

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.

IPR2023-01424
Patent 11,536,632 B2

Before DONNA M. PRAISS, CHRISTOPHER M. KAISER, and
JAMIE T. WISZ, *Administrative Patent Judges*.

PRAISS, *Administrative Patent Judge*.

PRELIMINARY GUIDANCE
PATENT OWNER'S MOTION TO AMEND

I. INTRODUCTION

On March 26, 2024, we instituted trial as to claims 1–16 and 18–20 of U.S. Patent No. 11,536,632 B2 (Ex. 1001, “the ’632 patent”). Paper 10 (“Institution Decision” or “Dec.”). After institution, Patent Owner filed a Motion to Amend that is non-contingent on the patentability of claims 1–16 and 18–20. Paper 16 (“Motion” or “Mot.”). In its Motion, Patent Owner proposes to amend the ’632 patent to cancel challenged claims 1–16 and 18–20 and substitute claims 21–39. Mot. 1. Petitioner timely filed an Opposition to Patent Owner’s Motion. Paper 19 (“Opposition” or “Opp.”).

In the Motion, Patent Owner requests that we provide preliminary guidance in accordance with the Board’s Pilot Program. Mot. 1; *see also* Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019) (providing a patent owner with the option to receive preliminary guidance from the Board on its motion to amend) (“Notice”). We have duly considered Patent Owner’s Motion and Petitioner’s Opposition.

In this Preliminary Guidance, we provide our initial, preliminary, and non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in an *inter partes* review and whether Petitioner (or the record) establishes a reasonable likelihood that the substitute claims are unpatentable. *See* Notice, 84 Fed. Reg. at 9,497 (“The preliminary guidance . . . provides preliminary, non-binding guidance from the Board to the parties about the [motion to amend]”); *see also* 35 U.S.C. § 316(d) (statutory requirements for a motion to

amend); 37 C.F.R. § 42.121 (regulatory requirements and burdens for a motion to amend); *Lectrosonics, Inc. v Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential) (providing information and guidance regarding motions to amend).

For purposes of this Preliminary Guidance, we focus on the proposed substitute claims, and specifically on the amendments proposed in the Motion. *See* Notice, 84 Fed. Reg. at 9,497. We do not address the patentability of the originally issued and challenged claims. *Id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties' other substantive papers on the underlying merits of Petitioner's challenges. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision. *See id.* at 9,500.

II. PRELIMINARY GUIDANCE

A. Statutory and Regulatory Requirements

For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Patent Owner has not shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend.

1. Reasonable Number of Substitute Claims

We first consider whether Patent Owner proposes a reasonable number of substitute claims. 35 U.S.C. § 316(d)(1)(B)); 37 C.F.R. § 42.121(a)(3).

We conclude yes. Patent Owner proposes no more than 1 substitute claim for each challenged claim. Mot. 1, 3–6, 26–31 (App. A). Petitioner does not argue otherwise. *See generally* Opp.

2. Respond to Ground of Unpatentability

We next consider whether the Motion responds to a ground of unpatentability involved in the trial. 37 C.F.R. § 42.121(a)(2)(i).

We conclude yes. Patent Owner responds to the grounds of unpatentability by amending the claims in response to the Petition’s asserted prior art. Mot. 2, 10–24. Petitioner does not argue otherwise. *See generally* Opp.

3. Scope of Amended Claims

We consider whether the amendment seeks to enlarge the scope of the claims. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii).

We conclude no. Patent Owner’s substituted independent claim 21 includes “an outer wall” as an additional component of the claimed system and added limitations that relate the additional component to existing components in the claim. Therefore, substitute claim 21 and each proposed substitute dependent claim depending therefrom is narrower in scope than the corresponding original claims. Mot. 2–6, 26–31 (App. A). Petitioner does not argue otherwise. *See generally* Opp.

4. New Matter

We consider whether the amendment seeks to add new subject matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii).

We conclude yes. Based on this record and for the reasons discussed below, it appears that proposed substitute claims 21–39 introduce new matter in violation of 35 U.S.C. § 316(d)(3) and 37 C.F.R. § 42.121(a)(2)(ii).

Patent Owner asserts that the proposed substitute claims are supported by the specifications of the application from which the '632 patent issued (U.S. Patent Application No. 17/510,003 (Ex. 2015, the "'003 application'")) and the provisional application (U.S. Patent Application No. 61/498,584 (Ex. 2022, the "'584 application'")) to which the '003 application claims priority. Mot. 3. Patent Owner contends the '003 application and the '584 application support the "outer wall" limitation recited in proposed substitute claim 21. *Id.* at 4 (citing Ex. 2015, ¶¶ 22, 60, 75, Figs. 3A, 3B; Ex. 2022, 4–6, 8–9, Figs. 3A, 3B), 7–8 (citing Ex. 2014, ¶ 29; Ex. 2015, ¶¶ 22, 60, 75, Fig. 3B). Petitioner does not dispute that there is written description support for "an outer wall" in the disclosed biological sample collection system. The record supports the "outer wall" limitation being in the inventors' possession as of the effective filing date of the '632 patent. *See, e.g.*, Ex. 2015 ¶ 22 ("the cap comprises an outer wall"); Ex. 2022, 4 ("the sample collecting device comprises a cap, comprising an outer wall").

Patent Owner asserts that the '003 application and the '584 application support the additional limitations reciting that the "first cylinder" and the "second cylinder" are "housed within the boundaries of the outer wall" in proposed substitute claim 21. Mot. 4 (citing Ex. 2015, ¶¶ 43–44, 75, Figs. 3A, 3B; Ex. 2022, 4–6, 8–9, Figs. 3A, 3B), 8–9 (citing Ex. 2014, ¶¶ 30–31; Ex. 2015, ¶¶ 43, 75, Figs. 3A, 3B). Patent Owner contends that the '003 application and the '584 application support the limitation reciting that the "first cylinder" and "second cylinder" are "relatively movable within the boundaries of the outer wall of the cap" in proposed

substitute claim 21. *Id.* at 4 (citing Ex. 2015, ¶¶ 43–44, 75–76, 78, Figs. 3A, 3B; Ex. 2022, 4–6, 8–9, Figs. 3A, 3B), 9–10 (citing Ex. 2014, ¶¶ 32–33; Ex. 2015, ¶¶ 75, 78, Figs. 3A, 3B).

Petitioner argues that the meaning of “housed within the boundaries of the outer wall of the cap” applied by Patent Owner is “housed *entirely* within the boundaries of the outer wall of the cap.” Opp. 6 (citing Mot. 15, 21). As such, Petitioner argues the proposed substitute claims are unpatentable as failing to satisfy the written description standard because “there is no written description support for the first and second cylinders to be housed entirely within the boundaries of the outer wall of the cap.” *Id.* at 19 (emphasis omitted). Petitioner contends that none of the ’003 application’s disclosures Patent Owner cites provide written description support for “the first and second cylinders as being housed entirely within the boundaries of the outer wall of the cap.” *Id.* at 21 (citing Ex. 2015, ¶¶ 43, 44, 75, 76, 78, Figs. 3A, 3B). Petitioner argues that the portions of the ’003 application’s specification cited by Patent Owner “merely refer to Figs. 3A and 3B under the heading ‘Brief Description of the Drawings’ and explain only that the ‘movable annular valve’ (i.e., the claimed first cylinder) can cover the ‘aperture’ (i.e., the claimed vent) in one instance, and leave it uncovered in another instance” and “describe this covering and uncovering process in slightly more detail and do so without ever discussing if the ‘inner wall 18’ or ‘annular blocking member 62’ extend less than, equal to, or further than the bottom opening of the outer wall 24 of the cap 12.” *Id.* (citing Ex. 2015, ¶¶ 43, 44, 75, 76, 78, Figs. 3A, 3B).

Petitioner argues further that Patent Owner’s citations to Figures 3A and 3B in the ’003 application do not satisfy the written description requirement. Opp. 21–

22. Petitioner contends “the drawings in the ’003 application cannot be used for written description support for [Patent Owner’s] implied construction that requires the first and second cylinders to be housed entirely within the boundaries of the outer wall of the cap” because, as discussed above, “[t]he ’003 application is silent regarding the locations of the first and second cylinders relative to the boundaries of the outer wall of the cap.” *Id.* at 20 (emphasis omitted). Moreover, Petitioner argues that Figures 3A and 3B are insufficient because they are “imprecise and contradictory.” *Id.* According to Petitioner, Figures 3A and 3B (reproduced below with Petitioner’s annotations) “depict the claimed components inconsistently and without precision” because Figure 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’¹ and not entirely within the outer wall or ‘boundary’ of the cap,” but Figure 3B “shows that the same inner wall 18 is recessed inside the cap.” *Id.* at 8–9 (emphasis omitted, citing Ex. 2015, Figs. 3A, 3B; Ex. 1027, ¶ 15).

¹ We note that the current record does not define the recited “boundaries of the outer wall of the cap” nor does it explain how an aperture defines a boundary.

FIG. 3A

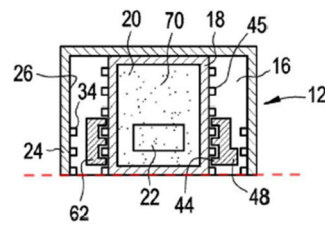
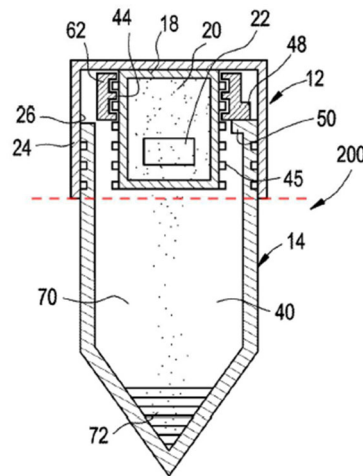


FIG. 3B



Petitioner contends Figures 3A and 3B (reproduced below with Petitioner’s annotations) in the ’584 application are also internally inconsistent because they “flip flop” the arrangement of the inner cylinder and show “a slanted inner cylinder (‘inner wall 5’) as slightly recessed” in Figure 3A and the inner cylinder “extending into the aperture of the outer wall 2 of the cap” in Figure 3B. Opp. 8–9 (citing Ex. 2022, Figs. 3A, 3B; Ex. 1027, ¶ 16).

FIG 3A

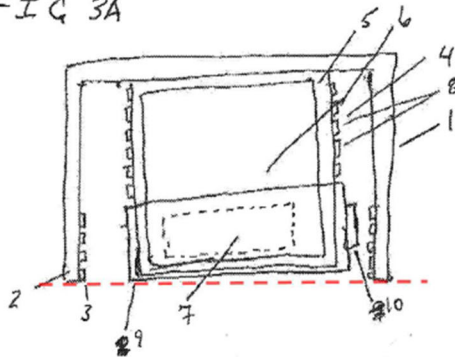
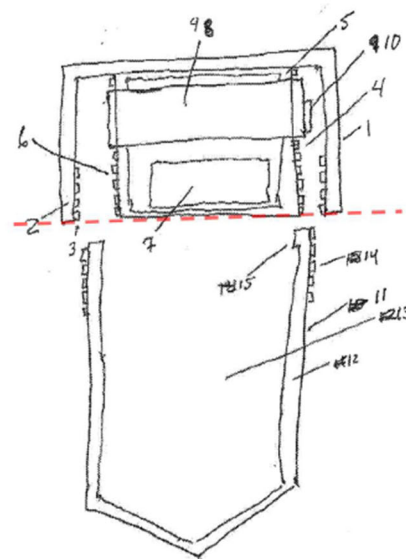


FIG 3B



On this record, we agree with Petitioner's position that Patent Owner's Motion does not appear to sufficiently set forth written description support for the proposed substitute claims because Patent Owner's citations do not reasonably convey that the inventors had possession of the claimed biological sample collection system with a movable annular valve comprising "a first cylinder comprising a third aperture, wherein the first cylinder is housed within the boundaries of the outer wall of the cap" and "a second cylinder comprising the vent, the second cylinder positioned in the third aperture, wherein the second cylinder is housed within the boundaries of the outer wall of the cap," as recited in proposed substitute claim 21. *See* Mot. 3–5, 26–27 (App. A). We agree with Petitioner that Patent Owner's citation to Figures 3A and 3B in the '003 application is insufficient to provide written description support for the claim limitations in proposed substitute claim 21 requiring that the first cylinder and second cylinder are "housed within the boundaries of the outer wall of the cap" because patent drawings are not necessarily drawn to scale and generally cannot be used to define the precise proportions of the elements or to show particular sizes when, as here, the specification is completely silent on the issue. *See Hockerson-Halberstadt, Inc. v. Avia Group. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000).

We note that Patent Owner has not yet had an opportunity to respond to the arguments and evidence cited in Petitioner's Opposition or this Preliminary Guidance. Patent Owner will have the opportunity to do so in a Reply or in a Revised Motion to Amend in this proceeding.

B. Patentability

For the reasons discussed below, at this stage of the proceeding, and based upon the current record,² it appears that Petitioner has shown a reasonable likelihood that proposed substitute claims 21–39 are unpatentable.

We note that Patent Owner has not yet had an opportunity to respond to the arguments and evidence cited in Petitioner’s Opposition or this Preliminary Guidance. Patent Owner will have the opportunity to do so in a Reply or in a Revised Motion to Amend in this proceeding.

1. Claim Construction

As an initial matter, we address the parties’ claim construction assertions regarding the claim language “within the boundaries of the outer wall of the cap” recited in proposed substitute claim 21, which appears to be in dispute between the parties.³

² We express no view on the patentability of original claims 1–16 and 18–20 in this Preliminary Guidance. Instead, we focus on the proposed amendments to those claims in the proposed substitute claims in Patent Owner’s Non-Contingent Motion to Amend and Request for Preliminary Guidance.

³ We note that the parties do not construe the potentially unclear claim language reciting “*the boundaries* of the outer wall of the cap” at this time. Based on their discussion of the prior art and the proposed substitute claims, it appears that the parties interpret this claim language as referring to the region defined by the three surfaces of the outer wall of the cap and the dashed horizontal line in Petitioner’s annotated versions of Figures 3A and 3B. *See* Opp. 9. For purposes of this Preliminary Guidance, we apply this interpretation of “the boundaries of the outer wall of the cap.”

Patent Owner contends the claim language “within the boundaries of the outer wall of the cap” recited in proposed substitute claim 21 indicates that

the annular valve comprising the first cylinder, the second cylinder, and the vent are housed within a volume defined by the outer wall 24 of cap 12 (*i.e., within the boundaries of the outer wall of the cap*), regardless of whether the annular valve is in the closed configuration (as illustrated in FIG. 3A) or the open configuration (as illustrated in FIG. 3B).

Mot. 11 (emphasis in original).

According to Petitioner, Patent Owner also implicitly construes “within the boundaries of the outer wall of the cap” to mean “housed entirely within the boundaries of the outer wall of the cap.” Opp. 5–6 (emphasis omitted). Petitioner argues that Patent Owner contends that the amended claims are allegedly patentable over the prior art from the Petition because “the first and second cylinders in the prior art are not entirely within the volume defined by the boundary of the outer wall of the cap.” *Id.* More specifically, Petitioner contends Patent Owner argues that “Cho does not satisfy the substitute claims because Cho’s ‘inner cylindrical component (slider 636)’ ‘extends beyond the boundaries of inner cap 634 and into the mouth of bottle body 610 . . .’” and “Ueda allegedly does not meet the claim limitations because its components ‘extend beyond the boundaries of cap 3 and into the opening of container main body 2.’” *Id.* at 6 (citing Mot. 15, 21). Petitioner disagrees with Patent Owner’s implied construction because “neither the plain language of the claims, the specification, the prosecution history, nor extrinsic evidence supports [Patent Owner’s] proposed narrowed interpretation of the well-understood term ‘within.’” *Id.*

Petitioner contends, with support from dictionaries,⁴ that “[t]he plain meaning of ‘within’ encompasses being located entirely in the interior, as well as extending into the interior.” Opp. 7 (emphasis omitted, citing Ex. 1028, 1439; Ex. 1029, 2183; Ex. 1030, 1976; Ex. 1027, ¶¶ 9–10). According to Petitioner, “[t]he specification does not include any disclosure that supersedes or limits the plain and ordinary meaning of ‘within’” such that “[t]he plain meaning of the term ‘within’ is broad enough to encompass first and second cylinders that extend into the boundary of the outer wall of the cap.” *Id.* Thus, Petitioner argues that “where substitute claim 21 recites ‘a movable annular valve positioned in the second aperture,’ it means that the first and second cylinders of the moveable annular valve are positioned in the opening of the cap, i.e., extend into the second aperture” because “the moveable annular valve cannot be within the second aperture defined by the outer wall of the cap” if the moveable annular valve “is entirely within the interior space 20 defined by the outer wall of the cap.” *Id.* at 8 (citing Ex. 1027, ¶ 13). In other words, “the first and second cylinders cannot be entirely within the boundaries of the outer wall of the cap and simultaneously ‘positioned in the [cap’s] second aperture,’ as required by substitute claim 21.” *Id.*

Petitioner contends further that the ’632 patent’s Figures 3A and 3B do not support Patent Owner’s implied claim construction because Figures 3A and 3B

⁴ We note that Patent Owner objects to Petitioner’s evidence of dictionary definitions for “within” and “aperture” (Exhibits 1029–1032) on the basis of hearsay, authentication, and relevance under FRE 401–403. Paper 20, 3–4. However, the current record does not provide alternative definitions of these terms.

“depict the claimed components inconsistently and without precision” (*see* Opp. 8–10) for the reasons discussed for its written description analysis.

Based on the current record, we agree with Petitioner that the plain meaning of the term “within” is broader than Patent Owner’s implied construction and, for the reasons discussed above, agree that Figures 3A and 3B do not support a construction that requires that the first and second cylinders are housed entirely within the boundaries of the outer wall of the cap. Despite agreeing with Petitioner’s proposed construction of “within the boundaries of the outer wall of the cap,” for the purposes of this Preliminary Guidance, we consider Petitioner’s obviousness arguments under Patent Owner’s implied construction and Petitioner’s proposed construction because Petitioner analyzed the claims under both constructions.

2. Obviousness over Plante and Cho

i. Obviousness under Petitioner’s Proposed Construction of “within the boundaries of the outer wall of the cap”

Petitioner argues the combination of Plante⁵ and Cho⁶ renders proposed substitute claims 21–39 obvious when “within the boundaries of the outer wall of the cap” is construed such that the claim language does not require that the first and second cylinders are housed entirely within the boundaries of the outer wall of the cap, and encompasses first and second cylinders that extend into the boundary of the outer wall of the cap. Opp. 2–5. Petitioner contends that “even with the newly-added limitations, the substitute claims remain unpatentable over the same

⁵ US 2012/0325721 A1, published Dec. 27, 2012 (Ex. 1003).

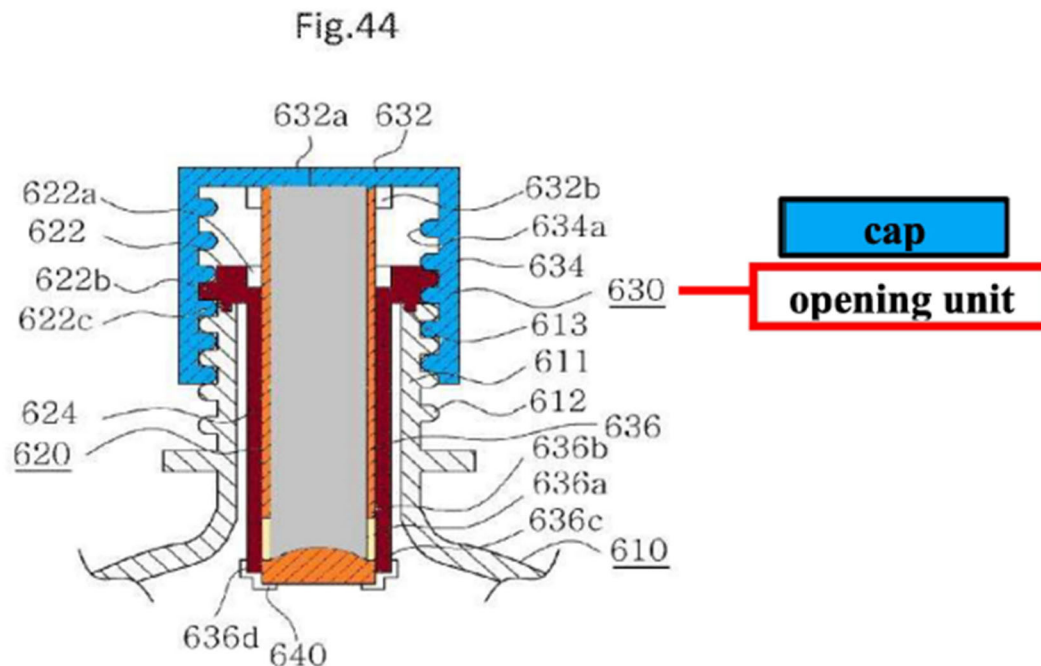
⁶ WO 2005/051775 A2, published June 9, 2005 (Ex. 1004).

prior art in Grounds 1 and 2 of the Petition.” *Id.* at 2. Petitioner argues that “[a]s set forth in the Petition, the combination of Plante and Cho renders claim 1 unpatentable.” *Id.* (citing Pet. 11–65). We address Petitioner’s arguments regarding each of the newly-added limitations below.

1. Proposed Substitute Claim 21

a. “a cap comprising an outer wall”

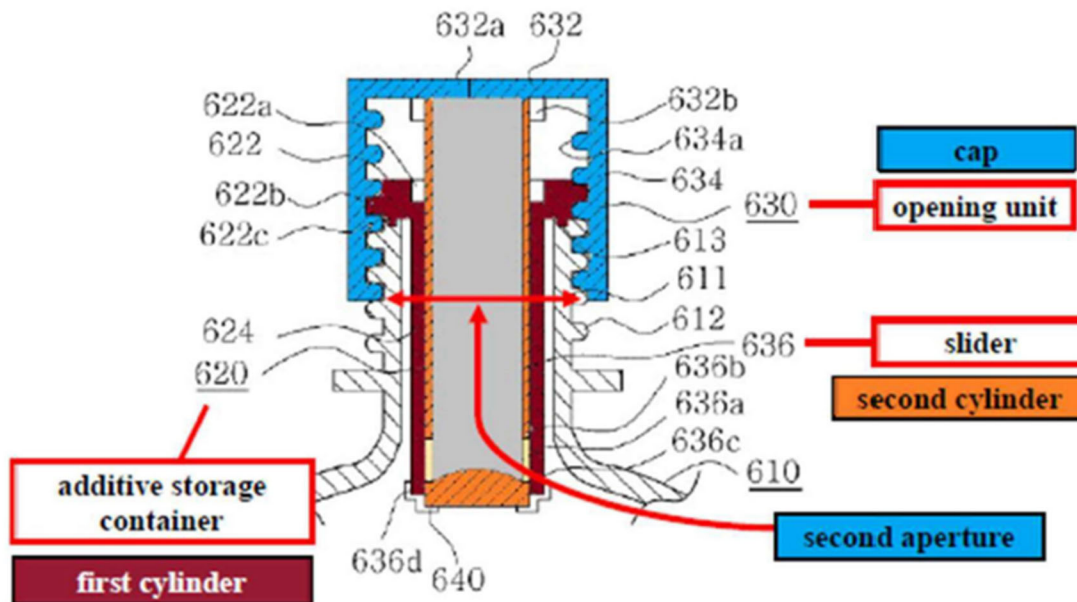
Petitioner contends Cho discloses the limitation in proposed substitute claim 21 reciting “a cap comprising an outer wall” because Cho’s Figure 44 illustrates “a cap 630 that includes an outer wall (blue).” Opp. 2–3 (citing Ex. 1004, 48:15–34, Fig. 44; Ex. 1027, ¶ 17). Cho’s Figure 44 is reproduced below with annotations added by Petitioner.



Id. (citing Ex. 1004, 48:15–34, Fig. 44).

b. “a moveable annular valve positioned in the second aperture”

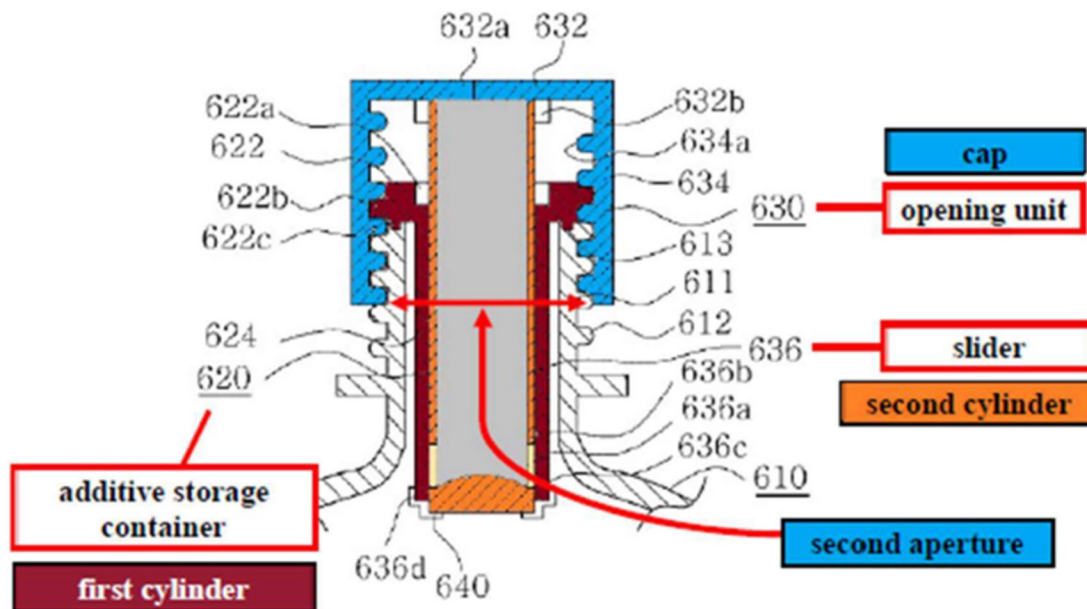
Petitioner contends Cho discloses the limitation in proposed substitute claim 21 reciting “a moveable annular valve positioned in the second aperture” because “Cho’s valve is in the second aperture, which is the aperture of the cap,” as shown in Cho’s Figure 44. Opp. 3 (citing Pet. 31–33; Ex. 1002, ¶¶ 99–100). Cho’s Figure 44 is reproduced below with annotations added by Petitioner.



Id. (citing Ex. 1004, Fig. 44; Ex. 1002, ¶¶ 99–100; Ex. 1027, ¶ 17).

c. “the [first/second) cylinder is housed within the boundaries of the outer wall of the cap”

Petitioner contends Cho discloses the limitations in proposed substitute claim 21 reciting “the [first/second) cylinder is housed within the boundaries of the outer wall of the cap” because “Cho’s annular valve is disposed in the cap and extends into and through the cap’s second aperture,” as shown in Cho’s Figure 44. Opp. 3–4 (citing Pet. 32–33; Ex. 1004, Fig. 44; Ex. 1002, ¶¶ 99–100; Ex. 1027, ¶¶ 18–19). Cho’s Figure 44 is reproduced below with Petitioner’s annotations.



Id. at 4 (citing Pet. 32–33; Ex. 1004, Fig. 44; Ex.1002, ¶¶ 99–100; Ex. 1027, ¶¶ 18–19).

d. “relatively moveable within the boundaries of the outer wall of the cap”

Petitioner contends that Cho discloses the limitation in proposed substitute claim 21 reciting “relatively moveable within the boundaries of the outer wall of the cap” because “[a]s explained above, the first and second cylinders are within the boundaries of the outer wall of the cap” and “[w]hen Cho’s cap is tightened on the bottle, the second cylinder (slider 636) ‘moves downward’ through the first cylinder 620 ‘so that the additive is discharged . . . through the discharge ports 636a.’” Opp. 4–5 (citing Ex. 1004, 49:34–50:12, Fig. 45A; Ex. 1002 ¶¶ 121–22; Ex. 1027 ¶¶ 20–21) (second alteration in original).

2. Proposed Substitute Claims 22–24, 26–36, 38, and 39

Petitioner contends substitute claims 22–24, 26–36, 38, and 39 are “unpatentable based on the combination of Plante and Cho as set forth in Ground 1

of the Petition” because “the only amendments PO made in substitute claims 22-24, 26-36, and 38-39 was to update the claim dependencies for original claims 2-4, 6-16, and 18-20, to make them depend directly or indirectly back to substitute claim 21.” Opp. 5 (citing Mot. 28–31; Pet. 45–65).

Based on the current record, Petitioner’s contentions appear to show that proposed substitute claims 21–39 would have been obvious over the combination of Plante and Cho under Petitioner’s proposed construction of “within the boundaries of the outer wall of the cap” because Cho appears to disclose each of proposed substitute claim 21’s newly-added limitations. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the combined teachings of Plante and Cho would have rendered proposed substitute claims 21–39 obvious.

*ii. Obviousness under Patent Owner’s Proposed Construction of
“within the boundaries of the outer wall of the cap”*

Petitioner argues the combination of Plante and Cho renders proposed substitute claims 21–24, 26–36, and 38–40 obvious when “within the boundaries of the outer wall of the cap” is construed such that the claim language requires that the first and second cylinders are housed entirely within the boundaries of the outer wall of the cap. Opp. 11–18. Petitioner contends that “[e]ven if substitute claim 21 required that the first and second cylinders are housed entirely within the boundaries of the outer wall of the cap, substitute claim 21 would still be obvious over Plante and Cho” because “[i]t would have been obvious to modify Cho’s cap to house the cylinders entirely within the boundaries of the outer wall of the cap, and [a person of ordinary skill in the art] would have had a reasonable expectation of success in doing so.” *Id.* at 11–12.

1. Motivation to Modify Cho

Petitioner contends that it would have been obvious to modify Cho's cap to house the cylinders entirely within the boundaries of the outer wall of the cap for several reasons. Opp. 13–15.

First, Petitioner argues that a person of ordinary skill in the art “would have been motivated to modify Cho's cap in order to reduce the potential risk of sample contamination when, for example, the device is handled by an unskilled user.” Opp. 13. Petitioner contends a person of ordinary skill in the art “would have been motivated to fully recess Cho's movable annular valve in the cap to minimize the potential of an unskilled user contacting the reagent reservoir and thus potentially contaminating the biological sample when the preservation reagent is mixed with the biological sample”, as Plante suggests. *Id.* (citing Ex. 1027 ¶¶ 26–30); *see also id.* at 14 (citing Ex. 1027 ¶¶ 29–30). Petitioner argues that Patent Owner's own briefs and declarations identified Cho's cap with first and second cylinders that extend below the bottom of the cap as “introduc[ing] a failure mechanism that increases the risk of sample contamination, which would render a sample defective.” *Id.* at 13–14 (citing Ex. 1037, 61, 63–65; Ex. 1038; Ex. 1039 ¶¶ 90–100; Ex. 2014 ¶¶ 70–71).

Second, Petitioner contends that it would have been obvious to modify Cho's cap because “there [are] only two options for placement of the moveable annular valve in the cap—either extending into or below the opening of the cap, or housed entirely within the cap.” Opp. 15 (citing Ex. 1027 ¶ 31). Thus, Petitioner argues “it would have been obvious to try, with a reasonable expectation of success, positioning Cho's first and second cylinders entirely within the boundaries of the outer wall of the cap.” *Id.*

Third, Petitioner contends that it would have been obvious to modify Cho's cap because a person of ordinary skill in the art "would have been motivated by design choices" such as "the amount of additive added to the cap and the width of the bottle neck and the reservoir in the cap." Opp. 15 (citing Ex. 1027 ¶¶ 32–34). Petitioner argues that "when the design calls for a smaller quantity of additive in the cap, a POSA would be motivated to reduce the vertical length of the reagent chamber in Cho's cap and thereby bring the first and second cylinders entirely within the boundaries of the outer wall of the cap," or when the design requires a wider neck as part of Cho's bottle, the cap will also be wider, and a POSA would be motivated to expand the width of the reagent chamber horizontally and reduce the vertical length of the reagent chamber, which brings the first and second cylinders entirely within the boundaries of the outer wall of the cap. *Id.*

2. Reasonable Expectation of Success

Petitioner contends that a person of ordinary skill in the art would have had a reasonable expectation of success modifying Cho's cap to house the cylinders entirely within the boundaries of the outer wall of the cap because a person of ordinary skill in the art would have "understood that Cho's size and volume could be modified based on the intended use of the device." Opp. 16 (citing Ex. 1027 ¶¶ 35–40). Petitioner argues that testimony from Patent Owner's declarant and other prior art references show that a person of ordinary skill in the art would have understood modifying Cho's device based on its intended use. *Id.* at 16–17 (citing Ex. 1034, 35:10–19, 35:21–36:14, 38:1–7, 69:13–70:9; Ex. 1035 ¶¶ 51–52; Ex. 1036 ¶¶ 2, 26; Ex. 1027 ¶¶ 37–39).

Based on the current record, Petitioner's contentions appear to show that proposed substitute claims 21–24, 26–36, and 38–40 would have been obvious

over the combination of Plante and Cho under Patent Owner’s proposed construction of “within the boundaries of the outer wall of the cap” because it appears that a person of ordinary skill in the art would have been motivated to modify Cho’s cap to house the cylinders entirely within the boundaries of the outer wall of the cap with a reasonable expectation of success. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the combined teachings of Plante and Cho would have rendered proposed substitute claims 21–24, 26–36, and 38–40 obvious.

3. Obviousness over Plante, Cho, and Patterson

Petitioner argues that the combination of Plante, Cho, and Patterson⁷ renders proposed substitute claim 25 unpatentable as obvious. According to Petitioner, proposed substitute claim 25 “depends from substitute claim 21 (original claim 1)” and Patent Owner “has not substantively amended claim 25.” Opp. 18. Petitioner contends proposed substitute claim 25 “is thus obvious over Plante and Cho (as explained above with respect substitute claim 21) and in view of Patterson as set forth in the Petition under Ground 2.” *Id.* (citing Pet. 66–71; Ex. 1002 ¶¶ 165–172); *see also id.* at 5 (citing Pet. 66–71).

Based on the current record, Petitioner’s contentions appear to show that proposed substitute claim 25 would have been obvious over the combination of Plante, Cho, and Patterson for the reasons discussed above and in Ground 2 of the Petition. Thus, it is our preliminary, non-binding opinion that Petitioner has

⁷ US 2006/0260959 A1, published Nov. 23, 2006 (Ex. 1010).

established a reasonable likelihood that the combined teachings of Plante, Cho, and Patterson would have rendered proposed substitute claim 25 obvious.

III. CONCLUSION

This concludes the Preliminary Guidance, which is Patent Owner's first option under the Board's Pilot Program. Notice, 84 Fed. Reg. at 9,497. Per the Joint Notice of Stipulation to Modify Due Dates 1 and 2 dated June 5, 2024 (Paper 15), Patent Owner has the additional option under the Board's Pilot Program to file a revised motion to amend by October 22, 2024 (Due Date 3). These two options are in addition to Patent Owner's original option to file a reply brief in response to Petitioner's opposition to the motion to amend.

In addition to those two options under the Board's Pilot Program and the option to file a reply brief, Patent Owner is reminded that amendments of the challenged claims may also be pursued in a separate reissue or reexamination proceeding before, during, or after an AIA trial proceeding, including subsequent to the issuance of the Final Written Decision. We draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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