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Paper No. 9
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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*.

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

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 have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted unless the information presented in the Petition shows that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *See also* 37 C.F.R § 42.4(a). Taking into account the arguments presented in the Preliminary Response, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in challenging claims 1–65 of the '158 patent. Accordingly, we institute an *inter partes* review as to these claims.

B. Related Proceedings

The parties represent that the '158 patent is at issue in *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass.) and in co-pending PTAB proceeding, IPR2017-00511. Pet. 1; Paper 3, 2.

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.

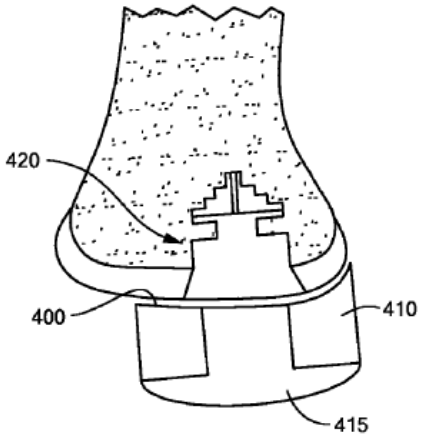

FIG. 22

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

[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.

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

Of the challenged claims, claims 1 and 38 are independent. Claims 2–37 depend directly or indirectly from claim 1, and claims 39–65 depend directly or indirectly from claim 38. Independent claims 1 and 38 are illustrative of the challenged claims and are 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;
>
> 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 [the] 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. Prior Art Relied Upon

Petitioner relies upon the following prior art references, as well as the Declaration of Dr. Jay D. Mabrey, M.D. (Ex. 1002):

Reference	Patent or Publication	Relevant Dates	Exhibit No.
Radermacher	WO 93/25157 A1	Filed June 17, 1993 Published December 23, 1993	1003
Alexander	WO 00/35346 A2	Filed December 16, 1999 Issued June 22, 2000	1004
Woolson	US 4,841,975	Filed April 15, 1987 Issued June 27, 1989	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")			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")			1084
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")			1085

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–65 of the ’158 patent based on the following grounds (Pet. 20):

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

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see In re Cuozzo Speed Techs., LLC*, 136 S. Ct. 2131, 2142–46 (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). We construe claim terms only as relevant to the parties’ contentions and only to the extent necessary to resolve the issues in dispute. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Neither party proposes any claim terms for express construction. Nonetheless, we determine it prudent to construe the phrase “surface of the

joint," which appears in independent claims 1 and 38. 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 the Declaration of Dr. Mabrey, who testifies:

> 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; *see also id.* ¶ 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, for purposes of this Decision, we construe the term "surface of the joint" as "the surface of an articulating bone that includes cartilage and/or exposed subchondral bone."

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, i.e., secondary considerations. *See Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17–18 (1966).

"A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors, and it is error to reach a conclusion of obviousness until all those factors are considered." *Apple v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) (citations omitted). "This requirement is in recognition of the fact that each of the *Graham* factors helps inform the ultimate obviousness determination." *Id.*[2]

"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). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). Furthermore, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

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

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[2] Patent Owner has not provided any evidence of secondary considerations. *See generally* Prelim. 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. 19 (citing Ex. 1002 ¶¶ 29–31). Dr. Mabrey bases his opinion on his experience as a surgeon in the 1990 to early 2000 timeframe. Ex. 1002 ¶ 31.

Patent Owner contends that Petitioner's position is incomplete, because it does not include an understanding of imaging technologies, to which the '158 patent claims are directed. Prelim. Resp. 8–9. Patent Owner contends that a person of ordinary skill in the art "would also have experience with and an understanding of imaging technologies, including how particular images are obtained and what image data are produced" or "would have access to or work with individuals such as a radiologist with such experience or understanding." *Id.* at 9.

Based on our review of the '158 patent, the types of problems and solutions described in the '158 patent and cited prior art, and the testimony of Dr. Mabrey, at this stage of the proceeding, we agree with Patent Owner that a person of ordinary skill in the art 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. Dr. Mabrey's experience appears to align with this requirement. *See* Ex. 1002 ¶¶ 4–9, 16–19, 43–57 (discussing personal and industry use of imaging). 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).

D. Alleged Obviousness over CAOS, Woolson, and Alexander

Petitioner contends 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 under 35 U.S.C. § 103(a) in view of CAOS, Woolson, and Alexander. Pet. 21–57. Patent Owner disputes Petitioner's contentions regarding only claims 3, 7, 24, 26, and 38–65. Prelim. Resp. 10–19. For reasons that follow, we determine Petitioner has demonstrated a reasonable likelihood of prevailing as to the challenged claims.

1. Overview of CAOS

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

2. Overview of Woolson

Woolson is a U.S. Patent titled "Preoperative Planning of Bone Cuts and Joint Replacement Using Radiant Energy Scan Imaging." Ex. 1031, [54]. Woolson uses "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

Alexander is a published PCT Application titled "Assessing the Condition of a Joint and Preventing Damage." Ex. 1004, (54). Alexander is directed to using MRI, CT, or ultrasound to obtain images of joint cartilage, which is used to develop a three-dimensional map of the cartilage. *Id.* at (57), 14:16–21.

4. Analysis of Cited Art

a. Independent Claim 1

Petitioner contends that CAOS, Woolson, and Alexander render obvious independent claim 1. *See* Pet. 22–39. Patent Owner makes no argument regarding this claim. *See generally* Prelim. Resp. The burden, however, remains on Petitioner to demonstrate unpatentability. *See Dynamic Drinkware*, 800 F.3d at 1378.

(1) preamble

Petitioner contends that CAOS discloses a method of generating a patient-matched surgical tool, as required by claim 1, 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). At this stage of the proceeding, we are persuaded by Petitioner. 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." Ex. 1033, 28.

(2) "obtaining first image data"

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. Pet. 22–23, 33–34 (citing, e.g., Ex. 1033, 29, 30–32, 34, 37). At this stage of the proceeding, we are persuaded by Petitioner. 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.

(3) "obtaining second image data"

Petitioner contends that CAOS obtains second image data associated with a patient's joint, as required by claim 1, because CAOS discloses taking topograms of the joint to identify a bone axis. Pet. 23, 34 (citing, e.g., Ex. 1033, 29–32, 34). At this stage of the proceeding, we are persuaded by Petitioner. CAOS explains that "topograms could be used to identify the bone axis." Ex. 1033, 31.

(4) "deriving an electronic model" and "creating a surgical tool using . . . the electronic model"

Petitioner contends that CAOS derives an electronic model of a portion of the joint using first image data and uses that model to create a surgical tool, as required by claim 1, because CAOS discloses customizing templates based on three-dimensional reconstructions obtained from CT data. Pet. 24, 34–36 (citing, e.g., Ex. 1033, 29–37, Figs. 1B–1C). At this stage of the proceeding, we are persuaded by Petitioner. CAOS explains that "templates are customized on the basis of three-dimensional reconstructions . . . extracted from computerized tomographic (CT) image data," and CAOS' Figures 1B and 1C depict the process of "computer assisted planning" on an electronic model. Ex. 1033, 29, Fig. 1B–1C.

(5) "the tool includes . . . a guide"

Petitioner contends that CAOS discloses that the customized template includes a guide for directing movement of a surgical instrument, as required by claim 1, 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). At this stage of the proceeding, 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.

(6) "the tool includes a contact surface"

With respect to the language of claim 1 requiring that "the tool includes a contact surface substantially matched to a corresponding surface of the joint," Petitioner contends that CAOS discloses matching the customized tool to bone, and Alexander discloses matching a customized tool to cartilage. Pet. 24–26, 36–37 (citing, e.g., Ex. 1003, 29–31; Ex. 1004,

14:16–21, 61:19–25, Fig. 18C). Petitioner also contends that it would have been obvious to incorporate Alexander's teachings. *Id.* at 26–27. At this stage of the proceeding, and based upon our construction of "surface of the joint," we are persuaded by Petitioner. 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.

(7) "the position or orientation of the guide . . . [is] based on information derived from the second image data"

With respect to the language of claim 1 requiring that "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," Petitioner contends that this limitation is disclosed by CAOS or would have been obvious. Pet. 27–33, 37–38. Petitioner contends that CAOS uses topograms to align the template relative to the bone. *Id.* Specifically, CAOS explains that the position and orientation of the template, including its tool guide, is fit exactly against the bone surface. Ex. 1033, 29. CAOS also explains that, "[i]n total knee arthroplasty 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." *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).

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 to orient a tool guide relative to the bone's mechanical axis. Pet. 31–32, 38. Specifically, Woolson explains that:

> regions of the body adjacent a bone to be resectioned are scanned with radiant energy to obtain representations of the regions . . . . From the representations, desired positions of a cutting guide relative to the bone are determined. Thus . . . accurate and precise placement during the surgical procedure is provided.

Ex. 1031, 2:28–40, 4:27–29 (identifying mechanical axis from CT image data), 4:13–26.

Petitioner argues, *inter alia*, that it would have been obvious to use CAOS' topograms to orient the template's cutting guide relative to the contact surface and the mechanical axis of the bone, as explicitly taught by Woolson, to achieve long-term surgical success. Pet. 32 (citing Ex. 1002 ¶¶ 5–7). Specifically, 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. Petitioner also argues that the proposed modification would have been use of a known technique to improve a similar procedure in a predictable way. Pet. 33.

Although CAOS does not state explicitly that the axis identified by the topogram (i.e., second image data) is used to position the template's guide relative to the contact surface, we are persuaded, at this stage of the proceeding, that Petitioner has shown sufficiently that Woolson provides such a teaching. Pet. 31–32; Ex. 1031, 2:28–40, 4:13–26. We further determine that Petitioner's proffered rationale and evidence is sufficient to support, on this record, the proposed modification to the surgical technique of CAOS in view of Woolson, for the stated purpose of providing a more successful surgery. Pet. 32–33; Ex. 1031, 1:26–36, 2:28–40.

(8) Summary

Based on the record before us, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that CAOS, Woolson, and Alexander render obvious independent claim 1.

b. Independent Claim 38

Petitioner contends that CAOS, Woolson, and Alexander render obvious independent claim 38. *See* Pet. 52–57. 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.a.

(1) "obtaining x-ray image data"

Petitioner contends it would have been obvious to use "x-ray image data 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. 40, 53. Petitioner also contends it was standard practice to use x-ray image data or CT image data to determine a mechanical axis and to orient cutting paths, as taught by Woolson. *Id.* (citing, e.g., Ex. 1031, Abstract, 1:37–50, 2:28–59; Ex. 1002 ¶ 113). 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. *Id.* at 40–41 (citing Ex. 1002 ¶ 113; *KSR*, 550 U.S. at 417).

Patent Owner disagrees, arguing that topograms obtain a preliminary image that is necessary for subsequent CT scanning. Prelim. Resp. 13–14.[3] Patent Owner's expert, Dr. Christopher M. Gaskin, M.D. (Ex. 2011), explains that a topogram determines where a subsequent CT scan should start and stop, and links the patient's position on the CT scanning table to the CT scanner. Ex. 2001 ¶ 17. Thus, according to Patent Owner, replacing CAOS' topogram with an x-ray image "would not provide the information needed to orient the patient's position on the CT scanning table to the CT scanner." Prelim. Resp. 15; Ex. 2001 ¶ 19.

On the current record, Petitioner shows sufficiently that it would have been obvious to utilize x-ray image data instead of CAOS' topograms to identify a mechanical axis. At this stage of the proceeding, 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* 37 C.F.R. § 42.108(c). Indeed, Dr. Mabrey's testimony appears consistent with that of Patent Owner's 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."). Thus, even Dr. Gaskin testifies that a topogram is, in fact, a form of x-ray image data. *Id.* To the extent a topogram is not, in and of

[3] Patent Owner also objects to Petitioner's reliance on documents that are not identified as part of the asserted grounds of unpatentability. Prelim. Resp. 24–25. Because we do not rely upon such documents in this Decision, Patent Owner's argument is moot.

itself, x-ray image data, we are sufficiently persuaded that they are at least alternatives.

We are persuaded by Petitioner's contentions even after considering Patent Owner's argument that an x-ray image would not establish the patient's position for the CT scanner. Prelim. Resp. 15–17. Patent Owner has not shown persuasively that CAOS's topograms are used to obtain patient-positioning information. Rather, CAOS explains only that topograms are used to identify a bone axis. Ex. 1033, 31. CAOS is silent as to whether the topogram is also used for patient positioning.

On the current record, we are also unpersuaded by Patent Owner's argument that Woolson teaches away from x-ray images because Woolson discloses a preference for CT imaging. Prelim. Resp. 17–18 (citing Woolson's disclosure that x-ray imaging may introduce error and is eliminated by Woolson's present invention). Although the invention disclosed by Woolson prefers use of CT image data over x-ray image data, Woolson also discloses that radiant imaging was the prevalent state of the art. *See, e.g.*, Ex. 1031, 1:37–62 ("Reproducing the mechanical axis at surgery is presently done by one of two different techniques."). When considered together with the testimony of both parties' experts, on this record, we are persuaded that topograms and x-ray images are acceptable alternatives, even if Woolson expresses a preference for CT image data. *See, e.g.*, *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) ("[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine."); *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("The fact that the motivating benefit comes at the expense

of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another."); *see also In re Urbanski*, 809 F.3d 1237, 1244 (Fed. Cir. 2016).

Finally, we are persuaded that Petitioner's proffered rationale and evidence is sufficient to support, on this record, 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.

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

Petitioner contends that CAOS as modified by Woolson uses x-ray image data to determine the mechanical axis and to orient cutting paths relative to that axis, as discussed above. Pet. 53 (citing Ex. 1002 ¶ 148; referring to claims 1, 3); *see also* Sections II.D.4.a.7, II.D.4.b.1. Petitioner also contends that Woolson uses x-ray image data to determine an anatomical axis. Pet. 46, 53–54 (referring to claim 25). At this stage of the proceeding, we are persuaded by Petitioner. 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.

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

Petitioner contends that CAOS as modified by Woolson and Alexander discloses creating a tool from first image data (e.g., CT image

data) and x-ray image data. Pet. 54; *see also* Sections II.D.4.a.4–6, II.D.4.b.1–2. At this stage of the proceeding, we are persuaded by Petitioner. CAOS discloses that "templates are customized on the basis of three-dimensional reconstructions . . . extracted from computerized tomographic (CT) image data," and Woolson explains that x-ray image data is used to properly position cutting guides on the instrument. Ex. 1033, 29; Ex. 1031, 1:37–50; *see also* Ex. 1033, 31.

(4) "guide having a predetermined orientation based at least in part of the determined axis"

Petitioner contends that CAOS as modified by Woolson discloses orienting the tool guide such that cuts are made perpendicular to the mechanical axis. Pet. 54; *see also* Sections II.D.4.a.7, II.D.4.b.1–3. At this stage of the proceeding, we are persuaded by Petitioner. 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.

(5) Summary

Based on the record before us, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that CAOS, Woolson, and Alexander render obvious independent claim 38.

c. Dependent Claims 2, 5, 6, 11–14, 19–23, 25, 27, 28, 30, 31, 33–35, and 37

Petitioner identifies teachings of CAOS and Woolson that Petitioner contends render obvious each limitation of these claims. *See* Pet. 39, 41–52. Patent Owner makes no argument regarding these claims. *See* Prelim. Resp.

We carefully reviewed the evidence relied upon by Petitioner and, at this stage of the proceeding, we agree that the cited portions of the record sufficiently support Petitioner's contentions. Accordingly, we determine that Petitioner has established a reasonable likelihood of prevailing with respect to claims 2, 5, 6, 11–14, 19–23, 25, 27, 28, 30, 31, 33–35, and 37, for similar reasons as provided for independent claim 1.

d. Dependent Claims 3, 7, 24, 26, 39–41, 45, 46, 51–56, 58, 59, 61–63, and 65

Petitioner identifies teachings of CAOS and Woolson that Petitioner contends render obvious each limitation of these claims. *See* Pet. 40–41, 46–47, 57. Patent Owner argues that CAOS' topogram could not be replaced with x-ray image data, as considered in relation to independent claim 38 above. Prelim. Resp. 10–19; *see supra* Section II.D.4.b.1.

We carefully reviewed the evidence relied upon by Petitioner and, at this stage of the proceeding, we agree that the cited portions of the record sufficiently support Petitioner's contentions. Accordingly, we determine that Petitioner has established a reasonable likelihood of prevailing with respect to claims 3, 7, 24, 26, 39–41, 45, 46, 51–56, 58, 59, 61–63, and 65, for similar reasons as provided for independent claims 1 and 38.

e. Summary

On this record and for purposes of this Decision, we determine Petitioner has presented sufficient evidence to establish a reasonable likelihood it would prevail in showing 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 are unpatentable under 35 U.S.C. § 103(a).

E. Alleged Obviousness over CAOS, Woolson, Alexander, and Radermacher

Petitioner contends claims 4, 29, 32, 36, 57, 60, and 64 of the ’158 patent are unpatentable under 35 U.S.C. § 103(a) in view of CAOS, Woolson, Alexander, and Radermacher. Pet. 57–63. Patent Owner disputes Petitioner’s contentions regarding only claims 4, 57, 60, and 64. Prelim. Resp. 10–19 (claims 57, 60, and 64), 19–23 (claim 4). For reasons that follow, we determine Petitioner has demonstrated a reasonable likelihood of prevailing as to the challenged claims.

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)”[4] 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).

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

2. Analysis of Cited Art

a. Dependent Claim 4

Petitioner identifies teachings of CAOS, Woolson, and Radermacher that Petitioner contends render obvious claim 4, which requires that the first image data is MRI data and the second image data is x-ray data. Regarding x-ray image data, Petitioner incorporates its prior discussion. *See supra* Section II.D.4.b.1. 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. Pet. 58. Petitioner also contends that Radermacher discloses using MRI data to make a patient-matched surgical instrument. Pet. 58–59. Petitioner contends it would have been obvious to use MRI with CAOS' 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).

Patent Owner disagrees, arguing, "Petitioner's proposed modification of *CAOS* is prefaced on retaining *CAOS*'s CT topogram so that it can separately be replaced with an x-ray image," and "one of ordinary skill would not have obtained a CT topogram in the first instance if CAOS's CT image were replaced with an MRI image, as the CT topogram is incident to

the CT image." Prelim. Resp. 21–22.[5] Patent Owner also argues that neither topograms nor x-rays are useful with MRI, because they do not provide positioning information relative to the MRI table. *Id.* at 22–23.

On the current record, Petitioner shows sufficiently that it would have been obvious to modify CAOS' method to obtain MRI data instead of CT data. 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 also credit Dr. Mabrey's testimony, supported by Radermacher, that these techniques are alternatives. Ex. 1002 ¶ 158; Ex. 1003, 10, Figs. 18–19.

We are persuaded by Petitioner's contentions even after considering Patent Owner's arguments. Similar to our discussion above, Patent Owner has not shown persuasively that CAOS's topograms, or the proposed x-rays replacing those topograms, are used to obtain patient-positioning information. Rather, CAOS explains only that topograms are used to identify a bone axis. Ex. 1033, 31. Accordingly, it is not dispositive that neither topograms nor x-rays provide this information.

Finally, we determine that Petitioner's proffered rationale and evidence is sufficient to support, on this record, the proposed modification to utilize MRI data, as a substitution of one imaging technique for another to obtain the predictable result of obtaining a joint image. *See* Ex. 1002 ¶ 159.

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[5] Regarding claim 4, Patent Owner also argues that CAOS' topogram could not be replaced with an x-ray image, which argument was considered above. Prelim. Resp. 10–19; *see supra* Section II.D.4.b.1.

b. Dependent Claims 29, 32, 36, 57, 60, 64

Petitioner contends that CAOS as modified by Woolson, Alexander, and Radermacher render obvious these claims, which require a linkage or connector that connects a separate component to the tool. *See* Pet. 60–63. Petitioner identifies Radermacher's "engagement points," used for attaching additional components and aligning cutting guides. *Id.*; Ex. 1003, 26, Fig. 13a. Petitioner contends a person of ordinary skill in the art would have been motivated to modify CAOS with Radermacher for the reasons discussed above regarding claim 4. Pet. 61.

Patent Owner makes no argument regarding claims 29, 32, and 36. *See generally* Prelim. Resp. With respect to claims 57, 60, and 64, Patent Owner argues that CAOS' topogram could not be replaced with an x-ray image, as considered in relation to independent claim 38. Prelim. Resp. 10–19; *see supra* Section II.D.4.b.1.

We carefully reviewed the evidence relied upon by Petitioner and, at this stage of the proceeding, we agree that the cited portions of the record sufficiently support Petitioner's contentions. Ex. 1003, 11, 26. Furthermore, on this record, we conclude that a person of ordinary skill in the art would have found it obvious to modify CAOS' tool to include a linkage or connector, as taught by Radermacher, to permit optional use of complimentary devices. *Id.*

c. Summary

Based on the record before us, we determine Petitioner has established a reasonable likelihood of prevailing on its contention that CAOS, Woolson, Alexander, and Radermacher render obvious claims 4, 29, 32, 36, 57, 60, and 64.

F. Alleged Obviousness over CAOS, Woolson, Alexander, and Chao

1. Overview of Chao

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 Cited Art

a. Dependent Claims 8–10, 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 in a "weight-bearing" x-ray or position. Petitioner incorporates its previous discussion of x-ray image data, and contends that Chao discloses weight-bearing x-rays. Pet. 63–64. Specifically, Chao discloses taking "full-length standing plain radiographs of the lower extremity for the measurement of mechanical axial alignment for preoperative planning of knee osteotomies [because use] of the mechanical axis description of alignment is reported to be more reliable than the anatomic description." Ex. 1084, 6, 10. 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. Pet. 64 (citing, e.g., Ex. 1002 ¶ 172).

Patent Owner makes no argument regarding claim 10. *See generally* Prelim. Resp. With respect to claims 8, 9, and 42–44, Patent Owner argues that CAOS' topogram could not be replaced with an x-ray image, as considered in relation to independent claim 38. Prelim. Resp. 10–19; *see supra* Section II.D.4.b.1.

We carefully reviewed the evidence relied upon by Petitioner and, at this stage of the proceeding, we agree that the cited portions of the record sufficiently support Petitioner's contentions. Furthermore, on this record, we conclude that a person of ordinary skill in the art would have found it obvious to use standing and weight-bearing x-rays, as taught by Chao, to obtain reliable information about the mechanical axis of the bone. *See, e.g.*, Ex. 1002 ¶ 172; Ex. 1084, 6.

b. Summary

Based on the record before us, we determine Petitioner has established a reasonable likelihood of prevailing on its contention that CAOS, Woolson, Alexander, and Chao render obvious claims 8–10 and 42–44.

G. Alleged Obviousness over CAOS, Woolson, Alexander, and Arima

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 Cited Art

a. 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. Pet. 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. Pet. 67–68, 70, 72 (citing, e.g., Ex. 1002 ¶¶ 180, 186, 190).

Patent Owner makes no arguments regarding claims 15–18. *See generally* Prelim. Resp. With respect to claims 47–50, Patent Owner argues that CAOS' topogram could not be replaced with an x-ray image, as

considered in relation to independent claim 38. Prelim. Resp. 10–19; *see supra* Section II.D.4.b.1.

We carefully reviewed the evidence relied upon by Petitioner and, at this stage of the proceeding, we agree that the cited portions of the record sufficiently support Petitioner's contentions. *See* Ex. 1085, 1331 (stating that the anteroposterior axis is reliable for a valgus knee, the posterior aspects of the femoral condyles are reliable indicators in a normal knee, and a transepicondylar axis can be used), 1332 (Figure 3 depicting resection relative to anteroposterior, epicondylar, and posterior condylar axes). On this record, Petitioner has shown persuasively that a person of ordinary skill in the art would have been motivated to use any of these axes in determining a rotational position of the joint because this would be a simple substitution of one known reference axis for another, to obtain the predictable result of properly reconstructing the knee joint. *See* Ex. 1002 ¶¶ 180, 186, 190.

b. Summary

Based on the record before us, we determine Petitioner has established a reasonable likelihood of prevailing on its contention that CAOS, Woolson, Alexander, and Arima render obvious claims 15–18 and 47–50.

III. CONCLUSION

For the foregoing reasons, we determine Petitioner has demonstrated there is a reasonable likelihood it would prevail in establishing the unpatentability of claims 1–65 of the '158 patent.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or to the construction of any claim term.

IV. ORDER

For the reasons given, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–65 of the ’158 patent on the following asserted grounds:

1. 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 under 35 U.S.C. § 103(a) as unpatentable over CAOS, Woolson, and Alexander;

2. Claims 4, 29, 32, 36, 57, 60, and 64 under 35 U.S.C. § 103(a) as unpatentable over CAOS, Woolson, Alexander, and Radermacher;

3. Claims 8–10 and 42–44 under 35 U.S.C. § 103(a) as unpatentable over CAOS, Woolson, Alexander, and Chao;

4. Claims 15–18, 47–50 under 35 U.S.C. § 103(a) as unpatentable over CAOS, Woolson, Alexander, and Arima.

FURTHER ORDERED that the trial is limited to the grounds identified above, and no other grounds are authorized; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, the trial commencing on the entry date of this Decision.

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