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On behalf of **Spectrum Solutions LLC**

By: Ali S. Razai (Reg. No. 60,771)
Joseph F. Jennings (Reg. No. 40,664)
Paul N. Conover (Reg. No. 44,087)
Benjamin J. Everton (Reg. No. 60,659)
Benjamin B. Anger (Reg. No. 62,207)
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel.: 949-760-0404 Fax: 949-760-9502
Email: BoxSpectrum8@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS LLC

Petitioner

v.

DNA GENOTEK INC.

Patent Owner

IPR2023-01424
Patent 11,536,632

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
REVISED NON-CONTINGENT MOTION TO AMEND**

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 11,536,632 to Biadillah, et al.
1002	Declaration of Karl R. Leinsing, MSME, PE
1003	U.S. Patent Pub. No. US 2012/0325721 to Plante, et al. (“Plante”)
1004	International Patent Publication No. WO 2005/051775 to Cho (“Cho”)
1005	Certified Translation of Japanese Patent Application Publication No. 2010-213660 to Ueda (“Ueda”)
1006	Japanese Patent Application Publication No. 2010-213660 to Ueda
1007	Claim Construction Order issued in <i>DNA Genotek Inc. v. Spectrum Solutions LLC</i> , C.A. No. 3:21-cv-0516 (S.D. Cal.) (Dkt. 177)
1008	Excerpts of Prosecution History of Application No. 17/510,003
1009	U.S. Patent No. 4,761,379 to Williams et al. (“Williams”)
1010	U.S. Patent Publication No. 2006/0260959 to Patterson, et al. (“Patterson”)
1011	Institution Decision for IPR2022-01347 (’646 Patent IPR)
1012	“Needle Stick Safety and Prevention Act” of Nov. 6, 2000, Public Law 106-430, 114 Stat. 1901
1013	Workbook for Designing, Implementing and Evaluating a Sharps Injury Prevention Program, Center for Disease Control and Prevention (2008) (“CDC Workbook”)
1014	Injection Molding Handbook, Ch. 8 (3d ed. 2000)
1015	The Complete Part Design Handbook For Injection Molding Of Thermoplastics, Ch. 10 (2006)
1016	Reserved

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1017	<i>Curriculum Vitae</i> of Karl R. Leinsing, MSME, PE
1018	U.S. Patent No. 4,589,548 to Fay (“Fay”)
1019	U.S. Patent No. 4,741,346 to Wong (“Wong”)
1020	U.S. Patent No. 3,518,164 to Adelin (“Adelin”)
1021	2024-01-17 PTAB Email - RE_ IPR2023-01424 - Request for Reply Briefing
1022	Declaration of Natalia Lehmann [SERVED ONLY]
1023	Printout of https://www.osha.gov/bloodborne-pathogens/evaluating-controlling-exposure [SERVED ONLY]
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1025	FIGS. 3A-3C (annotated) from U.S. Application No. 17/510,003
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1028	Definition of “Within,” <i>Merriam-Webster Collegiate Dictionary</i> (11th ed., 2004).
1029	Definition of “Within,” <i>Random House Unabridged Dictionary</i> (2d ed. 1993)
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1033	Deposition Transcript of Stephen Wereley, Ph.D. (September 10, 2024)
1034	Ex. 1022 of IPR2022-01347 – Deposition Transcript of Stephen Wereley, Ph.D. (July 19, 2023)

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1035	U.S. Patent Publication No. 2009/0216213 to Muir et al. (“Muir”)
1036	U.S. Patent Publication No. 2009/0212003 to Gudmundsson (“Gudmundsson”)
1037	Patent Owner Response in IPR2022-01347
1038	Ex. 2012 of IPR2022-01347 – Declaration of Michael Metzker, Ph.D.
1039	Ex. 2013 of IPR2022-01347 – Declaration of Steven Wereley, Ph.D.
1040	2024-12-09 Email from USPTO to Counsel re Revised Scheduling Order (Submitted at the Board’s Request)
1041	Declaration of Karl R. Leinsing, MSME, PE, in Support of Petitioner’s Opposition to Patent Owner’s Revised Non-Contingent Motion to Amend
1042	Saint Gobain Performance Plastics Brochure for Stopcock Valves (2001)
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1044	Final Written Decision in IPR2022-1347

I. INTRODUCTION

In its revised Motion to Amend (“rMTA”), Patent Owner (“PO”) amends claim 1 of the ’632 patent to eliminate one limitation of the claim and add others. PO alleges that these amendments make the substitute claims of the ’632 patent patentable over the prior art. *Id.*, 10-24. They do not.

As an initial matter, PO’s amendment impermissibly broadens the claims, violating the statutory and regulatory prohibition against claim broadening in a motion to amend. If a substitute claim is broader *in any respect*, the rMTA must be denied. Here, PO has broadened substitute claim 21 by removing the original claim requirement that the movable annular valve be in the aperture of the cap (referred to as the “second aperture” in the claim). PO’s failure to comply with the statutory and regulatory requirements for a motion to amend is dispositive and should end the inquiry.

Nonetheless, even considering PO’s claims against the prior art, they remain unpatentable as obvious over the combination of Plante and Cho. In arguing otherwise, PO attempts to distinguish Cho with a new limitation in substitute claim 21 that merely relates to the sizing of the movable annular valve. As Petitioner explained in response to the original motion to amend, it would have been obvious to size the valve depending on the amount of additive desired. The new amendment does not change this conclusion. The new claims remain obvious.

PO also argues against any motivation to combine Plante and Cho. Here, PO repeats arguments previously rejected by the Board in IPR2022-01347, where the Board held there was a motivation to combine Plante and Cho. Ex. 1044 (FWD finding claims of related '646 patent unpatentable). The arguments should be rejected here as well. PO also argues that one skilled in the art ("POSA") would lack an expectation of success in using an annular valve as disclosed in Cho in Plante's application, but this argument was also rejected when the Board previously held the related '646 patent was unpatentable.

PO separately argues substitute dependent claims 29, 33, and 36. These claims also would have been obvious over Plante and Cho, and claim 33 additionally fails to satisfy the written description requirement under 35 U.S.C. § 112.

II. THE REVISED MOTION TO AMEND SHOULD BE DENIED BECAUSE IT BROADENS THE CLAIMS

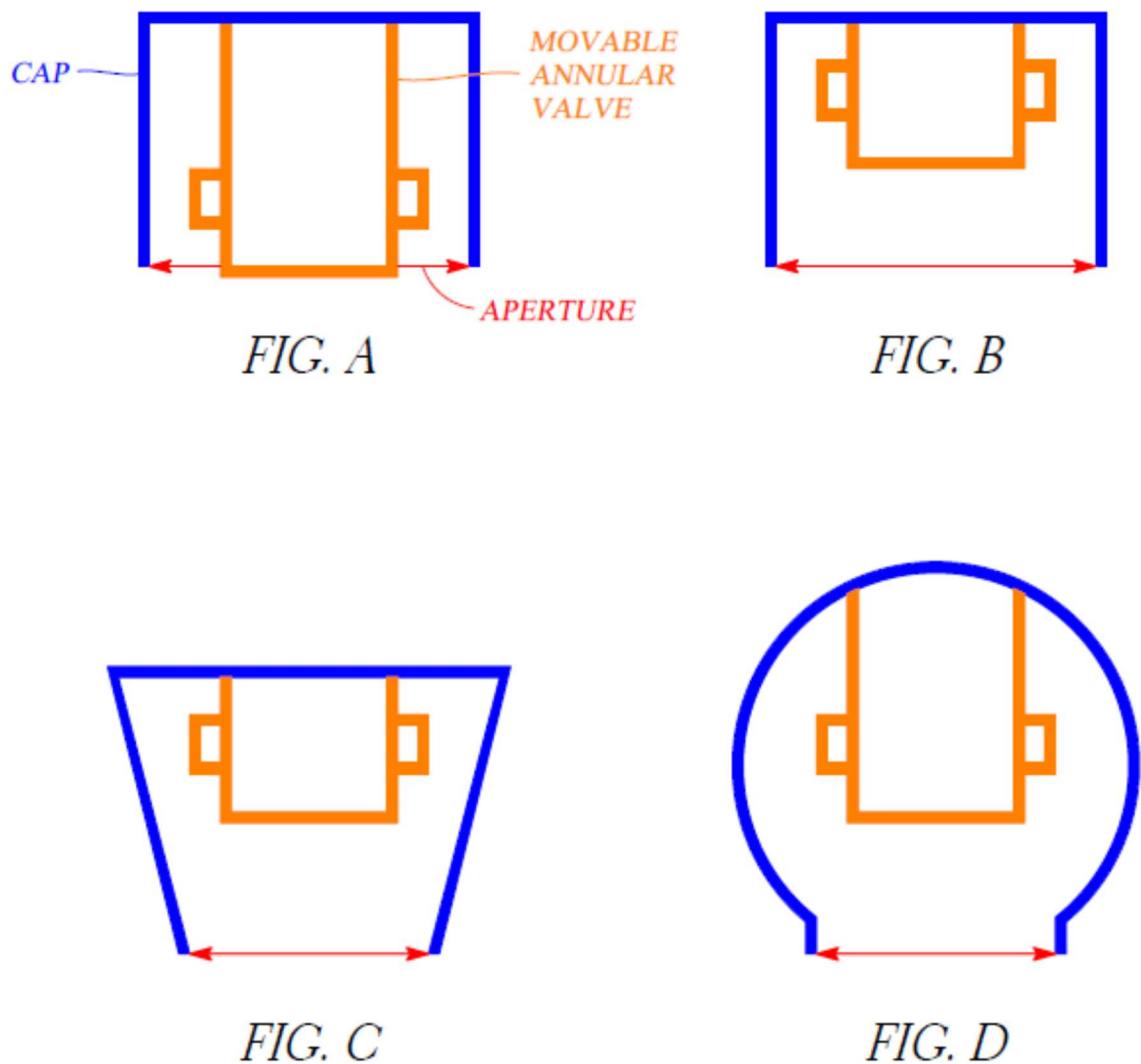
Patent Owner proposes amending the independent claim of the '632 patent to remove a claim limitation, namely that the movable annular valve is in the aperture of the cap (referred to as the "second aperture" in the claim). The relevant proposed amendment to substitute claim 21 provides: "a movable annular valve positioned in the second aperture~~interior volume of the cap~~, the movable annular valve comprising" Motion, 4, 27.

This broadening amendment violates the statutory and regulatory requirements for a motion to amend in IPRs. An amendment during an IPR "may

not enlarge the scope of the claims” 35 U.S.C. § 316 (d)(3); *see also* 37 C.F.R. § 42.121(2)(ii) (“a motion to amend may be denied where . . . [t]he amendment seeks to enlarge the scope of claims”). “If a substitute claim is broader *in any respect* it is considered to be broader than the original claim even though it may be narrower in other respects.” *Sisvel Int’l S.A. v. Sierra Wireless, Inc.*, 81 F.4th 1231, 1241 (Fed. Cir. 2023) (alterations and quotation marks omitted) (emphasis in original); *see also* 37 C.F.R. § 1.175(b) (“A claim is a broadened claim if the claim is broadened in any respect.”); *Pannu v. Storz Instruments, Inc.*, 258 F. 3d 1366, 1377 (Fed. Cir. 2001) (A “claim that does not include a limitation present in the original claims is broader in that respect.”).

As shown above, PO has broadened the claim by removing the “second aperture” limitation. With the proposed amendment, the substitute claims encompass a device not encompassed by the original claims. Specifically, the original claims required the movable annular valve to be in the aperture of the cap (the claimed “second aperture”), whereas the amended claims merely require the valve be positioned in the interior volume of the cap. This amendment broadens the claims because a movable annular valve can be positioned in the interior volume of the cap without being in the aperture of the cap. The examples below illustrate PO’s improper broadening. Fig. A shows a device with the movable annular valve in the aperture of the cap, as required by the original claims. On the other hand, Figs. B-

D depict devices where the movable annular valve *is not* in the aperture of the cap, but *is* in the interior volume of the cap, as required by the new amendment. Thus, the devices in Figs. B-D would be covered by the amended claims, but not covered by the original claims, confirming that the proposed amendment impermissibly broadened the original claims.



The Federal Circuit’s decision in *Sisvel* is directly on point. In affirming the Board’s denial of a motion to amend in an IPR, the Court emphasized that broadening a claim “*in any respect*” is not permitted. *Sisvel*, 81 F.4th at 1241. The Federal Circuit noted that the petitioner provided examples of how the proposed new claims encompassed embodiments not encompassed by the original claims. *Id.* at 1240 (describing the “helpful illustration” used to explain that “there could be embodiments that would come within the scope of substitute claim 36 but would not have infringed original claim 10.”). That is the case here, as illustrated above.

PO alleges that this claim amendment was “clarifying,” but fails provide any explanation of how the removal of the claim limitation was not broadening. Motion, 2. It is PO’s burden in seeking to amend a claim during the IPR to show that “the proposed amendment complies with relevant statutory and regulatory requirements.” *Id.* at 1238 (citing 37 C.F.R. § 42.121(d)(1)). PO has not and cannot meet that burden here. As explained above, the amendment removes a limitation and thereby broadens the claims.

In a different context, PO’s expert asserted that an aperture should be equated with an interior volume, e.g. the aperture of a cap would be the same as the interior volume of the cap. Ex. 2025, ¶ 33. The expert’s assertion is unsupported, and PO also never cites to it in connection with its burden to show the proposed claim amendments did not broaden the claims. Nonetheless, Petitioner addresses the

expert's erroneous assertion here. Specifically, the expert's unexplained assertion is contradicted by the patent and the plain meaning of the claim language. An aperture, consistent with its plain meaning, is the opening into a space, not the space itself. The claims define aperture in this way, reciting "a cap comprising an outer wall defining an open end of the cap, ... and an interior volume of the cap, *said open end defining a second aperture*" Motion, 3 (emphasis added). The aperture is defined by the open end and is distinguished from the interior volume. The patent specification uses the term in exactly this manner.¹ The specification refers to an aperture in the context of the reagent chamber. The aperture 22 is the opening in the inner wall 18. Ex. 1001, 14:24-27, Figs. 3A and 3B. The inner wall 18 defines an interior space 20. *Id.*, 14:20-22, Figs. 3A and 3B. The specification consistently distinguishes the interior space from the aperture that provides entry to the space. *Eg., id.*, 5:24-26, 6:14-17, 10:33-36.

The claim language and specification are consistent with the plain meaning of aperture. For example, the aperture of a camera is the opening that allows light to

¹ The Petition also consistently addressed the "second aperture" limitation in this manner, i.e. identifying the aperture as the opening. *See, e.g.*, Petition, 26, 27, 33.

enter a camera, not the space contained within the camera. *See, e.g.*, Exs 1031, 1032 and 2028. (dictionary definitions of aperture).

Because substitute independent claim 21 is improperly broadened, the dependent claims, which also do not include the limitation removed from original claim 1, are also improperly broadened.

In sum, because PO removed a limitation present in the original claims and thereby impermissibly broadened the claims in that respect, PO's motion should be denied.

III. THE SUBSTITUTE CLAIMS ARE UNPATENTABLE AS OBVIOUS

PO's amendments do not make the claims patentable. PO added a limitation that the first cylinder of the valve be positioned externally of the sample collection vessel in the closed and open configuration and relies on this limitation in arguing substitute claim 21 is patentable. Motion, 13. This new limitation relates to the sizing of the movable annular valve, which a POSA would know to adjust depending upon the amount of additive to be added. Ex. 1041, ¶¶ 10-12. It would have been obvious to modify the size of Cho's valve such that the first cylinder² is positioned

² Cho refers to what is claimed as the "first cylinder" in the '632 patent as the "additive storage container 120." For clarity Petitioner refers to it as the first and/or outer cylinder herein.

externally to the sample collection vessel, and a POSA would have had a reasonable expectation of success in doing so. Ex. 1041, ¶ 15.

As an initial matter, the movable annular valve of Cho is essentially identical to that described in the '632 patent. Ex. 1041, ¶¶ 7-9. In each, an inner cylinder³ defines a space for an additive and an outer cylinder or blocking member blocks an aperture in the inner cylinder. When the cap is added to a container, the outer cylinder abuts the upper rim of the container. As the cap is screwed onto the container, the outer cylinder recesses further into the cap. The movement of the outer cylinder relative to the inner cylinder unblocks the aperture and permits the release of the additive contained within the space defined by the inner cylinder. Ex. 1041, ¶ 9; *see also* Ex. 1002, ¶ 98.

PO's added limitation merely relates to a size distinction. The degree to which the outer, first cylinder of the movable annular valve of Cho would extend into the container or not would be determined by the amount of additive contained in the inner, second cylinder of the movable annular valve. Ex., 1041, ¶10. And the amount of additive determines the axial length of the inner, second cylinder. A

³ Cho refers to what is claimed as the "second cylinder" in the '632 patent as the "slider 636." For clarity Petitioner refers to it as the second and/or inner cylinder herein.

POSA would and could adjust these proportions as he or she saw fit. Ex. 1027, ¶¶23-25. This includes sizing the valve such that the outer, first cylinder does not extend into the container. Ex. 1041, ¶¶ 11-12, 15.

PO does not, and cannot, point to anything in the '632 patent that even mentions its added limitation, let alone describes it as an inventive feature. If it were an inventive feature, one would expect the inventors to have discussed its absence in the Background section when explaining the challenges with “currently available sample collection devices.” Ex. 2015, ¶¶14-15; Ex. 1041, ¶13. They did not. Similarly, one would expect the inventors to have discussed the concept in the “Summary of the Disclosure” along with the “features [that] may be provided with a sample collection device.” Ex. 2015, ¶21; Ex. 1041, ¶ 13. Again, they did not. The specification never describes the concept at all, and certainly never as an inventive feature. Ex. 1027, ¶¶23-25. This is true whether the size of the movable annular valve is expressed as entirely within the cap or external to the container (as per the revised motion). Ex. 1041, ¶ 15. There would be no unexpected results when sizing the annular valve for a smaller amount of additive such that the outer, first cylinder would not extend into the container. It is a simple design choice well within the skill of a POSA. Ex. 1041, ¶¶ 15-16.

Moreover, in multiple embodiments of the '632 patent the “blocking member,” what the patent specification calls the element that blocks the aperture of

the interior space containing the additive, does extend into the sample collection vessel. Ex. 1001, Figs. 1A, 2A, 4A, 5A; Ex. 1041, ¶ 14. Thus, the '632 patent does not suggest maintaining the blocking member external to the container adds any patentable significance to the claimed invention.

A. A POSA Would Have Been Motivated to Modify Cho Such that the First Cylinder Remains External to the Sample Collection Vessel⁴

A POSA also would have been motivated for several reasons to modify Cho's cap to size the valve such that the outer, first cylinder did not extend into the sample collection vessel. PO's initial amendment purported to recite the size of the annular valve in the context of whether it was contained within the cap. PO's new amendment recites the size in relation to whether the outer, first cylinder is external to the sample collection vessel in both the closed and open configuration. These amendments address the same concept (size) in different language.

As Petitioner explained in response to the original motion, there were multiple reasons a POSA would have been motivated to modify Cho's cap to maintain the annular valve within the cap. These reasons also apply to the new amended claim language. Ex. 1041, ¶ 11.

⁴ PO also argues against the rationales for any combination of Cho and Plante, an issue previously decided against PO. PO's arguments against the combination per se are addressed in Section III, C, *infra*.

First, as Petitioner explained in response to the original motion, a POSA would have been motivated to modify Cho's cap to reduce the potential risk of sample contamination when, for example, the device is handled by an unskilled user. Ex. 1027, ¶¶26-30. PO has acknowledged this motivation. In the IPR for the related '646 patent, PO asserted that the size of Cho's cap increased the risk of sample contamination. Ex. 1037, 61. According to PO, the risk was caused by Cho's first and second cylinders extending beyond the opening of the cap, making it more likely a user would touch the valve. *Id.*, 64-65. PO submitted declarations by Dr. Wereley and Dr. Metzker to support these arguments. *See, e.g.*, Ex.1038, ¶19_ and Ex.1039, 90-100. Dr. Wereley now makes these same points here. Ex. 2014, ¶71.

In the '646 patent IPR, PO contrasted Cho's potential for contamination with Plante's low-profile design that minimizes the risk of contamination:

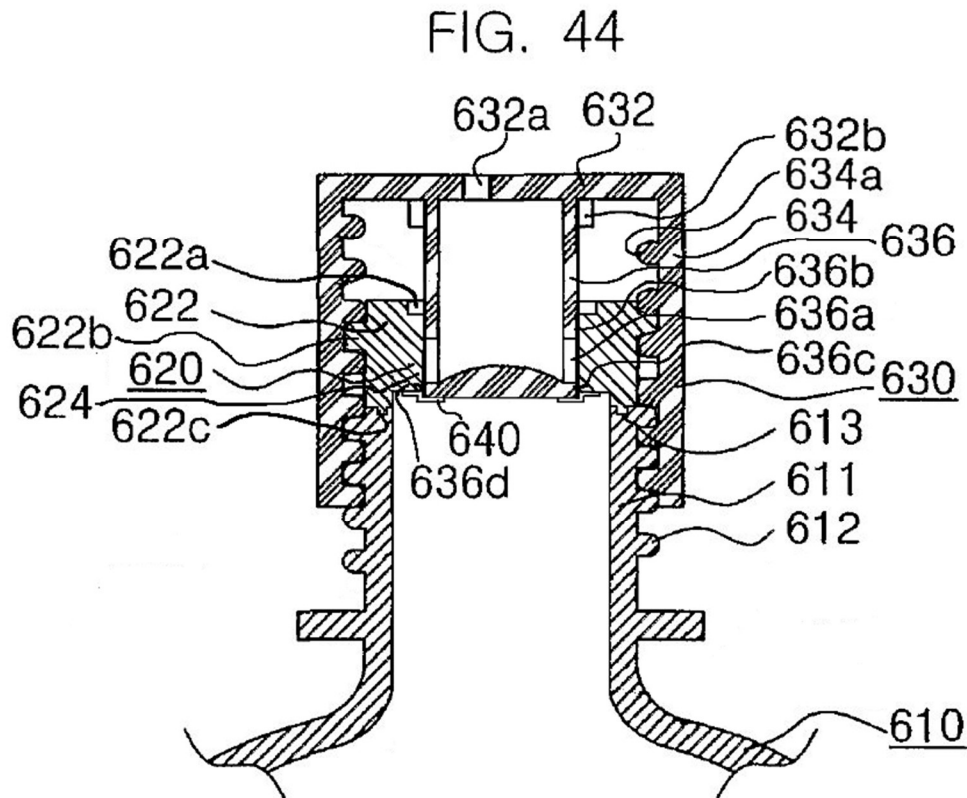
Plante's cap provides minimal risk of contamination....Plante's reservoir protrudes slightly beyond Plante's cap. This significantly reduces the risk that someone would touch the reservoir film, which could render the sample defective.

Ex.1037, 63-64, citing Ex.1039, 90-100; accord Ex. 2014, ¶70.

Recognizing the risk of contamination with a valve extending out of a cap, a POSA would have been motivated to modify Cho's moveable annular valve by having the valve fully recessed in the cap. Ex. 1027, ¶¶29-30. This same rationale

holds true for PO's new sizing limitation. It is a simple design choice to size the valve, and well within the skill of a POSA as described above. Ex. 1041, ¶ 15.

Second, as Petitioner pointed out in response to the original motion, a POSA would have recognized there are only two options for placement of the moveable annular valve in the cap—either extending into or below the opening of the cap, or housed entirely within the cap. Ex. 1027, ¶31. Thus, with a finite number of identified, predictable solutions—and Cho already disclosing one solution—it would have been obvious to try, with a reasonable expectation of success, positioning Cho's first and second cylinders entirely within the boundaries of the outer wall of the cap. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). This same rationale holds true for PO's new amendment. Based on the amount of additive to be used and thus the axial length of the inner, second cylinder, a POSA would recognize the aperture in the inner, second cylinder would be placed either above or below where the outer, first cylinder abuts the container. Ex. 1041, ¶ 15. With a lesser amount of additive, the inner cylinder would have a shorter axial length and the aperture would be above where the outer cylinder abuts the container. In this case, the outer cylinder would not extend into the container in either the closed or open configuration as depicted below.



Ex. 1041, ¶¶ 11-12.

Third, a POSA would have been motivated by design choices to modify Cho's cap to include the first and second cylinders entirely within the boundaries of the outer wall of the cap. Ex. 1027, ¶¶ 32-34. These design choices include, as described above, the amount of additive added to the cap and also the width of the bottle neck and the reservoir in the cap. When the design calls for a smaller quantity of additive in the cap, as described above, a POSA would be motivated to reduce the vertical length of the reagent chamber in Cho's cap. Ex. 1041, ¶ 15. This would satisfy PO's amended claim language as depicted above. Ex. 1041, ¶¶ 11-12.

The above motivations addressed PO's initial amendment language, which described the sizing issue with respect to the cap. PO's new amendment goes to the same issue, but describes the degree of size adjustment in relation to the outer, first cylinder and the container. Because a POSA would have recognized that different applications call for different volumes of additive, it would have been obvious to size the inner cylinder such that the outer, first cylinder would not extend into the container. The outer cylinder in Cho functions by abutting the upper edge of the container rim. This is the same as in the '632 patent. It then recesses into the cap as the cap is screwed onto the container. The outer cylinder extends down into the container as a function of the volume of additive/size of the inner cylinder. In cases where less additive is necessary, a POSA would recognize that the axial length of the inner cylinder would be adjusted accordingly and the aperture would and could be placed above where the outer cylinder abuts the container. Such a sizing adjustment would not affect functionality and would have been a simple design alternative obvious to a POSA. Ex. 1041, ¶ 15.

The Board has recognized that optimizing sizes of known elements is within the level of skill in the art. *Ex Parte Martin Uram*, No. APPEAL 2017-002323, 2018 WL 799041 (P.T.A.B. Jan. 8, 2018) (affirming rejection of claims where "it would have been obvious to optimize the sizes of claimed individual components"). The movable annular valve of the '646 patent was a known element in view of the

essentially identical valve in Cho. Ex. 1041, ¶¶ 7-9. Further, “it has generally been held that changes in sizes and shapes of known elements are within the level of skill in the art, especially in the absence of unexpected results of critically.” *Id. citing Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 1349 (Fed. Cir. 1984) (holding that, where the only difference between the prior art and the claims was a recitation of relative dimensions, the claimed device was not patentably distinct from the prior art device); *see also In re Dailey*, 357 F.2d 669, 672-673 (CCPA 1966) (change in shape ordinarily prima facie obvious); *see also In re Kirke*, 40 F.2d 765, 767 (CCPA 1930) (“Obviously, as a general proposition, there is nothing patentable in making a machine or apparatus larger or smaller, if it produces the same result in the same manner.”). That is also the case here – the Cho movable annular valve produces the same result regardless of its size. Ex. 1041, ¶ 15.

B. PO’s Arguments Against the Rationales for Adjusting the Size of Cho’s Annular Valve Should be Rejected

PO argues that rather than sizing the annular valve to reduce risk of contamination or choosing an annular valve recessed within a cap, a POSA would choose not to combine Cho with Plante at all. Motion, 22-23. This ignores the rationales for combining Cho in the first place, namely (1) reducing the risk of injury by removing sharps as dictated by design directives, (2) avoiding the need to mold a long, sharply, pointed knife, (3) providing a seal before the valve is opened to

release a reagent, and (4) the simple substitution of one known element for another. Pet., 14-17; Ex. 1002, ¶¶ 62-75.

PO next argues that adjusting the size of the annular valve to account for different amounts of additive would “require extensive and costly redesign.” Motion, 23. This is unsupported hyperbole. Adjusting the size of the valve would be simple and well within the skill in the art. Adjusting the size also would not impact the operation of Cho’s valve. Ex. 1041, ¶ 15. Dr. Wereley’s assertions to the contrary are beyond overstated and also never connected to anything specific about adjusting the size. *See* Ex. 1041, ¶¶ 26-27. Moreover, molding Cho’s annular valve cap would require three basic molds. Ex. 1041, ¶¶ 18-25. This would be true both for a larger additive volume as depicted in Cho and for a lesser volume wherein the outer, first cylinder would be positioned externally of the container. *Id.*

C. A POSA Would Have Had a Reasonable Expectation of Success in Modifying Cho Such that the First Cylinder Remains External to the Sample Collection Vessel

A POSA would have reasonably expected success in modifying the dimensions of Cho’s annular valve. A POSA would have understood that Cho’s size and volume could be modified based on the intended use of the device. Ex. 1027, ¶¶ 35-40. A POSA would have recognized this included sizing the valve such that the outer cylinder did not extend into the container. Ex. 1041, ¶¶ 15, 24-25.

As Petitioner pointed out, Dr. Wereley agreed. He testified in the '646 patent IPR that a POSA would recognize that Cho's size and volume could be changed based on need. Ex. 1034, 35:10-19 (“[O]ne of skill in the art would recognize that the additive storage container, the size or the volume of the additive storage container could be changed to accommodate some operation...”); *id.*, 35:21-36:14, 38:1-7. He further testified that the volume of the additive storage container could be adjusted by adjusting the axial length of Cho's first and second cylinders (making up the “additive storage container”). *Id.*, 69:13-70:9 (“[A] POSA in 2012 would realize that the axial length of the additive compartment could be changed to some extent” and “[c]hanging the length of the cylinder...would necessarily change its volume.”).

Dr. Wereley and PO attempt to walk back these admissions. Motion, 19-20. But they cannot change the unsurprising admissions. He plainly admitted a POSA would know the size/volume of the Cho valve could be adjusted by adjusting its axial length. And the admissions directly contradict his new assertions that such adjustments would be too difficult. And any argument that a POSA would not be motivated to do so, knowing, of course, that different applications would call for different amounts of additive, is not credible.

Moreover, the prior art demonstrates a POSA understood that the dimensions in a lid containing additives would and could be modified depending on a particular

application. Cho teaches that the invention permits mixing two materials in precise ratios (Ex. 1004, Abstract, 1:25-27), which informs a POSA (as they would know) that the volumes of the additive compartment in the cap could be adjusted for a particular application. Furthermore, it was known generally that the size and shape of caps containing additives could be adjusted based on the amount of additive and intended use. *See, e.g.*, Ex. 1035, ¶52 (“shape and size” of the lid’s vertical wall “is dependent upon the intended use of the container system.”), ¶51 (“Lid 100 and reservoir 102 can be sized to accommodate a range of volumes of a substance.”); Ex. 1036, ¶¶2, 26 (describing uses of cap dispensing system, including “medicine or other chemicals,” and disclosing that “[a] person skilled in the art realizes that the exact form and size of the closure and its different parts may be varied due to the form and size of the container and the additive.”); Ex. 1027, ¶¶37-39.

Finally, the ‘632 patent discloses that “[t]he dimensions of the device can be modified to suit the specific processing the sample will be subjected to[,]” Ex. 2015, ¶66, but the patent provides no teaching of how to make any such modifications. Of course, that is because the inventors recognized it was within the skill in the art. PO cannot now claim adjusting the dimensions in a device that functions identically to its claimed annular valve is somehow patentably distinguishable. *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1341 (Fed. Cir. 2006) (explaining that the patent demonstrates that alleged invention was within scope of the ordinary skill in

the art, “and it does so not by what [the patent] discloses but by what it *does not* disclose.”) (emphasis in original); *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994); *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1381 (Fed. Cir. 2013).

In sum, a POSA would have had a reasonable expectation of success in modifying the dimensions of Cho’s cap to adjust the size of the additive container such that the outer cylinder did not extend into the container. Ex. 1041, ¶¶ 11-12, 15, 24-25; *see also* Ex. 1027, ¶¶ 35-40.

D. A POSA Would Have Been Motivated to Combine Cho and Plante and PO’s Contrary Arguments Should be Rejected

In attempting to evade the obviousness of its further amended claims, PO again argues against the basic premise of whether there is any motivation to combine Cho with Plante at all. The arguments are not particular to the ’632 patent claims or the specific amendments added in the rMTA. Rather, the arguments mostly repeat arguments rejected by the Board when it determined the related ’646 patent was unpatentable in view of Cho combined with Plante. Ex. 1044, 34-42.

PO argues Cho is addressing a different need, and therefore there would be no reason to combine. Motion, 16-17. As Petitioner explained, however, Plante and Cho are each in the same field of endeavor of the ’632 patent and address the same need or problem. Pet., 14-15; Ex. 1002, ¶¶ 63-65. Furthermore, the FWD rejected this same argument, which Petitioner labelled a non-analogous argument art, in the prior IPR. Ex. 1044, 35-40.

PO argues a POSA would not recognize Plante's sharply pointed knife presented a safety risk and therefore would not provide a reason to combine. Motion, 17-18. As Petitioner explained, however, safety design incentives would have motivated a POSA to replace Plante's approach of using a sharp knife in the vessel, which pointed at the opening into which the saliva sample was delivered, with Cho's safer design using an annular valve in the cap. Pet., 15; Ex. 1002, 67-70. Furthermore, the FWD held that eliminating the sharp component in Plante provided a rational reason to modify Plante with Cho's annular valve. Ex. 1044, 40-42.

PO argues a POSA would not recognize any molding reasons to avoid Plante's long, sharply pointed knife. Motion, 18-19. PO argues this based on a comparison with Cho, which it alleges has "22 sharp features." *Id.*, 19. That is a mistaken comparison – the issue with Plante was its long, sharp point, not merely a "sharp" corner.⁵

PO argues there would be "no *a priori* guarantee of success," in using an annular valve as in Cho and modifying its size. Motion, 19. Initially, PO's

⁵ The Board found it unnecessary to address this additional rationale for combining Plante and Cho given its finding that there was a sufficient rationale on other grounds. FWD, 42. Nonetheless, this remains a valid and sufficient reason to combine, even if unnecessary in view of other rationales.

arguments go to use of an annular valve as taught by Cho and do not address anything specific as to adjusting the size. Second, PO errs when it seeks to require a “guarantee of success.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (“the expectation of success need only be reasonable, not absolute”). Regardless, adjusting the size of the annular valve was a simple design choice within the skill in the art. Ex. 1041, ¶ 15.

Finally, although PO repeats most of its rejected arguments against combining Plante and Cho, it fails to address an additional rationale Petitioner provided here. Specifically, a POSA would have understood that using an annular valve like Cho’s instead of Plante’s knife design would allow the cap to be sealed onto the vessel before the valve is opened. Pet., 16; Ex. 1002, ¶73. This provides yet another motivation to combine Plante and Cho.

E. The Substitute Dependent Claims Are Also Unpatentable for Obviousness

PO separately argues three dependent claims. They add nothing to make the invention patentable and are each unpatentable for obviousness as described in the Petition and below.

1. Substitute Dependent Claim 29 Would Have Been Obvious

Substitute dependent claim 29 adds that the first and second cylinders “are relatively moveable entirely within the interior volume of the cap” to change from the closed to open configuration. Motion, 14, 30. The claim is obvious over Plante

and Cho because, as described above, adjusting the size of the movable annular valve and inner/outer cylinders would have been obvious. Based upon such obvious size adjustments the first and second cylinders would be relatively moveable entirely within the interior volume of the cap. Ex. 1041, ¶ 29.

2. Substitute Dependent Claim 33 Would Have Been Obvious

Substitute dependent claim 33 adds “a flange extending from at least one of the first and second cylinders” and “wherein initial contact between the flange and a portion of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration[.]” Motion, 14-15, 31. As described below, the claim does not have written description support for several reasons. One reason is that *initial contact* between the flange of the blocking member (the claimed first cylinder) and the sample collection vessel of the disclosed embodiment of the ’632 patent does not cause the annular valve to change from the closed configuration to the open configuration. Ex. 1041, ¶32. To the extent the claim had support, however, the Cho movable annular valve functions the same as the ’632 patent embodiment that provides the alleged written description support. Ex. 1041, ¶ 34. Specifically, after the outer, first cylinder contacts the container in both the ’632 patent and Cho, the cap is then screwed further down to cause the outer, first cylinder to recess into the cap. This ultimately causes the annular valve to change from the closed

configuration to the open configuration. Thus, to the extent claim 33 had written description support, the claim would have been obvious. *Id.*

3. Substitute Dependent Claim 36 Would Have Been Obvious

Substitute dependent claim 36 is identical to original claim 16 (subject to the amendments to claim 1). The claim is obvious over Plante and Cho for the reasons described in the Petition. Pet., 61-62, Ex. 1002, ¶¶ 156-159; Ex. 1041, ¶ 35. PO's argument to the contrary ignores that the combination of using Cho's annular valve in Plante's application renders the claim obvious. PO again erroneously attempts to limit Cho to a beverage application.

IV. SUBSTITUTE DEPENDENT CLAIM 33 LACKS WRITTEN DESCRIPTION SUPPORT

PO bears the burden to show that the amended claims do not introduce new matter and satisfy the written description requirement. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 41.121(a)(2)(ii).

Substitute claim 33 recites, *inter alia*, “a flange extending from at least one of the first and second cylinders” and “wherein initial contact between the flange and a portion of the sample collection vessel upon engagement of the cap to the sample collection vessel causes the annular valve to change from the closed configuration to the open configuration[.]” Motion, 31. The patent specification does not describe an embodiment of the invention having a flange on the inner cylinder. Ex. 1041, ¶ 31. It also does not describe that “*initial contact* between the flange and a portion

of the sample collection vessel ... *causes* the annular valve to change from” the closed to open configuration. Ex. 1041, ¶¶ 31-32.

In the disclosed embodiment that supposedly supports the ’632 patent claims, initial contact with the flange of the first cylinder does not cause the valve to change from closed to open. The cap must be rotated after initial contact. This causes the outer cylinder to rotate relative to the inner cylinder. And only after the outer cylinder has been rotated or screwed up the inner cylinder sufficient to pass the aperture, does the valve change from closed to open. Ex. 1041, ¶¶ 9, 32.

PO makes a conclusory assertion the claim is supported, but the materials PO cites for support do not provide support. Motion, 5, 10-11. PO’s expert does not even address the “initial contact ...causes” requirement. Ex. 2025, ¶ 37. PO also erroneously cites to what it refers as “Claim 13 as originally filed.” Motion, 5 (citing Ex. 2022). This claim was not “originally filed,” but is a claim added in the continuation filed in in 2021, many years after the actual original priority date. In *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) (“For a claim in a later-filed application to be entitled to the filing date of an earlier application under 35 U.S.C. § 120 (1994), the earlier application must comply with the written description requirement of 35 U.S.C. § 112, ¶ 1 (1994)”). Because the parent application does not disclose a flange extending from the second cylinder, amended claim 33 is not

entitled to priority to that application, and does not have written description support for this additional reason.

V. CONCLUSION

For the reasons set forth above, the substitute claims are unpatentable and the motion to amend should be denied.

Dated: December 13, 2024

By: /Benjamin B. Anger/

Ali S. Razai (Reg. No. 60,771)

Joseph F. Jennings (Reg. No. 40,664)

Paul N. Conover (Reg. No. 44,087)

Benjamin J. Everton (Reg. No. 60,659)

Benjamin B. Anger (Reg. No. 62,207)

KNOBBE MARTENS OLSON & BEAR, LLP

CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e) and with the agreement of counsel for Patent Owner, a true and correct copy of **PETITIONER'S OPPOSITION TO PATENT OWNER'S REVISED NON-CONTINGENT MOTION TO AMEND** is being served electronically on December 13, 2024, to the e-mail addresses shown below:

Brian M. Kramer BMKramer@mofo.com Drew Alan Hillier DHillier@mofo.com MORRISON & FOERSTER LLP 12531 High Bluff Drive Suite 100 San Diego, CA 92130	Mehran Arjomand MArjomand@mofo.com Alex S. Yap AYap@mofo.com MORRISON & FOERSTER LLP 707 Wilshire Blvd. Suite 6000 Los Angeles, CA 90017
DNAGSpectrum@mofo.com	

Dated: December 13, 2024

By: /Benjamin B. Anger/

Ali S. Razai (Reg. No. 60,771)
Joseph F. Jennings (Reg. No. 40,664)
Paul N. Conover (Reg. No. 44,087)
Benjamin J. Everton (Reg. No. 60,659)
Benjamin B. Anger (Reg. No. 62,207)
KNOBBE MARTENS OLSON & BEAR, LLP

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