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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. IPR2017-00778
U.S. Patent No. 8,062,302

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-3, 5-8, 11, 13, 18, 20-21, 24-25, 28-29, 34-38, and 47 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	Declaration of Jay D. Mabrey, M.D.
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")
1071-1089	***Exhibit Number Not Used***
1090	Aaron A. Hofmann et al., *Effect of the Tibial Cut on Subsidence Following Total Knee Arthroplasty*, 269 Clinical Orthopaedics and Related Research 63 (1991) ("Hofmann")
1091-1094	***Exhibit Number Not Used***
1095	Excerpts from ConforMIS, Inc.'s Preliminary Infringement Disclosures in *ConforMIS, Inc. v. Smith & Nephew, Inc.*, Civil Action No. 1:16-cv-10420-IT (D. Mass.)

Petitioner Smith & Nephew, Inc. ("Petitioner" or "Smith & Nephew") hereby requests *inter partes* review in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 et seq. of Claims 1-3, 5-8, 11, 13, 18, 20-21, 24-25, 28-29, 34-38, and 47 of U.S. Patent No. 8,062,302 ("the '302 patent"), which issued 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 is the real party-in-interest. Smith & Nephew 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)

Smith & Nephew 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 St., 14th Fl. Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (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 St., 14th Fl. Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (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 Telephone: (206) 405-2000 Facsimile: (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@knobbe.com.

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

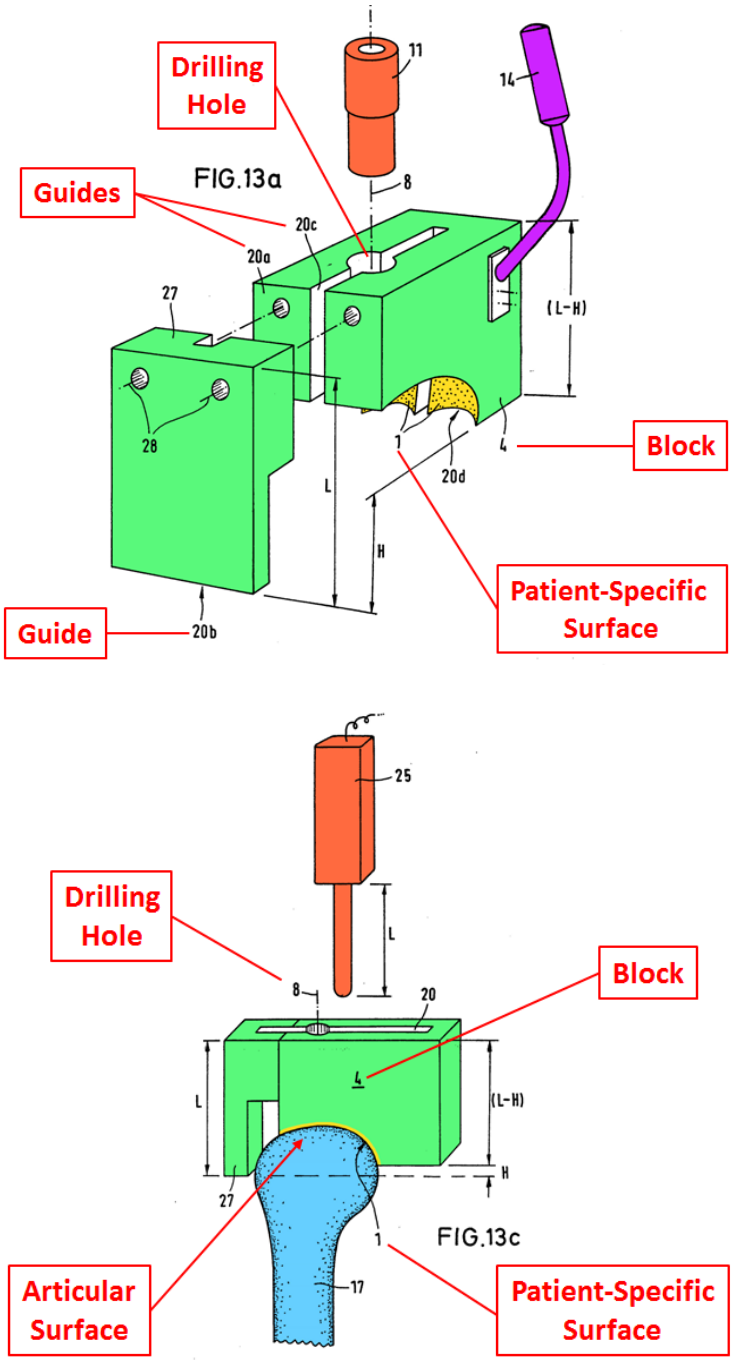
Petitioner certifies that the '302 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition. This Petition is being filed within one year of service of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

II. SUMMARY OF ISSUES PRESENTED

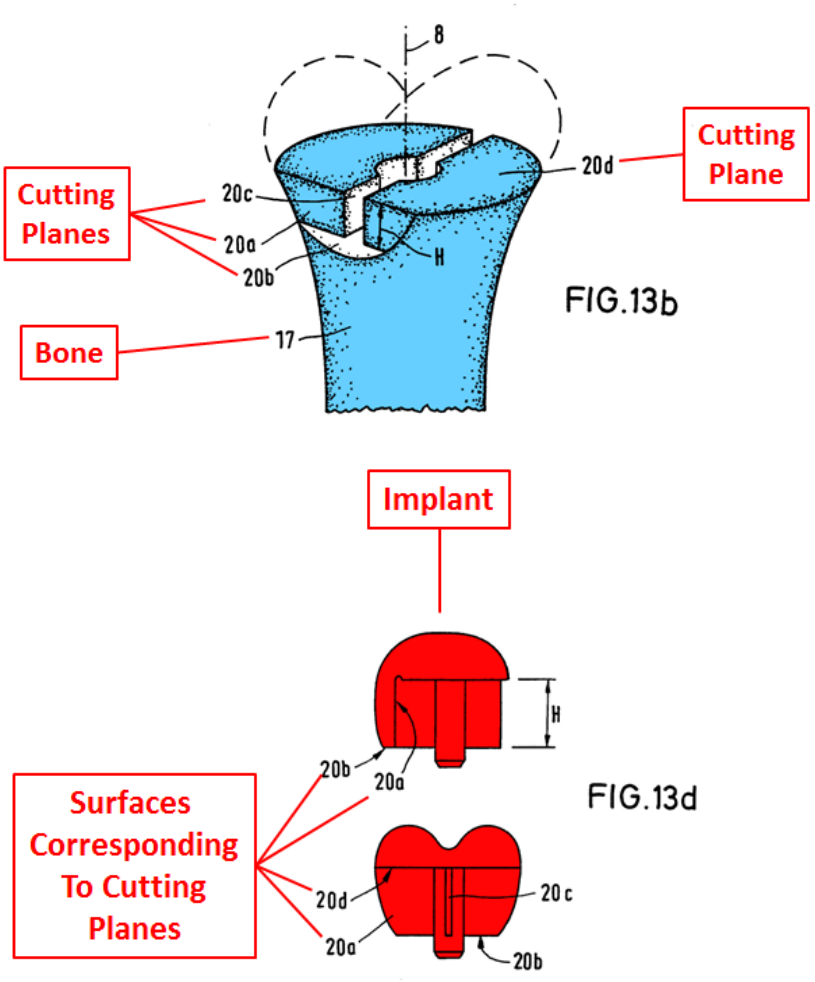
The challenged claims relate to a tool (sometimes referred to as a "cutting guide" or "cutting block") for performing joint surgery (e.g., preparing the femur or tibia in knee replacement surgery). The tool comprises a block that includes: (1) a patient-specific surface that is "substantially a negative" of an articular surface of a joint; and (2) two drilling holes, e.g., for guiding a surgical drill. The dependent claims include trivial limitations relating to the orientation of the holes or the addition of other conventional components.

Such tools were not patentable at the time of the patent's earliest possible priority date in November, 2002. By that time, surgical tools having the purportedly inventive feature—a patient-specific surface—had been described in many publications. For example, in 1993, nearly a decade before ConforMIS's earliest possible priority date, Radermacher disclosed using MRI and/or CT data to create a tool comprising a block ("individual template" 4) having a patient-specific

surface ("contact faces" 1) that is substantially a negative of a patient's articular joint surface. The tool included a drill hole (about axis 8) and several cutting guides (defining planes 20a-d):



During surgery, the drill hole and cutting guides guided the surgeon's tools to provide a resected bone (Fig. 13b) onto which an implant (Fig. 13d) can be seated:



As described in detail below, many other references also disclosed tools having patient-specific surfaces and guides for guiding surgical tools.

The claims at issue in this Petition specify that, in addition to the patient-specific surface, the block comprises two drilling holes. As shown above, the exemplary block for a knee joint surgery illustrated in Figure 13 of Radermacher included a single drill hole; however, that is only because the corresponding

implant included a single peg (*see* Figure 13d, above). A person of ordinary skill in the art would have understood that two holes would be necessary if the implant to be seated was a conventional, two-pegged implant rather than the single-peg implant shown in Radermacher. Indeed, implants having two pegs, and corresponding blocks having two drilling holes, were widely known in the 1990s (and earlier). For example, in 1989, Woolson disclosed a "conventional cutting guide 72" having two drilling holes, which corresponded to an implant's two pegs:

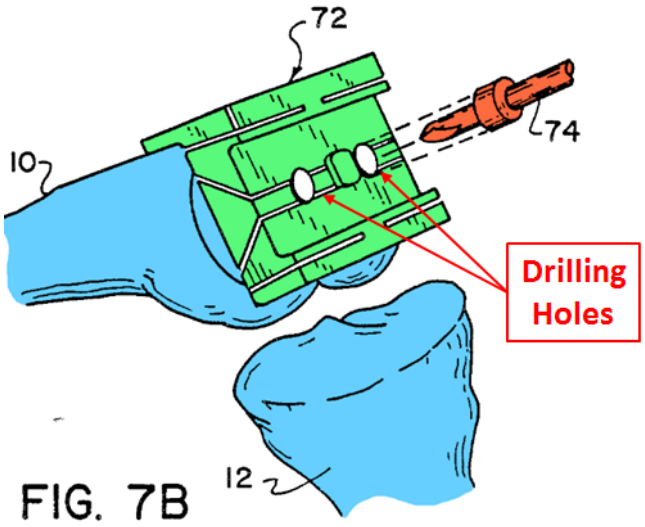


FIG. 7B

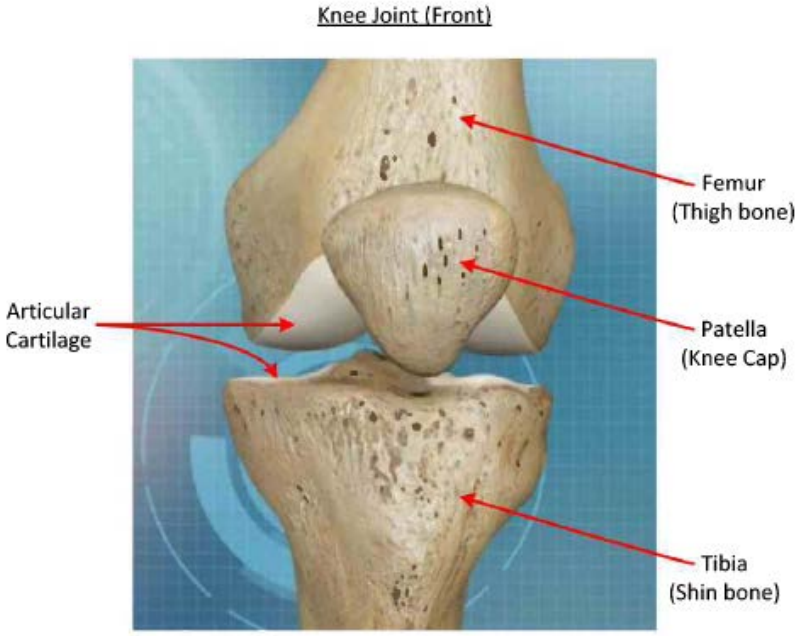
The widespread use of guides comprising two drilling holes is confirmed by Petitioner's expert, who used such guides hundreds of times in the two decades before ConforMIS's priority date. Because it would have been obvious to a person of ordinary skill in the art that Radermacher's "individual template" could be modified to include two drilling holes as described in Woolson, or alternatively that the "conventional cutting guide" in Woolson could be modified to include a

patient-specific surface as taught by Radermacher, ConforMIS's claims are unpatentable and should therefore be canceled.

III. INTRODUCTION AND 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):

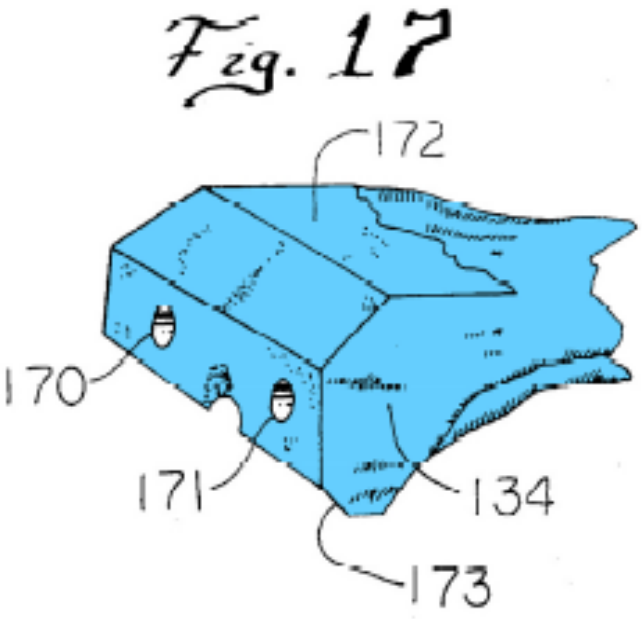


Ex. 1002 ¶36. The bottom of the femur has two round projections called "condyles." *Id.* In a healthy knee, the lower end of the femur and the upper end of the tibia are covered by articular cartilage, which provides a low-friction surface that facilitates rotation and absorbs shock. *Id.*

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. Ex. 1002 ¶39. Such surgery, referred to as "knee arthroplasty," was known for decades before ConforMIS filed the '302 patent. *Id.* ¶54.

During knee arthroplasty, a surgeon prepares a patient's bone to receive an implant by removing a portion of the bone and shaping it to receive the implant. *Id.* ¶40. The image below shows the end of a femur prepared in a typical manner, with flat bone surfaces for seating an implant component and holes for receiving pegs on the implant. *Id.*



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. 1002 ¶¶41-42. The figures below show the similarity between the claimed patient-specific tool with cutting slots (left) and prior art tools (right) having cutting slots oriented in the same way:

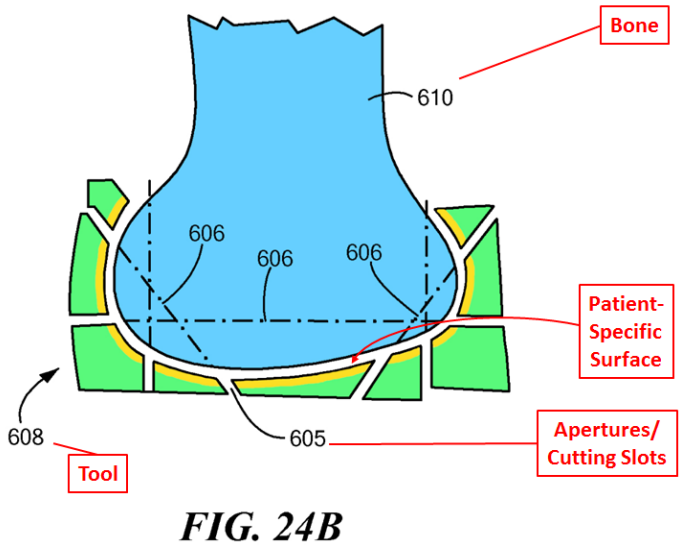
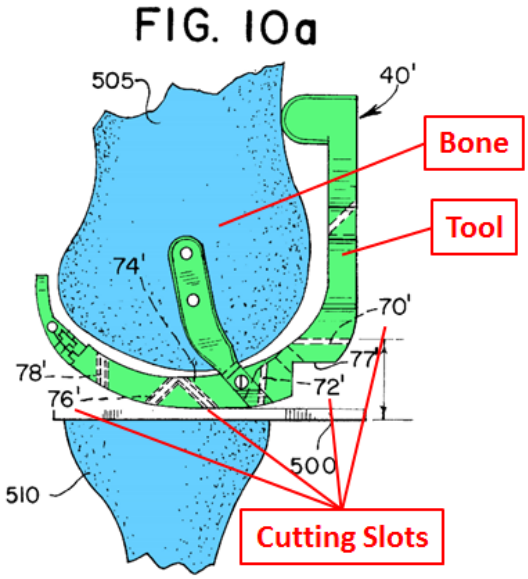


FIG. 24B



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

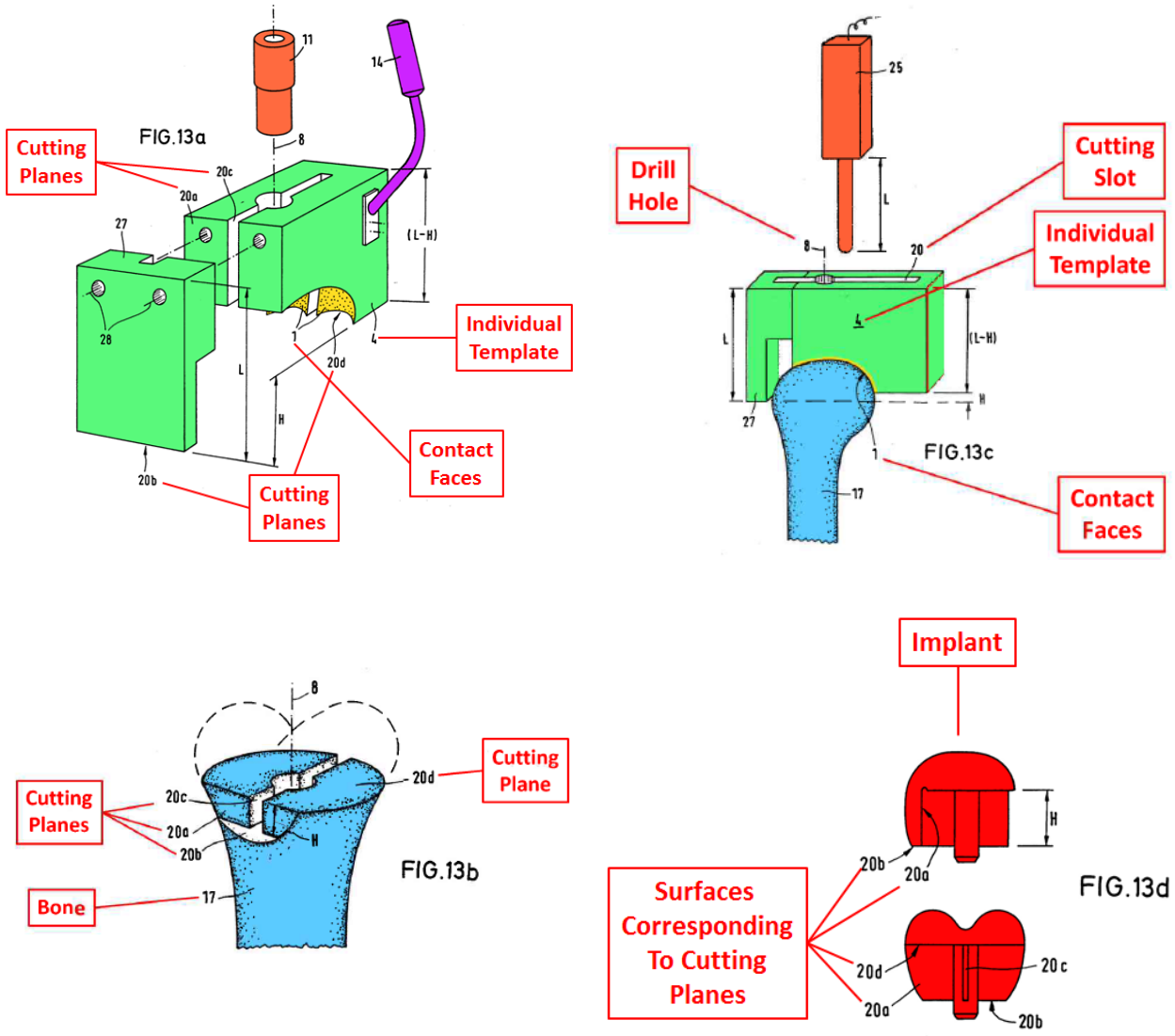
Robie (Ex. 1012, Fig. 10a)

C. Using Imaging to Create Patient-Specific Guides

1. Using Imaging to Create Patient-Specific Instruments With 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. 1002 ¶54. 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. *Id.* ¶¶45-53.

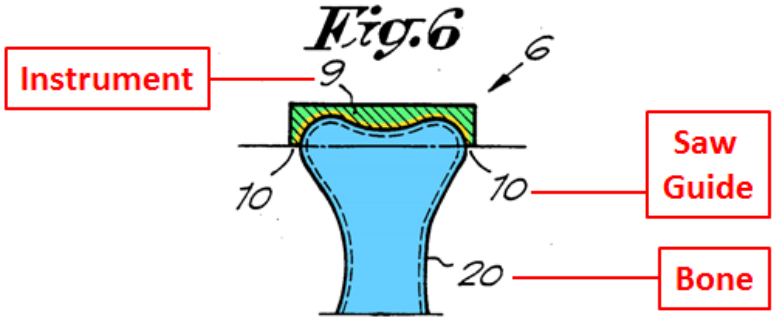
For example, Radermacher (1993) described using MRI and/or CT data to create an "individual template" for guiding surgical tools. The template included a surface that is a "copy" or "negative" of the "natural (i.e. not pre-treated) surface" of a patient's joint. Ex. 1003 at 10, 12. In Radermacher, an 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.



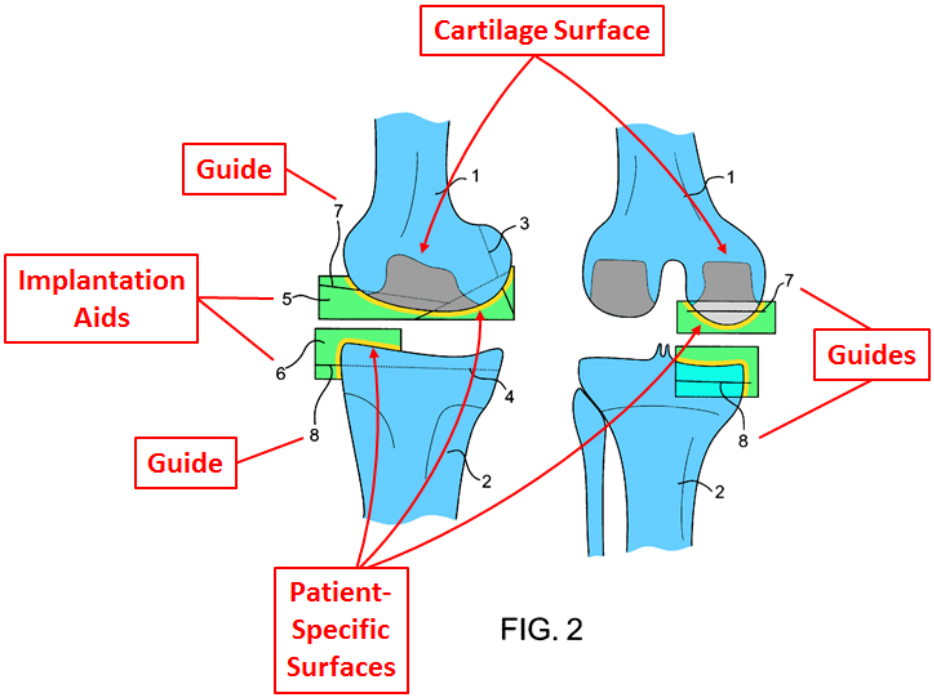
Id. at Fig. 13a-d.

In 1995, Swaelens disclosed an instrument 9 having a patient-specific surface (yellow) derived from MRI data 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. Swaelens also taught that the guide can be a drilling hole. *Id.*, Fig. 2, 5:48-53.



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:



Ex. 1008, 2:59-64, 3:50-57. The blocks included drilling holes for receiving pegs on implants. *Id.*, Fig. 5.

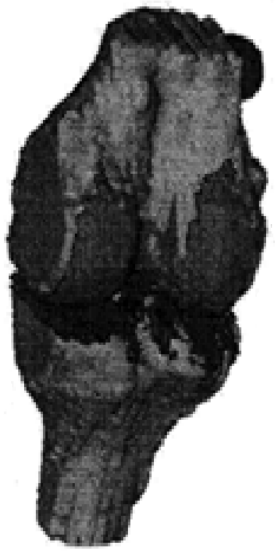
Numerous other references also described instruments having patient-specific surfaces. Ex. 1009, 2:11-3:2; Ex. 1010, 2:48-3:45; Ex. 1006, 7:53-8:41; Ex. 1002 ¶¶45-53.

2. Using Imaging to Determine the Contour of Joint Surfaces Was Well-Known

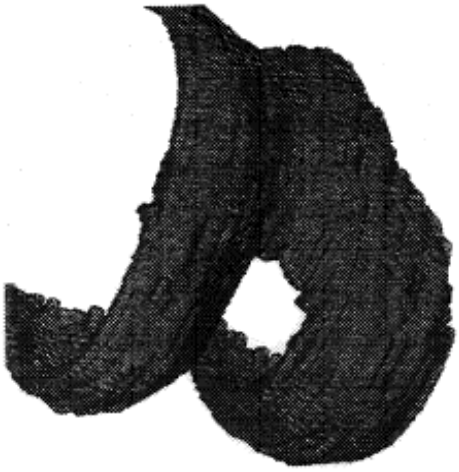
It was well known before 2002 that the contour of an articular surface of a joint, including the cartilage surface, could be determined through various imaging techniques, including MRI and CT. Ex. 1002 ¶¶43-44. All of the prior art references discussed above disclose imaging the patient's joint surface using CT and/or MRI. The '302 patent admits that "conventional" methods of x-ray, ultrasound, CT, and MRI were "within the skill of the art," "explained fully in the literature" (Ex. 1001, 30:32-51), and "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 (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:



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



Alexander (Ex. 1004, Fig. 19)

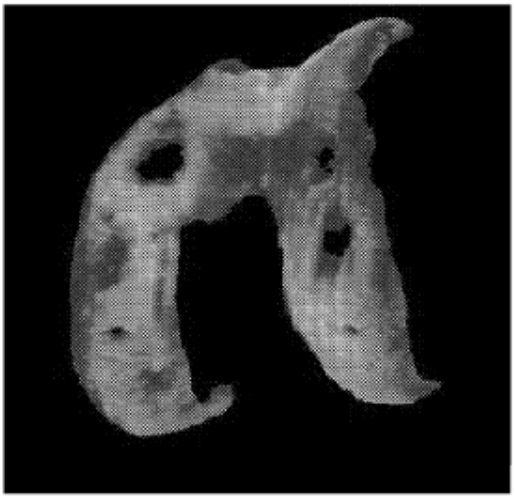


FIG. 2

'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[1] 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 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. 1002 ¶¶43-44.

[1] Some references refer to "nuclear spin tomography" or "NMR," which is old terminology for what is now referred to as MRI. Ex. 1002 ¶48; *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.).

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. 1002 ¶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 cartilage, subchondral bone and/or other bone surface and shape," as was well-known. *Id*., 70:39-52; Ex. 1002 ¶60.

As with all prior art cutting guides, the instrument can include "apertures" or "holes to accommodate surgical instruments such as drills[.]" Ex. 1001, 70:48-51.

B. Prosecution of the '302 Patent

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

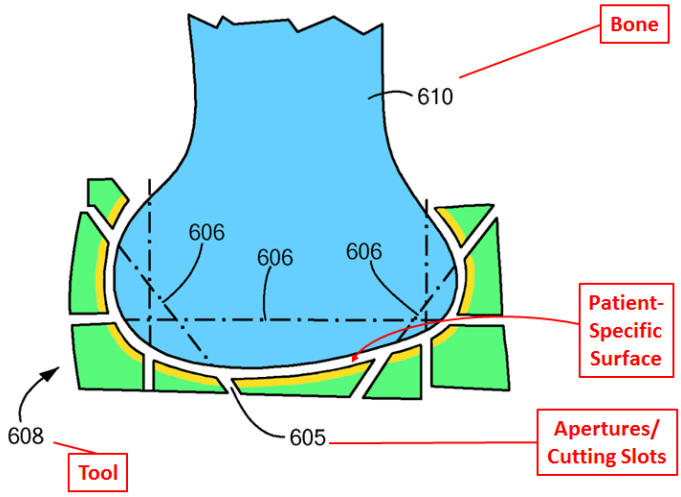
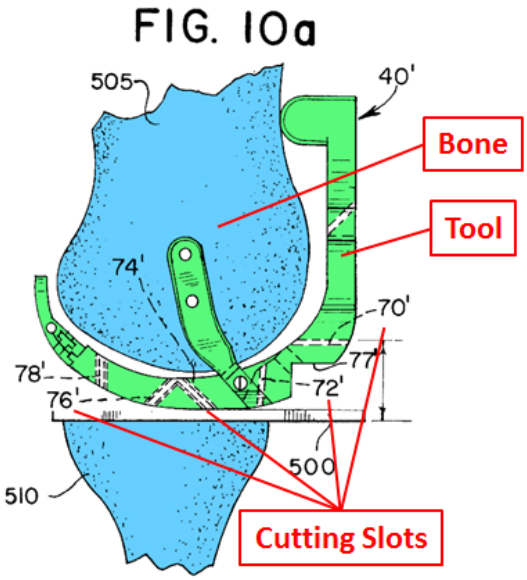


FIG. 24B



'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 the joint surface or cartilage surface. Ex. 1017 at 109-29, 136. The claims were allowed. *Id.* at 30-31.

During prosecution, several of 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. Ex. 1017 at 314, 336, 386. None of these references were applied by the Examiner. The remaining reference relied on herein, Kenna, was neither submitted to the Patent Office nor applied by the Examiner.

C. Claims

The ’302 patent includes 125 claims. This Petition challenges Claims 1-3, 5-8, 11, 13, 18, 20-21, 24-25, 28-29, 34-38, and 47. Of the challenged claims, only Claim 1 is independent, and it generally recites a tool comprising: (1) a patient-specific surface that is substantially a negative of a patient’s articular joint surface; and (2) two drilling holes. The dependent claims add variations that were widely known in the art, such as the orientation of the holes. Ex. 1002 ¶63.

D. 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.[2] Ex. 1002 ¶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.

[2] 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.

Cir. 2008). None of the earlier applications in the priority chain discloses this feature. Ex. 1002 ¶65; Exs. 1021-22, 1025-28, 1070.

E. Level of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") would have been: (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 has at least three years of experience learning from these doctors about the use of such devices in joint replacement surgeries. Ex. 1002 ¶¶29-31.

V. CLAIM CONSTRUCTION

Solely for 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 the Board cancel Claims 1-3, 5-8, 11, 13, 18, 20-21, 24-25, 28-29, 34-38, and 47 for the following reasons:

Ground 1: Claims 1-3, 5-8, 11, 20-21, 24-25, 28-29, 34-37, and 47 are unpatentable under 35 U.S.C. § 103(a) in view of Radermacher, Alexander, and Woolson.

Ground 2: Claims 13, 18, and 38 are unpatentable under 35 U.S.C. § 103(a) in view of the references in Ground 1 and further in view of Kenna.

Ground 3: Claims 1-3, 5-8, 11, 13, 18, 20-21, 24-25, 28-29, 34-38, and 47 are unpatentable under 35 U.S.C. § 103(a) in view of Radermacher, Fell, Woolson, and Kenna.

Grounds 1 and 2 collectively address the same claims as Ground 3. However, Ground 3 is not redundant of Grounds 1 and 2 because Ground 3 relies on a different secondary reference (Fell), which involves a different, but related, technology and provides a different motivation to combine. Ex. 1002 ¶¶189-94.

Additional support is included in the Declaration of Jay D. Mabrey, M.D. (Ex. 1002). Dr. Mabrey is the Chief of the Department of Orthopaedics at Baylor University Medical Center in Dallas, Texas, and a Professor of Surgery at Texas A&M Health Science Center College of Medicine. *Id.* ¶¶5-8.

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 in 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.
- Kenna published on March 3, 1987.

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 1-3, 5-8, 11, 20-21, 24-25, 28-29, 34-37, and 47 Are Unpatentable Under 35 U.S.C. § 103(a) in View of Radermacher, Alexander, and Woolson.

1. Claim 1

The preamble of Claim 1 recites a "patient-specific surgical tool for use in surgically repairing a joint." Radermacher discloses a patient-specific surgical tool used in surgically repairing a knee or hip joint. Ex. 1003 at 25, 30, Figs. 10, 13, 18; Ex. 1002 ¶¶83-85. Each of the claim limitations are addressed below.

a. A Patient-Specific Surface

Claim 1 recites a block having a patient-specific surface having two features: (i) at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged articular surface; and (ii) a predetermined position and orientation relative to the corresponding joint portion. As described below, Radermacher, alone or in combination with Alexander, discloses these limitations. Ex. 1002 ¶¶86-91.

b. Substantially a Negative of an Articular 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.

Ex. 1003 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, to a POSITA, 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. 1002 ¶¶88-91. 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 nevertheless argue that Radermacher does not disclose that the patient-specific surface is substantially a negative of the diseased or damaged "articular surface." However, this limitation cannot save the claims because it is disclosed by Radermacher, it would have been

obvious to a POSITA reading Radermacher, and/or it would have been obvious to a POSITA in view of Alexander.

i. Radermacher

Radermacher discloses that the patient-specific surface is substantially a negative of the articular surface, which can include articular cartilage and any exposed subchondral bone. Ex. 1001, 6:56-58 ("The articular surface can comprise cartilage and/or subchondral bone."). 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. 1002 ¶¶88-91. 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 the patient's natural articular surface. *Id.* And, as long as diseased or damaged cartilage exists on the patient's joint, the contact faces of Radermacher's individual template would also 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.* 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 known to provide data regarding the cartilage surface. Ex. 1001, 30:32-51, 32:1-34:43, 70:39-52; Ex. 1002 ¶89. 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 surface or the exposed subchondral bone—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. 1002 ¶90. 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.* at 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. 1002 ¶90.

Accordingly, Radermacher discloses that at least a portion of the patient-specific surface is substantially a negative of a corresponding "articular surface." *Id.* ¶91.

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 (and therefore articular surface), such a template would have been obvious to a POSITA in view of Radermacher. *Id.* ¶¶92-93.

As described above, Radermacher discloses using MRI to determine the three-dimensional shape of the patient's joint. Ex. 1003 at 10-12 (referring to "nuclear spin tomograph"), Fig. 18 (referring to "MR"). The '302 patent admits that MRI was conventional, well-known, and used 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 known that MRI provided information regarding the cartilage surface. Ex. 1002 ¶¶92-93; 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 (and therefore articular) surface. Ex. 1002 ¶¶92-93.

A POSITA would have been motivated to match the surface of Radermacher's template to the cartilage surface for several reasons. Ex. 1002 ¶93. 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. *Id.* 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. 1002 ¶93. 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 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 articular surface or cartilage surface as derived from the MRI data. Ex. 1002 ¶¶92-93.

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 (and therefore articular) surface, this feature would have been obvious to a POSITA in view of Alexander. Ex. 1002 ¶¶94-103.

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. 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, 14:16-15:14, 2:5-6 (MRI is accurate "for visualization of articular cartilage in osteoarthritis, particularly in knees").

Alexander discloses using 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

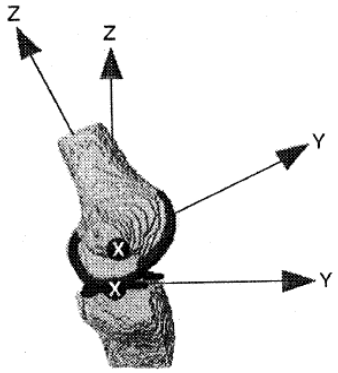


FIG._18H

Id., Figs. 18C-I, 61:19-25. Alexander describes reconstructing the articular cartilage from the MRI data and providing a thickness map (Ex. 1004, 31:7-11), just as described in the '302 patent (Ex. 1001, 25:16-22):

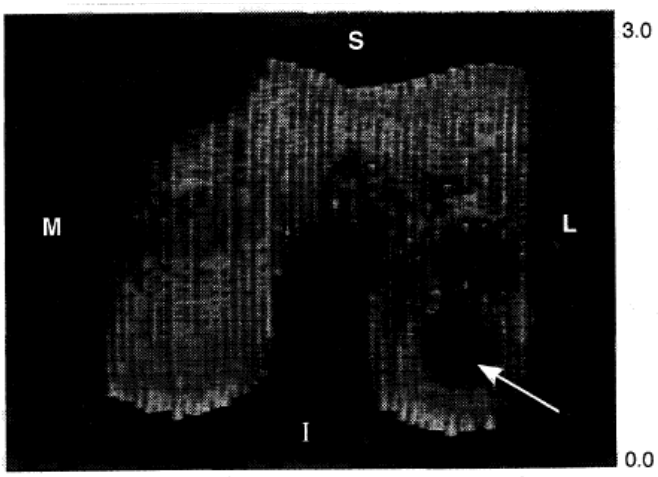


FIG._22B

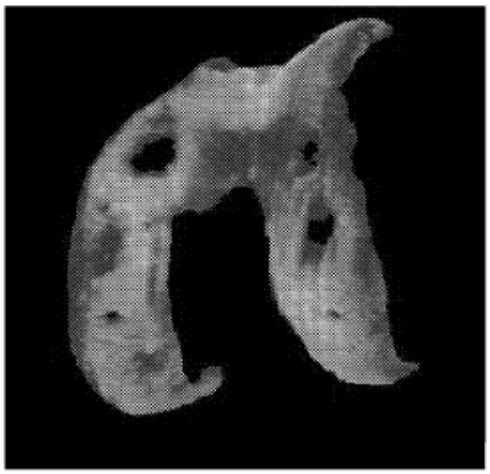


FIG. 2

Alexander (Ex. 1004, Fig. 22B)

'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. 1002 ¶¶100-03. First, both Radermacher and Alexander relate to methods of treating diseased or damaged cartilage in a knee joint. *Id.* Second, both references disclose using 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.* ¶101. 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.* ¶102; 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 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. 1002 ¶103.

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

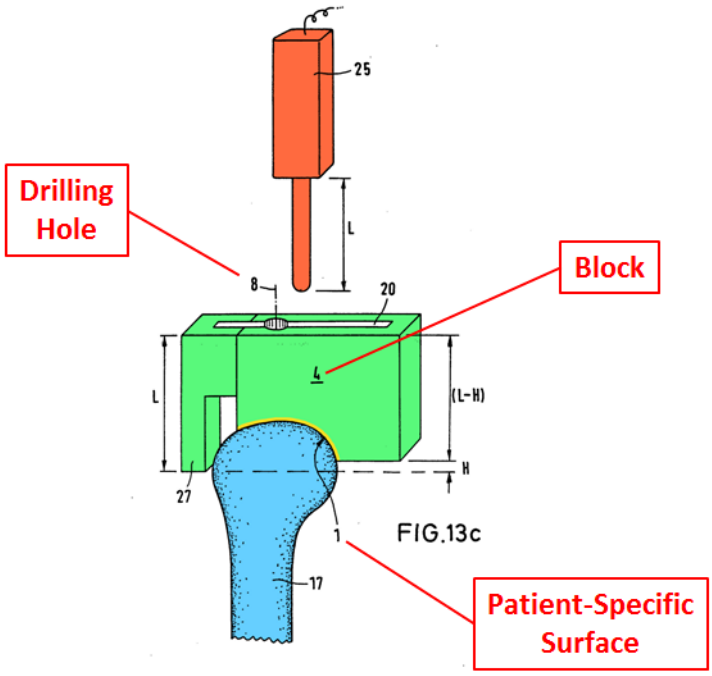
c. Predetermined Position and Orientation Relative to the Corresponding Joint Portion

Radermacher discloses that the patient-specific surface has a predetermined position and orientation relative to the joint because Radermacher discloses that the patient-specific surface of the template is designed, during the preoperative planning stages, such that it fits onto the joint surface in "exactly one spatially uniquely defined position." Ex. 1003 at Abstract; *see also id.* at 9 (positioning is shifted to preoperative planning phase), 10 (template is seated "in a clearly defined position and with mating engagement"), 10 (template can be set onto the bone "in exclusively one clearly defined position"), 11 (surgical plan is "three-dimensionally charted in said coordinate system fixed relative to the osseous structure"), 13 (preoperative planning using three-dimensional reconstruction of joint), 22 (the joint surface is used for a "basis for the individual template 4 to be

constructed in the coordinate system fixed relative to the model"), 30 (template set onto bone "in a defined manner, abutting the contact faces"); Ex. 1002 ¶104.

d. First and Second Drilling Holes

Radermacher discloses a template for a knee joint that includes one drilling hole:

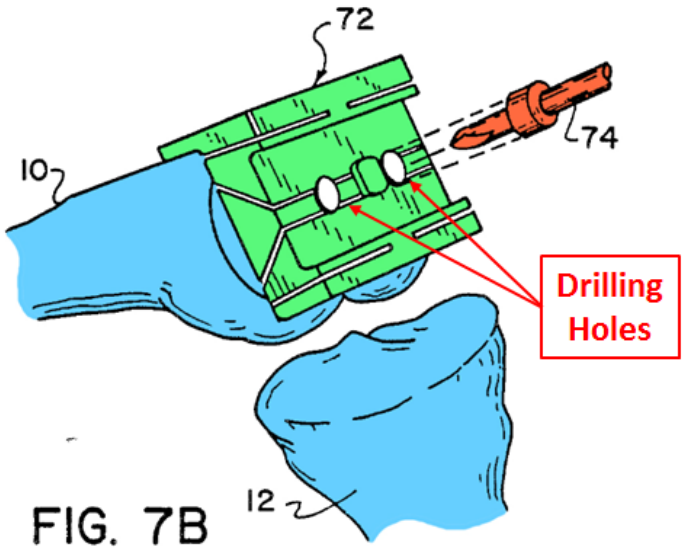


Ex. 1003 at Fig. 13c. However, Radermacher states that this template is intended to prepare the seat for the implant "illustrated by way of example in Fig. 13d," which has a single peg. *Id.* at 30.

Radermacher's disclosure is not limited to this exemplary embodiment. 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." *Id.* at 13. In addition, 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. 1002 ¶114. Such a template certainly would have been obvious in view of Woolson.

Woolson discloses a "conventional cutting guide 72" having two drilling holes for guiding drill 74:



Ex. 1031, Fig. 7B, 6:58-63; Ex. 1002 ¶108. The holes drilled in the femur "correspond to the pegs in the actual femoral prosthesis." Ex. 1031, 6:58-63.

Woolson is just one of many prior art references that disclosed blocks having first and second drilling holes. Ex. 1002 ¶¶108-12 (citing and discussing Exs. 1011, 1031-34, 1037). Petitioner's expert confirms that blocks containing

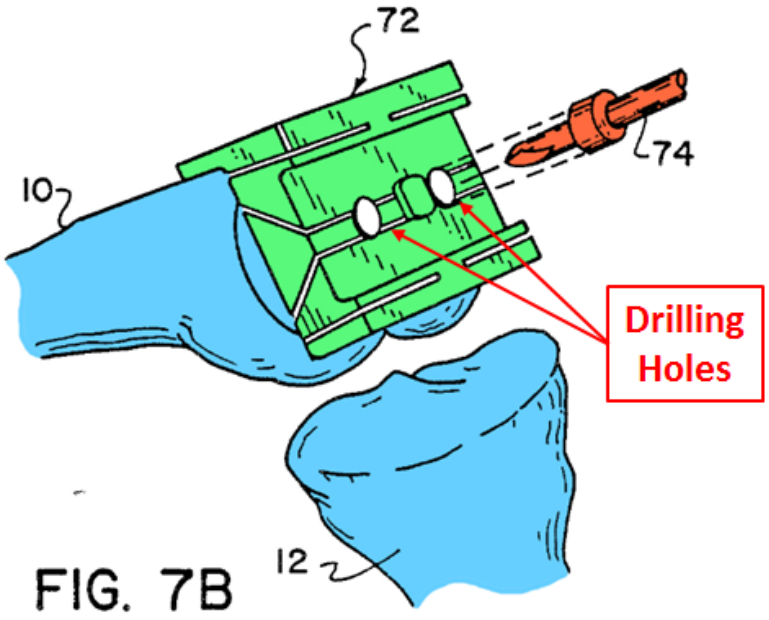
first and second drilling holes were widely known. *Id.* ¶109-113. Indeed, Petitioner's expert used blocks having multiple drill holes hundreds of times during the 1980s and 1990s. *Id.* ¶109. Thus, blocks having first and second drilling holes were conventional, widely known, and it would have been obvious to a POSITA that Radermacher's template could include two drilling holes. *Id.* ¶¶105-14.

A POSITA would have been motivated to modify Radermacher to incorporate two drilling holes as disclosed in Woolson, or alternatively to modify Woolson's conventional block to include the patient-specific surface described in Radermacher, for numerous reasons. First, 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). *Id.* ¶115. 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, e.g., if the implant contained two pegs (instead of a single peg as shown in Radermacher), then block would also contain two drilling holes. Ex. 1002 ¶115. Indeed, the '302 patent admits that this was within the knowledge of a POSITA. Ex. 1001, 102:61-65 ("As will be appreciated by those of skill in the art, the location and orientation of the [guides] will change depending on the design of the ... implant."). Fourth, having two drilling holes in a tool guide was commonplace. Ex 1002 ¶¶ 109, 115. Fifth,

Woolson states that the method described therein has "general applicability to any bone resectioning in which the bone cuts are defined by a cutting guide surface of a guide member placeable adjacent the bone for guiding resectioning[,]" which is what Radermacher describes. Thus, including first and second drilling holes in Radermacher's template would have involved nothing more than combining its teachings with common knowledge and/or Woolson according to known methods to yield predictable results. *Id.*

Claim 1 also requires that the drilling holes "have predetermined positions and orientations relative to the patient-specific surface." Radermacher discloses this limitation. *Id.* ¶116. Each of Radermacher's guides has a "predetermined position and orientation relative to the patient-specific surface" because the location and orientation of each drill hole is determined and fixed along with the patient-specific surface during 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 form of guide means").

Finally, Claim 1 requires that each drilling hole have an axis that extends through a portion of the joint when the patient-specific surface is fit to the corresponding portion of the articular surface. Figure 13c of Radermacher shows that bore axis 8 extends through a portion of the joint when the patient-specific surface is set on a patient's knee joint. *See also* Ex. 1003 at Fig. 13b. If Radermacher's template was modified to incorporate Woolson's drill holes, they would extend through a joint surface:

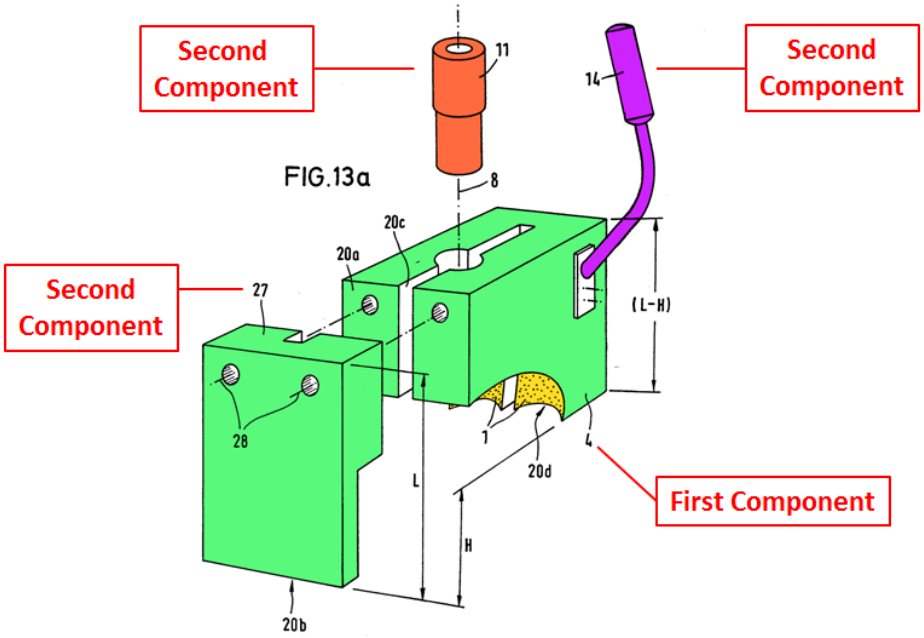


Ex. 1002 ¶118 (citing Ex. 1031, Fig. 7B).

Accordingly, Claim 1 would have been obvious in view of Radermacher in combination with Alexander and Woolson.

2. Claim 2

Dependent Claim 2 further specifies that the tool "is comprised of multiple components." Radermacher discloses that the tool may include components in addition to the block ("individual template 4"), including drill sleeves, parallel guides, saw templates, milling devices, and additional templates, each of which constitutes a second component as recited in Claim 2:



Ex. 1003 at Fig. 13a; *id.* at 13-14, 26, 30 (disclosing the "individual template 4," the "drill sleeve 11" which is "inserted" into the individual template, and an "additional template 27"). Radermacher teaches that second components, such as "suitable tool guides," can be provided "on" the template and can be "coupled (releasably or non-releasably) in a mechanically rigid manner." *Id.* at 13; Ex. 1002 ¶120.

3. Claim 3

Claim 3 depends from Claim 1 and specifies that "the block containing the patient-specific surface and the drilling holes are comprised of a single component." This limitation is disclosed by, and would have been obvious in view of, Radermacher and Woolson as set forth above for Claim 1. Radermacher discloses a single-component block ("individual template 4") comprising a drill hole, and modifying such a single-component block to include two drilling holes would have been obvious as described above for Claim 1. In addition, Woolson discloses a single-component block ("conventional cutting guide 72") that includes two drilling holes. Ex. 1002 ¶121.

4. Claim 5

Claim 5 depends from Claim 1 and recites that "the patient-specific surface is a continuous surface." The '302 patent distinguishes a "continuous surface" from a surface defined by a "plurality of pins." Ex. 1001, Claim 4, 76:41-60. Radermacher discloses a patient-specific surface that is continuous, as opposed to defined by a plurality of pins. Ex. 1003 at 10-12, 14-15, 21-22, Figs. 13a, c; Ex. 1002 ¶122.

5. Claim 6

Claim 6 depends from Claim 5 and further specifies that "the patient-specific surface is made of a polymer." Radermacher discloses this limitation because

Radermacher states that the template may be made "from UV curable polymer." Ex. 1003 at 23; Ex. 1002 ¶123.

6. Claim 7

Claim 7 depends from Claim 1 and specifies that the patient-specific surface corresponds to a femoral surface and the drilling holes are "configured to define a path through a femoral surface when the patient-specific surface is engaged or aligned" with the articular surface. Radermacher discloses that the surface is a femoral surface and that the drill holes define a path through the femoral surface. Ex. 1003 at 30, Figs. 13a-13d; Ex. 1002 ¶124. In addition, Woolson's "conventional cutting guide 72" is for a femur and includes two drilling holes. Ex. 1031, Figs. 7A-B. A modified, two-drilling hole version of Radermacher's template, or a modified, patient-specific version of Woolson's cutting guide 72, would meet the additional limitations of Claim 7 and define paths through a femoral surface. Ex. 1002 ¶124.

7. Claim 8

Claim 8 depends from Claim 7 and recites that the drilling paths extend through a distal portion of a femoral condyle. The two drilling holes disclosed in Woolson, if incorporated into Radermacher's individual template as discussed above for Claims 1 and 7, would define a cutting path configured to extend through

a distal portion of a femoral condyle when the patient-specific surface is engaged and aligned with the articular surface. Ex. 1031, Fig. 7B; Ex. 1002 ¶125.

8. Claim 11

Claim 11 also depends from Claim 7, and further specifies that the path is configured to extend through a portion of two femoral condyles. The two drilling holes disclosed in Woolson, if incorporated into Radermacher's individual template as discussed above for Claim 1, would define a cutting path configured to extend through a portion of two femoral condyles. Ex. 1031, Fig. 7B; Ex. 1002 ¶129.

9. Claims 20-21 and 24-25

Claim 20 depends from Claim 1 and recites that the tool includes a spacer selected to fit between a femoral surface and a tibial surface to balance ligaments. Claim 21 specifies that the spacer is not connected to the block.

The '302 patent admits that spacers were known in the art. Ex. 1001, 73:67-74:3. Petitioner's expert confirms that using spacers to balance ligaments was widely known and was a conventional practice in all knee arthroplasty procedures. Ex. 1002 ¶¶131-33. Woolson discloses the use of a spacer for ligament balancing and further confirms that the use of spacers was "conventional." Ex. 1031, 7:49-53 ("After making the tibial and the distal femoral bone cuts, a trial tibial component and a trial femoral spacer is inserted into the joint space to test the adequacy of

bone resection with the knee in extension, ***as is conventionally done***."); *id.*, 6:54-58 (emphasis added). Thus, it would have been obvious to a POSITA that Radermacher's tool could include a spacer, as taught by Woolson, for ligament balancing. Ex. 1002 ¶132.

Claim 21 specifies that "the spacer is not connected to the block." On its face, Claim 21 depends from Claim 13; however, Claim 13 does not provide any antecedent basis for "the spacer." Accordingly, Petitioners address Claim 21 here in the event that ConforMIS contends that it should depend from Claim 20. To the extent that it depends from Claim 13, it is invalid for the reasons set forth herein and below with respect to Claim 13.

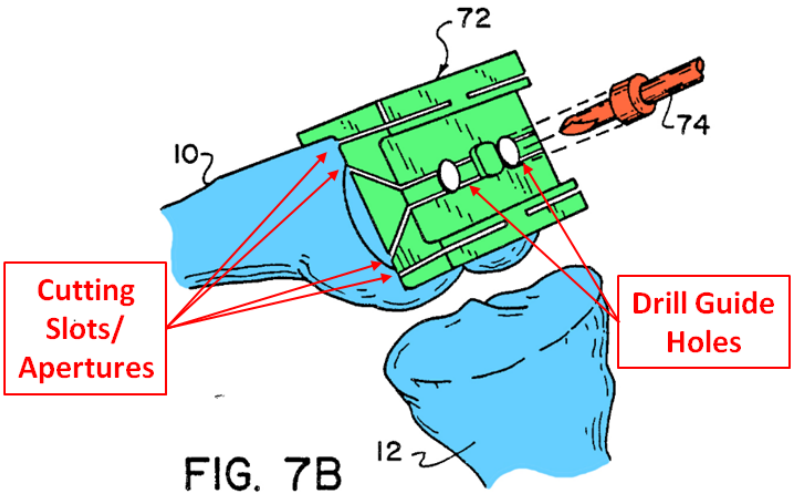
Regardless of the claim from which it depends, Claim 21 should be canceled because specifying that a spacer "is not connected to the block" cannot make the claim patentable. Spacers that are unconnected to the block were conventional, and the spacers disclosed in Woolson were not connected to the block, as the cuts had already been made and the purpose of the spacer was to test ligament balancing. Ex. 1031, 7:49-53, 6:54-58; Ex. 1002 ¶132.

Claims 24-25 recite "an adjustment mechanism to balance ligaments" and specify that the mechanism is not connected to the block. A spacer is a type of adjustment mechanism. Ex. 1001, 113:11-14 ("adjustments may be made intraoperatively, for example via spacers"), 19:37-40, 73:67-74:3, 104:17-20.

Thus, these claims are invalid for the same reasons as Claims 20-21 above. In addition, a tensiometer is an "adjustment mechanism" and the '302 patent admits that tensiometers were known in the art and are not an inventive aspect of the claim. *Id*. at 103:45-47. Therefore, these limitations cannot make the claims patentable.

10. Claims 28-29

Claim 28 depends from Claim 1 and requires the tool to comprise a plurality of guide apertures in addition to the two drilling holes recited Claim 1. Claim 29 further specifies that the additional apertures are configured at an angle—any angle—to each other. As shown in Woolson, conventional cutting guides comprised several guide apertures (e.g., cutting slots) in addition to the two drilling holes, and those apertures are at an angle to each other:



Ex. 1031, 6:54-64, Figs. 7A-7B; *see* Ex. 1002 ¶¶134-38. Therefore, Woolson discloses the limitations in Claims 28-29.

11. Claims 35-36

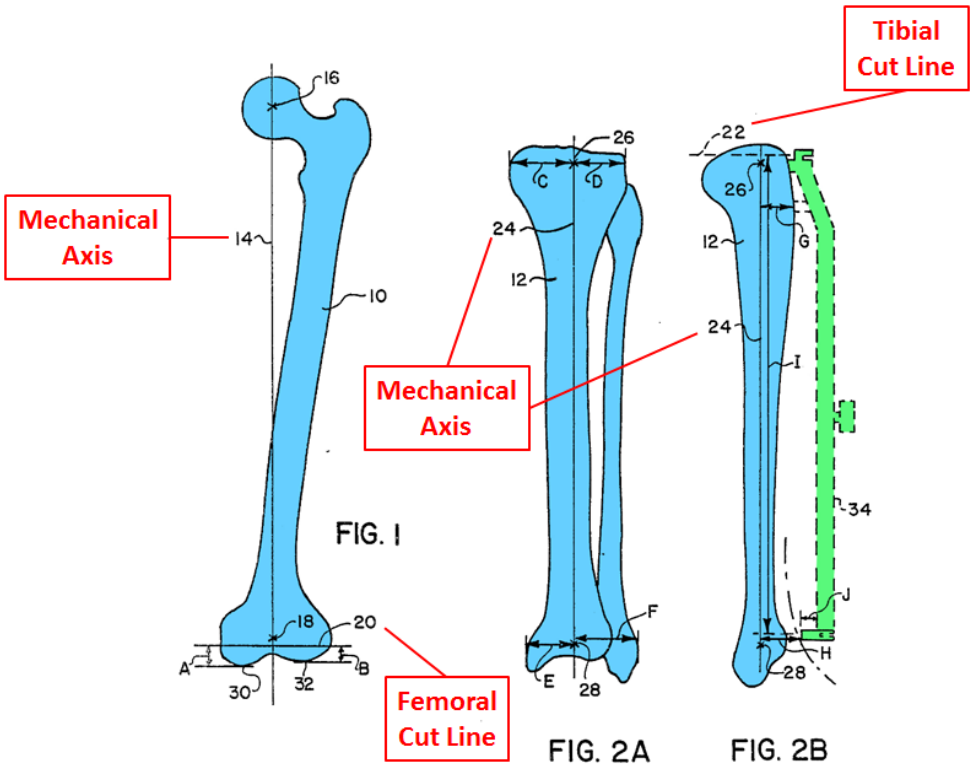
Claim 35 depends from Claim 1 and specifies that the tool is oriented relative to a mechanical axis of the joint. Claim 36 specifies that the tool is oriented relative to an anatomic axis which, for the tibia, is the same as the mechanical axis. Ex. 1002 ¶145.

It would have been obvious to a POSITA that Radermacher's tool would be "oriented relative to a mechanical axis of the joint" as recited in Claim 35. Indeed, the '302 patent admits that determining the mechanical axis and relying on that axis when performing knee arthroplasty was widely known. Ex. 1001, 30:32-51, 34:46-39:47. Thus, this limitation cannot make the claim patentable.

Petitioner's expert further confirms that aligning cutting tools relative to a patient's mechanical and anatomical axes was well-known and commonplace in knee arthroplasty. Ex. 1002 ¶¶162-71. POSITAs knew that maintaining proper knee alignment post-surgery was critical because the mechanical axis determines the distribution of forces in the knee. Ex. 1002 ¶163; 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. 1002 ¶163. This, in turn, requires the surgical tool, as well as the cutting and drilling paths defined thereby, 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.* Thus, such alignment was entirely conventional and widely known by POSITAs in the 1990s.

This limitation also would have been obvious in view of Woolson, which discloses orienting the surgical tool to provide cutting or drilling paths that are aligned relative to a mechanical axis. 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. Woolson teaches 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 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. *Id.*, 4:7-19. Woolson further discloses that the implants, which would include the implant pegs (and thus the corresponding drill holes and tool) are preoperatively aligned relative to the axes. *Id.*, 2:50-59, 4:20-26 (cut is made perpendicular to mechanical axis of tibia), 1:46-50, 4:7-6:3, 5:36-41, 6:50-53, 7:32-36, 7:63-67, 1:54-57, Abstract, Fig. 1, Figs. 2A-B, 1:8-18. 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:



Configuring Radermacher's template to be oriented along a mechanical or anatomical axis would merely involve using a common 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. Ex. 1002 ¶172.

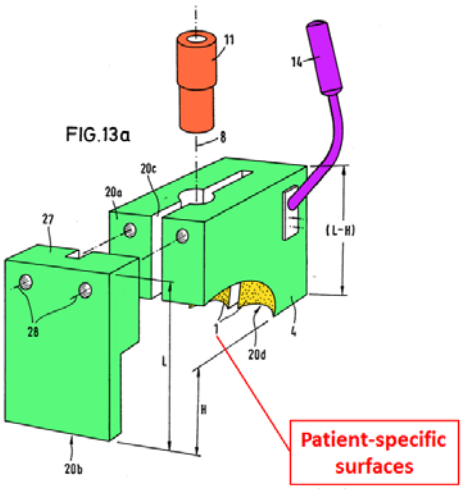
Numerous prior-art references further confirm that aligning tools relative to a patient's mechanical and anatomic axes was well-known. Ex. 1032, 3:1-3, Fig. 1, 3:1-52, 8:27-30, 9:37-41; Ex. 1037 at 22 (the importance of taking the mechanical axis into account when performing knee arthroplasty was "generally

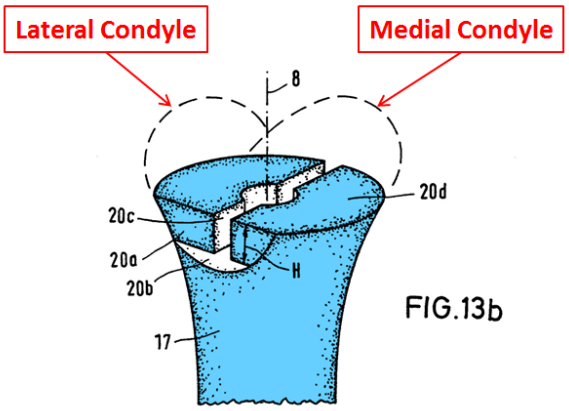
agreed [upon]"); Ex. 1033 at 31 (accurate placement of implant components with respect to the individual mechanical axis of the leg is "essential").

Accordingly, it would have been obvious to a POSITA that the tool of Claim 1 would be oriented along a mechanical or anatomical axis. Ex. 1002 ¶172.

12. Claim 37

Claim 37 specifies that the patient-specific surface corresponds to a surface of the joint that includes a medial or lateral condyle. Radermacher discloses the patient-specific surface that corresponds to the femur, e.g., the medial and lateral condyles. Ex. 1003 at Figs. 13a-b; Ex. 1002 ¶146.

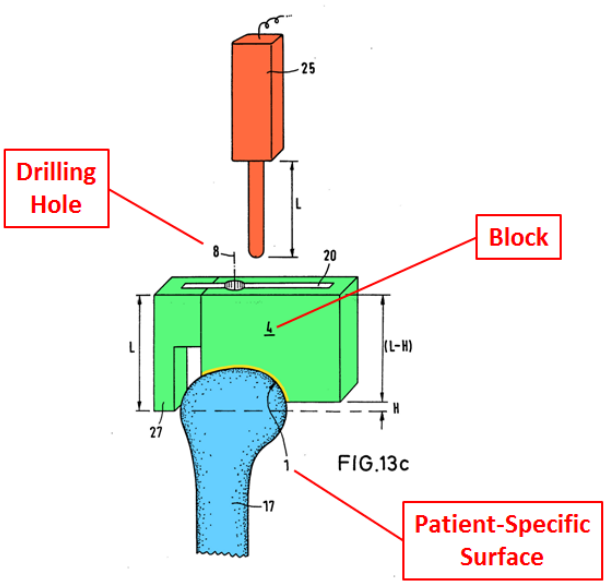




Ex. 1003 at Figs. 13a-b; Ex. 1002 ¶146.

The claim chart below further demonstrates how Claims 1-3, 5-8, 11, 20-21, 24-25, 28-29, 34-38, and 47 are disclosed by the prior art under Ground 1. *See also* Ex. 1002 ¶154.

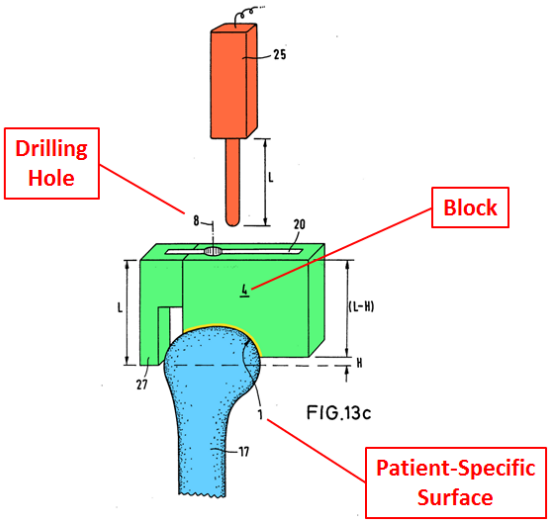
Claim 1	Exemplary Disclosures in Prior Art
A patient-specific surgical tool for use in surgically repairing a joint of a patient, comprising:	**Radermacher** discloses "treatment tools" for surgically repairing a patient's joint. Ex. 1003 at 1, 25 (hip), 30 (knee), Figs. 10, 13, 18.
[a] a block having a patient-specific surface and first and second drilling holes;	**"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, and is therefore patient-specific. *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[.]"); *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."); *id.* at 21 (the structure is "scanned by a tomographic method"); *id.* at 21-22 ("the defined contact faces 1 are used (as a negative, a 'cast', 'reproduction') for a basis for the individual template 4[.]"); Fig. 18 (referring to "Tomographic images (CT, MR, …)" and creating "individual templates"); Figs. 13a, c.



Ex. 1002 ¶¶86-93.

“first and second drilling holes”

Radermacher 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 drill hole (defining axis 8):



Id. at Fig. 13c.

Radermacher discloses other embodiments in which the template has two holes. *Id.* at 25-26, Figs. 6b and 9.

Radermacher teaches that the cuts are made "according to the geometry of the prosthesis." *Id.* at 30.

Woolson discloses a "conventional cutting guide 72" having two drilling holes, as shown in Fig. 7B. Ex. 1031, Fig. 7B, 6:58-63.

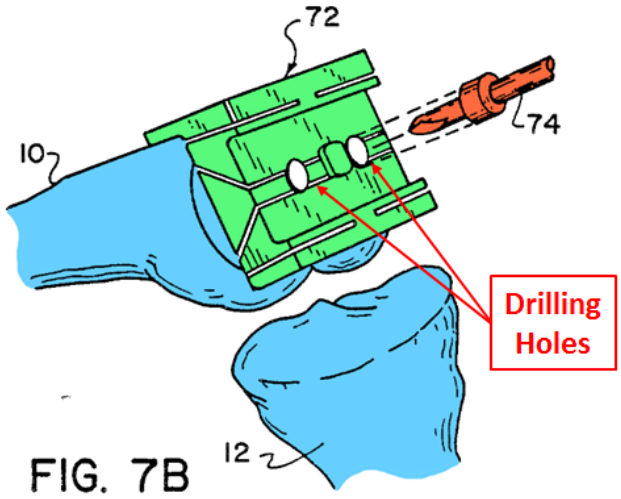


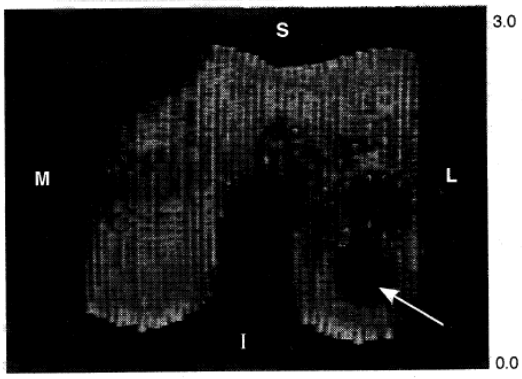
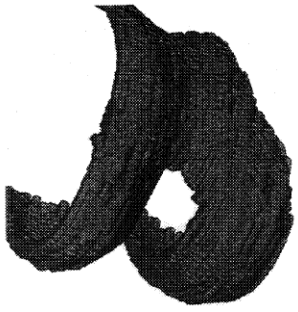
FIG. 7B

Ex. 1002 ¶¶105-08.

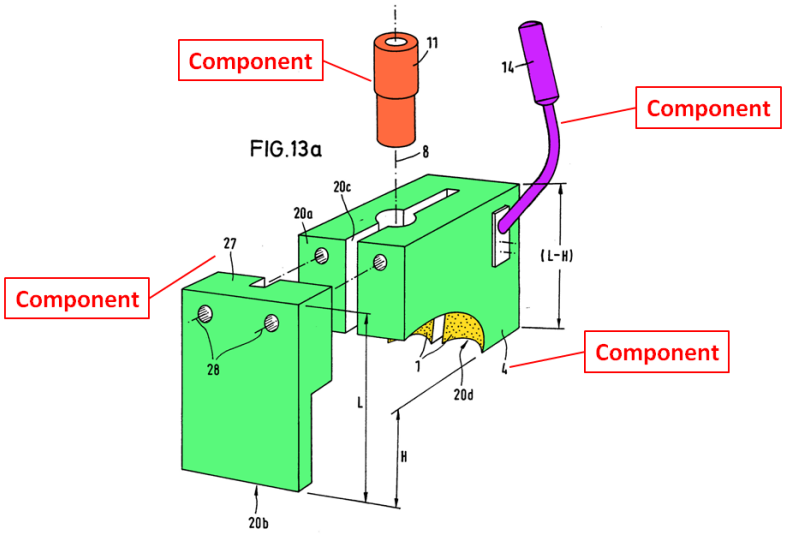
The '302 Patent admits that varying the block to correspond to other implant designs was within the knowledge of a POSITA. Ex. 1001, 102:61-65 ("As will be appreciated by those of skill in the art, the location and orientation of the [guides] will change depending on the design of the femoral implant and the shape required of the femur to communicate with the implant.").

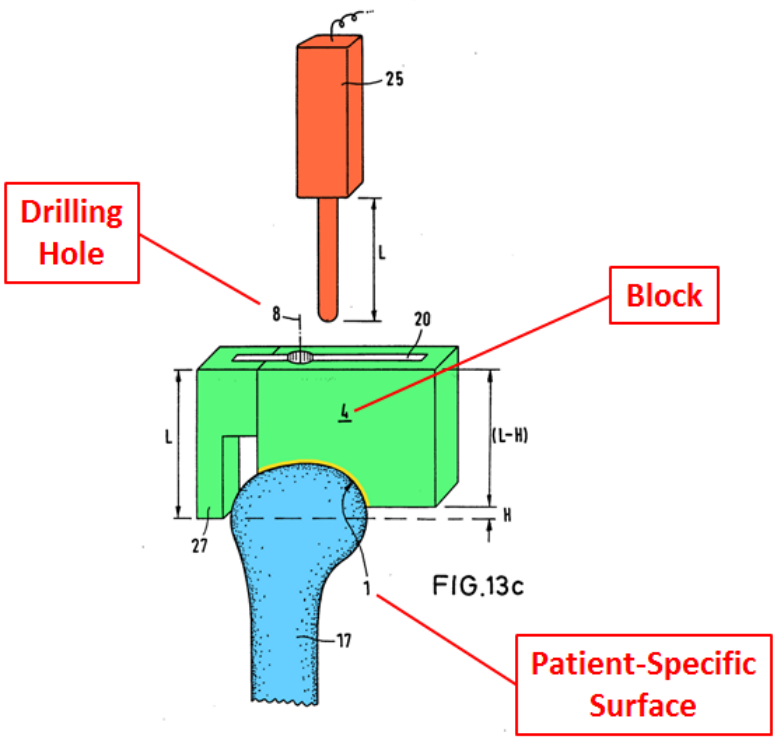
Knowledge of a POSITA: Blocks having multiple drilling holes were within the knowledge of POSITA. Ex. 1002 ¶¶105-19; *see, e.g.*, Ex. 1032, Figs 14, 30B; *id.*, 5:34-43, 8:11-22, 9:13-23, 10:15-20.

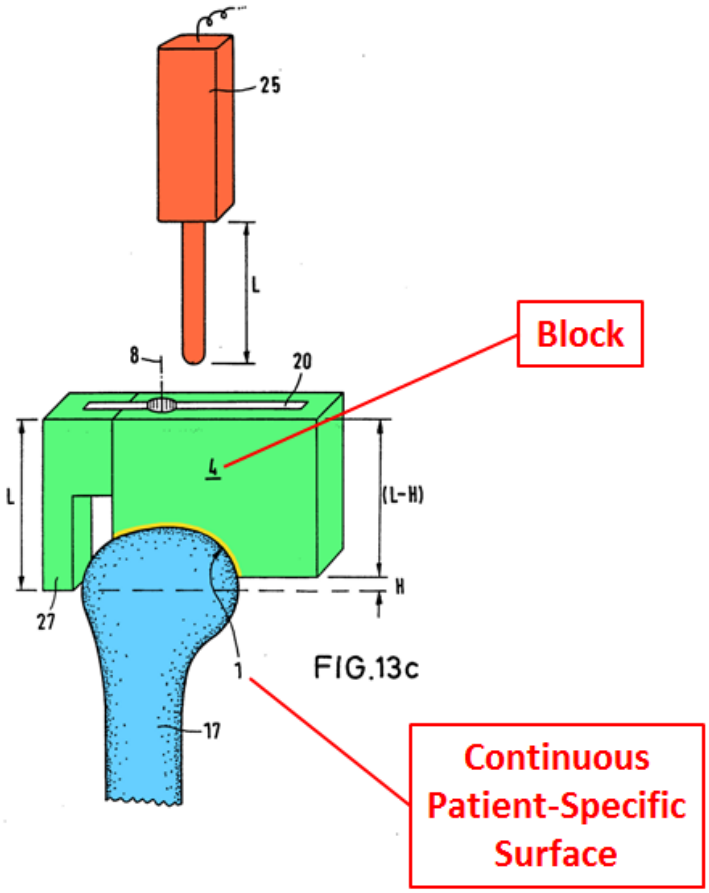
[b] the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged articular surface of the joint and having a predetermined position and orientation relative to the corresponding portion;	**Radermacher** discloses generating "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." Ex. 1003 at 12 (emphasis added). Where the structure is a knee joint, the contact face would be substantially a negative of at least a portion of the diseased or damaged articular surface. A POSITA would have understood that Radermacher discloses matching the cartilage surface (and therefore the articular surface) because Radermacher discloses that the images are obtained by CT or MRI. Ex. 1003 at 10, 12, 21-22, Figs. 18, 19. As the '302 patent admits, determining the size, shape, curvature and contour of a diseased cartilage surface 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."); *id.*, 32:1-34:43. Radermacher 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. Ex. 1002 ¶¶86-104. **Alexander** discloses methods for assessing the condition of cartilage in a joint, such as the knee, based on MRI imaging. Ex. 1004, Abstract ("The methods include converting an image such as an MRI to a three dimensional map of the cartilage."); 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[.]");*id.*, 14:16-32 ("[A] number of internal imaging techniques known in the art are useful for electronically generating a cartilage image.

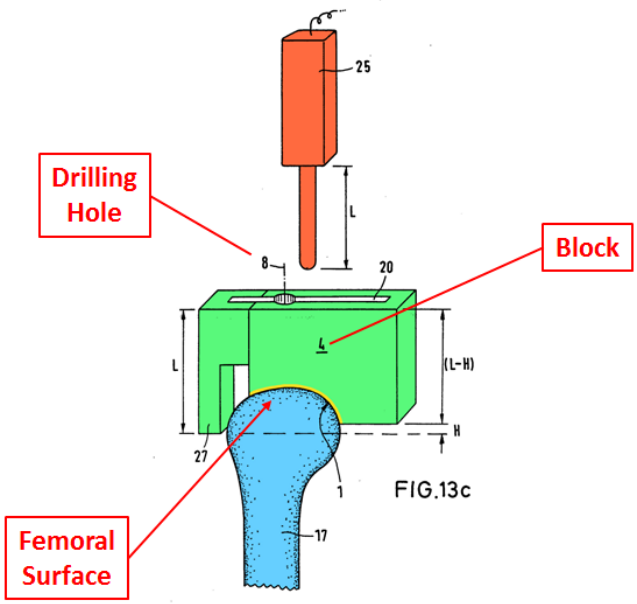
	These include magnetic resonance imaging (MRI), computed tomography scanning (CT …).”); *id.*, 14:30 (MRI “can provide accurate assessment of cartilage thickness”); *id.*, 15:16-26 (3D MRI techniques were “well known”); *id.*, 26:20-27:26; *id.*, 61:19-25 (discussing Fig. 18C); Figs. 18-19. Alexander 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. 1002 ¶¶94-104.

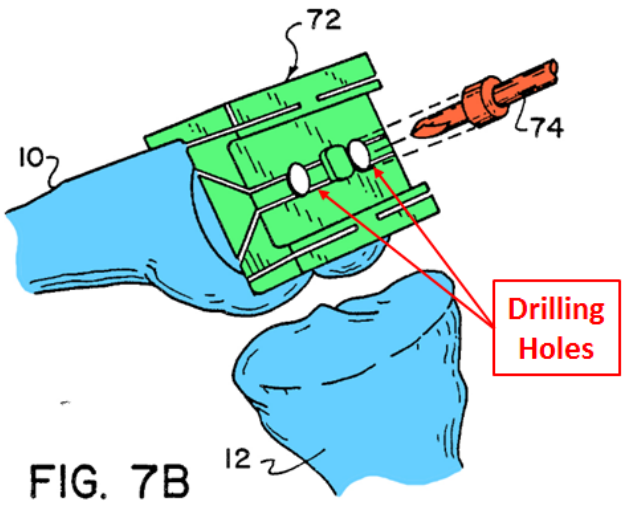
[c] the first and second drilling holes having predetermined positions and orientations relative to the patient-specific surface and each having an axis that extends through a portion of the joint when the patient-specific surface is fit to the corresponding portion of the diseased of damaged articular surface of the joint.	**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 Figs. 13a, c; 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"). *Id.* at 13, 15, 20, 22-23, 25, 30, Figs. 13a-b, 6, 9, 10a-d. The axes extend through a portion of the joint. **Woolson** also discloses first and second drilling holes having pre-determined positions relative to the surface of the block and having axes that extend through a portion of the joint. Ex. 1031, Figs. 7A-B. Ex. 1002 ¶¶116-19.

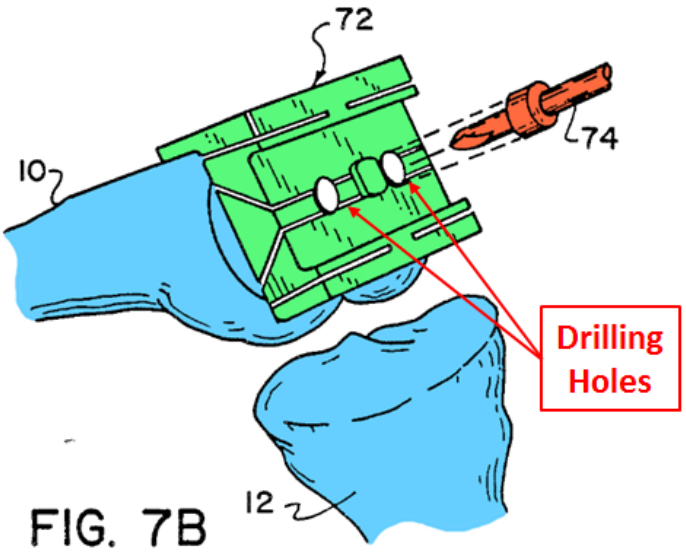
Claim 2	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the tool is comprised of multiple components.	**Radermacher** discloses that the tool may be comprised of multiple components. Ex. 1003 at 30 (disclosing the "individual template 4," the "drill sleeve 11" which is "inserted" into the individual template, and the "additional template 27"); *id.* at 13, 22-23, 25, Fig.13a; Figs. 10a-b, 11b.  Radermacher discloses that "any suitable tool guides" (second components) can be provided "on" the template and can be "coupled (releasably or non-releasably) in a mechanically rigid manner." *Id.* at 13. Ex. 1002 ¶120.

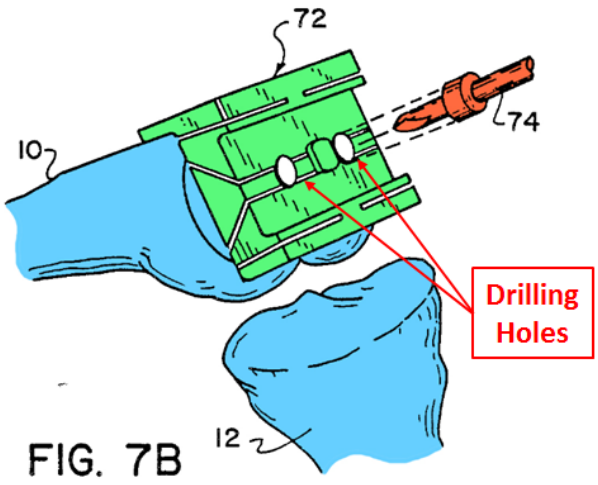
Claim 3	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the block containing the patient-specific surface and the drilling holes are comprised of a single component.	**Radermacher** discloses a single-component block (individual template 4) that contains the patient-specific surface and a drill hole. Ex. 1003 at Fig. 13a, c.  FIG.13c Radermacher discloses other embodiments in which a single-component block includes two holes and a patient-specific surface. *Id.* at Figs. 6b, 10c. **Woolson** discloses a single-component block having a surface that mates with the joint and the two drilling holes. Ex. 1031, Figs. 7A-B. Ex. 1002 ¶121.

Claim 5	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the patient-specific surface is a continuous surface.	**Radermacher** discloses that the patient-specific surface 1 may be a continuous surface (as opposed to a surface defined by many individual pins). Ex. 1003 at 10-12, 14-15, 21-22, Figs. 13a, c; Ex. 1002 ¶122.  FIG.13c

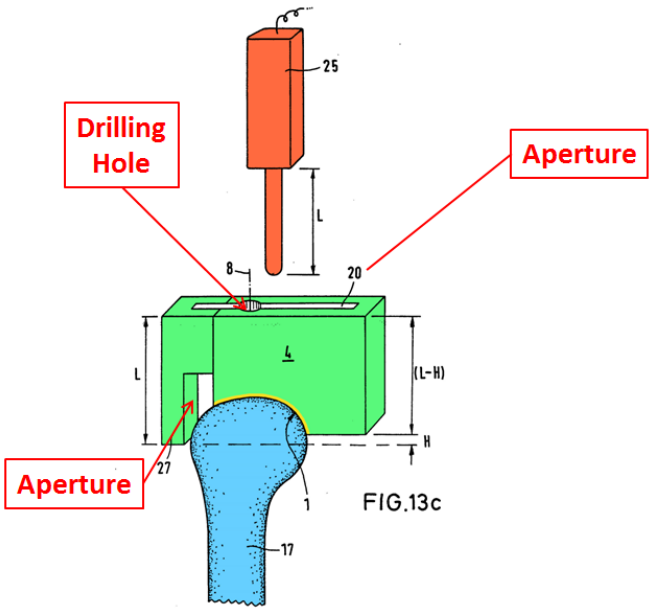
Claim 6	
The patient-specific surgical tool of claim 5,	*See* Claim 5.
wherein the patient-specific surface is made of a polymer.	**Radermacher** discloses that "the individual template 4 is produced ... from UV curable polymer." Ex. 1003 at 23; Ex. 1002 ¶123.
Claim 7	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the surface of the joint is a femoral surface of a knee of the patient and the drilling holes are configured to define a path through a femoral surface when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged	**Radermacher** discloses that the surface is a femoral surface. Ex. 1003 at 30 ("the seat for the knee-joint head prosthesis."); Figs. 13a-13d. The drill hole is configured to define a path through a femoral surface:  *Id.* at Fig. 13c, b; *id.* at 30.

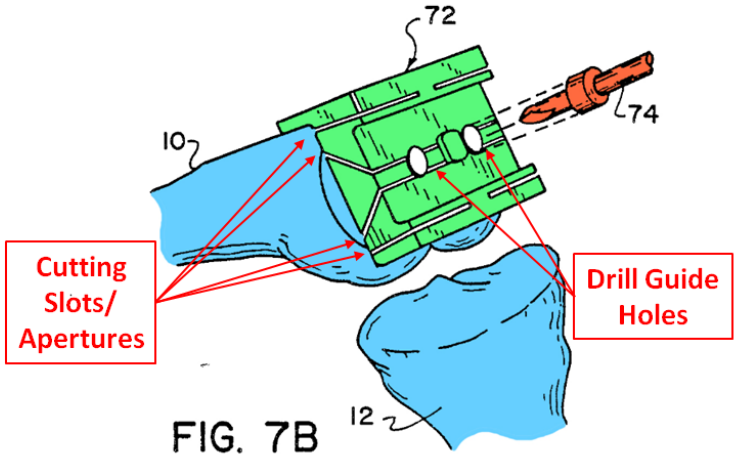
articular surface of the joint.	**Woolson** discloses a "conventional cutting guide 72" for the femur having two drill holes. Ex. 1031, Fig. 7B; 6:54-64.  FIG. 7B Ex. 1002 ¶124 (If Radermacher's template included the drill holes described in Woolson, or if Woolson's conventional guide was modified to include a patient-specific surface, the resulting block would include drilling holes configured to define a path through a femoral surface.) **Knowledge of a POSITA:** Femoral cutting blocks having two drilling holes that define a path through a femoral surface were conventional, widely known, and within the knowledge of a POSITA. Ex. 1002 ¶109; *see also* Ex. 1032, 5:34-43, 8:11-22, 9:13-26, 10:15-20, Figs. 2B, 14, 30B, 52, 53.

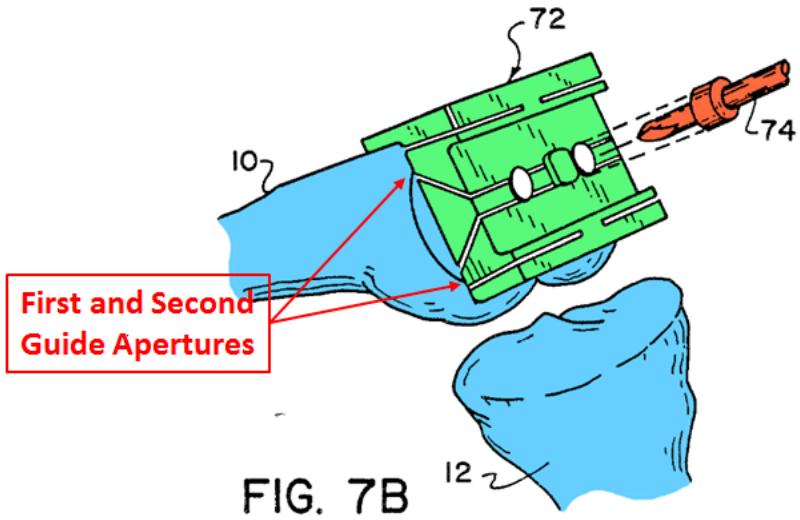
Claim 8	
The patient-specific surgical tool of claim 7,	*See* Claim 7.
wherein the path is configured to extend through a distal portion of a femoral condyle when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged articular surface of the joint.	*See* Claim 7. If Radermacher's template was modified to include two drilling holes, as was conventional and described in Woolson, the paths defined by the drilling holes would extend through a distal portion of a femoral condyle. Ex. 1002 ¶125.  FIG. 7B Ex.1031, Fig. 7B. Such drill paths were within the knowledge of a person of ordinary skill. Ex. 1002 ¶125.
Claim 11	
The patient-specific surgical tool of claim 7,	*See* Claim 7.
wherein the path is configured to extend through	*See* Claims 7-8. If modified to incorporate two drilling holes as disclosed in Woolson, Radermacher's template would include holes that define a path configured to extend through a portion of two femoral condyles:

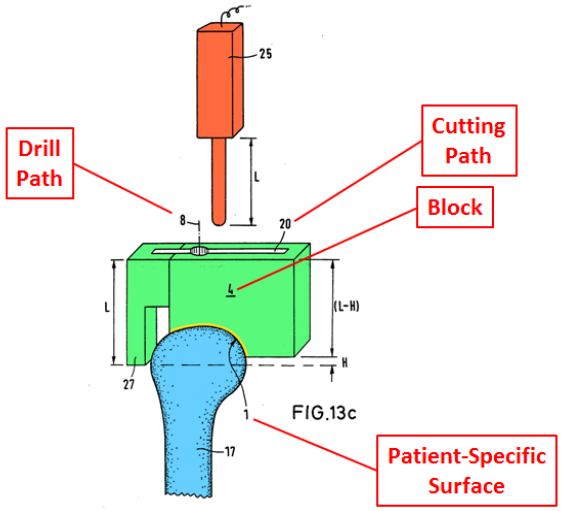
a portion of two femoral condyles when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged articular surface of the joint.	 FIG. 7B Ex. 1031, Fig. 7B; Ex. 1002 ¶129.
Claim 20	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the joint is a knee joint and further comprising a spacer selected to fit in a space between a femoral surface and a tibial surface of the knee and to balance ligaments associated with the knee.	**Radermacher** and **Woolson** both disclose using the block for a knee joint. Ex. 1003 at 30; Ex. 1031, 1:14-15. **Woolson** discloses the use of a spacer to check ligament balance in the joint during knee arthroplasty. Ex. 1031, 7:49-53 ("After making the tibial and the distal femoral bone cuts, a trial tibial component and trial femoral spacer is inserted into the joint space to test the adequacy of bone resection with the knee in extension, as is conventionally done."). **The '302 patent** admits that spacers were "known in the art." Ex. 1001, 73:67-74:3. **Knowledge of a POSITA:** Spacers were widely known and used by POSITAs for ligament balancing. *See, e.g.*, Ex. 1031, 7:49-53; Ex. 1034 at 19-20, 23-25, Figs. 7, 17, 19; Ex. 1041 at 29; *see also* Ex. 1002 ¶¶131-33; *id.* ¶133 (use of spacers was "standard protocol for all total knee replacements").

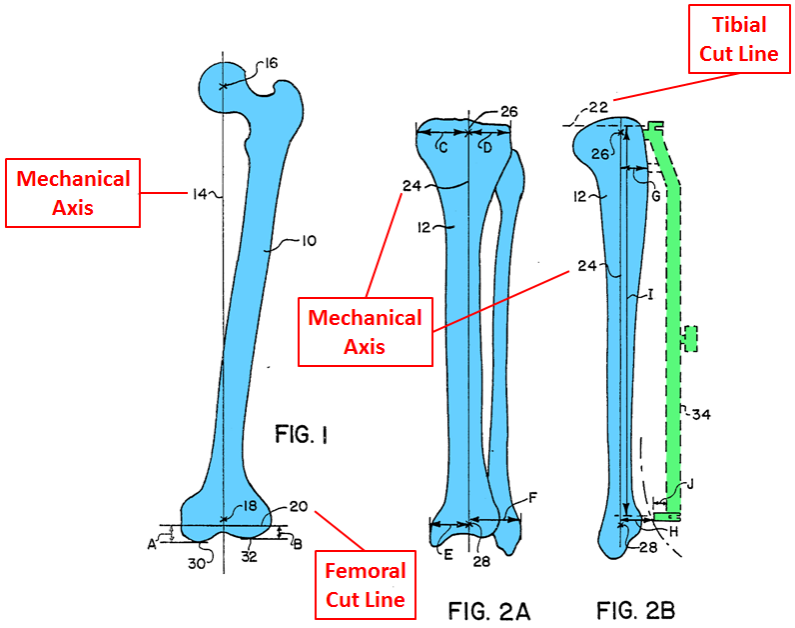
Claim 21	
The patient-specific surgical tool of claim 13,	*See* Claim 13.
wherein the spacer is not connected to the block.	**Woolson** discloses a spacer that is not connected to the block. Ex. 1031, 7:49-53; Ex. 1002 ¶132. **Knowledge of a POSITA:** The use of spacers not connected to a block was "standard protocol for all total knee replacements" (Ex. 1002 ¶133) and disclosed in many references. *See, e.g.*, Ex. 1034 at 23-25, Figs. 17, 19; Ex. 1041 at 29; Ex. 1002 ¶¶131-33.
Claim 24	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the joint is a knee joint and further comprising an adjustment mechanism to balance ligaments associated with the knee.	Because a spacer is an "adjustment mechanism" (Ex. 1001, 113:11-14, 19:37-40, 73:67-74:3, 104:17-20), this claim is invalid for the same reasons as Claim 20. In addition, the '302 patent admits that other adjustment mechanisms, such as tensiometers, were well-known and not part of the invention. Ex. 1001, 103:45-47 ("The design of tensiometers are known in the art and are not included herein to avoid obscuring the invention. Suitable designs include, for example, those described in U.S. Pat. No. 5,630,820 to Todd issued May 20, 1997."). Ex. 1002 ¶¶131-33.

Claim 25	
The patient-specific surgical tool of claim 24,	*See* Claim 24.
wherein the adjustment mechanism is not connected to the block.	*See* Claims 21 and 24.
Claim 28	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
further comprising a plurality of guide apertures.	**Radermacher** discloses a two guide apertures (slots defining cutting paths 20a and 20c) in addition to a drilling hole (along axis 8):  FIG.13c Ex. 1003 at Fig. 13c. Radermacher further discloses two

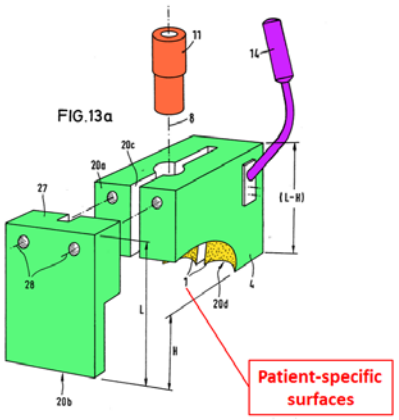
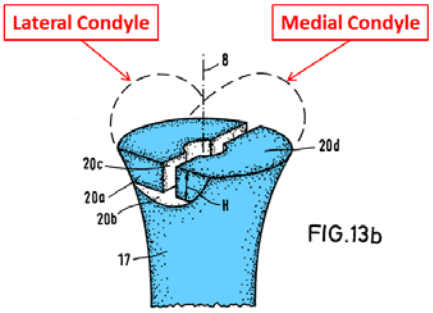
	additional guide surfaces (20b and 20d) that a POSITA would readily understand could be replaced with apertures. Ex. 1003 at 30, Fig. 13a; Ex. 1002 ¶135. **Woolson** discloses a block further comprising a plurality of cutting slots (guide apertures). Ex. 1031, 6:54-64, Figs. 7A-B; Ex. 1002 ¶137.  FIG. 7B *See also* Ex. 1002 ¶138 (having two drilling holes and two cutting slots at an angle "was a common configuration used by surgeons in the 1990s").
Claim 29	
The patient-specific surgical tool of claim 28,	*See* Claim 28.
wherein a first guide aperture is configured at an angle to a second guide aperture of the plurality of guide apertures.	**Radermacher** discloses that a first guide aperture (e.g., 20a) is at an angle to a second guide aperture (e.g., 20c). In addition, if surfaces 20b and 20d were replaced with slots as discussed for Claim 27, those apertures would be at an angle to 20a or 20c. **Woolson** discloses multiple cutting slots (guide apertures). Ex. 1031, 6:54-64, Figs. 7A-B. Many combinations of the cutting guides satisfy this claim limitation. For example, either of the two anterior guides (or either of the two posterior guides) could

	be the first guide aperture and either of the two central guides could be the second guide aperture. Alternatively, the two central guides could be the first and second guide apertures. One such combination is shown below:  FIG. 7B Ex. 1031, Fig. 7B. Ex. 1002 ¶¶134-38.
Claim 34	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the joint is one of a hip, knee, ankle, shoulder, elbow and wrist joint.	**Radermacher** discloses that the individual template technique may be used for the hip and knee joints. Ex. 1003 at 10, 25-26 (hip joint), 30 (knee joint).

Claim 35	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the tool is configured to be oriented along a mechanical axis of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or damaged articular surface.	**Radermacher:** The tool is configured to be oriented along a mechanical axis of the joint. Ex. 1003 at Figs. 13b, 13c.  Ex. 1002 ¶¶162-65. **The '302 patent** admits that determining a biomechanical axis and accounting for such axes in knee arthroplasty was well-known. Ex. 1001, 38:49-39:4. **Knowledge of a POSITA:** Orienting cutting guides along a mechanical axis to provide drilling or cutting paths that are aligned relative to the mechanical axis was within the knowledge of a POSITA, as this was standard practice in knee arthroplasty procedures. Ex. 1002 ¶¶163-65; *see also* Ex. 1033 at 31 ("accurate placement of implant components with respect to the individual mechanical axis of the leg is essential"), 29; 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 along the mechanical axis such that a cutting path (e.g., lines 20, 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. 1002 ¶¶145, 161-69, 172.

Claim 36	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the tool is configured to be oriented along an anatomical axis of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or damaged articular surface.	*See* Claim 35. For the tibia, the mechanical and anatomical axes are the same. *See* Ex. 1001, 68:66-67 ("The long axis of the tibia 1936 is collinear with the mechanical axis of the lower extremity 1910"); Ex. 1002 ¶145.
Claim 37	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the corresponding portion of the diseased or damaged articular surface of the	**Radermacher** discloses the patient specific surface matched to both the medial and lateral condyles. Ex. 1003 at 30, Fig. 13a-13c.

joint includes portions of at least one of a medial condyle and a lateral condyle.	  **Woolson** discloses using a surgical spanning both condyles. Ex. 1031, 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.")
Claim 47	
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the corresponding portion of the diseased or damaged surface of the joint is a portion of a cartilage surface of the joint.	*See* element 1[a], above. Ex. 1002 ¶¶88-103.

B. Ground 2: Claims 13, 18, and 38 Are Unpatentable Under 35 U.S.C. § 103(a) in View of Radermacher, Alexander, Woolson, and Kenna.

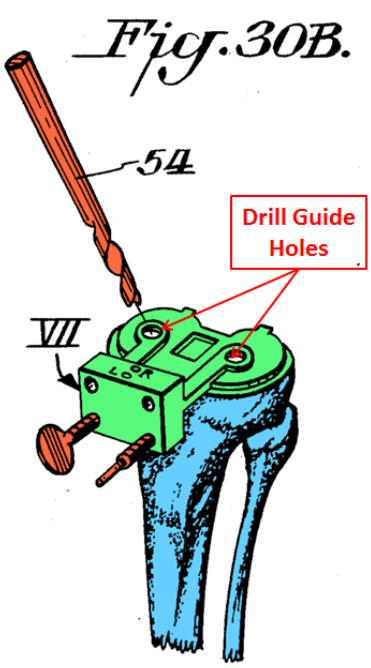
1. Claim 13

Claim 13 specifies that the patient-specific surface matches the tibial surface and that the drilling holes define a path "through a tibial plateau of the tibia."

a. Substantially a Negative of a Tibial Surface

Although Radermacher describes a template for a femoral surface in detail, it would have been obvious to a POSITA that it could be used for resecting the tibia for several reasons. First, Radermacher discloses that the individual template technique may be used with any osseous structure (Ex. 1003 at 9-13, 30), which would include the tibia. Second, Radermacher explains that standard tool guides, upon which Radermacher seeks to improve, were provided for both the femur and the tibia. *Id.* at 2. Thus, a POSITA would have understood that Radermacher's patient-specific template could be used for the tibia. Ex. 1002 ¶156. Third, in the 1990s, knee arthroplasty virtually always involved resecting both the femur and the corresponding portion of the tibia. *Id.* Thus, those of ordinary skill knew that tools, such as those described in Radermacher, would be used for resecting both the femur and the tibia. Indeed, several references disclosed the use of patient-specific templates, like those in Radermacher, for resecting the tibia. Ex. 1033 at 31-32, Figs. 2A-B; Ex. 1008, 3:40-4:49, Fig.2; Ex. 1007, 6:48-64, Fig. 6.

In addition, Kenna (Ex. 1032) disclosed a tibial block that rests on the tibial surface, as shown below:

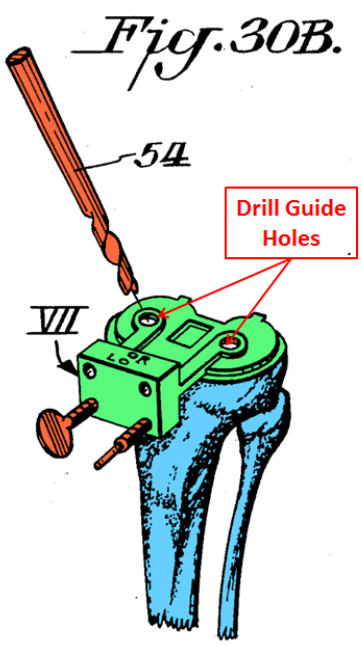


Ex. 1032, Fig. 30B. Thus, it would have been obvious to a POSITA that the patient-specific surface of Radermacher's template could be substantially a negative of a tibial surface. Ex. 1002 ¶157.

b. Drilling Holes Defining a Path Through a Tibial Plateau

Tibial implants in the 1990s commonly included two pegs. Ex. 1002 ¶156. Accordingly, tibial blocks also commonly included two corresponding drilling holes. *Id.* Thus, it would have been obvious to a POSITA that the patient-specific surface of Radermacher's template could match a tibial surface and that the drill holes would extend vertically through the tibial plateau. *Id.*

In addition, Kenna (Ex. 1032) disclosed a tibial block having two drilling holes. Specifically, Kenna discloses a "tibial positioning/fixation jig" that includes two drilling holes oriented through the tibial plateau to create holes for two implant pegs. Ex. 1032, 8:16-20, 10:15-27, Figs. 30B, 89, 90.

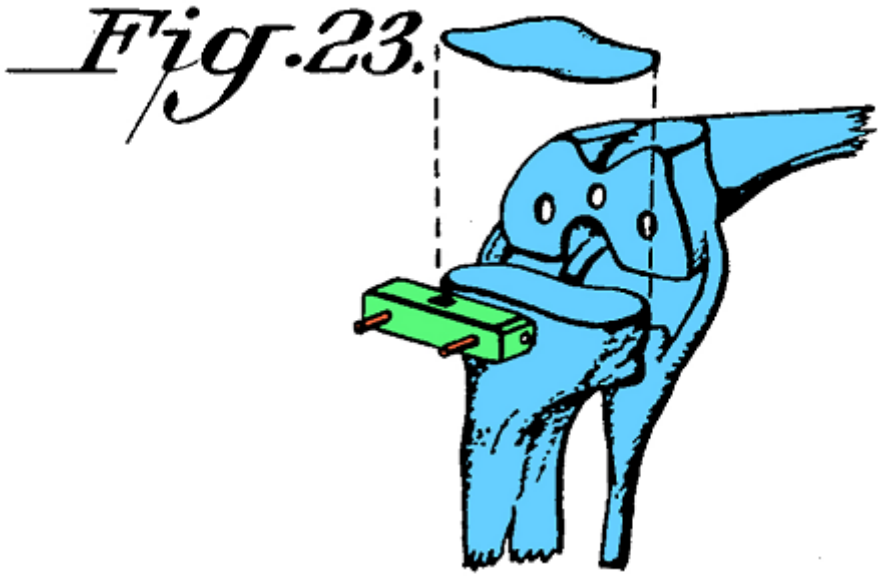


Id., Fig. 30B.

A POSITA would have been motivated to modify Radermacher to incorporate two drilling holes through the tibial plateau as disclosed in Kenna, or alternatively to modify Kenna's conventional block to include the patient-specific surface described in Radermacher, for numerous reasons. First, Kenna and Radermacher are in the same field (knee arthroplasty) and describe the same devices (cutting guides). Ex. 1002 ¶158. Second, Radermacher contemplates

multiple drilling holes and 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 presence and number of drill holes would depend on the implant being used, i.e., if the implant contained two pegs, then block would also contain two drilling guides. Ex. 1002 ¶158. As previously noted, the '302 patent admits that this was within the knowledge of a POSITA. Ex. 1001, 102:61-65. Fourth, having two drilling holes in a tibial cutting guide was commonplace. Ex 1002 ¶158. Thus, including two drilling holes that define a path vertically "through the tibial plateau" in Radermacher's template would have involved nothing more than combining Radermacher's teachings with common knowledge and/or Kenna according to known methods to yield predictable results. *Id.* It would therefore have been obvious to a POSITA that Radermacher's individual template, as applied to a tibia, would include two drilling holes that define a path vertically "through the tibial plateau." *Id.*

In addition, in the co-pending litigation, ConforMIS contends that holes in a block intended for pins for securing the block to the joint (as opposed to holes for receiving pegs on the implant) also constitute "drilling holes." *See* Ex. 1095 at 21-52. Under ConforMIS's proposed construction, this claim also would have been obvious in view of Kenna. Kenna discloses a jig for resecting the tibia (jig IV) that is secured in place by drilling through holes in the jig and inserting pins:



Ex. 1032 at Figs. 21-22, 6:67-7:2. As described above, Kenna also discloses a jig for drilling two vertical holes in the tibia (jig VII, Figure 30B), and that jig is also secured to the tibia using screws. Ex. 1032, 7:50-56, Figs. 25, 30B.

A POSITA would have immediately recognized that an individual template as described in Radermacher could include two anteriorly-positioned horizontal holes for guiding a drill such that the patient-specific tool could be secured to the tibia. Ex. 1002 ¶160. Indeed, Radermacher expressly contemplates the use of such fixation mechanisms. Ex. 1003 at 23 (screw connections can be provided for fixing the template to the osseous structure), 25 (fixation nails, screws, etc. can be used). Moreover, securing tibial cutting blocks using horizontal drill holes was common practice. Ex. 1002 ¶160. Thus, it would have been obvious to a POSITA that Radermacher's tibial template could be secured with horizontal pins as

disclosed in Kenna and, therefore, obvious that the template could include corresponding holes defining a path horizontally "through the tibial plateau." *Id.*

2. Claim 18

Claim 18 recites that the drilling holes define a path that "is at a predetermined orientation relative to a mechanical axis of the joint." It would have been obvious to a POSITA to align the drilling holes for the tibial implant pegs in Radermacher and Kenna relative to the mechanical axis because this was common practice in the industry and is taught by both Woolson and Kenna.

As described above, the '302 patent admits that determining the mechanical axis and relying on that axis when performing knee arthroplasty was widely known. Ex. 1001, 30:32-51, 34:46-39:47. As was also described above in connection with Claim 35, a POSITA would have known that the mechanical axis determines the distribution of forces in the knee and that both the femoral and tibial components must be aligned properly relative to the axis. Ex. 1002 ¶163. This, in turn, requires the surgical tool and drilling paths to be precisely aligned relative to the mechanical axis. *Id*. Thus, such alignment was entirely conventional and widely known by POSITAs in the 1990s. *Id.*

As described previously, Woolson discloses the importance of orienting the surgical tool to provide cutting or drilling paths that are aligned relative to a mechanical axis. *See* discussion of Claim 35, *supra*. Specifically, Woolson

discloses that the tibial cut is made perpendicular to the mechanical axis. *See id.* Accordingly, the drilling holes for pegs, which are typically oriented at a right angle to that surface, would be parallel to the mechanical axis. Ex. 1002 ¶166. Thus, the drilling path would also be at a "predetermined orientation" relative to the axis.

Kenna also discloses this limitation. Kenna further confirms that aligning cuts and drill holes relative to a patient's mechanical and anatomic axes was well-known. Ex. 1032, 3:1-3, Fig. 1, 3:1-52, 8:27-30, 9:37-41. Kenna discloses cutting the tibia relative to the mechanical axis. *Id.* Kenna discloses drilling holes 50 at an incline. *Id.* at 10:21-23. Thus, the drill holes define a path having a predetermined orientation relative to a mechanical axis of a patient. Ex. 1002 ¶170.

Alternatively, since ConforMIS contends that drilling holes for pins for securing the template to the bone constitute the claimed "drilling holes," Kenna discloses this limitation because Kenna discloses pin holes that are parallel to the cutting guide, and thus oriented relative to the mechanical axis just as the cutting guide is. Ex. 1032, 6:67-7:2, 9:62-67, Figs. 21-22, 69-75.

Accordingly, it would have been obvious to a POSITA to provide drilling holes through the tibial plateau, either vertically or horizontally, that define a path

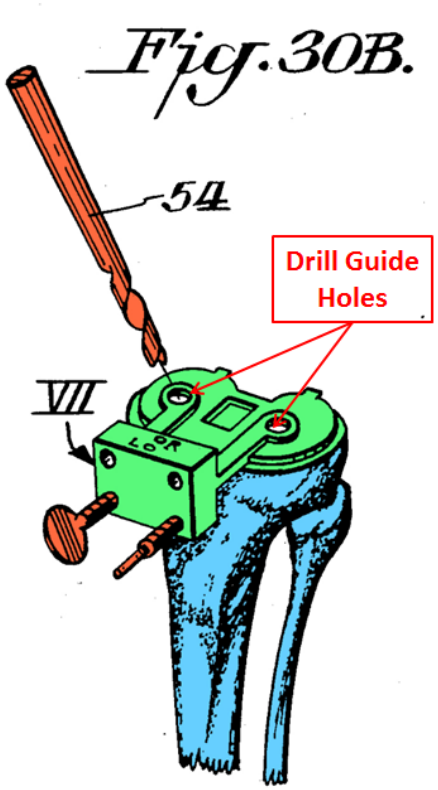
having a predetermined orientation relative to a mechanical axis (i.e., either perpendicular to the axis or parallel to the axis). Ex. 1002 ¶172.

3. Claim 38

Claim 38 depends from Claim 1 and further specifies that the corresponding portion of the joint includes portions of at least one of a medial and a lateral tibial plateau. For the reasons discussed above for Claims 13 and 18, it would have been obvious to a POSITA that Radermacher's template could be applied to the surfaces of the tibia. Ex. 1002 ¶174.

The chart below further demonstrates how Claims 13, 18, and 38 are disclosed by the prior art under Ground 2. *See also* Ex. 1002 ¶176.

Claim 13	Exemplary Disclosure in Prior Art
The patient-specific surgical tool of claim 1,	*See* Claim 1.
wherein the surface of the joint is a tibial surface of a tibia of the patient [and] the drilling holes define a path through a tibial plateau of the tibia.	**Radermacher** discloses that the individual template technique may be used with any osseous structure (Ex. 1003 at 9-13, 30), which would include the tibia. Radermacher discloses that standard tool guides, upon which Radermacher seeks to improve, were provided for both the femur and the tibia. *Id.* at 2. **Kenna** discloses a tibial cutting block including two drilling holes that define a path through the tibial plateau to seat the tibial implant. Ex. 1032, 8:16-20, 10:15-27, Figs. 30B, 89-90.



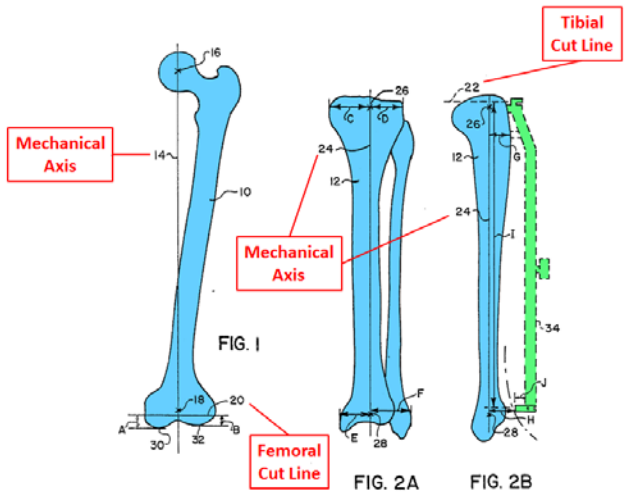
Id., Fig. 30B.

Woolson discloses resecting the tibia and "the remainder of the surgical procedure is carried out as usual." Ex. 1031 at 4:20-21, 6:65-7:62, Fig. 2B. A POSITA would understand that the "usual" procedure includes placing drill holes that define a path through the tibial plateau to seat the tibial implant. Ex. 1002 ¶159.

To the extent that "drilling holes" is construed to include holes drilled for pins to secure the tool to the bone, Kenna also discloses at least two such holes through the tibial plateau. Ex. 1032, 6:66-7:2, 9:62-67, Figs. 21-22.

Ex. 1002 ¶¶155-60.

Claim 18	
The patient-specific surgical tool of claim 13,	*See* Claim 13.
wherein the path is at a predetermined orientation relative to a mechanical axis of the joint.	**Radermacher:** The drilling path in Radermacher is predetermined, and is inherently oriented relative to the mechanical axis. **The '302 patent** 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. **Knowledge of a POSITA:** Orienting cutting guides to provide drilling or cutting paths that are aligned relative to a mechanical axis was standard practice in knee arthroplasty procedures. Ex. 1002 ¶¶163-65; *see also* Ex. 1033 at 31 ("accurate placement of implant components with respect to the individual mechanical axis of the leg is essential"), 29. Persons of ordinary skill understood that orienting the drilling paths relative to the mechanical axis would prevent the implant from loosening. Ex. 1002 ¶163. **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. **Kenna** discloses aligning tibial cuts relative to the mechanical axis (Ex. 1032, 3:1-3, Fig. 1, 3:1-52, 8:27-30, 9:37-41). Kenna further discloses vertical drilling holes 50 that define a path through the tibial plateau. *Id.*, 10:21-23. Such paths are oriented relative to the mechanical axis. Kenna also discloses horizontal drilling holes for pins for securing the tool to the tibia. Under ConforMIS's construction, these holes also constitute "drilling holes" that define a path "through a tibial plateau" (as recited in Claim 13). Such a path would also be at a predetermined orientation relative to the mechanical axis. Ex. 1002 ¶¶161-72.
Claim 38	
The patient-specific surgical tool of	*See* Claim 1.

claim 1,	
wherein the corresponding portion of the diseased or damaged surface of the joint includes portions of at least one of a medial tibial plateau and a lateral tibial plateau.	*See* Claims 13, 18.

C. Ground 3: Claims 1-3, 5-8, 11, 13, 18, 20-21, 24-25, 28-29, 34-38, and 47 Are Unpatentable Under 35 U.S.C. § 103(a) in View of Radermacher, Fell, Woolson, and Kenna.

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 articular or 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. 1002 ¶183. 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/articular 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. 1002 ¶¶189-95. 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. 1002 ¶¶191-95. 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.*

Fourth, a POSITA would have recognized that such a patient-specific template would simplify the surgery. *Id.* ¶193. 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/articular surface would have been obvious over the combination of Radermacher and Fell. Because the relevant disclosures of Radermacher, Woolson, and Kenna, as well as the knowledge of a POSITA, are the same as in Grounds 1 and 2, the chart below provides only the claim elements to which Fell is relevant along with the additional corresponding disclosure from Fell. *See* Ex. 1002 ¶196.

No.	Claim Limitation	Disclosures in Prior Art
1[b].	the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged articular surface of the joint and having a predetermined position and orientation relative to the corresponding portion;	**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 articular/cartilage surface. *See, e.g.*, Ex. 1005 at 14, 15, 22.
47.	The patient-specific surgical tool of claim 1,	*See* Claim 1.
	wherein the corresponding portion of the diseased or damaged surface of the joint is a portion of a cartilage surface of the joint.	*See* Claim 1[b].

VIII. SECONDARY CONSIDERATIONS

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 above, Petitioner has established a reasonable likelihood of prevailing in showing that Claims 1-3, 5-8, 11, 13, 18, 20-21, 24-25, 28-29, 34-38, and 47 of the ’302 patent are unpatentable, and therefore requests that the Board order an *Inter Partes* Review Trial and cancel those claims. Petitioner authorizes the Patent and Trademark Office to charge any required fees to Deposit Account No. 11-1410, including the fee as 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

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing **PETITION FOR INTER PARTES REVIEW OF CLAIMS 1-3, 5-8, 11, 13, 18, 20-21, 24-25, 28-29, 34-38, and 47 OF U.S. PATENT NO. 8,062,302**, exclusive of the parts exempted as provided in 37 C.F.R. § 42.24(a), contains 13,680 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24(a).

Dated: January 26, 2017

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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 1-3, 5-8, 11, 13, 18, 20-21, 24-25, 28-29, 34-38, and 47 OF U.S. PATENT NO. 8,062,302 AND EXHIBITS 1001-1017, 1019, 1021-1022, 1024-1028, 1031-1034, 1036-1037, 1041-1043, 1070, 1090, 1095** 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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