

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.

Case No. PGR2023-00041

U.S. Patent No. 11,547,436

PETITION FOR POST-GRANT REVIEW

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LIST OF EXHIBITS

Exhibit	Description
EX1001	U.S. Patent No. 11,547,436 to Matthew J. Allaway (the “’436 Patent”)
EX1002	File History of the ’436 Patent, produced by Corbin Clinical as CORBIN_CLINICAL-001928 - CORBIN_CLINICAL-002356
EX1003	Declaration of Edward J. Yun, M.D.
EX1004	<i>Curriculum Vitae</i> of Edward J. Yun, M.D.
EX1005	Giovanni Novella et al., <i>Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle</i> , 62 UROLOGY 689 (2003) (“Novella”)
EX1006	Bard Biopsy Systems, Bard® TruGuide® Disposable Coaxial Biopsy Needle Instructions for Use (May 2012)
EX1007	BK Medical, Prostate Biplane Transducer Type 8808e, User Guide (June 2012) (“BK Medical”)
EX1008	Antonio Galfano et al., <i>Prostate Biopsy: The Transperineal Approach</i> , 5 EUR. ASS’N UROLOGY 241 (2007) (“Galfano”)
EX1009	BK Medical, Endoscopic Probe Type 1850, User Guide (Aug. 2006) (“BK Medical 2”)
EX1010	Stephan Zangos, et al., <i>MR-Guided Transgluteal Biopsies with an Open Low-Field System in Patients with Clinically Suspected Prostate Cancer: Technique and Preliminary Results</i> , 15 EUR. RADIOL. 174 (Sept. 4, 2004) (“Zangos”)
EX1011	U.S. Patent No. 5,494,039 to Gary Onik, et al. (“Onik”)
EX1012	Japanese Patent No. 4,550,531 to Hisashi Nakamura (“Nakamura”) with certified English language translation and certification of accurate translation
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EX1015	Declaration of František Zat'ura, M.D., Ph.D. from Related Proceeding in the Netherlands and certified English translation of the same
EX1016	Internet Archive Reports for BK Medical References
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EX1018	The Parties' Claim Construction Statements in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789-SAG (D. Md.)
EX1019	Patent Owner's Amendment Infringement Contentions for the '436 Patent in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789-SAG (D. Md.)
EX1020	File History of Application No. 17/314,845 (now U.S. Patent No. 11,246,677), produced by Corbin Clinical as CORBIN_CLINICAL-000722 - CORBIN_CLINICAL-001527
EX1021	Docket Navigator Reports for the U.S. District Court for the District of Maryland

I. INTRODUCTION

Pursuant to 35 U.S.C. § 321 and 37 C.F.R. § 42.200, Advance Medical Designs, Inc. (“Petitioner”) requests this post-grant review (“PGR”) of claims 1, 4-6, 11-13, 16-18, 23, 24, 28, 29 (“Challenged Claims”) of U.S. Patent No. 11,547,436 (“the ’436 Patent,” EX1001), assigned on its face to Corbin Clinical Resources, LLC (“Corbin”). As explained below, the Petition demonstrates that it is more likely than not that the Challenged Claims are unpatentable.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this Petition:

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

The real party-in-interest is Petitioner Advance Medical Designs, Inc., a Georgia corporation having a principal place of business at 1120 Atlanta Industrial Dr., Marietta, GA 30066. No other parties exercised or could have exercised control over this Petition, and no other parties funded or directed this Petition.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

Petitioner identifies the following proceedings that may affect a decision in this proceeding: *Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC*, No. 1:22-cv-00789-SAG (D. Md.).

C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner designates the following counsel:

Lead Counsel	Backup Counsel
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	Richard Uberto (Reg. No. 75,680) Lee & Hayes, P.C. 75 14th Street, Suite 2500 Atlanta, GA 30309 404-736-1911 509-323-8979 (fax) richard.uberto@leehayes.com

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney has been submitted.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Patent Owner may serve Petitioner as indicated in the counsel information above and further consents to email service at AMD-PGR@leehayes.com.

III. GROUNDS FOR STANDING

Petitioner certifies that the '436 Patent is available for PGR. Petitioner is not barred or estopped from requesting this post-grant review on the grounds herein.

IV. PRECISE RELIEF REQUESTED

A. Claims for Which Review is Requested Under 37 C.F.R. § 42.204(b)

Petitioner requests PGR and cancellation of Challenged Claims 1, 4-6, 11-13, 16-18, 23, 24, 28, 29 of the '436 Patent as unpatentable:

B. Specific Statutory Grounds

Petitioner requests review of the Challenged Claims based on the following Grounds:

Challenge	Claims	Statutory Ground	Prior Art References
Ground 1	1, 4-6, 12, 13, 16-18, 24, 28	35 U.S.C. § 103 ¹	<ul style="list-style-type: none">• Giovanni Novella, et al., <i>Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle</i>, 62 UROLOGY 689 (2003) (“Novella,” EX1005)• BK Medical, Prostate Biplane Transducer Type 8808e, User Guide (June 2012) (“BK Medical,” EX1007)

¹ AIA provisions govern this proceeding.

Challenge	Claims	Statutory Ground	Prior Art References
Ground 2	11, 23, 29	§ 103	<ul style="list-style-type: none"> • Novella • BK Medical • Stephan Zangos et al., <i>MR-Guided Transgluteal Biopsies with an Open Low-Field System in Patients with Clinically Suspected Prostate Cancer: Technique and Preliminary Results</i>, 15 EUR. RADIOL. 174 (Sept. 4, 2004) (“Zangos,” EX1010)
Ground 3	1, 4-6, 12, 13, 16-18, 24, 28	§ 103	<ul style="list-style-type: none"> • Novella • U.S. Patent No. 5,494,039 to Onik, et al. (“Onik”EX1011) • Japanese Patent No. 4,550,531 to Nakamura (“Nakamura,” EX1012)
Ground 4	11, 23, 29	§ 103	<ul style="list-style-type: none"> • Novella • Onik • Nakamura • Zangos

C. How the Challenged Claims Are to Be Construed Under 37 C.F.R. § 42.204(b)(3)

Petitioner addresses construction of Challenged Claims in Section VI below.

D. How the Construed Claims Are Unpatentable Under 37 C.F.R. § 42.204(b)(4)

Petitioner provides a detailed explanation of why the Challenged Claims are unpatentable below in Sections VII through XI.

E. Supporting Evidence Under 37 C.F.R. § 42.204(b)(5)

Petitioner discusses the evidence in support of Grounds 1-4 in the analysis below. Among other things, Petitioner submits:

- A Declaration of Edward J. Yun, MD (EX1003) in support of Grounds 1-4;
- A Declaration of Ingrid Hsieh-Yee, PhD (EX1013) in support of the public availability of Novella, BK Medical, BK Medical 2, Zangos, and Galfano before the claimed priority date of the '436 Patent;
- A Declaration of Nico Eelbode (EX1014) regarding BK Medical and the public availability of its product manuals on BK Medical's website before the claimed priority date of the '436 Patent; and
- A Declaration of František Zat'ura, M.D., Ph.D. (EX1015), from a related proceeding in the Netherlands (and English translation), regarding his personal use of the BK Medical Type 1850 transrectal probe with its transperineal guide UA0650, an access needle, and a biopsy needle inserted through the access needle in prostate biopsy procedures before the claimed priority date of the '436 Patent.

V. THE '436 PATENT**A. Priority**

The '436 Patent was filed on March 18, 2022, as U.S. Application No. 17/698,641 (the "'641 Application"). The '436 Patent claims priority, through a series of continuation and continuation-in-part applications, to U.S. Provisional Application No. 61/974,826 (the "'826 Provisional") filed April 3, 2014. Petitioner reserves the right to dispute the '436 Patent's priority date, but it does not matter

for this proceeding because Petitioner’s prior art predates the April 2014 filing date of the ’826 Provisional.

B. Prior Art Background

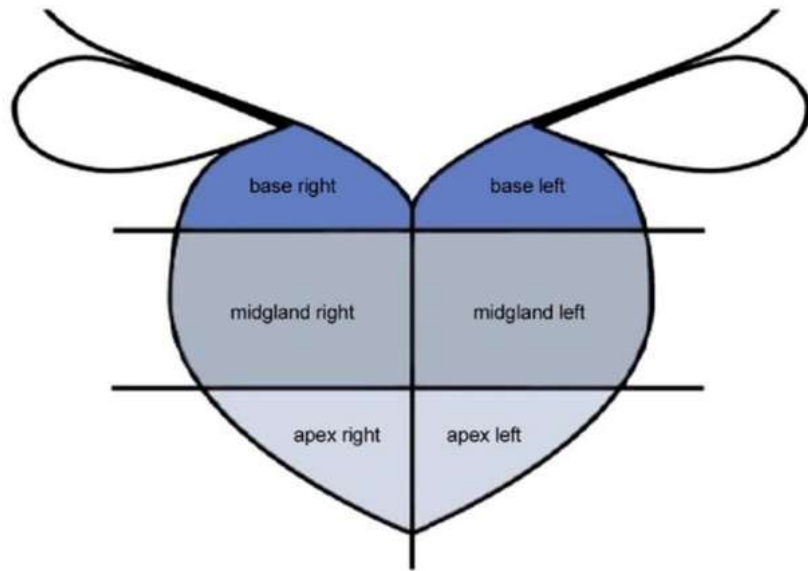
1. Prostate Biopsy Procedures

The ’436 Patent relates to prostate biopsy procedures—procedures that sample and remove tissue from the prostate of a patient for further examination and analysis, such as for cancerous tissue. EX1001, Abstract, 1:40-47; EX1003, ¶22. There are two types of prostate biopsy procedures: transrectal ultrasound-guided (TRUS) biopsies and transperineal ultrasound-guided (TPUS) biopsies. EX1001, 1:47-49; EX1003, ¶22.

A TRUS biopsy “involves obtaining tissue or cell specimens by passing a biopsy needle or other biopsy instruments through the rectal wall and into the prostate at various locations.” EX1001, 1:50-52. A TPUS biopsy, meanwhile, “obtain[s] tissue or cell[] specimens by passing one or more biopsy needles through the perineum and into the prostate.” *Id.*, 2:1-3. In both procedures, the practitioner typically uses a transrectal ultrasound probe to guide the needle to target locations of the prostate. *Id.*, 1:40-2:35; EX1003, ¶23.

One common type of prostate biopsy—called a sextant biopsy—involves sampling tissue from six areas of the prostate: the left and right sides of each of the base, midgland, and apex regions of the prostate. EX1003, ¶24; EX1005, 2. The

figure on the right shows the six areas of the prostate viewed in the sagittal plane (looking through the perineum), which divides the body into upper and lower halves.

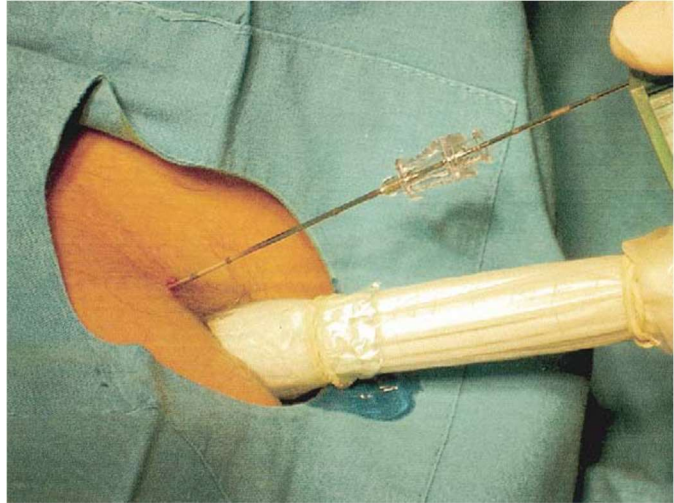


EX1003, ¶24.

2. Biopsy Needles

Practitioners use one of two needle configurations in prostate biopsy procedures: (1) a biopsy needle only; and (2) a coaxial needle including an outer lumen through which the biopsy needle is inserted. EX1005, 1, 2, 4; EX1003, ¶25. If using a biopsy needle only, the practitioner must puncture the patient's perineum multiple times to take multiple tissue samples from the prostate—one puncture per sample. EX1005, 1, 2, 4; EX1003, ¶25. If using a coaxial needle, however, the practitioner need only puncture the patient's perineum once to take multiple tissue samples. EX1005, 1, 2, 4; EX1003, ¶25. This is because the practitioner leaves the coaxial needle in place in the patient's perineum and repeatedly passes the biopsy needle through the lumen of the coaxial needle to sample different locations of the

prostate. EX1005, 1, 2, 4; EX1008, 1, 3, 4 (discussing the “fan technique”); EX1003, ¶25. The prior art Figure on the right shows a biopsy needle being inserted through a coaxial needle. EX1005, 2.



3. Biopsy Guides

Practitioners often use biopsy guides in prostate biopsy procedures to guide placement of the needle and ultrasound probe. EX1003, ¶26. One type of transperineal biopsy guide mounts to the ultrasound probe and contains a platform with needle guiding channels at different vertical positions relative to the ultrasound probe, allowing the practitioner to select the best channel to target a desired location of the patient’s prostate through the perineum. EX1007; EX1011; EX1012; EX1003, ¶26. The prior art figures below show an example of a transperineal biopsy guide, with multiple needle-guiding channels on a sliding platform, mounted on an ultrasound probe. EX1007, 12 (FIGS. 7, 8):

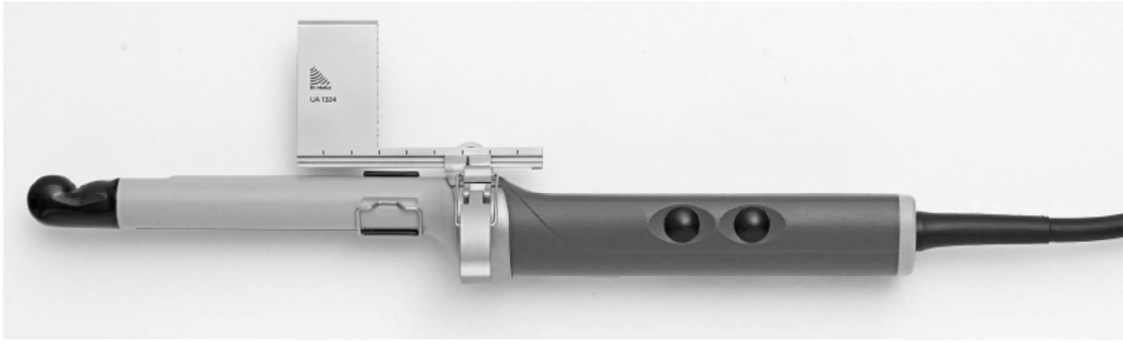


Figure 8. Puncture attachment UA1324 mounted on 8808e.

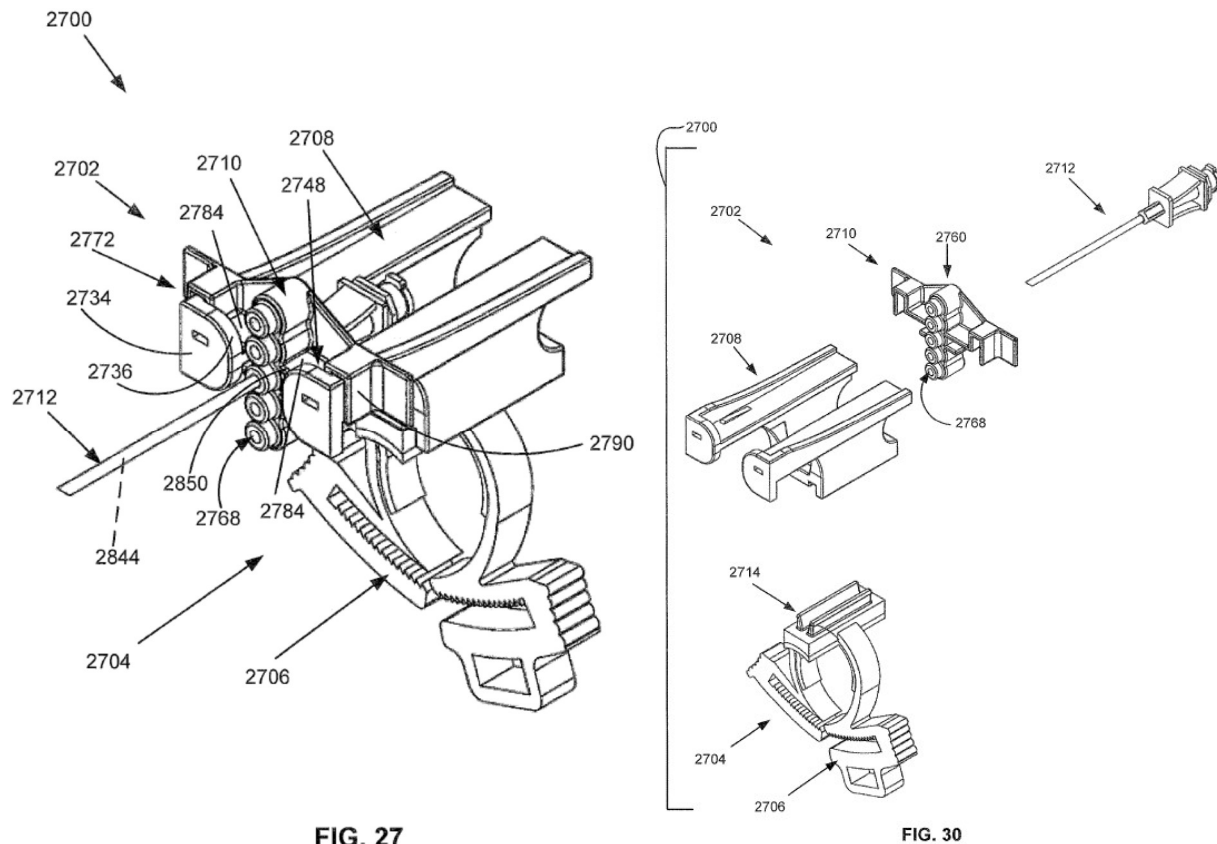


Figure 7. Puncture attachment UA1324.

It was known in the art before the claimed priority date to use a coaxial biopsy needle with a probe-mounted transperineal biopsy guide in prostate biopsy procedures. EX1003, ¶27; EX1015, ¶¶11, 12. For example, BK Medical 2, discussed below, shows a probe-mounted biopsy guide UA0650 configured with a coaxial needle. EX1009, 1, 14.

C. The Transperineal Biopsy Guide of the '436 Patent

The '436 Patent describes and claims a method of using a transperineal biopsy guide with a coaxial needle, which the '436 Patent calls an “access needle.” EX1001, Abstract, 1:32-36. Figures 27 and 30 the '436 Patent respectively show isometric and exploded views of the claimed transperineal biopsy guide 2700:



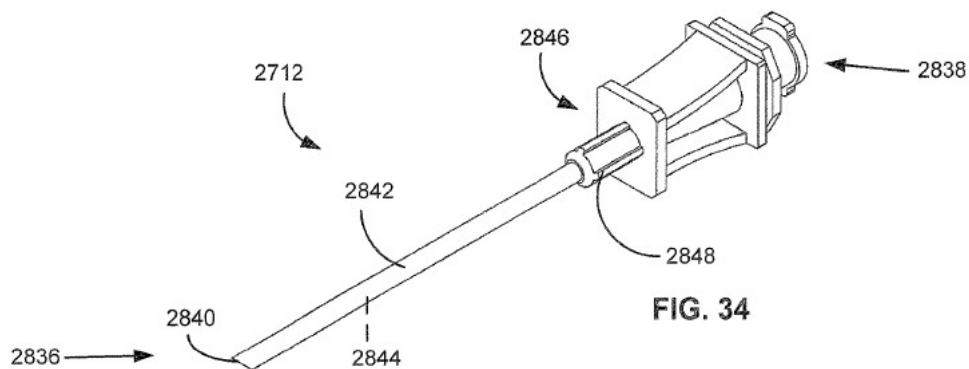
'436 Patent, FIGS. 27, 30

As seen above, guide 2700 has (1) upper mount 2702, (2) lower mount 2704, (3) guide member 2708, and (4) and displacement member 2710 (also called a “translating member” or “sliding platform”). EX1001, 20:10-27.

Lower mount 2704 couples to the transrectal probe. *Id.*, 20:14-17. Upper mount 2702 couples to lower mount 2704 and has guide member 2708 on which displacement member 2710 slides to displace the access needle and displacement member along a trajectory fixed relative to the guide member 2708. *Id.*, 20:24-37.

Displacement member 2710 has “needle receiving ports 2768” defining openings 2770 “generally vertically aligned with each other” and having “a trajectory axis 2776 defining a trajectory of the access needle 2712 when positioned within the opening 2770.” *Id.*, 22:26-35. Trajectory axis 2776 is also “generally parallel with a longitudinal axis of the probe when the biopsy guide 2700 is coupled with the probe.” *Id.*, 22:38-40. “Thus, when the access needle 2712 is coupled with the displacement member 2710, the access needle 2712 is also displaceable” along trajectory axis 2776. *Id.*, 22:22-25.

As shown in Figure 34 below, access needle 2712 includes a hub 2846 and a lumen 2844 for receiving “a shaft of a smaller gauge biopsy needle.” EX1001, 25:1-11.



Once access needle 2712 is in position in the patient's perineum, the physician inserts a biopsy needle through lumen 2844 of the access needle into the prostate to biopsy a target location. *Id.*, 27:6-10. 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.*, 9:47-50.

D. Prosecution History

In the first Office Action, the Examiner rejected all claims as anticipated by U.S. Patent No. 5,931,786 ("Whitmore"). EX1002, 208-210. Patent Owner argued that Whitmore failed to teach "inserting an access needle into the perineal access site of the patient and inserting a biopsy needle through the access needle." EX1002, 197. According to Applicant, "[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.*, 198.

Applicant and Examiner then held an interview in which Examiner "suggested amending the claims to recite 'securing position and angle of the access needle relative to the displacement member' to further clarify the claim and put the case in condition for allowance." *Id.*, 39. Following the interview, the Examiner issued a Notice of Allowance and concurrently amended the independent claims to

reflect the position and angle limitations discussed during the interview. *Id.*, 30, 35-37. The Examiner cited these limitations in the Examiner's Reasons for Allowance, stating that Whitmore, Onik, and two other references of record 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." *Id.*, 36-37.

As explained below, Petitioner's prior art addresses the reason the Examiner allowed the '436 Patent claims. BK Medical (EX1007) discloses a transperineal biopsy guide having a displacement member with multiple needle receiving ports that retain a position and angle of a needle coupled to the displacement ports. Nakamura (EX1012) also discloses a transperineal biopsy guide with multiple needle receiving ports to retain the position and angle of the needle. And although the Examiner did not find Patent Owner's "access needle" argument persuasive or cite it in the Reasons for Allowance, Novella (EX1005) shows this was not only known in the art to use a coaxial needle (access needle) in transperineal prostate biopsies but advantageous to using a biopsy needle alone.

Patent Owner cited Petitioner's initial invalidity contentions from the parallel litigation in an Information Disclosure Statement, but those contentions did not include Nakamura. EX1002, 180-190. Moreover, the record suggests that the

Examiner overlooked and/or failed to appreciate the content of Novella, BK Medical, or Zangos alone or in Petitioner's proposed combinations. *Infra* Section XII.A.2. And while the Examiner may have considered Onik alone, the Examiner did not consider Onik as presented in the combinations in Grounds 3 and 4 of the Petition. *See* EX1002, 36, 37; EX1001, 1.

E. Level of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") at the time of the claimed priority date of the '436 Patent in April 2014 would have had 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. EX1003, ¶12. Less experience may be compensated by more or different education or training, or vice versa. *Id.*

VI. CLAIM CONSTRUCTION

In PGR, claims are given their plain meaning under *Phillips v. AWH Corporation*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (en banc). 37 C.F.R. § 42.200(b). The Board only construes the claims when necessary to resolve the underlying controversy. *Toyota Motor Corp. v. Cellport Sys., Inc.*, No. IPR2015-00633, Paper 11, 16 (PTAB Aug. 14, 2015). Petitioner submits that no express constructions are needed to resolve the Grounds in this Petition but discusses the

scope of “coupling” for element [1.8] and “securing” for elements [13.7] and [24.7] below. Additionally, Petitioner submits the parties’ claim construction statements in the related litigation. *See* EX1018. Petitioner reserves the right to raise claim construction and other arguments in this and other proceedings as relevant and necessary.

A. “Coupling ...” (Element [1.4]) and “Securing ...” (Elements [13.7] and 24.7))

Independent claim 1 recites “coupling the access needle to the one of the plurality of needle receiving ports ... such that a position and angle of the access needle ... is retained.” EX1001, 36:1-5. Independent claims 13 and 27 recite similar “securing” elements. *Id.*, 36:59-61, 38:3-8. These terms do not require locking the access needle in place to completely prevent any movement of the access needle. EX1003, ¶¶37-41.

The claim language only requires coupling or securing to retain “[a] position and angle”—not necessarily locking all degrees of freedom of the access needle. Dependent 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. For example, the access needle hub may have “ridges 2848 [that] engage with corresponding and negatively shaped features on ... the needle receiving ports 2768” so “access

needle 2712 may be restrained from rotating by the ridges 2848.” EX1001, 25:11-13, 25:64-26:2, FIG. 34. Or “threaded features on the hub 2846 and openings 2770 of the ports 2768” 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.*, 26:2-7. But the independent claims do not require such structure or completely locking the access needle to the displacement member. Thus, the claim language and specification support Petitioner’s interpretation of the “coupling” and “securing” elements.

Patent Owner applies the same understanding in its infringement contentions against Petitioner. *See* EX1019. Petitioner’s accused product—the SureFire Transperineal Needle Guide—has substantially the same needle guide structure as BK Medical’s UA1324 biopsy guide discussed in Grounds 1 and 2 below. *Compare* EX1019, with EX1007, 12; EX1003, ¶40.



Figure 7. Puncture attachment UA1324.

Petitioner's SureFire Biopsy Guide**BK Medical UA1324 Biopsy Guide**

Patent Owner does not contend that “coupling” or “securing” an access needle on the SureFire 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.” EX1019, 22.

Accordingly, for purposes of this Petition, the “coupling” and “securing” elements should be applied as in Patent Owner’s infringement contentions—not to require locking the access needle in place but maintaining the stability and directionality of the access needle.

VII. THE PRIOR ART**A. References Describing Use of a Coaxial Needle in Transperineal Biopsy****1. Novella (EX1005)**

Novella is a study published in 2003 in *Urology*, a well-known urology journal. EX1005, 1; EX1013, ¶42. Novella was published in the journal online by Elsevier Inc. in September 2003, published in print in October 2003, cataloged in the Library of Congress by November 2003, available in the PubMed database in November 2003, and cited by other urology publications by September 2005. EX1013, ¶¶31-45. Thus, Novella qualifies as a prior art printed publication to the ’436 Patent under Section 102(a)(1).

Novella compared two variations of transperineal prostate biopsy procedures: (1) with a biopsy needle alone and (2) with a coaxial needle. EX1005, 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. EX1005, 1; EX1003, ¶¶42-47.

A first group of patients underwent transperineal biopsy with a 17-gauge coaxial needle (TruGuide Bard) and 18-gauge biopsy needle to minimize the invasiveness of the procedure. *Id.*, 1-2. The coaxial needle provided “an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” *Id.* That is, Novella punctured the perineum with the coaxial needle once, and then repeatedly passed the biopsy needle through the coaxial needle to biopsy the prostate multiple times. EX1003, ¶44.

A second group of patients underwent biopsy with a biopsy needle alone in which “the [biopsy] needle [was] repeatedly inserted through the perineal plane under local anesthesia.” EX1005, 1. That is, instead of inserting the biopsy needle through an already-placed coaxial needle, the practitioner punctured the perineum multiple times with the biopsy needle to take multiple biopsies. EX1003, ¶45. In both groups 1 and 2, “[f]ourteen cores were sampled in every patient (double

sextant biopsy from the peripheral and two cores from the transition zone).”
EX1005, 1; *see also* EX1005, 2, 4.

Following the procedure, the patients received a pain questionnaire. *Id.*, 1, 2. The group 1 (coaxial) patients experienced significantly less pain than group 2 (biopsy needle only). *Id.*, 2. “In group 1, 49 (96.1%) had mild pain and 2 (3.9%) had moderate pain. No group 1 patients reported a score greater than 6.” *Id.* But in group 2, 42 patients (82.4%) recorded mild pain, 8 (15.6%) moderate pain, and 1 (2%) severe pain (Table II).” *Id.*

TABLE II. <i>Difference in subjective measures between studied groups</i>		
	Group 1 (%)	Group 2 (%)
Whole procedure		
No pain (0)	0	0
Mild pain (1–4)	49 (96.1)	42 (82.4)
Moderate pain (5–7)	2 (3.9)	8 (15.6)
Severe pain (>7)	0	1 (2)
Multiple-core sampling		
No pain (0)	14 (27.5)	6 (11.8)
Mild pain (1–4)	35 (68.5)	37 (72.5)
Moderate pain (5–7)	2 (4)	7 (13.7)
Severe pain (>7)	0	1 (2)

Id., 3.

The authors concluded “the use of a coaxial needle significantly reduced the experienced pain during prostate sampling and improved patient compliance compared with the conventional transperineal biopsy technique.” *Id.*, 4. And the

“results support the widespread use of a coaxial needle during transperineal prostate biopsy.” *Id.* The coaxial needle “makes the procedure easier and quicker” because “[t]he guiding cannula forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” *Id.*

2. Bard TruGuide Disposable Coaxial Biopsy Needle Instructions for Use (EX1006, “TruGuide Manual”)

TruGuide Manual is an instruction manual for the coaxial needle used by Novella and thus shows characteristics of that coaxial needle and knowledge a POSITA using that needle would have had. EX1006; *see Cont’l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991); MPEP § 2131.01.

Novella used “a 17-gauge coaxial needle (TruGuide Bard, 13 cm long)” with an “18-gauge Tru-Cut, 20 cm long” biopsy needle “loaded on a spring-driven biopsy gun “Magnum Bard Biopsy Instruments”). EX1005, 2. TruGuide Manual shows this 18 x 20 version in Figure 1 as reorder no. C1820B. EX1006, 3.

TruGuide Manual explains that “BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle is a three-part device consisting of an outer cannula [with a hub and inner stylet]” and “designed for use with BARD® disposable biopsy instruments and BARD® disposable biopsy needles.” *Id.*, 2. The cannula with hub is shown below:



Id., 1. The Manual instructs the practitioner to “[p]lace the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be biopsied,” “[p]erform the biopsy and remove the biopsy needle from the guiding cannula,” and “[l]eave the guiding cannula in place” for further biopsies. *Id.*, 3-4; EX1003, ¶50.

3. Galfano (EX1008)

Galfano is a study in the European Association of Urology in 2007 by some of the same authors of Novella (including Galfano). EX1008, 1. Galfano was published online and in print by Elsevier in August 2007 and cataloged in the National Library of Medicine (NLM) by November 2007. EX1013, ¶63-73_. Thus, Galfano qualifies as a prior art printed publication to the ’436 Patent under Section 102(a)(1).

Like Novella, Galfano studied TRUS prostate biopsy and found that patients undergoing biopsy with “the coaxial needle showed a reduction in pain during the biopsy and a better compliance” than patients who underwent biopsy with the biopsy needle alone. EX1008, 4. This is because, with a biopsy needle alone, “the execution of multiple punctures on perineal skin and multiple perineal paths ... makes it almost impossible to perform adequate local anesthesia. *Id.*, 3; EX1003,

¶52. Thus, most patients “use a general or spinal anesthesia” instead of local. EX1008, 3. “The main disadvantage of this technique is the need for spinal or general anesthesia” apart from increased invasiveness. EX1008, 4.

In contrast, with a coaxial needle, “biopsies are performed by repeatedly inserting the same biopsy needle through the anesthetized perineal path,” using the “coaxial needle [to] perform[] the several needle passages through the same path.” *Id.* This “makes the procedure easier and quicker, allowing the repeated introduction of the needle with low perineal trauma.” *Id.* Since the technique only requires “one or two skin punctures following the same perineal path, local anesthesia is feasible with good results.” *Id.*, 3. EX1003, ¶53.

4. Zangos (EX1010)

Zangos is a prostate biopsy study published by Springer in *European Radiology* in January 2005. EX1010; EX1013, ¶¶87-91. Zangos was cataloged in the NLM by February 2005 and available on the PubMed database in May 2005. EX1013, ¶¶92-107. Thus, Zangos qualifies as a prior art printed publication to the ’436 Patent under Section 102(a)(1).

Zangos sought to determine the feasibility of MR-guided transgluteal prostate biopsies. EX1010, 1 (Abstract). “The prostate gland was biopsied repeatedly with a coaxial technique through a 15-gauge pencil tip with a 16-gauge biopsy handy (median 3.8 samples per patient).” *Id.* Out of 25 patients, the

technique revealed prostate cancer in ten. *Id.* The authors concluded that the technique “is a safe and promising approach for histological clarification of uncertain or suspicious lesions.” *Id.*

B. References Disclosing Transperineal Biopsy Guides

1. BK Medical (EX1007)

a. Prior Art Status

BK Medical is a User Guide for a BK Medical Type 8808e Prostate Biplane Transducer (2012). EX1007, 1. It qualifies as a prior art “printed publication” to the ’436 Patent.

For several decades, BK Medical (now a GE Healthcare company) has been an industry leader in transrectal ultrasound probes and other medical equipment. EX1014, ¶3-7; *see also* EX1003, ¶56. BK Medical’s products have been used in hundreds of medical institutions, and sold, in Europe. EX1014, ¶7. In Scandinavia, BK Medical holds 90% of the ultrasound transducer market. *Id.* Thus, a POSITA would have been aware of BK Medical and its products before the claimed 2014 priority date of the ’436 Patent.

The Type 8808e transducer was on the market since at least 2012. *Id.*, ¶6. BK Medical has routinely published its product user guides on its website since at least that time. *Id.* Exhibit 1016 shows archived versions of BK Medical’s Transducer User Manual web page, providing links to download user guides for its

various ultrasound transducers—including the Type 8808e Prostate Biopsy Biplane Transducer of EX1007. EX1016; EX1013, ¶¶55-57. This page was archived 41 times between February 2012 and January 2013. EX1013, ¶56. BK Medical was publicly available via BK Medical’s user manual web page since at least 2012. *Id.*, ¶58.

Because (1) POSITAs were aware of BK Medical and its products and (2) the Type 8808e User Guide was available on BK Medical’s website since at least 2012, the Type 8808e User Guide of EX1007 “has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.” *Jazz Pharms., Inc. v. Amneal Pharms., Inc.*, 895 F.3d 1347, 1355 (Fed. Cir. 2018); *see also id.* at 1356, (“If accessibility is proved, there is no requirement to show that particular members of the public actually received the information”) (quotation and citation omitted). Thus, BK Medical qualifies as a prior art printed publication to the ’436 Patent under Section 102(a)(1).²

² In a related proceeding in the Netherlands, Patent Owner did not dispute that BK Medical’s User Guides were prior art to a European counterpart of the ’436 Patent. *See* EX1017.

b. Overview

BK Medical describes the BK Medical Type 8808e ultrasound transducer and its UA1324 transperineal biopsy guide:



Figure 7. Puncture attachment UA1324.



Figure 8. Puncture attachment UA1324 mounted on 8808e.

EX1007, 12. Designed for “transperineal puncture and biopsy,” the “UA1324 consists of a needle guide and a mounting ring with clamp.” *Id.* “To mount the

transperineal puncture attachment, ensure that the dummy channel bracket UA1325 is in place,” “[l]oosen the clamp on UA1324, and slide the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer.” *Id.*

UA1324’s “needle guide comprises 9 parallel guide channels, spaced 5mm apart, each with an internal diameter of 2.1mm, suitable for a 14-gauge needle. The guide is parallel to the centerline of the transducer.” *Id.* Additionally, “[t]he needle guide can be adjusted 70mm lengthwise with respect to the mounting ring, using the adjustment screw.” *Id.*

The puncture lines for UA1324 on 8808e are shown in Figure 9.

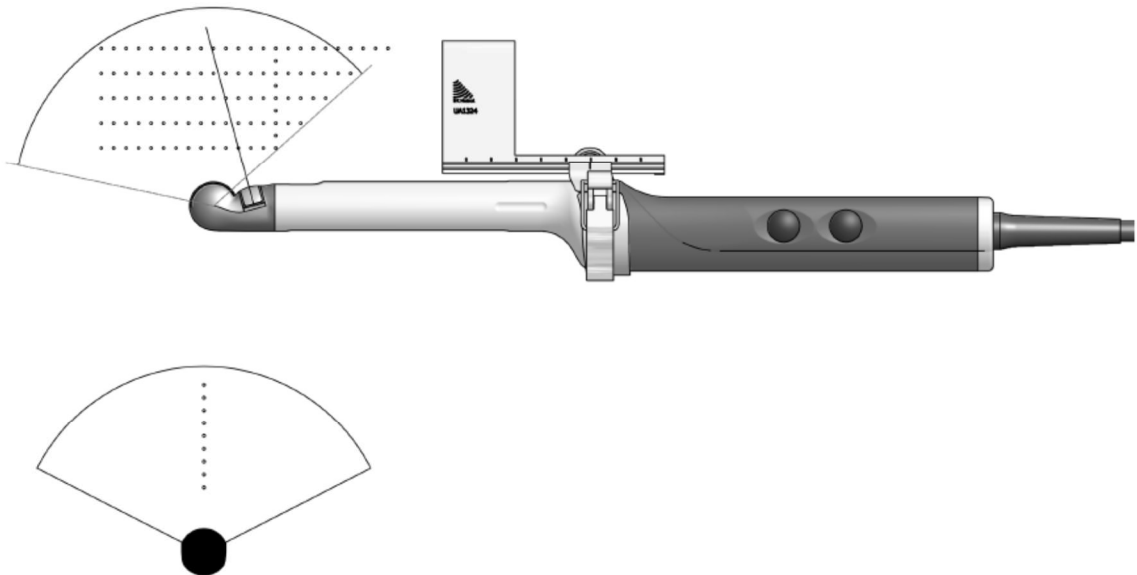


Figure 9. Illustration of the puncture line for puncture attachment UA1324.

EX1007, 13

As seen in Figure 9 above, the nine needle channels of UA1324 align with puncture lines displayed on the system monitor during a biopsy procedure. EX1007, 13. “In the sagittal plane, the puncture path is indicated by a line of dots” 5mm apart. *Id.* When taking a biopsy, the practitioner “[m]ove[s] the transducer until the [desired] puncture line transects the target” on the prostate, “[i]nser[t] the needle and monitor[s] it as it moves along the puncture line to the target.” EX1007, 13.

2. BK Medical 2 (EX1009)

BK Medical 2 is a User Guide for a BK Medical Type 1850 Endosonic Probe and its transperineal biopsy guide UA0650 (August 2006). EX1009, 1, 14. For substantially the same reasons discussed above for EX1007, BK Medical 2 qualifies as a printed publication: POSITAs were aware of BK Medical and its products, and BK Medical provided the Type 1850 User Guide on its website for download before the claimed priority date of the '436 Patent. *Supra* Section VII.B.1; EX1013, ¶¶74-86; EX1016.

BK Medical 2 discloses using a coaxial needle with a probe-mounted transperineal biopsy guide. EX1009, 15, 16. EX1003, ¶61. In Figure 11 below, BK Medical 2 shows the Type 1850 probe “assembled for transrectal scanning with puncture attachment UA0650.” EX1009, 14.

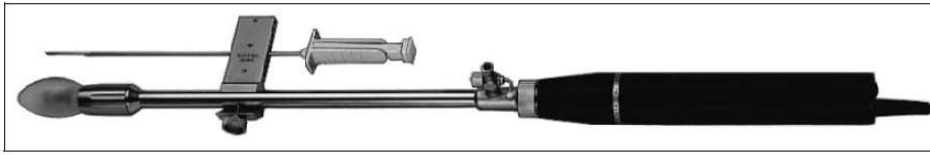
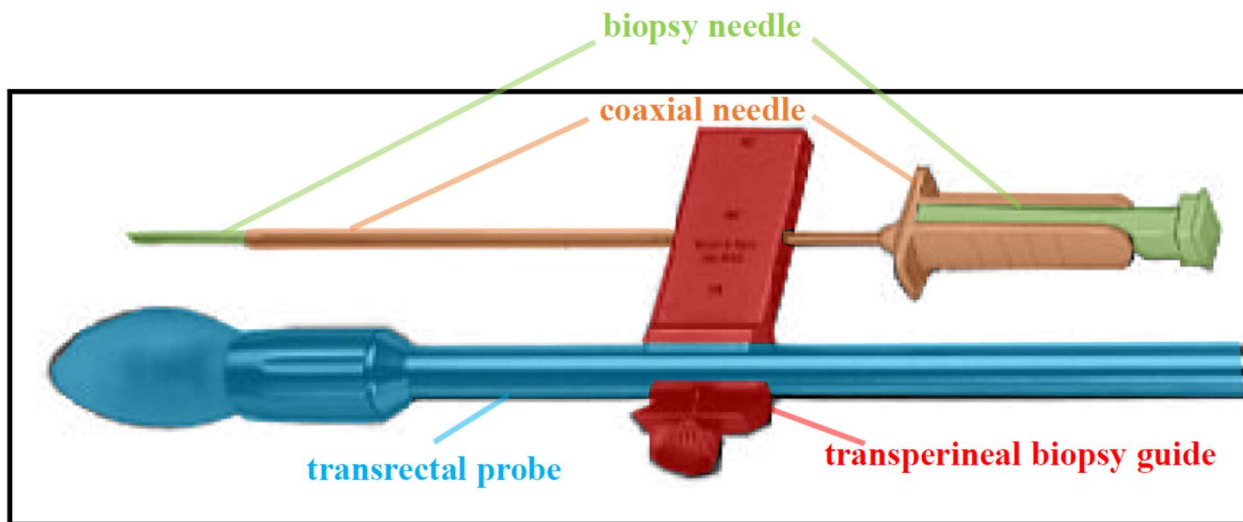


Fig. 11. Type 1850 assembled for transrectal scanning with puncture attachment UA0650

EX1009, FIG. 11

As highlighted below, puncture attachment UA0650 has an installed coaxial needle with a biopsy needle inserted through the coaxial needle. *Id.*, 14; EX1003, ¶61.



EX1009, FIG. 11*³

BK Medical 2 explains that “[i]f a fine needle is used, it may be helpful to use an additional needle guide.” EX1009, 16. Here, “fine needle” and “needle guide” respectively refer to the biopsy needle and coaxial needle. EX1015, ¶12; EX1003, ¶61. The coaxial needle supports the “fine” biopsy needle by preventing it from straying from the chosen direction. EX1015, ¶13; EX1003, ¶62. The coaxial needle

³ Petitioner uses “*” to indicate annotated figures.

also prevents the tumor sample from entering the puncture canal and moving further into the prostate during the procedure. EX1015, ¶13; EX1003, ¶62.

Dr. Zat'ura testifies that he personally “used the UA0650 in the configuration shown above on patients between 1983 and 1985 ... to perform transperineal prostate biopsies” and “inserted access needles through the UA0650 needle opening.” EX1015, ¶¶11, 12; *see also* EX1003, ¶27.

3. Onik (EX1011)

Onik is a U.S. Patent filed in 1993 and issued in 1996, qualifying as prior art to the '436 Patent under § 102(a)(1). EX1011, 1. Onik discloses “[a] biopsy needle insertion guide and method of use with an ultrasound probe in medical procedures to accurately position biopsy needles in internal tissues.” EX1011, Abstract.



Onik, FIG. 1

Onik's insertion guide "is used in conjunction with the ultrasound probe to accurately place one or more biopsy needles into a patient's prostate." *Id.*, 6:60-65. It "includes a main body portion 3 which is made up of an elongated anterior-posterior adjustment guide 4 extending upward from a first clamp body 8." EX1011, 3:34-39. The "first clamp body forms the upper portion of a clamp 3' whereby the insertion guide 1 is removably mountable to ultrasound probe 2." *Id.*, 3:39-41.

“Slidably associated with anterior-posterior adjustment guide 4 is a slide block 16 which provides anterior and posterior positioning adjustment for a biopsy

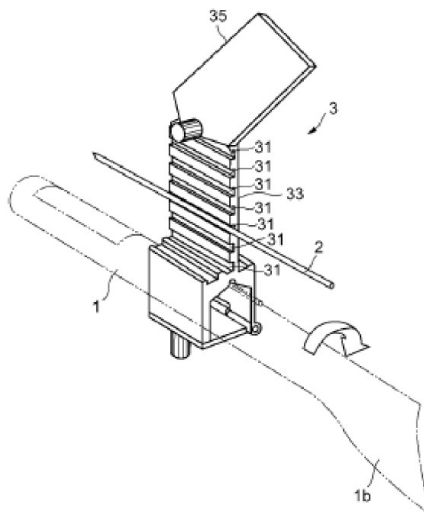
needle relative to ultrasound probe 2.” EX1011, 4:36-39. “Extending through the slide block 16 in a direction parallel to the longitudinal axis of ultrasound probe 2 is at least one channel 18 which slidably receives a needle holder and guide assembly 27.” *Id.*, 4:58-61.

In use, the position of the needle holder and guide assembly 27 adjusts relative to the slide block 16 to position needle holder assembly 28 firmly against the perineum of the patient. EX1011, 7:16-26. “The combination of the firm engagement of the perineum by needle holder assembly 28 and the fixation of insert guide 1 to ultrasound probe 2 provides a stable guide for accurate insertion of biopsy needles into the prostate.” *Id.*, 7:30-34. 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.*, 5:39-46.

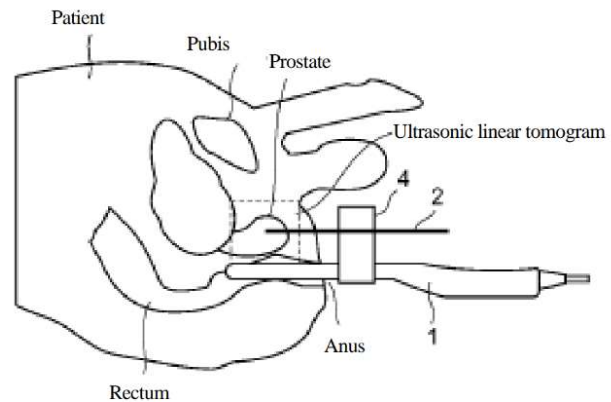
4. Nakamura (EX1012)

Nakamura is a Japanese Patent Application published on September 22, 2010, qualifying as prior art to the '436 Patent under § 102(a)(1). EX1012, 17. Like BK Medical, Nakamura describes “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.” EX1012, ¶[0001].

[FIG. 10]



[FIG. 18]



Nakamura, FIGS. 10, 18

As seen above, “puncture adapter 3 for transrectal probe transperineal puncture” has “mounting part 34 for mounting to a transrectal probe 1.” EX1012, ¶[0038]. Protruding vertically from mounting part 34, adapter 3 has “a guide plate 33, on which are formed a plurality of channels 31 used in guiding a puncture needle 2.” *Id.*, ¶[0038]. The “guide holes formed by the channels 31 and the cover plate 35 are formed so that the puncture needle 2 can be inserted at a plurality of levels in the vertical direction and at a desired position.” *Id.*, ¶[0047].

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. *Id.*, ¶[0048]. 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.*

VIII. GROUND 1: NOVELLA IN VIEW OF BK MEDICAL RENDERS OBVIOUS CLAIMS 1, 4-6, 12-13, 16-18, 24, and 28

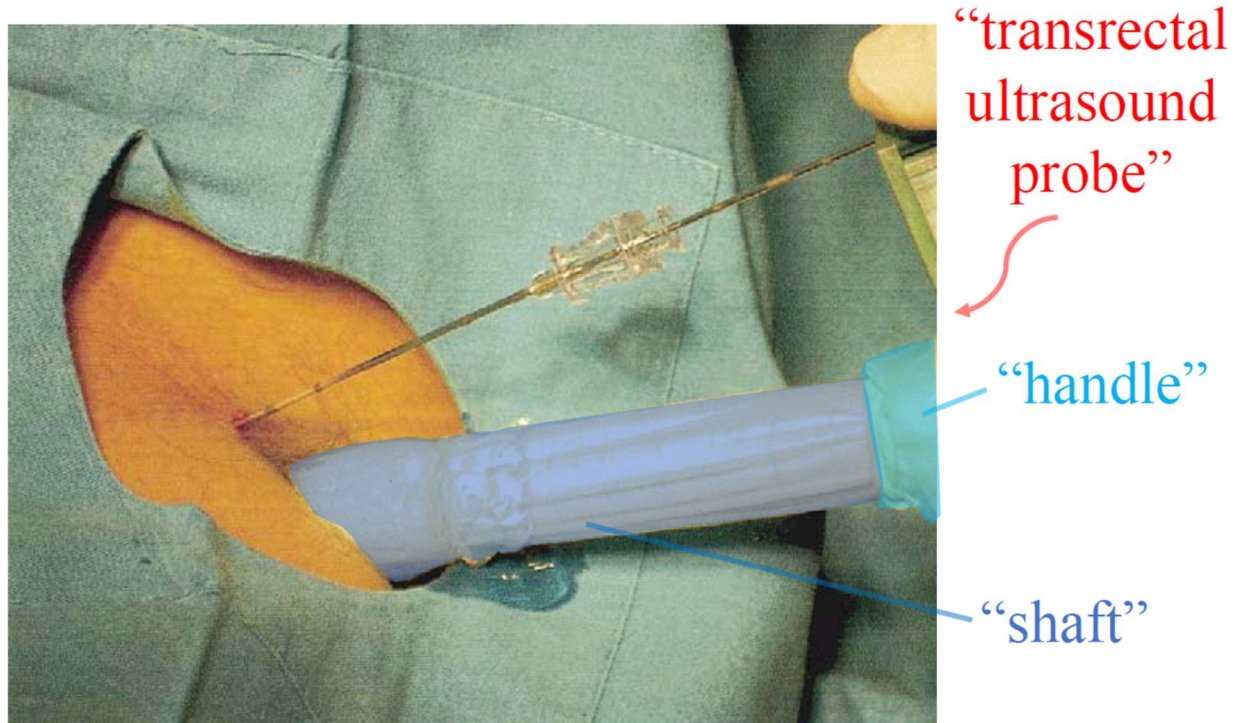
A. Independent Claim 1

1. [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:”*

To the extent the preamble is limiting, Novella discloses a method of performing a transperineal biopsy procedure (transperineal biopsy with coaxial needle) 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. EX1003, ¶¶71-73.

Specifically, “[i]n every case, we performed a 14-core transperineal prostate biopsy under transrectal ultrasound guidance.” EX1005, Abstract. “All biopsies were performed by a single urologist (G.N.)” and “TRUS was carried out using the Siemens Sonoline Omnia Diagnostic Ultrasound System, with a 7.75-MHz linear

probe.” *Id.*, 2. As seen below, the probe has a shaft and handle proximal the shaft, as claimed (EX1003, ¶72):



Novella, FIG. 1*

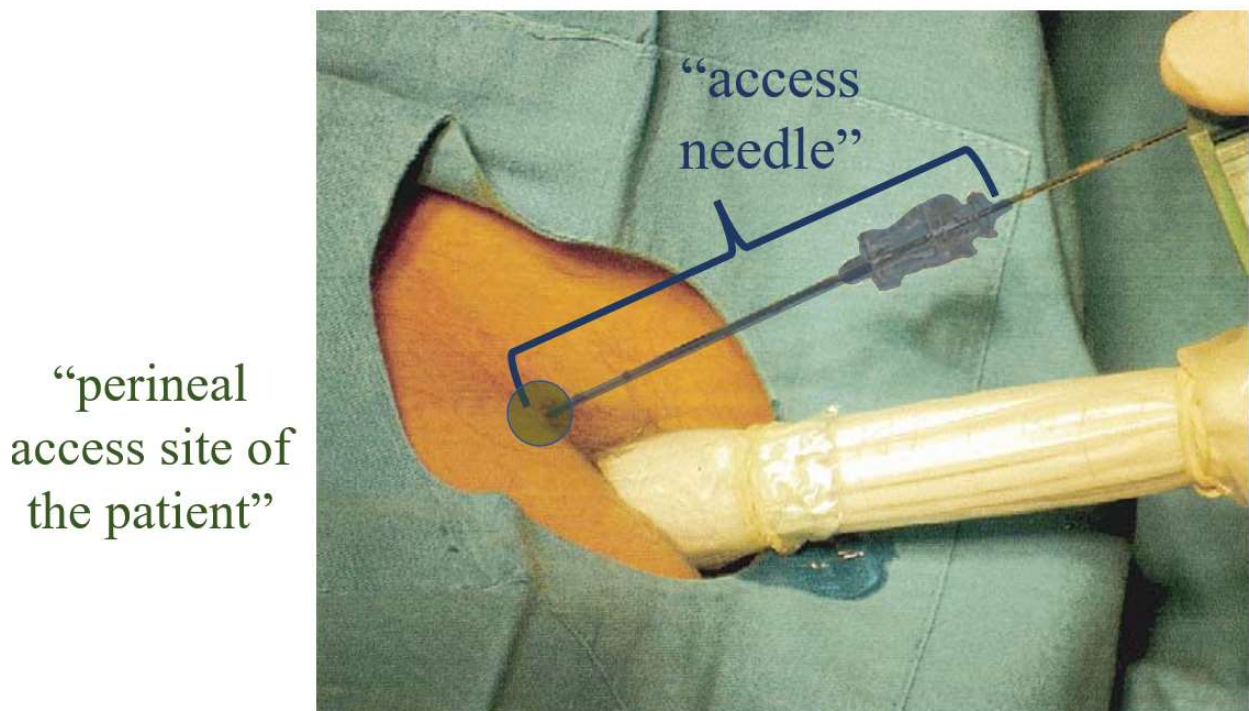
Additionally, male patients comprise a perineal access site leading to the prostate. *See generally* EX1005. The researchers inserted “a 17-gauge coaxial needle ... up to the prostate apex through the anesthetized perineal path under TRUS guidance.” *Id.*, 2.

2. [1.1] “inserting an access needle into the perineal access site of the patient,”

Novella discloses inserting a coaxial needle (access needle) into the perineal access site of the patient, as claimed. EX1003, ¶¶74. In Novella’s first patient

group, the practitioner inserted a “17-gauge coaxial needle (TruGuide Bard, 13 cm long) ... up to the prostate apex through the anesthetized perineal path under TRUS guidance.” EX1005, 2. The coaxial needle (access needle) provided “an optimal transperineal path for repeated atraumatic passage of the biopsy needle.”

Id.

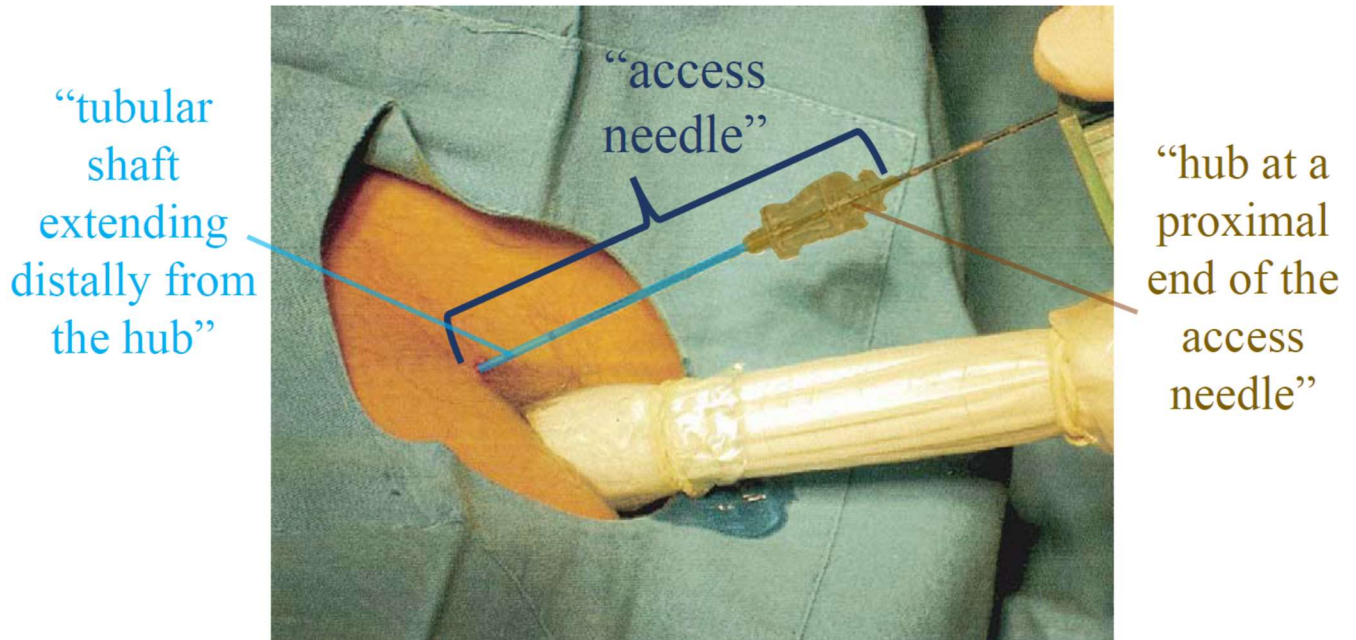


Id.

3. [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,”*

Novella’s coaxial needle (access needle) includes a hub at a proximal end of the coaxial needle and a tubular shaft (cannula) extending distally from the hub, as

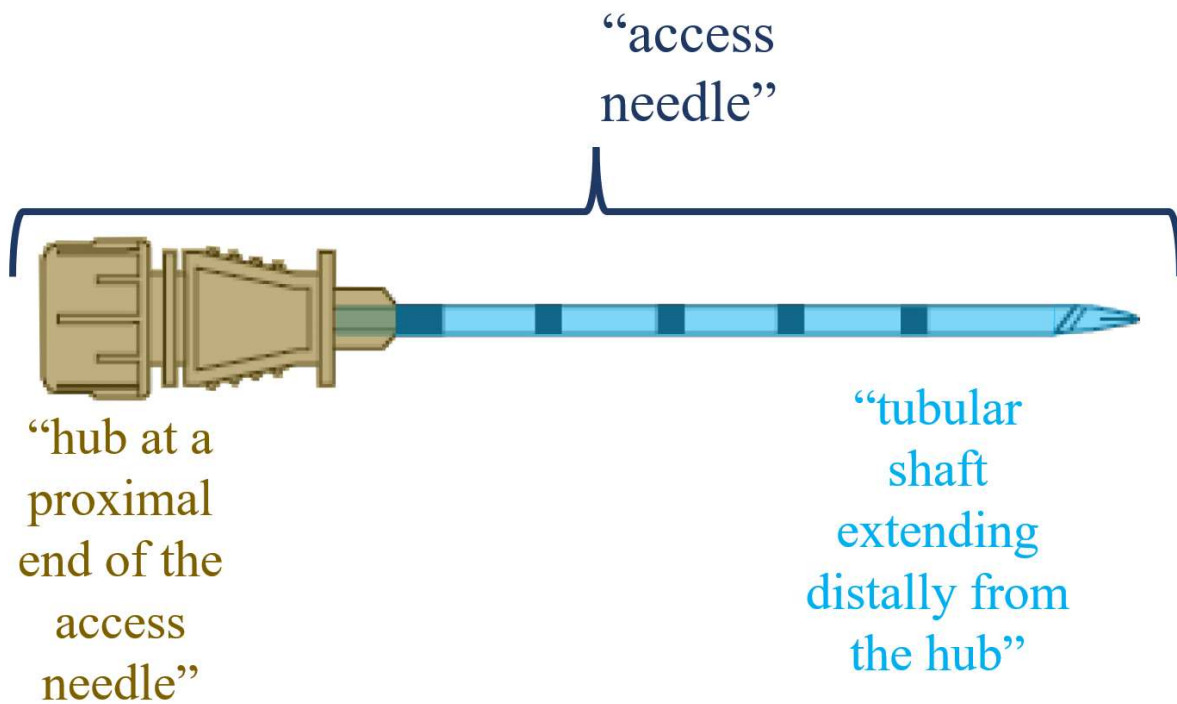
claimed. EX1003, ¶75. Figure 1 of Novella shows that the 17-gauge coaxial needle (access needle) has the claimed features:



Novella, FIG. 1*

In the procedures, Novella inserted an 18-gauge Tru-Cut biopsy needle, on a spring-loaded biopsy gun, into the hub of the “guiding cannula” (tubular shaft) of the 17-gauge coaxial needle (access needle). EX1005, 2; EX1003, ¶75.

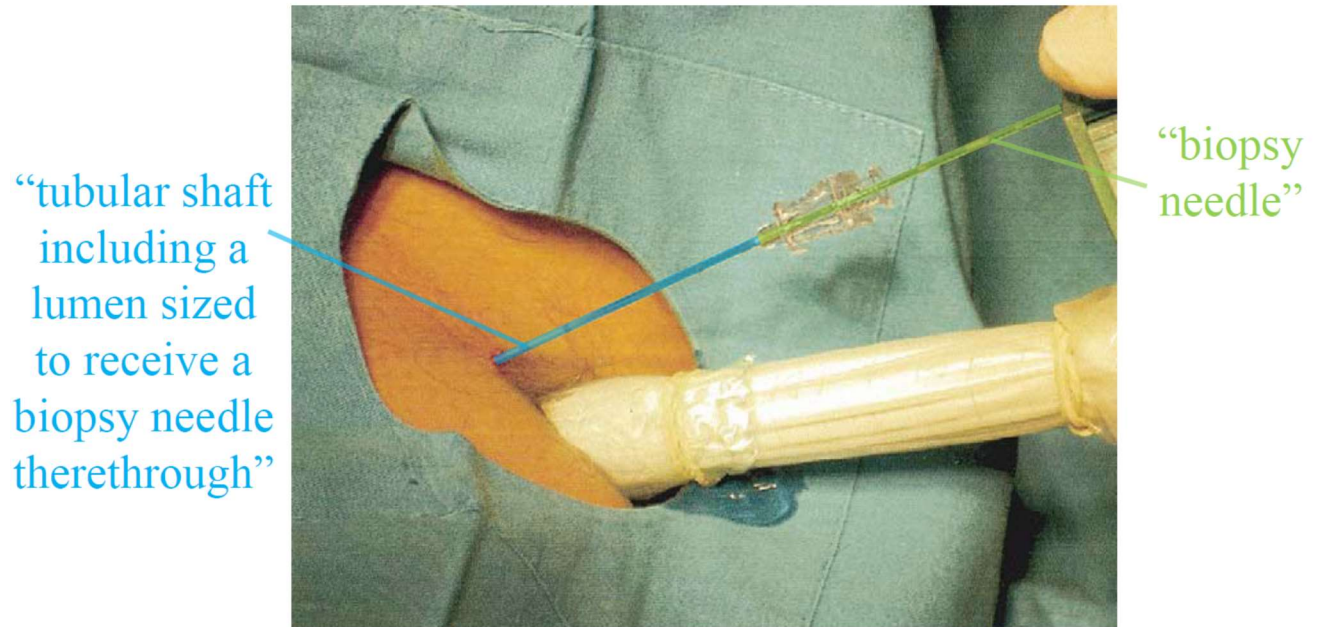
The manual for the 17-gauge TruGuide coaxial needle used in Novella also shows the coaxial needle satisfies element [1.2]:



EX1006, 1. The coaxial needle comprises a “guiding cannula needle hub”—a “hub” and “tubular shaft extending distally from the hub,” as claimed. *Id.*, 3.

4. [1.3] *“the tubular shaft including a lumen sized to receive a biopsy needle therethrough;”*

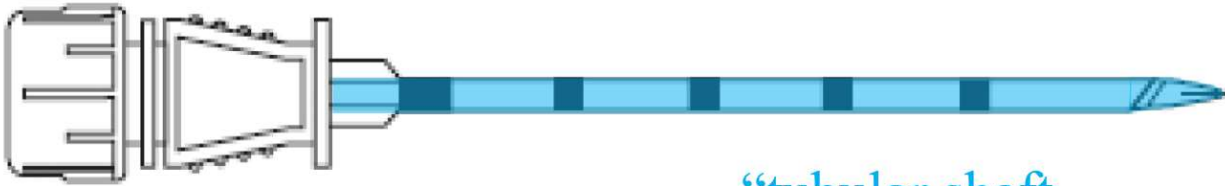
Novella discloses this claim element. EX1003, ¶¶77-78. Specifically, Figure 1 shows the cannula (tubular shaft) of the 17-gauge coaxial needle includes a lumen sized to receive a biopsy needle therethrough. EX1005, 2.



Novella, FIG. 1*

“On the removal of the blunt tip stylet, the guiding cannula of the coaxial needle was an optimal transperineal path for repeated atraumatic passage of the biopsy needle (18-gauge Tru-Cut, 20 cm long), loaded on a spring-driven biopsy gun (Magnum Bard Biopsy Instruments) with a cutting length of 22 mm (Fig. 1).” *Id.*

The manual for the 17-gauge TruGuide coaxial needle provides a closeup view of the lumen:



“tubular shaft
including a lumen
sized to receive a
biopsy needle
therethrough”

EX1006, 1. As the manual explains, the practitioner “[p]lace[s] the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be biopsied,” and then “[p]erform[s] the biopsy and remove[s] the biopsy needle from the guiding cannula.” EX1006, 3. The practitioner “[l]eave[s] the guiding cannula in place” to take additional samples. *Id.*, 3-4; EX1003, ¶78.

5. [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,”***

Novella used a pure freehand technique, manipulating the coaxial biopsy needle and probe by hand without assistive equipment. EX1003, ¶79. Thus, Novella does not expressly disclose inserting a coaxial needle (access needle) into a “transperineal biopsy guide” as in element [1.4]. *Id.* But BK Medical discloses this element, and a POSITA would have combined Novella and BK Medical in a manner that renders obvious element [1.4]. *Id.*

a. BK Medical discloses element [1.4]

BK Medical describes a transrectal ultrasound probe Type 8808e and its accompanying transperineal biopsy guide UA1324 used for transperineal biopsy procedures. EX1007, 9, 12-13; EX1003, ¶80. As highlighted below, BK Medical discloses inserting a needle (at least a portion of a tubular shaft of an access needle) into one of nine needle guide channels (plurality of needle receiving ports) of a needle guide (displacement member) of the UA1324 (transperineal biopsy guide), as claimed. EX1003, ¶80.

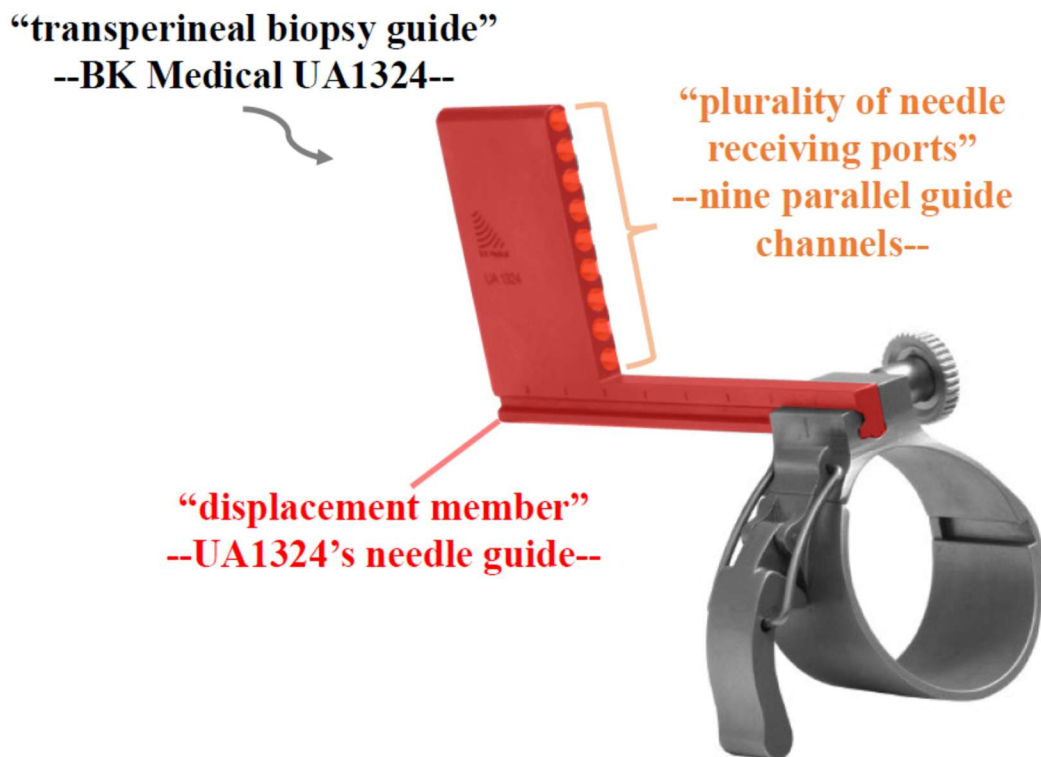


Figure 7. Puncture attachment UA1324.

EX1007, FIG. 7*

Regarding the UA1324's needle guide (displacement member), BK Medical explains:

UA1324 consists of a needle guide and a mounting ring with clamp. The needle guide comprises 9 parallel guide channels, spaced 5mm apart, each with an internal diameter of 2.1mm, suitable for a 14-gauge needle. The guide is parallel to the centerline of the transducer.

Note: The needle guide can be adjusted 70mm lengthwise with respect to the mounting ring, using the adjustment screw.

EX1007, 12.

Figure 8 shows UA1324 mounted to the probe:

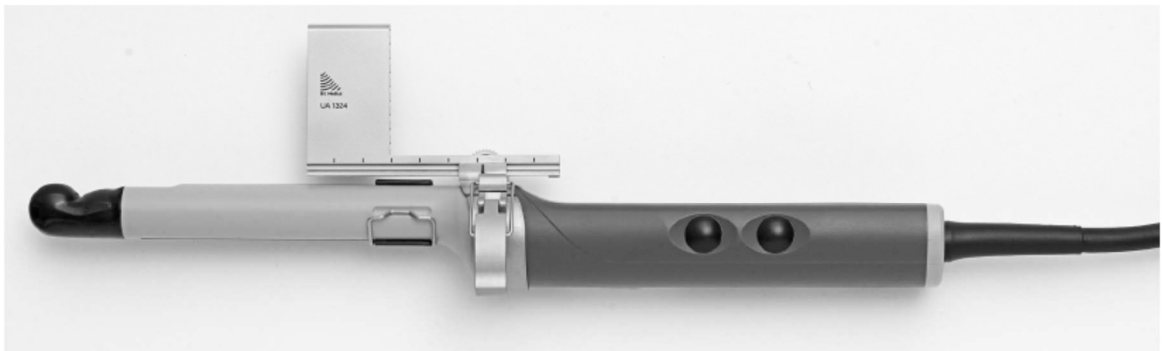


Figure 8. Puncture attachment UA1324 mounted on 8808e.

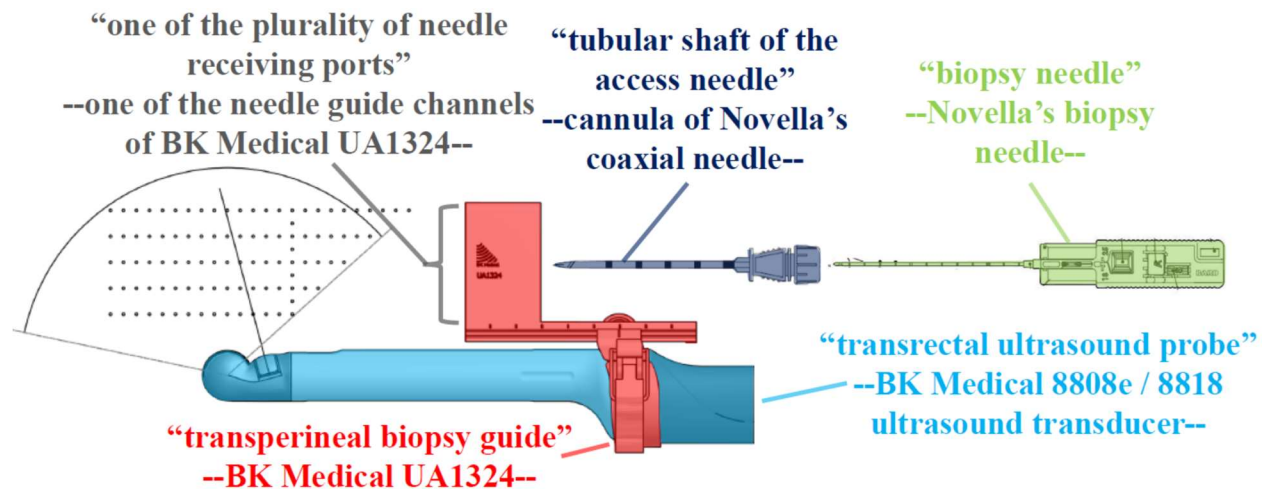
Id., 12; *see also id.*, 13 (FIG. 9). The ultrasound probe system displays “puncture lines” that provide “an indication of the expected needle path” when inserted into each needle guide channel. *Id.*, 13.; EX1003, ¶81. BK Medical teaches to “[m]ove the transducer until the puncture line transects the target. Insert the needle and monitor it as it moves along the puncture line to the target.” EX1007, 13. The

needle of BK Medical may be considered an “access needle” as claimed because it accesses tissue in the patient’s body. EX1003, ¶81.

Accordingly, BK Medical discloses element [1.4].

b. The Novella-BK Medical Combination

A POSITA would have used the BK Medical UA1324 puncture attachment and Type 8808e ultrasound probe in Novella’s coaxial biopsy procedures as follows (EX1003, ¶82):



Novella-BK Medical Combination*

As shown above, and for the reasons discussed below, a POSITA would have mounted UA1324 attachment to the probe, using UA1324 to guide ultrasound imaging and placement of the coaxial and biopsy needles. EX1003, ¶82. Thus, the combination renders obvious inserting the cannula of Novella’s coaxial needle (portion of the tubular shaft of the access needle) into a guide channel (one of a

plurality of needle receiving ports) of needle guide (displacement member) of UA1324 (transperineal biopsy guide), as claimed. *Id.*

c. Rationale to Combine Novella and BK Medical

A POSITA would have found it obvious to use the BK Medical UA1324 biopsy guide and Type 8808e ultrasound probe in Novella's transperineal biopsy procedures performed with a coaxial needle in the manner shown above. EX1003, ¶83. First, the references provide "teaching, suggestion, or motivation" for this combination. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007). Novella's practitioner used a completely freehand technique, handling both the coaxial needle and probe by hand. EX1005, 1-2. Performing biopsies this way has drawbacks, such as:

Fatigue: The technique involves manually manipulating the biopsy needle and ultrasound probe simultaneously throughout the procedure. This can be physically demanding and fatigue the practitioner. EX1003, ¶84. Fatigue from prolonged procedures may decrease precision and increase risk of errors or complications. *Id.*, ¶84.

Time/cost: The technique can be more time-consuming and costly. *Id.*, ¶85. The manual manipulation of both the biopsy needle and ultrasound probe separately requires extra time and effort, extending the duration and/or increasing the cost of the procedure, especially as the number of cores taken increases. *Id.* In

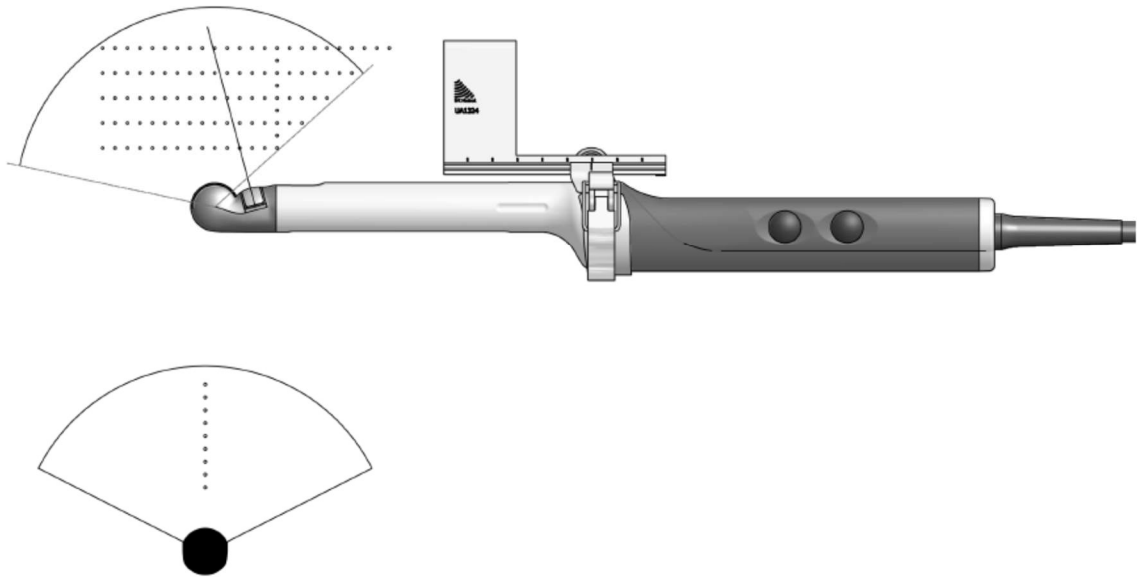
some cases, procedures may require multiple practitioners—one to handle the ultrasound probe and another to perform needle insertion and sample collection. *Id.* In addition to cost, this adds complexity by requiring effective communication and coordination between the team members. *Id.*

Skill: Simultaneous, independent manipulation of the needle and probe demands a higher level of skill from the practitioner than procedures aided by guidance equipment. EX1003, ¶86. The challenge of achieving and maintaining optimal imaging while simultaneously manipulating the needle increases the risk of inaccurate sampling, affecting the overall effectiveness of the procedure. *Id.* Additionally, the need for a precise and steady hand to accurately guide the needle into the prostate while maintaining imaging may require more experienced practitioners—increasing cost, decreasing availability, and/or excluding younger or more inexperienced practitioners from performing the procedure.

A POSITA would have recognized that using UA1324 with the Type 8808e ultrasound probe would address some of the drawbacks of the pure freehand technique used in Novella’s study. EX1003, ¶87. For example, as BK Medical explains, UA1324 mounts directly to the Type 8808e probe by its “mounting ring with clamp.” EX1007, 12. “To mount the transperineal puncture attachment,” the user “slide[s] the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer” and tightens the clamp. *Id.* Once mounted, the

nine parallel guide channels of UA1324 have a fixed alignment with the longitudinal axis of the probe as shown in Figure 9 below:

The puncture lines for UA1324 on 8808e are shown in Figure 9.



EX1007, 13

Fixing alignment of the needle channels to the probe axis allows the practitioner to achieve and hold desired ultrasound imaging by manipulating the probe alone, without needing to coordinate separate movement of the needle. EX1003, ¶87. Thus, using UA1324 guide and Type 8808e probe would alleviate some of the fatigue, time/cost, and skill issues described above. *Id.*

The BK Medical UA1324 and Type 8808e probe would further improve upon the pure freehand technique in Novella by helping practitioners more easily and precisely biopsy desired target areas of the prostate. *Id.*, ¶88. As seen in Figure

9 above, the nine guide channels of UA1324 align with dotted puncture lines displayed on the system monitor during a biopsy procedure. EX1007, 13. “In the sagittal plane,” the longitudinal plane dividing the body into left and right sides, “the puncture path is indicated by a line of dots” displayed on the screen. *Id.*; EX1003, ¶88. And “[t]he distance between each puncture dot is 5mm.” EX1007, 13. While “[i]n the transverse plane,” which divides the body into upper and lower sections, “a single dot indicates the point at which the needle will transect the imaging plane” for a given needle guide channel on UA1324. EX1007, 14; EX1003, ¶88.

When taking a biopsy, the practitioner “[m]ove[s] the transducer until the [desired] puncture line transects the target” on the prostate, “[i]nser[t] the needle and monitor[s] it as it moves along the puncture line to the target.” EX1007, 13. That is, the practitioner selects a needle channel of UA1324 corresponding to a displayed dotted line in the transverse plane that best aligns with a target area of the prostate, inserts the biopsy needle to a depth corresponding to the number of dots needed to reach the target area, and samples the tissue at that location. EX1003, ¶89. Because the BK Medical UA1324 and Type 8808e probe would enable Novella’s practitioner to more easily and accurately biopsy target areas of the prostate, a POSITA would have been motivated to use the BK Medical biopsy guide and probe in the biopsy procedures of Novella. *Id.*

The Novella-BK Medical combination would merely involve applying a known technique (using BK Medical’s puncture attachment and probe) to a known method (Novella’s coaxial-biopsy-needle technique) ready for improvement to yield predictable results. *KSR*, 550 U.S. at 405; EX1003, ¶90. Here, Novella’s coaxial biopsy technique provides the base prior art method ready for improvement. EX1003, ¶90. This base technique involves manipulating both the coaxial biopsy needle and imaging probe purely by hand without assistive equipment. *Id.* And BK Medical discloses transperineal biopsy guide UA1324 and Type 8808e ultrasound probe applicable to improve the biopsy procedure of Novella. *Id.*

A POSITA would have recognized that using the BK Medical transperineal puncture attachment and probe would have yielded predictable results, resulting in an improved biopsy method. *Id.*, ¶91. In the combination, Novella’s practitioner would have performed the biopsies the same way as Novella describes but using the BK medical probe and UA1324 biopsy guide to guide placement of the coaxial needle (and biopsy needle) and ultrasound imaging—instead of separately manipulating the needle and probe by hand. *Id.* The assistance from the BK Medical equipment would have predictably improved the results of Novella’s biopsies for the reasons discussed above. *Id.*

Additionally, a POSITA would have had a reasonable expectation of success combining Novella and BK Medical because the combination simply uses BK Medical's equipment as intended in transperineal biopsies. EX1003, ¶92. The UA1324 puncture attachment is designed for the BK Medical Type 8808e probe. *See* EX1007, 12-13. The guide channels of the UA1324 have a diameter of 2.1mm—large enough to accommodate the 17-gauge coaxial needle of Novella. EX1007, 12; EX1003, ¶92. Novella's practitioner would have performed the coaxial procedures as described in Novella, using the BK Medical probe/attachment to guide and improve the procedures. EX1003, ¶92. Thus, a POSITA would have had a reasonable expectation of success using BK Medical's equipment in Novella's transperineal biopsy procedures. *Id.*

The references provide “teaching, suggestion, and motivation” to use Novella's coaxial needle and the BK Medical equipment in the above configuration rather than use a biopsy needle alone. *KSR*, 550 U.S. at 419; EX1003, ¶93. First, Novella concluded that the coaxial technique resulted in less pain and better compliance for patients than the technique using a biopsy needle alone. Novella divided the patients “into two groups: group 1 ... in which we used the 17-gauge coaxial TruGuide needle, and group 2 ... in which the conventional transperineal technique was used.” EX1005, 1. Group 1 (coaxial) reported better outcomes than group 2 (biopsy needle alone) because “[t]he use of a coaxial needle

reduces the procedure's invasiveness and patient's pain compared with the conventional transperineal prostate biopsy" using a biopsy needle alone. *Id.*; *see id.*, 3 (Table II showing more patients experienced more, and more severe, pain in group 2 than in group 1); EX1003, ¶93.

This is because, "[i]n the conventional transperineal technique, the needle is repeatedly inserted through the perineal plane under local anesthesia." EX1005, 1. Novella "performed 14 biopsies in every patient," requiring fourteen corresponding perineal punctures in the conventional technique. *Id.*, 4; EX1003, ¶94. And "the execution of multiple punctures on perineal skin and multiple perineal paths ... makes it almost impossible to perform adequate local anesthesia" for the conventional technique. EX1008, 3; EX1003, ¶94. Thus, "[t]he main disadvantage of this technique is the need for spinal or general anesthesia" apart from increased invasiveness. EX1008, 4; EX1003, ¶94.

In contrast, the coaxial technique "allow[s] the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle." EX1005, 1; *see also* EX1005, 2 ("the coaxial needle was an optimal transperineal path for repeated atraumatic passage of the biopsy needle"); EX1003, ¶95. For example, long before the claimed priority date of the '436 Patent, physicians practiced "a single-access fan technique" that "us[es] a common [perineal] access for all the cores." EX1008, 1, 3; EX1003, ¶95. The coaxial technique does not require general

anesthesia—only local “anesthetic ... administered along the [coaxial] needle path.” EX1008, 2; EX1003, ¶95. Repeatedly passing a biopsy needle through a coaxial needle and only puncturing the perineum once—opposed to repeatedly puncturing the perineum with the biopsy needle for each sample—minimizes invasiveness, reduces pain, and improves the procedure:

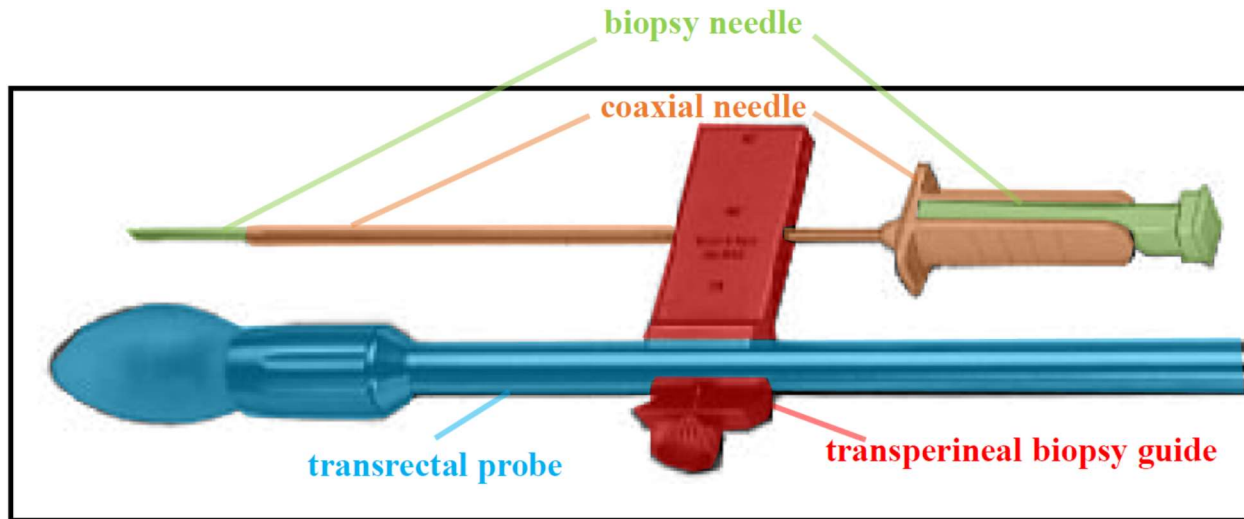
According to the conventional fan technique, biopsies are performed by repeatedly inserting the same biopsy needle through the anesthetized perineal path[.] To minimize the invasiveness of the technique, a coaxial needle can be used with the aim of performing the several needle passages through the same path[.] The coaxial needle makes the procedure easier and quicker, allowing the repeated introduction of the needle with low perineal trauma. [P]atients undergoing transperineal PBx using the coaxial needle showed a reduction of pain during the biopsy and a better compliance for patients using the coaxial needle.

EX1008, 4; EX1003, ¶95. Thus, a POSITA would have used Novella’s preferred coaxial technique with the BK Medical puncture attachment and probe to reduce invasiveness and pain while avoiding the problems with a completely freehand technique, discussed above. EX1003, ¶95.

Additionally, retaining the coaxial needle with the BK Medical equipment would have helped improve cancer-detection rate for a given invasiveness level.

Id., ¶96. It was known in the art that detection rate “directly relate[s] to the number of cores obtained,” and the coaxial technique permits taking multiple cores per puncture. *See, e.g.*, EX1008, 1 (12-16 cores using the single-access fan technique); EX1003, ¶96. In group 1, Novella took fourteen biopsies through a single perineal puncture by the coaxial needle, whereas the group 2 patients received one puncture for each of the fourteen biopsies. EX1005, 1, 2; EX1003, ¶96. Thus, the combination would have increased detection rate for a given invasiveness level by allowing the practitioner to take more samples through fewer perineal punctures, further motivating a POSITA to use Novella’s coaxial technique with the BK Medical equipment. EX1003, ¶96.

Moreover, it was known in the art to use a coaxial needle with a probe-mounted transperineal puncture guide. EX1003, ¶97. For example, Figure 11 of BK Medical 2 shows a probe “assembled for transrectal scanning with puncture attachment UA0650.” EX1009, 14; EX1003, ¶97. The puncture attachment has an installed coaxial needle with a biopsy needle inserted through the coaxial needle:

**EX1009, FIG. 11***

It explains that “[i]f a fine needle is used, it may be helpful to use an additional needle guide.” EX1009, 16. Here, “fine needle” and “needle guide” respectively refer to a biopsy needle and coaxial needle. EX1003, ¶97; EX1015, ¶12. In fact, Dr. Zat’ura testifies that he personally “used the UA0650 in the configuration shown above on patients between 1983 and 1985 ... to perform transperineal prostate biopsies” and “inserted access needles through the UA0650 needle opening.” EX1015, ¶11-12; *see also* EX1003, ¶22.

Novella used an 18-gauge biopsy needle, which a POSITA would consider a “fine needle.” EX1005, 2; EX1003, ¶98. The coaxial needle supports the “fine” biopsy needle by preventing it from straying from the chosen direction. EX1015, ¶13; EX1003, ¶98. The coaxial needle also prevents tumor samples from entering the puncture canal and moving further into the prostate during the procedure.

EX1015, ¶13; EX1003, ¶98. Thus, a POSITA would have retained Novella's coaxial needle (i.e., an "additional needle guide") in performing Novella's biopsy procedures. EX1003, ¶98.

Third, the manufacturer (Bard) of the coaxial needle used in Novella describes the coaxial needle as a needle system in which "[t]he coaxial biopsy needle guide is intended for use as a guiding needle." EX1006, 2; EX1003, ¶99. TruGuide Manual explains, "BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle is a three-part device consisting of an outer cannula [with a hub and inner stylet]" and "designed for use with BARD® disposable biopsy instruments and BARD® disposable biopsy needles." EX1006, 2; *see also* EX1006, 2 (Figure 1 identifies Novella's coaxial needle (with 18-gauge, 20cm biopsy needle) as reorder no. C1820B); EX1003, ¶99. The Manual instructs the practitioner to pass the biopsy needle through the cannula to perform a biopsy, rather than use the biopsy needle alone. EX1006, 3-4 ("Place the appropriate BARD® through the guiding cannula to the lesion to be biopsied" and "Perform the biopsy and remove the biopsy needle from the guiding cannula. Leave the guiding cannula in place"). EX1003, ¶99. Because the biopsy and coaxial needles work together as a system, a POSITA would have retained this configuration in the combination to use the Bard equipment properly. EX1003, ¶99.

6. [1.5] *“the transperineal biopsy guide comprising: a mount releasably coupled to the transrectal ultrasound probe;”*

In the Novella-BK Medical combination, the UA1324 attachment (transperineal biopsy guide) has a mounting ring (mount) releasably coupled to the Type 8808e probe (transrectal ultrasound probe). EX1003, ¶100.

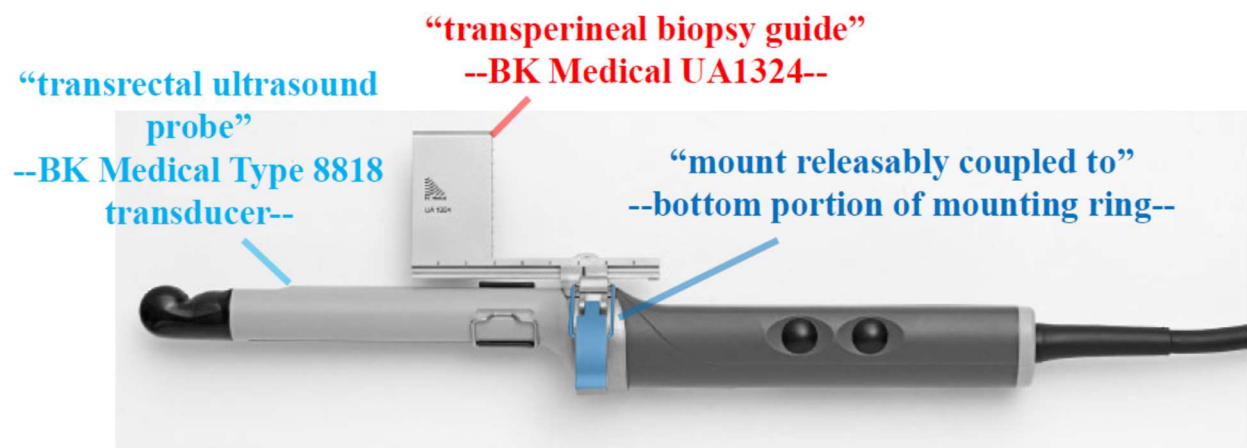


Figure 8. Puncture attachment UA1324 mounted on 8808e.



Figure 7. Puncture attachment UA1324.

EX1007, FIGS. 7, 8*

“UA 1324 consists of a needle guide and a mounting ring with clamp.” EX1007, 12. The bottom portion of the mounting ring with clamp corresponds to the claimed mount. EX1003, ¶100. “To mount the transperineal puncture attachment,” “[l]oosen the clamp on UA1324, [] slide the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer,” and tighten the clamp. EX1007, 12; EX1003, ¶100.

7. [1.6] “a guide member coupled to the mount; and”

The mounting ring of UA1324 has an upper portion (guide member) coupled to the lower portion with clamp (mount), as claimed (EX1003, ¶101):

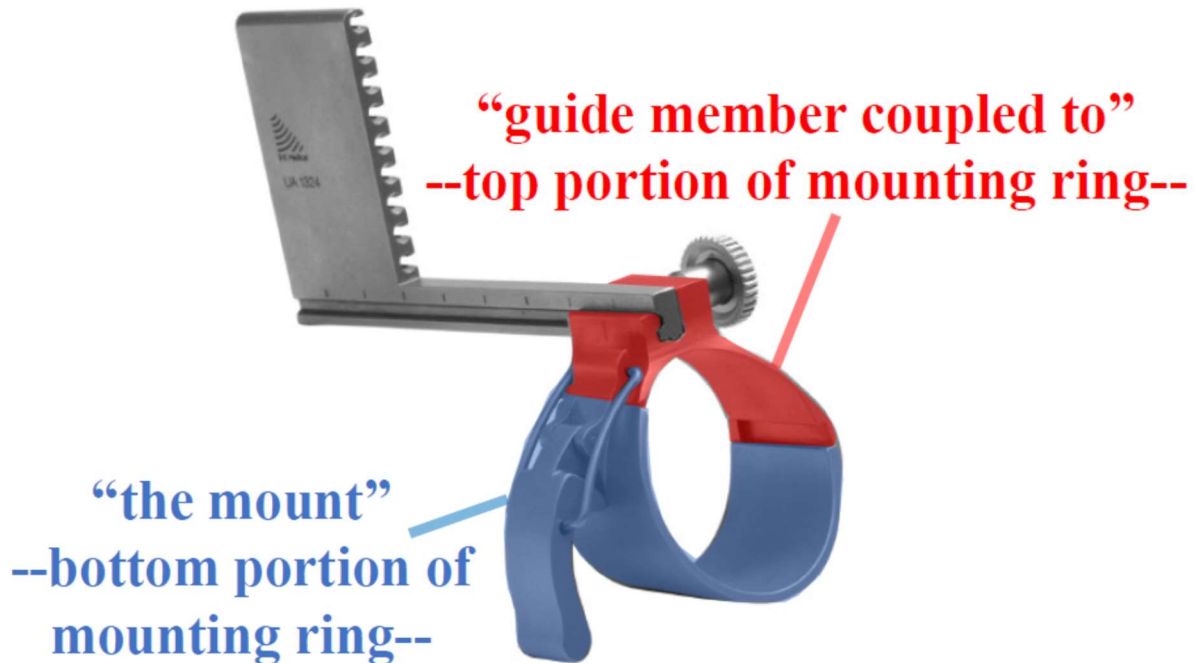


Figure 7. Puncture attachment UA1324.

EX1007, FIG. 7*

The clamp of the lower portion (mount) couples the upper portion (guide member) to the lower portion, as claimed. EX1007, 12; EX1003, ¶101.

8. [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;”*

The needle guide (displacement member) of UA1324 is configured to slide relative to the upper portion of the mounting ring (guide member) and includes a vertical fin (vertically extending member) including the nine needle-guide channels (plurality of needle receiving ports), as claimed (EX1003, ¶102):

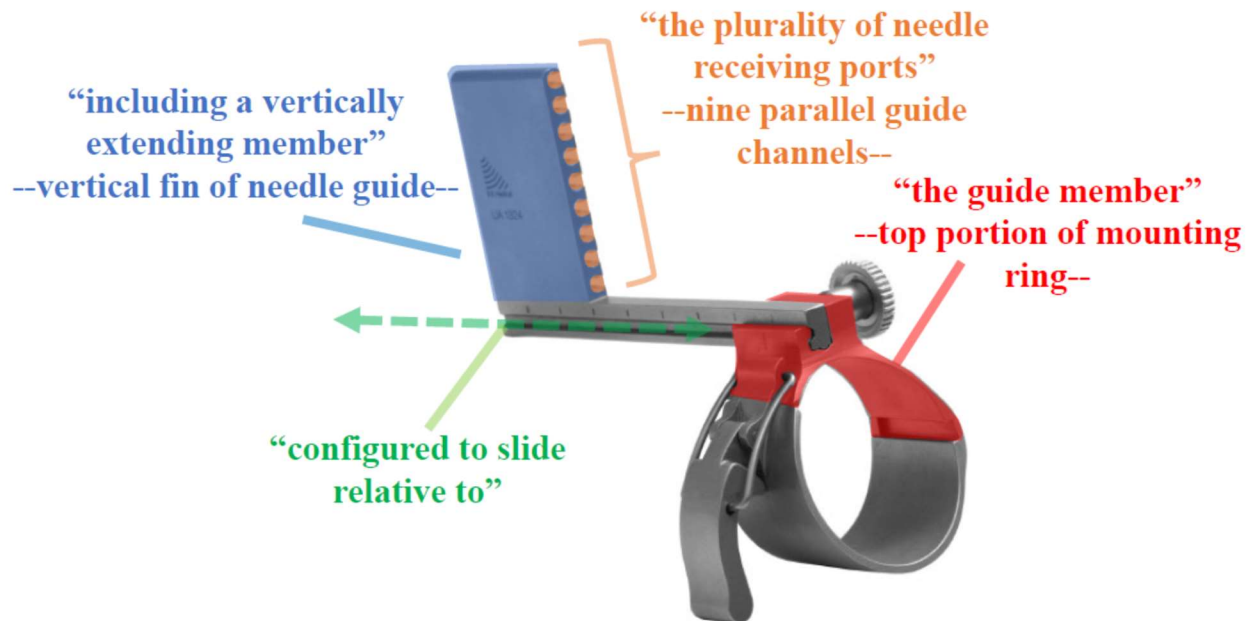


Figure 7. Puncture attachment UA1324.

EX1007, FIG 7*

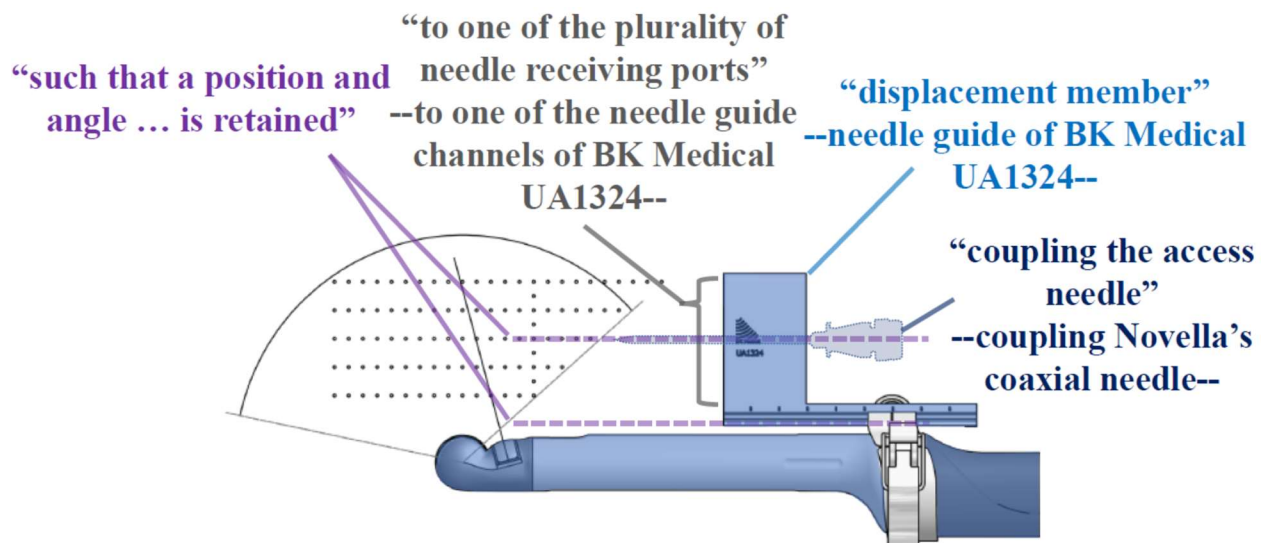
UA1324's needle guide has a vertical fin with "9 parallel guide channels, spaced 5mm apart, each with an internal diameter of 2.1mm, suitable for a 14-gauge needle." EX1007, 12. As explained above for element [1.4], UA1324's needle guide and nine guide channels respectively correspond to the claimed displacement member and plurality of needle receiving ports. *Supra* Section VIII.A.5. Here, UA1324's vertical fin discloses the claimed vertically extending member. EX1003, ¶102.

UA1324's needle guide (displacement member) is configured to slide relative to the upper portion of the mounting ring (guide member), as claimed.

EX1003, ¶103. Specifically, “[t]he needle guide can be adjusted 70mm lengthwise with respect to the mounting ring, using the adjustment screw.” EX1007, 12.

9. [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”*

The Novella-BK Medical combination renders this element obvious. EX1003, ¶104; Sections VIII.A.5.b, VIII.A.5.c. The combination includes 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), such that a position and angle of the coaxial needle (access needle) relative to the needle guide (displacement member) is retained, as claimed:



Novella-BK Medical Combination*

In combination, Novella's coaxial needle (access needle) is coupled within a selected guide channel (needle receiving port) of UA1324 (transperineal biopsy guide). EX1003, ¶105; Section VIII.A.5. The practitioner "[i]nsert[s] the needle and monitor[s] it as it moves along the puncture line to the target," where "[t]he puncture line on the image is an indication of the expected needle path." EX1007, 13. Thus, as illustrated above, 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. EX1003, ¶105; EX1007, 12 (The "9 parallel guide channels" align with the puncture lines and run "parallel to the centerline of the transducer").

As explained above, the claimed "coupling" does not require completely locking the access needle in place to prevent any movement of the access needle. *Supra* Section VI.A. Rather, as Patent Owner contends, coupling the access needle to the receiving port "maintain[s] the stability and directionality of the coaxial needle or the puncture needle" *Id.*; EX1019, 22. BK Medical's UA1324 biopsy guide does this in several ways. EX1003, ¶106.

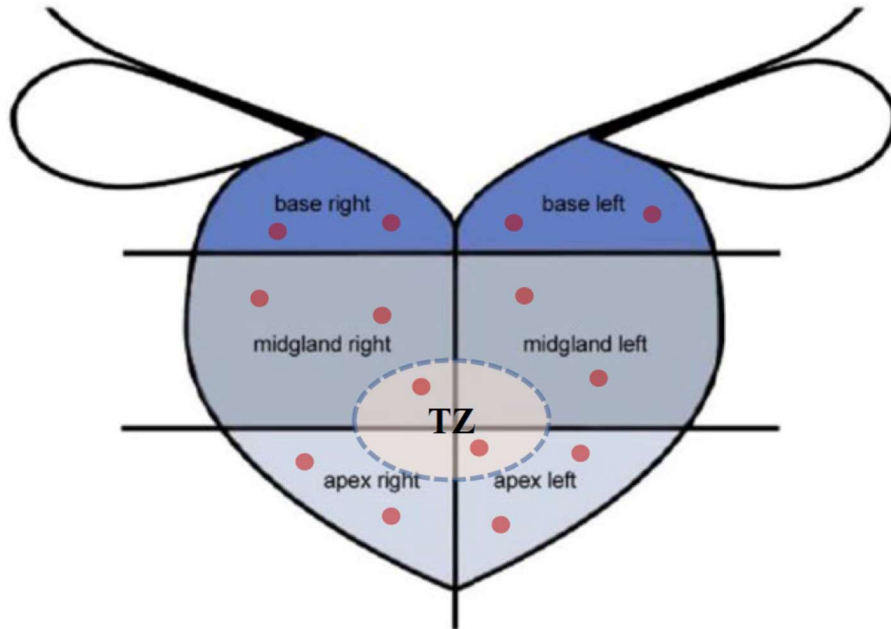
For example, the needle channel maintains the stability of the access needle's direction parallel to the centerline of the transducer. EX1007, 12-13; EX1003, ¶107. When in the channel, the access needle cannot rotate in the plane of

the vertical needle guide fin. EX1003, ¶107. The needle channel also maintains and stabilizes the vertical position of the needle relative to the probe. *Id.* 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.*

10. [1.9] “inserting the biopsy needle through the access needle and into a first location of the prostate of the patient.”

Novella discloses this element. EX1003, ¶108. Novella “performed 14 biopsies in every patient,” accessing the fourteen locations by inserting the biopsy needle through the coaxial needle as a single access point. EX1005, 1, 2, 4 (Novella used the coaxial needle to create an optimum transperineal path for “repeated atraumatic passage of the biopsy needle”). The instruction manual for Novella's coaxial needle also instructs the practitioner to insert the biopsy needle through the access needle (“cannula”) to biopsy a prostate location: “Place the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be biopsied,” “[p]erform the biopsy and remove the biopsy needle from the guiding cannula,” and “[l]eave the guiding cannula in place.” EX1006, 3-4; EX1003, ¶108.

To biopsy fourteen cores, Novella performed a “double sextant biopsy from the peripheral” and also took “two cores from the transition zone.” EX1005, 2; EX1003, ¶109. The Figure below shows the fourteen locations (red dots), across seven regions of the prostate, biopsied in Novella. EX1003, ¶109.



Novella's Biopsy

A double sextant biopsy takes two cores from the left and right sides of the base, midgland, and apex regions of the prostate (12 total), and Novella took two additional cores from the transition zone (TZ) for a total of 14. EX1005, 2; EX1003, ¶109. Any of the fourteen biopsy locations and/or seven regions of the prostate may correspond to the claimed “first location.” EX1003, ¶109.

B. Claim 4

1. [4.1] *“The method of claim 1, further comprising taking a first biopsy of the first location of the prostate of the patient via the biopsy needle.”*

For the reasons discussed above for element [1.9], Novella discloses element [4.1]. *Supra* Section VIII.A.10; EX1005, 1, 2, 4; EX1003, ¶110.

C. Claim 5

1. [5.1] *“The method of claim 4, further comprising taking a second biopsy of a second location of the prostate of the patient via the biopsy needle, the second location being different than the first location.”*

Novella discloses his element. As explained above for element [1.9], Novella biopsied fourteen locations across seven regions of the prostate. *Supra* Section VIII.A.10; EX1005, 1, 2, 4; EX1003, ¶111. Any biopsied location or region of the prostate corresponds to the claimed first location while any remaining biopsied location or region discloses the claimed second location different than the first location. EX1003, ¶111.

D. Claim 6

1. [6.1] *“The method of claim 5, wherein the access needle remains positioned within the perineal access site of the patient for the first biopsy and the second biopsy.”*

Novella discloses this element. EX1003, ¶112. In Novella, the coaxial needle (access needle) remained positioned within the perineal access site of the patient for fourteen biopsies (the first and second biopsies). *Id.*

As explained for element [1.9], Novella biopsied fourteen prostate locations across seven regions of the prostate using a coaxial needle. *Supra* Section VIII.A.10; EX1005, 1, 2, 4; EX1003, ¶113. The coaxial needle remained in place for all fourteen biopsies because Novella used the coaxial needle to “creat[e] ... an optimal transperineal path for repeated atraumatic passage of the biopsy needle.”

EX1005, 1; *see also* EX1005, 2 (“the guiding cannula of the coaxial needle was an optimal transperineal path for repeated atraumatic passage of the biopsy needle”), 4 (“The guiding cannula forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness”); EX1003, ¶113.

The instruction manual for the coaxial needle also teaches that the coaxial needle should remain positioned within the perineal access site of the patient for multiple passes of the biopsy needle. EX1006, 3-4; EX1003, ¶114. Specifically, it instructs the practitioner to “[p]lace the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be biopsied,” “[p]erform the biopsy and remove the biopsy needle from the guiding cannula,” and “[l]eave the guiding cannula in place.” EX1006, 3-4.

E. Claim 12

1. [12.1] *“The method of claim 1, wherein the biopsy needle has a needle size of 18 gauge.”*

Novella discloses this element because the practitioner used “[a]n 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun” in the study. EX1005, 2; EX1003, ¶115.

F. Independent Claim 13

Independent claim 13 is virtually identical in substance to independent claim 1. Novella and BK Medical render obvious claim 13 for the reasons discussed

above for claim 1. Petitioner addresses any additional minor differences between independent claims 13 and 1 below:

1. [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:”***

See discussion above for element [1.pre]. *Supra* Section VIII.A.1; EX1003, ¶117.

2. [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,”***

See discussion above for element [1.4]. *Supra* Section VIII.A.5; EX1003, ¶118. Moreover, as explained above, in the Novella-BK Medical combination, UA1324 (transperineal biopsy guide) is secured to BK Medical Type 8808e. *Supra* Sections VIII.A.5, VIII.A.6; EX1003, ¶118.

3. [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,”***

See discussion above for element [1.2]. *Supra* Section VIII.A.3; EX1003, ¶119.

4. [13.3] *“the tubular shaft including a lumen sized to receive a biopsy needle therethrough,”*

See discussion above for element [1.3]. *Supra* Section VIII.A.4; EX1003,

¶120.

5. [13.4] *“the transperineal biopsy guide comprising a mount configured to releasably couple to the transrectal ultrasound probe,”*

See discussion above for element [1.5]. *Supra* Section VIII.A.6; EX1003,

¶121.

6. [13.5] *“a guide member extending from the mount, and”*

See discussion above for element [1.6]. *Supra* Section VIII.A.7; EX1003, ¶122. Additionally, UA1324’s needle guide (guide member) extends from the upper portion of the mounting ring (mount), as claimed. See EX1007, 12 (right).

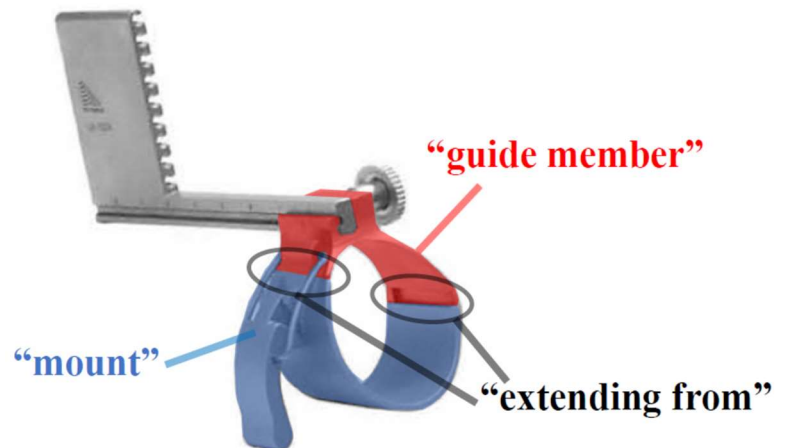


Figure 7. Puncture attachment UA1324.

7. [13.6] *“the displacement member configured to slide relative to the guide member;”*

See discussion above for element [1.7]. *Supra* Section VIII.A.8; EX1003,

¶123.

8. [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;”*

See discussion above for element [1.8]. *Supra* Section VIII.A.9; EX1003, ¶124.

9. [13.8] *“imaging the prostate of the patient with the transrectal ultrasound probe;”*

Novella discloses this element. EX1003, ¶125. In Novella, “we performed a 14-core transperineal prostate biopsy under transrectal ultrasound guidance.” EX1005, 1. “All biopsies were performed by a single urologist (G.N.)” and “TRUS [transrectal ultrasound] was carried out using the Siemens Sonoline Omnia Diagnostic Ultrasound System, with a 7.75-MHz linear probe.” *Id.*, 2. Moreover, the Novella-BK Medical combination includes this element by disclosing imaging the prostate with the BK Medical Type 8808e ultrasound probe. *Supra* Section VIII.A.5.

10. [13.9] *“inserting the access needle into the perineal access site of the patient; and”*

See discussion above for element [1.1]. *Supra* Section VIII.A.2; EX1003, ¶126.

11. [13.10] *“inserting the biopsy needle through the access needle and into the prostate of the patient.”*

See discussion above for element [1.9]. *Supra* Section VIII.A.10; EX1003, ¶127.

G. Claims 16-18

Claims 16-18 depend directly or indirectly from claim 13, which the previous section shows is rendered obvious by the combination of Novella and BK Medical. *Supra* Section VIII.F. Additionally, claims 16-18 recite features shown above to be rendered obvious by the combination of Novella and BK Medical (EX1003, ¶128):

Claim	Citation
16. The method of claim 13, further comprising taking a first biopsy of a first location of the prostate of the patient via the biopsy needle.	See discussion above for claim 4. <i>Supra</i> Section VIII.B.
17. The method of claim 16, further comprising taking a second biopsy of a second location of the prostate of the patient via the biopsy needle, the second location being different than the first location.	See discussion above for claim 5. <i>Supra</i> Section VIII.C.
18. The method of claim 17, wherein the access needle remains positioned within the perineal access site of the patient for the first biopsy and the second biopsy.	See discussion above for claim 6. <i>Supra</i> Section VIII.D.

H. Independent Claim 24

Independent claim 24 is largely identical in substance to independent claims 1 and 13. Novella and BK Medical render obvious claim 1 for the reasons

discussed above for claims 1 and 13. Petitioner addresses any additional minor differences between independent claim 24 and claims 1 and/or 13 below:

1. [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:”***

See discussion above for element [1.pre]. *Supra* Section VIII.A.1; EX1003, ¶130.

2. [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,”***

See discussion above for element [13.1]. *Supra* Section VIII.F.2; EX1003, ¶131. Moreover, as explained above, in the Novella-BK Medical combination, UA1324 (transperineal biopsy guide) is secured to BK Medical probe Type 8808e (transrectal ultrasound probe). *Supra* Sections VIII.A.5, VIII.A.6; EX1003, ¶131.

3. [24.2] ***“the access needle including a tubular shaft and a lumen extending through the tubular shaft,”***

See discussion above for elements [1.2], [1.3]. *Supra* Sections VIII.A.3, VIII.A.4; EX1003, ¶132.

4. [24.3] *“the lumen sized to receive a biopsy needle therethrough,”*

See discussion above for element [1.3]. *Supra* Section VIII.A.4; EX1003, ¶133.

5. [24.4] *“the transperineal biopsy guide operably coupled to the ultrasound probe and”*

See discussion above for element [1.5]. *Supra* Section VIII.A.6; EX1003, ¶134. The clamp of the lower portion of the UA1324 mounting ring operably couples to the BK Medical probe Type 8808e (ultrasound probe). EX1007, 12; EX1003, ¶134.

6. [24.5] *“including a guide member and the displacement member,”*

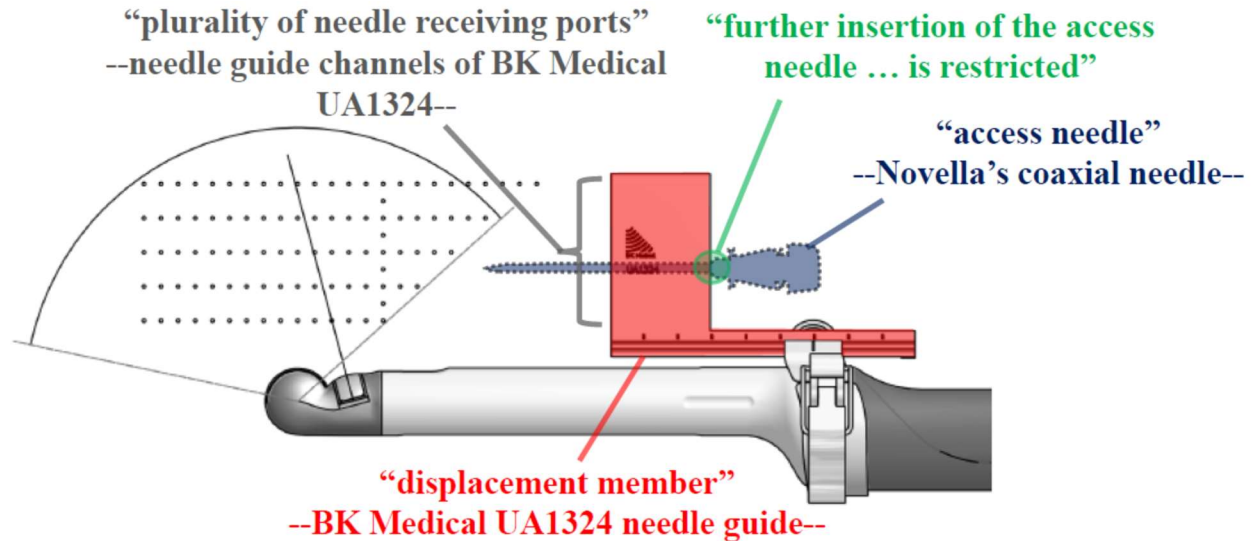
See discussion above for elements [1.4], [1.6]. *Supra* Sections VIII.A.5, VIII.A.7; EX1003, ¶135. In the combination, UA1324 has a guide member (upper portion of mounting ring) and the needle guide (displacement member). EX1007, 12; EX1003, ¶135.

7. [24.6] *“the displacement member configured to slide relative to the guide member,”*

See discussion above for element [1.7]. *Supra* Section VIII.A.8; EX1003, ¶136.

8. [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;”*

See discussion above for element [1.8]. *Supra* Section VIII.A.9. Moreover, the combination renders obvious inserting such that “further insertion of the access needle relative to the displacement member is restricted” in two ways. EX1003, ¶137. First, apparent from the discussion above, the hub of Novella’s coaxial needle has a larger diameter than the needle guide channels of UA1324, so at most the access needle can be inserted until the hub contacts the vertical fin containing the needle guide channels. *Supra* Section VIII.A.5; EX1003, ¶137. In a procedure, the practitioner uses the screw to adjust the length of UA1324’s needle guide so the coaxial needle punctures the perineum to a desired depth when the needle is fully inserted with the hub abutting the needle guide fin as shown below. EX1007, 12; EX1003, ¶137.



Novella-BK Medical Combination*

Second, the coaxial needle has a depth stop—“a flexible slip ring” that “is color coded to match the gauge size of the appropriate BARD® biopsy needle or BARD® biopsy instrument, e.g., Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge, Green=14 gauge and Light Blue=12 gauge.” EX1006, 2. The manual instructs the practitioner to “place the supplied depth stop at the predetermined placement depth” during the biopsy procedure. *Id.*, 3. The depth stop functions “as an aid for proper placement” and “should be adjusted so that the needle is in proper position.” *Id.* Depending on the patient’s anatomy, the practitioner would have used the provided depth stop as a guide to prevent inserting the coaxial too far into the patient’s perinium. EX1003, ¶138. That is, the depth stop contacts the vertical

needle guide fin of UA1324 at the proper perineal depth to prevent further insertion of the coaxial needle into the patient's perineum. *Id.*

9. [24.8] “*imaging the prostate of the patient with the transrectal ultrasound probe;*”

See discussion above for element [13.8]. *Supra* Section VIII.F.9; EX1003, ¶139.

10. [24.9] “*inserting the access needle into the perineal access site of the patient; and*”

See discussion above for element [1.1]. *Supra* Section VIII.A.2; EX1003, ¶140.

11. [24.10] “*inserting the biopsy needle through the access needle and into a first location of the prostate of the patient.*”

See discussion above for element [1.9]. *Supra* Section VIII.A.10; EX1003, ¶141.

I. Claim 28

1. [28.1] “*The method of claim 24, further comprising: taking a first biopsy of the first location of the prostate of the patient via the biopsy needle;*”

See discussion above for element [4.1]. *Supra* Section VIII.B; EX1003, ¶142.

[28.2] “taking a second biopsy of a second location of the prostate of the patient via the biopsy needle, the second location being different than the first location, wherein the access needle remains positioned within the perineal access site of the patient for the first biopsy and the second biopsy.”

See discussion above for element [5.1]. *Supra* Section VIII.C; EX1003,

¶143.

IX. GROUND 2: NOVELLA AND BK MEDICAL, FURTHER IN VIEW OF ZANGOS, RENDERS OBVIOUS CLAIMS 11, 23, AND 29

A. Claims 11, 23, 29

1. [11.1]: *“The method of claim 1, wherein the access needle has a needle size of 15 gauge or 16 gauge.”*

[23.1] “The method of claim 13, wherein the access needle has a needle size of 15 gauge or 16 gauge, and wherein the biopsy needle has a needle size of 18 gauge.”

[29.1] “The method of claim 24, wherein the access needle has a needle size of 15 gauge or 16 gauge, and wherein the biopsy needle has a needle size of 18 gauge.”

Novella-BK Medical in view of Zangos renders these elements obvious.

EX1003, ¶144. While Novella used a 17-gauge coaxial needle, Zangos discloses using 15-gauge coaxial needle in prostate biopsy, and a POSITA would have found it obvious to use 15-gauge coaxial needle in the Novella-BK Medical combination. EX1010, 1; EX1003, ¶144.

2. **Zangos discloses elements [11.1], [23.1], [29.1]**

In Zangos, “[t]he prostate gland was biopsied repeatedly with a coaxial technique through a 15-gauge pencil tip with a 16-gauge biopsy handy (median 3.8

samples per patient).” EX1010, 1. Thus, Zangos discloses the 15- or 16-gauge access needle of elements [11.1], [23.1], and [29.1]. EX1003, ¶145. Moreover, as discussed above, Novella discloses that “the biopsy needle has a needle size of 18 gauge” as claimed in element [29.1]. *Supra* Section VIII.A.4; EX1005, 2 (“An 18-gauge Tru-Cut biopsy needle”).

3. Rationale to Combine Zangos with Novella-BK Medical

A POSITA would have found it obvious to use Zangos’s 15-gauge coaxial needle in the Novella-BK Medical combination with a reasonable expectation of success. EX1003, ¶146. The ’436 Patent explains that the platform’s “hole may be configured to accommodate a needle having a range of 14-18 gauges, such as a reusable 14 gauge spinal needle,” but does not identify any significance to 15- or 16-gauge, specifically. EX1001, 11:34-38.

Zangos, however, successfully used a 15-gauge coaxial needle to identify prostate cancer in ten of 25 patients, taking only 3.8 samples per patient. EX1010, 1. Zangos concluded that the technique “is a safe and promising approach for histological clarification of uncertain or suspicious lesions.” *Id.* Thus, a POSITA would have wanted to use a 15-gauge access needle, instead of the smaller 17-gauge in Novella, to achieve a high detection rate. EX1003, ¶147.

Indeed, if tolerated by the patient, a POSITA generally would have wanted to use a larger coaxial/biopsy needle because larger needles allow taking larger

samples, improving diagnostic accuracy. *Id.*, ¶147. Larger tissue samples reduce the chance of missing cancerous cells, particularly in larger prostates or heterogenous tumors. *Id.* For example, instead of taking 14 samples per patient with a 17-gauge coaxial needle, Novella could have taken fewer cores with Zangos’s 15-gauge coaxial needle while maintaining the same detection rate with less intrusiveness. *Id.* Thus, a POSITA would have had motivation to use Zangos’s 15-gauge needle in Novella’s procedure. *Id.*

A POSITA would have had a reasonable expectation of success because Zangos reported that “[t]he biopsies were performed technically successfully in all patients” and that “[a]t the time of the biopsies all patients tolerated the treatment with minimal or no discomfort after local anesthesia.” EX1010, 3-4. Additionally, the needle guide channels of UA1324 have a diameter of 2.1mm, suitable for up to a 14-gauge needle, and thus could accommodate Zangos’s 15-gauge coaxial needle. EX1007, 15. Because Zangos achieved good results with a 15-gauge coaxial needle, and that needle would work with UA1324, a POSITA would have had both motivation and a reasonable expectation of success using Zangos’s 15-gauge needle in the Novella-BK Medical combination. EX1003, ¶149.

Additionally, the combination would have merely involved simple substitution of one known element (a 15-gauge coaxial needle) for another (a 17-gauge coaxial needle) to obtain predictable results. *KSR*, 550 U.S. at 416. Novella

and Zangos both used coaxial needles in prostate biopsy procedures, so the combination would not change the nature of Novella's procedure. EX1003, ¶150. Novella's procedure would be performed in the same way but using a 15-gauge instead of a 17-gauge coaxial needle. Additionally, Zangos achieved good results with a 15-gauge coaxial needle, so a POSITA also would have expected to have good results using that needle in the Novella-BK Medical biopsy procedure. *Id.*

X. GROUND 3: NOVELLA AND ONIK, FURTHER IN VIEW OF NAKAMURA, RENDERS OBVIOUS CLAIMS 1, 4-6, 12-13, 16-18, 24, and 28

A. Independent Claim 1

1. [1.pre]

As explained in Ground 1, Novella discloses this element. *Supra* Section VIII.A.1; EX1003, ¶151.

2. [1.1]

As explained in Ground 1, Novella discloses this element. *Supra* Section VIII.A.2; EX1003, ¶152.

3. [1.2]

As explained in Ground 1, Novella discloses this element. *Supra* Section VIII.A.3; EX1003, ¶153.

4. [1.3]

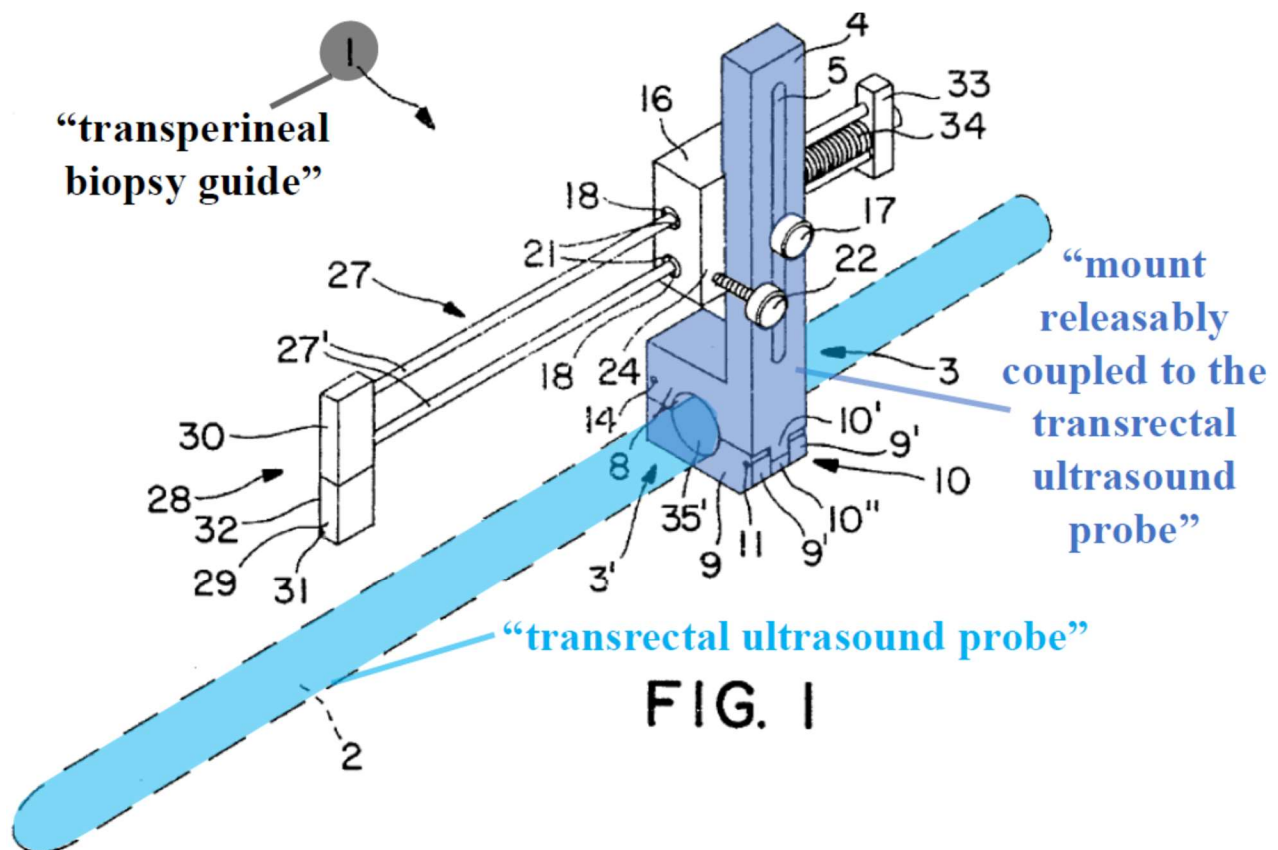
As explained in Ground 1, Novella discloses this element. *Supra* Section VIII.A.4; EX1003, ¶154.

5. [1.5]

Novella in view of Onik renders this element obvious. EX1003, ¶155. Since Novella's practitioners used a pure freehand technique, Novella does not expressly disclose a transperineal biopsy guide as in element [1.5]. But Onik remedies the deficiency of Novella, and a POSITA would have found it obvious to combine the references as explained below. *Id.*

a. Onik Discloses Element [1.5]

Onik discloses a biopsy needle insertion guide 1 (transperineal biopsy guide) comprising a main body 3 (mount) releasably coupled to an ultrasound probe 2 (transrectal ultrasound probe), as claimed (EX1003, ¶156):



Onik, FIG. 1*

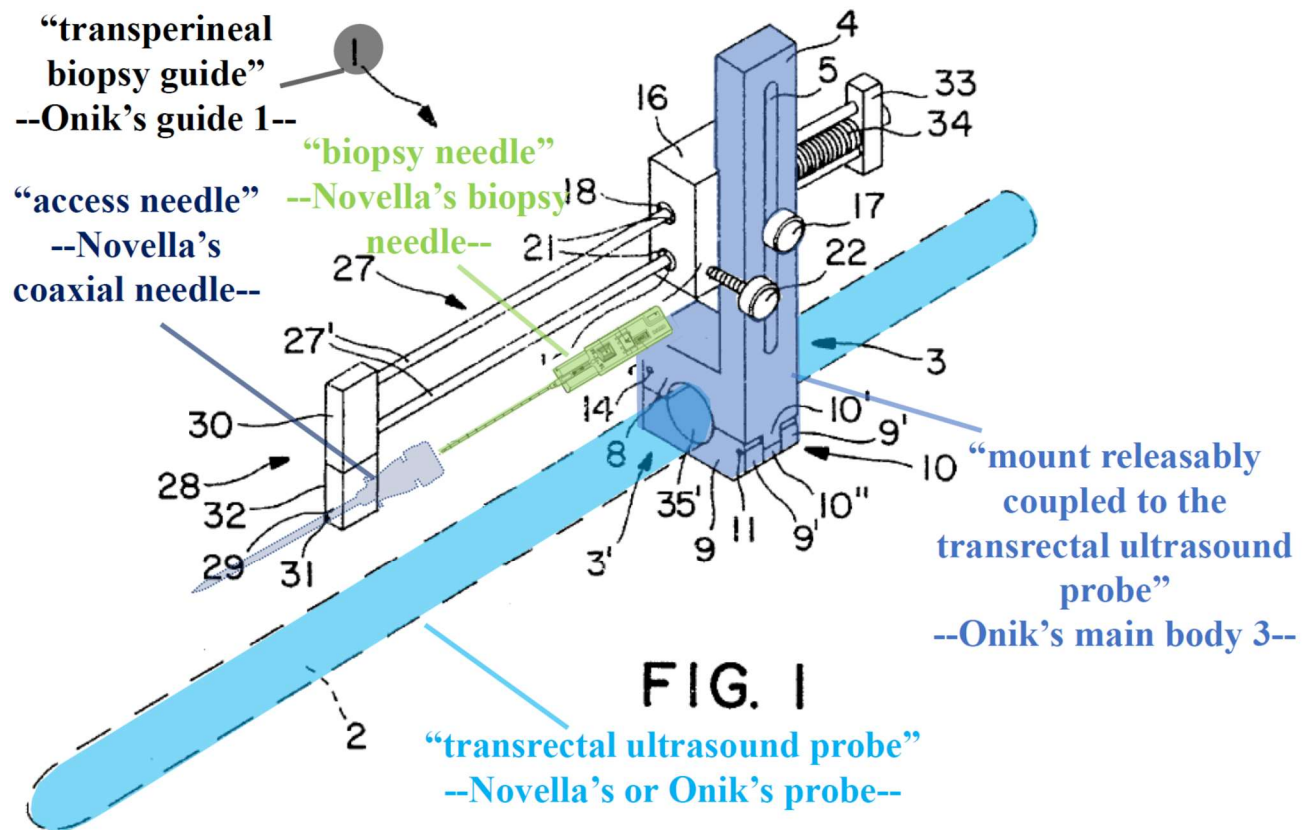
Guide 1 discloses the claimed transperineal biopsy guide. EX1003, ¶157. It is a “biopsy needle insertion guide” that is “used in conjunction with the ultrasound probe [2] to accurately place one or more biopsy needles in a patient’s prostate with the needles[.]” EX1011, 3:34-35, 6:61-63. During a biopsy procedure, “the assembly of the insert guide 1 and probe 2 is advanced proximally until needle holder assembly 28 engages and bears firmly against the patient’s perineum.” *Id.* Guide 1 has a block 29 with “[n]otch 31 ... to provide guidance for a biopsy needle being inserted.” EX1011, 5:43-47. Disclosing the claimed transrectal probe, Onik teaches “ultrasound probe is [2] inserted into the patient’s rectum and is activated to image the prostate.” *Id.*, 7:3-4.

In Onik, main body 3 (mount) of guide 1 is releasably coupled to the ultrasound probe 2, as claimed. EX1003, ¶158. Specifically, the “L” shaped main body 3 has first and second clamp bodies 8, 9 with opposing semicircular cutouts 35. EX1011, 3:47-4:10; EX1003, ¶158. “[W]hen clamp bodies 8 and 9 are brought into closed engagement a substantially cylindrical channel 35’ is provided within which ultrasound probe 2 is retained,” making “insertion guide 1 [] removably mountable on ultrasound probe 2.” EX1011, 4:3-7.

Alternatively, first and/or second clamp bodies 8, 9, without adjustment guide 4, may be considered the claimed mount. EX1003, ¶159. These components releasably couple to the transrectal probe, as claimed. EX1011, 5:52-6:12.

b. The Novella-Onik Combination

A POSITA would have used Onik's guide 1 with the BK Medical Type 8808e ultrasound probe in Novella's biopsy procedures as follows (EX1003, ¶160):



Novella-Onik Combination*

As seen above, a POSITA would have mounted Onik's guide 1 to Novella's probe, using guide 1 to guide ultrasound imaging and placement of Novella's coaxial and

biopsy needles. EX1003, ¶161. For the reasons discussed above for the Novella-BK Medical combination, a POSITA would have retained the coaxial needle in the Novella-Onik combination rather than use a biopsy needle alone with Onik’s guide. *Supra* Section VIII.A.5.c; EX1003, ¶161.

c. Rationale to combine Onik with Novella

For at least similar reasons to those discussed above for the BK Medical UA1324 puncture guide, a POSITA would have been motivated to use Onik’s guide 1 in Novella’s coaxial biopsy procedures. *Supra* Sections VIII.A.5.b, VIII.A.5.c; EX1003, ¶162. While Novella used a pure freehand technique with no assistive tools, Onik’s transperineal guide 1 helps “accurately place biopsy needles in a human prostate” while retaining ultrasound probe 2. EX1011, Abstract, 4:1-6; *see also id.*, 1:8-17, 2:22-29, 6:58-65. Like the needle guide channels of UA1324, Onik’s notch 31 “provide[s] guidance for a biopsy needle being inserted.” EX1011, 5:43-47. And by retaining probe 2 within cutouts 25 of first and second clamp bodies 8, 9, guide 1 maintains “[a]ccurate orientation of insertion guide 1 relative to probe 2.” *Id.*, 4:1-6, 6:5-8. Thus, like UA1324, using Onik’s guide in Novella’s procedures would, for example, mitigate the fatigue, time/cost, and skill drawbacks of Novella’s pure freehand technique discussed above. *Supra* Section VIII.A.5.c.; EX1003, ¶162.

Additionally, for reasons like those discussed above for the BK Medical UA1324, using Onik's guide 1 in Novella's procedures would merely involve applying a known technique (using Onik's transperineal biopsy guide in prostate biopsy) to a known method (Novella's coaxial-biopsy-needle technique) ready for improvement to yield predictable results. *Supra* Section VIII.A.5.c; EX1003, ¶163. Likewise, a POSITA would have had a reasonable expectation of success using Onik's guide for the reasons discussed above for UA1324. EX1003, ¶163.

As highlighted on the right in Figure 2, Onik's guide 1 fits probes of varying sizes because it has "changeable inserts 36 positionable within cut-outs 35 to provide different sizes or shapes of channels 38 in

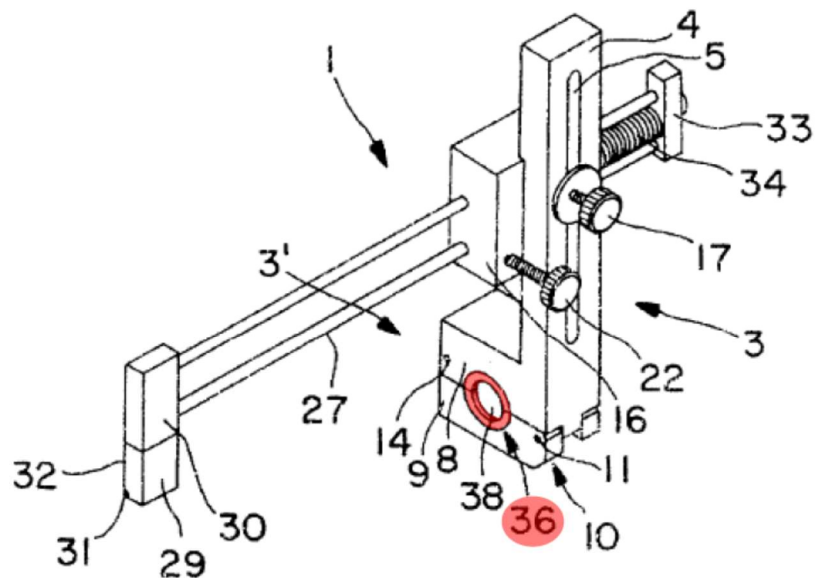


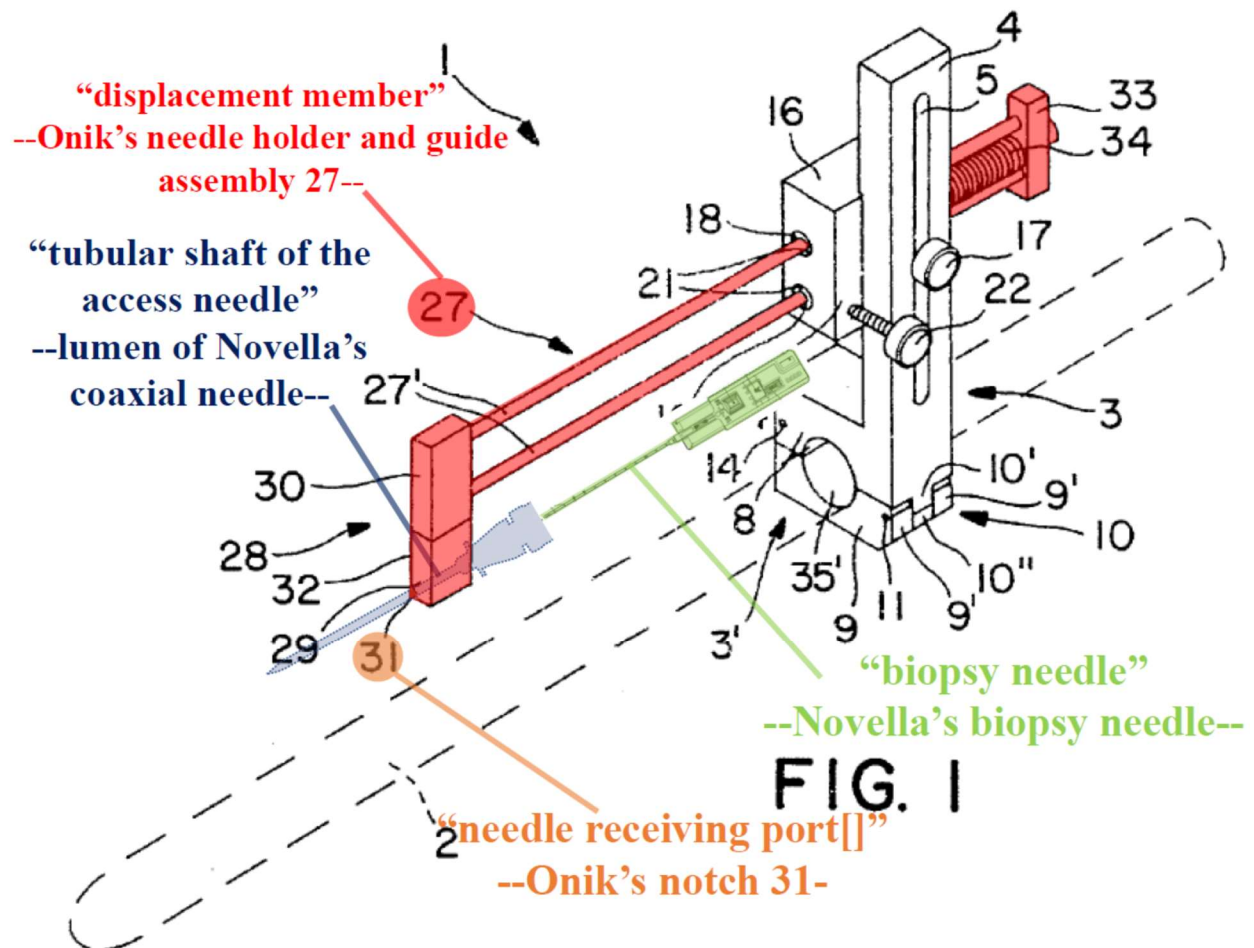
FIG. 2

which an ultrasound probe 2 is received and held.” EX1011, 5:58-60. If necessary, a POSITA would have used these inserts 36 to properly fit and secure Novella’s probe in guide 2. EX1003, ¶164. Alternatively, a POSITA would have simply used Onik’s probe—which fits without inserts 36--instead of Novella’s probe. *Id.*, ¶164. Likewise, notch 31’s “V” shape allows it to accommodate different size needles,

including the coaxial needle of Novella. EX1011, 5:39-50; EX1003, ¶164. For these additional reasons, a POSITA would have had reasonable expectation of success in using Onik's guide with Novella's procedures. EX1003, ¶164.

6. [1.4]

The Novella-Onik combination includes inserting at least a portion of the cannula (tubular shaft) of Novella's coaxial needle (access needle) into notch 31 (needle receiving port) of needle holder and guide assembly 27 (displacement member) of guide 1 (transperineal biopsy guide) (EX1003, ¶165):



Novella-Onik Combination*

Needle holder and guide assembly 27 of Onik's guide 1 corresponds to the claimed displacement member. EX1003, ¶166. "[A]ssembly 27 has a shaft 27' which is slidable through channels 18 in slide block 16." EX1011, 5:19-21. The user displaces assembly 27 toward or away from the patient's perineum by "[l]oosening thumb screw 22," which "allows shaft 27' to be slidably repositioned." *Id.*, 5:8-9. Then, "thumb screw 22 ... can be tightened against shaft 27' to fix assembly 27 in a desired position." *Id.*, 5:5-8.

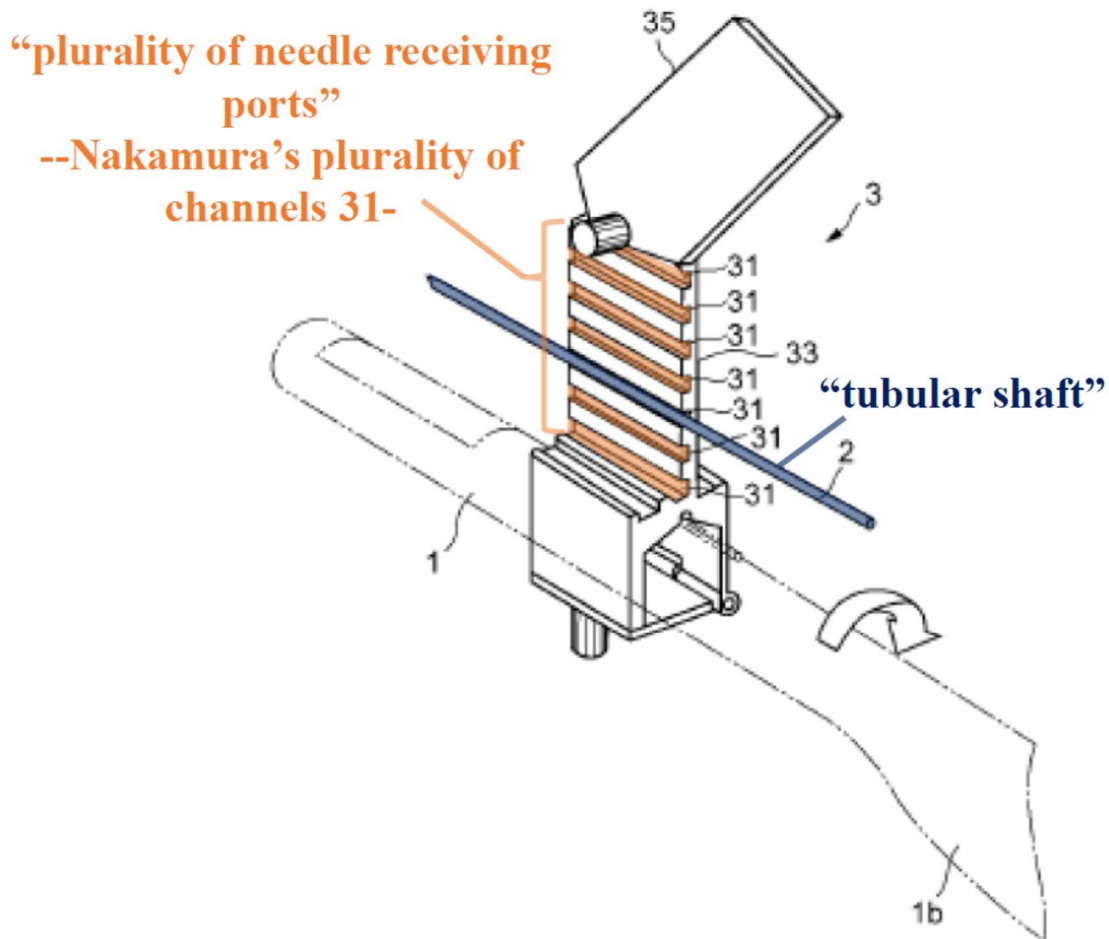
Onik's assembly 27 (displacement member) has a notch 31 corresponding to the claimed "needle receiving port[]." EX1003, ¶167. Specifically, "[a]ffixed to the proximal end of shaft 27' is a needle holder assembly 28 comprising a guide block 29 and a shield 30." EX1011, 5:37-37. "Guide block 29 ... [has] an elongated notch 31 in one face adjacent the lower end of block 29" to "provide guidance for a biopsy needle being inserted." *Id.*, 5:39-46. As seen above, the combination includes inserting at least a portion of the tubular shaft of Novella's coaxial needle (access needle) into notch 31 (needle receiving ports) of assembly 27 (displacement member) of guide 1 (transperineal biopsy guide), as claimed. EX1003, ¶167; *supra* Section X.A.5.b.

Since Onik's assembly 27 has one notch 31, Onik does not disclose a "plurality" of needle receiving ports, as claimed. But Nakamura discloses a

transperineal biopsy guide with a plurality of needle guide channels, and a POSITA would have found it obvious to modify Onik's assembly 27 to have a plurality of needle receiving notches or channels as taught by Nakamura. EX1003, ¶168.

a. Nakamura discloses a “plurality” of needle receiving ports

Nakamura discloses “a puncture adapter 3 for transrectal probe transperineal puncture” having “a guiding part main body 32 composed of a guide plate 33, on which are formed a plurality of channels 31 used in guiding a puncture needle 2.” EX1012, ¶[0038]. Nakamura's channels 31 disclose the claimed plurality of needle receiving ports, as highlighted below. EX1003, ¶169.

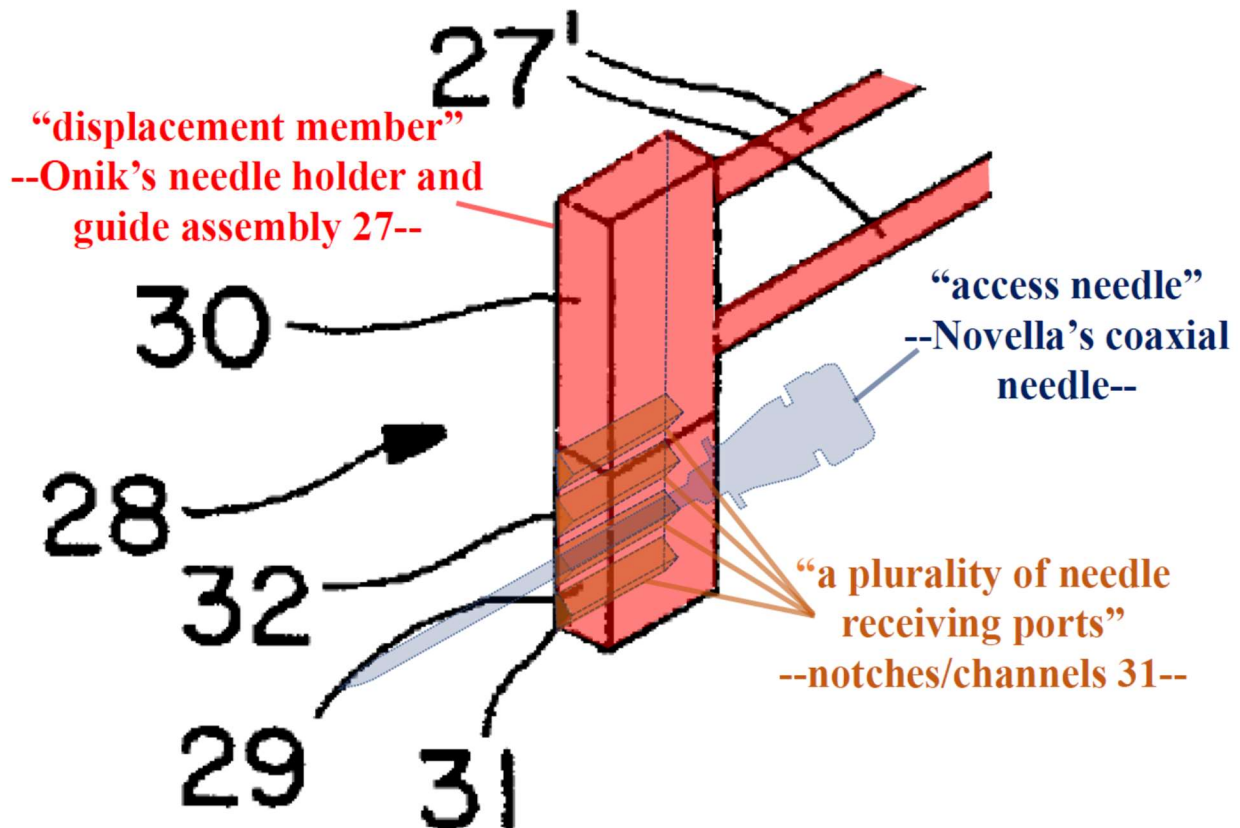


Nakamura, FIG. 10*

In Nakamura, “channels 31 ... are formed so that the puncture needle 2 can be inserted at a plurality of levels in the vertical direction and at a desired position.” EX1012, ¶[0047]. During a biopsy procedure, “a guide hole corresponding to a target position is selected from the plurality of guide holes formed by ... the plurality of channels 31, the puncture needle 2 is entered into the selected guide hole, and the puncture needle 2 is inserted.” *Id.*, ¶[0048]; EX1003, ¶170.

b. The Novella-Onik-Nakamura Combination

A POSITA would have modified Onik's guide 1 to add more notches or channels 31 based on Nakamura's disclosure of multiple channels 31 (EX1003, ¶171):



Novella-Onik-Nakamura Combination*

Like Nakamura, modified block 29 of Onik's assembly 27 has multiple notches/channels 31 instead of one. EX1003, ¶171. Now, as in Nakamura, Onik's needle holder assembly 7 has a plurality of "channels 31 ... formed so that the puncture needle 2 can be inserted at a plurality of levels in the vertical direction and at a desired position." EX1012, ¶[0047]. During a biopsy procedure, a

practitioner may select “a guide hole corresponding to a target position ... from the plurality of guide holes formed by ... the plurality of channels 31” and insert “the puncture needle 2 ... into the selected guide hole” *Id.*, ¶[0048]; EX1003, ¶171. Thus, once the height of block 16 has been set for the procedure, the practitioner may select different notches 31 to target different areas of the prostate without removing probe from the patient to adjusting thumbscrew 17 or attempting adjustment with the probe inserted. EX1003, ¶171; *infra* Section X.A.6.c.

c. Rationale to Combine Nakamura with Novella-Onik

Based on Nakamura’s disclosure of a transperineal biopsy guide with a plurality of needle-receiving channels 31, a POSITA would have found it obvious to modify Onik’s guide block 29 to have more needle-receiving notches/channels 31. EX1003, ¶172. This combination would have offered more convenient positioning of the coaxial needle during biopsy procedures. *Id.*

Onik’s guide 1 has a single “[n]otch 31 ... to provide guidance for a biopsy needle being inserted.” EX1011, 5:43-46. To adjust vertical positioning of the notch/needle, “[t]humb screw 17 is loosened to permit slide block 16 to move along adjustment guide 4 and is tightened against the outer face of adjustment guide 4 to fix slide block 16 in a desired position.” *Id.*, 4:45-52. But making this adjustment during a biopsy procedure may be awkward, inefficient, or uncomfortable for the patient. EX1003, ¶173. For example, the practitioner may

remove the ultrasound probe from the patient's rectum, loosen thumbscrew 17, adjust block 16 up or down, retighten thumbscrew 17, and reinsert the ultrasound probe into the rectum. *Id.* This makes the procedure more inefficient and intrusive for the patient. *Id.* Alternatively, the practitioner may attempt to adjust guide 1 with the probe in the patient's rectum—cumbersome for the practitioner and potentially uncomfortable for the patient as the practitioner manipulates guide 1. *Id.*

Thus, a POSITA considering Novella-Onik would have sought better ways to adjust needle positioning, especially mid-procedure. *Id.*, ¶174. And Nakamura's design, with its plurality of needle channels 31, provides a solution. *Id.* With multiple notches 31 in Onik's block 29 like Nakamura's adapter 3, a practitioner would be able to generally set Onik's guide 1 for a given's patient anatomy using thumbscrew 17 before starting the procedure. *Id.* Then, during the procedure, the practitioner would simply select from multiple notches 31 to precisely target desired areas of the prostate—without necessarily removing/reinserting the probe from the patient's rectum for adjustment or attempting adjustment with the probe inserted. *Id.*

This modification merely involves use of known technique (providing multiple needle guide channels on a transperineal biopsy guide) to improve a similar device (another transperineal biopsy guide) in the same way. *KSR* at 417.

Here, Onik discloses a base transperineal biopsy guide with one needle-receiving notch 31, upon which multiple needle-receiving notches would be seen as an improvement. EX1003, ¶175. Nakamura discloses a comparable transperineal biopsy adapter for an ultrasound probe—improved relative to Onik’s guide with multiple needle-receiving “channels 31 ... so that the puncture needle 2 can be inserted at a plurality of levels in the vertical direction and at a desired position.” EX1012, ¶[0047]. This allows “a target position [to be] selected from the plurality of guide holes formed by ... the plurality of channels 31, the puncture needle 2 [to be] entered into the selected guide hole, and the puncture needle 2 [to be] inserted.” *Id.*, ¶[0048].

A POSITA would have applied Nakamura’s known improvement of multiple needle channels to Onik’s guide, benefiting Onik’s guide in the same way it benefits Nakamura’s adapter. EX1003, ¶176. This modification would have yielded predictable results because Onik’s guide would be used in the same way as Onik describes, except the modified guide has multiple notches 31 in guide block 29 to aid the practitioner to target desired areas of the prostate. *Id.* And the practitioner would not need to attempt cumbersome or intrusive readjustment of Onik’s guide using thumbscrew 17 during the procedure. *Id.*

A POSITA would have had a reasonable expectation of success modifying Onik’s guide to have multiple notches instead of one. EX1003, ¶177. As seen

above, guide bock 29 already has one notch 31 and room for more. *Id.* The additional notches would be added above the existing notch 31. *Id.* If needed, a POSITA would make guide block 29 slightly larger to provide more room for the notches and/or clearance to manipulate the needle(s) while installed in the notches. *Id.* “Notch 31 is preferably a simple ‘V’ notch and ... oriented parallel to the longitudinal axis of shaft 27’ and of ultrasound probe 2.” EX1011, 5:42-45. The additional notches could be made in the same way as the existing notch, such as by grinding guide block 29 or making it from a mold. EX1003, ¶177.

7. [1.6]

The Novella-Onik combination includes this element. EX1003, ¶¶178-180; *supra* Section X.A.5. Onik's guide 1 has slide block 16 (guide member) coupled to main body 3 (mount), as claimed:

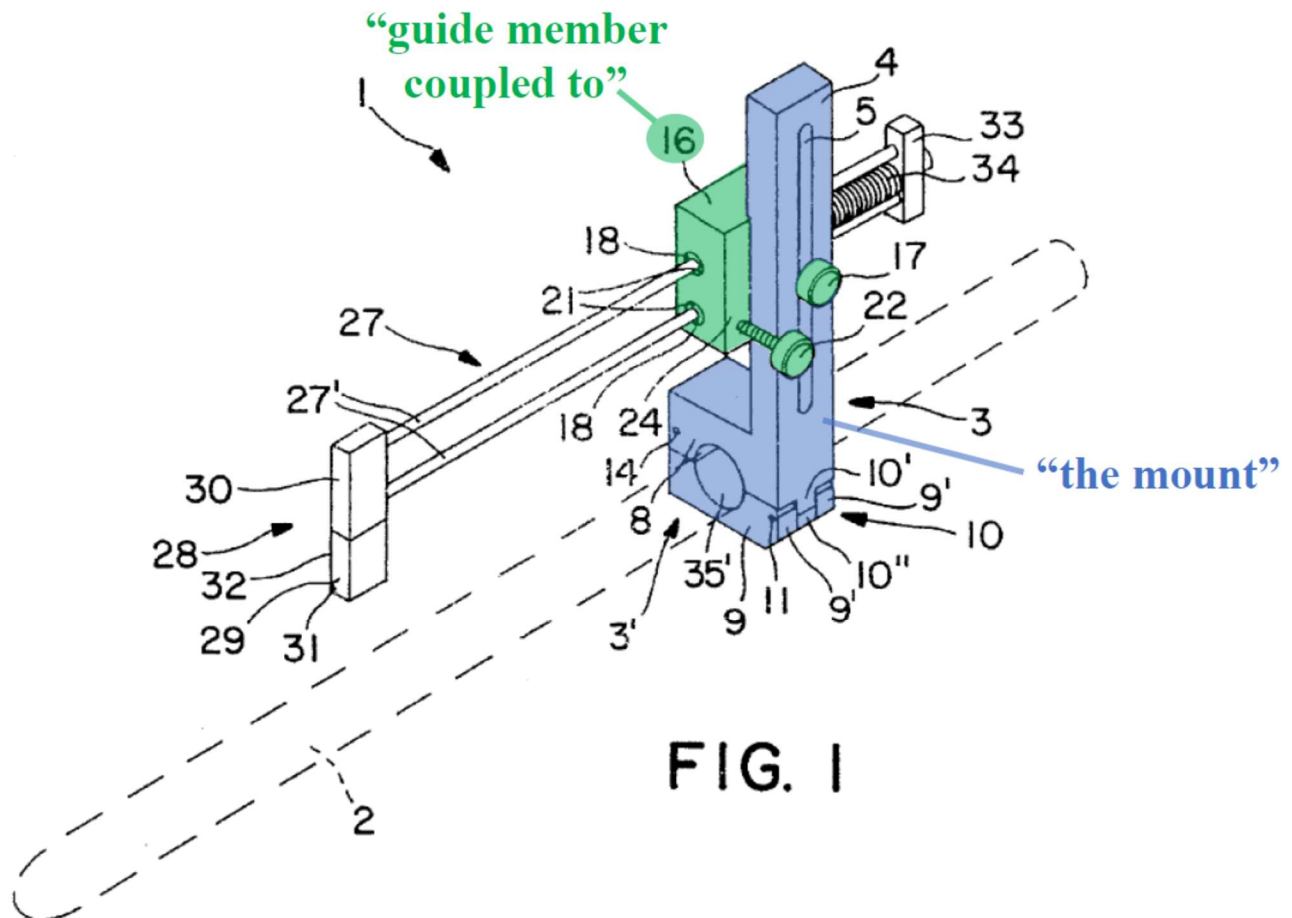


FIG. 1

Novella-Onik Combination*

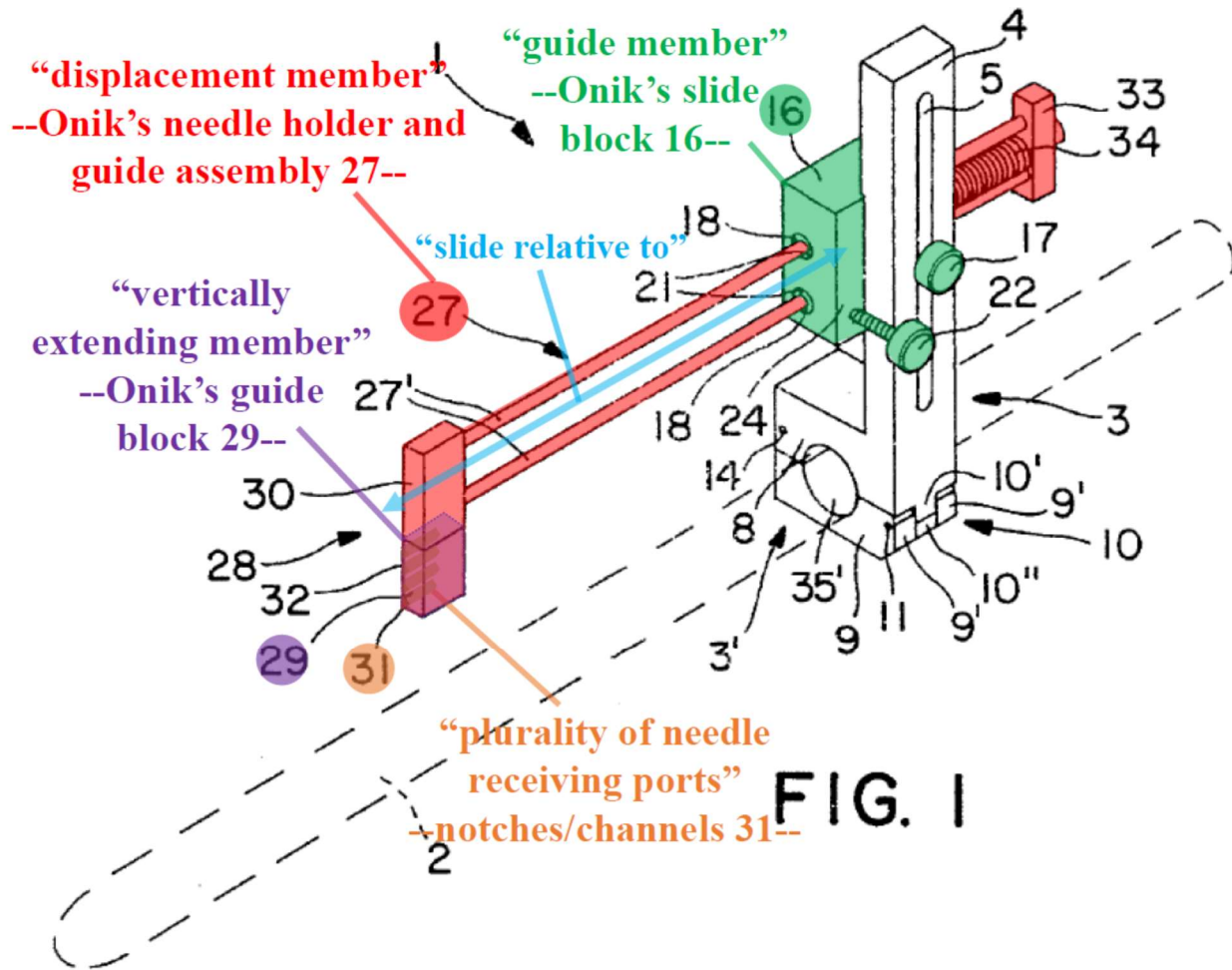
As highlighted above, slide block 16, corresponding to the claimed guide member, couples to main body 3 (mount) through thumbscrew 17 and slot 5. EX1003, ¶178; EX1011, 4:37-5:36, 7:12-20.

Specifically, “[s]lidably associated with anterior-posterior adjustment guide 4 is a slide block 16 which provides anterior-posterior positioning adjustment for a biopsy needle relative to ultrasound probe 2.” EX1011, 4:37-40. “[S]lide block 16 is designed to cooperate with slot 5 and slot track 6 in adjustment guide 4.” *Id.*, 4:40-42. Slide block 16 has “a position locking thumb screw 17 which ... extends through slot 5 to engage slide block 16.” *Id.*, 4:46-48. “Thumb screw 17 is loosened to permit slide block 16 to move along adjustment guide 4 and is tightened against the outer face of adjustment guide 4 to fix slide block 16 in a desired position.” *Id.*, 4:49-52.

As explained above, alternatively first and/or second clamp bodies 8, 9, without adjustment guide 4, may be considered the claimed mount. *Supra* Section X.A.5. Under this interpretation, adjustment guide 4 portion of main body 3 may be viewed as part of the claimed guide member. EX1003, ¶180.

8. [1.7]

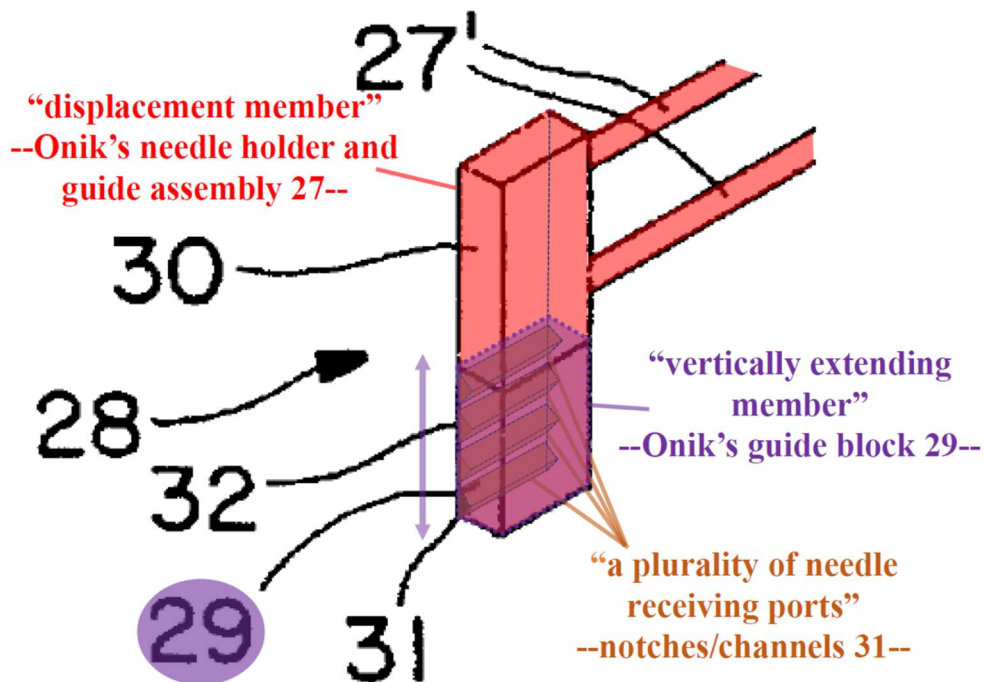
The Novella-Onik-Nakamura combination includes this element. EX1003, ¶¶181-183; *supra* Section X.A.5. Specifically, Onik’s needle holder and guide assembly 27 (displacement member) is configured to slide relative to slide block 16 (guide member) and includes guide block 29 (vertically extending member) including the plurality of notches/channels 31 (needle receiving ports):

**FIG. 1****Novella-Onik-Nakamura Combination***

Assembly 27 (displacement member) is configured to slide relative to slide block 16 (guide member), as claimed. EX1003, ¶181. Slide block 16 has “[p]air of channels 18 ... to slidably receive the double rod shaft 27’ of the needle holder and guide assembly 27.” EX1011, 4:58-63. And “[l]oosening thumb screw 22 allows shaft 27’ to be slidably repositioned” relative to slide block 16. *Id.*, 5:8-9. “The needle holder and guide assembly 27 is then locked in place by tightening thumb screw 22 against shaft 27’.” *Id.*, 7:22-24.

The combination also satisfies this element under an interpretation in which adjustment guide 4 corresponds to part of the claimed guide member. EX1003, ¶182; *supra* Section X.A.7. This is because assembly 17 (displacement member), by sliding along sliding block 16, is also configured to slide relative to adjustment guide 4 (guide member). EX1003, ¶182.

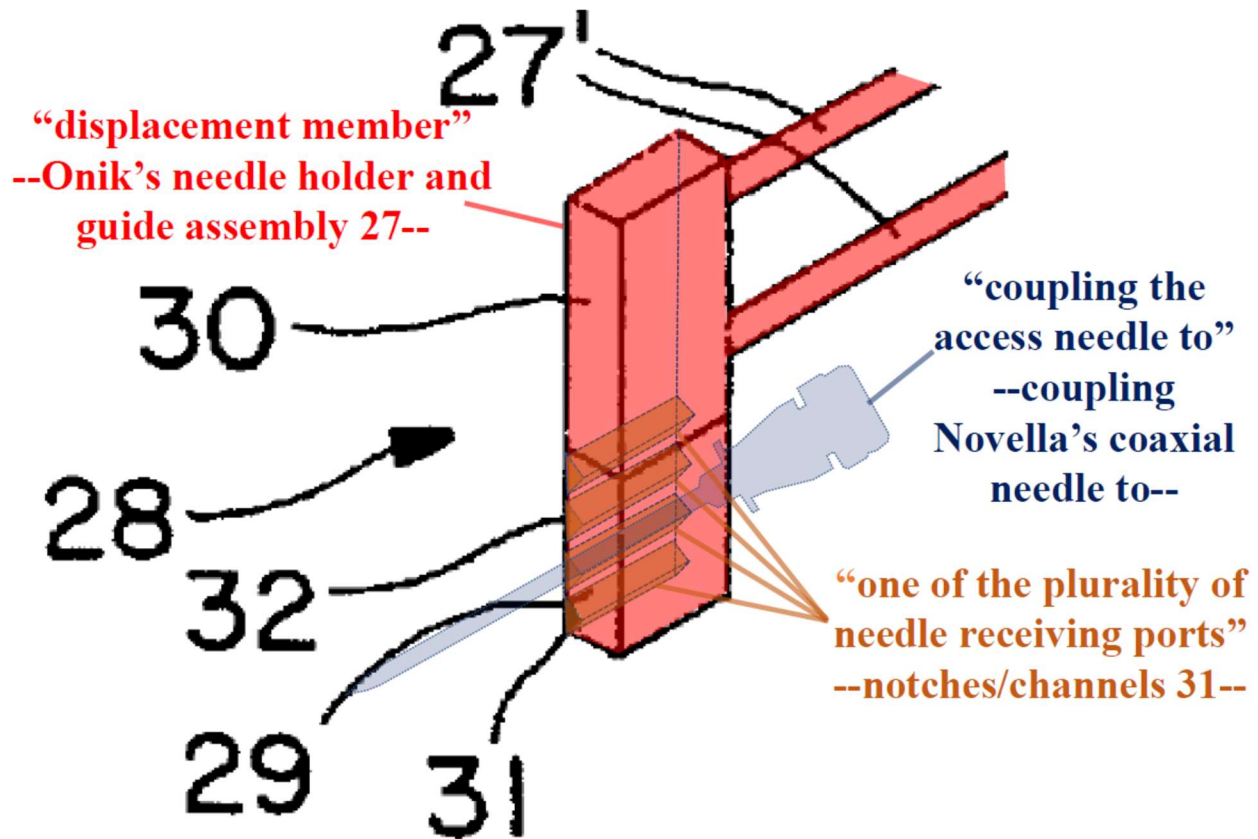
Moreover, in the combination, Onik's assembly 27 (displacement member) includes guide block 29—a vertically extending member including the plurality of notches/channels 31 (needle receiving ports) (EX1003, ¶183):



Novella-Onik-Nakamura Combination*

9. [1.8]

The Novella-Onik-Nakamura combination includes this element. EX1003, ¶184; *supra* Section X.A.5. As explained above for element [1.5], it would have been obvious to use Onik's guide 1 in the coaxial needle biopsy procedures of Novella. *Supra* Section X.C.5. In this combination, Novella's coaxial needle is coupled within needle receiving notch 31 of Onik's guide 1. *Id.* And, as explained above for element [1.4], it would have been obvious based on Nakamura to add more needle receiving notches/channels 31 to Onik's guide 2 based on the disclosure of Nakamura. *Supra* Section X.A.6. Thus, 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 claimed (EX1003, ¶184):



Novella-Onik-Nakamura Combination*

In the combination, as in Nakamura, “a guide hole corresponding to a target position is selected from ... the plurality of channels 31,” and the coaxial needle “is entered into the selected guide hole, and the puncture needle 2 is inserted.” EX1012, ¶[0048]; EX1003, ¶184.

Moreover, for the reasons explained above in Ground 1, the coaxial needle (access needle) is coupled to the notch/channel 31 such that a position and angle of the coaxial needle access needle relative to the Onik’s assembly 27 (displacement member) is retained, as claimed. *Supra* Section VIII.A.9; EX1003, ¶185. Once inserted within a selected notch 31, a position and parallel angle of the coaxial

needle (access needle) relative to Onik's assembly 27 (displacement member) are retained. EX1003, ¶185. The notch maintains the vertical position of the coaxial needle and abutment of the needle hub or depth stop against block 29 and maintains the longitudinal position of the access needle once inserted. *Id.* The notch also maintains the parallel direction of the needle relative to the probe because each "notch ... is oriented parallel to the longitudinal axis of shaft 27" and of ultrasound probe 2 to provide guidance for a biopsy needle being inserted." EX1011, 5:42-46. Thus, the notch maintains the stability and directionality of the coaxial needle. EX1003, ¶185.

Moreover, though the claims do not require locking the access needle in place, Onik's guide block 29 has shield 30 for this purpose. EX1003, ¶186. As shown in Onik's Figure 7 on the right, "[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

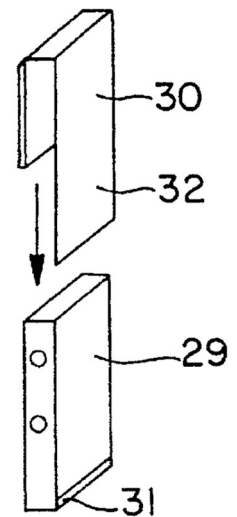


FIG. 7

31." EX1011, 5:45-51 (emphasis added), FIG. 7. In the combination, shield 30 holds Novella's coaxial needle in place in one of notches/channels 31. EX1003, ¶186.

10. [1.9]

As explained in Ground 1, Novella discloses this element. EX1003, ¶187; *supra* Section VIII.A.10.

B. Claims 4-6 and 12

As explained in Ground 1, Novella discloses the elements of claims 4-6 and 12. *Supra* Sections VIII.B-VIII.E; EX1003, ¶188

C. Independent Claim 13

Novella and Onik, further in view of Nakamura, renders obvious independent claim 13 for similar reasons to those discussed above for independent claim 1:

1. [13.pre]

See discussion above for element [1.pre]. *Supra* Section X.A.1; EX1003, ¶190.

2. [13.1]

See discussion above for element [1.4]. *Supra* Section X.A.6; EX1003, ¶191. Moreover, as explained above for element [1.5], in the Novella-Onik combination, Onik's guide 1 is secured to Novella's ultrasound probe or Onik's ultrasound probe. *Supra* Section X.A.5; EX1003, ¶191.

3. [13.2]

See discussion above for element [1.2]. *Supra* Section X.A.3; EX1003, ¶192.

4. [13.3]

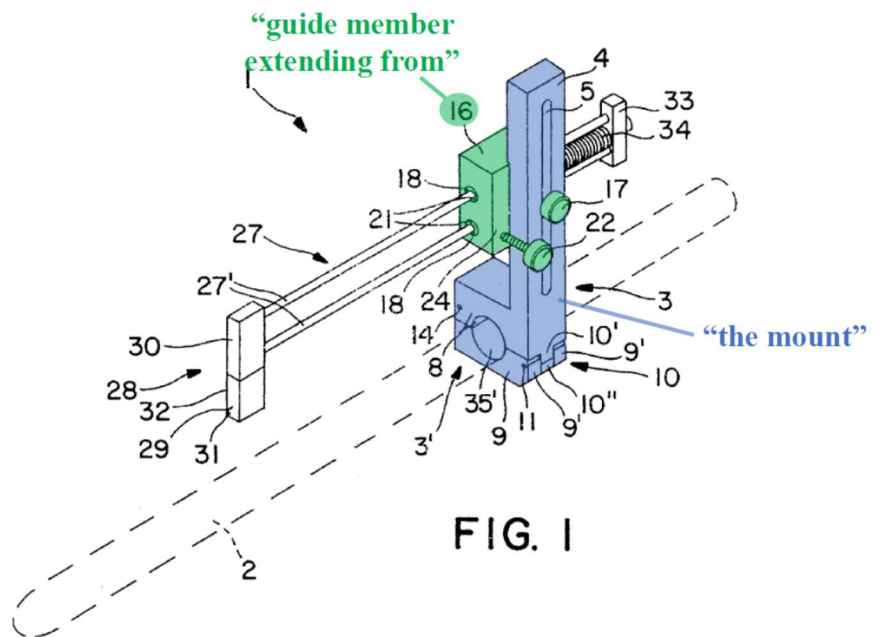
See discussion above for element [1.3]. *Supra* Section X.A.4; EX1003, ¶193.

5. [13.4]

See discussion above for element [1.5]. *Supra* Section X.A.5; EX1003, ¶194.

6. [13.5]

See discussion above for element [1.6]. *Supra* Section X.A.7; EX1003, ¶¶195-196. Additionally, Onik's slide block 16 (guide member) extends from main body 3 (mount) because it is mounted to



adjustment guide 4 of main body 3. EX1003, ¶195. As seen in Figure 1 of Onik annotated below, “slide block 16 is designed to cooperate with slot 5 and slot track 6 in adjustment guide 4” of main body 3. EX1011, 4:40-42. Slide block 16 has “a position locking thumb screw 17 which ... extends through slot 5 to engage slide block 16.” *Id.*, 4:46-48. “Thumb screw 17 is loosened to permit slide block 16 to

move along adjustment guide 4 and is tightened against the outer face of adjustment guide 4 to fix slide block 16 in a desired position.” *Id.*, 4:49-52.

As discussed, alternatively, adjustment guide 4, alone or in combination with sliding block 16, may correspond to the claimed guide while first and/or second clamp body 8, 9 may be considered the claimed mount. *Supra* Sections X.A.5, X.A.7; EX1003, ¶196. Under this interpretation, adjustment guide 4 (guide) extends from clamp bodies 8, 9, as claimed. *Id.*

7. [13.6]

See discussion above for element [1.7]. *Supra* Section X.A.8; EX1003, ¶197.

8. [13.7]

See discussion above for element [1.8]. *Supra* Section X.A.9; EX1003, ¶198.

9. [13.8]

Novella discloses this element. EX1003, ¶199. In Novella, we performed a 14-core transperineal prostate biopsy under transrectal ultrasound guidance.” EX1005, 1. “All biopsies were performed by a single urologist (G.N.)” and “TRUS [transrectal ultrasound] was carried out using the Siemens Sonoline Omnia Diagnostic Ultrasound System, with a 7.75-MHz linear probe.” *Id.*, 2. Moreover,

the Novella-BK Medical combination includes this element by disclosing imaging the prostate with the Type 8808e ultrasound problem. *Supra* Section VIII.A.5.

10. [13.9]

See discussion above for element [1.1]. *Supra* Section X.A.2; EX1003, ¶200.

11. [13.10]

See discussion above for element [1.9]. *Supra* Section X.A.10; EX1003, ¶201.

D. Claims 16-18

Claims 16-18 depend directly or indirectly from claim 13, which the previous section shows is rendered obvious by the combination of Novella, Onik, and Nakamura. *Supra* Section X.C. Additionally, claims 16-18 recite features disclosed by Novella (EX1003, ¶202):

Claim	Citation
16. The method of claim 13, further comprising taking a first biopsy of a first location of the prostate of the patient via the biopsy needle.	See discussion above for claim 4. <i>Supra</i> Section VIII.B.
17. The method of claim 16, further comprising taking a second biopsy of a second location of the prostate of the patient via the biopsy needle, the second location being different than the first location.	See discussion above for claim 5. <i>Supra</i> Section VIII.C.

Claim	Citation
18. The method of claim 17, wherein the access needle remains positioned within the perineal access site of the patient for the first biopsy and the second biopsy.	See discussion above for claim 6. <i>Supra</i> Section VIII.D.

E. Independent Claim 24

Novella and Onik, further in view of Nakamura, renders obvious independent claim 24 for reasons similar to those discussed above for independent claims 1 and 13:

1. [24.pre]

See discussion above for element [1.pre]. *Supra* Section X.A.1; EX1003, ¶204.

2. [24.1]

See discussion above for element [13.1]. *Supra* Section X.C.2; EX1003, ¶205. Moreover, as explained above, in the Novella-Onik combination, Novella's guide 1 (transperineal biopsy guide) is secured to Novella's or Onik's probe (transrectal ultrasound probe). *Supra* Sections X.C.5, X.C.6; EX1003, ¶205.

3. [24.2]

See discussion above for elements [1.2], [1.3]. *Supra* Sections X.A.3, X.A.4; EX1003, ¶206.

4. [24.3]

See discussion above for element [1.3]. *Supra* Section X.A.4; EX1003, ¶207.

5. [24.4]

See discussion above for element [1.5]. *Supra* Section X.A.5; EX1003, ¶208.

6. [24.5]

See discussion above for elements [1.4], [1.6]. *Supra* Sections X.A.6, X.A.7; EX1003, ¶209. Onik's guide 1 includes both slide block 16 (guide member) and needle holder and guide assembly 27 (displacement member). EX1003, ¶209. Under an interpretation in which first and/or second clamp bodies 8, 9 correspond to the claimed mount and adjustment guide 4 corresponds to the claimed guide member, Onik's guide 1 still includes both adjustment guide 4 (guide member) and needle holder and guide assembly 27 (displacement member). *Id.*

7. [24.6]

See discussion above for element [1.7]. *Supra* Section X.A.8; EX1003, ¶210.

8. [24.7]

See discussion above for element [1.8]. *Supra* Section X.A.9. Moreover, the Novella-Onik-Nakamura combination renders obvious securing the access needle such that “further insertion of the access needle relative to the displacement member is restricted” in three ways. EX1003, ¶211.

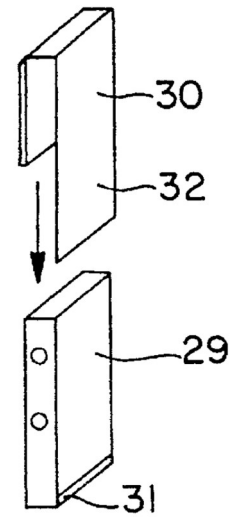


FIG. 7

First, as explained above for element [1.8], Onik’s guide block 29 has shield 30 that, once engaged, locks the access needle in place and thus prevents further insertion. *Supra* Section X.A.9; EX1003, ¶212. As shown in Figure 7 of Onik above, “[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.” EX1011, 5:45-51, FIG. 7. In the combination, shield 30 holds Novella’s coaxial needle in one of notches/channels 31 and prevents further insertion. EX1003, ¶212.

Second, as explained above in Ground 1, the hub of Novella’s coaxial needle (access needle) prevents further insertion when it abuts the needle guide of the UA1324 puncture attachment. *Supra* Section VIII.H.8. The same is true of using Novella’s coaxial needle with Onik’s modified guide block 29 in Ground 3.

27

27'

“a plurality of needle receiving ports”

--notches/channels 31--

30

28

32

29

31

“access needle”
--Novella's coaxial needle--

“further insertion of the access needle ... is restricted”

Onk's guide block 29-

Third, the manufacturer of Novella’s coaxial needle instructs practitioners to use a depth stop. *Supra* Section VIII.H.8. The depth stop would contact Onik’s guide block 29 at the proper perineal depth, signaling the practitioner to stop further insertion of the coaxial needle. *Id.*; EX1003, ¶214.

See discussion above for element [13.8]. *Supra* Section X.C.9; EX1003, ¶215.

10. [24.9]

See discussion above for element [1.1]. *Supra* Section X.A.3; EX1003, ¶216.

11. [24.10]

See discussion above for element [1.9]. *Supra* Section X.A.10; EX1003, ¶216.

F. Claim 28

As explained above in Ground 1, Novella discloses the elements of claim 28. *Supra* Section VIII.I; EX1003, ¶218.

XI. GROUND 4: NOVELLA, NAKAMURA, AND ONIK, FURTHER IN VIEW OF ZANGOS, RENDERS OBVIOUS CLAIMS 11, 23, AND 29

As explained above in Ground 2, Zangos discloses the 15 or 16-gauge access needle recited in claims 11, 23, and 29. *Supra* Section IX.A.2. Additionally, for the same reasons discussed above in Ground 2, a POSITA would have found it obvious to use Zangos' coaxial needle in Novella's procedure with Onik's modified guide 1. *Supra* Section IX.A.2; EX1003, ¶219. And as to element [29.1], Novella discloses that "the biopsy needle has a needle size of 18 gauge" as in element [29.1]. *Supra* Section VIII.A.4; EX1006, 2 ("An 18-gauge Tru-Cut biopsy needle"); EX1003, ¶219.

XII. INSTITUTION IS PROPER UNDER 35 U.S.C. §§ 324(a), 325(d)

A. PTAB Should Grant Institution Under *Becton, Dickinson and Advanced Bionics*

The Board has discretion to deny institution when “the same or substantially the same prior art or arguments previously were presented to the Office,” but should not do so here. 35 U.S.C. § 325(d). The Board has articulated six non-exclusive factors for considering whether to exercise discretion to deny institution under § 325(d). *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, No. IPR2017-01586, Paper 8, 17-28 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first para.). *Becton* factors (a), (b), and (d) address whether the same or substantially the same art or arguments previously were presented to the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, No. IPR2019-01469, Paper 6, 10 (PTAB Feb. 13, 2020) (precedential). *Becton* 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.* Here, although some of the applied art—Onik, Novella, and BK Medical—was either cited by the Examiner or provided with an information disclosure statement (“IDS”) in a parent application, the *Becton* factors firmly weigh in favor of institution.

1. *Advanced Bionics* Prong 1—*Becton* factors (a), (b), and (d)

Nakamura was not previously presented to the Office in prosecution of the ’436 Patent or any family member, and only Onik and Zangos appear on the face

of the '436 Patent. EX1001, 1-2. Zangos was submitted in an IDS in the '436 Patent, and Onik was cited by the Examiner. EX1002, 178-179, 213. In the same IDS, Patent Owner cited Petitioner's initial invalidity contentions in the related litigation that assert BK Medical and Onik, but the '436 Patent had not yet issued. *Id.*, 176. But Patent Owner did not specifically identify BK Medical on the IDS. *Id.*, 175-176. Moreover, the initial contentions do not include Novella, Nakamura, or any of the combinations presented in this Petition.

Patent Owner submitted Novella and a product data sheet for the Type 8808e probe in an IDS in Application No. 17/314,845 (now U.S. Patent No. 11,246,677)—the '436 Patent's grandparent application. EX1020, 73, 354-357, 364-367. But the product data sheet does not contain the same information as the User Guide of EX1007 or describe its biopsy guide UA1324. *Id.*, 354-357. Patent Owner also cited a User Guide for a similar Type 8818 BK Medical probe. *Id.*, 73, 457-474.

Regardless of whether this satisfies the first *Advanced Bionics* prong, the second prong—*Becton, Dickinson* factors (c), (e), and (f)—weighs strongly in favor of institution.

2. *Advanced Bionics* Prong 2—*Becton* factors (c), (e), and (f)

Regarding *Becton, Dickinson* factor (c), none of the Petitioner's references—Novella, BK Medical, Onik, Nakamura, or Zangos—served as a basis

for rejection in prosecution of the '436 Patent or any family member. *See generally* EX1002; *Intel Corp. v. Qualcomm Inc.*, No. IPR2019-00128, Paper 9, 16 (PTAB May 29, 2019) (“The fact that [a reference] was not the basis of rejection weighs strongly against exercising our discretion to deny institution under 35 U.S.C. § 325(d).”). Rather, the Examiner rejected original claims 1-24 as anticipated by Whitmore and never applied another reference in prosecution. EX1002, 207-210. The Office’s silence on Petitioner’s references suggests they were not properly evaluated or appreciated during prosecution.

Accordingly, “the record of the Office’s previous consideration of the art is not well developed or silent,” so “petitioner may show the Office erred by overlooking something persuasive under factors (e) and (f).” *Advanced Bionics*, Paper 6, 10;; *Samsung Elecs. Co. v. Evolved Wireless LLC*, No. IPR2021-00943, Paper 9, 11-12 (PTAB Dec. 1, 2021). Here, the record reflects the Office overlooked the materiality of Petitioner’s prior art to the patentability of the '436 Patent.

In the Notice of Allowance, the Examiner stated that the closest prior art of record was Whitmore, Onik, and two additional references not used in this Petition. EX1002, 35-37. But none of these references even discloses (1) a probe-mounted transperineal biopsy guide with multiple needle-receiving channels like BK Medical or Nakamura or (2) performing a transperineal biopsy with a

coaxial/access needle as disclosed in Novella. This suggests that the Examiner did not analyze or appreciate the significance of Novella or BK Medical, either alone or in combination.

And although the Examiner considered Onik, the Examiner stated Onik did not “alone or in combination” teach “coupling the access needle to the one of the plurality of needle receiving ports ... such that a position and angle of the access needle ... is retained.” EX1002, 36-37. But the Examiner overlooks that Novella (not appreciated), when combined with Onik and Nakamura (uncited) as described Ground 3, render this feature obvious.

Thus, the record’s silence on Petitioner’s prior art reflects the Office failed to appreciate the significance of Petitioner’s proposed grounds. In similar situations with an underdeveloped or silent record on the prior art and a petition that appears likely to prevail, the Board finds *Advanced Bionics* prong 2 weighs in favor of institution. *See, e.g., Samsung Elecs.*, Paper 9, 11-12; *Carrier Fire & Sec. Ams. Corp v. Sentrilock, LLC*, No. IPR2021-00664, Paper 12, 21-23 (PTAB Sept. 16, 2021); *Advanced Energy Indus. Inc. v. Reno Techs. Inc.*, No. IPR2021-01397, Paper 7, 7-8 (PTAB Feb. 16, 2022).

Furthermore, under *Becton* factor (f), additional facts and evidence here warrant institution, including:

- Dr. Yun’s declaration in support of Grounds 1-4 and his personal knowledge that it was known in the art to use a probe-mounted transperineal biopsy guide with an access needle in prostate biopsy procedures;
- Dr. Zat’ura’s testimony that, in the 1980s, he personally performed transperineal biopsies with this configuration; and
- Exhibit 1009 showing a coaxial/access needle coupled to a probe-mounted transperineal biopsy guide (with a plurality of needle receiving channels), corroborating that it was known in the art to perform transperineal biopsies with this configuration.

Accordingly, the Office never evaluated the same or substantially the same prior art or arguments as those presented in Grounds 1-4.

B. Institution is Warranted Under *Fintiv*

Regarding § 324(a), the *Fintiv* factors favor institution. *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, Paper 11, 5-6 (PTAB Mar. 20, 2020) (precedential). The first factor favors institution because no motion to stay has been filed in the related litigation, and the Board does not infer the outcome of such a motion. *Intel Corp. v. VLSI Tech. LLC*, No. IPR2020-00158, Paper 16, 7 (PTAB May 20, 2020); *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, Paper 15, 12 (PTAB May 13, 2020). The district court has granted or partially granted all motions to stay pending a PGR or IPR filed with the court. EX1021, 1.

The second factor favors institution because no trial date has been set yet. The litigation schedule has been extended twice and the court has yet to set a date for the Markman hearing. The average time to jury trial for a patent case in the district court is 52 months from filing. EX1021, 2. Should the Board institute, a final written decision would likely be due in late 2024—well ahead of any expected trial date for the litigation.

Factor three favors institution because the litigation is still in its early states, with minimal investment by the parties and the court. The parties have only begun discovery, and the court has not yet issued a ruling on claim construction.

Factor four strongly favors institution because Petitioner stipulates that, if the Board institutes this proceeding, Petitioner will not maintain in the related district court litigation Grounds 1-4 or other grounds that Petitioner raised or reasonably could have raised in this PGR. By eliminating any potential overlap on invalidity between the PGR and the related litigation, this factor strongly favors institution and should override other arguments for exercising discretion. *Sotera Wireless, Inc. v. Masimo Corp.*, No. IPR2020-01019, Paper 12, 18-19 (PTAB Dec. 1, 2020); Director's Memorandum Regarding Interim Procedure for Discretionary Denials in AIA Post-grant Proceedings with Parallel District Court Litigation of June 21, 2022, 3.

The fifth factor favors institution because Petitioner is a defendant in the related litigation. Thus, this PGR is likely to help the parties resolve their dispute.

Factor six also favors institution. Petitioner was diligent, filing the present Petition before the nine-month PGR deadline. The '436 Patent was not subject to a particularly rigorous examination, as the Office issued just one action before allowance. *See* EX1002. And, as explained above, none of the prior art combinations in this Petition was considered by the Office during original prosecution.

XIII. CONCLUSION

Petitioner respectfully requests institution of this Petition and cancelation of the Challenged Claims as unpatentable.

Respectfully submitted,

Dated: July 21, 2023

By: /James D. Stein/

James D. Stein (Reg. No. 63,782)
Lead Counsel for Patent Owner

CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

The foregoing PETITION FOR POST-GRANT REVIEW complies with the requirements of 37 C.F.R. § 42.24. As calculated by the word count feature of Microsoft Word, plus any annotated words in the figures, the Response contains 18,643 words which is less than the 18,700 allowed and excludes the words contained in the following: Title Page, signature block, Table of Contents, Table of Authorities, List of Exhibits, List of Abbreviations, Certification Under § 42.24(d), and Certificate of Service.

Dated: July 21, 2023

By: /James D. Stein/

James D. Stein (Reg. No. 63,782)

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing PETITION, Power of Attorney, and accompanying exhibits were served by placing a copy with FedEx Priority Overnight on July 21, 2023 as follows:

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