

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.

IPR2023-01424
Patent 11,536,632 B2

Before LYNNE H. BROWNE, CHRISTOPHER M. KAISER, and
JAMIE T. WISZ, *Administrative Patent Judges*.

BROWNE, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Granting-in-Part and Denying-in-Part
Patent Owner's Revised Non-Contingent Motion to Amend
35 U.S.C. § 318(a3)

I. INTRODUCTION

Spectrum Solutions, L.L.C. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of U.S. Patent No. 11,536,632 B2 (Ex. 1001, “the ’632 patent”), claims 1–16 and 18–20. We issued an Institution Decision (Paper 10) instituting trial in this proceeding.

DNA Genotek Inc. (“Patent Owner”) then filed a Patent Owner Response (Paper 6) to the Petition, defending the challenged ’632 patent claims. Petitioner filed a Reply (Paper 7) to the Patent Owner Response and Patent Owner filed a Sur-reply (Paper 9).

Patent Owner also filed a non-contingent motion to amend the ’632 patent (Paper 16), to which Petitioner filed an opposition (Paper 19). We issued Preliminary Guidance (Paper 21) concerning the initial motion to amend. Following the Preliminary Guidance, Patent Owner filed a revised non-contingent motion to amend the ’632 patent (Paper 26, “Motion to Amend” or “Mot.”), replacing the initial motion to amend. Petitioner filed an Opposition to the Motion to Amend (Paper 32, “Mot. Opp.”).

Patent Owner filed an Objection to Evidence Submitted with Petitioner’s Opposition to the Motion (Paper 33). Patent Owner also filed a Motion to Exclude Evidence (Paper 35). Petitioner filed an Opposition to Patent Owner’s Motion to Exclude Evidence (Paper 36). Patent Owner filed a Reply to Petitioner’s Opposition (Paper 38, “Mot. Reply”). Petitioner filed a Sur-reply to Patent Owner’s Reply (Paper 40, “Mot. Sur-reply”).

An oral hearing was held on January 24, 2025, for which the transcript was entered into the record. Paper 43.

We *grant* the Motion to Amend as to cancelling original claims 1–16 and 18–20. As a result, we do not reach the grounds of unpatentability asserted in the Petition against these original claims.

We also *deny* the Motion to Amend as to adding proposed substitute claims 21–39 to the '632 patent, because proposed substitute claims 21–39 seek to broaden the scope of the challenged claims.

We do not rule on Patent Owner's Objection to Evidence Submitted with Petitioner's Opposition to the Motion and Patent Owner's Motion to Exclude Evidence, because we do not rely on the cited Evidence in formulating our Decision below.

II. BACKGROUND

Petitioner identifies itself as the real party in interest. Pet. 1. In addition, Petitioner notes that Spectrum Holdco LLC is its parent company and that Spectrum Holdco LLC and Spectrum Intermediate LLC “have a financial interest in, or could be substantially affected by the outcome of, this proceeding.” *Id.* Patent Owner identifies itself as the real party in interest and notes that it is a wholly owned subsidiary of OraSure Technologies, Inc. Paper 4, 2.

The parties indicate that U.S. Patent No. 11,002,646 B2 (“the '646 patent”), which is related to the '632 patent, is the subject of *DNA Genotek Inc. v. Spectrum Solutions LLC*, No. 3:21-cv-0516-RSH-DDL (S.D. Cal.), which is currently on appeal. Pet. 1; Paper 4, 2.

The parties also indicate that the '646 patent is challenged in IPR2022-01347. Pet. 2; Paper 4, 2. We issued a final written decision in IPR2022-01347 on February 7, 2024, determining that claims 1, 3–8, 11,

and 12 of the '646 patent are unpatentable. *See Spectrum Solutions, L.L.C. v. DNA Genotek Inc.*, IPR2022-01347, Paper 43 (PTAB Feb. 7, 2024).

III. ORIGINAL CLAIMS 1–16 and 18–20

As discussed above, the Motion to Amend includes a non-contingent request to cancel original claims 1–16 and 18–20 of the '632 patent, which are all of the claims challenged in the Petition. *See* Mot. 1. Petitioner does not oppose this portion of the Motion to Amend. *See generally* Mot. Opp. Therefore, we grant Patent Owner's request to cancel original claims 1–16 and 18–20. As a result, we do not reach the grounds of unpatentability asserted in the Petition against these original claims.

IV. PROPOSED SUBSTITUTE CLAIMS 21–39

A. Introduction

The Motion to Amend proposes to add substitute claims 21–39 to the '632 patent. *See* Mot. 1, 27–33 (App. A). We determine these claims broaden the challenged claims. We therefore deny the Motion to Amend.

B. The '632 Patent Disclosure

The '632 patent is titled “Biological Collection System.” Ex. 1001, code (54). The '632 patent describes the field of disclosure as relating 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).” *Id.* at 1:20–23. The '632 patent describes saliva and urine as examples of bodily fluids that “may enable large-scale ‘population-sized’ epigenetic research.” *Id.* at 2:50–52. Specifically, the '632 patent states that “home-base[d]

sample collection . . . may allow for a much wider range of research options available as it can greatly increase participant numbers and samples can be more easily shipped by the subjects from anywhere.” *Id.* at 2:52–57.

The ’632 patent describes as beneficial the ability to “securely house a toxic preservative solution in a closed chamber” of the device to preserve specimens from a widely geographically dispersed population without exposing the donor or laboratory technician to the toxic solution. *Id.* at 3:59–4:7. The ’632 patent states that existing sample collection devices utilize “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.” *Id.* at 4:15–30. In addition, the ’632 patent describes existing treatments for treating cells to maintain their antigen profiles and epigenomic profiling containing lysine, glycine, and formaldehyde for stabilizing cells from blood, which will not protect cells from proteases found in bodily fluids such as saliva. *Id.* at 4:36–48.

The ’632 patent describes the invention as providing a safe and easy to use sample collection device for naturally expressed bodily fluids that uses a minimum number of parts, does not include sharp objects, and does not require removal or exchange of a piece or object thereof apart from depositing the sample and closing the sample collection device. *Id.* at 4:52–5:8. The ’632 patent describes an embodiment as having a tube with a reservoir for collecting sample fluid, a cap being securely coupled to the tube, and an annular blocking member that moves from a position where the annular blocking member is covering an aperture to a position in which the annular blocking member is not covering the aperture, thus allowing sample

preserving fluid or material to release from an interior space to interact with the sample. *Id.* at 14:45–61. The '632 patent describes the cap and tube as being threadably engaged and also the annular blocking member being threadably engaged along the side of the inner walls. *Id.* at 14:62–15:13. Figure 3B below depicts an embodiment.

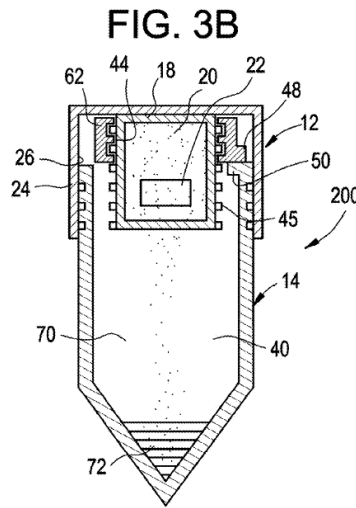


Figure 3B above shows a sample collection device in which cap 12 is coupled to tube 14 and movable annular member 62 is moved to a position where it does not cover aperture 22 in the inner wall, thereby allowing the sample preserving fluid to be released from interior space 20 and to interact with sample 72. *Id.* at 8:54–58, 14:45–56. The Specification further discloses that “interior space 20 may be at least partially defined by at least one of an inner wall 18 or outer wall 24 of the cap 12.” *Id.* at 14:20–22.

C. *The Proposed Substitute Claims*

Patent Owner proposes to amend the '632 patent by adding new claims 21–39, as respective substitutes for original claims 1–16 and 18–20. *See Mot. 1, 27–33 (App. A).*

Proposed substitute independent claim 21, the sole independent claim,

is reproduced below. Underlined language reflects subject matter added to the original claims, and struck through language reflects subject matter omitted from the original claims:

21. A biological sample collection system, the system comprising:

a sample collection vessel comprising

a sample collection reservoir,

a first connection member, and

a first aperture for receiving a biological sample;

a cap comprising

an outer wall defining an open end of the cap, an opposing closed end of the cap, and an interior volume of the cap, said open end defining a second aperture,

a reagent chamber storing a reagent therein and positioned in the interior volume of the cap, and

a second connection member complementary to the first connection member; and

a moveable annular valve positioned in the interior volume of the cap~~second aperture~~, the moveable annular valve comprising

a vent,

a first cylinder comprising a third aperture,

a second cylinder comprising the vent, the second cylinder positioned in the third aperture,

a closed configuration, and

an open configuration, wherein

in the moveable annular valve's closed configuration, the first and second cylinders create a fluid-tight seal with the cap and the first cylinder obstructs the vent to retain the reagent in the reagent chamber,

the first cylinder and second cylinder are relatively moveable to thereby change the annular valve from the closed

configuration to the open configuration, wherein the first cylinder is positioned externally to the sample collection vessel in both the closed configuration and the open configuration of the moveable annular valve, and

in the moveable annular valve's open configuration, the first cylinder does not obstruct the vent to thereby allow flow of the reagent from the reagent chamber, through the vent, and into the sample collection reservoir.

Mot. 27–29 (App. A).

D. Proposed Substitute Claims 21–39 Would Improperly Enlarge the Scope of the Challenged Claims of the '632

For the following reasons, we determine proposed substitute claims 21–39 seek to enlarge the scope of the challenged claims of the '632 patent. For this reason, we deny the Motion to Amend as to adding these claims to the '632 patent.

1. Statement of Law

A motion to amend “may not enlarge the scope of the claims of the patent or introduce new matter.” 35 U.S.C. § 316(d)(3). “*Before considering the patentability of any substitute claims . . . the Board first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in § 316(d) and 37 C.F.R. § 42.121.*” *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential, “*Lectrosonics*”) (emphases added). This includes the prohibition against enlarging the scope of the claims. *See Lectrosonics*, at 6–7.

“*[T]he patent owner must satisfy the Board that the statutory criteria in [35 U.S.C.] § 316(d)(3) are met and that any reasonable procedural*

obligations imposed by the Director are satisfied.” *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1305–06 (Fed. Cir. 2017) (emphasis added) (lead plurality opinion by J. O’Malley); *see also id.* at 1341 (“There is no disagreement that the patent owner bears a burden of production in accordance [with] 35 U.S.C. § 316(d).”) (majority opinion by J. Reyna).

Accordingly: “Any motion to amend may be denied where . . . [t]he amendment seeks to enlarge the scope of the claims of the patent.”

37 C.F.R. § 42.121(a)(2)(ii); *see also* PTAB Consolidated Trial Practice Guide (Nov. 2019), 69, 71.¹

“[I]f 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.”).

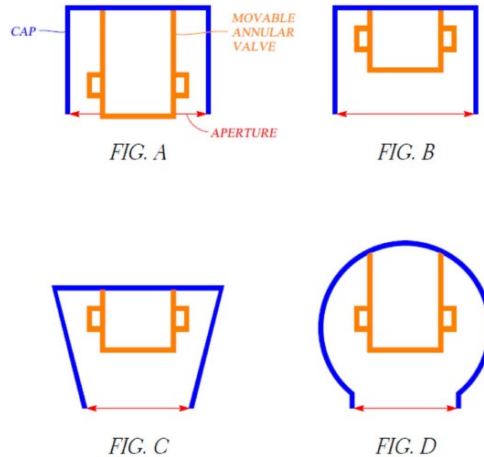
2. *Proposed Substitute Independent Claim 21*

Patent Owner asserts that proposed substitute independent claim 21 does not enlarge the scope of challenged independent claim 1. Mot. 2, 27–29 (App. A). Patent Owner asserts that proposed substitute independent claim 21 “clarif[ies] that the ‘reagent chamber’ and the ‘moveable annular valve’ are ‘positioned in the interior volume of the cap.’” *Id.* at 2. In particular, the relevant proposed amendment to substitute claim 21 provides:

¹ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

“a movable annular valve positioned in the interior volume of the cap~~second aperture.~~” *Id.* at 4, 28 (App. A).

Petitioner argues that Patent Owner “has broadened the claim by removing the ‘second aperture’ limitation” and the amended claims now “merely require the valve be positioned in the interior volume of the cap.” Mot. Opp. 3. Petitioner argues, “a movable annular valve can be positioned in the interior volume of the cap without being in the aperture of the cap.” *Id.* To demonstrate this, Petitioner provides Figures A–D, which are reproduced below.



Id. at 4. Petitioner argues that Figure A “shows a device with the movable annular valve in the aperture of the cap, as required by the original claims” whereas Figures B, C, and 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.” *Id.* at 3–4. Petitioner argues that although Patent Owner asserts that that proposed amendment was for “clarifying” the claimed subject matter, Patent Owner “fails [to] provide any explanation of how the removal of the claim limitation was not broadening.” *Id.* at 5.

Petitioner further argues that although Patent Owner did not cite to the following assertion by its expert to show that there is no broadening of the claims, Patent Owner'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." *Id.* (citing Ex. 2025 ¶ 33). Petitioner argues, however, that this assertion "is unsupported." *Id.* Petitioner argues, this assertion "is contradicted by the patent and the plain meaning of the claim language" because "[a]n aperture, consistent with its plain meaning, is the opening into a space, not the space itself." *Id.* at 6. Petitioner contends that the Specification of the '632 patent uses the term "aperture" in exactly this manner by disclosing aperture 22 is the opening in the inner wall 18 in contrast to an interior space. *Id.* (citing Ex. 1001 5:24–26, 6:14–17, 10:33–36, 14:24–27, Figs. 3A, 3B). Petitioner further points to an example of the aperture of a camera as "the opening that allows light to enter a camera, not the space contained within the camera." *Id.* (citing Exs. 1031, 1032, 2028 (dictionary definitions of aperture)).

In reply to Petitioner's Opposition, Patent Owner contends that "[t]he amendment is merely clarifying, given the definition of 'aperture.'" Mot. Reply 1. Quoting the American Heritage Dictionary, Patent Owner asserts that an aperture is "[a]n opening, such as a hole." *Id.* (citing Ex. 2028). Given this definition of aperture, Patent Owner contends that "[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." *Id.* Patent Owner further contends that "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.” *Id.*

Replying to Patent Owner’s arguments, Petitioner asserts that “referring to an aperture as a hole does not somehow mean the aperture is the volume of space to which it leads.” Mot. Sur-reply 1. In addition to referring to its camera aperture example discussed above, Petitioner provides an additional colorful, yet illustrative, example of the difference between an aperture and a hole. Specifically, the example that “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 [hole] to which the aperture led.” *Id.* at 2.

Petitioner also asserts that Patent Owner’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.*’” Mot. Sur-reply 2.

Original claim 1 recites “a cap comprising a second aperture and “a moveable annular valve in the second aperture.” Ex. 1001, 22:17–28, 32. Proposed substitute claim 21 recites a cap comprising an outer wall defining three separate elements: an open end of the cap, an opposing closed end of the cap, and an *interior volume* of the cap. Mot. 27. Proposed substitute claim 21 goes on to specify that the open end of the outer wall defines a second aperture and that the moveable annular valve is positioned in the interior volume of the cap. Thus, as set forth in proposed amended claim 21, the moveable annular valve is no longer “in the second aperture”

but instead is “in the interior volume of the cap.” Ex. 1001, 22:32; Mot. 27. We agree with Petitioner that the requirement in proposed substitute claim 21 that the movable annular valve be in the interior volume of the cap is broader than the requirement in original claim 1 that it be in the second aperture. This is succinctly illustrated by Petitioner’s Figures A–D, reproduced above, which show that the language of proposed substitute claim 21 encompasses more than original claim 1.

Further, we find Patent Owner’s argument that the claimed second aperture is a hole, and thus, a volume, unsupported by the record. Mot. Sur-reply 1. We are troubled by Patent Owner’s reliance on a general, non-technical dictionary to support its assertion that an aperture and a hole are the same thing. “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips v. ASW Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005)). Extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)). Here, Patent Owner has not considered the intrinsic evidence, in particular the language of the claim itself which clearly distinguishes a second aperture from an interior volume.

Upon review of the foregoing, we agree with Petitioner’s position that deletion of the term “second aperture” relative to the positioning of the movable annular valve broadens the scope of independent claim 1. With the

plain meaning of “aperture” as “an opening, as a hole, slit, crack, gap, etc.,” Petitioner’s Figures A–D demonstrate that a movable annular valve being positioned in the interior volume of a cap does not necessarily require that the movable annular valve be positioned in the aperture of the cap.

Ex. 1031; Opp. Mot. 4.

For the foregoing reasons, we conclude that adding proposed substitute claim 21 would broaden challenged claim 1, and we accordingly deny the Motion to Amend the ’632 patent with respect to adding proposed substitute claim 21.

3. *Proposed Substitute Dependent Claims 22–39*

The proposed substitute claims 22–39 each depend from proposed substitute independent claim 21, and therefore incorporate the deletion of the second aperture limitation recited in that independent claim. *See* Mot. App. A. Therefore, for the reasons provided in Section IV.D.2 above, we conclude that adding the proposed substitute dependent claims 22–39 would enlarge the scope of the challenged claims of the ’632 patent, and we accordingly deny the Motion to Amend the ’632 patent as to these claims.

E. Petitioner’s Remaining Arguments

In light of our determination above that proposed substitute claims 21–39 seek to enlarge the scope of the challenged claims of the ’632 patent, we do not reach the grounds of unpatentability set forth in Petitioner’s Opposition for these claims. For the same reason we do not address Petitioner’s argument that claim 33 lacks written description support. *See* Mot. Opp. 10–25.

V. SUMMARY OF CONCLUSIONS

We *grant* Patent Owner’s non-contingent request to cancel original claims 1–16 and 18–20 of the ’632 patent, and we *deny* Patent Owner’s request to add proposed substitute claims 21–39 to the ’632 patent.² The result of this Decision is summarized by the following table.

Motion to Amend Outcome	Claim(s)
Original Claims Canceled by Amendment	1–16 and 18–20
Substitute Claims Proposed in the Amendment	21–39
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	21–39
Substitute Claims: Not Reached	

² Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Amend is *granted* as to the non-contingent request to cancel original claims 1–16 and 18–20 of the '632 patent;

FURTHER ORDERED that Patent Owner's Motion to Amend is *denied* as to the request to add proposed substitute claims 21–39 to the '632 patent; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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