

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2017-00778
Case IPR2017-00779
Case IPR2017-00780¹
Patent 8,062,302 B2

Before PATRICK R. SCANLON, 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)

¹ This Decision addresses petitions filed in three proceedings, which are directed to the same patent but with differing asserted grounds. We issue a single Decision to be entered in each proceeding. The parties may use this caption when filing a single paper in these proceedings, provided that such caption includes a footnote attesting that "the word-for-word identical paper is filed in each proceeding identified in the caption."

I. INTRODUCTION

In three Petitions filed across these proceedings, Petitioner Smith & Nephew, Inc. requested an *inter partes* review of, collectively, claims 1–3, 5–21, 24, 25, 28–43, 47, and 95–125 of U.S. Patent No. 8,062,302 B2 (Ex. 1001, “the ’302 patent”)² pursuant to 35 U.S.C. § 311(a). Paper 1 (“Pet.”); *see also* -779 Paper 1 (“-779 Pet.”); -780 Paper 1 (“-780 Pet.”). Patent Owner ConforMIS, Inc., filed a Preliminary Response in each proceeding. Paper 6 (“Prelim. Resp.”); -779 Paper 6 (“-779 Prelim. Resp.”); -780 Paper 6 (“-780 Prelim. Resp.”).

In our Decision dated August 7, 2017 (Paper 7, “Dec.”), we instituted an *inter partes* review of claims 1–3, 5–8, 11, 20, 21, 24, 25, 28–37, 39–43, 47, and 95–125 as obvious over Radermacher, Alexander, and Woolson, and denied institution of the remaining grounds presented in the Petitions. Dec. 1, 3, 6, 39–40. For example, we found that Petitioner had failed to make a threshold showing that claims 13, 18, and 38 of the ’302 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 16–23. Additionally, we found that Petitioner had failed to make a threshold showing that claims 9, 10, and 12 of the ’302 patent are unpatentable under 35 U.S.C. § 103(a) over the combination of Radermacher, Alexander, and Woolson. *See id.* at 23–24. We also found that Petitioner had failed to make a threshold showing that claims 14–17 and 19 of the ’302 patent are unpatentable under

² References to papers and exhibits cited herein are to those filed in Case IPR2017-00778, unless otherwise specified with a “-779” or “-780” prefix.

35 U.S.C. § 103(a) over the combination of Radermacher, Alexander, Woolson, Kenna, and Hoffmann, *see id.* at 26–31, or that claims 9, 10, 12, 14–17, and 19 are unpatentable under 35 U.S.C. § 103(a) over the combination of Radermacher, Fell, Woolson, Kenna, and Hoffmann. *See id.* at 32. Finally, we exercised our discretion under 35 U.S.C. § 314(a) and 37 C.F.R. § 42.108(a) not to institute trial on the remaining grounds in the Petitions. *Id.* at 22–23, 31–32, 39.

Petitioner requests rehearing of our decision not to institute an *inter partes* review of claims 9, 10, 12–19, and 38 based on the asserted grounds. *See* Paper 9, (“Req. Reh’g”) 1. Petitioner’s stated basis for rehearing is that the Decision: (1) incorrectly found that a theory of modifying Radermacher in view of Kenna was explained insufficiently for claims 13, 18, and 38; (2) overlooked Petitioner’s argument that these claims would have been obvious based on Patent Owner’s claim construction and the prior art’s disclosure of drill holes used for securing the block to the bone; (3) overlooked that the Petition presented different arguments for claims 14–17 and 19 than for claim 13; and (4) overlooked and/or misunderstood Petitioner’s arguments for claims 9, 10, and 12 and the disclosures in the prior art. Req. Reh’g 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 Industries, 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 Misunderstood and Overlooked Petitioner's Arguments for Claims 13, 18, and 38

Petitioner argues that the Decision only analyzed Petitioner's argument that it would have been obvious to modify Kenna's device with Radermacher's teachings, but failed to analyze Petitioner's argument that it would have been obvious "to **modify Radermacher** to include two drilling holes as disclosed by Kenna." Req. Reh'g 4 (emphasis in original). Petitioner refers to the following passage from the Petition which it contends to have been overlooked:

Thus, including two drilling holes that define a path vertically "through the tibial plateau" **in Radermacher's template** would have involved nothing more than combining Radermacher's teachings with common knowledge and/or Kenna according to known methods to yield predictable results. . . . It would therefore have been obvious to a POSITA [(a person of ordinary skill in the art)] that **Radermacher's individual template, as applied to a tibia, would include two drilling holes** that define a path vertically "through the tibial plateau."

Req. Reh'g 4–5 (quoting Pet. 71) (emphasis in Req. Reh'g). Petitioner argues that the Board erred by summarily stating that Petitioner did not explain how a POSITA would have incorporated the teaching of Kenna into the device of Radermacher. *Id.* at 5. Petitioner asserts that the Petition explained that Radermacher's device could include any number of drill holes and that this modification would require nothing more than modifying Radermacher's template according to known methods to yield a predictable

result, i.e., a patient-specific block for the tibia comprising two drilling holes, as suggested by Kenna. *Id.* at 5–6 (citing Pet. 68–73). Petitioner asserts that its arguments in this regard were undisputed. *Id.* at 6–7.

Petitioner contends that the Decision erred as follows:

The Board’s single paragraph addressing Petitioner’s primary theory does not address any of Petitioner’s arguments as to why a POSITA would have been motivated to modify Radermacher’s template to include a second drilling hole. Decision at 20–21. Nor does the Board’s decision explain why the Board rejected those arguments. *Id.*

Instead, the Board wrote that Petitioner “does not explain how a person of ordinary skill would have adapted the teachings of Kenna, which discloses alignment during an operation, to provide alignment pre-operatively, as in Radermacher.” *Id.* Petitioner respectfully submits that this is irrelevant. Petitioner’s argument depends only on whether it was obvious to include a second hole in Radermacher’s template in view of Kenna. Whether Kenna’s alignment method could be combined with Radermacher’s alignment method is entirely irrelevant. Whether Radermacher’s patient-specific instrument and Kenna’s tibial jig could be physically combined is also irrelevant. *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016).

....

There is no meaningful difference between modifying Radermacher’s template to include two drilling holes for the femur (as disclosed in Woolson for Claim 7) and modifying Radermacher’s template to include two drilling holes for the tibia (as disclosed in Kenna for Claim 13).

Reh’g Req. 7–8.

The panel addressed Petitioner’s theory of modifying Radermacher’s teachings with Kenna’s teachings on, *inter alia*, pages 20–21 of the Decision, as referred to by Petitioner immediately above. *Id.*; *see also id.* at

16–21. Although we are mindful that issues of bodily incorporation may be irrelevant to a combination, *see In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc), the Decision considered the fact that Kenna’s surgical approach is based on intra-operative alignment while Radermacher’s surgical approach is directed to pre-operative alignment, and that Petitioner did not identify a sufficient rationale to combine the different disclosed approaches. Dec. 18–21. We are not persuaded that this difference is irrelevant to whether a person of ordinary skill would have combined these approaches. The Petition does not explain adequately how to adapt Kenna’s teachings to Radermacher’s template, or why this would have been obvious to a POSITA, in light of the references’ different alignment approaches. Pet. 71–73; *see* Dec. 20–21.

Accordingly, we conclude that the Decision did not misapprehend or overlook any arguments in the Petition.

The Decision did not identify a similar problem in Woolson, with respect to intraoperative alignment and hole placement, but the parties are free to brief the combination as it relates to Woolson during the *inter partes* review proceeding.

*B. Petitioner Argues That the Board Erred by Overlooking
Petitioner’s Alternative Obviousness Theory*

Petitioner argues that the Decision also overlooked Petitioner’s alternative argument that claims 13, 18, and 38 would have been obvious in view of Radermacher and Kenna under Patent Owner’s proposed construction of “drilling holes,” as including holes in the block that are used for securing the block to the joint. Req. Reh’g 8–10 (citing Pet. 71–73). Petitioner argues that “[a] POSITA would have immediately recognized that

an individual template as described in Radermacher could include two . . . horizontal holes for guiding a drill such that the patient-specific tool could be secured to the tibia” as disclosed in Kenna. *Id.* at 9 (citing Pet. 71–73; Ex. 1003, 23, 25; Ex. 1032, 6:67–7:2, 7:50–56, Figs. 21, 22, 25, 30B). Petitioner thus argues that the recited “drilling holes” may be used for fixation rather than alignment. However, the above-identified problem remains with the combination of Radermacher and Kenna. Even if the recited structures are present in the individual references, the burden remains on Petitioner to show that it would have been obvious to a person of ordinary skill in the art to combine the teachings of the references as proposed. This issue was analyzed on pages 17–21 of the Decision. As the Decision finds, the Petition does not explain adequately how or why a person of ordinary skill in the art would have combined the pre-operative approach of Radermacher with the intra-operative approach of Kenna to arrive at a usable surgical tool. *See* Dec. 18–21. As such, we remain unpersuaded that a person of ordinary skill in the art would have combined the teachings of Radermacher and Kenna to create the recited tool.

Accordingly, the Decision did not misapprehend or overlook any arguments with respect to claims 13, 18, and 38.

C. Petitioner Argues That the Board Misunderstood and Overlooked Petitioner’s Arguments for Claims 14–17 and 19

Claims 14–17 and 19 depend, directly or indirectly, from claim 13. Petitioner contends that the Petition argued claims 14–17 and 19 separately from claim 13, and that the Decision dismissed as conclusory the following arguments:

Petitioner provided multiple reasons why a POSITA would have been motivated to combine [Radermacher's and Kenna's] teachings, including: (a) Radermacher itself discloses holes for securing the template to the bone using nails or pins (-779 Pet. at 65 (citing Ex. 1003 at 23, 25[]; Ex. 1002 ¶160); (b) securing cutting guides in such a manner was conventional practice (-779 Pet. at 65 (citing Ex. 1002 ¶¶ 160, 143)); and (c) using two drill holes for securing a cutting block to a tibia was explicitly disclosed in Kenna (-779 Pet. at 64–66). Petitioner further explained that modifying Radermacher's block to include two horizontal drill holes as disclosed in Kenna would have simply required using a known method to yield a predictable result, i.e., adding pin holes to Radermacher's individual template to ensure that the template did not move during surgery. Ex. 1002 ¶¶ 160, 143, 158; -779 Pet. at 65–66. Petitioner's explanation was fully supported and undisputed.

Reh'g Req. 10; *see also id.* at 1. Petitioner refers to the following statement in the Decision: “[I]t would have been inconsistent to use a patient-specific surface for a template, as taught in Radermacher, with Kenna's system, which relies on adjustment and rotation of its cutting jigs[.]” *Id.* at 11 (quoting Dec. 30). Petitioner argues that this statement is “irrelevant.” *Id.* Petitioner contends that “[t]here is no inconsistency” and “the adjustment and rotation of Kenna's jigs has nothing to do with drill holes for securing the jig to the bone.” *Id.* We are unpersuaded for similar reasons as discussed above for claim 13. Even if the recited structures are present in the individual references, the burden remains on Petitioner to show that it would have been obvious to a person of ordinary skill in the art to combine the teachings of the references. As the Decision finds, the Petition does not explain adequately how a person of ordinary skill in the art would have combined the pre-operative approach of Radermacher with the intra-operative approach of Kenna to arrive at a usable surgical tool. *See* Dec. 30.

We conclude that the Decision did not overlook or misapprehend any arguments in the Petition with respect to claims 14–17 and 19.

D. Petitioner Argues That the Board Overlooked Petitioner’s Arguments Relating to Claims 9, 10, and 12

According to Petitioner, the Board erred by finding that “Petitioner’s primary rationale for the asserted modification appears to be that anterior drill holes were ‘common in the industry’ or ‘within the knowledge of a POSITA,’” and that such a rationale is insufficient. Req. Reh’g 12 (quoting Dec. 24). Petitioner argues that Radermacher already discloses using holes for securing the patient-specific template to the joint. *Id.* at 13 (citing -779 Pet. 39–40 (citing Ex. 1003, 25, Fig. 10c (item 19))). Petitioner contends that it would have been obvious to modify Radermacher’s femoral template to include anteriorly positioned drill holes as described in Woolson. *Id.* (citing -779 Pet. 41). Petitioner argues that its contentions were undisputed and that its expert also testified that Claim 9 “recites nothing more than modifying Radermacher’s patient-specific template to include Woolson’s conventional pin hole patterns.” *Id.* at 14 (citing -779 Pet. 55; Ex. 1002 ¶ 126). Petitioner argues that the Petition also referred to other prior art that disclosed anterior drill holes. Req. Reh’g (citing Ex. 1002 ¶ 143; Ex. 1041; Ex. 1037; Ex. 1034; Ex. 1033; and Ex. 1012).

Contrary to Petitioner’s arguments, the Decision recognized that the prior art, i.e., Woolson, discloses the recited anterior drill holes. *See* Dec. 24. Nonetheless, the Decision determined that the Petition did not provide “sufficient articulated reasoning with rational underpinnings for the asserted combination” of the teachings of Radermacher and Woolson. *Id.* Petitioner reliance on its expert assertion that anterior placement of holes is

“conventional” is consistent with the Decision’s conclusion that Petitioner’s rationale for the proposed modification was that it was “common in the industry.” See Req. Reh’g 14 (citing -779 Pet. 55; Ex. 1002 ¶ 126); and Dec. 24.

Petitioner also argues that the Petition provided the motivation of securing the template to the bone, and that Radermacher itself disclosed drill holes. *Id.* at 13 (citing -779 Pet. 39–40). However, this portion of the Petition does not concern the proposed modification to Radermacher, i.e., the specific anterior placement of drill holes.

As such, the Decision did not overlook or misapprehend any arguments with respect to claims 9, 10, and 12 in determining that the Petition failed to state more than a conclusory rationale for combining the teachings of Radermacher and Woolson. See Dec. 24.

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 9, 10, 12–19, and 38 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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