

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2017-00373
Patent 8,551,169 B2

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

WORTH, *Administrative Patent Judge*.

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

I. INTRODUCTION

On November 30, 2016, Smith & Nephew, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 29 and 30 (the “challenged claims”) of U.S. Patent No. 8,551,169 B2 (Ex. 1001, “the ’169 patent”). On March 15, 2017, Patent Owner, ConforMIS, Inc. (“Patent Owner”), filed a Preliminary Response (Paper 6, “Prelim. Resp.”) thereto.

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 29 and 30 are unpatentable. Accordingly, we institute an *inter partes* review of claims 29 and 30 based on the grounds identified in the Order section of this decision.

A. Related Matters

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

B. The '169 Patent (Ex. 1001)

The '169 patent is titled “Joint Arthroplasty Devices and Surgical Tools” and relates to methods, systems, and devices for articular resurfacing, and to surgical molds designed to achieve optimal cut planes in a joint in preparation for installation of a joint implant. *See* Ex. 1001, 1:31–34. The '169 patent states that prior art devices did not always provide ideal alignment with the articular surfaces and the resultant joint congruity, and that poor alignment or congruity can lead to instability of the joint, particularly lateral instability. *Id.* at 1:3–8. The '169 patent stated a need in the art for tools that increase the accuracy of cuts made to the bone in a joint in preparation for surgical implantation of an artificial joint. *Id.* at 1:9–15.

In one embodiment, the '169 patent discloses providing an imaging test to a patient to determine the articular anatomy of a knee joint, e.g., the width of the femoral condyles, the tibial plateau, etc., as well as information on femoral and tibial axes, deformities such as varus and valgus conditions, and other articular alignments *Id.* at 50:60–67. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. *Id.* at 51:2–8. According to the '169 patent, the imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan, an MRI scan, or combinations thereof. *Id.* at 50:67–51:2.

C. Illustrative Claim

Claim 29, reproduced below, is the sole challenged claim recited in independent form, and is illustrative of the subject matter:

29. A method of creating a patient-specific instrument for implanting an orthopedic implant in or about a joint of a patient, the method comprising:

creating a patient-specific surgical instrument based at least in part on a first magnetic resonance image data set and a second image data set,

wherein the second image data set is of a type that is different from the first magnetic resonance image data set;

wherein the surgical instrument has a patient-specific surface that is derived from at least the first magnetic resonance image data and that substantially matches a corresponding surface portion associated with the joint; and

wherein the surgical instrument has a guide that is oriented relative to the patient-specific surface based on information derived from the second image data set.

Ex. 1001, 62:65–63:34.

D. The Alleged Grounds of Unpatentability

Relying on the Declaration of Dr. Jay D. Mabrey, M.D. (Ex. 1002), Petitioner sets forth its contentions that claims 29 and 30 are unpatentable based on the grounds list in the following table. Pet. 20–65. As a preliminary matter, we observe that the Petitioner sets forth the ground of unpatentability based on Swaelens and Woolson as one grouping of references but pleads this ground of unpatentability in the alternative based on the use of references individually, e.g., based on Swaelens alone or Swaelens in combination with Woolson. *See* Pet. 42–65. Similarly, for the ground of unpatentability based on CAOS, Radermacher, and Woolson,

Petitioner relies on multiple references for individual limitations. Taking the references in the alternative as presented would, as a practical matter, expand what is asserted as one ground into three (or more) separate grounds of unpatentability. The function of the Board is not to comb through Petitioner’s arguments in order to decipher the strongest argument or to determine the strongest combination of references to challenge the claims. As such, we exercise our discretion and consider all of the references in combination as one ground of unpatentability. *See* 35 U.S.C. § 314(a); 35 C.F.R. § 42.108; *see generally LG Elecs., Inc. v. Rosetta-Wireless Corp.*, Case IPR2016-01516 (PTAB Apr. 3, 2017) (Paper 25) (denying rehearing).¹

References	Basis	Claims challenged
CAOS ² , Radermacher ³ , and Woolson ⁴	§ 103(a)	29 and 30
Swaelens ⁵ and Woolson	§ 103(a)	29 and 30

¹ Patent Owner argues throughout its Preliminary Response that the grounds asserted in the Petition are horizontally and vertically redundant, i.e., within and across grounds. *See* Prelim. Resp. 36–45. Based on our determination to consider the references in each ground as one group, Patent Owner’s arguments with respect thereto are generally moot.

² Radermacher et al., *Computer Assisted Orthopaedic Surgery With Image Based Individual Templates*, 354 CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 28–38 (Lippincott Williams & Wilkins 1998) (Ex. 1033, “CAOS”).

³ Radermacher, WO 93/25157, pub. Dec. 23, 1993 (Ex. 1003).

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

⁵ Swaelens, WO 95/28688, pub. Oct. 26, 1995 (Ex. 1007).

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). Neither Petitioner nor Patent Owner proposes construction of any terms. For purposes of this Decision, we do not provide a special construction for any term.

B. *Level of Skill in the Art*

Petitioner asserts that the level of skill in the art is person of ordinary skill in the art for purposes of the '169 patent 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. 19 (citing Ex. 1002 ¶¶ 29–31). Although Patent Owner does not disagree, Patent Owner nevertheless requests that we clarify that experience with, or an understanding of, imaging technology is required of a person of ordinary skill in the art. Prelim. Resp. 9–10. Patent Owner asserts that a person of ordinary skill would understand how particular images are obtained and what image data are produced, or in the alternative would have “access to or work with individuals such as a radiologist with such experience or understanding.” *Id.* at 10.

Based on the language of independent claim 29, i.e., a first magnetic resonance image data set and a second image data set, the specification of the ’169 patent, and the problems to which it is directed, based on the evidence of record we agree with Patent Owner’s assertion that a person of ordinary skill in the art would have an understanding of, or experience working with, imaging technology, e.g., in preparation for performing surgery. Further, Radermacher, which was prior art cited during the prosecution of the ’169 patent, indicates that the level of skill in the art includes an understanding of imaging for use in preparation for orthopedic surgery. *See* Ex. 1001, [56]; Ex. 1003; *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (applied prior art reflects the appropriate level of skill at the time of the claimed invention).

C. *Obviousness over CAOS (Ex. 1033), Radermacher (Ex. 1003), and Woolson (Ex. 1031)*

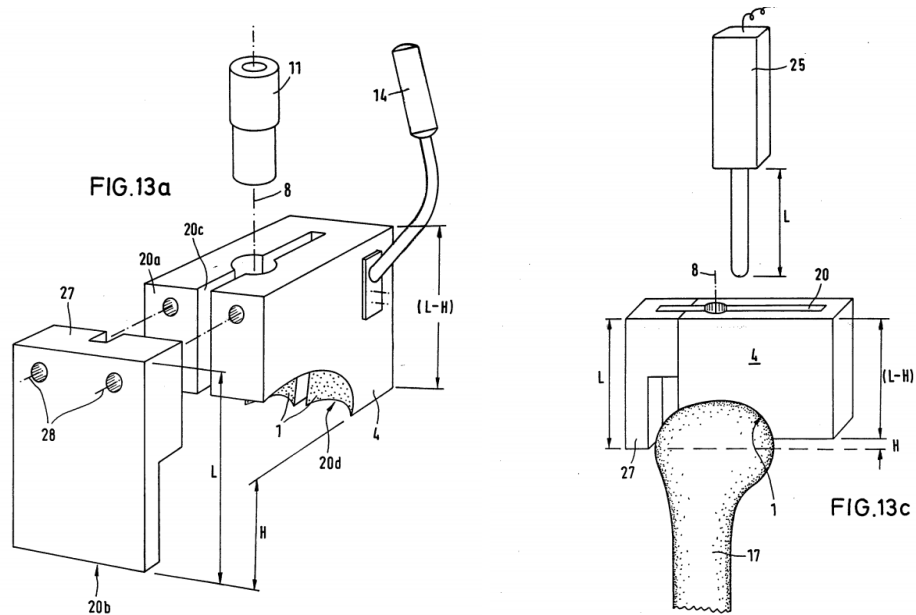
Petitioner contends that claims 29 and 30 are unpatentable as obvious over CAOS, Radermacher, and Woolson. Pet. 21–42. Patent Owner disagrees. Prelim. Resp. 10–45.

1. CAOS

CAOS is a paper titled “Computer Assisted Orthopaedic Surgery with Image Based Individual Templates.” Ex. 1033, 28. CAOS explains that “accurate placement of implant components with respect to the individual mechanical axis of the leg is essential.” *Id.* at 31. Accordingly, CAOS discloses the design and manufacture of individual customized templates for use in, e.g., knee replacement surgery, which are formed from three-dimensional reconstructions of bone structures, extracted from CT image data. *Id.* at 29. Additionally, CAOS explains that “topograms could be used to identify the bone axis.” *Id.* at 31. “[G]uides for drills, saws, chisels, or milling tools are adaptable or integrated into these individual templates in predefined positions for different types of interventions.” *Id.* at 29.

2. 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:

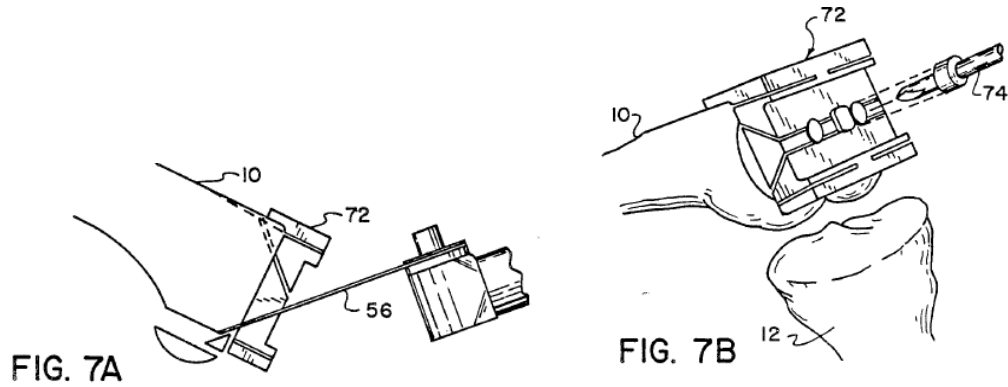


Figures 13a and 13c schematically show an individual template 4 for the preparation of the seat for a knee-joint head prosthesis. *Id.* at 30:5–8.

3. Overview of Woolson

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

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



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

4. Analysis

In its Petition, Petitioner sets forth its contentions as to how the limitations of claims 29 and 30 are disclosed in, or obvious over, the combination of CAOS, Radermacher, and Woolson. Pet. 21–42.

a. Claim 29

As to the preamble and the limitation “wherein the surgical instrument has a patient-specific surface that . . . substantially matches a corresponding surface portion associated with the joint,” Petitioner relies on the disclosure in CAOS of individual templates. Pet. 23–26, 34, 37 (citing, e.g., Ex. 1033, 28–36). We determine that Petitioner has made a sufficient showing on this record. For example, CAOS discloses creating customized mechanical tool guides for orthopedic surgery using a three-dimensional printer. *See* Ex. 1033, 28.

As to the limitations “creating a patient-specific surgical instrument based at least in part on a first magnetic resonance image data set and a second image data set” and “wherein the second image data set is of a type that is different from the first magnetic resonance image data set,” as recited

by claim 29, Petitioner relies on the disclosure in CAOS of two image data sets and the disclosure in Radermacher of MRI imaging. Pet. 26–27, 34–37 (citing, e.g., Ex. 1033, 28–32, 34, 36–37; Ex. 1003, 10–13, 21–22, 42, Figs. 13a–d, 18–19). Petitioner asserts that it would have been obvious to combine the teachings of CAOS and Radermacher because (a) the references share the same first named author/inventor; (b) the references describe related subject matter; (c) the references are both directed to the problem of treating diseased joints; (d) CT and MRI were known in the art to be alternative imaging methods; (e) Radermacher discloses using both CT and MRI; (f) the use of MRI instead of CT would be a substitution of known methods with predictable results; and (g) such a substitution would represent a choice from a finite number of identified solutions. Pet. 25–26 (citing, e.g., Ex. 1003, 10, Figs. 18, 19; Ex. 1001, 12:23–41, 13:25–14:3; Ex. 1002 ¶ 85; *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)).

Patent Owner argues, relying on the Declaration of Dr. Gaskin, that a topogram would no longer be taken if a CT scan were substituted with an MRI image because, according to Patent Owner, a topogram is only taken in conjunction with a CT scan as a preliminary image and would not be useful without a corresponding CT scan. *See* Prelim. Resp. 15 (citing, e.g., Ex. 2001 ¶¶ 26, 28). Dr. Gaskin avers, *inter alia*, that “[t]he topogram is used primarily to determine the start and end locations of the CT scan, as the patient’s anatomy is depicted on the topogram in a fashion that is linked to the table position.” Ex. 2001 ¶ 17; *see also id.* ¶¶ 26 (“[A] CT topogram would not be acquired as part of an MRI scan.”), 28. However, in the absence of the opportunity for cross-examination of Patent Owner’s Declarant in a preliminary proceeding (i.e., prior to any trial), we resolve a

disputed question of fact raised by Patent Owner's declarant in favor of the Petitioner at this stage of the proceeding. *See* 37 C.F.R. § 42.108(c).

Patent Owner also argues that Petitioner inappropriately relies on the knowledge of a person of ordinary skill in the art. Prelim. Resp. 36–37. However, on the current record, we determine that Petitioner is properly relying on references cognizable as prior art under 35 U.S.C. § 311.

On the current record at this stage of the proceeding, we determine that Petitioner has made a sufficient showing that the combination of CAOS and Radermacher disclose two different imaging data sets, including an MRI image data set. In particular, CAOS discloses taking two sets of images, i.e., a CT image and a topogram. Ex. 1033, 31. Further, Radermacher discloses the use of MRI imaging in the creation of a negative mold of a patient's joint. Ex. 1003, 10, 12.

We further determine on this record that Petitioner has made a sufficient showing that it would have been obvious to substitute an MRI for a CT scan. In particular, the disclosure of Radermacher treats CT and MRI scans as interchangeable. Ex. 1003, 10 (“According to the inventive method, there is used a split-field device (e.g. a computer or a nuclear spin tomograph).” Dr. Mabrey avers that it was well-known to persons of ordinary skill in the art at the time of the invention to use MRI in preparation for orthopedic surgery as a replacement for CT scans. Ex. 1002 ¶ 80. CAOS also discloses the use of MRI “processing modules and enhanced models for efficient biomechanical analysis” (Ex. 1033, 37), cited in the Declaration of Dr. Mabrey in support of the Petition (*see* Ex. 1002 ¶ 80).

As to the limitation “wherein the surgical instrument has a guide that is oriented relative to the patient-specific surface based on information

derived from the second image data set,” recited by claim 29, Petitioner relies on the individual templates of CAOS in combination with the disclosure of determining a biomechanical axis in Woolson, as well as on the prior art discussed above with respect to the preamble. Pet. 28–34, 37–41 (citing Ex. 1033, 28–37, Fig. 1B; Ex. 1031, Abstr., 1:26–36, 1:37–57, 2:28–59, 3:50–6:3, 5:9–49, 6:26–31, 6:50–53, 7:32–36, 7:63–67, 3:50–54, Figs. 1, 2A–2B, Figs. 1, 2A–2B; Ex. 1001, 12:23–41, 14:55–16:36).

We determine that Petitioner has made a sufficient showing on the current record. In particular, Woolson discloses using a pre-operative CT scan to produce bone cuts perpendicular to a mechanical axis (Ex. 1031, 7:63–67), and CAOS discloses the use of topograms to determine the bone axis (Ex. 1033, 31).

For the foregoing reasons, we determine that Petitioner has demonstrated a reasonable likelihood that the combination of CAOS, Radermacher, and Woolson renders obvious the repair system and tool of claim 29.

b. Claim 30

Claim 30 depends from claim 29 and further recites “the second image data is x-ray image data.” Ex. 1001, 63:14–15. Petitioner relies, for the further recitation, on Woolson’s disclosure of using x-ray imaging data to determine a mechanical axis. Pet. 41–42 (citing Ex. 1031, e.g., Abstr., 1:26–50; 2:28–50). Petitioner asserts that a person of ordinary skill would have combined Woolson’s teachings with those of CAOS for the reasons described above with respect to claim 29. *Id.* at 42. Patent Owner argues that Woolson teaches away from the use of x-ray images. Prelim. Resp. 21–23. Patent Owner asserts that Woolson seeks to eliminate x-ray images

because cutting techniques based on intraoperative or pre-operative x-rays may “produce error resulting from inaccuracies,” and instead Woolson proposes a technique using CT images. *Id.* at 22.

On the basis of the current record, we determine that Petitioner has made a sufficient showing. Even if Woolson teaches away from the use of x-ray imaging in favor of CT scans to increase accuracy, as argued, Woolson indicates that the use of x-rays was standard practice and was known to be used in orthopedic surgery, i.e., at the time of Woolson’s disclosure. Ex. 1031, 1:36–50. Thus, even if there are advantages to a CT-scan, we determine on this record that an x-ray was an acceptable alternative that a surgeon might select based upon other considerations, for example simplicity, availability, or cost. *See, e.g., Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.”); *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) (“The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.”); *see also In re Urbanski*, 809 F.3d 1237, 1244 (Fed. Cir. 2016).

For the foregoing reasons, we determine that Petitioner has demonstrated a reasonable likelihood that the combination of CAOS, Radermacher, and Woolson renders obvious the repair system and tool of claim 30.

D. Obviousness over Swaelens (Ex. 1007) and Woolson

Petitioner contends that claims 29 and 30 are unpatentable as obvious over the combination of Swaelens and Woolson. Pet. 42–65. Patent Owner disagrees. Prelim. Resp. 23–42.

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

a. Claim 29

As to the preamble and the limitation “wherein the surgical instrument has a patient-specific surface that . . . substantially matches a corresponding surface portion associated with the joint,” Petitioner relies, *inter alia*, on the disclosure in Swaelens of manufacturing a template and a prosthesis. Pet.49, 55–56, 61–62 (citing Ex. 1007, Abstract, 1:6–14, 4:1–5:20, 5:22–34, 8:17–28, 9:1–13, 11:6–21, 13:4–14, 13:17–14:1, Figs. 3–8). On the current record, Petitioner has made a sufficient showing. For example, Swaelens

discloses creating a template for surgery (Ex. 1007, 9:2–8), and also describes creating a prosthesis for the knee (*id.* at 5:22–34).

As to the limitations “creating a patient-specific surgical instrument based at least in part on a first magnetic resonance image data set and a second image data set” and “wherein the second image data set is of a type that is different from the first magnetic resonance image data set,” as recited by claim 29, Petitioner relies on the disclosures in Swaelens of using MRI scans and additional digital information, in combination with the disclosure in Woolson of using x-ray or CT imaging to determine the mechanical axis. Pet. 43–45, 57–61 (citing, e.g., Ex. 1007, Abstract, 3:30–4:15, 4:19–22, 5:1–10, 7:17–21, 7:23–8:14, 9:1–13, 10:23–30, 13:4–14:31, Figs. 6–8; Ex. 1031, 1:8–18, 1:26–59; 3:50–6:3, 6:26–31, 6:50–53, 7:32–36, 7:63–67, Figs. 1, 2A–2B; Ex. 1002 ¶¶ 47–49, 99–103, 128; Ex. 1001, 14:55–15:21, 16:55–17:10, 14:41–46).

Patent Owner argues that the additional digital information of Swaelens is not necessarily *image* information. Prelim. Resp. 29–34. Patent Owner asserts that the functional element may be a position, a direction, a length, an angle, a point of attachment, the formation of a tooth filling, or a prosthetic function. Prelim. Resp. 28 (citing Ex. 1001, 5:1–5). However, Petitioner also relies on Woolson for a second set of image information.

We determine that on the current record, Petitioner has made a sufficient showing that it would have been obvious for a surgeon to use more than one image set in planning a surgery based on the teachings of Swaelens and Woolson. For example, Swaelens discloses the use of MRI imaging in gathering information to create a model (*see* Ex. 1007, 6:24–29, 7:23–8:14, 9:2–8) and Swaelens indicates the benefit of adding a functional element

with “additional digital information from outside” (*id.* at 7:16–21). Woolson discloses one critical type of functional information is to cut the bone perpendicular to the mechanical axis, as derived from x-ray or CT image data (*see* Ex. 1031, 1:26–50, 4:6–19, 3:50–6:3). Thus, whether or not the second set of data from Swaelens, i.e., for functional information, is image data, Woolson teaches relying on a set of image data to supply functional information.

As to the limitation “wherein the surgical instrument has a guide that is oriented relative to the patient-specific surface based on information derived from the second image data set,” as recited by claim 29, Petitioner relies, *inter alia*, on the disclosure in Woolson of using x-ray data or CT-imaging to determine the biomechanical axis of the bone. Pet. 54 (citing Ex. 1031, 1:26–50, 2:28–59, 3:50–4:48, 5:9–49, 7:63–67; *see also* Pet. 45–55, 62–66 (citing, e.g., Ex. 1031, Abstract, 1:37–50, 2:28–59, 3:50–4:48, 5:9–49, 7:63–37; Ex. 1007, Abstract, 2:12–14, 3:30–34, 4:28–5:10, 4:48–5:20, 7:17–21, 9:1–13, 10:23–30; 10:32–11:4, 13:4–14:31, 17:13–17, Figs. 2, 6–8; Ex. 1002 ¶ 129; Ex. 1001, 12:23–41, 14:55–16:34). On this record, Petitioner has made a sufficient showing for the same reason as for the immediately previous limitation, i.e., Swaelens teaches the use of MRI data to create a template and Woolson teaches the use of x-ray data to determine the mechanical axis.

Petitioner argues that it would have been obvious to a person of ordinary skill to combine the teachings of Woolson and Swaelens (i.e., to use the x-ray data or CT image data representing the biomechanical axis, as taught by Woolson, as the additional information for positioning and orienting functional elements as taught by Swaelens) for at least the

following reasons: (a) Swaelens and Woolson both describe cutting devices in the field of arthroplasty, (b) Woolson teaches that alignment of tool guides and cutting paths relative to the biomechanical axis is critical to the long-term success of the knee replacement, and (c) using Woolson's data to modify Swaelens's arthroplasty would improve a similar procedure in a predictable way. Pet. 49–50. On this record, Petitioner has made a sufficient showing that it would have been obvious to combine the teachings of Woolson and Swaelens. For example, Woolson discloses that it is necessary to cut perpendicular to the mechanical axis. Ex. 1031, 4:6–19.

For the foregoing reasons, we determine that Petitioner has demonstrated a reasonable likelihood that the combination of Swaelens and Woolson renders obvious the repair system and tool of claim 29.

b. Claim 30

Petitioner relies, for the further recitation of claim 30, on Woolson's disclosure of using x-ray imaging data to determine a mechanical axis. Pet. 65 (citing, e.g., Ex. 1031, Abstr., 1:26–50; 2:28–50; Ex. 1002 ¶¶ 149–50). Patent Owner disagrees, for similar reasons as for the ground based on CAOS, Radermacher, and Woolson. Prelim. Resp. 34–35. On this record, we determine that Petitioner has made a sufficient showing, for the same reasons set forth above with respect to ground based on CAOS, Radermacher, and Woolson. *See* Section II.B.4.b.

III. CONCLUSION

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 29 and 30 of the '169 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 29 and 30 as obvious over CAOS, Radermacher, and Woolson;

Claims 29 and 30 as obvious over Swaelens and Woolson;

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.

IPR2017-00373
Patent 8,551,169 B2

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