

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2017-00983
Case IPR2017-00984¹
Patent 8,657,827 B2

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

WORTH, *Administrative Patent Judge*.

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

¹ A copy of this Decision is to be entered in each of the referenced proceedings. Although we are using a consolidated caption for this Decision, we note that the proceedings have not been consolidated and the parties have not been authorized to use a consolidated caption or to otherwise treat the proceedings as consolidated.

I. INTRODUCTION

Petitioner Smith & Nephew, Inc. filed two petitions requesting *inter partes* review of claims 1–25, 28, 29, 32–46, and 50–64 of U.S. Patent No. 8,657,827 B2 (Ex. 1001, “the ’827 patent”)² pursuant to 35 U.S.C. § 311(a), as indicated in the chart below. Patent Owner ConforMIS, Inc. filed a Preliminary Response in each proceeding, as indicated in the chart below.

Case Number	Challenged Claims	Petition	Preliminary Response
IPR2017-00983	1–25, 28, 29, 32–46	Paper 2 (“Pet.”)	Paper 6 (“Prelim. Resp.”)
IPR2017-00984	50–64	Paper 1 (“-984 Pet.”)	Paper 7 (“-984 Prelim. Resp.”)

Institution of an *inter partes* review is authorized by statute when “the information presented in the petition filed under [35 U.S.C. §] 311 and any response filed under [35 U.S.C. §] 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108. For the reasons set forth below, we determine that Petitioner has not demonstrated a reasonable likelihood that claims 1–25, 28, 29, 32–46, and 50–64 are unpatentable. Accordingly, we do not institute an *inter partes* review of claims 1–25, 28, 29, 32–46, and 50–64 of the ’827 patent based on the grounds asserted in the petitions.

² Unless otherwise specified with the “-984” prefix, references to papers and exhibits cited herein are to those filed in Case IPR2017-00983.

A. Related Matters

The parties identify the following district court proceeding as a related matter: *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass. Feb. 29, 2016). Pet. 1; Paper 4, 2. Petitioner identifies the following Board proceedings as related: IPR2016-01874; IPR2017-00115; IPR2017-00307; IPR2017-00372; IPR2017-00373; IPR2017-00487; IPR2017-00488; IPR2017-00510; IPR2017-00511; IPR2017-00544; IPR2017-00545; IPR2017-00778; IPR2017-00779; and IPR2017-00780. Pet. 1–2; *see also* Paper 4, 2 (Patent Owner Mandatory Notice).

B. The '827 Patent (Ex. 1001)

The '827 patent is titled “Surgical Tools for Arthroplasty” and relates to methods, systems, and prosthetic devices for articular resurfacing. Ex. 1001, 1:65–67. The '827 patent also relates to surgical molds designed to achieve optimal cut planes in a joint in preparation for installation of a joint implant. *Id.* at 1:67–2:4.

The '827 patent describes a problem in the prior art with available devices that do not always provide ideal alignment with the articular surfaces and joint congruity. *Id.* at 5:37–39. The '827 patent states that poor alignment and poor joint congruity can, for example, lead to instability of the joint, e.g., lateral instability of the knee joint. *Id.* at 5:39–42.

The '827 patent discloses forming a template with at least one contact surface to engage a surface associated with a joint. *Id.* at 9:56–10:5. The template may avoid a deformity, such as an osteophyte, and engage a portion of a surface not affected by the deformity, or the deformity may be removed prior to placing a mold. *Id.* at 73:25–50.

Placement of a template is depicted in Figures 32 and 33:

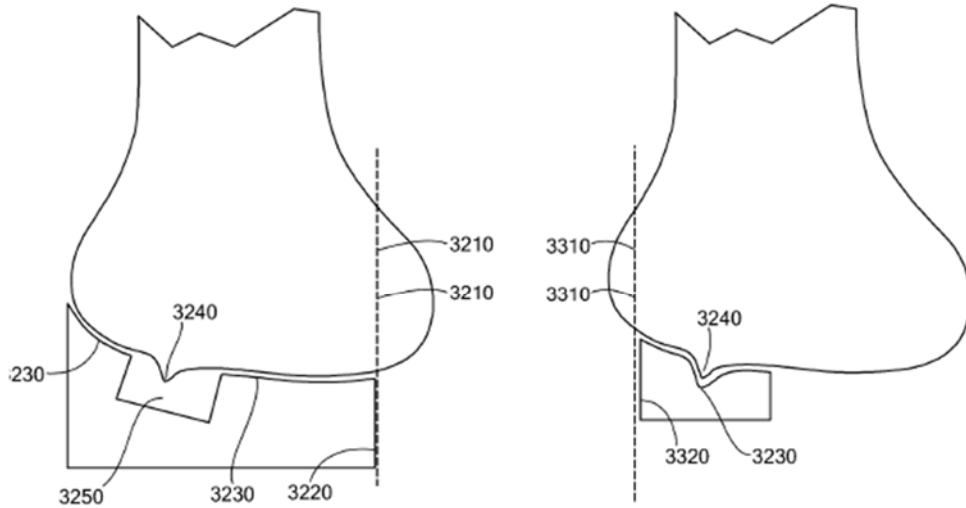


FIG. 32

FIG. 33

Figures 32 and 33 illustrate 3D guidance templates designed to guide a posterior and an anterior cut, respectively, using posterior and anterior reference planes, in accordance with embodiments of the invention. *Id.* at 28:31–42. In Figure 33, the facing surface of the template is, at least in part, a mirror image of portions of the joint that are altered by the arthritic process, including osteophyte 3240. *Id.* at 28:37–42; 84:2–7. However, in Figure 32, the template contains recess 3250 to avoid the osteophyte. *Id.* at 83:61–62.³

³ The '827 patent is subject to a certificate of correction, which issued on Sept. 30, 2014. Ex. 1001, 140.

C. Illustrative Claim

Claims 1, 50, 53, 56, and 59 are independent. Independent claim 1, reproduced below, is illustrative of the subject matter:

1. A patient-specific surgical instrument for use in surgically repairing a diseased or damaged joint of a patient, the instrument comprising:
 - a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint, the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint, wherein the corresponding portion of the diseased or damaged joint includes an osteophyte, wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint; and
 - a guide sized and shaped to accommodate a surgical tool, wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool.

Ex. 1001, 119:11–28.

D. The Prior Art

Petitioner relies on the following prior art:

- US 4,759,350, iss. July 26, 1988 (Ex. 1036, “Dunn”);
US 4,841,975, iss. June 27, 1989 (Ex. 1031, “Woolson”);
WO 93/25157, pub. Dec. 23, 1993 (Ex. 1003, “Radermacher”);
WO 95/28688, pub. Oct. 26, 1995 (Ex. 1007, “Swaelens”);
WO 00/35346, pub. June 22, 2000 (Ex. 1004, “Alexander”);
WO 00/59411, pub. Oct. 12, 2000 (Ex. 1005, “Fell”);

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EP 1,074,229 A2, pub. Feb. 7, 2001 (-984 Ex. 1047, “Schuster I”)⁴;

US 6,510,334 B1, iss. Jan. 21, 2003 (Ex. 1008, “Schuster II”);

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

E. The Alleged Grounds of Unpatentability

Petitioner challenges claims 1–25, 28, 29, 32–46, and 50–64 of the ’827 patent as unpatentable under 35 U.S.C. § 103(a) on the following grounds:

Case Number	References	Claims Challenged
IPR2017-00983	Radermacher and Alexander	1–13, 32, 33, 38, and 44–46
IPR2017-00983	Radermacher, Alexander, and Woolson	14–19, 22–25, 28, 29, 34–37, and 39–43
IPR2017-00983	Radermacher, Alexander, Woolson, and Hofmann	20 and 21
IPR2017-00983	Radermacher and Fell	1–13, 32, 33, 38, and 44–46
IPR2017-00983	Radermacher, Fell, and Woolson	14–19, 22–25, 28, 29, 34–37, and 39–43
IPR2017-00983	Radermacher, Fell, Woolson, and Hofmann	20 and 21
IPR2017-00984	Schuster I, Schuster II, and Alexander	50–58

⁴ We will refer herein to the pages of the English Translation of record, -984 Ex. 1046.

Case Number	References	Claims Challenged
IPR2017-00984	Schuster I, Schuster II, Alexander, and Dunn	59–64
IPR2017-00984	Radermacher, Swaelens, and Alexander	50–58
IPR2017-00984	Radermacher, Swaelens, Alexander, and Woolson	59–64

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); see *Cuozzo Speed Techs. v. Lee, LLC*, 136 S. Ct. 2131, 2142–46 (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood 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 requests a construction of the term “references the osteophyte.” Pet. 17–18. Patent Owner does not propose construction of any terms.

As to “references the osteophyte,” Petitioner states that the ’827 patent does not define the term “reference,” but argues the broadest reasonable construction of the limitation includes “at least a patient-specific surface that engages or avoids an osteophyte.” *Id.* Patent Owner does not address this issue directly in this proceeding.

For purposes of this Decision, we determine that the broadest reasonable construction of the “references the osteophyte” limitation includes a patient specific surface that “engages or avoids the osteophyte,” consistent with the embodiments of Figures 32 and 33 of the ’827 patent. We note that dependent claims 2 and 3 use the phrase “not engage” with respect to a “second osteophyte.” Ex. 1001, 119:30, 119:36–37 (claims 2, 3). Nevertheless, dependent claims 4 and 5 require that the patient-specific surface “substantially engage[s]” an osteophyte (*id.* at 119:41–46), and therefore the principle of claim differentiation indicates that independent claim 1 has a broader scope than dependent claims 4 and 5.

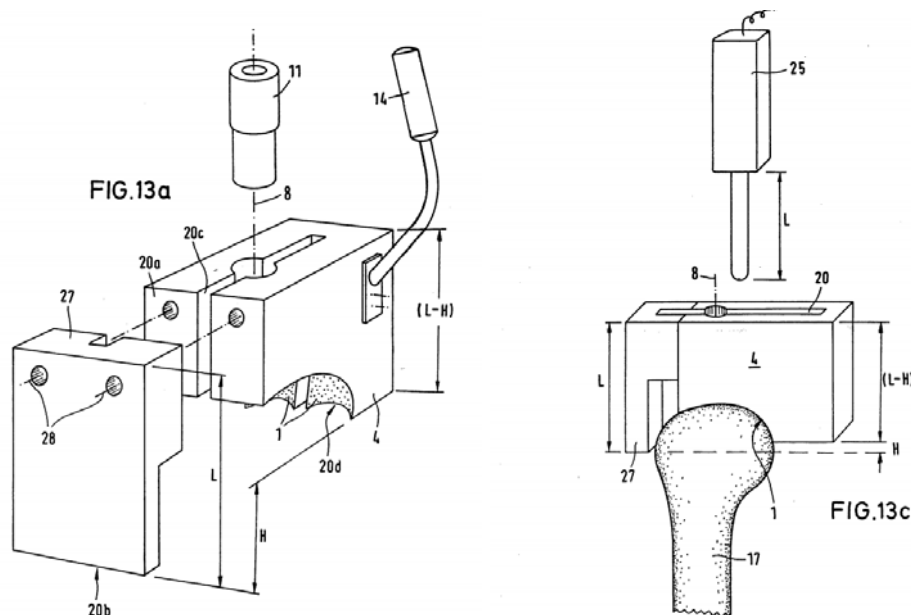
B. Obviousness of Claims 1–13, 32, 33, 38, and 44–46 over Radermacher (Ex. 1003) and Alexander (Ex. 1004)

Petitioner contends that claims 1–13, 32, 33, 38, and 44–46 are unpatentable as obvious over Radermacher and Alexander. Pet. 20–48. Patent Owner disagrees. Prelim. Resp. 11–24, 28–30.

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



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

2. Overview of Alexander

Alexander is titled “Assessing the Condition of a Joint and Preventing Damage” and relates to using joint assessment in aiding in prevention of damage to the joint or treatment of diseased cartilage in the joint. Ex. 1004, 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 3:2–8. Alexander also describes creating a 3D thickness map. *Id.* at 3:8–9.

3. Analysis

In its Petition, Petitioner sets forth its contentions as to how the limitations of claims 1–13, 32, 33, 38, and 44–46 are disclosed in, or obvious over, the combination of Radermacher and Alexander. Pet. 20–48.

Claim 1 recites, in relevant part, the limitation:

a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint, the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint, wherein the corresponding portion of the diseased or damaged joint includes an osteophyte, wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.

Ex. 1001, 119:14–23. Petitioner argues that this limitation is satisfied by Radermacher, in combination with the knowledge of a person of ordinary skill in the art and Alexander. Pet. 20–31, 40. Patent Owner opposes. *See* Prelim. Resp. 11–24, 28–30.

Petitioner argues that when Radermacher discloses that the template is “set onto the bone” (Ex. 1003, 30), a person of ordinary skill would have understood that the template is set onto the un-treated bone surface, i.e., on

top of any remaining cartilage, any exposed subchondral bone, and any osteophytes, or that this would have been obvious to a person of ordinary skill in the art in view of Radermacher. Pet. 24, 29–30 (citing Ex. 1002 ¶¶ 93–95, 115–117). Petitioner asserts that Radermacher discloses using CT or MRI to generate a three-dimensional negative mold of parts of the individual “natural” (i.e., not pre-treated) surface of the osseous structure. Pet. 23, 29–30, 37, 40 (citing, e.g., Ex. 1003, 10–12, 21–22, 30, Fig. 18; Ex. 1002 ¶¶ 93–94 111–117). Petitioner relies, *inter alia*, on the ’827 patent for the contention that osteophytes may be part of the “natural” surface of a joint. *Id.* at 29 (citing Ex. 1001, 83:56–84:7, 13:2–24, 73:25–27; 93:53–94:2, Figs. 32, 33; Ex. 1002 ¶¶ 118). Petitioner asserts that osteophytes are present in the vast majority of patients requiring knee replacement surgery (over 90% of patients who undergo knee replacement), and “Radermacher’s template would inherently have a portion that engages an osteophyte, if present.” *Id.* at 29 (citing, e.g., Ex. 1002 ¶¶ 111–113).

The cited portions of Radermacher, however, disclose creating an individual template to match a bone surface based on imaging of a joint (Ex. 1003, 10–12, 21–22, 30) and surgical planning (*id.* at Figs. 18, 19). As argued, Radermacher discloses creating a negative mold to fit onto the natural surface of an osseous structure. *Id.* at 12. Radermacher also states that an individual template can “reproduce geometries of osseous structures or reflect them in some other manner.” *Id.* at 30. We find that this disclosure, with respect to the presence or absence of osteophytes, is ambiguous at best. Radermacher does not contain a disclosure of osteophytes, nor matching the surfaces of osteophytes, as argued, nor

“referencing” osteophytes as recited by independent claim 1. We regard this as a gap in the prior art reference.

In support of Petitioner’s assertion that a person of ordinary skill in the art would have understood Radermacher to disclose referencing osteophytes or that it would have been obvious to do so in view of Radermacher, Petitioner relies on the declaratory evidence of Dr. Mabrey. Dr. Mabrey avers that Radermacher’s template surface would also match osteophytes (Ex. 1002 ¶¶ 113, 117), that over 90% of Dr. Mabrey’s patients who undergo knee replacement surgery have osteophytes (*id.* ¶ 111), and that osteophytes were well-known and well-documented in the literature (*id.*). Dr. Mabrey relies on articles from the scientific literature that report radiographic findings of osteophytes in patients, e.g., patients with osteoarthritis. Exs. 1066–1069 (*cited in* Ex. 1002 ¶ 111).

In response, Patent Owner argues that Petitioner cannot establish that the “osteophyte” limitation is inherent in any of the asserted references, and cites case law for the proposition that inherency “may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” Prelim. Resp. 11–13 (citing, e.g., *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)) (emphasis omitted). Patent Owner maintains that Petitioner fails to show that osteophytes are necessarily present in the diseased or damaged joints assessed by the prior art. *Id.* at 14. Patent Owner insists that Petitioner’s own characterizations, using language such as “most patients,” constitute an acknowledgement that the joints disclosed and assessed in the prior art do not necessarily have osteophytes, and that the references are silent on this

issue. *Id.* at 16 (citing Pet. 29). Patent Owner adds that the simple fact that MRI imaging “could be used” to obtain information about osteophytes does not cure the primary problem that osteophytes are not necessarily present in the prior-art references. *Id.* at 17.

The Federal Circuit has explained that “the use of inherency, a doctrine originally rooted in anticipation, must be carefully circumscribed in the context of obviousness.” *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014). The Court further states:

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that *the natural result flowing* from the operation as taught would result in the performance of the questioned function, it seems well settled that the disclosure should be regarded as sufficient.

Id. (quoting *In re Oelrich*, 666 F.2d at 581).

We find that Petitioner has not established sufficiently that Radermacher expressly or inherently discloses osteophytes or referencing osteophytes. As above, Radermacher does not mention osteophytes. Admittedly, Petitioner does not assert that Radermacher inherently anticipates independent claim 1, as this is a ground based on obviousness. Nevertheless, to the extent that Petitioner contends that a person reading Radermacher would have understood Radermacher to disclose referencing osteophytes, we disagree. The declaratory evidence does not establish that Radermacher’s disclosure necessarily concerns patients with osteophytes, or that Radermacher necessarily contemplates osteophytes as being subject to its method. The Petition’s logic appears to be that Radermacher teaches a

method of matching the “natural,” not pre-treated, surface of a joint (citing Ex. 1003, 12), but the Petition and the Declaration do not offer more than conclusory assertions that an osteophyte is necessarily part of the “natural” or “not pre-treated” surface of the bone described in Radermacher, beyond mere possibilities or probabilities.

The next question is whether referencing osteophytes is the “natural result flowing from” Radermacher’s technique, under the aforementioned *Oelrich* test, or whether it otherwise would have been obvious to apply Radermacher’s technique to a bone surface with osteophytes. Petitioner argues that it would have been obvious to apply Radermacher’s technique to a bone surface with osteophytes because (1) such a template would be a negative of the “natural (i.e. not pre-treated) surface”; (2) referencing any osteophyte would, in some cases, aid in alignment because the unique structure of the osteophyte would help ensure that the template was placed in the proper position; and (3) it would eliminate the need to pre-treat the joint to remove the osteophyte in a preliminary surgical step, thus reducing surgical time and improving patient safety. Pet. 30 (citing, e.g., Ex. 1003, 10, 12; Ex. 1002 ¶¶ 116–117).

Patent Owner responds that Petitioner provides no evidence to support this position and that one of ordinary skill would not have been motivated to modify a reference to account for osteophytes when the reference does not expressly or inherently disclose this feature. See Prelim. Resp. 18–19. Patent Owner argues that Petitioner cannot rely on general knowledge and the ’827 patent because they are not printed publications or patents under 35 U.S.C. § 311, and also argues that Petitioner improperly refers to other

exhibits not formally relied upon in a stated ground. *Id.* at 28–30 (citing, e.g., *Deere & Co. v. Graham*, Case IPR2015-00898, slip op. at 20-21 (PTAB Sept. 23, 2015) (Paper 7)).

We determine that Petitioner has not established adequately that referencing an osteophyte would have been “the natural result flowing from” Radermacher’s technique, or that it would have been obvious in light of Radermacher’s disclosure. In particular, Petitioner admits with respect to dependent claims 2 and 3 that a person of ordinary skill in the art might “not engage an osteophyte if the shape of the osteophyte was too complex to mimic or would cause other alignment problems.” Pet. 35 (citing Ex. 1002 ¶ 124). As such, Petitioner admits that there is not necessarily a reasonable likelihood of success when engaging an osteophyte using a template. Or, in the language of *Oelrich*, Petitioner admits that engaging an osteophyte is not necessarily the natural result flowing from Radermacher’s technique because the osteophyte may present too complex a shape or cause alignment problems. *See id.*

Indeed, the ’827 patent explains that alternate surgical methods exist, i.e., to cut off an osteophyte before placing a template or to place a template on areas of the bone free of the osteophyte. *See* Ex. 1001, 56:7–8; 73:36–39. We determine that the declaratory evidence does not establish adequately that a person reading Radermacher would have understood Radermacher to have engaged an osteophyte (or otherwise referenced an osteophyte) as opposed to performing an alternative surgical method on a bone with an osteophyte, such as removing the osteophyte.

Petitioner additionally contends with respect to dependent claims 2 and 3, that Radermacher discloses a second embodiment whereby a surgeon can form a template that extends over a plurality of geometrically non-abutting partial segments of bone, instead of engaging the bone segments. *See* Pet. 33–35 (citing, e.g., Ex. 1003, 12, 22, Fig. 3b, 4). In this embodiment, Radermacher discloses a template for operating on a vertebra where the template extends over the spinous processes. Although Petitioner does not explicitly rely on this embodiment for the unpatentability of independent claim 1 in the body of the Petition, Petitioner does include, in its claim chart for independent claim 1, citations to pages 21 and 22 of Radermacher and to portions of the Declaration of Dr. Mabrey that refer to this second embodiment of Radermacher. *See* Pet. 40 (citing, e.g., Ex. 1003, 22; Ex. 1002 ¶¶ 114). Petitioner asserts that avoiding osteophytes, if not engaging osteophytes, would have been obvious because a person of ordinary skill would have made a choice from a finite number of options, i.e., removing the osteophyte, engaging the osteophyte, or avoiding the osteophyte. Pet. 25 (citing Ex. 1002 ¶ 98). However, we find that the Petition and cited portions of the Declaration do not provide anything more than conclusory assertions that a surgeon would have treated an osteophyte in a similar manner to the spinous processes of a vertebra, as argued by Petitioner. In other words, Petitioner has not established a sufficient basis that it would have been obvious or feasible to treat an osteophyte in the same manner as a spinous process.

We further note that the asserted ground of unpatentability is not based on any prior art reference, i.e., a patent or printed publication,

cognizable under 35 U.S.C. § 311 for the “osteophyte” element of independent claim 1. Petitioner and Dr. Mabrey refer to certain articles on imaging of osteophytes. Exs. 1066–1068 (*cited in* Pet. 30; Ex. 1002 ¶¶ 111, 115). However, we agree with Patent Owner that the Petition has not relied on these articles for its stated grounds of unpatentability. We decline the invitation to rewrite the asserted grounds of unpatentability set forth in the Petition to include additional references, or combinations thereof.

Petitioner also asserts that Alexander discloses imaging bones and cartilage, that this would provide information regarding osteophytes, and that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Radermacher and Alexander because the patient-specific surface described in Radermacher “could engage (and therefore reference) an osteophyte.” Pet. 31, 40 (citing, e.g., Ex. 1004, Abstract, 23:31–32, 26:20–27:26, 39:22–24, 61:19–25, Figs. 10A–C, 12A–B, 18C–I; Ex. 1002 ¶ 118). However, the cited passages of Alexander disclose only imaging of cartilage and the use of biomechanical data. The cited passages of Alexander do not disclose osteophytes. Further, the portions of the Mabrey Declaration discussing Alexander do not show that Alexander necessarily disclosed osteophytes. *See, e.g.*, Ex. 1002 ¶ 118. For these reasons, we conclude that Petitioner does not adequately show that Alexander renders obvious a surgical technique of engaging an osteophyte or otherwise referencing an osteophyte when applying the template of Radermacher.

Thus, the prior art relied upon in the asserted ground does not disclose referencing an osteophyte, expressly or inherently. Additionally, Petitioner

does not provide adequate evidence that it would have been obvious to apply the technique of Radermacher in patients with osteophytes to engage (or avoid or reference) the osteophyte, as opposed to performing an alternate technique, such as first removing the osteophytes. In particular, Petitioner has not provided adequate evidence of a reasonable likelihood of success of applying Radermacher's technique to a bone surface with osteophytes beyond unsupported and conclusory assertions thereof.

For these reasons, we determine that Petitioner has not demonstrated a reasonable likelihood that the combination of Radermacher and Alexander renders obvious independent claim 1. Accordingly, we determine that Petitioner has failed to establish a reasonable likelihood that it would prevail in its assertion that independent claim 1, or dependent claims 2–13, 32, 38, and 44–46, are unpatentable as obvious over Radermacher and Alexander.⁵

*C. Obviousness of Claims 14–19, 22–25, 28, 29, 34–37, and
39–43 over Radermacher, Alexander, and Woolson (Ex.
1031)*

Petitioner contends that claims 14–19, 22–25, 28, 29, 34–37, and 39–43 are unpatentable as obvious over Radermacher, Alexander, and Woolson. Pet. 49–77. Patent Owner disagrees. Prelim. Resp. 11–24, 28–30.

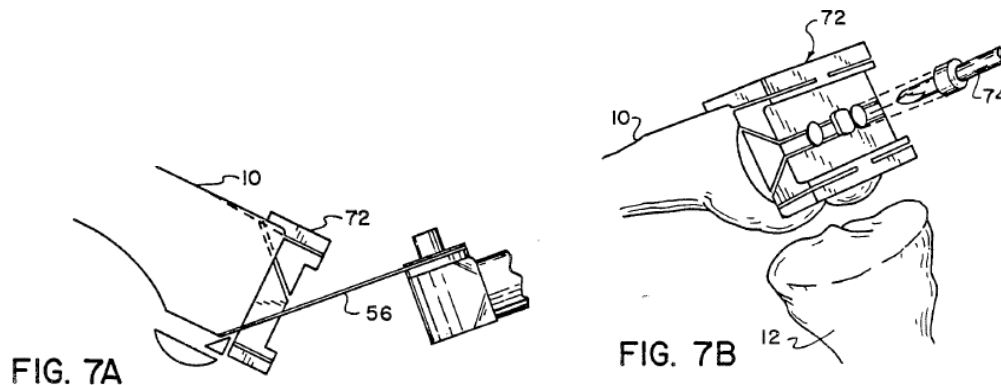
1. Overview of Woolson (Ex. 1031)

Woolson is titled “Preoperative Planning of Bone Cuts and Joint Replacement Using Radiant Energy Scan Imaging” and relates to a method of preoperative planning to determine the position of a bone-cut-defining

⁵ We consider Patent Owner's additional arguments, i.e., that Petitioner's asserted grounds are redundant, to be moot.

guide relative to the bone to be cut. Ex. 1031, 1:12–14. Woolson discloses steps of (1) preoperative determination of the angle between the anatomical and mechanical axes of the femur from radiographs; (2) localization of the center of the femoral head by external markers after operative radiographs are taken and correct estimation of the center of the distal femur for the external alignment system of femoral alignment; and (3) visual estimation of the centers of the proximal tibia and of the ankle joint in both the coronal and sagittal planes for correct tibial component alignment. *Id.* at 1:65–2:10.

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



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

2. Analysis

Petitioner does not argue, and we do not find, that Woolson remedies the deficiency in the asserted ground of obviousness of independent claim 1 based on Radermacher and Alexander. Accordingly, we determine that Petitioner has not established a reasonable likelihood that Radermacher, Alexander, and Woolson render obvious claims 14–19, 22–25, 28, 29, 34–

37, and 39–43 (which all depend, directly or indirectly, from claim 1), for similar reasons as for the ground based on Radermacher and Alexander. *See supra* Section II.B.3.

D. Obviousness of Claims 20 and 21 over Radermacher, Alexander, Woolson, and Hofmann (Ex. 1090)

Petitioner contends that claims 20 and 21 are unpatentable as obvious over Radermacher, Alexander, Woolson, and Hofmann. Pet. 78–80. Patent Owner disagrees. Prelim. Resp. 21–24, 34–36.

1. Overview of Hofmann (Ex. 1090)

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

2. Analysis

Claims 20 and 21 depend from claim 19, which ultimately depends from claim 1. Ex. 1001, 120:27–36. Petitioner does not argue, and we do not find, that Hofmann remedies the deficiency in the asserted ground of obviousness of dependent claim 19 based on Radermacher, Alexander, and Woolson. Accordingly, we determine that Petitioner has not established a reasonable likelihood that Radermacher, Alexander, Woolson, and Hofmann render obvious claims 20 and 21, for similar reasons as for the ground based on Radermacher, Alexander, and Woolson. *See supra* Section II.C.2.; *see also* Section II.B.3 (discussing ground of obviousness based on Radermacher and Alexander).

E. Obviousness of Claims 1–13, 32, 33, 38, and 44–46 over Radermacher and Fell (Ex. 1005)

Petitioner contends that claims 1–13, 32, 33, 38, and 44–46 are unpatentable as obvious over Radermacher and Fell. Pet. 81–84. Patent Owner disagrees. Prelim. Resp. 12–20, 25–30.

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 shapes of the affected femoral condyle and tibial plateau are ascertained using X-ray or MRI imaging to determine the correct geometry of the meniscal device for a given patient. *Id.* at 14:5–28. Figure 7 of Fell is depicted below:

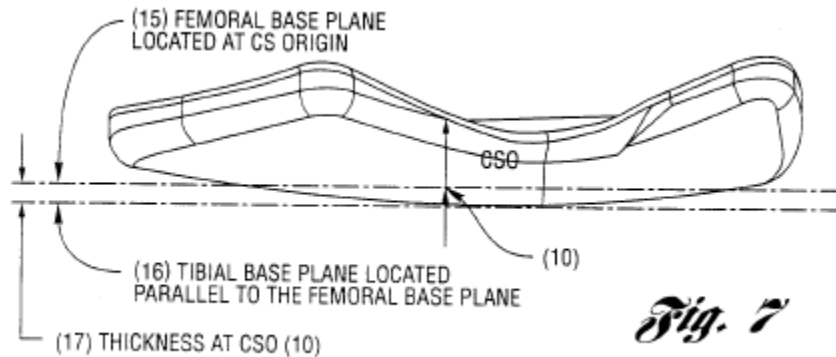


Figure 7 of Fell illustrates a device contour and its relationship with the femoral and tibial base planes. *Id.* at 5:1–2.

2. Analysis

Petitioner relies on Radermacher in the same manner, i.e., for disclosing the same features, as for the ground based on Radermacher and Alexander. *See* Pet. 81–85. We have determined, *supra*, that Petitioner does not establish adequately that Radermacher discloses or renders obvious engaging (or otherwise referencing) osteophytes with a surgical template. *See supra* Section II.B.3.

Petitioner additionally asserts that Fell discloses that the imaging is used to determine the size and shape of the bones and cartilage, which would include any osteophytes, and also discloses creating a patient-specific

implant that matches and mates with the contour of such surfaces. Pet. 81, 84 (citing, e.g., Ex. 1005, 13–15, 22; Ex. 1002 ¶¶ 186–192).

Patent Owner argues, as above, that the prior art does not disclose the “osteophyte” limitation of independent claim 1. See Prelim. Resp. 12–20. Patent Owner further argues that the Petition’s asserted ground of obviousness over Radermacher and Fell lacks the requisite particularity and specificity to set forth a prima facie case of obviousness. Prelim. Resp. 12–20, 25–28.

We determine that the cited portions of Fell relate to imaging the knee and creating an insert with a mating surface (Ex. 1005, 13–15) and to imaging a damaged joint (*id.* at 22). None of the cited portions of Fell discusses osteophytes. As such, Fell’s disclosure of creating an insert with a mating surface suffers from the same deficiency as Radermacher, i.e., there is no express or inherent disclosure of applying the technique when osteophytes are present, and Petitioner has not sufficiently demonstrated that it would have been obvious to do so. Further, the declaratory testimony does not remedy the deficiency for similar reasons as set forth, *supra*, with respect to the ground based on Radermacher and Alexander, i.e., it does not provide more than conclusory assertions that Fell would have been

understood to disclose osteophytes, or that Fell rendered obvious an implant referencing osteophytes, as opposed to removing them.

Accordingly, we determine that Petitioner has not established a reasonable likelihood that Radermacher and Fell render obvious claims 1–13, 32, 33, 38, and 44–46.

*F. Obviousness of Claims 14–19, 22–25, 28, 29, 34–37, and 39–43
over Radermacher, Fell, and Woolson*

Petitioner contends that claims 14–19, 22–25, 28, 29, 34–37, and 39–43 are unpatentable as obvious over Radermacher, Fell, and Woolson. Pet. 85. Patent Owner disagrees. Prelim. Resp. 12–20, 25–28.

Petitioner does not argue, and we do not find, that Woolson remedies the deficiency in the asserted ground of obviousness of independent claim 1 based on Radermacher and Fell. Accordingly, we determine that Petitioner has not established a reasonable likelihood that Radermacher, Fell, and Woolson render obvious claims 14–19, 22–25, 28, 29, 34–37, and 39–43, for similar reasons as for the ground based on Radermacher, Alexander, and Woolson. *See supra* Section II.C.2.

*G. Obviousness of Claims 20 and 21 over Radermacher, Fell,
Woolson, and Hofmann*

Petitioner contends that claims 20 and 21 are unpatentable as obvious over Radermacher, Fell, Woolson, and Hofmann. Pet. 85. Patent Owner disagrees. Prelim. Resp. 12–20, 25–28.

Petitioner does not argue, and we do not find, that Hofmann remedies the deficiency in the asserted ground of obviousness of claim 19 based on Radermacher, Fell, and Woolson. Accordingly, we determine that Petitioner has not established a reasonable likelihood that Radermacher, Fell, Woolson,

and Hofmann render obvious claims 20 and 21, for similar reasons as for the ground based on Radermacher, Fell, and Woolson. *See supra* Section II.F.; *see also* Section II.E.2. (discussing the ground of obviousness over Radermacher and Fell).

H. Obviousness of Claims 50–58 over Schuster I (-984 Ex. 1046), Schuster II (Ex. 1008), and Alexander

Petitioner contends that claims 50–58 are unpatentable as obvious over Schuster I, Schuster II, and Alexander. -984 Pet. 22–52. Patent Owner disagrees. -984 Prelim. Resp. 11–27, 30.

1. Overview of Schuster I (-984 Ex. 1046)

Schuster I is a European Patent Application Publication titled “Method for producing an endoprosthesis to replace a knee joint” and relates to knee joint surgery using such an endoprosthesis. *See* -984 Ex. 1046, (54), ¶ 1. Schuster I describes a problem in the prior art with approximate restoration of the features of a healthy knee, which may lead to complications such as mechanical interactions of the implanted components of the endoprosthesis and frontal knee joint pain syndrome, which is caused by misaligned sliding of the patella, which places a physiologically improper stress on the femur-patella sliding joint and the femur-shin joint. *Id.* ¶ 3. Schuster I discloses a method of taking images with a CT or MRI machine prior to surgery, and adjusting the preoperative image on at least the femur and tibia to achieve an approximation of the image of the damaged knee to the contours of a healthy knee. *Id.* ¶¶ 8–9. The adjusted femoral and tibial joint parts are then virtually segmented or separated and specified with cutting planes, whereby the image templates are subjected to a rapid

prototyping method to form templates for the casting of metal and plastic endoprostheses. *Id.* ¶¶ 10, 12. A virtual image of the damaged knee is then used for the production of an implantation aid, fitted exactly to the knee joint. *Id.* at 5:24–28 (claim 1); *see also id.* ¶ 11. The cutting surfaces adopted for the endoprosthesis are transferred to the template for the implementation aid as guide slots in an implantation aid for an oscillating saw blade during surgery. *Id.* at 5:41–60 (claim 1); *see also id.* ¶ 11. Care is taken to ensure that the implantation aid is seated “with adequate precision” so that the resection surfaces on the knee match up with the endoprosthesis. *Id.* at ¶ 11. Accordingly, the templates and implantation aids are designed “roughly in the shape of caps.” *Id.*

2. Overview of *Schuster II* (Ex. 1008)

Schuster II is a United States Patent titled “Method of Producing an Endoprosthesis as a Joint Substitute for a Knee Joint” and relates to an operative set for carrying out operations on damaged knee joints utilizing an endoprosthesis. Ex. 1008, (54), 1:9–11. *Schuster II* discloses a process with the steps of obtaining a CT or MRI image “to define very sharp contours of the damaged knee” (*see id.* at 2:55–64); virtually altering the image for approximating the contours of the damaged knee to a healthy knee (*id.* at 2:65–3:1); virtually severing components of a healthy knee to create a visual pattern for an endoprosthesis, corresponding to knee components to be severed during the factual operation (*id.* at 3:15–22); marking severing areas to the damaged knee joint to create a template for an implantation aid (*id.* at 3:40–46); and preparing an endoprosthesis and an implantation aid using rapid prototyping (*id.* at 4:6–24).

3. Analysis

Independent claims 50, 53, and 56 each recite, in pertinent part, “wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint.” Ex. 1001, 122:14–16, 122:38–40, 122:65–67. Independent claims 50, 53, and 56 thus contain a similar requirement as independent claim 1, with respect to “referenc[ing]” an osteophyte.

Petitioner contends that Schuster I and Schuster II disclose the “osteophyte” limitations of independent claims 50, 53, and 56, or that the “osteophyte” limitations would have been obvious in view of Schuster I and Schuster II. -984 Pet. 32–33 (citing, e.g., Ex. 1008, 3:40–46, 3:57–67; -984 Ex. 1046 ¶ 11; Ex. 1102 ¶¶ 125–127); *see also id.* at 37–41. Petitioner asserts that the implantation aids disclosed in Schuster I and Schuster II would have a portion that engages an osteophyte because Schuster I and Schuster II disclose that the surface of the implantation aid is “fitted exactly to” or “fits snugly to” the damaged knee joint. -984 Pet. 32 (citing, e.g., -984 Ex. 1046 ¶ 11; Ex. 1008, 3:40–46, 3:57–67; Ex. 1102 ¶ 107). However, none of the cited portions of Schuster I or Schuster II describes osteophytes, and the Mabrey Declaration does not establish persuasively that a person of ordinary skill in the art would have understood Schuster I and Schuster II to disclose osteophytes. Petitioner simply asserts that the “vast majority” of patients would have had osteophytes. -984 Pet. 32 (citing Ex. 1102 ¶ 125). However, Petitioner does not argue persuasively that Schuster I and Schuster II inherently disclose osteophytes nor that Schuster I and Schuster II necessarily describe patients with osteophytes.

As to Petitioner's contention that Schuster I and II render obvious use of an implantation aid fitted "exactly to" or fitted "snugly to" a bone surface with osteophytes, Petitioner argues that a person of ordinary skill would have been motivated to configure a portion of an implantation aid to engage (and thereby reference) an osteophyte because (1) such a template would be consistent with the statements in Schuster I and Schuster II that the aid be placed "on the damaged knee joint"; (2) referencing an osteophyte would aid in alignment because the unique structure of the osteophyte would help ensure that the implantation aids are placed in the proper position; and (3) it would eliminate the need to pre-treat the joint to remove the osteophyte in a preliminary surgical step, thus reducing surgical time and improving patient safety. -984 Pet. 33 (citing Ex. 1102 ¶¶ 126–128).

Patent Owner argues that the prior art does not disclose the "osteophyte" limitations. See -984 Prelim. Resp. 11–19. Patent Owner further argues that the Petitioner improperly treats Schuster I and Schuster II as if it were a single reference without a rationale for combining Schuster I and Schuster II. -984 Prelim. Resp. 19–27 (citing *Enovate Medical, LLC v. InterMetro Industries Corp.*, Case IPR2015-00300, slip op. at 3, 11–12 (Paper 12) (PTAB May 20, 2015)).

Neither Petitioner nor the Mabrey Declaration establishes that a person of ordinary skill would have had a reasonable expectation of success in applying the technique of Schuster I or Schuster II when osteophytes are present. Moreover, neither Petitioner nor the Declaration offer more than conclusory support for the argument that a person of ordinary skill would

have engaged or substantially engaged an osteophyte, rather than removing the osteophyte prior to placement of an implantation aid.

Further, we note that none of the references relied on for this ground disclose “osteophytes.” Although Petitioner and the Declaration make passing reference to certain scientific articles on imaging of osteophytes (-984 Pet. 33 (citing Exs. 1066–1069); Ex. 1102 ¶¶ 49, 126), we decline the invitation to rewrite the Petition in order to create a ground based on these references.

Petitioner relies on the same portions of Alexander as relied on in the ground based on Radermacher and Alexander. We determine that Alexander does not render obvious the application of the techniques of Schuster I and Schuster II to patients with osteophytes for similar reasons as for the ground based on Radermacher and Alexander, i.e., Alexander only discloses imaging of cartilage and does not describe osteophytes. *See supra*, Section II.B.3.

Accordingly, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that Schuster I, Schuster II, and Alexander render obvious independent claims 50, 53, and 56 and dependent claims 51, 52, 54, 55, 57, and 58.

*I. Obviousness of Claims 59–64 over Schuster I,
Schuster II, Alexander, and Dunn*

Petitioner contends that claims 59–64 are unpatentable as obvious over Schuster I, Schuster II, Alexander, and Dunn. -984 Pet. 53–60. Patent Owner disagrees. -984 Prelim. Resp. 11–27, 30.

1. Overview of Dunn (Ex. 1036)

Dunn is titled “Instruments for Shaping Distal Femoral and Proximal Tibial Surfaces” and relates to medical instruments for shaping the distal femur and proximal tibia surfaces to receive components of a knee prosthesis for knee replacement surgery. Ex. 1036, (54), (57), 1:7–11. Dunn recognized that prior art systems required a high level of skill by the surgeon in order to properly align and fit a prosthesis. *Id.* at 1:13–32. Dunn’s system determines the angle between a patient’s anatomical axis and mechanical axis; verifies the anatomical axis by drilling a reference hole; secures a femoral alignment guide to the distal femur surface with a locator; attaches an anterior femoral cutting guide to the femoral alignment guide; and fits a cutting device through a cutting guide slot of the anterior femoral cutting guide to cut across femoral condyles in order to fit a distal femoral cutting guide to the bone surface after removal of the anterior femoral cutting guide. *Id.* at 3:1–24.

2. Analysis

Independent claim 59 recites, in pertinent part, “wherein the patient-specific surface is configured to reference the osteophyte.” Ex. 1001, 123:22–24. Independent claim 59 thus contains a similar requirement as independent claim 1, with respect to “referenc[ing]” an osteophyte.

Petitioner relies on the same portions of Schuster I, Schuster II, and Alexander as for the ground of obviousness of claims 50–58 over Schuster I, Schuster II, and Alexander, and we find the same deficiency therein. -984 Pet. 53; *see supra* Section II.I.3. Petitioner does not argue, and we do not find, that Dunn remedies the deficiency in the ground of obviousness of

claims 50–58 based on Schuster I, Schuster II, and Alexander. Accordingly, we determine that Petitioner has not established a reasonable likelihood that Schuster I, Schuster II, Alexander, and Dunn render obvious claims 59–64, for the same reasons as for the ground based on Schuster I, Schuster II, and Alexander.

J. Obviousness of Claims 50–64 over Radermacher, Swaelens, and Alexander, alone or further in view of Woolson

Petitioner contends that claims 50–64 are unpatentable as obvious over Radermacher, Swaelens, and Alexander, alone or further in view of Woolson. -984 Pet. 61–89. Patent Owner disagrees. -984 Prelim. Resp. 11–19, 27–30.

1. Overview of Swaelens

Swaelens is titled “Method for Making a Perfected Medical Model on the Basis of Digital Image Information of a Part of the Body” and relates to a technique for creating a model which perfectly shows the positive or negative form of at least a part of the part of the body, by converting image information with a processing unit and a rapid prototyping machine. Ex. 1007, 1:6–14. Swaelens’s rapid prototyping technique builds an object layer by layer, or point by point, by adding or hardening material. *Id.* at 1:16–19. Such free form manufacturing techniques include stereo-lithography, selective laser sintering, fused deposition modelling, and related techniques. *Id.* at 1:17–28. Swaelens discloses that a person may collect digital image information for manufacturing prototypes using a computer tomography scanner or a magnetic resonance machine. *Id.* at 1:30–31, 6:24–29.

2. Analysis

Petitioner relies on the same portions of Radermacher and Alexander as for the ground challenging independent claim 1 based on Radermacher and Alexander. *Compare* -984 Pet. 30, 61–82, *with id.* at 20–38. We determine that Radermacher and Alexander fail to disclose (or render obvious) the “osteophyte” limitations of independent claims 50, 53, 56, and 59 for the same reason as for the ground challenging independent claim 1 based on Radermacher and Alexander. *See supra* Section II.B.3.

Petitioner does not argue, and we do not find, that Swaelens or Woolson remedy the deficiency in the asserted grounds of obviousness of independent claim 1 based on Radermacher and Alexander. Accordingly, we determine that Petitioner has not established a reasonable likelihood that claims 50–64 are obvious over Radermacher, Swaelens, and Alexander, alone or further in view of Woolson, for the same reasons as for the grounds based on Radermacher and Alexander. *See supra* Section II.B.3.

III. CONCLUSION

We conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–25, 28, 29, 32–46, and 50–64 of the ’827 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby ORDERED that the Petitions are *denied*, and no trial is instituted.

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