

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*.

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

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.

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.

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).

F. The Asserted Grounds

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

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

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. Radermacher ’157 (Ex. 1003) and 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.

Radermacher '157 discloses an individual template obtained by imaging a patient's bone structure and forming a surface of the template to correspond to the bone structure. Ex. 1003, 10.² Tool guides can be mounted thereon. *Id.* at 11. The individual template can be used to perform different types of surgeries, such as knee surgery. *Id.* at 30, figs. 13a-13d.

The Radermacher Article discusses the individual template in additional detail. For example, the individual template can be used as a way to position and orient reusable cutting guides and tools relative to the patient's anatomy. Ex. 1004, 456.³

The subject matter of challenged claim 40 is directed to a method of performing joint surgery using a custom fabricated alignment guide. Ex. 1001, 116:18-24. Petitioner asserts that Radermacher '157 discloses an alignment guide (individual template) custom fabricated based on patient imaging. Pet. 28-30 (citing Ex. 1003, 10-12). Petitioner asserts that Radermacher '157 discloses referencing a cutting guide (drill sleeve) using the alignment guide, and further points to the Radermacher Article as disclosing how cutting guides are fixed to the custom fabricated alignment guides. Pet. 29-30 (citing Ex. 1003, 10-12; Ex. 1004, 454-455). Petitioner asserts that it would have been obvious to consult the Radermacher Article for additional teachings and details because it has the same author and is directed to the same individual template technology. Pet. 28.

² All references to page numbers in Radermacher '157 are to the page numbers originally in the reference (top center), not the page numbers added by Petitioner (bottom right, preceded by "Ex. 1003").

³ All references to page numbers in the Radermacher Article are to the page numbers originally in the reference (bottom right or bottom left), not the page numbers added by Petitioner (bottom right, preceded by "Ex. 1004").

Challenged claim 41 depends from claim 40 and specifies that the particular type of surgery is total knee replacement surgery. Ex. 1001, 11:32-33. Petitioner asserts that Radermacher '157 discloses its customized individual template as being applicable to total knee replacement surgery. Pet. 31 (citing Ex. 1003, 30, figs. 13a-13d, depicting an individual template used to perform knee replacement). Claim 44 specifies that the joint can be a knee. Ex. 1001, 116:40-42. Petitioner asserts Radermacher '157 discloses the joint is a knee. Pet. 31 (citing Ex. 1003, 30, figs 13a-13d). Claim 45 specifies that a portion of the articulating surface of the joint is replaced. Ex. 1001, 116:43-45. Petitioner asserts Radermacher '157 discloses replacing at least a portion of the condyles of the femur (i.e., of the knee joint). Pet. 31-32 (citing Ex. 1003, 30, figs. 13a-13d, depicting a resected femur).

Having reviewed Petitioner's assertions and the cited portions of the record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on its contention that the subject matter of claims 40, 41, 44, and 45 would have been obvious in view of Radermacher '157 and the Radermacher Article.

2. Radermacher '157,
the Radermacher Article, and
optionally NexGen (Ex. 1008)

Claim 42 depends from claim 40 and adds a step of positioning a pin into the bone to secure the cutting guide to the bone. Ex. 1001, 116:34-37. Petitioner asserts that the Radermacher disclosures "inherently or expressly teach . . . positions of pins used to secure standard cutting guides to the bone," and relies on the declaration of Dr. Erdman (Ex. 1002), who, in turn, points to pages 454-455 of the Radermacher Article. Pet. 32 (citing Ex.

1002 ¶ 92). Reviewing this portion of the Radermacher Article, we find the individual template is described as having “reference points (bores) for the fixation of reusable standard tool guides [to the individual template],” and “[o]ptional fixation of the template on bone by small pins or screws.” Ex. 1004, 455. Accordingly, pins are inserted into the bone to secure the alignment guide (individual template) to the bone, which, in turn, secures the cutting guide (tool guide, secured to the alignment guide) to the bone. Petitioner’s assertions with respect to claim 42 persuade us that it has a reasonable likelihood of prevailing on its contention that the subject matter of claim 42 would have been obvious in view of Radermacher ’157 and the Radermacher Article.

Petitioner also asserts that NexGen discloses a step of positioning a pin in a bone to secure a cutting guide. Pet. 32-33. However, Petitioner proposes to incorporate this feature into the disclosures of Radermacher ’157 and the Radermacher Article for the sole reason that each “relate to total knee replacement instruments.” *Id.* at 32. At best, Petitioner indicates that these prior art references are analogous art. However, merely pointing out that a reference is analogous art does not amount to providing an articulated reason with a rationale underpinning to support a conclusion of obviousness. As such, we determine that Petitioner has not provided sufficient rationale to support its asserted ground on the basis of Radermacher ’157, the Radermacher Article, and NexGen. Accordingly, we do not institute an inter partes review of claim 42 based on obviousness over Radermacher ’157, the Radermacher Article, and NexGen. *See* 37 C.F.R. § 42.108(a).

3. Radermacher '157,
the Radermacher Article, and either
Androphy (Ex. 1005) or Casey (Ex. 1007)

With respect to claim 43, Petitioner asserts that it would have been obvious to include teachings from Androphy or Casey into the disclosures of the individual templates in Radermacher '157 and the Radermacher Article because these references “all relate to total knee replacement instruments.” Pet. 34. As above, arguing that references are analogous art is insufficient, by itself, to show it would have been obvious to combine the teachings of those references in a particular manner to arrive at the claimed invention. As such, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in its contention that the subject matter of claim 43 would have been obvious in view of Radermacher '157, the Radermacher Article, and either Androphy or Casey.

4. Radermacher '157,
the Radermacher Article, and
Insall (Ex. 1006)

Claim 46 depends from claim 45 and specifies that the replacement is made of a particular material. Ex. 1001, 116:46-51. Petitioner asserts that it would have been implicit or obvious from the disclosures of Radermacher '157 and the Radermacher Article to use metal because “it was common knowledge at the time of the invention that femoral implants could be formed from metal.” Pet. 36. In support of this assertion, Petitioner cites to Insall, which, in turn, discloses a meniscal component made of metal and plastic. *See* Pet. 38 (citing Ex. 1006, 4:63). In view of this, we are persuaded by Petitioner’s assertion, and determine Petitioner has demonstrated a reasonable likelihood of prevailing in its contention that the subject matter of claim 46 would have been obvious in view of Radermacher

'157, the Radermacher Article, and Insall.

Claim 47 depends from claim 40 and specifies that the joint has a plurality of articulating surface compartments, and at least a portion of the articulating surface is not replaced in all articulating surface compartments. Ex. 1001, 116:52-55. Petitioner asserts that the Radermacher references and Insall disclose replacing the articulating surface of the condyles, but not the articulating surface of the patella. Pet. 37. Thus, Petitioner concludes that it would have been obvious to a person of ordinary skill in the art to not replace all articulating surface components. *Id.* at 37-38 (citing Ex. 1002 ¶¶ 97, 98). Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in its contention that the subject matter of claim 47 would have been obvious in view of Radermacher '157, the Radermacher Article, and Insall.

5. Radermacher '157,
the Radermacher Article, and
NexGen

Petitioner asserts claims 40 and 42 are unpatentable over these references. Pet. 39-40. We are not persuaded Petitioner has demonstrated a reasonable likelihood of prevailing on this ground because Petitioner, in the manner we discussed above, has not provided an articulated reason with a rational underpinning in support of the proposed combination. *See* Pet. 39-40 (“Since [the three references] all relate to total knee arthroplasty, it would have been obvious to . . .”).

C. Conclusions

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 40-42 and 44-47 of the '896 patent are unpatentable.

We conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claim 43 of the '896 patent is unpatentable.

At this stage of the proceeding, we have not made a final determination on the patentability of any claim.

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that we authorize an *inter partes* review of claims 40-42 and 44-47, but do not authorize an *inter partes* review as to claim 43;

FURTHER ORDERED that that this proceeding is authorized as to the following grounds presented in the petition:

A. Claims 40-42, 44, and 45 under 35 U.S.C. § 103 as obvious in view of Radermacher '157 and the Radermacher Article.

B. Claims 46 and 47 under 35 U.S.C. § 103 as obvious in view of Radermacher '157, the Radermacher Article, and Insall.

FURTHER ORDERED that no other grounds set forth in the petition are authorized;

FURTHER ORDERED that this decision is to be considered as entered simultaneously with the decision to institute in IPR2014-00354; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of the '896 patent is instituted, commencing on the entry date of this Decision, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is given of the institution of a trial.

Case IPR2014-00321
Patent 7,806,896 B1

PETITIONER:

Walter Linder
Daniel Lechleiter
FAEGRE BAKER DANIELS LLP
Walter.Linder@FaegreBD.com
Daniel.Lechleiter@FaegreBD.com
patentdocketing@faegrebd.com

PATENT OWNER:

Cary Kappel
William Gehris
DAVIDSON, DAVIDSON & KAPPEL, LLC
ckappel@ddkpatent.com
wgehris@ddkpatent.com