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On behalf of **Spectrum Solutions L.L.C.**

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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

Case No. IPR2023-01424
Patent 11,536,632

PETITIONER'S AUTHORIZED PRELIMINARY REPLY BRIEF

A. Introduction

At Petitioner's request, the Board authorized Petitioner to file this Preliminary Reply Brief to address the proper claim construction of the term "cap" in the '632 patent. *See* Ex. 1021. The Board should adopt the plain and ordinary meaning of "cap," which is simply "a lid or cover" for the sample collection vessel. As explained below, this construction is supported by the claims and the specification. In contrast, Patent Owner's ("PO") proposed construction—"a cover for the sample collection vessel that is not co-extensive with the movable annular valve"—introduces a negative limitation that finds no support in the claims, specification, or prosecution history. Indeed, PO initially introduced this negative construction in the IPR for the related '646 patent solely in an attempt to read out the invalidating prior art. PO's manufactured construction is divorced from sound claim construction principles and should be rejected.

B. The Board Should Adopt the Plain Meaning of "Cap"

"There is a heavy presumption that claim terms are to be given their ordinary and customary meaning." *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013). Here, the plain and ordinary meaning of "cap" in the context of the '632 patent is simply "a lid or cover" for the sample collection vessel. The specification explains that the sample collection device includes "two mating bodies, a cap and a tube." Ex. 1001, Abstract; *id.*, 5:9-11 (same); *id.*, 10:11-

16 (same); *id.*, 8:54-55 (“the cap is coupled to the tube”). The specification uses the term “cap” in its ordinary sense as an object to cover and close the tube: “the cap...mates with the tube to constitute the (closed) sample collection device.” *Id.*, Abstract; *id.*, 5:11-13 (“The cap can...mate with the tube to constitute the closed sample collection device.”); 10:13-16 (same). Thus, the specification explains that the cap mates with the sample collection vessel (i.e., tube) to cover and close it.

The claims also support this plain meaning. Claim 1 of the '632 patent recites that the “cap” comprises, *inter alia*, “a second connection member [e.g., threads] complementary to the first connection member [on the sample collection vessel].” Thus, when the cap's connection member engages the connection member of the vessel, the cap covers and closes the vessel. There is nothing in the claims or specification to suggest that the inventors have disclaimed the full scope of the term “cap.” Accordingly, the Board should adopt the plain meaning.

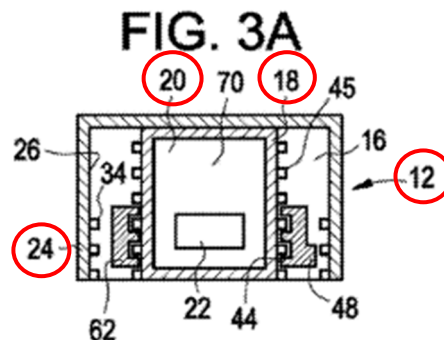
C. The Board Should Reject PO's Manufactured Construction

In the POPR (Paper 6), PO proposes construing “cap” to mean “a cover for the sample collection vessel that is not co-extensive with the movable annular valve.” POPR at 11. PO does not even attempt to justify its construction as the plain meaning, nor does PO contend that it meets either exception to a plain meaning construction: disclaimer or lexicography. *See Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

PO first alleges the “text of the claims” supports its limiting construction because the cap is listed as a distinct structure from the valve. POPR, 12. PO fails to explain why this would require importing a negative limitation—“not co-extensive with the movable annular valve”—into the claims. Indeed, claim 1 makes clear that the movable annular valve is *part of* the cap; the cap comprises the “reagent chamber” and the reagent chamber is part of the valve’s second cylinder. Ex. 1001, 22:27-29, 22:43-44, 22:49-53. Similarly, the specification describes the claimed reagent chamber as part of the cap and not separate from the cap. Ex. 1001, Abstract (“the cap includes a closed interior space for holding a sample preservation solution.”); *id.*, 5:11-13, 6:8-9, 10:12-13. PO also alleges “it would be impossible” for the “first and second cylinders to create a fluid-tight seal with the cap” as recited in claim 1 if the valve and cap could be co-extensive. But PO offers no support for this argument and never explains why the cap and valve components would need to be “not co-extensive” to create a fluid-tight seal in the valve’s closed configuration.

Next, PO points to the specification, and Fig. 3A specifically, as allegedly supporting its construction. POPR, 12. But the figure’s associated description explains that the reagent chamber and its components are *part of* the cap: “FIG. 3A shows an embodiment of the cap of the sample collection device in which *the cap contains an inner chamber with a movable annular member* that can cover an aperture in the inner wall.” *Id.*, 8:49-53 (label 12 points to the *entirety of the cap* in

Fig. 3A, which includes the chamber/valve components). Further, it states that “the interior space 20 [reagent chamber] may be at least partially defined by at least one of an inner wall 18 or outerwall 24 of the cap 12.” *Id.*, 14:20-22. Thus, the inner wall of the cap (the claimed second cylinder of the valve) defines the reagent chamber of the cap in the Fig. 3 embodiment.



PO next quotes the specification regarding “an annular member at the base of the cap that is partially secured to the cap.” POPR, 13 (quoting Ex. 1001, 11:41-43). However, this “annular member” is different, it is not a part of the claimed “movable annular valve;” rather, it is a “tamper-evident” ring like “those used to attach a cap to a soda bottle.” Ex. 1001, 11:41-48; *id.*, Figs. 7A, 7B. PO also quotes the ’632 patent at 14:46-49, which explains that the “annular blocking member” may interact with features of the tube, but PO fails to explain how this supports its contention that “the cap is not co-extensive with the annular components of the valve.” POPR, 13. In sum, the specification does not support PO’s argument to depart from the plain meaning of “cap.” There is no lexicography or disavowal to limit the term to PO’s proposed construction.

Likewise, PO’s citations to the ’646 patent prosecution history do not even suggest lexicography or disavowal, much less meet their exacting standards. PO argues that “[t]he Examiner understood that the cap is not co-extensive with the

valve” by pointing to (i) the Examiner’s use of parentheses; and (ii) the Examiner’s statement about the prior art. POPR, 13. These fragments from prosecution history in no way establish the Examiner understood “cap” differently than its ordinary meaning; PO’s argument otherwise is pure speculation. And the Federal Circuit has held that even express statements by an examiner—much less PO’s speculation of the Examiner’s understanding—do not create disclaimer. *3M Innov. Prop. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1332 (Fed. Cir. 2013) (holding that claim construction is not decided based on isolated *statements* of an examiner). Next, PO suggests that claim amendments in the prosecution history “underscore[] that the claimed cap is not co-extensive with the valve.” POPR, 13-14. Not so. At the time of these amendments, “cap” and “movable annular valve” were already existing elements in the claims (Ex. 2002, 13). It is unclear how the amendments underscore anything, let alone meet the high standard for clear and unmistakable disavowal.

Finally, PO asserts that Petitioner’s experts “talked about caps as a separate component from the valve,” and this supports PO’s construction. POPR, 14. PO cites Dr. Fischetti’s declaration (Ex. 2005, 9), but the cited page is literally just a copy of claim 1 of the ’646 patent. PO also cites Mr. Leinsing’s deposition testimony from the district court (Ex. 2004), but Mr. Leinsing was opining on non-infringement of the accused product, Spectrum’s SDNA device. *See* Ex. 2004, 24:3-9, 28:8-12. The expert testimony provides no support for PO’s proposed construction of “cap.”

Dated: January 25, 2024 By: /Benjamin B. Anger/

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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 AUTHORIZED PRELIMINARY REPLY BRIEF AND EXHIBIT 1021** is being served electronically on January 25, 2024, to the e-mail addresses shown below:

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