 1004, FIG. 44). Mr. Leinsing has modified the part so that bursting film 640 is just sealed on the bottom face of the inner cap. That changes the seal and makes it less robust. Cho's specification doesn't describe how bursting film 640 is fabricated or attached to the other parts, but he clearly draws how it is meant to be affixed to the lateral sides of the inner cap.

43. At least two of the parts shown in Leinsing's modified Cho valve have actually been significantly increased in size (cap 634 and end plate 622) rather than decreased in relation to Cho's original design, while others have been shrunk (e.g., the length of slider 636). As such, the device illustrated in this figure is not a mere re-sizing of Cho's device but a significant structural redesign that is neither taught nor suggested in Cho. Furthermore, the device illustrated in Mr. Leinsing's modified version of Cho still operates in a different manner than that of the claimed device, i.e., the cap is attached to the bottle to form a fluid-tight seal while the annular valve remains in the closed configuration, and it is only after the cap is further tightened that the annular valve moves to the open configuration.

3. Redesign of Cho's device would require addressing a number of challenging molding and manufacturing issues

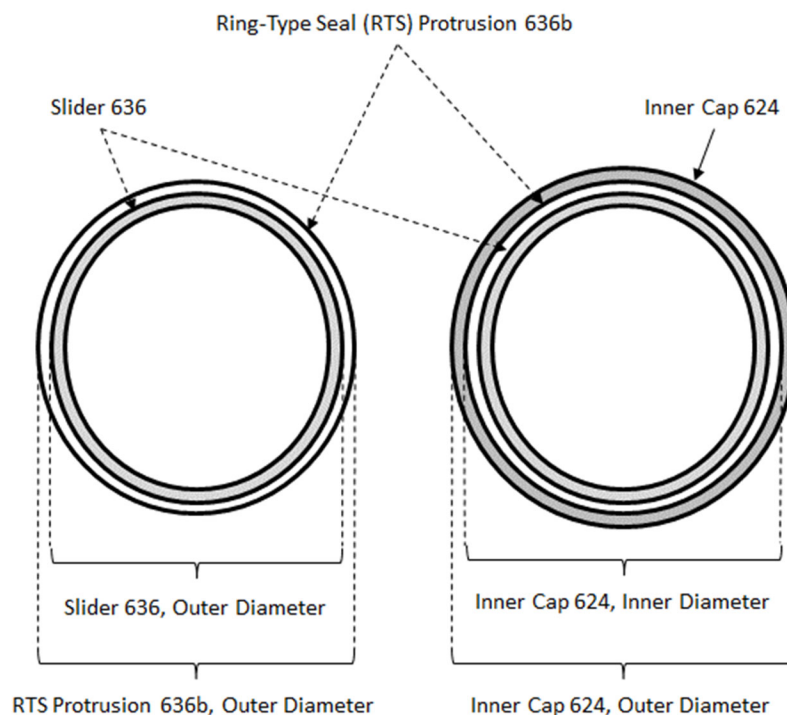
44. The many differences in design between Cho's cap and the claimed device (and the resulting differences in the operation of these devices) refute the statements made by Mr. Leinsing that combining Cho's annular valve with Plante's sample collection device would be a "*simple substitution of one known element for another*" (see, e.g., Petition, p. 16, third para.; Ex. 1002, ¶¶ 16, 74). Rather than a simple resizing of Cho's valve, combining Plante's device with Cho's device would require a significant redesign of Cho's valve – as discussed above – that would entail addressing a number of molding and manufacturing issues that can be problematic. These problems were discussed in my second declaration (see, e.g., Ex. 2025, ¶¶ 66 – 85), which is incorporated herein, and are also discussed in the injection molding references cited by Mr. Leinsing in his previous declarations (see, e.g., Exhibits 1014, 1015, and 2029) which provide numerous examples of parts and features that can be problematic to fabricate by injection molding. I note in passing that Mr. Leinsing failed to respond to these arguments in any detail in the most recent Leinsing declaration (Ex. 1041).

45. As noted in my second declaration, examination of Cho's FIGS. 43, 44, and 45A indicates that Cho's opening unit 630 comprises approximately three separately fabricated parts – upper cap 634 (including integrated slider 636), inner

cap 624, and bursting film 640 (or four separate parts including bottle 610) – that collectively include about 15 – 17 distinct parts and/or part features (see, e.g., Ex. 2025, ¶¶ 67, 77).

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 (Ex. 2025, ¶78.) 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. For example, ring-type seal protrusions require a very tight tolerance on both their outer diameter and their concentricity with a mating cylindrical surface, as schematically illustrated in the figure below, and are often damaged when being

withdrawn from a mold. This cross-sectional view of the cylindrical components of Cho's valve (slider 636 is shown at left; slider 636 inserted into inner cap 624 is shown at right), illustrates some of the critical dimensions that would be required to mold this device, e.g., the outer diameters of slider 636 and ring-type seal protrusion 636b (which must mate with the inner diameter of inner cap 624), the inner and outer diameters of inner cap 624, and the concentricity of all of these parts. Failure to hold these parts to tight tolerances would result, for example, in leakage between the cylinders and/or binding of parts, such as between external threads 622b and the internal threads of the cap (Ex. 2025, ¶79). This is in direct



contradiction to Mr. Leinsing's statement that "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” (Ex. 1041, ¶ 24).

47. I note that Mr. Leinsing has submitted two references (Exhibits 1042 and 1043) to support the assertion that high volume injection molding of parts such as medical stop-cock valves requiring tolerances such as those required for Cho’s device was conventional at the time the application that issued as the ’632 Patent was filed (Ex. 1041, ¶¶ 22 - 23). However, the required tolerances for these devices are not recited in Mr. Leinsing’s declaration or in the cited references, and the amount of iterative design, prototyping, and testing that was required to bring these products to market is also not specified.

48. Mr. Leinsing asserts that Cho’s annular valve “could be made in a *very straightforward manner* using three molds and NOT “at least six molds” as suggested by Dr. Wereley” (Ex. 1041, ¶ 18; emphasis added), and has provided several figures which he asserts illustrate mold designs that could be used to easily manufacture Cho’s device, or a modified version thereof (Ex. 1041, ¶¶ 18 – 21, 25). However, I note that each of these “three molds” comprises multiple parts (e.g., upper and lower molds, unwinding core pins, sliders, etc.) and that Mr. Leinsing does not address the fabrication of the bottle (which includes a lower ratchet 613 that engages with upper ratchet 622c on the underside of circular end plate 622 to ensure that the additive storage container 620 is allowed to rotate only

in one direction relative to the mouth of the bottle). 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. 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 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.

51. As noted by Mr. Leinsing (Ex. 1041, ¶ 20), if molded separately from the cap, the second cylinder (Cho's slider 636) would then need to be connected to the cap using, e.g., ultrasonic welding, spin welding, or another technique. Some of these techniques, e.g., sonic welding, can be difficult to perform on small parts due to, e.g., insufficient access for insertion of the ultrasonic welding head, but in any case would require the addition of additional steps (and associated cost) to the manufacturing (fabrication and assembly) process.

52. These same arguments apply to the mold designs provided by Mr. Leinsing for the modified version of Cho's device (Ex. 1041, ¶ 25).

53. Mr. Leinsing disagrees with my previously stated opinion that scaling down or modifying Cho's annular valve would require "extensive redesign and testing with an unpredictable outcome." (see, e.g., Ex. 1041, ¶¶ 15 and 26), and goes on to state that "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." For at least the reasons outlined above, my opinion remains unchanged – a POSITA would not have been motivated to redesign Cho's valve in an attempt to combine it with Plante's saliva collection device because to do so would entail addressing a number of molding and manufacturing issues that would increase the complexity and cost of manufacturing the device.

54. Mr. Leinsing goes on to state that my previous declaration provided "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. 1041, ¶ 27), and goes on to state that he "disagree[s] that molding issues would disincentivize a POSITA 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." I disagree with the statement that my previous declaration provided "generalities"

but “few specifics” and note that, in Mr. Leinsing’s latest declaration (Ex. 1041), Mr. Leinsing has not responded in detail even to the “few specifics” that he recited. With regard to ratchet teeth, Mr. Leinsing provides the example of existing products (medicine bottles, milk bottles, soda bottles, etc.) but provides no discussion of how the inclusion of ratchet features might impact molding yields at a much smaller scale (e.g., in a saliva sample collection device) instead of large scale bottles.

55. Mr. Leinsing goes on to state that “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 POSITA would readily know how to design interference fits that provided a sealed arrangement of the parts” (Ex. 1041, ¶ 27). Again, Mr. Leinsing provides no detailed discussion of what tolerances would be required, but rather points to two new references (Exhibits 1042 and 1043) which, as pointed out above, do not recite the tolerances required for manufacturing these devices, and do not specify the amount of development time that was required to bring these products to market.

56. Finally, Mr. Leinsing states that “a POSITA would readily know how to design interference fits that provided a sealed arrangement of the parts” and that “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...” (Ex. 1041, ¶ 27).

However, as discussed in Cho at, e.g., p. 49, lines 16 – 21, it is the ring-type seal protrusions 636b and 636c, not an interference fit between cylindrical components, that prevents leakage between the inner and outer cylinders of Cho’s device.

57. Thus, based on a review of the figures provided by Mr. Leinsing in his latest declaration, I believe that the process for fabricating Cho’s valve, or a modified version thereof, would be significantly more complicated than that required to fabricate Plante’s original device, and that a POSITA would have no incentive for attempting to modify Cho’s valve in order to combine with Plante’s saliva sample collection device.

4. A POSITA would have no motivation to combine Plante with Cho, and attempting to do so would have led to an unpredictable result

58. As stated in my previous declarations, and as discussed in some of the arguments outlined above, in my opinion a POSITA would have had no motivation to attempt to combine Cho’s annular valve with Plante’s device to arrive at the claimed invention. Furthermore, even if a POSITA had chosen to attempt to modify Cho’s valve, successfully doing so would have required them to address design and manufacturing issues leading to an unpredictable result. To reiterate some of those arguments:

59. A POSITA would have had no reason to try modifying Plante's simple design by combining it with Cho's more complex valve mechanism in the first place, especially in the field of clinical diagnostics where sensitivity to the cost of goods sold is often a driver in decision making. In looking for alternatives to Plante's design, a POSITA would have looked at analogous art within the same field (clinical diagnostics / sample collection devices) rather than to prior art in unrelated fields, such as that of the beverage container industry. Furthermore, a POSITA would be looking for a design that requires a minimal number of parts and/or features in the interest of keeping fabrication and assembly costs down.

60. Even if a POSITA had decided to do so, modifying Cho's valve so that it could be combined with Plante's device would have required significant redesign as discussed above (not a simple "adjustment of size", as repeatedly claimed by Mr. Leinsing). Redesign of Cho's valve would, in turn, require additional prototyping and testing of a scaled down version of Cho's device (i.e., this would not have been a "simple substitution", as repeatedly claimed by Mr. Leinsing), and would have introduced additional manufacturing steps and associated cost as compared to that required to produce Plante's original device.

61. As noted in my second declaration (see, e.g., Ex.2025, ¶ 65), Mr. Leinsing has continued to mischaracterize my previous testimony regarding the possibility of modifying Cho's valve. My previous acknowledgement that a

POSITA would understand that Cho's design *could be modified* is not the same as stating that *it would be easily done by a POSITA*, nor is it the same as saying that a POSITA *would be motivated to attempt to do so*. 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. Furthermore, I don't think the inner cylinder (Cho's slider 636) can be manufactured using the molds Mr. Leinsing describes due to the presence of the ring-type seal protrusions 636b as discussed above.

62. Yet another argument for why a POSITA would not have been motivated to try to modify and combine the devices of Plante and Cho is that Cho's design would defeat the purpose of Plante. Cho's cap is designed to be attached to

a beverage bottle prior to distribution of the product. If incorporated into a sample collection device similar to that of Plante that is shipped to a user for sample collection, the design would require the user to remove the cap from the sample collection vessel prior to depositing a sample. Furthermore, the ratchet features included in Cho's design allow rotation of additive storage container 620 (corresponding roughly to Plante's sealing cap 21) and opening unit 630 (again, corresponding roughly to Plante's sealing cap 21) in only one direction (Ex. 1004, p. 49, lines 1-4 and lines 28-33). Thus, an attempt to combine Plante and Cho would yield a device which would be difficult to open by the user and, if forced, could prevent a fluid tight seal when the cap was replaced by the user after depositing a sample.

63. One of the alleged motivations originally put forth by the Petitioner and Mr. Leinsing for why a POSITA would have attempted to modify Cho's valve and combine it with Plante's device is that a POSITA would allegedly have been motivated by safety incentives to eliminate Plante's knife using Cho's safer annular valve in the cap (see, e.g., Petition, p. 15, second para.). As noted in my previous declaration (Ex. 2025, ¶¶ 57-58; incorporated herein by reference), a POSITA would not have viewed Plante's device as presenting a significant risk of injury as commercial devices similar to Plante's are already on the market, with no reported safety issues. Furthermore, even if concerned about safety, simple design

choices were available to a POSITA to modify Plante's device (e.g., the diameter of the sample collection tube and/or the position of knife relative to top of tube could be modified to prevent accidental contact).

64. Another of the alleged motivations originally put forth by the Petitioner and Mr. Leinsing for why a POSITA would have attempted to modify Cho's valve and combine it with Plante's device is that a POSITA would allegedly have known that it is difficult and more expensive to mold sharp thin features in plastic, like Plante's knife (see, e.g., Petition, p. 15, third para.). I disagree, as noted in my previous declaration (Ex. 2025, ¶ 57). Furthermore, a POSITA would not have considered molding Plante's knife as being insurmountable because, again, commercial devices similar to that of Plante were already on the market.

65. Yet another one of the alleged motivations originally put forth by Mr. Leinsing for why a POSITA would have attempted to modify Cho's valve and combine it with Plante's device is that using an annular valve like Cho's instead of Plante's knife design would allow the cap to seal onto the vessel before the valve is opened (see, e.g., Petition, p. 16, second para.). It would make no sense for a POSITA to attempt to modify Cho's design and combine it with Plante's saliva collection device, as the cap and sample collection vessel for a saliva collection device would be shipped as separate components, both to minimize the amount of manipulation required of the end user and to avoid a potential source of

contamination and/or exposure to toxic chemicals if the end user were to accidentally twist the cap in the wrong direction while attempting to remove it from the sample collection vessel prior to depositing a sample.

66. Finally, another of the alleged motivations originally put forth by Mr. Leinsing for why a POSITA would have attempted to modify Cho's valve and combine it with Plante's device is that the combination of Plante and Cho would allegedly involve *the simple substitution of one known element for another*—Plante's cap for Cho's cap—to *yield predictable results* (see, e.g., Petition, p. 16, third para.). As discussed extensively in my previous declarations and above, I disagree with both of these assertions. The modification of Cho's valve in an effort to combine it with Plante's device would not be considered a "*simple substitution*" by one of skill in the art, nor would it yield "*predictable results*".

67. Thus, in my opinion, revised substitute independent claim 21 is both novel and non-obvious in view of Plante and Cho.

IX. SUBSTITUTE DEPENDENT CLAIMS 29, 33, AND 36 ARE PATENTABLE OVER PLANTE IN VIEW OF CHO

1. Substitute dependent claim 29

68. Substitute dependent claim 29 recites "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." Plante's device does not include an annular valve. As

illustrated in FIGS. 43, 44, and 45A of Cho, the outer and inner cylinders of Cho's "annular valve" (i.e., additive storage container 620 (a first cylindrical component) and slider 636 (a second cylindrical component) as described above) clearly are not confined to be "relatively moveable entirely within the interior volume of the cap" as is required by substitute dependent claim 29. Thus, in my opinion, substitute dependent claim 29 is patentable over the combination of Plante and Cho both because it depends from, and further limits, substitute independent claim 21, and for this additional reason.

2. Substitute dependent claim 33

69. Substitute dependent claim 33 recites "wherein initial contact between the flange [extending from at least one of the first and second cylinders] 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." Again, Plante's device does not include an annular valve. As illustrated in FIGS. 43, 44, and 45A of Cho, a flange (endplate 622) attached to Cho's first cylinder (additive storage container 620, comprising inner cap 624) is already in contact with a portion of the mouth of bottle body 610 (i.e., lower ratchet 613) prior to changing the "annular valve" from the closed configuration (FIG. 44) to the open configuration (FIG. 45A) upon tightening of upper cap 634 to the threaded mouth of bottle body 610. As discussed in detail

above, this is a different mechanism for opening the annular valve than that described in Cho. Thus, in my opinion, substitute dependent claim 33 is patentable over the combination of Plante and Cho both because it depends from, and further limits, substitute independent claim 21, and for this additional reason.

3. Substitute dependent claim 36

70. Substitute dependent claim 36 recites the feature “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.”

71. Plante describes a saliva collection device for direct-to-consumer use in diagnostic application. (Ex. 1003, [0017].) As described in Plante, the sealing cap comprising the reagent reservoir is provided as a separate component of the kit that includes the sealing cap (storing a reagent) and the empty sample receiving vessel. (See, e.g., Ex. 1003, [0018]–[0022].) Cho’s device is designed for commercial sale and distribution of a beverage in a configuration where the cap has already been attached to the bottle. As described by Cho: “Accordingly, the present invention has been made keeping in mind the above problems occurring in the prior art, and 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.) As illustrated in Cho, FIGS. 43, 44, and 45A, Cho’s opening unit 630 is designed to be attached to bottle body 610 prior to release of the additive stored within the additive storage container 620. Only after upper cap 634 is further tightened is slider 636 pushed past the end of inner cap 624 to open the discharge ports 636a.

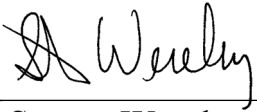
72. Cho’s device thus addresses a different need, i.e., shipment of two kinds of materials stored separately (e.g., to prevent deterioration) in a single bottle for subsequent mixing (e.g., a coffee-based beverage to be mixed with sugar or cream powder. (Ex. 1004, 1:8–12, 55:22-25)) than that addressed by Plante’s device (or the device claimed in the ’632 patent), i.e., the need to ship a sample preservative stored in a separate container (e.g., a cap) from the sample collection vessel, but configured for reliable and safe release of the preservative when the cap is attached to the sample collection vessel.

73. Thus, in my opinion, a POSITA would have had no motivation to combine Cho’s valve (or a modified version thereof) with Plante’s sample collection device, and therefore submit that substitute dependent claim 36 is patentable over the combination of Plante and Cho both because it depends from, and further limits, substitute independent claim 21, and for this additional reason.

* * *

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 that these statements were made with 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.

Dated: Jan 03, 2025



Dr. Steven Wereley