UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADVANCE MEDICAL DESIGNS, INC.

Petitioner,

v.

CORBIN CLINICAL RESOURCES, LLC

Patent Owner.

Case No. PGR2023-00041

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

DECLARATION OF DR. EDWARD YUN

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1. [1.pre] "*A method of performing a transperineal biopsy procedure on a prostate of a patient using a transrectal ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the transrectal ultrasound probe including a shaft and a handle proximal to the shaft, the method comprising:*" 35

2. [1.1] "*inserting an access needle into the perineal access site of the patient,*" 37

3. [1.2] "*the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub,*" 38

4. [1.3] "*the tubular shaft including a lumen sized to receive a biopsy needle therethrough;*" 39

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6. [1.5] "*the transperineal biopsy guide comprising: a mount releasably coupled to the transrectal ultrasound probe;*" 55

7. [1.6] "*a guide member coupled to the mount; and*" 57

8. [1.7] "*the displacement member configured to slide relative to the guide member and including a vertically extending member including the plurality of needle receiving ports;*" 58

9. [1.8] "*coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained; and*" 59

10. [1.9] "*inserting the biopsy needle through the access needle and into a first location of the prostate of the patient.*".....61

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1. [13.pre] "*A method of performing a transperineal biopsy procedure on a prostate of a patient using a transrectal ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the transrectal ultrasound probe including a shaft and a handle proximal to the shaft, the method comprising:*".....65

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3. [13.2] "*the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub,*".....66

4. [13.3] "*the tubular shaft including a lumen sized to receive a biopsy needle therethrough,*" 66

5. [13.4] "*the transperineal biopsy guide comprising a mount configured to releasably couple to the transrectal ultrasound probe,*" 66

6. [13.5] "*a guide member extending from the mount, and*" 67

7. [13.6] "*the displacement member configured to slide relative to the guide member;*" 67

8. [13.7] "*securing the access needle to the displacement member such that a position and angle of the access needle relative to the displacement member is maintained;*" 67

9. [13.8] "*imaging the prostate of the patient with the transrectal ultrasound probe;"* 67

10. [13.9] "*inserting the access needle into the perineal access site of the patient; and*" 68

11. [13.10] "*inserting the biopsy needle through the access needle and into the prostate of the patient.*" 68

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1. [24.pre] "*A method of performing a transperineal biopsy procedure on a prostate of a patient using an ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the ultrasound probe including a shaft and a handle proximal to the shaft, the method comprising:*" 69

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3. [24.2] "*the access needle including a tubular shaft and a lumen extending through the tubular shaft,*" 70

4. [24.3] "*the lumen sized to receive a biopsy needle therethrough,*" 70

5. [24.4] "*the transperineal biopsy guide operably coupled to the ultrasound probe and*" 70

6. [24.5] "*including a guide member and the displacement member,*" 70

7. [24.6] "*the displacement member configured to slide relative to the guide member;*" 70

8. [24.7] "*securing the access needle to the one of a plurality of needle receiving ports of the displacement member such that position and angle of the access needle relative to the displacement member is maintained and further insertion of the access needle relative to the displacement member is restricted;*" 71

9. [24.8] "*imaging the prostate of the patient with the transrectal ultrasound probe;*" 73

10. [24.9] "*inserting the access needle into the perineal access site of the patient; and*" 73

11. [24.10] "*inserting the biopsy needle through the access needle and into a first location of the prostate of the patient.*" 73

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1. [1.pre] "*A method of performing a transperineal biopsy procedure on a prostate of a patient using a transrectal ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the transrectal ultrasound probe including a shaft and a handle proximal to the shaft, the method comprising:*".....77

2. [1.1] "*inserting an access needle into the perineal access site of the patient,*" 77

3. [1.2] "*the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub,*".....77

4. [1.3] "*the tubular shaft including a lumen sized to receive a biopsy needle therethrough;*".....78

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7. [1.6] "*a guide member coupled to the mount; and*" 91

8. [1.7] "*the displacement member configured to slide relative to the guide member and including a vertically extending member including the plurality of needle receiving ports;*" 93

9. [1.8] "*coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained; and*" 96

10. [1.9] "*inserting the biopsy needle through the access needle and into a first location of the prostate of the patient.*" 99

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

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2. [13.1] "*inserting an access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide that is secured to the transrectal ultrasound probe,*" 99

3. [13.2] "*the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub,*"....100

4. [13.3] "*the tubular shaft including a lumen sized to receive a biopsy needle therethrough,*" 100

5. [13.4] "*the transperineal biopsy guide comprising a mount configured to releasably couple to the transrectal ultrasound probe,*" 100

6. [13.5] "*a guide member extending from the mount, and*" 100

7. [13.6] "*the displacement member configured to slide relative to the guide member;*" 101

8. [13.7] "*securing the access needle to the displacement member such that a position and angle of the access needle relative to the displacement member is maintained;*"....101

9. [13.8] "*imaging the prostate of the patient with the transrectal ultrasound probe;"*....101

10. [13.9] "*inserting the access needle into the perineal access site of the patient; and*" 102

11. [13.10] "*inserting the biopsy needle through the access needle and into the prostate of the patient.*"....102

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1. [24.pre] "*A method of performing a transperineal biopsy procedure on a prostate of a patient using an ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the ultrasound probe including a shaft and a handle proximal to the shaft, the method comprising:*" 103

2. [24.1] "*inserting an access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide that is secured to the ultrasound probe,*" 103

3. [24.2] "*the access needle including a tubular shaft and a lumen extending through the tubular shaft,*" 104

4. [24.3] "*the lumen sized to receive a biopsy needle therethrough,*" 104

5. [24.4] "*the transperineal biopsy guide operably coupled to the ultrasound probe and*" 104

6. [24.5] "*including a guide member and the displacement member,*" 104

7. [24.6] "*the displacement member configured to slide relative to the guide member;*" 105

8. [24.7] "*securing the access needle to the one of a plurality of needle receiving ports of the displacement member such that position and angle of the access needle relative to the displacement member is maintained and further insertion of the access needle relative to the displacement member is restricted;*" 105

9. [24.8] "*imaging the prostate of the patient with the transrectal ultrasound probe;*" 107

10. [24.9] "*inserting the access needle into the perineal access site of the patient; and*" 107

11. [24.10] "*inserting the biopsy needle through the access needle and into a first location of the prostate of the patient.*" 107

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I. INTRODUCTION

1. I have been retained by counsel for Advance Medical Designs, Inc. ("Petitioner") in connection with the proceeding identified above. I have been asked to provide my opinions and views on the materials I have reviewed in relation to U.S. Patent No. 11,547,436 ("the '436 Patent") (EX1001) and my medical knowledge regarding the subject matter of the '436 Patent before and at the earliest effective U.S. filing date. I submit this Declaration in support of Petitioner's Petition for post-grant review of the '436 Patent against Clinical Corbin Resources, LLC ("Patent Owner").

II. PROFESSIONAL BACKGROUND

2. I received a Bachelor of Science degree in Cellular and Molecular Biology from the University of Michigan in 1994. I received my medical degree from Columbia University in 1998 and completed my urology residency training at the University of California, San Francisco in 2004. I became board-certified by the American Board of Urology in 2006, and recertified in 2014.

3. Since 2004, I have been in full-time urologic practice at the Urology Center of Southern California. I have also served as Chief of Urology at Riverside Community Hospital. Additionally, I am an Assistant Clinical Professor in the Department of Urology at the University of California, Irvine.

4. I am involved in a number of professional organizations, including the American Urological Association and the American Association of Clinical Urologists. I have also served on several hospital committees, including the Medical Staff Quality Review Committee, Surgical Quality Review Committee, and Ethics Committee. Additionally, I have received academic honors and awards related to my work, such as being the American Urological Association Gerald P. Murphy Scholar in 2004. I have been recognized by the America's Top Urologists' Consumers' Research Council of America.

5. As a practicing urologist, I have extensive experience with both transrectal and transperineal procedures. These approaches to the prostate and urethra are commonly used in urologic practice, for both treatment of benign and malignant conditions, including prostate cancer. Also, in my capacity as a faculty member of the Department of Urology at University of California, Irvine, and my role as an attending physician in our local hospitals, I teach and oversee the proper use of transrectal and transperineal techniques to medical students and to physicians in training.

6. I understand that my *curriculum vitae* is attached to the Petition as **EX1004**.

7. I am being paid at my standard hourly rate of $650 for writing this report. I am being paid regardless of the conclusions or opinions I reach. I have no personal or financial stake or interest in the outcome of the present post-grant review.

III. MATERIALS CONSIDERED

8. My opinions and views set forth in this report are based on my education, training, and experience in field of urology, as well as the materials I reviewed in this case, and the medical knowledge regarding the same subject matter that existed prior to the earliest effective filing date of the '436 Patent. I have been informed that the earliest effective filing date of the '436 Patent is April 3, 2014.

9. I have considered information from various sources in forming my opinions. Besides drawing from my experience as a urologist for the past fourteen years, I also have reviewed the following documents:

Exhibit	Description
EX1001	U.S. Patent No. 11,547,436 to Matthew J. Allaway (the "'436 Patent")
EX1002	File History of the '436 Patent
EX1004	*Curriculum Vitae* of Edward J. Yun, M.D.
EX1005	Giovanni Novella et al., *Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle*, 62 UROLOGY 689 (2003) ("Novella")
EX1006	Bard Biopsy Systems, Bard® TruGuide® Disposable Coaxial Biopsy Needle Instructions for Use (May 2012)
EX1007	BK Medical, Prostate Biplane Transducer Type 8808e, User Guide (June 2012) ("BK Medical")

Exhibit	Description
EX1008	Antonio Galfano et al., Prostate Biopsy: The Transperineal Approach, 5 EUR. ASS'N UROLOGY 241 (2007) ("Galfano")
EX1009	BK Medical, Endoscopic Probe User Guide, Type 1850 (Aug. 2006) ("BK Medical 2")
EX1010	Stephan Zangos, et al., *MR-Guided Transgluteal Biopsies with an Open Low-Field System in Patients with Clinically Suspected Prostate Cancer: Technique and Preliminary Results*, 15 EUR. RADIOL. 174 (Sept. 4, 2004) ("Zangos")
EX1011	U.S. Patent No. 5,494,039 to Gary Onik, et al. ("Onik")
EX1012	Japanese Patent No. 4,550,531 to Hisashi Nakamura ("Nakamura") with English language translation and certification of accurate translation
EX1018	The Parties' Claim Construction Statements in *Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC*, No. 1:22-cv-00789-SAG (D. Md.)
EX1019	Patent Owner's Amendment Infringement Contentions for the '436 Patent in *Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC*, No. 1:22-cv-00789-SAG (D. Md.)

IV. RELEVANT LEGAL STANDARDS

10. I am not an attorney. My analysis and opinions are based on my expertise in this technical field, as well as the instructions I have been given by counsel for the legal standards relating to patentability.

11. I have been informed by counsel for Petitioner that the following legal principles may apply to analysis of patentability based on 35 U.S.C. §§ 102 for anticipation and 103 for obviousness. I have also been informed that, in a post-grant proceeding such as this proceeding, a patent claim is unpatentable if it is shown by

a preponderance of the evidence that the claim would have been anticipated by a prior art patent or publication or that the claim would have been obvious by one or more properly combined prior art patents or publications.

A. Level of Ordinary Skill in the Art

12. I have been instructed to consider patentability of the Challenged Claims through the lens of a person of ordinary skill in the art ("POSITA") at the time of the claimed priority date of the '436 Patent: April 3, 2014. I am familiar with the level of ordinary skill in the subject matter of the '436 Patent in April 2014. Based on my review of the technology, and drawing on my own experience in the field, my analysis below assumes that a POSITA would have had at least an advanced medical degree (*e.g.*, a Doctor of Medicine or a Doctor of Osteopathic Medicine), at least two years of experience performing prostate biopsy procedures, and some exposure to transperineal prostate biopsies and medical device design. In my opinion, however, less experience may be compensated by more or different education or training, or vice versa.

13. Based on my qualifications discussed above, I qualified at least as a POSITA of the '436 Patent by April 3, 2014.

14. My analysis below considers how a POSITA would have understood the references listed above with respect to the Challenged Claims of the '436 Patent.

B. Anticipation

15. I have been informed a patent claim is unpatentable as anticipated under 35 U.S.C. § 102 if every limitation of the claimed invention is found in a single prior art reference—either expressly or required through inherency—as arranged in the claim.

C. Obviousness

16. I have been informed that, even if a single prior art reference does not disclose each and every element of a patent claim, the patent claim is still unpatentable as obvious under 35 U.S.C. § 103. It is my understanding that a claimed invention is unpatentable as obvious over a combination of prior art references if the differences between the claimed invention and the prior art are such that a POSITA would have found the subject matter as a whole obvious.

17. I understand that obviousness is determined by evaluating: (1) the scope and content of the prior art, (2) the differences between the prior art and the claim, (3) the level of ordinary skill in the art, and (4) any secondary considerations of non-obviousness. To establish obviousness based on a combination of the elements disclosed in the prior art, it is my understanding that a challenger must provide a clear articulation of the reasons why the claimed invention would have been obvious. I understand this articulation may, but does not necessarily, require record evidence

of an explicit teaching, suggestion, or motivation to combine the prior art in the way recited in a patent claim. Rather, prior art may be combined based on an express teaching, suggestion, or motivation from the prior art itself or from a reasoned explanation of an expert witness or some other rationale.

18. For example, it is my understanding that this articulation can come from a number of rationales, which include but are not limited to (1) combining prior art elements according to known methods to yield predictable results; (2) simple substituting one known element for another to obtain predictable results; (3) using a known technique to improve similar devices, methods, or products in the same way; (4) applying a known technique to a known device, method, or product ready for improvement to yield predictable results; (5) choosing from a finite number of identified, predictable solutions with a reasonable expectation of success (*e.g.*, the combination is "obvious to try"); (6) citing known work in one field of endeavor that may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to a POSITA; and (7) relying on some teaching, suggestion, or motivation in the prior art that would have led a POSITA to modify the prior art reference or to combine its teachings to arrive at the claimed limitation.

19. I further understand that these rationales may be found explicitly or implicitly (1) in the prior art, (2) in the knowledge of a POSITA that certain references, or disclosures in those references, are of special interest or importance in the field, or (3) from the nature of the problem to be solved. Additionally, I understand that the legal determination of the motivation to combine references allows recourse to logic, judgment, and common sense. In order to resist the temptation to read into prior art the teachings of the invention in issue, however, it should be apparent that the expert is not conflating "common sense" and what appears obvious in hindsight. I understand that if the teachings of a prior art reference would lead a POSITA to make a modification that would render another prior art device inoperable, then such a modification may not be obvious. I also understand that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there may be no suggestion or motivation to make the proposed modification.

20. I understand that it may be improper to combine references where the references teach away from their combination. I understand that a reference may be said to teach away when a POSITA, upon reading the reference, would be discouraged from following the path set out in the reference or would be led in a direction divergent from the path that was taken by the patent applicant. In general, a reference teaches away if it suggests that the line of development flowing from the

reference's disclosure is unlikely to be productive of the result sought by the patentee. I understand that a reference teaches away, for example, if (1) the combination would produce a seemingly inoperative device or if (2) the references leave the impression that the product would not have the property sought by the patentee. I also understand, however, that a reference does not teach away if it merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the invention claimed.

D. Claim Construction

21. Counsel has instructed me that, in a post-grant proceeding, the words of a claim are to be given their broadest reasonable interpretation consistent with the specification. Under this standard, I am instructed that the U.S. Patent and Trademark Office determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction in light of the specification as it would be interpreted by a POSITA. In my analysis, I have applied this standard.

V. THE '436 PATENT

A. Prior Art Background

1. Prostate Biopsy Procedures

22. The '436 Patent relates to prostate biopsy procedures—procedures that sample and remove tissue from the prostate of a patient for further examination and

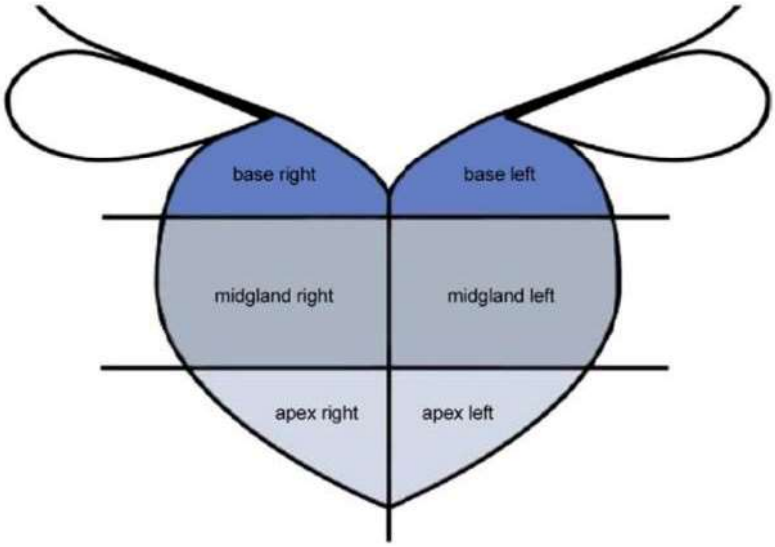
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analysis, such as for cancerous tissue. EX1001, Abstract, 1:40-47. There are two types of prostate biopsy procedures: transrectal ultrasound-guided (TRUS) biopsies and transperineal ultrasound-guided (TPUS) biopsies. *Id*., 47-49. The first reported prostate needle biopsy in the United States was performed more than a century ago via the transperineal approach, and the interest in these two approaches has vacillated back and forth since that time. For example, the rise in utilization of brachytherapy at in the late 1990s and early 2000s allowed urologists to become familiar with the use of probe-mounted needle guides and access/coaxial needles for other percutaneous transperineal prostate procedures, such as cryotherapy and transperineal biopsies. Therefore, probe-mounted needle guides and access/coaxial needles were in use well before April 3, 2014 for multiple urological procedures, including an alternative access route for prostate biopsy. I am personally familiar with these types of devices being in active use from the first year of my urology residency in 2000 to the present day.

23. A TRUS biopsy "involves obtaining tissue or cell specimens by passing a biopsy needle or other biopsy instruments through the rectal wall and into the prostate at various locations." *Id*., 1:50-52. A TPUS biopsy, meanwhile, "obtain[s] tissue specimens by passing one or more biopsy needles through the perineum and into the prostate." *Id*., 2:1-3. In both procedures, the practitioner typically uses a

transrectal ultrasound probe to guide the needle to target locations of the prostate. *Id*., 1:40-2:35.

24. One common type of prostate biopsy—called a sextant biopsy—involves sampling tissue from six areas of the prostate: the left and right sides of each of the base, midgland, and apex regions of the prostate. EX1005, 2. The figure on the right shows the six areas of the prostate viewed in the sagittal plane (looking through the perineum), which divides the body into upper and lower halves.



2. Biopsy Needles

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

once to take multiple tissue samples. EX1005, 1, 2, 4. This is because the practitioner leaves the coaxial needle in place in the patient's perineum and repeatedly passes the biopsy needle through the lumen of the coaxial needle to sample different locations of the prostate. EX1005, 1, 2, 4; EX1008, 1, 3, 4 (discussing the "fan technique"). The prior art Figure on the right shows a biopsy needle being inserted through a coaxial needle. EX1005, 2.

3. Biopsy Guides

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



Figure 8. Puncture attachment UA1324 mounted on 8808e.

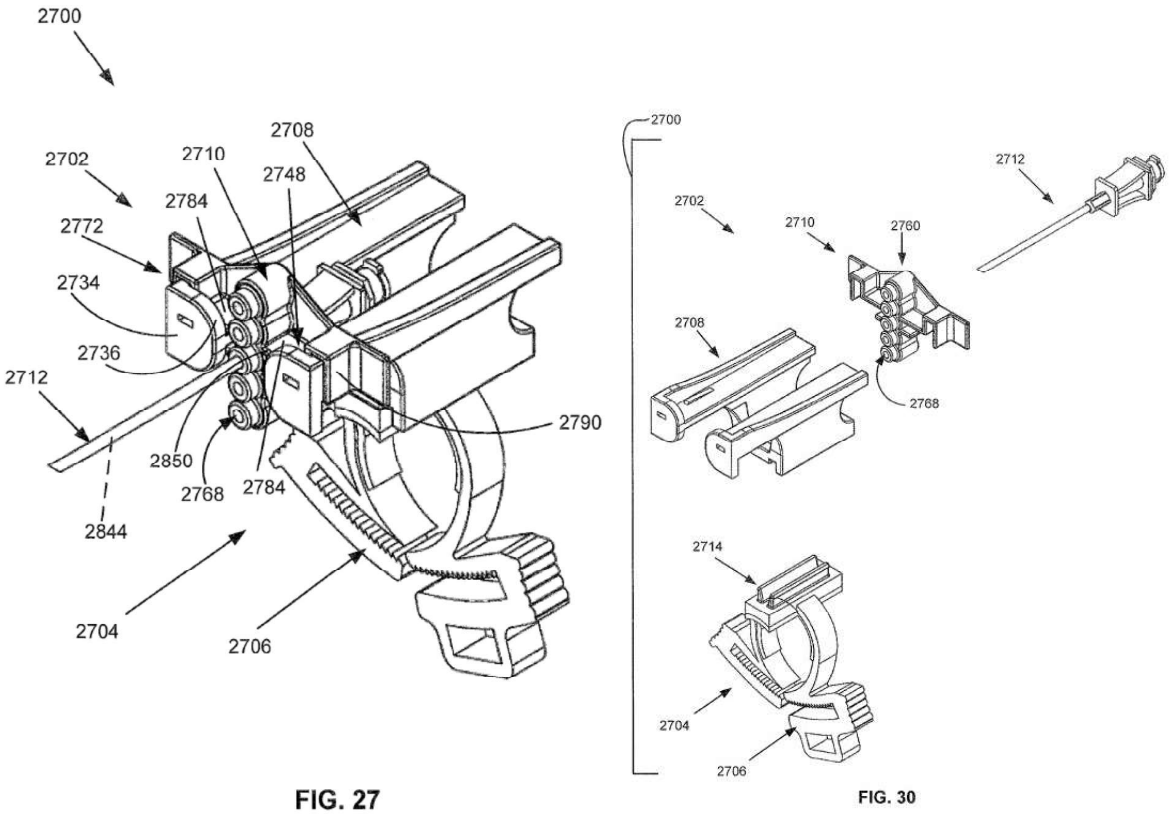


Figure 7. Puncture attachment UA1324.

27. It was known in the art before the claimed priority date to use a coaxial biopsy needle with a probe-mounted transperineal biopsy guide in prostate biopsy procedures. For example, as I explain below, BK Medical 2 shows a probe-mounted biopsy guide UA0650 configured with a coaxial needle. EX1009, 1, 14.

B. The Transperineal Biopsy Guide of the '436 Patent

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



'436 Patent, FIGS. 27, 30

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

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

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

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

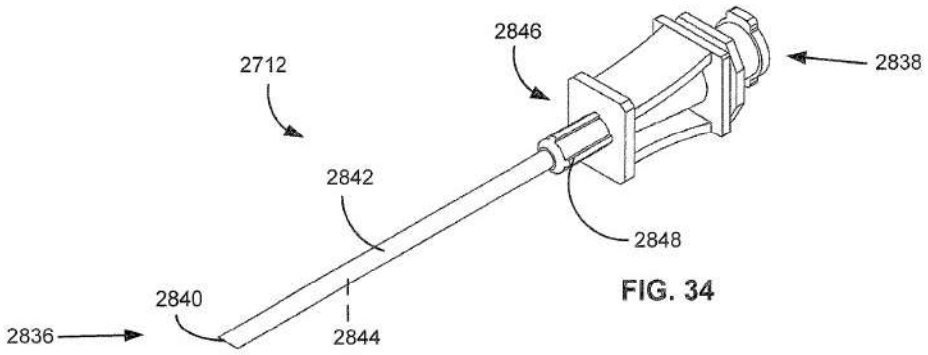


FIG. 34

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

C. Prosecution History

32. I understand that in the first Office Action, the Examiner rejected all claims as anticipated by U.S. Patent No. 5,931,786 ("Whitmore"). EX1002, 208-210. Patent Owner argued that Whitmore failed to teach "inserting an access needle into the perineal access site of the patient and inserting a biopsy needle through the access needle." *Id*., 197. According to Applicant, "[n]owhere in Whitmore is there description of an access needle or inserting an access needle into the perineal access site of the patient" or any "description of inserting a biopsy needle through the access needle." *Id.*, 198.

33. I understand Applicant and Examiner then held an interview in which Examiner "suggested amending the claims to recite 'securing position and angle of the access needle relative to the displacement member' to further clarify the claim and put the case in condition for allowance." *Id.*, 39. Following the interview, I understand the Examiner issued a Notice of Allowance and concurrently amended the independent claims to reflect the position and angle limitations discussed during the interview. *Id.*, 30, 35-37. The Examiner cited these limitations in the Examiner's Reasons for Allowance, stating that Whitmore, Onik, and two other references of record did not disclose "coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained." *Id*., 36-37.

34. As I explain below, it is my opinion that Petitioner's prior art addresses the reason the Examiner allowed the '436 Patent claims. BK Medical (EX1007), in my opinion, discloses a transperineal biopsy guide having a displacement member with multiple needle receiving ports that retain a position and angle of a needle coupled to the displacement ports. It is my further opinion that Nakamura (EX1012) also discloses a transperineal biopsy guide with a multiple needle receiving ports to retain the position and angle of the needle. And although the Examiner did not find Patent Owner's "access needle" argument persuasive or cite it in the Reasons for

Allowance, Novella (EX1005), in my opinion, shows this was not only known in the art to use a coaxial needle (access needle) in transperineal prostate biopsies but advantageous to using a biopsy needle alone.

35. I understand that Patent Owner cited Petitioner's initial invalidity contentions from the parallel litigation in an Information Disclosure Statement, but those contentions did not include Nakamura. *Id*., 179-189. Moreover, it appears the record suggests that the Examiner overlooked and/or failed to appreciate the content of Novella, BK Medical, or Zangos alone or in Petitioner's proposed combinations. And while the Examiner may have considered Onik alone, the Examiner did not consider Onik as presented in the combinations in Grounds 3 and 4 of the Petition. *See* EX1002, 36, 37; EX1001, 1.

VI. CLAIM CONSTRUCTION

36. In a post-grant review, I understand claim terms are generally given their ordinary and customary meaning, which is the meaning that the term would have to a POSITA at the time of the invention, *i.e.*, as of the effective filing date of the patent application. I further understand that the POSITA is deemed to have read the claim terms not only in the context of the particular claim language in which the terms appear, but in the context of the entire patent, including the specification and prosecution history.

37. The Board, I understand, only construes the claims when necessary to resolve the underlying controversy. I understand that Petitioner submits that no express constructions are needed to resolve the Grounds in this Petition but discusses the scope of "coupling" for element [1.8] and "securing" for elements [13.7] and [24.7] below. Additionally, Petitioner submits the parties' claim construction statements in the related litigation. *See* EX1018. I understand Petitioner reserves the right to raise claim construction and other arguments in this and other proceedings as relevant and necessary. Below I identify where the intrinsic record of the patent supports Petitioner's proposed constructions

A. Coupling …" (Element [1.4]) and "Securing …" (Elements [13.7] and 24.7])

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

39. It is my opinion that the claim language only requires coupling or securing to retain "[a] position and angle"—not necessarily locking all degrees of freedom of the access needle. Dependent claims 10, 22, 25, and 26 recite inserting a

portion of the access needle hub or other structure into one of the needle receiving ports, which would restrict the access needle beyond that required by the independent claims. For example, the access needle hub may have "ridges 2848 [that] engage with corresponding and negatively shaped features on … the needle receiving ports 2768" so "access needle 2712 may be restrained from rotating by the ridges 2848." EX1001, 25:11-13, 25:64-26:2, FIG. 34. Or "threaded features on the hub 2846 and openings 2770 of the ports 2768" allow "needle 2712 and the displacement member 2710 [to] be threadably engaged and disengaged with each other" (i.e., "screwing" the access needle into the port). *Id*., 26:2-7. But the independent claims, in my opinion, do not require such structure or completely locking the access needle to the displacement member. Thus, in my opinion, the claim language and specification support Petitioner's interpretation of the "coupling" and "securing" elements.

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





Figure 7. Puncture attachment UA1324.

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

Thus, I understand Patent Owner does not contend that "coupling" or "securing" an access needle on the SureFire completely locks the access needle in place on the needle guide—only that it "maintain[s] the stability and directionality of the coaxial needle or the puncture needle." EX1019, 22.

41. Accordingly, for purposes of my declaration, I interpret the "coupling" and "securing" elements as in Patent Owner's infringement contentions—not requiring locking the access needle in place but maintaining the stability and directionality of the access needle.

VII. THE PRIOR ART

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

1. Novella (EX1005)

42. Novella is a study published in 2003 in *Urology*, a well-known urology journal. EX1005, 1. I have been asked to assume Novella qualifies as a prior art printed publication to the '436 Patent.

43. Novella compared two variations of transperineal prostate biopsy procedures: (1) with a biopsy needle alone and (2) with a coaxial needle. EX1005, Abstract. Novella aimed to "assess whether the use of a coaxial needle reduces discomfort in patients undergoing multiple-core transperineal prostate biopsy to detect prostate cancer." *Id*. Novella concluded that the coaxial technique was "significantly less painful" for patients than those using the biopsy needle alone. EX1005, 1.

44. Novella divided 102 patients into two groups. *Id*., 1. The first group underwent transperineal biopsy with the coaxial technique using a 17-gauge coaxial needle (TruGuide Bard) and 18-gauge biopsy needle to minimize the invasiveness of the procedure. *Id*., 1-2. The coaxial needle provided "an optimal transperineal path for repeated atraumatic passage of the biopsy needle." *Id*. That is, Novella

punctured the perineum with the coaxial needle once, and then repeatedly passed the biopsy needle through the coaxial needle to biopsy the prostate multiple times.

45. In the second group, Novella's practitioner used a biopsy needle only, without a coaxial needle. EX1005, 1. In this method, "the [biopsy] needle is repeatedly inserted through the perineal plane under local anesthesia." *Id.*, 1. That is, instead of inserting the biopsy needle through an already-placed coaxial needle, the practitioner punctured the perineum multiple times with the biopsy needle to take multiple biopsies. In both groups 1 and 2, "[f]ourteen cores were sampled in every patient (double sextant biopsy from the peripheral and two cores from the transition zone)." EX1005, 1; *see also* EX1005, 2, 4.

46. At the end of the biopsy procedure, each patient received a questionnaire to assess the level of pain at various steps of the procedure. *Id.*, 1, 2. The results revealed that group 1 (coaxial) patients experienced significantly less pain than group 2 (biopsy needle only). *Id*., 2. "In group 1, 49 (96.1%) had mild pain and 2 (3.9%) had moderate pain. No group 1 patients reported a score greater than 6." *Id*. But in group 2, 42 patients (82.4%) recorded mild pain, 8 (15.6%) moderate pain, and 1 (2%) severe pain (Table II)." *Id.*

TABLE II. ***Difference in subjective measures between studied groups***

	Group 1 (%)	Group 2 (%)
Whole procedure		
No pain (0)	0	0
Mild pain (1–4)	49 (96.1)	42 (82.4)
Moderate pain (5–7)	2 (3.9)	8 (15.6)
Severe pain (>7)	0	1 (2)
Multiple-core sampling		
No pain (0)	14 (27.5)	6 (11.8)
Mild pain (1–4)	35 (68.5)	37 (72.5)
Moderate pain (5–7)	2 (4)	7 (13.7)
Severe pain (>7)	0	1 (2)

Id.

47. The authors concluded "the use of a coaxial needle significantly reduced the experienced pain during prostate sampling and improved patient compliance compared with the conventional transperineal biopsy technique." *Id*., 4. Novella also concluded the "results support the widespread use of a coaxial needle during transperineal prostate biopsy." *Id*. The coaxial needle "makes the procedure easier and quicker" because "[t]he guiding cannula forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle." *Id.*

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

48. TruGuide Manual is an instruction manual for the coaxial needle used by Novella and thus, in my opinion, shows the characteristics of that coaxial needle and knowledge a POSITA using that needle would have had. EX1006.

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

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



Id., 1. To biopsy tissue, the Manual instructs the practitioner to "[p]lace the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be

biopsied," "[p]erform the biopsy and remove the biopsy needle from the guiding cannula," and "[l]eave the guiding cannula in place" for further biopsies. *Id*., 3-4.

3. Galfano (EX1008)

51. Galfano is a study in the European Association of Urology in 2007 by some of the same authors of Novella (including Galfano). EX1008, 1. Counsel has instructed me to assume that Galfano qualifies as a prior art printed publication to the '436 Patent.

52. Like Novella, Galfano studied TRUS prostate biopsy and found that patients undergoing biopsy with "the coaxial needle showed a reduction in pain during the biopsy and a better compliance" than patients who underwent biopsy with the biopsy needle alone. EX1008, 4. This is because, with a biopsy needle alone, "the execution of multiple punctures on perineal skin and multiple perineal paths … makes it almost impossible to perform adequate local anesthesia. *Id*., 3. Thus, most patients "use a general or spinal anesthesia" instead of local. EX1008, 3. "The main disadvantage of this technique is the need for spinal or general anesthesia" apart from increased invasiveness. *Id*., 4.

53. In contrast, with a coaxial needle, "biopsies are performed by repeatedly inserting the same biopsy needle through the anesthetized perineal path," using the "coaxial needle [to] perform[] the several needle passages through the same path." *Id*. The coaxial needle "makes the procedure easier and quicker,

allowing the repeated introduction of the needle with low perineal trauma." *Id*. And because the coaxial technique involves "the execution of only one or two skin punctures following the same perineal path, local anesthesia is feasible with good results." *Id*., 3. General or spinal anesthesia is not needed.

4. Zangos (EX1010)

54. Zangos is a prostate biopsy study published by Springer in *European Radiology* in January 2005. Counsel instructs me to assume Zangos qualifies as a prior art printed publication to the '436 Patent.

55. Zangos sought to determine the feasibility of MR-guided transgluteal prostate biopsies. EX1010, 1. "The prostate gland was biopsied repeatedly with a coaxial technique through a 15- gauge pencil tip with a 16-gauge biopsy handy (median 3.8 samples per patient)." *Id.* Out of 25 patients, the technique revealed prostate cancer in ten. *Id.* The authors concluded that the technique "is a safe and promising approach for histological clarification of uncertain or suspicious lesions." *Id*.

B. References Disclosing Transperineal Biopsy Guides

1. BK Medical (EX1007)

56. BK Medical is a User Guide for a BK Medical Type 8808e Prostate Biplane Transducer (2012). EX1007, 1. I have been instructed to assume that BK

Medical qualifies as prior art to the '436 Patent. I have been familiar with BK Medical and its urology-related products since roughly the early 2000s.

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



Figure 7. Puncture attachment UA1324.



Figure 8. Puncture attachment UA1324 mounted on 8808e.

EX1007, 12. Designed for "transperineal puncture and biopsy," the "UA1324 consists of a needle guide and a mounting ring with clamp." *Id*. "To mount the transperineal puncture attachment, ensure that the dummy channel bracket UA1325 is in place," "[l]oosen the clamp on UA1324, and slide the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer." *Id*.

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

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

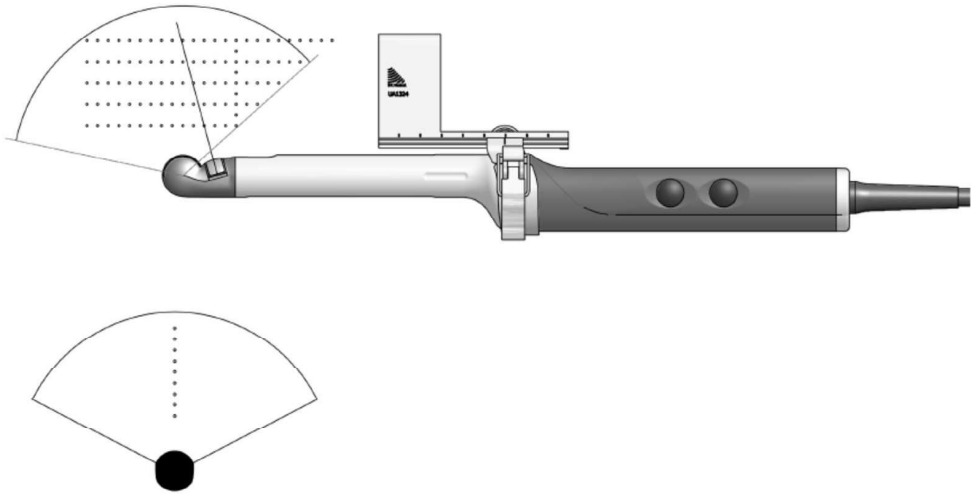


Figure 9. Illustration of the puncture line for puncture attachment UA1324.

EX1007, 13

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

2. BK Medical 2 (EX1009)

60. I have been asked to assume that BK Medical 2, a user guide for the BK Medical Type 1850 probe, is prior art to the '436 Patent.

61. In my opinion, BK Medical 2 demonstrates that it was known in the art to use a coaxial needle with a probe-mounted transperineal biopsy guide. EX1009, 15, 16. In Figure 11 below, BK Medical 2 shows the Type 1850 probe "assembled for transrectal scanning with puncture attachment UA0650." EX1009, 14. This is consistent with my understanding of the prior art.

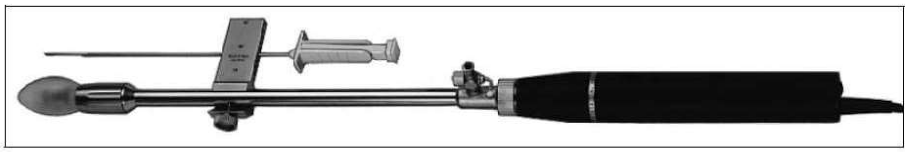
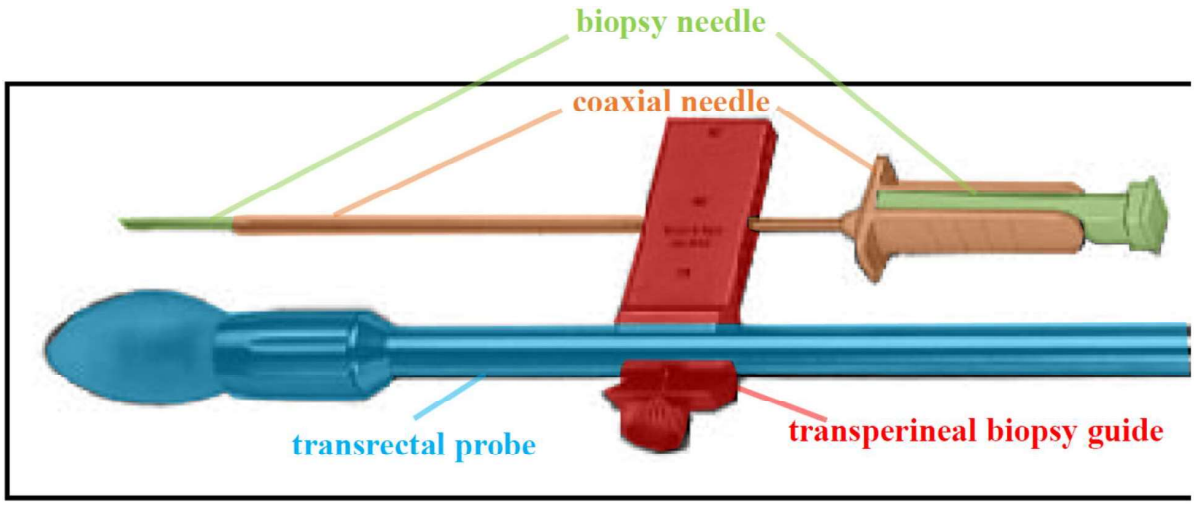


Fig. 11. Type 1850 assembled for transrectal scanning with puncture attachment UA0650

EX1009, FIG. 11

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



EX1009, FIG. 11*

BK Medical 2 explains that "[i]f a fine needle is used, it may be helpful to use an additional needle guide." EX1009, 16. Here, "fine needle" and "needle guide" respectively refer to the biopsy needle and coaxial needle. Thus, in Figure 11, it is my opinion that the coaxial needle supports the "fine" biopsy needle.

62. In my opinion, the coaxial needle supports the "fine" biopsy needle by preventing it from straying from the chosen direction. Furthermore, in my opinion, coaxial needle also prevents the tumor sample from entering the puncture canal and moving further into the prostate during the procedure.

3. Onik (EX1011)

63. Onik is a U.S. Patent filed in 1993 and issued in 1996, which I understand qualifies as prior art to the '436 Patent. EX1011, 1.

64. Onik discloses "[a] biopsy needle insertion guide and method of use with an ultrasound probe in medical procedures to accurately position biopsy needles in internal tissues." EX1011, Abstract.

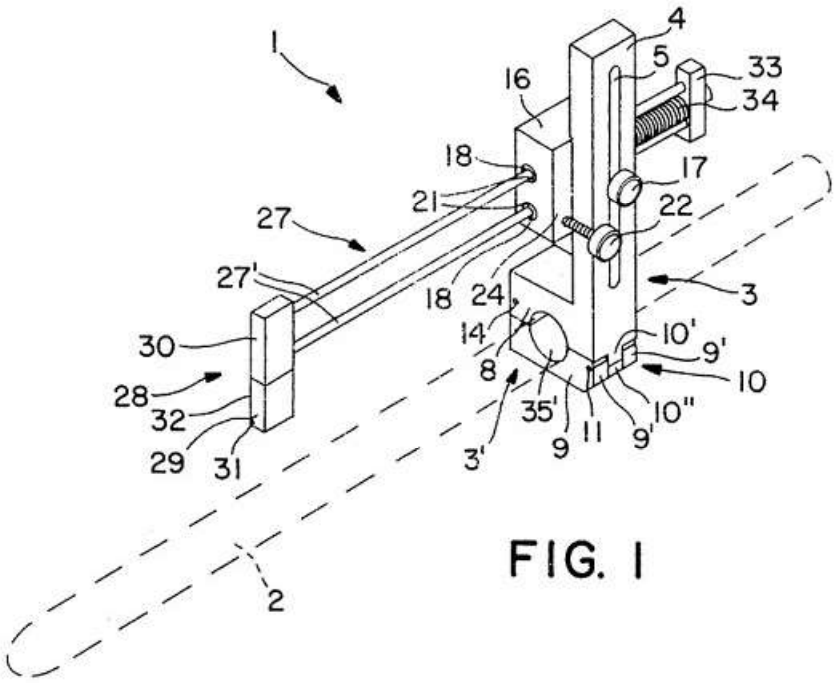


FIG. 1

Onik, FIG. 1

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

65. "Slidably associated with anterior-posterior adjustment guide 4 is a slide block 16 which provides anterior and posterior positioning adjustment for a biopsy needle relative to ultrasound probe 2." EX1011, 4:36-39. "Extending through the slide block 16 in a direction parallel to the longitudinal axis of ultrasound probe 2 is at least one channel 18 which slidably receives a needle holder and guide assembly 27." *Id.*, 4:58-61.

66. In use, the position of the needle holder and guide assembly 27 is adjustable relative to the slide block 16 to position needle holder assembly 28 firmly against the perineum of the patient. EX1011, 7:16-26. "The combination of the firm engagement of the perineum by needle holder assembly 28 and the fixation of insert guide 1 to ultrasound probe 2 provides a stable guide for accurate insertion of biopsy needles into the prostate." *Id.*, 7:30-34. Guide block 29 of guide assembly 27 has "an elongated notch 31 in one face adjacent the lower end of block 29," such as "a simple 'V' notch" that "provide[s] guidance for a biopsy needle being inserted." *Id.*, 5:39-46.

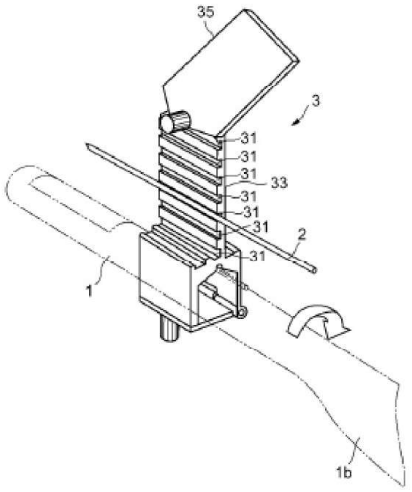
4. Nakamura (EX1012)

67. Nakamura is a Japanese Patent Application published on September 22, 2010, which I understand qualifies it as prior art to the '436 Patent. EX1012, 17.

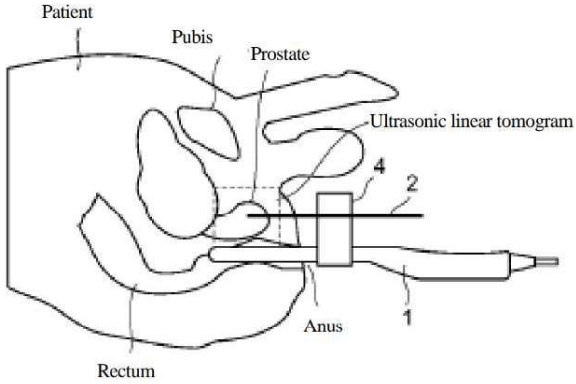
68. Like BK Medical, Nakamura describes "a puncture adapter for transperineal puncture, mounted on a transrectal probe" in which "a puncture needle

is inserted into a subject to sample or treat tissue in an affected area." EX1012, ¶[0001].

[FIG. 10]



[FIG. 18]



Nakamura, FIGS. 10, 18

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

70. To perform a transperineal procedure, "transrectal probe 1 is inserted into the rectum of a patient, an ultrasonic linear cross-sectional image is referenced,

the … transrectal probe 1 is controlled with one hand, the puncture needle 2 is held in the other hand, and the puncture needle 2 is inserted at a site where examination or treatment is being performed. *Id.*, ¶[0048]. The practitioner selects "a guide hole corresponding to a target position … from the plurality of guide holes" and "the puncture needle 2 is entered into the selected guide hole, and the puncture needle 2 is inserted" into the treatment area. *Id.*

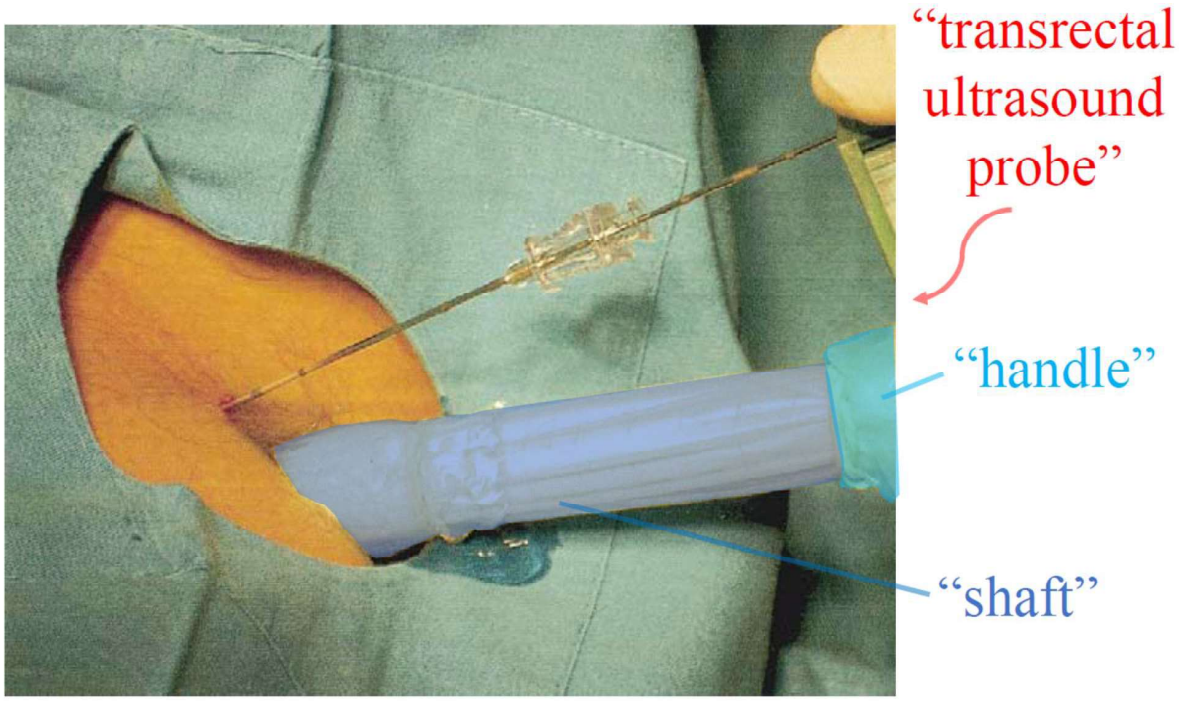
VIII. GROUND 1: NOVELLA IN VIEW OF BK MEDICAL RENDERS OBVIOUS CLAIMS 1, 4-6, 12-13, 16-18, 24, and 28

A. Independent Claim 1

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

71. To the extent the preamble is limiting, it is my opinion that Novella discloses a method of performing a transperineal biopsy procedure (transperineal biopsy with coaxial needle) on a prostate of a patient using a transrectal ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate. Novella sought to "assess whether the use of a coaxial needle reduces discomfort in patients undergoing multiple-core transperineal prostate biopsy to detect prostate cancer." EX1005, Abstract.

72. Novella performed transperineal biopsy procedures with a transrectal ultrasound probe configured to provide imaging, as claimed: "In every case, we performed a 14-core transperineal prostate biopsy under transrectal ultrasound guidance." *Id.* Specifically, "[a]ll biopsies were performed by a single urologist (G.N.)" and "TRUS was carried out using the Siemens Sonoline Omnia Diagnostic Ultrasound System, with a 7.75-MHz linear probe." *Id*., 2. As seen below, the probe has a shaft and handle proximal the shaft, as claimed:



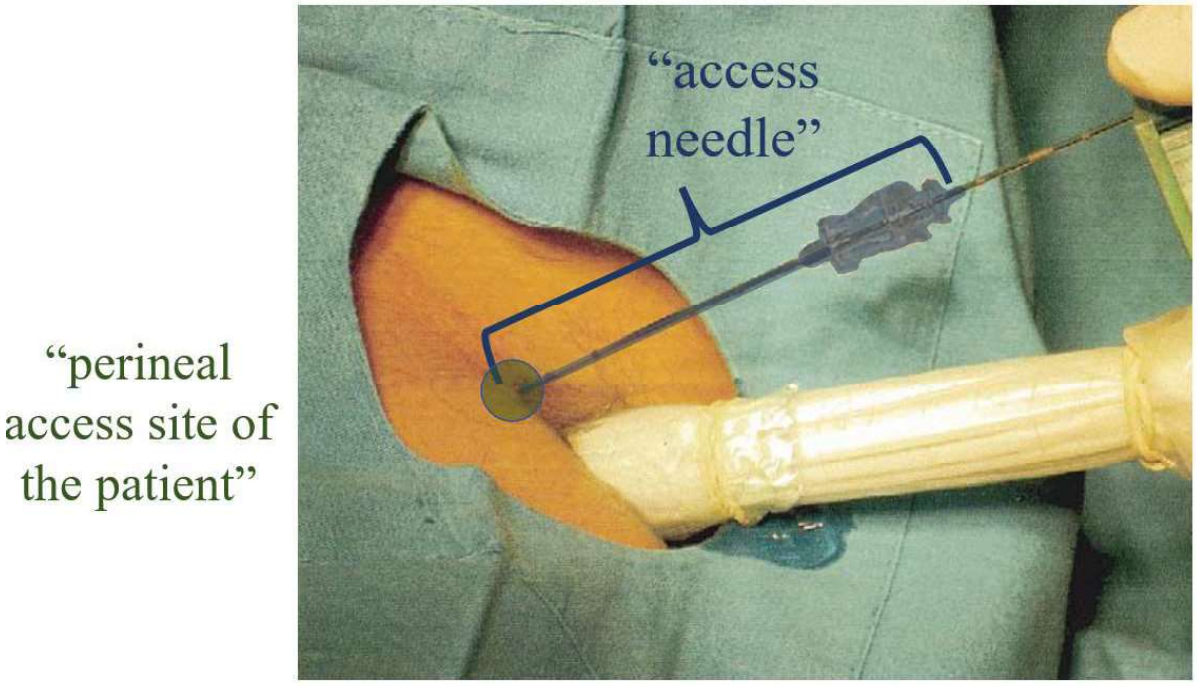
Novella, FIG. 1*

73. Additionally, the patients comprised a perineal access site leading to the prostate. *See generally* EX1005. The researchers inserted "a 17-gauge coaxial

needle … up to the prostate apex through the anesthetized perineal path under TRUS guidance." *Id.*, 2.

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

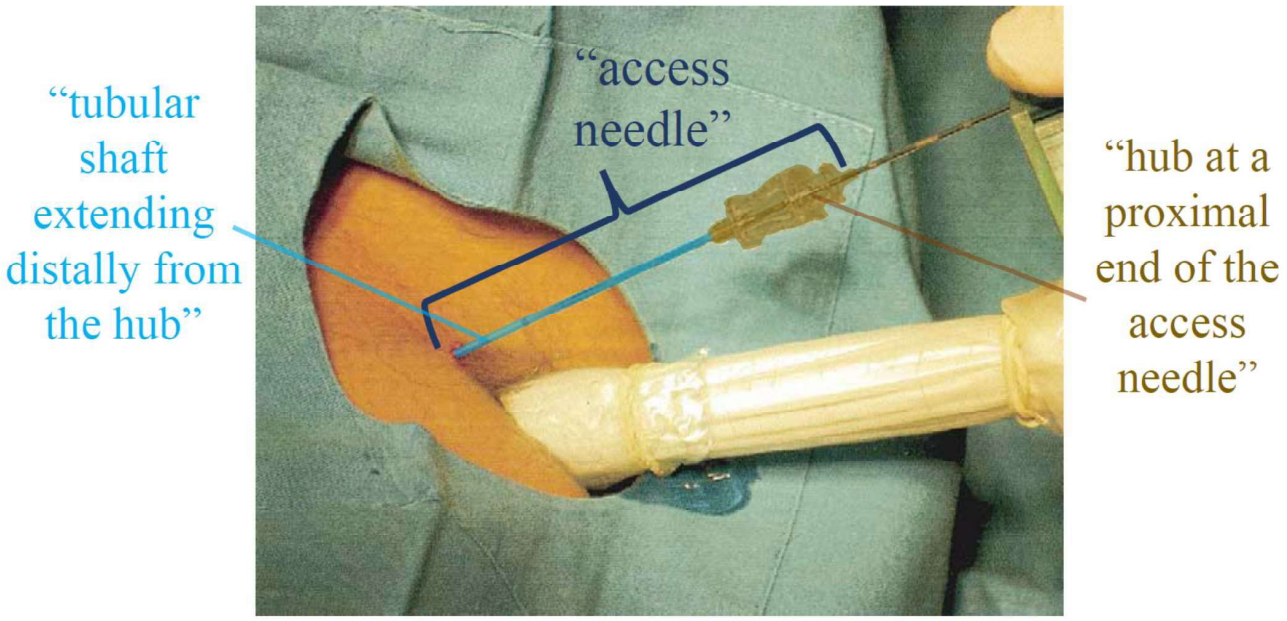
74. In my opinion, Novella discloses inserting a coaxial needle (access needle) into the perineal access site of the patient, as claimed. In Novella's first patient group, the practitioner inserted a "17-gauge coaxial needle (TruGuide Bard, 13 cm long) … up to the prostate apex through the anesthetized perineal path under TRUS guidance." EX1005, 2. The coaxial needle (access needle) provided "an optimal transperineal path for repeated atraumatic passage of the biopsy needle." *Id.*



Id.

3. [1.2] "*the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub,*"

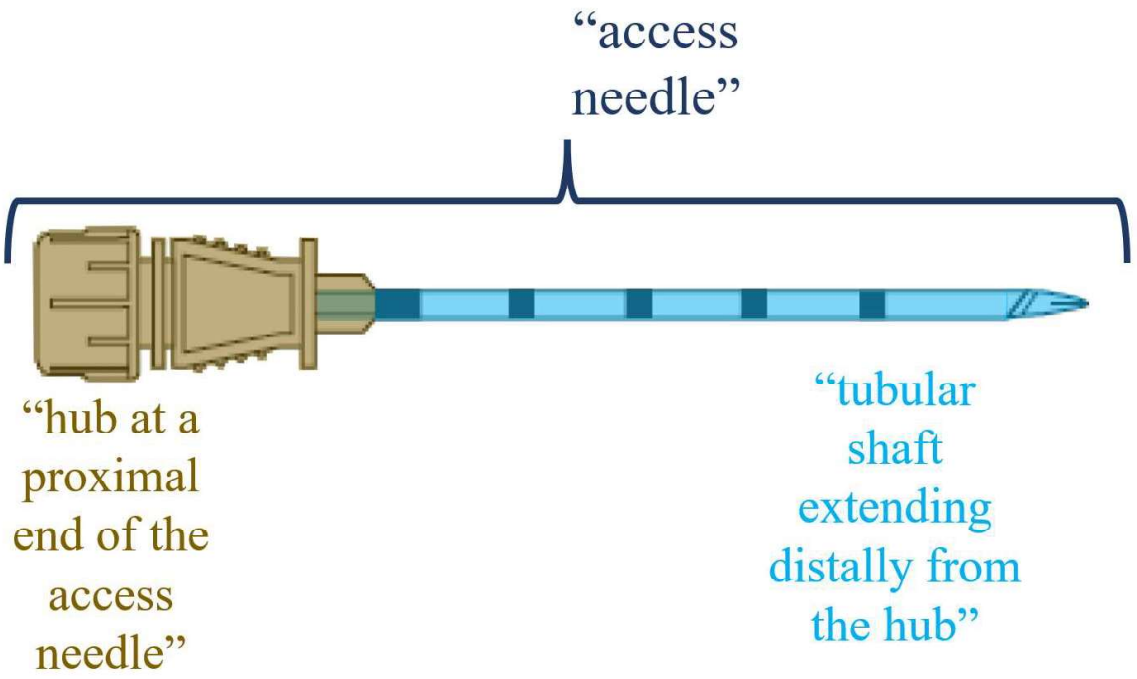
75. In my opinion, Novella's coaxial needle (access needle) includes a hub at a proximal end of the coaxial needle and a tubular shaft (cannula) extending distally from the hub, as claimed. Figure 1 of Novella shows that the 17-gauge coaxial needle (access needle) has the claimed features:



Novella, FIG. 1*

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

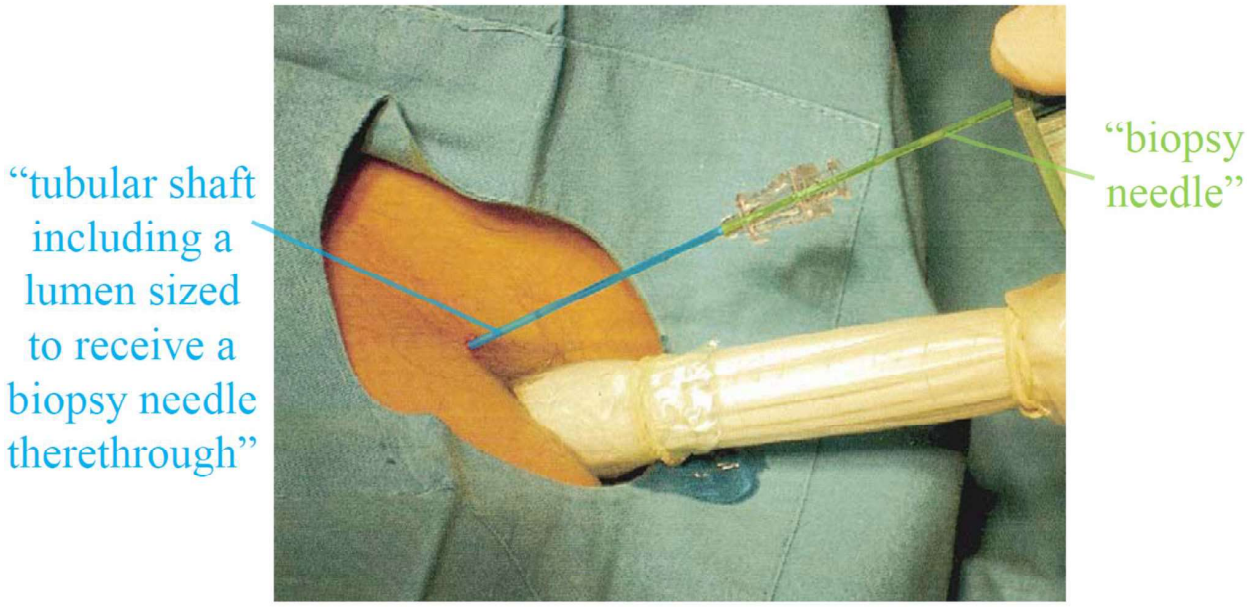
76. In my opinion, the manual for the 17-gauge TruGuide coaxial needle used in Novella also shows the coaxial needle satisfies element [1.2]:



EX1006, 1. The coaxial needle comprises a "guiding cannula needle hub"—in my opinion these are a "hub" and "tubular shaft extending distally from the hub," as claimed. *Id*., 3.

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

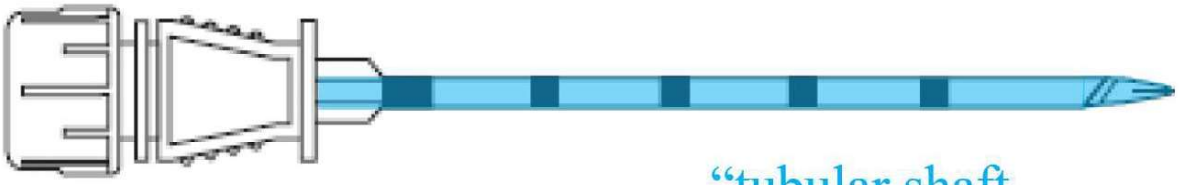
77. It is my opinion that Novella discloses this claim element. Specifically, Figure 1 shows the cannula (tubular shaft) of the 17-gauge coaxial needle includes a lumen sized to receive a biopsy needle therethrough. EX1005, 2.



Novella, FIG. 1*

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

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



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

5. [1.4] "*inserting at least a portion of the tubular shaft of the access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide,*"

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

a. BK Medical discloses element [1.4]

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

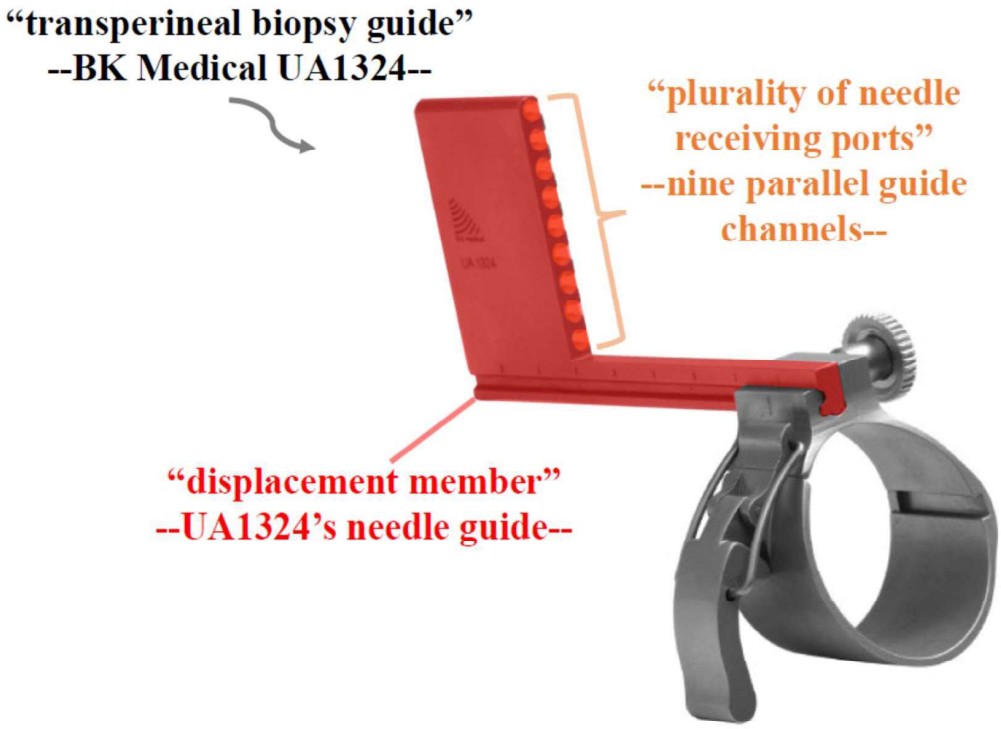


Figure 7. Puncture attachment UA1324.

EX1007, FIG. 7*

Advance Medical Designs, Inc. - EX1003
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Regarding the UA1324's needle guide (displacement member), BK Medical explains:

> UA1324 consists of a needle guide and a mounting ring with clamp. The needle guide comprises 9 parallel guide channels, spaced 5mm apart, each with an internal diameter of 2.1mm, suitable for a 14-gauge needle. The guide is parallel to the centerline of the transducer.
> ***Note:*** The needle guide can be adjusted 70mm lengthwise with respect to the mounting ring, using the adjustment screw.

EX1007, 12.

81. Figure 8 shows UA1324 mounted to the probe:



Figure 8. Puncture attachment UA1324 mounted on 8808e.

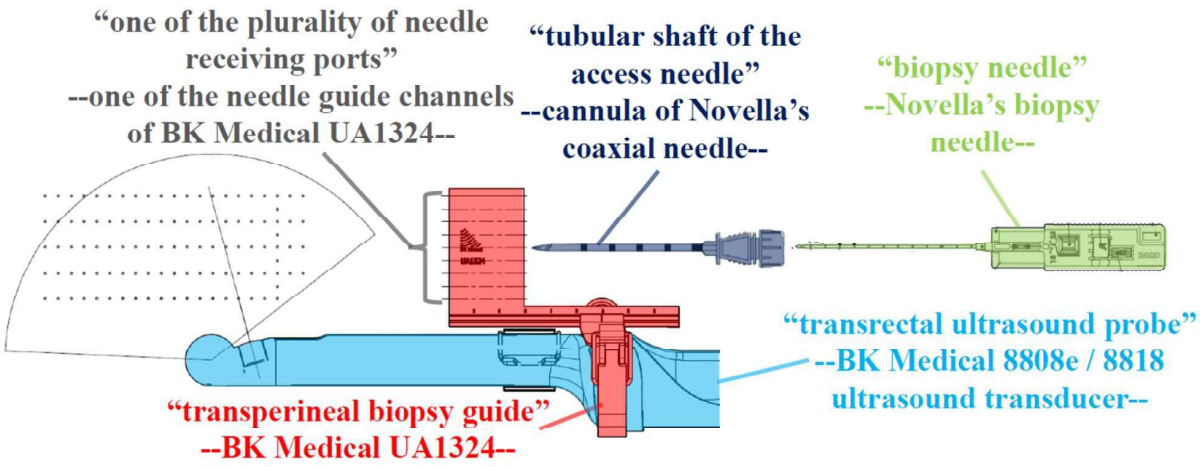
Id., 12; *see also id*., 13 (FIG. 9). The ultrasound probe system displays "puncture lines" that provide "an indication of the expected needle path" when inserted into each needle guide channel. *Id.*, 13. BK Medical teaches to"[m]ove the transducer until the puncture line transects the target. Insert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

along the puncture line to the target." *Id.*, 13. In my opinion, the needle of BK Medical is an "access needle" as claimed because it provides access to the patient's body.

Accordingly, it is my opinion that BK Medical discloses element [1.4].

b. The Novella-BK Medical Combination

82. In my opinion, a POSITA would have used the BK Medical UA1324 puncture attachment and Type 8808e ultrasound probe in Novella's coaxial biopsy procedures as follows:



Novella-BK Medical Combination*

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

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

c. Rationale to Combine Novella and BK Medical

83. In my opinion, a POSITA would have found it obvious to use the BK Medical UA1324 biopsy guide and Type 8808e ultrasound probe in Novella's transperineal biopsy procedures performed with a coaxial needle in the manner shown above. First, the references provide teaching, suggestion, and motivation for this combination. Novella's practitioner used a completely freehand technique, handling both the coaxial needle and probe by hand. EX1005, 1-2. In my opinion, performing biopsies this way has drawbacks, such as:

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

85. **Time/cost:** The technique can be more time-consuming and costly. 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. In some cases, procedures may require multiple practitioners—one to handle the ultrasound probe and another to perform needle insertion and sample collection. In addition to cost,

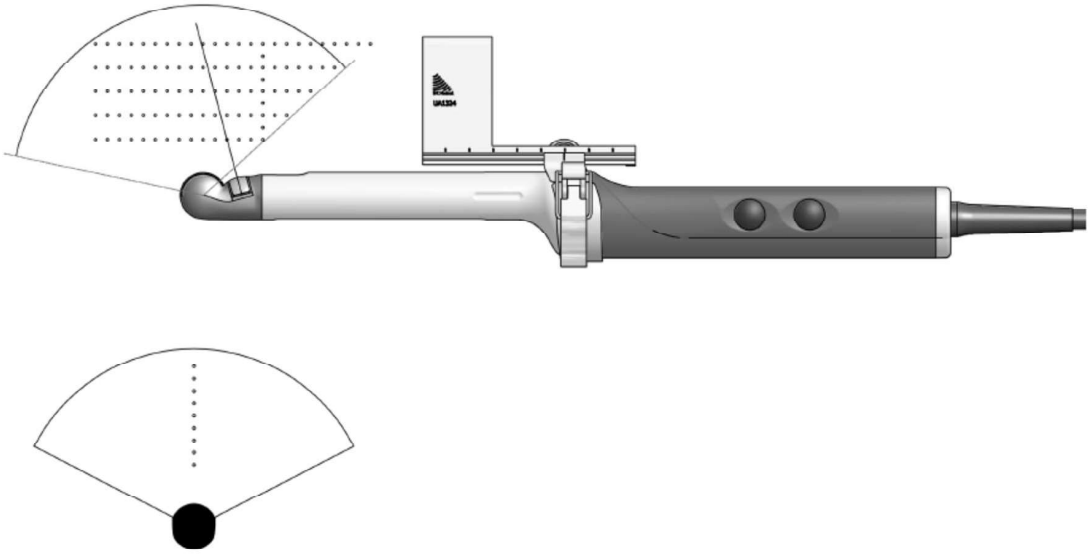
this adds complexity by requiring effective communication and coordination between the team members.

86. **Skill:** Simultaneous, independent manipulation of the needle and probe demands a higher level of skill from the practitioner than procedures aided by guidance equipment. 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. 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.

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

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

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



EX1007, 13

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

88. Furthermore, in my opinion, 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. 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.* And "[t]he distance between each puncture dot is 5mm." *Id.* 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.

89. 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. 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, it is my opinion that a POSITA would have been motivated to use the BK Medical biopsy guide and probe in the biopsy procedures of Novella.

90. In my opinion, 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. Here, Novella's coaxial biopsy technique provides the base prior art method ready for improvement. This base technique involves manipulating both the coaxial biopsy needle and imaging probe purely by hand without assistive equipment. And BK Medical discloses transperineal biopsy guide UA1324 and Type 8808e ultrasound probe applicable to improve the biopsy procedure of Novella.

91. A POSITA, in my opinion, would have recognized that using the BK Medical transperineal puncture attachment and probe would have yielded predictable results, resulting in an improved biopsy method. 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. In my opinion, the assistance from the BK Medical equipment would have predictably improved the results of Novella's biopsies for the reasons discussed above.

92. Additionally, it is my opinion that 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. 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. 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. Thus, it is my opinion that a POSITA would have had a reasonable expectation of success using BK Medical's equipment in Novella's transperineal biopsy procedures.

93. In my opinion, 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. 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).

94. This is because, "[i]n the conventional transperineal technique, the needle is repeatedly inserted through the perineal plane under local anesthesia." *Id.*, 1. Novella "performed 14 biopsies in every patient," requiring fourteen corresponding perineal punctures in the conventional technique. *Id*., 4. 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. Thus, "[t]he main disadvantage of this technique is the need for spinal or general anesthesia" apart from increased invasiveness. EX1008, 4.

95. 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"). For example, long before the claimed priority date of the '436 Patent, physicians practiced "a single-access fan technique" that "us[es] a common [perineal] access for all the cores." EX1008, 1, 3. The coaxial technique does not require general anesthesia—only local "anesthetic

… administered along the [coaxial] needle path." EX1008, 2. 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:

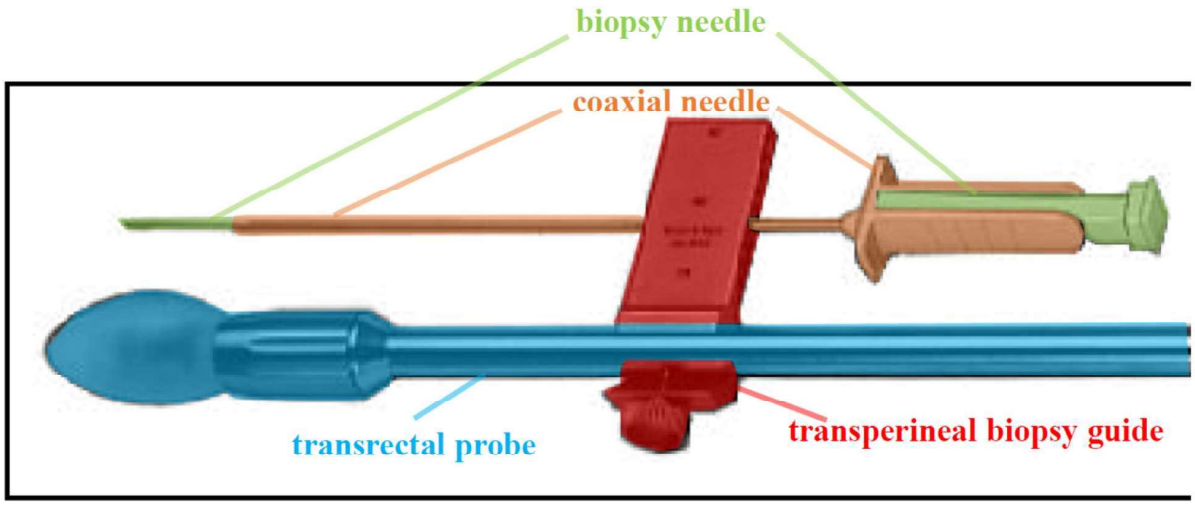
> According to the conventional fan technique, biopsies are performed by repeatedly inserting the same biopsy needle through the anesthetized perineal path[.] To minimize the invasiveness of the technique, a coaxial needle can be used with the aim of performing the several needle passages through the 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. Thus, in my opinion, a POSITA would have used Novella's preferred coaxial technique with the BK Medical puncture attachment and probe to reduce invasiveness and pain while avoiding the problems with a completely freehand technique, discussed above.

96. Additionally, it is my opinion that retaining the coaxial needle with the BK Medical equipment would have helped improve cancer-detection rate for a given invasiveness level. 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). 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. Thus, in my opinion, the combination would have increased the detection rate for a given invasiveness level by allowing the practitioner to take more samples through fewer perineal punctures, further motivating a POSITA to use Novella's coaxial technique with the BK Medical equipment.

97. Moreover, it was known in the art to use a coaxial needle with a probe-mounted transperineal puncture guide. For example, Figure 11 of BK Medical 2 shows a probe "assembled for transrectal scanning with puncture attachment UA0650." EX1009, 14. 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, in my opinion, "fine needle" and "needle guide" respectively refer to a biopsy needle and coaxial needle.

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

99. 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. 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 (Figure 1 identifies Novella's coaxial needle (with 18-gauge, 20cm biopsy needle) as reorder no. C1820B). *Id*., 3. The Manual instructs the practitioner to pass the biopsy needle through the cannula to perform a biopsy, rather than use the biopsy needle alone. *Id*., 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"). Because the biopsy and coaxial needles work together as a system, it is my opinion that a POSITA would have retained this configuration in the combination to use the Bard equipment properly.

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

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

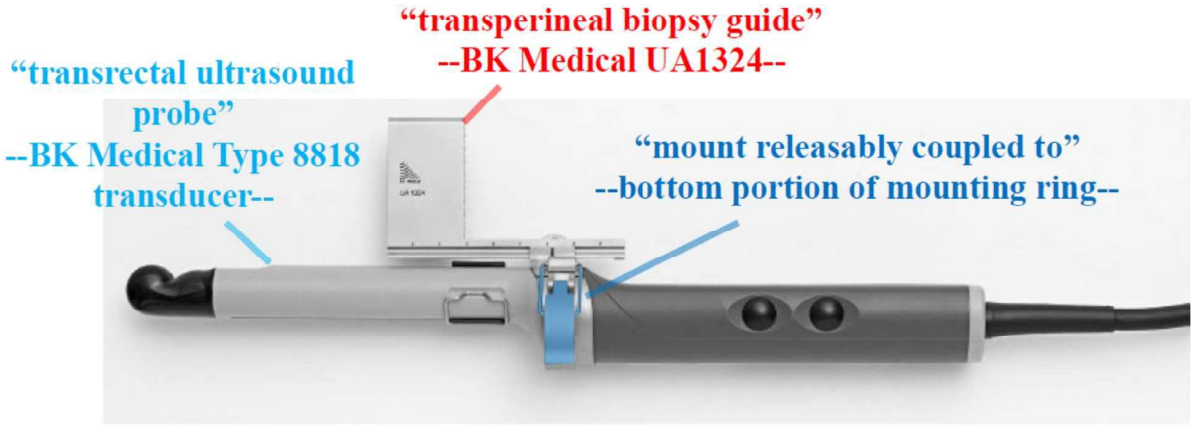


Figure 8. Puncture attachment UA1324 mounted on 8808e.

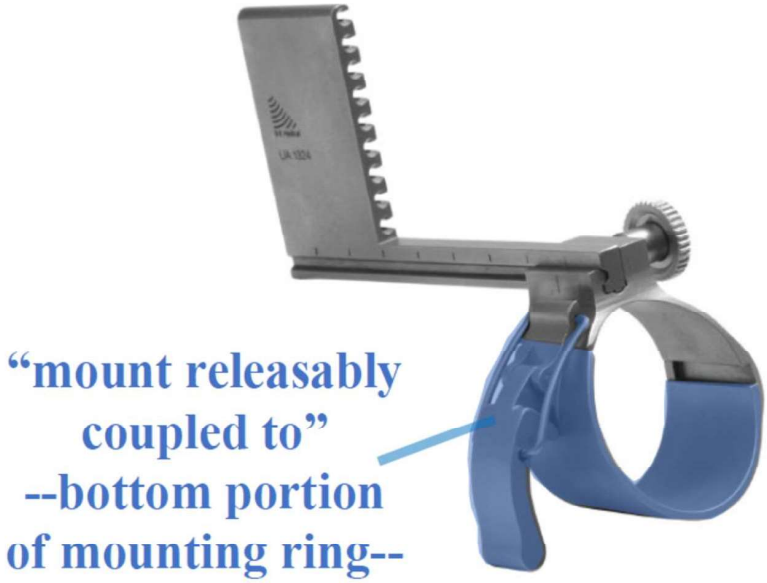


Figure 7. Puncture attachment UA1324.

EX1007, FIGS. 7, 8*

As seen above, "UA 1324 consists of a needle guide and a mounting ring with clamp." EX1007, 12. In my opinion, the bottom portion of the mounting ring with claim corresponds to the claimed mount. "To mount the transperineal puncture

attachment," "[l]oosen the clamp on UA1324, [] slide the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer," and tighten the clamp. *Id.*

7. [1.6] "*a guide member coupled to the mount; and*"

101. In my opinion, the mounting ring of UA1324 has an upper portion (guide member) coupled to the lower portion with clamp (mount), as claimed:



Figure 7. Puncture attachment UA1324.

EX1006, FIG. 7*

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

8. [1.7] "*the displacement member configured to slide relative to the guide member and including a vertically extending member including the plurality of needle receiving ports;*"

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

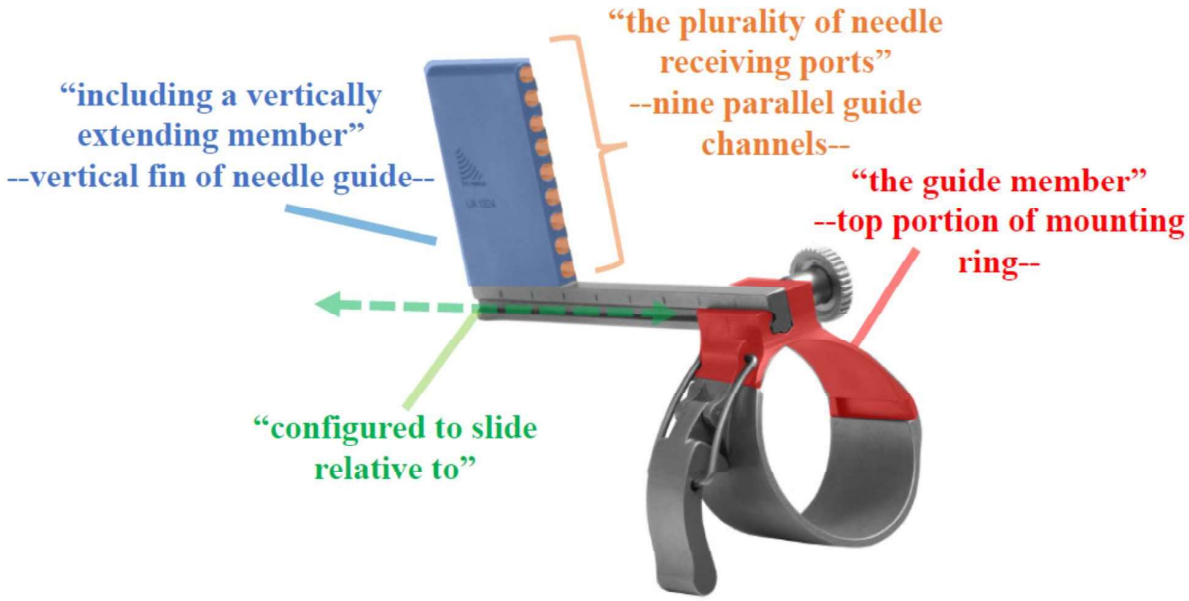


Figure 7. Puncture attachment UA1324.

EX1007, FIG 7*

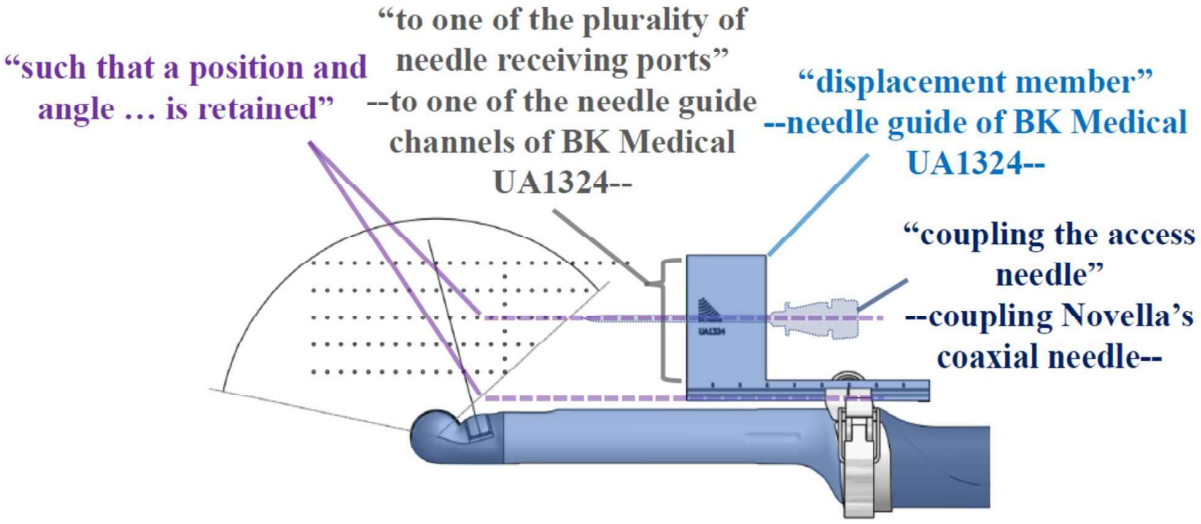
UA1324's needle guide has a vertical fin with "9 parallel guide channels, spaced 5mm apart, each with an internal diameter of 2.1mm, suitable for a 14-gauge needle." EX1007, 12. As explained above for element [1.4], UA1324's needle guide

and nine guide channels respectively correspond to the claimed displacement member and plurality of needle receiving ports. *Supra* Section VIII.A.5. Here, it is my opinion that UA1324's vertical fin discloses the claimed vertically extending member.

103. In my opinion, UA1324's needle guide (displacement member) is configured to slide relative to the upper portion of the mounting ring (guide member), as claimed. Specifically, "[t]he needle guide can be adjusted 70mm lengthwise with respect to the mounting ring, using the adjustment screw." EX1007, 12.

9. [1.8] "*coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained; and*"

104. In my opinion, the Novella-BK Medical combination renders this element obvious. Section VIII.A.5.b, VIII.A.5.c. The combination includes coupling Novella's coaxial needle (access needle) to one of the nine parallel needle guide channels (needle receiving ports) of the needle guide (displacement member) of UA1324 (transperineal biopsy guide), such that a position and angle of the coaxial needle (access needle) relative to the needle guide (displacement member) is retained, as claimed:



Novella-BK Medical Combination*

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

106. As I explain above, the claimed "coupling," in my opinion, does not require completely locking the access needle in place to prevent any movement of

the access needle. *Supra* Section VI.A. Rather, as I understand Patent Owner contends, coupling the access needle to the receiving port "maintain[s] the stability and directionality of the coaxial needle or the puncture needle" *Id.*; EX1019, 22. BK Medical's UA1324 biopsy guide, in my opinion, does this in several ways.

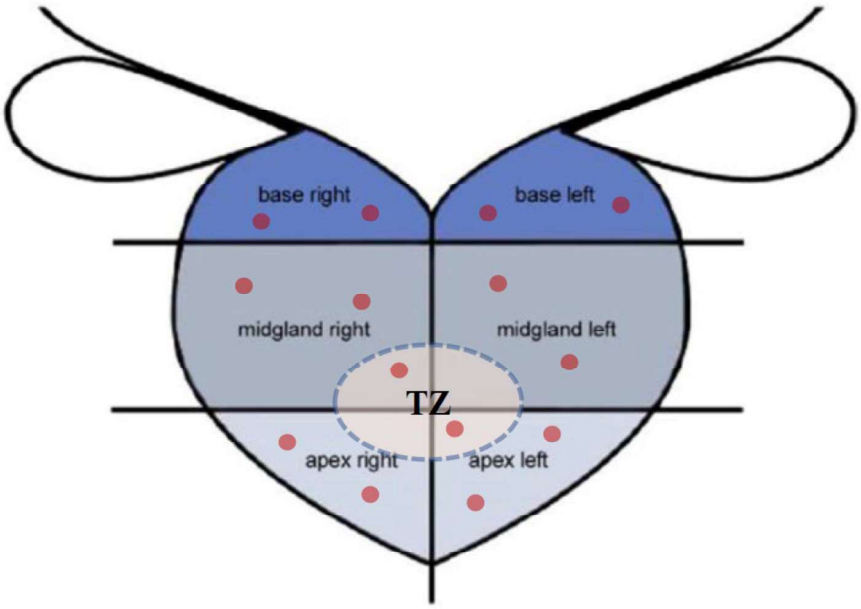
107. For example, it is my opinion that the needle channel maintains the stability of the access needle's direction parallel to the centerline of the transducer. EX1007, 12-13. When in the channel, I understand that the access needle cannot rotate in the plane of the vertical needle guide fin. The needle channel, I further understand, also maintains and stabilizes the vertical position of the needle relative to the probe. And, once inserted up to its hub, I understand that the needle channel maintains and stabilizes the axial position of the access needle in the direction of the probe's centerline.

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

108. In my opinion, Novella discloses this element. Novella "performed 14 biopsies in every patient," accessing the fourteen locations by inserting the biopsy needle through the coaxial needle as a single access point. EX1005, 1, 2, 4 (Novella used the coaxial needle to create an optimum transperineal path for "repeated atraumatic passage of the biopsy needle"). The instruction manual for Novella's coaxial needle also instructs the practitioner to insert the biopsy needle through the

access needle ("cannula") to biopsy a prostate location: "Place the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be biopsied," "[p]erform the biopsy and remove the biopsy needle from the guiding cannula," and "[l]eave the guiding cannula in place." EX1006, 3-4.

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



Novella's Biopsy

A double sextant biopsy involves taking two cores from the left and right sides of the base, midgland, and apex regions of the prostate—twelve total. And Novella took two additional cores from the transition zone (TZ) for a total of fourteen. EX1005,

2. Here, in my opinion, any of the fourteen biopsy locations and/or seven regions of the prostate may correspond to the claimed "first location."

B. Claim 4

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

110. For the reasons I discuss above for element [1.9], it is my opinion that Novella discloses element [4.1]. *Supra* Section VIII.A.10; EX1005, 1, 2, 4.

C. Claim 5

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

111. In my opinion, Novella discloses his element. As I explain above for element [1.9], Novella biopsied fourteen locations across seven regions of the prostate. *Supra* Section VIII.A.10; EX1005, 1, 2, 4. 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.

D. Claim 6

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

112. In my opinion, Novella discloses this element. In Novella, the coaxial needle (access needle) remained positioned within the perennial access site of the patient for fourteen biopsies (the first and second biopsies).

113. As I explain above for element [1.9], Novella biopsied fourteen prostate locations across seven regions of the prostate using a coaxial needle. *Supra* Section VIII.A.10; EX1005, 1, 2, 4. 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").

114. In my opinion, 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. Specifically, it instructs the practitioner to "[p]lace the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be biopsied," "[p]erform the

biopsy and remove the biopsy needle from the guiding cannula," and "[l]eave the guiding cannula in place." EX1006, 3-4.

E. Claim 12

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

115. In my opinion, 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.

F. Independent Claim 13

116. I understand that independent claim 13 is virtually identical in substance to independent claim 1. In my opinion, Novella and BK Medical render obvious claim 13 for the reasons I discuss above for claim 1. Petitioner addresses any additional minor differences between independent claims 13 and 1 below:

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

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

2. [13.1] "*inserting an access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide that is secured to the transrectal ultrasound probe,*"

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

3. [13.2] "*the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub,*"

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

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

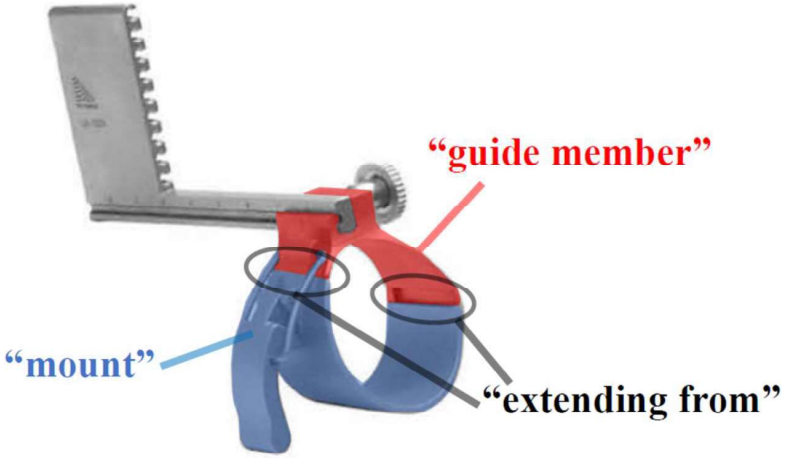
120. See discussion above for element [1.3]. *Supra* Section VIII.A.4.

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

121. See discussion above for element [1.5]. *Supra* Section VIII.A.6.

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

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



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

123. See discussion above for element [1.7]. *Supra* Section VIII.A.8.

8. [13.7] "*securing the access needle to the displacement member such that a position and angle of the access needle relative to the displacement member is maintained;*"

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

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

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

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

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

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

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

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

G. Claims 16-18

128. I understand that Claims 16-18 depend directly or indirectly from claim 13, which I show in the previous section is rendered obvious, in my opinion, by the combination of Novella and BK Medical. *Supra* Section VIII.F. Additionally, claims 16-18 recite features that I have already opined are obvious by the combination of Novella and BK Medical:

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

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

H. Independent Claim 24

129. I understand independent claim 24 is largely identical in substance to independent claims 1 and 13. Novella and BK Medical, in my opinion, render obvious claim 1 for the reasons I discuss above for claims 1 and 13. I address any additional minor differences between independent claim 24 and claims 1 and/or 13 below:

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

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

2. [24.1] "*inserting an access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide that is secured to the ultrasound probe,*"

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

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

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

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

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

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

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

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

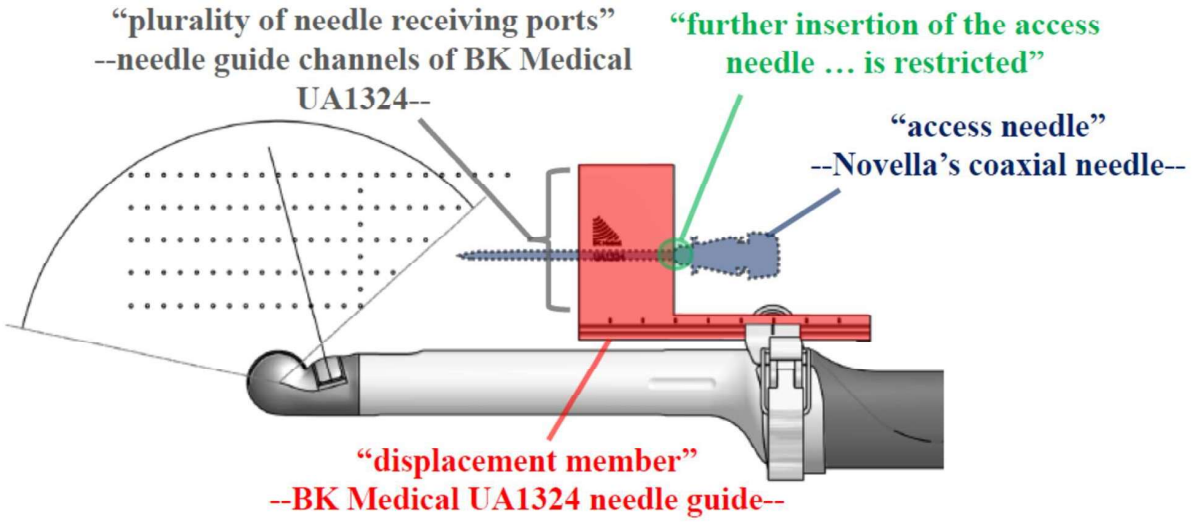
135. See discussion above for elements [1.4], [1.6]. *Supra* Sections VIII.A.5, VIII.A.7. In the combination, UA1324 has a guide member (upper portion of mounting ring) and the needle guide (displacement member), in my opinion. EX1007, 12.

7. [24.6] "*the displacement member configured to slide relative to the guide member;*"

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

8. [24.7] "*securing the access needle to the one of a plurality of needle receiving ports of the displacement member such that position and angle of the access needle relative to the displacement member is maintained and further insertion of the access needle relative to the displacement member is restricted;*"

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



Novella-BK Medical Combination*

138. Second, the coaxial needle has depth stop—"a flexible slip ring" that "is color coded to match the gauge size of the appropriate BARD® biopsy needle or BARD® biopsy instrument, e.g., Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge, Green=14 gauge and Light Blue=12 gauge." EX1006, 2. The manual instructs the practitioner to "place the supplied depth stop at the predetermined placement depth" during the biopsy procedure. *Id*., 3. The depth stop functions "as an aid for proper placement" and "should be adjusted so that the needle is in proper position." *Id*. Depending on the patient's anatomy, the practitioner would have used the provided depth stop as a guide to prevent inserting the coaxial too far into the patient's perinium. That is, the depth stop contacts the vertical needle guide fin of UA1324 at the proper perineal depth to prevent further insertion of the coaxial needle into the patient's perineum.

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

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

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

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

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

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

I. Claim 28

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

142. See discussion above for element [4.1]. *Supra* Section VIII.B.

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

143. See discussion above for element [5.1]. *Supra* Section VIII.C.

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

A. Claims 11, 23, 29

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

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

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

144. In my opinion, Novella-BK Medical in view of Zangos renders these elements obvious. While Novella used a 17-gauge coaxial needle, Zangos discloses using 15-gauge coaxial needle in prostate biopsy, and it is my opinion that a POSITA would have found it obvious to use 15-gauge coaxial needle the Novella-BK Medical combination. EX1010, 1.

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

145. 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, in my opinion, Zangos discloses the 15- or 16-gauge access needle of elements [11.1], [23.1], and [29.1]. Moreover, as I discuss above, Novella discloses that "the biopsy needle has a needle size of 18 gauge" as claimed in element [29.1]. *Supra* Section VIII.A.4; EX1005, 2 ("An 18-gauge Tru-Cut biopsy needle").

3. Rationale to Combine Zangos with Novella-BK Medical

146. In my opinion, 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. The '436 Patent explains that the platform's "hole may be configured to accommodate a needle having a range of 14-18 gauges, such as a reusable 14 gauge spinal needle," but does not identify any significance of the claimed 15- or 16-gauge, specifically. EX1001, 11:34-38.

147. 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, in my opinion, 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.

148. Indeed, if tolerated by the patient, it is my opinion that a POSITA generally would have wanted to use a larger coaxial/biopsy needle because larger needles allow taking larger samples, improving diagnostic accuracy. Larger tissue samples reduce the chance of missing cancerous cells, particularly in larger prostates or heterogenous tumors. 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. Thus, in my opinion, a POSITA would have had motivation to use Zangos' 15-gauge needle in the Novella's procedure.

149. It is my further opinion that a POSITA would have had a reasonable expectation of success because Zangos reported that "[t]he biopsies were performed technically successfully in all patients" and that "[a]t the time of the biopsies all patients tolerated the treatment with minimal or no discomfort after local anesthesia." EX1010, 3-4. Additionally, the needle guide channels of UA1324 have a diameter of 2.1mm, suitable for up to a 14-gauge needle, and thus could accommodate Zangos's 15-gauge coaxial needle. EX1007, 12. Because Zangos achieved good results with a 15-gauge coaxial needle, and that needle would work with UA1324, it is my opinion that a POSITA would have had both motivation and a reasonable expectation of success to use Zangos's 15-gauge needle in the Novella-BK Medical combination.

150. 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. Novella and Zangos both used coaxial needles in prostate biopsy procedures, so the combination would not change the nature of Novella's procedure. 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 in my opinion also would have expected to have good results using that needle in the Novella-BK Medical biopsy procedure. *Id*.

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

A. Independent Claim 1

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

151. As I explain in Ground 1, Novella discloses this element. *Supra* Section VIII.A.1.

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

152. As I explain in Ground 1, Novella discloses this element. *Supra* Section VIII.A.2.

3. [1.2] "*the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub,*"

153. As I explain in Ground 1, Novella discloses this element. *Supra* Section VIII.A.3.

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

154. As I explain in Ground 1, Novella discloses this element. *Supra* Section VIII.A.4.

5. [1.5] "*[a] transperineal biopsy guide comprising: a mount releasably coupled to the transrectal ultrasound probe;*"

155. In my opinion, Novella in view of Onik renders this element obvious. Since Novella's practitioners used a pure freehand technique, it is my opinion that Novella does not expressly disclose a transperineal biopsy guide as in element [1.5]. But Onik remedies the deficiency of Novella, and a POSITA in my opinion would have found it obvious to combine the references as I explain below.

a. Onik Discloses Element [1.5]

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

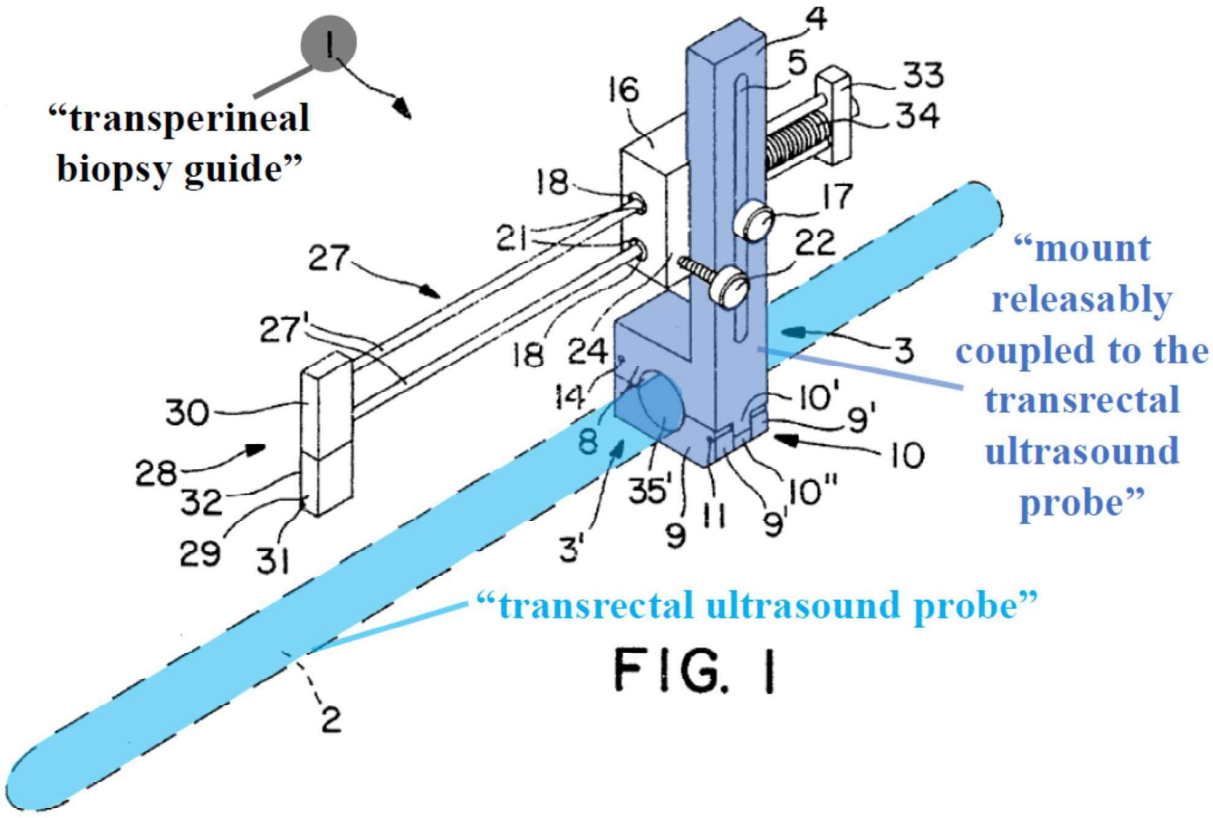


FIG. 1

Onik, FIG. 1*

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

teaches "ultrasound probe is [2] inserted into the patient's rectum and is activated to image the prostate." *Id*., 7:3-4.

158. In Onik, in my opinion, main body 3 (mount) of guide 1 is releasably coupled to the ultrasound probe 2, as claimed. 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. "[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 is removably mountable on ultrasound probe 2." EX1011, 4:3-7.

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

b. The Novella-Onik Combination

160. In my opinion, a POSITA would have used Onik's guide 1 with the BK Medical Type 8808e ultrasound probe in Novella's biopsy procedures as follows:

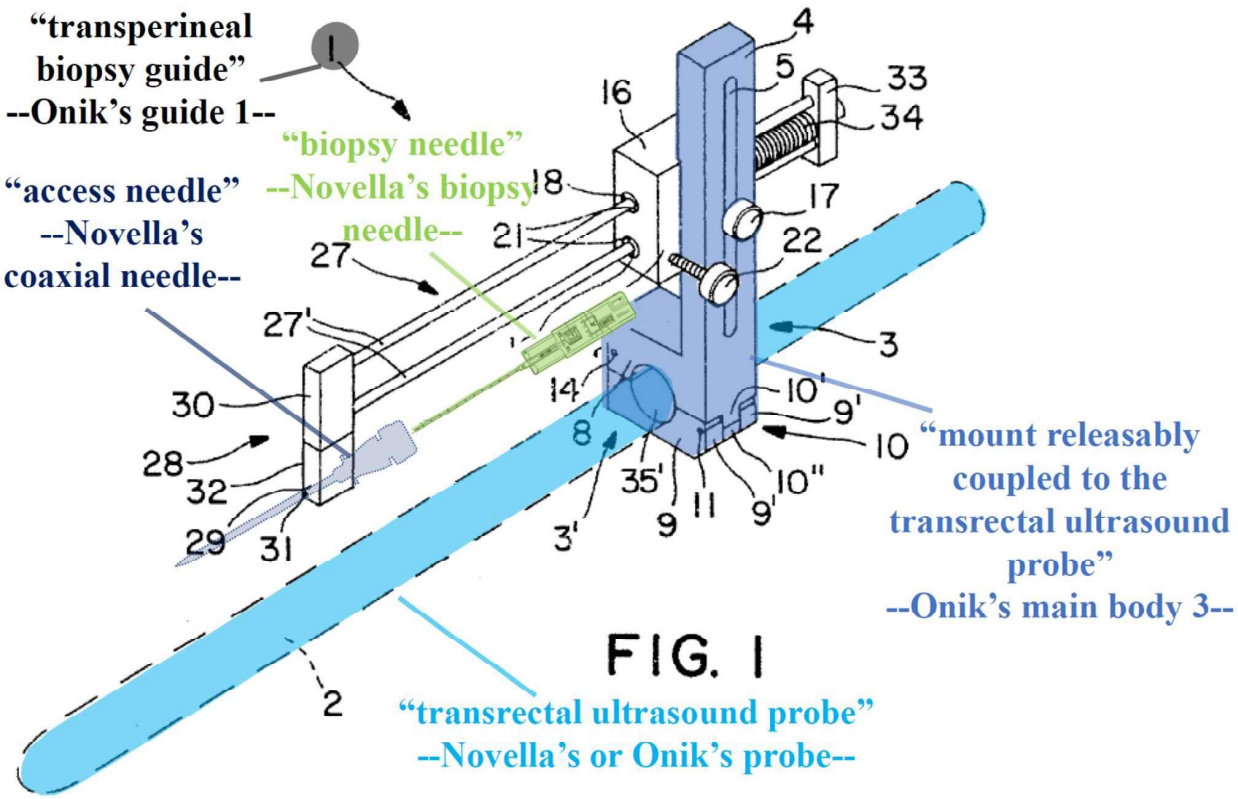


FIG. 1

Novella-Onik Combination*

161. As seen above, it is my opinion that 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. For the reasons discussed above for the Novella-BK Medical combination, it is my opinion that a POSITA would have retained the coaxial needle in the Novella-Onik combination rather than use a biopsy needle alone with Onik's guide. *Supra* Section VIII.A.5.c.

c. Rationale to combine Onik with Novella

162. For at least similar reasons to those I discuss above for the BK Medical UA1324 puncture guide, it is my opinion that a POSITA would have been motivated

to use Onik's guide 1 in Novella's coaxial biopsy procedures. *Supra* Sections VIII.A.5.b, VIII.A.5.c. 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." *Id.*, 5:43-47. And by retaining probe 2 within cutouts 25 of first and second clamp bodies 8, 9, guide 1 maintains "[]accurate orientation of insertion guide 1 relative to probe 2." *Id*., 4:1-6, 6:5-8. Thus, like UA1324, it is my opinion that using Onik's guide in Novella's procedures would, for example, mitigate the fatigue, time/cost, and skill drawbacks of Novella's pure freehand technique discussed above. *Supra* Section VIII.A.5.c.

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

164. 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, in my opinion, would have used these inserts 36 to properly fit and secure Novella's probe in guide 2. Alternatively, in my view, a POSITA would have simply used Onik's probe—which fits without inserts 36—instead of Novella's probe. Likewise, notch 31's "V" shape allows it to accommodate different size needles, including the coaxial needle of Novella. EX1011, 5:39-50. For these additional reasons, in my opinion, a POSITA would have had a reasonable expectation of success in using Onik's guide with Novella's procedures.

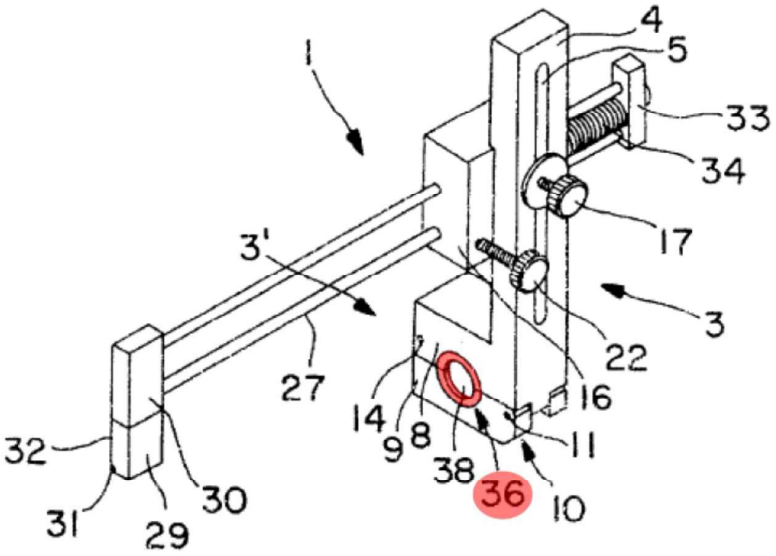


FIG. 2

6. [1.4] "*inserting at least a portion of the tubular shaft of the access needle into one of a plurality of needle receiving ports of a displacement member of [the] transperineal biopsy guide,*"

165. In my opinion, the Novella-Onik combination includes inserting at least a portion of the cannula (tubular shaft) of Novella's coaxial needle (access needle)

into notch 31 (needle receiving port) of needle holder and guide assembly 27 (displacement member) of guide 1 (transperineal biopsy guide):

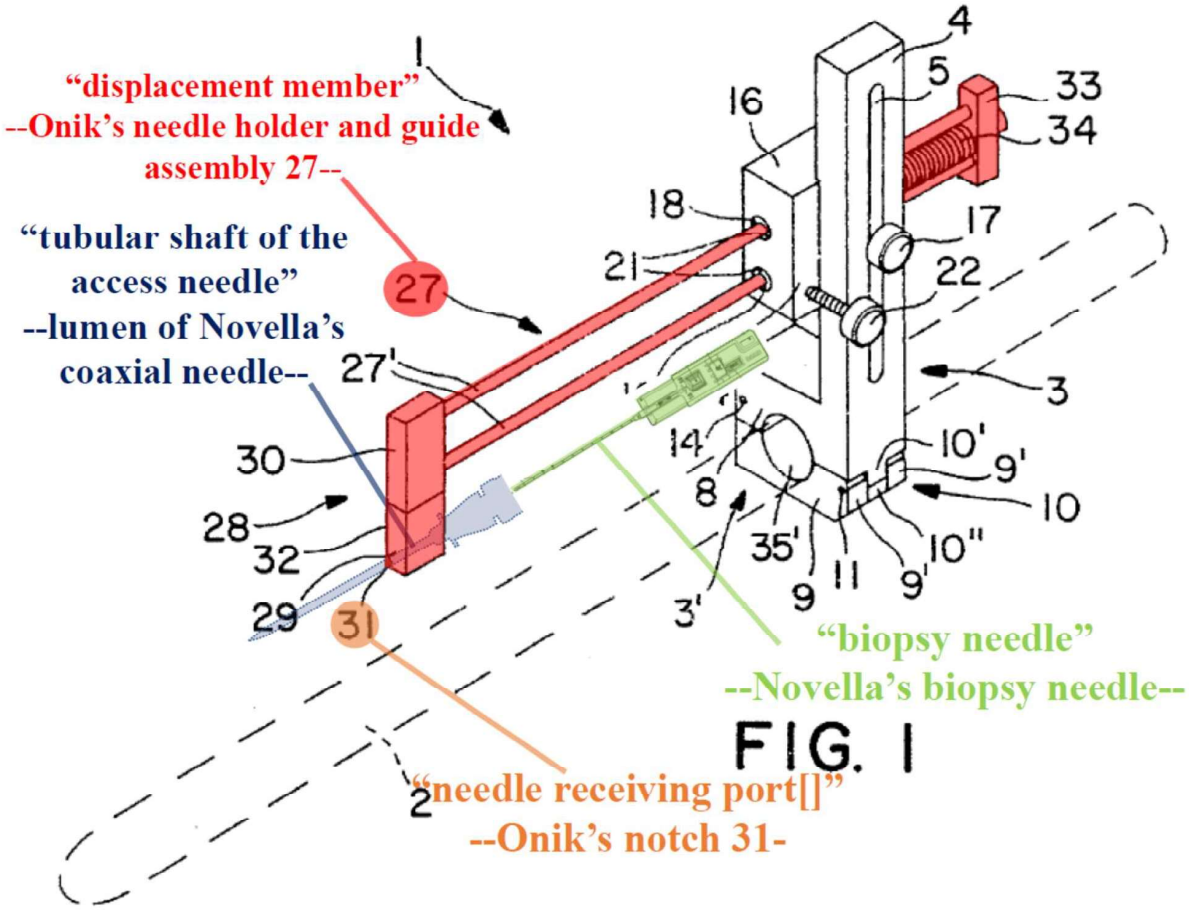


FIG. 1

Novella-Onik Combination*

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

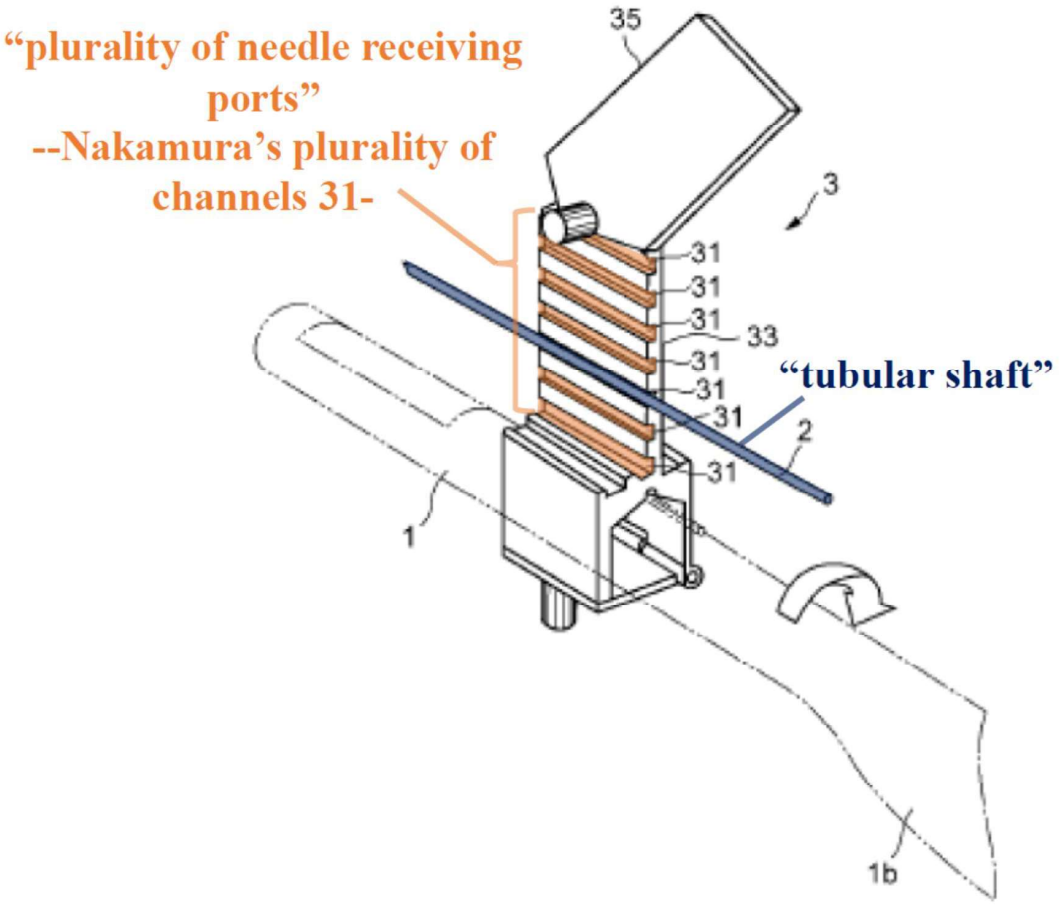
Then, "thumb screw 22 … can be tightened against shaft 27' to fix assembly 27 in a desired position." *Id*., 5:5-8.

167. Onik's assembly 27 (displacement member) has a notch 31 corresponding to the claimed "needle receiving port[]." 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." *Id*., 5:37-37. "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." *Id*., 5:39-46. As seen above, in my opinion, the combination includes inserting at least a portion of the tubular shaft of Novella's coaxial needle (access needle) into notch 31 (needle receiving ports) of assembly 27 (displacement member) of guide 1 (transperineal biopsy guide), as claimed. *Supra* Section X.A.5.b.

168. Since Onik's assembly 27 has one notch 31, Onik does not disclose a "plurality" of needle receiving ports, as claimed. But Nakamura, in my opinion, discloses a transperineal biopsy guide with a plurality of needle guide channels, and it is my further opinion that a POSITA would have found it obvious to modify Onik's assembly 27 to have a plurality of needle receiving notches or channels as taught by Nakamura.

a. Nakamura discloses a "plurality" of needle receiving ports

169. 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]. In my opinion, Nakamura's channels 31 disclose the claimed plurality of needle receiving ports, as highlighted below.

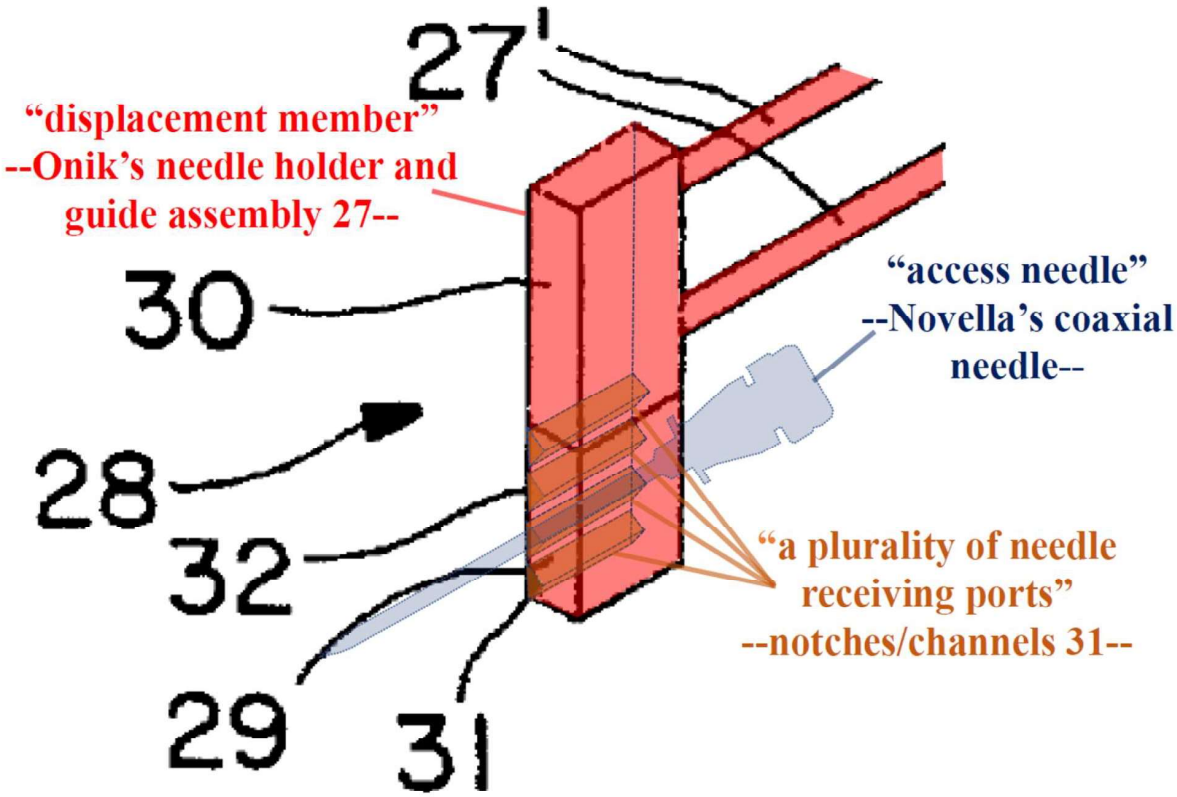


Nakamura, FIG. 10*

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

b. The Novella-Onik-Nakamura Combination

171. In my opinion, a POSITA would have modified Onik's guide 1 to add more notches or channels 31 based on Nakamura's disclosure of multiple channels 31:



Novella-Onik-Nakamura Combination*

Like Nakamura, modified block 29 of Onik's assembly 27 has multiple notches/channels 31 instead of one. Now, as in Nakamura, Onik's needle holder assembly 7 has a plurality of "channels 31 … formed so that the puncture needle 2 can be inserted at a plurality of levels in the vertical direction and at a desired position." EX1012, ¶[0047]. During a biopsy procedure, a practitioner may select "a guide hole corresponding to a target position … from the plurality of guide holes formed by … the plurality of channels 31" and insert "the puncture needle 2 … into the selected guide hole …." *Id*., ¶[0048]. Thus, once the height of block 16 has been set for the procedure, the practitioner may select different notches 31 to target different areas of the prostate without removing probe from the patient to adjusting thumbscrew 17 or attempting adjustment with the probe inserted. *Infra* Section X.A.6.c.

c. Rationale to Combine Nakamura with Novella-Onik

172. Based on Nakamura's disclosure of a transperineal biopsy guide with a plurality of needle-receiving channels 31, it is my opinion that a POSITA would have found it obvious to modify Onik's guide block 29 to have more needle-receiving notches or channels 31. In my opinion, this combination would have offered more convenient positioning of the coaxial needle during biopsy procedures. *Id*.

173. 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, in my opinion. 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. But this makes the procedure more inefficient and intrusive for the patient. Alternatively, the practitioner may attempt to adjust guide 1 with the probe in the patient's rectum, but this would be cumbersome for the practitioner and potentially uncomfortable for the patient as the practitioner manipulates guide 1.

174. Thus, in my opinion, a POSITA considering Novella-Onik would have sought better ways to adjust needle positioning, especially mid-procedure. And Nakamura's design, with its plurality of needle channels 31, provides a solution, in my opinion. With multiple notches 31 in Onik's block 29 like Nakamura's adapter 3, a practitioner would be able to generally set Onik's guide 1 for a given's patient anatomy using thumbscrew 17 before starting the procedure. 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.*

175. In my opinion, this modification merely involves use of a known technique (providing multiple needle guide channels on a transperineal biopsy guide) to improve a similar device (another transperineal biopsy guide) in the same way. 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. 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].

176. In my opinion, 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. 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. And the practitioner would not need to attempt cumbersome or intrusive readjustment of Onik's guide using thumbscrew 17 during the procedure.

177. A POSITA, in my opinion, would have had a reasonable expectation of success modifying Onik's guide to have multiple notches instead of one. As seen above, guide block 29 already has one notch 31 and room for more in my opinion. The additional notches would be added above the existing notch 31. 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. "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.

7. [1.6] "*a guide member coupled to the mount; and*"

178. In my opinion, the Novella-Onik combination includes this element. *Supra* Section X.A.5. Onik's guide 1 has slide block 16 (guide member) coupled to main body 3 (mount), as claimed:

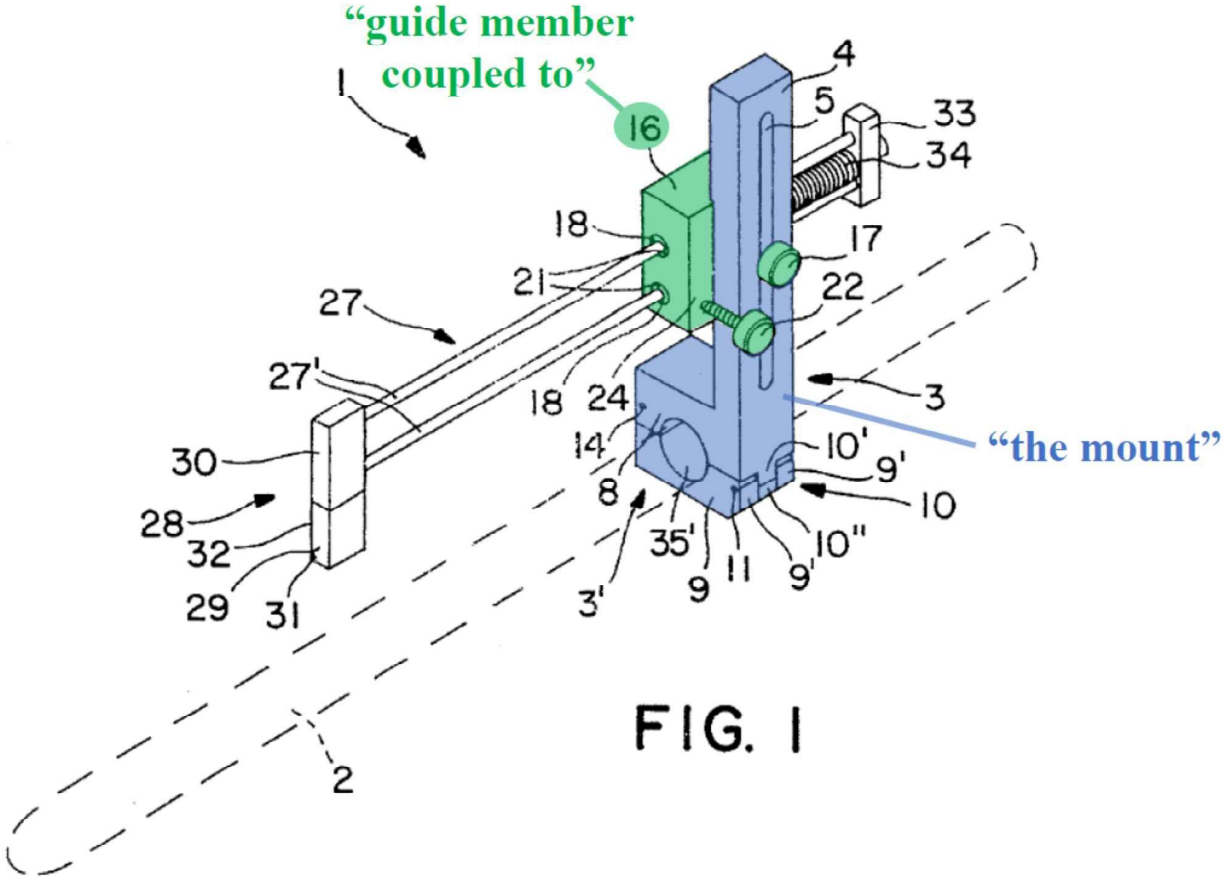


FIG. 1

Novella-Onik Combination*

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

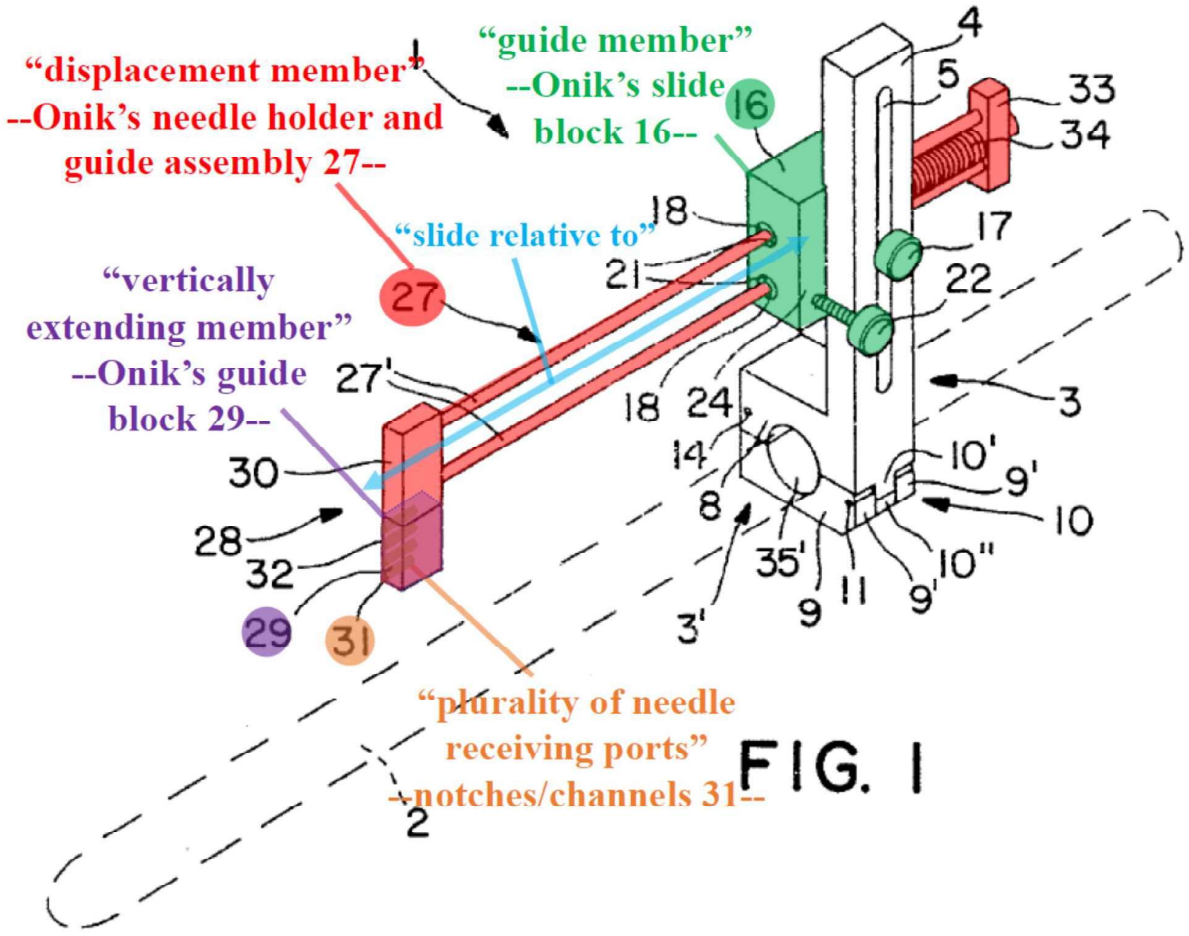
179. Specifically, "[s]lidably associated with anterior-posterior adjustment guide 4 is a slide block 16 which provides anterior-posterior positioning adjustment for a biopsy needle relative to ultrasound probe 2." EX1011, 4:37-40. "[S]lide block 16 is designed to cooperate with slot 5 and slot track 6 in adjustment guide 4." *Id.*,

4:40-42. Slide block 16 has "a position locking thumb screw 17 which … extends through slot 5 to engage slide block 16." *Id*., 4:46-48. "Thumb screw 17 is loosened to permit slide block 16 to move along adjustment guide 4 and is tightened against the outer face of adjustment guide 4 to fix slide block 16 in a desired position." *Id*., 4:49-52.

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

8. [1.7] "*the displacement member configured to slide relative to the guide member and including a vertically extending member including the plurality of needle receiving ports;*"

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

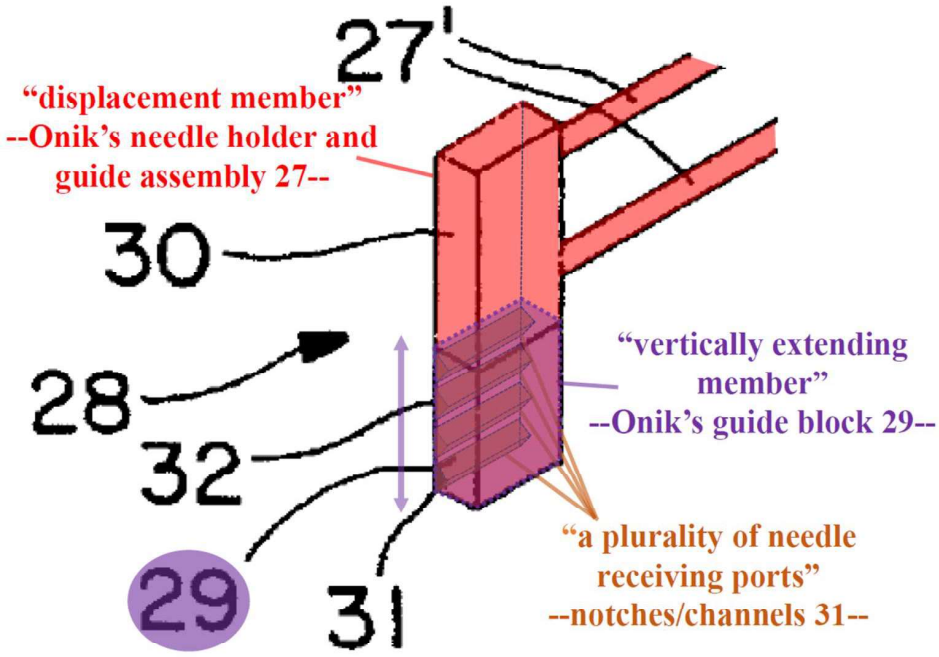


Novella-Onik-Nakamura Combination*

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

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

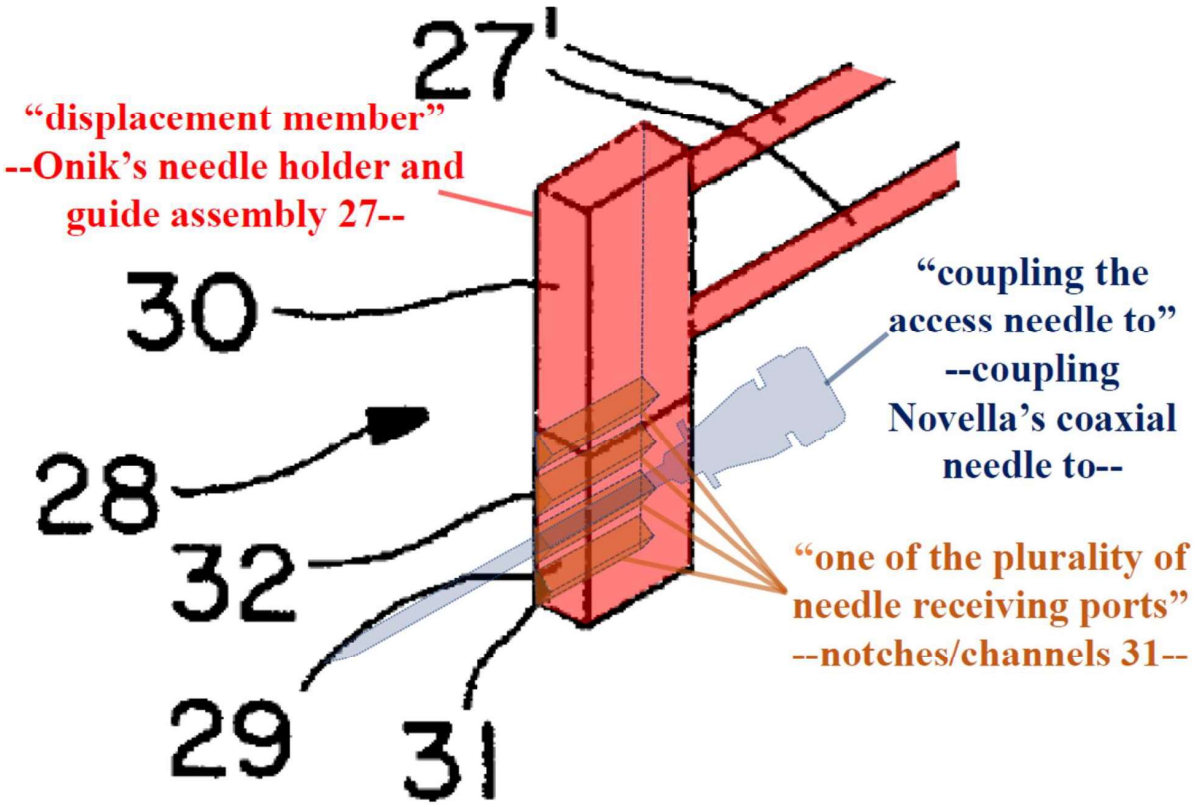
183. Moreover, in the combination, Onik's assembly 27 (displacement member) includes guide block 29—a vertically extending member including the plurality of notches/channels 31 (needle receiving ports):



Novella-Onik-Nakamura Combination*

9. [1.8] "*coupling the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained; and*"

184. In my opinion, the Novella-Onik-Nakamura combination includes this element. *Supra* Section X.A.5. As I explain above for element [1.5], it would have been obvious to use Onik's guide 1 in the coaxial needle biopsy procedures of Novella. *Supra* Section X.A.5. In this combination, Novella's coaxial needle is coupled within needle receiving notch 31 of Onik's guide 1. *Id*. And, as I explain above for element [1.4], it would have been obvious based on Nakamura to add more needle receiving notches/channels 31 to Onik's guide 2 based on the disclosure of Nakamura. *Supra* Section X.A.6. Thus, in my opinion, the Novella-Onik-Nakamura combination includes coupling Novella's coaxial needle (access needle) to one of the plurality of notches/channels 31 (needle receiving ports) of guide assembly 27 (displacement member) of Onik's guide 1 (transperineal biopsy guide), as claimed:



Novella-Onik-Nakamura Combination*

In the combination, as in Nakamura, "a guide hole corresponding to a target position is selected from the plurality of guide holes formed by … the plurality of channels 31," and the coaxial needle "is entered into the selected guide hole, and the puncture needle 2 is inserted." EX1012, ¶[0048].

185. Moreover, for the reasons I explain above in Ground 1, the coaxial needle (access needle) is coupled to the notch/channel 31 such that a position and angle of the coaxial needle access needle relative to the Onik's assembly 27 (displacement member) is retained, as claimed. *Supra* Section VIII.A.9. That is, once fully inserted within a selected notch 31, a longitudinal position and parallel angle

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

186. Moreover, although I understand the claims do not require locking the access needle in place, Onik's guide block 29 has shield 30 for this purpose. As shown in Onik's Figure 7 on the right, "[t]o ensure that the needle is securely held in and guided by notch 31, shield 30 is provided with a spring tab 32 which has sufficient resiliency to allow it to be laterally displaced by insertion of a needle into slot 31 while remaining biased against the needle to hold it in place in slot 31." EX1011, 5:45-51 (emphasis added), FIG. 7. In the combination, shield 30 holds Novella's coaxial needle in place in one of notches/channels 31.

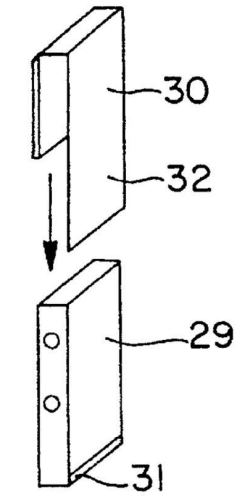


FIG. 7

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

187. As I explain in Ground 1, Novella discloses this element. *Supra* Section VIII.A.10.

B. Claims 4-6 and 12

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

C. Independent Claim 13

189. In my opinion, Novella and Onik, further in view of Nakamura, renders obvious independent claim 13 for similar reasons to those I discuss above for independent claim 1:

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

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

2. [13.1] "*inserting an access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide that is secured to the transrectal ultrasound probe,*"

191. See discussion above for element [1.4]. *Supra* Section X.A.6. Moreover, as I explain above for element [1.5], in the Novella-Onik combination,

Onik's guide 1 is secured to Novella's ultrasound probe or Onik's ultrasound probe. *Supra* Section X.A.5.

3. [13.2] "*the access needle including a hub at a proximal end of the access needle and a tubular shaft extending distally from the hub,*"

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

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

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

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

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

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

195. See discussion above for element [1.6]. *Supra* Section X.A.7. Additionally, in my opinion, Onik's slide block 16 (guide member) extends from main body 3 (mount) because it is mounted to adjustment guide 4 of main body 3. As seen in Figure 1 of Onik annotated above,

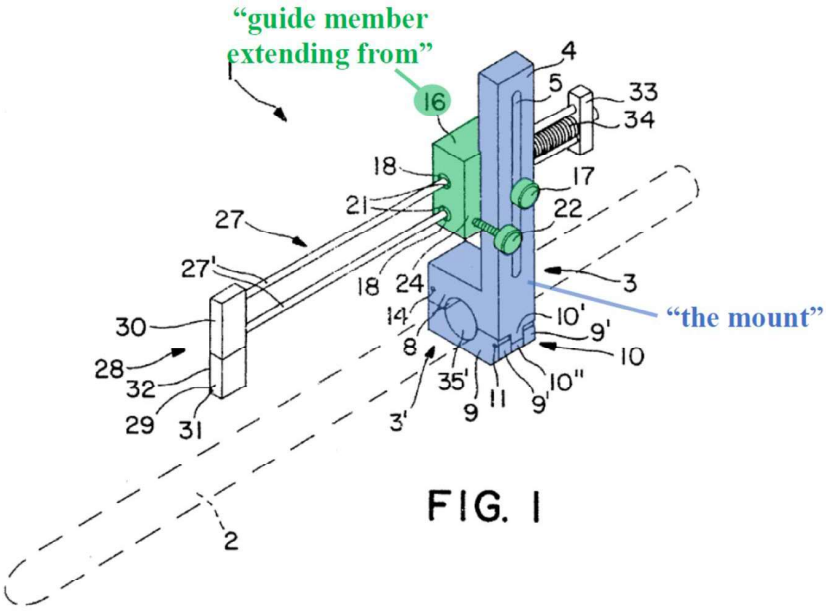


FIG. 1

"slide block 16 is designed to cooperate with slot 5 and slot track 6 in adjustment guide 4" of main body 3. EX1011, 4:40-42. Slide block 16 has "a position locking thumb screw 17 which … extends through slot 5 to engage slide block 16." *Id*., 4:46-48. "Thumb screw 17 is loosened to permit slide block 16 to move along adjustment guide 4 and is tightened against the outer face of adjustment guide 4 to fix slide block 16 in a desired position." *Id*., 4:49-52.

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

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

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

8. [13.7] "*securing the access needle to the displacement member such that a position and angle of the access needle relative to the displacement member is maintained;*"

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

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

199. In my opinion, Novella discloses this element. In Novella, we performed a 14-core transperineal prostate biopsy under transrectal ultrasound

guidance." EX1005, Abstract. "All biopsies were performed by a single urologist (G.N.)" and "TRUS [transrectal ultrasound] was carried out using the Siemens Sonoline Omnia Diagnostic Ultrasound System, with a 7.75-MHz linear probe." *Id.*, 2. Moreover, the Novella-BK Medical combination includes this element by disclosing imaging the prostate with the Type 8808e ultrasound problem. *Supra* Section VIII.A.5.

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

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

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

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

D. Claims 16-18

202. I understand that claims 16-18 depend directly or indirectly from claim 13, which I opine in the previous section is rendered obvious by the combination of Novella, Onik, and Nakamura. *Supra* Section X.C. Additionally, claims 16-18 recite features disclosed by Novella:

Claim	Citation
16. The method of claim 13, further comprising taking a first biopsy of a first location of the prostate of the patient via the biopsy needle.	See discussion above for claim 4. *Supra* Section VIII.B.

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

E. Independent Claim 24

203. In my opinion, Novella and Onik, further in view of Nakamura, render obvious independent claim 24 for reasons similar to those I discuss above for independent claims 1 and 13:

> **1. [24.pre] "*A method of performing a transperineal biopsy procedure on a prostate of a patient using an ultrasound probe configured to provide imaging, the patient comprising a perineal access site leading to the prostate, the ultrasound probe including a shaft and a handle proximal to the shaft, the method comprising:*"**

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

> **2. [24.1] "*inserting an access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide that is secured to the ultrasound probe,*"**

205. See discussion above for element [13.1]. *Supra* Section X.C.2. Moreover, as I explain above, in the Novella-Onik combination, Novella's guide 1

(transperineal biopsy guide) is secured to Novella's or Onik's probe (transrectal ultrasound probe). *Supra* Sections X.C.5, X.C.6.

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

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

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

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

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

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

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

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

7. [24.6] "*the displacement member configured to slide relative to the guide member;*"

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

8. [24.7] "*securing the access needle to the one of a plurality of needle receiving ports of the displacement member such that position and angle of the access needle relative to the displacement member is maintained and further insertion of the access needle relative to the displacement member is restricted;*"

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

212. First, as I explain above for element [1.8], Onik's guide block 29 has shield 30 that, once engaged, locks the access needle in place and thus prevents further insertion of the access needle. *Supra* Section X.A.9. As shown in Figure 7 of Onik on the right, "[t]o ensure that the needle is securely held in and guided by notch 31, shield 30 is provided with a spring tab 32 which has sufficient resiliency to allow it to be laterally displaced by insertion of a needle into slot 31 while remaining biased against the needle to hold it in place in slot 31." EX1011, 5:45-51, FIG. 7. In

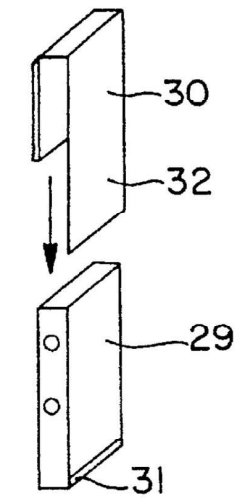
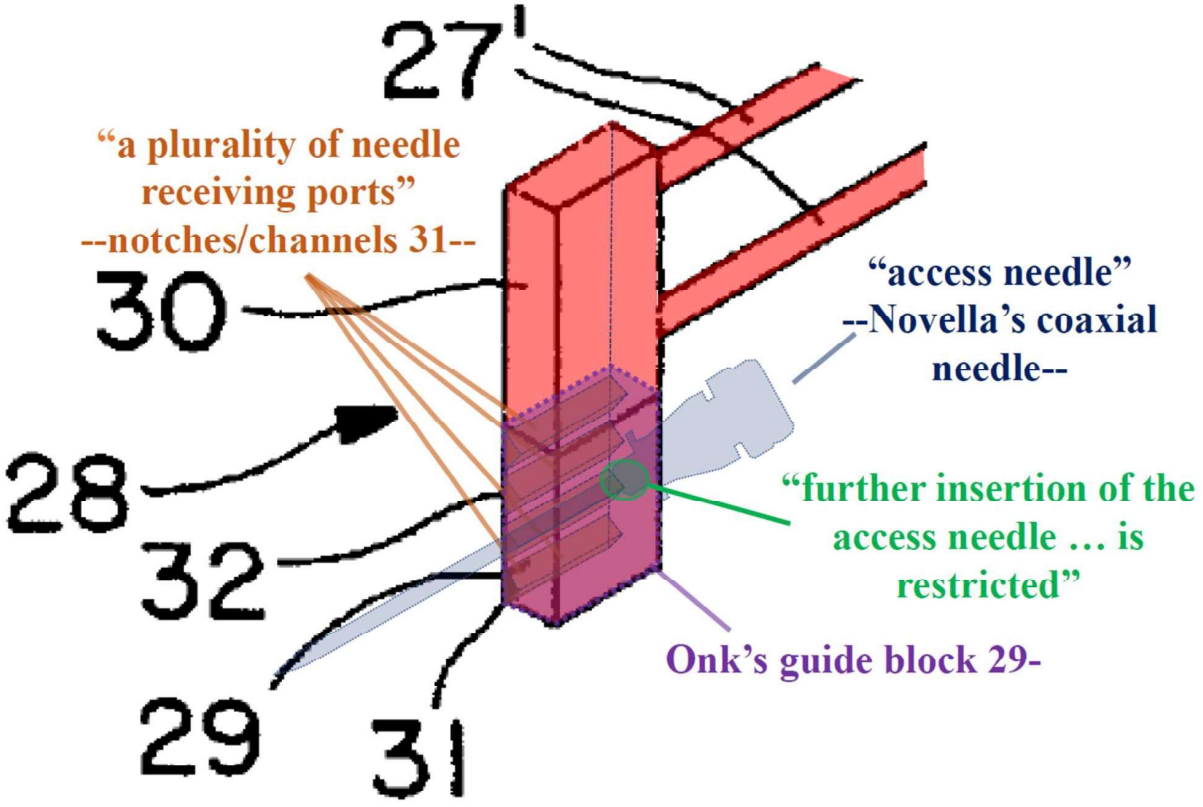


FIG. 7

the combination, shield 30 holds Novella's coaxial needle in one of notches/channels 31 and prevents further insertion.

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



Novella-Onik-Nakamura Combination*

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

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

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

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

216. See discussion above for element [1.1]. *Supra* Section X.A.2.

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

217. See discussion above for element [1.9]. *Supra* Section X.A.10.

F. Claim 28

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

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

219. As I explain above in Ground 2, Zangos discloses the 15 or 16-gauge access needle recited in claims 11, 23, and 29. *Supra* Section IX.A.2. Additionally, for the same reasons discussed above in Ground 2, it is my opinion that a POSITA would have found it obvious to use Zangos' coaxial needle in Novella's procedure with Onik's modified guide 1. *Supra* Section IX.A.3. And as to element [29.1],

Novella discloses that "the biopsy needle has a needle size of 18 gauge" as in element [29.1]. Supra Section VIII.A.4; EX1006, 2 ("An 18-gauge Tru-Cut biopsy needle").

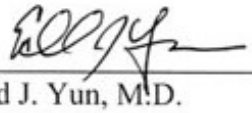
XII. CONCLUSION

Accordingly, for these reasons, it is my opinion that the Challenged Claims are unpatentable.

I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: July 19, 2023

Respectfully Submitted,



Edward J. Yun, M.D.

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