

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 SUR-REPLY TO PETITIONER'S REPLY TO
PRELIMINARY RESPONSE**

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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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I. PETITIONER’S STIPULATION IS NOT THE SAME AS IN *SOTERA*

Petitioner’s Reply argues the Board should treat a *Sotera* stipulation as a bright line rule, but Petitioner’s stipulation lacks the hallmarks of a *Sotera* stipulation and should not be regarded as one. As set forth by the Director, a *Sotera* stipulation:

[M]itigates concerns of potentially conflicting decisions and duplicative efforts between the district court and the PTAB.... avoids inconsistent outcomes between the PTAB and the district court and allows the PTAB to review grounds that the parallel district court litigation will not resolve.

Interim Proc. for Discretionary Denials in AIA Post-Grant Procs. with Parallel Dist. Ct. Litig. at 7-8 (“Director’s Memo”) (June 21, 2022).

Petitioner’s stipulation does not mitigate the concerns.

As explained in Patent Owner’s Preliminary Response, the District Court will have to decide many of the same issues as decided in this PGR due to overlapping issues in patents asserted in the litigation but not subject to PGR/IPR . POPR at 30-31. Petitioner’s Response concedes this point by noting “[c]ommon validity issues span the five related asserted patents.” Pet. Response at 3. As such, the District Court will have to consider whether the same prior art and arguments presented in this PGR invalidate claims in related patents with overlapping subject matter with the ’436 patent. *Id.* Because of this, if this PGR is instituted, there is a certainty of duplicative efforts and a high chance of conflicting decisions relating to claim construction, teachings of the prior art, and motivation to combine. *Id.*

Perhaps most importantly, Petitioner could have challenged all five patents in a single forum (e.g., District Court or PTAB) to avoid the above problems. Petitioner complains that it couldn't challenge certain patents in PGR/IPR because it filed a declaratory judgment of invalidity. Pet. Reply at 2. However, that was Petitioner's choice to file a declaratory judgment of invalidity instead of an PGR/IPR on those patents. Rather than an excuse, Petitioner's decision to request two different forums to decide "[c]ommon validity issues span[ing] the five related asserted patents" is why the Board should deny this PGR under *Fintiv*. Petitioner's legal defense strategy has created the duplicative efforts and potential for conflicting decisions.

Petitioner's reliance on the legislative history statement that IPRs were intended to "provid[e] a more efficient system for challenging patents" is quite surprising given Petitioner has undertaken perhaps the most inefficient approach to challenge the validity of the five related patents. Pet. Reply at 1-2 (quoting H.R. Rep. No. 112-98(I), at 39-40 (2011)). In addition to the separation between the District Court and PTAB discussed above, Petition has also requested the Central Reexamination Unit to review the same overlapping issues via reexamination. Thus, Petitioner requested three different fact-finding bodies to look at the same facts and arguments. Petitioner's approach to challenging validity is the opposite of efficiency.

In sum, there was nothing that precluded Petition from asking the PTAB to consider all five asserted patents other than Petitioner's own actions (by filing

declaratory judgment of invalidity or waiting more than a year after being served a complaint). Given Petitioner's legal strategies, a PGR proceeding on the '436 Patent will cause duplicative efforts and possible conflicting results with the District Court regardless of Petitioner's stipulation. Thus, Petitioner's stipulation does not address the same concerns that the Director indicated are addressed by a *Sotera* stipulation. Director's Memo at 7-8.

Lastly, on specific *Fintiv* factors, for Factor 1 the Petitioner fails to explain why a District Court would stay the litigation when only one of five asserted patents is subject to PGR/IPR. Moreover, as previously explained, the District Court's local rules preclude requesting a stay due to reexamination prior to an office action, which has not occurred (not to mention three of the five asserted patents are not subject to any PGR/IPR or reexamination). Ex. 2006 at 102. On Factor 2, Petitioner criticizes the median time to trial that the Director herself used in the Director's Memo and instead asks the Board to adopt a different median trial time. Pet. Reply at 3. Petitioner provides no rebuttal that Factor 4-6 favor denial as set forth in the preliminary response. See POPR at 27-32.

II. PETITIONER PROVIDES NO EVIDENCE OFFICE MATERIALLY ERRED DURING PROSECUTION

Petitioner's alleged error is nothing more than that the '436 Patent was allowed without the Examiner issuing a rejection over the art cited in the PGR.

Pet. Reply at 3. If the standard for material error were so low then *Advanced Bionics* would serve no purpose since nearly every PGR/IPR filed involves art that was not discussed in an Examiner's rejection. Moreover, the record here shows that the Examiner considered both the prior art and the arguments in this PGR.

As explained in the preliminary response, Patent Owner submitted Petitioner's invalidity contentions in an IDS. *See* Ex. 2012 at 17 (Petitioner's invalidity contentions arguing claims are obvious over Novella in combination with BK Medical or Onik); Ex. 1002 at 176 (Examiner initialed consideration of these invalidity contentions). Thus, Patent Owner took affirmative steps to ensure that the Examiner considered the same prior art and arguments presented in this PGR. That the Examiner did not agree with those arguments is not material error.

Petitioner's reliance on the grant of an *ex parte* reexamination of the '056 Patent to show material error is misplaced. Patent Owner has not submitted any papers in that proceeding so the Central Reexamination Unit made that determination without the consideration of any rebuttal arguments raised by Patent Owner. Moreover, no Office Action has issued in that proceeding and it is possible none ever will. Patent Owner believes the result of the '056 reexamination will be that all claims are confirmed patentable reinforcing that no error was committed. In any event, any suggestion that the reexamination indicates that the Office materially

erred in granting the '056 Patent (or the '436 Patent) is premature and speculative.

III. BK MEDICAL 2 IS KEY TO ALLEGED MOTIVATION TO COMBINE

After Patent Owner exposed Petitioner's material misrepresentations about BK Medical 2, Petitioner seeks to downplay its reliance on it as merely background material. Pet. Reply at 5. Yet, BK Medical 2 is the only evidence that Petitioner's cites to as showing "it was known in the art to use a coaxial needle with a probe-mounted transperineal puncture guide." Petition at 51-52. This is the crux of Petitioner's obviousness case that argues it would have been obvious to combine art teaching a coaxial needle (Novella) with art teaching probe-mounted guides (BK Medical and Onik).

Petitioner's material misrepresentation of BK Medical 2 also undercuts the credibility on its analysis of the other prior art including BK Medical, which shares some common disclosure with BK Medical 2. Petitioner cannot dismiss these challenges to its analysis as attorney argument, since Patent Owner's response is based on statements from the evidence of record, namely disclosure in BK Medical and BK Medical 2.

Finally, Petitioner refers to Dr. Zat'ura's testimony about procedures he personally performed, but those personal experiences only provide evidence of what Dr. Zat'ura personally knew and do not provide evidence what was known generally to persons of skill in the art.

Dated: November 21, 2023

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

The undersigned hereby certifies that a copy of the foregoing **PATENT OWNER SUR-REPLY TO PETITIONER'S REPLY TO PRELIMINARY RESPONSE** has been served via Electronic Mail on November 21, 2023, upon the following:

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