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Paper 12
Date: January 23, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADVANCE MEDICAL DESIGNS, INC.,
Petitioner,

v.

CORBIN CLINICAL RESOURCES, LLC,
Patent Owner.

PGR2023-00041
Patent 11,547,436

Before ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and JAMIE T. WISZ, *Administrative Patent Judges.*

WISZ, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 325(d)

I. INTRODUCTION

Advance Medical Designs, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting a post-grant review of claims 1, 4–6, 11–13, 16–18, 23, 24, 28, and 29 of U.S. Patent No. 11,547,436 (Ex. 1001, "the '436 Patent"). Corbin Clinical Resources, LLC ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

Under 35 U.S.C. § 324(a), a post-grant review may not be instituted "unless . . . the information presented in the petition . . . , if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." The Board has discretion to deny a request for institution when the information presented shows a petitioner raises "the same or substantially the same prior art or arguments previously presented to the Office," for example, during patent examination. 35 U.S.C. § 325(d).

Upon considering the arguments and evidence, we exercise our discretion to deny institution of post-grant review under 35 U.S.C. § 325(d).

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies itself, Advance Medical Designs, Inc., as the real-party-in-interest. Pet. 1. Patent Owner identifies itself, Corbin Clinical Resources, LLC, as the real party-in-interest. Paper 4, 2.

B. Related Proceedings

Both parties identify the following as a related proceeding: *Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC,* No. 1:22-cv-00789-SAG (D. Md.) ("the Maryland District Court litigation").

C. The '436 Patent (Ex. 1001)

The '436 patent relates to methods of performing a transperineal biopsy procedure using "a biopsy guide configured to couple with a transrectal probe and for use in guiding an access needle in a transperineal prostate biopsy procedure." Ex. 1001, 2:29–32. Prostate biopsy procedures include transrectal ultrasound-guided (TRUS) biopsies and transperineal ultrasound-guided (TPUS) biopsies. *Id.* at 1:47–49. TRUS procedures present multiple disadvantages, including requiring the patient to take antibiotics prior to the procedure, requiring the patient to perform bowel preparation, and increased risk of infection or other complications. *Id.* at 1:55–64.

The '436 patent discloses real-time visualization, free-handed, guided, and multi-sample transperineal methods for performing a biopsy. Ex. 1001, 9:3–5. According to the '436 Patent, the methods also enable a complete biopsy of the prostate with only one perforation. *Id.* at 9:6–10. The '436 patent describes how the biopsy is performed using a biopsy guide as depicted in Fig. 30 shown below.

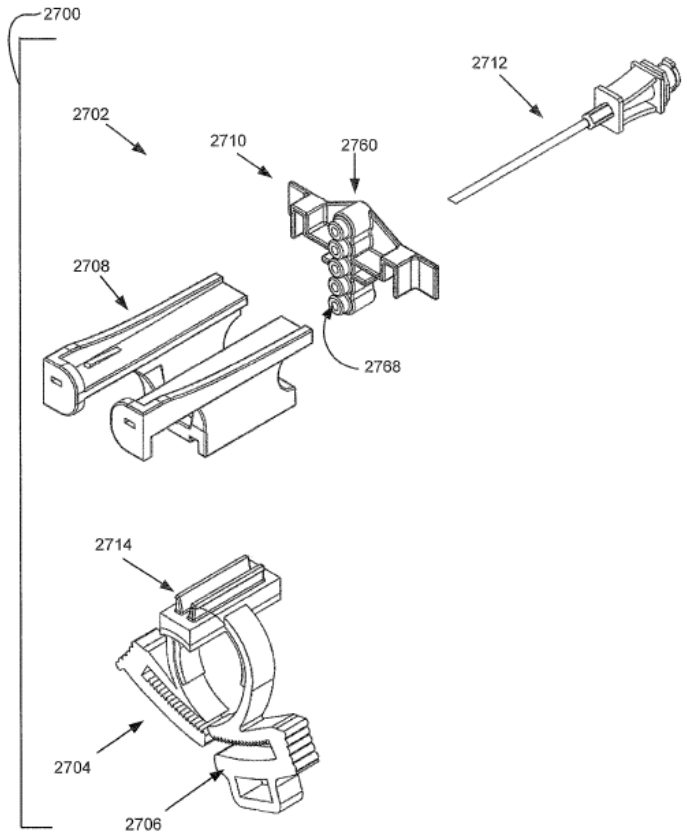


FIG. 30

Id. at Fig. 30. Figure 30 shows a biopsy guide according to the '436 patent. The biopsy guide 2700 includes an upper mount 2702 and a lower mount 2704. *Id.* at 20:12–14. The lower mount 2704 includes a probe coupling or fastening mechanism 2706. *Id.* at 20:14–15. This fastening mechanism 2706 couples the lower mount 2704 with a transrectal probe. *Id.* at 20:15–17. The lower mount 2704 includes an upper mount coupling mechanism 2714 to couple the lower mount 2704 with the upper mount 2702. *Id.* at 20:17–20.

The upper mount 2702 may couple with the lower mount 2704 and may include a guide member 2708. Ex. 1001, 20:24–26. An access needle can be inserted into a needle receiving port 2768 on a displacement

member 2710 and then coupled to the needle receiving port 2768, for example by using ridges and/or threading. *Id.* at 25:58–26:7. The displacement member 2710 slides along the guide member 2708 to displace the access needle and displacement member along a trajectory fixed relative to the guide member 2708. *Id.* at 20:24–37.

As shown in Figure 34 below, the access needle 2712 includes a hub 2846 and a lumen 2844 for receiving "a shaft of a smaller gauge biopsy needle." Ex. 1001, 25:1–11.

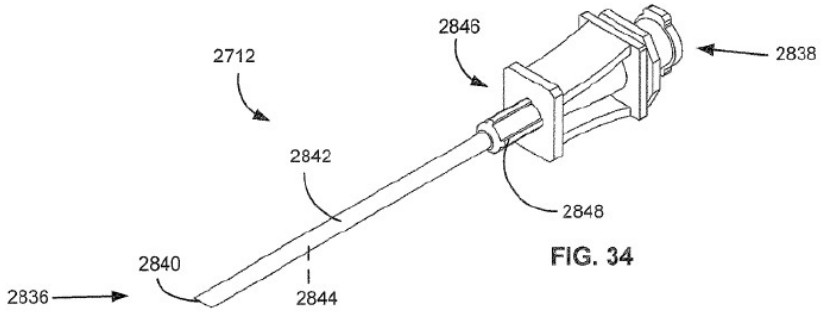


FIG. 34

Id. at Fig. 34. Figure 34 is an isometric view of an access needle 2712. Once the access needle 2712 is in position in the patient's perineum, the physician inserts a biopsy needle through the lumen 2844 of the access needle into the prostate to biopsy a target location. *Id.* at 27:6–10. According to the '436 patent, the access needle "can reduce or eliminate multiple skin perforations by using a single access location or access site, while allowing multiple extractions of tissue or cell specimens from the prostate." *Id.* at 9:47–50.

D. Challenged Claims

Petitioner challenges claims 1, 4–6, 11–13, 16–18, 23, 24, 28, and 29 of the '436 patent. Claims 1, 13, and 24 are independent claims, and are reproduced below:

1. [Pre] A method of performing a transperineal biopsy procedure on a prostate of a patient using a transrectal ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the transrectal ultrasound probe including a shaft and a handle proximal to the shaft, the method comprising:

[1.1] inserting an access needle into the perineal access site of the patient, [1.2] the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub, [1.3] the tubular shaft including a lumen sized to receive a biopsy needle therethrough;

[1.4] inserting at least a portion of the tubular shaft of the access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide, [1.5] the transperineal biopsy guide comprising: a mount releasably coupled to the transrectal ultrasound probe; [1.6] a guide member coupled to the mount; and [1.7] the displacement member configured to slide relative to the guide member and including a vertically extending member including the plurality of needle receiving ports;

[1.8] coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained; and

[1.9] inserting the biopsy needle through the access needle and into a first location of the prostate of the patient.

Ex. 1001, 35:46–36:7 (annotated with bracketed numbers).

13. [Pre] A method of performing a transperineal biopsy procedure on a prostate of a patient using a transrectal ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the transrectal ultrasound probe including a shaft and a handle proximal to the shaft, the method comprising:

> [13.1] inserting an access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide that is secured to the transrectal ultrasound probe, [13.2] the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub, [13.3] the tubular shaft including a lumen sized to receive a biopsy needle therethrough, [13.4] the transperineal biopsy guide comprising a mount configured to releasably couple to the transrectal ultrasound probe, [13.5] a guide member extending from the mount, and [13.6] the displacement member configured to slide relative to the guide member;
>
> [13.7] securing the access needle to the displacement member such that a position and angle of the access needle relative to the displacement member is maintained;
>
> [13.8] imaging the prostate of the patient with the transrectal ultrasound probe;
>
> [13.9] inserting the access needle into the perineal access site of the patient; and
>
> [13.10] inserting the biopsy needle through the access needle and into the prostate of the patient.

Id. at 36:41–67 (annotated with bracketed numbers).

> 24. [Pre] A method of performing a transperineal biopsy procedure on a prostate of a patient using an ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the ultrasound probe including a shaft and a handle proximal to the shaft, the method comprising:
>
> [24.1] inserting an access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide that is secured to the ultrasound probe, [24.2] the access needle including a tubular shaft and a lumen extending through the tubular shaft, [24.3] the lumen sized to receive a biopsy needle therethrough, [24.4] the transperineal biopsy guide operably coupled to the ultrasound

> probe and [24.5] including a guide member and the displacement member, [24.6] the displacement member configured to slide relative to the guide member;
>
> [24.7] securing the access needle to the one of a plurality of needle receiving ports of the displacement member such that position and angle of the access needle relative to the displacement member is maintained and further insertion of the access needle relative to the displacement member is restricted;
>
> [24.8] imaging the prostate of the patient with the ultrasound probe;
>
> [24.9] inserting the access needle into the perineal access site of the patient; and
>
> [24.10] inserting the biopsy needle through the access needle and into a first location of the prostate of the patient.

Id. at 37:33–38:14 (annotated with bracketed numbers). Challenged claims 4–6, 11, and 12, depend, directly or indirectly, from claim 1. Challenged claims 16–18 and 23 depend, directly or indirectly, from claim 13. Challenged claims 28 and 29 depend directly from claim 24.

E. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1, 4–6, 11–13, 16–18, 23, 24, 28, and 29 are unpatentable in view of the following grounds.

Ground	Claims Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1	1, 4–6, 12, 13, 16–18, 24, 28	103	Novella[2] BK Medical[3]
2	11, 23, 29	103	Novella BK Medical Zangos[4]
3	1, 4–6, 12, 13, 16–18, 24, 28	103	Novella Onik[5] Nakamura[6]
4	11, 23, 29	103	Novella Onik Nakamura Zangos

Pet. 3–4. Petitioner relies on the Declarations of Dr. Edward Yun (Ex. 1003), Dr. Ingrid Hsiehi-Yee (Ex. 1013), Nico Eelbode (Ex. 1014), and Dr. František Záťura (Ex. 1015) in support of institution of post-grant review.

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[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the '436 patent claims priority to applications that were filed after this date, the post-AIA version of § 103 applies to this proceeding.

[2] Giovanni Novella, et al., *Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle*, 62 UROLOGY 689 (2003) (Ex. 1005, "Novella").

[3] BK Medical, Prostate BiPlane Transducer Type 8808e, User Guide (June 2012) (Ex. 1007, "BK Medical").

[4] Stephan Zangos et al., *MR-Guided Transgluteal Biopsies with an Open Low-Field System in Patients with Clinically Suspected Prostate Cancer: Technique and Preliminary Results*, 15 EUR. RADIOL. 174 (Sept. 4, 2004) (Ex. 1010, "Zangos").

[5] Onik et al., U.S. Patent No. 5,494,039, issued Feb. 27, 1996 (Ex. 1011, "Onik").

[6] Japanese Patent No. 4,550,531, published Sept. 22, 2010 (Ex. 1012, "Nakamura").

III. BACKGROUND

A. Person of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner describes the person of ordinary skill in the art (POSA) as having:

> at least an advanced medical degree (e.g., a Doctor of Medicine or a Doctor of Osteopathic Medicine), at least two years of experience performing prostate biopsy procedures, and some exposure to transperineal prostate biopsies and medical device design. Less experience may be compensated by more or different education or vice versa.

Pet. 14 (citing Ex. 1003, ¶12). Patent Owner does not provide a definition for a person of ordinary skill in the art. We adopt Petitioner's definition and find that is it consistent with the level of ordinary skill in the art at the time of the invention as reflected in the prior art in this proceeding. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.200(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

1. Petitioner's Position

Petitioner contends that no express constructions are needed to resolve the grounds of the Petition. Pet. 14. However, Petitioner does discuss the scope of the claim terms "coupling" (limitation [1.8]) in claim 1 and "securing" (limitations [13.7] and [24.7]) in claims 13 and 24. Pet. 14–15. Specifically, Petitioner asserts that the "coupling" and "securing" limitations, "do not require locking the access needle in place to completely prevent any movement of the access needle." Pet. 15 (citing Ex. 1003, ¶¶ 37–41).

In support of their proposed construction, Petitioner contends that "[d]ependent claims 10, 22, 25, and 26 recite inserting a portion of the access needle hub or other structure into one of the needle receiving ports, which would restrict the access needle beyond that required by the independent claims." *Id.* Petitioner cites to disclosure from the '436 patent specification that describes an embodiment in which the access needle hub may have "ridges 2848 [that] engage with corresponding negatively shaped features on . . . the needle receiving ports 2768" so "access needle 2712 may be restrained from rotating by the ridges 2848." *Id.* at 15–16 (citing Ex. 1001, 25:11–13, 25:64–26:2, Fig. 34). Petitioner also cites to the

specification's disclosure of "threaded features on the hub 2846 and openings 2770 of the ports 2768," which allow "needle 2712 and the displacement member 2710 [to] be threadably engaged and disengaged with each other" (i.e., "screwing" the access needle into the port). *Id.* at 16 (citing Ex. 1001, 26:2–7). According to Petitioner, "the independent claims do not require such structure or completely locking the access needle to the displacement member." *Id.*

Petitioner also asserts that Patent Owner's infringement contentions in the co-pending Maryland District Court litigation support Petitioner's construction. Pet. 16 (citing Ex. 1003 ¶ 40; Ex. 1007, 12; Ex. 1019). According to Petitioner, "Patent Owner does not contend that 'coupling' or 'securing' an access needle on the [accused product] completely locks the access needle in place on the needle guide—only that it 'maintain[s] the stability and directionality of the coaxial needle or the puncture needle.'" *Id.* at 17 (citing Ex. 1019, 22). Petitioner concludes by asserting that the terms "coupling" and "securing" should be construed "not to require locking the access needle in place but maintaining the stability and directionality of the access needle." *Id.*

2. Patent Owner's Position

Patent Owner argues that these limitations should be given their plain and ordinary meaning based on a reading of the claims and that Petitioner's proposed construction should not be adopted. Prelim. Resp. 32–40. According to Patent Owner, Petitioner's proposed construction replaces the words "coupling" or "securing" the access needle with "inserting" the access needle. *Id.* at 34 (citing Ex. 2008, 26). Patent Owner further asserts that Petitioner's construction "erases the recitation in the claims that 'a position

and angle of the access needle relative to the displacement member is retained[/maintained]' and replaces it with 'wherein the needle receiving port is configured to support the access needle at an angle and position relative to the displacement member.'" *Id.* (citing Ex. 2008, 26).

3. Analysis

We agree with Patent Owner that the terms "coupling" and "securing" are defined by the claims themselves. For example, claim 1 recites "*coupling the access needle* to one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide *such that a position and angle of the access needle relative to the displacement member is retained*." Ex. 1001, 36:1–5 (emphasis added). Similarly, claim 13 recites "*securing the access needle* to the displacement member *such that a position and angle of the access needle relative to the displacement member is maintained*." *Id.* at 36:59–61 (emphasis added).

Petitioner has not provided any persuasive evidence from the specification or file history to support its proposed construction that "coupling" should "not [] require locking the access needle in place but maintaining the stability and directionality of the access needle." Pet. 17. While Petitioner points to the dependent claims as support for their proposed construction, we agree with Patent Owner that the dependent claims describe embodiments demonstrating how the "coupling" or "securing" may occur. Prelim. Resp. 37. For example, claim 10 states, "wherein coupling the access needle to one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide comprises inserting a portion of the hub into one of the plurality of needle receiving ports." Ex. 1001, 36:32–36. As asserted by Patent Owner, the "hub" of claim 10 is

the specific method of "coupling" the access needle to the needle receiving port of claim 1. Prelim. Resp. 37.[7]

We also agree with Patent Owner that the terms "coupling" and "securing" must mean something more than "inserting" because the claims already require "inserting" an access needle and separately "coupling" or "securing" the access needle. Prelim. Resp. 35–36. For example, claim 1 requires the step of "inserting at least a portion of the tubular shaft of the access needle into one of a plurality of needle receiving ports" (limitation [1.4]) and separately requires the step of "coupling the access needle to the one of the plurality of needle receiving ports of the displacement member…" (limitation [1.8]). Ex. 1001, 35:58–60; 36:1–3. Similarly, independent claim 13 requires "inserting an access needle into one of the plurality of needle receiving ports of a displacement member . . ." (limitation [13.1]) and separately requires the step of "securing the access needle to the displacement member." (limitation [13.7]). *Id.* at 36:47–48, 36:59–60.

Thus, for purposes of this Decision, we determine that the terms "coupling" and "securing" should be given their plain and ordinary meaning in the context of the claim language such that, for claim 1, the access needle is "coupl[ed]" to "the one of the plurality of needle receiving ports of the displacement member . . . such that a position and angle of the access needle

[7] We are also not persuaded by Petitioner's arguments regarding Patent Owner's infringement contentions in the co-pending Maryland District Court litigation because the infringement contentions cite to the use of an adaptor in the accused product for "coupling the access needle to the one of the plurality of needle receiving ports." Ex. 1019, 22. We, therefore, do not find this evidence to be particularly instructive on the proposed claim construction of "coupling" with respect to other potential embodiments.

relative to the displacement member is retained." For claim 13, the access needle is "secur[ed]" to "the access needle in the displacement member such that a position and angle of the access needle relative to the displacement member is maintained." Lastly, for claim 24, the access needle is "secur[ed]" to "the one of a plurality of needle receiving ports of the displacement member such that position and angle of the access needle relative to the displacement member is maintained." For purposes of this Decision, we also clarify that "coupling" and "securing" do not simply mean "inserting." *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

C. Asserted Prior Art

1. Novella (Ex. 1005)

Novella, titled, "Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle," describes a study that compared two variations of transperineal prostate biopsy procedures: (1) with a biopsy needle alone and (2) with a coaxial needle. Ex. 1005, abstract. Novella aimed to "assess whether the use of a coaxial needle reduces discomfort in patients undergoing multiple-core transperineal prostate biopsy to detect prostate cancer." *Id.* Novella concluded that the coaxial technique was

"significantly less painful" for patients than those using the biopsy needle alone. Ex. 1005, 1.[8]

2. BK Medical (Ex. 1007)

BK Medical is a User Guide for BK Medical Type 8808e Prostate Biplane Transducer (2012). Ex. 1007. BK Medical describes the BK Medical Type 8808e ultrasound transducer and its UA1324 transperineal biopsy guide as shown below:



Figure 7. Puncture attachment UA1324.



Figure 8. Puncture attachment UA1324 mounted on 8808e.

[8] The cited page numbers in Exhibit 1005 refer to the bates numbers of the document.

Id. at 12.[9] Figure 7 from BK Medical shows the puncture attachment UA1324 and Figure 8 shows the puncture attachment UA1324 mounted on the 8808e ultrasound transducer.

BK Medical discloses that the UA1324 puncture attachment has a needle guide and a mounting ring with a clamp. Ex. 1007, 12. The needle guide has "9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle." *Id.* The guide is parallel to the transducer. *Id.* The positioning of the transducer and the needle in UA1324 puncture attachment allows for puncture lines that are parallel to the transducer. *Id.* at 13.

3. Zangos (Ex. 1010)

Zangos, titled, "MR-guided transgluteal biopsies with an open low-field system in patients with clinically suspected prostate cancer: technique and preliminary results," describes a study that examined the feasibility and safety of MR-guided biopsies with a transgluteal approach in patients with prostate lesions. Ex. 1010, 1.[10] The study found that "[t]ransgluteal MR-guided biopsy of the prostate gland is a safe and promising approach for histological clarification of uncertain or suspicious lesions." *Id.*

4. Onik (Ex. 1011)

Onik, titled, "Biopsy Needle Insertion Guide and Method of Use in Prostate Cryosurgery," is a U.S. Patent issued in 1996 that discloses "[a]

[9] The cited page numbers in Exhibit 1007 refer to refer to the bates numbers of the document.

[10] The cited page numbers in Exhibit 1010 refer to the bates numbers of the document.

biopsy needle insertion guide and method of use with an ultrasound probe in medical procedures to accurately position biopsy needles in internal issues." Ex. 1011, code (57). Onik discloses that the insertion guide is "securely mountable on and useable with a rectally inserted ultrasound probe to insert biopsy needles into the prostate at specific target points identified on an ultrasound image of the prostate." *Id.* at 1:10–14. Onik's insertion guide is shown in Figure 1 below:

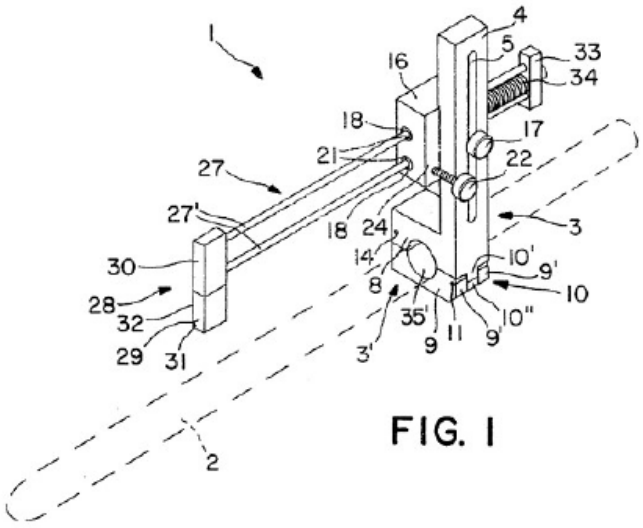


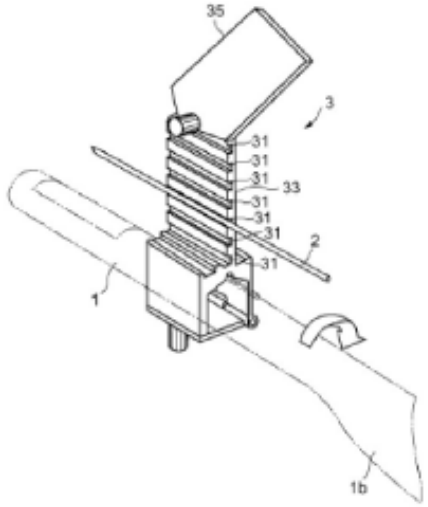
FIG. 1

Ex. 1011, Figure 1. Figure 1 from Onik is a perspective view of the insertion guide mounted on an ultrasound probe. *Id.* at 2:66–67. Onik discloses that guide block 29 of guide assembly 27 has "an elongated notch 31 in one face adjacent the lower end of block 29," such as "a simple 'V' notch" that "provide[s] guidance for a biopsy needle being inserted." *Id.* at 5:39–46.

5. Nakamura (Ex. 1012)

Nakamura, titled "Puncture Adapter," is a Japanese patent publication that discloses "a puncture adapter for transperineal puncture, mounted on a

transrectal probe" in which "a puncture needle is inserted into a subject to sample or treat tissue in an affected area." Ex. 1012, 18–19.[11] The puncture adapter of Nakamura is shown below:



Id. at Figure 10.

To perform a transperineal procedure, "transrectal probe 1 is inserted into the rectum of a patient, an ultrasonic linear cross-sectional image is referenced, the … transrectal probe 1 is controlled with one hand, the puncture needle 2 is held in the other hand, and the puncture needle 2 is inserted at a site where examination or treatment is being performed. Ex. 1012, 25. The practitioner selects "a guide hole corresponding to a target position … from the plurality of guide holes," "puncture needle 2 is entered into the selected guide hole, and the puncture needle 2 is inserted" into the treatment area. *Id.*

[11] The cited page numbers in Exhibit 1012 refer to the bates numbers of the document.

IV. DENIAL UNDER 35 U.S.C. § 325(d)

Patent Owner asserts that we should deny the Petition under 35 U.S.C. § 325(d) because the Petition presents the same or substantially the same art that the Office previously analyzed and Petitioner fails to show that the Office erred during prosecution. Prelim. Resp. 10–20.

We have discretion to deny review when "the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d) ("Section 325(d)"). In that respect, Section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based on matters previously presented to the Office.[12] *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7 (PTAB Feb. 13, 2020) (precedential) ("*Advanced Bionics*").

In evaluating the exercise of discretion to deny institution under Section 325(d), the Board uses the following two-part framework: (1) determining whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, determining whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics*, Paper 6 at 8.

In applying the two-part framework, we consider several non-exclusive factors, including:

[12] The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

> (a) the similarities and material differences between the asserted art and the prior art involved during examination;
>
> (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
>
> (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
>
> (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art or patent owner distinguishes the prior art;
>
> (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and
>
> (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) ("*Becton, Dickinson*").

Factors (a), (b), and (d) of the *Becton, Dickinson* factors relate to whether the art or arguments presented in the Petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, Paper 6 at 10. Factors (c), (e), and (f) "relate to whether the petitioner has demonstrated a material error by the Office" in its prior consideration of that art or arguments. *Id.* Only if the same or substantially the same art or arguments were previously presented to the Office do we then consider whether petitioner has demonstrated a material error by the Office. *Id.* "At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown." *Id.* at 9.

A. The '436 Patent Prosecution History

The original application for the '436 patent was filed with twenty-four claims. Ex. 1002, 390–429.[13] In a Non-Final Office Action on May 25, 2022, the Examiner rejected claims 1–24 as anticipated by Whitmore.[14] Ex. 1002, 208–210. In an August 25, 2022 response, the applicant argued, *inter alia*, that "[n]owhere in Whitmore is there description of an access needle or inserting an access needle into the perineal access site of the patient" or any "description of inserting a biopsy needle through the access needle." *Id.* at 198.

The applicant also submitted an Information Disclosure Statement ("IDS") on August 26, 2022, which included Zangos and Plaintiff's [Petitioner's] Initial Invalidity Contentions, dated August 1, 2022, from the co-pending Maryland District Court litigation.[15] Ex. 1002, 178–79. The Invalidity Contentions identified Novella, Onik, BK Medical, and Zangos as "prior art . . . on which [Petitioner] may rely to contend that the Asserted Claims are invalid as anticipated and/or obvious under 35 U.S.C. §§ 102, 103." Ex. 2012, 5–7. The Examiner indicated that Zangos and the

[13] The cited page numbers in Exhibit 1002 refer to the bates numbers of the document.

[14] Whitmore, III et al., U.S. Patent No. 5,931,786, issued Aug. 3, 1999 ("Whitmore").

[15] At the time of the filing of the IDS with Plaintiff's Initial Invalidity Contentions, related patents U.S. Patent Nos. 10,064,681 ("the '681 patent"), 11,096,762 ("the '762 patent"), and 11,246,677 ("the '677 patent"), were involved in the Maryland District Court litigation. Ex. 2012, 1. The '436 patent was not yet part of the litigation because it had not issued yet.

Invalidity Contentions were considered during examination. Ex. 1002, 175–176.

A telephonic interview was held between applicant's attorney and the Examiner on September 22, 2022 and an Interview Summary filed by applicant indicated that the response to the Non-Final Office Action was discussed, in particular, the arguments regarding Whitmore. Ex. 1002, 26. According to the Interview Summary, "[t]he Examiner agreed with the arguments presented and suggested a clarifying amendment to the claims to recite 'securing position and angle of the access needle relative to the displacement member.'" *Id.*

The Examiner then issued a Notice of Allowance on October 4, 2022, in which the Examiner amended claim 1 by adding the limitation of:

> inserting at least a portion of the tubular shaft of the access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide, the transperineal biopsy guide comprising: a mount releasably coupled to the transrectal ultrasound probe; a guide member coupled to the mount; and the displacement member configured to slide relative to the guide member and including a vertically extending member including the plurality of needle receiving ports.

Ex. 1002, 35. The Examiner also replaced the limitation in claim 1 of:

> coupling the access needle to one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide such that a position of the access needle relative to the displacement is retained, the transperineal biopsy guide comprising: a mount releasably coupled to the transrectal ultrasound probe; a guide member coupled to the mount; and the displacement member configured to slide relative to the guide member and including a vertically extending member including the plurality of needle receiving ports"

with:

> coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained.

Id. at 36.

In the Reasons for Allowance, the Examiner stated that the closest prior art of record are Whitmore, Onik, Yap,[16] and Baumann.[17] Ex. 1002, 36. The Examiner also stated that:

> none of the prior art alone or in combination teaches the limitations of the independent claim specifically, "coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained."

Id. at 36–37.

B. Same or Substantially the Same Art or Arguments Previously Presented to the Office

We first consider whether Petitioner asserts the same or substantially the same art or arguments that previously were presented to the Office. *Advanced Bionics*, Paper 6 at 8.

Petitioner's grounds rely on five references—Novella, BK Medical, Zangos, Onik, and Nakamura—to show obviousness of the challenged claims. Pet. 3–4. Zangos was submitted in an IDS in the '436 patent and Onik was cited by the Examiner. Ex. 1002, 36, 178–79, 213. Both

[16] Yap et al., U.S. Pub. No. 2015/0366544, published Dec. 24, 2015 ("Yap").

[17] Baumann et al., U.S. Pub. No. 2015/0119715, published Apr. 30, 2015 ("Baumann").

references appear on the face of the '436 patent. Ex. 1001, code (56). Novella and BK Medical were cited in Plaintiff's Initial Invalidity Contentions from the co-pending Maryland District Court litigation, which was also submitted in an IDS. Ex. 1002, 76; Ex. 2012, 17. Novella and a product data sheet for BK Medical (Type 8808e probe), along with a User Guide for a similar Type 8818 BK Medical probe, were also cited in a grandparent application to the '436 patent. Ex. 1020, 73, 354–57, 364–67, 457–74 ("Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent." *Advanced Bionics*, Paper 6 at 7–8).

Therefore, the only reference that was not previously considered by the Examiner is Nakamura. Patent Owner contends, and we agree, that Petitioner relied on Nakamura for the limited teaching of a "plurality" of needle receiving ports. Prelim. Resp. 14 (citing Pet. 84–85). Patent Owner also contends that this teaching is substantially the same teaching as in other prior art considered by the Examiner, including the Whitmore reference, which was used in a rejection during prosecution. *Id.* (citing Ex. 1002, 209 (Examiner citing Whitmore's teaching of a "plurality of holes for needle access element 70"). We agree with Patent Owner that Nakamura's teaching of a "plurality" of needle receiving ports is cumulative to Whitmore's teaching of the same.

Thus, we find that the same or substantially the same art was previously presented and we move on to the second part of the *Advanced Bionics* framework.

C. Whether the Office Erred in a Manner Material to Patentability

Because we find that the same or substantially the same art previously was presented to the Office, we turn to whether Petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 8, 10; *see Becton, Dickinson*, Paper 8 at 24. We conclude that Petitioner has failed to do so.

1. The Parties' Positions

Petitioner asserts that none of their references—Novella, BK Medical, Onik, Nakamura, or Zangos—served as the basis for a rejection, and thus, "were not properly evaluated or appreciated during prosecution." Pet. 108–109. Specifically, Petitioner alleges that the Examiner's statement that Whitmore, Onik, Yap, and Baumann were the closest prior art shows that the Examiner did not appreciate the significance of Novella or BK Medical because the references cited by the Examiner do not disclose (1) a probe-mounted transperineal biopsy guide with multiple needle-receiving channels or (2) performing a transperineal biopsy with a coaxial/access needle. *Id.* at 109–110. Petitioner also argues that, although the Examiner stated that Onik does not "alone or in combination" teach "coupling the access needle to the one of the plurality of needle receiving ports . . . ," the Examiner overlooked that Novella, when combined with Onik and Nakamura, render this feature obvious. *Id.* at 110 (citing Ex. 1002, 36–37). Petitioner also cites to the testimony from their declarants, Dr. Yun and Dr. Záťura, as well as Exhibit 1009, as additional facts and evidence that warrant institution. *Id.* at 110–111 (citing Ex. 1003, Ex. 1009, Ex. 1015).

Petitioner further argues that the Office granted *ex parte* reexamination of a related patent (U.S. Patent No. 11,446,056), and found a

substantial new question of patentability based on the same four grounds presented in the Petition. Pet. Reply 5. According to Petitioner, the granting of the reexamination "objectively shows" that the Office materially erred in considering Petitioner's prior art during prosecution. *Id.*

According to Patent Owner, "Petitioner's alleged error is nothing more than that the '436 Patent was allowed without the Examiner issuing a rejection over the art cited in the PGR," which is not sufficient to show material error. Sur-Reply 3. Patent Owner also argues that "Petitioner does not show that the Examiner failed to comprehend the scope of the claims or the prior art since neither Novella nor BK Medical teach the Examiner's noted reason for allowance." As referenced above, the Examiner stated that none of the prior art alone or in combination teaches the limitation of, "coupling the access needle to one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained." Prelim. Resp. 17 (citing Ex. 1002, 36–37).

Patent Owner further argues that Plaintiff's Initial Invalidity Contentions from the co-pending litigation, which "presented Novella in combination with BK Medical and Novella in combination with Onik just as they are presented in the PGR petition" were submitted to the Examiner during prosecution. Prelim. Resp. 17–19 (citing Ex. 1002, 176; Ex. 2012, 13, 17). According to Patent Owner, the fact "that the Examiner did not agree with those arguments is not material error." Sur-Reply 4.

2. Analysis

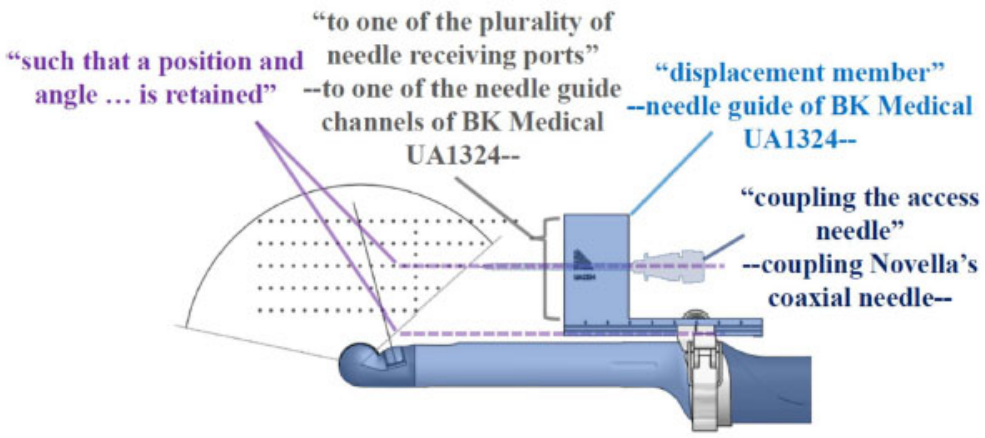
In order to assess whether Petitioner has sufficiently demonstrated that the Office committed a material error, we analyze whether Petitioner

has sufficiently shown that the art cited by Petitioner contradicts the Examiner's Reason for Allowance, namely, that the prior art alone or in combination does not teach the limitation of "coupling the access needle to one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained." Ex. 1002, 36–37. We analyze below Petitioner's arguments regarding this limitation.[18]

a. Asserted Obviousness over Novella and BK Medical

Petitioner asserts that claims 1, 4–6, 12, 13, 16–18, 24, and 28 are obvious over Novella in view of BK Medical. Pet. 3. Specifically, with regard to the "coupling the access needle" limitation, Petitioner contends that this limitation is rendered obvious by "coupling Novella's coaxial needle (access needle) to one of the nine parallel needle guide channels (needle receiving ports) of the needle guide (displacement member) of UA1324 (transperineal biopsy guide) [of BK Medical], such that a position and angle of the coaxial needle (access needle) relative to the needle guide (displacement member) is retained, as claimed." Pet. 58. Petitioner provides the figure below showing the proposed Novella-BK Medical combination in support of this argument:

[18] Petitioner argues this limitation for grounds 1 and 3, while grounds 2 and 4 are directed to dependent claims 11, 23, and 29. *See* Pet. 3–4,



Id. The figure above shows Petitioner's proposed combination of Novella's access needle with the transperineal biopsy guide of BK Medical.

According to Petitioner, "[i]n combination, Novella's coaxial needle (access needle) is coupled within a selected guide channel (needle receiving port) of UA1324 (transperineal biopsy guide)." Pet. 59 (citing Ex. 1003 ¶ 105). Petitioner further contends that, "once coupled within a needle guide channel, a longitudinal position and parallel angle of the coaxial needle (access needle) relative to the UA1324 needle guide (displacement member) are retained." *Id.* (citing Ex. 1003 ¶ 105; Ex. 1007, 12 (The "9 parallel guide channels" align with the puncture lines and run "parallel to the centerline of the transducer").

As discussed *supra*, Petitioner asserts that the "coupling" limitation does not completely require locking the access needle in place to prevent any movement of the needle. Pet. 59. According to Petitioner,

> the needle channel maintains the stability of the access needle's direction parallel to the centerline of the transducer. When in the channel, the access needle cannot rotate in the plane of the vertical needle guide fin. The needle channel also maintains

> and stabilizes the vertical position of the needle relative to the probe. And, once inserted up to its hub, the needle channel maintains and stabilizes the axial position of the access needle in the direction of the probe's centerline.

Id. at 59–60 (citing Ex. 1003 ¶ 107; Ex. 1007, 12–13) (internal citations omitted).

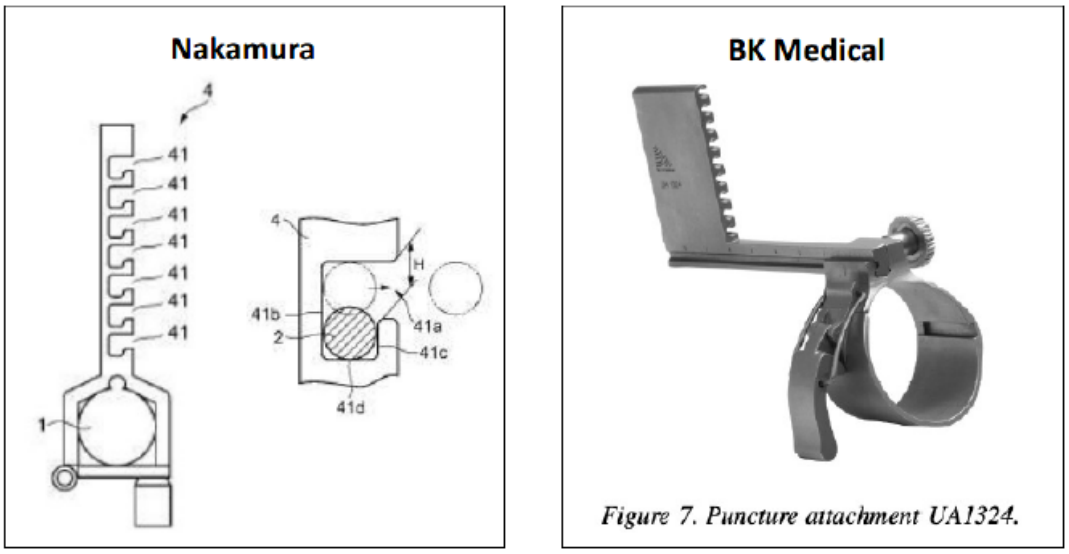
Patent Owner contends that Petitioner's argument is "premised on Petitioner's incorrect understanding that "inserting" a needle into a port is the same as "coupling" a needle to that port." Prelim. Resp. 41 (citing Pet. 59). In contrast, according to Patent Owner, claim 1 requires that an access needle is both inserted and coupled to a needle receiving port. *Id.*

Patent Owner also argues that Petitioner relies on conclusory expert testimony to supports its argument that BK Medical's needle guide "maintains and stabilizes" the needle position and that such testimony is contradicted by Nakamura, one of Petitioner's other cited references. Prelim. Resp. 44–47 (citing Ex. 1012, 19–20, Fig. 16, Fig. 17). According to Patent Owner, Nakamura explains that needle guides like the one disclosed in BK Medical were known to not maintain the needle's vertical or horizontal positions during insertion. *Id.* at 45 (citing Ex. 1012, 20).

First, we agree with Patent Owner that Petitioner appears to be using the term "coupling" the same as the term "inserting" in its obviousness analysis. As discussed *supra*, claim 1 requires "inserting at least a portion of the tubular shaft of the access needle into one of a plurality of needle receiving ports . . . " (element [1.4]), as well as "coupling the access needle to the one of the plurality of needle receiving ports." (element [1.8]). Ex. 1001, 35:57–61, 36:1–2.

Further, although Petitioner contends that BK Medical's needle guide "maintains and stabilizes" the needle position, they provide no explanation as to how it does so and do not appear to account for forces that would move the position of the needle during insertion. Petitioner cites to testimony from their declarant, Dr. Yun, to provide support for this argument; however, Dr. Yun's testimony is essentially a verbatim repetition of Petitioner's argument without a discussion of *how* BK Medical's needle guide provides such stability. *Compare* Pet. 59–60 *with* Ex. 1003 ¶ 107. Thus, we accord little weight to Dr. Yun's testimony on this topic. 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."); *see also Xerox Corp. et al., v. Bytemark*, IPR2022-00624, Paper No. 9 at 15 (PTAB Aug. 24, 2022) (precedential) ("Conclusory expert testimony "is particularly problematic in cases where, like here, expert testimony is offered not simply to provide a motivation to combine prior-art teachings, but rather to supply a limitation missing from the prior art.").

In addition, Nakamura, which discusses needle guides such as the one in BK Medical, discloses that such needle guides do not maintain the needle's horizontal or vertical positions. Ex. 1012, 20. The figures below show the similarity of the needle guide criticized by Nakamura (on the left) and the needle guide disclosed by BK Medical (on the right):



Nakamura Figs. 16 and 17 (left) and BK Medical Fig. 7 (right)

Ex. 1012, Fig. 16; Ex. 1007, Fig. 7. The figures above compare the needle guide disclosed in Nakamura with the needle guide disclosed in BK Medical. In discussing such needle guides, Nakamura states:

> However, in such a puncture adapter 4, the puncture needle 2 is inserted while being supported and guided by the guide walls in three directions, and **is not stable in the vertical direction**. Furthermore, when the puncture needle 2 rests on the open portion 41a during insertion, **it may not be stable in the horizontal direction either**, and the puncture needle 2 cannot be easily inserted.

Id. at 20 (emphasis added). We agree with Patent Owner that Nakamura demonstrates that the needle is subject to both vertical and horizontal movement while inside a needle guide similar to the one disclosed in BK Medical. Prelim. Resp. 46.

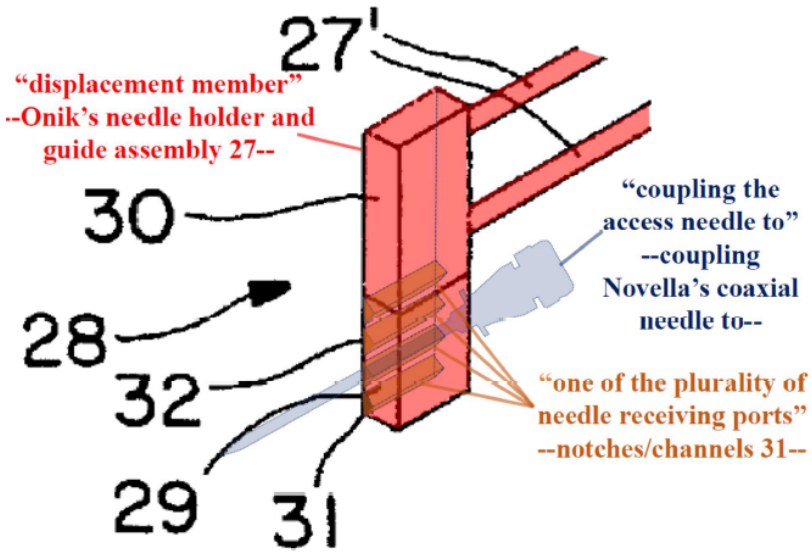
Thus, after reviewing the arguments and evidence discussed above, we find that Petitioner has not sufficiently demonstrated that the Examiner materially erred in finding that Novella and BK Medical did not disclose

"coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained."[19]

b. Asserted Obviousness over Novella, Onik, and Nakamura

Petitioner asserts that claims 1, 4–6, 12, 13, 16–18, 24, and 28 are obvious over Novella, Onik, and Nakamura. Pet. 4. With regard to the "coupling the access needle" limitation, Petitioner contends that it would have been obvious to use Onik's guide 1 in the coaxial needle biopsy procedures of Novella, where the Novella coaxial needle is coupled within needle receiving notch 31 of Onik's guide 1. Pet. 95. Petitioner also alleges that it would have been obvious based on Nakamura to add more needle receiving notches/channels to Onik's guide 2. *Id.* Thus, according to Petitioner, "the Novella-Onik-Nakamura combination includes coupling Novella's coaxial needle (access needle) to one of the plurality of notches/channels 31 (needle receiving ports) of guide assembly 27 (displacement member) of Onik's guide 1 (transperineal biopsy guide)" as shown in the figure below:

[19] Although we do not specifically discuss the "securing" limitation of claims 13 and 24, the same analysis would apply.



Novella-Onik-Nakamura Combination*

Pet. 95–96 (citing Ex. 1003 ¶ 184). The figure above shows Petitioner's proposed combination of Novella's access needle with Onik's needle holder and guide assembly, along with a plurality of needle receiving ports of Nakamura.

Petitioner contends that once the Novella coaxial needle is inserted within a selected notch, a position and parallel angle of the coaxial needle (access needle) relative to Onik's assembly 27 (displacement member) are retained. Pet. 96–97 (citing Ex. 1003 ¶ 185). Petitioner asserts that the notch maintains both the vertical position and the parallel direction of the needle relative to the probe, and thus, maintains the stability and directionality of the coaxial needle. *Id.* at 97 (citing Ex. 1003 ¶ 185; Ex. 1011, 5:42–46).

Petitioner further contends that, "though the claims do not require locking the access needle in place, Onik's guide block 29 has shield 30 for this purpose." Pet. 97 (citing Ex. 1003 ¶ 186). Petitioner cites to Figure 7 from Onik as well as its disclosure that, "[t]o ensure that the needle is

securely held in and guided by notch 31, shield 30 is provided with a spring tab 32 which has sufficient resiliency to allow it to be laterally displaced by insertion of a needle into slot 31 while remaining biased against the needle to hold it in place in slot 31." *Id.* (citing Ex. 1011, 5:45–51, Fig. 7).

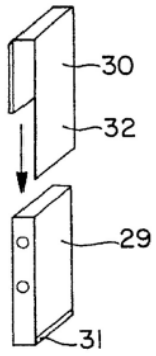


FIG. 7

Ex. 1011, Fig. 7. Figure 7 from Onik is a perspective view of the needle holder illustrating the guide block and shield. *Id.* at 3:11–12. Petitioner concludes that, "[i]n the combination, shield 30 holds Novella's coaxial needle in place in one of [the] notches/channels 31." Pet. 97 (citing Ex. 1003 ¶ 186).

Patent Owner contends that Petitioner's obviousness arguments are flawed for the same reasons as for ground 1 and also because Petitioner "ignores Onik's express teaching that the needle moves relative to the needle holder assembly (the alleged displacement member)." Prelim. Resp. 54 (citing Ex. 1011, 7:18–20, 7:28–35). Patent Owner asserts that Onik teaches locking the position of the needle holder assembly and then advancing the position of the coaxial needle into the patient. *Id.* at 54. Thus, according to Patent Owner, "Onik teaches to move a position of a needle relative to the alleged displacement device," rather than "retaining the position of a needle relative to the displacement device," as required by the claims. *Id.* at 54–55.

Patent Owner also argues that "Onik's shield designed to hold a needle in a notch at the bottom edge of the shield would not be operable to hold a needle in the additional notches proposed by Petitioner that extend further up the shield." *Id.* at 57–58.

As discussed *supra*, in order to show that the access needle is "coupl[ed]" to the needle receiving ports, Petitioner must show something more than merely "inserting" the access needle into the ports. We find that Petitioner has not sufficiently shown this for purposes of finding material error.

First, we agree with Patent Owner that Onik teaches that the needle moves relative to the needle holder assembly. Onik discloses that "probe 2 is advanced proximally until needle holder assembly 28 engages and bears firmly against the patient's perineum." Ex. 1011, 7:18–20. The position of the needle holder assembly is then "locked in place by tightening thumb screw 22." *Id*. at 7:22–24. As disclosed in Onik, when the position of the needle holder assembly is locked in place, the surgeon inserts a needle into notch 31 and advances the needle into the patient's prostate. *Id*. at 7:28–35. Thus, we agree with Patent Owner that Onik "instructs a POSITA to move the longitudinal position of the needle relative to the needle holder assembly when inserting the needle into the patient." Prelim. Resp. 54. Because Onik teaches moving a position of the needle relative to the displacement device, it does not teach retaining the position of the needle relative to the displacement device as required by claim 1. This is in contrast to the access needle in the '436 patent, which is "coupled" to the displacement device so that they retain their relative position and angle. *See* Ex. 1001, 2:40–46, 5:14–19, 26:30–56, 27:10–15 (disclosing how the access needle can be

advanced into the patient's body by pushing on the back wall of the displacement device or removed from the patient's body by pulling on the displacement device).

We are also not persuaded by Petitioner's argument regarding the shield of Onik. As discussed above, Onik discloses moving the longitudinal position of the needle relative to the needle holder assembly when inserting the needle into the patient. Petitioner does not show how the shield of Onik prevents such movement (or if this would even be desirable given the disclosure of Onik). Further, we agree with Patent Owner that, while Onik's shield is designed to hold a needle in a notch at the bottom edge of the shield, Petitioner does not sufficiently explain or address how "Onik's spring tab would maintain 'sufficient resiliency to allow it to be laterally displaced by insertion of a needle into' the additional notches proposed by Petitioner" that would extend further up the shield. *See* Prelim. Resp. 57–58.

As discussed above, in the Notice of Allowance for the '436 patent, the Examiner identified Onik as one of the closest pieces of prior art and found that "none of the prior art alone or in combination" teaches the limitation of "coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained." Ex. 1002, 36–37. After reviewing the arguments and evidence discussed above, we find that Petitioner has not sufficiently demonstrated that the Examiner materially erred in this

finding.[20] *Advanced Bionics*, Paper 6 at 9 ("[I]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.").

We also agree with Patent Owner that the grant of an *ex parte* reexamination of the '056 patent is not evidence itself of material error. Petitioner has provided no persuasive arguments or evidence for the assertion that the finding of a substantial new question of patentability in a related case with different claims provides evidence of a material error in this case, nor does Petitioner compare the claims of the '436 and '056 patents to show that the same limitations are relevant.[21]

D. Conclusion as to Section 325(d)

For the reasons set forth above, we do not institute review of claims 1, 4–6, 11–13, 16–18, 23, 24, 28, and 29 because, under 35 U.S.C. § 325(d), the same or substantially the same art previously was presented to the Office, and Petitioner has not shown that the Office erred in a manner material to patentability.

V. 35 U.S.C. § 324(a)

Patent Owner also contends that the Board should discretionarily deny institution of the post-grant review under 35 U.S.C. § 314(a) in view of the co-pending Maryland District Court litigation, pursuant to *Fintiv*. Prelim. Resp. 21–32; s*ee Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB

[20] Although we do not specifically discuss the "securing" limitation of claims 13 and 24, the same analysis would apply.

[21] We also do not find the testimony of Dr. Záťura or Ex. 1009 to be relevant to the question of whether the Examiner materially erred in finding that the prior art does not teach the "coupling" limitation.

Mar. 20, 2020) (precedential). Because we deny the petition under 35 U.S.C. § 325(d), this argument is moot.

Further, we note that Petitioner has filed a stipulation under *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 19 (PTAB Dec. 1, 2020) (precedential as to § II.A). Pet. 112. Our analysis under *Fintiv* is guided by the USPTO Director's Memorandum issued on June 21, 2022, titled "Interim Procedure for Discretionary Denials in AIA Post Grant Proceedings with Parallel District Court Litigation" ("Director's Memorandum").[22] Pursuant to the Director's Memorandum, we "will not discretionarily deny institution of an IPR or PGR in view of parallel district court litigation where a petitioner stipulates not to pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have reasonably been raised in the petition." Director's Memorandum, 7.

VI. CONCLUSION

For the foregoing reasons, we exercise discretion not to institute post-grant review under 35 U.S.C. § 325(d).

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* and no post-grant review is instituted.

[22] *Available at* https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf.

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