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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 IPR2017-00511
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 66–81 ("the challenged claims") of U.S. Patent No. 7,981,158 (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 66–72 and 81, pursuant to 35 U.S.C. § 314. Paper 9 ("Dec. on Inst.").[1]

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 two 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 IPR2017-00373, and a transcript of the hearing is included in the record. Paper 41 ("Tr.").

[1] Pursuant to the U.S. Supreme Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018), we issued an Order modifying our Decision on Institution to include the challenge to claims 73–80, for which we originally denied institution. Paper 42. However, the parties filed—and we granted—a joint motion to limit the Petition to only the challenge to claims 66–72 and 81. Papers 44, 45. Accordingly, we do not treat claims 73–80 in this Decision.

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 66–72 and 81 are unpatentable.

B. Related Proceedings

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.

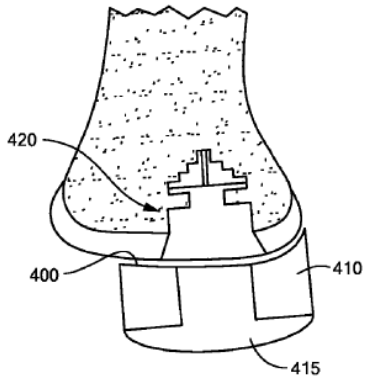

FIG. 22

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.[2] 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 are identified by, e.g., CT, MRI, or CT scout scans. *Id.* at 77:1–10.

D. Illustrative Claims

Challenged claims 66, 69, 72, and 81 are independent. Independent claim 66 is illustrative and is reproduced below.

> 66. 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 first and second image data sets,
>
> wherein the first image data set is of a type that is different from the second image data set, and the second image data set is x-ray image data;
>
> wherein the surgical instrument has a patient-specific surface that is derived from at least the first image data and that

[2] 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.

> 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, 122:9–24.

E. Applied References

Petitioner relies upon the following references:

> 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); and
>
> 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).

Pet. 21.

Petitioner also relies upon the Declaration of Jay D. Mabrey, M.D. ("the Mabrey Declaration," Ex. 1102), 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 ground (Pet. 21; Dec. on Inst. 27; *see supra* n.1):

References	Basis	Claims Challenged
CAOS, Woolson, and Alexander	§ 103	66–72 and 81

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 the Petition, Petitioner stated that no terms required construction; however, Petitioner provided a construction of "articular surface of [a] joint," which appears in independent claim 81. Pet. 20. Accordingly, we determined it prudent to construe this phrase, as well as similar language in claims 66, 69, and 72 ("surface portion associated with the joint," "surface contours of at least a portion of a surface of or near a joint"). Dec. on Inst. 5–7. In their post-institution papers, neither party addresses our construction of these terms.

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 with 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. 1102 ¶ 36; *see also id.* ¶¶ 68–71 (asserting "to a person of ordinary skill, the broadest reasonable interpretation of 'articular joint surface' in light of the specification is 'the bone surface and/or cartilage surface of an articulating portion of a joint'), ¶ 113 (asserting "a person of ordinary skill in the art would have understood that 'a corresponding surface portion associated with the joint' recited in Claim 66 includes bone surface, particularly when the cartilage is worn out").

Accordingly, we maintain our constructions of these phrases 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.[3] *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).

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

[3] Patent Owner does not provide evidence regarding secondary considerations. *See generally* PO Resp.; *see also* Pet. 75.

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. 20 (citing Ex. 1102 ¶¶ 29–31). Dr. Mabrey bases his opinion on his experience as a surgeon in the 1990/2000 timeframe. Ex. 1102 ¶ 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. PO Resp. 17.

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. 18–20. Moreover, Dr. Mabrey's experience aligns with our assessment of the appropriate skill level. *See* Ex. 1102 ¶¶ 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 66–72 and 81 of the '158 patent are unpatentable as obvious over the combined teachings of CAOS, Woolson, and Alexander. Pet. 22–56. 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 66

Petitioner contends that the combined teachings of CAOS, Woolson, and Alexander would have rendered claim 66 obvious to a person of ordinary skill in the art. *See* Pet. 23–43.

Patent Owner contends that claim 66 would not have been obvious. PO Resp. 20–42.[4] For example, Patent Owner contends that it would not have been obvious to replace CAOS's CT topogram with Woolson's x-ray images because such a modification "would make obtaining CT . . . images technically infeasible" and would be "[n]onsensical." *Id.* at 23, 31 (emphasis omitted).

After considering the parties' arguments and evidence, we determine Petitioner has demonstrated that claim 66 is unpatentable by a preponderance of the evidence.

i. Preamble

Independent claim 66 recites "A method of creating a patient-specific instrument for implanting an orthopedic implant in or about a joint of a patient." Ex. 1001, 122:9–11. 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 and are used for orthopedic surgery. *See, e.g.*, Pet. 36–37 (citing, e.g., Ex. 1033, 28–31; Ex. 1102 ¶¶ 82–83).

[4] Patent Owner presents consolidated arguments for claims 66–71 and 81. PO Resp. 20.

We are persuaded by Petitioner's contention. CAOS explains that a three-dimensional printer creates an "individual template" for use in surgery 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, 30 (discussing implanting an orthopedic implant); Ex. 1102 ¶¶ 82–83.

ii. "creating a patient-specific instrument based . . . on first and second image data sets"

Independent claim 66 recites "creating a patient-specific surgical instrument based at least in part on first and second image data sets." Ex. 1001, 122:12–13. Petitioner contends that CAOS discloses utilizing CT image data—a "first image data set"—to create an individual template that fits exactly against the bone, wherein the template includes a tool guide. Pet. 23–25, 37–39 (citing, e.g., Ex. 1033, 28–31; Ex. 1102 ¶¶ 85–89).

We are persuaded by Petitioner's contention. CAOS explains that "[i]ndividual templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data." Ex. 1033, 29; Ex. 1102 ¶ 85.

Petitioner also contends that CAOS teaches using topograms—a "second image data set"—to identify the bone's mechanical axis and to position the template and tool guide accordingly. Pet. 25–26, 37–39 (citing Ex. 1033, 29, 31; Ex. 1102 ¶¶ 90–95). Further, Petitioner contends that Woolson discloses orienting tool guides based on x-ray or CT image data—also an "image data set"—to align a cutting path relative to a mechanical axis, to ensure long term surgical success. Pet. 28–29, 39–40 (citing, e.g., Ex. 1031, Abstract, 1:27–57, 2:50–59, 4:7–26; Ex. 1102 ¶¶ 98–102).

Accordingly, Petitioner contends that the combined teachings of CAOS and Woolson teach the step of creating an instrument based on a first image data set (CT data, taught by CAOS) and a second image data set (topogram data, taught by CAOS, or x-ray or CT data, taught by Woolson). *Id.* at 29–30; Ex. 1102 ¶ 84. Petitioner also contends that it would have been obvious to modify CAOS to use image data to align cuts relative to a mechanical axis of the bone, as taught by Woolson, to ensure long-term surgical success. *Id.* at 29 (citing Ex. 1031, 1:26–36; Ex. 1102 ¶ 103). Petitioner argues that this modification would have been use of a known technique to improve a similar procedure in a predicable way. *Id.* at 29–30.

We are persuaded by Petitioner's contentions. In addition to the first image data discussed above (CT image data), CAOS also teaches that "topograms [second image data] could be used to identify the bone axis." Ex. 1033, 31; Ex. 1102 ¶¶ 90–92. Although CAOS does not state explicitly that the axis identified by the topogram is used to create the patient-specific template, e.g., to position the template relative to the contact surface, Petitioner has shown that Woolson teaches using x-ray or CT image data to align surgical cuts relative to a mechanical axis. Ex. 1031, 1:27–57, 2:28–59, 4:13–26; Ex. 1102 ¶ 92. For example, Woolson teaches that prior art systems used a "preoperative radiograph of the femur in order to determine the angle between the anatomical and the mechanical axes of the femur for proper orientation of the femoral cutting guide," such that "[t]he proximal tibia is cut perpendicular to the mechanical axis of the tibia by adjusting the tibial cutting guide in relation to the knee and ankle joints." *Id.* at 1:41–58; Ex. 1102 ¶¶ 92–104.

Petitioner's rationale and evidence establish that the proposed modification to CAOS' surgical technique would have been obvious to a person of ordinary skill in the art, because the proposed modification would have been expected to provide a more successful surgery, as taught by Woolson. Pet. 29–30; Ex. 1031, 1:26–36 ("[A]ll total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis . . . . [T]his results in the placement of the total knee prostheses in a common mechanical axis which correspondingly is highly likely to produce a successful long-term result."), 2:28–40; Ex. 1102 ¶¶ 102–104. Moreover, we are persuaded that using, in CAOS's method, second image data to determine the proper orientation of a patient-specific surgical instrument's guide relative to a mechanical axis is merely the use of 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. Ex. 1102 ¶ 103.

iii. "x-ray image data" and "different" types of image data

Independent claim 66 also recites that "the second image data set is x-ray image data," and "the first image data set is of a type that is different from the second image data set." Ex. 1001, 122:14–16.

Petitioner contends that it would have been obvious to use "x-ray imaging in place of [CAOS'] topograms" because topograms "are similar to two-dimensional CT scout images [and] are an alternative to x-ray image data." Pet. 30 (citing Ex. 1102 ¶ 105), 41–42. Petitioner also contends that Woolson discloses using x-ray image data to determine a mechanical axis and to orient cutting paths relative to that axis. *Id.* at 30 (citing, e.g.,

Ex. 1031, Abstract, 1:26–50, 2:28–59, 6:5–7:67; Ex. 1102 ¶ 106). Therefore, according to Petitioner, "it would have been obvious to modify CAOS to use x-ray image data in place of topograms," because this would be a "'simple substitution of one known element for another.'" *Id.* at 30–31 (citing Ex. 1102 ¶ 106; quoting *KSR*, 550 U.S. at 417).

In the Response, Patent Owner argues that a person of ordinary skill in the art would have recognized that CAOS's method was successful because its two data sets—CT images and CT topograms—are "intrinsically co-registered." PO Resp. 2, 15, 23, 25. 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 14. 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 15 (citing Ex. 2003 ¶ 27; Ex. 1060, 6:34–46), 33. 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 be "difficult, time-consuming, and often inaccurate." *See id.* at 23–25, 28–31.

Patent Owner also contends that "Petitioner provides insufficient reasons for completely deviating from CAOS's successful method," and that Petitioner does not identify shortcomings in CAOS's method or improvements that would have motivated the proposed modification. PO Resp. 24–28. 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." *Id.* at 28 (citing Ex. 2003 ¶¶ 25–26, 59; Ex. 2005 ¶¶ 62–64, 66–71; Ex. 2022, 69:19–70:2).

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 28–31 (citing, e.g., 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 ¶¶ 28–29, 59–61).

Further, Patent Owner contends that the proposed modification is impractical. PO Resp. 31. 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 33. 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 34.

In its 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 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 66 does not require steps of co-registering the claimed first image data set and x-ray image data. First, we consider the claim language. Claim 66 does not require that the "first image data set" and the "x-ray image data" be co-registered, or combined, in any manner. Ex. 1001, 122:9–24. 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 a method of creating a surgical instrument that is based in part on first image data and x-ray image data, wherein the instrument includes a patient-specific surface derived from the first image data, and includes a guide that is oriented relative to the patient-specific surface of the instrument based on information derived from the x-ray image data. Ex. 1001, 122:9–24. 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 set and the x-ray image data be co-registered, in order to create the instrument or orient the guide.[5]

For example, Petitioner relies upon Dr. Mabrey's testimony and contends that "it would have been obvious to a POSITA . . . to identify the

[5] 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.

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 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.[6] 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 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 66 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-

[6] We are not persuaded that this discussion, or the cited declarant testimony, is made improperly in the 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. 19, 28; Paper 35, 1.

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.* 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(c). *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.[7] 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.

[7] 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).

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. 30, 41–42.[8] 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. 1102 ¶¶ 105–106; *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]

[8] 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.

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 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. 11–12, 13–14, 33–34. However, Petitioner's proposed modification to CAOS does not impact any additional use of topograms. Specifically, Petitioner proposes modifying CAOS such that x-rays are used instead of topograms "to identify this essential [mechanical] axis" and "to specify the positioning and orientation of surgical tool guides." Pet. 25, 30–31. 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. 1102 ¶¶ 105–106; 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. 1102 ¶ 106.

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 66. *See, e.g.*, Ex. 1202 ¶¶ 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. 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* 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 with x-ray image data. Pet. Reply 1, 6–10; *see, e.g.*, *id.* at 7–8 (citing Exs. 1213–1216, 1014, 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.[9] *See also* Ex. 2029,

[9] 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

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 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.

Petitioner also contends that the image data sets discussed above are different, as required by claim 66, because CAOS's CT image data (first image data set) is different from Woolson's x-ray image data (second image data set). Pet. 31, 41–42 (citing, e.g., Ex. 1102 ¶¶ 107–109). We are persuaded by Petitioner. For example, CT image data is three-dimensional data, while x-ray is two-dimensional. *See, e.g.*, Ex. 1102 ¶ 107; *see also id.* ¶¶ 108–112; *compare* PO Resp. 9 ("X-ray imaging uses radiation to capture a single two-dimensional projection image representing a shadow or summation of the patient's anatomy."), *with id.* at 10 ("CT imaging uses radiation to produce images of a patient's anatomy. . . . CT imaging produces a series of two-dimensional cross-sectional slices . . . [that] may be reformatted into a three-dimensional CT image.").

(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).

iv. "a patient-specific surface"

Claim 66 also recites "wherein the surgical instrument has a patient-specific surface that is derived from at least the first image data and that substantially matches a corresponding surface portion associated with the joint." Ex. 1001, 122:18–21. Petitioner contends that CAOS's instrument includes a patient-specific surface that is derived from the first image data and substantially matches a corresponding surface portion of the patient's joint, as required by claim 66, because CAOS discloses customizing templates based on three-dimensional reconstructions obtained from CT data so they fit exactly against the bone. Pet. 33, 42–43 (citing, e.g., Ex. 1033, 29; Ex. 1102 ¶¶ 113–114). Petitioner also contends that "[e]ven if ConforMIS attempts to argue that substantially matching the corresponding surface [portion] of the joint requires matching the cartilage surface, this would have been obvious" in light of Alexander's discussion of using CT or MRI to generate images of cartilage. *Id.* at 33–34 (citing Ex. 1102 ¶¶ 115–118; 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 instrument would include a patient-specific surface substantially matched to a corresponding surface portion associated with the joint, whether that 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 CAOS's tool could be matched, wherein selection between them is simply a design choice. *Id.* at 34–35 (citing Ex. 1102 ¶¶ 116–117), 36–37, 42–43.

We are persuaded by Petitioner's contentions. As discussed in Section II.A, *supra*, we construe "surface portion associated with 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; Ex. 1102 ¶¶ 113–114. 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's methods, because bone and cartilage are the only two surfaces to which CAOS's tool could be matched. Pet. 34–35; Ex. 1102 ¶¶ 115–117 (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. 1102 ¶¶ 89–90.

v. "a guide"

Claim 66 also recites "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, 122:22–24. Petitioner contends that CAOS discloses that the customized template includes a guide, as required by claim 66, because CAOS discloses a tool guide for directing a saw or drill. Pet. 35, 42–43 (citing, e.g., Ex. 1033, 29–31). Petitioner also contends that this CAOS discloses that the "position and orientation of the tool guide in spatial relation to the bone . . . can be reproduced in situ adjusting the position of the contact faces of the template until they fit exactly on the bone." Pet. 35–36 (citing Ex. 1033, 29; Ex. 1102 ¶¶ 119–120). Further, Petitioner contends that the combined teachings of CAOS and Woolson orient a tool guide relative to a mechanical axis based on x-ray image data. *Id.* at 36; *see also* Ex. 1031, 1:26–57. According to Petitioner, "[b]ecause CAOS's instrument includes a patient-specific surface that exactly reproduces the knee joint surface, the instrument incorporates the position of the mechanical axis. Thus, [this limitation] would have been obvious." Pet. 36 (citing Ex. 1102 ¶¶ 94, 119–120).

We are persuaded by Petitioner's contentions. CAOS discloses that "[m]echanical guides for drills, saws, chisels, or milling tools are adaptable or integrated into these individual templates." Ex. 1033, 29. CAOS also discloses that the guide may be oriented by adjusting the position of the template on the bone. *Id.* Although CAOS does not state explicitly that its topogram (i.e., a second image data set) is used to position the template's guide relative to the contact surface, Petitioner has shown that the combined teachings of CAOS and Woolson teach aligning planned cuts with respect to

a mechanical axis identified by x-ray image data, such that this limitation would have been obvious. For example, as discussed in Section II.D.4.iii, 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. 30, 41–42; Ex. 1031, 1:46–50, 4:13–44, 5:9–16, 7:62–67.

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 x-ray image date to orient CAOS's template (and its guide) relative to the patient-specific surface and mechanical axis of the bone, as taught by Woolson, for the stated purpose of providing a more successful surgery. Pet. 30, 32–33, 35–36, 41–42; Ex. 1031, 1:26–36, 2:28–40; Ex. 1102 ¶ 101 ("This would ensure the accurate alignment of the knee prosthesis with the mechanical axis, which both Woolson and CAOS recognize is essential."), ¶ 103 ("[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 procedure (Woolson's) to improve a similar knee arthroplasty procedure (CAOS's) in the same predictable way."), ¶¶ 119–122. Additionally, we are persuaded that Petitioner's proposed modification is a simple substitution of one known imaging technique for another to obtain the predictable result of obtaining an image of the joint. *See supra* Section II.D.4.iii.

5. Analysis of Independent Claim 69

Independent claim 69 is nearly identical to independent claim 66, "except that Claim 69 recites 'designing' rather than 'creating' a patient-

specific surgical instrument." *See* Pet; *compare* Ex. 1001, 122:9–24, *with id.* at 122: 30–44. Patent Owner presents identical arguments to those presented with respect to claim 66. *See* PO Resp. 20–40.

After considering the parties' arguments and evidence, we determine Petitioner has demonstrated that claim 69 is unpatentable by a preponderance of the evidence, for the same reasons articulated above with respect to claim 66. *See supra* Section II.D.4; Ex. 1102 ¶ 130.

6. Analysis of Independent Claim 72

Independent claim 72 is similar to independent claim 66, except that claim 72 varies from claim 66 in the following ways:

> (1) "surface contours" (rather than "surface portion") of the joint are determined from the first image data set; (2) the joint axis is determined from the second image data set; and (3) the guide is oriented relative to the patient-specific surface based on the joint axis. Unlike Claim 66, Claim 72 does not require the second image data set to be x-ray image data or the first image data set to be of a type that is different from the second image data set.

Pet. 45–46; *compare* Ex. 1001, 122:9–24, *with id.* at 122:50–63.

Patent Owner incorporates arguments made with respect to claims 66–71, however, those arguments are not responsive to the Petition's contentions because, *inter alia*, for this claim, Petitioner does not propose modifying CAOS to substitute x-ray image data for topogram image data. PO Resp. 42; Pet. 45–51; Pet. Reply 1 n.1 ("The Board also instituted on claim 72, which does not require x-ray image data. ConforMIS makes no separate patentability argument regarding claim 72.").

After considering the parties' arguments and evidence, we determine Petitioner has demonstrated that claim 72 is unpatentable by a

preponderance of the evidence, for the same reasons articulated above with respect to claim 1.

For example, claim 72 recites, "A patient specific surgical instrument for use in implanting an orthopedic implant in a patient."[10] Ex. 1001, 122:50–52. We are persuaded by Petitioner's contentions with respect to the subject matter recited in the preamble. Pet. 49; *see supra* Section II.D.4.i; Ex. 1033, 28.

Claim 72 also recites "determining at least in part from a first set of image data the surface contours of at least a portion of a surface of or near a joint of the patient." Ex. 1001, 122:53–55. We are persuaded by Petitioner's contentions with respect to this limitation. Pet. 46–47, 49–50; *see supra* Section II.D.4.ii, iv. CAOS explains that "[i]ndividual templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data," wherein CT image data is a "first set of image data." Ex. 1033, 29; Ex. 1102 ¶¶ 136–137.

Claim 72 also recites "determining at least in part from a second set of image data an axis associated with the joint." Ex. 1001, 122:56–57. We are persuaded by Petitioner's contentions with respect to this limitation. Pet. 47–48, 50. Specifically, CAOS discloses that "topograms could be used

[10] The preamble of claim 72 recites a "patient specific surgical instrument"—an apparatus—yet proceeds to further recite "the process comprising . . . [a series of method steps]." Ex. 1001, 122:50–52. As discussed herein, the Petition establishes that the prior art satisfies each claim limitation, as written and reasonably broadly construed. Pet. 45–51; *see also* 37 C.F.R. § 42.104(b)(2).

to identify the bone axis." Ex. 1033, 31; *see also supra* Section II.D.4.iii; Ex. 1031, 1:37–57, 5:9–14, 6:4–15; Ex. 1102 ¶¶ 139–140.

Claim 72 also recites "incorporating a patient-specific surface into the surgical instrument such that the patient-specific surface substantially matches the determined surface contours." Ex. 1001, 122:58–60. We are persuaded by Petitioner's contentions with respect to this limitation. Pet. 50. As discussed above in Section II.D.4.iv, we are persuaded that CAOS, or the combined teachings of CAOS and Alexander, teach that the template substantially matches a corresponding surface portion associated with the joint, i.e., "surface contours of at least a portion of a surface of or near a joint," whether that portion includes bone and/or cartilage. Ex. 1033, 28, 29, 31 (knee joint), Figs. 1B–1C; Ex. 1004, 14, 61; Ex. 1102 ¶¶ 135–138.

Claim 72 also recites "incorporating a guide into the surgical instrument, wherein the guide is oriented relative to the patient-specific surface based at least in part on the determined axis." Ex. 1001, 122:61–63. We are persuaded by Petitioner's contentions with respect to this limitation. Pet. 48, 50–51. As discussed in Section II.D.4.v, CAOS discloses adjusting the orientation of the tool guide relative to the bone. Ex. 1033, 29. Further, the combined teachings of CAOS and Woolson would have rendered it obvious to orient the position of planned cuts with respect to a mechanical axis. Ex. 1031, 1:26–57, 2:28–40, 4:13–26; Ex. 1033, 29, 31; Ex. 1102 ¶¶ 141–142.

7. Analysis of Independent Claim 81

Independent claim 81 is similar to independent claim 66, except that claim 81 varies from claim 66 in the following ways:

> (1) information about the desired alignment or correction of the joint is determined from x-ray image data; (2) the contact surface is substantially matched to the articular joint surface; and (3) the guide is oriented based on information about the desired alignment or correction of the joint.

Pet. 51; *compare* Ex. 1001, 122:9–24, *with id.* at 124:7–22. Patent Owner presents identical arguments to those presented with respect to claim 66. *See* PO Resp. 20–40.

After considering the parties' arguments and evidence, we determine Petitioner has demonstrated that claim 81 is unpatentable by a preponderance of the evidence, for substantially the same reasons articulated above with respect to claim 66. *See supra* Section II.D.4.

For example, claim 81 recites "[a] method of making a patient-matched surgical tool." Ex. 1001, 124:7–8. We are persuaded by Petitioner's contentions with respect to the subject matter recited in the preamble. Pet. 54; *see supra* Section II.D.4.i; Ex. 1033, 28.

Claim 81 also recites "obtaining first image data associated with at least a portion of a joint of a patient." Ex. 1001, 124:9–10. We are persuaded by Petitioner's contentions with respect to this limitation. Pet. 55; *see supra* Section II.D.4.ii; Ex. 1033, 29, 31 (knee joint), Figs. 1B–1C.

Claim 81 also recites "obtaining x-ray image data associated with at least a portion of the joint." Ex. 1001, 124:11–12. We are persuaded by Petitioner's contentions with respect to this limitation. Pet. 55; *see supra* Section II.D.4.iii; Ex. 1031, 1:26–58.

Claim 81 also recites "determining from the x-ray image data information about a desired alignment or correction of the joint." Ex. 1001, 124:13–14. We are persuaded by Petitioner's contentions with respect to

this limitation. Pet. 51–52, 55; *see supra* Section II.D.5.ii–iii; Ex. 1031, 1:26–58 (explaining that "all total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis" and such an axis can be determined using x-ray image data); Ex. 1033, 31 (using topograms to identify mechanical axis); Ex. 1102 ¶¶ 145–146.

Claim 81 also recites "creating a surgical tool based at least in part on the first image data and the x-ray image data." Ex. 1001, 124:15–16. We are persuaded by Petitioner's contentions with respect to this limitation. Pet. 55; *see supra* Section II.D.4.ii–iii; Ex. 1033, 29, 31, Figs. 1B–1C; Ex. 1031, 1:27–58, 2:28–59, 4:13–26; Ex. 1102 ¶¶ 105–109; Ex. 2001 ¶¶ 15, 17, 25 n.3.

Claim 81 also recites "wherein the surgical tool includes a contact surface substantially matched to a corresponding articular surface of the joint." Ex. 1001, 124:17–19. We are persuaded by Petitioner's contentions with respect to this limitation. Pet. 53–54, 55–56; *see supra* Sections II.D.4.vi, II.D.5.x; Ex. 1033, 29, 31; Ex. 1004, 61; Ex. 1102 ¶ 147.

Claim 81 also recites "wherein the surgical tool includes . . . a guide for directing movement of a surgical instrument, the guide having a predetermined orientation based at least in part on the information about the desired alignment or correction of the joint." Ex. 1001, 124:17–22. We are persuaded by Petitioner's contentions with respect to this limitation. Pet. 54, 55–56; *see supra* Section II.D.4.v–vii, 5.ix, xi; Ex. 1033, 29, 31; Ex. 1031, 1:26–57, 2:28–40, 4:13–26, 6:4–15; Ex. 1102 ¶ 148.

8. Analysis of Dependent Claims

Although Patent Owner does not argue separately the patentability of any dependent claims, it remains Petitioner's burden to demonstrate that the claims are unpatentable. We determine that Petitioner has met its burden.

Claims 67 and 70

Claims 67 and 70 recite that "the orientation of the guide is based at least in part on at least one of a mechanical axis and an anatomical axis." Petitioner contends that these claims would have been obvious over the combined teachings of CAOS and Woolson, for the reasons discussed above regarding claim 66. Pet. 43, 45.

We are persuaded by Petitioner for the same reasons discussed above in Section II.D.4.v. Namely, Woolson discloses using x-ray image data to orient the guide relative to a mechanical axis. Ex. 1031, 1:26–58; *see also* Ex. 1102 ¶¶ 123–124 (explaining relationship between anatomical and mechanical axes, and use of x-ray in identification), ¶ 131.

Claims 68 and 71

Claim 68 and 71 recite that "the at least one axis is derived at least in part from the second image data set." Petitioner contends that these claims would have been obvious over the combined teachings of CAOS and Woolson, for the reasons discussed above regarding claim 66. Pet. 43–44, 45.

We are persuaded by Petitioner for the same reasons discussed above in Section II.D.4.v. Namely, Woolson discloses using x-ray image data to orient the guide relative to a mechanical axis. Ex. 1031, 1:26–58; *see also* Ex. 1102 ¶¶ 123–124, 126–128, 132.

E. Patent Owner's Observations on Cross-Examination

As noted above, Patent Owner filed two 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 66–72 and 81 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 66–72 and 81 of the '158 patent are shown to be 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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