

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADVANCED MEDICAL DESIGNS, INC.,

Petitioner,

v.

CORBIN CLINICAL RESOURCES, LLC.,

Patent Owner.

Case No. PGR2023-00041

Patent No. 11,547,436

**PATENT OWNER PRELIMINARY RESPONSE TO
POST-GRANT REVIEW PETITION**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	STATE OF TECHNOLOGY AT THE TIME OF THE INVENTION	3
A.	Transperineal Biopsy Procedures.....	3
B.	Petitioner Falsely States it was Known in the Art to Use a Coaxial Needle with a Probe-Mounted Transperineal Biopsy Guide	5
III.	PROSECUTION HISTORY	9
IV.	THE PETITION SHOULD BE DENIED UNDER 35 U.S.C. § 325(d).....	10
A.	<i>Advanced Bionics</i> Part I - The Office Considered the Same Prior Art or Arguments During Prosecution	12
B.	<i>Advanced Bionics</i> Part II – No Material Error by the Examiner	14
V.	PETITION SHOULD BE DENIED UNDER 35 U.S.C. § 314(a)	21
A.	Factor 1: whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted.....	23
B.	Factor 2: proximity of the court’s trial date and the Board’s projected statutory deadline for a FWD	25
C.	Factor 3: investment in the parallel proceeding by the court and the parties	26
D.	Factor 4: overlap between issues raised in the petition and in the parallel proceeding	27

E.	Factor 5: petitioner and defendant in the parallel proceeding are the same party.....	29
F.	Factor 6: other circumstances.....	29
VI.	CLAIM CONSTRUCTION.....	32
A.	Petitioner’s hiding the ball on claim construction	32
B.	Limitations 1.8, 13.7 and 24.7 should be given their plain and ordinary meaning instead of Petitioner’s construction	34
VII.	PROPOSED GROUNDS OF REJECTION ARE NOT LIKELY TO SUCCEED	40
A.	Ground 1 – Novella in View of BK Medical	40
B.	Ground 2 – Novella in View of BK Medical and Zangos	53
C.	Ground 3 – Novella in View of Onik and Nakamura	53
D.	Ground 4 – Novella in View of Onik, Nakamura and Zangos	62
VIII.	CONCLUSION.....	63

LIST OF EXHIBITS

Exhibit No.	Description
2001	Declaratory Judgement filed by AMD in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789- SAG (D. Md.) (October 22, 2021)
2002	Merit Medical Product Brochure for Tru-cut biopsy needles
2003	Jankowski M, et. al., Kidney biopsy in dogs and cats, <i>Pak. Vet. J.</i> , 33(2): 133-138 (2013)
2004	Order transferring case to the District of Maryland in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789- SAG (D. Md.) (April 1, 2022)
2005	Order staying litigation in <i>Paice LLC et al v. BMW et al.</i> , No. 1:19-cv-03348- SAG (D. Md.) (November 25, 2020)
2006	United States District Court for the District of Maryland Local Rules, published July 1, 2023 supplemented on September 23, 2023
2007	United States District Courts — National Judicial Caseload Profile, accessible at https://www.uscourts.gov/statistics-reports/analysis-reports/federal-court-management-statistics (last access on October 11, 2023)
2008	Plaintiff AMD’s Updated Opening Claim Construction Brief in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789- SAG (D. Md.) (July 31, 2023)
2009	Defendant Corbin’s Amended Opening Claim Construction Brief in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789- SAG (D. Md.) (July 31, 2023)
2010	Plaintiff AMD’s Amended Responsive Claim Construction Brief in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789- SAG (D. Md.) (September 15, 2023)
2011	Defendant Corbin’s Amended Responsive Claim Construction Brief in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789- SAG (D. Md.) (September 15, 2023)

2012	Plaintiff AMD's Initial Invalidity Contentions in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789- SAG (D. Md.) (August 1, 2022)
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TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (Feb. 13, 2020 PTAB). 1, 10, 11, 12, 13, 14, 15, 19, 20	
<i>Advanced Energy Indus. Inc. v. Reno Techs. Inc.,</i> No. IPR2021-01397, Paper 7, 7-8 (PTAB Feb. 16, 2022)	16, 17
<i>Apple Inc. v. Fintiv, Inc.,</i> No. IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) 1, 2, 22, 23, 25, 27, 29, 34	
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG,</i> IPR2017- 01586	11
<i>Carrier Fire & Sec. Ams. Corp v. Sentrilock, LLC,</i> No. IPR2021-00664, Paper 12, 21-23 (PTAB Sept. 16, 2021)	16
<i>CommScope Techs. LLC. v. Dali Wireless, Inc.,</i> IPR2022-01242, Paper 23 (February 27, 2023)	21, 22
<i>DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.,</i> 567 F.3d 1314 (Fed. Cir. 2009)	49
<i>Flex-Rest, LLC v. Steelcase, Inc.,</i> 455 F.3d 1351 (Fed. Cir. 2006)	39
<i>Intelligent BioSys., Inc. v. Illumina Cambridge Ltd.,</i> 821 F.3d 1359 (Fed. Cir. 2016)	48
<i>InTouch Technologies, Inc. v. VGo Communications, Inc.,</i> 751 F.3d 1327 (Fed. Cir. 2014)	48
<i>Juniper Networks, Inc. v. Mobile Telecom. Tech., LLC,</i> IPR2017-00642, Paper 31, 22 (PTAB Mar. 14, 2018)	19
<i>Kayak Software Corp. v. Int’l Bus. Mach. Corp.,</i> CBM2016-00075, Paper 16 (PTAB Dec. 15, 2016)	14

<i>Polaris Indus., Inc. v. Arctic Cat, Inc.</i> , 882 F.3d 1056 (Fed. Cir. 2018)	50
<i>PowerOasis, Inc. v. T-Mobile USA, Inc.</i> , 522 F.3d 1299 (Fed. Cir. 2008)	14
<i>Samsung Elecs. Co. v. Evolved Wireless LLC</i> , No. IPR2021-00943, Paper 9 (PTAB Dec. 1, 2021)	16
<i>Supercell OY v. Gree, Inc.</i> , IPR2020-00310, Paper 13 (PTAB Jun. 18, 2020)	27
<i>Weatherford U.S., L.P. v. Enventure Global Tech., Inc.</i> , IPR2020-01661, Paper 19 (PTAB Apr. 15, 2021)	12
<i>Xerox Corp. et al., v. Bytemark</i> , IPR2022-00624, Paper No. 9 (PTAB Aug. 24, 2022).....	45
Statutes	
35 U.S.C. § 102	9
35 U.S.C. § 314(a)	21, 22
35 U.S.C. § 325(d)	10, 12, 20
Other Authorities	
37 C.F.R. § 42.65(a).....	44
37 C.F.R. § 42.200(b)	32
MPEP §609.02	13

I. INTRODUCTION

Advanced Medical Designs, Inc. (“Petitioner”) filed a post-grant review petition (the “Petition”) challenging claims 1, 4-6, 11-13, 16-18, 23, 24, 28 and 29 of U.S. Patent No. 11,547,436 (the ’436 Patent) on July 21, 2023.

The Petitioner acknowledges that the U.S. Patent and Trademark Office has previously considered the references presented in the Petition yet does little to explain why the Board should consider these references again under the *Advanced Bionics* framework. See *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-9 (Feb. 13, 2020 PTAB) (precedential). The factors weighing for denial under *Advanced Bionics* are particularly compelling here as the Examiner considered the same prior art and arguments as presented in this Petition and found the subject matter allowable.

Similarly, the Petitioner largely brushes aside the status of co-pending litigation with respect to the *Fintiv* factors. *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, Paper 11 at 5-6 (PTAB Mar. 20, 2020) (precedential). However, this case presents an unusual fact pattern where Petitioner purposefully chooses a legal strategy to try to get two bites at the invalidity apple, one from the Board and one from the District Court. Petitioner does this by asking the PTAB to review only one asserted patent while the District Court considers four other asserted patents that share common subject matter with the patent challenged in this PGR. Moreover, the

instant PGR Petition does not even challenge all the asserted claims of the asserted '436 Patent.¹ Thus, regardless of the outcome of this PGR proceeding, the District Court will have to consider the same claim constructions and prior art with respect to the other asserted patents and the unchallenged claims in the '436 Patent. Deciding the same invalidity issues in two different forums is precisely what *Fintiv* is designed to avoid, and the Board should not condone Petitioner's gamesmanship to subvert the intent of PTAB proceedings.

Assuming the Board reaches the prior art arguments despite these factors weighing in favor of discretionary denial, the references fail to teach an access needle with a probe mounted guide for transperineal biopsies as recited in the claims. In particular, the proposed prior art combinations do not teach "coupling" or "securing" the access needle "such that a position and angle of the access needle relative to the displacement member is retained[/maintained]" as recited in independent claims 1, 13 and 24. Given the glaring defects in the prior art as to this limitation, Petitioner tries to erase these explicit claim terms via claim construction. *See* Petition at 15-17. Instead of showing the prior art teaches the express words of the independent claims, Petitioner wrongly contends that it need only show the prior art maintains the stability and directionality of the access needle. Petition at 59.

¹ The PGR Petition does not challenge claims 25 and 30 of the '436 Patent which are asserted in the underlying litigation. *See* Ex. 1019 at 2.

Petitioner's misguided claim construction is necessitated by the fact that the prior art teaches a needle moving relative to the probe. For example, BK Medical gives an express warning to retract the needle when moving the probe while Onik discloses inserting a needle while the probe is stationary. Nonetheless, Petitioner *still* fails to show how the prior art renders obvious the claimed elements even under its alleged interpretation. For example, Petitioner's combination suggests using BK Medical in a manner it explicitly warns against while the combination with Onik results in a device with two redundant positioning systems.

Therefore, the Board should exercise its discretion to deny institution or find that the Petition fails to demonstrate that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable.

II. STATE OF TECHNOLOGY AT THE TIME OF THE INVENTION

A. Transperineal Biopsy Procedures

The '436 Patent relates to a transperineal prostate biopsies. Ex. 1001 at Abstract. A biopsy is a medical procedure that involves sampling and removing tissues or cells from a living body for further examination and analysis. *Id.* at 1:40-42. One type of biopsy procedure is a transperineal ultrasound-guided (TPUS) biopsy that uses an ultrasound probe to guide a biopsy needle through the perineum and into the prostate. *Id.* at 1:43-49 and 2:1-3.

Prior art systems configured for TPUS include a biopsy grid that may be fixed

to, for example, a floor, platform, or table on which the patient receiving the biopsy lies. *Id.* at 2:13-15. The biopsy grid may provide multiple apertures through which a biopsy needle or other biopsy instruments may be inserted. *Id.* at 2:15-17. Further, TPUS uses an ultrasound probe to axially guide the biopsy needle or other biopsy instruments. *Id.* at 2:17-20. Thus, TPUS systems require imaging in an axial plane of the ultrasound or a transverse transducer for positioning the biopsy needle. *Id.* at 2:20-23.

However, these TPUS prostate biopsy systems and methods do not allow free-hand movement of the ultrasound probe, rely on the axial ultrasound plane to confirm positioning of the biopsy needle or other instruments, and require separate punctures into the transperineal tissue for each biopsy of the prostate. *Id.* at 5:43-49. Accordingly, at the time of the invention of the '436 Patent, there was a demand for a less burdensome transperineal biopsy system for the patient and practitioner. *Id.* at 6:18-24.

In contrast to these known TPUS systems that did not use an access needle, the invention of the '436 Patent solves the above issues by involving a biopsy guide configured to couple with a transrectal probe for use in guiding an access needle in a transperineal prostate biopsy procedure. *Id.* at 2:29-32. The access needle can be inserted into a receiving port on the displacement device of biopsy guide and then coupled to the port, for example by using ridges and/or threading. Ex. 1001 at 25:58-

26:7. When the access needle is coupled to the displacement device, they move together retaining their relative position and angle. Ex. 1001 at 26:30-56 and 27:10-15. The access needle may then perforate and be positioned within subcutaneous tissue of a perineum at an access site of a target area of a patient for the TPUS biopsy procedure. *Id.* at 2:33-34.

The invention of the '436 Patent thus enables a complete biopsy of the prostate with only one or a minimal number of perforations of a patient's skin by way of an initial access site, such that the access needle is freely moveable. *Id.* at 9:6-10.

B. Petitioner Falsely States it was Known in the Art to Use a Coaxial Needle with a Probe-Mounted Transperineal Biopsy Guide

A critical issue in this case is whether it was obvious to couple Novella's coaxial needle with either BK Medical's or Onik's guide device at the time of the invention. As discussed above, the coupling of an access needle to a probe mounted biopsy guide for use with transperineal biopsies is part of the solution invented by the '436 Patent to overcome deficiencies in the prior art. *Id.* at 2:29-34 and 9:6-10.

The prior art is silent as to this solution and there is no evidence that anyone other than the inventor of the '436 Patent contemplated this solution for transperineal biopsies. In a misguided attempt fill that void, Petitioner cites to BK Medical 2 for the proposition that "it was known in the art before the claimed priority date to use a coaxial needle with a probe-mounted transperineal biopsy guide." Petition at 9

(citing Ex. 1009); *see also* 51-53. This argument is a material misrepresentation of what is disclosed in BK Medical 2.

Petitioner relies entirely on the statement in BK Medical 2 that “[i]f a fine needle is used, it may be helpful to use an additional needle guide.” Petition at 52 (citing Ex. 1009 at 16. Petitioner then wrongly concludes that the “needle guide” in this sentence refers to a coaxial needle. *Id.* Yet, BK Medical and BK Medical 2 make it clear that the “needle guide” term is used to describe the guide channels in the puncture attachments, such as UA1324 and UA0650, as highlighted below.

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

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



Figure 7. Puncture attachment UA1324.

Ex. 1007 at 12 (emphasis added).²

² All emphasis added by Patent Owner unless otherwise noted.

Similarly, both BK Medical and BK Medical 2 reference “needle guide” multiple times when providing warnings that refer to the puncture attachment rather than a coaxial needle. Ex. 1007 at 14; Ex. 1009 and 15 and 19.

Thus, the “needle guide” in BK Medical 2 are the needle guide channels in the puncture attachment and not a coaxial needle as alleged by Petitioner and its expert. In this context, the phrase in BK Medical 2 that “[i]f a fine needle is used, it may be helpful to use an additional needle guide” is a reference to using a second set of guide channels with a fine biopsy needle to help prevent flexing of that needle. Ex. 1009 at 16. An illustration of Figure 11 modified to use an additional needle guide is shown below:

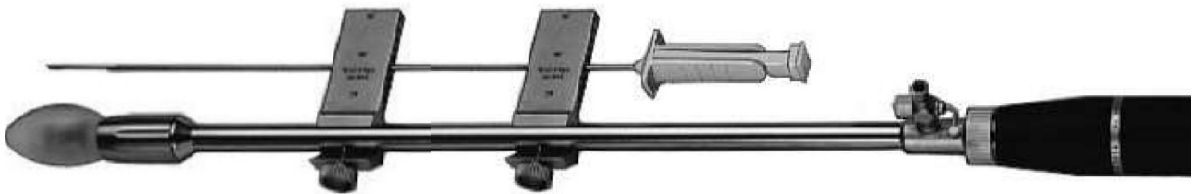
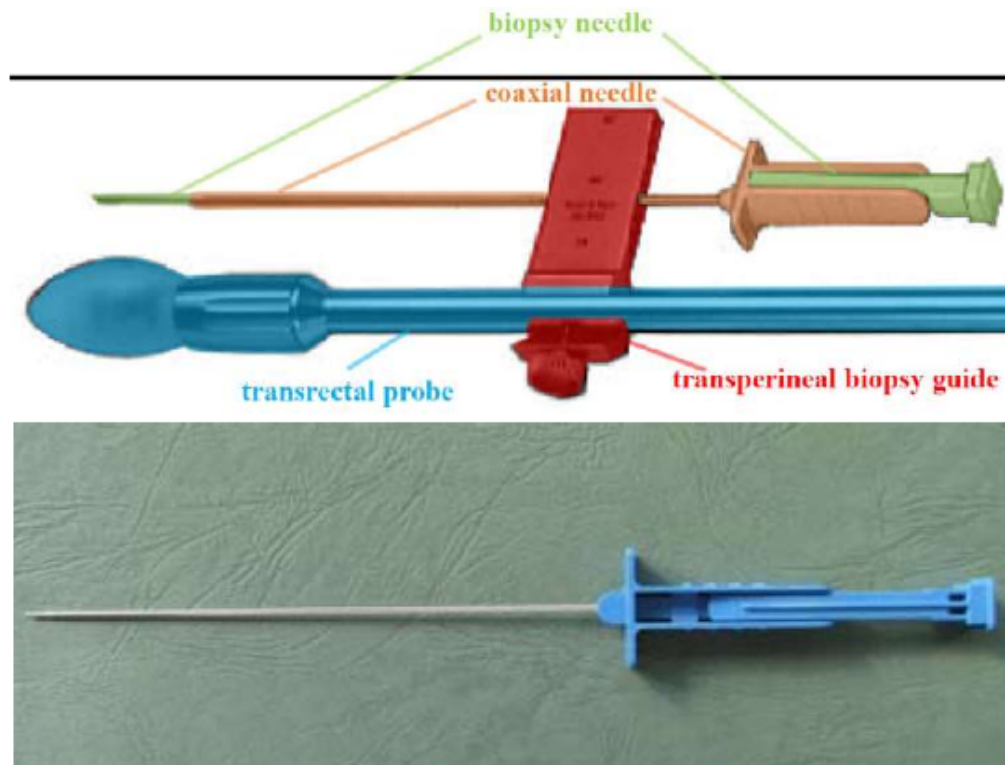


Illustration of Ex. 1009 Fig. 11 modified “to use an additional needle guide”

Perhaps more egregious is Petitioner’s colored annotations of BK Medical 2 that wrongly depicts the external cannula and inner stylet of a single biopsy needle as two separate needles: a coaxial needle and a biopsy needle. Petition at 52 (annotating Figure 11). One example of a biopsy needle with the form factor shown in Figure 11 commonly used at the time of the invention was the Tru-cut biopsy

needle. Ex. 2003 at 134 (“At present the most commonly used kidney biopsy needles are Tru-cut needles.”); *see also* Ex. 2002 at 2.

A comparison of Petitioner’s mistaken annotations depicting two needles to the single Tru-cut biopsy needle is provided below:



**Comparison of Petitioner’s annotations with a Tru-cut biopsy needle
(Ex. 1007, Fig. 11 on top and Ex. 2003, Fig. 1 on bottom)**

For the Tru-cut type of biopsy needle, the external cannula is moved relative to the inner stylet to cut the tissue sample into the specimen notch for extraction. Ex. 2003 at Fig 1 and 134; Ex. 2002 at 2. A close-up of the Tru-cut’s inner stylet with specimen notch extending past the external cannula is shown below:



Ex. 2002 at 2

Petitioner’s attempt to distort Figure 11 of BK Medical 2 via colorized overlays to argue a commercially available biopsy needle is both a “a biopsy needle and coaxial needle” lacks credibility. Petition at 52.

III. PROSECUTION HISTORY

U.S. Patent Application No. 17/698,641 (the ’641 Application) was filed on March 18, 2022 and issued as the ’436 Patent on January 10, 2023. Patent Examiner Sanjay Cattungal examined the ’641 Application, as well as the applications of the four other asserted patents in the district court litigation.

The ’641 Application received a Non-Final Office action on May 25, 2022 with a 35 U.S.C. § 102 rejection in view of U.S. Patent No. 5,931,786 to Whitmore, III *et al.* Applicant filed a Response to the Non-Final Office action on August 25, 2022 with no amendments to the independent claims, with a cancellation of claim 24, and with new claims 25-31. In the subsequently issued Notice of Allowance, the Patent Examiner submitted an Examiner’s Amendment and provided the reason for allowance is that “none of the prior art alone or in combination teaches [...] ‘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’.”

Since the district court litigation was concurrent with the prosecution of the ’641 Application, various documents associated with the litigation were disclosed by the Applicant to the Examiner in an Information Disclosure Statement on August 26, 2022. Patent Examiner Cattungal was familiar with the litigation since information regarding the litigation had been previously disclosed in U.S. Patent Application No. 17/314,845 (the ’845 Application), which is a parent application of the ’641 Application. Ex. 1020 at 72-74. The ’845 Application was pulled from issuance on November 23, 2021 in order to disclose information related to the U.S. district court litigation and a related proceeding in the Netherlands, which included the prior art relied on in this PGR Petition. *See id.* at 133 (RCE request based on submission of IDS and petition to withdraw from issuance).

IV. THE PETITION SHOULD BE DENIED UNDER 35 U.S.C. § 325(d)

The Board has discretion to deny institution under 35 U.S.C. § 325(d) where “the same or substantially the same prior art or arguments previously were presented to the Office.” In determining if a petition should be denied under § 325(d), the Board uses the two-step *Advanced Bionics* framework:

- (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and

(2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics at 8-9. Resolution of these steps may involve consideration of the six factors provided for in *Becton, Dickinson. Id.* at 9, n. 10 (citing *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017- 01586, Paper 8, at 17-18 (PTAB 2017) (precedential as to § III.C.5, first para)).

On the first step of *Advanced Bionics*, there is no reasonable dispute that the same or substantially same art was previously presented to the Office given that Petitioner acknowledges that Novella, BK Medical, Onik and Zangos were considered by the Examiner during prosecution. Petition at 107. The only reference asserted by Petitioner to be new is Nakamura, but it is cumulative to other art previously considered by the Office showing that biopsy guides with multiple through holes were known in the art. Adding a “new” reference to teach a well-known concept does not overcome the Office’s previous consideration of the remaining references that are alleged by Petitioner teach a majority of the limitations in the ’436 Patent claims.

Regarding the second step of *Advanced Bionics*, there is no evidence that the Examiner committed material error. Rather, the record shows the Examiner performed a comprehensive evaluation of the prior art in the ’436 Patent prosecution and related family members. Moreover, the record shows that the Examiner already

considered the Novella, BK Medical, and Onik in nearly the exact form and combination as the Petitioner presents in the present Petition.

Given there is no explicit error for Petition to point to, Petition relies on a theory of implicit error based on the Examiner's allowance the '436 Patent despite consideration of the references in this Petition. While Petitioner is incorrect that the Petition demonstrates unpatentability, such a generalized allegation of implicit error is insufficient to satisfy *Advanced Bionics* in any event.

In view of the Office's prior consideration of the same or substantially same art and arguments, the Board should exercise its discretion and deny the PGR petition under 35 U.S.C. § 325(d).

A. *Advanced Bionics* Part I - The Office Considered the Same Prior Art or Arguments During Prosecution

Petitioner does not dispute that *Advanced Bionics* part one is met in view of the prosecution of the '436 Patent and its parent applications. As Petitioner notes, each of "Onik, Novella, and BK Medical—was either cited by the Examiner or provided with an information disclosure statement ("IDS") in a parent application" and that "Zangos was submitted in an IDS in the '436 Patent." Petition at 107-08; *see e.g., Weatherford U.S., L.P. v. Enventure Global Tech., Inc.*, IPR2020-01661, Paper 19 at 15-16 (PTAB Apr. 15, 2021) (finding art cited in IDS and considered by the Examiner met *Advanced Bionics* part one).

While the above consideration admitted by Petitioner should be sufficient under *Advanced Bionics*, for the avoidance of any doubt Patent Owner notes that Onik and Zangos appear on the face of the '436 Patent and thus are presumptively considered. *Amneal Pharms., LLC*, 802 F.3d 1301, 1307 (Fed. Cir. 2015); *see* Ex. 1001 at 1-2. In addition, despite Petitioner's statements otherwise, Novella, and BK Medical were also cited and considered by the Examiner during prosecution of the '436 Patent itself. *See* Ex. 1002 at 176 (Examiner initialing that he considered "U.S. Patent Litigation Document, Plaintiff's Initial Invalidity Contentions dated 8-1-2022").

Yet, even assuming the Examiner only considered Novella and BK Medical in the parent 17/314,845 application (the '845 Application), that means the Examiner presumptively considered these references in the child 17/698,641 application (the '641 Application) maturing into the '436 Patent. *See* MPEP §609.02 ("The examiner will consider information which has been considered by the Office in a parent application...A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent."); *see* Ex. 1020 at 73, 354-357, 364-367 and 457-474. Finally, the Examiner is presumed to have properly performed their job duties during patent prosecution. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008).

The only reference not expressly considered by the Office previously is Nakamura. Petitioner relies on Nakamura only for the limited teaching of a “plurality” of needle receiving ports. *See* Petition at 84-85. Yet, this teaching is substantially the same teaching in other prior art considered by the Examiner, including the Whitmore reference used in a rejection during prosecution. *See* Ex. 1002 at 209 (Examiner citing Whitmore’s teaching of a “plurality of holes for needle access element 70”). Petitioner does not dispute that Nakamura’s relevant disclosure is cumulative to what the Office already considered.

Even if Nakamura’s teachings could be considered new, the Petitioner only applies it to a single term for a subset of asserted Grounds. The majority of Petitioner’s arguments are based on Novella, BK Medical, and Onik, which Petitioner concedes were previously considered. Petition at 107-08. In similar scenarios, Board panels have found that the addition of a newly considered reference of limited relevance is insufficient to overcome *Advanced Bionics* part one. *See e.g., Kayak Software Corp. v. Int’l Bus. Mach. Corp.*, CBM2016-00075, Paper 16 (PTAB Dec. 15, 2016) (informative).

Therefore, the Board should find that the prior art relied on in the Petition is the same or substantially same art was previously presented to the Office.

B. *Advanced Bionics* Part II – No Material Error by the Examiner

Since the Office has previously considered the same prior art and arguments,

the Board should deny the Petition unless the Petitioner shows material error in the Office's prior consideration. *Advanced Bionics* at 8-9. Petitioner's argument for error is premised on the belief that "the record's silence on Petitioner's prior art reflects the Office failed to appreciate the significance of Petitioner's proposed grounds." Petition at 108-110. Factually, this statement is incorrect since the record shows that the Examiner explicitly mentions Petitioner's primary reference for Grounds 3 and 4, Onik, as one of the closest prior art references for the '641 Application. *See* Ex. 1002 at 36. In addition, the Examiner addressed Onik, in detail when issuing a rejection in the parent '845 Application and would have been aware of that analysis in the child '641 Application that issued as the '436 Patent. Ex. 1020 at 715-16.

While the Examiner didn't expressly rely on Novella or BK Medical in a rejection, disagreement by the Petitioner with the Examiner's assessment that the four other references identified as the "closest prior art or record" (including Onik) were more relevant than Novella or BK Medical is not material error. For example, given that the Examiner perceived Whitmore as an anticipatory reference teaching all pending claim limitations in the '461 Application there is little explanation needed for why the Examiner rejected the claims over Whitmore instead of Novella or BK Medical. *See* Ex. 1002 at 208-09. Not even Petitioner alleges Novella or BK Medical could be asserted as anticipatory references elevating them in relevance

above Whitmore.

Moreover, the present case is unlike the cases cited by Petitioner where the Board cited an underdeveloped or silent record as a factor to institute. *See* Petition at 110. In the *Samsung* and *Carrier* decisions cited by Petitioner, the Examiners issued no prior art rejections during prosecution. *Samsung Elecs. Co. v. Evolved Wireless LLC*, No. IPR2021-00943, Paper 9 at 11 (PTAB Dec. 1, 2021) (Board noting Examiner only issued §112 and double patenting rejections); *Carrier Fire & Sec. Ams. Corp v. Sentrilock, LLC*, No. IPR2021-00664, Paper 12, 21-23 (PTAB Sept. 16, 2021) (Board agreeing the Examiner issued no rejections). Conversely, the Examiner here issued a prior art rejection and cited multiple references when discussing the closest prior art of record. *See* Ex. 1002 at 208-09 and 36-37. Thus, unlike the cases cited by Petitioner, the record here is not underdeveloped or silent but rather demonstrates the Examiner substantively considered and appreciated the prior art.

Petitioner's remaining citation, *Advanced Energy*, is inapposite to the facts here. Petition at 110 (citing *Advanced Energy Indus. Inc. v. Reno Techs. Inc.*, No. IPR2021-01397, Paper 7, 7-8 (PTAB Feb. 16, 2022)). The *Advanced Energy* decision primarily addresses an error made by the Examiner in evaluating a prior art reference during prosecution that was later cited in the Petition. *See Id.* at 9 ("It is also apparent that the Examiner's reliance on Mavretic during examination of the grandparent

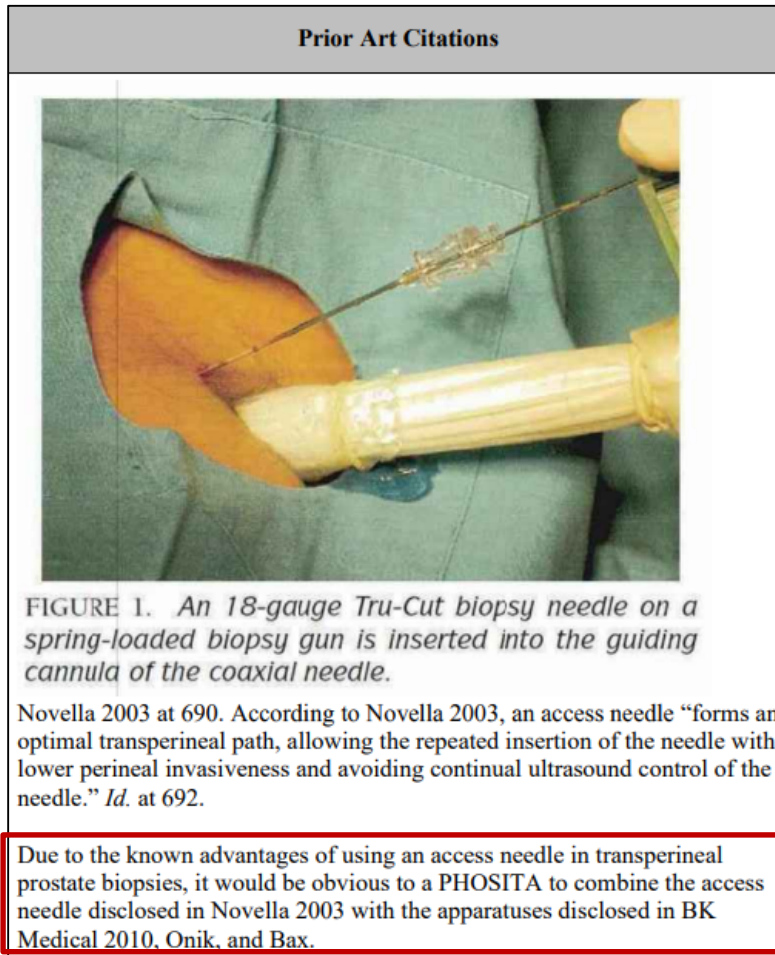
application did not extend to the prior art impedance matching network depicted in Mavretic's Figure 1.”). Petitioner does not even rely on the same prior art reference in the IPR petition as the Examiner relied on during prosecution as was the case in *Advanced Energy*. Quite the opposite as Petitioner argues silence about the prior art references relied on in the Petition is the error.

Importantly, Petitioner does not show the Examiner failed to comprehend the scope of the claims or the prior art since neither Novella nor BK Medical teach the Examiner's noted reason for allowance. Namely, the Examiner determined that none of the prior art teaches “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.” Ex. 1002 at 36-37.

Instead of pointing to an Examiner error, the Petitioner tries to explain away the fact that the Examiner already considered the same arguments as in the PGR Petition and found they were not persuasive. While Petition admits its invalidity contentions from the underlying litigation were considered by the Examiner, Petition alleges that those “contentions do not include Novella, Nakamura, or any of the combinations presented in this Petition.” Petition at p. 108. Petitioner is mistaken.

The invalidity contentions presented Novella in combination with BK Medical and Novella in combination with Onik just as they are presented in the PGR

Petition. Ex. 2012 at 17 (showing Novella in combination with BK Medical and Onik); Ex. 1002 at 176 (Examiner initialed consideration of these invalidity contentions)



Ex. 2012 at 17.

EXHIBIT A

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

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

The Secondary References cited include:

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

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

Ex. 2012 at 13.

While Petitioner's obviousness argument lacks merit, as discussed *infra*, this line of argument could not show the Examiner committed a material error in any event. *Advanced Bionics'* material error showing requires more than an assertion that the claims are unpatentable in view of the grounds raised in the Petition. *Advanced Bionics*. See *Advanced Bionics* at 21; *Juniper Networks, Inc. v. Mobile Telecom. Tech., LLC*, IPR2017-00642, Paper 31, 22 (PTAB Mar. 14, 2018) (to show a material error, Petitioner must identify a "compelling reason").

Indeed, if the arguments in the Petition alone could be enough to show material error, then *Advanced Bionics* part II would have no purpose since it would simply mirror the same standard as that to institute a PGR. Since *Advanced Bionics* provides a framework for when the Board may deny an otherwise meritorious

petition, Petitioner's reliance on a meritorious petition without any showing of error cannot satisfy the *Advanced Bionics* material error prong.

Finally, Petitioner's "additional facts and evidence" do not alter this outcome. Petition at 110-111. Dr. Yun's declaration is a copy-paste of the Petition, and, therefore, it does not provide any additional facts and evidence beyond the Petition itself. Moreover, Dr. Yun does not provide any new teachings for consideration. He merely arrives at a different conclusion than the Examiner based on the same teachings previously considered. Dr. Zat'ura's contradictory testimony about his own personal experiences performing transperineal biopsies is even less relevant since Dr. Zat'ura's personal experiences does nothing to explain what a POSITA would have known about the prior art cited in Petitioner's rejections. Lastly, Petitioner's reliance on BK Medical as a new teaching is misplaced since BK Medical was considered by the Examiner specifically in combination with Novella as shown above. *See* Ex. 1002 at 12 and 17. Even if BK Medical was never considered, Petition acknowledges it provides no new teachings over what was previously considered by the Examiner. Petition at 108 (admitting Examiner considered "a User Guide for a similar Type 8818 BK Medical probe.").

At most, Petitioner's argument shows a disagreement with the Examiner's analysis of the prior art references of record, but it does not show the Examiner committed a material error. Therefore, the Board should deny institution under 35

U.S.C. § 325(d).

V. PETITION SHOULD BE DENIED UNDER 35 U.S.C. § 314(a)

In view of the co-pending litigation, the Board should exercise its discretion to deny institution of the Petition under Section 314(a). “The AIA’s post-grant proceedings improve and ensure patent quality by providing quick and cost-effective alternatives to litigation for challenging issued patents.” *CommScope Techs. LLC. v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 at 3 (February 27, 2023) (precedential) (internal quotations omitted). Unlike most IPR/PGR proceedings, here the Petitioner is the party that initiated the co-pending litigation via a declaratory judgment action requesting invalidity of Patent Owner’s patents. Ex. 2001 at 2 (Petitioner asserts “each of the claims of the Patent-in-Suit are invalid”).

The Petitioner could have initially sought to address validity issues before the Board, but instead filed a declaratory judgement with the Federal Courts in its home state of Georgia to resolve validity of Patent Owner’s patents. Ex. 2001. Only after the federal court case was transferred out of its home district in Georgia to the District of Maryland, and months after the Petitioner agreed to permit newly granted patents to be added to the litigation did Petitioner decide to seek relief through this alternative PTAB forum. *See* Ex. 2004 at 20 (order transferring case).

In addition, Petitioner has only asked the PTAB to address the validity of the '436 Patent even though Patent Owner accuses Petitioner of infringing four other related patents that share subject matter with the '436 Patent. *See* Ex. 2008 at 1 (Petitioner's claim construction brief listing the asserted patents and stating that "[t]he written disclosures of the Asserted Patents have substantial overlap and, therefore, are cited collectively.") This piecemeal approach guarantees duplication of efforts and greatly increases the chances of conflicting outcomes between the Federal Courts and the Board. Regardless of any final Board decision with respect to the '436 Patent, some of the same issues will arise in the federal court litigation on the other four related patents given the subject matter overlap.

In assessing whether to deny a petition under Section 314(a), the Board first analyzes the *Fintiv* Factors. *CommScope* at 4 (citing *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential). If the first five *Fintiv* factors weigh in favor of denial, then the Board must consider under the sixth *Fintiv* factor if there is a showing of compelling merits that nonetheless compels the Board to institute. *Id.*; *see also* USPTO Memorandum, Interim Procedure for Discretionary Denials in AIA Post Grant Proceedings with Parallel District Court Litigation at 4 ("Guidance Memo") (June 21, 2022). However, in any circumstance, "the PTAB retains

discretion to deny institution for proceedings where abuse has been demonstrated.” Guidance Memo at 4.

As discussed below, the *Fintiv* factors favor denial. In addition, the Petitioner has abused the PGR process by: 1) first seeking relief on validity from the federal courts rather than the PTAB; and, 2) by seeking relief on a single patent before the PTAB rather than all asserted patents sharing the same subject matter. Petitioner’s action has led to inefficient parallel proceedings with potentially conflicting outcomes.

A. Factor 1: whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted

Petitioner has not requested a stay in the parallel litigation. Should Petitioner request a stay pending this PGR, the facts demonstrate that the district court is unlikely to grant such a request.

Most importantly, Petitioner has sought IPR/PGR of only one patent even though it is accused of infringing five patents. While Petitioner can challenge those remaining four patents via *ex parte* reexamination, Maryland’s local rules states the Court will not even consider a stay pending reexamination unless the reexamination has been ordered and a first office action has issued. Ex. 2006 at 102. However, there are currently no

reexamination orders or first office actions for any of those four patents.³ Thus, the District Court litigation will not even consider staying the other four patents regardless of the outcome of this PGR on the '436 Patent. Therefore, the evidence shows that the District Court is unlikely to stay the litigation since the majority of the asserted patents are not subject to either IPR/PGR or have reexamination office actions.⁴

While Petitioner asserts the Maryland District Courts have granted “all” motions to stay pending a PGR or IPR, they leave out that “all” is only five examples. Petitioner has also not attempted to show that the facts in the current case are similar to the facts in any of the cases where a stay was granted. For example, in the single case where a motion to stay pending IPR was decided by the same judge overseeing the underlying litigation here, Judge S. Gallagher, the stay issued in 2020 was chiefly due to COVID-19 related restrictions during the height of the recent pandemic. Ex. 2005 at 1 (“The current pandemic is creating public health dangers throughout the

³ At the time this Preliminary Response, Petitioner has filed a reexamination request against one of those four patents, but the Office has not made any determinations or issued any office actions. *See* Reexamination Control No. 90/019,257.

⁴ Petitioner’s decision to seek District Court relief instead of IPR/PGR of the other four patents is discussed in more detail with respect to Factor 6 as it demonstrates Petitioner’s attempt to abuse the PGR process.

world,...this Court is not inclined to require persons to travel...”). That reasoning is inapplicable to the pending litigation related to this PGR.

Therefore, there is no evidence that a stay will be granted if this PGR is instituted but there is evidence that a stay is unlikely given that four asserted patents are not subject to any IPR/PGR proceedings. As such, Factor 1 favors denial of institution.

B. Factor 2: proximity of the court’s trial date and the Board’s projected statutory deadline for a FWD

Factor 2 looks at the proximity of the district court’s trial date to the expected statutory deadline for the Board’s final decision. “If the court’s trial date is earlier than the projected statutory deadline [for the final written decision], the Board generally has weighed this fact in favor of exercising authority to deny institution under *NHK*.” *Fintiv*, IPR2020-00019, Paper 11 at 9 (PTAB Mar. 20, 2020).

Here, the Court has not yet scheduled a trial date. However, the Federal Court data from the most current yearly statistics shows an average of 35 months from filing to trial in the District of Maryland. Ex. 2007 at 20 (35 months is the average of the median time to civil trial over the last five years).⁵

⁵ These stats for median trial time are from the source cited in the Director’s Guidance Memo on this issue. Guidance Memo at 3, FN 4 (citing

The original DJ complaint was filed by Petitioner on October 22, 2021. Thus, the historical average would indicate a trial date sometime around September 2024. This would occur before any Final Board decision is likely to issue in this proceeding.

For the foregoing reasons, Factor 2 favors denial of institution.

C. Factor 3: investment in the parallel proceeding by the court and the parties

The parties have spent considerable resources in the parallel proceedings having already produced infringement contentions, produced invalidity contentions, engaged in other discovery, and have fully briefed claim construction disputes for the District Court. *See* Exs. 1018, 1019, and 2008-2012. Notably, the invalidity and claim construction issues overlap the issues that will be addressed should PGR be instituted caused duplication of effort and potentially conflicting outcomes.

By the time the Board decides whether to institute this PGR, it is likely the District Court will have issued its claim construction order or be close to doing such. “[I]f, at the time of the institution decision, the district court has issued substantive orders related to the patent at issue in the petition, this fact

“<https://www.uscourts.gov/statistics-reports/analysis-reports/federal-court-management-statistics>”).

favors denial.” *Fintiv* at 9-10. “[D]istrict court claim construction orders may indicate that the court and parties have invested sufficient time in the parallel proceeding for favor denial.” *Id.*; *see also Supercell OY v. Gree, Inc.*, IPR2020-00310, Paper 13 at 14 (PTAB Jun. 18, 2020) (finding that the parties and district court had invested substantial resources into the parallel proceeding from the issuance of “a detailed Claim Construction Memorandum Opinion and Order, after several rounds of briefing by the parties, that provides constructions of numerous claim terms that appear in five related, asserted patents”).

For the foregoing reasons, Factor 3 favors denial of institution.

D. Factor 4: overlap between issues raised in the petition and in the parallel proceeding

There is no dispute that the issues raised in the Petition overlap those raised in the underlying District Court litigation since Petitioner relies on the same prior art in the PGR as in the litigation. *Fintiv* at 12. (“[I]f the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial.”); *see also Ex. 1002* (invalidity contentions raise same obviousness grounds as presented in this PGR)

Petitioner seeks to moot that overlap through a *Sotera* type stipulation. Petition at 112. However, Petitioner’s stipulation does not eliminate the

overlap of issues as in *Sotera* because here the Petitioner has not challenged the other four patents that share some common subject matter with the '436 Patent. Assuming Petitioner was estopped from challenging the validity of the '436 Patent in the underlying litigation, Petitioner could seek to relitigate some of the same issues addressed in this PGR with regards the other four asserted patents.

For example, the parties agree that certain contested claim limitations including “access needle” and “biopsy needle” are recited in the '436 Patent as well as the other asserted patents. *See* Ex. 1018 at 5-9. Assuming the stipulation precludes Petitioner from arguing the prior art teaches those limitations in the '436 Patent, its stipulation does not preclude it from arguing the prior art teaches those limitations in the related asserted patents. By not challenging all the asserted patents in IPR/PGR proceedings, Petitioner's stipulation provides a hollow shell of the stipulation provided in *Sotera*.

As noted by the Director, the benefits of a *Sotera* stipulation is that it “mitigates concerns of potentially conflicting decisions and duplicative efforts between the district court and the PTAB.” Director's Guidance Memo at 7. The stipulation provided by Petitioner achieves neither of those benefits since the concern of potentially conflicting decisions and duplicative efforts will remain even with Petitioner's stipulation.

For the foregoing reasons, Factor 4 favors denial of institution.

E. Factor 5: petitioner and defendant in the parallel proceeding are the same party

Where the parties involved in the Petition are in the parallel proceeding, this factor favors the Board exercising its discretion to deny institution. *Fintiv*, at 13-14. There is no dispute that the parties here are the same as in the parallel litigation.

For the foregoing reasons, Factor 5 favors denial of institution

F. Factor 6: other circumstances

Fintiv also prescribed that the factors considered in exercising discretion are “part of a balanced assessment of all the relevant circumstances in the case, including the merits.” *Fintiv* at 14–15.

This case presents the unusual circumstance of a Petitioner’s legal strategy being used to evade a statutory bar that strongly weighs in favor of denial. To wit, Petitioner initially sought relief via a declaratory judgment (DJ) action in district court on invalidity issues it now seeks the Board to address in this PGR. While a DJ normally is a statutory bar to a PGR, Petitioner attempts to evade that statutory bar though filing a DJ against multiple asserted patents that share subject matter with the ’436 Patent while simultaneously challenging the ’436 Patent before the PTAB.

Petitioner's actions to have two different forums consider the same subject matter have invariably set the course for potentially conflicting decisions and duplicative efforts between the District Court and the PTAB. For example, both actions will require construction of some of the same claim terms, analysis of the same prior art, and consideration of substantially the same expert testimony on issues like motivation to combine.

Perhaps most importantly is that prior to filing the DJ action, Petitioner could have sought relief from the PTAB via *inter partes* review on the related patents sharing subject matter with the '436 Patent. Alternatively, it could challenge the validity of the '436 Patent in the District Court just as it is challenging the related patents in District Court. Either approach would have enabled a single forum to address the common prior art invalidity issues between all the asserted patents. However, Petitioner's actions have deliberately split invalidity proceedings on the same subject matter into two separate forums.

Petitioner's legal strategy to first file a DJ and then ask the Board to address the same issue has subverted the PGR process as an alternative to litigation. Indeed, the statutory framework for PGR precludes instituting PGR on a patent that Petitioner filed a DJ against. Petitioner has employed a loophole to avoid this statutory prohibition. By doing so, the Petitioner hopes to obtain a Board PGR

decision on issues impacting the validity of patents that the Petitioner is statutorily barred from challenging via PGR. *See* 35 U.S.C. 325(a)(1).

Furthermore, Petitioner's strategy undercuts the estoppel provisions of Section 325. By challenging only one out of five asserted patents in an IPR/PGR proceeding, Petitioner attempts to avoid any estoppel related to the remaining four patents. Assuming the Board were to institute this PGR and find all claims patentable, Petitioner could try to get a second bite at the apple in litigation on the remaining patents that share subject matter with the '436 Patent. Indeed, assuming no estoppel applies to those patents, Petitioner could use the very same prior art and arguments in the litigation as it does in the PGR.

Finally, while a case of "compelling merits" can weigh in favor of institution, there is no such showing here. *Commscore* at 3. A PGR has a higher standard of institution than an IPR and "the compelling merits standard is a higher standard than the standard for institution set by statute." *Id.* Thus, the standard for a "compelling merits" showing in a PGR is quite high. As discussed below, the Petition is based on faulty claim construction, misreading the prior art, and conclusory expert testimony.

Even if compelling merits could be shown, "the PTAB retains discretion to deny institution for proceedings where abuse has been demonstrated." Guidance Memo at 4. Petitioner's decision to seek PGR here only after Petitioner sought relief in the District Court on the same issues in related patents is an abuse of the PGR

process to subverts Congress's intent to provide an alternative to litigation. Petitioner could have chosen the PTAB to address these common validity issues from the start, but it did not. Alternatively, the Petitioner can seek to challenge the '436 Patent in the District Court where it is challenging the other related patents. Instead, it chooses a strategy to try and challenge validity in both forums.

As such, the Board should deny Petitioner's attempt to circumvent the statutory intent of PGR proceedings. For the foregoing reasons, Factor 6 favors denial of institution.

VI. CLAIM CONSTRUCTION

A. Petitioner's hiding the ball on claim construction

While Petitioner asserts that no constructions are needed to resolve this PGR, Petitioner provides a lengthy discussion of its interpretation of the scope of claim limitations 1.8, 13.7 and 24.7. *See* Petition at 15-17 and 59-60. Petitioner's interpretation of the scope of these limitations in this PGR is an implicit claim construction intended to broaden the claims beyond their plain and ordinary meaning. *See* 37 C.F.R. § 42.200(b) (claims in PGR construed according to their "ordinary and customary meaning").

Petitioner's attempt to hide its actual claim construction from the Board is dubious given Petitioner's submission of an express construction of these limitations in the underlying litigation. Ex. 1018 at 28; Ex. 2008 at 26; *see also* Ex. 2010. In

contrast to Petitioner, Patent Owner asserts that limitations 1.8, 13.7 and 24.7 do not need construing because they are comprised of common everyday words whose meaning and scope is clear from a simple reading of the patent claims. Ex. 2009 at 23; Ex. 2011 at 35.

Indeed, the Petitioner identified the parties' respective positions on these claim limitations as shown below:

XII. TERM 11: “COUPLING [SECURING] 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 [MAINTAINED]”	
Advance Medical’s Construction	Corbin’s Construction
“inserting the access needle into one of the plurality of needle receiving ports, wherein the needle receiving port is configured to support the access needle at an angle and position relative to the displacement member”	No construction necessary – plain and ordinary meaning

Ex. 2008 at 26. Moreover, Petitioner’s PGR arguments are premised on this improper construction that re-writes the claim limitation to recite a needle receiving port supporting an inserted access needle. *See* Petition at 60 (for limitation 1.8 arguing Novella’s “needle channel maintains and stabilizes” an “inserted” access needle) and 97 (arguing Onik’s “notch maintains the...position of the access needle once inserted”).

The parties are vigorously fighting over the meaning of these claim limitations in the underlying litigation. *See* Ex. 2008-2011. The timing of the District Court’s

order on the resolution of this dispute is uncertain and may occur before the Board's institution decision in this proceeding or after the institution decision. This potential for conflicting decisions between the Board and the District Court is likely why Petitioner has hidden its claim construction in this proceeding under the guise of discussing scope. As discussed above with regards to *Fintiv* analysis, Petitioner created this potential conflict by dividing up its challenges between the Board and the District Court and cannot now pretend its construction does not exist.

As discussed below, the Board should reject Petitioner's construction of claim limitations 1.8, 13.7 and 24.7 that attempts to re-write the claims.

B. Limitations 1.8, 13.7 and 24.7 should be given their plain and ordinary meaning instead of Petitioner's construction

Petitioner's proposed construction of these limitations replaces the words "coupling" or "securing" the access needle" with "inserting the access needle." Ex. 2008 at 26. Moreover, Petitioner's construction erases the recitation in the claims that "a position and angle of the access needle relative to the displacement member is retained[/maintained]" and replaces it with "wherein the needle receiving port is configured to support the access needle at an angle and position relative to the displacement member." Ex. 2008 at 26. Petitioner requires its construction to advance the arguments in this PGR that these limitations are taught merely by needle ports supporting an inserted access needle.

Although Petitioner’s construction wholesale changes the wording of the claim, Petitioner contends this “construction is appropriate as it clarifies that neither ‘coupling’ nor ‘securing’ require locking the access needle in place to completely prevent any movement of the access needle.” Ex. 2008 at 26; *see also* Petition at 15 (“These terms do not require locking the access needle in place to completely prevent any movement of the access needle.”). Yet, this is nothing more than a straw-man argument apparent from Petitioner’s failure to cite any supporting evidence of what this locking requirement is or where it comes from.

Rather, Patent Owner asserts in this PGR and in the underlying litigation that the claims require “coupling” or “securing” in accordance with their plain and ordinary meaning. Ex. 2009 at 23. The inventor of the ’436 Patent never offered alternate definitions of these terms, never identified a clear intent to modify the meaning of such terms, and never provided any indication that the plain and ordinary meaning of the terms are insufficient. Petitioner tries to avoid showing how the prior art teaches “coupling” or “securing” by construing the claims to not use those terms.

Moreover, the construction proposed by Petitioner ignores that each of the independent claims require “inserting” an access needle and separately “coupling” or “securing” the access needle. For instance:

- Independent claim 1 requires the step of “inserting at least a portion of the tubular shaft of the access needle into one of a plurality of needle

receiving ports” and separately requires the step of “coupling the access needle to the one of the plurality of needle receiving ports of the displacement member...” Ex. 1001 at 35:58-60; 36:1-3.

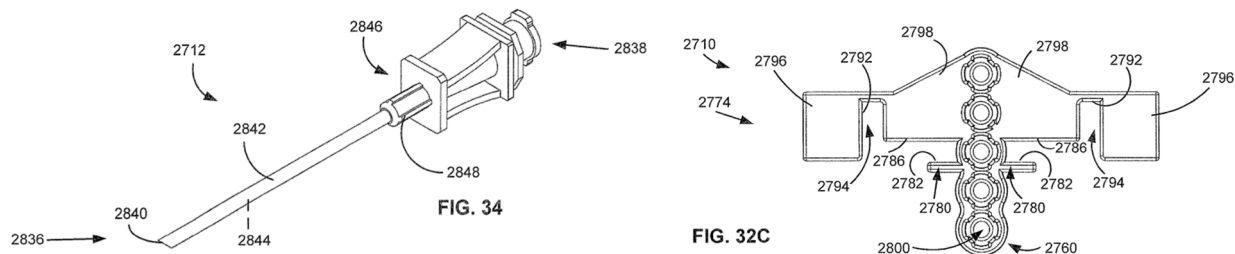
- Independent claim 13 requires “inserting an access needle into one of a plurality of needle receiving ports of a displacement member...” and separately requires the step of “securing the access needle to the displacement member...” Ex. 1001 at 36:47-48; 36:59-60.
- Independent claim 24 requires the step of “inserting an access needle into one of a plurality of needle receiving ports of a displacement member...” and separately includes the step of “securing the access needle to the one of a plurality of needle receiving ports...” Ex. 1001 at 37:39-40; 38:3-4.

Hence, the access needle must be coupled or secured to the receiving port or displacement member. Petitioner deletes this requirement and merely reiterates the requirement of “inserting.” Clearly, the inventor intended the “coupling” and “securing” limitations to mean something different than merely “inserting.”

As described in the Abstract, the invention is comprised of “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; securing the access needle to the displacement member such that a position

of the access needle relative to the displacement member is maintained.” *Id.* at Abstract. Each independent claim requires the access needle to be either “secured” or “coupled” to the displacement member. *Id.* at 36:1-2; 36:59-61; 38:3-4. In particular, claims 10, 22 and 25 are dependent claims describing how the “coupling” or “securing” may occur. Claim 10 states “wherein coupling the access needle to one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide comprises inserting a portion of the hub into one of the plurality of needle receiving ports.” *Id.* at 36:32-36. The “hub” is the specific method of “coupling” the access needle to the needle receiving port of Claim 1. Claim 22 similarly describes that “securing” the access needle to the displacement member is comprised of “inserting a portion of the hub into one of the plurality of needle receiving ports.” *Id.* at 37:26-29. Claim 25 describes a similar requirement, but does not specify that a “hub” effectuates the securing of the access needle. *Id.* at 38:14-19.

An example of a “hub” is shown as 2846 in Figure 34. *See* below. The hub may have “ridges 2848” that “engage with corresponding and negatively shaped features on the proximal side 2800 of the needle receiving ports 2768.” *Id.* at 25:8-13; *see* Figures 34 and 32C below. This demonstrates that “coupling” or “securing” is more than just “inserting.”



The specification further describes the “coupling” and “securing” limitations. There are 53 references to the root word of “secure” (including “securing”), describing that “securing” is not the same as “inserting.” For example, the specification states that “[i]n certain embodiments, the access needle 2712 may be secured to the displacement member 2710 by, for example, a threaded features on the hub 2846 and openings 2770 of the ports 2768 such that the needle 2712 and the displacement member 2710 may be threadably engaged and disengaged with each other.” *Id.* at 26:2-7. This passage describes now a securing mechanism may work and reaffirms that the word “securing” is not the same as “inserting” as used in the patent. Numerous other references reinforce this notion. *See, e.g., id.* at 12:8-10 (“[t]his configuration allows the lower mounts and the upper mounts to be secured to each other and to the probe.”); 11:12-14 ([t]he flange may be configured to snap into the guide to secure the needle.”)

Similarly, the word “coupling” is not the same as “inserting.” There are 82 references to the root word “couple” (including “coupling” and “couples”), describing that “coupling” means more than just “inserting.” *See, e.g., id.* at 5:9-13

(“[i]n certain embodiments, the guide member may operably couple with the transrectal probe via at least one of a sheath arrangement, a ratchet arrangement, a biased collar arrangement, a flexible strap arrangement, a clamping arrangement, or a clamshell collar arrangement.”); 24:16-18 (“[t]he platform 2766 is coupled with the probe coupling mechanism 2706, which, as seen in the figures, may be a snap-grip or snap-clip type of hose or tube clamp.”). The inventor even noted that “[j]oiner references (e.g., attached, coupled, connected, and the like) are to be construed broadly.” *Id.* at 35:15-16.

In its proposed construction, Petitioner also arbitrarily deletes the language “... of the displacement member of the transperineal biopsy guide.” While that language may be implied, it is an explicit requirement of the claim that cannot be ignored. *Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1361 (Fed. Cir. 2006).

Petitioner then replaces the term “such that a position and angle of the access needle relative to the displacement member is retained [maintained]” with “wherein the needle receiving port is configured to support the access needle at an angle and position relative to the displacement member.” Ex. 2008 at 26. Again, this construction is unsupported, arbitrary and contrary to the precise wording of the claims. For example, it reads out the requirement that the position and angle of the access needle relative to the displacement member be “retained” or “maintained.” No such concept is articulated in Petitioner’s proposed re-write of the claim

language. As a result, any angle and position of the access needle would meet the requirement, even if it was subsequently changed.

Petitioner asserts that its construction clarifies that “neither ‘coupling’ nor ‘securing’ require locking the access needle in place to completely prevent any movement of the access needle.” Ex. 2008 at 26; Petition at 15. Yet, the claim language is clear and unambiguous, and nothing needs “clarifying.” Even if such clarification was necessary, Petitioner’s proposed definition only adds confusion without providing any supposed clarification on that point as its proposed definition does not even mention “locking.”

VII. PROPOSED GROUNDS OF REJECTION ARE NOT LIKELY TO SUCCEED

A. Ground 1 – Novella in View of BK Medical

Petitioner’s arguments for Ground 1 are deficient for at least two reasons. First, Petitioner has not demonstrated the prior art teaches all the limitations of the independent claims, particularly limitations 1.8, 13.7 and 24.7. Second, Petitioner has not shown a POSITA would have been motivated to combine the references as proposed or had a reasonable expectation of success in using the proposed combination in a TPUS biopsy procedure.

1. Claim 1, limitation 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”

a. No teaching of “coupling the access needle to the one of the plurality of needle receiving ports”

Petitioner’s argument for limitation 1.8 of claim 1 is premised on Petitioner’s incorrect understanding that “inserting” a needle into a port is the same as “coupling” a needle to that port:

The practitioner “[i]nser[t]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.

Petition at 59. However, claim 1 of the ’436 Patent recites an access needle is both inserted into and coupled to a needle receiving port, as shown in the limitations below:

[1.4] inserting at least a portion of the tubular shaft of the access needle into one of a plurality of needle receiving ports...;

[1.8] coupling the access needle to the one of the plurality of needle receiving ports...;

Id.

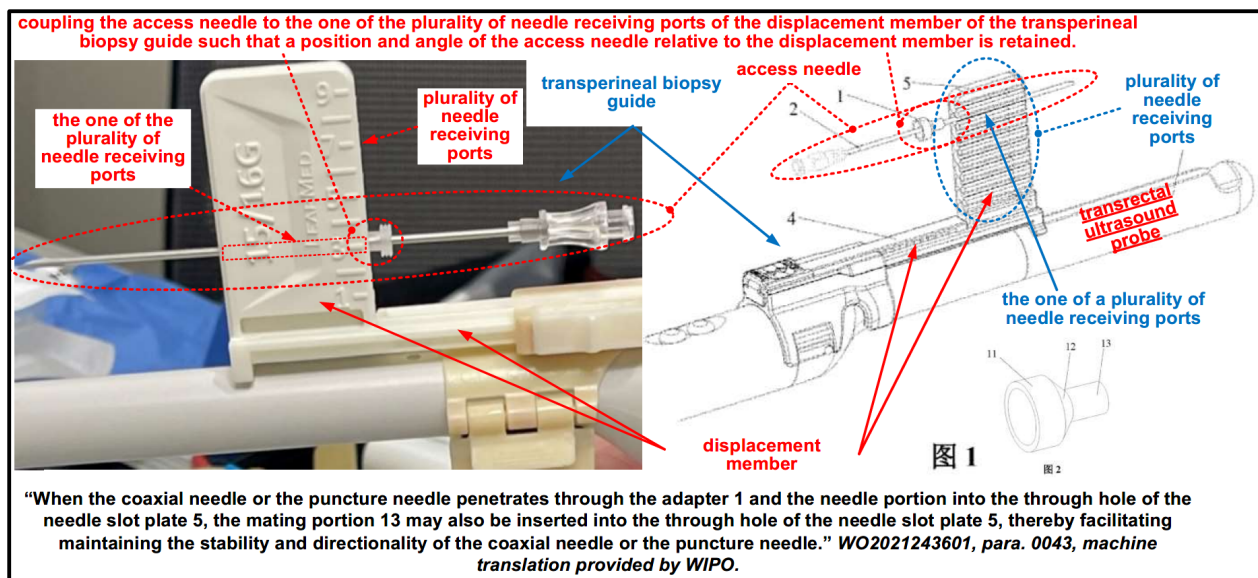
Thus, Petitioner's allegation that inserting and coupling are the same cannot be correct since limitation 1.4 of the '436 Patent recites inserting as a distinct requirement from the coupling recited in limitation 1.8. Ex. 1001 at 35:58-59. This distinction is also supported by the specification of the '436 Patent that gives an example of inserting an access needle into a receiving port then coupling the access needle to the port using ridges and/or threading. Ex. 1001 at 25:58-26:7. While ridges or threading are merely examples of coupling mechanisms contemplated by the invention, it evidences that coupling requires more than merely inserting in the '436 Patent. Although prior art need not disclose the exact same examples of coupling as used in specification of the '436 Patent, the prior art cited in the Petition fail to show any mechanism for the claimed coupling.

Petitioner never explains how Novella's coaxial needle (the alleged access needle) is coupled to the BK Medical UA1324 needle guide channels (the alleged plurality of needle receiving ports). Instead, Petitioner hopes to write the "coupling" limitation out of the claim via its claim construction and replace it with a second instance of "inserting." Ex. 1018 at 28; Ex. 200[AMD Opening CC Brief] at 26. As explained previously with regards to claim construction, Petitioner's attempt to re-write the claim has no basis and the Board should not adopt Petitioner's construction.

Petitioner's reliance on an alleged admission by Patent Owner as to the scope of this limitation also does not help Petitioner. Petitioner cites Patent Owner's

infringement contentions to wrongly suggest that Patent Owner reads the claim as only requiring “maintaining the stability and directionality of the coaxial needle or puncture needle.” Petition at 59 (citing Ex. 1019 at 22). Petitioner’s mischaracterization of the infringement contentions purposefully omits critical details.

In particular, Petitioner omits that the quoted language of “maintaining the stability and directionality of the coaxial needle or puncture needle” is about using an adapter to couple the access needle to a needle receiving port. Ex. 1019 at 22. As shown in the images provided in the infringement contentions (reproduced below), Patent Owner draws a circle around the adapter and included a specific figure of the adapter in the infringement contentions. *Id.* Petitioner does not allege the use of any adapter, or other coupling mechanism, in the combination of Novella and BK Medical. Thus, Petitioner’s reliance on the infringement contentions to help prove its flawed obviousness analysis is misplaced.



Ex. 1019 at 22, Patent Owner's Infringement Contentions (annotations in original)

- b. *No teaching of "coupling the access needle...such that a position and angle of the access needle relative to the displacement member is retained"*

Petitioner relies on conclusory expert testimony to assert that even without some coupling mechanism the combination teaches 1) "the access needle cannot rotate in the plane of the vertical needle guide fin," 2) "the needle channel also maintains and stabilizes the vertical position of the needle relative to the probe," and 3) "once inserted up to its hub, the needle channel maintains and stabilizes the axial position of the access needle." Petition at 59-60 (citing Ex. 1003 at ¶107.).

However, Petitioner's expert declaration is entitled to no weight on this issue since it merely repeats the Petitioner's conclusions verbatim and does not disclose how the expert arrived at these conclusions. Ex. 1003 at ¶107; 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the

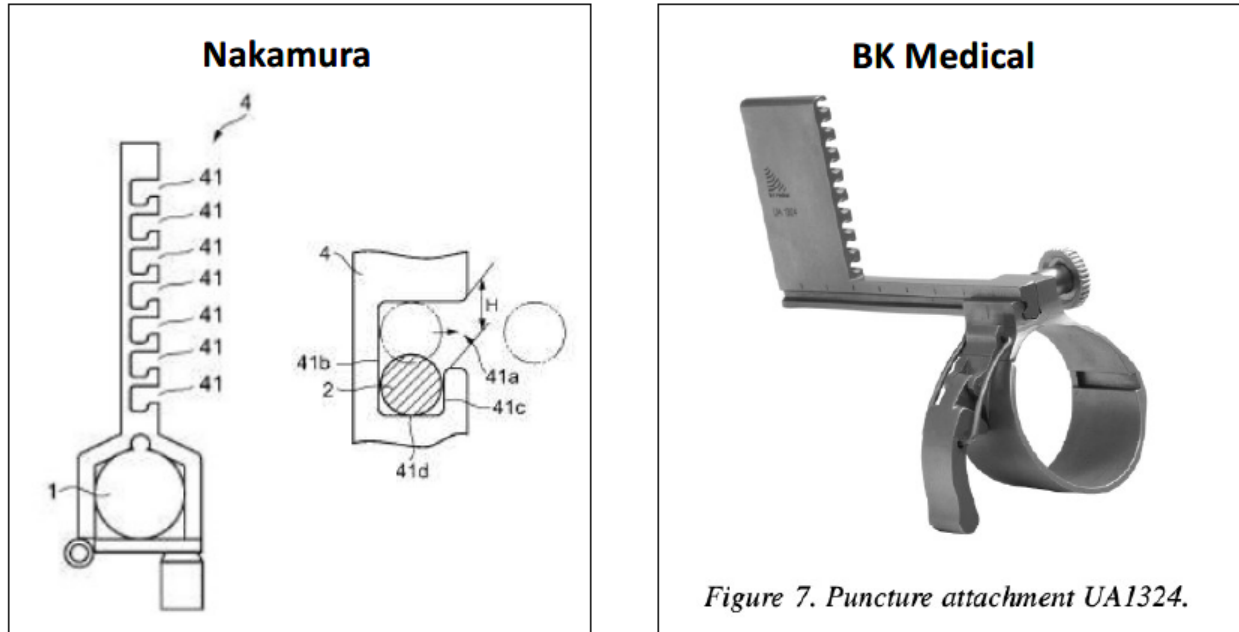
opinion is based is entitled to little or no weight.”). Conclusory expert testimony “is particularly problematic in cases where, like here, expert testimony is offered not simply to provide a motivation to combine prior-art teachings, but rather to supply a limitation missing from the prior art.” *Xerox Corp. et al., v. Bytemark*, IPR2022-00624, Paper No. 9 at 15 (PTAB Aug. 24, 2022) (Precedential).

Notably, Petitioner’s conclusory analysis that BK Medical’s needle guide “maintains and stabilizes” the needle position contradicts the statements in one of Petitioner’s other cited references, Nakamura. Ex.1012 at Fig. 16, Fig. 17 and 19-20. In describing prior art needle guides substantially the same as BK Medical, Nakamura states a known problem is that those needle guides do not maintain the needle’s vertical or horizontal positions during insertion:

However, in such a puncture adapter 4, the puncture needle 2 is inserted while being supported and guided by the guide walls in three directions, and **is not stable in the vertical direction.** Furthermore, when the puncture needle 2 rests on the open portion 41a during insertion, **it may not be stable in the horizontal direction either**, and the puncture needle 2 cannot be easily inserted. Furthermore, an image of the puncture needle 2 appearing on an ultrasonic linear tomogram may be unclear if the puncture needle is not stable in the horizontal direction

Ex. 1012 at 20. A comparison showing the similarity of the needle guide criticized by Nakamura and the needle guide disclosed by BK Medical are shown below.

Figure 17 in Nakamura shows the needle is subject to both vertical and horizontal movement while inside the needle guide.



Nakamura Figs. 16 and 17 (left) and BK Medical Fig. 7 (right)

Claim 1 of the '436 Patent recites a method where the access needle's position and angle to be retained (as recited in limitation 1.8) while the access needle is inserted into the patient (as recited in limitation 1.1). Ex. 1001 at 35:52-53. Thus, as explained by Nakamura, BK Medical's needle guide would not maintain position of a needle relative to the needle guide during insertion. The reason is simple, the anatomy of the body creates forces on the needle during insertion that alters the position of the needle.

Unlike the '436 patent, there is no proposed mechanism in the prior art that couples Novella's coaxially needle to BK Medical's needle guide to maintain the

relative position of the needle coupled to a displacement member. *See e.g.*, Ex. 1001 at 26:2-7.

Therefore, Petitioner has not demonstrated in the proposed combination that “a position and angle of the access needle relative to the displacement member is retained” when performing the method as recited in claim 1 of the ’436 Patent.

c. Claim 13, limitation 13.7 and Claim 24, limitation 24.7

For limitations 13.7 and 24.7, Petitioner relies on its argument for limitation 1.8. *See* Petition at 66 (limitation 13.7) and 70 (limitation 24.7). While Patent Owner does not agree with Petitioner’s apparent interpretation that the scope of these three claim limitations are identical, the previous explanations for why Petitioner failed to show claim 1 was obvious is likewise applicable to claims 13 and 24 in light of Petitioner’s use of the same rationale for all three claims. *See* Section VII(A)(1).

The only additional argument Petitioner makes is with respect to the last phrase in limitation 24.7 reciting “further insertion of the access needle relative to the displacement member is restricted.” Petition at 70-71. However, Petitioner’s argument for this additional phrase in 24.7 does not address the deficiency of the prior art with respect to the other recitations of limitations 24.7 for which Petitioner’s relies on its analysis of limitation 1.8.

Therefore, the Board should find that Petition fails to show the prior art renders claims 13 or 24 obvious for the same reasons as claim 1.

2. No motivation to combine or reasonable expectation of success for any claims

An obviousness determination requires finding “both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *Intelligent BioSys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367-68 (Fed. Cir. 2016) (citation omitted). In addition, this analysis must be performed based on what a POSITA would have known “at the time of the invention.” *InTouch Technologies, Inc. v. VGo Communications, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014).

Here, Petitioner relies on the same rationale for all claims to combine the access needle from Novella and the probe-mounted transperineal biopsy needle guide from BK Medical. However, BK Medical teaches away from the proposed combination. In addition, Petitioner identifies no evidence of record prior to the invention of the ’436 Patent that would have motivated a person of skill in the art to combine an access needle with a probe-mounted needle guide for performing TPUS procedures. Even if there were a motivation, there is no evidence that the proposed combination would have a reasonable expectation of success.

a. BK Medical teaches away from the proposed combination

BK Medical provides an explicit warning that the needle should be fully drawn back inside the needle guide before moving the probe, as shown below:

**WARNING**

When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the probe.

Ex. 1007 at 14. This warning is a teaching away since it expressly discourages a POSITA from the proposed combination. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009).

BK Medical's warning is consistent with prior art techniques of using biopsy needles without an access needle. Yet, Petitioner's proposed combination is that Novella's coaxial needle would be coupled to BK Medical's probe-mounted needle guide and remain inserted in the patient body while the ultrasound probe is moved around to take multiple biopsy core samples per puncture. Petition at 50-51 ("the coaxial technique permits taking multiple cores per puncture...the combination would have increased detection rate for a given invasiveness level by allowing the practitioner to take more samples through fewer perineal punctures").

Leaving a needle coupled to the probe and inside the patient during a TPUS procedure directly contradicts the express warning in BK Medical to "make sure the needle is fully drawn back inside the needle guide before moving the probe." Ex. 1007 at 14. Therefore, BK Medical teaches away from Petitioner's proposed combination and the invention claimed in the '436 Patent.

b. No motivation to combine Novella with BK Medical

“[E]ven if a reference is not found to teach away, its statements regarding preferences are relevant to a finding regarding whether a skilled artisan would be motivated to combine that reference with another reference” *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 (Fed. Cir. 2018). Petitioner does not provide any explanation why a person of skill in the art would be motivated to combine Novella and BK Medical in a manner that contradicts the express warnings in BK Medical as just discussed.

Rather than address that contradiction, Petitioner’s expert sets out some supposed “drawbacks” of Novella’s “completely freehand technique” for performing biopsies, such as fatigue, time/cost, and skill. Ex. 1003 at ¶¶84-86. The expert then suggests that those drawbacks are addressed by BK Medical’s probe-mounted transperineal biopsy needle guide. Ex. 1003 at ¶¶87-89 (citing various disclosure from BK Medical). The problem with this analysis is that all the supposed benefits taught by BK Medical relied on by the expert are obtained using the BK Medical needle guide without an access needle.

Indeed, BK Medical describes these benefits without even mentioning an access needle. *See* Petition at 34-45 and 42 (relying on Novella to teach an access needle instead of BK Medical). Missing from Petitioner’s expert declaration is an explanation why any benefits of using BK Medical in taking biopsies without an

access needle would motivate a POSITA to couple an access needle to the BK Medical needle guide. Instead, the expert simply opines on the two references in isolation.

Moreover, according to Petition, Novella was published in 2003 and BK Medical probe-mounted transperineal biopsy needle guides were available since at least 2006. Petition at 17 and 27 (citing Ex. 1005 and Ex. 1009). Thus, these teachings were available to a POSITA for nearly a decade before the earliest priority date of the '436 Patent. If those of skill in the art were aware of the advantages of the combination suggested in the Petition, Petitioner should have been able to find some contemporaneous evidence indicating such...but it could not. Petitioner does not explain this decade long silence in the prior art.

Therefore, there is no evidence in the Petition that a POSITA would modify BK Medical in a manner that contradicts the express warnings provided in BK Medical. In addition, there is no evidence prior to the '436 Patent that any of the alleged benefits of using Novella or Bk Medical individually would have been maintained or improved when trying to combine these two technologies together. Petitioners' only evidence is conclusory expert testimony based on hindsight gleaned from the '436 Patent, which carries no weight.

c. No reasonable expectation of success at the time of the invention

There is also no evidence that Petitioner's proposed combination would have been successful prior to the disclosure of the invention of the '436 Patent. Petitioner's expert opines 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." Ex. 1003 at 92. Yet, the combination uses BK Medical's equipment in unintended ways undercutting this rationale by Petitioner's expert.

As discussed with respect to teaching away, BK Medical provides an explicit warning that the needle should be fully drawn back inside the needle guide before moving the probe, as shown below:



WARNING

When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the probe.

Ex. 1007 at 14. Petitioner's combination proposed leaving Novella's coaxial needle inserted into the patient while the probe is moved to perform multiple biopsies per puncture. Petition at 50-51. That is not an intended use of a needle inserted into BK Medical's needle guide.

Prior to '436 Patent family, there was no evidence suggesting an access needle that remains in the patient could successfully and safely be used with a biopsy guide like BK Medical. Thus, Petitioner has not shown that a person of skill in the art at

the time of the invention would have a reasonable expectation of success of in combining Novella and BK Medical for use with a TPUS biopsy procedure.

B. Ground 2 – Novella in View of BK Medical and Zangos

Petition cites Zangos to teach limitations of dependent claims 11, 23 and 29. *See* Petition at 73-76. Thus, Zangos does not remedy any of the deficiencies of the independent claims 1, 13 or 24 discussed with respect to Ground 1. Since claims 11, 23 and 29 depend on claims 1, 13 and 14 respectively, they are patentable for the same reasons as claims 1, 13 and 14.

C. Ground 3 – Novella in View of Onik and Nakamura

Petitioner's arguments for Ground 3 are deficient for at least two reasons. First, Petitioner has not demonstrated the prior art teaches all the limitations of the independent claims, particularly limitations 1.8, 13.7 and 24.7. Second, Petitioner has not shown a POSITA would have been motivated to combine the references as proposed.

1. Limitation [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”

- a. No teaching of “coupling the access needle...such that a position and angle of the access needle relative to the displacement member is retained”*

Petitioner's argument for Ground 3 relies on the same flawed rationale as provided for Ground 1. Petition at 96 (“Moreover, for the reasons explained 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." Petitioner's argument for Ground 1 is not persuasive as previously discussed, for example, because Petitioner does not account for forces that would move the position of the needle during insertion.

Perhaps more importantly for Ground 3 is that Petitioner willfully ignores Onik's express teaching that the needle moves relative to the needle holder assembly (the alleged displacement member). In Onik, "probe 2 is advanced proximally until needle holder assembly 28 engages and bears firmly against the patient's perineum." Ex. 1011 at 7:18-20. The position of the needle holder assembly is then "locked in place by tightening thumb screw 22." *Id.* at 7:22-24. When the position of the needle holder assembly is locked in place, the surgeon inserts a needle into notch 31 and advances the needle into the patient's prostate. *Id.* at 7:28-35. Thus, Onik explicitly instructs a POSITA to move the longitudinal position of the needle relative to the needle holder assembly when inserting the needle into the patient.

As such, even assuming a POSITA would use Novella's coaxial needle with Onik, the teachings of Onik would be to first lock the position of the needle holder assembly (the alleged displacement device) and then advanced the position of the coaxial needle into the patient. Thus, Onik teaches to move a position of a needle

relative to the alleged displacement device. Nowhere does Onik, or the other cited prior art, teach retaining the position of a needle relative to the displacement device.

In contrast, the access needle of the '436 Patent is coupled to the displacement device so that they retain their relative position and angle. Ex. 1001 at 2:40-46, 5:14-19, 26:30-56 and 27:10-15. For example, in the 483 Patent, the access needle can be advanced into the patient's body by pushing on the back wall of the displacement device or removed from the patient's body by pulling on the displacement device because the access needle is coupled to the displacement device. *Id.* at 26:30-56 and 27:10-15.

Therefore, Petition has not demonstrated in the proposed combination that "a position and angle of the access needle relative to the displacement member is retained" when performing the method as recited in claim 1 of the '436 Patent

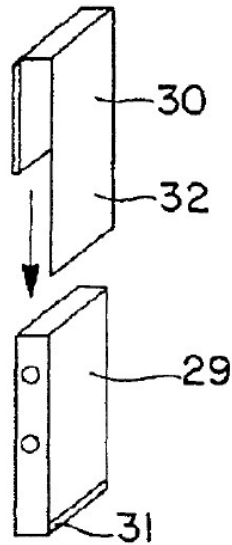
b. No teaching of "coupling the access needle to the one of the plurality of needle receiving ports"

For the Onik combination, Petitioner argues that an access needle is "coupled to the notch channel 31" because inserting an access needle into the notch "maintains the stability and directionality of the coaxial needle." Petition at 96-97. As discussed in Ground 1, this argument is premised on Patent Owner's infringement contentions about using an adapter to couple the access needle to a needle receiving port. Ex. 1019 at 22. Petitioner does not allege the use of any adapter, or other coupling mechanism, in the combination of Novella, Onik and Nakamura. Thus, Petitioner's

reliance on the infringement contentions to suggest that inserting is the same as coupling is not persuasive.

In addition, as discussed previously, claim 1 of the '436 Patent recites an access needle is both inserted into and coupled to a needle receiving port. Ex. 1001 at 35:58-59 and 36:1-2; *see also id.* at 25:58-26:7 (example of inserting an access needle into a receiving port then coupling the access needle to the port using ridges and/or threading). Thus, the claimed coupling requires more than merely inserting a needle into Onik's notch.

Petitioner then makes an alternative argument that Onik's "shield 30 holds Novella's coaxial needle in place in one of notches/channels 31." Petition at 97. Onik's shield is based on a spring tab design to hold a needle in notch 31 "adjacent to the lower end of block 29." Ex. 1011 at 5:39-50. The spring mechanism has sufficient resiliency to allow it to be laterally displaced when the needed is inserted into slot 31 while remaining biased against the needle. *Id.*; *see also id.* at 7:27:28 ("A biopsy needle is placed in notch 31 between guide block 29 and spring tab 32 and is held there by spring tab 32.")



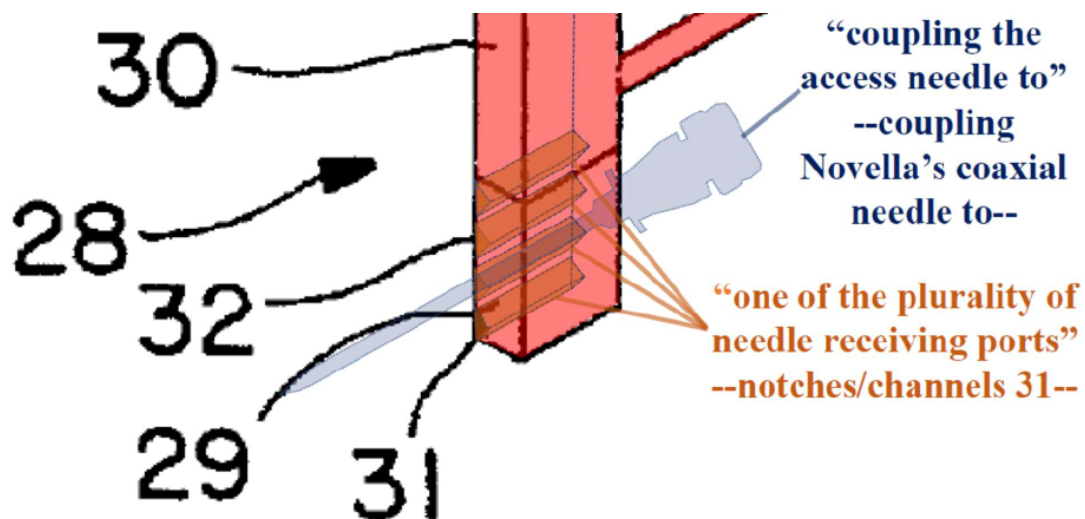
“shield 30 is provided with a spring tab 32 which has sufficient resiliency to allow it to be laterally displaced by insertion of a needle into slot 31 ”

“elongated notch 31 in one face adjacent the lower end of block 29”

FIG. 7

Onik Figure 7 (quoting Ex. 1011 at 5:39-50)

While Onik’s shield may hold a needle in a single notch adjacent to the lower end of block 29 so it does not fall out of the notch 31, Petitioner relies on a modified device with multiple notches that are not adjacent to the lower end of block 29. *See* Petition at 95-96.



Petitioner’s Proposed Modification (Petition at 96)

Onik's shield designed to hold a needle in a notch at the bottom edge of the shield would not be operable to hold a needle in the additional notches proposed by Petitioner that extend further up the shield. Neither Petitioner nor its expert explain, or even addresses, how Onik's spring tab would maintain "sufficient resiliency to allow it to be laterally displaced by insertion of a needle into" the additional notches proposed by Petitioner. Instead, Petitioner appears to have overlooked that its proposed modification would substantively change the operation of Onik with respect to shield 30.

2. Claim 13, limitation 13.7 and Claim 24, limitation 24.7

For limitations 13.7 and 24.7, Petitioner relies on its argument for limitation 1.8. *See* Petition at 100 (limitation 13.7) and 104 (limitation 24.7). While Patent Owner does not agree with Petitioner's apparent interpretation that the scope of these three claim limitations is identical, the previous explanations for why Petitioner failed to show claim 1 was obvious is likewise applicable to claims 13 and 24 in light of Petitioner's use of the same rationale for all three claims. *See* Section VII(C)(1).

The only additional argument Petitioner makes is with respect to the last phrase in limitation 24.7 reciting "further insertion of the access needle relative to the displacement member is restricted." Petition at 105-105. However, Petitioner's argument for this additional phrase in 24.7 does not address the deficiency of the

prior art with respect to the other recitations of limitations 24.7 for which Petitioner's relies on its analysis of limitation 1.8.

Therefore, the Board should find that Petition fails to show the prior art renders claims 13 or 24 obvious for the same reasons as claim 1

3. No motivation to combine either Novella or Nakamura with Onik

a. Novella's coaxial needle with Onik's needle assembly guide

Petitioner relies on the same motivation and expectation of success arguments provided to combine Novella's access needle with BK Medical's needle guide for the reasonable expectation of success for the combination of Novella's access needle with Onik's needle assembly guide. Petition at 80-81. For the reasons previously discussed, a POSITA would have neither a motivation to combine nor a reasonable expectation of success using an access needle with BK Medical. Those same reasons apply to the combination with Onik.

First, Onik's device is used in prostate cryosurgery. Ex. 1101 at Title. Cryosurgery is a procedure to freeze prostate tissue in order to kill cancerous tissue. Ex. 1101 at 6:65-67. As such, cryosurgery is performed subsequently to performing a biopsy that confirms cancerous tissue. Thus, a POSITA would not be motivated to combine Novella or Nakamura, which teach biopsy devices, with Onik, which teaches treatment devices.

Second, like with BK Medical, Onik's device is not intended to be used with a coupled access needle that remains in the patient during the procedure. Rather, Onik teaches, "[w]hen the needle is in place it is disengaged from needle holder assembly 28 by releasing spring tab 32 and insert guide 1 can be re-positioned to insert additional needles." Ex. 1011 at 7:34-37. In contrast to Onik's teachings, Petitioner's combination proposes using Onik's device to insert a coaxial needle coupled to the probe that remains in the patient while it is re-positioned to allow access for additional biopsy needles to perform the biopsy procedure of Novella. Petition at 50-51 ("the coaxial technique permits taking multiple cores per puncture").

None of the prior art cited by Petitioner suggest using an access needle that remains in the patient with a needle guide like Onik's or that such a combination would be successful. Thus, Petitioner has not shown that a person of skill in the art at the time of the invention would have a motivation to combine Novella's access needle with Onik's needle assembly guide or have a reasonable expectation of success of using the combination with a TPUS biopsy procedure.

b. Nakamura's plurality of channels with Onik's needle assembly guide

Petitioner argues that a POSITA would add additional notches to Onik based on Nakamura's teaching "that the puncture needle 2 can be inserted at a plurality of levels in the vertical direction." Petition at 86. However, Petitioner also

acknowledges that Onik already discloses controlling the vertical position of the needle by moving slide block 16 vertically along adjustment guide 4. Petition at 87 (citing Ex. 1011 at 4:45-52). To get around the fact that Petitioner's combination provides redundant vertical positioning functionality already existing in Onik, Petitioner suggests that using both Nakamura's and Onik's vertical positioning systems is more "convenient." Petition at 87. However, suggesting a combination that has two redundant systems is driven by hindsight – not convenience.

Moreover, Petitioner's theory of convenience is facially flawed. Petitioner argues that using both Nakamura and Onik's vertical position systems would allow a practitioner to make adjustments during a TPUS procedure to the vertical needle position without removing the probe from the rectum. Petition at 88. While Petitioner admits that Onik's vertical positioning system alone can already do this, Petitioner contends it would be "cumbersome for the practitioner and potentially uncomfortable for the patient as the practitioner manipulates guide 1." *Id.* Putting aside the conclusory nature of this assertion, the proposed combination having a plurality of notches in Onik would also require manipulating guide 1 to vertically re-position the needle. Thus, the proposed combination does not solve even this alleged problem with Onik.

In particular, Petitioner alleges "[i]n the combination, shield 30 holds Novella's coaxial needle in place in one of notches/channels 31." Petition at 97; *see*

Ex. 1011 at 5:36-59. Petitioner fails to account for the fact that a practitioner would need to manipulate this shield 30 of guide 1 in order to re-position a needle to a different vertical notch under its proposed combination. Yet, Onik teaches a needle would need to be “disengaged from needle holder assembly 28 by releasing spring tab 32” of shield 30 in order to be re-positioned. Ex. 1011 at 34-37.

Thus, assuming adjusting vertical position of Onik alone was “cumbersome for the practitioner and potentially uncomfortable for the patient as the practitioner manipulates guide 1” then the combination would have the same problem since it to requires manipulation of components on guide 1(i.e., shield 30) to adjust vertical positioning.

Petitioner’s proposed rationale is conclusory and does not demonstrate any benefit over using Onik’s pre-existing vertical positioning system alone. Therefore, Petition has failed to provide a sufficient reason a POSITA would be motivated to modify Onik to add the additional notches proposed by Petitioner.

D. Ground 4 – Novella in View of Onik, Nakamura and Zangos

Petition cites Zangos to teach limitations of dependent claims 11, 23 and 29. *See* Petition at 73-76. Thus, Zangos does not remedy any of the deficiencies of the independent claims 1, 13 or 24 discussed with respect to Ground 3. Since claims 11, 23 and 29 depend on claims 1, 13 and 14 respectively, they are patentable for the same reasons as claims 1, 13 and 14.

VIII. CONCLUSION

Therefore, the Board should decline to institute a PGR proceeding based on the Petition.

Dated: October 26, 2023

Respectfully submitted:

/James P. Murphy/

James P. Murphy (Reg. No. 55,474)

POLSINELLI PC

1000 Louisiana, Suite 6400

Houston, TX 77002

Attorney for Patent Owner

CERTIFICATE OF WORD COUNT

Under the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the Microsoft Office word count for the foregoing Patent Owner's Preliminary Response Under 35 U.S.C. § 313 and 37 C.F.R. § 42.107, excluding the table of contents, table of authorities, certificate of word count, and certificate of service, totals 13,183 words, which is less than the 14,000 words allowed under 37 C.F.R. § 42.24(b)(1).

Dated: October 26, 2023

/James P. Murphy/
James P. Murphy (Reg. No. 55,474)
POL SINELLI PC
1000 Louisiana, Suite 6400
Houston, TX 77002

CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6 (e)(4)

The undersigned hereby certifies that a copy of the foregoing **PATENT OWNER'S PRELIMINARY RESPONSE AND ASSOCIATED EXHIBITS** has been served via Electronic Mail on October 26, 2023, upon the following:

James D. Stein
james.stein@leehayes.com

Ryan P. Gentes
ryan.gentes@leehayes.com

Richard Uberto
richard.uberto@leehayes.com

AMD-PGR@leehayes.com

/ Ericka McNeil /
Ericka McNeil

POLSINELLI PC
1000 Louisiana, Suite 6400
Houston, TX 77002