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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 SUR-REPLY TO PATENT OWNER'S
REVISED NON-CONTINGENT MOTION TO AMEND**

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OTHER AUTHORITIES

35 U.S.C. § 316	1
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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

Exhibit No.	Description
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
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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)
1030	Definition of “Within,” <i>American Heritage Dictionary</i> (4th ed. 2000)
1031	Definition of “Aperture,” printout of https://www.dictionary.com/browse/aperture
1032	Definition of “Aperture,” printout of https://dictionary.cambridge.org/us/dictionary/english/aperture
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)

Exhibit No.	Description
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)
1043	U.S. Patent No. 5,578,016 issued November 26, 1996 to Zinger, et al. titled “Stopcock”
1044	Final Written Decision in IPR2022-1347
1045	Saint Gobain Performance Plastics Brochure for Stopcock Valves (2001)

I. PATENT OWNER IMPERMISSIBLY BROADENS CLAIM 21

In its revised Motion to Amend (“rMTA”), Patent Owner (“PO”) amends claim 21 to provide: “a movable annular valve positioned in the ~~second aperture~~interior volume of the cap, ...” Motion, 4, 27. By deleting the requirement that the valve is “in the second aperture” the amendment broadens the claim in violation of the statutory requirements for a motion to amend. 35 U.S.C. § 316(d)(3). PO ignores the clear precedent that 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).

PO argues its amendment “is merely clarifying” because an aperture should be defined as a “hole” and a hole is “an open space having a volume.” Reply, 1 (citing its expert’s unexplained assertion that an aperture is “open space” (Ex. 2025, ¶ 33)). But referring to an aperture as a hole does not somehow mean the aperture is the volume of space to which it leads. For example, as Petitioner explained, an aperture of a camera is the opening that allows light to enter a camera, not the space contained within the camera. Indeed, PO’s expert, in deposition testimony cited by PO, acknowledges the distinction between the camera aperture and the interior space of the camera. Reply, 2, citing Ex. 1033, 44:16-18 (aperture is the hole that lets light into a camera to an imaging element within the camera). The distinction is similarly

illustrated with a hole in the ground. For example, Elmer Fudd could see Bugs Bunny when Bugs was in the aperture of his hole in the ground, but then not see Bugs if he was not in the aperture but within his den, i.e. the space to which the aperture led.

PO argues that Petitioner's "entire argument is premised on reading aperture as an infinitely thin, planar feature," which it argues is contrary to dictionaries. Reply, 1. Not so. PO's broadening of the claim is evident from the plain meaning of aperture as the opening into a space, not the space itself. And the claim language, consistent with this plain meaning, makes the distinction crystal clear: "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 the open end and not the interior volume. The patent specification is consistent. Paper 32 ("Opp."), 6.

PO's amendment plainly 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. Petitioner's Opposition illustrated 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 amended claims. Opp., 4 (Figs B-D). These devices would be covered by the amended claims, but not covered by the original claims. PO has not and cannot refute this.

PO's argues Figure 3B of the '632 patent "would cover" Petitioner's Figure B-D devices because Petitioner previously explained how the valve in Figure 3B was drawn inconsistently with Figure 3A and was recessed within the cap. Reply, 2. PO utterly fails to explain how this point supports its position. It does not. The fact that the valve in Figure 3B is drawn such that it is not in the aperture of the cap, does not change the fact that the original claims required the valve to be in the aperture of the cap and PO removed that requirement in its amendment.

In sum, PO removed a limitation present in the original claims - "a movable annular valve *in the second aperture*." The amendments impermissibly broadened the claims in that respect. Thus, PO's motion should be denied.

II. THE SUBSTITUTE CLAIMS WOULD HAVE BEEN OBVIOUS

A. PO's Amended Sizing Limitation Does Not Make Claim 21 Inventive

PO asserts that the system of claim 21 has advantages, namely minimal parts and limited risk of contamination because the valve opens upon attachment of the cap to the sample collection vessel. Reply, 3.¹ But these asserted advantages do not relate to the claim limitation that purports to distinguish the amended claims from

¹ PO's Reply ignores the '646 patent's acknowledgment about the advantage of avoiding sharp objects, Ex. 1011, 5:5-6, because that acknowledgement obviously contradicts PO's attempt to avoid the motivation to combine Cho with Plante.

the combination of Plante and Cho. PO's new limitation merely 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. As the Board recognized in finding the related '646 patent unpatentable:

Precedent has long held that the person having ordinary skill in the art must be regarded as skillful and ordinarily creative, not as a mere literalistic automaton. [citations omitted] A person having ordinary skill in the art would have understood how to size, scale, and otherwise form the sample collection kit taught by Plante using Cho's cap

Ex. 1044, 43.

PO cites to a portion of the specification that states “[i]n some embodiments, use of the sample collection devices provide improved safety for both the sample donor and the end user, since, for example, sharp objects are not included and there is limited to no risk of exposure to toxic solutions.” Ex. 1001, 5:3-8. But this does not relate to the amended claims that recite positioning the first cylinder of the valve external the sample collection vessel. The specification never describes the valve sizing concept at all, and certainly never as an inventive feature. Ex. 1027, ¶¶ 23-25; Ex. 1041, ¶¶ 13-14. And it does not distinguish Cho. Pet., 16; Ex. 1002, ¶¶ 73.

Moreover, the '632 patent specification includes embodiments depicting the “blocking member,” what the patent specification calls the element that blocks the aperture of the interior space containing the additive, extending into the sample

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

PO's reference to minimal parts, Reply, 3 (citing Ex. 1001, 4:64-65), relates to the number of parts the user must manipulate to use the product (i.e., the cap and tube) not the number of parts required to manufacture the cap. *See* Ex. 1001, 4:31-32 (prior device required exchanging cap prior to sending sample to end user). This purported advantage of minimal parts also does not distinguish the amended claims from the combination of Plante and Cho, which merely require a cap and collection vessel, with no need for any later exchange of the cap.

B. Cho's Valve Is Essentially Identical To The Claimed Valve

Cho's valve includes the same basic parts as the claimed valve and functions in the same way. Ex. 1041, ¶¶ 7-10. A POSITA could have easily sized Cho's annular valve to be positioned externally to the sample collection vessel in the closed and open configurations. *Id.* at ¶¶ 11-12. Instead of addressing this simple modification, PO's Reply focuses on irrelevant differences between Cho and the embodiments of the '632 patent.

PO asserts that Cho is "directed to a beverage bottle designed to ship a beverage with a separately stored additive." Reply, 4. PO further argues that Cho's cap involves a "two-step cap attachment process," whereas the cap of the '632 patent

is “shipped separately” and attached in a single step. (emphasis omitted) *Id.*, 5. PO fails to explain how its characterization of Cho renders the amended claims non-obvious. Moreover, PO’s characterizations are incorrect. Cho is not limited to beverage applications. Both Cho’s and the ’632 patent’s caps involve a two-step process: (1) attaching the cap to the container and (2) further rotating the cap to open the valve. Ex. 1041, ¶¶ 7-10. The amended claims say nothing about the timing of these steps or the configuration in which the container and cap are shipped. In using Cho’s valve in Plante’s application, it would have been obvious to do so in the same manner as the ’632 patent device. Pet., 62; Ex. 1002, ¶¶ 156-159.

PO also points to Cho’s ratchet features that help direct the rotation of the cylinders and cap. Reply, 6. PO argues that the claimed invention does not have such ratchets, without any explanation of why this is relevant to the claim or obviousness. *Id.* The lack of relevant differences between the two valves confirms that Cho’s valve is essentially identical and functions identically to the claimed invention. Opp., 8, 14.

C. It Would Have Been Obvious To Resize Cho’s Annular Valve

It would have been obvious to modify the size of Cho’s valve such that the first cylinder is positioned externally to the sample collection vessel, and a POSA would have had a reasonable expectation of success in doing so. Ex. 1041, ¶ 15. The degree to which the first and second cylinders 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. *Id.*, ¶10. A POSA would and could adjust these proportions such that the outer, first cylinder does not extend into the container. *Id.*, ¶¶ 11-12, 15.

PO argues that “Petitioner has completely modified Cho to try to address the recitations of current claim 21,” calling the modification a “*structural redesign* of Cho.” Reply, 6 (emphasis in original). PO emphasizes the number of potential individual modifications and attempts to enlarge their significance. But these exaggerations are unsupported. At their core, PO’s listed modifications are mere size changes to Cho’s valve parts and cap. According to PO, the proposed modification of Cho’s valve “modified the length of slider 636,” “enlarged the vertical dimensions of cap 634,” enlarged “circular end plate 622,” and “modified bursting film 640” to accommodate for the size changes. Reply, 6-7.² PO’s identified modifications confirm that Cho’s valve would only require size adjustments without any new parts, supporting the obviousness ground. Ex. 1041, ¶¶11-16.

² PO incorrectly asserts that the modification eliminates inner cap 624, which remains in both the unmodified and modified valves. Ex. 1041, ¶¶ 11-12.

There were multiple reasons a POSA would have been motivated to reduce the size of Cho's valve so that the first cylinder does not extend into the container. Ex. 1041, ¶¶ 11, 15. PO unsuccessfully attempts to rebut these motivations. First, PO argues that modifying Cho's valve would have required "confronting challenging molding and manufacturing/assembly issues." Reply, 8. But PO fails to explain or show why Cho's modified valve would be more difficult to mold and manufacture than Cho's unmodified valve. Wereley's testimony regarding molding long, thin parts and sharp corners does not differentiate between Cho's unmodified valve and the modified valve. Ex. 2025, ¶¶ 66-85.

Moreover, Wereley testified that a POSA would recognize that Cho's size and volume could be changed based on need. Ex. 1034, 35:10-19, 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. *Id.*, 69:13-70:9. Dr. Wereley's previous testimony directly contradicts his new opinions that Cho could *not* be modified because of supposed difficulties of molding Cho's valve. This undermines any argument that a POSA would not be motivated to use Cho's valve and adjust its size for a desired amount of additive.

PO arguments go to details of manufacturing commercial products, which details are not disclosed in the '632 patent, not beyond the level of skill in the art, Ex. 1041, ¶¶ 15-27, and not the purpose of patent specifications. *Application of Gay*,

309 F.2d 769, 774 (C.C.P.A. 1962) (patent specifications are not intended to be production specifications).

For example, PO argues the basic molds proposed in response to PO's initial critique comprise multiple parts. Reply, 8. But all injection molds require multiple parts. PO also argues Cho's ratchet features would interfere with the molding process. Reply, 9. But ratchet teeth are common features that have been used on medicine bottles, milk bottles, soda bottles, etc. Ex. 1041, ¶ 27. And PO's critique about molding the ratchets and using a core pin (1) again, goes to manufacturing details not required for obviousness nor are they beyond the level of skill, and (2) could be addressed by molding the ratchet with the same pitch as the unwinding core pin. And Cho's tolerances also are no different from well known types of bottles and a POSA would readily know how to design interference fits that provided a sealed arrangement using ratchet teeth as necessary. *Id.*

Second, PO argues that the "molding challenges associated with Cho's redesign are not commensurate with a POSITA's level of skill." Reply, 9. According to Wereley, a POSITA's level of skill is exceeded given the smaller parts and tighter tolerances, and mold design engineers are highly trained with extensive experience. Ex. 2030, ¶ 61. But Wereley's statements about difficulties in the molding process that exceed the level of skill are not supported. *Id.* Instead, Wereley uses phrases such as "I believe that" and "I don't think" without any

evidence to support his conjecture. *Id.* In contrast, Leinsing provided specific details and evidence showing how a POSITA would have molded the different parts of the modified and non-modified Cho valves. Ex. 1041, ¶¶ 17-26. PO also ignores the established precedents 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 or critically. Opp., ¶¶ 14-15 (citing authorities).

Third, PO repeats its previous argument that a POSITA would not be motivated to substitute Cho's valve for Plante's approach because of the associated costs. Reply, 10. But PO and Wereley fail to provide any evidence supporting or quantifying the alleged increased costs. Ex. 2030, ¶¶ 34, 59. There is no evidence showing that Cho's modified valve would be any more costly to make than its unmodified valve. PO's conclusory statements cannot rebut Leinsing's explanation that adjusting the size of Cho's valve would have been a simple design alternative that would not affect the functionality. Ex. 1041, ¶¶ 15-27.

Fourth, PO also repeats its argument that the combination of Plante's device with a modified Cho valve would negate Plante's advantage of using minimal steps and minimal parts. Reply, 10-11. PO misconstrues Plante, which refers to the number of parts the donor must manipulate to use the product (i.e., the cap and tube) not the number of parts required to manufacture the cap. Ex. 1004, ¶¶ [0013]- [0014]. Unlike the four discrete parts in the prior art system, Plante and Cho each have just

two discrete parts, the vessel and the cap. The argument also fails to rebut 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.

Fifth, PO contends that its arguments, which were previously rejected by the Board in IPR2022-01347, should not be rejected here because the rMTA presents new claim limitations. Reply, 11. But the obviousness ground for the rMTA involves the same combination of Plante and Cho and PO fails to explain how new claim limitations change the motivations to combine these references.

III. CLAIM 33 LACKS WRITTEN DESCRIPTION SUPPORT

PO does not dispute that the '632 patent fails to describe an embodiment of the invention having a flange on the inner cylinder. Reply at 12. Instead, PO argues that a POSITA would have recognized only two options for using a flange to change the valve position. *Id.* This argument is unsupported by any evidence and Mr. Leinsing's explanation stands un rebutted. The flange limitation does not involve two species and PO's reliance on *Hynix Semiconductor Inc. v. Rambus Inc.* 645 F.3d 1336, 1352 (Fed. Cir. 2011) is misplaced. Contrary to PO's unsupported arguments, FIGS. 1A-B and 3A-B do not disclose an embodiment with a flange on the inner

cylinder. Ex. 1041, ¶ 31. And FIGS. 1A-B do not disclose an embodiment of the '632 patent claims at all.

Regarding the claimed “initial contact” between the flange and the sample collection vessel causing the annular valve to change to an open configuration, PO argues that the claim also mentions “upon engagement of the cap to the sample collection vessel.” Reply at 12. Without further explanation, PO concludes that “initial contact brought about by engagement of the cap with the sample collection vessel brings about the valve configuration change, as illustrated in FIGS. 3A-B.” *Id.* But the engagement of the cap to the collection vessel identifies when the “initial contact” occurs, not the details of the contacting parts. PO refers to FIGS. 3A-B, but those figures and the corresponding description fail to describe any initial contact that causes the annular valve to change to the open configuration. In each of the disclosed embodiments, the cap must be rotated after initial contact to move the inner cylinder sufficiently to pass the aperture and open the valve. Ex. 1041, ¶¶ 9, 32. Claim 33 is not supported by the specification and PO’s hand waving does not show otherwise.

IV. CONCLUSION

For the foregoing reasons, the revised Motion to Amend should be denied.

Dated: January 10, 2025

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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 SUR-REPLY TO PATENT OWNER'S REVISED NON-CONTINGENT MOTION TO AMEND** is being served electronically on January 10, 2025, to the e-mail addresses shown below:

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