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Paper No. 47
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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.").

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[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.

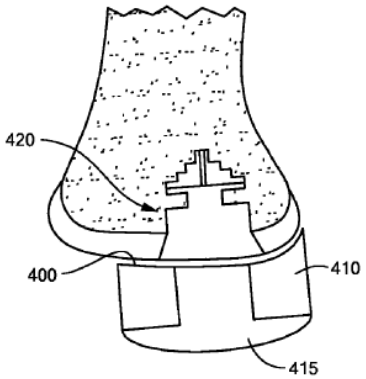

FIG. 22

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).

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