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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 IPR2017-00511
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 66–81 ("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 66–72 and 81 of the '158 patent. Accordingly, we institute an *inter partes* review as to only 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, IPR2017-00510. 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.

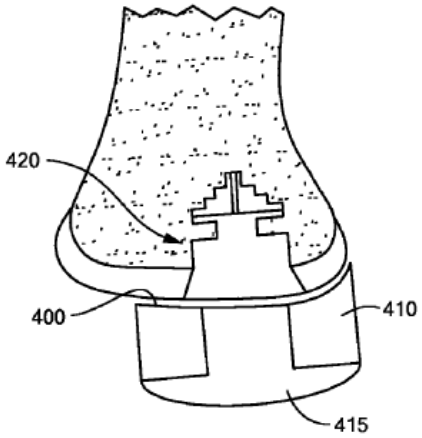

FIG. 22

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 66, 69, 72, 73, and 81 are independent. Claims 67 and 68 depend directly from claim 66; claims 70 and 71 depend directly from claim 69; and claims 74–80 depend directly or indirectly from claim 73. Independent claim 66 is illustrative of the challenged claims 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 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. 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. 1102):

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

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 66–81 of the '158 patent based on the following grounds (Pet. 21):

References	Basis	Claims Challenged
CAOS, Woolson, and Alexander	§ 103(a)	66–72 and 81
CAOS, Woolson, Alexander, and Radermacher	§ 103(a)	73–80

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).

Although Petitioner states that no terms require construction, Petitioner construes "articular surface of [a] joint," in claim 81, as "the bone surface and/or cartilage surface of an articulating portion of a joint." Pet. 20. We determine it prudent to construe this phrase, as well as similar language in claims 66, 69, 72, and 73 ("surface portion associated with the joint," "surface contours of at least a portion of a surface of or near a joint," or "surface portion of or near a joint"). 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. 1102 ¶ 36; *see also id.* ¶¶ 68–71, 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, for purposes of this Decision, we construe these terms 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]

[2] Patent Owner has not provided any evidence of secondary considerations. *See generally* Prelim. Resp.; *see also* Pet. 78.

"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.

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 to early 2000 timeframe. Ex. 1102 ¶ 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. 1102 ¶¶ 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 66–72 and 81 of the '158 patent are unpatentable under 35 U.S.C. § 103(a) in view of CAOS, Woolson, and Alexander. Pet. 22–56. Patent Owner disputes Petitioner's contentions regarding all claims except claim 72. Prelim. Resp. 9–22. 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 66

Petitioner contends that CAOS, Woolson, and Alexander render obvious independent claim 66. *See* Pet. 23–43.

(1) preamble

Petitioner contends that CAOS discloses a method to create a patient-specific instrument for implanting an orthopedic implant, as required by claim 66, 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.*, *id.* at 36–37 (citing, e.g., Ex. 1033, 28–31; Ex. 1102 ¶¶ 82–83). At this stage of the proceeding, we are persuaded by Petitioner. 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." Ex. 1033, 28.

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

Petitioner contends that CAOS discloses, or CAOS in combination with Woolson render obvious, the step of creating a patient-specific instrument based on first and second image data sets, as required by claim 66. First, Petitioner contends that CAOS discloses utilizing CT image data (a first image data set) to create an individual template having tool guides whose orientation may be adjusted to fit exactly against the bone. Pet. 23–25, 37–39 (citing, e.g., Ex. 1033, 28–31; Ex. 1102 ¶¶ 85–89). At this stage of the proceeding, we are persuaded by Petitioner because the citations provided by Petitioner support this proposition. *See* Ex. 1033, 29

("Individual templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data.").

Second, Petitioner contends that CAOS teaches using topograms (a second image data set) to identify the bone's mechanical axis and position the 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 (a second 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 CAOS and Woolson render obvious 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. Petitioner argues that it would have been obvious to modify CAOS in light of Woolson because using image data to align cuts relative to a mechanical axis of the bone, as explicitly taught by Woolson, is critical to 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.

Although CAOS does not state explicitly that the axis identified by the topogram (i.e., a second image data set) 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 teaches using x-ray or CT image data (i.e., a second image data set) to properly align

surgical cuts relative to a mechanical axis. Pet. 28–29; Ex. 1031, 1:27–57, 2:28–40, 4:13–26. We further determine that Petitioner's rationale and evidence is sufficient to support, on this record, the proposed modification to CAOS' surgical technique, for the stated purpose of providing a more successful surgery. Pet. 29–30; Ex. 1031, 1:26–36, 2:28–40.

(3) "first image data set is of a type different from the second . . . and the second image data set is x-ray image data"

(a) "x-ray image data"

Petitioner contends 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, 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 ¶¶ 105–106). Therefore, according to Petitioner, "it would have been obvious to modify CAOS to use x-ray image data in place of topograms." *Id.* at 31 (citing Ex. 1102 ¶ 106).

Patent Owner disagrees, arguing that topograms obtain a preliminary image that is necessary for subsequent CT scanning. Prelim. Resp. 11–14. 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. 14; 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. 1102 ¶ 105; *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 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. 11–14. 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. 16–18 (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, on the current record, we are persuaded 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 ¶¶ 105–106; Ex. 2001 ¶¶ 15, 17.

(b) "different"

Petitioner also contends that the image data sets discussed above are different, as required by claim 66, because CAOS' 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). At this stage of the proceeding, we are persuaded by Petitioner. *See*, *e.g.*, Ex. 1102 ¶¶ 107–109; *see supra* Section II.D.4.a.2.[3]

(4) "patient-specific surface that is derived from at least the first image data and that substantially matches a corresponding surface portion"

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 Alexander discloses imaging joint cartilage and that it would have been obvious to incorporate Alexander's teachings into CAOS' method. *Id.* at 33–35. At this stage of the proceeding, and based upon our construction of "surface portion

[3] Patent Owner also argues that it would not have been obvious to utilize MRI image data as "first" or "other" image data. Prelim. Resp. 18–22. We do not address this argument because, at this stage of the proceeding, we do not rely on Petitioner's contentions regarding MRI. Similarly, because we do not rely upon documents that are not identified as part of the asserted grounds of unpatentability, *see id.* at 22–23, Patent Owner's additional argument is moot.

associated with the joint," 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," such that they "fit exactly on the bone." Ex. 1033, 29.

(5) "the surgical instrument has a guide that is oriented . . . based on information derived from the second image data set"

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). 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.

With respect to the language requiring that the guide is oriented based on information derived from the second image data set, Petitioner contends that this limitation is disclosed by CAOS or would have been obvious. Pet. 35–36, 43. Petitioner relies on CAOS' disclosure that the "the planned 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." *Id.* at 35 (citing Ex. 1033, 29). Further, as discussed above, Petitioner contends that CAOS in combination with Woolson discloses orienting a tool guide relative to a mechanical axis based on x-ray image data. *Id.* at 36. Specifically, Woolson explains that placement of a knee prosthesis along a mechanical axis "is highly likely to produce a successful long-term result," and explains that radiographs were

taken to identify this axis and to adjust the cutting guide in relation to the axis. Ex. 1031, 1:26–57.

At this stage of the proceeding, we are persuaded by Petitioner. CAOS discloses adjusting the orientation of the tool guide relative to the bone. Ex. 1033, 29. Although CAOS does not state explicitly that the topogram (i.e., a second image data set) 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 CAOS in light of Woolson would have rendered it obvious to align planned cuts with respect to a mechanical axis identified by x-ray image data, such that this limitation would have been obvious. Pet. 28–29, 35–36; Ex. 1031, 1:26–57, 2:28–40, 4:13–26.

(6) 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 66.

b. Independent Claim 69

Petitioner contends that CAOS, Woolson, and Alexander render obvious independent claim 69, which Petitioner contends to be nearly identical to claim 66, "except that Claim 69 recites 'designing' rather than 'creating' a patient-specific surgical instrument." *See* Pet. 44. At this stage of the proceeding, we are persuaded by Petitioner, for the same reasons discussed above regarding claim 66. *See* Section II.D.4.a.

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 69.

c. Independent Claim 72

Petitioner contends that CAOS, Woolson, and Alexander render obvious independent claim 72. *See* Pet. 45–51. Petitioner states, and we agree, 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.

Id. at 45–46; *compare* Ex. 1001, 122:9–24, *with id.* at 122:50–63. We focus our analysis on these differences and otherwise incorporate our analysis of claim 66. *See* Section II.D.4.a.

(1) "determining . . . from a first set of image data the surface contours . . . of a surface of or near a joint"

Petitioner contends that CAOS discloses the step of determining the surface contours of a joint surface from a first set of image data, as required by claim 72. Specifically, Petitioner contends that CAOS discloses utilizing CT image data (a first image data set) to create an individual template that has contact faces fitting exactly against the bone. Pet. 46–47, 49 (citing, e.g., Ex. 1033, 28–29, 31; Ex. 1102 ¶¶ 136–137) (relying also on Alexander). At this stage of the proceeding, we are persuaded by Petitioner because the citations provided by Petitioner support this proposition. *See* Ex. 1033, 29 ("Individual templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data."); *see also* Section II.D.4.a.4.

(2) "determining . . . from a second set of image data an axis associated with the joint"

Petitioner contends either that CAOS discloses determining a joint axis from a second set of image data, as required by claim 72, or that such a limitation would have been obvious in light of CAOS and Woolson. Pet. 47–48, 50 (citing, e.g., Ex. 1033, 31; Ex. 1102, 84–104, 119–120, 123–128, 140). At this stage of the proceeding, we are persuaded by Petitioner. Specifically, CAOS discloses that "topograms could be used to identify the bone axis." Ex. 1033, 31. Further, Woolson discloses using radiographs or CT image data to identify a mechanical axis. Ex. 1031, 1:37–57, 5:9–14, 6:4–15; *see also* Section II.D.4.a.2.

(3) "the guide is oriented . . . based at least in part on the determined axis"

Petitioner contends that CAOS and Woolson render obvious the step of orienting a guide relative to the joint axis, as required by claim 72. Pet. 48, 50–51 (citing Ex. 1033, 29–31; Ex. 1102 ¶¶ 84–104, 119–120, 123–125, 141–142). Similar to our analysis in Section II.D.4.a.5, we are persuaded by Petitioner. Specifically, CAOS discloses adjusting the orientation of the tool guide relative to the bone. Ex. 1033, 29. Further, Petitioner has shown sufficiently that CAOS in light of Woolson would have rendered it obvious to orient the position of planned cuts with respect to a mechanical axis. Pet. 28–29, 35–36; Ex. 1031, 1:26–57, 2:28–40, 4:13–26.

(4) 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 72.

d. Independent Claim 81

Petitioner contends that CAOS, Woolson, and Alexander render obvious independent claim 81. *See* Pet. 51–56. Petitioner states, and we agree, 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.

Id. at 51; *compare* Ex. 1001, 122:9–24, *with id.* at 124:7–22. We focus our analysis on these differences and otherwise incorporate our analysis of claim 66. *See* Section II.D.4.a.

(1) "determining from the x-ray image data information about a desired alignment or correction of the joint"

Petitioner contends that CAOS and Woolson render obvious the step of determining information about desired joint alignment or correction from x-ray image data, as required by claim 81. Pet. 51–52, 55. At this stage of the proceeding, we are persuaded by Petitioner. Woolson explains that "all total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis" and explains that such an axis can be determined using x-ray image data. Ex. 1031, 1:26–57.

(2) "the surgical tool includes a contact surface substantially matched to a corresponding articular surface of the joint"

Petitioner contends that CAOS discloses that the tool includes a contact surface substantially matched to a corresponding articular surface of the joint, as required by claim 81. Pet. 53–56. Specifically, Petitioner

contends that CAOS discloses an individual template with contact faces that fit exactly against the bone. Pet. 53–54 (citing, e.g., Ex. 1033, 29; Ex. 1102 ¶¶ 115–118, 147) (relying also on Alexander). At this stage of the proceeding, we are persuaded by Petitioner because the citations provided by Petitioner support this proposition. *See* Ex. 1033, 29 ("Individual templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data."); *see also* Section II.D.4.a.4.

(3) "the guide having a predetermined orientation based . . . on the information about the desired alignment or correction of the joint"

Petitioner contends that CAOS and Woolson render obvious a guide oriented based on information about desired joint alignment, as required by claim 81. Pet. 54, 56 (citing Ex. 1033, 29–31; Ex. 1102 ¶¶ 148–149). Similar to our analysis in Section II.D.4.a.5, we are persuaded by Petitioner. Specifically, CAOS discloses adjusting the orientation of the tool guide relative to the bone. Ex. 1033, 29. Further, Petitioner has shown sufficiently that CAOS in light of Woolson would have rendered it obvious to orient the position of planned cuts with respect to a mechanical axis, in order to properly align the knee joint. Pet. 51–53; Ex. 1031, 1:26–57, 2:28–40, 4:13–26.

(4) 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 81.

e. Dependent Claims 67, 68, 70, and 71

Petitioner identifies teachings of CAOS and Woolson that Petitioner contends render obvious each limitation of these claims. *See* Pet. 43–45. Patent Owner relies on the arguments discussed above, in relation to independent claim 66. Prelim. Resp. 10–22; *see supra* Section II.D.4.a.

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 67, 68, 70, and 71, for similar reasons as provided for independent claim 66.

f. 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 66–72 and 81.

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

Petitioner contends claims 73–80 of the '158 patent are unpatentable under 35 U.S.C. § 103(a) in view of CAOS, Woolson, Alexander, and Radermacher. Pet. 56–77. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 10–22. For reasons that follow, we determine Petitioner has not 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).

2. Analysis of Cited Art

a. Independent Claim 73

Claim 73 is reproduced below, with relevant portions italicized for emphasis.

> 73. A method of *using a patient-matched surgical instrument* to implant an orthopedic implant, comprising:
>
> *placing a patient-specific surface of the implant* against a corresponding surface portion of or near a joint of the patient such that the patient-specific surface is substantially entirely engaged against the corresponding surface portion of the patient;
>
> cutting or drilling a portion of the tissue in or near the joint of the patient *using a guide of or attached to the patient matched surgical instrument*; and
>
> *implanting an implant* in or near the joint;
>
> wherein the guide has a predetermined alignment relative to the patient-specific surface derived at least in part from x-ray image data of at least a portion of the joint; and
>
> wherein the patient-specific surface is derived from other image data of at least a portion of the joint.

Ex. 1001, 122:54–123:12. As drafted, the preamble of claim 73 purports to describe the use of a patient-matched surgical *instrument*, yet the first limitation in the body of claim 73 recites steps taken by "a patient-specific

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

surface of *the implant*." *Id.* (emphasis added). Accordingly, Petitioner contends that claim 73 is indefinite because its scope would not be understood with reasonable certainty. Pet. 57. Petitioner alternatively contends that, "[t]o the extent ConforMIS intended to draft Claim 73 to recite 'placing a patient-specific surface of *the instrument*' against the joint surface consistent with the other claims, Claim 73 would have been obvious." *Id.*; *see also id.* at 58–59, 65 (analyzing the prior art according to this proposed correction).

Patent Owner responds that Petitioner's indefiniteness contention is not a proper basis for an *inter partes* review. Prelim. Resp. 1 (citing 35 U.S.C. § 311(b)).

Petitioner's contentions regarding how the prior art applies to claim 73 amount to a request that we rewrite this claim to correct what Petitioner suggests *may have been* a drafting error. Pet. 57. However, a patent claim may be corrected through claim construction "only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1357 (Fed. Cir. 2003). Furthermore, "courts may not redraft claims, whether to make them operable or to sustain their validity." *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004). In this circumstance, it is Petitioner's burden to show that claim 73 contains a drafting error that warrants correction. *See* 37 C.F.R. § 42.20(c).

In this case, neither Petitioner nor Dr. Mabrey demonstrate that the purported error in claim 73 is "not subject to reasonable debate" or that the

prosecution history does not suggest a different interpretation. Pet. 57; Ex. 1102 ¶ 151 (explaining that Dr. Mabrey "has been asked to analyze Claim 73 under the assumption" that it has been corrected). For example, although Petitioner's proposed correction appears plausible, Petitioner has not provided an analysis of the specification or prosecution history in a manner that demonstrates such a correction is proper. *See, e.g.*, Ex. 1017, 242–243 (in a Preliminary Amendment, adding prosecution claim 93, which later issued as claim 73), 180–185 (issuing a Double Patenting rejection of prosecution claim 93). We, therefore, decline to adopt Petitioner's proposed correction of claim 73.

Petitioner submits no evidence or arguments to show unpatentability of claim 73, as the claim is written. *See* Pet. 56–77 (asserting that claim 73 is unpatentable under Petitioner's proposed correction). Accordingly, we are not persuaded that Petitioner demonstrates a reasonable likelihood of prevailing on its assertion that claim 73, or claims 74–80 depending therefrom, are unpatentable.

b. Summary

Based on the record before us, we determine Petitioner has not established a reasonable likelihood of prevailing on its contention that CAOS, Woolson, Alexander, and Radermacher render obvious claims 73–80.

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 66–72 and 81 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 66–72 of the '158 patent on the following asserted ground:

1. Claims 66–72 and 81 under 35 U.S.C. § 103(a) as unpatentable over CAOS, Woolson, and Alexander.

FURTHER ORDERED that the trial is limited to the ground 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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