

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

SECOND DECLARATION OF DR. STEVEN WERELEY

I, Dr. Steven Wereley, make this second 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 second declaration in support of Patent Owner’s Revised Motion to Amend (“Revised Motion”) 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

III. MATERIALS CONSIDERED

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

¹ Ex. 1001.

² Ex. 2014 at ¶¶ 4–13.

6. In preparing this second declaration, 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 to which my declarations relate, (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); and

(o) the Injection Molding Handbook, Chapter 8 (3d ed. 2000) (Ex. 1014) and Chapters 4-7 (Ex. 2029).

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 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

³ Ex. 2014 at ¶¶ 16–18.

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

⁵ *Id.* at 1352.

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.

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

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.

⁹ Ex. 2014 at ¶¶ 22–25.

as set forth in this second declaration are patentable even under Mr. Leinsing's definition of the level of ordinary skill in the art.

VII. CLAIM CONSTRUCTION

11. I understand that, in an IPR proceeding, claim terms are construed under the same standard that is used by a federal court to construe a claim in a civil action. Therefore, I have reviewed the revised substituted claims based on how a person of ordinary skill in the art ("POSITA") at the time of invention (*i.e.*, June 19, 2011) would have understood the claim terms in view of the claim language, the specification, and the prosecution history. Extrinsic evidence, such as dictionaries, may also be considered.

12. Revised substitute claim 21 provides in part "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." In my opinion, the word "externally" would have been understood based on its ordinary and customary meaning, *i.e.*, the first cylinder is "outside of" or "exterior to" the sample collection vessel. For example, the American Heritage Dictionary defines external (as an adjective) as "[r]elating to, existing on, or connected with the *outside* or an outer part; *exterior*."¹⁰

¹⁰ Ex. 2027 (defining the word "external").

13. I understand that Mr. Leinsing had a similar understanding of the term “external” in answering questions at his deposition relating to Cho:

14. Q. So let me ask you: How do you understand the term “external thread 622B” and “external thread 612” on Page 49 of the Cho reference?

A. So it would be on the exterior or external surface of those particular features. So the converse would be in Line 8 of Page 49, it says “internal thread 634A” so that would be on the internal cylindrical surface where the others would be on the external portion or the outer cylindrical surface.”¹¹

15. I understand that Cho uses “external” in a largely consistent way. Cho describes a bottle body 610 with “a mouth 611 having an external thread 612 formed around the outer circumferential surface of the mouth 611,” meaning “external” components are on the outside or “outer” portion of a component.¹² Cho thus similarly uses “external” as a modifier to describe components that are on the outside.

¹¹ Ex. 2026 at 115:24–16:8.

¹² Ex. 1004 at 48:16–18.

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

16. I understand that Patent Owner has presented a revised substitute independent claim (claim 21) for independent claim 1. A marked-up copy of claim 21 that shows the differences between substitute claim 21 and claim 1 of the '632 patent is presented below.

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

A sample collection vessel comprising

a sample collection reservoir,

a first connection member, and

a first aperture for receiving a biological sample;

a cap comprising

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

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

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

a moveable annular valve positioned in the 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.

18. As shown above, substitute independent claim 21 adds new features to challenged independent claim 1 that modify the claim in three significant ways: (1) by amending the description of the “cap” to specify that the cap comprises “an outer wall defining an open end of the cap, an opposing closed end of the cap, and an interior volume of the cap”; (2) by clarifying that the reagent chamber and the moveable annular valve are “positioned in the interior volume of the cap”; and (3) by clarifying that 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.” Based on my review of substitute independent claim 21, I believe that it is supported by the ’003 application (Ex. 2015) – the original disclosure of the application that issued as the ’632 patent.

A. The “outer wall” of the cap defines “an open end of the cap, an opposing closed end of the cap, and an interior volume of the cap”

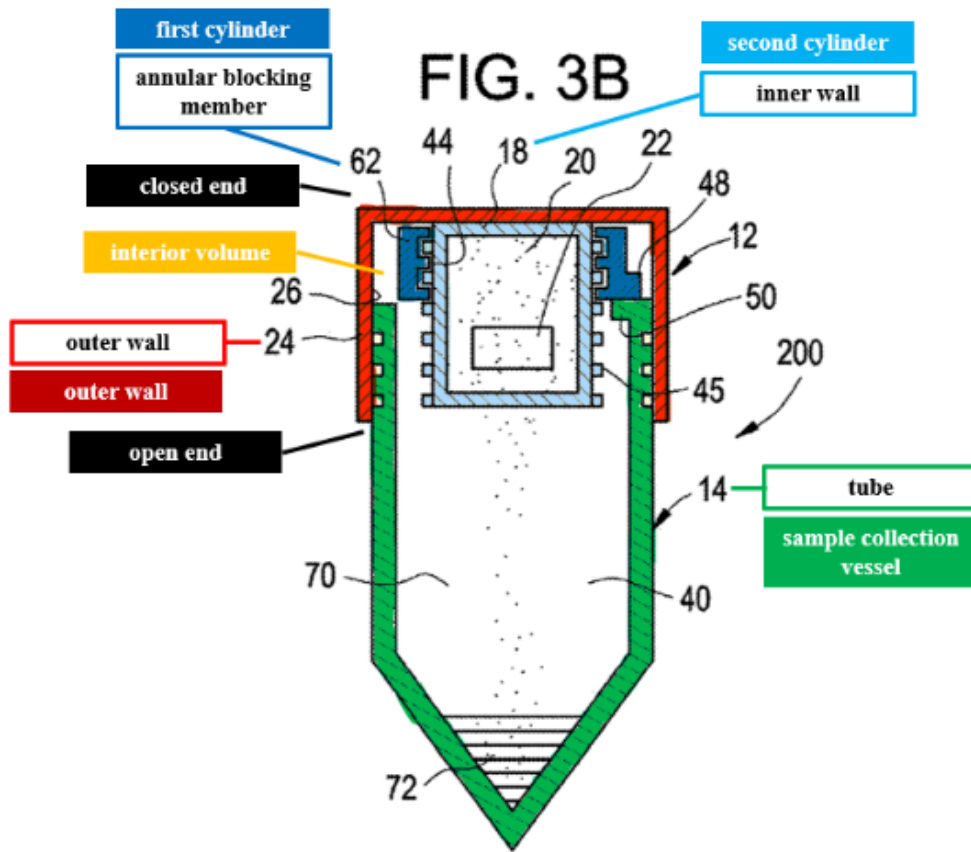
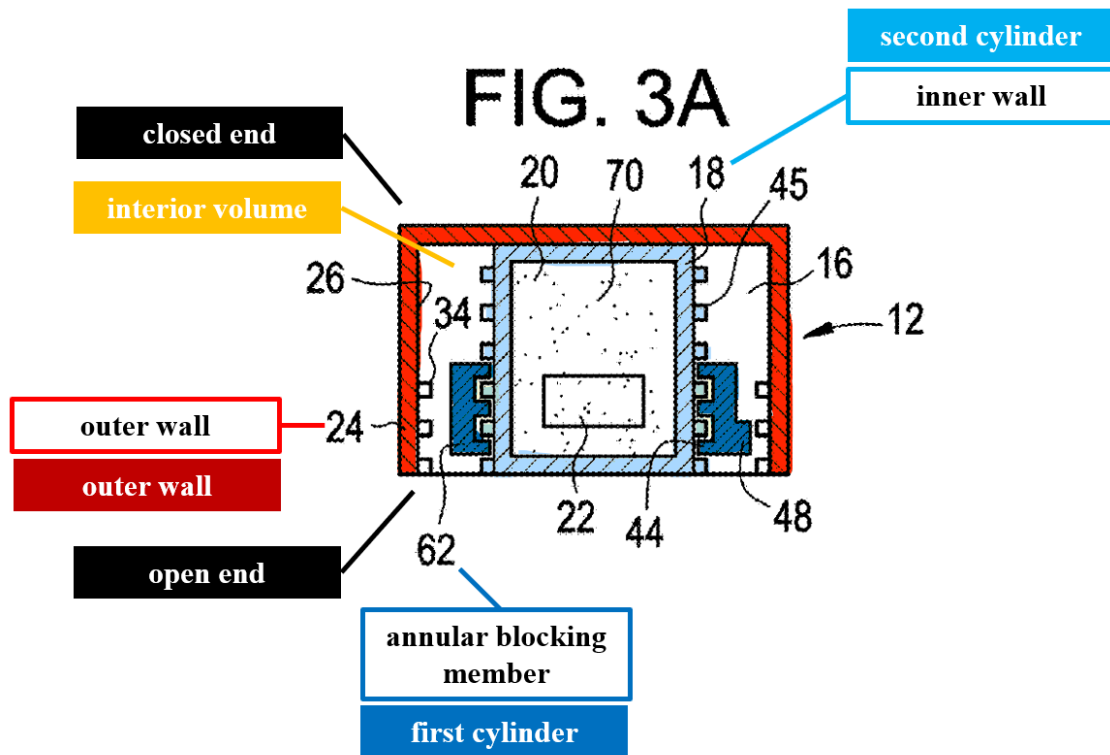
19. The ’003 application describes a biological sample collection system having a cap that “comprises an *outer wall*.”¹³ I understand that the Petitioner does

¹³ Ex. 2015 at [0022].

not dispute that there is written description support for the “outer wall,” and the Board agreed in its Preliminary Guidance.¹⁴

20. Annotated FIGS. 3A and 3B from the '003 application, illustrating biological sample collection system 200, are provided below.

¹⁴ Paper 21 at 5.



21. As indicated in these figures, biological sample collection system 200 includes a cap 12 with an outer wall 24 (indicated in red), and a tube (or sample collection vessel) 14. In my opinion, a POSITA looking at these figures would interpret cap 12 with outer wall 24 as defining an “an open end of the cap, an opposing closed end of the cap, and an interior volume of the cap”, where the open end of the cap can be said to define an “aperture.”

22. Thus, in my opinion, the combination of originally filed FIGS. 3A-B and their accompanying description establishes support for a cap comprising an “outer wall” that defines an “open end” of the cap, an opposing “closed end” of the cap, and an “interior volume” of the cap in substitute independent claim 21. I note that Mr. Leinsing also understood that FIGS. 3A-B support this description of the cap, noting that the cap “would be generally . . . understood as a generally cylindrical component with one capped end and one opened end.”¹⁵ I also note that Mr. Leinsing commented that the cap, if oriented open-end up, was “cup-like” and that if one were to fill the cup with, e.g., sand, one could say that “it was in the entirety of the volume of the cup” (*Id.* at 66:19–67:5.)

¹⁵ Ex. 2026 at 43:7–44:3; *see also, id.* at 51:21–24; *id.* at 66:19–25.

**B. The reagent chamber and moveable annular valve are
“positioned in the interior volume of the cap”**

23. Looking again at the original disclosure in the '003 application, I see the specification describes a biological sample collection system with “a cap having an “*interior chamber*” and an “*interior space*”.”¹⁶ Within the cap there is “a movable annular member that can cover an aperture in the inner wall.”¹⁷ The specification also states that the “annular member” (also referred to as an “annular blocking member” in some embodiments) may be removably coupled to aperture 22 such that when “the annular blocking member 62 is covering the aperture 22, fluid or material . . . may be contained within the interior space 20. . . .”¹⁸

24. As noted above, FIGS. 3A-B in the '003 application illustrate a biological sample collection system 200 that includes a cap 12 with an outer wall 24 (indicated in red), and a tube (or sample collection vessel) 14. In looking at FIGS. 3A-B, a POSITA would understand annular blocking member 62 (a first cylindrical component) and inner wall 18 (a second cylindrical component) – which includes aperture 22 – to collectively function as an annular valve, where a

¹⁶ Ex. 2015 at [0022].

¹⁷ *Id.* at [0043].

¹⁸ *Id.* at [0075].

reagent stored in interior space 20 (*i.e.*, a reagent chamber) when annular blocking member 62 is in a position to seal aperture 22 (as illustrated in FIG. 3A, the “closed” configuration of the valve) is released when annular blocking member 62 moves relative to inner wall 18 and opens aperture 22 (as illustrated in FIG. 3B, the “open” configuration of the valve).

25. Thus, in my opinion, the combination of originally filed FIGS. 3A-B and their accompanying description provides support for the amendments to substitute claim 21 that specify that the reagent chamber is “positioned in the interior volume of the cap.” and that the “moveable annular valve [is] positioned in the interior volume of the cap.” I note that Mr. Leinsing similarly testified that the cap comprises an “open volume with other components inside of it like a [cup] shape.” (Ex. 2026, 44:18–25; see also 53:12–23.)

C. 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”

26. The original disclosure in the ’003 application also indicates that “the annular blocking member 62 may be configured to interact with one or more features, such as a coupling member 50, of the tube 14 such that as the cap 12 is being securely coupled to the tube 14, the one or more features of either the tube 14 or annular blocking member 62 can cause the annular blocking member 62 to move from a position where the annular blocking member 62 is covering the

aperture 22 to a position where the annular blocking member 62 is not covering the aperture 22, thus allowing the sample preserving fluid or material 72 to release from the interior space 20 and interact with the sample 72.”¹⁹

27. This passage indicates that “annular blocking member 62” (*i.e.*, the first cylinder of the annular valve) “interact[s] with one or more features, such as a coupling member 50, of the tube 14” upon securing the cap 12 to tube 14 (*i.e.*, the sample collection vessel) to “cause the annular blocking member 62 to move from a position where the annular blocking member 62 is covering the aperture 22 to a position where the annular blocking member 62 is not covering the aperture 22.”²⁰

I interpret this passage to provide support that annular blocking member 62 (the “first cylinder”) – which is external to the sample collection vessel prior to attachment of cap 12 to tube 14 (the sample collection vessel) – remains external to tube 14 as it moves relative to inner wall 18 (the “second cylinder”) because it engages with one or more features, such as a coupling member 50, of the tube 14, as the cap is tightened.

28. FIGS 3A-B from the ’003 application (annotated versions provided above) further emphasize this point. These figures illustrate biological sample

¹⁹ Ex. 2015 at [0076].

²⁰ *Id.*

collection system 200 in the “closed configuration” of the annular valve (FIG. 3A) and the “open configuration” (FIG. 3B). In the closed configuration illustrated in FIG. 3A, annular blocking member 62 (*i.e.*, the first cylinder, dark blue) covers the vent (aperture 22) of inner wall 18 (*i.e.*, the second cylinder, light blue).²¹ In the open configuration illustrated in FIG. 3B, the cap 12 has been attached to tube 14 (*i.e.*, the sample collection vessel, green) and annular blocking member 62 has moved relative to inner wall 18 to open the vent. In the embodiment illustrated in FIGS. 3A-B, annular blocking member 62 is engaged with inner wall 18.²² Note that, as illustrated in FIG. 3B, annular blocking member 62 is pushed up into the cap 12 upon initial engagement of the cap with the tube 14. FIGS. 3A-B thus clearly indicate that, as the annular valve transitions from the “closed” to the “open” configuration, the first cylinder necessarily remains external to the tube 14.²³

29. Thus, in my opinion, the combination of originally filed FIGS. 3A and 3B and their accompanying description clearly establishes support for an annular valve where the “first cylinder is positioned externally to the sample collection

²¹ Ex. 2015 at [0076].

²² *See, e.g., id.* at [0078].

²³ *Id.* at FIGS. 3A–3B.

vessel in both the closed configuration and the open configuration of the moveable annular valve.” For completeness, I incorporate the charts in my first declaration for the remaining limitations of substitute claim 21 and the dependent claims, except as immediately noted below.²⁴

D. Support for substitute dependent claims 29 and 33

30. I understand that Patent Owner has also presented revised substitute dependent claims 29 and 33.

1. Substitute dependent claim 29

31. Revised 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.” As discussed above, the original disclosure in the ’003 application describes a biological sample collection system 200 that includes a cap 12 with an outer wall 24 (indicated in red in the annotated versions of FIGS. 3A-B provided above), and a tube (or sample collection vessel) 14. As discussed above, a POSITA would understand, based on a review of these figures and the accompanying description, that the cap defines an interior volume, and that the moveable annular valve (comprising a first cylinder (annular blocking

²⁴ Ex. 2014 at ¶ 34.

member 62) and second cylinder (inner wall 18)) is positioned in the interior volume of the cap. Furthermore, upon review of these figures a POSITA would understand that the “the first cylinder and second cylinder are relatively moveable *entirely within* the interior volume of the cap” when the moveable annular valve is changed “from the closed configuration to the open configuration.”

32. I understand that the Petitioner and Mr. Leinsing have asserted that FIGS. 3A and 3B depict the claimed components of the annular valve inconsistently and without precision.²⁵ The Petitioner argued, for example, that “Fig. 3A shows that the second cylinder (“inner wall 18”) extends into the cap’s aperture, where the inner wall 18 is equal and in line with the aperture or “boundary” and not entirely within the outer wall or “boundary” of the cap.”²⁶

33. I disagree with this statement. First, although the term “aperture” has now been replaced by “interior volume” in amended substitute claim 29, I note that an “aperture” is not an infinitely thin, planar feature but rather an “opening” or “open space” (*e.g.*, a hole).²⁷ FIG. 3A, as drawn, shows the bottom of inner cylinder 18 to be flush with a bottom edge of the outer wall 24 of cap 12. This

²⁵ Paper 19 at 8; *see also* Ex. 1027 at ¶¶ 14–16.

²⁶ *Id.*

²⁷ *See, e.g.*, Ex. 2028.

does not preclude that cylinder 18 (*i.e.*, the second cylinder of the annular valve) would be considered by a POSITA to be “entirely within” the “aperture” (or interior volume of the cap) that is defined by boundary of the outer wall 24 (or by the open end of the cap) in either the closed or open configuration of the annular valve.

34. The Petitioner goes on to argue that “Fig. 3B, however, shows that the same inner wall 18 is recessed inside the cap.”²⁸ Petitioner also points to the hand-drawn versions of FIGS. 3A-B taken from Prov. App. No. 61/498,584 (the ’584 provisional) as evidence that the drawings are internally inconsistent and therefore cannot be relied upon for support.²⁹

35. Again, I disagree. As I testified in my deposition, “These drawings, 3A and 3B in Exhibit 2015, are meant to show the relationship among the various components of those -- of the drawings, but not necessarily indicate their precise sizes.”³⁰ In my opinion, a POSITA would understand the minor inconsistencies between these figures to be merely drafting errors, and would note that regardless of the minor inconsistencies, all four figures (*i.e.*, FIGS. 3A-B from the ’003

²⁸ Paper 19 at 9.

²⁹ Paper 19 at 9-10.

³⁰ Ex. 1033 at 65:7–16.

application, and FIGS. 3A-B from the '584 provisional) consistently show that both “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.” I also note that Mr. Leinsing was asked “[i]f you were to take a cup and fill it with sand all the way to its top lip, would that sand be *entirely within the volume* of the cup,” and he responded: “You could say it was in the *entirety of the volume* of the cup” (Ex. 2026, 66:19–67:5.)

36. Thus, in my opinion, the combination of originally filed Figures 3A and 3B and their accompanying description clearly establishes support for the amendment in substitute claim 29 “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.”

2. Substitute dependent claim 33

37. 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.” The original

disclosure of application '003 describes how “the annular blocking member 62 may be configured to interact with one or more features, such as a coupling member 50, of the tube 14”, and how interaction between “one or more features of either the tube 14 or annular blocking member 62” as cap 12 is securely coupled to tube 14 “can cause the annular blocking member 62 to move from “a position where the annular blocking member 62 is covering the aperture 22 [the “closed” position] to a position where the annular blocking member 62 is not covering the aperture 22 [the “open” position].”³¹ FIGS. 3A-B illustrate an embodiment where coupling feature 48 (*e.g.*, a “flange”) is part of inner cylinder 18 (the “first cylinder”) and interacts with coupling member 50 (part of tube 14) on the end of the tube 14 that is proximal to the cap 12. FIGS. 1A-B of the '003 application³² illustrate a different embodiment in which coupling feature 48 is part of a cylindrical blocking member 46 (the “second cylinder”) and is, again, configured to interact with a coupling member 50 that is part of tube 14. Finally, claim 13 as originally filed in the '003 application indicates that “the annular valve comprises a flange extending from at least one of the first and second cylinders.”³³

³¹ Ex. 2015 at [0076].

³² *Id.* at FIG. 1A, 1B.

³³ Ex. 2015 at claim 13.

38. Thus, in my opinion, the amendment in substitute claim 33 is fully supported.

IX. GROUND I—SUBSTITUTE INDEPENDENT CLAIM 21 IS PATENTABLE OVER PLANTE IN VIEW OF CHO

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

39. I understand that original claims 1–4, 6–16, and 18–20 have 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.

40. I incorporate the description of the Plante and Cho references in my first declaration herein.³⁴

³⁴ Ex. 2014 at ¶¶ 36–39.

41. An annotated version of FIG. 1 of Plante is reproduced below.

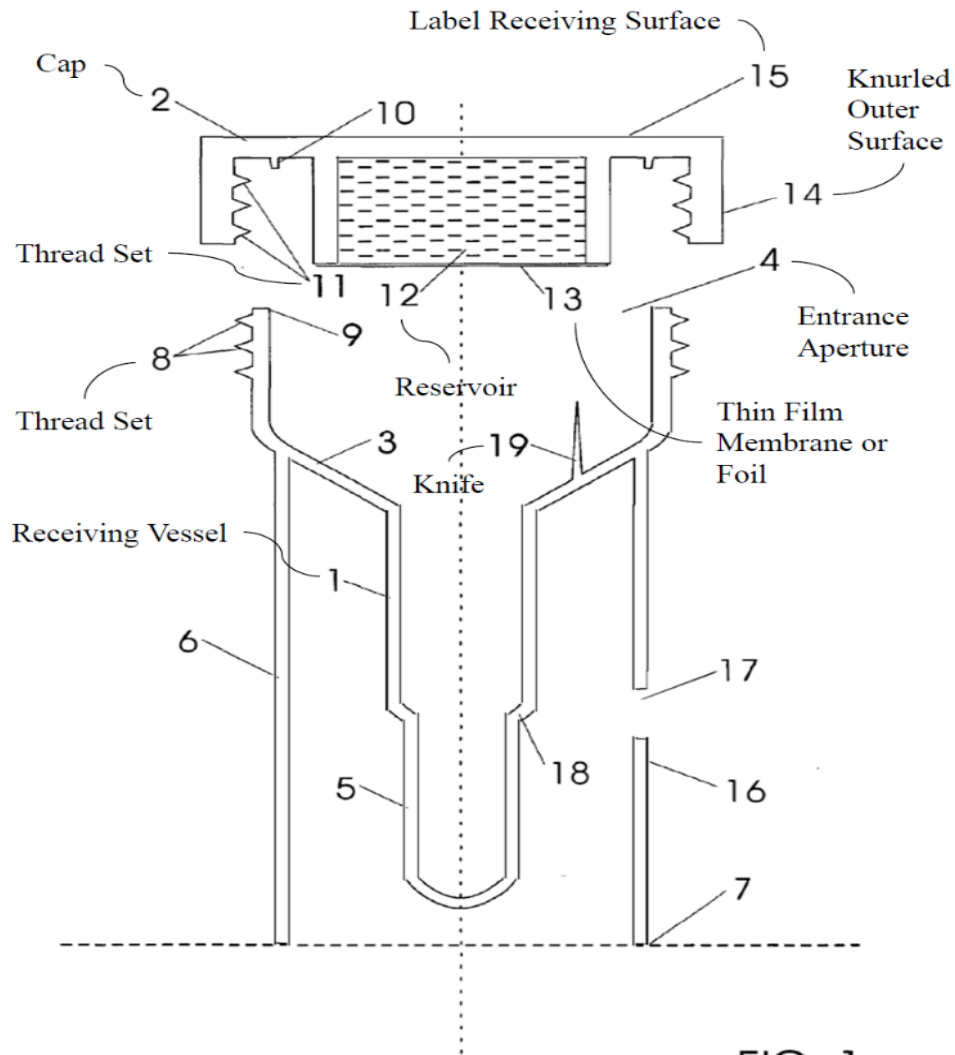
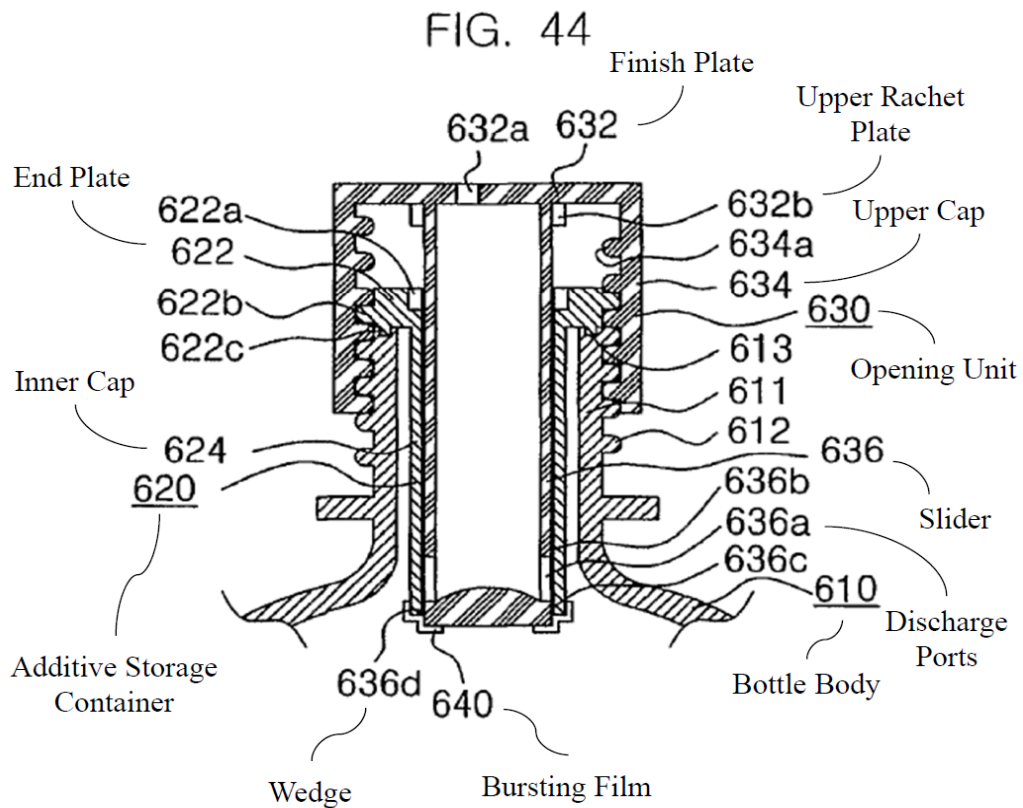


FIG. 1

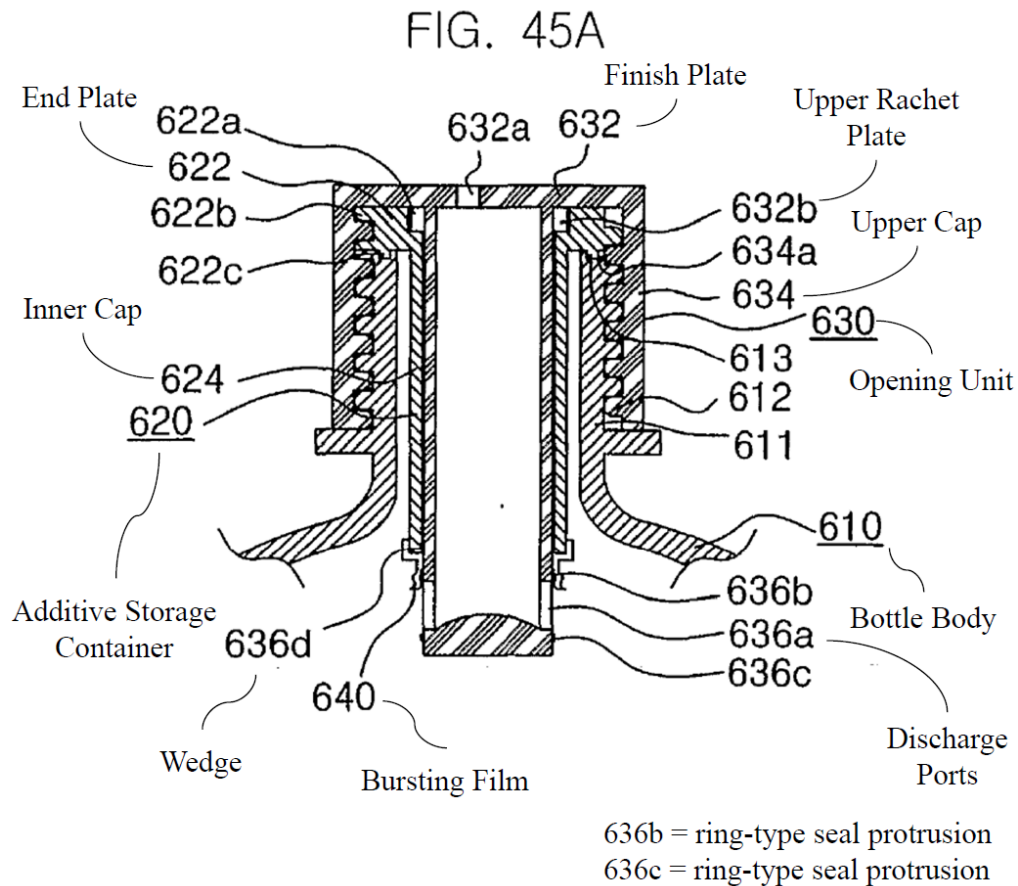
42. As can be seen in FIG. 1, Plante's device includes a cap 2, which further includes a reservoir 12 that is sealed by a thin film or membrane 13. Although Plante's cap 2 includes an outer wall (corresponding to the wall comprising knurled outer surface 14) that defines "*an outer wall defining an open 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,*" there is clearly no "moveable

annular valve positioned in the interior volume of the cap” as is required by substitute claim 21. There is also no “first cylinder” (*i.e.*, a component of a moveable annular valve) that “*is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve*” as also required by substitute claim 21.

43. Annotated versions of FIG. 44 and FIG. 45A of Cho are reproduced below.



636b = ring-type seal protrusion
636c = ring-type seal protrusion



44. As can be seen in FIG. 44 (closed configuration) and FIG. 45A (open configuration), Cho's device includes an upper cap 634, an additive storage container 620 that is positioned within the mouth 611 of bottle body 610, and an opening unit 630 that is combined with the additive storage container 620 through

a screw-type engagement.³⁵ It is clear from these figures and the description thereof provided in Cho that the “first cylinder” (*i.e.*, which Petitioner maps to inner cap 624) 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.

45. 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 patentable over the combination of Plante and Cho for at least the above reasons.

46. Furthermore, in my opinion, neither Plante nor Cho disclose or suggest the elements of amended substitute dependent claims 29, 33 and 36 for additional reasons.

47. 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

³⁵ Ex. 1004 at 48:16–22.

the open configuration.” Plante’s device does not include an annular valve. As illustrated in FIGS. 43, 44, and 45A of Cho,³⁶ the inner and outer cylinders of Cho’s “annular valve” (*i.e.*, inner cap 624 (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 for this additional reason.

48. 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,³⁷ a flange (endplate 622) attached to Cho’s first cylinder (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

³⁶ Ex. 1004 at FIGS. 43, 44, 45A.

³⁷ Ex. 1004 at FIGS. 43, 44, 45A.

(FIG. 45A) upon tightening of upper cap 634 to the threaded mouth of bottle body 610. Thus, in my opinion, substitute dependent claim 33 is patentable over the combination of Plante and Cho for this additional reason.

49. 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.”

50. Plante describes a saliva collection device intended 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].)

51. Cho’s device is intended for commercial sale 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.

52. Cho’s device thus addresses a different need, *i.e.*, shipment of two kinds of materials 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)) 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.

53. 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 also patentable over the combination of Plante and Cho for this additional reason.

54. I understand that Petitioner has asserted that original claims 2–4, 6–16, and 18–20 are also obvious in view of Plante and Cho. Since, in addition to the specific substitute dependent claims discussed above, the remaining substitute dependent claims depend from and include all of the elements of substitute

independent claim 21, I believe that these claims are also patentable in view of Plante and Cho as noted above.

B. A POSITA Would Not Have Been Motivated to Replace Plante's Knife with Cho's Valve

55. I understand that Mr. Leinsing has argued that a POSITA would have been motivated by design incentives to combine Cho's cap (or a modified version thereof) with Plante's saliva collection device in order to replace Plante's knife, *e.g.*, for safety reasons, due to the difficulty of molding sharp features, to reduce the risk of sample contamination, to reduce the volume of the reagent chamber, and/or to reduce the likelihood of tampering.³⁸ These arguments, some of which are reiterated by the Petitioner in their Opposition,³⁹ have also been summarized in the Preliminary Guidance provided by the Board.⁴⁰

56. I disagree with Mr. Leinsing. It is my opinion that a POSITA would not have been motivated to replace Plante's knife for at least the following reasons.

³⁸ Ex. 1002 at ¶¶ 66–72; Ex. 1027 at ¶¶ 26–34.

³⁹ Paper 19 at 13.

⁴⁰ Paper 21 at 18.

1. A POSITA would not recognize Plante's knife as presenting a risk of injury

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

⁴¹ Ex. 2014 at ¶¶ 43–47.

⁴² Ex. 1002 at ¶ 67.

58. Thus, in my opinion, a POSITA would not have been motivated to substitute Cho's valve mechanism for Plante's relatively simple puncturable membrane and knife-based approach because a POSITA would not recognize Plante's knife as presenting a significant risk of injury.

2. A POSITA would not recognize molding Plante's knife as being unduly difficult

59. As noted in my first declaration,⁴³ I disagree with Mr. Leinsing's assertion that a POSITA would have been motivated to combine Plante and Cho because a POSITA would have known it is difficult to mold sharp thin features in plastic.⁴⁴ Although sharp corners and other sharp features can be problematic to injection mold (potentially requiring iterative refinements of mold design and/or molding process parameters to achieve a robust manufacturing process), a POSITA would understand that injection molding could be used to create features sufficiently pointed to puncture a thin film membrane, as required in Plante.

60. Furthermore, as pointed out in my first declaration,⁴⁵ not only does Cho's device in its 21st embodiment (cited by the Petitioner as a substitution for

⁴³ Ex. 2014 at ¶¶ 48–54.

⁴⁴ Ex. 1002 at ¶ 71.

⁴⁵ Ex. 2014 at ¶¶ 50–53.

Plante's knife) include sharp features, it includes a larger number of sharp features (as well as features requiring tight tolerances). Plante's device comprises a single sharp feature (*i.e.*, knife 19), whereas inspection of Cho's FIG. 43 indicates that the device comprises at least 22 sharp features (*i.e.*, the complementary sharp features on upper ratchet plate 632b and lower ratchet plate 622a (eight sharp features shown on each part in FIG. 43 of Cho), the sharp features of upper ratchet 622c formed on the lower surface of end plate 622 (three sharp features shown in FIG. 43 of Cho), and the corresponding sharp features on lower ratchet 613 formed on the top of mouth 611 (three more sharp features shown in FIG. 43 of Cho)).⁴⁶

61. Thus, in my opinion, a POSITA would not have been motivated to substitute Cho's valve mechanism for Plante's puncturable membrane and knife-based approach because even a POSITA that was concerned about molding a single sharp feature would not be inclined to replace a design comprising a single sharp feature (Plante's knife) with one that comprises a significantly larger number of sharp features (e.g., Cho's opening unit 630 comprising an "annular valve").

⁴⁶ See also, Ex. 1004 at 49:1–4, 49:28–33.

C. Scaling Down and/or Modifying Cho’s Device as a Replacement for Plante’s Knife Would Require Extensive Redesign and Testing with an Unpredictable Outcome

62. I understand that the Petitioner and Mr. Leinsing have characterized replacement of Plante’s membrane and knife with Cho’s annular valve design in its 21st embodiment as a “simple substitution.”⁴⁷ I disagree. Even if a POSITA decided to attempt to modify Cho’s device, despite the considerations outlined above, there would be no *a priori* guarantee of success *i.e.*, the outcome would be unpredictable without engaging in extensive redesign, prototyping, and testing of the device).

63. In their Opposition to the Patent Owner’s Non-Contingent Motion to Amend, the Petitioner stated that “Indeed, *both parties’ experts agree a POS[IT]A would have been motivated to modify Cho’s reagent chamber to meet the new claim limitations, and agree it was easily within the skill of the art to do so.*”⁴⁸

64. Quoting from my testimony from a related proceeding (*i.e.*, IPR2022-01347 relating to Patent 11,002,646 B2) in its Opposition, the Petitioner goes on to state that: “Dr. Wereley agrees, having testified in the ’646 patent IPR that a POS[IT]A would recognize that Cho’s size and volume could be changed based on

⁴⁷ See, e.g., Ex. 1002 at 74.

⁴⁸ Paper 19 at 1 (emphasis added).

need.”⁴⁹ The Petitioner further states that I “testified that 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’).”⁵⁰

65. This is a mischaracterization of my previous testimony. An acknowledgement that one of skill in the art would understand that Cho’s design *could be modified* (e.g., the size or volume of the additive storage container) is *not* the same as stating that *a POSITA would be motivated to do so*. Nor is it the same as stating that *it would be within the skill in the art to do so*.

66. Replacement of Plante’s puncturable membrane and knife-based design with Cho’s valve design is not a simple substitution and would require

⁴⁹ Paper 19 at 16 citing Ex. 1034 at 35:10–19 (“[O]ne 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”) (emphasis added).

⁵⁰ Paper 19 at 16 citing Ex. 1034 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*” (emphasis added) and “[c]hanging the length of the cylinder...would necessarily change its volume.”).

significant rescaling and redesign—directing a POSITA against the combination.

As I discuss below, there are a number of potential problems that could arise.

1. Examples of Difficult Features to Mold

67. 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 – that collectively include about 15 distinct features, including features that are potentially difficult to fabricate by injection molding.

68. As is well known in the art, there are a number of different features that can be problematic to mold. As stated by Mr. Leinsing in his declaration, “a POSA would have understood that it is difficult and more expensive to mold sharp thin features, like Plante’s knife, in plastics.”⁵¹

69. However, there are a number of other features that can also be problematic, as described in the *Injection Molding Handbook*, Third Edition, Rosato, Rosato, and Rosato, ed., Kluwer Academic Publishers, Boston/Dordrecht/London (Ex. 1014) cited by Mr. Leinsing in his first declaration.⁵²

⁵¹ Ex. 1002 at 71.

⁵² *Id.*

70. For example, the Injection Molding Handbook states that: “[V]arying wall thicknesses from thick and thin sections in a part will lead to problems in molding. Having a uniform wall throughout a part gives it good strength and appearance. Thick and thin sections will have molded in stresses, different rates of shrinkage (causing warpage), and possibly void formation in the thick portion.”⁵³ This passage was cited by Mr. Leinsing in his first declaration.⁵⁴

71. The Injection Molding Handbook also states that: “part quality can be considered a direct outcome of a plastic melt's flow behavior in its mold cavity or cavities. *Excessive restrictions and obstructions to the flow of material spell trouble in injection molding.*”⁵⁵ This passage was also cited by Mr. Leinsing in his first declaration.⁵⁶

72. Petitioner’s expert witness, Mr. Leinsing, thus acknowledges that there can be a number difficulties with injection molding depending on the nature of the parts and/or features thereof.

⁵³ Ex. 1014 at 729.

⁵⁴ Ex. 1002 at 71.

⁵⁵ Ex. 1014 at 733.

⁵⁶ Ex. 1002 at 71.

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

74. Chapters 4 - 7 of the Injection Molding Handbook (Ex. 2029) discuss in detail the many challenges of injection molding. Additional examples of the many issues that can give rise to difficulties with injection molding that are discussed in this reference include part or feature shape, parts requiring critical dimensions, and part complexity—all of which are implicated by Cho’s design. For example:

- *“Both shape geometry and design are heavily process-related. As an example, the ability to mold ribs may depend on the thickness and length of the rib, the ability of the melt to flow adequately during processing, the flowability of a plastic reinforced with glass fiber or other reinforcements or fillers, and so on.”*⁵⁸

⁵⁷ Ex. 1014 at 728.

⁵⁸ Ex. 2029 at 224 (emphasis added).

- “Third, *a part that has many critical dimensions will be more difficult to mold to tolerance than a part with fewer such dimensions.*”⁵⁹
- “Shorter cycle times and *thinner or more complex parts continually increase the need for precise control in injection molding.*”⁶⁰

75. Another reference cited by Mr. Leinsing, *The Complete Part Design Handbook for Injection Molding of Thermoplastics*, E. Campo, Hanser Publishers, Munich, Chapter 10 (2006) (Ex. 1015) cites additional examples and states that “When designing injection molded thermoplastic parts, *the product designer must also be aware of some part configurations that pose potential problems during the injection molding process.*”⁶¹

76. Therefore, in my opinion, an engineer, let alone a POSITA, would not have a reasonable expectation of success in redesigning and/or scaling down Cho’s device without having to invest in expensive iterations of redesign, prototyping, and testing with an unpredictable outcome.

⁵⁹ Ex. 2029 at 595 (emphasis added).

⁶⁰ *Id.* at 704 (emphasis added).

⁶¹ Ex. 1015 at 546 (emphasis added).

2. Cho's Device Includes Features That Can Be Difficult to Mold and Require Tight Tolerances

77. Examination of Cho's FIGS. 44 and 45A indicate that Cho's opening unit 630 and bottle 610 comprise approximately four parts that would be injection molded as separate components (*e.g.*, upper cap 634 (which includes integrated slider 636 as indicated by the cross-hatching in the figures), inner cap 624, optionally, bursting film 640, and bottle 610). Collectively, these four components include about *seventeen* different parts and/or part features, as enumerated in FIGS. 43, 44, and 45A, *e.g.*:

- (i) upper cap 634 (including integrated slider 636; inner cylinder)
 - (ii) open port 632a
 - (iii) open port 632a sealing means (not shown; described at Cho, page 49, line 35)
 - (iv) upper ratchet plate 632b
 - (v) internal thread 634a
 - (vi) discharge ports 636a
 - (vii) ring-type seal protrusion 636b
 - (viii) ring-type seal protrusion 636c
 - (ix) wedge 636d
- (x) inner cap 624 (outer cylinder) – *comprising additive storage container 620*
 - (xi) end plate 622

- (xii) lower ratchet plate 622a
- (xiii) external thread 622b
- (xiv) upper ratchet 622c
- (xv) bursting film 640
- (xvi) bottle body
 - (xvii) external threads at neck

78. Some of these features can present difficulties for injection molding, *e.g.*, those that include sharp edges (*e.g.*, upper ratchet plate 632b, lower ratchet plate 622a, upper ratchet 622c, and lower ratchet 613), as described above. 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.

79. 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 (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). Failure to hold these parts to tight tolerances could result in, for example, leakage and/or binding. Thus, the engineering precision needed to build a functioning cap after Cho's design is particularly high, rendering the simple substitution of Cho's cap for Plante's cap unpredictable in 2011.

80. Another example of difficult features to mold in Cho's device are the discharge ports 636a. Regardless of exactly where the mold for upper cap 634 is filled with polymer, the polymer would have to flow around the hole and fill in the space on the opposite side of it from the filling hole.

81. As depicted in Cho's FIGS. 44 and 45A, bottle 610 looks like a standard 2L soda bottle, which would require two molds. The upper cap 634 is not manufacturable as drawn. The interior volume would prevent most forms of manufacturing – with the possible exception of resin-based stereo lithography – which I do not believe one of skill in the art would have considered to be a technology that was reliable enough in the 2010 – 2011 timeframe to enable a simple substitution of Cho's cap for Plante's cap.

82. The cap would have to be split up and molded as separate pieces, and then glued, bonded, or otherwise fused together after manufacturing the sub-components. The most feasible route to manufacturing the cap (in my opinion) would be to manufacture the threads, vertical wall of the cap and top of the cap separately from the rest of the parts using two molds. This would look like a standard soda bottle cap. The remainder of the cap (*e.g.*, the long vertical cavity for holding the reagent formed by slider 636) could be manufactured using two molds. The two pieces would need to be glued or otherwise bonded together following the molding step. However, the cross-hatching in FIGS. 44 and 45A of Cho indicates

that upper cap 634 is a monolithic part. Inner cap 624 appears to form the outer part of the additive storage container 620, and could be made using two additional molds. Altogether, at least 6 molds and a gluing or bonding operation would be required to make opening unit 630 without ensuring a predictability in result as of 2011.

83. In one of the embodiments of Cho's device, bursting film 640 is described as also being injection molded (Ex. 1004, page 51, lines 22 - 26), and would likely require the use of another two molds.

84. In contrast, Plante's device (as illustrated in Plante, FIG. 1 and described above) is relatively simple and, although it also includes a number of features (only the threads used to attach the cap to the sample collection tube would require tight tolerances), it would require only two molds to fabricate with no gluing or bonding.

85. Thus, in my opinion, there would be no motivation for a POSITA to attempt to substitute Cho's valve mechanism for Plante's knife, or to attempt to modify Cho's design by rescaling dimensions and volumes so as to be able to substitute Cho's valve for Plante's knife.

D. Petitioner's Alleged Motivations for a POSITA to Modify Cho

86. As summarized in the Petitioner's Opposition to Patent Owner's Non-Contingent Motion to Amend, the Petitioner and Mr. Leinsing now assert that a POSITA would have 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.⁶² The alleged motivations for a POSITA to thus modify Cho include: (i) to minimize the likelihood of contact by a user, and thus reduce the risk of contamination,⁶³ (ii) that 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, and that it would have been obvious for a POSITA to try positioning Cho's first and second cylinders entirely within the boundaries of the outer wall of the cap,⁶⁴ (iii) that design choices (*e.g.*, the amount of additive stored in the cap and the width of the neck of the bottle) would have motivated a POSITA to modify Cho's cap to include the first and second cylinders entirely within the boundaries of the outer

⁶² Paper 19 at 13.

⁶³ Ex. 1027 at ¶ 30.

⁶⁴ *Id.* at ¶ 31.

wall of the cap,⁶⁵ and (iv) that a POSITA 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 of Plante's device.⁶⁶

87. I disagree with these arguments. With respect to the first and second of these alleged motivating factors, Mr. Leinsing states that "Dr. Wereley has contrasted Cho's potential for contamination with Plante's low-profile design that minimizes the risk of contamination . . . 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 could touch the film,' which would render the sample defective."⁶⁷ This is an argument for *not* trying to combine Cho with Plante in the first place, not an argument to try to modify Cho. There is no reason that a POSITA would embark on an uncertain undertaking as the Petitioner proposes when Plante's device already comprises minimal risk of contamination due to a user touching the film.

⁶⁵ Ex. 1027 at ¶ 32.

⁶⁶ *Id.* at ¶ 34.

⁶⁷ *Id.* at ¶ 29.

88. With respect to the third of these alleged motivating factors, the design choices (*e.g.*, the amount of additive stored in the cap and the width of the neck of the bottle) highlighted by Mr. Leinsing again provide an argument for why a POSITA would *not* be motivated to try to combine Cho's device with that of Plante, *i.e.*, it would require extensive and costly redesign and would raise potential problems, as discussed above.

89. Finally, with respect to the fourth of these alleged motivating factors, I find it unconvincing that a POSITA would be motivated to undertake a lengthy and costly redesign to reduce the likelihood of tampering or purposely or accidentally peeling off or damaging the foil of Plante's device. Tampering with Plante's device, or accidentally peeling off or damaging the foil of Plante's device would be self-evident, and a less expensive option to prevent accidental damage would be to simply recess the reagent reservoir 12 of Plante's device a bit so that it is protected by the walls of the cap 12.

X. GROUND II— THE SUBSTITUTE DEPENDENT CLAIMS ARE PATENTABLE OVER PLANTE, CHO, AND PATTERSON

90. I understand that original claim 5 has been challenged under 35 U.S.C. § 103(a) as allegedly being unpatentable in view of Plante, Cho and Patterson.

91. I incorporate the description of Patterson in my first declaration herein.⁶⁸ There is no disclosure in Patterson of “a moveable annular valve positioned in the interior volume of the cap” (the first cylindrical component of Patterson’s “annular valve” is integrated with cap 20), as is required by substitute claim 21. Thus, in my opinion, Plante, Cho, and Patterson, either individually or in combination, fail to disclose the new features of substitute claim 21, and therefore substitute claim 21, and all of the substitute claims that depend from it (including claim 25 which corresponds to original claim 5) are patentable over the combination of Plante, Cho, and Patterson.

XI. GROUNDS III-V – THE SUBSTITUTE CLAIMS ARE PATENTABLE OVER UEDA, PATTERSON, AND WILLIAMS

92. I understand that original claims 1-8, 10-16, 18-20 have been challenged as allegedly being unpatentable over Ueda (Ex. 1005), but that it was not raised as the basis for a Ground in the Petitioner’s Opposition. Ueda discloses a cap comprising a reagent chamber and an annular valve, where the annular valve comprises a first cylinder (mapped by the Petitioner to outer cylindrical member 7) and a second cylinder (mapped by Petitioner to sample holding member 8). As indicated in FIGS. 1, 2, and 3A-B of Ueda, and the description thereof, there is no

⁶⁸ Ex. 2014 at ¶¶ 74–75.

teaching or suggestion of a moveable annular valve 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” as is required by substitute independent claim 21. Thus, in my opinion, substitute independent claim 21, and all of the substitute claims that depend from substitute claim 21, are patentable over Ueda.

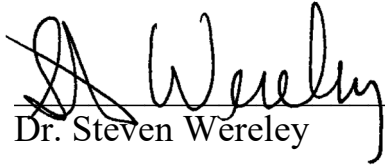
93. I understand that claim 5 has been challenged as allegedly being unpatentable over the combination of Ueda and Patterson (Ex. 1010). Patterson describes a “pre-loaded” mixing cap 10 for discharging dry or liquid ingredients using an annular valve comprising a first cylinder (mapped by the Petitioner to outer housing 20) and a second cylinder (mapped by the Petitioner to inner tube 40). (*See, e.g.*, Ex. 1010, Abstract, FIGS. 1–3.). However, there is no teaching or suggestion in Patterson of a moveable annular valve 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” as is required by substitute independent claim 21. Thus, in my opinion, substitute independent claim 21, and all of the substitute claims that depend from substitute claim 21 (including claim 25 which corresponds to original claim 5), are patentable over the combination of Ueda and Patterson.

94. I understand that claim 9 has been challenged as allegedly being unpatentable over the combination of Ueda and Williams (Ex. 1009). However, Williams does disclose the new features recited in substitute claim 21. Thus, in my opinion, substitute independent claim 21, and all of the substitute claims that depend from substitute claim 21, are patentable over the combination of Ueda and Williams.

* * *

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: Nov 5, 2024


Dr. Steven Wereley