

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:

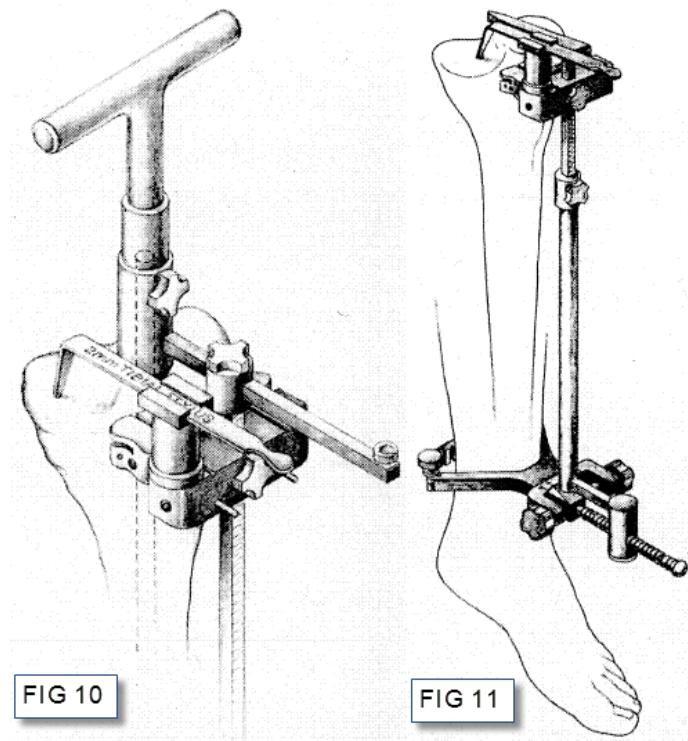


Figure 10 depicts a cutting guide secured to a patient using an intramedullary rod inserted into the medullary canal of the tibia. Ex. 1002 ¶ 34. Figure 11 depicts a cutting guide secured to a patient using an extramedullary rod strapped to the patient's ankle. *Id.*

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.”

“obtaining a customized cutting guide fabricated for the patient based on preoperative information” and “disposing of the cutting guide.”

D. Exemplary Claims

Claims 1 and 13 are the only claims challenged. Pet. 2. Both are independent and are reproduced below.

1. A method of replacing at least a portion of a patient's knee, the method comprising the steps of:
 - making an incision in a knee portion of a leg of the patient;
 - determining a position of a cutting guide using references derived independently from an intramedullary device;
 - positioning a cutting guide using the determined position, passing the cutting guide through the incision and on a surface of a distal end portion of an unresected femur, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod;
 - moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and
 - forming at least an initial cut on the femur by moving the cutting tool along the guide surface;
 - attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

Ex. 1001, 112:60-113:10.

13. A method of replacing at least a portion of a joint in a patient, the method comprising the steps of:
 - obtaining a customized cutting guide fabricated for the patient based on preoperative information, the cutting guide positionable in a pre-determined position on a bone of the joint using references derived independently from an intramedullary device;
 - making an incision adjacent to the joint in the patient;
 - positioning the cutting guide in the pre-determined position by passing the cutting guide through the incision and on

a surface of an end portion of an unresected bone of the joint;
 moving a cutting tool through the incision into engagement with a guide surface on the positioned cutting guide;
 cutting the unresected bone of the joint for the first time, by moving the cutting tool along the guide surface;
 attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface; and
 disposing of the cutting guide, as it is no longer safely usable the bone for which it was custom fabricated having been cut and therefore changed.

Id. at 113:64-114:21.

E. The Prior Art

Petitioner relies on the following prior art:

Reference	Number	Published	Exhibit
Delp '018	US 5,871,018	Feb. 16, 1999	1004
Radermacher '157	WO 93/25157	Dec. 23, 1993	1007

Scott L. Delp, *et al.*, “Computer Assisted Knee Replacement,” 354 Clinical Orthopaedics and Related Research (1998) (“Delp Article”) (Ex. 1003).

S. David Stulberg, *et al.*, “Computer-Assisted Total Knee Replacement Arthroplasty,” 10(1) Operative Techniques in Orthopaedics (Jan. 2000) (“Stulberg”) (Ex. 1005).

Klaus Radermacher, *et al.*, “Computer Assisted Orthopaedic Surgery With Image Based Individual Templates,” 354 Clinical Orthopaedics and Related Research (1998) (“Radermacher Article”) (Ex. 1006).

Roderick H. Turner, *et al.*, “Geometric and Anametric Total Knee Replacement,” in Total Knee Replacement (A.A. Savastano, M.D. ed. 1980) (“Turner”) (Ex. 1008).

Stryker Howmedica Osteonics, *Scorpio Single Axis Total Knee System – Passport Total A.R. Total Knee Instruments – Passport A.R. Surgical Technique* (May 2000)² (“Scorpio”) (Ex. 1009).

F. The Asserted Grounds

Reference(s)	Basis	Claims Challenged
Delp Article and either Turner or Scorpio	§103	1
Delp '018 and either Turner or Scorpio	§103	1
Stulberg and either Turner or Scorpio	§103	1
Radermacher '157	§102	13
Radermacher Article and either Turner or Scorpio	§103	13

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

² Petitioner asserts this reference is prior art under 35 U.S.C. § 102(b). Pet. 4. The reference indicates a copyright date of “2000” and “REV 05/00” on the back cover page. The Scorpio Single Axis Total Knee System is mentioned by name in the '629 patent as a “known anterior resection guide” that is “commercially available.” Ex. 1001, 18:27-31.

must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes constructions for three terms. Pet. 5-6.

Term	Found in Claims	Petitioner's Proposed Construction
"cutting guide"	1, 13	"guide that has a guide surface"
"guide surface"	1, 13	"a surface that guides a cutting instrument"
"customized cutting guide"	13	"a cutting guide modified for a specific patient"

These proposed constructions are consistent with the way these terms are used in the '896 patent's written description and represent their plain and ordinary meaning. *See* Pet. 5-6 (citing Ex. 1001, 24:57-59 ("cuts are made by moving the saw blade 170 or other cutting tool along the guide surfaces on the femoral cutting guide"); Exs. 1010, 1011, 1012 (providing dictionary definitions for "customize," a term not described in the specification of the '896 patent, outside of the claims)).

We adopt Petitioner's proposed constructions for purposes of this decision, and see no utility in further explanation at this time. Likewise, for purposes of this decision, all other terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art upon reviewing the specification, and need not be construed explicitly at this time.

B. Asserted Grounds of Unpatentability

Petitioner asserts five grounds of unpatentability; three addressing claim 1 only and two addressing claim 13 only. We discuss the ground addressing claim 1 and relying on Stulberg first.

1. Stulberg and either Turner or Scorpio

Petitioner asserts that the subject matter of claim 1 is obvious in view of Stulberg in combination with either Turner or Scorpio. Pet. 43-47. We first describe some features of these references before turning to the proposed grounds of unpatentability.

Stulberg (Ex. 1005)

Stulberg teaches that successful knee replacement surgery is driven by proper alignment of the replacements. Ex. 1005, p. 25. To that end, Stulberg discusses and contrasts computer-assisted total knee replacement arthroplasty with conventional, mechanically-assisted arthroplasty. *Id.* Stulberg states that the computer-assisted method “improve[s] the accuracy of the surgical technique.” *Id.* In the computer-assisted method, the surgeon uses the computer to align a cutting block over the bone, and then secures the cutting block using a wire. *Id.* at 30, fig. 16. The cuts are made and the replacement is fitted and tested. *Id.* at 32.

Stulberg contrasts the mechanical and computer-assisted techniques with respect to femoral cuts in further detail. Stulberg states that the mechanical technique uses an intramedullary rod; the rod is depicted in figure 15, reproduced below:

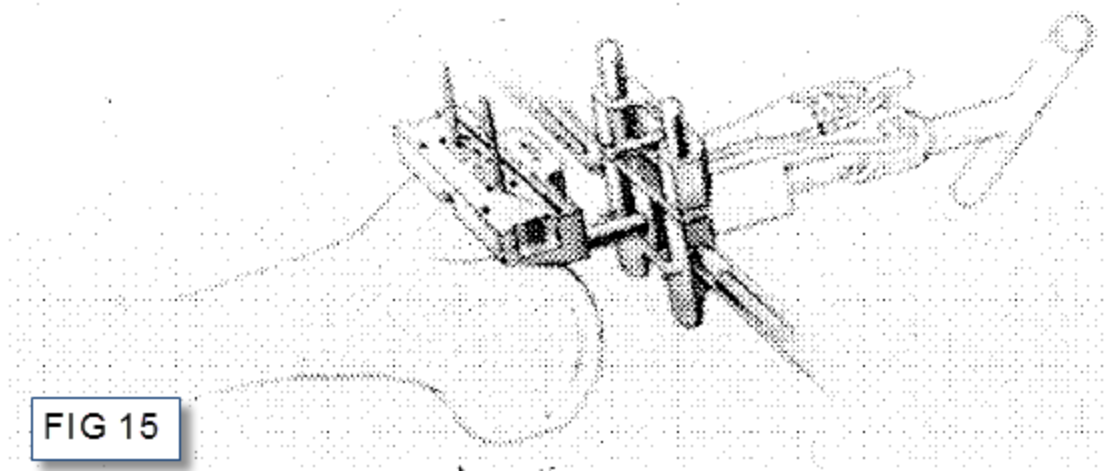


Figure 15 of Stulberg depicts an intramedullary rod (ghosted), introduced into the femoral medullary canal to secure the distal femoral cutting block. *Id.* at 35.

To contrast the mechanical technique, Stulberg presents figure 16B, showing the cutting block used in the computer-assisted technique, reproduced below:

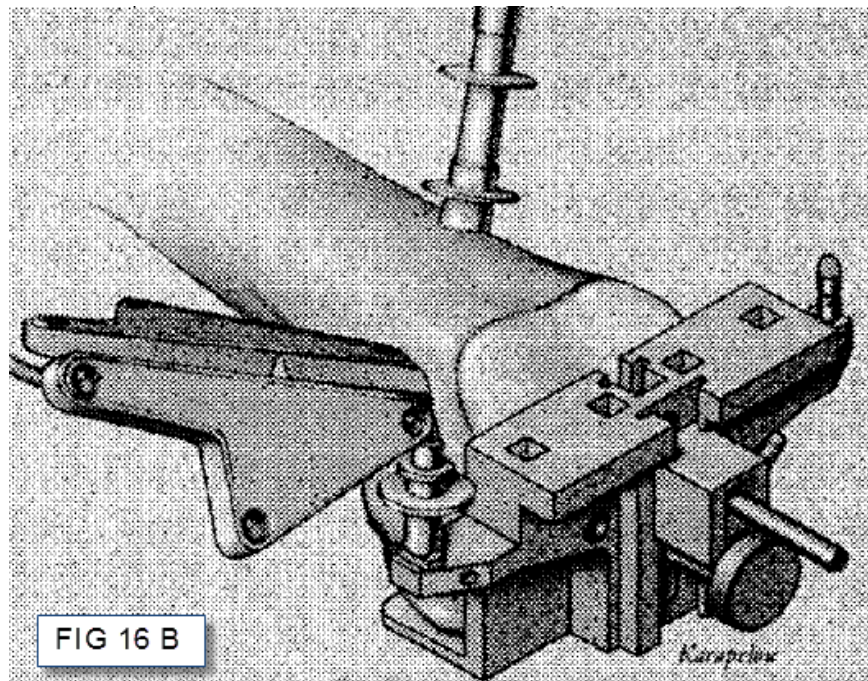


Figure 16B of Stulberg depicts the distal femoral cutting block placed in the

sagittal (front-rear) plane during the computer-assisted technique. *Id.* at 35. Figure 16B does not depict, nor does the accompanying text describe, an intramedullary or extramedullary rod, however, Figure 16B depicts the use of rigid bodies attached to the femur and the cutting block, which are tracked by a computer. *Id.* at 30. The cutting block is secured by threaded wire to the femur. *Id.*

Turner (Ex. 1008)

The Turner reference describes the state of the knee replacement art as of 1980. Ex. 1008, inside cover.³ Of importance to the discussion in this decision, Turner discloses a femoral cutting guide. *Id.* at fig. 8. “The femoral cutting guide is inserted in the midline, deep to the suprapatellar pouch.” *Id.* at 181.⁴ Figures 8 and 9 of Turner are reproduced below.

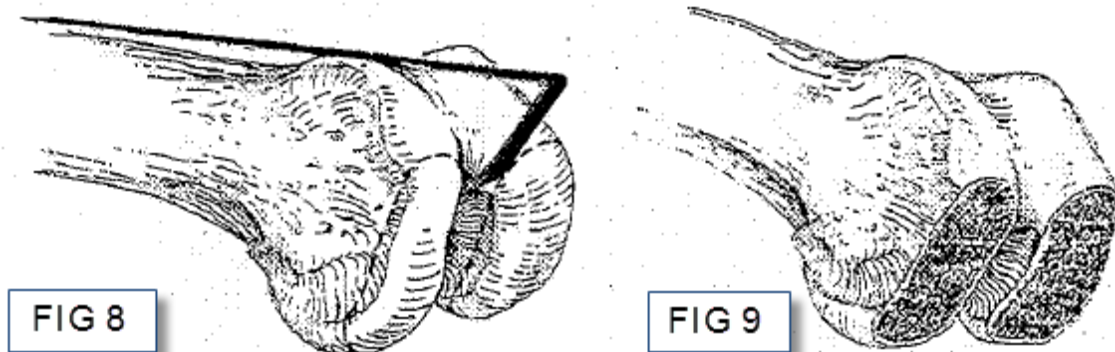


Figure 8 of Turner depicts a femoral cutting guide that fits in the midline of the femur, such that its width is much smaller than the width of the resected bone. Figure 9 depicts the resulting appearance of the femur after the cut.

³ This Exhibit begins with two unnumbered pages, which we refer to as the cover and inside cover.

⁴ The suprapatellar pouch extends between the quadriceps tendon and the front of the femur, and is an extension of the synovial sac that encloses and lubricates the knee joint.

The portions of the femur that are cut are later covered by the prosthesis. *See, e.g., id.*, fig. 20. Accordingly, the transverse dimension of the prosthesis will be larger than the transverse dimension of the cutting guide shown in figure 8. *See also* Pet. 33.

Scorpio (Ex. 1009)

The Scorpio reference provides instructions for surgeons installing the “*Scorpio*® Total Knee” replacement (Ex. 1009, p. 2) using the “Passport A/R” surgical technique and tools (*id.* at 1). *See also id.* at 48-49 (providing various product limitations and warnings). Of importance to the discussion in this decision, Scorpio discloses an anterior (frontal) femoral cutting guide. *Id.* at 9. After installing a femoral alignment guide onto the distal end of the femur (*see id.* at 4-8), the anterior resection guide is inserted on top of the femoral alignment guide (*id.* at 9-11). Figure 15 of Scorpio, which is reproduced below with annotations added, depicts the anterior resection guide placed on the femoral alignment guide.

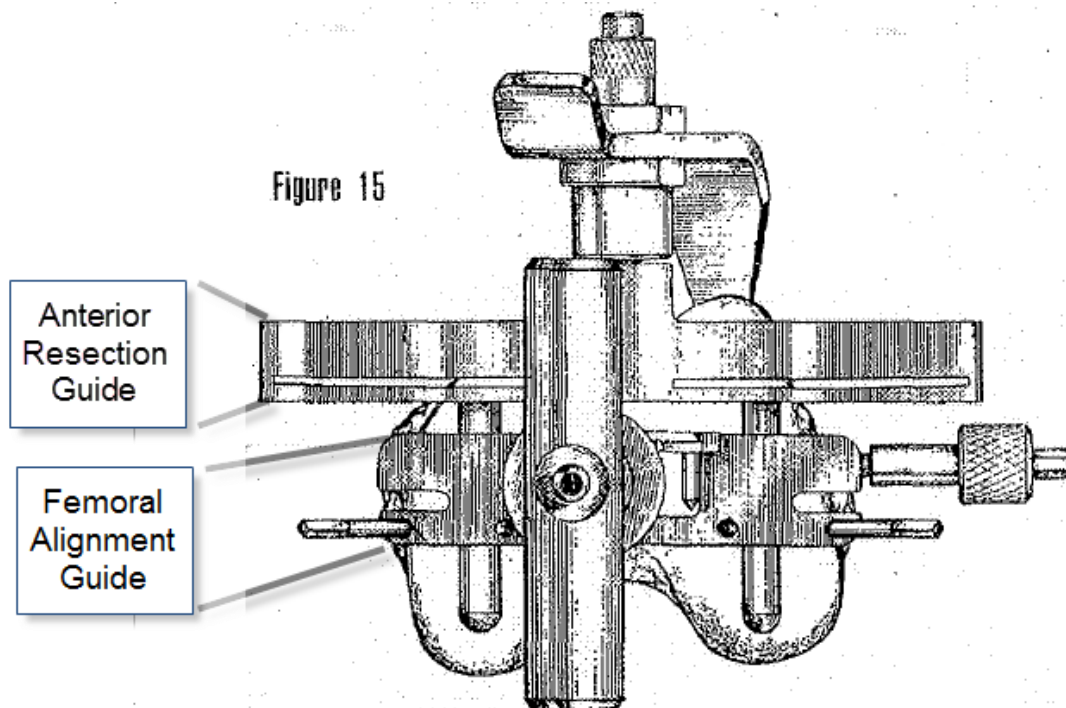


Figure 15 of Scorpio depicts an anterior resection guide having two laterally spaced cutting guide slots, the guide seated atop a femoral alignment guide attached to the distal end of the femur. *See also id.* at fig. 17 (depicting a saw inserted into one cutting guide slot).

The Stulberg-Turner and Stulberg-Scorpio Combinations

In the Petition, Petitioner asserts that Stulberg teaches every limitation of claim 1 except for the limitation, “the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.” Pet. 43-47. Petitioner asserts that Turner and Scorpio each disclose this feature. *Id.*

Petitioner asserts that the width of the cutting guide shown in Turner, figure 8, is substantially smaller than the implant. Pet. 33 (citing Ex. 1008, figs. 3, 8, pp. 177, 181; Ex. 1002 ¶ 69).

Petitioner also asserts that the width of the cutting guide shown in Scorpio, figure 15 (i.e., one of the slots), is smaller than the implant. Pet. 33 (citing Ex. 1009, pp. 2, 9, fig. 15; Ex. 1002 ¶ 70).

Petitioner asserts that it would have been obvious to use “the cutting guides and implants disclosed in Turner or Scorpio” along with the “computer-assisted system disclosed in Stulberg.” Pet. 45. Petitioner’s reason for such a combination is to “overcome the deficiencies of standard mechanical measuring techniques.” Pet. 45-46. Petitioner points to a declaration of Dr. Jay D. Mabrey, who declares that the proposed combination is “no more than the predictable use of prior art technology according to its established function to achieve a predictable result.” Ex. 1002 ¶ 92.

Discussion of the Stulberg-Turner and Stulberg-Scorpio Combinations

Based on the information provided in the Petition, Petitioner has shown a reasonable likelihood of prevailing in showing claim 1 to be unpatentable over Stulberg in combination with either Turner or Scorpio.

As we discussed above, Stulberg describes a method of replacing at least a portion of a patient's knee, including the steps of making an incision, positioning a cutting guide, and using the cutting guide to guide a cutting tool to form a cut. *See* Ex. 1005, fig. 2 (depicting the incision), fig. 16B (depicting a cutting guide on a femur), fig. 19B (depicting cuts), fig. 20A (depicting a trial implant); *see also* Ex. 1002 ¶¶ 29-41 (describing a typical knee replacement surgery); Pet. 43-47.

Reviewing Petitioner's citations and supporting analysis, discussed above, we address three limitations recited in claim 1 in further detail below.

“determining a position [without] an intramedullary device” (claim 1)

Stulberg describes a method of positioning a cutting guide using a computer. Ex. 1005, p. 30 (“The surgeon can then track on the monitor the position of the cutting block relative to the distal femur”). This computer-assisted technique is contrasted with the mechanical technique, in which positioning requires placing the cutting guide onto an intramedullary rod. *Id.* (“Mechanical technique[:] . . . The distal femoral cutting block device is placed onto the rod.”); *see also id.* at Abstract. (pointing out the superiority of computer-assisted procedures over the mechanically-assisted procedure); Ex. 1002 ¶ 87 (declaring that an intramedullary rod is not used in the computer-assisted technique). Further, the main purpose of the intramedullary device is to position the cutting guide (Ex. 1002 ¶ 34), a

function that would be redundant in view of more precise computer positioning. Based on these considerations, Petitioner's assertion (Pet. 44) that Stulberg's computer-assisted technique does not use an intramedullary rod to determine the position of the cutting guide is reasonable.

"the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod"(claim 1)

In the computer-assisted technique of Stulberg, the cutting guide is secured to the femur using wire. Ex. 1005, p. 30. In contrast, in the mechanical technique, the cutting guide is secured to the femur with pins. *Id.*; see also Ex. 1002 ¶ 88 (declaring that one of ordinary skill in the art would understand that no rod is used in Stulberg because wire is used instead). Further, the cutting guide used in the mechanical technique is depicted as attached to the rod of the intramedullary device (Ex. 1005, fig. 15), whereas no corresponding intramedullary rod is depicted in the analogous figure for the computer-assisted technique (*id.*, fig. 16). Accordingly, Petitioner's assertion that Stulberg's technique secures the cutting guide to the bone free of an extramedullary or intramedullary alignment rod (Pet. 44) is reasonable.

"the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface"(claim 1)

Turner

The femoral cutting guide in Turner is sized to fit in the groove between the condyles of the femur, which, in turn, are to be covered by the replacement. Ex. 1008, 181, 177. Thus, the relative size of the guide relative to the bone depicted in figure 8 sufficiently represents their true

spatial relationship to support a finding that the guide in Turner is smaller in a transverse dimension than the replacement. As such, based on this record, Petitioner has made a threshold showing that Turner describes the relative size relationship of the replacement portion and the guide surface as claimed.

Scorpio

Regarding Scorpio, close inspection of figure 15 of Scorpio (reproduced above) reveals that either one of the guides is narrower than the distal end of the femur to be replaced, and, thus, would be smaller than the replacement of that portion of the femur. *See also* Ex. 1002 ¶ 70 (“the implant is approximately the width of the thighbone”). It is well established that patent drawings are typically not to scale, however, and that written support for the proportional relationship is generally necessary to support such findings. *See, e.g., Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.* 222 F.3d 951, 956 (Fed. Cir. 2000) (“it is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue”) *but see In re Mraz*, 455 F.2d 1069, 1072 (CCPA 1972) (notwithstanding the general rule, “things patent drawings show clearly are [not] to be *disregarded*.”). While Scorpio is not a patent, the rationale behind the *Hockerson-Halberstadt* and *Mraz* holdings is instructive with respect to drawings in non-patent literature such as Scorpio. To that end, we determine whether it is reasonable to rely on the particular size relationship depicted in figure 15 of Scorpio.

Petitioner does not offer an explanation, and merely cites to Dr. Mabrey’s declaration, which, in turn, offer no more explanation than the

Petition. Pet. 33; Ex. 1002 ¶¶ 69-70. We do not find any explicit discussion as to the precision of the drawings in Scorpio. Reviewing these drawings, however, we find detail, precision, and consistency of the objects depicted. *See Mraz*, 455 F.2d at 1072 (“things patent drawings show clearly are [not] to be *disregarded*”). Further, the purpose of Scorpio is to instruct surgeons on how to perform a surgical technique. Thus, it would seem particularly important that the relative sizes of the objects depicted in the drawings would be to scale, because out-of-proportion objects would not be as instructive in showing proper technique and alignment, reducing the usefulness of this document.

Furthermore, to the extent the precision of the drawings in Scorpio may not be relied on, Petitioner asserts that it would have been obvious to one with ordinary skill in the art to narrow the slots, because reducing the length of the guide surface “was a known solution for reducing trauma.” Pet. 34 (citing Ex. 1002 ¶ 70 (“modifying the length of a guide surface is a matter of routine practice”)); Ex. 1004, 22:45-50 (“smaller jigs” allow “a smaller incision to be made,” which “will result in a less invasive procedure”)). In view of the above, on this record, Petitioner has made a threshold showing that Scorpio describes the relative size relationship of the replacement portion and the guide surface as claimed.

Reason for Combination

Petitioner offers an articulated reason with a rational underpinning to combine the teachings of Stulberg with either Turner or Scorpio. According to Petitioner, the combination “overcome[s] the deficiencies of standard mechanical measuring techniques,” such as those of Turner and Scorpio, by utilizing the computer-assisted system of Stulberg. Pet. 45-46. As

explained above, Stulberg explains that computer-assisted surgical techniques “improve[] the accuracy of the surgical technique.” Ex. 1005, p. 25. This improved technique “uses currently available mechanical total knee instruments.” *Id.* at 33; *see also* Pet. 46. Accordingly, the proposed combination appears to be nothing more than using a known technique to improve a similar device in the same way. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007).

In view of the above, Petitioner has shown a reasonable likelihood that it would prevail in showing that claim 1 is obvious in view of the combined teachings of Stulberg with either Turner or Scorpio.

2. Delp Article and either Turner or Scorpio

Petitioner asserts that the subject matter of claim 1 is unpatentable in view of the Delp Article and either Turner or Scorpio. Pet. 27-37. We first turn to the Delp Article’s disclosure, then to the proposed ground of unpatentability.

Delp Article (Ex. 1003)

The Delp Article discusses the limitations of mechanical alignment guides, such as intramedullary and extramedullary devices, and proposes three computer-based systems to improve the success of knee replacement surgeries. Ex. 1003, p. 49. The first system utilizes computer-integrated instruments to “augment[] mechanical instruments through the addition of measurement probes that can be used to locate joint centers, track surgical tools, and align prosthetic components.” *Id.* at 50-51. In this system, a computer “displays the position of the cutting block relative to the desired position.” *Id.* at 51. The cutting block (jig) is secured and the cuts are

made. *Id.* According to the Delp Article, this method “eliminates the need for intramedullary and extramedullary alignment guides.” *Id.* at 55. The second system in the Delp Article includes the use of computer imaging to determine a preoperative plan that guides the placement of the components. *Id.* at 50. The third system uses a robotic device to perform the cutting operations. *Id.*

The Delp Article-Turner and Delp Article-Scorpio Combinations

Petitioner asserts that the Delp Article teaches every limitation of claim 1. Pet. 27-37. Petitioner asserts that Turner and Scorpio additionally disclose the “transverse dimension” limitation. Pet. 32-33.

Petitioner asserts that the width of the cutting guide shown in Turner at figure 8 is substantially smaller than the implant. Pet. 33 (citing Ex. 1008, figs. 3, 8, pp. 177, 181; Ex. 1002 ¶ 69).

Petitioner also asserts that the width of the cutting guide shown in Scorpio at figure 15 (i.e., one of the slots) is smaller than the implant. Pet. 33 (citing Ex. 1009, pp. 2, 9, fig. 15; Ex. 1002 ¶ 70).

Petitioner determines that it would have been obvious to one of ordinary skill in the art to use “the cutting guides and implants disclosed in Turner or Scorpio” along with the “systems described in the Delp Article.” Pet. 34. One reason for doing this, according to Petitioner, is because “[u]sing ‘measurement probes’ . . . disclosed in the Delp Article to improve the accuracy of mechanical instruments from Turner or Scorpio would have been no more than the predictable use of prior art elements according to their established functions.” Pet. 35; *see also* Ex. 1002 ¶ 72; Ex. 1003, p. 50 (the purpose of the computer-integrated instruments are to “augment[] mechanical instruments”). Petitioner also relies on the opinion of

Dr. Mabrey that the proposed combination is “no more than the predictable use of prior art elements according to their established functions” requiring no more than “routine skill.” Pet. 35 (citing Ex. 1002 ¶ 72).

Discussion of the Delp Article-Turner and Delp Article-Scorpio Combinations

Based on the information provided in the Petition, Petitioner has shown a reasonable likelihood of prevailing in showing claim 1 to be unpatentable over the Delp Article and either Turner or Scorpio. As we explained above, the Delp Article describes a method of replacing at least a portion of a patient’s knee. Based on our review of the Delp Article, we agree with Petitioner that the Delp Article teaches the steps of making an incision, positioning a cutting guide, and using the cutting guide to guide a cutting tool to form a cut. *See* Ex. 1003, p. 51 (“Once a jig is oriented properly it is secured . . . and the cuts are made with a standard oscillating saw,” “Knee implants were installed in seven cadavers to test this system”); *see also* Ex. 1002 ¶¶ 60-67; Pet. 27-32. In addition, the Delp Article explicitly discloses eliminating intramedullary and extramedullary alignment devices. Ex. 1003, p. 55.

We are not persuaded by Petitioner’s assertion that the Delp Article discloses the limitation regarding the transverse dimension of the replacement portion being larger than the transverse length of the cutting guide. *See* Pet. 31-32. The particular figures of the Delp Article that Petitioner relies upon, namely figures 2 and 3, are too blurry to discern any meaningful size relationships, and none are discussed in the written portions of the article. *See Hockerson-Halberstadt*, 222 F.3d at 956.

However, on this record, Petitioner has made a threshold showing that Turner and Scorpio each disclose this feature (*see* Pet. 32-35), for the

reasons explained above. Furthermore, the reason for combining the Delp Article with either Turner or Scorpio offered by the Petitioner serves as an articulated reason with a rational underpinning to justify the legal conclusion of obviousness. *See* Pet. 34-35 (to “improve the accuracy of mechanical instruments”). As explained above, the Delp Article teaches augmenting existing mechanical guides using computers. Ex. 1003 at 50. Thus, applying this teaching and augmenting the existing mechanical guides of Turner or Scorpio appears to be nothing more than using a known technique to improve a device in a known way. *See KSR*, 550 US at 417.

In view of the above, we are persuaded that Petitioner has shown a reasonable likelihood that it would prevail in showing that claim 1 is obvious in view of the teachings of the Delp Article and either Turner or Scorpio.

3. Delp '018 and either Turner or Scorpio

We determine that this ground is redundant in view of the two grounds addressing claim 1 discussed above. Accordingly, we do not authorize an *inter partes* review on the grounds of unpatentability based on Delp '018 and either Turner or Scorpio against claim 1 of the '896 patent. *See* 37 C.F.R. § 42.108(a).

4. Radermacher '157

We are not persuaded that Petitioner has shown a reasonable likelihood that it would prevail in showing that claim 13 is anticipated by Radermacher '157. In particular, we are not persuaded that Radermacher '157 discloses a method of replacing at least a portion of a joint wherein the

replacement portion has a transverse dimension that is larger than a transverse dimension of the guide surface, as required by claim 13.

Petitioner relies on the relative sizes of the cutting guide of figures 13a and 13d illustrated in Radermacher '157. Pet. 51. Petitioner asserts that the width of the prosthesis in figure 13d is approximately twice the extent as the height labeled "H" in that figure. *Id.* at 51-52; *see also* Ex. 1002 ¶ 101. Petitioner asserts the width of the template 4 is approximately the same extent of the height labeled "H" in figure 13a. *Id.* Thus, according to Petitioner, the width of the cutting guide is approximately "H" and the width of the replacement portion is approximately "2H," which would satisfy the limitation regarding the relative sizes of the guide and replacement. Figures 13a and 13d, on which Petitioner relies, are reproduced below:

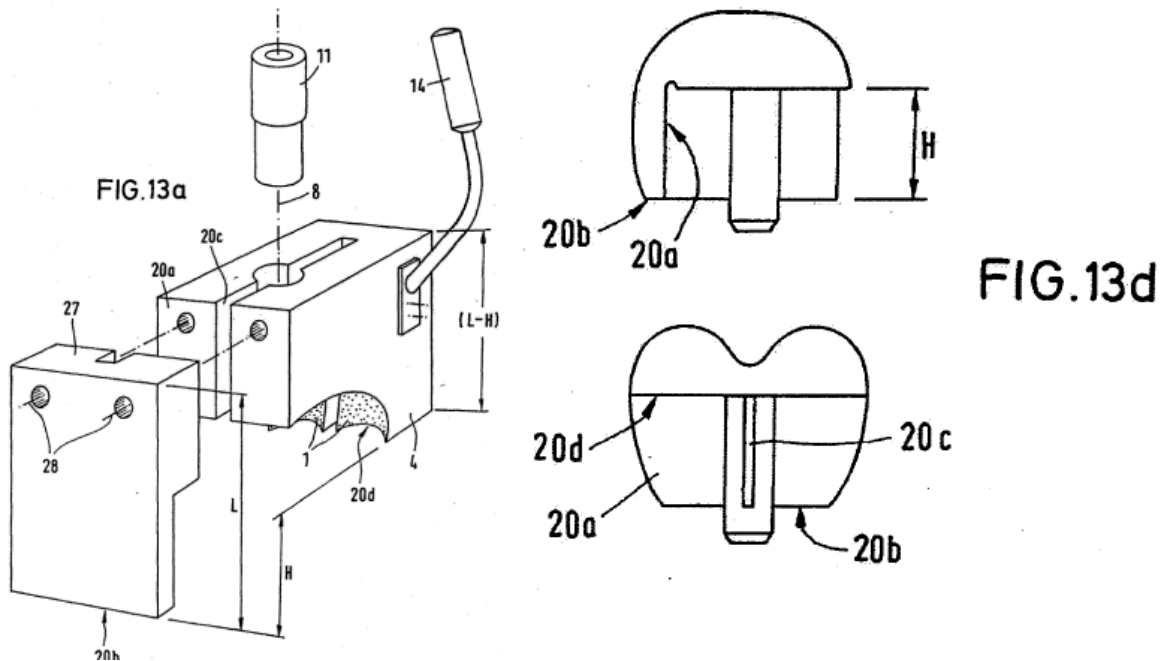


Figure 13a of Radermacher '157 depicts "individual template 4 for the preparation of the seat for the knee-joint." Ex. 1007, p. 30. The bone to be cut abuts contoured contact faces 1 and cuts are performed along cutting planes 20a-d. *Id.* Figure 13d is not described in detail, but appears to depict

a replacement for a femur, as well as the cutting planes 20a-d as they correspond to the shape of the replacement.

Petitioner's reliance on the precision of the drawings of Radermacher '157 is unsubstantiated. We are not persuaded that these drawings are to scale. First, there is no indication from the textual description of these drawings that would indicate they are to scale. *See Hockerson-Halberstadt*, 222 F.3d at 956. Second, figures 13b and 13c show different proportions with respect to "H" compared to those of figures 13a and 13d. For comparison, figures 13b and 13c are reproduced below:

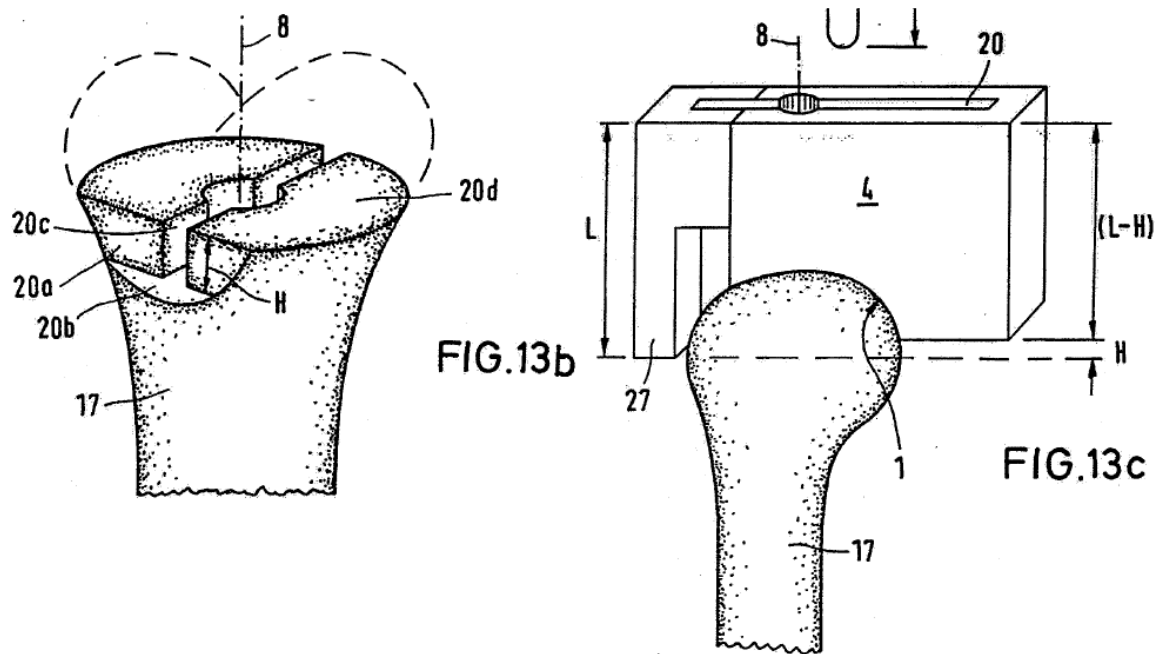


Figure 13b depicts a femur resected along planes 20a-d. Figure 13c depicts a cutting block (template 4) attached to the distal end of a femur. Neither figure is described in detail in Radermacher '157.

Comparing figures 13a and 13c, the relative size of "H" versus "L" is significantly different, despite the fact that both measurements are of the same portion of individual template 4. In figure 13a, distance "H" appears nearly the same as distance "L." In figure 13c, however, distance "H"

appears significantly less than distance “L.” Accordingly, little to no weight can be assigned to the measurement of “H” in figures 13a-d upon which Petitioner relies.

In view of the above, we are not persuaded that Radermacher ’157 depicts the particular spatial relationships required by claim 13. Accordingly, Petitioner has not shown a reasonable likelihood it would prevail in showing claim 13 is anticipated by Radermacher ’157.

5. Radermacher Article and either Turner or Scorpio

We are not persuaded that Petitioner has shown a reasonable likelihood that it would prevail in showing that claim 13 is unpatentable over the Radermacher and either Turner or and Scorpio. We first turn to the Radermacher Article and then to Petitioner’s proposed ground.

Radermacher Article (Ex. 1006)

The Radermacher Article discusses several different orthopedic surgical uses for preoperatively customized tool guides. Ex. 1006. According to the article, it is essential to the success of these procedures to match the “precise spatial correspondence between the individual bone structure in situ and the intended position of the tool guides.” *Id.* at 29. The Radermacher Article proposes to create individual templates based on pre-operative image data such that the template “fit[s] exactly on the bone.” *Id.* Based on the image data, a desktop milling machine makes the templates. *Id.* These templates include guides for cutting and provide a reference base for attaching other, standard tool guides. *Id.* at 29, 31.

*The Radermacher Article-Turner and Radermacher Article-Scorpio
Combinations*

Petitioner asserts that the Radermacher Article, in combination with Turner and Scorpio, teaches the limitation regarding the width of the replacement portion being greater than the guide surface limitation, as required by claim 13. Pet. 56-57. Petitioner points to the same teachings of Turner and Scorpio discussed above. *Id.* at 57. With respect to the proposed combinations, Petitioner asserts that it would have been obvious to one of ordinary skill in the art “to utilize the individual templates disclosed in the Radermacher Article in combination with the cutting guides and implants disclosed in Turner or Scorpio” because the Radermacher Article discloses “using computer assisted techniques ‘for the preoperative customization’ of ‘mechanical tool guides,’ such as those disclosed in Turner or Scorpio.” *Id.*

*Discussion of the Radermacher Article-Turner and Radermacher Article-
Scorpio Combinations*

Petitioner’s assertion that the Radermacher Article discloses preoperative customization of mechanical tool guides “such as those disclosed in Turner or Scorpio” has insufficient factual underpinning. *Id.* The Radermacher Article discloses that the individual guides are milled using a desktop milling machine. Ex. 1006 at 29. Thus, the Radermacher Article does not discuss customizing *existing* cutting guides, but rather makes new, customized guides. In addition, the customized guides in the Radermacher Article are created to fit over the bone (*id.*, Abstract), whereas the Turner guide is slid into an anatomical feature (Ex. 1008 at 181) and the Scorpio guide is pinned to the bone (Ex. 1009 at 6). Thus, the guides of Turner and Scorpio do not attach to the bone in the same way as the guide of the Radermacher Article, and Petitioner does not explain this incongruity. In

view of the above, we are not persuaded that the customization of cutting guides in the Radermacher Article extends to the Turner or Scorpio guides in the manner suggested by Petitioner.

Accordingly, Petitioner has not shown a reasonable likelihood it would prevail in showing that claim 13 is obvious in view of the Radermacher Article and either Turner or Scorpio.

C. Conclusion

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claim 1 of the '896 patent is unpatentable. However, we conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claim 13 of the '896 patent is unpatentable. At this stage of the proceeding, we have not made a final determination on the patentability of claim 1.

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is granted as to the following grounds proposed:

1. Claim 1 as unpatentable under 35 U.S.C. § 103 over Stulberg and either Turner or Scorpio; and
2. Claim 1 as unpatentable under 35 U.S.C. § 103 over the Delp Article and either Turner or Scorpio;

FURTHER ORDERED that the Petition is denied as to the remaining grounds proposed.

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a), *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; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for 2:00 PM Eastern Time on March 20, 2014. The parties are directed to the Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765-66 (Aug. 14, 2012), for guidance in preparing for the initial conference call, and should come prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

Case IPR2013-00629

Patent 7,806,896 B1

PETITIONER:

David Cavanaugh

David.cavanaugh@wilmerhale.com

Michael Smith

Michael.smith@wilmerhale.com

PATENT OWNER:

Cary Kappel

ckappel@ddkpatent.com

William Gerhis

wgerhis@ddkpatent.com