

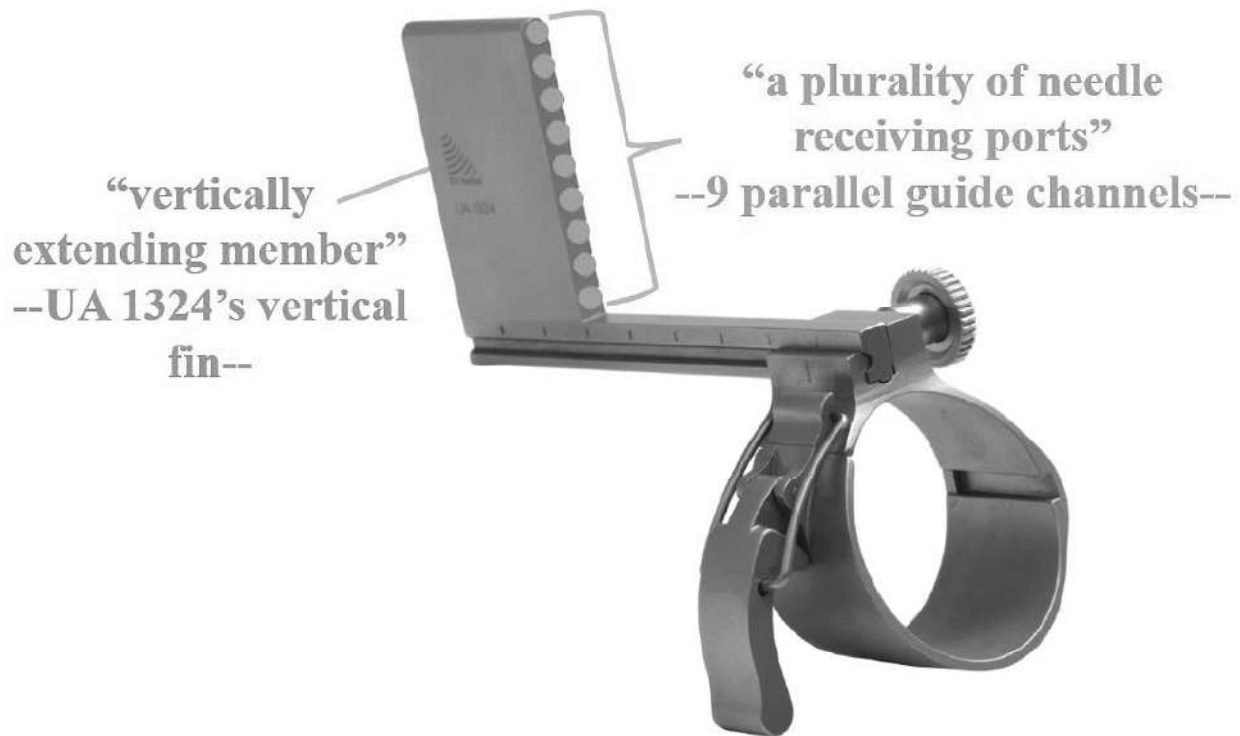


Figure 7. Puncture attachment UA1324.

EX1007, FIG. 7*

“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.” EX1007, 12; EX1003, ¶ 102.

Accordingly, BK Medical discloses element [1.4].

- f. [1.5]: “***wherein the rail receiving channel is positioned generally parallel with a longitudinal axis of the transrectal ultrasound probe;***”

BK Medical discloses or suggests this element. See EX1003, ¶¶ 104-107. BK Medical discloses wherein the rail receiving channel (channel 18) is positioned generally parallel with a longitudinal axis of the transrectal ultrasound probe (Type 8808e probe):

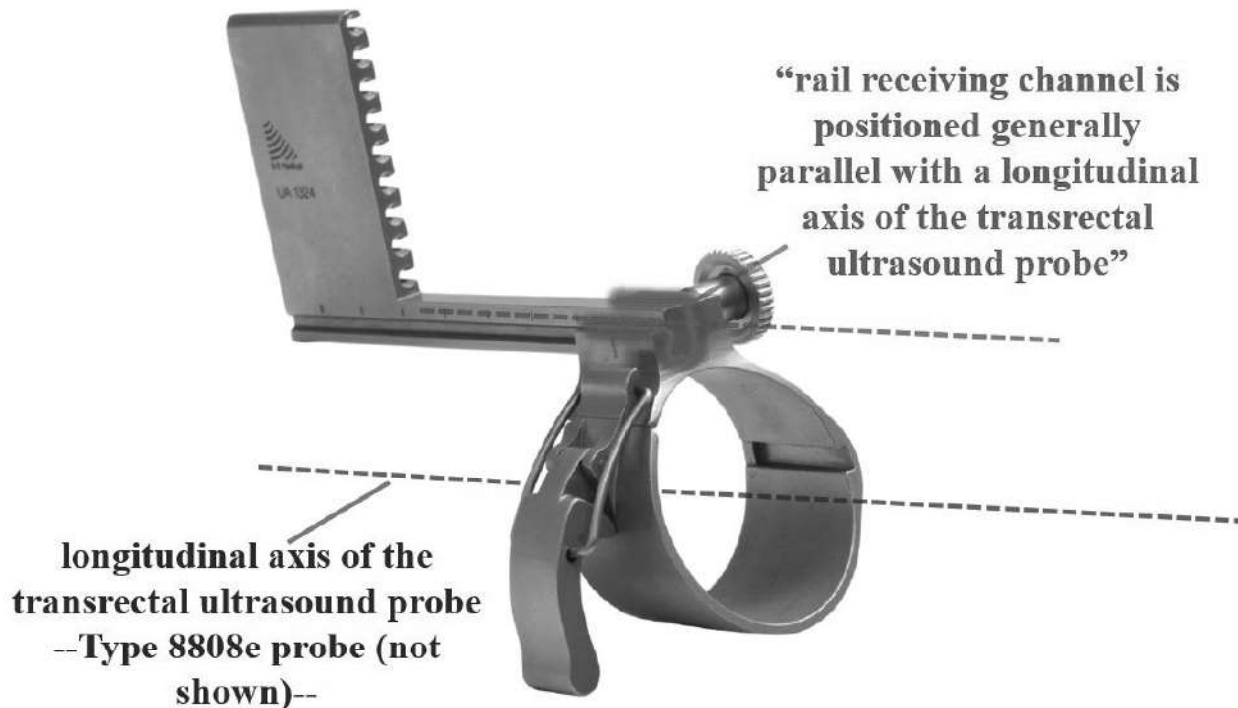


Figure 7. Puncture attachment UA1324.

EX1007, FIG. 7*

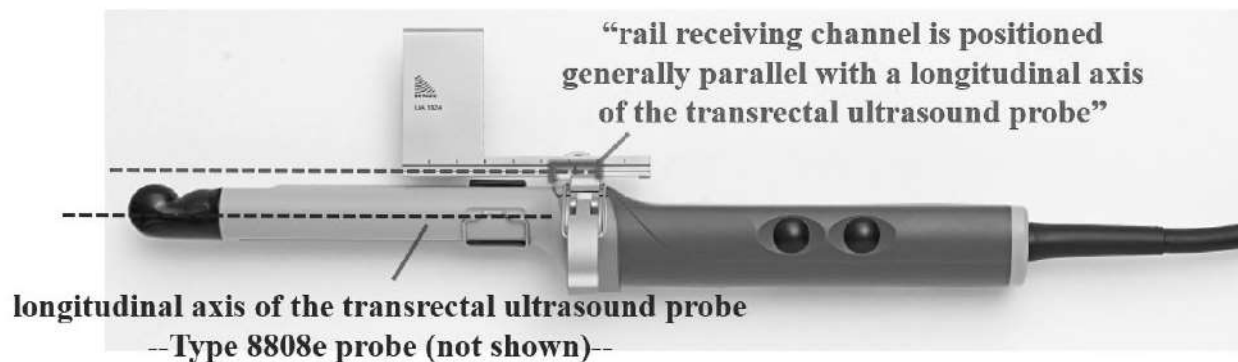


Figure 8. Puncture attachment UA1324 mounted on 8808e.

EX1007, FIG. 8*

As BK Medical explains, “[t]he needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw. The guide is parallel to the centerline of the transducer.” EX1007, 12. Thus, BK Medical discloses that the rail receiving channel (opening at top of ring mount) runs generally parallel with a longitudinal axis of the Type 8808e probe.

Accordingly, BK Medical discloses element [1.5].

- g. [1.6]: “*sliding the rail member within the rail receiving channel so as to position the vertically extending member of the displacement member adjacent the perineal access site of the patient;*”

BK Medical discloses or suggests this element. See EX1003, ¶¶ 102-103. Specifically, BK Medical discloses sliding the rail member (rail of displacement member) within the rail receiving channel (opening at top of the mounting ring) so as to position the vertically extending member (vertical fin) of the displacement member (needle guide) adjacent the perineal access site of the patient:

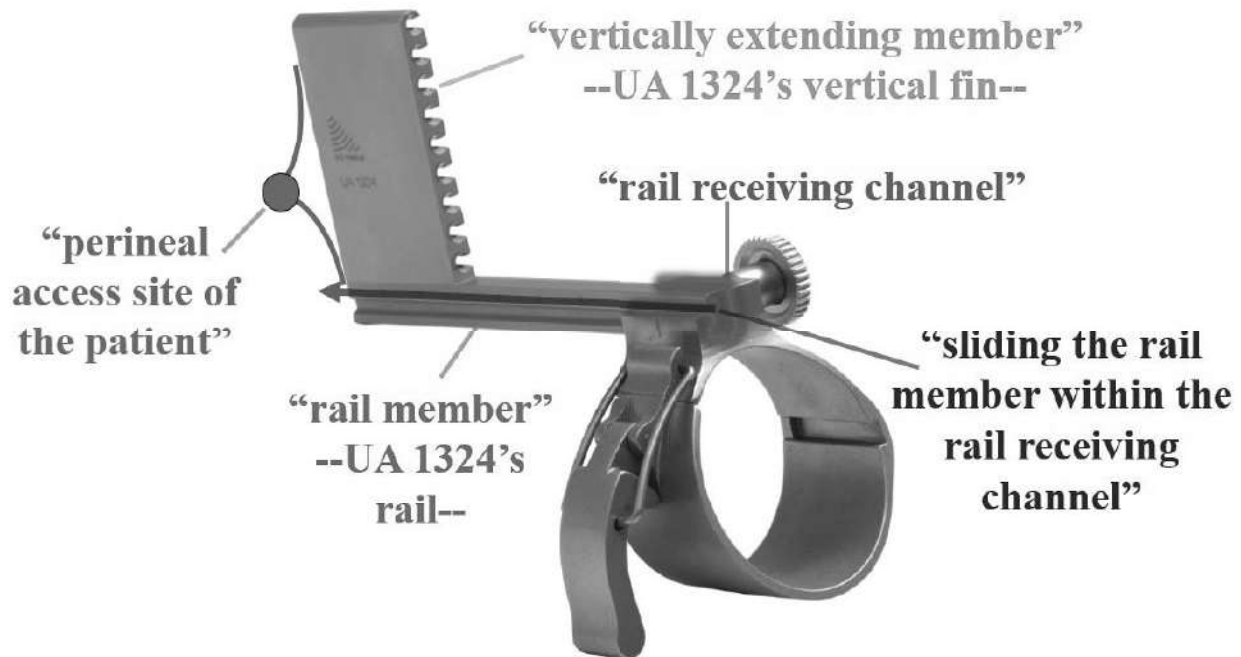


Figure 7. Puncture attachment UA1324.

EX1007, FIG. 7*

To position the vertical fin of the UA1324 adjacent the perineal access site, as claimed, BK Medical explains that “[t]he needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.” EX1007, 12.

Accordingly, BK Medical discloses element [1.6].

- h. [1.7]: “*inserting an access needle into the perineal access site of the patient, the access needle supported by one of the plurality of needle receiving ports; and*”

[1.8]: “*inserting a needle through the access needle and into a first location of the prostate of the patient.*”

BK Medical in view of Novella render these elements obvious. EX1003, ¶¶ 79-99, 108-109. Specifically, BK Medical and Novella render obvious inserting an access needle (Novella’s coaxial needle) into the perineal access site of the patient, the access needle supported by one of the plurality of needle receiving ports (needle receiving channels of the BK Medical UA1324’s needle guide) and inserting a needle (Novella’s biopsy needle) through the access needle (Novella’s coaxial needle) and into a first location of the prostate of the patient, as claimed. *Id.*

- i. BK Medical discloses [1.7] “*inserting a/ ... needle into the perineal access site of the patient, the access needle supported by one of the plurality of needle receiving ports*”

BK Medical discloses inserting a needle into the perineal access site of the patient, the needle supported by one of the plurality of needle receiving ports (9 parallel guide channels) and inserting a needle into a first location of the prostate of the patient:

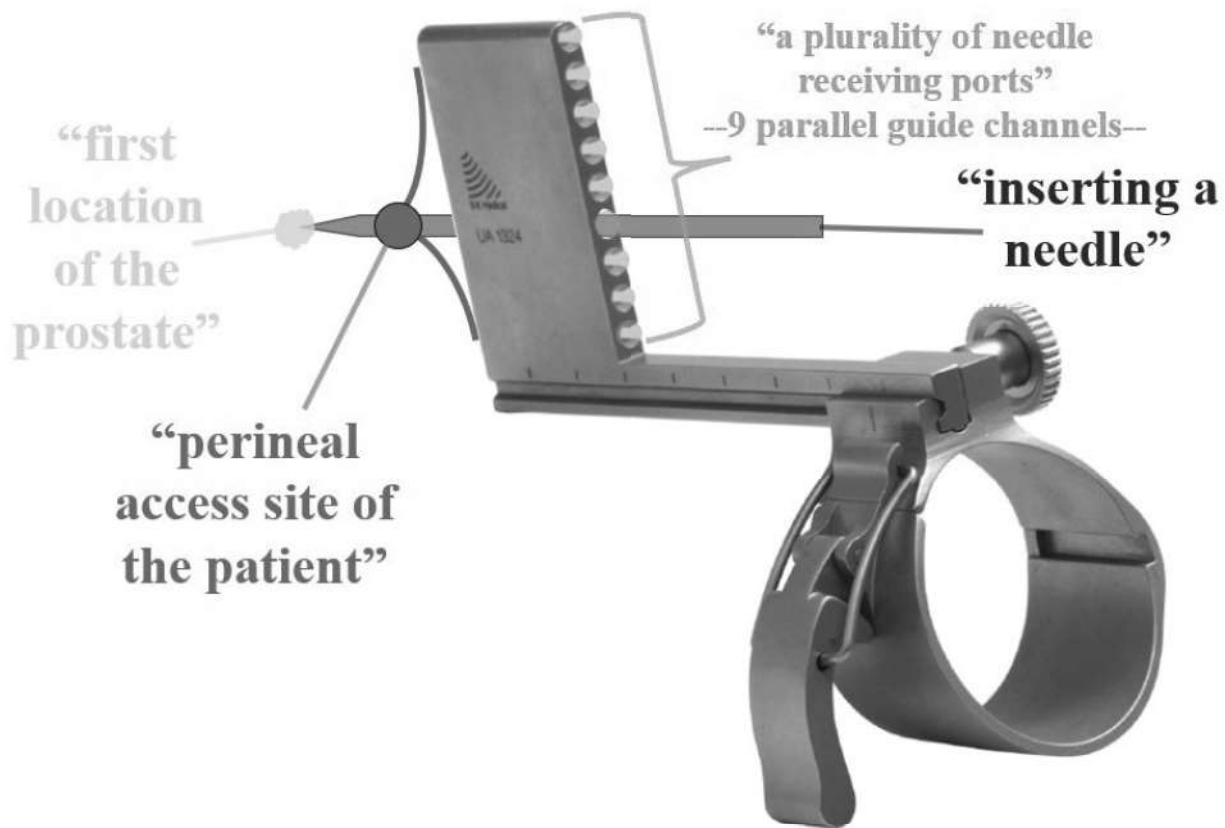
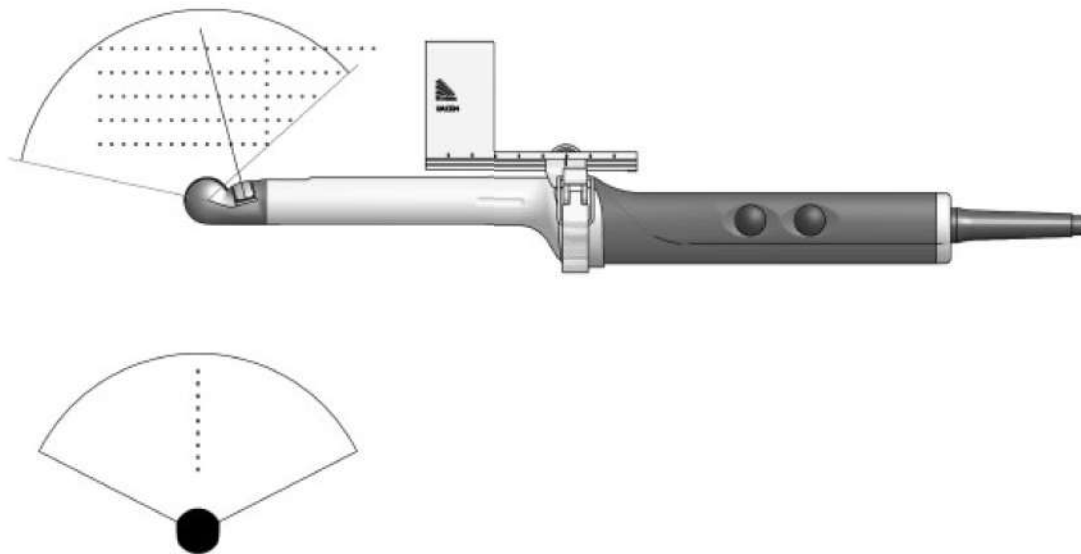


Figure 7. Puncture attachment UA1324.

EX1007, FIG. 7*

As discussed above, the UA1324 biopsy guide has a needle guide with nine parallel guide channels spaced 5 mm apart. *Supra* Section II.A.1.d. *See also* EX1007, 12; EX1003, ¶ 80. Each guide channel has "an internal diameter of 2.1 mm" and therefore can support a 14-gauge needle. EX1007, 12; EX1003, ¶ 80. These nine parallel guide channels correspond to different puncture lines shown on the ultrasound display for the Type 8808e probe:



EX1007, FIG. 9

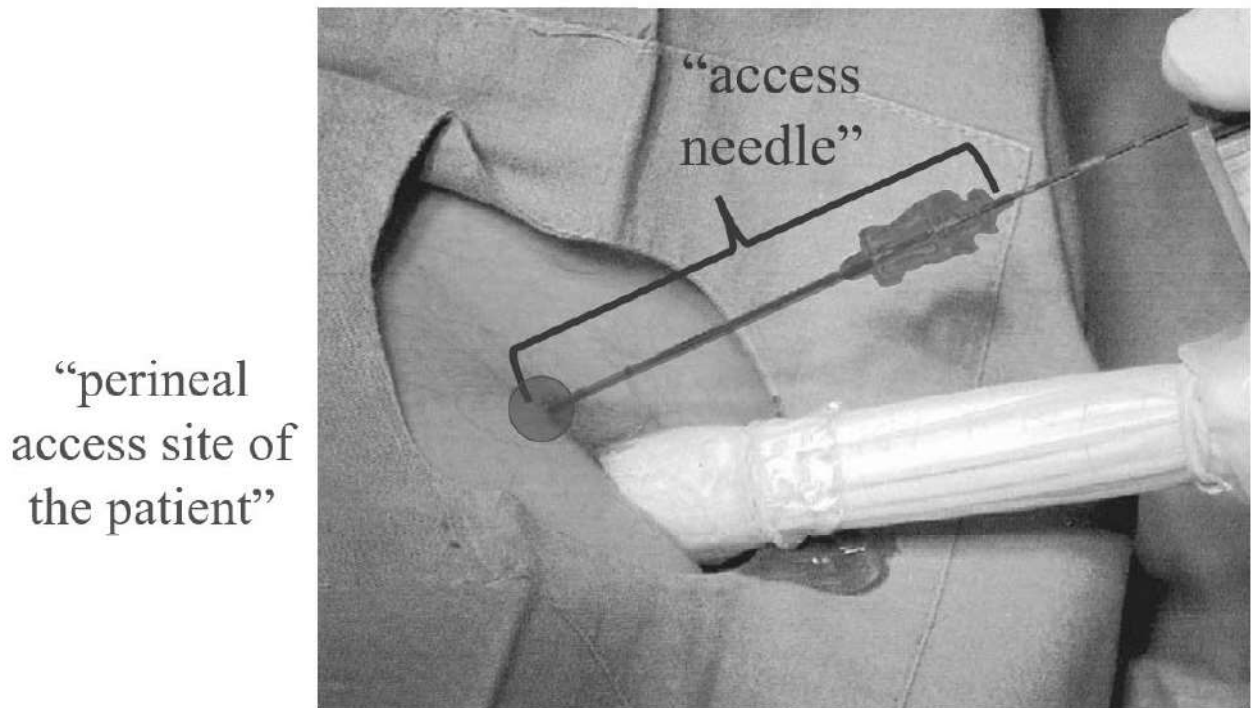
A physician selects a puncture line that intersects with the targeted prostate region to be biopsied. “Move the transducer until the puncture line transects the target.” EX1007, 13; EX1003, ¶ 81. The physician then inserts a needle into the appropriate guide channel corresponding to the displayed puncture line and further inserts the needle through the patient’s perineal access site into the prostate. “Insert the needle and monitor it as it moves along the puncture line to the target. The needle tip echo will be seen as a bright dot on the screen.” EX1007, 13; EX1003, ¶ 81. “The puncture line on the image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.” EX1007, 13; EX1003, ¶ 81. Thus, the physician inserts a needle into the perineal access site of the patient while the needle is supported by one of the plurality of needle receiving ports (nine parallel guide channels), as claimed.

ii. Novella discloses using an “access” needle and “inserting a needle through the access needle and into a first location of the prostate of the patient,” as claimed.

To the extent BK Medical does not disclose performing element [1.7] with an “access” needle and “inserting a needle through the access needle” as recited in element [1.8], Novella remedies the deficiencies of BK Medical. *See* EX1003, ¶¶ 71-74, 108-109.

Novella discloses a method of performing a transperineal biopsy procedure on a prostate of a patient using a coaxial needle (access needle). EX1005, 1; EX1003, ¶¶ 42-47. In Novella’s

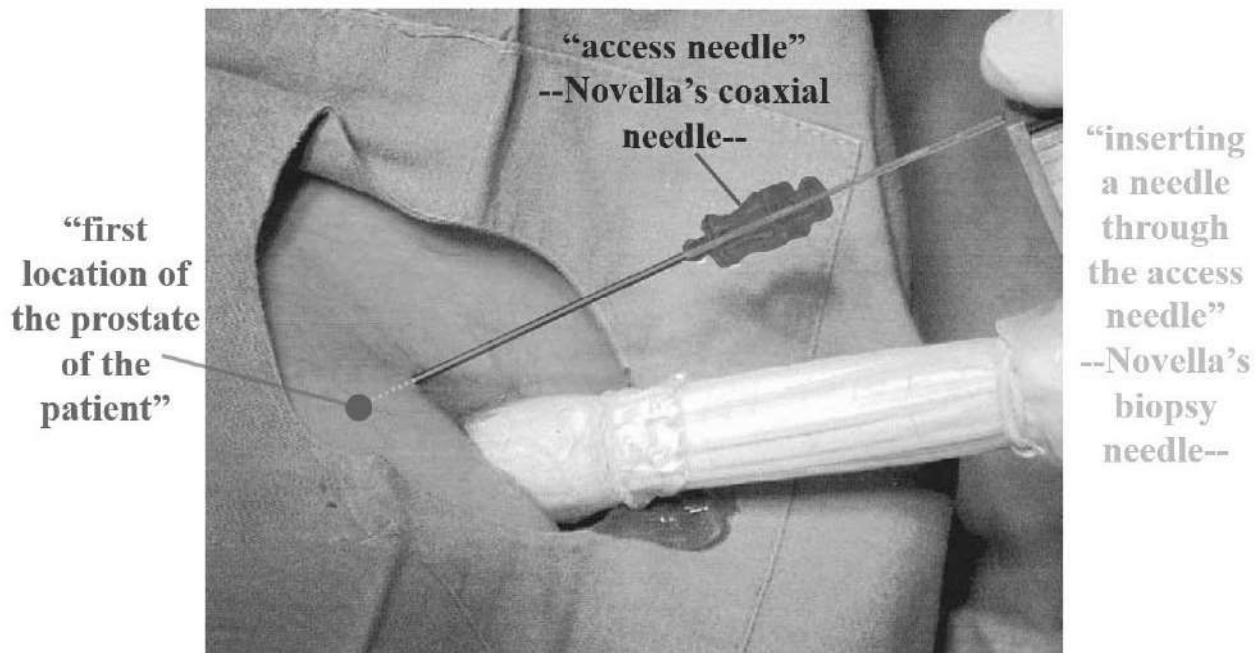
first patient group, the practitioner inserted a “17-gauge coaxial needle (TruGuide Bard, 13 cm long) ... up to the prostate apex through the anesthetized perineal path under TRUS guidance.” EX1005, 2; *see* EX1003, ¶ 47. The coaxial needle (access needle) provided “an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” EX1005, 2; *see* EX1003, ¶ 47.



EX1005, FIG. 1*

Thus, Novella discloses inserting an “access” needle, as recited in element [1.7]. EX1003, ¶ 74.

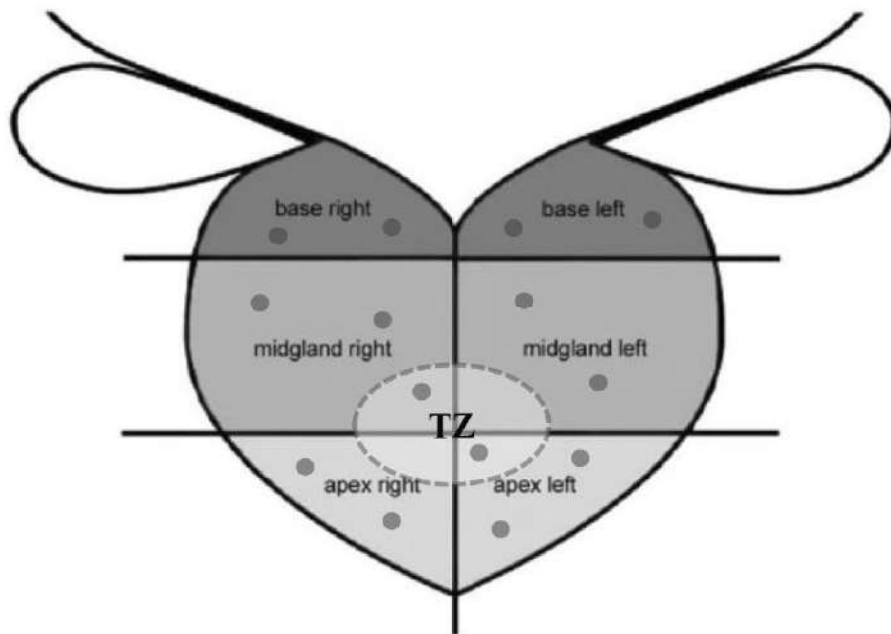
Regarding element [1.8], Novella further discloses inserting a biopsy needle (needle) through the coaxial needle (access needle) and into a first location of the prostate of the patient. EX1003, ¶¶ 108-109. Specifically, Figure 1 shows a practitioner inserting an 18-gauge biopsy needle through a 17-gauge coaxial needle: “a 17-gauge coaxial needle (TruGuide Bard, 13 cm long) was inserted up to the prostate apex through the anesthetized perineal path under TRUS guidance. 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” EX1005, 2; EX1003, ¶ 108.



EX1005, FIG. 1*

Novella “performed 14 biopsies in every patient,” accessing the fourteen locations by inserting the biopsy needle through the coaxial needle as a single access point. EX1005, 1, 2, 4 (Novella used the coaxial needle to create an optimum transperineal path for “repeated atraumatic passage of the biopsy needle”); EX1003, ¶ 180. The instruction manual for Novella’s coaxial needle also instructs the practitioner to insert the biopsy needle through the access needle to biopsy a prostate location: “Place the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be biopsied,” “[p]erform the biopsy and remove the biopsy needle from the guiding cannula,” and “[l]eave the guiding cannula in place.” EX1006, 3-4; EX1003, ¶ 108.

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



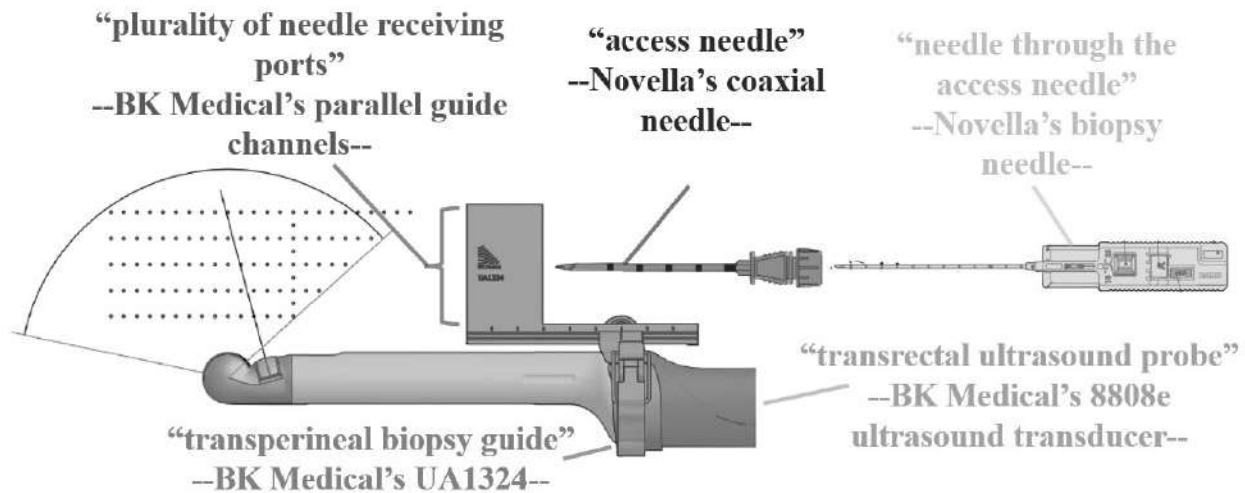
Novella's Biopsy

A double sextant biopsy takes two cores from the left and right sides of the base, midgland, and apex regions of the prostate (12 total), and Novella took two additional cores from the transition zone (TZ) for a total of 14. EX1005, 2; EX1003, ¶ 109. Any of the fourteen biopsy locations and/or seven regions of the prostate may correspond to the claimed “first location” in element [1.8]. EX1003, ¶ 109. Thus, Novella discloses inserting an “access” needle and “inserting a needle through the access needle and into a first location of the prostate of the patient,” as claimed.

Accordingly, Novella discloses element [1.7] and [1.8].

iii. The BK Medical-Novella Combination

A POSITA would have used Novella's coaxial biopsy procedure with BK Medical's UA1324 puncture attachment and Type 8808e ultrasound probe as follows (*see* EX1003, ¶ 82):



BK Medical-Novella Combination*

As shown above, and for the reasons discussed below, a POSITA would have used Novella's coaxial needle with BK Medical's UA1324 and Type 8808e probe by inserting Novella's coaxial needle into the parallel guide channels mounted UA1324 attachment to the probe, using UA1324 to guide ultrasound imaging and placement of the coaxial and biopsy needles. EX1003, ¶ 82. Thus, the combination renders obvious inserting Novella's coaxial needle (access needle) into a guide channel (one of the plurality of needle receiving ports) and inserting a biopsy needle (needle) through the coaxial needle (access needle) and into a first location of the prostate of the patient, as claimed. *Id.* See also EX1003, ¶ 108.

iv. Rationale to Combine BK Medical and Novella

A POSITA would have found it obvious to use Novella's method of performing prostate biopsies with a coaxial needle with BK Medical's UA1324 transperineal biopsy guide and Type 8808e probe. See EX1003, ¶¶ 83-99.

The references provide "teaching, suggestion, and motivation" to use Novella's coaxial needle and the BK Medical equipment in the above configuration rather than use a biopsy needle alone. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007); EX1003, ¶ 93. First, Novella concluded that the coaxial technique resulted in less pain and better compliance for patients than the technique using a biopsy needle alone. Novella divided the patients "into two groups: group 1 ... in which we used the 17-gauge coaxial TruGuide needle, and group 2 ... in which the conventional transperineal technique was used." EX1005, 1; EX1003, ¶ 44. Group 1 (coaxial) reported better outcomes than group 2 (biopsy needle alone) because "[t]he use of a coaxial needle

reduces the procedure's invasiveness and patient's pain compared with the conventional transperineal prostate biopsy" using a biopsy needle alone. EX1005, 1; *see* EX1005, 3 (Table II showing more patients experienced more, and more severe, pain in group 2 than in group 1); EX1003, ¶ 93.

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

In contrast, the coaxial technique "allow[s] the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle." EX1005, 1; *see also* EX1005, 2 ("the coaxial needle was an optimal transperineal path for repeated atraumatic passage of the biopsy needle"); EX1003, ¶ 95. For example, long before the claimed priority date of the '056 Patent, physicians practiced "a single-access fan technique" that "us[es] a common [perineal] access for all the cores." EX1008, 1, 3; EX1003, ¶ 95. The coaxial technique does not require general anesthesia—only local "anesthetic ... administered along the [coaxial] needle path." EX1008, 2; EX1003, ¶ 95. Repeatedly passing a biopsy needle through a coaxial needle and only puncturing the perineum once—opposed to repeatedly puncturing the perineum with the biopsy needle for each sample—minimizes invasiveness, reduces pain, and improves the procedure:

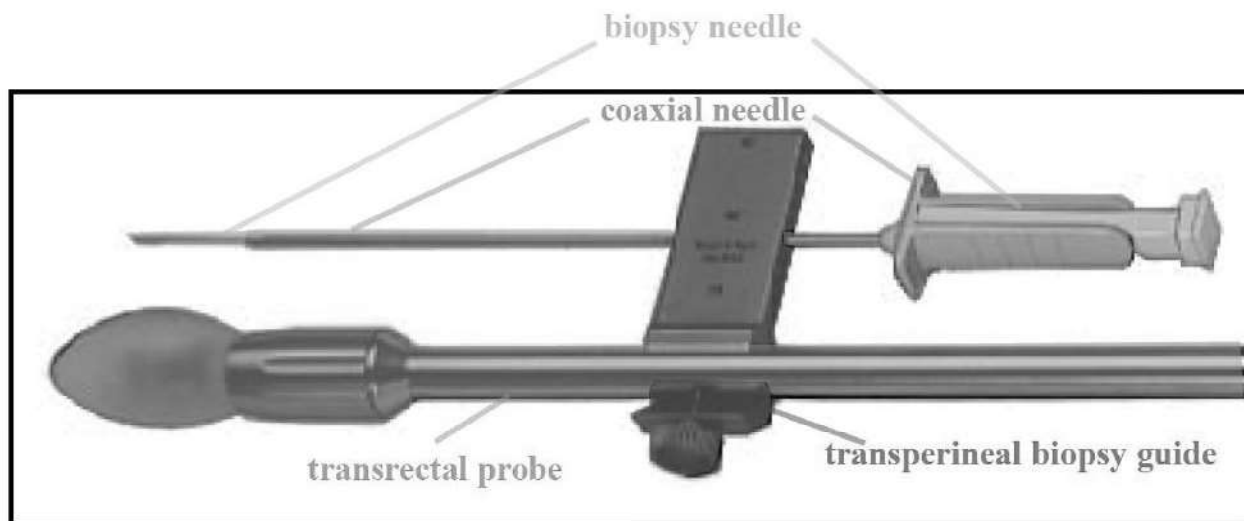
According to the conventional fan technique, biopsies are performed by repeatedly inserting the same biopsy needle through the anesthetized perineal path[.] To minimize the invasiveness of the technique, a coaxial needle can be used with the aim of performing the several needle passages through the same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

EX1008, 4; EX1003, ¶ 95. Thus, a POSITA would have used Novella's preferred coaxial technique with the BK Medical UA1324 biopsy guide and Type 8808e probe to reduce

invasiveness and pain while avoiding the problems with a completely freehand technique, discussed below. EX1003, ¶ 95.

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

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



EX1009, FIG. 11*

It explains that “[i]f a fine needle is used, it may be helpful to use an additional needle guide.” EX1009, 16. Here, “fine needle” and “needle guide” respectively refer to a biopsy needle and coaxial needle. EX1003, ¶ 97; EX1015, ¶ 12. In fact, Dr. Zat’ura testifies that he personally “used

the UA0650 in the configuration shown above on patients between 1983 and 1985 ... to perform transperineal prostate biopsies” and “inserted access needles through the UA0650 needle opening.” EX1015, ¶ 11-12; *see also* EX1003, ¶ 22.

Novella used an 18-gauge biopsy needle, which a POSITA would consider a “fine needle.” EX1005, 2; EX1003, ¶ 98. The coaxial needle supports the “fine” biopsy needle by preventing it from straying from the chosen direction. EX1015, ¶ 13; EX1003, ¶ 98. The coaxial needle also prevents tumor samples from entering the puncture canal and moving further into the prostate during the procedure. EX1015, ¶ 13; EX1003, ¶ 98. Thus, a POSITA would have retained Novella’s coaxial needle (i.e., an “additional needle guide”) in performing Novella’s biopsy procedures. EX1003, ¶ 98.

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

A POSITA considering Novella’s coaxial biopsy technique would also have found obvious and had motivation to use the BK Medical equipment in Novella’s technique. *Id.*, ¶ 83. Novella’s practitioner used a completely freehand technique, handling both the coaxial needle and probe by hand. EX1005, 1-2; EX1003, ¶ 83. Performing biopsies this way has drawbacks, such as:

Fatigue: The technique involves manually manipulating the biopsy needle and ultrasound probe simultaneously throughout the procedure. This can be physically demanding and can fatigue

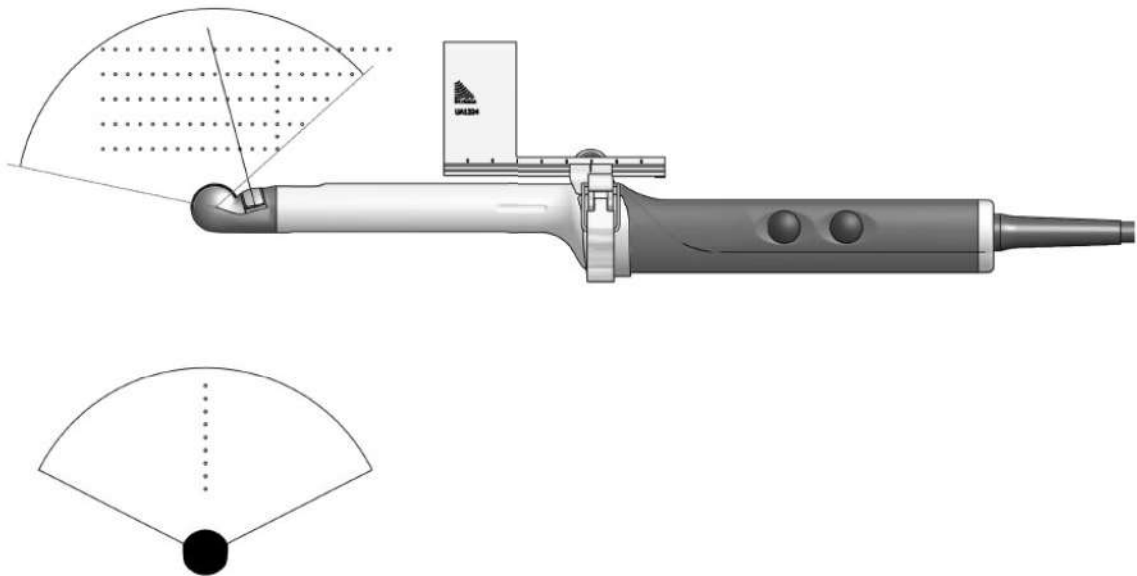
the practitioner. EX1003, ¶ 84. Fatigue from prolonged procedures may decrease precision and increase risk of errors or complications. *Id.*, ¶ 84.

Time/cost: The technique can be more time-consuming and costly. *Id.*, ¶ 85. The manual manipulation of both the biopsy needle and ultrasound probe separately requires extra time and effort, extending the duration and/or increasing the cost of the procedure, especially as the number of cores taken increases. *Id.* In some cases, procedures may require multiple practitioners—one to handle the ultrasound probe and another to perform needle insertion and sample collection. *Id.* In addition to cost, this adds complexity by requiring effective communication and coordination between the team members. *Id.*

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

A POSITA would have recognized that using UA1324 and Type 8808e ultrasound probe would address some of the drawbacks of the pure freehand technique used in Novella’s study. EX1003, ¶ 87. For example, as BK Medical explains, UA1324 mounts directly to the Type 8808e probe by its “mounting ring with clamp.” EX1007, 12. “To mount the transperineal puncture attachment,” the user “slide[s] the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer” and tightens the clamp. *Id.* Once mounted, the nine parallel guide channels of UA1324 have a fixed alignment with the longitudinal axis of the probe as shown in Figure 9 below:

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



EX1007, FIG. 9

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

The BK Medical UA1324 and Type 8808e probe would further improve upon the pure freehand technique in Novella by helping practitioners more easily and precisely biopsy desired target areas of the prostate. *Id.*, ¶ 88. As seen in Figure 9 above, the nine guide channels of UA1324 align with dotted puncture lines displayed on the system monitor during a biopsy procedure. EX1007, 13. “In the sagittal plane,” the longitudinal plane dividing the body into left and right sides, “the puncture path is indicated by a line of dots” displayed on the screen. *Id.*; EX1003, ¶ 88. And “[t]he distance between each puncture dot is 5mm.” EX1007, 13. While “[i]n the transverse plane,” which divides the body into upper and lower sections, “a single dot indicates the point at which the needle will transect the imaging plane” for a given needle guide channel on UA1324. EX1007, 14; EX1003, ¶ 88.

When taking a biopsy, the practitioner “[m]ove[s] the transducer until the [desired] puncture line transects the target” on the prostate, “[i]nsert[s] the needle and monitor[s] it as it moves along the puncture line to the target.” EX1007, 13. That is, the practitioner selects a needle

channel of UA1324 corresponding to a displayed dotted line in the transverse plane that best aligns with a target area of the prostate, inserts the biopsy needle to a depth corresponding to the number of dots needed to reach the target area, and samples the tissue at that location. EX1003, ¶ 89. Because the BK Medical UA1324 and Type 8808e probe would enable Novella's practitioner to more easily and accurately biopsy target areas of the prostate, a POSITA would have been motivated to use the BK Medical biopsy guide and probe in the biopsy procedures of Novella. *Id.*

The Novella-BK Medical combination would merely involve applying a known technique (using BK Medical's puncture attachment and probe) to a known method (Novella's coaxial-biopsy-needle technique) ready for improvement to yield predictable results. *KSR*, 550 U.S. at 405; EX1003, ¶ 90. Here, BK Medical's method involving the transperineal biopsy guide UA1324 and Type 8808e ultrasound probe is the base prior art method ready for improvement. And Novella discloses the use of a coaxial needle to guide the path of the biopsy needle applicable to BK Medical.

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

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

Accordingly, BK Medical and Novell render obvious elements [1.7] and [1.8].

2. Dependent Claim 4

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

For the reasons discussed above for element [1.7], Novella discloses or suggests this claim element. *Supra* Section II.A.1.h; EX1005, 1, 2, 4; EX1003, ¶ 110.

3. Dependent Claim 5

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

Novella discloses or suggests this claim element. EX1003, ¶ 111. As explained above for element [1.7], Novella biopsied fourteen locations across seven regions of the prostate. *Supra* Section II.A.1.h, EX1005, 1, 2, 4; EX1003, ¶ 111. Any biopsied location or region of the prostate corresponds to the claimed first location while any remaining biopsied location or region discloses the claimed second location different than the first location. EX1003, ¶ 111.

4. Dependent Claim 6

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

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

As explained above for element [1.7], Novella biopsied fourteen locations across seven regions of the prostate. *Supra* Section II.A.1.h, EX1005, 1, 2, 4; EX1003, ¶ 113. The coaxial needle remained in place for all fourteen biopsies because Novella used the coaxial needle to “creat[e] ... an optimal transperineal path for *repeated atraumatic passage* of the biopsy needle.” EX1005, 1; *see also* EX1005, 2 (“the guiding cannula of the coaxial needle was an optimal transperineal path for repeated atraumatic passage of the biopsy needle”), 4 (“The guiding cannula forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness”); EX1003, ¶ 113.

The instruction manual for the coaxial needle also teaches that the coaxial needle should remain positioned within the perineal access site of the patient for multiple passes of the biopsy

needle. EX1006, 3-4; EX1003, ¶ 114. It instructs the practitioner to “[p]lace the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be biopsied,” “[p]erform the biopsy and remove the biopsy needle from the guiding cannula,” and “[l]eave the guiding cannula in place.” EX1006, 3-4.

5. Dependent Claim 11

- a. **[11.1]: “*The method of claim 10, wherein the needle is a biopsy needle with a needle size of 18 gauge.*”**

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

6. Dependent Claim 12

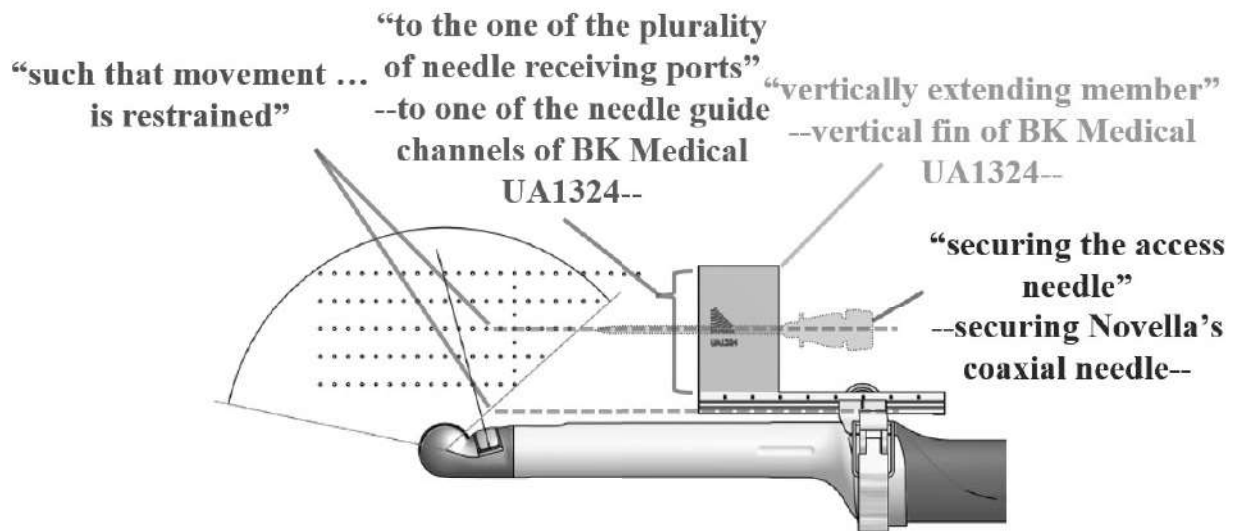
- a. **[12.1]: “*The method of claim 1, wherein the needle is a biopsy needle with a needle size of 18 gauge.*”**

Novella discloses or suggests this claim element. EX1003, ¶ 115. As discussed above for element [11.1], Novella discloses this element because the practitioner used “[a]n 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun” in the study. EX1005, 2; EX1003, ¶ 115. *Supra* Section II.A.5.a.

7. Dependent Claim 13

- a. **[13.1]: “*The method of claim 1, further comprising securing the access needle to the one of the plurality of needle receiving ports such that movement of the access needle relative to the vertically extending member is restrained.*”**

The Novella-BK Medical combination renders this element obvious. EX1003, ¶ 104; *supra* Sections II.A.1.h.iii, II.A.1.h.iv. The combination includes coupling Novella’s coaxial needle (access needle) to one of the nine parallel needle guide channels (needle receiving ports) of the vertical fin (vertically extending member) of the needle guide of UA1324 (transperineal biopsy guide), such that a position and angle of the coaxial needle (access needle) relative to the needle guide (vertically extending member) is retained, as claimed:



Novella-BK Medical Combination*

In combination, Novella's coaxial needle (access needle) is coupled within a selected guide channel (needle receiving port) of UA1324 (transperineal biopsy guide). EX1003, ¶ 105; Section II.A.1.h. The practitioner "[i]nser[t] the needle and monitor[s] it as it moves along the puncture line to the target," where "[t]he puncture line on the image is an indication of the expected needle path." EX1007, 13; EX1003, ¶ 105. Thus, as illustrated above, once coupled within a needle guide channel, a longitudinal position and parallel angle of the coaxial needle (access needle) relative to the UA1324 needle guide (vertically extending member) are retained. EX1003, ¶ 105; EX1007, 12 (The "9 parallel guide channels" align with the puncture lines and run "parallel to the centerline of the transducer").

As explained above, the claimed "securing" does not require completely locking the access needle in place to prevent any movement of the access needle. *Supra* Section I.B. Rather, as Patent Owner contends, securing the access needle to the receiving port "maintain[s] the stability and directionality of the coaxial needle or the puncture needle" *Id.*; EX1019, 13. BK Medical's UA1324 biopsy guide does this in several ways. EX1003, ¶ 106.

For example, the needle channel maintains the stability of the access needle's direction parallel to the centerline of the transducer. EX1007, 12-13; EX1003, ¶ 107. When in the channel, the access needle cannot rotate in the plane of the vertically extending member. EX1003, ¶ 107. The needle channel also maintains and stabilizes the vertical position of the needle relative to the

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

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

1. Dependent Claim 10

- a. [10.1]: “*The method of claim 1, wherein the access needle has a needle size of 14 gauge, 15 gauge, or 16 gauge.*”

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

b. Zangos Discloses Element [10.1]

In Zangos, “[t]he prostate gland was biopsied repeatedly with a coaxial technique through a 15-gauge pencil tip with a 16-gauge biopsy handy (median 3.8 samples per patient).” EX1010, 1. Thus, Zangos discloses the 14-gauge, 15-gauge, or 16-gauge access needle of element [10.1]. EX1003, ¶ 145.

c. Rationale to Combine Zangos with BK Medical-Novella

A POSITA would have found it obvious to use Zangos's 15-gauge coaxial needle in the Novella-BK Medical combination with a reasonable expectation of success. EX1003, ¶ 146. The '056 Patent explains that the vertical fin's “hole may be configured to accommodate a needle having a range of 14-18 gauges, such as a reusable 14 gauge spinal needle,” but does not identify any significance of 14 gauge, 15 gauge, or 16 gauge, specifically. EX1001, 11:29-33.

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

Indeed, if tolerated by the patient, a POSITA generally would have wanted to use a larger coaxial/biopsy needle because larger needles allow taking larger samples, improving diagnostic accuracy. *Id.*, ¶ 147. Larger tissue samples reduce the chance of missing cancerous cells, particularly in larger prostates or heterogenous tumors. *Id.* For example, instead of taking 14

samples per patient with a 17-gauge coaxial needle, Novella could have taken fewer cores with Zangos's 15-gauge coaxial needle while maintaining the same detection rate with less intrusiveness. *Id.* Thus, a POSITA would have had motivation to use Zangos's 15-gauge needle in Novella's procedure. *Id.*

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

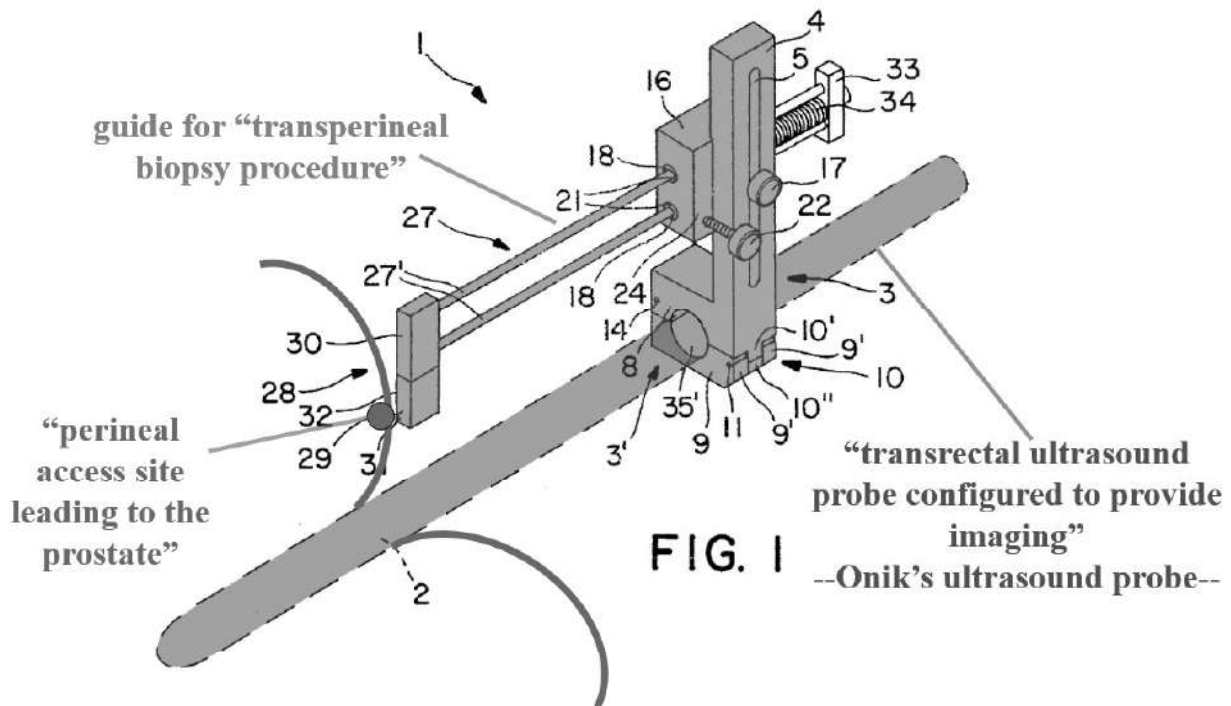
Additionally, the combination would have merely involved simple substitution of one known element (a 15-gauge coaxial needle) for another (a 17-gauge coaxial needle) to obtain predictable results. *KSR*, 550 U.S. at 416. Novella and Zangos both used coaxial needles in prostate biopsy procedures, so the combination would not change the nature of Novella's procedure. EX1003, ¶ 150. Novella's procedure would be performed in the same way but using a 15-gauge instead of a 17-gauge coaxial needle. Additionally, Zangos achieved good results with a 15-gauge coaxial needle, so a POSITA also would have expected to have good results using that needle in the BK Medical-Novella biopsy procedure. *Id.*

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

1. Independent Claim 1

- a. [1.pre]: ***"A method of performing a transperineal biopsy procedure on a prostate of a patient using a transrectal ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the method comprising:"***

To the extent the preamble is limiting, Onik discloses or suggests this claim element. *See* EX1003, ¶¶ 156-58.



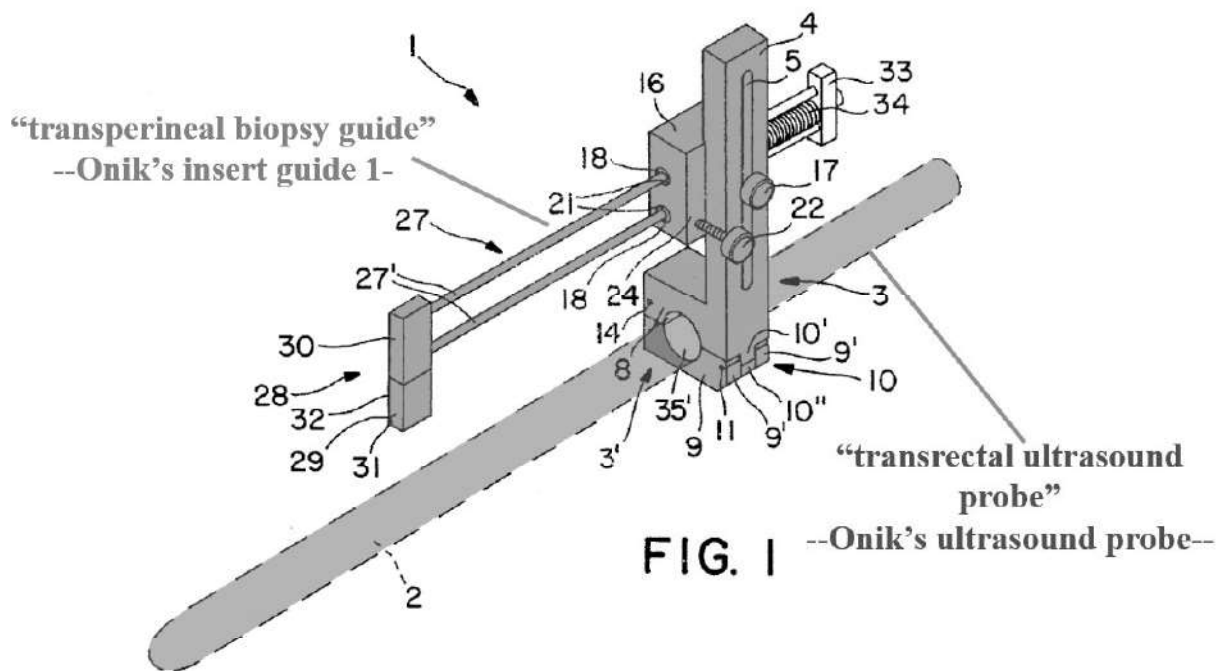
EX1007, FIG. 1*

Onik discloses “[a] biopsy needle insertion guide and method of use with an ultrasound probe” wherein “the insertion guide is used to accurately place biopsy needles in a human prostate.” EX1011, Abstract; EX1003, ¶ 64. The ultrasound probe is a “rectally inserted ultrasound guide used to image a prostate.” EX1011, 2:46-48. A “needle holder assembly 28 engages and bears firmly against the patient's perineum” during the prostate biopsy (transperineal biopsy procedure). *Id.*, 7:18-20; EX1003, ¶ 157. At that point, “[t]he surgeon need then only maintain a firm grip and slight proximal pressure . . . for the insertion of a biopsy needle.” EX1011, 7:24-27.

Accordingly, Onik discloses or suggests element [1.pre].

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

Onik discloses or suggests this claim element. EX1003, ¶¶ 156-58. Onik discloses imaging the prostate of the patient with the transrectal ultrasound probe, wherein a transperineal biopsy guide (insert guide 1) is coupled to the transrectal ultrasound probe:



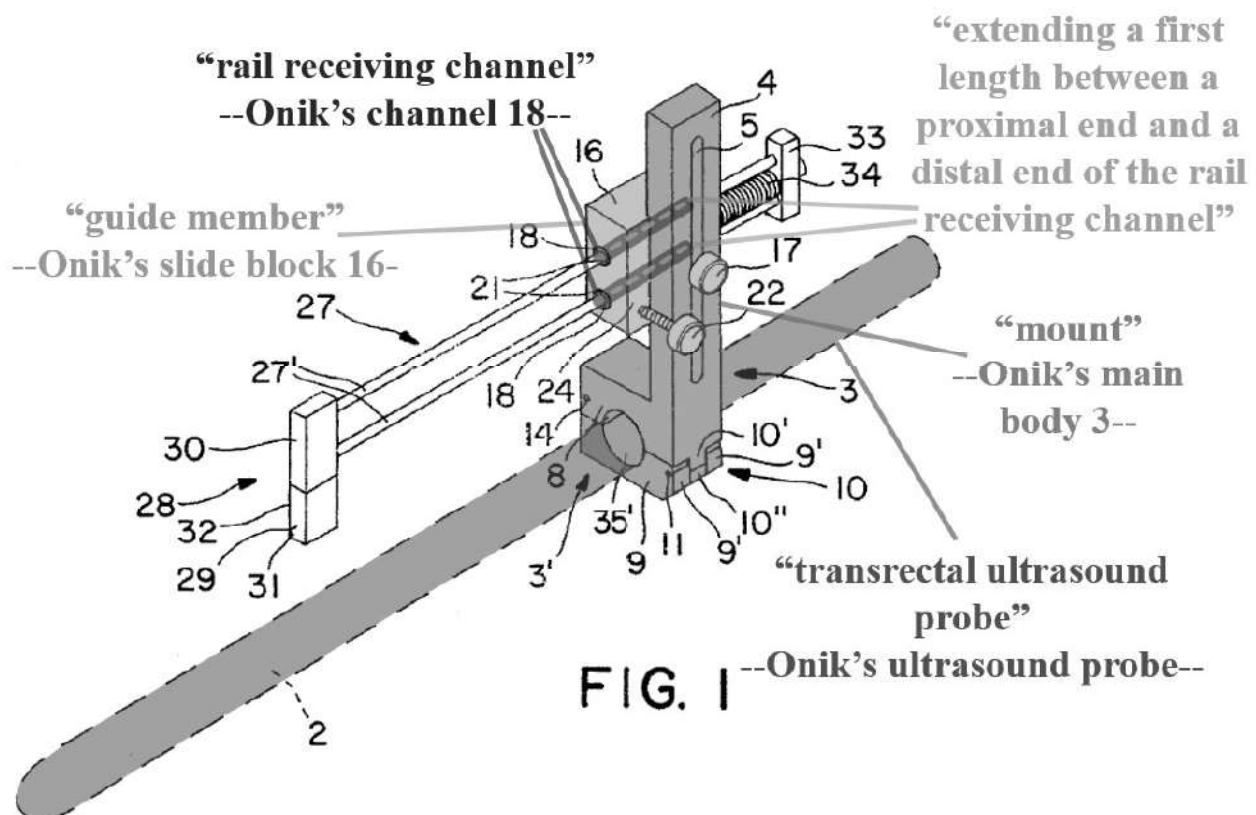
EX1011, FIG. 1*

As discussed above, Onik discloses a transrectal ultrasound probe that images the prostate. *Supra* Section II.C.1.a. EX1011, 6:58-61; EX1003, ¶ 157. Onik further discloses that insert guide 1 (transperineal biopsy guide) “is used in conjunction with the ultrasound probe to accurately place one or more biopsy needles in a patient’s prostate with the needles” EX1011, 6:60-63; EX1003, ¶ 157. Onik’s transperineal biopsy guide is coupled to the transrectal probe: “The insertion guide comprises a body which is removably mountable on an ultrasound probe” EX1011, Abstract; EX1003, ¶ 158. “Imaging of the prostate is readily obtained by use of an ultrasound probe inserted into the patient’s rectum. Because of the proximity of the prostate to the rectum, a high resolution image is obtained and the ultrasound probe can be used as basis from which to gauge probe placement.” EX1011, 1:47-52. The “ultrasound probe is inserted into the patient’s rectum and is activated to image the prostate.” EX1011, 7:3-4; EX1003, ¶ 157.

Accordingly, Onik discloses or suggests claim element [1.1].

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

Onik discloses or suggests this claim element. *See* EX1003, ¶¶ 178-80. Onik discloses that the transperineal biopsy guide (insert guide 1) comprises a mount (main body 3) coupled to the transrectal ultrasound probe, a guide member (slide block 16) coupled to the mount (main body 3) and including a rail receiving channel (channel 18) extending a first length between a proximal end and a distal end of the rail receiving channel (channel 18):



EX1011, FIG. 1*

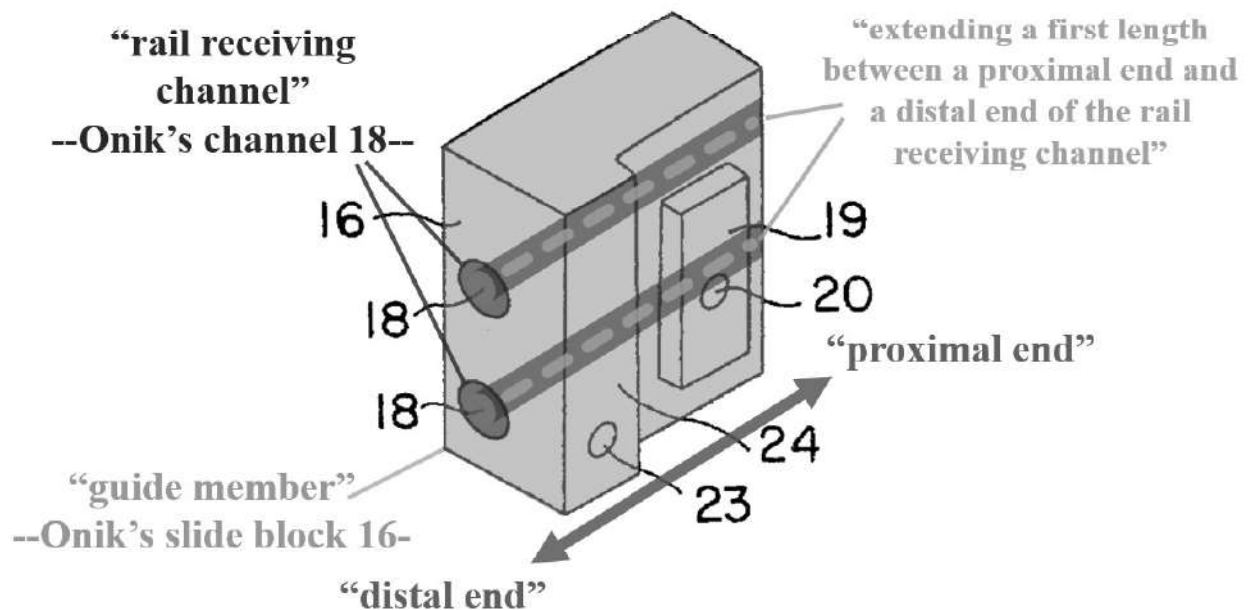
Onik discloses that the transperineal biopsy guide (insert guide 1) comprises a mount (main body 3) that is coupled to the transrectal ultrasound probe, as claimed. EX1003, ¶ 158. Specifically, the “L” shaped main body 3 has first and second clamp bodies 8, 9 with opposing semicircular cutouts 35. EX1011, 3:47-4:10; EX1003, ¶ 158. “[W]hen clamp bodies 8 and 9 are brought into closed engagement a substantially cylindrical channel 35’ is provided within which

ultrasound probe 2 is retained,” making “insertion guide 1 [] removably mountable on ultrasound probe 2.” EX1011, 4:3-7; EX1003, ¶ 158.

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

Onik further discloses that guide 1 (transperineal biopsy guide) has slide block 16 (guide member) coupled to main body 3 (mount), as claimed. EX1003, ¶ 178. Specifically, slide block 16 (guide member) couples to main body 3 (mount) through thumbscrew 17 and slot 5. EX1003, ¶ 178; EX1011, 4:37-5:36, 7:12-20.

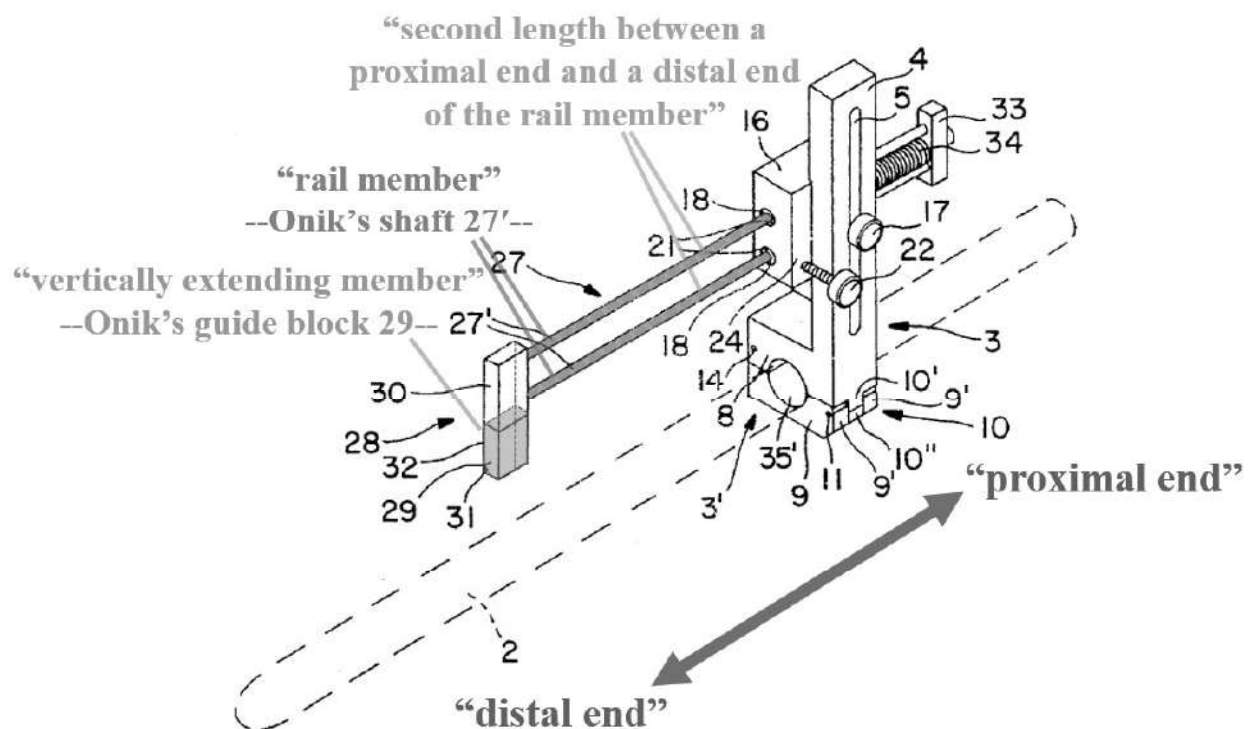
As highlighted above, Onik additionally discloses that slide block 16 (guide member) has a “[p]air of channels 18” (“rail receiving channel[s]”) that “slidably receive the double rod shaft 27’ of the needle holder and guide assembly 27.” EX1011, 4:58-63; EX1003, ¶ 181. As shown below, Onik discloses that the “rail receiving channel” extends “a first length between a proximal end and a distal end of the rail receiving channel.”



EX1011, FIG. 8*

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

Onik discloses or suggests this claim element. EX1003, ¶¶ 180-81. Onik discloses a displacement member (needle holder and guide assembly 27) including a rail member (shaft 27') extending a second length between a proximal end and a distal end of the rail member (shaft 27') and a vertically extending member (guide block 29) extending from the distal end of the rail member (shaft 27'):



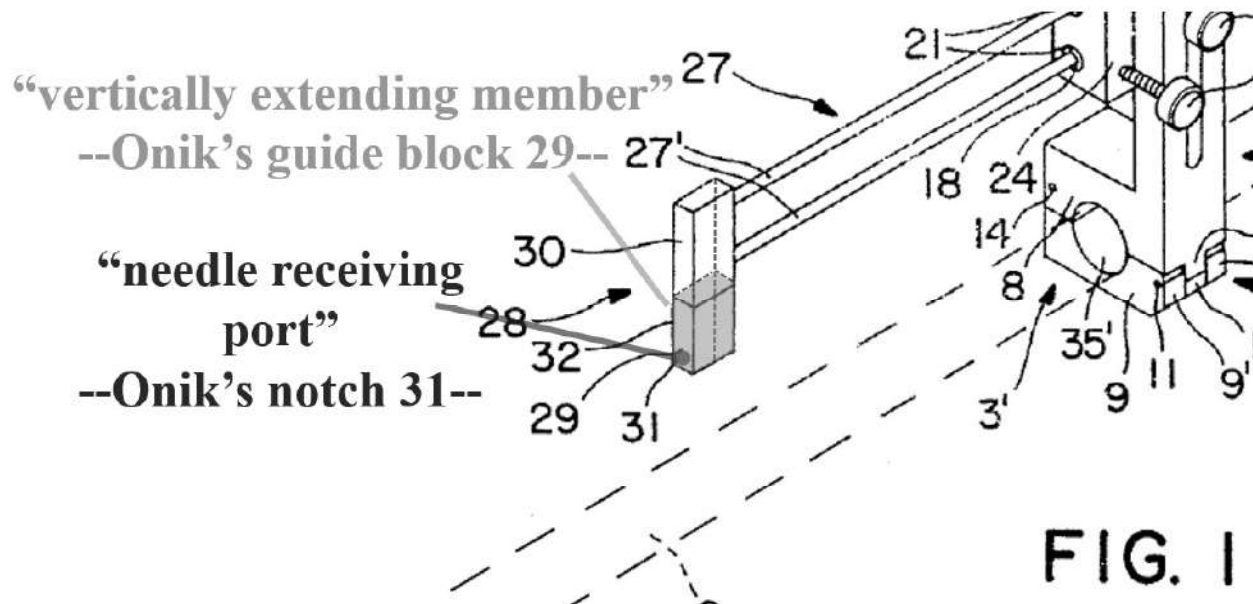
EX1011, FIG. 1*

The displacement member (needle holder and guide assembly 27) includes a rail member (shaft 27'). "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." EX1011, 4:58-61; EX1003, ¶ 65. Onik discloses that there may be one or two rail members (shaft 27'). "In the illustrated embodiment shaft 27' comprises parallel spaced rods. However, shaft 27' may also be a single rod which is preferably square in its cross-sectional shape." EX1011, 5:21-23. "[A] pair of channels 18 are provided to slidably receive the double rod shaft 27' of the needle holder and guide assembly 27." *Id.*, 4:61-63.

Onik further discloses a vertically extending member (guide block 29) extending from the distal end of the rail member. EX1003, ¶ 167. Specifically, “[a]ffixed to the proximal end of shaft 27’ is a needle holder assembly 28 comprising a guide block 29 and a shield 30.” EX1011, 5:37-37; EX1003, ¶ 167. “Guide block 29 ... is provided with an elongated notch 31 in one face adjacent the lower end of block 29” to “provide guidance for a biopsy needle being inserted.” EX1011, 5:39-46; EX1003, ¶ 167.

e. [1.4]: “the vertically extending member including a plurality of needle receiving ports,”

Onik discloses the vertically extending member (guide block 29) including a needle receiving port. EX1003, ¶ 167.



EX1011, FIG. 1*

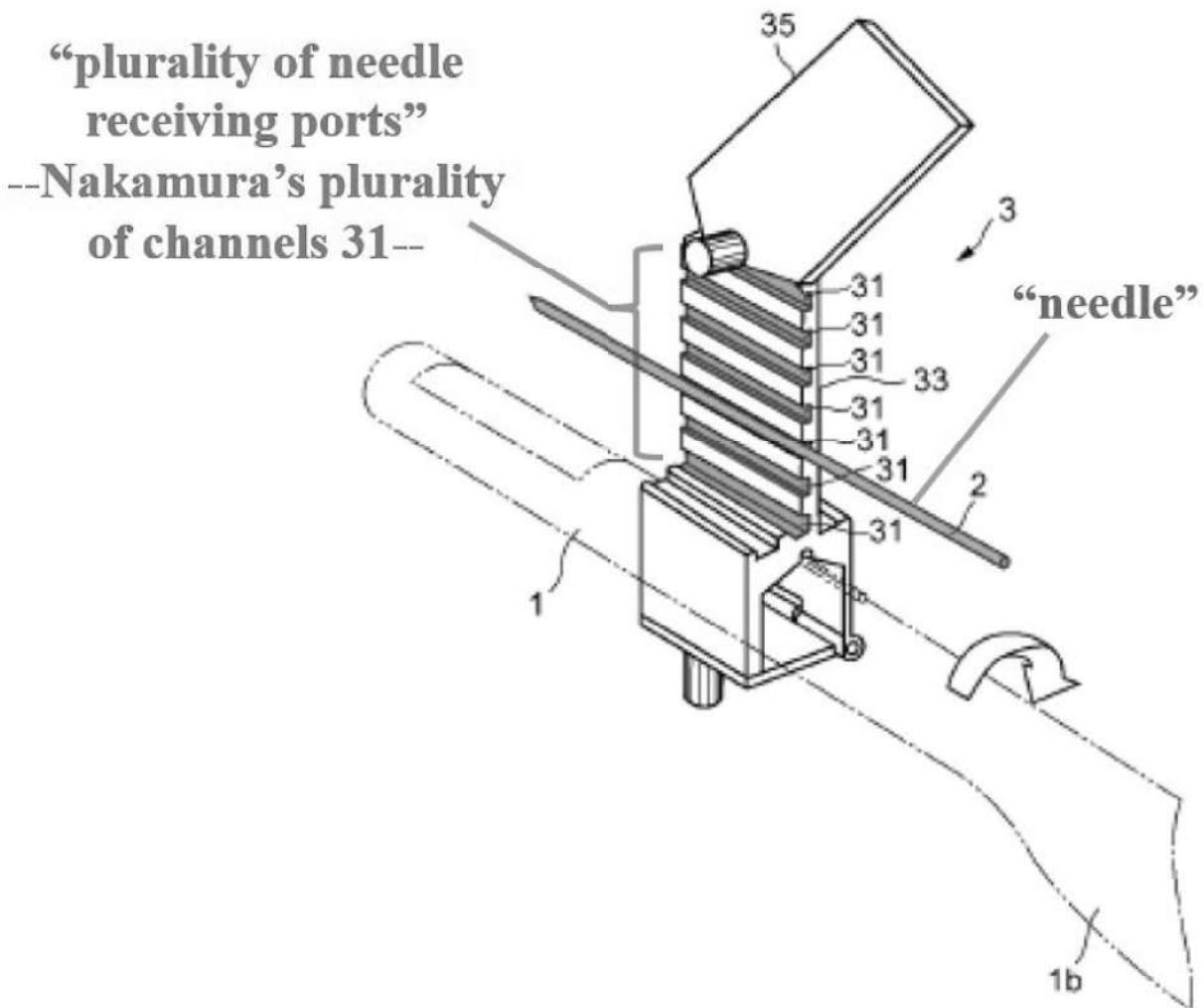
Onik’s vertically extending member (guide block 29) has a notch 31 corresponding to the claimed “needle receiving port[.]” EX1003, ¶ 167. Specifically, “[a]ffixed to the proximal end of shaft 27’ is a needle holder assembly 28 comprising a guide block 29 and a shield 30.” EX1011, 5:37-37; EX1003, ¶ 167. “Guide block 29 ... [has] an elongated notch 31 in one face adjacent the lower end of block 29” to “provide guidance for a biopsy needle being inserted.” EX1011, 5:39-46; EX1003, ¶ 167.

Since Onik’s vertically extending member (guide block 29) has one needle receiving port (notch 31), Onik does not disclose a “plurality” of needle receiving ports, as claimed. EX1003, ¶ 168. But Nakamura discloses a transperineal biopsy guide with a plurality of needle guide

channels, and a POSITA would have found it obvious to modify Onik's vertically extending member (guide block 29) to have a plurality of needle receiving notches or channels as taught by Nakamura. EX1003, ¶ 168.

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

Nakamura discloses a plurality of needle receiving ports (plurality of channels 31). EX1003, ¶ 169.



EX1012, FIG. 10*

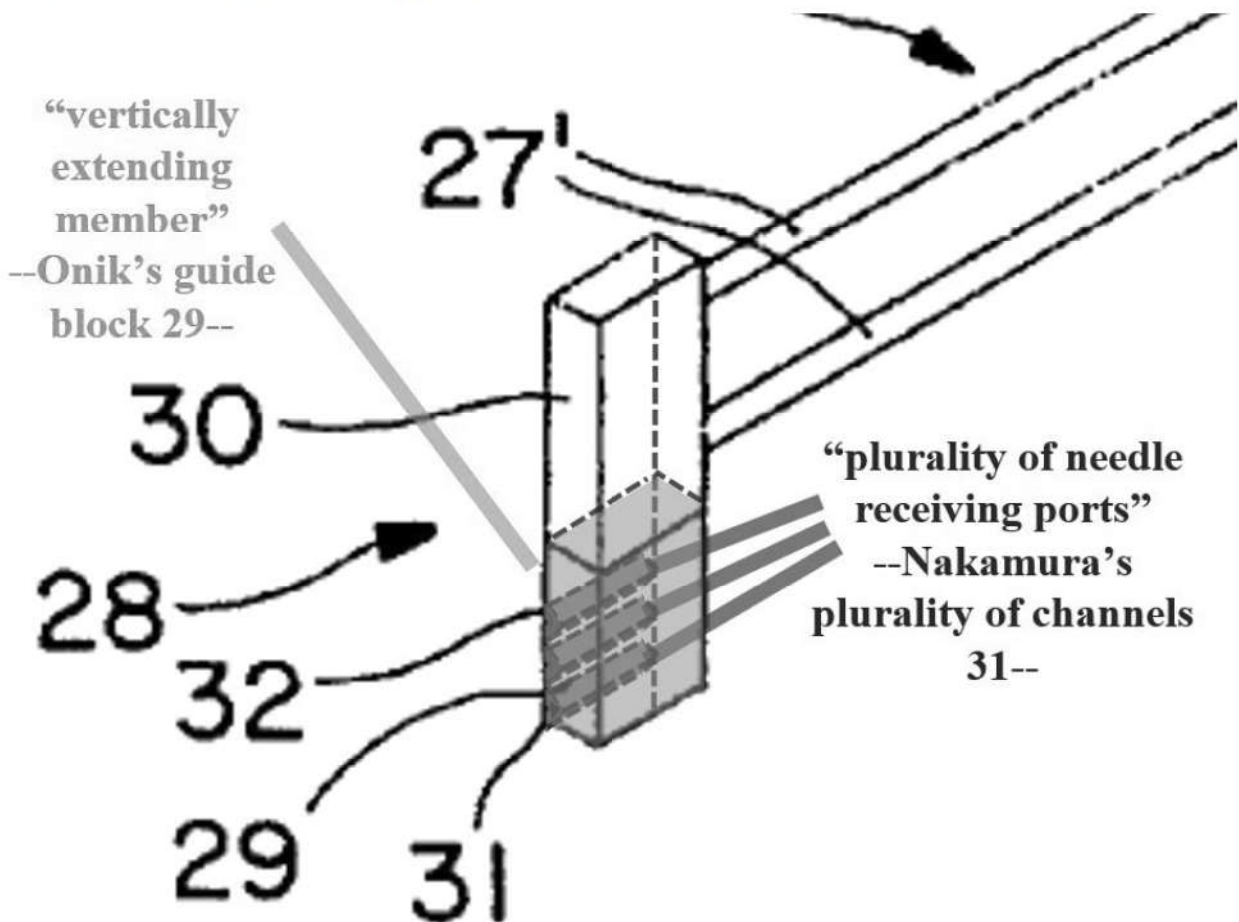
Nakamura discloses “a puncture adapter 3 for transrectal probe transperineal puncture” having “a guiding part main body 32 composed of a guide plate 33, on which are formed a plurality of channels 31 used in guiding a puncture needle 2.” EX1012, ¶ [0038]; EX1003, ¶ 169.

Nakamura's channels 31 disclose the claimed plurality of needle-receiving ports, as highlighted above. EX1003, ¶ 169.

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

ii. The Onik-Nakamura Combination

A POSITA would have modified Onik’s guide 1 (“transperineal biopsy guide”) to add more notches or channels 31 (“plurality of needle receiving ports”) based on Nakamura’s disclosure of multiple channels 31 (EX1003, ¶ 171):



Onik-Nakamura Combination*

Like Nakamura, Onik's modified vertically extending member (guide block 29) has multiple notches/channels 31 ("needle receiving ports") instead of one. EX1003, ¶ 171. Now, as in Nakamura, Onik's guide block 29 ("vertically extending member") has a plurality of "channels 31 . . . formed so that the puncture needle 2 can be inserted at a plurality of levels in the vertical direction and at a desired position." EX1012, ¶ [0047]. During a biopsy procedure, a practitioner may select "a guide hole corresponding to a target position . . . from the plurality of guide holes formed by . . . the plurality of channels 31" and insert "the puncture needle 2 . . . into the selected guide hole" *Id.*, ¶ [0048]; EX1003, ¶ 171. Thus, once the height of the guide member (slide block 16) has been set for the procedure, the practitioner may select different needle receiving ports (notches 31) to target different areas of the prostate without removing the probe from the patient to adjusting thumbscrew 17 or attempting adjustment with the probe inserted. EX1003, ¶ 171; *infra* Section II.A.1.h.iv.

Accordingly, the combination of Onik and Nakamura disclose element [1.4].

iii. Rationale to Combine Nakamura with Onik

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

Onik's guide 1 has a single "[n]otch 31 . . . to provide guidance for a biopsy needle being inserted." EX1011, 5:43-46. To adjust vertical positioning of the notch/needle, "[t]humb screw 17 is loosened to permit slide block 16 to move along adjustment guide 4 and is tightened against the outer face of adjustment guide 4 to fix slide block 16 in a desired position." *Id.*, 4:45-52. But making this adjustment during a biopsy procedure may be awkward, inefficient, or uncomfortable for the patient. EX1003, ¶ 173. For example, the practitioner may remove the ultrasound probe from the patient's rectum, loosen thumbscrew 17, adjust block 16 up or down, retighten thumbscrew 17, and reinsert the ultrasound probe into the rectum. *Id.* This makes the procedure more inefficient and intrusive for the patient. *Id.* Alternatively, the practitioner may attempt to adjust guide 1 with the probe in the patient's rectum—cumbersome for the practitioner and potentially uncomfortable for the patient as the practitioner manipulates guide 1. *Id.*

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

This modification merely involves use of known techniques (providing multiple needle guide channels on a transperineal biopsy guide) to improve a similar device (another transperineal biopsy guide) in the same way. *KSR*, 550 U.S. at 417. Here, Onik discloses a base transperineal biopsy guide with one needle-receiving notch 31, upon which multiple needle-receiving notches would be seen as an improvement. EX1003, ¶ 175. Nakamura discloses a comparable transperineal biopsy adapter for an ultrasound probe—improved relative to Onik's guide with multiple needle-receiving “channels 31 ... so that the puncture needle 2 can be inserted at a plurality of levels in the vertical direction and at a desired position.” EX1012, ¶ [0047]. This allows “a target position [to be] selected from the plurality of guide holes formed by ... the plurality of channels 31, the puncture needle 2 [to be] entered into the selected guide hole, and the puncture needle 2 [to be] inserted.” *Id.*, ¶ [0048].

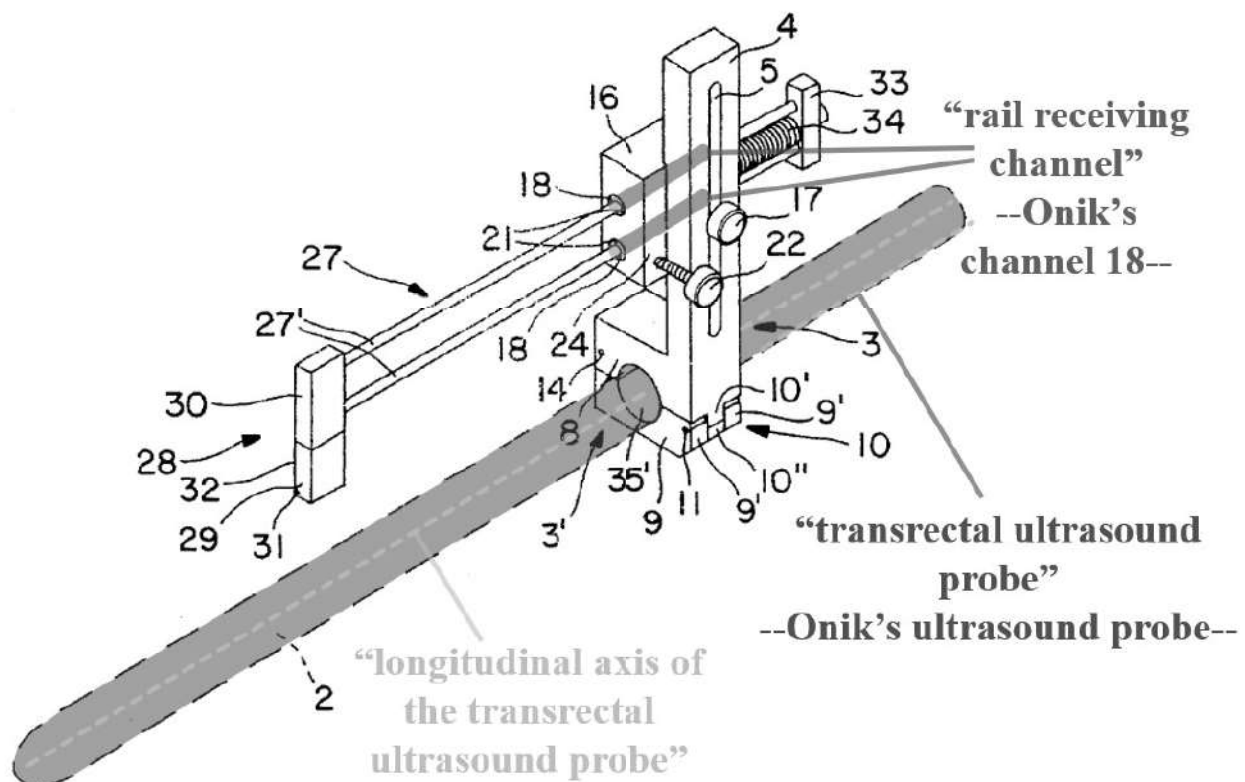
A POSITA would have applied Nakamura's known improvement of multiple needle channels to Onik's guide, benefiting Onik's guide in the same way it benefits Nakamura's adapter. EX1003, ¶ 176. This modification would have yielded predictable results because Onik's guide would be used in the same way as Onik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

A POSITA would have had a reasonable expectation of success modifying Onik's guide to have multiple notches instead of one. EX1003, ¶ 177. As seen above, guide block 29 already has one notch 31 and room for more. *Id.* The additional notches would be added above the existing notch 31. *Id.* If needed, a POSITA would make guide block 29 slightly larger to provide more room for the notches and/or clearance to manipulate the needle(s) while installed in the notches.

Id. “Notch 31 is preferably a simple ‘V’ notch and ... oriented parallel to the longitudinal axis of shaft 27’ and of ultrasound probe 2.” EX1011, 5:42-45. The additional notches could be made in the same way as the existing notch, such as by grinding guide block 29 or making it from a mold. EX1003, ¶ 177.

f. [1.5]: “wherein the rail receiving channel is positioned generally parallel with a longitudinal axis of the transrectal ultrasound probe;”

Onik discloses or suggests this claim element. Onik discloses wherein the rail receiving channel (channel 18) is positioned generally parallel with a longitudinal axis of the transrectal ultrasound probe:



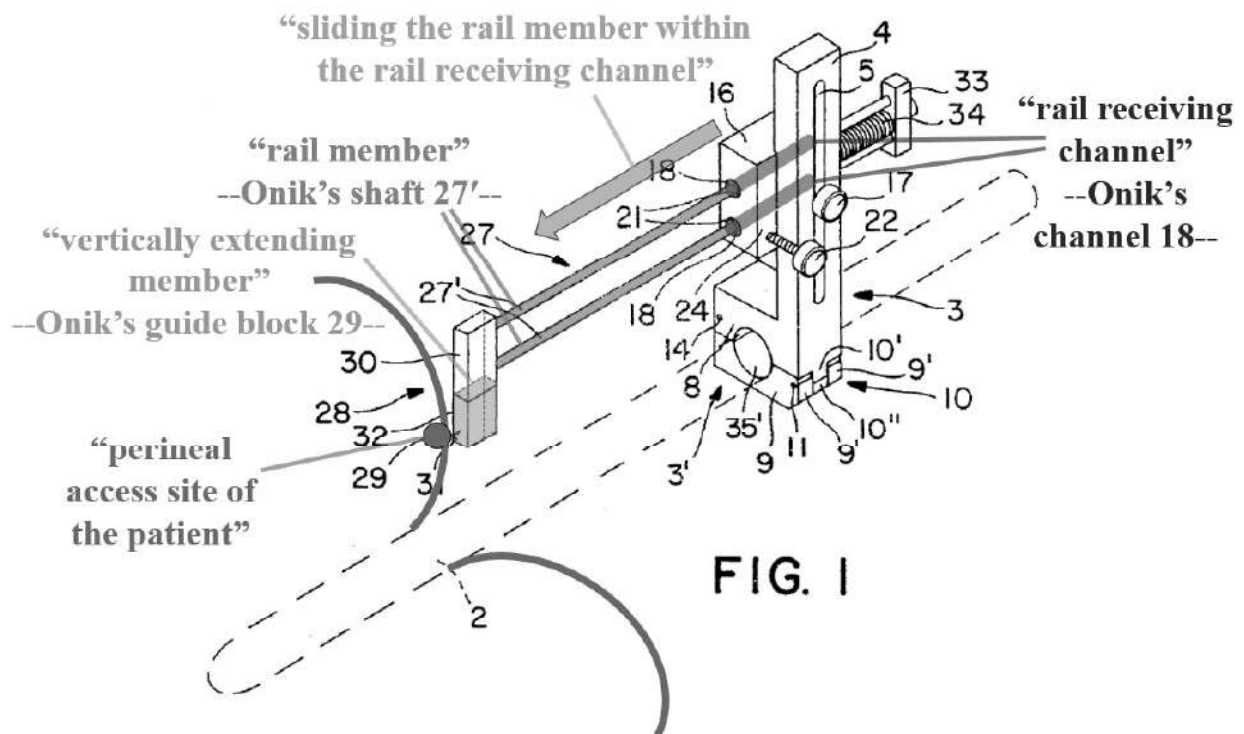
EX1011, FIG. 1*

“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.” EX1011, 4:58-61; EX1003, ¶ 65. “[A] pair of channels 18 are provided to slidably receive the double rod shaft 27’ of the needle holder and guide assembly 27.” EX1011, 4:61-63.

Accordingly, Onik discloses or suggests element [1.5].

- g. [1.6]: “sliding the rail member within the rail receiving channel so as to position the vertically extending member of the displacement member adjacent the perineal access site of the patient;”

Onik discloses or suggests this claim element. EX1003, ¶¶ 181-83. Onik discloses sliding the rail member (shaft 27') within the rail receiving channel (channel 18) so as to position the vertically extending member (guide block 29) of the displacement member (needle holder and guide assembly 27) adjacent the perineal access site of the patient:



EX1011, FIG. 1*

Onik discloses that “needle holder and guide assembly 27 has a shaft 27’ which is slidable through channels 18 in slide block 16.” EX1011, 5:19-21; EX1003, ¶ 66. “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.” EX1011, 4:61-63.

When a practitioner uses the disclosed transperineal biopsy guide, “the assembly of the insert guide 1 and probe 2 is advanced proximally until needle holder assembly 28⁴ engages and bears firmly against the patient’s perineum.” *Id.*, 7:17-20; EX1003, ¶ 157. This movement slides shaft 27’ (“rail member”) within channel 18 (“rail receiving channel”) so as to “place[] spring 34 under tension[,] which serves to maintain needle holder assembly firmly against the perineum.” EX1011, 7:20-22. At this point, “needle holder and guide assembly 27 is then locked in place by tightening thumb screw 22 against shaft 27’.” *Id.*, 7:22-24; EX1003, ¶ 181. Thus, “the needle holder and guide assembly is adjustable relative to the slide block in a direction parallel to the longitudinal axis of the ultrasound probe in order to engage the perineum of the patient” EX1011, 2:56-60.

Accordingly, Onik discloses or suggests claim element [1.6].

- h. [1.7]: “*inserting an access needle into the perineal access site of the patient, the access needle supported by one of the plurality of needle receiving ports; and*”**

[1.8]: “*inserting a needle through the access needle and into a first location of the prostate of the patient.*”

Onik does not disclose elements [1.7] and [1.8]. Novella and Nakamura, however, disclose these claim elements, and it would have been obvious to a POSITA to combine Onik-Nakamura with Novella before the ’056 Patent’s priority date for the reasons discussed below.

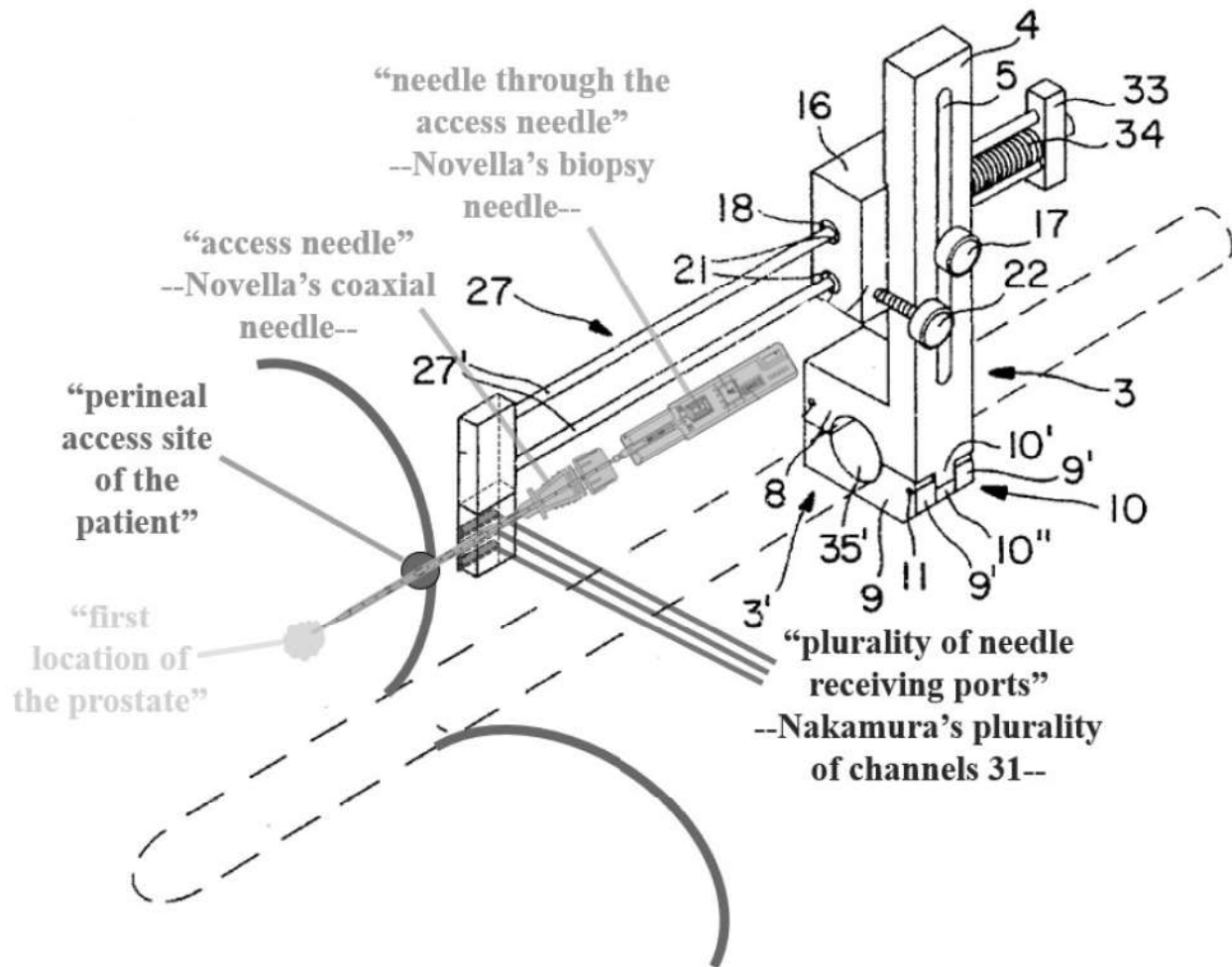
i. Novella Discloses Elements [1.7] and [1.8]

Novella discloses elements [1.7] and [1.8] for the reasons discussed above. *See supra* Section II.A.1.h.ii.

ii. The Onik-Nakamura-Novella Combination

A POSITA would have used Onik’s modified guide 1 with Novella’s biopsy procedures as follows (EX1003, ¶ 171):

⁴ Needle holder assembly 28 “compris[es] a guide block 29 [“vertically extending member”] and a shield 30.” EX1011, 5:36-37.



Onik-Nakamura-Novella Combination*

As seen above, a POSITA would have mounted Onik's guide 1 to Novella's probe, using guide 1 to guide ultrasound imaging and placement of Novella's coaxial and biopsy needles. EX1003, ¶ 161. For the reasons discussed above for the BK Medical-Novella combination, a POSITA would have retained the coaxial needle in the Onik-Nakamura-Novella combination rather than use a biopsy needle alone with Onik's modified guide. *Supra* Section II.A.1.h.iv; EX1003, ¶ 161.

iii. Rationale to Combine Novella with Onik-Nakamura

For at least similar reasons to those discussed above for the BK Medical UA1324 puncture guide, a POSITA would have been motivated to use Novella's coaxial biopsy procedures with Onik's modified guide 1. *Supra* Sections II.A.1.h.iii, II.A.1.h.iv; EX1003, ¶ 162.

The references provide “teaching, suggestion, and motivation” to use Novella’s coaxial needle and the modified Onik guide in the above configuration rather than use a biopsy needle alone. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007); EX1003, ¶ 93. First, Novella concluded that the coaxial technique resulted in less pain and better compliance for patients than the technique using a biopsy needle alone. Novella divided the patients “into two groups: group 1 ... in which we used the 17-gauge coaxial TruGuide needle, and group 2 ... in which the conventional transperineal technique was used.” EX1005, 1. Group 1 (coaxial) reported better outcomes than group 2 (biopsy needle alone) because “[t]he use of a coaxial needle reduces the procedure’s invasiveness and patient’s pain compared with the conventional transperineal prostate biopsy” using a biopsy needle alone. *Id.*; *see id.*, 3 (Table II showing more patients experienced more, and more severe, pain in group 2 than in group 1); EX1003, ¶ 93.

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

In contrast, the coaxial technique “allow[s] the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.” EX1005, 1; *see also* EX1005, 2 (“the coaxial needle was an optimal transperineal path for repeated atraumatic passage of the biopsy needle”); EX1003, ¶ 95. For example, long before the claimed priority date of the ’056 Patent, physicians practiced “a single-access fan technique” that “us[es] a common [perineal] access for all the cores.” EX1008, 1, 3; EX1003, ¶ 95. The coaxial technique does not require general anesthesia—only local “anesthetic ... administered along the [coaxial] needle path.” EX1008, 2; EX1003, ¶ 95. Repeatedly passing a biopsy needle through a coaxial needle and only puncturing the perineum once—opposed to repeatedly puncturing the perineum with the biopsy needle for each sample—minimizes invasiveness, reduces pain, and improves the procedure:

According to the conventional fan technique, biopsies are performed by repeatedly inserting the same biopsy needle through the anesthetized

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

EX1008, 4; EX1003, ¶ 95. Thus, a POSITA would have used Novella's preferred coaxial technique with Onik's modified guide and probe to reduce invasiveness and pain while avoiding the problems with a completely freehand technique, discussed below. EX1003, ¶ 95.

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

Novella used an 18-gauge biopsy needle, which a POSITA would consider a "fine needle." EX1005, 2; EX1003, ¶ 98. The coaxial needle supports the "fine" biopsy needle by preventing it from straying from the chosen direction. EX1015, ¶ 13; EX1003, ¶ 98. The coaxial needle also prevents tumor samples from entering the puncture canal and moving further into the prostate during the procedure. EX1015, ¶ 13; EX1003, ¶ 98. Thus, a POSITA would have retained Novella's coaxial needle (i.e., an "additional needle guide") in performing Novella's biopsy procedures. EX1003, ¶ 98.

Third, the manufacturer (Bard) of the coaxial needle used in Novella describes the coaxial needle as a needle system in which "[t]he coaxial biopsy needle guide is intended for use as a guiding needle." EX1006, 2; EX1003, ¶ 99. TruGuide Manual explains, "BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle is a three-part device consisting of an outer cannula [with a hub and inner stylet]" and "designed for use with BARD® disposable biopsy instruments and

BARD® disposable biopsy needles.” EX1006, 2; *see also* EX1006, 2 (Figure 1 identifies Novella’s coaxial needle (with 18-gauge, 20cm biopsy needle) as reorder no. C1820B); EX1003, ¶ 99. The Manual instructs the practitioner to pass the biopsy needle through the cannula to perform a biopsy, rather than use the biopsy needle alone. EX1006, 3-4 (“Place the appropriate BARD® through the guiding cannula to the lesion to be biopsied” and “Perform the biopsy and remove the biopsy needle from the guiding cannula. Leave the guiding cannula in place”). EX1003, ¶ 99. Because the biopsy and coaxial needles work together as a system, a POSITA would have retained this configuration in the combination to use the Bard equipment properly. EX1003, ¶ 99.

A POSITA similarly would have found obvious the addition of Onik’s modified guide to Novella’s use of a coaxial needle.

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

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

As highlighted on the right in Figure 2, Onik’s guide 1 fits probes of varying sizes because it has “changeable inserts 36 positionable within cut-outs 35 to provide different sizes or shapes of channels 38 in which an ultrasound probe 2 is received and held.” EX1011, 5:58-60. If necessary, a POSITA would have used these inserts 36 to properly fit and secure Novella’s probe in guide 2. EX1003, ¶ 164. Alternatively, a POSITA would have simply used Onik’s probe—which fits without inserts 36--instead of Novella’s probe. *Id.*, ¶ 164. Likewise, notch 31’s “V”

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

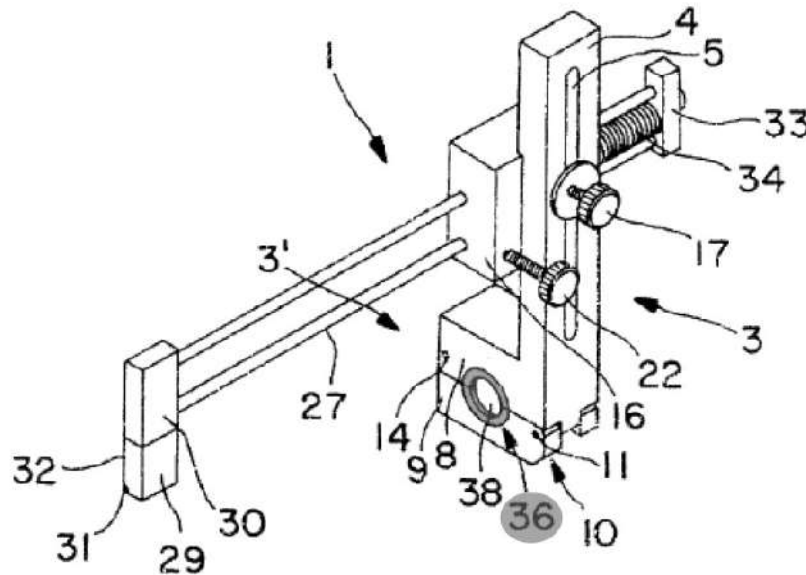


FIG. 2

EX1011, FIG. 2*

2. **Dependent Claim 4**

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

As explained in Ground 1, Novella discloses this element. *Supra* Section II.A.2.a.

3. **Dependent Claim 5**

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

As explained in Ground 1, Novella discloses this element. *Supra* Section II.A.3.a.

4. Dependent Claim 6

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

As explained in Ground 1, Novella discloses this element. *Supra* Section II.A.4.a.

5. Dependent Claim 11

- a. [11.1]: “*The method of claim 10, wherein the needle is a biopsy needle with a needle size of 18 gauge.*”

As explained in Ground 1, Novella discloses this element. *Supra* Section II.A.5.a.

6. Dependent Claim 12

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

As explained in Ground 1, Novella discloses this element. *Supra* Section II.A.6.a.

7. Dependent Claim 13

- a. [13.1]: “*The method of claim 1, further comprising securing the access needle to the one of the plurality of needle receiving ports such that movement of the access needle relative to the vertically extending member is restrained.*”

As explained in Ground 1, Novella discloses this element. *Supra* Section II.A.7.a.

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

1. Dependent Claim 10

- a. [10.1]: “*The method of claim 1, wherein the access needle has a needle size of 14 gauge, 15 gauge, or 16 gauge.*”

As explained above in Ground 2, Zangos discloses the 14-gauge, 15-gauge, or 16-gauge access needle recited in claim 10. *Supra* Section II.B. For the same reasons discussed above in Ground 2, a POSITA would have found it obvious to use Zangos’s coaxial needle with Onik’s modified guide 1 using Novella’s biopsy procedure. *Supra* Section II.B; EX1003, ¶ 219.

III. DISCLOSURE OF CONCURRENT LITIGATION, REEXAMINATION, AND RELATED PROCEEDINGS

Based on the information available to Requester, the ’056 Patent is the subject of one pending District Court litigation, as listed in the table below. Requester is unaware of any prior reexaminations or other post-grant proceedings involving the ’056 Patent.

Title	Case No.	Court	Filed	Status
<i>Advance Medical Designs, Inc. v. Corbin Clinical Resources, LLC</i>	1-22-cv-00789	D. Md.	April 1, 2022	Pending

Additionally, U.S. Patent 11,547,436, a patent related to the '056 Patent, is at issue *Advance Medical Designs, Inc. v. Corbin Clinical Resources, LLC*, PGR2023-00041 (PTAB Jul. 21, 2023 (Pending)).

IV. CONCLUSION

Requester requests the Office to issue an office action rejecting the Challenged Claims based on Grounds 1-4 described above. The Commissioner is hereby authorized to charge Deposit Account 29150 the *Ex Parte* Reexamination fee of \$5,040.00 for a small entity under 37 C.F.R. § 1.20(c)(2). Although Requester believes no other fee is due with this submission, the Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment to Deposit Account 29150.

Please direct all correspondence in this matter to the undersigned.

Dated: September 22, 2023

Respectfully submitted,

By: /James D. Stein/

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 1.248 and 1.550 and MPEP § 2266.03, the undersigned attorney for the Requester certifies that a copy of the foregoing **REQUEST FOR *EX PARTE* REEXAMINATION OF U.S. PATENT NO. 11,446,056** and accompanying Exhibits EX1001 to EX1019 were served by First Class U.S. Mail or equivalent at the following address of record for the subject patent:

24030 - Polsinelli PC
PO Box 140310
Kansas City, MO 64114-0310
United States

Dated: September 22, 2023

By: /James D. Stein/

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



ELECTRONIC PAYMENT RECEIPT

APPLICATION #
90/019,257

RECEIPT DATE / TIME
09/22/2023 09:48:47 AM ET

ATTORNEY DOCKET #
A236-0010RE

Title of Invention

TRANSPERINEAL PROSTATE BIOPSY DEVICE, SYSTEMS, AND METHODS OF USE

Application Information

APPLICATION TYPE Utility / ex parte reexam

PATENT # 11446056

CONFIRMATION # 4521

FILED BY Gwendolyn Ramsey

PATENT CENTER # 62847378

AUTHORIZED BY James Stein

CUSTOMER # 24030

FILING DATE -

CORRESPONDENCE
ADDRESS -

FIRST NAMED
INVENTOR Matthew J. ALLAWAY

Payment Information

PAYMENT METHOD
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PAYMENT TRANSACTION ID
E20239L050236703

PAYMENT AUTHORIZED BY
Gwendolyn Ramsey

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2812	REQUEST FOR EX PARTE REEXAM- NON-STREAMLINED	5040.00	1	5040.00
TOTAL AMOUNT:				\$5,040.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.