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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMMER HOLDINGS, INC. and ZIMMER, INC., Petitioner,

v.

BONUTTI SKELETAL INNOVATIONS LLC, Patent Owner

> Case IPR2014-00321 Patent 7,806,896 B1

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

SAINDON, Administrative Patent Judge.

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

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I. INTRODUCTION

Petitioner filed a corrected petition (Paper 7, "Pet.") requesting an *inter partes* review of claims 40-47 of U.S. Patent No. 7,806,896 B1 (Ex. 1001, "the '896 patent") pursuant to 35 U.S.C. § 311-319. Patent Owner 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 claims 40-42 and 44-47, but not claim 43, of the '896 patent. Accordingly, pursuant to 35 U.S.C. § 314, we authorize an *inter partes* review to be instituted only as to claims 40-42 and 44-47 of the '896 patent.

A. Related Proceedings

Petitioner states that the '896 patent is involved in co-pending district court proceeding *Bonutti Skeletal Innovations LLC v. Zimmer, Inc.*, 1:12-cv-01107-GMS (D. Del.). Pet. 1. Petitioner also states the '896 patent is involved in *Smith & Nephew, Inc. v. Bonutti Skeletal Innovations LLC*, IPR2013-00629 ("Smith & Nephew IPR"). *Id*. We note that a trial was commenced in the Smith & Nephew IPR on February 28, 2014 (Paper 10), and also note that another petition, *Wright Medical Group, Inc. v. Bonutti Skeletal Innovations LLC*, IPR2014-00354, was filed against the '896 patent.

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B. 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. Ex. 1001 at [21], [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. Ex. 1001 at [63].

Claim 40 is the sole independent claim challenged, and is directed to a method for performing joint replacement surgery. An alignment guide is custom fabricated for the patient based on patient imaging information. Ex. 1001, 116:18-24. A cutting guide is referenced to the alignment guide, and using the cutting guide, a cut is made. *Id.* at 116:25-31. Claims 41-47 dependent directly or indirectly from independent claim 40.

D. Illustrative Claim

Independent claim 40 is the only independent claim challenged and is reproduced below.

40. A method of replacing at least a portion of a joint in a patient, the method comprising the steps of:

obtaining an alignment guide positionable on a bone using references derived independently of an intramedullary device, wherein the alignment guide is custom fabricated for the patient based on patient imaging information;

positioning the alignment guide in relation to the surface of an unresected bone of the joint;

referencing a cutting guide with respect to the alignment guide; and

cutting the unresected bone of the joint for the first time, by moving a cutting tool along a guide surface of the cutting guide. Case IPR2014-00321 Patent 7,806,896 B1

Id. at 116:18-31.

E. The Asserted Prior Art

Petitioner relies on the following prior art:

| Reference | Number | Issued/Published | Exhibit |
|------------------|--------------|------------------|---------|
| Androphy | US 4,567,885 | Feb. 4, 1986 | 1005 |
| Radermacher '157 | WO 93/25157 | Dec. 23, 1993 | 1003 |
| Insall | US 6,068,658 | May 30, 2000 | 1006 |

Klaus Radermacher et al., *Computer-Integrated Orthopaedic Surgery: Connection of Planning and Execution in Surgical Intervention*, in *Computer-Integrated Surgery* (Russell H. Taylor et al. eds., 1996) ("Radermacher Article") (Ex. 1004).

Zimmer Holdings, Inc. and Zimmer, Inc., *casey total knee*, (1976) ("Casey") (Ex. 1007).

Zimmer Holdings, Inc. and Zimmer, Inc., NexGen® Complete Knee Solution, (1996) ("NexGen") (Ex. 1008).

| References | Basis | Claims |
|------------------------------------------|------------|----------------|
| | | Challenged |
| Radermacher '157 and Radermacher Article | §§ 102/103 | 40, 41, 44, 45 |
| Radermacher '157, Radermacher Article, | §§ 102/103 | 42 |
| and NexGen | | |
| Radermacher '157, Radermacher Article, | § 103 | 43 |
| Androphy and/or Casey | | |
| Radermacher '157, Radermacher Article, | §§ 102/103 | 46, 47 |
| and Insall | | |
| Radermacher '157, Radermacher Article, | § 103 | 40, 42 |
| and NexGen | | |

F. The Asserted Grounds

II. ANALYSIS

A. Claim Construction

As a step in our analysis for determining whether to institute a trial,

we determine the meaning of the claims. Consistent with the statute and

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legislative history of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 329 (2011), claims of unexpired patents are construed by applying the broadest reasonable interpretation in light of the specification. 37 C.F.R. § 42.100(b); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Under the broadest reasonable interpretation standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Regarding claim construction, Petitioner points out that "alignment guide" and "cutting guide," as claimed, recite two distinct elements. Pet. 26-27. We agree. The specification of the '896 patent shows, for example, extramedullary alignment guide 504 upon which tibial resection (cutting) guide 500 is placed. Ex. 1001, 44:21-30, figs. 37, 38.

B. Asserted Grounds of Unpatentability

1. <u>Radermacher '157 (Ex. 1003) and</u> the Radermacher Article (Ex. 1004)

Petitioner asserts that the subject matter of claims 40, 41, 44, and 45 would have been obvious in view of Radermacher '157 and the Radermacher Article.¹ Pet. 27-32.

¹ While Petitioner presents the ground as one based on anticipation or obviousness, the ground includes two references and a discussion regarding their combination. We treat the ground presented as one directed to obviousness.

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