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By: David L. Cavanaugh, Reg. No. 36,476  
Michael H. Smith, Reg. No. 71,190  
Wilmer Cutler Pickering Hale and Dorr LLP  
1875 Pennsylvania Ave., NW  
Washington, DC 20006  
Tel: (202) 663-6000  
Email: David.Cavanaugh@wilmerhale.com  
MichaelH.Smith@wilmerhale.com

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SMITH & NEPHEW INC., WRIGHT MEDICAL GROUP, INC. AND WRIGHT  
MEDICAL TECHNOLOGY, INC.  
Petitioners

v.

BONUTTI SKELETAL INNOVATIONS, LLC  
Patent Owner of U.S. Patent No. 7,806,896 to Peter M. Bonutti

IPR Trial No. IPR2013-00629, Consolidated

**PETITIONERS' DEMONSTRATIVE EXHIBITS FOR ORAL ARGUMENT**

**Smith & Nephew, Inc.,  
Wright Medical Group, Inc., and  
Wright Medical Technology, Inc.,  
Petitioners**

**v.**

**Bonutti Skeletal Innovations LLC,  
Patent Owner of U.S. Patent No. 7,806,896  
IPR Trial No. IPR2013-00629**

**PETITIONERS' ORAL ARGUMENT**

**CLAIM 1 OF U.S. PATENT NO. 7,806,896**

# Overview

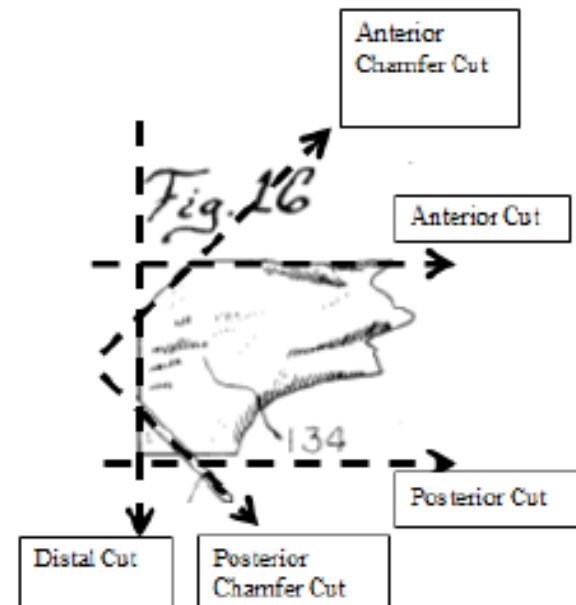
- Overview of Applied Prior Art & Obviousness of Claim 1
- Issues Raised by Patent Owner
  - Whether the Scorpio reference discloses the “transverse dimension” limitation (regardless, Patent Owner does not dispute the Turner reference discloses this limitation)
  - Whether the references would have been combined

# The Technology



**Illustration of Components of Human Knee**

(Mabrey Decl. ¶ 23 (EX. 1002))



**Illustrations of Knee Resection Cuts**

(Pet. at 11)

# The Challenged Claim – Claim 1

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.

*'896 at Claim 1*

# The Board's Decision on Institution

## COMPUTER-ASSISTED TOTAL KNEE REPLACEMENT ARTHROPLASTY

S. DAVID STULBERG, MD, FREDERIC PICARD, MD,  
and DOMINIQUE SARAGAGLIA, MD

The reliability of techniques to position a total knee replacement (TKR) is still limited by the relative inaccuracy of the instrumentation. The main obstacle encountered by mechanical instrumentation systems is the inconsistency of the reference points. These reference points are the centers of joint articulation that will allow the establishment of the mechanical axis for the lower limb. These references guide the placement of the bone-cutting guides. At present, it is impossible to accurately locate these articular centers preoperatively. This handicaps the accuracy of the mechanical instruments and limits their accuracy. 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. We have chosen to present the steps of the computer-assisted TKR technique next to the corresponding steps of a currently available, mechanically based technique that is representative of many that are presently in use.

**KEY WORDS:** TKR, surgical technique, computer-assisted surgery

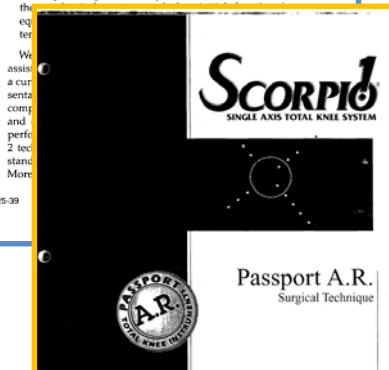
The success of total knee replacement (TKR) surgery depends on several factors, including proper patient selection, appropriate implant design, correct surgical technique, and effective perioperative care. The outcome of TKR surgery is particularly sensitive to variations in surgical technique.<sup>1,2</sup> 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.<sup>2-11</sup>

Mechanical alignment guides have improved the accuracy with which implants can be inserted. Although mechanical alignment systems are continually being refined, errors in implant and limb alignment continue to occur. It has been estimated that errors in tibial and femoral alignment of more than 3° occur in at least 10% of total knee arthroplasties, even when performed by experienced surgeons using mechanical alignment systems of modern design.<sup>1,2</sup> Mechanical alignment systems have fundamental limitations that limit their ultimate accuracy. The accuracy of preoperative planning is limited by the errors inherent to standard radiographs. With standard instrumen-

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

Computer-based alignment systems have been developed to address the problems inherent in mechanical total knee instrumentation. Although a number of computer-assisted TKR approaches are currently being developed,<sup>12-17</sup> we have chosen to describe in detail a technique that

- Incorporates the use of a currently available and clinically validated state-of-the-art mechanical instrumentation system
- Uses commonly available, relatively inexpensive computer equipment (eg, a desktop computer, low-end optical localizer)
- Is currently available for clinical use
- Has available preliminary multicenter results comparing the use of the system with a mechanical system. These results confirm that the system is safe, that limb and implant alignment is superior to that achieved with the



## Stulberg in combination with Scorpio or Turner

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.

'896 at Claim 1

# The Board's Decision on Institution

CLINICAL ORTHOPAEDICS AND RELATED RESEARCH  
Number 354, pp 49-56  
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## Computer Assisted Knee Replacement

Scott L. Delp, PhD\*; S. David Stulberg, MD\*\*; Brian Davies, PhD†; Frederic Picard, MD††; and Francois Leitner, PhD||

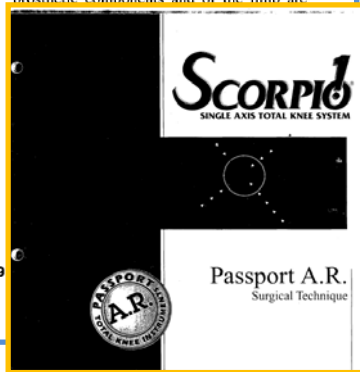
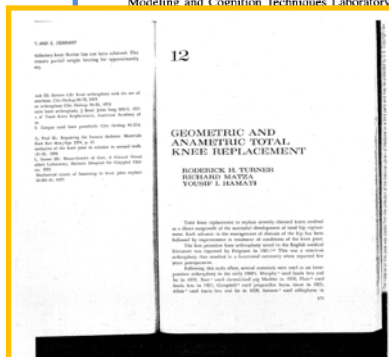
Accurate alignment of knee implants is essential for the success of total knee replacement. Although mechanical alignment guides have been designed to improve alignment accuracy, there are several fundamental limitations of this technology that will inhibit additional improvements. Various computer assisted techniques have been developed to examine the potential to install knee implants more accurately and consistently than can be done with mechanical guides. For example, computer integrated instrumentation incorporates highly accurate measurement devices to locate joint centers, track surgical tools, and align prosthetic components. Image guided knee replacement provides a three-dimensional preoperative plan that guides the placement of the cutting blocks and prosthetic components. Robot assisted knee

replacement allows one to machine bones accurately without the use of standard cutting blocks. The rationale for the development of computer assisted knee replacement systems is presented, the operation of several different systems is described, the advantages and disadvantages of different approaches are discussed, and areas for future research are suggested.

Total knee replacement is widely used to relieve pain and improve function in patients with degenerative joint disease. Although total knee replacement is generally successful, failures from component loosening, instability, dislocation, fracture, or infection occur in approximately 5% to 8% of cases.<sup>1,17,20</sup> Less severe complications, such as patellofemoral pain or limited flexion, also contribute to sub-optimal outcomes in 20% to 40% of cases.<sup>2,9,13</sup>

The success of total knee replacement depends on several factors, including patient selection, prosthesis design, soft tissue balancing, and alignment of the limb. Proper rotational and translational alignment of the prosthetic components and of the limb are

From the \*Departments of Biomedical Engineering and Physical Medicine and Rehabilitation, Northwestern University, Chicago, IL; \*\*Rehabilitation Institute of Chicago, Chicago, IL; \*\*Department of Orthopaedic Surgery, Northwestern University Medical School, Chicago, IL; †Department of Mechanical Engineering, Imperial College, London, United Kingdom; ††Department of Orthopaedic Surgery, Grenoble South Hospital, Grenoble, France; and ||PRAXIM Company, Imaging, Modeling, and Computation Technologies Laboratory, University of Illinois at Urbana-Champaign, Urbana, IL.



## Delp in combination with Scorpio or Turner

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.

'896 at Claim 1

# The Board's Claim Construction

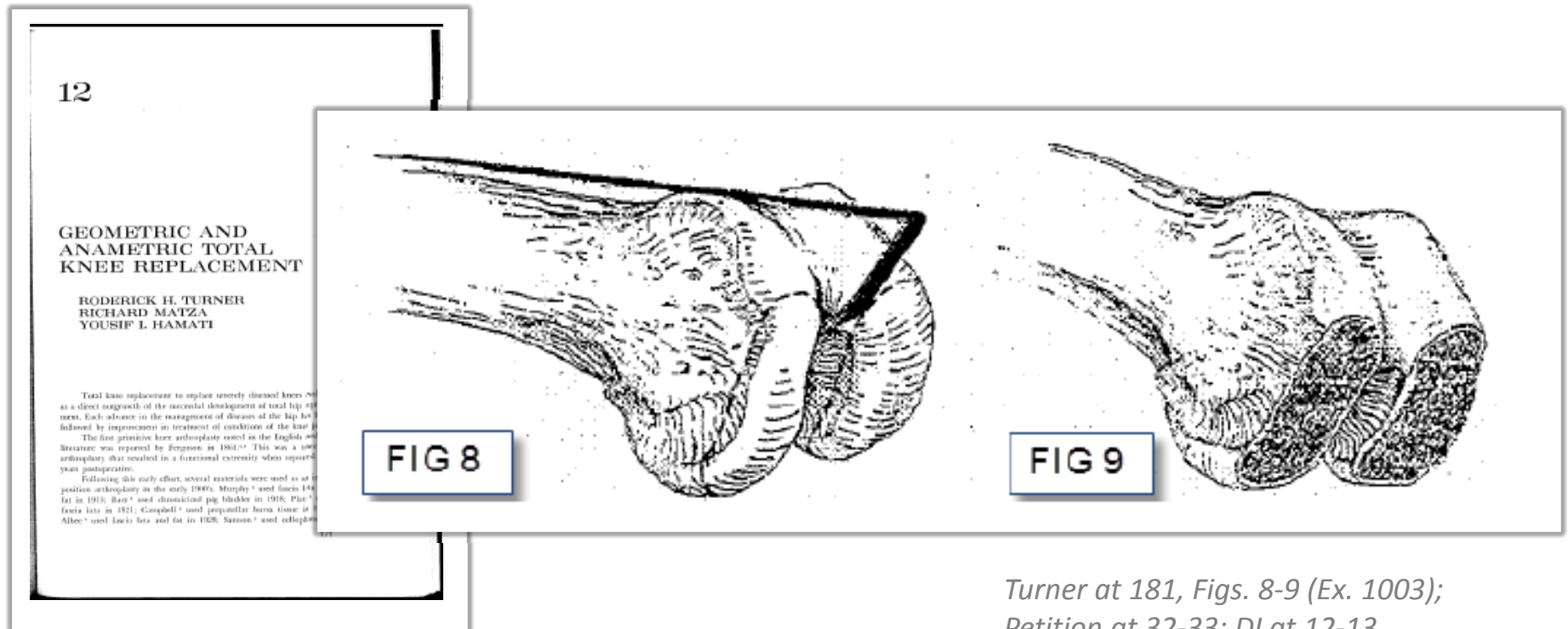
- The Board adopted the following claim constructions
  - “cutting guide” means a “guide that has a guide surface”
  - “guide surface” means “a surface that guides a cutting instrument”

*DI at 9*



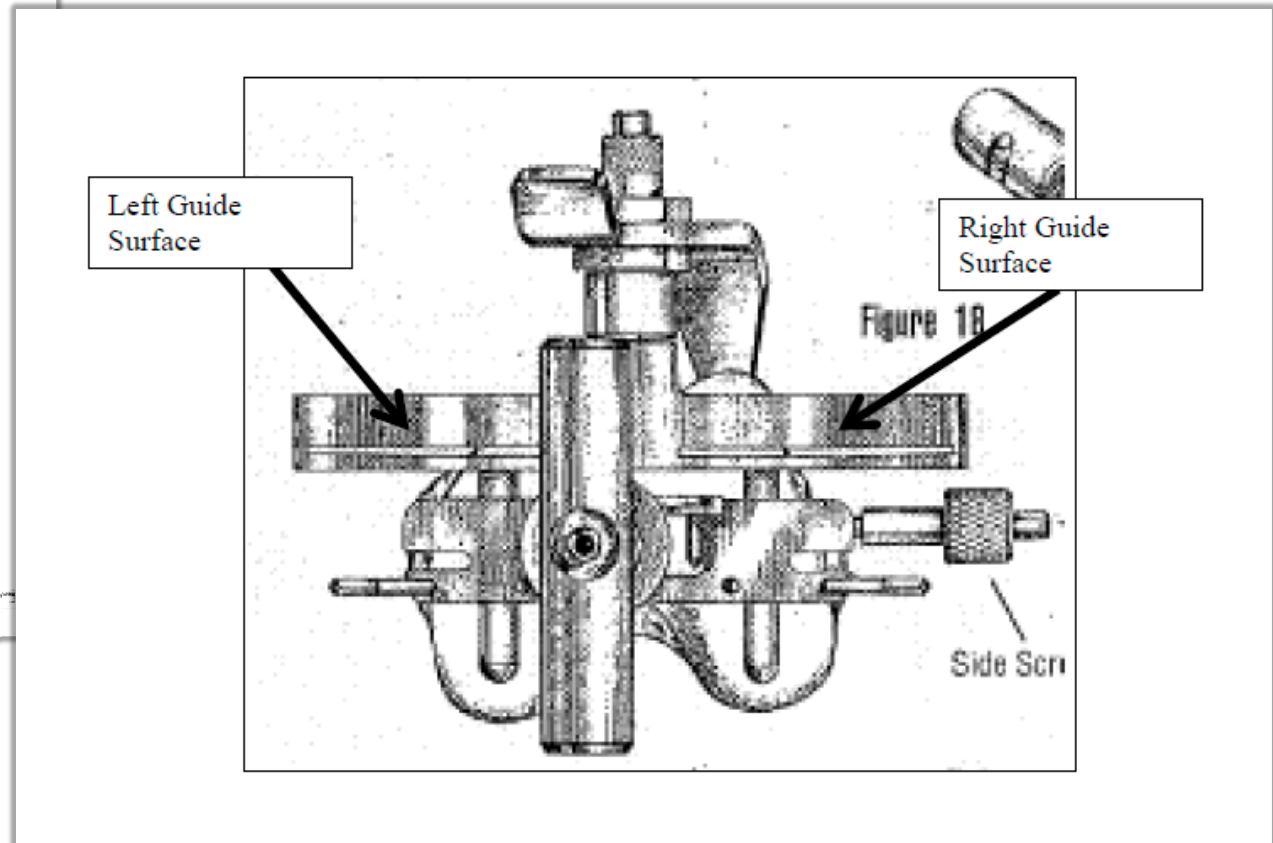
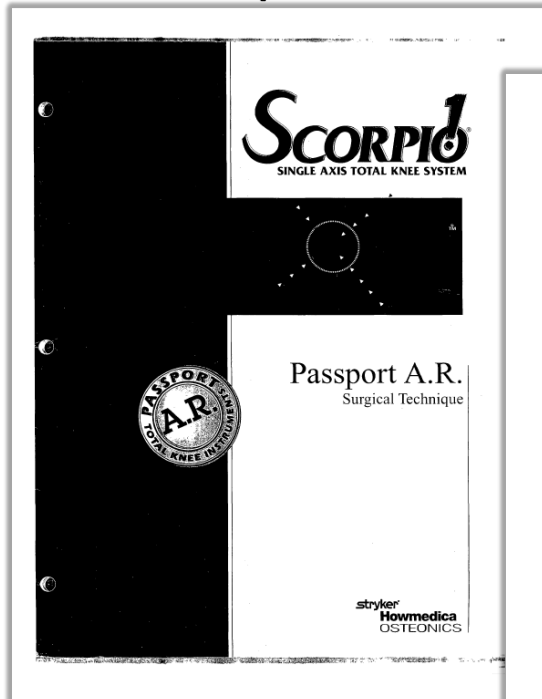
# Applied Prior Art: Turner

- Turner discloses:



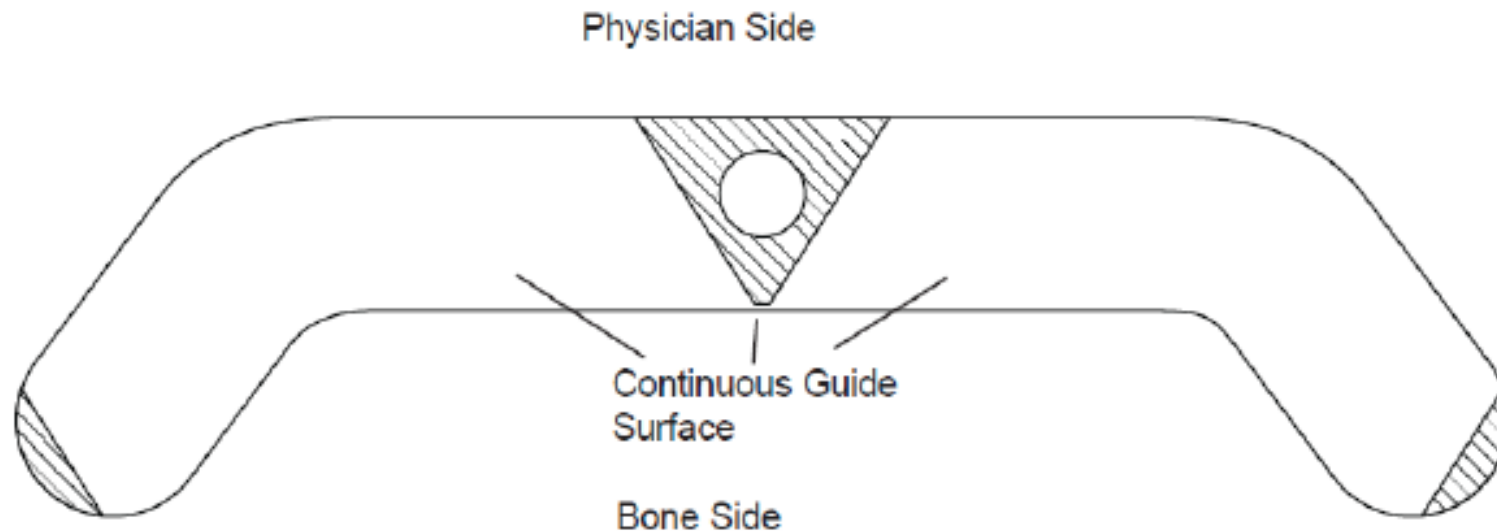
# Applied Prior Art: Scorpio

- Scorpio discloses:



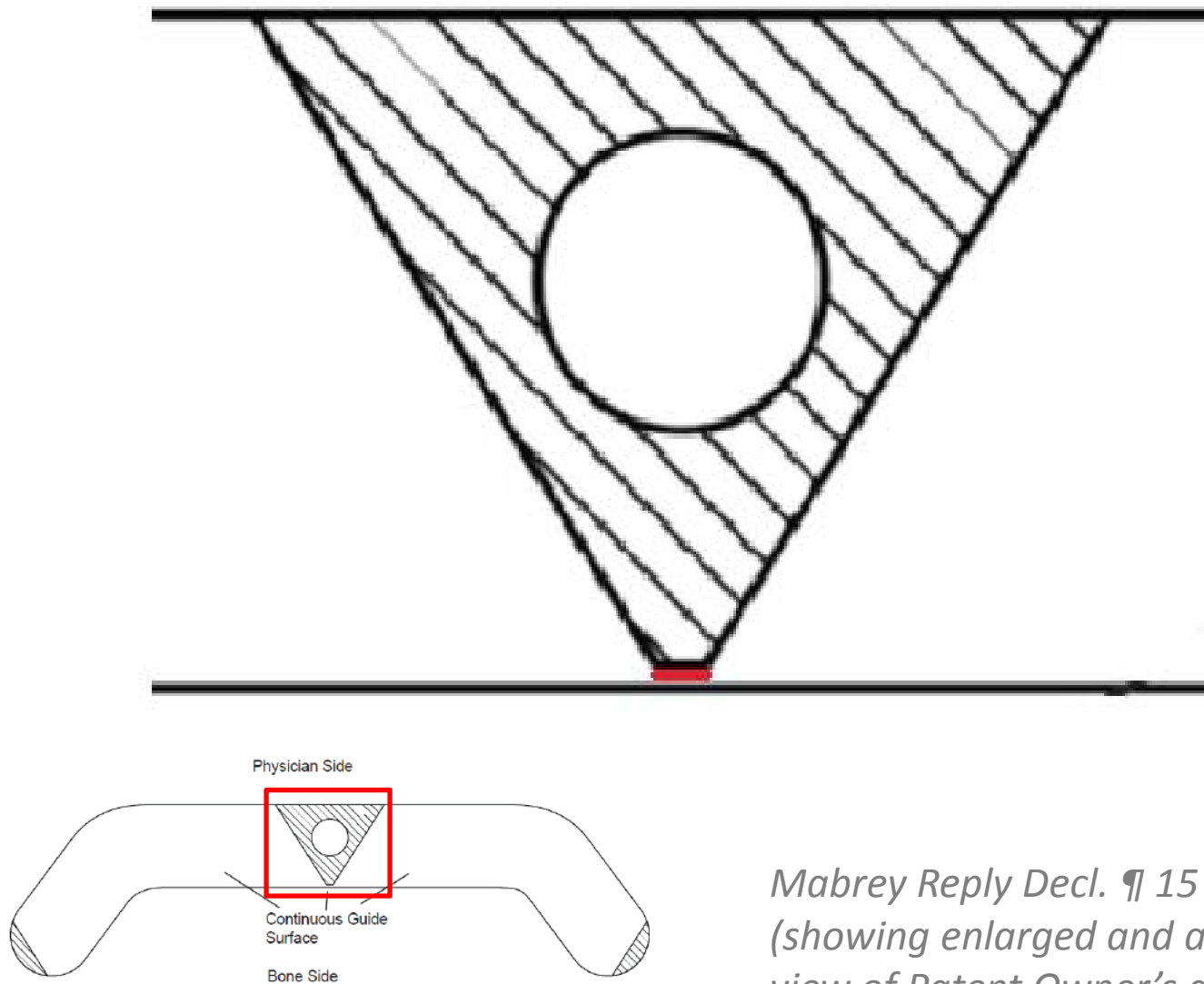
*Scorpio at 9, Fig. 15 (Ex. 1009); Mabrey Reply Decl. ¶ 13 (Ex. 1023); DI at 17*

# Scorpio: Response to Patent Owner Arguments



*BSI Drawings at 2 (Ex. 2007) (drawing of alleged cross section of Scorpio's left and right guide surfaces and truncated triangular divider)*

# Scorpio: Response to Patent Owner Arguments



*Mabrey Reply Decl. ¶ 15 (Ex. 1023)  
(showing enlarged and annotated  
view of Patent Owner's drawing)*



# Obviousness

# Patent Owner's Legally Deficient Arguments

- BSI Asserts Three Legally Deficient Arguments Against Obviousness
  - Unclaimed Features Cannot Make Patentable An Obvious Combination
  - Physical Combinability Is Not the Standard
  - BSI Improperly Argues Against The References Individually

# The Obviousness Dispute

- Consistent with the Board's Decision on Institution, Petitioners have demonstrated that the prior art would have been combined by the person of skill in the art to obtain the claimed invention.
- Patent Owner argues that the references cannot be combined.

# The References Would Have Been Combined

## COMPUTER-ASSISTED TOTAL KNEE REPLACEMENT ARTHROPLASTY

S. DAVID STULBERG, MD, FREDERIC PICARD, MD,  
and DOMINIQUE SARAGAGLIA, MD

The reliability of techniques to position a total knee replacement (TKR) is still limited by the relative inaccuracy of mechanical alignment systems. The main obstacle encountered by mechanical instrumentation systems is the inaccurate reference points. These reference points are the centers of joint articulation that will allow the accurate mechanical axis for the lower limb. These reference points guide the placement of the bone cutting guide. All responsible to accurately locate these reference centers preoperatively. This handicaps the accuracy of the instruments and limits their accuracy. The goal of the total knee instrumentation procedure is to achieve perpendicularity to the mechanical axis of the femur and the tibia. The longevity of total knee arthroplasty related to its intraoperative positioning. The computer-assisted procedure offers an effective and rapid method that improves the accuracy of the surgical technique of the TKR. We have chosen to present a computer-assisted TKR technique next to the corresponding steps of a currently available, mechanically based technique that is representative of many that are presently in use.

**KEY WORDS:** TKR, surgical technique, computer-assisted surgery

The success of total knee replacement (TKR) surgery depends on several factors, including proper patient selection, appropriate implant design, correct surgical technique, and effective postoperative care. The outcome of TKR surgery is particularly sensitive to variations in surgical technique.<sup>1-4</sup> 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.<sup>5-10</sup>

Mechanical alignment guides have improved the accuracy with which implants can be inserted. Although mechanical alignment systems are continually being refined, errors in implant and limb alignment continue to occur. It has been estimated that errors in distal and femoral alignment of more than 3° occur in at least 10% of total knee arthroplasties, even when performed by experienced surgeons using mechanical alignment systems of modern design.<sup>11</sup> Mechanical alignment systems have fundamental limitations that limit their ultimate accuracy. The accuracy of preoperative planning is limited by the errors inherent in standard radiographs. With standard instrumentation, the correct location of crucial alignment landmarks (eg, the center of the femoral head, the center of the ankle) is limited during the performance of a TKR. Moreover,

mechanical alignment and sizing devices provide distorted bone geometry that may not apply to the patient. Even the most elaborate mechanical alignment systems rely on visual inspection for accuracy of the limb and implant alignment.<sup>12</sup>

Computer-based alignment systems have been developed to address the problems inherent in total knee instrumentation. Although a number of computer-assisted TKR approaches are currently in use,<sup>13-17</sup> we have chosen to describe in detail that

- Incorporates the use of a currently available, validated state-of-the-art mechanical alignment system
  - Uses commonly available, relatively simple computer equipment (eg, a desktop computer, optical localizer)
  - Is currently available for clinical use
  - Has available preliminary multicenter results showing the use of the system with a mechanical alignment system
- These results confirm that the system is safe and implant alignment is superior to that of the mechanical system, and that results equivalent to that obtained with the mechanical system.<sup>18,19</sup>

We have chosen to present the steps of the computer-assisted TKR technique next to the corresponding steps of a currently available, mechanically based technique of many that are presently in use. A computer-based surgical technique introduces equipment not currently familiar to us to perform TKR surgery. We hope that the juxtaposition of the two techniques will allow surgeons to more readily understand the rationale and function of the computer-assisted technique. Moreover, by juxtaposing the 2 techniques, we

An overview of a computer-assisted TKR surgical technique has been presented to illustrate the principles of this new technology. The system that has been described is now in clinical use. Preliminary results with the system indicate that the alignment results that have been achieved are more accurate and reproducible than the mechanical system used to insert identical implants. The system is simple to understand and the computer hardware used is relatively inexpensive. The system uses currently available mechanical total knee instruments. The surgeon can use these instruments in the conventional way at any point in

From the Section of Joint Reconstruction and Implant Surgery, Northwestern University, Chicago, IL, and the University Department of Orthopaedic Surgery, Bordeaux, France.  
Address reprint requests to S. David Stulberg, MD, Professor Clinical Orthopaedic Surgery, Director, Section of Joint Reconstruction and Implant Surgery, 680 N. Lake Shore Drive, Suite 1200 A, Chicago, IL 60611.  
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1048-8826/01/0008-0000

*Stulberg at 33 (Ex. 1005)*



# The References Would Have Been Combined

Three types of computer based systems recently have been developed to overcome the problems with mechanical alignment systems. The first type, computer integrated instruments, augments mechanical instruments through the addition of measurement probes that can be used to locate joint centers, track surgical tools, and align prosthetic components. The second type, image guided knee replacement, provides a three-dimensional preoperative plan that guides the placement of the components. The third

## Computer Assisted Knee Replacement

Scott L. Delp, PhD\*; S. David Stulberg, MD\*\*; Brian Davies, PhD†; Frederic Picard, MD‡; and Francois Lettier, PhD§

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. For example, computer integrated instrumentation incorporates highly accurate measurement devices to locate joint centers, track surgical tools, and align prosthetic components. Image guided knee replacement provides a three-dimensional preoperative plan that guides the placement of the cutting blocks and prosthetic components. Robot assisted knee

replacement allows one to machine bones accurately without the use of standard cutting blocks. The rationale for the development of computer assisted knee replacement systems is presented, the operation of several different systems is described, the advantages and disadvantages of different approaches are discussed, and areas for future research are suggested.

Total knee replacement is widely used to relieve pain and improve function in patients with degenerative joint disease. Although total knee replacement is generally successful, failures from component loosening, instability, dislocation, fracture, or infection occur in approximately 5% to 8% of cases.<sup>1,2,3</sup> Less severe complications, such as patellofemoral pain or limited flexion, also contribute to sub-optimal outcomes in 20% to 40% of cases.<sup>2,4,5</sup>

The success of total knee replacement depends on several factors, including patient selection, prosthesis design, soft tissue balancing, and alignment of the limb. Proper rotational and translational alignment of the prosthetic components and of the limb are important factors that influence the outcome of knee replacement.<sup>6</sup> Incorrect positioning or orientation of implants can lead to accelerated wear, component loosening, and degraded functional performance.<sup>6,7</sup>

An error in alignment of the components in any of the anatomic planes can have a detrimental effect. Abnormal varus or valgus alignment has been reported to be a major cause of implant loosening.<sup>8</sup> Rotation of the femoral and tibial components has a strong influence on patellar tracking, and malrotation

From the \*Department of Biomedical Engineering and Physical Medicine and Rehabilitation, Northwestern University, Chicago, IL; \*\*Department of Orthopaedic Surgery, Northwestern University Medical School, Chicago, IL; †Department of Mechanical Engineering, Imperial College, London, United Kingdom; ‡Department of Orthopaedic Surgery, Grosvenor South Hospital, Grosvenor, France; and §PRAXIM Company, Imaging, Modeling and Caption Techniques Laboratory, University of Grenoble, Grenoble, France.

Funding for the project as computer integrated instrumentation was provided by the European Commission, within the ICRS (Image Guided Orthopaedic Surgery) project and by the Anecap Co. Funding for the project on image guided knee replacement was provided by Computer-Assisted Surgical Technologies, Inc., Implants Corporation, and Musculoskeletal Inc. and funding for the project on robot assisted knee replacement was provided by the Department of Health in the United Kingdom as part of a DTL Link funding.

Reprint requests to Scott L. Delp, PhD, Rehabilitation Institute of Chicago, Room 1406, 345 East Superior Street, Chicago, IL 60611.

*Delp Article at 50 (Ex. 1003)*

## The References Would Have Been Combined

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 at 22:45-50 (Ex. 1004)*

# The References Would Have Been Combined

infection. Reducing incision size is therefore always a major motivation for any surgical procedure, and therefore it can be assumed that a known procedure is already using the shortest

*File History for U.S. Patent No. 8,133,229 to Bonutti,  
June 18, 2009 Office Action Response at 20 (Ex. 1024)*

# The References Would Have Been Combined

9	Following up on your computer assisted	10:35:33AM
10	TKA experience with Stryker, that experience	10:35:37AM
11	happened after 2004, correct?	10:35:43AM
12	A I'll preface that by my experience with	10:35:46AM
13	it would be seeing it in the lab, yes.	10:35:51AM
14	Q But you never used a computer assisted	10:35:57AM
15	TKA in an operation?	10:36:02AM
16	A I didn't feel at the time and still	10:36:05AM
17	today that computer assisted added much to the	10:36:08AM
18	technique or outcomes, so I have not.	10:36:12AM

*Schoifet Dep. at 67:9-18 (Ex. 1031)*

# The References Would Have Been Combined

24	Q	So in none of your 10,000 TKAs you've	10:02:31AM
25		used a computer assisted alignment such as	10:02:34AM
2		described in Stulberg or Delp?	10:02:38AM
3	A	I had been trained in them in labs, but	10:02:41AM
4		I did not deem them necessary to get a	10:02:45AM
5		satisfactory and well aligned total knee. So I	10:02:48AM
6		did not use them in the surgical procedures in	10:02:52AM
7		the approximately 10,000 that I've performed.	10:02:58AM

*Schoifet Dep. at 51:24-52:7 (Ex. 1031)*

# The References Would Have Been Combined

- Patent Owner Offers No Evidence Of Secondary Considerations
  - Patent Owner does not identify any unexpected results
  - “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).



# Appendix

# Applied Prior Art: Turner

- “The cutting guide that is relied upon by Dr. Mabrey (Figure 8) is employed in the geometric technique [of Turner].” Schoifet Decl. ¶ 48 (EX. 2004)

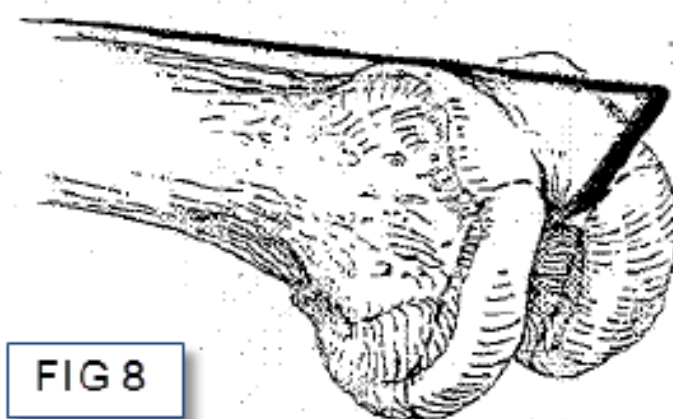
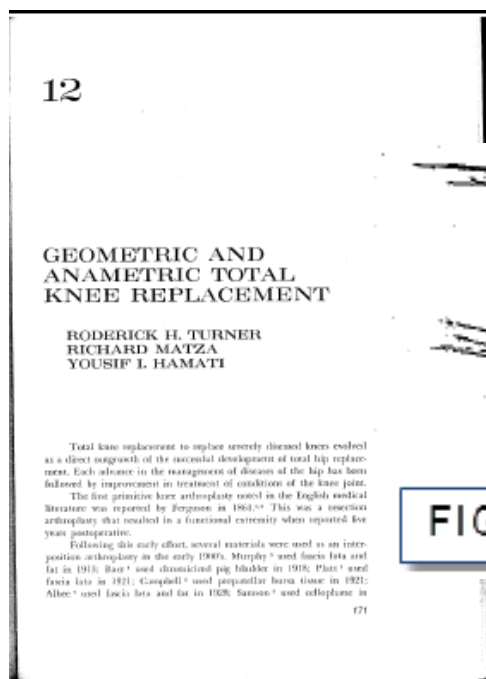


FIG 8



FIG 9



# Applied Prior Art: Turner

- Patent Owner's Expert Dr. Schoifet admitted:

8	Q	And that transverse dimension is	01:56:00PM
9		greater or smaller than the transverse dimension	01:56:07PM
10		of the implant?	01:56:11PM
11	A	It's so small that it actually doesn't	01:56:12PM
12		guide the sawblade very well, that you have to	01:56:15PM
13		use your eye to guide the sawblade.	01:56:17PM
14		MR. CAVANAUGH: My question is a	01:56:20PM
15		yes-or-no question, and perhaps the reporter	01:56:21PM
16		can repeat it.	01:56:23PM
17		(Question read)	01:56:23PM
18		MR. KAPPEL: Objection to form.	01:56:38PM
19	A	And my answer is that the dimensions	01:56:42PM
20		are so much smaller than the implant that it does	01:56:44PM
21		not accurately guide the blade and you need to	01:56:47PM
22		make an eyeball cut or a hand cut to complete the	01:56:50PM
23		cuts depicted.	01:56:54PM

Schoifet Tr. at 169:8-23 (Ex. 1031)

# The Turner Technique Was Successful

## Geometric Total Knee Arthroplasty

### A TWO-YEAR FOLLOW-UP STUDY

BY MATTHEW D. SKOLNICK, M.D.\*, MARK B. COVENTRY, M.D.\*, AND  
DUANE M. ILSTRUP, M.S.†, ROCHESTER, MINNESOTA

From the Mayo Clinic and Mayo Foundation, Rochester

**ABSTRACT:** In a study of our experience with the first 119 geometric arthroplasties of the knee done at the Mayo Clinic, reported after a minimum follow-up period of two years, we noted that relief of pain was the primary goal in 84 per cent of the cases and this was achieved in the majority. The average total motion was relatively unchanged but it became more useful postoperatively.

From April 1971 through June 1972, 119 knees were operated on and the geometric total knee prosthesis was inserted. The results of these arthroplasties have been analyzed in the same way as the results of polycentric arthroplasties done during a similar period<sup>6</sup>. Follow-up visits were carried out eight weeks after the operation, when the patient was interviewed and examined and roentgenograms were made. One year after operation, a special postoperative data sheet was completed subsequent to interview, examination, and roentgenographic studies. At two years, when most patients returned for the interview, examination, and roentgenographic studies, the two-year follow-up form was completed. The one-year and two-year data sheets were then compared with the preoperative data sheet. A few patients did not return for the two-year follow-up; in several instances the patient as well as the home physician was contacted by telephone. One patient died and eight were lost to follow-up between the first and second years.

This study was undertaken to determine, in light of our continuing experience with geometric total knee arthroplasty: (1) whether selection of patients for operation was correct; (2) whether technical surgical aspects had changed and were influencing the results; and (3) whether any design problems in the prostheses were emerging. We evaluated all complications and attempted to find their cause. Furthermore, we attempted to determine whether the goals of the patient and orthopaedist were realized two years or more after geometric total knee arthroplasty.

#### Material

Of the 119 arthroplasties, 43 per cent were unilateral (Table I). Thirty-four (38 per cent) of the patients were men and fifty-five (62 per cent) were women, with an age range of from twenty-five to eighty-four years (mean, sixty-one years). Fifty-three per cent of the knees had rheumatoid involvement and 41 per cent were osteoarthritic. In 48 per

\* 200 First Street, S.W., Rochester, Minnesota 55901. Please address reprint requests to Dr. Skolnick, c/o Section of Publications.

VOL. 58-A, NO. 6, SEPTEMBER 1976

cent, the total knee arthroplasty followed previous surgery on the knee. A large majority had had one or more articular injections of steroids. Relief of pain was the primary goal of surgery in 84 per cent of the cases and this was achieved in the majority. The average total motion was relatively unchanged but it became more useful postoperatively.

TABLE I  
DEMOGRAPHIC DATA ON ONE HUNDRED AND NINE

Side	N	%
Right	25	21
Left	26	22
Right of bilateral	32	27
Left of bilateral	36	30
Diagnosis		
Rheumatoid arthritis	51	43
Osteoarthritis	6	5
Post-traumatic state	1	1
Other (psoriatic arthritis)	1	1
Primary goal of operation		
Relieve pain	100	84
Increase motion	6	5
Correct deformity	13	11

#### Technique

The surgical technique previously described<sup>1</sup> followed with few alterations. Cheilectomy of the femur, tibia, and patella was done in all knees. Synovectomy was done on knees with severely hypertrophic synovium more commonly on rheumatoid knees. Patellectomy and capsular reconstruction were done infrequently (Table II).

#### Preparation of Bone Bed

The surface of the proximal part of the tibia should be made as flat and congruous as possible to provide maximum contact between the tibial component and the bone bed and to prevent bending of the component at the condyle during seating of the prosthesis, which can produce a distraction force on at least a portion of the prosthetic cement or cement-bone interface. In addition, the slope receiving the flanges of the tibial component should be small as is compatible with a snug fit and ease of insertion in order to reduce the amount of cement used and to provide maximum prosthesis-to-bone contact.

#### Axial Alignment

The most critical factor preventing loosening ap

articular injections of steroids. Relief of pain was the primary goal of surgery in 84 per cent of the cases. The goal

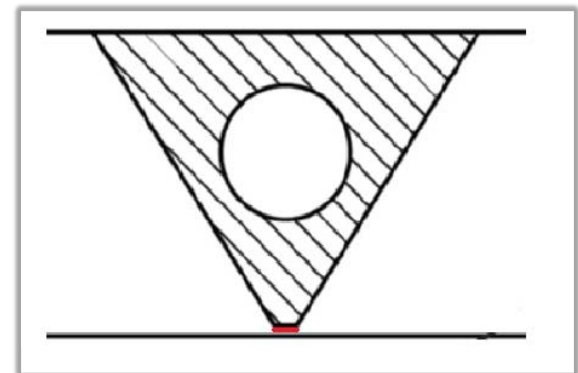
Whereas pain was significant in 106 of 110 knees (96 per cent) before operation, little or no pain was present in eighty-two of eighty-nine (92 per cent) at two-year follow-up (Table IV). Twenty-one of the 110 knees were

Significantly greater independence in this series of patients was reflected by the decrease in use of ambulatory aids (Table V) and the increase in distance walked (Table VI). In 15 per cent of the knees the patients required no walking aids preoperatively, whereas postoperatively 49 per cent needed no aids. In five per cent of the knees the patients had been unable to walk at all before operation, compared with 1 per cent postoperatively. Improvement in the use of

# Scorpio: Response to Patent Owner Arguments

side. (Mabrey Tr., 89-91). I disagree. A person of ordinary skill in the art in 2000-2003 would clearly recognize from the figures that Scorpio would not function as an anterior resection guide if the center metal piece in front of the guide surface extended all of the way to the bone side of the guide surface. The metal piece cannot extend all of the way to the bone side of the cutting guide because if it did a physician would not be able to cut the entire condyle portion of the bone. A person

*Schoifet Decl. ¶ 77 (Ex. 2004)*



*Mabrey Reply Decl. ¶ 15 (Ex. 1023) (showing enlarged and annotated view of Patent Owner's drawing)*

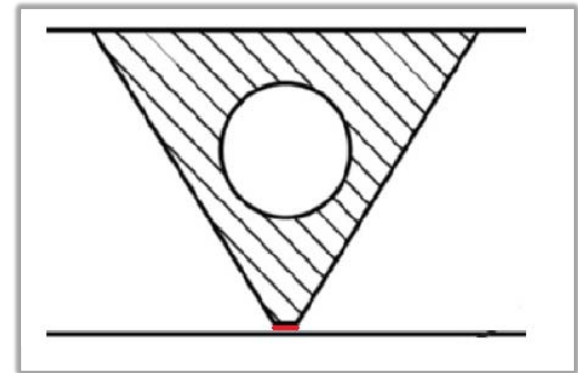
# Scorpio: Response to Patent Owner Arguments

15 Q Okay. So what I'd like you to do is 01:32:54PM  
16 hypothesize that the triangle is not a truncated 01:32:59PM  
17 triangle but a triangle that extends all the way 01:33:06PM  
18 to the bone side of the cutting guide. 01:33:08PM  
19 Can you do that for me? 01:33:15PM  
20 A I have it right here. 01:33:16PM

*Schoifet Dep. at 151:15-20 (Ex. 1031)*

7 Q And with that hypothetical, is there a 01:33:48PM  
8 continuous guide surface? 01:33:50PM  
9 A With this hypothetical you do not have 01:33:54PM  
10 a continuous guide surface. Might I also add 01:33:57PM  
11 that we may have created a nonfunctioning cutting 01:34:18PM  
12 guide so we do have a cutting guide that I've 01:34:22PM  
13 commented doesn't have a continuous guide surface 01:34:26PM  
14 that may very well not function for this 01:34:30PM  
15 particular purpose in doing an anterior 01:34:33PM  
16 referencing cut. 01:34:35PM

*Schoifet Dep. at 152:7-16 (Ex. 1031)*



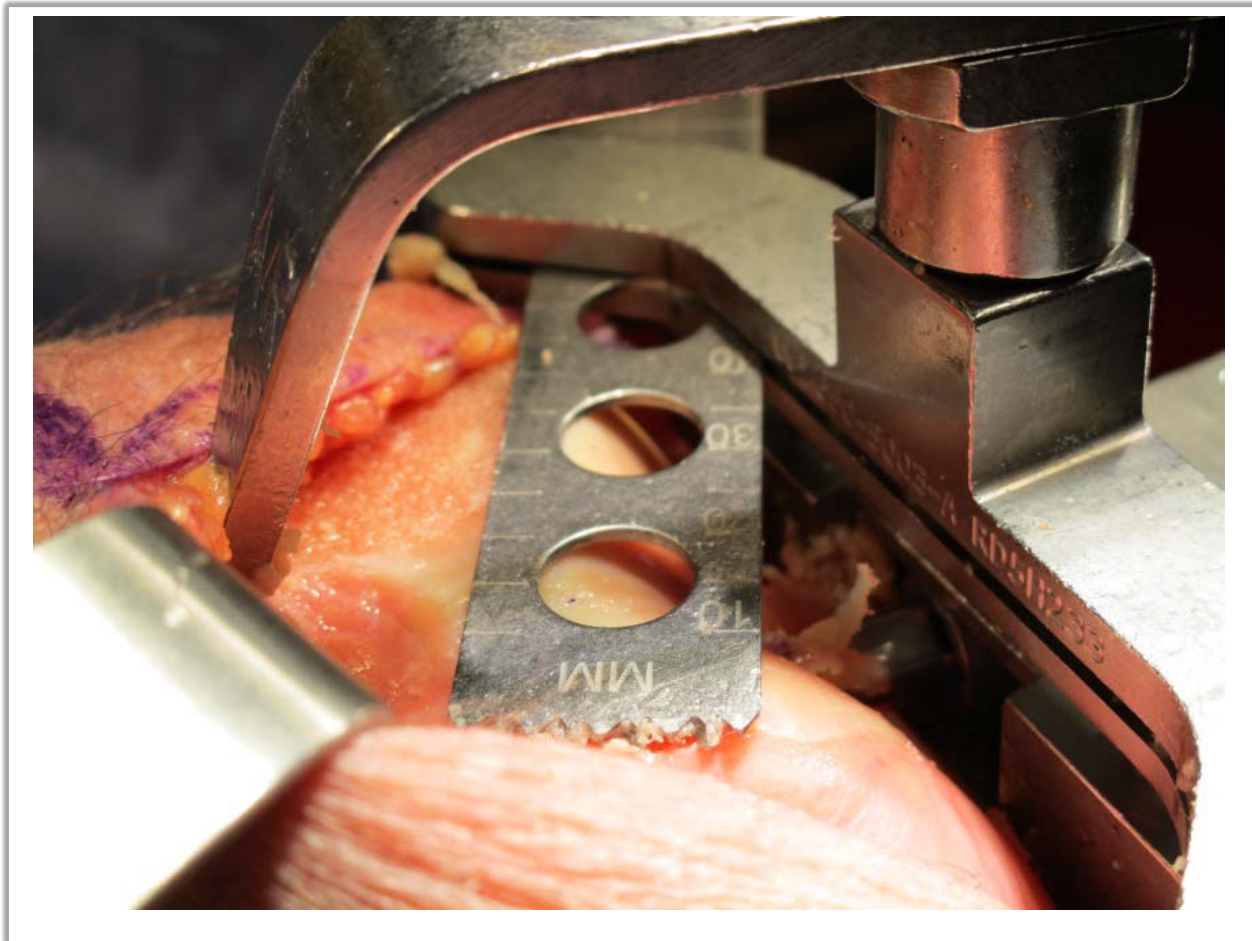
*Mabrey Reply Decl. ¶ 15  
(Ex. 1023) (showing  
enlarged and annotated  
view of Patent Owner's  
drawing)*

# Scorpio: Response to Patent Owner Arguments

21	So you can't answer whether or not	12:25:20PM
22	there is an ability using simply half of the	12:25:23PM
23	cutting guide -- of the resection guide in order	12:25:31PM
24	to complete an anterior cut?	12:25:35PM
25	MR. KAPPEL: Objection. Form.	12:25:37PM
1	S. Schoifet	
2	A To render an expert opinion I would	12:25:38PM
3	want to see the guide.	12:25:41PM

*Schoifet Dep. at 146:21-147:3 (Ex. 1031)*

# Scorpio: Response to Patent Owner Arguments



*Scorpio Photos at 29 (Ex. 1030); Mabrey  
Reply Decl. ¶ 19 (Ex. 1023)*

# The References Would Have Been Combined

12	Q	And accuracy is really important to	02:08:48PM
13		these surgeries, correct?	02:08:50PM
14	A	Accuracy is important to these	02:08:51PM
15		surgeries more so to the computer assisted of	02:08:56PM
16		which my declaration is about, but accuracy is	02:08:59PM
17		important to all surgeons at some level, yes.	02:09:03PM

*Schoifet Dep. at 178:12-17 (Ex. 1031)*

Respectfully submitted,

Customer Number: 24395

Tel: 202-663-6055

Fax: 202-663-6363

/Michael H. Smith/  
Michael H. Smith  
Registration No. 71,190  
Wilmer Cutler Pickering  
Hale and Dorr LLP



**CERTIFICATE OF SERVICE**

I hereby certify that on October 22, 2014, I caused a true and correct copy of  
the foregoing materials:

- Petitioners' Demonstrative Exhibits for Oral Argument

to be served by email, as previously agreed between the parties, on the following  
counsel of record for Patent Owner:

Cary Kappel, Lead Counsel  
William Gehris, Backup Counsel  
Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue  
New York, NY 10018  
ckappel@ddkpatent.com  
wgehris@ddkpatent.com  
Tel.: 212-736-1257

/Michael H. Smith/

Michael H. Smith

Registration No. 71,190