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Paper No. __
Filed: August 13, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2017-00373
Patent No. 8,551,169

PATENT OWNER'S NOTICE OF APPEAL

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

Pursuant to 35 U.S.C. §§ 141(c) and 319 and 37 C.F.R. § 90.2(a), Patent Owner Conformis, Inc. ("Conformis") hereby provides notice that it appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered June 12, 2018, (Paper No. 47), and from all underlying orders, decisions, rulings, and opinions relating to U.S. Patent No. 8,551,169 ("the '169 patent"), set forth in *Inter Partes* Review IPR2017-00373.

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

- the United States Patent and Trademark Office ("PTO") Patent Trial and Appeal Board ("Board") unpatentability determinations, including without limitation issues relating to (i) the Board's legally deficient *Graham* analysis, including its improper motivation-to-combine and reasonable-expectation-of-success analyses; (ii) its consideration of arguments and evidence raised by Petitioner for the first time in reply; (iii) its violation of the Administrative Procedure Act when it failed to adhere to the arguments and positions presented by the Petitioner in the petition; and (iv) the lack of substantial evidence support for its

findings regarding the asserted references' disclosures; and (v) the Board's failure to comply with 35 U.S.C. § 316(e);

- the Board's determination that claims 29 and 30 of the '169 patent are unpatentable under 35 U.S.C. § 103 over *CAOS*,[1] *Radermacher*,[2] and *Woolson*[3];
- the Board's determination that claims 29 and 30 of the '169 patent are unpatentable under § 103 over *Swaelens*[4] and *Woolson*; and
- any other issue decided adversely to Conformis in an order, decision, ruling, or opinion underlying or supporting the Board's Final Written Decision.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a), this Notice is being filed with the Director of the PTO, and a copy of this Notice is being filed with the Board. In addition, a copy of this Notice and the required docketing fees are being

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[1] Klaus Radermacher et al., *Computer Assisted Orthopaedic Surgery With Imaged Based Individual Templates*, 354 CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 28-38 (1998).

[2] PCT Publication WO 93/25157.

[3] U.S. Patent No. 4,841,975.

[4] PCT Publication WO 95/28688.

filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit via CM/ECF.

Respectfully submitted,

Date: August 13, 2018

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

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE AND FILING

I hereby certify that on this 13th day of August, 2018, in addition to being filed and served electronically through the Board's E2E System, a true and correct copy of the foregoing Patent Owner's Notice of Appeal was served on the Director of the PTO, via Express overnight delivery at the following address:

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

I also hereby certify that on this 13th day of August, 2018, a true and correct copy of the foregoing Patent Owner's Notice of Appeal and the filing fee, were filed with the Clerk's Office of the United States Court of Appeals for the Federal Circuit, via CM/ECF.

I also hereby certify that on this 13th day of August, 2018, a true and correct copy of the foregoing Patent Owner's Notice of Appeal was served, by electronic mail, upon the following:

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Paper 47
Entered: June 12, 2017

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*.

BUNTING, *Administrative Patent Judge*.

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

I. INTRODUCTION

Smith & Nephew, Inc. ("Petitioner") filed a Petition (Paper 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"). Patent Owner, ConforMIS, Inc. ("Patent Owner"), filed a Preliminary Response (Paper 6, "Prelim. Resp.") thereto. Upon consideration of the information presented in the Petition, we determined that Petitioner had demonstrated that there was a reasonable likelihood that it would prevail with at least one challenged claim, and instituted this trial pursuant to 35 U.S.C. § 314(a), as to claims 29 and 30 ("the instituted claims") of the '169 patent. Paper 8, 19 (Dec.").

Subsequent to institution, Patent Owner filed a Patent Owner Response (Paper 16, "PO Resp."), and Petitioner filed a Reply (Paper 22, "Reply"). Petitioner filed evidentiary objections to certain of Patent Owner's Exhibits (Paper 18) but did not file a motion to exclude, which is required to preserve any evidentiary objection. *See* 37 C.F.R. § 42.64(c). Additionally, with our authorization, Patent Owner filed a list of purportedly improper arguments contained in Petitioner's Reply, to which Petitioner responded (Paper 35). Patent Owner also filed Motions for Observation on the Cross-Examinations of Garry E. Gold, M.D. (Paper 31) and Jay D. Mabrey, M.D. (Paper 32), to which Petitioner responded (Papers 37, 38).

A consolidated oral hearing was held on March 13, 2018, between this proceeding, IPR2017-00510, and IPR2017-00511, and a transcript of the oral hearing has been entered into the record as Paper 41 ("Tr.").

Pursuant to the U.S. Supreme Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018), we modified our Decision on Institution to

include the challenge to claims 29 and 30 based on Swaelens alone. Paper 42 (modifying the Decision on Institution to include all claims and all grounds presented in the Petition). Based on authorization from the Board (Paper 44, 5 n.4), the parties stipulated to waive further briefing as to the challenge based on Swaelens alone, agreeing to rely on the existing record. Paper 46, 1.

This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that claims 29 and 30 of the '169 patent are unpatentable.

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. 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, which can lead to instability of the joint, particularly lateral instability in the knee. *Id.* at

5:3–8. 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 5:9–15.

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. This information 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, 62:65–63:12 (emphasis added).

D. Instituted Grounds of Unpatentability

We instituted *inter partes* review based upon the following grounds of unpatentability (Dec. 27; Paper 42):

Reference(s)	Basis	Claims challenged
CAOS[1], Radermacher[2], and Woolson[3]	§ 103(a)	29 and 30
Swaelens[4]	§ 103(a)	29 and 30
Swaelens and Woolson	§ 103(a)	29 and 30

II. ANALYSIS

A. Legal Principles

In *inter partes* reviews, petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never

[1] Klaus Radermacher et al., *Computer Assisted Orthopaedic Surgery With Image Based Individual Templates*, 354 CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 28–38 (1998) (Ex. 1033, "CAOS").
[2] Radermacher et al., WO 93/25157, pub. Dec. 23, 1993 (Ex. 1003).
[3] Woolson, US 4,841,975, issued June 27, 1989 (Ex. 1031).
[4] Swaelens et al., WO 95/28688, pub. Oct. 26, 1995 (Ex. 1007).

shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail in this proceeding, Petitioner must support its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). Accordingly, all of our findings and conclusions are based on a preponderance of the evidence.

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of elements produces a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

We analyze the following grounds of unpatentability in accordance with the above-stated principles. Because Patent Owner does not provide evidence regarding secondary considerations, our determination is based on the first three factors. *See generally* PO Resp.; Pet. 65–66.

B. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted).

Petitioner supports its arguments and evidence with the Declaration of Jay D. Mabrey, M.D. ("the Mabrey Declaration," Ex. 1002), the Declaration of Jay D. Mabrey, M.D. in Support of Petitioner's Reply ("the Mabrey Reply Declaration," Ex. 1202), and the Declaration of Garry E. Gold, M.D. in Support of Petitioner's Reply ("the Gold Declaration," Ex. 1211). In turn, Patent Owner supports its arguments with the Declaration of Christopher M. Gaskin, M.D. ("the Gaskin Declaration," Ex. 2001), the Declaration of J. Bruce Kneeland, M.D. ("the Kneeland Declaration," Ex. 2003), and the Declaration of Charles R. Clark, M.D. ("the Clark Declaration," Ex. 2005).

Petitioner relies upon the testimony of Dr. Mabrey in contending that a person of ordinary skill in the art would be "an orthopedic surgeon having at least three years of experience in knee arthroplasty surgery" or "an engineer having a bachelor's degree in biomedical engineering (or closely related discipline) who works with surgeons in designing cutting guides and who has at least three years of experience learning from these doctors about the use of such devices in joint replacement surgeries." Pet. 19 (citing Ex. 1002 ¶¶ 29–31). Dr. Mabrey bases his opinion on his experience as a surgeon in the 1990/2000 timeframe. Ex. 1002 ¶ 31.

In our Decision on Institution, we agreed with Patent Owner 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. Dec. 7. We also noted that the applied prior art, e.g., Radermacher, reflects the appropriate level of skill at the time of the claimed invention. *Id*. (citing *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Patent Owner again argued in its Patent Owner Response that Petitioner's position is incomplete because it does not include "experience with and an understanding of imaging technologies" or access to a person having such experience or understanding. PO Resp. 16–17.

In his Reply Declaration, Dr. Mabrey agrees that "a POSITA 'would have an understanding of, or experience working with, imaging technology, e.g., in preparation for performing surgery.'" Ex. 1202 ¶ 15.

Based on the entire record, we find that the person of ordinary skill in the art would be "an orthopedic surgeon having at least three years of experience in knee arthroplasty surgery" or "an engineer having a bachelor's degree in biomedical engineering (or closely related discipline) who works with surgeons in designing cutting guides and who has at least three years of experience learning from these doctors about the use of such devices in joint replacement surgeries." Additionally, this person would have experience with, or an understanding of, surgical imaging technologies, or would have access to such a person.

Patent Owner challenges whether Dr. Mabrey has this additional qualification. PO Resp. 17–19. Our review of Dr. Mabrey's experience, however, reveals that it aligns with our assessment of the appropriate skill level. *See* Ex. 1002 ¶¶ 4–9, 16–19, 43–57 (discussing personal and industry

use of imaging); Ex. 1202 ¶¶ 17, 18, 19, 20 ("I have been formally trained on various forms of medical imaging, including x-ray, CT, MRI, and fluoroscopy in connection with both my orthopedic surgery residency and my decades-long practice as an orthopedic surgeon at four major academic medical centers."). Thus, we find that Dr. Mabrey qualifies as one of skill in the art.

C. 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); *Cuozzo Speed Techs. v. Lee,* 136 S. Ct. 2131, 2142–46 (2016). Under that standard, and absent any special definitions, we generally give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). 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). In the absence of such a definition, limitations are not to be read from the specification into the claims. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

In its Petition, Petitioner does not propose that any specific claim term requires construction. Pet. 19–20 (citing Ex. 1002 ¶ 64). Patent Owner does not address whether express construction of any term is necessary in its Patent Owner Response. *See generally* PO Resp.

Having considered the entire record, our determination regarding the obviousness of the challenged claims does not turn on the interpretation of

any of the claim terms. Thus, based on the final trial record before us, we determine that express construction of these terms or limitations is not necessary. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

D. Obviousness over CAOS, Radermacher, and Woolson

Petitioner challenges the patentability of claims 29 and 30 of the '169 patent under 35 U.S.C. § 103 as obvious based on CAOS, Radermacher, and Woolson. Pet. 21–42. Petitioner identifies the disclosures in the cited references alleged to describe the subject matter in each of the challenged claims. *Id*. Petitioner also provides an articulated reasoning with rational underpinning to support its conclusion of obviousness. *Id*. Petitioner supports its arguments and evidence with the Mabrey Declaration (Ex. 1002), the Mabrey Reply Declaration (Ex. 1202), and the Gold Declaration (Ex. 1211).

Patent Owner disagrees, arguing that one of skill in the art would not have modified CAOS based on the teachings of Radermacher and Woolson. PO Resp. 19–38. Patent Owner supports its arguments with the Gaskin Declaration (Ex. 2001), the Kneeland Declaration (2003), and the Clark Declaration (Ex. 2005).

We have reviewed the parties' contentions and supporting evidence of record in this trial. For the reasons given below, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 29 and 30 would have been obvious based on CAOS, Radermacher, and Woolson. We begin our analysis with a brief summary of these references, and then address the parties' contentions in turn.

1. Overview of CAOS (Ex.1033)

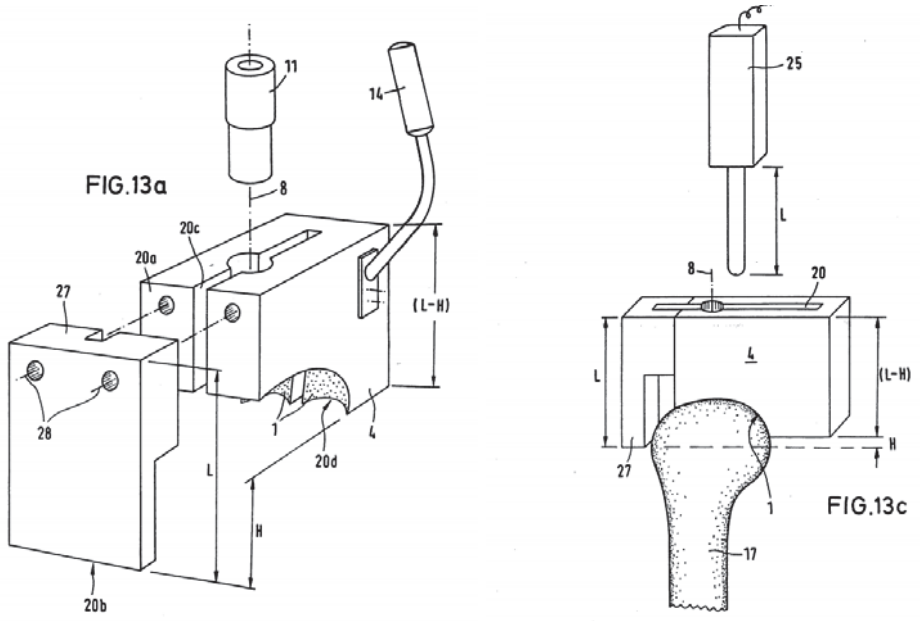
CAOS is a paper titled "Computer Assisted Orthopaedic Surgery With Image Based Individual Templates." Ex. 1033, 28. CAOS explains that "accurate placement of implant components with respect to the individual mechanical axis of the leg is essential." *Id.* at 31. Accordingly, CAOS discloses the design 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. Overview of Radermacher Ex. 1003

Radermacher is titled "Template for treatment tools and method for the treatment of osseous structures" and relates to certain improvements in the planning and performance of orthopedic surgery. *See* Ex. 1003, 1, 9. Radermacher describes a method in which 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[5] so that an individual template can be set intra-operatively onto the osseous structure with mating attachment. *Id.* at 10. 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

[5] Dr. Kneeland states that "nuclear-spin imaging" is another term for MRI imaging. Ex. 2003 ¶ 61 n.7.

positioning and guidance of the cutting tool. *Id.* at 16. 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.

3. 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 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:

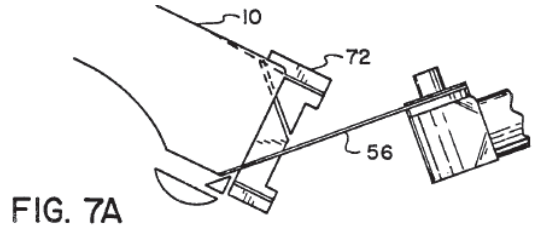


FIG. 7A

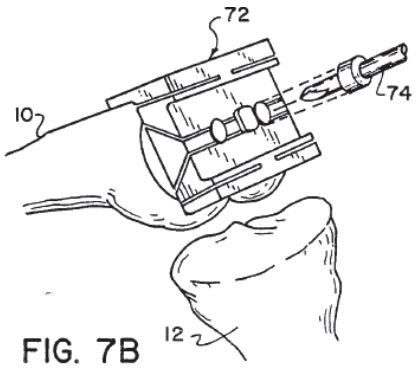


FIG. 7B

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. Discussion

a. Claim 29

Claim 29 recites in its preamble "[a] method of creating a patient-specific instrument for implanting an orthopedic implant in or about a joint of a patient." Ex. 1001, 62:65–67. Petitioner relies on the disclosure in CAOS of individual templates. Pet. 22, 34 (citing Ex. 1033, 28–36). Patent Owner does not dispute that CAOS discloses creating customized mechanical tool guides using a three-dimensional printer for orthopedic surgery. PO Resp. 21–22. We find that CAOS, as contended by Petitioner, teaches the preamble of claim 29.

Claim 29 also recites "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." Ex. 1001, 63:1–6. As to the patient-specific surgical instrument claim element, we

find persuasive Petitioner's contention that CAOS teaches the generation of a patient specific instrument, e.g., individual template. Pet. 23 (citing Ex. 1033, 28–29, 31; Ex. 1002 ¶¶ 75–77). For example, CAOS explains that "templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data." Ex. 1033, 29, 31 (obtaining CT images of the knee).

The parties dispute centers on whether CAOS's instrument is "based at least in part on a first magnetic resonance image data set and a second image data set." Petitioner contends that CAOS discloses the instrument is '"customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data' to include 'contact faces' (a contact surface) that 'fit exactly on the bone.'" Pet. 23 (citing Ex. 1033, 29). Petitioner also contends that CAOS teaches proper positioning of the surgical tool guides on the instrument (*id*. (citing Ex. 1002 ¶¶ 78–79)) using "topograms 'to identify the bone axis' and then mounting a saw guide on the instrument so that the instrument 'serves as a reference base for subsequent work on the bone"' (*id*. (citing Ex. 1033, 31; *see also id*. at 29 (surgical tool guides are integrated or mounted on the instrument "in predefined positions for different types of interventions"))).

Specifically, Petitioner also argues that COAS teaches the use of MRI data sets, i.e., the first magnetic resonance image data set. Pet. 24 (citing Ex. 1033, 37). Relying on the testimony of Dr. Mabrey, Petitioner argues that a "POSITA would have understood that the first image data set (CT data) could alternatively be an MRI data set, which persons of ordinary skill knew would provide the contour of the knee joint and therefore provide the data necessary to create a patient-specific surface." *Id*. (citing Ex. 1002

¶ 80). Petitioner directs us to the specification of the '169 patent as further evidence that it was known to use MRI to determine the contour of the knee joint. *Id*. (citing Ex. 1001, 12:23–41, 13:25–34, 13:55–14:3; Ex. 1002 ¶ 80).

Petitioner presents an alternative argument, which relies on the teaching in Radermacher regarding the use of MRI imaging to make a patient-specific surface (e.g., individual template) that '"copies the surface of the osseous structure' of the joint." Pet. 25 (citing Ex. 1003, 10–11, Figs. 18, 19; Ex. 1002 ¶ 82). Patent Owner does not dispute that Radermacher teaches MRI imaging. Instead, Patent Owner challenges Petitioner's argument 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*, 550 U.S. at 417).

Patent Owner also challenges Petitioner's assertion that the proposed combination of CAOS and Radermacher would result in the creation of an instrument "based on an MRI data set (for creating the patient-specific surface as disclosed in CAOS and Radermacher) and a second image data set that is different from MRI data (topograms as disclosed in CAOS)." Pet. 26. Specifically, Petitioner argues that a POSITA would have

understood that topograms are a different type of image data than MRI data because (1) a topogram is a low resolution image, whereas MRI scanning produces higher resolution image data (*id*. at 26–27 (citing Ex. 1001, 14:41–46; Ex. 1002 ¶¶ 87–88)); (2) one of ordinary skill in the art would know that topograms are an alternative to an x-ray (*id*. at 27 (citing Ex. 1002 ¶ 88)). We address below the parties' arguments regarding the proposed modification of CAOS using Radermacher.

Claim 29 further recites that 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." Ex. 1001, 63:7–10. Petitioner argues that CAOS discloses that "the instrument is 'customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data' to include a patient-specific surface ('contact faces') that 'fit[s] exactly on the bone'" and further suggests the use of MRI scanning. Pet. 27 (citing Ex. 1033, 29, 37). Petitioner argues that the proposed combination would have been obvious to one of ordinary skill in the art in view of the teachings of Radermacher, "which discloses creating a patient-specific surface based on MRI data." *Id*. at 28 (citing Ex. 1003, 10–11; Figs. 18–19; Ex. 1002 ¶¶ 91–93). Patent Owner challenges the proposed modification of CAOS using Radermacher, but does not dispute specifically that Radermacher teaches creating a patient-specific surface based on MRI data. We address the parties' arguments below regarding the proposed modification of CAOS using Radermacher below.

Claim 29 additionally recites that "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, 63:11–13. Petitioner asserts that

> [a] POSITA would have understood that CAOS in combination with Radermacher and Woolson discloses designing the patient-specific surface of an instrument based on MRI data (as disclosed in CAOS and Radermacher) and using second image data (e.g., topograms as disclosed in CAOS or CT or x-ray data as disclosed in Woolson) to determine the mechanical axis for orienting the tool guide relative to the patient-specific surface.

Pet. 28 (citing Ex. 1002 ¶ 94). Specifically, Petitioner relies on the disclosure in CAOS that second image data, i.e., a topogram, may be used to orient the guide relative to the patient-specific surface. *Id*. at 29 (citing Ex. 1002 ¶ 95). Petitioner also relies on the disclosure in CAOS that the instrument includes standard or custom tool guides (*id*. (citing Ex. 1033, 29–31)) and concludes that "CAOS discloses that the tool guide is oriented relative to the patient-specific surface of the instrument (i.e., 'contact faces of the template')" (*id*. (citing Ex. 1002 ¶¶ 96-97)).

Petitioner further argues that it would have been obvious in light of Woolson's disclosure concerning the use of image data (e.g., x-ray or CT) to preoperatively identify the mechanical axis and plan the cuts to align the knee replacement implant with the patient's mechanical axis. Pet. 32 (citing Ex. 1002 ¶¶ 104–110; Ex. 1031, 1:26–50, 2:28–59, 3:50–4:48, 4:20–26, 4:9–44, 5:9–49, 7:63–67 Abstract; Ex. 1036, 6:45–7:35, Abstract).

Specifically, Petitioner argues

> a POSITA would have understood that topogram data is used to align the cutting guide relative to the mechanical axis. Ex. 1002 ¶ 108. In addition, because CAOS's instrument includes a

> patient-specific surface that exactly reproduces the knee joint surface, the instrument incorporates the position of the mechanical axis. *Id.* ¶ 109. Thus, a POSITA would have understood that CAOS in combination with Woolson discloses orienting the guide relative to the instrument's patient-specific surface based on second image data (topograms). *Id.* ¶ 109.

Id. at 33. Petitioner reasons that one of ordinary skill in the art would combine CAOS with Woolson because (1) Woolson teaches the importance of alignment relative to the mechanical axis for long-term success of knee-replacement surgery (*id*. (citing Ex. 1002 ¶ 110; Ex. 1031, 1:26–36)); (2) CAOS discloses the importance of alignment of the knee implant with the mechanical axis (*id*. (citing Ex. 1033, 31)); (3) both Woolson and CAOS are in the same field and describe the same device using similar imaging technology (*id*.); and (4) the proposed combination involving "orienting the surgical tool guides in CAOS relative to the mechanical axis based on second image data (topograms) would merely involve using a technique that has been employed to improve one knee arthroplasty procedure (Woolson's) to improve a similar knee arthroplasty procedure (CAOS's) in the same predictable way" (*id*. at 33–34 (citing Ex. 1002 ¶ 110)).

Patent Owner does not dispute specifically that Woolson discloses the use of imaging data to preoperatively identify the mechanical axis and plan the cuts to align the knee replacement implant with the patient's mechanical axis. Rather, Patent Owner challenges the reasons offered by Petitioner to combine CAOS and Woolson, which we address below.

b. Claim 30

Claim 30 depends from claim 29 and further recites that "the second image data is x-ray image data." Ex. 1001, 63:14–15. Petitioner asserts that CAOS discloses "taking topograms to 'identify the bone axis'" (Pet. 41

(citing Ex. 1033, 31) and that one of ordinary skill in the art "would have understood that topograms are an alternative to x-ray image data" (*id*. (citing Ex. 1002 ¶ 113)). Based on this understanding, Petitioner argues that it would have been obvious to one of skill in the art to use x-ray imaging instead of topograms. *Id*. (citing Ex. 1002 ¶ 113). Petitioner further argues that Woolson discloses the use of x-ray image data to determine the mechanical axis, and to orient the cutting paths relative to the mechanical axis. *Id*. at 41–42 (citing Ex. 1002 ¶ 113; Ex. 1031, 1:26–50; 2:28–29, Abstract). Petitioner concludes that claim 30 would have been obvious for the same reasons as claim 29. *Id*. at 42. Patent Owner does not dispute specifically that Woolson discloses the use of x-ray image data. Rather, Patent Owner challenges the reasons offered by Petitioner to combine CAOS and Woolson, which we address below.

c. Reason to combine CAOS, Radermacher, and Woolson

Patent Owner presents various arguments challenging the reasons offered by Petitioner to combine CAOS, Radermacher and Woolson for claims 29 and 30.[6] PO Resp. 19–38. For example, Patent Owner argues that Petitioner's obviousness analysis "grossly oversimplifies imaging technologies, fills evidentiary gaps by relying on 'inherent obviousness,'" and is based entirely on hindsight." *Id*. at 20. Patent Owner characterizes Petitioner's reasoning as "superficial, conclusory, and legally insufficient" (*id*. at 27), as well as "[n]onsensical" (*id*. at 31(emphasis omitted)).

For the reasons discussed below, we find that Petitioner has provided articulated reasoning with rational underpinning explaining why a person

[6] Because Patent Owner argues claims 29 and 30 together, our findings as to claim 29 are equally applicable to claim 30.

with ordinary skill in the art would have combined the teachings of CAOS, Radermacher, and Woolson, namely, that the POSITA would modify CAOS's patient specific instrument using Radermacher's teaching regarding the use of MRI imaging to make a patient-specific surface, and Woolson's disclosure concerning the use of image data (e.g., x-ray or CT) to preoperatively identify the mechanical axis and plan the cuts to align the knee replacement implant with the patient's mechanical axis, with a predictable result. *See KSR*, 550 U.S. at 418 (citing *Kahn*, 441 F.3d at 988 ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")). As the Federal Circuit has made clear, when a reason to combine or modify references is in dispute, we must make a finding of a motivation to combine and must have an adequate evidentiary basis for that finding. *See In re Nuvasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016). "'[C]onclusory statements' alone are insufficient and, instead, the finding must be supported by a 'reasoned explanation.'" *Id*. at 1383 (quoting *In re Lee*, 277 F.3d 1338, 1342, 1345 (Fed. Cir. 2002)); *accord id.* at 1384 (not permitting the Board to effectively adopt the petitioner's argument, which "amount[ed] to nothing more than conclusory statements that a PHOSITA would have been motivated to combine the prior art references to obtain additional information."). Moreover, the Board "cannot rely solely on common knowledge or common sense to support [its] findings." *Id*. at 1383.

i. Whether Petitioner's Proposed Modification of CAOS Deviates from CAOS Method that Uses a Single Imaging Modality

According to Patent Owner, Petitioner's proposed "replac[ement] of *CAOS's* CT images with *Radermacher's* MRI images and using *CAOS's* CT

topogram or *Woolson's* x-ray image with *Radermacher's* MRI images" would not be successful because it "deviates from *CAOS's* successful method" that uses a single imaging modality. PO Resp. 22–23. Key to Patent Owner's argument is its contention that "one of ordinary skill would not modify *CAOS* in a manner that would destroy its advantages only to introduce problems related to co-registering images from different imaging modalities." *Id*. at 23.

Patent Owner explains that "[c]o-registration is the process of aligning two or more images so that corresponding pixels or voxels representing the same object may be integrated or fused" (*id*. at 13–14 (citing Ex. 2003 ¶ 25)), and a "CT image data set, however, is intrinsically co-registered" (*id*. at 14 (citing Ex. 2003 ¶ 27)). Patent Owner further explains that the location of each CT image relative to the CT topogram is known (*id*. at 15) because "a CT topogram is required to plan the start and end points of the CT images" (*id*. at 14 (citing Ex. 2003 ¶ 27; Ex. 1060, 6:34–46)) and "the CT topogram is taken on the same CT scanner seconds before the CT images are taken" (*id.* (citing Ex. 2003 ¶ 27; Ex. 1060, 6:34–46)). Patent Owner argues that "[b]ecause the CT topogram and CT images are intrinsically coregistered, the tibial mechanical axis and proximal tibia cut determined from that axis can be accurately transferred to the CT images depicting the shape of the proximal tibia." PO Resp. 24–25 (citing Ex. 2003 ¶ 83; Ex. 1064, Figs. 6a, 6b).

Patent Owner further argues that Petitioner does not offer "any reasoned motivation for eliminating CAOS's intrinsically co-registered CT image data set" (PO Resp. 26 (citing Ex. 2005 ¶ 78)), nor identified shortcomings in CAOS's method or improvements "that would have

motivated one of ordinary skill to use two different imaging modalities instead of the single disclosed modality" of CAOS (*id*. (citing Ex. 2005 ¶ 78)). The proposed modification would not have been made, in Patent Owner's view, due to the increased risk of misalignment from co-registering different imaging modalities. *Id*. at 26 (citing Ex. 2003 ¶¶ 82–88; Ex. 2005 ¶¶ 79–80, 82–87).

In its Reply, Petitioner contends that co-registration is not recited in the '169 patent claims and that the prior art as well as the '169 patent specification demonstrates that "no co-registration problem existed." Reply 1. Petitioner argues that the problems raised by Patent Owner are not a basis for finding non-obviousness because "nothing in the claims makes co-registration easier, faster, or more accurate." *Id*. (citing Ex. 1211 ¶ 48).

Additionally, Petitioner argues that the '169 patent specification demonstrates that co-registration would not have been a problem and is within the skill of the art. Reply 2. Petitioner supports this contention by arguing that Patent Owner is bound by the admission in the specification that a person of ordinary skill in the art would have appreciated that different types of image data can be combined, i.e., "co-registered," without further describing any co-registration technique or details. *Id*. (quoting Ex. 1001, 14:41–42 ("As will be appreciated by those of skill in the art, imaging techniques can be combined, if desired.")); (citing Ex. 1202 ¶ 10; Ex. 1211 ¶ 49; Ex. 1210, 99:1–9 (the patent states that "it can be done"); (citing *PharmaStem Therapeutics, Inc. v. ViaCell*, Inc., 491 F.3d 1342, 1362 (Fed. Cir. 2007); *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1380–81 n.6 (Fed. Cir. 2013)); *MRSI Systems, LLC v. Palomar Techs., Inc.*, IPR2016-00043, slip op. at 22–23 (PTAB Mar. 29, 2017) (Paper 29 (Final Written Decision)).

Petitioner observes that the specification (1) "repeatedly states that multiple imaging modalities can be combined, including MRI and x-ray, and never suggests any problem with doing so" (Reply 2 (citing Ex. 1001, 14:56–58, 16:55–56, 16:67–17:1; Ex. 1202 ¶ 10; Ex. 1211 ¶ 50)); (2) the specification provides no details on how to combine various imaging modalities (*id*. (citing Ex. 1210, 31:23–33:14, 36:11–13, 36:24–37:1, 40:9–15, 43:8–44:24, 128:2–11); (3) Patent Owner represents that "combining MRI and x-ray data could be done by a POSITA 'without undue experimentation'" (*id*. at 3 (citing *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1341 (Fed. Cir. 2006)); and (4) Patent Owner cannot avoid obviousness with arguments that contradict the specification (*id*. (quoting *Abbott Labs* (patent's failure to disclose any problem demonstrates it was within the ordinary skill); *Alcon Res., Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012) (rejecting argument of no reasonable expectation of success where specification does not include teaching allegedly missing from prior art)).

According to Petitioner,

> [w]ith no such disclosure [of co-registration] in the specification, only two possibilities exist. Either co-registration was within the ordinary skill, or the '169 patent is not enabled under § 112. For purposes of obviousness, the Board presumes that the patent satisfies § 112, i.e., that co-registration was within the knowledge and skill of a POSITA. *Abbott*, 452 F.3d at 1341.

Reply 3. Petitioner contends that Patent Owner cannot argue that co-registration of image data was "difficult, time-consuming, and often inaccurate," and thus would have been a technical barrier precluding the proposed combination of CAOS, Radermacher, and Woolson, while "at the same time, claim[ing] that very combination, without disclosing 'how it was

done.'" *Id*. Petitioner analogizes Patent Owner's argument to the Federal Circuit's decision in *Smith & Nephew, Inc. v. Rea*, in which the Federal Circuit stated that such an argument "naturally raises the question of how [the patent owner] managed to make such a combination work." Reply 3–4 (quoting *Smith & Nephew*, 721 F.3d at 1381. The Federal Circuit further explained, the problem with this argument "is that it is contending that a standard non-locking screw would be inoperative to obtain compression in a threaded hole, while at the same time claiming that it managed to achieve exactly that objective, all through the *deus ex machina* of a 'specialized screw.'" *Id.* '"But an unclaimed and undisclosed feature such as the 'specialized screw' cannot be the basis for finding [the] patent to be non-obvious over the prior art." *Id.*

We agree with Petitioner that claim 29 does not require steps of co-registering the claimed first magnetic resonance image data set and second image data set. In considering the language of the claim itself—claim 29 does not require that the "first magnetic resonance image data set" and the "second image data set" be co-registered, or combined, in any manner. Ex. 1001, 63:1–6. We recognize Patent Owner's argument that two different types of image data must be reflected in the surgical tool made by the claimed method; however, this requirement does not entail necessarily co-registration. Tr. 20:17–21:12. Here, claim 29 simply requires a method of creating a surgical instrument that is based in part on a patient-specific surface derived from the first magnetic resonance image data set, and the surgical instrument includes a guide that is oriented relative to the patient-specific surface of the instrument based on information derived from the second image data set. Ex. 1001, 63:7–15. Claim 29 does not prescribe the

manner in which these steps occur; in other words, the claim does not require that the first magnetic resonance image data set and the second image data set be co-registered, in order to create the instrument or orient the guide.[7]

As to Patent Owner's argument that one of skill in the art would combine MRI and X-ray image data only if the two images could be co-registered, we agree with Petitioner that "[t]he claims simply require deriving the patient-specific surface from MRI and orienting a guide 'based on information derived from' the second image data set (e.g., x-ray)." Reply 15. Moreover, we credit the testimony of Dr. Mabrey that "it would have been obvious to a POSITA . . . to identify the mechanical axis on a standing x-ray, calculate the angle between the transcondylar axis and the mechanical axis, and manually transfer the mechanical axis to the [first] image," e.g., an MRI or CT image, for use in creating a tool. *Id*. (citing Ex. 1202 ¶¶ 7–9, 40; Ex. 1211 ¶ 21; Ex. 1210, 37:11–41:19). More specifically, Dr. Mabrey states:

> In the mid-1990s, I used multiple image data sets to plan surgery, including transferring a line representing a patient's anatomical axis to a three-dimensional model. On a radiograph (i.e., standard x-ray) of a patient's hip, I determined the hip offset and anatomical axis. Using anatomical landmarks identifiable on the x-ray and on a three-dimensional model of the patient's proximal femur (created from a CT scan), I was able to easily transfer the hip offset and anatomical axis to the three-dimensional model of the patient's proximal femur.

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[7] We agree with Petitioner that many antecedent steps are required in order to perform the steps recited in the claims. For example, "the MRI machine may need to be plugged . . . in order to obtain the first image data from the MRI machine." Tr. 48:21–22. We also agree "[t]hat does not make plugging in the MRI machine a claim limitation." *Id.* at 48:22–23.

> A similar method would have applied equally well to manually transferring a patient's mechanical axis from a standing, full-leg x-ray to a three-dimensional model of the patient's knee derived from a CT or MRI scan. On the x-ray film, one would identify the mechanical axis of the patient's leg, as was standard practice, by drawing a line between the center of the femoral head and the intercondylar notch of the distal femur. Then one would identify the transcondylar axis of the patient's femur on the x-ray by drawing a line connecting the distal end of each of the medial and lateral condyles of the femur. This is simple to do because the condyles are bony landmarks and easily identifiable on the x-ray image. The lines drawn for the transcondylar axis and the mechanical axis intersect; at that intersection, one measures the angle between these two axes (which I refer to as the transcondylar angle, or "TCA").
>
> Because the femoral condyles are easily identifiable on MRI and CT scans, one can also locate the transcondylar axis on the three-dimensional model of the knee in the CAD software. At that point, knowing the location of the transcondylar axis on the three-dimensional model, one applies the measured TCA derived from the x-ray to the transcondylar axis in the three-dimensional model of the knee to establish the mechanical axis on the three-dimensional model. This process allows one to transfer the mechanical axis information from the x-ray to the three-dimensional model derived from the MRI or CT scan, and thereby accurately plan the position and orientation of the distal cut on the femur perpendicular to the mechanical axis. This method could have easily been used to align the cutting angles in [either CT-] or MRI-based patient-specific template[s (as disclosed by CAOS and Radermacher)], and it certainly would have been obvious to a POSITA in 2001 that they could do so.

Ex. 1202 ¶¶ 7–9.[8] Thus, Dr. Mabrey was able to transfer the anatomical axis to a three-dimensional model of the patient's proximal femur, created from a

[8] We are not persuaded that Petitioner's reliance on this testimony is improper, in a Reply. Paper 29, 1. Because the claims do not require co-

CT scan. *Id.* ¶ 7. Using such a technique, Petitioner contends that co-registration would not have been required. *Id*. at 15. We find Dr. Mabrey's testimony, which is based on his personal use of a similar technique in the mid-1990s, to be persuasive. Ex. 1202 ¶¶ 7–9, 40; *see also* Paper 32, 10 (noting Dr. Mabrey's testimony that he performed a similar technique on the hip, not the knee). This testimony supports our conclusion that claims 29 and 30 do not require co-registration.

Moreover, we agree with Petitioner that the specification of the '169 patent does not disclose any details of co-registration that might be utilized in the claimed methods, nor does the '169 patent suggest that co-registration was beyond the skill level of an ordinarily skilled artisan. Rather, the '169 patent describes that combining different imaging modalities, i.e., co-registration, was "appreciated by those of skill in the art." Ex. 1001, 14:41–42. Additionally, the '169 patent explains that axis information can be obtained by x-ray and "can then be combined with a CT or MRI scan of one or more joints." *Id*. at 16:59–60. For example, "[l]andmarks seen on radiography can then . . . be cross-referenced on the CT or MRI scan. Axis measurements performed on radiography can be subsequently applied to the CT or MRI scans or other imaging modalities." *Id.* at 16:61–64. Thus, Patent Owner does not cite any portion of the '169 patent that would suggest that specialized co-registration techniques were disclosed.

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registration, as discussed above, Petitioner was not obliged to address co-registration in its Petition. We deem this discussion to be responsive to Patent Owner's arguments in its Response regarding the difficulty of co-registration. Paper 35, 1–2 (citing PO Resp. 2–4, 6, 13–16, 18, 27–31).

During the oral argument, Patent Owner relied upon a PCT Publication, WO 02/22014 ("the WO publication"), cited in the '169 patent specification, as providing the '169 patent's description of how to co-register image data from different imaging modalities. *See* Tr. 25:18–26:14. According to Patent Owner's counsel, this reference provides "a lengthy explanation as to how you co-register, the algorithms you might need to use and the different modalities that you can use to co-register those images, and that is the explanation in the ['169] patent." *Id*. at 26:8–14. Counsel argued that although this publication is not explicitly incorporated by reference into the '169 patent, a person of ordinary skill in the art would have known to look to this publication for its disclosure of co-registration because two of its inventors, Philipp Lang and Daniel Steines, were also inventors on the '169 patent. *Id*. at 26:15–28:20.

We disagree. The '169 patent refers to the WO publication at the beginning of a section of the specification titled "Imaging Techniques," "Thickness and Curvature." Ex. 1001, 13:55–56 (title), 13:65 (reference to WO publication). That section only states that "[a]s will be appreciated by those of skill in the art, imaging techniques can be combined, if desired." *Id*. at 14:41–42. In making this statement, the '169 patent does not reference the WO publication, or any other publication cited within this section of the specification. Moreover, the '169 patent identifies the inventors of the WO publication as "Alexander, et al.," which provides little support for Patent Owner's contention that a person of ordinary skill in the art would have known to look to this publication for its discussion of co-registration, due to Philipp Lang's and Daniel Steines's common inventorship. *Id.* at 14:23.

Moreover, 37 C.F.R. § 1.57(b) (2007) requires that "an incorporation by reference must be set forth in the specification and must: (1) Express a clear intent to incorporate by reference by using the root words 'incorporat(e)' and 'reference' (*e.g.*, 'incorporate by reference'); and (2) Clearly identify the referenced patent, application, or publication." Thus, the '169 patent does not properly incorporate the WO publication because it does not express a clear intent to incorporate by reference. *See* Tr. 26:15–28:18. Additionally, in light of Patent Owner's argument that the claims require co-registration of first magnetic resonance image data and second image data, e.g., topogram or x-ray, the relied-upon disclosure of the WO publication would be "essential material," because it is necessary to comply with 35 U.S.C. § 112, first paragraph. *See* 37 C.F.R. § 1.57(c) (2007). As such, even if the WO publication were incorporated in a manner that complied with 37 C.F.R. § 1.57(b), such incorporation would not satisfy 37 C.F.R. § 1.57(c). *See* 37 C.F.R. § 1.57(d) (2007) ("'Essential material' may be incorporated by reference, but only by way of an incorporation by reference to a *U.S. patent or U.S. patent application publication*." (Emphasis added)).

Finally, Patent Owner's reliance on the WO publication is inconsistent with Patent Owner's argument that the prior art only disclosed co-registration "for diagnostic purposes," not for "clinical applications," such as that in the '169 patent claims. Tr. 28:20–22 ("What the prior art taught was co-registration for diagnostic purposes."), 31:9–19 ("[C]o-registration is not done in the past in the prior art for clinical applications. The [claimed] surgical instrument is a clinical application."). The WO publication appears

to be prior art to the '169 patent.[9] Patent Owner cannot credibly argue that the WO publication provides essential disclosure of co-registration for the clinical application claimed in the '169 patent, while also arguing that the prior art failed to disclose co-registration in a clinical application.

We agree with Petitioner that the facts here are similar to those at issue in the cited *Smith & Nephew v. Rea* case. As in that case, Patent Owner relies on unclaimed features (here, co-registration) to demonstrate patentability, but the '169 patent fails to provide an enabling disclosure of that subject matter, and fails to recite it in the challenged claims. "[A]n unclaimed and undisclosed feature . . . cannot be the basis for finding [the] patent to be non-obvious over the prior art." *Smith & Nephew*, 721 F.3d at 1381. In sum, the '169 patent claims do not require co-registration. As such, we find the majority of Patent Owner's arguments directed to co-registration to be non-responsive because they are directed to an element that is not required by the claims.

We are, likewise, unpersuaded by Patent Owner's argument that "[o]ne of ordinary skill would not have selected CAOS as a primary reference, only to dismantle the successful method that resulted in its selection in the first place." PO Resp. 24. This argument is unavailing because Patent Owner ignores the fact that CAOS itself expressly suggests this modification. Specifically, CAOS states: "[i]t is planned to integrate additional tools into the system (in particular for hip, knee, and spine

[9] The '169 patent claims priority to four provisional application, filed May 25, 2001, May 12, 2002, and May 14, 2002. Pet. 18 (citing Ex. 1001, 1:17–25). PCT Publication WO 02/22014 was filed on September 14, 2001 (claiming priority to U.S. Patent Application No. 09/662,224, filed on September 14, 2000), and was published on March 21, 2002. *Id*. at 19.

surgery), magnetic resonance image processing modules and enhanced models for efficient biomechanical analysis." Ex. 1033, 37.

Thus, Petitioner presents sufficient arguments and credible evidence to support a finding that one of skill in the art would have been motivated to use Radermacher's teaching regarding the use of MRI to image the joint surface in creating the patient specific instrument taught by CAOS, and that Petitioner's proffered rationale and evidence adequately supports its proposed modification. Reply 9–11. For example, CAOS expressly discloses the use of MRI imaging instead of CT imaging. *Id*. at 10 (citing Ex. 1033, 37 ("It is planned to integrate . . . magnetic resonance image processing modules."). Moreover, the prior art cited by Petitioner, i.e., Radermacher and Schiffers, also suggest "a reasonable expectation of success in using, MRI." *Id*. (citing Pet. 24–26; Ex. 1202 ¶ 47).

We are also persuaded by Petitioner's argument and evidence that MRI was one of only two available options. Pet. 25–26; Reply 10–11 (quoting *KSR* 550 U.S. at 421 (When "there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.")). Specifically, modifying CAOS to use MRI would have been obvious, in view of Radermacher, "because MRI and CT were the only imaging options available in 2001 to model a patient's knee." Reply 10–11 (citing Ex. 1209, 105:21–106:16; Ex. 1202 ¶ 43; Ex. 1210, 63:6–25). And, the specification of the '169 specification confirms that MRI and CT were well known imaging techniques for modeling a patient's knee. *Id*. at 11 (citing Ex. 1001, 12:23–41, 13:25–34, 13:55–14:40; Ex. 1210, 40:9–15). This evidence supports Petitioner's contention that use of Radermacher's MRI image data

would have been a known substitution of one imaging technique (e.g., CT imaging) for another (MRI imaging) to obtain the predictable result of obtaining a joint image. *See* Ex. 1002 ¶ 85.

ii. Whether CAOS's CT Topogram or Woolson's x-ray image are co-registerable with Radermacher's MRI image.

Alternatively, Patent Owner argues that even if one of ordinary skill in the art would modify CAOS by replacing its CT images with Radermacher's MRI images, Petitioner has not established that one of ordinary skill would have a reasonable expectation of success in doing so because MRI, CT, and x-ray imaging are different modalities involving different devices. PO Resp. 27–28 (citing Ex. 2003 ¶ 85). According to Patent Owner, "one of ordinary skill would not be motivated to deviate from CAOS's method and risk misalignment" due to the need to co-register images, and increased risk of misalignment. *Id*. at 28 (citing Ex. 2003 ¶¶ 25–26, 85; Ex. 2005 ¶¶ 79–80, 82–87; Ex. 2022, 69:19–70:2). Patent Owner contends that Petitioner fails to explain how one of ordinary skill would transfer a *mechanical axis* determined using a CT topogram or x-ray image date to a *patient specific surface* created using MRI images. *Id*. (citing Ex. 2022, 94:15–24). Patent Owner notes that Petitioner's expert, Dr. Mabrey stated during cross-examination that the proposed combination "would be 'inherently obvious'" to one of ordinary skill. *Id*. at 29 (citing Ex. 2022, 81:4–9, 91:19–92:18, 94:14–96:14, 98:5–23, 107:13–109:9). Patent Owner points out that neither the Petition nor the Mabrey Declaration rely on "inherent obviousness" as a reason for the proposed modification of CAOS using the teachings of Radermacher or Woolson. *Id*. at 30. Co-registration, according to Patent Owner, "is the 'natural result' of using a single imaging modality, such as a

CT topogram and CT images" and not the natural result of combining a CT topogram or x-ray images with MRI images. *Id*. (citing Ex. 2003 ¶¶ 85–88).

Patent Owner further argues that Petitioner's reliance on Schiffers (Ex. 1064) is likewise deficient because Schiffers "suggests using a single image data set—a CT image data set," and not integrating two different imaging modalities. PO Resp. 30 (citing Ex. 1064, 96:3–18; Ex. 2003 ¶¶ 28–29, 85–86.

For the reasons provided above, we are not persuaded by Patent Owner's argument that CAOS requires co-registration between the first magnetic resonance image data set and second image data set, whether a CT topogram or an x-ray image.

As discussed above we are persuaded by Petitioner's arguments and evidence that one of ordinary skill in the art in 2001 would have used a standard x-ray with the patient in a standing position to determine the mechanical axis for orienting a guide. Reply 12–14. For example, Dr. Clark admitted during cross-examination that "by 2001, the standing x-ray had been 'the primary way to determine [the mechanical and anatomical] axes for a long time and it's been a tried and trusted way of doing it." *Id*. at 12 (emphasis omitted) (citing Ex. 1209, 23:14–24:5; *see also id.* at 32:13–33:3, 33:23–34:9 (it was standard practice in 2001), 35:14–36:14 (Clark used x-ray to determine the mechanical axis for the "majority, if not all" patients), 41:2–22 (so did his colleagues), 41:10-22 (x-ray is routine); 40:3–8 (x-ray was the standard in 2001 for determining position and orientation of cutting guide)). Petitioner observes that Kneeland and Mabrey agree with Dr. Clark regarding the use of standing x-ray for this purpose. *Id*. at 13 (citing Ex. 1210, 35:11–17; Ex. 1202 ¶ 42). Also persuasive is the cross-

examination testimony of Dr. Clark that "even where he has obtained MRI or CT imaging for a patient, he still orders standard x-ray imaging and uses a standing x-ray to determine the mechanical axis." *Id*. (citing Ex. 1209, 52:22–53:20, 70:4–8). Also persuasive is the testimony of Dr. Clark that a POSITA "making a patient-specific template using MRI to image the joint surface as taught by Radermacher, would have known that the mechanical axis could be determined using x-ray imaging" (*id*. at 14 (citing Ex. 1209, 116:17–25; *see also* Ex. 1206, 86:16–21)); and having read Radermacher, "would have known that a 'plain X-ray matched with an MRI' would have been the most likely way a POSITA would have made Radermacher's device even before CAOS was published" (*id*. (citing Ex. 1209, 117:1–11)).

As discussed above, Patent Owner's argument is unpersuasive based on the teaching in the '169 patent that combining images, i.e., co-registration, was known by those skilled in the art. Ex. 1001, 34:32–37. Along this vein, we are unpersuaded by Patent Owner's reliance on Dr. Kneeland's testimony that co-registration would have been difficult, time-consuming, and inaccurate, such that a person of ordinary skill in the art would not have modified CAOS as proposed. PO Resp. 14, 28; Ex. 2003 ¶¶ 25–26. "Expert opinions that are contrary to admissions in the specification do not create a factual issue." *Smith & Nephew*, 721 F.3d at 1380 n.6; *Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1358 (Fed. Cir. 2018) ("The PTAB [i]s entitled to weigh the credibility of the witnesses." (alteration in original) (quoting *Trs. of Columbia Univ. v. Illumina, Inc.*, 620 F. App'x 916, 922 (Fed. Cir. 2015))). Additionally, Dr. Kneeland provides no evidence to support this opinion, and we afford it little weight. *See* Ex. 2003 ¶ 25; 37 C.F.R. § 42.65(a); *see also* Reply 6–7

(citing Dr. Kneeland's deposition testimony regarding his lack of personal knowledge about co-registration problems); *see, e.g.*, Ex. 1210, 78:12–13 ("I was not working with co-registration at the time [of 2001]."); *see also id.* at 71:24–72:12, 75:20–77:20, 78:5–20, 80:25–82:4, 153:5–154:4.

Furthermore, the additional evidence cited by Petitioner demonstrates that co-registration was well known and would not have prevented a person of ordinary skill in the art from using MRI image data with CT topograms or x-ray image data. Reply 1, 4–8; *see, e.g., id.* at 6–7 (citing Exs. 1213–1216; Ex. 1014; Ex. 1060). Patent Owner does not dispute that co-registration was well known in the prior art, but argues instead that prior art co-registration did not address clinical applications. However, as noted above, Patent Owner's reliance on the WO publication for its purported disclosure of co-registration for clinical use belies this argument. Moreover, the evidence cited by Petitioner is consistent with the testimony of Petitioner's declarant, Dr. Gold, who testified that co-registration was well known by 2001. Dr. Gold testified that landmark-based registration, such as that discussed by Dr. Mabrey, was used to co-register CT or MRI data with x-ray image data.[10] *See also* Ex. 2029, 158:16–24. This testimony is consistent with the cited prior art to Maintz and Betting, which disclose landmark-based co-

[10] We are not persuaded by Patent Owner's argument that Dr. Gold's opinions "are not founded on any relevant experience or knowledge and are instead based on publications that he was not aware of before his involvement in this proceeding." Paper 31, 9. Dr. Gold states that he has conducted research on co-registering various types of MRI image data (Ex. 1211 ¶ 9), that he is a named inventor on two patents concerning co-registration (*id.* ¶¶ 10–11), and that he is an actively practicing radiologist (*id.* ¶ 12). *See also* Paper 37, 8 (citing Ex. 2029, 24:11–26:8, 79:12–83:8; Ex. 1211 ¶¶ 10–11).

registration, as well as with the testimony of Patent Owner's declarant, Dr. Clark, who also acknowledged that landmarks are readily identifiable in MRI and x-ray image data sets. Ex. 1209, 116:17–117:11 (also opining that he does not see an advantage to using plain x-ray as opposed to the topogram disclosed by CAOS).

Turning to Petitioner's contentions, we are persuaded that it would have been obvious to one of ordinary skill in the art to further modify CAOS to utilize second image data (e.g., CAOS's topogram or Woolson's x-ray), to identify a mechanical axis and to orient cutting guides relative to that axis. Pet. 41–42; Reply 12. Specifically, Petitioner has identified teachings in both CAOS and Woolson for this purpose. For example, Woolson explains that conventionally, a preoperative radiograph, i.e., an x-ray, was taken "to determine the angle between the anatomical and the mechanical axes of the femur for proper orientation of the femoral cutting guide." Ex. 1031, 1:46–50; *see also id.* at 4:13–44, 5:9–16, 7:62–67 (disclosing preferred embodiments using CT); Ex. 2022, 15:10–22 (Dr. Mabrey testifying that "x-ray" and "radiograph" can be used "interchangeably").

We credit Dr. Mabrey's testimony that a person of ordinary skill in the art would have found topograms and x-rays to be alternatives. Ex. 1002 ¶¶ 105–106; *see also* Ex. 1202 ¶ 43 ("[I]n practice, just two options were available in 2001 for evaluation of the patient's mechanical axis: a full-leg standing x-ray and a CT topogram x-ray."). This is consistent with Dr. Gold's testimony that in 2001, "a radiologist would have known how to quickly and accurately co-register MRI image data of the knee joint with either topogram x-ray data or conventional x-ray image data of the leg." Ex. 1211 ¶ 36; *see also id.* ¶¶ 19–20.

Indeed, Dr. Mabrey testifies that CT topograms are a *form of* x-ray image data. Ex. 1202 ¶ 34 ("[A] CT topogram is an x-ray obtained from a CT scanner."). This testimony is consistent with that of Patent Owner's initial expert, Dr. Gaskin, who testifies that "[a] CT topogram is a low-resolution, two-dimensional x-ray image taken by the CT scanner." Ex. 2001 ¶ 17 (footnote omitted); *see also id.* ¶¶ 15, 25 n.3 ("X-ray imaging and CT imaging both use x-ray radiation but in different manners."). Moreover, this testimony is consistent with that of Dr. Gold, who also testifies that "[a] CT topogram is x-ray image data taken by a CT scanner." Ex. 1211 ¶ 19 n.2. These experts agree that topograms are a form of x-ray image data, which further supports Petitioner's contention that x-rays and topograms are known alternatives.

We appreciate Patent Owner's argument that topograms are different from x-rays because topograms are *also* used to identify start and end points for subsequent CT image acquisition. PO Resp. 10–12, 13, 33–34. With respect to claim 29, Petitioner's proposed modification to CAOS based on using Radermacher's MRI image does not impact any additional use of topograms, or other forms of positioning image data, e.g., MRI localizers. Thus, considering the evidence and arguments of record, we determine that Petitioner has demonstrated convincingly that x-ray image data and topograms were known alternatives for use in identifying a mechanical axis.

iii. Whether the Proposed Modification separates CT and MRI data image data sets.

Patent Owner's argument that Petitioner's proposed modification of CAOS is "[n]onsensical" is not persuasive. PO Resp. 31–37 (emphasis omitted). Specifically, Patent Owner argues that Petitioner's proposed modification "improperly treat[s] CT and MRI image data sets as separable

suggest that the individual components (e.g., CT images and CT topogram; MRI images and MRI localizer) are interchangeable, and ignore the processes for obtaining CT and MRI images." *Id*. at 31. According to Patent Owner, CT images and the topogram are "directly linked" to form an operable image data set (*id*. (citing Ex. 2003 ¶ 72)) and "one of ordinary skill would not obtain CT images without first obtaining a CT topogram and, similarly, would not obtain a CT topogram if MRI images were to be used instead of CT images" (*id*. (citing Ex. 2003 ¶¶ 72–74)). Patent Owner argues that Petitioner's proposed modification of CAOS is based on hindsight "[b]ecause the CT topogram is used to plan and obtain the CT images, eliminating the CT images would eliminate the need to acquire a CT topogram, and Petitioner offers no rationale for why one of ordinary skill would separately obtain a CT topogram." *Id*. at 32 (citing Ex. 2003 ¶¶ 72–75).

Patent Owner argues, in the alternative, that even if CT and MRI image data sets are separable and their components interchangeable, the proposed modification of CAOS makes no sense because it would result in the use of a CT topogram to obtain MRI images instead of an MRI localizer. PO Resp. 33. According to Patent Owner, "[a]lthough CT topograms and MRI localizers serve comparable roles, CT and MRI imaging are based on completely different devices and technologies, and they are not interchangeable with one another or with x-ray images." *Id*. (citing Ex. 2003 ¶¶ 76–78). Patent Owner explains that "CT topograms and x-ray images cannot be used to acquire MRI images because CT topograms and x-ray images provide no information to plan the start and end points of a scan to obtain MRI images." *Id*. at 33–34 (citing Ex. 2003 ¶¶ 77–78, 81).

Depending on how CT and MRI images are obtained, Patent Owner maintains that replacing CAOS's CT images with Radermacher's MRI images would likewise require replacing CAOS's CT topogram with an MRI localizer (*id*. at 34 (citing Ex. 2003 ¶¶ 80–81)) in order to obtain MRI images, and would eliminate the CT topogram Petitioner relies on to meet the second image data set limitation (*id.)*.

Similar to arguments addressed above, Petitioner's proposed modification does not require that the portion of the MRI data set used for planning (the MRI localizer) be separated from the MRI images that are ultimately taken. *See* Pet. 24–26; Reply 20–21. As Petitioner point out, it "never suggested that a POSITA would have replaced an MRI localizer in the machine with an x-ray." Reply 20 (citing Ex. 1202 ¶¶ 49–56). We agree. As Petitioner point out, it argued that

> a POSITA would have used MRI images (rather than CT images) ***for the purpose*** of creating a patient-specific surface and would have used a standing x-ray image (rather than) a topogram x-ray ***for the purpose*** of orienting the guide relative to the mechanical axis. *See* Pet. 23-28, 41-42; *see also* Ex. 2022, 157:17-158:1 (explaining that using "x-ray imaging instead of topograms in CAOS" means relying on standard full-leg standing x-rays to determine the mechanical axis). Ex. 1202 ¶¶53-55. Kneeland admitted he was "taking it more by implication" that Mabrey proposed separating an MRI localizer from the MRI images. Ex.1210, 185:25-187:20.

Reply 21.

Indeed, Dr. Mabrey states "to the extent Dr. Kneeland is suggesting that I proposed de-coupling MRI images from a corresponding MRI localizer, and replacing the MRI localizer with either a CT topogram x-ray or conventional standing x-ray, for the purpose of facilitating acquisition of

MRI images, I disagree." Ex. 1202 ¶ 52 (emphasis omitted)). Dr. Mabrey explained that

> using Radermacher's MRI images to derive a patient-specific surface would not preclude a clinician from also obtaining a CT topogram x-ray for determining the patient's mechanical axis. A POSITA could order a CT topogram x-ray for the specific purpose of determining the mechanical axis, in which case the full CT images would not be necessary.

Id. ¶ 42.

Thus, for claim 29, Petitioner present sufficient arguments and credible evidence to support a finding that one of skill in the art would have been motivated to use Woolson's teaching regarding the use of second imaging data, such as CT topograms or x-ray, to align the guide (i.e., cutting paths) relative to the mechanical axis. Pet. 32–34. As discussed above, Petitioner has provided a sufficient rationale, supported by evidence of record, to demonstrate that a person of ordinary skill in the art would have found it obvious to use CAOS's topogram to position CAOS's template (and its guide) with respect to the contact surface and mechanical axis of the bone, as taught by Woolson, for the stated purpose of providing a more successful surgery. Pet. 32–33; Ex. 1031, 1:26–36, 2:28–40; Ex. 1002 ¶ 108 ("This would ensure the accurate alignment of the knee prosthesis with the mechanical axis, which both Woolson and CAOS recognize is essential."), ¶ 110 ("[O]rienting the surgical tool guides in CAOS relative to the mechanical axis based on second image data (topograms) would merely involve using a technique that has been employed to improve one knee arthroplasty procedure (Woolson's) to improve a similar knee arthroplasty procedure (CAOS's) in the same predictable way.").

For claim 30, Petitioner proposes modifying CAOS such that x-ray images are used instead of topograms for the second image data set. Petitioner relies on the disclosure in Woolson regarding the use of x-ray image data to "determine the mechanical axis and orientation of the cutting paths relative to such axis." Pet. 41–42 (citations omitted). We are persuaded that Petitioner presents sufficient rationale and credible evidence to support the conclusion that it would have been obvious to utilize x-ray image data instead of CAOS' topograms, as a simple substitution of one known imaging technique for another to obtain the predictable result of obtaining an image of the joint for use in determining the mechanical axis and orientation of the cutting guides. *See, e.g.*, Ex. 1002 ¶¶ 106–108; Ex. 2001 ¶¶ 15, 17; Ex. 1031, Abstract, 1:37–50, 2:28–59. As explained by Woolson, and noted by Dr. Mabrey, determining a mechanical axis, for example, through x-ray, provides "a successful long-term result." Ex. 1031, 1:26–62; Ex. 1002 ¶ 108.

To the extent Patent Owner argues that a person of ordinary skill in the art would not have been motivated to modify CAOS to utilize x-ray image data, or that such a modification would have lacked a reasonable expectation of success due to problems with co-registration, we disagree. As discussed above, the claims do not require co-registration. *See, e.g.*, Ex. 1202 ¶¶ 6–9. Moreover, we credit the testimony of Dr. Mabrey that the specification of the '169 patent confirms his understanding that "combining images would have been within the skill of the art as of 2001." *Id*. ¶ 10 (citing Ex. 1001, 14:41–42).

Thus, upon review of the entirety of the cited evidence, we are persuaded by Petitioner's contention that it would have been obvious to

modify CAOS to utilize x-ray image data for the second image data set, as taught by Woolson.

5. Summary

In view of the foregoing, we conclude that Petitioner has established by a preponderance of the evidence that claims 29 and 30 are unpatentable under 35 U.S.C. § 103(a) as obvious over CAOS, Radermacher, and Woolson.

E. Obviousness based on Swaelens (Ex. 1007)

Petitioner also challenges the patentability of claims 29 and 30 as obvious based on Swaelens alone and Swaelens and Woolson. Pet. 42–65. In support thereof, Petitioner identifies the disclosures in the cited references alleged to describe the subject matter in the challenged claims. *Id*. Petitioner also provides an articulated reasoning with rational underpinning to support its conclusion of obviousness. *Id*. Petitioner again supports its arguments and evidence with the Mabrey Declaration (Ex. 1002), the Mabrey Reply Declaration (Ex. 1202), and the Gold Declaration (Ex. 1211).

Patent Owner disagrees, arguing that Swaelens does not disclose the second image data set limitation and that one of skill in the art would not have used Woolson to modify Swaelens. PO Resp. 38–62. Patent Owner supports its arguments with the Gaskin Declaration (Ex. 2001), the Kneeland Declaration (Ex. 2003), and the Clark Declaration (Ex. 2005).

We have reviewed the parties' contentions and supporting evidence of record in this trial. For the reasons given below, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 29 and 30 would have been obvious based on the combination of Swaelens and Woolson, but not Swaelens alone. We begin our analysis with a brief

summary of these references, and then address the parties' contentions in turn.

1. Overview of Swaelens (Ex. 1007)

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 portion of a body part, by converting image information with a processing unit and a rapid prototyping machine. Ex. 1007, 1:3–14 (emphasis omitted). Swaelens' 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. Discussion

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). Patent Owner does not dispute expressly that Swaelens discloses the preamble and the surgical instrument having a patient specific surface. PO Resp. 38–46. We

find that Swaelens, as contended by Petitioner, teaches the preamble of claim 29. 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).

Claim 29 also recites "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." Ex. 1001, 63:1–6. Petitioner relies on the disclosures in Swaelens of obtaining MRI scans of the joint and "transforming the image data into contours or 'voxels,' which are 'three-dimensional pixel[s] and thus represent[] a cube'" for the first magnetic resonance image data set (Pet. 43 (citing Ex. 1007, 6:24–29, 7:23–8:3, 8:17–28)). Patent Owner does not dispute Petitioner's contention in this regard. *See* PO Resp. 40 ("Swaelens is directed to recovering grey value data that is lost from CT or MRI image data when the image data is used in a modeling system to generate a three-dimensional model."). As such, we find that Swaelens, as contended by Petitioner, teaches the first magnetic resonance image data set.

For the second image data set claim element, Petitioner relies on the teaching in Swaelens regarding the generation of a negative or mirror image of the joint using '"additional digital information from outside.'" Pet. 43–44 (citing Ex. 1007, 5:22–34, 7:17–21, 8:17–28, 9:1–13, 10:23–30, 13:10–14; Ex. 1002 ¶ 116). Specifically, Petitioner argues that (1) "additional digital information from outside'" or functional elements such as cutting guides and drill guides, are added to the negative image (*id.* at 43 (citing Ex. 1007, 7:17-21; *see also id*. at 5:22–34, 10:23–30, 13:10–14)) (2) the additional

information from outside or functional elements are used to create a combined image "by adding the digital information representing the functional elements (converted into contours or voxels) to the negative image" (*id*. at 44 (citing Ex. 1007, 4:19–22, 8:5–9, 8:17–28)); (3) the combined image is converted into an image representation (*id*. (citing Ex. 1007, 9:1–13)); and (3) the image representation is "converted into a physical model that 'can be placed as a template on the bone of the patient 1 during a surgery and which fits perfectly to it'" (*id*. (citing Ex. 1007, 9:1–13; Ex. 1002 ¶¶ 117–118)).

Additionally, claim 29 recites that "the second image data set is of a type that is different from the first magnetic resonance image data set." Ex. 1001, 63:4–6. Petitioner argues that Swaelens teaches this limitation because the additional digital information "represents the 'position and direction' of the functional elements" (Pet. 45 (citing Ex. 1007, 9:10–13; 5:1–5, 10:23–30, Abstract)) and this additional digital information is converted into voxels and contours and used to create the model (*id*. at 46 (citing Ex. 1007, 8:5–9:13)). Petitioner contends that model for knee arthroplasty includes a saw guide "for resecting the tibia or the femur." *Id.* (citing Ex. 1007, 13:17–25, Fig. 6; Ex. 1002 ¶ 127).

Petitioner relies on the knowledge of one of ordinary skill in the art, as discussed above with respect to the ground based on CAOS, and argues that "it was well-known to align the cutting paths of the knee perpendicular to a patient's mechanical axis and to determine the mechanical axis and the orientation of the cuts from x-ray or CT data." *Id*. (citing Ex. 1002 ¶ 128; Ex. 1037, 758–60; Ex. 1036, 6:45–7:35, Abstract; Ex. 1032, 3:1–53, 8:27–30, 9:37–41). The cornerstone of Petitioner's analysis is its contention that

"[a] POSITA would have been motivated to follow the widely-accepted practice of using x-ray or CT image data representing the mechanical axis and the orientation of the cutting guides for the positioning and orientation of the functional elements in Swaelens," and that the x-ray or CT image data would be used as the additional information of Swaelens. *Id*. (citing Ex. 1002 ¶ 128).

Patent Owner disputes that Swaelens alone teaches the second image data set, and that the second data image data set is different than the first magnetic resonance image data set. Specifically, Patent Owner argues that

> one of ordinary skill attempting to create a surgical instrument having a patient-specific surface and a guide oriented relative to that surface would not start with *Swaelens* but would instead start (and end) with *CAOS*, which provides a single imaging modality solution to this very problem and comes years after *Swaelens*.

PO Resp. 38–39 (citing Ex. 2003 ¶ 107; Ex. 2005 ¶¶ 100–101). Patent Owner argues that Petitioner's interpretation of Swaelens alone is based on "hindsight." *Id*. at 39.

We recognize the impropriety of basing a conclusion of obviousness upon facts gleaned only through hindsight. Nonetheless,

> [a]ny judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper.

In re McLaughlin, 443 F.2d 1392, 1395 (CCPA 1971); *see also KSR*, 550 U.S. at 421 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning.").

Here, Petitioner does not provide sufficient argument and credible evidence demonstrating why one of skill in the art would use x-ray or CT image data as the additional digital information of Swaelens, based upon Swaelens alone. At the outset, we note that Petitioner refers to the prior art of CAOS (Pet. 53–54, 64), without explaining sufficiently the relevance of CAOS to this claim limitation. *See* 37 C.F.R. § 42.22 (a)(2) ("(a) Each petition or motion must be filed as a separate paper and must include: . . . (2) A full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence including material facts, and the governing law, rules, and precedent."). As such, without more, we agree that Petitioner's modification of Swaelens using the knowledge of one of skill in the art for the second image data set limitation appears to be based on hindsight.

Petitioner argues alternatively that "using x-ray or CT image data as the additional digital information representing the position and direction of the functional elements would have been obvious to a POSITA in view of Woolson." Pet. 47 (citing Ex. 1002 ¶¶ 129–131). For example Petitioner argues (1) that Woolson teaches the use of imaging data to orient guides to provide cutting paths aligned perpendicular to the mechanical axis of the knee (*id*.); (2) "**all** knee replacement systems align the implant with the patient's mechanical axis" to produce better results (*id*. (citing Ex. 1031, 1:26–36)); (3) Woolson explains the importance and necessity of positioning knee implants on an axis perpendicular to the mechanic axis (*id*. (citing Ex. 1031, 2:50–59, 4:20–26, 4:7–19, Abstract)); and (3) preoperatively identifying the mechanical axis and planning cuts using x-ray or CT imaging

(*id*. (citing Ex. 1031, 1:37–50, 2:28–59, 3:50–4:48, 5:9–49, 7:63–37, Abstract; Ex. 1002 ¶ 129)).

Petitioner argues that "[a] POSITA would have known to use x-ray or CT image data representing the mechanical axis and the orientation of the cuts perpendicular to the mechanical axis, as taught by Woolson, as the additional digital information for positioning and orienting the functional elements of Swaelens" and that "[a] POSITA would have been motivated to modify Swaelens to use x-ray or CT image data representing the mechanical axis and the orientation of the cuts as the additional digital information for several reasons." Pet. 49 (citing Ex. 1002 ¶ 131). Petitioner reasons that one of ordinary skill in the art would combine Swaelens with Woolson because (1) both describe cutting guides used in the field of knee arthroplasty; (2) "us[ing] x-ray or CT image data representing the mechanical axis and the orientation of the cuts perpendicular to such axis as the additional digital information" would ensure proper alignment of Swaelens' saw guide on the knee joint; and (3) "[d]oing so would merely involve using a technique that has been employed to improve one knee arthroplasty procedure (Woolson's) to improve a similar knee arthroplasty procedure (Swaelens'[]) in the same predictable way." *Id*. (citing Ex. 1002 ¶ 131).

Petitioner further argues that one of ordinary skill in the art would know that x-ray and CT image data are different types of image data than MRI data. Pet. 49 (citing Ex. 1002 ¶¶ 132, 33). For example, Petitioner points out that MRI imaging uses magnetic fields and radio waves, whereas x-ray and CT imaging use x-ray radiation, and MRI imaging produces a higher resolution image than x-ray imaging. *Id.* at 49–50 (citing Ex. 1002

¶¶ 132–33). Petitioner notes that the '169 patent describes MRI scanning, x-ray imaging, and CT as different imaging modalities. *Id*. (citing Ex. 1001, 14:55–15:21, 16:55–17:10 (identifying x-ray, CT, and MRI as different "imaging modalities"), 14:41–46 (characterizing x-ray and MRI as separate imaging techniques).

Patent Owner challenges Petitioner's contentions regarding the proposed modification of Swaelens' additional digital information, using Woolson's teachings regarding the use of x-ray or CT image data, to represent the position and direction of the functional elements. We address the parties' arguments below.

Claim 29 also recites that 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." Ex. 1001, 63:7–10. Petitioner argues that Swaelens discloses "processing MRI data of a joint to create a model that 'can be placed as a template on the bone of the patient 1 during a surgery and which fits perfectly to it.'" Pet. 50 (citing Ex. 1007, 1:6–14, 4:1–10, 6:24–9:13.

To the extent Patent Owner argues that one of ordinary skill in the art would not combine MRI images with an x-ray image, including its related argument regarding the incorporation of two-dimensional pixel data into Swaelens three-dimensional, voxel-oriented system (PO Resp. 6), we address such arguments below. Additionally, we address below Patent Owner's argument that "one of ordinary skill attempting to create a surgical instrument having a patient-specific surface" would start and end with CAOS. PO Resp. 38–40.

Claim 29 further recites that 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, 63:11–13. Petitioner contends that Swaelens teaches "a functional element can be a surgical tool guide that indicates 'a place where, a direction in which, a length over which, or an angle at which, one must cut, saw or drill'" (Pet. 50 (citing Ex. 1007, 10:23–11:4, 13:4–14:31, 17:13–17, Figs. 2, 6); and that "positioning of the functional element on the instrument (model) is determined based on second image data (additional digital information)" (*id*. (citing Ex. 1007, 7:17–21, 9:1–13, Abstract; Ex. 1002 ¶ 135)). Petitioner further contends that Swaelens teaches using the additional digital information, i.e., second image data, to orient the functional element, i.e., drill guide, relative to the patient-specific surface of the model. *Id*. at 51 (citing Ex. 1002 ¶ 136). Specifically, Petitioner argues that Swaelens teaches that "the functional element (e.g., drill guide) is oriented relative to the mirror image (patient-specific surface) based on the additional digital information (second image data)." *Id*. at 52 (citing Ex. 1002 ¶¶ 135–39).

Petitioner argues in the alternative that "[e]ven if Swaelens did not explicitly disclose that a surgical tool guide is oriented relative to the patient-specific surface based on the additional digital information, this would have been obvious to POSITA." Pet. 53 (citing Ex. 1002 ¶¶ 140–142). Petitioner explains that "it was well-known to align the cutting paths of the knee joint perpendicular to a patient's mechanical axis and to determine the mechanical axis and the orientation of the cuts from x-ray or CT data." *Id*. (citing Ex. 1002 ¶ 141; Ex. 1037, 7:58–60; Ex. 1036, 6:45–7:35, Abstract; Ex. 1032, 3:1–52, 8:27–30, 9:37–41). For example, Petitioner

argues that Swaelens' saw guide aligns the cuts of the femur or tibia, and positioning of the saw guide is based on the additional digital information. *Id*. (citing Ex. 1007, 7:17–21, 9:1–13, 13:17–41:31, Fig. 6. Petitioner reasons that

> [a]ligning the saw guide based on the additional digital information, such as x-ray or CT data identifying the mechanical axis, to make cuts perpendicular to such axis would have been obvious to a POSITA because this was standard practice that ensures long-term success of knee surgery. Ex. 1002 ¶ 142. In addition, a POSITA would have understood that because Swaelens'[] model fits perfectly on the joint, the patient-specific surface of model (mirror image) incorporates the position of the mechanical axis. *Id*.

Pet. 54. Petitioner concludes that it would have been obvious to one of skill in the art "to orient the saw guide relative to the patient-specific surface (mirror image) of the Swaelens'[] instrument (model) based on the additional digital information (second image data)." *Id*. (citing Ex. 1002 ¶ 142).

As discussed above, we are not persuaded by Petitioner's contention that Swaelens alone teaches the second image data claim element. Nonetheless, Petitioner alternatively relies on Woolson to teach the second image data claim limitation, as well as a guide that is oriented relative to the patient-specific surface based on information derived from the second image data set. Specifically, Petitioner argues that Woolson discloses preoperatively identifying the mechanical axis and planning cuts using x-ray or CT imaging to align the implant with the patient's mechanical axis to "produce[] successful long-term results." Pet. 54 (citing Ex. 1031, 1:26–50, 2:28–59, 3:50–4:48, 5:9–49, 7:63–67). Petitioner reasons that one of

skill in the art would modify Swaelens to use Woolson's CT or x-ray image data to "ensure[] long-term success of knee surgery." *Id*. at 54–55 (citing Ex. 1002 ¶¶ 144–145). Additionally, Petitioner reasons that

> a POSITA would have understood that because Swaelens'[] model fits perfectly on the joint, the contact surface of the model incorporates the position of the mechanical axis. *Id*. ¶ 146. Thus, orienting the saw guide relative to the patient-specific surface of the model based on the additional digital information (second image data) would have been obvious to a POSITA in view of Swaelens and Woolson. *Id*.

Id. at 55.

Patent Owner does not dispute specifically the teachings of Woolson. Rather, Patent Owner challenges whether one of ordinary skill in the art would combine Swaelens and Woolson and address the parties' arguments below.

b. Claim 30

Claim 30 depends from claim 29 and further recites that "the second image data is x-ray image data." Ex. 1001, 63:14–15. Petitioner asserts that "a POSITA would have been motivated to follow the widely-accepted practice of using x-ray image data representing the mechanical axis and the orientation of the cutting paths as the second image data (additional digital information) for positioning the functional elements (surgical tool guides) in Swaelens." Pet. 65 (citing Ex. 1002 ¶ 149). Petitioner further argues that Woolson discloses the use of x-ray image data to determine the mechanical axis, and to orient the cutting paths relative to the mechanical axis. *Id*. (citing Ex. 1002 ¶ 150; Ex. 1031, 1:26–50; 2:28–59, Abstract). Petitioner concludes that claim 30 would have been obvious for the same reasons as claim 29. *Id*. (citing Ex. 1002 ¶ 150). Patent Owner does not dispute specifically that Woolson discloses the use of x-ray image data. Rather,

Patent Owner challenges the reasons offered by Petitioner to combine Swaelens and Woolson, which we address below.

c. Discussion of the Parties' Contentions

i. Whether the proposed combination of Swaelens and Woolson teaches a second image data set that is different from a first magnetic resonance image data set.

Turning to the parties' contentions, Patent Owner characterizes Petitioner's position that the additional digital information is a second image data set that is different from the first magnetic resonance image data set as "pure speculation." PO Resp. 51. Patent Owner first argues that Swaelens does not state that the "additional digital information" is a second image data set, and that it is clear that the functional elements obtained from the additional digital information "is not a second image data set different from the originally obtained CT or MRI images." PO Resp. 47. Patent Owner contends that Swaelens teaches obtaining one set of digital image data that is manipulated using a processing unit to add functional elements '"possibly with *additional digital information* from outside.'" *Id*. (citing Ex. 1007, 7:17–21, 8:5–7; Ex. 2003 ¶ 100). The additional functional elements could be many things, in Patent Owner's view, including "a shape, color, texture, or label for facilitating the identification of a model, through the use of three-dimensional modeling software." *Id*. at 48 (citing Ex. 1007, 4:32–5:10, 8:5–7. Patent Owner contends that none of these functional elements require the incorporation of second image data in the model. *Id*. (citing Ex. 2003 ¶¶ 101, 103). Further, Patent Owner argues that

> Even the functional elements (indication of position, direction, length, or angle) that Dr. Mabrey considers relevant (Ex. 2022 at 118:5-119:5) can be obtained from *Swaelens'[]* original image data. *See* Ex. 2003 at 68. And one would understand that the

> "additional digital information" does not need to be from a second, different, image data set because such functional elements are incorporated without a second image data set. Ex. 2005 ¶ 90. In Figure 2, for example, the position and direction of the functional element (an opening for a boring bit) is based on the original image data only. Ex. 1007 at 9:10-13; *see also* Ex. 2003 ¶ 103; Ex. 2005 ¶ 92.

PO Resp. 49.

Patent Owner also argues that Petitioner mischaracterizes Figure 2 because Swaelens "does not contemplate use of any 'additional digital information' added from outside the first image data set, much less a second, different, image data set as Petitioner suggests." PO Resp. 50 (citing Ex. 1007, 8:17–9:13, 10:32–11:21; Ex. 2003 ¶¶ 102, 103; Ex. 2005 ¶ 92). Figure 2 is based on a single image data set, according to Patent Owner. *Id*. (citing Ex. 1007, 9:10–13; Ex. 2003 ¶ 103; Ex. 2005 ¶ 92). Further Patent Owner argues that Swaelens teaches "creating a negative model of a bone that includes an edge, or functional element that serves as a saw guide for the bone incision" (*id*. at 51 (citing Ex. 1007, 13:17–25)); and that functional elements e.g., orientation pins, could be added to the base (*id*. (citing Ex. 1007, 13:27–34)).

In its Reply, Petitioner first argues that Patent Owner and its experts acknowledge that Swaelens discloses "using MRI imaging to create a joint surface-matching instrument, and using 'information from outside' that imaging to create 'functional elements' such as guides." Reply 23 (citing PO Resp. 47; Ex 2005 ¶¶ 65, 89). Next, Petitioner directs us to the passage in Swaelens describing preparation of its instrument, which

> "includes the manipulation of medical image data, possibly **with additional digital information from outside**[.]" Ex. 1007, 7:17-19 (emphasis added); Ex. 1202 ¶¶24-25, 30, 60, 62, 65-66,

> 69. Swaelens further discloses that "functional element[s]," e.g. guides, are incorporated into the instrument on the basis of "new information added from outside." Ex. 1007, 4:28-30; Ex. 1202 ¶¶26-27, 30, 61-62, 65-66, 69. These functional elements serve "useful function[s]" such as indicating "a position, a direction, a length or an angle which are important during a surgery." Ex. 1007, 5:1-3; Ex. 1202 ¶¶28-30, 61.

Id. In a knee surgery, Petitioner argues that one of ordinary skill in the art would understand that position, direction, length, or angle would refer to orientation of the cut. *Id*. at 24. Based on the teachings of Woolson, Petitioner contends that one of ordinary skill in the art would have understood that "additional image data, such as an x-ray of the patient's leg, would provide the 'additional digital information' (e.g. position of the mechanical axis) that a POSITA would need to orient the guide to make the necessary cut." *Id.*

We agree. Swaelens explains that "[t]he processing or preparation includes the manipulation of medical digital image data, possibly with additional digital information from outside, in such a way that an artificial, functional element 10 with a useful function is added to the produced basic model 9." Ex. 1007, 7:17–21. Swaelens further explains that "[i]f external technical elements are added, for example coming from a CAD system, these elements must be represented as voxels or contours as well. This can be easily done by means of cross section and shading algorithms." *Id.* at 8:5–7. Based on Swaelens disclosure, Petitioner argues persuasively that "Swaelens need not limit the 'additional digital information' to image data for a POSITA to have understood that image data is one type of additional information that could be used." Reply 24 (citing Ex. 1202 ¶¶ 60, 65-66, 69;

Ex. 1210, 229:11–13, 231:20–24 (Swaelens does not exclude second image data).

ii. Whether Swaelens Prosthesis and Cutting Guide are Infeasible

Next, we consider Patent Owner's argument that one of skill in the art would not use Swaelens as a starting point for further modification. PO Resp. 54 (citing Ex. 2005 ¶ 95). According to Patent Owner, one of skill in the art, including Dr. Mabrey, would consider Swaelens prosthesis and cutting guide design '"'impossible' to use." *Id*. at 52 (citing Ex. 2022, 102:6–104:15, 119:18–120:19; Ex. 2005 ¶ 97). Patent Owner support its position with the testimony of Dr. Clark, explaining that he would not use a base similar to the one shown in Figure 8 of Swaelens. *Id*. (citing Ex. 1007, Fig. 2; Ex. 2005 ¶ 97). Patent Owner contends that "[o]ne of ordinary skill would readily recognize these deficiencies in the proposed design and discount the applicability of Swaelens']] knee embodiment." *Id*. at 53 (citing Ex. 2005 ¶ 97). Patent Owner points out that (1) Swaelens is primarily direct to dental implants, not knee arthroplasty; (2) Swaelens '"'impossible implant' would inform one of ordinary skill in the art that "Swaelens has a limited understanding of knee arthroplasty"; and (3) by picking and choosing the disclosure of Swaelens, Dr. Mabrey did not consider the reference as a whole. *Id*. (citing Ex. 2005 ¶ 97). Dr. Clark explains that one of ordinary skill in the art would not use a "perfected model" similar to the one shown in Figure 6 of Swaelens because it would require extensive manipulation of soft tissues. *Id*. at 54 (citing Ex. 2005 ¶ 96).

To the extent Patent Owner argues that one of ordinary skill in the art would not have been motivated to use Swaelens as a primary reference for

modification because of its shortcomings in actual use, or that the proposed modification would have lacked a reasonable expectation of success due to problems associated with actual use, we disagree. More persuasive is Petitioner's position that the expert's testimony that they would *not* have relied on Swaelens' knee implant in practice, does not provide a basis for ignoring Swaelens' express disclosure of techniques for creating patient-specific instruments. Reply 24–25 (citing PO Resp. 52–53; Ex. 1202 ¶¶ 67–68). As Petitioner points out, both Swaelens and the instrument in the '169 patent show an instrument that "protrudes around the bone.'" *Id*. (citing Ex. 1001, Fig. 26O). We credit the rebuttal testimony of Dr. Mabrey that "Swaelens, published in 1995, expressly teaches the use of MRI for developing its patient-specific surgical tool. Ex. 1007 at 1:30–31. It does not make sense that a POSITA would have disregarded that teaching because CAOS, published in 1998, later discloses the use of MRI or CT for a similar purpose." Ex. 1202 ¶ 70.

iii. Whether Petitioner's Proposed Modification is Based on Hindsight

We further consider Patent Owner's contention that Petitioner's proposed modification of Swaelens is "undermined by its own reliance on CAOS" because CAOS solves the same problem as the '169 patent using a single image data set. PO Resp. 55. In Patent Owner's view, one of skill in the art would look to a newer technique, such as the later reference of CAOS, to develop a patient-specific tool with guides oriented to the patient-specific surface, instead of Swaelens. *Id*. (citing Ex. 2005 ¶¶ 94, 100–101). Patent Owner argues that

> [i]n making both modifications, Petitioner and Dr. Mabrey completely ignore CAOS and instead suggest a combination of MRI imaging and x-ray imaging based only on hindsight. *See*

> Ex. 2003 ¶¶ 106-107; Ex. 2005 ¶¶ 102-103; Ex. 2022 at 75:9-76:6. But one of ordinary skill would not ignore CAOS's use of CT images and a CT topogram and instead use other imaging modalities because doing so would introduce risk of misalignment, both of which run contrary to Dr. Mabrey's stated goal of ensuring alignment to the mechanical axis and one of ordinary skill's motivation to implement techniques to guarantee that alignment. Ex. 2003 ¶¶ 106-109; Ex. 2005 ¶¶ 102-103; Ex. 2022 at 69:19-70:2.

PO Resp. 57.

Patent Owner's argument is not convincing, because as Petitioner point out, Swaelens expressly teaches the use of MRI, and one of ordinary skill would not disregard that teaching simply because a later reference discloses the use of CT. Reply 24–25 (citing Ex. 1202 ¶¶ 70, 74). Consistent with our discussion in above Section II.D.4(c), and for the same reasons, we are persuaded that one of ordinary skill in the art would understand how to align the mechanical axis using second image data based on the teachings of Woolson. We credit the rebuttal testimony of Dr. Mabrey that (1) Dr. Gold confirms "that co-registration techniques were well known prior to 2001 and would have facilitated combining Woolson's x-ray images or CT images with Swaelens'[] MRI images" (Ex. 1202 ¶ 72 (citing Ex. 1211 ¶¶ 13–36)); and (2) Swaelens teaches the use of MRI images to design a patient-specific surface, thus in view of Woolson "a POSITA would have been motivated to use x-ray or CT to determine a position, direction, length or angle of, e.g. a mechanical axis, and use this information as the basis for a functional element, e.g. surgical tool guide, on Swaelens'[] patient-specific instrument" (*id.*).

We are also not persuaded by Patent Owner's contention that Swaelens "evidences a preference for CT image data." PO Resp. 56. As

Petitioner point out, "Swaelens' states that the imaging may be obtained 'by means of a computer tomography scanner 2 **or any other digital image processing unit such as a Magnetic Resonance Image machine**[.]"' Reply 25 (citing Ex. 1007, 6:25–28; Ex. 1202 ¶ 73). Petitioner supports its position with the cross-examination testimony of Dr. Kneeland, who states that "Swaelens expresses no preference for the type of imaging used." *Id*. (citing Ex. 1210, 225:13–226:21). We credit the rebuttal testimony of Dr. Mabrey that "Swaelens expressly teaches the use of other digital imaging processing units, and specifically identifies MRI as an alternative," and Patent Owner's declarant Dr. Clark agrees. Ex. 1202 ¶ 73 (citing Ex. 2005 ¶ 89 ("*Swaelens* uses a CT (or an MRI) scanner to obtain digital image information")).

Patent Owner further argues that Swaelens does not show either an anatomical or mechanical axis, nor does it teach that the model is aligned relative to a mechanical axis. PO Resp. 58 (citing Ex. 2003 ¶ 109; Ex. 2005 ¶¶ 98–99). This argument is not persuasive based on the proposed combination of Swaelens and Woolson. Consistent with our discussion above in Section II.D.4(c), and for the same reasons, we are persuaded that one of ordinary skill in the art would understand how to align the mechanical axis using the second image data based on the teachings of Woolson. We credit the rebuttal testimony of Dr. Mabrey that Woolson, "when viewed in combination with Swaelens, teaches a device that relies on MRI data to create a patient-specific surface and an x-ray image to orient a tool guide relative to the mechanical axis." Ex. 1202 ¶ 74.

For these reasons, we disagree with Patent Owner's contention that the proposed combination of Swaelens and Woolson is based on hindsight.

iv. Whether Woolson's X-ray and CT images are Co-Registered with Swaelens MRI Images

Patent Owner argues that Petitioner's proposed modification of Swaelens using Woolson is unavailing because x-ray or CT images are not co-registered with MRI images. PO Resp. 58. And, even if one of ordinary skill in the art started with MRI images, Patent Owner argues that Petitioner has not established a reasonable expectation of successfully achieving the claimed invention, as MRI, CT, and x-ray imaging are different imaging modalities involving different devices. *Id*. at 58–59 (citing Ex. 2003 ¶¶ 110–113.

To the extent Patent Owner argues that a person of ordinary skill in the art would not have been motivated to modify Swaelens to utilize x-ray image data, or that such a modification would have lacked a reasonable expectation of success due to problems with co-registration, we disagree. As discussed above in Section II.D.4(c), co-registration is not needed to perform claim 29, nor claim 30. Nonetheless, as discussed above, Dr. Gold testified that co-registration was well known, and Dr. Mabrey agrees. *See, e.g.*, Ex. 1202 ¶ 72; Ex. 1211 ¶¶ 13–36.

v. Whether the Proposed Modification is Technically Infeasible.

Patent Owner further argues that Petitioner's proposed combination is unavailing "because Woolson's x-ray images are two-dimensional, pixel images whereas *Swaelens*'[] method requires a processing unit with a three-dimensional, voxel-oriented system." PO Resp. 59 (citing Ex. 2003 ¶ 110). Patent Owner argues that "*Swaelens* explains that if external information is used to determine the functional elements, it must be presented as voxels." *Id*. at 60 (citing Ex. 1007, 4:19–22, 8:5–9). A voxel is a three-dimensional pixel. *Id*. (citing Ex. 1007, 7:27–28; Ex. 2003 ¶ 111). MRI and CT images,

however, are voxel images, while an x-ray is a two dimensional pixel image. *Id*. (citing 1003 ¶ 111).

Patent Owner disputes the use of Woolson's x-ray image, which is a two-dimensional pixel image, as additional digital information to determine the orientation of functional elements in Swaelens' three-dimensional, voxel-oriented system. PO Resp. 60 (citing Pet. 47–55). Patent Owner directs us to the passage in Swaelens cited by Petitioner, namely that

> "[i]f external technical elements are added, for example coming from a CAD system, these elements must be represented as voxels or contours as well," and "[t]his can be easily done by means of cross section and shading algorithms."

Id. at 61, citing Ex. 1007, 8:5–9. Patent Owner contends that

> [t]his statement in *Swaelens* is not related to converting two-dimensional images into a three-dimensional system, but instead refers to manipulating technical elements in *Swaelens*'[] system. Ex. 2003 ¶ 112. *Swaelens* never mentions x-ray images or explains how the technical elements are converted from two-dimensions into three-dimensions. *See id*.

Id. Patent Owner argues that x-ray images are not convertible into voxel images because they are a two-dimensional summation of the target anatomy. *Id*. (citing Ex. 2003 ¶¶ 112–113).

More persuasive, however, is the rebuttal testimony of Dr. Mabrey that (1) "Swaelens discloses that 'functional element[s],' based on 'possible new information added from outside,' may also be presented as 'contours'" (Ex. 1202 ¶ 62 (citing Ex. 1007, 4:28–30)); (2) one of ordinary skill in the art "would have understood that such 'new information added from outside'" could include x-ray or CT-topogram data (*id.*); a contour is a two-dimensional representation of an object (*id*.); (3) "Swaelens'[] method utilizes a combination of three-dimensional (i.e. 'voxel-oriented') and two-

dimensional (i.e. 'contour'-based) image processing techniques to create its perfected model, add functional elements, and build the resulting patient-specific instrument" (*id*. ¶ 63); and (4) Dr. Gold confirms that well-known techniques were available for "co-registering two-dimensional images, such as x-rays, with three-dimensional images, such as MRI images, [and] would have been straightforward" (*id*. (citing Ex. 1211 ¶¶ 13–36)). *See also* Ex. 1202 ¶ 77 ("Swaelens'[] use of the term 'contours', which refers to a two-dimensional representation of a three-dimensional object, such as a bone contour visible on a conventional x-ray image or CT topogram x-ray, confirms that Swaelens contemplates the use of two-dimensional image information as the basis for 'functional element[s],' e.g. surgical tool guides, on Swaelens patient-specific instrument." (citing Ex. 1007, 4:28–32)).

3. Summary

Thus, upon review of the entirety of the record, we find that the proposed modification of Swaelens functional elements with Woolson's x-ray (e.g., as required in claim 30) or CT image data satisfies the second image data set claim element, including that the second image data set is of a different type than the first magnetic resonance image data set. We also find that the proposed combination of Woolson's use of x-ray or CT imaging representing the mechanical axis and orientation of the cuts perpendicular to the mechanical axis as the additional digital information for positioning and orienting the functional elements of Swaelens, satisfies the claim element of a guide oriented relative to the patient specific surface based on the second image data claim element. Moreover, Petitioner has provided a sufficient rationale, supported by evidence of record, to demonstrate that a person of ordinary skill in the art would have found the proposed combination obvious

for the stated purpose of using "one knee arthroplasty procedure (Woolson's) to improve a similar knee arthroplasty procedure (Swaelens'[]) in the same predictable way." Pet. 49. For example, Petitioner explains that a "POSITA would have understood that, in view of Woolson, the functional element's position, direction, length, or angle could be derived from a second image data set." Reply 24. As discussed above, Woolson explains that placement of a knee prosthesis along a mechanical axis "is highly likely to produce a successful long-term result." Pet. 54 (citing Ex. 1031, 1:26–36; 2:28–40, 4:13–26, 4:27–29).

In view of the foregoing, we conclude that Petitioner has established by a preponderance of the evidence that claims 29 and 30 are unpatentable under 35 U.S.C. § 103(a) as obvious over Swaelens and Woolson, but not Swaelens alone.

F. Patent Owner's Observations on Cross-Examination

As noted above, Patent Owner filed Motions for Observation on the Cross-Examinations of Garry E. Gold, M.D. (Paper 31) and Jay D. Mabrey, M.D. (Paper 32), to which Petitioner responded (Papers 37, 38).

We have considered Patent Owner's observations and Petitioner's responses in rendering this Decision, and we have accorded appropriate weight to the testimony of Dr. Gold and Dr. Mabrey.

III. CONCLUSION

For the foregoing reasons, we determine Petitioner has demonstrated that challenged claims 29 and 30 of the '169 patent are unpatentable by a preponderance of the evidence.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 29 and 30 of the '169 patent are unpatentable; and

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

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