

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADVANCE MEDICAL DESIGNS, INC.

Petitioner,

v.

CORBIN CLINICAL RESOURCES, LLC

Patent Owner.

Case No. PGR2023-00041

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

**PETITIONER’S REPLY TO PATENT OWNER’S
PRELIMINARY RESPONSE**

LIST OF EXHIBITS

Exhibit	Description
EX1001	U.S. Patent No. 11,547,436 to Matthew J. Allaway (the “’436 Patent”)
EX1002	File History of the ’436 Patent, produced by Corbin Clinical as CORBIN_CLINICAL-001928 - CORBIN_CLINICAL-002356
EX1003	Declaration of Edward J. Yun, M.D.
EX1004	<i>Curriculum Vitae</i> of Edward J. Yun, M.D.
EX1005	Giovanni Novella et al., <i>Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle</i> , 62 UROLOGY 689 (2003) (“Novella”)
EX1006	Bard Biopsy Systems, Bard® TruGuide® Disposable Coaxial Biopsy Needle Instructions for Use (May 2012)
EX1007	BK Medical, Prostate Biplane Transducer Type 8808e, User Guide (June 2012) (“BK Medical”)
EX1008	Antonio Galfano et al., <i>Prostate Biopsy: The Transperineal Approach</i> , 5 EUR. ASS’N UROLOGY 241 (2007) (“Galfano”)
EX1009	BK Medical, Endoscopic Probe Type 1850, User Guide (Aug. 2006) (“BK Medical 2”)
EX1010	Stephan Zangos, et al., <i>MR-Guided Transgluteal Biopsies with an Open Low-Field System in Patients with Clinically Suspected Prostate Cancer: Technique and Preliminary Results</i> , 15 EUR. RADIOLOGY 174 (Sept. 4, 2004) (“Zangos”)
EX1011	U.S. Patent No. 5,494,039 to Gary Onik, et al. (“Onik”)
EX1012	Japanese Patent No. 4,550,531 to Hisashi Nakamura (“Nakamura”) with certified English language translation and certification of accurate translation
EX1013	Declaration of Ingrid Hsieh-Yee, PhD
EX1014	Declaration of Eelbode Nico

Exhibit	Description
EX1015	Declaration of František Zat'ura, M.D., Ph.D. from Related Proceeding in the Netherlands and certified English translation of the same
EX1016	Internet Archive Reports for BK Medical References
EX1017	Papers from Related Proceeding in the Netherlands with certified English translation
EX1018	The Parties' Claim Construction Statements in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789-SAG (D. Md.)
EX1019	Patent Owner's Amendment Infringement Contentions for the '436 Patent in <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. 1:22-cv-00789-SAG (D. Md.)
EX1020	File History of Application No. 17/314,845 (now U.S. Patent No. 11,246,677), produced by Corbin Clinical as CORBIN_CLINICAL-000722 - CORBIN_CLINICAL-001527
EX1021	Docket Navigator Reports for the U.S. District Court for the District of Maryland
EX1022	Order Granting Request for <i>Ex Parte</i> Reexamination of U.S. Patent No. 11,446,056, Control No. 90/019,257 mailed October 26, 2023
EX1023	Email from Trials@USPTO.gov to James Stein dated November 8, 2023
EX1024	Email from Michael Dulin to Ryan Gentes dated October 3, 2023
EX1025	Letter to Counsel from Mediator Judge Simms (D. Md. Oct. 26, 2023), D.I. 93.
EX1026	U.S. Patent No. 5,931,786 to Whitmore ("Whitmore")
EX1027	Request for <i>Ex Parte</i> Reexamination of U.S. Patent No. 11,446,056, filed Sept. 22, 2023

Petitioner Advance Medical Designs, Inc. (“Petitioner”) submits this Reply to Patent Owner’s Preliminary Response (“POPR”) on the topics authorized by the Board via email on November 8, 2023. EX1023.

I. Petitioner’s *Sotera* Stipulation Disposes of a *Fintiv* Analysis

Director Vidal’s June 2022 Memorandum provides a bright-line rule that a petitioner’s *Sotera* stipulation disposes entirely of a *Fintiv* analysis such that the Board will not deny a petition in view of a parallel district court. *Interim Proc. for Discretionary Denials in AIA Post-Grant Procs. with Parallel Dist. Ct. Litig.* (June 21, 2022), 3, 7 (“Interim Procedure”) (citing *Sotera Wireless, Inc. v. Masimo Corp.*, No. IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to § II.A)). Here it is simple: the Petition includes a *Sotera* stipulation, so the Board will not deny the Petition in view of parallel district court litigation. Pet., 112.

Patent Owner criticizes Petitioner’s *Sotera* stipulation because “Petitioner has not challenged the other four patents that share some common subject matter with the ’436 Patent.” POPR, 27-28. First, this ignores Director Vidal’s bright-line rule—neither the Interim Procedure nor any other authority requires a petitioner to challenge every asserted patent or claim in IPR or PGR to use a *Sotera* stipulation in a particular proceeding. Indeed, every patent presents a different risk profile, and the AIA allows a challenger to choose a strategy that best allocates limited resources. H.R. Rep. No. 112-98(I), at 39-40 (2011) (An aim of the AIA was to

“provid[e] a more efficient system for challenging patents that should not have issued.”). This includes strategies challenging a subset of asserted patents or claims or using a combination of post-grant review and *ex parte* reexamination. Petitioner has not, as Patent Owner contends, “abused the PGR process ... by seeking relief on a single patent ... rather than all asserted patents” POPR, 23.

Second, Patent Owner leaves out important context: Petitioner has challenged two of the asserted patents: (1) the ’436 Patent in this proceeding; and (2) related Patent No. 11,446,056 (“the ’056 Patent) in Reexamination Control No. 90/019,257, which the Office ordered on October 26, 2023. EX1022. Patent Owner filed a declaratory judgment action for non-infringement and invalidity of related asserted Patent No. 10,064,681 on October 22, 2021, making at least that patent unavailable for IPR or PGR. 35 U.S.C. §§ 315(a)(1), 324(a)(1). EX2001.

Moreover, before and during mediation, Patent Owner claimed that Petitioner’s filing further USPTO challenges would hinder potential settlement and asked Petitioner to pause filing challenges on the remaining patents until mediation finishes. *See, e.g.*, EX1024. In a good faith effort to allow mediation to work, Petitioner obliged. Settlement discussions have continued through a settlement conference last week. EX1025.

While Petitioner’s *Sotera* stipulation renders moot the remaining *Fintiv* factors, Petitioner briefly addresses each. **Factor 1:** The district court is likely to

grant a stay because the Office has already ordered reexamination of the '056 Patent and the district court has granted or partially granted all motions to stay pending post-grant review. EX1021, 1. Common validity issues span the five related asserted patents, so Petitioner's current Office challenges will simplify the issues across all patents before the district court. Additionally, the Office should grant Petitioner's forthcoming *ex parte* reexaminations of the remaining three asserted patents because it already granted the '056 Patent request.

Factor 2: The court has not set a trial date. For patent cases, the average time to trial in the District of Maryland is 52 months—late 2025 or early 2026 in this case. EX1021, 2. Here, a final written decision would issue by January 2025. Patent Owner cites a 35-month average time-to-trial, but that figure includes all civil trials. POPR, 25-26. **Factor 3:** The litigation is still in its early stages. A Markman hearing has not occurred. While the parties have produced some documents, no depositions, expert discovery on infringement or validity, etc., have occurred.

II. The Office Materially Erred During Prosecution of the '436 patent

The Office materially erred during prosecution because (1) the record of the '436 Patent is largely silent on the prior art and arguments in the Petition; and (2) the Office granted reexamination of the '056 Patent over all previously-considered material, effectively admitting material error. Thus, Patent Owner is incorrect that

“the record shows the Examiner performed a comprehensive evaluation of the prior art.” POPR, 11.

Except the Notice of Allowance’s mentioning Onik as one of the closest prior art references, EX1002, 35-37, the prosecution record of the ’436 Patent is silent on the prior art and arguments in the Petition. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, No. IPR2019-01469, Paper 6 at 9-10 (PTAB Feb. 13, 2020) (precedential); *see also Shenzhen Chic Elecs. Co. v. Pilot, Inc.*, No. IPR2023-00810, Paper 12 at 20-21 (PTAB Nov. 8, 2023); *Nintendo Co. v. Gamevice, Inc.*, No. IPR2023-00643, Paper 11 at 16-19 (PTAB Nov. 6, 2023); *Parse Biosciences, Inc. v. 10x Genomics, Inc.*, No. IPR2023-00876, Paper 7 at 12-13 (PTAB Oct. 13, 2023) (declining to exercise 325(d) discretion where the prosecution record reflected no substantive evaluation of the petition’s prior art).

Unlike a prior art rejection or applicant arguments about prior art, silence does not reflect that the Examiner appreciated references like Novella disclosing performing a transperineal biopsy procedure with a coaxial (access) needle and its advantage of less intrusiveness and pain. Nor does silence reflect that the Examiner appreciated references like BK Medical or Nakamura disclosing probe-mounted transperineal biopsy guides with vertically-aligned needle channels for performing freehand transperineal biopsies with accuracy. Inapposite to BK Medical and Nakamura, the Whitmore reference concerns a complicated table-top

brachytherapy apparatus using a brachytherapy grid template 70. POPR, 14-16; EX1026.

The Office granted reexamination of the '056 Patent, with the Examiner expressly finding that the same four grounds presented in this Petition demonstrate substantial new questions of patentability (SNQ). EX1022, 7-13; EX1027. This finding of SNQs objectively shows the Office materially erred in considering Petitioner's prior art and arguments during prosecution.

III. Background Reference BK Medical 2 (EX1009)

With attorney argument, Patent Owner asserts that BK Medical 2 does not disclose using a biopsy needle with an "access needle" POPR, 2. But Petitioner's interpretation is supported by the declaration of Dr. Zat'ura, who testified that he personally used the puncture attachment of BK Medical 2 with an access needle in biopsy procedures in the 1980s. Pet., 28-29, 52; EX1015, ¶¶ 11-12. Regardless, institution does not hinge on the disclosure of BK Medical 2 or Dr. Zat'ura's declaration because BK Medical 2 is not the basis of any obviousness combination or ground. Petitioner merely relies on these background materials to show that it was known in the art to use a coaxial needle with a probe-mounted biopsy guide and that a person of ordinary skill in the art would have retained Novella's coaxial needle configuration, rather than used a biopsy needle alone, with BK Medical's and Onik's biopsy guides. Pet., 51-53.

Respectfully submitted,

Dated: November 14, 2023

/James D. Stein/

James D. Stein (Reg. No. 63,782)
Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing
PETITIONER’S REPLY TO PATENT OWNER’S PRELIMINARY RESPONSE
has been provided electronically to counsel of record for the related litigation as
follows:

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