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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case No. IPR2017-00511
U.S. Patent No. 7,981,158

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 66-81 OF U.S. PATENT 7,981,158

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 7,981,158 (“the ’158 patent”)
1002	***Exhibit Number Not Used***
1003	PCT Publication No. WO 93/25157 (“Radermacher”)
1004	PCT Publication No. WO 00/35346 (“Alexander”)
1005	PCT Publication No. WO 00/59411 (“Fell”)
1006	U.S. Patent No. 6,712,856 (“Carignan”)
1007	PCT Publication No. WO 95/28688 (“Swaelens”)
1008	U.S. Patent No. 6,510,334 (“Schuster II”)
1009	***Exhibit Number Not Used***
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”)
1013-1014	***Exhibit Numbers Not Used***
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 ’158 Patent Prosecution History
1018	***Exhibit Number Not Used***
1019	CV of Jay D. Mabrey, M.D.

Exhibit No.	Description
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”)
1033	Klaus Radermacher et al., *Computer Assisted Orthopaedic Surgery with Image Based Individual Templates*, 354 Clinical Orthopaedics and Related Research 28 (1998) (“CAOS”)
1034-1035	***Exhibit Numbers Not Used***

Exhibit No.	Description
1036	U.S. Patent No. 4,759,350 (“Dunn”)
1037	Excerpts from *Surgery of the Knee* (John N. Insall et al., eds., 2d ed. 1993) (“Insall”)
1038-1041	***Exhibit Numbers Not Used***
1042	Excerpts from Dror Paley, *Principles of Deformity Correction* (2002) (“Principles of Deformity Correction”)
1043	U.S. Patent No. 5,107,824 (“Rogers”)
1044-1057	***Exhibit Numbers Not Used***
1058	N. Schiffers et al., *Planning and Realization of Orthopedic Surgery with the Aid of Individual Templates*, 29 Orthopäde (Orthopedist) 636 (2000)
1059	K.-H. Englmeier et al., *Methods and Applications of Three-Dimensional Imaging in Orthopedics*, 109 Archives of Orthopaedic Trauma Surgery 186 (1990) (“Englmeier”)
1060	U.S. Patent No. 6,023,495 (“Adler”)
1061	Lawrence Manco & Michael Berlow, Meniscal Tears – Comparison of Arthrography, CT, and MRI, 29(2) Critical Reviews in Diagnostic Imaging, 151 (1989) (“Manco”)
1062	U.S. Patent No. 3,789,832 (“Damadian”)
1063	U.S. Patent No. 4,058,486 (“Mallozzi”)
1064	English Translation of N. Schiffers et al., *Planning and Realization of Orthopedic Surgery with the Aid of Individual Templates*, 29 Orthopäde (Orthopedist) 636 (2000) (“Schiffers”)

Exhibit No.	Description
1065	Declaration of Michael Degn re: Translation of N. Schiffers et al., *Planning and Realization of Orthopedic Surgery with the Aid of Individual Templates*
1066-1069	***Exhibit Numbers Not Used***
1070	U.S. Provisional Patent Application No. 60/416601 (filed October 2, 2002) (“the ’601 application”)
1071	U.S. Patent Application No. 10/681750 (filed October 27, 2003) and published as U.S. Publication 2004/0133276 (“the ’750 application”)
1072	U.S. Patent No. 7,534,263 (“the ’263 patent”)
1073	U.S. Patent No. 7,634,119 (“the ’119 patent”)
1074	U.S. Provisional Patent Application No. 60/894744 (filed March 14, 2007) (“the ’744 application”)
1075	U.S. Provisional Patent Application No. 60/975028 (filed September 25, 2007) (“the ’028 application”)
1076	U.S. Provisional Patent Application No. 60/765592 (filed February 6, 2006) (“the ’592 application”)
1077	U.S. Provisional Patent Application No. 60/785168 (filed March 23, 2006) (“the ’168 application”)
1078	U.S. Provisional Patent Application No. 60/788339 (filed March 31, 2006) (“the ’339 application”)
1079	U.S. Provisional Patent Application No. 60/431176 (filed December 4, 2002) (“the ’176 application”)
1080	U.S. Provisional Patent Application No. 60/467686 (filed May 2, 2003) (“the ’686 application”)
1081-1083	***Exhibit Numbers Not Used***
1084	Edmund Y.S. Chao & Franklin H. Sim, *Computer-Aided Preoperative Planning in Knee Osteotomy*, 15 Iowa Orthopedic Journal 4 (1995) (“Chao”)
1085	Arima et al., *Femoral Rotational Alignment, Based on the Anteroposterior Axis, in Total Knee Arthroplasty in a Valgus Knee*, 77-A(9) Journal of Bone and Joint Surgery) 1331 (1995) (“Arima”)

Exhibit No.	Description
1086	Kosmas Karadimitriou & John M. Tyler, Min-Max Compression Methods for Medical Image Databases, 26(1) SIGMOD Record 47 (1997) (“Karadimitriou”)
1087	Richard A. Berger et al., *Determining the Rotational Alignment of the Femoral Component in Total Knee Arthroplasty Using the Epicondylar Axis*, 286 Clinical Orthopaedics and Related Research 40 (1993) (“Berger”)
1088	U.S. Patent Application No. 11/671745 (filed February 6, 2007) issued as U.S. Patent No. 8,066,708 (“the ’745 application”)
1102	Declaration of Jay D. Mabrey, M.D.

Petitioner Smith & Nephew, Inc. ("Petitioner" or "Smith & Nephew") requests *inter partes* review in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.* of Claims 66-81 of U.S. Patent No. 7,981,158 ("the '158 patent"), which issued on July 19, 2011, and is purportedly owned by ConforMIS, Inc. ("ConforMIS").

I. MANDATORY NOTICES PURSUANT TO 37 C.F.R. § 42.8(A)(1)

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

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

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

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

ConforMIS asserted the '158 patent against Smith & Nephew in co-pending litigation captioned *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass. filed Feb. 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 (IPR 2017-00115 and 2017-00307); 8,377,129 (IPR2017-00372); 8,551,169 (IPR2017-00373); and 9,295,482 (IPR2017-00487 and IPR2017-00488). Petitioner is filing a petition challenging claims 1-65 of the '158 patent concurrently herewith.

C. Lead and Backup 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.

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

Please address all correspondence to counsel at the addresses above. Petitioner also consents to electronic service by email to BoxSMNPHL.168LP2-2@knobbe.com.

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

Petitioner certifies that the ’158 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the patent claims on the grounds identified in this petition. The present petition is being filed within one year of service of the original complaint against Petitioner in the district court litigation.

II. SUMMARY OF ISSUE PRESENTED

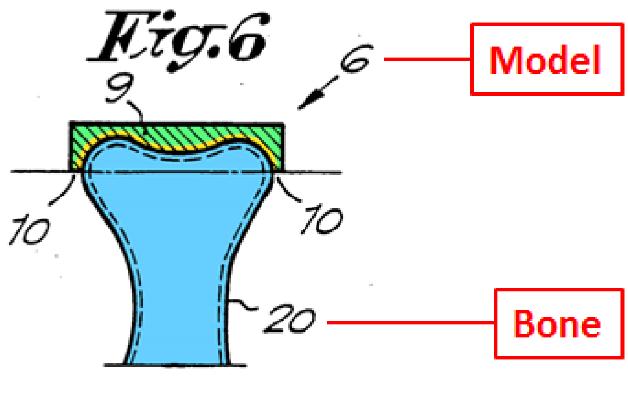
The claims of the ’158 patent generally recite a method of creating a “patient-specific instrument” (or a “patient-matched surgical tool”) for implanting an implant (e.g., a knee implant). Independent Claim 66, for example, claims a method of creating the instrument based on two sets of image data: (1) a first image data set; and (2) a second image data set, which is x-ray image data. The first image data set is of a different type than the second image data set. The instrument has a patient-specific surface that is derived from the first image data set and a tool guide (e.g., a slot, surface, or hole for guiding a drill or saw) that is oriented based on information derived from the second image data set.

Independent Claims 69 and 81 are similar to Claim 66. Independent Claim 72 is also similar, but it does not specify that the second image data set is x-ray image data. Claim 72 recites determining a joint axis (e.g., the mechanical axis) from the second image data set and orienting the guide relative to the joint axis.

Independent Claim 73 recites a method of implanting an implant using the patient-specific instrument similar to the instrument claimed in Claim 66. The dependent claims add limitations regarding orientation of the guide relative to a joint axis, deriving the joint axis from the second image data set, linking or attaching an additional surgical instrument, and cutting or drilling the joint for implanting the implant.

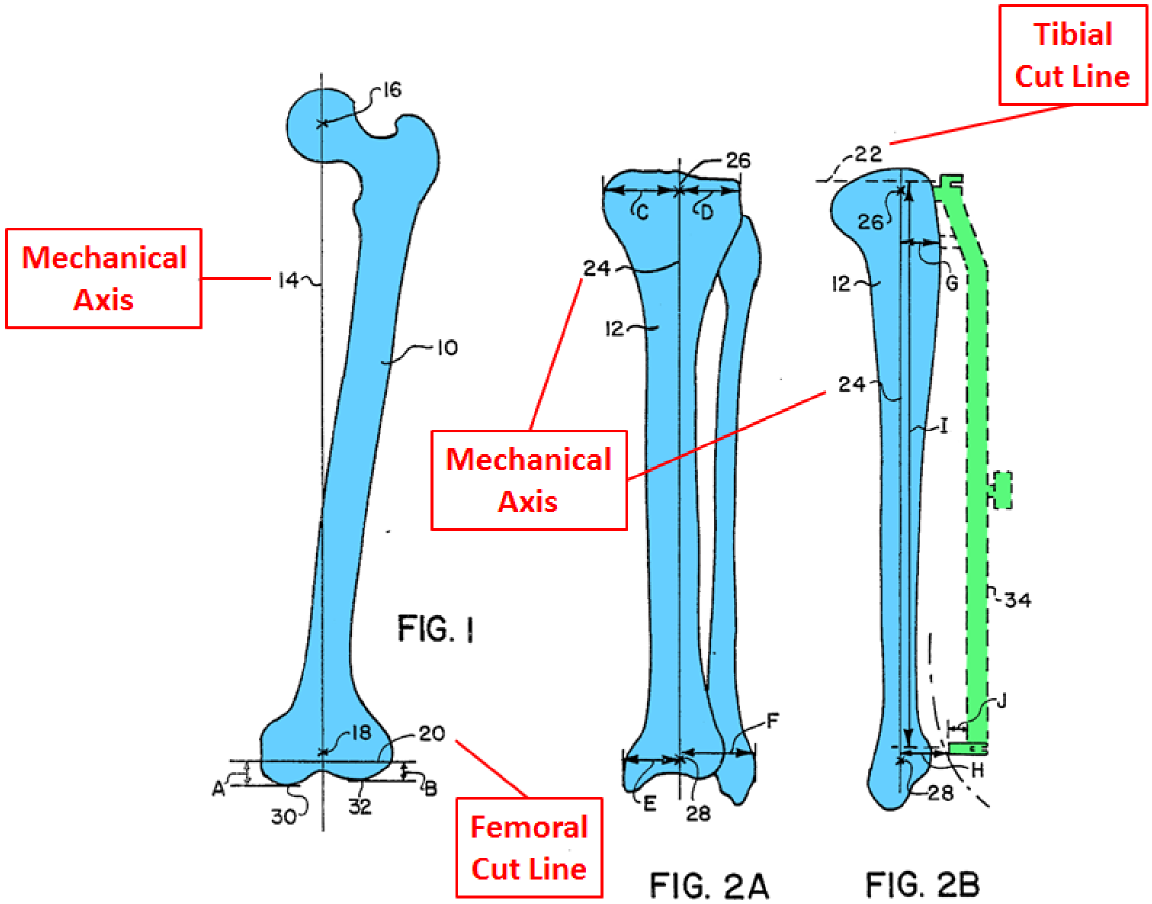
The ’158 patent describes that the purported invention includes obtaining first image data (e.g., CT or MRI) of a joint to determine the surface contours of the instrument. Ex. 1001 at 30:34-52, 65:2-8, 70:41-56. Second image data (e.g., x-ray image data) is used to determine the mechanical axis, which in turn determines the orientation of the instrument’s tool guide. *Id.* at 34:47-64, 72:5-7, 76:64-77:7.

Methods for making such instruments were not patentable at the time of the patent’s earliest possible priority date in May, 2001. By that time, using image data (e.g., CT or MRI) to create an instrument having a surface that matches a corresponding surface of a patient’s joint was well-known. For example, Radermacher, which published in 1993, and CAOS, which published in 1998, disclosed creating a patient-specific instrument customized based on MRI and/or CT data to match the surface of a patient’s joint, such as the knee. Similarly, in 1995, Swaelens disclosed using CT or MRI data to create a patient-specific instrument that "fits perfectly" on a patient's joint. As shown below, Swaelens's instrument (model) matches the surface of the joint.[1]



By May, 2001, it was also well-known to use image data (e.g., x-ray data) to determine a patient's mechanical axis, and to use such data to orient the guides of the instrument, e.g., to align guides so that the cuts are perpendicular to the mechanical axis. For example, Woolson, which published in 1989, disclosed using "radiant energy" imaging data (e.g., x-ray) to identify a patient's mechanical axis and to make cuts that are perpendicular to such axis. As shown below, Woolson disclosed determining the axes (14, 24) and orienting a cutting guide such that the cutting paths (20, 22) are aligned perpendicular to the axis:

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



Numerous references taught that such alignment was essential to the success of the knee surgery. *See, e.g.*, Ex. 1031 at Abstract, 1:26-36; Ex. 1036 at Abstract, 2:18-35, 7:7-36; Ex. 1037 at 758-60; Ex. 1032 at 1:20-22, 1:41-46, 3:1-33.

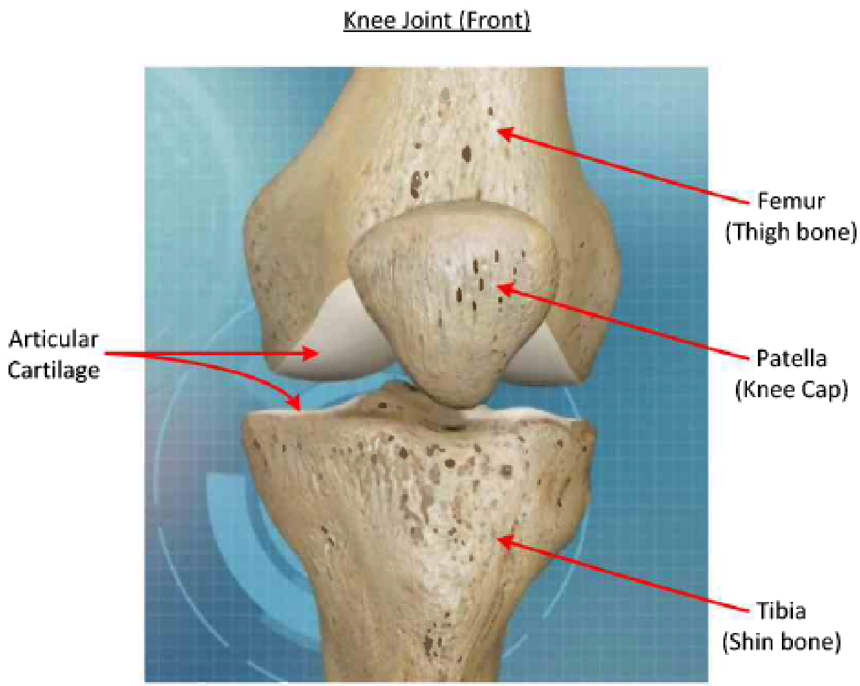
Not only was it well-known to use first image data, such as CT or MRI, to create instruments with patient-specific surfaces (as disclosed in CAOS, Radermacher, and Swaelens), and not only was it commonplace to use second image data to orient a guide (as disclosed in Woolson), but several references disclosed both of these features. CAOS disclosed that the orientation of the instrument's tool guide is based on separate image data, namely topograms. Swaelens disclosed that the instrument's tool guide is oriented based on additional image data that specifies "a place where, a direction in which, … or an angle at which one must cut." Ex. 1007 at 7:17-21, 10:25-30.

In view of the prior art, ConforMIS's claims should have never issued. As one of 60+ patent applications in a family of continuation applications that was serially prosecuted for nearly 14 years (and continues today), the claims of the '158 patent slipped through the Patent Office with nothing but a double-patenting rejection despite the vast array of highly relevant—and invalidating—prior art references. Upon issuance, and despite ConforMIS's knowledge of the highly relevant prior art that published nearly a decade before its patent applications were filed, ConforMIS asserted its unpatentable claims against Smith & Nephew, one of the world's leading knee-implant companies. Although the claims of the '158 patent avoided substantive examination during the application process, the claims are clearly unpatentable and should therefore be canceled.

III. INTRODUCTION AND STATE OF THE ART

A. Knee Joint Anatomy

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



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

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

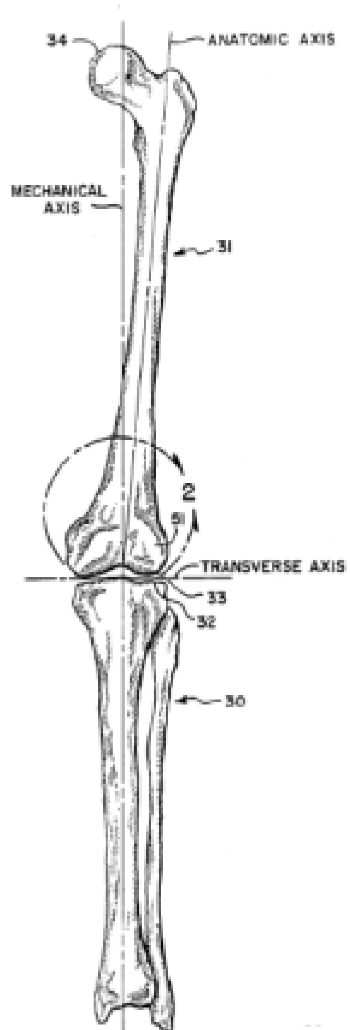


FIG. 1

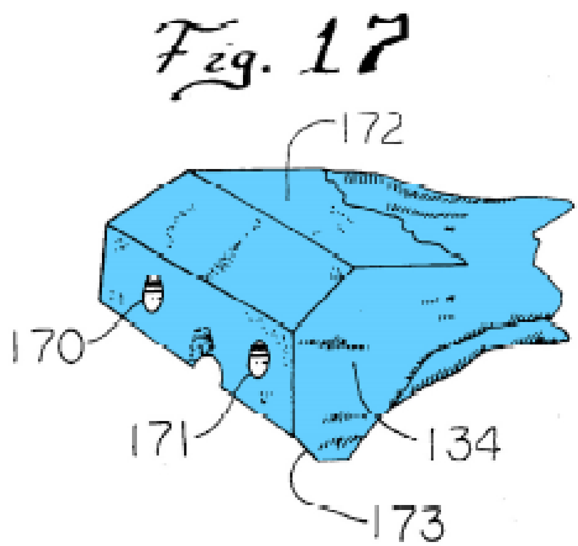
The femur and tibia also each define an “anatomic axis” which, as shown above, represents the axis that extends along the center of the bone. Ex. 1102 ¶¶37-38.

B. Knee Replacement Procedures

When articular cartilage has been damaged by disease such as osteoarthritis, a surgeon can replace portions of the knee with artificial components. *Id.* ¶¶39-42.

Such surgery, which is referred to as "knee arthroplasty," was known for decades before ConforMIS filed the '158 patent. *Id.* ¶34.

During knee arthroplasty, a surgeon must prepare a patient's bone to receive an implant. *Id.* ¶¶39-42. As part of the preparation, the surgeon typically removes a portion of the bone to shape the bone to receive the implant. *Id.* The image below shows the end of a femur that has been prepared in a typical manner, i.e., with flat bone surfaces onto which an implant component can be seated and holes into which pegs on the implant can be placed. *Id.*



Ex. 1011 at 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 instruments or tools with holes, slots, or surfaces that guide the surgeon's tools as the surgeon cuts (resects) the bone or drills holes into bone, rather than cutting free-handed. Ex. 1102 ¶¶41-42. Tools having slots for guiding a saw blade, for example, have long been known in the art. *Id.* The tool disclosed in Robie (shown below) is just one example:

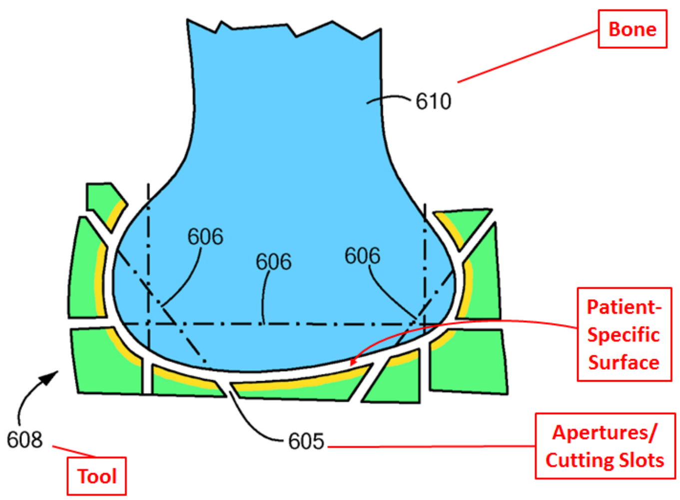
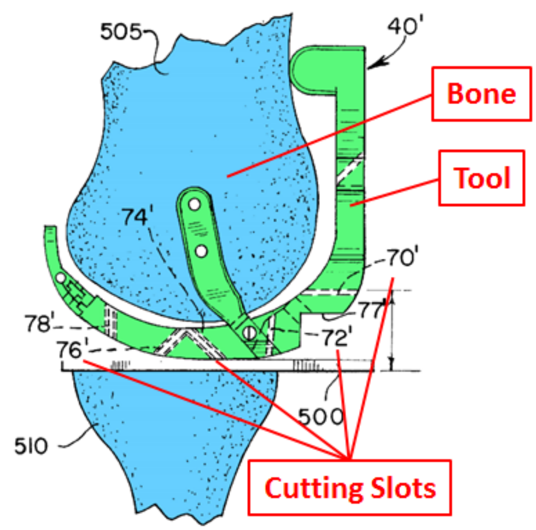


FIG. 24B

FIG. 10a



<u>’158 Patent (Ex. 1001 at Fig. 24B)</u> <u>Robie (Ex. 1012 at Fig. 10a)</u>

To ensure the proper orientation of a knee implant, and to ensure that the leg is in its proper alignment after surgery, surgeons typically use imaging (e.g., x-ray, CT, etc.) to determine an axis of the joint and then align the cuts relative (e.g., perpendicular) to the axis. Ex. 1102 ¶¶47-49; Ex. 1032 & 1036 (X-ray); Ex. 1031 (X-ray, CT); Ex. 1033 (topograms). The ’158 patent admits that this practice was conventional and known in the art. Ex. 1001 at 30:34-52, 34:47-39:50.

C. Creating Patient-Specific Instruments Based on Imaging the Joint

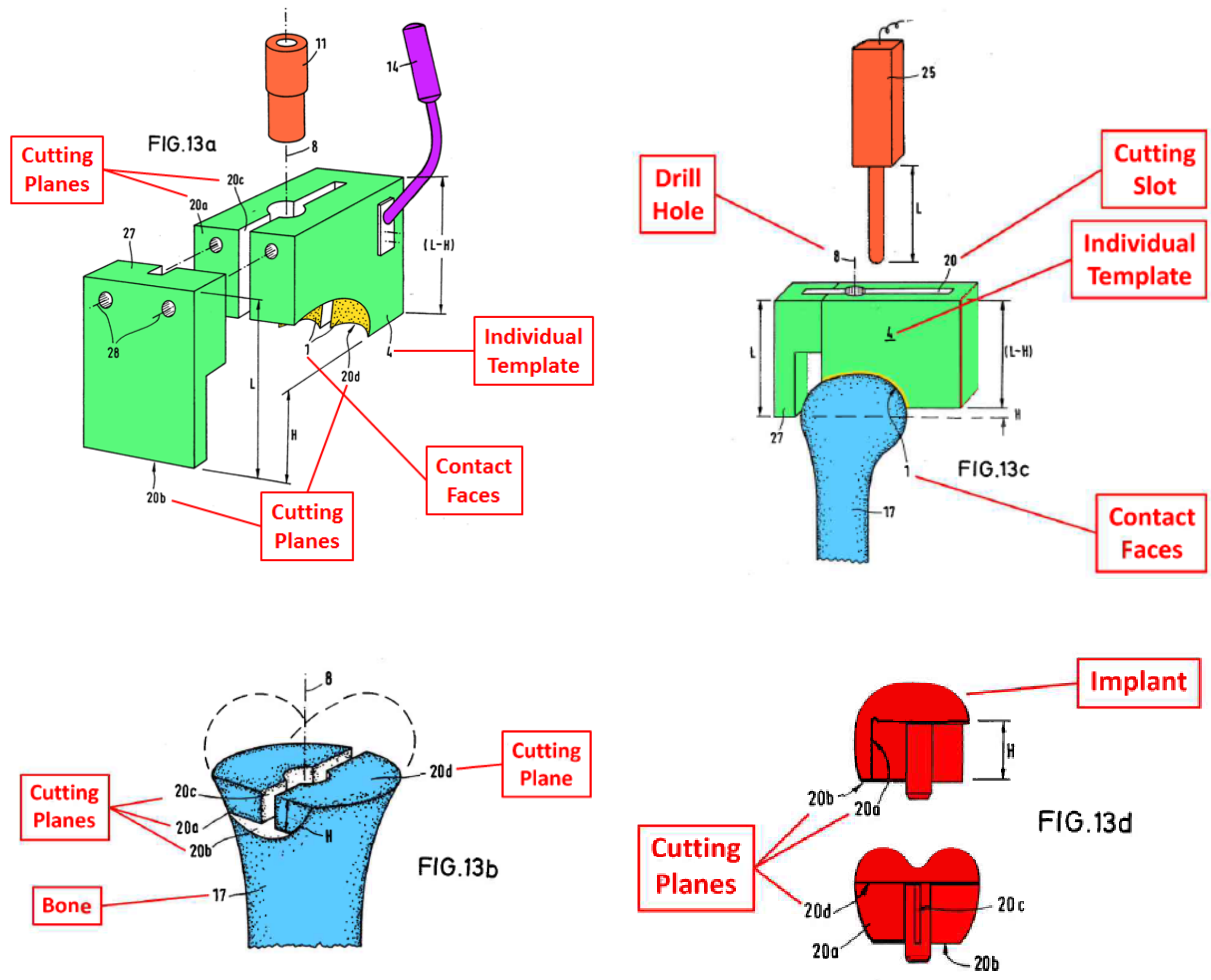
1. Using First Image Data to Create Instruments Having Patient-Specific Surfaces Was Well-Known

Prior to the 1990s, surgeons had various ways of aligning cutting blocks so that the cutting slots and drill holes would be properly oriented. Ex. 1102 ¶45. In the 1990s, however, patient-specific cutting guides—guides that included a patient-specific surface such that the guide could be positioned by placing the instrument on a particular patient's joint surface—became widely known. *Id.* ¶¶43-44, 50-57.

For example, in 1993, Radermacher described using MRI[2] and/or CT data to create an "individual template" for guiding surgical drills and saws during orthopedic surgery. *Id.* ¶50. 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. Referring to Figures 13a-d (reproduced below), Radermacher disclosed that 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

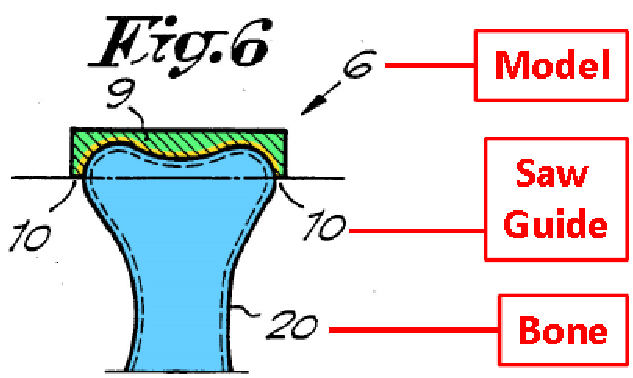
[2] Some references refer to "nuclear spin tomography" or "NMR," which is old terminology for what is now referred to as MRI. Ex. 1102 ¶44, n.1; *see also* Ex. 1015 at 1 (Magnetic resonance imaging or MRI is known by a variety of other names, including NMR, nuclear magnetic resonance, spin imaging and various other names.).

drilled, and cuts made along cutting planes 20a-d, resulting in a resected bone (Fig. 13b) onto which an implant (Fig. 13d) could be seated. *Id.* at 30.



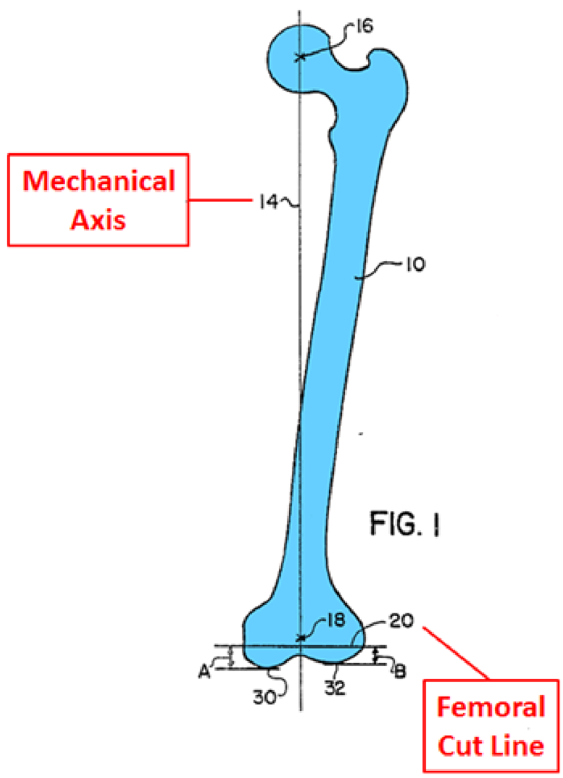
In 1998, CAOS, which is co-authored by Radermacher, described designing patient-specific surgical instruments to achieve a "precise spatial correspondence between the individual bone structure in situ and the intended position of the tool guides." Ex. 1033 at 29. In particular, CAOS described designing patient-specific surgical instruments for the knee, spine, and hip joints by taking multiple CT and/or MRI images of the joint, creating a computer model of a surgical instrument that matches the surface of the bone, and making the instrument using a 3D printer. *Id.* at 28, 29, 31, 34, 37. The position and orientation of surgical guides relative to the joint axis is incorporated into the instrument. *Id.* at 29-31; *see also* Ex. 1102 ¶55.

In 1995, Swaelens disclosed obtaining CT or MRI images of a patient's knee joint, creating a digital model, adding image data indicating the orientation of cutting slots and/or drill holes to the digital model to create a "perfected model," and then making a "model" that "can be placed as a template on the bone of the patient 1 during surgery and which fits perfectly to it." Ex. 1007 at 5:1-5, 6:24-29, 7:17-21, 8:30-9:13, 10:23-30; *see also* Ex. 1102 ¶56. As shown below, Swaelens's instrument includes a saw guide. *Id.* at 13:19-25, Fig. 6.



2. Using Second Image Data to Align Guides Relative to the Mechanical Axis Was Well-Known

Because the location and angle of the cuts made by the surgeon are critical to the success of the surgery, the alignment of the tool guide is also critical. Since the 1980s, surgeons have used alignment guides (rather than cutting free-hand) to ensure that the tool guides are properly aligned with the mechanical axis. Ex. 1102 ¶45. For example, Dunn, which published in 1988, disclosed positioning the "cutting surface of the guide [in] a plane that is perpendicular to the patient's mechanical axis," which is determined from x-rays. Ex. 1036 at 3:25-30, 6:49-55. As illustrated below, surgeons typically use the mechanical axis as a reference for aligning the guides. Ex. 1102 ¶¶45-46.



Ex. 1031 at Fig. 1.

By 1990, using x-ray or CT imaging for determining the mechanical axis was commonplace. *See* Ex. 1102 ¶¶46-49; Ex. 1032 at 3:22-33; Ex. 1036 at 6:45-7:29; Ex. 1031 at Abstract, 1:37-46, 2:28-59. The ’158 patent admits that this practice was conventional and known in the art. Ex. 1001 at 30:34-52, 34:47-39:50.

In 1998, CAOS described determining the “bone axis” using topograms, which are an alternative to x-rays. Ex. 1033 at 31; Ex. 1102 ¶¶55, 105. CAOS also disclosed that the patient-specific instrument’s saw guide is oriented relative to the bone axis to ensure the “accurate placement of [knee] implant components with respect to the individual mechanical axis of the leg.” Ex. 1033 at 31; Ex. 1102 ¶55.

IV. THE ’158 PATENT

A. Overview of the ’158 Patent

The ’158 patent discloses nothing more than the conventional use of two sets of imaging data (e.g., CT and x-ray data) to create conventional patient-specific instruments. Specifically, the ’158 patent describes using “conventional” imaging techniques to determine the bone surface and shape. Ex. 1001 at 30:34-52, 65:1-8, 70:41-56, 96:33-97:7. The images are used to shape the instrument so that it has a patient-specific surface, i.e., a “surface and shape that will match all or portions of the articular … or other bone surface and shape, e.g. similar to a 'mirror image,'" as was well-known. *Id.* at 70:41-56; Ex. 1102 ¶¶58-59.

Just as in the prior art, the '158 patent explains that the bone may be resected along line 1958, which is "perpendicular to the mechanical axis 1910." Ex. 1001 at 69:32-42; Ex. 1102 ¶60.

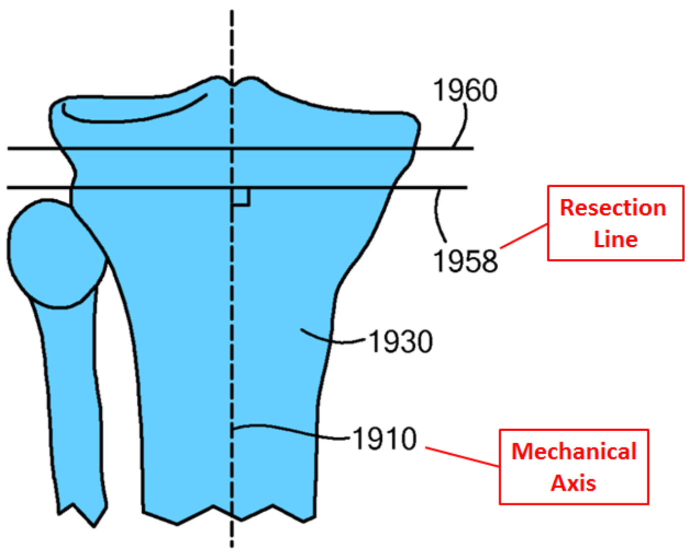


FIG. 21B

Id. at Fig. 21B. The '158 patent admits that it was well-known that conventional imaging, e.g., x-ray imaging, could be used to determine a patient's anatomical and biomechanical (i.e., mechanical) axes. Ex. 1001 at 30:34-52, 34:47-39:50; Ex. 1102 ¶61.

B. Prosecution History

The application that led to the ’158 patent was filed on June 9, 2008, with 81 claims added by a preliminary amendment. Ex. 1017 at 233-45. The Examiner rejected the claims for nonstatutory double patenting over a related patent U.S. 7,534,263. *Id.* at 180-84 (noting that while the ’263 patent claims use of a single set of image data, it would have been obvious to a POSITA to “duplicate the image data”). In response, ConforMIS filed a terminal disclaimer, and the Examiner allowed the claims. *Id.* at 19, 44.

During prosecution, applicant submitted the CAOS, Radermacher, Woolson, and Alexander to the Patent Office, but they were among more than 450 patent and non-patent documents, and they were never applied by the Examiner. *Id.* at 255-78, 282-94.

C. Priority

The ’158 patent claims priority to a number of provisional and continuation-in-part applications dating back to May 25, 2001. Ex. 1001. However, the earliest possible priority date for the ’158 patent is November 25, 2003 (filing date of the ’451 patent), which is the earliest disclosure of first and second image data sets. In co-pending litigation, ConforMIS contends that the earliest effective priority date for the claims of the ’158 patent is May 14, 2002. For purposes of this petition, and as long as ConforMIS does not assert that it is entitled to an earlier priority date, Petitioner does not challenge the asserted priority date (May 14, 2002) because all of the references relied on herein pre-date that date. Petitioner reserves the right to challenge the priority date if necessary.

D. Level of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") for purposes of the '158 patent 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 has at least three years of experience learning from these doctors about the use of such devices in joint replacement surgeries. Ex. 1102 ¶¶29-31.

V. CLAIM CONSTRUCTION

Pursuant to 37 C.F.R. § 42.100(b), and solely for the purposes of this review, Petitioner construes the claim language such that the claims are given their broadest reasonable interpretation in light of the specification of the '158 patent. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016). Petitioner does not believe that any claim construction is necessary. However, Petitioner understands the term "articular surface of [a] joint," as recited in Claim 81, to refer to "the bone surface and/or cartilage surface of an articulating portion of a joint." Ex. 1102 ¶¶68-71.

VI. STATEMENT OF PRECISE RELIEF REQUESTED

A. Grounds

Petitioner requests that Claims 66-81 be canceled for the following reasons:

Ground 1. Claims 66-72 and 81 are unpatentable under 35 U.S.C. § 103(a) in view of CAOS in combination with Woolson and Alexander.

Ground 2. Claims 73-80 are unpatentable under 35 U.S.C. § 103(a) in view of CAOS in combination with Woolson, Alexander, and Radermacher.

Additional support for this Petition is included in the Declaration of Jay D. Mabrey, M.D. Ex. 1102. Dr. Mabrey received his M.D. degree from Weill Cornell Medical College in 1981 and is currently the Chief of the Department of Orthopaedics at Baylor University Medical Center in Dallas, Texas. *Id.* ¶¶5-8. Dr. Mabrey is also a Professor of Surgery at Texas A&M Health Science Center College of Medicine. *Id.*

B. Status of References as Prior Art

CAOS, Woolson, Alexander, and Radermacher are prior art to the ’158 patent under § 102(b) because they were published in 1998, 1989, 2000, and 1993, respectively, which is more than one year before May 14, 2002.

VII. SPECIFIC PROPOSED GROUNDS OF UNPATENTABILITY

A. Ground 1: Claims 66-72 and 81 Are Unpatentable as Obvious Over CAOS in Combination with Woolson and Alexander.

1. Overview of CAOS

CAOS recognizes that, because standard surgical tool guides were based "on average anatomic geometries," their positioning on the bone was not accurate. Ex. 1033 at 29. To solve this problem, CAOS discloses designing patient-specific surgical instruments ("individual templates") to achieve "the precise spatial correspondence between the individual bone structure in situ and the intended position of the tool guides." *Id.*; Ex. 1102 ¶¶73-75. The instruments are designed by taking multiple CT or MRI images of the joint and topograms, creating a computer model of an instrument that matches the surface of the bone, and making the tool using a 3D printer. Ex. 1033 at 29, 31, 34, 37. The instruments can be used for knee, spine, and hip surgeries. *Id.* at 28, 30-36; Ex. 1102 ¶75.

For knee arthroplasty, CAOS discloses the importance of placing implant components accurately in relation to the patient's mechanical axis of the leg. Ex. 1033 at 31. To ensure that the knee joint is correctly prepared for implantation, topograms are used to identify the bone axis and to align the tool guides. *Id.*; Ex. 1102 ¶¶76-78. The position and orientation of the guides relative to the axis is incorporated into the instrument. Ex. 1033 at 29, 31; Ex. 1102 ¶79.

2. Independent Claim 66

Independent Claim 66 recites a method of creating a patient-specific instrument based on a first image data set and a second image data set, which is x-ray image data. The first image data set is of a type that is different from x-ray image data. The instrument has: (i) a patient-specific surface that is derived from the first image data set and that substantially matches a corresponding surface portion of a joint; and (ii) a surgical instrument guide oriented relative to the patient-specific surface based on information derived from x-ray image data. CAOS in combination with Woolson and Alexander would have rendered this claim obvious.

a. Creating an Instrument Based on First and Second Image Data Sets

The '158 patent describes determining the patient-specific surface of the instrument based on a first image data set (e.g., CT image data) of the knee. Ex. 1001 at 30:34-52, 65:2-12, 70:41-56. Second image data set (e.g., x-ray data) is used to identify the joint axis (e.g., mechanical axis), which in turn determines the orientation of the instrument's surgical tool guide relative to the patient-specific surface of the instrument. *Id.* at 34:47-39:50, 72:5-7, 76:64-77:22. A POSITA would have understood that CAOS in combination with Woolson discloses designing the instrument based on a first image data set (as disclosed in CAOS) and a second image data set (as disclosed in CAOS and Woolson). Ex. 1102 ¶¶84-104.

ConforMIS admits that CAOS discloses creating a custom instrument based on CT image data (first image data set) of the knee joint. Ex. 1024 at 26. CAOS discloses obtaining CT images of a joint and generating a patient-specific surgical instrument (referred to as an "individual template"). Ex. 1033 at 28-29, 31; Ex. 1102 ¶85. The instrument is "customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data" to include "contact faces" (patient-specific surface) that "fit exactly on the bone." Ex. 1033 at 29; Ex. 1102 ¶¶85-86.

CAOS also discloses that the instrument includes one or more standard or custom tool guides. *Id.* at 29, 30, 31. For example, a "conventional saw guide can be mounted on the individual template, which serves as a reference base for subsequent work on the bone." *Id.* at 31; *see also id.* at 29 (surgical tool guides are integrated or mounted on the instrument "in predefined positions for different types of interventions"). CAOS discloses that "the planned position and orientation of the tool guide in spatial relation to the bone is stored in a structural way and can be reproduced in situ adjusting the position of the contact faces of the template until they fit exactly on the bone." *Id.* at 29. Such design allows the instrument to serve as the reference base that ensures "the precise spatial correspondence between the individual bone structure … and the intended position of the tool guides," which facilitates "exact, safe, and fast implementation of planned surgery." *Id.* at 29, 31 ("By mounting these conventional tool guide systems on an individual template as a basic customized reference, it is possible to reproduce the preoperatively planned position exactly" during surgery.); Ex. 1102 ¶¶87-89.

CAOS also discloses that that "accurate placement of [knee] implant components with respect to the individual mechanical axis of the leg is essential." Ex. 1033 at 31. This is not surprising. By the 1990s, it was commonplace to align the cutting paths perpendicular to a patient's mechanical axis, as such alignment was necessary to ensure proper alignment of the knee implant. Ex. 1102 ¶¶90-93; *see also* Ex. 1031 at Abstract, 1:26-36, 4:7-19; Ex. 1036 at Abstract, 1:56-67, 10:60-11:11.

CAOS teaches that topograms (second image data set) are used to identify this essential axis. Ex. 1033 at 31 ("topograms could be used to identify the bone axis"); Ex. 1102 ¶94. CAOS also discloses that, for the "preservation of the posterior cruciate ligaments and the nerves and vessels," the "geometry of the cut with its position, orientation, and limitations was planned on the basis of CT images." Ex. 1033 at 31. While CT data is used to preserve these vital structures during surgery, CAOS teaches using a second image data set (topograms) to specify the positioning and orientation of surgical tool guides (e.g., a cutting guide) on the instrument, which serves as "a reference base" for surgical work on the bone. *Id.*; *see also id.* at 29 (tool guides are "adaptable or integrated into the[] individual templates in predefined positions"); Ex. 1102 ¶94. This ensures alignment of the cuts with the mechanical axis and, accordingly, "accurate placement of [knee] implant components with respect to the individual mechanical axis of the leg." Ex. 1033 at 31; Ex. 1102 ¶¶94-95.

A closely related article (Schiffers), co-authored by Radermacher (first-named author of CAOS), that published in 2000[3] confirms that topograms are used to identify the mechanical axis and to orient the cutting guides. Schiffers discloses that "the application of the individual templates for performing the tibial incision in knee replacement" is being tested. Ex. 1064 at 640. Schiffers illustrates the "[p]lanning of the tibial incision …. [a]ided by 3D reconstructions" (Figure 6a) and "topogram" (Figure 6b). *Id.* at 639. As shown below, topogram data is used for orienting the tibial cut relative (e.g., perpendicular) to the mechanical axis. *See also* Ex. 1102 ¶94.

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[3] This article was originally published in German. Ex. 1058. Accordingly, pursuant to 37 C.F.R. § 42.63(b), Petitioner submits herewith an English translation and an affidavit attesting to the accuracy of the translation. Ex. 1064; Ex. 1065.

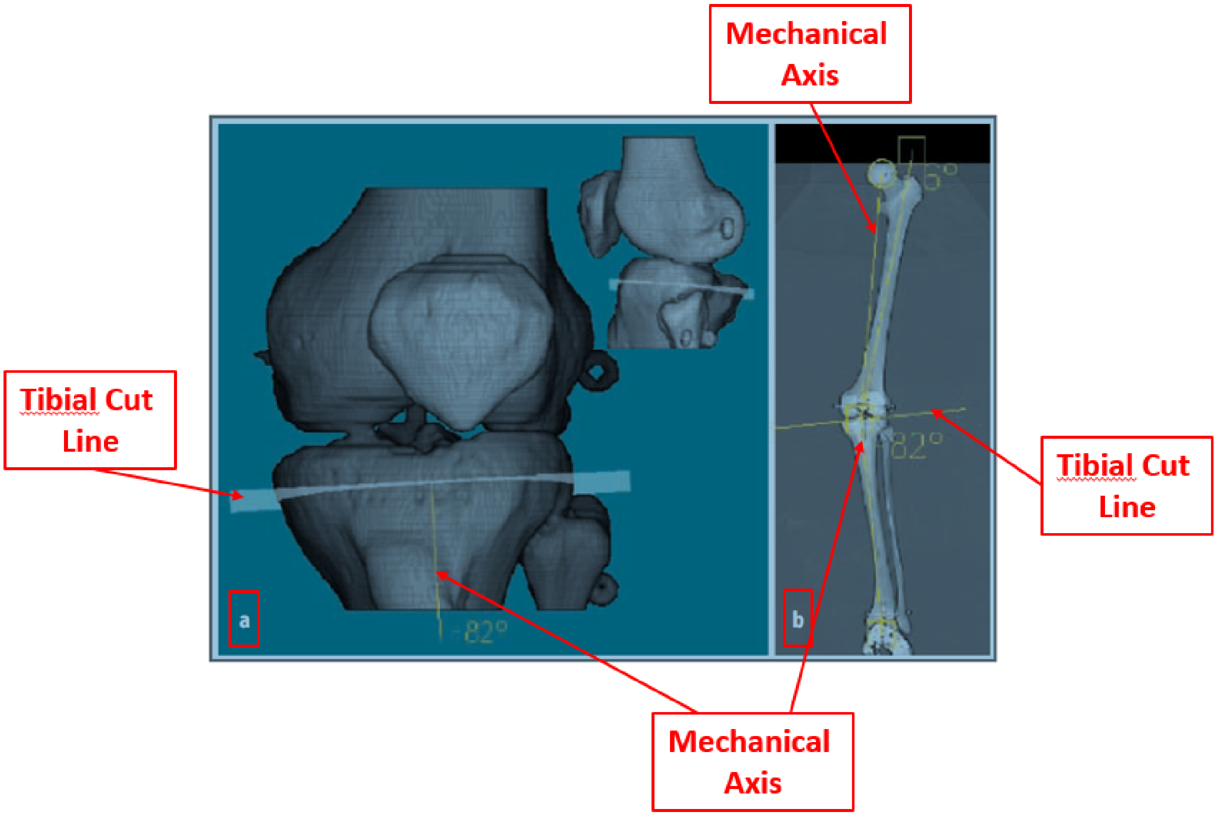


Fig 6 a, b ▲ **Planning of the tibial incision for the endoprosthetic restoration of the knee joint. Aided by 3D reconstructions** (a) **and topogram** (b)

Ex. 1064 at Figure 6a, b.

Thus, CAOS discloses creating the instrument based on: (1) first image data set (e.g., CT or MRI data), which ensures the exact fit of the instrument on the bone; and (2) second image data set (e.g., topograms), which ensures proper positioning of surgical tool guides on the instrument and alignment of the cutting paths relative to the mechanical axis. Ex. 1102 ¶96.

Even if CAOS did not explicitly disclose that topograms ensure proper positioning of tool guides on the instrument, it would have been obvious to a

POSITA in view of Woolson. *Id.* ¶¶97-103. To ensure proper alignment of the knee implant with the mechanical axis, it was standard practice to determine the mechanical axis and the orientation of the cuts from image data (e.g., x-ray or CT data). Ex. 1102 ¶¶98-102; *see also* Ex. 1031 at Abstract, 1:26-50, 4:9-44, 5:9-49; Ex. 1036 at Abstract, 6:45-7:35. For example, Woolson discloses orienting surgical tool guides based on image data to provide cutting paths that are aligned perpendicular to the mechanical axis. In particular, Woolson first recognizes that all knee replacement systems align the implant with the patient's mechanical axis because doing so produces better long-term results. Ex. 1031 at 1:26-36. Woolson then 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. *Id.* at 4:7-19; *see also id.* at Abstract, 2:50-59, 4:20-26. Woolson discloses preoperatively identifying the mechanical axis and planning the cuts (i.e., aligning the cutting guides) using x-ray or CT imaging. *Id.* at Abstract, 1:37-50, 2:28-59, 3:50-4:48, 5:9-49, 6:5-7:67; Ex. 1102 ¶¶99-101.

Like Woolson, CAOS teaches identifying the bone axis based on topograms and aligning the implant relative to the mechanical axis. Ex. 1033 at 31; Ex. 1102 ¶101. Also, consistent with Woolson, Schiffers confirms that topograms are used for orienting the cutting paths relative to the mechanical axis. Ex. 1064 at 639-40.

Thus, in view of Woolson, a POSITA would have understood that topograms are used to position or orient the surgical tool guides (e.g., align a cutting guide relative to the mechanical axis). Ex. 1102 ¶101. Accordingly, a POSITA would have understood that CAOS in combination with Woolson discloses creating the patient-specific instrument based on: (1) first image data set (e.g., CT data as disclosed in CAOS), which ensures the exact fit of the instrument on the bone; and (2) second image data set (e.g., topograms as disclosed in CAOS or CT or x-ray image data as disclosed in Woolson), which ensures proper positioning of surgical tool guides on the instrument so that cutting paths are aligned (e.g., perpendicular) with the mechanical axis. *Id.* ¶102.

A POSITA would have been motivated to combine CAOS with Woolson because Woolson teaches that alignment relative to the mechanical axis occurs in all knee replacement systems and is critical to the long-term success of knee-replacement surgery. *Id.* ¶103; Ex. 1031 at 1:26-36. Similarly, CAOS discloses that alignment of the knee implant with the mechanical axis is essential. Ex. 1033 at 31. Further, Woolson and CAOS are in the same field (knee arthroplasty) and describe the same devices (cutting guides), and rely on similar imaging technology (e.g., x-rays and topograms). Ex. 1102 ¶103. Moreover, orienting the surgical tool guides in CAOS relative to the mechanical axis based on second image data (topograms) 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 (CAOS's) in the same predictable way. *Id.*

Accordingly, it would have been obvious to create a patient-specific instrument based on first and second sets of image data. *Id.* ¶104.

b. Second Image Data Set is X-Ray Image Data

A POSITA would have known that topograms, which are similar to two-dimensional CT scout images, are an alternative to x-ray image data. *Id.* ¶105. The '158 patent admits that a "CT scout scan is typically a single, 2-D radiographic [i.e., x-ray] image" and describes CT scout scans and x-rays as alternatives. Ex. 1001 at 38:38-40, 36:21-26 (use of cross-sectional or volumetric imaging is more accurate "when compared to x-rays or CT scout scans"); *see also id.* at 41:67-42:7 ("[CT] scout scan … or a weight bearing x-ray"); Ex. 1102 ¶105. Thus, it would have been obvious to a POSITA to use x-ray imaging in place of topograms. Ex. 1102 ¶105; *see also see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("simple substitution of one known element for another" is obvious).

In addition, Woolson discloses using x-ray image data to determine the mechanical axis and the orientation of the cutting guides and cutting paths relative to such axis. Ex. 1031 at Abstract, 1:26-50; *see also id.* at 2:28-59 (scanning using "radiant energy," such as x-ray imaging), 6:5-7:67; Ex. 1102 ¶106.

Thus, it would have been obvious to modify CAOS to use x-ray image data in place of topograms. Ex. 1102 ¶106.

c. First Image Data Set Is of a Type that Is Different From X-Ray Image Data

A POSITA would have understood that CT data is of type that is different from x-ray data. *Id.* ¶¶107-09. A POSITA would have known that three-dimensional CT data has higher resolution and is more accurate than two-dimensional x-ray image data. *Id.* ¶¶108-09; Ex. 1033 at 29 (CT imaging produces "three-dimensional reconstructions of the bone structures"); *see also id.* at 28, 30, 32, 34. The '158 patent confirms this by admitting that CT imaging is "cross-sectional or volumetric imaging" that produces "more accurate identification of … anatomical and/or biomechanical axis ... when compared to x-rays." Ex. 1001 at 36:6-26; *see also id.* at 38:38-40 ("CT scout scan is typically a single, 2-D radiographic image ... lacking high spatial resolution"). Further, the '158 patent admits that x-ray and CT imaging are different imaging modalities. *Id.* at 34:51-35:6, 37:48-38:14 (axis measured on an x-ray "can be cross referenced with another imaging modality such a CT or MRI scan"), 40:4-27, 77:1-12, 110:33-36 (describing x-ray imaging "but also cross-sectional imaging modalities such as CT").

In addition, a POSITA would have understood that CAOS discloses using MRI scanning in place of CT imaging. Ex. 1033 at 37 ("It is planned to integrate additional tools into the system (in particular for hip, knee, and spine surgery) [and] magnetic resonance image processing modules...."); Ex. 1064 at 640 ("reduction and partial replacement of the required CT data with corresponding MRI data" was planned for the design of individual templates); Ex. 1102 ¶¶86, 110. A POSITA would have known that MRI image data is of a different type than x-ray image data because MRI scanning uses magnetic fields and radio waves rather than x-ray radiation and produces higher resolution, three-dimensional image data. Ex. 1102 ¶¶110-12. The '158 patent admits that x-ray imaging and MRI scanning are different imaging modalities. Ex. 1001 at 34:51-35:6, 37:48-38:14, 40:4-27, 77:1-12, 110:33-36.

Accordingly, a POSITA would have understood that first image data set in CAOS (CT or MRI) is of type that is different from x-ray data. Ex. 1102 ¶¶107-112.

d. A Patient-Specific Surface that is Derived from the First Image Data Set and that Substantially Matches a Corresponding Surface Portion of a Joint

The '158 patent describes deriving a contact surface "for engaging a surface of a joint" using conventional imaging techniques, such as CT imaging. Ex. 1001 at 16:48-53, 17:32-40, 30:34-52. A POSITA would have understood that a surface portion of a joint includes bone surface, particularly when the cartilage is worn out. Ex. 1102 ¶113.

ConforMIS admits that CAOS discloses creating an instrument with a contact surface that matches and fits the bone surface. Ex. 1024 at 26. CAOS discloses that the instrument is "customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data" to include a patient-specific surface that "fit[s] exactly on the bone." Ex. 1033 at 29. Accordingly, CAOS discloses that the patient-specific surface *substantially* matches a corresponding surface portion of a joint, which includes the bone surface. Ex. 1102 ¶¶113-14.

Even if ConforMIS attempts to argue that substantially matching the corresponding surface potion of the joint requires matching the cartilage surface, this would have been obvious. *Id.* ¶¶115-18. Alexander discloses that imaging techniques, including CT and MRI, "are useful for electronically generating a cartilage image." Ex. 1004 at 14:16-21. Alexander discloses that CT or MRI imaging provides a model of a patient's knee joint, including both bone (gray) and cartilage (black) surfaces:

Id. at Fig. 18C (cropped), 61:19-25; Ex. 1102 ¶116. The ’158 patent relies on Alexander’s prior-art method of determining the shape of the bone and cartilage surfaces of a joint to create patient-specific instruments. Ex. 1001 at 32:1-33:5 (citing WO 02/22014 (Ex. 1016), a later publication of Alexander); Ex. 1102 ¶¶115-16.

Thus, a POSITA would have known that CT or MRI image data disclosed in CAOS can be used to design a patient-specific surface that matches the bone and cartilage surfaces of a joint. Ex. 1102 ¶116. A POSITA would have been motivated to combine CAOS with Alexander because both references are directed to methods of treating diseased and/or damaged joints, are in the same field of endeavor, i.e., imaging the knee joint for preoperative planning of joint surgery, and rely on the same imaging technology. *Id.* ¶117. In addition, bone and cartilage surfaces are the only two joint surfaces to which CAOS's patient-specific instrument could be matched. Given Alexander's disclosure of using imaging 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 bone surface is simply a design choice. *Id.* Thus, the modification would merely reflect a choice from a finite number of identified, predictable solutions with a reasonable expectation of success. *Id.*; *see KSR*, 550 U.S. at 417.

e. A Guide Oriented Relative to the Patient-Specific Surface Based on the Second Image Data Set

CAOS discloses that the instrument (individual template) includes one or more standard or custom tool guides. Ex. 1033 at 29, 30, 31. For example, a "conventional saw guide can be mounted on the individual template [i.e., patient-specific instrument], which serves as a reference base for subsequent work on the bone." *Id.* at 31; *see also id.* at 29. CAOS discloses that "the planned position and orientation of the tool guide in spatial relation to the bone is stored in a structural way and can be reproduced in situ adjusting the position of the contact faces of the template until they fit exactly on the bone." *Id.* at 29. Thus, CAOS discloses that the tool guide is oriented relative to the patient-specific surface of the instrument (i.e., "contact faces of the template"). Ex. 1102 ¶119.

Also, as explained above, CAOS in combination with Woolson discloses orienting a tool guide relative to the mechanical axis of the knee based on second image data (e.g., x-ray image data) to ensure that the cutting paths are aligned perpendicular to this axis. *Id.* ¶120. Because CAOS's instrument includes a patient-specific surface that exactly reproduces the knee joint surface, the instrument incorporates the position of the mechanical axis. *Id.* ¶¶94, 120. Thus, orienting the guide relative to the instrument's patient-specific surface based on the second image data set would have been obvious. *Id.* ¶120.

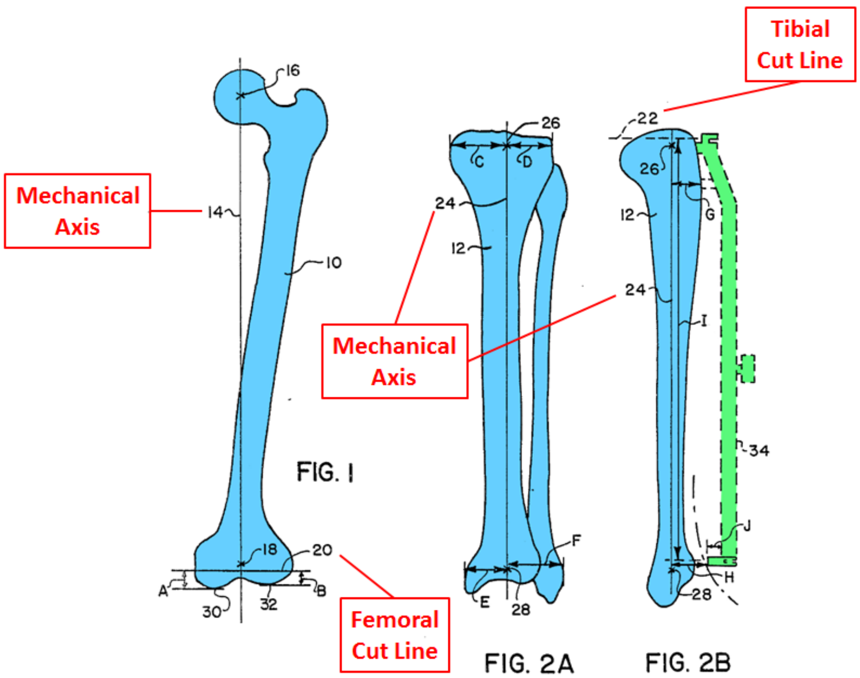
In sum, the method recited in Claim 66 would have been obvious to a POSITA in view of CAOS in combination with Woolson and Alexander. Additional analysis of Claim 66 is provided in the following claim chart. *See also id.* ¶¶121-22.

Claim 66	Exemplary Disclosure in Prior Art
[**preamble**] A method of creating a patient-specific instrument for implanting an orthopedic implant in or about a joint of a patient, the	**<u>CAOS</u>** discloses: "An alternative technique for computerized tomographic image based preoperative three-dimensional planning and precise surgery on bone structures using ***individual templates*** has been developed. For the preoperative customization of these mechanical tool guides, a desktop computer controlled milling device is used as a three-dimensional printer ***to mold the shape of small reference areas of the bone surface automatically into the***

method comprising:	***body of the template*** …" Ex. 1033 at 28 (emphasis added), 29. CAOS is titled: "Computer Assisted ***Orthapaedic*** Surgery With Image Based Individual Templates." *Id.* at 28 (emphasis added); *see also id.* ("The feasibility of this approach has been shown in spine, hip, and knee surgery …."), 30 ("Among the applications of this technique are pedicle screw placement (especially in scoliosis therapy; Fig 2); repositioning osteotomies in spine surgery; puncture of a cystic cavity in the femoral head; intertrochanteric repositioning osteotomy; initial reference osteotomies for total knee replacement (especially in the case of pathologic deformations); periacetabular repositioning osteotomies; open door decompression in the cervical spine; transcorporal decompression in the cervical spine; and decompression in the lumbal spine."), 31. *See also* Ex. 1102 ¶¶82-83.
[a] creating a patient-specific surgical instrument based at least in part on first and second image data sets,	<u>**CAOS**</u> discloses creating a patient-specific instrument ("individual template") based on both the CT images of the joint (first image data set) and topograms used to define the bone axis (second image data set): "Figure 2 shows a feasibility study with a ***CT image based individual template*** for the reference tibial cut for total knee replacement …. The geometry of the cut with its position, orientation, and limitations was planned on the basis of ***CT images*** (slices 2-mm thick and 2-mm apart). ***In addition, topograms could be used to identify the bone axis*****…. *The template has been customized in the areas of the reference surface and the individual copying profile corresponding to the dorsal contour of the tibial bone within the cut plane*.**" *Id.* at 31 (emphasis added), *id.* at 34 ("Computed tomographic scans of the patients normally are done at 3- to 4-mm slice distances with 30 to 40 images including one AP topogram. The data are transmitted to the DISOS planning system with which a nontechnical user can generate individual templates autonomously."); *see also id.* at 28, 29 ("Individual templates are customized on the basis of three-dimensional

	reconstructions of the bone structures extracted from computerized tomographic (CT) image data in accordance with individual preoperative surgical planning…. [T]he planned position and orientation of the tool guide in spatial relation to the bone … can be reproduced in situ adjusting the position of the contact faces of the template until they fit exactly on the bone”), 30, 32, 36. CAOS also discloses that orientation of a surgical tool guide is incorporated into the instrument (“individual template”): “Individual templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data in accordance with individual preoperative surgical planning…. By this means the planned position and ***orientation of the tool guide in spatial relation to the bone is stored in a structural way and can be reproduced in situ adjusting the position of the contact faces of the template until they fit exactly on the bone***.” *Id.* at 29 (emphasis added), 29 (“Mechanical guides for drills, saws, chisels, or milling tools are adaptable or integrated into these individual templates in predefined positions for different types of interventions. Moreover, individual templates can be used for fixation of a reference base for standard tool guides or other devices in a defined position on the bone.”), 30, 31 (“By mounting these conventional tool guide systems on an individual template as a basic ***customized reference***, it is possible to reproduce the preoperatively planned position exactly even in the case of severely deformed bone.” (emphasis added)), 31 (“A conventional saw guide can be mounted on the individual template, ***which serves as a reference base for subsequent work on the bone***.” (emphasis added)), 36 (one of the “main benefit[s]” of individual templates “is avoiding an iterative search of the optimal cut planes and correction angles”). CAOS also discloses the importance of alignment relative to the mechanical axis: “In total knee arthroplasty accurate placement of implant components with respect to the

	individual mechanical axis of the leg is essential." *Id.* at 31 (emphasis added). CAOS further discloses identifying the bone axis using topograms (second image data) to orient a cutting guide: "The geometry of the cut with its position, orientation, and limitations was planned on the basis of CT images (slices 2-mm thick and 2-mm apart). ***In addition, topograms could be used to identify the bone axis.*** A conventional saw guide can be mounted on the individual template, which serves as a ***reference base*** for subsequent work on the bone." *Id.* (emphasis added); *see also id.* at 28-30, 32, 34, 36. **Woolson** discloses that alignment relative to the mechanical axis was standard practice: "[A]ll 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 at 1:26-36; *see also id.* at 3:50-54 ("[T]his preoperative CT planning method produces distal femoral and proximal tibial bone cuts which are perpendicular to the coronal mechanical axis ...."), 7:63-67, Figs. 1, 2A-2B. Woolson also discloses using imaging data, such as CT or x-ray, to align the cutting guides and cuts perpendicular to the mechanical axis. Ex. 1031 at Abstract (CT imaging), 1:37-57 (x-ray imaging), 2:28-59 (imaging with "radiant energy"), 7:63-67 ("It is seen that this preoperative CT planning method produces distal femoral and proximal tibial bone cuts which are ***perpendicular*** to the coronoal mechanical axis ...." (emphasis added)); *see also id.* at 1:8-18, 3:50-7:67. Woolson illustrates making cuts perpendicular to the mechanical axis:

	 *Id.* at Figs. 1, 2A-2B. **<u>The ’158 patent</u>** admits that the biomechanical and anatomical axes—as well as methods of determining them based on imaging such as x-ray, CT scans, CT scout scans (which are similar to topograms), etc.—were widely known. Ex. 1001 at 30:34-52, 34:47-39:50, 76:64-77:22; Ex. 1102 ¶105. **<u>ConforMIS</u>** admits that CAOS “discloses using pre-operative ***CT imaging*** to create a three-dimensional model of a knee joint and using the model ***to create a custom instrument*** ….” Ex. 1024 at 26 (emphasis added); *id.* at 47, 57, 83, 97. *See also* Ex. 1102 ¶¶84-104.

[b] wherein the first image data set is of a type that is different from the second image data set, and the second image data set is x-ray image data;	**CAOS** discloses identifying the bone axis using topograms (second image data) to orient a cutting guide: "The geometry of the cut with its position, orientation, and limitations was planned on the basis of CT images (slices 2-mm thick and 2-mm apart). ***In addition, topograms could be used to identify the bone axis.*** A conventional saw guide can be mounted on the individual template, which serves as a reference base for subsequent work on the bone." Ex. 1033 at 31 (emphasis added); *see also id.* at 28-30, 32, 34, 36. CAOS discloses that CT image data allows for a three-dimensional reconstruction of the joint: "Individual templates are customized on the basis of ***three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data*** in accordance with individual preoperative surgical planning." *Id.* at 29 (emphasis added), 28, 30, 32, 34. CAOS further discloses MRI scanning: "It is planned to integrate additional tools into the system (in particular for hip, knee, and spine surgery) [and] magnetic resonance image processing modules…." *Id.* at 37. **The '158 patent** admits that a "CT scout scan is typically a single, 2-D radiographic [i.e., x-ray] image" and describes CT scout scans and x-rays as alternatives. Ex. 1001 at 38:38-40, 36:21-26 (use of cross-sectional or volumetric imaging is more accurate "when compared to x-rays or CT scout scans"), 41:67-42:7 ("[CT] scout scan … or a weight bearing x-ray"). The '158 patent also admits that CT imaging is "cross-sectional or volumetric imaging" that produces "more accurate identification of … anatomical and/or biomechanical axis … when compared to x-rays." *Id.* at 36:6-26. The '158 also admits that x-ray and CT imaging are different imaging modalities. *Id.* at 34:51-35:6, 37:48-38:14 (axis

	measured on an x-ray "can be cross referenced with another imaging modality such a CT or MRI scan."), 40:4-27, 77:1-12, 110:33-36 (describing x-ray imaging "but also cross-sectional imaging modalities such as CT"). The '158 patent also admits that unlike x-ray imaging, MRI imaging is high resolution, three-dimensional imaging. *Id.* at 34:33-35, 36:6-26. The '158 patent further admits that x-ray imaging and MRI scanning are different imaging modalities. *Id.* at 34:51-35:6, 37:48-38:14, 40:4-27, 77:1-12, 110:33-36. **<u>Woolson</u>** discloses using x-ray image data to determine the mechanical axis and the orientation of the cutting paths relative to such axis. Ex. 1031 at Abstract, 1:26-50; *see also id.* at 2:28-59 (scanning using "radiant energy," such as x-ray imaging), 6:5-7:67. *See also* Claim 66[a]; Ex. 1102 ¶¶105-12.
[c] wherein the surgical instrument has a patient-specific surface that is derived from at least the first image data and that substantially matches a corresponding surface portion associated with the joint; and	*See* Claim 66[a]. **<u>ConforMIS</u>** admits that CAOS discloses creating "a custom instrument ('template') with a tissue ***contacting surface that matches and fits the bone surface*** …." Ex. 1024 at 26 (emphasis added); *id.* at 47, 57, 83, 97. **<u>Alexander</u>** discloses determining cartilage and bone surface of the knee joint using image data (CT or MRI). Ex. 1004 at 14:16-15:14, 22:22-24, 61:19-25, Figs. 18C, 18H; *see also id.* at 1, 3, 11-12, 25, 31, Figs. 19, 22A-B, 23A-E. *See also* Ex. 1102 ¶¶113-18.

[d] wherein the surgical instrument has a guide that is oriented relative to the patient-specific surface based on information derived from the second image data set.	**<u>CAOS</u>** discloses that the template can include guides for guiding saws, drills, etc. *Id.* at 29 ("Mechanical guides for drills, saws, chisels, or milling tools are adaptable or integrated into these individual templates in predefined positions for different types of interventions. Moreover, individual templates also can be used for fixation of a reference base for standard tool guides or other devices in a defined position on bone."), 30, 31("A conventional saw guide can be mounted on the individual template, which serves as a reference base for subsequent work on the bone."); *see also id.* at 28, 34, 36-37. *See also* Claim 66[a]; Ex. 1102 ¶¶119-20.

3. Claim 67

Claim 67 depends from Claim 66 and adds the limitation that "the orientation of the guide is based at least in part on at least one of a mechanical axis and an anatomical axis." As explained for Claim 66, CAOS in combination with Woolson discloses orienting the guide relative to the mechanical axis. In addition, Petitioner's expert confirms that determining the anatomical axis (e.g., from x-ray image data) to orient tool guides was well-known. Ex. 1102 ¶¶123-24. Accordingly, Claim 67 would have been obvious. *Id.* ¶125.

4. Claim 68

Claim 68 depends from Claim 66 and adds the limitation that "the at least one axis is derived at least in part from the second image data set." In co-pending litigation, ConforMIS contends that Claim 68 has a typographical error in that it should instead depend from Claim 67. Claim 68 would have been obvious under ConforMIS's interpretation or as drafted. *Id.* ¶¶126-27.

The '158 patent admits that the biomechanical and anatomical axes—as well as methods of determining them based on imaging such as x-ray, CT scans, CT scout scans, etc.—were widely known. Ex. 1001 at 30:34-52, 34:47-39:50, 76:64-77:22; Ex. 1102 ¶127. Also, as explained for Claims 66 and 67: (1) CAOS in combination with Woolson discloses determining the mechanical axis from x-ray image data (i.e., second image data set); and (2) determining the anatomical axis from x-ray image data was widely known. Ex. 1102 ¶128. Accordingly, Claim 68 would have been obvious. *Id.*

5. Independent Claim 69

Independent Claim 69 is nearly identical to Claim 66 except that Claim 69 recites "designing" rather than "creating" a patient-specific surgical instrument. CAOS discloses designing individual templates "on the basis of three-dimensional reconstructions of the bone structures … in accordance with individual preoperative surgical planning." Ex. 1033 at 29-31, 32 (illustrating "design of an individual template"), 34-36; Ex. 1102 ¶130. Thus, Claim 69 would have been obvious for the same reasons as Claim 66. Ex. 1102 ¶130.

6. Claims 70 and 71

Claims 70 and 71[4] depend from Claim 69, but are otherwise identical to Claims 67 and 68, respectively. Thus, Claims 70 and 71 would have been obvious for the above reasons. *Id.* ¶¶131-32.

7. Independent Claim 72

Independent Claim 72 recites a patient specific surgical instrument "for use in implanting an orthopedic implant in a patient, the process comprising:" (1) determining the surface contours of a at least a portion of a surface a joint from a first image data set; (2) determining a joint axis from a second image data set; (3) incorporating a patient-specific surface into the instrument such that it substantially matches the surface contours; and (4) incorporating a guide into the instrument. The guide is oriented relative to the patient specific surface based on the joint axis.

Claim 72 differs from Claim 66 in that: (1) "surface contours" (rather than "surface portion") of the joint are determined from the first image data set; (2) the joint axis is determined from the second image data set; and (3) the guide is oriented relative to the patient-specific surface based on the joint axis. Unlike Claim 66, Claim 72 does not require the second image data set to be x-ray image

[4] ConforMIS contends that Claim 71 has a typographical error in that it should depend from Claim 70.

data or the first image data set to be of a type that is different from the second image data set. CAOS in combination with Woolson and Alexander would have rendered Claim 72 obvious. Ex. 1102 ¶¶134-42.

a. Determining Surface Contours of a Portion of a Joint Surface from a First Image Data Set

The ’158 patent admits that the contour of a knee joint surface can be determined using image data (e.g., CT or MRI) and admits that this was known in the art. Ex. 1001 at 30:34-52, 31:38-46, 32:1-17; *see also* Ex. 1102 ¶135. A POSITA would have understood that CAOS discloses determining surface contours of a joint from first image data set (e.g., CT or MRI image data). Ex. 1102 ¶¶136-38.

CAOS discloses obtaining CT images of a joint and generating a patient specific surgical instrument (“individual template”). Ex. 1033 at 28-29, 31. The instrument is “customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data” to include “contact faces” that “fit exactly on the bone.” Ex. 1033 at 29; *see also* Ex. 1102 ¶136.

CAOS also discloses designing, using CT image data, an instrument that “has been customized in the areas of the reference surface and the individual copying profile corresponding to the dorsal ***contour*** of the tibial bone within the cut plane." Ex. 1033 at 31 (emphasis added). This instrument limits the cutting depth in order to preserve "the posterior cruciate ligaments and the nerves and vessels in the hollow of the knee." *Id.*; Ex. 1102 ¶137.

Even if ConforMIS attempts to argue that determining surface contours of a portion of the joint surface includes determining the contours of cartilage surface, this would be obvious in view of Alexander as explained for Claim 66. Ex. 1102 ¶¶115-18, 138. Accordingly, a POSITA would have understood that CAOS alone or in combination with Alexander discloses determining surface contours of a portion of a joint surface from a first image data set (e.g., CT data). *Id.* ¶138.

b. Determining a Joint Axis from a Second Image Data Set

The '158 patent admits that the biomechanical and anatomical axes—as well as methods of determining them based on imaging such as x-ray, CT scans, CT scout scans (which are similar to topograms), etc.—were widely known. Ex. 1001 at 30:34-52, 34:47-39:50, 76:64-77:22; Ex. 1102 ¶139. Thus, determining the joint axis cannot make the claim patentable. *See* Ex. 1102 ¶¶139-40.

Moreover, CAOS discloses using topograms (i.e., second image data) to identify the "bone axis" (i.e., joint axis). Ex. 1033 at 31. Further, as explained for Claims 66-68, CAOS in combination with Woolson discloses determining the mechanical axis using second image data (e.g., topograms or x-ray image data), and it was well-known to determine the anatomical axis using image data. *Id.* ¶¶84-104, 119-20, 123-28, 140.

Thus, determining a joint axis from a second image data set would have been obvious. *Id.* ¶140.

c. A Guide Oriented Relative to the Patient-Specific Surface Based on the Joint Axis

CAOS discloses that the instrument (individual template) includes one or more standard or custom surgical tool guides. Ex. 1033 at 29, 30, 31. As explained for Claim 66: (1) CAOS in combination with Woolson discloses orienting a surgical tool guide relative to the mechanical axis; and (2) because CAOS's instrument includes a patient-specific surface that exactly reproduces the knee joint surface, the instrument incorporates the position of the mechanical axis. Ex. 1102 ¶¶84-104, 119-20, 141. Moreover, as explained for Claim 67, it was standard practice to orient surgical tool guides based on an anatomical axis. *Id.* ¶¶123-25. Accordingly, this limitation would have been obvious. *Id.* ¶141.

In sum, the process recited in Claim 72 would have been obvious to a POSITA in view of CAOS in combination with Woolson and Alexander. Additional analysis of Claim 72 is provided in the following claim chart. *See also id.* ¶142.

Claim 72	Exemplary Disclosure in Prior Art
[**preamble**] A patient specific surgical instrument for use in implanting an orthopedic implant in a patient, the process comprising:	*See* Claim 66[preamble].
[a] determining at least in part from a first set of image data the surface contours of at least a portion of a surface of or near a joint of the patient;	**CAOS** discloses customizing the individual template based on the contour of the tibia: "[F]or preservation of the posterior cruciate ligaments and the nerves and vessels in the hollow of the knee, not only the reference surface of the bone but also a copying surface limiting the cutting depth to the dorsal contour of the tibia can be molded into the template (Fig 2B)…. Figure 2 shows a feasibility study with a ***CT image based individual template*** for the reference tibial cut for total knee replacement on a plastic bone model…. The ***template has been customized*** in the areas of the reference surface and the individual copying profile corresponding ***to the dorsal contour of the tibial bone*** within the cut plane" Ex. 1033 at 31 (emphasis added); *see also id.* at 29 ("Individual templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data in accordance with individual preoperative surgical planning…. [T]he planned position and orientation of the tool guide in spatial relation to the bone is stored in a structural way and can be reproduced in situ adjusting the position of the contact faces of the template until they fit exactly on the bone."), 34. **The '158 patent** admits that the contour of a knee joint surface can be determined using image data (e.g., CT or MRI) and admits that this was known in the art. Ex. 1001 at 30:34-52, 31:28-32:17. *See also* Claim 66[a], [c]; Ex. 1102 ¶¶135-38.

[b] determining at least in part from a second set of image data an axis associated with the joint;	CAOS discloses identifying the bone axis from topograms (second image data set): "Figure 2 shows a feasibility study with a CT image based individual template for the reference tibial cut for total knee replacement on a plastic bone model. The geometry of the cut with its position, orientation, and limitations was planned on the basis of CT images (slices 2-mm thick and 2-mm apart). In addition, ***topograms could be used to identify the bone axis***." Ex. 1033 at 31 (emphasis added). **<u>The '158 patent</u>** admits that the biomechanical and anatomical axes—as well as methods of determining them based on imaging such as x-ray, CT scans, CT scout views (which are similar to topograms), etc.—were widely known. Ex. 1001 at 30:34-52, 34:47-35:15, 38:52-39:50, 77:1-22; Ex. 1102 ¶105. *See also* Claims 66[a]-[b], [d], 67, and 68; Ex. 1102 ¶¶139-40.
[c] incorporating a patient-specific surface into the surgical instrument such that the patient-specific surface substantially matches the determined surface contours;	*See* Claim 72[a].
[d] incorporating a guide into the surgical instrument, wherein the guide is oriented relative to the patient-specific surface based at least in	*See* Claims 66[a], [d], 67, and 68; Ex. 1102 ¶141.

part on the determined axis.	

8. Independent Claim 81

Independent Claim 81 recites a method of making a patient-matched surgical tool based on first image data and x-ray image data of a joint. The method includes determining from x-ray image data information about a desired alignment or correction of the joint and creating the tool using the first image data and x-ray image data. The tool has: (1) a contact surface substantially matched to an articular surface of the joint; and (2) a surgical tool guide that is oriented based on the desired alignment or correction of the joint.

Claim 81 differs from Claim 66 in that: (1) information about the desired alignment or correction of the joint is determined from x-ray image data; (2) the contact surface is substantially matched to the articular joint surface; and (3) the guide is oriented based on information about the desired alignment or correction of the joint. CAOS in combination with Woolson and Alexander would have rendered Claim 81 obvious. Ex. 1102 ¶¶144-49.

a. Determining Information about a Desired Alignment or Correction of a Joint from X-Ray Image Data

Woolson discloses that "all total knee implantation systems attempt to ***align*** the reconstructed knee joint in the mechanical axis" because "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 at 1:26-36 (emphasis added). As explained above, it was standard practice to align the cuts perpendicular to a patient's mechanical axis because such alignment is essential for ensuring that the knee implant is correctly positioned on the knee joint and for restoring the proper anatomical alignment of the knee joint. Ex. 1102 ¶¶84-120, 145. It was also commonplace to determine the mechanical axis using image data, such as x-ray image data. *Id.* In fact, the '158 patent admits that the biomechanical and anatomical axes—as well as methods of determining them based on imaging such as x-ray, CT scans, CT scout scans, etc.—were widely known. Ex. 1001 at 30:34-52, 34:47-39:50, 76:64-77:22.

Moreover, as explained above, a POSITA have understood that CAOS in combination with Woolson discloses determining from x-ray image data the mechanical axis and alignment of the cutting paths perpendicular to the mechanical axis in order to correct the alignment of the knee joint (i.e., restore proper anatomical alignment). Ex. 1102 ¶¶84-120, 146. Accordingly, determining the desired alignment or correction of a joint from x-ray image data would have been obvious. *Id.*

b. Contact Surface is Substantially Matched to an Articular Joint Surface

As explained in Section V. articular joint surface means “the bone surface and/or cartilage surface of an articulating portion of a joint.” *See also id.* ¶147; Ex. 1001 at 6:56-58 (“The articular surface can comprise cartilage and/or subchondral bone.”), 23:45-46 (“The articular surface may be at least one of an articular cartilage surface and a bone surface.”).

CAOS’s instrument (individual template) is “customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data” to include a contact surface (“contact faces”) that “fit[s] exactly on the bone.” Ex. 1033 at 29. In addition, the ’158 patent admits that conventional imaging techniques provide information regarding the articular surface of a joint. *See*, *e.g.*, Ex. 1001 at 30:34-52 (conventional imaging methods are used); *id.* at 96:33-52 (“***articular surface and shape*** as well as alignment information generated with the [conventional] imaging test can be used to shape the surgical assistance device”) (emphasis added)). Moreover, even if ConforMIS attempts to argue that articular joint surface includes cartilage surface, this would be obvious in view of Alexander as explained for Claim 66. Ex. 1102 ¶¶115-18, 147.

Accordingly, CAOS alone or in combination with Alexander discloses that the instrument includes a contact surface that matches the articular joint surface. *Id.*

c. A Guide Having a Predetermined Orientation Based on Information about the Desired Alignment or Correction of the Joint

CAOS discloses that the surgical tool includes one or more standard or custom surgical tool guides. Ex. 1033 at 29, 30, 31. As explained above, CAOS is combination with Woolson discloses orienting a surgical tool guide (e.g., a cutting guide) relative to the mechanical axis to align the cutting paths perpendicular to the mechanical axis in order to correct alignment of the knee joint. Ex. 1102 ¶148. Accordingly, this limitation would have been obvious. *Id.*

In sum, the method recited in Claim 81 would have been obvious to a POSITA in view of CAOS in combination with Woolson and Alexander. Additional analysis of Claim 81 is provided in the following claim chart. *See also id.* ¶149.

Claim 81	Exemplary Disclosure in Prior Art
[**preamble**] A method of making a patient-matched surgical tool, the method comprising:	*See* Claim 66[preamble].

[a] obtaining first image data associated with at least a portion of a joint of a patient;	*See* Claim 66[a].
[b] obtaining x-ray image data associated with at least a portion of the joint;	*See* Claim 66[a]-[b].
[c] determining from the x-ray image data information about a desired alignment or correction of the joint;	*See* Claim 66[a]-[b], [d] and Claims 67-68. **<u>The ’158 patent</u>** admits that the biomechanical and anatomical axes—as well as methods of determining them based on imaging such as x-ray, CT scans, CT scout scans, etc.—were widely known. Ex. 1001 at 30:34-52, 34:47-39:50, 76:64-77:22. *See also* Ex. 1102 ¶¶145-46.
[d] creating a surgical tool based at least in part on the first image data and the x-ray image data;	*See* Claim 66[a]-[b].
[e] wherein the surgical tool includes a contact surface substantially matched to a corresponding articular surface of the joint and a guide for directing movement of a	**<u>CAOS</u>** discloses that the individual template (surgical tool) matches the articular surface: “Individual templates are customized on the basis of ***three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data*** in accordance with individual preoperative surgical planning…. By this means the planned position and orientation of the tool guide in spatial relation to the bone is stored in a structural way and can be reproduced in situ adjusting the position of the ***contact faces of the template until they fit exactly on the bone***.” Ex. 1033 at 29 (emphasis added); *see also id.* at 28, 34, 36-37.

surgical instrument,	**<u>The ’158 patent</u>** admits that conventional imaging techniques provide information regarding the articular surface of a bone. *See, e.g.*, Ex. 1001 at 30:34-52 (“The practice of the present invention employs, unless otherwise indicated, ***conventional methods*** of x-ray imaging and … computed tomography (CT scan)**,** magnetic resonance imaging (MRI) … within the skill of the art. Such techniques are explained fully in the literature….”) (emphasis added); *id.* at 96:33-52 (“The imaging test can be x-ray image, … a CT or spiral CT scan or an MRI scan…. ***The articular surface and shape*** as well as alignment information generated with the imaging test can be used to shape the surgical assistance device….”) (emphasis added). *See also* Claim 66[a], [c]-[d]; Ex. 1102 ¶¶68-71, 147.
[f] the guide having a predetermined orientation based at least in part on the information about the desired alignment or correction of the joint.	*See* Claim 66[a]-[b], [d]; Ex. 1102 ¶148.

B. Ground 2: Claims 73-80 Are Unpatentable as Obvious Over CAOS in Combination with Woolson, Alexander, and Radermacher.

1. Independent Claim 73

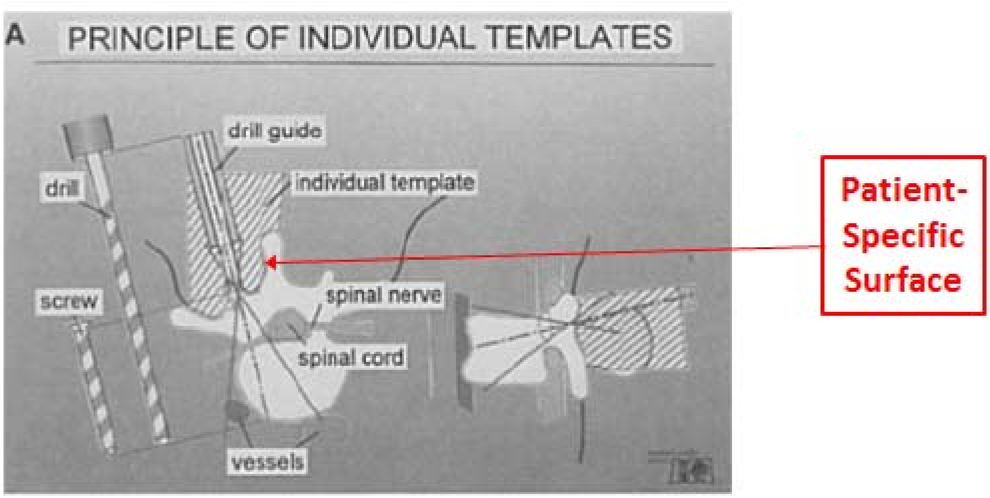
Independent Claim 73 recites a method of using a patient-matched surgical instrument to implant an orthopedic implant by: (1) placing a patient-specific surface of the implant against a corresponding surface portion of a patient’s joint "such that the patient-specific surface is substantially entirely engaged against the corresponding surface portion of the patient;" (2) cutting or drilling a portion of joint tissue using a guide "of or attached to the patient-matched surgical instrument;" (3) and implanting "an implant in or near the joint." The guide is aligned relative to the patient-specific surface based on x-ray image data of the joint. The patient-specific surface is derived from "other image data" of the joint.

A person of ordinary skill in the art would not understand with reasonable certainty the scope of Claim 73 because it recites a method of using an instrument to "implant an orthopedic implant" in the preamble, while the body recites "placing a patient-specific surface of *the implant* against" the joint surface, cutting or drilling "using a guide of or attached to the ... *instrument*," and "implanting *an implant*." Ex. 1102 ¶151. Thus, Claim 73 is invalid as indefinite. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct 2120, 2124 (2014).

The other claims of the '158 patent recite creating an instrument having a patient-specific surface. To the extent ConforMIS intended to draft Claim 73 to recite "placing a patient-specific surface of *the instrument*" against the joint surface consistent with the other claims, Claim 73 would have been obvious over CAOS in combination with Woolson, Alexander, and Radermacher. Ex. 1102 ¶¶151-69.

a. Placing a Patient-Specific Surface of the Instrument Against a Corresponding Surface Portion of a Joint such that the Patient-Specific Surface is Substantially Engaged Against the Joint Surface

As explained for Claim 66, CAOS discloses patient-matched surgical instruments that substantially match a corresponding surface portion of a joint. Also, CAOS discloses placing such instruments on various joints and cutting and drilling the joints using surgical tool guides of the instruments. Ex. 1033 at 29-36; Ex. 1102 ¶152. For example, CAOS illustrates that implanting a spinal screw involves engaging a patient-specific surface of the instrument against a joint surface of a vertebrae. Ex. 1102 ¶152.



Id. at 30-31 ("Intraoperatively, the defined position of the bore is reproduced by placing the self locating template where it fits exactly on the bone."); *see also id.* at 29 ("adjusting the position of the contact faces of the template until they fit exactly on the bone.”). CAOS also discloses clinical application of patient-matched instruments to correct neck decompression and deformation and misalignment of the hip. *Id.* at 32-37; Ex. 1102 ¶152. Further, CAOS dicsloses an instrument used for guiding a tibial incision in knee-replacement surgery. Ex. 1033 at 31.

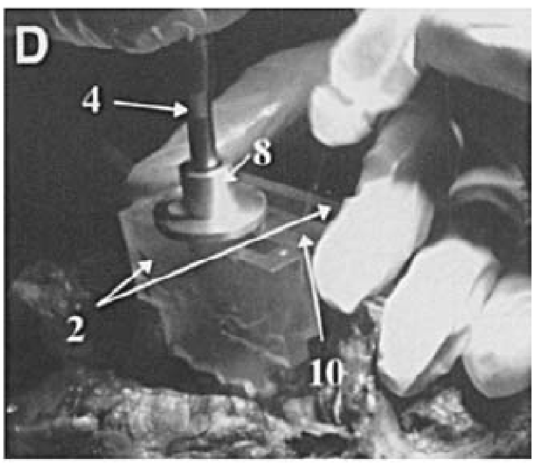
Accordingly, CAOS discloses placing a patient-specific surface of the instrument against a corresponding surface portion of a joint such that the patient-specific surface is substantially engaged against corresponding surface portion. Ex. 1102 ¶153.

Claim 73 also recites that the patient-specific surface of the instrument is derived from “other image data.” As explained below, this limitation would have been obvious. *Id.* ¶¶154, 168.

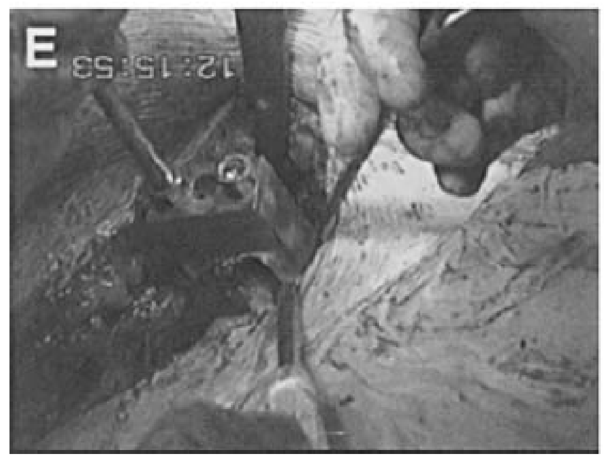
b. Cutting or Drilling a Portion of Joint Tissue using a Guide of the Instrument

CAOS discloses that surgical tool “guides for drills, saws, chisels, or milling tools are adaptable or integrated into these individual templates in predefined positions for different types of interventions.” Ex. 1033 at 29. For implantation of a spinal screw, CAOS discloses that the “position and orientation of the related drill guide [] is specified and can be incorporated into the individual template.” *Id.* at 30; Ex. 1102 ¶155. For knee-replacement surgery, CAOS discloses mounting a saw guide on the instrument. *Id.* at 31; Ex. 1102 ¶155.

Petitioner's expert confirms that CAOS discloses drilling and cutting the joint surface and the tissue using surgical tool guides. *Id.* at 30 (drilling the vertebrae), 31 ("osteotomies and bores for the preparation of the [knee] implant's seat"), 32-34 (drilling the spinal cord and cutting the hip bone); Ex. 1102 ¶¶156-57. CAOS illustrates drilling and cutting the tissue using surgical tool guides of instruments:



Ex. 1033 at Fig. 3D (drilling the spinal cord)



Id. at Fig. 4E (cutting the hip)

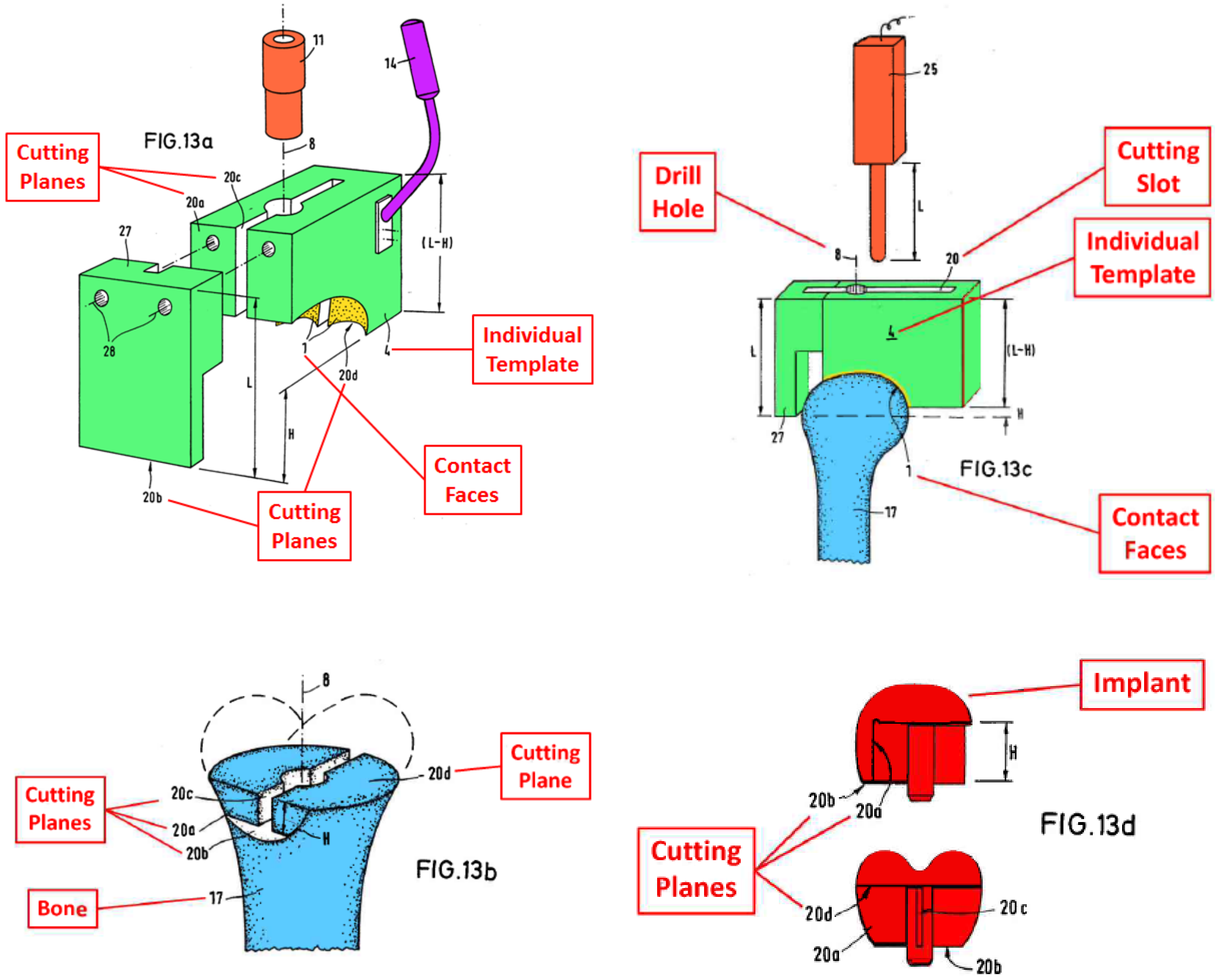
Thus, CAOS discloses cutting or drilling a portion of joint tissue using a guide attached to or integrated into the instrument. Ex. 1102 ¶157.

Claim 73 recites that the guide is aligned relative to a patient-specific surface of an instrument based on x-ray image data. As explained below, this limitation would have been obvious. *Id.* ¶¶158, 164-67.

c. Implanting an Implant in the Joint

CAOS discloses implanting a spinal screw. Ex. 1033 at 30-31; Ex. 1102 ¶159. For total knee arthroplasty, which involves replacing damaged portions with implants, CAOS discloses that "accurate placement of implant components … is essential." *Id.* at 31; Ex. 1102 ¶159.

Even if CAOS did not explicitly disclose implanting a knee implant, this would have been obvious. Ex. 1102 ¶¶160-62. Radermacher discloses using CT or MRI scanning to make a patient-matched instrument ("individual template") having a contact surface that "copies the surface of the osseous structure" of the joint. Ex. 1003 at 9-11. The instrument guides surgical drills and saws during orthopedic surgery. *Id.* at Abstract, 9-11, 30. Referring to Figures 13a-d (reproduced below), Radermacher discloses that an individual template 4 having patient-specific surface 1 could be set on a bone 17 of a patient's knee joint, a bore axis 8 drilled, and cuts made along cutting planes 20a-d, resulting in a resected bone (Fig. 13b) onto which an implant (Fig. 13d) could be seated. Ex. 1003 at 30; Ex. 1102 ¶161.



A POSITA would have been motivated to combine CAOS with Radermacher for several reasons. Ex. 1102 ¶162. Both references share the same first named author/inventor (Radermacher) and describe closely related subject matter. Both references are directed to treating diseased and/or damaged joints using patient-specific instruments ("individual templates") created using CT and/or MRI data. *Id.* Both references describe using patient-specific surgical instruments for knee-replacement surgery. Ex. 1033 at 31; Ex. 1003 at 30; Ex. 1102 ¶162.

Thus, they address the same problem, are in the same field of endeavor, and use the same technology. Ex. 1102 ¶162.

Accordingly, it would have been obvious in view of CAOS in combination with Radermacher to use the instrument for implanting an implant. *Id.* ¶163.

d. The Guide is Aligned Relative to the Patient-Specific Surface Based on X-Ray Image Data

As stated above, CAOS discloses using topograms to identify the bone axis and underscores that "accurate placement of [knee] implant components with respect to the individual mechanical axis of the leg is essential." Ex. 1033 at 31. CAOS further discloses mounting a cutting guide on "the individual template, which serves as a reference base for subsequent work on the bone." *Id.*; Ex. 1102 ¶164.

Woolson discloses using image data (e.g., x-ray image data) to determine the mechanical axis and alignment of the tool guides relative to this axis so that cuts are made perpendicular to the mechanical axis. Ex. 1031 at Abstract, 1:26-50, 2:28-59, 3:5-7:67; Ex. 1102 ¶165. This ensures that the knee implant is properly aligned with the mechanical axis, which is the goal in knee-replacement surgery. Ex. 1031 at 1:26-36; Ex. 1102 ¶165.

Thus, as explained for Claim 66, a POSITA would have understood that CAOS in combination with Woolson discloses using x-ray image data to align a surgical tool guide (e.g., a cutting guide) of a patient-matched surgical instrument (individual template) relative to the mechanical axis. Ex. 1102 ¶¶84-120, 166. In addition, a POSITA would have understood that because CAOS's instrument includes a patient-specific surface that exactly reproduces the knee joint surface, the instrument incorporates the position of the mechanical axis. *Id.* ¶¶84-104, 119-20, 166. A POSITA would have been motivated to combine CAOS with Woolson for the same reasons as explained for Claim 66. *Id.* ¶¶103, 166.

Accordingly, aligning a tool guide relative to the patient-specific surface of an instrument based on x-ray image data would have been obvious. *Id.* ¶167.

e. The Patient-Specific Surface Is Derived from Other Image Data

As explained for Claim 66, CAOS alone or in combination with Alexander discloses that a patient-specific surface of the instrument, which substantially matches both the bone and cartilage surfaces, is derived from CT or MRI image data (i.e., other image data). Ex. 1102 ¶¶113-18, 168.

In sum, the method recited in Claim 73 would have been obvious to a POSITA in view of CAOS in combination with Woolson, Alexander, and Radermacher. Additional analysis of Claim 73 is provided in the following claim chart. *See also id.* ¶169.

Claim 73	Exemplary Disclosure in Prior Art
[**preamble**] A method of using a patient-matched surgical instrument to implant an orthopedic implant, comprising:	*See* Claim 66[preamble].
[a] placing a patient-specific surface of the [instrument] against a corresponding surface portion of or near a joint of the patient such that the patient-specific surface is substantially entirely engaged against the corresponding surface portion of the patient;	**<u>CAOS</u>** discloses: "[T]he planned position and orientation of the tool guide in spatial relation to the bone is stored in a structural way and ***can be reproduced in situ adjusting the position of the contact faces of the template until they fit exactly on the bone***." Ex. 1033 at 29 (emphasis added). CAOS illustrates implanting a spinal screw using a patient-matched surgical instrument (individual template):

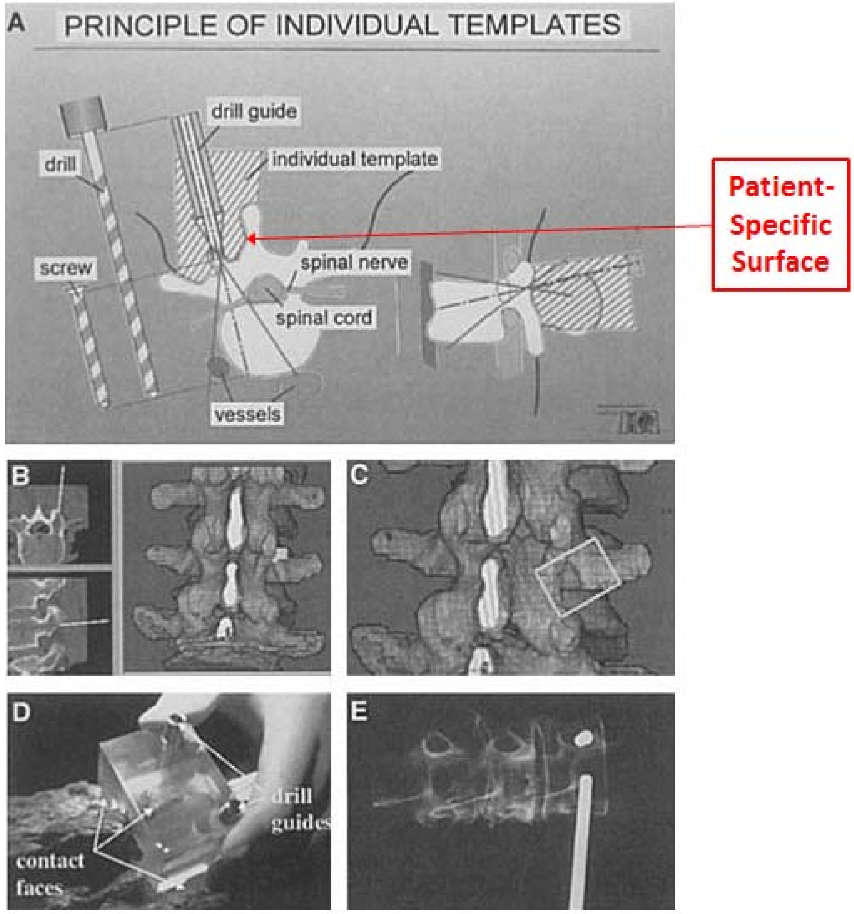
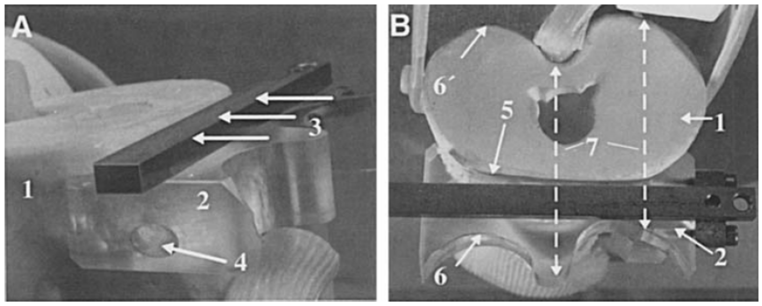


Fig 1. Pedicle screw placement: (A) the principle of individual templates based on preoperative CT imaging and computer based planning; (B) computer assisted planning of a pedicle screw placement with the DISOS planning system; (C) interactive specification of the reference contact face; (D) formclosed intraoperative fitting of the template; and (E) radiographic control of the placement of 5-mm rods in the pedicles without any perforation in situ.

Id. at Fig, 1.

CAOS also discloses that for spinal surgery: "Intraoperatively, the defined position of the bore is reproduced by ***placing the self locating template where it fits exactly on the bone***." *Id.* at 31 (emphasis added); *see also id.* at 29.

	CAOS also discloses and illustrates using a patient-matched surgical instrument (individual template) for knee-replacement surgery:  **Fig 2A–B.** Total knee arthroplasty: (A) laboratory investigation on a plastic bone model (1): individual template guiding the reference osteotomy (3) in tibial bone, optional fixation with a bone pin (4); (B) customized reference contact face (5) and copying profile (6) limiting cutting depth (7) to the dorsal contour (6) of tibial bone. *Id.* at Fig. 2A-B; *see also id.* at 31 ("The template has been customized in the areas of the reference surface and the individual copying profile corresponding to the dorsal contour of the tibial bone within the cut plane."); *id.* at 28, 30, 32-37 (describing the use of patient-matched instruments for correcting decompression of a spine and hip deformation and misalignment (dysplasia)). *See also* Claim 66[a], [c]; Ex. 1102 ¶¶152-54.
[b] cutting or drilling a portion of the tissue in or near the joint of the patient using a guide of or attached to the patient matched surgical instrument;	**<u>CAOS</u>** discloses drilling and cutting the joint surface and tissue. *Id.* at 30 (drilling the vertebrae); 31 (cutting the tibia), 31 ("osteotomies and bores for the preparation of the [knee] implant's seat"), 32-34 (drilling the spinal cord and cutting the hip bone). *See also* Claims 66[c]-[d], 73[a]; Ex. 1102 ¶¶155-58.
[c] and implanting an implant in or near the joint;	**<u>CAOS</u>** discloses: "In total knee arthroplasty ***accurate placement of implant components*** with respect to the individual mechanical axis of the leg is essential." Ex. 1033 at 31 (emphasis added).

	CAOS further discloses: "The ***selection of a pedicle screw of the appropriate length and caliber*** and its accurate fixation in the cortical bone of the pedicles and the vertebral body is essential for good anchoring." *Id.* at 30 (emphasis added). **Radermacher** discloses the use of CT or nuclear spin tomography (MRI) to create an individual template (patient-matched surgical instrument): "According to the inventive method, there is used a split-field device (*e.g.* a ***computer or a nuclear spin tomograph***) by which split images are produced …, and from these split images, ***data regarding the three-dimensional shape of the osseous structure and the surface thereof are obtained***. In the preoperative planning phase, these data are used as a basis for defining … a ***rigid individual template which*** … ***copies the surface of the osseous structure*** in such a manner that the individual template can be intraoperatively set onto these – then freely exposed – contact faces or points in exclusively one clearly defined position[.]" Ex. 1003 at 10 (emphasis added). *See also id.* at 3-4, 9, 11-13, 21-22, 42, Figs. 13a-d. Figs. 18-19. Radermacher also discloses performing knee-replacement surgery: "Figs. 13a to 13c schematically show an individual template 4 for the preparation of the seat for the ***knee-joint head prosthesis*** illustrated by way of example in Fig. 13d." *Id.* at 30 (emphasis added); *see also id.* at 5, 19-20. Radermacher further illustrates preparing the knee joint for implanting an implant:

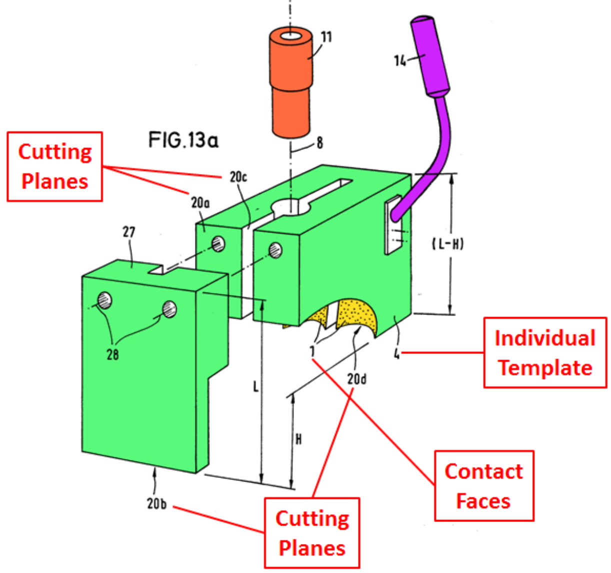
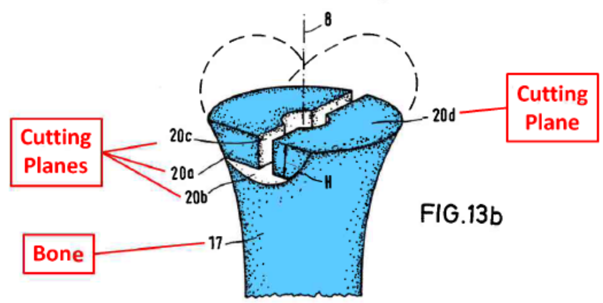
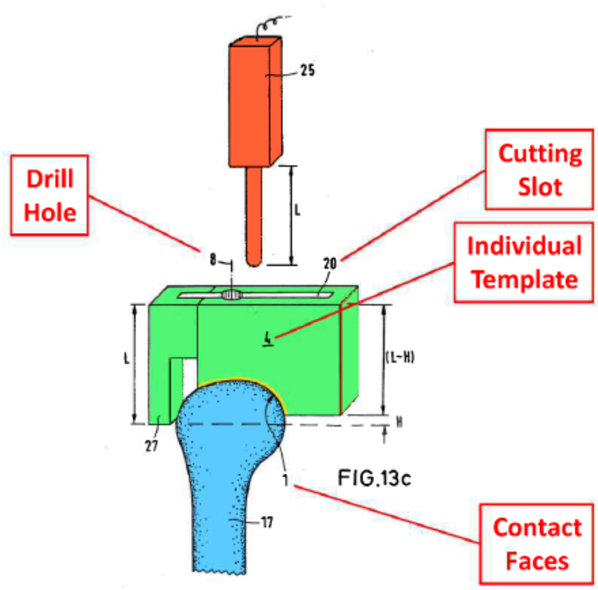
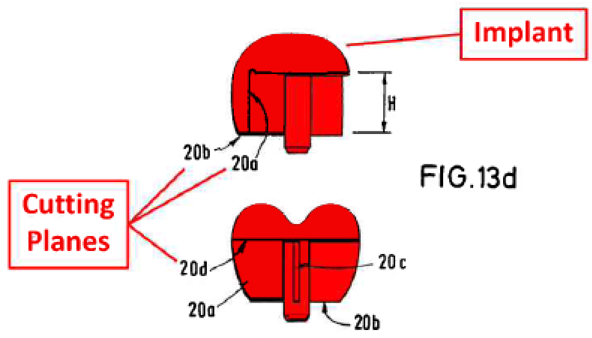


FIG.13a
11
14
8
Cutting Planes
20c
20a
27
(L-H)
28
Individual Template
4
1
20d
L
H
Contact Faces
20b
Cutting Planes

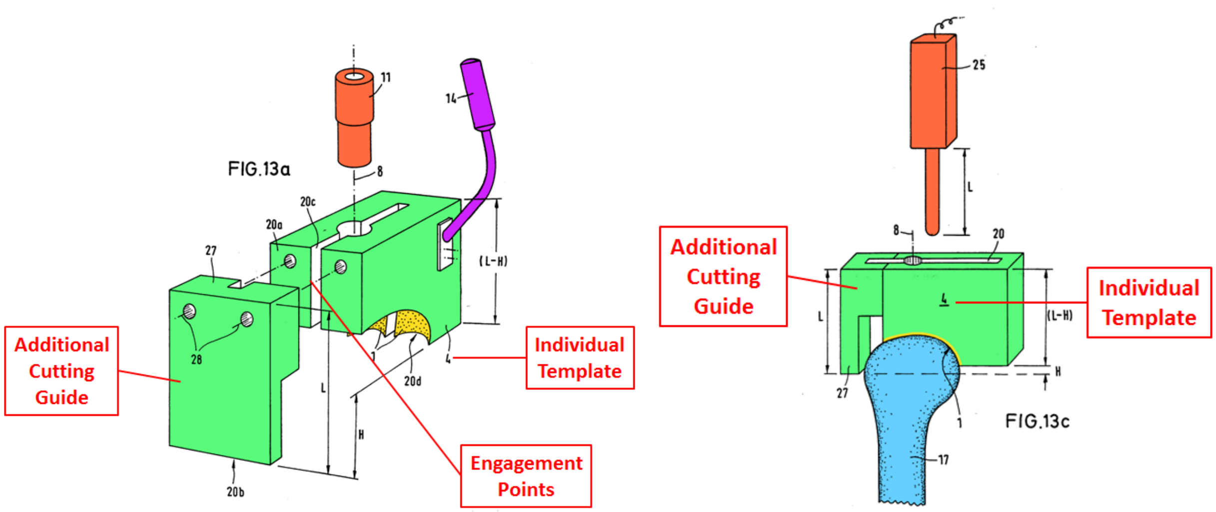

8
Cutting Plane
20d
Cutting Planes
20c
20a
20b
H
FIG.13b
Bone
17


25
Drill Hole
Cutting Slot
L
8
20
Individual Template
4
L
(L-H)
H
27
FIG.13c
1
Contact Faces
17

	 *See also* Claim 73[a]-[b]; Ex. 1102 ¶¶159-63.
[d] wherein the guide has a predetermined alignment relative to the patient-specific surface derived at least in part from x-ray image data of at least a portion of the joint;	*See* Claim 66[a]-[d]; Ex. 1102 ¶¶164-67.
[e] and wherein the patient-specific surface is derived from other image data of at least a portion of the joint.	*See* Claim 66[a]-[d]; Ex. 1102 ¶168.

2. Claim 74

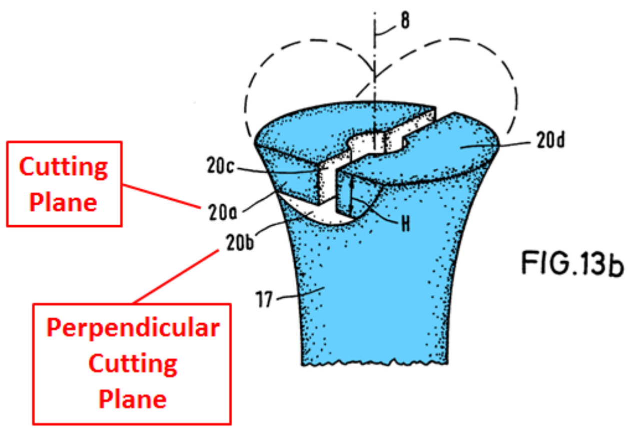
Claim 74 depends from Claim 73 and adds "linking a second surgical instrument to the patient-matched surgical instrument." CAOS discloses that drill and saw guides as well as a copying cam can be mounted on the instrument. Ex. 1033 at 29-32.; Ex. 1102 ¶170. Radermacher discloses individual templates and tool guides with "engagement points" (i.e., a linkage) for attaching additional components. Ex. 1003 at 11, 25-26, 30; *see also* Ex. 1102 ¶171. As is illustrated below, an additional cutting guide is linked via such engagement points to the instrument.



Ex. 1003 at Figs. 13a, c; Ex. 1102 ¶171. Thus, Claim 74 would have been obvious. Ex. 1102 ¶172.

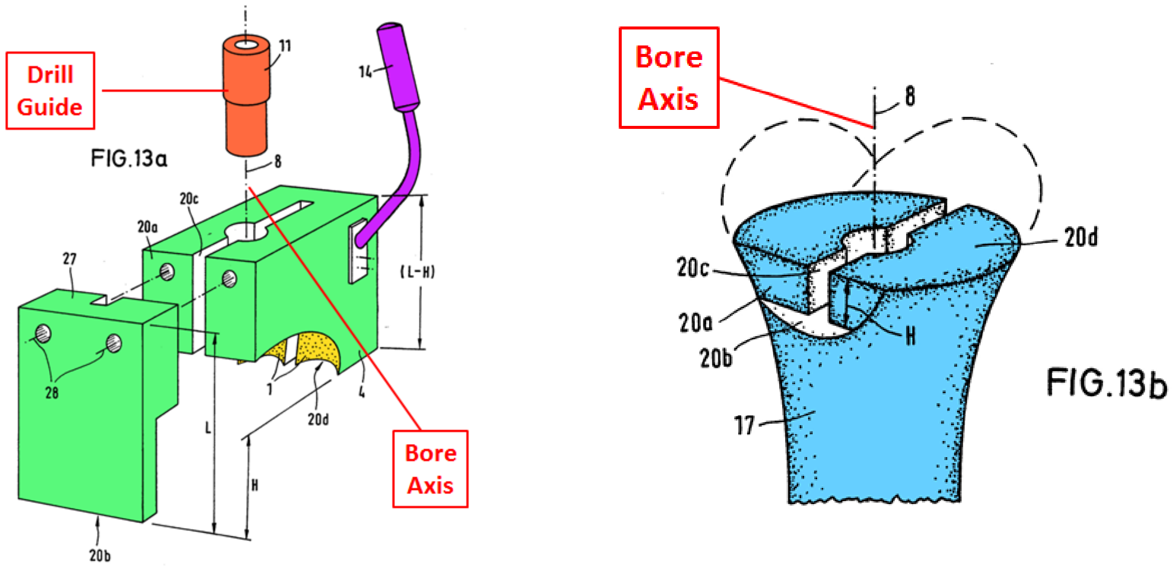
3. Claim 75

Claim 75 depends from Claim 73 and adds the limitation of "cutting or drill tissue of or near the joint using the second component." As discussed above, Radermacher discloses using an additional cutting guide for guiding a cut. Ex. 1003 at 30 ("[A] cut 20b can be performed free-handed at a right angle to cut 20a. (To this effect, also an additional template 27 can be provided)."); Ex. 1102 ¶173. This additional cut (20b) is illustrated below:



Id. at Fig. 13b; *see also id.* at Figs. 13a, c-d; Ex. 1102 ¶173.

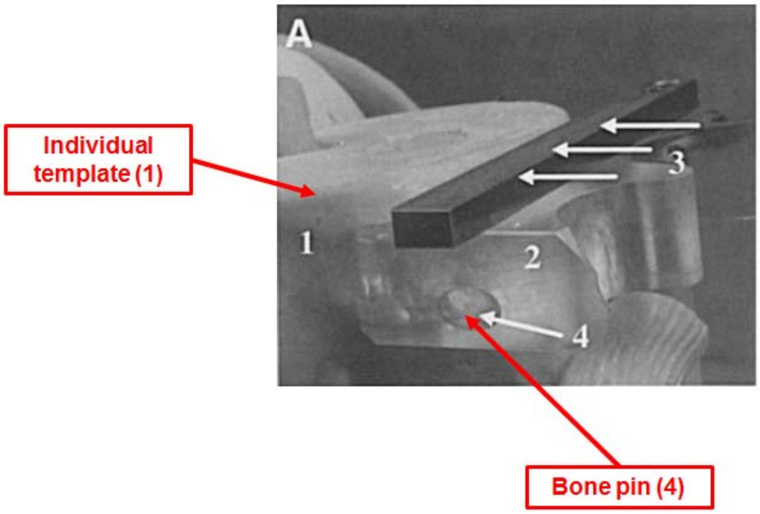
Also, as illustrated below, Radermcher dicloses using a separate drill guide ("drill sleeve") and drilling a bore axis 8. *Id.* at 30.



Id. at Figs. 13a-b; Ex. 1102 ¶174. Thus, Claim 75 would have been obvious. Ex. 1102 ¶175.

4. Claim 76

Claim 76 depends from Claim 73 and adds the limitation of "pinning the surgical instrument to tissue of or near the joint." CAOS discloses that instrument for knee-replacement surgery can be fixed "with a bone pin," as illustrated below. Ex. 1033 at 31; *see also id.* at 35-36; Ex. 1102 ¶176.

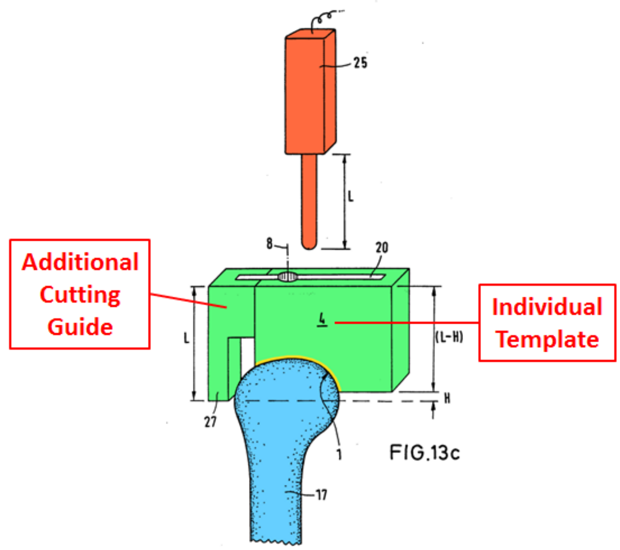


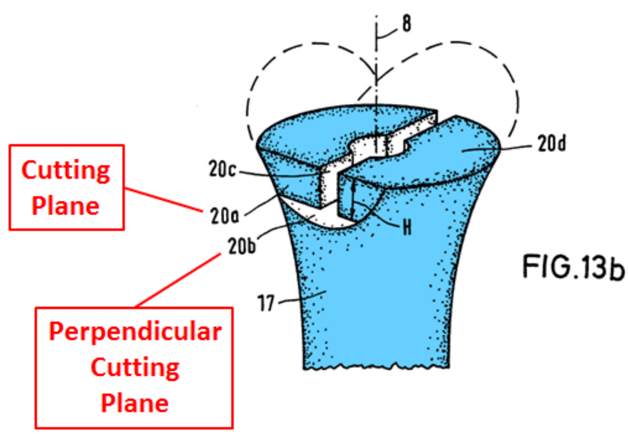
Id. at Fig. 2A.

Also, Radermacher discloses the use of "clamping devices or screw connections" to fix the instrument. Ex. 1003 at 23, Figs. 6A-B, 9, 10A-E, 11A-E. A POSITA would have understood that pinning the instrument using the bone pin of CAOS or attachment mechanisms of Radermacher would result in pinning the instrument to tissue of or near the joint. Ex. 1102 ¶¶176-77. Accordingly, Claim 76 would have been obvious. *Id.*

5. Claim 77

Claim 77 depends from Claim 73 and adds the limitation of "attaching a second surgical instrument to tissue of the patient" based on the cut or drilled surface. As explained for Claims 74 and 75, Radermacher discloses attaching an additional cutting guide to make an additional cut that is perpendicular to the previous cut. Ex. 1003 at 30, Fig. 13a-d; Ex. 1102 ¶179.





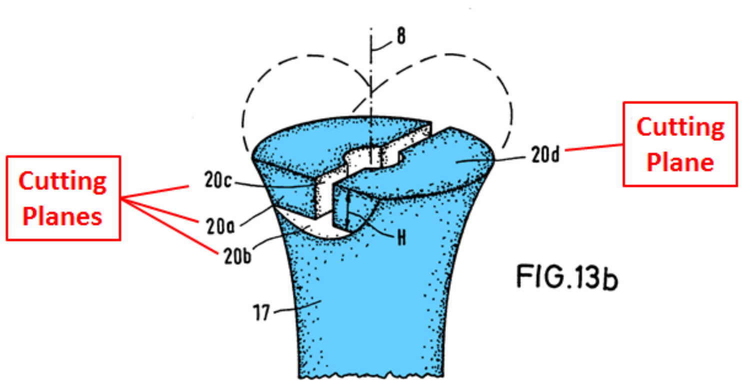
Ex. 1003 at Figs. 13b-c.

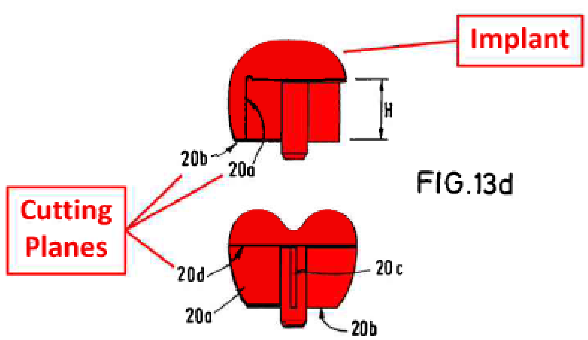
A POSITA would have understood that the additional cutting guide is attached to the tissue based on the cut surface in order to make the perpendicular cut. Ex. 1102 ¶180. Accordingly, Claim 77 would have been obvious. *Id.*

6. Claim 78

Claim 78 depends from Claim 73 and adds the limitation of "forming a series of cuts" based on the cut or drilled surface.

Radermacher discloses making a first cut 20a and then making an additional cut 20b perpendicular to cut 20a, which is followed by making cuts 20c and 20d. Ex. 1003 at 30; Ex. 1102 ¶181. This is illustrated below:





Id. at Figs. 13b, d; Ex. 1102 ¶181. A POSITA would have understood that cuts 20b, 20c, and 20d are formed based on the first cut 20a to correctly prepare the knee joint for implanting the illustrated implant. Ex. 1102 ¶182. Accordingly, Claim 78 would have been obvious. *Id.*

7. Claim 79

Claim 79 depends from Claim 73 and adds the limitation of "aligning a second instrument based at least in part on the cut or drilled surface created during the step of cutting or drilling." As explained for Claim 77, Radermacher discloses attaching an additional cutting guide to make an additional cut (20b) perpendicular to the previous cut (20a). Ex. 1003 at 30, Figs. 13a-d; Ex. 1102 ¶183.

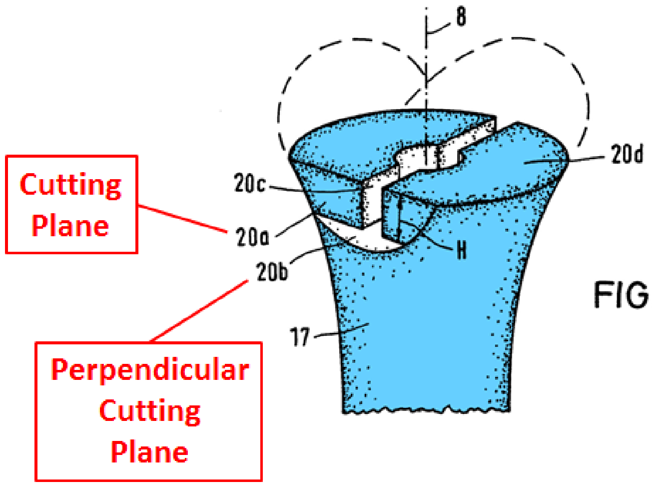


FIG.13b

A POSITA would have understood that the additional template is aligned based on the cut surface 20a so that the additional cut (20b) is made at a right angle to the cut surface. Ex. 1102 ¶183. Accordingly, Claim 79 would have been obvious. *Id.* ¶184.

8. Claim 80

Claim 80 depends from Claim 79 and adds the limitation of "using the second instrument to cut or drill" the joint tissue. As explained above, the additional cutting guide is used to make an additional cut (20b). Accordingly, Claim 80 would have been obvious. *Id.* ¶185.

VIII. SECONDARY CONSIDERATIONS CANNOT OVERCOME THE STRONG EVIDENCE OF OBVIOUSNESS

Secondary considerations should be considered but do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Where a strong *prima facie* obviousness showing exists, even relevant secondary considerations supported by substantial evidence may not dislodge the primary conclusion of obviousness. *See, e.g., Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

Petitioner is unaware of any secondary considerations. To the extent any evidence of secondary considerations is alleged by ConforMIS, such evidence cannot outweigh the strong *prima facie* case of obviousness and Petitioner will respond to such evidence in due course.

IX. CONCLUSION

For the reasons above, Petitioner has established a reasonable likelihood that Claims 66-81 of the ’158 patent are unpatentable as obvious in view of the prior art. Petitioner therefore requests that the Board institute an *inter partes* review of each of those claims.

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

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 20, 2016

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that foregoing **PETITION FOR INTER PARTES REVIEW OF CLAIMS 66-81 OF U.S. PATENT NO. 7,981,158**, exclusive of the parts exempted as provided in 37 C.F.R. § 42.24(a), contains 13,840 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24(a).

Dated: December 20, 2016

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR INTER PARTES REVIEW OF CLAIMS 66-81 OF U.S. PATENT 7,981,158 AND EXHIBITS 1001-1088, AND 1102** is being served on December 20, 2016 via FedEx Priority Overnight to counsel of record for U.S. Patent 7,981,158 patent owner **CONFORMIS, INC.**, at the addresses below:

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