UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

_____

Case IPR2017-00510
Patent 7,981,158 B2

_____

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

WIEKER, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

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

After institution, Patent Owner filed a Response (Paper 16 ("PO Resp.")) to the Petition, and Petitioner filed a Reply (Paper 22 ("Pet. Reply")). Additionally, with our authorization, Patent Owner filed a list of purportedly improper arguments contained in Petitioner's Reply (Paper 29), to which Petitioner responded (Paper 35). Patent Owner also filed Motions for Observation on the Cross-Examinations of Garry E. Gold, M.D. (Paper 31) and Jay D. Mabrey, M.D. (Paper 32), to which Petitioner responded (Papers 37, 38).

A consolidated oral hearing was held on March 13, 2018, between this proceeding, IPR2017-00511, and IPR2017-00373, and a transcript of the hearing is included in the record. Paper 41 ("Tr.").

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

B.   Related Proceeding

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

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

C.   The '158 Patent

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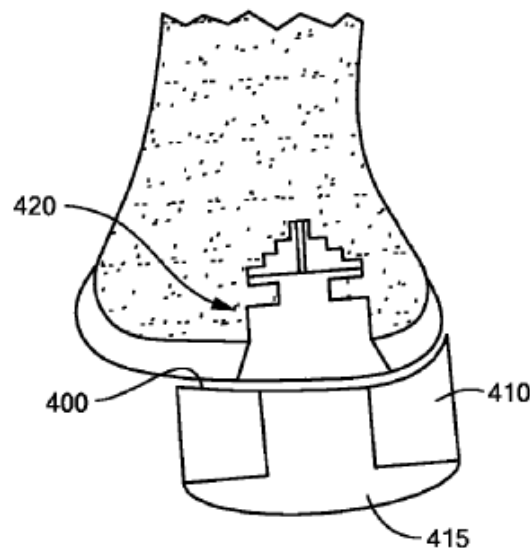
FIG. 22

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

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

D.   Illustrative Claims

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

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

---

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

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

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

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

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

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

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

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

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

Ex. 1001, 119:10–26, 120:54–121:2.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.

fastcase®
Smarter legal research.