

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS L.L.C.,
Petitioner,

v.

DNA GENOTEK INC.,
Patent Owner.

Patent No. 11,536,632 B2

Inter Partes Review No. IPR2023-01424

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

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Other Authorities

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EXHIBIT LIST

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

Exhibit Description	Exhibit #
Deposition Transcript of Karl Leinsing taken on August 25, 2023 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347, filed as Exhibit 2057	2009
OraSure Technologies to Acquire DNA Genotek Inc., DNA GENOTEK (July 25, 2011), https://www.dnagenotek.com/us/company/news-events/press-releases/2011/2011-07-25.html , filed as Exhibit 2002 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2010
TIME MAGAZINE, December 12, 2005, filed as Exhibit 2005 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2011
Declaration of Karl R. Leinsing, MSME, PE, in Support of Petitioner's Reply, filed as Exhibit 1019 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2012
Declaration of Dr. Michael Metzker, filed as Exhibit 2012 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2013
Declaration of Dr. Steven Wereley	2014
U.S. Patent Application 17/510,003 (filed Oct. 25, 2021)	2015
U.S. Patent Application 16/023,772 (filed June 29, 2018)	2016
U.S. Patent Application 15/227,693 (filed Aug. 3, 2016)	2017
U.S. Patent Application 14/127,832 (filed as PCT application on June 19, 2012)	2018
U.S. Patent 9,442,046	2019
U.S. Provisional Patent Application 61/598,601 (filed Feb. 14, 2012)	2020
U.S. Provisional Patent Application 61/598,618 (filed Feb. 14, 2012)	2021

Exhibit Description	Exhibit #
U.S. Provisional Patent Application 61/498,584 (filed June 19, 2011)	2022
Patent Owner's Response in <i>Inter Partes</i> Review No. IPR2022-01347	2023
U.S. Provisional Patent Application 61/861,329 (filed Aug. 1, 2013) filed as Exhibit 2028 in <i>Spectrum Solutions, LLC, v. DNA Genotek Inc.</i> , IPR2022-01347	2024
Second Declaration of Dr. Steven Wereley (Wereley II)	2025
Deposition Transcript of Karl Leinsing taken on October 29, 2024	2026
Definition of "External," <i>American Heritage Dictionary of the English Language</i> (5th ed. 2011)	2027
Definition of "Aperture," <i>American Heritage Dictionary of the English Language</i> (5th ed. 2011)	2028
Injection Molding Handbook, Ch. 4-7 (3d ed. 2000)	2029
Third Declaration of Dr. Steven Wereley (Wereley III)	2030

**Patent Owner's Exhibits 2001-2029 were previously filed and are listed again here based on 37 C.F.R. § 42.63.*

***Patent Owner's Exhibit 2030 is newly filed.*

Patent Owner submits this Reply to Petitioner's Opposition ("Opp."; Paper 32) to Patent Owner's revised Motion to Amend ("RMTA"; Paper 26).

I. CLAIM 21 IS NOT IMPERMISSIBLY BROAD

Petitioner asserts that Patent Owner has impermissibly broadened the claims by replacing "second aperture" with "interior volume of the cap" in claim 21. (Opp., 2-7.) Petitioner is incorrect. The amendment is merely clarifying, given the definition of "aperture." The *American Heritage Dictionary* defines aperture as "[a]n opening, such as a hole. . . ." (Ex. 2028.) A hole is an open space having a volume. (Ex. 2025, ¶ 33.) Thus, replacing "aperture" with "volume" is not improper, and Patent Owner has complied with all relevant requirements.

This conclusion is consistent with both the issued claim language of the relevant limitation and the '632 specification. The valve is "in" the aperture, connoting a space where the annular valve is positioned. The '632 patent, in turn, describes the "inner wall 18" defining "an aperture 22." (Ex. 1001, 14:24-27.) FIGS. 3A-3B show inner wall 18 having a thickness, thereby making clear that aperture 22 has a volume. (Ex. 1033, 39:18-43:13 (Dr. Wereley testifying that the "thickness of the Aperture 22 . . . goes from the outside of 18 to the inside of 18").)

Petitioner's entire argument is premised on reading aperture narrowly as an infinitely thin, planar feature. (*See, e.g.*, Opp., 4 (showing aperture as a plane).) None of its dictionary definitions define the aperture in this manner. To the

contrary, Ex. 1031 defines aperture as a “hole” just like Patent Owner’s dictionary. Ex. 1032 refers to an exemplary camera aperture, but even that has volume. (*See* Ex. 1033, 44:16-18 (Dr. Wereley describing a camera aperture as a “hole.”).)

Petitioner’s understanding of aperture is also at odds with the ’632 patent and its previous arguments. (Opp., 6.) If aperture is as an infinitely thin, planar feature, as Petitioner urges, there would be at least two apertures in FIGS. 3A and 3B: one aperture associated with the outside surface of element 18 and another aperture associated with the inside surface of element 18. But these figures, of course, reference only a single aperture 22. Furthermore, Petitioner previously argued that FIG. 3B shows inner wall 18 “recessed inside the cap” (Paper 19, 9), which would cover FIGS. B-D that Petitioner cites in its current Opposition as proof of broadening. (Paper 32, 4.) As for the written description of the ’632 patent, its description of an interior space 20 does not mean that other features, such as aperture 22, have no volume. And the claim language “said open end defining a second aperture” is consistent with an aperture being a “hole.”

Accordingly, the substitute claims do not impermissibly broaden scope. *NXP USA., Inc. v. Impinj, Inc.*, IPR2020-00514, Paper 37, at 15 (P.T.A.B. Aug. 11, 2021) (“tuning element” for “variable impedance” found not broadening); *see also* Preliminary Guidance, Paper 21 at 4 (finding no broadening for annular valve being housed within boundaries of the outer wall of the cap).

II. THE CLAIMS ARE PATENTABLE OVER PLANTE AND CHO

A. The Claimed Invention And Its Advantages

Claim 21 is directed to a biological sample collection system comprising only three elements: a sample collection vessel, a cap, and an annular valve positioned in the interior volume of the cap. (RMTA, 3-4.) The annular valve comprises only three elements as well: a first cylinder positioned externally to the sample collection vessel in operation, a second cylinder, and a vent. (*Id.*)

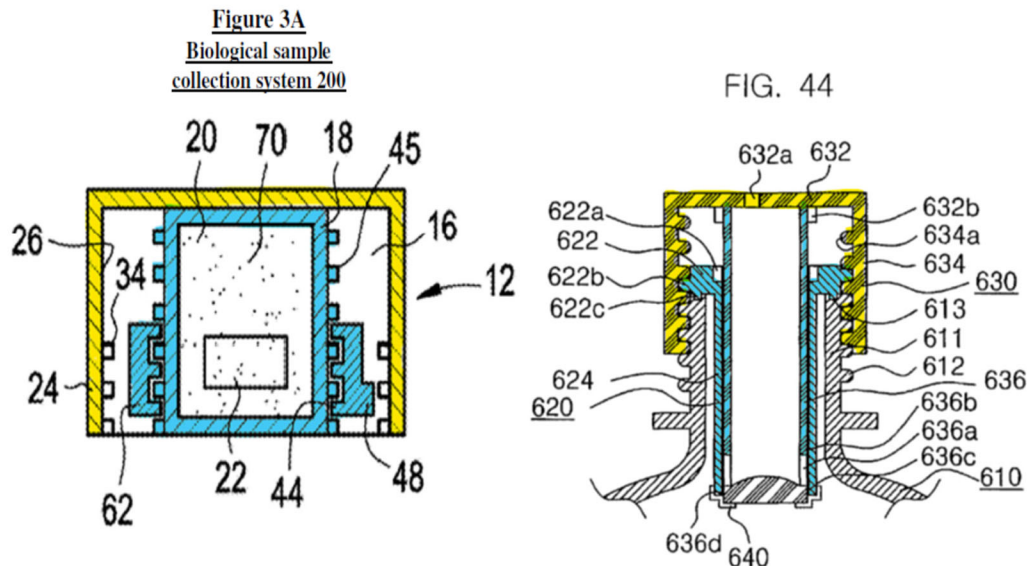
The '632 patent describes the advantages of the claimed invention. For example, the claimed invention has minimal parts, both overall and with respect to the annular valve. (Ex. 1001, 4:64-65.) There is also limited or no risk of contamination or exposure to toxic solutions, because the valve is positioned in the interior volume of the cap and the attachment of the cap to the sample collection vessel causes the valve to open by uncovering the vent. (*Id.*, 5:6-8.)

Petitioner seeks to denigrate the claimed invention by asserting that the '632 patent is silent about the "added limitation" as "an inventive feature." (Opp., 9.) But its assertion is factually and legally incorrect. Petitioner has not challenged the claimed invention as being unsupported. The claimed invention and its advantages are described in the '632 patent as discussed in the RMTA and above. Further, where one is challenging patentability under § 103, as Petitioner is here, the analysis must consider the claimed invention as a whole. *Jones v. Hardy*, 727 F.2d

1524, 1528 (Fed. Cir. 1984) (“[I]t is improper to consider the *difference* [in a claimed invention from the prior art] as the *invention*.”) (emphasis in original).

B. The Claimed Invention Differs From Cho

The claimed invention differs from Cho in many ways.



First, both cylindrical components of Cho’s valve—inner cap 624 and slider 636—extend well into the mouth of bottle 610 (shown above in FIG. 44). In contrast, the annular valve of the claimed invention is positioned in the interior volume of the cap, and its first cylinder is positioned externally to the sample collection vessel in operation. This difference reflects that Cho is fundamentally directed to a beverage bottle designed to ship a beverage with a separately stored additive and for enhancing mixing upon use. (Ex. 2030, ¶¶ 25-31, 36, 71-72; Ex. 1004, 55:13-25.)

Second, Cho’s “outer cylinder” 620 includes external threads 622b and engages directly with both bottle 610 and internal threads 634a of the upper cap. This structure reflects a two-step cap attachment process. The cap is attached to the bottle during assembly at the factory and filled to create a fluid tight seal, with the valve remaining in the closed configuration during distribution. (Ex. 1001, 22:41-44.) In this first attachment step, the outer cylinder is fully inserted in bottle 610, abuts the upper edge of the bottle mouth 611, and is engaged with internal threads 634a of upper cap 634. It is only upon further tightening of upper cap 634 by the user that the inner cylinder (slider 636) is further advanced into bottle 610 and the valve changes to the open configuration. (Ex. 2030, ¶¶ 32, 35-36, 40.)

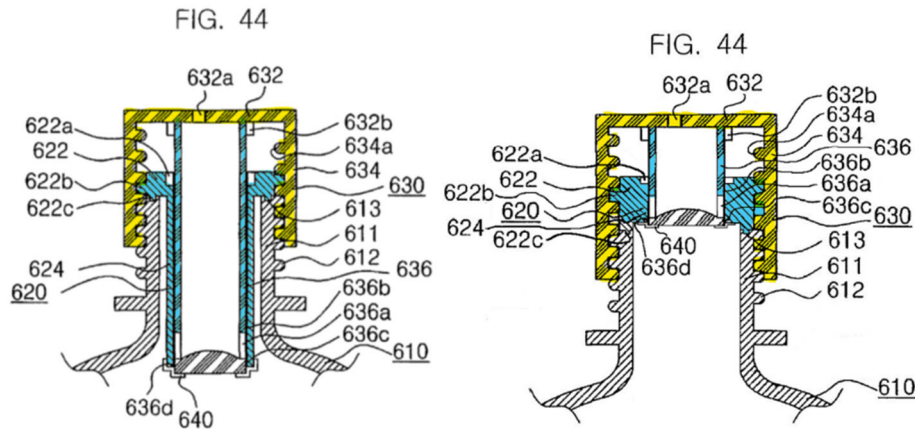
In contrast, the cap of the ’632 patent is shipped *separately* from the empty biological sample collection vessel. When the cap is attached to the biological sample collection vessel, it brings a flange (coupling feature 48) on the outer cylinder (annular blocking member 62) into contact with the rim (coupling member 50) of the biological sample collection vessel, which causes the outer cylinder (annular blocking member 62) to recess further into cap 12 and moves the annular valve from the closed configuration to the open configuration *as the cap is tightened*. (Ex. 2030, ¶¶ 35-36.) This structural difference is reflected in claim language, such as claim 33.

Third, Cho’s valve relies upon multiple ratchets 622a, 632b, 622c and 613 to direct the rotations of container 620, opening unit 630 and mouth 611. None of these features are in the claimed invention. Nor would they be, as having minimal parts and features is an advantage of the claimed invention. (Ex. 2030, ¶¶ 33, 46, 48-49, 62.)

Petitioner repeatedly asserts that Cho’s valve is “essentially identical” and “functions identically” to the claimed invention. (Opp., 8, 14.) These general statements ring hollow, because Petitioner, in making these statements, fails to address the many differences with Cho.

C. The Claimed Invention Is Patentable

When the claimed invention of the ’632 patent is considered as a whole, including the recited differences, it is patentable over the sole ground of Plante and Cho, even though Patent Owner does not bear a burden of persuasion to demonstrate patentability. *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1327 (Fed. Cir. 2017). Petitioner has completely modified Cho to try to address the recitations of current claim 21. It has modified the length of slider 636 and eliminated inner cap 624. (Ex. 1004, 49:16-21.) Petitioner enlarged the vertical dimensions of cap 634 by extending the outer walls (below right) to increase the number of threads available to engage with the threaded neck of the bottle as compared to Cho’s original FIG. 44 (below left). (Ex. 2030, ¶¶ 39-43.)



Petitioner significantly enlarged one element of the additive storage container 620—circular end plate 622—presumably to enable contact with both ring-type seal protrusions 636b and 636c uniquely required by Cho to prevent leakage of the additive from the cap. (Ex. 1004, 49:16-21.) Finally, Petitioner has also modified bursting film 640 from the way it is drawn by Cho on the left. (Ex. 2030, ¶¶ 39-43.) At least two components of Petitioner’s modified valve have actually been materially increased in size (cap 634 and end plate 622) rather than decreased in relation to Cho’s original design. (Ex. 2030, ¶ 43.)

Petitioner frames its modifications as only a simple adjustment of the size of Cho's valve, leading to a conclusion of obviousness. (Opp., 8, 10, 12-13.) But, once again, Petitioner is factually and legally incorrect. Petitioner has engaged in a *structural redesign* of Cho. (Ex. 2030, ¶ 43.) Thus, Petitioner and Mr. Leinsing's repeated statements of "resizing" ring hollow again. And Petitioner's use of a redesigned Cho compels a legal conclusion of *non-obviousness* for several reasons.

First, redesigning Cho’s valve (and Plante’s sample collection vessel) would have required confronting challenging molding and manufacturing/assembly issues. (Ex. 2030, ¶¶ 44-47.) For example, as Dr. Wereley previously testified, long, thin parts (*e.g.*, Cho’s inner and outer cylindrical components) and sharp corners (*e.g.*, Cho’s ratchet features) are difficult to mold, as are parts that require tight tolerances (*e.g.*, Cho’s ring-type seal protrusions 636b and 636c). (Ex. 2025, ¶¶ 66-85.) This testimony was supported by the very molding references cited by Mr. Leinsing. (Ex. 1014, Ex.1015, Ex. 2029.) Rather than respond substantively, Petitioner simply engaged in high-level rhetoric. (Opp., 15-16, 19.)

The redesign of Cho would present the same challenges, notwithstanding Mr. Leinsing’s assertion that it could be molded using “*three basic molds*.” (Ex. 1041, ¶¶ 8-21, 25.) As discussed by Dr. Wereley (Ex. 2030, ¶¶ 48-57), each of these “*three basic molds*” comprises multiple parts. The molds do not address the fabrication of a modified sample collection vessel to fit with Cho’s valve. Nor do they include all the features required by Cho’s design and included in Petitioner’s combination. *Ethicon Endo-Surgery, Inc. v. Covidien LP*, No. 16-12556-LTS, 2020 U.S. Dist. LEXIS 72133, at *12 (D. Mass. Apr. 24, 2020) (“Mr. Leinsing did not consider the amount of time or resources it would have taken to modify [prior art] Gallo Modifying the device disclosed in Gallo to arrive at the ’759 patent device would have required an extensive re-design of the Gallo device”).

Moreover, Mr. Leinsing's mold would not work as illustrated—due, for example, to the presence of Cho's ratchet features which would interfere with the use of unwinding core pins and the like. Mr. Leinsing also suggests that Cho's second cylinder would be molded separately from the cap, which would require it to be bonded to the cap using, *e.g.*, ultrasonic welding. This in turn requires adding additional fabrication and/or assembly steps (and associated costs) to the manufacturing process. (Ex. 2030, ¶¶ 34, 51, 53, 60.) In short, there is nothing predictable about restructuring Cho's valve device as Petitioner urges.

Second, these molding challenges associated with Cho's redesign are not commensurate with a POSITA's level of skill. Dr. Wereley testified that the level is a bachelor's degree and "some experience." (Ex. 2014, ¶¶ 23-24; Ex. 1002, ¶ 52 (similar, but defining "three" years of experience.)) That level is exceeded given the smaller parts and the tighter tolerances required under Petitioner's combination. (Ex. 2030, ¶ 61.) Mold design engineers, unlike the POSITA here, are highly trained, highly specialized engineers with extensive experience in both mold design and troubleshooting injection molding processes. (*Id.*) Petitioner and Mr. Leinsing fail to address the level of skill with any evidence, other than either misstating Dr. Wereley's testimony (Opp., 16-17) or stating in a conclusory fashion that "[m]olding the parts of the Cho annular valve would be a simple process well within the level of skill of a POSA" (Ex. 1041, ¶ 17). *Ethicon*, 2020

U.S. Dist. LEXIS 72133, at *52 n.20 (Mr. Leinsing testified that a “person of ordinary skill in the art would have been motivated to replace Gallo’s straight lever handle But such testimony is not evidence of a motivation to modify—it is only evidence that Mr. Leinsing was able, with the full benefit of hindsight, to articulate how Gallo might have been improved by redesigning it to be more like the device claimed in the ’759 patent.”).

Third, a POSITA would have no motivation to substitute Cho’s complex, redesigned valve for Plante’s simple approach, especially in the field of clinical diagnostics where sensitivity to the cost of goods sold is often a driver in product decision making. *Hulu v. Sound View Innovations*, IPR2018-00582, Paper 34 at 19 (P.T.A.B. Aug. 5, 2019) (finding “costly” databases supported non-obviousness). Modification and incorporation of Cho’s complex, multi-component valve design would have led to a long development time and increased fabrication and assembly costs for the biological sample collection device. (Ex. 2030, ¶¶ 34, 59.)

Fourth, the combination of Plante’s device with a modified Cho valve would negate an advantage of Plante’s device, i.e., that it allows a user to “capture a sample with a minimal amount of steps and a minimal number of parts.” (Ex. 1003, ¶ 6.) Cho’s complex cap is designed to be attached to a beverage bottle to a specific predetermined position prior to distribution of the product. If incorporated into a sample collection device similar to that of Plante that is shipped to a user for

biological sample collection, the design would require the user to remove the cap from the sample collection vessel prior to *depositing* a biological sample.

Furthermore, the complex ratchet features included in Cho's design allow rotation of opening unit 630 (corresponding roughly to Plante's sealing cap 21) and its components in only one direction relative to the mouth 611 of the bottle (Ex. 1004, 49:1-4, 28-33). Thus, an attempt to combine Plante and Cho would yield a device difficult to open by the user and, if forced, may prevent a fluid tight seal when the cap is replaced after depositing a biological sample. (Ex. 2030, ¶ 62.)

Fifth, Petitioner keeps repeating the mantra that Patent Owner's arguments have been previously rejected by the Board in IPR2022-01347. (Opp., 19-21.) But the RMTA presents claim limitations and arguments that have not been addressed or considered by the Board and belie Petitioner's oft assertion of a "simple substitution of one known element for another." (Opp., 16; Ex. 2030, ¶¶ 60, 66.)

D. Claims 29, 33, And 36 Are Patentable Over Plante And Cho

Petitioner's challenges to certain dependent claims are meritless for the reasons discussed above and in the RMTA. (Opp., 21-23; Ex. 2030, ¶¶ 68-73.)

III. CLAIM 33 IS SUPPORTED

Petitioner argues that the '632 patent allegedly "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." (Opp.,

23-24 (emphasis in original).) But Petitioner elides claim 33, which reads in full: “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”—not “*initial contact...causes*” the annular valve to change configurations. The initial contact brought about by engagement of the cap with the sample collection vessel brings about the valve configuration change, as is illustrated in FIGS. 3A-B.

Petitioner also argues the ’632 patent allegedly “does not describe an embodiment of the invention having a flange on the inner cylinder.” (Opp., 23.) A POSITA would have recognized only two options for using the flange to change the valve from closed to open: attached to the outer (first) cylinder or to the inner (second) cylinder. *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1352 (Fed. Cir. 2011) (finding support based on two species). Further, FIGS. 1A-B (Ex. 2015, ¶¶ 67-73) illustrate an embodiment in which coupling feature 48 is part of an inner cylindrical blocking member 46 and is, again, configured to contact a coupling member 50 that is part of the biological sample collection vessel. Collectively, FIGS. 3A-B and 1A-B illustrate embodiments of both options and provide the requisite support for claim 33. (Ex. 2030, ¶¶ 18-21.)

IV. CONCLUSION

For all the foregoing reasons, the Board should grant the RMTA.

IPR2023-01424

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CERTIFICATE OF SERVICE

I hereby certify that the attached PATENT OWNER'S REPLY TO
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