Filed: January 26, 2017

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case No. IPR2017-00780
U.S. Patent No. 8,062,302

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 95-125 OF U.S. PATENT NO. 8,062,302

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TABLE OF AUTHORITIES

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OTHER AUTHORITIES

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 8,062,302 (“the ’302 patent”)
1002	***Exhibit number not used***
1003	PCT Publication No. WO 93/25157 (“Radermacher”)
1004	PCT Publication No. WO 00/35346 (“Alexander”)
1005	PCT Publication No. WO 00/59411 (“Fell”)
1006	U.S. Patent No. 6,712,856 (“Carignan”)
1007	PCT Publication No. WO 95/28688 (“Swaelens”)
1008	U.S. Patent No. 6,510,334 (“Schuster II”)
1009	U.S. Patent No. 5,098,383 (“Hemmy”)
1010	European Patent No. EP 0 908 836 (“Vomlehn”)
1011	U.S. Patent No. 4,502,483 (“Lacey”)
1012	U.S. Patent No. 6,575,980 (“Robie”)
1013	U.S. Patent No. 5,735,277 (“Schuster ’277”)
1014	U.S. Patent No. 5,320,102 (“Paul”)
1015	J.B. Antoine Maintz & Max A. Viergever, *A Survey of Medical Image Registration*, 2 Med. Image Analysis 1 (1998) (“Maintz”)
1016	PCT Publication No. WO 02/22014 (“WO ’014”)
1017	Excerpts of the ’302 Patent Prosecution History
1018	***Exhibit number not used***

Exhibit No.	Description
1019	CV of Jay D. Mabrey, M.D.
1020	***Exhibit number not used***
1021	U.S. Provisional Patent Application No. 60/293488 (filed May 25, 2001) (“the ’488 application”)
1022	U.S. Provisional Patent Application No. 60/363527 (filed March 12, 2002) (“the ’527 application”)
1023	***Exhibit Number Not Used***
1024	Excerpts from ConforMIS, Inc.’s Preliminary Invalidity and Noninfringement Disclosures in *ConforMIS, Inc. v. Smith & Nephew, Inc.*, Civil Action No. 1:16-cv-10420-IT (D. Mass.)
1025	U.S. Provisional Patent Application No. 60/380692 (filed May 14, 2002) (“the ’692 application”)
1026	U.S. Provisional Patent Application No. 60/380695 (filed May 14, 2002) (“the ’695 application”)
1027	U.S. Patent Application No. 10/160667 (filed May 28, 2002) (“the ’667 application”)
1028	U.S. Patent No. 7,468,075 (“the ’075 patent”)
1029-1030	***Exhibit number not used***
1031	U.S. Patent No. 4,841,975 (“Woolson”)
1032	U.S. Patent No. 4,646,729 (“Kenna”)
1033	Klaus Radermacher et al., *Computer Assisted Orthopaedic Surgery with Image Based Individual Templates*, 354 Clinical Orthopaedics and Related Research 28 (1998) (“CAOS”)
1034	PCT Publication No. WO 01/66021 (“Pinczewski”)

Exhibit No.	Description
1035	***Exhibit Number Not Used***
1036	U.S. Patent No. 4,759,350 ("Dunn")
1037	Excerpts from *Surgery of the Knee* (John N. Insall et al., eds., 2d ed. 1993) ("Insall")
1038-1040	***Exhibit Number Not Used***
1041	Smith & Nephew Richards, *Genesis® Total Knee System Primary Surgical Technique* (1993) ("Genesis Technique Guide")
1042	Excerpts from Dror Paley, *Principles of Deformity Correction* (2002) ("Principles of Deformity Correction")
1043	U.S. Patent No. 5,107,824 ("Rogers")
1044-1069	***Exhibit Number Not Used***
1070	U.S. Provisional Patent Application No. 60/416601 (Filed on October 7, 2002) ("the '601 application")
1071-1101	***Exhibit Number Not Used***
1102	Declaration of Jay D. Mabrey, M.D.

Petitioner Smith & Nephew, Inc. ("Petitioner" or "Smith & Nephew") requests *inter partes* review in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.* of Claims 95-125 of U.S. Patent No. 8,062,302 ("the '302 patent"), which issued on November 22, 2011, and is purportedly owned by ConforMIS, Inc. ("ConforMIS").

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

The following mandatory notices are provided as part of this Petition.

A. Real Party-in-Interest Under 37 C.F.R. § 42.8(b)(1)

Smith & Nephew, Inc. is the real party-in-interest. Smith & Nephew, Inc. is a wholly owned subsidiary of Smith & Nephew plc, which is publicly traded on the London Stock Exchange.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

ConforMIS asserted the '302 patent (Ex. 1001) against Smith & Nephew in co-pending litigation captioned *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass. filed February 29, 2016; served March 1, 2016). Petitioner filed petitions requesting *inter partes* review of related ConforMIS patents: U.S. Patent Nos. 9,055,953 (IPR2016-01874); 9,216,025 (IPR2017-00115 and 2017-00307); 8,377,129 (IPR2017-00372); 8,551,169 (IPR2017-00373); 9,295,482 (IPR2017-00487 and IPR2017-00488); 7,981,158 (IPR2017-00510 and 2017-00511); and 7,534,263 (IPR2017-00544 and 2017-00545). Petitioner is filing other petitions challenging other claims of the ’302 patent concurrently herewith.

C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Smith & Nephew’s Power of Attorney:

Lead Counsel	Back-up Counsel
Christy G. Lea (Reg. No. 51,754) 2cgl@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson, & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Tel.: (949) 760-0404 Fax: (949) 760-9502	Joseph R. Re (Reg. No. 31,291) 2jrr@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson, & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Tel.: (949) 760-0404 Fax: (949) 760-9502 Colin B. Heideman (Reg. No. 61,513) 2cbh@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson, & Bear, LLP 925 Fourth Ave., Suite 2500 Seattle, WA 98104 Tel.: (206) 405-2000 Fax: (206) 405-2001

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to lead and back-up counsel at the address shown above. Smith & Nephew also consents to electronic service by email to BoxSMNPHL.168LP3-3@knobbe.com.

E. Grounds for Standing Under 37 C.F.R. § 42.104(a)

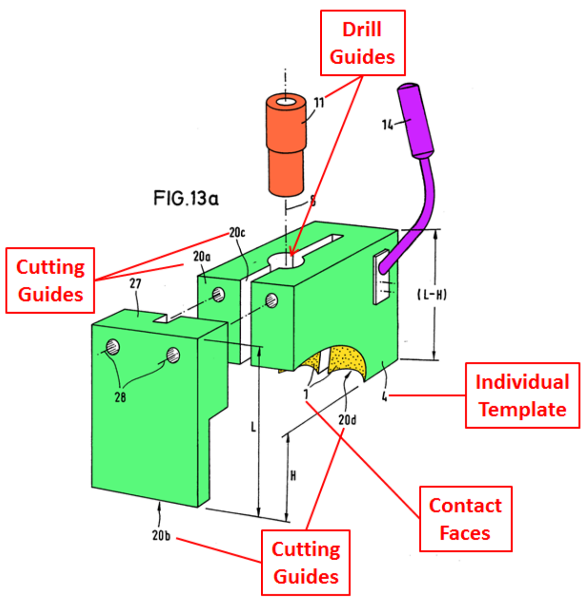
Petitioner certifies that the ’302 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition. Petitioner filed the present petition within one year of service of the original complaint against Petitioner in the district court litigation.

II. SUMMARY OF ISSUE PRESENTED

Claims 95-125 of the ’302 patent generally recite a simple surgical tool for performing joint surgery (e.g., preparing the femur or tibia in knee replacement surgery). The tool includes a “block” for preparing the bone to receive an implant. The block rests on the joint surface and includes guides (e.g., slots, surfaces, or holes) for guiding surgical tools during surgery.

Independent Claim 95 recites a “block” having: (1) a patient-specific surface that is “substantially a negative of” a cartilage surface of the joint; and (2) first and second guides that are aligned relative to an axis of the joint. The dependent claims add limitations regarding the type, number, and orientation of the guides. The other independent claims at issue in this Petition are similar to, but even broader than, Claim 95.

Such systems were not patentable at the time of the patent’s earliest alleged priority date of November, 2002. By that time, surgical tools having patient-specific surfaces and multiple cutting or drilling guides were widely known and had been described in numerous prior art references. For example, in 1993, Radermacher disclosed a system that included a patient-specific block for guiding saws and drills to prepare a knee to receive an implant. Radermacher disclosed an "individual template" 4 (block) having at least five guides including cutting guides defining planes 20a-d and a drill guide about axis 8, as well as "contact faces" 1 (patient-specific surface) that were customized based on CT and/or MRI data to match the natural surface of the particular patient's knee joint:[1]



[1] For clarity, diagrams are colored and annotated.

The cuts result in a resected bone (Fig. 13b) onto which an implant (Fig. 13d) can be seated:

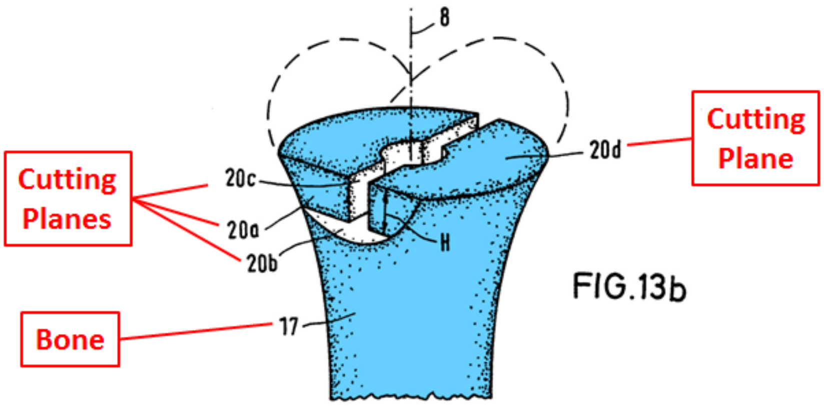


FIG.13b

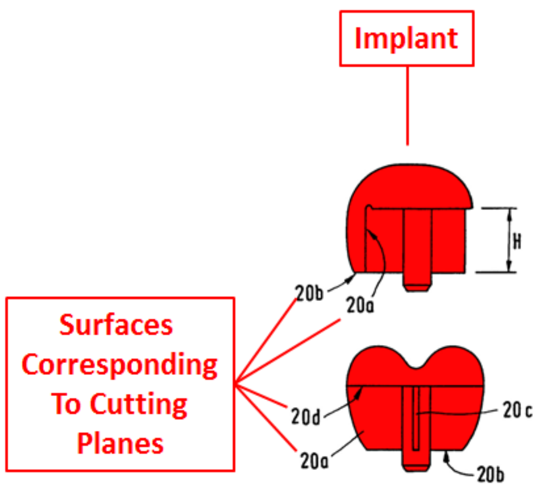
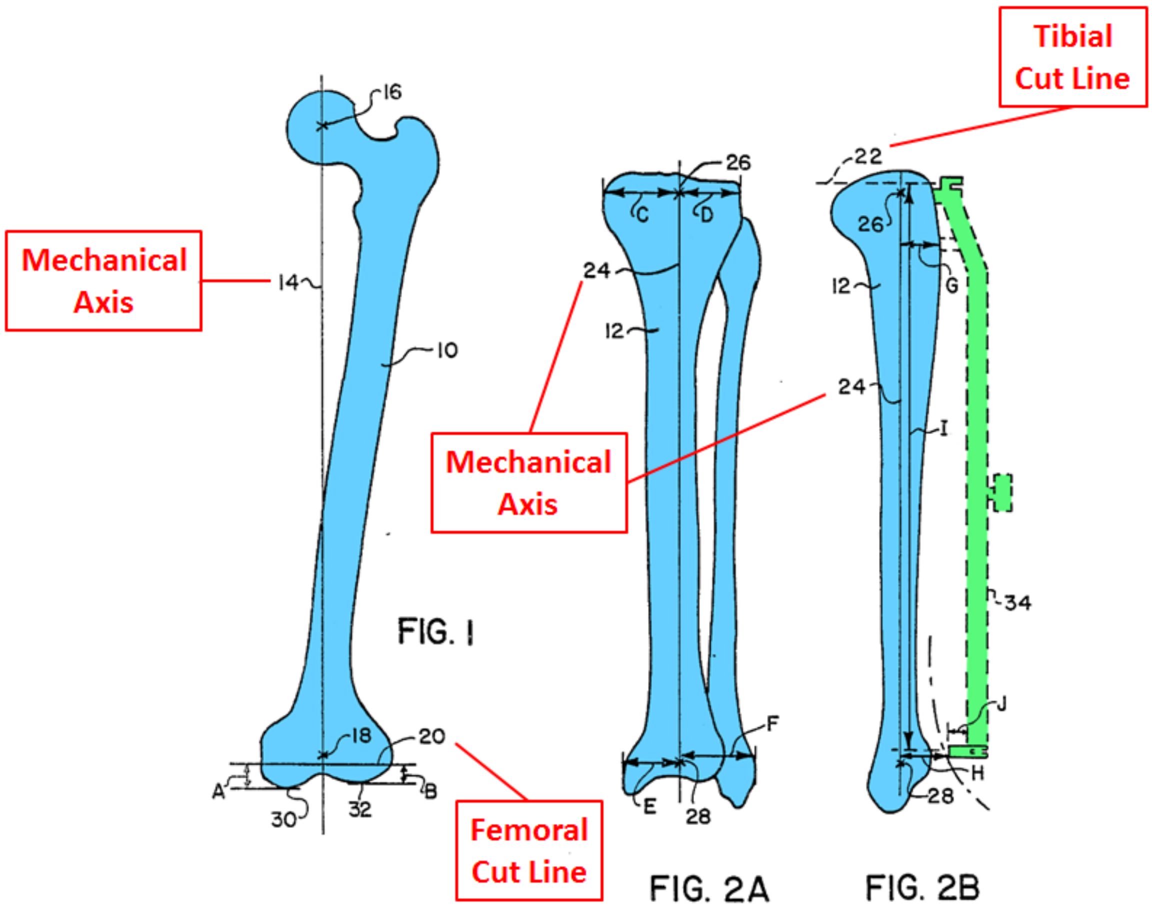


FIG.13d

By the 1990s, it was also commonplace for such tools to define cutting and/or drilling paths with a particular alignment (e.g., perpendicular) to a patient's biomechanical or anatomical axes, as such alignment was necessary to ensure proper alignment of the implant. For example, Woolson (1989) disclosed that "***all*** total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis" and that, to do so, the cutting planes must be perpendicular to the axis. As shown below, Woolson disclosed determining the axes (14, 24) and orienting a cutting guide such that the cutting paths (20, 22) are aligned perpendicular to the axis:



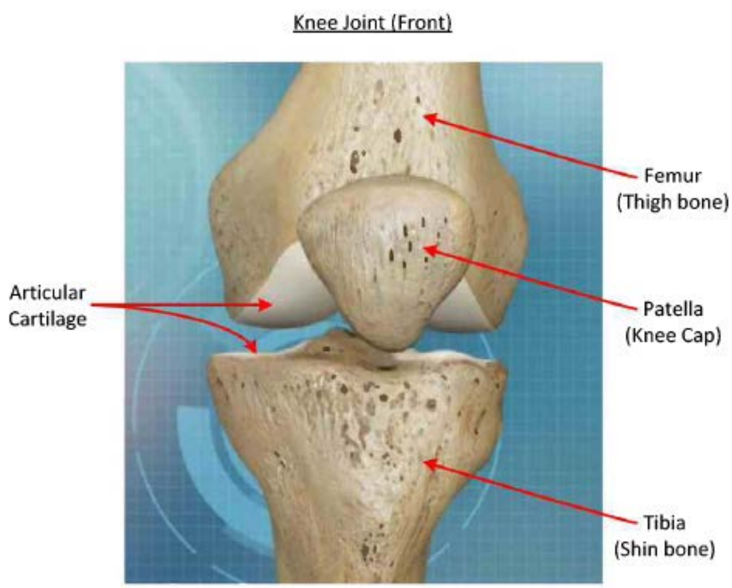
Numerous references taught that such alignment was "important" or "essential" to the success of knee implant surgery. The limitations recited in the dependent claims, which generally relate to the orientation of the guides, were equally well-known.

Despite a vast array of highly relevant—and invalidating—prior art references, the claims of the ’302 patent slipped through the Patent Office with only a single formal anticipation rejection and no obviousness rejections. While the claims of the ’302 patent avoided substantive examination during the application process, the claims are unpatentable and should therefore be canceled.

III. INTRODUCTION & STATE OF THE ART

A. Knee Joint Anatomy

The knee joint includes the femur (thigh bone), the tibia (shin bone), and the patella (knee cap), as shown below:



Ex. 1102 ¶36. In a healthy knee, the lower end of the femur and the upper end of the tibia are covered by articular cartilage, which provides a low-friction surface that facilitates rotation and absorbs shock. *Id.* In arthritic joints, some of the articular cartilage is often worn or torn away, which can cause severe pain. *Id.*

A patient's femur and tibia define a "mechanical axis," which is the axis that extends from the center of the femoral head at the hip, through the center of the knee, and through the ankle joint, as shown below. *Id.* ¶¶37-38; Ex. 1036, Fig. 1; Ex. 1008, 1:28-37.

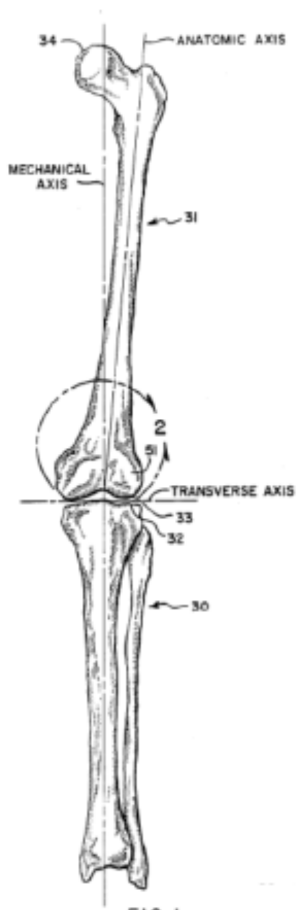


FIG. 1

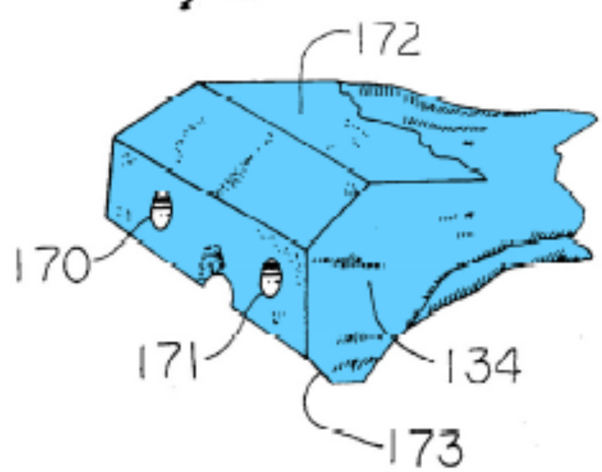
The femur and tibia also each define an "anatomic axis" which, as shown above, represents the axis that extends along the center of the bone. Ex. 1036, Fig. 1.

B. Knee Replacement Procedures

When articular cartilage has been damaged by disease such as osteoarthritis, a surgeon can replace portions of the knee with artificial components. *Id.* ¶¶39-42. Such surgery, which is referred to as "knee arthroplasty," was known for decades before ConforMIS filed the '302 patent. *Id.* ¶45.

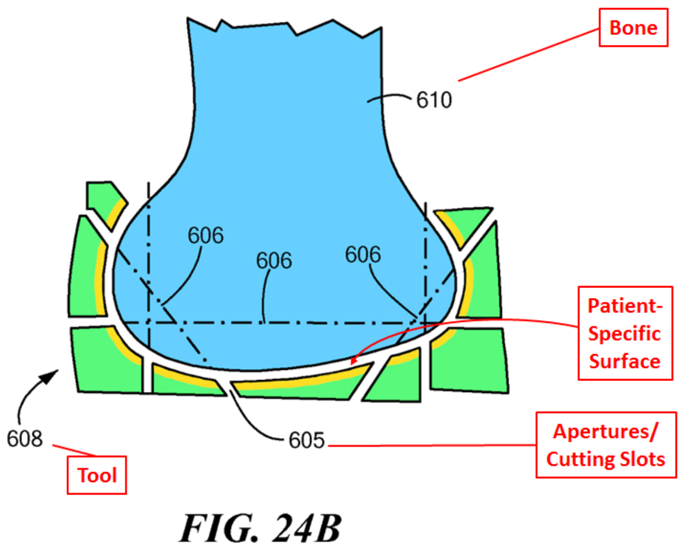
During knee arthroplasty, a surgeon must prepare a patient's bone to receive an implant. *Id.* ¶¶40-42. As part of the preparation, the surgeon typically removes a portion of the bone to shape it to receive the implant. *Id.* ¶40. The image below shows the end of a femur that has been prepared in a typical manner, i.e., with flat bone surfaces onto which an implant component can be seated and holes into which pegs on the implant can be placed. *Id.*

Fig. 17

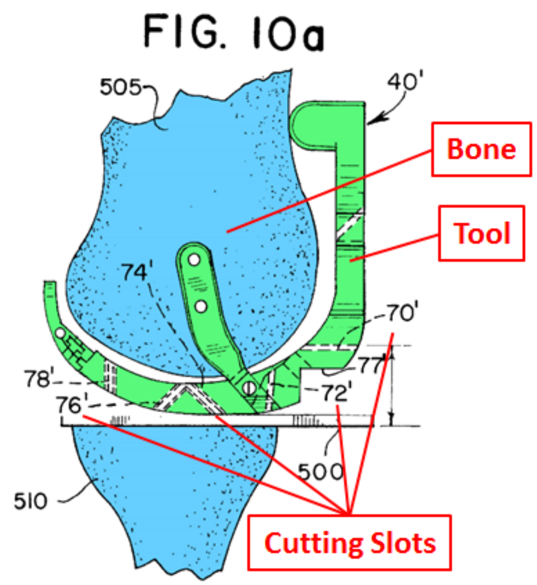


Ex. 1011, Fig. 17.

To help ensure that the cuts and drill holes are made accurately—and thus the implant component is implanted in the proper orientation—a surgeon typically uses tools with holes, slots, or surfaces that guide the surgeon's tools as the surgeon cuts (resects) the bone or drills holes into bone, rather than cutting free-handed. Ex. 1102 ¶¶41-42. The figures below show the similarity between the claimed patient-specific tool with cutting slots (left) and prior art tools (right) having virtually identical cutting slots oriented in the same way:



'302 Patent (Ex. 1001, Fig. 24B)



Robie (Ex. 1012, Fig. 10a)

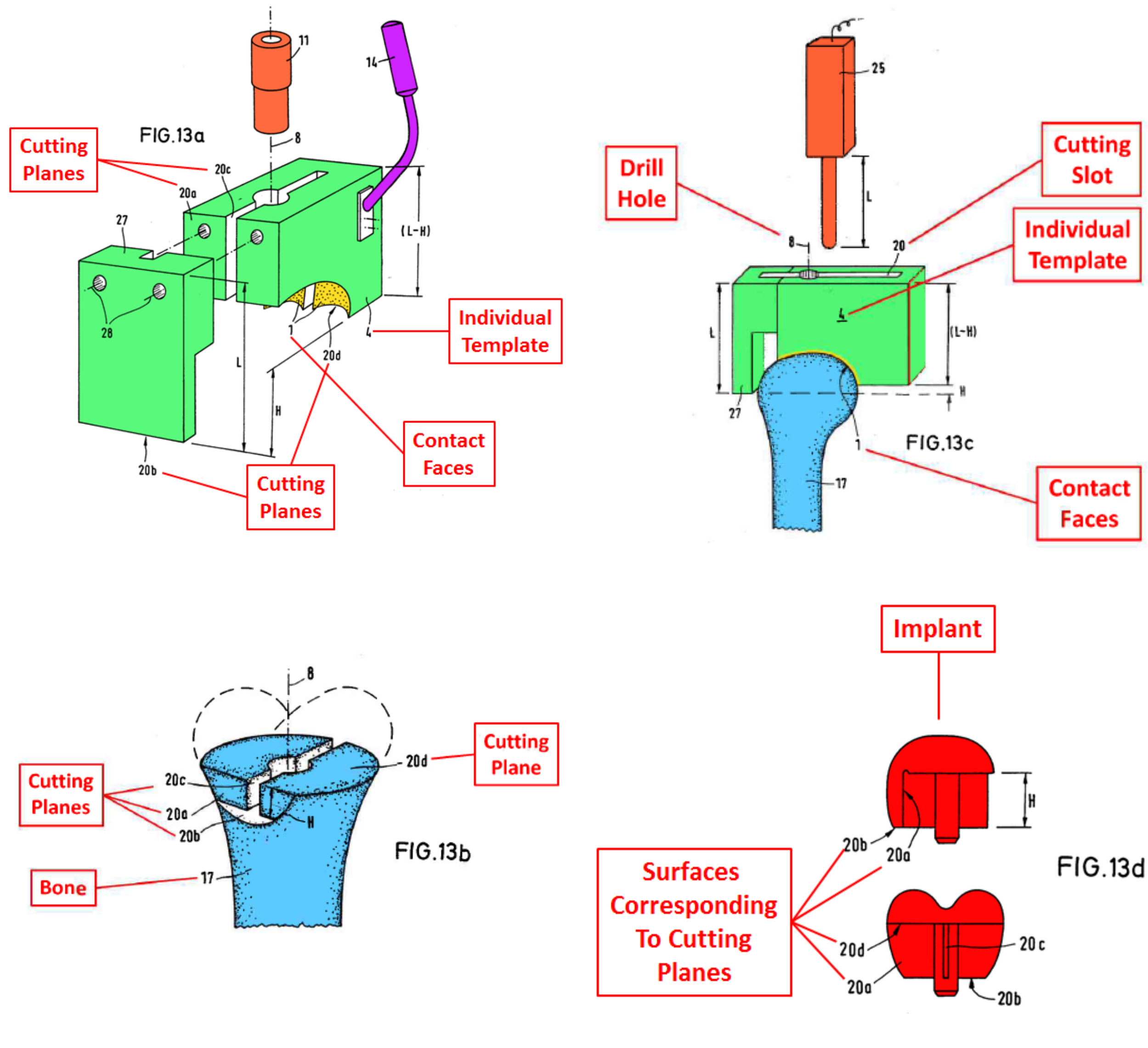
To ensure that the knee implant is properly oriented and thus the leg is in its proper alignment after surgery, and to prevent mechanical forces from dislodging the implant, surgeons typically use imaging (e.g., x-ray, CT, MRI, etc.) to determine an axis of the joint and then align the cuts perpendicular to the axis. Ex. 1102 ¶¶43-49; Ex. 1036 (X-ray); Ex. 1031 (CT); Ex. 1033 (topograms). The '302 patent admits that this practice was conventional and known in the art. Ex. 1001, 30:32-51, 34:46-39:47.

C. Using Imaging to Create Patient-Specific Guides

1. Using MRI to Create Patient-Specific Cutting and Drilling Guides Was Well-Known.

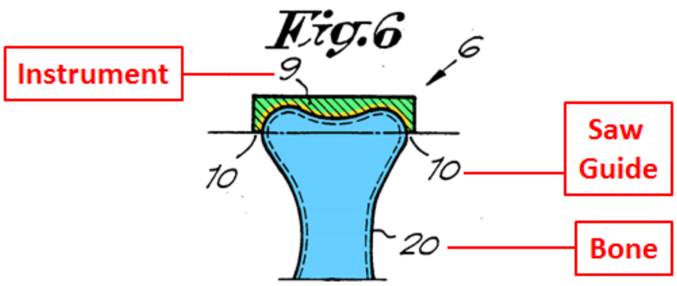
Prior to the 1990s, surgeons had various ways of aligning cutting blocks so that the cutting slots and drill holes would be properly oriented. Ex. 1102 ¶45. In the 1990s, however, patient-specific cutting guides—guides that included a patient-specific surface such that the guide could be positioned by placing the tool on a particular patient's joint surface—became widely known. *See id.* ¶¶50-57.

For example, Radermacher (1993) described using MRI and/or CT data to create an "individual template" for guiding surgical tools. The template included a surface that is a "copy" or "negative" of the "natural (i.e. not pre-treated) surface" of a patient's joint. Ex. 1003 at 10, 12. In Radermacher, an individual template 4 having patient-specific contact faces 1 (yellow) could be set on the surface of a bone 17 of a patient's knee joint, a bore axis 8 drilled, and cuts made along cutting planes 20a-d, resulting in a resected bone (Fig. 13b) onto which an implant (Fig. 13d) could be seated. *Id.* at 30.



Id. at Fig. 13a.

In 1995, Swaelens disclosed an instrument 9 having a patient-specific surface (yellow) such that the instrument "can be placed as a template on the bone of the patient 1 during surgery and which fits perfectly to it." Ex. 1007, 6:24-29, 9:1-13, 10:23-30. Swaelens's instrument included a functional element 10 that "serves as a guide for the saw." *Id.*, 13:17-25, Fig. 6; Ex. 1102 ¶51.



Schuster II described using CT or MRI data to create a patient-specific surgical tool comprising a block ("implantation aid") having a surface that is substantially a negative of the damaged knee joint, including the cartilage surface:

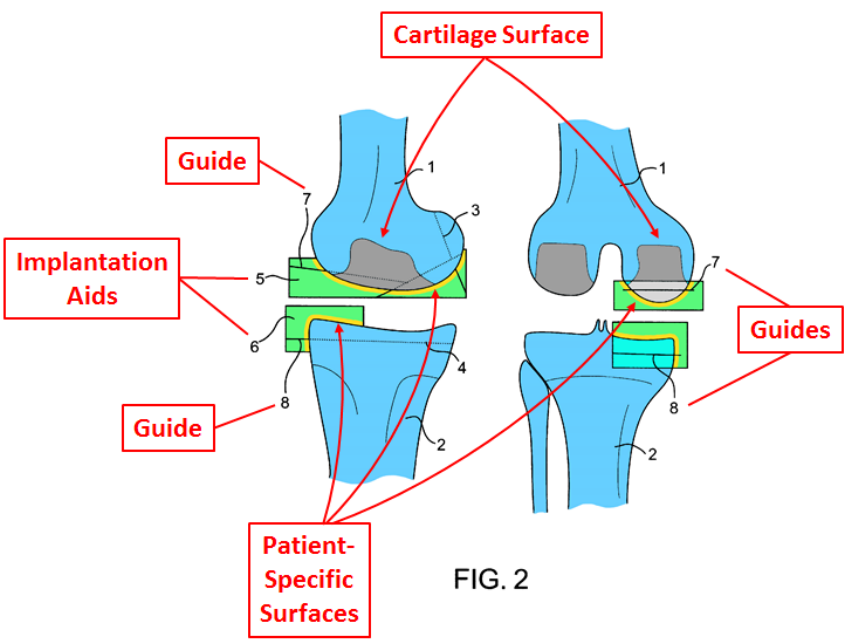


FIG. 2

Ex. 1008, 2:59-64, 3:50-57. As shown above, the blocks included multiple guides at various angles for guiding a saw. *Id.*, 3:50-4:5, 4:35-38. Numerous other prior art references similarly disclosed surgical tools having patient-specific surfaces and multiple cutting or drilling guides. Ex. 1010, 2:48-55, 3:38-45; Ex. 1006, 7:53-8:41, 8:15-20, Fig. 4.

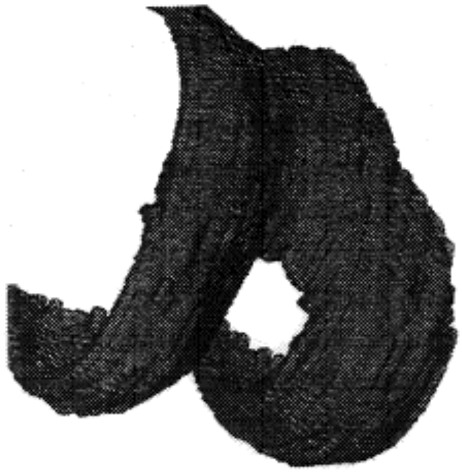
As illustrated by the references above, using imaging to create tools having patient-specific surfaces and multiple guides was well-known. Ex. 1102 ¶58.

2. Using Imaging to Determine the Contour of a Patient's Cartilage Surface Was Well-Known.

It was well known before 2002 that the contour of a patient's cartilage surface could be determined through various imaging techniques, including MRI and CT. Ex. 1102 ¶¶43-44. All of the prior art references discussed above disclose imaging the patient's joint surface using CT and/or MRI. The '302 patent admits that "conventional" methods of x-ray, ultrasound, CT, and MRI, which were "within the skill of the art" and "explained fully in the literature" (Ex. 1001, 30:32-51), were "suitable for measuring thickness and/or curvature (e.g., of cartilage and/or bone) or size of areas of diseased cartilage or cartilage loss." *Id.*, 32:3-16.

The prior art confirms that various imaging techniques could be used to determine the contours of a patient's articular cartilage. For example, Alexander, which published in 2000, recognized that "a number of internal imaging techniques known in the art are useful for electronically generating a cartilage image[,]" including MRI and CT. Ex. 1004, 14:16-21. Alexander disclosed that MRI could be used to create a three-dimensional model of a patient's knee joint, including both bone (gray) and cartilage (black) surfaces:

Ex. 1004, Fig. 18C (cropped). Moreover Alexander disclosed virtually the same cartilage image as in the '302 patent:



Alexander (Ex. 1004, Fig. 19)

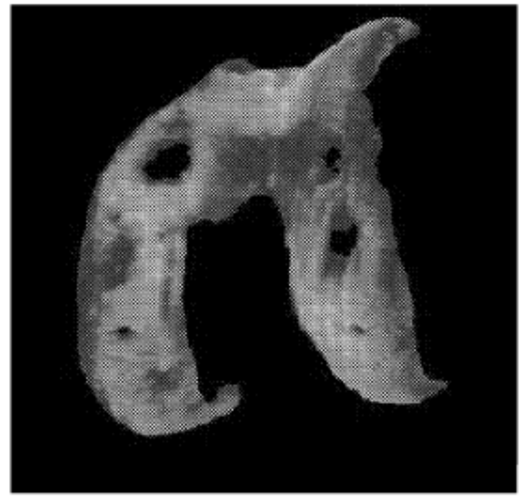


FIG. 2

’302 Patent (Ex. 1001, Fig. 2)

In fact, the ’302 patent relies on Alexander’s prior art method of determining the contours of the bone and cartilage surfaces to generate the claimed patient-specific instrument. Ex. 1001, 32:1-34:43 (citing WO 02/22014 (Ex, 1016), a later publication of Ex. 1004). Many other prior art references also taught that MRI[2] could be used to determine the contour of a patient’s articular cartilage. *See, e.g.*, Ex. 1013, 2:8-17 (MRI “makes possible an especially sharp definition of the joint

[2] Some references refer to “nuclear spin tomography” or “NMR,” which is old terminology for what is now referred to as MRI. Ex. 1102 ¶53; *see also* Ex. 1015 at 1 (Magnetic resonance imaging or MRI is known by a variety of other names, including NMR, nuclear magnetic resonance, spin imaging and various other names.).

contour by representing the cartilaginous tissue and other soft parts of the damaged knee joints"); *see generally* Ex. 1014 (articular cartilage shape and thickness can be determined using MRI); Ex. 1005, 22:6-8 (MRI provides contour plots of articular cartilage). Petitioner's expert further confirms that it was known before 2002 that the topography of a patient's articular cartilage could be determined using MRI and/or CT scans. Ex. 1102 ¶¶43-44.

IV. THE '302 PATENT

A. Overview of the '302 Patent

The '302 patent discloses nothing more than using conventional MRI or CT data to create conventional patient-specific cutting guides. Ex. 1102 ¶59. Specifically, the '302 patent describes determining the curvature and dimensions of a patient's joint surface using "conventional" imaging techniques, such as MRI, that were well-known in the art and "explained fully in the literature." Ex. 1001, 32:1-34:43; 30:32-51. The '302 patent describes using such conventional images to create a tool having an inner surface that is a "mirror image" of the patient's articular surface, i.e., the surface of the device "match[es] all or portions of the articular or bone surface and shape," as was well-known. *Id.*, 70:39-52; Ex. 1102 ¶60.

The '302 patent explains that it was well-known that conventional imaging, e.g., x-ray, MRI, and CT, could be used to determine a patient's anatomical and biomechanical axes. Ex. 1001, 34:46-39:47. The '302 patent admits that it was known that these axes should be considered in knee arthroplasty. *Id.* For example, consistent with the conventional practice, the '302 patent explains that the bone may be resected "perpendicular to the mechanical axis 1910." *Id.*, 69:28-39.

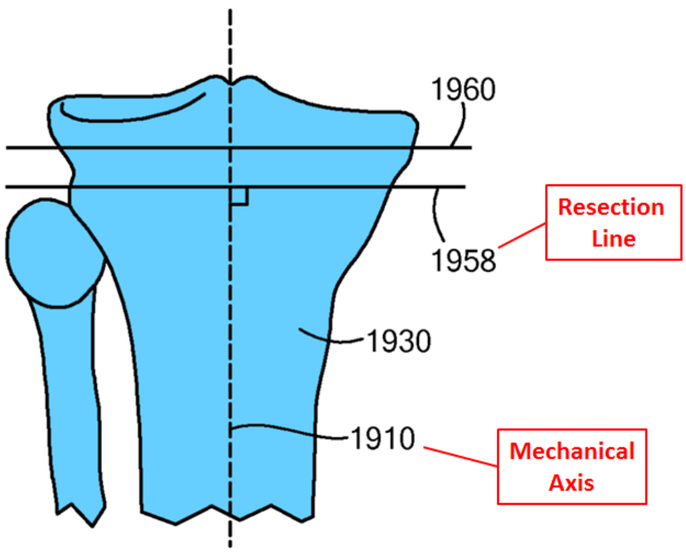


FIG. 21B

Id., Fig. 21B.

B. Prosecution History of the '302 Patent

The '302 patent was filed on June 9, 2008. The claims were originally rejected as anticipated by Robie (Ex. 1017 at 272-73), which discloses a cutting block designed to make precisely the same cuts as those described in the '302 patent:

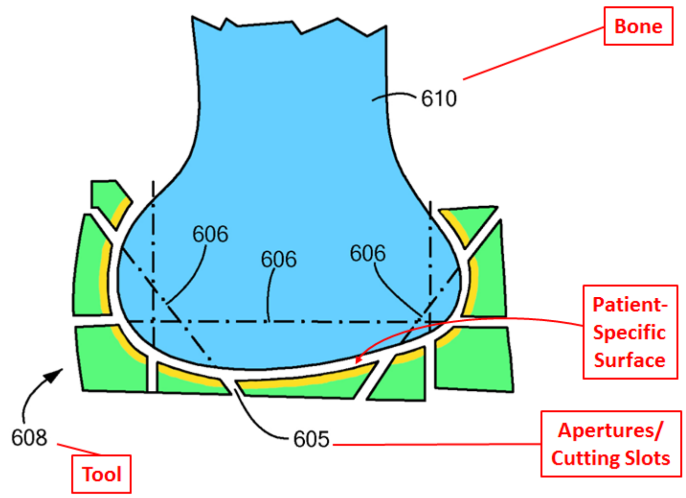
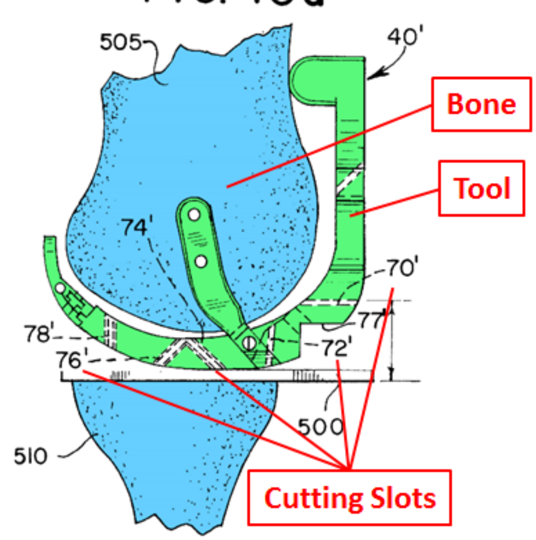


FIG. 24B



’302 Patent (Ex. 1001, Fig. 24B)

Robie (Ex. 1012, Fig. 10a)

After a pair of interviews, ConforMIS overcame the Robie rejection by amending the claims to specify that the patient-specific surface is substantially a negative of a damaged or diseased joint surface or cartilage surface and arguing that none of the references disclosed such a limitation. Ex. 1017 at 109-29, 136. The claims were allowed. *Id.* at 30-31.

During prosecution, the references relied on herein (Radermacher, Woolson, Fell, and Alexander) were submitted to the Patent Office, but they were among more than 800 patent and non-patent documents submitted. *Id.* at 316, 336, 386. None of these references were applied by the Examiner.

C. Priority

The '302 patent claims priority to eight continuation or continuation-in-part applications and twelve provisional applications dating back to May 25, 2001. Ex. 1001, 1-2. However, the earliest possible priority date for the '302 patent is November 27, 2002, the filing date of U.S. application number 10/305,652, which is the earliest disclosure in the priority chain of patient-specific instruments that include more than one guide.[3] Ex. 1102 ¶65; 35 U.S.C. §§ 119(e)(1), 120; *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008). None of the earlier applications in the priority chain discloses this feature. Ex. 1102 ¶65; Exs. 1021-1022, 1025-1028, 1070.

D. Level of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") would be: (a) an orthopedic surgeon having at least three years of experience in knee arthroplasty surgery; or (b) an engineer having a bachelor's degree in biomedical engineering (or closely related discipline) who works with surgeons in designing cutting guides and who

[3] Petitioner does not concede that the '302 patent is entitled to this priority date and reserves it right to challenge any priority date asserted by ConforMIS.

has at least three years of experience learning from these doctors about the use of such devices in joint replacement surgeries. Ex. 1102 ¶¶29-32.

V. CLAIM CONSTRUCTION

Solely for the purposes of this review, the claims are given their broadest reasonable interpretation in light of the specification. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016); 37 C.F.R. § 42.100(b). Petitioner does not believe that any claim construction is necessary to resolve the issues presented in this petition.

VI. STATEMENT OF PRECISE RELIEF REQUESTED

A. Grounds

Petitioner requests that Claims 95-125 be canceled for the following reasons.

Ground 1. Claims 95-125 are unpatentable under 35 U.S.C. § 103(a) in view of Radermacher, Alexander, and Woolson.

Ground 2. Claims 95-125 are unpatentable under 35 U.S.C. § 103(a) in view of Radermacher, Fell, and Woolson.

Ground 2 is not redundant of Ground 1 because Ground 2 relies on a different secondary reference (Fell), which involves a different, but related, technology and provides a different motivation to combine. Ex. 1102 ¶167.

Additional support for this Petition is included in the Declaration of Jay D. Mabrey, M.D. Ex. 1102. Dr. Mabrey is the Chief of the Department of

Orthopaedics at Baylor University Medical Center in Dallas, Texas, and is also a Professor of Surgery at Texas A&M Health Science Center College of Medicine. *Id.* ¶¶4-19.

B. Status of References as Prior Art

All of the references relied on in these grounds are prior art under 35 U.S.C. § 102(b) because they published more than one year before the earliest possible priority date of November, 2002:

- Radermacher published on December 23, 1993.
- Alexander published on June 22, 2000.
- Fell published on October 12, 2000.
- Woolson published on June 27, 1989.

Even if the ’302 patent was entitled to its earliest claimed priority date of May 25, 2001, which it is not, Alexander and Fell would still be prior art under §§ 102(a) and (e).

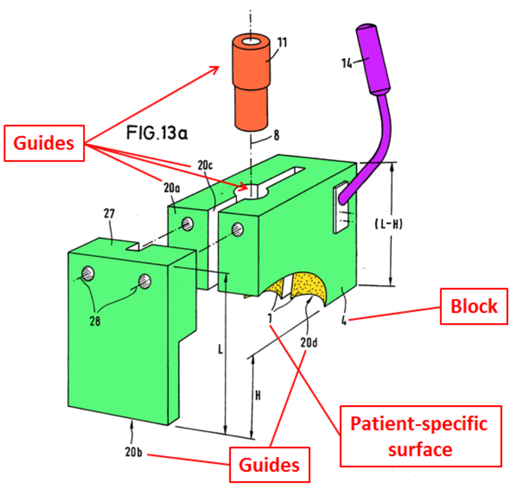
VII. SPECIFIC PROPOSED GROUNDS FOR REJECTION

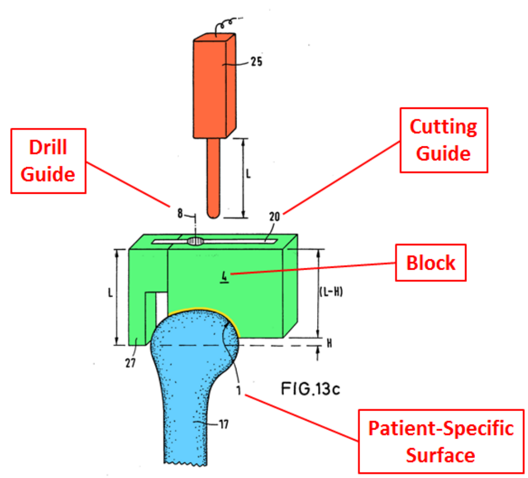
A. Ground 1: Claims 95-125 Are Unpatentable as Obvious Over Radermacher, Alexander, and Woolson.

1. Independent Claim 95

Claim 95 recites a patient-specific surgical tool comprising a block having [i] a patient-specific surface and [ii] first and second guides. The patient-specific surface has at least a portion that is substantially a negative of a patient's cartilage surface. The first and second guides: [a] have predetermined positions and orientations relative to the patient-specific surface; and [b] are oriented to provide predetermined drilling or cutting paths that are aligned relative to a biomechanical or anatomical axis of the joint. Radermacher, either alone or in combination with Alexander and Woolson, renders this claim obvious.

Radermacher discloses a patient-specific surgical tool comprising an "individual template" (block) and multiple guides, for use in knee joint surgery:





Ex. 1003 at Figs. 13a, c; *id.*, 19, 30; *see also id.*, 18, Figs. 10a-10e, 25-26. The remaining claim limitations are addressed below.

a. A Patient-Specific Surface that Is Substantially a Negative of a Patient's Cartilage Surface

Radermacher describes using MRI and/or CT scans to create a three-dimensional reconstruction of a patient's joint, which is used to create an "individual template" having a patient-specific surface:

> According to the inventive method, there is used a split-field device (e.g. a computer [CT] or a nuclear spin [MRI] tomograph) by which split images are produced . . . and from these split images, ***data regarding the three-dimensional shape of the osseous structure and the surface thereof are obtained***. In the preoperative planning phase, these data are used as a basis for defining … a rigid ***individual template which … copies the surface of the osseous structure*** in such a manner that the individual template can be intraoperatively set onto these – then freely exposed – contact faces or points in exclusively one clearly defined position in form-closed manner.

Id. at 10-11 (emphases added); *see id.* at 12 ("By 3D reconstruction of a tomographically imaged object … there is generated a three-dimensional negative mold of parts of the individual natural (i.e. not pre-treated) surface of the osseous structure intraoperatively accessed by the surgeon."), 22 (the contact faces "are used (as a negative, a 'cast', 'reproduction') for a basis for the individual template

4 to be constructed"), 10 (the surface of the osseous structure is "copied" to provide "mating engagement."), Fig. 18 ("CT, MR").

Thus, Radermacher discloses a tool having a patient-specific surface, at least a portion of which is substantially a negative of a corresponding portion of a diseased or damaged surface of the patient's joint. Ex. 1102 ¶82. ConforMIS has admitted as much. In co-pending litigation, ConforMIS admitted that Radermacher discloses using pre-operative image data to create a "custom" instrument "with a tissue contacting surface that matches and fits" the joint surface. Ex. 1024 at 21, 57 (Radermacher "discloses that the individual template may be custom formed to match the surface of a knee joint.").

Petitioner understands that ConforMIS may argue that Radermacher does not disclose that the patient-specific surface is substantially a negative of the diseased or damaged *cartilage* surface. However, this limitation cannot save the claim because it is disclosed by Radermacher, would have been obvious to a POSITA reading Radermacher, and/or would have been obvious to a POSITA in view of Alexander, as explained below.

i. Radermacher

Radermacher discloses that the patient-specific surface of the template is substantially a negative of the articular cartilage surface. Specifically, Radermacher describes generating a three-dimensional negative mold of "the individual ***natural (i.e. not pre-treated) surface*** of the osseous structure." Ex. 1003 at 12 (emphasis added). In an articulating joint such as the knee joint, the "natural (i.e. not pre-treated) surface" of the osseous structure would include the articular cartilage (as well as any subchondral bone that may be exposed by virtue of the cartilage being worn away). Ex. 1102 ¶¶75, 82-85. Thus, to a POSITA, Radermacher discloses precisely the same patient-specific surface that is described in the '302 patent, namely one that is a "negative" or a "copy" of, and therefore matches, the patient's natural articular surface. *Id.* As long as diseased or damaged cartilage exists on the patient's joint, the contact faces of Radermacher's individual template would be substantially a negative of a portion of a diseased or damaged cartilage surface. *Id.*

This understanding is further supported by Radermacher's disclosure of the types of imaging used and the surgical process employed. *Id.*; *id.* ¶76. Radermacher discloses using CT and/or MRI data to customize the template's inner surface and, as the '302 patent admits, these imaging techniques were widely known to provide data regarding the cartilage surface. Ex. 1001, 30:32-51, 32:1-

34:43, 70:39-52; Ex. 1102 ¶83. Moreover, Radermacher describes the steps necessary to use the individual template and does not describe removing cartilage. Ex. 1003 at 30. If Radermacher's individual template was configured to match only the underlying subchondral bone—but not match the cartilage—Radermacher would have described additional surgical steps in which the bone was pre-treated, i.e., cartilage was removed by the surgeon to prepare the site for the individual template. Ex. 1102 ¶84. But Radermacher teaches the opposite, namely matching the individual template to the "natural (i.e. not pre-treated) surface." *Id.*; Ex. 1003 at 12. Radermacher also states that the template is positioned without further positioning work. Ex. 1003 at 15. Thus, when Radermacher discloses that the template is generated via a three-dimensional negative mold of parts of the individual natural, not pre-treated surface and "set onto the bone" (*id.*, 30), a POSITA would have understood that the template is set onto the un-treated bone, i.e., on top of any remaining cartilage (and any exposed subchondral bone). Ex. 1102 ¶84.

Accordingly, Radermacher discloses that at least a portion of the patient-specific surface is substantially a negative of a corresponding cartilage surface. *Id.* ¶85.

ii. The Knowledge of a POSITA

Even if Radermacher did not disclose that the template's patient-specific surface matched the patient's cartilage surface, such a template would have been obvious to a POSITA in view of Radermacher. *Id.* ¶¶86-88.

As described above, Radermacher disclosed using MRI to determine the three-dimensional shape of the patient's joint. Ex. 1003 at 10-12. The '302 patent admits that MRI was conventional, well-known, and used by POSITAs to determine the contour of a patient's cartilage surface. Ex. 1001, 30:32-51, 32:1-34:43. Petitioner's expert and the prior art further confirm that it was widely known that MRI provided information regarding the cartilage surface. Ex. 1102 ¶¶43-44, 86-87; *see also* Ex. 1004, 14:16-18; Ex. 1013, 2:8-17; Ex. 1014; Ex. 1005, 22:6-9. Accordingly, it would have been obvious to a POSITA to use MRI (as taught by Radermacher) to image the patient's cartilage surface (as was common knowledge) and to make the contact faces of Radermacher's individual template match the patient's cartilage surface. Ex. 1102 ¶¶86-88.

A POSITA would have been motivated to match the surface of Radermacher's template to the cartilage surface for several reasons. *Id.* ¶87. First, the cartilage surface and the subchondral bone surface are the only two surfaces of the articulating portion of the joint to which Radermacher's custom template could be matched. Given a POSITA's knowledge that MRI could be used to determine the topography of either the bone or the cartilage surface, the choice between the two simply reflects a choice from a finite number of identified, predictable solutions with a reasonable expectation of success. *Id.*; *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402-403 (2007). Second, as between the two surfaces, a POSITA would have been motivated to design the inner surface to match the cartilage surface because it would simplify the surgery, e.g., the cartilage would not have to be removed in order for the template to precisely fit on the femur or tibia. Ex. 1102 ¶87. Third, Radermacher teaches that the contact faces match the "natural (i.e. not pre-treated) surface," as described above. *Id.* Fourth, a POSITA would understand that matching the cartilage would result in a template that has "one spatially uniquely defined position," reduces surgical time, and increases accuracy, as Radermacher teaches. *Id.*; Ex. 1003 at Abstract; *id.*, 9.

Thus, it would have been obvious to a POSITA to make the "contact faces" of Radermacher's template substantially a negative of the patient's cartilage surface as derived from the MRI data. Ex. 1102 ¶¶86-88. As discussed below, it also would have been obvious in view of Alexander.

iii. Alexander

Even if Radermacher alone did not disclose or render obvious that a portion of the surfaces were substantially a negative of a cartilage surface, this feature would have been obvious to a POSITA in view of Alexander. Ex. 1102 ¶¶89-98.

The ’302 patent admits that cartilage contours can be obtained using the methods described in International Patent Publication WO 02/22014 (“WO ’014”). Ex. 1001, 32:1-34:43. WO ’014 (Ex. 1016) published on March 21, 2002, and is therefore prior art to the ’302 patent. However, another application with virtually the same disclosure published nearly two years earlier on June 22, 2000. The earlier publication (Ex. 1004, “Alexander”), which is prior art under § 102(b), is relied on herein.

Alexander describes various imaging techniques for assessing the condition of cartilage in a knee joint. Alexander recognizes that, by 2000, a number of imaging techniques, including MR and CT, were “known in the art” for “electronically generating a cartilage image.” Ex. 1004, 2:5-6 (MRI is accurate “for visualization of articular cartilage in osteoarthritis, particularly in knees.”); *id.*, 14:16-15:14.

Alexander discloses the use of imaging techniques to obtain the “surface of the joint, e.g. the femoral condyles.” *Id.*, 22:22-24. Alexander discloses that MRI provides a three-dimensional reconstruction of the femoral and tibial bones (gray) and cartilage (black):

FIG._18C

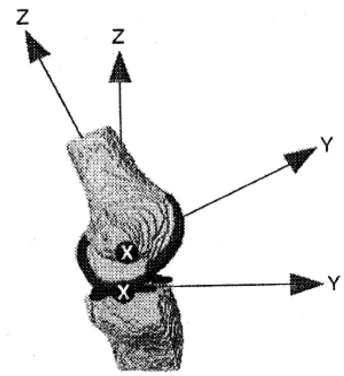


FIG._18H

Id., Figs. 18C-I, 61:19-25. Alexander also describes reconstructing the articular cartilage using a thickness map, just as described in the ’302 patent:

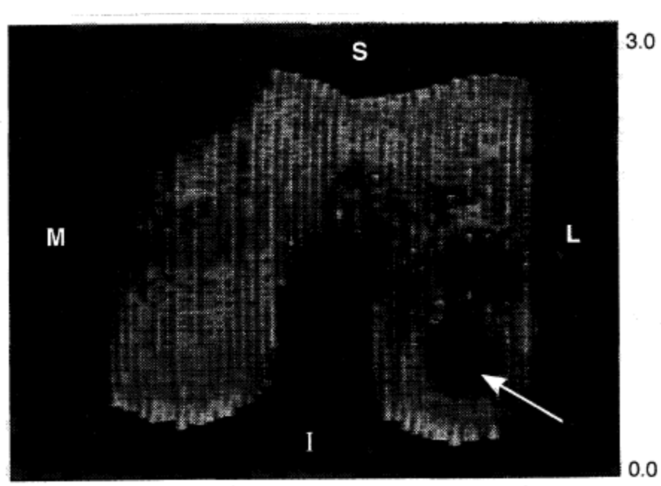


FIG._22B

Alexander (Ex. 1004, Fig. 22B)

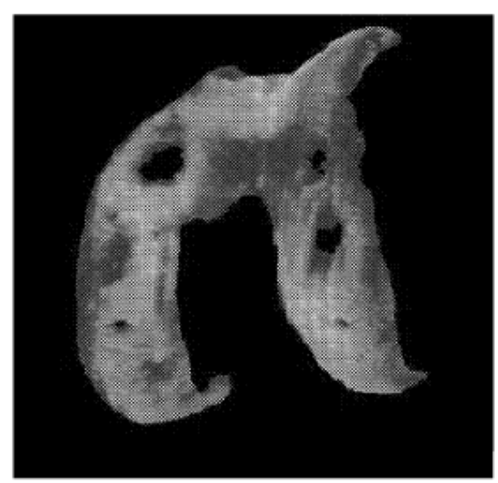


FIG. 2

’302 Patent (Ex. 1001, Fig. 2)

It would have been obvious to a POSITA to combine the teachings of Radermacher and Alexander such that the contact faces of Radermacher’s template are substantially a negative of the patient’s cartilage surface for several reasons. Ex. 1102 ¶¶95-98.

First, both references relate to methods of treating diseased or damaged cartilage in a knee joint. *Id.* Second, both references disclose the use of MRI to obtain joint images. *Id.* Thus, they address the same problem, are in the same field of endeavor, and use the same imaging technology. *Id.*

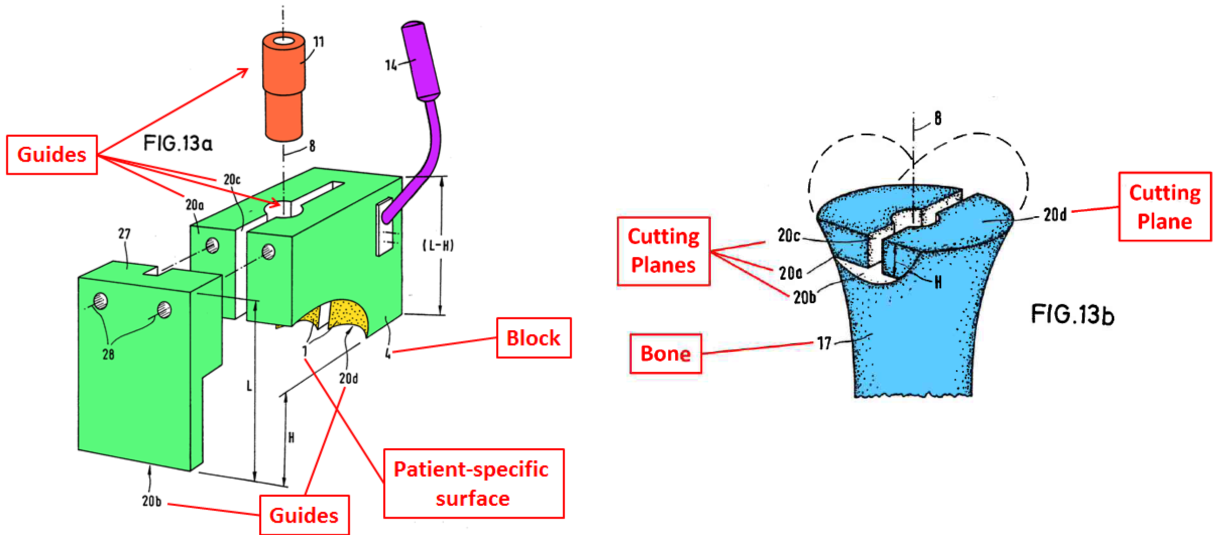
Third, as described above, the cartilage surface and the subchondral bone surface are the only two surfaces of the articulating portion of the joint to which Radermacher's custom template could be matched. Given Alexander's disclosure that the imaging techniques disclosed in Radermacher (e.g., MRI) could be used to determine the shape of either the bone or the cartilage surface, the choice between matching the cartilage surface instead of (or in addition to portions of) the underlying bone surface is simply a design choice. *Id.* ¶96. Fourth, as described above, a POSITA would have been motivated to match the cartilage surface because it would simplify the surgery, and because such a modification would be consistent with Radermacher's goals. *Id.* ¶97; Ex. 1003 at Abstract, 3-5, 9. Fifth, the modification would merely: (a) require the combination of one known element (Alexander's MRI data of the cartilage/articular surface) with another known element (Radermacher's MRI data of the joint surface) to obtain a predictable result (a device tailored to the patient's cartilage surface); and (b) represent a choice from a finite number of identified, predictable solutions (imaging the bone surface and/or the cartilage surface), with a reasonable expectation of success. Ex. 1102 ¶98.

Accordingly, having a patient-specific surface that is substantially a negative of the cartilage surface is disclosed by Radermacher or would have been obvious to a POSITA in view of Alexander. *Id.* ¶¶82-98.

b. First and Second Guides Having Predetermined Positions and Orientations Relative to the Patient-Specific Surface

Claim 95 requires that the block have first and second guides (e.g., for guiding a saw or drill) and that such guides have "predetermined positions and orientations relative to the patient-specific surface."

Radermacher discloses this limitation. Specifically, Radermacher discloses that the block ("individual template") can have any number of guides, including multiple guides for drills and saws. *See, e.g.*, Ex. 1003 at 13 ("[A]ny suitable tool guides, particularly drill sleeves, parallel guides, saw templates … can be provided. These tool guides … can be provided in/on the basic body of the individual template[.]"). In one embodiment, Radermacher discloses a block having five different "guides" (Fig. 13a, below), including a drill guide along axis 8 and four cutting guides that define, and result in, cuts 20a-d (Fig. 13b).



Ex. 1003 at Fig. 13a, 13b; *id.*, 30; *see also id.*, 10-11. Moreover, ConforMIS has admitted that Radermacher "discloses that tool guides can be provided in or on the basic body of the template." Ex. 1024 at 21.

Each of these guides has a "predetermined position and orientation relative to the patient-specific surface" because their location and orientation are determined and fixed during the preoperative planning. Ex. 1003 at 13 ("These tool guides … will effect a three-dimensional guiding of the treatment tools or measuring devices exactly as provided by the surgical planning."), 25 (the bore is defined in the surgical planning), 11 (cutting, boring, and milling steps are "three-dimensionally charted in said coordinate system fixed relative to the osseous structure, can be clearly defined in or on the individual template in from of guide means"); Ex. 1102 ¶102.

c. The Guides Provide Drilling or Cutting Paths Aligned Relative to a Biomechanical or Anatomical Axis

Claim 95 also requires that the first and second guides "provide two predetermined drilling or cutting paths that are aligned relative to a biomechanical or anatomical axis of the joint and through a portion of the joint when the patient-specific surface is placed against the … cartilage surface[.]" This limitation is either inherent in Radermacher or would have been obvious to a POSITA in view of Woolson.

i. Radermacher

Claim 95 does not require that the drilling or cutting paths have any particular relationship to any axis. Ex. 1102 ¶106. Nor is it a method claim that requires determining an axis of the joint or orienting the guides at any particular angle to such an axis. Instead, Claim 95 simply requires that the paths are aligned "relative to" an axis when the block is placed against the cartilage surface. This limitation is inherently met by all cutting or drilling paths, regardless of orientation, and is therefore disclosed by Radermacher. *Id.* ¶¶106-09. In other words, although Radermacher does not refer to a biomechanical or anatomical axis, the guides in Radermacher's individual template define predetermined drilling (axis 8) or cutting (planes 20a-d) paths that are necessarily aligned relative to a biomechanical or anatomical axis of the joint. Ex. 1003 at Figs. 13b, 13c.

Even if this limitation requires a determination of the biomechanical or anatomical axes during the pre-operative planning stage and/or that the orientation of the first and second guides depend on such an axis, this limitation would have been obvious to a POSITA in view of his/her knowledge at the time.

ii. Knowledge of a POSITA

The obviousness of this claim, and Radermacher's disclosure, must be viewed from the perspective of a POSITA. There can be no dispute that it was within the knowledge of a POSITA that, when planning knee replacement surgery, drilling and cutting paths should be aligned relative to a patient's biomechanical or anatomical axis. The '302 patent admits that determining the biomechanical and anatomical axes and relying on those axes when performing knee arthroplasty was known. Ex. 1001, 30:32-51, 34:46-39:47.

Petitioner's expert further confirms that aligning the cutting guides relative to a patient's mechanical axis was widely known. Ex. 1102 ¶¶47-49, 105. POSITAs knew that maintaining proper knee alignment post-surgery was critical because the mechanical axis determines the distribution of forces in the knee. Ex. 1102 ¶¶49, 120; Ex. 1037 at 739. To achieve proper alignment, the implant components—both tibial and femoral—must be aligned properly relative to the mechanical axis. Ex. 1102 ¶¶47, 105, 108, 111, 116, 120. This, in turn, requires the cutting paths to be precisely aligned relative to the mechanical axis. *Id*. It was also widely known that proper alignment relative to the mechanical axis ensured that the forces exerted on the implant would not loosen the implant over time. *Id.* ¶120. Thus, such alignment was entirely conventional and widely known by POSITAs in the 1990s. *Id.* ¶¶105, 119.

Numerous prior-art references further confirm that aligning cutting guides relative to a patient's biomechanical or anatomical axis was well-known. For example, this was disclosed by Kenna in 1987. Ex. 1032, 3:1-3; *id.*, Fig. 1, 3:1-52, 8:27-30, 9:37-41. By 1993, the importance of taking the mechanical axis into account when performing knee arthroplasty was "generally agreed [upon]." Ex. 1037 at 758. And in 1998, CAOS explained that accurate placement of implant components with respect to the individual mechanical axis of the leg is "essential." Ex. 1033 at 31.

Accordingly, even if Radermacher did not explicitly disclose aligning the cutting or drilling paths relative to the biomechanical or anatomical axis, it would have been obvious to a POSITA that Radermacher's cutting slots and drilling hole should be oriented to provide paths that are aligned relative to such axes. Ex. 1102 ¶¶108-09.

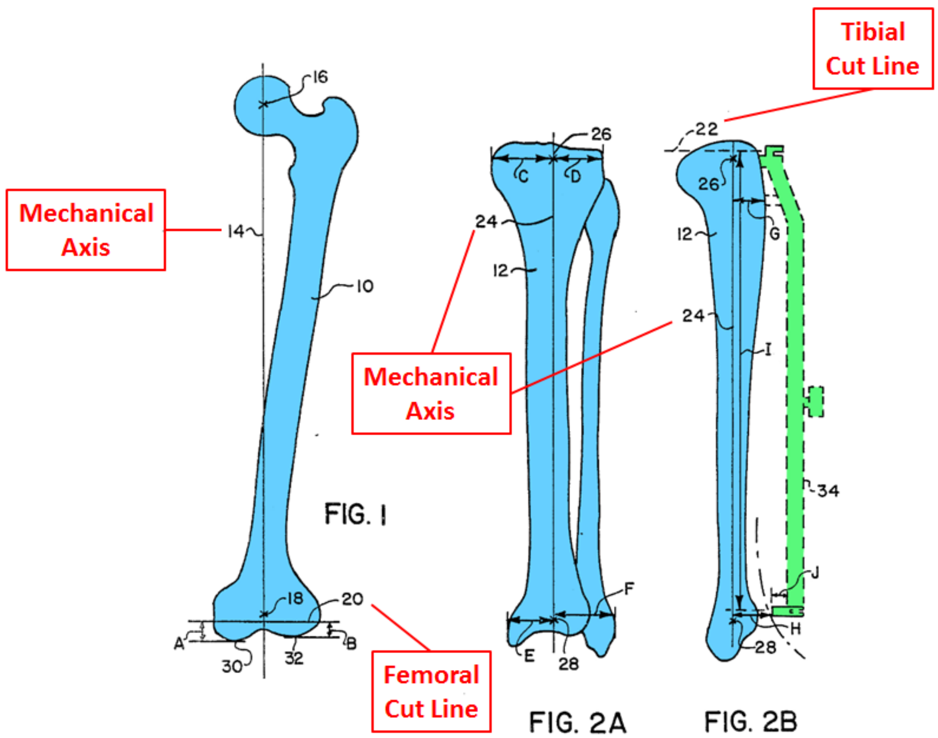
iii. Woolson

Even if this limitation required a determination of the biomechanical or anatomical axes during the pre-operative planning stage and/or that the orientation of the first and second guides depends on such an axis, this limitation also would have been obvious to a POSITA in view of Woolson. Ex. 1102 ¶¶111-13, 119-20. Woolson is one of many prior art references that discloses orienting guides to provide cutting or drilling paths that are aligned relative to a biomechanical or anatomical axis of the joint. Woolson explains that it is "important" that knee implants be positioned on an axis perpendicular to the mechanical axis and, consequently, it is "necessary" that the cutting paths also be perpendicular to the mechanical axis. Ex. 1031, 4:9-19. For example, Woolson first recognizes that ***all*** knee replacement systems align the implant with the patient's mechanical axis because doing so produces better long-term results. *Id.*, 1:26-36. Woolson then explains that, in order for the implant to be aligned properly, the cutting guides must be oriented such that the cutting paths are also aligned relative to the axis:

> [I]t is important that the knee prosthesis be positioned on, and for relative rotation about, an axis perpendicular to the mechanical axis of a femur and corresponding tibia.… During the knee replacement surgical procedure, ***it will be necessary to resection the medial and lateral condyles of the distal femur by cutting along a line 20 which is perpendicular to axis 14***.

Id., 4:7-19 (emphasis added); *see also id.*, 2:50-59 ("[T]he replacing prostheses are aligned relative to axes associated with each joint-forming bone so that the resulting prostheses will have a specific alignment relative to those axes. By determining the position of the gauge member relative to the axis, the position of the cutting guide surface is established prior to the surgical procedure, with corresponding precise placement of the guide during the procedure."), 4:20-26 ("The proximal end of tibia 12 will be resectioned along a cut plane identified by the dashed line 22 in FIG. 2B. The line of this cut must be perpendicular, or slightly angled as will be discussed subsequently, relative to a mechanical axis 24 of the tibia."), 1:46-50, 4:7-6:3, 5:36-41, 6:50-53, 7:32-36, 7:63-67 ("It is seen that this preoperative CT planning method produces distal femoral and proximal tibial bone cuts which are perpendicular to the coronal mechanical axis[.]"), 1:54-57 ("The proximal tibia is cut perpendicular to the mechanical axis of the tibia by adjusting the tibial cutting guide in relation to the knee and ankle joints."), Abstract, 1:8-18, Figs. 1, 2A-B.

Figures 1 and 2A-B of Woolson show the determination of the mechanical axis and the cutting guide oriented such that a cutting path (e.g., lines 20 (femur) and 22 (tibia)) is aligned relative to (e.g., perpendicular to) the axis:



Several other prior art references (including Kenna, Insall, Dunn, and CAOS) confirm that this fundamental concept was well-known and would have been obvious to a POSITA. Ex. 1032, 3:1-52, 8:27-30, 9:37-41, Fig. 1; Ex. 1037 at 758; Ex. 1033 at 31; Ex. 1036, 6:36-42, 6:45-55, 7:7-29, 7:36-50; Ex. 1102 ¶¶114-20.

Accordingly, orienting cutting or drilling guides to provide paths that are aligned relative to a patient's biomechanical or anatomical axis of a joint was widely known, within the knowledge of a POSITA, and would have been obvious to a POSITA in view of at least Woolson. Ex. 1102 ¶¶119-20.

A POSITA would have been motivated to combine Woolson and Radermacher, and thus orient the cutting guides in Radermacher to be relative to a biomechanical or anatomical axis, because Woolson teaches that such alignment occurs in ***all*** knee replacement systems and is critical to the long-term success of knee replacement surgery. *Id*. Woolson and Radermacher are in the same field (knee arthroplasty), describe the same devices (cutting guides), and rely on the same imaging technology (e.g., CT scans). Thus, modifying Radermacher to account for the biomechanical and/or anatomical axes would merely involve using a technique that has been employed to improve one knee arthroplasty procedure (Woolson's) to improve a similar knee arthroplasty procedure (Radermacher's) in the same predictable way. *Id.* ¶120. Accordingly, orienting the first and second guides in Radermacher such that the drilling or cutting paths were aligned relative to an axis of the joint would have been obvious to a POSITA.

In sum, the surgical tool recited in Claim 95 is either disclosed by, or would have been obvious to a POSITA in view of, Radermacher alone or in combination with Alexander (one of many references that disclose imaging a patient's cartilage surface) and Woolson (one of many references that disclose aligning cutting guides relative to a patient's biomechanical axis). Accordingly, Claim 95 is unpatentable.

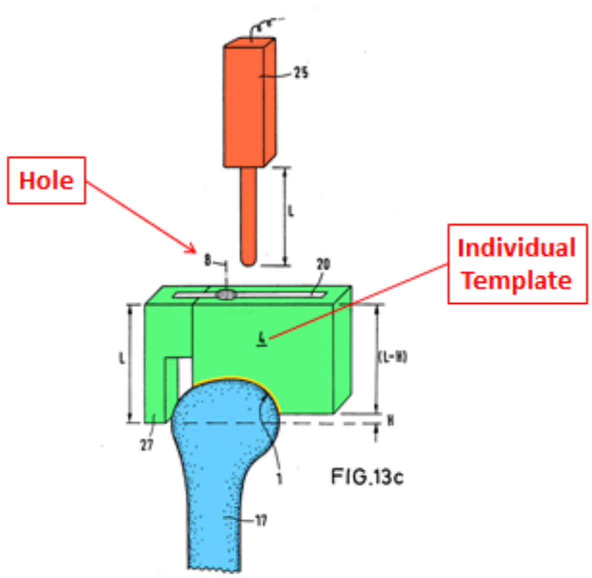
2. Dependent Claim 96

Claim 96 recites that the first and second guides are holes. This limitation would have been obvious in view of Radermacher and Woolson.

a. Radermacher

Radermacher discloses that the individual template (block) may have multiple (e.g., first and second) drilling holes. Specifically, Radermacher states that "drill sleeves"—plural—can "be provided in/on the basic body of the individual template." Ex. 1003 at 13. Radermacher discloses embodiments in which the patient-specific template includes two "bores 19" that can accommodate a drill. *Id.* at 25-26, Figs. 10a-d; *id.* at Figs. 6b, 9.

In one embodiment, Radermacher discloses a template for a knee joint that includes one drilling hole, as shown below:



Ex. 1003 at Fig. 13c. This template is intended to prepare the seat for the implant "illustrated by way of example in Fig. 13d," which has a single peg. *Id.* at 30, Fig. 13d. As described above, Radermacher's disclosure is not limited to this exemplary embodiment. A POSITA would have understood that Radermacher's template for knee replacement surgery could have had more than one drilling hole if an implant containing two pegs—which was commonplace and widely known in the art—was to be implanted. Ex. 1102 ¶¶127 (used cutting guides having multiple drill holes "at least 500 times" before 2002); *id.* ¶131. Such a template certainly would have been obvious in view of Woolson.

b. Woolson

Woolson discloses a "conventional cutting guide 72" having two drilling holes that provide two cutting paths through a portion of the joint when the guide is placed on the joint:

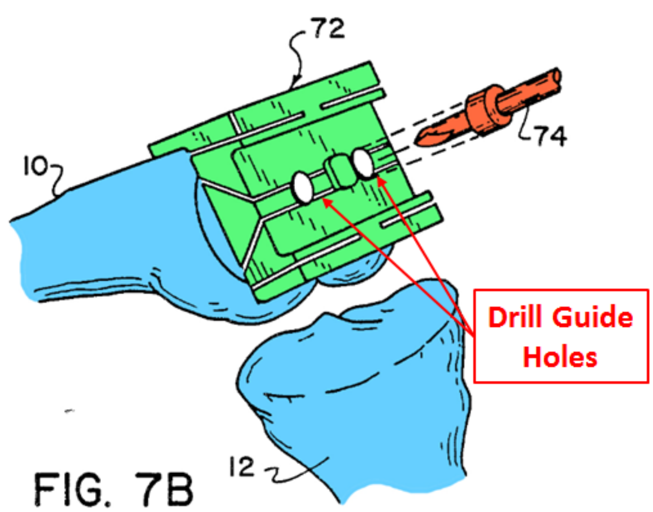
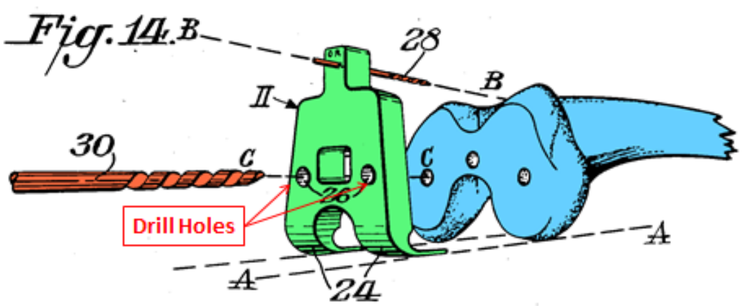


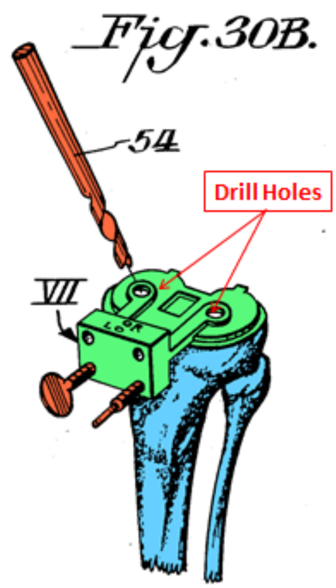
FIG. 7B

Ex. 1031, Fig. 7B. The resulting holes "correspond to the pegs in the actual femoral prosthesis." *Id.*, 6:58-63. Thus, it would have been obvious to a POSITA to modify the knee joint instrument shown in Figure 13c of Radermacher to include two drilling holes as disclosed in Woolson, or to modify Woolson to include the patient-specific surface disclosed in Radermacher. Ex. 1102 ¶¶124-31.

c. Knowledge of a POSITA

Moreover, Woolson is just one of many prior art references that disclosed blocks having first and second drilling holes. Numerous other references disclose blocks containing two drilling holes. For example, Kenna also disclosed blocks for both the femur ("jig II") and tibia ("jig VII") having two drill holes:





Ex. 1032, Fig. 14, 30B; *id.*, 5:34-43, 8:11-22, 9:13-23, 10:15-20. Lacey also disclosed a cutting block having holes 107, 108, for drilling holes 170, 172 in the femur 134 so that the prosthesis "can then [be] affixed in accordance with methods known to those of skill in the art":

Fig. 12

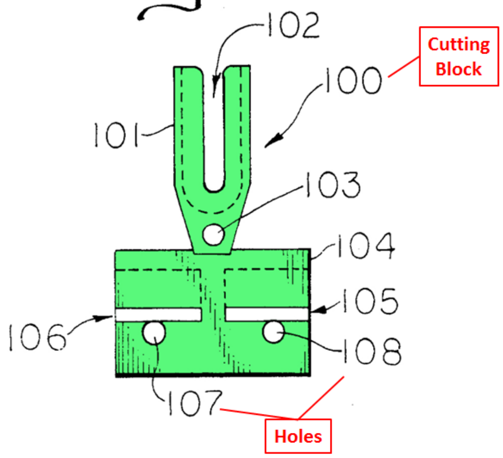
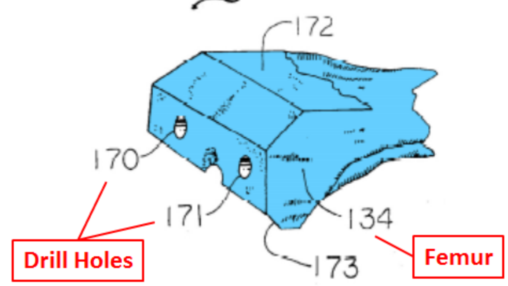


Fig. 17



Ex. 1011, Fig. 12, 17; *id.*, 9:56-68. Medical textbooks also disclosed blocks having two drilling holes. Ex. 1037 at Fig. 29-27, 29-32, 29-34.

Accordingly, blocks having first and second drilling holes were conventional, widely known, and it would have been obvious to a POSITA that the knee joint template in Figure 13c of Radermacher could include two drill holes. Ex. 1102 ¶¶121-31.

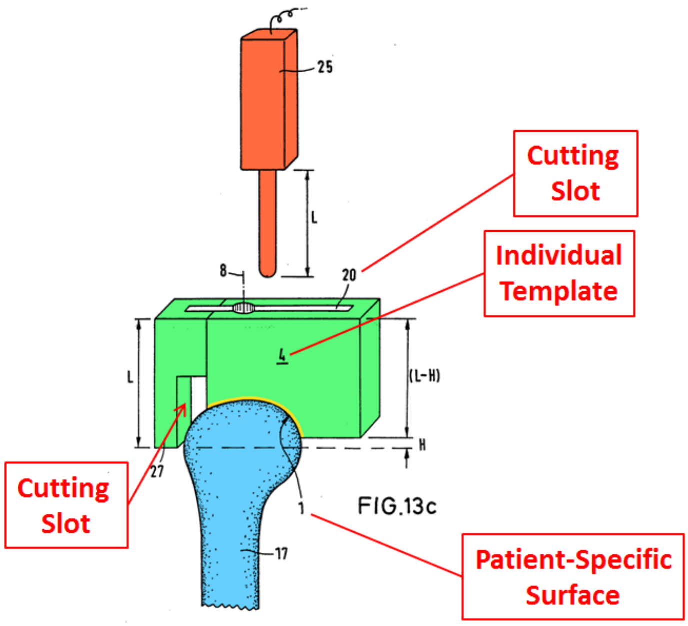
d. Motivation to Combine

A POSITA would have been motivated to modify Radermacher's knee joint template to incorporate two drilling guides as disclosed in Woolson for numerous reasons. Ex. 1102 ¶125, 127, 130-31. First, as described above, Radermacher and

Woolson address the same problem and are in the same field of endeavor. Second, Radermacher expressly states that multiple drill "sleeves" can be used in the template. Ex. 1003 at 13. Third, it would have been readily apparent to a POSITA that the number of drill holes would depend on the implant being used, i.e., if the implant contained two pegs (instead of a single peg as shown in Radermacher), then the block would also contain two drilling guides. Ex. 1102 ¶130-31. And such implants were commonplace. *Id.* ¶127, 131. Alternatively, it would have been obvious to a POSITA that Woolson's "conventional cutting guide" could be modified to include a patient-specific surface as disclosed in Radermacher. *Id.* ¶130. Accordingly, Claim 96 would have been obvious and is unpatentable.

3. Dependent Claim 97

Claim 97 recites that first and second guides are slots. Radermacher's knee arthroplasty template comprises two "slots" (defining cuts 20a and c) and multiple cutting surfaces (20b, d). Ex. 1003 at Fig. 13a, 13c, 30.



Moreover, Radermacher states the template may include additional tool guides, including "saw templates" (*id.* at 13), which a POSITA would have understood to include cutting slots. Ex. 1102 ¶132. A POSITA also would have understood that the additional cut planes (20b or 20d) could have been formed from slots rather than cutting surfaces. Ex. 1102 ¶133 (slots and surfaces were "interchangeable"). Indeed, many cutting blocks were sold in two versions—one with cutting slots and one with cutting surfaces—so that the surgeon could choose his/her preferred type of guide. *Id.*

Even if Radermacher alone did not disclose or render obvious a block comprising two cutting slots, such a block would have been obvious to a POSITA in view of Woolson. As shown in Fig. 7A below, Woolson discloses a "conventional cutting guide 72" that includes at least four cutting slots. Ex. 1031, 6:63-64.

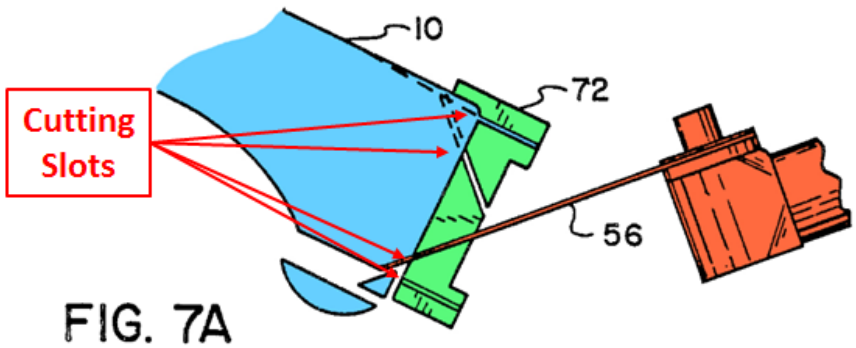


FIG. 7A

Id., Fig. 7A. A POSITA would have immediately recognized that the cutting paths in Radermacher's template could be defined by slots (as in Woolson) rather than surfaces. Ex. 1102 ¶¶132-34. In addition, a POSITA would have immediately recognized that Woolson's slots could have been incorporated into Radermacher's template if the surgeon was implanting the type of implant used in Woolson. *Id.* Alternatively, a POSITA would have been motivated to modify the block in Woolson to include a patient specific surface as disclosed in Radermacher. *Id.*

4. Dependent Claims 98-108

Claims 98-108 recite trivial limitations specifying the orientation and/or number of the guides, all of which were common in the art and disclosed by Radermacher and/or Woolson, as set forth in the claim chart below. Ex. 1102 ¶¶135-46.

5. Independent Claim 109

Claim 109 is similar to Claim 95, but does not require guides that define paths that are aligned relative to a biomechanical or anatomical axis. In addition, claim 109 recites that the block has "two or more slots" rather than "first and second guides." As discussed above for Claim 97, a block having two or more slots would have been obvious in view of Radermacher and Woolson. Additional differences between Claims 109 and 95 are addressed below.

a. A Patient-Specific Surface that Is Substantially a Negative of a Patient's Joint Surface

Claim 109 recites that the patient-specific surface is substantially a negative of a portion of a diseased or damaged *surface* of the joint, rather than a diseased or damaged *cartilage surface*.[4] Because Radermacher, either alone or in combination with Alexander, discloses a patient-specific surface that is at least partially a negative of the diseased or damaged *cartilage surface* as described above for claim 95, it also discloses a patient-specific surface that is at least partially a negative of a diseased or damaged *surface*. Ex. 1102 ¶148.

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[4] The term "surface" is broader because it includes, for example, the entire articular surface, which "can comprise cartilage and/or subchondral bone." Ex. 1001, 6:57-58; Ex. 1102 ¶148.

b. The Guides Each Located Along a Plane to Provide a Cutting Path Through the Joint

Claim 109 recites that the guides are each located along a plane to provide a predetermined cutting path through the joint when the patient-specific surface is engaged with the joint. Each of the cutting slots in Radermacher and Woolson are located along a plane and provide a predetermined cutting path that is aligned through a portion of the joint. Ex. 1003 at 30, Figs. 13a-c; Ex. 1031, Figs. 7A-B; Ex. 1102 ¶149. Accordingly, claim 109 is unpatentable for the reasons set forth above in addition to the reasons discussed with regard to claims 95 and 97.

6. Independent Claim 110

Claim 110 also recites that the patient-specific surface is substantially a negative of the joint *surface* rather than the *cartilage surface*, and does not require that any guides be aligned relative to an axis of the joint.

a. First and Second Sets of Guides

Claim 110 recites first and second sets of guides. However, a "set of guides" may comprise only one guide. *See* Ex. 1001, Claims 113, 115. Thus, the prior art disclosure of first and second guides discussed above for Claim 95 (and Claim 109) is sufficient to render this limitation obvious. Ex. 1102 ¶151.

However, even if each set of guides is required to comprise more than one guide, this limitation would have been obvious in view of Woolson, which discloses a cutting block comprising several "sets of guides," any two of which could be considered the first and second set.

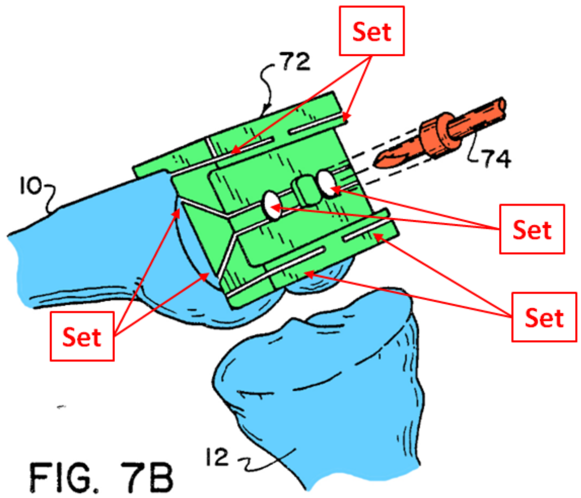


FIG. 7B

Ex. 1031, Fig. 7B.

b. The Sets of Guides Being Located Along Corresponding Axes

Claim 110 recites that each set of guides is "located along corresponding axes." This limitation is met by all guides, regardless of their orientation, because every guide is necessarily located along at least one axis that corresponds to the guide. Claim 110 does not require the guides to correspond to any specific axis. Ex. 1102 ¶152. However, to the extent that this limitation is construed to require the guides to be aligned relative to a biomechanical or anatomical axis of the joint, this limitation was disclosed by Woolson. *See* § VII.A.1.c, *supra*.

Accordingly, the surgical tool in Claim 110 would have been obvious.

7. Dependent Claims 111-116

Claims 111-116 depend from Claim 110 and recite trivial limitations specifying the type or number of the guides, all of which were common in the art and disclosed by Radermacher and/or Woolson, as set forth in the claim chart below. Ex. 1102 ¶¶153-56.

8. Independent Claim 117

Claim 117, like Claim 110, recites first and second sets of guides. In addition, it recites that each set of guides is located along a plane to provide a cutting path through the joint. As discussed above with regards to Claim 109, it was inherent and would have been obvious to a POSITA that guides would be located along a plane to provide a cutting path through a joint. Ex. 1102 ¶157. Since each set of guides can comprise a single guide (*see* Ex. 1001, Claim 118), this is sufficient to render this limitation of Claim 117 obvious. Additionally, it would have been exceedingly obvious that multiple guides could be located along the same plane, as surgical tools having just such a configuration were well-known. *See, e.g.*, Ex. 1031, Fig. 7A; Ex. 1011, Fig. 12; Ex. 1032, Fig. 14, 30B; Ex. 1036, Fig. 11; Ex. 1102 ¶157.

Woolson also discloses this limitation. For example, Woolson discloses several sets of guides, any two of which constitute first and second sets aligned along first and second planes:

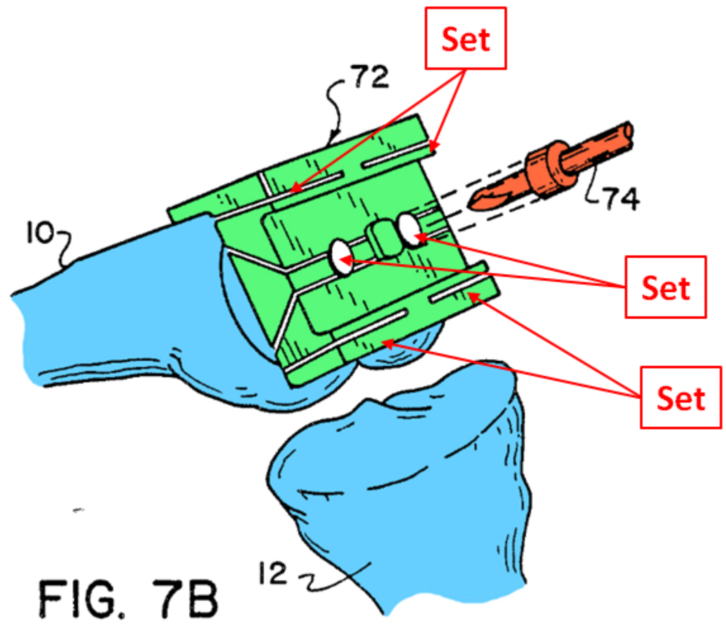


FIG. 7B

Ex. 1031, Fig. 7B.

9. Dependent Claims 118-125

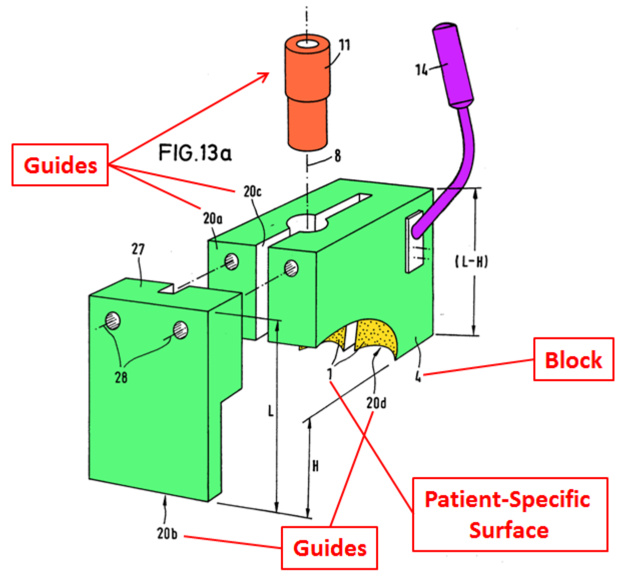
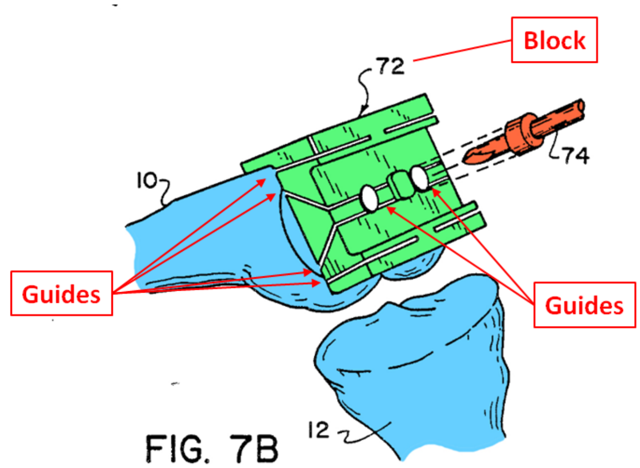
Claims 118-125 depend from Claim 117 and recite trivial limitations that were common in the art and disclosed by Radermacher and/or Woolson, as set forth in the claim chart below. Ex. 1102 ¶¶158-65.

The claim chart below further demonstrates how Claims 95-125 are disclosed by the prior art under Ground 1. *See also* Ex. 1102 ¶166.

Claim 95	Exemplary Disclosure in the Prior Art[5]
[preamble] A patient-specific surgical tool for use in surgically repairing a joint of a patient, comprising:	**Radermacher** discloses a patient-specific surgical tool for use in surgically repairing a joint (e.g., knee, hip). Ex. 1003 at 10, 19, 25-26, 30, Figs. 10a-e, 13a-d.
[a] a block having a patient-specific surface and first and second guides;	**"a patient-specific surface"** **Radermacher** discloses an "individual template" (block) having a "contact face" (surface) that, based on MRI and/or CT data of the patient's joint, is a "copy" or "negative" of the surface of the patient's joint. *See, e.g.*, Ex. 1003 at 10 ("According to the inventive method, there is used a split-field device (*e.g.* a computer or a nuclear spin tomograph) by which split images are produced … , and from these split images, ***data regarding the three-dimensional shape of the osseous structure and the surface thereof are obtained***. In the preoperative planning phase, these data are used as a basis for defining … a ***rigid individual template which … copies the surface of the osseous structure*** in such a manner that the individual template can be intraoperatively set onto these – then freely exposed – contact faces or points in exclusively one clearly defined position[.]" (emphases added)), 12 ("By 3D reconstruction of a tomographically imaged object ..., there is generated a three-dimensional negative mold of parts of the individual natural (i.e., not pre-treated) surface of the osseous structure intraoperatively accessible by the surgeon."), 21, 21-22 ("the defined contact faces 1 are used (as a ***negative***, a 'cast', 'reproduction') for a

[5] The claim chart includes annotated figures that provide non-limiting examples of how the prior art discloses the claim limitations. The limitations may also be met by other, non-annotated, disclosures in the prior art.

	basis for the individual template 4[.]" (emphasis added)), Fig. 18 (referring to "Tomographic images (CT, MR, …)" and creating "individual templates"), Figs. 13a, c. **<u>ConforMIS</u>** admits that Radermacher "discloses that the individual template may be ***custom formed to match the surface of a knee joint***."). Ex. 1024 at 21 (emphasis added); *id.* at 57 ("Radermacher discloses using pre-operative CT imaging data to create a three-dimensional model of an osseous structure (including a knee joint) and using the model to create a ***custom instrument*** ("template") with a tissue ***contacting surface that matches and fits the bone surface*** in a predefined spatial arrangement.")(emphasis added). **<u>"first and second guides"</u>** **<u>Radermacher</u>** discloses that the block can have any number of guides, including multiple guides for drills and saws. Ex. 1003 at 13 ("[A]ny suitable tool guides, particularly drill sleeves, parallel guides, saw templates … can be provided. These tool guides … can be provided in/on the basic body of the individual template[.]"). Radermacher discloses a template (block) having five different "guides" (Fig. 13a), including a drill guide along axis 8 and four cutting guides that define, and result in, cuts 20a-d (shown in Fig. 13b); *see also id.* at 25-26, Figs. 6b, 9.

	 **<u>ConforMIS</u>** admits that "Radermacher further discloses that tool guides can be provided in or on the basic body of the template." Ex. 1024 at 21. **<u>Woolson</u>** discloses a "conventional cutting guide 72" having at least 10 guides including 8 cutting slots and two drill holes, as shown in FIG. 7B. Ex. 1031, Fig. 7B (reproduced below), 6:58-63.  FIG. 7B

[b] the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged cartilage surface of the joint;	*See* claim 95[a]. In addition: **<u>Radermacher</u>** discloses generating a three-dimensional negative mold of "the individual ***natural (i.e. not pre-treated) surface*** of the osseous structure intraoperatively accessed by the surgeon." Ex. 1003 at 12 (emphasis added). Where the structure is a knee joint, the natural, not pre-treated structure would include the cartilage. Ex. 1102 ¶82. Radermacher further discloses that the images are obtained by CT or MRI. Ex. 1003 at 10, 12, 21-22, Figs. 18, 19. **<u>The '302 patent</u>** admits that delineating the surface of diseased cartilage using CT or MRI was within the knowledge of a POSITA. Ex. 1001, 30:32-51 ("The practice of the present invention employs, unless otherwise indicated, ***conventional methods*** of x-ray imaging and . . . computed tomography (CT scan), magnetic resonance imaging (MRI) . . . and positron emission tomography (PET) ***within the skill of the art***. Such techniques are ***explained fully in the literature***." (emphases added)); *id.*, 32:1-34:43. Radermacher further discloses that the individual template is set onto the bone surface "without any further intraoperative devices … and without intraoperative measuring and positioning work." Ex. 1003 at 15. Thus, Radermacher discloses that at least a portion of the template's patient-specific surface is substantially a negative of at least a portion of the diseased cartilage. Ex. 1102 ¶¶82-88. **<u>Alexander</u>** discloses assessing joint cartilage using MRI or CT. Ex. 1004, Abstract ("The methods include converting an image such as an MRI to a three

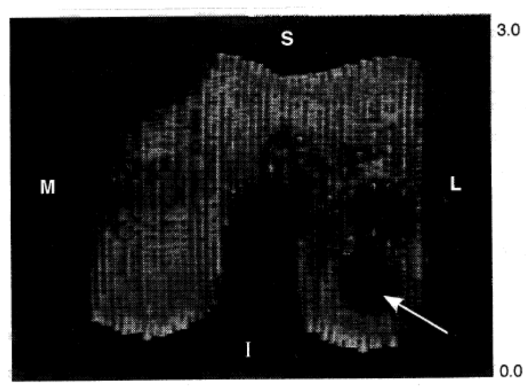
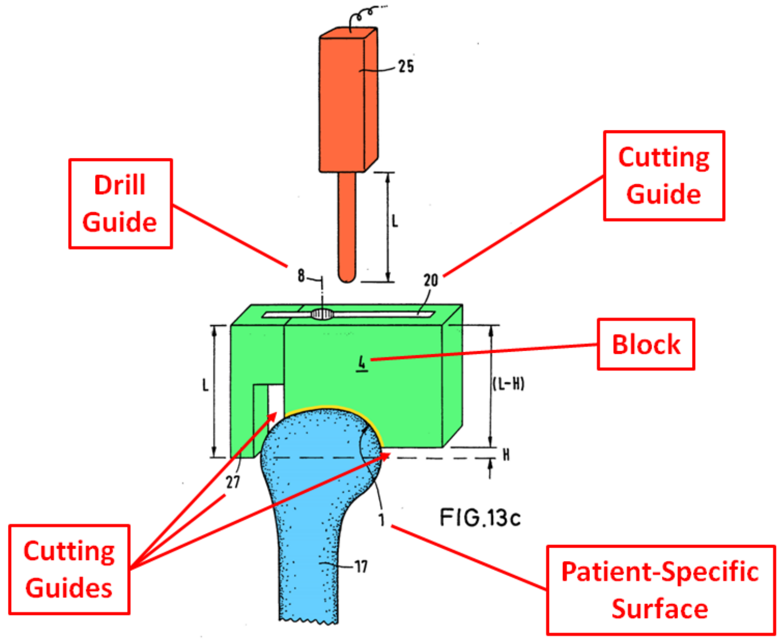
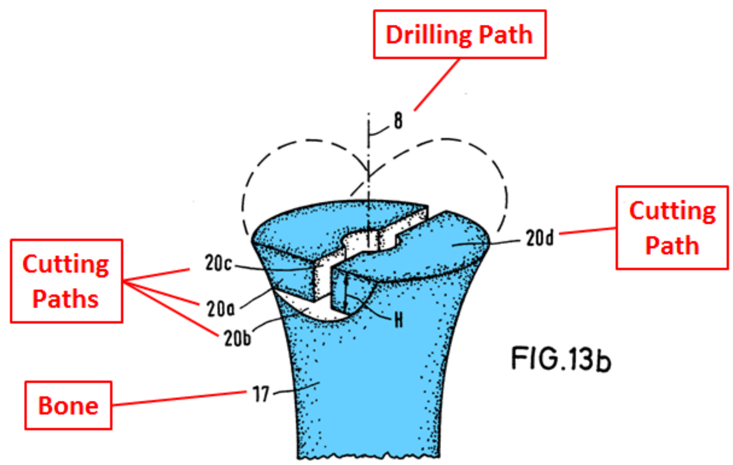
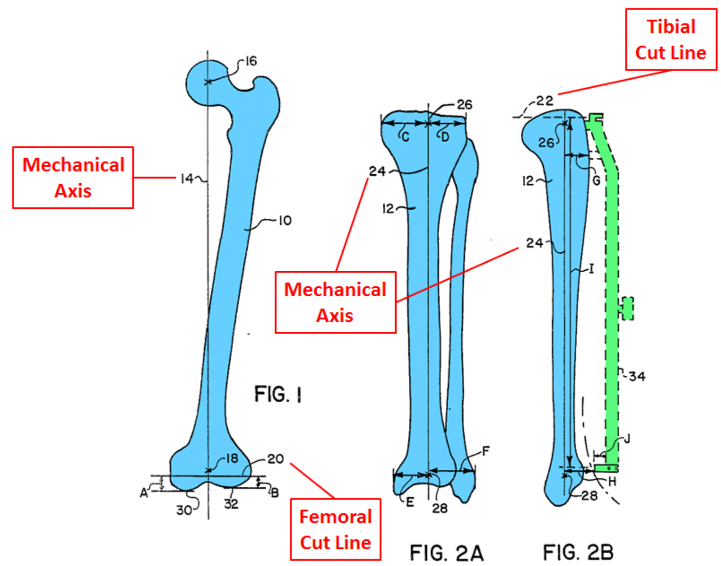
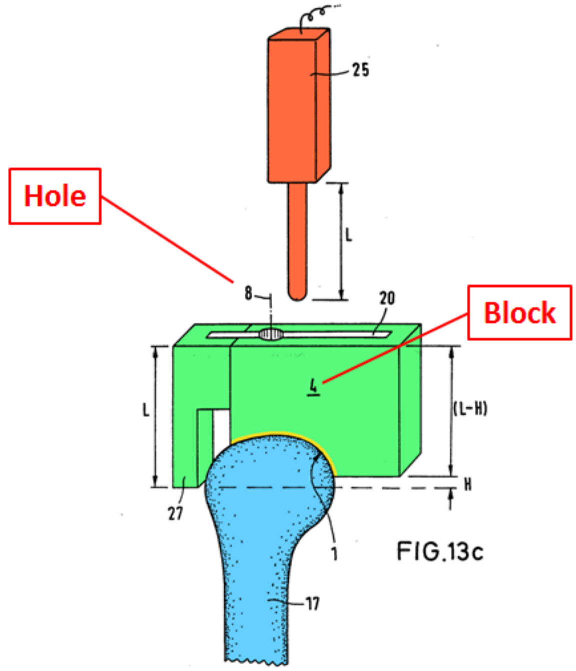
	dimensional map of the cartilage. … Information on thickness of cartilage and curvature of cartilage or subchondral bone can be used to plan therapy."), 2-3, 11:31-12:16 ("[T]he first step 10 represents obtaining an image of the cartilage itself. This is typically achieved using MRI techniques to take an image of the entire knee[.]"), 14:16-32 ("[A] number of internal imaging techniques known in the art are useful for generating a cartilage image. These include magnetic resonance imaging (MRI), computed tomography scanning (CT …)."), *id.* (MRI "can provide accurate assessment of cartilage thickness"), 15:16-26 (3D MRI techniques were "well known"), 26:20-27:26, 61:19-25 (discussing Fig. 18C), Figs. 18-19. Alexander discloses that this data may be used to "guide the choice of therapy," which includes "joint replacement surgery." *Id.*, 42:10-16. Alexander discloses creating a three-dimensional map of the patient's cartilage. *Id.*, 3, 12, 31, Figs. 22A-B, 23A-E.  ***FIG._22B*** Alexander describes using MRI to create a three-dimensional reconstruction of the femoral and tibial bones and cartilage, as shown in Figures 18C-I of Alexander. *Id.*, 61. Alexander also describes the ability to reconstruct the articular cartilage alone. *Id.*, Fig. 19, 61-62.

	 FIG._19 Ex. 1102 ¶¶89-98.
[c] the first and second guides [i] having predetermined positions and orientations relative to the patient-specific surface and	**Radermacher** discloses that the position and orientation of the guides (e.g., 8, 20a, and 20c) are fixed during the preoperative planning. Ex. 1003 at Fig. 13a, 13c; 13 ("These tool guides ... will effect a three-dimensional guiding of the treatment tools or measuring devices exactly as provided by the surgical planning."), 25 (the bore is defined in the surgical planning), 11 (cutting, boring, and milling steps are "three-dimensionally charted in said coordinate system fixed relative to the osseous structure, can be clearly defined in or on the individual template in from of guide means"). Ex. 1102 ¶¶99-102.
[ii] being oriented to provide two predetermined drilling or cutting paths that are aligned relative to a biomechanical or anatomical axis of the joint and through a portion of the joint of the patient when the patient-specific surface is placed against the corresponding diseased or damaged cartilage	**Radermacher:** The multiple predetermined cutting or drilling guides on the individual template inherently provide cutting or drilling paths that are aligned relative to the biomechanical or anatomical axis of the joint and through a portion of the joint. Ex. 1003 at Figs. 13b, 13c. Ex. 1102 ¶¶103-09.

surface of the joint.	 FIG.13c  FIG.13b **<u>The '302 patent</u>** admits that determining a biomechanical or anatomical axis and accounting for such axes in knee arthroplasty was well-known. Ex. 1001, 38:49-39:4. **<u>Knowledge of a POSITA:</u>** Orienting cutting guides to provide drilling or cutting paths that are aligned relative to a biomechanical or anatomical axis and through a

	portion of the joint was within the knowledge of a POSITA, as this was standard practice in knee arthroplasty procedures. Ex. 1102 ¶¶110-20; *see also* Ex. 1033 at 31 ("accurate placement of implant components with respect to the individual mechanical axis of the leg is essential"), 29 ("The geometry of the cut with its position, orientation, and limitations was planned on the basis of CT images .... In addition, topograms could be used to identify the bone axis."); Ex. 1032, 3:1-52, 8:27-30, 9:37-41 (disclosing a knee arthroplasty procedure involving determining the mechanical axis and cutting guides that are aligned relative to that axis). **Woolson** discloses that: "all total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis in both the coronal and the sagittal planes. If achieved, this results in the placement of the total knee prostheses in a common mechanical axis which correspondingly is highly likely to produce a successful long-term result." Ex. 1031, 1:26-36. Woolson discloses determining the mechanical axis and orienting the cutting guide such that a cutting path (e.g., line 22) is aligned relative to (e.g., perpendicular to) the axis:

	 *Id.*, Figs 1, 2A-B; *see also id.*, 4:7-19 ("During the knee replacement surgical procedure, it will be necessary to resection the medial and lateral condyles of the distal femur by cutting along a line 20 which is perpendicular to axis 14."), 2:50-59, 1:46-50, 4:7-6:3, 5:36-41, 6:50-53, 7:32-36, 7:63-67, 1:54-57, 1:8-18. Ex. 1102 ¶¶110-120.
Claim 96	
The patient-specific surgical tool of claim 95, wherein the first and second guides are holes.	**<u>Radermacher</u>** discloses that "any suitable tool guides, particularly ***drill sleeves***, parallel guides, saw templates ... can be provided." Ex. 1003 at 13 (emphasis added). Radermacher discloses one example of a tool guide for use in knee arthroplasty that includes one hole (defining axis 8) configured to accommodate and direct a surgical drill:



Id., Fig. 13c.

Woolson discloses a "conventional cutting guide 72" having two drill holes whose axes extend through the distal end of a bone (e.g., femur) of a joint, as shown in FIG. 7B. Ex. 1031, Fig. 7B (reproduced below), 6:58-63.

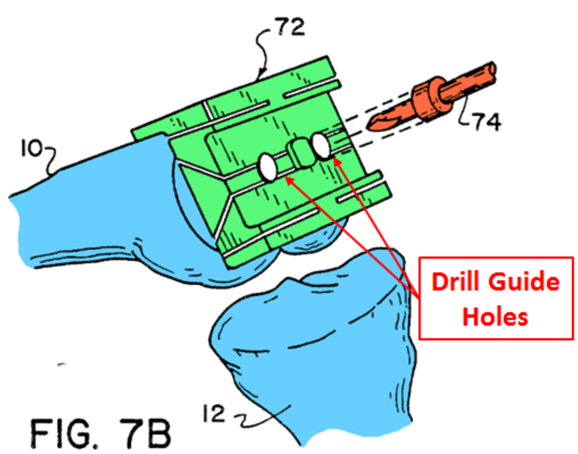
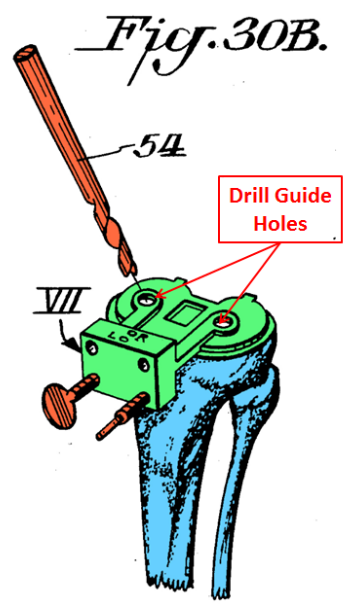
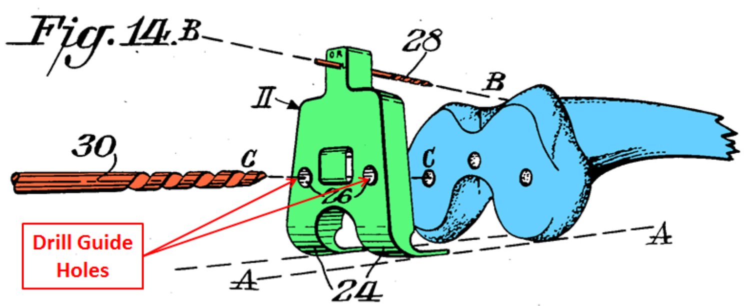
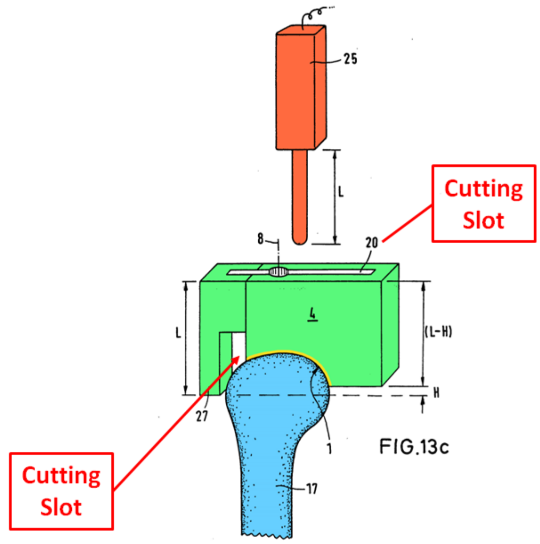
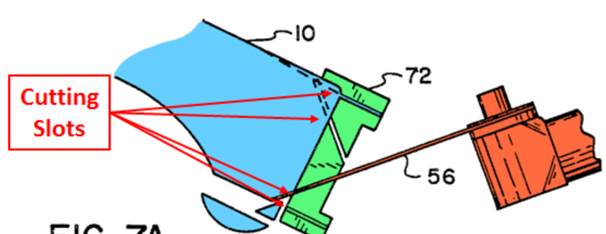


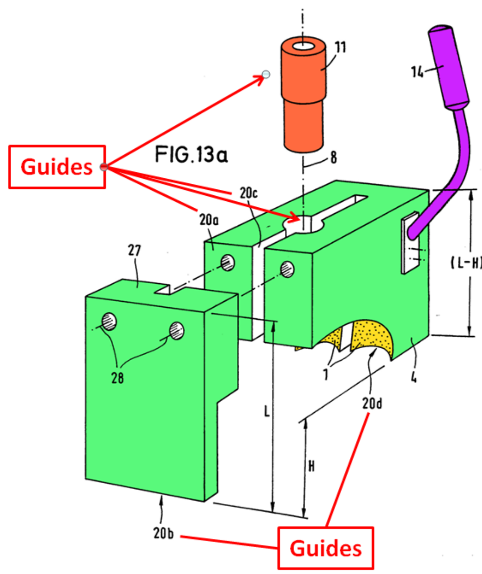
FIG. 7B

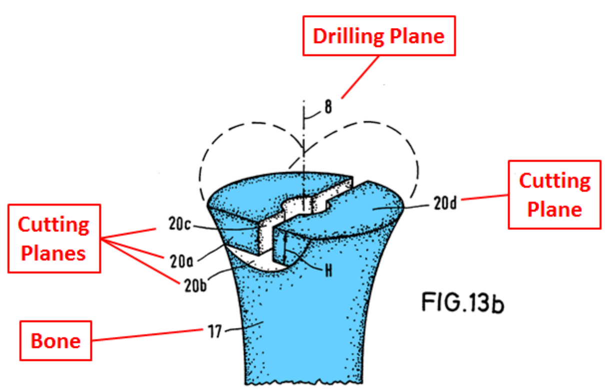
Ex. 1102 ¶¶121-31.

	Knowledge of a POSITA: Cutting blocks having multiple drilling holes were within the knowledge of a POSITA. Ex. 1102 ¶127 (used such blocks at least 500 times prior to 2002); *see also* Ex. 1032, 5:34-43, 8:11-22, 9:13-23, 10:15-20, Figs. 14, 30B (reproduced below); Ex. 1037 at Fig. 29-27, 29-32, 29-34; Ex. 1034, 22:16-23:2, Fig. 10a, 12; Ex. 1033 at Fig. 1(D) (showing a patient-specific block having two "drill guides").  

Claim 97	
The patient-specific surgical tool of claim 95, wherein the first and second guides are slots.	**<u>Radermacher</u>** discloses two cutting slots (20a and c) and additional guides that are cutting surfaces (e.g., 20b, 20d).  Ex. 1003 at 13, Figs. 13a, 13c. Radermacher discloses that the template may include additional tool guides, including "saw templates." *Id.*, 13. A POSITA would have understood that guide surfaces and slots are interchangeable, and that Radermacher's cutting guide surfaces (e.g., 20b, 20d) could have been "slots." Ex. 1102 ¶¶132-34. **<u>Woolson</u>** discloses a block comprising first and second cutting slots. Ex. 1031, 6:63-64; *see also id.*, Fig. 7A (showing at least four cutting slots):  FIG. 7A

Claim 98	
The patient-specific surgical tool of claim 95, wherein the first and second guides are aligned along distinct cutting planes when the patient-specific surface is fit to the corresponding portion of the diseased or damaged cartilage surface of the joint.	**Radermacher** discloses first and second guides aligned along distinct cutting planes. Ex. 1003 at 30, Figs. 13a-c. For example, the drill hole (first guide) and the surface defining cutting path 20d (second guide) are aligned along distinct cutting planes. The cutting slot (first guide) that defines cut 20c and the surface (second guide) defining cutting path 20d are aligned along distinct cutting planes. Many other combinations of Radermacher's guides meet this limitation. Ex. 1102 ¶135.





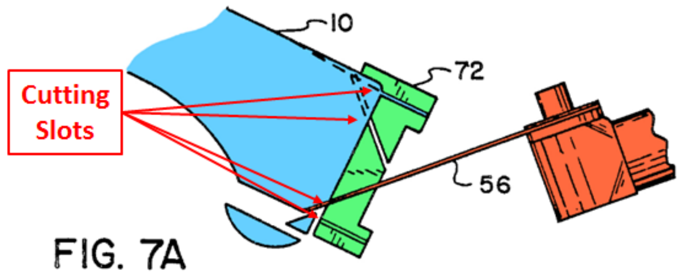
<table>
<tr><td></td><td><u>Woolson</u> discloses first and second guides (e.g., any combination of the four cutting slots shown in Fig. 7A below) aligned along distinct cutting planes:


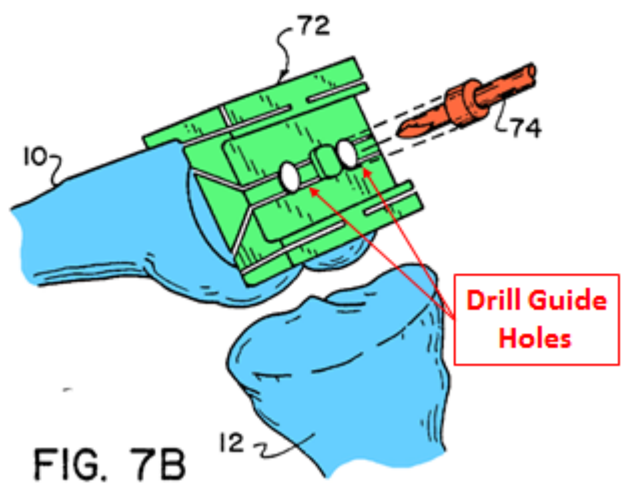
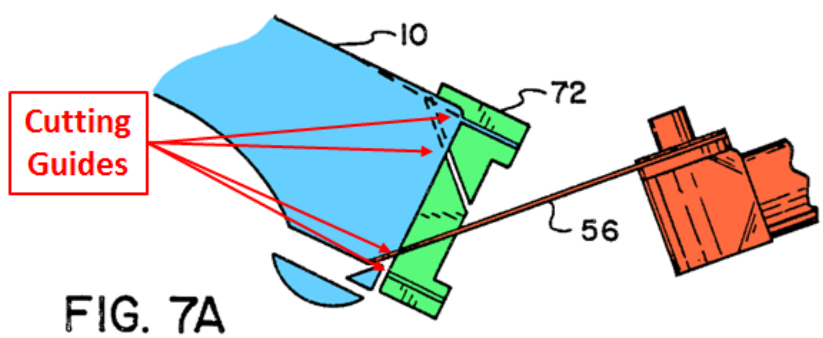
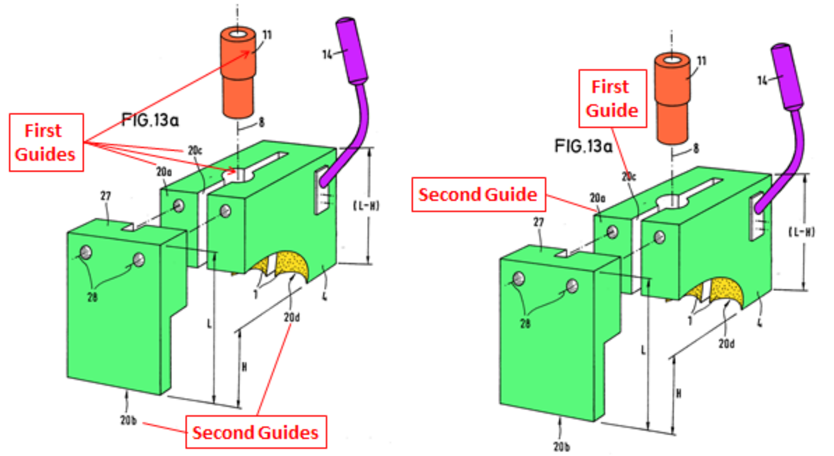
FIG. 7A
Ex. 1031, Fig. 7A.</td></tr>
<tr><td>Claim 99</td><td></td></tr>
<tr><td>The patient-specific surgical tool of claim 98, wherein the first and second guides are co-planar.</td><td><u>Radermacher</u> discloses a drill hole (first guide) and a cutting slot 20c (second guide) that are co-planar as recited in Claim 99, and are aligned along distinct cutting planes as recited in Claim 98. Ex. 1102 ¶136.
<u>Woolson</u> discloses two drill guide holes that are co-planar as recited in Claim 99. Ex. 1031, Fig. 7A-7B. Such holes would also define distinct cutting planes (e.g., two planes extending along the axes of each hole and vertically). Ex. 1102 ¶136.


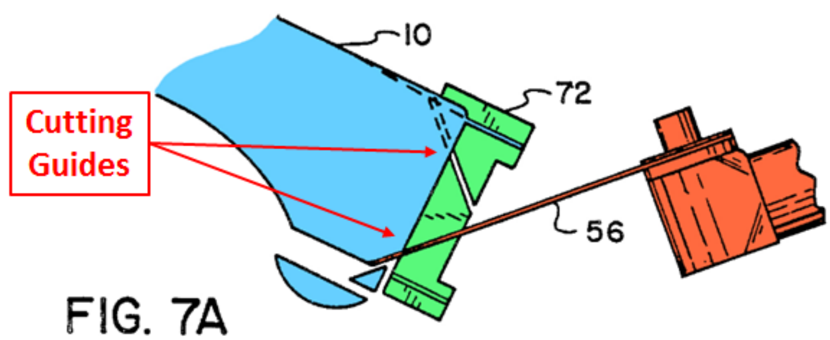
FIG. 7B</td></tr>
</table>

Claim 100	
The patient-specific surgical tool of claim 98, wherein the first and second guides are not co-planar.	*See* Claim 98. **Radermacher** disclose several guides that are not co-planar. For example, guides defining cutting planes 20a, b and d are not co-planar. Ex. 1003 at 30, Figs 13a-d. Any two of these could serve as the first or second guide. **Woolson** discloses several guides that are not co-planar. For example, the four cutting guides shown below are not co-planar:  FIG. 7A Ex. 1102 ¶137.
Claim 101	
The patient-specific surgical tool of claim 98, wherein the first and second guides are oriented at an angle of substantially 90 degrees relative to each other.	**Radermacher** discloses guides that are oriented at an angle of substantially 90 degrees relative to each other. For example, the drill hole, guide 20c, or guide 20a, each of which could be a "first guide," are at right angles to the guides for cut 20b or 20d, each of which could be a "second guide." Alternatively, slot 20a (first guide) is at a right angle to slot 20c (second guide).

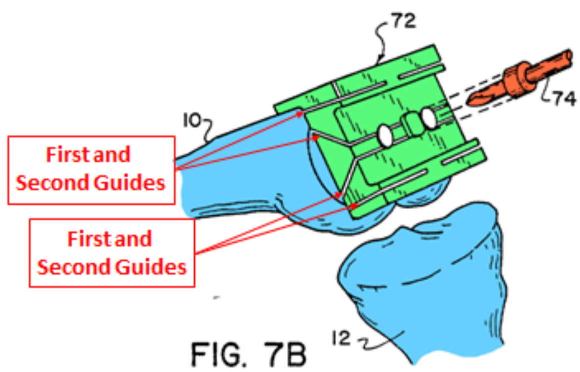


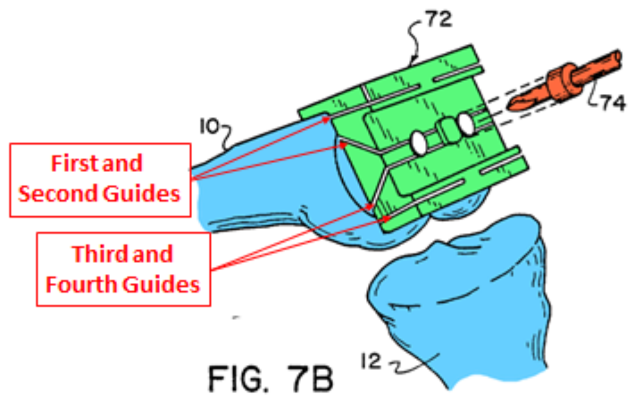
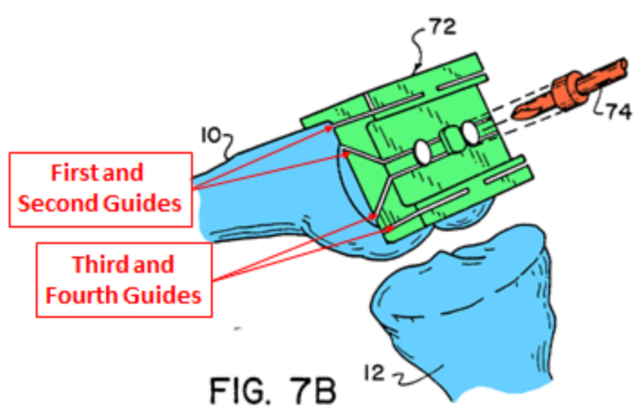
See Claim 95[a]; Ex. 1003 at Figs. 13a-b.

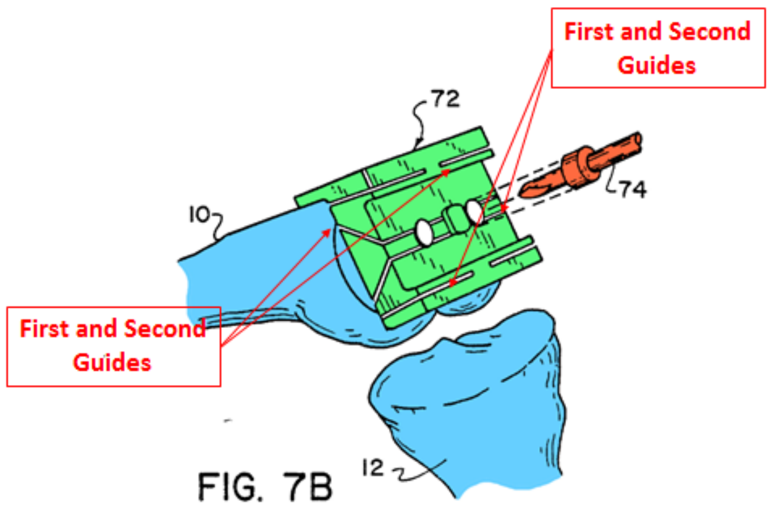
<u>Woolson</u> discloses a "conventional" block where the center-most guides are oriented at an angle of substantially 90 degrees relative to eachother.



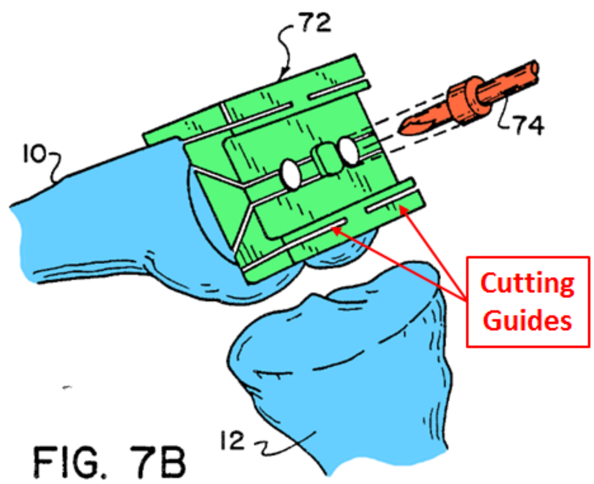
Ex. 1102 ¶138.

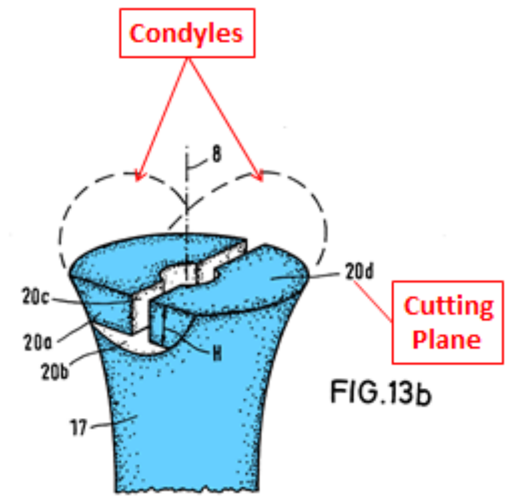
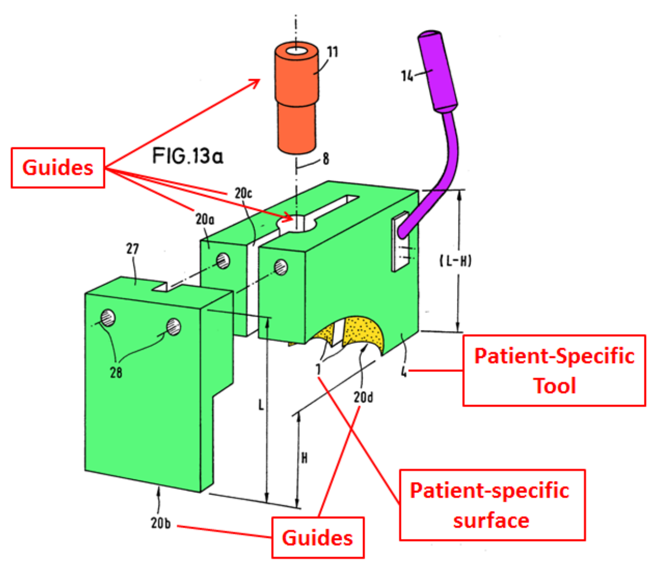
Claim 102	
The patient-specific surgical tool of claim 98, wherein the first and second guides are oriented at an angle different than zero and different than 90 degrees relative to each other.	**<u>Woolson</u>** discloses a "conventional" block wherein a first and second guide may be oriented at an angle that is different than zero and different than 90 degrees relative to each other. Ex. 1031, 6:54-64, Fig. 7A-7B. The first guide may be one of the two anterior guides or one of the two posterior guides, and the second guide may be either of the two center guides. For example:  FIG. 7B It would have been obvious to a POSITA that the first and second guides disclosed in Radermacher could be oriented at an angle that is not zero and not 90 degrees relative to each other depending on the shape of the implant. Ex. 1102 ¶ 139-40.

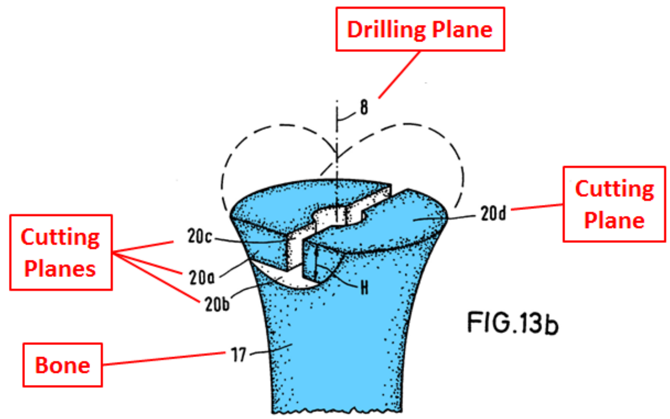
Claim 103	
The patient-specific surgical tool of claim 102, further comprising a third guide aligned along a third distinct cutting plane.	*See* Claim 102. **<u>Woolson</u>** discloses this limitation because it discloses, e.g., four guides aligned along distinct cutting planes. For example, the claimed "third guide' could be either the "third" or "fourth" guide identified below:  FIG. 7B Ex. 1102 ¶141. It would have been obvious to a POSITA that the Radermacher tool could include additional guides oriented along additional distinct cutting planes. *Id.*
Claim 104	
The patient-specific surgical tool of claim 102, further comprising a fourth guide aligned along a fourth distinct cutting plane.	*See* Claims 102-103.  FIG. 7B

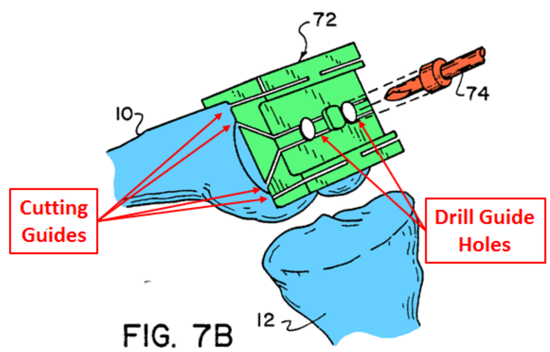
Claim 105	
The patient-specific surgical tool of claim 102, wherein the first guide is oriented through a portion of a first femoral condyle of the joint, and the second aperture [guide][6] is oriented through a portion of a second femoral condyle of the joint when the patient-specific surface is fit to the corresponding portion of the diseased or damaged cartilage surface of the joint.	**Woolson** discloses first and second guides wherein the first guide is oriented through one femoral condyle and the second guide is oriented through a second femoral condyle. Ex. 1031, 6:54-64, Fig. 7A-7B; Ex. 1102 ¶142.  FIG. 7B

[6] This claim is indefinite because the term "the second aperture" lacks antecedent basis. For purposes of this Petition only, Petitioner construes the claim as referring to a second "guide" as recited in Claim 102.

Claim 106	
The patient-specific surgical tool of claim 102, wherein the first guide extends across first and second condyles of the joint when the patient-specific surface is engaged against the corresponding portion of the diseased or damaged cartilage surface of the joint.	**Woolson** discloses that the cuts extend across first and second condyles of the joint. It would have been obvious to a POSITA that such cuts could be made by a single guide. For example, a POSITA would have understood that, based on surgeon preference, the guides below could be replaced with a single guide surface that extends across both condyles.  FIG. 7B Ex. 1102 ¶143. **Radermacher** discloses guide 20d, which extends across first and second condyles of the joint. Ex. 1003 at Fig. 13a-b. It would have been obvious to a POSITA that a second guide could be included at an angle other than zero or 90 in order to shape the bone as described in Woolson. Ex. 1102 ¶144.

	
Claim 107	
The patient-specific surgical tool of claim 98, further comprising a third guide.	**<u>Radermacher</u>** discloses a third guide. Ex. 1003 at Fig. 13a (showing at least five cutting or drilling guides along 20a-d and axis 8); 30, Figs. 13b-c. 

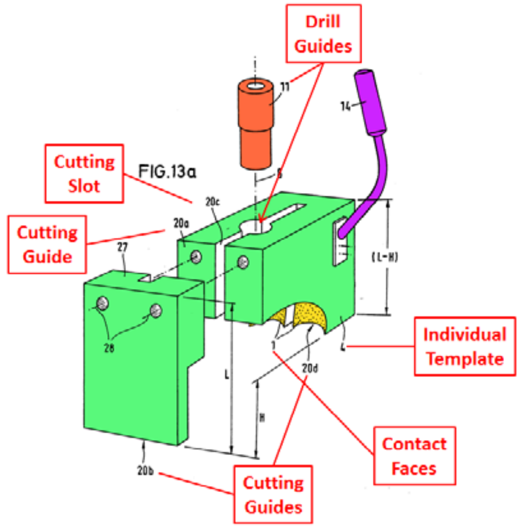
<table>
<tr><td></td><td>

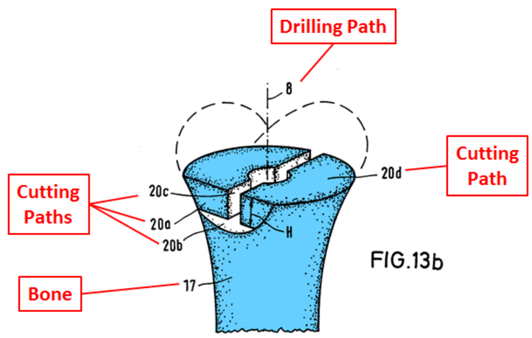
<u>Woolson</u> discloses a third guide (e.g., either drilling hole or any cutting slot that is not the first or second guide):


Ex. 1031, Fig. 7B; Ex. 1102 ¶145.</td></tr>
<tr><th>Claim 108</th><th></th></tr>
<tr><td>The patient-specific surgical tool of claim 98 [sic, 107],[7] wherein the third guide is a slot aligned along a second</td><td><u>Radermacher</u> discloses a "slot," e.g., the slot that defines cutting path 20c. The first and second guides could be any two of the surfaces defining cutting paths 20a, 20b, or 20d, each of which is aligned along a distinct plane.</td></tr>
</table>

[7] This claim is indefinite because "the third guide" lacks antecedent basis. For purposes of this Petition only, Petitioner construes the term as depending from Claim 107.

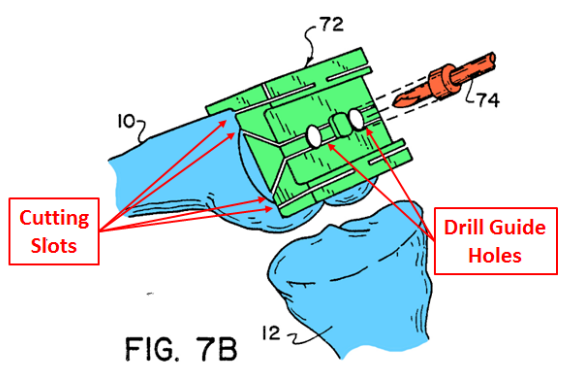
<table>
<tr>
<td>plane to provide a second cutting path that is aligned through a portion of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or damaged cartilage surface of the joint.</td>
<td>





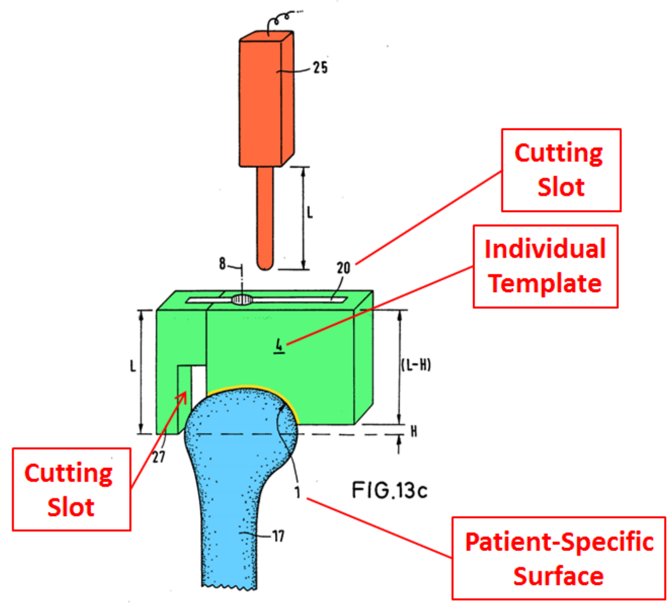
Ex. 1003 at Figs. 13a-b.

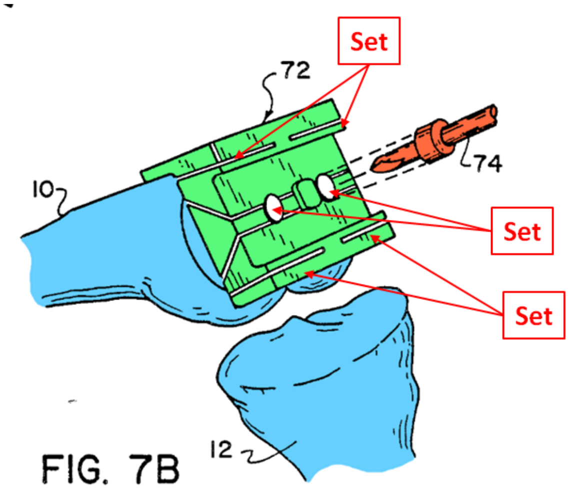
<u>**Woolson**</u> discloses at least four slots aligned along four distinct cutting planes:



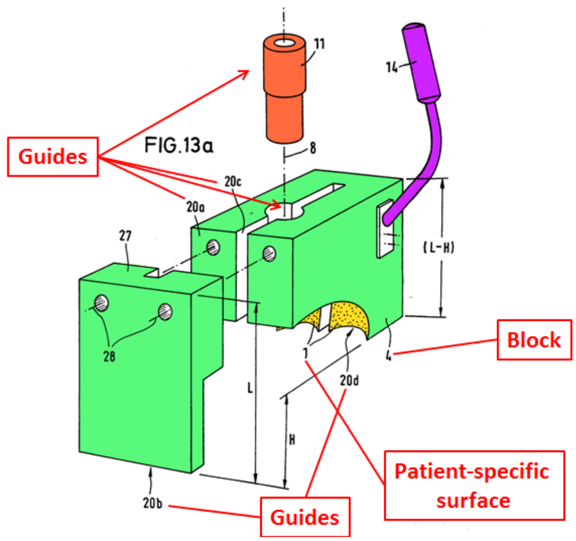
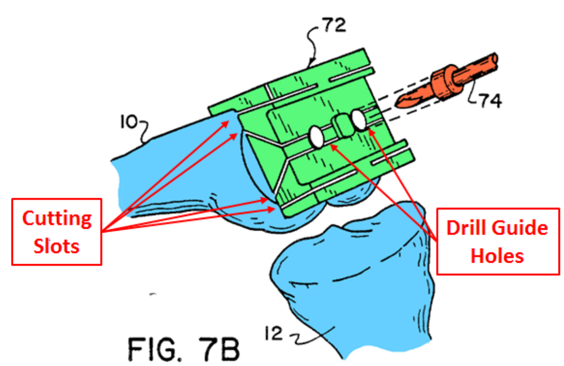
Ex. 1031, Fig. 7A-7B; Ex. 1102 ¶146.
</td>
</tr>
</table>

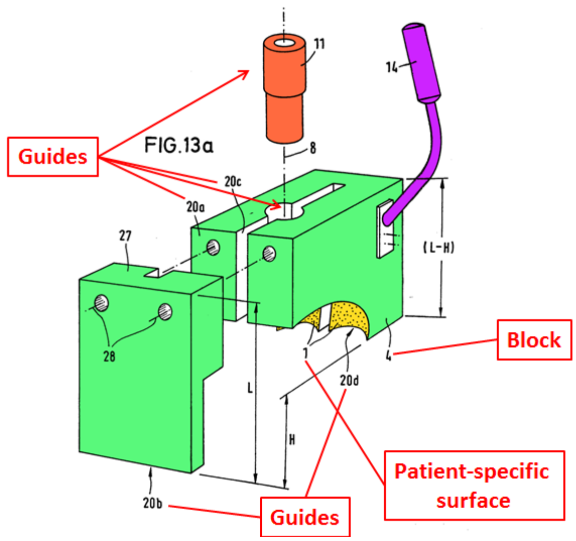
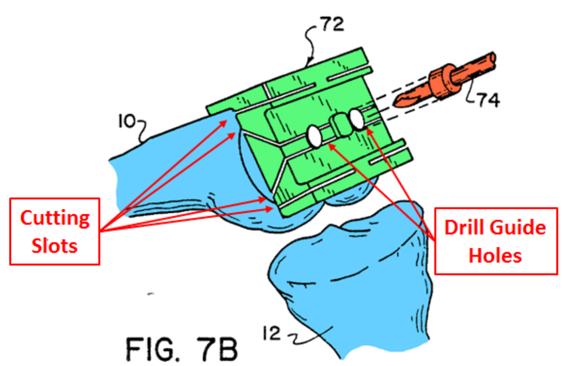
Claim 109	
[preamble] A patient-specific surgical tool for use in surgically repairing a joint of a patient, comprising:	*See* Claim 95[preamble].
[a] a block having a patient-specific surface and two or more slots;	*See* Claims 95[a], 97.
[b] the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged surface of the joint;	*See* Claim 95[b].
[c] the two or more slots having predetermined positions and orientations relative to the patient-specific surface and each being located along a plane to provide a predetermined cutting path for a cutting tool that is aligned through a portion of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or	*See* Claim 95[c]. Each of Radermacher's slots is located along a plane and provides a predetermined cutting path aligned through a portion of the joint:

damaged surface of the joint.	 Ex. 1003 at 30, Figs. 13a-c; Ex. 1102 ¶149. **<u>Woolson</u>** discloses a block containing multiple cutting slots, each of which is located along a plane extending through the joint. Ex. 1031, Figs. 7A-B.
Claim 110	
[preamble] A patient-specific surgical tool for use in surgically repairing a joint of a patient, comprising:	*See* Claim 95[preamble].
[a] a block having a patient-specific surface and multiple guides;	*See* Claim 95[a].
[b] the patient-specific surface having at least a portion that is substantially a negative	*See* Claim 109[b].

of a corresponding portion of a diseased or damaged surface of the joint;	
[c] a first set of guides oriented relative to the patient-specific surface and being located along corresponding axes and defining one or more predetermined paths for a cutting tool that is aligned through a portion of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or damaged surface of the joint; and	*See* Claim 95[c]. It is inherent that the guides are located along corresponding axes. Every guide is located along at least one axis that corresponds to the guide. Ex. 1102 ¶152. To the extent that this limitation is construed to require the guides to be oriented relative to an axis of the joint, the limitation was disclosed by Radermacher and/or Woolson. *See* Claim 95[c][ii]. Because the set of guides can comprise only one guide (*see* Ex. 1001, Claims 113, 115), **Radermacher** (in addition to numerous other references) disclose this limitation. *See* Claim 95[a]; Ex. 1102 ¶152. Even if each set of guides must comprise multiple guides, **Woolson** discloses this limitation. For example, Woolson discloses a cutting block with multiple sets of guides:  FIG. 7B Ex. 1031, Fig. 7B. Any combination of the pictured sets of guides could comprise the first set of guides.

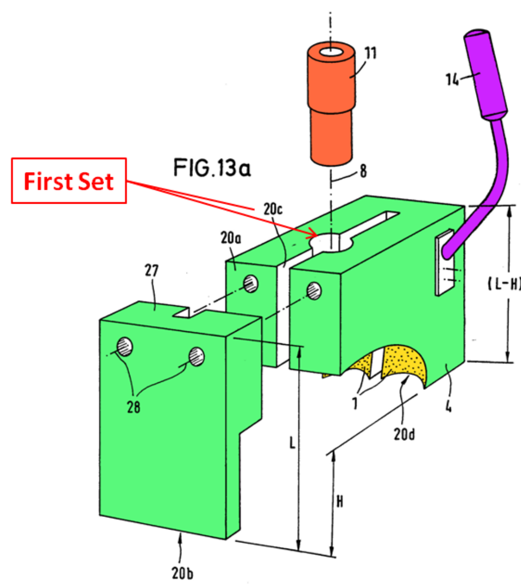
[d] a second set of guide guides [sic] oriented relative to the patient-specific surface and being located along corresponding axes and defining one or more predetermined paths for a cutting tool that is aligned through a portion of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or damaged surface of the joint.	*See* Claims 95[c], 110[c].
Claim 111	
The patient-specific surgical tool of claim 110, wherein the first set of guides are drilling holes.	*See* Claims 96, 110. Ex. 1102 ¶153.
Claim 112	
The patient-specific surgical tool of claim 110, wherein the second set of guides are cutting slots sized to accommodate a surgical saw.	*See* Claims 97, 110. Ex. 1102 ¶154.

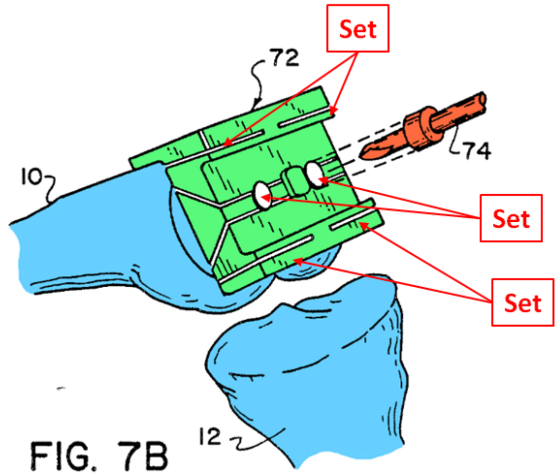
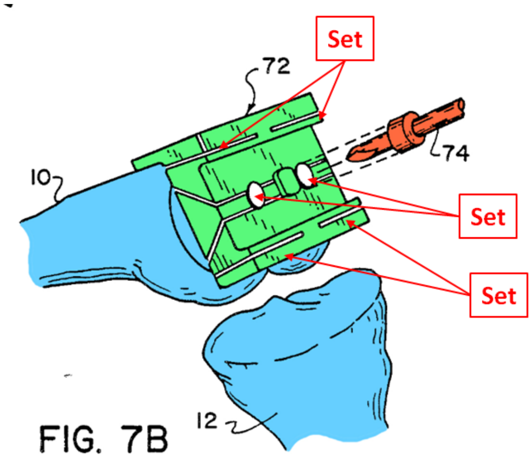
Claim 113	
The patient-specific surgical tool of claim 110, wherein the first set of guides includes only one guide.	**Radermacher** discloses that the first and/or second sets of guides can include only one guide. *See* Ex. 1003 at 30, Figs. 13a, c. Radermacher shows a femoral cutting block with at least five guides, any one of which could comprise a first or second set of guides having only one guide:  Ex. 1003 at Fig. 13a. Ex. 1102 ¶155. **Woolson** also discloses this limitation. For example, Woolson discloses a cutting block with at least four guides:  Ex. 1031, Fig. 7B. Any one of the pictured guides could comprise the first set of guides.

Claim 114	
The patient-specific surgical tool of claim 110, wherein the first set of guides includes more than one guide.	**Radermacher** discloses that the first set of guides can include more than one guide. *See* Ex. 1003 at 30, Figs. 13a, c. Radermacher shows a femoral cutting block with five guides, any two of which could comprise a first set of guides having more than one guide:  Ex. 1003 at Fig. 13a, c. In addition, **Woolson** discloses an embodiment having at least four guides:  Ex. 1031, Fig. 7B. Any two of the pictured guides could comprise a set having more than one guide. Ex. 1102 ¶156.

Claim 115	
The patient-specific surgical tool of claim 110, wherein the second set of guides includes only one guide.	*See* Claim 113.
Claim 116	
The patient-specific surgical tool of claim 110, wherein the second set of guides includes more than one guide.	*See* Claim 114.
Claim 117	
[preamble] A patient-specific surgical tool for use in surgically repairing a joint of a patient, comprising:	*See* Claim 95[preamble].
[a] a block having a patient-specific surface and first and second sets of guides;	*See* Claims 95[a], 110[c], [d].
[b] the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged cartilage surface of the joint;	*See* Claim 95[b].

[c] a first set of guides oriented relative to the patient-specific surface and being located along a first plane to define a predetermined cutting path for a cutting tool that is aligned through a portion of a bone of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or damaged surface of the joint; and	*See* Claim 110[c], 109[d].
[d] a second set of guides oriented relative to the patient-specific surface and being located along a second plane to define a predetermined cutting path for a cutting tool that is aligned through a portion of a bone of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or damaged of [sic] the joint.	*See* Claim 110[d], 109[c], 117[c].

Claim 118	
The patient-specific surgical tool of claim 117, wherein the first set includes only one guide.	See Claim 113.
Claim 119	
The patient-specific surgical tool of claim 117, wherein the first set includes more than one guide.	*See* Claims 99, 114, 117. **Radermacher** discloses a first set of guides that includes guide 20c and the drilling hole, which are located along a first plane. Ex. 1003 at 30, Figs. 13a-d.  **<u>Woolson</u>** discloses at least three sets of guides, each of which could be the "first set," as shown below. Ex. 1031, Fig. 7B.

	 FIG. 7B Ex. 1102 ¶159.
Claim 120	
The patient-specific surgical tool of claim 119, wherein the second set includes only one guide.	*See* Claim 113. Ex. 1102 ¶160.
Claim 121	
The patient-specific surgical tool of claim 119, wherein the second set includes more than one guide.	**Woolson** discloses a "conventional" block comprising at least eight guides. Any of the sets shown below that is not considered a "first set" could constitute the "second set." Ex. 1031, 6:54-64, Fig. 7A-7B; Ex. 1102 ¶161.  FIG. 7B

Claim 122	
The patient-specific surgical tool of claim 117, wherein the first and second set of guides are co-planar.	*See* Claim 99. As discussed above the guide "sets" may consist of a single guide. Ex. 1102 ¶162. **<u>Radermacher</u>** discloses a drill hole (first set) and cutting slot 20c (second set) that are co-planar. Ex. 1003 at Figs. 13a, c. **<u>Woolson</u>** discloses a first slot (first set) and second slot (second set) that are co-planar. Ex. 1031 at Figs. 7A-B.
Claim 123	
The patient-specific surgical tool of claim 117, wherein the first and second set of guides are not co-planar.	*See* Claim 100, as discussed above the guide "sets" may consist of a single guide. Ex. 1102 ¶163.
Claim 124	
The patient-specific surgical tool of claim 117, wherein the first and second set of guides are oriented at an angle of substantially 90 degrees relative to each other.	*See* Claim 101, as discussed above the guide "sets" may consist of a single guide. Ex. 1102 ¶164.
Claim 125	
The patient-specific surgical tool of claim	*See* Claim 102, as discussed above the guide "sets" may consist of a single guide. Ex. 1102 ¶165.

117, wherein the first and second set of guide slots [sic] are oriented at an angle different than zero and different than 90 degrees relative to each other.	

B. Ground 2: Claims 95-125 Are Unpatentable as Obvious Over Radermacher, Fell, and Woolson.

Ground 2 relies on Fell rather than Alexander to show that it would have been obvious for Radermacher's patient-specific to include a portion that is substantially a negative of a corresponding cartilage surface. Unlike Alexander, which discloses imaging the cartilage and bone surfaces of the knee joint, Fell discloses a patient-specific implant that replaces the meniscus, which is cartilage that exists between a femoral condyle and a corresponding tibial plateau. Ex. 1102 ¶168. Fell teaches that the size and shape of the implant may be customized for each patient using MRI data. Ex. 1005 at 14:13-15:21. Fell explains that the MRI data is used to determine the shape of the femur and tibia, including the articular cartilage:

> [E]ach patient receives one or more meniscal devices that are custom tailored for the individual by producing a contour plot of the femoral and tibial mating surfaces and the size of the meniscal cavity. Such a contour plot may be construct from imaging data, i.e. MRI data, by a suitable computer program. From the contour plot, the correct surface

> geometry of the meniscal device is determined from the shape of the respective tibial plateau … and the shape of the femoral condyle …. In general, ***the shapes just mentioned also include the articular cartilage***, which, in general, is maintained substantially intact.

Id. at 15:12-21 (emphasis added); *see also id.* at 22:6-9 ("From the MRI images obtained, contour radii plots and surface descriptions of the femoral condyle and tibial plateau of the affected area, ***complete with articular cartilage***, are generated and analyzed ...." (emphasis added)). Fell further discloses that the surface of the implant device is designed to "substantially mate with the corresponding tibial and femoral surfaces," which include the cartilage surfaces. *Id.* at 13:15-17. Thus, Fell discloses: (1) using MRI to determine the size, shape, and curvature of an articular cartilage surface: and (2) creating a patient-specific device that is substantially a negative of that cartilage surface.

A POSITA would have been motivated to combine the teachings of Radermacher and Fell, and thus modify Radermacher's template to be substantially a negative of the cartilage surface for several reasons. Ex. 1102 ¶¶174-80. First, both references relate to methods of treating damaged cartilage in a knee joint. Second, both references disclose the use of MRI for creating patient-specific medical devices having inner surfaces that match the patient's natural joint surface.

Thus, they address the same problem, are in the same field of endeavor, and use the same imaging technology (e.g., MRI). *Id.*

Third, Radermacher expressly suggests such a combination. Radermacher states that individualized surgical procedures were "lagging behind the technology of implant manufacture." Ex. 1003 at 6. Thus, Radermacher provides the motivation for a POSITA to consider patient-specific implant technologies, such as the implant described in Fell, and to adapt those technologies to cutting guides as disclosed in Radermacher. Ex. 1102 ¶179. Since Fell discloses creating a patient-specific implant that matches the patient's cartilage surface, a POSITA would have understood that Radermacher's template could also match the cartilage surface. *Id.* ¶¶174-80.

Fourth, a POSITA would have recognized that such a patient-specific template would simplify the surgery. *Id.* ¶178. Finally, as with Ground 1, the modification would merely: (a) require the combination of one known element (Fell's MRI data which includes the cartilage surface) with another known element (Radermacher's MRI data of the joint surface) to obtain a predictable result (a device tailored to the patient's cartilage surface); and (b) represent a choice from a finite number of identified, predictable solutions (imaging the bone surface and/or the cartilage surface), with a reasonable expectation of success. *Id.*

Accordingly, the claim limitations requiring a surface of the block to be substantially a negative of the cartilage surface would have been obvious over the combination of Radermacher and Fell. Because the relevant disclosures of Radermacher and Woolson, as well as the knowledge of a POSITA, are the same as in Ground 1, the chart below provides only the claim elements to which Fell is relevant along with the additional corresponding disclosure from Fell. *See* Ex. 1102 ¶181.

Claims 95 & 117	Exemplary Disclosure in Fell
[b] the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged cartilage surface of the joint;	**Fell** discloses a patient-specific surface, at least a portion of which is substantially a negative of a corresponding portion of a diseased or damaged cartilage surface. *See, e.g.*, Ex. 1005 at 14, 15, 22.
Claims 109 & 110	
[b] the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged surface of the joint;	*See* Claim 95[b], above, for the relevant disclosure in Fell.

VIII. SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

Secondary considerations should be considered but do not control an obviousness conclusion, particularly where, as here, a strong prima facie showing of obviousness exists. *Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007); *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Petitioner is unaware of evidence of secondary considerations, and any such evidence that ConforMIS may provide cannot possibly outweigh the strong *prima facie* case of obviousness. Petitioner reserves the right to respond to evidence of secondary considerations in due course.

IX. CONCLUSION

For the reasons set forth above, Petitioner has established a reasonable likelihood that Claims 95-125 of the ’302 patent are unpatentable as obvious in view of the prior art. Petitioner therefore requests that the Board institute an *inter partes* review of each of those claims.

Petitioner authorizes the Patent and Trademark Office to charge any required fees to Deposit Account No. 11-1410, including the fee set forth in 37 C.F.R. § 42.15(a) and any excess claim fees.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 26, 2017

By: /Christy G. Lea/

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that foregoing **PETITION FOR INTER PARTES REVIEW OF CLAIMS 95-125 OF U.S. PATENT NO. 8,062,302**, exclusive of the parts exempted as provided in 37 C.F.R. § 42.24(a), contains 13,668 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24(a).

Dated: January 26, 2017

By: /Christy G. Lea/

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR INTER PARTES REVIEW OF CLAIMS 95-125 OF U.S. PATENT NO. 8,062,302** and **Exhibits 1001, 1002-1017, 1019, 1021-1022, 1024-1028, 1031-1034, 1036-1037, 1041-1043, 1070, 1102** are being served on January 26, 2017, via FedEx Priority Overnight to counsel of record for U.S. Patent No. 8,062,302 patent owner **CONFORMIS, INC.**, at the addresses below:

Correspondence Address of Record for U.S. Patent No. 8,062,302 at the U.S. Patent and Trademark Office:

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