UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SPECTRUM SOLUTIONS L.L.C.
Petitioner,

v.

DNA GENOTEK INC.
Patent Owner.

U.S. Patent No. 11,002,646

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Inter Partes Review No. IPR2022-01347

PATENT OWNER'S RESPONSE

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DNA Genotek Inc. ("Genotek," "Patent Owner") submits this Patent Owner Response ("POR") to the Petition filed by Spectrum Solutions LLC ("Spectrum," "Petitioner") requesting *Inter Partes* Review ("IPR") of U.S. Patent No. 11,002,646 ("the '646 Patent")[1].

I. INTRODUCTION

The Petition offers three theories, combining four references across four grounds, and argues that all claims are unpatentable under each combination: Plante and Cho; Plante and Patterson; and Maples combined with Plante and Cho or with Plante and Patterson.[2] For each theory, Petitioner fails to show that any claim is unpatentable.

For the Petition's Plante and Cho theory, Petitioner offers three "motivations" to combine the references: the references are analogous art, design incentives would motivate a POSA to modify Plante, and the combination of Cho and Plante is a simple substitution of Cho's cap for Plante's cap.[3] As the Board

[1] Ex. 1001.

[2] Pet., 23.

[3] *Id.*, 29-31.

found, being analogous art alone is not sufficient reasoning to combine teachings of prior art references.[4]

The Petition's other two Plante-Cho arguments also fail. To support its design incentives argument, the Petition generalizes safety concerns and molding difficulties in the medical device industry, but does not prove that any such concerns or difficulties apply to Plante's device. And evidence from the field shows otherwise. For the simple substitution of Cho's cap for Plante's cap, the Petition does not explain how a POSA would substitute Cho's cap when that cap does not fit in Plante's vessel nor explain how Cho would perform various functions of Plante's cap required by Plante's device. Finally, when weighing the advantages (none) and disadvantages (many) of substituting Cho's cap for Plante's cap in Plante's device, a POSA would not substitute Cho's cap for Plante's cap.

The Petition's Plante and Patterson theory relies on the same "design incentives" argument[5] and thus fails for the same reasons as Plante and Cho. But Plante in view of Patterson fails for an additional reason: the proposed combination omits a limitation required by claim 1. The Petition does not explain the omission.

[4] Inst. Dec., 26, 39.

[5] Pet., 65.

The Maples theory also fails. Petitioner offers Ground 2 and Ground 4 to address a specific construction of "preserving a biological sample."[6] That construction includes two sub-parts.[7] But when the Petition analyzes Maples for that claim construction, the Petition only address one part of the construction.[8] Thus, the Petition's Maples theories fail because Petitioner does not show Maples meets the specific construction.

Because all of the Petition's theories fail to show any claim is unpatentable, Patent Owner respectfully requests the Board determine that no challenged claims are unpatentable.

II. THE '646 PATENT

The '646 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, urine)."[9] In addition to biological sample collection devices, the '646 Patent

[6] *Id.*, 57-58, 81-82.

[7] *Id.*, 58 (*citing* Ex. 1001, 16:23-27).

[8] *Id.*, 59 (*citing* Ex.1009, 31; Ex.1001, 16:47-17:14; Ex.1011, 32).

[9] Ex. 1001, 1:21-24.

describes inventions specific to preserving cells.[10] Petitioner correctly describes the ’646 Patent’s claims to be directed to a mechanical invention that includes a sample collection vessel, a cap, and a movable annular valve.[11]

The ’646 Patent background recognizes a risk presented by the inadvertent release of a toxic preservative.[12] With this context, the ’646 Patent identifies a problem with known sample collection device utilizing “sharp extruding objects and thin pierceable membranes” that “represent 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.”[13] This is the safety issue described in the’646 Patent: in devices that utilize a thin-film membrane to house a toxic

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[10] *Id.*, 1:24-29.

[11] Pet., 3.

[12] *See, e.g.,* Ex. 1001, Abstract, 4:1-8.

[13] *Id.*, 4:16-26 (*citing* U.S. Patent No. 7,482,116) (“Some currently available sample collection devices . . . [use] sharp extruding objects and thin pierceable membranes. The thin pierceable membranes can represent 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.”); *see also id.* 4:26-31 (*citing* U.S. Patent Publication No. 2009/0216213 A1.)

preservative with a corresponding piercing member, a thin film membrane presents a risk of inadvertent rupturing of the reservoir.

III. CLAIM CONSTRUCTION

On November 29. 2022, the District Court in the related litigation issued a claim construction order covering four limitations of the ’646 Patent.[14] The District Court construed “biological sample” as “biological sample containing cells,”[15] “preserving a biological sample” as “"preventing cells in the biological sample from having their antigens degraded such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome,”[16] “annular valve” as “ring-shaped valve,”[17] and “associates with” as plain and ordinary meaning.[18]

Patent Owner reiterates here all the arguments[19] made in Patent Owner’s Preliminary Response. “The Board is required to construe ‘only those terms . . .

[14] Ex. 2031.

[15] *Id.*, 57.

[16] *Id.,* 59.

[17] *Id.,* 66.

[18] *Id.,* 69.

[19] POPR, 11-12.

that are in controversy, and only to the extent necessary to resolve the controversy.'" *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). For the purposes of determining patentability of all challenged claims, construction of the claim terms would not change Petitioner's failure to show that any combination of references render the challenged claims unpatentable. Patent Owner submits that no construction is necessary for the Board to determine patentability.

IV. LEVEL OF SKILL IN THE ART

Patent Owner agrees with the Board that the obviousness analysis does not turn on which level of ordinary skill, Patent Owner's or Petitioner's, is adopted.[20] Patent Owner reiterates[21] here all the arguments made in Patent Owner's Preliminary Response.

V. THE PETITION FAILS TO SHOW THAT ANY CLAIMS ARE OBVIOUS UNDER GROUND 1

The Parties agree that claim 1 requires three primary elements: a sample collection vessel, a cap, and a moveable annular valve.[22] The parties further agree

[20] Inst. Dec., 9.

[21] POPR, 12-14.

[22] Pet., 3.

that Plante teaches a sample collection vessel and a cap, but does not teach a moveable annular valve.

Under Ground 1, Petitioner argues that Cho teaches a cap with the claimed moveable annular valve, and it would have been obvious to substitute Cho's cap for Plante's cap, providing three "motivations." The first motivation is that Cho and Plante are in the same field of endeavor. The field of endeavor is a "threshold inquiry" and does not motivate a POSA to combine two references.[23]

Petitioner's second motivation is that a POSA would replace Plante's knife because of design incentives, namely that a POSA would be generally concerned with a risk of injury to the user and generally have difficulty with molding sharp

[23] Inst. Dec., 26, 39; *see also Johns Mansville Corp. v. Knauf Insulation, Inc.*, IPR2018-00827, Paper 9, Page 10 (Informative) ("Demonstrating that a reference is analogous art or relevant to the field of endeavor of the challenged patent is not sufficient to establish that one of ordinary skill would have had reason to combine its teachings with other prior art in the manner set forth in the claim."); *Microsoft Corp. v. Enfish, LLC,* 662 F. App'x 981, 990 (Fed. Cir. 2016); *Securus Techs Inc. v. Global Tel*Link Corp.* 701 F. App'x 971, 977 (Fed. Cir. 2017) (non-precedential).

objects.[24] As explained in Section A below, the Petition fails to show that Plante's device presents these concerns or difficulties. Petitioner fails to tie its general concerns to Plante's device.

Petitioner's third "motivation" isn't a motivation at all, but a *KSR* rationale[25]—Cho's cap is purportedly a simple substitution for Plante's cap in Plante's device, for which there would have been a reasonable expectation of success. As explained in Section B below, a POSA would not have a reasonable expectation of success because Cho's cap would not fit in Plante's device and Cho was not designed to provide many of the functions required by Plante's device.

Finally, as explained in Section C, a POSA weighing the benefits gained against the benefits los, would recognize that the substituting Cho's cap for Plante's cap in Plante's device provides no benefits. Further, the substitution loses many benefits identified in Plante and renders Plante inoperable for its purpose.

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[24] Pet., 30.

[25] *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); MPEP § 2143.I ("Examples of rationales that may support a conclusion of obviousness include: . . . (B) Simple substitution of one known element for another to obtain predictable results.").

Weighing these advantages and disadvantages, a POSA would not find substituting Cho's cap for Plante's cap in Plante's device to be desirable.

A. The Petition does not show that a POSA would have been motivated to replace Plante's "knife"

Petitioner argues that a POSA would have been motivated to replace Plante's knife, giving two justifications.[26] First, "[a] POSA would have been motivated by design incentives to replace Plante's approach of using a knife in the vessel with Cho's safer design using an annular valve in the cap."[27] Second, a "POSA would have known it is also difficult to mold sharp thin features in plastic."[28]

To support its justifications, Petitioner points to nothing in the field of biological sample collection and preservation. Objective evidence from the field of the invention demonstrates that a POSA would not recognize Plante as

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[26] Pet., 30; *see also id.,* 65 ("Further, as described above, a POSA would have been motivated by design incentives to replace Plante's approach of using a knife in the vessel and a pierceable membrane in the cap with a safer design of using an annular valve in the cap. . . . This applies to Patterson, as it does for Cho addressed above.").

[27] *Id.*, 30, citing (Ex. 1002, 71.)

[28] Pet., 30, citing (Ex. 1002, 71.)

presenting a risk of injury. Petitioner points to the Needlestick Safety and Prevention Act (NSPA) to support its argument that a POSA would consider Plante as presenting a risk of injury to a user, but fails to appreciate that the NSPA does not seek to protect a sample donor from injury. Moreover, the NSPA recognizes that sharp objects can be used when engineering controls address the risk of injury. For its molding justification, Petitioner relies solely on a general description from Mr. Leinsing of molding difficulties with sharp objects, but does not tie those general statements to biological sample collection and preservation devices, much less to Plante's device.

1. A POSA would not recognize Plante's device as creating a risk of injury

The Petition argues that a "POSA would have recognized that the knife in Plante's sample collection system created a risk of injuring a user."[29] Petitioner does not identify the scenario that a POSA would recognize as creating a risk of injury to a user. To the extent Petitioner believes normal use of Plante's device presents an unacceptable risk of injury, there is no such risk and the Petition fails to provide evidence or argument otherwise.[30] But even under a non-normal use, a

[29] Pet., 30.

[30] Ex. 2013, 31.

POSA would not recognize a risk of injury from pointed members used in the field.[31] Both scenarios are addressed below.

Normal use. Although the Petition does not explain the scenario that presents a risk of injury to the user,[32] Mr. Leinsing suggests it is normal use of the device, namely when the user is delivering the saliva sample: "[D]esign incentives would have motivated a POSA to replace Plante's approach of using a knife in the vessel, which *pointed at the opening into which the saliva sample was delivered*."[33] A POSA would not consider Plante as presenting a risk of injury during saliva delivery.[34] At the time of the '646 Patent's invention, Genotek's saliva collection kits were well known in the DNA collection and preservation industry.[35]

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[31] Ex. 2013, 32-34.

[32] Pet., 30 (citing Ex. 1002, 71).

[33] Ex. 1002, 71 (emphasis added); *see also* Ex. 2029, 50:2-9 ("The user would be the person that would handle the reservoir and the cap. That could be the -- that's intended to be, I believe, the primary person as the person who's actually depositing the saliva.").

[34] Ex. 2013, 31.

[35] *See, e.g.,* Ex. 1003, 0011 ("One kit manufactured by DNA Genotech Co. of Ontario, Canada is quite widely used by many professionals of the DNA

Genotek's RE-100, for example, teaches a saliva deposition procedure usable with Plante's device.[36] The figure below is copied from the RE-100 instructions[37] from 2011.[38]

diagnostics industries."); Ex. 2027, 1:42-46 (citing five patents and patent publication as "[e]xamples of devices and compositions" for the field of "sample collection devices useful for, e.g., in-home patient collection of human saliva for DNA analysis," all of which are assigned to Patent Owner); Ex. 1001, 4:16-36 (filed by Abogen, Inc. and citing only Patent Owner's products as "some currently available sample collection devices").

[36] Ex. 2013, 28 (*citing* Ex. 2014).

[37] Similar instructions can be found in Genotek's OG-250 (Ex. 2015.)

[38] Ex. 2014.

Plante's device is similar to the RE-100.[39] Both include a collection tube with an integral funnel.[40] In Plante and the RE-100, the funnel includes at least one piercing member to pierce a membrane and release fluid into the collection tube.[41] Figure 23[42] of Genotek's corresponding U.S. Patent No. 8,221,381 (the '381 Patent) depicts the RE-100:

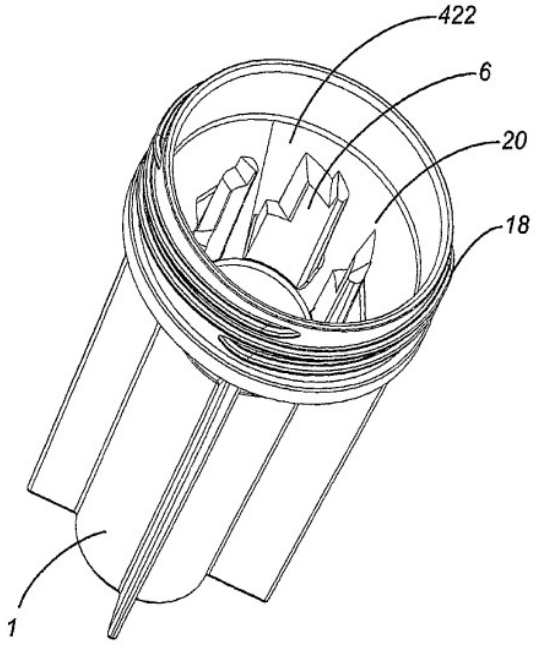

FIG. 23

[39] Ex. 2013, 30.

[40] *Id.*

[41] *Id.*

[42] Ex. 2016 ('381 Patent), Figure 23.

Dr. Steven Wereley inspected the RE-100.[43] [44] Dr. Wereley concluded that the figures of the '381 Patent correctly depict the shape and position of the piercing members with respect to the position of the top of the collection tube.[45] Further, Dr. Wereley used the RE-100 as instructed and found no risk of injury to the user.[46]

Mr. Leinsing testified that he did not test any devices to assess whether there is an unacceptable risk of injury by known piercing members in the biological sample collection and preservation field.[47] Mr. Leinsing dismissed the relevance of Plante Figure 1 because a patent figure "is not meant to be dimensioned."[48] Although it is true that a POSA would not be limited by the scale in Plante Figure 1, it is reasonable to assume that a POSA, implementing Plante's device, would

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[43] Ex. 2013, 29.

[44] Patent Owner affirmatively withdraws the testimony of Dr. Paul Slowey provided in support of Patent Owner's Preliminary Response. *See Patent Trial and Appeal Board Consolidated Trial Practice Guide*, November 2019, 51.

[45] Ex. 2013, 29.

[46] Ex. 2013, 31.

[47] Ex. 2029, 11:8-13.

[48] *Id.*, 56:10-16, 57:7-17.

take Figure 1's relative dimensions as at least a starting point.[49] Moreover, if some changes were required,[50] it is unreasonable to suggest that a POSA would—if, as Petitioner argues, the POSA was concerned about the positioning of the knife—*increase* the risk of injury.[51] Indeed, Plante describes its knife as "carefully positioned,"[52] indicating that the knife's position should be considered when designing an embodiment of the device.[53] The Petition provides neither argument nor evidence for why a POSA would, perceiving a risk of injury, ignore Plante's guidance for a "carefully positioned" knife and instead increase that perceived risk of injury.

Plante does not specifically outline its method for delivering saliva, but likewise does not suggest a non-standard deposition procedure that would increase the risk.[54] As described above, the standard method for delivering saliva does not

[49] Ex. 2013, 32.

[50] The similarity of the RE-100 to Plante's figures demonstrates that Plante's scale is a suitable design. Ex. 2013, 32.

[51] Ex. 2013, 34.

[52] Ex. 1003, 0035.

[53] Ex. 2013, 32.

[54] *Id.*

present a risk of injuring a user by piercing members positioned in a funnel.[55] But even if a user were to mishandle the device in a non-standard use, there is no risk of injury to a user.[56]

Non-normal use. The Petition does not articulate a non-standard use of Plante that would present a risk of injury. But even if Petitioner did, the positioning of Plante's piercing member reduces the risk of contact between a user and the piercing member and, even if there was some contact, the sharpness required to puncture a thin film membrane is less than the sharpness required to cause an injury.[57]

Plante includes a "carefully positioned knife 19."[58] That position of the knife is close to the wall of the receiving vessel, providing protection against an inadvertent contact by the user.[59] If a user were to bring their finger directly down on the knife, the user's finger would likely contact the wall, and thereby be

[55] Ex. 2013, 31.

[56] *Id.* at 32-34.

[57] *Id.* at 34.

[58] Ex. 1003, 0035.

[59] Ex. 2013, 35.

diverted from the knife.[60] Thus, Plante's wall provides an engineering control against a user inadvertently contacting the closely positioned knife.[61] The relative positioning of Plante's knife and wall is similar to the relative position of the RE-100's piercing member and wall.[62] Dr. Wereley tested the RE-100 and confirmed that the relative position of the piercing member and wall provided a natural protection from inadvertent contact.[63] Note too that Plante's knife is lower relative to its wall than the RE-100's piercing members are to its wall (compare the position of Plante's "knife" to the RE-100's pointed members[64] in the figures below, relative to their respective walls).[65] Thus, Plante's device is further engineered to control the risk of an inadvertent contact by a user on the piercing member.[66]

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[60] Ex. 2013, 33.

[61] *Id.*

[62] *Id.* at 35.

[63] *Id.*

[64] Ex. 2016, Figure 24.

[65] Ex. 2013, 35.

[66] *Id.*

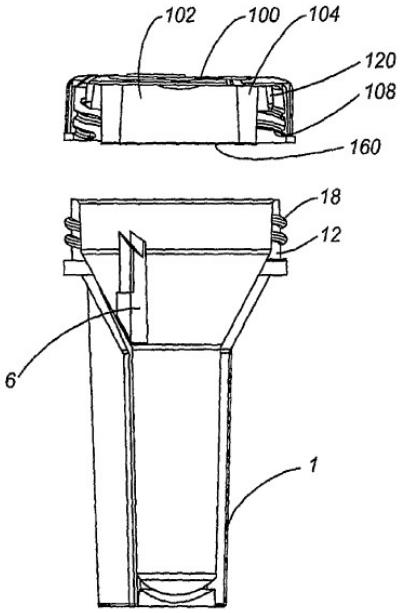

FIG. 24

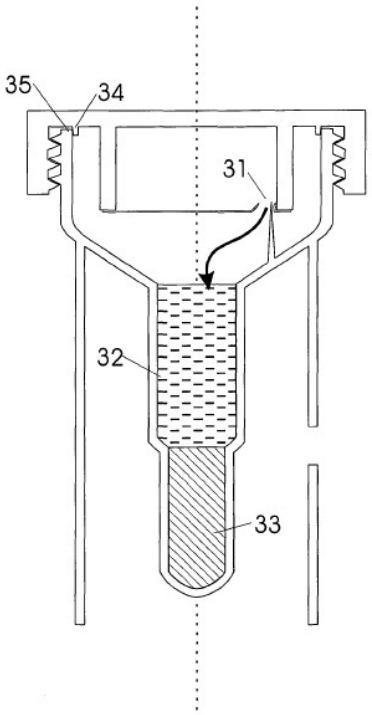

FIG. 3

Even if a user were to contact the piercing member (for example, a user intentionally contacts the piercing member or inadvertently contacts the piercing member but does not first contact the side wall), Dr. Wereley examined the risk of injury and determined that there was no such risk from the RE-100 piercing members.[67] Dr. Wereley placed his finger directly on a piercing member of the RE-100 and applied pressure.[68] Even applying pressure, Dr. Wereley did not perceive a risk of injury.[69]

[67] Ex. 2013, 34.

[68] *Id.* at 36.

[69] *Id.*

As described above, the Genotek devices were well-known and commonly used.[70] This was the state of the art in 2011, the time of the '646 Patent's priority filing.[71] There is no evidence that a POSA would consider any of these devices as presenting a risk of injury to a user.

As described above, known devices in 2011 did not present a risk of injury to a user and nothing suggests a POSA would consider Plante as increasing that risk. One reason is the molding process commonly used to create such devices.[72] It is difficult to mold a piece with sufficient sharpness to injure a user.[73] However, such sharpness is not necessary to pierce a thin-film.[74] The Petition argues that a sharp piece would injure a user and that such sharpness is difficult to mold.[75] The Petition's argument misunderstands that Plante's knife does not need to be so sharp to perform its function of piercing a thin-film membrane.[76] The RE-100

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[70] *See*, fn. 35, *supra*.

[71] Ex. 1001, Page 2.

[72] Plante teaches molding its device. Ex. 1003, 0018.

[73] Ex. 1002, 71-72.

[74] Ex. 2013, 34.

[75] Pet., 30.

[76] Ex. 2013, 34 (citing Ex. 1003, 0035).

demonstrates that a piercing member can pierce a membrane without presenting a risk of injury to a user. Petitioner provides no evidence that Plante's design increases that risk.

To be clear, Patent Owner does not contend that a POSA would ignore a sharp that creates a risk of injury. Patent Owner's position is that while some sharps present this risk, some do not. For example, an IV needle is necessarily sharp enough to puncture skin and perform its function, and this sharpness necessarily creates a risk of injury. A piercing member to rupture a thin film need not be that sharp. For example, the '646 Patent specifically teaches that thin membranes can be pierced by accidental contact with a finger nail and specifically refers to the '381 patent family.[77] The '381 patent family covers the RE-100 and OG-250 which include a thin film like Plante, which Dr. Wereley investigated and confirmed that the thin film's corresponding piercing members do not present a

[77] Ex. 1001, 2:16-26 (*citing* U.S. Patent No. 7,482,116) ("Some currently available sample collection devices . . . [use] sharp extruding objects and thin pierceable membranes. The thin pierceable membranes can represent 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."); *see also id.* 26-31 (*citing* U.S. Patent Publication No. 2009/0216213 A1.)

risk of injury. This is the level of sharpness at issue in Plante—a sharpness sufficient to rupture a thin film. A thin film that can be punctured by accidental contact with a finger nail need not be so sharp that it risks injuring a user.[78] Nothing in the '646 Patent suggests that Plante's "knife" presents a risk of injuring the user. And the Petition does not specifically tie its general "risk" statements with the specific embodiments taught by Plante.

2. The Needlestick Safety and Prevention Act did not create a "a federal mandate to choose devices without sharps where possible"

The Petition provides no evidence from the biological sample collection and preservation field to support its argument that Plante presents a risk of injury. Instead, Petitioner relies on the NSPA, arguing "since the adoption of the [NSPA] of 2000, there has been a federal mandate to choose devices without sharps where possible."[79] The NSPA does not support the Petition's arguments. The NSPA teaches the opposite—engineering controls can be used to manage the risk of sharps.

The NSPA was enacted on November 6, 2000.[80] The Act required changes in an Occupational Safety and Health Administration standard that regulates

[78] Ex. 2013, 34.

[79] Pet., 30.

[80] Ex. 1015, Page 1, right column.

occupational exposure to bloodborne pathogens.[81] Congress found that "[c]ompliance with the bloodborne pathogens standard has significantly reduced the risk that workers will contract a bloodborne disease in the course of their work."[82] But more was needed: "Nevertheless, occupational exposure to bloodborne pathogens from accidental sharps injuries in health care settings continues to be a serious problem." [83] That is the problem—occupational exposure due to sharps in health care settings[84]—that Congress sought to address with the NSPA.

[81] *Id.,* Section 1; Section 2, ¶ 2.

[82] *Id.,* Section 2, 3.

[83] *Id.,* Section 2, 4.

[84] *Id.* ("Estimates for all health care settings are that 600,000 to 800,000 needlestick and other percutaneous injuries occur among health care workers annually. Such injuries can involve needles or other sharps contaminated with bloodborne pathogens."); *see also id.,* Section 2, 1 ("Numerous workers who are occupationally exposed to bloodborne pathogens have contracted fatal and other serious viruses and diseases, . . . from exposure to blood and other potentially infectious materials in their workplace.")

Before addressing the federal mandate, it is important to note that the NSPA does not apply to users of the'646 Patent's and Plante's biological sample collection devices. These devices are at-home kits to be used and shipped by the patient.[85] There is no healthcare worker.[86] There is no risk of occupational exposure to another's bloodborne pathogens: should the user of Plante be injured and consequently exposed to bloodborne pathogens, it would be to their own pathogens.[87] The NSPA is not concerned with the risk of a patient being exposed to their own pathogens.

The Petition does not argue that a POSA would be motivated to protect a lab technician from Plante's knife. Even if it did, there is no risk of injuring a lab technician in spit collection devices.[88] Procedures in place at a laboratory eliminate lab technician exposure.[89] Laboratories are configured to analyze a

[85] Ex. 2012, 11-13.

[86] *Id.* at 12-13.

[87] *Id.* at 14.

[88] *Id.* at 15-17, 20.

[89] Ex. 2012, 15-17, 20; Ex. 2030, 162:19-163:17 ("But then you have to take extra precautions when dealing with needles and infectious disease. Needles cannot be recapped. They have to be placed in a proper device to prevent them from -- from

biological sample without contaminating the sample.[90] For example, when analyzing a biological sample's DNA or testing the sample for infection, if lab technicians' DNA or infections were to contaminate the sample, the analysis or test would fail.[91] For this reason, lab technicians do not handle samples.[92] Typically, these labs use automated handling processes that remove a device's cap and handle the biological sample.[93] For those labs, the lab technician is not exposed to the sample and there is no risk of injury.[94]

But even without automated handling systems, a lab technician has no risk of injury.[95] First, the lab technician must be trained not to contaminate the

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sticking the individual. And there -- there are several procedures that need to be adhered to when dealing with needles and infectious disease, and we do them all.").

[90] Ex. 2012, 17-18, 20.

[91] *Id.* at 18.

[92] *Id.* at 17.

[93] *Id.*

[94] *Id.*

[95] *Id.* at 15-16, 20.

sample.[96] This training would include handling the tube on the outside, avoiding the inside.[97] Second, lab requirements stipulate that there must not be a risk to the lab technician of being contaminated by the sample.[98] This risk is not based on a risk of injury, but more general exposure to potentially contaminated samples.[99] For a lab technician to "stick" themselves on Plante's needle, they would have to violate numerous lab protocols designed to prevent sample contamination and technician exposure to the sample.[100]

Returning now to the "federal mandate" that the Petition relies upon, no such mandate exists. The Petition asserts that "since . . . 2000, there has been a federal mandate to choose devices without sharps where possible."[101] The Petition mischaracterizes the NSPA. Although the Petition cites to the NSPA for this federal mandate, it does not provide a pin cite.[102] And although the Petition cites to

[96] *Id.* at 15, 18, 20.

[97] *Id.*

[98] *Id.*

[99] *Id.*

[100] Ex. 2012, 15, 17-18, 20; *see also* fn 89.

[101] Pet., 30 (citing Ex. 1002, 71, Ex. 1015).

[102] Pet., 30 (citing Ex. 1015 generally).

Mr. Leinsing to support this proposition, Mr. Leinsing includes exactly the same sentence without further analysis of or citation to the NSPA.[103] *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (precedential) (*citing* 37 C.F.R. § 42.65(a); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000); *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986) ("the cited declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight"). Mr. Leinsing says the NSPA "had a great impact on myself and others working in the design and manufacture of medical devices."[104] Mr. Leinsing then claims that "one of [his] most successful inventions arose from this mandate to choose devices without sharps."[105] For that invention, Mr. Leinsing points to the SmartSite® Needle-Free Valve and four patents that cover that valve.[106] But three of those patents were filed before the NSPA was

[103] Ex. 1002, 71.

[104] *Id.*

[105] *Id.*

[106] *Id.*

promulgated.[107] And the SmartSite® Needle Free Valve was designed and publicly available before the NSPA was enacted.[108]

On closer inspection, the NSPA does not teach a "mandate to choose devices without sharps where possible."[109] Instead, the NSPA teaches that engineering controls can address sharps' injury risk. The NPSA reports that "[n]umerous studies have demonstrated that the use of safer medical devices, such as needleless

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[107] US Patent Nos. 5,549,577 (filed Dec. 29, 1993) (Ex. 2017), 5,676,346 (claiming priority to an application filed May 16, 1996) (Ex. 2018), and 6,706,022 (filed Jul. 27, 1999) (Ex. 2019).

[108] *See, e.g.,* Ex. 2020 (Trademark Registration for "SmartSite", Registration number 75096727 (First Use in Commerce: 7-1-1996); Ex. 2021 (ATech Designs Press Release, Jan 26, 1998), 1 ("ATech Designs, Inc. and its the SmartSite® Valve receives award from Canon Communications, LLC."); Ex. 2022 (ATech Designs Press Release, Jan 26, 1999), 1 ("ATech Designs, Inc. and its the SmartSite® Valve receives award from Governor Hunt of North Carolina and the Professional Engineers of North Carolina."); Ex. 2023 ("PENC Presents the 1999 Governor's New Product Awards," The Professional Engineer/ September-October 1999), 14; Ex. 2024 (ATech Designs Press Release, Jan 26, 2000), 1.

[109] Pet., 30.

systems and sharps with engineered sharps injury protections, . . . can be extremely effective in reducing accidental sharps injuries."[110] The NSPA consistently refers to two ways to reduce the risk of occupational exposure: "needleless systems" and "engineering controls." For example, the NSPA adds "additional examples of controls" that include "sharps with engineered sharps injury protections."[111]

Instead of mandating devices without sharps, the NSPA does the opposite—the NSPA teaches that sharps are acceptable if the risk is controlled. When analyzing the claims of the '646 Patent, Mr. Leinsing only considered needleless systems as a solution to the purported problem in Plante. Mr. Leinsing did not consider whether Plante's engineering had sufficiently reduced the risk of injury to the user or even explain what that risk is. As explained above, Plante's system does not create a risk of injury to a user of Plante's device.[112] Further, lab

[110] Ex. 1015, Section 2, 7.

[111] *Id.*, Section 3, 1; *see also id.*, Section 3, 2 (definition of "Sharps with Engineered Sharps Injury Protections" includes "built-in safety feature or mechanism that effectively reduces the risk of an exposure incident");

[112] Ex. 2013, 31-34.

technicians—those occupationally at risk—are protected from exposure to a sample, including exposure to the inside of the sample collection device.[113]

Petitioner's "federal mandate" argument in this IPR is inconsistent with its arguments in district court. There, Petitioner challenged Patent Owner's U.S. Patent No. 10,619,187 (the '187 Patent) as obvious over a combination of references, including U.S. Patent No. 5,643,767 to Fischetti et al. [114] Mr. Leinsing provided a supporting declaration.[115] When combining Fischetti et al. with other references, Petitioner and Mr. Leinsing relied on a modification of the main embodiment in Fischetti et al. that added a pointed member to pierce a membrane.[116] In analyzing the '187 Patent, Petitioner and Mr. Leinsing used 2002 as the priority date, two years after the NSPA.[117] If the Petition is correct that the NSPA created a "federal mandate" since 2000 for a POSA "to choose devices without sharps where possible," then the POSA would not combine Fischetti et

[113] Ex. 2012, 15-17, 20.

[114] Ex. 2026, Pages 94-143.

[115] *Id*.

[116] *Id.*, 295.

[117] *Id.,* 50.

al.'s pointed member embodiment with another reference because that embodiment would be inconsistent with the "federal mandate."

Mr. Leinsing was unable to explain this inconsistency between his litigation arguments and his argument here. The Fischetti et al. device presents a much higher risk of injuring a user than Plante's device,[118] yet Mr. Leinsing could not explain why a POSA would be motivated to use Fischetti et al.'s higher risk pointed member and yet be motivated to change Plante's lower risk "knife." When pressed on the inconsistency, Mr. Leinsing testified that "I think a person would be motivated to not use either of these inventions."[119]

Furthermore, Petitioner's argument that "since the adoption of the [NSPA] of 2000, there has been a federal mandate to choose devices without sharps where possible"[120] and Mr. Leinsing's contention that the NSPA "had a great impact on myself and others working in the design and manufacture of medical devices"[121] is inconsistent with Mr. Leinsing's patent filings since the NSPA was promulgated. For example, Mr. Leinsing is the lead inventor on US Patent Application

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[118] Ex. 2013, 46.

[119] Ex. 2029, 112:21-22.

[120] Pet., 30.

[121] Ex. 1002, 71.

Publication No. 2009/0062596 ('596 Publication), titled "Heart Band With Fillable Chambers to Modify Heart Valve Function," filed in 2007.[122] The "fillable chambers" each has a filling tube.[123] In the '596 Publication, Mr. Leinsing teaches that "the separate filling tubes . . . may be [f]illable through a blunt needle port . . . , a sharp needle port, or through a subcutaneous port."[124] And Mr. Leinsing is the sole inventor on U.S. Patent Application Publication 2013/0153895 ('895 Publication),[125] which he filed in February 2002, after the NSPA. The '895 Publication teaches a "vial adapter having a needle-free valve"[126] with a recessed sharp (see '895 Publication Figure 3 reproduced below). In the '895 Publication, Mr. Leinsing teaches that the "the shroud 27 in this embodiment is longer than the length of the sharpened cannula 33 and surrounds the sharpened cannula to protect an operator of the adapter 21 from being punctured by the sharpened tip of the cannula 33."[127]

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[122] Ex. 2025, Cover Page.

[123] *Id.*, 0019, 0066.

[124] *Id.,* 0068; *see also id.*, 0019; Claim 16.

[125] Ex. 2009, Cover Page.

[126] *Id*.

[127] *Id.,* 0044; *see also id*, 0008, 0012, 0015, 0039, 0058.

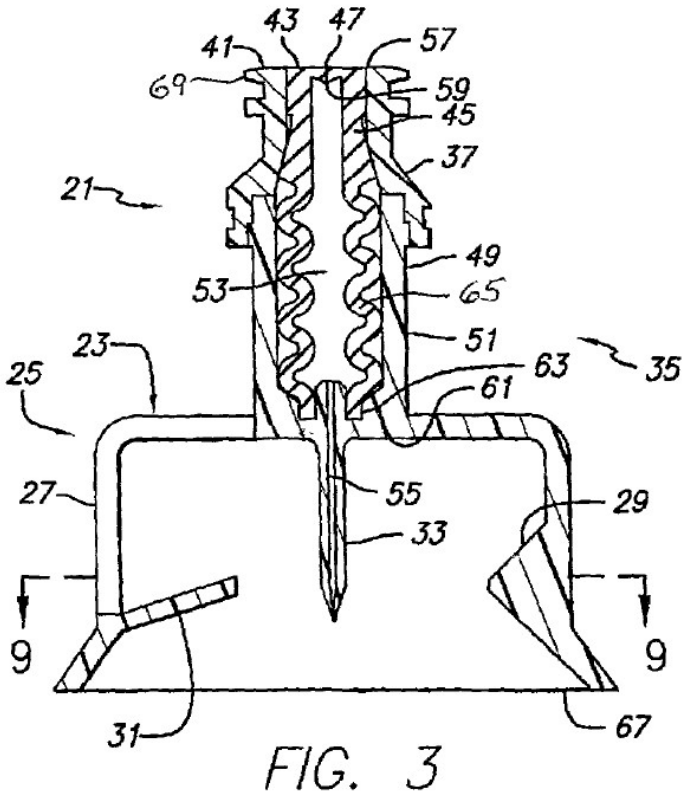


FIG. 3

Plante's piercing member is also "disposed within a protective shroud," but is positioned closer to the sidewall and far more recessed than Mr. Leinsing's sharpened cannula (see Plante's receiving vessel below, excerpted from Plante Figure 1).[128] Thus, Plante's device has more engineering controls than the device depicted in Mr. Leinsing's '895 Publication. Moreover, the sharpness of a cannula required "for piercing a vial closure"[129] presents a far greater risk of injury to a user

[128] Ex. 2013, 49.

[129] Ex. 2009, 0001.

than the sharpness required to pierce a thin film, such as in Plante's device.[130] Yet Mr. Leinsing's engineering controls (a shroud around the sharp object) justified the sharpness of his cannula.[131]

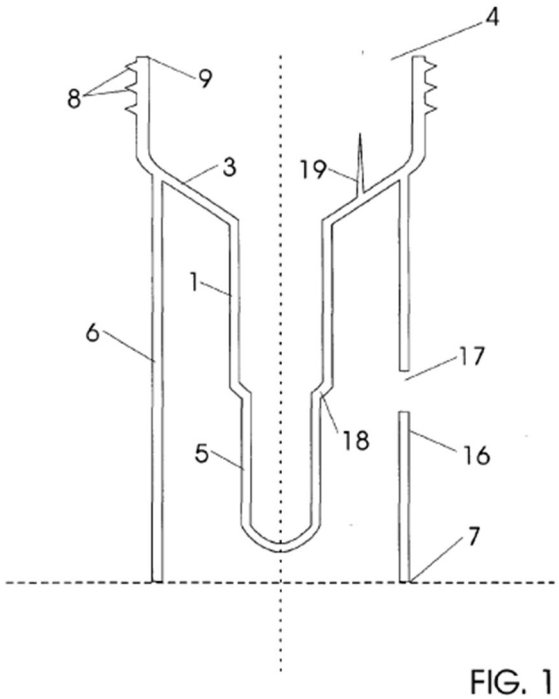


FIG. 1

In summary, the NSPA does not support the Petition and, in fact, supports the use of engineering controls to manage risk. Moreover, nothing in the Petition ties the general guidance of the NSPA to Plante's device. As shown in the previous section, a POSA would not understand Plante as creating a risk of injury to the user.

[130] Ex. 2013, 50.

[131] Ex. 2009, 0015, 0039, 0044.

3. A POSA would not have difficulty molding Plante's device

The Petition's second design incentive for modifying Plante is that "a POSA would have known it is also difficult to mold sharp thin features in plastic."[132] As with the risk of injury to a user, the Petition makes general statements about molding. Petitioner does not tie general molding problems to the field of biological sample collection and preservation nor specifically to Plante's design. Evidence from the biological sample collection and preservation field demonstrates that molding structures for piercing thin-films presented no difficulty.

In 2011, the biological sample collection and preservation field was replete with examples of pointed members puncturing membranes to release preservative. As described above, Genotek had numerous successful devices on the market, each using a piercing member to release preservative from a membrane-sealed reservoir.[133] The Petition provides no evidence that such devices presented a problem to manufacture.

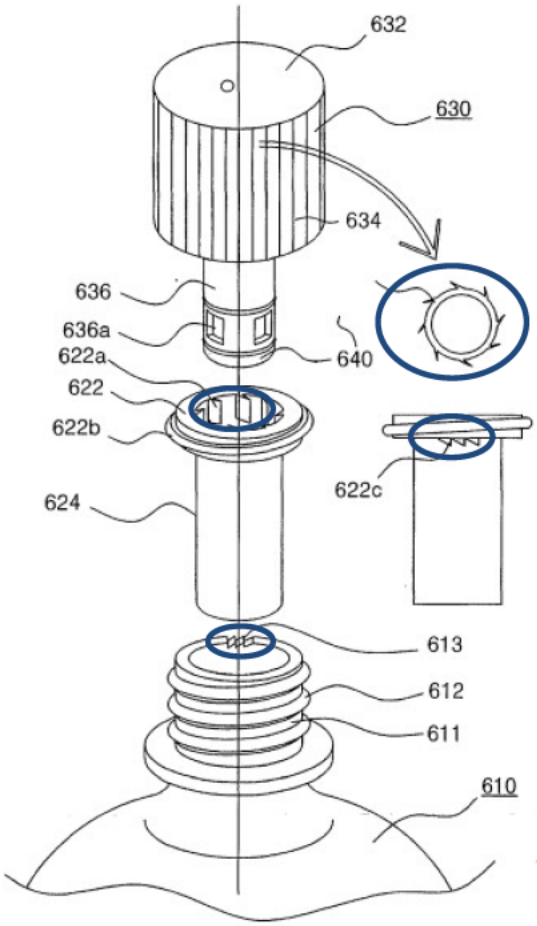
Petitioner's general statements about molding are inconsistent with the Petition's reliance on Cho. Like Plante, Cho teaches injection molding to create its

[132] Pet., 30 (citing Ex. 1002, 72).

[133] See Section V.B.1 *supra.*

beverage caps.[134] The specific Cho embodiment that the Petition cites is illustrated in Figure 43. Cho's design is complicated, including a number of ratchet mechanisms (e.g., 622a/632b[135] and 622c/613) that ensure that the two cylinders turn in only one direction relative to the cap and bottle.[136]

FIG. 43

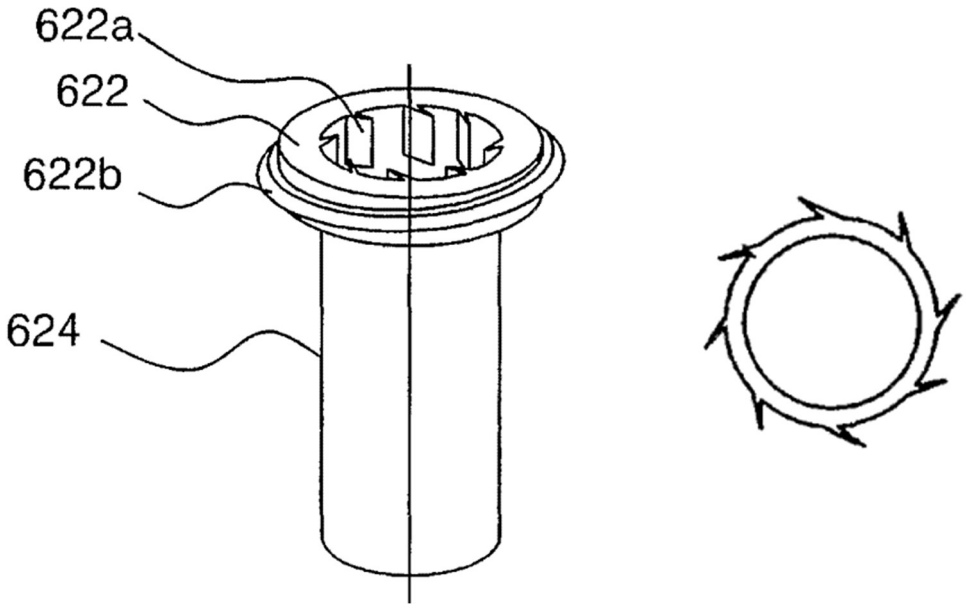


[134] Ex. 2013, 53 (citing Ex. 1004, 22:10-15, 37:1-2, 54:23-29.).

[135] Note that Cho, Figure 43 is missing the label for 632b.

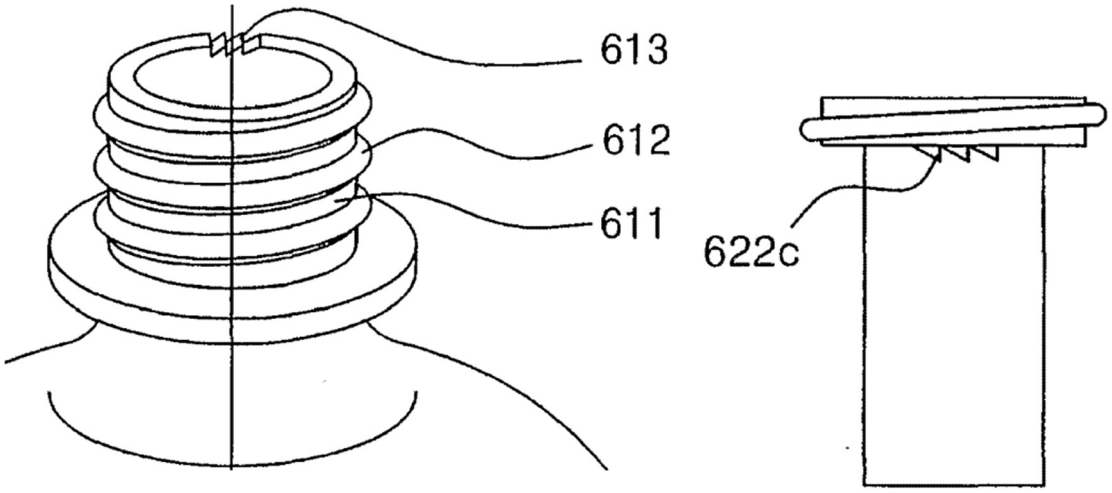
[136] Ex. 1004, 49:1-4, 49:28-33.

As highlighted in the figure below, many of the components of the ratchet mechanisms include "sharp thin features," features that Petitioner argues would motivate a POSA away from Plante's design.[137] The figure below is a close-up of the 622a/632b ratchet mechanism illustrated in Figure 43, showing sharp features on both sides of the mechanism.



The figure below is a close-up of the 622c/613 ratchet mechanism illustrated in Figure 43, showing sharp features on both sides of the mechanism.

[137] Pet., 30.



If Petitioner consistently applied its own logic, then a POSA would not be motivated to use Cho because it too teaches "sharp thin features."[138] Cho demonstrates that molding "sharp thin features" was not considered difficult at the time of the invention.[139]

The field's ability to mold pointed members sufficient to puncture a thin-film membrane is evidenced by Petitioner's own manufacturing and commercial activities. In 2013, Ancestry.com filed provisional patent application no. 61/861,329 (the '329 Application") titled "Sample Collection Device."[140]

[138] *Id*.

[139] *See also* Cho Figs. 2, 6, 9-11, 17, 26, 30, 34A, 36, and 47 (illustrating "sharp thin features").

[140] Ex. 2027, cover page; Ex. 2028, 1.

Petitioner manufactured and sold this device for Ancestry.com.[141] The '329 Application describes a "sample collection device having a sample tube, funnel, and cap having a capsule and a piercing insert, the capsule having a stabilization solution."[142] The '329 Application's device is in the same field as Plante and the '646 Patent[143]: "The device can be used at home without [clinical] supervision for collecting a saliva sample and transporting the sample to an analysis location for DNA analysis."[144] The '329 Application's Figure 1A depicts the components of the device, including the sample tube (100 and 700), funnel (200), and cap (300) having a capsule (400 and 500) and a piercing insert (600). The figures below reproduce the components from the '329 Application's Figure 1A.

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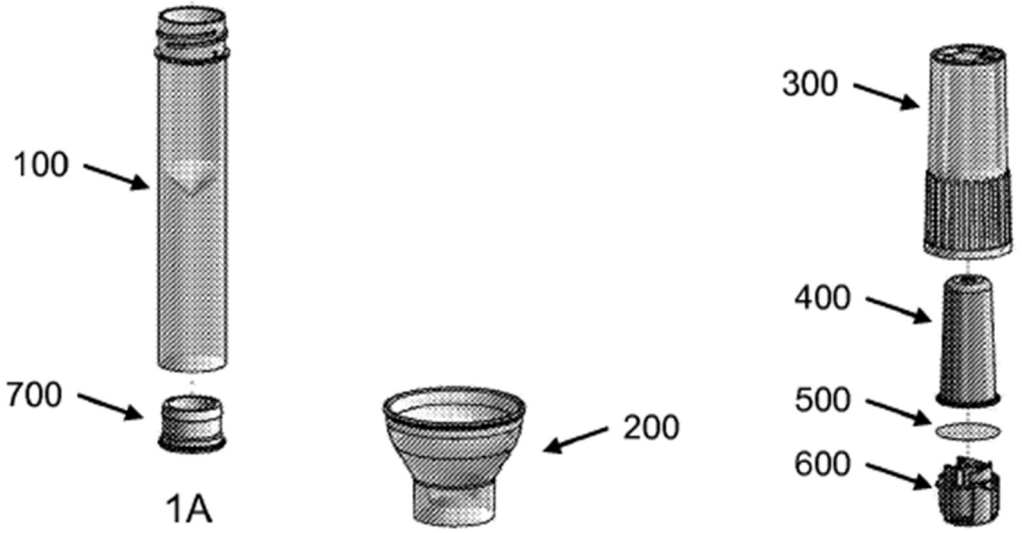
[141] Spit Matters: Spectrum Solutions co-founder talks about the race to develop the first approved saliva collection device for COVID-19, Healthcare Performance Insider, https://www.healthcareperformanceinsider.com/spit-matters-with-bill-phillips-from-spectrum-solutions/ (last accessed May 9, 2023).

[142] Ex. 2028, Abstract.

[143] Ex. 2013, 59.

[144] *Id.*; *see also id.*, 0005 ("The invention relates to sample collection devices useful for, e.g., in-home patient collection of human saliva for DNA analysis."), 0018.



To deposit and ship a sample, the ’329 Application teaches that after the user places the sample in tube 100, funnel 200 is removed and cap 300 is screwed onto the tube.[145] By screwing cap 300 onto tube 100, “the piercing device [600] is moved towards the capsule [400] and contacts the seal [500],” resulting in piercing device 600 piercing seal 500.[146] The ’329 Application’s Figure 6 (relevant portion reproduced below) illustrates piercing insert 600.[147] The piercing insert 600 includes “piercing structures 611, 612, and 613 . . . configured to pierce the seal 500 once the cap is screwed onto the sample tube.”[148] The piercing seal 500 is

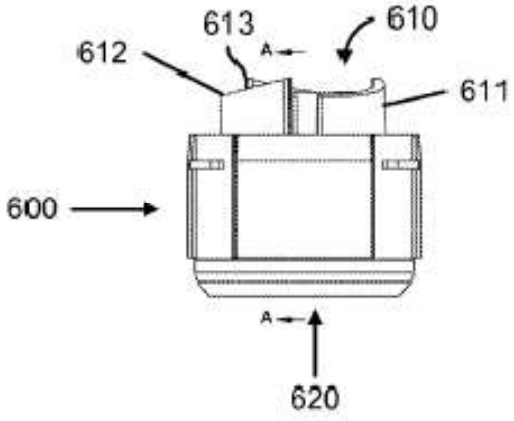
[145] *Id.*, 0022.

[146] *Id.*

[147] *Id.*, 0031.

[148] *Id.*

manufactured from foil and has the following properties: "ability to withstand corrosion by the stabilization fluid, resistance to breakage during manufacture and transport to the user and before piercing by the piercing insert, and ease of piercing by the piercing insert upon contact with force."[149] These same properties are needed by Plante's thin film.[150]



The '329 application does not claim to have invented a new molding method that overcame difficulties in the prior art. There is no description of an inventive shape to the piercing structures that allowed for "ease of piercing by the piercing insert upon contact with force"[151] while also overcoming the challenges of molding such features. Indeed, although Ancestry.com sought and received patent

[149] *Id.*, 0029

[150] Ex. 2013, 63.

[151] Ex. 2028, 0029

protection for this invention, the claims do not include any specifics on the piercing structures, merely referring to "at least one piercing protrusion" without any additional detail.[152]

A POSA, reading the '349 application, would not find the piercing members to be anything other than the result of routine molding in a routine manufacturing process of a sample collection and preservation device.[153] The '329 application, along with Petitioner's manufacturing, demonstrate that a POSA would have understood molding of features sufficient to pierce a thin membrane to present no difficulty.[154]

Finally, the Petition relies on Mr. Leinsing's testimony to support its molding-related design incentive, but Mr. Leinsing merely repeats the same sentences from the Petition. *See Xerox Corp.*, IPR2022-00624, Paper 9 at 15

[152] Ex. 2027, 4:55. A patent is presumed valid (35 U.S.C. § 282), which includes enablement of the invention. *See also Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003) (holding that the patent office and district courts presume the enablement of unclaimed and claimed material in a prior art patent).

[153] Ex. 2013, 64.

[154] Ex. 2013, 64.

("[T]he cited declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight."). Mr. Leinsing testified that he has never designed a saliva collection and preservation device.[155] Mr. Leinsing testified that he did not consider whether Genotek's devices have pointed members in forming his opinions and did not see the relevance of Genotek's devices to his opinion.[156] Further, Mr. Leinsing testified that he never tested any biological sample and collection devices in preparing his testimony.[157] If Mr. Leinsing had tested saliva collection and preservation devices, like Genotek's RE-100 and OG-250, he would have learned that an edge can be sharp enough to pierce a thin film membrane without presenting a risk of injury.

Patent Owner does not contend that no sharp objects are difficult to mold. But Patent Owner does contend that Petitioner has not shown that Plante's device includes a sharp object that is difficult to mold. The Petition makes general statements, without tying it specifically to the piercing members in Plante. There

[155] Ex. 2029, 16:18-23.

[156] *Id.*, 115:1-7.

[157] *Id.*, 11:8-25.

is nothing in the Petition to suggest that a POSA would think Plante's piercing member would need to be so sharp that it would be difficult to mold.

For at least the reason that the Petition has not shown that a POSA would be motivated by design incentives to replace Plante's knife, Patent Owner respectfully requests that the Board find no claims unpatentable under Grounds 1 and 2.

B. Even if a POSA replaced Plante's knife, the Petition fails to show the POSA would substitute Cho's cap for Plante's cap

The Petition argues "the combination of Plante and Cho involves the simple substitution of one known element for another—Plante's cap for Cho's cap."[158] As explained, the Petition does not show that a POSA would have been motivated to replace Plante's knife. For at least this reason, Petitioner has not carried its burden that any challenged claim of the '646 Patent is invalid under any of Grounds 1-4. But even if a POSA was motivated to replace Plante's knife, Petitioner has not shown that the POSA would substitute Cho's cap for Plante's cap.

First, the Petition fails to show that Cho is analogous art to the '646 Patent. But even if Cho is analogous art, the Petition fails to show that Cho's cap would have "provided all the same desired functionality" as Plante's cap.[159] Finally, the

[158] Pet., 30.

[159] Pet, 31 (citing Ex. 1002, 76).

Petition does not show that a simple substitution of Cho's cap for Plante's cap would provide a reasonable expectation of success.

1. The Petition fails to show Cho is analogous art

The Board recognized that Petitioner did not perform an analogous art analysis.[160] Patent Owner agrees and reiterates here all the arguments[161] made in Patent Owner's Preliminary Response.

Patent Owner, once again, disagrees that the Petition has shown Cho to be analogous art. There is no disagreement between the parties that the '646 Patent and Plante are in the same field.[162] There is also no disagreement that the field is biological sample collection and preservation.[163] The issue is whether Cho is analogous art.[164]

In the POPR, Patent Owner referred to Cho as being designed for immediate consumption.[165] The Institution Decision suggested Patent Owner's argument

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[160] Ins. Dec., 22, 35.

[161] POPR, 14-49.

[162] Ins. Dec., 22.

[163] *Id*., 22-23.

[164] *Id*., 23.

[165] POPR, 30.

intended "consumption" to be synonymous with "ingestion": "Cho states the combination of two materials is applicable to 'a variety of industrial fields' including 'chemicals,' which appears to suggest a non-consumable mixture."[166] When describing Cho's mixture as intended for "immediate consumption," Patent Owner meant the mixture is used immediately. In the case of Cho's primary application (beverages), the mixture is ingested immediately. This contrasts with a container for transport, where the mixture would be stored during transport and opened at a later time for ingestion. For Cho's chemical and medical applications, the mixture would also be used immediately. Of course, in the chemical application, the mixture would not be ingested, but the purpose of Cho is the same: to provide a single device to create a fresh mixture of ingredients where previous approaches required two bottles to mix those ingredients. This applies to chemicals and medicines, just like with beverages.

Cho confirms that the mixture is intended for immediate use. In describing the problem solved by Cho's invention, Cho describes "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

[166] Ins. Dec., 23.

two materials can be mixed *to be used*."[167] This solves the prior art problem of requiring two bottles to mix before use.[168] In describing the applicability of its solution, Cho describes the user mixing and using the mixture: "When using the materials, the isolated spaces communicate with each other as a result of a predetermined operation, *so that a user can mix and use the two materials easily*."[169] An advantage of Cho's device is it provides a *fresh* mixture for use: "For actual use (for example, [for] distributing beverage samples), this bottle enhances the freshness of the materials and the reliability of the products."[170] If a user were to mix the ingredients and then transport or ship the mixture, then freshness would not have been an issue. This would render Cho's problem moot, whether the mixture is beverages, chemicals, or medicines. Nothing in Cho suggests that the device could be applied to long-term storage and shipping of the mixture. Indeed, Cho teaches that long term storage results in deterioration in the mixture: "the present invention prevents the properties of the materials from being

[167] Ex. 1004, 1:3-6 (emphasis added).

[168] *Id.*, 55:17-20.

[169] *Id.,* 55:15-17 (emphasis added).

[170] *Id.*, 55:20-22.

changed or deteriorated, which may occur when they are stored in a mixed state for a lengthy period."[171]

Petitioner relies exclusively on the Cho embodiment of Figures 43-45B. Cho describes use of that embodiment consistently with its problem-solution. A user "rotates the opening unit" which causes the annular valve to open "so that the additive is discharged from the additive storage container."[172] Once the contents are mixed, the user again "rotates the opening unit" and causes the cap and annular valve to "rise up and [be] removed from the bottle."[173] This state is illustrated in Figure 45B, reproduced below. Nothing suggests that the user could store the mixture in the container for a prolonged period of time (which would render Cho's problem-solution moot) or ship the mixture between the steps of turning the cap and removing the cap. In fact, if the user did, that storage would be inconsistent with Cho's stated advantages: "the present invention prevents the properties of the materials from being changed or deteriorated, which may occur when they are stored in a mixed state for a lengthy period."[174]

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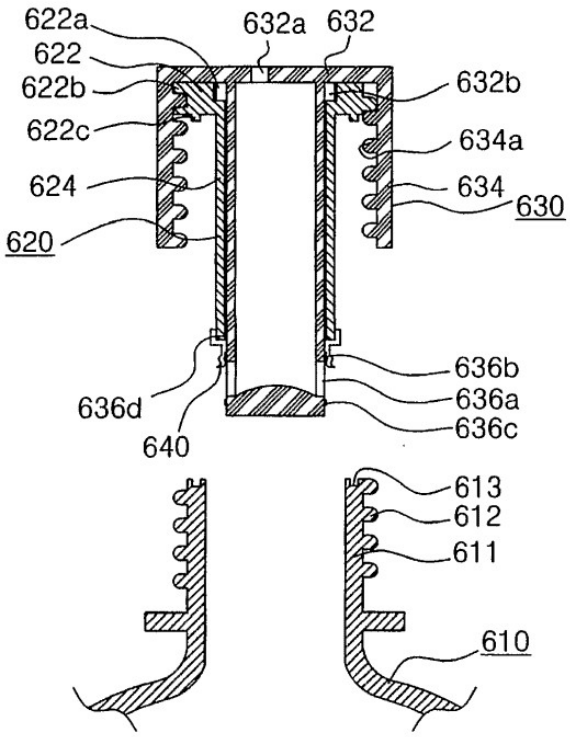
[171] *Id.*, 55:22-25.

[172] *Id.*, 50:4-12.

[173] *Id.*, 50:16-27.

[174] *Id.*, 55:22-25.

FIG. 45B



In fact, Cho does not teach a fluid-tight interaction between its cap and bottle. The Petition identifies Cho's annular valve as providing a fluid-tight seal: "a fluid-tight seal is created between the outer cylinder (additive storage container 620) and the opening (mouth 611) of the container when the outer cylinder is associated with, i.e. contacts, the opening of the container."[175] The Petition explains that "[t]he circular end plate 622 . . . surface that abuts the top of mouth 611, creating a fluid-tight seal therebetween."[176] Petitioner provides no evidence

[175] Pet., 51 (citing Ex. 1002, ¶ 121).

[176] *Id.*, 51 (citing Ex. 1004, 48:27-31, Figs. 44-45B; Ex. 1002, 121).

that the circular end plate does prevent leaking, but cites to Mr. Leinsing. Mr. Leinsing concludes that "[a] POSA would have understood this abutting contact to be fluid-tight because it retains the fluid in the bottle,"[177] but does not explain why Cho's device would find it necessary to retain the fluid in the bottle.

Because Cho does not teach storage of the mixture, there is no reason to suspect the circular plate component is configured with the unnecessary function of a fluid-tight seal.[178] When Cho does have a fluid-tight seal between components, Cho provides detail. For example, Cho explains the "[r]ing-type seal protrusions 636b and 636c formed around the circumferential surface" of the inner cylinder below the discharge port 636a "thus preventing an additive from leaking through the discharge ports 636a."[179] There is no similar mention of a fluid-tight seal created by the circular plate and the bottle of Figures 43-45B.

Cho has no need for a fluid-tight seal between the cap and bottle and does not provide any detail that suggests otherwise. And Cho's ratchet mechanism suggests the opposite.[180] As shown in Figure 43 below, the ratchet mechanism

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[177] Ex. 1002, 121.

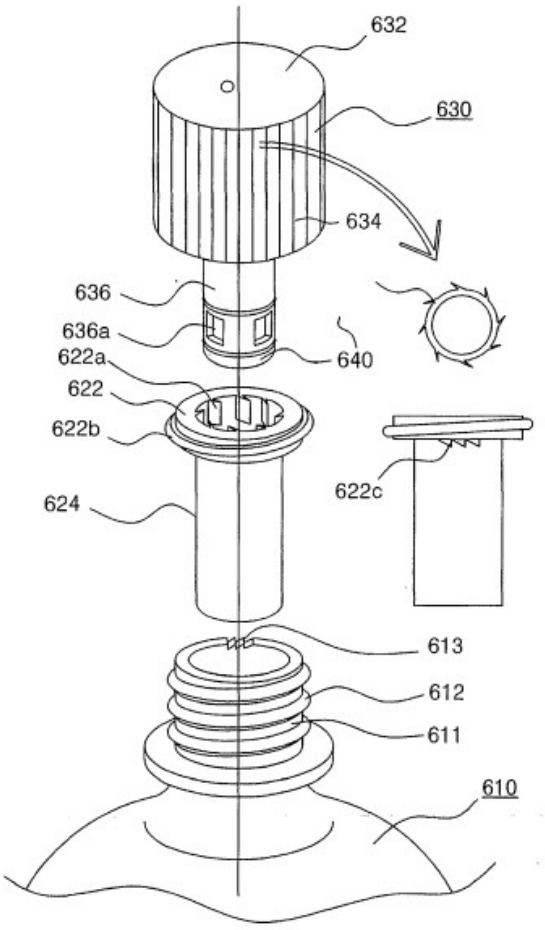
[178] Ex. 2013, 70.

[179] *Id.* (citing Ex. 1004, 49:16-21).

[180] Ex. 2013, 71-72.

includes a saw tooth design on the bottle which matches to a corresponding sawtooth on the outer cylinder.[181]

FIG. 43

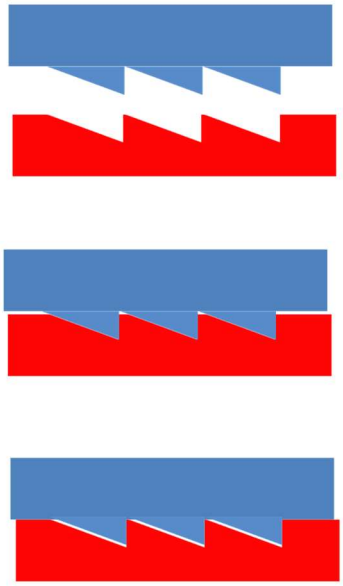


When the cap is tightened, these saw tooth components are pushed in one direction, meaning one side of each "tooth" is squeezed while another side is opened (i.e., not sealed).[182] The series of schematics below illustrate the saw tooth

[181] Ex. 2013, 71-72.

[182] Ex. 2013, 71-72.

components approaching and interacting with each other.[183] This design requires highly precise molding so that the two portions will properly align and couple.[184] Once coupled, there is only force between two faces and thereby sealing the pair of faces, but another pair of faces are not forced together and will remain unsealed.[185] This presents a risk of leakage, rendering Cho's solution inappropriate for long-term storage or shipping.[186]



[183] Ex. 2013, 71-72.

[184] *Id.*

[185] *Id.*

[186] *Id.*

The ’646 Patent and Plante are solving a different problem than Cho. Where Cho’s device is for immediate use of the mixture and is not concerned with long-term storage and shipment, the ’646 Patent and Plante mix the ingredients and provide a container for long-term storage and shipment.

Because Cho is not in the same field of endeavor as the ’646 Patent nor attempting to solve the same problem, the Petition has not shown that Cho is analogous art to the ’646 Patent.

2. Cho’s cap does not provide the same desired functionality as Plante’s cap

The Petition argues that “the combination [of Cho’s cap with Plante’s receiving vessel] would have involved no more than the routine substitution of one cap (having an annular valve) for another (having a pierceable membrane) that eliminated the need for a sharp knife but provided all the same desired functionality.”[187] Plante teaches several desired functions for its saliva sample collection device.[188] Petitioner’s substitution analysis focuses on meeting one function: “The cap disclosed in Cho is used to release a reagent into a bottle when fastened to the bottle, and a POSA would have expected success in using Cho’s cap to perform the same function when connected to Plante’s sample collection

[187] Pet, 31 (citing Ex. 1002, 76).

[188] Ex. 2013, 78.

vessel."[189] Mr. Leinsing's declaration repeats this sentence, adding no further functions, and concludes that the substitution of Cho "provide[s] the same functionality" as Plante.[190]

Plante teaches several functions for a cap that Cho's cap does not provide.[191] Plante's background highlights that different containers serve different functions, depending on their purpose: "Container arts and engineering presently enjoys an advanced state whereby container design and function is configured for particular purpose."[192] An important and frequently repeated function of Plante's device is that the container must be "suitable for safe transmission of biological matter via the mails and private delivery services."[193] Safe transmission is not a function provided by Cho's device or cap.

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[189] Pet., 31 (citing Ex. 1002, 76.)

[190] Ex. 1002, 76.

[191] Ex. 2013, 78-88.

[192] Ex. 1003, 0004.

[193] *Id.*, 0006; *see also id.*, Abstract ("Saliva sample collection systems are configured with special attention to . . . safe transport and delivery by a conventional delivery services such as Federal Express.").

Petitioner acknowledges that Plante's device includes a function where, once mixed with the preserving fluid, the biological sample is preserved in the sample collection vessel and the vessel is "'configured for safe conveyance via standard shipping services.'"[194] Petitioner further acknowledges that Plante's device is configured so "the biological sample can be preserved in the sample collection vessel for extended periods of time."[195] Plante teaches that the long-term storage function is met by a liquid tight seal between the receiving vessel and the cap: "A receiving vessel and sealing cap which couple together . . . [to] form a liquid tight containment cavity suitable for long-term and durable storage of a DNA in a saliva sample."[196] There is nothing in Cho that suggests Cho creates a fluid-tight seal once the components are mixed.[197]

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[194] *See* Pet., 24 (citing Ex. 1003, 0017.)

[195] *See* Pet., 24-25 (citing Ex. 1003, ¶ 0018.)

[196] Ex. 1003, 0018; *see also id.*, 0022 ("When a cap element is coupled to a receiving vessel . . . forming a seal between the receiving vessel and the sealing cap such that no liquid can escape containment."); 0035 (describing an important function as "forming a liquid tight seal between the cap element and the receiving vessel element.").

[197] See above Section V.B.1.

Because it does not provide a fluid-tight seal, Cho's device (and cap) is not suitable for transport. The size of Cho's cap also makes it unsuitable for another of Plante's desired functions, a packaging solution. Plante teaches a two-way packing system, illustrated in Figure 4 (reproduced below).[198] Plante's device is shipped to the user with the cap 44 and receiving vessel 46 separately.[199] The packaging includes corresponding recesses 43 and 45, respectively.[200] In Plante's solution, the user removes the cap 44 and receiving vessel 46, deposits the sample, and couples the cap and receiving vessel to mix preservative with saliva.[201] At this point, the cap and receiving vessel are one sealed container.[202] Then the user places the sealed container within cavity 47 and ships the container to a laboratory for processing.[203]

[198] Ex. 1003, 42.

[199] *Id.*

[200] *Id.*

[201] *Id.*

[202] *Id.*

[203] *Id.*

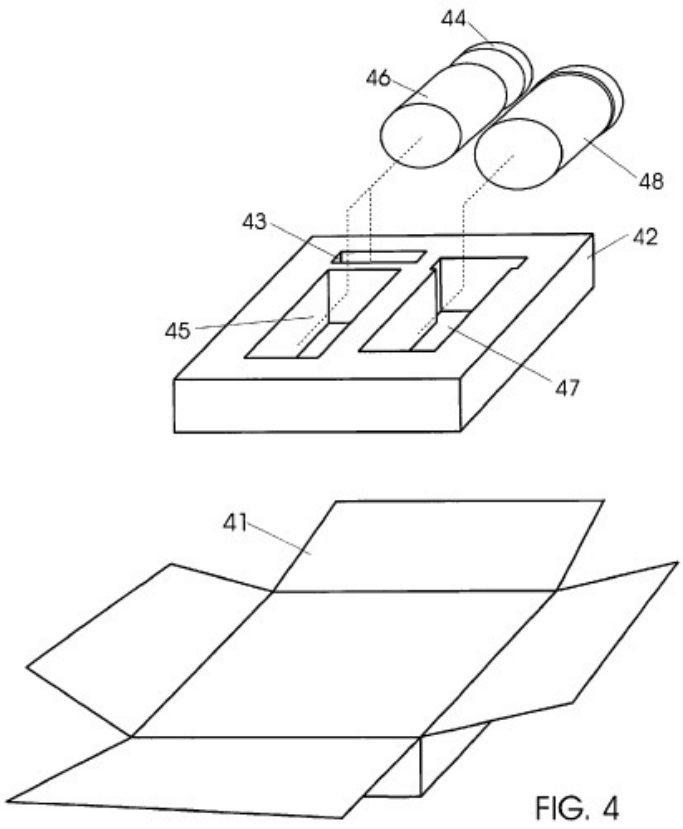


FIG. 4

Plante's packaging solution is feasible because Plante's cap has a low profile.[204] The space needed for cavities 43 and 45 (i.e., to house the device when shipped to the user) is not significantly bigger than the space needed for cavity 47 (i.e., to house the device when shipped from the user).[205] In contrast, the space needed to ship Cho's cap with Plante's container would be significantly greater.[206]

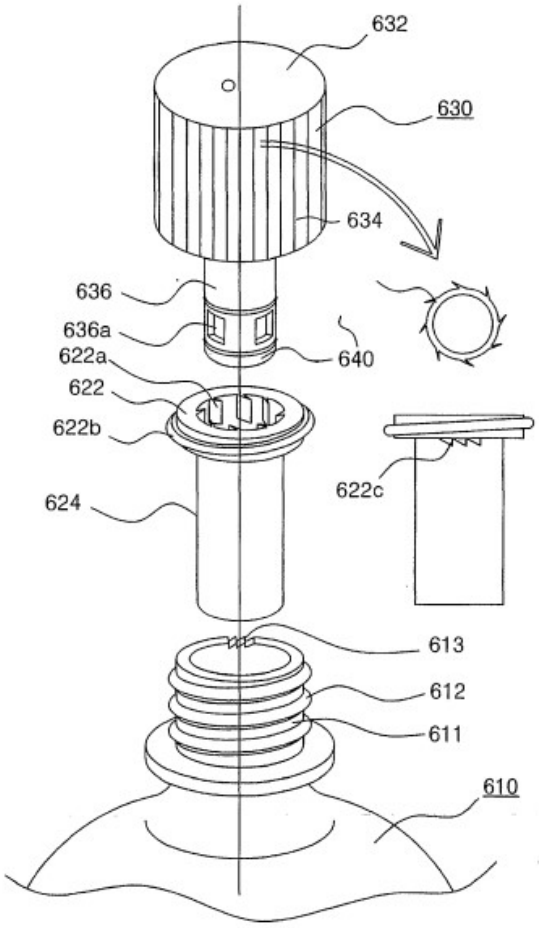
[204] Ex. 2013, 81.

[205] *Id.*

[206] *Id.*

Cho's cap has a large profile (see Cho Figure 43, reproduced below).[207] Adding Cho's cap would increase the width of Plante's packaging by 50% because a third cavity of similar size would be needed for the cap when the package is shipped to the user.[208]

FIG. 43



[207] *Id.*

[208] *Id.*

Plante teaches another function, reduced parts and improved reliability: "It is also an objective to provide systems of reduced parts and increased ease of use for improved reliability."[209] Substituting Cho's cap increases parts and adds complexity that reduces reliability.[210] Plante's cap and Cho's caps are pictured side-by-side below, with the different parts identified using the color scheme adopted by Petitioner. Plante's cap (left[211]) has two distinct parts—the cap[212] (blue) and the thin membrane (purple) which covers the reservoir. Cho's cap

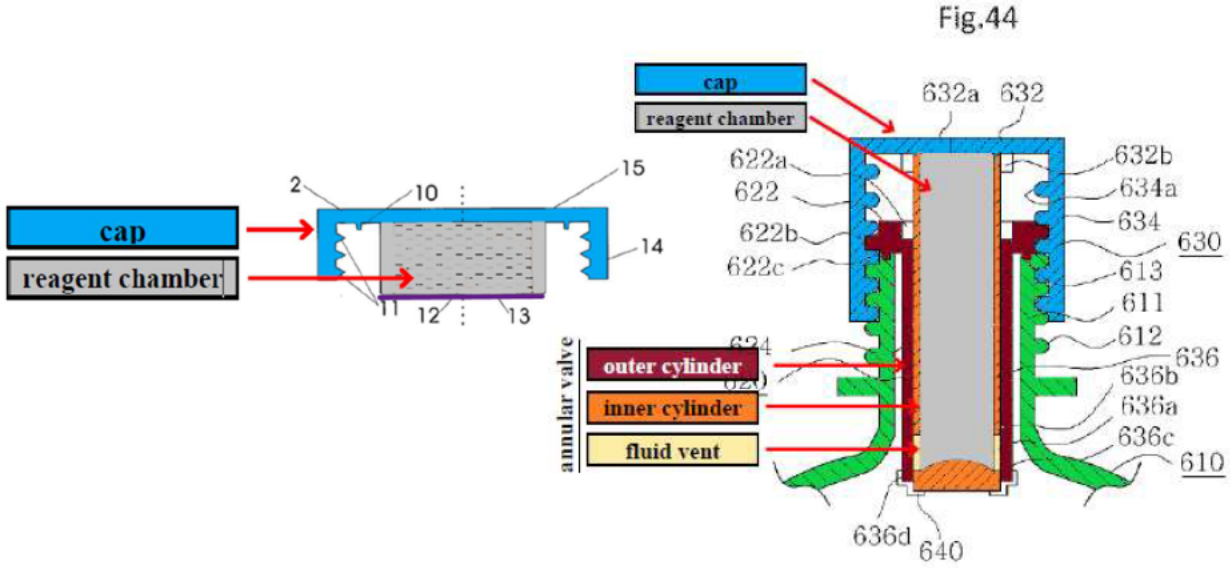
[209] Ex. 1003, ¶ 0028; *see also id.* 0006 ("[C]ontainers which effectively capture a sample with a minimal amount of steps and a minimal number of parts is a great benefit with respect to system success.").

[210] Ex. 2013, 84-86.

[211] Image excerpted from Pet., 6. The purple line was added to identify the thin film.

[212] Plante teaches the seal 10 and the walls of reservoir 12 can be molded with the cap as one part. Ex. 1003, 0038, 0041.

(right[213]) has three distinct parts—the cap (blue)/the inner cylinder (orange)[214], the outer cylinder (burgundy), and the bursting film (no color, labeled 640).



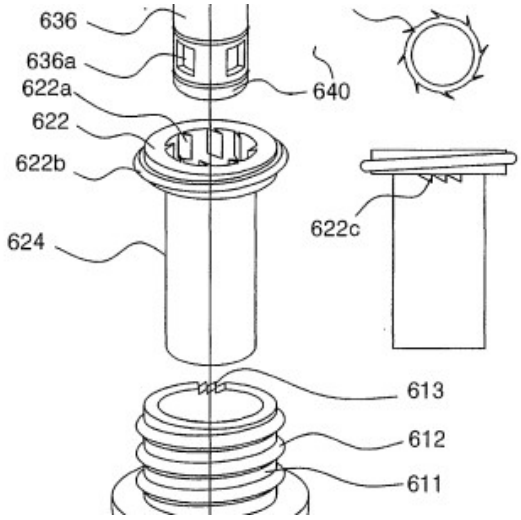
Many of Cho's main parts have sub-parts. For example, the outer cylinder has an upper ratchet 622c (see Cho Figure 43, relevant portion reproduced below) that interferes with an upper ratchet 613 on a bottle "so that the additive storage container 620 is allowed to rotate only in one direction relative to the mouth 611."[215] Similarly, Cho's outer cylinder includes a lower ratchet plate 622a and the

[213] Image excerpted from Pet., 7.

[214] Cho teaches that the inner cylinder can be molded with the cap as one part. Ex. 1004, 51:22-26.

[215] *Id.*, 49:1-5.

cap includes an upper ratchet plate 632b[216] that interfere "so that the opening unit 630 is allowed to rotate in only one direction relative to the additive storage container 620."[217]



In addition, Cho teaches that the cap includes "open port 632a" so that the beverage additive can be loaded into the inner cylinder.[218] After beverage additive is loaded into the inner cylinder, the open port 632a is "sealed with a separate sealing means."[219] The seal can be "[a]n aluminum plate or a thin synthetic resin film." [220]

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[216] Note that Cho, Figure 43 is missing the label for 632b.

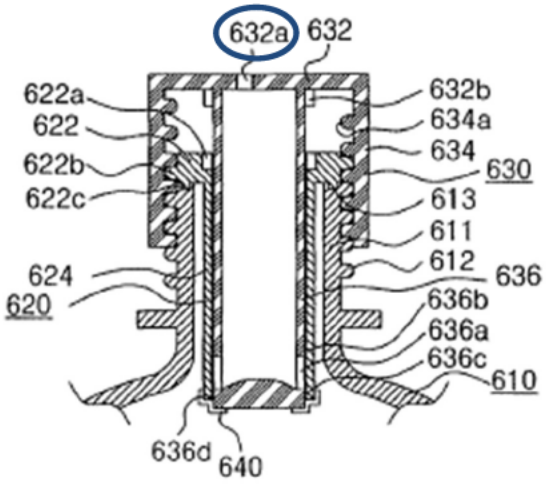
[217] Ex. 1004, 49:28-33.

[218] *Id.*, 49:34-35.

[219] *Id.*, 49:35–50:2.

[220] *Id.*, 50:2-3.

FIG. 44



Thus, substituting Cho's cap for Plante's cap adds a number of additional parts and reduces reliability.[221]

As another function, Plante explains that "[i]n home collection systems, the container . . . must be devoid of failure mechanisms which tend to render collection of a sample defective."[222] As discussed below, Cho's cap introduces a failure mechanism that increases the risk of sample contamination, which would render a sample defective.[223] Thus, substituting Cho's cap for Plante's cap frustrates

[221] Ex. 2013, 84-86.

[222] Ex. 1003, ¶ 0006.

[223] Ex. 2013, 87.

Plante's objective of avoiding failure mechanisms which tend to render a sample defective.[224]

The Petition argues that Cho's cap "provided all the same desired functionality" as Plante's cap, but address only one of those desired functions. Petitioner does not show that Cho's cap meets many of the desired functions of Plante, including functions necessary for its operation. For at least this reason, Petitioner has not shown that a POSA would replace Cho's cap for Plante's cap.

3. A POSA would not have a reasonable expectation of success substituting Cho's cap for Plante's cap

The Petition argues that "the combination of Plante and Cho involves the simple substitution of one known element for another—Plante's cap for Cho's cap"[225] and that a "POSA also would have reasonably expected success in combining a cap having an annular valve as disclosed in Cho with the biological sample collection system of Plante."[226] Petitioner is mistaken. A POSA would not substitute Cho's cap for Plante's cap and expect success.[227] First, Cho's cap would

[224] Ex. 2013, 90-93.

[225] Pet., 30-31 (citing Ex. 1002, 74-75).

[226] *Id.*, 31 (citing Ex. 1002, 66-77).

[227] Ex. 2013.

significantly increase the risk of a defective sample.[228] Second, Cho's cap would not fit in Plante's receiving vessel. Third, Cho's cap includes features that require complimentary features on a collection tube, features absent in a simple substitution.[229]

First, Cho's cap significantly increases the risk of a defective sample.

Plante's cap provides minimal risk of contamination.[230] As shown in the image below[231], Plante's reservoir protrudes slightly beyond Plante's cap. This significantly reduces the risk that someone would touch the reservoir film, which could render the sample defective.[232] This configuration is consistent with Plante's stated function for "[i]n home collection systems": the device "must be devoid of failure mechanisms which tend to render collection of a sample defective."[233]

[228] Ex. 2013, 90-93.

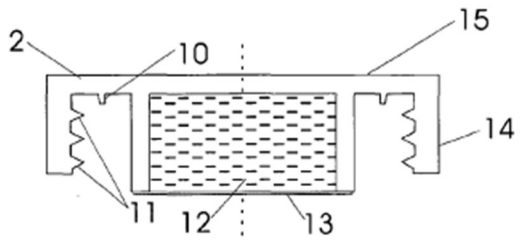
[229] Ex. 2013, 95-100.

[230] Ex. 2013, 95-100 (citing Ex. 1004, 49:16-21).

[231] Relevant portions excerpted from Ex. 1003, Figure 1.

[232] Ex. 2013, 91 (citing Ex. 1004, 49:16-21).

[233] Ex. 1003, 0006; *see also* Ex. 2013.



Cho's cap introduces a failure mechanism. [234] Specifically, Cho's annular valve extends significantly beyond the bottom of Cho's cap.[235] This increases the risk that a hand touches the interior of the device.[236] Such a touch could lead to a defective sample.[237] The risk is heightened because the annular valve resembles a handle (see excerpted portion of Cho Figure 44 below) and naturally suggests itself to be an interaction point for a user. [238]

[234] Ex. 2013, 91 (citing Ex. 1004, 49:16-21).

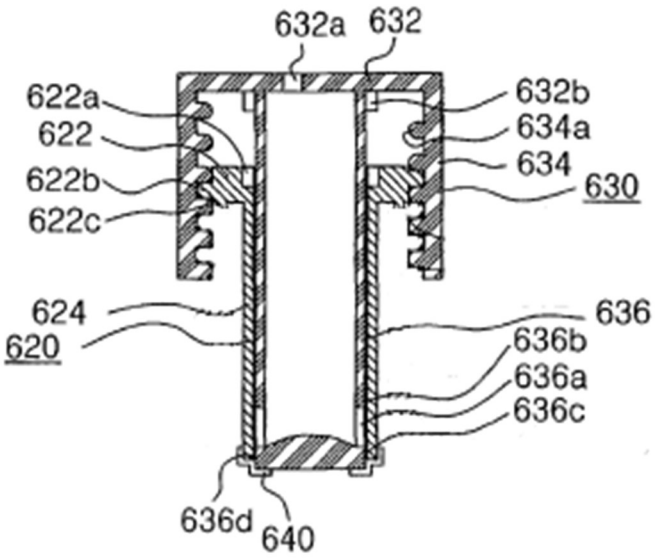
[235] Ex. 2013, 91-92 (citing Ex. 1004, 49:16-21).

[236] Ex. 2013, 91-92 (citing Ex. 1004, 49:16-21).

[237] Ex. 2012, 19.

[238] Ex. 2013, 92 (citing Ex. 1004, 49:16-21).

FIG. 44



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.[239]

Mr. Leinsing did not consider the risk of contamination. Mr. Leinsing testified that he never talked with Dr. Fischetti, Petitioner's biochemistry expert. [240]

[239] Ex. 2012, 18-19.

[240] Ex. 2029, 10:3-5.

Dr. Fischetti confirmed.[241] Mr. Leinsing testified that he reviewed Dr. Fischetti's declaration.[242] And then, only for the biochemistry skill in the art and whether the biochemistry limitations were met.[243] Dr. Fischetti's declaration does not address whether a POSA would be motivated to combine Plante and Cho in Ground 1. Dr. Fischetti's declaration explicitly states that he relied on Mr. Leinsing for whether a POSA would find claim 1 obvious over Plante in view of Cho.[244] Neither Mr. Leinsing's declaration nor Dr. Fischetti's declaration suggests that either considered whether a POSA would have recognized an increased risk of contamination by substituting Cho's cap for Plante's cap.

Second, Cho's cap would not fit in Plante's receiving vessel. Petitioner argues that "the combination would have involved no more than the routine substitution of one cap (having an annular valve) for another (having a pierceable membrane) that eliminated the need for a sharp knife but provided all the same desired functionality."[245] For this substitution, the only change suggested by the

[241] Ex. 2030, 18:16-21.

[242] Ex. 2029, 12:15-17.

[243] Ex. 1002, 40, 49, 54.

[244] Ex. 1011, 23.

[245] Pet., 31 (citing Ex. 1002, 76).

Petition and Mr. Leinsing's declaration is that "a POSA would have readily understood that Cho's cap could be made to accommodate the sample collection vessel disclosed in Plante."[246] Mr. Leinsing testified that some changes would be necessary, including changing the threads of Cho's cap to correspond to threads on Plante's receiving vessel and removing the knife from Plante's receiving vessel.[247] And that's all.

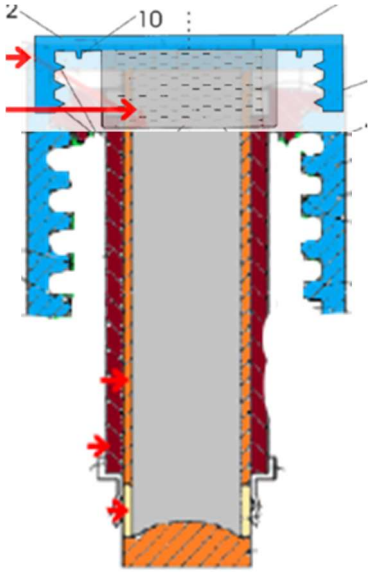
Another necessary change is to scale Cho's cap so that its threads can engage with Plante's receiving vessel.[248] Below is an overlay of Cho's cap and Plante's cap, scaled so that the threads on Cho's cap will engage with Plante's receiving vessel.[249]

[246] Pet., 31 (citing Ex. 1002, 76).

[247] Ex. 2029, 102:24-103:6; *see also Id.*, 122:7-13, 123:7-17; *compare with* Inst. Dec., 28-29 (*citing* Pet. 34–35) ("[T]he Petition provides a basis to conclude that Cho's threaded connection to screw a cap on a container is the same as that disclosed by Plante and the '646 patent.").

[248] Ex. 2013, 95-100.

[249] Ex. 2013, 99.



As shown, a simple substitution of Cho's cap with Plante's cap would result in a cap that is considerably longer than the original Plante design.[250] This additional length would prevent a user from inserting the cap into Plante's receiving vessel after the user deposits the saliva sample.[251] As shown in Plante's original design below, there is little separation between the bottom of the preservative reservoir and the funnel portion of the receiving vessel when the cap and vessel are coupled.[252]

[250] Ex. 2013, 95-100.

[251] Ex. 2013, 95-100.

[252] Ex. 2013, 96.

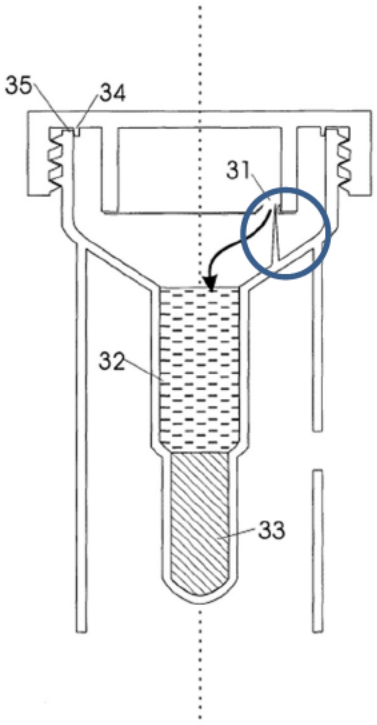


FIG. 3

Substituting Cho's cap for Plante's cap would prevent Cho's cap from operating.[253] Figure 1 from Plante[254] on the left below includes Cho's cap scaled to correspond to the size of Plante's receiving vessel's mouth (so that Cho's cap's threads and Plante's cap's threads can engage).[255] On the left, Cho's cap is separated from Plante's receiving vessel to illustrate the relative dimensions.[256] In

[253] Ex. 2013, 97.

[254] Figures excerpted from the Pet., 6 (the Plante cap and receiving vessel) and 7 (the Cho cap).

[255] Ex. 2013, 97.

[256] Ex. 2013, 97.

the figure on the right, Cho's cap has replaced Plante's cap in the Plante device.[257] At this juncture, the bottom threads on Cho's cap have engaged the threads on Plante's receiving vessel.[258]

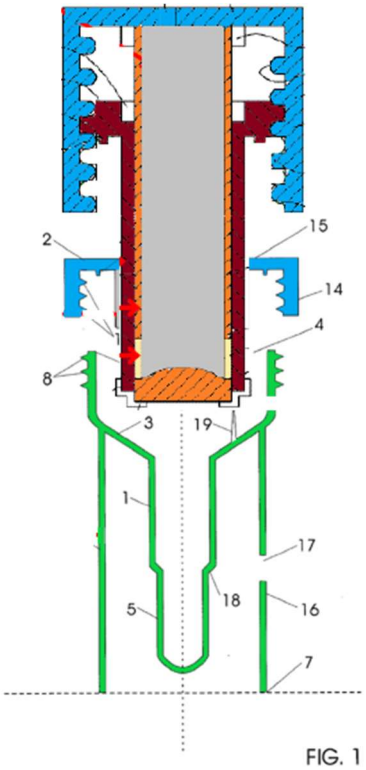


FIG. 1

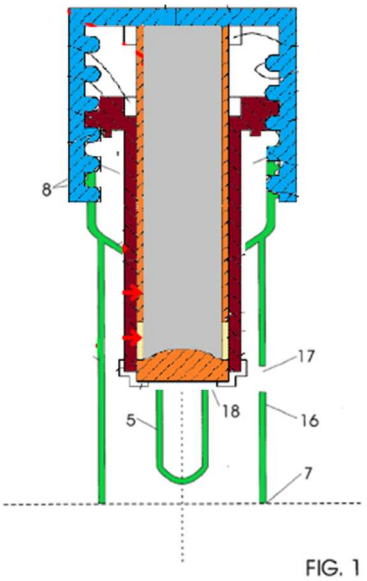


FIG. 1

As can be seen above, even in this pre-coupled position, Cho's cap does not fit into Plante's receiving vessel.[259] At this stage in operating the Plante-Cho combination, Plante's receiving vessel has not engaged Cho's outer cylinder and

[257] Ex. 2013, 97-98.

[258] Ex. 2013, 98.

[259] Ex. 2013, 98.

Cho's cap needs to travel further so that the outer cylinder can engage the top of Plante's receiving vessel to begin Cho's release mechanism.[260]

The figure below shows Cho's cap on Plante's receiving vessel after the vessel has engaged Cho's outer cylinder and fully actuated the release mechanism.[261] Note that the bottom of Cho's cap has extended; this is Cho's inner cylinder passing through the "bursting film" to release the contents within the chamber. [262] As shown, Cho's cap now extends completely to the depth of the Plante receiving vessel.[263]

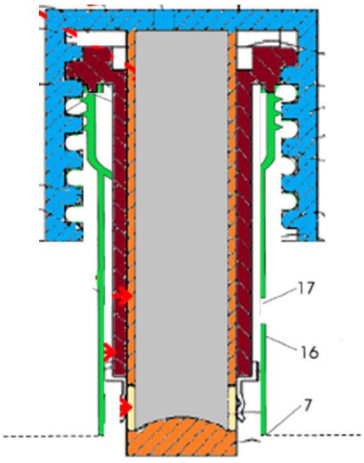


FIG. 1

[260] Ex. 2013, 98-99.

[261] Ex. 2013, 99.

[262] Ex. 2013, 99.

[263] Ex. 2013, 99.

As shown above, a simple substitution of Cho's cap with Plante's cap would not operate.[264] A POSA would not have a reasonable expectation of success in Petitioner's proposed combination.[265]

Third, Cho's cap requires features that are not present in Plante's receiving vessel. Cho teaches a complicated device.[266] For example, "so that the additive storage container 620 is allowed to rotate in only one direction relative to the mouth 611," Cho's outer cylinder has an upper ratchet 622c (see Cho Figure 43, reproduced below) that interferes with an upper ratchet 613 on a bottle.[267]

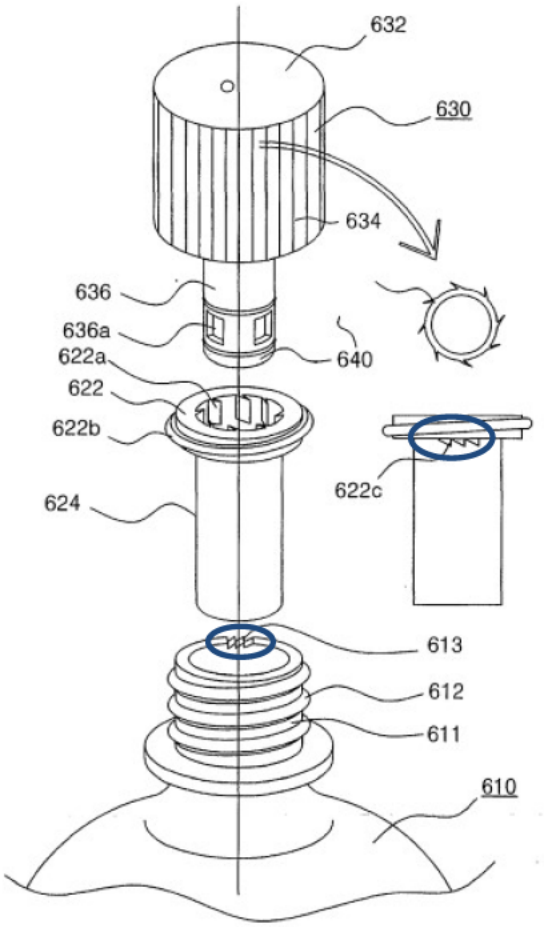
[264] Ex. 2013, 89-100.

[265] Ex. 2013, 100.

[266] Ex. 2013, 54.

[267] Ex. 1004, Page 49, Lines 1-5.

FIG. 43



In a simple substitution of Cho's cap for Plante's cap, Cho's lower ratchet 613 would not be present on Plante's receiving vessel. This means that the upper ratchet 622c would not have a corresponding seat, thereby creating a gap between upper plate 622 and the top of Plante's receiving vessel and preventing the Cho-Plante combination from having any chance of sealing. Such a device would leak during transport, rendering it unsuccessful for Plante's purpose: "A receiving vessel and sealing cap which couple together . . . [to] form a liquid tight

containment cavity suitable for long-term and durable storage of a DNA in a saliva sample."[268]

For at least the reason that the Petition fails to show that a POSA would have a reasonable expectation of success when substituting Cho's cap for Plante's cap in Plante's device, the Petition has failed to demonstrate any challenged claim is unpatentable under Grounds 1 and 2.

C. Balancing the advantages and disadvantages of the Plante-Cho combination, no challenged claim is obvious

As explained above, the Petition does not show that a POSA would have been motivated by design incentives to modify Plante, either because of molding difficulties or because of a risk of injury to a user. This is fatal to all grounds. Petitioner has also not shown that a POSA would have a reasonable expectation of success when substituting Cho's cap for Plante's cap. This is fatal to Petitioner's Plante-Cho combination in Grounds 1 and 2. Even if these deficiencies were not fatal, weighing the lost and gained benefits[269] makes clear that a POSA would not find substituting Cho's cap for Plante's cap desirable.

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[268] Ex. 1003, 0018; Ex. 2013.

[269] *See* Inst. Dec., 28 (citing *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000)).

Starting with the benefits of the combination, there are none. As described earlier, a POSA would not recognize any benefits because of a perceived "difficulty to mold sharp thin features in plastic."[270] Not only does evidence show that there was no known problem molding piercing members to rupture thin films, Cho's cap requires more "sharp thin features" than Plante's cap. If Petitioner is right that a "POSA would have known it is also difficult to mold sharp thin features in plastic,"[271] substituting Cho's cap adds more of that difficulty. A POSA would perceive no "molding" benefits because of the Plante-Cho combination.

Nor would a POSA perceive benefit because of "a risk of injuring a user."[272] As with its "molding difficulties" argument, the Petition just makes general statements that all sharps are dangerous, then postulates that because Plante has a "sharp," it too must be dangerous. But this assumes all sharps present the same risk. They do not. For example, an IV needle is necessarily sharp enough to puncture skin. A piercing member to rupture a thin film need not be. The '646 Patent background recognizes a risk presented by the inadvertent release of a toxic

[270] Pet., 30.

[271] *Id*.

[272] *Id*.

chemical.[273] The '646 Patent specifically teaches that thin membranes could be pierced by accidental contact with a finger nail.[274] A membrane that can be punctured by accidental contact with a finger nail need not be so sharp that it risks injury to a user.

Because there are no benefits gained by substituting Cho's cap for Plante's cap, there are no "benefits, . . . lost and gained,"[275] to be weighed. But there are significant disadvantages of substituting Cho's cap for Plante's cap, disadvantages that make the combination unsuitable for its intended function. As explained above, Cho's cap does not fit in Plante's receiving vessel. Because it doesn't fit, it cannot release preservative. Without releasing preservative to mix with a sample, a "biological sample collection and preservation" device cannot function. Even if

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[273] *See, e.g.,* Ex. 1001, Abstract, 4:1-8.

[274] *Id.*, 4:16-26 (*citing* U.S. Patent No. 7,482,116) ("Some currently available sample collection devices . . . [use] sharp extruding objects and thin pierceable membranes. The thin pierceable membranes can represent 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."); *see also id.* 4:26-31 (*citing* U.S. Patent Publication No. 2009/02116213 A1.)

[275] *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000).

Cho's cap could fit, it does not provide a fluid-tight seal, rendering it inoperable for long-term storage and/or shipment. Regardless of the benefits proposed, Petitioner cannot justify an inoperable device.

There are other disadvantages that, while not rending the device inoperable, present significant disadvantages. For one, Cho's cap increases the risk of contamination. Given the accuracy of DNA testing and its sensitivity to contamination, Cho's cap presents a disadvantage that would require a significant advantage to justify. The Petition does not articulate one. Further, the Cho cap is more complicated, has more parts, and is less reliable, contrary to many of Plante's stated goals: "the container . . . must be devoid of failure mechanisms which tend to render collection of a sample defective"[276] and "it is also an objective to provide systems of reduced parts and increased ease of use for improved reliability."[277] The Petition has not presented any actual benefit to substituting Cho's cap for Plante's cap, much less one that balances the Cho cap's increased likelihood for

[276] Ex. 1003, 0006.

[277] *Id.*, 0028; *see also id.* 0006 ("[C]ontainers which effectively capture a sample with a minimal amount of steps and a minimal number of parts is a great benefit with respect to system success."); Ex. 2029, 130:7-17 (testifying that POSA would be motivated to look for a reliable solution).

defective sample collection, increased complication, increased parts, and decreased reliability.

In addition to the specific combination of Plante and Cho, the Petition also makes more general statements about annular valves being obvious: "It was also well known to use a movable annular valve to release the reagent stored in a cap into a container. It would have been obvious to use such a well-known annular valve in a biological sample collection system."[278] These general statements are inconsistent with research and development by POSAs in the field of biological sample collection and preservation since the priority filing of the '646 Patent. For example, both Ancestry.com and the Petitioner have designed and sold sample collection devices with movable annular valves in the cap and both have filed patent applications to those collection devices.

Ancestry.com filed a PCT application in November 2018 claiming priority to a provisional application filed November 2017.[279] The application was titled "Sample Collection Kit Including Cap Having Selectively Moveable Sleeve."[280] The provisional application describes a sealing cap 110 with a selectively movable

[278] Pet., 5.

[279] Ex. 2033, Cover Page.

[280] *Id.,* Cover Page, 1.

annular valve 104 that releases reagents from within the cap to mix with a sample in the container 103.[281] Figures 2 and 3, reproduced below, illustrate the annular valve in the closed and open positions, respectively.[282]

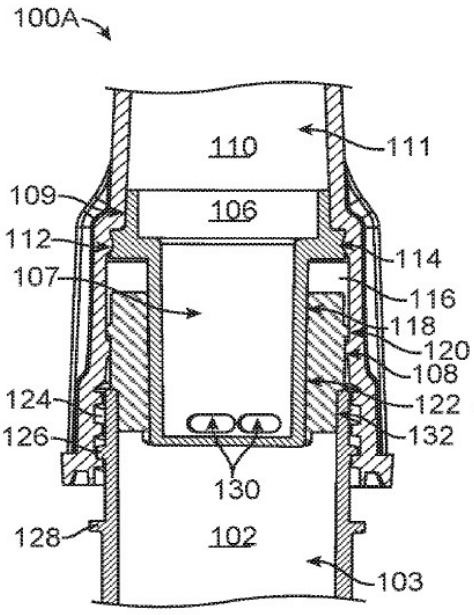

FIG. 2

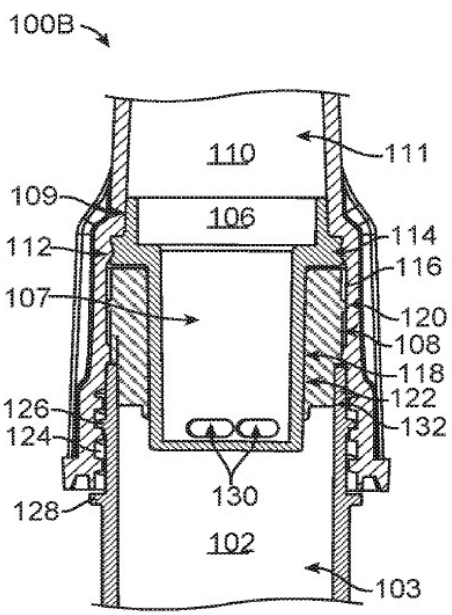

FIG. 3

Petitioner followed later with their own moveable annular valve. In June 2019, Petitioner filed a provisional application which they then filed as a full application in June 2020.[283] This application included a selectively moveable

[281] *Id.*, 0037.

[282] *Id.*, 0014-15.

[283] Ex. 2035, Cover Page.

annular valve comprising a core and a collar.[284] The application's annular valve also releases reagent stored in a cap into a container:[285]

> [A] sample preservation fluid can be introduced into the sample collection chamber 103 and mixed with the deposited biological sample as a result of the sealing cap 110 being attached to the sample collection vessel 102. . . . [T]his can be due to the selectively movable valve 104 opening and allowing reagent to be released through fluid vent 116 defined by the open valve 104 and into the sample collection chamber 103.

Figures 2B and 2C[286], reproduced below, illustrate the moveable annular valve in the closed and open configurations, respectively.

[284] *Id.*, Abstract.

[285] *Id.,* 0041.

[286] *Id.*, Figures 2B and 2C.

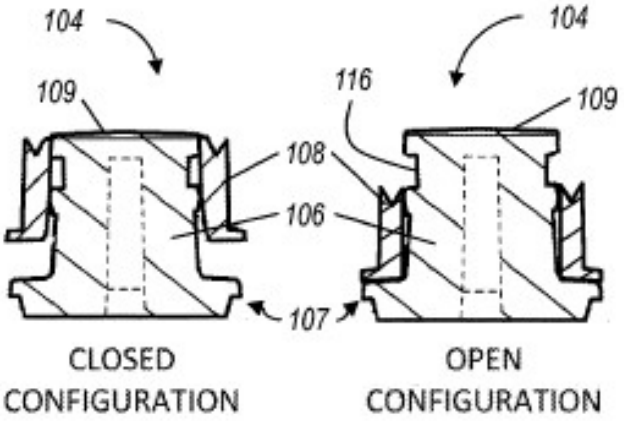

FIG. 2B FIG. 2C

Both Petitioner[287] and Ancestry.com[288] have embodied their moveable annular valves in products currently on the market.

Petitioner's annular valve product and patent application came after Petitioner tried a number of other approaches to releasing a reagent stored in a cap into a container. In addition to the '895 Publication described earlier, Petitioner filed a number of patent applications describing different mechanical approaches

[287] *See, e.g.,* Spectrum *Biomax,* Spectrum Solutions, https://spectrumsolution.com/spectrum-dna/medical-science-and-clinical-products/sdna-whole-saliva-dna-collection-devices/ (last visited May 9, 2023).

[288] *See, e.g., Collecting a Saliva Sample,* Ancestry.com, https://support.ancestry.com/s/article/Collecting-a-Saliva-Sample?language=en_US (last visited May 9, 2023).

to collecting and preserving a biological sample.[289] After all this development and failure, Petitioner discovered a "movable annular valve to release the reagent stored in a cap into a container," filed a patent application on the moveable annular valve design, and then chose that design, over all the others it previously developed, to embody in its only commercial device. Petitioner now argues that "[i]t was also well known to use a movable annular valve to release the reagent stored in a cap into a container. It would have been obvious to use such a well-known annular valve in a biological sample collection system."[290] Petitioner's actual activities in the field are inconsistent with the arguments in the Petition and further demonstrate the advantages of a moveable annular design to release the reagent stored in a cap into a container of biological sample collection system.

VI. GROUND 3: PLANTE IN VIEW OF PATTERSON

A. A POSA would not be motivated to substitute Patterson's cap for Plante's cap

The Petition incorporates by reference its arguments from Plante in view of Cho under Grounds 1 and 2 for Plante in view of Patterson under Grounds 3 and 4. Patent Owner incorporates here its arguments above from the discussion of Plante in view of Cho in Section V.

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[289] *See generally* Ex. 2036, Ex. 2037, Ex. 2038, and Ex. 2039.

[290] Pet., 5.

Petitioner has failed to show that POSA would be motivated to substitute Patterson's cap for Plante's cap.

B. Assuming a POSA would be motivated to modify Plante, the combination of Plante and Patterson would not meet the claimed "cap".

Petitioner argues that a POSA would be motivated to replace Plante's cap with Patterson's annular valve,[291] but, in doing so, eliminates the claimed "cap." The figures below show Plante's cap and device (left) and Patterson's annular valve (right) using Petitioner's color scheme.[292] Petitioner's proposed combination removes Patterson's blue cap and grey reagent chamber and replaces it with Patterson's orange/burgundy annular valve. [293]

[291] Pet., 65 (citations omitted) ("[A] POSA would have been motivated by design incentives to replace Plante's approach of using a knife in the vessel and a pierceable membrane in the cap with a safer design of using an annular valve in the cap. . . . This applies to Patterson, as it does for Cho addressed.").

above.

[292] Pet., 6, 9.

[293] *Id.*, 66.

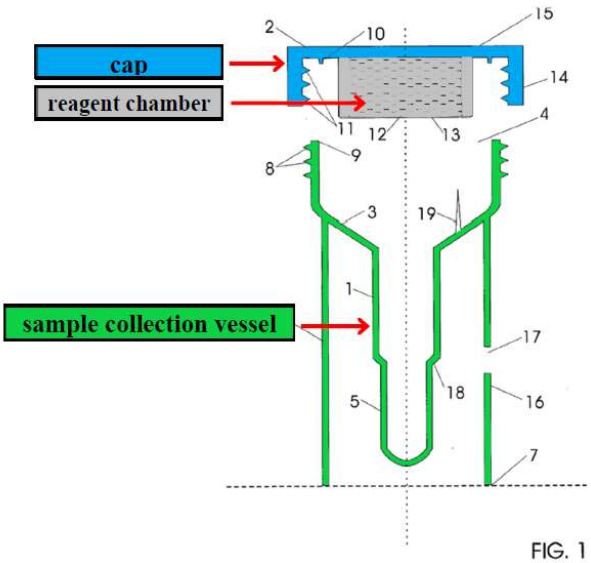


FIG. 1

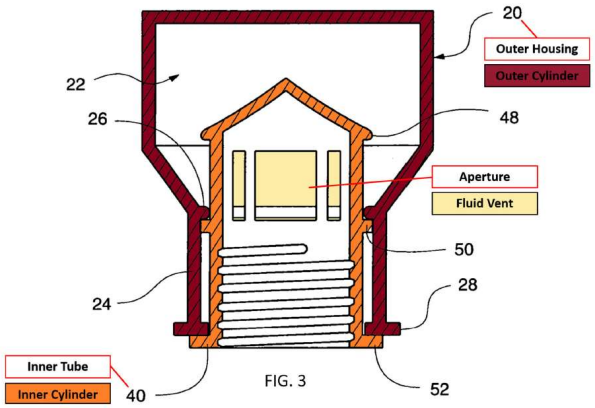


FIG. 3

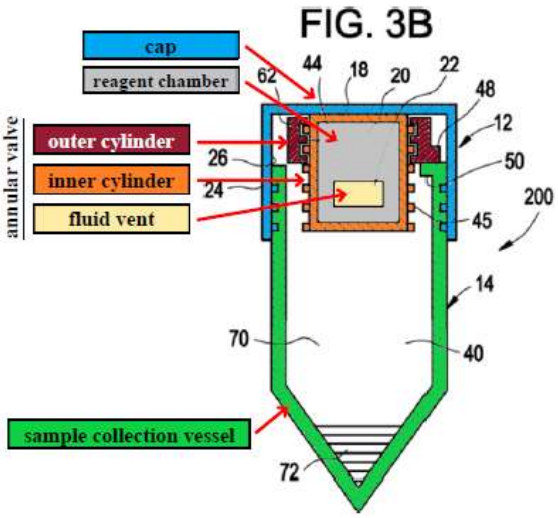
When analyzing the claim 1 limitations for the combination of Plante and Patterson[294], Petitioner cites only to Plante as teaching the claimed "cap," which Petitioner identifies as limitation 1[b]: "As described above, Plante discloses a kit for collecting and preserving a biological sample meeting the preamble of claim 1 and limitations 1[a] – 1[b][ii]."[295] But after substituting Patterson's annular valve, Plante's cap is removed. Petitioner points to nothing in Patterson that meets the cap limitation of claim 1 and does not argue that Patterson teaches the claimed cap.

The cap is a required limitation of claim 1. The Parties agree that claim 1 requires three primary elements: a sample collection vessel, a cap, and a moveable

[294] Grounds 3 and 4.

[295] Pet., 66 (citing Pet §§ VIII(C)(3)-(7)).

annular valve.[296] Throughout the Petition, these primary elements are represented with green for the sample collection vessel, blue for the cap, and orange/burgundy for the moveable annular valve.[297] For example, Petitioner points to the '646 Patent's FIG. 3B and uses its color scheme to identify the primary elements.[298]



For Plante, Petitioner uses the same color scheme to identify a cap in blue and a sample collection vessel in green.[299] There is no annular valve in Plante[300] and so no orange/burgundy.

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[296] *Id.*, 3.

[297] For the annular valve, Petitioner also uses gray to represent the reagent chamber and cream to represent the fluid vent of claim 1.

[298] Pet., 4.

[299] *Id.*

[300] *Id.*, 29.

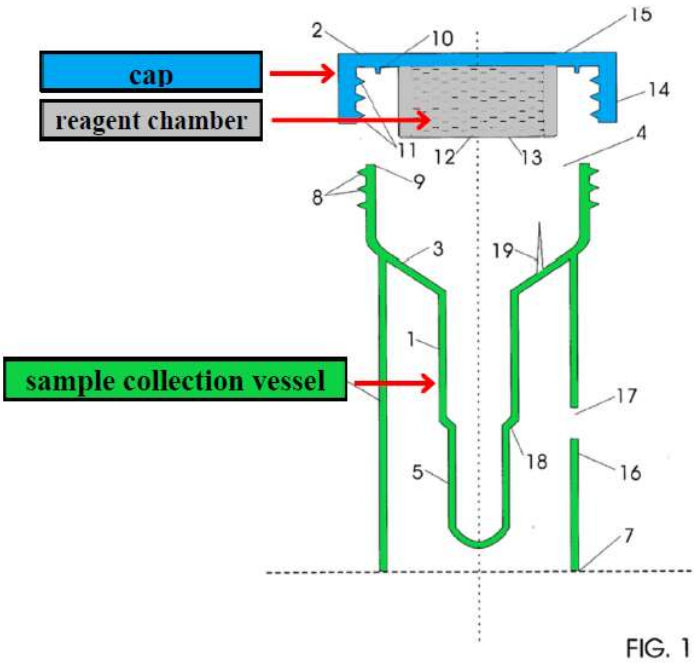
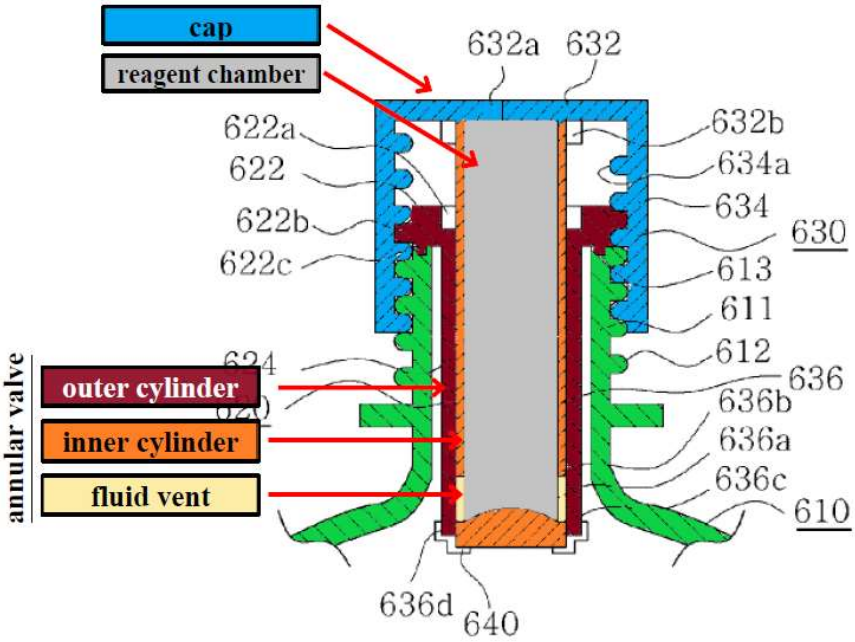


FIG. 1

Petitioner uses the same color scheme for Cho, identifying a cap in blue, an inner cylinder in orange, an outer cylinder in burgundy, and a bottle in green.

Fig.44



When Petitioner identifies the components of Patterson,[301] the Petition does not include a blue component that corresponds to a cap. Petitioner only identifies the orange and burgundy of a different element, the annular valve.

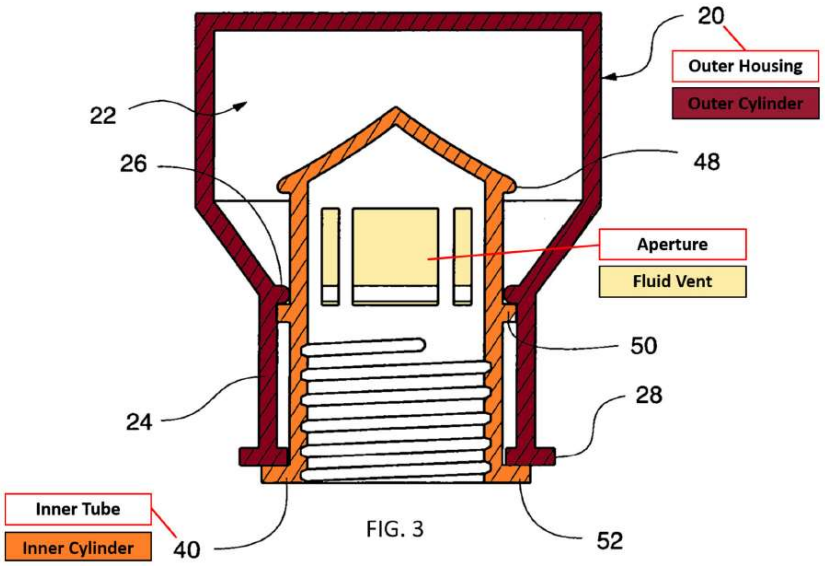


FIG. 3

When Petitioner combines Plante and Patterson, the combination replaces Plante's cap with Patterson's inner and outer cylinders: "The combination of Plante and Patterson involves the simple substitution of one known element for another—Plante's cap for Patterson's cap—to yield predictable results."[302] But this substitution completely removes Plante's cap from the device, the only structure

[301] *Id.*,9.

[302] *Id.*, 65.

that Petitioner points to for the cap limitation.[303] With that removal, Grounds 3 and 4 are missing a required claim limitation.

For at least the reason that the combination of Plante and Patterson does not meet all the limitations of claim 1, Petitioner has failed to meet its burden that any claim is unpatentable under Grounds 3 and 4.

VII. GROUNDS 2 AND 4: THE PETITION DOES NOT SHOW THAT MAPLES MEETS PETITIONER'S CONSTRUCTION

Petitioner offers Ground 2 and Ground 4 to address its construction of "preserving a biological sample:"[304] "'preventing the cells from having their antigens degraded, such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome.'"[305] That construction includes two sub-parts: (1) preserving cells such that the cells' antigens are not degraded[306] and (2) preventing alterations in the cellular

[303] *Id*.

[304] Pet., 57-58, 81-82.

[305] *Id.,* 58 (*citing* Ex. 1001, 16:23-27).

[306] Ex. 2032, 15 ("DNA Genotek cannot carry its burden to show that the Accused Product preserves cells such that 'they can be purified or enriched.'"); *see also id.,* 16-17.

epigenome[307]. But when the Petition analyzes Maples for that claim construction, the Petition only addresses one part of the construction, preserving antigenicity of cells: "Maples states that a Solution A, which includes an ammonium citrate protease inhibitor, in combination with a solution B, which includes formaldehyde and a buffer, preserves the antigenicity of cells."[308] When Dr. Fischetti summarizes Petitioner's Maples argument, he highlights the deficiency: "In sum, the challenged claims would have been obvious if the preamble of claim 1 is limiting and construed in accordance with the definition in the '646 Patent specification, *i.e., preserving cells such that cells' antigens are not degraded*."[309] The Petition does not address the "preventing alterations in the cellular epigenome" requirement of its own construction.[310]

[307] *Id.*, 15 ("DNA Genotek cannot carry its burden to show that the Accused Product 'prevent[s] alterations in the cellular epigenome.'").

[308] *Id.,* 59 (*citing* Ex.1009, 31; Ex. 1001, 16:47-17:14; Ex.1011, 32).

[309] Ex. 1011, 37 (emphasis added).

[310] *See* Ex. 2032, 15-16 (arguing that the construction requires a preservative to chemically fix histones to DNA so that epigenome can be studied).

Since the Petition fails to show that Maples meets all the requirements of its own construction that predicate Grounds 2 and 4, Petitioner has failed to show that any claims are unpatentable in those grounds.

VIII. CONCLUSION

For the foregoing reasons, the challenged claims of the '646 Patent are patentable over all instituted grounds.

Date: May 9, 2023

By: /Desmond P. O'Sullivan/
Desmond P. O'Sullivan, Reg. No.: 67,576
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, CA 92130
Email: DOSullivan@mofo.com
Tel: (858) 314-7794

Attorney for Patent Owner

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

I hereby certify that this Patent Owner's Response has 13,458 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: May 9, 2023

By: /Desmond P. O'Sullivan /
Desmond P. O'Sullivan, Reg. No.: 67,576

CERTIFICATE OF SERVICE

I hereby certify that the attached Patent Owner's Response was served as of the below date via electronic mail by agreement to the following counsel of record for the Petitioner:

Joseph F. Jennings
2JFJ@knobbe.com
Ali S. Razai
2AZR@knobbe.com
Paul N. Conover
2PNC@knobbe.com
Benjamin B. Anger
2BBA@knobbe.com
Knobbe, Martens, Olson, & Bear, LLP
2040 Main St., 14th Floor
Irvine, CA 92614
BoxSpectrum4@knobbe.com

Dated: May 9, 2023

Respectfully submitted,

By: /Desmond P. O'Sullivan/
Desmond P. O'Sullivan, Reg. No.: 67,576