

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.

PGR2023-00041
Patent 11,547,436 B2

Before ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and
JAMIE T. WISZ, *Administrative Patent Judges*.

WISZ, *Administrative Patent Judge*.

DECISION

Denying Petitioner's Request on Rehearing of Decision on Institution
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Advance Medical Designs, Inc. (“Petitioner”) requests rehearing of the Board’s Decision (Paper 12) (“Decision”) denying institution of post-grant review of claims 1, 4–6, 11–13, 16–18, 23, 24, 28, and 29 of U.S. Patent No. 11,547,436 B2 (Ex. 1001, “the ’436 patent”). Paper 13 (“Request for Rehearing” or “Req. Reh’g”). For the reasons that follow, Petitioner’s Request for Rehearing is *denied*.

II. ANALYSIS

Pursuant to 37 C.F.R. § 42.71(d):

A party dissatisfied with a decision may file a single request for rehearing without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, [or] a reply.

When reconsidering a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion exists where a “decision [i]s based on an erroneous conclusion of law[,] . . . clearly erroneous factual findings, or . . . a clear error of judgment.” *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988). A rehearing request is not an opportunity for the requesting party to reargue its case or merely to express disagreement with the underlying decision. *See* 37 C.F.R. § 42.71(d). Nor is it an opportunity for the requesting party to present new arguments that were not in its original submissions. *See id.*

Petitioner contends that we (1) overlooked Petitioner’s reliance on Novella’s depth stop for the claimed “coupling” and “securing” steps of the independent claims, (2) overlooked Petitioner’s reliance on the hub of Novella’s coaxial needle for the claimed “coupling” and “securing” steps, and (3) overlooked Onik’s teaching of a shield that “secures” the needle and “holds” the needle “in place” on block 29. Req. Reh’g 1–10. As an alternative to Petitioner’s third argument, Petitioner alleges that, if the Board did not overlook the disclosure of Onik’s shield, then we misapprehended the claims to add an unrecited timing requirement to the claimed “coupling” and “securing” steps. *Id.* at 10–12. We consider Petitioner’s arguments below.

Before we analyze the specific assertions in Petitioner’s Request for Rehearing, we note that we discretionarily denied institution of the current proceeding under 35 U.S.C. § 325(d) because we found that the same or substantially the same art was previously presented to the Office and Petitioner did not show that the Office erred in a manner material to patentability. Decision 20–38. Specifically, during prosecution of the application that issued as the ’436 patent, in the Reasons for Allowance, the Examiner stated that the closest prior art of record included Onik and also found that:

none of the prior art alone or in combination teaches the limitations of the independent claim specifically, “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, 36–37. Petitioner’s Request for Rehearing does not demonstrate that the Examiner erred in this finding nor that we misapprehended or overlooked the teachings discussed in the request for rehearing in our denial under 35 U.S.C. § 325(d).

A. Reliance on Novella’s Depth Stop and Needle Hub

According to Petitioner, the Board overlooked and did not address Petitioner’s reliance on the “depth stop” and needle hub of Novella’s coaxial needle for the “coupling” and “securing” steps of the independent claims. Req. Reh’g 3–7.

With respect to the depth stop, Petitioner asserts that Novella’s coaxial needle has a “depth stop that contacts the vertical needle guide fin of UA1324 at the proper perineal depth to *prevent further insertion* of the coaxial needle into the patient’s perineum.” Req. Reh’g 3 (citing Petition (“Pet.”) 71–72). According to Petitioner, the function of the depth stop meets the independent claims’ requirement to retain or maintain a relative position of Novella’s coaxial needle (access needle) and UA1324’s needle guide (displacement member). *Id.* at 3–4 (citing Pet. 70–71). Petitioner contends that the Decision is silent on the depth stop and does not explain how the depth stop fails to satisfy the “coupling” and “securing” steps. *Id.* at 4.

Petitioner also asserts that “[t]he Board did not specifically address Petitioner’s argument that the hub of Novella’s coaxial needle stops insertion of the coaxial needle and thus maintains the relative position of the coaxial needle (access needle) and needle guide (displacement member).” Req. Reh’g 5. According to Petitioner, the Decision does not explain why

Novella's hub does not satisfy the claimed requirement to "maintain" or "retain" position relative to the needle guide. *Id.* at 6.

We are not persuaded by Petitioner's arguments. First, the Petition did not argue that Novella's depth stop or hub "coupl[es]" or "secur[es]" the access needle such that a position and angle of the access needle relative to the displacement member is retained/maintained. Instead, for the obviousness ground over Novella and BK Medical, Petitioner argued, with respect to claims 1 and 13:

the needle channel maintains the stability of the access needle's direction parallel to the centerline of the transducer. When in the channel, the access needle cannot rotate in the plane of the vertical needle guide fin. The needle channel also maintains and stabilizes the vertical position of the needle relative to the probe. And, once inserted up to its hub, the needle channel maintains and stabilizes the axial position of the access needle in the direction of the probe's centerline.

Pet. 59–60, 66 (citing Ex. 1003 ¶ 107; Ex. 1007, 12–13) (emphasis added) (internal citations omitted). As evidenced by the excerpt above, Petitioner argued that the needle channel of BK Medical's needle guide — not the depth stop or hub of Novella's coaxial needle — maintains and stabilizes the position of the access needle. In fact, the depth stop is not even mentioned in Petitioner's obviousness arguments for claims 1 and 13 on these grounds. *See* Pet. 58–60, 66.

Further, with regard to the alleged obviousness over Novella, Onik, and Nakamura, the Petition argued that:

Once inserted within a selected notch 31, a position and parallel angle of the coaxial needle (access needle) relative to Onik's assembly 27 (displacement member) are retained. The notch maintains the vertical position of the coaxial needle and abutment of the needle hub or depth stop against block 29 and

maintains the longitudinal position of the access needle once inserted. The notch also maintains the parallel direction of the needle relative to the probe because each “notch . . . is oriented parallel to the longitudinal axis of shaft 27’ and of ultrasound probe 2 to provide guidance for a biopsy needle being inserted.” *Thus, the notch maintains the stability and directionality of the coaxial needle.*

Pet. 96–97 (emphasis added) (internal citations omitted) (citing Ex. 1003 ¶ 185; Ex. 1011, 5:42–46). As evidenced by the excerpt above, Petitioner argued that notch 31 of Onik’s guide assembly — not the depth stop or hub of Novella’s coaxial needle — maintains the position and angle of the access needle relative to the displacement member.

With respect to claim 24, the Petition asserted that “the hub of Novella’s coaxial needle has a larger diameter than the needle guide channels of UA1324, so at most the access needle can be inserted until the hub contacts the vertical fin containing the needle guide channels.” Pet. 70. Similarly, the Petition also asserted that “the depth stop contacts the vertical needle guide fin of UA1324 at the proper perineal depth *to prevent further insertion of the coaxial needle into the patient’s perineum.*” *Id.* at 71–72 (emphasis added). Petitioner did not argue that the hub or depth stop “secure” the access needle to “the one of a plurality of needle receiving ports of the displacement member such that position and angle of the access needle relative to the displacement member is maintained.” Rather, Petitioner only argued that the hub and depth stop *prevent further insertion* of the coaxial needle into the patient’s perineum. Petitioner cannot now overcome the shortcomings in its Petition by presenting new arguments in the Request for Rehearing. We could not have misapprehended or

overlooked an argument that was never made in the Petition. *See* 37 C.F.R. § 42.71(d).

However, even if we were to consider Petitioner's arguments regarding the depth stop and hub of Novella's coaxial needle, we are not persuaded that we erred in the Decision, particularly in determining that Petitioner had not shown that the Examiner materially erred in finding that the "coupling" and "securing" steps of the independent claims are missing from the prior art. Decision 27–38. With regard to the obviousness ground over Novella and BK Medical, Petitioner did not explain how the depth stop or hub would be used to maintain the needle's position in the needle guide of BK Medical. As discussed in our Decision, Nakamura, which discusses needle guides such as those in BK Medical, discloses that such needle guides do not maintain the needle's horizontal or vertical positions. *Id.* at 31–32. In discussing such needle guides, Nakamura states:

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.

Id. at 32 (citing Ex. 1012, 20). Petitioner, as well as its Declarant, did not discuss how the depth stop or hub of Novella's coaxial needle would be used in conjunction with BK Medical's needle guide, nor did they explain how (or if) such a depth stop or hub would prevent the horizontal and vertical movement that existed with this type of needle guide, as discussed in Nakamura. *See* Ex. 1012, 20.

With regard to the obviousness ground over Novella, Onik, and Nakamura, as discussed above, Petitioner argued in the Petition that the depth stop and hub of Novella prevent *further insertion* of the coaxial needle into the patient’s perineum but did not explain how the depth stop or hub maintain the position and angle of the access needle relative to the displacement member. *See* Pet. 71–72. Neither Petitioner nor its Declarant discussed the angle of the access needle relative to the displacement member in discussing the depth stop or hub. Further, Petitioner argued in the Petition that “the depth stop contacts the vertical needle guide fin of UA1324 at the proper perineal depth to prevent further insertion of the coaxial needle into the patient’s perineum.” *Id.* However, the Bard TruGuide manual, which discusses the depth stop used in Novella, notes that “[t]he depth stop should be adjusted so that the needle is in proper position *when the depth stop is in contact with the skin.*” Ex. 1006, 3 (emphasis added). Neither Petitioner nor its Declarant discussed the significance of the usage of the depth stop against the displacement member as opposed to the patient’s skin. Again, Petitioner failed to explain how the depth stop maintains the angle of the needle relative to the displacement member.

Petitioner has not shown that we misapprehended or overlooked Petitioner’s arguments that the depth stop or hub on Novella’s coaxial needle meet the “coupling” and “securing” steps of the independent claims of the ’436 patent.¹ Thus, Petitioner has also not shown that we misapprehended

¹ Petitioner also argues that the “adaptor” identified by Corbin Clinical Resources, LLC (“Patent Owner”) in its infringement contentions in the co-pending Maryland District Court litigation is the same as the “depth stop” used in Novella (and discussed in the Bard TruGuide manual (“Bard’s ‘depth stop’”). Req. Reh’g 4 (citing Paper 6, 43–44; Ex. 1019, 22).

or overlooked these teachings in finding that Petitioner failed to show material error in the Examiner's prior consideration of Novella.

B. Reliance on Onik's Shield

Petitioner further contends that, for the obviousness grounds over Novella, Onik, and Nakamura, the Board overlooked a passage in Onik that allegedly teaches both the "inserting" and "securing" claim steps.

Req. Reh'g 8. Petitioner cites the following passage from Onik in support of its position:

Notch **31** is preferably a simple "V" notch and is oriented parallel to the longitudinal axis of shaft **27'** and of ultrasound probe **2** to provide guidance for a biopsy needle being *inserted*. To ensure that the needle is *securely held in* and guided by notch **31**, shield **30** is provided with a spring tab **32** which has sufficient resiliency to allow it to be laterally displaced by *insertion* of a needle into slot **31** while remaining biased against the needle to *hold it in place in slot 31*.

Id. at 8–9 (citing Ex. 1011, 5:42–51; Pet. 90, 97). Petitioner argues that the Board seemingly recognized this passage only for its "inserting" disclosure, and overlooked the description that shield 30 "secure[s]" the needle "to hold it in place in slot 31" relative to block 29. *Id.* at 9 (citing Decision 35–36; Ex. 1011, 5:42–51).

We are not persuaded by Petitioner's arguments. Contrary to Petitioner's contentions, we addressed Petitioner's assertion that the Onik

However, the Petition did not make this argument nor did it compare Bard's "depth stop" to the adaptor identified in Patent Owner's infringement contentions. *See generally* Pet. Therefore, on this record, there is not enough information to determine whether Bard's "depth stop" and the "adaptor" from the infringement contentions are the same or have the same function with regard to "coupling" and "securing."

shield meets the “securing” claim step. Decision 33–37. As we explained in the Decision:

Onik discloses moving the longitudinal position of the needle relative to the needle holder assembly when inserting the needle into the patient. Petitioner does not show how the shield of Onik prevents such movement (or if this would even be desirable given the disclosure of Onik). Further, we agree with Patent Owner that, while Onik’s shield is designed to hold a needle in a notch at the bottom edge of the shield, Petitioner does not sufficiently explain or address 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” that would extend further up the shield.

Id. at 37 (citing Prelim. Resp. 57–58). Even if Petitioner disagrees with the Board’s analysis with regard to Onik’s disclosure of moving the longitudinal position of the needle relative to the needle holder assembly when inserting the needle into the patient, Petitioner’s arguments on rehearing do not address our reasoning that Petitioner failed to sufficiently explain how Onik’s spring tab would be used in the needle holder assembly with multiple notches extending further up the shield, given that Onik’s shield is designed to hold a needle in a notch at the bottom edge of the shield. *See id.*

Petitioner has not shown that we overlooked Onik’s disclosure of a shield that allegedly holds the needle in place. Thus, Petitioner has also not shown that we misapprehended or overlooked this disclosure in finding that Petitioner failed to show material error in the Examiner’s prior consideration of Onik, which the Examiner specifically found failed to teach the “coupling” step. Decision 24, 37 (citing Ex. 1002, 36–37).

C. Addition of an Unrecited Temporal Limitation

Lastly, Petitioner contends that, to the extent the Board finds it did not overlook Onik's teaching that shield 30 secures the needle, the Board misapprehended the claim language. Req Reh 'g 10. Specifically, Petitioner contends that the Board implicitly added a timing requirement that a relative position of the needle and displacement member must be retained while inserting the needle into the patient, as shown in the underlined language added to the portion of claim 1 reproduced below:

[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 while inserting the access needle into the patient; and

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

Id. at 10–11 (citing Ex. 1001, 36:1–7).

We are not persuaded by Petitioner's arguments. Petitioner asserts that the claims do not require preventing movement of the access needle relative to the displacement member when inserting the needle into the patient. Req. Reh 'g 11. In other words, Petitioner contends that the needle does not need to be "coupl[ed]" or "secur[ed]" to the displacement member during insertion of the needle into the patient's prostate. However, Petitioner has not provided an alternative explanation for what time period the needle does need to be "coupl[ed]" or "secur[ed]" to the displacement member in order to satisfy the claims. Further, as discussed above, Petitioner also failed to sufficiently explain 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" that

would extend further up the shield, during any period of time (whether during insertion into the patient or otherwise). *See* Decision 37. Thus, Petitioner has not demonstrated that we misapprehended the claims of the '436 patent.

III. CONCLUSION

For the reasons given, Petitioner has not demonstrated that we abused our discretion in denying institution of a post-grant review of claims 1, 4–6, 11–13, 16–18, 23, 24, 28, and 29 of the '436 patent under 35 U.S.C. § 325(d) because the same or substantially the same art previously was presented to the Office and Petitioner did not show that the Office erred in a manner material to patentability.

IV. ORDER

Accordingly, it is

ORDERED that Petitioner's Request for Rehearing is *denied*.

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FOR PETITIONER:

James Stein
Ryan Gentes
Richard Uberto
LEE & HAYES, P.C.
james.stein@leehayes.com
ryan.gentes@leehayes.com
richard.uberto@leehayes.com

FOR PATENT OWNER:

James Murphy
Josh Pranckun
POLSINELLI PC
jpmurphy@polsinelli.com
jpranckun@polsinelli.com