

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
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

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 that has been 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

Petitioner Smith & Nephew, Inc. filed three petitions requesting *inter partes* review of 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), as indicated in the chart below. Patent Owner ConforMIS, Inc. filed a Preliminary Response in each proceeding.

Case Number	Challenged Claims	Petition	Preliminary Response
IPR2017-00778	1–3, 5–8, 11, 13, 18, 20, 21, 24, 25, 28, 29, 34–38, and 47	Paper 1 (“Pet.”)	Paper 6 (“Prelim. Resp.”)
IPR2017-00779	9, 10, 12, 14–17, 19, 30–33, and 39–43	Paper 1 (“-779 Pet.”)	Paper 6 (“-779 Prelim. Resp.”)
IPR2017-00780	95–125	Paper 1 (“-780 Pet.”)	Paper 6 (“-780 Prelim. Resp.”)

Institution of an *inter partes* review is authorized by statute when “the information presented in the petition filed under [35 U.S.C. §] 311 and any response filed under [35 U.S.C. §] 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108. For the reasons set forth below, we determine that Petitioner has

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.

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demonstrated that there is a reasonable likelihood that claims 1–3, 5–8, 11, 20, 21, 24, 25, 28–37, 39–43, 47, and 95–125 are unpatentable.

Accordingly, we institute an *inter partes* review of claims 1–3, 5–8, 11, 20, 21, 24, 25, 28–37, 39–43, 47, and 95–125 based on the grounds identified in the Order section of this Decision.

A. *Related Matters*

The parties identify the following district court proceeding as a related matter: *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass. Feb. 29, 2016). Pet. 1; Paper 4, 2. The parties identify the following Board proceedings as related: IPR2016-01874; IPR2017-00115; IPR2017-00307; IPR2017-00372; IPR2017-00373; IPR2017-00487; IPR2017-00488; IPR2017-00510; IPR2017-00511; IPR2017-00544; and IPR2017-00545. Pet. 1; Paper 4, 2–3.

B. *The '302 Patent (Ex. 1001)*

The '302 patent is titled “Surgical Tools for Arthroplasty” and relates to methods, systems, and devices for articular resurfacing. Ex. 1001, 1:65–67. The '302 patent also relates to surgical molds designed to achieve optimal cut planes in a joint in preparation for installation of a joint implant. *Id.* at 2:1–3.

The '302 patent describes a need for methods and compositions for joint repair that facilitate the integration between the cartilage replacement system and the surrounding cartilage, and that increase the accuracy of cuts made to the bone in a joint in preparation for surgical implantation of an artificial joint. *Id.* at 5:42–49.

The '302 patent discloses a method of designing an articular implant comprising the steps of obtaining an image of a joint, wherein the image

includes both normal cartilage and diseased cartilage; reconstructing dimensions of the diseased cartilage surface to correspond to normal cartilage; and designing the articular implant to match the dimensions of the reconstructed diseased cartilage surface or to match an area slightly greater than the diseased cartilage surface. *Id.* at 8:20–28. The '302 patent also discloses a method of joint arthroplasty in which a template is created having at least one contact surface that conforms with the joint surface. *Id.* at 10:22–26.

In one embodiment, the '302 patent discloses an expandable or ratchet-like device, as depicted in Figure 37D, reproduced below (*see id.* at 74:36–44):

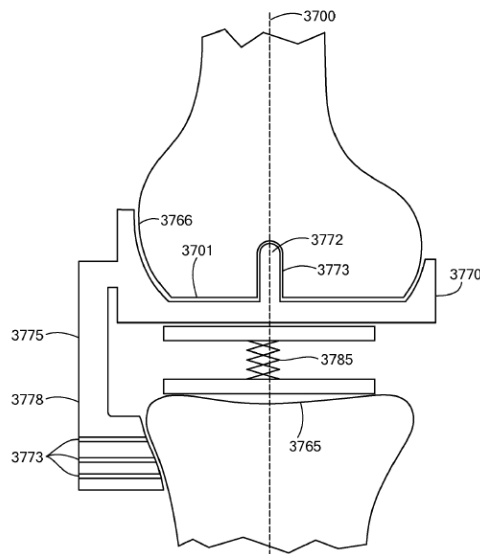


FIG. 37D

Figure 37D shows a mold with linkages connected to an opposing articular surface. *Id.* at 29:6–9. The '302 patent discloses that such devices are helpful for soft-tissue tension optimization and ligament balancing in different joints for different static positions and during joint motion. *Id.* at 74:55–58.

C. Illustrative Claim

Challenged claims 1, 95, 109, 110, and 117 are independent.

Independent claim 1, reproduced below, is illustrative of the subject matter:

1. A patient-specific surgical tool for use in surgically repairing a joint of a patient, comprising:
 - a block having a patient-specific surface and first and second drilling holes;
 - the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged articular surface of the joint and having a predetermined position and orientation relative to the corresponding portion;
 - the first and second drilling holes having predetermined positions and orientations relative to the patient-specific surface and each having an axis that extends through a portion of the joint when the patient-specific surface is fit to the corresponding portion of the diseased of [sic] damaged articular surface of the joint.

Ex. 1001, 119:9–25.

D. The Prior Art

Petitioner relies on the following prior art:

US 4,646,729, iss. Mar. 3, 1987 (Ex. 1032, “Kenna”);

US 4,841,975, iss. June 27, 1989 (Ex. 1031, “Woolson”);

WO 93/25157, pub. Dec. 23, 1993 (Ex. 1003, “Radermacher”);

WO 00/35346, pub. June 22, 2000 (Ex. 1004, “Alexander”);

WO 00/59411, pub. Oct. 12, 2000 (Ex. 1005, “Fell”); and

Aaron A. Hofmann et al., *Effect of the Tibial Cut on Subsidence Following Total Knee Arthroplasty*, 269 CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 63 (1991) (Ex. 1090, “Hofmann”).

E. The Alleged Grounds of Unpatentability

Petitioner challenges claims 1–3, 5–21, 24, 25, 28–43, 47, and 95–125 of the '302 patent as unpatentable under 35 U.S.C. § 103(a) on the following grounds:

Case Number	References	Claims Challenged
IPR2017-00778	Radermacher, Alexander, and Woolson	1–3, 5–8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47
IPR2017-00778	Radermacher, Alexander, Woolson, and Kenna	13, 18, and 38
IPR2017-00778	Radermacher, Fell, Woolson, and Kenna	1–3, 5–8, 11, 13, 18, 20, 21, 24, 25, 28, 29, 34–38, and 47
IPR2017-00779	Radermacher, Alexander, and Woolson	9, 10, 12, 30–33, and 39–43
IPR2017-00779	Radermacher, Alexander, Woolson, Kenna, and Hofmann	14–17 and 19
IPR2017-00779	Radermacher, Fell, Woolson, Kenna, and Hofmann	9, 10, 12, 14–17, 19, 30–33, and 39–43
IPR2017-00780	Radermacher, Alexander, and Woolson	95–125
IPR2017-00780	Radermacher, Fell, and Woolson	95–125

As a preliminary matter, we observe that Petitioner sets forth several grounds of unpatentability based on Radermacher, Alexander, and Woolson as one grouping of references but pleads this ground of unpatentability in the alternative based on the use of references individually, e.g., based on Radermacher alone, Radermacher in combination with the knowledge of a

person of ordinary skill, or Radermacher in combination with the knowledge of ordinary skill and Alexander, and further in view of Woolson. *See* Pet. 21–67; -779 Pet. 23–62; -780 Pet. 23–88. Petitioner additionally pleads certain other grounds in the alternative. Taking the references in the alternative as presented would, as a practical matter, expand what is asserted as one ground into three (or more) separate grounds of unpatentability. The function of the Board is not to comb through Petitioner’s arguments in order to decipher the strongest argument or to determine the strongest combination of references to challenge the claims. As such, we exercise our discretion and consider all of the references in combination as one ground of unpatentability. *See* 35 U.S.C. § 314(a); 35 C.F.R. § 42.108; *see generally* *LG Elecs., Inc. v. Rosetta-Wireless Corp.*, Case IPR2016-01516 (PTAB Apr. 3, 2017) (Paper 25) (denying rehearing).³

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see* *Cuozzo Speed Techs. v. Lee, LLC*, 136 S. Ct. 2131, 2142–46 (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood

³ Patent Owner argues throughout its Preliminary Response that the grounds asserted in the Petition are horizontally and vertically redundant, i.e., within and across grounds. *See* Prelim. Resp. 21–30; -779 Prelim. Resp. 23–32; -780 Prelim. Resp. 19–23. Based on our determination to consider the references in each ground as one group, Patent Owner’s arguments with respect thereto are generally moot.

by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Neither Petitioner nor Patent Owner requests construction of any term. Nevertheless, we request that Patent Owner, in its Response, and Petitioner, in its Reply, brief (1) whether the term “adjustment mechanism,” as recited in claim 24, i.e., “adjustment mechanism to balance ligaments associated with the knee,” falls within the ambit of former-35 U.S.C. § 112 ¶ 6 and (2) if so, what if any, is the corresponding structure for the term in the specification.

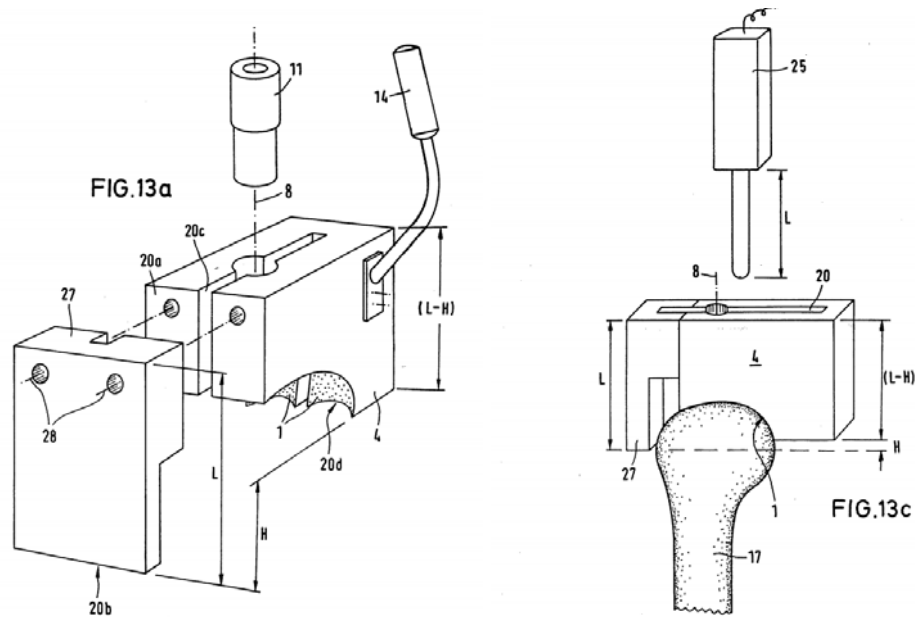
B. Obviousness of Claims 1–3, 5–8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47 over Radermacher (Ex. 1003), Alexander (Ex. 1004), and Woolson (Ex. 1031)

Petitioner contends that claims 1–3, 5–8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47 are unpatentable as obvious over Radermacher, Alexander, and Woolson. Pet. 21–67. Patent Owner disagrees. Prelim. Resp. 9–13.

1. Overview of Radermacher

Radermacher is titled “Template for Treatment Tools and Method for the Treatment of Osseous Structures” and relates to certain improvements in the planning and performance of orthopedic surgery. *See Ex. 1003, (54), 1, 9.* Radermacher describes a method in which parts of the surface of an arbitrary osseous structure, which are to be operated upon, are copied as a negative image using computer or nuclear-spin imaging so that an individual template can be set intra-operatively onto the osseous structure with mating

attachment. *Id.* at 10:5–13. Radermacher discloses that the template can provide a guide corresponding to the limiting edge of a cut through the osseous structure (e.g., a vertebra) and can guarantee sufficient accuracy by exact positioning and guidance of the cutting tool. *Id.* at 16:5–19. Figures 13a and 13c of Radermacher are depicted below:



Figures 13a and 13c schematically show an individual template 4 for the preparation of the seat for a knee-joint head prosthesis. *Id.* at 30:5–8.

2. Overview of Alexander

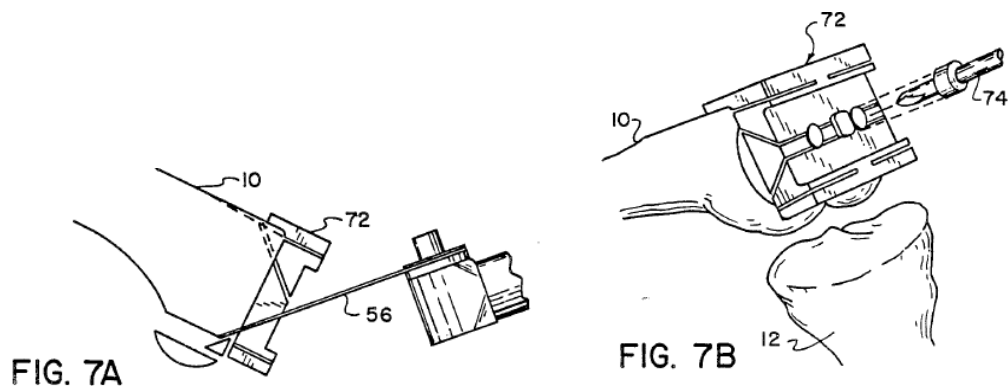
Alexander is titled “Assessing the Condition of a Joint and Preventing Damage” and relates to using joint assessment in aiding in prevention of damage to the joint or treatment of diseased cartilage in the joint. Ex. 1004, (54), 1:15–17. Alexander discloses a method of obtaining an image of cartilage, (preferably a magnetic resonance image), converting the image to a three-dimensional degeneration pattern, and evaluating the degree of degeneration in a volume of interest of the cartilage. *Id.* at 2:25–27. Alexander further discloses calculating the thickness or regional volume of

the region thought to contain degenerated cartilage, both at an initial time and a later time, to determine a loss in thickness. *Id.* at 3:3–8. Alexander also describes creating a 3D thickness map. *Id.* at 3:8–9.

3. Overview of Woolson

Woolson is titled “Preoperative Planning of Bone Cuts and Joint Replacement Using Radiant Energy Scan Imaging” and relates to a method of preoperative planning to determine the position of a bone-cut-defining guide relative to the bone to be cut. Ex. 1031, (54), 1:12–14. Woolson discloses steps of (1) preoperative determination of the angle between the anatomical and mechanical axes of the femur from radiographs; (2) localization of the center of the femoral head by external markers after operative radiographs are taken and correct estimation of the center of the distal femur for the external alignment system of femoral alignment; and (3) visual estimation of the centers of the proximal tibia and of the ankle joint in both the coronal and sagittal planes for correct tibial component alignment. *Id.* at 1:65–2:10.

Woolson further discloses surgical guides, as shown in Figures 7A and 7B, which are reproduced below:



Figures 7A and 7B present a lateral view and a perspective view of a cutting guide for making final femoral cuts. *Id.* at 3:39–40.

4. Analysis

In its Petition, Petitioner sets forth its contentions as to how the limitations of claims 1–3, 5–8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47 are disclosed in, or obvious over, the combination of Radermacher, Alexander, and Woolson. Pet. 21–67. Patent Owner disagrees. Prelim. Resp. 8–13. We note that, although the burden of proof remains on Petitioner (*see* 35 U.S.C. § 316(e)), Patent Owner does not dispute whether the asserted prior art discloses any of the individual limitations. Rather, Patent Owner disputes whether Petitioner has shown adequately that a person of ordinary skill in the art would have been motivated to combine the references. We address these contentions below. We emphasize that the following determinations regarding the sufficiency of the Petition are preliminary in nature at this stage of the proceeding.

i. Independent claim 1

preamble and “a block having a patient-specific surface and first and second drilling holes the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged articular surface of the joint”

Petitioner asserts that Radermacher discloses a patient-specific tool for use in surgically repairing a joint. Pet. 21 (citing, e.g., Ex. 1003, 25, 30, Figs. 10, 13, 18; Ex. 1002 ¶¶ 83–85). Petitioner further asserts that Radermacher describes using MRI and/or CT scans to create a three-dimensional reconstruction of a patient’s joint, which is used to create an individual template having a patient-specific surface. Pet. 22–27 (citing, e.g., Ex. 1003, 10–12, 15, 22, Fig. 18; Ex. 1002 ¶¶ 88–91). We are

persuaded that Petitioner has made an adequate showing that Radermacher discloses a patient-specific surface. In particular, Radermacher discloses creating an individual template based on CT or MRI imaging that is a negative mold of an osseous structure. Ex. 1003, 10–12.

Petitioner asserts that Alexander discloses imaging of articular cartilage, and that it would have been obvious to apply Radermacher’s technique to fit onto the cartilage surface, if any cartilage is present, in view of Alexander’s teachings. Pet. 28–31 (citing, e.g., Ex. 1004, 2:5–6, 14:16–15:14, 22:22–24, 61:19–25, Figs. 18C–I; Ex. 1002 ¶¶ 100–103). Petitioner argues that a person of ordinary skill would have combined the teachings of Radermacher and Alexander for the following reasons: (1) both Radermacher and Alexander relate to treating diseased or damaged cartilage in a knee joint; (2) both references disclose using MRI to image joints; (3) as a design choice; (4) to simplify surgery, as consistent with Radermacher’s goals; (5) as the combination of known elements to achieve a predictable result; and (6) as the choice from a finite number of options. Pet. 30–31. We are persuaded that Petitioner has made an adequate showing that Alexander discloses imaging cartilage. In particular, Alexander discloses creating a three dimensional map of the cartilage based on MRI imaging. Ex. 1004, Abstract; *see also id.* at 14:30, 15:16–26.

Patent Owner argues that Petitioner fails to explain how or why one of ordinary skill would make such a modification to obtain “a device tailored to the patient’s cartilage surface.” Prelim. Resp. 10. Nevertheless, we are persuaded at this stage of the proceeding that a person of ordinary skill would have modified Radermacher’s individual template to match any cartilage if present based on Radermacher’s teaching of forming a negative

mold of the natural, pre-treated structure, and Alexander's disclosure of imaging cartilage, at least to simplify the surgery, as discussed by Petitioner. Ex. 1003, 10, 12; Ex. 1004, Abstract.

Petitioner asserts that Radermacher discloses a single peg in Figure 13d (Ex. 1003, 30) and Woolson discloses two drilling holes in Figure 7B (Ex. 1031, Fig. 7B, 6:58–63). Pet. 32–33. Petitioner asserts that it would have been obvious for a person of ordinary skill to modify Radermacher to include two drilling holes, as taught by Woolson, for several reasons: (1) Woolson and Radermacher are in the same field of arthroplasty; (2) Radermacher discloses that multiple “drill sleeves” can be used (citing Ex. 1003, 13); (3) the number of drilling holes depends on the type of implant used; and (4) two drilling holes was commonplace. Pet. 34–35 (citing Ex. 1002 ¶¶ 109, 115). We are persuaded that Petitioner has made an adequate showing that Woolson discloses two drilling holes. In particular, Figure 7B of Woolson depicts two drilling holes. Ex. 1031, Figs. 7B.

Patent Owner argues that Petitioner does not explain adequately how and why a person of ordinary skill would have combined Radermacher and Woolson. Prelim. Resp. 12–13. On the record at this stage of the proceeding, we are persuaded that Petitioner has made a sufficient showing that a person of ordinary skill would have modified the femoral template of Radermacher with multiple drilling holes, as taught by Woolson, *inter alia*, based on the express teaching in Radermacher that multiple tool guides can be connected to the template of Radermacher. Ex. 1003, 13.

“having a predetermined position and orientation relative to the corresponding portion”

Petitioner asserts that Radermacher discloses that a patient-specific surface has a predetermined position relative to the joint because Radermacher discloses that the patient-specific surface is designed during pre-operative planning to fit onto the joint surface in “exactly one spatially defined position.” Pet. 31–32 (quoting Ex. 1003, Abstr.; citing *id.* at 9–11, 13, 30; Ex. 1002 ¶ 104). We are persuaded that Petitioner has made an adequate showing that Radermacher discloses a block with a predetermined orientation. In particular, Radermacher discloses an individual template, designed pre-operatively based on imaging, with a spatially-defined position. Ex. 1003, Abstr., 10–12.

“the first and second drilling holes having predetermined positions and orientations relative to the patient-specific surface and each having an axis that extends through a portion of the joint when the patient-specific surface is fit to the corresponding portion of the diseased or damaged articular surface of the joint”

Petitioner asserts that Radermacher discloses that cutting, milling, and boring steps are “three-dimensionally charted” in a coordinate system fixed relative to the osseous structure. Pet. 35, 52 (quoting Ex. 1003, 11; citing *id.* at 13, 15, 20, 22–23, 25, 30, Figs. 6, 9, 10a–d, 13a–b). Petitioner also asserts that Woolson discloses first and second drilling holes with axes relative to the surface of the block that extend through a portion of the joint. Pet. 52 (citing Ex. 1031, Figs. 7A–B).

We are persuaded that Petitioner has made an adequate showing that Radermacher discloses that drilling holes have a predetermined orientation. In particular, we are persuaded, on this record, that Radermacher discloses that cutting, milling, and boring steps are “three-dimensionally charted” in a

coordinate system fixed relative to the osseous structure. Ex. 1003, 11. As such, Petitioner has made a sufficient showing that Radermacher, as modified with the drilling holes of Woolson, would have first and second drilling holes with the required orientation.

Summary

For the preceding reasons, we determine that Petitioner has established a reasonable likelihood of prevailing on its contentions with respect to independent claim 1.

ii. claim 7

Claim 7 depends from claim 1, and further recites “wherein the surface of the joint is a femoral surface of a knee of the patient and the drilling holes are configured to define a path through a femoral surface when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged articular surface of the joint.” Ex. 1001, 119:38–43. Petitioner asserts that Radermacher discloses a drill hole that defines a path through the femoral surface (Ex. 1003, 30, Figs. 13a–d) and Woolson discloses two drilling holes (Ex. 1031, Figs. 7A–B). Pet. 39. We determine that Petitioner has made a sufficient showing that Radermacher and Woolson render obvious the further recitation of claim 7, for similar reasons as for claim 1, from which it depends. As discussed immediately above with respect to independent claim 1, Radermacher discloses that the cutting, boring, and milling steps are three-dimensionally charted in a coordinate system relative to the osseous structure. Ex. 1003, 25. As such, Petitioner has made a sufficient showing that the drilling holes of Radermacher, as modified by Woolson, would define a path through the femoral surface, as recited by claim 7.

iii. claims 2, 3, 5, 6, 8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47

Petitioner sets forth its contentions as to how Radermacher, Alexander, and Woolson render obvious the additional recitations of dependent claims 2, 3, 5, 6, 8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47. Pet. 37–46, 53–67. Based on our review of Petitioner’s contentions, and our own review of the evidence at this stage of the proceeding, we determine that Petitioner has made an adequate showing as to the additional recitations of dependent claims 2, 3, 5, 6, 8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47. For similar reasons as for independent claim 1, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on its contentions that Radermacher, Alexander, and Woolson render obvious dependent claims 2, 3, 5, 6, 8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47.

C. Obviousness of Claims 13, 18, and 38 over Radermacher, Alexander, Woolson, and Kenna (Ex. 1032)

Petitioner contends that claims 13, 18, and 38 are unpatentable as obvious over Radermacher, Alexander, Woolson, and Kenna. Pet. 68–79. Patent Owner disagrees. Prelim. Resp. 13–14.

1. Overview of Kenna

Kenna is titled “Prosthetic Knee Implantation” and relates to prostheses designed to reproduce anatomic movement of the knee without compromising stability, to the bone cutting techniques required for accommodating a prosthetic knee system, and to the guides and cutting jigs that assure accurate bone cuts. *See* Ex. 1032, (54), 1:20–54. Kenna refers to a prosthesis that provides a “screw home” mechanism to increase stability in extension. *Id.* at 1:22–24. Kenna explains that, as flexion proceeds, the femoral condyles roll posteriorly, and through asymmetric condylar and

tibial compartments, “the natural and changing axes of rotation are preserved.” *Id.* at 1:24–26. Kenna states that this asymmetry prevents the development of abnormal tension in retained ligaments, minimizes sheer stress, and enhances the potential for long term function of the replaced knee. *Id.* at 1:24–40.

2. Analysis

Claim 13 depends from independent claim 1, and further recites “wherein the surface of the joint is a tibial surface of a tibia of the patient the drilling holes define a path through a tibial plateau of the tibia.” Ex. 1001, 120:1–4. Petitioner asserts that Kenna discloses a tibial block having two drilling holes. Pet. 70 (citing, e.g., Ex. 1032, 8:16–20, 10:15–27, Figs. 30B, 89, 90). Petitioner asserts that although Radermacher describes a patient-specific template for the femur, it would have been obvious to use Radermacher’s template for resecting the tibia for the following reasons: (1) Radermacher discloses that its technique may be used on any osseous structure (citing Ex. 1003, 9–13, 30); (2) Radermacher states that standard tool guides, which it seeks to improve, were used for both the femur and tibia (citing *id.* at 2); (3) knee arthroplasty typically involved resection of both the femur and a corresponding portion of the tibia; and (4) other references disclose a patient specific template for the tibia (citing Ex. 1033, 31–32, Figs. 2A–B; Ex. 1008, 3:40–49, Fig. 2; Ex. 1007, 6:48–64, Fig. 6). Pet. 68–69. Petitioner alternatively argues that it would have been obvious to modify Kenna’s tibial block to incorporate a patient-specific surface as taught by Radermacher, because Radermacher and Kenna are in the same field; Radermacher contemplates multiple drilling holes; a person of ordinary skill would understand that the number of drilling holes depends on

the implant; and the use of two drilling holes was commonplace. Pet. 70–73.

Patent Owner argues that Petitioner improperly relies on the same motivation for Ground 2 as for Ground 1. Prelim. Resp. 13. Patent Owner further asserts that Kenna would not have been improved by the use of a patient-specific surface as taught by Radermacher because Kenna teaches that its jigs already “lock onto their respective bones to insure the accuracy of the cuts.” *Id.* (quoting Ex. 1032, 2:67–68).

At the outset, we note that Petitioner argues in the alternative that the teachings of Kenna would have been modified by a person of ordinary skill in view of Radermacher, or that the teachings of Radermacher would have been modified in view of Kenna. We determine that Petitioner has not set forth adequate explanation for the combination of Radermacher and Kenna for several reasons.

First, Petitioner’s asserted rationale for the modification of Kenna in view of Radermacher appears to be that the references are in the same field of endeavor, and Petitioner offers only a conclusory statement that Radermacher’s teachings would improve Kenna without further explanation. *See* Pet. 70–73; *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) (explaining that Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements”); *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016) (reviewing case law and explaining that findings must be supported by a reasoned basis). In particular, Petitioner does not explain how the patient-specific surface disclosed by Radermacher would have improved Kenna, or more generally, why a person of ordinary skill would have sought to combine the references

as applied to the tibia beyond relating to the same field of invention.

Although Radermacher, in its background section, does review prior art tools for both femur and tibia surgeries, Radermacher itself describes femur surgery only. *Compare* Ex. 1003, 2, *with id.* at 30. We also agree with Patent Owner that Kenna already provides an alignment mechanism (Ex. 1032, 7:20–8:22), and Petitioner has not explained why a person of ordinary skill would have modified it with the teachings of Radermacher. Nor does the Declaration of Dr. Mabrey provide further analysis. *See* Ex. 1002 ¶¶ 156–160.⁴

Second, we further determine that it would have been incompatible with the system of Kenna to use a patient-specific surface as taught by Radermacher inasmuch as Kenna’s system is based on rotating a jig against a cut-surface of bone. Petitioner relies on Figure 30B of Kenna, which discloses drilling holes into the tibia using jig VII. Ex. 1032, Fig. 30B.

⁴ We also note that Petitioner does not rely on Kenna with respect to independent claim 1, from which this claim depends.

Figure 30B of Kenna is reproduced below:

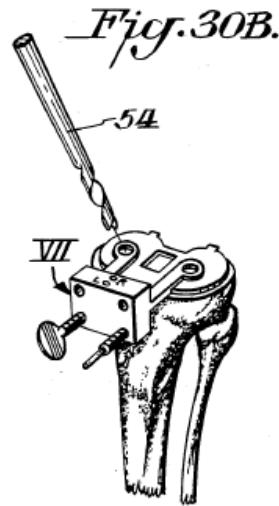


Figure 30B depicts drill guides in jig VII. *See id.* at 8:16–22; 2:1–3. Kenna indicates that if posterior tabs 44 of jig VII are fastened behind the posterior rims of the tibial plateau then tabs 44 “will position the jig in correct rotation” because the posterior margins of the tibial plateau are “nearly parallel” to the transverse axis of the tibia. Ex. 1032, 7:46–50. Kenna further relies on a procedure to correct alignment of the tibia by verifying through inspection that axial alignment guide 19 is centered over the ankle joint, with the medial malleolus 30 degrees anterior to the lateral malleolus, and manipulating the jig into proper alignment. *Id.* at 7:50–61. Therefore, even though Kenna provides a target orientation for placement of the cutting guide, it relies on operative adjustment of the cutting guide to ensure proper alignment. It would be inconsistent with this procedure to use a patient-specific surface which cannot be adjusted, as taught by Radermacher. *See* Ex. 1003, 15.

Third, as to Petitioner’s alternate theory for combining Radermacher and Kenna, Petitioner does not explain how a person of ordinary skill would

have incorporated the teachings of Kenna into the device of Radermacher. In particular, 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. *Compare* Ex. 1032, 7:50–61, *with* Ex. 1003, 10–12.

We determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that Radermacher, Alexander, Woolson, and Kenna render obvious claim 13, and claim 18 which depends therefrom. For similar reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combination of Radermacher, Alexander, Woolson, and Kenna renders obvious the tibial block of claim 38.

D. Obviousness of Claims 1–3, 5–8, 11, 13, 18, 20, 21, 24, 25, 28, 29, 34–38, and 47 over Radermacher, Fell (Ex. 1005), Woolson, and Kenna

Petitioner contends that claims 1–3, 5–8, 11, 13, 18, 20, 21, 24, 25, 28, 29, 34–38, and 47 are unpatentable as obvious over Radermacher, Fell, Woolson, and Kenna. Pet. 79–82. Patent Owner disagrees. Prelim. Resp. 14–15.

1. Overview of Fell

Fell is titled “Surgically Implantable Knee Prosthesis” and relates to prosthetic devices and, more particularly, to self-centering knee joint prostheses which may be surgically implanted between the femoral condyle and tibial plateau of the knee. Ex. 1005, (54), 1:4–5. Fell discloses a hard, self-centering meniscal device suitable for implantation into the knee compartment defined by the space between the femoral condyle and the

respective tibial plateau. *Id.* at 4:6–9. Fell discloses that the natural meniscus may be maintained in position or may be wholly or partially removed. *Id.* at 5:13–15. Fell further discloses that the meniscal device allows for the provision of non-contacting or recessed areas to encourage articular cartilage regeneration. *Id.* at 8:28–30. Fell describes that the shapes of the affected femoral condyle and tibial plateau are ascertained using X-ray or MRI imaging to determine the correct geometry of the meniscal device for a given patient. *Id.* at 14:5–28. Figure 7 of Fell is depicted below:

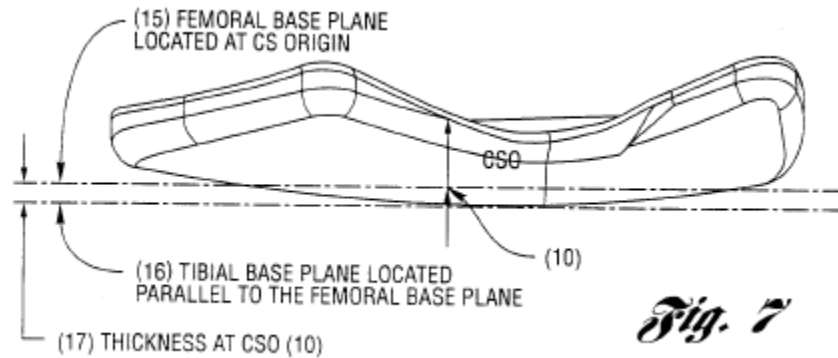


Figure 7 of Fell illustrates a device contour and its relationship with the femoral and tibial base planes. *Id.* at 5:1–2.

2. Analysis

i. claims 1–3, 5–8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47

Petitioner's contentions with respect to claims 1–3, 5–8, 11, 20, 21, 24, 25, 28, 29, 34–37, and 47 are similar to the ground based on Radermacher, Alexander, and Woolson, but Petitioner relies on Fell instead of Alexander for the teaching of imaging cartilage. *See* Pet. 79. We note that Petitioner has not explained why it is relying on Kenna for these claims as part of this ground. In view of the above, we exercise our discretion and do not institute an *inter partes* review of claims 1–3, 5–8, 11, 20, 21, 24, 25,

28, 29, 34–37, and 47 based on this ground. *See* 35 U.S.C. § 314(a);
37 C.F.R. § 42.108(a).

ii. claims 13, 18, and 38

Petitioner does not argue, and we do not find, that Fell remedies the deficiency in the ground based on Radermacher, Alexander, Woolson, and Kenna. We determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combination of Radermacher, Alexander, Woolson, and Kenna render obvious claims 13, 18, and 38 for similar reasons as for the ground based on Radermacher, Alexander, Woolson, and Kenna. *See supra*, Section II.C.2.

*E. Obviousness of Claims 9, 10, 12, 30–33, and 39–43 over
Radermacher, Alexander, and Woolson*

Petitioner contends that claims 9, 10, 12, 30–33, and 39–43 are unpatentable as obvious over Radermacher, Alexander, and Woolson. -779 Pet. 23–62. Patent Owner disagrees. -779 Prelim. Resp. 14–15.

1. claims 9, 10, and 12

Claim 9 depends from claim 7, and further recites “wherein the path is configured to extend through an anterior portion of a femoral condyle when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged articular surface of the joint.” Ex. 1001, 119:49–53. Petitioner asserts that Radermacher discloses that pins or nails can be used to affix the template to the bone, and Woolson discloses holes through an anterior portion of a femoral condyle. -779 Pet. 39–41, 54 (citing Ex. 1003, 25; Ex. 1031, Figs. 6A, 6B).

Although we determine that Petitioner has provided a sufficient rationale for the asserted combination of Radermacher, Alexander, and

Woolson with respect to independent claim 1 and dependent claim 7, we determine that Petitioner has not provided a sufficient rationale for further modifying the device of Radermacher with the additional features of Woolson, i.e., anterior drill holes, as recited in dependent claim 9.

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." -779 Pet. 41, 42. We determine that these are conclusory statements of obviousness and do not provide sufficient articulated reasoning with rational underpinnings for the asserted combination. Further, Petitioner does not explain how the device of Radermacher would have been modified with anterior drill holes, as depicted in Woolson.

Accordingly, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention with respect to claim 9. For similar reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention with respect to claims 10 and 12.

2. claims 30–33 and 39–43

Claim 30 depends from claim 1, and recites that the surgical tool further comprises "at least one stabilizer oriented to engage the joint surface." Ex. 1001, 120:48–50. Petitioner asserts that Radermacher discloses the use of nails and screws with a template and Woolson discloses that a block can be fixed in position with pins. -779 Pet. 43, 57–58 (citing, e.g., Ex. 1003, 23, 25–26, 35; Ex. 1031, 6:58–63). We determine that Petitioner has made a sufficient showing on this record with respect to claim 30. In particular, Radermacher discloses that screw connections 19 can be

provided for intraoperative fixation of individual template 4 onto osseous structure 17. Ex. 1003, 23.

As to the rationale for the asserted combination, Petitioner asserts that Radermacher discloses that nails and screws can be provided for intraoperative fixation, and that “nails” and “pins” were used interchangeably by those of skill in the art. -779 Pet. 43 (citing Ex. 1003, 25–26, 35, Figs. 6a–b; Ex. 1002 ¶ 140). We determine that Petitioner has asserted adequate reasoning for the asserted modification of Radermacher, i.e., that Radermacher already discloses the use of nails for fixation. Ex. 1003, 25.

Petitioner sets forth its additional contentions for claims 31–33 and 39–43. -779 Pet. 58–60. Based on our independent review of the evidence at this stage of the proceeding, we determine that Petitioner has made an adequate showing for claims 31–33 and 39–43.⁵

⁵ For purposes of this Decision, we treat claim 43 as depending from claim 42, as argued by Petitioner, such that the term “metal insert” in claim 43 is understood to have antecedent basis in claim 42. *See* -779 Pet. 62 n.5; *see also* -779 Prelim. Resp. 45 (similarly interpreting the dependency).

F. Obviousness of Claims 14–17 and 19 over Radermacher, Alexander, Woolson, Kenna, and Hofmann (Ex. 1090)

Petitioner contends that claims 14–17 and 19 are unpatentable as obvious over Radermacher, Alexander, Woolson, Kenna, and Hofmann. -779 Pet. 66–87. Patent Owner disagrees. -779 Prelim. Resp. 9–20, 22–25, 33–35.

1. Overview of Hofmann

Hofmann is an article, titled “Effect of the Tibial Cut on Subsidence Following Total Knee Arthroplasty,” and reviews the follow-up for 33 knee arthroplasties conducted on 31 patients between 1982 and 1984. *See* Ex. 1090, 64. Tibial tray subsidence was assessed as follows: subsidence was defined roentgenographically as at least 2 mm sinking of the prosthesis into cancellous bone associated with any secondary sclerosis of the cancellous bone when combined with lift-off of the prosthesis on the opposite side. *Id.* The authors found that subsidence of the tibial component occurred in ten of 33 knees. *Id.* Patients with subsidence had a mean preoperative tibial slope of “ $9^{\circ} \pm 2^{\circ}$ (range, 4° to 12°).” *Id.* The authors also conducted a laboratory study of force to failure. *Id.* at 65–67. The authors concluded that cutting the tibial parallel to the articular surface of the tibia during total knee arthroplasties provides increased load carrying capacity and stiffness to the bone supporting the tibial prosthesis. *Id.* at 68.

2. Analysis

As above, claim 13 depends from claim 1 and recites “wherein the surface of the joint is a tibial surface of a tibia of the patient [and] the drilling holes define a path through a tibial plateau of the tibia.” *See supra*, Section II.C.2. Claim 14 depends from claim 13, and further recites

“wherein the path has a predetermined cutting slope relative to the tibial plateau.”

Above, for the ground of obviousness of claim 13 based on Radermacher, Alexander, Woolson, and Kenna, Petitioner primarily relies on drilling holes from Figure 30B of Kenna that travel from the joint surface inward into the tibia. However, for this ground of obviousness of claim 14 based on Radermacher, Alexander, Woolson, Kenna, and Hoffman, Petitioner primarily relies on a different set of drilling holes, i.e., drilling holes from Figures 21–23 of Kenna that travel inward from the side of the tibia. -779 Pet. 66, 70. Kenna discloses a process for the placement of the cutting (and drilling) guide and subsequent cutting of the tibial plateau as follows.

First, jig IV (with items 36 and 38) is placed on a cut surface of the femur and jig V is slid onto jig IV. Ex. 1032, 5:56–6:15, 9:37–52. Second, jig V is then placed on the corresponding portion of the tibia and the alignment is checked/corrected using alignment guides 16 and 18, as depicted in Figures 17 and 18, reproduced below.

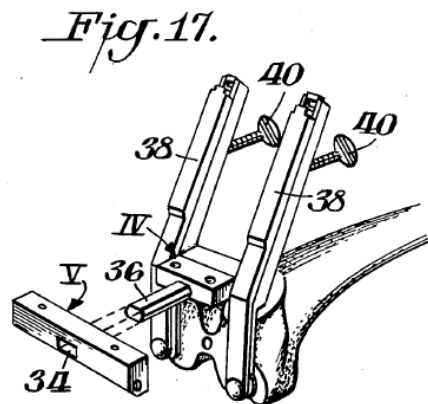


Figure 17 depicts jib V slipped over tongue 36 of the femoral spacer jig. *Id.* at 6:6–7.

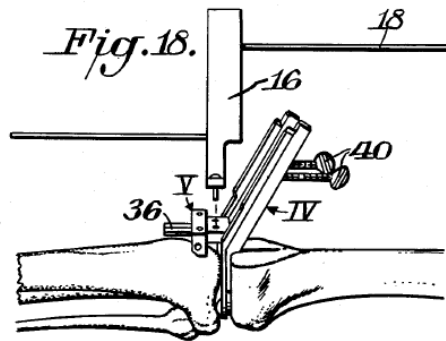


Figure 18 depicts the placement of alignment guide 16 with both tibial and femoral alignment pins. *Id.* at 6:14–16; *see also id.* at 6:55–59.

Third, holes are drilled into the tibia to affix jig V to the tibia, as depicted Figure 21, reproduced below:

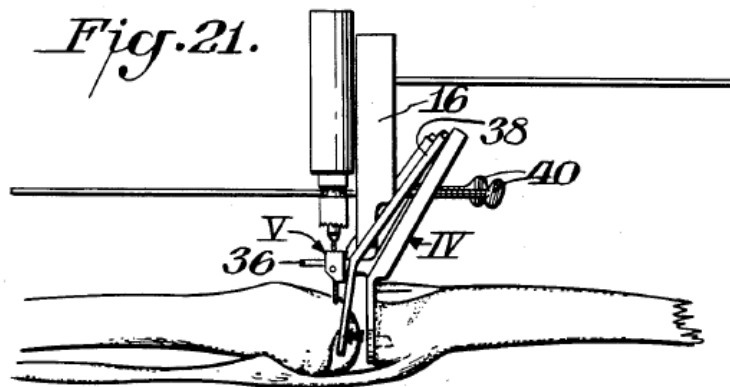


Figure 21 depicts the locking of cutting jig V in place with pins in appropriate holes. *Id.* at 6:67–7:2.

Fourth, jig IV is slid out of place, as depicted in Figure 22, reproduced below:

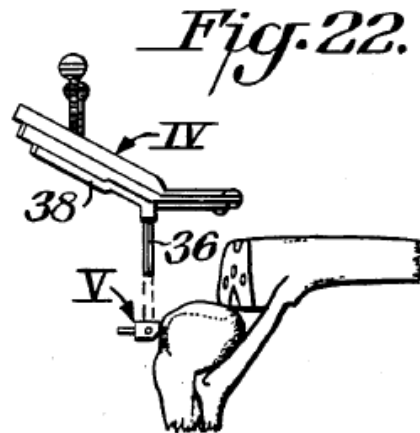


Figure 22 depicts the disengagement of jig V from jig IV. *Id.* at 7:2–6. Fifth, the surgeon cuts/saws off the surface of the tibial plateau, as depicted below in Figure 23, reproduced below:

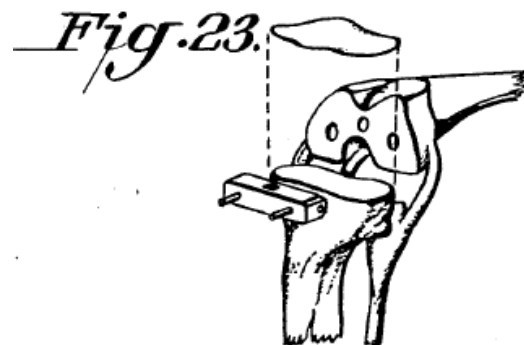


Figure 23 depicts a cut in the transverse tibial plateau. *Id.* at 7:8–11. Petitioner does not appear to rely on Hofmann for claim 14. -799 Pet. 63–66, 70–71.

Petitioner asserts that a person of ordinary skill would have been motivated to modify Radermacher to incorporate two drilling holes as discussed in Kenna, *or* alternatively to modify Kenna to include a patient-specific surface. -799 Pet. 65. In other words, Petitioner argues the nature of the combination in the alternative. Petitioner provides the following reasons: (1) Kenna and Radermacher are in the same field of arthroplasty;

(2) Radermacher contemplates the use of multiple drilling holes (citing Ex. 1003, 13); (3) two drilling holes in a guide was commonplace; and (4) it was nothing more than a combination of known methods to achieve predictable results. -779 Pet. 65–66. Petitioner provides further motivation for the combination of Kenna with Hofmann, i.e., to provide parallel pin holes so as not to interfere with a cut and to match the normal slope of the tibia. -799 Pet. 67–68.

Patent Owner argues that Petitioner fails to assert adequate motivation to combine the references because Kenna already achieves accuracy of the cuts and that there would be no need to include a patient-specific surface to improve positioning. -799 Prelim. Resp. 14. We agree with Patent Owner that Petitioner has not provided an adequate rationale for combining the teachings of Radermacher and Kenna, for similar reasons as for the asserted ground of unpatentability based on Radermacher, Alexander, Woolson, and Kenna. *See supra*, Section II.C.2. In particular, Petitioner does not offer more than a conclusory rationale for the combination of Radermacher and Kenna; it 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; and Petitioner does not explain how the teachings of Kenna would have been incorporated into the patient-specific surface of Radermacher.

Petitioner does not argue, and we do not find, that Hofmann remedies the deficiency in the combination of Radermacher and Kenna. At most, Hofmann is relied on for its disclosure of the appropriate slope for a tibial cut, with respect to dependent claims 15–17. *See -779 Pet. 66–67*. Nor does

the Declaration of Dr. Mabrey provide further analysis. *See* Ex. 1002 ¶¶ 156–160.

We therefore determine that Petitioner has not established a reasonable likelihood that the combination of Radermacher, Alexander, Woolson, and Hofmann would have rendered obvious claim 14. We also determine that Petitioner has not established a reasonable likelihood that the combination of Radermacher, Alexander, Woolson, and Hofmann render obvious claims 15–17 and 19, which are argued by Petitioner on a similar basis as claim 14.

G. Obviousness of Claims 9, 10, 12, 14–17, 19, 30–33, and 39–43 over Radermacher, Fell, Woolson, Kenna, and Hofmann

Petitioner contends that claims 9, 10, 12, 14–17, 19, 30–33, and 39–43 are unpatentable as obvious over Radermacher, Fell, Woolson, Kenna, and Hofmann. -779 Pet. 74–77. Patent Owner disagrees. -779 Prelim. Resp. 16–21.

1. Claims 30–33 and 39–43

Petitioner argues the asserted ground of obviousness of claims 30–33 and 39–43 over Radermacher, Fell, Woolson, Kenna, and Hofmann on a similar basis as the ground of obviousness over Radermacher, Alexander, and Woolson, but relying on Fell instead of Alexander for the teaching of imaging cartilage. -779 Pet. 74. We note that Petitioner does not explain why Kenna and Hofmann are included in this ground of unpatentability with respect to claims 30–33 and 39–43. In light of the above, we exercise our

discretion and do not institute an *inter partes* review of claims 30–33 and 39–43 based on this ground. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(a).

2. Claims 9, 10, 12, 14–17, and 19

Petitioner argues the asserted ground of obviousness of claims 9, 10, 12, 14–17, and 19 over Radermacher, Fell, Woolson, Kenna, and Hofmann on a similar basis as the asserted grounds of obviousness, discussed above, of claims 9, 10, and 12, over Radermacher, Alexander, and Woolson, and of claims 14–17 and 19 over Radermacher, Alexander, Woolson, Kenna, and Hofmann. Petitioner relies on Fell instead of Alexander for imaging of cartilage in this ground. *See* -779 Pet. 74. Petitioner does not argue, and we do not find, that Fell remedies the deficiencies in these asserted grounds. *See supra*, Sections II.E.1., II.E.3, II.F. Nor has Petitioner, in connection with this asserted ground of obviousness, remedied the deficiency in its stated reasoning for combining the references. We, therefore, determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that Radermacher, Fell, Woolson, Kenna, and Hofmann would have rendered obvious claims 9, 10, 12, 14–17, and 19.

*H. Obviousness of Claims 95–125 over Radermacher,
Alexander, and Woolson*

Petitioner contends that claims 95–125 are unpatentable as obvious over Radermacher, Alexander, and Woolson. -780 Pet. 23–88. Patent Owner disagrees. -780 Prelim. Resp. 8–12.

1. Claim 95

preamble and “a block having a patient-specific surface and first and second guides”

Petitioner asserts that Radermacher discloses a patient-specific surgical tool for use in surgically repairing a joint. -780 Pet. 24–29, 54 (citing, e.g., Ex. 1003, 10, 12, 21–22, 25–26, 30, Figs. 10a–e, 13a–d). On the current record, we determine that Petitioner has made a sufficient showing that Radermacher discloses an articular repair system with a patient-specific surgical tool. In particular, Radermacher indicates that a prosthesis will be implanted after the knee-joint is prepared by cutting (and drilling) the femur with the assistance of the template of Figures 13a–13c. *See* Ex. 1003, 19, 30.

As to the first and second guides, Petitioner asserts, *inter alia*, that Radermacher discloses a template (block) having five different “guides” (citing Ex. 1003, Fig. 13a), including a drill guide along axis 8 and four cutting guides that define, and result in, cuts 20a–d. -780 Pet. 33–34, 55–56 (citing, e.g., Ex. 1003, 13, 25–26, 30, Figs. 6b, 9, 13a, 13b). On the current record, we determine that Petitioner has made a sufficient showing that Radermacher discloses multiple guides. In particular, Radermacher discloses drill guide 8 and cutting guides 13a–d in Figure 13a. *See* Ex. 1003, 30.

“the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged cartilage surface of the joint”

Petitioner asserts that Radermacher discloses generating a three-dimensional negative mold of “the individual natural (i.e. not pretreated) surface of the osseous structure intraoperatively accessed by the surgeon.”

-780 Pet. 24–33, 56 (citing, e.g., Ex. 1003, 10, 12, 21–22, Figs. 18–19). On the current record, we determine that Petitioner has made a sufficient showing that Radermacher discloses a patient-specific surface. In particular, Radermacher discloses using CT and MRI to generate an individual template—that is a negative mold of an osseous structure. Ex. 1003, 10–12.

Petitioner also relies, in combination with Radermacher, on the knowledge of a person of ordinary skill in the art, in asserting that it would have been obvious to match the template of Radermacher with the contact faces of the cartilage surface, i.e., to the extent that the articular surface is covered with cartilage. *See* -780 Pet. 28–29 (citing Ex. 1102 ¶¶ 86–88). According to Petitioner, the person of ordinary skill in the art would have understood that when Radermacher discloses that the template is generated via a three-dimensional negative mold of parts of the individual natural, not pre-treated surface and ‘set onto the bone’ (Ex. 1003, 30), this means that the template is set onto the un-treated bone, i.e., on top of any remaining cartilage (and any exposed subchondral bone). -780 Pet. 27 (citing Ex. 1102 ¶ 84).

With respect to the knowledge of a person of ordinary skill, Petitioner asserts that a person of ordinary skill would have been motivated to match the contact faces to cartilage rather than underlying subchondral bone because (1) the cartilage surface and the subchondral bone surface are the only two surfaces to which Radermacher’s custom template could be matched; (2) the choice between the two is merely a design choice and reflects a choice from a finite number of identified, predictable solutions with a reasonable expectation of success; (3) matching the cartilage surface would simplify the surgery, if it does not have to be removed in order for the

template to precisely fit; (4) Radermacher teaches that the contact faces match the “natural (i.e. not pre-treated) surface”; and (5) a person of ordinary skill would understand that matching the cartilage would result in a template that has “one spatially uniquely defined position,” reduces surgical time, and increases accuracy, as Radermacher teaches. -780 Pet. 28–29 (citing Ex. 1102 ¶¶ 86–88; Ex. 1003, Abstract, 9; citing also *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 402–403 (2007)). On this basis, Petitioner reasons that it would have been obvious to a person of ordinary skill in the art to match the “contact faces” of Radermacher’s template to the size, shape, and/or curvature of the patient’s articular cartilage as derived from the MRI data. -780 Pet. 29 (citing Ex. 1102 ¶¶ 86–88).

With respect to Alexander, Petitioner asserts that it would have been obvious to combine Alexander’s teaching of imaging and mapping articular cartilage therewith such that the contact faces of Radermacher’s template are substantially a negative of the patient’s cartilage surface. -780 Pet. 31–32, 57–59 (citing, e.g., Ex. 1004, 2–3). Petitioner argues that it would have been obvious to a person of ordinary skill in the art to combine Alexander’s disclosure that imaging techniques could be used to determine the dimensions of joint cartilage, with Radermacher’s imaging techniques, in order to achieve the goal of simplifying surgery and because it would have been consistent with Radermacher’s goals for creating a custom template. *See id.* at 32. Petitioner also asserts, *inter alia*, that this would have been a combination of known elements to achieve a predictable result with a reasonable expectation of success. *Id.*

On the current record, we determine that Petitioner has made a sufficient showing that the combination of Radermacher and Alexander,

taken in light of the knowledge of a person of ordinary skill, render obvious the limitation of a patient-specific surface that is based on a negative image of the articular surface. In particular, Radermacher discloses a template that is a negative mold of parts of the individual natural (i.e., not pre-treated) surface based on radiographic imaging. Ex. 1003, 10–12. Further, Alexander discloses radiographic imaging to determine the size and shape of the articular cartilage. Ex. 1004, 2:25–27. We further determine that Petitioner has made a sufficient showing that it would have been obvious to a person of ordinary skill to incorporate Alexander’s imaging of cartilage in the manufacture of Radermacher’s surgical tool, *inter alia*, because Radermacher discloses a negative mold of the articular joint. Ex. 1003, 12.

“the first and second guides [i] having predetermined positions and orientations relative to the patient-specific surface and [ii] being oriented to provide two predetermined drilling or cutting paths that are aligned relative to a biomechanical or anatomical axis of the joint and through a portion of the joint of the patient when the patient-specific surface is placed against the corresponding diseased or damaged cartilage surface of the joint.”

Petitioner asserts that Radermacher discloses that the position and orientation of the guides (e.g., 8, 20a, and 20c) are fixed during the preoperative planning. -780 Pet. 33–34, 58 (citing, e.g., Ex. 1003, 11, 13, 25, Fig. 13a, 13b). Petitioner asserts that the multiple predetermined cutting or drilling guides on the individual template inherently provide cutting or drilling paths that are aligned relative to the biomechanical or anatomical axis of the joint and through a portion of the joint. *Id.* at 35.

We determine that Petitioner has made a sufficient showing that Radermacher discloses first and second guides with predetermined orientations relative to the surface. In particular, Radermacher discloses that “the cutting, boring, milling and other treatment steps . . . are three-

dimensionally charted in said coordinate system fixed relative to the osseous structure” “in the preoperative surgical planning phase.” Ex. 1003, 11.

Petitioner asserts that the multiple predetermined cutting or drilling guides on the individual template of Radermacher inherently provide cutting or drilling paths that are aligned relative to the biomechanical or anatomical axis of the joint and through a portion of the joint. -780 Pet. 35, 59 (citing Ex. 1003, Figs. 13b, 13c; Ex. 1102 ¶¶103–109). Further, Petitioner relies in combination on the teaching in Woolson that it is “necessary” that the cutting paths be perpendicular to the mechanical axis. -780 Pet. 38–41, 62 (citing Ex. 1031, 4:7–19). Petitioner further contends that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Woolson regarding cutting perpendicular to a mechanical axis with Radermacher’s surgical tool because of Woolson’s teaching that it would have been “necessary” to do so. *See id.* at 38–41.

On the current record, we determine that Petitioner has made a sufficient showing that Woolson discloses cutting perpendicular to the biomechanical axis. Ex. 1031, 4:9–19. We further determine that Petitioner has made a sufficient showing that it would have been obvious to a person of ordinary skill to combine the teachings of Woolson with those of Radermacher (and Alexander) because Woolson discloses that it would have been “necessary” to cut perpendicular to the biomechanical axis to achieve better results. *Id.*; -780 Pet. 41.

We note that Patent Owner does not, in the Preliminary Response, dispute Petitioner’s individual factual contentions. Rather, the Preliminary Response primarily argues that the grounds asserted in the Petition are horizontally and vertically redundant, i.e., within and across grounds. *See*

- 780 Prelim. Resp. 19–24. Further, Patent Owner argues that the Petition provides insufficient evidence for instituting based on Radermacher alone, Radermacher in combination with the knowledge of a person of ordinary skill in the art, or Radermacher and Alexander. *See id.* at 10–16. Based on our determination not to institute based on Radermacher alone or Radermacher in combination with the knowledge of a person of ordinary skill as discussed in Section I.E., many of Patent Owner’s arguments are moot at this time.

Patent Owner also argues that Petitioner has impermissibly broken independent claim 1 into individual elements for purpose of analysis.

-780 Prelim. Resp. 22–24. Although we are mindful that obviousness for any given claim is determined in light of the claim as a whole, we do not find, at this stage of the proceeding, that Petitioner has focused impermissibly on individual elements of independent claim 1 to the exclusion of analyzing the claim as a whole.

Finally, Patent Owner argues that Petitioner impermissibly relies on the knowledge of a person of ordinary skill in the art and on the ’302 patent itself. -780 Prelim. Resp. 17–18. However, our analysis herein is based on Radermacher, Alexander, and Woolson for the limitations of claim 95.

For the foregoing reasons, we determine that Petitioner has demonstrated a reasonable likelihood that the combination of Radermacher, Alexander, and Woolson renders obvious the tool of claim 95.

2. Claim 96–125

Based on our review of Petitioner’s contentions, and on our independent review of the record at this stage of the proceeding, we determine that Petitioner has demonstrated a reasonable likelihood of

prevailing on its contentions with respect to claims 96–125, for similar reasons as for independent claims 1 and 95.⁶

I. Obviousness of Claims 95–125 over Radermacher, Fell, and Woolson

Petitioner contends that claims 95–125 are unpatentable as obvious over Radermacher, Fell, and Woolson. -780 Pet. 88–91. Patent Owner disagrees. -780 Prelim. Resp. 13–18.

Having instituted an *inter partes* review on the asserted ground of obviousness of claims 95–125 over Radermacher, Alexander, and Woolson, we exercise our discretion not to institute an *inter partes* review with respect to the asserted ground of claims 95–125 over Radermacher, Fell, and Woolson. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108.

III. CONCLUSION

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–3, 5–8, 11, 20, 21, 24, 25, 28–37, 39–43, 47, and 95–125 of the '302 patent are unpatentable. We conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claims 9, 10, 12–19, and 38 of the '302 patent are unpatentable.

⁶ Patent Owner does not dispute any of Petitioner's contentions as to the individual limitations at this stage of the proceeding. Nevertheless, we note that prior art figures may not be relied on for precise numerical measurements when not drawn to scale. *See generally Hockerson-Halberstadt, Inc. v. Avia Group Intern., Inc.*, 222 F.3d 951 (Fed. Cir. 2000); *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977) (“Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.”).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on the following ground:

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;

FURTHER ORDERED that no other proposed grounds of unpatentability are authorized;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this Decision; and

FURTHER ORDERED that the parties are requested to brief—Patent Owner in its Response and Petitioner in its Reply—the following issues: (1) whether the term “adjustment mechanism,” as recited in claim 24, i.e., “adjustment mechanism to balance ligaments associated with the knee,” falls within the ambit of former-35 U.S.C. § 112 ¶ 6 and (2) if so, what if any, is the corresponding structure for the term in the specification.

IPR2017-00778, IPR2017-00779, IPR2017-00780
U.S. Patent 8,062,302 B2

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