

Filed on behalf of: BONUTTI SKELETAL INNOVATIONS LLC Paper _____
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By: Cary Kappel, Lead Counsel
William Gehris, Backup Counsel
Davidson, Davidson & Kappel, LLC
485 Seventh Avenue
New York, NY 10018
Telephone (212) 736-1257
(212) 736-2015
Facsimile (212) 736-2427
E-mail: ckappel@ddkpatent.com
wgehris@ddkpatent.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.

Petitioner,

v.

BONUTTI SKELETAL INNOVATIONS LLC

Patent Owner

Case: IPR2013-00629

Patent 7,806,896

**PATENT OWNER'S RESPONSE
PURSUANT TO 37 C.F.R. § 42.120**

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Pursuant to 35 U.S.C. § 316(a)(8) and 37 C.F.R. § 42.120, Patent Owner Bonutti Skeletal Innovations, LLC ("Bonutti") responds to the Petition filed by Smith & Nephew, Inc. ("Smith & Nephew") concerning claim 1 of U.S. Patent No. 7,806,896 ("the '896 patent") (Paper 3), with respect to Grounds A(1) and A(3) of the Petition, the only grounds on which the Board instituted *inter partes* review: A(1) "Delp Article in View of Any One of Turner or Scorpio" (Petition, pp. 27-37); and A(3) "Stulberg in View of Any One of Turner or Scorpio" (*Id.*, pp. 42-47). (See Institution Decision, Paper 10, page 27).

Petitioner bears "the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e). For the reasons set forth herein, Petitioner has failed to meet its burden to show by a preponderance of the evidence that claim 1 is unpatentable as obvious over the Delp Article in view of either Turner or Scorpio, or that claim 1 is unpatentable as obvious over Stulberg in view of either Turner or Scorpio.

I. The '896 patent

Claim 1 of the '896 patent recites:

1. A method of replacing at least a portion of a patient's knee, the method comprising the steps of:
 - making an incision in a knee portion of a leg of the patient;
 - determining a position of a cutting guide using references derived independently from an intramedullary device;

positioning a cutting guide using the determined position, passing the cutting guide through the incision and on a surface of a distal end portion of an unresected femur, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod;

moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and

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

attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

Accordingly, as recited in claim 1, the *cutting guide* is passed through the incision and onto the surface of a distal end portion of an unresected femur, the cutting guide has a *guide surface* and is *secured* to the bone *free of an extramedullary or intramedullary alignment rod*. At least an *initial* cut is formed in the femur by moving a cutting tool along the guide surface. A replacement portion of the knee is attached to the cut surface, and that replacement portion has “a *transverse dimension that is larger than a transverse dimension of the guide surface.*”

The '896 patent describes a number of inventive surgical devices and surgical methods. In particular, the '896 patent describes the use of reduced size cutting guides in knee replacement surgery. ('896 patent, col. 3, ll. 15-30, col. 17, ll. 47-60, cols. 69-71, cols. 103-104). The '896 patent explains that the “benefits of having a

smaller incision include improved cosmetic results, improved rehab, less dissection of muscle and soft tissue, and preservation of the quadriceps mechanism.” (Id., col. 15, ll. 15-18). By using reduced size cutting guides, “the size of the incision ... can be reduced”, and “reducing the size of the incision ... reduces damage to body tissue of the patient.” (Id., col. 18, ll. 36-38).

The '896 patent explains:

Although any one of many known surgical procedures may be undertaken through the limited incision, down sized instrumentation for use in the making of cuts in a femur and/or tibia may be moved through or part way through the incision. The down sized instrumentation may be smaller than implants to be positioned in the knee portion of the patient. . . .

It is contemplated that the down sized instrumentation may have cutting tool guide surfaces of reduced length. The length of the cutting tool guide surfaces may be less than the length of a cut to be made on a bone. A cut on a bone in the patient may be completed using previously cut surfaces as a guide for the cutting tool.

Col. 3, ll. 15-30 (emphasis added).

The '896 patent contrasts its reduced size cutting guides from conventional cutting guides such as the Scorpio cutting guides of Exhibit 1009:

The distance between opposite ends of the known . . . anterior resection guide are greater than the transverse dimensions of the femoral and tibial implants. This known anterior resection guide and femoral

alignment guide are commercially available from Howmedica Osteonics of 359 Veterans Boulevard, Rutherford, N.J. under the designation "Scorpio" (trademark) Single Axis Total Knee System. (Col. 18, ll. 18-31).

The reduced size cutting guides of the '896 patent include: femoral and tibial cutting guides secured with intramedullary alignment rods (col. 17, ll. 15-17, Figs. 9-13), femoral and tibial cutting guides secured with extramedullary alignment rods (Figs. 37-38, col. 17, ll. 15-17, col. 44, ll. 20-36); and femoral *cutting guides which* are secured to the bone *free of an extramedullary or intramedullary alignment rod* (Figs. 53, 54, cols. 69-71, Figs. 94, 95, cols. 103-105).¹ The latter cutting guides are the subject of claim 1 of the '896 patent.

The '896 patent also discusses the "guide surface" of the aforementioned cutting guides. (Col. 20, ll. 15-21 (Figs. 9-13), col. 45, ll. 46-48 (Fig. 38), col. 69, ll. 6-34 (Fig. 53), col. 70, ll. 27-63 (Fig. 54), col. 104, ll. 37-38, col. 105, ll. 13-27 (Fig. 94)).

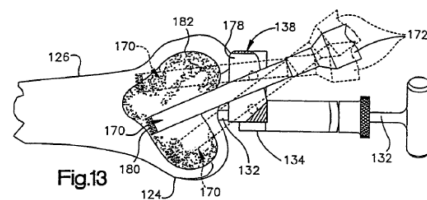
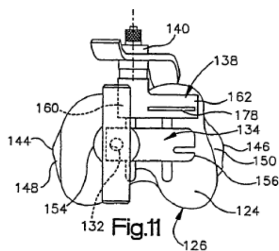
¹ Although he chose not to mention it in his Declaration, Petitioner's expert Dr. Mabrey agrees that the cutting guides of Figures 53 and 54 are secured "free of an extramedullary or intramedullary alignment rod", and that the cutting guide of Figure 94 can be. (Exhibit 2003, Mabrey Transcript, p. 33, ll. 11-17 (Fig. 53); p. 33, l. 25 to p. 34, l. 7 (Fig. 54), and p. 35, ll. 20-23 (Fig. 94), hereinafter "Mabrey Tr., page:line").

The '896 patent explains that the guide surface extends only part way across the femur (or tibia in the case of Figs. 37-38). (Col. 20, ll. 18-19 (Fig. 13), col. 45, ll. 45-62 (Fig. 38), col. 69, ll. 47-49 (Fig. 53), col. 71, ll. 9-12, 22-25, 45-48 (Fig. 54), col. 105, ll. 17-19 (Fig. 94)).

The '896 patent explains that an initial cut can be made with the guide surface, and then the remainder of the cut can be made using the initial cut as a guide. (Col. 20, l. 52 - col. 21, line 9 (Fig. 13), col. 45, ll. 57-67 (Fig. 38), col. 69, ll. 51-63 (Fig. 53), col. 71, ll. 12-16, 22-29, 45-49 (Fig. 54), col. 105, ll. 19-22 (Fig. 94), col. 110, ll. 45-50).

The use of shorter cutting surfaces allows for reduced incision sizes (Id., col. 17, ll. 47-50) and, accordingly “improved cosmetic results, improved rehab, less dissection of muscle and soft tissue, and preservation of the quadriceps mechanism.” (Id., col. 15, ll. 15-18, see also col. 18, ll. 34-38, col. 19, ll. 36-42, col. 21, ll. 28-30).

With reference to the cutting guide of Figures 10-13 which is secured with an intramedullary alignment rod, the '896 patent describes guide surface 178:

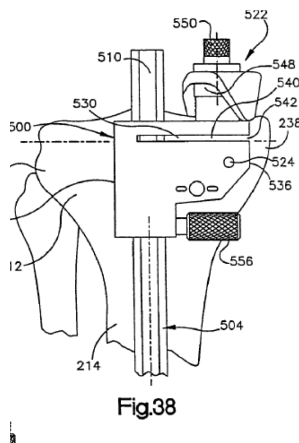


('896 patent, col. 20, ll. 15-46).

It is noteworthy that guide surface 178 is shown as extending substantially

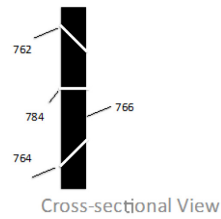
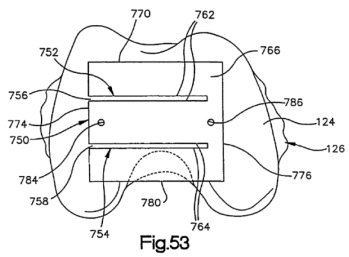
across the entire cutting guide 138 (Fig. 13) notwithstanding the fact that the slot extends across only about two-thirds of the front face of the cutting guide 138 (Fig. 11). The guide surface 178 narrows in thickness as it extends from top to bottom of Figure 13 (or right to left from the perspective of Fig. 11), but remains continuous on the bone-side² of the guide. (Mabrey Tr., 82: 2-21, Exhibit 2002, Declaration of Scott D. Schoifet, M.D. (Schoifet Decl.), par. 33).

With regard to the cutting guide 500 of Figure 37-38 which is secured with an extramedullary alignment rod, the '896 patent describes guide surface 530 at column 45, line 45 to column 46, line 20:



With regard to the cutting guide 750 of Figure 53, which is “*secured to the bone free of an extramedullary or intramedullary alignment rod*” as claimed, the '896 patent describes guide surfaces 762, 764, 770 and 780:

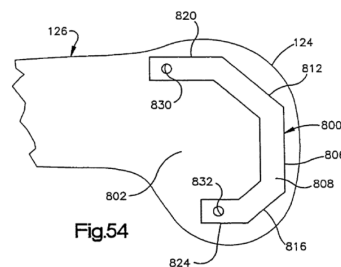
² From the perspective of Figure 13, the bone side is the left side of the guide 138.



(896 patent, col. 69, ll. 1-50). As shown in Figure 53, and a corresponding cross-sectional sketch, femoral cutting guide 750 is positioned on the on the distal end of the femur 126 and is secured to the femur 126 by pins 784, 786. (*Id.*, col. 69, ll. 35-41). No intramedullary or extramedullary alignment rod is used. The “guide surfaces 762 for the guide slot 752 are skewed at an acute angle of forty-five degrees to a major side surface 766 of the femoral cutting guide 750;” “the guide surfaces 764 are skewed at an angle of forty-five degrees to the major side surface”; and “[t]he guide surfaces 762 extend perpendicular to the guide surfaces 764.” (*Id.*, col. 69, ll. 6-12) (emphasis added). The anterior guide surface 770 “extends across the femoral cutting guide 750 between the lateral end portion 774 and a medial end portion 776” and “extends perpendicular to the major side surface 766 of the femoral cutting guide 750.”(*Id.*, col. 69, ll. 20-24) (emphasis added). Similarly, the posterior guide surface 780 “extends perpendicular to the major side surface 766.” (*Id.*, col. 69, ll. 30-31) (emphasis added). Accordingly, as with the guide surface 178 of Figure 13, the guide surfaces of Figure 53 extend to the bone side of the cutting

guide.

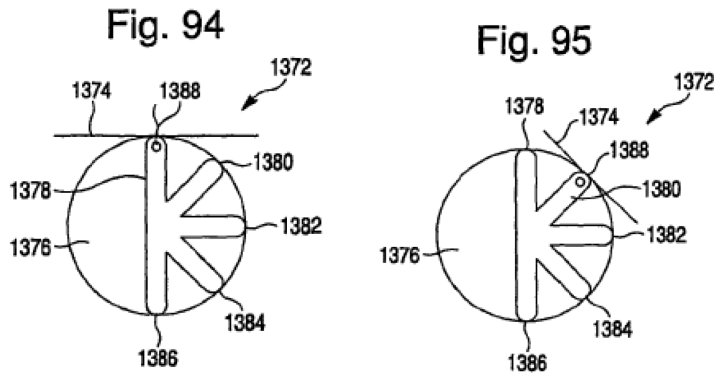
With regard to the cutting guide 800 of Figure 54, which is “*secured to the bone free of an extramedullary or intramedullary alignment rod*” as claimed, the '896 patent describes guide surfaces 806, 812, 816, 820, 824:



(Col. 70, ll. 19-62). Figure 54 is in fact discussed in this regard in the prosecution history (Exhibit 1014, p. 13). As shown in Figure 54, femoral cutting guide 800 is positioned on a lateral surface 802 of the femur 126 and secured to the femur 126 by pins 830, 832. ('896 patent, col. 70, ll. 64-67). No intramedullary or extramedullary alignment rod is used. The “distal guide surface 806 is disposed in a plane which extends perpendicular to a longitudinal central axis of the femur 126 and extends through the lateral and medial condyles;” and “[t]he distal guide surface 806 extends perpendicular to a major side surface 808 of the femoral cutting guide 800.” (*Id.*, col. 70, ll. 28-32) (emphasis added). Guide surfaces 812, 816, 820, and 824 also extend perpendicular to the major side surface 808, and extend between the opposite major sides of the cutting guide 800. (*Id.*, col. 70, ll. 38-41, 49-53, 57-62). Accordingly, as with the guide surfaces of Figures 13 and 53, the guide surfaces of Figure 54 extend

to the bone side of the cutting guide.

Cutting guide 1372 shown in Figures 94 and 95 includes a base 1376 and cutting guide surface 1374:



Cutting guide 1372 can be secured to the bone *free of an extramedullary or intramedullary alignment rod*” as claimed. (*Id.*, col. 104, ll. 49-51 (“If desired, the base 1376 could be pinned directly to the femur in a manner analogous to the cutting guide 800 (FIG. 54)”). Further, “the guide surface 1374 can be made so that the size of the guided portion of the cuts can be adjusted depending upon the size of the bone and the implant that is to be used;” and “the guide surface 1374 can be made to have a length less than the extent of the cut to be formed on the distal end portion of the femur.” (*Id.*, col. 105, ll. 13-19). The cutting guide 1372 can be “positioned on the femur using a computer navigation system.” (*Id.*, col. 104, ll. 53-54).

II. The Priority Date of Claim 1 of the '896 patent

Petitioner alleges that claim 1 is entitled to an effective filing date of November 25, 2003. Patent Owner disagrees and contends that claim 1 of the '896

patent is entitled to an effective filing date of August 28, 2001, the earliest date which contained the disclosure of Figures 53 and 54 discussed above.³

However, as noted by the Petitioner, all of the prior art asserted in this proceeding has a publication date earlier than August 28, 2000.

III. The Prior Art of the Instituted Grounds

Although the Petition includes seven documents alleged as prior art patents and printed publications (Petition, pp. 2-3), this proceeding was instituted solely with regard to claim 1 and solely on the basis of four publications: 1) S. David Stulberg, et al., “Computer-Assisted Total Knee Replacement Arthroplasty,” (Jan. 2000) (“Stulberg” (Exhibit 1005)); 2) Scott L. Delp, et al., “Computer Assisted Knee Replacement,” (1998) (“Delp ” (Exhibit 1003)); 3) Roderick H. Turner et al., “Geometric and Anametric Total Knee Replacement,” (1980) (“Turner” (Exhibit

³ The '896 patent was filed as U.S.S.N. 10/722,102 on November 25, 2003 (“102 application”) and is: (i) a 35 U.S.C. §120 continuation of U.S.S.N. 10/191,751, filed on July 8, 2002 (which has the same specification and drawings as the '102 application); (ii) a 35 U.S.C. §120 continuation-in-part of U.S.S.N. 09/976,396, filed on October 11, 2001 (which includes Figs. 1-66 of the '896 patent, and the corresponding description thereof); and (iii) a continuation-in-part of U.S.S.N. 09/941,185, filed on August 28, 2001 (which includes Figs. 1-58 of the '896 patent, and the corresponding description thereof).

1008)); and 4) Stryker Howmedica Osteonics, “Scorpio Single Axis Total Knee System: Passport A.R. Surgical Technique” (“Scorpio” (Exhibit 1009)).

A. Stulberg

Stulberg is an article purportedly published in January 2000 that is directed to computer-assisted total knee replacement. Stulberg reports that “alignment errors of greater than 3° are associated with more rapid failure and less satisfactory results” (Stulberg, p. 25). Stulberg further reports that while “[m]echanical alignment guides have improved . . . accuracy” (*id.*), they are still unsatisfactory in that they have “fundamental limitations that limit their ultimate accuracy.” (*Id.*).

Stulberg notes that the computer assisted techniques it describes use “conventional incision and exposure.” (*Id.* p. 27). Stulberg does not indicate that a smaller incision size is necessary, and does not in any way indicate that the size of the alignment guides or cutting guides is of interest. Nothing in Stulberg suggests that the size of conventional mechanical alignment guides or cutting guides is problematic. Indeed, Stulberg does not object to extramedullary or intramedullary alignment guides *per se*, but rather is concerned with more *accurate placement* of the cutting and alignment guides. Thus, for example, in its computer-assisted tibial procedure, an extramedullary alignment guide is used (Fig. 12), and the computer technique is used to more finely tune the position of the cutting guide. (*Id.*, p. 29, final two pars.).

As shown in Figures 16B and 17, the guide surface of the cutting guide is larger than the replacement component. In particular, it can be seen that the guide surface extends beyond the femur. Thus, the replacement component (Fig. 20) clearly has a transverse dimension that is smaller than the transverse dimension of the guide surface. (Schoifet Decl., par. 40). There is no indication whatsoever that this is disadvantageous and in fact no indication anywhere in Stulberg that the relative sizes of the guide surface and the replacement portion are of interest. Rather, Stulberg is concerned with accurate placement of the cutting guides so that a more precise cut can be made:

The reliability of techniques for total knee replacement (TKR) is still limited by the relative inaccuracy of instrumentation. (Id. at p. 25 (Abst.))

The goal of the total knee instrumentation procedure is to achieve cuts that are perpendicular to the mechanical axes of the femur and the tibia. The longevity of total knee arthroplasty is closely related to its intraoperative positioning. The computer-assisted procedure offers an effective and novel positioning method that improves the accuracy of the surgical technique of the TKR. (Id.).

Incorrect positioning or orientation of implants and improper alignment of the limb can lead to accelerated implant wear and loosening and suboptimal functional performance. A number of studies have suggested that alignment errors of greater than 3° are associated with more rapid failure and less satisfactory functional results of total knee

arthroplasties. (Id. at p. 25)

Computer-based alignment systems have been developed to address the problems inherent in mechanical total knee instrumentation. (Id.)

B. Delp

Like Stulberg, Delp is directed to computer assisted knee replacement, and is concerned with the *accuracy* of mechanical alignment systems: “[a]lthough mechanical alignment guides have been designed to improve alignment accuracy, there are several fundamental limitations of this technology that will inhibit additional improvements.” (Delp, p. 49, left col.).

Like Stulberg, Delp does not express any concern for the size of conventional incisions, or the size of conventional alignment devices or cutting guides. (Schoifet Decl., pars. 42, 62, 88). Rather, it is the *accuracy* of the alignment and cutting guides that is of concern. (Id., p. 49, left col. to p. 50, left col.).

Delp discusses three distinct technologies: (i) computer integrated instruments, (id., pp. 50-51); (ii) image guided knee replacement, (id., pp. 51-53); and (iii) robot assisted knee replacement, (id., pp. 53-54).

computer integrated instruments - This technique uses an optical localizer to determine the mechanical axes of the femur and tibia, and then uses a computer workstation to display the position of the cutting block relative to its desired position. Once the cutting block is “oriented properly it is secured in position and the

cuts are made with a standard oscillating saw.” (Id., p. 51, left col.). As reported at page 55, this technique uses “standard cutting guides.” (emphasis added).

Accordingly, although Delp does not specifically discuss how the cutting guide is secured, it follows that since a “standard cutting guide” is used, it is to be secured in the standard way.

image guided knee replacement – In this technique, three dimensional computer models of the patient’s femur and tibia are constructed using computer tomographic data. (Id., p. 51, last par.). An intraoperative system is used to “determine the position and orientation of the patient’s femur and tibia and to guide the surgeon in the placement of the cutting jigs.” (Id., p. 52, last two pars.). According to Delp, the intraoperative system includes a graphics workstation, a coordinate measurement probe, and “a set of cutting blocks that have been modified to attach to the measurement probe.” (Id.). There is no suggestion that the cutting blocks/cutting jigs are in any other way different than standard cutting blocks/jigs. There is no indication that they are not secured to the femur/tibia in a conventional manner.

Robot assisted knee replacement- Three robot assisted techniques are described: Kienzle et al - In this technique, a robotic procedure is used to more accurately “drill the alignment holes for conventional cutting blocks for femoral and tibial implants.” (Id., p. 54, 1st par.); Fadda et al- In this technique, “a sophisticated

pre-operative planning system [is linked] to a standard industrial robot to allow placement of cutting blocks and machining of the bones.” (Id., p. 54, 2nd par.); and Davies et al.- In this technique, an active constraint robot (ACROBOT) is used to cut the femur without the use of cutting guides. (Id., p. 54 (“virtual cutting block”)).

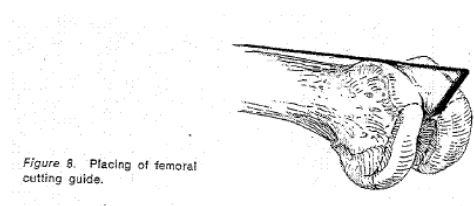
The computer integrated technique, the image guided technique and the first two robot assisted techniques use standard cutting blocks, presumably secured in their standard way, and the last uses no cutting block at all. However, in each technique, Delp is concerned with the accuracy of the placement of the cuts, not the size of the cutting surfaces:

- “Accurate alignment of knee implants is essential for the success of total knee replacement. Although mechanical alignment guides have been designed to improve alignment accuracy, there are several fundamental limitations of this technology that will inhibit additional improvements. Various computer assisted techniques have been developed to examine the potential to install knee implants more accurately and consistently than can be done with mechanical guides.” (Id., p. 49, Abst.) (emphasis added).
- “Even a small (2.5 mm) anteroposterior displacement of the femoral component has been shown to alter knee range of motion (ROM) as much as 20°.” (Id., p. 50).
- “Even when using state of the art intramedullary alignment systems, surgeons find that it is difficult to install knee implants within 2° to 3° varus or valgus alignment.” (Id.).

C. Turner

Turner is an article published in 1980, 18 years prior to Delp, and 20 years prior to Stulberg. Turner is directed to geometric and anametric total knee replacement (“TKR”) techniques. The cutting guide that is relied upon by the Petitioner (Fig. 8) is employed in the geometric technique. The geometric TKR was a primitive design that had been abandoned as a failure by 1990, long before Delp or Stulberg. (Schoifet Decl., pars. 48, 65). In particular, it was found that while the theory of the geometric TKR was that “(4) although stability in flexion [as the knee flexes] may be sacrificed somewhat with spherical surfaces, the requirements for stability in flexion are no nearly as significant functionally as are the requirements for stability at or near full extension,” (Turner, p. 174), the opposite was in fact true because flexion instability is one of the primary causes of total knee pain and failure, not extension instability. (Schoifet Decl., pars. 48, 67). By 1988, it the geometric TKR was known to have a 10 year survivability of only 69%. (Id., pars. 48, 68).

In the technique described in Turner, the femoral cutting guide is mounted with an extramedullary alignment rod, as illustrated in Figure 8:



A person of ordinary skill in the art at the time of the invention would

recognize the above figure as an extramedullary alignment rod that terminates with a cutting guide. (Mabrey Tr. 72:6-11; Schoifet Decl., pars. 50, 66). A person of ordinary skill in the art at the time of the invention would also recognize that this cutting guide, whose extramedullary alignment is achieved by inserting “[t]he femoral cutting guide ... in the midline, deep to the suprapatellar pouch,” and which is thereafter used to cut the femur “with a power or hand saw parallel with the guide that is approximately 30 degrees to the long axis of the femur,” would provide a far more imprecise cut than the techniques criticized in Delp and Stulberg. (Schoifet Decl., pars. 50, 66, 70). At the time of the invention, a person of ordinary skill in the art would not have considered using the femoral cutting guide of Figure 8 in a knee replacement surgery. (Schoifet Decl., pars. 50, 65).

There is no discussion of limiting incision sizes in Turner, and no indication that the relative size of the cutting surface of the cutting guide and the replacement component is of any interest.

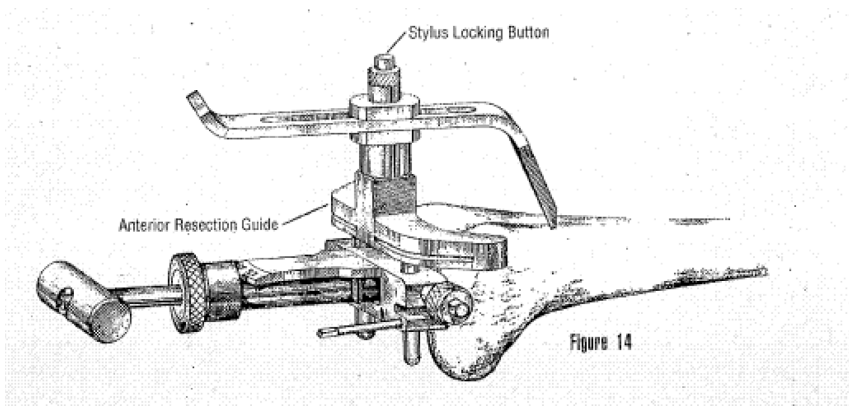
D. Scorpio

Scorpio was considered by the United States Patent and Trademark Office during prosecution of the '896 patent, and moreover, the Scorpio system was discussed in the specification of the '896 patent. In particular, the '896 patent describes the following:

The distance between opposite ends of the known femoral alignment guide and the distance between opposite ends of the known anterior resection guide are greater than the transverse dimensions of the femoral and tibial implants 286, 290 and 294 (FIG. 29). This known anterior resection guide and femoral alignment guide are commercially available from Howmedica Osteonics of 359 Veterans Boulevard, Rutherford, N.J. under the designation "Scorpio" (trademark) Single Axis Total Knee System.

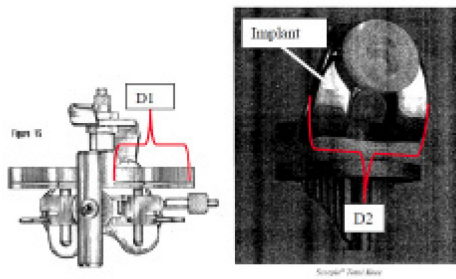
Col. 8, ll. 18-31

In Scorpio, the initial femoral cut is made using the anterior resection guide shown below:

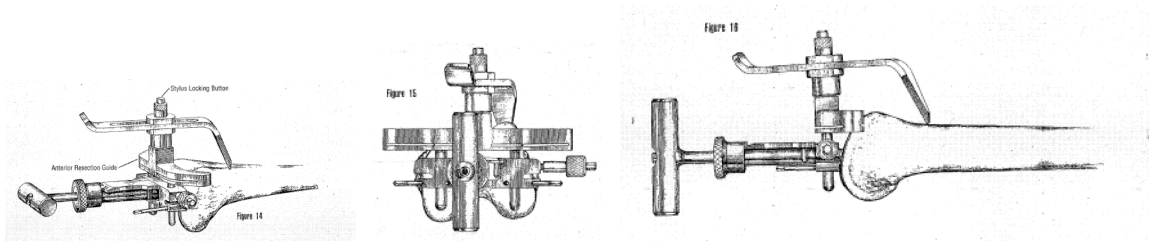


The anterior resection guide is mounted to the femur with an intramedullary alignment rod, as clearly shown in Figure 9: “[i]nset the femoral alignment guide into the intramedullary hole (Fig. 9)”, (*id.*, p. 6) and in Figure 12: “[i]nset the femoral alignment guide into the intramedullary hole. (Figs. 11, 12)”, (*id.*, p. 7).

In the Petition, the Petitioner alleges that the Anterior Resection Guide is composed of two guide surfaces, of which Petitioner alleges surface D1 (below) is less than the transverse dimension of the replacement portion (implant D2):



However, Scorpion only illustrates the cutting guide from the perspective of the physician.

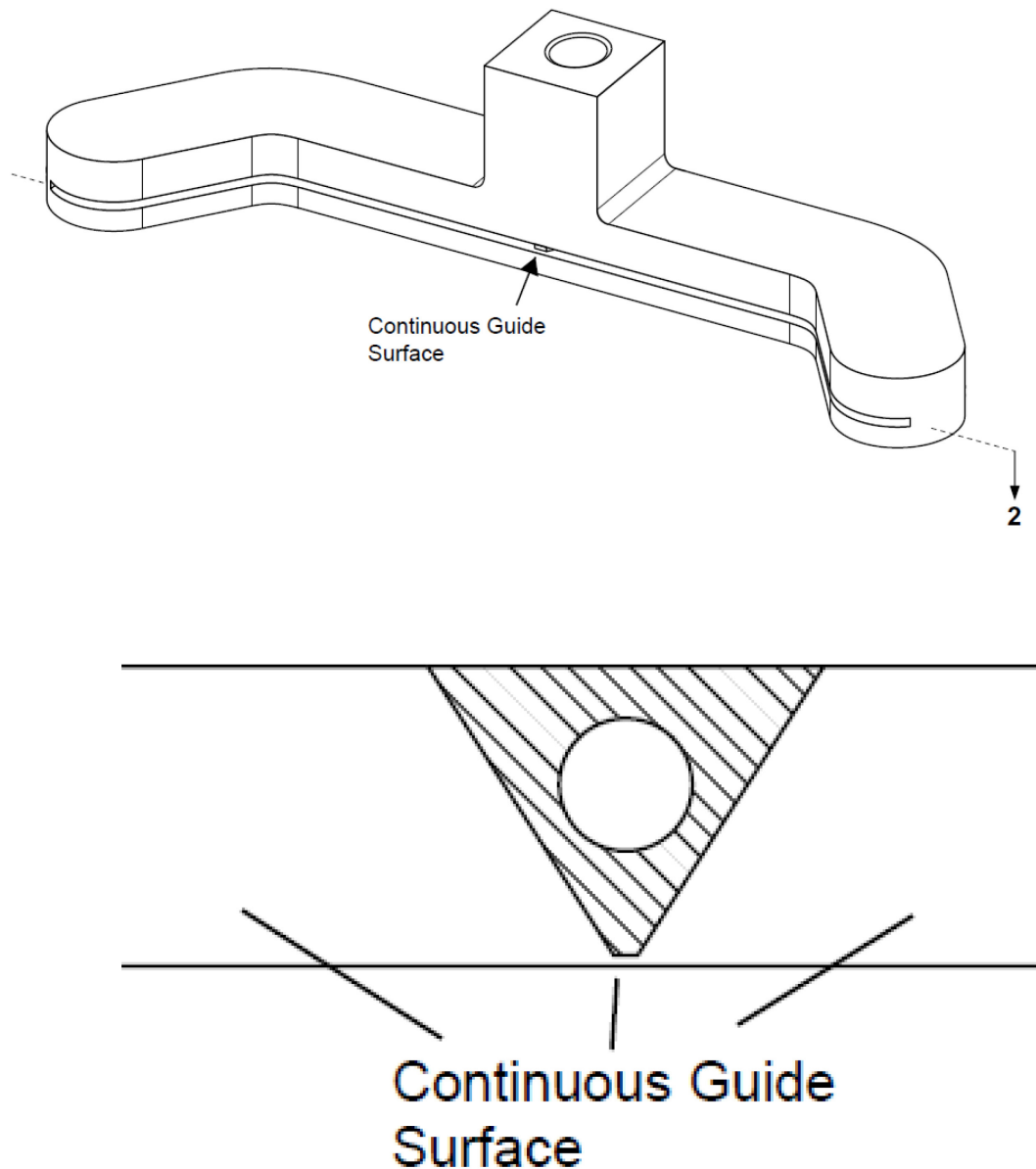


There is no illustration in Scorpion which shows the cutting guide from the opposite (i.e. bone-side) perspective from Figure 15. (Schoifet Decl., par. 57). Dr. Mabrey agrees. (Mabrey Tr., 77:14-17, 102:24-103:10).

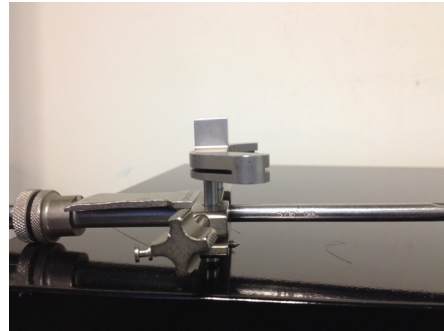
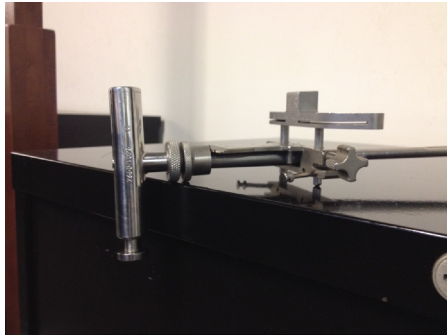
A person of ordinary skill in the art considering Scorpion at the time of the invention would have understood that in order to create the anterior cut on the femur, the guide surface on the bone side of the anterior resection guide would have had to extend continuously between the lateral and medial sides of the cutting guide (i.e. from the right side to the left side of the guide when viewed from the perspective of Fig. 15). (Schoifet Decl., par. 58).

Further, as shown in the photos and illustration below, the cutting guide in fact has a single continuous guide surface that extends across the entire cutting guide.

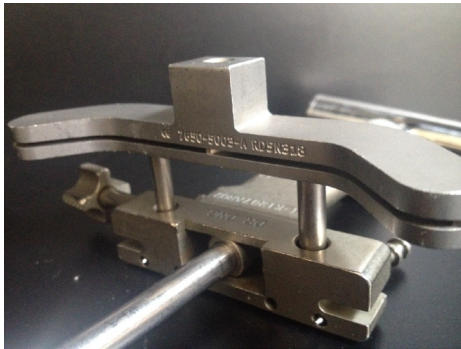
The guide surface narrows and widens from one side of the cutting guide to the other, but extends as a single continuous surface throughout:



(Exhibit 2007, Schoifet Decl., par. 59)



(Exh. 2005, Photos from the perspective of Scorpio Figs. 14 and 16)



(Exh. 2005, Photos from the bone side of the device of Scorpio)

(Schoifet Decl., pars. 10, 59, 76, 78)

There is no discussion of limiting incision sizes in Scorpio, and no indication that the relative size of the cutting surface of the cutting guide and the replacement component is of any interest.

IV. Petitioner Has Not Established that Claim 1 is Unpatentable Under 35 U.S.C. §103 as Obvious Over Stulberg in view of Turner or Scorpio

Petitioner cannot meet its burden to prove, by a preponderance of the evidence, that claim 1 of the '896 patent is obvious under 35 U.S.C. § 103 over

Stulberg in view of Turner or Scorpio. Stulberg is concerned with providing improved accuracy in positioning cutting guides, and proposes using computer-assisted techniques to more accurately position the cutting guide on the femur.

Petitioner admits that Stulberg does not disclose or suggest providing the claimed cutting tool, which has a guide surface, where a replacement portion of the knee has “*a transverse dimension that is larger than a transverse dimension of the guide surface.*” (Petition, p. 45; Institution Decision, p. 14).⁴ In fact, Stulberg expresses no interest at all in the size of the cutting surface. (Schoifet Decl., par. 62, Mabrey Tr. 51:19-52:17). Furthermore, Stulberg is not even concerned with performing a minimally invasive procedure. (Schoifet Decl., par. 62). Petitioner relies, in the

⁴ During his deposition, after discussing the prior art with counsel in a break between cross-examination and redirect testimony, (Mabrey Tr., 94:14-95:22), Dr. Mabrey stated in redirect testimony that the cutting guide and guide surface of Stulberg was narrower than the femur. (Id., 88:13-89:2) However, in re-cross, Dr. Mabrey was forced to withdraw that assertion. (Id., 100:19-102:2) In any event, the fact that the cutting guide and guide surface of Stulberg (Figs.16-17) is wider than the femur is clear from Stulberg itself. (Institution Decision, p. 14). Further, the claim requires that that the replacement portion of the knee be larger in the transverse dimension than the guide surface, and the replacement portion is narrower than the femur (Fig. 20).

alternative, on either Turner or Scorpio to cure the deficiencies in Stulberg.

In its Decision to Institute, the Board, citing KSR Int’l Co. v. Teleflex, Inc., 550 U.S. 398, 417 (2007), states:

According to Petitioner, the combination “overcome[s] the deficiencies of standard mechanical measuring techniques,” such as those of Turner and Scorpio, by utilizing the computer-assisted system of Stulberg. Pet. 45-46. As explained above, Stulberg explains that computer-assisted surgical techniques “improve[] the accuracy of the surgical technique.” Ex. 1005, p. 25. This improved technique “uses currently available mechanical total knee instruments.” Id. at 33; see also Pet. 46.

Accordingly, the proposed combination appears to be nothing more than using a known technique to improve a similar device in the same way. KSR Int’l Co. v. Teleflex, Inc., 550 U.S. 398, 417 (2007).

In view of the above, Petitioner has shown a reasonable likelihood that it would prevail in showing that claim 1 is obvious in view of the combined teachings of Stulberg with either Turner or Scorpio. (Institution Decision, pp. 18-19)(emphasis added).

Such a finding under KSR requires, *inter alia*, that the person of ordinary skill in the art could have applied a known improvement from the secondary reference in the same way to the base device of the primary reference and that the results would have been predictable to the person of ordinary skill in the art. See, e.g., Ex parte HOEG et al, Appeal 2011-011778, 2014 Pat. App. LEXIS 1132 (Pat. App. 2014)(“If a technique has been used to improve one device, and a person of ordinary skill in the

art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. KSR, 550 at 417”); Ex parte LIN et al, Appeal 2011-009169, 2014 Pat. App. LEXIS 951 (Pat. App. 2014) (same); Manual of Patent Examining Procedure (MPEP) §2143 (9th Ed., March 2014). Petitioner has not established, by a preponderance of the evidence that this requirement has been met.

A. Stulberg In view of Turner.

Petitioner relies upon the femoral cutting guide of Figure 8 of Turner for the claimed cutting guide having a guide surface, where a replacement portion of the knee has “*a transverse dimension that is larger than a transverse dimension of the guide surface,*” a cutting guide admittedly absent from Stulberg. However, Stulberg and Turner are not combinable. Further, even if combined, they would not result in the invention of claim 1.

1. Stulberg and Turner are Not Combinable

A person of ordinary skill in the art at the time of the invention considering the computer-assisted total knee replacement techniques of the Stulberg would have no apparent reason to employ the crude femoral cutting guide of Turner in such techniques. Stulberg seeks to improve the accuracy of cuts to the femur through the use of computer-assisted techniques. (Stulberg, Abst.) (Schoifet Decl., par. 61). A

person or ordinary skill in the art considering the teachings of Stulberg would not consider the crude femoral cutting guide illustrated in Figure 8 of Turner to be appropriate to achieve the precise cuts that are key to Stulberg. (Schoifet Decl., pars. 69, 70). In Turner, the “femoral cutting guide is inserted in the midline, deep to the suprapatellar pouch.” (Turner, p. 181). There is no indication it is secured in position with anything other than the physician’s hand. (Schoifet Decl., par. 69). Thereafter, the cutting guide is used to cut the femur “with a power or hand saw parallel with the guide that is approximately 30 degrees to the long axis of the femur.” Such a cutting guide would not be considered suitable for use in knee replacement surgery at the time of the invention. (Schoifet Decl., par. 69).

Rather, the cutting guide of Turner, and the geometric TKR technique in which it was used, was “a primitive design with poor outcomes when compared to modern (post 1990) knees.” (Schoifet Decl., pars. 65, 68). As explained by Dr. Schoifet, the short vertical surface of the cutting guide of Figure 8 of Turner provides no more than a rough reference for what is essentially a “free-hand” or “eyeball” cut made by the physician, and would be “far more imprecise” than the mechanical techniques criticized in Stulberg. (Schoifet Decl., par. 70).

Stulberg itself discloses a femoral cutting guide for making an initial cut in a femur, which in the Stulberg technique is the distal cut. (Stulberg, pp. 30, 35). That cutting guide is designed to be accurately placed and secured to the femur. (Id.).

There is no apparent reason for a person of ordinary skill in the art to abandon the cutting guide of Stulberg for the crude cutting guide of Turner. (Schoifet Decl., pars. 69, 70). See Ex Parte Kudas, et al, Appeal 2008-3302, 2008 Pat. App. LEXIS 8431 (Pat. App. 2008), quoting KSR Int'l. Co. v. Teleflex Inc., 127 S. Ct. 1727, 1740-41 (2007) (“For a prima facie case of obviousness to be established there must be ‘an apparent reason to combine the known elements in the fashion claimed.’”)

Further, the cutting guide of Turner is designed to make an entirely different distal cut than Stulberg. In particular, the crude cutting guide of Turner is for cutting the “distal condyles” (Turner, Fig. 9) for a seating of a geometric total knee (Turner, Fig. 1), which, as discussed above, was a failed technology. This is not a cut that is even made in the technique of Stulberg. Rather, as Dr. Mabrey concedes, the distal cut made in Stulberg was perpendicular to the mechanical axis of the femur, whereas the distal cut made by cutting guide of Figure 8 of Turner clearly was not. (Mabrey Tr., 72:13- 73:13, Schoifet Decl., par. 71, also Stulberg, Abst (“perpendicular” cuts)).

Moreover, Stulberg is concerned with providing extremely precise cuts in the femur (Stulberg, Abst.), and the distal cutting guide of Stulberg provides a long cutting surface, providing for the precise cuts. (Id., Fig 17). The femoral cutting guide of Turner has a short vertical cutting surface, which is used to guide a cutting saw that makes a transverse cut. It provides more than a rough reference for what is essentially a “free-hand” or “eyeball” cut made by the physician, and would be “far

more imprecise” than the mechanical techniques criticized in Stulberg. (Schoifet Decl., par. 70). Such a short, vertical cutting surface, which guides the saw only at a single vertical plane in the center of the femur, would be an anathema to Stulberg, whose overarching concern is with precision. As Dr. Schoifet explains “[u]sing computer-assisted navigation to make an eyeball cut is not going to make the procedure any better.” (Schoifet Decl., par. 73)

Petitioner selects the crude cutting guide of Turner because of the dimensions of the femoral cutting guide, which it alleges would make the replacement part have *“a transverse dimension that is larger than a transverse dimension of the guide surface.”* However, Turner itself attributes no significance to the dimensions of the guide surface of the cutting guide of Figure 8, or any other cutting guide, nor does Stulberg. It is the '896 patent that teaches that surgical results can be improved by a reduced size cutting surface. (See supra Section I, pp. 3-5). It is only due to the disclosure of the '896 patent, which describes the desirability of reduced size cutting surfaces, that the Petitioner seeks to combine the cutting guide of Turner in the techniques of Stulberg. This is clearly impermissible hindsight reconstruction. See In re NTP, Inc., 654 F.3d 1279 (Fed. Cir. 2011), quoting Grain Processing Corp. v. American-Maize Prods. Co., 840 F.2d 902, 907 (Fed. Cir. 1988) and Orthopedic Equip Co. v. United States, 702 F.2d 1005, 1012 (Fed. Cir. 1983)(“Board improperly relied on hindsight reasoning to piece together elements to arrive at the claimed

invention. "Care must be taken to avoid hindsight reconstruction by using 'the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.'"); In re Hedges, 783 F.2d 1038, 1041 (Fed. Cir. 1986) ("It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." (citations omitted)).

Petitioner ignores that Turner is an extramedullary mounted cutting guide for use in a different and discredited technique to make an entirely different cut and its alleged motivation to combine Stulberg with Scorpio or Turner consists of the following:

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 . . . 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

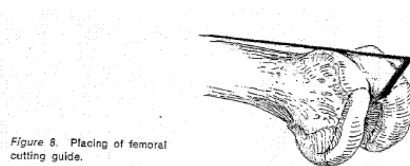
function to achieve a predictable result. Mabrey Decl. ¶ 92 (Ex. 1002).
(Petition, p. 45-46)

This is insufficient to establish a motivation to the combine Stulberg with Turner. First, it is again noted that Stulberg provides a femoral cutting guide which is positioned and mounted without an intramedullary or extramedullary alignment rod. There is simply no apparent reason for a person of ordinary skill in the art to seek to replace this cutting guide with the cutting guide of Turner. Further, the allegation that such a substitution would “yield the predictable improvement of a more accurate surgical outcome” is entirely unsupported. Petitioner has offered no reason that the use of the cutting guide of Turner would improve upon the cutting guide of Stulberg, much less that it would, at the time of the invention, been known to improve a surgical outcome. See Ex parte HOEG et al, 2014 Pat. App. LEXIS 1132 (Under KSR “If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill”)(emphasis added); Ex parte LIN et al, 2014 Pat. App. LEXIS 951; and MPEP 2143. In fact, the proposed combination does not result in a more accurate surgical outcome. Turner is a primitive instrument with a cutting guide surface that is so small that a cutting blade would pivot about the guide surface during a cut, providing far less precision than the guides of Stulberg, even when used

by an experienced physician. (Schoifet Decl., pars. 63, 73, 74). The proposed combination of Stulberg and Turner yields a less accurate surgical instrument and thus a less accurate surgical outcome. (Schoifet Decl., pars. 73, 74). Further, the statement that “[t]his combination is no more than the predictable use of prior art technology according to its established function to achieve a predictable result” is demonstrably false. (Schoifet Decl., pars. 72-74). The femoral cutting guide of Turner is designed for use in a different surgical procedure (geometric knee replacement) to make a different cut in the femur than the cutting guide of Stulberg. There is no apparent reason to use this cutting guide in Stulberg. (Schoifet Decl., pars. 63, 71).

**2. Even if Combined, Stulberg and Turner Would Not Create
the Claimed Invention**

Further, even if combined, Stulberg and Turner would not create the invention as claimed. Claim 1 requires “*the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod.*”



A person of ordinary skill in the art at the time of the invention would recognize the above figure as an extramedullary alignment rod that terminates with a cutting guide. (Mabrey Tr. 72:6-11, Schoifet Decl., par. 66). This rod rests on the

femur, and provides extramedullary alignment. Accordingly, to the extent the femoral cutting guide can be said to be “secured to the bone” at all, it is clearly secured with an extramedullary alignment rod.

Stulberg itself uses extramedullary alignment rods in its computer-assisted TKR techniques. (Stulberg, p. 33 (“An extramedullary alignment device for the tibial cut used during the computer-assisted technique.”)). Accordingly, if a person of ordinary skill in the art were to combine the teachings of the femoral cutting guide of Figure 8 of Turner with Stulberg, there would be no apparent reason to abandon the extramedullary alignment feature of that cutting guide. Without the extramedullary alignment portion, the Turner guide is nothing more than a cutting edge with no way of being positioned or attached to the femur. Indeed, there would be no apparent way to position the cutting surface of the femoral cutting guide without the extramedullary alignment rod. (Schoifet Decl., par. 75).

Accordingly, even if somehow combinable (which they are not), Stulberg in view of Turner does not render obvious the invention of claim 1 of the '896 patent. Ex parte Frede, Appeal 2010-008757, 2012 Pat. App. LEXIS 4492 (Pat. App. 2012)(reversing rejection where “proposed combination . . . fails to include” limitation of claim).

Stulberg and Turner are not combinable, and even if combined, would not result in the invention as claimed. Accordingly, the Petitioner cannot meet its burden

of establishing by a preponderance of the evidence that claim 1 is obvious over Stulberg in view of Turner.

B. Stulberg in view of Scorpio

Petitioner relies upon the anterior resection guide of Scorpio for the claimed cutting guide have a guide surface, where a replacement portion of the knee has “*a transverse dimension that is larger than a transverse dimension of the guide surface,*” a cutting guide admittedly absent from Stulberg. However, the teachings of Stulberg and Scorpio are not combinable. Further, even if combined, they would not result in the invention of claim 1.

1. Stulberg and Scorpio are Not Combinable

A person of ordinary skill in the art at the time of the invention considering the computer-assisted total knee replacement techniques of Stulberg would have no apparent reason to employ the intramedullary mounted cutting guide of Scorpio in such techniques. Stulberg seeks to improve the accuracy of cuts to the femur through the use of computer-assisted techniques. (Stulberg, Abst.).

Stulberg itself discloses a femoral cutting guide for making an initial cut in a femur, which in the Stulberg technique is the distal cut. (Stulberg, pp. 30, 35, Figs. 16-17). The cutting guide of Stulberg is positioned and secured to the femur without an intramedullary alignment rod. There is no apparent reason that a person of ordinary skill in the art would abandon the cutting guide of Stulberg in favor of the

cutting guide of Scorpio which is designed to make an entirely different cut on the femur, an anterior cut, and is aligned and secured to the femur using an intramedullary alignment rod, the very type of mechanical alignment system Stulberg found unacceptable. (Stulberg, p. 30).

A person of ordinary skill in the art reviewing Scorpio would recognize that the intramedullary rod of Scorpio is critical to the ability of the anterior resection guide to make the anterior cut, and that it would not function as intended if it were simply pinned to the femur. Knee replacement surgery is performed on damaged knees. As explained by Dr. Schoifet, when the Scorpio anterior referencing guide is properly located, it only rests only on the non-eroded condyle, and the intramedullary rod allows proper placement perpendicular to the mechanical axis of the femur. (Schoifet Decl., par. 81). If Scorpio were pinned to the femur, it would need to be pinned to both condyles, and then it would no longer be perpendicular to the mechanical axis, and accordingly, would not be able to make the required anterior cut. (Schoifet Decl., par. 81). A person of ordinary skill in the art would recognize that if the anterior resection guide of Scorpio is to be used, it would need to be mounted with an intramedullary alignment rod. (Schoifet Decl., par. 81).

Petitioner entirely ignores the fact that Scorpio is an intramedullary mounted cutting guide, and its alleged motivation to combine Stulberg with Scorpio consists of the following three sentences:

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 . . . 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). (Petition, pp. 45-46)

This is insufficient to establish a motivation to the combine Stulberg with Scorpio. First, it is again noted that Stulberg provides a distal femoral cutting guide, which is positioned and mounted without an intramedullary or extramedullary alignment rod. There is simply no apparent reason for a person of ordinary skill in the art to seek to replace this cutting guide with the cutting guide of Scorpio, which is an anterior resection guide that is mounted with an intramedullary alignment rod. (Schoifet Decl., par. 81). Rather, knowing that intramedullary rods produce bleeding and can cause extravasation of marrow into the bloodstream, a person of ordinary skill in the art would find the cutting guide of Stulberg to be superior, and would not modify it based on Scorpio. (Schoifet Decl., par. 81). Further, as noted above, a

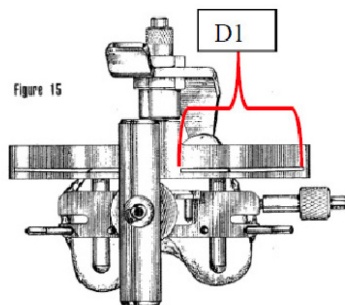
person of ordinary skill in the art examining Scorpio would recognize that its shape and function would prevent it from being secured to the femur with pins, like the Stulberg cutting guide. (Schoifet Decl., pars. 81, 85).

Finally, the allegation that such a substitution would “yield the predictable improvement of a more accurate surgical outcome” is entirely unsupported, and the statement that “[t]his combination is no more than the predictable use of prior art technology according to its established function to achieve a predictable result” is demonstrably false. (Schoifet Decl., pars. 81, 82). The anterior resection guide of Scorpio is designed to be positioned and mounted with an intramedullary rod. There is no apparent way to modify it to work with computer assisted techniques such as Stulberg. (Schoifet Decl., pars. 81, 82).

**2. Even if Combined Stulberg and Scorpio Would Not Create
the Claimed Invention**

Petitioner alleges that the anterior resection guide of Scorpio is a “cutting tool” which has a “guide surface”, where a “replacement portion of the knee” has “*a transverse dimension that is larger than a transverse dimension of the guide surface*” as claimed. It does not.

Petitioner relies on one Figure in Scorpio as showing two guide surfaces, but that Figure shows only one side of the guide:



(Petition, p. 33). Nothing in this figure indicates whether or not slot D1 connects to the left side slot. Indeed, as Dr. Mabrey admits, no Figure in Scorpio shows the cutting guide from the bone-side (i.e., opposite from Fig. 15), and nothing in Scorpio indicates that the central metal portion shown in the center of Figure 15 to the left of D1 extends to the bone-side of the cutting guide. (Mabrey Tr., 78:20-79:16). Rather Dr. Mabrey admits that this central portion of Scorpio could extend only part way towards the other side of the cutting guide, similar to Figures 11-13 of the '896 patent, so that a single continuous guide surface is provided (Id., 80:12-84:17).

Further, as explained above, a person of ordinary skill in the art considering Scorpio at the time of the invention would understand that in order to create the anterior cut on the femur (visible in Fig. 20), the guide surface on bone side of the anterior resection guide of Figures 14-19 would have to extend continuously between the lateral and medial sides of the cutting guide (i.e. from the right side to the left side of the guide when viewed from the perspective of Fig. 15). (Schoifet Decl., par.

77). If the central metal portion extended through to the bone side so that the guide surface was discontinuous, the cutting guide could not make the anterior skim cut required. (Schoifet Decl., par. 77).

Dr. Mabrey, Petitioner's expert, testified (i) under cross-examination that the anterior resection guide is designed for use on either the left knee or the right knee., and for a given knee, only one slot (e.g. D1) is used (Mabrey Tr. 78:13-19); and (ii) under cross-examination and again on re-cross after his direct testimony that he could not tell from Scorpio whether the central metal portion shown in Figure 15 extends to the bone-side of the guide (Id., 78:20- 79:16, 80:12-84:17, 103:19-104:11). During his redirect testimony, and after discussing Scorpio with his Petitioner's counsel (Id., 94:4-11), Dr. Mabrey testified:

Q. . . . So looking at Figures 14, 15, 17, and 18 of Scorpio and focusing on the metal piece between the two separate guide surfaces, please tell us whether or not a person of ordinary skill in the art would understand that metal piece to be a solid divider between the guide surfaces.

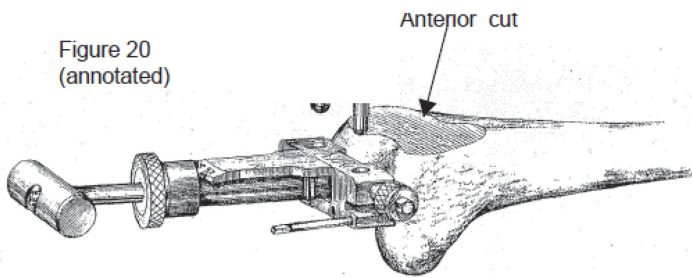
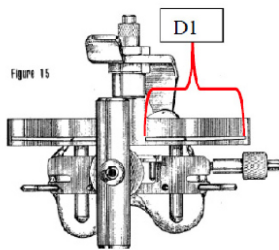
A. Someone normally skilled in the art of knee replacement would assume that that metal went all the way through to the other side.

Q. And so they would understand that that solid piece divides the two guide surfaces?

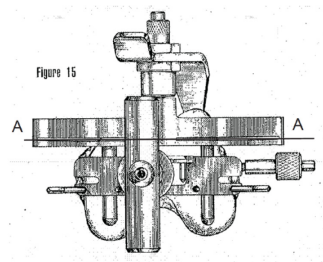
A. Yes. (Mabrey Tr. 92:9-20)

It is respectfully submitted that Dr. Mabrey's testimony is clearly inconsistent with Scorpio. Even a cursory examination of Scorpio reveals that a surgeon

accessing the femur from only slot D1 could not make the resulting cut (which extends from the medial side of the femur to the lateral side of the femur) shown in Figure 20 if the central metal piece shown on the physician side face of Figure 15 extended through to the bone side of the guide:



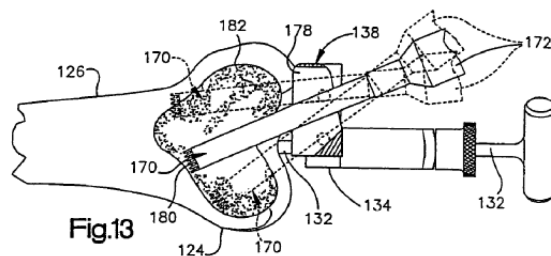
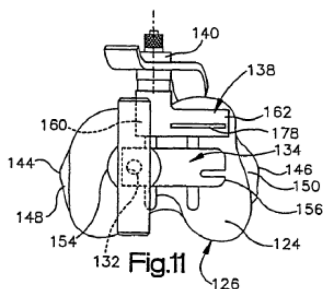
Finally, as discussed above, the device depicted in Scorpio in fact has a single continuous guide surface that extends across the cutting guide:



Petitioner's supposition that the solid center portion of Scorpio extends to the bone-side of the cutting guide to create to separate cutting surfaces is therefore rebutted not only by the fact that such a construction would leave the guide

inoperable for making the cut described, but also by the fact that the Scorpio cutting guide (shown in Exhibit 2005) has a continuous cutting surface on the bone-side of the guide. See, e.g., Ex parte McKiernan et al, Appeal 2011-012188, 2012 Pat. App. LEXIS 5598, *9-11 (Pat. App. 2012)(finding that patentee rebutted prima facie obviousness based on an allegation of inherency with evidence that the product lacks the allegedly inherent property).

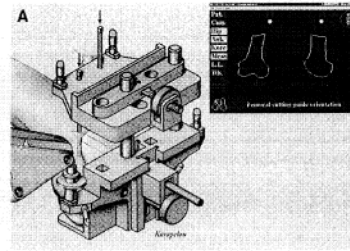
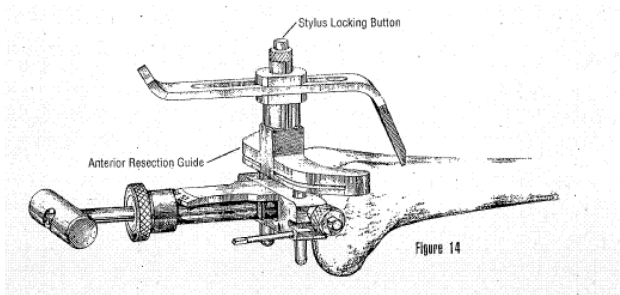
To the extent that Petitioner alleges that Scorpio has two guide surfaces because the slot on the physician side of the cutting guide does not have the same extent as the slot at the bone side, this interpretation of the term guide surface would be clearly inconsistent with the '896 specification. See, e.g., In re Abbott Diabetes Care, Inc., 696 F.3d 1142 (Fed. Cir. 2012), citing In re Suitco Surface, Inc., 603 F.3d 1255, 1260 (Fed. Cir. 2011)(broadest reasonable construction cannot contradict specification). As noted above, the specification describes the cutting guide of Figures 11 and 13 as having a single guide surface 178 extending across the entire cutting guide 138 notwithstanding the fact that the slot extends across only a part of the handle side of the cutting guide 138 ('896 patent, Col. 20, ll. 15-46):



Although the Board (currently⁵) interprets claim terms under the broadest reasonable construction standard, Patent Owner notes that the broadest reasonable construction must be consistent with the specification. See In re Abbott Diabetes Care, Inc., supra. It is respectfully submitted that if the cutting surface 178 is one cutting surface, it would be contrary to the specification to find that the cutting surface of Scorpio is two separate cutting surfaces.

Further, Petitioner's allegation that in any event "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," (Petition, pp. 34, 44-46, Institution Decision, p. 18), is entirely without support in Stulberg or Scorpio. (Schoifet Decl., pars. 80, 97). In fact, a person of ordinary skill in the art reading Stulberg and Scorpio would immediately recognize that the guide surface of Scorpio (Fig. 14, below) wraps around the femur and accordingly is longer than the guide surface of Stulberg (Fig. 17A, below):

⁵ Patent Owner does not agree that this is the proper standard and notes that the issue of the proper standard for claim construction in an inter partes review is currently before the Court of Appeal for the Federal Circuit in Versata Development Group, Inc., v. Sap America, Inc., Appeal No. 2014-1194.



Accordingly, if anything, Scorpio would suggest lengthening the guide surface of Stulberg, not shortening it.

In the Institution Decision at page 18, the Board cites to page 34 of the Petition as alleging that Delp '018 shows “smaller jigs” allow “a smaller incision to be made,” which “will result in a less invasive procedure”, for the proposition that it would be obvious to “narrow the slots” of Scorpio. First, it should be noted that Petitioner’s arguments at page 34 were directed the combination for Delp and Scorpio, not the combination of Stulberg and Scorpio. In any event, as discussed in more detail below in Section V(B)(2) at page 55-56 with regard to the combination of Delp and Scorpio, nothing in Delp '018 suggests reducing the size of cutting surfaces. (Schoifet Decl., par. 97).

When considered in view of the combination of Stulberg and Scorpio, Delp '018 is of even less relevance. The cited passage of Delp '018 is discussing the advantage of using a computer to replace “large, complicated mechanical alignment systems.” The later published Stulberg already describes a computer assisted

procedure using a cutting guide (Figures 16-17) which (i) has no intramedullary alignment rod; and (ii) is smaller than the Scorpio guide which is mechanically aligned with an intramedullary alignment rod. Nothing in Delp '018 would suggest that the cutting guide of Stulberg is too large or should be reduced in size.

Furthermore, Scorpio is larger than Stulberg and has a longer cutting surface than Stulberg. Accordingly if a person of ordinary skill in the art were for some reason concerned with size, he or she would not look to Scorpio to begin with.

Also unsupported is the Petitioner's statement that "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." (Petition, pp. 34, 44-46). To the contrary, at the time of the invention, cutting surfaces of cutting guides in the were fixed in length, and moreover, cutting guides were typically provided in kits that are made to work with a given manufacturer's replacement knee. (Schoifet Decl., par. 96). Cutting guides are not something that a physician would modify ad hoc. (Schoifet Decl., par. 96). Petitioner does not explain how one could routinely modify the length of a guide surface of a device, such as Turner or Scorpio, each of which has a fixed cutting guide length that is not adjustable.⁶ Conclusory statements of an expert cannot take the place of evidence, and are entitled to little or no weight.

⁶Dr. Mabrey, in fact, concedes that the cutting surface of Scorpio is not adjustable. (Mabrey Tr., 86:6-21).

See, e.g., Velander v. Garner, 348 F.3d 1359, 1371 (Fed. Cir. 2003) ("[A]ccord[ing] little weight to broad conclusory statements [in expert testimony before the Board] that it determined were unsupported by corroborating references [was] within the discretion of the trier of fact to give each item of evidence such weight as it feels appropriate."); Ex parte Habashi et al, Appeal 2011-008847, 2013 Pat. App. LEXIS 8057 (Pat. App. 2013) (affirming rejection where Examiner found "declaration merely included opinions and conclusory statements rather than evidence"); Ex parte Vanscoyok, Appeal 2011-011717, 2013 Pat. App. LEXIS 7627 (Pat. App. 2013) (rejecting "conclusory statements in the appended declarations that the combination was not obvious").

In fact, a person of ordinary skill in the art at the time of the invention considering Stulberg in view of Scorpio would be discouraged from reducing the size of the cutting surface, so that it is less than transverse dimension than the replacement part, because to do so would reduce precision, and not allow the entire anterior cut of the femur to be guided as precisely. (Schoifet Decl., pars. 63, 84, 87).

It is the '896 patent that teaches that surgical results can be improved by a reduced size cutting surface. (See supra Section I, pp. 3-5). It is only with the benefit of the disclosure of the '896 patent, which describes the desirability of reduced size cutting surfaces that Petitioner argues to reduce the size of the cutting surface in Scorpio. This is clearly impermissible hindsight reconstruction. See In re NTP, Inc.,

654 F.3d 1279 (Fed. Cir. 2011).

Further, as discussed above, the anterior resection guide of Scorpio is a guide that is positioned and secured to the bone with an intramedullary alignment rod. A person of ordinary skill in the art combining Stulberg and Scorpio would recognize that the Scorpio guide cannot be effectively positioned without the intramedullary rod. Accordingly, if such a person were to combine Stulberg and Scorpio, he or she would use the computer-assisted technique of Stulberg to more accurately position the guide using an intramedullary rod. (Schoifet Decl., par. 81). Although, this may be considered an improvement to Scorpio, it is significantly different than what is claimed in the present invention. There would be no apparent reason to discard the intramedullary rod and seek some other way to secure the guide. See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention); Ex parte Datacard Corp., Appeal 2009-013947, 2010 Pat. App. LEXIS 15588 (Pat. App. 2010), citing W.L. Gore & Assoc., Inc. (“A prior art reference must be considered in its entirety, as a whole, including portions that would lead away from the claimed invention”).

Accordingly, even if combinable (which they are not), Stulberg in view of Scorpio does not render obvious the invention of claim 1 of the '896 patent. See Ex

parte Frede, Appeal 2010-008757, 2012 Pat. App. LEXIS 4492 (Pat. App.

2012)(reversing rejection where “proposed combination . . . fails to include”

limitation of claim).

Stulberg and Scorpio are not combinable, and even if combined, would not result in the invention as claimed. Accordingly, the Petitioner cannot meet its burden of establishing by a preponderance of the evidence that claim 1 is obvious over Stulberg in view of Scorpio.

V. Petitioner Has Not Established that Claim 1 is Unpatentable Under 35 U.S.C. §103 as Obvious Over Delp in view of Turner or Scorpio

Petitioner cannot meet its burden to prove, by a preponderance of the evidence, that claim 1 of the '896 patent is obvious under 35 U.S.C. § 103 over Delp in view of Turner or Scorpio. Like Stulberg, Delp is concerned with providing improved accuracy in positioning cutting guides, (Delp., pp. 49, 50). Delp proposes two computer-assisted techniques to more accurately position the cutting guide on the femur: (i) computer integrated instruments, (id., pp. 50-51); (ii) image guided knee replacement, (id., pp. 51-53).

Delp does not disclose or suggest providing the claimed cutting guide which has a guide surface, where a replacement portion of the knee has “*a transverse dimension that is larger than a transverse dimension of the guide surface.*”

Petitioner points to the computer generated representation of a cutting guide in

Figure 2 as meeting the claim limitation, but the Board correctly found that “[t]he particular figures of the Delp Article that Petitioner relies upon, namely figures 2 and 3, are too blurry to discern any meaningful size relationships, and none are discussed in the written portions of the article.” (Institution Decision, p. 21, Schoifet Decl., par. 89).⁷

In fact, Delp expresses no interest at all in the size of the cutting surface. (Mabrey Tr. 63:9-19). To the contrary, a person of ordinary skill in the art at the time of the invention considering Delp would be discouraged from reducing the size of the cutting surface so that it is less than transverse dimension than the replacement part because it would reduce precision, and not allow the femur cuts to be guided with precision. (Schoifet Decl., par. 87). Indeed, Delp finds it problematic that “not all degrees of freedom are controlled by the current alignment procedure” used in the computer integrated instrument technique. (*Id.*, p. 55). Further, Petitioner’s Expert Mabrey himself states that cutting guides with slots provide greater guidance of a saw blade. (Mabrey Decl., par. 33).

Petitioner relies, in the alternative, on either Turner or Scorpio to cure the deficiencies in Delp.

⁷ Further, even if one were to accept Petitioner’s interpretation of Figure 2, its reliance on half of the allegedly illustrated cutting surface fails for the same reasons discussed above with regard to Scorpio. (Schoifet Decl., pars. 77, 89).

In its Decision to Institute at page 22, the Board states:

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

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

As noted above, however, such a finding under KSR requires, *inter alia*, that the person of ordinary skill in the art could have applied a known improvement from the secondary reference in the same way to the base device of the primary reference and that the results would have been predictable to the person of ordinary skill in the art. See, e.g., Ex parte HOEG et al; Ex parte LIN et al, MPEP §2143, supra. Petitioner has not established, by a preponderance of the evidence that this requirement has been met.

A. Delp in view of Turner

Petitioner relies upon the femoral cutting guide of Figure 8 of Turner for the

claimed cutting guide that has a guide surface, where a replacement portion of the knee has “*a transverse dimension that is larger than a transverse dimension of the guide surface*,” admittedly absent from Delp. However, Delp and Turner are not combinable. Further, even if combined, they would not result in the invention of claim 1.

1. Delp and Turner are Not Combinable

A person of ordinary skill in the art at the time of the invention considering the computer-assisted cutting guide techniques of Delp would have no apparent reason to employ the crude femoral cutting guide of Turner in such techniques. Rather, Delp is concerned with the accuracy of the placement of the cuts, not the size of the cutting surfaces:

- “Accurate alignment of knee implants is essential for the success of total knee replacement. Although mechanical alignment guides have been designed to improve alignment accuracy, there are several fundamental limitations of this technology that will inhibit additional improvements. Various computer assisted techniques have been developed to examine the potential to install knee implants more accurately and consistently than can be done with mechanical guides.” (Delp, p. 49, Abst.)(emphasis added).
- “Even a small (2.5 mm) anteroposterior displacement of the femoral component has been shown to alter knee range of motion (ROM) as much as 20°.” (Id. , p. 50.)
- “Even when using state of the art intramedullary alignment systems,

surgeons find that it is difficult to install knee implants within 2° to 3° varus or valgus alignment.”(Id.)

Delp seeks to improve the accuracy of cuts to the femur through the use of computer assisted techniques. (Delp, pp. 49, 50). A person of ordinary skill in the art at the time of the invention would not consider the crude femoral cutting guide of Turner to be appropriate to achieve the precise cuts that are key to Delp. (Schoifet Decl., par. 90). In Turner, “femoral cutting guide is inserted in the midline, deep to the suprapatellar pouch.” There is no indication in Turner that the guide is secured in position with anything other than the physicians’ hand. Thereafter, the cutting guide is used to cut the femur “with a power or hand saw parallel with the guide that is approximately 30 degrees to the long axis of the femur.” Delp reports in 1998 that “[e]ven when using state of the art intramedullary alignment systems, surgeons find that it is difficult to install knee implants within 2° to 3° varus or valgus alignment.” (Id., p. 50). A person of ordinary skill in the art at the time of the invention would not have even considered using the crude Turner cutting guide in the computerized system of Delp. (Schoifet Decl., par. 90).

Even more generally, the cutting guide of Turner would not have been considered suitable for use in knee replacement surgery at the time of the invention at all, for the reasons discussed in detail in Section IV(A)(1), supra pages 24-30.

Delp is concerned with providing extremely precise cuts in the femur, and

finds it problematic that “not all degrees of freedom are controlled by the current alignment procedure” used in the computer integrated instrument technique. (Delp, p. 55). The femoral cutting guide of Turner has a short vertical cutting surface, which is used to guide a cutting saw that makes a transverse cut. Such a short, vertical cutting surface, which guides the saw only at a single vertical plane in the center of the femur, and is in essence a freehand or eye-ball cut, would be an anathema to Delp, whose overarching concern is with precision. As Dr. Schoifet explains “[u]sing computer-assisted navigation to make an eyeball cut is not going to make the procedure any better.” (Schoifet Decl., par. 90).

Petitioner selects the crude cutting guide of Turner because of the dimensions of the femoral cutting guide, which it alleges would make the replacement part have *“a transverse dimension that is larger than a transverse dimension of the guide surface.”* However, Turner itself attributes no significance to the dimensions of the guide surface of the cutting guide of Figure 8, or any other cutting, nor does Delp. It is the '896 patent that teaches that surgical results can be improved by a reduced size cutting surface. (See supra Section I, pp. 3-5). It is only with the benefit of the disclosure of the '896 patent, which describes the desirability of reduced size cutting surfaces that Petitioner seeks to employ the cutting guide of Turner in the techniques of Delp. This is clearly impermissible hindsight reconstruction. See In re NTP, Inc.; Grain Processing Corp. v. American-Maize Prods. Co.; and Orthopedic Equip Co. v.

United States, supra.

**2. Even if Combined Delp and Turner Would Not Create the
Claimed Invention**

Further, even if combined, Delp and Turner would not create the invention as claimed. Claim 1 requires “*the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod.*” As explained in Section IV(A)(2), supra pages 30-32, to the extent the femoral cutting guide can be said to be “secured to the bone” at all, it is clearly secured with an extramedullary alignment rod.

Accordingly, if a person of ordinary skill in the art were to combine the femoral cutting guide of Figure 8 of Turner with Delp, the guide would be secured with the assistance of an extramedullary alignment rod. Turner without the extramedullary alignment portion is nothing more than a cutting guide edge with no way of being positioned or attached to the femur. Indeed, without the extramedullary alignment portion, there would be no apparent way to position the cutting surface of the femoral cutting guide. (Schoifet Decl., par. 91).

Petitioner alleges that Delp “discloses computer-assisted surgical systems for improving the alignment of mechanical instruments, such as those disclosed in Turner or Scorpio,” and discusses Delp’s use of “preoperative imaging” and “measurement probes.” (Petition, pp. 35-36). However, this only serves to highlight

the problem in Petitioner's reasoning. Turner is an extramedullary aligned and mounted cutting guide. Assuming for purposes of argument that a person of ordinary skill in the art were to conclude that the Turner cutting guide can be used with the teachings of Delp, the only predictable result would be to use the computer imaging and probes of Delp to more accurately position the extramedullary mounting of the cutting guide, which is significantly different than the claimed invention. See W.L. Gore & Assoc., Inc., 721 F.2d 1540 (Fed. Cir. 1983) (must consider reference as a whole, including portions that would lead away from the claimed invention); Ex parte Datacard Corp., 2010 Pat. App. LEXIS 15588 (Pat. App. 2010). The combination of Delp and Turner would thus still fail to meet the claim requirement of "the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod." Ex parte Frede, Appeal 2010-008757, 2012 Pat. App. LEXIS 4492 (Pat. App. 2012)(reversing rejection where proposed combination lacks claim limitation).

Delp and Turner are not combinable, and even if combined, would not result in the invention as claimed. Accordingly, the Petitioner cannot meet its burden of establishing by a preponderance of the evidence that claim 1 is obvious over Delp in view of Turner.

B. Delp in view of Scorpio

Petitioner relies upon the anterior resection guide of Scorpio for the claimed cutting guide that has a guide surface, where a replacement portion of the knee has *“a transverse dimension that is larger than a transverse dimension of the guide surface,”* admittedly absent from Delp. However, the teachings of Delp and Scorpio are not combinable. Further, even if somehow combinable, they would not result in the invention of claim 1.

1. Delp and Scorpio are Not Combinable

A person of ordinary skill in the art at the time of the invention considering the computer-assisted techniques of Delp would have no apparent reason to employ the intramedullary mounted cutting guide of Scorpio in such techniques. Delp seeks to improve the accuracy of cuts to the femur through the use of computer assisted techniques (Delp, pp. 49, 50 55), and specifically states that its system “eliminates the need for intramedullary and extramedullary alignment guides.” (Id. at p. 55).

There is no apparent reason that a person of ordinary skill in the art considering Delp would seek to employ the cutting guide of Scorpio which is aligned and secured to the femur using an intramedullary alignment rod, the very type of mechanical alignment system Delp found unacceptable. (Id., pp. 49, 50, 55). Rather, knowing that intramedullary rods produce bleeding and can cause extravasation of marrow into the bloodstream, a person of ordinary skill in the art would not use

Scorpio in the computer assisted technique of Delp. (Schoifet Decl., par. 92).

**2. Even if Combined Delp and Scorpio Would Not Create the
Claimed Invention**

Petitioner alleges that the anterior resection guide of Scorpio is a “cutting guide” which has a “guide surface”, where a “replacement portion of the knee” has *“a transverse dimension that is larger than a transverse dimension of the guide surface”* as claimed. For the reasons set forth in Section II(B)(2), incorporated by reference, it does not.

Further, Petitioner’s allegation that in any event “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” and that “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” (Petition, p. 34, 44-46) is entirely without support in Delp or Scorpio. (Schoifet Decl., pars. 95, 96). Neither express any concern for the size of the cutting surface, and neither discloses or suggests that a surgeon can “modify the length of a guide surface.” The Mabrey Declaration simply restates, verbatim, the quoted language from the Petition, and accordingly is entitled to little or no weight. See, Velander v. Garner, 348 F.3d at 1371 (Fed. Cir. 2003); Ex parte Habashi et al , 2013 Pat. App. LEXIS 8057 (Pat. App. 2013); Ex parte Vanscoyok, 2013 Pat. App. LEXIS 7627 (Pat. App. 2013), supra.

Petitioner does not explain how one could routinely modify the length of a guide surface of a device, such as Scorpio, which has a fixed cutting guide length that is not adjustable, as Dr. Mabrey concedes. (Mabrey Tr., 86:5-21).

Nor does Petition provide any evidence that a person of ordinary skill in the art at the time of the invention would find a reduction in the size of the cutting surface desirable. At page 34 of the Petition, the Petitioner provides an oblique reference to column 22, lines 45-50 of U.S. 5,871,018 (Exhibit 1004, “Delp '018), alleging that it teaches that a “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,’” but despite this careful parsing, Delp '018 in no way suggests that reducing the cutting surface of a cutting guide is advantageous. The statement referenced in Delp '018 refers to eliminating mechanical alignment systems so that the overall size of the “cutting jig” can be reduced: “Mechanical instrumentation systems in use today rely on cutting jigs that align cuts using discrete metrics and visual means, which can introduce alignment errors. . . . The instrumentation is large because it needs to cover certain anatomical landmarks to align the cutting jigs.” Col. 22, ll. 35-41; “The computer replaces large complicated mechanical alignment systems allowing smaller cutting jigs to be used, and thus a smaller incision to be made.” Col. 22, ll. 45-48. It does not at all suggest reducing the size of the cutting

surface. (Schoifet Decl., par. 97).

It is the '896 patent that teaches that surgical results can be improved by a reduced size cutting surface. (See supra Section I, pp. 3-5). It is only with the benefit of the disclosure of the '896 patent, which describes the desirability of reduced size cutting surfaces that Petitioner seeks to reduce the size of the cutting surface in Scorpio. This is clearly impermissible hindsight reconstruction. See In re NTP, Inc., 654 F.3d 1279 (Fed. Cir. 2011).

To the contrary, a person of ordinary skill in the art at the time of the invention considering Delp would be discouraged from reducing the size of the cutting surface so that it is less than transverse dimension than the replacement part because it would reduce precision, and not allow the entire anterior cut of the femur to be guided with precision. (Schoifet Decl., pars. 95, 98). Indeed, Delp finds it problematic that “not all degrees of freedom are controlled by the current alignment procedure” used in the computer integrated instrument technique. (Delp, p. 55).

Further, as discussed above, the anterior resection guide of Scorpio is a guide that is positioned and secured to the bone with an intramedullary alignment rod. Petitioner alleges that Delp “discloses computer-assisted surgical systems for improving the alignment of mechanical instruments, such as those disclosed in Turner or Scorpio,” and discusses Delp’s use of “preoperative imaging” and “measurement probes.” (Petition, pp. 35-36).

Based on the teachings of Scorpio, a person of ordinary skill in the art would have chosen a different modification than that asserted by Petitioner. Delp discloses improving the alignment of mechanical instruments and Scorpio is aligned by a femoral alignment guide having an intramedullary rod. As noted above, a person of ordinary skill in the art would have recognized that the shape of the Scorpio guide, and the cut it is designed to achieve, make the intramedullary alignment rod essential to properly positioning the Scorpio guide. (Schoifet Decl., pars. 81, 85, 94).

Accordingly, if such a person were to have combined Delp and Scorpio, he or she would have used an intramedullary rod to support the cutting guide, and have used preoperative imaging and measurement probes to more accurately position the cutting guide on the femur. (Schoifet Decl., par. 94). See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (must consider reference as a whole including portions that lead away from claimed invention).

There would be no apparent reason to seek some other way to secure the guide. This would clearly be impermissible hindsight reconstruction. See In re NTP, Inc., supra. Indeed, Petitioner itself contends that Delp seeks to more accurately position existing instruments (Petition, p. 35), and nowhere does Delp suggest that modification of the manner in which such existing instruments are secured to the bone.

Accordingly, even if combined, Delp in view of Scorpio does not render obvious the invention of claim 1 of the '896 patent, as the combination would still lack (i) the claimed “cutting tool” which has a “guide surface”, where a “replacement portion of the knee” has “*a transverse dimension that is larger than a transverse dimension of the guide surface*” as required by claim 1; and (ii) “the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod” as required by claim 1. See Ex parte Frede, Appeal 2010-008757, 2012 Pat. App. LEXIS 4492 (Pat. App. 2012)(reversing rejection where proposed combination fails to meet claim limitation).

Delp and Scorpio are not combinable, and even if combined, would not result in the invention as claimed. Accordingly, the Petitioner cannot meet its burden of establishing by a preponderance of the evidence that claim 1 is obvious over Delp in view of Scorpio.

VI. Conclusion

For the foregoing reasons, Petitioner has failed to establish by a preponderance of the evidence that claim 1 of the '896 patent is unpatentable. Accordingly, the Petition should be denied.

Respectfully submitted,

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By: /Cary Kappel/
Cary Kappel, Reg. 36,561
William Gehris, Reg. 38,156
Davidson, Davidson & Kappel, LLC
485 Seventh Avenue
New York, NY 10018

Counsel for Patent Owner
BONUTTI SKELETAL INNOVATIONS
LLC

List of Exhibits for Patent Owner's Response

Exhibit No.	Description
Exhibit 2001	Pages 180-181 of Turner Annotated by Mabrey at Mabrey Deposition (May 13, 2014)
Exhibit 2002	Page 36 of Stulberg Annotated by Mabrey at Mabrey Deposition (May 13, 2014)
Exhibit 2003	Deposition Transcript of Jay D. Mabrey (May 13, 2014)
Exhibit 2004	Declaration of Scott Schoifet, M.D.
Exhibit 2005	Photographs of Scorpio A/R Anterior Skim Cutting Guide, Model 7650-5003-A with femoral alignment guide I-K1287AR02 and rod 7650-1026
Exhibit 2006	Rand, Coventry, <u>Ten Year Evaluation of Geometric Total Knee Arthroplasty</u> , Clin Orthop Relat Res. 1988 Jul;(232):168-73.
Exhibit 2007	Illustration of bone side of Scorpio A/R Anterior Cutting Guide.

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of May, 2014, a true and correct copy of the foregoing PATENT OWNER'S RESPONSE and Exhibits was served by U.S. Post Office Express Mail, upon the following counsel of record for Petitioner Smith and Nephew, Inc.:

David L. Cavanaugh
Jacob Oyloe
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
Tel: (202) 663-6000
Email: David.Cavanaugh@wilmerhale.com
Jacob.Oyloe@wilmerhale.com

/Cary Kappel/
Cary Kappel
