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REQUEST FOR *EX PARTE* REEXAMINATION TRANSMITTAL FORM

Address to:
Mail Stop *Ex Parte* Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attorney Docket No.: A236-0010RE

Date: September 22, 2023

1. ☒ This is a request for *ex parte* reexamination pursuant to 37 CFR 1.510 of patent number 11,446,056 issued September 20, 2022. The request is made by:
☐ patent owner. ☒ third party requester.
2. ☒ The name and address of the person requesting reexamination is:
Advance Medical Designs, Inc.
1241 Atlanta Industrial Drive
Marietta, GA 30066
3. Requester ☐ asserts small entity status (37 CFR 1.27) or ☐ certifies micro entity status (37 CFR 1.29). Only a patent owner requester can certify micro entity status. Form PTO/SB/15A or B must be attached to certify micro entity status.
4. This request is accompanied by payment of the reexamination fee as set forth in:
☒ 37 CFR 1.20(c)(2); or
☐ 37 CFR 1.20(c)(1). In checking this box for payment of the fee set forth in 37 CFR 1.20(c)(1), requester asserts that this request has forty (40) or fewer pages and complies with all other requirements of 37 CFR 1.20(c)(1).
Payment of the reexamination fee is made by the method set forth below.
a. ☐ A check in the amount of \$ _____ is enclosed to cover the reexamination fee;
b. ☐ The Director is hereby authorized to charge the reexamination fee
to Deposit Account No. _____;
c. ☐ Payment by credit card. Form PTO-2038 is attached; or
d. ☒ Payment made via EFS-Web.
☒ In addition, the Director is hereby authorized to charge any fee deficiencies to
Deposit Account No. 12-0769.
5. ☒ Any refund should be made by ☐ check or ☒ credit to Deposit Account No. 12-0769.
37 CFR 1.26(c). If payment is made by credit card, refund must be to credit card account.
6. ☒ A copy of the patent to be reexamined having a double column format on one side of a separate paper is enclosed. 37 CFR 1.510(b)(4).
7. ☐ CD-ROM or CD-R in duplicate, Computer Program (Appendix) or large table
☐ Landscape Table on CD

[Page 1 of 3]

This collection of information is required by 37 CFR 1.510. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) a request for reexamination. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 18 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop *Ex Parte* Reexam, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
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8. ☐ Nucleotide and/or Amino Acid Sequence Submission
If applicable, items a. – c. are required.
- a. ☐ Computer Readable Form (CRF)
- b. Specification Sequence Listing on:
- i. ☐ CD-ROM (2 copies) or CD-R (2 copies) or
- ii. ☐ paper
- c. ☐ Statements verifying identity of above copies.
9. ☐ A copy of any disclaimer, certificate of correction or reexamination certificate issued in the patent is included.
10. ☒ Reexamination of claim(s) 1, 4-6, and 10-13 is requested.
11. ☒ A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on Form PTO/SB/08, PTO-1449, or equivalent.
12. ☒ An English language translation of all necessary and pertinent non-English language patents and/or printed publications is attached.
13. ☒ The attached detailed request includes at least the following items:
- a. A statement identifying each substantial new question of patentability based on prior patents and printed publications. 37 CFR 1.510(b)(1).
- b. An identification of every claim for which reexamination is requested, and a detailed explanation of the pertinency and manner of applying the cited art to every claim for which reexamination is requested. 37 CFR 1.510(b)(2).
14. ☐ A proposed amendment is included (only where the patent owner is the requester). 37 CFR 1.510(e).
15. ☒ It is certified that the statutory estoppel provisions of 35 U.S.C. 315(e)(1) or 35 U.S.C. 325(e)(1) do not prohibit requester from filing this *ex parte* reexamination request. 37 CFR 1.510(b)(6).
16. Service
- a. ☒ It is certified that a copy of this request (if filed by other than the patent owner) has been served in its entirety on the patent owner as provided in 37 CFR 1.33(c).
- The name and address of the party served are:
- PTO Address of Record: Joshua J. Pranckun, Polsinelli PC
- Post Office Box 140310
- Kansas City, MO 64114-0310
- Date of Service: September 22, 2023
- OR
- b. ☐ A duplicate copy is enclosed since service on patent owner was not possible. An explanation of the efforts made to serve patent owner is attached. See MPEP 2220.

[Page 2 of 3]

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17. Correspondence Address: Direct all communication about the reexamination to:

☒ The address associated with Customer Number: 29150

OR

☐ Firm or Individual Name _____
(at the address identified below)

Address

City

State

Zip

Country

Telephone

Email

18. ☒ The patent is currently the subject of the following concurrent proceeding(s):

- a. ☐ Copending reissue Application No. _____
- b. ☐ Copending reexamination Control No. _____
- c. ☐ Copending Interference No. _____
- d. ☒ Copending litigation styled:
See Request

WARNING : Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

/James D. Stein/

September 22, 2023

Authorized Signature

Date

James D. Stein

63782

Typed/Printed Name

Registration No.

☐ For Patent Owner Requester☒ For Third Party Requester

[Page 3 of 3]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<i>In re</i> patent of Matthew J. Allaway	§	Attorney Docket No.: A236.0010RE
	§	
U.S. Patent No. 11,446,056	§	
	§	
Issue Date: Sept. 20, 2022	§	Customer No.: 29150
	§	
Filing Date: Oct. 6, 2021	§	
	§	
For: TRANSPERINEAL PROSTATE	§	
BIOPSY DEVICE, SYSTEMS,	§	
AND METHOD OF USE	§	

Mail Stop “*Ex Parte* Reexam”
Attn: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**REQUEST FOR *EX PARTE* REEXAMINATION OF
U.S. PATENT 11,446,056**

Dear Commissioner:

Pursuant to the provisions of 35 U.S.C. §§ 301-307, Advance Medical Designs, Inc. (“Requester”) hereby requests an *ex parte* reexamination of claims 1, 4-6, and 10-13 (the “Challenged Claims”) of U.S. Patent No. 11,446,056 (the “’056 Patent,” EX1001), which issued on September 20, 2022, to Matthew J. Allaway from U.S. Patent Application No. 17/494,962 (the “’962 Application”), filed on October 6, 2021, which is a continuation in-part of Application Nos. 17/314,845 (the “’845 Application”) and 16/991,150 (the “’150 Application”). The ’845 Application is a continuation of Application No. 16/115,180, which is a continuation of Application No. 14/677,286, which claims priority to Provisional Application No. 61/974,826 (the “’826 Provisional”), filed on April 4, 2014. The ’150 Application is a continuation of Application No. 14/874,104, which is a continuation in-part of Application No. 14/677,286, which claims priority to the ’826 Provisional. The ’056 Patent is currently purportedly assigned to Corbin Clinical Resources, LLC (“Corbin” or “Patent Owner”) according to the assignment record recorded in the U.S. Patent and Trademark Office (“USPTO”) at reel/frame 057713/0818.

Ex Parte Patent Reexamination Filing Requirements

Pursuant to 37 C.F.R. § 1.510(b)(1), statements pointing out at least one substantial new question of patentability (SNQ) based on material, non-cumulative reference patents and printed publications for the Challenged Claims of the '056 Patent are provided in Section II of this Request.

Pursuant to 37 C.F.R. § 1.510(b)(2), reexamination of the Challenged Claims of the '056 Patent is requested, and a detailed explanation of the pertinence and manner of applying the cited references to the Challenged Claims is provided in Section II of this Request. In addition, for each statement of the Patent Owner and accompanying information submitted pursuant to § 1.501(a)(2) that is relied upon in the detailed explanation, the Request explains how that statement is being used to determine the proper meaning of a patent claim in connection with the prior art applied to that claim and how each relevant claim is being interpreted.

Pursuant to 37 C.F.R. § 1.510(b)(3), copies of every patent or printed publication relied upon or referred to in the statement pointing out each substantial new question of patentability or in the detailed explanation of the pertinence and manner of applying the cited references are provided as Exhibits EX1005 to EX1012 of this Request. Requester also includes an Information Disclosure Statement listing all documents on the Exhibit List below.

Pursuant to 37 C.F.R. § 1.510(b)(4), a copy of the '056 Patent is provided as EX1001 of this Request, along with a copy of any disclaimer, certificate of correction, and reexamination certificate issued corresponding to the patent.

Pursuant to 37 C.F.R. § 1.510(b)(5), the attached Certificate of Service indicates that a copy of this Request, in its entirety, has been served on Patent Owner at the following address of record for Patent Owner, in accordance with 37 C.F.R. § 1.33(c):

24030 - Polsinelli PC
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Kansas City, MO 64114-0310
United States

In addition, Requesters have served a courtesy copy of the Request by email on Patent Owner's litigation counsel as follows:

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Pursuant to 37 C.F.R. § 1.510(b)(6), Requester hereby certifies that the statutory estoppel provisions of 35 U.S.C. § 315(e)(1) and 35 U.S.C. § 325(e)(1) do not prohibit Requester from filing this *ex parte* patent reexamination request.

Also submitted herewith is the fee set forth in 37 C.F.R. § 1.20(c)(l).

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TABLE OF EXHIBITS

Exhibit	Description
EX1001	U.S. Patent No. 11,446,056 to Matthew J. Allaway (the "'056 Patent")
EX1002	File History of the '056 Patent, produced by Corbin Clinical as CORBIN CLINICAL-001538
EX1003	Declaration of Edward J. Yun, M.D. in PGR2023-00041
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
EX1013	Declaration of Ingrid Hsieh-Yee, Ph.D. in PGR2023-00041
EX1014	Declaration of Nico Eelbode in PGR2023-00041
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
EX1017	Papers from Related Proceeding in the Netherlands with certified English translation
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 Amended Infringement Contentions for the '056 Patent in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789-SAG (D. Md.)

I. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY

Before describing the substantial new questions of patentability presented in this Request, provided below is an overview of the '056 Patent, a discussion of claim construction, and a summary of the prior art applied in this Request.

A. The '056 Patent

1. Priority

The '056 Patent was filed on October 6, 2021, as U.S. Application No. 17/494,962 (the "'926 Application"). The '056 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. For purposes of this Request, Requester assumes the '056 Patent is entitled to its claimed priority date of April 3, 2014, but Requester reserves the right to dispute the '056 Patent's priority date in other proceedings. Requester's prior art predates the April 2014 filing date of the '826 Provisional, so it does not matter whether the '056 Patent is entitled to its earliest claimed priority date.

2. Prior Art Background

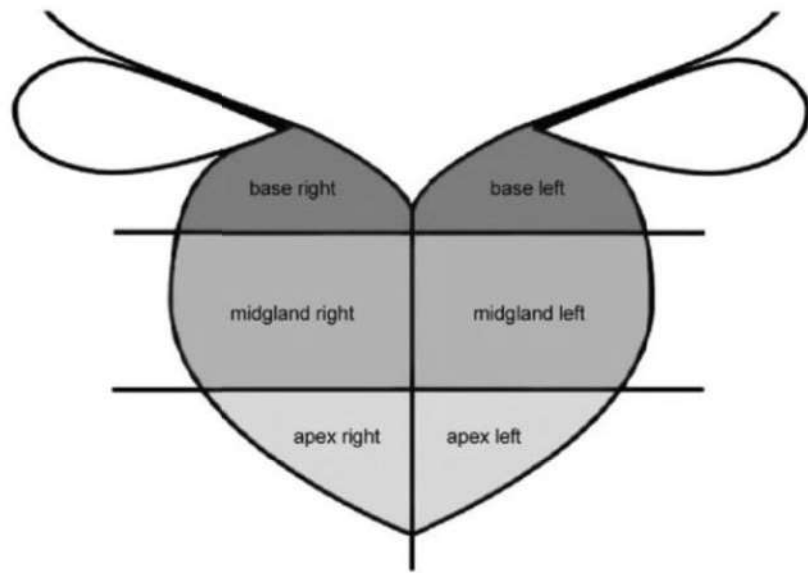
a. Prostate Biopsy Procedures

The '056 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, 1:38-45; EX1003, ¶ 22. There are two types of prostate biopsy procedures: transrectal ultrasound-guided (TRUS) biopsies and transperineal ultrasound-guided (TPUS) biopsies. EX1001, 1:45-47; 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, 1:48-50. 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.*, 1:66-2:1. In both procedures, the practitioner typically uses a transrectal ultrasound probe to guide the needle to target locations of the prostate. *Id.*, 1:38-2:23; EX1003, ¶ 23.

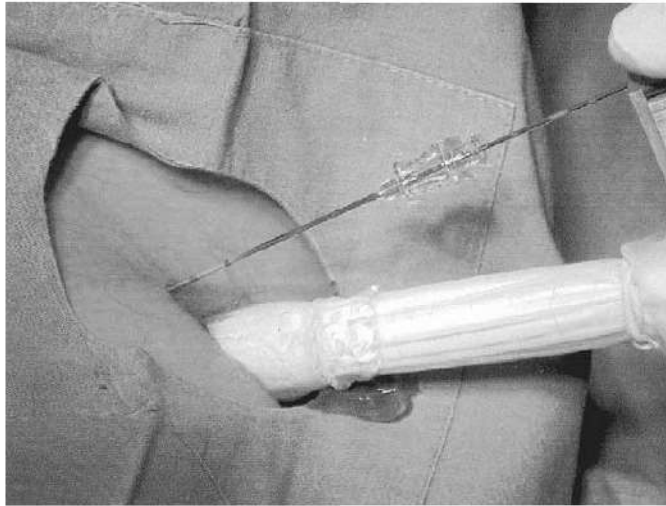
One common type of prostate biopsy—called a sextant biopsy—involves sampling tissue from six areas of the prostate: the left and right sides of each of the base, midgland, and apex

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.



b. 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 below shows a biopsy needle being inserted through a coaxial needle. EX1005, 2.



EX1005, FIG. 1

c. 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.

EX1007, FIG. 8



Figure 7. Puncture attachment UA1324.

EX1007, FIG. 7

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.

3. The Transperineal Biopsy Guide of the '056 Patent

The '056 Patent describes and claims a method of using a transperineal biopsy guide with a coaxial needle, which the '056 Patent calls an “access needle.” EX1001, Abstract, 1:30-34. Figures 27 and 30 of the '056 Patent respectively show isometric and exploded views of the claimed transperineal biopsy guide 2700:

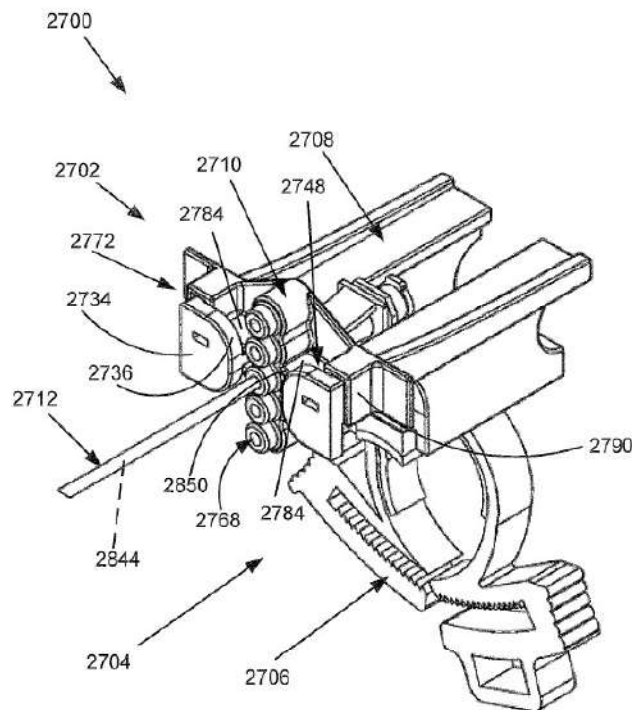


FIG. 27

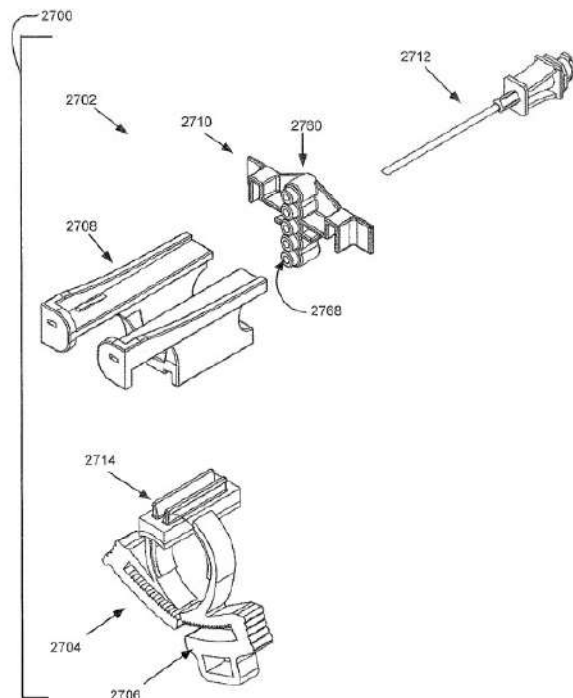


FIG. 30

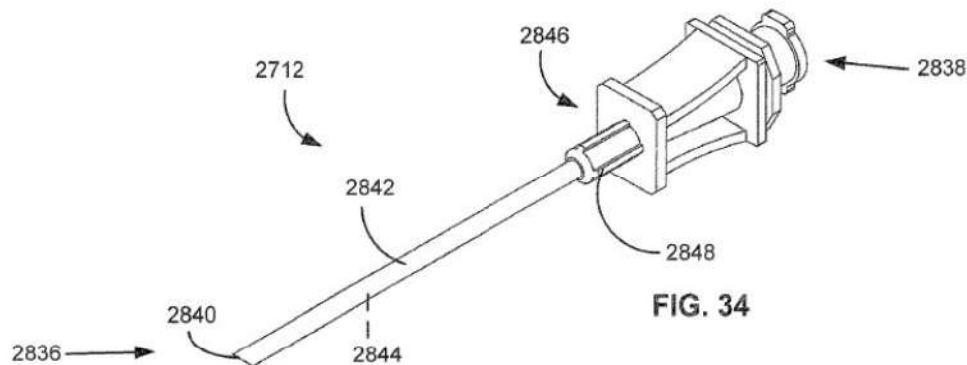
EX1001, FIGS. 27, 30

As seen above, guide 2700 has (1) upper mount 2702, (2) lower mount 2704, (3) guide member 2708, and (4) displacement member 2710 (also called a “translating member” or “sliding platform”). EX1001, 20:1-18.

Lower mount 2704 couples to the transrectal probe. *Id.*, 20:5-8. 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 as “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.*, 22:18-27. 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.*, 22:30-32. “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.*, 22:14-16.

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, 24:59-25:4.



EX1001, FIG. 34

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.*, 26:63-67. 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.*, 9:43-36.

4. Prosecution History

In the first Office Action, the Examiner rejected all claims for nonstatutory, obviousness-style double patenting over U.S. Patent Nos. 11,246,677, 10,064,681, 11,096,762, and 10,743,909. EX1002, 180-90. Applicant, in response, submitted a terminal disclaimer. *Id.*, 173. The Examiner subsequently issued a Notice of Allowance. *Id.*, 56.

5. 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 ’056 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.*

B. Claim Construction

Because the '056 Patent does not expire until April 2, 2035, the Challenged Claims should be given their broadest reasonable interpretation. MPEP § 2258.I.G (citing *In re Yamamoto*, 740 F.2d 1569, 222 USPQ 934 (Fed. Cir. 1984)); 37 C.F.R. § 1.555.

Requester submits that no express constructions are needed to resolve the Grounds in this Request but discusses the scope of “securing” for element [13.1] below. Additionally, Requester submits the parties’ claim construction statements in the related litigation. *See* EX1018. Requester reserves the right to raise claim construction and other arguments in this and other proceedings as relevant and necessary.

1. “Securing the access needle . . .” (Element [13.1])

Dependent claim 13 recites “securing the access needle to the one of the plurality of needle receiving ports such that movement of the access needle relative to the vertically extending member is restrained.” EX1001, 36:34-37. This term does 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 securing to restrain “movement of the access needle relative to the vertically extending member”—not necessarily locking all degrees of freedom of the access needle. Dependent claims 14 and 30 recite “the access needle and the plurality of needle receiving ports including corresponding features that restrain relative movement when secured together,” which would restrict the access needle beyond that required by the independent claims. EX1001, 36:34-37; 38:24-27. For example, an 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.” *Id.*, 25:2-4, 25:59-60, 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.*, 25:62-65. 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 Requester’s interpretation of the “securing” term.

Patent Owner applies the same understanding in its infringement contentions against Requester. *See* EX1019. Requester’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.

Requester’s SureFire Biopsy Guide (left) and BK Medical’s UA1324 Biopsy Guide (right)
Patent owner does not contend that “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, 13.

Accordingly, for purposes of this Request, the “securing” element 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.

C. Listing of Prior Art Patents and Printed Publications

Requester requests reexamination of the Challenged Claims in view of the following references. In support of the public availability of the non-patent literature prior art references, Requester submits the declaration of Ingrid Hsieh-Yee, Ph.D (EX1013).

1. References Describing Use of a Coaxial Needle in Transperineal Biopsy

a. 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 '056 Patent under 35 U.S.C. § 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 patient 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. *Difference in subjective measures between studied groups*

	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.*

b. 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:



EX1006, 1

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.

c. 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 ’056 Patent under 35 U.S.C. § 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.

d. 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 '056 Patent under 35 U.S.C. § 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.*

2. References Disclosing Transperineal Biopsy Guides

a. BK Medical (EX1007)

i. 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 '056 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 '056 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.* EX1016 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 '056 Patent under 35 U.S.C. § 102(a)(1).¹

ii. Overview

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



Figure 7. Puncture attachment UA1324.

EX1007, FIG. 7

¹ 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 '056 Patent. *See* EX1017.



Figure 8. Puncture attachment UA1324 mounted on 8808e.

EX1007, FIG. 8

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.

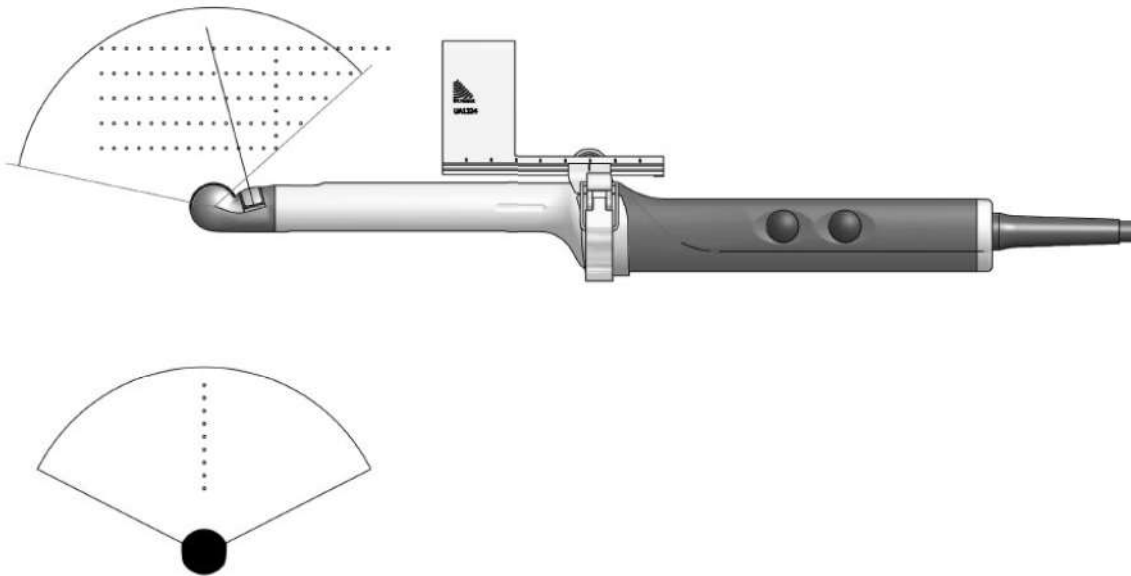


Figure 9. Illustration of the puncture line for puncture attachment UA1324.

EX1007, FIG. 9

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.

b. 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 '056 Patent. *Supra* Section I.C.2.a.i; 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.

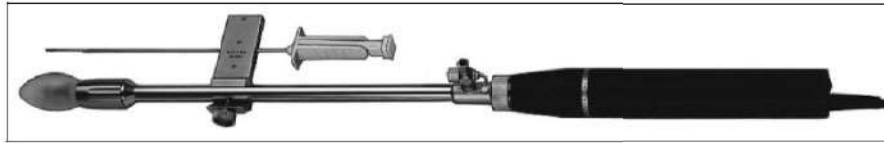
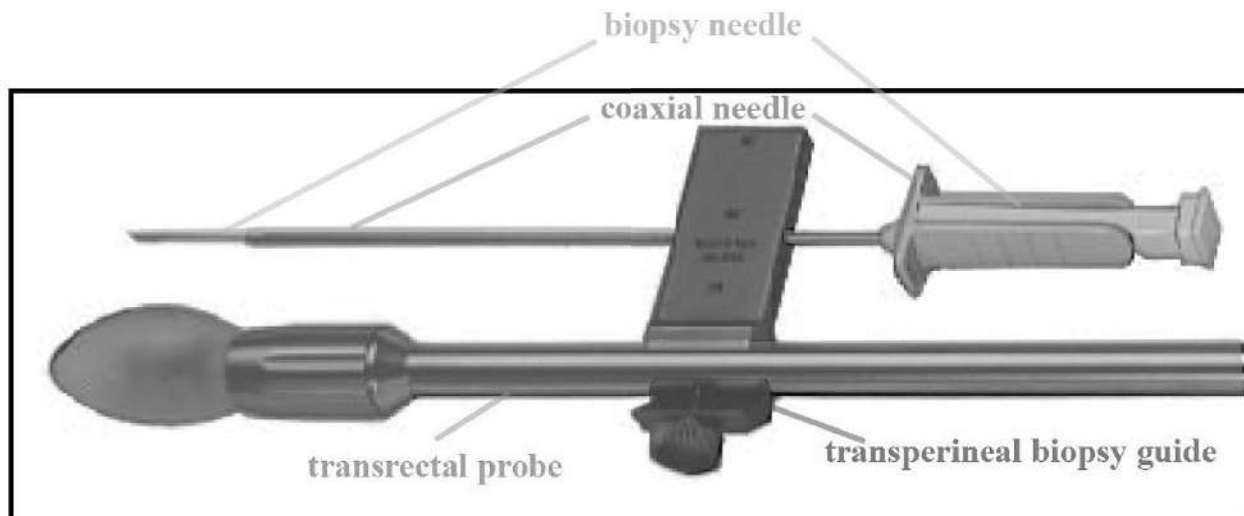


Fig. 11. Type 1850 assembled for transrectal scanning with puncture attachment UA0650

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*²

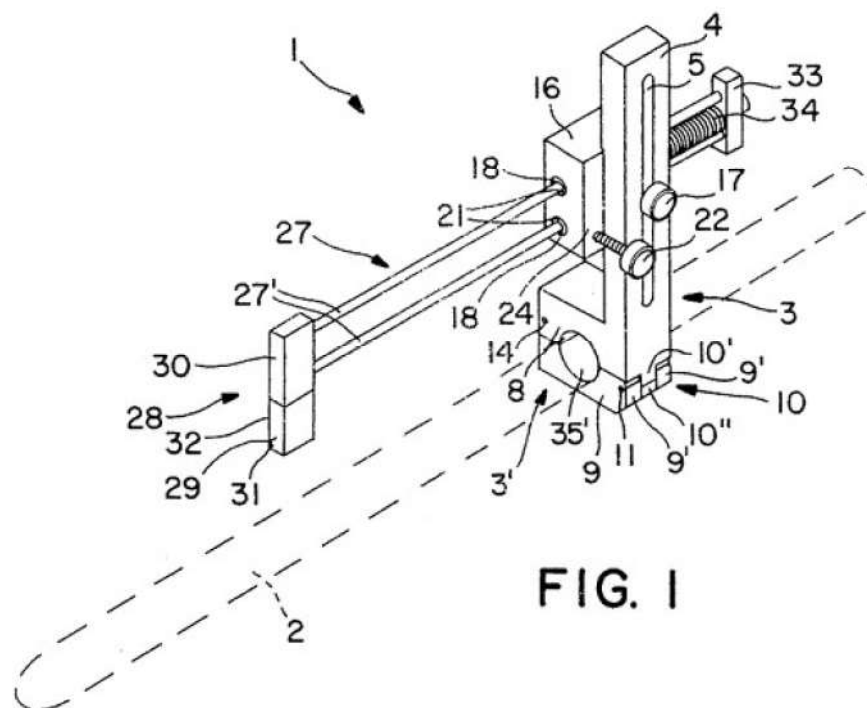
BK Medical 2 explains that “[i]f a fine needle is used, it may be helpful to use an additional needle guide.” EX1009, 16. Here, “fine needle” and “needle guide” respectively refer to the biopsy needle and coaxial needle. EX1015, ¶ 12; EX1003, ¶ 61. The coaxial needle supports the “fine” biopsy needle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

² Requester uses “*” to indicate annotated figures.

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.

c. Onik (EX1011)

Onik is a U.S. Patent filed in 1993 and issued in 1996, qualifying as prior art to the '056 Patent under 35 U.S.C. § 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.



EX1011, 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.

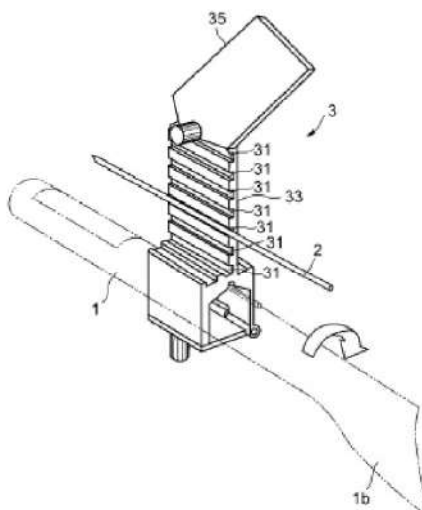
“Slidably associated with anterior-posterior adjustment guide 4 is a slide block 16 which provides anterior and posterior positioning adjustment for a biopsy needle relative to ultrasound probe 2.” EX1011, 4:36-39. “Extending through the slide block 16 in a direction parallel to the longitudinal axis 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 the 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.

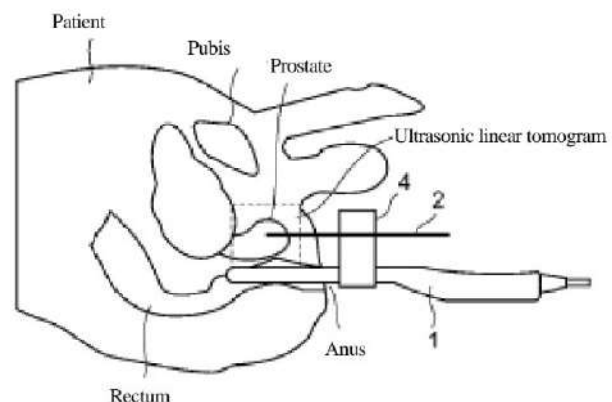
d. Nakamura (EX1012)

Nakamura is a Japanese Patent Application published on September 22, 2010, qualifying as prior art to the '056 Patent under 35 U.S.C. § 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]



EX1012, 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.*

3. Supporting Declarations

In support of this Request, Requester submits the following declarations:

- A Declaration of Edward J. Yun, MD (EX1003) from PGR2023-00041³ in support of Grounds 1-4;
- A Declaration of Ingrid Hsieh-Yee, Ph.D. (EX1013) from PGR2023-00041 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) from PGR2023-00041 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

³ Although PGR2023-00041 pertains to Patent No. 11,547,436 (“the '436 Patent”), the claims of the '436 Patent substantially overlap with the claims of the '056 Patent. Accordingly, the declarations from PGR2023-00041 are relevant here.

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.

D. Grounds 1-4 Present Substantial New Questions of Patentability

As explained below, Requester submits that Grounds 1-4 raise substantial new questions of patentability as to the Challenged Claims because “the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable.” *See* MPEP § 2242. Specifically, as discussed below here and in the Detailed Application section, the references disclose or suggest the elements of the challenged claims, including the purportedly novel combinations of features that led the examiner to allow the claims:

a guide member coupled to the mount and including a rail receiving channel extending a first length between a proximal end and a distal end of the rail receiving channel, and

a displacement member including a rail member extending a second length between a proximal end and a distal end of the rail member and a vertically extending member extending from the distal end of the rail member, the vertically extending member including a plurality of needle receiving ports, wherein the rail receiving channel is positioned generally parallel with a longitudinal axis of the transrectal ultrasound probe;

sliding the rail member within the rail receiving channel so as to position the vertically extending member of the displacement member adjacent the perineal access site of the patient;

inserting an access needle into the perineal access site of the patient, the access needle supported by one of the plurality of needle receiving ports; and

inserting a needle through the access needle and into a first location of the prostate of the patient.

EX1002, 22, 23 (emphasis in original).

1. Ground 1: BK Medical in View of Novella Renders Obvious Claims 1, 4-6, and 11-13

BK Medical and Novella raise a substantial question of patentability with respect to the Challenged Claims of the '056 Patent. BK Medical discloses a transperineal biopsy coupled to a

transrectal ultrasound probe including: (1) a guide member coupled to a mount and including a rail receiving channel extending a first length between a proximal end and a distal end of the rail receiving channel; (2) a displacement member including a rail member extending a second length between a proximal end and a distal end of the rail member and a vertically extending member extending from the distal end of the rail member, the vertically extending member including a plurality of needle receiving ports; and (3) wherein the rail receiving channel is positioned generally parallel with a longitudinal axis of the transrectal ultrasound probe. BK Medical also discloses sliding the rail member within the rail receiving channel so as to position the vertically extending member of the displacement member adjacent the perineal access site of the patient. BK Medical also discloses inserting a needle into the perineal access site of the patient, the needle supported by one of the plurality of needle receiving ports, similar to the system claimed in the '056 Patent. *Infra* Section II.A.1. Indeed, the transperineal biopsy guide disclosed in BK Medical is nearly identical to the Requester's SureFire Transperineal Needle Guide that Patent Owner accuses of infringement. *Compare* EX1019, 3, with EX1007, 7. Novella further discloses performing transperineal biopsy procedures (1) by using an access needle (coaxial needle) and (2) by inserting a biopsy needle through the coaxial needle, as well as the benefits of such a procedure.

Thus, as described above and below in Section II, BK Medical and Novella disclose the features that the Examiner found to be allowable and in combination render the allowed claims unpatentable. Moreover, neither BK Medical nor Novella served as a basis for rejection during prosecution of the '056 Patent or any family member. *See generally* EX1002. Rather, the Examiner rejected original claims 1-20 as invalid due to double patenting. *Id.*, 178-80. Thus, BK Medical and Novella present a substantial new question of patentability with respect to the Challenged Claims.

2. Ground 2: BK Medical and Novella, Further in View of Zangos, Render Obvious Claim 10

BK Medical and Novella present a substantial new question of patentability with respect to the Challenged Claims for the reasons discussed above. *Supra* Section I.D.1. Additionally, Zangos discloses the advantageous uses of a 14-gauge, 15-gauge, or 16-gauge access needle, recited in Challenged Claim 10, in prostate biopsy procedures. *Infra* Section II.B. Furthermore, Zangos was never cited at any point during the prosecution history of the '056 Patent. *See generally*

EX1002. Accordingly, Zangos presents a substantial new question of patentability with respect to the Challenged Claims.

3. Ground 3: Onik and Novella, Further in View of Nakamura, Render Obvious Claims 1, 4-6, and 11-13

Onik, Nakamura, and Novella present a substantial new question of patentability with respect to the Challenged Claims for similar reasons to BK Medical and Novella. For example, Onik—which did not serve as a basis for rejection during prosecution of the '056 Patent—discloses a transperineal biopsy guide coupled to a transrectal ultrasound probe and including a guide member with a rail receiving channel and a displacement member with a vertically extending needle guide member, similar to the device claimed in the '056 Patent. *Infra* Section II.C; *see generally* EX1002. And Nakamura discloses a similar transperineal biopsy guide with a vertically extending needle guide member, the needle guide member having a plurality of needle receiving ports. *Infra* Section II.C. Nakamura was not cited or considered during origination prosecution of the '056 Patent. Thus, in combination, Onik and Nakamura present a substantial new question of patentability similar to that posed by BK Medical. In combination with Novella, Onik and Nakamura render the challenged claims obvious. *Id.*

4. Ground 4: Onik, Novella, and Nakamura, Further in View of Zangos, Render Obvious Claim 10

Zangos, combined with Onik, Novella, and Nakamura, presents a substantial new question of patentability with respect to Challenged Claim 10 for the same reasons discussed above for Ground 2. *Supra* Section I.D.2.

II. DETAILED APPLICATION OF THE PRIOR ART TO EVERY CLAIM FOR WHICH REEXAMINATION IS REQUESTED

In Grounds 1-4 below, Requester explains in detail how the prior art references listed above establish the unpatentability of the Challenged Claims as obvious under 35 U.S.C. § 103. Requester respectfully requests the Office to issue an office action rejecting the Challenged Claims based on each of Grounds 1-4. This Request is supported by a declaration of Requester's technical expert, Dr. Edward Yun (EX1003).

A. Ground 1: BK Medical in View of Novella Renders Obvious Claims 1, 4-6, and 11-13

1. Independent Claim 1

- a. [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 method comprising:***”

To the extent the preamble is limiting, BK Medical discloses a method of performing a transperineal biopsy procedure on a prostate of a patient using a transrectal ultrasound probe (Type 8808e probe) configured to provide imaging, the patient comprising a perineal access site leading to the prostate. EX1003, ¶¶ 58-59, 89.

Specifically, BK Medical discloses the claimed “transrectal ultrasound probe configured to provide imaging” as the “Prostate Biplane Transducer Type 8808e [that] is designed for transrectal prostate imaging.” EX1007, 5. BK Medical further discloses a method of performing a transperineal biopsy procedure on a prostate using the transrectal ultrasound probe: “Transrectal and transperineal puncture and biopsy are possible with 8808e.” *Id.*, 9. For transperineal biopsy procedures specifically, a “metal puncture attachment UA1324” is used. *Id.*, 12. Figure 9 below shows the transperineal biopsy guide UA1324 mounted on the Type 8808e probe:

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

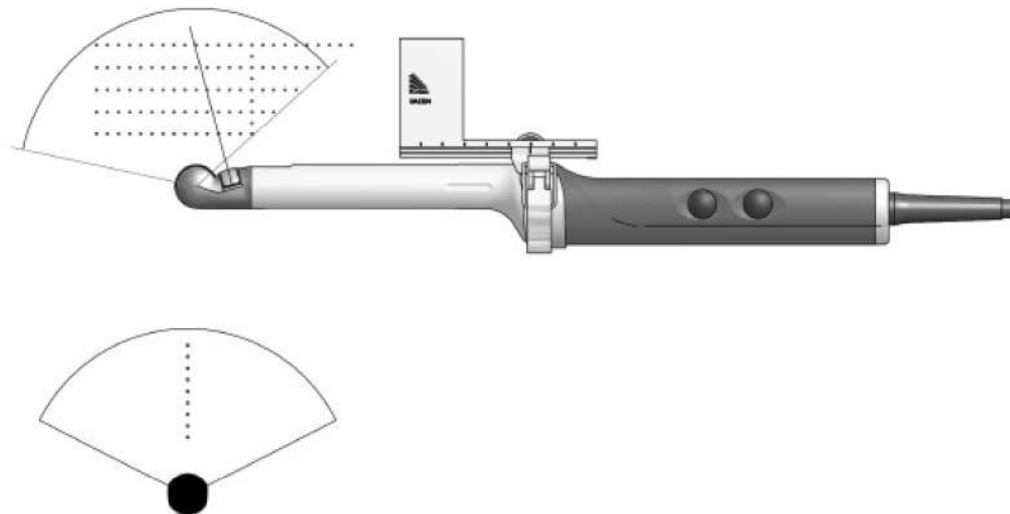


Figure 9. Illustration of the puncture line for puncture attachment UA1324.

EX1007, FIG. 9.

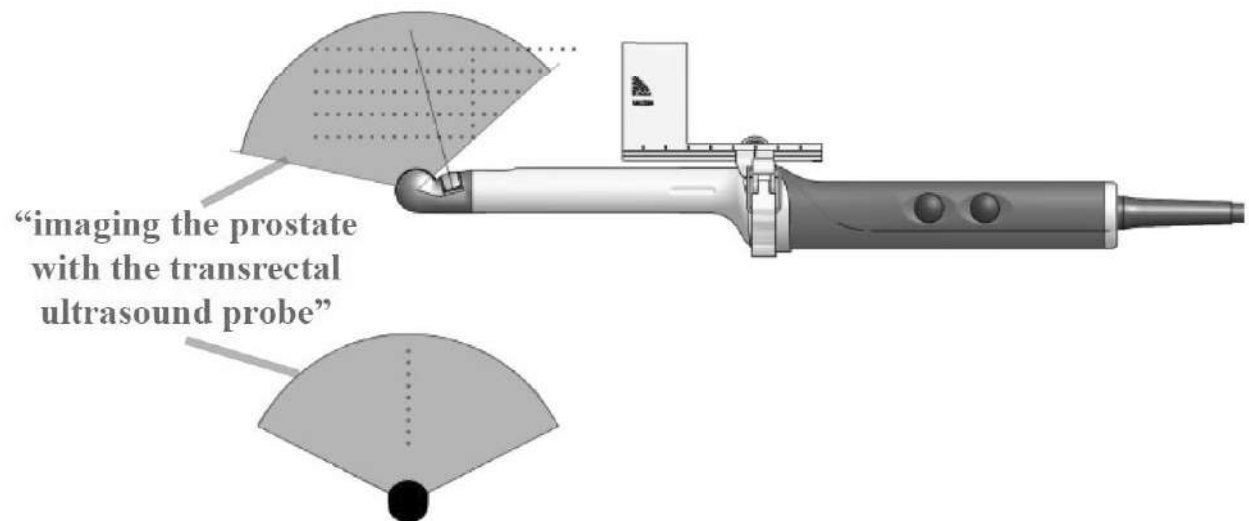
To perform a prostate biopsy procedure, “[m]ove the transducer until the puncture line transects the target. Insert the needle and monitor it as it moves along the puncture line to the target.” *Id.*, 13. Moreover, a prostate biopsy procedure like that in BK Medical is performed on a male “patient comprising a perineal access site leading to the prostate,” as claimed.

Accordingly, BK Medical discloses element [1.pre].

- b. [1.1]: “***imaging the prostate of the patient with the transrectal ultrasound probe, wherein a transperineal biopsy guide is coupled to the transrectal ultrasound probe,***”

BK Medical discloses or suggests this claim element. *See* EX1003, ¶¶ 87-89. As discussed above, BK Medical discloses imaging the prostate of the patient with the Type 8808e transducer (ultrasound probe). *Supra* Section II.A.1.a. Figure 9 of BK Medical shows the Type 8808e transducer imaging the prostate in the sagittal plane:

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



EX1007, FIG. 9*

In describing how to use the Type 8808e probe and imaging system to image the prostate, BK Medical explains:

The puncture line on the image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.

...

Press the system Puncture or Biopsy control button to superimpose a puncture line on the image.

If more than one puncture line is available, refer to the applicable system user guide for instructions on how to change which one appears.

Move 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. The needle tip echo will be seen as a bright dot on the screen.

The puncture line will differ depending on the imaging plane orientation. In the sagittal plane, the puncture path is indicated by a line of dots. The distance between each puncture dot is 5mm.

In the transverse plane, a single dot indicates the point at which the needle will transect the imaging plane.

...

To remove the puncture line from the scan image, refer to the applicable system user guide for instructions.

EX1007, 13-14; EX1003, ¶¶ 87-89.

BK Medical further discloses that the UA1324 (transperineal biopsy guide) is coupled to the Prostate Biplane Transducer Type 8808e (transrectal ultrasound probe), as seen in the figure below:

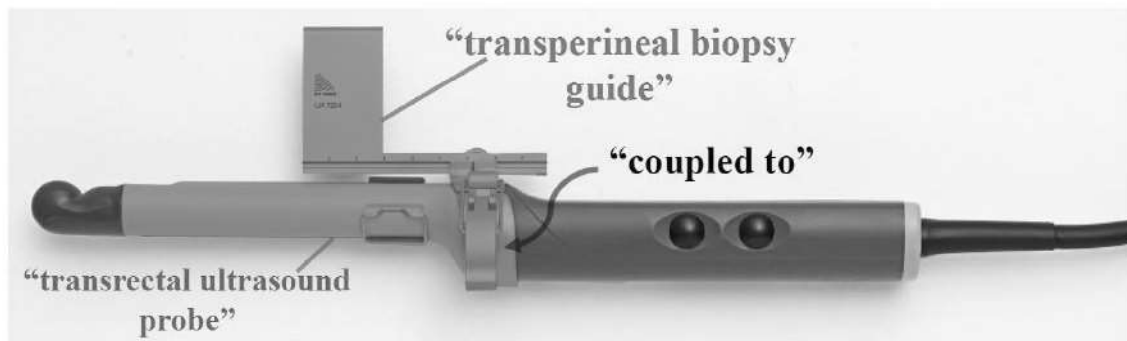


Figure 8. Puncture attachment UA1324 mounted on 8808e.

EX1007, FIG. 8*

To couple the UA1324 to the Type 8808e probe, BK Medical explains:

Mounting the Transperineal Puncture Attachment

To mount the transperineal puncture attachment, ensure that the dummy channel bracket UA1325 is in place. Pull a sterile transducer cover over the transducer. Loosen 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. The puncture attachment should be correctly positioned so that the groove slides easily over stud. No force should be used when attaching the puncture attachment to the transducer.

EX1007, 12; *see also* EX1003, ¶ 100.

Accordingly, BK Medical discloses element [1.1].

- c. [1.2]: ***“the transperineal biopsy guide comprising a mount coupled to the transrectal ultrasound probe, a guide member coupled to the mount and including a rail receiving channel extending a first length between a proximal end and a distal end of the rail receiving channel, and”***

BK Medical discloses or suggests this claim element. *See* EX1003, ¶ 100. BK Medical discloses the transperineal guide (UA1324) comprising a mount (bottom portion of mounting ring) coupled to the transrectal ultrasound probe (Type 8808e probe) and a guide member (top portion of mounting ring) coupled to the mount (lower portion of mounting ring). EX1003, ¶¶ 100-101.

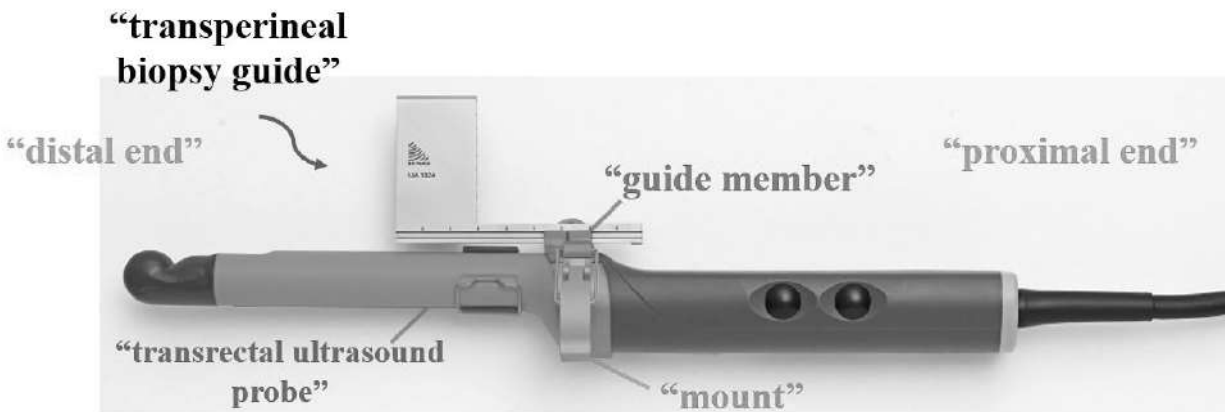


Figure 8. Puncture attachment UA1324 mounted on 8808e.

EX1007, FIG. 8*

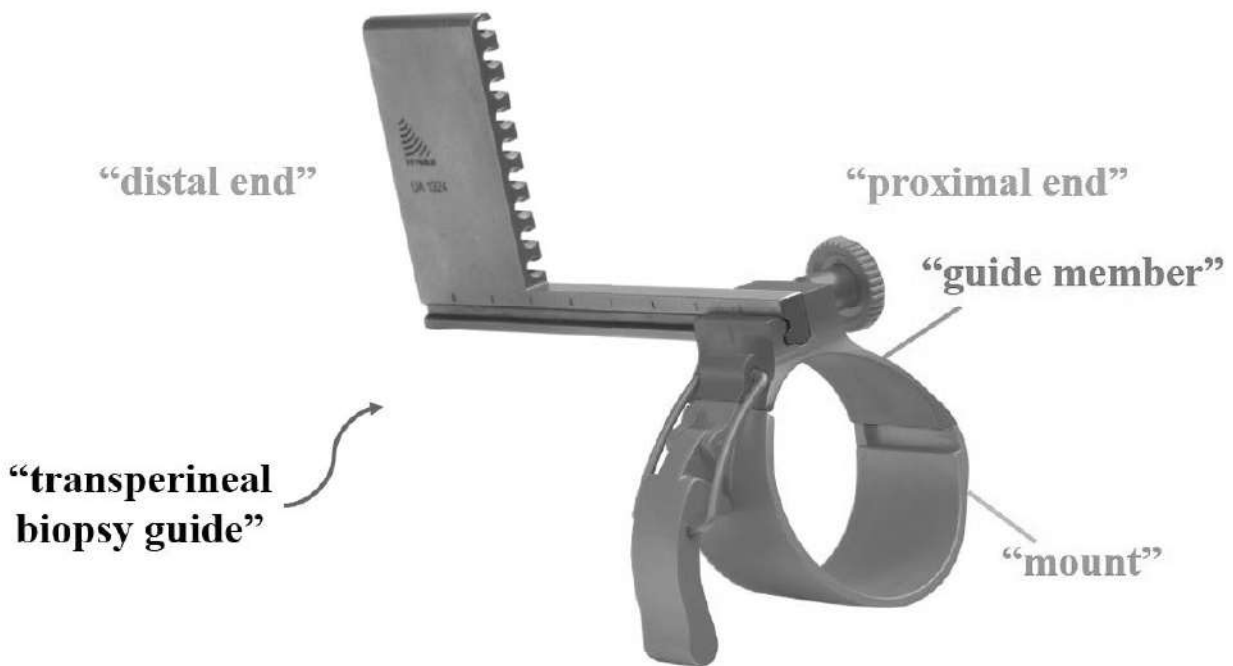
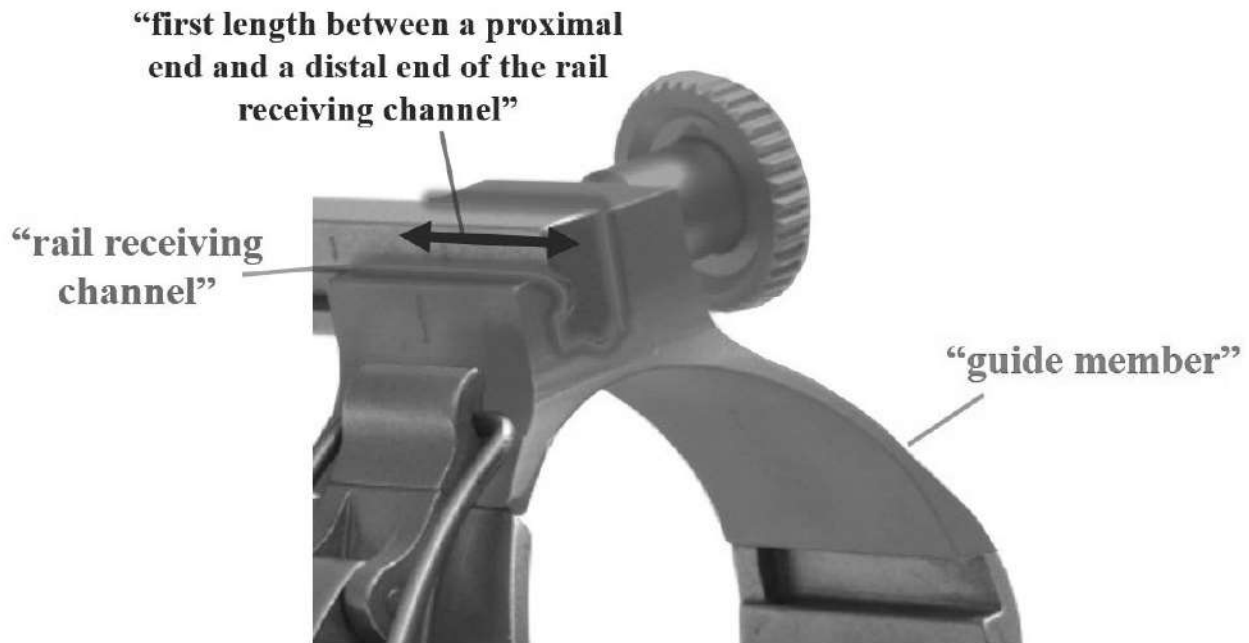


Figure 7. Puncture attachment UA1324.
EX1007, FIG. 7*

BK Medical explains that the “UA1324 consists of a needle guide and a mounting ring with clamp,” and the bottom portion of the mounting ring and clamp discloses the claimed mount, as highlighted above in Figure 7. EX1007, 12; EX1003, ¶ 57. “To mount the transperineal puncture attachment,” “[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. The puncture attachment should be correctly positioned so that the groove slides easily over stud. No force should be used when attaching the puncture attachment to the transducer.” EX1007, 12; *see* EX1003, ¶ 57.

BK Medical’s guide member further includes a rail receiving channel extending (channel opening at the top of the mounting ring) a first length between a proximal end and a distal end of the rail receiving channel.



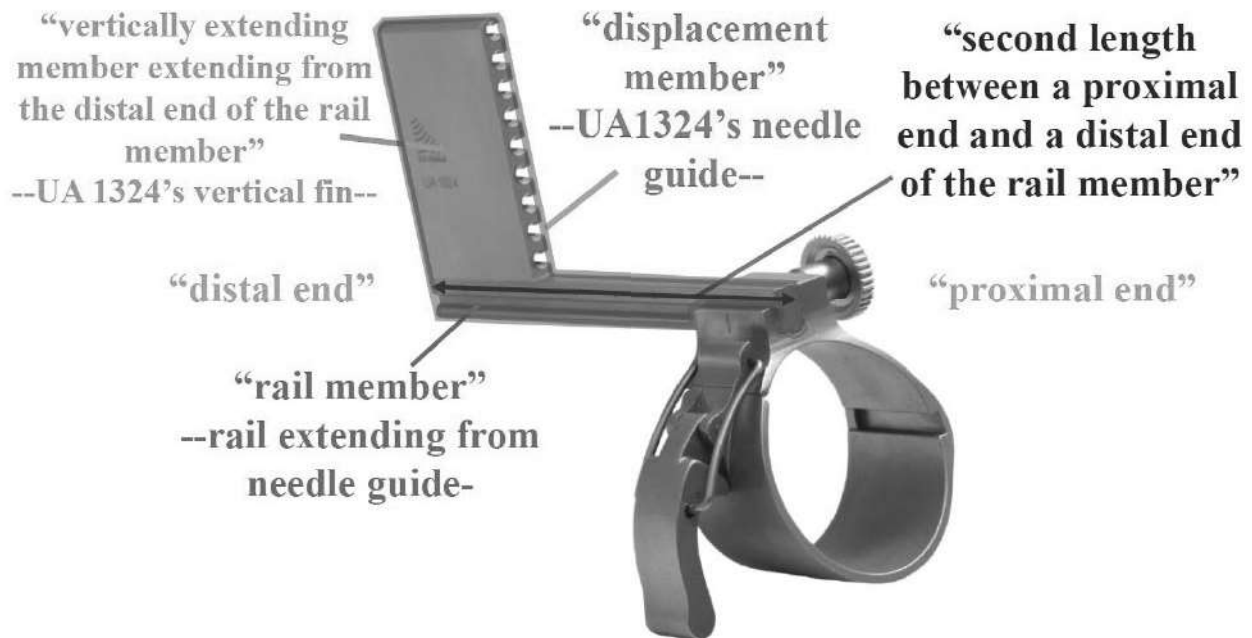
EX1007, FIG. 7*

As seen above, UA1324 needle guide has a rail with a groove that slides within a channel opening at the top of the mounting ring. EX1007, 12 (“UA1324 consists of a needle guide and a mounting ring with clamp” allowing “[t]he needle guide [to] be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.”). *See* EX1003, ¶ 58. The channel opening at the top of the mounting ring, which receives the rail of the needle guide, discloses the claimed “rail receiving channel.”

Accordingly, BK Medical discloses element [1.2].

- d. [1.3]: ***“a displacement member including a rail member extending a second length between a proximal end and a distal end of the rail member and a vertically extending member extending from the distal end of the rail member,”***

BK Medical discloses or suggests this claim element. *See* EX1003, ¶¶ 80, 102. Specifically, BK Medical discloses a displacement member (needle guide) including a rail member (rail extending from the needle guide) extending a second length between a proximal end and a distal end of the rail member and a vertically extending member (vertical fin) extending from the distal end of the rail member.



EX1007, FIG. 7*

As highlighted above, the "UA1324 consists of a needle guide and a mounting ring with clamp" allowing "[t]he needle guide [to] be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw." EX1007, 12; EX1003, ¶ 80. Here, the UA1324's needle guide with rail extending from the doctor toward the patient's perineum and having a groove for sliding along the mounting ring discloses the claimed "displacement member including a rail member extending a second length between a proximal end and a distal end of the rail member."

Also highlighted above, the UA1324's "needle guide comprises 9 parallel guide channels, spaced 5mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle." EX1007, 12; EX1003, ¶ 80. The vertical fin extending from the rail and having the nine parallel needle guide channels discloses the claimed "vertically extending member extending from the distal end of the rail member."

Accordingly, BK Medical discloses element [1.3].

- e. [1.4]: ***"the vertically extending member including a plurality of needle receiving ports,"***

BK Medical discloses or suggests this element. *See* EX1003, ¶¶ 102-103. Specifically, BK Medical shows the vertically extending member (vertical fin extending from the UA1324 needle guide) including a plurality of needle receiving ports (9 parallel guide channels):