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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.
Petitioner

v.

Patent Owner of
U.S. Patent No. 7,806,896 to Peter M. Bonutti

IPR Trial No. TBD

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 7,806,896
UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104**

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I. MANDATORY NOTICES

A. Real Party-in-Interest

Smith & Nephew, Inc. (“Petitioner”) is the real party-in-interest and submits this *inter partes* review Petition (“Petition”) for review of certain claims of U.S. Patent No. 7,806,896 (“the ’896 patent”).

B. Related Matters

The following litigation matter would affect or be affected by a decision in this proceeding: *Bonutti Skeletal Innovations LLC v. Smith & Nephew, Inc.*, Civil Action No. 12-1111-GMS (D. Del.). The litigation involves six patents: the ’896 patent and U.S. Patent Nos. 5,980,559; 6,702,821; 7,087,073; 7,749,229; and 8,133,229. The ’896 patent is the subject of this Petition. Separate petitions for *inter partes* review of the other patents above are also being filed. Because the technology and disclosure in the patents are similar and for the sake of administrative efficiency and consistent outcome, Petitioner requests that the Patent Trial and Appeals Board (“PTAB”) have a single Administrative Panel address these *inter partes* reviews.

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II. CERTIFICATION OF GROUNDS FOR STANDING

Petitioner certifies pursuant to Rule 42.104(a) that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

III. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges claims 1 and 13 of the '896 patent (Ex. 1001).

A. Prior Art Patents and Printed Publications

Petitioner relies upon the following patents and printed publications:

1. Scott L. Delp, *et al.*, "Computer Assisted Knee Replacement," 354 Clinical Orthopaedics and Related Research, pp. 49-56 (1998) ("Delp Article" (Ex.

1003)), which has a publication date of 1998, and is prior art to the '896 patent under 35 U.S.C. § 102(b).¹

2. U.S. Patent No. 5,871,018 (“Delp ’018” (Ex. 1004)), which has a filing date of June 6, 1997, and an issue date of February 16, 1999, and is prior art to the '896 patent under 35 U.S.C. § 102(b).
3. S. David Stulberg, *et al.*, “Computer-Assisted Total Knee Replacement Arthroplasty,” 10(1) Operative Techniques in Orthopaedics, pp. 25-39 (Jan. 2000) (“Stulberg” (Ex. 1005)), which has a publication date of Jan. 2000, and is prior art to the '896 patent under 35 U.S.C. § 102(b).
4. International Patent Application Publication No. WO 93/25157 (“Radermacher ’157” (Ex. 1007)), which has an international filing date of June 17, 1993, and an international publication date of December 23, 1993, and is prior art to the '896 patent under 35 U.S.C. § 102(b).
5. Klaus Radermacher, *et al.*, “Computer Assisted Orthopaedic Surgery With Image Based Individual Templates,” 354 Clinical Orthopaedics and Related Research, pp. 28-38 (1998) (“Radermacher Article” (Ex. 1006)), which has a

¹ The '896 patent was issued prior to the America Invents Act (“AIA”). Therefore, Petitioner has used the pre-AIA statutory framework to refer to the prior art.

publication date of 1998, and is prior art to the '896 patent under 35 U.S.C. § 102(b).

6. Roderick H. Turner, Richard Matzan, and Yousif I. Hamati, “Geometric and Anametric Total Knee Replacement,” *in* Total Knee Replacement (A.A. Savastano, M.D. ed. 1980) (“Turner” (Ex. 1008)), which has a publication date of 1980, and is prior art to the '896 patent under 35 U.S.C. § 102(b).
7. Stryker Howmedica Osteonics, “Scorpio Single Axis Total Knee System: Passport A.R. Surgical Technique” (“Scorpio” (Ex. 1009)), which has a publication date of May 2000, and is prior art to the '896 patent under 35 U.S.C. § 102(b).

B. Grounds for Challenge

Petitioner requests cancellation of claims 1 and 13, the challenged claims, as unpatentable under 35 U.S.C. § 102 and 35 U.S.C. § 103.

This Petition, supported by the declaration of Dr. Jay Mabrey (“Mabrey Declaration” or “Mabrey Decl.” (Ex. 1002)) filed with this Petition, demonstrates that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited in this Petition. *See* 35 U.S.C. § 314(a).

IV. CLAIM CONSTRUCTION

A claim in *inter partes* review is given the “broadest reasonable construction in light of the specification.” 37 C.F.R. § 42.100(b). Any claim term that lacks a definition in the specification is therefore also given a broad interpretation.² *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007). The following discussion proposes constructions of and support therefore of those terms in the claims listed below. Any claim terms not included in the following discussion are to be given their broadest reasonable interpretation in light of the specification as commonly understood by those of ordinary skill in the art. Moreover, should the Patent Owner, in order to avoid the prior art, contend that the claims have a construction different from their broadest reasonable interpretation, the appropriate course is for the Patent Owner to seek to amend the claims to expressly correspond to its contentions in this proceeding. *See* 77 Fed. Reg. 48764 (Aug. 14, 2012). Any such amendment would only be permissible if the proposed amended claims comply with 35 U.S.C. § 112.

Claim 1 recites a “cutting guide” and a “guide surface.” These terms are not defined in the ’896 patent. The ’896 patent specification describes cutting guides

² The present analysis applies the “broadest reasonable construction” standard. A construction under, *e.g.*, the standard applied in a District Court may be different.

such as the “anterior resection guide 138” and the “femoral cutting guide 210.”

’896 patent, col. 38, ll. 9-18 (Ex. 1001). The specification describes these cutting guides as having “guide surfaces,” and describes the “guide surfaces” as guiding cutting instruments. *E.g.*, ’896 patent, col. 36, ll. 22-24 (“anterior resection guide 138 . . . has a guide surface 178”); col. 24, ll. 57-59 (“cuts are made by moving the saw blade 170 or other cutting tool along guide surfaces on the femoral cutting guide”) (Ex. 1001). Therefore, the terms “cutting guide” and “guide surface” should be given their broadest reasonable interpretations and should be construed to mean a “guide that has a guide surface” and “a surface that guides a cutting instrument,” respectively. Mabrey Decl. ¶ 15 (Ex. 1002).

Claim 13 recites a “customized cutting guide.” This term is not defined in the ’896 patent. The Petitioner proposes that the term “customized cutting guide” should be given its broadest reasonable interpretation and should be construed to mean “a cutting guide modified for a specific patient.” *See* ’896 patent, col. 108, ll. 19-21 (Ex. 1001); *see also, e.g.*, The New Oxford American Dictionary (2d ed. 2005) (defining “customize” as “modify (something) to suit a particular individual or task”); Webster’s New College Dictionary (2007); The American Heritage College Dictionary (3d ed. 1993) (Exs. 1010, 1011, 1012); Mabrey Decl. ¶ 16 (Ex. 1002).

V. OVERVIEW OF KNEE ANATOMY AND KNEE REPLACEMENT

The challenged claims of the '896 patent relate to methods for knee replacement surgery, also known as knee arthroplasty.

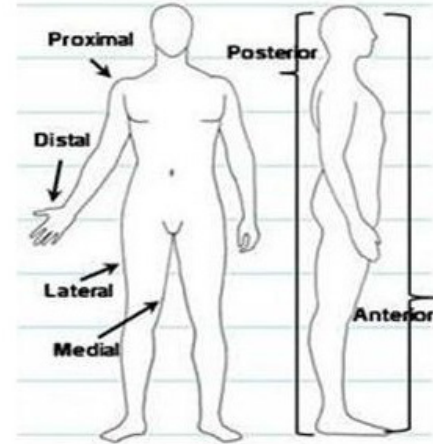
Generally, there are two types of knee replacement surgeries: total knee and partial knee replacement. Mabrey Decl. ¶ 19 (Ex. 1002). During either type of knee replacement, an orthopedic surgeon replaces either a portion of or all of a damaged knee with an artificial device (also known as a prosthesis or an implant). *Id.* Although a total knee arthroplasty ("TKA") is the most common procedure, some people can benefit from replacing only a portion of the knee, such as the medial femoral-tibial joint. *Id.* This partial replacement is sometimes called a unicondylar knee arthroplasty ("UKA"). *Id.*

Knee replacement was not new when the '896 patent was filed. *Id.* ¶ 20 (Ex. 1002). Some elementary background in the anatomical terms of location, the knee anatomy, and the surgical procedure is helpful to understand fully the claim limitations in the challenged claim and to appreciate how the prior art renders the claim unpatentable. *Id.*

A. Anatomical Terms of Location

The following standard anatomical terms are relevant to knee replacement:

- *Anterior* – Front of the body
- *Posterior* – Rear of the body
- *Medial* – Toward the center of the body
- *Lateral* – Left and right of the body
- *Proximal* – End of an appendage closer to torso
- *Distal* – End of an appendage further from torso



Mabrey Decl. ¶ 21 (Ex. 1002).

B. Relevant Knee Anatomy

At a simple conceptual level, the knee works like a modified hinge on a door. *Id.* ¶ 22 (Ex. 1002). Bending of the knee is called “flexion” and straightening of the knee is called “extension.” *Id.* The knee is more complex than a simple hinge and actually rotates around its central axis as it flexes and extends. *Id.*

The illustration to the right shows the components of the knee. *Id.* ¶ 23 (Ex. 1002).



The knee is a major weight-bearing joint that is held together by muscles,

ligaments, and soft tissue. *Id.* Cartilage inside the joint provides shock absorption, which is used to walk, run, lift, climb stairs, etc. *Id.*

A human knee is comprised of four main components: bones, ligaments, cartilage, and tendons. *Id.* ¶ 24 (Ex. 1002). With respect to bones, a knee is made up of the thighbone (femur), the shinbone (tibia), the fibula, and the kneecap (patella). *Id.* ¶ 25 (Ex. 1002). The thighbone and shinbone come together to form a hinge. *Id.* Two major supporting ligaments of the knee are the medial and lateral collateral ligaments. *Id.* They attach to the medial and lateral femoral epicondyles. *Id.* The epicondyles serve as reference points for positioning total knee implants during surgery. *Id.* The features are shown below:

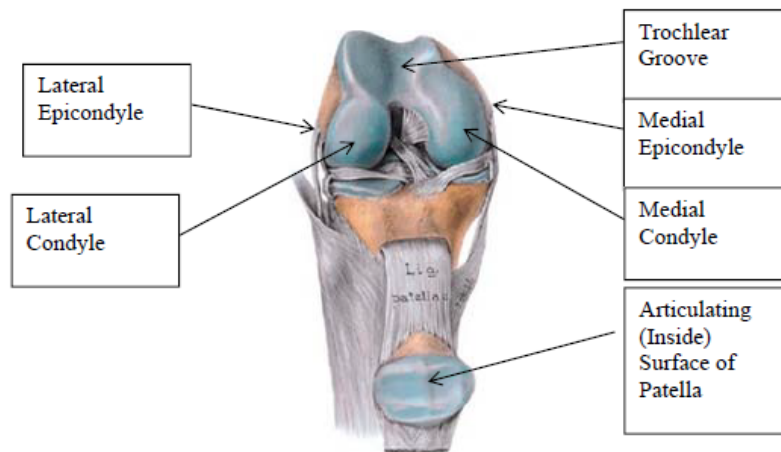


Illustration of Bent Knee with Patella Cut Away from Thighbone

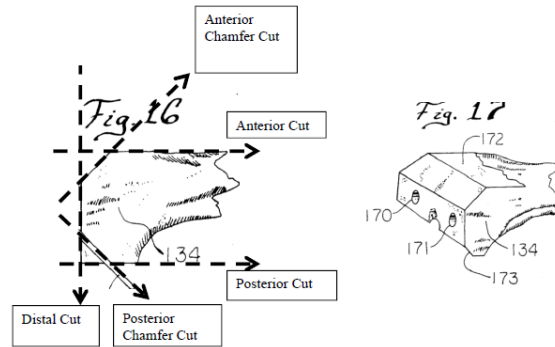
C. Knee Replacement Surgery

When a knee has been damaged by a disease like osteoarthritis, knee replacement surgery can replace the damaged portions with artificial components.

Mabrey Decl. ¶ 29 (Ex. 1002). Before the surgeon can begin the procedure, however, the parts of the knee to be replaced must be exposed. *Id.* A surgeon will expose the operative areas by first making an incision through the patient's skin. *Id.* The surgeon will then typically access the operative area by moving the patella out of the trochlear groove to expose the condyles and the intercondyle notch. *Id.* The surgeon offsets the patella to the side of the knee by either pushing it over (displacing it laterally) without flipping it over, or by lifting the patella off of the knee and rotating it to the side such that the articulating surface is no longer facing the femur (referred to as everting). *Id.* Once the surgeon offsets the patella, unless she is resurfacing the patella, the surgeon will maintain the patella in the offset position, so that she has access to the bones of the knee during the surgery. *Id.*

Once the knee is exposed, the surgeon will conduct the replacement through four phases: preparing the bone; positioning the implant; resurfacing the patella; and inserting a spacer. *Id.* ¶ 30 (Ex. 1002). The first two phases are discussed below.

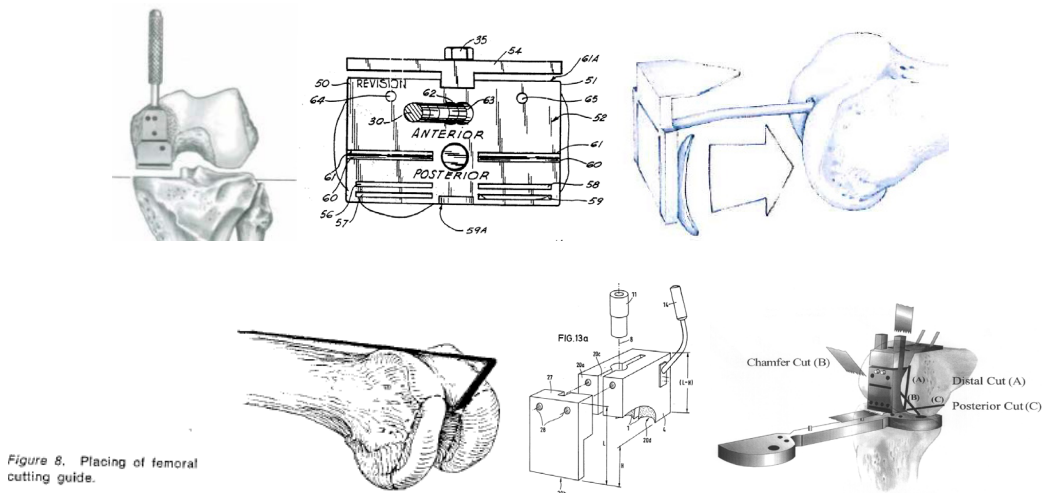
Preparing the Bone – The surgeon removes the damaged cartilage surfaces at the ends of the femur and tibia and a small amount of underlying bone. *Id.* ¶ 31 (Ex. 1002). The figures below show an example of the cuts a surgeon would typically make to a femur during surgery and the results of those cuts.



Illustrations of Knee Resection Cuts (Fig. 16) and Resected Knee (Fig. 17)

U.S. Patent No. 4,502,483, filed March 9, 1983 (“Lacey ’483”), Figs. 16 & 17 (Ex. 1013)); Mabrey Decl. ¶ 31 (Ex. 1002).

To help ensure that cuts are made accurately, surgeons typically use cutting guides with a guide surface that guides the saw used to cut (or “resect”) the bone. Mabrey Decl. ¶ 32 (Ex. 1002). Cutting guides, also known as resection guides or guide members, come in many different shapes and sizes. *Id.* A few illustrative examples of prior art cutting guides are shown below:



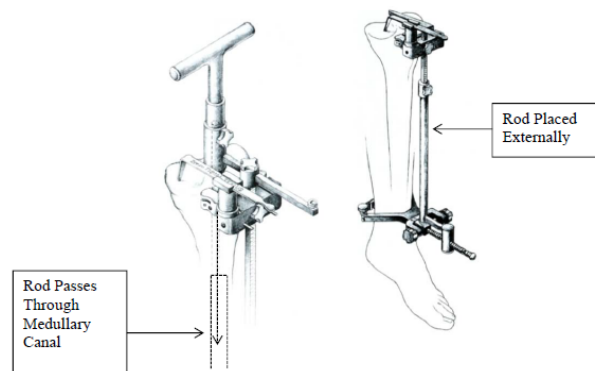
Illustrative Examples of Prior Art Cutting Guides

Smith & Nephew Genesis Uni, p. 16; Figs. 29 (Ex. 1018) (top left); Lackey '803, Fig. 11 (Ex. 1019) (assigned to Smith & Nephew Richards) (top center); Richards, p. 3 (Ex. 1020) (top right); Turner, Fig. 8; p. 181 (Ex. 1008) (bottom left); Radermacher '157, Fig. 13a (Ex. 1007) (bottom center); Keblish, Fig. 10 (Ex. 1021) (bottom right); Mabrey Decl. ¶ 32 (Ex. 1002).

As shown above, in some cutting guides, such as the Smith & Nephew Genesis Uni, the guide surface is a slot. Mabrey Decl. ¶ 33 (Ex. 1002). In other cutting guides, such as the Turner example, the cutting surface is provided without a slot. *Id.* Other cutting guides, such as the Radermacher example, contain open guide surfaces (*e.g.*, 20b) and a slot (*e.g.*, 20c). Whether a slot is used is a matter of surgeon preference. *Id.* Some surgeons prefer cutting guides with slots, which provide greater guidance of the saw blade, whereas other surgeons prefer open cutting surfaces, which are easier to clean, generate less metallic debris, and make it easier for the surgeon to adjust the cut. *Id.* The design choice between slots and open cutting guides was within the level of ordinary skill to design and modify when the '896 patent was filed. *Id.* The placement and extent of the cutting surface is also within the level of ordinary skill. *Id.* Each had known attributes and predictable results. *Id.*

Initially, surgeons positioned cutting guides by hand. *Id.* ¶ 34 (Ex. 1002). Beginning in the 1960's and 1970's, surgeons started using mechanical alignment

guides to assure that cutting guides were properly aligned with the leg when placed on the bone. *Id.* Two common types of alignment guides are intramedullary alignment rods, which are inserted into the medullary canal (bone marrow cavity) of the bone and extramedullary alignment rods, which are placed externally along the medullary canal of the bone.



Illustrations of an Intramedullary Alignment Device (Left) and an Extramedullary Alignment System (Right)

Stulberg, p. 32, Figs. 10-11 (Ex.1005); Mabrey Decl. ¶ 34 (Ex. 1002).

More recently, during the 1990's, surgeons began using computer assisted techniques to guide the placement of cutting blocks and create customized cutting guides adapted to fit a specific patient's bone. Mabrey Decl. ¶ 35 (Ex. 1002).

Positioning the Metal Implants – The surgeon replaces the removed cartilage and bone with metal components that recreate the surface of the joint. *Id.* ¶ 36 (Ex. 1002). Before implanting a metal implant, the surgeon will typically test the fit of the implant with a trial prosthesis that is the same size as the metal implant, but is

not implanted. *Id.* After confirming the fit with the trial prostheses, the metal implants may be cemented or “press-fit” into the bone. *Id.*

D. Computer Assisted Knee Surgery

Computer-assisted knee replacement was not new when the '896 patent was filed. *Id.* ¶ 40 (Ex. 1002); '896 patent, col. 42, ll. 30-39 (Ex. 1001) (acknowledging image-guided surgery systems were “known” and “commercially available”). One approach developed in the 1990's uses preoperative scanning techniques (*e.g.*, MRI, CT-scan, etc.) to visualize an individual patient's bony knee anatomy. Mabrey Decl. ¶ 40 (Ex. 1002). Other systems utilize bony landmarks and centers of rotation acquired at the time of surgery to establish proper axes of alignment. *Id.* These techniques permit the surgeon to identify important landmarks that ensure that the implants are properly installed. *Id.* In addition, those techniques that utilize scans can be used to create customized cutting blocks that interface precisely with the patient's bony anatomy and ensure accurate placement of the implants. *Id.* These were developed due to the failings of standard mechanical techniques:

Mechanical alignment systems have fundamental limitations that limit their ultimate accuracy. The accuracy of preoperative planning is limited by the errors inherent to standard radiographs. With standard instrumentation, the correct location of crucial alignment landmarks . . . is limited during the performance of a TKR

[M]echanical alignment and sizing devices presume a standardized bone geometry that may not apply to a specific patient. Even the most elaborate mechanical instrumentation systems rely on visual inspection to confirm the accuracy of the limb and implant alignment.

Stulberg, p. 25 (Ex.1005). Computer-based systems were designed to address these problems, and were designed with standard instruments and implants in mind. *Id.*, pp. 25, 33 (Ex.1005). For example, the computer-assisted knee replacement technique discussed in 1999 in Stulberg “uses currently available mechanical total knee instruments” with computer-assisted techniques. *Id.*, p. 33 (Ex. 1005).

Beyond alignment, computer-assisted surgery was used for customizing cutting blocks. The Radermacher Article, published in 1998, describes development of individual templates based on a patient’s CT-scan that are “customized on the basis of. . . the bone structures.” Radermacher Article, p. 29 (Ex. 1006). This system “facilitates exact, safe, and fast implementation of planned surgery on bone structures, [and] eliminates the need for continual radiographic monitoring.” *Id.* (Ex. 1006).

VI. SUMMARY OF THE ’896 PATENT AND RELEVANT FILE HISTORY

The application that issued as the ’896 patent (Ex. 1001) was filed Nov. 25, 2003, and was a continuation of U.S. patent application Ser. No. 10/191,751, filed

Jul. 8, 2002 and a continuation-in-part of Ser. Nos. 09/976,396, filed Oct. 11, 2001; 09/941,185, filed Aug. 28, 2001; 09/566,070, filed May 5, 2000; 09/737,380, filed Dec. 15, 2000; 09/569,020, filed May 11, 2000; 09/483,676, filed Jan. 14, 2000; 09/798,870, filed Mar. 1, 2001; 09/526,949, filed Mar. 16, 2000; and 09/789,621, filed Feb. 21, 2001. '896 patent, cover page (Ex. 1001).

A. The Challenged Claims of the '896 Patent

The challenged claims of the '896 patent merely recite conventional techniques and instrumentation for performing knee surgery. Mabrey Decl. ¶ 42 (Ex. 1002). Challenged claims 1 and 13 are reproduced below:

1. A method of replacing at least a portion of a patient's knee, the method comprising the steps of:

- (a)³ making an incision in a knee portion of a leg of the patient;
- (b) determining a position of a cutting guide using references derived independently from an intramedullary device;
- (c) 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;
- (d) moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and

³ Identifiers (a), (b), etc. have been added to facilitate discussion.

(e) forming at least an initial cut on the femur by moving the cutting tool along the guide surface;

(f) 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.

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

(a) 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;

(b) making an incision adjacent to the joint in the patient;

(c) 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;

(d) moving a cutting tool through the incision into engagement with a guide surface on the positioned cutting guide;

(e) cutting the unresected bone of the joint for the first time, by moving the cutting tool along the guide surface;

(f) 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

(g) 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.

'896 patent, claims 1 & 13 (Ex. 1001).

As set forth in detail below, claims 1 and 13 do nothing more than describe and claim the conventional steps for performing a knee surgery using surgical techniques and instrumentation that was old and well-known as of the earliest possible priority date of the '896 patent. *See* Mabrey Decl. ¶ 43 (Ex. 1002). That is, prior to August 28, 2001, surgeons knew of and had performed a knee replacement with reduced-size instrumentation and no intramedullary or extramedullary guidance (Claim 1) and with a custom cutting guide placed without intramedullary guidance (Claim 13). *See id.*

B. Summary of Portion of the Specification Related to Challenged Claim

The background of the specification acknowledges that many of the claimed steps were known. *See* '896 patent, col. 1, l. 52 - col. 2, l. 38; col. 10, l. 25 - col. 11, l. 2 (Ex. 1001). The specification states that during a known total or partial knee replacement “an incision is made in a knee portion of the leg to obtain access to the knee joint” (making an incision, recited in claim 1, limitation (a), and claim 13, limitation (b)). *Id.*, col. 1, ll. 52-55 (Ex. 1001). The specification further states that the incision is made “to enable instrumentation, such as a femoral alignment guide, femoral cutting guide, anterior resection guide, distal resection guide, posterior and chamfer resection guide to be positioned relative to a distal end

portion of the femur” (passing instrumentation through an incision, recited in claim 1, limitations (c) and (d), and claim 13, limitations (c) and (d)). *Id.*, col. 1, ll. 55-59 (Ex. 1001). The specification also states that “[c]uts are made on a femur and tibia” (cutting the bone, recited in claim 1, limitation (e), and claim 13, limitation (e)) and “implants [are] positioned in the knee portion of the patient’s leg” (attaching a replacement portion of the knee, recited in claim 1, limitation (f), and claim 13, limitation (f)). *Id.*, col. 2, ll. 28-29; col. 10, l. 62 (Ex. 1001).

Of the 112 columns of material in the specification, only a few paragraphs even arguably relate to the purportedly novel features claimed. For example, the specification states: “A cut on a bone in the patient may be completed using previously cut surfaces as a guide for the cutting tool.” *Id.*, col. 3, ll. 28-30 (Ex. 1001). During prosecution, Applicant appears to have relied—without explanation—on this disclosure for the conclusion that: “the present invention provides a means for cutting bone, where the guide member is free of extramedullary or intramedullary members.” ’896 patent file history, April 30, 2007, Response, p. 13 (Ex. 1014).⁴

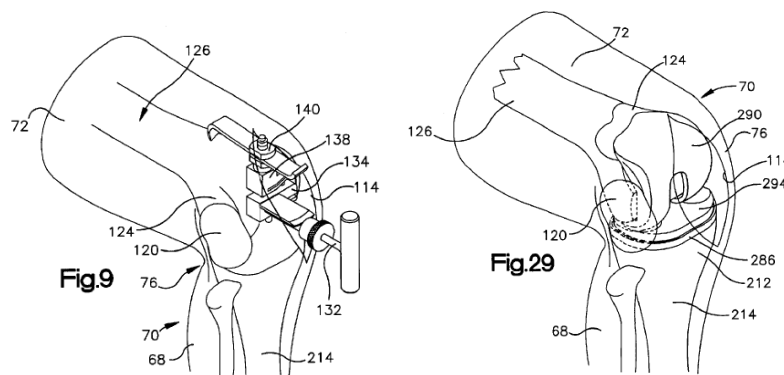
⁴ By contrast, the specification provides extensive description of “exemplary embodiment[s]” of the invention that disclose the opposite, namely, the use of

The specification also describes “computer navigation systems”:

It is contemplated that emitters, receivers, and/or reflectors of computer navigation systems could be pinned or otherwise attached onto the femur 126 and tibia 214 to provide cutting positions

’896 patent, col. 36, ll. 55-58 (Ex. 1001). The specification acknowledges that image-guided surgery systems were “known” and “commercially available.” *Id.*, col. 42, ll. 30-39 (Ex. 1001).

The specification additionally describes “downsized instrumentation”:



[T]he femoral alignment guide 134 and anterior resection guide 138 have transverse dimensions, perpendicular to a longitudinal central axis of the femur 126, which are smaller than transverse dimensions of a femoral implant 290, tibial bearing insert 294, and a tibial tray 286 (FIG. 29) in a direction perpendicular to the longitudinal central axis of the femur 126 (FIG. 9).

intramedullary and extramedullary alignment devices. *E.g.*, ’896 patent, col. 17, ll. 15-19; col. 103, ll. 37-39; Fig. 16 (showing “intramedullary rod 132”) (Ex. 1001).

Id., Figs. 9, 29; col. 17, ll. 53-59 (Ex. 1001). The specification acknowledges that the instrumentation in Figure 9 (as well as in Figures 10 through 21), “with the exception of being down sized, is generally similar to known instrumentation which is commercially available . . . under the trademark ‘Scorpio’ single access total knee system.” *Id.*, col. 36, ll. 61-65 (Ex. 1001).

The specification also notes that “customized instrumentation” is possible and discusses benefits associated with disposable instrumentation. *Id.*, col. 108, ll. 19-26 (Ex. 1001).

C. The Effective Filing Date of the ’896 Issued Claims

The earliest effective filing date of Claims 1 and 13 of the ’896 patent is November 25, 2003. Even if Applicant asserts the effective filing date is August 28, 2001, the filing date of U.S. Pat. No. 6,702,821, challenged in a separate petition, the references are still prior art as described above.

D. Summary of the Prosecution History of the ’896 Patent

The application that issued as the ’896 patent had no fewer than seven Office Actions and one Advisory Action. After five office actions, the Examiner allowed asserted claims 1 and 13 without comment. ’896 patent file history, March 25, 2009 Office Action, p. 2 (Ex. 1015).

Throughout prosecution, Applicant repeatedly characterized “the present invention” as using guide members free of extramedullary or intramedullary

members. *See, e.g.*, '896 patent file history, April 30, 2007 Response, p. 13 (Ex. 1014); '896 patent file history, October 9, 2007 Response, p. 11 (Ex. 1016).

The Applicant additionally characterized the invention as using disposable cutting guides: “the present invention provides for disposable cutting blocks.” '896 patent file history, October 9, 2007 Response, p. 11 (Ex. 1016). The Examiner found this feature insufficient to distinguish the invention over the prior art, noting that “anything could be disposable, if one so desired.” '896 patent file history, March 25, 2009 Office Action, p. 3 (Ex. 1015).

After cancelling other rejected claims, Applicant additionally amended allowed claims 1 and 13 to recite “the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.” '896 patent file history, March 22, 2010 Response, pp. 2, 4 (Ex. 1017).

VII. THE PRIOR ART RENDERS THE CHALLENGED CLAIMS UNPATENTABLE

The challenged claims recite features long known by persons of skill in the art in the field of knee arthroplasty. *See* Mabrey Decl. ¶ 49 (Ex. 1002). The purported invention is a combination of known features, each of which was well known to those skilled in the art before and at the time to which the '896 patent claims priority. *See id.* As discussed in the grounds presented below, the claimed methods were known, the claimed steps performed in expected ways, and any

benefit that the steps achieve was expected. *See id.* Based on the prior art cited herein, the claimed limitations of the alleged invention perform known functions with an expected result, and are therefore unpatentable. *See id.*

A. The References

1. Delp Article

The Delp Article describes computer-assisted surgical systems developed to overcome problems with mechanical alignment systems. Delp Article, pp. 49-56 (Ex. 1003). Computer-assisted systems can use “computer integrated instruments” that 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.*, p. 50 (Ex. 1003). The Delp Article explains that “[c]omputer integrated instruments that combine standard cutting guides with highly accurate measurement equipment are a natural extension of current techniques and offer several potential advantages.” *Id.*, p. 55 (Ex. 1003). In particular, the Delp Article explains that a computer-integrated instrument system “eliminates the need for intramedullary and extramedullary alignment guides.” *Id.* Computer-assisted systems can also use “image guided knee replacement,” where a three-dimensional preoperative plan guides component placement. *Id.*, p. 50 (Ex. 1003). A person of ordinary skill in the art would understand from reading the Delp Article that a

computer-assisted surgical system can use both computer-integrated instruments and image-guided knee replacement. Mabrey Decl. ¶ 50 (Ex. 1002).

2. Delp '018

Delp '018 “relates generally to computer-assisted surgical systems, and in particular to a computer-assisted knee replacement system used to achieve accurate limb alignment with minimal surgical invasiveness.” Delp '018, col. 1, ll. 8-11 (Ex. 1004). Delp '018 aims “to provide a method of performing knee arthroplasty that does not require the use of an intramedullary rod in the femur.” *Id.*, col. 5, ll. 49-51 (Ex. 1004). It explains that the “invention overcomes alignment problems by determining optimal alignment preoperatively and using computer guidance to help the surgeon achieve this alignment.” *Id.*, col. 22, ll. 42-44 (Ex. 1004). Delp '018 further explains that the “computer replaces large, complicated mechanical alignment systems, allowing smaller jigs to be used, and thus a smaller incision to be made.” *Id.*, col. 22, ll. 45-47 (Ex. 1004).

3. Stulberg

Stulberg compares computer-assisted total knee replacement techniques with mechanically based techniques. Stulberg, p. 25 (Ex. 1005). For example, Stulberg explains that with a computer-assisted technique, the surgeon can track the position of the cutting block relative to the distal femur using a computer system, whereas

with a “[m]echanical technique,” an “intramedullary rod is introduced into the femoral canal” to position the cutting block. *Id.*, pp. 30-31 (Ex. 1005).

4. Radermacher ’157

Radermacher ’157 discloses “individual templates” manufactured for specific patients based on preoperative imaging. Radermacher ’157, pp. 9-10 (Ex. 1007). An individual template has a “negative image” of the unique structure of a specific patient’s bone so that it can be positioned on the bone “in a clearly defined position.” *Id.* An individual template can also have “guide means” for the “cutting . . . steps” of an orthopedic surgery. *Id.*, p. 11 (Ex. 1007). Because an individual template has a negative image of a specific unique bone structure, it is positioned “without any further intraoperative devices” such as intramedullary and extramedullary devices. *Id.*, p. 15 (Ex. 1007). Individual templates can be used for “treatment of osseous [bone] structures for any orthopedic intervention,” including a knee arthroplasty. *Id.*, pp. 11, 19 (Ex. 1007).

5. Radermacher Article

The Radermacher Article describes a “technique for computerized tomographic image based preoperative three-dimensional planning and precise surgery on bone structures using individual templates.” Radermacher Article, p. 28 (Ex. 1006). The Radermacher Article explains that “[i]ndividual templates are customized on the basis of three-dimensional reconstructions of the bone structures

extracted from computerized tomographic (CT) image data in accordance with individual preoperative surgical planning.” *Id.*, p. 29 (Ex. 1006).

6. Turner

Turner discloses instruments and techniques for performing a TKA, including the “Geometric Total Knee.” *See* Turner, pp. 174-187 (Ex. 1008). Turner explains this TKA design has been used “since 1969.” *Id.*, p. 176 (Ex. 1008). As discussed in detail below, in Turner, the femoral cutting guide is substantially smaller than the implant. Mabrey Decl. ¶ 55 (Ex. 1002).

7. Scorpio

Scorpio discloses “Surgical Technique” for a “Total Knee System.” Scorpio, cover page (Ex. 1009). The ’896 patent states embodiments of the invention, “with the exception of being down sized, [are] generally similar to known instrumentation which [is] commercially available . . . under the trademark ‘Scorpio’ single access total knee system.” ’896 patent, col. 35, ll. 61-65 (Ex. 1001). Moreover, as discussed below, the replacement portion is larger than the guide surface as required by claims 1 and 13. Mabrey Decl. ¶ 56 (Ex. 1002).

VIII. IDENTIFICATION OF HOW THE CHALLENGED CLAIMS ARE UNPATENTABLE

Pursuant to Rule 42.104(b)(4)-(5), specific grounds identified below and discussed in the Mabrey Declaration show in detail the prior art disclosures that

render the challenged claims unpatentable.

A. Independent Claim 1

Each of the steps of challenged claim 1 is shown in the prior art. *See* Mabrey Decl. ¶ 58 (Ex. 1002).

1. Claim 1 is Obvious Over the Delp Article in View of Any One of Turner or Scorpio

As shown in the summary chart below and in the Mabrey Declaration, claim 1 is rendered obvious by the Delp Article in view of any one of Turner or Scorpio.

The Delp Article discloses a method of replacing at least a portion of a patient's knee, as recited in the preamble. For example, the Delp Article is entitled "Computer Assisted Knee Replacement," which by definition addresses replacing at least a portion of a patient's knee. Delp Article, p. 49 (Ex. 1003).

The Delp Article discloses limitation (a), "making an incision in a knee portion of a leg of the patient." For example, Figure 1 of the Delp Article discloses a knee exposed by making an incision in the knee. *Id.*, p. 51 (Ex. 1003).

The Delp Article discloses limitation (b), "determining a position of a cutting guide using references derived independently from an intramedullary device." For example, the Delp Article discloses a computer-assisted system that "displays the position of the cutting block relative to the desired position" and

states that this system “eliminates the need for intramedullary and extramedullary alignment guides.” *Id.*, pp. 51, 55 (Ex. 1003); Mabrey Decl. ¶ 62 (Ex. 1002).

Additionally, the Delp Article discloses that an “intraoperative system determines the position and orientation of the patient’s femur and tibia and guides the placement of the cutting jigs onto the bones.” Delp Article, pp. 51-52 (Ex. 1003); Mabrey Decl. ¶ 63 (Ex. 1002). A person of ordinary skill in the art would understand that this system positions the cutting guide “using references derived independently from an intramedullary device” because it was “developed to overcome the problems with mechanical alignment systems” and because it uses image-guided alignment instead of an intramedullary device. Delp Article, p. 50 (Ex. 1003); Mabrey Decl. ¶ 63 (Ex. 1002).

The Delp Article discloses limitation (c), “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.” For example, the Delp Article discloses that a “computer workstation displays the position of the cutting block relative to the desired position . . . [and] [o]nce a jig is oriented properly it is secured in position,” which the Delp Article discloses can be on a surface of a distal end portion of an unresected femur. Delp Article, p. 51 (Ex. 1003); Mabrey Decl. ¶ 64 (Ex. 1002). Additionally, the Delp Article discloses an

“intraoperative system [can] determine[] the position and orientation of the patient’s femur and tibia and guides the placement of the cutting jigs onto the bones.” Delp Article, pp. 51-52 (Ex. 1003); Mabrey Decl. ¶ 64 (Ex. 1002). A person of ordinary skill in the art would understand that the Delp Article discloses “passing the cutting guide through the incision” because it discloses “secur[ing] [the cutting block] in position” on the bone and “placement of the cutting jigs onto the bones.” Delp Article, pp. 51-52 (Ex. 1002); Mabrey Decl. ¶ 64 (Ex. 1002). Further, the cutting guide is “secured to the bone free of an extramedullary or intramedullary alignment rod” because the Delp Article’s disclosure explicitly “eliminates the need for intramedullary and extramedullary alignment guides,” and because it discloses systems “developed to overcome the problems with mechanical alignment systems.” Delp Article, pp. 50, 55 (Ex. 1002); Mabrey Decl. ¶ 64 (Ex. 1002). To the extent the Patent Owner asserts that the Delp Article does not disclose “passing the cutting guide through the incision,” this requirement additionally would be clear to a person of ordinary skill in the art reading the Delp Article because doing so is a routine step during a knee surgery. Mabrey Decl. ¶ 64 (Ex. 1002)

The Delp Article discloses limitation (d), “moving a cutting tool through the incision into engagement with a guide surface on the cutting guide.” For example, the Delp Article discloses “[o]nce a jig is oriented properly it is secured in position

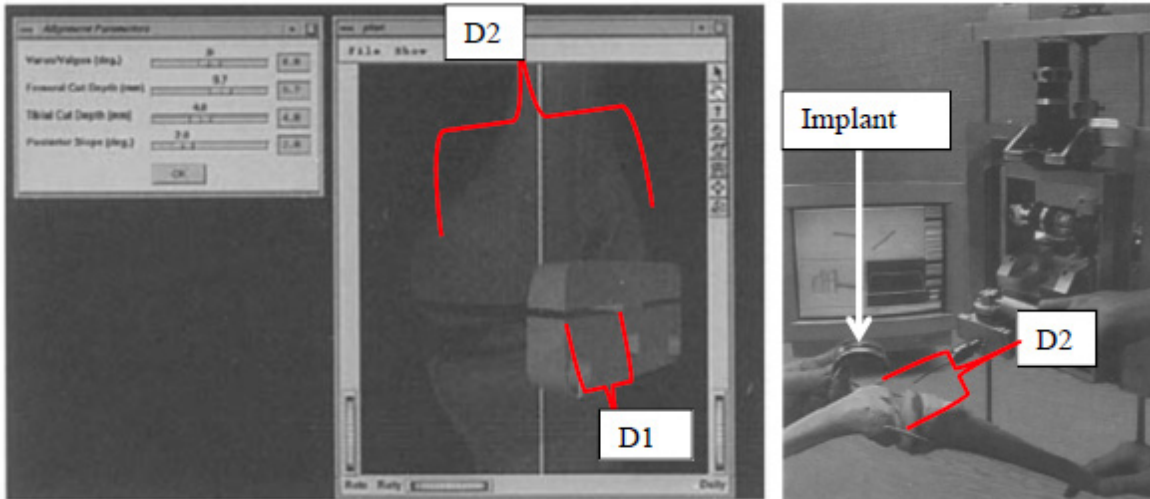
and the cuts are made with a standard oscillating saw.” Delp Article, p. 51 (Ex. 1003). A person of ordinary skill in the art would understand the Delp Article discloses limitation (d) because a standard oscillating saw (“cutting tool”) is moved through the incision into engagement with a guide surface on the cutting guide in order for “the cuts [to be] made with a standard oscillating saw” and a cutting “jig.” Mabrey Decl. ¶ 65 (Ex. 1002). Additionally, the Delp Article discloses an “intraoperative system is used . . . to guide the surgeon in the placement of the cutting jigs so that the resections specified in the preoperative plan can be made.” Delp Article, p. 52 (Ex. 1003). A person of ordinary skill in the art would understand this discloses limitation (d) because a cutting tool is moved through the incision into engagement with a guide surface on the cutting guide in order for the surgeon to use the “cutting jigs” to make the “resections specified in the preoperative plan.” Mabrey Decl. ¶ 65 (Ex. 1002). To the extent the Patent Owner asserts that the Delp Article does not disclose limitation (d), this limitation additionally would be clear to a person of ordinary skill in the art reading the Delp Article because moving a cutting tool through an incision into engagement with a cutting guide is a routine surgical step for cutting the bone. Mabrey Decl. ¶ 65 (Ex. 1002).

The Delp Article discloses limitation (e), “forming at least an initial cut on the femur by moving the cutting tool along the guide surface.” For example, the

Delp Article discloses “[o]nce a jig is oriented properly it is secured in position and the cuts are made with a standard oscillating saw.” Delp Article, p. 51 (Ex. 1003). A person of ordinary skill in the art would understand this discloses limitation (e) because making “the cuts . . . with a standard oscillating saw” and a “jig” involves forming at least an initial cut on the femur by moving a standard oscillating saw (“cutting tool”) along the guide surface of the jig. Mabrey Decl. ¶ 66 (Ex. 1002). Additionally, the Delp Article discloses an “intraoperative system is used . . . to guide the surgeon in the placement of the cutting jigs so that the resections specified in the preoperative plan can be made.” Delp Article, p. 52 (Ex. 1003). A person of ordinary skill in the art would understand this discloses limitation (e) because using the “cutting jigs” to make the “resections specified in the preoperative plan” involves forming at least an initial cut on the femur by moving the cutting tool along the guide surface. Mabrey Decl. ¶ 66 (Ex. 1002).

The Delp Article in combination with Turner or Scorpio discloses limitation (f), “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.” For example, the Delp Article discloses systems that can “align prosthetic components [implants]” and “guide[] the placement of the components [implants]” to replace the cut surface of the knee. Delp Article, p. 49 (Ex. 1003). The Delp Article also discloses that these implants (“replacement portions”) are

approximately the width of the knee D2, whereas each guide surface has a length D1 that is approximately half the width of the knee, as shown below:

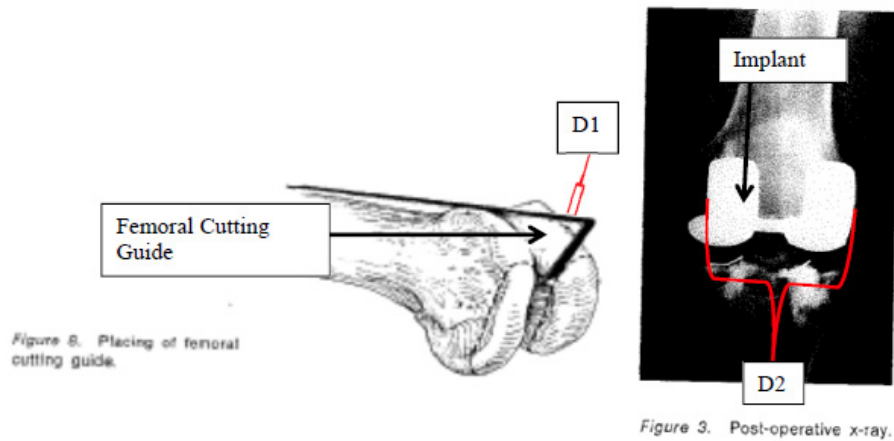


Id., Figs. 2, 3; pp. 53, 54 (Ex. 1003); Mabrey Decl. ¶ 67 (Ex. 1002). As such, a person of ordinary skill in the art would understand that the Delp Article discloses a replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

To the extent the Patent Owner asserts that the Delp Article does not disclose limitation (f), Turner or Scorpio discloses this limitation. For example, Turner discloses “attaching a replacement portion of the knee to the cut surface” in steps VII and IV, where “the femoral component [is] inserted,” and reinserted. Turner, p. 185, 187 (Ex. 1008); Mabrey Decl. ¶ 68 (Ex. 1002).

Additionally, Turner discloses an implant having “a transverse length [D2] that is larger than the guide surface length [D1]” because the femoral cutting guide

(“guide member”) disclosed in Turner has a guide surface length (D1) that is substantially less than the transverse (across the knee) length (D2) of the implant, as shown below:



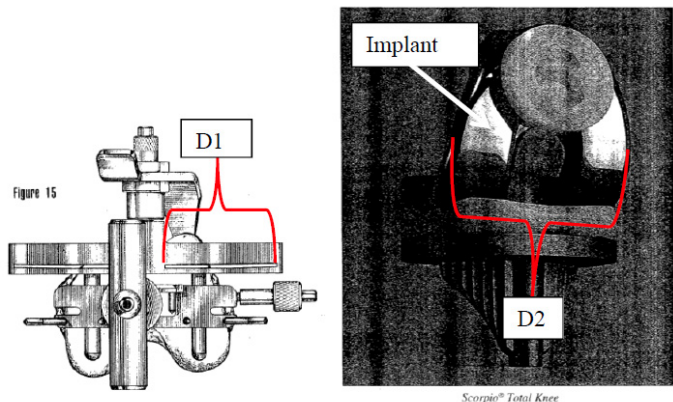
Turner, Figs. 3, 8; pp. 177, 181 (Ex. 1003); Mabrey Decl. ¶ 69 (Ex. 1002).

Additionally, Scorpio discloses that the femoral implant (shown below) is “place[d] . . . on the prepared femur . . . [for] implantation.” Scorpio, p. 47 (Ex.

1009). As shown to the right, the

femoral implant disclosed in

Scorpio has “a transverse length [D2] that is larger than the guide surface length [D1].” Scorpio, pp.



2, 9; Fig. 15 (Ex. 1009); Mabrey Decl. ¶ 70 (Ex. 1002). A person of ordinary skill in the art would understand that D2 is larger than D1 because the implant is approximately the width of the thighbone (femur) whereas D1 is smaller than the

width of the thighbone (femur). Mabrey Decl. ¶ 70 (Ex. 1002). To the extent the Patent Owner asserts that Scorpio does not disclose “the implant has a transverse length that is larger than the guide surface length,” as recited in limitation (g), it would have been obvious to reduce the length of the guide surface in this manner so that the guide could fit through a smaller incision, because doing so was a known solution for reducing trauma. Mabrey Decl. ¶ 70 (Ex. 1002); *see also, e.g.*, Delp ’018, col. 22, ll. 45-50 (known benefit of using “smaller jigs” is to allow “a smaller incision to be made,” which “will result in a less invasive procedure, and will lead to a shorter rehabilitation time, thereby reducing costs, morbidity, and patient complaints”) (Ex. 1005). Moreover, the sizes of cutting guides and guide surfaces vary according to the preferences of surgeons, and modifying the length of a guide surface is a matter of routine practice. Mabrey Decl. ¶ 70 (Ex. 1002).

It would have been obvious to a person of ordinary skill in the art to combine the systems described in the Delp Article with the cutting guides and implants disclosed in Turner or Scorpio to yield predictable results. Mabrey Decl. ¶ 71 (Ex. 1002). It was known in the prior art that “alignment of prosthetic components and of the limb are important factors” and that “[i]ncorrect positioning or orientation of implants can lead to accelerated wear, component loosening, and degraded functional performance.” Delp Article, p. 49 (Ex. 1003). It was further known that “[t]here are fundamental limitations of mechanical alignment systems.”

Id., p. 50 (Ex. 1003). The Delp Article discloses computer-assisted surgical systems for improving the alignment of mechanical instruments, such as those disclosed in Turner or Scorpio. Mabrey Decl. ¶ 71 (Ex. 1002). For example, the Delp Article explains that mechanical instruments may be augmented “through the addition of measurement probes that can be used to . . . align prosthetic components.” Delp Article, p. 50 (Ex. 1003). Additionally, the Delp Article discloses the use of preoperative imaging “to guide the surgeon in the placement of the cutting jigs.” *Id.*, p. 52-53 (Ex. 1003).

Using “measurement probes,” preoperative imaging, or other computer-assisted techniques 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. Mabrey Decl. ¶ 72 (Ex. 1002). Additionally, combining them would have required no more than routine skill, as the computer-assisted systems disclosed in the Delp Article are intended to be used to enhance instruments such as those disclosed in Turner or Scorpio. *Id.* Moreover, combining the computer-assisted techniques from the Delp Article with the mechanical devices from Turner or Scorpio would not have yielded unexpected results. *Id.* Thus, it would have been obvious to a person of ordinary skill in the art to augment the mechanical instruments in Turner or Scorpio with measurement probes to achieve predictable benefits such as the

ability to align prosthetic components more accurately. *Id.* Doing so is no more than the predictable use of prior art elements according to their established functions. *Id.*

In summary, the chart below identifies where the above prior art references disclose and/or make obvious the limitations of claim 1 of the '896 patent.

<u>Claim 1:</u> A method of replacing at least a portion of a patient's knee, the method comprising the steps of:	<i>See, e.g.</i> , Delp Article, pp. 49-56; Figs. 1-3 (Ex. 1003); Scorpio, cover; pp.1-47 (Ex. 1009); Turner, cover; pp. 171, 173-187; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(a) making an incision in a knee portion of a leg of the patient;	<i>See, e.g.</i> , Delp Article, pp. 50-53, 55; Figs. 1-3 (Ex. 1003); Scorpio, Figs. 1-3; p. 3 (Ex. 1009); Turner, pp. 180-181, 187 (Ex. 1008).
(b) determining a position of a cutting guide using references derived independently from an intramedullary device;	<i>See, e.g.</i> , Delp Article, pp. 49-56; Figs. 1-3 (Ex. 1003); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(c) 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;	<i>See, e.g.</i> , Delp Article, pp. 49-56; Figs. 1-3 (Ex. 1003); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)

(d) moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and	<i>See, e.g.</i> , Delp Article, pp. 49-56; Figs. 1-32 (Ex. 1003); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(e) forming at least an initial cut on the femur by moving the cutting tool along the guide surface;	<i>See, e.g.</i> , Delp Article, pp. 49-56; Figs. 1-3 (Ex. 1003); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(f) 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.	<i>See, e.g.</i> , Delp Article, pp. 49-56; Figs. 1-3 (Ex. 1003); Turner, pp. 172-177, 180-183, 185-189, 191-192; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008); Scorpio, pp. 2, 5-19, 21, 23, 25, 41, 47; Figs. 6-31, 36-37, 41-42, 45, 73, 86 (Ex. 1009)

2. Claim 1 is Obvious Over Delp '018 in View of Any One of Turner or Scorpio

As shown in the summary chart below and in the Mabrey Declaration, the method of claim 1 is rendered obvious by Delp '018 in view of Turner or Scorpio. As discussed in the previous section, the Delp Article discloses computer-assisted surgical systems developed to overcome problems with mechanical alignment systems. Delp '018 discloses an example of such a system, and expressly states that it is designed for “minimal surgical invasiveness” and to allow the use of “a

smaller incision.” Delp ’018, col. 1, ll. 8-11; col. 22, ll. 42-50 (Ex. 1004); Mabrey Decl. ¶ 72 (Ex. 1002).

Delp ’018 discloses a method of replacing at least a portion of a patient’s knee, as recited in the preamble. For example, Delp ’018 discloses “a method for implanting unicompartmental knee arthroplasty components.” Delp ’018, col. 5, ll. 53-54 (Ex. 1004).

Delp ’018 discloses claim 1, limitation (a). For example, Delp ’018 discloses that “an incision is made on the patient’s leg.” *Id.*, col. 16, ll. 5-7 (Ex. 1004).

Delp ’018 discloses claim 1, limitation (b). For example, Delp ’018 discloses “planning software [that] determines the poses of the femoral and tibial cutting jigs, as reflected by block 730,” where “pose” refers to “position and [] orientation.” *Id.*, col. 3, ll. 49-51; col. 14, ll. 45-48 (Ex. 1004). Delp ’018 explicitly states that the disclosed method of performing knee arthroplasty “does not require the use of an intramedullary rod in the femur.” *Id.*, col. 5, ll. 49-51 (Ex. 1004).

Delp ’018 discloses claim 1, limitation (c). For example, in addition to the disclosures described in the previous paragraph, Delp ’018 further discloses that the “pins may be placed in order to secure the contouring jig 1000 to the bone.” *Id.*, col. 19, ll. 16-19 (Ex. 1004). This describes a “method of performing knee

arthroplasty that does not require the use of an intramedullary rod in the femur.”

Id., col. 5, ll. 49-51 (Ex. 1004). Moreover, a person of ordinary skill in the art would understand that the femoral contouring jig (“cutting guide”) is secured to the bone free of an extramedullary or intramedullary alignment rod because the femoral contouring jig (“cutting guide”) is “pinned into place” rather than using such rods. *Id.*, col. 19, ll. 16-19 (Ex. 1004); Mabrey Decl. ¶ 78 (Ex. 1002). For example, Delp ’018 states that “[t]he computer replaces large, complicated mechanical alignment systems,” and identifies “an intramedullary rod” and an “extramedullary rod” as examples of such systems. Delp ’018, col. 22, ll. 45-47; col. 5, ll. 49-51; col. 2, ll. 23-31; col. 2, ll. 55-57 (Ex. 1004). Additionally, a person of ordinary skill in the art would understand that Delp ’018 discloses that a surgeon should “pass[] the cutting guide through the incision,” because the cutting guide necessarily passes through the incision in order to be positioned on the femur since no other incision is disclosed for this purpose. Mabrey Decl. ¶ 78 (Ex. 1002). Additionally, this portion of limitation (c) would have been obvious to a person of ordinary skill in the art because moving a cutting guide through an incision is a routine step during a knee surgery. *Id.*

Delp ’018 discloses claim 1, limitation (d). For example, Delp ’018 discloses “femoral resection involv[ing] three different cuts.” Delp ’018, col. 21, ll. 24-25 (Ex. 1004). A person of ordinary skill in the art would understand that

Delp '018 discloses limitation (d), first because the cutting tool necessarily passes through the incision to make the cuts since no other incisions are disclosed for this purpose. Mabrey Decl. ¶ 79 (Ex. 1002). A surgeon would also understand that the cutting guides disclosed in Delp '018 are designed to guide the tool when it is engaged with the guide surface because that is the very purpose of the guide. *Id.*

Delp '018 discloses claim 1, limitation (e). For example, Delp '018 discloses the “posterior cut is made first with either a saw or long burr along the front face 1030 of the femoral docking jig 1000.” Delp '018, col. 21, ll. 24-34 (Ex. 1004).

Delp '018 in combination with any one of Turner or Scorpio discloses claim 1, limitation (f). For example, Delp '018 discloses the “prosthetic components [] are cemented into place.” *Id.*, col. 22, ll. 22-26 (Ex. 1004). Further, as set forth above for limitation (f) in section VIII.A.1, Turner and Scorpio each disclose a “replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.” Turner, Figs. 3, 8; pp. 177, 181 (Ex. 1004); Scorpio Technique Guide, Figs. 14, 45; pp. 2, 9, 25 (Ex. 1009); Mabrey Decl. ¶ 81 (Ex. 1002).

It would have been obvious to a person of ordinary skill in the art to combine the system disclosed in Delp '018 with the implants and reduced size cutting guides disclosed in Turner or Scorpio. Mabrey Decl. ¶ 82 (Ex. 1002). For

example, Delp '018 discloses that a known benefit of using “smaller jigs” is to allow “a smaller incision to be made.” Delp '018 patent, col. 22, ll. 45-50 (Ex. 1004). The '896 patent in fact identifies the same expected benefit: “[T]he instrumentation is down sized to enable the size of the incision 114 (FIG. 9).” '896 patent, Figs. 9, 29; col. 17, ll. 49-50 (Ex. 1001). Thus, it would have been obvious to a person of ordinary skill in the art to combine the computer-assisted techniques disclosed in Delp '018, which enable the use of “smaller jigs,” with the smaller jigs disclosed in Turner or Scorpio, to obtain expected benefits such as “a smaller incision.” Mabrey Decl. ¶ 82 (Ex. 1002). Moreover, combining the computer-assisted techniques disclosed in Delp '018 with the instrumentation disclosed in Turner or Scorpio would improve the accuracy of the limb alignment with minimal invasiveness. Delp '018, col. 1, ll. 7-11 (Ex. 1004). Combining Delp '018 with Turner or Scorpio is no more than the predictable use of prior art elements according to their established functions because the established function of the computer-assisted techniques disclosed in Delp '018 are to improve the accuracy of knee replacement systems, and Turner and Scorpio are knee replacement systems whose established functions of providing tools for knee replacement benefit from improved accuracy. Mabrey Decl. ¶ 82 (Ex. 1002).

In summary, the chart below identifies where the above prior art references disclose and/or make obvious the limitations of claim 1 of the '896 patent.

<u>Claim 1:</u> A method of replacing at least a portion of a patient's knee, the method comprising the steps of:	<i>See, e.g.,</i> Delp '018, col. 5, ll. 53-56; col. 7, ll. 23-29 (Ex. 1004); Scorpio, Cover; pp.1-47 (Ex. 1009); Turner, cover, pp. 171, 173-187; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(a) making an incision in a knee portion of a leg of the patient;	<i>See, e.g.,</i> Delp '018, col. 1, ll. 40-44; col. 3, ll. 20-31; col. 4, ll. 23-25; col. 5, ll. 52-55, 63-65; col. 7, l. 16; col. 16, ll. 4-7; col. 22, ll. 25, 45-50; Figs. 19, 34 (Ex. 1004); Scorpio, Figs. 1-3; p. 3 (Ex. 1009); Turner, pp. 180-181, 187 (Ex. 1008)
(b) determining a position of a cutting guide using references derived independently from an intramedullary device;	<i>See, e.g.,</i> Delp '018, col. 2, ll. 21-57; col. 3, ll. 20-31; col. 3, ll. 49-51; col. 4, l. 20 – col. 5, l. 22; col. 5, ll. 49-55, 63-65; col. 5, l. 66 – col. 6, l. 2; col. 14, ll. 45-48; col. 18, l. 55 – col. 20, l. 37; col. 21, ll. 24-34; col. 22, ll. 35-50; Figs. 1, 3, 23-26, 31 (Ex. 1004); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(c) 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;	<i>See, e.g.,</i> Delp '018, col. 2, ll. 21-57; col. 3, ll. 20-31, 49-51; col. 4, l. 20 – col. 5, l. 22; col. 5, ll. 49-51, 63-65; col. 5, l. 66 – col. 6, l. 2; col. 14, ll. 45-48; col. 18, ll. 55-61; col. 19, ll. 16-19; col. 18, l. 55 – col. 20, l. 37; col. 21, ll. 24-34; col. 22, ll. 35-50; Figs. 1, 3, 23-26, 31 (Ex. 1004); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(d) moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and	<i>See, e.g.,</i> Delp '018, col. 2, ll. 21-57; col. 3, ll. 20-31; col. 4, l. 20 – col. 5, l. 22; col. 5, ll. 52-55, 63-65; col. 5, l. 66 – col. 6, l. 2; col. 18, l. 55 – col. 20, l. 37; col. 21, ll. 24-34; col. 22, ll. 35-50; Figs. 1, 3, 23-26, 31 (Ex. 1004); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)

(e) forming at least an initial cut on the femur by moving the cutting tool along the guide surface;	<i>See, e.g.</i> , Delp '018, col. 2, ll. 21-57; col. 3, ll. 20-31; col. 4, l. 20 – col. 5, l. 22; col. 5, ll. 52-55, 63-65; col. 5, l. 66 – col. 6, l. 2; col. 18, l. 55 – col. 27, l. 37; col. 21, ll. 24-34; col. 22, ll. 35-50; Figs. 1, 3, 23-26, 31 (Ex. 1004); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(f) 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.	<i>See, e.g.</i> , Delp '018, col. 1, ll. 7-11; col. 2, ll. 21-57; col. 3, ll. 20-31; col. 4, l. 20 – col. 5, l. 22; col. 5, ll. 52-55, 63-65; col. 5, l. 66 – col. 6, l. 2; col. 18, l. 55 – col. 27, l. 37; col. 21, ll. 24-34; col. 22, ll. 13-25, 35-50; Figs. 1, 3, 11-12, 15, 23-26, 31 (Ex. 1004); Turner, pp. 172-177, 180-183, 185-189, 191-192; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008); Scorpio, pp. 2, 5-19, 21, 23, 25, 41, 47; Figs. 6-31, 36-37, 41-42, 45, 73, 86 (Ex. 1009)

3. Claim 1 is Obvious Over Stulberg in View of Any One of Turner or Scorpio

As shown in the summary chart below and in the Mabrey Declaration, the method of claim 1 is rendered obvious by Stulberg in view of Turner or Scorpio.

Stulberg discloses a method of replacing at least a portion of a patient's knee, as recited in the preamble. For example, Stulberg is entitled "Computer-Assisted Total Knee Replacement Arthroplasty." Stulberg, p. 25 (Ex. 1005).

Stulberg discloses claim 1, limitation (a). For example, Stulberg discloses using "a straight midline skin incision." Stulberg, p. 27 (Ex. 1005); *see also* Stulberg, p. 26, Fig. 2 (Ex. 1005).

Stulberg discloses claim 1, limitation (b). For example, Stulberg discloses a “computer-assisted technique” where the surgeon can “track . . . the position of the cutting block,” rather than introducing an “intramedullary rod . . . into the femoral canal.” Stulberg, p. 30 (Ex. 1005).

Stulberg discloses claim 1, limitation (c). For example, Stulberg discloses the surgeon can “then track on the monitor the position of the cutting block relative to the distal femur.” Stulberg, p. 30 (Ex. 1005). Moreover, a person of ordinary skill in the art would understand that Stulberg discloses that the “cutting guide [is] secured to the bone free of an extramedullary or intramedullary alignment rod” because the cutting guide is aligned using the computer and “secured to the femur with a 5-mm threaded wire” instead. Stulberg, p. 30 (Ex. 1005); Mabrey Decl. ¶ 88 (Ex. 1002). Additionally, a person of ordinary skill in the art would understand that Stulberg discloses “passing the cutting guide through the incision,” or alternatively, it would have been obvious to do so, because the femoral cutting guide is necessarily moved through the incision so it may be positioned on the femur, as no other incision is disclosed for this purpose. Mabrey Decl. ¶ 88 (Ex. 1002).

Stulberg discloses claim 1, limitation (d). For example, Stulberg discloses that the “distal femur is . . . resected.” Stulberg, Fig. 17B; pp. 30-31, 36 (Ex. 1005). A person of ordinary skill in the art would understand that Stulberg

discloses “moving a cutting tool through the incision,” or alternatively, it would have been obvious to do so, because the cutting tool is necessarily moved through the incision, as there is no other incision disclosed for this purpose. Mabrey Decl. ¶ 89 (Ex. 1002).

Stulberg discloses claim 1, limitation (e). For example, as shown in Figure 17B above, Stulberg discloses forming at least an initial cut on the femur by moving the cutting tool along the guide surface. Stulberg, Fig. 17B (Ex. 1005); Mabrey Decl. ¶ 90 (Ex. 1002).

Stulberg in combination with Turner or Scorpio discloses claim 1, limitation (f). For example, Stulberg discloses that the alignment of the leg is confirmed with the implants installed. Stulberg, Fig. 19B; p. 37 (Ex. 1005). Further, as set forth above for limitation (f) in section VIII.A.1, Turner and Scorpio each disclose a “replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.” Turner, Figs. 8, 14 (Ex. 1004); Scorpio Technique Guide, Figs. 14, 45 (Ex. 1009); Mabrey Decl. ¶ 91 (Ex. 1002).

It would have been obvious to a person of ordinary skill in the art to utilize the computer-assisted system disclosed in Stulberg in combination with the cutting guides and implants disclosed in Turner or Scorpio. Mabrey Decl. ¶ 92 (Ex. 1002). The person of ordinary skill would be motivated to follow the teachings of Stulberg that computer-assisted surgery can overcome the deficiencies of standard

mechanical measuring techniques, such as the inability to locate crucial alignment landmarks, the presumption that bone geometry is standardized, and the reliance on visual inspection to verify proper alignment of the implant. Stulberg, p. 25 (Ex. 1005). As such, a person of ordinary skill in the art would want to combine the teachings of Stulberg with mechanical instruments from Turner or Scorpio to yield the predictable improvement of a more accurate surgical outcome. Stulberg, p. 33 (Ex. 1005). This combination is no more than the predictable use of prior art technology according to its established function to achieve a predictable result. Mabrey Decl. ¶ 92 (Ex. 1002).

In summary, the chart below identifies where the above prior art references disclose and/or make obvious the limitations of claim 1 of the '896 patent.

<u>Claim 1:</u> A method of replacing at least a portion of a patient's knee, the method comprising the steps of:	<i>See, e.g.</i> , Stulberg, pp. 25-39; Figs. 1-20 (Ex. 1005); Scorpio, cover; pp.1-47 (Ex. 1009); Turner, cover; pp. 171, 173-187; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(a) making an incision in a knee portion of a leg of the patient;	<i>See, e.g.</i> , Stulberg, pp. 26-28, 39; Figs. 2, 6 (Ex. 1005); Scorpio, Figs. 1-3; p. 3 (Ex. 1009); Turner, pp. 180-181, 187 (Ex. 1008)
(b) determining a position of a cutting guide using references derived independently from an intramedullary device;	<i>See, e.g.</i> , Stulberg, pp. 25, 27-32, 35-36; Figs. 1-4, 7, 9-11, 15, 16, 19 (Ex. 1005); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)

(c) 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;	<i>See, e.g.</i> , Stulberg, pp. 25, 27-32, 35-39; Figs. 1-4, 6-7, 9-11, 15, 16, 19 (Ex. 1005); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(d) moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and	<i>See, e.g.</i> , Stulberg, pp. 25, 27-32, 35-39; Figs. 1-4, 6-7, 9-11, 15, 16, 19 (Ex. 1005); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(e) forming at least an initial cut on the femur by moving the cutting tool along the guide surface;	<i>See, e.g.</i> , Stulberg, pp. 25, 27-32, 35-39; Figs. 1-4, 7, 9-11, 15, 16, 17, 19 (Ex. 1005); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(f) 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.	<i>See, e.g.</i> , Stulberg, pp. 25, 27-32, 35-37, 39; Figs. 1-4, 7, 9-11, 15, 16, 17, 19-20 (Ex. 1005); Turner, pp. 172-177, 180-183, 185-189, 191-192; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008); Scorpio, pp. 2, 5-19, 21, 23, 25, 41, 47; Figs. 6-31, 36-37, 41-42, 45, 73, 86 (Ex. 1009)

B. Independent Claim 13

Each of the steps of claim 13 are shown in the prior art. *See* Mabrey Decl. ¶ 94 (Ex. 1002).

1. Claim 13 is Anticipated by Radermacher '157

As shown in the summary chart below and in the Mabrey Declaration, the

method of claim 13 is anticipated by Radermacher '157.

Radermacher '157 discloses a method of replacing at least a portion of a joint in a patient, as recited in the preamble. For example, Radermacher '157 discloses replacing a “knee-joint.” Radermacher '157, pp. 19, 30; Figs. 13a-13d (Ex. 1007).

Radermacher '157 discloses limitation (a), “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.” For example, Radermacher '157 discloses “individual templates” with “guide means” that are manufactured for specific patients based on “preoperative” images. Radermacher '157, pp. 9-11 (Ex. 1007); Mabrey Decl. ¶ 97 (Ex. 1002). The individual templates are customized with a “negative image” of the unique structure of a specific patient’s bone so that they can be positioned on the bone “in a clearly defined position.” Radermacher '157, pp. 9-10 (Ex. 1007); Mabrey Decl. ¶ 97 (Ex. 1002). The individual templates are positioned with the negative image of the bone structure, “without any further intraoperative devices,” such as intramedullary and extramedullary devices. Radermacher '157, p. 15 (Ex. 1007); Mabrey Decl. ¶ 97 (Ex. 1002). A person of ordinary skill in the art would therefore understand Radermacher '157 discloses “individual templates” (“customized cutting

guide[s]”) 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. Mabrey Decl. ¶ 97 (Ex. 1002).

Radermacher ’157 discloses limitation (b), “making an incision adjacent to the joint in the patient.” For example, Radermacher ’157 discloses pre-operative planning of the “incision” for a surgery. Radermacher ’157, p. 1 (Ex. 1007). Additionally, a person of ordinary skill in the art would understand that Radermacher ’157 discloses limitation (b) because a person of ordinary skill in the art would understand that the incision disclosed in Radermacher ’157 is the incision adjacent to the joint that is routinely used by surgeons in knee replacement surgery such as that disclosed in Radermacher ’157. Radermacher ’157, pp. 19, 30; Figs. 13a-13d (Ex. 1007); Mabrey Decl. ¶ 98 (Ex. 1002).

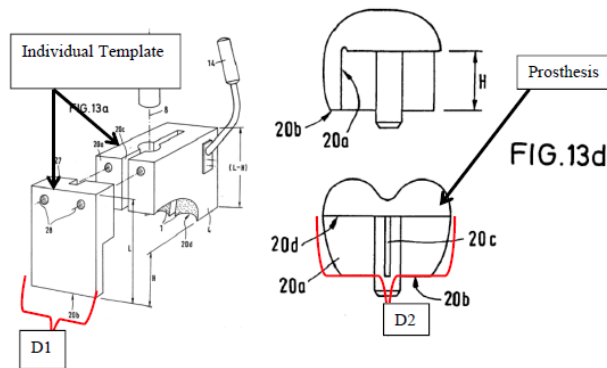
Radermacher ’157 discloses limitation (c), “positioning the cutting guide in the pre-determined position by passing the cutting guide through the incision and on a surface of an end portion of an unresected bone of the joint.” For example, Radermacher ’157 discloses an “intraoperative procedure” where “the individual template 4 is set onto the bone 17 in a defined manner.” Radermacher ’157, p. 30; Fig. 13c (Ex. 1007); Mabrey Decl. ¶ 99 (Ex. 1002). Additionally, a person of ordinary skill in the art would understand that Figure 13c of Radermacher ’157

shows an individual template (“cutting guide”) positioned in a pre-determined position on a surface of an end portion of unresected bone (17) in the knee joint. Radermacher ’157, Fig. 13c (Ex. 1007); Mabrey Decl. ¶ 99 (Ex. 1002). A person of ordinary skill in the art would understand that Radermacher ’157 discloses “passing the cutting guide through the incision” because placing the individual template on the bone necessarily requires passing the cutting guide through the incision so that it can be placed on the bone. Mabrey Decl. ¶ 99 (Ex. 1002).

Radermacher ’157 discloses limitation (d), “moving a cutting tool through the incision into engagement with a guide surface on the positioned cutting guide,” and limitation (e), “cutting the unresected bone of the joint for the first time, by moving the cutting tool along the guide surface.” For example, Radermacher ’157 discloses that a “cut is formed along the cutting plane 20a. . . . cut 20b can be performed . . . [with] additional template 27 . . . the groove (cut 20c) is milled or sawed . . . and then, cut 20d is formed along the lower edge of the individual template 4.” Radermacher ’157, p. 30; Figs. 13a, 13c (Ex. 1007); Mabrey Decl. ¶ 100 (Ex. 1002). A person of skill in the art would understand Radermacher ’157 to disclose limitation (d) because making cuts with individual templates necessarily involves moving a cutting tool through the incision into engagement with a guide surface on the positioned cutting guide. Mabrey Decl. ¶ 100 (Ex. 1002). A person of ordinary skill in the art would additionally understand Radermacher ’157

discloses limitation (e) because making the cuts with an individual template necessarily requires cutting the unresected bone of the joint for the first time by moving the cutting tool along the guide surface of the individual template. *Id.*

Radermacher '157 discloses limitation (f), “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.” For example, Radermacher '157 discloses a “knee joint head prosthesis” (“replacement portion”) implanted in the cut surface of a femur (17). Radermacher '157, p. 30; Fig. 13b (Ex. 1007); Mabrey Decl. ¶ 101 (Ex. 1002). A person of skill in the art would understand that Radermacher '157 discloses that the “knee joint head prosthesis” (“replacement portion”) has a transverse dimension D2 that is larger than a transverse dimension of the guide surface D1, as shown below:



Radermacher '157, p. 30; Figs. 13a, 13d (Ex. 1007); Mabrey Decl. ¶ 101 (Ex. 1002). One can see from Fig. 13d that the transverse length of the prosthesis D2 is approximately twice the height “H,” whereas the guide surface length D1 in Fig.

13a is approximately the same as height “H,” and therefore, the transverse length of the prosthesis D2 is larger than the guide surface length D1.

Radermacher '157 discloses limitation (g), “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.” Radermacher '157 expressly acknowledges that its templates are designed to create a “negative image” of the unique structure of a specific patient’s bone. Radermacher '157, pp. 9-11 (Ex. 1006). Therefore, these templates are incapable of being safely used on the bone of another patient who will have different bone structure or even for the same patient at a later date once her bones have been cut, and thus no longer conform to the template. Mabrey Decl. ¶ 102 (Ex. 1002)

In summary, the chart below identifies where the above prior art references disclose and/or make obvious the limitations of claim 13 of the '896 patent.

<u>Claim 13:</u> A method of replacing at least a portion of a joint in a patient, the method comprising the steps of	<i>See, e.g.,</i> Radermacher '157, cover; pp. 1-44; Figs. 1-29 (Ex. 1007)
(a) 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;	<i>See, e.g.,</i> Radermacher '157, cover; pp. 1-44; Figs. 1-29 (Ex. 1007)

(b) making an incision adjacent to the joint in the patient;	<i>See, e.g.</i> , Radermacher '157, pp. 1, 9-11, 15, 19, 22, 30; Fig. 13a-d (Ex. 1007)
(c) 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;	<i>See, e.g.</i> , Radermacher '157, pp. 1-20, 22, 30, 34-44; Figs. 13a-d, 15-19 (Ex. 1007)
(d) moving a cutting tool through the incision into engagement with a guide surface on the positioned cutting guide;	<i>See, e.g.</i> , Radermacher '157, pp. 1-20, 22, 30, 34-44; Figs. 13a-d, 15-19 (Ex. 1007)
(e) cutting the unresected bone of the joint for the first time, by moving the cutting tool along the guide surface;	<i>See, e.g.</i> , Radermacher '157, pp. 1-20, 22, 30, 34-44; Figs. 13a-d, 15-19 (Ex. 1007)
(f) 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	<i>See, e.g.</i> , Radermacher '157, pp. 1-20, 22, 30, 34-44; Figs. 13a-d, 15-19 (Ex. 1007)
(g) 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.	<i>See, e.g.</i> , Radermacher '157, pp. 1-20, 22, 30, 34-44; Figs. 13a-d, 15-19 (Ex. 1007)

2. Claim 13 is Obvious Over the Radermacher Article in View of Any One of Turner or Scorpio

As shown in the summary chart below and in the Mabrey Declaration, the method of claim 13 is rendered obvious by the Radermacher Article in view of Turner or Scorpio.

The Radermacher Article discloses a method of replacing at least a portion of a joint in a patient, as recited in the preamble. For example, the Radermacher

Article is titled “Computer Assisted Orthopaedic Surgery with Image Based Individual Templates.” Radermacher Article, pp. 29, 31-32 (Ex. 1006).

The Radermacher Article discloses claim 13, limitation (a). First, the Radermacher Article, for example, discloses “[i]ndividual templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data in accordance with individual preoperative surgical planning.” Radermacher Article, p. 29 (Ex. 1006). Second, the Radermacher Article discloses, for example, that individual templates make it “possible to reproduce the preoperatively planned position exactly.” Radermacher Article, p. 31 (Ex. 1006). A person of ordinary skill in the art would understand that the Radermacher Article thus discloses “using references derived independently from an intramedullary device” because the individual templates use a preoperatively planned position, rather than a references derived from an intramedullary device. Mabrey Decl. ¶ 106 (Ex. 1002).

The Radermacher Article discloses claim 13, limitation (b). A person of ordinary skill in the art would understand that the Radermacher Article discloses limitation (b) because a person of ordinary skill in the art would understand that to conduct the surgery disclosed in the Radermacher Article, she would have to make the incision adjacent to the joint that is routinely used by surgeons in knee

replacement surgery in order to access the damaged portions of the bone that need to be replaced. Mabrey Decl. ¶ 107 (Ex. 1002).

The Radermacher Article discloses claim 13, limitation (c). For example, the Radermacher Article states that with the disclosed individual templates, “it is possible to reproduce the preoperatively planned position exactly.” Radermacher Article, p. 31 (Ex. 1006); *see also* Radermacher Article, p. 28-29 (Ex. 1006). A person of ordinary skill in the art would understand the Radermacher Article discloses “passing the cutting guide through the incision” because placing the individual template in the “preoperatively planned position” on the bone necessarily requires passing the cutting guide through the incision so that it can be placed on the bone. Mabrey Decl. ¶ 108 (Ex. 1002). Additionally, this portion of limitation (c) would have been obvious to a person of ordinary skill in the art because moving a cutting guide through an incision is a routine step during a knee surgery. *Id.*

The Radermacher Article discloses claim 13, limitation (d). For example, the Radermacher Article discloses that a “conventional saw guide can be mounted on the individual template, which serves as a reference base for subsequent work on the bone.” Radermacher Article, p. 31 (Ex. 1006). A person of ordinary skill in the art would understand the Radermacher Article discloses limitation (d) because making the planned cuts with individual templates necessarily involves moving a

cutting tool through the incision into engagement with a guide surface on the positioned cutting guide. Mabrey Decl. ¶ 109 (Ex. 1002). Additionally, limitation (d) would have been obvious to a person of ordinary skill in the art because moving a cutting tool such as a bone saw through an incision is a routine and necessary part of knee replacement procedures so that the surgeon can reach the bone, and no other incision is disclosed for that purpose. *Id.*

The Radermacher Article discloses claim 13, limitation (e). For example, as described in the preceding paragraph, the Radermacher Article discloses making a “cut” using an individual template with a “saw guide.” Radermacher Article, p. 31 (Ex. 1006). A person of ordinary skill in the art would understand the Radermacher Article discloses limitation (e) because making the planned cuts with individual templates necessarily requires cutting the unresected bone of the joint for the first time by moving the cutting tool along the guide surface of the “saw guide.” Mabrey Decl. ¶ 110 (Ex. 1002). Additionally, limitation (e) would have been obvious to a person of ordinary skill in the art because it is a routine part of knee replacement. *Id.*

The Radermacher Article in combination with Turner or Scorpio discloses claim 13, limitation (f). For example, the Radermacher Article discloses “placement of implant components” in a “total knee arthroplasty.” Radermacher Article, p. 31 (Ex. 1006). Further, as set forth above for limitation (f) in section

VIII.A.1, Turner and Scorpio each disclose a “replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.” Turner, Figs. 8, 14 (Ex. 1004); Scorpio Technique Guide, Figs. 14, 45 (Ex. 1009); Mabrey Decl. ¶ 111 (Ex. 1002).

It would have been obvious to a person 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. Radermacher Article, p. 28 (Ex. 1006); Mabrey Decl. ¶ 112 (Ex. 1002). Thus, combining the Radermacher Article with Turner or Scorpio would yield the predictable results of providing the surgeon with “the precise spatial correspondence between the individual bone structure in situ and the intended position of the tool guides,” such that the surgeon can more accurately position the tool guides disclosed in Turner or Scorpio. Radermacher Article, p. 29 (Ex. 1006); Mabrey Decl. ¶ 112 (Ex. 1002). Doing so is no more than the predictable use of prior art elements according to their established functions, such as using them for knee replacement (Turner or Scorpio), and improving the accuracy with which such instrumentation can be placed on the bone (Radermacher). Mabrey Decl. ¶ 112 (Ex. 1002).

The Radermacher Article discloses claim 13, limitation (g). The Radermacher Article expressly acknowledges that its templates are designed to have “the precise spatial correspondence between the individual bone structure in situ and the intended position of the tool guides.” Radermacher Article, p. 29 (Ex. 1006). Therefore, these templates are incapable of being safely used on the bone of another patient who will have different “individual bone structure,” or even for the same patient at a later date once her bones have been cut, and thus no longer conform to the template. It would have been obvious to a person of ordinary skill in the art to dispose of a cutting guide after performing the procedures disclosed in the Radermacher Article. Mabrey Decl. ¶ 113 (Ex. 1002).

In summary, the chart below identifies where the above prior art references disclose and/or make obvious the limitations of claim 13 of the '896 patent.

<u>Claim 13:</u> A method of replacing at least a portion of a joint in a patient, the method comprising the steps of	<i>See, e.g.,</i> Radermacher Article, pp. 28-38; Figs. 1-4 (Ex. 1006); Scorpio, Cover; pp.1-47 (Ex. 1009); Turner, cover, pp. 171, 173-187; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
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(a) 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;	<i>See, e.g.</i> , Radermacher Article, pp. 28-38; Figs. 1-4 (Ex. 1006); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(b) making an incision adjacent to the joint in the patient;	<i>See, e.g.</i> , Radermacher Article, pp. 28-32; Fig. 2 (Ex. 1006); Scorpio, Figs. 1-3; p. 3 (Ex. 1009); Turner, pp. 180-181, 187 (Ex. 1008)
(c) 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;	<i>See, e.g.</i> , Radermacher Article, pp. 28-31; Fig. 2 (Ex. 1006); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(d) moving a cutting tool through the incision into engagement with a guide surface on the positioned cutting guide;	<i>See, e.g.</i> , Radermacher Article, pp. 28-31; Fig. 2 (Ex. 1006); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(e) cutting the unresected bone of the joint for the first time, by moving the cutting tool along the guide surface;	<i>See, e.g.</i> , Radermacher Article, pp. 28-31; Fig. 2 (Ex. 1006); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
(f) 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	<i>See, e.g.</i> , Radermacher Article, pp. 28-31; Figs. 1-4 (Ex. 1006); Turner, pp. 174-175, 181-183, 185-186 (Ex. 1008); Scorpio Technique Guide, Figs. 14, 45 (Ex. 1009); Turner, pp. 172-177, 180-183, 185-189, 191-192; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008); Scorpio, pp. 2, 5-19, 21, 23, 25, 41, 47; Figs. 6-31, 36-37, 41-42, 45, 73, 86 (Ex. 1009)

(g) 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.	<i>See, e.g.</i> , Radermacher Article, p. 28-32; Fig. 1-4 (Ex. 1006); Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1009); Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1008)
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IX. CONCLUSION

Based on the foregoing, claims 1 and 13 of the '896 patent recite subject matter that is unpatentable. The Petitioner requests institution of an *inter partes* review to cancel these claims.

Respectfully submitted,

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LIST OF EXHIBITS FOR
PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 7,806,896

<u>Exhibit</u>	<u>Description</u>
1001	U.S. patent No. 7,806,896 (“’896 patent”)
1002	Declaration of Jay Mabrey, M.D., M.B.A. (“Mabrey Declaration” or “Mabrey Decl.”)
1003	Scott L. Delp, <i>et al.</i> , “Computer Assisted Knee Replacement,” 354 Clinical Orthopaedics and Related Research (1998) (“Delp Article”)
1004	U.S. Patent No. 5,871,018 (“Delp ’018”)
1005	S. David Stulberg, <i>et al.</i> , “Computer-Assisted Total Knee Replacement Arthroplasty,” 10(1) Operative Techniques in Orthopaedics (Jan. 2000) (“Stulberg”)
1006	Klaus Radermacher, <i>et al.</i> , “Computer Assisted Orthopaedic Surgery With Image Based Individual Templates,” 354 Clinical Orthopaedics and Related Research (1998) (“Radermacher Article”)
1007	International Patent Application Publication No. WO 93/25157 to Radermacher (“Radermacher ’157”)
1008	Roderick H. Turner, Richard Matzan, and Yousif I. Hamati, “Geometric and Anametric Total Knee Replacement,” <i>in</i> Total Knee Replacement (A.A. Savastano, M.D. ed. 1980) (“Turner”)
1009	Stryker Howmedica Osteonics, “Scorpio Single Axis Total Knee System: Passport A.R. Surgical Technique” (“Scorpio”)
1010	The New Oxford American Dictionary (2d ed. 2005)
1011	Webster’s New College Dictionary (2007)
1012	The American Heritage College Dictionary (3d ed. 1993)
1013	U.S. Patent No. 4,502,483 (“Lacey ’483”)

U.S. Patent 7,806,896
Petition for *Inter Partes* Review

<u>Exhibit</u>	<u>Description</u>
1014	'896 patent file history, Response dated April 30, 2007
1015	'896 patent file history, Office Action dated March 25, 2009
1016	'896 patent file history, Response dated October 9, 2007
1017	'896 patent file history, Response dated March 22, 2010
1018	Smith & Nephew, "Genesis Unicompartmental Knee System," 1994
1019	U.S. Patent No. 5,282,803 ("Lackey '803")
1020	Richards Manufacturing Co., Inc., "Richards Intracondylar Knee" (1979) ("Richards")
1021	Peter A. Keblish, Jr., M.D., "Surgical Techniques in the Performance of Unicompartmental Arthroplasties," 8(3) Operative Techniques in Orthopaedics, pp. 134-145 (July 1998) ("Keblish")

CERTIFICATE OF SERVICE

I hereby certify that on September 26, 2013, I caused a true and correct copy of the foregoing materials:

- Petition for *Inter Partes* Review of U.S. Patent No. 7,806,896 Under 35 U.S.C. § 312 and 37 C.F.R. § 42.104
- Exhibits 1001-1021
- List of Exhibits for Petition for *Inter Partes* Review of U.S. Patent No. 7,806,896 (Ex. 1001-1021)
- Fee Authorization
- Power of Attorney

to be served via Federal Express on the following attorney of record as listed on PAIR:

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