Trials@uspto.gov
571-272-7822

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2017-00510
Patent 7,981,158 B2

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

WIEKER, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Smith & Nephew, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–65 ("the challenged claims") of U.S. Patent No. 7,981,158 B2 (Ex. 1001, "the '158 patent"). Paper 1 ("Pet."). ConforMIS, Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). We instituted an *inter partes* reviews of challenged claims 1–65, across four grounds of unpatentability, pursuant to 35 U.S.C. § 314. Paper 9 ("Dec. on Inst.").

After institution, Patent Owner filed a Response (Paper 16 ("PO Resp.")) to the Petition, and Petitioner filed a Reply (Paper 22 ("Pet. Reply")). Additionally, with our authorization, Patent Owner filed a list of purportedly improper arguments contained in Petitioner's Reply (Paper 29), 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, IPR2017-00511, and IPR2017-00373, and a transcript of the hearing is included in the record. Paper 41 ("Tr.").

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has shown by a preponderance of the evidence that challenged claims 1–65 are unpatentable.

B. Related Proceeding

The parties identify the following matter related to the ’158 patent (Pet. 1; Paper 3, 2):

ConforMIS, Inc. v. Smith & Nephew, Inc., No. 1:16-cv-10420-IT (D. Mass.).

C. The ’158 Patent

The ’158 patent, titled “Patient Selectable Joint Arthroplasty Devices and Surgical Tools,” issued July 19, 2011, from U.S. Patent Application No. 12/135,603, filed June 9, 2008. Ex. 1001. The ’158 patent discloses a surgical template that conforms to the surface of a patient’s patella, wherein the template includes a guide aperture that directs movement of a surgical instrument, e.g., a drill or saw. *Id.* at (57), 70:53–56. Specifically, the ’158 patent explains that the template is designed by obtaining images of the patient’s joint, and using those images to construct the device. *Id.* at 70:43–48. Figure 22 is reproduced below, for example.

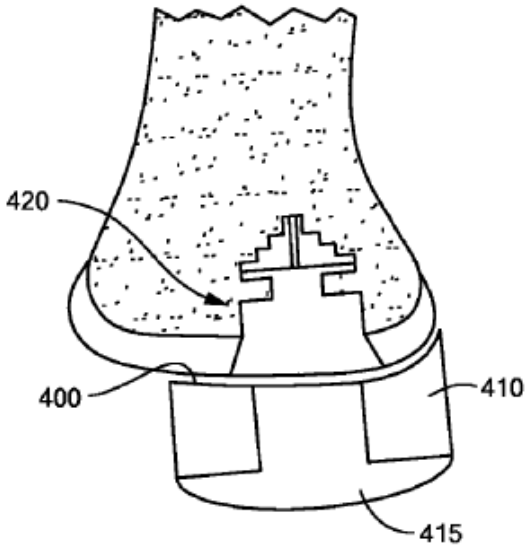

FIG. 22

Figure 22 depicts "surgical tool 410 having one surface 400 matching the geometry of an articular surface of the joint . . . [and] aperture 415 in the tool 410 capable of controlling drill depth and width of the hole and allowing implantation or insertion of implant 420." *Id.* at 78:60–65.

The '158 patent also explains that when planning a total knee arthroplasty, "[t]he resections should be made to enable the installed artificial knee to achieve flexion-extension movement within the MAP-plane and to optimize the patient's anatomical and mechanical axis of the lower extremity." *Id.* at 69:27–31.[1] Accordingly, "axis and alignment information of a joint or extremity can be included when selecting the position of the . . . cut planes, apertures, slots or holes on the template." *Id.* at 76:64–67. These axes may be identified by, e.g., CT, MRI, or CT scout scans. *Id.* at 77:1–10.

D. Illustrative Claims

Of the challenged claims, claims 1 and 38 are independent, illustrative, and reproduced below.

> 1. A method of generating a patient-matched surgical tool, the method comprising:
>
> obtaining first image data associated with at least a portion of a joint of a patient;
>
> obtaining second image data associated with at least a portion of the joint;
>
> deriving an electronic model of at least a portion of the joint using at least the first image data;
>
> creating a surgical tool using, at least in part, the electronic model;

[1] The '158 patent explains that "[t]he biomechanical axis may extend from a center of a hip to a center of an ankle," and "[t]he anatomic axis 1920 aligns 5–7˚ offset Θ from the mechanical axis in the valgus, or outward, direction." *Id.* at 10:66–67, 69:1–3; *see also id.* at Fig. 21A.

wherein the tool includes a contact surface substantially matched to a corresponding surface of the joint and a guide for directing movement of a surgical instrument; and

wherein the position or orientation of the guide relative to contact surface is adapted at least in part based on information derived from the second image data.

38. A method of making a patient-matched surgical tool, the method comprising:

obtaining first image data associated with at least a portion of a joint of a patient;

obtaining x-ray image data associated with at least a portion of the joint;

determining from the x-ray image data at least one of an anatomical and mechanical axis associated with the joint;

creating a surgical tool based at least in part on the first image data and the x-ray image data;

wherein the surgical tool includes a contact surface substantially matched to a corresponding surface of the joint and a guide for directing movement of a surgical instrument, the guide having a predetermined orientation based at least in part on the determined axis.

Ex. 1001, 119:10–26, 120:54–121:2.

E. Applied References

Petitioner relies upon the following references:

> Radermacher, WO Publication No. 93/25157 A1, filed June 17, 1993, published December 23, 1993 ("Radermacher," Ex. 1003);
>
> Alexander et al., WO Publication No. 00/35346 A2, filed December 16, 1999, published June 22, 2000 ("Alexander," Ex. 1004);
>
> Woolson, U.S. Patent No. 4,841,975, filed April 15, 1987, issued June 27, 1989 ("Woolson," Ex. 1031);
>
> Radermacher et al., *Computer Assisted Orthopaedic Surgery With Image Based Individual Templates*, 354 CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 28 (Carl T. Brighton ed., 1998) ("CAOS," Ex. 1033);
>
> Edmund Y.S. Chao & Franklin H. Sim, *Computer-Aided Preoperative Planning in Knee Osteotomy*, 15 THE IOWA ORTHOPAEDIC JOURNAL 4 (Steven M. Madey et al. eds., 1995) ("Chao," Ex. 1084); and
>
> Junichi Arima et al., *Femoral Rotational Alignment, Based on the Anteroposterior Axis, in Total Knee Arthroplasty in a Valgus Knee*, 77 A THE JOURNAL OF BONE AND JOINT SURGERY 1331 (Henry R. Cowell et al. eds., 1995) ("Arima," Ex. 1085).

Pet. 20.

Petitioner also presents 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).

Patent Owner presents 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).

F. Asserted Grounds of Unpatentability

We instituted *inter partes* review based upon the following grounds (Pet. 20; Dec. on Inst. 30):

References	Basis	Claims Challenged
CAOS, Woolson, and Alexander	§ 103	1–3, 5–7, 11–14, 19–28, 30, 31, 33–35, 37–41, 45, 46, 51–56, 58, 59, 61–63, and 65
CAOS, Woolson, Alexander, and Radermacher	§ 103	4, 29, 32, 36, 57, 60, and 64
CAOS, Woolson, Alexander, and Chao	§ 103	8–10 and 42–44
CAOS, Woolson, Alexander, and Arima	§ 103	15–18 and 47–50

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, we generally give claim terms their ordinary and customary meaning, as understood by a person 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).

In their pre-institution papers, neither party proposed any claim terms for express construction. *See generally* Pet.; Prelim. Resp. Nonetheless, in our Decision on Institution, we determined it prudent to construe the phrase "surface of the joint," which appears in independent claims 1 and 38. Dec. on Inst. 6–7. In their post-institution papers, neither party addresses our construction of this term.

Our review of the '158 patent reveals that a patient's "articular surface can comprise cartilage and/or subchondral bone" and that the customized device "can have a surface and shape that will match all or portions of the articular cartilage, subchondral bone and/or other bone surface and shape." Ex. 1001, 6:56–58, 70:43–50. This is consistent Dr. Mabrey's testimony:

> In a healthy knee, the lower end of the femur and the upper end of the tibia are covered by articular cartilage. The layer of bone directly beneath the articular cartilage is called "subchondral bone." In arthritic joints, some of the articular cartilage is often worn or torn away, resulting in a surface that is partially articular cartilage and partially exposed subchondral bone.

Ex. 1002 ¶¶ 36, 85 (asserting "a person of ordinary skill in the art would have understood that 'a corresponding surface of the joint' recited in Claim 1 includes bone surface, particularly when the cartilage is worn out").

Accordingly, we maintain our construction of "surface of the joint" as "the surface of an articulating bone that includes cartilage and/or exposed subchondral bone."

We determine that no other claim term requires express construction. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if "the differences between the subject matter sought to be patented 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) objective evidence of nonobviousness.[2] *Graham v. John Deere Co.*, 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.

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must support its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

[2] Patent Owner does not provide evidence regarding objective evidence of nonobviousness. *See generally* PO Resp.; *see also* Pet. 75.

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17.

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.

Patent Owner contends 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, such as a radiologist. PO Resp. 18.

Based on our review of the '158 patent and the types of problems and solutions described in the '158 patent and cited prior art, we agree with Patent Owner that a person of ordinary skill in the art also would have experience with, or an understanding of, surgical imaging technologies, or would have access to such a person, in addition to the qualifications articulated by Petitioner. We also note that the applied prior art reflects the

appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Furthermore, even under Patent Owner's articulation of the appropriate level of skill in the art, a person of ordinary skill need only possess experience with, and an understanding of, imaging technologies (or access to such a person), and need not possess a degree in imaging technology, as suggested by Patent Owner's argument. PO Resp. 19–21. Moreover, Dr. Mabrey's experience 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 ¶¶ 16, 18, 19 ("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.").

D. Obviousness over the Combined Teachings of CAOS, Woolson, and Alexander

Petitioner contends that claims 1–3, 5–7, 11–14, 19–28, 30, 31, 33–35, 37–41, 45, 46, 51–56, 58, 59, 61–63, and 65 of the '158 patent are unpatentable as obvious over the combined teachings of CAOS, Woolson, and Alexander. Pet. 21. For reasons that follow, we determine Petitioner has demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

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, wherein the templates 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 Woolson (Ex. 1031)

Woolson is titled "Preoperative Planning of Bone Cuts and Joint Replacement Using Radiant Energy Scan Imaging." Ex. 1031, [54]. Woolson discloses using "radiant energy scan imaging to determine the position of a bone-cut-defining guide relative to the bone to be cut," preferably for knee replacement surgery. *Id.* at 1:9–15. Woolson explains that long-term surgical success requires aligning a reconstructed knee joint with the bone's mechanical axis. *Id.* at 1:26–36. Conventionally, radiographs were taken to define this axis. *Id.* at 1:37–62. In Woolson's preferred embodiments, CT scans are taken to define the mechanical axis so that cuts can be made perpendicular to that axis. *Id.* at 4:13–44, 5:9–16, 7:62–67, Figs. 1, 2A, 2B.

3. Overview of Alexander (Ex. 1004)

Alexander is titled "Assessing the Condition of a Joint and Preventing Damage" and relates to "the use of [joint] assessment in aiding in prevention of damage to the joint or treatment of diseased cartilage in the joint." Ex. 1004, 1:15–17. More specifically, Alexander discloses a joint

assessment method in which an image of cartilage is obtained, preferably by magnetic resonance imaging, and converted into a three-dimensional degeneration pattern, from which the degree of degeneration in the cartilage can be evaluated. *Id.* at 2:25–27. Alexander further discloses that a loss in cartilage may be determined through use of, for example, a "3D . . . thickness map." *Id.* at 3:8–9; *see also id.* at 14:16–21.

4. Analysis of Independent Claim 1

Petitioner contends that the combined teachings of CAOS, Woolson, and Alexander would have rendered claim 1 obvious to a person of ordinary skill in the art. *See* Pet. 22–39.

Patent Owner contends that claim 1 would not have been obvious "for substantially the same reasons as claims 3, 4, 7–9, 24, 26, and 38–65." PO Resp. 44. However, Patent Owner's arguments with respect to those claims rest upon Patent Owner's contention that it would not have been obvious to modify CAOS to incorporate *x-ray or MRI* image data, as taught by Woolson or Radermacher, respectively. *Id.* at 21–44. As discussed herein, Petitioner's contentions with respect to claim 1 do not rely on incorporating x-ray or MRI image data. Pet. 22–39. Therefore, Patent Owner's arguments are not responsive to Petitioner's contentions. Nonetheless, it remains Petitioner's burden to demonstrate that claim 1 would have been obvious, by a preponderance of the evidence.

After considering the arguments and evidence of record, we determine Petitioner has demonstrated that claim 1 is unpatentable by a preponderance of the evidence.

i. Preamble

Independent claim 1 recites "[a] method of generating a patient-matched surgical tool." Ex. 1001, 119:10–11. Petitioner contends that CAOS discloses the subject matter recited in the preamble because CAOS teaches manufacturing individual templates that are molded to the shape of an individual bone surface. *See, e.g.*, Pet. 33 (citing, e.g., Ex. 1033, 28–29).

We are persuaded by Petitioner's contention. CAOS explains that a three-dimensional printer creates an "individual template" by "mold[ing] the shape of small reference areas of the bone surface automatically into the body of the template," such that it forms an "exact fit to the bone." Ex. 1033, 28.

ii. "obtaining first image data"

Independent claim 1 recites "obtaining first image data associated with at least a portion of a joint of a patient." Ex. 1001, 119:12–13. Petitioner contends that CAOS teaches this limitation because CAOS discloses obtaining CT image data. Pet. 22–23, 33–34 (citing, e.g., Ex. 1033, 29–32, 34, 37).

We are persuaded by Petitioner's contention. 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).

iii. "obtaining second image data"

Independent claim 1 recites "obtaining second image data associated with at least a portion of the joint." Ex. 1001, 119:14–15. Petitioner contends that CAOS teaches this limitation because CAOS discloses taking

topograms of the joint to identify a bone axis. Pet. 23, 34 (citing, e.g., Ex. 1033, 29–32, 34).

We are persuaded by Petitioner's contention. CAOS explains that in conjunction with a "total knee replacement," "topograms could be used to identify the bone axis." Ex. 1033, 31.

During oral argument, Patent Owner argued that a topogram is not "second" image data, different from the "first," because both are taken by a CT machine. Tr. 41:7–42:8. This argument was not made in the Patent Owner Response and, thus, is waived. Paper 10, 3 ("[A]ny arguments for patentability not raised in the [patent owner] response will be deemed waived."); Tr. 45:1–45:22, 57:14–59:12.[3]

Nonetheless, the evidence of record demonstrates that CT images and topograms are different image data, i.e., "first" and "second" image data. *See, e.g.*, Ex. 1202 ¶ 26 ("[A] CT topogram is an x-ray obtained from a CT scanner. After obtaining a topogram x-ray, subsequent scans may be taken to obtain CT image slices. . . . The topogram x-ray and CT image are two different types of image data sets that are viewed separately on a computer monitor and used independently in clinical practice."); Ex. 2003 ¶¶ 18 ("The CT scanner takes two scans—the CT topogram and the series of CT images. . . . The resulting CT topogram is a low-resolution, projection image."), 19

[3] Patent Owner argues that the Board did not institute an asserted ground of unpatentability relying on CAOS's CT data as "first image data." Tr. 57:17–58:12. Patent Owner is incorrect. *See* Dec. on Inst. 12 ("Petitioner contends that CAOS obtains first image data associated with a patient's joint, as required by claim 1, *because CAOS discloses obtaining CT image data*. At this stage of the proceeding, *we are persuaded by Petitioner*." (emphases added) (citation omitted)). Petitioner's proposed modification to replace CT with MRI image data relates to claim 4, not claim 1. *Id.* at 22–24.

("For the second scan, the scanning table moves slowly through the rotating bore of the gantry. . . . [T]he source is rotated around the patient's anatomy to produce views from many angles. A computer is used to construct the various views into a full cross-sectional image of the patient's anatomy."); PO Resp. 11–12.

iv. "deriving an electronic model" and "creating a surgical tool using . . . the electronic model"

Independent claim 1 recites "deriving an electronic model of at least a portion of the joint using at least the first image data" and "creating a surgical tool using, at least in part, the electronic model." Ex. 1001, 119:16–19. Petitioner contends that CAOS teaches these limitations because CAOS discloses customizing templates based on three-dimensional reconstructions of CT data. Pet. 24, 34–36 (citing, e.g., Ex. 1033, 29–37, Figs. 1B–1C).

We are persuaded by Petitioner's contentions. CAOS explains that "templates are customized on the basis of three-dimensional reconstructions . . . extracted from computerized tomographic (CT) image data," and CAOS's Figures 1B and 1C depict the process of "computer assisted planning" on the electronic model. Ex. 1033, 29, Fig. 1B–1C. That model is used to create a surgical tool, which is generated by "a desktop computer controlled milling device . . . used as a three-dimensional printer." *Id.* at 28.

v. "the tool includes . . . a guide"

Independent claim 1 recites "the tool includes . . . a guide for directing movement of a surgical instrument." Ex. 1001, 119:20–22. Petitioner contends that CAOS teaches this limitation because CAOS discloses a tool guide for directing a saw or drill. Pet. 25, 36–37 (citing, e.g., Ex. 1033, 28–31, 34, 36–37).

We are persuaded by Petitioner. CAOS explains that "[m]echanical guides for drills, saws, chisels, or milling tools are adaptable or integrated into these individual templates." Ex. 1033, 29.

vi. "the tool includes a contact surface"

Independent claim 1 recites "the tool includes a contact surface substantially matched to a corresponding surface of the joint." Ex. 1001, 119:20–21. Petitioner contends that CAOS discloses matching the customized template to bone, which "'fit[s] exactly on the bone." Pet. 24–25 (quoting Ex. 1033, 29). Petitioner also contends that "[e]ven if ConforMIS attempts to argue that substantially matching the corresponding surface of the joint requires matching the cartilage surface, this would have been obvious" in light of Alexander's disclosure of using CT or MRI to generate images of cartilage. *Id.* at 25–26 (citing Ex. 1002 ¶¶ 88–91; Ex. 1004, 14:16–21, 61:19–25, Fig. 18C). Petitioner contends that it would have been obvious to incorporate Alexander's teachings into CAOS, such that the template would have included a contact surface substantially matched to a corresponding surface of the joint, whether that joint surface includes bone (in light of CAOS) and/or cartilage (in light of Alexander), because bone and cartilage are the only two surfaces to which the template could be matched, and selection between them is simply a design choice. *Id.* at 26–27 (citing Ex. 1002 ¶¶ 89–90, 154), 36–37.

We are persuaded by Petitioner's contentions. As discussed in Section II.A, *supra*, we construe "surface of the joint" as "the surface of an articulating bone that includes cartilage and/or exposed subchondral bone." CAOS explains that "the position of the contact faces of the template [can be

adjusted] until they fit exactly on the bone." Ex. 1033, 29. Thus, to the extent the surface of the joint includes bone, CAOS satisfies this limitation.

To the extent the surface of the joint includes cartilage, alone or in conjunction with bone, we are persuaded that matching cartilage would have been obvious in view of Alexander's teaching that CT or MRI—the same imaging techniques used by CAOS to generate the patient-specific tool—also generate images of cartilage. Ex. 1004, 14, 61 ("3D reconstruction of femoral and tibial bones . . . femoral cartilage . . . and tibial cartilage"); Ex. 1031, 29 (CT), 37 (MRI). We are persuaded by Petitioner's undisputed contention that a person of ordinary skill in the art would have found it obvious to utilize Alexander's teachings with CAOS, because bone and cartilage are the only two surfaces to which CAOS's template could be matched. Pet. 26–27; PO Resp. 43; Ex. 1002 ¶¶ 89–90 (Dr. Mabrey opining that a person of ordinary skill in the art would have been motivated to combine CAOS and Alexander because, *inter alia*, bone and cartilage are the only surfaces to which the template could match and choosing between them "is simply a design choice and a matter of the surgeon's preference"). Given CAOS's teaching that the tool is customized to have an "exact fit to the bone," we are persuaded that a person of ordinary skill in the art would have found it obvious for the tool's surface to "exact[ly] fit" the joint surface, whether that surface includes bone, cartilage, or both, in accordance with the surgeon's preference. Ex. 1002 ¶¶ 89–90.

vii. "*the position or orientation of the guide . . . [is] based on information derived from the second image data*"

Independent claim 1 recites "the position or orientation of the guide relative to [the] contact surface is adapted at least in part based on

information derived from the second image data." Ex. 1001, 119:24–26. Petitioner contends that CAOS teaches this limitation, or it would have been obvious in view of Woolson. Pet. 27–33, 37–38.

Petitioner contends that CAOS uses topograms to align the template and its guide relative to the bone. *Id.* Specifically, CAOS explains that the template, including its tool guide, is fit exactly against the bone surface. Ex. 1033, 29. CAOS also explains that "accurate placement of implant components with respect to the individual mechanical axis of the leg is essential," and "topograms could be used to identify the bone axis." *Id.* at 31. Thus, according to Petitioner, "CAOS teaches using second image data (topograms) to align the cutting guide relative to the contact surface of the [template], which serves as 'a reference base' for surgical work on the bone." Pet. 29 (citing Ex. 1033, 31).

Additionally, to the extent CAOS does not explicitly disclose this limitation, Petitioner contends it would have been obvious in light of Woolson's disclosure of using image data (e.g., x-ray or CT) to orient a tool guide relative to the bone's mechanical axis. Pet. 31–32, 38. Woolson explains that placement of a knee prosthesis along a mechanical axis "is highly likely to produce a successful long-term result." Ex. 1031, 1:26–36; 2:28–40, 4:13–26 ("cutting along a line 20 which is perpendicular to [mechanical] axis 14"), 4:27–29 (identifying mechanical axis from CT data). Petitioner argues, *inter alia*, that it would have been obvious to use CAOS's topograms to orient the template's cutting guide relative to the contact surface and the mechanical axis of the bone, as taught by Woolson, to

achieve long-term surgical success. Pet. 32 (citing Ex. 1002 ¶¶ 105–107).[4] According to Petitioner, this would have been use of a known technique to improve a similar procedure in a predictable way. Pet. 33.

We are persuaded by Petitioner's obviousness contention. Although CAOS does not state explicitly that the axis identified by the topogram is used to position the template and its guide relative to the contact surface, Petitioner has shown sufficiently that the combined teachings of CAOS and Woolson satisfy this limitation. Pet. 31–32; Ex. 1031, 2:28–40, 4:13–26. 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 ¶ 105 ("This would ensure the accurate alignment of the knee prosthesis with the mechanical axis, which both Woolson and CAOS recognize is essential."), ¶ 107 ("[O]rienting the surgical tool guides in CAOS relative to the mechanical axis based on second image data would merely involve using a technique that has been employed to improve one knee arthroplasty

[4] For claim 1, Petitioner does not propose modifying CAOS to use x-ray image data, as Petitioner contends regarding claim 38. *See* PO Resp. 44; *compare* Pet. 31–33 (regarding claim 1, "a POSITA would have understood that CAOS in combination with Woolson and Alexander discloses orienting the guide relative to the instrument's contact surface based on second image data (e.g., topograms)"), *with id.* at 40–41 (regarding claims 3 and 38, "using x-ray image data in place of topograms to determine the mechanical axis and orient the cutting paths relative to this axis would have been obvious").

procedure (Woolson's) to improve a similar knee arthroplasty procedure (CAOS's) in the same predictable way.").

For the foregoing reasons, we determine that Petitioner has demonstrated claim 1 to be unpatentable by a preponderance of the evidence.

5. Analysis of Independent Claim 38

Petitioner contends that CAOS, Woolson, and Alexander would have rendered claim 38 obvious to a person of ordinary skill in the art. *See* Pet. 52–57 (incorporating Pet. 40–41). Petitioner states, and we agree, that claim 38 varies from claim 1 in the following ways: "(a) second image data is x-ray image data; (b) determining the anatomical and/or a mechanical axis from x-ray image data; (c) creating the tool from first image data and x-ray image data; and (d) the guide is oriented based on the determined axis." *Id.* at 52; *compare* Ex. 1001, 119:10–26, *with id.* at 120:54–121:2. We focus our analysis on these differences and otherwise incorporate our analysis of claim 1. *See* Section II.D.4.

Patent Owner disputes Petitioner's contentions. PO Resp. 21–44.[5] For example, Patent Owner contends that it would not have been obvious to replace CAOS's CT topogram with Woolson's x-ray image data because such a modification "would make obtaining CT . . . images technically infeasible" and "nonsensical." *Id.* at 24, 33.

It is Petitioner's burden to demonstrate unpatentability. After considering the parties' arguments and evidence, we determine Petitioner

[5] Patent Owner presents consolidated arguments for claims 3, 4, 7–9, 24, 26, and 38–65. PO Resp. 21.

has demonstrated that claim 38 is unpatentable by a preponderance of the evidence.

viii. "obtaining x-ray image data"

Petitioner contends it would have been obvious to use "x-ray image data in place of [CAOS'] topograms" because they are alternatives. Pet. 40 (citing, e.g., Ex. 1002 ¶¶ 111–112), 53. Petitioner also contends that Woolson demonstrates that it was known to use either x-ray or CT image data to determine a mechanical axis and orient cutting paths. *Id.* (citing, e.g., Ex. 1031, Abstract, 1:37–50 (radiographs),[6] 2:28–59 (radiant energy scans); Ex. 1002 ¶ 113); *see also* Ex. 1031, 4:27–32 (CT). Therefore, according to Petitioner, "using x-ray image data in place of topograms to determine the mechanical axis and orient the cutting paths relative to this axis would have been obvious," as a simple substitution of one known element for another. Pet. 40–41 (citing Ex. 1002 ¶ 113; *KSR*, 550 U.S. at 417), 53 (citing Ex. 1002 ¶¶ 112–113 (citing, e.g., Ex. 1031, 1:26–50, 2:28–59 (use of x-ray image data to determine the mechanical axis "produce[s] a successful long-term result" and allows "accurate and precise placement")), 147).

In the Response, Patent Owner argues that CAOS's method was successful because its two data sets—CT images and CT topograms—are "intrinsically co-registered." PO Resp. 24, 26, 39; *see also id.* at 29, 33, 38, 41–42 (similar arguments regarding integrated MRI data sets). 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

[6] *See* Ex. 2022, 15:10–22 ("x-ray" and "radiograph" can be used "interchangeably"); Ex. 1203, 35:12–16 ("plain radiographs" are "[w]hat people think of as X-rays").

may be integrated or fused." *Id.* at 15. According to Patent Owner, "a CT topogram is required to plan the start and end points of the CT images. Because the CT topogram is taken on the same CT scanner seconds before the CT images are taken, the resulting CT images are intrinsically co-registered with the CT topogram." *Id.* at 16 (citing Ex. 2003 ¶ 27), 26. Therefore, Patent Owner argues that one skilled in the art would not eliminate the intrinsic co-registration of a CT data set by replacing CT topograms with x-ray image data, because such a modification "would make obtaining CT . . . images technically infeasible" and would "introduce problems related to co-registering images from different imaging modalities." *Id.* at 24–25, 27; *see also id.* at 29, 33, 38, 41–42 (MRI).

Patent Owner also contends that "Petitioner provides insufficient reasons for completely deviating from CAOS's successful method," and does not identify shortcomings in CAOS's method or improvements that would have motivated the proposed modification. PO Resp. 25, 27–28. For example, Patent Owner argues that this modification would require x-ray image data to be co-registered with CAOS's CT data, which is "difficult, time-consuming, and often inaccurate, all of which would increase the risk of misalignment compared to CAOS's use of CT images and a CT topogram." PO Resp. 30 (citing Ex. 2003 ¶¶ 25–26; Ex. 2005 ¶¶ 69–71; Ex. 2022, 69:19–70:2); *see also id.* at 15, 28–33.

Additionally, Patent Owner contends that the Petition fails to explain how the proposed modification would be achieved, including how to reconcile differences in 2D (x-ray) and 3D (CT) images, imaging modalities, magnifications, projection angles, resolutions, and patient positions. *Id.* at

30–32 (citing Ex. 2022, 81:4–9, 91:19–92:18, 94:14–96:14, 98:5–23, 107:13–109:9, 128:12–21, 139:25–141:25; Ex. 2003 ¶¶ 64–66).

Further, Patent Owner contends that the proposed modification is impractical. PO Resp. 33. For example, because topograms are used to plan the start and end points of a subsequent CT scan, Patent Owner argues that one "would not (and practically cannot) obtain CT images without first obtaining a CT topogram," and an x-ray image would not provide the same type of information. *Id.* at 34–35. According to Patent Owner, this demonstrates that there is no motivation and no reasonable expectation of success in using an x-ray image instead of a CT topogram. *Id.* at 35.

In Reply, Petitioner contends that co-registration is not recited in the '158 patent claims and, nonetheless, the '158 patent specification demonstrates that "co-registration would not have been a problem." Pet. Reply 2–3. Petitioner contends that Patent Owner is bound by its admission 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.* at 3–4 (quoting Ex. 1001, 34:32–33 ("As will be appreciated by those of skill in the art, imaging techniques can be combined, if desired."); citing Ex. 1001, 37:63–38:14 (example of combining x-ray with CT or MRI), 40:4–11 (same), 40:16–18 (same)) (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)).

According to Petitioner,

> With no such disclosure [of co-registration] in the specification, only two possibilities exist. Either co-registration was within the ordinary skill, or the '158 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.

Id. at 4–5. Petitioner thus contends that Patent Owner cannot argue that co-registration of image data was "difficult, time-consuming, and often inaccurate," while "at the same time, claim[ing] that very combination, without disclosing 'how it was done.'" *Id.* at 5.

Petitioner analogizes to the Federal Circuit's decision in *Smith & Nephew, Inc. v. Rea*, in which the patent owner "argued that achieving compression with non-locking screws in conically tapered, partially threaded holes was unknown in the prior art and, in fact, would have been inoperable." Pet. Reply 5; *Smith & Nephew*, 721 F.3d at 1381. In that case, the Federal Circuit stated that such an argument "naturally raises the question of how [the patent owner] managed to make such a combination work." *Smith & Nephew*, 721 F.3d at 1381. The Federal Circuit further explained that 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 38 does not require steps of co-registering the claimed first image data and x-ray image data. First, we consider the claim language. Claim 38 does not require that the "first image data" and the "x-ray image data" be co-registered, or combined, in any manner. Ex. 1001, 120:54–121:2. We recognize Patent Owner's argument

that the two types of image data must be reflected in the surgical tool made by the claimed method; however, this does not require co-registration. Tr. 20:17–21:12. The claim simply requires that x-ray image data is used to determine an axis; that the tool is created based at least in part on first image data and the x-ray image data; and that the guide is based at least in part on the determined axis. Ex. 1001, 120:54–121:2. The claim does not prescribe the manner in which these steps occur; in other words, the claim does not require that the first image data and the x-ray image data be co-registered, in order to determine the axis, to create the tool, or to locate the guide.[7]

For example, Petitioner relies upon Dr. Mabrey's testimony and contends 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. Pet. Reply 17 (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

[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 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.

transfer the hip offset and anatomical axis to the three-dimensional model of the patient's proximal femur.

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 templates (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 CT scan. *Id.* ¶ 7. Using such a technique, Petitioner contends that co-registration would not have been required. *Id.* at 17–18. We find Dr. Mabrey's testimony, which is based on his personal use of a similar landmark-based 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 claim 38 does not require co-registration.

Moreover, we agree with Petitioner that the specification of the '158 patent does not disclose any details of co-registration that might be utilized in the claimed methods, nor does the '158 patent suggest that co-registration was beyond the skill level of an ordinarily skilled artisan. Rather, the '158 patent describes that combining different imaging modalities, i.e., co-registration, was "appreciated by those of skill in the art." Ex. 1001, 34:32–37. Additionally, the '158 patent explains that axis information can be obtained by x-ray and "can be combined with a CT or MRI scan of one or more joints." *Id.* at 40:4–10. 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 40:4–27; *see also id.*

[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-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. *See*, *e.g.*, PO Resp. 15, 20, 30; Paper 35, 1.

at 37:63–65. Patent Owner does not cite any portion of the '158 patent that would suggest that specialized co-registration techniques were disclosed.

During the oral argument, Patent Owner relied upon a PCT Publication, WO 02/22014 ("the WO publication," Ex. 1016), cited in the '158 patent specification, as providing the '158 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 ['158] patent." *Id.* at 26:8–14. Counsel argued that although this publication is not explicitly incorporated by reference into the '158 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 '158 patent. *Id.* at 26:15–28:20.

We disagree. The '158 patent refers to the WO publication at the beginning of a section of the specification titled "Imaging Techniques," "Thickness and Curvature." Ex. 1001, 32:1–2 (title), 32:11 (reference to WO publication). That section does not mention co-registration until nearly three columns later, when the '158 patent states that "[a]s will be appreciated by those of skill in the art, imaging techniques can be combined, if desired." *Id.* at 34:32–33. In making this statement, the '158 patent does not reference the WO publication, or any other publication cited within this section of the specification. Moreover, the '158 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.

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 '158 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 image data and x-ray image data, 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(d). *See* 37 C.F.R. § 1.57(c)(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 '158 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 '158 patent.[9] Patent Owner cannot credibly argue that the WO publication provides essential disclosure of co-registration for the clinical application claimed in the '158 patent, while also arguing that the prior art failed to disclose co-registration in a clinical application.

Thus, 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 '158 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 '158 patent claims do not require co-registration. Thus, the majority of Patent Owner's arguments are non-responsive, because they are directed to an element that is not required by the claims.

Turning to Petitioner's contentions, we are persuaded that it would have been obvious to modify CAOS to utilize x-ray image data, as taught by Woolson, to identify a mechanical axis and to orient cutting guides relative to that axis. Pet. 40–41, 53.[10] For example, Woolson explains that conventionally, a preoperative radiograph, i.e., an x-ray, was taken "to

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[9] According to Petitioner, Patent Owner contends that the earliest effective filing date is May 14, 2002. Pet. 18–19. PCT Publication WO 02/22014, which lists a different inventive entity, 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. Ex. 1016, (22), (30), (43), (75).

[10] We do not address Petitioner's contention that this claim is unpatentable over CAOS alone, because this contention was not made in the Petition. Reply 10–11, 14.

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).

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 ¶¶ 112–113; *see also* Ex. 1202 ¶ 35 ("[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 a radiologist would have understood how to co-register first image data "with either topogram x-ray data or conventional x-ray image data." Ex. 1211 ¶ 36; *see also id.* ¶¶ 19–20.

Indeed, Dr. Mabrey testifies that topograms are a *form of* x-ray image data. Ex. 1202 ¶ 34 ("While a CT topogram x-ray and a conventional standing x-ray are produced from different machines (CT scanner vs. classic x-ray machine), both are x-ray image data."). 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 were 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. 34–35, 41–42. However, Petitioner's proposed modification to CAOS does not impact any additional use of topograms. Specifically, Petitioner states that "using x-ray image data in place of topograms *to determine the mechanical axis and orient the cutting paths* relative to this axis would have been obvious." Pet. 40 (emphasis added). The proposed modification does not preclude the continued use of topograms for other purposes, unrelated to axis identification, such as CT planning. *Id.*; *see also* Ex. 1202 ¶¶ 23, 44–45, 47 ("I never proposed replacing a CT topogram x-ray with a conventional standing x-ray image for the purpose of obtaining CT images. Rather, I proposed using a conventional standing x-ray image for the purpose of determining the mechanical axis." (emphasis omitted)); Pet. Reply 22–24. Thus, considering the evidence and arguments of record, we determine that Petitioner has shown that x-ray image data and topograms were known alternatives for use in identifying a mechanical axis.

Finally, we are persuaded that Petitioner's rationale and evidence are sufficient 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. *See, e.g.*, Ex. 1002 ¶¶ 112–113; 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 ¶ 113.

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, co-registration is not needed to perform claim 38. *See, e.g.*, Ex. 1201 ¶¶ 7–9.

As also discussed above, the '158 patent demonstrates that combining images, i.e., co-registration, was known by those skilled in the art. Ex. 1001, 34:32–37. In light of the '158 patent's own disclosure, we find Patent Owner's argument unpersuasive. Moreover, 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. 15, 30; 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* Pet. 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 CT (or MRI) with x-ray image data. Pet. Reply 1, 6–10; *see, e.g.*, *id.* at 7–8 (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.[11] *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-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

[11] 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).

he does not see an advantage to using plain x-ray as opposed to the topogram disclosed by CAOS).

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, as taught by Woolson.

ix. "determining from the x-ray image data . . . an anatomical [or] mechanical axis"

Petitioner contends that the combined teachings of CAOS and Woolson teach that x-ray image data may be used to determine the mechanical axis and to orient cutting paths relative to that axis, as discussed above. Pet. 53 (citing Ex. 1002 ¶ 148); *see also* Sections II.D.4.vii, II.D.5.viii. Petitioner also contends that Woolson uses x-ray image data to determine an anatomical axis. Pet. 46, 53–54.

We are persuaded by Petitioner's contentions for the reasons discussed above in Section II.D.5.viii. Additionally, Woolson uses a preoperative radiograph "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* Ex. 1033, 31.

x. "creating a surgical tool based . . . on the first image data and the x-ray image data"

Petitioner contends that the combined teachings of CAOS, Alexander, and Woolson teach creating a tool from first image data (e.g., CAOS's CT image data) and x-ray image data (taught by Woolson). Pet. 54; *see also* Sections II.D.4.iv–vii, II.D.5.viii–ix.

We are persuaded by Petitioner's contention. CAOS discloses that "templates are customized on the basis of three-dimensional reconstructions . . . extracted from computerized tomographic (CT) image data," and that

topograms are used to identify a mechanical axis. Ex. 1033, 29, 31. Woolson explains that x-ray image data is used to identify a mechanical axis and properly position cutting guides on the instrument. Ex. 1031, 1:37–50. As discussed above in Section II.D.5.viii, we are persuaded that it would have been obvious to a person of ordinary skill in the art to have modified CAOS to utilize x-ray image data instead of topograms to identify a mechanical axis. Consistent with our discussion in Sections II.D.4.iv–vii, and for the same reasons, we are persuaded that it would have been obvious to a person of ordinary skill in the art to create a surgical tool based on the first image data and that x-ray image data.

xi. "guide having a predetermined orientation based at least in part on the determined axis"

Petitioner contends that the combined teachings of CAOS and Woolson teach this limitation by orienting the tool guide such that cuts are made perpendicular to the mechanical axis. Pet. 54; *see also* Sections II.D.4.vii, II.D.5.viii–x.

We are persuaded by Petitioner's contention. CAOS explains that "accurate placement of implant components with respect to the individual mechanical axis of the leg is essential," and that "topograms could be used to identify the bone axis." Ex. 1033, 31. Further, Woolson explains that "the surgeon is able to determine mechanical axes 14, 24 and distances A–J . . . [used] for presetting the cutting guides . . . . Thus, when these cutting guides are placed in position adjacent the bone to be resectioned, precise positioning and alignment are achieved." Ex. 1031, 6:4–15; *see also id*. at 2:28–40, 4:13–26. Consistent with our discussion in Section II.D.4.vii, and for the same reasons, we are persuaded that it would have been obvious to a

person of ordinary skill in the art to orient the guide based at least in part on the determined axis.

6. Analysis of Dependent Claims

Although Patent Owner does not present specific argument regarding any dependent claims, *see generally* PO Resp., it remains Petitioner's burden to demonstrate that the claims are unpatentable. We determine that Petitioner has met its burden.

Claims 2 and 39

Petitioner contends that these claims would have been obvious because CAOS discloses that the first image data is CT or MRI image data. Pet. 39, 57. We are persuaded by Petitioner. CAOS discloses CT and MRI image data. Ex. 1033, 29 (CT), 37 (MRI).

Claim 3

Petitioner contends that this claim would have been obvious because the combined teachings of CAOS and Woolson teach second image data that is x-ray image data. Pet. 40–41. We are persuaded by Petitioner's contention that using x-ray image data instead of topograms would have been obvious to a person of ordinary skill in the art. *See supra* Section II.D.5.viii.

Claims 5–6 and 40–41

Petitioner contends that these claims would have been obvious because a person of ordinary skill in the art would have understood that CAOS's first and second image data is "digital data." Pet. 41, 57. We are persuaded by Petitioner. CAOS discloses that CT image data is "transferred to the personal computer" and, therefore, is "digital data." Ex. 1033, 30, Fig. 1B–1C ("computer assisted planning"). Further, we are persuaded that

a person of ordinary skill in the art would have understood that topograms are digital data. Ex. 1002 ¶ 115; Ex. 1202 ¶ 26.

Claim 7

Petitioner contends that this claim would have been obvious because the combined teachings of CAOS and Woolson teach first image data that is CT and second image data that is x-ray. Pet. 41. We are persuaded by Petitioner. *See supra* Sections II.D.4.ii (CT), II.D.5.viii (x-ray); Ex. 1033, 29 (CT); Ex. 1002 ¶ 116.

Claim 11

Petitioner contends that this claim would have been obvious because a person of ordinary skill in the art would have understood that CAOS's electronic model is derived from first and second image data. Pet. 42. We are persuaded by Petitioner. CAOS explains that the templates are generated from "three-dimensional reconstructions . . . extracted from computerized tomographic (CT) image data," and CAOS's Figures 1B and 1C depict the process of "computer assisted planning" on an electronic model. Ex. 1033, 29, Fig. 1B–1C. CAOS also explains that "[t]he geometry of the cut . . . was planned on the basis of CT images (slices 2-mm thick and 2-mm apart). In addition, topograms could be used to identify the bone axis." Ex. 1033, 31. In light of this evidence, and the testimony of Dr. Mabrey, we are persuaded by Petitioner. Ex. 1002 ¶¶ 117–118 (citing Ex. 1064, 639); *see supra* Section II.D.4.iv.

Claim 12

Petitioner contends that this claim would have been obvious because the combined teachings of CAOS and Woolson teach "aligning the guide relative to the mechanical axis, which is incorporated into the electronic

model." Pet. 42–43. We are persuaded by Petitioner. *See supra* Sections II.D.4.v, II.D.4.vii, II.D.5.xi, II.D.6 (regarding claim 11); Ex. 1002 ¶ 119; Ex. 1033, 29, 31; Ex. 1031, 1:26–36.

Claims 13 and 45

Petitioner contends that these claims would have been obvious because the combined teachings of CAOS and Woolson teach determining a position of an implant. Pet. 43. We are persuaded by Petitioner. *See* Ex. 1033, 31; Ex. 1031, 1:26–36; Ex. 1002 ¶ 120.

Claims 14 and 46

Petitioner contends that these claims would have been obvious because the combined teachings of CAOS and Woolson teach a guide aligned based on the determined position of the implant. Pet. 43, 57. We are persuaded by Petitioner. As discussed above, the combined teachings of CAOS and Woolson align a guide relative to a mechanical axis, and CAOS discloses that it is essential to accurately place the implant with respect to the mechanical axis. *See* Sections II.D.4.vii, II.D.5.xi, II.D.6 (regarding claim 13); Ex. 1002 ¶¶ 121–122.

Claims 19 and 51

Petitioner contends that these claims would have been obvious because CAOS determines a size of an implant. Pet. 43–44, 57. We are persuaded by Petitioner. CAOS states that "mechanical devices corresponding to the intrinsic shape of the implant components are used to guide the osteotomies and bores for the preparation of the [knee] implant's seat." Ex. 1033, 31, 30 (selecting "pedicle screw of the appropriate length and caliber"); Ex. 1002 ¶¶ 123–124; *see also* Ex. 1031, 3:11–14.

Claims 20 and 52

Petitioner contends that these claims would have been obvious because a person of ordinary skill in the art would have understood that CAOS discloses aligning a tool guide based upon an implant's size. Pet. 44, 57. We are persuaded by Petitioner. We credit Dr. Mabrey's testimony that a person of ordinary skill in the art would have understood that CAOS's guide is aligned based on implant size to ensure correct joint preparation. Ex. 1002 ¶¶ 125–127; Ex. 1033, 30, 31.

Claims 21 and 53

Petitioner contends that these claims would have been obvious because CAOS teaches determining a dimension of an implant, for the same reasons discussed with respect to claims 19 and 20. Pet. 45, 57. We are persuaded by Petitioner, for the same reasons set forth above. *See also* Ex. 1002 ¶ 128.

Claims 22 and 54

Petitioner contends that these claims would have been obvious because CAOS teaches aligning a guide based on an implant's dimension, for the same reasons discussed with respect to claim 21. Pet. 45, 57. We are persuaded by Petitioner, for the same reasons set forth above. *See also* Ex. 1002 ¶ 129.

Claim 23

Petitioner contends that this claim would have been obvious because the combined teachings of CAOS and Woolson teach determining a mechanical axis of the joint from second image data, for the same reasons discussed with respect to claim 1. Pet. 45–46. We are persuaded by

Petitioner, for the same reasons set forth above. *See supra* Section II.D.4.ii, vii; Ex. 1002 ¶ 130.

Claim 24

Petitioner contends that this claim would have been obvious because the combined teachings of CAOS and Woolson teach second image data that is x-ray image data, for the same reasons discussed with respect to claim 3. Pet. 46. We are persuaded by Petitioner, for the same reasons set forth above. *See supra* Section II.D.5.viii; Ex. 1002 ¶ 131.

Claim 25

Petitioner contends that this claim would have been obvious because Woolson teaches determining an anatomical axis of the joint from second image data. Pet. 46. We are persuaded by Petitioner. Woolson states that pre-operative radiographs can be used "to determine the angle between the anatomical and the mechanical axes of the femur for proper orientation of the femoral cutting guide." Ex. 1031, 1:37–50; Ex. 1002 ¶¶ 132–134.

Claim 26

Petitioner contends that this claim would have been obvious because the combined teachings of CAOS and Woolson teach second image data that is x-ray image data for the same reasons discussed with respect to claim 3. Pet. 46–47. We are persuaded by Petitioner, for the same reasons set forth above. *See supra* Section II.D.5.viii; Ex. 1002 ¶ 135.

Claims 27–28 and 55–56

Petitioner contends that these claims would have been obvious because CAOS discloses cutting guides and drilling guides. Pet. 47, 57. We are persuaded by Petitioner. CAOS discloses use of "guides for drills,

saws," and contemplates "guide drills and saws in total knee replacement." Ex. 1033, 29, 31; Ex. 1002 ¶¶ 136–137.

Claims 30 and 58

Petitioner contends that these claims would have been obvious because the combined teachings of CAOS and Woolson teach a cutting guide having a slot. Pet. 48–49, 57. We are persuaded by Petitioner. CAOS discloses cutting guides, and Woolson demonstrates that it would have been obvious to utilize slots in known cutting guides. Ex. 1033, 29, 31; Ex. 1031, Figs. 4–5; Ex. 1002 ¶ 138.

Claims 31 and 59

Petitioner contends that these claims would have been obvious because CAOS teaches a guide that is a circular hole. Pet. 49, 57. We are persuaded by Petitioner. CAOS teaches use of "mechanical guides for drills." Ex. 1033, 29, Fig. 1; *see also* Ex. 1031, Fig. 7B; Ex. 1002 ¶ 140.

Claims 33 and 61

Petitioner contends that these claims would have been obvious because CAOS teaches incorporating information regarding a surgical plan, and creating the surgical tool based in part on that information. Pet. 50, 57. We are persuaded by Petitioner. CAOS teaches that the template is customized based on "three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data in accordance with individual preoperative surgical planning." Ex. 1033, 29; Ex. 1002 ¶ 141.

Claims 34 and 62

Petitioner contends that these claims would have been obvious because CAOS teaches that the contact surface and guide may be located on

a single body. Pet. 51, 57. We are persuaded by Petitioner. CAOS teaches that tool guides may be "integrated into the[] individual templates." Ex. 1033, 29, Figs. 1D, 5A–B; Ex. 1002 ¶ 142.

Claims 35 and 63

Petitioner contends that these claims would have been obvious because CAOS teaches that the contact surface and guide are located on first and second components of the tool. Pet. 51–52, 57. We are persuaded by Petitioner. CAOS teaches that a saw guide can be "mounted on" the template, which serves as a "reference base" for work on the bone. Ex. 1033, 31. Thus, the tool and contact surfaces are located on different components of the tool. Ex. 1002 ¶ 143.

Claims 37 and 65

Petitioner contends that these claims would have been obvious because CAOS teaches that the surgical tool includes multiple components. Pet. 52, 57. We are persuaded by Petitioner. CAOS teaches that a saw guide can be "mounted on" the template, which serves as a "reference base" for work on the bone. Ex. 1033, 31. Thus, the tool and contact surfaces are located on different components of the tool. Ex. 1002 ¶¶ 143–144.

E. Obviousness over the Combined Teachings of CAOS, Woolson, Alexander, and Radermacher

Petitioner contends that claims 4, 29, 32, 36, 57, 60, and 64 of the '158 patent are unpatentable as obvious over the combined teachings of CAOS, Woolson, Alexander, and Radermacher. Pet. 57–63. For reasons that follow, we determine Petitioner has demonstrated that challenged claims 4, 29, 32, 36, 57, 60, and 64 are unpatentable by a preponderance of the evidence.

1. Overview of Radermacher

Radermacher is a published PCT Application titled "Template for Treatment Tools and Method for the Treatment of Osseous Structures." Ex. 1003, (54), (57). Radermacher explains that a "split-field device (e.g. a computer or a nuclear spin tomograph)"[12] obtains images of the bone, from which an individual template is created. *Id.* at 10–11, Fig. 18–19. Accordingly, the template "mount[s] on the osseous structure in form-closed manner in exactly one spatially uniquely defined position." *Id.* at (57).

2. Analysis of Dependent Claims 4, 29, 32, 36, 57, 60, and 64

Petitioner contends that CAOS, Woolson, Alexander, and Radermacher would have rendered dependent claims 4, 29, 32, 36, 57, 60, and 64 obvious to a person of ordinary skill in the art. *See* Pet. 57–63.

Patent Owner presents similar arguments as those presented and discussed above with respect to, *inter alia*, claim 38. PO Resp. 21–41. For example, Patent Owner relies upon its position that co-registration is required by the claims, and that it would not have been obvious to co-register the MRI images suggested by CAOS or disclosed by Radermacher with CT topogram or x-ray image data. *Id.* at 39–33, 38–41.

After considering the parties' arguments and evidence, we determine Petitioner has demonstrated that claims 4, 29, 32, 36, 57, 60, and 64 are unpatentable by a preponderance of the evidence.

Claim 4

Petitioner identifies teachings of CAOS, Woolson, and Radermacher that Petitioner contends render obvious claim 4, which requires that the first

[12] Nuclear spin tomography is MRI. Ex. 1002 ¶ 44 n.1.

image data is MRI data and the second image data is x-ray data. Ex. 1001, 119:32–34. Regarding x-ray image data, Petitioner incorporates its prior discussion. *See supra* Section II.D.5.viii. Regarding MRI data, Petitioner contends that CAOS contemplates use of MRI. Pet. 57–58 (citing Ex. 1033, 37 ("It is planned to integrate . . . magnetic resonance image processing modules . . . ."). Thus, according to Petitioner, a person of ordinary skill in the art would have understood that MRI data is an alternative to CT image data. *Id.* at 58. Petitioner also contends that Radermacher discloses using MRI data to make a patient-matched surgical instrument. *Id.* at 58–59. Petitioner contends it would have been obvious to use MRI in CAOS's method because, *inter alia*, this is the substitution of one imaging method for another to obtain predictable results, e.g., a patient-matched instrument, and is a choice from a finite number of identified predictable solutions with a reasonable expectation of success. *Id.* at 59–60 (citing Ex. 1002 ¶¶ 157–160).

We are persuaded by Petitioner's contentions regarding use of x-ray image data for the same reasons discussed with respect to claim 38. *See supra* Section II.D.5.viii. We are also persuaded that it would have been obvious to modify CAOS's method to use MRI data instead of CT data, and that Petitioner's rationale and evidence are sufficient to support this proposed modification. Specifically, Petitioner has identified teachings in both CAOS and Radermacher disclosing use (or contemplated use) of MRI for this purpose. Ex. 1033, 37; Ex. 1003, 10–11, Figs. 18–19. We credit Dr. Mabrey's testimony (Ex. 1002 ¶ 158) that CT and MRI are known alternatives, wherein that testimony is supported by CAOS's suggestion that MRI be used in the future (Ex. 1033, 10) and by Radermacher's disclosure

that either CT or MRI may be used to obtain joint images (Ex. 1003, 10, Figs. 18–19). This evidence supports Petitioner's contention that use of MRI data would have been a known substitution of one imaging technique for another to obtain the predictable result of obtaining a joint image. *See* Ex. 1002 ¶ 159.

As discussed above, we have considered Patent Owner's co-registration arguments, but we are not persuaded that the claims require co-registration or that co-registration would have been beyond the capabilities of an ordinarily skilled artisan. *See supra* Section II.D.5.viii.

Moreover, we are 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. 26. This argument is unavailing because Patent Owner ignores the fact that CAOS itself *expressly suggests* this modification. CAOS states: "It is planned to integrate additional tools into the system (in particular for hip, knee, and spine surgery), *magnetic resonance image processing modules* and enhanced models for efficient biomechanical analysis." Ex. 1033, 37 (emphasis added).

Patent Owner's argument that "MRI and CT images are each part of an integrated image data set and are not simply interchangeable with one another" is unpersuasive. PO Resp. 29, 38–42. Similar to Patent Owner's CT arguments addressed above, Petitioner's proposal 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. 58–60; Ex. 1202 ¶ 44 ("[T]o 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." (emphasis omitted)). Dr. Mabrey explained that

> using 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.

Ex. 1202 ¶ 42.

Similar to our discussion above, we are unpersuaded by Patent Owner's argument that Petitioner fails to explain how to reconcile differences between, e.g., x-ray images and MRI images. PO Resp. 30–31. Claim 4 does not require co-registration. Moreover, Petitioner relies upon Dr. Mabrey's testimony and contends 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 MRI image," for use in creating a tool. Pet. Reply 17 (citing Ex. 1202 ¶¶ 7–9, 40; Ex. 1211 ¶ 21; Ex. 1210, 37:11–41:19). 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.

For the foregoing reasons, we determine that Petitioner has demonstrated claim 4 to be unpatentable, by a preponderance of the evidence.

Claims 29 and 57

Petitioner contends that the combined teachings of CAOS and Radermacher teach a guide with a linkage for attaching a separate

component, because CAOS discloses a copying cam mounted on a saw guide and Radermacher discloses tool guides with engagement points for attaching additional components. Pet. 60–61 (citing Ex. 1033, 31; Ex. 1003, 11, 25–26, 30; Ex. 1002 ¶ 161). Patent Owner does not provide separate argument regarding these claims. *See generally* PO Resp.

We are persuaded by Petitioner's contention that a person of ordinary skill in the art would have found it obvious to modify CAOS's tool to include a guide with a linkage, as taught by Radermacher, which would permit optional use of complimentary additional devices. Ex. 1001 ¶ 161; Ex. 1003, 11, 26.

Claims 32 and 60

Petitioner contends that the combined teachings of CAOS and Radermacher teach that the guide is a connector having an orientation to provide a predetermined alignment of a separate cutting or drilling guide when connected to the connector, because, e.g., it was standard practice to use alignment guides with connectors for aligning cutting guides, as taught by Radermacher. Pet. 61–62 (citing Ex. 1002 ¶¶ 164–166; Ex. 1003, 30, 26, Fig. 13a–b). Patent Owner does not provide separate argument regarding these claims. *See generally* PO Resp.

We are persuaded by Petitioner's contention that a person of ordinary skill in the art would have found it obvious to modify CAOS's tool to include a connector that provides alignment of a separate cutting or drilling guide, as taught by Radermacher, and known in the art. Ex. 1002 ¶¶ 164–166; Ex. 1003, 30, 26, Fig. 13a–b.

Claims 36 and 64

Petitioner contends that CAOS discloses that the individual template includes a linkage to connect to additional components, because CAOS explains that standard surgical tool guides may be attached to the template. Pet. 63 (citing Ex. 1033, 29, 31; Ex. 1002 ¶ 167). Petitioner also contends that this would have been obvious in view of Radermacher's disclosure of tool guides with engagement points. *Id.* (citing Ex. 1003, 26, 30; Ex. 1002 ¶ 168).

We are persuaded by Petitioner's contention that a person of ordinary skill in the art would have found it obvious to modify CAOS's tool to include a linkage, as taught by Radermacher, which would permit optional use of complimentary additional devices. Ex. 1002 ¶¶ 167–168; Ex. 1003, 11, 26, 30.

F. Obviousness over the Combined Teachings of CAOS, Woolson, Alexander, and Chao

Petitioner contends that claims 8–10 and 42–44 of the '158 patent are unpatentable as obvious over the combined teachings of CAOS, Woolson, Alexander, and Chao. Pet. 63–65. For reasons that follow, we determine Petitioner has demonstrated that challenged claims 8–10 and 42–44 are unpatentable by a preponderance of the evidence.

1. Overview of Chao (Ex. 1084)

Chao is a paper titled "Computer-Aided Preoperative Planning in Knee Osteotomy." Ex. 1084, 4. Chao explains that "accurate modeling and analysis of the involved system based on the patient's 2D (radiographic) imaging data can offer significant information for operative planning to optimize treatment results." *Id.* at 6. Chao refers to previously reported use

of "full-length standing plain radiographs" and "weight bearing radiographs" to identify axes of the bone. *Id.* at 6, 10.

2. Analysis of Dependent Claims 8–10 and 42–44

Petitioner contends that CAOS as modified by Woolson, Alexander, and Chao render obvious claims 8–10 and 42–44, which require that x-ray image data is: taken from a standing or weight-bearing x-ray (claims 8, 42), includes the hip and ankle joint (claims 9, 43), or is obtained in a weight-bearing position (claims 10, 44). Pet. 63–65. Petitioner incorporates its previous discussion of x-ray image data, and further contends that Chao discloses the use of standard, weight-bearing x-rays. *Id.* at 63–64. Petitioner contends that a person of ordinary skill in the art would have been motivated to modify CAOS as modified by Woolson to utilize weight-bearing x-rays, as taught by Chao, because the references are directed to similar methods of treating damaged joints, in the same field of endeavor, and utilize similar imaging technology. *Id.* at 64 (citing, e.g., Ex. 1002 ¶ 172).

Patent Owner does not provide separate argument regarding these claims, other than to argue that Chao does not cure alleged deficiencies in Petitioner's contentions regarding CAOS, Alexander, and Woolson. *See* PO Resp. 43.

We are persuaded by Petitioner's contentions. We are persuaded that a person of ordinary skill in the art would have found it obvious to use standing and weight-bearing x-rays of the lower extremity, as taught by Chao, to obtain reliable information about the mechanical axis of the bone. *See, e.g.*, Ex. 1002 ¶ 172; Ex. 1084, 6 (explaining that prior publications "have reported using full-length standing plain radiographs of the lower

extremity for the measurement of mechanical axial alignment for preoperative planning of knee osteotomies. Use of the mechanical axis description of alignment is reported to be more reliable than the anatomic description"), 10.

G. Obviousness over the Combined Teachings of CAOS, Woolson, Alexander, and Arima

Petitioner contends that claims 15–18 and 47–50 of the '158 patent are unpatentable as obvious over the combined teachings of CAOS, Woolson, Alexander, and Arima. Pet. 65–75. For reasons that follow, we determine Petitioner has demonstrated that challenged claims 15–18 and 47–50 are unpatentable by a preponderance of the evidence.

1. Overview of Arima

Arima is a paper titled "Femoral Rotational Alignment, Based on the Anteroposterior Axis, in Total Knee Arthoplasty in a Valgus Knee." Ex. 1085, 1331. Because the "landmarks used to achieve correct rotational alignment of the femoral component in total knee arthroplasty may be indistinguishable or unreliable in the distal architecture of a valgus knee," as compared with a normal knee, Arima reviews thirty cadaveric specimens to determine the reliability of the anteroposterior axis, posterior condylar axis, and transepicondylar axis when operating on a valgus knee. *Id.* Arima discloses that the anteroposterior axis is the most useful landmark to determine rotational alignment of a femoral component in a valgus knee. *Id.*

2. Analysis of Dependent Claims 15–18 and 47–50

Petitioner contends that CAOS as modified by Woolson, Alexander, and Arima render obvious claims 15–18 and 47–50, each of which requires determining a position of an implant (in claims 18 and 50, a "rotational

position") based at least in part on an epicondylar axis (claims 15, 47), an anteroposterior axis (claims 16, 48), or a posterior condylar axis of the joint (claims 17, 49), where the guide is aligned based on the determined position. Petitioner contends that reliance upon these axes was well known, and that these axes could be used as a reference for aligning the cutting paths and to position an implant. Pet. 66–67, 70–71, 72. Petitioner also contends that Arima discloses making cuts in relation to these axes. *Id.* at 67, 71, 72–73 (citing Ex. 1085, 1331–1334). Petitioner argues that Arima discloses using these axes to position an implant and align the cutting paths in order "to achieve correct rotational alignment" of the implant. *Id.* at 74 (citing Ex. 1085, 1331–1334). Accordingly, Petitioner contends that a person of ordinary skill in the art would have been motivated to use these axes as a reference axis to correctly position an implant on the knee joint because, *inter alia*, this would be a simple substitution of one known reference axis for another, to obtain the predictable result of properly reconstructing the knee joint. *Id.* at 67–68, 70, 72 (citing, e.g., Ex. 1002 ¶¶ 180, 186, 190).

Patent Owner does not provide separate argument regarding these claims, other than to argue that Arima does not cure alleged deficiencies in Petitioner's contentions regarding CAOS, Alexander, and Woolson. *See* PO Resp. 43–44.

We are persuaded by Petitioner's contentions. Arima discloses that the anteroposterior axis is reliable landmark for rotational alignment in a valgus knee, the posterior aspects of the femoral condyles are reliable landmarks for rotational alignment in a normal knee, and a transepicondylar axis may be used as a (less reliable) landmark for rotational alignment in the knee. *See* Ex. 1085, 1331. Additionally, Arima's Figure 3 depicts resection

relative to anteroposterior, epicondylar, and posterior condylar axes. *Id.* at 1332. Accordingly, we are persuaded that a person of ordinary skill in the art would have been motivated to use any of these axes in determining an appropriate rotational position of the implant because this would be a simple substitution of one known reference axis for another, to obtain the predictable result of properly reconstructing the implant within the knee joint. *See* Ex. 1002 ¶¶ 180, 186, 190.

H. 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 1–65 of the '158 patent are unpatentable by a preponderance of the evidence.

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 1–65 of the '158 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.

PETITIONER:

Christy Lea
Joseph Re
Colin Heideman
Benjamin Anger
KNOBBE, MARTENS, OLSON & BEAR LLP
2cgl@knobbe.com
2jrr@knobbe.com
2cbh@knobbe.com
2bba@knobbe.com

PATENT OWNER:

Sanya Sukduang
Timothy McAnulty
Daniel Klodowski
Kassandra Officer
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
sanya.sukduang@finnegan.com
timothy.mcanulty@finnegan.com
daniel.klodowski@finnegan.com
kassandra.officer@finnegan.com