

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

ADVANCE MEDICAL DESIGNS, INC.,

Plaintiff,

v.

CORBIN CLINICAL RESOURCES, LLC

Defendant.

Civ. A. No. 1:22-cv-00789-SAG

JURY TRIAL DEMANDED

PLAINTIFF'S INITIAL INVALIDITY CONTENTIONS

I. INTRODUCTION

Plaintiff Advance Medical Designs, Inc., (“Advance Medical” or “Plaintiff”) hereby submits its Invalidity Contentions and accompanying identification of documents. Defendant Corbin Clinical Resources, Inc. (“Corbin” or “Defendant”) alleged in its Infringement Contentions that Advance Medical infringes claims 1, 3, 8, 9, and 17 of U.S. Patent No. 10,064,681 (“the ’681 Patent”); claims 13, 14, 15, 20, 36, 37, 38, and 40 of U.S. Patent No. 11,096,762 (“the ’762 Patent”); and claims 1, 3, 4, 9, 10, 11, 12, 13, 16, 22, 25, 28, 29, and 30 of U.S. Patent No. 11,246,677 (“the ’677 Patent”). The ’681 Patent, ’762 Patent, and ’677 Patent collectively are “the Asserted Patents.” The claims of Asserted Patents that Corbin alleges Advance Medical infringes collectively are “the Asserted Claims.”

These Invalidity Contentions address each Asserted Claim. Advance Medical reserves the right to modify, amend, and/or supplement its invalidity contentions should Corbin attempt to modify its asserted claims. These Invalidity Contentions are made without the benefit of a claim construction ruling, and without Corbin having disclosed its contentions on the meaning of the terms recited in the Asserted Claims. Advance Medical in no way accepts Corbin’s apparent reading of the claims in its Infringement Contentions as reflecting the proper scope of the claims. These contentions are not intended to reflect Advance Medical’s claim construction contentions, which will be disclosed in due course pursuant to the Local Patent Rules and case schedule. Advance Medical reserves the right to modify its contentions should any of the claim limitations be construed, whether previously construed or not, by the Court.

In addition to the Invalidity Contentions provided below, Advance Medical incorporates by reference as if stated fully herein the prior art, grounds for unpatentability, and associated rationales discussed in the following any future petitions for *ex parte* reexamination filed by Advance Medical regarding the Asserted Patents.

Discovery in this action still is at an early stage. These contentions are based on Advance Medical's current knowledge and understanding of the prior art. For example, Advance Medical has not deposed any individual identified as an inventor of the Asserted Patents. Advance Medical may modify or supplement its invalidity contentions, whether in response to any amendment of Corbin's Infringement Contentions or otherwise by becoming aware of additional prior art or further material information.

Much of the prior art identified in the attached exhibits reflects common knowledge and the state of the art before the respective filing dates of the Asserted Patents. In many instances where a particular contention calls for combining references, any one of a number of references can be combined. The inclusion of certain exemplary combinations of prior art references does not exclude other combinations based upon the claim charts attached hereto.

Certain pieces of identified prior art inherently disclose features of the Asserted Claims. To the extent that inherency is not already expressed asserted in the attached charts, Advance Medical may rely on inherency to demonstrate the invalidity of the asserted claims. Moreover, certain prior art references and solutions may inherently disclose certain features of the Asserted Claims as asserted and apparently construed by Corbin, Advance Medical may rely on cited or uncited portions of the prior art, other documents, and expert testimony to establish the inherency of certain features of the prior art to invalidate the asserted claims.

Each Asserted Claim is anticipated by or rendered obvious in view of one or more of the prior art references identified here alone or in combination with other prior art references. Appendices A – C accompanying this document provide explanations detailing how a number of prior art references or commercial prior art devices anticipate or render obvious the Asserted Claims. Those Appendices are incorporated here by reference. In some cases, Advance Medical

has listed both anticipation and obviousness theories to preserve its rights to pursue either or both, depending upon the claim construction and the ultimate question of what a particular reference teaches. A combination of prior art references that renders a dependent claim obvious also renders obvious any claim from which that claim depends. A claim that is obvious over a single prior-art reference is also obvious over that reference in combination with another reference or references.

While Advance Medical has endeavored to identify the most relevant portions of the prior-art references in the accompanying Appendices, the cited references may contain additional support for particular claim limitations. Advance Medical may rely upon these portions that have not been specifically identified, any documents or statements identified in the cited references, any documents that claim priority to the cited references, any foreign counterparts to the cited references, their file histories (as applicable), or fact and expert testimony/documents not yet in evidence to provide context in understanding the references.

Advance Medical's investigation for prior art and third-party discovery is not yet complete. Advance Medical may present additional items of prior art under 35 U.S.C. § 102 or § 103 located during discovery.

Advance Medical reserves the right to revise its ultimate contentions concerning the invalidity of the Asserted Claims, which may change depending upon any findings as to the priority date of those claims or positions that Corbin or expert witnesses may take concerning infringement or invalidity issues.

Advance Medical objects to the disclosure of information that is protected by the attorney-client privilege, attorney work-product doctrine, the common interest privilege, or any other applicable privilege or immunity. If Advance Medical inadvertently discloses information that may be protected from discovery under any applicable privilege or immunity, such inadvertent

disclosure does not constitute a waiver of any such privilege or immunity. The information set forth in these contentions is provided without waiving: (1) the right to object to the use of any statement for any purpose, in this action or any other, on the grounds of privilege, relevance, materiality, or any other appropriate grounds; (2) the right to object to any request involving or relating to the subject matter of the statements made here; or (3) the right to revise, correct, supplement, or clarify any of the statements provided below at any time.

If Corbin challenges any aspect of these Invalidity Contentions, including whether a particular reference constitutes prior art or whether a combination of prior art references identified by Advance Medical is properly combinable, Advance Medical may supplement these Invalidity Contentions to address any such challenge.

II. PRIORITY AND EFFECTIVE FILING DATES FOR THE ASSERTED PATENTS

The Asserted Patents are entitled to a priority date no earlier than April 3, 2014.

III. PERSON HAVING ORDINARY SKILL IN THE ART

The disclosures and teachings of a prior art reference should be understood from the perspective of a person of ordinary skill in the art in the relevant time period, whose understanding of the prior art reference necessarily involves other information available in the prior art, including the background information, education, and the level of skill (including the ability to conduct testing and carry out studies) such a person would have. The prior art discussed herein necessarily is in view of, and inclusive of, the knowledge of a person of ordinary skill in the art, including without limitation, the knowledge of the state of the art and references that may provide evidence as to the state of the art.

IV. IDENTIFICATION OF PRIOR ART

Advance Medical may rely on the prior art listed and described below to contend that the Asserted Claims are invalid.

A. Identification of Prior Art Patents and Patent Applications

Advance Medical hereby discloses the following prior art on which it may rely to contend that the Asserted Claims are invalid as anticipated and/or obvious under 35 U.S.C. §§ 102, 103:

- U.S. Patent No. 5,494,039 to Onik (“Onik”) issued February 27, 1996 (produced as AMD_00000034 – AMD_00000043).
- U.S. Patent No. 5,871,448 to Ellard (“Ellard”) issued February 16, 1999 (produced as AMD_00000044 – AMD_00000052).
- U.S. Patent No. 7,959,573 to Furia (“Furia”) issued June 11, 2011 (produced as AMD_00000111 – AMD_00000127).
- U.S. Patent Appl. Pub. No. 2009/0234369 A1 to Bax (“Bax 2009”) published September 17, 2009 (produced as AMD_00000128 – AMD_00000145).
- U.S. Patent Appl. Pub. No. 2012/0203095 A1 to Krieger (“Krieger”) published August 9, 2012 (produced as AMD_00000146 – AMD_00000188).
- U.S. Patent No. 7,559,935 to Solar (“Solar”) issued July 14, 2009 (produced as AMD_00000082 – AMD_00000110).
- U.S. Patent No. 6,846,283 to Green (“Green”) issued January 15, 2005 (produced as AMD_00000061 – AMD_00000081).
- U.S. Patent No. 6,485,426 to Sandhu (“Sandhu”) issued November 26, 2002 (produced as AMD_00000053 – AMD_00000060).
- U.S. Patent Appl. Publ. No. 2008/0004481 A1 to Bax (“Bax”) issued June 28, 2006 (produced as AMD_00000199 – AMD_00000224).

B. Identification of Prior Art Publications

Advance Medical hereby discloses the following prior art publications on which it may rely to contend that the Asserted Claims are invalid as anticipated and/or obvious under 35 U.S.C. §§ 102, 103:

- BK Medical 8808e August 2010 Product Data Sheet (“BK Medical 2010”) (produced as AMD_00000001 – AMD_00000017).
- Giovanni Novella, *et al.*, *Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle*, 62 Urology 689 (2003) (“Novella 2003”) (produced as AMD_00000030 – AMD_00000033).
- Gencay Hatiboglu, *et al.*, *Application Technique: Placement of a Prostate-Rectum Spacer in Men Undergoing Prostate Radiation Therapy*, 110 BJU Int’l E647 (May 10, 2012) (“Hatiboglu 2012”) (produced as AMD_00000030 – AMD_00000033).
- Stephan Zangos, *et al.*, *MR-Guided Transgluteal Biopsies with an Open Low-Field System in Patients with Clinically Suspected Prostate Cancer: Technique and Preliminary Results*, 15 Euro Radiology 174 (Sept. 4, 2004) (“Zangos 2005”) (produced as AMD_00000189 - AMD_00000197).
- Vincenzo Ficarra, *et al.*, *Needle Core Length Is a Quality Indicator of Systematic Transperineal Prostate Biopsy*, 50 EUROPEAN UROLOGY 266 (2006) (“Ficarra 2006”) (produced as AMD_00000018 – AMD_00000023).

C. Identification of Commercial Prior Art

Advance Medical hereby discloses the following commercial prior art on which it may rely to contend that the Asserted Claims are invalid as anticipated and/or obvious under 35 U.S.C. §§ 102, 103:

- BK Medical Endorectal Biplane Transducer Type 8808e (as disclosed in BK Medical 2010)
- BK Medical Metal Puncture Attachment UA1324 (as disclosed in BK Medical 2010)

III. THE SCOPE AND CONTENT OF THE PRIOR ART

Advance Medical relies on at least the following prior art references in support of its invalidity contentions related to the Asserted Patents based on anticipation under Section 102 and/or obviousness under Section 103. Unless otherwise stated, it should be presumed that Advance Medical intends to rely upon each reference in its entirety to the extent relevant and/or appropriate, including references cited in and/or referenced within the references identified below.

IV. IDENTIFICATION OF BASIS FOR INVALIDITY UNDER 35 U.S.C. § 102, 103

The following prior art references, either alone or in combination with the knowledge of one skilled in the art, and/or in combination with other prior art references, render one or more asserted claims of the Asserted Patents invalid as anticipated or obvious. The inclusion of certain exemplary combinations herein does not exclude other combinations based upon the prior art references identified herein. Advance Medical contends that all claims that are anticipated by a particular reference are also rendered obvious by that same reference alone, or in combination with the other references discussed below. Claim charts demonstrating how the below prior art and/or combinations of prior art renders the asserted claims of the patents-in-suit obvious is attached hereto as Appendices A – C. These combinations are not intended to be exhaustive, as there are many possible combinations of the references listed herein

V. IDENTIFICATION OF BASIS FOR INVALIDITY UNDER 35 U.S.C. § 112

Defendants contend that claims 1, 9-10, 13, 16, 22, and 28-29 of the '677 Patent are invalid under 35 U.S.C. § 112 as indefinite. The term “a lumen sized to receive a biopsy needle there through” is indefinite. The specification fails to define, with reasonable certainty, neither the size

of a “biopsy needle” nor the size of a lumen needed to receive a biopsy needle. Accordingly, the asserted claims of the ’677 Patent fail to inform, with a reasonable certainty, persons of skill in the art regarding its scope.

Defendants also contend that the term “frictional engagement” is indefinite, rendering claims 1, 3-4, 9-13, 16, 22, 25, and 28-30 of the ’677 Patent are invalid under 35 U.S.C. § 112. The specification fails to define, with reasonable certainty, the meaning of “frictional engagement.” Accordingly, the asserted claims of the ’677 Patent fail to inform, with a reasonable certainty, persons of skill in the art regarding its scope.

The term “distal point of the pair of stabilization members is offset” is also indefinite. The specification fails to define with a reasonable certainty the definition of “offset” and does not provide any standard for measuring what is (and what is not) “offset.” Accordingly, claims 10 and 29 of the ’677 Patent fail to inform, with a reasonable certainty, persons of skill in the art regarding its scope.

VI. IDENTIFICATION OF CLAIM TERMS GOVERNED BY 35 U.S.C. § 112(f)

All asserted claims of the ’677 Patent include a means-plus-function claim term governed by 35 U.S.C. § 112(f). The claim term “a biopsy guide configured to couple to the transrectal transducer” in all asserted claims of the ’677 Patent is a means-plus-function claim term under 35 U.S.C. § 112(f). It is a claim term that is defined by its function “coupl[ing] to the transrectal transducer” without reciting the structure for performing this function. While there is a presumption that claim terms lacking the word “means” are not governed by § 112(f), the Federal Circuit has held that the presumption is not strong and can be overcome when “nonce” words substituting for “means” are used in a claim and the claim fails to recite structure. *See, Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015).

Under 35 U.S.C. § 112(f), claims “may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof” but “such claims shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” Here, the specification of the ’677 Patent describes the structure that couples the biopsy guide to the transrectal transducer as a “fastener” securing an upper mount to a lower mount (shown in FIG. 2A), a “sheath-based fastener” (shown in FIG. 2B) or a “zip-tie style fastener” (shown in FIG 2C). *See* ’677 Patent, 8:49-9:37.

VII. DOCUMENT PRODUCTION ACCOMPANYING INVALIDITY CONTENTIONS

Accompanying these preliminary invalidity contentions are documents bates-stamped AMD_00000001 – AMD_00000224. Advance Medical reserves the right to supplement this production.

Dated: August 1, 2022

Respectfully submitted,

/s/ Ryan P. Gentes

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CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2022, I served a true and correct copy of the foregoing document on all attorneys of record by email:

/s/ Ryan P. Gentes

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EXHIBIT A

Invalidity Claim Chart for U.S. Patent No. 10,064,681 B2 ('681 Patent) Based on BK Medical Type 8808e User Guide (Aug. 2010) ("BK Medical 2010").

BK Medical 8808e August 2010 Product Data Sheet (BK Medical 2010) (AMD_00000001 – AMD_00000017) qualifies as prior art to the '681 Patent under 35 U.S.C. § 102(a) and anticipates and/or renders obvious one or more of the asserted claims of the '681 Patent either in combination with, or modified based on, the knowledge of a person of ordinary skill in the art, or in combination with, or modified based on, any prior art identified in Plaintiff's invalidity contentions.

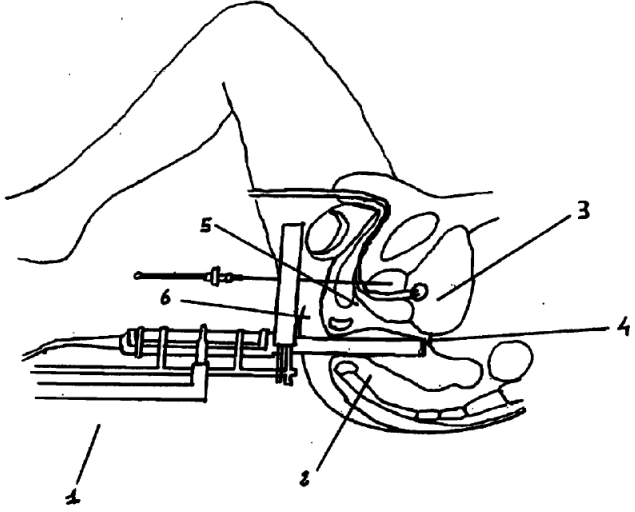
The Secondary References cited include:

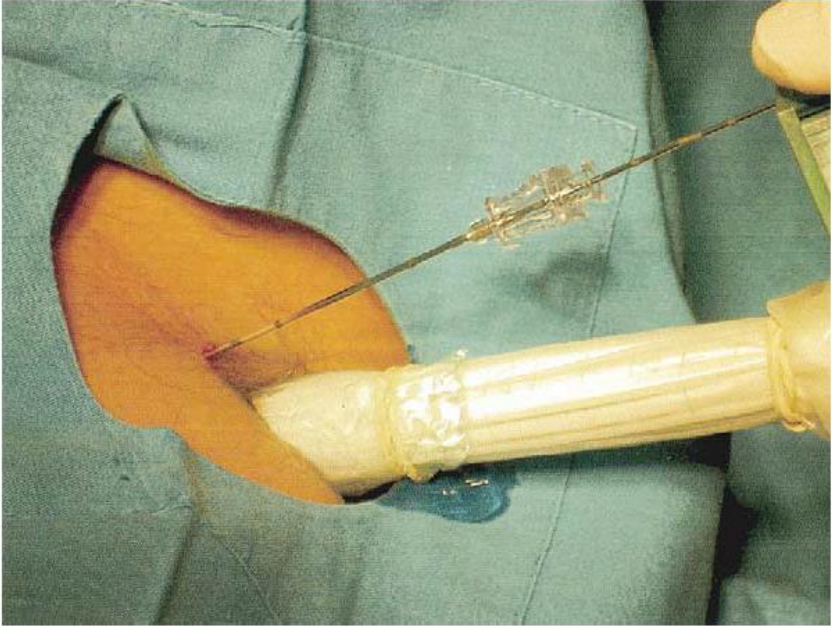
- U.S. Patent No. 5,494,039 to Onik ("Onik") (AMD_00000034 – AMD_00000043)
- U.S. Patent No. 5,871,448 to Ellard ("Ellard") (AMD_00000044 – AMD_00000052)
- Giovanni Novella, *et al.*, *Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle*, 62 UROLOGY 689 (2003) ("Novella 2003") (AMD_00000030 – AMD_00000033)
- U.S. Patent No. 7,959,573 to Furia ("Furia") (AMD_00000111 – AMD_00000127)
- U.S. Patent Pub. No. 2008/0004481 A1 to Bax ("Bax") (AMD_00000199 – AMD_00000224)
- U.S. Patent Pub. No. 2012/0203095 A1 to Krieger ("Krieger") (AMD_00000146 – AMD_00000188)
- U.S. Patent No. 7,559,935 to Solar ("Solar") (AMD_00000082 – AMD_00000110)
- U.S. Patent No. 6,846,283 to Green ("Green") (AMD_00000061 – AMD_00000081)

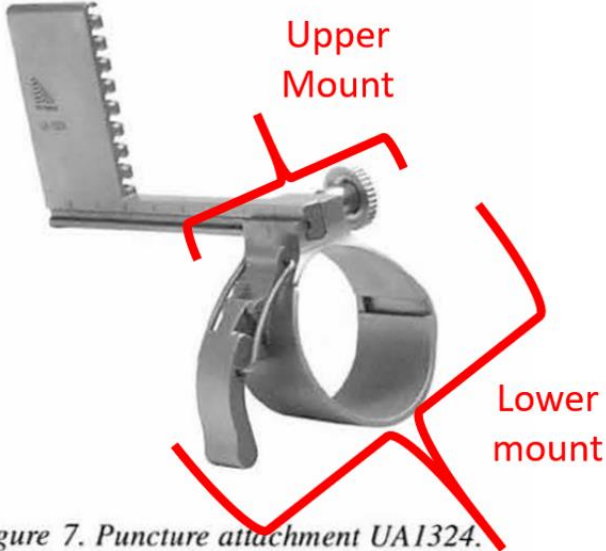
Plaintiff reserves the right to combine additional prior art references identified in its invalidity contentions with BK Medical 2010 even if not explicitly listed in the claim chart below. Plaintiff reserves the right to rely on other portions of a cited reference's disclosure, including, but not limited to, any figures discussed in cited text or any text relating to cited figures. Plaintiff reserves the right to supplement or amend this claim chart depending upon the claim construction order issued by the Court and how Defendant construes the claims in an attempt to assert infringement. All citations and proposed combinations for independent claims apply for all dependent claims.

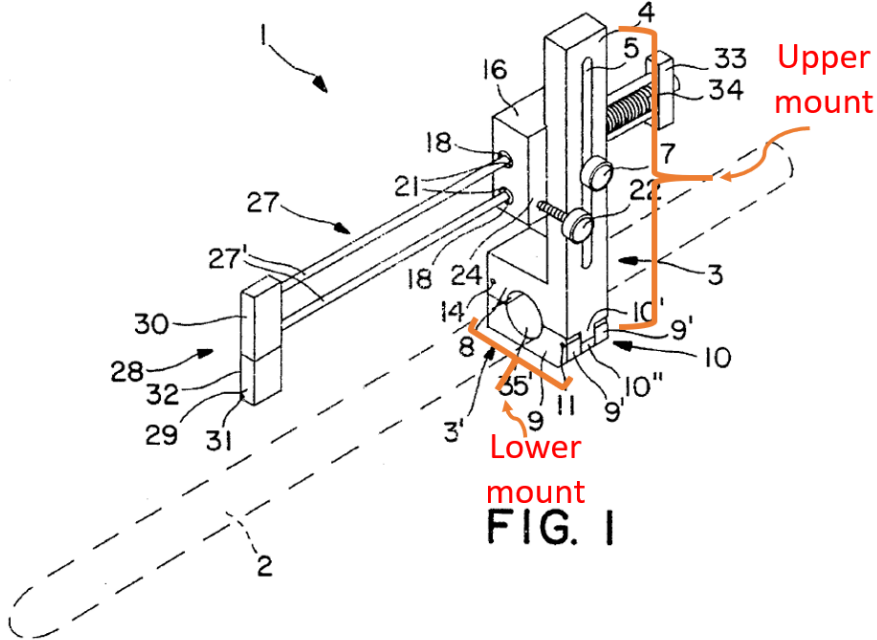
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
Claim 1		
1.pre	An apparatus configured to couple with a transrectal probe and for use in guiding an access needle in a transperineal prostate biopsy procedure, the access needle configured to perforate and be positioned within subcutaneous tissue of a perineum at an access site of a target area of a patient, the apparatus comprising:	BK Medical 2010 discloses an apparatus configured to couple with a transrectal probe and for use in guiding a biopsy needle in a transperineal prostate biopsy procedure, the biopsy needle configured to perforate and be positioned within subcutaneous tissue of a perineum at an access site of a target area of a patient: “The 8808e is designed for transrectal scanning.” <i>Id.</i> at 1. “The metal puncture attachment UA1324 is designed for transperineal puncture and biopsy.” <i>Id.</i>  <i>Figure 7. Puncture attachment UA1324.</i> <i>Id.</i> at 14.

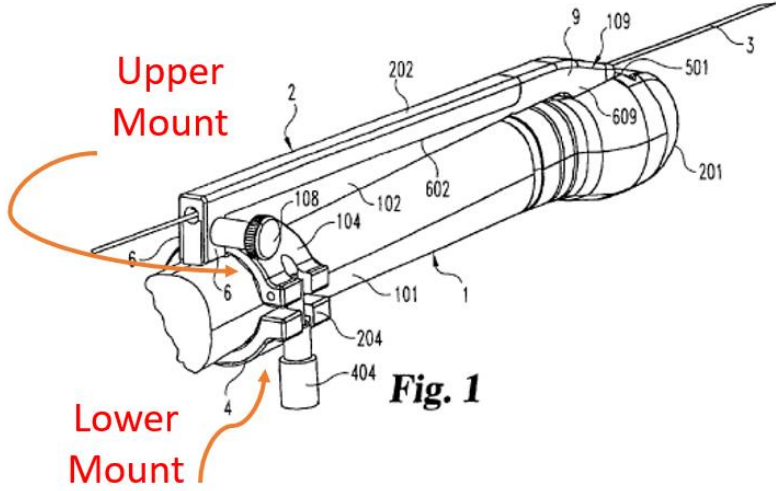
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 <i>Figure 8. Puncture attachment UA1324 mounted on 8808e.</i> <i>Id.</i> at 14. Onik discloses the same. "Most particularly the invention relates to a biopsy needle insertion guide which is securely mountable on and useable with a rectally inserted ultrasound probe to insert biopsy needles into the prostate at specific target points identified on an ultrasound image of the prostate." Onik, 1:10-15. Bax discloses the same. "The apparatus and method are particularly useful in prostate brachytherapy and in prostate biopsy." <i>Id.</i>, Abstract. "Automatic positioning of the guide is accomplished with reference to three-dimensional transrectal ultrasound images that can also be used to show needle insertion in real-time." <i>Id.</i>.

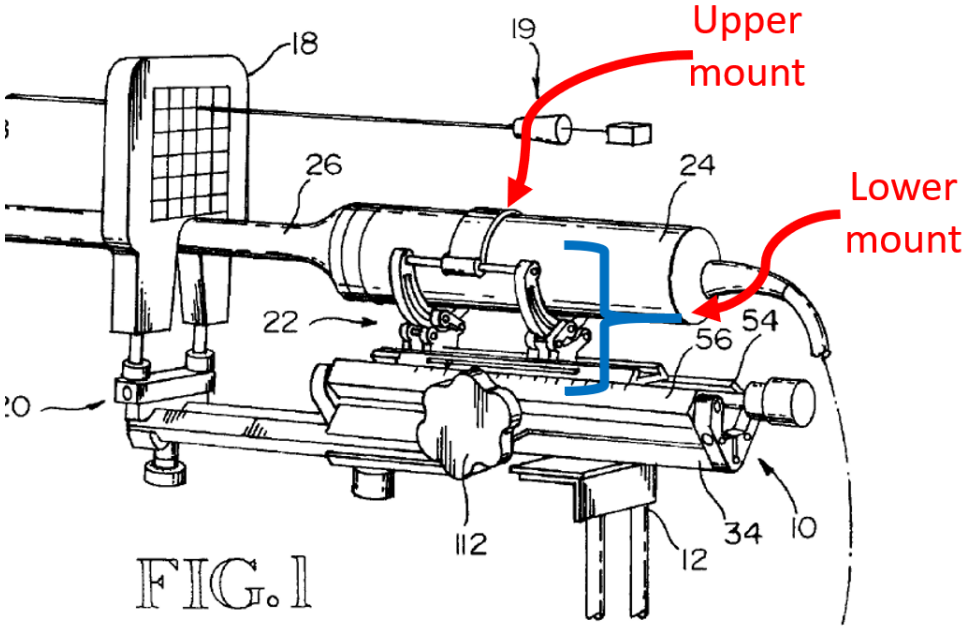
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 FIG. 1 While the above references refer to apparatuses configured for use with a “biopsy needle,” it would have been obvious to a PHOSITA to use an access needle with the BK Medical, Onik, or Bax devices. Novella 2003 discloses that “[t]he insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.

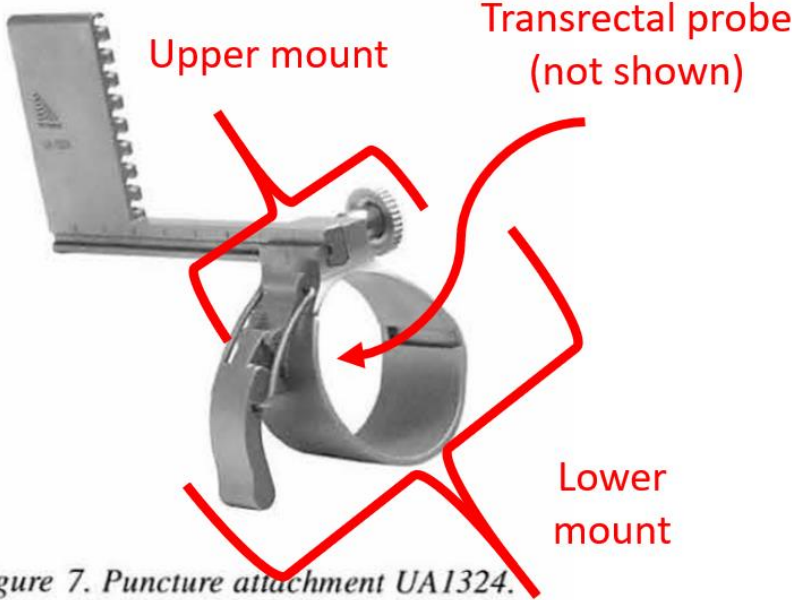
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> Novella 2003 at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. Due to the known advantages of using an access needle in transperineal prostate biopsies, it would be obvious to a PHOSITA to combine the access needle disclosed in Novella 2003 with the apparatuses disclosed in BK Medical 2010, Onik, and Bax.

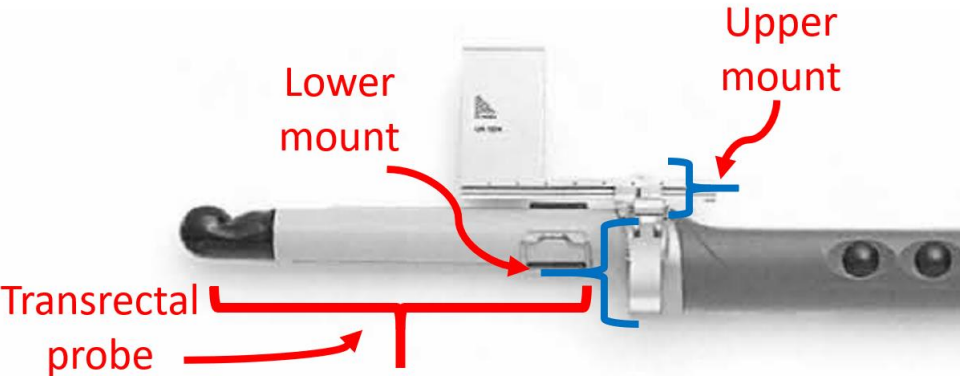
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
1.1	an upper mount and a lower mount configured to couple to each other,	BK Medical 2010 discloses an upper mount and a lower mount configured to couple to each other:  <i>Figure 7. Puncture attachment UA1324.</i> <i>Id.</i> at 14. Onik discloses the same:

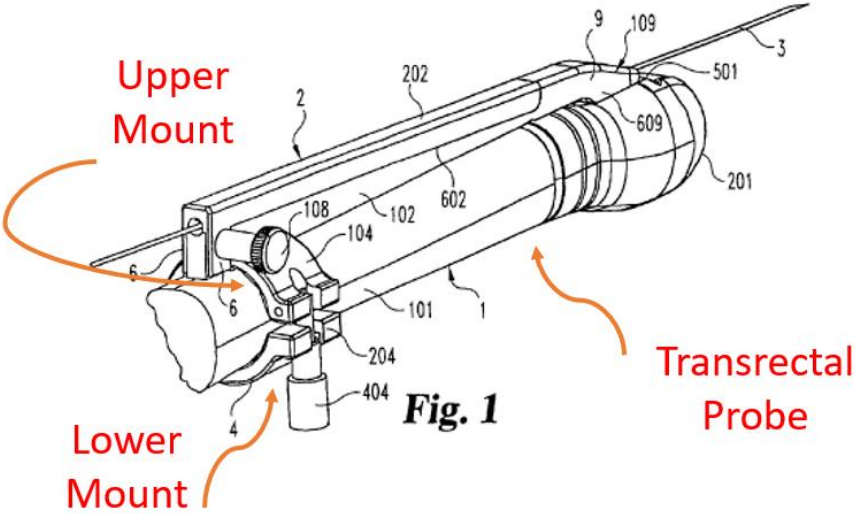
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 Onik at Figure 1. Furia discloses the same. "The base 102 of the needle-guide has a clamping collar 4 at the rear end (with reference to the head 201 of the probe 1), one half 104 thereof being integral with said base 102, whereas the other half 204 of the collar 4 is hinged by hinge 304 to an end of said first half 104, and the two opposite free ends of the halves 104 [the upper mount], 204 [the lower mount] may be clamped together by screw threaded means 404 in a manner which is typical for clamping collars." Furia, 8:53-60.

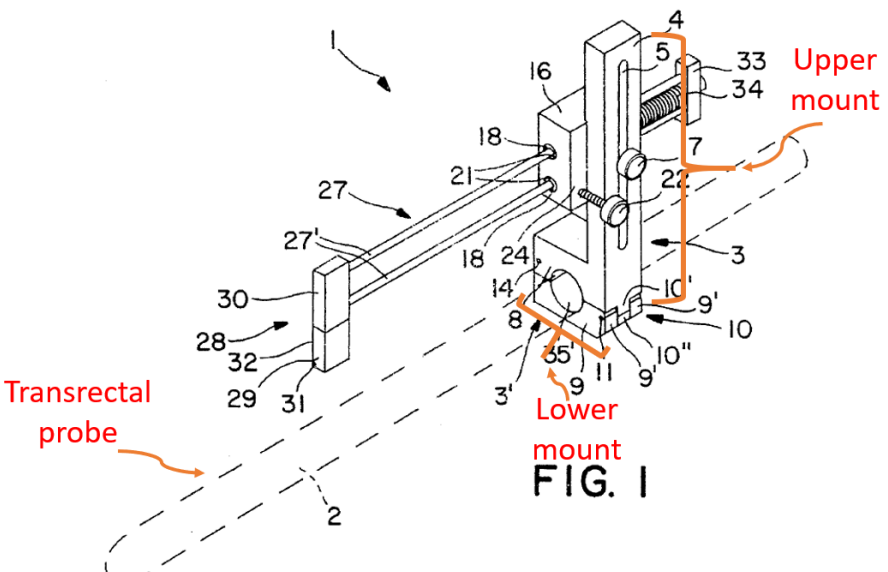
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 Furia, at Figure 1.

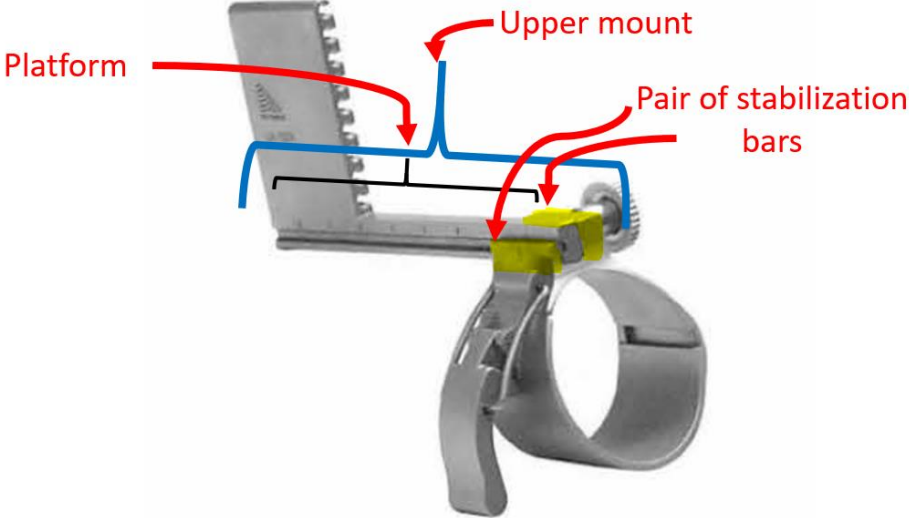
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		Ellard discloses the same:  FIG. 1
1.2	the lower mount configured to engage the transrectal probe and secure the upper mount relative to the transrectal probe,	BK Medical 2010 discloses the lower mount configured to engage the transrectal probe and secure the upper mount relative to the transrectal probe.

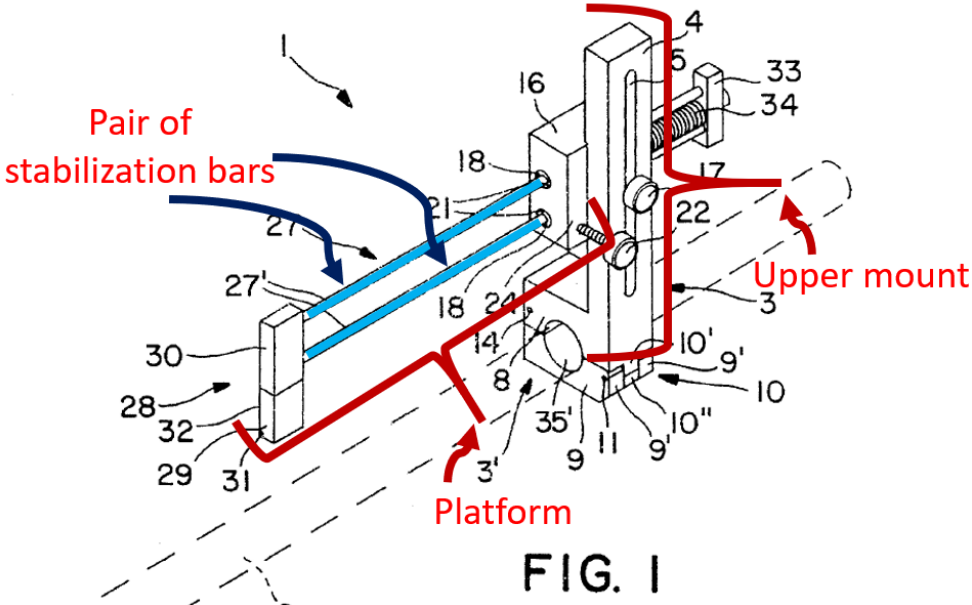
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 <i>Figure 7. Puncture attachment UA1324.</i> BK Medical 2010 at 14.

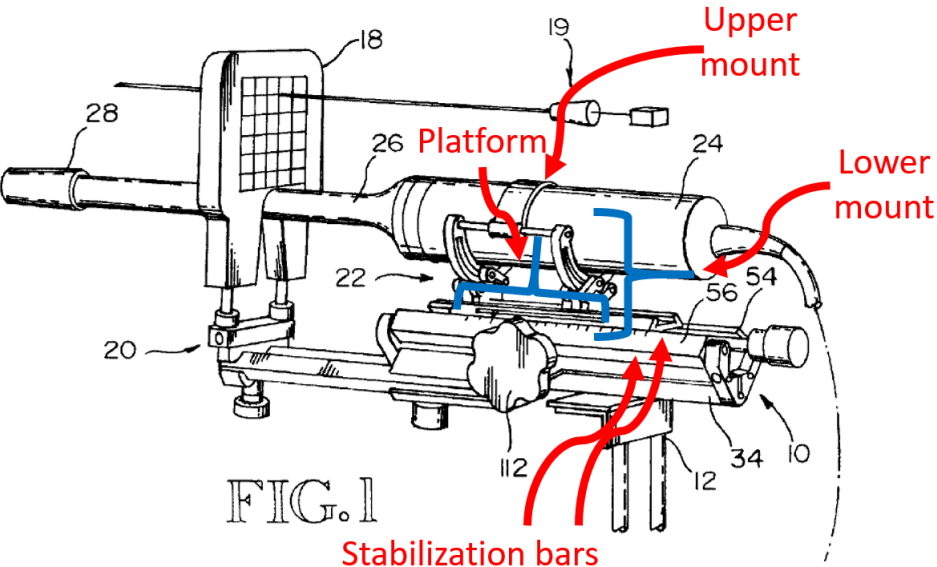
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 <i>Figure 8. Puncture attachment UA1324 mounted on 8808e.</i> BK Medical 2010 at 14. Furia discloses the same:

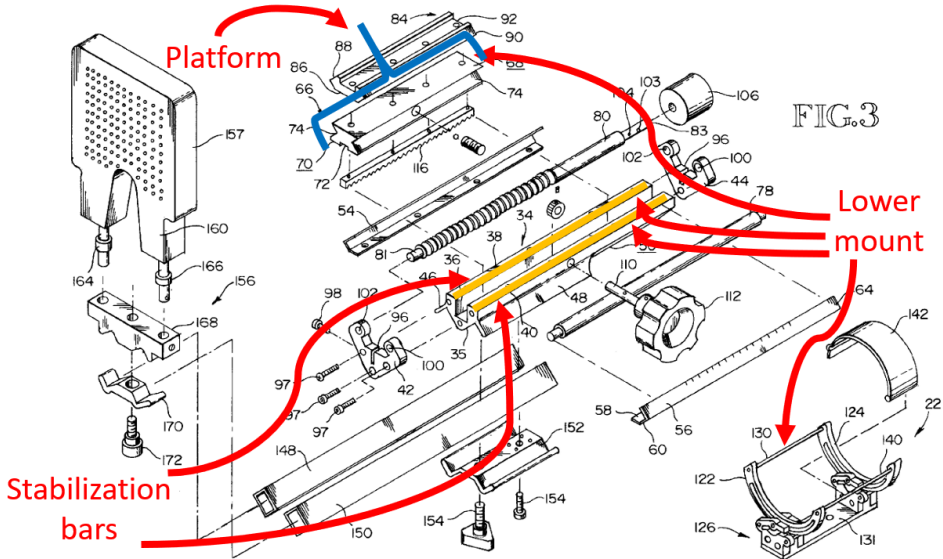
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 Fig. 1 Upper Mount Lower Mount Transrectal Probe Furia at Figure 1.

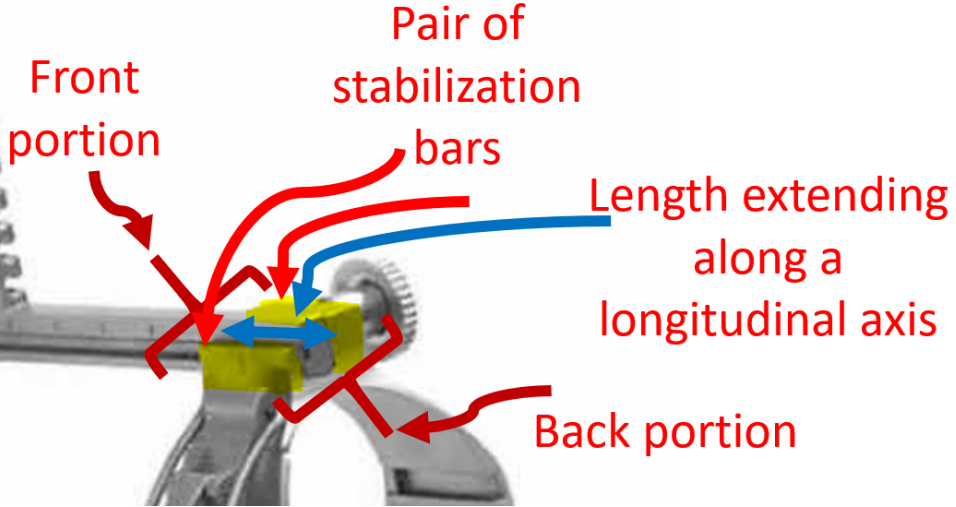
Ref. No.	U.S. Patent No. 10,064,681 ('681 Patent)	Prior Art Citations
		Onik discloses the same:  Onik at Figure 1.
1.3	the upper mount comprising a platform and a pair of stabilization bars spaced-apart from each other,	BK Medical 2010 discloses the upper mount comprising a platform and a pair of stabilization bars spaced-apart from each other:

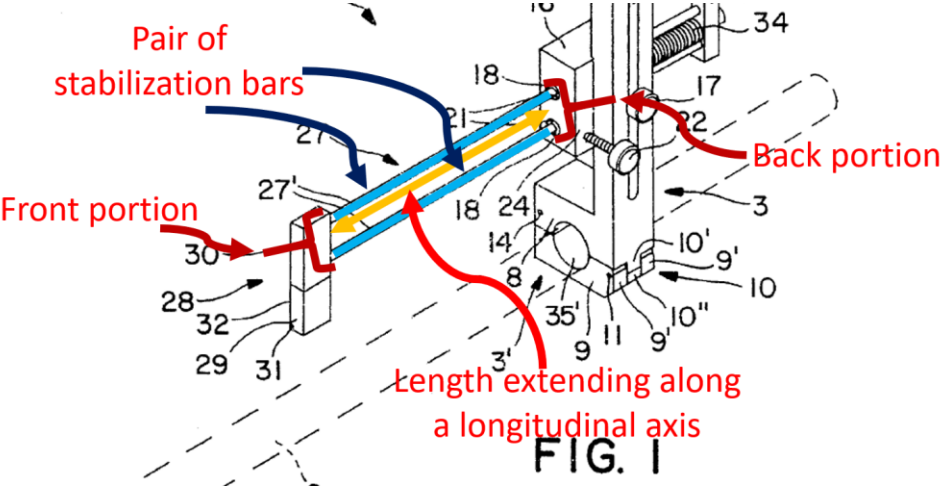
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 <i>Figure 7. Puncture attachment UA1324.</i> BK Medical 2010 at 14. Onik discloses the same:

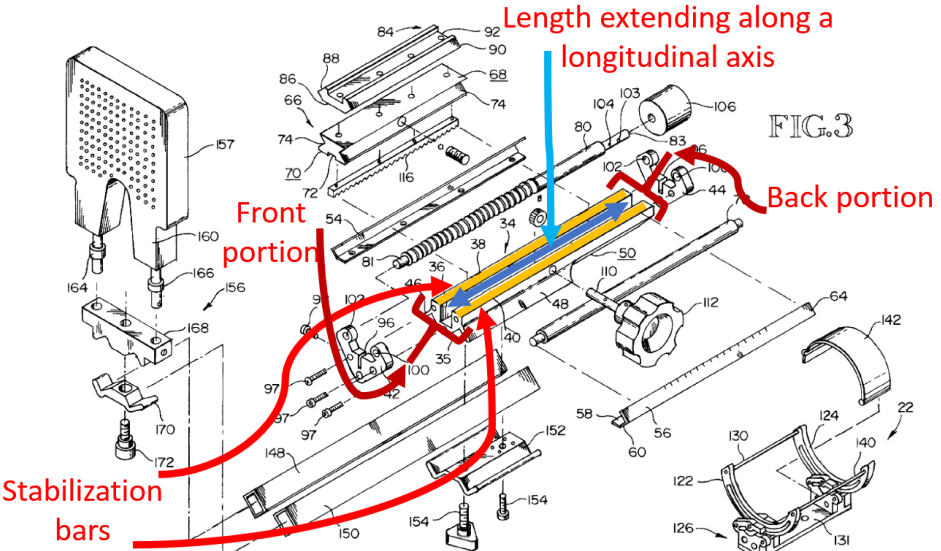
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 FIG. 1 Onik at Figure 1. Ellard discloses a lower mount comprising a platform and a pair of stabilization bars spaced apart from each other. It would be obvious to a PHOSITA to combine Ellard and BK Medical 2010 by moving the stabilization bars of the lower mount in Ellard to the upper mount as disclosed in BK Medical 2010.

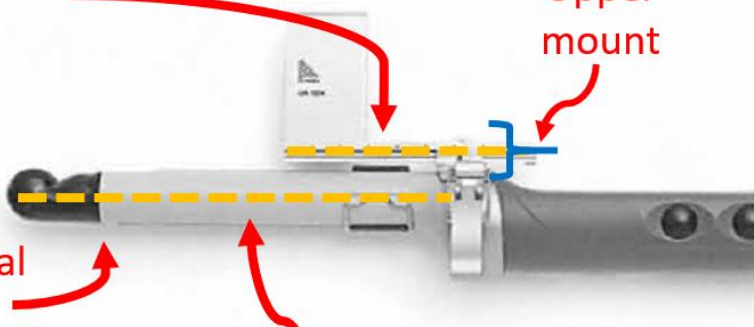
Ref. No.	U.S. Patent No. 10,064,681 ('681 Patent)	Prior Art Citations
		 FIG. 1 Upper mount Platform Lower mount Stabilization bars Ellard at Figure 1.

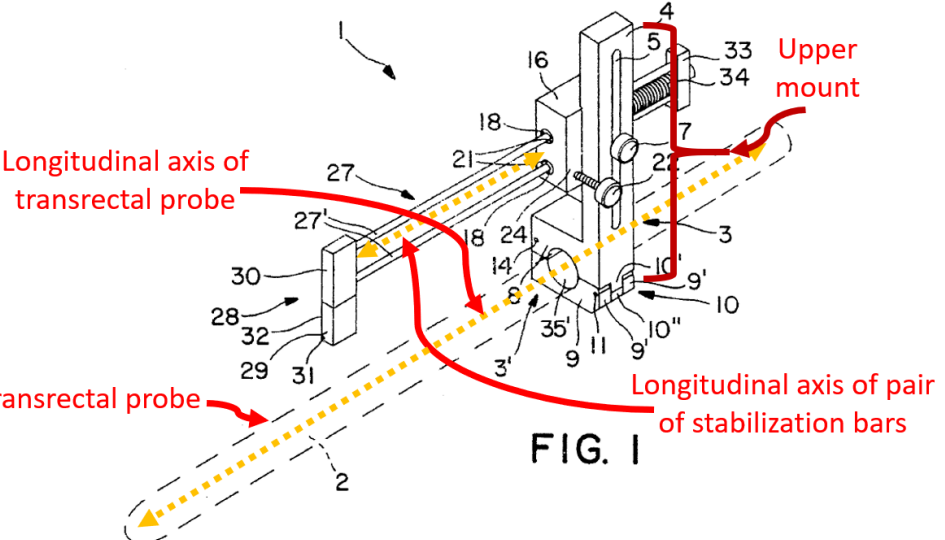
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 FIG. 3 Platform Lower mount Stabilization bars Ellard at Figure 3.
1.4	the pair of stabilization bars including a back portion, a front portion, and a length extending along a longitudinal axis between the back and front portions,	BK Medical 2010 discloses the pair of stabilization bars including a back portion, a front portion, and a length extending along a longitudinal axis between the back and front portions.

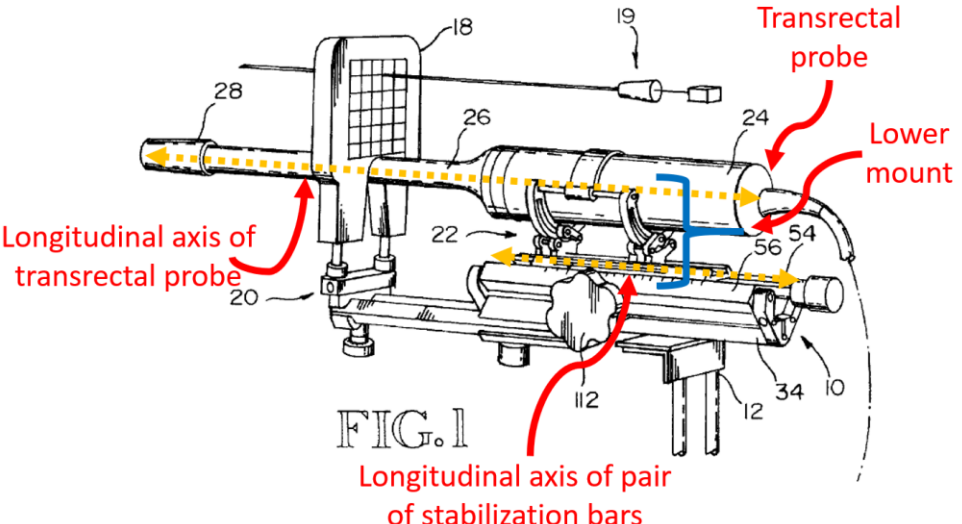
Ref. No.	U.S. Patent No. 10,064,681 (‘681 Patent)	Prior Art Citations
		 Front portion Pair of stabilization bars Length extending along a longitudinal axis Back portion BK Medical 2010 at 14. Onik discloses the same:

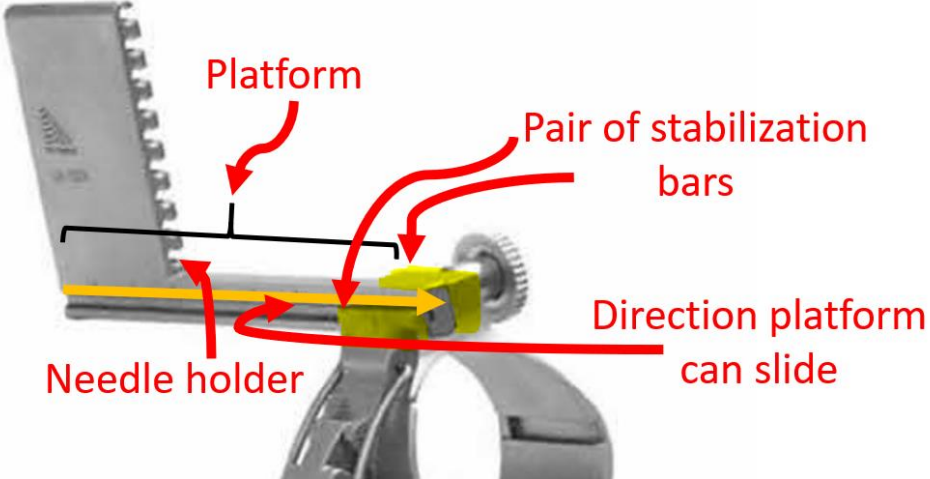
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 Onik at Figure 1. Ellard discloses the same:

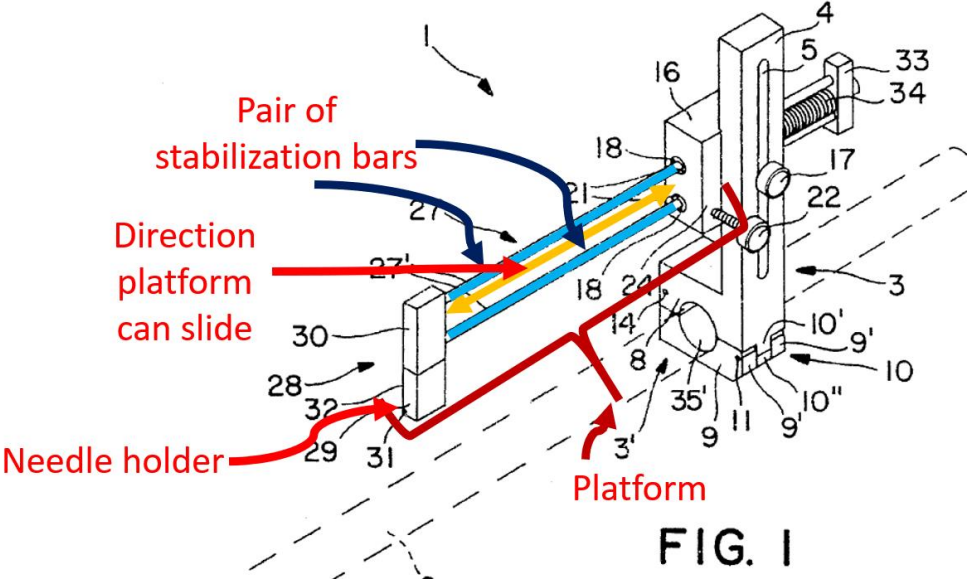
Ref. No.	U.S. Patent No. 10,064,681 ('681 Patent)	Prior Art Citations
		 FIG. 3 Length extending along a longitudinal axis Front portion Back portion Stabilization bars Ellard at Figure 3.
1.5	the longitudinal axis of the pair of stabilization bars being generally parallel with a longitudinal axis of the transrectal probe when the upper mount is secured to the transrectal probe,	BK Medical 2010 discloses that the longitudinal axis of the pair of stabilization bars is generally parallel with a longitudinal axis of the transrectal probe when the upper mount is secured to the transrectal probe.

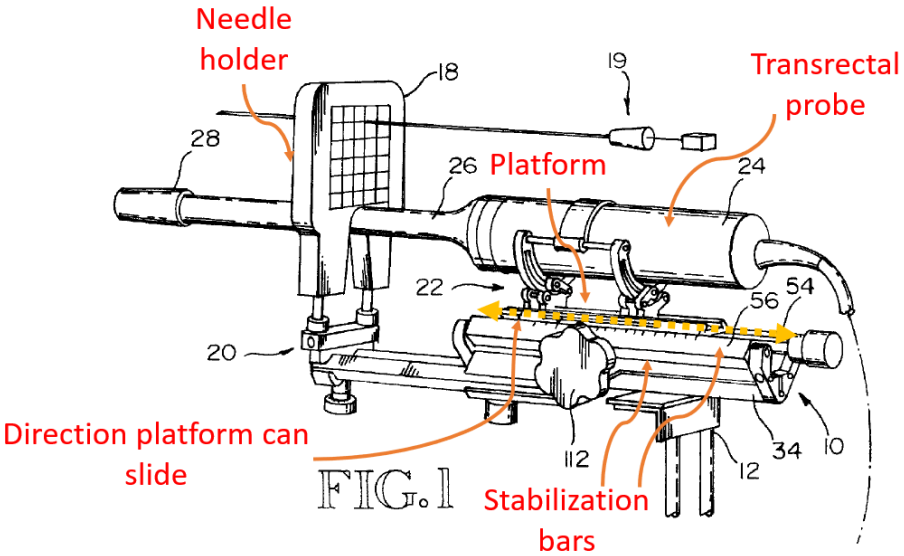
Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		Longitudinal axis of the pair of stabilization bars Upper mount  Transrectal probe <i>Figure 8. Puncture attachment UA1324 mounted on 8808e.</i> Longitudinal axis of the transrectal probe BK Medical 2010 at 14. Onik discloses the same:

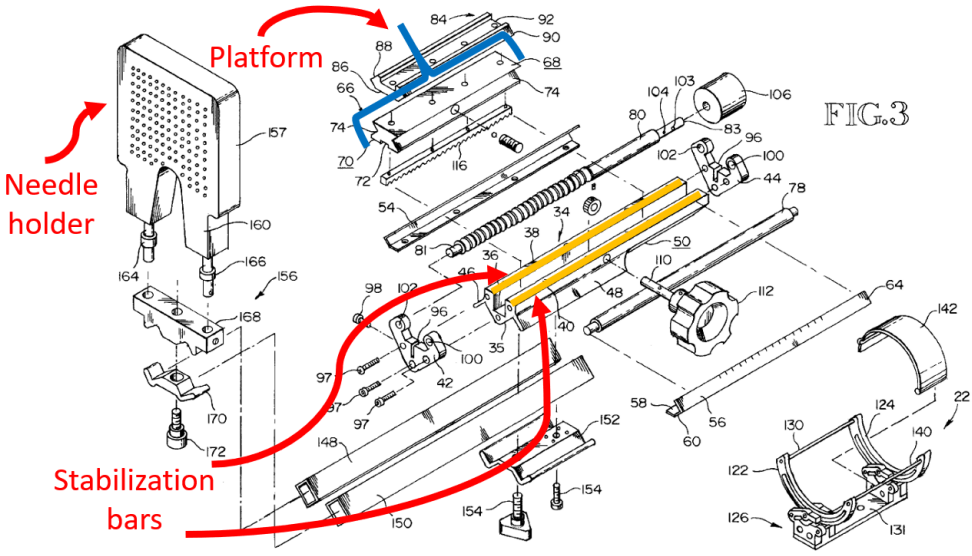
Ref. No.	U.S. Patent No. 10,064,681 ('681 Patent)	Prior Art Citations
		 Onik at Figure 1. Ellard discloses the longitudinal axis of the pair of stabilization bars being generally parallel with a longitudinal axis of the transrectal probe when the lower mount is secured to the transrectal probe. It would be obvious to a PHOSITA to combine Ellard and BK Medical 2010 by combining the “longitudinal axis of the pair of stabilization bars being generally parallel with a longitudinal axis of the transrectal probe” element disclosed in Ellard with the “when the upper mount is secured to the transrectal probe” element disclosed in BK Medical 2010.

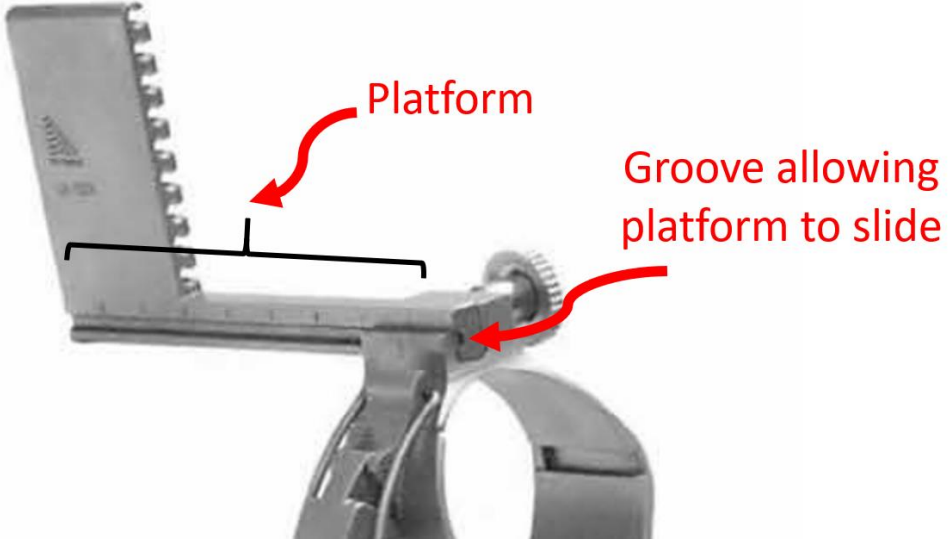
Ref. No.	U.S. Patent No. 10,064,681 ('681 Patent)	Prior Art Citations
		 FIG. 1 Ellard at Figure 1.
1.6	the platform configured to support the access needle and the platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the access needle along the at least a portion of the length.	BK Medical 2010 discloses a platform configured to support the biopsy needle and the platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the biopsy needle along the at least a portion of the length.

Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 BK Medical 2010 at 14. “The needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.” <i>Id.</i> Onik discloses the same. “Extending through slide block 16 [the platform] 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. In the illustrated embodiment, a pair of channels 18 are provided to slidably receive the double rod shaft 27’ [pair of stabilization bars] of the needle holder and guide assembly 27.” Onik, 4:58-63.

Ref. No.	U.S. Patent No. 10,064,681 ('681 Patent)	Prior Art Citations
		 FIG. 1 Onik at Figure 1. Ellard discloses a sliding platform configured to support the transrectal probe with the platform configured to slide on the pair of stabilization bars along at least a portion of the length. It would be obvious to a PHOSITA to combine Ellard with BK Medical 2010 or Onik by substituting the transrectal probe supported on the sliding platform (as disclosed in Ellard) for the needle supported on the sliding platform (as disclosed in BK Medical 2010 and Onik). In all three references, both the needle support and transrectal probe slide in relation to each other.

Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 FIG. 1 Needle holder Transrectal probe Platform Direction platform can slide Stabilization bars Ellard at Figure 1. Ellard further discloses, “Turning the knob 112 one way or the other will move slide 66 [platform] and carriage 84 mounted thereto longitudinally relative to body 34, which remains stably positioned.” Ellard, 5:4-6. “[B]ody portion 34 resembles an upside-down ‘W’ with a rectangular channel 36 extending the length thereof. Two longitudinal, flat, spaced upper surfaces 38 and 40 [pair of stabilization bars] border channel 36.” Ellard, 3:32-35.

Ref. No.	U.S. Patent No. 10,064,681 ('681 Patent)	Prior Art Citations
		 Ellard at Figure 3.
Claim 3		
3	The apparatus of claim 1, wherein each of the pair of stabilization bars include grooves on an inner portion that allow the platform to slide thereon.	BK Medical 2010 discloses that the pair of stabilization bars include grooves on an inner portion that allow the platform to slide thereon.

Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		 BK Medical 2010 at 14. Additionally, the use of grooves would be obvious to a PHOSITA wherever a sliding mechanism is involved. Krieger, for instance, discloses grooves 230 along a trans-orifice guidance apparatus 100 that allows a saddle [platform] to slide thereon (and thus adjusting the angle of needle tube 108). [0063]. Therefore, it would have been obvious to a PHOSITA to combine Krieger’s grooves allowing the platform to slide with BK Medical 2010’s pair of stabilization bars on which the platform slides.

Ref. No.	U.S. Patent No. 10,064,681 ('681 Patent)	Prior Art Citations
		Krieger at Figure 2F.
Claim 8		
8	The apparatus of claim 1, wherein the platform is removably coupled with the pair of stabilization bars.	BK Medical 2010 discloses a platform configured to slide on a pair of stabilization bars. See Citations for '681 Patent at 1.6. Furia discloses a “combination of a needle-guide [platform] and an ultrasound probe, wherein the base of the needle-guide [platform] is removably attachable to the probe body in a stable and predetermined position, said base [of the platform] having one or more shape mating extensions [stabilization bars] which adhere to a portion of the outer surface of the ultrasound probe body and/or mutual interlock engagement means, as

Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		well as clamping means.” Furia, 4:56-62. It would have been obvious to a PHOSITA to combine Furia’s platform with stabilization bars removably coupled to an ultrasound probe with BK Medical 2010’s platform configured to slide on a pair of stabilization bars. <i>See Citations for ’681 Patent at 1.6.</i>
Claim 9		
9	The apparatus of claim 8, wherein the platform is interchangeable with alternate platforms of different sizes.	BK Medical 2010 discloses a platform configured to slide on a pair of stabilization bars. <i>See Citations for ’681 Patent at 1.6.</i> A medical device with interchangeable parts of different sizes would be obvious to a PHOSITA. For instance, Solar discloses apparatuses for introducing instruments in desired trajectories (such as into a skull). <i>Id.</i>, Abstract. Solar further discloses “an appropriate unitary positioning assembly [platform], with side arms 128A-B having lengths fabricated to correspond to a particular depth or the like, is selected from a kit of such pre-fabricated positioning assemblies with varying length side arms 128A-B corresponding to various possible target depths (in one example, the particular depth is printed on the particular assembly, thereby allowing the user to easily select the desired depth).” <i>Id.</i> at 9:47-54. As another example, Green describes apparatuses for “loading therapeutic materials into brachytherapy needles,” comprising radioactive seed and spacer cartridges. <i>Id.</i>, Abstract. In the disclosed invention, “cartridges 34 and 36 may have any one of a variety of alternative structures described hereinafter with respect to FIGS. 5A-5D, depending upon the intended context for use of the apparatus.” Green at 5:28-33.

Ref. No.	U.S. Patent No. 10,064,681 (’681 Patent)	Prior Art Citations
		Accordingly, it would be obvious to a PHOSITA for the platform disclosed in BK Medical 2010 to be interchangeable with alternate platforms of different sizes.
Claim 17		
17	The apparatus of claim 1, further comprising the access needle.	BK Medical 2010 in view of Novella 2003 teaches the apparatus of claim 1. <i>See Citations for ’681 Patent at 1.</i> Given the known advantages of using an access needle in prostate biopsies as described above, a PHOSITA would understand it would be obvious to provide an access needle. <i>See Citations for ’681 Patent at 1.pre.</i>

EXHIBIT B

Invalidity Claim Chart for U.S. Patent No. 11,096,762 B2 ('762 Patent) Based on BK Medical Type 8808e User Guide (Aug. 2010) ("BK Medical 2010").

BK Medical 8808e August 2010 Product Data Sheet ("BK Medical 2010") (AMD_00000001 – AMD_00000017) qualifies as prior art to the '762 Patent under 35 U.S.C. § 102(a) and anticipates and/or renders obvious one or more of the asserted claims of the '762 Patent either in combination with, or modified based on, the knowledge of a person of ordinary skill in the art, or in combination with, or modified based on, any prior art identified in Plaintiff's invalidity contentions.

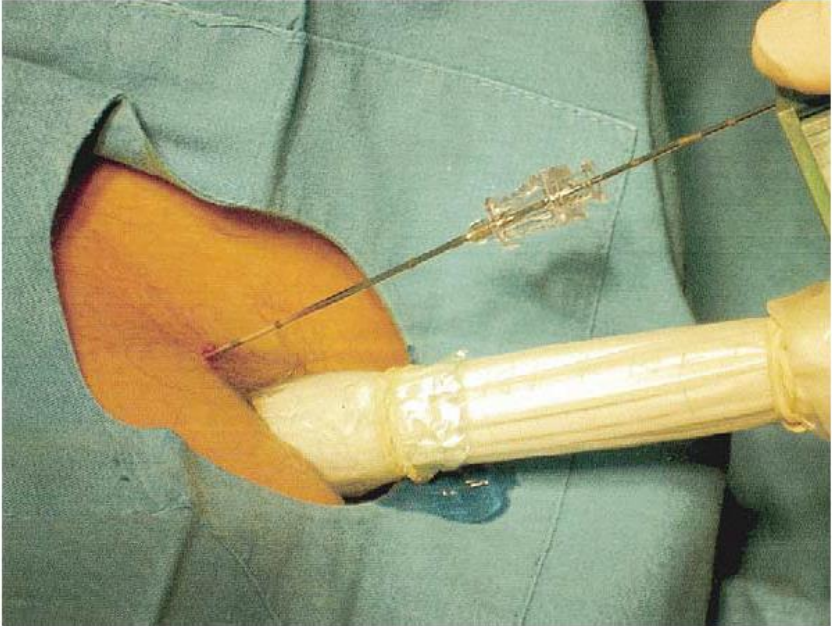
The Secondary References cited include:

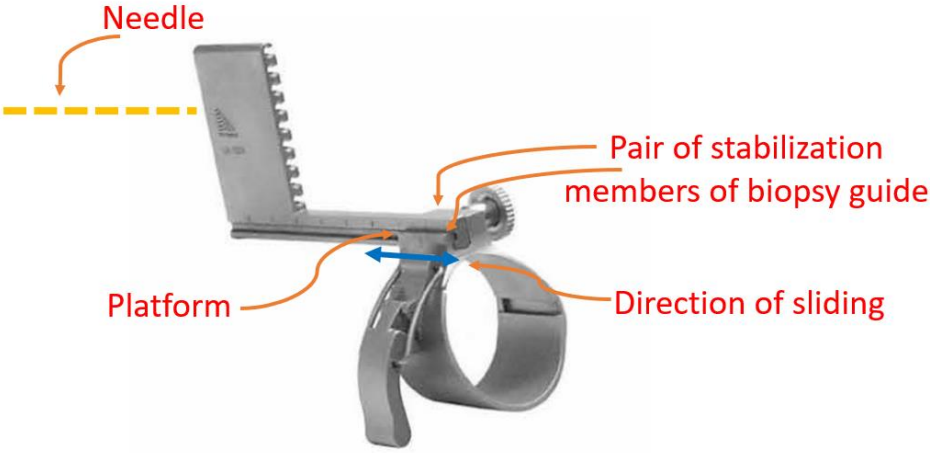
- U.S. Patent No. 5,494,039 to Onik ("Onik") (AMD_00000034 – AMD_00000043)
- U.S. Patent No. 6,485,426 to Sandhu ("Sandhu") (AMD_00000053 – AMD_00000060)
- Giovanni Novella, *et al.*, *Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle*, 62 UROLOGY 689 (2003) ("Novella 2003") (AMD_00000030 – AMD_00000033)
- Vincenzo Ficarra, *et al.*, *Needle Core Length is a Quality Indicator of Systematic Transperineal Prostate Biopsy*, 50 EUROPEAN UROLOGY 266 (2006) ("Ficarra 2006") (AMD_00000018 – AMD_00000023)
- Gencay Hatiboglu, *et al.*, *Application Technique: Placement of a Prostate-Rectum Spacer in Men Undergoing Prostate Radiation Therapy*, 110 BJU INT'L E647 (May 10, 2012) (AMD_00000024 – AMD_00000029)

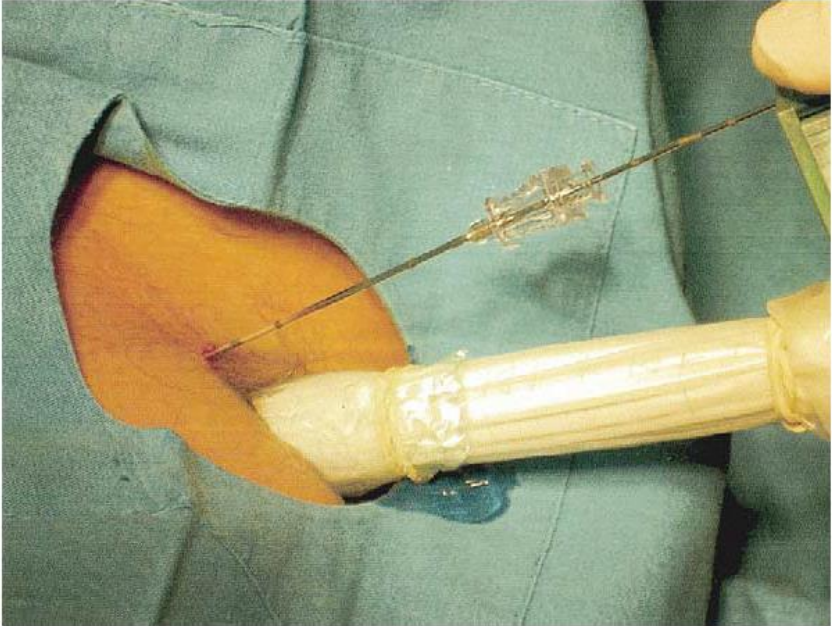
Plaintiff reserves the right to combine additional prior art references identified in its invalidity contentions with BK Medical 2010 even if not explicitly listed in the claim chart below. Plaintiff reserves the right to rely on other portions of a cited reference's disclosure, including, but not limited to, any figures discussed in cited text or any text relating to cited figures. Plaintiff reserves the right to supplement or amend this claim chart depending upon the claim construction order issued by the Court and how Defendant construes the claims in an attempt to assert infringement. All citations and proposed combinations for independent claims apply for all dependent claims.

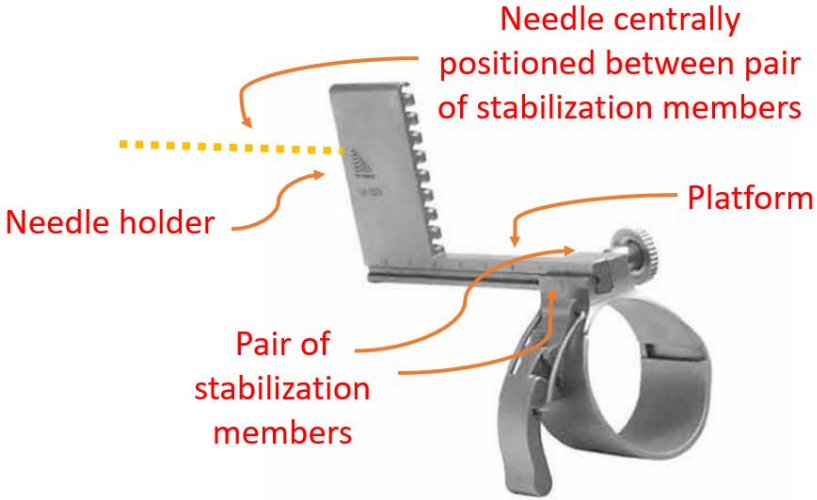
Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
Claim 13		
13.pre	A method of performing a transperineal prostate biopsy procedure on a prostate of a patient using an ultrasound probe, the method comprising:	BK Medical 2010 discloses a method of performing a transperineal prostate biopsy procedure on a prostate of a patient using an ultrasound probe. “The 8808e is designed for transrectal scanning.” <i>Id.</i> at 1. “The metal puncture attachment UA1324 is designed for transperineal puncture and biopsy.” <i>Id.</i>  <i>Figure 7. Puncture attachment UA1324.</i> <i>Id.</i> at 14.  <i>Figure 8. Puncture attachment UA1324 mounted on 8808e.</i>

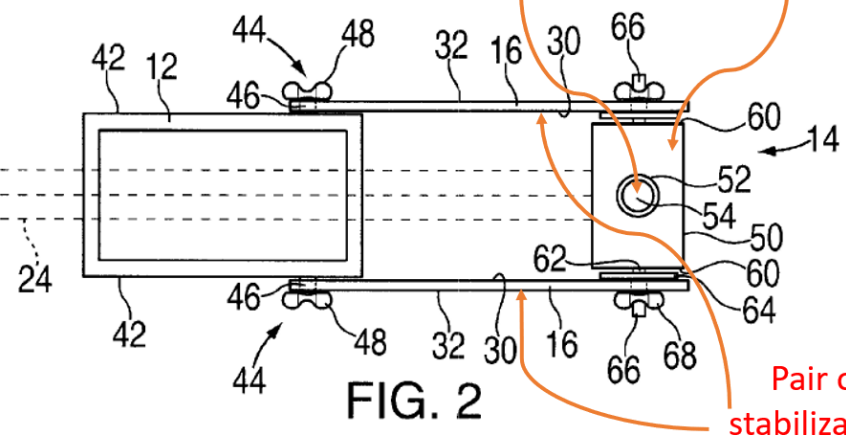
Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		<i>Id.</i> at 14. Onik discloses the same. "Most particularly the invention relates to a biopsy needle insertion guide which is securely mountable on and useable with a rectally inserted ultrasound probe to insert biopsy needles into the prostate at specific target points identified on an ultrasound image of the prostate." Onik, 1:10-15.
13.1	inserting an access needle into a perineal access site leading to the prostate,	BK Medical 2010 discloses an apparatus to be used for performing transperineal prostate biopsies with biopsy needles but does not specifically disclose access needles. <i>See id.</i> at 14 (“The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy. . . . The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.”) Novella 2003 discloses inserting an access needle into a perineal access site leading to the prostate. “The insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.

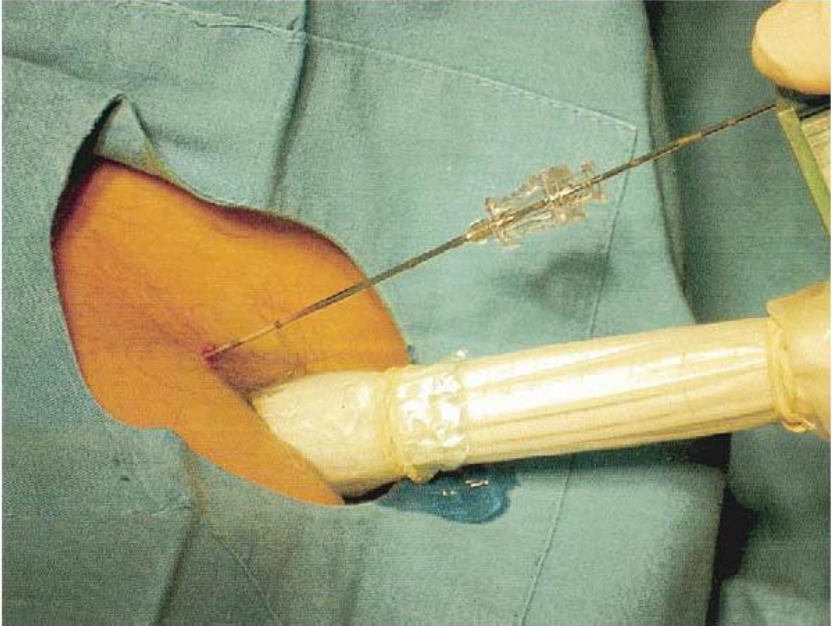
Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. Due to the known advantages of using an access needle in transperineal prostate biopsies, it would be obvious to a PHOSITA to combine the access needle disclosed in Novella 2003 with the method disclosed in BK Medical

Ref. No.	U.S. Patent No. 11,096,762 B2 ('762 Patent)	Prior Art Citations
		2010.
13.2	the access needle engaged with a platform that is configured to slide on a pair of stabilization members of a biopsy guide,	BK Medical 2010 discloses a needle engaged with a platform that is configured to slide on a pair of stabilization members of a biopsy guide.  <i>Figure 7. Puncture attachment UA1324.</i> <i>Id.</i> at 14. “The needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.” <i>Id.</i> Onik discloses the same. “Extending through 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. In the illustrated embodiment, a pair of channels 18 are provided to slidably receive the double rod shaft 27' of the needle holder and guide assembly 27.” Onik, 4:58-63.

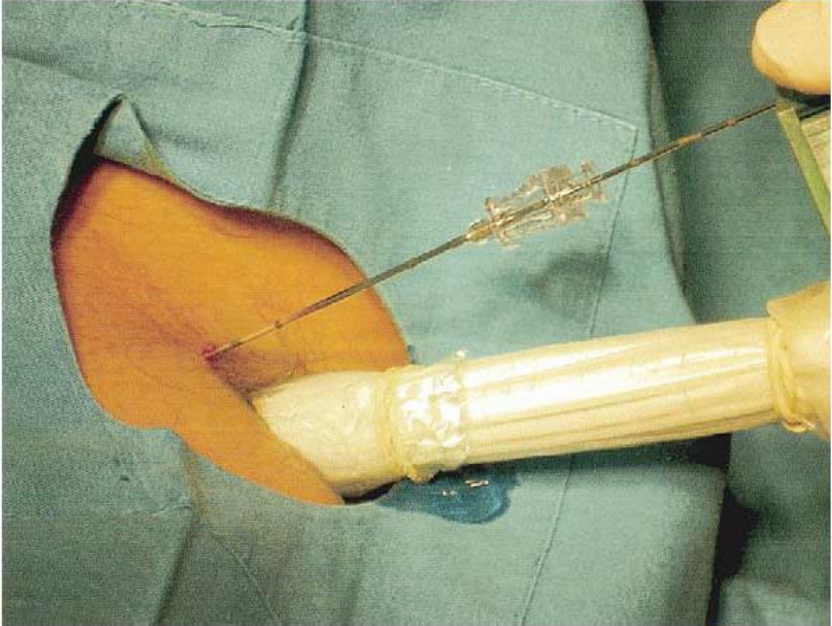
Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. Due to the known advantages of using an access needle for prostate biopsy procedures, it would have been obvious to a PHOSITA to combine the access needle of Novella 2003 with the “platform that is configured to slide

Ref. No.	U.S. Patent No. 11,096,762 B2 ('762 Patent)	Prior Art Citations
		on a pair of stabilization members of a biopsy guide” disclosed in BK Medical 2010 and Onik.
13.3	the access needle being centrally positioned between the pair of stabilization members when the access needle is engaged with the platform; and	BK Medical 2010 discloses a needle being centrally positioned between the pair of stabilization members when the access needle is engaged with the platform. “The 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. The guide is parallel to the centerline of the transducer.” <i>Id.</i> at 14.  <i>Figure 7. Puncture attachment UA1324.</i> <i>Id.</i> at 14. Sandhu discloses a “needle guidance device for use with an ultrasound

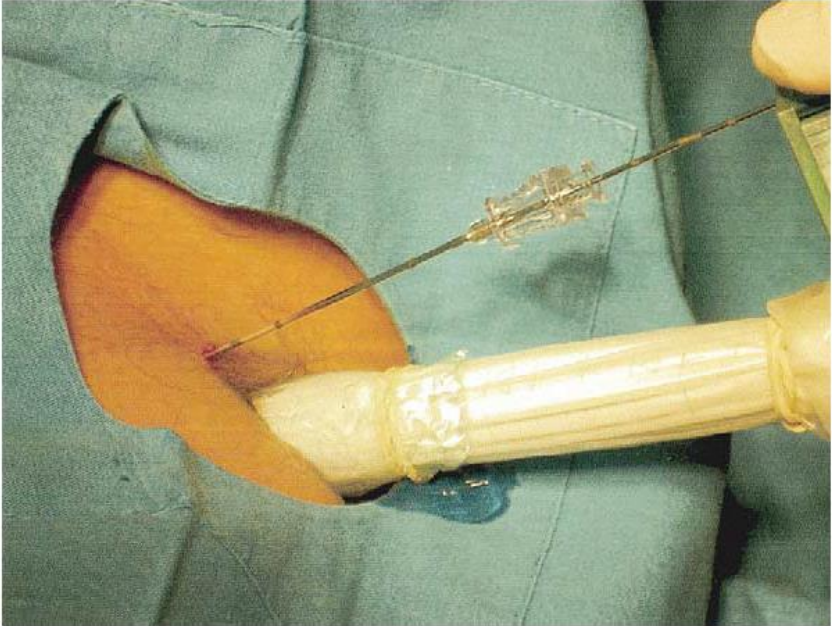
Ref. No.	U.S. Patent No. 11,096,762 B2 ('762 Patent)	Prior Art Citations
		transducer” with a platform comprising “bore 54 through which needle 56 is inserted” centrally positioned between a pair of stabilization members. Sandhu, Abstract; 3:36-37. Needle centrally positioned between pair of stabilization members Platform  FIG. 2 Pair of stabilization members Sandhu at Figure 2. Novella 2003 discloses that “[t]he insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.

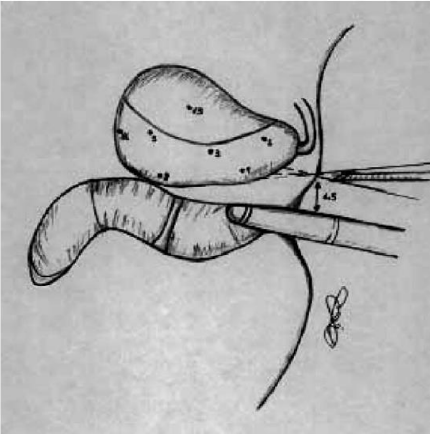
Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. Due to the known advantages of using an access needle for prostate biopsy procedures, it would have been obvious to a PHOSITA to combine the access needle of Novella 2003 with the “needle being centrally positioned

Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		between the pair of stabilization members when the access needle is engaged with the platform” of BK Medical 2010 and Sandhu.
13.4	inserting a biopsy needle through the access needle and into a first location within the prostate.	BK Medical 2010 discloses an apparatus to be used for performing transperineal prostate biopsies with biopsy needles but does not specifically disclose inserting a biopsy needle through the access needle and into a first location within the prostate. <i>See id.</i> at 14 (“The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy. . . . The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.”) Novella 2003 discloses inserting a biopsy needle through the access needle and into a first location within the prostate. “The insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.

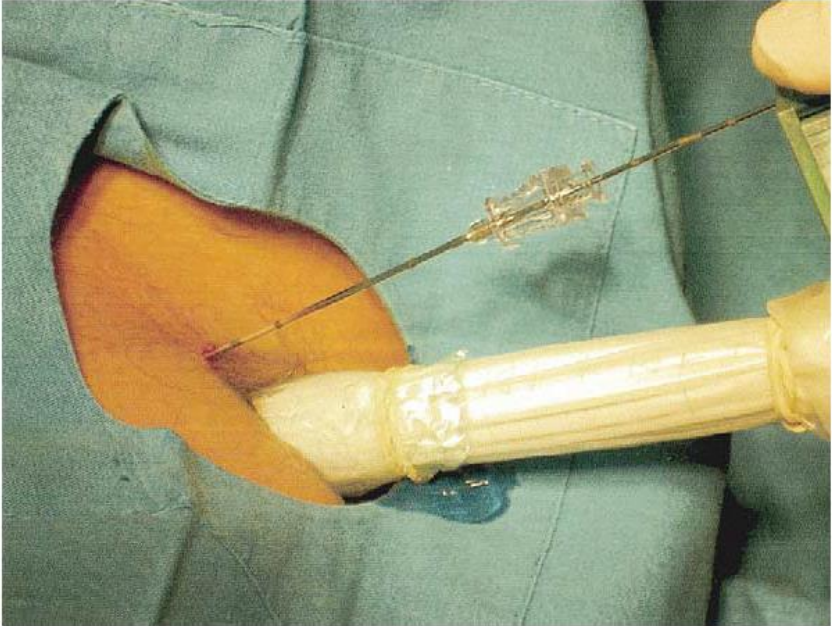
Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. Due to the known advantages of using an access needle in transperineal prostate biopsies, it would be obvious to a PHOSITA to combine the method of inserting a biopsy needle through an access needle and into a first location

Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		within the prostate disclosed in Novella 2003 with the method disclosed in BK Medical 2010.
Claim 14		
14	The method of claim 13, further comprising inserting the biopsy needle through the access needle and into a second location within the prostate, the second location being different than the first location.	BK Medical 2010 discloses an apparatus to be used for performing transperineal prostate biopsies with biopsy needles but does not specifically disclose inserting the biopsy needle through an access needle and into a second location within the prostate. <i>See id.</i> at 14 (“The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.”) Novella 2003 discloses inserting the biopsy needle through the access needle and into a second location within the prostate, the second location being different than the first location. “The insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.

Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. “Fourteen cores were sampled in every patient (double sextant biopsy from the peripheral and two cores from the transition zone).” <i>Id.</i> at 690. Ficarra 2006 discloses the same. “A 17-gauge coaxial needle (TruGuide

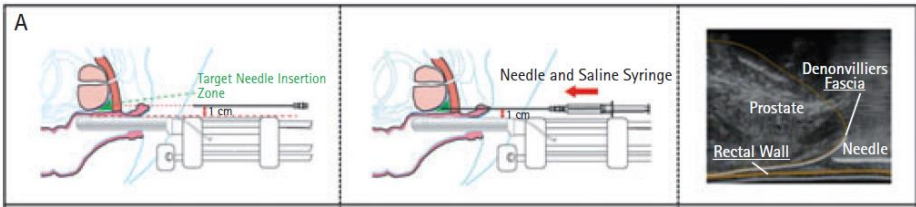
Ref. No.	U.S. Patent No. 11,096,762 B2 ('762 Patent)	Prior Art Citations
		Bard, 13 cm long) was inserted up to the prostate apex through the anesthetised perineal path under TRUS guidance On the removal of the blunt tip stylet, the guiding cannula of the coaxial needle was used as transperineal metallic path for repeated atraumatic passage of the biopsy needle Fourteen cores were sampled in every patient: double sextant biopsy from the peripheral zone and two cores from the transitional zone (Fig. 1).”  Fig. 1 – site of core sampling at the right prostate's lobe. Cores 1, 3, and 5 correspond to the traditional sextant biopsy protocol. Cores 7, 9, and 11 refer to the additional, peripheral, lateral sextant. Core 13 comes from the transitional zone. The coaxial needle, which allows the atraumatic passage of biopsy needle, is inserted 1.5 cm above the anal sphincter on the median line under local anaesthesia. <i>Id.</i> at 267. Because the prior art describes taking multiple prostate biopsies as standard practice, it would be obvious to a PHOSITA to combine the method of inserting the biopsy needle through the access needle and into a second location within the prostate (the second location being different than the first

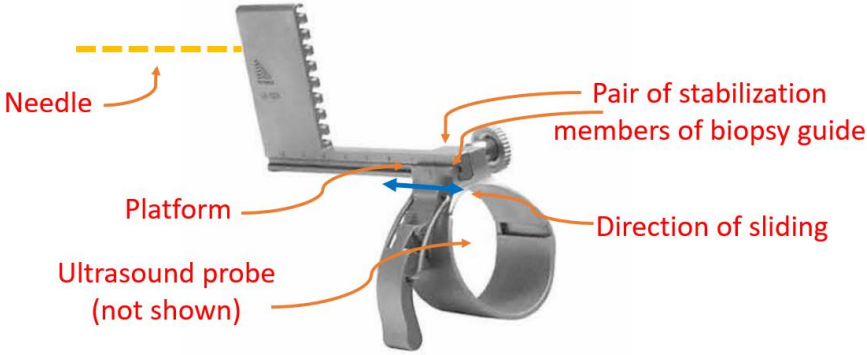
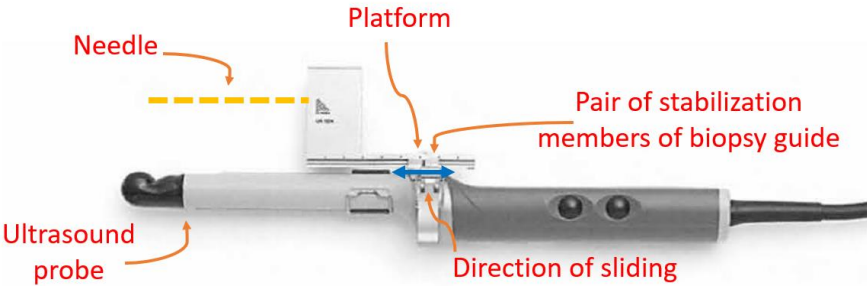
Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		location) as disclosed in Novella 2003 and Ficarra 2006 with the method of performing a transperineal prostate biopsy disclosed in BK Medical 2010.
Claim 15		
15	The method of claim 14, wherein the access needle remains positioned within the perineal access site of the prostate during the insertion of the biopsy needle into both of the first and second locations within the prostate.	BK Medical 2010 discloses an apparatus to be used for performing transperineal prostate biopsies with biopsy needles but does not specifically disclose an access needle that remains positioned within the perineal access site of the prostate during the insertion of the biopsy needle into both of the first and second locations within the prostate. <i>See id.</i> at 14 (“The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.”) Novella 2003 discloses that the access needle remains positioned within the perineal access site of the prostate during the insertion of the biopsy needle into both of the first and second locations within the prostate. “The insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.

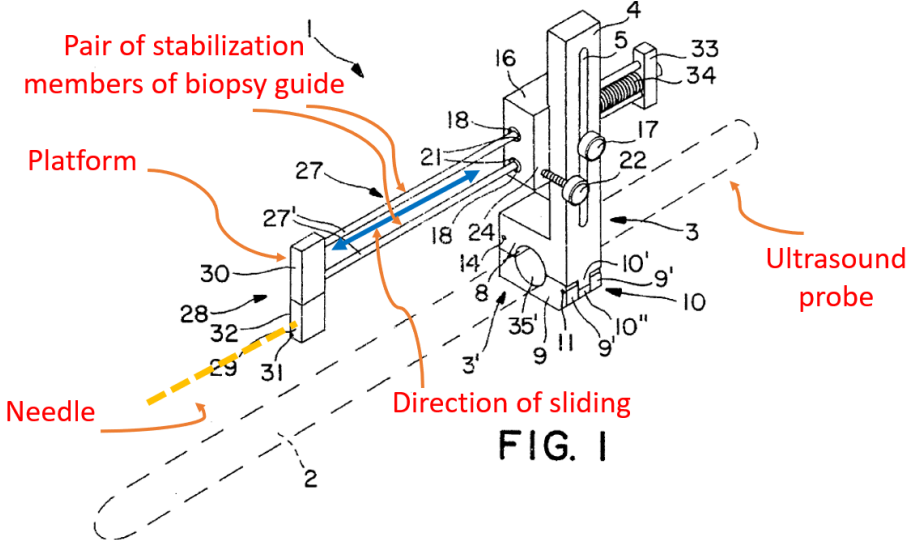
Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. “Fourteen cores were sampled in every patient (double sextant biopsy from the peripheral and two cores from the transition zone).” <i>Id.</i> at 690. Ficarra 2006 discloses the same. “A 17-gauge coaxial needle (TruGuide

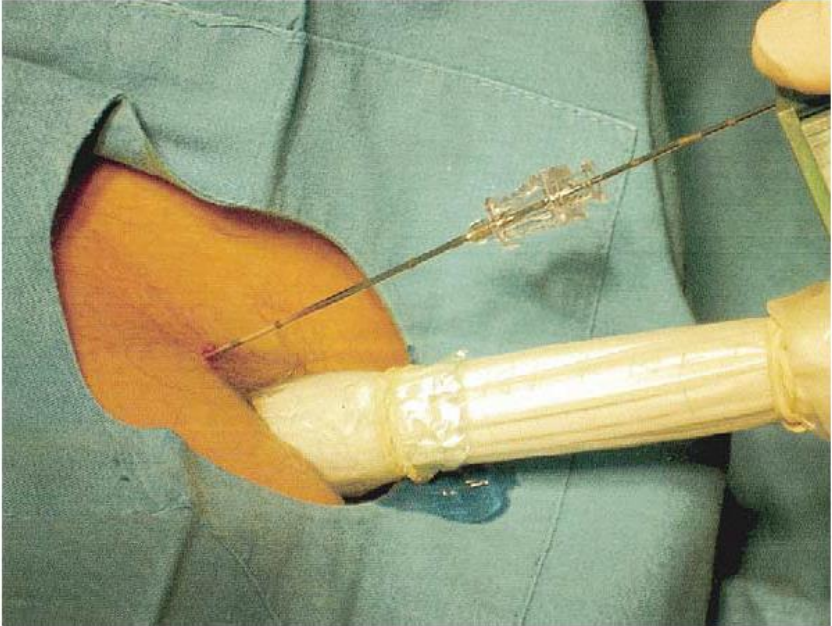
Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		to remain positioned within the perineal access site of the prostate during the insertion of the biopsy needle into both of the first and second locations within the prostate (as disclosed in Novella 2003 and Ficarra 2006) with the method of performing a transperineal prostate biopsy disclosed in BK Medical 2010.
Claim 20		
20	The method of claim 13, further comprising obtaining at least one of a cell and tissue sample from the prostate with the biopsy needle.	BK Medical 2010 discloses an apparatus to be used for performing transperineal prostate biopsies with biopsy needles but does not specifically disclose obtaining at least one of a cell and tissue sample from the prostate with the biopsy needle. <i>See id.</i> at 14 (“The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.”) Ficarra 2006 discloses obtaining at least one of a cell and tissue sample from the prostate with the biopsy needle. “Fourteen cores were sampled in every patient: double sextant biopsy from the peripheral zone and two cores from the transitional zone (Fig. 1). Needle cores were stretched and placed in tissue cassettes between two nylon meshes according to the pre-embedding methods of prostate needle biopsy specimens described by Rogatsch et al.” Ficarra 2006 at 267.
Claim 36		
36.pre	A method of performing a transperineal prostate biopsy procedure on a prostate of a patient using an ultrasound probe configured	BK Medical 2010 discloses a method of performing a transperineal prostate biopsy procedure on a prostate of a patient using an ultrasound probe configured to provide imaging in at least a sagittal plane.

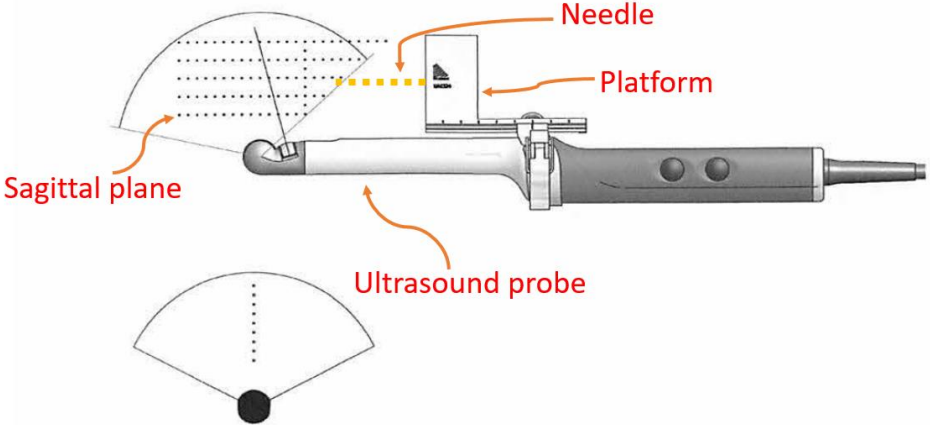
Ref. No.	U.S. Patent No. 11,096,762 B2 (‘762 Patent)	Prior Art Citations
	to provide imaging in at least a sagittal plane, the method comprising:	“The 8808e is designed for transrectal scanning.” <i>Id.</i> at 1. “The metal puncture attachment UA 1324 is designed for transperineal puncture and biopsy.” <i>Id.</i> “It has two convex arrays, one for transverse scanning and one for sagittal scanning.” <i>Id.</i>  <i>Figure 7. Puncture attachment UA1324.</i> <i>Id.</i> at 14.  <i>Figure 8. Puncture attachment UA1324 mounted on 8808e.</i> <i>Id.</i> at 14.

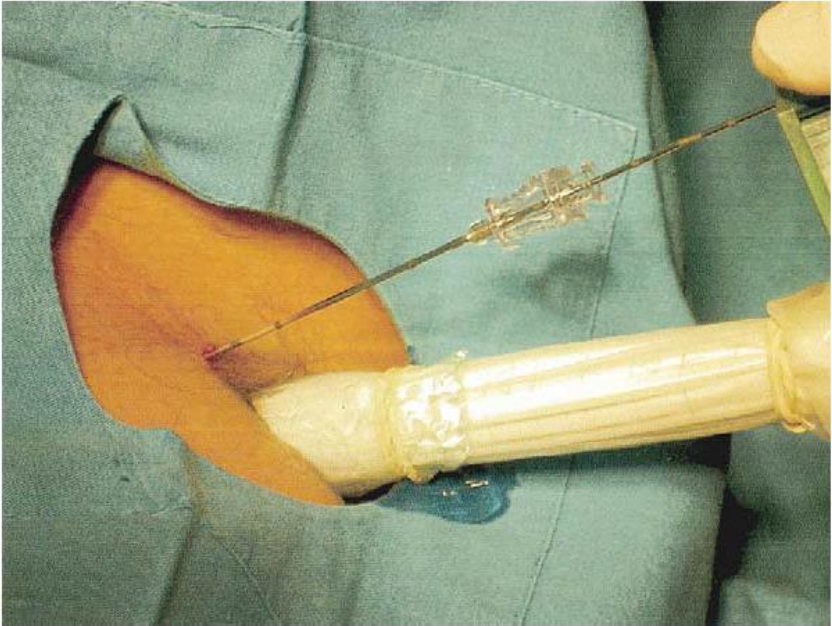
Ref. No.	U.S. Patent No. 11,096,762 B2 ('762 Patent)	Prior Art Citations
		Additionally, Hatiboglu 2012 discloses a technique for injecting a hydrogel spacer between the prostate and rectum for men undergoing prostate cancer radiotherapy. <i>Id.</i>, Objective. The technique involves using a needle on a needle guide coupled to an ultrasound probe with sagittal views. <i>Id.</i> at E649. “Under real-time TRUS guidance in the sagittal plane, the injection needle (18G × 15 cm), with an attached syringe containing saline or lidocaine 0.5 – 1.0% diluted in 15 mL saline, was inserted ~ 1 cm above the TRUS probe.” <i>Id.</i> <i>FIG. 4. A, Needle alignment and placement with ultrasonography sagittal view. B, Hydrodissection with ultrasonography sagittal view. C, Hydrogel injection with ultrasonography sagittal view.</i>  <i>Id.</i>
36.1	inserting an access needle into a perineal access site leading to the prostate,	See Citations for '762 Patent at 13.1.
36.2	the access needle engaged with a platform that is configured to slide on a pair of stabilization members of a biopsy guide that is secured to the ultrasound probe,	BK Medical 2010 discloses a needle engaged with a platform that is configured to slide on a pair of stabilization members of a biopsy guide that is secured to an ultrasound probe.

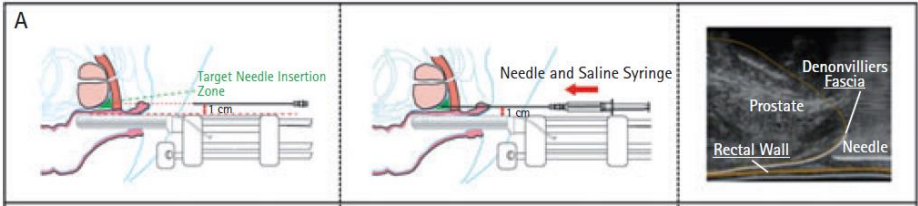
Ref. No.	U.S. Patent No. 11,096,762 B2 ('762 Patent)	Prior Art Citations
		 <i>Figure 7. Puncture attachment UA1324.</i> <i>Id.</i> at 14. “The needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.” <i>Id.</i>  <i>Figure 8. Puncture attachment UA1324 mounted on 8808e.</i> <i>Id.</i> at 14. Onik discloses the same. “Extending through slide block 16 in a direction

Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		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. In the illustrated embodiment, a pair of channels 18 are provided to slidably receive the double rod shaft 27' of the needle holder and guide assembly 27.” Onik, 4:58-63.  Onik at Figure 1. Novella 2003 discloses that “[t]he insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.

Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. Due to the known advantages of using an access needle for prostate biopsy procedures, it would have been obvious to a PHOSITA to combine the access needle of Novella 2003 with the “platform that is configured to slide

Ref. No.	U.S. Patent No. 11,096,762 B2 ('762 Patent)	Prior Art Citations
		on a pair of stabilization members of a biopsy guide that is secured to the ultrasound probe” disclosed by BK Medical 2010 and Onik.
36.3	the access needle positioned within the sagittal plane when the access needle is engaged with the platform and when the ultrasound probe provides imaging in the sagittal plane; and	BK Medical 2010 discloses a needle positioned within a sagittal plane when the needle is engaged with a platform and when the ultrasound probe provides imaging in the sagittal plane. “Transrectal puncture and biopsy can be performed using simultaneous biplane scanning, where both the sagittal and transverse planes are visualized live at the same time, the advantage is that the needle is visible in both planes throughout the puncture and biopsy procedures.” <i>Id.</i> at 1. The puncture lines for UA1324 on 8808e are shown in Figure 9.  <i>Id.</i> at 15. “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 5 mm.” <i>Id.</i> Novella 2003 discloses that “[t]he insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation

Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
		of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.  FIGURE 1. An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle. <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692.

Ref. No.	U.S. Patent No. 11,096,762 B2 ('762 Patent)	Prior Art Citations
		Additionally, Hatiboglu 2012 discloses a technique for injecting a hydrogel spacer between the prostate and rectum for men undergoing prostate cancer radiotherapy. <i>Id.</i>, Objective. The technique involves using a needle on a needle guide coupled to an ultrasound probe with sagittal views. <i>Id.</i> at E649. “Under real-time TRUS guidance in the sagittal plane, the injection needle (18G × 15 cm), with an attached syringe containing saline or lidocaine 0.5 – 1.0% diluted in 15 mL saline, was inserted ~ 1 cm above the TRUS probe.” <i>Id.</i> FIG. 4. A, Needle alignment and placement with ultrasonography sagittal view. B, Hydrodissection with ultrasonography sagittal view. C, Hydrogel injection with ultrasonography sagittal view.  <i>Id.</i> Due to the known advantages of using an access needle for prostate biopsy procedures, it would have been obvious to a PHOSITA to combine the access needle of Novella 2003 with the “needle positioned within the sagittal plane when the needle is engaged with the platform and when the ultrasound probe provides imaging in the sagittal plane” as disclosed in BK Medical 2010 and Hatiboglu 2012.
36.4	inserting a biopsy needle through the access needle and into a first location within the prostate.	See Citations for '762 Patent at 13.4.

Ref. No.	U.S. Patent No. 11,096,762 B2 (’762 Patent)	Prior Art Citations
Claim 37		
37	The method of claim 36, further comprising inserting the biopsy needle through the access needle and into a second location within the prostate, the second location being different than the first location.	<i>See Citations for ’762 Patent at 14.</i>
Claim 38		
38	The method of claim 37, wherein the access needle remains positioned within the perineal access site of the prostate during the insertion of the biopsy needle into both of the first and second locations within the prostate.	<i>See Citations for ’762 Patent at 15.</i>
Claim 40		
40	The method of claim 36, further comprising obtaining at least one of a cell and tissue sample from the prostate with the biopsy needle.	<i>See Citations for ’762 Patent at 20.</i>

EXHIBIT C

Invalidity Claim Chart for U.S. Patent No. 11,246,677 B2 ('677 Patent) Based on BK Medical Type 8808e User Guide (Aug. 2010) ("BK Medical 2010").

BK Medical 8808e August 2010 Product Data Sheet ("BK Medical 2010") (AMD_00000001 – AMD_00000017) qualifies as prior art to the '677 Patent under 35 U.S.C. § 102(a) and anticipates and/or renders obvious one or more of the asserted claims of the '677 Patent either in combination with, or modified based on, the knowledge of a person of ordinary skill in the art, or in combination with, or modified based on, any prior art identified in Plaintiff's invalidity contentions.

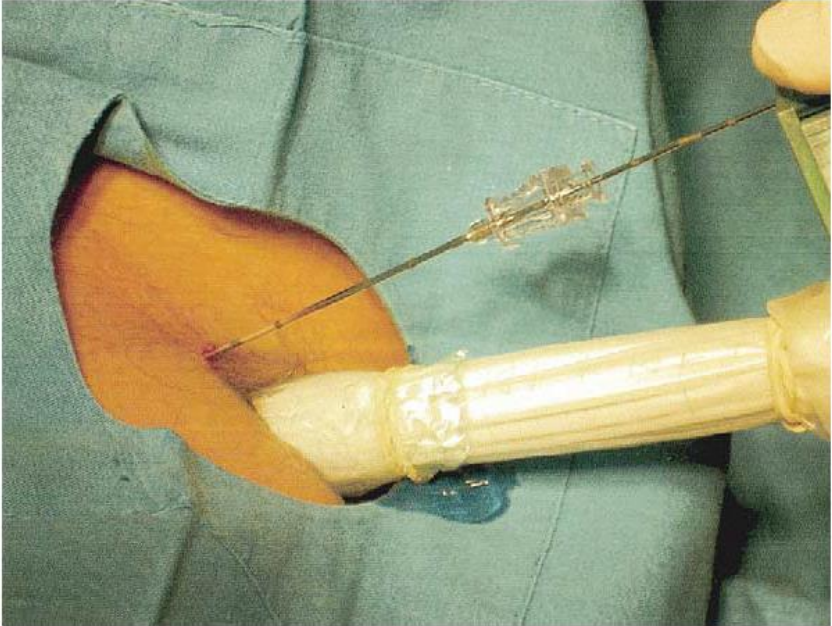
The Secondary References cited include:

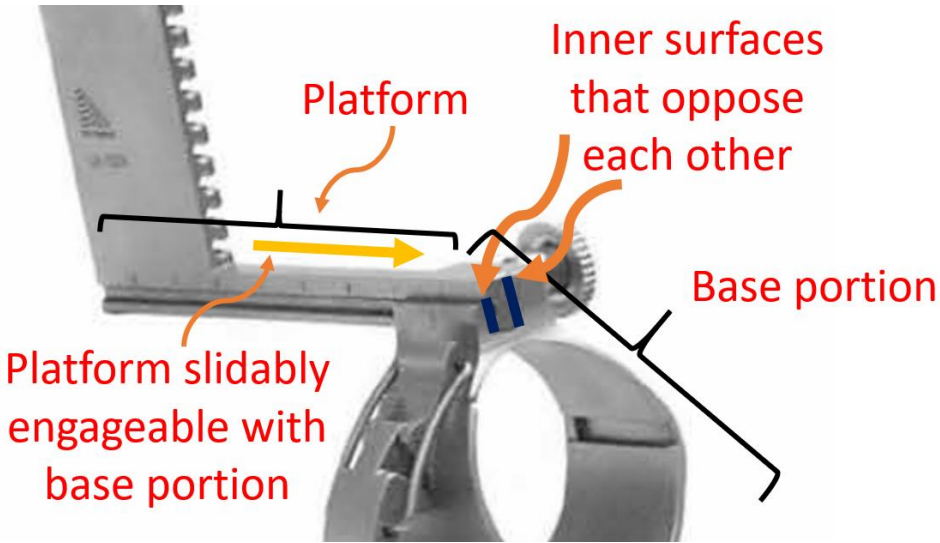
- U.S. Patent No. 5,494,039 to Onik ("Onik") (AMD_00000034 – AMD_00000043)
- U.S. Patent No. 5,871,448 to Ellard ("Ellard") (AMD_00000044 – AMD_00000052)
- Giovanni Novella, *et al.*, *Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle*, 62 UROLOGY 689 (2003) ("Novella 2003") (AMD_00000030 – AMD_00000033)
- Gencay Hatiboglu, *et al.*, *Application Technique: Placement of a Prostate-Rectum Spacer in Men Undergoing Prostate Radiation Therapy*, 110 BJU INT'L E647 (May 10, 2012) ("Hatiboglu 2012") (AMD_00000024 – AMD_00000029)
- Stephan Zangos, *et al.*, *MR-Guided Transgluteal Biopsies with an Open Low-Field System in Patients with Clinically Suspected Prostate Cancer: Technique and Preliminary Results*, 15 EURO RADIOLOGY 174 (Sept. 4, 2004) ("Zangos 2005") (AMD_00000189 - AMD_00000197)

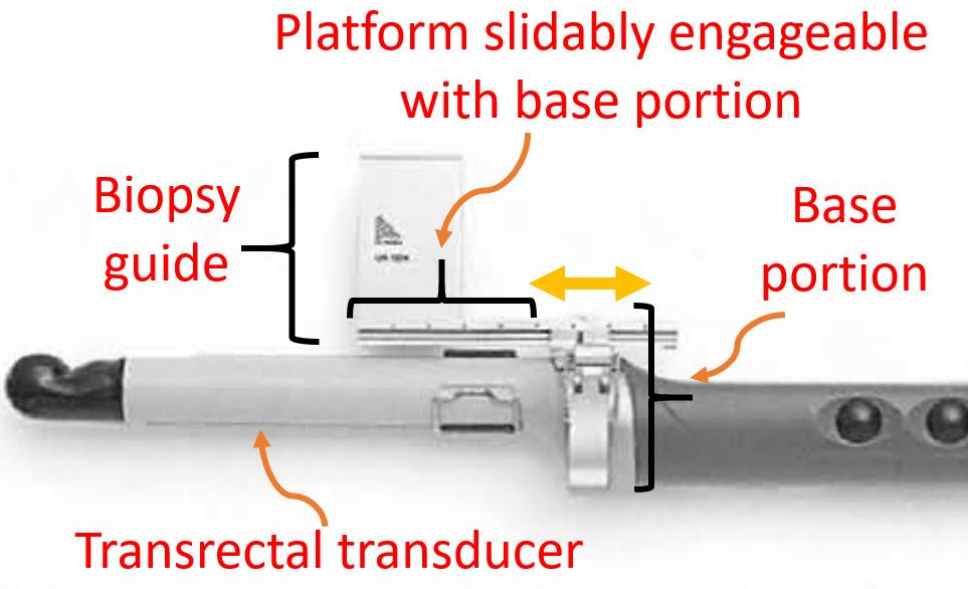
Plaintiff reserves the right to combine additional prior art references identified in its invalidity contentions with BK Medical 2010 even if not explicitly listed in the claim chart below. Plaintiff reserves the right to rely on other portions of a cited reference's disclosure, including, but not limited to, any figures discussed in cited text or any text relating to cited figures. Plaintiff reserves the right to supplement or amend this claim chart depending upon the claim construction order issued by the Court and how Defendant construes the claims in an attempt to assert infringement. All citations and proposed combinations for independent claims apply for all dependent claims.

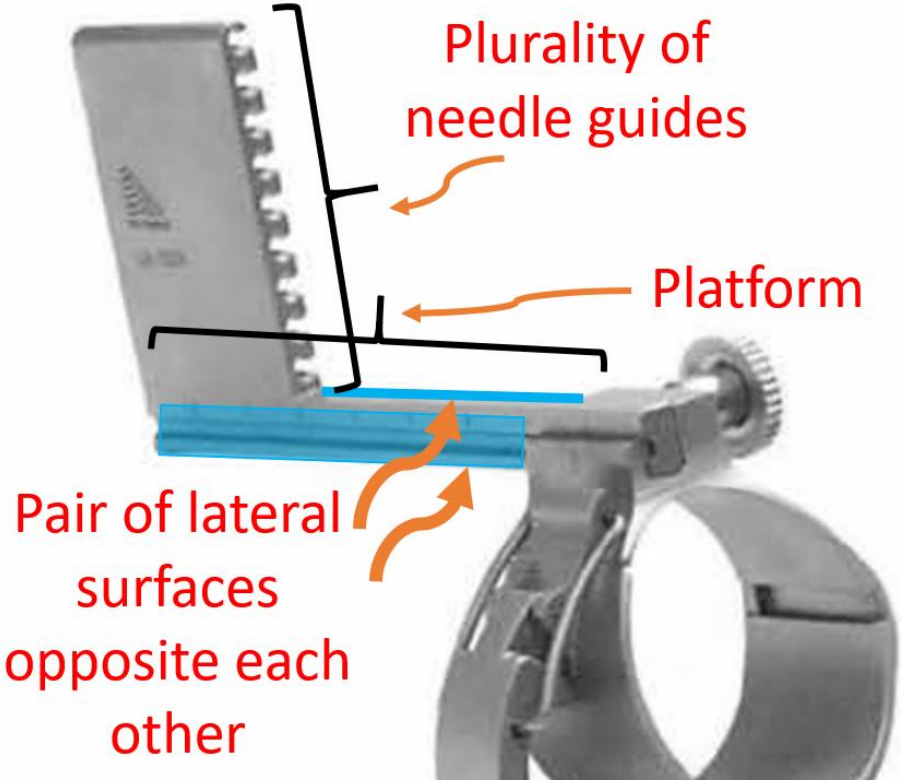
Ref. No.	U.S. Patent No. 11,246,677 B2 (‘677 Patent)	Prior Art Citations
Claim 1		
1.pre	An apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies, the apparatus comprising:	BK Medical 2010 discloses an apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies. “The 8808e is designed for transrectal scanning.” <i>Id.</i> at 1. “The metal puncture attachment UA1324 is designed for transperineal puncture and biopsy.” <i>Id.</i>  <i>Figure 7. Puncture attachment UA1324.</i> <i>Id.</i> at 14.

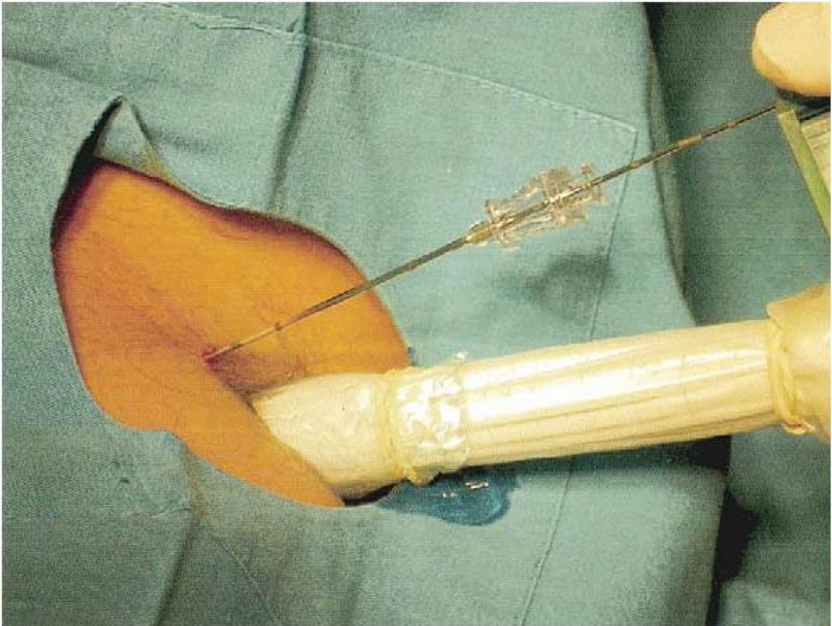
Ref. No.	U.S. Patent No. 11,246,677 B2 (’677 Patent)	Prior Art Citations
		 <i>Figure 8. Puncture attachment UA1324 mounted on 8808e.</i> <i>Id.</i> at 14. Onik discloses the same. "Most particularly the invention relates to a biopsy needle insertion guide which is securely mountable on and useable with a rectally inserted ultrasound probe to insert biopsy needles into the prostate at specific target points identified on an ultrasound image of the prostate." Onik, 1:10-15.
1.1	an access needle comprising a lumen sized to receive a biopsy needle there through; and	To the extent element 1.1 can be understood, BK Medical 2010 discloses an apparatus to be used with biopsy needles but does not specifically disclose access needles. <i>See id.</i> at 14 ("The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy. . . . The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.") Onik discloses the same. <i>See Citations for ’677 Patent at 1.pre.</i> Novella 2003 discloses an access needle comprising a lumen sized to receive a biopsy needle there through. "The insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle." <i>Id.</i> at 689.

Ref. No.	U.S. Patent No. 11,246,677 B2 (‘677 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. Due to the known advantages of using an access needle in transperineal prostate biopsies, it would be obvious to a PHOSITA to combine the access needle disclosed in Novella 2003 with the apparatuses disclosed in BK

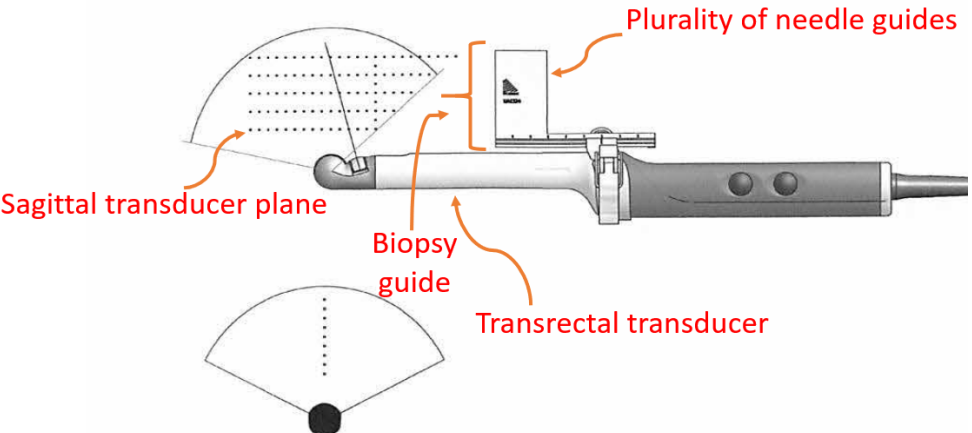
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		Medical 2010 and Onik.
1.2	a biopsy guide configured to couple to the transrectal transducer and comprising a base portion having inner surfaces that oppose each other, and a platform slidably engageable with the base portion,	BK Medical 2010 discloses a biopsy guide configured to couple to a transrectal transducer and comprising a base portion having inner surfaces that oppose each other, and a platform slidably engageable with the base portion. The BK Medical 2010 couples to the transrectal transducer with a sheath-based or sleeve fastener disclosed in '677 Patent specification. '677 Patent, 9:16-26. "To mount the transperineal puncture attachment ... [p]ull 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." <i>Id.</i> at 14.  <i>Id.</i> at 14. "The needle guide [platform] can be adjusted 70 mm lengthwise with respect to the mounting ring [base portion], using the adjustment

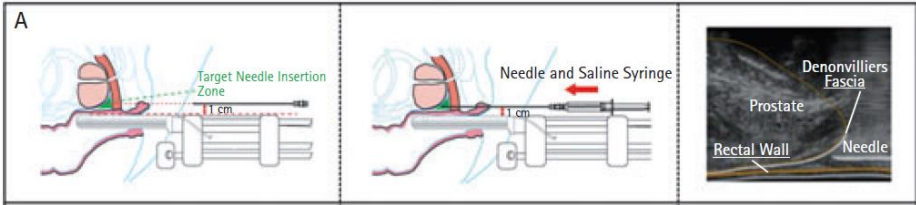
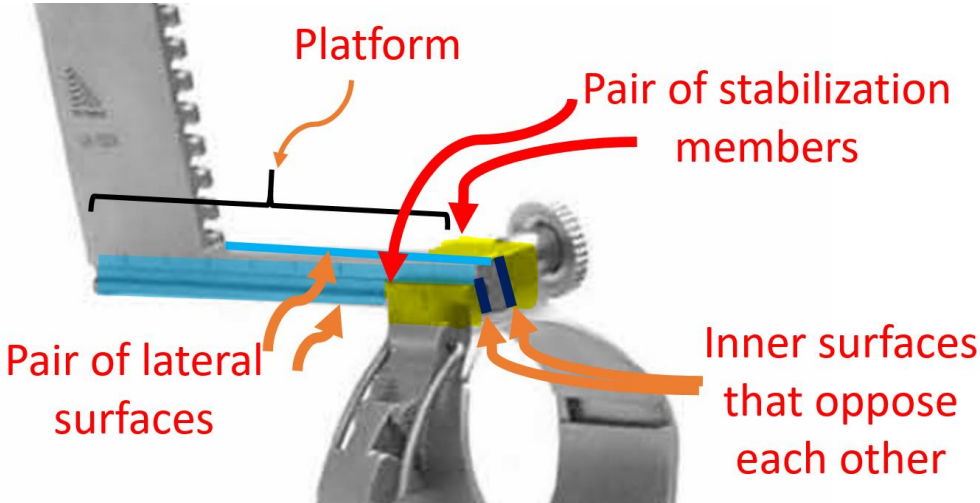
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		screw.” <i>Id.</i>  The diagram shows a medical device, likely a biopsy needle, with a handle and a needle assembly. A bracket labeled "Biopsy guide" points to a component on the needle. A yellow double-headed arrow labeled "Platform slidably engageable with base portion" indicates the sliding mechanism between the needle and the handle. A bracket labeled "Base portion" points to the handle. A bracket labeled "Transrectal transducer" points to a component on the handle. <i>Id.</i> at 14.
1.3	the platform including a pair of lateral surfaces opposite each other and a plurality of needle guides that are sized to support the access needle,	BK Medical 2010 discloses the platform including a pair of lateral surfaces opposite each other and a plurality of needle guides.

Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		 The diagram shows a medical device with a grey rectangular block containing a series of parallel channels. A blue cylindrical component is positioned within one of these channels. A grey mechanical assembly with a circular opening is attached to the side of the block. Red text labels with orange arrows point to specific features: 'Plurality of needle guides' points to the top of the grey block; 'Platform' points to a horizontal surface on the side of the block; and 'Pair of lateral surfaces opposite each other' points to the blue cylindrical component. <i>Id.</i> at 14. BK Medical 2010 further discloses that plurality of needle guides is sized to support an access needle. “The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.” <i>Id.</i> at 14. The '677 Patent acknowledges that an internal diameter of 14 gauge is suitable for an access needle. “The hole can accommodate various types of needles, including access needles having various diameters, for example, spinal needles having a gauge in the range of

Ref. No.	U.S. Patent No. 11,246,677 B2 (’677 Patent)	Prior Art Citations
		14-18.” See ’677 Patent at 6:10-13. Additionally, Novella 2003 discloses that “[t]he insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.  FIGURE 1. An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle. <i>Id.</i> at 690. According to Novella 2003, an access needle “forms an optimal

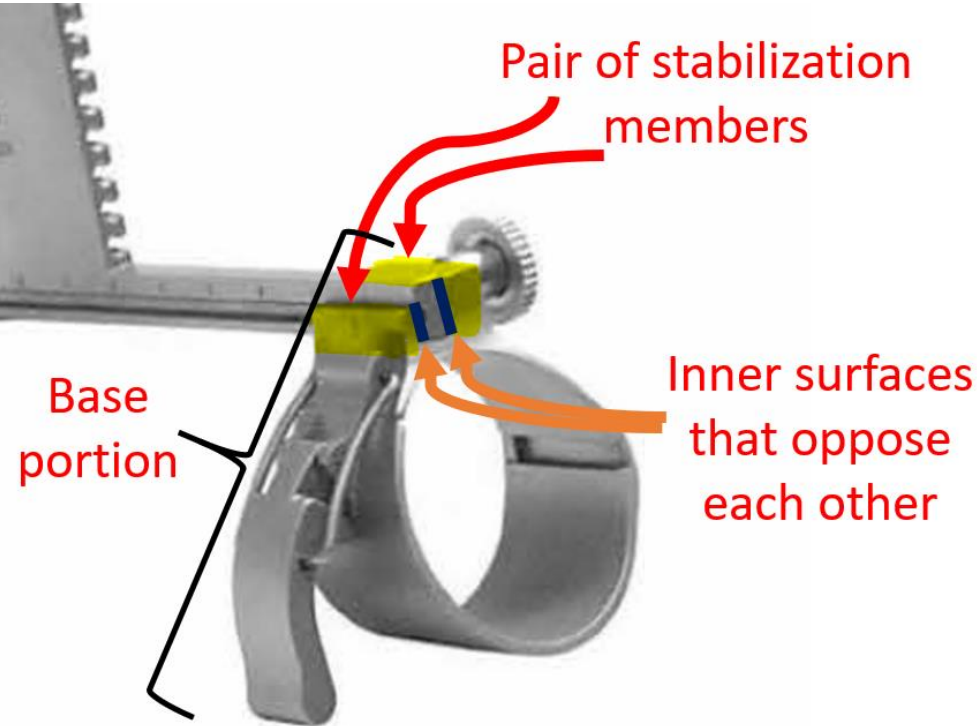
Ref. No.	U.S. Patent No. 11,246,677 B2 (‘677 Patent)	Prior Art Citations
		transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. Due to the known advantages of using an access needle for prostate biopsy procedures, it would have been obvious to a PHOSITA to combine the access needle of Novella 2003 with the “platform including a pair of lateral surfaces opposite each other and a plurality of needle guides that are sized to support the access needle” disclosed in BK Medical 2010.
1.4	the plurality of needle guides aligning with a sagittal transducer plane of the transrectal transducer when the biopsy guide is coupled to the transrectal transducer,	BK Medical 2010 discloses the plurality of needle guides aligning with a sagittal transducer plane of the transrectal transducer when the biopsy guide is coupled to the transrectal transducer. “Transrectal puncture and biopsy can be performed using simultaneous biplane scanning, where both the sagittal and transverse planes are visualized live at the same time, the advantage is that the needle is visible in both planes throughout the puncture and biopsy procedures.” <i>Id.</i> at 1.

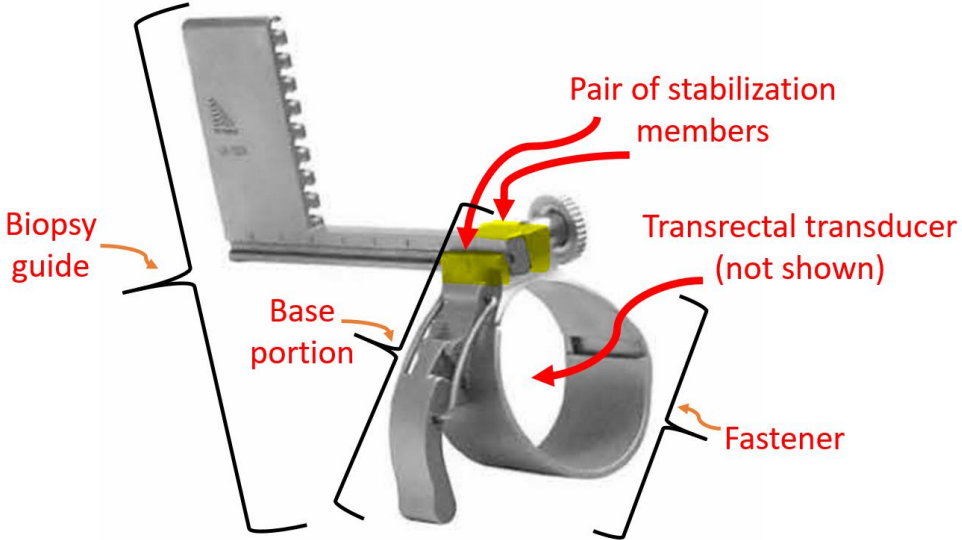
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		The puncture lines for UA1324 on 8808e are shown in Figure 9.  Figure 9. Illustration of the puncture line for puncture attachment UA1324. BK Medical 2010 at 15. “The puncture line will differ depending on the imaging plane orientation. In the sagittal plane, the puncture path is indicated by a line of dots. The distance between each puncture dot is 5 mm.” <i>Id.</i> Additionally, Hatiboglu 2012 discloses a technique for injecting a hydrogel spacer between the prostate and rectum for men undergoing prostate cancer radiotherapy. <i>Id.</i>, Objective. The technique involves using a needle on a needle guide coupled to an ultrasound probe with sagittal views. <i>Id.</i> at E649. “Under real-time TRUS guidance in the sagittal plane, the injection needle (18G × 15 cm), with an attached syringe containing saline or lidocaine 0.5 – 1.0% diluted in 15 mL saline, was inserted ~ 1 cm above the TRUS probe.” <i>Id.</i>

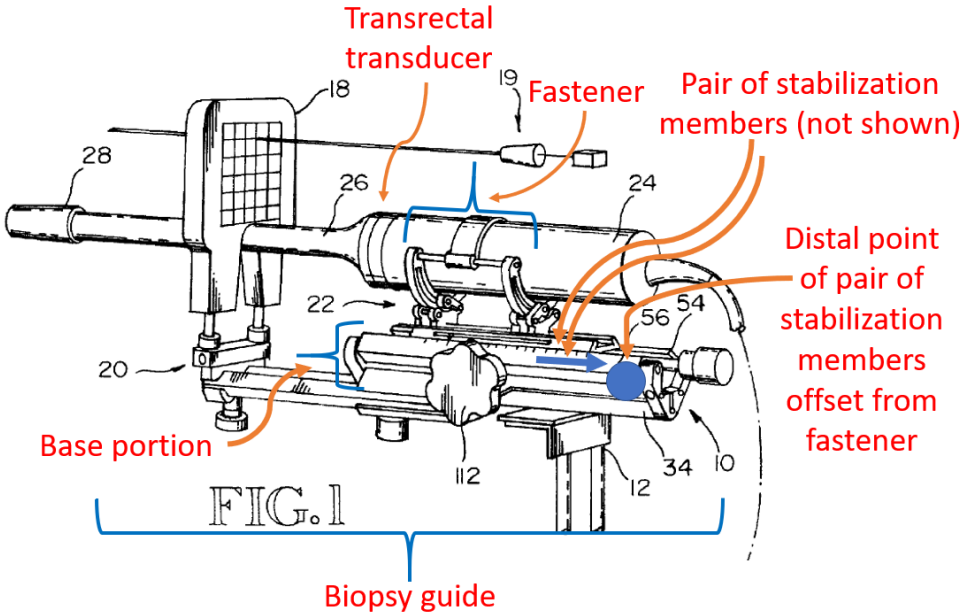
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		FIG. 4. A, Needle alignment and placement with ultrasonography sagittal view. B, Hydrodissection with ultrasonography sagittal view. C, Hydrogel injection with ultrasonography sagittal view.  Hatiboglu 2012 at E649. Therefore, it would have been obvious to a PHOSITA to align needle guides with a sagittal transducer plane of a transrectal transducer.
1.5	the platform configured to slide relative to the base portion with the pair of lateral surfaces of the platform in frictional engagement with the inner surfaces of the base portion.	BK Medical 2010 discloses the platform configured to slide relative to the base portion with the pair of lateral surfaces of the platform in, to the extent it can be understood, frictional engagement with the inner surfaces of the base portion. 

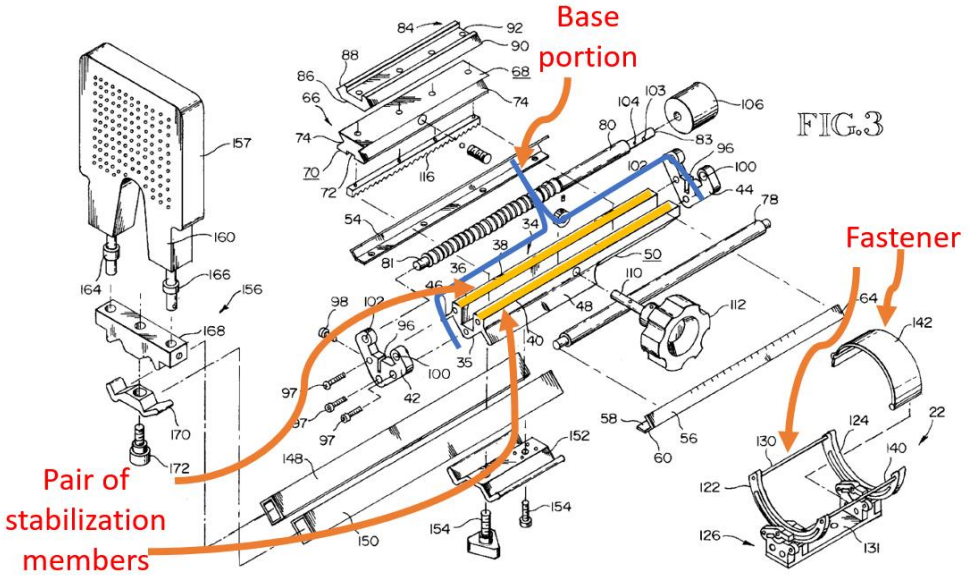
Ref. No.	U.S. Patent No. 11,246,677 B2 (’677 Patent)	Prior Art Citations
		<i>Id.</i> at 14. “The needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.” <i>Id.</i>
Claim 3		
3	The apparatus of claim 1, wherein the plurality of needle guides are sized to support the access needle having a needle size of 14 gauge, 15 gauge, or 16 gauge.	BK Medical 2010 discloses an apparatus with a plurality of needle guides to be used with biopsy needles but does not specifically disclose the use of access needles. <i>See id.</i> at 14 (“The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy. . . . 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.”) BK Medical 2010 further discloses that plurality of needle guides is sized to support an access needle having a needle size of 14 gauge. “The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.” <i>Id.</i> at 14. The ’677 Patent acknowledges that an internal diameter of 14 gauge is suitable for an access needle. “The hole can accommodate various types of needles, including access needles having various diameters, for example, spinal needles having a gauge in the range of 14-18.” <i>See</i> ’677 Patent at col. 6, lns. 10-13. Additionally, Zangos 2005 discloses taking prostate biopsies using a 15-gauge access needle. “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.” <i>Id.</i> at Abstract. Accordingly, because the prior art described taking prostate biopsies with 15-gauge access needles, a PHOSITA would find it obvious to modify the apparatus with the plurality of needle guides supporting biopsy needles (as

Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		disclosed in BK Medical 2010) to support an access needle having a needle size of 14 gauge, 15 gauge, or 16 gauge (as disclosed in Zangos 2005).
Claim 4		
4	The apparatus of claim 1, wherein the access needle has a needle size of 15 gauge or 16 gauge.	BK Medical 2010 discloses an apparatus with a plurality of needle guides to be used with biopsy needles but does not specifically disclose the use of access needles having a needle size of 15 gauge or 16 gauge. <i>See id.</i> at 14 (“The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy. . . . 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.”) Zangos 2005 discloses taking prostate biopsies using a 15-gauge access needle. “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.” <i>Id.</i> at Abstract. Accordingly, because the prior art described taking prostate biopsies with 15-gauge access needles, a PHOSITA would find it obvious to modify the apparatus with the plurality of needle guides supporting biopsy needles (as disclosed in BK Medical 2010) to support an access needle having a needle size of 14 gauge, 15 gauge, or 16 gauge (as disclosed in Zangos 2005).
Claim 9		
9	The apparatus of claim 1, wherein the base portion comprises a pair of stabilization members spaced apart from each other, the inner surfaces	BK Medical 2010 discloses that the base portion comprises a pair of stabilization members spaced apart from each other, the inner surfaces that oppose each other being defined on the pair of stabilization members.

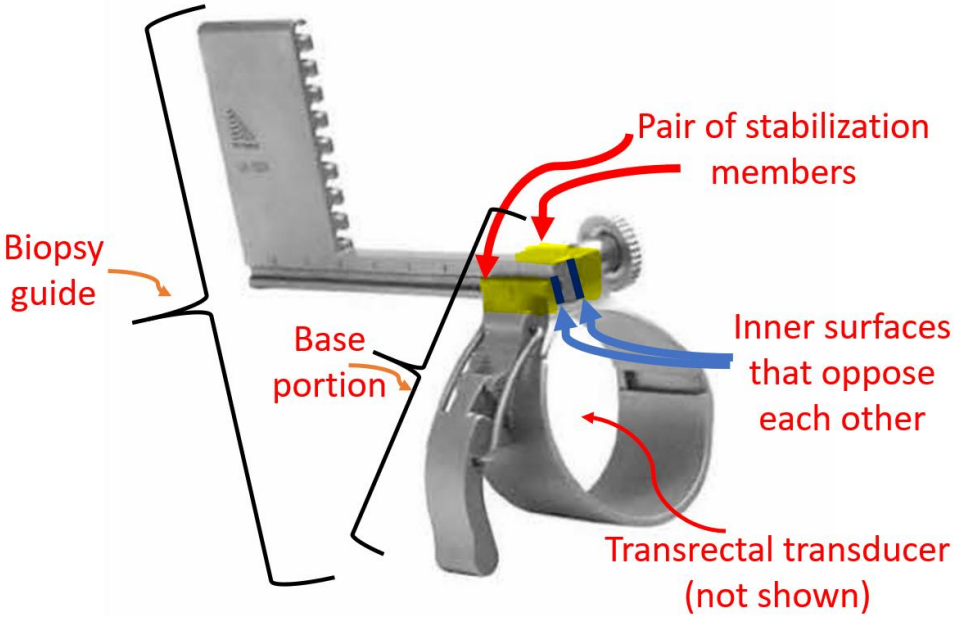
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
	that oppose each other being defined on the pair of stabilization members.	 <i>Id.</i> at 14.
Claim 10		
10	The apparatus of claim 9, wherein a distal point of the pair of stabilization members is offset from a fastener of the base portion that is configured to connect the biopsy guide to the transrectal transducer.	BK Medical 2010 discloses a pair of stabilization members and a fastener of the base portion that is configured to connect the biopsy guide to the transrectal transducer.

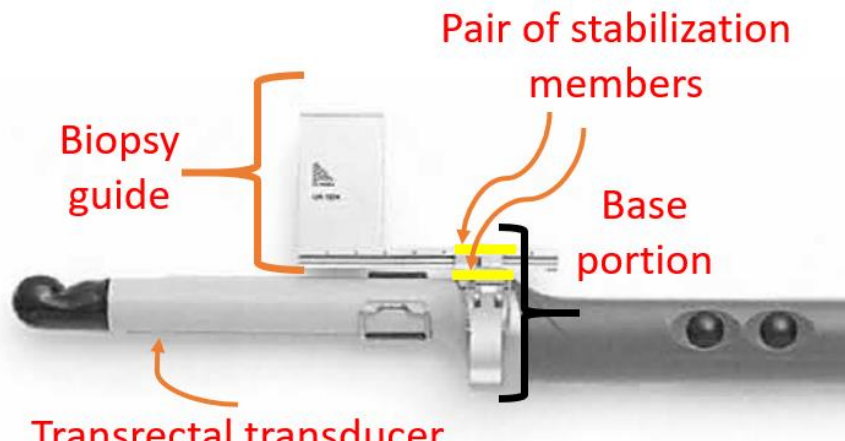
Ref. No.	U.S. Patent No. 11,246,677 B2 (’677 Patent)	Prior Art Citations
		 <i>Id.</i> at 14. Ellard discloses an “apparatus [biopsy guide] for use in imaging/treatment of prostate cancer” comprising (1) an “ultrasound probe holder 22” (a fastener) that connects an ultrasound probe (transrectal transducer) to the apparatus’s “body portion 34” (a base portion) that defines “[t]wo longitudinal, flat, spaced upper surfaces 38 and 40” (pair of stabilization members). Ellard, Abstract; 3:1-9; 3:28-34. The figures disclose that, to the extent it can be understood, a distal point of the pair of stabilization members is offset from the fastener because the stabilization members are longer than the fastener.

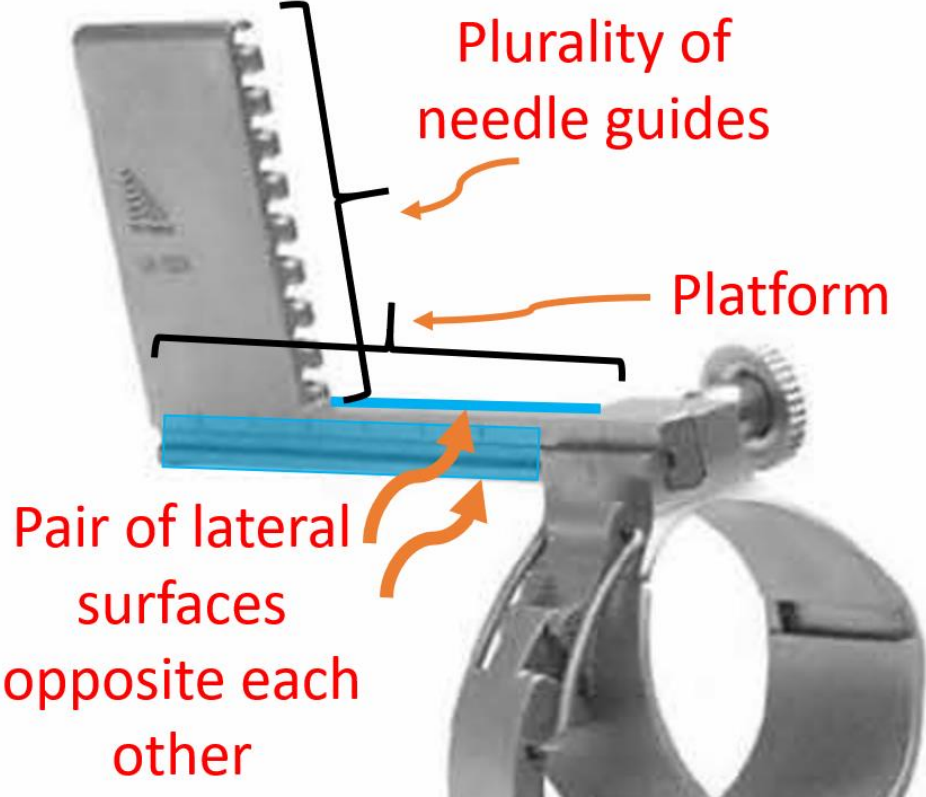
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		 Transrectal transducer Fastener Pair of stabilization members (not shown) Distal point of pair of stabilization members offset from fastener Base portion FIG. 1 Biopsy guide Ellard at Figure 1.

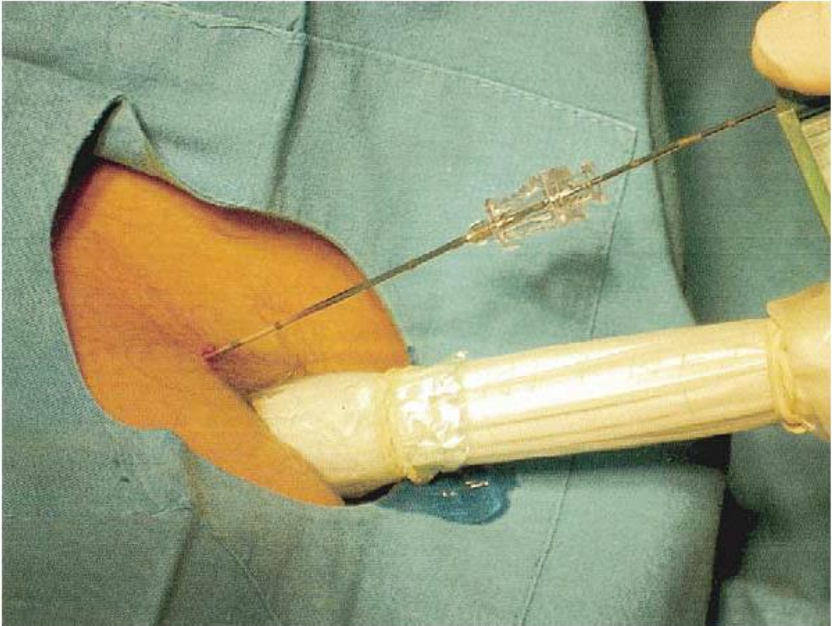
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		 FIG. 3 Base portion Fastener Pair of stabilization members Ellard at Figure 3. A PHOSITA would find it obvious to modify the apparatus of claim 9 (as disclosed by BK Medical 2010) by providing an offset between the fastener and a distal point of a stabilization member (as disclosed by Ellard).
Claim 11		
11	The apparatus of claim 1, wherein the biopsy needle has a needle size of 18 gauge.	BK Medical 2010 discloses an apparatus with a plurality of needle guides to be used with biopsy needles but does not specifically disclose the use of 18-gauge biopsy needles. <i>See id.</i> at 14 (“The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy. . . . The needle guide comprises 9 parallel guide channels, spaced 5mm apart, each

Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		with an internal diameter of 2.1mm, suitable for a 14-gauge needle.”) Novella 2003 discloses taking prostate biopsies using an 18-gauge biopsy needle through an access needle. “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).” <i>Id.</i> at 690. Accordingly, because the prior art described taking prostate biopsies with 18-gauge biopsy needles, a PHOSITA would find it obvious to modify the apparatus of claim 1 such that the biopsy needle has a needle size of 18 gauge.
Claim 12		
12	The apparatus of claim 4, wherein the biopsy needle has a needle size of 18 gauge.	See Citations for '677 Patent at 11.
Claim 13		
13.pre	An apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies, the apparatus comprising:	See Citations for '677 Patent at 1.pre.
13.1	a biopsy guide configured to couple to the transrectal transducer and comprising a base portion including a pair of stabilization members having inner surfaces that oppose each other,	BK Medical 2010 discloses a biopsy guide configured to couple to a transrectal transducer and comprising a base portion including a pair of stabilization members having inner surfaces that oppose each other. The BK Medical 2010 couples to the transrectal transducer with a sheath-

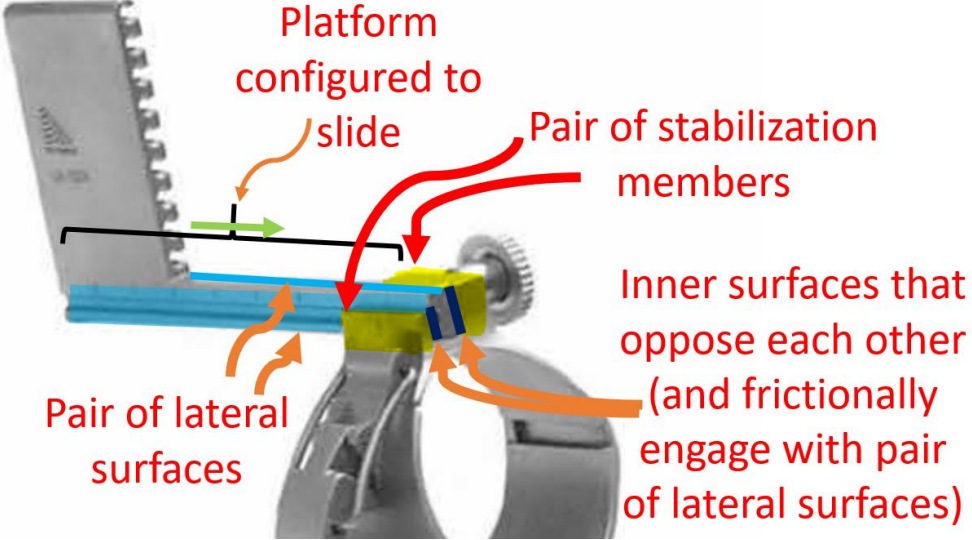
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		based or sleeve fastener disclosed in '677 Patent specification. '677 Patent, 9:16-26. "To mount the transperineal puncture attachment ... [p]ull a sterile transducer cover over the transducer. Loosen the clamp on UA1324, and slide the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer." <i>Id.</i> at 14.  The diagram illustrates a biopsy guide assembly. It features a long, thin, rectangular plate with a series of small, rounded protrusions along one edge. This plate is connected to a larger, more complex base portion. The base portion includes a pair of stabilization members that are positioned to hold a transducer in place. The inner surfaces of these members are shown opposing each other. A transrectal transducer is indicated as being positioned within the assembly, though it is not shown in detail. The entire assembly is labeled as a biopsy guide. <i>Id.</i> at 14.

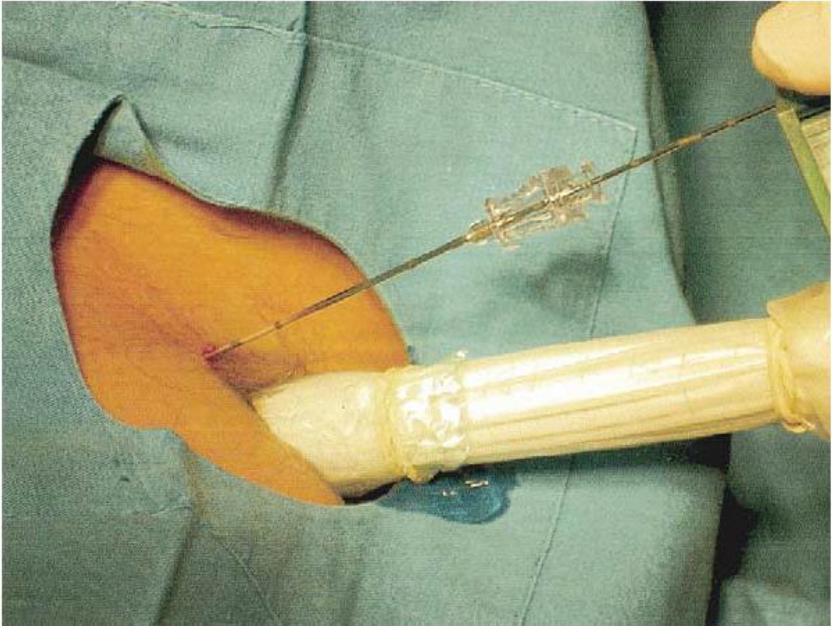
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		 Biopsy guide Pair of stabilization members Base portion Transrectal transducer <i>Figure 8. Puncture attachment UA1324 mounted on 8808e.</i> <i>Id.</i>
13.2	and a platform including a pair of lateral surfaces opposite each other, and a plurality of needle guides that are sized to support an access needle comprising a lumen sized to receive a biopsy needle there through,	BK Medical 2010 discloses a platform including a pair of lateral surfaces opposite each other and a plurality of needle guides. To the extent it can be understood, BK Medical 2010 also discloses the needle guides being sized to support an access needle comprising a lumen sized to receive a biopsy needle.

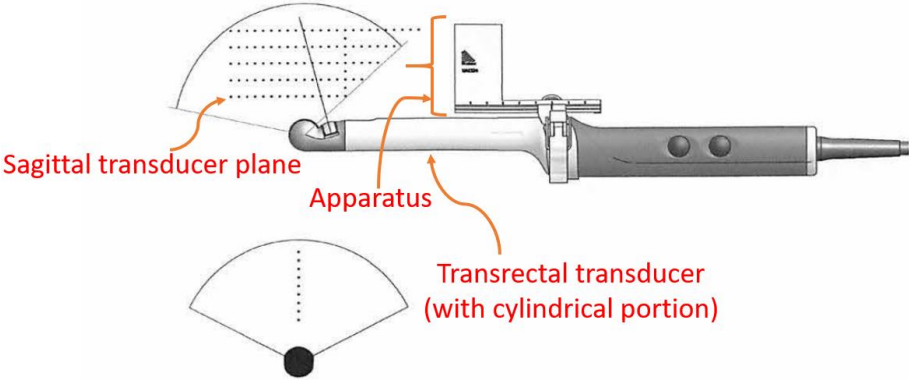
Ref. No.	U.S. Patent No. 11,246,677 B2 (’677 Patent)	Prior Art Citations
		 BK Medical 2010 at 14 (“The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.”). Novella 2003 discloses that “[t]he insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.

Ref. No.	U.S. Patent No. 11,246,677 B2 (‘677 Patent)	Prior Art Citations
		 FIGURE 1. <i>An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.</i> Novella 2003 at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692. Due to the known advantages of using an access needle for prostate biopsy procedures, it would have been obvious to a PHOSITA to combine the

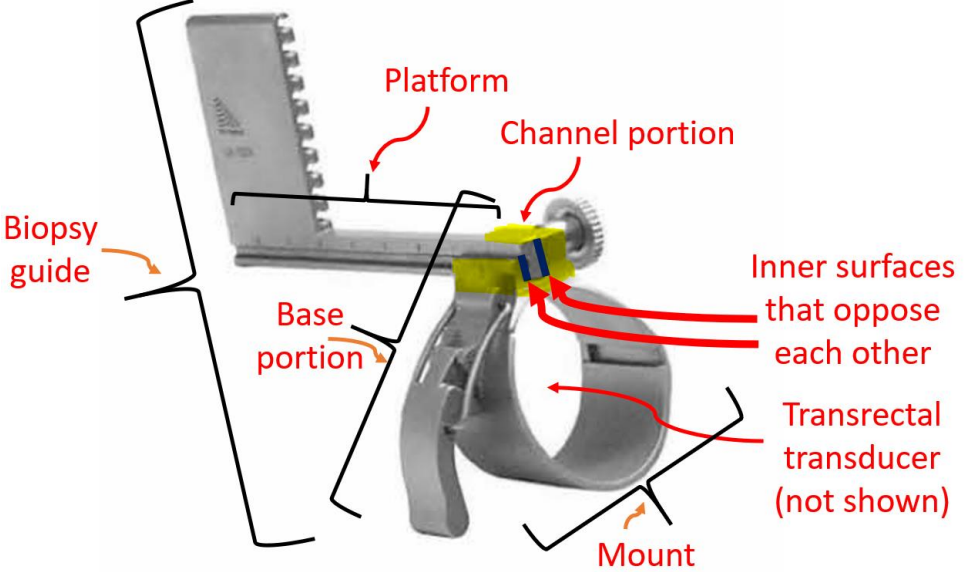
Ref. No.	U.S. Patent No. 11,246,677 B2 (’677 Patent)	Prior Art Citations
		access needle disclosed by Novella 2003 with the “platform including a pair of lateral surfaces opposite each other[] and a plurality of needle guides” disclosed by BK Medical 2010 such that the “plurality of needle guides [] are sized to support an access needle comprising a lumen sized to receive a biopsy needle there through.”
13.3	the plurality of needle guides aligning with a sagittal transducer plane of the transrectal transducer when the biopsy guide is coupled to the transrectal transducer,	See Citations for ’677 Patent at 1.4.
13.4	the platform configured to slide relative to the pair of stabilization members with the pair of lateral surfaces of the platform in frictional engagement with the inner surfaces of the pair of stabilization members.	BK Medical 2010 discloses the platform configured to slide relative to the pair of stabilization members with the pair of lateral surfaces of the platform in, to the extent it can be understood, frictional engagement with the inner surfaces of the pair of stabilization members.

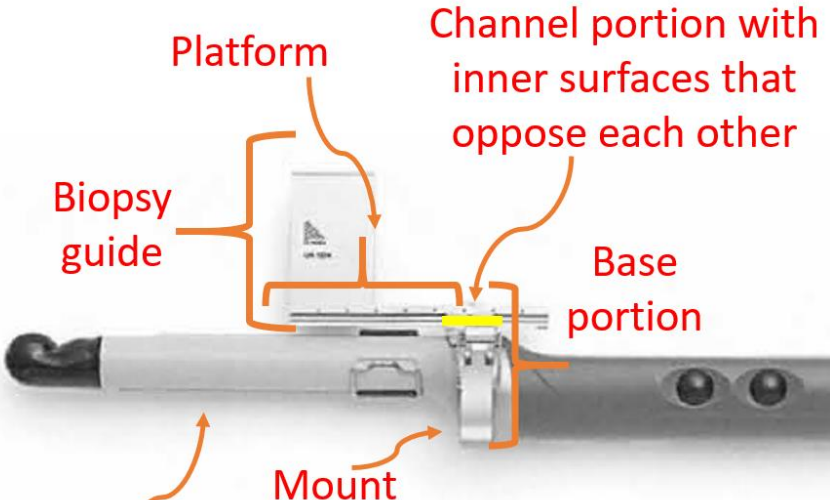
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		 BK Medical 2010 at 14. “The needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.” <i>Id.</i>
Claim 16		
16	The apparatus of claim 13, further comprising the access needle.	BK Medical 2010 discloses an apparatus to be used with biopsy needles but does not specifically disclose access needles. <i>See id.</i> at 14 (“The metal puncture attachment UA1324 . . . is designed for transperineal puncture and biopsy. . . . The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle.”) Onik discloses the same. <i>See Citations for '677 Patent at 1.pre.</i> Novella 2003 discloses that “[t]he insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation

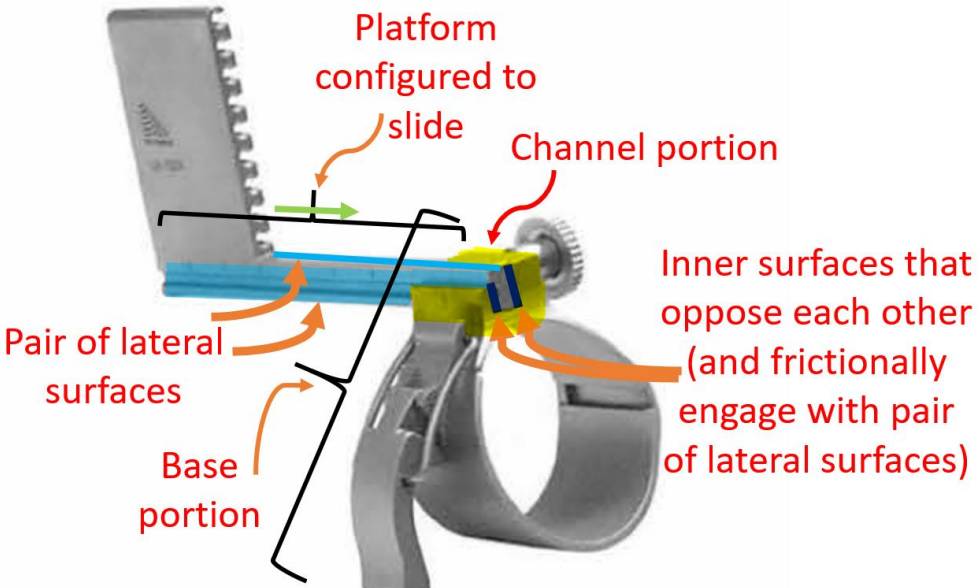
Ref. No.	U.S. Patent No. 11,246,677 B2 (‘677 Patent)	Prior Art Citations
		of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” <i>Id.</i> at 689.  FIGURE 1. An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle. Novella 2003 at 690. According to Novella 2003, an access needle “forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.” <i>Id.</i> at 692.

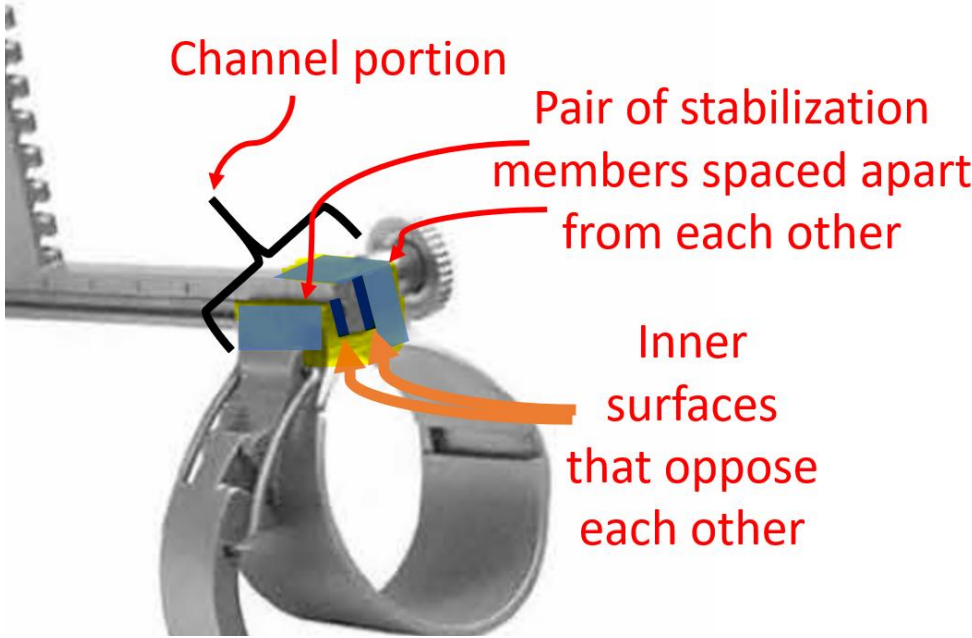
Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		Due to the known advantages of using an access needle for prostate biopsy procedures, it would have been obvious to a PHOSITA to combine the access needle of Novella 2003 with the apparatus disclosed by BK Medical 2010.
Claim 22		
22.pre	An apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies, the transrectal transducer configured to image in a sagittal plane and having a cylindrical portion, the apparatus comprising:	BK Medical 2010 discloses an apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies, the transrectal transducer configured to image in a sagittal plane and having a cylindrical portion. . “Transrectal puncture and biopsy can be performed using simultaneous biplane scanning, where both the sagittal and transverse planes are visualized live at the same time, the advantage is that the needle is visible in both planes throughout the puncture and biopsy procedures.” <i>Id.</i> at 1. The puncture lines for UA1324 on 8808e are shown in Figure 9.  <i>Figure 9. Illustration of the puncture line for puncture attachment UA1324.</i> <i>Id.</i> at 15. “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 5 mm.” <i>Id.</i>

Ref. No.	U.S. Patent No. 11,246,677 B2 (’677 Patent)	Prior Art Citations
22.1	an access needle comprising a lumen sized to receive a biopsy needle there through; and	See Citations for ’677 Patent at 1.1.
22.2	a biopsy guide configured to couple to the transrectal transducer and comprising a base portion and a platform, the base portion including a channel portion having inner surfaces that oppose each other, and a mount coupled to the channel portion and configured to releasably couple to the transrectal transducer,	BK Medical 2010 discloses a biopsy guide configured to couple to the transrectal transducer and comprising a base portion and a platform, the base portion including a channel portion having inner surfaces that oppose each other, and a mount coupled to the channel portion and configured to releasably couple to the transrectal transducer. The BK Medical 2010 couples to the transrectal transducer with a sheath-based or sleeve fastener disclosed in ’677 Patent specification. ’677 Patent, 9:16-26. “To mount the transperineal puncture attachment ... [p]ull 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.” <i>Id.</i> at 14.

Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		 The diagram illustrates a biopsy guide assembly. It includes a 'Platform' which is part of a 'Biopsy guide'. A 'Channel portion' is formed in the platform. A 'Base portion' is attached to the platform. A 'Transrectal transducer (not shown)' is positioned within the channel portion, with its 'Inner surfaces that oppose each other' facing the channel. The entire assembly is mounted on a 'Mount'. BK Medical 2010 at 14.

Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
		 <i>Figure 8. Puncture attachment UA1324 mounted on 8808e.</i> Transrectal transducer BK Medical 2010 at 14. “To mount the transperineal puncture attachment, ensure that the dummy channel bracket UA1325 is in place. . . . Loosen the clamp on UA 1324, and slide the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer.” <i>Id.</i>
22.3	the platform including a pair of lateral surfaces opposite each other and a plurality of needle guides that are sized to support the access needle,	See Citations for '677 Patent at 1.3.
22.4	the plurality of needle guides aligning with a sagittal transducer plane of the	See Citations for '677 Patent at 1.4.

Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
	transrectal transducer when the biopsy guide is coupled to the transrectal transducer,	
22.5	the platform configured to slide within the channel portion of the base portion such that the pair of lateral surfaces of the platform are in frictional engagement with the inner surfaces of the channel portion of the base portion.	BK Medical 2010 discloses the platform configured to slide within the channel portion of the base portion such that the pair of lateral surfaces of the platform are in, to the extent it can be understood, frictional engagement with the inner surfaces of the channel portion of the base portion.  <i>Id.</i> at 14. “The needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.” <i>Id.</i>

Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
Claim 25		
25	The apparatus of claim 22, wherein the access needle has a needle size of 15 gauge or 16 gauge.	See Citations for '677 Patent at 4.
Claim 28		
28	The apparatus of claim 22, wherein the channel portion is defined by a pair of stabilization members spaced apart from each other, the inner surfaces that oppose each other being defined on the pair of stabilization members.	BK Medical 2010 discloses the channel portion being defined by a pair of stabilization members spaced apart from each other, the inner surfaces that oppose each other being defined on the pair of stabilization members.  <i>Id.</i> at 14.

Ref. No.	U.S. Patent No. 11,246,677 B2 ('677 Patent)	Prior Art Citations
Claim 29		
29	The apparatus of claim 28, wherein a distal point of the pair of stabilization members is offset from the mount of the base portion that is configured to connect the biopsy guide to the transrectal transducer.	<i>See Citations for '677 Patent at 10.</i>
Claim 30		
30	The apparatus of claim 22, wherein the biopsy needle has a needle size of 18 gauge.	<i>See Citations for '677 Patent at 11.</i>