

Filed on behalf of: ConforMIS, Inc.

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Paper No. __

Filed: May 25, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2016-01874
Patent No. 9,055,953

PATENT OWNER'S NOTICE OF APPEAL

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
Madison Building East, 10B20
600 Dulany Street
Alexandria, VA 22314-5793

Pursuant to 35 U.S.C. §§ 141(c) and 319 and 37 C.F.R. § 90.2(a), Patent Owner ConforMIS, Inc. (“ConforMIS”) hereby provides notice that it appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered March 26, 2018, (Paper No. 31), and from all underlying orders, decisions, rulings, and opinions relating to U.S. Patent No. 9,055,953 (“the ’953 patent”), set forth in *Inter Partes* Review IPR2016-01874.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), the issues on appeal include, but are not limited to:

- the United States Patent and Trademark Office (“PTO”) Patent Trial and Appeal Board (“Board”) unpatentability determinations, including without limitation issues relating to (i) the Board’s reliance on a ground of unpatentability never instituted; (ii) the Board’s legally deficient *Graham* analysis, including its improper motivation-to-combine analysis and its complete lack of reasonable-expectation-of-success analysis; (iii) the lack of substantial evidence support for the

Board's findings regarding *Radermacher*'s¹ disclosure; and (iv) the Board's failure to comply with 35 U.S.C. § 316(e);

- the Board's determination that claims 4-6, 10, 12-16, 19, 24-26, 30, 32-36, 40, 55, and 57 of the '953 patent are unpatentable under 35 U.S.C. § 103 over *Radermacher* and *Alexander*;²
- the Board's determination that claims 17, 18, 20, 37-39, 41, 45-47, 49, and 54 of the '953 patent are unpatentable under 35 U.S.C. § 103 over *Radermacher*, *Carignan*,³ and *Alexander*;
- the Board's determination that claims 4-6, 10, 12-16, 19, 24-26, 30, 32-36, 40, 55, and 57 of the '953 patent are unpatentable under § 103 over *Radermacher* and *Fell*;⁴
- the Board's determination that claims 17, 18, 20, 37-39, 41, 45-47, 49, and 54 of the '953 patent are unpatentable under 35 U.S.C. § 103 over *Radermacher*, *Carignan*, and *Fell*;

¹ PCT Publication No. WO 93/25157

² PCT Publication No. WO 00/35346

³ U.S. Patent No. 6, 712,856

⁴ PCT Publication No. WO 00/59411

- any other issue decided adversely to ConforMIS in an order, decision, ruling, or opinion underlying or supporting the Board's Final Written Decision.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a), this Notice is being filed with the Director of the PTO, and a copy of this Notice is being concurrently filed with the Board. In addition, a copy of this Notice and the required docketing fees are being filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit via CM/ECF.

Respectfully submitted,

Date: May 25, 2018

By: /Sanya Sukduang/
Sanya Sukduang
Reg. No. 46,390

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE AND FILING

I hereby certify that on this 25th day of May, 2018, in addition to being filed and served electronically through the Board's E2E System, a true and correct copy of the foregoing Patent Owner's Notice of Appeal was served on the Director of the PTO, via Express overnight delivery at the following address:

Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I also hereby certify that on this 25th day of May, 2018, a true and correct copy of the foregoing Patent Owner's Notice of Appeal and the filing fee, were filed with the Clerk's Office of the United States Court of Appeals for the Federal Circuit, via CM/ECF.

I also hereby certify that on this 25th day of May, 2018, a true and correct copy of the foregoing Patent Owner's Notice of Appeal was served, by electronic mail, upon the following:

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Dated: May 25, 2018

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EXHIBIT 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2016-01874
Patent 9,055,953 B2

Before PATRICK R. SCANLON, JAMES A. WORTH, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

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

Opinion Dissenting filed by *Administrative Patent Judge* WORTH

SCANLON, *Administrative Patent Judge*.

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

I. INTRODUCTION

Smith & Nephew, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–61 of U.S. Patent No. 9,055,953 B2 (Ex. 1001, “the ’953 patent”). ConforMIS, Inc. (“Patent Owner”) did not file a Preliminary Response. The Board instituted a trial as to claims 1–61 of the ’953 patent. Paper 6 (“Dec. on Inst.”).

After institution of trial, Patent Owner filed a Patent Owner Response (“PO Resp.”) to the Petition. Paper 9. Patent Owner also filed a statutory disclaimer of claims 1–3, 7–9, 11, 21–23, 27–29, 31, 42–44, 48, 50–53, 56, and 58–61. PO Resp. 1 n.1; Ex. 2013. Accordingly, the only claims remaining for our consideration at trial are claims 4–6, 10, 12–20, 24–26, 30, 32–41, 45–47, 49, 54, 55, and 57. *See* 35 U.S.C. § 253 (disclaimer of claims considered effective as if part of original patent); 37 C.F.R. § 42.107 (Board will not institute trial on disclaimed claims). Petitioner filed a Reply (“Reply”) to the Patent Owner Response. Paper 13. Petitioner relies on the Declaration of Jay D. Mabrey, M.D. (Ex. 1002) in support of its Petition, and a second Declaration of Jay D. Mabrey, M.D. (Ex. 1202) in support of its Reply. Patent Owner relies on the Declaration of Charles R. Clark, M.D. (Ex. 2005) in support of its Response.

Patent Owner filed a Motion to Exclude Exhibit 1202. Paper 18 (“PO Mot. to Exclude”). Petitioner filed an Opposition to the Motion to Exclude and Patent Owner filed a Reply in Support of its Motion to Exclude. Paper 23 (“Pet. Exclude Opp.”); Paper 26 (“PO Exclude Reply”).

Patent Owner filed a Motion for Observations regarding the cross-examination of Dr. Mabrey. Paper 19 (“PO Mot. for Observation”).

Petitioner filed an Opposition to the Motion for Observations. Paper 24 (“Pet. Observation Opp.”).

An oral hearing was held on December 18, 2017, and the record contains a transcript of this hearing. Paper 30 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 4–6, 10, 12–20, 24–26, 30, 32–41, 45–47, 49, 54, 55, and 57 of the ’953 patent are unpatentable.

II. BACKGROUND

A. *Related Matters*

The parties identify the following district court proceeding as a related matter: *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass. Feb. 29, 2016). Pet. 1; Paper 5, 2; Paper 29 (noting dismissal).

B. *The ’953 Patent*

The ’953 patent is titled “Methods and Compositions for Articular Repair,” and relates to orthopedic methods, systems, and prosthetic devices for articular resurfacing. Ex. 1001, [54], 1:27–29. Patent Owner represented during prosecution that the priority date is March 12, 2002. Pet 23 (relying on Ex. 1017, 142 for priority date of March 12, 2002). In one embodiment, the ’953 patent discloses replacing a diseased portion of a joint (e.g., cartilage and/or bone) with a non-pliable, non-liquid (e.g., hard) implant material, such that the implant achieves a “near anatomic” fit with the surrounding structures and tissues. *Id.* at 2:54–59. The ’953 patent describes providing cartilage replacement according to measurements made

using imaging techniques such as ultrasound, MRI, CT scan, x-ray imaging obtained with x-ray dye, or fluoroscopic imaging. *Id.* at 3:4–31. The '953 patent also discloses replacing subchondral bone or providing a partial articular prosthesis composed of metal or metal alloy. *Id.* at 4:17–62.

In another embodiment, the '953 patent discloses a surgical tool, composed of lucite and/or silastic, which conforms to the shape of the articular surfaces of the joint (e.g., a femoral condyle and/or tibial plateau of a knee joint). *Id.* at 5:56–61. This surgical tool can be used to control drill alignment, depth, and width when preparing a site to receive an implant. *Id.* at 30:16–26, Figs. 13, 15, 16.

Figure 15 of the '953 patent is depicted below:

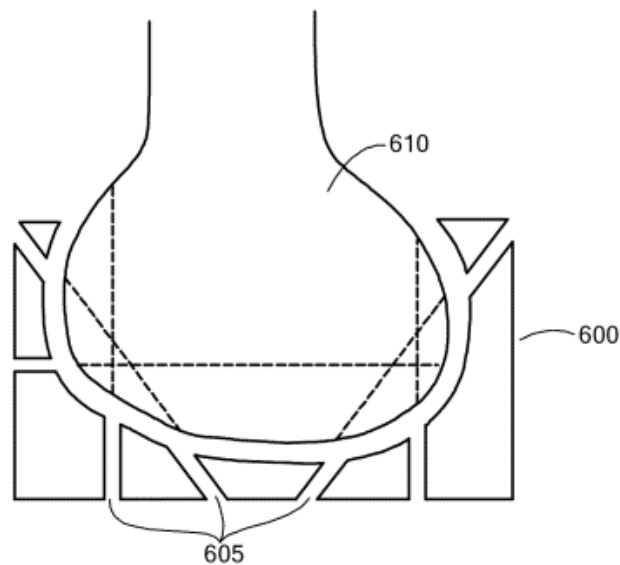


FIG. 15

Figure 15 illustrates, in cross-section, an example of surgical tool 600 containing apertures 605 through which a surgical drill or saw can fit and which guide the drill or saw to make cuts or holes in bone 610. *Id.* at 8:42–

44. Dotted lines represent where the cuts corresponding to the apertures will be made in bone. *Id.* at 8:44–46.

C. Illustrative Claims

The '953 patent has 61 claims, of which claims 1, 12, 21, 32, 42, 50, and 61 are independent. As noted above, Petitioner challenges claims 1–61, and Patent Owner disclaims claims 1–3, 7–9, 11, 21–23, 27–29, 31, 42–44, 48, 50–53, 56, and 58–61. Claims 12 and 32, therefore, are the only independent claims of the remaining claims (claims 4–6, 10, 12–20, 24–26, 30, 32–41, 45–47, 49, 54, 55, and 57), although claims 4–6 and 10 depend from claim 1, claims 24–26 and 30 depend from claim 21, claims 45–47 and 49 depend from claim 42, and claims 54, 55, and 57 depend from claim 50. Claims 12 and 32 are reproduced below.

12. A surgical instrument for the repair of a diseased or damaged cartilage surface of a joint, comprising:

an inner surface having a curvature or shape based on information from image data of the diseased or damaged cartilage surface; and

a slit defining a cutting path through at least a portion of the joint when the inner surface is applied to the diseased or damaged cartilage surface.

Ex. 1001, 35:20–27.

32. A surgical instrument for the repair of a diseased articular joint surface of a joint, comprising:

an inner surface having a curvature that matches a curvature of cartilage of the diseased articular joint surface; and

a slit defining a cutting path through at least a portion of the joint when the inner surface is applied to the diseased articular joint surface.

Id. at 36:22–29.

D. Grounds of Unpatentability at Issue

We instituted an *inter partes* review of claims 1–61 of the '953 patent on the following grounds:

| Reference(s) | Basis | Claims Challenged | Remaining Claims |
|---|--------------|--|--|
| Radermacher ¹ | § 103 | 1–3 and 21–23 | none |
| Radermacher and Alexander ² | § 103 | 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 50–53, and 55–61 | 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 55, and 57 |
| Radermacher, Alexander, and Carignan ³ | § 103 | 7–9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54 | 17, 18, 20, 37–39, 41, 45–47, 49, and 54 |
| Radermacher and Fell ⁴ | § 103 | 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 50–53, and 55–61 | 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 55, and 57 |
| Radermacher, Alexander, and Carignan | § 103 | 7–9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54 | 17, 18, 20, 37–39, 41, 45–47, 49, and 54 |

Dec. on Inst. 23. Because Patent Owner's disclaimer of claims 1–3, 7–9, 11, 21–23, 27–29, 31, 42–44, 48, 50–53, 56, and 58–61 moots our consideration of the first ground listed in the table above, we do not address that ground in this Final Written Decision.

¹ Radermacher, WO 93/25157, pub. Dec. 23, 1993 (Ex. 1003).

² Alexander, WO 00/35346, pub. June 22, 2000 (Ex. 1004).

³ Carignan, U.S. Patent No. 6,712,856 B1, iss. Mar. 30, 2004 (Ex. 1006).

⁴ Fell, WO 00/59411, pub. Oct. 12, 2000 (Ex. 1005).

III. ANALYSIS

A. *Relevant Legal Principles*

To prevail in challenging Patent Owner's claims, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "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) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). The burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review). Furthermore, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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) where in evidence, so-called secondary

considerations, including commercial success, long-felt but unsolved needs, failure of others, and unexpected results. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

For an obviousness analysis, prior art references must be “considered together with the knowledge of one of ordinary skill in the pertinent art.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)). Moreover, “it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). That is because an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418.

B. Level of Ordinary Skill

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. “The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991). The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the

technology, and the educational level of active workers in the field. *Id.* In a given case, one or more factors may predominate. *Id.* “A less sophisticated level of skill generally favors a determination of nonobviousness . . . while a higher level of skill favors the reverse.” *Innovention Toys, LLC v. MGA Entm’t, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011)).

Relying on the testimony of Dr. Mabrey, Petitioner submits that a person of ordinary skill in the art would be:

(a) an orthopedic surgeon having at least three years of experience in knee arthroplasty surgery; or (b) 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. 23 (citing Ex. 1002 ¶¶ 29–32). Patent Owner indicates that it generally accepts Petitioner’s proposed definition for purposes of this proceeding only, but also suggests that the appropriate skill level would include a resident in orthopedic surgery. PO Resp. 10 (citing Ex. 2005 ¶¶ 50–52).

We determine that the level of ordinary skill proposed by Dr. Mabrey is consistent with the challenged patent and the asserted prior art, and we therefore adopt this definition of the level of ordinary skill in the art for the purposes of the analysis below. We decline Dr. Clark’s suggestion to include both a surgeon who has completed a residency in orthopedic surgery and a resident in orthopedic surgery so long as the surgeon or resident had achieved 150 cases as a rationale for this addition was not provided. Our analysis would not differ, however, if we included Dr. Clark’s suggestion.

C. Claim Construction

In an *inter partes* review, “[a] claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b); *see also* *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under the broadest reasonable interpretation standard, claim terms are given their ordinary and customary meaning in view of the specification, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Furthermore, only those terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Prior to our Decision on Institution, Petitioner proposed a construction for “articular joint surface.” Pet. 25 (citing Ex. 1002 ¶¶ 93–96). In the Decision on Institution, we construed the term “articular joint surface” as “the surface of an articulating bone that includes cartilage and/or exposed subchondral bone.” Dec. on Inst. 7 (citing Ex. 1001, 3:56–58 (“The articular surface may comprise cartilage and/or subchondral bone.”), 35:7–9, 35:10–12; Ex. 1002 ¶ 36).

In its Response, Patent Owner indicates that, while not acquiescing to this interpretation for all proceedings, it “does not contest the Board’s initial interpretation of ‘articular surface’ for the purposes of this proceeding and these claims only.” PO Resp. 11. Petitioner does not address this construction in its Reply. Accordingly, after reviewing the complete record

anew, we reaffirm our prior interpretation of “articular joint surface” for this Final Written Decision.

D. Adverse Judgment

As noted above, Patent Owner has statutorily disclaimed claims 1–3, 7–9, 11, 21–23, 27–29, 31, 42–44, 48, 50–53, 56, and 58–61. PO Resp. 1 n.1; Ex. 2013. Petitioner argues that “[b]ecause the Board’s final written decision must address all challenged claims (35 U.S.C. § 318(a)), an adverse judgment should be entered on the disclaimed claims. 37 C.F.R. § 42.73(b).” Reply 1 n.1; *see also* Tr. 6:3–7:3 (arguing for adverse judgment with respect to the disclaimed claims).

Under the circumstances of this case, we do not agree that adverse judgment with respect to the disclaimed claims is appropriate. A statutory disclaimer “shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.” 35 U.S.C. § 253. The term “considered as part of the original patent” generally has been interpreted to mean that the patent is treated as though the disclaimed claims never existed. *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998). Furthermore, 37 C.F.R. § 42.73(b) provides that a party may request judgment *against itself*. Here, Patent Owner is not requesting adverse judgment against itself. And although 37 C.F.R. § 42.73(b) provides that “[a]ctions construed to be a request for adverse judgment include . . . (2) [c]ancellation or disclaimer of a claim such that the party has *no remaining claim* in the trial” (emphasis added), we decline to construe Patent Owner’s statutory disclaimer as a request for adverse judgment in this proceeding because Patent Owner does

not disclaim all challenged claims, and, therefore, some claims remain in this trial.

E. Asserted Obviousness over Radermacher and Alexander or Fell

As discussed above, Petitioner challenges claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 50–53, and 55–61 as obvious under 35 U.S.C. § 103(a) over Radermacher and Alexander, and over Radermacher and Fell. Pet. 27–38, 49–52. Patent Owner, however, filed a disclaimer for claims 50–53, 56, and 58–61. We, thus, analyze the challenge to the claims remaining at issue, claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 55, and 57.

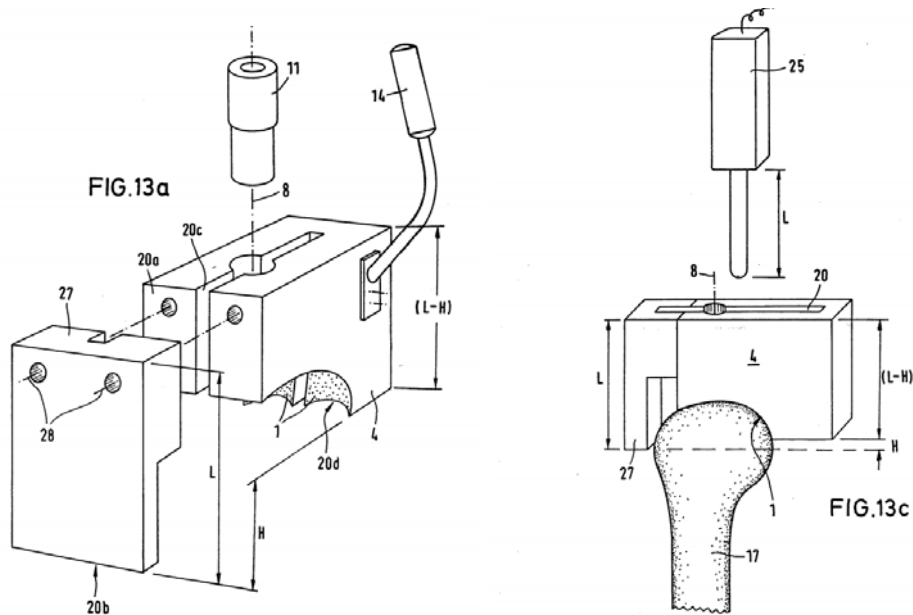
1. Overview of Radermacher

Radermacher, titled “Template for Treatment Tools and Method for the Treatment of Osseous Structures,” relates to certain improvements in the planning and performance of orthopedic surgery. Ex. 1003, 1, 9. Radermacher describes a method in which parts of the surface of an arbitrary osseous structure, which is to be operated upon, are copied as a negative image using computer or nuclear-spin imaging so that an individual template can be intra-operatively set onto the osseous structure with mating engagement. *Id.* at 10. In addition, Radermacher discloses “there is generated 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.” *Id.* at 12.

The template can be provided with any “suitable tool guides,” such as drill sleeves, parallel guides, saw templates, and milling devices, which “effect a three-dimensional guiding of the treatment tools or measuring

devices exactly as provided by the surgical planning.” *Id.* at 13 Use of the template allows treatment of the osseous structure (e.g., cutting, boring, milling, and the like) to be carried out in a safe, fast, and precise manner in accordance to the surgical planning without the need to intraoperatively check the orientation of the treatment tool. *Id.* at 11–12.

Figures 13a and 13c of Radermacher are depicted below:



Figures 13a and 13c schematically show individual template 4 for the preparation of the seat for a knee-joint head prosthesis. *Id.* at 30. Template 4 includes contact faces 1 for abutting bone, drill sleeve 11, cutting plane 20a, and groove 20c. *Id.* at 30, Fig. 13a.

2. Overview of Alexander

Alexander relates to methods “for assessing the condition of a cartilage in a joint, particularly a human knee.” Ex. 1004, Abstract. Alexander discloses a method of obtaining an image of cartilage (preferably a magnetic resonance image), converting the image to a three-dimensional degeneration pattern, and evaluating the degree of degeneration in a volume

of interest of the cartilage. *Id.* at 2. Alexander further discloses calculating the thickness or regional volume of the region thought to contain degenerated cartilage, both at an initial time and a later time, to determine a loss in thickness. *Id.* at 3. Alexander also describes creating a “3D” thickness map. *Id.*

3. Overview of Fell

Fell is titled “Surgically Implantable Knee Prosthesis,” and relates to prosthetic devices, and more particularly, to self-centering knee joint prostheses which may be surgically implanted between the femoral condyle and tibial plateau of the knee. Ex. 1005, 1:4–5. Fell discloses a hard, self-centering meniscal device suitable for implantation into the knee compartment defined by the space between the femoral condyle and the respective tibial plateau. *Id.* at 4:6–9. Fell discloses that the natural meniscus may be maintained in position or may be wholly or partially removed. *Id.* at 5:13–15. Fell further discloses that the meniscal device allows for the provision of non-contacting or recessed areas to encourage articular cartilage regeneration. *Id.* at 8:28–30. Fell describes that the shape of the affected femoral condyle and tibial plateau are ascertained using X-ray or MRI imaging to determine the correct geometry of the meniscal device for a given patient. *Id.* at 14:5–28. Figure 7 of Fell is depicted below:

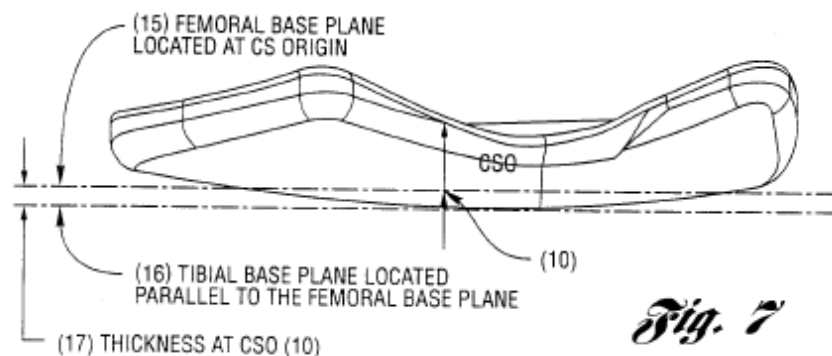


Figure 7 of Fell illustrates a device contour and its relationship with the femoral and tibial base planes. *Id.* at 5:1–2.

4. *Analysis*

As noted by Patent Owner, “[e]ach of claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 55, and 57 is directed to [a surgical] instrument with an inner surface that matches cartilage.” PO Resp. 31 (citing Ex. 1001, 34:62–38:31). Petitioner essentially agrees, stating “[i]n general, [claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 50–53, and 55–61] specify that the inner surface of the instrument matches a size, curvature, or shape of *cartilage* of the joint surface, or includes ‘information of’ the cartilage.”⁵ Pet. 31; *see also* Reply 1 (“The remaining claims recite that the patient-specific surface matches the cartilage portion of the articular surface.”). Due to their similarity, we treat these claims as a group, in accordance with the parties’ arguments. *See* Ex. 1001, claims 4, 14, 24, 34, 35 (concerning cartilage *size*), claims 5, 12, 15, 25, 32 (concerning cartilage *curvature*), claims 6, 12, 13, 16, 26, 33, 36 (concerning cartilage *shape*), claims 10, 19, 30, 40 (concerning *cartilage*), claim 55 (concerning cartilage *thickness*), 57 (concerning *shape* of tissue surrounding cartilage). In addition, each of claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 55, and 57 recites, or depends from a claim reciting, a slit defining a cutting path or configured to guide a surgical blade (“the slit limitation”). Ex. 1001, 34:55–57, 35:25–27, 35:58–60, 36:27–29, 36:61–63, 37:22–23.

⁵ We note that claims 54, 55, and 57 are directed to a surgical device rather than a surgical instrument, but do not see this as a significant distinction.

Petitioner contends that Radermacher's groove or slot 20c meets the slit limitation. Pet. 29–30, 55 (citing Ex. 1003, 11, 13, 25, 26, 30, Figs. 13a–c, 18), 65, 74, 78, and 81–82. Petitioner further contends that Patent Owner has admitted in co-pending litigation that Radermacher discloses providing tool guides in or on its template. *Id.* at 30 (citing Ex. 1024, 21). Based on the full record before us, we adopt Petitioner's contentions regarding the slit limitation, which are uncontested, as our findings because the cited portions of Radermacher support Petitioner's assertions. *See* Ex. 1003, 30, Figs. 13a, 13c (disclosing template 4 having groove 20c); *id.* at 26 (“[A] rear contour analogous limitation 24 of the cutting depth can be provided in/on the individual template 4 or/and the additional individual template 27.”).

Regarding the limitations of the inner surface matching cartilage, including matching its size, shape, curvature, thickness, and the shape of surrounding tissue, much of the parties' dispute is focused on whether Radermacher alone renders this limitation obvious. We note, however, that we declined to institute review of claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 55, and 57 as unpatentable in view of Radermacher alone. Dec. on Inst. 12, 23. Nevertheless, we consider the parties' arguments on this point as they inform our decision on obviousness in view of Radermacher and either Alexander or Fell.

Petitioner argues that

Radermacher discloses that the inner surface of the template matches the size, shape, and curvature of the articular cartilage because Radermacher describes generating a three-dimensional negative mold of “the individual *natural (i.e. not pre-treated) surface* of the osseous structure.” Ex. 1003 at 12 (emphasis added). In an articulating joint such as the knee joint, the “natural (i.e. not pre-treated) surface” of the osseous structure would

include the articular cartilage (as well as any subchondral bone that may be exposed by virtue of the cartilage being worn away). Ex. 1002 ¶¶ 104–105.

Pet. 31. According to Petitioner, “[w]hether [Radermacher’s] surface matches cartilage or subchondral bone or both would depend merely on the condition of a particular patient’s joint.” *Id.* at 32 (citing Ex. 1002 ¶¶ 104–105). Petitioner also argues that if Radermacher’s template was configured to match the subchondral bone, but not any remaining cartilage, then “Radermacher would have described additional surgical steps in which the bone was pre-treated, i.e., cartilage was removed by the surgeon to prepare the site for the individual template.” *Id.* at 32 (citing Ex. 1002 ¶ 105). Instead, argues Petitioner, Radermacher does the opposite in disclosing matching the template to the natural, not pre-treated surface. *Id.* at 32–33 (citing Ex. 1002 ¶ 105; Ex. 1003, 12).

Alternatively, Petitioner argues that if Radermacher does not disclose matching the inner surface of the template to a patient’s cartilage, doing so would have been obvious to one of ordinary skill in the art in view of Radermacher and the knowledge of an ordinarily skilled artisan. *Id.* at 33 (citing Ex. 1002 ¶¶ 107–109). Petitioner asserts that Radermacher discloses using MRI to determine the three-dimensional shape of the patient’s joint and the ’953 patent “admits that MRI was conventional, well-known, and used by those of ordinary skill to determine the size, shape, and curvature of a patient’s cartilage (and/or the subchondral bone).” *Id.* (citing Ex. 1003, 10–12; Ex. 1001, 9:12–27, 11:26–13:3, 14:1–44). Thus, according to Petitioner, it would have been obvious to one of ordinary skill in the art “to use MRI (as taught by Radermacher) to obtain information regarding the size, shape, and/or curvature of a patient’s cartilage (as was common

knowledge) and to make the contact faces of Radermacher's individual template match the patient's cartilage." *Id.* at 34 (citing Ex. 1002 ¶¶ 107–109).

Patent Owner presents several arguments contending that, contrary to Petitioner's assertion, Radermacher does not disclose a surgical instrument having an inner surface that matches cartilage. PO. Resp. 31–48. First, Patent Owner argues that Radermacher consistently states that its template matches "osseous" surfaces and, based on the plain meaning of the words "osseous structure," one of ordinary skill in the art would have understood that Radermacher's inner surface would match bone only. *Id.* at 31–32 (citing Ex. 2005 ¶¶ 99, 102–104). Patent Owner adds that Radermacher consistently uses "osseous" to mean "bone," and uses these two terms interchangeably without once using the term "cartilage." *Id.* at 32 (citing Ex. 2005 ¶¶ 102–104; Ex. 2010, 109:5–7).

With respect to the knee in particular, Patent Owner argues that Radermacher unequivocally states "the 'individual template 4 is *set onto the bone 17* in a defined manner, abutting the contact face 1.'" *Id.* (quoting Ex. 1003, 30 (emphasis added by Patent Owner), citing Ex. 2005 ¶ 110); *see also id.* at 35–37 (discussing Figures 13a–d of Radermacher). Thus, according to Patent Owner, "regardless of whether cartilage is present in the joint or whether the preoperative imaging techniques described by *Radermacher* would show the presence of cartilage, *Radermacher's* individual template is designed to match and be set only on bone." *Id.* at 33 (citing Ex. 2005 ¶ 98). Moreover, Patent Owner argues that "Dr. Mabrey acknowledged that, when *Radermacher* discusses the 'contact surface' of the individual template, it is always in reference to 'bone,' not the 'osseous

structure’ as Dr. Mabrey defined it, the ‘articular surface’ or the ‘joint surface.’” *Id.* at 37 (citing Ex. 2010, 99:8–22, 101:3–18, 110:19–111:11, 213:12–214:2).

Furthermore, Patent Owner argues that “Petitioner errs in its reading of the phrase ‘generat[ing] a three-dimensional negative mold of parts of the individual natural (i.e. not pretreated) surface of the osseous structure’ to mean the individual template matches cartilage.” *Id.* (citing Pet. 31–33; Ex. 1002 ¶ 104). Instead, Patent Owner contends that one of ordinary skill in the art would understand the phrase to mean the natural surface of the bone. *Id.* at 38 (citing Ex. 2005 ¶¶ 115–118). Patent Owner also contends that Radermacher’s description of natural, not pre-treated osseous structures does not necessarily include cartilage because, in addition to the knee, Radermacher describes procedures for vertebrae, hips, and thoracic limbs and these other bones do not include natural cartilage on the surfaces matched by the template. *Id.* (citing Ex. 2005 ¶ 119).

Patent Owner further argues that one of ordinary skill in the art would have considered Radermacher’s use of “not pre-treated” in context with how the reference uses the term “treatment.” *Id.* Patent Owner notes that Radermacher states “[t]he 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.” *Id.* at 38–39 (quoting Ex. 1003, 9 (emphases added by Patent Owner)). Patent Owner asserts that, in view of this disclosure, “one of ordinary skill would have more readily understood ‘not pre-treated’ to mean the bone surface had not been preliminarily treated by cutting, boring, or

milling or by invasive measuring and scanning.” *Id.* at 39 (citing Ex. 2005 ¶ 120).

Also, Patent Owner argues that “one of ordinary skill would have understood that cartilage and bone are two very different structures with different anatomical functions” and, thus, “would not understand ‘osseous structure’ to refer to both bone and cartilage.” *Id.* at 40–41 (citing Ex. 2005 ¶ 117; Ex. 2010, 148:12–152:9, 199:8–12). Patent Owner adds that Alexander, Fell, and Carignan, by referring to cartilage and bone separately, support the notion that “osseous structure” does not refer to bone and cartilage. *Id.* at 41 (citing Ex. 2005 ¶ 118; Ex. 1004, Abstract; Ex. 1005, 2:24–25; Ex. 1006, 6:66–7:2).

In view of the above, Patent Owner concludes:

Considering the full context of *Radermacher* and the meaning of the term “osseous,” one of ordinary skill would not have reached the conclusion that “the natural (i.e. not pre-treated) surface of the osseous structure” means a surface that includes cartilage, but rather understood that *Radermacher*’s individual template did not include cartilage-matching surfaces.

Id. (citing Ex. 2005 ¶ 123).

In reply, Petitioner contends Patent Owner’s argument that “Radermacher’s disclosure should be limited to bone because ‘osseous’ refers to something ‘bony’ . . . depends on a single term taken out of context.” Reply 3 (citing PO Resp. 32). Petitioner asserts that the sentence in *Radermacher* (i.e., “there is generated 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”) “does not refer to bone, but to the natural ‘surface of’ the osseous structure” and maintains that “[t]he natural surface of the femur is the articular surface, e.g., articular

cartilage and exposed subchondral bone.” *Id.* (citing Ex. 1002 ¶¶ 64, 104; Ex. 1202 ¶¶ 21–22, 35–36).

Petitioner also contends Patent Owner’s argument that cartilage and bone are two very different structures with different anatomical functions is irrelevant because, regardless of any such differences, the natural surface of an arthroplasty patient’s femur includes both cartilage and bone. *Id.* at 4. Petitioner similarly discounts Patent Owner’s argument that Radermacher’s entire disclosure does not include matching cartilage because each of Radermacher’s templates used in spine, hip, and foot surgeries matches only bone. *Id.* According to Petitioner, although no cartilage is present in the hip, spine, and foot embodiments, such that the natural surface is bone, that is not true of the femur or tibia in knee arthroplasty. *Id.* (citing Ex. 1202 ¶ 44).

Regarding Patent Owner’s argument that Alexander, Fell, and Carignan support the notion that “osseous structure” does not refer to bone and cartilage, Petitioner argues that none of the references uses the terms “osseous” or “osseous structure,” but show that the natural surfaces of the femur and tibia include both cartilage and exposed bone. *Id.* (citing Ex. 1202 ¶ 43). Furthermore, in response to the argument that “not pre-treated” does not refer to cartilage, Petitioner asserts that Dr. Clark admits that “removing cartilage is precisely the type of pre-treatment that Radermacher states is unnecessary.” *Id.* at 5 (citing Ex. 1203, 155:10–20, 180:11–19).

We agree with Patent Owner that “osseous” refers to “bone” or “bony” and that Radermacher consistently describes its template as contacting bone or osseous structure. We are not persuaded, however, that

Radermacher's phrase "the individual natural (i.e. not pre-treated) surface of the osseous structure intraoperatively accessed by the surgeon" means the natural surface of the bone excluding cartilage. There is no dispute that cartilage is naturally present in knee joints, and as noted by Petitioner, Dr. Clark testifies that over 90% of arthroplasty patients have some cartilage remaining. *See id.* at 3 (citing Ex. 1203, 51:25–52:8). Thus, we find that the natural, not pre-treated surface of the osseous structure comprising the knee will include some cartilage in a vast majority of patients. The fact that other osseous structures mentioned in Radermacher, such as vertebrae, hips, and thoracic limbs, may not include natural cartilage does not change our finding. Similarly, although we agree with Patent Owner that cartilage and bone are different structures with different anatomical functions, this argument also does not change our finding; differences between cartilage and bone do not mean that the majority of arthroplasty patients do not have cartilage in their knees.

Moreover, we agree with Petitioner that Radermacher's use of the term "not pre-treated" refers to cartilage as well as bone. *See id.* at 5. As Petitioner notes, Dr. Clark testifies "[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. Accordingly, we are persuaded that Radermacher's reference to a natural, not pre-treated surface of an osseous structure means that the osseous structure does not have cartilage removed prior to surgery. We also note that Radermacher's definition of "treatment" is open-ended (*see* Ex. 1002, 9 (the term "includes other forms of treatment . . . e.g. . . .")), such

that we are unpersuaded by Patent Owner's argument that Radermacher only refers to avoiding cutting, drilling, or milling prior to placing the template against the patient. PO Resp. 38–39.

In view of the above, we agree with Petitioner that, in an articulating joint such as the knee joint, Radermacher's phrase "the individual natural (i.e. not pre-treated) surface of the osseous structure intraoperatively accessed by the surgeon" includes the articular cartilage and any subchondral bone that may be exposed by virtue of the cartilage being worn away. *See* Pet. 31 (emphasis omitted). This assertion is supported by Dr. Mabrey's testimony, which we credit. *See* Ex. 1002 ¶ 104.

Next, Patent Owner argues that Dr. Mabrey's testimony that the "natural (i.e. not pre-treated) surface of the osseous structure" includes cartilage "is completely inconsistent with his prior statements acknowledging that *Radermacher's* individual template is set onto the 'bone.'" PO Resp. 42. Specifically, Patent Owner points to Dr. Mabrey's declaration in Case IPR2013-00629 in which "Dr. Mabrey interpreted *Radermacher* and explained that it discloses individual templates that 'can be used for 'treatment of *osseous [bone] structures* for any orthopedic intervention,' including a knee arthroplasty.'" *Id.* (quoting Ex. 2003 ¶ 53 (emphasis added by Patent Owner; brackets in original); citing Ex. 2003 ¶ 97; Ex. 2010, 113:3–118:17).

Patent Owner additionally argues that Dr. Mabrey provides a new definition of "osseous structure" that "subjectively includes some soft tissues (e.g. articular cartilage) and excludes others (e.g., meniscus)." *Id.* at 43 (citing Ex. 2010, 89:2–23). According to Patent Owner, Dr. Mabrey's explanation of this definition is inconsistent because he states "the 'osseous

structure’ does not include the meniscus because ‘there’s no bone in the meniscus[],’” but maintains “that the ‘osseous structure’ does include cartilage even though no bone is in the cartilage.” *Id.* (citing Ex. 2010, 90:5–7, 106:16–108:11). Patent Owner also argues “Dr. Mabrey excludes the meniscus even though it is a structure that is attached to and moves with a bone (the tibia).” *Id.* (citing Ex. 2010, 107:21–108:11).

Petitioner responds that Dr. Mabrey’s testimony is not inconsistent with his declaration in Case IPR2013-00629 because, in the declaration, “Mabrey never testified that Radermacher does not disclose *also* matching cartilage—an issue that was irrelevant to that proceeding. Mabrey’s testimony had nothing to do with Radermacher’s disclosure that the template matches the ‘natural (i.e. not pre-treated) surface of the osseous structure intraoperatively accessed by the surgeon.’” Reply 8 (citing Ex. 2003 ¶¶ 53, 97).

We find Petitioner’s argument persuasive. The passage from the prior declaration to which Patent Owner points 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 is 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.

Moreover, we do not agree with Patent Owner’s assertion that Dr. Mabrey’s definition of “osseous structure” is inconsistent because it includes articular cartilage but not the meniscus. Dr. Mabrey’s testimony regarding this definition is as follows:

Q “Osseous structures” as used in the Radermacher reference, how -- how are you interpreting that phrase?

A It’s a fairly general description. “Osseous structures” to me would include the structures with all of the -- in which all mechanical -- *in which all components acted together as one unit.*

So it would include the bone and whatever cartilage was attached to it as the cartilage moved with the bone as one entity.

Q Would it include the meniscus?

A No, it would not.

Q Would it include the ligaments?

A No.

Q Why not?

A Both structures do not move in conjunction with -- with the femur.

Q The meniscus does not move?

A *It moves, but it moves separately from the femur. The cartilage moves directly and exactly with the femur, as it is intimately attached.*

Ex. 2010, 89:2–23 (emphases added). As such, the definition does not rely simply on structures that are connected to a bone or include a bone; instead, it is based on components that act together as one unit. Furthermore, Dr. Mabrey differentiates the meniscus from cartilage because the meniscus moves separately from the femur (i.e., does not act together with the femur as one unit), while the cartilage “moves directly and exactly with the femur, as it is intimately attached.”

As for Patent Owner’s argument that the meniscus is attached to and moves with the tibia, we note Dr. Mabrey testifies “[a] portion of the meniscus is attached to bone. A good portion of it is not. And it moves in a very complex manner with respect to the femur and tibia.” *Id.* at 108:8–11.

Thus, a portion of the meniscus being attached to the tibia does not establish that the meniscus and tibia act together as one unit, and the exclusion of the meniscus from the definition is not inconsistent.

Next, Patent Owner argues that, contrary to Dr. Mabrey's testimony that a skilled artisan would have expected Radermacher to have described removing cartilage if the template matched bone only, "*Radermacher* does not need to expressly state that cartilage can be removed, as it explains that the individual template can be 'a cohesive region *or* a plurality of geometrically *non-abutting partial segments of a bone surface*,' allowing one to avoid structures in the surgical region, such as cartilage." PO Resp. 47 (citing Ex. 1003, 12 (emphasis added by Patent Owner), 22). Similarly, Patent Owner argues that cartilage would not need to be removed to use Radermacher's template because "the template incorporates recesses to accommodate other structures in the surgical region when matched to bone." *Id.* (citing Ex. 2005 ¶ 130; Ex. 1003, 22); *see also id.* at 34 ("*Radermacher*'s 'non-abutting partial segments of bone surface' account for and avoid structures in the surgical area, which can include, depending on the joint, bony protrusions, as seen on the vertebra, or other structures associated with the knee, such as ligaments, tendons, and cartilage."). Moreover, in view of Radermacher disclosing 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 (emphasis added)), Patent Owner argues "the negative mold avoids the cartilage by using just *parts of* the bone surface, i.e., those parts that do not have cartilage on them" and "one would have understood that those 'parts of' the

‘natural (i.e. not pre-treated) surface of the osseous structure’ are the bony parts.” *Id.* at 34 (citing Ex. 2005 ¶ 99).

In its Reply, Petitioner argues that Radermacher does not teach avoiding cartilage with its template. Reply 5–8. In particular, Petitioner argues that one of ordinary skill “would have understood that, while a larger portion of the ‘osseous structure’ may have been imaged, the negative mold is made only of the relevant portion” such that “‘parts’ does not distinguish between bony parts and non-bony parts, but between parts that need to be molded (e.g., articular surface) and other parts for which no mold is necessary (e.g., other parts of the femur).” *Id.* at 6 (citing Ex. 1202 ¶¶ 28, 46). According to Petitioner, “[n]othing in Radermacher suggests that ‘parts’ refers only to ‘bony parts’ or otherwise excludes cartilage.” *Id.* (citing Ex. 1202 ¶ 46).

Petitioner also argues that Dr. Clark admits that “Radermacher never describes using recesses to avoid any soft tissue, let alone cartilage” and “the ‘only thing’ that Radermacher’s figures show the recesses avoiding are ‘bony protuberances.’” *Id.* (citing Ex. 1203, 158:5–9, 158:19–159:3). In addition, Petitioner argues that Dr. Clark admits that Radermacher’s knee template matches a cohesive region and has no recesses and he is “‘postulating’ and ‘assuming’ that the cartilage ‘may be’ in a recess.” *Id.* at 6–7 (citing Ex. 1203, 159:12–22, 230:6–16, 231:11–232:1).

We find Petitioner’s arguments persuasive. Figures 3b and 4 of Radermacher show a template having recesses 5 for accommodating the bony protuberances of vertebra 17. Radermacher does not describe, however, using recesses to avoid any structure other than bony protuberances, such as cartilage; as Patent Owner repeatedly argues,

Radermacher never even uses the term “cartilage.” *See e.g.*, PO Resp. 32. On the other hand, Figures 13a–d of Radermacher show a template for knee arthroplasty. Radermacher does not disclose that this template has a recess, and Dr. Clark testifies that the figures do not show a recess. Ex. 1203, 159:17–22. In other words, Radermacher contemplates providing recesses to avoid at least bony protuberances, but not all embodiments of the template include recesses. *See* Ex. 1003, 10 (disclosing that the template, completely or by segments, copies the surface of the osseous structure). For these reasons, we are not persuaded that Radermacher discloses avoiding cartilage on a natural, not pre-treated surface of an osseous structure intraoperatively accessed by the surgeon.

We now turn to Petitioner’s contention that the limitation of the inner surface matching cartilage would have been obvious in view of Radermacher in combination with Alexander. Specifically, Petitioner contends that matching the contact surface of a template to a patient’s cartilage surface would have been obvious in view of Alexander. Pet. 35 (citing Ex. 1002 ¶¶ 110–115). Petitioner argues that Alexander discloses using various imaging techniques, including MRI and CT scans, to assess the condition of cartilage in a knee joint. *Id.* at 36 (citing Ex. 1004, 2:5–6, 14:16–15:14). Petitioner argues that it would have been obvious to a person of ordinary skill in the art “to combine the teachings of Radermacher and Alexander to create a template that matches the patient’s cartilage surface.” *Id.* at 37 (citing Ex. 1002 ¶¶ 112–115).

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 38 (citing Ex. 1002 ¶ 115; Ex. 1003, Abstract, 3–5, 9).

Patent Owner argues that “[w]hile *Alexander* describes generating three-dimensional cartilage thickness maps, it only teaches using those maps for monitoring the changes in cartilage over time and for diagnostic purposes” and therefore “provides no indication that they would be useful in designing an individual template that includes a cutting guide, such as *Radermacher*'s individual template.” PO Resp. 50–51 (citing Ex. 2005 ¶ 132). Patent Owner adds that *Alexander* does not “relate to methods or surgical instruments for total knee replacement surgeries.” *Id.* at 48 (citing Ex. 2005 ¶¶ 131–133).

In response, Petitioner argues that this argument is contradicted by Patent Owner's expert, Dr. Clark, asserting the Dr. Clark admits that “*Alexander* discloses methods for assessing the condition of a patient's cartilage, and that arthroplasty surgeons are interested in exactly that.” Reply 12 (citing Ex. 1203, 209:22–210:23, 222:24–223:9). Petitioner

further contends that Dr. Clark testifies “if he was designing a patient-specific instrument as in Radermacher, he would be interested in the imaging and modeling that Alexander describes” and one of ordinary skill in the art “designing a patient-specific template would have been interested in references describing methods of mapping the joint surface,” as Alexander discloses. *Id.* (citing Ex. 1203, 207:22–208:6, 224:22–225:1).

Petitioner further argues that “Alexander specifically states that the purpose of assessing the patient’s cartilage is to determine whether ‘joint replacement surgery’ is necessary, or whether alternative treatment options exist.” *Id.* (citing Ex. 1004, 42:10–16; Ex. 1202 ¶12). Furthermore, Petitioner argues that Patent Owner erroneously considers Alexander in isolation, instead of in combination with Radermacher, and Alexander is relevant even if it describes using cartilage maps for a different purpose. *Id.* at 13 (citing *KSR*, 550 U.S. at 420–21).

We find Petitioner’s arguments persuasive. First, Dr. Clark’s testimony indicates that the teachings of Alexander are relevant to the field of patient-specific templates for knee arthroplasty. Second, we agree that Alexander is in the same field of endeavor as the ’953 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). As such, both Alexander and the ’953 patent relate to the treatment of diseased joints. Thus, Patent Owner’s assertion that Alexander is not relevant does not adequately establish that it is a non-analogous reference. *See In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (expressing two tests for defining the scope of analogous art: “(1) whether the art is from the same field of endeavor, regardless of the

problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved").

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. 51 (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. Reply 15–16 (citing Ex. 1004, 15:18–26; Ex. 1202 ¶ 55). Moreover, *Alexander* identifies someone having an advanced degree in imaging technology as just an *example* 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.

Next, Patent Owner argues that *Alexander* discloses cartilage images that are not useful for generating a patient-specific cartilage surface, such as Figure 22B, which includes dark, vertical lines that are not a feature of the actual cartilage. PO Resp. 51–52 (citing Ex. 2005 ¶ 60; Ex. 2010, 185:20–191:17). Petitioner responds that the lines are merely artifacts caused by post-processing of the MRI data. Reply 16 (citing Ex. 2010, 180:23–181:16). Petitioner notes that Dr. Mabrey repeatedly explains that he would use the data underlying *Alexander*'s image to generate a patient-specific template. *Id.* (citing Ex. 2010, 185:9–12, 187:14–16, 188:22–25; Ex. 1202 ¶ 64). On the other hand, Dr. Clark testified that he has no opinion as to whether someone of skill in the art could have used *Alexander*'s imaging

technology to make a patient-specific instrument. Ex. 1203, 222:12–17. Accordingly, based on the evidence before us, we disagree with Patent Owner’s contention that Alexander’s disclosure is not useful for generating a patient-specific cartilage surface.

Patent Owner also argues that Dr. Mabrey admits neither Alexander nor Fell pertain “to tools or implants for arthroplasty procedures and would generally be references directed to sports medicine orthopedic surgeons, not arthroplasty orthopedic surgeons.” PO Resp. 48 (citing Ex. 2010, 139:7–12, 140:4–142:6). Patent Owner then asserts that it would not have been obvious to combine Radermacher and Alexander because sports medicine orthopedic surgeons and arthroplasty orthopedic surgeons focus on different solutions. *Id.* at 51 (citing Ex. 2005 ¶¶ 137–138).

Petitioner argues that any distinction between sports medicine orthopedic surgeons and arthroplasty orthopedic surgeons should be rejected, noting that Dr. Clark testifies that “general orthopedic surgeons ‘treat a lot of sport injuries’ and ‘often prescribe the same treatments’ as sports medicine surgeons.” Reply 14 (citing Ex. 1203, 225:19–24). We agree. Although the focus of sports medicine orthopedic surgeons and arthroplasty orthopedic surgeons may vary, they are all orthopedic surgeons. Any distinction would be too subtle to dissuade one of ordinary skill in the art from considering Alexander when designing a patient-specific template.

Next, Patent Owner argues that the first two reasons presented by Petitioner for combining Radermacher and Alexander—both references relate to methods of treating diseased or damaged cartilage in a knee joint and both references disclose using MRI imaging technology—are improper. PO Resp. 54–55. We agree that these reasons, by themselves, are

insufficient to support a legal conclusion of obviousness. We also agree with Patent Owner that Petitioner's assertion that the proposed modification is simply a design choice, by itself, is an insufficient rationale to cause one of ordinary skill in the art to make the modification. *See id.* 55–58.

As noted above, however, Petitioner asserts that it would have been obvious to combine Radermacher and Alexander in the manner proposed because matching the contact surface to the cartilage surface would simplify the surgery, consistent with Radermacher's goals. Pet. 38. In support of this rationale, Dr. Mabrey testifies that the modification would simplify surgery because “the cartilage would not have to be removed in order for the template to precisely fit on the femur or tibia.” Ex. 1002 ¶ 114.

In response, Patent Owner argues that Radermacher “already simplifies surgery because its individual template specifically contemplates avoiding structures in the surgical region,” e.g., by using a template with recesses to avoid cartilage. PO Resp. 58 (citing Ex. 1003, 22; Ex. 2005 ¶¶ 145–146). For the reasons discussed above, however, we disagree with Patent Owner's contention that Radermacher discloses avoiding cartilage on a natural, not pre-treated surface of an osseous structure intraoperatively accessed by the surgeon. Therefore, based on the full record before us, we determine that this rationale for combining the teachings of Radermacher and Alexander suffices as an articulated reasoning with a rational underpinning that supports the legal conclusion of obviousness. *See KSR*, 550 U.S. at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”).

Regarding Petitioner’s last stated reason for combining the teachings of the prior art, Patent Owner argues that “substituting *Alexander*’s MRI data for *Radermacher*’s MRI data would not result in ‘a device tailored to the patient’s cartilage surface’” because Radermacher’s individual template matches bone surfaces only. PO Resp. 60 (citing Ex. 2005 ¶ 149). This argument is not persuasive because it attacks Radermacher individually and fails to address the proposed combination of references—that is, the argument does not take into account the reliance on Alexander as disclosing using imaging techniques to assess the condition of cartilage in a knee joint. One cannot show nonobviousness by attacking references individually where the rejections are based on a combination of references. *See In re Keller*, 642 F.2d 413, 426 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Moreover, as discussed above, we are not persuaded that Radermacher discloses avoiding or excluding cartilage, as Patent Owner’s argument presumes.

In view of the foregoing and based on the full record before us, we adopt Petitioner’s contentions that the combination of Radermacher and Alexander suggests an inner surface that “matches a size” of cartilage (claims 4, 14, 24, 34, and 35), “matches a curvature” of cartilage (claims 5, 15, 25, and 32), “matches a shape” of cartilage (claims 6, 13, 16, 26, 33, and 36), “includes information” of cartilage (claims 10, 19, 30, and 35), and is “based on information” of cartilage (claim 12).

Regarding claim 55, which recites “the information includes thickness of the normal or diseased cartilage surrounding a cartilage defect of the diseased or damaged joint of the patient” (Ex. 1001, 38:9–12), Petitioner asserts that “it would have been obvious to [one of ordinary skill in the art]

to use information about the thickness of the cartilage surrounding a cartilage defect in order to make the template larger than the defect.” Pet. 85 (citing Ex. 1002 ¶ 116). Petitioner also asserts that Alexander discloses this limitation, relying on the following citations:

Ex. 1004 at 14:23–32 (MRI data allows for assessment of “tissue and its defects, for example articular cartilage and cartilage lesions” and can provide “information about the area of damage”); *id.* (MRI provides accurate assessment of cartilage thickness); *id.* at 27:6–26 (describing cartilage thickness maps); *id.* at 61:19–25; Figs. 18–19.

Id. We have reviewed Dr. Mabrey’s testimony, which we credit, and the cited disclosures from Alexander, and we agree with Petitioner’s uncontested assertion that one of ordinary skill in the art would have considered assessing the thickness of the articular cartilage when designing a patient-specific template for treating a patient’s joint.

Patent Owner argues that, although Petitioner includes claim 55 in the grounds based on Radermacher and either Alexander or Fell, claim 55 depends from claim 54, which is included in the grounds based on Radermacher, either Alexander or Fell, and Carignan. PO Resp. 68. As such, Patent Owner argues that “Petitioner’s arguments regarding claim 55 lack the necessary specificity and particularity” by failing to address Carignan. *Id.* (citing *Nissan North America, Inc. v. Joao Control & Monitoring Sys., LLC*, Case IPR2015-01508, slip op. at 35–37 (PTAB Jan. 25, 2017) (Paper 31)).

Petitioner replies that, although a clerical error was made in placing claim 55 in the grounds not including Carignan, the Petition’s analysis for claim 55 includes claim 54. Reply 24 (citing Pet. 84–85). Petitioner also argues that *Nissan* can be distinguished because the Board’s concern in that

case “was whether the Patent Owner had been provided with proper notice of the allegations against the claim,” while Patent Owner in this case “was provided with proper notice because the Petition addresses claim 55 inclusive of claim 54.” *Id.* (citing *Nissan*, slip op. at 37).

We agree with Petitioner. The claim chart in the Petition references claim 54 as part of its analysis of claim 55. Pet. 85. The analysis for claim 54 asserts how the prior art references, including Carignan, disclose the claimed limitations. *Id.* at 84–85. As such, we determine that the claim chart makes clear that Petitioner intended to rely on Radermacher, together with either Alexander or Fell, and Carignan in asserting that claim 55 was unpatentable. In addition, in *Nissan*, the petitioner’s arguments in regards to claim 104 relied upon the Pagliaroli and LeBlanc references, while the petitioner’s arguments regarding claim 103, from which claim 104 depended, relied upon the Frossard reference. *Nissan*, slip op. at 35–36. The Board noted that the petition lacked “a specific allegation as to how and why the teachings of all three references, Frossard, LeBlanc, and Pagliaroli, may be combined.” *Id.*, slip op. at 37. In this case, the Petition includes specific allegations as to how and why Radermacher, Alexander, and Carignan (discussed above), and Radermacher, Fell, and Carignan (discussed below) would be combined. Accordingly, we determine that the Petition sufficiently (although not ideally because of the clerical error) meets its burden of providing notice of the allegations against claim 55.

Regarding claim 57, which recites “a shape of the area of diseased or damaged joint includes a shape of tissue surrounding or adjacent diseased cartilage” (Ex. 1001, 38:16–18), Petitioner asserts that both Radermacher and Alexander disclose matching a shape at least slightly larger than the area

of the diseased or damaged joint. Pet. 86–87 (citing Ex. 1003, 12; Ex. 1004, 31:5–11, Fig. 22B; Ex. 1002 ¶ 116).

We have reviewed the cited disclosures and agree with Petitioner’s uncontested assertion that these disclosures would have caused one of ordinary skill in the art to consider including the shape of tissue surrounding or adjacent diseased cartilage when designing a patient-specific template for treating a patient’s joint.

After considering all 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 and Alexander in the manner provided. We also determine that Petitioner has provided analysis explaining how the combination would have conveyed to one of ordinary skill in the art the claim limitations. Accordingly, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 55, and 57 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 and Alexander.

Last, we address Petitioner’s contention that the limitation of the inner surface matching cartilage, including its shape, size, curvature, and thickness, would have been obvious in view of Radermacher and Fell. Petitioner relies on Fell instead of Alexander to establish that it would have been obvious to have an inner surface that matches the size, shape, and/or curvature of the cartilage surface. Pet. 49. Petitioner notes that “[u]nlike Alexander, which discloses imaging the cartilage and bone surfaces of the

knee joint, Fell discloses a patient-specific implant that replaces the meniscus, which is cartilage that exists between a femoral condyle and a corresponding tibial plateau.” *Id.* (citing Ex. 1002 ¶ 72).

Petitioner argues that Fell discloses using MRI data to determine the shape of the femur and tibia, including the articular cartilage. *Id.* 49–50 (citing Ex. 1005, 13:15–17, 15:12–21, 22:6–9). According to Petitioner, Fell thus discloses: “(1) using MRI to determine the size, shape, and curvature of an articular cartilage surface: and (2) creating a patient-specific device that matches and mates with the contour of that cartilage surface.” *Id.* at 50.

Petitioner argues that a person of ordinary skill in the art “would have been motivated to combine the teachings of Radermacher and Fell, and thus modify Radermacher’s template to match the size, shape, or curvature of the *cartilage* or *cartilage surface* for several reasons.” *Id.* (citing Ex. 1002 ¶¶ 133–138). These reasons are: (i) both references 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 statement that individualized surgical procedures were “lagging behind the technology of implant manufacture” (Ex. 1003, 6) 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 50–51 (citing Ex. 1002 ¶¶ 134–137; Ex. 1003, 6).

Patent Owner argues that “*Radermacher* and *Fell* relate to different levels of ordinary skill: while *Radermacher* is relevant to an arthroplasty orthopedic surgeon, *Fell* is more relevant to a sports medicine orthopedic surgeon.” PO Resp. 61. For similar reasons as discussed above in connection with Alexander, this argument is not persuasive. Namely, any distinction between sports medicine orthopedic surgeons and arthroplasty orthopedic surgeons would be too subtle to dissuade one of ordinary skill in the art from considering *Fell* when designing a patient-specific template.

Next, Patent Owner argues that the first two reasons presented by Petitioner for combining *Radermacher* and *Fell*—both references relate to methods of treating damaged cartilage in a knee joint and both references disclose using MRI imaging technology—are improper. PO Resp. 62–65. We agree that these reasons, by themselves, are insufficient to support a legal conclusion of obviousness. However, as discussed above with respect to Alexander, the Petition provides further reasoning.

Moreover, we are not persuaded by Patent Owner’s argument 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.” *See* PO Resp. 63–65 (citing Ex. 1002 ¶ 134; Ex. 2010, 161:7–9, 161:10–162:16, 177:4–7, 208:23–213:8). According to Patent Owner, if *Fell*’s device “precisely matched” the cartilage surface, “it would lock in one position and

prohibit the joint from articulating.” *Id.* at 64. As such, Patent Owner contends there would not have been a reasonable expectation of success. *Id.*

We find this argument unpersuasive because it is not responsive to the proposed modification, which involves using Fell’s teaching of using cartilage information obtained through MRI to “modify Radermacher’s template to match the size, shape, or curvature of the *cartilage* or *cartilage surface* for several reasons.” Pet. 50. The proposed modification does not involve bodily incorporating the patient-specific surface 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*, such that it substantially matches 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).

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.” *Id.* at 65 (citing Ex. 2005 ¶ 164).

The only support provided for asserting that the issue of bone treatment technology lagging behind the technology of implant manufacture was addressed by Radermacher’s individual template is the testimony of Dr. Clark. *Id.* (citing Ex. 2005 ¶ 164). Dr. Clark’s testimony, however, merely repeats this statement from the Patent Owner Response without

providing any supporting evidence or reasoning. Ex. 2005 ¶ 164. There is no 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 when designing bone treatment technology.

Furthermore, Patent Owner argues that Petitioner's assertion that it would have been obvious to combine Radermacher and Fell because the combination would simplify the surgery is erroneous for the same reasons argued in connection with Alexander. PO Resp. 66. We find this argument unpersuasive for the same reasons set forth above; namely, that the argument is based on the flawed assertion that Radermacher's template avoids cartilage. Patent Owner also argues that Petitioner's fifth reason for combining Radermacher and Fell is erroneous for the same reasons argued in connection with Alexander. *Id.* at 66–67. Again, we find this argument unpersuasive for the same reasons set forth above.

In view of the foregoing and based on the full record before us, we adopt Petitioner's contentions that the combination of Radermacher and Fell suggests an inner surface that "matches a size" of cartilage (claims 4, 14, 24,

34, and 35), “matches a curvature” of cartilage (claims 5, 15, 25, and 32), “matches a shape” of cartilage (claims 6, 13, 16, 26, 33, and 36), “includes information” of cartilage (claims 10, 19, 30, and 35), and is “based on information” of cartilage (claim 12).

Regarding claim 55, Petitioner asserts that “it would have been obvious to [one of ordinary skill in the art] to use information about the thickness of the cartilage surrounding a cartilage defect in order to make the template larger than the defect.” Pet. 85 (citing Ex. 1002 ¶ 116). Petitioner also asserts that Fell discloses “obtaining cartilage information for the femoral and tibial surfaces, which would include normal or diseased cartilage surrounding a defect.” *Id.* (citing Ex. 1005, 15:12–21, 14:13–15:21, 22:6–9; Ex. 1002 ¶¶ 72–73). We have reviewed Dr. Mabrey’s testimony, which we credit, and the cited disclosures from Fell and agree with Petitioner’s uncontested assertion that one of ordinary skill in the art would have considered assessing the thickness of the articular cartilage when designing a patient-specific template for treating a patient’s joint.

Regarding claim 57, Petitioner asserts that both Radermacher and Fell disclose matching a shape at least slightly larger than the area of the diseased or damaged joint. Pet. 86–87 (citing Ex. 1003, 12; Ex. 1005, 15:12–21; Ex. 1002 ¶ 116).

We have reviewed the cited disclosures and agree with Petitioner’s uncontested assertion that these disclosures would cause one of ordinary skill in the art to consider including the shape of tissue surrounding or adjacent diseased cartilage when designing a patient-specific template for treating a patient’s joint.

After considering all 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 and Fell in the manner provided. We also determine that Petitioner has provided analysis explaining how the combination would have conveyed to one of ordinary skill in the art the claim limitations. Accordingly, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 55, and 57 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 and Fell.

F. Asserted Obviousness over Radermacher, Carignan, and Alexander or Fell

As discussed above, Petitioner challenges claims 7–9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54 as obvious under 35 U.S.C. § 103(a) over Radermacher, Alexander, and Carignan and over Radermacher, Fell, and Carignan. Pet. 39–49, 52. Patent Owner, however, filed a disclaimer for claims 7–9, 11, 27–29, 31, 42–44, and 48. We, thus, analyze the challenge to the claims remaining at issue, claims 17, 18, 20, 37–39, 41, 45–47, 49, and 54.

1. Overview of Carignan

Carignan is titled “Custom Replacement Device for Resurfacing a Femur and Method of Making Same,” and relates to a replacement device for a knee joint, and more particularly, to a customized device for resurfacing the trochlear groove of a femur. Ex. 1006, 1:7–12. In order to implant the replacement device, Carignan discloses a step of removing the natural

cartilage that is diseased in order to better secure the prosthesis to the bone and to allow the patient's bone to grow into the prosthesis. *Id.* at 7:4–8, 7:43–46. Carignan proceeds to describe the use of marking template 300 with a first surface that matches the trochlear groove of the femur, and with a second surface that contains holes 306 to serve as drilling guides. *Id.* at 7:53–8:14. After drilling holes for pins, the surgeon removes the marking template and replaces it with the replacement device. *Id.* at 8:9–14, 8:42–44. Figure 4 of Carignan, depicting the custom marking template, is reproduced below:

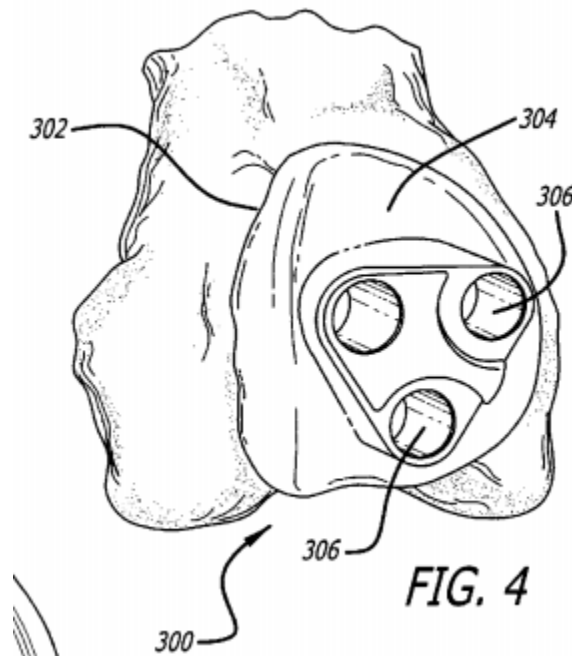


Figure 4 of Carignan discloses a perspective view of the femur associated with a custom marking template having guide holes that correspond to the pin on a replacement device, residing on the trochlear groove surface of the femur. *Id.* at 3:48–52.

2. *Analysis*

Each of claims 17, 18, 20, 37–39, 41, 45–47, 49, and 54 recites, or depends from a claim reciting, that the inner surface of the instrument matches a size, curvature, or shape of subchondral bone, or includes information of the of subchondral bone, or matches a size, shape, or curvature of the articular joint surface. *See* Ex. 1001, claims 17, 38 (concerning *shape* of subchondral bone), claims 18, 37, 39 (concerning *curvature* of subchondral bone), claims 20, 41 (concerning *information* of subchondral bone), claims 45–47, 49 (concerning *size, shape, curvature, and information* of the articular joint surface), claim 54 (concerning *curvature* of subchondral bone, cartilage *curvature, thickness, volume, dimensions* and volume of *tissues* associated with the joint).

Petitioner relies on the disclosure in Carignan of removing articular cartilage and placing a customized marking template on the bone. Pet. 44, 62 (citing Ex. 1006, 7:53–62, 8:15–41, Fig. 4). Petitioner asserts that Carignan describes using CT scans to create a customized guide having a surface that matches the femur in addition to describing that the surgeon may remove the rest of the diseased or damaged cartilage. *Id.* at 44 (citing Ex. 1006, 8:5–29, 2:42–45, 7:57–62, 5:13–63, 8:15–18, Fig. 4). Petitioner contends that Carignan recognizes that some subchondral bone would be exposed. *Id.* at 44–45 (citing Ex. 1002 ¶ 125). Petitioner argues that “[i]n view of Carignan, it would have been obvious to [one of ordinary skill in the art] that they could use imaging to obtain the shape and curvature of the subchondral bone.” *Id.* at 45 (citing Ex. 1002 ¶ 125). Petitioner also adds that “would have been motivated to combine the teachings of Radermacher, Alexander, and Carignan, and thereby modify the contact faces of Radermacher’s

template to have at least a portion that matches the shape or curvature of the exposed subchondral bone.” *Id.* (citing Ex. 1002 ¶¶ 126–127).

Petitioner sets forth several reasons for combining Radermacher, Alexander, and Carignan: (i) all of the references relate to methods of treating diseased and/or damaged cartilage in a knee joint; (ii) all of the references use the same imaging techniques, address the same problem, are in the same field of endeavor, and use the same imaging technology; (iii) a skilled artisan would have recognized that the images disclosed in Radermacher could be used to determine the shape and/or curvature of exposed subchondral bone; (iv) Carignan teaches a method that is consistent with Radermacher’s goals; and (v) the modification would merely:

(a) require the combination of one known element (Carignan’s CT data of the subchondral bone surface) for another known element (Radermacher’s CT data of the joint surface) to obtain a predictable result (a device tailored to the subchondral bone 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 45–46 (citing Ex. 1002 ¶¶ 126–127; Ex. 1003, Abstract, 3–5, 9, 30; Ex. 1006, 8:25–29, Abstract).

On the full record before us, we determine that Petitioner demonstrates sufficiently that Carignan meets the “subchondral bone” and “articular joint surface” limitations. In particular, Carignan discloses that “[t]o surgically implant the replacement device to the patellar face **5** of the femur **2**, a surgeon may first need to remove some or all remaining diseased or damaged articular cartilage **102** on the patellar surface **5** of the femur (FIG. **8**). The surgeon may then scrape away the articulate cartilage until a substantial bony surface **37** of the patellar face shows.” Ex. 1006, 8:15–20.

Patent Owner argues that one of ordinary skill in the art would not have combined Radermacher and Carignan. PO Resp. 69. According to Patent Owner, “*Carignan*’s replacement device is also incompatible with *Radermacher*’s prosthesis because, in situations where *Carignan*’s trochlear groove replacement device is appropriate, *Carignan* specifically states that a total knee replacement with a standardized prosthesis is ‘far from ideal’ because too much of the femur must be resected,” and Radermacher is directed, in part, to this very procedure. *Id.* (citing Ex. 1006, 1:59–62, 6:33–35, 6:63–7:8; Ex. 2005 ¶ 170).

We find this argument unpersuasive. Petitioner does not propose combining Carignan’s trochlear groove replacement device with Radermacher’s template. Rather, as discussed above, Petitioner relies on the disclosure in Carignan of removing articular cartilage and placing a customized marking template on the bone. The test for obviousness is not whether the features of a reference may be bodily incorporated into another reference to produce the claimed subject matter; rather, it is what the combination of references makes obvious to one of ordinary skill in the art. *See In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) (“It is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements.”).

Patent Owner argues that one of ordinary skill in the art would not have combined Radermacher, Alexander, and Carignan. PO Resp. 70–73. In particular, Patent Owner argues one of ordinary skill in the art would have had no reason to image the cartilage (as taught by Alexander) if it was

simply going to be removed during surgery (as taught by Carignan). *Id.* at 70 (citing Ex. 2005 ¶ 174).

In response, Petitioner argues one of ordinary skill would have modified Radermacher's template so that *a portion* of the contact face would match subchondral bone. Reply 25–26 (citing Pet. 45). Petitioner also argues that Carignan does not require all cartilage be removed and discloses leaving some articular cartilage intact. *Id.* at 26 (citing Ex. 1006, 8:15–18).

Carignan discloses that “a surgeon may first need to remove *some* or all remaining diseased or damaged articular cartilage.” Ex. 1006, 8:16–18 (emphasis added). We, thus, agree with Petitioner that one of ordinary skill in the art would consider removing only a portion of the cartilage in some instances. Accordingly, we find Patent Owner's argument unpersuasive.

In addition, we disagree with Patent Owner's argument that Radermacher, Alexander, and Carignan are directed to different fields of endeavor. *See* PO Resp. 71. Although Alexander and Carignan are directed to avoiding knee replacement procedures of the type contemplated by Radermacher, each reference, as Petitioner argues, “is directed to the treatment of damaged knee cartilage, uses MRI/CT to create a three-dimensional model of the knee, and describe patients typically seen by orthopedic surgeons.” Reply 26. Accordingly, we determine that these references are in the same field of endeavor.

Patent Owner also argues that Dr. Mabrey's declaration is internally inconsistent because on one hand he asserts that a skilled artisan would not be motivated to remove cartilage (Ex. 1002 ¶ 114), but then asserts “Carignan teaches a method that is consistent with Radermacher's stated

goals of increasing accuracy and speed,’ despite the fact that *Carignan* teaches the removal of cartilage” (*id.* ¶¶ 125, 127). PO Resp. 72.

Petitioner responds that no inconsistency exists because “Mabrey explained that matching both cartilage and exposed bone would increase accuracy and speed relative to conventional procedures,” in paragraph 114, and stated that “[r]emoving a portion of the cartilage would also increase accuracy and speed *relative to conventional methods*, even though it might not be as fast as matching the natural surface,” in paragraphs 125–127. Reply 26. Petitioner’s argument persuades us that there is no inconsistency.

After considering all 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, Alexander, and Carignan in the manner provided. We also determine that Petitioner has provided analysis explaining how the combination would have conveyed to one of ordinary skill in the art the claim limitations. Accordingly, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that claims 17, 18, 20, 37–39, 41, 45–47, 49, and 54 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 Carignan.

We now turn to Petitioner’s contention that claims 17, 18, 20, 37–39, 41, 45–47, 49, and 54 would have been obvious in view of Radermacher, Fell, and Carignan. In this ground, Petitioner relies on Carignan’s disclosure of a template having an inner surface that matches the shape or curvature of subchondral bone that is exposed or underlies the diseased or damaged

cartilage, as set forth in the ground based on Radermacher, Alexander, and Carignan. Pet. 52. Petitioner asserts that one of ordinary skill in the art would have been motivated to combine the teachings of Radermacher, Fell, and Carignan for the reasons discussed above and with respect to the grounds based on Radermacher, Alexander, and Carignan. *Id.* (citing Ex. 1003 ¶¶ 127, 129, 139).

Patent Owner argues that one of ordinary skill in the art would not have combined Radermacher, Fell, and Carignan. PO Resp. 73–74. Patent Owner notes that “[b]ecause Petitioner substantially incorporates its same assertions for the combination of *Radermacher*, *Carignan*, and *Fell*, this combination fails for the same reasons stated above as the combination of *Radermacher*, *Carignan*, and *Alexander*.” *Id.* at 73. Accordingly, our discussion with respect to Radermacher, Alexander, and Carignan applies equally here.

After considering all 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 Carignan in the manner provided. We also determine that Petitioner has provided analysis explaining how the combination would have conveyed to one of ordinary skill in the art the claim limitations. Accordingly, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that claims 17, 18, 20, 37–39, 41, 45–47, 49, and 54 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 Carignan.

IV. MOTION FOR OBSERVATION

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

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. *See* PO Mot. for Observation; Pet. Observation Opp.

V. MOTION TO EXCLUDE

Patent Owner filed a Motion to Exclude Exhibit 1202. Paper 18 ("PO Mot. to Exclude"). Petitioner filed an Opposition to the Motion to Exclude and Patent Owner filed a Reply in Support of its Motion to Exclude. Paper 23 ("Pet. Exclude Opp."); Paper 26 ("PO Exclude Reply").

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 moves to exclude Exhibit 1202. PO Mot. to Exclude, 1. Patent Owner argues that Exhibit 1202, the second Mabrey Declaration, is inadmissible under Federal Rule of Evidence 702. *Id.* Specifically, Patent Owner objects to paragraphs 6, 9, 11, 19, 20, 27, 38, 40, 46, 53, 56, 57, 59, 60, 61, 69, 70, 72, 74, and 82 for failing to disclose the underlying facts or data relied. *Id.* at 3. We, however, do not rely on any of these paragraphs in rendering our decision. Accordingly, Patent Owner's Motion to Exclude is *dismissed* as moot.

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 4–6, 10, 12–20, 24–26, 30, 32–41, 45–47, 49, 54, 55, and 57 of the '953 patent have been shown to be *unpatentable*;

FURTHER ORDERED that Patent Owner's Motion to Exclude (Paper 18) is *dismissed* as moot;

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.

IPR2015-00108
Patent 8,566,361 B2

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2016-01874
Patent 9,055,953 B2

Before PATRICK R. SCANLON, 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* SCANLON.

Opinion Dissenting filed by *Administrative Patent Judge* WORTH.

JAMES A. WORTH, *Administrative Patent Judge, Dissenting*.

Because I would determine that Petitioner has failed to prove certain elements of its case, I respectfully dissent.

Radermacher and Alexander

Claim 4 requires a template that matches the cartilage surface of a joint, i.e., “The surgical instrument of claim 1, wherein the inner surface matches a size of diseased cartilage of the diseased articular joint surface.” The issue is whether the prior art relied on by Petitioner taught putting a template 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. 28). 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 3. 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, literally and in context. Ex. 2005 ¶¶ 114–115.

Petitioner argues that, in context, the “osseous structure” is “not pre-treated,” “natural,” and “intra-operatively accessed.” Pet. 28, 31. 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. 38–39). 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 ¶ 120. Petitioner has not shown that the “not pre-treated” “osseous structure” necessarily includes cartilage. In fact, Radermacher discloses placement of the template on the “exposed bone surface.” Ex. 1003, 15.

Petitioner argues that Radermacher does not disclose removing cartilage.⁶ Pet. 32. 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*

⁶ By way of comparison, the Carignan reference discloses that cartilage may be eroded and that it may be necessary to remove cartilage. Ex. 1006, 8:15–20.

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 ¶¶ 84, 105. 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 central 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. 34, 38, 42, 46, 51; Ex. 1002 ¶¶ 127, 137. 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. 56 (citing Ex. 2005 (Clark Decl.) ¶¶ 112, 142; Ex. 2010 (Mabrey Depo.), 148:21–150:16.). Dr. Clark, Patent Owner’s Declarant, explains it this way: “When hyaline cartilage becomes diseased or damaged, it becomes frayed and may be similar in appearance to seaweed.” Ex. 2005 ¶ 142. Dr. Mabrey, Petitioner’s Declarant, similarly testified that damaged cartilage can be “fibrillated” with a “shag carpet” appearance. Ex. 2010, 149:21–22. The claim at issue is based on matching the surface of the cartilage. Petitioner does not adequately explain how one would have matched a template to damaged cartilage that is frayed or delaminated. Petitioner’s expert testified on cross-examination that cartilage is firm and compressible. Ex. 2010, 145:20–147:14. I would find that the potential to compress cartilage does not indicate that the cartilage surface is *matched*. I would determine that Petitioner has not satisfied its burden of proof on this issue.

There are reasons to doubt Petitioner’s assertion that a person of ordinary skill in the art would have combined Radermacher and Alexander to arrive at the claimed invention. Petitioner’s Declarant indicated that removing some articular cartilage during surgeries was the standard of care. *See* Ex. 2010, 35:20–22, 39:4–24, 203:13–19. Dr. Mabrey testified: “THE WITNESS: Removing cartilage from areas around exposed subchondral bone, I believe, is what this -- what a surgeon would do.” Ex. 2010, 203:13–19.

There are also reasons to doubt that a person of ordinary skill at the time of the invention would have been technologically able to convert an MRI signal into a template that matches cartilage. For example, there was this colloquy on cross-examination:

Q Why would the imaging of the cartilage surface be inadequate to provide information regarding the cartilage surface?

A Severely damaged cartilage could still provide an image on an MRI, but not a clear surface.

Q But would that information still be accurate regarding whatever cartilage is left?

MR. HEIDEMAN: Objection. Form.

THE WITNESS: A person of skill the in art in creating that device would use the data from the subchondral bone in that area to provide contact.

BY MR. SUKDUANG:

Q What type -- you mentioned damaged cartilage might have inadequate information. What other type of -- what other reason would the image of the cartilage not provide adequate information of the cartilage surface?

A Are you asking what other reasons besides having the cartilage damaged?

Q Right. You said there's instances where there might be -- the imaging wouldn't provide adequate information regarding the cartilage surface. You mentioned the damaged cartilage. Is there any other reason?

A If there is no cartilage.

Q Okay. Then you wouldn't even get the cartilage surface; correct?

A Correct.

Ex. 2010, 204:16–205:18. As such, Dr. Mabrey concedes that an MRI may have provided inadequate information, e.g., when there is damaged cartilage or no cartilage. *See also* Ex. 2010, 181:2–183:15 (agreeing that vertical lines are artifacts in reconstruction of MRI data; relying on Alexander's

three-dimensional imaging while responding that individual images from declaration cannot be used to match cartilage). Dr. Mabrey also conceded that it was rare for him to have requested an MRI (as in Alexander). Ex. 2010, 35:19.

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 4, or that claim 4 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, 6, 13–16, 24–26, 30, 32–36, 55, and 57 contain similar language and requirements, e.g., matching a cartilage surface. Accordingly, I would determine that Petitioner has not proven its case with respect to claims 5, 6, 13–16, 24–26, 30, 32–36, 55, and 57, for similar reasons as for claim 4.

Claim 10 recites a template “wherein the inner surface includes information of cartilage of the diseased articular joint surface.” This claim presents a closer case inasmuch as it does not recite “matching” a surface. Nevertheless, Petitioner has not explained how a surface would “include[] information of cartilage” without matching cartilage. As such, I would determine that Petitioner has not proven that a person of ordinary skill would have combined Radermacher and Alexander to arrive at the invention of claim 10. Claim 12, 19, and 40 contain similar language and requirements as to claim 10. I would conclude that Petitioner has not proven its case with respect to claims 12, 19, and 40 for similar reasons as claim 10.

Radermacher, Alexander, and Carignan

Petitioner asserts that Radermacher, Alexander, and further in view of Carignan render obvious claims 17, 18, 20, 37–39, 41, 45–47, 49, and 54.

Carignan discloses that cartilage may be eroded and that it may be necessary to remove cartilage. Ex. 1006, 8:15–20. Carignan thereby discloses putting a template on bone rather than on cartilage. As such, Carignan does not remedy the deficiency in the asserted ground based on Radermacher and Alexander. Accordingly, I would conclude that Petitioner has not proven its case with respect to claims 17, 18, 20, 37–39, 41, 45–47, 49, and 54.

Radermacher and Fell, alone or further in view of Carignan

Fell discloses imaging cartilage and providing an implant for insertion into the knee. The outer contours of Fell’s implant may “substantially mate” with condylar surfaces during extension but Fell’s implant lacks mating ridges and depressions. *Compare* Ex. 1005, 13:14–25, *with* Ex. 1006, 6:10–12; Ex. 2005 ¶ 150. Fell’s implant is intended to mimic the meniscus, and therefore serves a different purpose than the claimed invention which is directed to a “surgical instrument,” “surgical device,” or template for cutting bone during surgery. Notably, as Dr. Clark explains, Fell’s implant is designed to move. Ex. 2005 ¶ 150; *see also* Ex. 1005, 13:13–25. Accordingly, I would find that Fell’s device lacks the stability to be used as a surgical template. In my view, Petitioner has not adequately demonstrated that there would have been a reasonable expectation of success in adapting Fell’s implant to serve as a surgical template for cutting bone. *See* Ex. 2005 ¶¶ 62, 64, 133, 150. For this reason, I would conclude that Fell does not remedy the deficiencies in the grounds based on Radermacher and Alexander, alone or in view of Carignan.

IPR2016-01874
Patent 9,055,953 B2

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