

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

WORTH, *Administrative Patent Judge*.

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

I. INTRODUCTION

On September 21, 2016, Smith & Nephew, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–61 (the “challenged claims”) of U.S. Patent No. 9,055,953 B2 (Ex. 1001, “the ’953 patent”). Patent Owner, ConforMIS, Inc. (“Patent Owner”), did not file a Preliminary Response.

Institution of an *inter partes* review is authorized by statute when “the information presented in the petition filed under [35 U.S.C. §] 311 and any response filed under [35 U.S.C. §] 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108. For the reasons set forth below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that claims 1–61 are unpatentable. Accordingly, we institute an *inter partes* review of claims 1–61 based on the grounds identified in the Order section of this decision.

A. *Related Matter*

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.

B. *The ’953 Patent (Ex. 1001)*

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, at [54], 1:27–29. The 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:

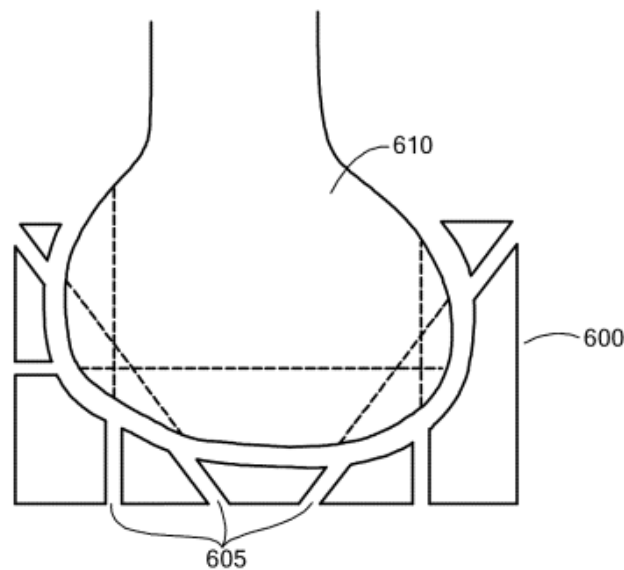


FIG. 15

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 Claim

Claims 1, 12, 21, 32, 42, 50, and 61 are independent. Independent claim 1, reproduced below, is illustrative of the subject matter:

1. A surgical instrument for the repair of a diseased articular joint surface of a joint, comprising:
 - an inner surface having a curvature or shape based on information from image data 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.

Ex. 1001, 34:50–57.

D. The Alleged Grounds of Unpatentability

Relying on the Declaration of Dr. Jay Mabrey (Ex. 1002), Petitioner sets forth its contentions that claims 1–61 are unpatentable based on the following grounds (Pet. 27–89):

Reference(s)	Basis	Claims challenged
Radermacher ¹	§ 103	1–61 ²

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

² Petitioner identifies grounds of unpatentability in the alternative. The function of the Board is not to comb through Petitioner’s arguments in order to decipher the strongest argument or to determine the strongest combination of references to challenge the claims. As such, we first consider

Reference(s)	Basis	Claims challenged
Radermacher and Alexander ³	§ 103	1–6 ⁴ , 10, 12–16, 19, 21–26, 30, 32–36, 40, 50–53, and 55–61
Radermacher, Alexander, and Carignan ⁵	§ 103	7–9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54
Radermacher and Fell ⁶	§ 103	1–6, 10, 12–16, 19, 21–26, 30, 32–36, 40, 50–53, and 55– 61
Radermacher, Fell, and Carignan	§ 103	7–9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54

Radermacher alone as to all claims, and then proceed to consider the cited references in combination.

³ Alexander, WO 00/35346, pub. June 22, 2000 (Ex. 1004).

⁴ As explained, *supra*, note 2, Petitioner pleads the grounds in the alternative. As discussed in more detail, *infra*, there is a lack of correspondence for certain grounds and certain claims between Petitioner’s reliance on references in the headings of the body of the Petition and in the claim chart provided by Petitioner on pages 53–89 of the Petition. This chart follows the allegations listed in Petitioner’s headings contained in the body of the Petition.

⁵ Carignan, U.S. Patent No. 6,712,856 B1, iss. Mar. 30, 2004 (Ex. 1006).

⁶ Fell, WO 00/59411, pub. Oct. 12, 2000 (Ex. 1005).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); see *In re Cuozzo Speed Techs., LLC*, 136 S. Ct. 2131, 2142–46 (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. See *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. See *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We construe claim terms only as relevant to the parties' contentions and only to the extent necessary to resolve the issues in dispute. See *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). Petitioner proposes that the claim term "articular joint surface" be construed as "the bone surface and/or cartilage surface of an articulating portion of a joint." Pet. 25 (citing Ex. 1002 ¶¶ 93–96). Petitioner contends that the specification defines "articular surface" as "a surface of an articulating bone that is covered by cartilage." *Id.* at 24 (citing Ex. 1001, 9:54–55). Petitioner also directs our attention to a passage from the specification indicating that when the cartilage is worn out and subchondral bone is exposed, "the articular surface' also includes subchondral bone." *Id.* (citing Ex. 1001, 3:56–58, 5:56–60, 22:59–67). The claims also distinguish between

subchondral bone “of the diseased articular joint surface” and subchondral bone “underlying diseased cartilage of the diseased articular joint surface,” according to Petitioner. Pet. 24–25 (discussing Ex. 1001, 13:17, claims 7, 9, 12).

Our review of the specification reveals that “[t]he articular surface may comprise cartilage *and/or* subchondral bone.” Ex. 1001, 3:56–58 (emphasis added). As such, we do not regard the statement in the specification that “articular surface” refers to a surface of an articular bone that is covered by cartilage, as limiting. Moreover, the claims differentiate between subchondral bone “of the diseased articular joint surface” and subchondral bone “underlying diseased cartilage of the diseased articular joint surface.” *Compare* Ex. 1001, 35:7–9 (claim 8), *with id.* at 35:10–12 (claim 9). As such, the claims recognize that subchondral bone may underlie cartilage but that subchondral bone may also be exposed, *i.e.*, in a diseased joint. For purposes of this Decision, based on the context of the claim language and on principles of claim differentiation, we construe the term “articular joint surface” as “the surface of an articulating bone that includes cartilage and/or exposed subchondral bone.” The Declaration of Dr. Mabrey is consistent with this understanding of the term “articular joint surface.” *See* Ex. 1002 ¶ 36.

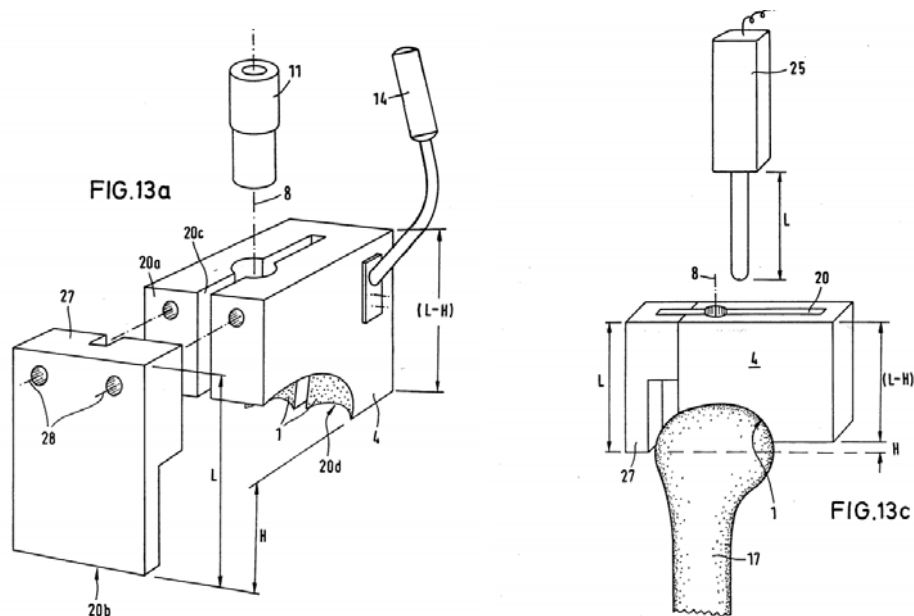
B. Obviousness over Radermacher (Ex. 1003)

Petitioner contends that claims 1–61 are unpatentable as obvious over Radermacher. Pet. 27–89. *See supra* note 2.

1. Radermacher

Radermacher is titled “Template for Treatment Tools and Method for the Treatment of Osseous Structures,” and relates to certain improvements in

the planning and performance of orthopedic surgery. *See* Ex. 1003, 1, 9. Radermacher describes a method in which parts of the surface of an arbitrary osseous structure, which are to be operated upon, are copied as a negative image using computer or nuclear-spin imaging so that an individual template can be intra-operatively set onto the osseous structure with mating attachment. *Id.* at 10:5–13. Radermacher discloses that the template can provide a guide corresponding to the limiting edge of a cut through the osseous structure (e.g., a vertebra) and can guarantee sufficient accuracy by exact positioning and guidance of the cutting tool. *Id.* at 16:5–19. Figures 13a and 13c of Radermacher are depicted below:



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

2. Analysis

In its Petition, Petitioner sets forth its contentions as to how the limitations of claims 1–61 are disclosed in, or obvious over, Radermacher. Pet. 27–89.

a. Independent claim 1

As to the preamble and the limitation “an inner surface having a curvature or shape based on information from image data of the diseased articular joint surface,” as recited by claim 1, Petitioner relies on the disclosure in Radermacher of an individual template copied as a negative image from pre-operative computer imaging. Pet. 27–29, 53–54 (citing Ex. 1003, 1, 10–13, 21, 22, 25, 30, Figs. 13a, 13c, 18). For example, Radermacher states that

. . . the central functional element is a so-called individual template by which parts of the surface of an arbitrary osseous structure which is to be treated and is intraoperatively accessible to the surgeon, are copied as a negative image without undercut and in a mechanically rigid manner, so that the individual template can be set onto the osseous structure in a clearly defined position and with mating engagement.

According to the inventive method, there is used a split-field device (e.g. a computer or a nuclear spin tomograph) by which split images are produced of the layers extending through the body of the living organism and containing the osseous structure, and from these split images, data regarding the three-dimensional shape of the osseous structure and the surface thereof are obtained. In the preoperative planning phase, these data are used as a basis for defining, within the coordinate system fixedly positioned relative to the osseous structure, a rigid individual template which, completely or by segments (but at least by three intraoperatively clearly identifiable abutting points), copies the surface of the osseous structure in such a manner that the individual template can be intraoperatively set onto these – then freely exposed – contact faces or points in exclusively one clearly defined position in form-closed manner.

Ex. 1003, 10–11 (*cited and excerpted at Pet. 28*). Petitioner additionally relies on the disclosure in Radermacher of a negative mold of the natural surface of the osseous structure, as follows:

By 3D reconstruction of a tomographically imaged object, particularly of the osseous structures of a living human, and by visualizing this reconstruction on an output medium, particularly a computer monitor, and particularly by using a computer system or a computer-based display and construction system, 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.

Ex. 1003, 12 (*cited and excerpted at Pet. 28*).

As to the limitation “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” as recited by claim 1, Petitioner relies on the disclosure in Radermacher of a groove that defines a cutting path for a cut. Pet. 29, 55 (citing Ex. 1003 at 11, 13, 25, 26, 30, Figs. 13a–c, 18). For example, Radermacher states that “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.” Ex. 1003, 26.

To support its contention, Petitioner further relies on an alleged admission of Patent Owner from the co-pending District Court litigation:

Radermacher discloses using pre-operative CT imaging data [information from image data] to create a three-dimensional model of an osseous structure (including a knee joint) [articular joint surface] and using the model to create a custom instrument (‘template’) with a tissue contacting surface [inner surface] that matches and fits the bone surface [curvature and shape] in a predefined spatial arrangement. Radermacher further discloses that tool guides [slits] can be provided in or on the basic body of the template.

Pet. 30 (quoting Ex. 1024, 21). It appears that Petitioner is relying here on Exhibit 1024 to buttress its understanding of the Radermacher reference (*see id.*). In this manner, Petitioner asserts that Radermacher discloses a surgical instrument (template 4) with an inner surface (contact faces 1) based on image data (CT, MRI) of a diseased articular joint, with a slit (cutting slot) and a cutting path (20c) through at least a portion of a joint. Pet. 29–30.

Petitioner contends that even if Radermacher does not disclose the instrument of independent claim 1, such instrument would have been obvious to a person of ordinary skill in the art in view of Radermacher. Pet. 27 (“Such an instrument is disclosed by, or would have been obvious to a POSITA in view of, Radermacher.”). We determine that Petitioner has demonstrated a reasonable likelihood that Radermacher renders obvious the surgical instrument of claim 1. In particular, we note that our claim construction of “articular joint surface” includes the case in which there is at least some subchondral bone exposed on the surface of the joint, *e.g.*, by reason of a pre-operative disease process. Radermacher discloses a surgical instrument which is a negative image of, and which mates with, the surface of an osseous structure. *See* Ex. 1003, 10–12; Ex. 1002 ¶¶ 102–103 (discussing osseous structure of Radermacher). We determine that Petitioner demonstrates sufficiently that a person of ordinary skill in the art would have found it obvious to adapt the instrument of Radermacher for use in the operation of a diseased articular joint, *i.e.*, a joint in which there is exposed subchondral bone on the articular joint surface. *See also* Pet. 30 n.7 (pleading in the alternative that, if the joint surface includes cartilage, then the “articular joint surface” limitation of independent claim 1 would be unpatentable for reasons set forth in claims 4–6). Further, Petitioner

demonstrates sufficiently that Radermacher's slot 20c meets the cutting path limitation of independent claim 1. *See* Ex. 1003, 26, 30.

Accordingly, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that Radermacher renders obvious independent claim 1.

b. Claims 2, 3, and 21–23

We have carefully reviewed Petitioner's arguments and evidence. *See* Pet. 30, 56–57, 68–70. Based on the record before us, we find that Petitioner has established a reasonable likelihood of prevailing on its contention that Radermacher renders obvious claims 2, 3, and 21–23, for similar reasons as provided for independent claim 1.

c. Claims 4–20 and 24–61

Petitioner contends that claims 4–20 and 24–61 are disclosed by Radermacher alone or would have been obvious in view of Radermacher alone given the knowledge of a person of ordinary skill in the art. Pet. 31–35, 39–42, 47–49. Petitioner's contention with respect to obviousness over Radermacher alone is made in the alternative to grounds based on Radermacher in combination with other references, discussed below. In light of the determination that there is a reasonable likelihood that the challenged claims are unpatentable based on the grounds on which we institute an *inter partes* review, *see infra*, we exercise our discretion and decline to institute review on this asserted ground of unpatentability. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(a); *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1316 (Fed. Cir. 2016) (holding that 37 C.F.R. § 42.108(a) is “plainly an exercise” of the PTO's rulemaking authority and “is a reasonable interpretation of the statutory provision governing the

institution of inter partes review”); *see also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1366–1368 (Fed. Cir. 2016) (pursuant to 37 C.F.R. § 42.108(b), the Board may decline to institute some grounds asserted by the petitioner).

C. Obviousness over Radermacher and Alexander (Ex. 1004)

Petitioner contends that claims 1–6, 10, 12–16, 19, 21–26, 30, 32–36, 40, 50–53, and 55–61 are unpatentable as obvious over Radermacher and Alexander. Pet. 31–38, 53–89.

1. Overview of Alexander

Alexander is titled “Assessing the Condition of a Joint and Preventing Damage,” and relates to assessment in aiding in prevention of damage to the joint or treatment of diseased cartilage in the joint. Ex. 1004, 1:15–17.

Alexander discloses a method of obtaining an image of cartilage, (preferably a magnetic resonance image), converting the image to a three-dimensional degeneration pattern, and evaluating the degree of degeneration in a volume of interest of the cartilage. *Id.* at 2:25–27. Alexander further discloses calculating the thickness or regional volume of the region thought to contain degenerated cartilage, both at an initial time and a later time, to determine a loss in thickness. *Id.* at 3:3–8. Alexander also describes creating a “3D” thickness map. *Id.* at 3:8–9.

2. Analysis

a. Claims 1–3 and 21–23

Although the text of the Petition includes claims 1–3 and 21–23 in the asserted grounds based on Radermacher and Alexander, the claim charts do not contained detailed allegations relying on Alexander for claims 1–3 and 21–23. In light of the determination that there is a reasonable likelihood that

the challenged claims are unpatentable based on the grounds on which we institute an *inter partes* review, *see supra*, we exercise our discretion and decline to institute review on this asserted ground of unpatentability. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(a).

b. Claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 50–53, and 55–61

Claim 4 depends from claim 1, and further recites “wherein the inner surface matches a size of diseased cartilage of the diseased articular joint surface.” Ex. 1001, 34:62–64. Petitioner relies on Radermacher, as discussed above, for the limitations of independent claim 1, and relies on Alexander, in combination therewith, for the further recitation of claim 4 relating to cartilage size. Pet. 31–38. In particular, Petitioner relies on the disclosure in Alexander concerning obtaining a three-dimensional map of a knee cartilage joint using an MRI. Pet. 36–37, 58 (citing, e.g., Ex. 1004, Abstract, 2:5–29, 11:31–12:16). Petitioner argues that it would have been obvious to a person of ordinary skill in the art to combine Alexander’s disclosure that imaging techniques could be used to determine the dimensions of joint cartilage, with Radermacher’s imaging techniques, in order to achieve the goal of simplifying surgery and because it would have been consistent with Radermacher’s goals for creating a custom template. *See id.* at 38. Petitioner also asserts, *inter alia*, that this would have been a combination of known elements to achieve a predictable result with a reasonable expectation of success. *Id.*

Further, with respect to the knowledge of a person of ordinary skill, Petitioner asserts that a person of ordinary skill would have been motivated to match the contact faces to cartilage rather than underlying subchondral bone because (a) cartilage surface and the subchondral bone surface are the

only two surfaces to which Radermacher's custom template could be matched; (b) the choice between the two is merely a design choice and reflects a choice from a finite number of identified, predictable solutions with a reasonable expectation of success; (c) matching the cartilage surface would simplify the surgery, if it does not have to be removed in order for the template to precisely fit; (d) Radermacher teaches that the contact faces match the "natural (i.e. not pre-treated) surface"; and (e) a person of ordinary skill would understand that matching the cartilage would result in a template that has "one spatially uniquely defined position," reduces surgical time, and increases accuracy, as Radermacher teaches. Pet. 34–35 (citing Ex. 1002 ¶ 108; Ex. 1003, Abstract, 9; citing also *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402–403 (2007)). On this basis, Petitioner reasons that it would have been obvious to a person of ordinary skill in the art to match the "contact faces" of Radermacher's template to the size, shape, and/or curvature of the patient's articular cartilage as derived from the MRI data. Pet. 35 (citing Ex. 1002 ¶¶ 107–109).

On the basis of the current arguments and evidence of record, we determine that Petitioner demonstrates sufficiently that Alexander meets the "cartilage" limitation of claim 4. In particular, Alexander discloses using a MRI to make a 3D map of articular cartilage. *See* Ex. 1004, 12:6–13, Fig. 19.

We further determine Petitioner's rationale and evidence is sufficient to demonstrate that it would have been obvious to a person of ordinary skill in the art to utilize the imaging techniques of Alexander in Radermacher's method of creating a surgical template. In particular, Radermacher discloses creating a negative mold of the natural (pre-treated) surface of the articular

structure. Ex. 1003, 12. To the extent that the natural (pre-treated) surface may contain cartilage, a negative mold of the surface structure would need to include the size and shape of the cartilage as well. *See* Ex. 1002 ¶¶ 102–103. Accordingly, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the combination of Radermacher and Alexander renders obvious claim 4.

We have carefully reviewed the evidence relied on by Petitioner relating to claims 5, 6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 50–53, and 55–61. *See* Pet. 59–88. Based on our own review of the evidence, we find that Petitioner has established a reasonable likelihood, on this record, of prevailing on its contention that the combination of Radermacher and Alexander renders obvious claims 5, 6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 50–53, and 55–61, for similar reasons as for claim 4. In particular, Alexander discloses providing information regarding the size and shape of the cartilage structure, which would inform a negative mold of an articular joint surface, as used by Radermacher.

D. Obviousness over Radermacher, Alexander, and Carignan (Ex. 1006)

Petitioner contends that claims 7–9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54 are unpatentable as obvious over Radermacher, Alexander, and Carignan. Pet. 39–49, 60–85.

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:

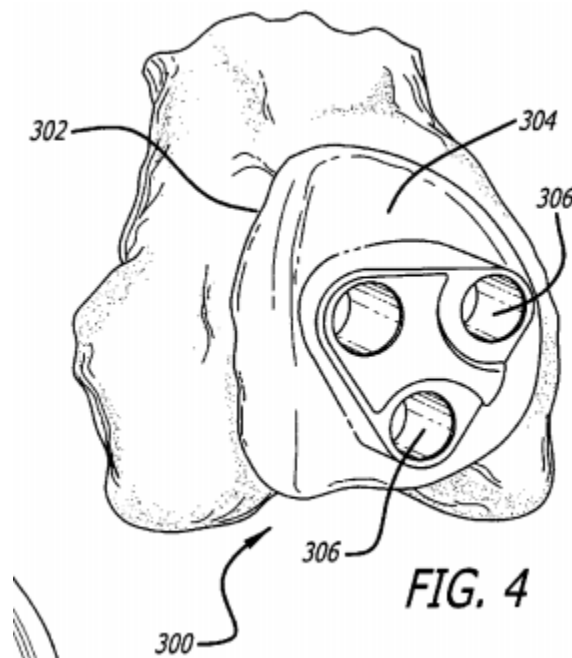


Figure 4 of Carignan discloses a perspective view of the femur associated with a custom marking template having guide holes that correspond to the pin on a replacement device, residing on the trochlear groove surface of the femur. *Id.* at 3:48–52.

2. Analysis

Claim 7 depends from claim 1, and further recites “wherein the inner surface matches a curvature of subchondral bone of the diseased articular joint surface.” Ex. 1001, 36:4–6. Petitioner relies on Radermacher, as above, for the limitations of independent claim 1, and relies on Carignan, in combination therewith, for the “subchondral bone” limitation of claim 7. In particular, 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. Pet. 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. Pet. 45 (citing Ex. 1002 ¶ 125). Petitioner argues that it would have been obvious to a person of ordinary skill in the art to combine Carignan’s disclosure of matching the surface of subchondral bone, and Alexander’s teachings of cartilage imaging, with Radermacher’s disclosure of a surgical template in order to better align and position the device. *See* Pet. 44–46 (citing, e.g., Ex. 1006, 8:25–29). Petitioner also asserts, *inter alia*, that this would have been a combination of known elements to achieve a predictable result with a reasonable expectation of success. *Id.* (citing, e.g., Ex. 1002 ¶¶ 126–127).

On the basis of the current record, we determine that Petitioner demonstrates sufficiently that Carignan meets the “subchondral bone” limitation of claim 7. 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.

We further determine that Petitioner’s proffered rationale and evidence is sufficient to support, on this record, the proposed modification to the surgical techniques of Carignan along with the imaging techniques of Alexander and the surgical techniques of Radermacher, discussed *supra*, in order to create a better matching complementary surface. In particular, Carignan discloses that when the template matches the contours of the patellar face with boundary conditions, the surgeon is assured that the marking template is aligned and positioned properly. *Id.* at 8:25–29. Accordingly, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the combination of Radermacher, Alexander, and Carignan renders obvious claim 7.

We have carefully reviewed the evidence relied on by Petitioner relating to claims 8, 9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54. *See* Pet. 60–85. Based on our own review of the evidence, we find that Petitioner has established a reasonable likelihood, on this record, of prevailing on its contention that the combination of Radermacher, Alexander, and Carignan renders obvious claims 8, 9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54, for similar reasons as for claim 7. In particular, Carignan discloses matching a template to the subchondral bone of an articular joint surface.

E. Obviousness over Radermacher and Fell (Ex. 1005), Alone or Further in View of Carignan

Petitioner contends that claims 1–61 are unpatentable as obvious over Radermacher and Fell, alone or further in view of Carignan. Pet. 49–52.

1. Overview of Fell

Fell is titled “Surgically Implantable Knee Prosthesis,” and relates to prosthetic devices, and more particularly, to self-centering knee joint prostheses which may be surgically implanted between the femoral condyle and tibial plateau of the knee. Ex. 1005, 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:

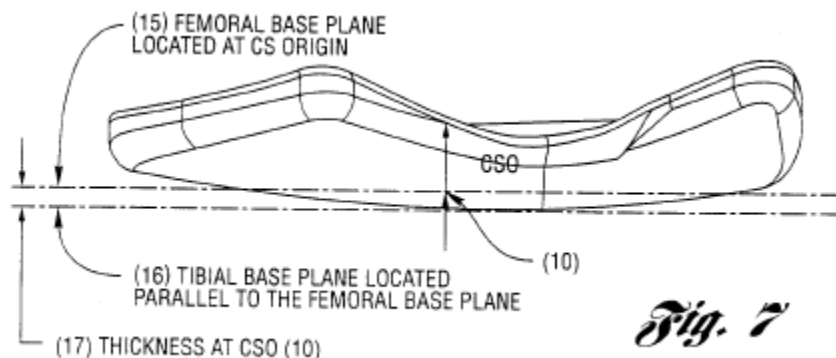


Figure 7 of Fell illustrates a device contour and its relationship with the femoral and tibial base planes. *Id.* at 5:1–2.

2. Analysis

a. Claims 1–3 and 21–23

Although the text of the Petition includes claims 1–3 and 21–23 in the asserted grounds based on Radermacher and Fell, the claim charts do not contained detailed allegations relying on Fell for claims 1–3 and 21–23. In light of the determination that there is a reasonable likelihood that the challenged claims are unpatentable based on the grounds on which we institute an *inter partes* review, *see supra*, we exercise our discretion and decline to institute review on this asserted ground of unpatentability. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(a).

b. Claims 4–20 and 24–61

Petitioner relies on Fell for similar teachings as Alexander, i.e., with respect to imaging of articular cartilage. *See* Pet. 49–50. With respect to claim 4, Petitioner relies on Radermacher, as above, for the teachings of independent claim 1, and relies on Fell for the further recitation of dependent claim 4, i.e., “wherein the inner surface matches a size of diseased cartilage of the diseased articular joint surface.” In particular, Petitioner relies on the teaching in Fell of determining the size, shape, and curvature of the cartilage surface using MRI data. *See* Pet. 49–50 (citing Ex. 1005, 13:15–17, 14:13–15:21, 22:6–9). On this record, Petitioner demonstrates sufficiently that Fell, like Alexander, discloses imaging the shape of the articular cartilage. For example, Fell discloses constructing a contour plot of the femoral and tibial mating surfaces and the size of the meniscal cavity, using MRI, in

order to produce a custom-tailored meniscal implant. *See* Ex. 1005, 15:12–16.

Petitioner reasons that a person of ordinary skill in the art would have adopted the techniques of Fell to create a cutting guide, as taught by Radermacher, *inter alia*, in order to match the patient’s joint surface. Pet. 50–51 (citing, e.g., Ex. 1002 ¶¶ 134–137). On this record, we determine that Petitioner’s proffered rationale and evidence is sufficient to support the proposed combination of the teachings of Fell regarding the measuring of cartilage in preparation for deployment of an orthopedic surgery device with the cutting guide of Radermacher. In particular, Fell discloses a method for producing “custom tailored” devices that specifically takes into account the shape of the articular cartilage. *See* Ex. 1006, 15:12–21. Therefore, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the combination of Radermacher and Fell renders obvious claim 4.

We have carefully reviewed Petitioner’s assertions set forth in the claim charts (Pet. 53–89) with respect to claims 5–20 and 24–61, and we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on its contention with respect to the combination of Radermacher and Fell, alone or further in view of Carignan, for similar reasons as set forth above for the grounds based on Radermacher and Alexander, alone or further in view of Carignan.

III. CONCLUSION

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–61 of the ’953 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

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

Claims 1–3 and 21–23 as obvious over Radermacher;

Claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 50–53, and 55–61 as obvious over Radermacher and Alexander;

Claims 7–9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54 as obvious over Radermacher, Alexander, and Carignan;

Claims 4–6, 10, 12–16, 19, 24–26, 30, 32–36, 40, 50–53, and 55–61 as obvious over Radermacher and Fell;

Claims 7–9, 11, 17, 18, 20, 27–29, 31, 37–39, 41–49, and 54 as obvious over Radermacher, Fell, and Carignan;

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

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

IPR2016-01874
Patent 9,055,953 B2

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