DOCKET NO: 0286868.00189 IPR2013-00620

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

PATENT: 6,702,821

INVENTORS: PETER M. BONUTTI

FILED: AUGUST 28, 2001 ISSUED: MARCH 9, 2004

TITLE: INSTRUMENTATION FOR MINIMALLY INVASIVE JOINT REPLACEMENT AND METHODS FOR USING SAME

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Patent Trial and Appeal Board
U.S. Patent & Trademark Office
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**FEE AUTHORIZATION**

The undersigned authorizes the Office to charge $23,000 to Deposit Account No. 080219 for the fee set forth in 37 C.F.R. § 42.15(a) for this Petition for Inter Partes Review. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

**/Michael Smith/**
Michael H. Smith
Registration No. 71,190

**S&N EXHIBIT 1025**
**S&N v. BSI**
**IPR2013-00629**

DOCKET NO.: 0286868-00189
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UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SMITH & NEPHEW, INC.
Petitioner

v.

Patent Owner of
U.S. Patent No. 6,702,821 to Peter M. Bonutti

IPR Trial No. TBD

# PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,702,821 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 a certain claim of U.S. Patent No. 6,702,821 ("'821 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 '821 patent, U.S. Patent No. 5,980,559, U.S. Patent No. 7,087,073, U.S. Patent 7,749,229, U.S. Patent No. 7,806,896, and U.S. Patent No. 8,133,229. The '821 patent is the subject of this Petition. Separate petitions for *inter partes* review of the other patents above are being filed in addition to this Petition. 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 claim 1 of the '821 patent (Ex. 1001).

### A. Prior Art Patents and Printed Publications

Petitioner relies upon the following patents and printed publications:

1. 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. 1003)), which has a publication date of 1980, and is prior art to the '821 patent under 35 U.S.C. § 102(b)[1].

2. Chitranjan S. Ranawat and Lawrence D. Dorr, "G. Technique of Total Knee Arthroplasty with Precision Cut Instruments," *in* Total-Condylar Knee Arthroplasty: Technique, Results, and Complications (Chitranjan S. Ranawat ed., 1985) ("Ranawat" (Ex. 1004)), which has a publication date of 1985, and is prior art to the '821 patent under 35 U.S.C. § 102(b).
3. Stryker Howmedica Osteonics, "Scorpio Single Axis Total Knee System: Passport A.R. Surgical Technique" ("Scorpio" (Ex. 1005)), which has a publication date of May 2000, and is prior art to the '821 patent under 35 U.S.C. § 102(b).
4. U.S. Patent No. 5,871,018 ("Delp '018" (Ex. 1006)), which has a filing date of June 6, 1997, and an issue date of February 16, 1999, and is prior art to the '821 patent under 35 U.S.C. § 102(b).

[1] The '821 patent was issued prior to the America Invents Act ("AIA"). Therefore, Petitioner has chosen to use the pre-AIA statutory framework to refer to the prior art.

5. U.S. Patent No. 5,282,803 ("Lackey '803" (Ex. 1014)), which has a filing date of March 30, 1992, and an issue date of February 1, 1994, and is prior art to the '821 patent under 35 U.S.C. § 102(b).

### B. Grounds for Challenge

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

This Petition, supported by the declaration of Dr. 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. LEGAL PRINCIPLES

The challenged claim is anticipated and/or obvious under 35 U.S.C. §§ 102 and 103, respectively. "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *See, e.g.*, *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

The challenged claim is also unpatentable because it is obvious under 35 U.S.C. § 103. A claim is invalid if it would have been obvious—that is,

> if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have

> been obvious at the time the invention was made to a person having ordinary skill in the art to which [the] subject matter pertains.

35 U.S.C. § 103; *see also Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1364 (Fed. Cir. 1998).

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the U.S. Supreme Court addressed the issue of obviousness and provided an "expansive and flexible approach" that is consistent with the "broad inquiry" set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). According to the Supreme Court, a person of ordinary skill in the art is "a person of ordinary creativity, not an automaton," *KSR*, 550 U.S. at 421, and "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 420. The Court held that:

> [w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 U.S.C.] § 103.

*Id.* at 421. Thus, *KSR* focused on whether a combination of known elements could be patentable if it yielded predictable results. The Court's guidance was clear: it

may not. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416. Further, "[i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417.

The Board must ask, as guided by *KSR*, whether the challenged claim recites an improvement that is "more than the predictable use of prior art elements according to their established functions." *Id.* The Board should conclude, based on the information in this Petition, that the challenged claim is merely a predictable combination of known elements that are used according to their established functions, that they are therefore unpatentable, and that an *inter partes* review of the challenged claims should therefore be instituted.

## V. 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.

[2] The proposed claim construction herein applies the "broadest reasonable construction" standard and a construction under a different standard of claim interpretation (*e.g.*, as applied in a District Court proceeding) may be different.

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 claim has a construction different from their broadest reasonable interpretation, the appropriate course is for the Patent Owner to seek to amend the claim 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 claim complies with 35 U.S.C. § 112.

Claim 1 recites a "guide member" and a "guide surface." These terms are not defined in the '821 patent. The '821 patent specification refers to an anterior resection guide (138), a distal resection guide (186), and the femoral cutting guide (210) as "guide members." '821 patent, col. 31, ll. 62-65; col. 33, ll. 25-34 (Ex. 1001). The specification describes these "guide members" as having "guide surfaces" (*e.g.*, '821 patent, col. 31, ll. 43-48 ("anterior resection guide 138 . . . has a guide surface 178"); col. 34, ll. 3-10 (Ex. 1001)), and describes the "guide surfaces" as guiding cutting instruments. *E.g.*, '821 patent, col. 5, ll. 57-60 (Ex. 1001). Therefore, the terms "guide member" and "guide surface" should be given their broadest reasonable interpretation and should be construed to mean a

"member that has a guide surface" and "a surface that guides a cutting instrument," respectively.

## VI. OVERVIEW OF KNEE ANATOMY AND KNEE REPLACEMENT

Challenged claim 1 of the '821 patent relates to a method for knee replacement, also known as knee arthroplasty.

Generally, there are two types of knee replacement surgeries: total knee and partial knee replacement. Mabrey Decl. ¶ 16 (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). Mabrey Decl. ¶ 16 (Ex. 1002). 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. Mabrey Decl. ¶ 16 (Ex. 1002). This partial replacement is sometimes called a unicondylar knee arthroplasty ("UKA"). Mabrey Decl. ¶ 16 (Ex. 1002).

Knee replacement was not new when the patent was filed.[3] Mabrey Decl. ¶ 17 (Ex. 1002). Some elementary background is helpful to understand fully the

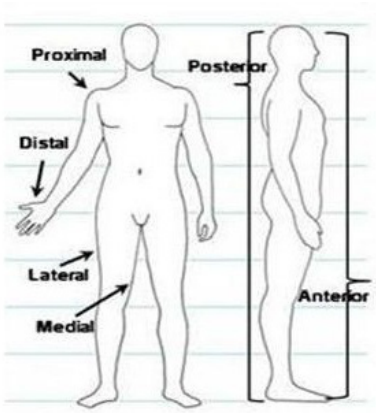
[3] The background of the invention in the '821 patent generally describes the method for a knee replacement. *See* '821 patent, col. 1, ll. 25 – col. 2 ll. 32.

claim limitations in the challenged claim and to appreciate how the prior art renders the claim unpatentable. Mabrey Decl. ¶ 17 (Ex. 1002).

### 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. ¶ 18 (Ex. 1002).

### B. Relevant Knee Anatomy

At a simple conceptual level, the knee works like a modified hinge on a door. Mabrey Decl. ¶ 19 (Ex. 1002). Bending of the knee is called "flexion" and straightening of the knee is called "extension." Mabrey Decl. ¶ 19 (Ex. 1002). The knee is more complex than a simple hinge and actually rotates around its central axis as it flexes and extends. Mabrey Decl. ¶ 19 (Ex. 1002).

The knee is a major weight-bearing joint that is held together by muscles, ligaments, and soft tissue. Mabrey Decl. ¶ 20 (Ex. 1002). Cartilage inside the joint provides shock absorption, which is used to walk, run, lift, climb stairs, etc.

and so on. Mabrey Decl. ¶ 20 (Ex. 1002). The illustration below shows the components of the knee:

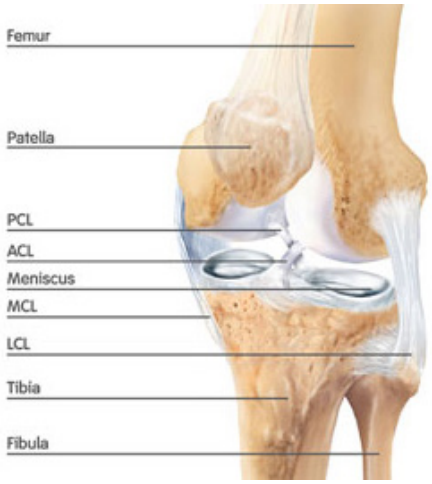



**Illustration of Components of Human Knee**

Mabrey Decl. ¶ 20 (Ex. 1002).

A human knee is comprised of four main components: bones, ligaments, cartilage, and tendons. Mabrey Decl. ¶ 21 (Ex. 1002).

*Bones* - A knee is made up of the thighbone (femur), the shinbone (tibia), the fibula, and the kneecap (patella). Mabrey Decl. ¶ 22 (Ex. 1002). The thighbone and shinbone come together to form a hinge. Mabrey Decl. ¶ 22 (Ex. 1002). The kneecap rests in front of this hinge to provide protection, but is not connected to the joint itself. Mabrey Decl. ¶ 22 (Ex. 1002). Instead, the back of the kneecap (called the articulating surface) sits in a groove in the thighbone that allows the thighbone to rotate as the patella slides in this groove. Mabrey Decl. ¶ 22 (Ex. 1002). When the knee bends or straightens, the patella slides through that groove.

Mabrey Decl. ¶ 22 (Ex. 1002). This groove is sometimes called the femoral groove, the patellar groove, or the trochlear groove. Mabrey Decl. ¶ 22 (Ex. 1002). The end of the thigh bone has two rounded areas called condyles, which glide against the cartilage of the shin bone. Mabrey Decl. ¶ 22 (Ex. 1002). Two major supporting ligaments of the knee are the medial and lateral collateral ligaments. Mabrey Decl. ¶ 22 (Ex. 1002). They attach to the medial and lateral femoral epicondyles. Mabrey Decl. ¶ 22 (Ex. 1002). The epicondyles serve as reference points for positioning total knee implants during surgery. Mabrey Decl. ¶ 22 (Ex. 1002). The features are shown below in the figure:

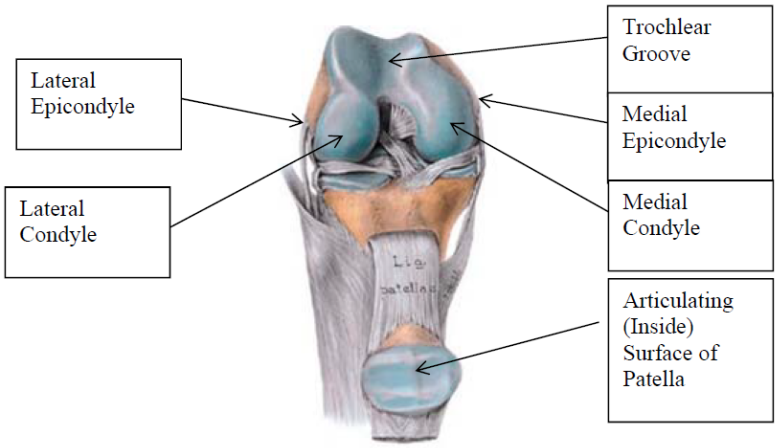



**Illustration of Bent Knee with Patella Cut Away from Thighbone**

Mabrey Decl. ¶ 22 (Ex. 1002).

*Ligaments* - Ligaments hold the components of the knee together and keep them stable. Mabrey Decl. ¶ 23 (Ex. 1002).

*Cartilage* – Cartilage act as shock absorbers and low friction surfaces so that the bones can easily rotate. Mabrey Decl. ¶ 24 (Ex. 1002).

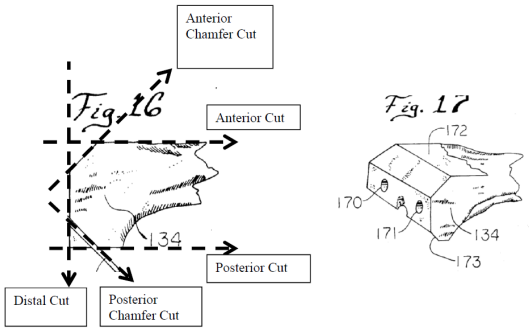
*Tendons* - Tendons connect muscle to the knee bones. Mabrey Decl. ¶ 25 (Ex. 1002).

### 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. ¶ 26 (Ex. 1002). Before the surgeon can begin the procedure, however, the parts of the knee to be replaced must be exposed. Mabrey Decl. ¶ 26 (Ex. 1002). A surgeon will expose the operative areas by first making an incision through the patient's skin. Mabrey Decl. ¶ 26 (Ex. 1002). 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. Mabrey Decl. ¶ 26 (Ex. 1002). 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). Mabrey Decl. ¶ 26 (Ex. 1002). Once the surgeon offsets the patella, unless she is resurfacing the patella (described below), the surgeon will maintain the patella in the offset position, so that she has access to the bones of the knee during the surgery. Mabrey Decl. ¶ 26 (Ex. 1002).

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. Mabrey Decl. ¶ 27 (Ex. 1002).

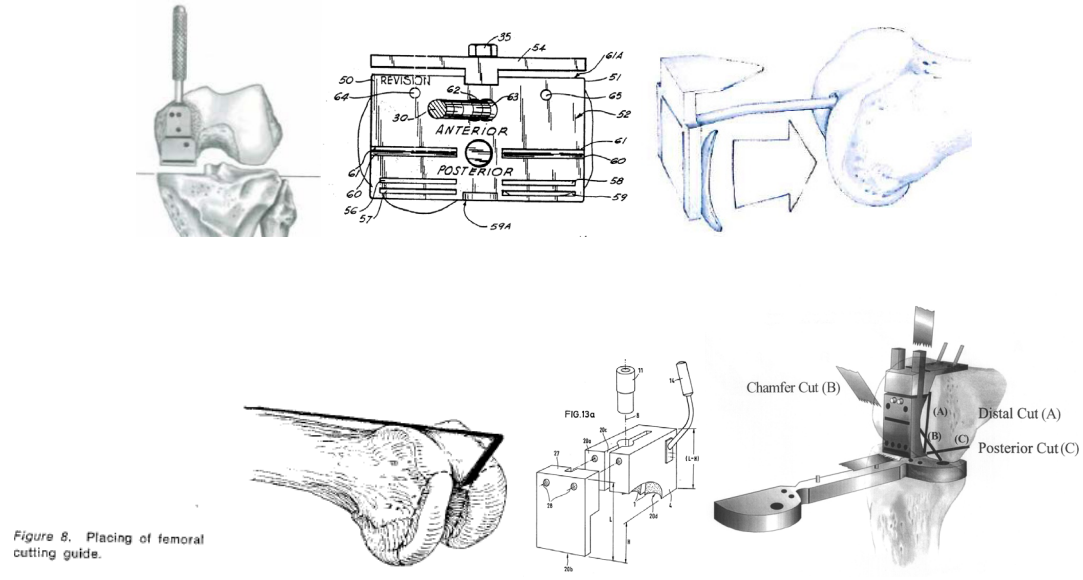
*Preparing the Bone* – The surgeon removes the damaged cartilage surfaces at the ends of the femur and tibia and a small amount of underlying bone. Mabrey Decl. ¶ 28 (Ex. 1002). The figures below show an example of the cuts a surgeon would typically make to a femur during surgery and the results of those cuts.




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

U.S. Patent No. 4,502,483 Figs. 16 & 17 (filed March 9, 1983) ("Lacey '483") (Ex. 1009); Mabrey Decl. ¶ 28 (Ex. 1002).

To help ensure that cuts are made accurately, surgeons typically use cutting guides with guide surfaces that guide the saw used to cut (or "resect") the bone. Mabrey Decl. ¶ 29 (Ex. 1002). Cutting guides, also known as resection guides or guide members, come in many different shapes and sizes. Mabrey Decl. ¶ 29 (Ex. 1002). A few illustrative examples of prior art cutting guides are shown below:



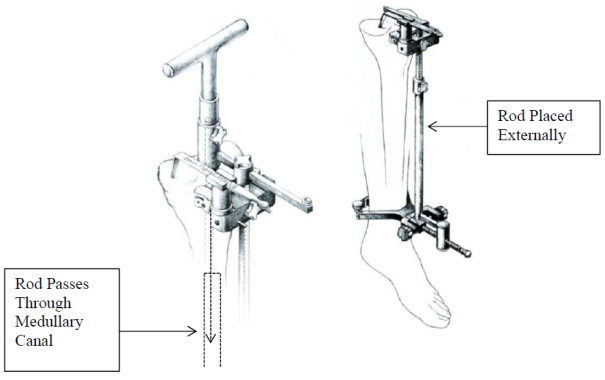

**Illustrative Examples of Prior Art Cutting Guides**

Smith & Nephew "Genesis Unicompartmental Knee System," 1994 , p. 16; Figs. 29-30 (Ex. 1012) (top left); Lackey '803, Fig. 11 (Ex. 1014) (assigned to Smith & Nephew Richards) (top center); Richards, p. 3 (Ex. 1011) (top right); Turner, Fig. 8; p. 181 (Ex. 1003) (bottom left); Radermacher '157, Fig. 13a (Ex. 1013) (bottom center); Peter A. Keblish, Jr., M.D., "Surgical Techniques in the Performance of Unicompartmental Arthroplasties" (Ex. 1015), Operative Techniques in Orthopaedics, Vol. 8, No. 3 (July), 1998: pp. 134-145, Fig. 10 (bottom right). Mabrey Decl. ¶ 29 (Ex. 1002).

As shown above, in some cutting guides, such as the Smith & Nephew Genesis Unicompartmental Knee System, the guide surface is a slot. Mabrey Decl. ¶ 30 (Ex. 1002). In other cutting guides, such as the Turner example, the cutting surface is provided without a slot. Mabrey Decl. ¶ 30 (Ex. 1002). 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. Mabrey Decl. ¶ 30 (Ex. 1002). 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. Mabrey Decl. ¶ 30 (Ex. 1002).

Initially, surgeons positioned cutting guides by hand. Mabrey Decl. ¶ 31 (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)**

S. David Stulberg, et al., "Computer-Assisted Total Knee Replacement Arthroplasty" ("Stulberg"), p. 32, Figs. 10-11 (Ex.1010); Mabrey Decl. ¶ 31 (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. ¶ 32 (Ex. 1002).

*Positioning the Metal Implants* – The surgeon replaces the removed cartilage and bone with metal components that recreate the surface of the joint. Mabrey Decl. ¶ 33 (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. Mabrey Decl. ¶ 33 (Ex. 1002). After confirming the fit with the trial prosthesis, the metal implant may be cemented or "press-fit" into the bone. Mabrey Decl. ¶ 33 (Ex. 1002).

*Resurfacing the Patella* – In some circumstances, the surgeon cuts and resurfaces the undersurface of the patella (kneecap) with a plastic button. Mabrey Decl. ¶ 34 (Ex. 1002).

*Inserting a Spacer* – The surgeon inserts a medical-grade plastic spacer between the metal components to create a smooth gliding surface. Mabrey Decl. ¶ 35 (Ex. 1002).

Once the surgeon has completed these four phases of the knee replacement surgery, she will place the various components of the now-updated knee into their original positions. Mabrey Decl. ¶ 36 (Ex. 1002). This includes moving the patella back into the replaced trochlear groove. Mabrey Decl. ¶ 36 (Ex. 1002). She will then perform various tests to assure that the knee has the proper functionality and mobility, and close the incision. Mabrey Decl. ¶ 36 (Ex. 1002).

The challenged claim of the ’821 patent relates to performing steps within the first two phases of knee replacement using a cutting guide that is smaller than the knee and the knee implant. Mabrey Decl. ¶ 37 (Ex. 1002).

## VII. SUMMARY OF THE ’821 PATENT AND RELEVANT FILE HISTORY

The application that issued as the ’821 patent was filed on August 28, 2001, and was a continuation-in-part of U.S. Patent Application Ser. Nos. 09/737,380, filed Dec. 15, 2000; 09/815,405, filed Mar. 22, 2001; 09/569,020, filed May 11, 2000; 09/483,676, filed Jan. 14, 2000; 09/602,743, filed Jun. 23, 2000; 09/526,949, filed on Mar. 16, 2000; and 09/789,621, filed Feb. 21, 2001. ’821 patent, cover (Ex. 1001).

### A. The Challenged Claim of the ’821 Patent

The challenged claim of the ’821 patent recites a method of performing surgery on a patient’s knee using a guide that is narrower than the knee and a knee

implant that is wider than the guide. Mabrey Decl. ¶ 38 (Ex. 1002). The challenged claim is reproduced below:

> 1. A method of performing surgery on a patient's knee, said method comprising the steps of
>
> (a)[4] supporting the patient on a support surface,
>
> (b) making an incision in a knee portion of one leg of the patient,
>
> (c) moving a guide member having opposite ends which are spaced apart by a distance which is less than two thirds (⅔) of a distance between tips of lateral and medial epicondyles on a femur in an upper portion of the one leg of the patient into the incision,
>
> (d) positioning the guide member on the femur in the one leg of the patient with opposite ends of the guide member substantially aligned with an axis through the lateral and medial epicondyles on the femur in the one leg of the patient,
>
> (e) moving a cutting tool through the incision into engagement with a guide surface on the guide member,
>
> (f) cutting the femur in the one leg of the patient with the cutting tool, said step of cutting the femur includes moving the cutting tool along the guide surface on the guide member, and

[4] The identifiers (a), (b), etc. and paragraph formatting have been added to the limitations to facilitate discussion of the claim.

> (g) positioning an implant in engagement with the femur in the one leg of the patient, wherein the implant has a transverse length that is larger than the guide surface length.

'821 patent, claim 1 (Ex. 1001).

The '821 patent does nothing more than describe and claim the conventional steps for performing a knee surgery using surgical instrumentation that were old and well-known as of the earliest possible priority date of the '821 patent. *See* Mabrey Decl. ¶ 39 (Ex. 1002). That is, more than a decade before 2001, when the patent application was filed, a surgeon knew to and did perform surgery on a patient's knee in the manner described by claim elements (a) through (g) above. Mabrey Decl. ¶ 39 (Ex. 1002).

### B. Summary of Portions of the Specification Related to Challenged Claim

The Applicant acknowledged in the Background of the Invention of the '821 patent that many of the claimed steps are performed as part of known procedures. *E.g.*, '821 patent, col. 1, l. 46 – col. 2, l. 32; col. 8, l. 43 – col. 9, l. 18 (Ex. 1001). Mabrey Decl. ¶ 40 (Ex. 1002). For example, the specification states that in the prior art, during a known total or partial knee replacement, "the patient is lying on his or her back" on a "patient support surface" such as an operating table (supporting a patient, recited in limitation (a)). *E.g.*, '821 patent, col. 1, ll. 59-61; col. 8, ll. 44-45 (Ex. 1001). The specification further states that in the prior art "an

incision is made in a knee portion of the leg to obtain access to the knee joint" (making an incision, recited in limitation (b)). *E.g.*, '821 patent, col. 1, ll. 46-48 (Ex. 1001). The specification also states that the prior art teaches 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 a cutting guide through an incision and positioning it on the femur, recited in limitations (c) and (d)). '821 patent, col. 1, ll. 49-53 (Ex. 1001). The specification also states that, in the prior art, "[c]uts are made on a femur and tibia" (cutting the bone, recited in limitation (f), which would be accomplished by moving a cutting tool through the incision into engagement with a guide surface on the guide member, as recited in limitation (e)). '821 patent, col. 9, l. 11 (Ex. 1001).

Indeed, of the 76 columns of material in the specification, only a few figures and paragraphs even arguably relate to the purportedly novel features of the claimed invention. Mabrey Decl. ¶ 41 (Ex. 1002). The specification describes "downsized instrumentation," as shown in Figure 9 (in relation to Figure 29) and described in the specification:

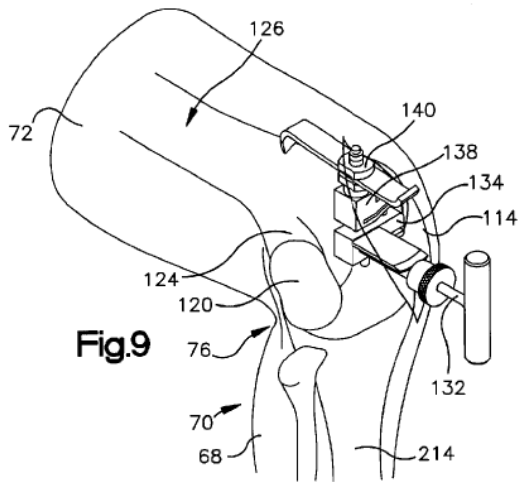


Fig.9

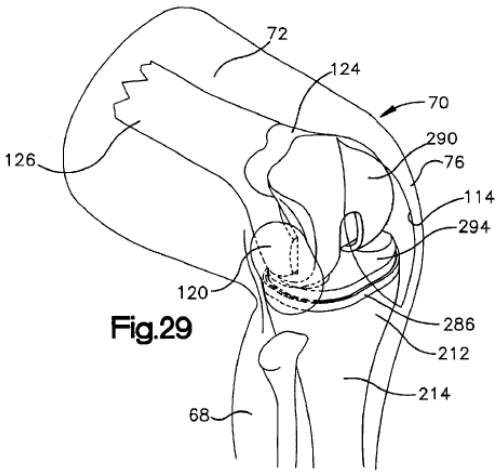


Fig.29

> [T]he instrumentation is down sized to enable the size of the incision 114 (FIG. 9) to be minimized. The downsized instrumentation [e.g., 134] has a transverse dimension which is smaller than a transverse dimension of an implant [e.g., 290] to be placed in the knee portion 76 (FIG. 9).

'821 patent, Figs. 9, 29, col. 13, l. 64 – col. 14, l. 2 (Ex. 1001).

The specification further states that the instrumentation in Fig. 9 (as well as Figs. 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." '821 patent, col. 31, ll. 17-22 (Ex. 1001); Mabrey Decl. ¶ 42 (Ex. 1002). The specification also states that the "femoral cutting guide 210 (FIGS. 19 and 20) may have . . . the construction disclosed in [Smith & Nephew's] U.S. Pat. No. 5,282,803 [Lackey '803 (Ex.

1014)],” but that “it is preferred to down size the known femoral cutting guides.” ’821 patent, col. 21, ll. 22 (Ex. 1001); Mabrey Decl. ¶ 42 (Ex. 1002).

### C. The Effective Filing Date of the ’821 Issued Claims

Throughout prosecution, Applicant never alleged an earlier-filed application contained a disclosure of the subject matter of the claims. Nor do any of the applications filed earlier disclose each of the elements of the independent claims. Thus the earliest effective filing date of the ’821 patent is August 28, 2001.

### D. Summary of the Prosecution History of the ’821 Patent

In the first office action, dated May 14, 2003, the Examiner rejected claim 1 (original claim 224) as anticipated by a Zimmer surgical technique guide that “shows a method of performing surgery on a patient’s knee having all the method steps as recited in [claim 1].” ’821 patent file history, May 14, 2003 Office Action, pp. 3-4 (Ex. 1007). In response, Applicant amended claim 1 to recite “wherein the implant has a transverse length that is larger than the guide surface length.” ’821 patent file history, October 7, 2003 Response, p. 9 (Ex. 1008). Applicant identified application page 34, lines. 13-25 (’821 patent, col. 13, l. 64 to col. 14., l. 9) as providing support for claim 1. ’821 patent file history, October 7, 2003 Response, pp. 23-24 (Ex. 1008).

Although Applicant stated generically that the amendment was “independent of patentability,” Applicant did not dispute the Examiner’s conclusion that each

step of claim 1, as originally drafted, was known in the prior art. '821 patent file history, October 7, 2003 Response, pp. 22-24 (Ex. 1008). To the contrary, Applicant merely argued that the claimed surgical method differed from the prior art because the claim was amended to recite using an "implant [that] has a transverse length that is larger than the guide surface length." '821 patent file history, October 7, 2003 Response, pp. 23-24 (Ex. 1008).

As described in detail below, the use of an "implant [that] has a transverse length that is larger than the guide surface length" for a knee surgery was known before the alleged invention recited in issued claim 1 of the '821 patent. *See* Mabrey Decl. ¶ 43 (Ex. 1002). Moreover, the purported advantage of the recited method, allowing a smaller incision, was also a well-known objective of reducing the size of the instrumentation prior the alleged invention of claim 1 of the '821 patent. *See* Mabrey Decl. ¶ 43 (Ex. 1002).

## VIII. THE PRIOR ART RENDERS THE CHALLENGED CLAIM UNPATENTABLE

The challenged claim recites features long known by persons of skill in the art in the field of knee arthroplasty. *See* Mabrey Decl. ¶ 44 (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 '821 patent claims priority. The grounds presented below demonstrate that each of the

methods was known, the claimed steps are performed in expected ways, and any benefit that the steps achieve was expected. *See* Mabrey Decl. ¶ 44 (Ex. 1002). Based on the prior art cited above and described below, the claimed limitations of the alleged invention perform known functions with an expected result.

### A. The References

#### 1. Turner

Turner discloses instruments and techniques for performing a total knee replacement. *E.g.*, Turner, pp. 174-187 (Ex. 1003) (describing the "geometric total knee" instruments and technique). One such technique and set of instruments is what Turner refers to as the "Geometric Total Knee." Turner explains that the "geometric design [of the Geometric Total Knee] has served as an excellent mode of total knee replacement since its inception in 1969." Turner, p. 176 (Ex. 1003). As depicted in Figures 1 and 3, the Geometric Total Knee has "a biocondylar Vitallium femoral component" with "two femoral weight-bearing surfaces [that] are spherical and [that] are joined by an anterior crossbar":

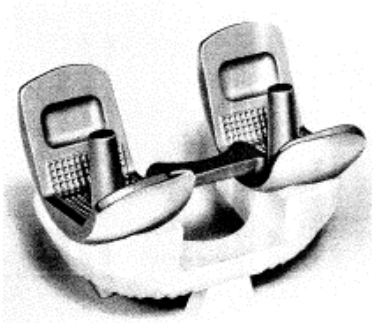


*Figure 1.* Geometric total knee.

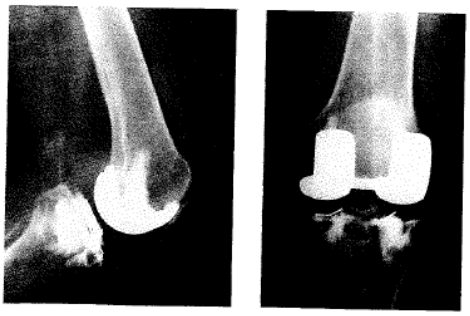


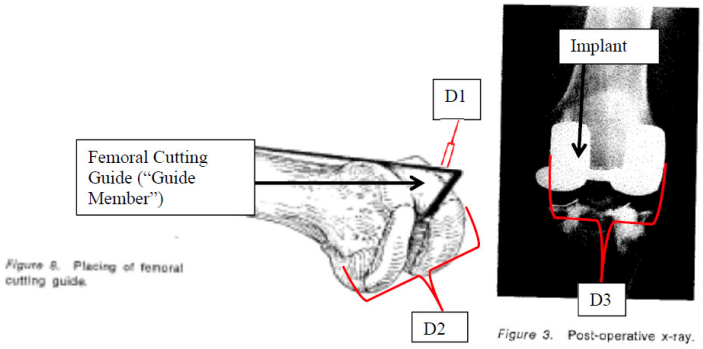
*Figure 3.* Post-operative x-ray.

Turner, Figs. 1, 3; pp. 174-175, 177 (Ex. 1003). The "overall width of the standard implant is 66.5 mm," or about 6.7 cm. Turner, pp. 174 (Ex. 1003).

Turner describes eleven steps for the "Geometric Total Knee Arthroplasty Technique," which include making a "parapatellar incision" (step I), inserting the "femoral cutting guide" depicted in Figure 8 and making "femoral osteotomies" (step II), and inserting the femoral component depicted in Figures 1 and 3 above (step VII and IX). Turner, pp. 180-187; Fig. 8 (Ex. 1003).

*Figure 8. Placing of femoral cutting guide.*

As shown below, the width (D1) of the femoral cutting guide disclosed by Turner is substantially narrower than the width (D2) of the thigh bone (femur) of the knee, and the width (D3) of the implant. Turner, Figs. 3, 8; pp. 177, 181 (Ex. 1003); Mabrey Decl. ¶ 47 (Ex. 1002).




### 2. Ranawat

Ranawat discloses "a system of instrumentation for performing total knee arthroplasty," and discusses "each step of the operation." Ranawat, p. 69 (Ex. 1004). In Ranawat, a "longitudinal incision is made over the anterior aspect of the

knee." Ranawat, Fig. 5G-3; p. 71; *see also* Ranawat, p. 69 (Ex. 1004). Ranawat utilizes a Chamfer guide with two cutting blocks to make "Chamfer" cuts (such as those described above):

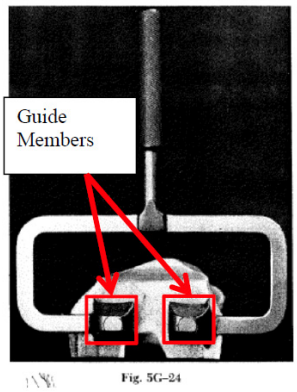



Fig. 5G–24

Ranawat, Fig. 5G-24; pp. 78, 80 (Ex. 1004); Mabrey Decl. ¶ 48 (Ex. 1002). Each cutting block has two guide surfaces, one on its top and one on its bottom:

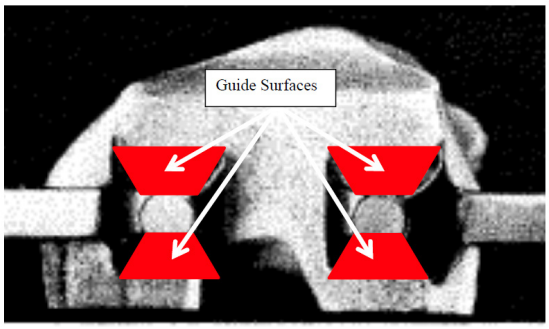
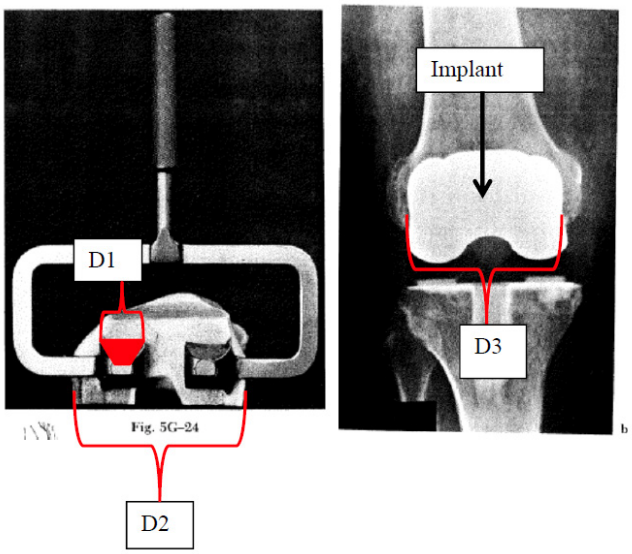



Fig. 5G–24

Ranawat, Fig. 5G-24; p. 80 (Ex. 1004); Mabrey Decl. ¶ 48 (Ex. 1002). The surgeon uses the guide surfaces to guide the cutting tool when making the anterior and posterior Chamfer cuts. Ranawat, pp. 78, 80 (Ex. 1004); Mabrey Decl. ¶ 48 (Ex. 1002).

Once the Chamfer cuts are made, Ranawat discloses inserting the implant shown in Fig. 5G-2b. Ranawat, Fig. 5G-2b; pp. 70, 80-81 (Ex. 1004). As shown below, the width (D1) of the guide member disclosed by Ranawat is substantially narrower than the width (D2) of the thigh bone (femur) of the knee and the width (D3) of the implant. Mabrey Decl. ¶ 49 (Ex. 1002).

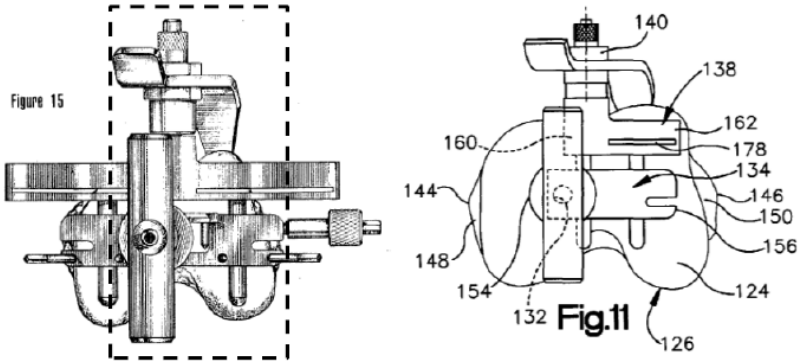



Ranawat, Figs. 5G-24, 5G-2b; pp. 70, 80 (Ex. 1004); Mabrey Decl. ¶ 49 (Ex. 1002).

### 3. Scorpio

Scorpio is a "Surgical Technique" guide for a "Total Knee System." Scorpio, cover (Ex. 1005). The '821 specification states that the disclosed 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." '821 patent, col.

31, ll. 17-22 (Ex. 1001). As shown below, the "anterior resection guide 138" described in the '821 patent is simply a smaller version of the "Anterior Resection Guide" disclosed in Scorpio, with parts of the left and right portions removed:




*Compare* Scorpio, Fig. 15; p. 9 (Ex. 1005) *with* '821 patent, Fig. 11 (Ex. 1001); Mabrey Decl. ¶ 50 (Ex. 1002).

**4. Delp '018**

Delp '018 relates 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. 1006). Delp '018 aims "to provide a method of performing knee arthroplasty that does not require the use of an intramedullary rod in the femur." Delp '018, col. 5, ll. 49-51 (Ex. 1006). Delp '018 explains:

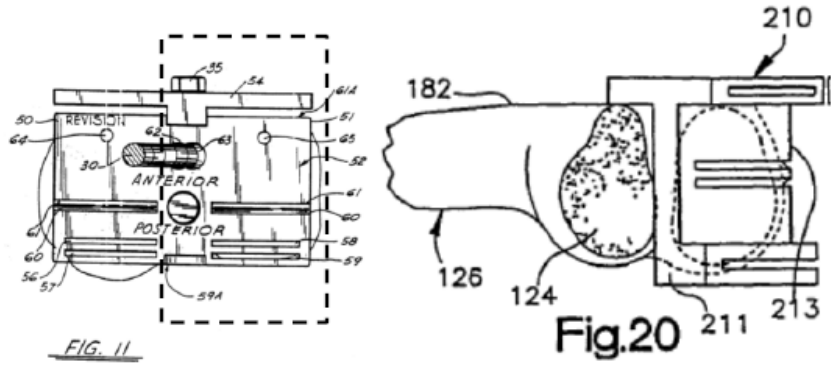
> The invention overcomes alignment problems by determining optimal alignment preoperatively and using computer guidance to help the surgeon achieve this alignment. The computer replaces large, complicated mechanical alignment systems, allowing smaller jigs to be used, and thus a smaller incision to be made. A smaller incision

> will result in a less invasive procedure, and will lead to a shorter rehabilitation time, thereby reducing costs, morbidity, and patient complaints.

Delp ’018, col. 22, ll. 42-50 (Ex. 1006); Mabrey Decl. ¶ 51 (Ex. 1002).

**5. Lackey ’803**

Lackey ’803, assigned to Smith & Nephew, relates to a “method and apparatus for use in knee surgery” and includes “cutting block 50.” Lackey ’803, col. 1, ll. 15-17; col. 8, ll. 1-6; Figs. 11-13 (Ex. 1014). The ’821 patent states that the “femoral cutting guide may have the construction disclosed in [Smith & Nephew’s] U.S. Pat. No[]. 5,282,803 [Lackey ’803 (Ex. 1014)],” but that “it is preferred to down size the known femoral cutting guides,” ’821 patent, col. 21, ll. 19-27 (Ex. 1001), as shown below:




*Compare* Lackey ’803, Fig. 11 (Ex. 1014) *with* ’821 patent, Fig. 20 (Ex. 1001); Mabrey Decl. ¶ 52 (Ex. 1002).

## IX. 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

Challenged claim 1 recites a method of performing surgery on a patient's knee. '821 patent, claim 1 (Ex. 1001). Each of the steps of claim 1 is shown in the prior art. *See* Mabrey Decl. ¶ 54 (Ex. 1002).

#### 1. Claim 1 is Anticipated by Turner

As shown in the summary chart below and in the Mabrey Declaration, the method of claim 1 is anticipated by Turner.

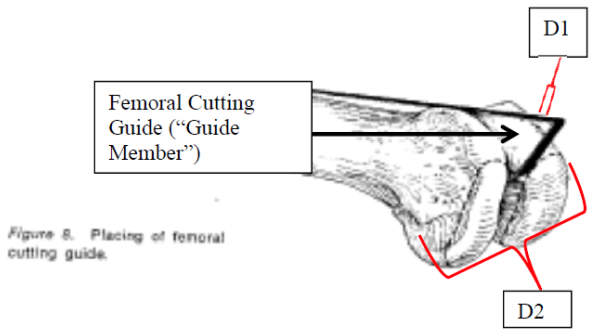
Turner discloses a method of performing surgery on a patient's knee, as recited in the preamble. For example, Turner is titled "Geometric and Anametric Total Knee Replacement." Turner, p. 171 (Ex. 1003). Mabrey Decl. ¶ 56 (Ex. 1002).

Turner discloses limitation (a), "supporting the patient on a support surface." For example, Turner discloses the "Geometric Total Knee" technique. Turner, pp. 174-187 (Ex. 1003). A person of ordinary skill in the art would understand Turner discloses limitation (a) because performing "Geometric Total Knee" surgery

necessarily requires supporting the patient on a support surface so that the surgeon can access the knee. Mabrey Decl. ¶ 57 (Ex. 1002).

Turner discloses limitation (b), "making an incision in a knee portion of one leg of the patient." For example, Turner discloses a "medial parapatellar incision." Turner, pp. 180-181 (Ex. 1003). Mabrey Decl. ¶ 58 (Ex. 1002).

Turner discloses limitation (c), "moving a guide member having opposite ends which are spaced apart by a distance which is less than two thirds (⅔) of a distance between tips of lateral and medial epicondyles on a femur in an upper portion of the one leg of the patient into the incision." For example, Turner discloses the "femoral cutting guide is inserted in the midline, deep to the suprapatellar pouch," as depicted in Figure 8:




Turner, Fig. 8; p. 181 (Ex. 1003); Mabrey Decl. ¶ 59 (Ex. 1002). As shown above, the femoral cutting guide ("guide member") has opposite ends that are spaced apart by a distance (D1) that is less than two thirds (2/3) of the distance (D2) between tips of the lateral and medial epicondyles of the femur. Mabrey Decl. ¶ 59 (Ex.

1002). A person of ordinary skill in the art would understand Turner discloses "moving a guide member . . . into the incision," because the femoral cutting guide ("guide member") is necessarily moved into the incision in order to be "inserted in the midline, deep to the suprapatellar pouch," as no other incision is disclosed for this purpose. Turner, p. 181 (Ex. 1003); Mabrey Decl. ¶ 59 (Ex. 1002).

Turner discloses limitation (d), "positioning the guide member on the femur in the one leg of the patient with opposite ends of the guide member substantially aligned with an axis through the lateral and medial epicondyles on the femur in the one leg of the patient." As shown in Figure 8, the femoral cutting guide ("guide member") is positioned on the femur and the opposite ends of that femoral cutting guide are substantially aligned with an axis (A1) through the lateral and medial epicondyles on the femur:

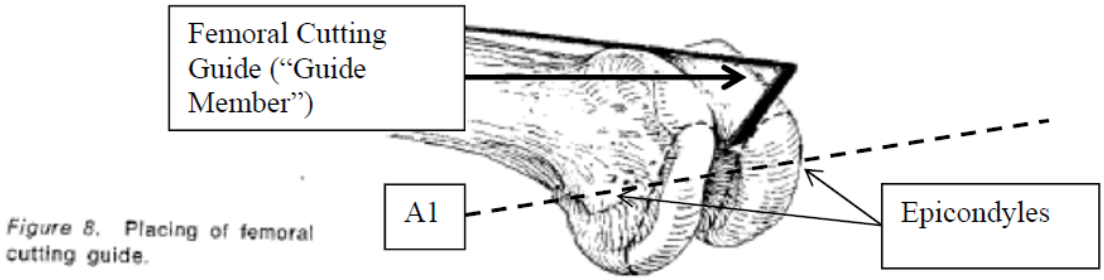



*Figure 8.* Placing of femoral cutting guide.

Turner, Fig. 8; p. 181 (Ex. 1003); Mabrey Decl. ¶ 60 (Ex. 1002).

Turner discloses limitation (e), "moving a cutting tool through the incision into engagement with a guide surface on the guide member." For example, Turner

discloses "initial transverse femoral osteotomies are made with a power or hand saw parallel with the guide." Turner, p. 181 (Ex. 1003). A person of ordinary skill in the art would understand Turner discloses "moving a cutting tool through the incision" because the power or hand saw ("cutting tool") is necessarily moved through the incision in order to make "initial transverse femoral osteotomies [cuts to the thigh bone]." Turner, p. 181 (Ex. 1003); Mabrey Decl. ¶ 61 (Ex. 1002). Likewise, a person of ordinary skill in the art would understand Turner discloses moving the cutting tool "into engagement with a guide surface on the guide member" because the cuts are made "with a power or hand saw parallel with the guide." Turner, p. 181 (Ex. 1003); Mabrey Decl. ¶ 61 (Ex. 1002).

Turner discloses limitation (f), "cutting the femur in the one leg of the patient with the cutting tool, said step of cutting the femur includes moving the cutting tool along the guide surface on the guide member." For example, Turner discloses that "initial transverse femoral osteotomies are made with a power or hand saw parallel with the guide," as schematically illustrated in Figure 8, with "the appearance of the femur after this initial osteotomy" shown in Figure 9:

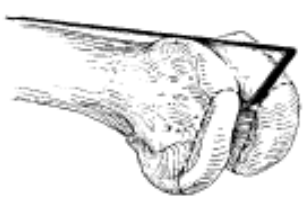


*Figure 8.* Placing of femoral cutting guide.

*Figure 9.* Appearance of femur after cutting of distal condyles.

Turner, Figs. 8, 9; p. 181 (Ex. 1003). A person of ordinary skill in the art would understand that Turner discloses "moving the cutting tool along the guide surface on the guide member" because the cuts are made "with a power or hand saw parallel with the guide." Turner, p. 181 (Ex. 1003); Mabrey Decl. ¶ 62 (Ex. 1002).

Turner discloses limitation (g), "positioning an implant in engagement with the femur in the one leg of the patient, wherein the implant has a transverse length that is larger than the guide surface length." For example, Turner discloses "positioning an implant in engagement with the femur in the one leg of the patient" in step VII where "the femoral component [is] inserted," and additionally in step IX where that component is reinserted. Turner, pp. 185-187 (Ex. 1003). Additionally, Turner discloses an implant having "a transverse length [D3] 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 (D3) of the implant, as shown below:

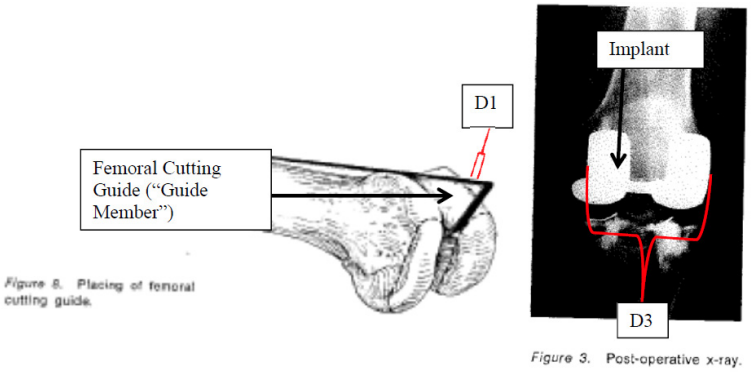



*Figure 8.* Placing of femoral cutting guide.

*Figure 3.* Post-operative x-ray.

Turner, Figs. 3, 8; pp. 177, 181 (Ex. 1003); Mabrey Decl. ¶ 63 (Ex. 1002).

In summary, the chart below identifies where the above prior art reference discloses the limitations of claim 1 of the '821 patent.

| | |
|---|---|
| **Claim 1: 1. A method of performing surgery on a patient's knee, said method comprising the steps of** | *See, e.g.*, Turner, cover, pp. 171, 173-187; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1003). |
| **(a) supporting the patient on a support surface,** | *See, e.g.*, Turner, pp. 171, 173-187 (Ex. 1003). |
| **(b) making an incision in a knee portion of one leg of the patient,** | *See, e.g.*, Turner, pp. 180-181, 187 (Ex. 1003). |
| **(c) moving a guide member having opposite ends which are spaced apart by a distance which is less than two thirds (⅔) of a distance between tips of lateral and medial epicondyles on a femur in an upper portion of the one leg of the patient into the incision,** | *See, e.g.*, Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1003). |
| **(d) positioning the guide member on the femur in the one leg of the patient with opposite ends of the guide member substantially aligned with an axis through the lateral and medial epicondyles on the femur in the one leg of the patient,** | *See, e.g.*, Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1003). |
| **(e) moving a cutting tool through the incision into engagement with a guide surface on the guide member,** | *See, e.g.*, Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1003). |
| **(f) cutting the femur in the one leg of the patient with the cutting tool, said step of cutting the femur includes moving the cutting tool along the guide surface on the guide member, and** | *See, e.g.*, Turner, pp. 180-182, 187-189; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1003). |
| **(g) positioning an implant in engagement with the femur in the one leg of the patient, wherein the implant has a transverse length that is larger than the guide surface length.** | *See, e.g.*, Turner, pp. 172-177, 180-183, 185-189, 191-192; Figs. 1-4, 6-15, 20-22, 24 (Ex. 1003). |

### 2. Claim 1 is Obvious Over Turner

As shown in the previous section and in the Mabrey Declaration, Turner discloses each limitation of the method of claim 1.

To the extent the Patent Owner asserts that Turner does not disclose limitation (a), "supporting the patient on a support surface," this limitation additionally would be clear to a person of ordinary skill in the art reading Turner because placing a patient on a support surface such as an operating table is routine surgical practice. Mabrey Decl. ¶ 66 (Ex. 1002).

To the extent the Patent Owner asserts that Turner does not disclose "moving a guide member . . . into the incision," as recited in limitation (c), this requirement additionally would be clear to a person of ordinary skill in the art reading Turner because moving an implant through an incision is a routine step during a knee surgery. Mabrey Decl. ¶ 67 (Ex. 1002).

To the extent the Patent Owner asserts that Turner does not disclose limitation (e), "moving a cutting tool through the incision into engagement with a guide surface on the guide member," this limitation additionally would be clear to a person of ordinary skill in the art reading Turner 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. ¶ 68 (Ex. 1002).

To the extent the Patent Owner asserts that Turner does not disclose "moving the cutting tool along the guide surface on the guide member," as recited in limitation (f), this requirement additionally would be clear to a person of ordinary skill in the art reading Turner because using the guide surface of the cutting guide to make femoral cuts by moving the cutting tool along the guide surface is a routine step for cutting the femur. Mabrey Decl. ¶ 69 (Ex. 1002).

In summary, the chart in the previous section identifies where the above prior art reference discloses the limitations of claim 1 of the '821 patent, and to the extent the Patent Owner asserts that Turner does not disclose certain limitations, those limitations additionally are obvious for the reasons above.

### 3. Claim 1 is Anticipated by Ranawat

As shown in the summary chart below and in the Mabrey Declaration, the method of claim 1 is anticipated by Ranawat.

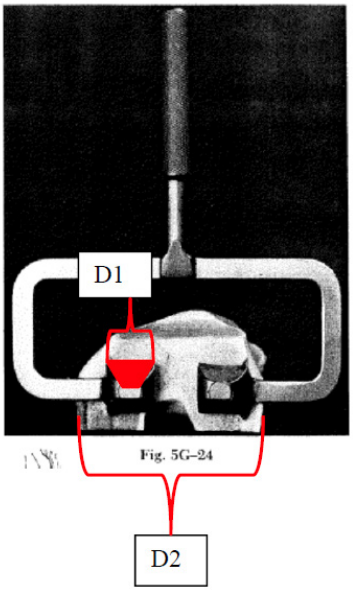
Ranawat discloses a method of performing surgery on a patient's knee, as recited in the preamble. For example, Ranawat is titled "Technique of Total Knee Arthroplasty with Precision Cut Instruments." Ranawat, p. 69 (Ex. 1004). Mabrey Decl. ¶ 72 (Ex. 1002).

Ranawat discloses limitation (a), "supporting the patient on a support surface." For example, Ranawat discloses that a "patient was placed supine after induction of general anesthesia (Fig. 5G-3)." Ranawat, p. 69 (Ex. 1004). A person

of ordinary skill in the art would understand Ranawat discloses limitation (a) because when a patient is placed in a supine position (lying down with the face up), the patient is supported on a support surface. Ranawat, p. 69 (Ex. 1004); Mabrey Decl. ¶ 73 (Ex. 1002).

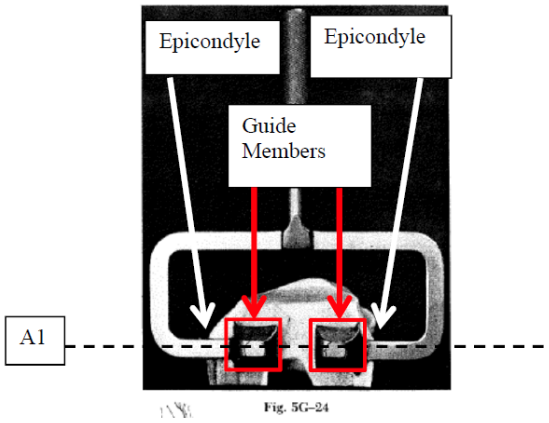
Ranawat discloses limitation (b), "making an incision in a knee portion of one leg of the patient." For example, Ranawat discloses "[a] longitudinal incision is made over the anterior aspect of the knee." Ranawat, pp. 69, 71; Fig. 5G-3 (Ex. 1004). Mabrey Decl. ¶ 74 (Ex. 1002).

Ranawat discloses limitation (c), "moving a guide member having opposite ends which are spaced apart by a distance which is less than two thirds (⅔) of a distance between tips of lateral and medial epicondyles on a femur in an upper portion of the one leg of the patient into the incision." For example, Ranawat discloses that the "Chamfer guide is applied to the distal femur." Ranawat, p. 80 (Ex. 1004). The cutting block ("guide member") disclosed in Ranawat has opposite ends that are spaced apart by a distance (D1) that is less than two thirds of a distance (D2) between the tips of the lateral and medial epicondyles of the femur. Ranawat, Figs. 5G-24; pp. 70, 80 (Ex. 1004); Mabrey Decl. ¶ 75 (Ex. 1002). A person of ordinary skill in the



art would understand Ranawat discloses "moving a guide member . . . into the incision," because the cutting block ("guide member") is moved into the incision in order to be "applied to the distal femur." Ranawat, p. 80 (Ex. 1004); Mabrey Decl. ¶ 75 (Ex. 1002).

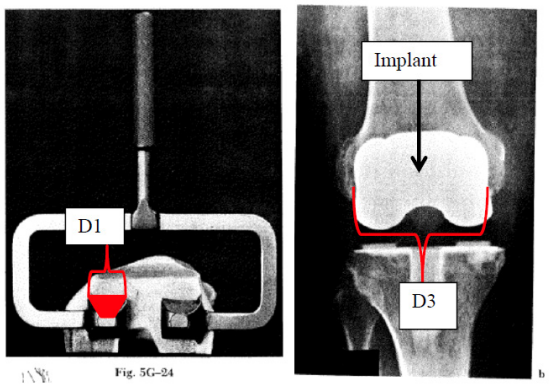
Ranawat discloses limitation (d), "positioning the guide member on the femur in the one leg of the patient with opposite ends of the guide member substantially aligned with an axis through the lateral and medial epicondyles on the femur in the one leg of the patient." For example, as shown in Fig. 5G-24, Turner discloses cutting blocks ("guide member[s]") positioned on the femur in the one leg of the patient, and the opposite ends of each cutting block ("guide member") are substantially aligned with an axis (A1) through the lateral and medial epicondyles on the femur in the one leg of the patient:




Ranawat, Fig. 5G-24; p. 70, 80 (Ex. 1004); Mabrey Decl. ¶ 76 (Ex. 1002).

Ranawat discloses limitation (e), "moving a cutting tool through the incision into engagement with a guide surface on the guide member," and limitation (f), "cutting the femur in the one leg of the patient with the cutting tool, said step of cutting the femur includes moving the cutting tool along the guide surface on the guide member." For example, Ranawat discloses that the "Chamfer guide is applied to the distal femur . . . [and] Chamfer cuts are made with the power saw." Ranawat, p. 80 (Ex. 1004). A person of ordinary skill in the art would understand Ranawat discloses "moving a cutting tool through the incision" because the power saw ("cutting tool") is necessarily moved through the incision in order to make the "Chamfer cuts." Ranawat, p. 80 (Ex. 1004); Mabrey Decl. ¶ 77 (Ex. 1002). Likewise, a person of ordinary skill in the art would understand Ranawat discloses moving the cutting tool "into engagement with a guide surface on the guide member" because the Chamfer guide is applied to the distal femur so that the power saw ("cutting tool") can make "Chamfer cuts" along the cutting surfaces of the cutting blocks ("guide member[s]"). Ranawat, p. 80 (Ex. 1004); Mabrey Decl. ¶ 77 (Ex. 1002). A person of ordinary skill in the art would further understand that Ranawat discloses "moving the cutting tool along the guide surface on the guide member" because Ranawat discloses that the "Chamfer guide is applied to the distal femur . . . [and] Chamfer cuts are made with the power saw." Ranawat, p. 80 (Ex. 1004); Mabrey Decl. ¶ 77 (Ex. 1002).

Ranawat discloses limitation (g), "positioning an implant in engagement with the femur in the one leg of the patient, wherein the implant has a transverse length that is larger than the guide surface length." For example, Ranawat discloses the "femoral component . . . is inserted." Ranawat, Fig. 5G-2b; pp. 70, 81 (Ex. 1004). As shown below, the femoral implant disclosed in Ranawat has "a transverse length [D3] that is larger than the guide surface length [D1]":




Ranawat, Figs. 5G-24, 5G-2b; p. 70, 80 (Ex. 1004); Mabrey Decl. ¶ 78 (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 '821 patent.

| | |
|---|---|
| **Claim 1: 1. A method of performing surgery on a patient's knee, said method comprising the steps of** | *See, e.g.*, Ranawat, cover, pp. 69-83; Figs. 5G-1 to 5G-4, 5G-24 (Ex. 1004). |
| **(a) supporting the patient on a support surface,** | *See, e.g.*, Ranawat, pp. 69, 71; Figs. 5G-3, 5G-4 (Ex. 1004). |
| **(b) making an incision in a knee portion of one leg of the patient,** | *See, e.g.*, Ranawat, pp. 69, 71; Figs. 5G-3, 5G-4 (Ex. 1004). |
| **(c) moving a guide member having opposite ends which are spaced apart by a distance which is less than two thirds (⅔) of a distance** | *See, e.g.*, Ranawat, pp. 69-71, 74-81; Figs. 5G-1 to 5G-4, 5G-11 to 5G-16, 5G-19 to 5G-24, |

| | |
|---|---|
| **between tips of lateral and medial epicondyles on a femur in an upper portion of the one leg of the patient into the incision,** | 5G-26 (Ex. 1004). |
| **(d) positioning the guide member on the femur in the one leg of the patient with opposite ends of the guide member substantially aligned with an axis through the lateral and medial epicondyles on the femur in the one leg of the patient,** | *See, e.g.*, Ranawat, pp. 69-71, 74-82; Figs. 5G-1 to 5G-4, 5G-11 to 5G-16, 5G-19 to 5G-24, 5G-26 (Ex. 1004). |
| **(e) moving a cutting tool through the incision into engagement with a guide surface on the guide member,** | *See, e.g.*, Ranawat, pp. 69-71, 74-82; Figs. 5G-1 to 5G-4, 5G-11 to 5G-16, 5G-19 to 5G-24, 5G-26 (Ex. 1004). |
| **(f) cutting the femur in the one leg of the patient with the cutting tool, said step of cutting the femur includes moving the cutting tool along the guide surface on the guide member, and** | *See, e.g.*, Ranawat, pp. 69-71, 74-82; Figs. 5G-1 to 5G-4, 5G-11 to 5G-16, 5G-19 to 5G-24, 5G-26 (Ex. 1004). |
| **(g) positioning an implant in engagement with the femur in the one leg of the patient, wherein the implant has a transverse length that is larger than the guide surface length.** | *See, e.g.*, Ranawat, pp. 69-72, 74, 76, 80-82; Figs. 5G-1 to 5G-4, 5G-11 to 5G-16, 5G-19 to 5G-24, 5G-26 (Ex. 1004). |

#### 4. Claim 1 is Obvious Over Ranawat

As shown in the previous section and in the Mabrey Declaration, Ranawat discloses each limitation of the method of claim 1.

To the extent the Patent Owner asserts that Ranawat does not disclose "moving a guide member . . . into the incision," as recited in limitation (c), this requirement additionally would be clear to a person of ordinary skill in the art reading Turner because moving an implant through an incision is a routine step during a knee surgery. Mabrey Decl. ¶ 81 (Ex. 1002).

To the extent the Patent Owner asserts that Ranawat does not disclose limitation (e), "moving a cutting tool through the incision into engagement with a guide surface on the guide member," this limitation additionally would be clear to a person of ordinary skill in the art reading Turner 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. ¶ 82 (Ex. 1002).

To the extent the Patent Owner asserts that Ranawat does not disclose "moving the cutting tool along the guide surface on the guide member," as recited in limitation (f), this requirement additionally would be clear to a person of ordinary skill in the art reading Ranawat because using the guide surface of the cutting guide to make femoral cuts by moving the cutting tool along the guide surface is a routine surgical step for cutting the femur. Mabrey Decl. ¶ 83 (Ex. 1002).

In summary, the chart in the previous section identifies where the above prior art reference discloses the limitations of claim 1 of the '821 patent, and to the extent the Patent Owner asserts that Ranawat does not disclose certain limitations, those limitations additionally are obvious for the reasons above.

### 5. Claim 1 is Obvious Over Scorpio in View of Delp '018

As shown in the summary chart below and in the Mabrey Declaration, the method of claim 1 is obvious over Scorpio in view of Delp '018.

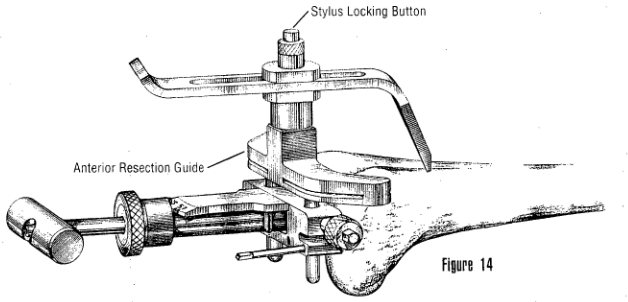
Scorpio discloses a method of performing surgery on a patient's knee, as recited in the preamble. For example, Scorpio is a "Surgical Technique" guide for a "Total Knee System." Scorpio, Cover (Ex. 1005); Mabrey Decl. ¶ 86 (Ex. 1002).

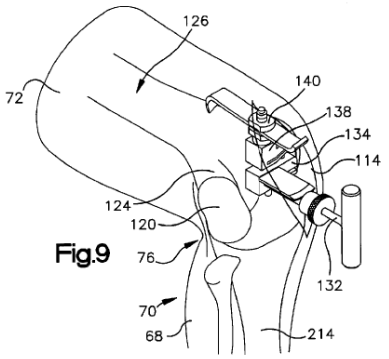
Scorpio discloses limitation (a), "supporting the patient on a support surface." For example, Scorpio discloses a "Surgical Technique" guide for a "Total Knee System." Scorpio, Cover (Ex. 1005). A person of ordinary skill in the art would understand Scorpio discloses limitation (a) because knee surgery necessarily requires supporting the patient on a support surface so that the surgeon can access the knee. Mabrey Decl. ¶ 87 (Ex. 1002). To the extent the Patent Owner asserts that Scorpio does not disclose limitation (a), this limitation additionally would be clear to a person of ordinary skill in the art reading Scorpio because placing a patient on a support surface such as an operating table is routine surgical practice. Mabrey Decl. ¶ 87 (Ex. 1002).

Scorpio discloses limitation (b), "making an incision in a knee portion of one leg of the patient." For example, Scorpio discloses making a "standard anterior midline incision" in the patient's knee. Scorpio, Fig. 1; p.3 (Ex. 1005); Mabrey Decl. ¶ 88 (Ex. 1002).

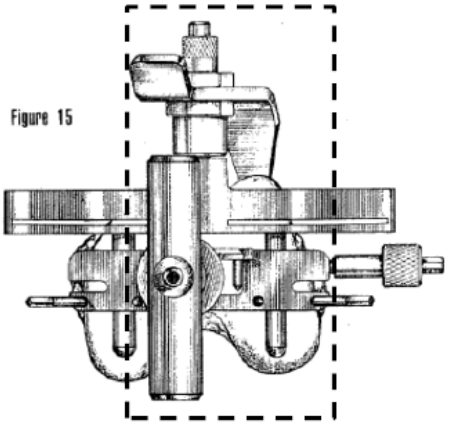
Scorpio in combination with Delp '018 renders obvious limitation (c), "moving a guide member having opposite ends which are spaced apart by a distance which is less than two thirds (⅔) of a distance between tips of lateral and

medial epicondyles on a femur in an upper portion of the one leg of the patient into the incision." As discussed, the specification states that the disclosed guide members, "with the exception of being down sized, [are] generally similar to known instrumentation which is commercially available from Howmedica Osteonics Corp. of Rutherford, N.J. under the trademark "Scorpio" single access total knee system." '821 patent, col. 31, ll. 17-22 (Ex. 1001). As shown below, the "anterior resection guide 138" ("guide member") described in the '821 patent is simply a smaller version of the Scorpio "Anterior Resection Guide" disclosed in Scorpio, with parts of the left and right portions removed:




*Compare* Scorpio, Fig. 14; p. 9 (Ex. 1005) with '821 patent, Fig. 9 (Ex. 1001);



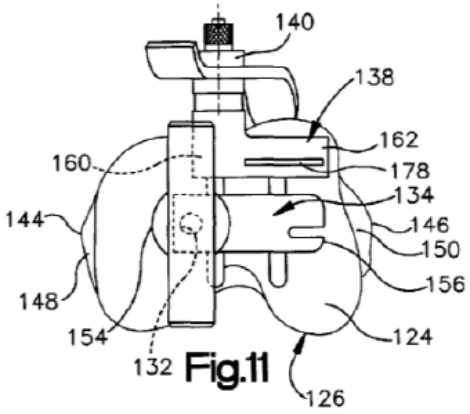



Fig.11

*compare* Scorpio, Fig. 15; p. 9 (Ex. 1005) *with* '821 patent, Fig. 11 (Ex. 1001); Mabrey Decl. ¶ 89 (Ex. 1002).

It would have been obvious to reduce the size of the instrumentation disclosed in Scorpio. Mabrey Decl. ¶ 90 (Ex. 1002). One known problem in the prior art was "rehabilitation time . . . cost, morbidity, and patient complaints" associated with larger incisions. Delp '018, col. 22, ll. 47-50 (Ex. 1006); Mabrey Decl. ¶ 90 (Ex. 1002). Thus, the '821 patent did not discover or identify any unknown problem. Mabrey Decl. ¶ 90 (Ex. 1002). Nor did the '821 patent arrive at an unknown solution. Mabrey Decl. ¶ 90 (Ex. 1002). It was known to address the known problem in the prior art by using "smaller jigs" that allow "a smaller incision to be made." Delp '018, col. 22, ll. 45-47 (Ex. 1006); Mabrey Decl. ¶ 90 (Ex. 1002).

Reducing the size of the Scorpio instrumentation according to this known solution would have been a routine modification. Mabrey Decl. ¶ 91 (Ex. 1002).

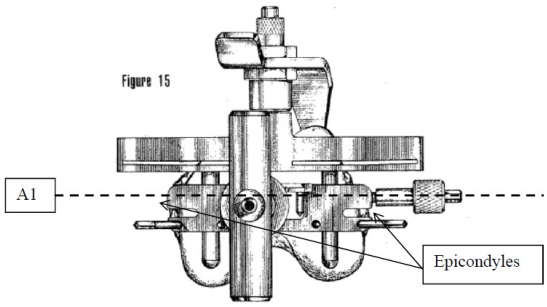
For example, orthopedic surgeons would have modified surgical instruments to suit the needs of specific patients, such as by removing portions of an instrument that are inappropriate or unneeded for that patient. Mabrey Decl. ¶ 91 (Ex. 1002). Additionally, orthopedic surgeons would have worked with manufacturers to implement known solutions for instrument designs, such as reducing the size of an instrument to avoid unnecessarily trauma. Mabrey Decl. ¶ 91 (Ex. 1002).

Reducing the size of the Scorpio instruments achieves expected benefits such as reducing trauma and being able to be fit through a smaller incision. Mabrey Decl. ¶ 92 (Ex. 1002). For example, Delp '018 discloses that one known benefit of using "smaller jigs" is to allow "a smaller incision to be made," which "result[s] in a less invasive procedure" and "lead[s] to a shorter rehabilitation time, thereby reducing costs, morbidity, and patient complaints." Delp '018, col. 22, ll. 45-50 (Ex. 1006). The '821 patent, in fact, identifies the same expected benefit: "[T]he instrumentation is down sized to enable the size of the incision 114 (FIG. 9) to be minimized." '821 patent, Figs. 9 & 29; col. 13, ll. 64-66 (Ex. 1001). Thus, it would have been obvious to a person of ordinary skill in the art to use the known technique of reducing the size of a cutting guide by, for example, eliminating some or all of one of the guide surfaces to reduce the width of the cutting guide, in order to obtain expected benefits such as the ability to use a smaller incision. Mabrey Decl. ¶ 92 (Ex. 1002).

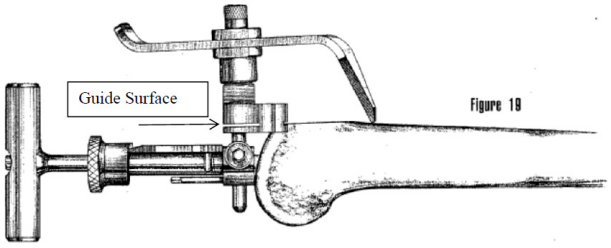
It would have been obvious to a person of skill in the art to reduce the width of the opposite ends of the cutting guide to less than two thirds of the distance between tips of lateral and medial epicondyles on a femur because making the cutting guide narrower allows it to pass through a smaller incision. Mabrey Decl. ¶ 93 (Ex. 1002). Additionally, the '821 patent identifies no criticality to the particular reduced size in the claim, and there is nothing unexpected produced by the size recited in the claim. Mabrey Decl. ¶ 93 (Ex. 1002). Moreover, the known solution yielded the expected benefit of reducing trauma. Mabrey Decl. ¶ 93 (Ex. 1002). The specification identifies no new function associated with the smaller cutting guide. Mabrey Decl. ¶ 93 (Ex. 1002). On the contrary, they are "generally similar" to known cutting guides. Mabrey Decl. ¶ 93 (Ex. 1002); '821 patent, col. 31, ll. 17-22 (Ex. 1001). There is no unexpected result from reducing the size of the cutting guide. Mabrey Decl. ¶ 93 (Ex. 1002). Any benefit was known and reasonably expected by one of ordinary skill in the art. Mabrey Decl. ¶ 93 (Ex. 1002).

Scorpio discloses limitation (d), "positioning the guide member on the femur in the one leg of the patient with opposite ends of the guide member substantially aligned with an axis through the lateral and medial epicondyles on the femur in the one leg of the patient." As shown in Figure 15, the anterior resection guide ("guide member") is positioned on the femur in the one leg of the patient and the opposite

ends of that cutting guide are substantially aligned with an axis (A1) through the lateral and medial epicondyles on the femur in the one leg of the patient. Scorpio, p. 9, Fig. 15 (Ex. 1005); Mabrey Decl. ¶ 94 (Ex. 1002).

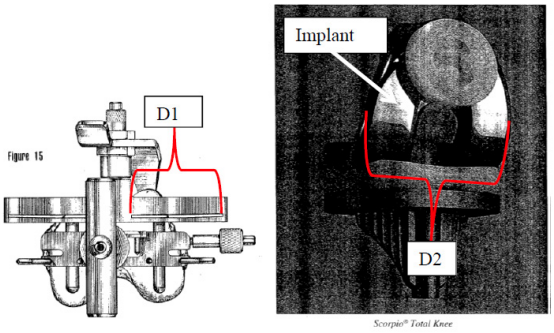



Scorpio discloses limitation (e), "moving a cutting tool through the incision into engagement with a guide surface on the guide member." For example, Scorpio discloses using "a .050" thick sawblade to make the resection" shown in Figure 19. Scorpio, p. 11, Fig. 19 (Ex. 1005). A person of ordinary skill in the art would understand this discloses limitation (e) because the sawblade ("cutting tool") is moved through the incision into engagement with a guide surface on the Anterior Resection Guide ("guide member"). Mabrey Decl. ¶ 95 (Ex. 1002). To the extent the Patent Owner asserts that Scorpio does not disclose limitation (e), this limitation additionally would be clear to a person of ordinary skill in the art reading Scorpio 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. ¶ 95 (Ex. 1002).



Scorpio discloses limitation (f), "cutting the femur in the one leg of the patient with the cutting tool, said step of cutting the femur includes moving the cutting tool along the guide surface on the guide member." For example, as shown above in Figure 19 above, Scorpio discloses a femoral cut ("cutting the femur in the one leg of the patient") made with the sawblade ("cutting tool") by moving that sawblade along the guide surface on the Anterior Resection Guide ("guide member"). Scorpio, p. 11 (Ex. 1005); Mabrey Decl. ¶ 96 (Ex. 1002). To the extent the Patent Owner asserts that Scorpio does not disclose "moving the cutting tool along the guide surface on the guide member," as recited in limitation (f), this requirement additionally would be clear to a person of ordinary skill in the art reading Scorpio because using the guide surface of the cutting guide to make femoral cuts by moving the cutting tool along the guide surface is a routine surgical step for cutting the femur. Mabrey Decl. ¶ 96 (Ex. 1002).

Scorpio discloses limitation (g), "positioning an implant in engagement with the femur in the one leg of the patient, wherein the implant has a transverse length that is larger than the guide surface length." For example, Scorpio discloses that the femoral implant (shown below) is "place[d] . . . on the prepared femur . . . [for] implantation." Scorpio, p. 47 (Ex. 1005). As shown below, 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. 1005); Mabrey Decl. ¶ 97 (Ex. 1002). A person of 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. ¶ 97 (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, for the reasons discussed above in connection with limitation (c), to reduce the length of the guide surface in this manner so that the guide could fit through a smaller incision. Mabrey Decl. ¶ 97 (Ex. 1002). A guide member that is less than two thirds the distance between the epicondyles would necessarily have a guide surface length that is smaller than the transverse length of the implant for the total knee replacement as disclosed in Scorpio.

In summary, the chart below identifies where the above prior art references disclose and/or make obvious the limitations of claim 1 of the '821 patent.

| | |
|---|---|
| **Claim 1: 1. A method of performing surgery on a** | *See, e.g.*, Scorpio, Cover; pp.1-47 (Ex. 1005); *see generally* Delp '018, col. 1-28; Figs. 1-24 |

| | |
|---|---|
| **patient's knee, said method comprising the steps of** | (Ex. 1006). |
| **(a) supporting the patient on a support surface,** | *See, e.g.*, Scorpio, Cover; pp.1-47 (Ex. 1005); *see generally* Delp '018, col. 1-28; Figs. 1-24 (Ex. 1006). |
| **(b) making an incision in a knee portion of one leg of the patient,** | *See, e.g.*, Scorpio, Figs. 1-3; p. 3 (Ex. 1005); 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. 1006). |
| **(c) moving a guide member having opposite ends which are spaced apart by a distance which is less than two thirds (⅔) of a distance between tips of lateral and medial epicondyles on a femur in an upper portion of the one leg of the patient into the incision,** | *See, e.g.*, Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1005); Delp '018, col. 2, ll. 21-54; 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. 1006); *see also* '821 patent, col. 13, ll. 64-66; col. 31, ll. 17-22; Figs. 9-21, 29 (Ex. 1001). |
| **(d) positioning the guide member on the femur in the one leg of the patient with opposite ends of the guide member substantially aligned with an axis through the lateral and medial epicondyles on the femur in the one leg of the patient,** | *See, e.g.*, Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1005); Delp '018, col. 2, ll. 21-54; 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. 1006). |
| **(e) moving a cutting tool through the incision into engagement with a guide surface on the guide member,** | *See, e.g.*, Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1005); Delp '018, col. 2, ll. 21-54; 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. 1006). |
| **(f) cutting the femur in the one leg of the patient with the cutting tool, said step of** | *See, e.g.*, Scorpio, pp. 5-19, 21, 23; Figs. 6-31, 36-37, 41-42 (Ex. 1005); Delp '018, col. 2, ll. 21-54; col. 3, ll. 20-31; col. 4, l. 20 – col. 5, l. 22; |

| | |
|---|---|
| **cutting the femur includes moving the cutting tool along the guide surface on the guide member, and** | 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. 1006). |
| **(g) positioning an implant in engagement with the femur in the one leg of the patient, wherein the implant has a transverse length that is larger than the guide surface length.** | *See, e.g.*, Scorpio, pp. 2, 5-19, 21, 23, 25, 41, 47; Figs. 6-31, 36-37, 41-42, 45, 73, 86 (Ex. 1005); Delp '018, col. 2, ll. 21-54; 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, 11-12, 15, 23-26, 31 (Ex. 1006); *see also* '821 patent, col. 13, ll. 64-66; col. 28, ll. 24-30; col. 31, ll. 17-22; Figs. 9-21, 29 (Ex. 1001). |

### 6. Claim 1 is Obvious Over Lackey '803 in View of Delp '018

As shown in the summary chart below and in the Mabrey Declaration, the method of claim 1 is obvious over Lackey '803 in view of Delp '018.

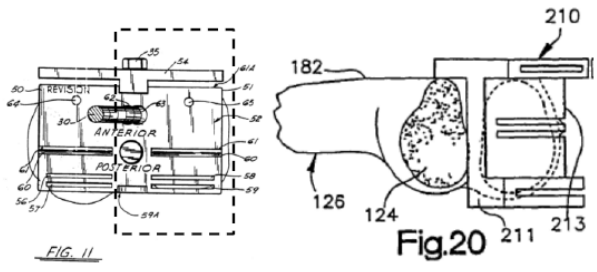
Lackey '803 discloses a method of performing surgery on a patient's knee, as recited in the preamble. For example, Lackey '803 relates to a "method and apparatus for use in knee surgery." Lackey '803, col. 1, ll. 15-17 (Ex. 1014); Mabrey Decl. ¶ 100 (Ex. 1002).

Lackey '803 discloses limitation (a), "supporting the patient on a support surface." For example, Lackey '803 relates to a "method and apparatus for use in knee surgery." Lackey '803, col. 1, ll. 15-17 (Ex. 1014). A person of ordinary skill in the art would understand Lackey '803 discloses limitation (a) because knee surgery necessarily requires supporting the patient on a support surface so that the surgeon can access the knee. Mabrey Decl. ¶ 101 (Ex. 1002). To the extent the

Patent Owner asserts that Lackey '803 does not disclose limitation (a), this limitation additionally would be clear to a person of ordinary skill in the art reading Lackey '803 because placing a patient on a support surface such as an operating table is routine surgical practice. Mabrey Decl. ¶ 101 (Ex. 1002).

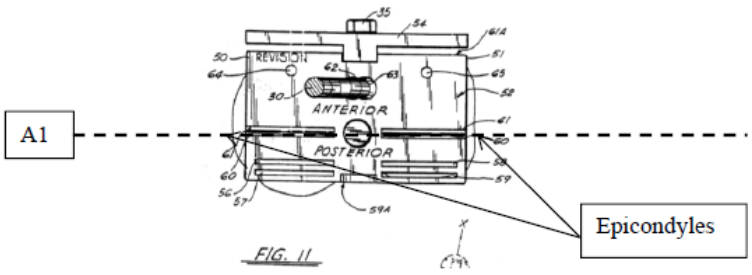
Lackey '803 discloses limitation (b), "making an incision in a knee portion of one leg of the patient." For example, Lackey '803 discloses the knee exposed through an incision in Figure 15. Lackey '803, Fig. 15 (Ex. 1014). Mabrey Decl. ¶ 102 (Ex. 1002).

Lackey '803 in combination with Delp '018 renders obvious limitation (c), "moving a guide member having opposite ends which are spaced apart by a distance which is less than two thirds (⅔) of a distance between tips of lateral and medial epicondyles on a femur in an upper portion of the one leg of the patient into the incision." As discussed, the '821 patent states that the "femoral cutting guide may have the construction disclosed in [Lackey '803 (Ex. 1014)]," but that "it is preferred to down size the known femoral cutting guides," '821 patent, col. 21, ll. 19-27 (Ex. 1001), as shown below:



*Compare* Lackey '803, Fig. 11 (Ex. 1014) *with* '821 patent, Fig. 20 (Ex. 1001); Mabrey Decl. ¶ 103 (Ex. 1002). For the reasons set forth above for Lackey '803, it would have been obvious to a person of skill in the art to reduce the width of the opposite ends of the cutting guide to less than two thirds of the distance between tips of lateral and medial epicondyles on a femur because making the cutting guide narrower allows it to pass through a smaller incision, which reduces trauma. Mabrey Decl. ¶ 103 (Ex. 1012).

Lackey '803 discloses limitation (d), "positioning the guide member on the femur in the one leg of the patient with opposite ends of the guide member substantially aligned with an axis through the lateral and medial epicondyles on the femur in the one leg of the patient." For example, as shown in Figure 11, cutting block (50) ("guide member") is positioned on the femur and the opposite ends of that cutting guide are substantially aligned with an axis (A1) through the lateral and medial epicondyles on the femur:

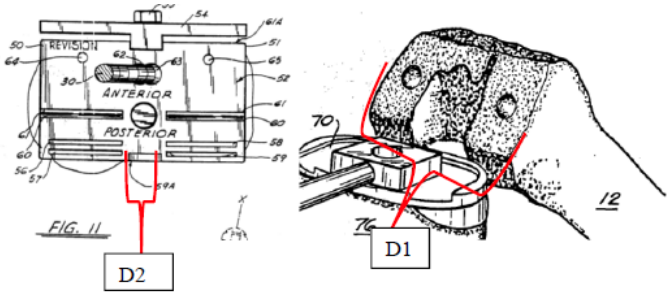



Lackey '803, Fig. 11 (Ex. 1014); Mabrey Decl. ¶ 104 (Ex. 1012).

Lackey '803 discloses limitation (e), "moving a cutting tool through the incision into engagement with a guide surface on the guide member," and limitation (f), "cutting the femur in the one leg of the patient with the cutting tool, said step of cutting the femur includes moving the cutting tool along the guide surface on the guide member." For example, Lackey '803 discloses "cutting block 50" with "a plurality of guide slots 56-59 and guide surface 59A," to "accommodate a cutting blade for making posterior femoral cuts," a "guide surface 61A" that "accommodates a cutting blade to make the anterior femoral cut," and a "plurality of diagonal slots 60, 61" for "diagonal cuts to the distal end of [the] femur." Lackey '803, Figs. 11-13; col. 8, ll. 13-21 (Ex. 1014). A person of ordinary skill in the art would understand this discloses limitations (e) and (f) because the cutting blade ("cutting tool") is moved through the incision into engagement with a guide surface on the "cutting block 50" ("guide member") such as "guide surface 59A," and moved along the guide surface to make cuts such as the "posterior femoral cuts." Mabrey Decl. ¶ 105 (Ex. 1002). To the extent the Patent Owner asserts that Lackey '803 does not disclose limitation (e), this limitation additionally would be clear to a person of ordinary skill in the art reading Lackey '803 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. ¶ 105 (Ex. 1002). To the extent the Patent Owner asserts that

Lackey '803 does not disclose "moving the cutting tool along the guide surface on the guide member," as recited in limitation (f), this requirement additionally would be clear to a person of ordinary skill in the art reading Lackey '803 because using the guide surface of the cutting guide to make femoral cuts by moving the cutting tool along the guide surface is a routine surgical step for cutting the femur. Mabrey Decl. ¶ 105 (Ex. 1002).

Lackey '803 discloses limitation (g), "positioning an implant in engagement with the femur in the one leg of the patient, wherein the implant has a transverse length that is larger than the guide surface length." For example, Lackey '803 discloses an "installation of a new long stem component 70" in the "femur 12." Lackey '803, Fig. 14; col. 8, ll. 36-38 (Ex. 1014). A person of ordinary skill in the art would understand Lackey '803 discloses "the implant has a transverse length that is larger than the guide surface length" because the implant substantially covers the end of the femur, and hence has a transverse length of approximately D1, whereas the guide surface length D2 of "guide surface 59A" is substantially less than D1, as shown below:



Lackey '803, Figs. 11, 19 (Ex. 1014); Mabrey Decl. ¶ 106 (Ex. 1002). Additionally, the "stem component 70" ("implant") has a transverse length that is larger than the guide surface lengths of the other guide surfaces, such as "guide slots 56-59," "guide surface 61A," and "diagonal slots 60, 61." Mabrey Decl. ¶ 106 (Ex. 1002). To the extent the Patent Owner asserts that Lackey '803 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, for the reasons discussed above in connection with limitation (c), to reduce the length of the guide surface in this manner so that the guide could fit through a smaller incision. Mabrey Decl. ¶ 106 (Ex. 1002). A guide member that is less than two thirds the distance between the epicondyles would necessarily have a guide surface length that is smaller than the transverse length of the implant as disclosed in Lackey '803. Mabrey Decl. ¶ 106 (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 '821 patent.

| | |
|---|---|
| **<u>Claim 1</u>: 1. A method of performing surgery on a patient's knee, said method comprising the steps of** | *See, e.g.*, Lackey '803, col. 1, ll. 15-17 (Ex. 1014); *see generally* Lackey '803, cols. 1-12; Figs. 1-19 (Ex. 1014); Delp '018, col. 1-28; Figs. 1-24 (Ex. 1006). |
| **(a) supporting the patient on a support surface,** | *See, e.g.*, Lackey '803, col. 1, ll. 15-17 (Ex. 1014); *see generally* Lackey '803, cols. 1-12; Figs. 1-19 (Ex. 1014); Delp '018, col. 1-28; Figs. 1-24 (Ex. 1006). |
| **(b) making an incision in a** | *See, e.g.*, Lackey '803, Fig. 15 (Ex. 1014); Delp |

| | |
|---|---|
| **knee portion of one leg of the patient,** | '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. 1006). |
| **(c) moving a guide member having opposite ends which are spaced apart by a distance which is less than two thirds (⅔) of a distance between tips of lateral and medial epicondyles on a femur in an upper portion of the one leg of the patient into the incision,** | *See, e.g.*, Lackey '803, col. 4, ll. 10-31; col. 4, l. 58 – col. 5, l. 5; col. 5, l. 38 – col. 6, l. 3; col. 8, ll. 1-35; Figs. 6-14 (Ex. 1014); Delp '018, col. 2, ll. 21-54; 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. 1006); *see also* '821 patent, col. 21, ll. 22; Fig. 20 (Ex. 1001). |
| **(d) positioning the guide member on the femur in the one leg of the patient with opposite ends of the guide member substantially aligned with an axis through the lateral and medial epicondyles on the femur in the one leg of the patient,** | *See, e.g.*, Lackey '803, col. 4, ll. 10-31; col. 4, l. 58 – col. 5, l. 5; col. 5, l. 38 – col. 6, l. 3; col. 8, ll. 1-35; Figs. 6-14 (Ex. 1014); Delp '018, col. 2, ll. 21-54; 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. 1006). |
| **(e) moving a cutting tool through the incision into engagement with a guide surface on the guide member,** | *See, e.g.*, Lackey '803, col. 4, ll. 10-31; col. 4, l. 58 – col. 5, l. 5; col. 5, l. 38 – col. 6, l. 3; col. 8, ll. 1-35; Figs. 6-14 (Ex. 1014); Delp '018, col. 2, ll. 21-54; 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. 1006). |
| **(f) cutting the femur in the one leg of the patient with the cutting tool, said step of cutting the femur includes moving the cutting tool along the guide surface on the guide member, and** | *See, e.g.*, Lackey '803, col. 4, ll. 10-31; col. 4, l. 58 – col. 5, l. 5; col. 5, l. 38 – col. 6, l. 3; col. 8, ll. 1-35; Figs. 6-14 (Ex. 1014); Delp '018, col. 2, ll. 21-54; 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. 1006). |
| **(g) positioning an implant in** | *See, e.g.*, Lackey '803, col. 1, ll. 21-24; col. 4, ll. |

| | |
|---|---|
| **engagement with the femur in the one leg of the patient, wherein the implant has a transverse length that is larger than the guide surface length.** | 10-31; col. 4, l. 58 – col. 5, l. 5; col. 5, l. 38 – col. 6, l. 3; col. 8, ll. 1-38; Figs. 6-14, 19 (Ex. 1014); Delp '018, col. 2, ll. 21-54; 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, 11-12, 15, 23-26, 31 (Ex. 1006). |

## X. CONCLUSION

Based on the foregoing, claim 1 of the '821 patent recites subject matter that is unpatentable. The Petitioner requests institution of an *inter partes* review to cancel that claim.

Respectfully submitted,

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**LIST OF EXHIBITS FOR**
**PETITION FOR *INTER PARTES* REVIEW OF**
**U.S. PATENT NO. 6,702,821**

| Exhibit | Description |
|---|---|
| 1001 | U.S. Patent No. 6,702,821 ("'821 patent") |
| 1002 | Declaration of Jay Mabrey, M.D., M.B.A. ("Mabrey Declaration" or "Mabrey Decl.") |
| 1003 | 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") |
| 1004 | Chitranjan S. Ranawat and Lawrence D. Dorr, "G. Technique of Total Knee Arthroplasty with Precision Cut Instruments," *in* Total-Condylar Knee Arthroplasty: Technique, Results, and Complications (Chitranjan S. Ranawat ed., 1985) ("Ranawat") |
| 1005 | Stryker Howmedica Osteonics, "Scorpio Single Axis Total Knee System: Passport A.R. Surgical Technique" ("Scorpio") |
| 1006 | U.S. Patent No. 5,871,018 to Delp ("Delp '018") |
| 1007 | '821 patent file history, Office Action dated May 14, 2003 |
| 1008 | '821 patent file history, Response dated October 7, 2003 |
| 1009 | U.S. Patent No. 4,502,483 ("Lacey '483") |
| 1010 | S. David Stulberg, et al., "Computer-Assisted Total Knee Replacement Arthroplasty" ("Stulberg") |
| 1011 | Richards, "Richards Intracondylar Knee," 1979 ("Richards") |
| 1012 | Smith & Nephew, "Genesis Unicompartmental Knee System," 1994 |
| 1013 | International Patent Application Publication No. WO 93/25157 ("Radermacher") |
| 1014 | U.S. Patent No. 5,282,803 to Lackey ("Lackey '803") |
| 1015 | Peter A. Keblish, Jr., M.D., "Surgical Techniques in the Performance of Unicompartmental Arthroplasties," Operative Techniques in Orthopaedics, Vol. 8, No. 3 (July), 1998: pp. 134-145 |

## CERTIFICATE OF SERVICE

I hereby certify that on September 25, 2013, I caused a true and correct copy of the foregoing materials:

- Petition for *Inter Partes* Review of U.S. Patent No. 6,702,821 Under 35 U.S.C. § 312 and 37 C.F.R. § 42.104
- Exhibits 1001-1015
- List of Exhibits for Petition for *Inter Partes* Review of U.S. Patent No. 6,702,821 (Exhibits 1001-1015)
- 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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