

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

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) and 37 C.F.R. § 42.73.

With respect to the grounds asserted in this trial, we have considered the papers submitted by the parties and the evidence cited therein. For the reasons discussed below, we determine that claim 42, the only remaining challenged claim of U.S. Patent No. 7,806,896 B1 (Ex. 1001, “the ’896 patent”), is unpatentable.

A. Procedural History

Zimmer Holdings, Inc. and Zimmer, Inc. (“Petitioner”) filed a corrected Petition requesting an *inter partes* review of claims 40–47 of the ’896 patent. Paper 7 (“Pet.”). Petitioner included a Declaration of Dr. Arthur G. Erdman, Ph.D. Ex. 1002. Bonutti Skeletal Innovations, LLC (“Patent Owner”) elected not to file a Preliminary Response to the Petition. Paper 12.

In our Decision Instituting *Inter Partes* Review, we granted review as to some of the challenged claims, namely, claims 40–42 and 44–47, but not claim 43. Paper 13 (“Dec. Inst.”). Patent Owner filed a Response to the Petition (Paper 28, “PO Resp.”). Patent Owner also filed notices indicating that it disclaimed claims 40, 41, and 44–47, leaving only claim 42 remaining of the challenged claims. Papers 15, 27; Exs. 2001, 2002. Petitioner then filed a Reply to the Response (Paper 31, “Pet. Reply”).

B. Related Matters

Petitioner states that the ’896 patent is involved in a co-pending district court proceeding titled *Bonutti Skeletal Innovations LLC v. Zimmer*,

Inc., 1:12-cv-01107-GMS (D. Del.). Paper 19, 1. The '896 patent also is discussed in a Final Written Decision determining claim 1 of the '896 patent to be unpatentable. *Smith & Nephew, Inc. v. Bonutti Skeletal Innovations LLC*, Case IPR2013-00629, slip op. at 35 (PTAB Feb. 18, 2015) (Paper 31).¹

C. The '861 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, [54], [45], [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. *Id.* at [63].

Claim 42 is the sole remaining claim challenged, and depends from independent claim 40. Independent claim 40 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. Claim 42 specifies how the “referencing” step is performed. *Id.* at 116:34–37.

D. Challenged Claim

Claim 42, which depends from claim 40, is the sole remaining challenged claim. Claims 40 and 42 of the '896 patent are reproduced below:

¹ *Wright Medical Group, Inc. v. Bonutti Skeletal Innovations LLC*, Case IPR2014-00354, was joined to IPR2013-00629.

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.
42. The method of claim 40, wherein referencing the cutting guide includes positioning a pin into the bone to secure the cutting guide to the bone and wherein the pin position is determined by the alignment guide.

Ex. 1001, 116:18–31, 34–37.

E. Asserted Grounds and Prior Art

The sole remaining ground in this proceeding is whether claim 42 is obvious in view of Radermacher '157² and the Radermacher Article.³

² WO 93/25157, published Dec. 23, 1993 (Ex. 1003).

³ 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).

II. ANALYSIS

A. Claim Construction

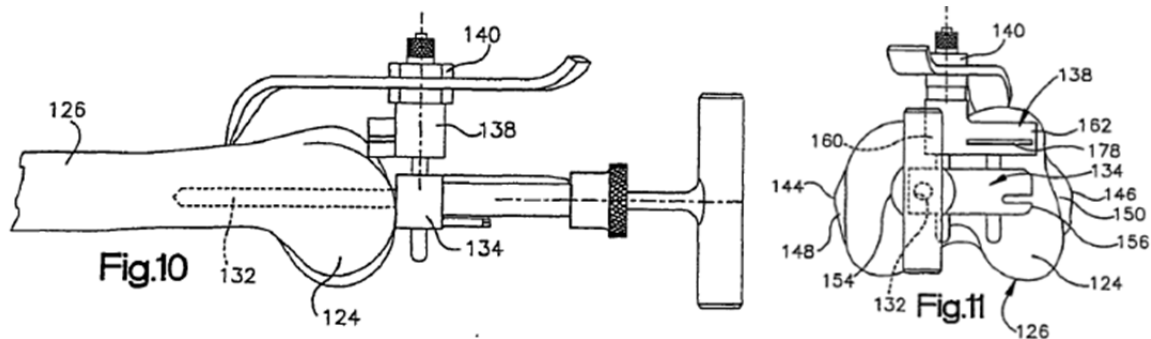
We interpret the claims of an unexpired patent using the broadest reasonable interpretation in light of the specification of the patent. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1281–82 (Fed. Cir. 2015). Under the broadest reasonable interpretation standard, claim terms 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).

Claim 40 includes a step of “positioning” an alignment guide “in relation to the surface of an unresected bone.” Ex. 1001, 116:25–26. The claim also includes a step of “referencing” a cutting guide with respect to the alignment guide. *Id.* at 116:27–28. Claim 42 further defines the “referencing” step, specifying that the step “includes positioning a pin into the bone to secure the cutting guide to the bone,” wherein the pin position is “determined by the alignment guide.” *Id.* at 116:34–37. A dispositive issue in this proceeding turns on the proper construction of these limitations.

Petitioner argues that the above limitations read on a procedure wherein an alignment guide is secured to the bone using pins and then a cutting guide is secured to the alignment guide, the pins thus securing the cutting guide to the bone via the alignment guide. *See* Pet. Reply 3–5. Patent Owner argues that the above limitations do not read on such a procedure, and that these limitations require that the cutting guide is secured

directly on the bone by pins. *See* PO Resp. 8–18. Petitioner replies that the claims simply recite that the “referencing . . . includes positioning a pin” and does not preclude the pin being used to secure the alignment guide, which, in turn, secures the cutting guide. *See* Pet. Reply 5–6.

In construing these limitations, we first turn to the specification. We are unable, however, to locate any description of a “referencing” step involving a cutting guide.⁴ With respect to how a cutting guide is attached to the femur, the ’896 patent describes, in one embodiment, *both* the alignment guide and the resection (cutting) guide as “connected with the femur” and “mounted on the . . . femur” even though only the alignment guide is directly connected to the femur. Ex. 1001, 19:44–50, 20:10–13. This arrangement is depicted in Figures 10 and 11, reproduced below.



⁴ The “referencing” step was not found in an original claim. It first appeared in new claim 58 in an amendment received June 25, 2009—that amendment did not discuss the new claim or the new limitation and simply stated “[n]o new matter has been added.” Ex. 3001, 14 (Response to Office Action, received June 25, 2009). The Examiner subsequently indicated that claim 58 was allowable, without explanation or analysis. Ex. 3002, 4 (Final Rejection, mailed Sept. 22, 2009).

Figures 10 and 11 of the '896 patent depict alignment guide 134 secured to femur 126 via intramedullary rod 132.⁵ Ex. 1001, 19:44–49, 20:10–17, 23:18–20. Cutting guide 138 is secured to alignment guide 134 via two pins (unlabeled). *See id.* at 17:39–41.

Patent Owner argues that when the claims state “securing a cutting guide to the bone,” they mean securing the cutting guide directly to the bone. *See, e.g.*, PO Resp. 9. In view of the above disclosures of the '896 patent, however, we are persuaded that a person of ordinary skill in the art reading the '896 patent would have understood that a cutting guide is secured to a bone even if it is secured indirectly by way of an alignment guide.

In addition, we are not persuaded that “positioning a pin . . . to secure the cutting guide” requires that, immediately after positioning the pin, the cutting guide is secure. Instead, the claim simply requires that positioning a pin secures the cutting guide; it does not say when this occurs. Thus, an action of placing a pin into a bone to secure an alignment guide *also* serves to secure a cutting guide to the bone once the cutting guide is attached to the bone via the alignment guide. Accordingly, we are not persuaded that the broadest reasonable interpretation of the “referencing” step, as further defined in claim 42, requires that the cutting guide is secured directly to the bone, that the claimed pins secure only the cutting guide to the bone, or that

⁵ We recognize that claim 40 is directed to a custom alignment guide positionable using references derived independently of an intramedullary device, and that Figures 10 and 11 depict an intramedullary device. We refer to the embodiments depicted in Figures 10 and 11, however, because, aside from the custom guide aspect, the examples and description of those figures are informative as to remainder of the claimed steps.

the cutting guide is secured to the bone immediately upon positioning the pins.

B. Radermacher '157 and the Radermacher Article

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, 10.⁶ 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 an 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, 455–56.⁷ The individual template also may be affixed to the bone using pins or screws. *Id.*

C. Petitioner's Asserted Ground

Petitioner asserts that the subject matter of claim 42, which depends from claim 40, is obvious in view of Radermacher '157 and the Radermacher Article. Pet. 27–31, 32–34. Regarding the “obtaining an alignment guide” limitation, Petitioner alleges that both references disclose

⁶ 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”).

⁷ 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”).

an individual template customized to a particular person's anatomy using, for example, tomography. Pet. 29–30 (citing Ex. 1002 ¶¶ 87–88; Ex. 1003, 10–12; Ex. 1004, 454–455).

Regarding the “positioning the alignment guide” limitation, Petitioner alleges that Radermacher '157 discloses that the individual template is placed onto the exposed surface of the bone. Pet. 30 (citing Ex. 1003, 11, 30, Figs. 13a, 13c; Ex. 1002 ¶ 90).

Regarding the “referencing a cutting guide” limitation, Petitioner alleges that Radermacher '157 discloses that the individual templates include attachment points for “standardized tool guides” or a “drill sleeve.” Pet. 30–31 (citing Ex. 1003, 11, 30, Figs. 13a, 13c; Ex. 1002 ¶¶ 64, 88). Petitioner further alleges that the Radermacher Article discloses that the individual template (alignment guide) is secured to the bone with pins. Pet. 33–34 (citing Ex. 1004, 454–455; Ex. 1002 ¶ 88).

Regarding the “cutting the unresected bone” limitation, Petitioner alleges that Radermacher '157 discloses cutting an unresected bone. Pet. 31 (citing Ex. 1003, 30, Figs. 13a, 13c; Ex. 1002 ¶¶ 65, 90).

Petitioner alleges that it would have been obvious to combine the teachings of Radermacher '157 and the Radermacher Article because they are both written by the same author and are directed to the same individual-template technology. Pet. 27–28 (citing Ex. 1002 ¶¶ 46–72, 86–91, 94, 95). Petitioner also alleges that it would have been obvious that these references “inherently or expressly teach the use of the individual templates . . . as guides for determining the positions of pins used to secure standard cutting guides to the bone.” Pet. 32 (citing Ex. 1002 ¶ 92).

D. Patent Owner's Arguments

Patent Owner's chief argument is that none of Radermacher '157 (PO Resp. 8–10), the Radermacher Article (*id.* at 10–11), and their respective combination (*id.* at 12–18) teach that “referencing the cutting guide includes positioning a pin into the bone to secure the cutting guide to the bone and wherein the pin position is determined by the alignment guide.” Patent Owner also argues that neither reference inherently teaches such a limitation. *Id.* at 18–20.

E. Analysis

Petitioner has shown that the Radermacher Article describes an individual template (alignment guide) that is secured to the bone using pins. Ex. 1004, 455 (“Optional fixation of the template on bone by small pins or screws can be useful”). Further, Petitioner has shown that the Radermacher Article describes the individual template having reference points for the attachment of standard tool guides (cutting guides). *Id.* (“Alternatively, we have to define reference points (bores) for the fixation of reusable standard tool guides.”). Based on these showings, we are persuaded that the Radermacher Article discloses that “pin position is determined by the alignment guide” because the pins are used to secure the individual template (alignment guide) and, thus, the pin position is determined by whatever bore is provided by the alignment guide for those pins. Further, we are persuaded that the Radermacher Article discloses “referencing a cutting guide with respect to the alignment guide” because the standard tool guide (cutting guide) is mounted to the individual template (alignment guide) in the proper position by using the provided reference points.

Where Petitioner and Patent Owner disagree is whether the act of securing Radermacher's individual template to the bone using pins, and then securing the standard tool guide to the individual template, satisfies the limitation in claim 42 of "wherein referencing the cutting guide includes positioning a pin into the bone to secure the cutting guide to the bone and wherein the pin position is determined by the alignment guide." Consistent with our analysis of this limitation in our claim construction section, we are persuaded that "positioning a pin into the bone to secure the cutting guide to the bone" is satisfied by the actions of first positioning a pin into the bone to secure the alignment guide, and then securing the cutting guide to the alignment guide. That is, the action of positioning the pin into the bone to secure the alignment guide to the bone also serves to secure the cutting guide to the bone once the cutting guide is secured to the alignment guide.

We are not persuaded by Patent Owner's arguments that such positioning is not part of any "referencing" step, because referencing the cutting guide to the alignment guide relies on the alignment guide being properly positioned, such that anything that serves to align the alignment guide also serves to align the cutting guide. Further, claim 42 states that the referencing step *includes* positioning a pin; the claim does not state that the entire referencing step consists solely of positioning a pin. Nor does the claim require positioning a pin into a cutting guide to secure the cutting guide to the bone. Lastly, as we discussed in the claim construction section, Petitioner's reading of the claim on the prior art is commensurate with the specification, which considers a cutting guide to be "mounted" or "connected" to a femur, terms synonymous with "secure," even when there is no direct contact between the bone and cutting guide.

In view of the above, we are persuaded that Petitioner has shown, by a preponderance of the evidence, that the combined disclosure of Radermacher '157 and the Radermacher Article teach all the limitations of claim 42 in the manner required by the claim.

III. RESULTS OF THE PROCEEDING

Patent Owner has disclaimed claims 40, 41, and 44–47 of the '896 patent. Papers 15, 27; Exs. 2001, 2002.

Petitioner has shown by a preponderance of the evidence that the subject matter of claim 42 of the '896 patent would have been obvious to a person of ordinary skill in the art at the time of the invention in view of Radermacher '157 and the Radermacher Article. *See supra* Section II(A–E).

IV. ORDER

In view of the foregoing, it is hereby:

ORDERED that claim 42 of U.S. Patent No. 7,806,896 B1 is unpatentable; and

FURTHER ORDERED that, because this is a final written decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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