

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2017-00372
Patent 8,377,129 B2

Before BEVERLY M. BUNTING, JAMES A. WORTH, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

WORTH, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71(d)

I. INTRODUCTION

On November 30, 2016, Smith & Nephew, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–83 (the “challenged claims”) of U.S. Patent No. 8,377,129 B2 (Ex. 1001, “the ’129 patent”). On March 15, 2017, Patent Owner, ConforMIS, Inc. (“Patent Owner”), filed a Preliminary Response (Paper 6, “Prelim. Resp.”) thereto.

In our Decision dated June 13, 2017 (Paper 7, “Dec.”), we denied institution of an *inter partes* review based on the grounds presented in the Petition. Dec. 1. In particular, we found that Petitioner had failed to make a threshold showing that claims 1–83 of the ’129 patent are unpatentable under 35 U.S.C. § 103(a) over the combination of Radermacher, Alexander, Woolson, and Kenna, or over the combination of Radermacher, Fell, Woolson, and Kenna. *See id.* at 11–18. Accordingly, we determined that Petitioner had not established a reasonable likelihood that it would prevail in asserting that claims 1–83 would have been obvious over the cited references. *Id.*

Petitioner now requests rehearing of our decision not to institute an *inter partes* review of claims 1–83 based on these obviousness grounds. Paper 8 (“Req. Reh’g”). Petitioner’s stated basis for rehearing is that we (1) “overlooked that the claim limitations require a drilling path that is merely **based on** a predetermined angle or orientation of an implant,” and (2) misapprehended the disclosure in the prior art of drilling paths based on a predetermined orientation or angle of an implant. *Id.* at 1.

For the reasons that follow, we deny Petitioner’s Request for Rehearing.

II. DISCUSSION

Under 37 C.F.R. § 42.71(c), “[w]hen rehearing a decision on petition, a panel will review the decision for an abuse of discretion.” An abuse of discretion occurs when a “decision was based on an erroneous conclusion of law or 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) (citations omitted). The party requesting rehearing has the burden of showing the decision should be modified, which includes specifically identifying all matters the party believes the Board misapprehended or overlooked. *See* 37 C.F.R. § 42.71(d).

A. Petitioner Argues that the Board Overlooked that the Drilling Path is “Based on” a Predetermined Angle of the Implant

Petitioner argues that we required a “specific” angle of internal or external rotation and did not allow for a path merely “based” on an angle. In Petitioner’s view,

[t]he claims require that the drilling path’s position merely be “based on” any predetermined rotation angle of an implant. The claims do not require a particular or “specific” angle of internal or external rotation, e.g., three degrees, as the Board incorrectly found. Decision at 12. Indeed, no such angle is disclosed in the specification of the ’129 patent. Rather, the claimed angle may be any “predetermined” angle, and the angle may differ from patient-to-patient or from one implant to another.

Req. Reh’g 3. Petitioner appears to argue that the Decision required a fixed angle of internal or external rotation that would apply to each and every patient and does not allow for individual “patient-to-patient” variation. *Id.* We disagree, however, with Petitioner’s characterization of the reasoning provided in the Decision. In this connection, the Decision does not specify

an angle of three degrees, or any other fixed angle, nor understand a fixed angle to have been a claim limitation. *See generally* Dec. 11–14. Rather, the Decision merely gave effect to the claim language of “the drilling path having a position *based on a predetermined internal rotation angle or external rotation angle* of an orthopedic implant” in analyzing whether the prior art took the angle of internal or external rotation into account before assigning a drilling path. *See id.* at 11–12 (emphasis added). To the extent we agree with Petitioner’s position that the “based on” language does not define a precise numerical relationship between the drilling path and a specific rotational angle, we decline to read out of the claims a requirement that the drilling path take into account the angle of internal and external rotation. We thus determine that the Decision did not misapprehend or overlook the “based on” limitation, as recited in independent claim 1.

*B. Petitioner Argues That the Board Misapprehended
Radermacher’s Disclosure Regarding Drilling Path Position*

Petitioner argues that page 30 and Figures 13b and 13d of Radermacher disclose “determining the position of the guides to ‘ensure a desired orientation of the implant.’” Reh’g Req. 4. According to Petitioner, Radermacher satisfies this limitation because groove 20c is milled according to the “geometry” of the prosthesis and is depicted as having a geometry that ensures the implant has the desired internal/external rotational alignment. *Id.* at 4–5 (citing Pet. 43, 55).

The cited portions of the Petition relate to the limitation “the drilling path having a position based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant.” We addressed this argument on page 12 of the Decision. As stated in the Decision,

Radermacher's disclosure is limited to a general disclosure of surgical planning and drill guides with dimensions of guides and anatomic angles for cutting, but does not describe an angle of internal or external rotation of the knee joint, let alone a predetermined angle of internal or external rotation. Dec. 12. Thus, we determine that the Decision did not overlook or misapprehend Radermacher's disclosure.

C. Petitioner Argues That the Board Overlooked Relevant Portions of Dr. Mabrey's Declaration

Petitioner contends that the "based on" limitation would have been obvious in view of Radermacher, and that the Board overlooked, or failed to find corroboration in, relevant portions of the Petition and Dr. Mabrey's Declaration. Reh'g Req. 5. Petitioner states that "it was well-known by the 1990s that, to achieve proper knee-joint movement/alignment, surgeons should account for the present condition of the knee joint and its intended movements when planning surgical drilling or cutting paths and selecting implants." *Id.* at 5–6 (citing Pet. 6–7, 9–11, 43–45; Ex. 1002 ¶¶ 63–64, 130–135). Petitioner argues that Dr. Mabrey also cited Kenna, as well as Exhibits 1051, 1054, 1055, and 1057, for a system "that accounts for internal/external rotation and varus-valgus conditions." *Id.* at 6 (citing Ex. 1002 ¶¶ 63–64).

Petitioner's reliance on Exhibits 1051, 1054, 1055, and 1057 is misplaced because the Petition did not contain developed arguments with respect thereto, and we regard this as a new argument. As such, we determine that we did not overlook or misapprehend any arguments with respect to Exhibits 1051, 1054, 1055, and 1057. To the extent that Petitioner relies on Kenna for the argued limitation, we address that contention below.

D. Petitioner Argues That the Board Misapprehended Kenna's Disclosure

According to Petitioner, the Board erred by finding that “Kenna: (1) does not disclose a **predetermined** internal/external rotation angle; and (2) discloses orienting an **instrument** rather than a **prosthesis**.” Reh’g Req. 6. Petitioner argues that the claims are directed to an instrument (or cutting guide), that the implant will have the orientation of the instrument, and that this is the approach taken by the specification of the ’129 patent. *Id.* at 7–8 (citing Ex. 1001, 51:24–26, 51:43–46, 54:26–29).

First, Petitioner asserts that “[a]ligning drilling paths using an anatomical landmark, such as the patello-femoral groove [as Kenna discloses], is based on a ‘predetermined angle.’” *Id.* at 7. Petitioner argues that Patent Owner, ConforMIS, did not dispute that Kenna discloses this limitation. *Id.* (citing Prelim. Resp. 20–21). In its Petition, Petitioner argued as follows:

Even if Radermacher alone did not disclose or render obvious the recited drilling path, this feature would have been obvious in view of Kenna. Ex. 1002 ¶¶ 130, 133. Kenna discloses the importance of preserving the “axes of rotation” and aligning the cutting paths accordingly:

The aforementioned prosthesis is designed to reproduce anatomic movement of the knee without compromising stability. This prosthetic knee, as the natural knee, provides a “screw home” mechanism which increases stability in extension. As flexion proceeds, the femoral condyles initially roll posteriorly. Through asymmetric condylar and tibial compartments, the natural and changing axes of rotation are preserved, thereby preventing the development of abnormal tension in retained ligaments. When abnormal ligamentous tension develops, it either restricts flexion and increases

shear stress at fixation interfaces and/or leads to eventual progressive ligament attenuation and joint instability. The design also allows natural internal and external rotation of the knee in flexion.... In order to make such prosthetic knee system feasible, the necessary bone cuts must be precisely accomplished. This, in turn, requires a set of proper instruments including guides and jigs. Such instruments should assure reproducibly accurate bone cuts, prosthetic seating, and lower limb alignment.

Ex. 1032, 1:20–46 (emphases added); *see also id.*, 5:34–43 (drill holes are aligned and drilled only after “correct medial-lateral and rotational positioning is assured”).

A POSITA would have been motivated to combine Radermacher and Kenna. They are in identical fields, relate to the same type of devices, and describe similar methods for using such devices. Both are directed at preparing the knee for orthopedic implants using guides with drilling and cutting paths. Combining their teachings such that the cutting and drilling paths disclosed in Radermacher have a position based, at least in part, on a predetermined internal rotation angle or external rotation angle of an orthopedic implant/component as taught by Kenna would merely require the use of techniques employed to improve one procedure (Kenna’s) to improve a similar procedure (Radermacher’s) in the same predictable way. Ex. 1002 ¶ 133.

Pet. 44–45 (emphases omitted).

Petitioner’s argument on rehearing appears to be based on its citation to Kenna at column 5, lines 34–43, which refers to placing a pin in alignment with the patella-femoral groove during surgery to align the cutting jig. *See* Ex. 1032, 5:35–42. The Decision did not misapprehend or overlook this argument, but rather set forth findings and analysis on pages 10–11 and

13. Specifically, the Decision concluded, *inter alia*, that placing a pin in the jig did not constitute determination of an angle. Dec. 13.

Petitioner further argues that the Board erred in finding that “Kenna discloses the determination of the orientation of a cutting guide rather than of a prosthesis[.]” Reh’g Req. at 7 (quoting Dec. 13). Petitioner asserts that “the claims are directed to an instrument (or cutting guide), not an implant.” *Id.* Petitioner argues that the Specification takes the same approach as Kenna. *Id.* at 7–8 (citing Ex. 1001, 54:26–29, 51:24–26, 51:43–46). We are not persuaded that the Decision erred in concluding that the claims refer to a predetermined angle *of the implant*. Ex. 1001, 61:30–32 (“the drilling path having a position based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant”). As the Decision finds, Kenna at most discloses an angle of an instrument (i.e., the cutting jig). See Dec. 13. As such, Petitioner’s arguments and evidence do not persuade us that we misapprehended Kenna’s teachings when finding that Kenna fails to disclose a predetermined angle *of the implant*, as recited.

E. Petitioner Argues That the Board Overlooked and Misapprehended Petitioner’s Proposed Radermacher-Kenna Combination

Petitioner contends that “[t]he Decision never addresses Petitioner’s argument that **the combination** of Radermacher and Kenna disclose the ‘based on’ limitation,” and that this alone “is grounds for rehearing.” Reh’g Req. 8 (citing *Handi Quilter, Inc. v. Bernina Int’l AG*, Case IPR2014-00270 (Paper 17) (PTAB Dec. 30, 2014)).

According to Petitioner, in Petitioner’s proposed combination, the internal/external rotation angle of the implant (as disclosed by Kenna) would be incorporated into the template during the planning stages (as disclosed in

Radermacher), and therefore would be “predetermined.” Reh’g Req. 9 (citing Pet. 36; Ex. 1002 ¶108). Petitioner further states that even if the Board were to maintain that the drilling path in Kenna is not based on a predetermined rotation angle “of an implant,” Radermacher discloses this feature. *Id.* (citing Pet. 43; Ex. 1003, 30, Ex. 1002 ¶ 131).

Petitioner argues that “[t]he Board’s concern appears to be that it would be inconsistent to rotate an instrument to achieve the desired internal/external rotation angle (as in Kenna) if the instrument has a patient-specific surface (as in Radermacher).” Reh’g Req. 10. Petitioner asserts that because Kenna’s step of ensuring rotational alignment would occur during Radermacher’s preoperative planning stages rather than intraoperatively, there is no inconsistency. *Id.* at 11. Petitioner contends that this argument does not depend on physically combining Radermacher’s template and Kenna’s jig. *Id.*

Petitioner thus appears to argue that the Decision only addressed a combination of Radermacher and Kenna in which a cutting guide (as in Radermacher) is aligned intra-operatively (as in Kenna), but that the Decision did not address a combination of Radermacher and Kenna in which there is angular alignment (as in Kenna) when the cutting guide is planned pre-operatively (which Petitioner argues to have been taught in Radermacher). First, we regard this latter argument to be a new argument. The argument in the Petition is reproduced above. We conclude that the Petition provided inadequate argument and reasoning for combining the references in this manner, i.e., to take the intra-operative teachings of Kenna and apply them pre-operatively. Neither the Petition nor Declaration explain how this would have been accomplished or persuade us that such a

combination would have been obvious (without intra-operative adjustment, as taught in Kenna).

In particular, the Petition does not explain adequately how a person of ordinary skill would have included Kenna's angle adjustment teaching in Radermacher's prosthesis with a patient-specific surface, rather than rotating Kenna's cutting guide intra-operatively. Although we appreciate Petitioner's argument that the combination does not require bodily incorporation of one prior art device into another, we are not persuaded that the Petition adequately set forth what that combination would be, or how it would be achieved. *See, e.g.*, Pet. 43–45 (quoting Kenna and asserting it would have been obvious to combine the teachings of the prior art).

Second, the Decision observed that the teachings of Kenna were inconsistent with the approach of the claims, as follows. Dec. 13–14. In the Decision, we concluded that (a) “the prior art does not disclose the predetermined angle of internal rotation or external rotation of the prosthesis, as required by independent claim 1”; (b) “Petitioner has not explained sufficiently how determination of the orientation of the cutting guide, as purportedly contemplated by Kenna, impacts the position of a drilling path”; and (c) “it would have been inconsistent with the system of claim 1 to rotate a cutting guide on already-cut bone,” as taught by Kenna. *Id.* As such, we are not persuaded that the Decision overlooked or misapprehended any of the arguments in the Petition.

F. Petitioner Argues That Petitioner Established A Reasonable Likelihood That Claims 62-83 Are Unpatentable

According to Petitioner, the Decision included three erroneous or unsupported factual findings: (A) Kenna does not disclose a predetermined

varus-valgus angle; (B) Kenna discloses orienting an instrument rather than a prosthesis; and (C) it would be “inconsistent” to combine an instrument having a patient-specific surface (Radermacher) with an instrument that could be adjusted with a mallet (Kenna). Reh’g Req. 12 (citing Dec. 16). For similar reasons as discussed in the previous section, we are not persuaded that the Decision misapprehended or overlooked any of Petitioner’s arguments. *See* Section II.F., *supra*.

III. CONCLUSION

For the reasons above, we conclude that Petitioner has not met its burden of showing that we misapprehended or overlooked any of Petitioner’s arguments as to whether the Petition established a reasonable likelihood that claims 1–83 are unpatentable over the asserted grounds. We, therefore, deny Petitioner’s request for rehearing.

IV. ORDER

In consideration of the foregoing, it is hereby ORDERED that the Request for Rehearing is *denied*.

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