Trials@uspto.gov
571-272-7822

Paper No. 33
Entered: April 19, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2017-00115
Patent 9,216,025 B2

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

Opinion for the Board filed by *Administrative Patent Judge* WIEKER

Opinion Concurring-in-part and Dissenting-in-part filed by *Administrative Patent Judge* WORTH

WIEKER, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Smith & Nephew, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–20 ("the challenged claims") of U.S. Patent No. 9,216,025 (Ex. 1001, "the '025 patent"). Paper 1 ("Pet."). ConforMIS, Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). We instituted an *inter partes* review of challenged claims 1–20, across four asserted grounds of unpatentability, pursuant to 35 U.S.C. § 314. Paper 8 ("Dec. on Inst.").

After institution, Patent Owner filed a Response (Paper 12, "PO Resp.") to the Petition, and Petitioner filed a Reply (Paper 16, "Pet. Reply"). Additionally, Patent Owner filed Observations on Cross Examination (Paper 21, "PO Obs.") and a Motion to Exclude (Paper 22, "PO Mot. Exclude"). Petitioner filed a Response to Observations on Cross Examination (Paper 25, "Pet. Resp. Obs.") and a Response to the Motion to Exclude (Paper 26, "Pet. Resp. Mot. Exclude"). Patent Owner filed a Reply in support of the Motion to Exclude. Paper 29 ("PO Reply Mot. Exclude").

An oral hearing was held on January 8, 2018, and a transcript of the hearing is included in the record. Paper 32 ("Tr.").

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has shown by a preponderance of the evidence that challenged claims 1–20 of the '025 patent are unpatentable.

B. Related Proceedings

The parties identify the following matters related to the '025 patent (Pet. 1; Paper 5, 2; Paper 27, 1):

> *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass.); and
>
> *Smith & Nephew, Inc. v. ConforMIS, Inc.*, IPR2016-01874 (PTAB) (involving U.S. Patent No. 9,055,953) (challenged claims found unpatentable) (Paper 31, 52).

C. The '025 Patent

The '025 patent is titled "Joint Arthroplasty Devices and Surgical Tools" and issued on December 22, 2015 from U.S. Application No. 13/405,797, filed on February 27, 2012. Ex. 1001, (21), (22), (54).

The '025 patent discloses compositions and tools for repairing articular surfaces, for example, through arthroplasty. *Id.* at (54), (57). The '025 patent describes a need in the art for "methods and compositions that facilitate the integration between [a] cartilage replacement system and the surrounding cartilage" and for "tools that increase the accuracy of cuts made to the bone in a joint in preparation for surgical implantation of, for example, an artificial joint." *Id.* at 5:9–15; *see also id.* at 5:3–8 (explaining that poor alignment between the articular surface and an implanted device causes joint instability). Thus, according to the '025 patent, the disclosed implants or prostheses may be customized to achieve optimal fit, and the disclosed surgical tools may be customized to the patient to increase the speed, accuracy, and simplicity of a surgical procedure. *Id.* at (57), 1:29–34; *see also id.* at 7:53–8:29 (certain embodiments).

In one embodiment, the '025 patent discloses an articular prosthesis comprising an external surface located in a load bearing area of an articular surface, wherein the external surface achieves "a near anatomic fit" with adjacent,

underlying, or opposing cartilage. Ex. 1001, 6:52–57. The ’025 patent also discloses that the shape of an implant, such as a prosthesis, can be based on an analysis of an electronic image (e.g., MRI, CT, digital tomosynthesis, or optical coherence tomography). *Id.* at 39:45–55; *see also id.* at 8:50–9:30.

In another embodiment, a tool for preparing a joint surface can be created based on a mold, which is formed with data acquired by CT or spiral CT imaging, and which reflects the thickness of articular cartilage at the joint. *See id.* at 50:39–64, Fig. 23. Figure 24B of the ’025 patent is depicted below:

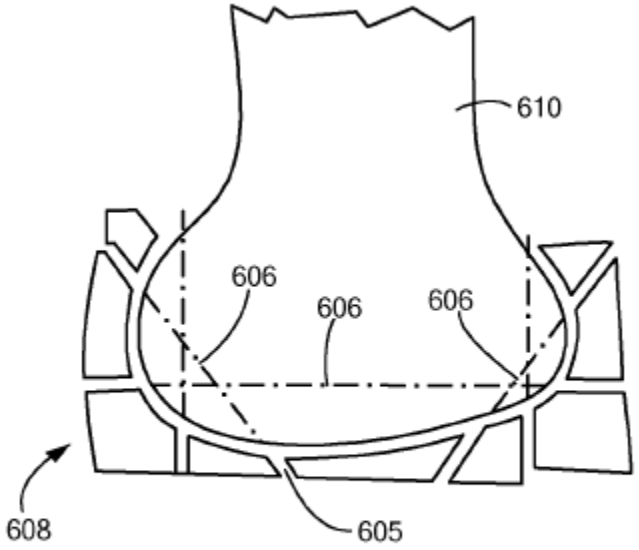


FIG. 24B

Figure 24B illustrates, in cross-section, surgical tool 608 containing apertures 605, through which a surgical drill or saw can fit, to guide the drill or saw in cutting bone 610. *See id.* at 11:57–59, 51:59–63. Cuts 606 in bone 610 are depicted with hashed lines in Figure 24B. *Id.* at 11:60–61, 51:59–63. After bone 610 is cut in accordance with the tool, the resulting bone shape corresponds to the interior surface of an implant, e.g., formed as discussed above. *Id.* at 51:63–65.

Additionally, the '025 patent discloses that biomechanical axis information, determined or estimated with a CT scan or X-ray imaging, is used when creating the disclosed surgical instruments and implants. *Id.* at 16:40–47, 16:60–62, 17:13–15. "The biomechanical axis can be defined as the axis going from the center of the femoral head, between the condylar surfaces and through the ankle joint." *Id.* at 15:38–40.

D. Illustrative Claim

Of the challenged claims, claims 1 and 15 are independent. Claim 1 is illustrative and is reproduced below, with added reference identifiers shown in brackets, in accordance with Petitioner's claim chart. *See* Pet. 54–61.

> 1. A surgical system including an articular repair system and a patient-specific surgical tool for use in surgically repairing a joint of a patient, wherein the patient-specific surgical tool comprises:
>
> [a] a block having a patient-specific surface and first and second guides;
>
> [b] 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 of the patient;
>
> [c.i] the first and second guides having predetermined positions and orientations relative to the patient-specific surface [c.ii] and 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 of the patient.

Ex. 1001, 61:16–34 (emphasis added). Independent claim 15 also recites a "surgical system" including, *inter alia*, "a block having a patient-specific surface," which has "at least a portion that is substantially a negative of a corresponding

portion of a diseased or damaged *articular surface* of the joint." *Id.* at 62:21–38 (emphasis added). Independent claim 15 also includes "first and second drilling holes," as opposed to the "guides" recited in claim 1. *Id.*

E. Applied References

Petitioner relies upon the following references:

> Woolson, U.S. Patent No. 4,841,975, filed April 15, 1987, issued June 27, 1989 (Ex. 1031, "Woolson");
>
> Biscup, U.S. Patent Application Publication No. 2004/0117015 A1, filed October 5, 2001, published June 17, 2004 (Ex. 1035, "Biscup");
>
> Radermacher, PCT Publication No. WO 93/25157, filed June 17, 1993, published December 23, 1993 (Ex. 1003, "Radermacher");
>
> Fell et al., PCT Publication No. WO 00/59411, filed April 2, 1999, published October 12, 2000 (Ex. 1005, "Fell"); and
>
> Alexander et al., PCT Publication No. WO 00/35346, filed December 16, 1999, published June 22, 2001 (Ex. 1004, "Alexander").

Pet. 22. Petitioner also relies upon the Declaration of Jay D. Mabrey, M.D. ("the Mabrey Declaration," Ex. 1002), and the Reply Declaration of Jay D. Mabrey, M.D. ("the Mabrey Reply Declaration," Ex. 1202). Patent Owner relies upon the Declaration of Charles R. Clark, M.D. ("the Clark Declaration," Ex. 2005).

F. Asserted Grounds of Unpatentability

We instituted an *inter partes* review based on the following grounds:

References	Basis	Claims Challenged
Radermacher, Alexander, and Woolson	§ 103	1, 5–15, 19, and 20
Radermacher, Alexander, Woolson, and Biscup	§ 103	2–4 and 16–18
Radermacher, Fell, and Woolson	§ 103	1, 5–15, 19, and 20
Radermacher, Fell, Woolson, and Biscup	§ 103	2–4 and 16–18[1]

During the oral hearing, counsel for Patent Owner stated (Tr. 18:3–14; *see also id.* at 18:19–19:25):

> Petitioner actually argued Radermacher alone with respect to all of those claims and that ground was not adopted, and the reason why these claims were not disclaimed[2] is because there needs to be a motivation to combine with a reasonable expectation of success of three references, Radermacher and Alexander and Woolson, or Radermacher, Fell and Woolson, and Petitioner has not established a reasonable motivation with an expectation of success of combining those references. That combination is required -- is required -- for those grounds with those claims and as you've heard today they're just relying on Radermacher alone. That is not a basis for unpatentability here.

We disagree with Patent Owner's position, as expressed during the oral hearing.

In our Decision on Institution, we noted that "Petitioner sets forth the [§ 103] ground of unpatentability based on Radermacher, Alexander, and Woolson

[1] Petitioner pled in the alternative and asserted claims 2 and 16 as part of the grounds based on Radermacher, Alexander/Fell, and Woolson, and also as part of the grounds based on those references in combination with Biscup. We consider claims 2 and 16 in the grounds that include Biscup. Dec. on Inst. 6–7 n. 5, 6, 8.
[2] In IPR2017-01874, Patent Owner disclaimed claims 1–3, 7–9, 11, 21–23, 27–29, 31, 42–44, 48, 50–53, 56, and 58–61 of U.S. Patent No. 9,055,953 B2, wherein those claims recited an "articular joint surface" or a "joint." *See Smith & Nephew, Inc. v. ConforMIS, Inc.*, Case IPR2016-01874, slip op. at 1 (Paper 31) (PTAB Mar. 26, 2018).

as one grouping of references but pleads this ground of unpatentability in the alternative based on the use of references in subgroupings or individually, e.g., based on Radermacher alone or Radermacher in combination with the knowledge of a person of ordinary skill in the art." Dec. on Inst. 5. For purposes of administrative efficiency, we declined to consider separately each alternative pleading, because "[t]aking 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." *Id.* Instead, we "consider[ed] all of the references in combination as one ground of unpatentability." *Id.* at 6. Our statement in this regard, however, did not serve to eliminate Petitioner's contentions based upon, e.g., Radermacher alone, as evidenced by our reliance on those portions of the Petition (*see, e.g.*, *id.* at 12 (citing, e.g., Pet. 24–25, 26–31)), as well as similar reliance by Patent Owner (*see*, *e.g.*, PO Resp. 40–41 (citing, e.g., Pet. 27–29), 46 (citing, e.g., Pet. 27–29)). Indeed, all of Petitioner's contentions made with respect to Radermacher carry over and form the basis of its contentions regarding the combination of Radermacher, Alexander, and Woolson. *Compare* Pet. 24–31, *with id.* at 31–34.

As such, Patent Owner was on notice, throughout the course of this proceeding, of Petitioner's obviousness contentions regarding Radermacher, both alone and in combination with Alexander and Woolson. Additionally, Patent Owner had the opportunity to submit evidence and to be heard as to Radermacher's teachings, and Patent Owner employed those opportunities. *See, e.g.*, PO Resp. 19–30 (summarizing Radermacher), 34–53 (presenting argument regarding Radermacher alone); *see generally* Tr.; *see also Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1325 (Fed. Cir. 2017) (stating that there was no "surprise" when the Board relied on a reference as part of its motivation to combine analysis,

because that reference was discussed in the petition and throughout the proceeding, including through the parties' experts, in the "same context" as discussed by the Board). Thus, although the grounds upon which we instituted trial (Dec. on Inst. 30) did not specify a separate ground based upon Radermacher alone, we deem our conclusions of unpatentability in this regard, *see infra* Section II.D.6.ii, to be consistent with the guidance presented in the Decision on Institution, consistent with principles of due process, and consistent with PTAB practice in other contexts. *See, e.g.*, *In re Bush*, 296 F.2d 491, 496 (CCPA 1961) (confirming that the Board may affirm an Examiner's finding of unpatentability based upon fewer than all references relied upon by the Examiner); *In re Boyer*, 363 F.2d 455, 458 n.2 (CCPA 1966).

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, generally we give claim terms their ordinary and customary meaning, as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

1. "articular surface"

In the Decision on Institution, we construed "articular surface," appearing in claims 15–20, as "the surface of an articulating bone that includes cartilage and/or exposed subchondral bone." Dec. on Inst. 8. Our reviewing court informs us that "a proper claim construction analysis endeavors to assign a meaning to a disputed

claim term 'that corresponds with . . . how the inventor describes his invention in the specification.'" *In re Power Integrations, Inc.*, __ F.3d __, slip op. at 13 (Fed. Cir. Mar. 19, 2018) (quoting *In re Smith Int'l, Inc.*, 871 F.3d 1375, 1383 (Fed. Cir. 2017)). We determined that this construction was supported by the intrinsic evidence. For example, the '025 patent explains that "[t]he articular surface can comprise cartilage *and/or* subchondral bone." Ex. 1001, 6:22–24 (emphasis added). As such, the '025 patent specification recognizes that subchondral bone may underlie cartilage but that subchondral bone also may be exposed, i.e., in a diseased joint where some or all cartilage has worn away. *See, e.g., id.* at 1:51–54. This construction is consistent with the extrinsic evidence, in the form of the testimony of Dr. Mabrey. *See* Ex. 1002 ¶¶ 36, 68 ("To a person of ordinary skill in the art reading the '025 patent, the term 'articular surface of the joint' would be understood to mean 'the bone surface and/or cartilage surface of an articulating portion of a joint.'"), 69–71.

Following institution, Patent Owner stated that it "does not contest" this construction of "articular surface." PO Resp. 12. Likewise, Petitioner did not provide any further discussion or evidence directed to the proper construction of this phrase. *See generally* Pet. Reply. Accordingly, we maintain that the proper construction of the phrase "articular surface" is "the surface of an articulating bone that includes cartilage and/or exposed subchondral bone."

2. "cutting slot"

In the Decision on Institution, we construed "cutting slot," appearing in claims 7 and 8, consistent with its ordinary meaning as "'an elongated cutting guide internal to a surgical tool,' as opposed to the surface of a surgical tool." Dec. on Inst. 8–9. We determined that this construction was consistent with the intrinsic evidence. For example, the '025 patent specification separately discusses

slots, apertures, and holes used to guide cuts into bone, suggesting that a "slot" differs from an aperture or hole. *See* Ex. 1001, 45:31–34, Fig. 25B (slots 2328), Fig. 25D (slots [2]328, aperture 2330), 52:56–67 (discussing Fig. 25B and Fig. 25D). Our construction is consistent also with the extrinsic evidence in the form of the testimony of Dr. Mabrey. Ex. 1002 ¶ 42 ("Some surgeons prefer cutting guides with slots, which provide greater guidance of the saw blade, while others prefer open cutting surfaces because they make it easier for the surgeon to adjust the cut.").

Following institution, Patent Owner stated that it "does not contest" this construction of "cutting slot." PO Resp. 12. Likewise, Petitioner did not provide any further discussion or evidence directed to the proper construction of this phrase. *See generally* Pet. Reply. Accordingly, we maintain that the proper construction of the phrase "cutting slot" is "'an elongated cutting guide internal to a surgical tool,' as opposed to the surface of a surgical tool."

3. Other Terms

We determine that no additional claim term requires express construction for purposes of this Final Written Decision. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope

and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of elements produces a predictable result is also given weight in the ultimate determination of obviousness. *Id.* at 416–417.

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must support its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

Petitioner identifies the skill level of a person of ordinary skill in the art as either "an orthopedic surgeon having at least three years of experience in knee arthroplasty surgery" or "an engineer having a bachelor's degree in biomedical engineering (or closely related discipline) who works with surgeons in designing cutting guides and who has at least three years of experience learning from these doctors about the use of such devices in joint replacement surgeries." Pet. 21. Petitioner relies upon the Mabrey Declaration to support this assessment. *Id.* (citing Ex. 1002 ¶¶ 29–31).

Patent Owner "generally accepts this definition, but also suggests that [such a person] would include a resident in orthopedic surgery." PO Resp. 11–12. In support of this position, Dr. Clark testifies that a resident in orthopedic surgery who "had achieved 150 cases" would be considered a person of ordinary skill in the art. Ex. 2005 ¶ 51.

Based upon our review of the '025 patent, the types of problems and solutions described therein and in the applied prior art, and the testimony of Dr. Mabrey and Dr. Clark, we determine that the parties' agreed-upon assessment of the skill level of a person of ordinary skill in the art is consistent with this evidence. Moreover, we note that our conclusions herein would not differ even if an orthopedic surgery resident, as identified by Dr. Clark, is included within the assessment. Therefore, for purposes of this Final Written Decision, we adopt the agreed-upon assessment of the skill level of a person of ordinary skill in the art, as articulated by Petitioner. Pet. 31; *see also* Ex. 2005 ¶ 51 ("[M]y analysis and opinions are the same regardless of whether the level of ordinary skill in the art is inclusive of a resident in orthopedic surgery.").

D. Obviousness over the Combined Teachings of Radermacher, Alexander, and Woolson

Petitioner contends that claims 1, 5–15, 19, and 20 of the '025 patent are unpatentable as obvious over the combined teachings of Radermacher, Alexander, and Woolson. Pet. 24–79; *see also* Dec. on Inst. 6 n.5 (including claim 2 with the asserted ground of obviousness over Radermacher, Alexander, Woolson, and Biscup). Patent Owner disputes Petitioner's contentions. PO Resp. 33–79. For reasons that follow, we determine Petitioner has met its burden and demonstrated by a preponderance of the evidence that these claims are unpatentable.

1. Overview of Radermacher (Ex. 1003)

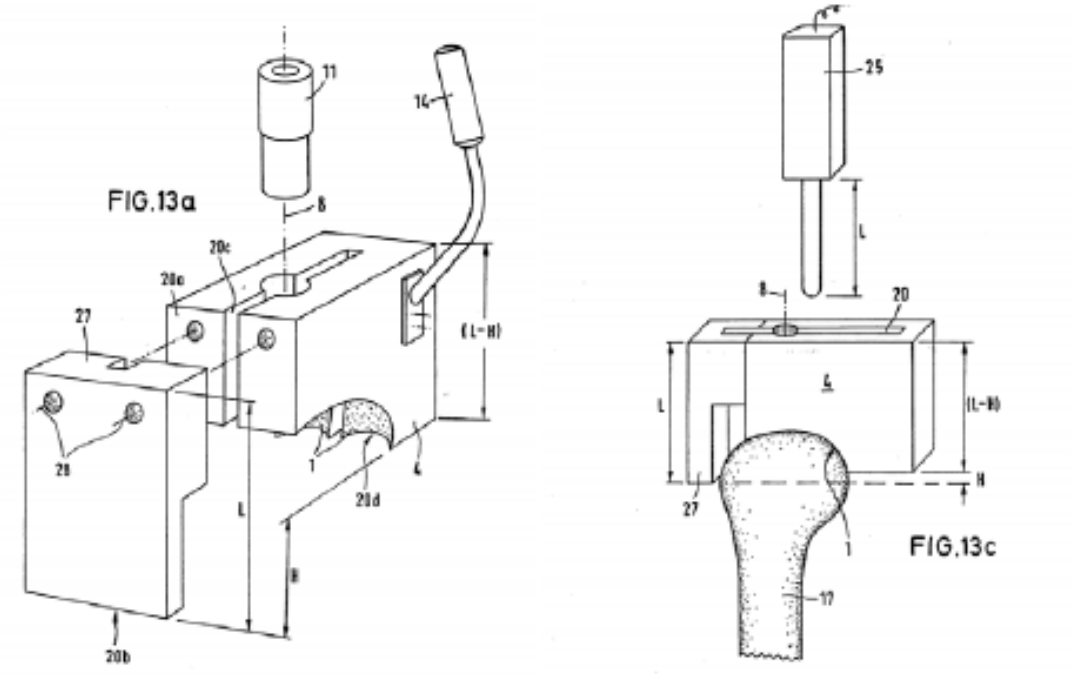
Radermacher is titled "Template for Treatment Tools and Method for the Treatment of Osseous Structures," and relates to certain improvements in the planning and performance of orthopedic surgery. *See* Ex. 1003, 1, 9. Radermacher describes a method in which an "individual template" is created, "by which parts of the surface of an arbitrary osseous structure . . . are copied as a negative image . . . so that the individual template can be set onto the osseous structure in a clearly defined position and with mating engagement." *Id.* at 10 (also describing use of CT or MRI imaging to create the individual template). Specifically, Radermacher describes generating "a three-dimensional negative mold of parts of the individual natural (i.e.[,] not pre-treated) surface of the osseous structure," that "reproduce[s] a cohesive region or a plurality of geometrically non-abutting partial segments of a bone surface." *Id.* at 12. Radermacher also explains that "any suitable tool guides . . . can be provided" in the mold for the template. *Id.* at 13.

Thereafter, the individual template is produced by a computer-based manufacturing device. *Id.* at 14. During surgical treatment, "the individual template with the face of the negative mold is set under mating engagement onto the then exposed bone surface, which is done without further intraoperative devices ([e.g., measuring arms]) and without intraoperative measuring and positioning work." *Id.* at 15.

Radermacher discloses various individual template embodiments adapted for use with different osseous structures. *Id.* at 17–20. For example, Figures 1–5 and Figures 11a–11e are directed to an individual template adapted to a vertebra; Figures 6–10e are directed to an individual template adapted to a hip joint;

Figure 12 is directed to an individual template adapted to a thoracic limb; and Figures 13a–13d are directed to an individual template adapted to a knee joint. *Id.*

Figures 13a and 13c are reproduced below:



Figures 13a and 13c depict "individual template 4 for the preparation of the seat for [a] knee-joint head prosthesis." Ex. 1003, 30. Radermacher explains that "individual template 4 is set onto the bone 17 in a defined manner, abutting the contact faces 1." *Id.* Thereafter, "drill sleeve 11 is inserted, and the bore . . . is formed in the bone" (along axis 8) and additional cuts are made (at 20a–20d). *Id.* A prosthesis is then placed upon prepared bone 17. *Id.* at Figs. 13b, 13d.

2. Overview of Alexander (Ex. 1004)

Alexander is titled "Assessing the Condition of a Joint and Preventing Damage" and relates to "the use of [joint] assessment in aiding in prevention of damage to the joint or treatment of diseased cartilage in the joint." Ex. 1004, 1:15–17. More specifically, Alexander discloses a joint assessment method in which an image of cartilage is obtained, preferably by magnetic resonance imaging, and

converted into a three-dimensional degeneration pattern, from which the degree of degeneration in the cartilage can be evaluated. *Id.* at 2:25–27. Alexander further discloses that a loss in cartilage may be determined through use of, for example, a "3D . . . thickness map." *Id.* at 3:8–9; *see also id.* at 14:16–21.

3. Overview of Woolson (Ex. 1031)

Woolson is titled "Preoperative Planning of Bone Cuts and Joint Replacement Using Radiant Energy Scan Imaging." Ex. 1031, [54]. Woolson discloses using "radiant energy scan imaging to determine the position of a bone-cut-defining guide relative to the bone to be cut," preferably for knee replacement surgery. *Id.* at 1:9–15. Woolson explains that long-term surgical success requires aligning a reconstructed knee joint with the bone's mechanical axis. *Id.* at 1:26–36. Conventionally, radiographs were taken to define this axis. *Id.* at 1:37–62. In Woolson's preferred embodiments, CT scans are taken to define the mechanical axis so that cuts can be made perpendicular to that axis. *Id.* at 4:13–44, 5:9–16, 7:62–67, Figs. 1, 2A, 2B.

4. Independent Claim 1

Petitioner contends that the combined teachings of Radermacher, Alexander, and Woolson would have rendered claim 1 obvious to a person of ordinary skill in the art. Pet. 24–43, 54–61 (chart). Patent Owner disputes Petitioner's contentions. PO Resp. 34–79. Primarily, Patent Owner argues that Radermacher fails to teach an instrument with an inner surface having a portion that is substantially a negative of a *cartilage* surface, *id.* at 34–53, and that it would not have been obvious to combine the teachings of Radermacher and Alexander to satisfy this limitation. *Id.* at 53–66; *see also id.* at 75–78 (regarding Woolson and Biscup).

After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated by a preponderance of evidence that claim 1 is unpatentable, for the reasons discussed below.

i. Preamble

Independent claim 1 recites "[a] surgical system including an articular repair system and a patient-specific surgical tool for use in surgically repairing a joint of a patient." Ex. 1001, 61:16–19.

We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Radermacher teaches the subject matter recited in the preamble.[3] Pet. 24–25, 54 (citing Ex. 1003, 10, 18–19, 25–26, 30, Figs. 10a–e, 13a–d). Specifically, Radermacher discloses a "knee-joint head prosthesis" (i.e., an articular repair system) and an "individual template" (i.e., a patient-specific surgical tool), which are used for surgically repairing a patient's knee joint. Ex. 1003, (57), 19, 30, Figs. 13a–d. According to Radermacher, individual template 4 is set upon bone 17 of a knee joint, and the joint is prepared, by boring and cutting bone 17, to receive the knee-joint head prosthesis. *Id.* at 30, Figs. 13a, 13c. Once so prepared, the prosthesis is applied to bone 17. *Id.* at 30, Figs. 13b, 13d.

ii. Element [a]

Independent claim 1 recites "a block having a patient-specific surface and first and second guides." Ex. 1001, 61:20–21.

[3] We previously instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived." Paper 10, 6; *see also* 37 C.F.R. § 42.23(a) ("Any material fact not specifically denied may be considered admitted.").

We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Radermacher satisfies this limitation. Pet. 54–56 (citing Ex. 1003, 10, 12–13, 21–22, 25–26, Figs. 6b, 9, 13a, 13c, 18); *see also id.* at 26–31. Specifically, Radermacher discloses that "parts of the surface of an arbitrary osseous structure . . . are copied as a negative image" for use in forming the individual template (i.e., a block having a patient specific surface). Ex. 1003, 10. Radermacher's "rigid individual template . . . copies the surface of the osseous structure in such a manner that the individual template can be intraoperatively set onto these – then freely exposed – contact faces or points in exclusively one clearly defined position." *Id.* For example, as shown in Figures 13a and 13c, individual template 4 "is set onto the bone 17 in a defined manner, abutting the contact faces 1" of the bone. *Id.* at 30.

Additionally, Radermacher discloses that the individual template may include "any suitable tool guides" (i.e., first and second guides). *Id.* at 13. For example, as shown in Figure 13a, individual template 4 includes at least first and second guides. Radermacher explains that once individual template 4 is set on bone 17,

> [t]he drill sleeve 11 is inserted, and the bore with the bore axis 8 is formed in the bone. . . . Then, the cut is formed along the cutting plane 20a. Then, the cut 20b can be performed free-handed at a right angle to cut 20a. . . . Thereafter, the groove (cut 20c) is milled or sawed (according to the geometry of the prosthesis), and then, cut 20d is formed along the lower edge of the individual template 4.

Id. at 30; *see also id.* at Fig. 13b (showing bore hole along axis 8 and cuts 20a–d).

iii. Element [b]

Independent claim 1 recites "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 of the patient." Ex. 1001, 61:22–25.

Petitioner's Positions

Petitioner takes two positions regarding this limitation. Pet. 26–34, 54–59.

Petitioner's first position relies upon Radermacher in combination with the knowledge of a person of ordinary skill in the art. Petitioner contends that Radermacher's individual template is formed from a mold that includes a negative copy of the surface of the patient's joint. *Id.* at 54; *see supra* Section II.D.4.ii. Because the mold reflects the "natural (i.e. not pre-treated) surface of the osseous structure," Petitioner reasons that "the natural, not pre-treated structure [of a knee joint] would include the cartilage." Pet. 56 (quoting Ex. 1003, 12); *see also id.* at 57. In other words, Petitioner contends that "[a]s long as diseased or damaged cartilage exists on the patient's joint, the contact faces of Radermacher's individual template would be substantially a negative of a portion of a diseased or damaged cartilage surface." *Id.* at 28. And because Radermacher does not disclose pre-treatment steps to *remove* cartilage, Petitioner contends that it at least would have been obvious to match the template to the existing cartilage on un-treated bone to, *inter alia*, simplify the surgery. *Id.* at 28–29, 30–31 (identifying other motivations), 57.

Petitioner's second position further relies upon Alexander. According to Petitioner, Alexander uses MRI imaging to assess the condition of cartilage in a knee joint. Pet. 31, 57; *see also id.* at 32–33, 58. Petitioner contends that Alexander's assessment "may be used to 'guide the choice of therapy,' which

includes 'joint replacement surgery.'" *Id.* at 57–58 (quoting Ex. 1004, 42:10–16). Thus, according to Petitioner, a person of ordinary skill in the art would have found it obvious "to combine the teachings of Radermacher and Alexander such that the contact faces of Radermacher's template are substantially a negative of the patient's cartilage surface." *Id.* at 33–34.

Petitioner sets forth several reasons for combining Radermacher and Alexander: (i) both references relate to methods of treating diseased or damaged cartilage in a knee joint; (ii) both references disclose using MRI to obtain joint images, address the same problem, are in the same field of endeavor, and use the same imaging technology; (iii) bone and cartilage are the only two surfaces to which the template could be matched, and the choice between them is simply a design choice; (iv) matching cartilage surface would simplify the surgery and be consistent with Radermacher's goals; and (v) the modification would merely

> (a) require the combination of one known element (Alexander's MRI data of the cartilage surface) with another known element (Radermacher's MRI data of the joint surface) to obtain a predictable result (a device tailored to the patient's cartilage surface); and (b) represent a choice from a finite number of identified, predictable solutions (imaging the bone surface and/or the cartilage surface), with a reasonable expectation of success.

Id. at 33–34 (citing Ex. 1002 ¶¶ 102–105; Ex. 1003, Abstract, 3–5, 9).

Patent Owner's Positions

There is no apparent dispute by Patent Owner that the interior surface of Radermacher's individual template "is substantially a negative of a corresponding portion . . . of the joint [of the patient]." PO Resp. 34. Rather, Patent Owner argues that the interior surface of the individual template "matches bone, not

cartilage, and one of ordinary skill in the art would not have modified it to match cartilage." PO Resp. 34.

With respect to Petitioner's first position, Patent Owner argues that Radermacher discloses individual templates that only contact bone or an "osseous structure." PO Resp. 34–40. According to Patent Owner, "regardless of whether cartilage is present in the joint" or "in the tomographic images produced in [Radermacher's] first step," Radermacher's template nonetheless matches *bone only*. *Id.* at 36–37; *see also id.* at 35–45, 52–53. For example, Patent Owner contends that Radermacher's template avoids "other structures in the surgical region," such as cartilage or bony processes on a vertebra, by contacting non-abutting bone regions, wherein recesses between the contact points avoid structures like cartilage. *Id.* at 38 (citing Ex. 1003, 12, 22, Figs. 3b, 4). Patent Owner also argues that a person of ordinary skill in the art would understand that the "'natural (i.e. not pre-treated) surface of the osseous structure' means the unaltered surface of the bone." PO Resp. 40–41. Patent Owner contends that this is apparent from the context of Radermacher's entire disclosure, which also concerns bones that lack natural cartilage, e.g., vertebrae. *Id.* at 41. As such, Patent Owner argues that this phrase refers to a lack of pre-treatment in the form "cutting, boring, milling," or "invasive measuring and scanning," but does not concern "any treatment of cartilage." *Id.* at 43, 44; *see id.* at 42–44 (citing Ex. 1003, 9).

With respect to Petitioner's second position, Patent Owner argues that it would not have been obvious to combine Radermacher and Alexander. PO Resp. 53–54. Patent Owner argues that the references are not sufficiently analogous because Alexander concerns preventative monitoring of cartilage degeneration through MRI imaging, not surgical methods or instruments. *Id.* at 54–57, 61. Patent Owner also argues that Alexander's images include artifacts, rendering them

unsuitable for use in generating a patient-specific surface with any reasonable expectation of success. *Id.* at 58–60. Moreover, Patent Owner contends that because cartilage and bone "are very different surfaces," it would not have been an obvious design choice to match cartilage. *Id.* at 61; *see also id.* at 62–63. Additionally, Patent Owner contends that the proposed modification would not simplify surgery by avoiding the need for cartilage removal because Radermacher already avoids structures like cartilage, without the need to remove it. *Id.* at 64. Patent Owner also contends that substituting Alexander's imaging data for Radermacher's does not provide a reason to match cartilage instead of bone. *Id.* at 65; *see also id.* at 56.

Analysis – Radermacher's Individual Template

Much of Patent Owner's argument is premised upon its contention that Radermacher discloses matching an individual template to *bone only*, and specifically does not match cartilage, even if present on the bone and even if imaged by Radermacher's disclosed MRI imaging. Thus, we start by reviewing Radermacher's disclosure.

In summarizing the invention, Radermacher broadly discloses "an individual template by which parts of *the surface of an arbitrary osseous structure* . . . are copied as a negative image . . . so that the individual template can be set onto *the osseous structure* in a clearly defined position and with mating engagement." Ex. 1003, 10 (emphases added). Throughout the disclosure, Radermacher consistently describes the generated negative mold as reproducing, and the resultant individual template as matching, the surface of the "bone" or "osseous structure," and does not explicitly mention cartilage. *See, e.g.*, *id.* at (57) ("the template can be mounted on the osseous structure"), 11 ("the individual template [is set] onto the exposed surface of the bone"), 12 ("a three-dimensional

negative mold of parts of the . . . surface of the osseous structure"; "[the] negative mold can reproduce . . . a bone surface"). Therefore, we agree with Patent Owner that Radermacher discloses that the individual template matches the surface of the "bone" or "osseous structure." PO Resp. 34–45.

However, we do not find that the template's patient-specific surface necessarily *excludes or avoids* matching any cartilage that is present on the bone. Radermacher discloses different embodiments in which the individual template is adapted to, and matches, different types of bones, wherein some naturally possess cartilage, like the knee, and others naturally lack cartilage, like vertebrae. Ex. 1003, 17–20; Ex. 2005 ¶¶ 11, 13–14 (knee),[4] 122 (vertebrae); PO Resp. 41. Therefore, we do not agree with Patent Owner's contention that Radermacher's use of the terms "bone" and "osseous structure" reflects an affirmative disclosure of matching *only* the actual bone or osseous material itself, or portions thereof, which lack cartilage. Rather, we find that use of this language reflects a broad disclosure of different *embodiments* of bones, some of which include natural cartilage on their outer surfaces and some of which do not.

This finding is supported by Radermacher's disclosure of generating "a three-dimensional negative mold of parts of the individual natural (i.e. not pre-treated) surface of the osseous structure intraoperatively accessed by the surgeon." Ex. 1003, 12. Petitioner contends that a skilled artisan would understand that this language refers to a bone surface that is not pre-treated to remove cartilage. Pet. 27–29; *see also* Ex. 1002 ¶¶ 80, 82, 88–92; Ex. 1202 ¶¶ 20–21, 24–27. Petitioner also relies upon Dr. Mabrey's testimony that the surface of the osseous structure "intraoperatively accessed by the surgeon" would be "the natural surface

[4] Dr. Clark testifies that over 90% of patients possess some articular cartilage in their knees. Ex. 1203, 51:25–52:8.

as it is accessed by the surgeon. In the case of the femur or tibia, that surface would include cartilage." Pet. Reply 2; Ex. 1202 ¶ 25. On the other hand, Patent Owner contends that a skilled artisan would understand that even if cartilage is present on the bone and imaged, this passage nonetheless refers to "the unaltered surface of the bone." PO Resp. 36–37, 40–41; Ex. 2005 ¶¶ 98–100. According to Patent Owner, the lack of "pre-treat[ment]" referenced by Radermacher does not refer to a surface that has not been treated to remove cartilage. PO Resp. 42–44; Ex. 2005 ¶¶ 99 ("'[N]ot pretreated' means the bone itself has not previously been cut, drilled, milled, or otherwise altered prior to the placement of the template, and it is not a statement pertaining to the presence or absence of cartilage on the joint."), 123–124.

We are not persuaded by Patent Owner's position, or Dr. Clark's testimony, regarding Radermacher's disclosure of matching the "natural (i.e. not pre-treated) surface." Radermacher explains that "'treatment' is understood to comprise *not only* the treatment of an osseous structure by suitable tools (cutting, boring, milling device) but also *other forms of treatment such as e.g.* invasive measuring and scanning of osseous structures by corresponding measuring devices." Ex. 1003, 9 (emphasis added). This definition is open-ended and includes "other forms of treatment" not recited therein. *Id.* ("such as e.g."). Therefore, the plain reading of Radermacher suggests that the template matches the natural surface of the bone, which has not been pre-treated by, e.g., cutting, boring, milling, or other forms of treatment. Moreover, Dr. Clark testified that "[t]he advantage of [Radermacher's] tool is that you don't have to pretreat it. Pretreatment could include cutting, drilling, milling. In fact, you could mill off cartilage. Those are pretreatment. [Radermacher] says you don't need to do this." Ex. 1203, 155:16–20. Therefore, we are not persuaded that one skilled in the art would have understood treatment of

cartilage, e.g., removal of cartilage, to be *excluded* by Radermacher's open ended definition of "treatment."

We find Dr. Mabrey's testimony on this point to be persuasive. Dr. Mabrey testifies that a person of ordinary skill in the art would understand Radermacher's disclosure of the "natural (i.e. not pre-treated) surface" to refer to the bone in the natural state in which a surgeon would find it. Ex. 1002 ¶ 80; Ex. 1202 ¶ 25. Dr. Mabrey notes that this natural state would vary with the patient—some patients' natural surfaces would include only cartilage, some would include both cartilage and bone, and others would include only exposed bone. Ex. 1002 ¶ 80. Indeed, Dr. Clark testifies that over 90% of patients possess some articular cartilage on the bones of the knee. Ex. 1203, 51:25–52:8. Therefore, we find Dr. Mabrey's testimony to be consistent with Radermacher's broad disclosure, which applies to various types of bones, some of which include, and some of which exclude, cartilage.

Additionally, we have considered the definition of "osseous," as provided in Dorland's Illustrated Medical Dictionary, as "of the nature or quality of bone" or "bony." Ex. 2008, 1196; *see also* PO Resp. 35–36. Although this definition may shed light on the plain and ordinary meaning of the term "osseous," in the abstract, it is less persuasive as to how a person of ordinary skill in the art would have understood the phrase "osseous structure" as used in Radermacher's description of various embodiments. Indeed, this definition is consistent with understanding "osseous structure" to broadly refer to various embodiments of bony structure, some with and some without natural cartilage. *See* Ex. 1202 ¶ 21.

We also have considered the competing testimony of the parties' experts, as to the meaning of the term "osseous structure." For example, Dr. Clark understands "osseous" to refer only to "bone," relying upon the definition provided

in Dorland's Illustrated Medical Dictionary. *See*, *e.g.*, Ex. 2005 ¶¶ 75 n.8, 118; *see also id.* ¶¶ 98 ("osseous structure, meaning the bone structure"), 102 ("One of ordinary skill would have understood that the term 'osseous structure' refers to the bone structure and not to any of the surrounding soft tissue (including cartilage) that may be present in conjunction with the bone structure being treated."), 118 ("'[O]sseous' means 'bone,' and an 'osseous structure' means a 'bone structure.'"). Dr. Clark opines that Radermacher's osseous structure would be understood to exclude cartilage because bone and cartilage are "very different structures," with different functions, complications, and diseases. *Id.* ¶ 120; PO Resp. 44–45. According to Dr. Clark, because of these differences, one of ordinary skill in the art would not have used "osseous structure" to refer to both cartilage and bone together. Ex. 2005 ¶ 120; *see also id.* ¶ 121 (noting other exhibits in which bone and cartilage are referenced separately).

On the other hand, Dr. Mabrey testifies that "[w]hile the term 'osseous,' in and of itself, refers to bone, Radermacher's disclosure is not as limited as Dr. Clark suggests." Ex. 1202 ¶ 20. According to Dr. Mabrey,

> A person of ordinary skill in the art would have understood that an "osseous structure" refers to more than just the bone; it would include tissues that are structurally attached to the bone and move with it, such as articular cartilage. In the case of the distal end of the femur or proximal end of the tibia, the "natural (i.e. not pre-treated) surface" of the "osseous structure" is the articular surface, including both articular cartilage and any exposed subchondral bone.

Id.; *see also id.* ¶ 21; Ex. 2014, 86:9–12 (Dr. Mabrey testifying that "[t]he term 'osseous' in and of itself refers to bone in general"), 88:10–89:9 (excluding the meniscus and ligaments from "osseous structure").[5]

[5] We note Dr. Clark's opinion that it is "inconsistent" for Dr. Mabrey to include cartilage in his understanding of "osseous structure," but to exclude other tissue,

We find Dr. Clark's testimony to be less helpful in discerning the meaning of "osseous structure" as used in Radermacher's disclosure. We recognize that the term "osseous" generally refers to bone. Ex. 2008, 1196. And we recognize that bone and cartilage are different structures, performing different functions. Ex. 2005 ¶¶ 120–121. However, Dr. Clark's testimony does not address sufficiently the fact that the various embodiments disclosed by Radermacher include some bones that naturally lack cartilage (e.g., vertebra) and some that naturally contain cartilage (e.g., knee). Dr. Clark's testimony does not demonstrate that, as used in Radermacher's disclosure, the term "osseous structure" intentionally omits the cartilage present on some bones, rather than providing a broad description of all types of bones within the full scope of Radermacher's disclosure. We find Dr. Mabrey's testimony in this regard to be more consistent with the full scope of Radermacher's disclosure.[6]

---

like the meniscus and ligaments. Ex. 2005 ¶ 119; PO Resp. 47–48. However, we do not find this criticism to detract from the credibility of Dr. Mabrey's testimony. For example, Dr. Clark's own explanation of the respective locations and functions of these structures is consistent with Dr. Mabrey's testimony that "[t]he meniscus and ligaments are not intimately attached to the bone and do not inextricably move with it, as articular cartilage typically does." Ex. 1202 ¶ 41; *see also* Ex. 2005 ¶¶ 11–14 (noting that articular cartilage "cover[s]" the surface of bones to reduce friction and distribute loads, while menisci "separate[]" the femur and tibia, and ligaments restrict movement of the knee).

[6] We are not persuaded that Dr. Mabrey's prior testimony in IPR2013-00629 is inconsistent. PO Resp. 45–51. The claims in that proceeding did not address cartilage. *See* Pet. Reply 9; Ex. 2003 ¶¶ 53, 97. The passage from the prior declaration identified by Patent Owner, *see* PO Resp. 46, is simply a quotation from Radermacher and, at most, an indication that Dr. Mabrey acknowledges that "osseous" refers to "bone," a fact that is not in dispute and not inconsistent with Dr. Mabrey's present testimony that the "natural (i.e. not pre-treated) surface of the osseous structure" in an articulating joint such as a knee includes cartilage.

Patent Owner also characterizes Radermacher's disclosure of placing the template against "'a plurality of geometrically non-abutting partial segments of a bone surface,'" as Radermacher teaching "one to avoid structures in the surgical region, such as cartilage." PO Resp. 52 (quoting Ex. 1003, 12), 37–38 (Patent Owner characterizing the negative template as having non-abutting partial segments to "account for and avoid structures in the surgical area, which can include . . . bony protrusions, . . . or . . . cartilage") (citing Ex. 1003, 12–13, 22). However, we find this interpretation of Radermacher's disclosure as teaching avoiding cartilage on bone to be inadequately supported.

In particular, Radermacher's Figure 4, referenced at 22, is reproduced below.

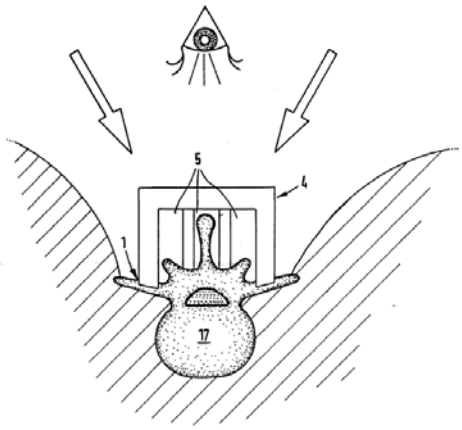


FIG. 4

Figure 4 depicts template 4 for vertebra 17, in which a series of recesses 5 are incorporated, such that the template avoids the patient's vertebral processes, i.e., such that the template contacts a plurality of non-abutting partial segments of a bone surface. Ex. 1003, 22. Contrary to Patent Owner's argument, Radermacher does not disclose that such a complex template structure might be utilized to avoid cartilage, here or elsewhere. *See* Ex. 1203, 158:7–9 (Dr. Clark testifying that "[t]he only thing I see in the figures [of Radermacher] specifically avoiding is bony

protuberances"), 159:1–3 (Dr. Clark testifying that Radermacher "doesn't say" that recesses are used to avoid cartilage). Rather, when depicting bones that contain cartilage, e.g., the femur or tibia in the knee, Radermacher discloses only templates having continuous surfaces, without recesses like those necessary to accommodate the unusual shape of a vertebrae. *See* Ex. 1003, Fig. 13c; Ex. 1203, 159:12–22 (Dr. Clark testifying "[n]one of the figures [13a–d, directed to the knee] show a recess . . . . They don't show it. You don't see the entire contact faces. But what you can see in the figures is -- are no -- no recesses"), 230:10–16 (Dr. Clark "postulating" that Radermacher might use a recess to avoid cartilage). Neither Patent Owner nor Dr. Clark demonstrates sufficiently that the features of Radermacher's vertebral embodiment, i.e., the recesses in the template, would be applied to Radermacher's knee embodiment, much less for the purpose of avoiding cartilage, in the absence of any such disclosure by Radermacher. *See* PO Resp. 37–38, 52; Ex. 2005 ¶¶ 103–105, 130.

Additionally, neither Patent Owner nor Dr. Clark explain how Radermacher's template would be set upon a femur or tibia that is fully covered by cartilage, if the template only contacts bone, as Patent Owner alleges. *See, e.g.*, Ex. 2005 ¶ 17 (Dr. Clark explaining the "five grades of cartilage degeneration," in which only the highest grade, Grade 4, includes "full thickness cartilage wear with exposed subchondral bone"). In other words, in patients experiencing any of the first four grades of cartilage degradation in which no exposed subchondral bone is present, we are unable to discern how the template would be set, given that those bones would not include *any* "non-abutting partial segments of a bone surface." *Id.* ¶¶ 18 (explaining that arthroplasty treatments are "usually reserved for patients with grade 4 cartilage degeneration," but not stating they are *only* performed on such patients), 28; *see also* Ex. 1002 ¶¶ 36, 39; Ex. 1203, 54:7–55:14 (Dr. Clark

explaining that he has performed arthroplasty on patients who did not exhibit grade 4 cartilage degeneration, that patients with grade 3 degeneration could be candidates for arthroplasty, and that patients with grade 2 degeneration are unlikely candidates).

Therefore, upon consideration of all of the evidence before us, we find that Radermacher discloses a template with a patient-specific surface having a portion that is substantially a negative of a corresponding portion of a surface of the osseous structure of the patient. We find that Radermacher does not disclose explicitly that the patient-specific surface of the template is a negative of a corresponding portion of a *cartilage surface*, as claimed. However, we find that where the joint is the knee, the natural and not pre-treated surface of the osseous structure may include some articular cartilage. Finally, we find that Radermacher does not disclose that the cartilage surface of a knee joint would be *excluded* in the template, when present on the underlying bone or osseous structure.

With this foundation, we turn to Petitioner's contention that it would have been obvious to match the template to cartilage.

Analysis – Obvious to Match Cartilage

"It [is Petitioner's] burden to demonstrate both 'that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016). Here, we are persuaded that a person of ordinary skill in the art would have been motivated to match Radermacher's template to cartilage, in light of Alexander's teachings and

the knowledge of a person of ordinary skill in the art, and that such a person would have had a reasonable expectation of success in doing so.

Petitioner contends that it would have been obvious to modify Radermacher's template such that its patient-specific surface is substantially a negative of a corresponding portion of diseased or damaged cartilage surface. Pet. 27–34. First, Petitioner contends, and we agree, that Radermacher discloses using MRI to image the patient's osseous structure prior to generating the individual template. Pet. 29; Ex. 1003, 10 (using "a computer or nuclear spin tomograph" to image the osseous structure); Ex. 1002 ¶ 53 (nuclear spin tomograph is MRI); Ex. 2005 ¶ 135 (same). As both parties' declarants acknowledge, images taken with MRI provide information regarding cartilage present on the bone. Ex. 1002 ¶ 43 (citing Ex. 1001, 13:62–14:6); Ex. 2005 ¶ 16. Indeed, Patent Owner does not appear to dispute that Radermacher images a patient's cartilage. PO Resp. 36 (stating, "[r]egardless of whether cartilage, in addition to bone, is present in the tomographic images produced in the first step"), 37 (stating, "even if cartilage is imaged"); *see also* Ex. 2005 ¶ 97.

Petitioner contends, and we agree, that Alexander also discloses using MRI to assess the condition of cartilage in a knee joint. Pet. 31–32; Ex. 1004, (57) ("Methods are disclosed for assessing the condition of cartilage in a joint, particularly a human knee."). Alexander utilizes MRI to reconstruct, in three dimensions, cartilage and bones. Ex. 1004, 11–12; Pet. 32, 57–58. For example, Alexander "obtain[s] an image of the cartilage itself . . . using MRI techniques to take an image of the entire knee and then, optionally, manipulat[es] (*e.g.*, 'subtract[s] out' or 'extract[s]') the non-cartilage images," such as bone and fluid. Ex. 1004, 11–12. Next, Alexander discloses combining the stack of acquired 2D images into a 3D image. *Id.* at 12 (alternatively, a 3D image may be

acquired directly). The 3D image is then used to construct "maps" or displays of the knee's cartilage, to reflect a cartilage degeneration pattern. *Id.* Alexander also discloses obtaining an image of the knee joint, together with or independent from the cartilage imaging, "to give a 3D image of the joint and associated bones." *Id.*; *see also id.* at Fig. 18C–I , 61 (Fig. 18C depicting a "3D reconstruction of femoral and tibial bones (light grey), external markers (dark grey), femoral cartilage (red), and tibial cartilage (blue)"). This information is utilized together with biomechanical data to determine appropriate therapy for the patient, for example, "joint replacement therapy." *Id.* at 41–42; *see also* Pet. 57–58.

In light of these teachings and the knowledge of a person of ordinary skill in the art, Petitioner contends that it would have been obvious to match Radermacher's individual template to the cartilage surface of a joint. Pet. 30–31, 33–34. Petitioner sets forth several reasons for combining Radermacher and Alexander: (i) both references relate to methods of treating diseased or damaged cartilage in a knee joint; (ii) both references disclose using MRI to obtain joint images, address the same problem, are in the same field of endeavor, and use the same imaging technology; (iii) the choice of matching the cartilage surface instead of the underlying bone surface is simply a design choice; (iv) matching the cartilage surface would simplify the surgery and be consistent with Radermacher's goals; and (v) the modification would merely:

> (a) require the combination of one known element (Alexander's MRI data of the cartilage surface) with another known element (Radermacher's MRI data of the joint surface) to obtain a predictable result (a device tailored to the patient's cartilage surface); and (b) represent a choice from a finite number of identified, predictable solutions (imaging the bone surface and/or the cartilage surface), with a reasonable expectation of success.

Id. at 33–34. In support of these contentions, Petitioner cites Dr. Mabrey's Declaration. *Id.* at 30–31, 33–34.

We find Dr. Mabrey's testimony to be credible and persuasive. For example, Dr. Mabrey testifies that "the cartilage surface and the subchondral bone surface are the only two surfaces to which Radermacher's custom template could be matched." Ex. 1002 ¶¶ 94, 103. Dr. Mabrey opines that because MRI, which is disclosed by both Radermacher and Alexander, is used to "determine the topography of either the bone or the cartilage surface, the choice between matching the cartilage surface instead of the bone surface is simply a design choice," and a person of ordinary skill in the art would have expected either approach to be successful. *Id.* ¶¶ 94, 103. According to Dr. Mabrey, matching the template to cartilage instead of bone would simplify the surgery because "the surgeon would not have to take any time to remove the cartilage in order for the template to precisely fit on the femur or tibia." *Id*. ¶¶ 94, 104. Dr. Mabrey testifies that this would reduce operating time and improve patient safety. *Id.*

We are also persuaded by Petitioner's contention that bone and cartilage are the only surfaces to which Radermacher's individual template could be matched. Pet. 30, 33.

> When there is a design need or market pressure to solve a problem and there are *a finite number of identified, predictable solutions*, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007) (emphasis added).

As the parties' declarants agree, a healthy human knee contains cartilage covering the ends of the femur and tibia. *See, e.g.*, Ex. 1002 ¶¶ 36–37; Ex. 2005 ¶ 13. Both declarants also agree that the cartilage in the knee can be worn away, exposing underlying subchondral bone. *See, e.g.*, Ex. 1002 ¶ 36; Ex. 2005 ¶¶ 16–17. Both declarants also agree that it was known in the art to utilize imaging, e.g., MRI, to determine the condition of the patient's joint surface, including its cartilage and bone. *See, e.g.*, Ex. 1002 ¶¶ 43–44; Ex. 2005 ¶¶ 16–17. As such, the evidence of record supports Petitioner's contention that cartilage and bone are the only surfaces to which a template could be matched.

We also find that the evidence of record establishes the existence of a "design need or market pressure to solve a problem." *KSR*, 550 U.S. at 421. For example, both parties' declarants agree that operative treatments, such as knee replacement surgery (arthroplasty), existed to treat cartilage loss. Ex. 1002 ¶ 39; Ex. 2005 ¶ 28. Both declarants also agree that it was known to use intramedullary and extramedullary rods and cutting guides to assist the surgeon in making the appropriate cuts to the femur and/or tibia, in connection with such surgeries. Ex. 1002 ¶¶ 41–42, 45; Ex. 2005 ¶¶ 31, 33–34. As Dr. Mabrey testifies, and as reflected, *inter alia*, in Radermacher, creating patient-specific cutting guides based on imaging data was also known in the art. Ex. 1002 ¶ 50; Ex. 1003, 12; *see also* Ex. 1002 ¶¶ 51–58 (discussing other patient-specific cutting guides in the prior art). In light of this evidence, we determine that a design need or market pressure existed to solve the problem of accurately matching a cutting guide to a patient's joint in "one spatially uniquely defined position," to assist a surgeon in cutting into the bones of the joint. *See, e.g.*, Ex. 1003, (57).

Patent Owner disputes Petitioner's contention that it would have been obvious to match cartilage in order to simplify the surgery, arguing that

Radermacher "already simplifies surgery because its individual template specifically contemplates avoiding structures [like cartilage] in the surgical region." PO Resp. 52–53, 64. However, we have already addressed Patent Owner's arguments in this regard. *See supra* pages 25–27. As discussed above, we are not persuaded that Radermacher's disclosure of using recesses to avoid *spinal processes* on a vertebra has any applicability to Radermacher's embodiments concerning the knee. Indeed, Radermacher does not disclose avoiding cartilage in any manner, and does not discuss using a template with recesses to accommodate any bones other than the vertebrae. As such, we credit Dr. Mabrey's testimony that matching cartilage would simplify surgery, because the resultant template could be placed directly onto the patient's joint, without the need to remove any existing cartilage. This testimony is consistent with Radermacher's aim of providing a template for use in orthopedic interventions that is "safe, fast, exact and is defined according to the surgical planning" such that the template can be mounted to the patient's osseous structure "in exactly one spatially uniquely defined position." Ex. 1003, (57), 9. Neither Patent Owner's declarant, Dr. Clark, nor Patent Owner provides any other reason to discredit Dr. Mabrey's stated opinion that matching cartilage would simplify the surgery.

Moreover, we also note that although Dr. Clark testifies that he "disagree[s]" with Dr. Mabrey's opinion that bone and cartilage are the only two surfaces to which a template could be matched, Dr. Clark does not identify any other surface to which a template could be matched. Ex. 2005 ¶ 144; *see also id.* ¶¶ 145–147. Rather, Dr. Clark opines that a person of skill in the art "would not have chosen or preferred to mount Radermacher's template" to cartilage, but Dr. Clark does not dispute that bone and cartilage are the only surfaces available. *Id.* ¶ 147.

Patent Owner also contends that a person of ordinary skill in the art would not have had a reasonable expectation of success in making this modification because Alexander's images are not useful for making a patient-specific surface on a template, due to the presence of artifacts in the image shown in Alexander's Figure 22B. PO Resp. 58–61 (also arguing that this combination substitutes "one known element (MRI imaging) for the very same element"), 65.

We are not persuaded by Patent Owner's arguments, which are not responsive to the modification proposed. Neither Petitioner nor Dr. Mabrey suggest that the cartilage thickness maps generated by Alexander, as shown in Figure 22B (*see, e.g.*, Ex. 1004, 11), would be utilized to generate Radermacher's template. PO Resp. 58–61. Nor does Petitioner or Dr. Mabrey suggest substituting "one known element (MRI imaging) for the very same element." *Id.* at 61. Rather, Petitioner contends that "[i]t would have been obvious to a POSITA to combine *the teachings* of Radermacher and Alexander such that the contact faces of Radermacher's template are substantially a negative of the patient's cartilage surface." Pet. 33 (emphasis added). As Petitioner notes in its Reply, "Alexander provides more detail regarding MRI and joint surface modeling than does Radermacher." Pet. Reply 18. For example, Alexander teaches using MRI, the same imaging modality disclosed by Radermacher, to obtain images of both the cartilage and the bones in the knee joint. *See, e.g.*, Ex. 1003, 10; Ex. 1004, 11–12.

Therefore, we do not understand Petitioner's proposed combination to require that Alexander's cartilage thickness maps, which display the artifacts noted by Patent Owner, be used in generating Radermacher's template, but rather that Alexander's *teaching* of using MRI to obtain images of joint cartilage be employed in Radermacher, such that Radermacher's MRI imaging also obtains data reflecting cartilage, to be used in generating the template. Pet. 33–34; *see, e.g.*, Ex. 2010,

183:11–14 (stating that Figure 22B "is used to indicate that with the technique of Alexander, one can generate a three-dimensional image of the cartilage surface"), 184:19–21, 187:14–16. Moreover, Patent Owner does not contend that *all* MRI image data of a joint containing cartilage, e.g., that data generated by the proposed modification of Radermacher, would contain artifacts like those shown in Alexander's cartilage thickness maps. As such, we find this argument unpersuasive.[7]

We have considered the remainder of Patent Owner's arguments, but we find them unpersuasive. We address several of those arguments below.

Patent Owner argues that Radermacher and Alexander "are not closely related," because Alexander concerns preventative treatments and does not relate to knee replacement surgery, and, Alexander "would generally be directed to sports medicine orthopedic surgeons, not arthroplasty orthopedic surgeons." PO Resp. 54, 56; *see also id.* at 53–57. Thus, Patent Owner contends Alexander pertains to "skilled artisans different from those defined by the Petitioner," and a person of ordinary skill in the art would not have combined these two references. PO Resp. 54, 56; *see id.* at 53–57.

However, the question is not whether one prior art reference is analogous to another prior art reference, but whether the prior art reference is analogous to the claimed invention. *See Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1321 (Fed. Cir. 2011) (citing *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992)). A reference is considered analogous art if it

[7] In support of this argument, Patent Owner relies on cited deposition testimony of Dr. Mabrey. For these same reasons, we do not find it probative to the modification proposed by Petitioner. *See* PO Resp. 58–59; Ex. 2010, 180:23–191:17; Ex. 2014, 97:6–100:16.

is either "in the field of the applicant's endeavor or . . . reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). We find that Alexander is in the same field of endeavor as the '025 patent. Not only does Alexander disclose using MRI for imaging articular joints such as knees (Ex. 1004, 2), it is also concerned with assessing the condition of a joint to aid in treatment of the joint (*id.* at 1), including through joint replacement surgery (*id.* at 42). As such, both Alexander and the '025 patent relate to the treatment of diseased joints. *See, e.g.*, Pet. Reply 13–16; *compare* Ex. 1001, (57), 5:20–67 (measuring cartilage in an intended implantation site, through imaging techniques like MRI, and providing a replacement material), 6:19–25 (determining shape of cartilage and/or subchondral bone), *with* Ex. 1004, (57), 11–12 (obtaining MRI images of cartilage and/or subchondral bone).

In addition, we are not persuaded by Patent Owner's argument that Alexander "defines one of ordinary skill for its subject matter as 'someone having an advanced degree in imaging technology.'" *See* PO Resp. 57 (citing Ex. 1004, 15:10–26). Rather, we agree with Petitioner that this passage in Alexander merely explains that the identified imaging techniques need not be described in detail because they are well known to one of skill in the art. Pet. Reply 16–18 (citing Ex. 1004, 15:18–26; Ex. 1202 ¶ 55). Moreover, Alexander identifies someone having an advanced degree in imaging technology as just an *example* of one of skill in the art. Ex. 1004, 15:23–25 (prefacing "someone having an advanced degree in imaging technology" with "e.g."). Accordingly, Alexander is not relevant only to someone with an advanced degree in imaging technology.

Finally, we are unpersuaded by Patent Owner's distinction between sports medicine orthopedic surgeons and arthroplasty orthopedic surgeons.

PO Resp. 54. Although the focus of sports medicine orthopedic surgeons and arthroplasty orthopedic surgeons may vary, they are all orthopedic surgeons. We find that any distinction between them would be too subtle to dissuade one of ordinary skill in the art from considering Alexander when designing a patient-specific template. *See* Ex. 1203, 225:19–24 (Dr. Clark agreeing that "general orthopedic surgeons often prescribe the same treatments that sports medicine orthopedic surgeons prescribe," and testifying that "general orthopedic surgeons treat a lot of sports injuries").

We are also unpersuaded by Patent Owner's argument that a person of ordinary skill in the art would not have found it to be an obvious "design choice" to select between matching cartilage and matching bone because these "are very different surfaces." PO Resp. 61–63 (citing, *e.g.*, Ex. 2005 ¶¶ 115, 120, 144–147, 150). For example, Patent Owner argues that damaged cartilage, as compared to bone, (1) is not as structurally sound, (2) may be weak, frayed, or delaminated, (3) is more compressible, and (4) may degenerate rapidly. *Id.* at 62–63. Patent Owner contends that, due to these features, the resulting template would not have one spatially uniquely defined position, as intended by Radermacher. *Id.* at 63.

We have considered Patent Owner's position, and the cited testimony of Dr. Clark, but we are not persuaded. With one exception in paragraph 115, the cited portions of the Clark Declaration do not identify any underlying evidentiary support for Dr. Clark's stated opinions and, as such, we afford them little weight. Ex. 2005 ¶¶ 144–147; 37 C.F.R. § 42.65(a).

In paragraph 115, in support of his opinion, Dr. Clark cites an article titled "Detecting and Staging of Chondromalacia Patellae: Relative Efficacies of Conventional MR Imaging, MR Arthography, and CT Arthography." *See id.* ¶ 115 (citing Ex. 2009, Fig. 5A). However, this article concerns damage to *patellar*

cartilage, and does not discuss damage to *tibial or femoral* cartilage. Ex. 2009, 629 ("Chondromalacia patellae is a condition characterized by softening, fraying, and ulceration of patellar articular cartilage. We compare [the efficacy of imaging techniques] in detecting and staging this abnormality."). Although Dr. Clark testifies that the same type of cartilage covers the patella, femur, and tibia, *see* Ex. 2005 ¶ 145, the cited portions of Dr. Clark's declaration do not provide any basis to support a finding that the described patellar cartilage damage also occurs on the femur or tibia in such a way that the described patellar damage is relevant to Petitioner's proposed modification to Radermacher. Ex. 2005 ¶ 115. Indeed, Dr. Clark is entirely silent as to whether this type of damage may occur in the tibia or femur. *Id.*

In contrast, Dr. Mabrey testifies that "the patella is subjected to lateral shearing forces when it dislocates," which may cause the appearance cited by Patent Owner. Ex. 1202 ¶ 38. Dr. Mabrey testifies that, in his experience, such damage is unlikely to occur on the femur and tibia. *Id.* We find this testimony to be more compelling than that offered by Dr. Clark, because Dr. Mabrey explains that his opinion is based on his personal experience. Moreover, we also credit Dr. Mabrey's opinion that damaged cartilage, such as that shown in Figure 5A of Exhibit 2009 is irrelevant to the proposed modification, which does not involve the arthroscopy procedures reflected in that example. *See id.*; *see also* Ex. 2009, Fig. 5A (reflecting an "[a]rthroscopic photograph"). Moreover, Dr. Mabrey testifies that he "routinely placed non-patient-specific cutting guides against [his] patients' articular cartilage and the surface did not indent, compress, or otherwise cause the cutting guide to be misaligned." Ex. 1202 ¶ 37. Although we recognize that cartilage and bone are "very different" structures with different functions, Patent Owner has not shown persuasively that those differences impact Petitioner's

proposed modification. Additionally, those differences alone do not alter the fact that the majority of arthroplasty patients have at least some cartilage in their knees, such that cartilage and bone are the only available surfaces to which Radermacher's template could be matched. *See, e.g.*, Ex. 1203, 51:25–52:8.

For the foregoing reasons, we are persuaded by Petitioner's contention that the combination of Radermacher and Alexander, in light of the knowledge of a person of ordinary skill in the art, teaches or suggests "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 of the patient" as recited in claim 1, and that Petitioner has presented valid reasons to modify Radermacher.

iv. Element [c.i]

Independent claim 1 recites "the first and second guides having predetermined positions and orientations relative to the patient-specific surface." Ex. 1001, 61:26–28.

We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Radermacher teaches this limitation. Pet. 35–36, 59 (citing Ex. 1003, 10–11, 13, 25, 30, Figs. 13a–13c). Specifically, Radermacher discloses that the positions and orientations of the first and second guides are determined during pre-operative planning. Radermacher explains that "in the preoperative surgical planning phase," "cutting, boring, milling and other treatment steps . . . are three-dimensionally charted in said coordinate system fixed relative to the osseous structure," so as to be "clearly defined in or on the individual template in the form of guide means." Ex. 1003, 11. For example, as shown in Figure 13a, the hole receiving drill sleeve 11 (at axis 8), cutting surfaces 20a, 20b, and 20d, and cutting groove 20c have predetermined positions and orientations relative to the patient-specific contact surface of individual template 4. *See id.* at Fig. 13a; *see also id.* at

13 ("[T]ool guides . . . can be provided in/on the basic body of the individual template, which . . . are oriented or constructed in such a manner that the tool guides . . . will effect a three-dimensional guiding of the treatment tools or measuring devices exactly as provided by the surgical planning.").

v. Element [c.ii]

Independent claim 1 recites:

> the first and second guides . . . 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 of the patient.

Ex. 1001, 61:28–34. Petitioner relies upon Radermacher and Woolson to satisfy this limitation. Pet. 37–43, 59–61.

Petitioner acknowledges that Radermacher does not refer to a "biomechanical or anatomical axis of the joint." Pet. 37. However, Petitioner suggests that Radermacher's tool necessarily is aligned relative to such an axis and that such alignment was conventional, widely known, and essential to maintain proper alignment after surgery. *Id.* at 37–38 (citing Ex. 1001, 12:27–46, 14:59–16:39; Ex. 1002 ¶¶ 49, 112, 117–127; Ex. 1037, 739). Petitioner also relies on Woolson's disclosure that it is "necessary" to align cutting paths such that they are perpendicular to the mechanical axis, and that doing so improves long-term results. *Id.* at 39–40 (citing, *e.g.*, Ex. 1031, 1:26–36, 2:50–59, 4:7–26, Figs. 1, 2A–B). Thus, Petitioner contends that it would have been obvious to a person of ordinary skill in the art to modify Radermacher's template in light of Woolson's teaching that it is "necessary" to make cuts perpendicular to a mechanical axis, to achieve

"better results" and "long-term success." *Id.* at 41–43 (citing, *e.g.*, Ex. 1002 ¶¶ 126–127).

Patent Owner argues that the Petition "fails to explain how one of ordinary skill in the art would have combined the teachings of the references, much less why one would have been motivated to do so." PO Resp. 76. According to Patent Owner, Woolson's use of extramedullary rods to align cutting guides is a "fundamentally different system" than that of Radermacher. *Id.* at 76–77. Patent Owner argues that the Petition and Dr. Mabrey fail to explain why a person of ordinary skill in the art would have considered Woolson. *Id.* at 77–78.

We have considered the evidence of record and the parties' positions, and we are persuaded by Petitioner. We find that the '025 patent, Radermacher, and Woolson are in the same field of endeavor and, thus, are analogous art. Namely, both references and the '025 patent concern treatment of diseased joints. *Compare* Ex. 1003, 30 (addressing "preparation of the seat for the knee-joint head prosthesis"), *with* Ex. 1031, [57] (addressing "total knee replacement"). That Radermacher and Woolson align their cutting guides to the bone in different manners is not dispositive. *See, e.g.*, Ex. 2005 ¶ 28 (Dr. Clark testifying that "[t]he most common types of arthroplasty are partial and total knee replacement surgeries. [Woolson] describes a total knee replacement surgery. [Radermacher] describes arthroplasty treatments and exemplifies, among other things, a total knee replacement surgery"), 73 (describing Woolson's use of "an *extra*medullary cutting guide" in knee arthroplasty), 75 (describing Radermacher's use of a "patient-customized individual template . . . as a cutting guide" in knee arthroplasty).

Moreover, we find that Woolson expressly provides a motivation for the modification proposed by Petitioner. Woolson explains that,

> One of the most important causes for failure of the [knee replacement] procedure is from prosthesis component loosening because of unbalanced loading of the tibial component caused by improper knee joint alignment. Because of this fact, *all total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis in both the coronal and the sagittal planes*. If achieved, this results in the placement of the total knee prostheses in a common mechanical axis which correspondingly is *highly likely to produce a successful long-term result*.

Ex. 1031, 1:26–36. In other words, Woolson explains that it is necessary to align the reconstructed knee with respect to the mechanical axis, to ensure proper knee-joint alignment over the long term. *Id.*; *see also id.* at 2:50–55. To achieve this result, Woolson explains,

> During the knee replacement surgical procedure, it will be necessary to resection the medial and lateral condyles of the distal femur by cutting along a line 20 which is perpendicular to [mechanical] axis 14. The proximal end of tibia 12 will be resectioned along a cut plane identified by the dashed line 22 in FIG. 2B. The line of this cut must be perpendicular, or slightly angled as will be discussed subsequently, relative to a mechanical axis 24 of the tibia.

Id. at 4:9–26.

In light of these express teachings, we are persuaded that the Petition has set forth a sufficient reason as to why a person of ordinary skill in the art would have modified Radermacher's template such that its guides are aligned with respect to the patient's mechanical axis. *Cf.* PO Resp. 76–78. Namely, the evidence demonstrates that such a modification would have been expected to improve knee alignment, leading to successful long-term results. Ex. 1031, 1:26–26, 4:9–26; *see also* Ex. 1002 ¶¶ 126–127 ("[A] person of ordinary skill in the art would immediately recognize that aligning the cutting guides relative to the patient's axes would improve the quality of the surgery and improve the long-term stability of the implant, as was known in the art and taught by Woolson."). For the same reasons,

we are also persuaded that such a modification "would merely involve using a technique that has been employed to improve one knee arthroplasty procedure (Woolson's) to improve a similar knee arthroplasty procedure (Radermacher's) in the same predictable way." Pet. 43.

For the foregoing reasons, we are persuaded by Petitioner's contention that the combination or Radermacher and Woolson, in light of the knowledge of a person of ordinary skill in the art, teach the subject matter of this limitation and that Petitioner has presented valid reasons to modify Radermacher.

vi. Objective Evidence of Non-Obviousness

Patent Owner directs us to no evidence regarding objective indicia of non-obviousness. *See generally* PO Resp.; Pet. 91.

vii. Summary

After considering all evidence and arguments of record, we determine that Petitioner has provided a persuasive articulated reason with rational underpinning to support its contention that a person of ordinary skill would have had a reason or motivation to combine Radermacher, Alexander, and Woolson in the manner proposed by Petitioner. We also determine that Petitioner has provided analysis explaining how the combination would have conveyed to one of ordinary skill in the art each of the limitations of claim 1. Accordingly, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that claim 1 is unpatentable under 35 U.S.C. § 103 as directed to subject matter that would have been obvious to a person of ordinary skill in the art in light of Radermacher, Alexander, and Woolson.

5. Dependent Claims 5–14

Claim 5

Dependent claim 5 recites that the joint is "one of a hip, knee, ankle, shoulder, elbow and wrist joint." Petitioner relies upon Radermacher to satisfy the additional limitations recited in dependent claim 5. *See* Pet. 45, 63. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp.

We are persuaded by Petitioner. Relevant to this limitation, Radermacher discloses a surgical system for a knee joint, as claimed. *See* Ex. 1003, 30, Figs. 13a–d.

Claim 6

Dependent claim 6 recites that "the first and second guides are holes configured to accommodate and direct a surgical drill." Petitioner relies upon Radermacher and Woolson to satisfy the additional limitations recited in dependent claim 6. *See* Pet. 45–50, 63–67. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp.

We are persuaded by Petitioner. Relevant to this limitation, Radermacher discloses that the template can include "drill sleeves" and "bores" for accommodating a drill. Ex. 1003, 13, 22, 25–26. Although only one "hole" is depicted in Radermacher's template adapted for the knee, Radermacher discloses other embodiments, *e.g.*, *id.* at Figs. 10a–d, with two holes. Additionally, Woolson discloses a cutting guide for the knee with two drill holes. Ex. 1031, Fig. 7B. We are persuaded that it would have been obvious to a person of ordinary skill in the art to modify Radermacher's template to include two drilling holes, as shown by Woolson and as suggested by Radermacher, to accommodate commonly-used implants containing two pegs. Ex. 1002 ¶ 136.

Claim 7

Dependent claim 7 recites that "the first and second guides are cutting slots." As discussed above, *see supra* Section II.A.2, we construe the phrase "cutting slot" as "'an elongated cutting guide internal to a surgical tool,' as opposed to the surface of a surgical tool." Petitioner relies upon Radermacher and Woolson to satisfy the additional limitations recited in dependent claim 7. *See* Pet. 50–51, 67. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp.

We are persuaded by Petitioner. Relevant to this limitation, Radermacher discloses that the template adapted for the knee includes cutting groove 20c, which is an elongated cutting guide internal to a surgical tool, as well as cutting surfaces 20a, 20b, and 20d. Ex. 1003, 30, Fig. 13a. Although only one "cutting slot" is depicted in Radermacher's template adapted for the knee, Radermacher discloses that additional tool guides, like "saw templates" could be employed. *Id.* at 13. Additionally, Woolson discloses a cutting guide with at least two cutting slots. Ex. 1031, Fig. 7A. We are persuaded that it would have been obvious to a person of ordinary skill in the art to modify Radermacher's template to include cutting slots, as shown by Woolson and as suggested by Radermacher, to accommodate the surgeon's preference for cutting slots rather than cutting surfaces. Ex. 1002 ¶¶ 145–147 (opining that a "saw template" was known to be a "cutting slot," and that "cutting surfaces" and "cutting slots" were interchangeable to accommodate surgeon preference).

Claim 8

Dependent claim 8 recites that "the first guide is a hole configured to accommodate and direct a surgical drill and the second guide is a cutting slot." Petitioner relies upon Radermacher and Woolson to satisfy the additional

limitations recited in dependent claim 8. *See* Pet. 52, 68. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp.

We are persuaded by Petitioner. Relevant to this limitation, Radermacher discloses such a configuration in Figures 13a–c, which depict a hole formed at drill axis 8 and a cutting slot 20c. Ex. 1003, 30, Figs. 13a–c.

Claims 9 and 12

Dependent claims 9 and 12 recite that "the first and second guides are aligned along distinct cutting planes when the patient-specific surface is fit to the corresponding portion of the diseased or damaged cartilage surface of the joint." Petitioner relies upon Radermacher and Woolson to satisfy the additional limitations recited in dependent claims 9 and 12. *See* Pet. 52, 69–70, 73. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp.

We are persuaded by Petitioner. Relevant to these limitations, Radermacher discloses such a configuration in Figures 13a–c, which depict guides (cutting surfaces 20a, 20b, and 20d, and cutting slot 20c) each of which are aligned along distinct planes when the template is fit to the patient's knee joint. *See* Ex. 1003, Fig. 13a–c.

Claim 10

Dependent claim 10 recites that "the first and second guides are co-planar." Petitioner relies upon Radermacher and Woolson to satisfy the additional limitations recited in dependent claim 8. *See* Pet. 52, 71–72. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp.

We are persuaded by Petitioner. Relevant to this limitation, Radermacher discloses such a configuration in Figures 13a–c, which depict cutting slot 20c in the same plane as the hole at bore axis 8. *See* Ex. 1003, Fig. 13a–c.

Claim 11

Dependent claim 11 recites that "the first and second guides are *not* co-planar." Petitioner relies upon Radermacher and Woolson to satisfy the additional limitations recited in dependent claim 8. *See* Pet. 52, 72–73. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp.

We are persuaded by Petitioner. Relevant to this limitation, Radermacher discloses such a configuration in Figures 13a–c, which depict, *inter alia*, cutting surfaces 20a and 20c that are *not* in the same plane. *See* Ex. 1003, Fig. 13a–c.

Claim 13

Dependent claim 13 depends from claim 12 and recites that "the patient-specific surgical tool includes a third guide." Petitioner relies upon Radermacher and Woolson to satisfy the additional limitations recited in dependent claim 8. *See* Pet. 52, 74–75. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp.

We are persuaded by Petitioner. Relevant to this limitation, Radermacher discloses such a configuration in Figures 13a–c, which depict at least five cutting guides, i.e., cutting surfaces 20a, 20b, and 20c, cutting slot 20c, and the hole at bore axis 8. *See* Ex. 1003, Fig. 13a–c.

Claim 14

Dependent claim 14 depends from claim 13 and recites that "the third guide is a slot aligned along a second plane to provide a second cutting path that is aligned through a portion of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or damaged cartilage surface of the joint." Petitioner relies upon Radermacher and Woolson to satisfy the

additional limitations recited in dependent claim 8. *See* Pet. 52, 75–76. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp.

We are persuaded by Petitioner. Relevant to this limitation, Radermacher discloses such a configuration in Figures 13a–c, which depict cutting slot 20c that provides a cutting path aligned along a distinct plane from the planes provided by the first and second guides, e.g., any of cutting surfaces 20a, 20b, and/or 20c. *See* Ex. 1003, Fig. 13a–c.

Summary

Therefore, in light of the foregoing, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that claims 5–14 are unpatentable under 35 U.S.C. § 103 as directed to subject matter that would have been obvious to a person of ordinary skill in the art in light of Radermacher, Alexander, and Woolson.

6. Independent Claim 15

Independent claim 15 is substantially similar to independent claim 1. *Compare* Ex. 1001, 61:16–34, *with id.* at 62:22–38. For example, both claims are drawn to a "surgical system" with an "articular repair system" and a "patient-specific surgical tool." Both claims further limit the tool to include "a block having a patient-specific surface." While claim 1 requires that the block include "first and second guides," claim 15 requires that the block include "first and second drilling holes," which we have addressed above with respect to claim 6. Additionally, while claim 1 requires that the patient-specific surface is a negative of a "cartilage surface," claim 15 requires that it is a negative of an "articular surface." Claim 15 also requires that the drilling holes have axes that extend through a portion of the joint, when the tool is seated on the joint. Finally,

claim 15 does not require that the holes be aligned relative to a biomechanical or anatomical axis of the joint.

Petitioner substantially relies upon its contentions made with respect to claims 1 and 6. Pet. 52, 76–78. Specifically, Petitioner contends that "[b]ecause Radermacher, either alone or in combination with Alexander, discloses a patient-specific surface that is at least partially a negative of the diseased or damaged *cartilage* surface, it also discloses a patient-specific surface that is at least partially a negative of a diseased or damaged *articular* surface." *Id.*; *see also id.* at 52 n.7 ("The term 'articular surface' . . . can comprise cartilage and/or subchondral bone" (quoting Ex. 1001, 6:22–24)).

In response, Patent Owner incorporates the arguments it presented with respect to claim 1. Namely, Patent Owner argues,

> Claims 15–20 are not obvious for substantially the same reasons as claims 1–14. Petitioner has not articulated an adequate motivation to combine the teachings of Radermacher and any of the secondary references with a reasonable expectation of success. As discussed above, neither Alexander nor Fell teaches a surface that is a substantial negative of a diseased or damaged cartilage surface. *See* §§ VII.B, VII.C. Each reference includes elements that are not present in the actual imaged structure and neither Woolson nor Biscup cures these deficiencies, Petitioner does not rely on them to do so, and a one [sic] of ordinary skill would not combine the references as proposed.

PO Resp. 78–79.

i. Matching Cartilage

For the same reasons articulated above with respect to claims 1 and 6, which we adopt as to the identical limitations present in claim 15, we are persuaded that claim 15 would have been obvious to a person of ordinary skill in the art. As discussed with respect to claim 1, we are persuaded that Petitioner provided a sufficient reason to modify Radermacher in light of Alexander, to provide a

patient-specific surface that matches cartilage. *See supra* Section II.D.4.iii. Moreover, as discussed with respect to claim 6, we are persuaded that Petitioner provided a sufficient reason to modify Radermacher in light of Woolson, to provide an individual template with two drilling holes. *See supra* Section II.D.5. When seated on the joint, we are persuaded that the axes of these holes would extend through a portion of the joint, due to the mating engagement of the tool on the joint. Ex. 1003, 10.

ii. Matching Radermacher's Osseous Structure

Furthermore, as noted in Section II.A.1, we construe the phrase "articular surface" as "the surface of an articulating bone that includes cartilage and/or exposed subchondral bone." Accordingly, we are persuaded that Radermacher discloses a surgical tool having a patient-specific surface that at least matches the patient's bone. *See supra* Section II.D.4.ii. Radermacher discloses an "individual template by which parts of the surface of an *arbitrary osseous structure* . . . are copied as a negative image . . . so that the individual template can be set onto the osseous structure in a clearly defined position and with mating engagement." Ex. 1003, 10. Patent Owner concedes as much. *See, e.g.*, PO Resp. 34 ("Radermacher's individual template matches bone."). Thus, we are persuaded that Petitioner has shown claim 15 to be unpatentable on this alternative basis, as well as the basis previously discussed in Section II.D.6.i, based on Radermacher, Woolson, and Alexander.

7. Dependent Claims 19 and 20

With respect to claim 19, which is substantially identical to claim 5 but for its dependency from claim 15, Petitioner relies on its contentions made with respect to claim 5. Pet. 53, 78. With respect to claim 20, which recites that the

block and the drilling holes "are comprised of a single component," Petitioner relies upon Radermacher and Woolson to satisfy the additional limitations. *See* Pet. 53, 79. Petitioner contends that Radermacher's template with its drilling holes and cutting surfaces may be provided "in" a single component, and also contends that this limitation would have been obvious in view of Woolson, which discloses a single cutting block with two holes. *Id.* at 53.

In response, Patent Owner incorporates the same arguments considered above, with respect to claim 15. PO Resp. 78–79.

For the same reasons articulated above with respect to claim 5, which we incorporate herein by reference, we are persuaded that claim 19 would have been obvious to a person of ordinary skill in the art.

We are also persuaded by Petitioner's contentions with respect to dependent claim 20. As discussed above with respect to claim 6, we are persuaded that it would have been obvious to a person of ordinary skill in the art to modify Radermacher's template to include two drilling holes, as shown by Woolson and as suggested by Radermacher, to accommodate commonly-used implants containing two pegs. Ex. 1002 ¶ 136. In such a modification, we are persuaded that it would have been obvious for the template and drilling holes to be "comprised of a single component," as disclosed by Woolson, to reduce the number of components. Ex. 1031, 3:39–40, Fig. 7B; Ex. 1002 ¶ 156 ("Woolson . . . discloses single-component cutting blocks having two drilling holes.").

E. Obviousness over the Combined Teachings of Radermacher, Alexander, Woolson, and Biscup

We instituted *inter partes* review for claims 2–4 and 16–18 based on the combination of Radermacher, Alexander, Woolson, and Biscup. *See supra* n.1 (including claim 2 in this ground).

Petitioner contends that claims 2–4 and 16–18 of the '025 patent are unpatentable as obvious over the combined teachings of Radermacher, Alexander, Woolson, and Biscup. Pet. 43–45 n.6, 80–85; *see also* Dec. on Inst. 6 n.5. Patent Owner argues that Biscup fails to cure deficiencies in Petitioner's presentation regarding Radermacher, Alexander, and Woolson. PO Resp. 78. For reasons that follow, we determine Petitioner has met its burden and demonstrated by a preponderance of the evidence that these claims are unpatentable.

1. Overview of Biscup (Ex. 1035)

Biscup is titled "Molded Surgical Implant and Method" and relates to a customized prosthetic implant for use in fully or partially replacing bone and/or tissue in a human or animal. Ex. 1035, [54], [57], ¶ 2. Biscup states that bone replacements typically do not provide full function or the full range of movement that is provided by a healthy, properly formed bone and that there remained a need for a prosthetic implant that closely matches a bone and/or tissue to be replaced. *Id.* ¶ 17. Biscup discloses a method of selecting a standard prosthetic implant having a close shape and size to that which is required and then further shaping the implant with molding material based on X-ray or MRI data to customize it to the specific patient. *See id.* ¶¶ 88–89.

2. Dependent Claims 2–4 and 16–18

i. Claims 2–4

Dependent claim 2 recites that "the articular repair system includes one or more implant components selected for the patient from preexisting systems," and dependent claim 3 further recites that the pre-existing implant component is "further shaped based on electronic image data of the joint of the patient." Petitioner relies upon Radermacher, Woolson, and Biscup to satisfy the additional

limitations recited in dependent claims 2, 3, 16, and 17. *See* Pet. 43–45, 62–63, 80–82, 83–84. Patent Owner does not dispute Petitioner's contentions. *See* PO Resp. 78 (arguing only that Biscup does not teach the claimed patient-specific surface).

Petitioner contends that because Radermacher teaches that its customized templates can be used in conjunction with "standard tool guides" (*see* Ex. 1003, 2, 11) and because Radermacher does not indicate that the implant is anything other than a conventional, off-the-shelf implant from a pre-existing system, a person of ordinary skill in the art would have understood Radermacher's implant to be a pre-existing, standard implant that is compatible with a pre-existing, standard tool guide. Pet. 44 (citing Ex. 1002 ¶¶ 138–139).[8]

Petitioner also contends that Biscup discloses "selecting a 'generic implant' for a patient." Pet. 45 n.6 (citing Ex. 1035 ¶ 88, Fig. 2; Ex. 1002 ¶ 142), 80. More specifically, Petitioner contends that

> Biscup describes acquiring patient data and then "a standard prosthetic implant having a close shape and size to the acquired data is selected." The "standard prosthetic" or "generic prosthetic implant" is inserted into a molding machine, where a molding material "is shaped on the surface of the standard prosthetic implant until the shape and size of the prosthetic implant is customized to the acquired data."

Id. at 80 (citation omitted) (quoting Ex. 1035 ¶ 88). Petitioner contends that the patient data is acquired by MRI, and may be used for knee surgery. *Id.* at 81 (citing Ex. 1035 ¶¶ 17–19, 89). Petitioner argues that it would have been obvious to a person of ordinary skill to modify Radermacher's system to include the implant component disclosed in Biscup because, *inter alia*, Biscup discloses that

[8] Petitioner also contends that this limitation would have been obvious in light of Woolson's teaching of "select[ing]" the implant to be implanted. *Id.* at 44–45 (citing Ex. 1002 ¶ 141).

selecting from pre-existing components and custom-forming them results in an implant that "can be quickly, accurately, and cost effectively customize[d]" for a particular patient. *Id.* at 82; Ex. 1035 ¶ 17 (citing Ex. 1002 ¶ 163).

We are persuaded by Petitioner. Biscup discloses selecting a standard prosthetic implant for further modification. Ex. 1035 ¶¶ 88–89. Specifically, Biscup discloses that (1) "data is first acquired for the prosthetic implant" by MRI or x-ray of the patient, (2) "a standard prosthetic implant having a close shape and size to the acquired data is selected," and (3) "molding material is shaped on the surface of the standard prosthetic implant until the shape and size of the prosthetic implant is customized to the acquired data." *Id.* ¶¶ 88–89. Biscup suggests that this process solves a need in the art to provide an implant that "can be quickly, accurately, and cost effectively customize[d] for a particular patient." *Id.* ¶ 17. Accordingly, we are persuaded that Petitioner has identified a sufficient reason that would have motivated a person of ordinary skill in the art to modify Radermacher's system as proposed.

Dependent claim 4 recites that "the articular repair system includes one or more implant components designed for the patient using electronic image data of the joint of the patient." Petitioner relies upon Radermacher and Biscup to satisfy the additional limitations recited in dependent claims 4 and 18. *See* Pet. 83, 85. Patent Owner does not dispute Petitioner's contentions. *See* PO Resp. 78 (arguing only that Biscup does not teach the claimed patient-specific surface).

Petitioner contends that "Biscup discloses a customized implant that is designed specifically for each patient based on image data such as MRI," relying on Biscup's teachings as discussed regarding claims 2 and 3. Pet. 83, 86 (citing, *e.g.*, Ex. 1035 ¶¶ 88–89, Fig. 2; Ex. 1002 ¶¶ 165, 185). According to Petitioner, "it

would have been obvious to a POSITA that Radermacher's implant could be replaced with a patient-specific implant." *Id.* at 83.

We are persuaded by Petitioner, for the same reasons as discussed regarding claims 2 and 3. Namely, Biscup discloses forming implant components based on image data of the patient's joint. Ex. 1035 ¶ 88. Likewise, we are persuaded that Petitioner has identified a sufficient reason that would have motivated a person of ordinary skill in the art to modify Radermacher's system as proposed, namely, to provide an implant that "can be quickly, accurately, and cost effectively customize[d] for a particular patient." *Id.* ¶ 17.

ii. Claims 16–18

Claims 16 and 17 depend directly and indirectly from claim 15, and contain the same additional recitations as claims 2 and 3. *Compare* Ex. 1001, 62:35–41, *with id.* at 61:38–44. For the same reasons as for claims 2 and 3, we are persuaded by Petitioner.

Claim 18 depends directly from claim 15, and contains the same additional recitations as claim 4. *Compare* Ex. 1001, 62:41–44, *with id.* at 61:45–48. For the same reasons as for claim 4, we are persuaded by Petitioner.

F. Obviousness over the Combined Teachings of Radermacher, Fell, and Woolson

1. Overview of Fell

Fell is titled "Surgically Implantable Knee Prosthesis," and relates to prosthetic devices, and more particularly, to a hard, self-centering knee-joint meniscal device that may be surgically implanted between the femoral condyle and the tibial plateau of the knee. Ex. 1005, 1:4–5, 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

material of the meniscal device encourages articular cartilage regeneration by providing non-contacting or recessed areas of the device. *Id.* at 8:28–30. Fell describes that the shape of the patient's 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:

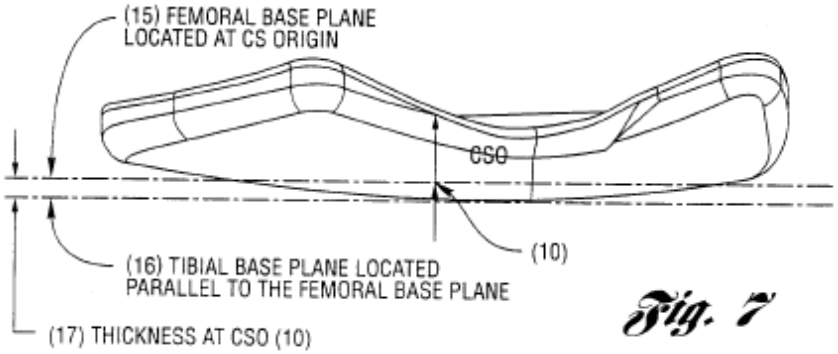


Figure 7 illustrates a device contour and its relationship with the femoral and tibial base planes. *Id.* at 5:1–2.

2. Claims 1 and 5–14

Petitioner contends that this asserted ground of unpatentability is similar to that which relied upon Radermacher, Alexander, and Woolson, except this ground relies on Fell for similar teachings as Alexander, i.e., "to establish that it would have been obvious to modify the contact faces 1 of Radermacher's template to be substantially a negative of the cartilage surface." Pet. 85.

Petitioner relies on Radermacher, as discussed above, for a surgical system comprising an articular repair system and a patient-specific surgical tool, and relies on Woolson, as discussed above, for teachings regarding alignment relative to a mechanical axis. *Id.* at 88 (incorporating prior analysis of Radermacher and Woolson); *see supra* Section II.D.4.i–vii.

Petitioner further contends that Fell discloses using MRI to obtain data regarding the shape of the femur and tibia, including their articular cartilage, for use in generating a patient-specific meniscal implant. *Id.* at 85–86, 88–89 (citing Ex. 1005, 14, 15, 22).

Petitioner contends that it would have been obvious to a person of ordinary skill in the art "to modify Radermacher's template such that the contact faces were substantially a negative of the cartilage surface for several reasons." *Id.* at 86. These reasons are similar to those discussed above, including: (i) both Radermacher and Fell relate to methods of treating damaged cartilage in a knee joint; (ii) both references disclose using MRI for creating patient-specific medical devices, address the same problem, are in the same field of endeavor, and use the same imaging technology; (iii) Radermacher expressly suggests the combination because Radermacher states that individualized surgical procedures were "lagging behind the technology of implant manufacture" (*see* Ex. 1003, 6), which would motivate a skilled artisan to consider patient-specific implant technologies, such as the implant described in Fell; (iv) matching the cartilage surface would simplify the surgery; and (v) the modification would merely:

> (a) require the combination of one known element (Fell's MRI data which includes the cartilage surface) with another known element (Radermacher's MRI data of the joint surface) to obtain a predictable result (a device tailored to the patient's cartilage surface); and (b) represent a choice from a finite number of identified, predictable solutions (imaging the bone surface and/or the cartilage surface), with a reasonable expectation of success.

Id. at 87–88 (citing Ex. 1002 ¶¶ 175–180).

Many of Patent Owner's arguments are similar to those discussed above. Specifically, Patent Owner argues that Fell does not relate to methods or surgical instruments for knee replacement surgery but instead concerns preventative treatments, and would be more relevant to a sports medicine orthopedic surgeon, not an arthroplasty orthopedic surgeon. PO Resp. 66–69.

For similar reasons as discussed above in connection with Alexander, this argument is not persuasive. We find that Fell is in the same field of endeavor as the '025 patent. Not only does Fell disclose using MRI for imaging articular joints such as knees (Ex. 1005, 14), it is also concerned with assessing the condition of a joint to aid in treatment of the joint through creation of a patient-specific implant (*id.* at 15). As such, both Fell and the '025 patent relate to the treatment of diseased joints. *See, e.g.*, Pet. Reply 23–24; *compare* Ex. 1001, (57), 5:20–67 (measuring cartilage in an intended implantation site, through imaging techniques like MRI, and providing a replacement material), 6:19–25 (determining shape of cartilage and/or subchondral bone), *with* Ex. 1005, 14 (obtaining MRI images of cartilage and/or subchondral bone), 15 (developing meniscal device). Moreover, as above, we find that any distinction between sports medicine orthopedic surgeons and arthroplasty orthopedic surgeons is too subtle to dissuade one of ordinary skill in the art from considering Fell.

Patent Owner also argues that Petitioner is incorrect in asserting that both Radermacher and Fell concern the use of MRI technology to create patient-specific devices, because Fell's device "does not precisely match the joint's cartilage surface." PO Resp. 69–72 (citing Ex. 1002 ¶ 172; Ex. 2010, 161:7–9, 161:10–162:16, 177:4–7, 208:23–213:8). According to Patent

Owner, if Fell's device did "precisely match" the cartilage surface, "it would not have worked for its intended purpose of being a moveable, self-centering device" because "it would lock in one position and prohibit the joint from articulating." *Id.* at 71. As such, Patent Owner contends there would not have been a reasonable expectation of success. *Id.* at 71–72.

We find Patent Owner's argument unpersuasive. This argument attacks the references individually, instead of considering the combination as a whole, wherein the proposed combination is premised upon using cartilage information obtained through MRI, as taught by Fell, "to modify Radermacher's template such that the contact faces were substantially a negative of the cartilage surface for several reasons." Pet. 86. Thus, Petitioner relies upon Radermacher, not Fell, for the teaching of a template that "precisely match[es]" the osseous structure, which allows the template to "lock" in place on one unique position. Ex. 1003, [57]; *cf.* PO Resp. 71. In other words, the combination does not incorporate the patient-specific surface as it is generated for *Fell's device* into Radermacher's template, but rather involves using MRI to obtain cartilage information for use in generating *Radermacher's template*, wherein the template is designed to substantially match the imaged cartilage. *See, e.g.*, Ex. 2010, 163:4–13 (Dr. Mabrey testifying that "using MRI data which included cartilage surface," as taught by Fell, would result in a device tailored to the patient's cartilage surface). Thus, even if Fell's surface does not "precisely match" the cartilage, that is irrelevant to the proposed combination. The test for obviousness is what the combined teachings of the references *as a whole* would have suggested to those of ordinary skill in the art, not merely what Fell disclosed. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981); *In re Merck &*

Co., *Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.").

Regarding Petitioner's assertion that Radermacher expressly suggests the combination, Patent Owner argues that "one of ordinary skill would not have been motivated to consider implant technologies because the issue that Radermacher identifies and Dr. Mabrey points to—that '[t]he technology of bone treatment has been lagging behind the technology of implant manufacture'—was addressed with Radermacher's individual template." PO Resp. 72–73 (citing Ex. 2005 ¶ 167).

To support this argument, Patent Owner relies upon Dr. Clark's testimony. Ex. 2005 ¶ 167. Dr. Clark's testimony, however, merely repeats this statement from the Patent Owner Response without providing any supporting evidence or reasoning. *Id.* There is no substantive explanation of how Radermacher's template addressed the issue of bone treatment technology lagging behind implant manufacturing technology. Accordingly, we give this testimony little weight. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little to no weight."). Rather, we agree with Petitioner that Radermacher's statement that bone treatment technology was "lagging behind the technology of implant manufacture" would have caused one of ordinary skill in the art to consider implant-manufacturing technology, such as Fell, when designing bone treatment technology. *See* Ex. 1003, 6.

Patent Owner also disputes Petitioner's assertion that it would have been obvious to combine Radermacher and Fell because the combination

would simplify the surgery, relying upon its arguments as discussed in connection with Alexander. PO Resp. 73. Patent Owner asserts here that substituting Fell's MRI data for Radermacher's MRI data would not result in a device tailored to cartilage and, even if one made the substitution, Radermacher's template only matches bone. *Id.* at 74.

We find this argument unpersuasive for the same reasons set forth above concerning the combination of Radermacher and Alexander. In particular, this argument is based on the flawed assertion that Radermacher's template already avoids cartilage, e.g., through use of recesses. As discussed above, we are unpersuaded that Radermacher's embodiments involving recesses apply to the templates that address the knee joint. As also discussed above, Petitioner's proposed modification does not involve substituting Fell's MRI data for Radermacher's, such that this argument is not responsive.

After considering all of the evidence and arguments, we determine that Petitioner has provided a persuasive articulated reason with rational underpinning to support its contention that a person of ordinary skill would have had a reason or motivation to combine Radermacher, Fell, and Woolson in the manner proposed by Petitioner. We also determine that Petitioner has provided analysis explaining how the combination would have conveyed to one of ordinary skill in the art each of the limitations of the claims. Accordingly, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that claim 1 is unpatentable under 35 U.S.C. § 103 as directed to subject matter that would have been obvious to a person of ordinary skill in the art in light of Radermacher, Fell, and Woolson.

With respect to dependent claims 5–14, Petitioner relies upon its analysis presented with respect to the ground of unpatentability based upon Radermacher, Alexander, and Woolson. Pet. 85–89. Patent Owner provides no substantive argument regarding these claims. PO Resp. 66–75 (addressing Fell, as discussed), 75–78 (addressing Woolson, as discussed above). Therefore, we find that Petitioner has demonstrated, by a preponderance of the evidence, that claims 5–14 are unpatentable under 35 U.S.C. § 103 as directed to subject matter that would have been obvious to a person of ordinary skill in the art in light of Radermacher, Fell, and Woolson, for the same reasons discussed above, in Section II.D.5, which analysis we incorporate by reference.

3. Claims 15, 19, and 20

With respect to independent claim 15, and dependent claims 19 and 20, Petitioner relies upon its analysis presented with respect to the ground of unpatentability based upon Radermacher, Alexander, and Woolson. Pet. 85–89. Patent Owner provides no substantive argument regarding these claims. PO Resp. 66–75 (addressing Fell, as discussed), 75–78 (addressing Woolson, as discussed above), 78–79 (addressing claims 15–20). Therefore, we find that Petitioner has demonstrated, by a preponderance of the evidence, that claims 15, 19, and 20 are unpatentable under 35 U.S.C. § 103 as directed to subject matter that would have been obvious to a person of ordinary skill in the art in light of Radermacher, Fell, and Woolson, for the same reasons discussed above, in Section II.D.6–7, which analysis we incorporate by reference.

G. Obviousness over the Combined Teachings of Radermacher, Fell, Woolson, and Biscup

We instituted *inter partes* review for claims 2–4 and 16–18 based on the combination of Radermacher, Fell, Woolson, and Biscup. *See supra* n.1 (including claim 2 in this ground).

Petitioner contends that claims 2–4 and 16–18 of the '025 patent are unpatentable as obvious over the combined teachings of Radermacher, Fell, Woolson, and Biscup. Pet. 88–90 (claims 2 and 16), 89–90; *see also* Dec. on Inst. 6 n.5. Patent Owner argues that Biscup fails to cure deficiencies in Petitioner's presentation regarding Radermacher, Fell, and Woolson. PO Resp. 78. For reasons that follow, we determine Petitioner has met its burden and demonstrated by a preponderance of the evidence that these claims are unpatentable.

Petitioner contends that Fell discloses selecting implants from a library of pre-existing implants, as required by claims 2 and 16. PO Resp. 88 (citing Ex. 1005, 14–15), 89. According to Petitioner, "Fell explains that patient-specific implants are 'more likely to be of correct size and shape.'" *Id.* at 89 (citing Ex. 1005, 15, 20–22). Petitioner acknowledges, however, that "Fell does not disclose a system that includes an implant component selected from a pre-existing system and then further shaped based on electronic image data of the patient," as required by claims 3 and 17, but argues that this is taught by Biscup and would have been obvious to incorporate. *Id.* at 90 (relying upon prior analysis (citing Ex. 1002 ¶¶ 182–184)). Finally, Petitioner contends that both Fell and Biscup disclose a customized template that is designed for the patient, as required by claims 4 and 18. *Id.*

Patent Owner does not dispute Petitioner's contentions. *See* PO Resp. 78 (arguing only that Biscup does not teach the claimed patient-specific surface).

We are persuaded by Petitioner. With respect to claims 2 and 14, Fell teaches that a "library" of "'standard' meniscal device molds" may be created. Ex. 1005, 14. This satisfies claims 2 and 14, which require implant components selected from "preexisting systems." *See also* Ex. 1035 ¶¶ 88–89.

With respect to claims 3 and 17, for the same reasons discussed above, *see supra* Section II.E, we are persuaded that Biscup discloses selecting a standard prosthetic implant for further modification. Ex. 1035 ¶¶ 88–89. Biscup suggests that this process solves a need in the art to provide an implant that "can be quickly, accurately, and cost effectively customize[d] for a particular patient." *Id.* ¶ 17. Accordingly, we are persuaded that Petitioner has identified a sufficient reason that would have motivated a person of ordinary skill in the art to modify Radermacher's system as proposed.

With respect to claims 4 and 18, and for the same reasons discussed above (concerning Biscup), *see supra* Section II.E, we are persuaded that Fell and Biscup disclose designing implant components based on image data of the patient's joint. Ex. 1005, 15 ("[E]ach patient receives one or more meniscal devices that are custom tailored for the individual by producing a contour plot of the femoral and tibial mating surfaces and the size of the meniscal cavity. Such a contour plot may be constructed from imaging data, i.e. MRI data."); Ex. 1035 ¶ 88. Likewise, we are persuaded that Petitioner has identified a sufficient reason that would have motivated a person of ordinary skill in the art to modify Radermacher's system as proposed, namely, to provide an implant that "can be quickly, accurately, and cost effectively customize[d] for a particular patient." *Id.* ¶ 17.

III. MOTION FOR OBSERVATIONS

Patent Owner filed a Motion for Observations regarding the cross-examination of Dr. Mabrey. *See* PO Obs. Petitioner, in turn, filed an Opposition to the Motion for Observations. *See* Pet. Resp. Obs.

We have considered Patent Owner's observations and Petitioner's responses in rendering this Final Written Decision, and we have accorded Dr. Mabrey's testimony appropriate weight where necessary.

IV. MOTION TO EXCLUDE

Patent Owner filed a Motion to Exclude Exhibit 1202, Dr. Mabrey's Reply Declaration. *See* PO Mot. Exclude. Petitioner filed an Opposition (*see* Pet. Resp. Mot. Exclude), and Patent Owner filed a Reply (*see* PO Reply Mot. Exclude).

In *inter partes* reviews, documents are admitted into evidence subject to an opposing party asserting objections to the evidence and moving to exclude the evidence. 37 C.F.R. § 42.64. As movant, Patent Owner has the burden of showing that an exhibit is not admissible. 37 C.F.R. § 42.20(c).

Patent Owner argues that Exhibit 1202 is inadmissible under Federal Rule of Evidence 702. PO Mot. Exclude 1–3. Specifically, Patent Owner objects to paragraphs 6, 9, 11, 22, 27, 40, 46, 53, 56, 57, 59, 60, 61, 69, 70, 72, and 74, as failing to disclose the underlying facts or data upon which they rely. *Id.* at 4. Patent Owner also argues that the declaration is unreliable because it mischaracterizes Dr. Clark's declaration, and is used to incorporate arguments by reference into Petitioner's Reply. *Id.* at 10–12.

First, we do not rely on any of the cited paragraphs in rendering our decision, rendering moot this basis for exclusion.

Second, we are not persuaded that Dr. Mabrey's Reply Declaration mischaracterizes Dr. Clark's Declaration, or is used to incorporate arguments by reference improperly into the Reply. *See* Pet. Resp. Mot. Exclude 11–14. We find that Dr. Mabrey's Reply Declaration, read in light of Dr. Clark's testimony, is sufficiently clear and accurate. *Compare* Ex. 1202 ¶¶ 59 (stating that Dr. Clark does not dispute that bone and cartilage are the only surfaces for matching, but acknowledging that Dr. Clark opines that a person of ordinary skill in the art "would not have considered matching cartilage"), 60 (stating that Dr. Clark does not dispute that matching cartilage would simplify surgery, but acknowledging that Dr. Clark opines that simplification is irrelevant because Radermacher avoids cartilage), *with* Ex. 2005 ¶¶ 144–147 (opining that matching either bone or cartilage is not a simple design choice because those surfaces are not interchangeable, such that one "would not have chosen" to match cartilage, but *not* opining that other surfaces are available for matching or that matching cartilage would not simplify surgery), 148–149 (disagreeing that matching cartilage would simplify surgery because of Dr. Clark's stated opinion that Radermacher already avoids cartilage, but *not* opining that matching cartilage would not simplify surgery in the absence of that reasoning).

We also find that Petitioner's Reply sufficiently sets forth its arguments without improperly incorporating Dr. Mabrey's Reply Declaration. *Compare* Ex. 1202 ¶¶ 20–27 (discussing Radermacher's disclosure, including the meaning of "natural (i.e. not pre-treated)"), *with* Pet. Reply 3–11 (same).

Finally, the Board accords the appropriate weight to the testimony of each declarant considering, in part, the identified basis for each declarant's opinion. *See* 37 C.F.R § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). Additionally, the Board disregards arguments that are not made explicitly in the Petition or Reply. The Board is able to make this determination by reviewing the arguments and evidence, and a Motion to Exclude on the basis that arguments from a declaration are improperly incorporated by reference into the Petition or Reply is unnecessary.

Accordingly, Patent Owner's Motion to Exclude is *denied*.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–20 of the '025 patent have been shown to be *unpatentable*;

FURTHER ORDERED that Patent Owner's Motion to Exclude (Paper 22) is *denied*;

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2017-00115
Patent 9,216,025 B2

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

WORTH, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

Opinion for the Board filed by *Administrative Patent Judge* WIEKER.

Opinion Concurring-in-part and Dissenting-in-part filed by *Administrative Patent Judge* WORTH.

JAMES A. WORTH, *Administrative Patent Judge, Concurring-in-part and Dissenting-in part.*

I respectfully dissent with respect to claims 1–14 because I would determine that Petitioner has failed to prove satisfaction of the "cartilage surface" limitation of independent claim 1. Independent claim 15 does not have a "cartilage surface" limitation, and I concur with the conclusion of unpatentability with respect to claims 15–20.

Radermacher, Alexander, and Woolson

Claims 1 and 5–14

Claim 1 requires a surgical tool that corresponds to the cartilage surface of a joint, i.e., "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 of the patient." The issue is whether the prior art relied on by Petitioner taught putting a surgical tool on a cartilage surface of a joint, or whether a person of ordinary skill would have had a reasonable expectation of success in doing so, on this record.

Petitioner relies on a passage in Radermacher which discloses generating a "three-dimensional negative mold of parts of the individual natural (i.e. not pre-treated) surface of the osseous structure intraoperatively accessed by the surgeon." Ex. 1003, 12 (*cited and excerpted at* Pet. 26). In this manner, Radermacher discloses a template to be placed on an "osseous structure" to serve as a cutting guide for orthopedic surgery prior to placement of a prosthesis. Ex. 1003, 13. Petitioner argues that an "osseous structure" is more than "osseous" or bony. *See* Reply 4–5. However, Petitioner and Petitioner's expert do not provide adequate support for the proposition that an "osseous structure" is necessarily more than bone (nor that "osseous structure" would have been recognized as a term of art).

Patent Owner's expert avers that an "osseous structure" refers to a "bone" structure. Ex. 2005 ¶ 75 and n.8.

Petitioner argues that, in context, the "osseous structure" is "not pre-treated," "natural," and "intra-operatively accessed." Pet. 26, 54. However, in order to define "not pre-treated," Patent Owner points to a definition in Radermacher for "treatment":

> The term "treatment" is understood to comprise not only the treatment of an osseous structure by suitable tools (cutting, boring, milling device) but also other forms of treatment such as e.g. invasive measuring and scanning of osseous structures by corresponding measuring devices.

Ex. 1003, 9 (cited in PO Resp. 20). Applying Radermacher's own definition, when Radermacher refers to a "not pre-treated" osseous structure, this includes an "osseous structure" that has not yet been subject to cutting or boring. Ex. 2005 ¶ 78. Petitioner has not shown that the "not pre-treated" "osseous structure" necessarily includes cartilage. In fact, as argued by Patent Owner, Radermacher discloses placement of the template on the "exposed bone surface." Ex. 1003, 15; PO Resp. 22.

Petitioner argues that Radermacher does not disclose removing cartilage. Pet. 28. However, Radermacher does not refer to cartilage at all. Radermacher is silent both as to the presence or absence of cartilage. I would find that Petitioner has not proven that Radermacher inherently teaches placing a template on top of cartilage. *See Southwire Co. v. Cerro Wire LLC*, 870 F.3d 1306, 1311 (Fed. Cir. 2017) ("While '[w]e have recognized that inherency may supply a missing claim limitation in an obviousness analysis,' *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1194–95 (Fed. Cir. 2014) (collecting cases), we have emphasized that 'the limitation at issue *necessarily* must be present' in order to be inherently

disclosed by the reference, *id.* (emphasis added)"); *see also Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A.*, 865 F.3d 1348, 1354–55 (Fed. Cir. 2017).

If anything, Radermacher expressly teaches placing the template on exposed bone. Dr. Mabrey's testimony that a person of ordinary skill would have placed Radermacher's template on cartilage is unsupported. Ex. 1002 ¶¶ 80–81. In the face of the express teaching of Radermacher of mating exposed bone, I regard Petitioner's arguments that cartilage was present to be speculative.

Petitioner argues that a person of ordinary skill in the art would have combined Radermacher with Alexander to arrive at a template that a person of ordinary skill in the art would have placed on cartilage. However, Alexander deals with imaging and does not teach a surgical template for cutting.

The next issue is whether Petitioner has proven a reasonable expectation of success in combining Radermacher with Alexander to place a template on cartilage. Petitioner bears the burden of proof on this issue. 35 U.S.C. § 316(e); 37 C.F.R. § 42.20(a); *see also Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. De C.V.*, 865 F.3d 1348, 1355 (Fed. Cir. 2017) (discussing allocation of the burdens in the context of reexamination). Petitioner and Petitioner's declarant provide assertions that there existed a reasonable expectation of success without support. Pet. 30, 34, 88; Ex. 1002 ¶¶ 105. I regard these assertions as conclusory. *See Dominion Energy v. Alstom Grid*, No. 2017-1158, 2018 WL 1325850 (Fed. Cir. Mar. 15, 2018) (non-precedential) ("Dr. Brown's testimony, however, does not provide substantial evidence to support the jury's verdict because his testimony was

conclusory, unsupported, contrary to the evidence in the case, or not directed to the claim limitation at issue.").

Further, Patent Owner contends that there is a problem with Petitioner's proposed combination because diseased or damaged cartilage is relatively weak and may become frayed or delaminated. PO Resp. 62 (citing Ex. 2005 (Clark Decl.) ¶¶ 115, 142; Ex. 2010, 148:21–150:16). Dr. Clark, Patent Owner's Declarant, explains it this way: "Diseased or damaged cartilage may be secured to the subchondral bone, but unlike healthy cartilage, it is relatively weak and may be frayed." Ex. 2005 ¶ 115. Dr. Mabrey, Petitioner's Declarant, similarly testified that damaged cartilage can be "fibrillated" with a "shag carpet" or "crab meat" appearance. Ex. 2014, 33:1–18. The claim at issue is based on creating a mating of the surface of the cartilage with a negative corresponding surface. Petitioner does not adequately explain how one would have corresponded a template to damaged cartilage that is frayed or delaminated. I would determine that Petitioner has not satisfied its burden of proof on this issue.

As such, I would determine that Petitioner has not proven that a person of ordinary skill in the art would have combined Radermacher with Alexander to arrive at the invention of claim 1, or that claim 1 would otherwise have been rendered obvious to a person of ordinary skill at the time of the invention based on the asserted prior art. Claims 5–14 depend directly or indirectly from claim 1. Accordingly, I would determine that Petitioner has not proven its case with respect to claims 5–14, for the same reasons as for claim 1.

Claims 15, 19, and 20

Claim 15 recites a tool that "is substantially a negative of a corresponding portion of a diseased or damaged articular surface of the joint." Claim 15 does not refer to the cartilage surface, but simply refers to the "articular surface." As discussed above, Patent Owner argues that Radermacher places the template on exposed bone. PO Resp. 22. Although Petitioner relies on joints with cartilage on the surface of the joints in the nondiseased state (*see* Pet. 54–61)[9, 10], some patients will have exposed bone where "portion[s]" of cartilage have worn away. Pet. 29; Ex. 2005 ¶ 17.3; PO Resp. 8 (citing Ex. 2005 ¶¶ 17–18; Ex. 2007, 753). Radermacher's surgical tool would correspond to a portion of the articular surface in these patients, e.g., the exposed bone, whether or not the surrounding cartilage would have to be removed before placement of the surgical tool. Accordingly, the claim limitation would be met sometimes, i.e., when surgical tools are made for the group of patients with exposed bone, which is sufficient for a showing of obviousness. *See Power Integrations, Inc. v. Fairchild Semiconductor International, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016) (anticipation of claim for power supply regulator where current threshold met in one mode of operation) (citing *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1002 (Fed. Cir. 2016); *Hewlett–Packard Co. v.*

[9] Some joints lack cartilage in the native state. Petitioner relies on the knee joint which is cartilaginous in the native state. *See* Pet. 56; Ex. 1002 ¶ 36.

[10] Patent Owner asserts that Radermacher discloses putting a mold on non-abutting segments of exposed bone. PO Resp. 21 (citing Ex. 1003, 12–13; Ex. 2005 ¶ 79). Although Radermacher suggests such a method for operating on vertebra, it is not clear that Radermacher suggests this approach for knee arthroplasty (as opposed to removing all cartilage). *See* Ex. 2005 ¶ 85.

Mustek Sys., Inc., 340 F.3d 1314, 1326 (Fed. Cir. 2003) (quoting *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 622–623 (Fed. Cir. 1995))); *cf. Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311–12 (Fed. Cir. 2005) (discussing law in context of infringement of apparatus claim) ("However, Cross Medical again fails to recognize that the limitation—the anchor seat being in contact with bone—is absent until the screw and anchor are put in place during surgery. . . . As to the predicate act of direct infringement, we conclude that there is a genuine issue of material fact as to whether surgeons infringe by making the claimed apparatus.").

Radermacher, Alexander, Woolson, and Biscup

Petitioner asserts that Radermacher, Alexander, Woolson and further in view of Biscup render obvious claims 2–4 and 16–18.

Claims 2–4

Biscup discloses a customized implant. Ex. 1035 ¶¶ 17, 88. Biscup discloses a prosthetic implant that matches "bone and/or tissue to be replaced," i.e., in the finished product, but does not explicitly disclose matching cartilage, and does not disclose a *surgical tool* that corresponds to a native cartilage surface to be operated on. *See* Ex. 1035 ¶ 17. As such, Biscup does not remedy the deficiency in the asserted ground based on Radermacher, Alexander, and Woolson, with respect to claim 1. Accordingly, I would conclude that Petitioner has not proven its case with respect to claims 2–4, which depend from claim 1.

Claims 16–18

Patent Owner does not separately argue the patentability of claims 16–18 from independent claim 15. I would conclude that Radermacher,

Alexander, Woolson and further in view of Biscup render obvious claims 16–18, for similar reasons as for claim 15.

Radermacher and Fell and Woolson, alone or further in view of Biscup

Petitioner relies on Fell instead of Alexander. I would reach the same conclusions for the grounds based on Radermacher, Fell, and Woolson, alone or further in view of Biscup, for similar reasons as for the grounds based on Radermacher, Alexander, and Woolson, alone or further in view of Biscup.

PETITIONER:

Christy G. Lea
Joseph R. Re
Colin B. Heideman
KNOBBE, MARTENS, OLSON, & BEAR, LLP
2cgl@knobbe.com
2jrr@knobbe.com
2cbh@knobbe.com

PATENT OWNER:

Sanya Sukduang
Timothy P. McAnulty
Daniel F. Klodowski
Kassandra M. Officer
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
sanya.sukduang@finnegan.com
timothy.mcanulty@finnegan.com
daniel.klodowski@finnegan.com
kassandra.officer@finnegan.com