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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. TBD
U.S. Patent No. 8,657,827

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-25, 28, 29, AND 32-46 OF U.S. PATENT NO. 8,657,827

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TABLE OF AUTHORITIES

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OTHER AUTHORITIES

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 8,657,827 (“the ’827 patent”)
1002	Declaration of Jay D. Mabrey, M.D.
1003	PCT Publication No. WO 93/25157 (“Radermacher”)
1004	PCT Publication No. WO 00/35346 (“Alexander”)
1005	PCT Publication No. WO 00/59411 (“Fell”)
1006	U.S. Patent No. 6,712,856 (“Carignan”)
1007	PCT Publication No. WO 95/28688 (“Swaelens”)
1008	U.S. Patent No. 6,510,334 (“Schuster II”)
1009	U.S. Patent No. 5,098,383 (“Hemmy”)
1010	European Patent No. EP 0 908 836 (“Vomlehn”)
1011	U.S. Patent No. 4,502,483 (“Lacey”)
1012	U.S. Patent No. 6,575,980 (“Robie”)
1013	U.S. Patent No. 5,735,277 (“Schuster ’277”)
1014	U.S. Patent No. 5,320,102 (“Paul”)
1015	J.B. Antoine Maintz & Max A. Viergever, *A Survey of Medical Image Registration*, 2 Med. Image Analysis 1 (1998) (“Maintz”)
1016	PCT Publication No. WO 02/22014 (“WO ’014”)
1017	Excerpts of the ’827 Patent Prosecution History

Exhibit No.	Description
1018	***Exhibit Number Not Used***
1019	CV of Jay D. Mabrey, M.D.
1020	***Exhibit Number Not Used***
1021	U.S. Provisional Patent Application No. 60/293488 (filed May 25, 2001) ("the '488 application")
1022	U.S. Provisional Patent Application No. 60/363527 (filed March 12, 2002) ("the '527 application")
1023	***Exhibit Number Not Used***
1024	Excerpts from ConforMIS, Inc.'s Preliminary Invalidity and Noninfringement Disclosures in *ConforMIS, Inc. v. Smith & Nephew, Inc.*, Civil Action No. 1:16-cv-10420-IT (D. Mass.)
1025	U.S. Provisional Patent Application No. 60/380692 (filed May 14, 2002) ("the '692 application")
1026	U.S. Provisional Patent Application No. 60/380695 (filed May 14, 2002) ("the '695 application")
1027	U.S. Patent Application No. 10/160667 (filed May 28, 2002) ("the '667 application")
1028	U.S. Patent No. 7,468,075 ("the '075 patent")
1029	U.S. Patent No. 7,618,451 ("the '451 patent")
1030	***Exhibit Number Not Used***
1031	U.S. Patent No. 4,841,975 ("Woolson")
1032	U.S. Patent No. 4,646,729 ("Kenna")

Exhibit No.	Description
1033	Klaus Radermacher et al., *Computer Assisted Orthopaedic Surgery with Image Based Individual Templates*, 354 Clinical Orthopaedics and Related Research 28 (1998) ("CAOS")
1034	International 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")
1038-1040	***Exhibit Numbers Not Used***
1041	Smith & Nephew Richards, *Genesis® Total Knee System Primary Surgical Technique* (1993) ("Genesis Technique Guide")
1042	Excerpts from Dror Paley, *Principles of Deformity Correction* (2002) ("Principles of Deformity Correction")
1043	U.S. Patent No. 5,107,824 ("Rogers")
1044-1065	***Exhibit Numbers Not Used***
1066	Felix Fernandez-Madrid et al., *MR Features of Osteoarthritis of the Knee*, 12 Magnetic Resonance Imaging 703-09 (1994) ("Fernandez-Madrid")
1067	C-J. Menkes et al., *Are Osteophytes Good or Bad?*, 12 OsteoArthritis and Cartilage S53-S54 (2004) ("Menkes")
1068	C. G. Peterfy et al., *Whole-Organ Magnetic Resonance Imaging Score (WORMS) of the Knee in Osteoarthritis*, 12 OsteoArthritis and Cartilage 177-90 (2004) ("Peterfy")
1069	Excerpts from Jarrold H. Mink et al., Magnetic Resonance Imaging of the Knee (1987)

Exhibit No.	Description
1070	U.S. Provisional Patent Application No. 60/416601 (Filed on October 7, 2002) ("the '601 application")
1071	U.S. Publication 2004/0133276 ("Lang")
1072	U.S. Patent No. 7,534,263 ("Burdulis Jr.")
1073	U.S. Patent No. 7,634,119 ("Tsougarakis")
1074	U.S. Provisional Patent Application No. 60/894744 (Filed February 6, 2007) ("the '744 application")
1075	U.S. Provisional Patent Application No. 60/975028 (Filed on March 14, 2007) ("the '028 application")
1076	U.S. Provisional Patent Application No. 60/765592 (Filed on February 6, 2006) ("the '592 application")
1077	U.S. Provisional Patent Application No. 60/785168 (Filed on March 2006) ("the '168 application")
1078	U.S. Provisional Patent Application No. 60/788339 (Filed on March 31, 2006) ("the '339 application")
1079	U.S. Provisional Patent Application No. 60/431176 (The December 4, 2002) ("the '176 application")
1080	U.S. Provisional Patent Application No. 60/467686 (Filed on May 2, 2003) ("the '686 application")
1081-1089	***Exhibit Numbers Not Used***
1090	Aaron A. Hofmann et al., *Effect of the Tibial Cut on Subsidence Following Total Knee Arthroplasty*, 269 Clinical Orthopaedics and Related Research 63 (1991) ("Hofmann")
1091-1095	***Exhibit Numbers Not Used***

Exhibit No.	Description
1096	Excerpts from ConforMIS, Inc.'s Opening Claim Construction Brief in ConforMIS, Inc. v. Smith & Nephew, Inc., Civil Action No. 1:16-cv-10420-IT (D. Mass.)

Petitioner Smith & Nephew, Inc. ("Petitioner" or "Smith & Nephew") hereby requests *inter partes* review in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 et seq. of Claims 1-25, 28-29, and 32-46 of U.S. Pat. No. 8,657,827 ("the '827 patent"), which issued on February 25, 2014, 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 is the real party-in-interest. Smith & Nephew is a wholly owned subsidiary of Smith & Nephew plc, which is publicly traded on the London Stock Exchange.

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

ConforMIS asserted the '827 patent (Ex. 1001) against Smith & Nephew in co-pending litigation captioned *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass. filed February 29, 2016 and served March 1, 2016). Petitioner filed petitions requesting *inter partes* review of related ConforMIS patents: U.S. Patent Nos. 9,055,953 (IPR2016-01874); 9,216,025 (IPR2017-00115 and 2017-00307); 8,377,129 (IPR2017-00372); 8,551,169 (IPR2017-00373); 9,295,482 (IPR2017-00487 and -00488); 7,981,158 (IPR2017-00510 and -00511); 7,534,263 (IPR2017-00544 and -00545); and 8,062,302 (IPR2017-00778, -00779,

and -00780). Petitioner is filing a petition challenging Claims 50-64 of the '827 patent concurrently herewith.

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

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

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

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

Please address all correspondence to lead and back-up counsel at the address shown above. Smith & Nephew also consents to electronic service by email to BoxSMNPHL.168LP6@knobbe.com.

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

Petitioner certifies that the '827 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition. This Petition is being filed within one year of service of the original complaint against Petitioner in the district court litigation.

II. SUMMARY OF ISSUES PRESENTED

Claims 1-25, 28, 29, and 32-46[1] of the '827 patent recite a simple surgical instrument for preparing a bone (e.g., the femur or tibia in knee replacement surgery) to receive an implant. The claimed instrument has two basic features: (a) a patient-specific surface that includes cartilage information and "references" an osteophyte (e.g., bone spur) of a patient's joint; and (b) a guide for surgical tools. According to ConforMIS, Figures 32 and 33 (below)[2] show the purported invention, i.e., a surgical instrument (green) having a patient-specific surface (yellow) that matches a surface of the patient's joint, references (e.g., engages or avoids) an osteophyte, and guides a saw (not shown) to make cuts (shown as dotted lines) in the bone (blue).

[1] Claim 1 is the only independent claim.
[2] For clarity, diagrams are colored and annotated.

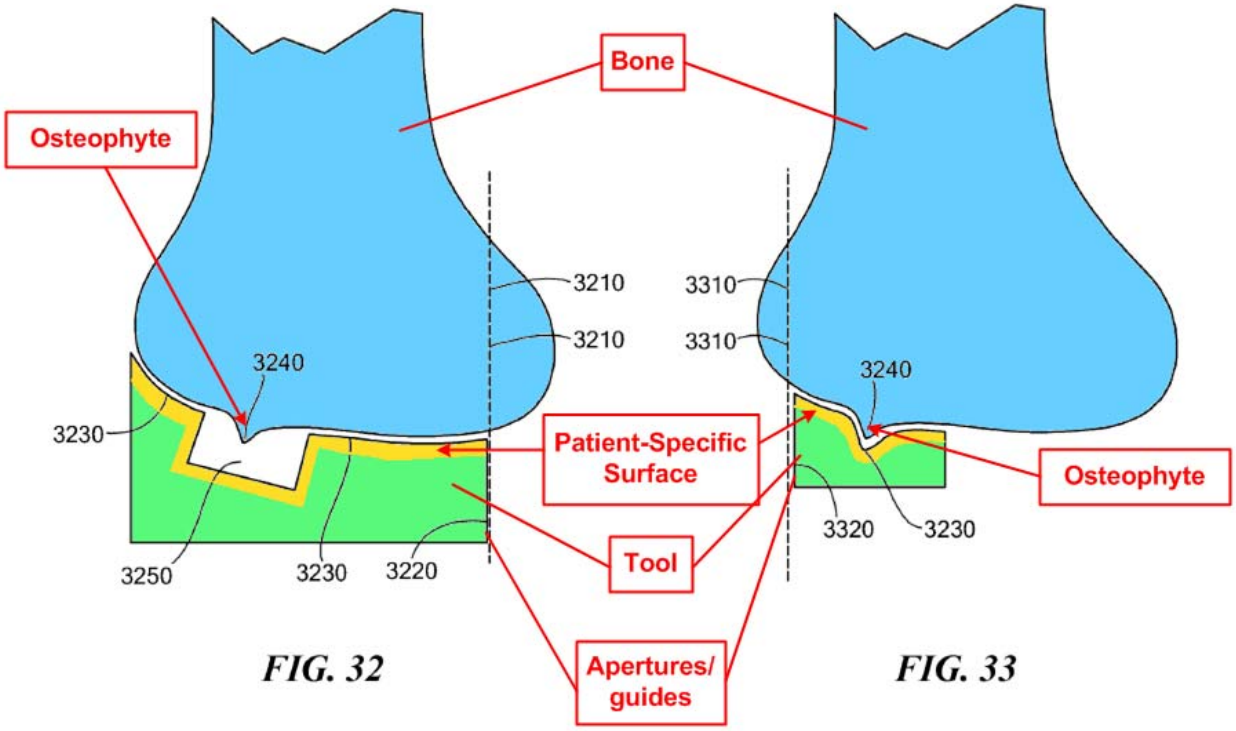
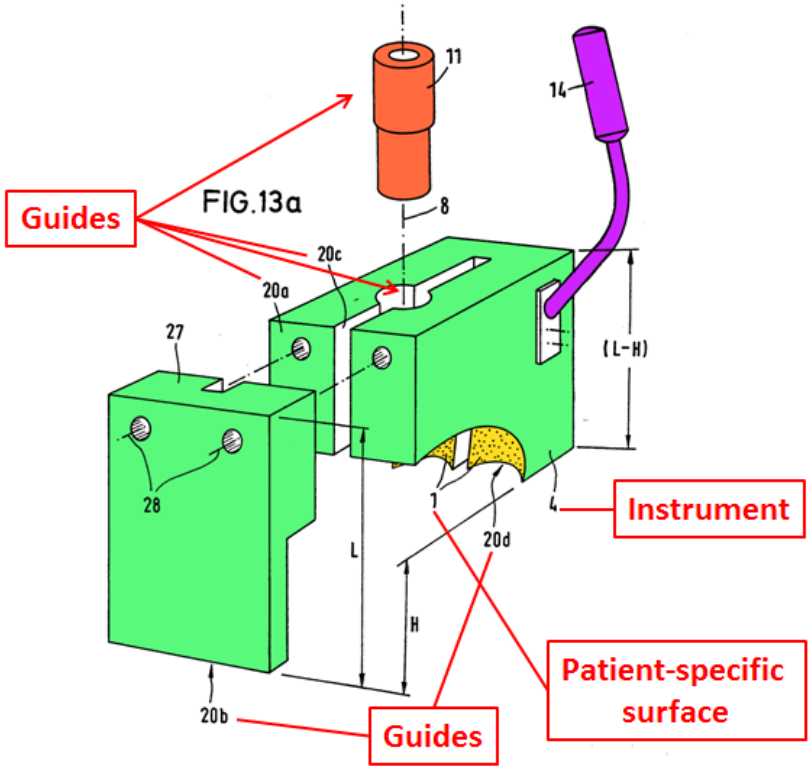


FIG. 32 *FIG. 33*

There was nothing inventive about such an instrument at the time the '827 patent was filed. By the 1990s, instruments having patient-specific surfaces were widely-known and described in numerous prior art references. For example, in 1993, Radermacher disclosed an instrument ("individual template 4") having guides (cutting guides defining planes 20a-d and a drill guide about axis 8), as well as a patient-specific surface ("contact faces 1") that was customized based on CT and/or MRI data to match the natural surface of a patient's knee joint:



Numerous other references similarly disclosed instruments containing patient-specific surfaces and tool guides.

The primary difference between the ’827 patent and Radermacher is that the ’827 patent expressly requires the patient-specific surface to “reference” (e.g., engage or avoid) an osteophyte. But osteophytes were commonly known and naturally occurring. It was widely-known that osteophytes (and other deformities) would be reflected in preoperative imaging and should be accounted for when planning surgery.

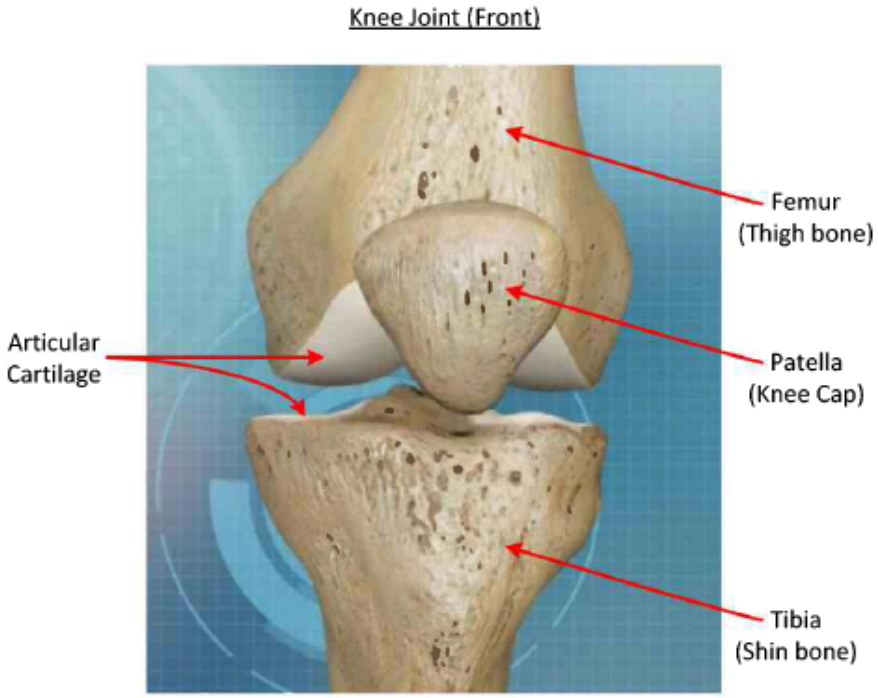
In view of the prior art, the challenged claims of the ’827 patent should have never issued. The claims slipped through the Patent Office with minimal

substantive examination despite the vast array of highly relevant—and invalidating—prior art.

III. INTRODUCTION & STATE OF THE ART

A. Knee Joint Anatomy

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



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.* In unhealthy knees, osteophytes, which are bony outgrowths or deformities, can occur on the articular surface of the femur and tibia. *Id.* ¶¶36-38.

A patient's femur and tibia define a "mechanical axis," which is the axis that extends from the center of the femoral head at the hip, through the center of the knee, and through the ankle joint, as shown below. *Id.* ¶¶39-40; Ex. 1036, Fig. 1.

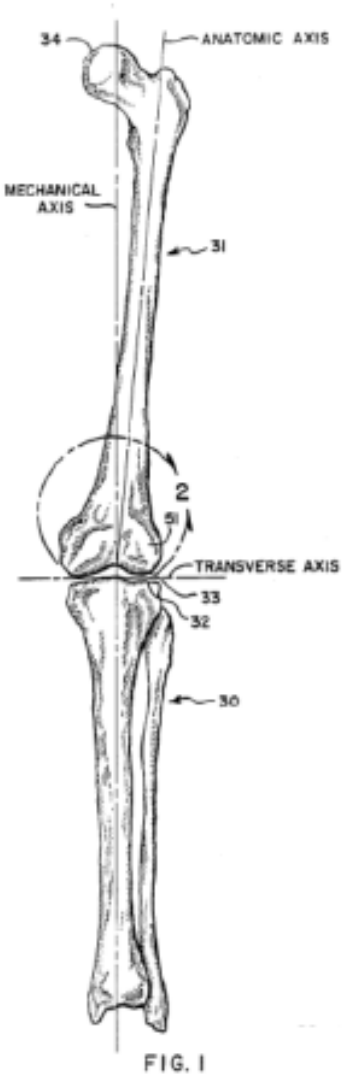


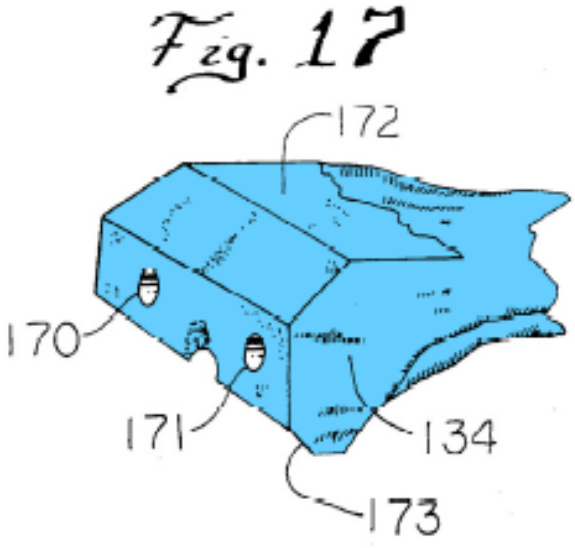
FIG. 1

The femur and tibia also each define an "anatomic axis" which, as shown above, represents the axis that extends along the center of the bone. Ex. 1002 ¶¶39-40.

B. Knee Replacement Procedures

When articular cartilage has been damaged by disease such as osteoarthritis, a surgeon can replace portions of the knee with artificial components. *Id.* ¶41. Such surgery, which is referred to as "knee arthroplasty," was known for decades before the '827 patent. *Id.* ¶¶34-35.

During knee arthroplasty, a surgeon prepares a patient's bone to receive an implant by removing a portion of the bone and shaping it to receive the implant. *Id.* ¶42. The image below shows the end of a femur that has been prepared in a typical manner, with flat bone surfaces for seating an implant and holes for receiving pegs on the implant. *Id.*



Ex. 1011, Fig. 17.

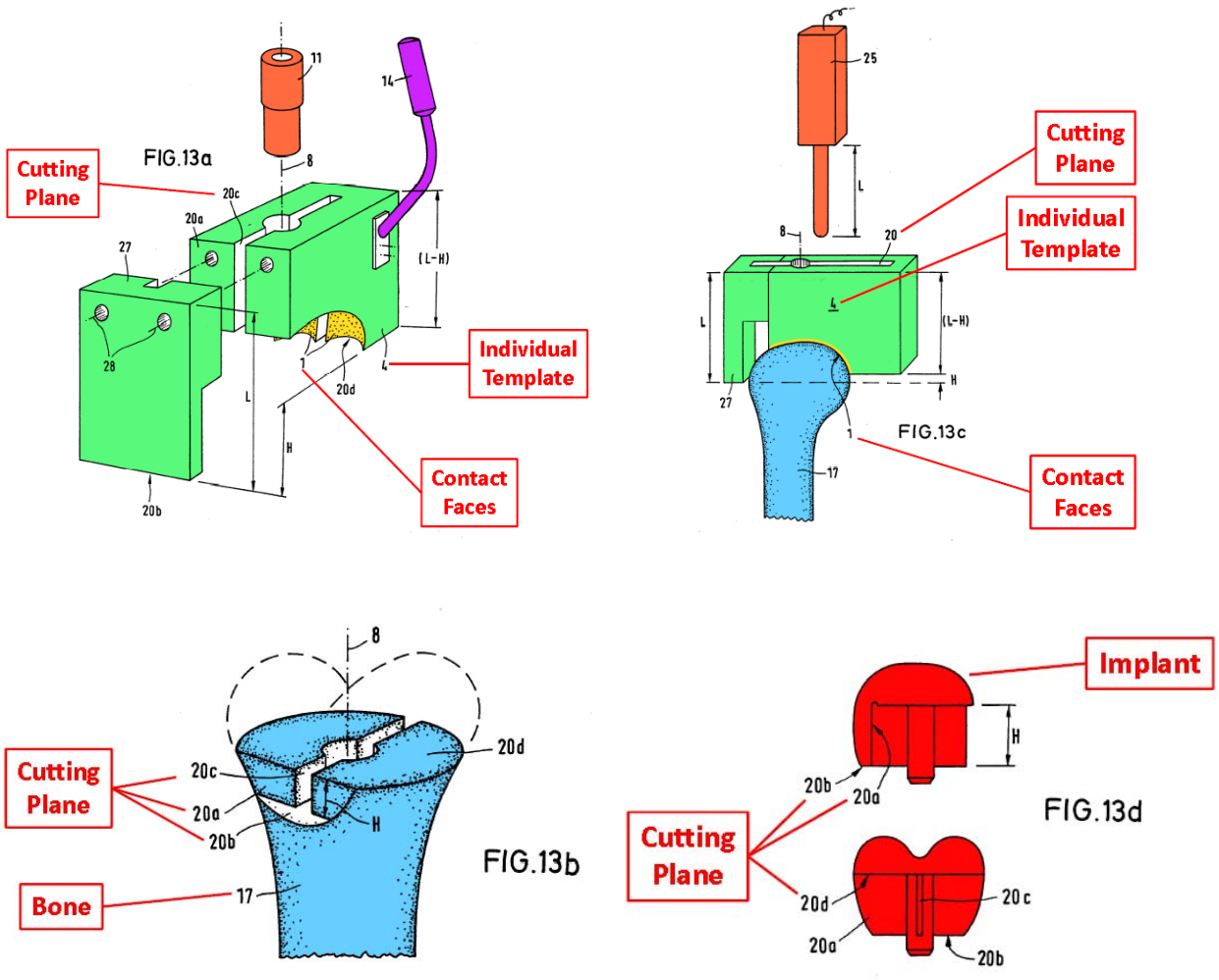
To help ensure that the cuts and drill holes are made accurately—and thus the implant component is implanted in the proper orientation—a surgeon typically

uses cutting guides with holes, slots, or surfaces that guide the surgeon's tools as the surgeon cuts (resects) the bone or drills holes into bone. Ex. 1002 ¶43.

C. Using Imaging to Create Patient-Specific Guides

1. Using Imaging to Create Patient-Specific Instruments With Tool Guides Was Well-Known

In the 1990s, it was known that patient-specific instruments (sometimes referred to as "blocks" or "cutting guides") with tool guides could be created based on MRI and/or CT data of a patient's joint. Ex. 1002 ¶55. For example, Radermacher (1993) described using MRI and/or CT data to create an "individual template" for guiding surgical tools during surgery. 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) for seating an implant (Fig. 13d):



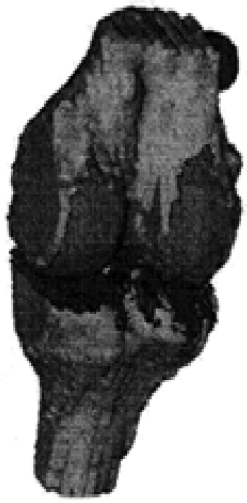
Id. at 30, Fig. 13b.

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

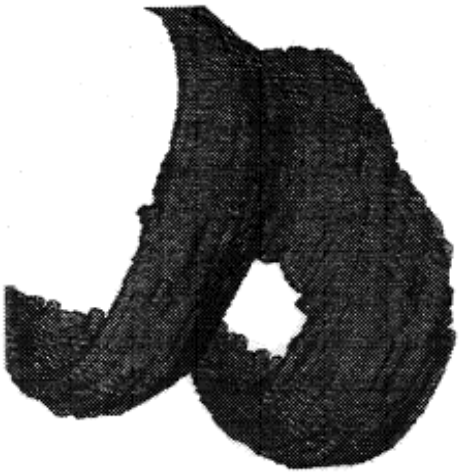
It was well-known for years prior to 2006 (and 2001) that the contour of a patient's cartilage surface could be determined through MRI and CT images. Ex. 1002 ¶¶46-47. Indeed, the '827 patent admits that "imaging techniques suitable for measuring thickness and/or curvature (e.g., of cartilage and/or bone) or size of areas of diseased cartilage or cartilage loss" were known in the art, and included

MRI and CT. Ex. 1001, 32:1-14. The '827 patent admits that MRI and CT could be used to image "other anatomical structures," which would include osteophytes. *Id.*, 65:58-66:28; 73:25-50; 83:65-84:7. The patent further admits that the 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.*, 30:34-52.

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



Id., Fig. 18C (cropped). Moreover, Alexander disclosed virtually the same "cartilage image" as in the '827 patent:



Alexander (Ex. 1004, Fig. 19)

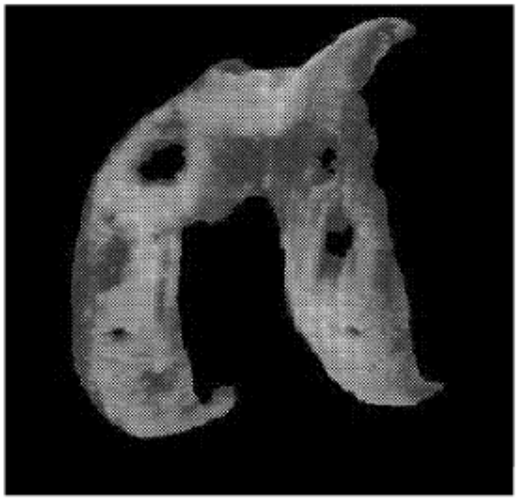


FIG. 2

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

In fact, the '827 patent relies on Alexander's prior art method of determining the shape of the bone and/or cartilage surfaces to generate the claimed patient-specific instrument. Ex. 1001, 32:1-33:3 (citing WO 02/22014 (Ex. 1016), which is a later publication of Ex. 1004).

Many other prior art references also described using MRI to image the cartilage surface. Ex. 1013, 2:8-17 (MRI "makes possible an especially sharp definition of the joint contour by representing the cartilaginous tissue and other soft parts of the damaged knee joints"); *see generally* Ex. 1014 (articular cartilage shape and thickness can be determined using MRI); Ex. 1005, 22:6-9 (MRI provides contour plots of articular cartilage).

The prior art also confirmed that MRI or CT scans could be used to obtain information about osteophytes. Ex. 1004, 39:22-24 (bone may be imaged similar to cartilage), Figs. 10A-C, 12A-B; Ex. 1006, 9:1-6 (CT scan provides three-dimensional contour of bone); Ex. 1067 at S53 (MRI "can provide interesting information with regard to the evolution of osteophytes"); Ex. 1066 at 703, 705-706, Fig. 1; Ex. 1068 at 183-86 ("Osteophytes are also well delineated with MRI[.]"); Ex. 1069 at 123-24. Petitioner's expert confirms that it was known that MRI and/or CT data provided information about a patient's cartilage and any osteophytes. Ex. 1002 ¶¶46-49.

IV. THE '827 PATENT

A. Overview

The '827 patent describes obtaining images of the joint that "define the articular and/or bone surface and shape" (Ex. 1001, 70:33-35), but admits that those images may be "conventional" x-rays, MRI, CT scans, ultrasound, or other technologies, which were "explained fully in the literature." *Id.*, 30:34-52, 32:1-33:3.

The patent describes using the images to create a cutting guide having a patient-specific surface that is a "mirror image" of the patient's joint surface, e.g., the surface of the device "match[es] all or portions of the articular cartilage,

subchondral bone and/or other bone surface and shape." *Id.*, 70:40-43, 70:35-40, 96:41-43, 96:46-48, 8:63-67, 97:6-9, 118:31-38.

The patent also states that the patient-specific surface may engage an osteophyte (Fig. 33), or include a recess to avoid the osteophyte (Fig. 32). *Id.*, 83:45-84:7, 73:25-50.

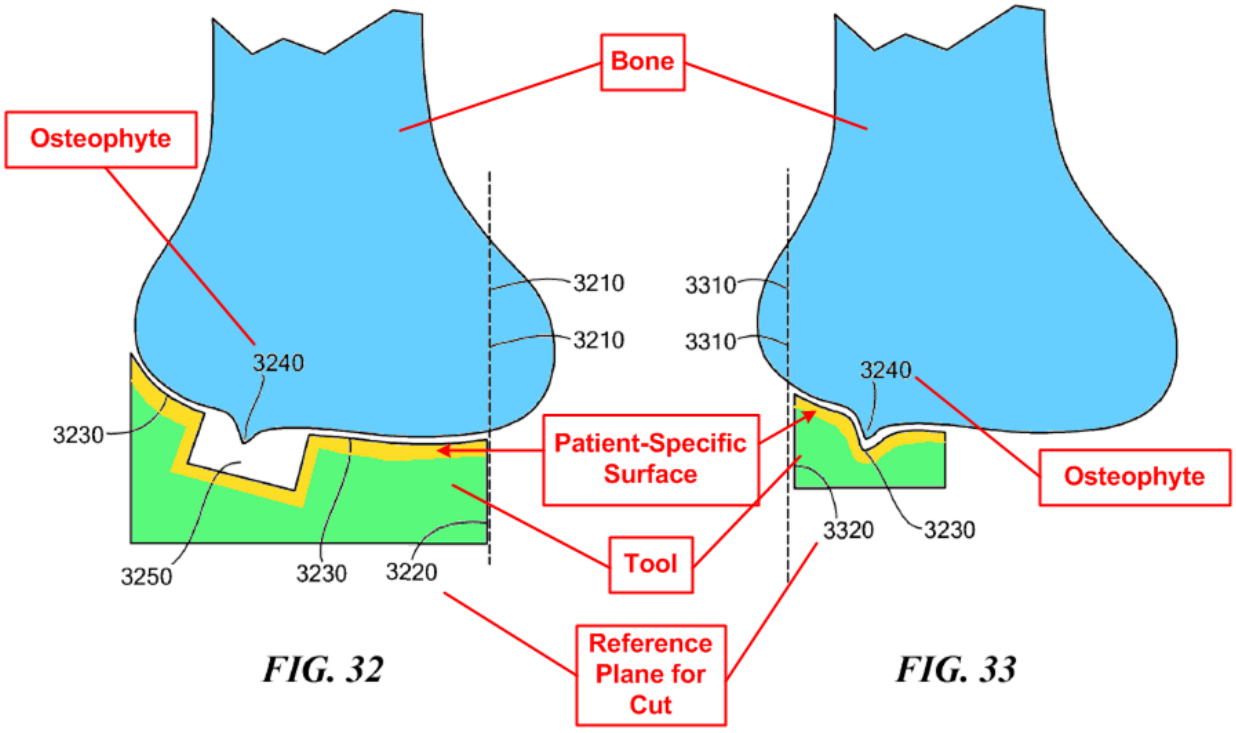


FIG. 32 *FIG. 33*

The patent also explains that the bone may be resected (e.g., along line 1958) "perpendicular to the mechanical axis 1910." *Id.*, 69:23-33.

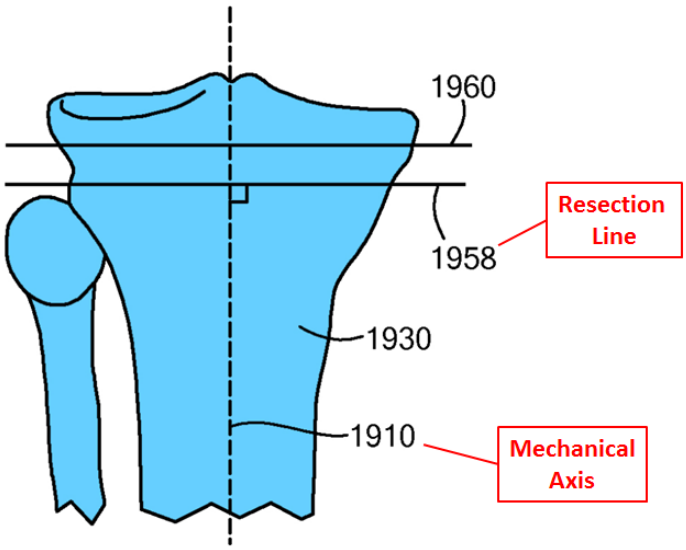


FIG. 21B

Id., Fig. 21B. The patent admits that it was well-known that a patient's anatomical and mechanical axes could be determined using conventional imaging (x-ray, MRI, CT). *Id.*, 34:42-39:45.

The instrument can include apertures, slots and/or holes to accommodate surgical tools such as drills or saws. *Id.*, 70:43-46.

B. Prosecution History

During prosecution, the Examiner rejected most of the claims as anticipated by U.S. Patent No. 6,712,856 to Carignan or as obvious over Carignan in view of other references. Ex. 1017 at 122-26. ConforMIS amended the independent claims to recite that the patient-specific surface references the osteophyte and the claims were allowed. *Id*. at 16, 48.

Although the references relied on herein (Radermacher, Alexander, Fell, and Woolson) were submitted during prosecution (*id.* at 153, 155, 163-64), they were among over 600 patent references and over 170 non-patent references submitted to the Examiner. Ex. 1001 at 1-9. These references were never applied by the Examiner.

C. Priority

The '827 patent was filed on November 22, 2011. The '827 patent cannot have an effective priority date earlier than March 23, 2006, which is the date of the first disclosure of osteophytes in the context of patient-specific instruments.[3] Ex. 1002 ¶74. Accordingly, all references relied on herein are prior art under § 102(b) because each reference published more than a year before March 23, 2006. Even if the '827 patent were entitled to an earlier priority date, which it is not, each of the references relied on herein would still be prior art under §§ 102(a), (b) or (e).

D. Level of Ordinary Skill in the Art

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

[3] Petitioner does not concede that the '827 patent is entitled to this priority date.

has at least three years of experience learning from these doctors about the use of such devices in joint replacement surgeries. Ex. 1002 ¶¶29-32.

V. CLAIM CONSTRUCTION

For purposes of this review, the claims are given their broadest reasonable interpretation in light of the specification. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016); 37 C.F.R. § 42.100(b). Because the claim construction standard at the Patent Office is different than that used during a U.S. District Court litigation, *see In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364, 1369 (Fed. Cir. 2004), MPEP § 2111, Petitioner reserves the right to argue a different claim construction in litigation.

A. "References the Osteophyte"

The claims of the '827 patent recite that the patient-specific surface "references the osteophyte." The specification does not define the term "reference." However, the specification describes a patient-specific surface that engages or avoids an osteophyte. Ex. 1001, 73:30-55; 83:50-84:13; Figs. 32-33. During co-pending litigation, ConforMIS has asserted that "references the osteophyte" means "takes the osteophyte into account." Ex. 1096 at 27-30. ConforMIS contends that, under this construction, a surface "references an osteophyte" if it "conforms to," "accommodates," or "avoids" the osteophyte. *Id.* The broadest reasonable interpretation must include the construction advanced by

ConforMIS in litigation, where a narrower claim construction standard applies. Thus, for this proceeding, the phrase "references the osteophyte" includes at least a patient-specific surface that engages or avoids an osteophyte. Ex. 1002 ¶76.

VI. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner requests that the Board cancel Claims 1-25, 28, 29, and 32-46 of the '827 patent as unpatenable under 35 U.S.C. §103 for the following reasons:

Ground 1. Claims 1-13, 32, 33, 38, and 44-46 are unpatentable as obvious over Radermacher in combination with Alexander.

Ground 2. Claims 14-19, 22-25, 28, 29, 34-37, and 39-43 are unpatentable as obvious over Radermacher in combination with Alexander and Woolson.

Ground 3. Claims 20 and 21are unpatentable as obvious over Radermacher in combination with Alexander, Woolson, and Hofmann.

Ground 4. Claims 1-13, 32, 33, 38, and 44-46 are unpatentable as obvious over Radermacher in combination with Fell.

Ground 5. Claims 14-19, 22-25, 28, 29, 34-37, and 39-43 are unpatentable as obvious over Radermacher in combination with Fell and Woolson.

Ground 6. Claims 20 and 21 are unpatentable as obvious over Radermacher in combination with Fell, Woolson, and Hofmann.

Collectively, Grounds 1-3 (collectively) address all challenged claims, as do Grounds 4-6 (collectively). Grounds 4-6 are not redundant of Grounds 1-3 because

Grounds 4-6 rely on a different secondary reference (Fell), involving a different but related technology and providing a different motivation to combine. Ex. 1002 ¶¶193-96.

This Petition is supported by the Declaration of Jay D. Mabrey, M.D. Ex. 1002. Dr. Mabrey is the Chief of the Department of Orthopaedics at Baylor University Medical Center in Dallas, Texas, and is also a Professor of Surgery at Texas A&M Health Science Center College of Medicine. *Id.* ¶8.

A. Status of References as Prior Art

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

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

VII. SPECIFIC PROPOSED GROUNDS FOR REJECTION

A. Ground 1: Claims 1-13, 32, 33, 38, and 44-46 Are Unpatentable Under § 103(a) Over Radermacher in Combination With Alexander

1. Claim 1

Claim 1 recites a patient-specific surgical instrument comprising a patient-specific surface and a tool guide. The patient-specific surface includes cartilage information derived from image data of the patient's joint and references an osteophyte. Radermacher, either alone or in combination with Alexander, renders this claim obvious.

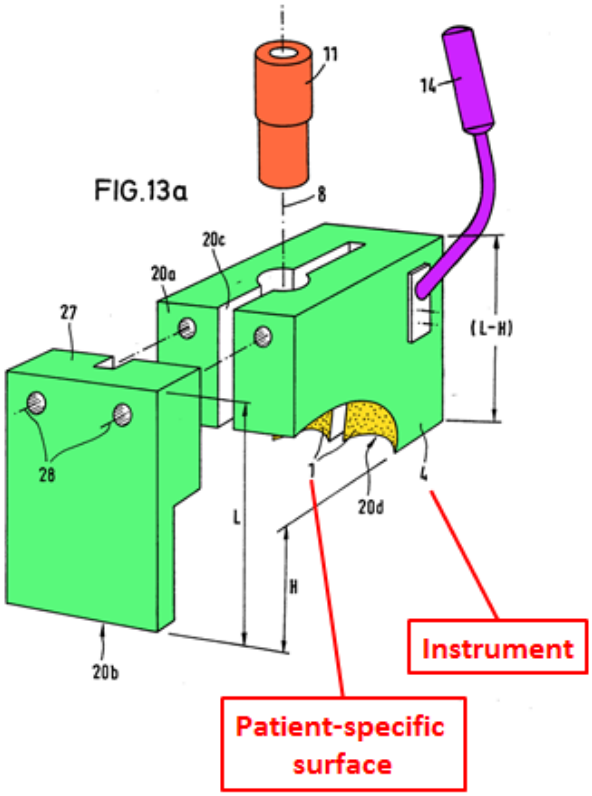
a. Patient-Specific Surgical Instrument Having a Patient-Specific Surface

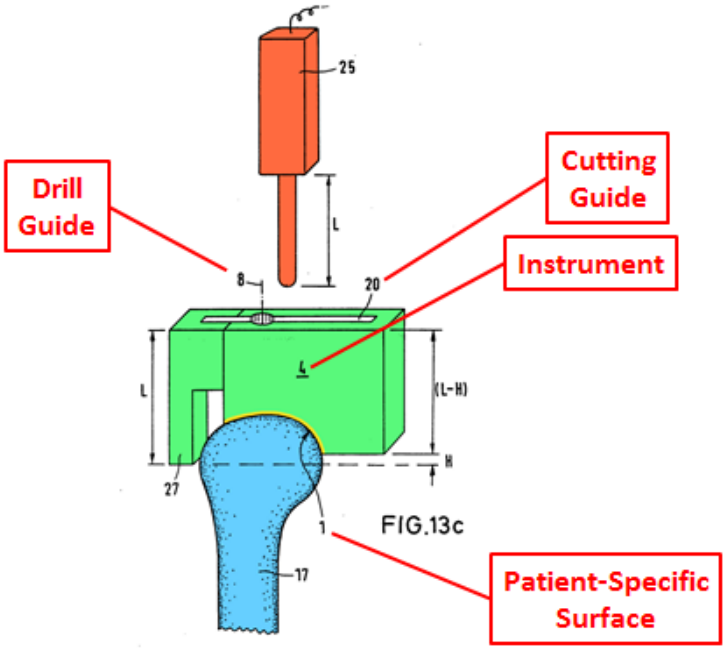
Radermacher discloses an instrument comprising a patient-specific surface for engaging a corresponding portion of a diseased or damaged joint. MRI and/or CT scans are used to create a three-dimensional reconstruction of a patient's joint, which is used to create an instrument ("individual template") having a patient-specific surface (contact faces 1):

> 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 (emphasis added), 12, 22; *id.* at 10 (the surface of the osseous structure is "copied" to provide "mating engagement."), Fig. 18. Thus, Radermacher discloses an instrument having a patient-specific surface for engaging a diseased joint:





Ex. 1003, Figs. 13a, c. ConforMIS admitted in co-pending litigation that Radermacher discloses a "custom" instrument "with a tissue contacting surface that matches and fits" the joint surface. Ex. 1024 at 21, 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 joint. "Information" includes, for example, measurements (e.g., size, shape, thickness, curvature, etc.). Ex. 1001, 25:7-15, 45:25-28, 98:55-57. This limitation is disclosed by Radermacher or would have been obvious over Radermacher given the knowledge of a POSITA in March, 2006 (or 2001). However, Petitioner

understands that ConforMIS may argue that this limitation is not disclosed by or obvious in view of Radermacher alone. Thus, Petitioner also relies on Alexander.

i. Radermacher

Radermacher discloses that the patient-specific surface includes cartilage information 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); Ex. 1002 ¶93. The "natural (i.e. not pre-treated) surface" of an articulating joint such as the knee would include the articular cartilage. Ex. 1002 ¶¶93, 111-13. Thus, Radermacher discloses the same "patient-specific surface" described in the '827 patent, namely one that is a negative of 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 types of imaging used and the surgical process employed further supports this understanding. *Id.* ¶94. Radermacher discloses using CT and/or MRI data to customize the patient-specific surface and, as the '827 patent admits, these imaging techniques provided cartilage information. Ex. 1001, 30:34-52, 32:1-33:3, 70:33-35; Ex. 1002 ¶94. Moreover, Radermacher describes the steps necessary to use the individual template and does not describe removing cartilage. Ex. 1003 at 30. If Radermacher's individual template was

configured to match only the bone—but not cartilage—Radermacher would have described additional surgical steps in which the bone was pre-treated, i.e., cartilage was removed by the surgeon to prepare the site for the individual template. Ex. 1002 ¶95. 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 states that the template is positioned without further positioning work. *Id.* at 15. Thus, a POSITA would have understood that when Radermacher discloses that the template is "set onto the bone" (*id.* at 30), this means that the template is set onto the un-treated bone, i.e., on top of any remaining cartilage and any exposed subchondral bone. Ex. 1002 ¶95.

Accordingly, Radermacher discloses that the patient-specific surface includes cartilage information. *Id*. ¶97-99.

ii. The Knowledge of a POSITA

Radermacher disclosed using MRI to determine the shape of the patient's joint. Ex. 1003 at 10-12. The '827 patent admits that MRI was conventional and used by POSITAs to determine the shape of a patient's cartilage. Ex. 1001, 30:34-52, 32:1-33:3. Petitioner's expert and the prior art further confirm that this was well-known. Ex. 1002 ¶97; Ex. 1004, 14:16-18; Ex. 1013, 2:8-17; Ex. 1014; Ex. 1005, 22:6-9. Accordingly, it would have been obvious to a POSITA to use MRI (as taught by Radermacher) to obtain cartilage information (as commonly known)

and to make the patient-specific surface match the patient's cartilage. Ex. 1002 ¶97.

A POSITA would have been motivated to match Radermacher's patient-specific surface to the cartilage rather than underlying subchondral bone for several reasons. *Id.* ¶98. First, the cartilage surface and the subchondral bone surface are the only two surfaces 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 simply reflects a choice from a finite number of identified, predictable solutions with a reasonable expectation of success. *Id.*; *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402-403 (2007). Second, as between the two surfaces, a POSITA would have been motivated to design the patient-specific surface to match the cartilage surface because it would simplify the surgery; the cartilage would not have to be removed for the template to precisely fit on the femur or tibia. Ex. 1002 ¶98. Third, Radermacher teaches that the contact faces match the "natural (i.e. not pre-treated) surface." *Id.* Fourth, a POSITA would understand that matching the cartilage would result in a template that has "one spatially uniquely defined position," reduces surgical time, and increases accuracy, as Radermacher teaches. *Id.*

Thus, it would have been obvious to match Radermacher's patient-specific surface to articular cartilage, and therefore include cartilage information derived from the image data. *Id.* ¶¶98-100.

iii. Alexander

Even if Radermacher alone did not disclose or render obvious that the patient-specific surface includes cartilage information, it would have been obvious in view of Alexander. Ex. 1002 ¶¶101-10.

The '827 patent admits that cartilage information can be obtained using the methods described in WO 02/22014 ("WO '014"). Ex. 1001, 32:1-15, 32:55-59. WO '014 (Ex. 1016) published on March 21, 2002. Another application with virtually the same disclosure published nearly two years earlier, on June 22, 2000. The earlier publication (Alexander, Ex. 1004) is relied on herein.

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

Alexander discloses using MRI to create a three-dimensional reconstruction of the femoral and tibial bones (gray) and cartilage (black):

FIG._18C

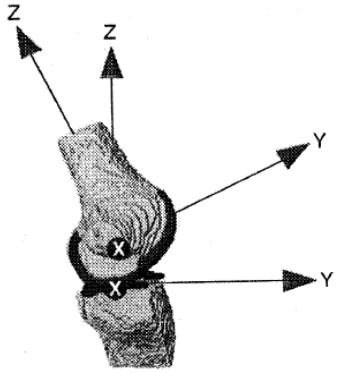


FIG._18H

Id., Figs. 18C-I, 61:19-25. Alexander describes reconstructing the articular cartilage using a thickness map, just as described in the '827 patent:

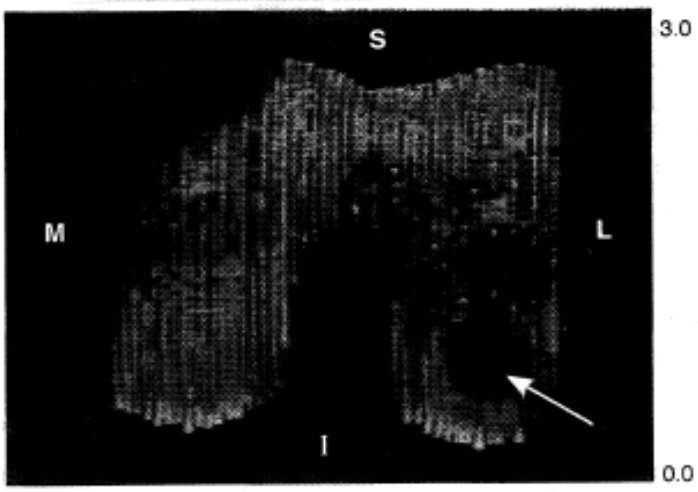


FIG._22B

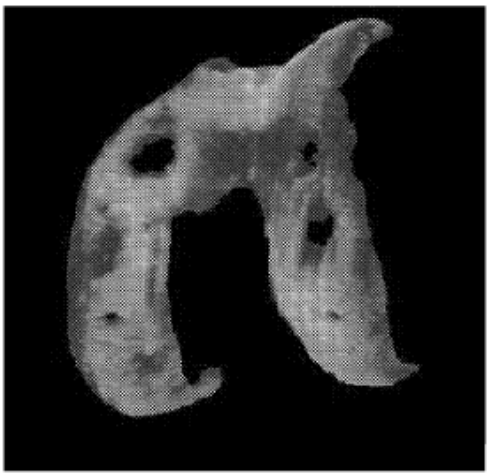


FIG. 2

Alexander (Ex. 1004, Fig. 22B) '827 Patent (Ex. 1001, Fig. 2)

It would have been obvious to combine the teachings of Radermacher and Alexander to create an individual template that matches the patient's cartilage surface, and therefore includes cartilage information, for several reasons. Ex. 1002 ¶¶107-10. First, both references relate to methods of treating diseased or damaged

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

Third, as described above, the cartilage surface and the subchondral bone surface are the only two surfaces to which Radermacher's custom template could be matched. Given Alexander's disclosure that the imaging techniques disclosed in Radermacher 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 simply a design choice. *Id.* Fourth, as described above, a POSITA would have been motivated to match the cartilage surface because it would simplify the surgery, reduce surgery time, improve patient safety, and be consistent with Radermacher's goals. *Id.*; Ex. 1003 at Abstract, 3-5, 9. Fifth, the modification would merely: (a) require the combination of one known element (Alexander's MRI data of cartilage surface) with another known element (Radermacher's MRI data of joint surface) to obtain a predictable result (a device tailored to the patient's cartilage surface); and (b) represent a choice from a finite number of identified, predictable solutions (imaging the bone surface and/or the cartilage surface), with a reasonable expectation of success. Ex. 1002 ¶110.

c. The Corresponding Portion of the Diseased or Damaged Joint Includes an Osteophyte

This limitation merely refers to the condition of the patient's joint. *Id.* ¶111. Osteophytes were widely-known and are present in most patients undergoing knee replacement surgery. *Id.*

d. The Patient-Specific Surface References the Osteophyte

Claim 1 specifies that the patient-specific surface "references the osteophyte" of the joint. Under ConforMIS's construction, a patient-specific surface "references an osteophyte" if it accounts for the osteophyte, for example, by engaging, accommodating, or avoiding the osteophyte.

i. Radermacher

Radermacher teaches that the patient-specific surface copies the joint's "natural (i.e. not pre-treated) surface." Ex. 1003 at 12. As recognized in the '827 patent, a patient's articular joint surface may naturally include osteophytes. Ex. 1001, Figs. 32-33, 83:56-84:7; 13:22-24; 73:25-27; 93:53-94:2; Ex. 1002 ¶¶115-17. Indeed, osteophytes are present in most patients. Ex. 1002 ¶111. Thus, Radermacher's template would inherently have a portion that engages an osteophyte, if present, and a POSITA would expect this to occur more than 90% of the time. *Id.* ¶¶111-13. Radermacher therefore discloses this limitation or it would

have been obvious to a POSITA in view of Radermacher. *Id.* Radermacher also discloses embodiments that avoid the osteophyte, as discussed for Claims 2 and 3.

ii. The Knowledge of a POSITA

The '827 patent admits that POSITAs knew that "conventional" imaging techniques provided information concerning osteophytes. Ex. 1001, 30:34-52, 32:1-33:3, 65:55-57, 65:58-66:28, 73:25-50, 83:65-84:7. Petitioner's expert (Ex. 1002 ¶115) and many prior art references (Ex. 1067 at S53, Ex. 1066 at 703-06, Fig. 1; Ex. 1068 at 183-86; Ex. 1069 at 123-24) confirm this.

In view of this knowledge, a POSITA would have been motivated to configure at least a portion of Radermacher's template to engage (and thereby reference) an osteophyte because: (1) Radermacher teaches that the patient-specific surface is a negative of the "natural (i.e. not pre-treated) surface" (Ex. 1003 at 12); (2) it would aid in alignment because the unique structure of the osteophyte would help ensure that the template was placed in the proper position (*id.* at 10); and (3) it would eliminate the need to pre-treat the joint to remove the osteophyte, thus reducing surgical time and improving patient safety. Ex. 1002 ¶116.

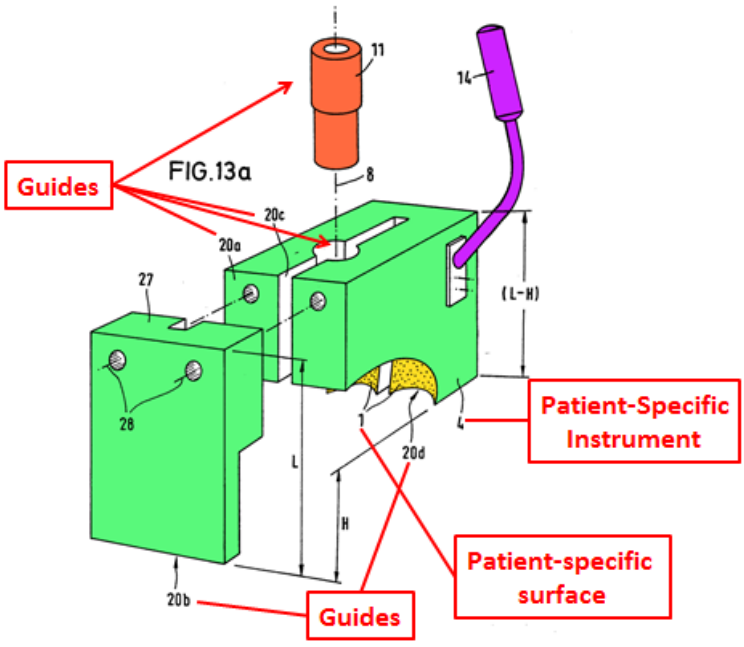
Accordingly, even if Radermacher did not disclose that the patient-specific surface could engage, and therefore "reference," an osteophyte, it would have been obvious in view of Radermacher. *Id.* ¶117.

iii. Alexander

It also would have been obvious to a POSITA that Radermacher's patient-specific surface would reference an osteophyte, if present, in view of Alexander. Alexander uses MRI to create a three-dimensional model of the bone and cartilage surfaces, which would show any osteophytes. Ex. 1004, Figs. 18C-I; Ex. 1002 ¶118. Thus, it would have been obvious that Radermacher's patient-specific surface could engage (and therefore reference) an osteophyte. Ex. 1002 ¶118.

e. Guide to Accommodate a Surgical Tool

Claim 1 recites that the instrument comprises a guide sized and shaped to accommodate a surgical tool. Radermacher discloses such guides. Radermacher, for instance, discloses a block having a drill guide and four cutting guides that define cuts 20a-d:



Ex. 1003 at Fig. 13a; *id.* at 11, 13 ("[A]ny suitable tool guides, particularly drill sleeves, parallel guides, saw templates, … can be provided in/on the basic body of the individual template[.]"). Moreover, ConforMIS admits that Radermacher "discloses that tool guides can be provided in or on the basic body of the template." Ex. 1024 at 21.

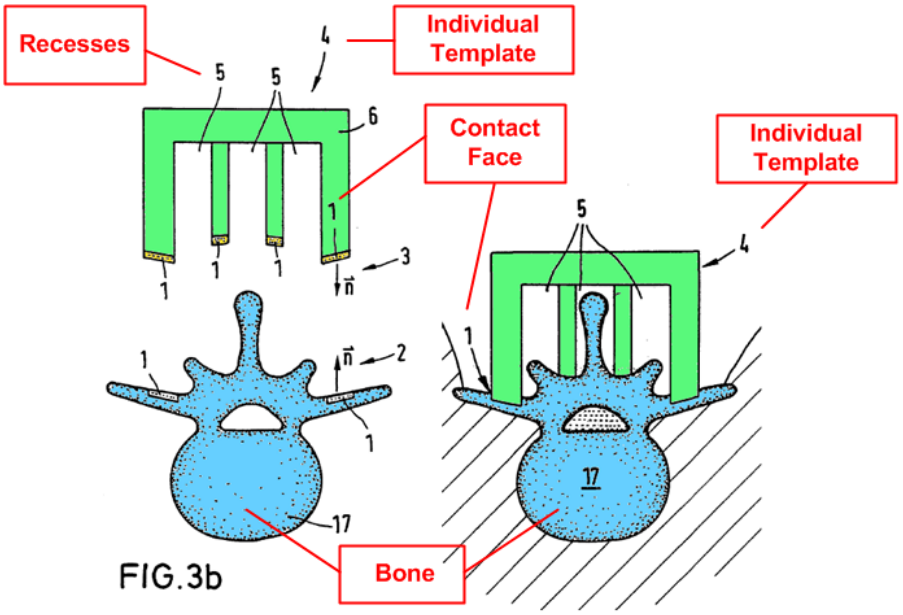
Radermacher further discloses that the guides have a position and orientation relative to the surface to provide a predetermined path for the tool, as recited in Claim 1, because it explains that the location and orientation of the guides are determined and fixed during the preoperative planning. Ex. 1003 at 13 ("These tool guides … will effect a three-dimensional guiding of the treatment tools or measuring devices exactly as provided by the surgical planning."), 25, 11 (cutting, boring, and milling steps, which are "three-dimensionally charted in said

coordinate system fixed relative to the osseous structure, can be clearly defined in or on the individual template in form of guide means"); Ex. 1002 ¶121.

Thus, Claim 1 would have been obvious to a POSITA over Radermacher alone or in combination with Alexander.

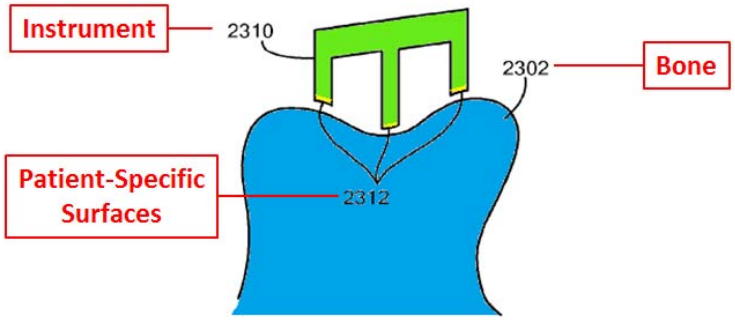
2. Claims 2 and 3

Claims 2 and 3 specify that the patient-specific surface "extends over but [substantially] does not engage" a second osteophyte. These limitations would have been obvious in view of Radermacher, which discloses that the patient-specific surface can be a negative of "a plurality of geometrically non-abutting partial segments of a bone surface." Ex. 1003 at 12. Radermacher further discloses embodiments where the contact faces 1 "can be set directly onto the exposed bone surface … without colliding with other structures in the surgical region." *Id.* at 22. For example, Radermacher discloses a template with a patient-specific surface that extends over but does not engage certain parts of the bone 17:



Id., Fig. 3B, Fig. 4 (excerpt); *id.*, Fig. 5c. Radermacher describes recesses in the patient-specific surface for avoiding certain structures. *Id.* at 22.

In view of this disclosure, a POSITA would have understood that the patient-specific surface could extend over osteophytes and other deformities. Ex. 1002 ¶¶123-24. Indeed, Radermacher's disclosure is virtually identical to an embodiment in the '827 patent:



A POSITA would have been motivated to configure a portion of Radermacher's template to extend over but not engage an osteophyte for several reasons. Ex. 1002 ¶124. First, a POSITA would have understood that only three options exist when designing a patient-specific instrument for a surface that contains a second osteophyte: (1) remove the osteophyte; (2) engage the osteophyte; or (3) avoid the osteophyte. *Id.* Thus, the option to engage or avoid an osteophyte is merely a design choice from a finite number of identified, predictable solutions with a reasonable expectation of success. *Id.*; *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402-403 (2007). Second, as between the choices, a POSITA would have been motivated to make the patient-specific surface extend over and not engage an osteophyte if the shape of the osteophyte was too complex to mimic or would cause other alignment problems, or if the imaging did not provide sufficient detail about the osteophyte to accurately generate a template. Ex. 1002 ¶124.

Accordingly, designing a patient-specific surface that "extends over but [substantially] does not engage" a second osteophyte would have been obvious. Ex. 1002 ¶¶123-24.

3. Claims 4 and 5

Claims 4 and 5 specify that the patient-specific surface is configured to substantially engage the osteophyte or a portion thereof. Radermacher teaches that

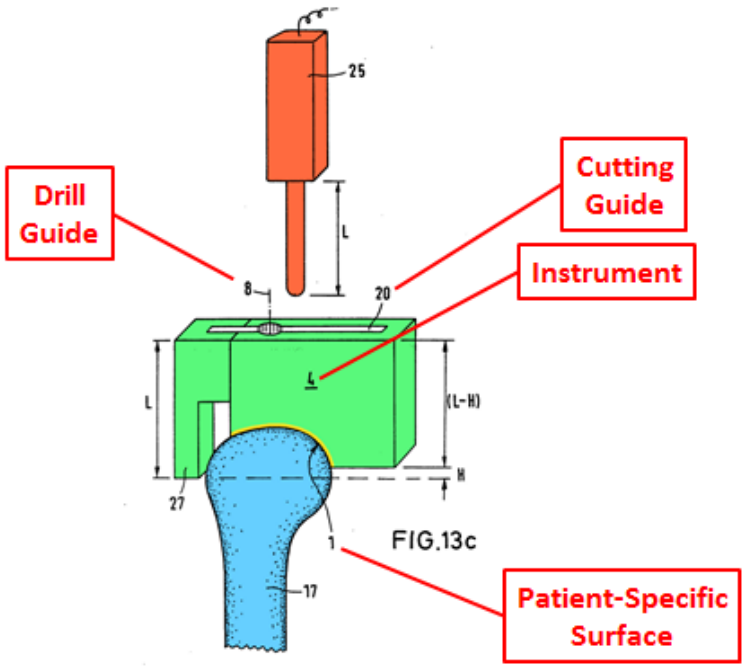
the patient-specific surface copies the "natural (i.e. not pre-treated) surface" "so that the individual template can be set onto the osseous structure in a clearly defined position and ***with mating-engagement***." Ex. 1003 at 12, 10 (emphasis added). Thus, Radermacher's patient-specific surface would engage (and therefore substantially engage at least a portion of) any osteophyte that is present. Ex. 1002 ¶¶125-26. This would occur in the vast majority of cases. *Id.* ¶111.

A POSITA would have been motivated to configure Radermacher's patient-specific surface to substantially engage at least a portion of an osteophyte that is present for the same reasons discussed above, namely it would: (a) be consistent with Radermacher's teaching; (b) aid in alignment; and (c) simplify surgery by eliminating surgical steps. *Id.* ¶125-26. Therefore, designing a patient-specific surface that engages an osteophyte, or a portion thereof, would have been obvious to a POSITA. *Id.*

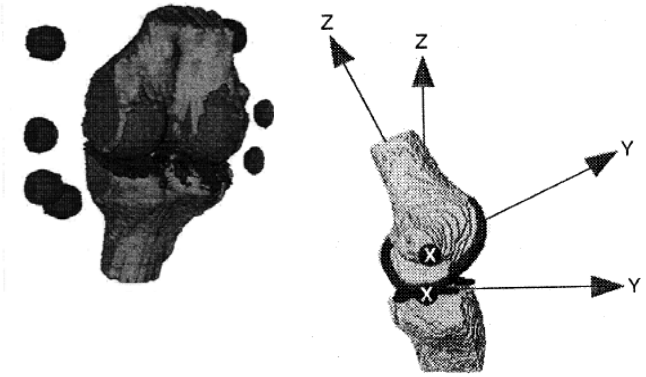
4. Claims 6-13, 32, 33, 38, and 44-46

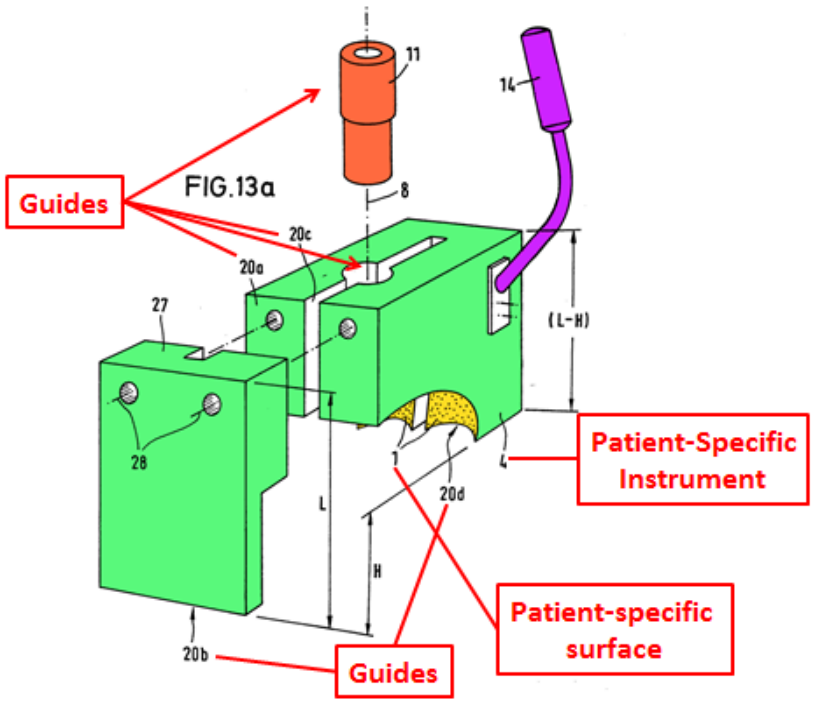
Claims 6-13, 32, 33, 38, and 44-46 recite trivial limitations which, as shown in the claim chart below, Radermacher discloses. The claim chart below further supports **Ground 1**.

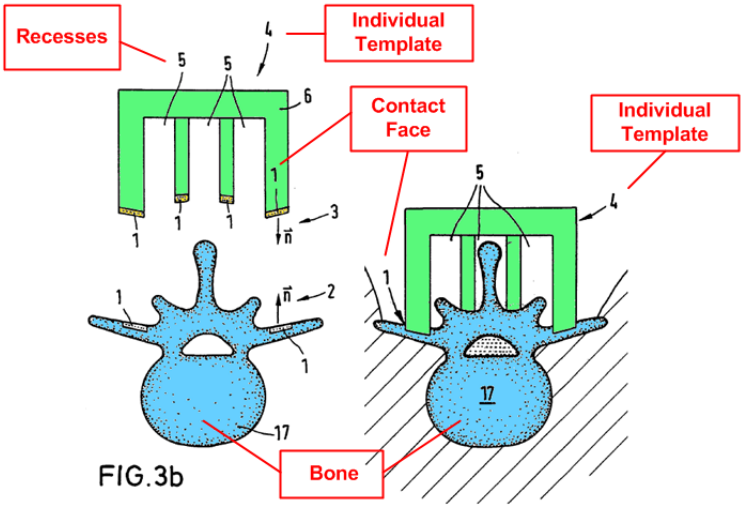
No.	Claim Limitation	Exemplary Disclosure in Prior Art
1.	A patient-specific surgical instrument for use in surgically repairing a diseased or damaged joint of a patient, the instrument comprising:	**Radermacher** discloses a patient-specific surgical instrument ("individual template") for repairing hip and knee joints. Ex. 1003 at 1, 9, 25, 30.
	[a] a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint,	**Radermacher** discloses an "individual template" having a patient-specific surface ("contact faces") created based on a patient's MRI/CT data. Ex. 1003 at 10 ("[T]here is used a split-field device (*e.g.* a computer or a nuclear spin tomograph) by which split images are produced … , and from these split images, ***data regarding the three-dimensional shape of the osseous structure and the surface thereof are obtained.*** In the preoperative planning phase, these data are used as a basis for defining … a ***rigid individual template which … copies the surface of the osseous structure*** in such a manner that the individual template can be intraoperatively set onto these – then freely exposed – contact faces or points in exclusively one clearly defined position[.]" (emphases added)), 21-22 ("the defined contact faces 1 are used (as a negative, a 'cast', 'reproduction') for a basis for the individual template 4"), 30, Fig. 18. The patient-specific surface is for engaging the joint:

No.	Claim Limitation	Exemplary Disclosure in Prior Art
		 Ex. 1003 at 30, Fig. 13c. Ex. 1002 ¶¶90-91. **ConforMIS** admits that Radermacher's template is "custom formed" for each patient. Ex. 1024 at 57, 21.
	[b] the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint, wherein the corresponding portion of the diseased or damaged joint includes an osteophyte,	*See* Claim 1[a]. **Radermacher** discloses using MRI to generate a "three-dimensional negative mold of parts of the individual ***natural (i.e., not pre-treated) surface*** of the osseous structure." Ex. 1003 at 12 (emphasis added). The natural, not pre-treated surface in a knee joint would include cartilage. Ex. 1002 ¶¶92-100. Radermacher discloses that the images are obtained by CT or MRI. Ex. 1003 at 10-12, 21-22, Figs. 18-19. **The '827 patent** admits that obtaining cartilage information from image data was within the knowledge

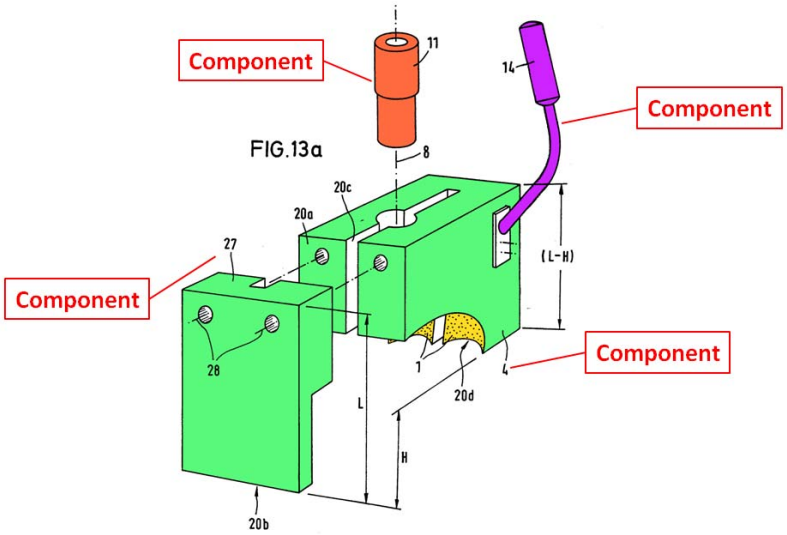
No.	Claim Limitation	Exemplary Disclosure in Prior Art
		of a POSITA. Ex. 1001, 30:34-52; 32:1-33:3; 65:55-57; 65:58-66:28; 70:33-35. **Alexander** discloses using MRI imaging to obtain cartilage information. Ex. 1004, Abstract, 2:5-29, 11:31-12:16 ("[T]he first step 10 represents obtaining an image of the cartilage itself."); *id.*, 14:16-32, 15:16-26, 26:20-27:26; *id.*, 61:19-25; Figs. 18-19. The data may be used to guide the choice of therapy, including joint replacement surgery. *Id.*, 42:10-16.  FIG._18C Ex. 1002 ¶101-10. **The '827 patent** recognizes that a patient's natural joint surface may include osteophytes. Ex. 1001, 73:25-27. Osteophytes were well-known. Ex. 1002 ¶111 (over 90% of knee replacement patients have osteophytes).

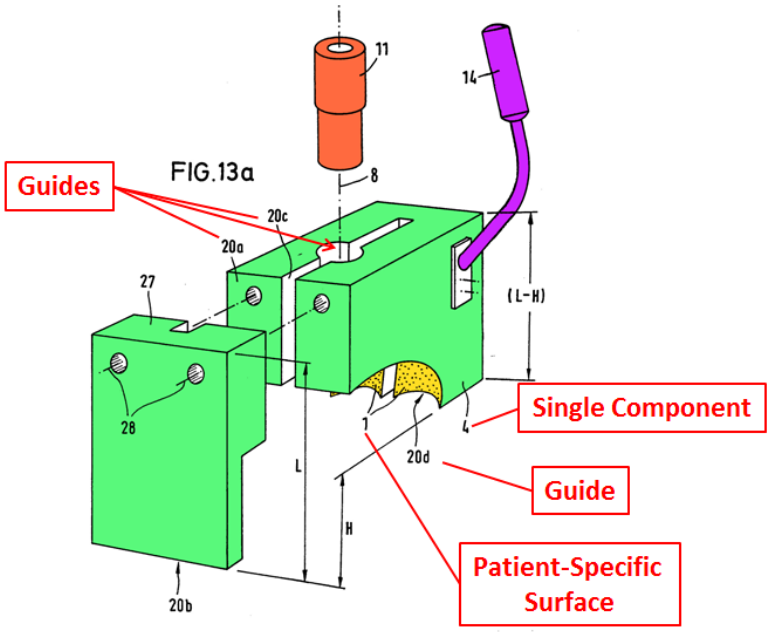
	[c] wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint; and	*See* Claim 1[a], 1[b]. Radermacher's contact face is a negative of, and engages, the "natural (i.e., not pre-treated) surface of the osseous structure[.]" Ex. 1003 at 12, 10, 21-22. Such a surface would include osteophytes. Ex. 1002 ¶¶112-17. *See* Claims 2 and 4. **Alexander** discloses imaging bones and cartilage, which would provide information regarding osteophytes: FIG._18C  FIG._18H Ex. 1004, Figs. 18C-I; *see id.*, 61:19-25, 23:31-33, 39:22-24, 26:20-28, Figs. 10A-C, 12A-B. Ex. 1002 ¶¶118.

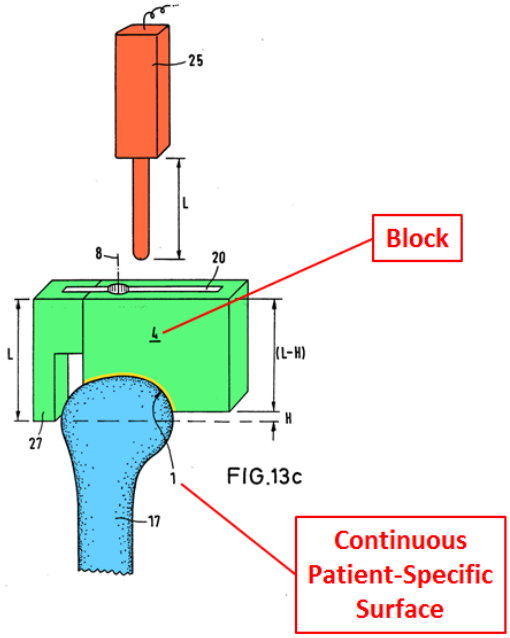
	[d] a guide sized and shaped to accommodate a surgical tool, wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool.	**Radermacher** discloses guides sized and shaped to accommodate drills and saws. Ex. 1003 at 30; Fig. 18 (saws are guided and positioned); *id.* at 11, 13 ("any suitable tool guides," including "saw templates," can be provided "in/on the basic body of the individual template").  Ex. 1002 ¶¶119-22. Radermacher's guides have positions and orientations relative to the patient-specific surface to provide predetermined paths for the surgical tools. Ex. 1003 at Fig. 13a-c; *id.* at 13, 25, 11. Ex. 1002 ¶¶119-22. **ConforMIS** admits that "Radermacher further discloses that tool guides can be provided in or on the basic body of the template." Ex. 1024 at 21.

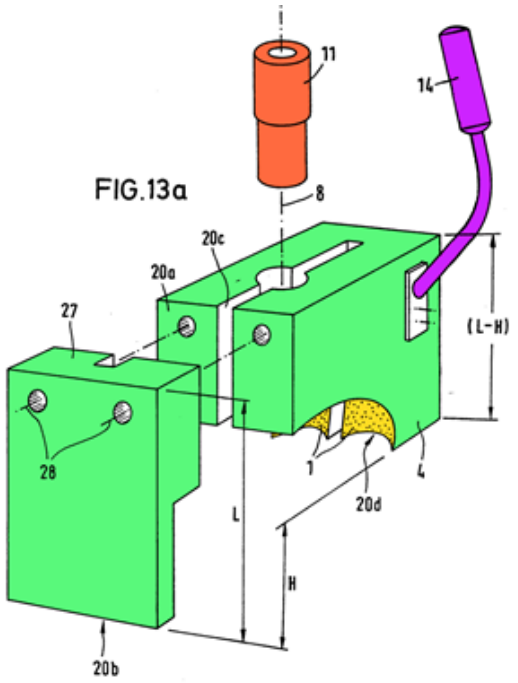
2. and 3.	The surgical instrument of claim 1, wherein the patient-specific surgical instrument is configured such that the patient-specific surface extends over but [substantially] does not engage a second osteophyte of the diseased or damaged joint when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.	*See* Claim 1. In addition: **Radermacher** discloses that the patient-specific surface can be a negative of "a cohesive region or a ***plurality of geometrically non-abutting partial segments of a bone surface*** and is constructed in a cohesive, mechanically rigid basic body (the individual template)." Ex. 1003 at 12 (emphasis added). Radermacher further discloses an embodiment where the contact faces 1 "can be set directly onto the exposed bone surface … without colliding with other structures in the surgical region." *Id.* at 22.  *Id.* at Fig. 3B, Fig. 4 (excerpt); Fig. 5c. Radermacher discloses recesses 5 "for structures in the vicinity of the contact faces 1." *Id.* at 22. Ex. 1002 ¶¶114, 123-24.

4. and 5.	The surgical instrument of claim 1, wherein the patient-specific surface is configured to substantially engage [a portion of] the osteophyte.	**Radermacher** discloses that the contact faces of the template "can be set onto the osseous structure in a clearly defined position and ***with mating-engagement***." Ex. 1003 at 12 (emphasis added), 10. Thus, Radermacher's patient-specific surface would engage any osteophyte (and therefore a portion thereof) that is present. Ex. 1002 ¶125-26.
6, 7, 8.	The surgical instrument of claim 1, wherein the surgical tool is a [drill/saw/reamer].	**Radermacher** discloses that the tool may be a drill (Ex. 1003 at 17) or saw (*id.* at 13). *Id.*, Figs. 1-5; *id.* at 30 (cutting planes may be "sawed"). A POSITA would understand this disclosure to enable the use of a reamer as well. Ex. 1002 ¶127.
9.	The surgical instrument of claim 1, wherein the surgical tool is a k-wire, curette or screw.	*See* Claims 6-8. **Radermacher** discloses embodiments where the guides may be for a screw. Ex. 1003 at 17, Figs. 1-5 (guiding a drill for application of bores for pedicle-screws into the vertebra.), 20. Radermacher also discloses that "[a]ccording to Fig. 16a, the individual template 4 is set with the contact face 1a onto the femur bone 17a and is fixed by two wires." *Id.* at 35.

10.	The surgical instrument of claim 1, wherein the instrument is comprised of multiple components.	**Radermacher** discloses an instrument having multiple components, for example, a template, a drill sleeve, and an optional template 27. Ex. 1003 at 30, 13, 22-23, 25, Fig.13a; Figs. 10a-b, 11b.  Radermacher discloses that "any suitable tool guides" (second components) can be provided "on" the template and can be "coupled (releasably or non-releasably) in a mechanically rigid manner." *Id.* at 13. Ex. 1002 ¶128-29.

11.	The surgical instrument of claim 1, wherein the patient-specific surface and the guide are contained in a single component.	**Radermacher:** "[T]ool guides … can be provided in … the basic body of the individual template." Ex. 1003 at 13. Fig. 13c shows a single component having a patient-specific surface and a guide (e.g., 20c, 8, 20a or 20d).  Ex. 1002 ¶130.

12.	The surgical instrument of claim 1, wherein the patient-specific surface is a continuous surface.	**Radermacher** discloses that the patient-specific surface 1 may be a continuous surface (as opposed to a surface defined by many individual pins). Ex. 1003 at 10-12, 14-15, 21-22, Figs. 13a, c; Ex. 1002 ¶131. 
13.	The surgical instrument of claim 1, wherein the diseased or damaged joint is a knee joint of the patient.	**Radermacher** discloses the use of the templates in knee surgeries. Ex. 1003 at 10-11, 19, 30, Figs. 13a-d.
32.	The surgical instrument of claim 1, further comprising a plurality of guides.	**Radermacher** discloses at least five guides. *See* Ex. 1003, Fig. 13a (cutting planes 20a-d and drill axis 8); *id.* at 30.

33.	The surgical instrument of claim 1, further comprising a second guide, wherein the second guide is configured at an angle relative to the guide.	**Radermacher** discloses several guides, many combinations of which include a first guide at an angle to a second guide. For example, the guide defining cut plane 20a is at an angle to the guide defining cut planes 20b, 20c, and 20d, any one of which could be the "second guide." Similarly, the guide defining the drilling hole about axis 8 (first guide) is at an angle to the guides defining cut planes 20b and 20d. Ex. 1003 at 30, Fig. 13a.  Ex. 1002 ¶135.
38.	The surgical instrument of claim 1, wherein the diseased or damaged joint is selected from the group consisting of a hip, a knee, an ankle, a shoulder, an elbow and a wrist joint.	**Radermacher** discloses using the templates in hip and knee surgeries. Ex. 1003 at 18 (hip), 19 (knee), Figs. 13a-d, Figs. 10a-d.

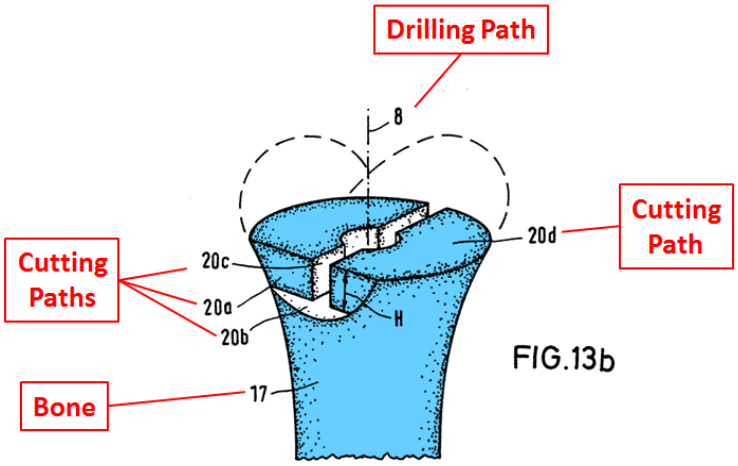
44.	The surgical instrument of claim 1, wherein the guide includes a stop to restrict the movement of the surgical tool.	**Radermacher** discloses a "limitation for the cutting depth." *Id.* at 16, 22-23 (drill sleeves "[w]ith a known drill length 12" "define drill depths and diameters which, in length and inner diameter, are exactly adapted to the surgical planning"). **The '827 Patent** admits that stops were known in the art. Ex. 1001, 111:51-52 ("Any stop known in the art can be used"). Drill stops were widely-known. Ex. 1002 ¶137.
45.	The surgical instrument of claim 1, wherein the guide includes a metal insert.	**Radermacher** discloses that a "drill sleeve 11 is inserted" into the individual template. Ex. 1003 at 30, Fig. 13a. Radermacher discloses that the template "is produced … other materials, e.g. metal[.]" Ex. 1003 at 23. A POSITA would have understood that the drill sleeve may be metal. Metal drilling inserts were known in the art. Ex. 1002 ¶138; Ex. 1033 at 31 (disclosing a "stainless steel drilling guide").
46.	The surgical instrument of claim 45, wherein the metal insert is a bushing.	*See* Claim 45. The disclosed drill sleeve is a bushing. Ex. 1002 ¶138.

B. Ground 2: Claims 14-19, 22-25, 28, 29, 34-37, and 39-43 Are Unpatentable As Obvious Over Radermacher in Combination with Alexander and Woolson

1. Claims 14-18 and 41-42

These claims relate to a patient-specific instrument for a femur. **Claim 14** requires the guide to define a cutting or drilling path through the femoral surface. **Claims 15-18** each further require the cutting path through various portions of the femoral condyles (distal, anterior, posterior, or both condyles, respectively). **Claims 41** and **42** require that the diseased or damaged joint includes portions of one or both of the medial and lateral condyles.

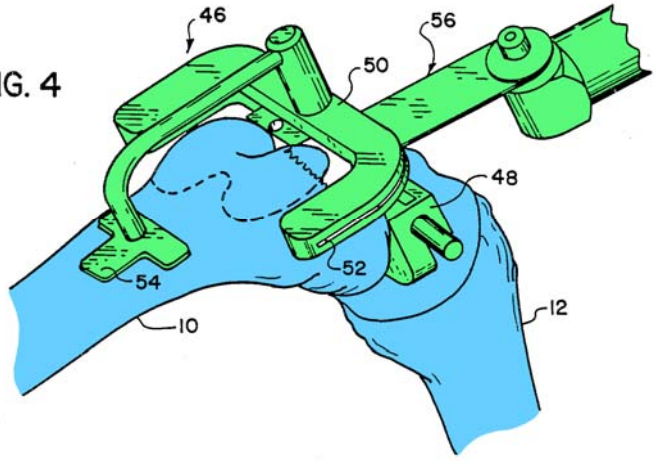
Radermacher discloses a patient-specific instrument for a femur, having guides defining cutting or drilling paths through all aspects of the femoral condyles, as shown in Figures 13a-c. Ex. 1003 at 30. Figure 13b shows a drilling path through a femoral surface and cutting paths through distal, anterior, and posterior portions of the medial and lateral femoral condyles. Ex. 1002 ¶141.



Ex. 1003, Fig. 13b. But even if Radermacher had not disclosed these limitations, they would have been obvious in view of Woolson.

Woolson discloses a surgical device that is positioned against both femoral condyles. *See* Ex. 1031, 6:16-23, Figs. 4 and 5. Woolson also discloses resecting the medial and lateral condyles with cutting paths that extend through the anterior and posterior portions of one or both condyles. *Id.*, 4:15-19, Fig. 1 (showing resecting distal end of femur along line 20), Fig. 4 (showing cutting an anterior portion of a femoral condyle), Figs. 7A and 7B (showing guides for cutting anterior and posterior portions of a femoral condyle).

FIG. 4



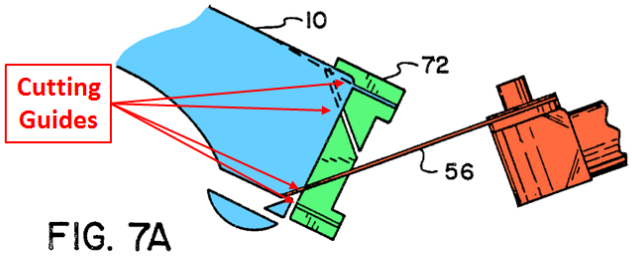


FIG. 7A

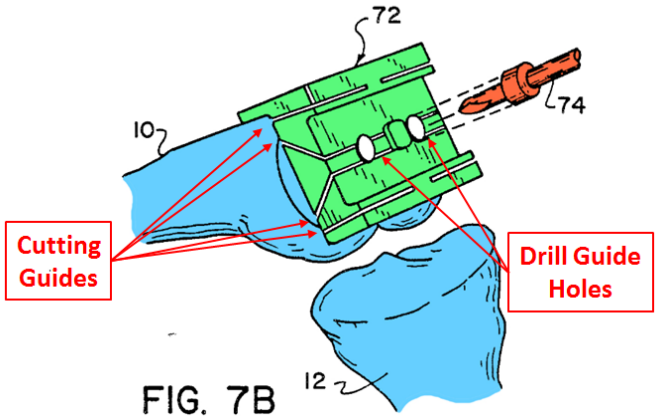


FIG. 7B

For the reasons set forth below, it would have been obvious to a POSITA that Woolson's devices could be modified to incorporate the patient-specific surface described in Radermacher. Alternatively, it would have been obvious to a POSITA to modify Radermacher's template to include the cutting slots and drill

holes from Woolson's devices. Ex. 1002 ¶¶142-43. Such a modified device would include guides defining cutting paths through the claimed portions of the femoral condyles (distal, anterior, posterior, or both condyles). *Id.*

A POSITA would have been motivated to modify Radermacher to accomplish the cuts disclosed in Woolson for several reasons. First, Woolson and Radermacher are in the same field (knee arthroplasty), describe the same devices (cutting guides), and rely on the same imaging technology. Second, the guide in Woolson, and the cuts defined thereby, are "conventional" and would be necessary to prepare the bone for a conventional implant. Ex. 1031, 6:57-64; Ex. 1002 ¶143. Third, it would have been readily apparent to a POSITA that the number and orientation of the drill holes and cutting paths would depend on the implant being used, e.g., if the implant contained two pegs and chamfer cuts as described in Woolson (instead of a single peg and cuts shown in Radermacher), then the instrument would be modified accordingly. Ex. 1002 ¶143. Indeed, the '827 patent admits that this was within the knowledge of a POSITA. Ex. 1001, 102:58-63 ("As will be appreciated by those of skill in the art, the location and orientation of the [guides] will change depending on the design of the ... implant."). Thus, modifying Radermacher such that the cutting paths extend through the distal, anterior, or posterior portions of one or both femoral condyles as in Woolson 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. Ex. 1002 ¶143. Alternatively, it would have been obvious to modify Woolson's "conventional" femoral cutting guides to include a patient-specific surface as taught by Radermacher. *Id.*

2. Claims 19 and 43

These claims relate to an instrument for the tibia rather than the femur. Claim 19 requires the guide to define a cutting path through a tibial plateau, whereas Claim 43 requires that the diseased or damaged joint includes portions of a medial or lateral tibial plateau. Although Radermacher describes a template for a femoral surface in detail, it would have been obvious to a POSITA that it could be used for resecting the tibia for several reasons. First, Radermacher discloses that the individual template technique may be used with any osseous structure (Ex. 1003 at 9-13, 30), which would include the tibia. Second, Radermacher explains that standard tool guides, upon which Radermacher seeks to improve, were provided for both the femur and the tibia. Ex. 1003 at 2. Thus, a POSITA would have understood that Radermacher's patient-specific template could be used for the tibia. Ex. 1002 ¶¶144-47. Third, in the 1990s, knee arthroplasty virtually always involved resecting both the femur and the corresponding portion of the tibia. *Id.* Thus, those of ordinary skill knew that instruments, such as those described in

Radermacher, would be used for resecting both the femur and the tibia. Indeed, several references disclosed the use of patient-specific templates, like those in Radermacher, for resecting the tibia. Ex. 1031 at 31-32, Figs. 2A-B; Ex. 1008, 3:40-4:49, Fig.2; Ex. 1007, 6:48-64, Fig. 6.

In addition, Woolson discloses instruments for cutting both the femur and tibia during total knee arthroplasty. In particular, Woolson discloses an instrument defining a cutting path (line 22) through the tibial plateau:

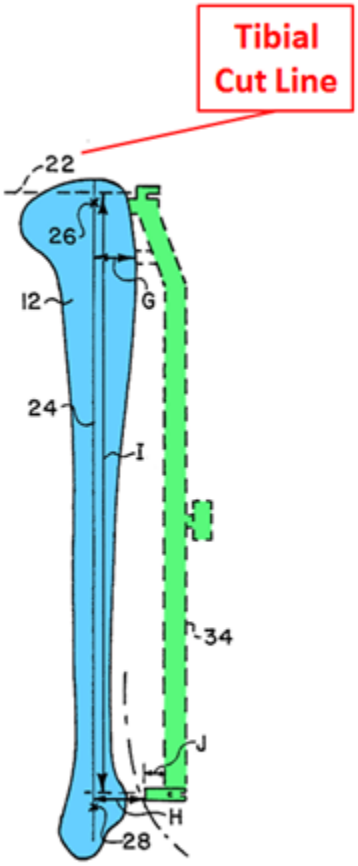


FIG. 2B

Ex. 1031, 7:42-47, Fig. 2B. A POSITA would have been motivated to modify Radermacher's patient-specific template to apply to the tibial surface and define a cutting path "through the tibial plateau" because Radermacher suggests such a use, as explained above. Moreover, it would require merely the substitution Woolson's tibial cutting guide for the improved template described in Radermacher. Ex. 1002 ¶¶144-47.

3. Claim 22

Claim 22 depends from Claim 19 and recites a cutting path that is "at a predetermined orientation relative to at least one of a mechanical axis and an anatomic axis of the knee joint of the patient." Claim 22 does not require that the cutting path have any particular relationship to any axis. Ex. 1002 ¶151. Moreover, Claim 22 is not a method claim. It does not require determining a mechanical or anatomic axis and does not require orienting the cutting path to have a particular angle to any mechanical or anatomic axis. Instead, Claim 22 simply requires that the cutting path is at a predetermined orientation "relative to" an axis. This limitation is inherently met by all cutting or drilling paths, regardless of orientation, and is therefore disclosed by Radermacher. *Id.* ¶151. In other words, the guides in Radermacher's individual template define predetermined drilling (axis 8) or cutting (paths 20a-d) paths that are necessarily oriented relative to a mechanical or anatomical axis of the joint. Ex. 1003, Figs. 13b, 13c.

Even if this limitation requires a determination of the mechanical or anatomical axes during the pre-operative planning stage and/or that the orientation of the cutting guide depends on such an axis, this limitation would have been obvious to a POSITA for many reasons. The '827 patent admits that the mechanical and anatomical axes—as well as methods of determining them based on imaging such as X-ray, CT scans, etc.—were well-known. Ex. 1001, 30:34-52, 34:42-39:45. The patent further admits that reliance on these axes while performing knee arthroplasty was well-known. *Id.*

Petitioner's expert further confirms that aligning cutting tools relative to a patient's mechanical and anatomical axes was well-known and commonplace in knee arthroplasty. Ex. 1002 ¶¶152-64. POSITAs knew that maintaining proper knee alignment post-surgery was critical because the mechanical axis determines the distribution of forces in the knee. *Id*. ¶¶54, 152-64; Ex. 1037 at 739. To achieve proper alignment, the implant components—both tibial and femoral—must be aligned properly relative to the mechanical axis. Ex. 1002 ¶¶152-64. This, in turn, requires the surgical tool, as well as the cutting and drilling paths defined thereby, to be precisely aligned relative to the mechanical axis. *Id.* It was also widely-known that proper alignment relative to the mechanical axis ensured that the forces exerted on the implant would not loosen the implant over time. *Id.*

Thus, such alignment was entirely conventional and well-known by POSITAs in the 1990s.

Furthermore, these limitations would have been obvious to a POSITA in view of Woolson. *Id.* ¶¶155-58. Woolson is one of many prior art references that discloses orienting guides to provide cutting or drilling paths that are oriented relative to a mechanical or anatomical axis of the joint. Woolson explains that it is "important" that knee implants be positioned on an axis perpendicular to the mechanical axis and, consequently, it is "necessary" that the cutting paths also be perpendicular to the mechanical axis. Ex. 1031, 4:9-19. Woolson teaches that ***all*** knee replacement systems align the implant with the patient's mechanical axis because doing so produces better long-term results. *Id.*, 1:26-36. Woolson then explains that, for the implant to be aligned properly, the cutting guides must be oriented such that the cutting paths are also aligned relative to the axis. *Id.*, 4:7-19, 4:20-26 (cut is made perpendicular to mechanical axis of tibia), 1:8-18, 1:54-57, 1:46-50, 2:50-59, 4:7-6:3, 5:36-41, 6:50-53, 7:32-36, 7:63-67, Abstract, Figs. 1, 2A, and 2B.

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

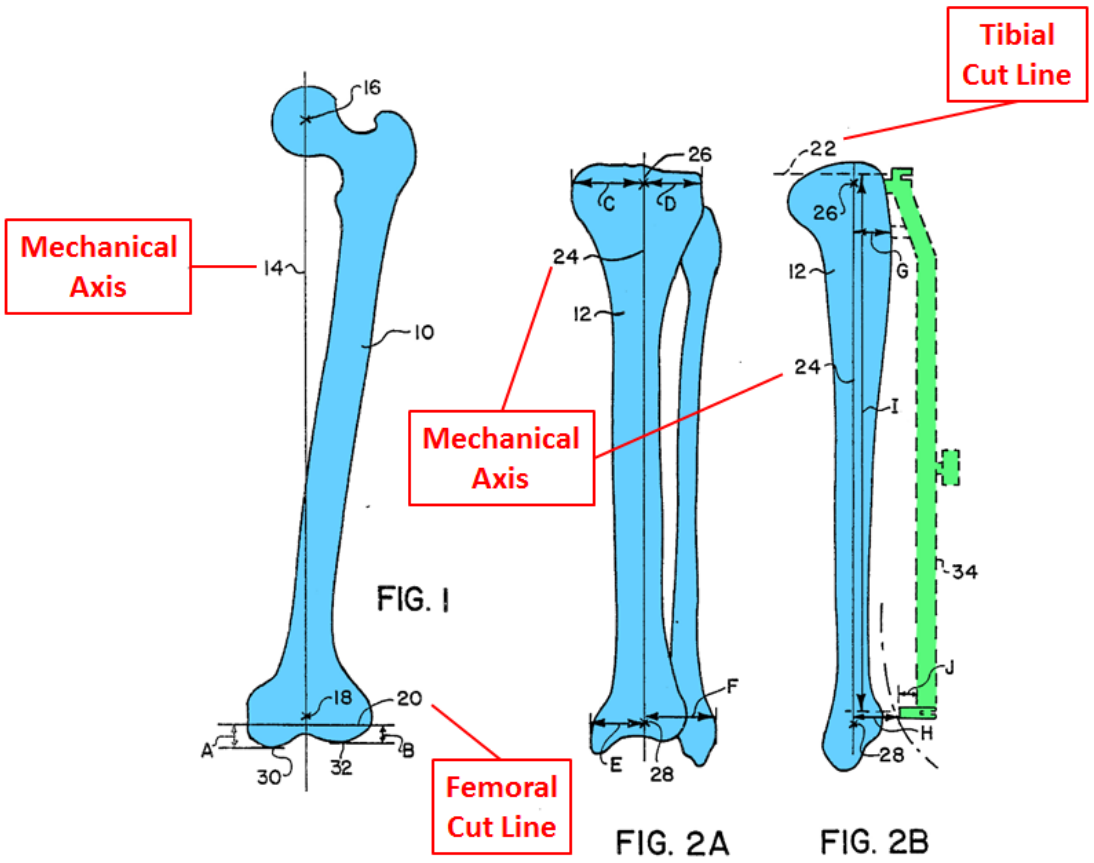


FIG. 1 FIG. 2A FIG. 2B

Numerous prior-art references further confirm that aligning tools relative to a patient's mechanical and anatomic axes was well-known. Ex. 1032, 3:1-3, Fig. 1, 3:1-53, 8:27-30, 9:37-41; Ex. 1037 at 758 (the importance of taking the mechanical axis into account when performing knee arthroplasty was "generally agreed [upon]"); Ex. 1033 at 31 (accurate placement of implant components with respect to the individual mechanical axis of the leg is "essential"); Ex. 1032, 3:1-53, 8:27-30, 9:37-41, Fig. 1.

Accordingly, orienting cutting or drilling guides to provide paths that are aligned relative to a patient's mechanical or anatomical axis of a joint was well-

known, within the knowledge of a POSITA, and would have been obvious to a POSITA in view of at least Woolson. Ex. 1002 ¶¶155-58, 164-65. Configuring Radermacher's template to be oriented along a mechanical or anatomical axis would merely involve using a common technique that has been employed to improve one knee arthroplasty procedure (Woolson's) to improve a similar knee arthroplasty procedure (Radermacher's) in the same predictable way. *Id.*

4. Claims 39 and 40

Claims 39 and 40 require that the instrument is configured to be oriented along a mechanical or anatomical axis of the joint, respectively. Again, these claims simply require the instrument to be "oriented along" the mechanical or anatomical axes, *i.e.*, positioned at any point on those axes. Ex. 1002 ¶¶178-80. Because Radermacher's individual template is positioned at the knee joint (*i.e.*, at the distal end of a femur or the proximal end of a tibia), a POSITA would have understood that such a template is necessarily oriented along both the mechanical and anatomical axes. *Id.* Woolson discloses a similarly-positioned instrument. *See* Ex. 1031, 6:19-21, Figs. 4-5. A POSITA would also have understood that if the cutting guide defines a path at a predetermined orientation relative to a mechanical or anatomical axis of the joint, as recited in Claim 22, the instrument containing that guide would also necessarily be aligned along such an axis. *Id.*

5. Claim 23

Claim 23 recites a cutting path that is "at a predetermined distance relative to a cartilage surface of the tibial plateau." As described previously, a POSITA would have understood that Radermacher's template could be used to resect a tibia. Ex. 1003 at 9 (template may be used "for any desired orthopedic interventions"). Radermacher's template, including the cutting paths, is constructed in the preoperative planning stage. *Id.* at 9-11. Radermacher discloses that the cutting guides are preoperatively charted and "fixed relative to the osseous structure." *Id.* at 11.

A POSITA would have understood that the preoperative placement of the cutting guides (e.g., horizontal guides 20b, 20d) necessarily means that the cutting path will be at a predetermined distance from the surface. Ex. 1002 ¶167. Therefore, Radermacher discloses this limitation, or it would have been obvious to a POSITA based on Radermacher's disclosure. *Id.*

Alternatively, this limitation would have been obvious in view of Woolson. Woolson discloses that the "reference points" for the proximal tibial cut "must be determined in two planes ***preoperatively***." Ex. 1031, 5:50-52 (emphasis added), 6:4-8. Woolson further discloses "precise positioning and alignment" of the cutting guides via various preoperative adjustments of axes and "determined distances." *Id.*, 6:8-15. Woolson also discloses that the tibial cut line may be

"below the most deficient tibial plateau." *Id.* at 7:42-44. A POSITA would have understood that Woolson's disclosure of precise preoperative determination of distances necessarily includes a distance of the cutting guide relative to the cartilage surface. Ex. 1002 ¶¶168-69. A POSITA would have been motivated to combine the predetermined distances of Woolson with the Radermacher template for the reasons discussed above. Alternatively, a POSITA would have been motivated to incorporate Radermacher's patient-specific surface into the guide disclosed in Woolson, which would include setting the tibial cutting path at a predetermined distance from the cartilage surface of the tibial plateau.

6. Claims 24, 25, 28, and 29

Claim 24 depends from Claim 13 and further requires that the surgical instrument include a "spacer sized to fit in a space between a femoral surface and a tibial surface of the knee joint of the patient and configured to balance ligaments associated with the knee joint of the patient."

The '827 patent admits that spacers were known in the art. Ex. 1001, 73:61-64. Petitioner's expert confirms that using spacers to balance ligaments was well-known and was a conventional practice in all knee arthroplasty procedures. Ex. 1002 ¶¶170-72. Woolson discloses the use of a spacer for ligament balancing and further confirms that the use of spacers was "conventional." Ex. 1031, 7:49-53 ("After making the tibial and the distal femoral bone cuts, a trial tibial component

and a trial femoral spacer is inserted into the joint space to test the adequacy of bone resection with the knee in extension, ***as is conventionally done***.") (emphasis added); *id.*, 6:54-58. Thus, it would have been obvious to a POSITA that Radermacher's instrument could include a spacer, as taught by Woolson, for ligament balancing. Ex. 1002 ¶¶170-72.

Claim 25 further states that the spacer is not connected to the component that comprises the patient-specific surface and the guide. This additional limitation cannot make the claim patentable. Spacers that are unconnected to the cutting block were conventional, and the spacers disclosed in Woolson were not connected to the block, as the cuts had already been made and the purpose of the spacer was to test ligament balancing. Ex. 1031, 7:49-53, 6:54-58; Ex. 1002 ¶¶170-72.

Claim 28 depends from Claim 1 and further recites that the instrument comprises an "adjustment mechanism to balance ligaments associated with the knee joint of the patient." Claim 29 further states that the adjustment mechanism is not connected to the component that includes the patient-specific surface and the guide. A spacer is a type of adjustment mechanism. *See* Ex. 1001, 19:37-40 (disclosing a method that includes a spacer for "adjusting the position of the guide"), 113:11-14 ("adjustments may be made intraoperatively, for example via spacers"), 73:61-64, 104:15-17; Ex. 1002 ¶170. Thus, these claims are invalid for the same reasons as Claims 20-21 above. In addition, a tensiometer is an

"adjustment mechanism" and the '827 patent admits that tensiometers were known in the art and are not an inventive aspect of the claim. *Id.*, 103:42-44. Therefore, these limitations cannot make the claims patentable.

7. Claims 34-37

Claim 34 recites a stabilizer on a surface of the instrument oriented to engage a surface portion of the joint. Claim 35 specifies that the stabilizer is one of a pin, peg, post, or nub. Claims 36 and 37 recite that the patient-specific instrument is configured to resist movement (Claim 36) and rotation (Claim 37) placed against the joint.

These limitations are disclosed by Radermacher and Woolson. Radermacher discloses that "clamping devices or screw connections (e.g. 19) can be provided for intraoperative fixation of the individual template 4 onto or to the osseous structure 17." Ex. 1003 at 23. "Also fixation (nails, screws, and the like) 19 on the bone 17 can optionally be performed." *Id.* at 25, 35, 26, Figs. 6a-b. Since "nails" and "pins" were used interchangeably by those of skill in the art (Ex. 1002 ¶173, 181), Radermacher discloses using a stabilizer (Claim 34) such as a pin (Claim 35) to resist movement (Claim 36) or rotation (Claim 37) of the template. *Id.*

Woolson also discloses the use of "pins" that fix the conventional cutting guide to the femur. Ex. 1031, 6:58-63. Such pins would result in the tool resisting movement and rotation. Ex. 1002 ¶¶174-75. Moreover, stabilizers such as nails,

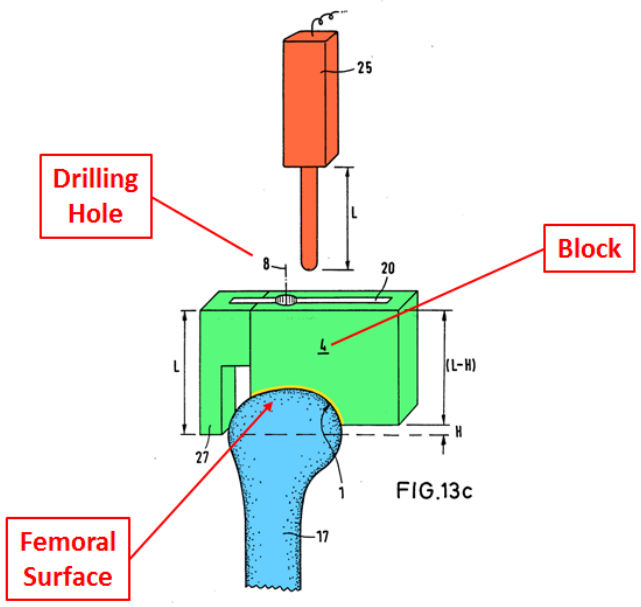
screws, pins, pegs, posts, etc. were commonly used to secure cutting guides to the joint, and a POSITA would have been motivated to secure Radermacher's patient-specific block to the joint surface. *Id.* ¶173-75.

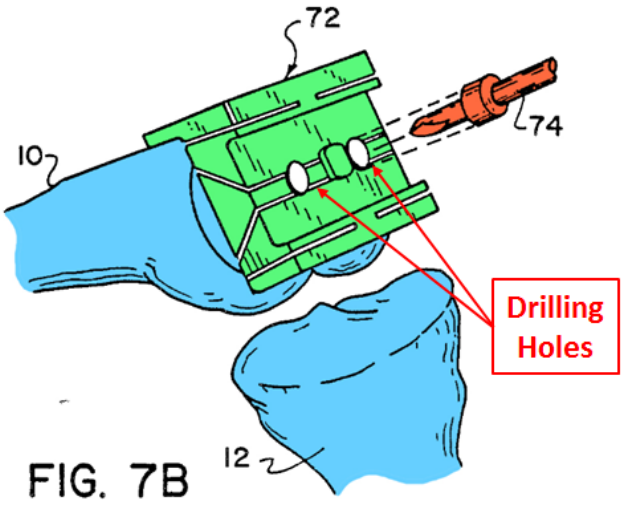
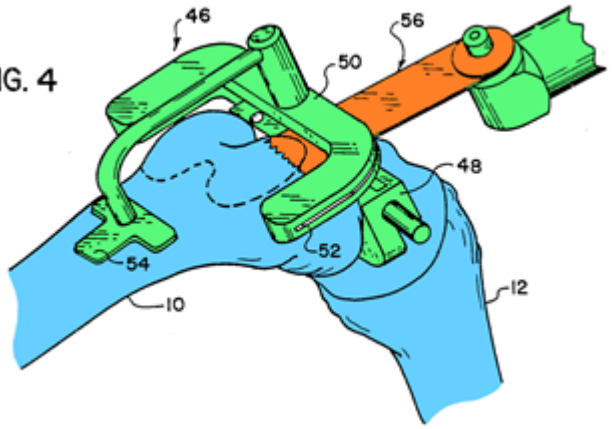
In addition, with respect to Claims 36 and 37, Radermacher discloses that the template is designed to resist movement and rotation when placed against the joint surface because Radermacher discloses that the patient-specific surface fits onto the patient's articular surface in only one position and location. Ex. 1003 at 10-11 ("the individual template can be set onto the osseous structure in a clearly defined position and with mating engagement" and the template fits "in exclusively one clearly defined position in form-closed manner."), 12, 14-15, 21-22, 25. Accordingly, Radermacher teaches that the shape of the template itself functions to resist movement and rotation when the patient-specific surface is placed against the articular surface. Ex. 1002 ¶¶173-177.

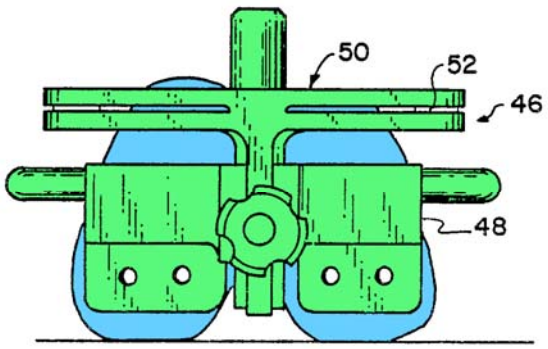
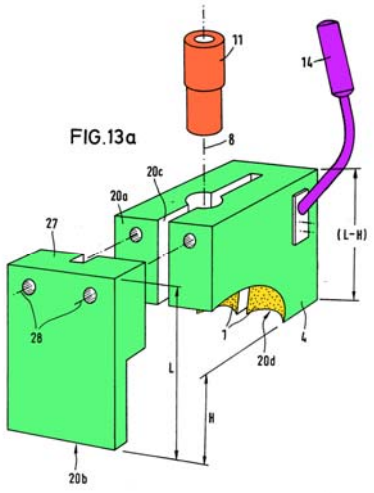
It would have been obvious to a POSITA to use the stabilizing pins of Woolson with the instrument of Radermacher. A POSITA would have understood the importance of stabilizing the instrument during surgery, to ensure proper placement as well as cutting paths in accordance with patient's treatment plan. *Id.* ¶175. Moreover, this was a common practice in the industry and widely-known. *Id.* The specific stabilizing means were merely a matter of design choice. *Id.* Thus, modifying Radermacher to include a stabilizer would merely involve using a

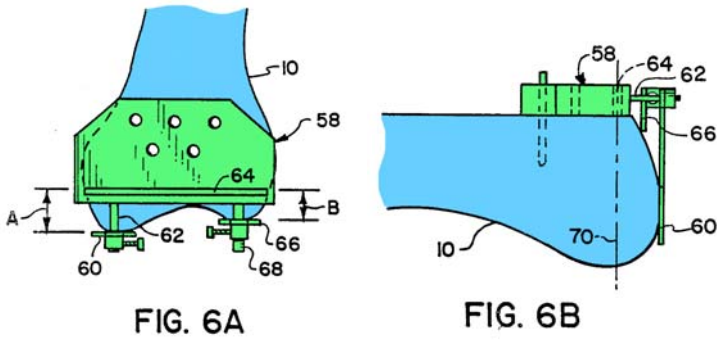
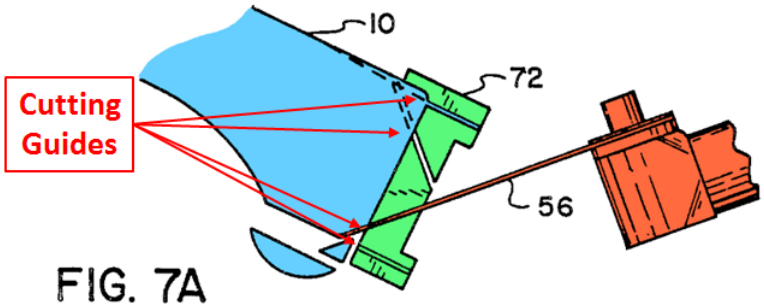
technique that has been employed to improve one knee arthroplasty procedure (Woolson) to improve a similar knee arthroplasty procedure (Radermacher) in the same predictable way.

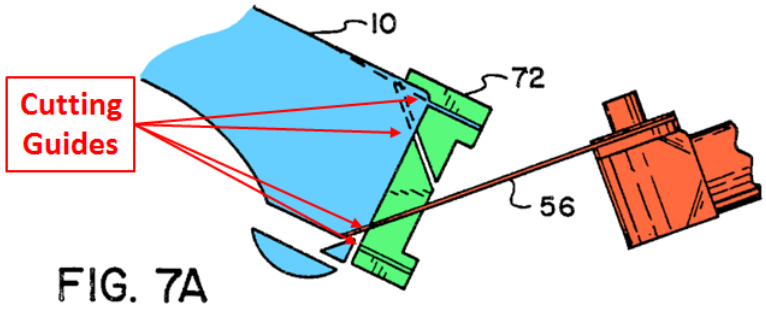
The claim chart below provides additional detail regarding how Claims 14-19, 22-25, 28, 29, 34-37, and 39-43 are disclosed by the prior art under **Ground 2**.

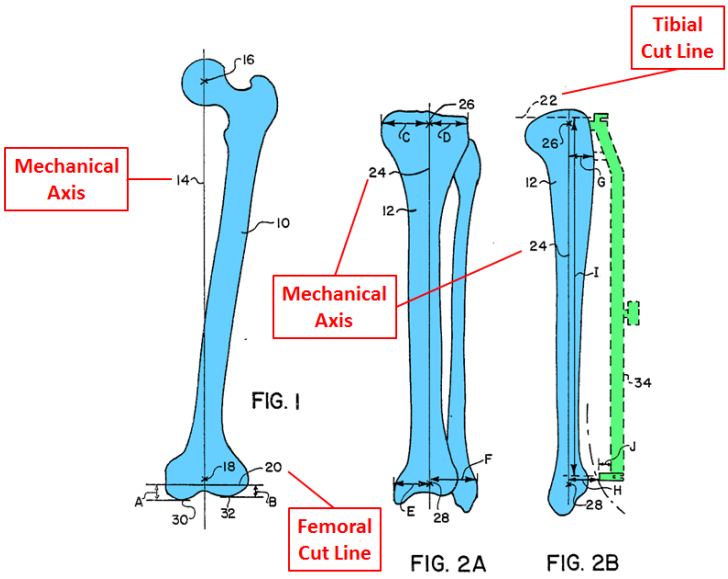
No.	Claim Limitation	Exemplary Disclosure in Prior Art
14.	The surgical instrument of claim 13, wherein the corresponding portion of the diseased or damaged joint is a femoral surface of the knee joint of the patient and the guide is configured to define a cutting or drilling path through the femoral surface when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.	**Radermacher** discloses that the surface is a femoral surface. Ex. 1003 at 30, Figs. 13a-13d. The drill hole and cut guides define paths through the femoral surface:  **Woolson** discloses a "conventional cutting guide 72" for the femur having two drill holes and multiple cutting slots that define paths through a femoral surface:

No.	Claim Limitation	Exemplary Disclosure in Prior Art
		 FIG. 7B Ex. 1031, Fig. 7B; 6:54-64. Ex. 1002 ¶140-43. **Woolson** also discloses other instruments that define paths through a femoral surface. Ex. 1031, 6:16-23, Figs. 4-5. FIG. 4 

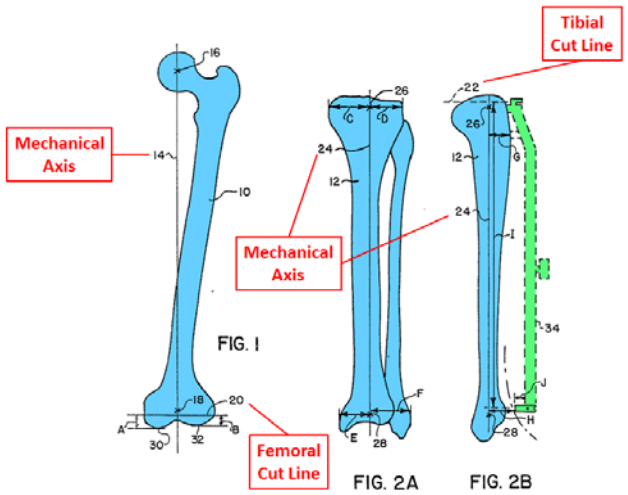
No.	Claim Limitation	Exemplary Disclosure in Prior Art
		 FIG. 5 **Knowledge of a POSITA:** Femoral cutting blocks having drilling and cutting paths through a femoral surface were within the knowledge of a POSITA. Ex. 1002 ¶¶140-43; Ex. 1032, 5:34-43, 8:11-22, 9:13-26, 10:15-20, Figs. 2B, 14, 30B, 52, 53.
15.	The surgical instrument of claim 14, wherein the cutting or drilling path is configured to extend through a distal portion of a femoral condyle of the knee joint of the patient when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.	*See* Claim 14. **Radermacher** discloses a cutting paths (20a and 20d) that extend through a distal portion of a femoral condyle of the knee joint.  Ex. 1003 at Fig. 13a. **Woolson** discloses "distal femur condylar cuts"

No.	Claim Limitation	Exemplary Disclosure in Prior Art
		using instrument 58 shown in FIGS. 6A and 6B. Ex. 1031, 6:32-38, Figs. 6A-B.  FIG. 6A FIG. 6B Woolson discloses that "final distal femoral cuts are made with a single conventional cutting guide 72":  FIG. 7A *Id.*, 6:58-64, Fig. 7A.

16., 17.	The surgical instrument of claim 14, wherein the cutting or drilling path is configured to extend through an [anterior/posterior] portion of a femoral condyle of the knee joint of the patient when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.	**Radermacher** discloses cutting paths 20a, 20b, and 20d that extend through anterior and posterior portions of femoral condyles of the knee. *See* Claims 14 and 15. **Woolson** discloses that "[t]he final anterior, posterior and chamfer cuts on the femur are made" as shown in Figs. 7A-B. Ex. 1031, 6:54-58, Figs. 7A-B.  FIG. 7A Woolson also discloses an anterior cutting path in Figs. 4 and 5.
18.	The surgical instrument of claim 14, wherein the cutting or drilling path is configured to extend through a portion of two femoral condyles of the knee joint of the patient when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.	*See* Claims 14-17. **Radermacher** discloses that cutting lines 20a, 20b, and 20d extend through a portion of two femoral condyles of the knee. *See* Claims 14 and 15. **Woolson** discloses multiple cutting paths and drilling paths that extend through a portion of two femoral condyles. *See* Figs. 4-6, 7A-B.

19.	The surgical instrument of claim 13, wherein the corresponding portion of the diseased or damaged joint is a portion of the tibia of the knee joint of the patient and the guide defines a cutting or drilling path through a tibial plateau of the tibia.	**Radermacher** discloses templates for "any desired orthopedic interventions." Ex. 1003 at 9. Radermacher discloses that standard tool guides were provided for the tibia. *Id.* at 2. **Woolson** discloses a cutting guide that defines a cutting or drilling path through a tibial plateau of the tibia. Ex. 1031, 7:42-47 ("It is sufficient, to align tibial cut line 22 below the most deficient tibial plateau as determined by the CT scan representations. … The bone cut is made along out line 22 by passing a saw 56 through slit 86."); Figs. 2A-B. 

22.	The surgical instrument of claim 19, wherein the cutting or drilling path is at a predetermined orientation relative to at least one of a mechanical axis and an anatomic axis of the knee joint of the patient.	*See* Claim 19. **Radermacher** discloses an individual template that defines predetermined drilling (axis 8) or cutting (paths 20a-d) paths that are oriented relative to a mechanical or anatomical axis of the joint. Ex. 1003, Figs. 13b, 13c. **The '827 patent** admits that determining a biomechanical or anatomical axis and accounting for such axes in knee arthroplasty was well-known. Ex. 1001, 38:47-39:2. **Woolson** discloses that: "all total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis in both the coronal and the sagittal planes. If achieved, this results in the placement of the total knee prostheses in a common mechanical axis which correspondingly is highly likely to produce a successful long-term result." Ex. 1031, 1:26-36. Woolson discloses determining the mechanical axis and orienting the cutting guide such that a cutting path (e.g., line 22) is aligned relative to (e.g., perpendicular to) the axis:

		 *Id.*, Figs 1, 2A-B, 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. **<u>Knowledge of a POSITA:</u>** Orienting cutting guides to provide drilling or cutting paths that are aligned relative to a mechanical axis was standard practice in knee arthroplasty procedures. Ex. 1002 ¶¶148-65; Ex. 1033 at 31, 29.

23.	The surgical instrument of claim 19, wherein the cutting or drilling path is at a predetermined distance relative to a cartilage surface of the tibial plateau.	*See* Claim 19. **Radermacher** discloses planning the cutting and drilling paths preoperatively. Ex. 1003 at 9, 10-11, Figs. 13a-d. **Woolson** discloses that "[u]sing this preoperative planning method, the surgeon is able to determine mechanical axes 14, 24 and distances A-J. These specific bone landmarks and distances correspond for presetting the cutting guides illustrated in FIGS. 4-8 … It will be appreciated that the various cutting guide adjustments which need to made are precisely determined. The gauge members of the guides are adjusted corresponding to the determined distances." Ex. 1031, 6:4-15; *id.*, 5:55-62 Woolson further discloses that "Adjustable plate 96 on shaft end 76a … is set at a distance which will result in the desired posterior inclination of the angle of proximal tibial bone cut defined by slit 86." *Id.*, 7:37-44.
24.	The surgical instrument of claim 13, further comprising a spacer sized to fit in a space between a femoral surface and a tibial surface of the knee joint of the patient and configured to balance ligaments associated with the knee joint of the patient.	**Woolson** discloses a spacer between the femoral and tibial surfaces to check ligament balance in the joint during knee arthroplasty. Ex. 1031, 7:49-53 ("After making the tibial and the distal femoral bone cuts, a trial tibial component and trial femoral spacer is inserted into the joint space to test the adequacy of bone resection with the knee in extension, as is conventionally done."). **The '827 patent** admits spacers were "known in the art." Ex. 1001, 73:61-64. **Knowledge of a POSITA:** Spacers were widely-known and used by POSITAs for ligament balancing. Ex. 1031, 7:49-53; Ex. 1034 at 19-20, 23-25, Figs. 7,

		17, 19; Ex. 1041 at 29; Ex. 1002 ¶¶170-72 (use of spacers was "standard protocol for all total knee replacements").
25.	The surgical instrument of claim 24, wherein the patient-specific surface and the guide are contained in a single component, wherein the spacer is not connected to the single component.	*See* Claim 24. **Radermacher** discloses that the patient-specific surface and the guide are contained in a single component. *See* Claim 11. **Woolson** discloses a spacer that is not connected to the component containing the guide. Ex. 1031, 7:49-53; Ex. 1002 ¶¶171. **Knowledge of a POSITA:** The use of spacers not connected to cutting blocks was "standard protocol for all total knee replacements." Ex. 1002 ¶172; Ex. 1034 at 23-25, Figs. 17, 19; Ex. 1041 at 29.
28.	The surgical instrument of claim 1, wherein the diseased or damaged joint is a knee joint, the instrument further comprising an adjustment mechanism to balance ligaments associated with the knee joint of the patient.	*See* Claims 1, 24. Because a spacer is an "adjustment mechanism" (Ex. 1001, 19:37-40, 113:11-14, 73:61-64, 104:15-17), this claim is invalid for the same reasons as Claim 24. In addition, the '827 patent admits that other adjustment mechanisms, including tensiometers, were well-known and not part of the invention. Ex. 1001, 103:42-46 ("The design of tensiometers are known in the art and are not included herein to avoid obscuring the invention. Suitable designs include, for example, those described in U.S. Pat. No. 5,630,820 to Todd issued May 20, 1997."). Ex. 1002 ¶¶170-72.

29.	The surgical instrument of claim 28, wherein the patient-specific surface and the guide are contained in a single component, wherein the adjustment mechanism is not connected to the single component.	*See* Claims 25 and 28. **Radermacher** discloses that the patient-specific surface and the guide are contained in a single component. *See* Claim 11.
34.	The surgical instrument of claim 1, further comprising at least one stabilizer on a surface of the instrument oriented to engage a surface portion of the diseased or damaged joint when the patient-specific surface engages the corresponding portion of the diseased or damaged joint.	**Radermacher** discloses the use of nails, screws, etc. (stabilizers) with the individual template. Ex. 1003 at 23 ("clamping devices or screw connections (e.g. 19) can be provided for intraoperative fixation of the individual template 4 onto or to the osseous structure 17"), 25 ("Also fixation (nails, screws, and the like) 19 on the bone 17 can be optionally performed"), 35. **Woolson** discloses that the instrument can be "fixed in position" by the use of pins. Ex. 1031, 6:58-63, Figs. 4, 5, 6, 7A-B, 7:44-46 (tibial cutting guide stabilized by pins), Figs. 8A-B. **Knowledge of a POSITA:** Stabilizers were well-known in the art. Ex. 1002 ¶¶173-175.
35.	The surgical instrument of claim 34, wherein the stabilizer is selected from the group consisting of pin, peg, post, and nub.	*See* Claim 34. A POSITA would have understood that nails, screws, and the like would encompass one of a pin, peg, post, or nub. Ex. 1002 ¶¶173-75, 181 ("nail" and "pin" were used interchangeably).

36.	The surgical instrument of claim 1, wherein the instrument is configured to resist movement when the patient-specific surface is placed against the corresponding portion of the diseased or damaged joint.	**Radermacher** discloses that the patient-specific surface of the individual template abuts the knee joint, thereby preventing movement and rotation. Ex. 1003 at Fig. 13a, Fig. 13c; 30 ("The individual template 4 is set onto the bone 17 in a defined manner, abutting the contact faces 1."); 10, 11, 12. Radermacher also discloses that the individual template "has a clearly defined spatial position because of the contact faces, also the spatial position and orientation of the individual components relative to the bone is known and can be clearly reproduced intraoperatively by mounting the individual template." Ex. 1003 at 25. Radermacher and **Woolson** further disclose the use of stabilizers to fix the template to the bone, preventing movement and rotation. *See* Claims 34-35.
37	The surgical instrument of claim 1, wherein the instrument is configured to resist rotation in at least one axis when the patient-specific surface is placed against the corresponding portion of the joint.	*See* Claim 36.

39. and 40.	The surgical instrument of claim 1, wherein the instrument is configured to be oriented along [a mechanical/an anatomical] axis of the diseased or damaged joint when the patient-specific surface is placed against and aligned with the corresponding portion of the diseased or damaged joint.	*See* Claim 22. In addition: **Woolson** discloses instruments oriented along the mechanical and anatomical axes. *See* Ex. 1031, 6:19-21, Figs. 4, 5, 6, 7A-B. Such orientation was known to POSITAs. Ex. 1002 ¶¶178-80.
43.	The surgical instrument of claim 13, wherein the corresponding portion of the diseased or damaged joint includes portions of at least one of a medial tibial plateau and a lateral tibial plateau of the knee joint of the patient.	*See* Claims 13 and 19.

C. Ground 3: Claims 20 and 21 Are Unpatentable As Obvious Over Radermacher in Combination With Alexander, Woolson, and Hofmann.

Claim 20 recites that the cutting path of Claim 19 has "a predetermined slope relative to the tibial plateau." Claim 20 does not require that the path have a particular slope. Thus, the limitations of Claim 20 would be met by any cutting path, regardless of its angle. Because Radermacher discloses pre-operatively aligned guides defining predetermined cutting paths, and because it would have been obvious that Radermacher's individual template could be used to resect a tibia, Claim 20 would have been obvious. Ex. 1002 ¶182; Ex. 1003 at 9.

Claim 21 depends from Claim 20 and further requires that the predetermined slope is between 0 and 7 degrees. Claims 20 and 21 would have further been obvious to a POSITA in view of Woolson, which discloses that the tibia may be resected "perpendicular to the sagittal mechanical axis … or inclined posteriorly up to 5 or 10 degrees." Ex. 1031, 5:65-67; Ex. 1002 ¶184.

The limitations of both Claim 20 and Claim 21 also would have been obvious in view of Hofmann. Hofmann discloses that knee replacement surgery may require cutting the tibia "with a specific posterior slope," while others require a perpendicular cut. Ex. 1090 at 63. Hofmann discloses a method in which the tibia is cut "parallel to the articular surface of the tibia" (i.e., at a slope of 0 degrees relative to the tibial plateau), and discloses that such a cut may be beneficial. *Id.* at

63, 68 ("this study indicated that the specimens cut parallel to the anatomic posterior slope were stronger and stiffer than their contralateral specimens cut perpendicular to the long axis."). A POSITA would have recognized that a tibial resection that is "parallel to the articular surface of the tibia" as disclosed in Hofmann would have a predetermined slope, as recited in Claim 20, and that the slope would be between 0 and 7 degrees, as recited in Claim 21. Ex. 1002 ¶183. A POSITA would have further recognized that a tibial resection that is perpendicular to the anatomic axis of the tibia, as is also disclosed in Hofmann, would similarly have a predetermined slope between 0 and 7 degrees, as the '827 patent admits. Ex. 1001, 69:24-27; Ex. 1002 ¶183. Therefore, the cutting paths would have a predetermined slope relative to the tibial plateau, and that slope would be between 0 and 7 degrees. Ex. 1002 ¶183.

A POSITA would have been motivated to combine Hofmann and Radermacher, and thus cut the tibia at a predetermined slope between 0 and 7 degrees, because Hofmann teaches the benefits of doing so. Ex. 1090 at 68 ("cutting the tibial [sic] parallel to the articular surface of the tibia during TKA provides increased load carrying capacity and stiffness to the bone supporting the tibial prosthesis"). Hofmann and Radermacher are also in the same field (knee arthroplasty). Thus, modifying Radermacher to make a tibial cut that matches the normal slope of the tibia would merely involve using a technique that has been

employed to improve one knee arthroplasty procedure (Hofmann's) to improve a similar knee arthroplasty procedure (Radermacher's) in the same predictable way. Ex. 1002 ¶183; Ex. 1090 at 68.

The claim chart below provides additional detail regarding how Claims 20 and 21 are disclosed by the prior art under **Ground 3**.

No.	Claim Limitation	Exemplary Disclosure in Prior Art
20.	The surgical instrument of claim 19, wherein the cutting path has a predetermined slope relative to the tibial plateau.	*See* Claim 19. **Radermacher** discloses that guides may be aligned on a preoperatively determined path or plane. Ex. 1003 at 11, 13, 30. **Hofmann** discloses that the tibia may be resected "with a specific posterior slope," including slopes that are either perpendicular to the mechanical axis of the tibia or that are parallel to the tibial plateau. Ex. 1090 at 63, 68. **Woolson** discloses that the tibia may be resected "perpendicular to the sagittal mechanical axis, as shown in FIG. 2B, or inclined posteriorly up to 5 or 10 degrees." Ex. 1031, 5:65-67. Ex. 1002 ¶¶182-84.
21.	The surgical instrument of claim 20, wherein the predetermined slope is between 0 and 7 degrees.	*See* Claim 20. A cut that is perpendicular to the mechanical axis of the tibia would be at a slope of 4-7 degrees relative to the tibial plateau, as the '827 patent admits. Ex. 1001, 69:24-27; Ex. 1002 ¶¶183-84. A cut that is parallel to the tibial plateau would be at a slope of zero degrees relative to the tibial plateau. Ex. 1002 ¶¶183-84.

D. Ground 4: Claims 1-13, 32, 33, 38, and 44-46 Are Unpatentable As Obvious Over Radermacher in Combination With Fell.

Ground 4 addresses the same claims as Ground 1, but relies on Fell rather than Alexander to show that it would have been obvious for Radermacher's patient-specific surface to include cartilage information derived from image data. Unlike Alexander, which discloses imaging the cartilage and bone surfaces of the knee joint, Fell discloses a patient-specific implant that replaces the meniscus, which is cartilage that exists between a femoral condyle and a corresponding tibial plateau. Ex. 1002 ¶¶186-92. 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 constructed 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, 15:12-21 (emphasis added), 22:6-9. Thus, Fell discloses: (1) using MRI to determine the shape of the cartilage surface, which would include any osteophytes; and (2) creating a patient-specific device that matches and mates with

the contour of such surfaces, and therefore includes "cartilage information" as recited in Claim 1 of the '827 patent. Ex. 1002 ¶¶186-92.

A POSITA would have been motivated to combine the teachings of Radermacher and Fell, and thus design Radermacher's template to match the shape of the cartilage surface (and therefore include cartilage information) for several reasons. *Id.* ¶193-96. First, both references relate to methods of treating damaged cartilage in a knee joint. Second, both references disclose the use of MRI for creating patient-specific medical devices having inner surfaces that match the patient's natural joint surface. Thus, they address the same problem, are in the same field of endeavor, and use the same imaging technology. *Id.* ¶194.

Third, Radermacher expressly suggests such a combination. Radermacher states that individualized surgical procedures were "lagging behind the technology of implant manufacture." Ex. 1003 at 6. Thus, Radermacher provides the motivation for a POSITA to consider patient-specific implant technologies, such as the implant described in Fell, and to adapt those technologies to cutting guides as disclosed in Radermacher. Ex. 1002 ¶195. Because Fell discloses creating a patient-specific implant that matches the patient's cartilage surface, which would include any osteophytes, a POSITA would have understood that Radermacher's template could also match the cartilage surface, including any osteophytes. *Id.* ¶194.

Fourth, a POSITA would have recognized that such a patient-specific template would simplify the surgery. *Id.* Finally, 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.*

Accordingly, the claim limitations requiring a patient-specific surface that "includ[es] cartilage information derived from image data" or that references an osteophyte of the joint would have, at the very least, been obvious over the combination of Radermacher and Fell.

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

No.	Claim Limitation	Exemplary Disclosure in Fell
1.	[b] the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint, wherein the corresponding portion of the diseased or damaged joint includes an osteophyte,	**Fell** discloses a patient-specific surface, at least a portion of which includes cartilage information derived from image data of the diseased or damaged joint. Ex. 1005 at 13, 14, 15, 22.
	[c] wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint; and	**Fell** also discloses that the imaging is used to determine the size, shape, etc. of the bones and cartilage, which would include any osteophytes. Ex. 1005 at 13, 14, 15, 22.

E. Grounds 5-6

Grounds 5 and 6 addresses the same claims as Grounds 2 and 3 respectively, but rely on Fell rather than Alexander to show that it would have been obvious for Radermacher's patient-specific surface to include cartilage information derived from image data, as set forth above in Ground 4. Because the relevant disclosures of Radermacher, Woolson, Hofmann, and the knowledge of a POSITA are the same as in Grounds 2 and 3, and the additional relevant disclosure from Fell is set forth above in Ground 4, no additional claim chart is necessary for Grounds 5 and 6. All of the relevant disclosures are set forth in the claim charts above.

VIII. SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

Secondary considerations do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Where, as here, a strong *prima facie* obviousness showing exists, secondary considerations may not dislodge the primary conclusion of obviousness. *Leapfrog Enters. Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). Petitioner is not aware of any relevant secondary considerations. If ConforMIS presents alleged evidence of secondary considerations, such evidence cannot outweigh the strong *prima facie* case of obviousness and Petitioner will address any such allegations in due course.

IX. CONCLUSION

For the reasons set forth above, the Board should institute an *inter partes* review of Claims 1-25, 28, 29, and 32-46 of the '827 patent.

Respectfully submitted,

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Dated: February 28, 2017

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the **PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-25, 28, 29, AND 32-46 OF U.S. PATENT NO. 8,657,827** exclusive of the parts exempt as provided in 37 C.F.R. § 42.24(a) contains approximately 13907 words, and therefore complies with the type-volume limitations of 374 C.F.R. § 42.24(a)

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 28, 2017

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-25, 28, 29, AND 32-46 OF U.S. PATENT NO. 8,657,827 and Exhibits 1001-1096** are being served on February 28, 2017 via FedEx Priority Overnight to counsel of record for U.S. Patent 8,657,827 patent owner **CONFORMIS, INC.**, at the addresses below:

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