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Paper 10
Entered: February 28, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.
Petitioner

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.*

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

I. INTRODUCTION

Smith & Nephew, Inc., filed a Petition (Paper 3, "Pet.") to institute an *inter partes* review of claims 1 and 13 of U.S. Patent No. 7,806,896 B1 (Exhibit 1001, the "'896 patent") pursuant to 35 U.S.C. § 311 *et seq*. Patent Owner, Bonutti Skeletal Innovations LLC, did not file a preliminary response. We have jurisdiction under 35 U.S.C. § 314.

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a):

> THRESHOLD – The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 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.

Upon consideration of the Petition, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claim 1 of the '896 patent. Accordingly, pursuant to 35 U.S.C. § 314, we authorize an *inter partes* review to be instituted only as to claim 1 of the '896 patent.

A. Related Proceedings

Petitioner states that the '896 patent is involved in co-pending litigation, styled *Bonutti Skeletal Innovations LLC v. Smith & Nephew, Inc.*, Civil Action No. 12-1111-GMS (D. Del.). Pet. 1. Petitioner states that the pending lawsuit includes certain other patents and that the Petitioner has filed concurrently other petitions for *inter partes* review challenging the validity of those patents. *Id*. Since the filing of those petitions, several have terminated; *Smith & Nephew, Inc. v. Bonutti Skeletal Innovations LLC*, IPR2013-00605, challenging U.S. Patent No. 7,749,229, remains pending.

B. 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.

"Accurate alignment of knee implants is essential for the success of total knee replacement." Ex. 1003, p. 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. 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 (Exhibit 1005) depict

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

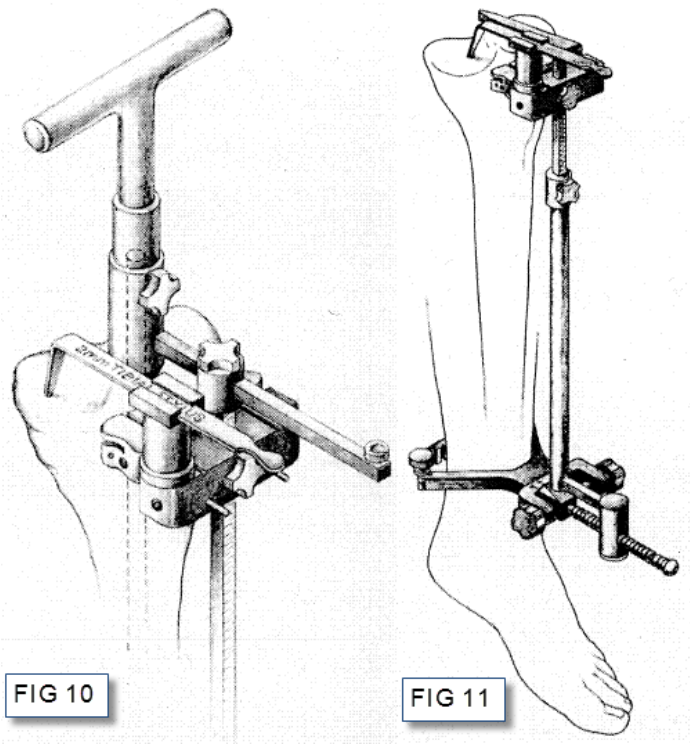

Figure 10 depicts a cutting guide secured to a patient using an intramedullary rod inserted into the medullary canal of the tibia. Ex. 1002 ¶ 34. Figure 11 depicts a cutting guide secured to a patient using an extramedullary rod strapped to the patient's ankle. *Id.*

C. The '896 Patent (Ex. 1001)

The '896 patent, titled "KNEE ARTHROPLASTY METHOD," issued October 5, 2010 from U.S. Patent Application No. 10/722,102, filed November 25, 2003. 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.

The '896 patent claims methods for performing knee replacement surgery.[1] The '896 patent discusses alignment systems that do not use intramedullary and/or extramedullary rods. Such alternative alignment systems are described as including percutaneous mounting (exterior mounting, through the skin), and the use of computer imaging devices. Ex. 1001, 38:9-12 (percutaneous mount), 36:55-62, 72:7 *et seq*. (computer imaging). Claim 1 specifies that the position of the cutting guide is determined "using references derived independently from an intramedullary device," and that the cutting guide is secured to the bone "free of an extramedullary or intramedullary alignment rod." Claim 13 specifies that the cutting guide is "positionable . . . using references derived independently from an intramedullary device."

The '896 patent also highlights the importance of smaller incisions, "[t]he benefits of [which] include improved cosmetic results, improved rehab, less dissection of muscle and soft tissue, and preservation of the quadriceps mechanism." *Id*. at 15:15-18. In order to have smaller incisions, smaller instruments must be used. *Id*. at 17:48-59. Claims 1 and 13 both specify that the "replacement portion [of the knee] ha[s] a transverse dimension that is larger than a transverse dimension of the [cutting] guide surface."

Lastly, the '896 patent considers the use of disposable cutting blocks that "could easily be modified for new or updated instrumentation or for customized instrumentation." *Id*. at 108:19-21. Claim 13 recites steps of

[1] Claim 1: "[a] method of replacing at least a portion of a patient's knee." Claim 13: "[a] method of replacing at least a portion of a joint . . . attaching a replacement portion of the knee."

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