

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

PATENT OWNER'S PRELIMINARY RESPONSE

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Patent Owner's Exhibit List for
Inter Partes Review of U.S. Patent No. 11,536,632

Exhibit Description	Exhibit #
<i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347 Order (Paper 37) Issued November 16, 2023	2001
Excerpts of Prosecution History of Application No. 16/879,506, filed as Exhibit 1012 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2002
DNA Genotek Inc.'s Opening Claim Construction Brief, <i>DNA Genotek Inc. v. Spectrum Solutions LLC</i> , C.A. No. 21-cv-0516 (S.D. Cal. February 18, 2022) (Dkt. 86), filed as Exhibit 1014 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2003
Deposition Transcript of Karl Leinsing taken on April 6, 2023 in <i>DNA Genotek, Inc. v. Spectrum Solutions, LLC</i> , No. 21-cv-516 (S.D. Cal.), filed as Exhibit 2011 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2004
Declaration of Vincent A. Fischetti, Ph.D. in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent 11,002,646 filed as Exhibit 1011 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347 on July 27, 2022	2005
Spectrum Solutions LLC's [Redacted] Opening Claim Construction Brief, <i>DNA Genotek Inc. v. Spectrum Solutions LLC</i> , C.A. No. 21-cv-0516 (S.D. Cal. February 18, 2023) (Dkt. 83), filed as Exhibit 1013 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2006
Deposition Transcript of Steven Wereley, Ph.D. taken on July 19, 2023 filed as Exhibit 1022 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2007
Declaration of Steven Wereley filed as Exhibit 2013 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2008
Deposition Transcript of Karl Leinsing taken on August 25, 2023 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347, filed as Exhibit 2057	2009

Exhibit Description	Exhibit #
<i>OraSure Technologies to Acquire DNA Genotek Inc.</i> , DNA GENOTEK (July 25, 2011), https://www.dnagenotek.com/us/company/news-events/press-releases/2011/2011-07-25.html , filed as Exhibit 2002 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2010
TIME MAGAZINE, December 12, 2005, filed as Exhibit 2005 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2011
Declaration of Karl R. Leinsing, MSME, PE, in Support of Petitioner's Reply, filed as Exhibit 1019 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2012
Declaration of Dr. Michael Metzker, filed as Exhibit 2012 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2013

I. INTRODUCTION

The challenged claims are directed to a novel biological sample collection system. The system comprises a moveable annular valve with a cap and tube for combining a preservative solution with a biological sample. The novel system can be used safely at home by an unskilled user without exposure to potentially toxic compounds. Nobody realized that the claimed system could be achieved until the inventors of the '632 Patent discovered it. Petitioner has failed to establish a reasonable likelihood of prevailing on any of the asserted grounds.

For Grounds 1 and 2, Petitioner relies on a primary reference, Plante, which uses a plastic pointed member to pierce a thin film membrane. Petitioner incorrectly asserts that the challenged claims would have been obvious in view of two beverage mixing containers, Cho and Patterson.¹ These grounds fail because the POSA would not have a motivation to combine or a reasonable expectation of success in the combinations: (1) Patterson and Cho are not analogous art to the '632 Patent, (2) Plante's piercing member poses no risk of occupational exposure to bloodborne pathogens, (3) molding of Plante's piercing member would not have been difficult, and (4) Cho's valve would make for a worse sample collection system.

¹ Paper 1 ("Pet.") at 11-65, 66-71.

Petitioner has also failed to show in Ground 3 that Ueda anticipates the challenged claims. Each of the challenged claims requires a cap that is distinct from the claimed valve. Indeed, in an IPR proceeding on a related patent, the Board tentatively construed “cap” as a “cover for the sample collection vessel that does not share a surface with the valve.” There is no structure in Ueda that corresponds to the claimed “cap.” Further, the challenged claims require a vessel with a first connection member that is complementary to a second connection member of the cap. Ueda’s alleged “cap,” the “plug member,” does not have a second connection member that is complementary to the first connection member. For the same reasons, Grounds 4 and 5, which rely on Ueda for the disclosure of the claimed “cap,” are also deficient.

II. BACKGROUND

The field of at-home biological sample collection has seen remarkable advances over the past decades as reflected by Genotek’s innovative intellectual property. During the COVID-19 pandemic, Petitioner took advantage of Genotek’s technology without compensation. Genotek sued Petitioner for patent infringement. Petitioner avoided infringement by urging the District Court to misapply basic principles of claim construction for the term “preserving a biological sample” as recited in the preamble of related U.S. Patent No. 11,002,646

(the “’646 Patent”). That case is now on appeal at the Federal Circuit. *See DNA Genotek Inc. v. Spectrum Solutions LLC*, No. 23-2017 (Fed. Cir. June 14, 2023)

The ’632 Patent has not been asserted against Petitioner. Petitioner filed this IPR as a tag-along petition to the ’646 Patent. The ’646 Patent is the subject of *Inter Partes* Review No. IPR2022-01347 (the “’646 Patent IPR”). The Board has heard oral argument and ordered additional briefing on the construction of the term “cap,” which has been completed.² The Board also ordered additional briefing on the meaning of “preserving a biological sample” in the ’646 Patent because Petitioner had taken inconsistent positions about the meaning of the term before the Board and the United States District Court for the District of Southern California.³

III. THE ’632 PATENT

The ’632 Patent is “relate[d] to devices, solutions, and methods for collecting samples of bodily fluids or other substances, including hazardous and/or toxic substances, and in particular, a naturally expressed bodily fluid (e.g., saliva,

² *See* Ex. 2001.

³ *See id.*

urine).”⁴ The devices allow an unskilled user to safely collect and preserve a biological sample and ship the sample to a laboratory for analysis.⁵

Among other things, Claim 1 requires a sample collection vessel, a cap, and a moveable annular valve.⁶ The sample collection vessel has a first connection member.⁷ The cap has second connection member complementary to the first connection member on the vessel.⁸ The valve has a first cylinder and a second cylinder, as well as a closed configuration and an open configuration.⁹ In the closed configuration, the valve’s cylinders create a fluid-tight seal with the cap.¹⁰ In the open configuration, a vent in the valve is unobstructed, which allows reagents to flow from a reagent chamber into vessel’s sample collection reservoir.¹¹

Prior to the claimed invention, nobody had designed such an innovative system for allowing unskilled users to release reagents directly into an at-home

⁴ Ex. 1001 at 1:20-23.

⁵ *Id.* at 3:59-4:14.

⁶ *Id.* at 22:21-53.

⁷ *Id.* at 22:25.

⁸ *Id.* at 22:30-31.

⁹ *Id.* at 22:32-53.

¹⁰ *Id.*

¹¹ *Id.*

sample collection device. The prior art required rupturable membranes or separate reagent tubes that could spill and expose users to reagents.

IV. THE ASSERTED PRIOR ART REFERENCES

A. Disclosure of Plante

Plante is titled “Saliva Sample Collection Systems”¹² and describes its field as “generally concerned with kits and systems for collection of biological matter and more specifically concerned with saliva collection, storage and transmission systems configured for non-expert use.”¹³ The Plante saliva collection systems are “configured for safe conveyance via standard shipping services”¹⁴ so that “the sample mixed with preserving fluid may be return shipped to the laboratory”¹⁵ for analysis. Figure 1 of Plante is below:

¹² Ex. 1003 at Title.

¹³ *Id.*, ¶ 0002.

¹⁴ *Id.*, ¶ 0017.

¹⁵ *Id.*, ¶ 0042.

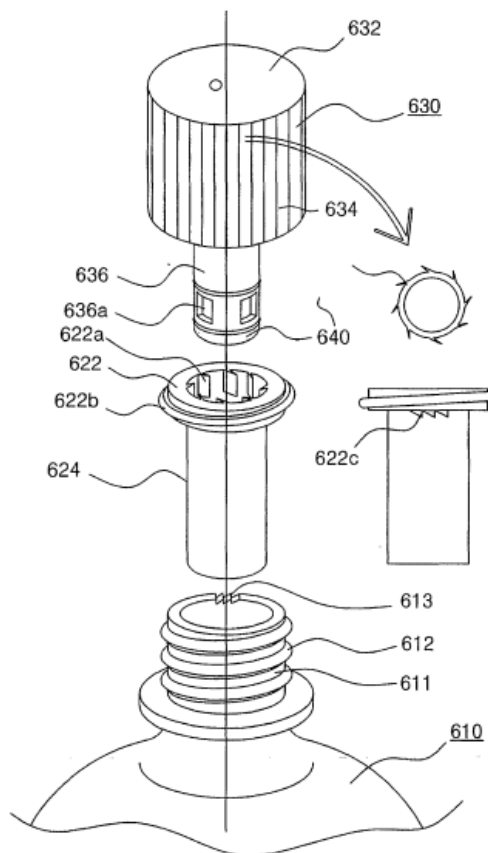


Cho is titled “Bottle.”¹⁶ Cho describes its “technical field” as directed “in general, to a bottle, which can not only contain two kinds of materials in two separate spaces in a bottle, but also cause the separate spaces to communicate with each other as necessary so that the two materials can be mixed to be used.”¹⁷ In describing the relevant art, Cho explains that some “bottles currently traded on the market” have materials in separate bottles that are mixed prior to consumption or

¹⁷ *Id.* at 1:1-6.

use.¹⁸ For example, Cho continues, “a coffee-based beverage may be mixed with sugar or cream powder therein; medicines and chemicals are similar cases.”¹⁹

With this context, Cho explains that one of its objectives 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.”²⁰ Figure 43 below is an example of such a bottle, the sole example cited in the Petition for Grounds 1 and 2.



¹⁸ *Id.* at 1:8-9.

¹⁹ *Id.* at 1:11-12.

²⁰ *Id.* at 1:21-24.

Ex. 1004, Fig. 43 at 119.

Another object, for Cho, is “to provide a bottle in which the additive storage container can be completely removed from a bottle body through an opening action of an opening unit.”²¹ This object reflects Cho’s field of endeavor—to mix ingredients in a bottle so that the bottle can be opened immediately after mixing, at which point the system is discarded. When a coffee-based beverage is mixed with sugar or cream powder, it is ready for consumption, at which point the lid is discarded. Similarly, when pharmaceuticals and chemicals are mixed, mixing is prior to use; the ingredients are kept apart until they are needed. Once mixed, the bottle and lid are discarded. In the “Industrial Applicability” section, Cho describes “the rotation of an opening unit relative to the mouth of a bottle body removes an additive storage container from the bottle body as well as releasing additive into the bottle body, so that the bottle is convenient to use.”²² In other words, the components are separate until mixed, then immediately consumed or used; the mixture is not stored.

²¹ *Id.* at 2:4-6; *see also id.* at Abstract (“The additive storage container can be completely removed from the bottle body.”).

²² *Id.* at 55:31-56:2.

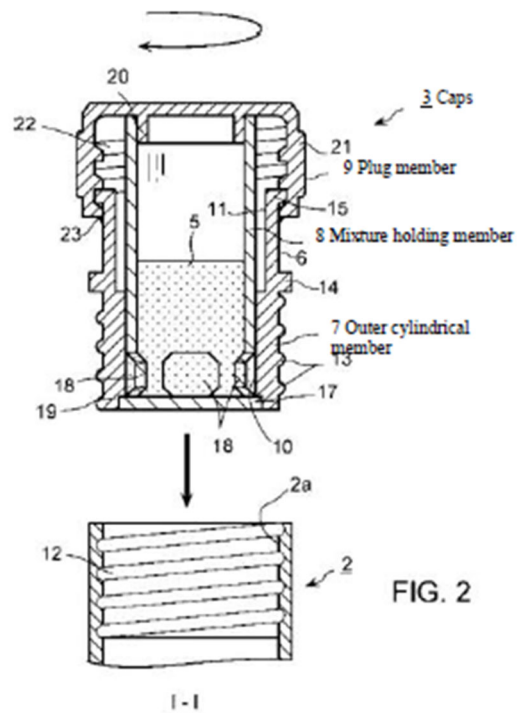
C. Disclosure of Patterson

Patterson teaches immediate removal of a “mixing cap” from a water bottle so that a resulting beverage can be consumed: “removal of the mixing cap enables consumption of the fully mixed beverage.”²³ Thus, once Patterson’s user has consumed the mixed contents, the bottle and “mixing cap” are to be discarded.

D. Disclosure of Ueda

Ueda teaches a container with a three-part threaded valve assembly. By screwing an outer cylindrical member onto a tube and then screwing a plug member onto the outer cylindrical member, a mixture holding member is forced downward relative to the outer cylindrical member, which allows the mixture to leave the holding member:

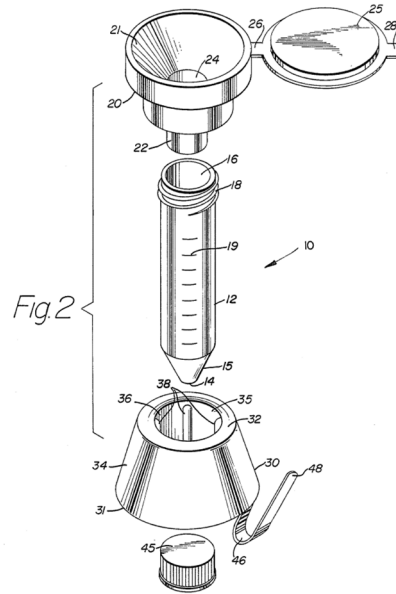
²³ Ex. 1010 at [0016], [0036].



Ex. 1005, Fig. 2.

E. Disclosure of Williams

Williams discloses a biological specimen collection device comprising a specimen receptacle and a funnel.



Ex. 1009, Fig. 2.

V. CLAIM CONSTRUCTION

A. “Cap”

In the pending IPR proceeding on the related ’646 Patent, the Board proposed a construction of “cap” as meaning “a cover for the sample collection vessel that does not share a surface with the valve” and requested briefing on its proposed meaning.²⁴ In response, Genotek explained that the Board could adopt its proposed construction of “cap” if it is made clear, as suggested by the proposal, that the valve and cap are not co-extensive. Genotek’s proposed construction of “a cover for the sample collection vessel that is not co-extensive with the movable annular valve” avoids possible disputes by Petitioner about what constitutes a

²⁴ Ex. 2001 at 3.

shared surface. Any construction that is faithful to the claims and specification will not encompass the claimed annular valve as being co-extensive with the cap.

The text of the claims supports Patent Owner's construction. The cap is listed as a distinct structure from the valve in Claim 1.²⁵ The valve is comprised of, among other things, a first and second cylinder.²⁶ The cap, for its part, is comprised of a second aperture and a reagent chamber. The claims are clear that the valve and cap are distinct components. In the "valve's closed configuration, the first and second cylinder create a fluid-tight seal with the cap."²⁷ If the valve and the cap could be co-extensive, then it would be impossible for the valve's components to create a fluid-tight seal with the cap.

The specification also supports Patent Owner's construction. The figures all show that the cap is not co-extensive with any depicted valve. Figure 3A, for example, demonstrates that the structure of the cap is not co-extensive with the valve: "FIG. 3A shows an embodiment of the cap of the sample collection device in which the cap contains an inner chamber with a movable annular member that can cover an aperture in the inner wall according to some embodiments of the

²⁵ Ex. 1001 at 22:21-53.

²⁶ *Id.*

²⁷ *Id.*

present disclosure.”²⁸ Whether or not the cap may form part of a cavity that holds reagents, the cap is not the valve: “some embodiments may further include an annular member at the base of the cap that is partially secured to the cap”²⁹

The specification further describes: “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**.”³⁰ The cap is not simply the sum of the parts of the annular valve.

In the prosecution of the related ’646 Patent, the Examiner understood that the cap is not co-extensive with the valve. The Examiner used parentheses to separately delineate each limitation for the cap and valve in the prior art.³¹ The Examiner described the cap and valve as being not co-extensive: “The valve is opened when the cap is unscrewed which allows the valve to open and the contents of the cap move to the sample collection vessel.”³² After a rejection, Patent Owner amended to specify that the movable annular valve comprised an inner and

²⁸ *Id.* at 8:49-53.

²⁹ *Id.* at 11:41-43.

³⁰ *Id.* at 14:46-49.

³¹ Ex. 2002 at 4.

³² *Id.* at 5; *see also id.* at 6 (“the movable annular valve associated with the cap”).

outer cylinder, which underscores that the claimed cap is not co-extensive with the valve and is consistent with its positions in the district court.³³

Expert testimony supports Patent Owner's construction. Petitioner's two experts in the '646 Patent IPR talked about caps as a separate component from the valve.³⁴ And, in the co-pending district court litigation relating to the '646 Patent, Petitioner maintains that Figures 3A and 3B depict the claims and labelled the cap as a distinct structure from the valve.³⁵ Petitioner cannot have it both ways.

VI. RESPONSE TO GROUNDS OF CHALLENGE

A. Plante, Cho, and Patterson (Grounds 1 and 2)

Petitioner argues that all claims of the '632 Patent, except Claim 5, are obvious in view of Plante and Cho. Petitioner argues that dependent Claim 5, which depends from Claim 1 and recites "wherein the first cylinder comprises a press-fit connection with the cap," is obvious in view of Plante, Cho and Patterson.

None of the reasons that Petitioner offers for these combinations holds water.³⁶

³³ *Id.* at 13, 18; Ex. 2003 at 28.

³⁴ Ex. 2004 at 28:8-12, 93:6-13, 99:17-21; Ex. 2005 at 9 (delineating the cap in the '646 Patent from the valve as separately numbered elements).

³⁵ Ex. 2006 at 10.

³⁶ Pet. at 15-16 (citing Ex. 1002 ¶¶ 67-74).

1. The NSPA Provides No Motivation to Combine Plante and Cho

In seeking to establish a motivation to replace Plante’s plastic knife and utilize Cho’s cap, the Petition argues that “[i]t has long been known in the field of medical devices to avoid sharp objects if possible” and cites to the “Needlestick Safety and Prevention Act” of 2000.³⁷ But Plante was filed in 2009 and would have been aware of the NSPA.³⁸ If the NSPA motivated a POSA not to use a plastic pointed member as Petitioner urges, the Plante device would never have been designed. A POSA would have understood that the plastic knife of Plante is not a “sharp” and that the Plante saliva sample collection system does not pose a risk of occupational exposure to bloodborne pathogens.³⁹ The NSPA is simply not relevant to saliva sample collection systems that are designed for at-home use, like those claimed by the ’632 Patent.

Even if a POSA would have considered the NSPA in designing certain at-home collection systems, there still would not have been a motivation to modify Plante’s specific design, because Petitioner presents zero evidence that anybody has ever been hurt by a Plante-type device. Indeed, testing shows that Plante’s

³⁷ Pet. at 15.

³⁸ Ex. 1003 at Cover Page.

³⁹ Ex. 2008, ¶ 34; Ex. 2013, ¶ 12.

plastic knife was not dangerous. Professor Steven Wereley, of Purdue University, tested embodiments of the invention that “meet the description in Plante of a knife,” and demonstrated that they pose no risk of sharps injury.⁴⁰ *Wabco Holdings Inc. v. Transtex Composite Inc.*, No. IPR2018-00737, 2018 WL 4691262, at *3 (PTAB Sept. 27, 2018) (the Board may consider testing of commercial embodiments). Mr. Leinsing never did any testing, nor did he testify that Dr. Wereley’s testing was inadequate.⁴¹

Further, even if the Plante-type plastic knife could pose a risk of harm, Plante already follows the prescriptions of the NSPA by employing engineering controls that eliminate or reduce the risk of harm, namely that the plastic knife is “carefully positioned” and placed below the protective shroud of the opening of the Plante device.⁴² Dr. Wereley provided testing and analysis on this point as well.

He showed that (1) a user would be unlikely to touch Plante’s knife because of engineering controls that carefully position the plastic knife outside the range of the user⁴³ ; (2) even in the highly unlikely event that a user came into contact with the plastic knife, the user would not be harmed through normal use or unintentional

⁴⁰ Ex. 2007 at 81:17-82:12; Ex. 2008, ¶¶ 26-45.

⁴¹ Ex. 2009 at 8:20-22.

⁴² Ex. 2008, ¶ 49

⁴³ Ex. 2008, ¶¶ 35, 49.

misuse⁴⁴; and (3) that a POSA would easily know to mold a plastic knife that was sharp enough to rip a foil membrane but not so sharp as to be dangerous to human skin.⁴⁵

In the IPR proceeding on the '646 Patent, Spectrum's expert admitted that Plante's plastic knife is not a needle, is not a cone-shaped point, and would only need to be a "knife that would be able to cut the Foil 13."⁴⁶ ("Q. A knife is not a needle; correct? A. "In general, I would agree")") How "sharp" is that? The '646 Patent itself teaches that the knife-foil devices could be ruptured with an ordinary fingernail.⁴⁷ The '632 Patent never teaches that "sharp" prior art plastic features pose a risk of cutting the user's skin. The '632 Patent instead focuses on the risk of piercing the "thin pierceable membrane" that would expose a user to reagents.⁴⁸

It is undisputed that at the time of the invention, the saliva collection device market was filled with Plante-type knives.⁴⁹ If those plastic knives were as

⁴⁴ *Id.*, ¶ 36.

⁴⁵ *Id.*, ¶¶ 34, 52-64.

⁴⁶ Ex. 2009 at 40:25-41:9; 42:14-24; 43:15-16.

⁴⁷ Ex. 1001 at 4:15-35.

⁴⁸ *Id.*

⁴⁹ Ex. 2008, ¶¶ 28-31; Ex. 2010; Ex. 2011 at 68.

dangerous as Spectrum claims, Spectrum would have filled its Petition with regulatory and product warnings. Of course, it did not. Instead, those devices were praised in Time Magazine.⁵⁰ In the real world, nobody thought plastic knives were unreasonably dangerous, and Plante-type knives continue to be popular.

Thus, Petitioner's primary motivation to modify Plante falls apart.

2. Plastic Molding Procedures Do Not Provide a Motivation to Combine

Similarly, the inventors of Plante would have been aware of plastic molding procedures and production costs when they designed their plastic-knife device. Petitioner incorrectly argue that injection molding difficulties would motivate a POSA to modify Plante. But injection molding is not the only way to form plastic objects. Experts agree that it was possible to use plastic molding to achieve Plante's knife.⁵¹ (Dr. Wereley: "[A] POSA would have known that the piercing members could be made from routine molding in a routine manufacturing process . . . Spectrum's own ability to manufacture a pointed member is further evidence that it was not difficult . . ."); (Mr. Leinsing: "injection molding could be used to create pointed members, like Plante's knife . . ." (emphasis in original)).⁵² A

⁵⁰ *Id.*

⁵¹ Ex. 2008 ¶¶ 53-64.

⁵² Ex. 2012 ¶ 6.

POSA would know how to mold a plastic knife that is “sharp” enough to rip foil but dull enough not to pose an unreasonable risk of harm.⁵³

The Injection Molding Handbook (“Handbook”) undermines Spectrum’s argument that molding a plastic knife is “difficult.”⁵⁴ The Handbook teaches that designs with varying thickness can be “unavoidable” and are easily made: “the transition should be gradual and coring should be utilized whenever possible.”⁵⁵

Regardless, Plante’s plastic knife would have posed fewer plastic molding difficulties than the valves of the cited art, such as Cho. For example, Cho uses a plastic gear and toothed ratchets to transmit rotational force to open the valve.⁵⁶ The Handbook teaches that “[g]ear design is one of the more complicated areas for designing with plastics, because the bending, shear, rolling, and sliding stress all act on a mechanism whose purpose is to transmit uniform motion and power.”⁵⁷ Thus, the Handbook discourages using plastic molding for Cho’s valve instead of Plante’s simple knife.

⁵³ Ex. 2008 ¶¶ 34, 57.

⁵⁴ Ex. 2012 ¶ 7; Ex. 1014 [Ex. 1021] at 729.

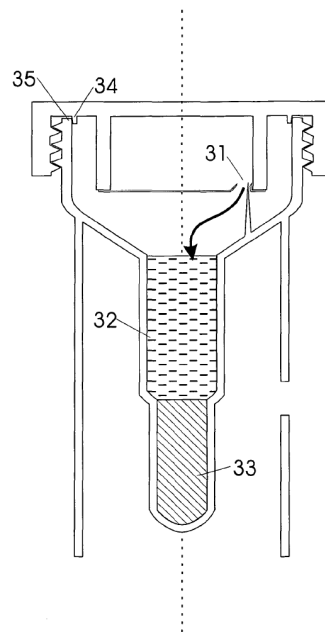
⁵⁵ *Id.*

⁵⁶ Ex. 1004 at 50:4-27.

⁵⁷ Ex. 1014 at 759.

3. Cho's "2-Stage" Valve Defeats Basic Objectives of Key Plante Features

Plante teaches a "saliva sample collection system"⁵⁸ and lists one of its objectives as "provid[ing] systems of reduced parts and increased ease of use for improved reliability."⁵⁹ Plante has a small number of parts—a knife and a foil—to release a preservative from the cap into the vial upon closing (see Plante Figure 3 below).⁶⁰



Plante also teaches another objective is to reduce the number of steps required to release preservative into the vial:

⁵⁸ Ex. 1003 at Cover Page.

⁵⁹ Ex. 1003, ¶ 0028.

⁶⁰ Ex. 1003 at Figure 3.

A thin-film or foil is used to complete the reservoir cell. As these support functionality related to release of the fluid from the reservoir at the appropriate time. Namely, when a cap element is coupled to the receiving vessel element, it is desirable to automatically have the fluid mixed with the saliva. Accordingly, without taking any extra steps, measuring, pouring, calculation, et cetera, an unskilled user preserves the saliva sample merely by screwing the cap to the receiving vessel together.⁶¹

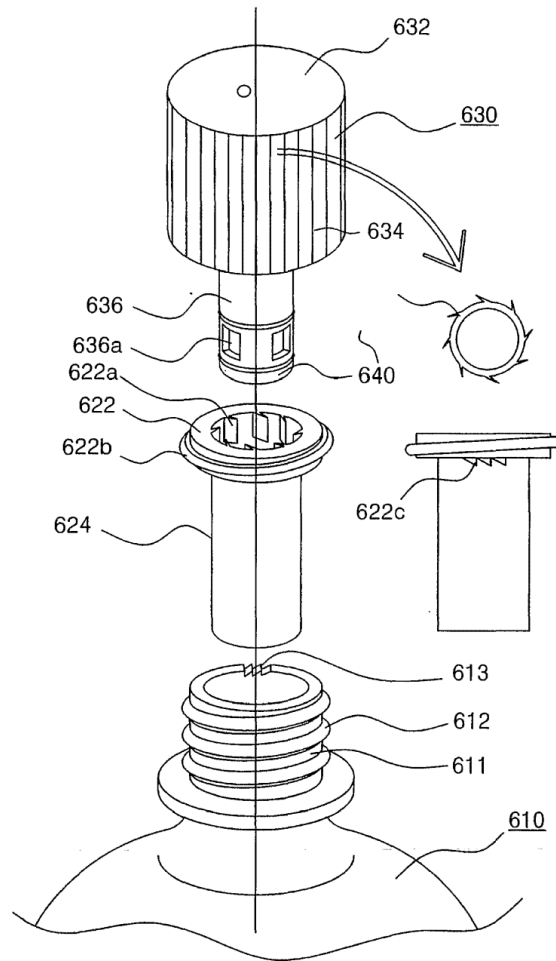
The basic objectives of Plante are destroyed by the Petition's proposed substitution. Petitioner argues that a POSA would prefer a cap that can seal onto the vessel before the valve is opened but overlooks disadvantages of the resulting design.⁶² The proposed substitution would add parts to Plante's design, increase the number of steps required to release the reagent, and raise the propensity for user error. For example, a user could cap the sample-containing container but unknowingly fail to release the reagent, either because Cho's cap was not sufficiently screwed on to engage the valve, or because the valve malfunctioned.

There is no motivation to combine references where the substitution would destroy the basic objective of a key feature one of the prior art designs. *See*

⁶¹ Ex. 1003, ¶ 0041.

⁶² Pet. at 16.

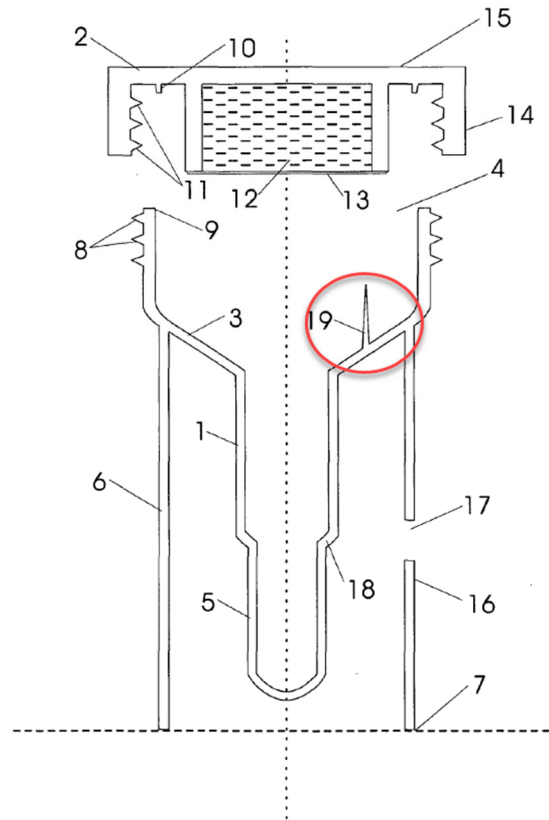
Trivascular Inc. v. Samuels, 812 F.3d 1056, 1068 (Fed. Cir. 2016). A basic objective of Plante is to reduce parts.⁶³ Rather than reduce parts, Cho would add parts to Plante's device:



Neither the Petition nor Dr. Leinsing's declaration addresses Plante's basic objectives. The Petition argues that POSA "would have been motivated by design incentives to replace Plante's approach of using a knife in the vessel and a

⁶³ Ex. 1003, ¶ 0028.

pierceable membrane in the cap with a safer design of using an annular valve in the cap.”⁶⁴ But there is nothing in the record to explain why POSA would destroy one of Plante’s basic design objectives simply to remove the plastic pointed member that is carefully and safely positioned deep within Plante’s vial.⁶⁵



⁶⁴ Pet. at 65; *see also id* at 30.

⁶⁵ Ex. 1003, Figure 1.

4. Cho Combinations Create an Unacceptable Risk of Contamination

Cho's cap introduces a failure mechanism.⁶⁶ Specifically, Cho's annular valve extends significantly beyond the bottom of Cho's cap.⁶⁷ This increases the risk that a hand touches the interior of the device.⁶⁸ Such a touch could lead to a defective sample.⁶⁹ The risk is heightened because the annular valve resembles a handle and naturally suggests itself to be an interaction point for a user.⁷⁰ A POSA would not have a reasonable expectation of success because of the contamination risk presented by Cho's cap. Because the annular valve and film of Cho are sample-exposed surfaces in the proposed combination, improper handling (e.g., touching the valve or film) prior to sample collection would introduce interfering contaminants that in many cases would lead to erroneous testing results. Mr. Leinsing did not consider these contamination risks.

⁶⁶ Ex. 2008, ¶ 91.

⁶⁷ *Id.*, ¶ 92.

⁶⁸ Ex. 2008, ¶ 92.

⁶⁹ Ex. 2013, ¶ 19.

⁷⁰ Ex. 2008, ¶ 92.

5. Simple Substitution Is Not a Motivation to Combine

Petitioner’s fourth purported motivation—simple substitution with predictable results—is no better.

“Mere compatibility of the references is . . . not sufficient.” *Johns Mansville Corp. v. Knauf Insulation Inc.*, IPR2018-00827, Paper 9 at 10-11 (PTAB Oct. 16, 2018) (citing *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993 (Fed. Cir. 2017) (“it is not enough to show that ‘a skilled artisan, once presented with the two references, would have understood that they could be combined’”). As with the Petitioner in the Board’s informative *Johns Mansville* decision,⁷¹ Petitioner here merely argues that the art *could* be combined with predictable results, styling that argument as a motivation to combine.⁷² That is insufficient for Petitioner to meet its burden. “Obviousness, however, requires ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.’” *Johns Mansville*, IPR2018-00827,

⁷¹ *Johns Mansville*, at 13 (“Third, Petitioner argues that ‘combining the teachings of the two references would have been well within the skill’ of an ordinarily skilled artisan, who would have had a ‘reasonable expectation of success in fabricating materials based on the teachings of [the art].’”).

⁷² Pet. at 16-17.

Paper 9 at 13 (*quoting KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)).

Petitioner assumes that all caps are useful in biological collection and preservation devices, without any argument or evidence to support that the beverage dispensing caps in Cho and Patterson are suitable. *Johns Mansville*, IPR2018-00827, Paper 9 at 11 (“Petitioner’s argument assumes that all thermoset binders are useful in a fiberglass insulation product of the type disclosed in Srinivasan—an assumption that Petitioner fails to support.”).

Thus, there would have been no reason or motivation to combine Plante and Cho, thereby rendering both Grounds 1 and 2 based on this proposed combination deficient.

B. Patterson and Cho Are Not Analogous Art to the ’632 Patent (Grounds 1, 2 and 4)

“To be considered within the prior art for purposes of the obviousness analysis, a reference must be analogous.” *Cir. Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1335 (Fed. Cir. 2015) (citing *Wang Lab’ys, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864 (Fed. Cir. 1993)). Because neither Cho nor Patterson is analogous to the ’632 Patent, the art should not be considered within the Petition’s obviousness analysis. “Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the

inventor is involved.” *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011) (quoting *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004)). Cho and Patterson fail both prongs of this analogous art test.

1. Neither Cho Nor Patterson Is from the Same Field of Endeavor as the '632 Patent

Cho and Patterson are not from the same field of endeavor as the '632 Patent. The '632 Patent is directed to collecting a biological sample and mixing the sample with a preservative prior to shipping the mixture for analysis; Cho and Patterson are directed to mixing water and a flavoring prior to drinking the mixture. These fields are different.

The '632 Patent explicitly states that its technical field is directed to “devices, solutions and methods for collecting samples of bodily fluids or other substances”⁷³ and, once collected, mixing the sample with a “preservation

⁷³ Ex. 1001 at 1:21-22, Abstract (“The disclosure relates to devices, solutions and methods for collecting and processing samples of bodily fluids containing cells”), 4:52-54 (“Embodiments of the disclosure provide safer and easy to use sample collection devices for naturally expressed bodily fluids (for example)”).

solution.”⁷⁴ This description is consistent with the ’632 Patent’s title (“BIOLOGICAL COLLECTION SYSTEM”)⁷⁵ and description of the illustrated devices.⁷⁶ The sample collection and preservation devices are used for “home-

⁷⁴ *See, e.g., id.* at Abstract (“With respect to devices for collection of bodily fluids, some embodiments include two mating bodies . . . [a] cap [that] includes a closed interior space for holding a sample preservative solution and mates with [a] tube to constitute the (closed) sample collection device”).

⁷⁵ *See, e.g., id.* at Title.

⁷⁶ *See, e.g., id.* at 8:28-30 (“FIG. 1 shows a sample collection device”), 8:39-40 (“FIG. 2A shows a longitudinal cross section view of a sample collection device”), 8:49-50 (“FIG. 3A shows an embodiment of the cap of the sample collection device”), 8:62-63 (“FIG. 4A shows an embodiment of the sample collection device”), 9:5 (“FIG. 5A shows a sample collection device”), 9:14 (“FIG. 6 shows a sample collection device”).

based sample collection”⁷⁷ such that “samples can be more easily shipped by the subjects from anywhere in the world.”⁷⁸

The Petition merely asserts that “Cho [is] in the same field of endeavor as the ’632 patent and address[es] the same problem.”⁷⁹ Dr. Leinsing’s declaration provides only a superficial analysis of Cho. He simply concludes that because “Cho is similarly directed to an easy-to-use container for mixing two materials . . . [a] POSA would thus understand that Cho is in the same [field] of endeavor and addresses the same problem as Plante and the ’632 patent.”⁸⁰ Regarding the

⁷⁷ *Id.* at 1:60-61; *see also id.* at 2:42-44 (“Naturally expressed bodily fluids, e.g., saliva and urine, can be an additional or alternative appropriate source material for home-based sample collection . . .”).

⁷⁸ *Id.* at 2:55-57; *see also id.* at 11:65-12:1 (“Additionally, the cap 12 and tube 14 can be configured to securely mate with one another in order to provide a secure containment of at least the sample bodily fluids for storing and shipping.”), 12:43-47 (“The one or more fluids or materials contained in the interior space . . . in the cap . . . may assist in preserving the sample body fluids contained in the reservoir . . . of the tube . . . during at least storage and shipping.”).

⁷⁹ Pet. at 14.

⁸⁰ Ex. 1002, ¶ 65.

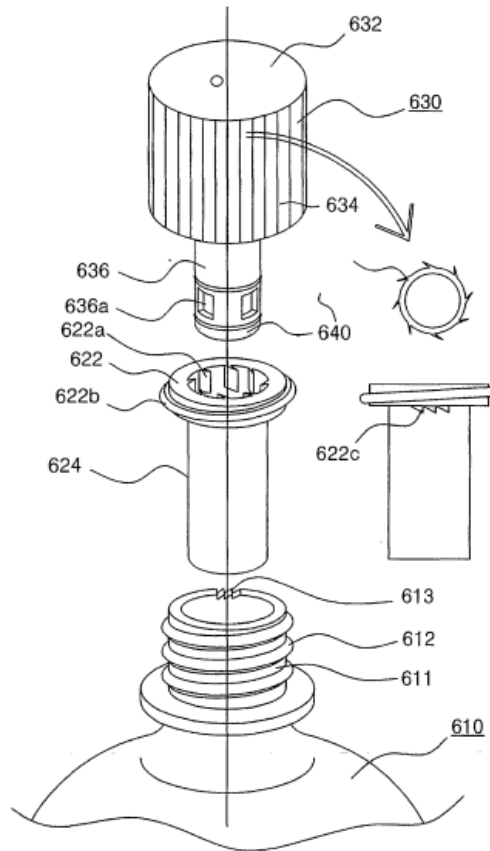
Patterson reference, neither the Petition nor Dr. Leinsing's expert declaration argues that Patterson is in the same field of endeavor or addresses the same problem as the '632 Patent. That is not good enough to take away Patent Owner's property rights in the challenged claims.

2. Neither Cho Nor Patterson Is Reasonably Pertinent to the Particular Problem Addressed by the '632 Patent

Cho and Patterson are not reasonably pertinent to the particular problem with which the '632 Patent is involved. "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). Cho and Patterson do not logically commend themselves to the '632 Patent's problem.

The '632 Patent is involved with addressing "wrong manipulation" and providing a "minimum number of parts," but the Petition has no evidence or argument that Cho and Patterson are reasonably pertinent to those problems. They are not. The Cho embodiment cited in the Petition⁸¹ includes numerous parts:

⁸¹ Ex. 1004 at Figure 43.



Cho's device would only compound the problems that the '632 Patent solves because Cho adds unnecessary and undesirable complexity. Cho's many-part cap would not logically commend itself to POSA addressing the '632 Patent's problem, and thus Cho's device is not reasonably pertinent to the '632 Patent's problem. There is nothing in the record to the contrary—neither the Petition nor Dr. Leinsing's declaration address why Cho's cap, with many parts, would be reasonably pertinent to the '632 Patent's purpose of providing a "minimum amount of parts."⁸²

⁸² Ex. 1001 at 4:64-65, 9:60.

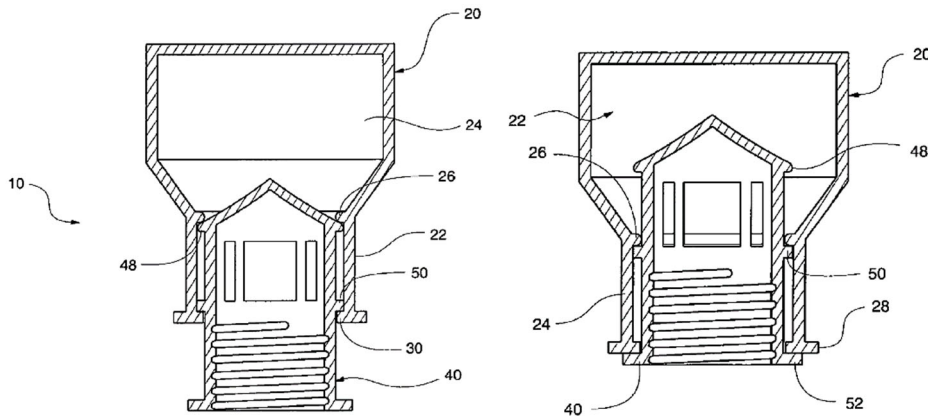
Although Patterson has fewer parts than Cho—including because Patterson’s valve assembly lacks the claimed cap—Patterson is not reasonably pertinent to another problem addressed by the ’632 Patent, “wrong manipulation.” The ’632 Patent is concerned with solving “wrong manipulation” of prior art devices: “a safety hazard to the sample donor as any wrong manipulation (such as with a finger nail) can lead to piercing of the membrane and release of the solution.”⁸³ Patterson does not address the “wrong manipulation” problem addressed by the ’632 Patent at all. In fact, it only makes things worse.

Unlike the ’632 Patent—which requires the vial to engage the cap to initiate release of the solution—Patterson simply requires the user to “push down.” Patterson Figure 2⁸⁴ shows the Patterson device in the closed position, i.e., prior to release; Patterson Figure 3⁸⁵ shows the Patterson device in the open position, i.e., after the beverage ingredient is released:

⁸³ *Id.* at 4:22-25.

⁸⁴ Ex. 1010 at Figure 2.

⁸⁵ *Id.* at Figure 3.



Patterson’s “mixing cap” does not require a vial to move the cap from the closed position (Figure 2) to the open position (Figure 3). A user could place the “mixing cap” on a tabletop and inadvertently apply pressure to the top, thereby releasing the beverage mixture. A user could hold the “mixing cap” in his or her hand and inadvertently apply pressure to release the beverage mixture. The ’632 Patent identifies a risk of “wrong manipulation” presented by a fingernail accidentally piercing a foil membrane; Patterson’s risk is more likely. Because Patterson increases the risk of a “wrong manipulation,” the Patterson device would not logically commend itself to a POSA addressing the ’632 Patent’s problems. There is nothing in the Petition nor Dr. Leinsing’s declaration to the contrary.

The Board denied institution in a similar case, *The Chamberlain Grp., LLC v. Overhead Door Corp.*, IPR2022-00842, Paper 9 (PTAB Oct. 25, 2022), because the petitioner did not show that its asserted references were analogous art to the challenged patent. The Board held that “Petitioner does not sufficiently show that [the reference] would logically have commended itself to an inventor’s attention in

considering a problem of” of the challenged patent. *Id.* at 37; *see also Polygroup Ltd. v. Willis Elec. Co.*, IPR2016-01609, Paper 16 at 37-38 (PTAB Feb. 26, 2018) (finding no analogous art where prior art “generally addresses problems with convenient assembly, disassembly, and electrically connecting sections of an artificially lit object” and “a problem faced by the inventor in this art is convenient assembly and disassembly, *but as it relates to artificial trees*”) (emphasis added)), *aff’d*, 759 F. App’x 934 (Fed. Cir. 2019). The result should be the same here.

Because Cho and Patterson fail the first and second prong of the analogous art test, Petitioner has not established a reasonable likelihood of prevailing on Grounds 1, 2, and 4 which rely on these two references.

C. Ueda (Ground 3) Is Deficient

Petitioner argues that Claim 1 and several claims that depend from Claim 1 are anticipated by Ueda. Not so. Ueda does not disclose at least limitation 1[b] “a cap comprising,” and therefore does not anticipate Claim 1 of the ’632 Patent or any of the claims that depend therefrom.

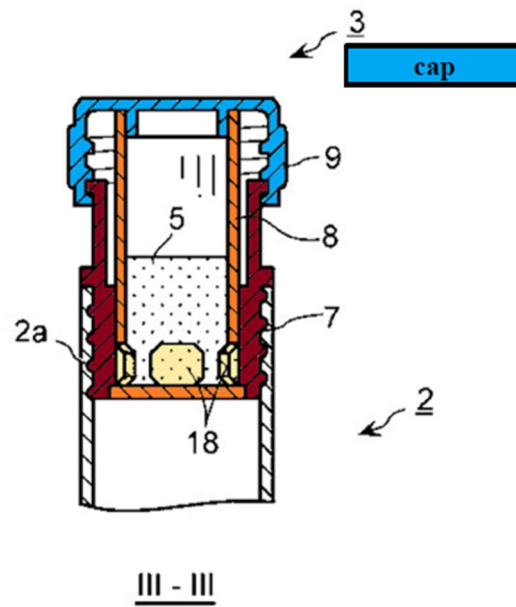
Further, Claim 1 requires that the first connection member of the vessel is complementary to the second connection member of the cap. Thus, even if Ueda discloses a cap, the connection member of Ueda’s alleged cap is not complimentary to the connection member of Ueda’s vessel. Indeed, Ueda’s design

would not function or even exist if Ueda's alleged cap screwed directly onto the vessel.

1. Ueda Does Not Have The Recited Cap

Ueda does not disclose a cap as recited in Claim 1. What Petitioner calls a "cap" is instead a three-part valve assembly. As discussed in Section V, in a related IPR proceeding, the Board proposed a construction of "cap" as meaning "a cover for the sample collection vessel that does not share a surface with the valve" and requested briefing on its proposed meaning.⁸⁶ In response, Genotek explained that the Board could adopt its proposed construction of "cap" if it is made clear, as suggested by the proposal, that the valve and cap are not co-extensive. As shown below in Petitioner's annotated Fig. 3, Ueda's valve shares a surface with the alleged cap (plug member 9). Thus, Ueda's cap does not meet the "cap" limitation of the '632 Patent, as properly construed.

⁸⁶ Ex. 2001 at 3.

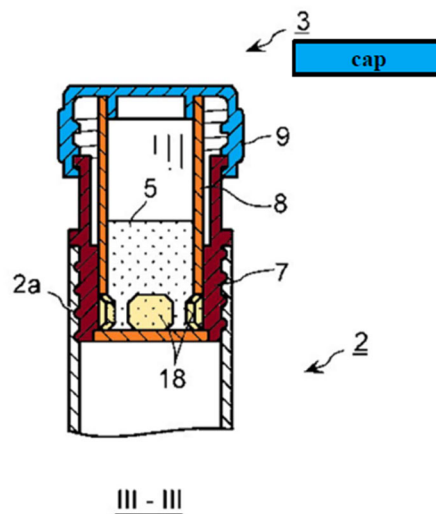


Moreover, plug member **9** at no point functions as a cover for the container of Ueda. The inner facing threads of the plug member cannot mate with inner facing threads of the tube. Nor would flipping the orientation of the threads help anything. Ueda's valve assembly functions because the plug member **9** engages with the outer cylinder member **7**, which itself engages with the tube (e.g., near reference numeral **2a**). The parts in combination form a valve—not the claimed cap.

Not even Ueda describes the plug member is a cap, as Spectrum urges in its annotated Fig. 3 above. The plug member is labeled by the number **9**. When Ueda uses the word “cap” in Spectrum's own translation, it instead refers to the *number 3*. Contrary to Petitioner's assertion, the plug member (blue) does not meet the “cap” limitation of the '632 Patent.

2. Ueda's "Cap" Does Not Have a Second Connection Member That Is Complementary to the First Connection Member of the Vessel

Ueda also fails because Claim 1 requires "a sample collection vessel comprising . . . a first connection member" and "a cap comprising . . . a second connection member complementary to the first connection member." Even if the plug member is a "cap," Ueda's plug member does not have a second connection member complementary to the first connection member of the sample collection vessel. As shown in Spectrum's annotated figure, the alleged cap's second connection member (the inner facing threads of **9**) are not complementary the vessel's first connection member (the internal threads of the tube, *e.g.*, near **2a**).



In other words, Claim 1 requires that the cap's connection member be complementary to the connection member on the vessel. But Ueda's plug member's connection member is not complementary to the vessel's connection member. Accordingly, Ueda does not anticipate.

D. Ueda and Patterson (Ground 4)

Petitioner asserts that dependent Claim 5 is obvious in view of Ueda and Patterson.⁸⁷ Claim 5 depends from Claim 1 and recites “wherein the first cylinder comprises a press-fit connection with the cap.” This Ground fails, including, because neither Ueda nor Patterson have the claimed cap, the required second connection member, and Patterson is not analogous art, as explained above.

E. Ueda and Williams (Ground 5)

Petitioner asserts that Claim 9 is obvious in view of Ueda and Williams. Claim 9 depends from Claim 1 and recites “further comprising a funnel attachable to the sample collection vessel.” Petitioner offers Williams only to provide the claimed funnel. This Ground fails at least because Ueda does not provide the claimed cap or the required second connection member complementary to the first connection member.

VII. THE BOARD SHOULD EXERCISE DISCRETION NOT TO INSTITUTE

The Board should decline institution pursuant to 35 U.S.C. § 325(d) because Petitioner puts forth substantially the same arguments that it presented to the Board in the '646 Patent IPR. Petitioner has still failed to show that Plante’s plastic design is dangerous or would otherwise motivate a POSA to modify it.

⁸⁷ Pet. at 117-118.

VIII. CONCLUSION

For the foregoing reasons, the Board should not institute this IPR.

Dated: December 28, 2023

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Certification of Word Count (37 C.F.R. § 42.24)

I hereby certify that this PATENT OWNER’S PRELIMINARY RESPONSE has 6,435 words (as counted by the “Word Count” feature of the Microsoft Word™ word-processing system), exclusive of “a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.”

Dated: December 28, 2023

By: /Mehran Arjomand/
Mehran Arjomand

CERTIFICATE OF SERVICE

I hereby certify that the attached PATENT OWNER'S PRELIMINARY RESPONSE was served as of the below date via email (by agreement) on the Petitioner at the following correspondence address:

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