UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Mako Surgical Corp.
Petitioner

v.

Blue Belt Technologies, Inc.
Patent Owner

Patent No. 6,205,411
Issue Date: March 20, 2001
Title: COMPUTER-ASSISTED SURGERY PLANNER AND INTRA-OPERATIVE GUIDANCE SYSTEM

Case IPR: Unassigned

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,205,411

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.1-.80, 42.100-.123

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Petitioner Mako Surgical Corp. ("Petitioner") respectfully petitions for *inter partes* review of claims 1-17 (the "Challenged Claims") of U.S. Patent No. 6,205,411 ("the '411 patent") (Ex. 1001) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.*

I. NOTICES AND STATEMENTS

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner identifies Mako Surgical Corp. and Stryker Corporation as the real parties-in-interest. Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner discloses as a related matter *Mako Surgical Corp. v. Blue Belt Technologies, Inc.*, No. 0:14-cv-61263-MGC (S.D. Fla.) (the "Concurrent Litigation"). Blue Belt Technologies, Inc. ("Patent Owner") served Petitioner with counterclaims asserting infringement of the '411 patent on September 2, 2014.

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Pursuant to 37 C.F.R. § 42.8(b)(4), service information for lead and back-up counsel is provided above. Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '411 patent is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

II. INTRODUCTION

The '411 patent was filed on November 12, 1998. It has three independent claims and 14 dependent claims, all directed to methods and systems for planning and guiding implantation of an artificial component into a joint (hip, knee, hand and wrist, elbow, shoulder, or foot and ankle). The same systems and methods, however, were described in detail by several of the named inventors in articles published at least as early as 1996 and 1995, both well over a year before the '411 patent was filed. As a result, the'411 patent claims are unpatentable.

The '411 patent is a continuation-in-part of an application filed February 21, 1997, which issued as U.S. Patent No. 5,880,976 ("the '976 patent"). The independent claims of the '411 patent, however, specifically recite implantation in "a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, [or] a foot and ankle joint." Other than the hip joint, this is new matter with no support in the parent application, as the parent merely disclosed a "joint" and only specifically discussed a hip joint. This new matter is included in each claim that remains in the '411 patent. All of the claims are therefore entitled only to their actual filing date of November 12, 1998.

The Examiner's views on priority are unclear from the prosecution history. In an April 5, 2000, office action, the Examiner stated that because the scope of the

’976 patent was open-ended, it covered “joint” generally as recited in the ’976 patent and also the specific joints recited in the ’411 patent claims. (Ex. 1002 at 265.) On the next page of the same office action, the Examiner incorrectly and more broadly stated that the ’976 patent actually disclosed and claimed “[a]n apparatus for facilitating the implantation of an artificial component in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint.” (*Id.* at 266.) In the September 21, 2000, Notice of Allowance, however, the Examiner pointed to the same specific language as the *patentable improvement* provided by the ’411 patent over the ’976 patent:

> The instant application is directed to a nonobvious improvement over the invention described in U.S. Patent No. 5,880,976 . . . . The improvement comprises an apparatus for facilitating the implantation of an artificial component in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint. This patentable distinction is included in each of the independent claims 1, 10, and 29. (*Id.* at 287-88.)

The Examiner’s September 21, 2000, view is partially correct: the specific list of joints is indeed a *distinction* between the ’411 patent and its parent. The distinction is not, however, *patentable*. The purported invention was thoroughly described years earlier, both in an article published at least as early as 1996, two years before the continuation-in-part filing date, which is the earliest priority date to which the ’411 patent is entitled; and in an article published at least as early as 1995, which is 1-2 years before even the filing date of the ’976 *parent* application.

This Petition for *inter partes* review shows how DiGioia (Ex. 1005), an article published at least as early as 1996, and DiGioia II (Ex. 1006), an article published at least as early as 1995, anticipate or render obvious each of the Challenged Claims of the ’411 patent. Indeed, these references disclose nearly all of the ’411 claimed methods and systems, with only a few minor differences that would have been obvious in view of other art. Part III of this Petition summarizes the ’411 patent, its prosecution history, and priority, and Part IV sets forth the detailed grounds for invalidity of the ’411 patent’s challenged independent and dependent claims in view of DiGioia, DiGioia II plus Chao, and other prior art. Petitioner has established a reasonable likelihood that it will prevail on at least one claim of the ’411 Patent, if not all of them. Accordingly, Petitioner respectfully requests a Decision to institute *inter partes* review.

III. THE ’411 PATENT

A. Background and Summary of Patent

The ’411 patent is directed to systems and methods for facilitating implantation of an artificial component in a hip joint, knee joint, hand and wrist joint, elbow joint, shoulder joint, or foot and ankle joint. The apparatus and related method consist of essentially two pieces: a pre-operative geometric planner and a pre-operative kinematic biomechanical simulator that communicates with the geometric planner.

The '411 specification describes as background several challenges and concerns related to hip arthroplasty, which is a procedure to restore the function of a joint by resurfacing, remodeling, or complete replacement. Dislocation of the implanted component was known to be a major problem, but could be lessened with certain implantation angles. (Ex. 1001 at 1:37-55.) Variations in individual anatomies were also known to cause complications, as there is no single optimal component design and orientation. (*Id.* at 2:56-61.) According to the '411 specification, most prior operation planning methods for hip joint surgery used acetate templates and a single anterior-posterior x-ray, providing only a two-dimensional image of the pelvis. (*Id.* at 3:10-18.) The '411 specification states that prior intra-operative positioning devices assumed that the pelvis and trunk were aligned in a known orientation and did not take into account individual anatomies. (*Id.* at 3:19-32.) Several other prior solutions assumed that a correct and precise implant position would be provided, and therefore did not solve the issue of determining or confirming a high-quality implant position. (*Id.* at 4:28-41.)

The ’411 applicants proposed to address these problems by combining a pre-operative geometric planner and a kinematic biomechanical simulator. (Ex. 1001 at 4:59-65.) The geometric planner creates geometric models of both the target joint and the artificial components to be implanted. (*Id.* at 5:63-67.) The simulator simulates movement of the joint to assist in determining implant positions, including angular orientation. (*Id.* at 6:1-5.) In some embodiments, the positions and geometric models are used with intra-operative navigational software to guide the surgeon. (*Id.* at 6:45-48.) In others, all three pieces—the planner, the simulator, and the navigational software—are implemented using a computer system with a display monitor. (*Id.* at 6:8-12.) The computer system could include a tracking device so relative locations of objects can be tracked and displayed during the operation. (*Id.* at 6:21-26.)

The ’411 patent has three independent claims and 14 dependent claims. Independent claim 1 specifies the joints into which an artificial component will be implanted and claims a pre-operative geometric planner and a pre-operative kinematic biomechanical simulator in communication with the geometric planner. Independent claim 10 claims a computer system with the components set out in claim 1, and adds a tracking device in communication with the system. Independent claim 17 is directed to a method of facilitating implantation of an artificial component into one of the specified joints, comprising the steps of:

creating a bone model; creating a component model; simulating movement of the joint with the implant; calculating a range of motion; determining an implant position based on a predetermined range of motion and the calculated range of motion; identifying the implant position in the bone model; aligning the bone model with the actual bone and placing the implant based on tracking data; and tracking the implant and bone to maintain alignment.

B. Prosecution History and Priority

The ’411 patent was filed on November 12, 1998. It is a continuation-in-part of application 08/803,993 (“the ’993 application”), which was filed on February 21, 1997, and issued as the ’976 patent. (Ex. 1003.) All three independent claims in the ’411 patent recite implantation in “a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, [or] a foot and ankle joint.” (Ex. 1001 at Abstract.) This specific list is in the preamble of each independent claim, and provides antecedent basis for “the joint” in the claim language of each. *See Highmark, Inc. v. Allcare Health Mgmt. Sys.*, 687 F.3d 1300, 1311 (Fed. Cir. 2012) (preamble limiting where “limitations in the body of the claim rely upon and derive antecedent basis from the preamble”) (quotations and citation omitted), *rev’d on other grounds*, 134 S. Ct. 1744 (2014).

The specific joints set out in the preamble constitute subject matter not found in the ’993 application or ’976 patent, as that application and patent disclosed "joint" generally with "hip" as the only specific example. (*See, e.g.*, Ex. 1003 at 21, 1:17-33 (discussing hip replacement operations).) Adding specificity to narrow claims after an earlier, broader disclosure constitutes new matter, and the '411 patent claims are therefore not supported by the disclosure of the '993 application. MPEP § 2163.05 Part II ("The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure" constitutes new matter.). As a result, the '411 patent is only entitled to its own filing date for all claims—not the filing date of the '993 application. *See Cordance Corp. v. Amazon.com, Inc.*, 658 F.3d 1330, 1333-35 (Fed. Cir. 2011) (continuation-in-part claims not entitled to parent filing date where parent lacks written description support for CIP claims).

The Examiner issued a single non-final rejection on April 5, 2000, on the grounds that 1) the claims were invalid due to non-statutory double patenting over claims of the '976 patent; 2) the claims (particularly claims 1 and 10) were directed to non-statutory subject matter under 35 U.S.C. § 101, because they were "devoid of any limitation to a practical application" (Ex. 1002 at 269); and 3) the claims were invalid due to statutory double patenting over claims that were exact duplicates of claims of the '976 patent.

To resolve the double patenting rejections, Patent Owner canceled the claims that were exact duplicates of claims of the '976 patent and submitted a terminal disclaimer for the remaining claims. To resolve the Section 101 rejection, Patent Owner amended claims 1 and 10 to claim that the "pre-operative geometric planner outputs at least one geometric model of the joint and the pre-operative kinematic biomechanical simulator outputs a position for implantation of the artificial component." (Ex. 1002 at 282.) Notably, this language specifies "the joint" and thus relies on the new matter language in the preamble for antecedent basis.

The Patent Office issued a notice of allowance on September 21, 2000, and the '411 patent issued on March 20, 2001.

IV. DETAILED EXPLANATION OF GROUNDS FOR INVALIDITY

Pursuant to 37 C.F.R. §§ 42.22(a)(1) and 42.104(b), Petitioner respectfully requests the cancellation of claims 1-17 of the '411 patent as they are unpatentable for the reasons set forth in this Petition. Specifically, Petitioner shows below that all of the claims of the '411 patent are anticipated or rendered obvious by the '411 inventors' own disclosures well over a year before the '411 patent was filed. As demonstrated in Part IV.B, DiGioia is an article published at least as early as 1996 that teaches nearly all of the elements of the claimed systems and methods, with only minor variations that would have been obvious to one of skill in the art. DiGioia II is an article published even earlier that teaches, in combination with another article by the same authors, the claimed systems and methods as well.

In each of the following sections, Petitioner sets forth the specific art and statutory grounds on which the challenge is based in a table at the beginning of the section. 37 C.F.R. §§ 42.22(a)(2) and 42.104(b)(2). Petitioner then presents a discussion of how the claims are unpatentable under the statutory grounds raised. 37 C.F.R. § 42.104(b)(4). Finally, Petitioner sets forth a claim chart that specifies where each element of each of the Challenged Claims is met by the prior art for ease of reference. *Id.* The showing in these sections establishes more than a reasonable likelihood of prevailing as to each ground of invalidity.

The grounds for invalidity set forth below are supported by the declaration of Robert Howe, who provides testimony regarding the prior art and the understanding of one of ordinary skill in the art. Robert Howe's declaration is attached as Exhibit 1004. Petitioner notes that during *inter partes* review a claim is given the "broadest reasonable construction in light of the specification." *See* 37 C.F.R. § 42.100(b). Petitioner submits, for the purposes of this *inter partes* review only, that claim terms are presumed to take on their broadest reasonable ordinary and customary meaning to a person of ordinary skill in the art in light of the specification of the '411 patent. Petitioner reserves the right to advocate a different claim construction in district court or any other forum.

A. DiGioia.

Ground 1 is based on DiGioia (Ex. 1005) and is addressed below.

Ground	35 U.S.C. §	Claims	References
1	103	1-17	A.M. DiGioia et al., "HipNav: Pre-operative Planning and Intra-operative Navigational Guidance for Acetabular Implant Placement in Total Hip Replacement Surgery," 2nd CAOS Symposium, 1996 ("DiGioia") (Ex. 1005), in view of "An Integrated Approach to Medical Robotics and Computer Assisted Surgery in Orthopaedics," *Proc. 1st Int'l Symposium on Medical Robotics and Computer Assisted Surgery*, pp. 106-111, 1995 ("DiGioia II") (Ex. 1006) and knowledge of person of ordinary skill.

DiGioia is an article published at least as early as 1996. (*See* Ex. 1002 at 96 (Patent Owner admitting in IDS that DiGioia has a 1996 publication date).) As discussed above, the earliest priority date for claims 1-17 of the '411 patent can be no earlier than November 12, 1998, two years later. Thus, DiGioia qualifies as prior art under § 102(b).

DiGioia describes a system and methods to determine optimal implant placement during hip replacement surgery through the use of pre-operative planning, a range of motion simulator, and intra-operative navigational tracking and guidance. As it explains, a common problem causing complications after hip replacement surgery is poor positioning of the implant. The DiGioia system, called HipNav, allowed the surgeon to specify a component position, after which the range of motion simulator would estimate femoral range of motion based on parameters provided by the pre-operative planner. The feedback from the simulator allowed the surgeon to determine patient-specific optimal implant placement. The intra-operative tracking and guidance helped place the implant in that optimal position, regardless of the position of the patient on the operating table.

DiGioia is clearly relevant to the patentability of the claims of the ’411 patent, as it describes in detail the systems and methods claimed in the ’411 patent over a year before the ’411 patent was filed. Like the system disclosed in the ’411’s independent system claims 1 and 10, DiGioia discloses:

(1) a computer system for facilitating implantation of an artificial component in one of the specified joint types (Ex. 1005 at 1 (HipNav “allows a surgeon to determine optimal patient specific acetabular implant placement and accurately achieve the desired acetabular implant placement during surgery”)) with

(2) a pre-operative geometric planner (*id.* at 2 (“[P]re-operative planner allows the surgeon to manually specify the position of the acetabular component within the pelvis based upon pre-operative CT images,” and is therefore geometric)) and

(3) a pre-operative kinematic biomechanical simulator in communication with the geometric planner (*id.* at Fig. 3 (depicting range of motion simulator with arrows illustrating communication between simulator and planner)), where

(4) the geometric planner outputs a geometric model of the joint (*id.* at 2 (simulator receives from pre-operative planner implant placement parameters, which are necessarily based upon and described relative to geometric model of joint)), and

(5) a tracking device communicating with the computer system (*id.* at 4 (intra-operative system includes Optotrak optical tracking camera capable of tracking special LEDs)).

Similarly, like the method disclosed in the '411's independent method claim 17, DiGioia discloses a computerized method:

(1) for facilitating implantation of an artificial implant in one of the specified joint types (Ex. 1005 at 1), comprising

(2) creating a three-dimensional bone model (*id.* at 5-6, Fig. 8 (system uses pelvic surface model constructed from CT data using techniques discussed in three-dimensional modeling article)),

(3) creating a three-dimensional component model (*id.* at Fig. 4 (depicting positioning of implant component across three orthogonal views of pelvis)),

(4) simulating movement of the joint with the artificial implant in a test position (*id.* at 2 (discussing range of motion simulator)),

(5) calculating a range of motion (*id.* at 3-4 (simulator performs kinematic analysis to determine envelope of safe range of motion))**,**

(6) identifying the implant position in the bone model (*id.* at 3 (surgeon can position cross sections of implant upon orthogonal view of pelvis)),

(7) aligning the bone model with the bone based on tracking data (*id.* at 5 (disclosing registration process to align position of patient to pre-operative plan)), and

(8) tracking the implant and bone to maintain alignment and determine the position of the implant relative to the bone (*id.* at 5-7 (discussing tracking of implant and bone and use of navigational feedback)).

The few claim elements that are not explicitly disclosed by DiGioia are minor, obvious variations. For example, claim 1 requires the pre-operative kinematic biomechanical simulator to output a position for implantation of the artificial component. The DiGioia system discloses that feedback from the simulator can aid the surgeon in determining optimal implant placement.

(Ex. 1005 at 2.) It would have been obvious to utilize the feedback to modify the position of an implant, re-run the simulation to determine optimal position, and output that position to the pre-operative planner. (Ex. 1004 ¶ 38.) This is also suggested by DiGioia Figure 3, which depicts bi-directional communication between the pre-operative planner and the range of motion simulator. (*Id.*) Similarly, claim 17 requires the system to determine an implant position based on a predetermined range of motion and the calculated range of motion. DiGioia discloses calculation of a range of motion and states the surgeon may choose to modify a selected position to achieve optimal implant positioning. (Ex. 1005 at 3.) It would have been obvious to consider the specific patient's functional needs and the range of motion needed to perform those functional needs, which could be predetermined, to help in determining optimal implant positioning. (Ex. 1004 ¶ 41.)

DiGioia also matches the '411 patent's dependent claims:

- Claims 2 and 15 add an intra-operative navigational module in communication with the pre-operative kinematic biomechanical simulator. DiGioia illustrates that the system also includes an "Intra-operative Tracking & Guidance" component. DiGioia indicates that this component includes an "intra-operative guidance system" which includes "registration of pre-operative information . . . to the position of the patient. (Ex. 1005 at 5.) Once anatomical location is determined "via registration, navigational feedback can be provided to the surgeon on a television monitor, as seen in Figure 9." (*Id.* at 6.)

- Claim 3 requires a tracking device in communication with said intra-operative navigational module. DiGioia discloses that the intra-operative system includes "an 'Optotrak' optical tracking camera . . . which is capable of tracking the position of special light emitting diodes . . . to allow highly reliably tracking." (Ex. 1005 at 4.) "In order to determine the location of the pelvis and the acetabular implant during surgery, Optotrak targets are attached to several conventional surgical tools, as seen in Figure 7." (*Id.*) DiGioia indicates that "[o]nce the location of the pelvis is determined . . . navigational feedback can be provided to the surgeon." (*Id.* at 6.) Thus, because the navigation module relies upon the tracking device, the navigation module is in communication with the tracking device.
- Claim 4 requires the pre-operative geometric planner to be responsive to a skeletal data source. DiGioia states that the "first step in using the HipNav system is the pre-operative CT scan which is used to determine the patient's specific bony geometry. The CT images are used in the pre-operative planner which allows the surgeon to

determine appropriate implant size and placement." (Ex. 1005 at 3.) Therefore, the data source inherently is a skeletal data source.

- Claim 5 adds that the skeletal data source includes geometric data. DiGioia states that "the pre-operative CT scan . . . is used to determine the patient's specific bony geometry" (Ex. 1005 at 3) and therefore the skeletal data source inherently includes geometric data.
- Claim 6 requires the geometric planner to output at least one geometric model of the component. DiGioia states that the "pre-operative planner allows the surgeon to manually specify the position of the acetabular component within the pelvis . . . [and then] [t]he range of motion simulator estimates femoral range of motion based upon the implant placement parameters provided by the pre-operative planner." (Ex. 1005 at 2.) Thus, the pre-operative planner outputs a geometric model of the component to the range-of-motion simulator.
- Claim 7 requires the pre-operative kinematic biomechanical simulator to be responsive to the geometric model and output an implant position. As noted under claim 6, "[t]he range of motion simulator estimates femoral range of motion based upon the implant placement parameters provided by the pre-operative planner" (Ex. 1005 at 2) and therefore is responsive to said geometric model. As discussed under

claim 1, it would have been obvious to a person of skill in the art to utilize the simulator feedback to modify the position of an implant, re-run the simulation to determine optimal position, and output that position to the pre-operative planner. (Ex. 1004 ¶ 38.)

- Claim 8 requires the implant position to include an angular orientation of the component. DiGioia notes that using navigational feedback provided to the surgeon, "[o]nce aligned, the implant is in the pre-operatively planned position and orientation." (Ex. 1005 at 6.) Thus, pre-operative planning involves determining both the position and orientation of the implant location.
- Claim 9 adds that the tracking device must be selected from the group consisting of an acoustic tracking system, shape based recognition tracking system, video-based tracking system, mechanical tracking system, electromagnetic tracking system and radio frequency tracking system, and claim 13 requires that the tracking device include at least one camera. DiGioia discloses an Optotrak camera-based tracking system. (Ex. 1005 at 4.) Even if this was not considered a video-based tracking system, video-based tracking systems were widely used and known to those of skill in the art in the mid-1990s, and it would have been obvious to combine video-based capability with the

DiGioia system or substitute a video-based tracking system for the Optotrak camera system. (*See* Ex. 1004 ¶ 39.)

- Claim 11 adds a display monitor in communication with the computer system of claim 10. DiGioia states that using "the planner, the surgeon can position cross sections of the acetabular implant upon orthogonal views of the pelvis, as seen in Figure 4." (Ex. 1005 at 3.) This user interface of the pre-operative planner is a display monitor in communication with the computer of the pre-operative planner.
- Claim 12 adds a controller in communication with the computer system. DiGioia states that the "pre-operative planner allows the surgeon to manually specify the position of the acetabular component within the pelvis." (Ex. 1005 at 2.) A controller, such as a mouse, joystick or keyboard, or voice-activated control, would necessarily have been provided to allow the surgeon to manually specify the implant position.
- Claim 14 adds that the tracking device includes at least one target. DiGioia states that "[i]n order to determine the location of the pelvis and the acetabular implant during surgery, Optotrak targets are attached to several conventional surgical tools, as seen in Figure 7. The pelvis is tracked by attaching a target to the pelvic portion of a

Harris leg length caliper . . . . The acetabular implant is tracked by attaching a second target to the handle of an HGP II acetabular cup holder and positioner . . . . A third Optotrak target is required by the HipNav system to determine operating room coordinates . . . ." (Ex. 1005 at 4-5.)

- Claim 16 adds the requirement of a robotic device and surgical tool. Several of the same authors, including DiGioia himself, previously published "An Integrated Approach to Medical Robotics and Computer Assisted Surgery in Orthopaedics," *Proc. 1st Int'l Symposium on Medical Robotics and Computer Assisted Surgery*, pp. 106-111, 1995 ("DiGioia II") (Ex. 1006). DiGioia II discloses an approach to improved surgical techniques incorporating pre-operative planning with biomechanical analysis and computer or robot-assisted surgery. (Ex. 1006 at 3.) It depicts a ceiling-mounted robotic arm and a surgical tool at the end of the arm. (*Id.* at Fig. 1.) It would have been obvious to a person of ordinary skill in the art to combine the robotic device and surgical tool from this similar prior reference with DiGioia, particularly in light of the fact that DiGioia II is an article by the same authors, addressing the same problems, only a short time before the publication of DiGioia. (Ex. 1004 ¶ 40.)

Thus, Petitioner has set forth above a discussion of how the claims are unpatentable. 37 C.F.R. § 42.104(b)(4). For ease of reference, Petitioner also sets forth below a claim chart that specifies where each element of a challenged claim is met by DiGioia. *Id.*

Text of Claim	DiGioia
1.1 An apparatus for facilitating the implantation of an artificial component in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint, comprising:	"The Hip Navigation or HipNav system allows a surgeon to determine optimal patient specific acetabular implant placement and accurately achieve the desired acetabular implant placement during surgery." (Ex. 1005 at 1.)
1.2 a pre-operative geometric planner	"HipNav includes . . . a pre-operative planner . . . ." (*Id.* at 1.) "The pre-operative planner allows the surgeon to manually specify the position of the acetabular component within the pelvis based upon pre-operative CT images." (*Id.* at 2.)
1.3 a pre-operative kinematic biomechanical simulator in communication with said pre-operative geometric planner	*See* Ex. 1005 at Fig. 3 ("Range of Motion Simulator" connected with arrows to and from "Pre-operative Planner").
1.4 wherein said pre-operative geometric planner outputs at least one geometric model of the joint and	"The range of motion simulator estimates femoral range of motion based upon the implant placement parameters provided by the pre-operative planner." (*Id.* at 2.) *See also supra* at 13.
1.5 the pre-operative kinematic biomechanical simulator outputs a position for implantation of the	"The range of motion simulator estimates femoral range of motion based upon the implant placement

Text of Claim	DiGioia
artificial component.	parameters provided by the pre-operative planner. The feedback provided by the simulator can aid the surgeon in determining optimal, patient specific acetabular implant placement." (Ex. 1005 at 2.) Obvious to utilize feedback to determine and output optimal position. *See supra* at 14-15; Ex. 1004 ¶¶ 38, 44.
2. The apparatus of claim 1, further comprising an intra-operative navigational module in communication with said pre-operative kinematic biomechanical simulator.	"HipNav includes . . . an intra-operative tracking and guidance system." (Ex. 1005 at 1.) "Several key steps are necessary to use the HipNav intra-operative guidance system. One of the most important is the registration of pre-operative information (i.e., the CT scan and pre-operative plan) to the position of the patient on the operating room table. . . . Once the location of the pelvis is determined via registration, navigational feedback can be provided to the surgeon on a television monitor, as seen in Figure 9." (*Id.* at 5-6.)
3. The apparatus of claim 2, further comprising a tracking device in communication with said intra-operative navigational module.	"[A]n 'Optotrak' optical tracking camera . . . is capable of tracking the position of special [LEDs]. . . . In order to determine the location of the pelvis and the acetabular implant during surgery, Optotrak targets are attached to several conventional surgical tools, as seen in Figure 7." (*Id.* at 4.) "[O]nce the location of the pelvis is determined . . . navigational feedback can be provided to the surgeon . . . ." (*Id.* at 6.)
4. The apparatus of claim 1, wherein	"The first step in using the HipNav

Text of Claim	DiGioia
said pre-operative geometric planner is responsive to a skeletal data source.	system is the pre-operative CT scan which is used to determine the patient's specific bony geometry. The CT images are used in the pre-operative planner which allows the surgeon to determine appropriate implant size and placement." (*Id.* at 3.)
5. The apparatus of claim 4, wherein said skeletal data source includes geometric data.	*See* claim 4; Ex. 1005 at 3 ("patient's specific bony geometry").
6. The apparatus of claim 4, wherein said pre-operative geometric planner outputs at least one geometric model of the component.	"The pre-operative planner allows the surgeon to manually specify the position of the acetabular component within the pelvis . . . [and then] [t]he range of motion simulator estimates femoral range of motion based upon the implant placement parameters provided by the pre-operative planner." (Ex. 1005 at 2.)
7. The apparatus of claim 6, wherein said pre-operative kinematic biomechanical simulator is responsive to said geometric model and outputs an implant position.	*See* element 1.5; *supra* at 17-18.
8. The apparatus of claim 7, wherein said implant position includes an angular orientation of the component.	"[O]nce aligned, the implant is in the pre-operatively planned position and orientation." (Ex. 1005 at 6.)
9. The apparatus of claim 3, wherein said tracking device is selected from the group consisting of an acoustic tracking system, shape based recognition tracking system, video-based tracking system, mechanical tracking system, electromagnetic	Anticipated to the extent Optotrak camera-based tracking system is video-based, obvious to the extent not. *See supra* at 18-19; Ex. 1004 ¶ 48.

Text of Claim	DiGioia
tracking system and radio frequency tracking system.	
10.1 A system for facilitating an implant position for at least one artificial component in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint, comprising:	*See* element 1.1.
10.2 a computer system including	*See* Ex. 1005 at 1 ("Keywords: computer assisted surgery"); Fig. 4 (depicting graphical user interface).
10.3 a pre-operative geometric planner; and	*See* element 1.2; Ex. 1005 at Fig. 4 (graphical user interface captioned "Pre-operative planner").
10.4 a pre-operative kinematic biomechanical simulator in communication with said pre-operative geometric planner	*See* element 1.3.
10.5 wherein pre-operative geometric planner outputs at least one geometric model of the joint and	*See* element 1.4; *supra* at 13.
10.6 the pre-operative kinematic biomechanical simulator outputs a position for implantation of the artificial component; and	*See* element 1.5; *supra* at 14-15.
10.7 a tracking device in communication with said computer system.	*See* claim 3; Ex. 1005 at Fig. 3 (depicting tracking camera as part of system).
11. The system of claim 10, further	Ex. 1005 at Fig. 4 (depicting graphical

Text of Claim	DiGioia
comprising at least one display monitor in communication with said computer system.	user interface); *id.*at 3 ("In the current version of the planner, the surgeon can position cross sections of the acetabular implant upon orthogonal views of the pelvis as seen in Figure 4.").
12. The system of claim 10, further comprising at least one controller in communication with said computer system.	"The pre-operative planner allows the surgeon to manually specify the position of the acetabular component within the pelvis . . . ." (*Id.* at 2.) *See supra* at 19.
13. The system of claim 10, wherein said tracking device includes at least one camera.	*See* claim 9.
14. The system of claim 10, wherein said tracking device includes at least one target.	"In order to determine the location of the pelvis and the acetabular implant during surgery, Optotrak targets are attached to several conventional surgical tools, as seen in Figure 7. The pelvis is tracked by attaching a target to the pelvic portion of a Harris leg length caliper . . . . The acetabular implant is tracked by attaching a second target to the handle of an HGP II acetabular cup holder and positioner . . . . A third Optotrak target is required by the HipNav system to determine operating room coordinates . . . ." (Ex. 1005 at 4-5.)
15. The system of claim 10, wherein said computer system further includes an intra-operative navigational module in communication with said pre-operative kinematic biomechanical simulator.	*See* claim 2.

Text of Claim	DiGioia
16. The system of claim 10, further comprising: a robotic device in communication with said computer system; and a surgical tool connected to said robotic device.	Obvious in view of DiGioia II. *See supra* at 20; Ex. 1004 ¶ 37.
17.1 A computerized method of facilitating the implantation of an artificial implant in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint, comprising:	*See* element 1.1.
17.2 creating a three dimensional bone model based on skeletal geometric data of a bone and a bony cavity into which the artificial implant is to be implanted;	"The pelvic surface model was constructed from CT data using techniques described in [1]." (Ex. 1005 at 5.) "[1] B. Geiger, *Three dimensional modeling of human organs and its application to diagnosis and surgical planning*, PhD thesis, Ecole des Mines de Paris, April 1993." (*Id.* at 7.) *See also id.* at Fig. 8 (depicting pelvic bone model). "[T]he surgeon can position cross sections of the acetabular implant upon orthogonal views of the pelvis, as seen in Figure 4." (*Id.* at 3.) *See supra* at 13-14.
17.3 creating a three dimensional component model of the artificial implant;	Ex. 1005 at Fig. 4 (depicting positioning of implant across three orthogonal views of pelvis).
17.4 simulating movement of the joint with the artificial implant in a test position;	"The range of motion simulator estimates femoral range of motion based upon the implant placement parameters provided by the pre-

Text of Claim	DiGioia
	operative planner." (*Id.* at 2.)
17.5 calculating a range of motion of the artificial implant and the bones comprising the joint for the test position based on the simulated movement;	"The range of motion simulator performs a kinematic analysis which determines an 'envelope' of the safe range of motion, as seen in Figure 5." (*Id.* at 3.) *See also id.* ("[T]he range of motion simulator is used to determine the femoral positions (in terms of extension/flexion, abduction/adduction, and internal/external rotation) at which impingement would occur for that specific implant design and position.").
17.6 determining an implant position based on a predetermined range of motion and the calculated range of motion;	"Based upon this range of motion information, the surgeon may choose to modify the selected position in an attempt to achieve the 'optimal' cup position for the specific patient." (*Id.* at 3.) Obvious to consider predetermined ranges of motion as well, *see supra* at 15; Ex. 1004 ¶ 41.
17.7 identifying the implant position in the bone model;	"[T]he surgeon can position cross sections of the acetabular implant upon orthogonal views of the pelvis, as seen in Figure 4." (Ex. 1005 at 3.)
17.8 aligning the bone model with the patient's bone and	"[T]he surfaces of a bone (such as the pelvis or acetabulum) can be used to accurately align the intra-operative position of the patient to the pre-operative plan . . . ." (*Id.* at 5.)
17.9 placing the implant based on positional tracking data providing the position of the implant and the bone; and	"Once the location of the pelvis is determined via registration, navigational feedback can be provided to the surgeon on a television monitor, as seen in Figure 9." (*Id.* at 6.) "To

Text of Claim	DiGioia
	accurately align the cup within the acetabulum in the position determined by the pre-operative plan, the cross hairs representing the tip of the implant and the top of the handle must be aligned at the fixed cross hair in the center of the image. Once aligned, the implant is in the pre-operatively planned position and orientation." (*Id.*)
17.10 tracking the implant and the bone to maintain alignment of the bone model and to determine the position of the implant relative to the bone.	*See* claim 14 (describing tracking targets). "Registration also allows the position of the pelvis to be tracked during surgery using the Optotrak system. . . . [t]his eliminates the need for rigid fixation of the pelvis." (Ex. 1005 at 6.) *See also* element 17.9 (describing use of tracked information to provide "navigation feedback" that is then used to align "the implant . . . in the pre-operatively planned position and orientation").

B. DiGioia II.

Grounds 2 and 3 are based on DiGioia II (Ex. 1006) and are addressed below.

Ground	35 U.S.C. §	Claims	References
2	102(b)	1-2, 4-8	Anthony M. DiGioia III et al., "An Integrated Approach to Medical Robotics and Computer Assisted Surgery in Orthopedics," *Proc. 1st Int'l Symp. on Medical Robotics and Computer Assisted Surgery*, pp.

			106–111, 1995 ("DiGioia II") (Ex. 1006).
3	103	1-17	DiGioia II in view of E.Y.S. Chao et al., "Simulation and Animation of Musculoskeletal Joint System," Transactactions of the ASME, Vol. 115, pp. 562-568, Nov. 1993 ("Chao") (Ex. 1007); R.V. O'Toole III et al., "Towards More Capable and Less Invasive Robotic Surgery in Orthopaedics," *Computer Vision, Virtual Reality and Robotics in Medicine Lecture Notes in Computer Science*, Vol. 905, pp. 123-130, 1995 ("O'Toole") (Ex. 1008); Russell H. Taylor et al., *An Image-Directed Robotic System for Precise Orthopaedic Surgery*, IEEE Transactions on Robotics and Automation, Vol. 10, No. 3, June 1994 ("Taylor") (Ex. 1009); and knowledge of person of ordinary skill.

As discussed above, DiGioia II is an article published at least as early as 1995, three years prior to the priority date to which the '411 patent is entitled and 1-2 years prior to even the parent application filing date. (Ex. 1006; http://www.ri.cmu.edu/person.html?type=publications&person_id=65 (listing publication date as 1995).) Thus, regardless of whether the '411 patent is entitled to its own filing date or the filing date of the parent application, DiGioia II qualifies as prior art under Section 102(b).

Much like DiGioia, DiGioia II describes systems and methods to improve accuracy of joint replacements through the use of pre-operative planning and computer systems. DiGioia proposes a pre-operative planning component and the use of a simulator to determine optimal implant positioning. It describes that if biomechanics-based preoperative planning is linked with patient and pre-determined implant data, as well as a computer or robot monitoring and assisting the surgery, surgical results could be improved. A main figure in the article, Figure 1, displays the combined system, indicating with arrows communication between the various components.

Like the '411 patent and the DiGioia reference discussed above, DiGioia II discloses an approach to improved surgical techniques incorporating pre-operative planning with biomechanical analysis and computer or robot-assisted surgery. (Ex. 1006 at 108.) Like the system disclosed in the '411's independent system claims 1 and 10, DiGioia II discloses a computer system:

(1) for facilitating implantation of an artificial component in one of the specified joint types (Ex. 1006 at Fig. 1 (depicting cup and femoral implants)) with

(2) a pre-operative geometric planner (*id.* (depicting "Biomechanics-based Preoperative Planning" portion of system with "3-D Templating")) and

(3) a pre-operative kinematic biomechanical simulator in communication with the geometric planner (*id.* (depicting biomechanical analysis system, shown to be in communication with geometric planner via arrows); *id.* at 107 (stating system will "provide the surgeon with feedback concerning the distribution of strain in the bone, and the amount of bone-implant contact for a given surgical plan" and consider "bone remodeling effects due to joint loading and varying load transfer mechanisms," which relates to movement and is therefore a kinematic biomechanical simulator)); where

(4) the geometric planner outputs a geometric model of the joint (*id.* at Fig. 1 (depicting that 3-D templating subsystem of pre-operative planner outputs geometric model of bones to biomechanical analyzer subsystem)); and

(5) the biomechanical simulator outputs a position for implantation of the artificial component (*id.* at 108-09 (stating that "the simulation may help indicate an 'optimal' bone cavity shape and implant location"); Fig. 1 (depicting return arrow from biomechanical analyzer subsystem, indicating that shape and location is being output back to planner)).

Similarly, like the method disclosed in the '411's independent method claim 17, DiGioia II discloses a computerized method:

(1) for facilitating implantation of an artificial implant in one of the specified joint types (Ex. 1006 at Fig. 1 (depicting computer and robotic surgical system for performing hip replacement surgeries)), comprising

(2) creating a three-dimensional bone model (*id.* (depicting software that utilizes radiological imaging data to generate 3-D skeleton models as well as database of implant models, which are provided to planning software that generates 3-D templates from models which then allow biomechanical simulator to evaluate selected implant position); Fig. 2 (depicting bone model, implant model, and bony cavity into which implant model is implanted)),

(3) creating a three-dimensional component model (*id.* at Fig. 1 (depicting computer with implant database used to generate 3-D model of implant)),

(4) simulating movement of the joint with the artificial implant in a test position (*id.* at 107 (describing biomechanical analysis system that will "provide the surgeon with feedback concerning the distribution of strain in the bone, and the amount of bone-implant contact for a given surgical plan" and consider "bone remodeling effects due to joint loading and varying load transfer mechanisms," which relate to movement and are therefore a kinematic biomechanical simulator)).

(5) identifying the implant position in the bone model (*id.* at Fig. 2 (depicting implant position in cavity of bone model)).

The few independent claim elements that are not explicitly disclosed by DiGioia II are minor variations that are obvious in view of other prior art or knowledge of one skilled in the art. For example, claim 10 requires a tracking device in communication with the computer system. DiGioia II discloses that its system includes a computer assisted or robot-assisted surgery system component, as shown in Figure 1, but does not expressly disclose any tracking device that used with a robot-assisted surgery system. However, it would have been obvious to include a tracking system with the robot-assisted surgery system as described by DiGioia II, particularly in view of O'Toole, another article written by several of the same authors. (Ex. 1004 ¶ 49.) A person of ordinary skill would be motivated to combine DiGioia with O'Toole, as O'Toole also describes a system for planning a hip surgery involving a femoral implant and a femur and shares most of its authors with DiGioia II (including respective lead authors O'Toole and DiGioia along with four other authors). (*Id.*¶ 33.) O'Toole is also Section 102(b) prior art to the '411 patent as it was published in 1995. (*Id.*) O'Toole explicitly states that with the use of high-speed tracking, the bone being milled does not have to be rigidly fixated, which necessarily requires a tracking device to communicate with the navigation module of the robotic system. (Ex. 1008 at 124, 129.)

Similarly, claim 17 requires calculating a range of motion of the implant and bones based on simulated movement. A person of ordinary skill in the art would be motivated to combine DiGioia II with Chao, an article published roughly one year earlier (November 1993) addressing the same subject matter as DiGioia II. (Ex. 1004 ¶ 32.) Like DiGioia II, Chao addresses simulation and animation of joints. Also like DiGioia II, Chao expresses a desire to allow a user to simulate joint pressure distribution in order to improve joint replacement, including hip replacements. Chao was published in 1993, and is therefore also Sections 102(a) and 102(b) prior art to the '411 patent. Chao indicates that its simulations may be used for "[s]election and planning in total joint replacement" and discloses examples where "[j]oint pressure and motion were obtained through model simulation." (Ex. 1007 at 565.) In light of Chao, it would have been obvious to simulate motion of the bones with the implant in place and therefore calculate the range of motion of the simulated motion. (Ex. 1004 ¶ 50.) It would also have been obvious to one of skill in the art when finalizing implant position to take into account the desired functional outcome of the patient, such as a predetermined desired range of motion, and this calculated range of motion. (*Id.*)

Claim 17 also requires aligning the bone model with the bone, placing the implant based on position tracking data, and tracking the implant and bone to maintain alignment of the bone model. Persons of ordinary skill would naturally have looked to O'Toole, another article published by several of the same authors as DiGioia II. (Ex. 1004 ¶ 51.) O'Toole describes intra-surgical registration as "the process of establishing a common reference frame between pre-surgical data and the corresponding patient anatomy." (Ex. 1008 at 128), which is a process that results in an alignment between the bone model and the patient's anatomy. This is necessarily maintained during surgery in order to perform accurate milling, and therefore also necessarily requires a tracking of the bone implant and bone.

O'Toole states further that the "modeling, simulation, and registration components manifest themselves in the robotic milling of a bone cavity. The focus . . . is on the milling of the acetabulum (socket in the pelvis) to prepare for the implantation of a cementless acetabular component." (*Id.*) O'Toole continues that with the use of high speed tracking, the bone being milled does not have to be rigidly fixated. This necessarily requires a tracking device that communicates with the navigation module of the robotic milling system to "compensate for this bone motion." (*Id.* at 129.) Thus, the position and placement of the acetabular component into the milled acetabulum is based upon the bone cavity milled for the implant, which is located on the bone being tracked by the robotic system. It would also have been obvious to track the implant relative to the bony implantation site in order to ensure accurate orientation and placement. (Ex. 1004 ¶51.)

DiGioia II also matches the '411 patent's dependent claims:

- Claims 2 and 15 add an intra-operative navigational module in communication with the pre-operative kinematic biomechanical simulator. DiGioia II indicates that "surgical robots actually improve the clinical usefulness of realistic surgical simulations" and that "surgical simulations also increase the utility of surgical robots." (Ex. 1006 at 109.) A surgical robot necessarily includes an intra-operative navigational module to accurately perform the surgical procedures, and Figure 1 of DiGioia II depicts the communication between an intra-operative navigational module and the pre-operative kinematic biomechanical simulator, via the pre-operative planner.

- Claim 3 requires a tracking device in communication with said intra-operative navigational module. DiGioia II discloses that its system includes a computer assisted or robot-assisted surgery system component, as shown in Figure 1, but does not expressly disclose any tracking device that used with a robot-assisted surgery system. It would have been obvious to include a tracking system such as one described in O'Toole, discussed above. (*See supra* at 33; Ex. 1004 ¶ 46.) As noted, O'Toole, another article by the same authors, discloses a system for planning a hip surgery involving a femoral implant and a femur. (Ex. 1008 at 124, Fig. 1.) O'Toole further states that with the use of high speed tracking, the bone being milled does not have to be rigidly fixated. This necessarily requires that the tracking device described by O'Toole that communicates with the navigation module of the robotic milling system to "compensate for this [bone] motion." (*Id.* at 129.)

- Claim 4 requires the pre-operative geometric planner to be responsive to a skeletal data source. Figure 1 of DiGioia II shows that the pre-operative planner utilizes skeletal data sources derived from patient imaging.
- Claim 5 adds that the skeletal data source includes geometric data. Figure 1 of DiGioia II shows that skeletal images of the pelvis and femur are used to perform pre-operative planning for a hip procedure
- Claim 6 requires the geometric planner to output at least one geometric model of the component. Figure 1 of DiGioia II shows that the pre-operative planner performs 3-D templating, which is output to the biomechanical analyzer component, and when the pre-operative plan is finalized, it is output to the computer- or robot-assisted surgery system
- Claim 7 requires the pre-operative kinematic biomechanical simulator to be responsive to the geometric model and output an implant position. Figure 1 of DiGioia II shows that the pre-operative kinematic biomechanical simulator receives the 3-D templates to

perform biomechanical analysis, and therefore is responsive to the geometric model from the pre-operative planner. Figure 1 further shows that that the biomechanical simulator feeds back its output to the 3-D templating component of the pre-operative planner, and that once the implant position is finalized, the implant position is necessarily output to the computer/robot-assisted surgery system. Thus, the pre-operative biomechanical simulator outputs an implant position to the pre-operative planner, and also to the computer/robot-assisted surgery system, as a component of the overall pre-operative system.

- Claim 8 requires the implant position to include an angular orientation of the component. Every implant position inherently includes an angular orientation, e.g., even if the yaw, pitch and roll are zero degrees angled from the base orientation. (*See* Ex. 1004 ¶ 47.)
- Claim 9 adds that the tracking device must be selected from the group consisting of an acoustic tracking system, shape based recognition tracking system, video-based tracking system, mechanical tracking system, electromagnetic tracking system and radio frequency tracking system. Claim 13 adds that the tracking device includes at least one camera. DiGioia II does not refer to any specific type of tracking

system for its system, but it would be obvious to utilize any of a variety of tracking systems known in the orthopedic literature. For example, one article well-known to those of skill in the art is Taylor (*see* Ex. 1004 ¶ 48 (discussing that Taylor was heavily cited and widely known)). Like DiGioia II, Taylor addresses a system to improve accuracy of orthopedic surgery. Taylor discloses a robotic surgery system that utilizes an "Optotrak™ 3D digitizer" which tracks light emitting diodes. (Ex. 1009 at 270.) As noted above, to the extent the Optotrak system was not video-based, video-based tracking systems were widely used and known to those of skill in the art in the mid-1990s. It would have been obvious to combine video-based capability with a known tracking system such as the Optotrak camera and the DiGioia II system. (*See* Ex. 1004 ¶ 48.)

- Claim 11 adds a display monitor in communication with the computer system of claim 10. Figure 1 of DiGioia II depicts the use of a display monitor with multiple functions of the computer system.
- Claim 12 adds a controller in communication with the computer system. Figure 1 of DiGioia II depicts a computer keyboard used with the system. Figure 1 of DiGioia II also depicts a surgeon utilizing a

wired controller that communicates with the robotic system, which in turn is in communication with a computer.

- Claim 14 adds that the tracking device includes at least one target. As discussed above with respect to claims 9 and 13, it would have been obvious to one of skill in the art to combine DiGioia II with the tracking system of Taylor. (Ex. 1004 ¶¶ 34, 48.) Taylor discloses that its optical tracking system utilizes cameras to track LED beacons, which are the targets. (Ex. 1009 at 270 (Optotrak tracker "is capable of tracking light emitting diodes . . . . We fabricated a rigid PC card with eight such beacons and affixed it to the robot[.]").)
- Claim 16 adds the requirement of a robotic device and surgical tool. Figure 1 depicts a robot-assisted surgery system that is in communication with the pre-operative computer system, and includes a robotic arm with a tool at its tip.

Thus, Petitioner has set forth above a discussion of how the claims are unpatentable. 37 C.F.R. § 42.104(b)(4). For ease of reference, Petitioner also sets forth below a claim chart that specifies where each element of a challenged claim is met by DiGioia II or DiGioia II in view of other prior art. *Id.*

Text of Claim	DiGioia II
1.1 An apparatus for facilitating the implantation of an artificial component in one of a hip joint, a knee joint, a	Ex. 1006 at Fig. 1 (depiction under "Implant Database").

Text of Claim	DiGioia II
hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint, comprising:	
1.2 a pre-operative geometric planner	Ex. 1006 at Fig. 1 ("Biomechanics-based Preoperative Planning"; "3-D Templating").
1.3 a pre-operative kinematic biomechanical simulator in communication with said pre-operative geometric planner	Ex. 1006 at 107 (biomechanical analysis system will "provide the surgeon with feedback concerning the distribution of strain in the bone, and the amount of bone-implant contact for a given surgical plan" and consider "bone remodeling effects due to joint loading and varying load transfer mechanisms"). Alternatively, obvious in view of Chao. Ex. 1007 at 563-66 (disclosing use of CT scans to develop 3D models for simulations); Ex. 1004 ¶ 32; *see supra* at 31.
1.4 wherein said pre-operative geometric planner outputs at least one geometric model of the joint and	Ex. 1006 at Fig. 1 (depicting "3-D Templating" with arrow connecting to "Biomechanical Analysis").
1.5 the pre-operative kinematic biomechanical simulator outputs a position for implantation of the artificial component.	Ex. 1006 at 108-09 ("the simulation may help indicate an 'optimal' bone cavity shape and implant location"); Fig. 1 (depicting return arrow from "Biomechanical Analysis" to "3-D Templating").
2. The apparatus of claim 1, further comprising an intra-operative navigational module in communication with said pre-operative kinematic biomechanical simulator.	Ex. 1006 at 109 ("[S]urgical robots actually improve the clinical usefulness of realistic surgical simulations."); *see supra* at 35-36.

Text of Claim	DiGioia II
3. The apparatus of claim 2, further comprising a tracking device in communication with said intra-operative navigational module.	Obvious in view of O'Toole. *See supra* at 36-37; Ex. 1004 ¶ 33.
4. The apparatus of claim 1, wherein said pre-operative geometric planner is responsive to a skeletal data source.	Ex. 1006 at Fig. 1; *see supra* at 37.
5. The apparatus of claim 4, wherein said skeletal data source includes geometric data.	Ex. 1006 at Fig. 1 (depicting "Imaging" with image of pelvis and femur, and arrow leading to "3-D Skeleton Model"); *see supra* at 37.
6. The apparatus of claim 4, wherein said pre-operative geometric planner outputs at least one geometric model of the component.	Ex. 1006 at Fig. 1; *see supra* at 37.
7. The apparatus of claim 6, wherein said pre-operative kinematic biomechanical simulator is responsive to said geometric model and outputs an implant position.	Ex. 1006 at Fig. 1; *see supra* at 37-38.
8. The apparatus of claim 7, wherein said implant position includes an angular orientation of the component.	*See supra* at 38.
9. The apparatus of claim 3, wherein said tracking device is selected from the group consisting of an acoustic tracking system, shape based recognition tracking system, video-based tracking system, mechanical	Obvious in view of Taylor or knowledge of a person of ordinary skill in the art. *See supra* at 38-39; Ex. 1004 ¶ 34.

Text of Claim	DiGioia II
tracking system, electromagnetic tracking system and radio frequency tracking system.	
10.1 A system for facilitating an implant position for at least one artificial component in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint, comprising:	*See* element 1.1.
10.2 a computer system including	*See* Ex. 1006 at Fig. 1 (depicting computer system).
10.3 a pre-operative geometric planner; and	*See* element 1.2.
10.4 a pre-operative kinematic biomechanical simulator in communication with said pre-operative geometric planner	*See* element 1.3.
10.5 wherein pre-operative geometric planner outputs at least one geometric model of the joint and	*See* element 1.4.
10.6 the pre-operative kinematic biomechanical simulator outputs a position for implantation of the artificial component; and	*See* element 1.5.
10.7 a tracking device in communication with said computer system.	Obvious in view of O'Toole. *See supra* at 33; Ex. 1004 ¶ 33.
11. The system of claim 10, further comprising at least one display monitor	Ex. 1006 at Fig. 1 (depicting display monitor); *see supra* at 39.

Text of Claim	DiGioia II
in communication with said computer system.	
12. The system of claim 10, further comprising at least one controller in communication with said computer system.	Ex. 1006 at Fig. 1 (depicting computer keyboard, wired controller held by surgeon); *see supra* at 39-40.
13. The system of claim 10, wherein said tracking device includes at least one camera.	Obvious in view of Taylor. *See supra* at 38-39; Ex. 1004 ¶ 34.
14. The system of claim 10, wherein said tracking device includes at least one target.	Obvious in view of Taylor. *See supra* at 40; Ex. 1004 ¶ 34.
15. The system of claim 10, wherein said computer system further includes an intra-operative navigational module in communication with said pre-operative kinematic biomechanical simulator.	*See* claim 2; *supra* at 35-36.
16. The system of claim 10, further comprising: a robotic device in communication with said computer system; and a surgical tool connected to said robotic device.	Ex. 1006 at Fig. 1 (depicting "Computer/Robot-Assisted Surgery" with image of robotic arm with tool at tip); *see supra* at 30.
17.1 A computerized method of facilitating the implantation of an artificial implant in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint, comprising:	*See* element 1.1.
17.2 creating a three dimensional bone	*See* Ex. 1006 at Fig. 1 (depicting

Text of Claim	DiGioia II
model based on skeletal geometric data of a bone and a bony cavity into which the artificial implant is to be implanted;	generation of "3-D Skeleton Model[s]"); Fig. 2 (depicting bone model, implant model, and bony cavity).
17.3 creating a three dimensional component model of the artificial implant;	Ex. 1006 at Fig. 1 (depicting "Implant Database" as part of "Patient Data," which is connected via arrow to "Biomechanics-based Preoperative Planning" that includes "3-D Templating").
17.4 simulating movement of the joint with the artificial implant in a test position;	*See* element 1.3. Alternatively, obvious in view of Chao. Ex. 1007 at 563-66 (disclosing use of CT scans to develop 3D models for simulations); Ex. 1004 ¶ 32.
17.5 calculating a range of motion of the artificial implant and the bones comprising the joint for the test position based on the simulated movement;	Obvious in view of Chao. *See supra* at 33-34; Ex. 1004 ¶ 32.
17.6 determining an implant position based on a predetermined range of motion and the calculated range of motion;	Obvious to one of skill in the art. *See supra* at 34; Ex. 1004 ¶ 50.
17.7 identifying the implant position in the bone model;	Ex. 1006 at Fig. 2 (depicting implant position in cavity of bone model).
17.8 aligning the bone model with the patient's bone and	Obvious in view of O'Toole. *See supra* at 34-35; Ex. 1004 ¶ 33.

Text of Claim	DiGioia II
17.9 placing the implant based on positional tracking data providing the position of the implant and the bone; and	Obvious in view of O'Toole. *See supra* at 34-35; Ex. 1004 ¶ 33.
17.10 tracking the implant and the bone to maintain alignment of the bone model and to determine the position of the implant relative to the bone.	Obvious in view of O'Toole. *See supra* at 34-35; Ex. 1004 ¶ 33.

V. Conclusion

For the reasons described above, there is a reasonable likelihood that Petitioner will prevail as to each of the ’411 patent claims at issue and a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable. 37 C.F.R. § 42.108(c). Accordingly *inter partes* review of claims 1-17 of the ’411 patent is respectfully requested.

Dated: January 28, 2015

Respectfully submitted,

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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached Petition for *Inter Partes* Review and supporting materials were served as of the below date by U.S. Express Mail on the Patent Owner at the correspondence address indicated for U.S. Patent No. 6,205,411:

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Dated: January 28, 2015

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