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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. IPR2017-00372
Patent 8,377,129

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,377,129

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OTHER AUTHORITIES

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 8,377,129 ("the '129 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 '334")
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 '129 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. 60/293,488 (filed May 25, 2001)
1022	***Exhibit Number Not Used***
1023	U.S. Patent No. 8,036,729
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.)
1025-1030	***Exhibit Numbers 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")
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")
1038-1041	***Exhibit Numbers Not Used***
1042	Excerpts from Dror Paley, Principles of Deformity Correction (2002) ("Principles of Deformity Correction")

Exhibit No.	Description
1043	U.S. Patent No. 5,107,824 (“Rogers”)
1044-1049	***Exhibit Numbers Not Used***
1050	U.S. Patent No. 8,333,723 (“Hunter”)
1051	European Patent Application No. EP 0732092 (“Colleran”)
1052-1053	***Exhibit Numbers Not Used***
1054	U.S. Patent No. 3,869,731 (“Waugh”)
1055	U.S. Patent No. 5,171,244 (“Caspari”)
1056	***Exhibit Number Not Used***
1057	U.S. Patent No. 5,152,796 (“Slamin”)

Petitioner Smith & Nephew, Inc. ("Petitioner") requests *inter partes* review of claims 1-83 of U.S. Patent No. 8,377,129 (Ex. 1001, "the '129 patent"), which issued on February 19, 2013, and is purportedly owned by ConforMIS, Inc. ("ConforMIS").

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

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

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

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

ConforMIS asserted the '129 patent against Petitioner in *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass.), filed February 29, 2016 and served on March 1, 2016. Petitioner also requested *inter partes* review of related ConforMIS U.S. Patent Nos. 9,055,953 and 9,216,025, which ConforMIS also asserted in the co-pending litigation. *See* IPR2016-01874 and IPR2017-00115.

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

Lead Counsel	Back-up Counsel
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D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to counsel at the addresses above. Petitioner also consents to electronic service by email at BoxSMNPHL.168LP4@knobbe.com.

II. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(A)

Petitioner certifies the '129 patent is available for *inter partes* review and that Petitioner is not barred or estopped from challenging the patent claims on the grounds identified in this Petition.

III. SUMMARY OF ISSUE PRESENTED

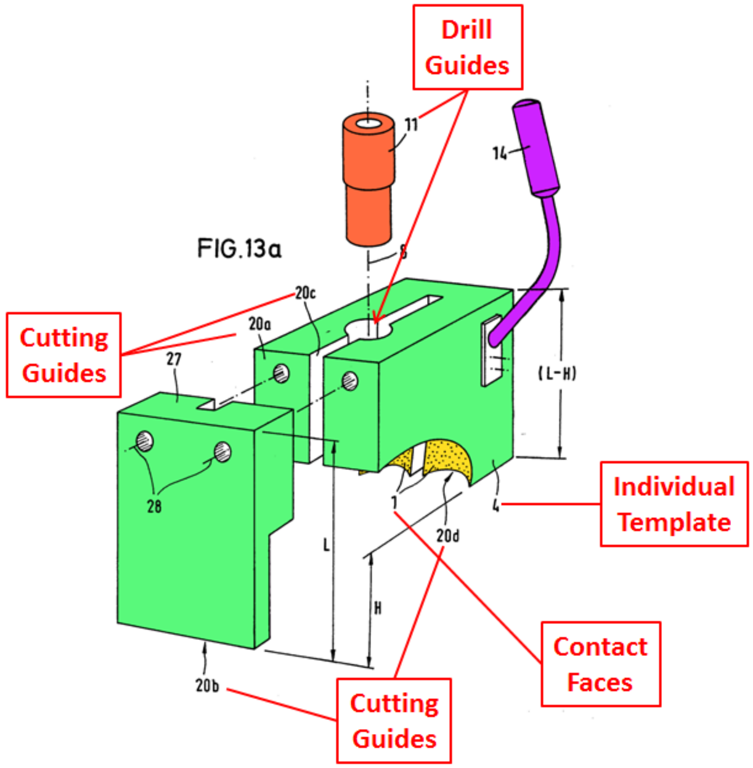
The ’129 patent claims generally recite a patient-specific instrument system for knee-joint surgery that includes a “patient-specific surface” and a “guide for directing a surgical instrument.” In claim 1, the patient-specific surface includes cartilage information derived from image data of a patient’s knee, and the guide: (1) has a predetermined position relative to the patient-specific surface; (2) has a predetermined orientation relative to an anatomical axis or a biomechanical axis of the patient’s knee; and (3) defines a drilling path having a position based on a predetermined internal or external rotation angle of an orthopedic implant. The other independent claims (claims 23, 44, and 62) have only minor differences. The dependent claims add trivial limitations regarding the patent-specific surface and guide.

By the patent’s earliest possible priority date in May 2002, surgical tools with patient-specific surfaces and guides were widely known and described in the prior art.

For example, Radermacher (1993) disclosed a system with a patient-specific instrument for preparing a knee to receive an implant. Radermacher[1] discloses an “individual template” 4 with five guides (cutting guides defining planes 20a-d and

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

a drill guide about axis 8) and "contact faces" 1 customized based on CT and/or MRI data to match the natural surface of the patient's knee joint:



Ex. 1003 at 12; Ex. 1002 ¶¶ 54, 81 (citing Ex. 1003, Fig. 13a)

The cuts/bores result in a resected bone (Fig. 13b) for seating an implant (Fig. 13d):

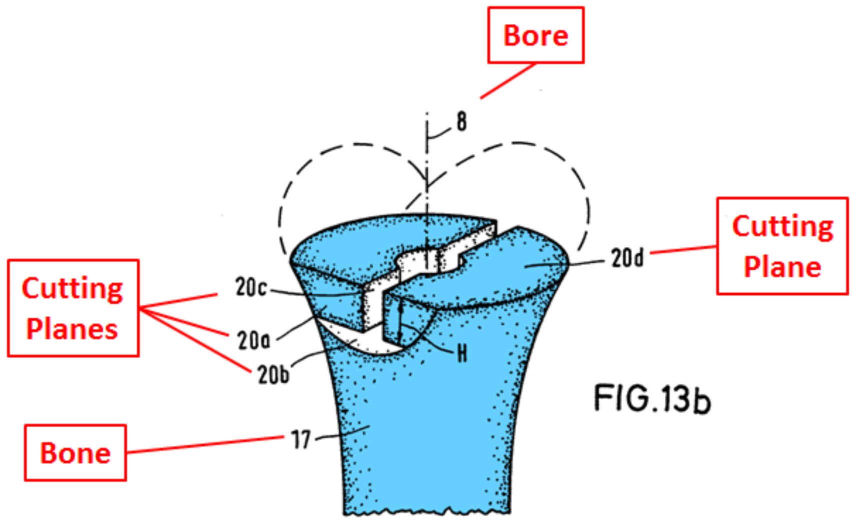


FIG.13b

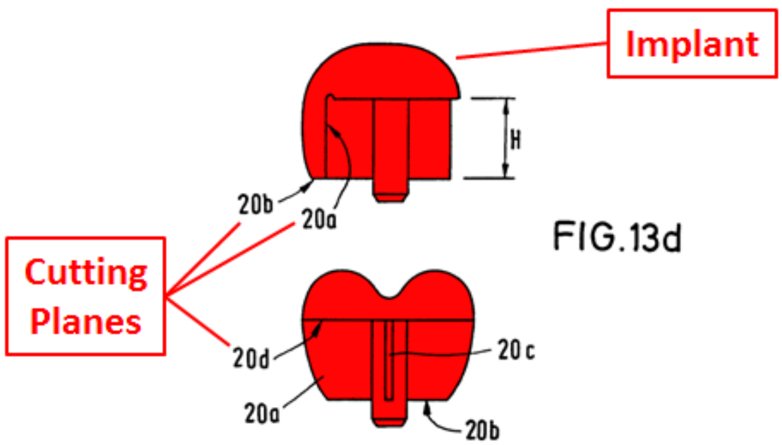


FIG.13d

Id. (citing Ex. 1003, Figs. 13b, 13d)

By the 1990s, it was also commonplace for surgical instruments to define cutting and/or drilling paths with a particular alignment relative to a patient's biomechanical or anatomical axes. Such alignment of the cutting or drilling paths ensured the implant itself was properly aligned. For instance, Woolson (1989) disclosed that "***all*** total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis" and that, to achieve such alignment, the cutting planes must be perpendicular to the axis. Ex. 1031, 1:26-36 (emphasis added). Woolson shows determining the axes (14, 24) and orienting a cutting guide so the cutting paths (20, 22) align perpendicular to the axis:

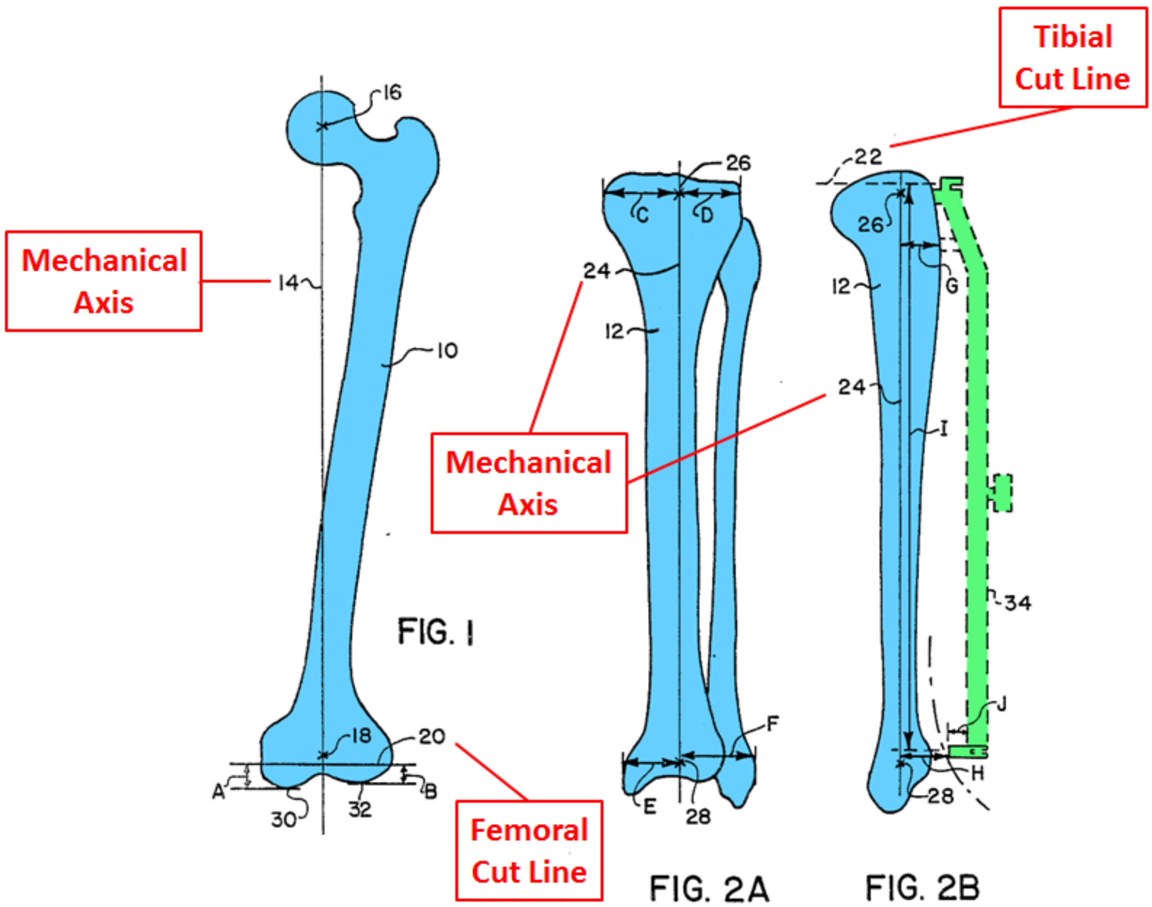


FIG. 1 FIG. 2A FIG. 2B

Ex. 1002 ¶ 120 (citing Ex. 1031, Figs. 1, 2A-2B). Many references taught such alignment was "important" or "essential" to the success of knee implant surgery.

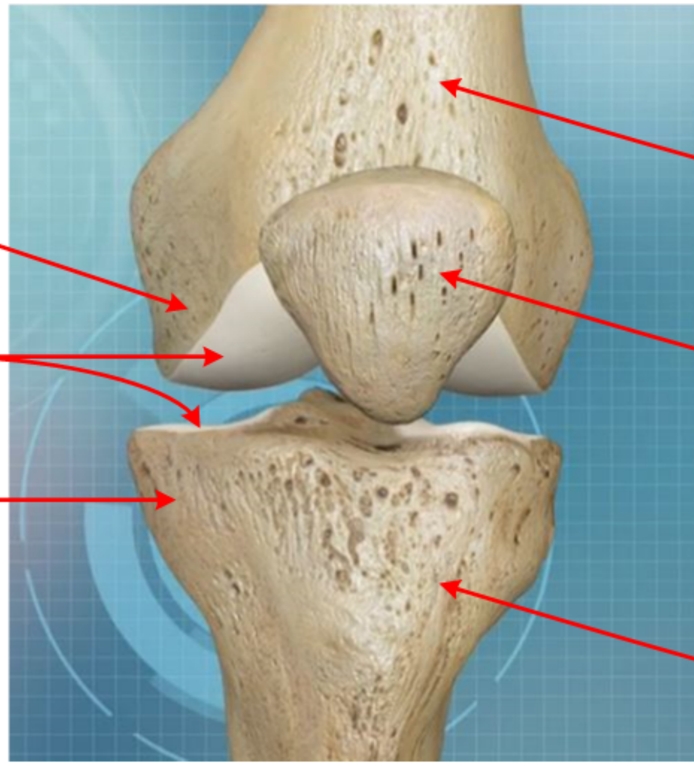
It was also well known by the 1990s that, to achieve proper knee-joint movement/alignment, surgeons should account for the present condition of the knee joint and its intended movements when planning surgical drilling or cutting paths and selecting implant components. Ex. 1002 ¶ 63. Kenna (1987), for instance, disclosed the need to account for anatomical movement of the knee, without compromising stability in knee implant surgery. Ex. 1032, 1:20-46. Kenna planned cutting or drilling paths based on the internal or external rotation angle of an orthopedic implant, while accounting for flexion extension, varus-valgus condition, and alignment of the femur and tibia. *Id.*, 1:20-46; 4:13-41; 5:34-43; 6:55-64; 9:13-26; 10:43-53.

IV. INTRODUCTION & STATE OF THE ART

A. Knee Joint Anatomy

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

Knee Joint (Front)



Ex. 1002 ¶ 36. In a healthy knee, the lower end of the femur and the upper end of the tibia are covered by articular cartilage, which provides a low-friction surface that facilitates rotation and absorbs shock. *Id.* The articular cartilage covers the subchondral bone. *Id.* In arthritic joints, some of the articular cartilage is often worn or torn away, exposing part of the subchondral bone. *Id.*

As shown below, a patient's femur and tibia define a "mechanical axis," namely, the axis extending from the center of the femoral head at the hip, through the center of the knee, and through the ankle joint. *Id.* ¶¶ 37-38.

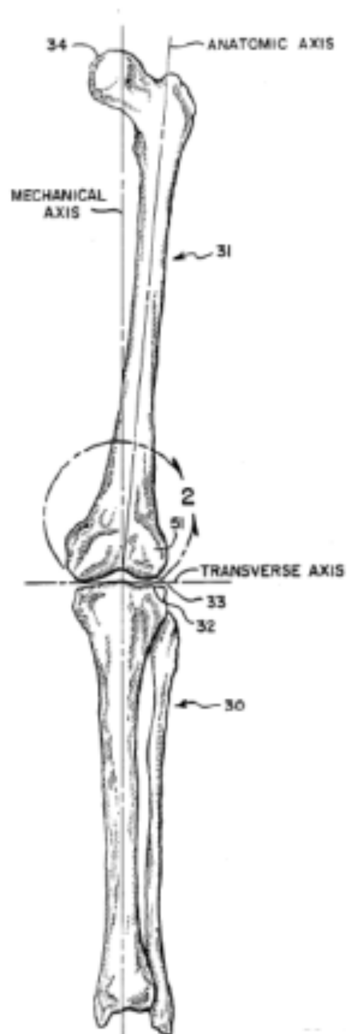


FIG. 1

Ex. 1036, Fig. 1.

The femur and tibia also each has an "anatomic axis," representing the axis extending along the center of the bone. *Id.*

The knee joint exhibits several distinct movements occurring simultaneously. One set of those movements is the internal and external rotation in the transverse plane of the knee joint ("ER ↔ IR"):

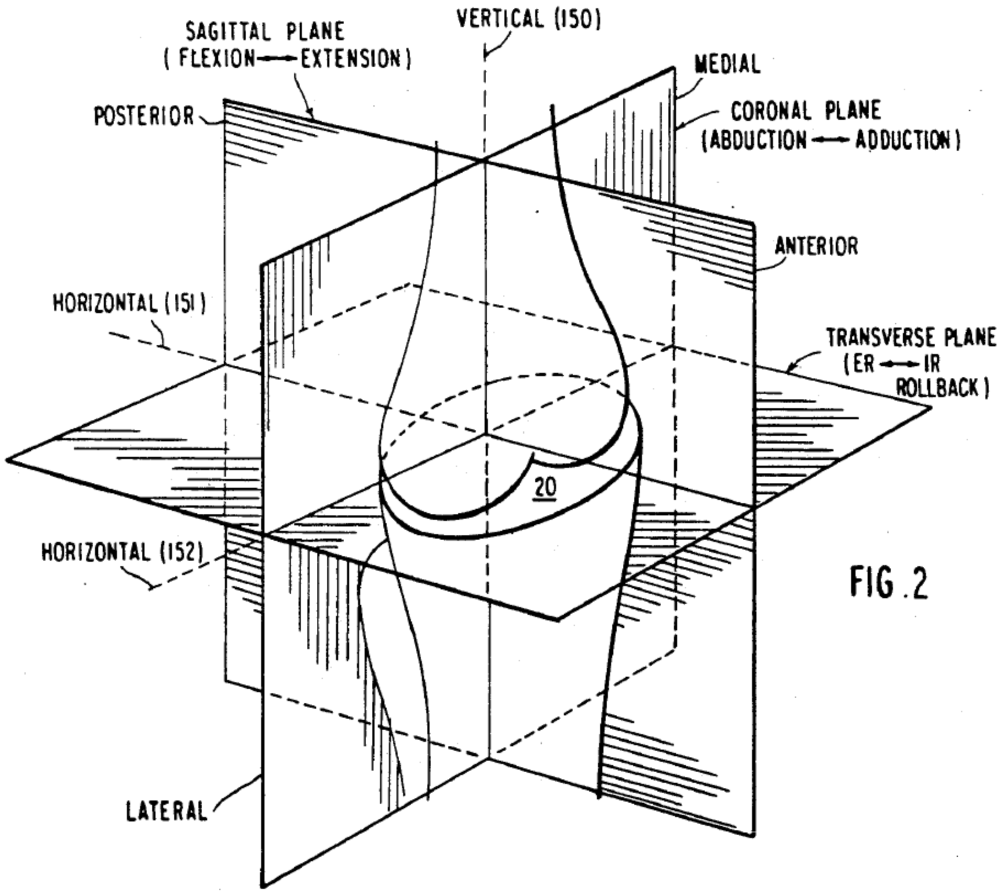


FIG. 2

Ex. 1043, Fig. 2; Ex. 1002 ¶¶ 39-41.

The knee joint can suffer from malalignments or deformities, such as the varus (bowed knee) condition or valgus (knocked-kneed) condition, as shown below:

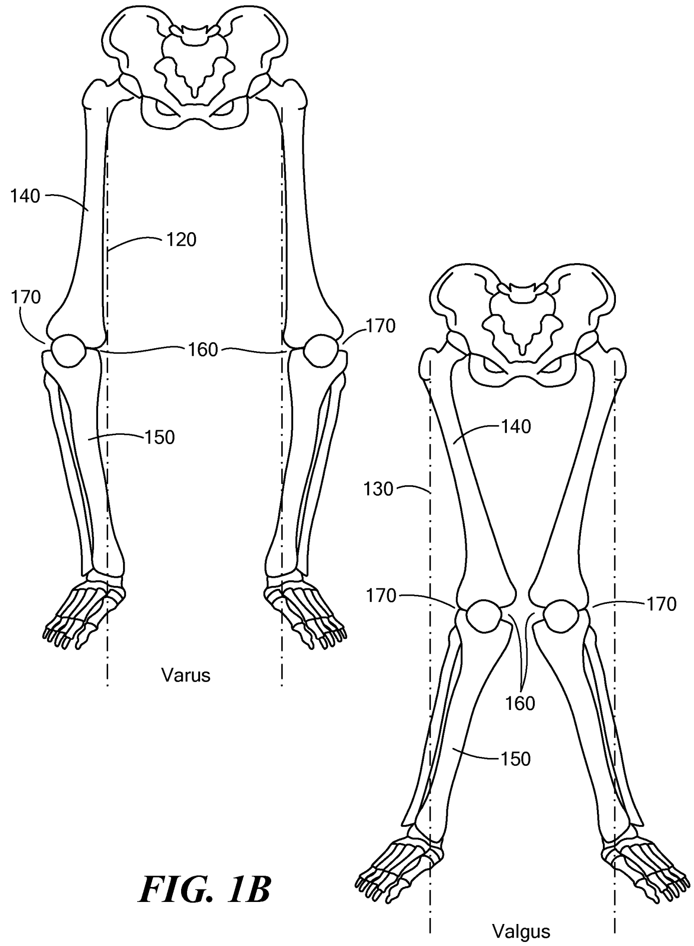


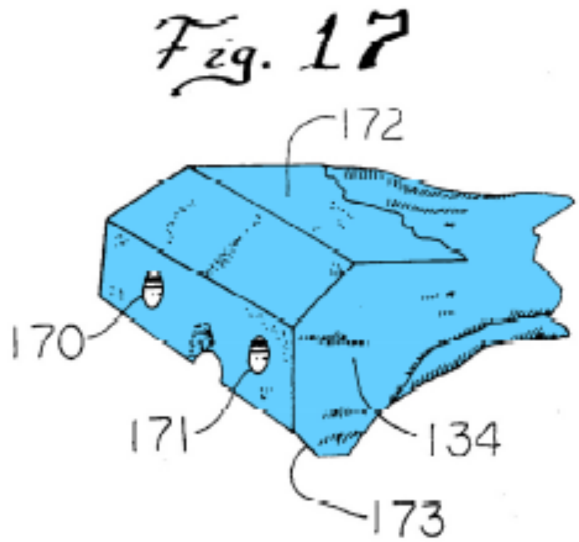
FIG. 1B

Ex. 1050, Fig. 1B.

B. Knee Replacement Procedures

When a disease such as osteoarthritis damages articular cartilage, a surgeon can replace portions of the knee with artificial components. Ex. 1002 ¶ 43. Such surgery, referred to as "knee arthroplasty," was known for decades before ConforMIS filed the '129 patent. *Id.* ¶ 34.

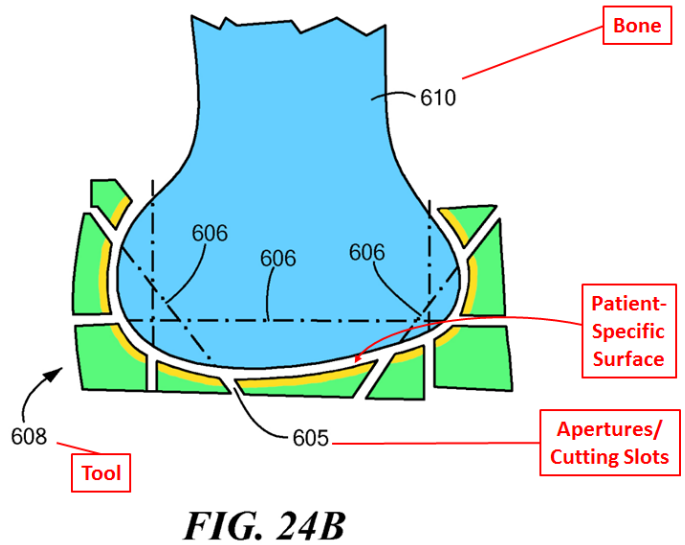
During knee arthroplasty, a surgeon prepares a patient's bone to receive an implant. *Id.* ¶¶ 43-44. During the preparation, the surgeon typically removes a portion of the bone and shapes it to receive the implant. *Id.* ¶ 44. The image below shows the end of a femur prepared in a typical manner, with flat bone surfaces for seating an implant component and holes for receiving pegs on the implant. *Id.*



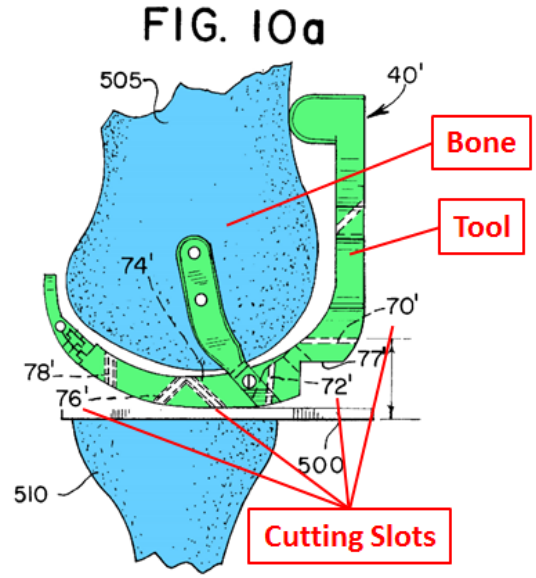
Id. (citing Ex. 1011, Fig. 17).

To promote accurate cuts and drill holes (which in turn ensure the implant component is properly oriented), a surgeon typically uses tools with holes, slots, or surfaces. They guide the surgeon's tools as the surgeon cuts (resects) the bone or drills holes into bone, so that the surgeon does not need to cut free-handed. *Id.* ¶ 45.

Indeed, tools having slots for guiding a saw blade have long been known in the art. *Id.* ¶ 46. The tool disclosed in Robie (shown below) is just one example:



’129 Patent (Ex. 1001, Fig. 24B)



Robie (Ex. 1012, Fig. 10a)

Ex. 1002 ¶¶ 45-46 (citing Exs. 1001, 1012).

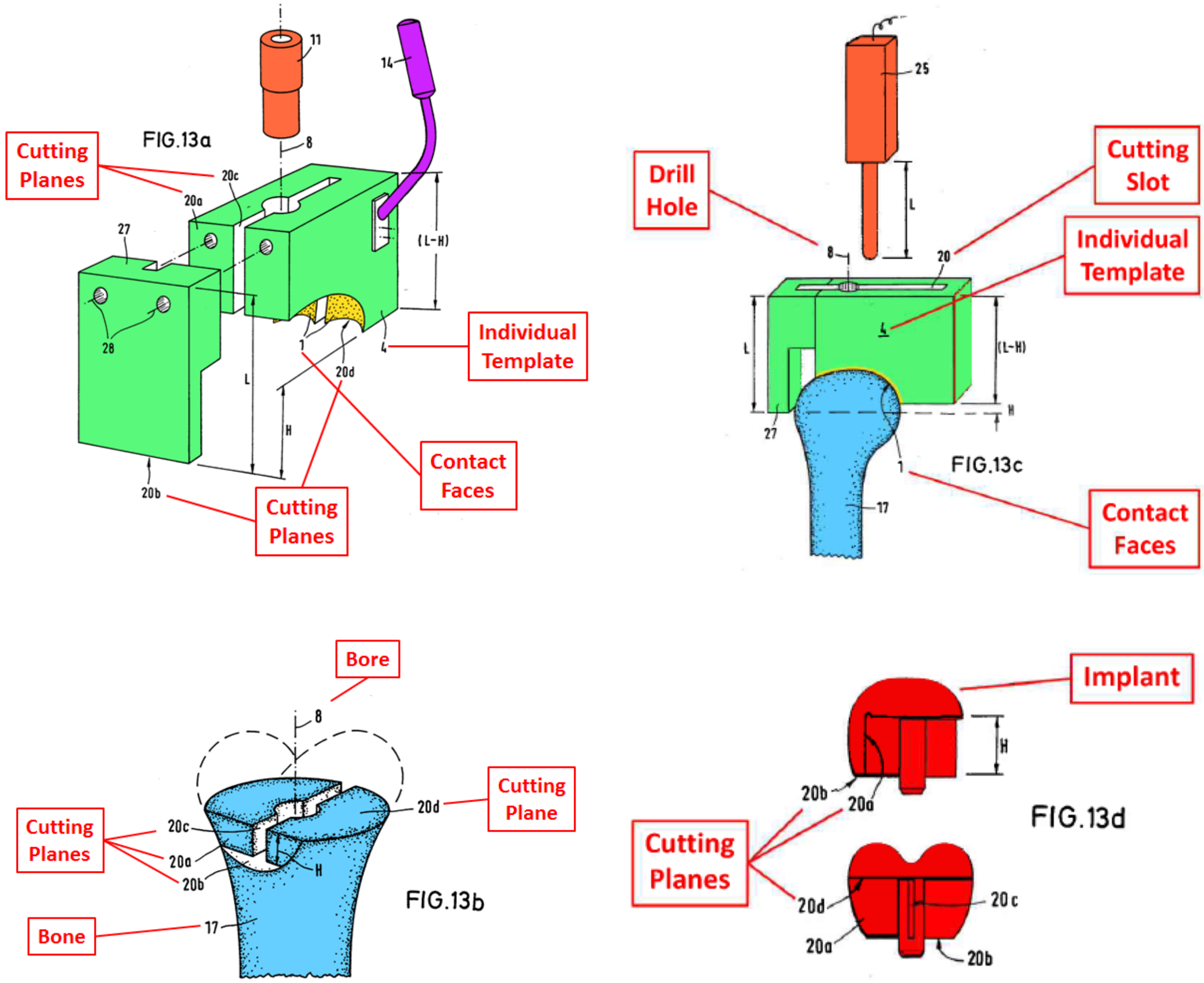
To ensure proper orientation of a knee implant, and to ensure the leg is properly aligned after surgery, surgeons typically use imaging (e.g., X-ray, CT, or MRI) to determine an axis of the joint and align the cuts perpendicular to that axis. Ex. 1002 ¶¶ 49-53; Ex. 1036 (X-ray); Ex. 1031 (CT); Ex. 1003 (MRI, CT); Ex. 1033 (topograms). The ’129 patent admits this practice was conventional. Ex. 1001, 12:17-35, 14:48-16:28.

C. Using Imaging to Create Patient-Specific Guides

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

Before the 1990s, surgeons could align 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 became widely known. *Id.* Such patient-specific guides included a patient-specific surface allowing the guide to be positioned by placing the tool on a patient's joint surface. *Id.*

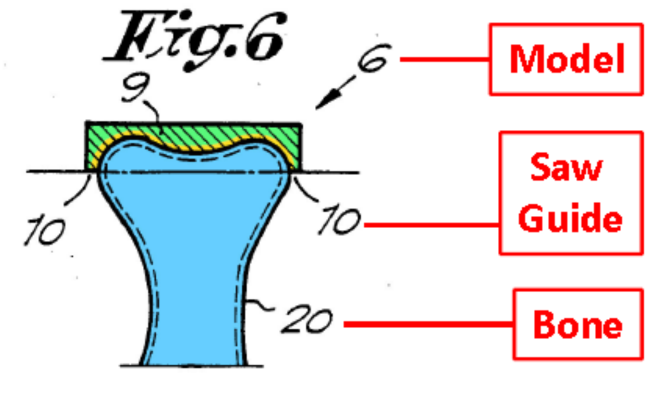
For example, Radermacher (1993) described using MRI and/or CT data to create an "individual template" for guiding surgical drills and saws during orthopedic surgery. *Id.* The individual template included a surface that is a "copy" or "negative" of the "natural (i.e. not pre-treated) surface" of a patient's joint. Ex. 1003 at 10, 12. In Radermacher, an individual template 4 having patient-specific contact faces 1 could be set on 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.



Ex. 1002 ¶¶ 54, 81.

Swaelens (1995) disclosed obtaining MRI images of a patient's knee joint, creating a digital model, adding "functional elements" (such as cutting slots or drill holes) to the digital model to create a "perfected model," and then using the design to make a "real model" that "can be placed as a template on the bone of the patient 1 during a surgery and which fits perfectly to it." Ex. 1007 at 6:24-29, 9:1-

13, 10:23-30; Ex. 1002 ¶ 55. Swaelens's tool includes a functional element 10 that "serves as a guide for the saw." Ex. 1007 at 13:17-25, Fig. 6.



Ex. 1002 ¶ 55. Swaelens further explained that the method can beneficially account for "grey value data," which includes cartilage. Ex. 1007 at 2:12-23, 4:16-17; Ex. 1002 ¶ 56.

Schuster '334 (2000) described using CT or MRI data to create a patient-specific "implantation aid" (cutting guide). Ex. 1008 at 2:59-64, 3:50-57; Ex. 1002 ¶ 57. Schuster's guides (5, 6) contained one or more slots (7, 8) at various angles for guiding a saw. Ex. 1008 at 3:50-4:5, 4:35-38.

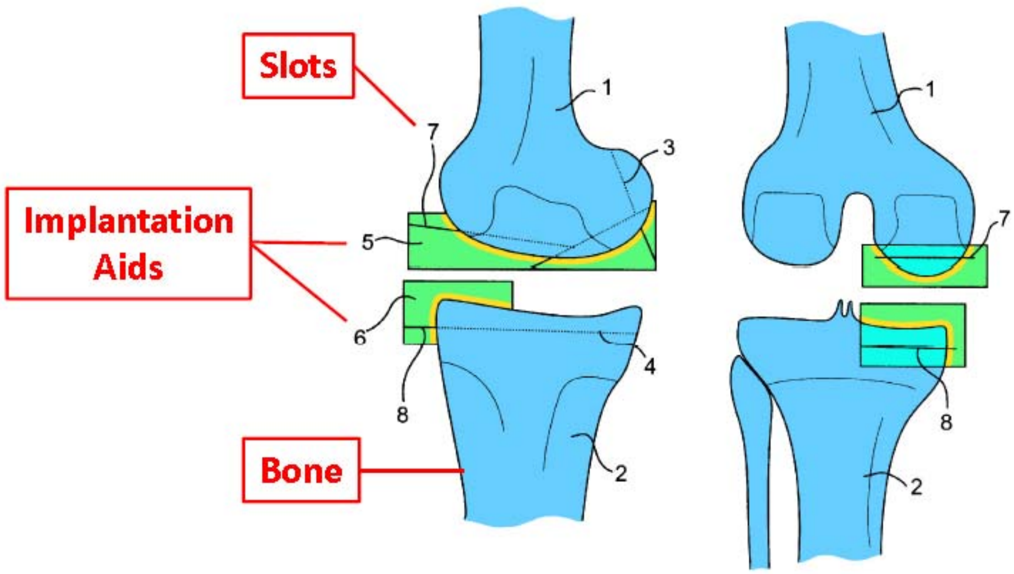


FIG. 2

Ex. 1002 ¶ 57.

Fell (2000) also disclosed using MRI to determine the contour of femoral and tibial surfaces, including the articular cartilage, and using this data to create a patient-specific device that conforms to and mates with the surface. Ex. 1005 at 13:15-17, 14:13-18, 15:12-21, 22:6-9; Ex. 1002 ¶ 58.

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

It was well-known by 2002 that the contour of a patient's cartilage surface could be determined through various imagining techniques, including MRI and CT. Ex. 1002 ¶ 47. Indeed, the '129 patent admits these imaging techniques were "suitable for measuring thickness and/or curvature (e.g., of cartilage and/or bone) or size of areas of diseased cartilage or cartilage loss." Ex. 1001, 13:51-64. The '129 patent further admits the alleged invention employs "conventional" methods of X-ray, ultrasound, CT, and MRI that are "within the skill of the art" and are "explained fully in the literature." *Id.*, 12:17-35.

The prior art confirms various imaging techniques could resolve the contours of a patient's articular cartilage. Ex. 1002 ¶¶ 47, 96-101. 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 created a three-dimensional model of a patient's knee joint, including both bone and cartilage surfaces:

Id., Fig. 18C (cropped).

Alexander disclosed virtually the same "cartilage image" as in the '129 patent:

Alexander (Ex. 1004, Fig. 19)

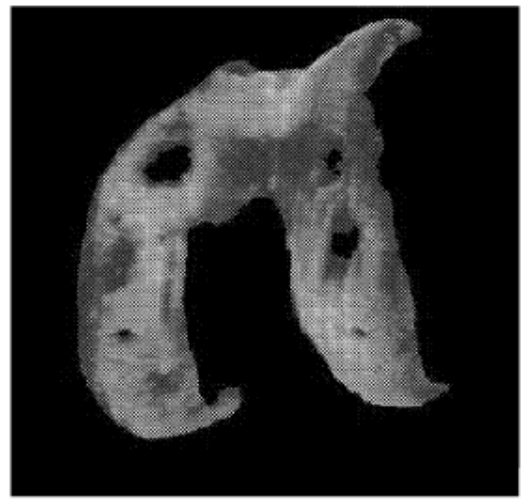


FIG. 2

'129 Patent (Ex. 1001, Fig. 2)

In fact, the '129 patent relies on Alexander's prior art method of determining bone and/or cartilage surface contours to generate the claimed patient-specific instrument. Ex. 1001, 13:49-14:47 (citing WO 02/22014 (Ex. 1016), a later publication of Ex. 1004).

Many prior art references similarly taught using MRI[2] 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

[2] Some references refer to "nuclear spin tomography" or "NMR," which is old terminology for what is now referred to as MRI. Ex. 1002 ¶ 57.

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 at 22:6-8 (MRI provides contour plots of articular cartilage). Petitioner's expert confirms 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 ¶¶ 47-48, 93-94, 97-101.

V. THE '129 PATENT

A. Overview of the '129 Patent

The '129 patent is directed to nothing more than using conventional MRI or CT data to create conventional patient-specific surgical guides. The '129 patent determines curvature and thickness of a patient's cartilage using "conventional" imaging techniques, such as MRI, that were well known in the art and "explained fully in the literature." Ex. 1001, 13:49-14:48, 12:17-35. The '129 patent uses these conventional images to create a tool with an inner surface that is a "mirror image" of the patient's articular surface. *Id.*, 45:24-26. That is, the surface of the device "match[es] all or portions of the articular or bone surface and shape." *Id.* Such devices were also well-known. *Id.*, 45:17-29; Ex. 1002 ¶ 59.

As in the prior art, the '129 patent describes determining a mechanical or anatomical axis and resecting the bone perpendicular to the mechanical axis. Ex. 1001, 44:12-22.

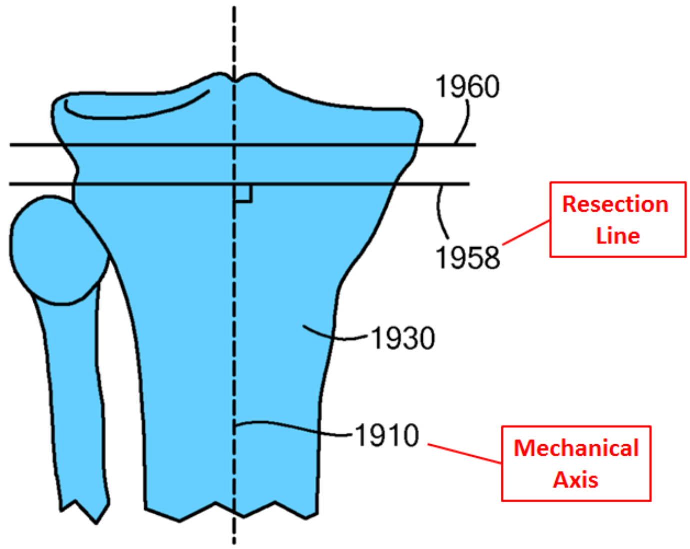


FIG. 21B

Id., Fig. 21B. The ’129 patent admits it was well known that conventional imaging, for example, X-ray, MRI, and CT, could be used to determine a patient’s anatomical and biomechanical axes. *Id.*, 14:48-16:28.

And, as in the prior art, the ’129 patent also discloses that the exact position of surgical cuts influences joint alignment and can be adjusted to “optimize[] for different flexion and extension, abduction, or adduction, internal and external rotation angles.” *Id.*, 45:66-46:16.

B. Prosecution History of the ’129 Patent

Applicants filed the application for the ’129 patent on October 27, 2009. The examiner rejected the claims as obvious over WO 98/32384 (Robie) in view of

U.S. Patent No. 5,682,886 (Delp). Ex. 1017 at 66-77. Applicants then interviewed the examiner. According to the examiner's Interview Summary:

> Applicant's arguments did not overcome the rejections in the last office action. However, applicant stated that he will amend the claims to read "the patient specific surface ……….'includes joint information derived from the image data of the patient's joint'". Applicant stated that neither Robie nor Delp teaches image data. The examiner agrees with applicant. Applicant later brought to the examiner's attention the reference to Carignan et al, however, applicant states that he will amend the claims to include "internal/external rotation" to overcome Carignan et al.

Id. at 78-80. In response, applicants amended some claims, as allegedly discussed during the interview, and canceled other claims. *Id.* at 81-97. The response included an Interview Summary, pointing out "related art," including Radermacher and CAOS, that was allegedly discussed and distinguished during the interview. *Id.* at 95-96.

Applicants again interviewed the examiner on November 8, 2012. *Id.* at 123. According to applicants' Interview Summary, the parties discussed another reference, Park (US 2009/0131941), and applicants proposed additional clarifying amendments. *Id*.

After the second interview, the examiner allowed the claims without explanation. *Id.* at 113-22.

During prosecution, applicants submitted Radermacher, Alexander, Woolson, and Fell. But these references were among more than 600 documents made of record. The examiner did not apply these references. Kenna was not submitted to or considered by the Patent Office.

C. Priority

In the co-pending litigation, ConforMIS alleges the earliest effective priority date for the '129 patent claims is May 12, 2002. For purposes of this Petition only, Petitioner does not challenge that alleged priority date because all of the prior art relied herein predates May 12, 2002. Petitioner reserves the right to challenge any alleged priority date.

D. 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.

VI. CLAIM CONSTRUCTION

Solely for the purposes of this review, the claims should be given their broadest reasonable interpretation, as understood by a POSITA and consistent with the disclosure. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016); 37 C.F.R. § 42.100(b). Construction of specific terms is unnecessary.

VII. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner requests the Board cancel claims 1-83 for the following reasons:

Ground 1. Claims 1-83 are unpatentable under 35 U.S.C. § 103(a) in view of Radermacher in combination with Alexander, Woolson, and Kenna.

Ground 2. Claims 1-83 are unpatentable under 35 U.S.C. § 103(a) in view of Radermacher in combination with Fell, Woolson, and Kenna.

Radermacher, Alexander, Woolson, Kenna, and Fell are prior art to the '129 patent under at least 35 U.S.C. § 102(b) because they were published in 1993, 2000, 1989, 1987, and 2000, respectively.

Each Ground addresses all claims. Ground 2 is not redundant of Ground 1 because Ground 2 relies on a different secondary reference (Fell), which involves a different but related technology and provides a different motivation to combine. Ex. 1002 ¶¶ 172-82.

The Declaration of Jay D. Mabrey, M.D. (Ex. 1002) provides additional support for this Petition. Dr. Mabrey received his M.D. degree from Weill Cornell Medical College in 1981. He is the Chief of the Department of Orthopaedics at Baylor University Medical Center in Dallas, Texas. *Id.* ¶¶ 5-8. He is also a

Professor of Surgery at Texas A&M Health Science Center College of Medicine. *Id.*

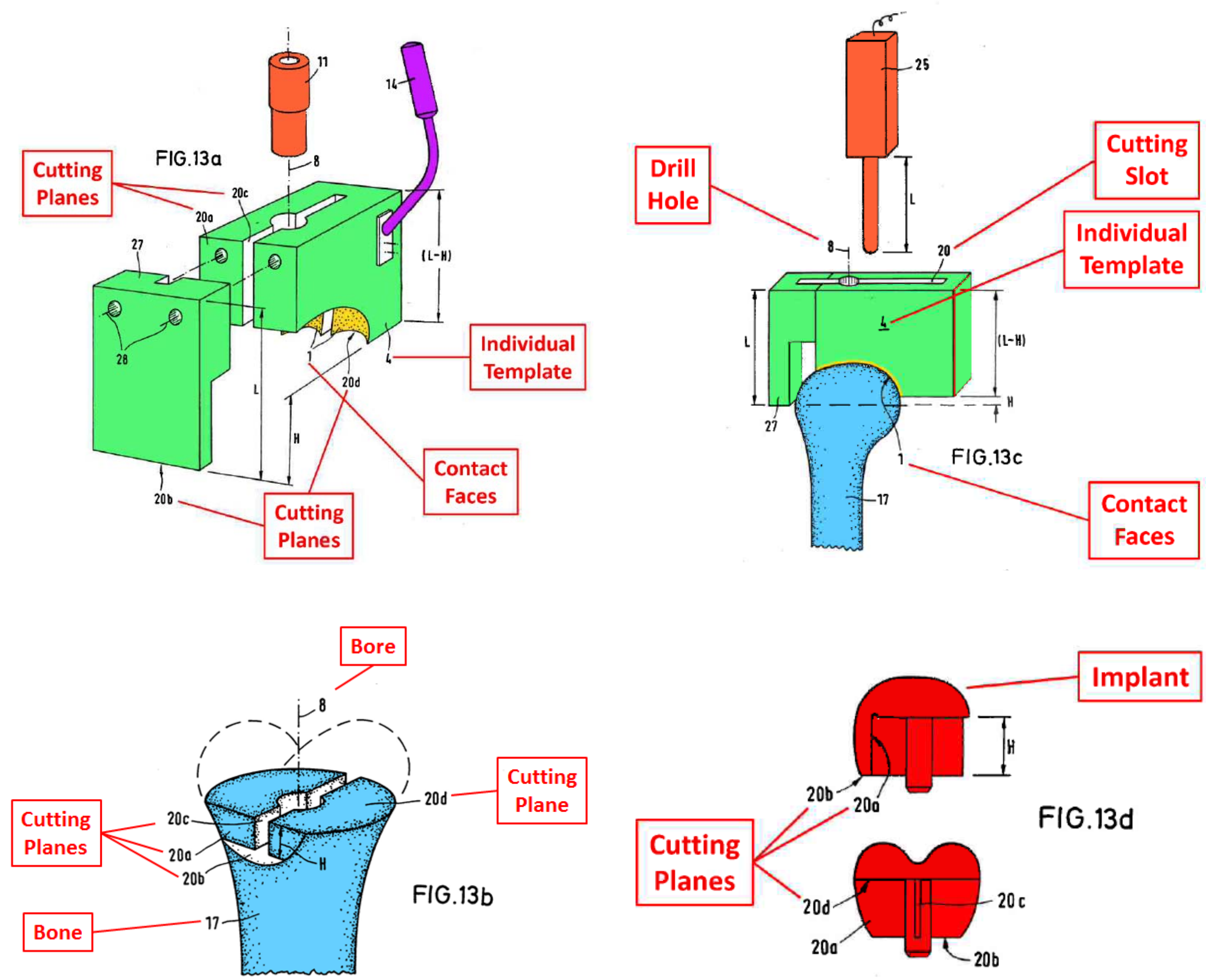
VIII. SPECIFIC PROPOSED GROUNDS FOR REJECTION

A. Ground 1: Claims 1-83 Are Unpatentable as Obvious Over Radermacher in Combination with Alexander, Woolson, and Kenna.

1. Claim 1

Claim 1 recites a patient-specific instrument system for knee joint surgery including: [a] a patient-specific surface for engaging at least a portion of a substantially uncut joint surface of the diseased or damaged knee joint of the patient; and [b] a guide for directing a surgical instrument. The patient-specific surface includes cartilage information derived from image data of the diseased or damaged knee joint of the patient. The guide: [i] has a predetermined position relative to the patient-specific surface; [ii] has a predetermined orientation relative to at least one of an anatomical and biomechanical axis associated with the knee joint; and [iii] defines a drilling path through at least of portion of the knee joint, the drilling path having a position based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant. Claim 1 is unpatentable over Radermacher in combination with Alexander, Woolson, and Kenna.

Radermacher discloses an "individual template" (patient-specific instrument system) for knee joint surgery, as shown below.



Ex. 1002 ¶ 81 (citing Ex. 1003 at Figs. 13a-d); *see also* Ex. 1003 at 18, Figs. 10a-10e, 25-26. The remaining claim limitations are addressed below.

a) A Patient-Specific Surface

Radermacher describes generating three-dimensional images of a patient's joint from MRI and/or CT scans. The imaging data is used to create an "individual template" having a patient-specific surface (contact faces 1) that engages at least a portion of a substantially uncut joint 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), 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; *see also* Ex. 1002 ¶¶ 78, 87-88.

Thus, Radermacher discloses an instrument system having a patient-specific surface for engaging at least a portion of a substantially uncut joint surface of the diseased or damaged joint of the patient. Ex. 1002 ¶ 89. Indeed, 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 ("Radermacher also discloses that the individual template may be custom formed to match the surface of a knee joint."). *Id.* at 57.

b) The Patient-Specific Surface Includes Cartilage Information

Claim 1 specifies that the patient-specific surface includes cartilage information derived from image data of the diseased or damaged knee. "Information" includes, for example, measurements (for example, size, shape, thickness, curvature, etc.). Ex. 1001, 9:33-41, 19:61-64, 52:45-47. Radermacher teaches this limitation. It also would have been obvious to include a template including cartilage information based on Radermacher and common knowledge in May 2002. ConforMIS may argue this limitation is not taught by Radermacher alone or was not common knowledge. In an abundance of caution, Petitioner also relies on Alexander.

i. <u>Radermacher</u>

Radermacher discloses that the patient-specific surface includes cartilage information derived from image data because 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" would include the articular cartilage (and any subchondral bone that may be exposed by the cartilage being worn away). Ex. 1002 ¶¶ 80, 88-89. To a POSITA, Radermacher discloses the same "patient-specific surface" as in the '129 patent—one that is a "negative" or a "copy" of, and therefore "matches," a patient's natural articular surface. *Id.* As long as some cartilage existed on the patient's joint, the contact faces of Radermacher's individual template would include cartilage information. *Id.*

Radermacher's disclosure of the imaging and surgical processes further supports this understanding. *Id.* Radermacher discloses using CT and/or MRI data to customize the patient-specific surface. The '129 patent admits these imaging techniques were widely known to provide cartilage information. Ex. 1001, 12:17-35, 13:49-14:34, 45:17-19; 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 were configured to match ***only*** the subchondral bone (and not the cartilage), Radermacher would have described additional surgical steps to prepare the site for the individual template, such as pre-treating the bone by removing cartilage. Ex. 1002 ¶ 91. But Radermacher teaches the opposite, namely matching the individual template to the "natural (i.e. not pre-treated) surface." Ex. 1003 at 12. Radermacher also discloses the template is positioned without further positioning work. *Id.* at 15. Thus, a POSITA would have understood that, when Radermacher discloses the template is "set onto the bone" (*id.* at 30), Radermacher means the template is set onto the ***un-treated*** bone surface, that is, on top of any remaining cartilage and any exposed subchondral bone. Ex. 1002 ¶ 91.

Accordingly, Radermacher teaches the patient-specific surface includes cartilage information. *Id.*

ii. <u>The Knowledge of a POSITA</u>

Even if Radermacher did not teach that the template's contact faces include cartilage information, such a template would have been obvious to a POSITA in view of common knowledge in the art in May 2002. Ex. 1002 ¶¶ 93-95.

Radermacher teaches using MRI to determine the three-dimensional shape of the patient's joint. Ex. 1003 at 10-12. The '129 patent admits MRI was conventional, well-known, and used by those of ordinary skill to determine the shape of a patient's cartilage. Ex. 1001, 12:17-35, 13:49-14:34. Petitioner's expert and the prior art further confirm it was widely known that MRI provided information regarding the patient's articular cartilage. Ex. 1002 ¶¶ 43, 93-95; Ex. 1004 at 14:16-18; Ex. 1013, 2:8-17; Ex. 1014; Ex. 1005 at 22:6-9. Accordingly, it would have been obvious to a POSITA to use MRI (as taught by Radermacher) to obtain cartilage information (as was common knowledge) and to make the contact faces of Radermacher's individual template match the patient's cartilage. Ex. 1002 ¶¶ 93-95.

A POSITA would have been motivated to match the contact faces to the cartilage rather than underlying subchondral bone for several reasons. Ex. 1002 ¶ 94. 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. Because MRI could be used to determine the size, shape, and contour of either surface, this limitation 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, 402-03 (2007). Second, as between the two surfaces, a POSITA would have been motivated to design the patient-specific surface to match the cartilage surface because it would simplify the surgery. Ex. 1002 ¶ 94. The cartilage would not have to be removed for the template to precisely fit on the femur or tibia. *Id.* Third, a POSITA would have been motivated to match the cartilage because Radermacher teaches that the contact faces match the "natural (i.e. not pre-treated) surface." *Id.* Fourth, a POSITA would have understood that matching the cartilage would have resulted in a template with "one spatially uniquely defined position," which reduces surgical time and increases accuracy, consistent with Radermacher's objectives. *Id.*

Thus, it would have been obvious to match the "contact faces" of Radermacher's template to the patient's articular cartilage, and therefore include cartilage information derived from the image data. *Id.* at ¶ 95.

iii. <u>Alexander</u>

Even if Radermacher alone did not disclose or render obvious that the patient-specific surface includes cartilage information, this feature would have been obvious in view of Alexander. Ex. 1002 ¶¶ 96-105.

The '129 patent admits that cartilage information can be obtained using the methods in WO 02/22014 (Exhibit 1016). Ex. 1001, 13:49-64; 14:19-23 ("[I]n preferred embodiments, the measurements produced are based on three-dimensional images of the joint obtained as described in Alexander, et al., WO 02/22014 …"). An earlier publication with virtually the same disclosure as WO'014 published in June 2000. The earlier publication is the Alexander reference (Exhibit 1004) of Ground 1.

Alexander describes various imaging techniques for assessing the condition of cartilage in a knee joint. Alexander recognizes that, by 2000, imaging techniques, including MRI and CT, were "known in the art" for "electronically generating a cartilage image." Ex. 1004 at 14:17-18; *see generally id.* at 14:16-15:14. Alexander specifically discloses imaging techniques to obtain the "surface of the joint, e.g. the femoral condyles." *Id.* at 22:22-24. Alexander further shows using MRI to create a three-dimensional reconstruction of the femoral and tibial bones (gray) and cartilage (black):

FIG._18C

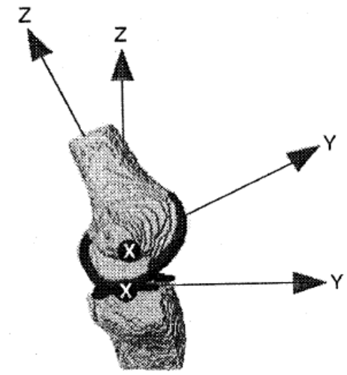


FIG._18H

Id. at 61:19-25, Figs. 18C-I. Alexander also describes reconstructing the articular cartilage using a thickness map, just as described in the '129 patent:

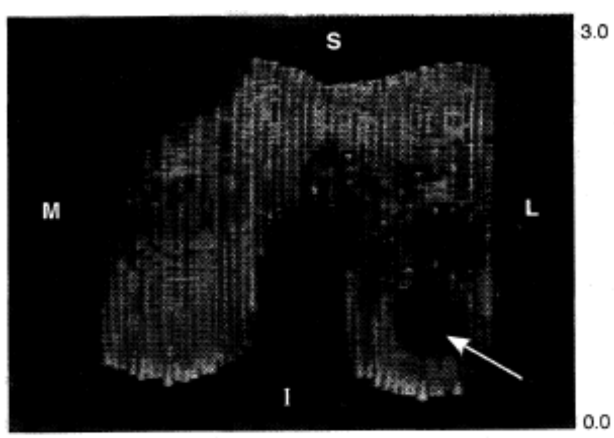


FIG._22B

Alexander (Ex. 1004 at Fig. 22B)

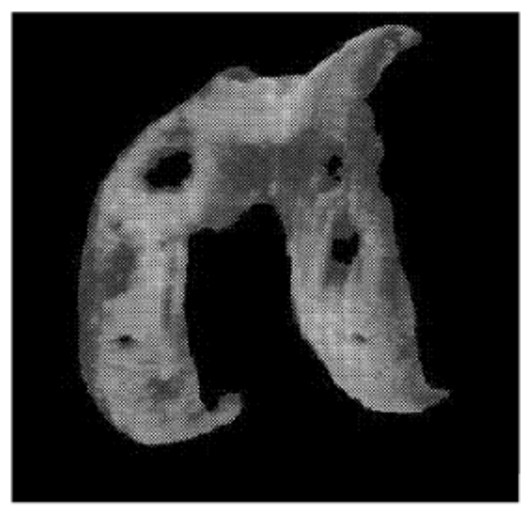


FIG. 2

'129 Patent (Ex. 1001, Fig. 2)

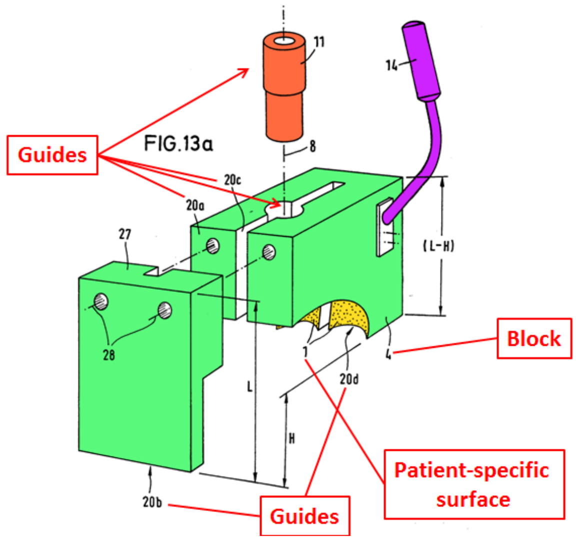
Therefore, Alexander teaches cartilage information derived from image data of a diseased or damaged knee

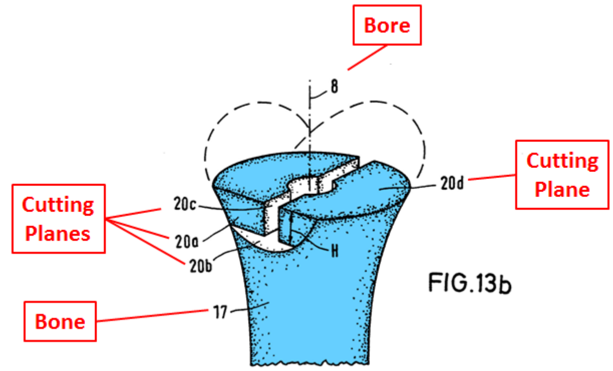
It would have been obvious to combine the teachings of Radermacher and Alexander to create a template that matches the patient's cartilage surface, and therefore includes cartilage information, for several reasons. Ex. 1002 ¶¶ 102-105. Both references relate to methods of treating diseased or damaged cartilage in a knee joint. *Id.* And 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.*

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) the underlying bone surface is a mere design choice. *Id.* 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 follow Radermacher's goals. *Id.*; Ex. 1003 at abs., 3-5, 9. The modification would have merely: (a) required the combination of one known element (Alexander's MRI data of the cartilage/articular surface) with another known element (Radermacher's MRI data of the joint surface) to obtain a predictable result (a device tailored to the patient's cartilage surface); and (b) represented 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 ¶ 105.

c) Guide for Directing a Surgical Instrument and Having a Predetermined Position Relative to the Patient-Specific Surface

Claim 1 requires "a guide for directing a surgical instrument, wherein the guide has a predetermined position relative to the patient-specific surface." Radermacher discloses this limitation. Radermacher teaches that the individual template can have any number of guides, including multiple guides for drills and saws. *See, e.g.*, Ex. 1003 at 13 ("[A]ny suitable tool guides, particularly drill sleeves, parallel guides, saw templates . . . can be provided. These tool guides . . . can be provided in/on the basic body of the individual template . . . ."). In one embodiment, Radermacher discloses an individual template having five "guides" (Fig. 13a), including a drill guide along axis 8 and four cutting guides that define, and result in, cuts 20a-d and bore along axis 8 (Fig.13b).





Ex. 1003 at Fig. 13a, 13b, 10-11, 30.

Each guide has a "predetermined position relative to the patient-specific surface" because their location and orientation are determined and fixed during preoperative planning. *Id.* 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***.") (emphasis added), 25 (the bore is defined in the surgical planning), 11 (cutting, boring, and milling steps are "three-dimensionally charted in said coordinate system fixed relative to the osseous structure, can be clearly defined in or on the individual template in from of guide means"); Ex. 1002 ¶¶ 107-08.

d) Guide Having a Predetermined Orientation Relative to an Anatomical or Biomechanical Axis

Claim 1 also requires the guide to have "a predetermined position relative to from at least one of an anatomical axis and a biomechanical axis associated with said knee joint." This limitation is inherent in Radermacher and would have been obvious in view of Woolson.

i. Radermacher

The claimed guide has no defined relationship to any axis. Ex. 1002 ¶ 113. Moreover, Claim 1 is not a method claim; it does not require determining a biomechanical or anatomic axis and does not require orienting the guide with a particular angle relative to any biomechanical or anatomical axis. Claim 1 only requires the guide be aligned "relative to" an axis. This limitation is inherently met by all cutting or drilling guides, regardless of orientation, and is therefore disclosed by Radermacher. *Id.* Although Radermacher does not refer to a biomechanical or anatomical axis, the guides in Radermacher's individual template define predetermined drilling (axis 8) or cutting (paths 20a-d) paths that are necessarily aligned relative to a biomechanical or anatomical axis of the joint. Ex. 1003 at Figs. 13b, 13c.

Even if this limitation required determining the biomechanical or anatomical axes during the pre-operative planning stage and/or requires the orientation of the guide to depend on such an axis, this limitation would have been obvious. The '129 patent admits biomechanical and anatomical axes—as well as methods of determining them using medical imaging technologies—were widely known. Ex. 1001, 12:17-35, 14:48-16:28. Indeed, Schuster '334 confirms that, in conventional systems, "vertical alignment is achieved" for the implant components "in relation to an axis" of the patient's joint. Ex. 1008, 1:19-37; Ex. 1002 ¶ 116. In Schuster '334, the biomechanical axis may be determined by preoperative X-rays and an intramedullary pin system. Ex. 1008, 1:19-37; Ex. 1002 ¶ 116. The '129 patent further admits that reliance on the biomechanical and anatomical axes while performing knee arthroplasty was known. Ex. 1001, 12:17-35, 14:48-16:28.

Petitioner's expert further confirms that aligning the cutting and drilling guides relative to a patient's mechanical axis was widely known by those of ordinary skill in the art. Ex. 1002 ¶¶ 112, 116-26. Because the mechanical axis determines force distribution in the knee, maintaining proper alignment post-surgery is critical. *Id.* ¶ 53; *see also* Ex. 1037 at 739. To achieve proper alignment, both the tibial and femoral implant components must be aligned relative to the mechanical axis. Ex. 1002 ¶¶ 112, 116-26. This, in turn, requires the cutting paths to be aligned relative to the mechanical axis. *Id*. Such alignment was entirely conventional and widely known in the 1990s. *Id.*

ii. Woolson

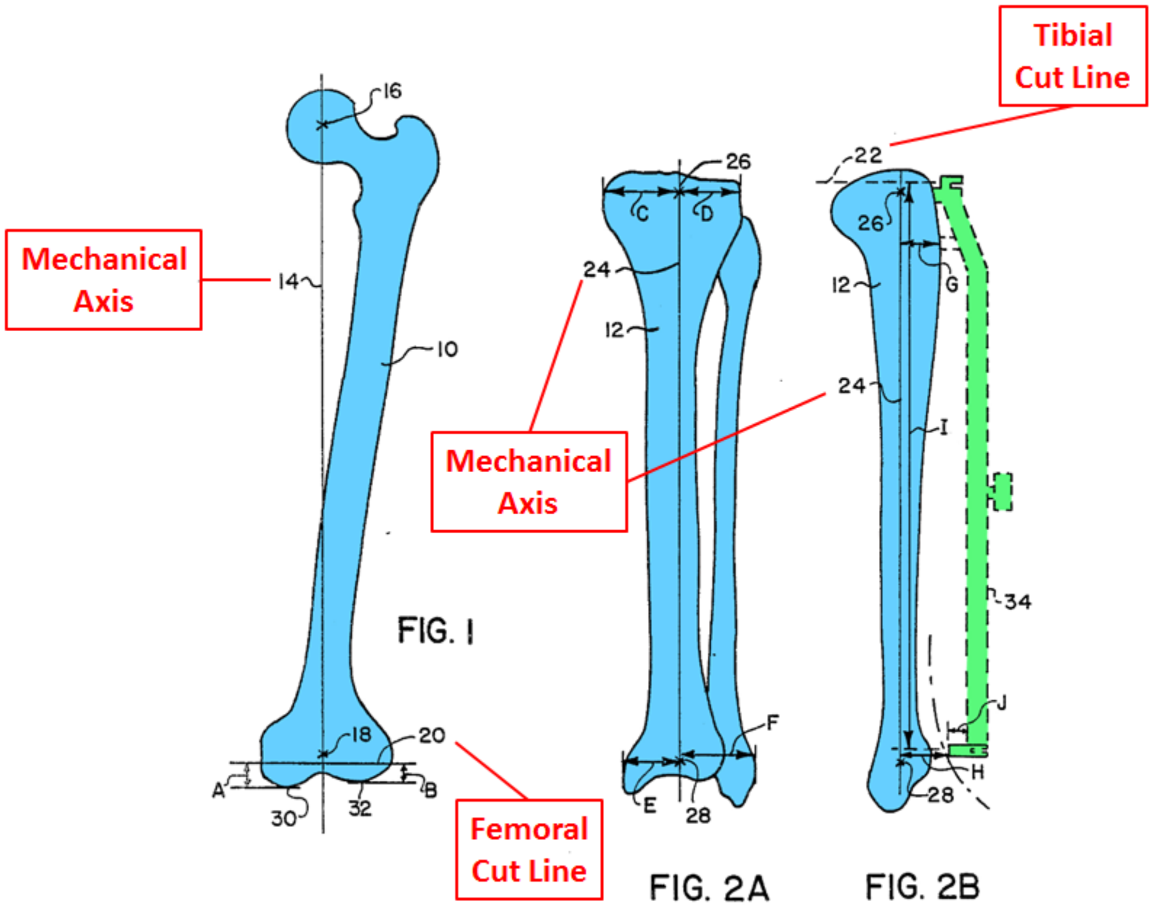
It also would have been obvious to include the features of the limitation in view of Woolson. Ex. 1002 ¶¶ 117-20. Woolson is just one of many prior art references that discloses orienting guides to provide cutting or drilling paths aligned relative to a biomechanical or anatomical axis of the joint. *Id.* ¶ 117.

Woolson explains it is "important" that knee implants be positioned on an axis perpendicular to the mechanical axis and, consequently, it is "necessary" that the cutting paths also be perpendicular to the mechanical axis. Ex. 1031, 4:9-19. For example, Woolson recognizes that ***all*** knee replacement systems align the implant with the patient's mechanical axis for better long-term results. *Id.*, 1:26-36. Woolson explains that, for the implant to be aligned properly, the cutting guides must be oriented so the cutting paths are also aligned relative to the axis:

> [I]t is important that the knee prosthesis be positioned on, and for relative rotation about, an axis perpendicular to the mechanical axis of a femur 10 and corresponding tibia 12 …. During the knee replacement surgical procedure, ***it will be necessary to resection the medial and lateral condyles of the distal femur by cutting along a line 20 which is perpendicular to axis 14***.

Id., 4:7-19 (emphasis added); *accord id.*, 1:8-18, 1:46-50, 1:54-57, 2:50-59, 4:20-26, 4:7-6:3, 5:36-41, 6:50-53, 7:32-36, 7:63-67, abs., Fig. 1, Figs. 2A-B; *see* Ex. 1002 ¶ 119.

Woolson also shows determining 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:



Ex. 1002 ¶ 120 (citing Ex. 1031, Figs. 1, 2A-B).

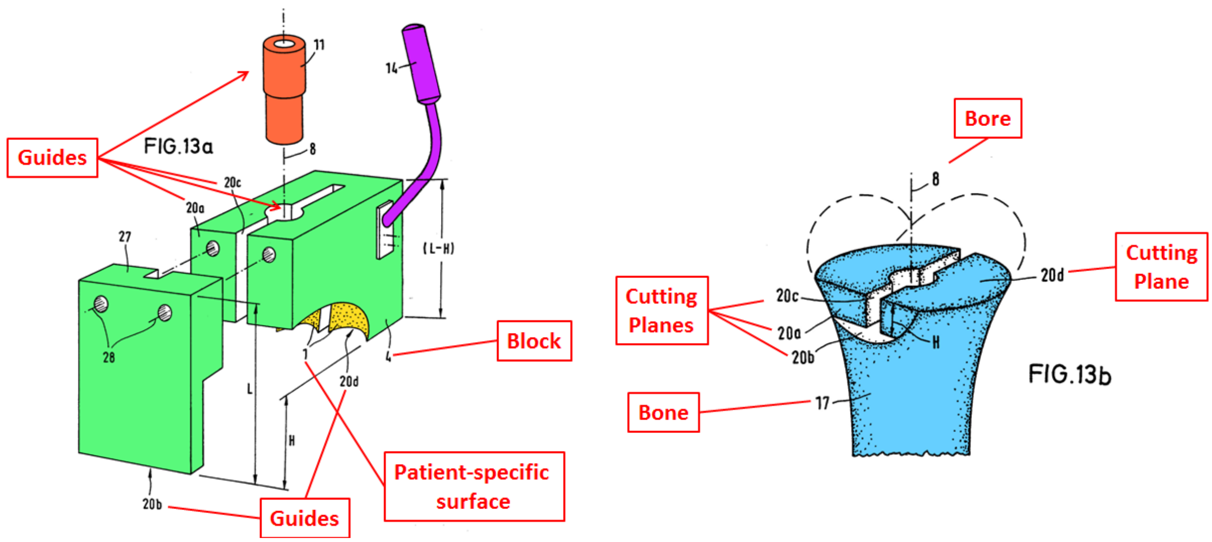
Accordingly, Woolson teaches orienting cutting or drilling guides to provide paths that are aligned relative to a patient's biomechanical or anatomical axis of a joint. *Id.* ¶ 120. Numerous other prior art references confirm that this fundamental concept was well-known. *Id.* ¶¶ 121-25 (citing and discussing Exs. 1032, 1033, 1037); Ex. 1037 (accounting for mechanical axis is generally agreed upon); Ex. 1033 (alignment relative to mechanical axis is "essential"); Ex. 1032 (aligning cuts relative to mechanical axis).

It would have been obvious to align Radermacher's cutting and drilling guides relative to one or more axes in view of Woolson's disclosure, which specifically teaches aligning the cutting paths relative to a patient's mechanical axis to achieve better results. Ex. 1002 ¶ 126. A POSITA would have been motivated to combine Woolson and Radermacher, and orient the guides in Radermacher to be relative to a biomechanical or anatomical axis, because Woolson teaches that such alignment occurs in ***all*** knee replacement systems and is critical to the long-term success of knee replacement surgery. *Id.* ¶¶ 118, 126. Woolson and Radermacher are in the same field (knee arthroplasty), describe the same devices (guides for surgical instruments), and rely on the same imaging technology (e.g., CT scans). Modifying Radermacher to account for the biomechanical and/or anatomical axes would merely involve using a technique that has been employed to improve one knee arthroplasty procedure (Woolson's) to improve a similar knee arthroplasty procedure (Radermacher's) in the same predictable way. *Id.* ¶ 127.

e) The Guide Defines a Drilling Path Through at Least a Portion of the Knee Joint

Claim 1 also requires that the guide "defines a drilling path through at least a portion of the knee joint." Radermacher discloses this limitation.

Radermacher discloses that the "individual template" can have any number of guides, including multiple guides for drills and saws. *See, e.g.*, Ex. 1003 at 13. In one embodiment, Radermacher discloses a block having five different "guides" (Fig. 13a), including a drill guide along axis 8 that defines a drilling path through at least a portion of the knee joint (Fig. 13b).



Ex. 1002 ¶ 129 (citing Ex. 1003 at Figs. 13a-b, 10-11).

f) The Drilling Path Having a Position Based on a Predetermined Internal Rotation Angle or External Rotation Angle of an Orthopedic Implant

Claim 1 also requires the drilling path to have a position based on a predetermined internal rotation angle or external rotation angle of an implant. Radermacher teaches this limitation. It certainly would have been obvious to include such a drilling path based on Radermacher given the knowledge of a POSITA. ConforMIS may argue that this limitation is not taught by Radermacher or was not common knowledge. In an abundance of caution, Petitioner also relies on Kenna.

i. Radermacher

Radermacher discloses determining the position, shape, and/or orientation of the guides so the changes induced on the implant site by the instruments (drills, saws, etc.) ensure a desired orientation of the implant. Ex. 1003 at 30 (tool guides direct the cutting and drilling of the osseous structure "according to the geometry of the prosthesis"), abs.; *see also id*. at 11, 15, Figs. 13b, 13d. To a POSITA, Radermacher teaches that the drill and cutting guides define paths that are based, at least in part, on a predetermined rotation angle of the implant, as is commonplace in knee surgery to achieve proper knee joint alignment and anatomic movement. Ex. 1002 ¶ 131.

ii. The Knowledge of a POSITA

Even if Radermacher does not itself disclose the drilling path has a position based on a predetermined internal rotation angle or external rotation angle of an implant, it would have been obvious to include such a drilling path in view of common knowledge in the art. Ex. 1002 ¶¶ 132.

At the time of the '129 patent, it was commonly understood that preparing a knee joint (in terms of the cutting and drilling paths) to receive an orthopedic implant must be done to achieve proper knee joint alignment and account for anatomic movement of the knee, which would include internal and external rotation angles. *Id.* Thus, positioning Radermacher's drilling path based on a predetermined internal rotation angle or external rotation angle of the implant would have involved nothing more than combining Radermacher's teachings with common knowledge according to known methods to yield predictable results.

iii. Kenna

Even if Radermacher alone did not disclose or render obvious the recited drilling path, this feature would have been obvious in view of Kenna. Ex. 1002 ¶¶ 130, 133. Kenna discloses the importance of preserving the "axes of rotation" and aligning the cutting paths accordingly:

> The aforenoted prosthesis is designed to reproduce anatomic movement of the knee without compromising stability. This prosthetic knee, as the natural knee, provides a "screw home" mechanism which increases stability in extension. As flexion proceeds, the femoral condyles initially roll posteriorly. Through asymmetric condylar and tibial compartments, ***the natural and changing axes of rotation are preserved, thereby preventing the development of abnormal tension in retained ligaments***. When abnormal ligamentous tension develops, it either restricts flexion and increases shear stress at fixation interfaces and/or leads to eventual progressive ligament attenuation and joint instability. The design also allows ***natural internal and external rotation of the knee in flexion***…. In order to make such prosthetic knee system feasible, ***the necessary bone cuts must be***

> ***precisely accomplished***. This, in turn, requires a set of proper instruments including guides and jigs. Such instruments should assure reproducibly accurate bone cuts, prosthetic seating, and lower limb alignment.

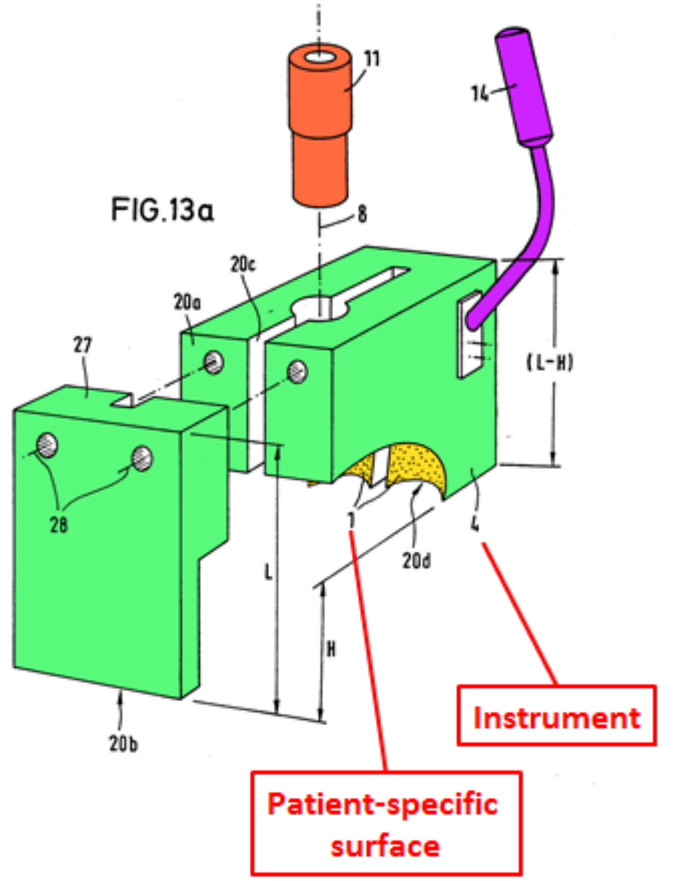
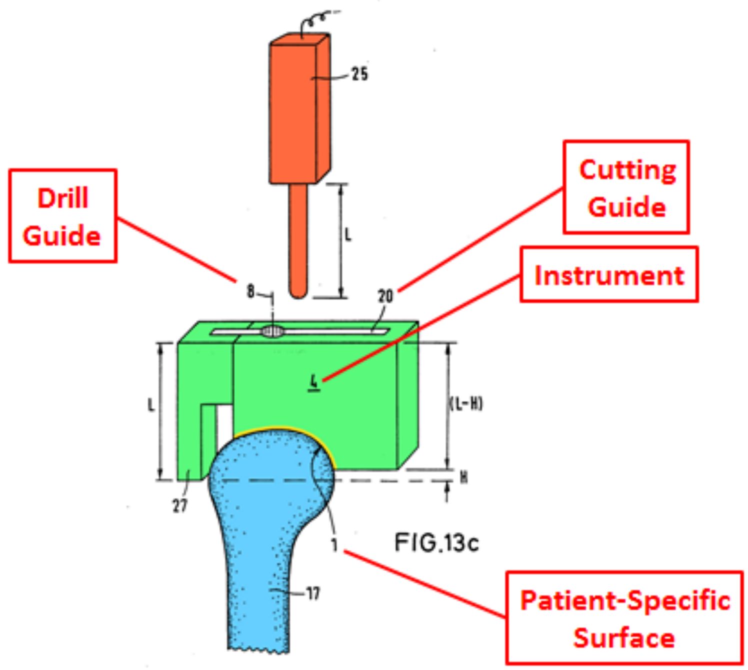
Ex. 1032, 1:20-46 (emphases added); *see also id.*, 5:34-43 (drill holes are aligned and drilled only after "correct medial-lateral and rotational positioning is assured").

A POSITA would have been motivated to combine Radermacher and Kenna. They are in identical fields, relate to the same type of devices, and describe similar methods for using such devices. Both are directed at preparing the knee for orthopedic implants using guides with drilling and cutting paths. Combining their teachings such that the cutting and drilling paths disclosed in Radermacher have a position based, at least in part, on a predetermined internal rotation angle or external rotation angle of an orthopedic implant/component as taught by Kenna would merely require the use of techniques employed to improve one procedure (Kenna's) to improve a similar procedure (Radermacher's) in the same predictable way. Ex. 1002 ¶ 133.

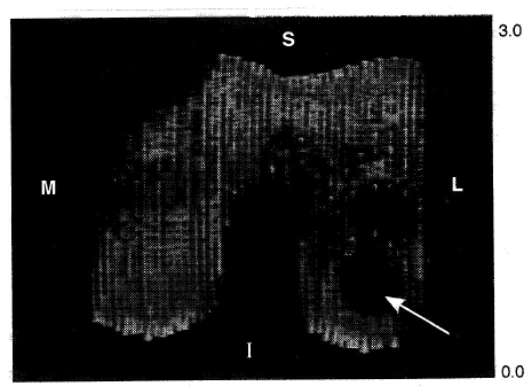
2. Independent Claims 23, 44, and 62

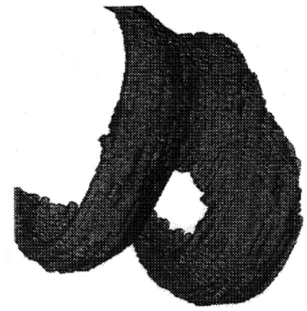
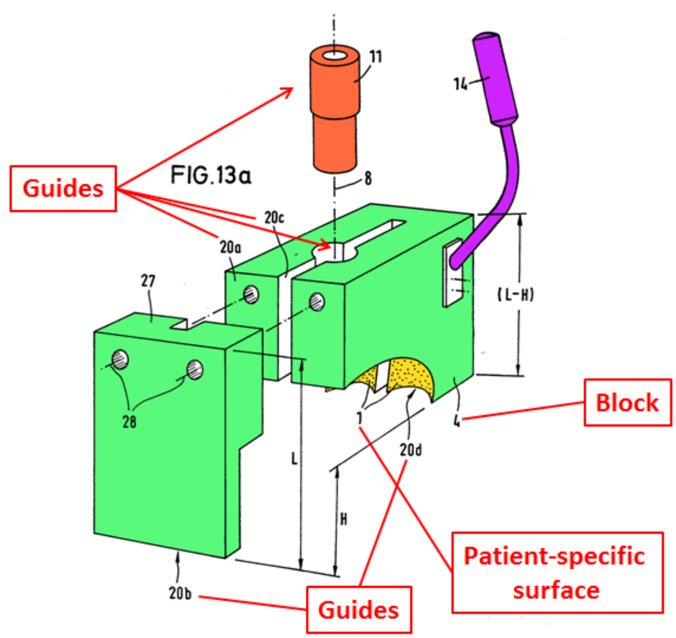
The analysis above with respect to claim 1 is also applicable to claims 23, 44, and 62 because the claims are largely identical and contain only minor differences. The claim chart below demonstrates how independent claims 1, 23, 44, and 62 are disclosed by the prior art under Ground 1. For simplicity, the chart focuses on claim 1 and contains further information directed to any differences between the claims.

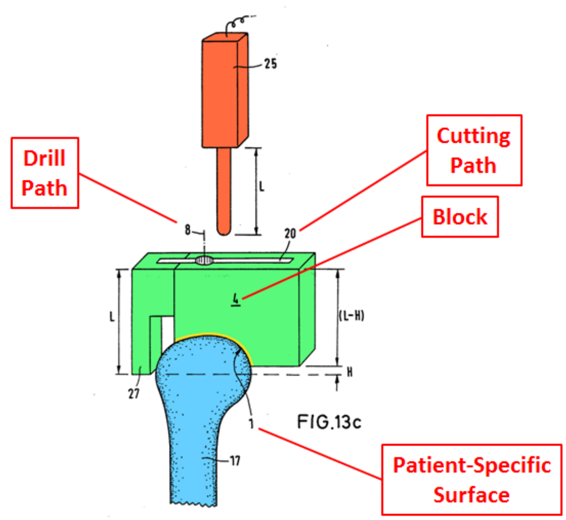
Claims 1, 23, 44, and 62	Exemplary Disclosure in the Prior Art
1. [preamble] A patient-specific instrument system for surgery of a diseased or damaged knee joint of a patient, the instrument system comprising: [The preambles of **Claims 23, 44, and 62** do not recite "diseased or damaged" knee joint.]	**Radermacher** discloses a patient-specific instrument system ("individual template") for surgery of a knee joint of a patient, including a diseased or damaged knee joint. Ex. 1003 at 10, 19, 30, Figs. 13a-d.
1. [a] a patient-specific surface for engaging at least a portion of a substantially uncut joint surface of the diseased or damaged knee joint of the patient, the patient-specific surface including cartilage information derived from image data of the diseased or damaged knee joint of the patient; and [**claim 23** recites "a substantially uncut joint surface *of a tibia* of the knee joint"]	**Radermacher** discloses an "individual template" having a "contact face" (patient-specific 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 that engages the substantially uncut joint surface of the knee joint (which would include the tibia or femoral condyle), as shown below. *E.g.*, Ex. 1003 at 10, 12, 21-22, 30, Figs. 13a, 13c, 18; Ex. 1002 ¶ 135 (claim chart).

[**claim 44** recites "a substantially uncut joint surface *of a femoral condyle* of the knee joint"] [**claim 62** recites "a substantially uncut joint surface of the knee joint"] [**claims 23, 44, and 62** recite "cartilage information derived from image data of the knee joint of the patient"]	 

	Radermacher further discloses that the patient-specific surface includes cartilage information derived from image data of the knee joint of the patient. Specifically, Radermacher describes generating a three-dimensional negative mold of "the individual ***natural (i.e. not pre-treated) surface*** of the osseous structure intraoperatively accessed by the surgeon." Ex. 1003 at 12 (emphasis added). Where the structure is a knee joint, the natural, not pre-treated structure would include the cartilage. Ex. 1002 ¶ 135 (claim chart). Radermacher further discloses that the images are obtained by CT or MRI. Ex. 1003 at 10, 12, 21-22, Figs. 18, 19. **The '129 patent** admits that delineating the surface of diseased cartilage using CT or MRI was within the knowledge of a POSITA. Ex. 1001, 12:17-35 ("[T]he 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***.") (emphasis added), 13:48-14:47. Radermacher further discloses that the individual template is set onto the bone surface "without any further intraoperative devices … and without intraoperative measuring and positioning work." Ex. 1003 at 15. **ConforMIS** admits that "Radermacher discloses using pre-operative CT imaging data to create a three-dimensional model of an osseous structure (including a knee joint) and using the model to create a ***custom instrument*** ("template") with a tissue ***contacting surface that matches and fits the bone surface*** in a predefined spatial arrangement." Ex. 1024 at 21

	(emphasis added), 57 ("Radermacher also discloses that the individual template may be custom formed to match the surface of a knee joint."). **Alexander** discloses methods for assessing the condition of cartilage in a joint, such as the knee, based on MRI imaging. Ex. 1004 at abs., 2-3, 11:31-12:16, 14:16-32, 15:16-26, 26:20-27:26, 61:19-25 (discussing Fig. 18C), Figs. 18-19; Ex. 1002 ¶ 135 (claim chart). Alexander discloses that this data may be used to "guide the choice of therapy," which includes "joint replacement surgery." Ex. 1004 at 42:10-16. Alexander discloses creating a three-dimensional map of the patient's cartilage. *Id*. at 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*. at 61. Alexander also describes the ability to reconstruct the articular cartilage alone. *Id*. at Fig. 19, 61-62.

	 FIG._19 Ex. 1002 ¶ 135 (claim chart).
[1/23/62] [b] a guide for directing a surgical instrument, wherein the guide has a predetermined position relative to the patient-specific surface and a predetermined orientation relative to at least one of an anatomical axis and a biomechanical axis associated with said knee joint; [**claim 44** recites "and *is fixed at* a predetermined orientation *from* at least one of an anatomical axis…"]	**<u>Radermacher</u>** discloses that the block can have any number of guides, including multiple guides for drills and saws. Ex. 1003 at 13 ("[A]ny suitable tool guides, particularly drill sleeves, parallel guides, saw templates . . . can be provided. These tool guides . . . can be provided in/on the basic body of the individual template . . . ."). Radermacher discloses a template having five different "guides" (Fig. 13a), including a drill guide along axis 8 and four cutting guides20a-d (Fig. 13b); *id.* at 25-26; Figs. 6b and 9. 

	<u>ConforMIS</u> admits that "Radermacher further discloses that tool ***guides*** can be provided in or on the basic body of the template." Ex. 1024 at 21 (emphasis added). Radermacher further discloses that the position and orientation of the guides are fixed during the preoperative planning, and therefore have a predetermined position relative to the patient-specific surface. Ex. 1003 at Fig. 13a, 13c; 13 ("These tool guides . . . will effect a three-dimensional guiding of the treatment tools or measuring devices exactly as provided by the surgical planning."); *accord id.* at 11, 25; Ex. 1002 ¶ 135 (claim chart). The multiple predetermined cutting or drilling guides on the individual template in Radermacher inherently provide a guide (cutting or drilling paths) that are aligned relative to the biomechanical or anatomical axis of the joint. Ex. 1003 at Figs. 13b, 13c. Ex. 1002 ¶¶ 110-113. 

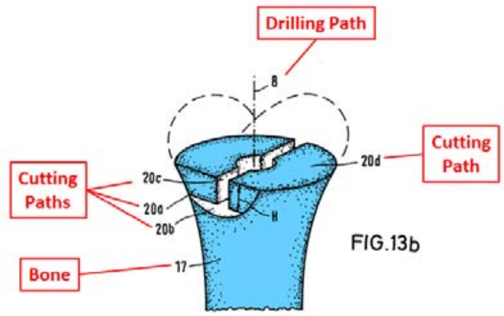


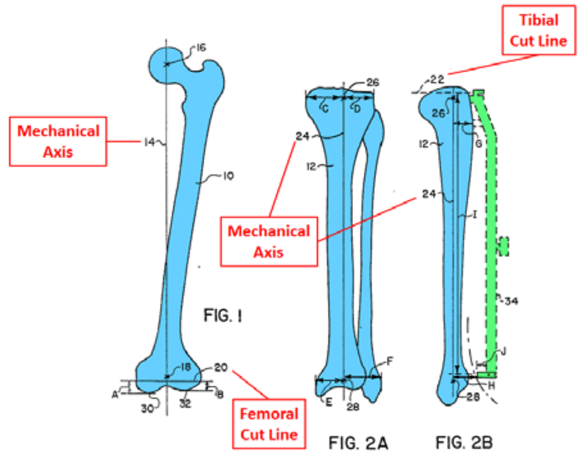
FIG.13b

<u>The '129 Patent</u> admits that determining a biomechanical or anatomical axis and accounting for such axes in knee arthroplasty was well-known. Ex. 1001, 15:30-52.

<u>Knowledge of a POSITA:</u> Orienting cutting guides to provide drilling or cutting paths that are aligned relative to a biomechanical or anatomical axis and through a portion of the joint was within the knowledge of a POSITA, as this was standard practice in knee arthroplasty procedures. Ex. 1002 ¶ 135 (claim chart); *see also* Ex. 1033 at 31 ("accurate placement of implant components with respect to the individual mechanical axis of the leg is essential"); Ex. 1032, 3:1-52, 8:27-30, 9:37-41 (disclosing determining the mechanical axis and cutting guides aligned relative to that axis).

<u>Woolson</u> 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:

	 *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 ¶ 135 (claim chart).

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1. [c] wherein the guide defines a drilling path through at least a portion of the knee joint, the drilling path having a position based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant.

[**claims 23, 44, and 62** recite "wherein the guide defines a *cutting or* drilling path"]

\- - -

[**claim 23** recites "a cutting or drilling path through at least a portion *of the tibia* of the knee joint"]

[**claim 44** recites "a cutting or drilling path through at least a portion *of the femoral condyle* of the knee joint"]

\- - -

[**claim 23** recites "*of a tibial component* of an orthopedic implant."

[**claim 44** recites "*of a femoral component* of an

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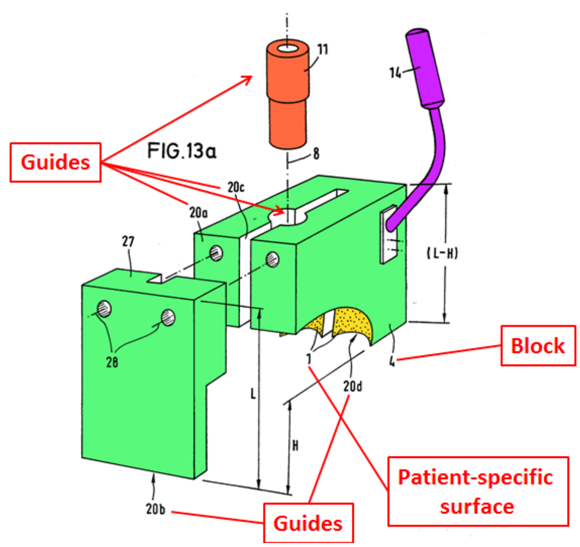
See element [b]. In addition:

<u>Radermacher</u> discloses that the guides define cutting or drilling paths through at least a portion of the knee joint, as in Figs. 13a-13b. Radermacher specifically discloses a guide defining cutting and drilling paths through a portion of the femoral condyle. *Id*. at Figs. 13a-d. Radermacher further discloses that the system can be used for any type of intervention and any type of joint. Such intervention would include the tibia, which Radermacher specifically identifies as one type of intervention that suffers from the alignment problems that the template is designed to fix. *See, e.g.*, *id*. at 11 ("Using the template of the invention allows a treatment of osseous structures for any orthopedic intervention"), 2 (prior art tool guides exist for the femur and tibia but suffer from drawbacks).



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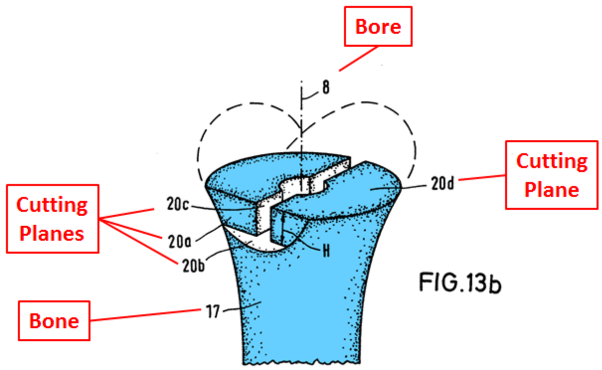
orthopedic implant.”] [**claim 62** recites “the cutting or drilling path having a position based on *at least one of a predetermined orientation* of an orthopedic implant *configured to correct a varus or valgus condition of the knee joint of the patient*.”]	 FIG.13b Radermacher discloses that the position, shape, and/or orientation of the guides are determined such that the changes induced on the implant site by the instruments (drills, saws, etc.) ensure a desired orientation of the implant. *Id. at* 30 (tool guides direct the cutting and drilling of the osseous structure “according to the geometry of the prosthesis”), abs.; *see also id*. at 11, 15, Figs. 13b, d. **<u>Knowledge of a POSITA:</u>** A POSITA would have understood that preparing the cutting and drilling paths for a knee joint receiving an implant is necessary to achieve proper knee joint alignment and account for anatomic movement of the knee, including internal and external rotation angles. Thus, positioning cutting and drilling paths such that they have a position based on a predetermined internal rotation angle or external rotation angle of an implant was within the knowledge of a POSITA, as this was standard practice in knee arthroplasty procedures. Ex. 1002 ¶¶ 135 (claim chart). **<u>Kenna</u>** teaches accounting for anatomic movement of the knee. Ex. 1032, 1:5-9, 1:20-46, 5:34-43. For example, Kenna discloses cutting or drilling paths based on the internal rotation angle or external rotation angle of an orthopedic implant (including the tibial and femoral component of an orthopedic implant). Ex. 1032, 1:20-46, 5:34-43, 9:13-26, 10:43-53 (claim 2). Regarding **claim 62**, for the same reasons discussed above, a POSITA would have understood that the

	position of Radermacher's cutting or drilling path was based on a predetermined orientation of an orthopedic implant configured to correct a varus or valgus condition. Such a condition was widely known and routinely considered by knee surgeons when planning surgery. Ex. 1002 ¶ 135(claim chart). And, for the reasons discussed above, it would have been obvious to include the features of this limitation with Radermacher in view of the knowledge of a POSITA. In addition, it would have been obvious in view of Kenna, which specifically discloses accounting for flexion extension, varus-valgus, etc. alignment of the femur and tibia. Ex. 1032 at 4:13–41 ("The long axial alignment guide 16 is used to establish proper varus-valgus and flexion extension alignment of the distal femoral cuts…."), 6:55–64, 10:29–42 (claim 1).

3. Dependent Claims 2, 24, 45, and 63

Radermacher discloses including the template and guides in an integrally formed body. Specifically, Radermacher discloses that the "tool guides … can be provided in/on the basic body of the individual template." Ex. 1003 at 13. Fig. 13c shows that patient-specific surface and the guide (e.g., groove 20c, drill hole 8) in an integrally formed body. *See also* Ex. 1002 ¶ 136.

4. Dependent Claims 3, 25, 46, and 64

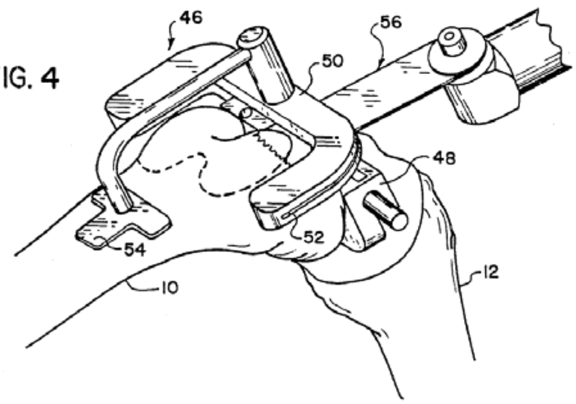
Radermacher discloses the claimed linkage mechanism:

Claim 3, 25, 46, and 64	Exemplary Disclosure in the Prior Art
The instrument system of claim [1/23/44/62], wherein the patient-	**Radermacher** discloses linkage mechanisms (e.g., engagement points 28) for connecting the first body (e.g., individual template 4) having a patient-specific

specific surface is included in a first body having a linkage mechanism and the guide is included in a second body having a complimentary linkage mechanism for connecting the first and second bodies.	surface (e.g., contact faces 1) and the second body (e.g., additional template 27) having a guide (e.g., cut 20b). Ex. 1003 at Figs. 13a, c; *see also id.* at 13 ("[T]he basic body of the individual template can have connecting elements, surfaces or points arranged thereon, which can be releasably coupled in mechanically rigid manner to the gripper piece of a manipulator and thus preoperatively define the position of the gripper piece of the manipulator relative to the three-dimensional reconstruction of the osseous structure."), 26 ("[I]ndividual template 4 can also be the basis for further, additional individual templates 27 which need not have contact faces 1 to the osseous structure 17 but are (rigidly) connected to the basic individual template 4 by defined flange engagement points 28. By use of such flange engagement points 28, also other additional devices, e.g. a parallel guide 26, can be coupled."), 30-31.

Including the limitation also would have been obvious. Connecting different guide bodies to each other in knee arthroplasty surgery was conventional practice. Ex. 1002 ¶ 138. For example, Woolson discloses guides attached to each other by linkage mechanism. Ex. 1031, 6:16-31 ("block member 48" and "cutting-surface-defining member 50"), Figs. 4-5. Including such connected guide bodies in Radermacher would have involved nothing more than combining prior art elements according known methods to yield predictable results. Ex. 1002 ¶ 139.

FIG. 4



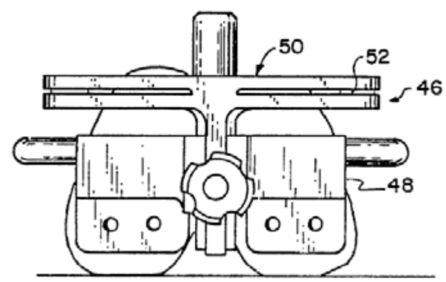
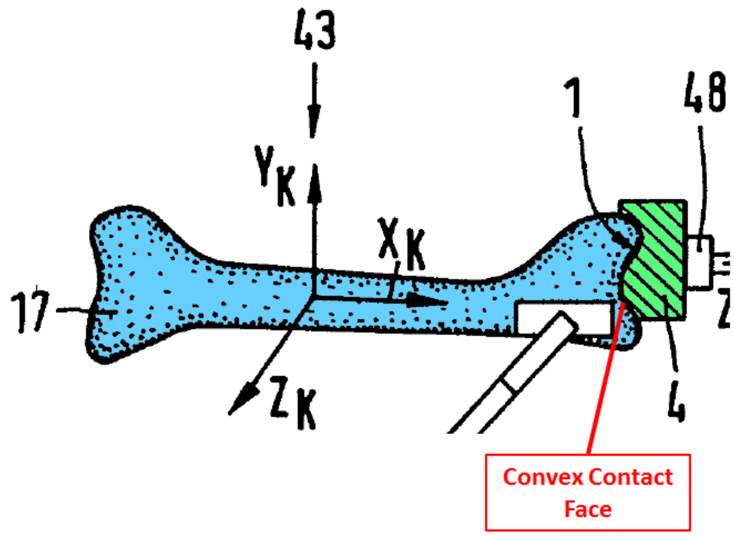


FIG. 5

5. Dependent Claims 4, 26, 47, and 65

Radermacher discloses that the patient-specific surface has a convex portion. Ex. 1003 at Fig. 15a (template 4) (excerpt below); *see also* Fig. 13a and Fig. 13c ("contact faces 1").



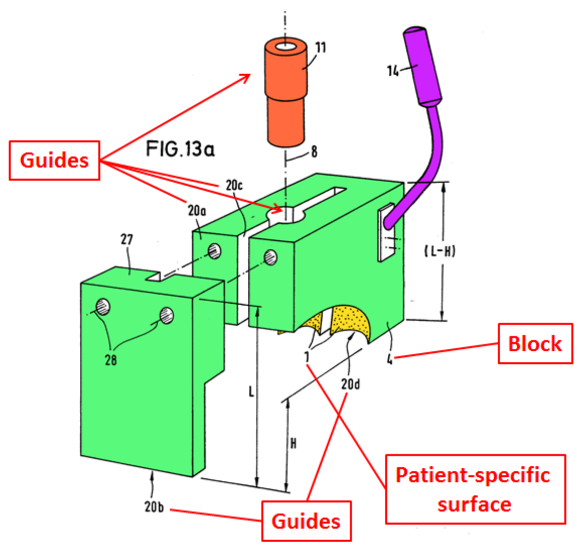
Moreover, a POSITA would have understood, as noted in the ’129 patent (Ex. 1001, 33:14-33), that the knee joint has curvatures with concave and convex portions. And a POSITA would have understood that any template that is the negative of such portions, as in Radermacher, would similarly have convex or concave portions. Ex. 1002 ¶ 141; *see also* Ex. 1003, Figs. 13a, 13c (contact faces 1). Radermacher’s patient-specific surface would have a convex portion to match the contours of the joint. And including such a patient-specific surface in Radermacher would have involved nothing more than combining prior art elements according known methods to yield predictable results. Ex. 1002 ¶ 142.

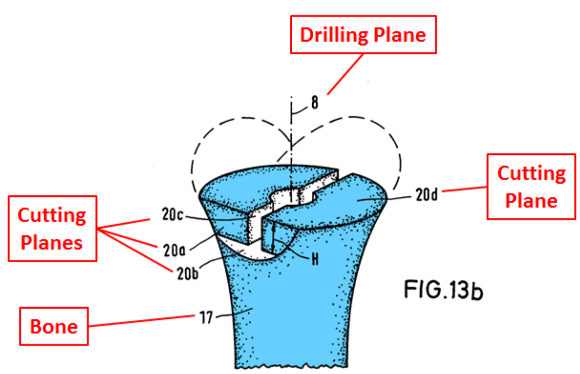
6. Dependent Claims 5, 27, 48, and 66

Radermacher discloses that the instrument system includes a plurality of guides. Ex. 1003 at 13 (“[A]ny suitable tool guides, particularly drill sleeves, parallel guides, saw templates … can be provided. These tool guides … can be provided in/on the basic body of the individual template …”), 30, Figs. 13a, c.

7. Dependent Claims 6, 7, 9-11, 28, 29, 31, 33, 49-50, 52, 53, 67, 68, 70–72

<table>
<tr><th>Claims 6, 28, 49, and 67</th><th>Exemplary Disclosure in the Prior Art</th></tr>
<tr><td>The instrument system of claim [5/27/48/66], wherein a first guide of the plurality of guides is configured at an angle to a second guide of the plurality of guides.</td><td><u>Radermacher</u> discloses a first guide configured at an angle to a second guide (e.g., drilling hole 8 and cutting guide along 20d, or cutting guides along 20a and 20c). Ex. 1003 at 30, Figs. 13a-c.





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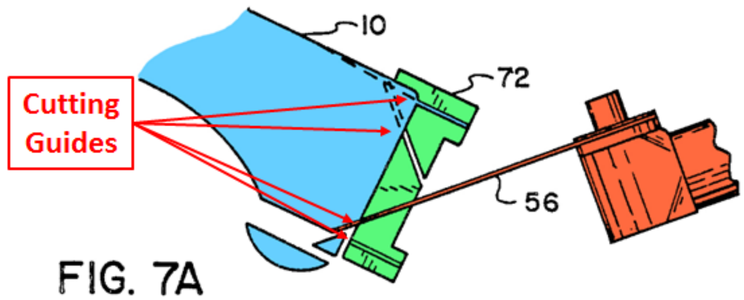
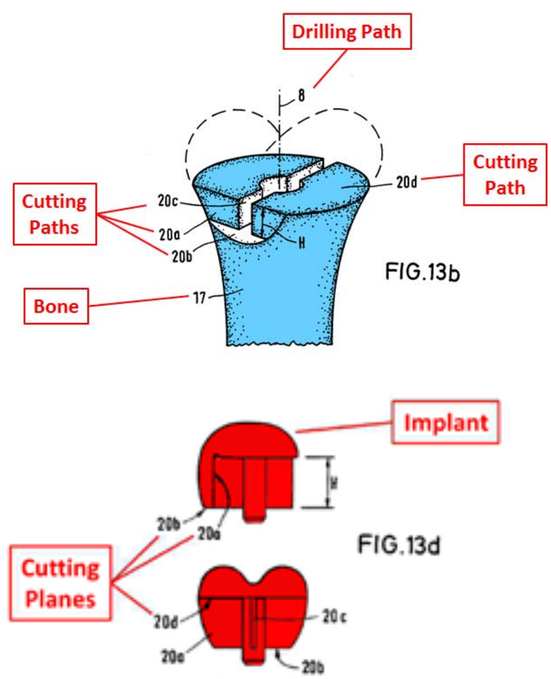
	Woolson discloses first and second guides (any two of the four cutting paths in Fig. 7A) that are not at the same angle:  FIG. 7A Ex. 1031; Ex. 1002 ¶ 144 (claim charts).
Claims 7, 29, 50, and 68	
The instrument system of claim [1/23/44/62] having a first guide and a second guide, wherein the first guide is configured at an angle to the second guide.	*See* Claim 6.
Claims 9, 31, 52, and 70	
The instrument system of claim [1/23/44/62], wherein the patient-specific surface is configured to prevent at least one	**Radermacher** discloses that the contact faces (patient-specific surface) abut the knee joint, thereby preventing at least axial, lateral, or rotational movement. Ex. 1003 at 30 ("The individual template 4 is set onto the bone 17 in a defined manner, abutting the contact faces 1."), 10-12, Figs. 13a, c.

movement selected from the group consisting of axial, lateral and rotational.	
Claims 10, 53, and 71	
10. The instrument system of claim 1, wherein the instrument system is configured to position the orthopedic implant, wherein the orthopedic implant is a femoral component of a knee implant. [**claims 53 and 71** recite "wherein the instrument system is configured to position [*the/a*] *femoral component of* the orthopedic implant."]	**<u>Radermacher</u>** discloses that the instrument system is configured to position an orthopedic implant, including knee implants and components thereof. Ex. 1003 at 30 ("Figs. 13a to 13c schematically show an individual template 4 for the preparation of the seat for the knee-joint head prosthesis illustrated by way of example in Fig. 13d.… The individual template 4 is set onto the bone 17 in a defined manner, abutting the contact faces 1."), Figs. 13b, d. Radermacher specifically discloses a template in which the patient-specific surface engages an uncut surface of the femur. *Id.* at Figs. 13a-d. 

Claims 11, 33, and 72	
11. The instrument system of claim 1, wherein the instrument system is configured to position the orthopedic implant, wherein the orthopedic implant is a tibial component of a knee implant. [**claims 33 and 72** recite "wherein the instrument system is configured to position [*the/a*] *tibial component of* the orthopedic implant."]	*See* Claim 10. In addition: **Radermacher** further discloses individualized surgical system for any type of intervention and any type of joint or portion thereof, which would include the tibia. Ex. 1003 at 10 ("parts of the surface of an arbitrary osseous structure which is to be treated"); 11 ("Using the template of the invention allows a treatment of osseous structures *for any orthopedic intervention*") (emphasis added). **Woolson** and **Kenna** disclose cutting guides engaging the tibia.Ex. 1031, 6:65-7:26; Ex. 1032, 4:20-26; *see also* Ex. 1033 at Figs. 2A-B.

8. Dependent Claims 8, 30, 51, and 69

Claims 8, 51, and 69 specify the instrument system has a second guide, wherein the second guide is configured for drilling. Claim 30 is similar: "wherein *the first is configured for drilling and the first guide is configured for drilling* [sic] *and* the second guide is configured for drilling."[3]

Radermacher discloses a template for a knee joint that includes multiple cutting guides and one drilling hole:

[3] The terms "the first," "the first guide," and "the second guide" in claim 30 lack antecedent basis.

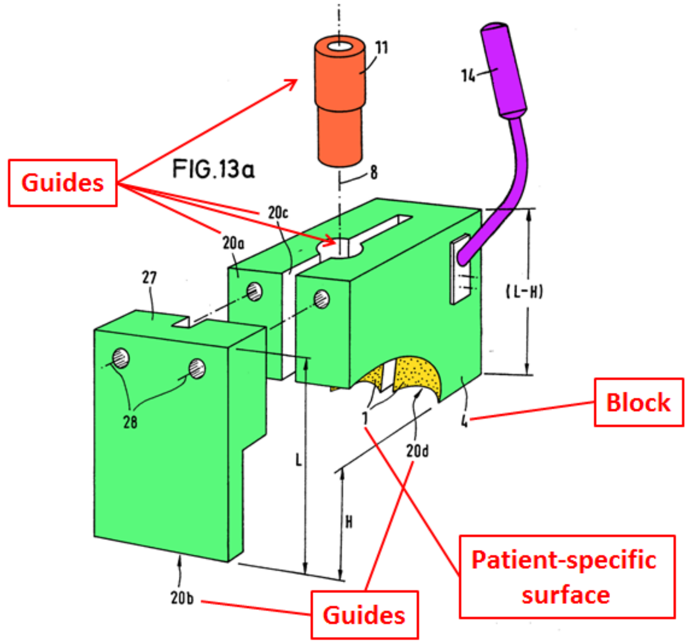


FIG.13a

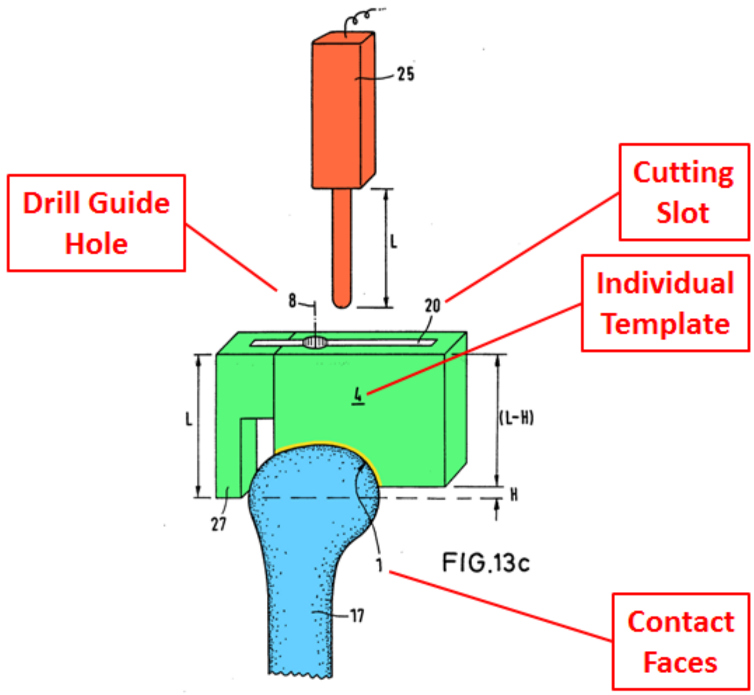


FIG.13c

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

Radermacher's disclosure is not limited to this exemplary embodiment. Radermacher discloses that the individual template may also have multiple (e.g., first and second) drilling holes. Radermacher states that "drill sleeves"—plural—can "be provided in/on the basic body of the individual template." *Id.* at 13. Radermacher also discloses other embodiments that include two "bores 19" for accommodating a drill. *Id.* at 25-26, Figs. 10a-d, 6b, 9.

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 widely known in the art—were to be implanted. Ex. 1002 ¶ 148. Including such drilling holes in Radermacher would have involved nothing more than combining its teachings with common knowledge according to known methods to yield predictable results. *Id.*

Numerous prior art references further support the conclusion that blocks having cutting guides and first and second drilling holes were conventional, widely known, and it would have been obvious that Radermacher's template could also include two drill holes. *Id.* ¶¶ 149-51. For example, Woolson discloses a "conventional cutting guide 72" having multiple cutting slots and two drill holes whose axes extend through the distal end of a bone (e.g., femur) of a joint:

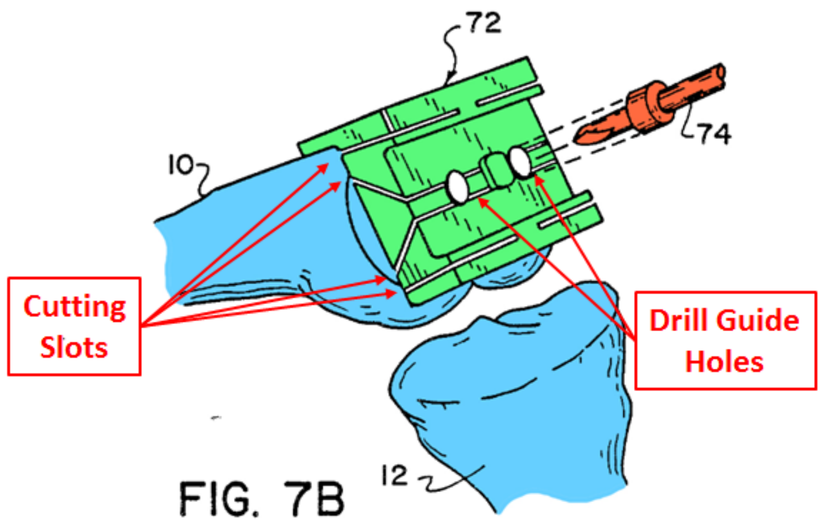


FIG. 7B

Ex. 1002 ¶ 149 (citing Ex. 1031, Fig. 7B). The resulting holes "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 ¶ 150 (citing and discussing Exs. 1011, 1031-34, 1037).

A POSITA would have been motivated to modify Radermacher to incorporate two drilling guides as disclosed in Woolson (or any other reference) for numerous reasons. As described above, Radermacher and Woolson address the same problem and are in the same field of endeavor. Radermacher expressly states that multiple drill "sleeves" can be used in the template. Ex. 1003 at 13. It would have been readily apparent to a POSITA that the number of drill holes would depend on the implant being used. If the implant contained two pegs (instead of a single peg as shown in Radermacher), then the block would also contain two drilling guides. Ex. 1002 ¶ 151.

9. Dependent Claims 12-15, 36, 37, 54, 55, and 73-76

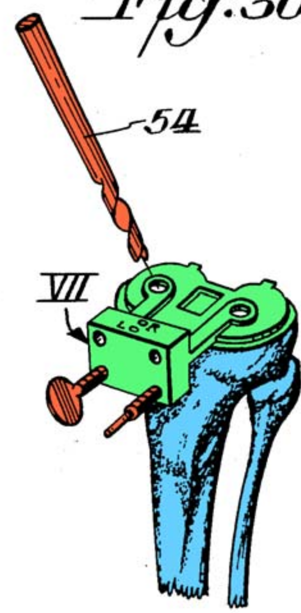
These claims specify the guide is configured to drill a hole on the medial or lateral femoral condyles or tibial plateaus. Radermacher does not expressly disclose these configurations. Nevertheless, Radermacher does disclose drilling a hole into the intramedullary canal, because the femoral implants shown in Figure 13d of Radermacher only had a single post. Ex. 1002 ¶ 52. And a POSITA would have understood Radermacher's guide could provide for drilling holes into the femur or tibia, e.g., for receiving the pegs of a prosthesis or for receiving a pin or screw to secure the guide in position. *Id.*; Ex. 1003 at 13 ("***[A]ny suitable tool guides***, particularly drill sleeves, parallel guides, saw templates … can be provided…. These tool guides … will effect a three-dimensional guiding of the treatment tools or measuring devices exactly as provided by the surgical planning.").

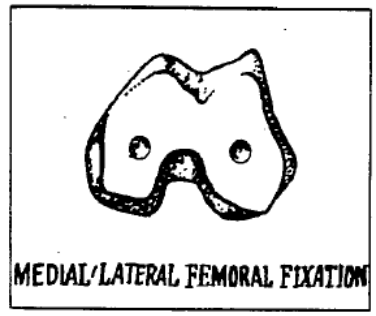
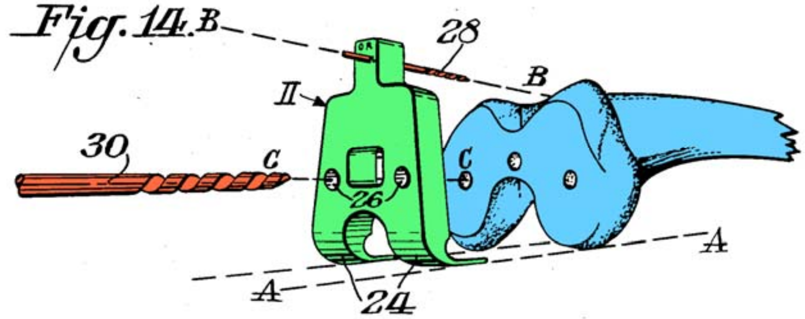
Moreover, a POSITA would have understood that femoral and tibial prostheses commonly had two fixation studs, each requiring two holes to be drilled into the femur and tibia, and that the holes were drilled into the medial tibial plateau, lateral tibial plateau, medial femoral condyle, and lateral femoral condyle. Ex. 1002 ¶ 152. Configuring the guides to allow drilling into specific portions of the knee joint cannot make the claim patentable. *Id.* This configuration would have involved nothing more than combining Radermacher's teachings with common knowledge according to known methods to yield predictable results. *Id.*; *see also* Ex. 1007 at Fig. 7 (showing "functional element 10" on a tibial template), 10:25-28 (indicating that, while shown as a post, functional element 10 could also be "the indication of a place where … one must cut, saw or drill ….").

Further, it would have been obvious to modify Radermacher to include such drill guides in view of Kenna. *Id.* ¶ 153. Kenna discloses drill guides for drilling into the medial and lateral tibial plateau to accommodate medial and lateral fixation studs of a tibial prosthesis. Ex. 1032, Fig. 30B, 8:11-22. Kenna also discloses drill guides for drilling into the medial femoral condyle and lateral femoral condyle to make holes for the femoral prosthesis fixation studs. *Id.*, 5:34-43, Figs. 2b, 14; *see also id.*, 1:67-68; 3:47-53.

The claim chart below further demonstrates how the prior art meets these limitations.

Claims 12, 13, 36, 37, 73, and 74	Exemplary Disclosure in the Prior Art
12. The instrument system of claim 8, wherein the first guide is configured for drilling on a *medial* tibial plateau of the knee joint. [**claims 36 and 73** recites "The instrument system of	**Radermacher** discloses individualized surgical system for any type of intervention and any type of joint or portion thereof, which would include the tibia. Ex. 1003 at 10 ("parts of the surface of an arbitrary osseous structure which is to be treated"); 11 ("Using the template of the invention allows a treatment of osseous structures *for any orthopedic intervention*") (emphasis added). **Kenna** discloses drill guides for drilling into the

claim [30/69], wherein the first guide is configured for drilling *a hole* on a medial plateau of [the/a] tibia of the knee joint *of the patient*."] - - - **13.** The instrument system of claim 8, wherein the second guide is configured for drilling on a *lateral* tibial plateau of the knee joint. [**claims 37 and 74** recite "The instrument system of claim [30/69], wherein the second guide is configured for drilling *a hole* on a lateral plateau of [the/a] tibia of the knee joint *of the patient*."]	medial and lateral tibial plateau to accommodate medial and lateral fixation studs of a tibial prosthesis. Ex. 1032, 8:11-22, Fig. 30B. Fig. 30B. 
Claims 14, 15, 54, 55, 75, and 76	
14. The instrument system of claim 8, wherein the first guide is configured for drilling on a *medial* femoral condyle of the knee joint. [**claims 54 and 75** recite "The instrument system of claim [51/69] wherein the first guide is configured	**<u>Radermacher</u>** discloses individualized surgical system for any type of intervention and any type of joint or portion thereof, which would include the femur. Ex. 1003 at 10 ("parts of the surface of an arbitrary osseous structure which is to be treated"); 11 ("Using the template of the invention allows a treatment of osseous structures *for any orthopedic intervention*") (emphasis added); Figs. 13a-d. **<u>Kenna</u>** discloses drill guides for drilling into the medial femoral condyle and lateral femoral condyle to make holes for the femoral prosthesis fixation studs. Ex. 1032, 5:34-43Figs. 2b, 14;; *see also id.*, 1:67-68,

for drilling *a hole* on a medial femoral condyle of the knee joint *of the patient*."] - - - **15.** The instrument system of claim 8, wherein the second guide is configured for drilling on a *lateral* femoral condyle of the knee joint. [**claims 55 and 76** recite "The instrument system of claim [51/69] wherein the second guide is configured for drilling a hole on a lateral femoral condyle of the knee joint *of the patient*."]	3:47-53 *Fig. 2b.*  *Fig. 14.* 

In light of Kenna, the claimed configuration would have involved nothing more than combining prior art elements according to known methods to yield predictable results. Ex. 1002 ¶ 155.

10. Dependent Claims 16, 38, 56, and 77

These claims specify the substantially uncut joint surface (or cartilage surface in claims 56 and 77[4]) includes normal or diseased cartilage, which is disclosed by Radermacher and would have been obvious to a POSITA. *E.g.*, Ex. 1003 at 12 (the template is made based on the negative mold of parts of the "individual ***natural (i.e. not pre-treated) surface*** of the osseous structure…") (emphasis added); Ex. 1002 ¶ 156. Radermacher discloses that the joint surface is "natural" and "not pre-treated," and therefore would include normal or diseased cartilage. Ex. 1003 at 12. Further, this limitation would have been obvious in view of Alexander, which discloses that a natural joint surface includes normal and/or diseased cartilage and discloses mapping the cartilage surface using MRI. *E.g.*, Ex. 1004 at 1, 32.

11. Dependent Claim 17

Claim 17 specifies the substantially uncut surface of the diseased or damaged knee includes subchondral bone, which Radermacher discloses. Radermacher describes generating a three-dimensional negative mold of "the individual ***natural (i.e. not pre-treated) surface*** of the osseous structure." Ex.

[4] The term "the substantially uncut cartilage surface" in claims 56 and 77 lacks antecedent basis.

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 and any subchondral bone that may be exposed by virtue of the cartilage being worn away. Ex. 1002 ¶¶ 80, 88-89. Subchondral bone is exposed in the vast majority of patients. *Id.* ¶ 157. Alexander also discloses this limitation. Ex. 1004 at Fig. 22B.

12. Dependent Claims 18, 19, 40, 41, 58, 59, 79, and 80

These claims merely specify who (operator or surgeon) selects the predetermined internal/external rotation angle of the orthopedic implant/component. Radermacher discloses these limitations, as set forth in the claim chart below. To the extent Radermacher does not explicitly disclose these limitations, they would have been obvious because selecting the claimed angle is nothing more than a well-known step in planning a joint surgery. Ex. 1002 ¶ 158.

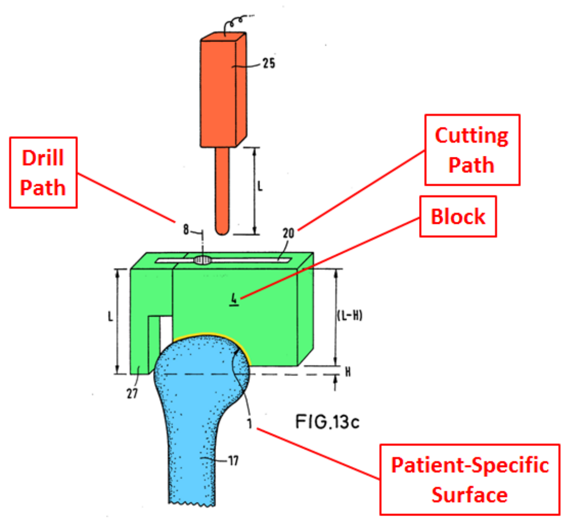
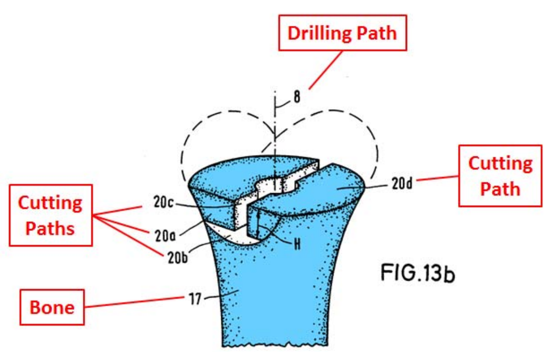
Claims 18, 40, 58, and 79	Exemplary Disclosure in the Prior Art
18. The instrument system of claim 1, wherein the predetermined internal rotation angle or external rotation angle of the orthopedic implant is selected by an operator. [**claims 40 and 58** recite "The instrument system of	<u>**Radermacher**</u> discloses that the angle is determined by an operator or surgeon because it is selected during the preoperative planning. Ex. 1003 at Fig. 18; *id.* at 12 ("[T]here 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…. The above negative mold … is constructed in a cohesive, mechanically rigid basic body (the individual template)."), 13 ("These tool guides … ***will effect a three-dimensional guiding of the treatment tools or***

claim [23/44], wherein the predetermined internal rotation angle or external rotation angle of the *[tibial/femoral] component of* the orthopedic implant is selected by an operator.”] [**claim 79** recites “The instrument system of claim 62, wherein the predetermined *orientation* of the orthopedic implant is selected by an operator.”]	***measuring devices exactly as provided by the surgical planning***.”) (emphasis added), 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”).

Claims 19, 41, 59, and 80	
The instrument system of claim [18/40/58/79] wherein the operator is a surgeon.	*See* Claim 18.

13. Dependent Claims 20, 21, 42, 60, 81 and 82

These claims specify the substantially uncut surface portion of the knee includes at least a portion of femoral condyle (claims 20, 60, and 81) or tibial plateau (21, 42, and 82). The claim charts below explain how Radermacher discloses these limitations. To the extent Radermacher does not expressly disclose these limitations, a POSITA would have understood that the uncut ends of a natural femur and tibia of a knee joint include a femoral condyle and tibial plateau. Ex. 1002 ¶¶ 160-61. It would have been obvious that the substantially uncut surface portion of the knee includes a portion of femoral condyle and/or tibial plateau. *Id.* ¶ 161.

Claims 20, 60, and 81	**Exemplary Disclosure in the Prior Art**
The instrument system of claim [1/44/62], wherein the substantially uncut [joint (claims 60, 81)] surface portion [of the femur (claim 60)] of the knee joint includes at least a portion of a femoral condyle.	**Radermacher** discloses that the substantially uncut portion of the joint includes at least a portion of femoral condyle, as shown below. Ex. 1003 at Fig. 13a-d (femoral condyle); 2; 11 ("Using the template of the invention allows a treatment of osseous structures for any orthopedic intervention …."); 30.  FIG.13c  FIG.13b

Claims 21, 42, and 82	
The instrument system of claim [1/23/62], wherein the substantially uncut [joint (claims 42, 82)] surface portion of the knee joint includes at least a portion of a tibial plateau.	*See* Claim 20. In addition: **Radermacher** further discloses individualized surgical system for any type of intervention and any type of joint or portion thereof, which would include the tibia. Ex. 1003 at 10 ("parts of the surface of an arbitrary osseous structure which is to be treated"); 11 ("Using the template of the invention allows a treatment of osseous structures *for any orthopedic intervention*") (emphasis added); 2 (discussing surgeries involving the tibia). **Woolson** and **Kenna** also disclose cutting guides that engage the tibia.Ex. 1031, 6:65-7:26; Ex. 1032, 4:20-26.

14. Dependent Claims 22, 43, 61, and 83

These claims specify the patient-specific surface is, at least in part, derived by estimating cartilage loss for at least a portion of the patient's knee joint. Radermacher does not expressly disclose this limitation. But, as discussed above, a POSITA would have understood that the imaging technologies identified in Radermacher (CT, MR tomography, nuclear spin tomography) were well known to be capable of depicting bone and cartilage, and therefore cartilage loss. The '129 patent admits this was known in the art. Ex. 1001, 13:50-14:23. Thus, estimating cartilage loss is inherent in, or would have been obvious in view of, the process described by Radermacher. Ex. 1002 ¶ 162.

In addition, Alexander discloses estimating cartilage loss using MRI. Ex. 1004 at 3-4, 22-23, 30. It would have been obvious to modify Radermacher or to combine Radermacher with Alexander, to include estimating cartilage loss as disclosed by Alexander since doing so would ensure an accurate reproduction of the patient-specific surface and eliminate the step of removing cartilage prior to applying the individual template on the patient. Ex. 1002 ¶ 163. A POSITA would have been motivated to improve the quality of the surgery and obviate the need to remove cartilage prior to applying the individual template. *Id.*

15. Dependent Claims 32, 34, and 35

These claims specify the cartilage information includes information about cartilage surface (claim 32), cartilage shape (claim 34), and normal and diseased cartilage of the knee joint (claim 35). As discussed above, the standard imaging techniques discussed in Radermacher would provide information about knee-joint cartilage (normal or diseased). Ex. 1003 at 12 ("[T]here 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…."), Fig. 18; Ex. 1002 ¶ 164. The CT or MR image data of the natural surface of the joint would include the natural status (e.g., healthy or diseased) of cartilage, including surface information and shape. Ex. 1002 ¶ 164.

To the extent Radermacher does not disclose that image data includes the recited cartilage information, it would have been obvious to modify the contact faces of Radermacher's template to include the recited cartilage information in view of Alexander, as explained above. *Id.* ¶ 165.

16. Dependent Claims 39, 57, and 78

These claims recite that the patient-specific surface includes information about subchondral bone.

i. Radermacher

As described above and as recognized in the '129 patent, a patient's articular joint surface includes subchondral bone when a portion of the articular cartilage has been worn or torn away. Ex. 1001, 9:42-47, Fig. 2; Ex. 1002 ¶ 167. This occurs in virtually all knee replacement patients. Ex. 1002 ¶ 167. By disclosing the contact faces of the template copy the "natural (i.e. not pre-treated) surface" (Ex. 1003 at 12), Radermacher discloses a patient-specific surface that includes information about subchondral bone. Ex. 1002 ¶ 167. Thus, Radermacher discloses this limitation or it would have been obvious in view of Radermacher. *Id.*

ii. The Knowledge of a POSITA

The '129 patent admits ordinarily-skilled artisans knew that information concerning the subchondral bone could be obtained via "conventional" imaging techniques such as MRI and/or CT scans. Ex. 1001, 12:17-35, 13:49-14:34, 40:33-35, 40:36-41:2. This is confirmed by Petitioner's expert (Ex. 1002 ¶ 168) and by numerous prior-art references. *See* Ex. 1004 at 14:16-15:8, 26:20-28, 39:1-24; Ex. 1050 at 9:1-6; Ex. 1010 at 2:48-55, 3:5-45, Ex. 1007 at 6:24-29, 9:1-13, 13:17-25, Fig. 6.

In view of this knowledge, a POSITA would have been motivated to design Radermacher's template to include information about subchondral bone at least because: (1) such a template would be consistent with Radermacher's statement that the template be a negative of the "natural (i.e. not pre-treated) surface" (Ex. 1003 at 12); (2) matching the exposed subchondral bone would ensure that the template can be "set onto the osseous structure in a clearly defined position and with mating engagement" (*id.* at 10); and (3) if the template corresponding to exposed subchondral bone did not include information about subchondral bone, the risk of misalignment would be increased. Ex. 1002 ¶ 169.

Accordingly, even if Radermacher did not disclose that the contact faces of the individual template include information about the patient's subchondral bone, such a template would have been obvious. *Id.* ¶ 170.

iii. Alexander

This limitation also would have been obvious in view of Alexander. Besides identifying the articular cartilage (black), Alexander teaches using MRI to create a three-dimensional model of the surface of the femoral and tibial bones (gray):

FIG._18C

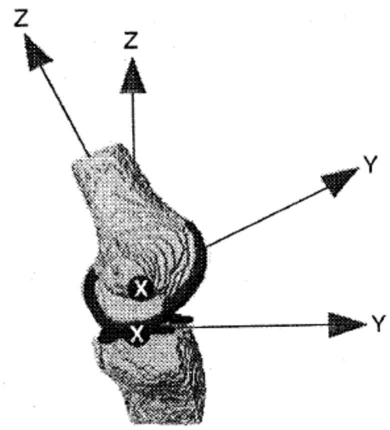


FIG._18H

Ex. 1004 at Figs. 18C-I; *see also id.* at 61:19-25, 23:31-32, 39:22-24 (MRI can be "manipulated to enhance the image of the bones"), 26:20-28 (imaging "the bones of the joint" in addition to the cartilage), Figs. 10A-C, 12A-B. Like the '129 patent, Alexander discloses that a portion of a patient's articular cartilage could be worn or town away, and thus subchondral bone exposed, as evidenced by the dark circles (indicated by arrow) in the following cartilage map:

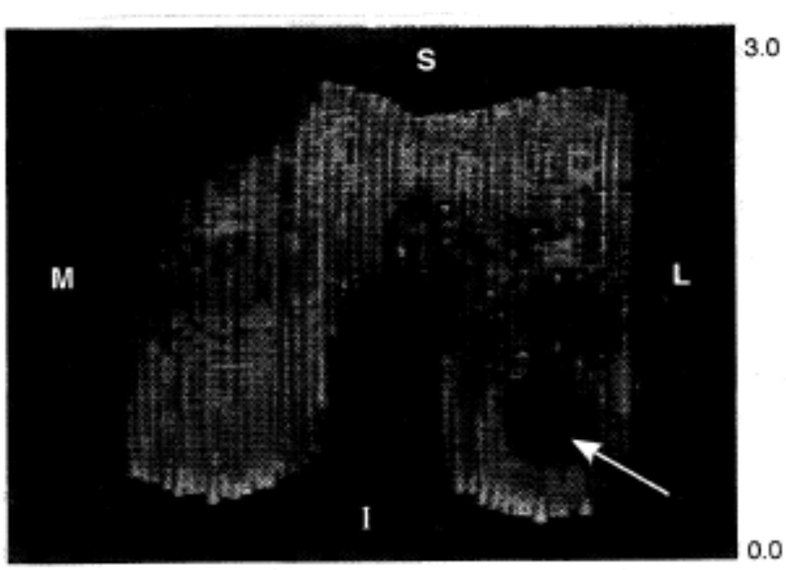


FIG._22B

Id. at Fig. 22B; *id.* at 31:6-7 (dark portions represent a "full thickness cartilage defect" having a "thickness of zero"); Ex. 1002 ¶ 171. It would have been obvious that, if a patient-specific template as described in Radermacher were created for the natural joint surface with exposed subchondral bone as described in Alexander, such a template would include information about subchondral bone, as claimed. Ex. 1002 ¶ 171.

A. Ground 2: Claims 1-83 Are Unpatentable as Obvious Over Radermacher in Combination with Fell, Woolson, and Kenna.

Ground 2 relies on Fell rather than Alexander. Fell discloses a patient-specific implant that replaces the meniscus (cartilage between a femoral condyle and a corresponding tibial plateau). Ex. 1002 ¶ 173. Fell explains that 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.

Ex. 1005 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 shape of the cartilage/articular surface, which would include any exposed subchondral bone; and (2) creating a patient-specific device that matches and mates with the contour of such surfaces. Ex. 1002 ¶ 174, 176-77.

A POSITA would have been motivated to combine the teachings of Radermacher and Fell, and design Radermacher's template to include cartilage information. Ex. 1002 ¶¶ 179. Both references relate to methods of treating damaged cartilage in a knee joint. And both references disclose the use of MRI for creating patient-specific medical devices having inner surfaces that match the patient's natural joint surface. They address the same problem, are in the same field of endeavor, and use the same imaging technology (e.g., MRI). *Id.*

Radermacher also expressly suggests the combination. *Id.* ¶ 180. Radermacher teaches 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 ¶ 180. Because Fell discloses creating a patient-specific implant that matches the patient's cartilage/articular surface, which would include any exposed subchondral bone, a POSITA would have understood that Radermacher's template could also match the cartilage/articular surface, including any exposed subchondral bone. *Id.*

In addition, a POSITA would have recognized that a patient-specific template would simplify surgery. *Id.*

Finally, as with Ground 1, the modification would merely: (a) require the combination of one known element (Fell's MRI data) with another known element (Radermacher's MRI data) to obtain a predictable result (a device tailored to the patient's cartilage and bone 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.* ¶ 179.

Because the disclosures of Radermacher, as well as the knowledge of a POSITA, are the same as in Ground 1, the chart below identifies only disclosures from Fell.

Claims	Disclosure in Radermacher, Fell, Woolson, and Kenna
Independent Claims 1, 23, 44, and 62	*See* Ground 1 for disclosure in Radermacher, Woolson, and Kenna. Regarding limitation **[a]**, **Fell** discloses a patient-specific surface that includes cartilage information derived from image data of a knee joint. *See, e.g.*, Ex. 1005 at 14, 15, 22.
Dependent Claims 2-22, 24-43, 45-61, 63-83	*See* Ground 1 for disclosure in Radermacher, Woolson, and Kenna. Regarding **claims 16, 38, 56, and 77, Fell** discloses that a joint surface includes normal or diseased cartilage. *E.g.*, Ex. 1005 at 1, 7, 14-15. Regarding **claims 32, 34, and 35**, *see* **Fell** under Claims 1, 23, 44, and 62, limitation [a], above.

IX. SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

Secondary considerations should be considered but do not control an obviousness conclusion, particularly where, as here, a strong prima facie showing of obviousness exists. *Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007); *Newell Cos., v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

Petitioner is unaware of evidence of secondary considerations. And any such evidence that ConforMIS may provide cannot possibly outweigh the strong *prima facie* case of obviousness here. Petitioner reserves the right to respond to evidence of secondary considerations in due course.

X. CONCLUSION

For the reasons above, Petitioner established a reasonable likelihood that claims 1-83 of the '129 patent are unpatentable as obvious over the prior art. *Inter partes* review on each claim is appropriate.

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

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 30, 2016

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CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i). This Petition contains 13,833 words, excluding the parts of the document exempted by 37 C.F.R. § 42.24(a)(1).

Dated: November 30, 2016

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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 U.S. PATENT NO. 8,377,129** and **EXHIBITS 1001-1057** are being served on November 30, 2016 via FedEx Priority Overnight on counsel of record for U.S. Patent 8,377,129 patent owner **CONFORMIS, INC.**, at the address below:

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