Trials@uspto.gov
Tel: 571–272–7822

Paper 31
Entered: February 18, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
WRIGHT MEDICIAL GROUP, INC., and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioners,

v.

BONUTTI SKELETAL INNOVATIONS LLC,
Patent Owner.

Case IPR2013-00629
Patent 7,806,896 B1

Before WILLIAM V. SAINDON, MICHAEL R. ZECHER, and RICHARD E. RICE, *Administrative Patent Judges*.

SAINDON, *Administrative Patent Judge*.

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

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a).

With respect to the asserted grounds in this trial, we have considered the positions set forth by Petitioners and Patent Owner in the Petition, Patent Owner's Response, Petitioners' Reply, and the evidence cited therein. For the reasons discussed below, we determine that Petitioners have shown, by a preponderance of the evidence, that claim 1 of the '896 patent is unpatentable.

A. Procedural History

Smith & Nephew, Inc., filed a Petition requesting an *inter partes* review (Paper 3, "Pet.") of claims 1 and 13 of U.S. Patent No. 7,806,896 B1 (Ex. 1001, "the '896 patent"). Pet. 2. Smith & Nephew included a Declaration of Dr. Jay Mabrey, M.D. (Ex. 1002). In our Decision to Institute *Inter Partes* Review (Paper 10, "Inst. Dec."), we instituted a trial only as to claim 1 of the '896 patent on four grounds. Inst. Dec. 27.

In another proceeding, Wright Medical Group, Inc. and Wright Medical Technology, Inc., filed a Petition requesting an *inter partes* review of claims 1 and 40 of the '896 patent, which we granted. IPR2014-00354, Paper 10. Subsequently, Bonutti Skeletal Innovations LLC ("Patent Owner") filed a notice disclaiming claim 40 of the '896 patent. IPR2014-00354, Paper 12.

On June 30, 2014, we issued a decision granting the parties' joint motion for joinder of Case IPR2013-00629 with Case IPR2014-00354. IPR2013-00629, Paper 18; IPR2014-00354, Paper 14.

Patent Owner filed a Response addressing the asserted grounds (Paper 17, "PO Resp.") with a Declaration of Dr. Scott D. Schoifet, M.D. (Ex. 2004). Smith & Nephew, Wright Medical Group, and Wright Medical Technology (collectively, "Petitioners") then filed a Reply to Patent Owner's Response (Paper 22, "Pet. Reply") with a Reply Declaration of Dr. Mabrey (Ex. 1023).

An oral hearing was held on October 27, 2014, with all parties present. Paper 30 ("Tr.").

No motions are outstanding.

B. Related Proceedings

Patent Owner identifies that an *inter partes* review has been instituted against the '896 patent in *Zimmer Holdings, Inc. v. Bonutti Skeletal Innovations LLC*, IPR2014-00321 (PTAB June 2, 2014) (Paper 13) (trial instituted on claims 40–42 and 44–47 of the '896 patent). Paper 9.

The '896 patent is involved in several district court actions: *Bonutti Skeletal Innovations LLC v. Smith & Nephew, Inc.*, Civil Action No. 12-1111-GMS (D. Del.); *Bonutti Skeletal Innovations LLC v. Zimmer Holdings Inc.*, Civil Action No. 1:2012-cv-01107 (D. Del.); *Bonutti Skeletal Innovations LLC v. Wright Medical Group Inc.*, Civil Action No. 1:2012-cv-01110 (D. Del. 2012); *Bonutti Skeletal Innovations LLC v. ConforMIS Inc.*, Civil Action No. 1:2012-cv-01109 (D. Del.); *Biomet Inc v. Bonutti Skeletal Innovations LLC*, Civil Action No. 3:2013-cv-00176 (N.D. Ind.); and *Bonutti Skeletal Innovations v. DePuy Mitek, Inc.*, Civil Action No. 1:2012-cv-11667 (D. Mass). Pet. 1; Paper 8, 2.

C. Technical Background

The human knee joint is formed by the lower (distal) end of the femur (thighbone) and the upper (proximal) end of the tibia (shinbone), with the patella (kneecap) covering the joint. Ex. 1002 ¶ 25. The distal end of the femur includes two rounded protrusions called condyles; the groove between them is known as the femoral groove, patellar groove, or trochlear groove. *Id.* The condyles glide on a piece of cartilage on top of the tibia to form the main load-bearing interface of the knee joint. *Id.* ¶¶ 23, 25.

In general, knee replacement surgery involves removal of one or more portions of the knee's bones and replacing them with artificial analogues. The process typically follows this procedure: exposing the knee by making an incision through the skin (*id.* ¶ 29), inserting one or more cutting guides (*id.* ¶¶ 32–35), resurfacing one or more bones (*id.*), and attaching the replacement portions (*id.* ¶ 36, noting the replacement also is called an implant). *See also* Pet. 9–13 (discussing knee replacement surgery).

"Accurate alignment of knee implants is essential for the success of total knee replacement." Ex. 1003, 49 (emphasis removed). Mechanical alignment guides typically are used "to assure that cutting guides were properly aligned with the leg when placed on the bone." Ex. 1002 ¶ 34; *see also* Ex. 1001, 17:16–18 (disclosing that intramedullary instrumentation is used to cut a femur). These mechanical device guides often come in the form of a rod that is secured to the patient. Installation of the rod can be either intramedullary, wherein the rod is inserted into the medullary canal (bone marrow cavity) of the tibia, or extramedullary, wherein the rod is attached to the patient's leg. Ex. 1002 ¶ 34; Ex. 1001, 17:16–18 ("either . . . can be utilized"). Figures 10 and 11 of Stulberg (Ex. 1005) depict

intramedullary and extramedullary rods, respectively, and are reproduced below:

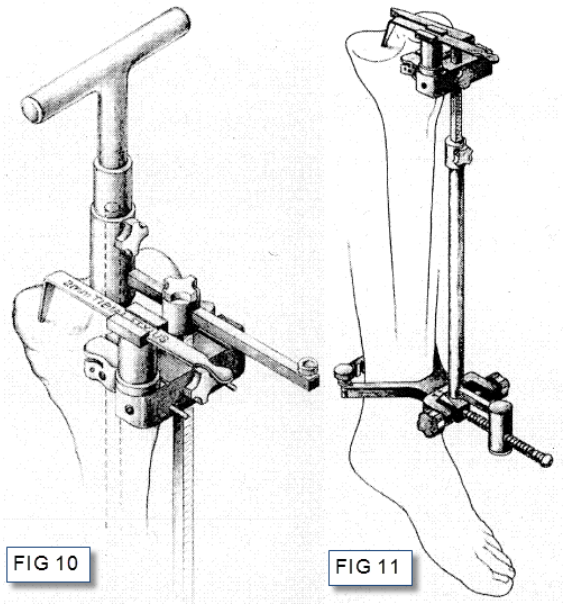

Figure 10 depicts a cutting guide secured to a patient using an intramedullary rod inserted into the medullary canal of the tibia. Ex. 1002 ¶ 34. Figure 11 depicts a cutting guide secured to a patient using an extramedullary rod strapped to the patient's ankle. *Id.*

D. The '896 Patent

The '896 patent, titled "KNEE ARTHROPLASTY METHOD," issued October 5, 2010 from U.S. Patent Application No. 10/722,102, filed November 25, 2003. Ex. 1001 at [54], [45], [21], and [22]. The '896 patent is a continuation of U.S. Patent Application No. 10/191,751, filed July 8, 2002, now U.S. Patent No. 7,104,996, and is a continuation-in-part of a number of earlier-filed applications. *Id*. at [63].

The '896 patent discusses methods for performing knee replacement surgery. Particularly, the '896 patent discusses alignment systems that do not use intramedullary and/or extramedullary rods. Such alternative

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