IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMMER HOLDINGS, INC. ZIMMER, INC. Petitioners

v.

BONUTTI SKELETAL INNOVATIONS LLC Patent Owner

Patent No. 7,837,736 Filing Date: October 30, 2007 Issue Date: November 23, 2010 Title: MINIMALLY INVASIVE SURGICAL SYSTEMS AND METHODS

Inter Partes Review No. Unassigned

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET SEQ*.

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LIST OF EXHIBITS

Exhibit 1001:	Bonutti U.S. Patent 7,837,736 ("Bonutti patent")
Exhibit 1002:	Walker et al. U.S. Patent 5,755,801 ("Walker patent")
Exhibit 1003:	Insall et al. U.S. Patent 6,319,283 ("Insall '283 patent")
Exhibit 1004:	Insall et al. U.S. Patent 6,068,658 ("Insall '658 patent")
Exhibit 1005:	Declaration of Arthur G. Erdman, Ph.D. ("Erdman Decl.")
Exhibit 1006:	Bonutti patent file history section - Response To Office Action, filed June 18, 2010
Exhibit 1007:	Zimmer "Mbk Mobile Bearing Knee" brochure ("Mbk brochure")
Exhibit 1008:	Zimmer "Mbk Mobile Bearing Knee Implant & Instrument Order Form" ("Mbk order form")
Exhibit 1009:	Zimmer "Micro-Mill Instrument Surgical Technique for Mobile Bearing Knees" surgical guide ("Mbk Micro-Mill surgical guide")
Exhibit 1010:	Zimmer "Mbk Intramedullary Instrument Surgical Technique for Mobile Bearing Knee" surgical guide ("Mbk intramedullary surgical guide")

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.*, Zimmer Holdings, Inc. and Zimmer, Inc. ("Petitioners") request *inter partes* review of claims 15-28 and 31-36 of the Bonutti U.S. Patent 7,837,736 ("Bonutti patent") (Ex. 1001).

I. NOTICES AND FORMALITIES

A. Real Parties in Interest

Zimmer Holdings, Inc. and Zimmer, Inc. are the real parties-in-interest for this petition ("Petition").

B. Related Matters

The Bonutti patent is the subject of a patent infringement lawsuit brought by Bonutti Skeletal Innovations LLC ("Patent Owner") against Petitioners in the United States District Court for the District of Delaware. The Case No. of the lawsuit is 1:12-cv-01107-GMS.

C. Lead and Back-Up Counsel and Request for *Pro Hac Vice* Motion

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Petitioners hereby request authorization to file a motion for Kenneth Liebman to appear *pro hac vice*. Mr. Liebman is an experienced litigation attorney, is the lead attorney for Petitioners in the litigation referred to in Section I.B. above, and has an established familiarity with the subject matter at issue in this proceeding. Petitioners will file such a motion upon the grant of this request.

D. Service Information

Please address all correspondence to the lead counsel at the address shown above. Petitioners consent to electronic service to the email addresses above.

E. Grounds for Standing

Petitioners hereby certify that the patent for which review is sought is available for *inter partes* review and that Petitioners are not barred or estopped from requesting an *inter partes* review challenging the Bonutti patent claims on the grounds identified in this Petition.

F. Power of Attorney

A power of attorney designating counsel is being filed with this Petition.

G. Fees

The Commissioner is authorized to charge the \$9,000 request fee, \$14,000 post-institution fee, \$2,000 post-institution excess claims fee (total of \$25,000), and any additional fees to our Deposit Account No. 06-0029, and to notify us of the same.

II. STATEMENT OF THE PRECISE RELIEF REQUESTED

Petitioners respectfully request that claims 15-28 and 31-36 of the Bonutti patent be canceled based on the following grounds. A full statement of the reasons for this request is presented in later sections of this Petition. These grounds are supported by a Declaration of Arthur G. Erdman, Ph.D. ("Erdman Decl.," Ex. 1005).

Ground 1: Claims 15-22, 25-28 and 31-36 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by the Walker et al. U.S. Patent 5,755,801 ("Walker patent," Ex.1002).^{1, 2}

Ground 2: Claims 15-22, 25-28 and 31-36 are unpatentable under 35 U.S.C. § 103 as being obvious over the Walker patent in combination with either or both

¹ The Bonutti patent issued prior to the America Invents Act ("AIA"). Petitioners therefore use the pre-AIA statutory framework in this petition.

² Petitioners are not challenging claim 37 in part because it fails to comply with the requirements of 35 U.S.C. § 112, ¶ 2. In particular, it is not clear what is meant by "said tibial tray slides with respect to said tibial tray." Petitioners reserve the right to challenge the patentability of claim 37 if the Patent Owner attempts to correct claim 37 or asserts that claim 37 is in compliance with 35 U.S.C. § 112.

of: (1) the Insall et al. U.S. Patent 6,319,283 ("Insall '283 Patent," Ex. 1003), and (2) the Insall U.S. Patent 6,068,658 ("Insall '658 patent," Ex. 1004).

Ground 3: Claims 23 and 24 are unpatentable under 35 U.S.C. § 103 as being obvious over the Walker patent in combination with the Insall '658 patent, and additionally or alternatively further in view of the Insall '283 patent (i.e., for the reasons of either or both Ground 1 and Ground 2 in combination with features relating to claims 23 and 24 disclosed in the Insall '658 patent).

Ground 4: Claims 15-16, 18-28, 31 and 34-36 are unpatentable under 35 U.S.C. §102(b) as being anticipated by the Insall '658 patent.

Ground 5: Claims 15-16, 18-22, 25-28, 31 and 34-36 are unpatentable under 35 U.S.C. § 102(a) and § 102(e) as being anticipated by the Insall '283 patent.

III. OVERVIEW OF KNEE ANATOMY AND KNEE REPLACEMENT

The challenged claims of the Bonutti patent relate generally to joint repair and replacement - surgical procedures known as joint arthroplasty. More particularly, the challenged claims relate to knee joint replacement implants. *See, e.g.,* Ex. 1001, claims 15 and 31.

A. Knee Anatomy

A simplified description of the components and operation of the knee that are relevant to the challenged claims of the Bonutti patent can be provided with

reference to the following illustrations of a right-side human knee joint and



schematic.

As shown, the knee joint connects the femur (upper leg bone) to the tibia (lower leg bone). The anterior side (front) of the joint is protected by the patella (kneecap). Two generally convex-shaped rounded areas, known as condyles, are located at the distal end (bottom) of the femur. The lateral condyle is located on the lateral side (outside) of the femur, and the medial condyle is located on the medial side (inside) of the femur. A groove-shaped area on the distal end of the femur, known as the trochlear groove, separates the lateral and medial condyles. Ex. 1005, Erdman Decl., ¶¶ 14-15.

The lateral and medial sides of the tibia have generally concave-shaped depressions that receive the corresponding condyles of the femur. A pad of

cartilage, known as the meniscus, is located on the proximal end (top) of the tibia to protect the surfaces of the femur and tibia. Ex. 1005, Erdman Decl., \P 16.

When the knee bends, the condyles on the end of the femur move in a hingelike manner with respect to the depressions in the tibia. The patella slides along the trochlear groove during bending of the knee. The kinematics of the knee joint are complex. In addition to providing the hinge-like movement, the condyles and meniscus accommodate axial rotation of the femur and tibia about their central longitudinal axes as the knee bends. Ex. 1005, Erdman Decl., ¶¶ 14, 18.

B. Knee Replacement Surgery

Features of a typical replacement knee implant or prosthesis that are pertinent to the challenged claims of the Bonutti patent can be described with reference to the following illustrations.



As shown, the replacement knee prosthesis includes a tibial component and a femoral component. The tibial component includes a tibial tray, and a bearing or articular surface on the proximal upper surface of the tray. A mounting structure, such as a stem or post, can extend distally from the underside or bottom of the tibial tray. The femoral component has lateral and medial condyles that replace the surfaces of the corresponding condyles of the patient's femur. Similarly, the articular surface replaces the meniscus of the patient's knee joint, and has lateral and medial depressions that receive the corresponding condyles of the femoral component. Ex. 1005, Erdman Decl., ¶¶ 21-26.

During a surgical procedure to implant a prosthesis of this type, the surgeon will remove any remaining meniscus and cut off a thin slice from the proximal end of the tibia bone, a process known as resecting the tibia. The surgeon will also resect the femur by cutting the surfaces of the condyles to a shape that corresponds to the backside shape of the femoral component. The tibial component is mounted to the resected tibia, for example, by urging the stem into the bone. The femoral component is similarly mounted to the resected condyles of the femur. The articular surface is mounted to the upper surface of the tibial tray, between the tray and the femoral component. Ex. 1005, Erdman Decl., ¶ 28-38.

In operation, the articular surface of the implant functions as a replacement for the meniscus. The condyles of the femoral component move in the depressions

of the articular surface when the knee bends. Ex. 1005, Erdman Decl., ¶¶ 24-25. Additional information on knee replacement prostheses and associated surgical instruments and techniques that were known at the time of the Bonutti patent invention is presented in the Zimmer Mbk brochure, Mbk order form, Mbk Micro-Mill surgical guide and Mbk intramedullary surgical guide. Exhibits 1007 -1010, respectively (the "Zimmer publications"). All of the Zimmer publications have copyright notices with publication dates of 1997 and/or 1998.

IV. OVERVIEW OF THE BONUTTI PATENT

A. The Claimed Invention

The specification of the Bonutti patent describes a number of different implants, instruments and surgical procedures relating generally to knee and other joint replacement. *See, e.g.,* Ex. 1001, col. 1, ln. 40-col. 2, ln. 61. All the claims of the Bonutti patent, however, are directed to joint replacement devices and methods having a sliding or otherwise movable component that corresponds to the meniscal component of the joint. In particular, all the claims generally recite: (1) a first or base component, such as a tibial tray, that is fixed to a bone on a first side of the joint (e.g., is fixed to the tibia), and (2) a second or movable component, such as a tibial tray insert, that moves with respect to the base component and has a surface that engages a bone on a second side of the joint (e.g., engages the condyles of the femur).

In the context of knee joint replacement prostheses for the tibial side of the joint (i.e., tibial components), devices of this type are often referred to as "mobile bearing" knee prostheses. The Bonutti patent admits that mobile bearing knee prostheses were known in the prior art. *See, e.g.,* Ex. 1001, col. 101, ll. 35-43. The prior art Zimmer publications disclose and relate to such a mobile bearing implant referred to as the "Mbk" device. Exs. 1007-1010.

The challenged claims of the Bonutti patent are directed to mobile bearing prostheses having specific features. In particular, the challenged claims are directed to mobile bearing prostheses that are configured to cause *asymmetric movement of the movable component or tibial tray insert* with respect to the center of the base component or tibial tray. An embodiment relating to the challenged claims is described in the Bonutti patent at columns 101-102 with respect to Fig. 90. An annotated version of Fig. 90 is reproduced below.



The implant 1290 is a mobile bearing knee implant that includes a tibial component 1292 and a femoral component (not shown in Fig. 90). Tibial component 1292 includes a tray 1294 and a bearing insert 1296 (also referred to as the "movable component" in the claims). Tray 1294 includes a plate member 1300 and a tapered spike 1298 (i.e., a stem or post) that extends from the bottom or underside of the plate member for fixing the tibial component to the patient's tibia. The upper surface 1302 of the plate member 1300 is provided with a post 1306 that cooperates with a recess 1308 located in the underside 1304 of the bearing insert 1296. The post 1306 and recess 1308 permit rotation of the bearing insert 1296 with respect to the tibial tray 1294. *See, e.g.*, Ex. 1001, col. 101, ll. 6-34.

As shown in Fig. 90, the post 1306 is not located directly over the spike 1298 (a location defined as the center of the tibia). Ex. 1001, col. 101, ll. 55-56. Instead, the post 1306 is *offset medially* toward the medial compartment of the knee. Offsetting the post 1306 toward the medial compartment of the knee is said to recreate the natural pivoting motion of the knee. *See, e.g.,* Ex. 1001, col. 101, ll. 67.

1. <u>Claims 15-28</u>

Independent claim 15 and its dependent claims 16-28 recite a device to

replace an articulating surface of a first side of a joint in a body. Limitations recited by claim 15 include, *inter alia*:

(1) "a base component, including a bone contacting side ... and a basesliding side on an opposite side ... relative to said bone contacting side;"

(2) "a movable component, including a movable sliding side ... matably positionable in sliding engagement with said base sliding side, and an articulating side on an opposite side ... relative to said movable sliding side ...;"

(3) "a protrusion extending from ... said base sliding side ..., said *protrusion substantially offset with respect to a midline of the first side of a joint*;" and

(4) "a recess sized to receive said protrusion, disposed in the … movable sliding side, said protrusion and recess matable to constrain movement of said first and second components relative to each other, thereby promoting movement of the joint within desired anatomical limits." (emphasis added).

In summary, claims 15-28 recite a mobile bearing prosthesis having a meniscal or movable component that *moves* with respect to the tray or base component *about an axis that is substantially offset with respect to a midline* on a first side of the joint.

2. <u>Claims 31-36</u>

Independent claim 31 and its dependent claims 32-36 recite a knee arthroplasty device. Limitations recited by claim 31 include, *inter alia*:

(1) "a tibial tray including ... an upper proximal surface, said proximal surface having ... a post ..., said *post* ... *offset from at least one of a medial-lateral centerline and an anterior-posterior centerline of said tibial tray*;"

(2) "a tibial tray insert engageable with said proximal surface and having a mating second cavity ..., said ... *mating cavity offset from at least one of the medial-lateral centerline and the anterior-posterior centerline of said tibial tray*, wherein said mating cavity is adapted to receive at least a portion of said post ...;"

(3) "wherein said tibial tray insert rotationally moves with respect to said tibial tray, about said post, when the device is used within the body such that the *rotation of the tibial tray insert is asymmetric with respect to at least one of the medial-lateral centerline and the anterior-posterior centerline* of said tibial tray." (emphasis added).

In summary, claims 31-36 recite a mobile bearing tibial knee component having a meniscal component or insert that *rotates asymmetrically* with respect to the tibial tray *about a post that is offset from either the medial-lateral centerline or the anterior-posterior centerline* of said tibial tray.

B. The Prosecution History

Challenged claim 15 was originally added to the Bonutti patent application (as claim 138) in a restriction requirement response filed on January 19, 2010. In the next Office Action mailed on March 11, 2010, claim 15 and all the claims depending therefrom were rejected under 35 U.S.C. § 102 as being anticipated by the Herrington U.S. Patent 5,997,577. In a responsive amendment filed on June 18, 2010, the applicant made amendments that it asserted "serve to clarify the present invention and are independent of patentability," and argued that the Herrington patent disclosed a tibial component having a tibial insert "firmly fixed" to the tibial tray when the tibial component is used in the body. Ex. 1006, June 18, 2010 response, pp. 11-12. In effect, the patent applicant distinguished the applied Herrington patent as not even disclosing a mobile bearing knee component, much less such a component having the features recited in the claims. All the claims were allowed in a Notice of Allowability that followed the June 18, 2010 response.

Challenged claim 31 was originally added to the Bonutti patent application (as claim 162), along with its dependent claims, in the June 18, 2010 response. Ex. 1006. These claims were also allowed in the Notice of Allowability that followed that response (i.e., they were never rejected on the basis of prior art). The issue fee was subsequently paid and the patent issued in due course.

C. Priority Date of the Bonutti Patent

The Bonutti patent claims priority to a number of other U.S. patent applications. Based on a review of these earlier applications, application no. 10/191,751, filed on July 8, 2002 (now patent 7,104,996), is the earliest that includes the mobile bearing tibial component embodiment discussed above and described with reference to Fig. 90 in the Bonutti patent. The priority date for the claims of the Bonutti patent challenged in this Petition is July 8, 2002.

The Petitioners reserve the right to respond accordingly in the event the Patent Owner alleges an earlier date of invention.

V. OVERVIEW OF THE PRIOR ART RELIED UPON FOR THE CHALLENGE

A. The Walker Patent

The Walker et al. U.S. Patent 5,755,801 ("Walker patent," Ex. 1002) discloses a replacement knee prosthesis. The Walker patent issued on May 26, 1998, and is a § 102(b) prior art patent to the Bonutti patent.

The prosthesis has a femoral component and a tibial component. The tibial component is a "mobile bearing" device that includes a tibia-engaging tibial platform and a meniscal component configured to provide for limited movement of the meniscal component on the tibial platform. Importantly, like the challenged claims of the Bonutti patent, the Walker patent discloses a *mobile meniscal*

component that moves about an axis that is substantially offset in the medial direction from the center of the component.

The "second embodiment" of the Walker patent shown in Figs. 2-2c has certain features of particular relevance to the challenged claims of the Bonutti patent. As noted in the Walker patent, the second embodiment shown in Figs. 2-2c "has a number of similarities with that shown in FIGS. 1 to 1e and only the differences are described." Ex. 1002, col. 4, ll. 3-6. FIGS. 4a-4d also show features of the embodiments shown in FIGS. 1-3. *See, e.g.,* Ex. 1002, col. 5, ll. 23-28. For these reasons, the relevant features of the device shown in the Walker patent are described below with reference to the drawing figures of the different embodiments.



As shown in the annotated version of Fig. 4c above, the replacement knee prosthesis has a femoral component 141 and a two-part tibial component that

includes a tibial platform 150 and the movable meniscal component 142. See, e.g.,

Ex. 1002, col. 4, ln. 59-col. 5, ln. 37.



As shown in the annotated version of Fig. 1b, above, the tibial platform 1 has an underside that engages the tibia, and an upper surface 4 to which the meniscal component 44 is mounted. The movable meniscal component 44 is shown in the annotated version of Fig. 1e, above, and has an underside and an upper bearing surface side. The upper side has depressions 23 to receive the condylar bearing surfaces of the femoral component 141 (shown in Fig. 4c, above). *See, e.g.*, Ex. 1002, col. 3, ln. 12-col. 4, ln. 53.



The above annotated version of Fig. 2 illustrates other features and the operation of the tibial component. An abutment 50 is upstanding on the upper surface of the tibial platform 41. As shown, the abutment 50 is located on the medial side of the medial-lateral centerline of the tibial platform 41. A recess 51 is formed in the medial side of the meniscal component 44. The meniscal component 44 is fitted to the tibial platform 41 by engaging the abutment 50 in the recess 51. The meniscal component 44 can thereby rotate along an arcuate path about the medially displaced axis of the abutment 50. A stop that limits the range of rotation of the meniscal component 44 in the posterior direction with respect to the tibial platform 41, and that prevents the meniscal component from lifting off the tibial platform, is provided by the stud 42 that extends from the tibial platform and is received in the slot 43 in the underside of the meniscal component. See, e.g., Ex. 1002, col. 4, ll. 3-53.

B. The Insall '283 Patent

The Insall et al. U.S. Patent 6,319,283 ("Insall '283 patent," Ex. 1003) discloses an orthopaedic knee implant. The Insall '283 patent was filed on July 2, 1999, issued on November 20, 2001, and is prior art to the Bonutti patent under §§ 102(a) and (e).

The implant has a femoral component and a tibial component. The tibial component is a "mobile bearing" device that includes a tibia-engaging tibial tray

and a bearing configured to provide for limited movement of the bearing on the tibial tray. Importantly, like the challenged claims of the Bonutti patent, the Insall '283 patent discloses a *mobile bearing that moves about an axis that is substantially offset from the centers* of the tray and bearing.



As shown in the annotated version of Fig. 5 above, the implant has a femoral component 14, and a two-part tibial component 10 that includes a tibial tray 18 and the movable bearing 20. *See, e.g.*, Ex. 1003, col. 3, ll. 1-13.



The annotated versions of Figs. 1 and 2, above, illustrate features of the tray 18 and bearing 20 in greater detail. Tibial plateau 22 has an underside that engages the tibia, and a proximal or upper surface to which the bearing 20 is mounted. The movable bearing 20 has an underside or backing surface 46 and an upper, articular bearing surface 34. The articular bearing surface 34 has a pair of concave portions on opposite sides of a projection 36 that engage the corresponding condyles of the femoral component 14. *See, e.g.*, Ex. 1003, col. 3, ln. 14-col. 4, ln. 14.

A projection 28 extends from the upper surface of the tibial plateau 22. As shown in Figs. 1 and 2, the projection 28 is located on the anterior side of the anterior-posterior centerline of the tibial plateau 22. The projection 28 is disposed in an opening 38 in the backing surface 46 of the bearing 20. The opening 38 and projection 28 allow rotational movement of the bearing 20 relative to the tibial plateau 22. A post 32 that extends from the tibial plateau 22 is received in a notch 44 in the bearing 20. The post 32 and notch 44 function as a stop to limit the rotational movement of the bearing 20. *See, e.g.,* Ex. 1003, col. 3, ln. 53-col. 4, ln. 14. Rotation of the bearing 20 about the anteriorly-displaced projection 28 is shown in the annotated version of Fig. 4 below.



C. The Insall '658 Patent

The Insall et al. U.S. Patent 6,068,658 ("Insall '658 patent," Ex. 1004) discloses an orthopaedic knee implant. The Insall '658 patent was filed on March 9, 1998, issued on May 30, 2000, and is prior art to the Bonutti patent under §§102(a) and (e).

The implant has a femoral component and a tibial component. The tibial component includes a tibial platform and a meniscal component configured to provide for limited movement of the meniscal component on the tibial platform. Importantly, like the challenged claims of the Bonutti patent, the Insall '658 patent discloses a *meniscal component that moves about an axis that is substantially offset from the centers* of the tibial platform and the meniscal component.



As shown in the annotated version of Fig. 1(b), above, the implant has a femoral component 2, a tibial component 6 that includes a tibial platform 20, and a meniscal component 7 interposed between the femoral component 2 and the tibial platform 20. *See, e.g.*, Ex. 1004, Abstract; col. 3, 11. 23-39.



As shown in the annotated version of Fig. 6, above, the tibial component 6 has an underside that engages the tibia, and an upper side having a tibial platform 20. A guide 23 extends upward from the tibial platform 20. The guide 23 comprises a post 24 and a cap 25. As shown in Fig. 6, the guide 23 is located on the anterior side of the anterior-posterior centerline of the tibial platform 20.



As shown in the annotated versions of Figs. 5 and 7, above, the meniscal component 7 has a top bearing side with a pair of dished bearing surfaces 41, 42 shaped to matingly engage spheroidal condylar articulating surfaces 10, 11 of the femoral component 2. See, e.g., Ex. 1004, col. 3, ll. 30-36; col. 4, ll. 36-41; Figs. 1(a), 1(b). The meniscal component 7 further includes a bottom sliding side with a recess 30 that provides access to a slot 32 within the meniscal component. The bottom sliding side of the meniscal component 7 is retained in sliding engagement with the tibial platform 20 by a snap-fit mating of the guide 23 in the recess 30 and slot 32 (also referred to as a "track"). See, e.g., Ex. 1004, Abstract. A rail 21 that projects from the tibial platform 20 engages a cut-away portion 34 having a notch 33 in the meniscal component 7 to asymmetrically limit rotation of the meniscal component. See, e.g., Ex. 1004, col. 4, ll. 19-28. Rotation of the meniscal component 7 about the anteriorly-displaced guide 23 is shown in the annotated version of Fig. 8(b), below:



VI. CLAIM CONSTRUCTION AND LEGAL STANDARDS

A. Construction of Certain Claim Terms

A claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). For purposes of this proceeding, claims terms are presumed to possess their broadest reasonable ordinary meanings. However, Petitioners note that the standards of construction applied in this proceeding are not necessarily those which will be applied in the related litigation, and, as such, reserves all rights to proffer in that related litigation claim construction positions in conformity with the standards applicable therein. In view of these legal standards, the Petitioners respectfully request that the Board consider the following claim construction questions.

1. "Protrusion" and "Recess" in Claims 15-21 and 25-28

As discussed above in Section IV.A., independent claim 15 and its dependent claims 16-21 and 25-28 recite a "protrusion" and a "recess" to receive the protrusion. The corresponding elements of the embodiment of the invention

described in connection with Fig. 90 are "post 1306" and "recess 1308." In Fig. 90, the post 1306 and recess 1308 are shown located inwardly from the medial side edge of the plate member 1300.

Invalidity Ground 1 presented in this Petition relies on the Walker patent (Ex. 1002). The Walker patent describes the abutment 50 as a "semicircular" element that controls rotation of the meniscal component about an axis "at the edge" of the tibial platform. The recess 51 is described as "a recess or notch [that] is formed in the corresponding portion of the meniscal component and is rounded." Ex. 1002, col. 4, ll. 22-27. In connection with Ground 1, the Petitioners assert that the abutment 50 and recess 51 shown in the Walker patent correspond to the claimed "post" and "recess," respectively, when these terms in claims 15-21 and 25-28 are given their broadest reasonable constructions.

Invalidity Ground 2 is presented in addition to Ground 1, and alternatively if the Board finds that the abutment 50 and recess 51 shown in the Walker patent do not correspond to the broadest reasonable constructions of the terms "post" and "recess," respectively, in claims 15-21 and 25-28. Briefly, Ground 2 points to: (1) the projection 28 and opening 38 in the Insall '283 patent (Ex. 1003), and (2) the upstanding guide 23 and track (including recess 30 and slot 32) in the Insall '658 patent (Ex. 1004), as being structurally and functionally equivalent to and substitutable for the abutment 50 and recess 51, respectively, of the Walker patent implant.

2. <u>"Pin" and "Hole" in Claim 22</u>

Claim 22 depends from independent claim 15 and recites the "protrusion" as being a "pin" and the "recess" as being a "hole." In connection with Ground 1, the Petitioners assert that the abutment 50 and recess 51 shown in the Walker patent correspond to the claimed "pin" and "hole," respectively, when these terms of claim 22 are given their broadest reasonable interpretations.

Invalidity Ground 2 is presented in addition to Ground 1, and alternatively if the Board finds that the abutment 50 and recess 51 shown in the Walker patent do not correspond to the broadest reasonable constructions of the terms "pin" and "hole," respectively, in claim 22. Briefly, Ground 2 points to: (1) the projection 28 and opening 38 in the Insall '283 patent (Ex. 1003), and (2) the upstanding guide 23 and track (including recess 30 and slot 32) in the Insall '658 patent (Ex. 1004), as elements that are structurally and functionally equivalent to and substitutable for, the abutment 50 and recess 51, respectively, of the Walker patent device.

3. <u>"Post" and "Cavity" in claims 31-36</u>

Independent claim 31 and its dependent claims 32-36 recite a "post" and a mating "cavity." In connection with Ground 1, the Petitioners assert that the abutment 50 and recess 51 shown in the Walker patent correspond to the claimed

"post" and "cavity," respectively, when these terms in claims 31-36 are given their broadest reasonable constructions.

Invalidity Ground 2 is presented in addition to Ground 1, and alternatively if the Board finds that the abutment 50 and recess 51 shown in the Walker patent do not correspond to the broadest reasonable constructions of the terms "post" and "cavity," respectively, in claims 31-36. Briefly, Ground 2 points to: (1) the projection 28 and opening 38 in the Insall '283 patent (Ex. 1003), and (2) the upstanding guide 23 and track (including recess 30 and slot 32) in the Insall '658 patent (Ex. 1004), as being structurally and functionally equivalent to, and substitutable for, the abutment 50 and recess 51, respectively, of the Walker patent implant.

4. <u>"Dovetail Joint," Dovetail Pin" and "Dovetail Tail" in</u> <u>Claims 23 and 24</u>

Claim 23 depends from independent claim 15 and recites the protrusion as a "dovetail pin" and the recess as a "dovetail tail" that together form a "dovetail joint." Claim 24 depends from claim 23 and recites the dovetail joint as being "elongated." However, there is no reference to or description of structures resembling dovetail joints in the embodiment of the invention described with reference to Fig. 90 in the Bonutti patent. *See, e.g.*, Ex. 1001, col. 101, ll. 6-67; Fig. 90.

Claims 23 and 24 (as well as non-challenged claims 39 and 40 that also include the term "dovetail") were added to the application that issued as the Bonutti patent after the application was originally filed. The description of the preferred embodiments section of the Bonutti patent refers to a "dove-tail shape" slot 1190 on the bottom, tibia-engaging side of the tibial tray 1186 shown in Fig. 80. Ex. 1001, col. 97, ln. 59-col. 98, ln. 5. Although not described as "dovetail" structures, the Board's attention is also directed to the groove 1286 and track 1276 shown in Fig. 89 of the Bonutti patent. *See, e.g.*, Ex. 1001, col. 99, ln. 34-col. 101, ln. 5.

In connection with Ground 3, the Petitioners point to the complimentaryshaped and interlocking guide 23 and track (including recess 30 and slot 32) of the Insall '658 patent as elements corresponding to the "dovetail" structures in claims 23 and 24 when those terms in claims 23 and 24 are given their broadest reasonable interpretations.

B. Threshold Requirement for *Inter Partes* Review

A petition for *inter partes* review must demonstrate "a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition." 35 U.S.C. § 314(a). This Petition meets this threshold. As explained below, all elements of claims 15-28 and 31-36 of the Bonutti patent

are taught in the prior art references, and reasons to combine the features of these

prior art references are established for each ground under 35 U.S.C. § 103(a).

VII. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Ground 1: Claims 15-22, 25-28 and 31-36 are Unpatentable as Being Anticipated by the Walker Patent

The Walker patent discloses a mobile bearing tibial component of a knee

implant having each and every limitation of claims 15-22, 25-28 and 31-36 of the

Bonutti patent. See, Ex. 1005, Erdman Decl., ¶¶ 45-69. Claim charts mapping the

features of the Walker patent to the limitations of these claims are provided below.

Claim 15	Walker Patent (Ex. 1002)
15. A device to replace	The Walker patent discloses a knee prosthesis having a
an articulating surface of	tibial component including a tibial platform 41 and a
a first side of a joint in a	plastic meniscal component 44 mounted on the tibial
body,	platform. <i>See, e.g.,</i> col. 4, ll. 3-33; Figs. 2-2c. The meniscal component 44 has an upper bearing surface with depressions 23 to receive the condylar bearing surfaces of the femoral part of the prosthesis (i.e., is configured to replace the articulating surface of the patient's natural tibia). <i>See, e.g.,</i> col. 3, ll. 37-40; Figs. 1e, 4c.
the joint having first and	The patient's knee joint that is replaced by the
second sides,	prosthesis has tibial (i.e., first) and femoral (i.e.,
comprising:	second) sides. See, e.g., Abstract; Fig. 4c.
a base component,	The tibial platform 41 is a base component.
including a bone contacting side connectable with bone on the first side of the joint, and	The tibial platform 41 has a bone contacting underside with downwardly extending projections 2, 3 and a post P for engaging the platform in the resected end of the tibia. <i>See, e.g.</i> , col. 3, ll. 12-21; col. 4, ll. 3-6; col. 5, ll. 25-28; Figs. 1a, 1b, 4c.

a base sliding side on an opposite side of said base component relative to said bone contacting side;	The tibial platform 41 has an upper surface 4 (i.e., a base sliding side) that is on a side opposite the bone contacting underside. <i>See, e.g.,</i> col. 3, ll. 12-21; col. 4, ll. 3-6; Figs. 1, 1b. The meniscal component 44 slides on the upper surface 4 of the tibial platform 41, so the upper surface of the tibial platform is a sliding side. <i>See, e.g.,</i> col. 4, ll. 37-40.
a movable component,	The meniscal component 44 is a movable component. <i>See, e.g.</i> , col. 4, ll. 16-21.
including a movable sliding side, said movable sliding side being matably positionable in sliding engagement with said base sliding side, and	The meniscal component 44 has an underside having a slot 43 that includes a groove 45. The underside of the meniscal component 44 slides on the tibial platform 41, and is therefore a sliding side. The slot 43 and groove 45 receive the head of the stud 42 extending from the tibial platform 41, so the underside of the meniscal component 44 is matably positionable in sliding engagement with the upper surface of the tibial platform. <i>See, e.g.</i> , col. 4, ll. 7-21.
an articulating side on an opposite side of said movable component relative to said movable sliding side, shaped to matingly engage an articulating surface of the second side of the joint;	The upper bearing surface side of the meniscal component 44 is opposite the underside and is shaped with depressions 23 to receive the condylar bearing surfaces of the femoral part of the prosthesis (i.e., is an articulating side shaped to engage and mate with the articulating surface of the femoral side). <i>See, e.g.</i> , col. 1, ll. 8-20; col. 3, ll. 37-40; Fig. 4c.
a protrusion extending from one of said base sliding side or movable sliding side,	Semicircular abutment 50 (i.e., a protrusion) is upstanding at the upper surface of the tibial platform 41 (i.e., extends from the base sliding side). <i>See, e.g.,</i> col. 4, ll. 22-28; Figs. 2-2c. Ex. 1005, Erdman Decl., ¶¶ 46, 50.
said protrusion substantially offset with respect to a midline of the first side of a joint;	The abutment 50 is at the medial side of the tibial platform 41, and is substantially offset from the medial- lateral centerline P-Q (i.e., the centerline that separates the medial and lateral sides of the platform). <i>See, e.g.</i> , col. 3, ll. 16-21; col. 4, ll. 22-28; Figs. 1, 2. The

	meniscal component 44 rotates about a medially
	displaced axis. Col. 5, ll. 38-40. Ex. 1005, Erdman
	Decl., ¶¶ 46, 50.
a recess sized to receive said protrusion, disposed in the other of said base sliding side or movable sliding side,	Notch or recess 51 is engaged by the abutment 50 and is formed in the corresponding portion of the meniscal component 44 (i.e., is disposed in the movable sliding side). See, e.g., col. 4, ll. 22-33; Figs. 2-2c. Ex. 1005, Erdman Decl., ¶¶ 46, 50.
said protrusion and recess matable to constrain movement of said first and second components relative to each other, thereby promoting movement of the joint within desired anatomical limits.	The engaged abutment 50 and recess 51 control the rotation of the meniscal component 44 about an axis at the medial side edge of the tibial platform 41. <i>See, e.g.</i> , col. 4, ll. 22-25; Figs. 2-2c. Movement of the meniscal component 44 is limited and constrained to rotation about the medially displaced axis. Col. 5, ll. 38-40. The recess 51 is formed to allow the meniscal component 44 to move approximately 2 mm in an anterior and posterior direction. Col. 4, ll. 25-28. Figs. 2a and 2b show different relative positions of the meniscal component 44 on the tibial platform 41 at different degrees of internal and external rotation. <i>See, e.g.</i> , col. 4, ll. 34-36. An aim of this prosthesis design is to replicate the natural movements of the knee. Col. 1 ll 5-20. Ex 1005 Erdman Decl. \P 46 50
Claim 16	Walker Patent (Ex. 1002)
16. The device of claim 15, wherein said protrusion and said recess are located substantially offset from a center of said device	The abutment 50 and recess 51 are on the medial side of the tibial platform 41, and are substantially offset from the medial-lateral centerline P-Q. <i>See, e.g.</i> , col. 2, ll. 1-8; col. 3, ll. 16-21; col. 4, ll. 22-28; Figs. 1, 2. The meniscal component 44 rotates about a medially displaced axis. Col. 5, ll. 38-40. Ex. 1005, Erdman Decl., ¶¶ 45, 52.
Claim 17	Walker Patent (Ex. 1002)
The device of claim 15, wherein the joint is a knee, and	The Walker patent discloses a knee prosthesis that is attached to a knee joint. <i>See, e.g.,</i> Abstract; Fig. 4c.
said protrusion and said recess are medially offset from a center of said	The abutment 50 and recess 51 are on the medial side of the tibial component, and are offset from the medial-lateral centerline P-Q. <i>See, e.g.</i> , col. 2, ll. 1-8; col. 3, ll.

device,	16-21; col. 4, ll. 22-28; Figs. 1, 2. The meniscal component 44 rotates about a medially displaced axis. Col. 5, ll. 38-40.
whereby said base sliding side and said movable sliding side are less constrained to slideably engage on a lateral side of engagement than on a medial side of engagement,	The rotational axis of the meniscal component 44 is at the edge of the medial side of the tibial platform 41 and is controlled by the abutment 50. Figs. 2a and 2b show different relative positions of the meniscal component 44 at different degrees of rotation. The arc length of the sliding rotational movement of the meniscal component 44 increases with increasing distance toward the lateral side from the rotational axis defined by the abutment 50. The upper surface of the tibial platform 41 (i.e., the base sliding side) and underside of the meniscal component 44 (i.e., the movable sliding side) are therefore less constrained on the lateral side than on the medial side. <i>See, e.g.</i> , col. 4, ll. 22-36; Figs. 2a, 2b. Ex. 1005, Erdman Decl., ¶ 45-46, 53.
thereby correlating to the movement of a natural knee joint.	The Walker patent discloses that the axial rotation of the natural knee joint is biased to the medial side of the knee, and that an aim of the prosthesis design is to replicate the natural movements of the knee. Col. 1, ll. 5-20.
Claim 18	Walker Patent (Ex. 1002)
18. The device of claim15, wherein the joint is a knee.	The Walker patent discloses a knee prosthesis that is attached to a knee joint. <i>See, e.g.</i> , Abstract; Fig. 4c. Ex. 1005, Erdman Decl., ¶¶ 45, 54
Claim 19	Walker Patent (Ex. 1002)
19. The device of claim 15, further including a second base component connectable to the second side of the joint, including an articulating surface matable with said articulating side of said movable component.	The Walker patent discloses a femoral component 141 connected to the femoral side (i.e., a second side) of the knee joint. The femoral component 141 has condyles 146 (i.e., articulating surfaces) that substantially correspond to the radius of the tibial bearing surfaces 147 of the meniscal component 142. <i>See, e.g.,</i> col. 4, ln. 66-col. 5, ln. 5; Figs. 4a-4c. Erdman Decl., ¶¶ 45, 55.
Claim 20	Walker Patent (Ex. 1002)

attached to a knee joint. See, e.g., Abstract, Fig. 4c.
The tibial platform 41 (i.e., the first base component) is connected to the tibia. The femoral component 141 (i.e., the second base component) is connected to the femur. <i>See, e.g.</i> , Fig. 4c. Ex. 1005, Erdman Decl., ¶¶ 45, 56.
Walker Patent (Ex. 1002)
Abutment 50 upstanding from the tibial platform 41 is engaged by the recess 51 in the meniscal component 44 to enable rotation of the upper surface of the tibial platform with respect to the undersurface of the meniscal component about the axis of the abutment. The meniscal component 44 rotates about a medially displaced axis. <i>See, e.g.,</i> col. 4, ll. 22-28; col. 5, ll. 38- 40; Figs. 2a-2b. Ex. 1005, Erdman Decl., ¶¶ 45-46, 57.
Walker Patent (Ex. 1002)
Abutment 50 is a pin and recess 51 is a hole sized to receive the abutment. <i>See, e.g.,</i> col. 4, ll. 22-33; Fig. 2. Ex. 1005, Erdman Decl., ¶¶ 45-46, 58.
Walker Patent (Ex. 1002)
Stud 42 is received in slot 43 of the meniscal component 44. The slot 43 includes an upper groove 45 for receiving the head of the stud 42 in such a way as to prevent lift-off of the meniscal component 44 from the tibial platform 41. <i>See, e.g.,</i> col. 4, ll. 7-21; Fig. 2. Because the stud 42 and slot 43 cooperate with the abutment 50 to constrain the motion of the meniscal

side.	component 44 with respect to the tibial platform 41, the
	stud and slot are associated with the abutment. Ex.
	1005, Erdman Decl., ¶¶ 46, 59.
Claim 26	Walker Patent (Ex. 1002)
26. The device of claim	The Walker patent discloses a prosthesis that replaces
15, wherein not all	only the medial and lateral condylar compartments of
articulating	the knee joint. The prosthesis does not replace the
compartments of the	patellar compartment of the knee joint. See, e.g.,
joint are replaced by said	Abstract; Fig. 4c. Ex. 1005, Erdman Decl., ¶¶ 19, 60.
device.	
Claim 27	Walker Patent (Ex. 1002)
27. The device of claim	The Walker patent discloses a prosthesis located on a
15, wherein the joint is	knee joint. See, e.g., Abstract; Fig. 4c. Ex. 1005,
located in a finger, wrist,	Erdman Decl., ¶¶ 45, 61.
elbow, shoulder, spine,	
hip, knee, ankle, or toe.	
Claim 28	Walker Patent (Ex. 1002)
28. The device of claim	The abutment 50 is offset with respect to an axis
15, wherein said	passing through the medial-lateral center of the tibial
protrusion is offset with	platform 41. The meniscal component 44 rotates about
respect to an axis passing	a medially displaced axis. <i>See, e.g.</i> , col. 4, ll. 22-28;
through the anterior-	col. 5, II. 38-40; Figs. 2-2b. Ex. 1005, Erdman Decl.,
posterior or the medial-	¶¶ 46, 62.
lateral center of said base	
component or movable	
component.	
	Walker Patent (Ex. 1002)
31. A knee arthroplasty	The Walker patent discloses a replacement knee
device, comprising:	prosthesis. See, e.g., Abstract; Fig. 4c. Ex. 1005,
,•1 • 1 , • 1 1•	Erdman Decl., 44 , 63.
a tibial tray including a	The prosthesis has a tibial component including a tibial
lower distal surface and	platform 41 (i.e., a tibial tray). The tibial platform 41
an upper proximal	has an underside (i.e., a lower distal surface) and an
surface,	upper surface 4 (i.e., an upper proximal surface). See,
	<i>e.g.</i> , col. 3, II. 12-21; col. 4, II. 3-6; F1gs. 1, 1b.
said proximal surface	Abutment 50 is upstanding on the medial side of the
having either a post or a	upper surface of the tibial platform 41 See, e.g. $col 4$
cavity,	11. 22-28; Figs. 2a-2b.

said post or cavity offset from at least one of a medial-lateral centerline and an anterior-posterior centerline of said tibial tray;	The abutment 50 is offset with respect to the medial- lateral centerline P-Q of the tibial platform 41 (i.e., the centerline that separates the medial and lateral sides of the platform). <i>See, e.g.,</i> col. 4, ll. 22-28; Figs. 1, 2. Ex. 1005, Erdman Decl., ¶¶ 46, 63.
a tibial tray insert engageable with said proximal surface and having a mating second cavity if said tibial tray has a post, or a mating post if said tibial tray has a cavity,	The prosthesis has a meniscal component 44 (i.e., a tibial tray insert) that is engaged with and slides on the upper surface of the tibial platform 41. The meniscal component 44 has a rounded recess 51 that is engaged by (i.e., mates with) the abutment 50. <i>See, e.g.</i> , col. 4, ll. 3-33; Fig. 2.
said mating post or mating cavity offset from at least one of the medial-lateral centerline and the anterior-posterior centerline of said tibial tray,	The recess 51 is offset with respect to the medial-lateral centerline of the tibial platform 41. <i>See, e.g.,</i> col. 4, ll. 22-28; Fig. 2. Ex. 1005, Erdman Decl., ¶¶ 46, 63.
wherein said mating cavity is adapted to receive at least a portion of said post, or said mating post is adapted to be received in at least a portion of said cavity;	The recess 51 in the meniscal component 44 is rounded and engaged with (i.e., is adapted to receive) the protrusion 50. <i>See, e.g.</i> , col. 4, ll. 3-33; Fig. 2.
wherein said tibial tray insert rotationally moves with respect to said tibial tray, about said post, when the device is used within the body	The meniscal component 44 rotates with respect to the tibial platform 41 about the abutment 50 when the prosthesis is implanted in a patient. <i>See, e.g.,</i> col. 2, ll. 13-16; col. 4, ll. 22-36; Figs. 2a, 2b.
such that the rotation of the tibial tray insert is	The meniscal component 44 is asymmetric about the medial-lateral center line P-Q of the tibial platform 41,

asymmetric with respect	and rotates about a medially displaced axis. Col. 5, ll.
to at least one of the	38-40. Ex. 1005, Erdman Decl., ¶¶ 46, 63.
medial-lateral centerline	
and the anterior-posterior	
centerline of said tibial	
tray.	
Claim 32	Walker Patent (Ex. 1002)
32. The knee arthroplasty	The meniscal component 44 rotates about a medially
device of claim 31,	displaced axis. Col. 5, ll. 38-40. The abutment 50 is
wherein said post or	offset medially with respect to the medial-lateral
mating post is offset	centerline of the tibial platform 41. See, e.g., col. 4, ll.
medially from a medial-	22-28; Fig. 2. Ex. 1005, Erdman Decl., ¶¶ 45-46, 65.
lateral centerline of said	
tibial tray.	
Claim 33	Walker Patent (Ex. 1002)
33. The knee arthroplasty	The meniscal component 44 rotates about a medially
device of claim 31,	displaced axis. Col. 5, ll. 38-40. The recess 51 in the
wherein said mating	meniscal component 44 is offset medially with respect
cavity or mating post of	to the medial-lateral centerline of the component. See,
said tibial tray insert is	e.g., col. 4, ll. 22-28; Fig. 2. Ex. 1005, Erdman Decl.,
offset medially from a	¶¶ 45-46, 66.
medial-lateral centerline	
of said tibial tray insert.	
Claim 34	Walker Patent (Ex. 1002)
34. The knee arthroplasty	Post P (i.e., a keel) extends from the underside of the
device of claim 31,	tibial platform 41 and has a central axis. The abutment
wherein the tibial tray	50 on the tibial platform 41 is offset from the central
has a keel with a central	axis of the post P. Col. 5, ll. 26-28; Figs. 1a, 1b, 2. Ex.
axis, and wherein said	1005, Erdman Decl., ¶¶ 45-46, 67.
post or cavity of said	
tibial tray is offset from	
the central axis of said	
keel.	
Claim 35	Walker Patent (Ex. 1002)
35. The knee arthroplasty	Post P (i.e., a keel) extends from the underside of the
device of claim 31,	tibial platform 41 and has a central axis. The recess 51
wherein the tibial tray	on the meniscal component 44 is offset from the central
has a keel with a central	axis of the post P. Col. 5, ll. 26-28; Figs. 1a, 1b, 2. Ex.
axis, and wherein said	1005, Erdman Decl., ¶¶ 45-46, 68.

mating post or mating	
cavity of said tibial tray	
insert is offset from the	
central axis of said keel.	
Claim 36	Walker Patent (Ex. 1002)
36. The knee arthroplasty	The upper bearing surface side of the meniscal
device of claim 31,	component 44 is thickened in the central part 24 (i.e.,
wherein a proximal	has a mound) with respect to the depressions 23 on the
surface of said tibial tray	opposite sides of the central part. The depressions 23
insert includes a mound	receive the condylar bearing surfaces of the femoral
interposing a medial	part of the prosthesis. See, e.g., col. 3, ll. 37-45; Fig.
condyle receiver and a	1e. Ex. 1005, Erdman Decl., ¶¶ 45-46, 69.
lateral condyle receiver.	

B. Ground 2: Claims 15-22, 25-28 and 31-36 are Unpatentable as Being Obvious Over the Walker Patent in Combination with Either or Both of: (1) the Insall '283 Patent, and (2) the Insall '658 Patent

As an additional basis, or alternatively if the Board construes the terms "protrusion" or "recess" in claims 15-21 and 25-28, the terms "pin" or "hole" in claim 22, or the terms "post" or "cavity" in claims 31-36 in such a manner as to not correspond to the abutment 50 or recess 51, respectively, of the device shown in the Walker patent, these claims are obvious over the Walker patent in view of either or both of: (1) the Insall '283 patent, and (2) the Insall '658 patent.

The abutment 50 and recess 51 of the Walker patent cooperate to provide an "offset" rotational axis for the meniscal component 44 with respect to the tibial platform 41 in a mobile bearing implant. The projection 28 and opening 38 of the Insall '283 patent are a "protrusion" and "recess," (claims 15-21 and 25-28), "pin"

and "hole' (claim 22), and "post" and "cavity" (claims 31-36), respectively. Ex. 1005, Erdman Decl., ¶¶ 48, 76, 82, 86. Like the abutment and recess of the Walker patent, the projection 28 and opening 38 of the Insall '283 patent cooperate to provide an "offset" rotational axis for the articular bearing 20 and tibial tray 18 of a mobile bearing implant. Ex. 1005, Erdman Decl., ¶ 48. Because of this substantial similarity of functionality in mobile bearing knee prostheses, it would have been obvious to a person of ordinary skill in the art at the time of the invention to substitute the projection and opening of the Insall '283 patent for the corresponding structures in the Walker patent. Ex. 1005, Erdman Decl., ¶ 47-48.

Similarly, the guide 23 and track (including recess 30 and slot 32) shown in the Insall '658 patent cooperate to provide an "offset" rotational axis for the meniscal component 7 and tibial platform 20 of a mobile bearing prosthesis. Ex. 1005, Erdman Decl., ¶ 49. Because of this substantial similarity of functionality in mobile bearing knee prostheses, it would have been obvious to a person of ordinary skill in the art at the time of the invention to substitute the guide and track of the Insall '658 patent for the corresponding structures in the Walker patent. Ex. 1005, Erdman Decl., ¶¶ 47, 49.

Claim charts mapping the features of the Insall '283 patent and the Insall '658 patent relevant to the "protrusion" and "recess" in claim 15, to the "pin" and "hole" in claim 22, and to the "post" and "cavity" in claim 31, are provided below.

In these claim charts reference is made to the corresponding claim charts in Section VII. A. above for the claim limitations common to those presented in connection with Ground 1. Claims 16-21 and 25-28 depend directly or indirectly from claim 15, and are unpatentable for the reasons of Ground 2 provided in this section for claim 15 in addition to the reasons provided in the corresponding Ground 1 claim charts in Section VII. A, above. Similarly, claims 32-36 depend directly from claim 31, and are unpatentable for the reasons of Ground 2 provided in this section for claim 31 in addition to the reasons provided above in the corresponding Ground 1 claim a charts in Section VII. A. Accordingly, the claim charts of Section VII. A. are hereby incorporated by reference.

Claim 15	Walker Patent (Ex. 1002), Insall '283 Patent (Ex.
	1003), Insall '658 Patent (Ex. 1004)
15. A device to replace	Walker Patent (Ex. 1002)
an articulating surface of	See, claim 15 chart for Ground 1 in Section VII. A.,
a first side of a joint in a	above.
body, the joint having	
first and second sides,	
comprising:	
a base component;	Walker Patent (Ex. 1002)
	See, claim 15 chart for Ground 1 in Section VII. A.,
	above.
a movable component	Walker Patent (Ex. 1002)
,	See, claim 15 chart for Ground 1 in Section VII. A.,
	above.
a protrusion extending	Walker Patent (Ex. 1002)
from one of said base	See, claim 15 chart for Ground 1 in Section VII. A.,
sliding side or movable	above.
sliding side, said	
protrusion substantially	Insall '283 Patent (Ex. 1003)
offset with respect to a	Projection 28 is a protrusion and extends from the

midline of the first side	upper surface (i.e., the base sliding side) of the tibial
of a joint;	plateau 22. See, e.g., col. 3, ll. 5-13; Figs. 1, 2.
	The projection 28 is substantially offset in the anterior
	direction with respect to the anterior-posterior
	centerline of the tibial plateau 22 (i.e., the centerline
	that separates the anterior and posterior sides of the
	plateau) See, e.g. Figs 1 2 Ex 1005 Erdman Decl
	¶¶ 46-48 51
	Insall '658 Patent (Ex. 1004)
	Guide 23 (i.e. protrusion) extends from the tibial
	nlatform 20 (i.e. the base sliding side) See e_{α}
	Abstract: Fig. 6 The guide 23 is substantially offset in
	the anterior direction with respect to the anterior-
	nosterior centerline of the tibial platform 20 (i.e. the
	centerline that senarates the anterior and posterior sides
	of the tibial platform 20) $S_{ac} = a$ Figs 6 8(b) Ex
	1005 Erdman Decl. $\P\P 46.47.40.51.01.05$
a recess sized to receive	Wolker Datent (Ex. 1002)
a recess sized to receive	$\frac{\text{Walker I atent (EX. 1002)}}{\text{See claim 15 chart for Ground 1 in Section VII A}}$
in the other of said base	above
sliding side or moveble	above.
sliding side said	Insoll '282 Detent (Ex. 1002)
situling side, said	<u>Insali 203 Fatelit (EX. 1003)</u> Opening 28 is a reason sized to reasive the prejection
protrusion and recess	Opening 58 is a recess sized to receive the projection
	28. The opening 58 is disposed in the backing surface $A(i)$ of the maximum 20.
movement of said first	40 (i.e., the movable shall give of the bearing 20.
and second components	See, e.g., col. 1, II. $22-30$; col. 3, II. $29-52$; Figs. 1-4.
relative to each other,	Ex. 1005, Erdman Decl., 11 46-48, 51.
thereby promoting	
movement of the joint	<u>Insall 658 Patent (Ex. 1004)</u>
within desired	The recess 30 on the bottom or distal side (i.e. the
anatomical limits.	movable sliding side) of the meniscal component / is
	sized to receive the guide 23 of the tibial platform 20
	for "snap-fit" mating. See, e.g., Abstract; col. 1, 11. 4/-
	56; Fig. 8(b). Mating of the guide 23 in the recess 30
	allows constrained rotational movement of the meniscal
	component 7 about an axis of the guide 23 and relative
	to the tibial platform 20. See, e.g., Abstract; col. 3, ll.
	46-52; col. 4, ll. 19-26; Figs. 8(a), 8(b). Ex. 1005,
	Erdman Decl., ¶¶ 46-47, 49, 51, 91-95. The nature of

the limited rotational movement allowed by the guide
23 and recess 30 is configured to avoid dislocation of
the meniscal component 7 from the tibial platform 20
and replicate the natural movements of the knee. See,
<i>e.g.</i> , col. 1, ll. 31-33; col. 2, ll. 45-49; col. 3, ll. 53-61.
Ex. 1005, Erdman Decl., ¶¶ 46-47, 49, 51, 91-95.

Claim 22	Walker Patent (Ex. 1002), Insall '283 Patent (Ex.
	1003), Insall '658 Patent (Ex. 1004)
22. The device of claim	Walker Patent (Ex. 1002)
15, wherein said	See, claim 22 chart for Ground 1 in Section VII. A.,
protrusion is a pin, and	above.
said recess is a hole sized	
to receive said pin.	Insall '283 Patent (Ex. 1003)
	Projection 28 is a pin, and opening 38 is a hole sized to
	receive the projection. See, e.g., col. 3, ll. 29-52; Fig.
	2. Ex. 1005, Erdman Decl., ¶¶ 46-48, 51.
	Insall '658 Patent (Ex. 1004)
	Guide 23 comprises a post 24 and a cap 25. See, e.g.,
	Abstract; col. 3, ll. 49; Fig. 6. The recess 30 is a hole
	sized to receive the guide 23, including the post 24 and
	the cap 25, for snap-fit mating. See, e.g., Abstract; col.
	1, ll. 47-56; Fig. 8(b). Ex. 1005, Erdman Decl., ¶¶ 46-
	47, 49, 51, 91-95.

Claim 31	Walker Patent (Ex. 1002), Insall '283 Patent (Ex.
	1003), Insall '658 Patent (Ex. 1004)
31. A knee arthroplasty	Walker Patent (Ex. 1002)
device, comprising:	See, claim 31 chart for Ground 1 in Section VII. A.,
	above.
a tibial tray including a	Walker Patent (Ex. 1002)
lower distal surface and	See, claim 31 chart for Ground 1 in Section VII. A.
an upper proximal	
surface, said proximal	Insall '283 Patent (Ex. 1003)
surface having either a	The upper proximal surface of the tibial plateau 22 has
post or a cavity, said post	a projection 28. See, e.g., col. 3, ll. 5-13; Figs. 1, 2.
or cavity offset from at	The projection 28 is offset in the anterior direction from
least one of a medial-	the anterior-posterior centerline of the tibial tray 18

lateral centerline and an	(i.e., the centerline that separates the anterior and
anterior-posterior	posterior sides). See, e.g., Figs. 1, 2. Ex. 1005,
centerline of said tibial	Erdman Decl., ¶¶ 46-48, 64.
tray;	
•	Insall '658 Patent (Ex. 1004)
	The Insall '658 patent discloses a tibial component 6
	having a stem 5 (i.e. a lower distal surface) and a tibial
	platform 20 (i.e. an upper proximal surface). See, e.g.,
	Abstract; col.3, ll. 37-39; Fig. 6. The platform 20
	includes a guide 23 that is offset in the anterior
	direction with respect to the anterior-posterior
	centerline of the tibial platform 20 (i.e., the centerline
	that separates the anterior and posterior sides of the
	platform 20). See. e.g., Figs. 6, 8(c). Ex. 1005.
	Erdman Decl., ¶¶ 46-47, 49, 64, 91-95.
a tibial trav insert	Walker Patent (Ex. 1002)
engageable with said	See, claim 31 chart for Ground 1 in Section VII. A.,
proximal surface and	above.
having a mating second	
cavity if said tibial trav	Insall '283 Patent (Ex. 1003)
has a post, or a mating	The tibial component 10 includes a bearing 20 (i.e., a
post if said tibial tray has	tibial tray insert) having a backing surface 46 that
a cavity, said mating post	engages with the upper surface of the tibial plateau 22.
or mating cavity offset	See, e.g., col. 3, ln. 66-col. 4, ln. 14; Figs. 1, 2. The
from at least one of the	bearing 20 has a cylindrical shaped opening 38 in
medial-lateral centerline	which the projection 28 is disposed (i.e., the opening
and the anterior-posterior	mates with the projection). See, e.g., col. 3, 11, 29-30.
centerline of said tibial	Figs 1, 2. The opening 38 is offset in the anterior
tray, wherein said mating	direction from the anterior-posterior centerline of the
cavity is adapted to	tibial trav 18 See, e.g. Figs 1 2 Ex 1005 Erdman
receive at least a portion	Decl $\P\P$ 46-48 51
of said post, or said	
mating post is adapted to	Insall '658 Patent (Ex. 1004)
be received in at least a	The Insall '658 patent discloses a meniscal component
portion of said cavity:	7 (i.e. tibial tray insert) that engages the tibial platform
F	20 (i.e. proximal surface). See, e.g., Abstract: col. 1. 11
	47-58: col. 4. ll. 36-46: Fig. 1(b). The meniscal
	component 7 includes a track with a recess 30 (i.e.
	mating second cavity) that receives the guide 23 for
	snap-fit mating. See, e.g., Abstract; col. 1, ll. 47-56;

col. 3, ln. 66-col. 4, ln. 3; Fig. 8(c). The track and
recess 30 (i.e. mating cavity) are offset from the
medial-lateral centerline of the tibial platform 20 (i.e.
tibial tray). See, e.g., Fig. 8(c). Ex. 1005, Erdman
Decl., ¶¶ 46-47, 49, 64, 91-95. The track and recess 30
(i.e. mating cavity) is adapted to receive at least a
portion of the guide 23 for snap-fit mating. See, e.g.,
Abstract; col. 1, ll. 47-56; Fig. 8(c).
Walker Patent (Ex. 1002)
See, claim 31 chart for Ground 1 in Section VII. A.,
above.

C. Ground 3: Claims 23 and 24 are Unpatentable as Being Obvious Over the Walker Patent in Combination with the Insall '658 Patent, and Additionally or Alternatively Further in View of the Insall '283 Patent

Claims 23 and 24 are unpatentable for the reasons of both Ground 1 and

Ground 2 (i.e., Ground 1 and additionally or alterntively in view of the Insall '283

patent), and further in view of additional features shown in the Insall '658 patent

relating to claims 23 and 24.

The Insall '658 patent discloses a mobile bearing prosthesis including a tibial platform 20 with upstanding guide 23, and a meniscal component 7 having an elongated track that is snap fit onto the guide. The guide comprises a post 24 having an enlarged-diameter cap 25. The track is a complimentary-shaped structure having a recess 30 and slot 32 that interlock with the guide 23. The complimentary-shaped interlocking structures of the guide 23 and track prevent the meniscal component 7 from lifting up off the tibial platform 20, while at the same

time allowing relative sliding motion of the meniscal component and tibial platform in the anterior-posterior direction. Ex. 1004, col. 4, ll. 9-32. The guide 23 and track of the implant shown in the Insall '658 patent is structurally at least equivalent to a dovetail joint, and is functionally substantially the same as a dovetail joint. It would have been obvious to a person of ordinary skill in the art at the time of the invention to substitute the guide and track of the Insall '658 patent for the abutment and recess, respectively, in the Walker patent. Ex. 1005, Erdman Decl., ¶¶ 47, 49.

Claim charts mapping the features of the Insall'658 patent relevant to the "dovetail joint" structures in claims 23 and 24 are provided below. Claims 23 and 24 depend directly or indirectly from independent claim 15. Accordingly, the claim charts for Grounds 1 and 2 in connection with claim 15 in Sections VII. A. and B., above, are hereby incorporated by reference.

Claim 23	Insall '658 Patent (Ex. 1004)
23. The device of claim	Guide 23 includes a lower post 24 and an upper cap 25.
15, wherein said	See, e.g., col. 1, ll. 46-52; col. 3, ln. 49; Fig. 6.
protrusion is a dovetail	Meniscal component 7 includes a slot 32 that is wider
pin and said recess is a	than the recess 35 that leads to the slot 32. See, e.g.,
dovetail tail, together	col. 4, ll. 9-12; Fig. 5. The guide 23 comprises a lower
forming a dovetail joint.	post 24 and an upper cap 25 to have a profile
	complementary to the recess 30 and slot 32 for snap-fit
	mating with the slot 32 and recess 30. See, e.g.,
	Abstract; col. 1, ll. 47-56; col. 4, ll. 9-12; Figs. 5, 6,
	8(b).
Claim 24	Insall '658 Patent (Ex. 1004)
24. The device of claim	Each of the recess 30 and the slot 32, which receive the
23, wherein said dovetail	guide 23, is longer along the anterior-posterior axis as

joint is elongated,	compared to its width along the medial-lateral axis (i.e.
extends in a substantially	the dovetail joint is elongated and extends in a
anterior-posterior	substantially anterior-posterior orientation). See, e.g.,
orientation, and enables	Fig. 5. The length of each of the recess 30 and the slot
anterior-posterior	32 along the anterior-posterior axis enables anterior-
displacement of the base	posterior displacement of the meniscal component 7
sliding side relative to	(i.e. having a movable sliding side) relative to the tibial
the movable sliding side.	platform 20 (i.e. the base sliding side) while the guide
_	23 is in snap-fit mating with the recess 30 and the slot
	32 of the meniscal component 7. See, e.g., Abstract;
	Fig. 8(c), 8(d).

D. Ground 4: Claims 15-16, 18-28, 31 and 34-36 are Unpatentable as Being Anticipated by the Insall '658 Patent

The Insall '658 Patent discloses a mobile bearing tibial component of a knee

implant having each and every limitation of claims 15-16, 18-28, 31 and 34-36 of

the Bonutti patent. Erdman Decl., ¶¶ 91-110. Claim charts mapping the features

of the Insall '658 Patent to the limitations of the challenged claims in the Bonutti

patent are provided below.

Claim 15	Insall '658 Patent (Ex. 2004)
15. A device to	The Insall '658 patent discloses an orthopedic knee
replace an articulating	implant having a femoral component 2, a tibial component
surface of a first side	6 including a tibial platform 20, and a meniscal component
of a joint in a body,	7 interposed between the femoral component and the tibial
the joint having first	component. See, e.g., Abstract; Fig. 1(b).
and second sides,	
comprising:	The patient's knee joint that is replaced by the implant comprises a tibia 4 (i.e., first side) and a femur 1 (i.e., second side). <i>See, e.g.</i> , col. 3, ll. 23-28; Fig. 1(b).
	The meniscal component 7 is retained on the tibial
	platform 20 and includes dished bearing surfaces 41, 42
	shaped for engagement with the femoral component 2 of
	the implant (i.e., the meniscal component replaces the

	articulating surface of the patient's natural knee joint).
	See, e.g., Abstract; col. 4, ll. 36-46; Figs. 1(a), 1(b), 7.
	Erdman Decl., ¶¶ 91-95.
a base component, including a bone contacting side connectable with bone on the first side of the joint, and a base sliding side on an opposite side of said base component relative to said bone contacting side;	The tibial component 6 is a base component. The tibial 4 (i.e. the first side of the joint) is resected to provide a flat base into which the tibial component 6 is fixed by a stem 5 on a bone contacting side of the tibial component. <i>See, e.g.,</i> col. 3, ll. 26-28; Figs 1(b), 6. The tibial component 6 further includes a tibial platform 20 (i.e. a base sliding side) that is on an opposite side of the tibial component relative to the bone contacting side. <i>See, e.g.,</i> Abstract; col. 3, ll. 37-39; Figs 1(b), 6. The meniscal component 7 is retained on, and slides along, the tibial platform 20 such that the tibial platform is a base sliding side. <i>See, e.g.,</i> Abstract; col.1, ll. 47-58; Figs. 8(a- d)
a movable component, including a movable sliding side, said movable sliding side being matably positionable in sliding engagement with said base sliding side, and	The meniscal component 7 is a movable component. <i>See,</i> <i>e.g.,</i> Abstract; col.1, ll. 47-58; Figs. 8(a-b). The meniscal component 7 has a bottom or distal side engaged with the tibial platform 20 and is allowed limited sliding movement along the tibial platform 20. <i>See, e.g.,</i> Abstract; col. 1, ll. 47-58; col. 3, ll. 46-48; Figs 1(b), 8(a), 8(b). The bottom or distal side of the meniscal component 7 is generally flat and accordingly is matably positionable in engagement with the generally flat tibial platform 20. <i>See, e.g.,</i> col. 3, ll. 37-39; Figs. 3, 4, 6.
an articulating side on an opposite side of said movable component relative to said movable sliding side, shaped to matingly engage an articulating surface of the second side of the joint;	The meniscal component 7 has a top or proximal side having dished bearing surfaces 41, 42 (i.e. articulating side) that are opposite the bottom or distal side (i.e. movable sliding side). <i>See, e.g.,</i> col. 4, ll. 36-41; Figs. 2-4, 7. The dished bearing surfaces 41, 42 are shaped to matingly engage spheroidal condylar articulating surfaces 10, 11 of the femoral component 2 (i.e. the articulating surface of the second side of the joint). <i>See, e.g.,</i> col. 3, ll. 30-36; col. 5, ll. 33-35; Figs. 1(a), 1(b), 7.

a protrusion	Guide 23 (i.e. protrusion) extends from the tibial platform
extending from one of	20 (i.e. the base sliding side). See, e.g., Abstract; Fig. 6.
said base sliding side	
or movable sliding	The guide 23 is substantially offset in the anterior direction
side, said protrusion	with respect to the anterior-posterior centerline of the tibial
substantially offset	platform 20 (i.e., the centerline that separates the anterior
with respect to a	and posterior sides of the tibial platform 20). See, e.g.,
midline of the first	Figs. 6, 8(b). Ex. 1005, Erdman Decl., ¶¶ 91-96.
side of a joint;	
a recess sized to	The track and recess 30 on the bottom or distal side (i.e.
receive said	the movable sliding side) of the meniscal component 7 is
protrusion, disposed	sized to receive the guide 23 of the tibial platform 20 for
in the other of said	"snap-fit" mating. See, e.g., Abstract; col. 1, ll. 47-56;
base sliding side or	Figs. 8(b).
movable sliding side,	5
said protrusion and	Mating of the guide 23 in the track and recess 30 allows
recess matable to	constrained rotational movement of the meniscal
constrain movement	component 7 about an axis of the guide 23 and relative to
of said first and	the tibial platform 20. See, e.g., Abstract; col. 3, 11. 46-52;
second components	col. 4, ll. 19-26; Figs. 8(a), 8(b). The nature of the limited
relative to each other,	rotational movement allowed by the guide 23 and recess
thereby promoting	30 is configured to avoid dislocation of the meniscal
movement of the joint	component 7 from the tibial platform 20 and replicate the
within desired	natural movements of the knee. See, e.g., See, e.g., col. 1,
anatomical limits.	ll. 31-33; col. 2, ll. 45-49; col. 3, ll. 53-61. Ex. 1005,
	Erdman Decl., ¶¶ 91-96.
Claim 16	Insall '658 Patent (Ex. 2004)
16. The device of	The guide 23 and recess 30 are substantially offset in the
claim 15, wherein	anterior direction from the anterior-posterior centerline
said protrusion and	that passes through the center of the tibial platform 20, and
said recess are located	from the central axis of the stem 5. See, e.g., Figs. 6, 8(b).
substantially offset	Ex. 1005, Erdman Decl., ¶ 91-95, 97.
from a center of said	
device	
Claim 18	Insall '658 Patent (Ex. 2004)
18. The device of	The Insall '658 patent relates to prostheses for knee
claim 15, wherein the	replacement. See, e.g., col. 1, ll. 8-10; Fig. 1(b). Ex. 1005,
joint is a knee.	Ex. 1005, Erdman Decl., ¶¶ 91-95, 98.
Claim 19	Insall '658 Patent (Ex. 2004)

19. The device of claim 15, further including a second base component connectable to the second side of the joint, including an articulating surface	The Insall '658 patent discloses a femoral component 2 (i.e. a second base component) connected to the femur 1 (i.e., a second side) of the knee joint. <i>See, e.g.</i> , Abstract; col. 3, ll. 23-3; Fig. 1(b). The femoral component 2 includes spheroidal condylar articulating surfaces 10, 11 (i.e. an articulating surface) shaped to matably engage dished bearing surfaces 41, 42 on the top or proximal side (i.e. articulating side) of the meniscal component 7 (i.e.
articulating side of	36-46; col. 5, ll. 33-35; Figs. 1(a), 1(b), 7. Ex. 1005, Ex.
said movable	1005, Erdman Decl., ¶¶ 91-95, 99.
Claim 20	Insall '658 Patent (Ex. 2004)
20 The device of	The Insell '658 patent relates to prostheses for knee
claim 19, wherein the	replacement. <i>See, e.g.</i> , col. 1, ll. 8-10; Fig. 1(b).
joint is a knee, and	
the first base	The tibial component 6 (i.e. the first base component) is
component is	connected to the tibia 4. See, e.g., col.3, II. 26-28; Figs
connectable to the	l(b).
tibia, and the second	
base component is	The femoral component 2 (i.e. the second base component)
connectable to the	is connected to the femur I. See, e.g., Abstract; col. 3, II.
temur, or the first	23-25; Fig. 1(b). Ex. 1005, Ex. 1005, Erdman Decl., ¶¶ 91-
base component is	95, 100.
connectable to the	
temur, and the second	
base component is	
connectable to the	
$\frac{\text{Claim 2I}}{21 \text{ The I}}$	Insall 658 Patent (Ex. 2004)
21. The device of	The guide 23 engages the recess 30 with shap-fit mating.
claim 15, wherein	<i>See, e.g., Abstract;</i> col. 1, II. 47-56; Figs. 8(a-d).
said protrusion and	Mating a Caluer of the 22 in the many 20 allows and a time of
recess engage to	Mating of the guide 23 in the recess 30 allows rotation of
permit relative	the meniscal component / (i.e. having a movable sliding
rotation of said base	side on its distal or bottom side) along the tibial platform 20 (i.e. a base sliding side) along the target is 2122
sliding side and said	20 (i.e. a base sliding side) about an axis of the guide 23.
movable sliding side	See, e.g., ADSITACI, COI. 4, II. 19-20; F1gS. $\delta(a)$, $\delta(b)$. EX.
about an axis of said	1005, EX. 1005, Eraman Deci., ¶¶ 91-95, 101.
protrusion.	

Claim 22	Insall '658 Patent (Ex. 2004)
22. The device of	The guide 23 comprises a post 24 and a cap 25. See, e.g.,
claim 15, wherein	Abstract; col. 3, ln. 49; Fig. 6.
said protrusion is a	
pin, and said recess is	The recess 30 and slot 32 are a hole sized to receive the
a hole sized to receive	guide 23, including the post 24 and the cap 25, for snap-fit
said pin.	mating. See, e.g., Abstract; col. 1, 11. 47-56; Figs. 8(b). Ex.
	1005, Ex. 1005, Erdman Decl., ¶¶ 91-95, 102.
Claim 23	Insall '658 Patent (Ex. 2004)
23. The device of	Guide 23 includes a lower post 24 and an upper cap 25.
claim 15, wherein	See, e.g., col. 1, ll. 46-52; col. 3, ll. 49; Figs. 6.
said protrusion is a	
dovetail pin and said	The meniscal component 7 includes a slot 32 that is wider
recess is a dovetail	than the recess 35 that leads to the slot 32. See, e.g., col. 4,
tail, together forming	11. 9-12; Fig. 5. The guide 23 comprises a lower post 24
a dovetail joint.	and an upper cap 25 to have a profile complementary to
	the recess 30 and slot 32 for snap-fit mating with the slot
	32 and recess 30. See, e.g., Abstract; col. 1, 11. 47-56; col.
	4, ll. 9-12; Figs. 5, 6, 8(b). Ex. 1005, Erdman Decl., ¶¶ 91-
	95.
Claim 24	Insall '658 Patent (Ex. 1004)
24. The device of	Each of the recess 30 and the slot 32, which receive the
claim 23, wherein	guide 23, is longer along the anterior-posterior axis as
said dovetail joint is	compared to its width along the medial-lateral axis (i.e. the
elongated, extends in	dovetail joint is elongated and extends in a substantially
a substantially	anterior-posterior orientation). See, e.g., Fig. 5.
anterior-posterior	
orientation, and	The length of each of the recess 30 and the slot 32 along
enables anterior-	the anterior-posterior axis enables anterior-posterior
posterior	displacement of the meniscal component 7 (i.e. having a
displacement of the	movable sliding side) relative to the tibial platform 20 (i.e.
base sliding side	the base sliding side) while the guide 23 is in snap-fit
relative to the	mating with the recess 30 and the slot 32 of the meniscal
movable sliding side.	component 7. See, e.g., Abstract; Fig. 8(c), 8(d). Ex.
	1005, Erdman Decl., ¶¶ 91-95.
Claim 25	Insall '658 Patent (Ex. 2004)
25. The device of	Guide 23 (i.e. protrusion) includes a lower post 24 and an
claim 15, further	upper cap 25. See, e.g., col. 1, ll. 46-52; Fig. 6. The
including means	meniscal component 7 includes a slot 32 that is wider than

associated with said protrusion to prevent a separation of said base sliding side and said movable sliding side.	the recess 35 that leads to the slot 32. <i>See, e.g.,</i> col. 4, ll. 9-12; Figs. 5. The dimensions of the cap 25 and of the recess 30 are such that the meniscal component 7 is snapped over the guide 23, reception of the cap 25 in the recess 30 and slot 32 preventing lift-off of the meniscal component 7 from the tibial platform 20. <i>See, e.g.,</i> col. 1, ll. 32-33; col. 2, ll. 23-26; col. 2, ll. 45-49; col. 3, ll. 53-61. Ex. 1005, Decl., ¶¶ 91-95, 103.
Claim 26	Insall '658 Patent (Ex. 2004)
26. The device of	The Insall '658 patent discloses an orthopaedic knee
claim 15, wherein not	component that replaces only the medial and lateral
all articulating	condular compartments of the knee joint and does not
compartments of the	replace the patellar compartment of the knee joint. See,
joint are replaced by	e.g., col. 3, 11. 23-28; Fig. 1(b). Ex. 1005, Erdman Decl.,
said device.	¶¶ 91-95, 104.
Claim 27	Insall '658 Patent (Ex. 2004)
27. The device of	The Insall '658 patent relates to prostheses for knee
claim 15, wherein the	replacement. See, e.g., Title; col. 1, ll. 8-10; Fig. 1(b). Ex.
joint is located in a	1005, Erdman Decl., ¶¶ 91-95, 105.
finger, wrist, elbow,	
shoulder, spine, hip,	
knee, ankle, or toe.	
Claim 28	Insall '658 Patent (Ex. 2004)
28. The device of	Guide 23 (i.e. protrusion) is offset in the anterior direction
claim 15, wherein	from the anterior-posterior centerline that passes through
said protrusion is	the center of the tibial platform 20 of the tibial component
offset with respect to	6 (i.e. the base component). See, e.g., Figs. 6, 8(c). Ex.
an axis passing	1005, Erdman Decl., ¶¶ 91-95.
through the anterior-	
posterior or the	
medial-lateral center	
of said base	
component or	
movable component.	
Claim 31	Insall '658 Patent (Ex. 2004)
31. A knee	The Insall '658 patent relates to prostheses for knee
arthroplasty device,	replacement. See, e.g., col. 1, ll. 8-10; Fig. 1(b). Ex. 1005,
comprising:	Erdman Decl., ¶¶ 91-95, 106.
a tibial tray including	The Insall '658 patent discloses a tibial component 6

a lower distal surface	having a stem 5 (i.e. a lower distal surface) and a tibial
and an upper	platform 20 (i.e. an upper proximal surface). See, e.g.,
proximal surface,	Abstract; col.3, ll. 37-39; Fig. 6.
said proximal surface	The platform 20 includes a guide 23 that is offset in the
having either a post	anterior direction with respect to the anterior-posterior
or a cavity, said post	centerline of the tibial platform 20 (i.e., the centerline that
or cavity offset from	separates the anterior and posterior sides of the platform
at least one of a	20). See. e.g., Figs. 6, 8(c). Ex. 1005. Erdman Decl., ¶¶
medial-lateral	91-95, 106.
centerline and an	
anterior-posterior	
centerline of said	
tibial tray;	
a tibial tray insert	The Insall '658 patent discloses a meniscal component 7
engageable with said	(i.e. tibial tray insert) that engages the tibial platform 20
proximal surface and	(i.e. proximal surface). See, e.g., Abstract; col. 1, ll. 47-
having a mating	58; col. 4, 11. 36-46; Fig. 1(b).
second cavity if said	
tibial tray has a post,	The meniscal component 7 includes a recess 30 (i.e.
or a mating post if	mating second cavity) that receives the guide 23 for snap-
said tibial tray has a	fit mating. See, e.g., Abstract; col. 1, ll. 47-56; col. 3, ln.
cavity,	66-col. 4, ln. 3; Figs. 8(c).
• •	
said mating post or	The track and recess 30 (i.e. mating cavity) is offset from
mating cavity offset	the medial-lateral centerline of the tibial platform 20 (i.e.
from at least one of	tibial tray). See, e.g., Figs. 8(c). Ex. 1005, Erdman Decl.,
the medial-lateral	¶¶ 91-95, 106.
centerline and the	
anterior-posterior	
tibiol tross	
tiblai tray,	
wherein said mating	
cavity is adapted to	The track and recess 30 (i.e. mating cavity) is adapted to
receive at least a	receive at least a portion of the guide 23 for snan-fit
nortion of said nost	mating $S_{PP} \rho \sigma$ Abstract col 1 11 47-56. Figs 8(c)
or said mating nost is	
adapted to he	
· 1 · / 1	

portion of said cavity;	
wherein said tibial tray insert rotationally moves with respect to said tibial tray, about said post, when the device is used within the body	Meniscal component 7 (i.e. tibial tray insert) rotates with respect to the tibial platform 20 (i.e. tibial tray) about an axis of the guide 23 (i.e. post) when the device is used within the body. <i>See, e.g.,</i> Abstract; col. 4, ll. 19-27; Figs. 8(a), 8(b).
such that the rotation of the tibial tray insert is asymmetric with respect to at least one of the medial-lateral centerline and the anterior-posterior centerline of said tibial tray.	Rotation of the meniscal component 7 (i.e. tibial tray insert) is asymmetric with respect to the anterior-posterior centerline of the tibial platform 20 (i.e. tibial tray) due to the guide 23, about which the meniscal component 7 rotates, being offset in the anterior direction with respect to the anterior-posterior centerline of the tibial platform 20. <i>See, e.g.</i> , Figs. 6, 8(a), 8(b). Ex. 1005, Erdman Decl., ¶¶ 91-95, 106.
Claim 34	Insall '658 Patent (Ex. 2004)
34. The knee arthroplasty device of claim 31, wherein the tibial tray has a keel with a central axis, and wherein said post or cavity of said tibial tray is offset from the central axis of said keel.	The tibial platform 20 (i.e. tibial tray) has a stem 5 (i.e., a keel) extending distally therefrom, the stem 5 having a central axis. <i>See, e.g.</i> , Abstract; col. 3, ll. 26-28; Fig. 6. The guide 23 of the tibial platform 20 is anteriorly offset from the central axis of the stem 5. <i>See, e.g.</i> , Fig. 6. Ex. 1005, Erdman Decl., ¶¶ 91-95, 107.
Claim 35	Insall '658 Patent (Ex. 2004)
35. The knee arthroplasty device of claim 31, wherein the tibial tray has a keel with a central axis, and wherein said mating post or mating cavity of said tibial tray insert is offset from the central axis	The tibial platform 20 (i.e. tibial tray) has a stem 5 (i.e., a keel) extending distally therefrom, the stem 5 having a central axis. <i>See, e.g.</i> , Abstract; col. 3, ll. 26-28; Fig. 6. The recess 30 of the meniscal component 7 is at least partially aligned with the guide 26 which itself is anteriorly offset from the central axis of the stem 5. <i>See, e.g.</i> , Figs. 6, 8(c). Ex. 1005, Erdman Decl., ¶¶ 91-95, 108.

of said keel.	
Claim 36	Insall '658 Patent (Ex. 2004)
36. The knee	The meniscal component 7 has a top or proximal side
arthroplasty device of	having a saddle 43 (i.e. mound) interposing medial and
claim 31, wherein a	lateral dished bearing surfaces 41, 42 which are shaped to
proximal surface of	receive condylar articulating surfaces 10 and 11 of the
said tibial tray insert	femoral component 2. See, e.g., col. 3, ln. 30-36; col. 4,
includes a mound	ln. 36-41; col. 5, ll. 33-35; Figs. 1(a), 1(b), 2-4, 7. Ex.
interposing a medial	1004, Erdman Decl., ¶¶ 91-95, 109.
condyle receiver and	
a lateral condyle	
receiver.	

E. Ground 5: Claims 15-16, 18-22, 25-28, 31 and 34-36 are Unpatentable as Being Anticipated by the Insall '283 Patent

The Insall '283 patent discloses a mobile bearing tibial component of a knee

implant having each and every limitation of claims 15-16, 18-22, 25-28, 31 and 34-

36 of the Bonutti patent. Erdman Decl., ¶¶ 71-89. Claim charts mapping the

features of the Insall '283 patent to the limitations of the challenged claims in the

Bonutti patent are provided below.

Claim 15	Insall '283 Patent (Ex. 1003)
15. A device to replace	The Insall '283 patent discloses an orthopaedic knee
an articulating surface of	implant having a tibial component 10 including a tibial
a first side of a joint in a	tray 18 and a bearing 20. See, e.g., col. 3, ll. 5-13; Fig.
body,	1. The bearing 20 has an articular bearing surface 34
	shaped for engagement with the femoral component 14
	of the implant (i.e., is configured to replace the
	articulating surface of the patient's natural tibia). See,
	<i>e.g.</i> , col. 3, ll. 22-28; Fig. 5.
the joint having first and	The patient's knee joint that is replaced by the implant
second sides,	has tibial (i.e., first) and femoral (i.e., second) sides.
comprising:	See, e.g., col. 3, ll. 1-4; Fig. 5. Ex. 1005, Erdman
	Decl., ¶¶ 71-76.

a base component,	The tibial tray 18 is a base component.
including a bone contacting side connectable with bone on the first side of the joint, and	The tibial tray 18 includes a tibial plateau 22 that has a lower, bone contacting underside and a distally extending stem 24 that is implanted in the intramedullary canal of the tibia. <i>See, e.g.,</i> col.1, ll. 10-15; col. 3, ll. 5-13; Fig. 5.
a base sliding side on an opposite side of said base component relative to said bone contacting side;	The tibial plateau 22 has a planar upper proximal surface (i.e., a base sliding side) that is on the side opposite the bone contacting underside. <i>See, e.g.</i> , col. 3, ll. 5-13; Figs. 1, 5. The bearing 20 engages and slides on the upper surface of the plateau 22, so the upper surface of the plateau is a sliding side. <i>See, e.g.</i> , col. 3, ln. 66-col. 4, ln. 14.
a movable component,	Bearing 20 is a movable component. <i>See, e.g.,</i> col. 3, ll. 53-64; Fig. 4.
including a movable sliding side, said movable sliding side being matably positionable in sliding engagement with said base sliding side, and	The bearing 20 has a backing surface 46 that is supported by (i.e., is in engagement with) and rotates (i.e., is movable) on the upper surface of the tibial plateau 22. The backing surface 46 of the bearing 20 is planar, and is therefore matably positionable in engagement with the planar upper proximal surface of the plateau 22. The backing surface 46 slides on the upper surface of the plateau 22, and is therefore a sliding side. <i>See, e.g.</i> , col. 3, ln. 66-col. 4, ln. 14; Figs. 1, 4.
an articulating side on an opposite side of said movable component relative to said movable sliding side, shaped to matingly engage an articulating surface of the second side of the joint;	The bearing 20 has an articular bearing surface 34 on the side opposite the side of the backing surface 46. The articular bearing surface 34 has concave regions on opposite sides of a center projection 36 that engage corresponding condyles (i.e., articulating surfaces) of the femoral component 14. <i>See, e.g.</i> , col. 3, ll. 22-28; Figs. 1, 5.
a protrusion extending from one of said base	Projection 28 is a protrusion and extends from the upper surface (i.e., the base sliding side) of the tibial

sliding side or movable sliding side,	plateau 22. See, e.g., col. 3, ll. 5-13; Figs. 1, 2.
said protrusion substantially offset with respect to a midline of the first side of a joint;	The projection 28 is substantially offset in the anterior direction with respect to the anterior-posterior centerline of the tibial plateau 22 (i.e., the centerline that separates the anterior and posterior sides of the plateau). <i>See, e.g.</i> , Figs. 1, 2. Ex. 1005, Erdman Decl., ¶¶ 71-76.
a recess sized to receive said protrusion, disposed in the other of said base sliding side or movable sliding side,	Opening 38 is a recess sized to receive the projection 28. The opening 38 is disposed in the backing surface 46 (i.e., the movable sliding side) of the bearing 20. <i>See, e.g.</i> , col. 3, ll. 29-52; Figs. 1, 2.
said protrusion and recess matable to constrain movement of said first and second components relative to each other, thereby promoting movement of the joint within desired anatomical limits.	The projection 28 and opening 38 mate to allow rotational movement of the bearing 20 relative to the tibial plateau 22 about the axis of rotation 40 (i.e., the movement is constrained or limited to rotation about the projection). <i>See, e.g.</i> , col. 3, ll. 29-53, Figs. 3, 4. The nature of the limited rotational movement allowed by the projection 28 and opening 38 is configured to replicate the natural movements of the knee. <i>See, e.g.</i> , col. 1, ll. 22-30; col. 3, ll. 29-65. Ex. 1005, Erdman Decl., ¶¶ 71-76.
Claim 16	Insall '283 Patent (Ex. 1003)
16. The device of claim15, wherein saidprotrusion and saidrecess are locatedsubstantially offset froma center of said device.	The projection 28 and opening 38 are substantially offset in the anterior direction from the anterior-posterior centerline that passes through the center of the tibial plateau 22, and from the central axis of the stem 24. <i>See, e.g.</i> , Figs. 1, 2. Ex. 1005, Erdman Decl., ¶¶ 71-75, 77.
Claim 18	Insall '283 Patent (Ex. 1003)
18. The device of claim15, wherein the joint is a knee.	The Insall '283 patent discloses an orthopaedic knee component for implanting in a knee joint. <i>See, e.g.,</i> Abstract; Fig. 5. Ex. 1005, Erdman Decl., ¶¶ 71-75, 78.
Claim 19	Insall '283 Patent (Ex. 1003)
19. The device of claim 15, further including a	The Insall '283 patent discloses a femoral component 14 connected to a femoral side (i.e., a second side) of

second base component	the knee joint. The femoral component 14 has
connectable to the	condyles with curved surfaces (i.e., articulating
second side of the joint,	surfaces) that are engaged with the articular bearing
including an articulating	surface 34 of the bearing 20. See, e.g., col. 3, 11. 22-28;
surface matable with said	Fig. 5. Ex. 1005, Erdman Decl., ¶¶ 71-75, 79.
articulating side of said	
movable component.	
Claim 20	Insall '283 Patent (Ex. 1003)
20. The device of claim	The Insall '283 patent discloses an orthopaedic knee
19, wherein the joint is a	component for implanting in a knee joint. See, e.g.,
knee, and	Abstract; Fig. 5.
,	, ,
the first base component	The tibial tray 18 (i.e., the first base component) is
is connectable to the	connected to the tibia. The femoral component 14 (i.e.
tibia and the second	the second base component) is connected to the femur
base component is	See $e \sigma$ col 1 10-15 col 3 1-13 Fig 5 Ex
connectable to the femur	1005 Erdman Decl ¶¶ 71-75 80
or the first base	
component is	
connectable to the femur	
and the second base	
component is	
connectable to the tibia	
Claim 21	Insall '283 Patent (Fx 1003)
21 The device of claim	Projection 28 is disposed in opening 38 The projection
15 wherein said	28 and opening 38 allow rotational movement of the
protrusion and recess	upper surface of the tibial plateau 22 (i.e. the base
engage to permit relative	sliding side) and the backing surface 16 of the bearing
rotation of said base	20 (i.e. the movable sliding side) about the axis of
sliding side and said	rotation 40 of the projection $See e g$ col 3 11 29-52
movable sliding side	Fig. 4 Ex 1005 Erdman Decl. $\P\P$ 71-75 81
about an axis of said	1 Ig. 4. LX. 1005, Eruman Deer., $\ \ / 1^{-75}$, 61.
protrusion	
Claim 22	Insall '283 Patent (Ex. 1003)
22 The device of claim	Projection 28 is a nin and opening 38 is a hole sized to
15 wherein coid	receive the projection $S_{ab} = c_{ab} = c_{ab} = 12$ 11 20 52. Fig
notrusion is a nin and	2 Ex 1005 Erdman Decl $\P\P$ 71 75 82
produsion is a pill, and	2. EX. 1005, Eruman Deci., $ / 1 - /5, 02$.
to receive and nin	
to receive sald pin.	

Claim 25	Insall '283 Patent (Ex. 1003)
25. The device of claim	Tibial knee component 50 that includes a bearing 52
15, further including	similar in material respects to the bearing 20 has a
means associated with	fastener in the form of a shoulder bolt 62 that extends
said protrusion to	through an opening 60 in the bearing and threadedly
prevent a separation of	engages an internally threaded hole 30 of the projection
said base sliding side and	28. The shoulder bolt 62 ensures that the bearing 52
said movable sliding	does not lift off of the projection 28 (i.e., prevents
side.	separation of the upper surface of the tibial plateau (the
	base sliding side) and the backing surface of the
	bearing (the movable sliding side). See, e.g., col. 4, ll.
	36-57; Figs. 6, 7. Ex. 1005, Erdman Decl., ¶¶ 71-75,
	83.
Claim 26	Insall '283 Patent (Ex. 1003)
26. The device of claim	The Insall '283 patent discloses an orthopaedic knee
15, wherein not all	component that replaces only the medial and lateral
articulating	condylar compartments of the knee joint. The
compartments of the	component does not replace the patellar compartment
joint are replaced by said	of the knee joint. See, e.g., col. 3, ln. 1-col. 4, ln. 28;
device.	Fig. 5. Ex. 1005, Erdman Decl., ¶¶ 71-75, 84.
Claim 27	Insall '283 Patent (Ex. 1003)
27. The device of claim	The Insall '283 patent discloses a knee component
15, wherein the joint is	located on a knee joint. See, e.g., Abstract; Fig. 5. Ex.
located in a finger, wrist,	1005, Erdman Decl., ¶¶ 71-75, 85.
elbow, shoulder, spine,	
hip, knee, ankle, or toe.	
Claim 28	Insall '283 Patent (Ex. 1003)
28. The device of claim	The projection 28 is offset in the anterior direction from
15, wherein said	the anterior-posterior centerline that passes through the
protrusion is offset with	center of the tibial plateau 22 of the tibial tray 18. See,
respect to an axis passing	<i>e.g.</i> , Figs. 1, 2. Ex. 1005, Erdman Decl., ¶¶ 71-75.
through the anterior-	
posterior or the medial-	
lateral center of said base	
component or movable	
component.	
Claim 31	Insall '283 Patent (Ex. 1003)
31. A knee arthroplasty	The Insall '283 patent discloses an orthopaedic knee
device, comprising:	implant having a tibial component 10. See, e.g.,

	Abstract; col. 3, ll. 1-4; Fig. 5. Ex. 1005, Erdman Decl., ¶¶ 71-75, 86.
a tibial tray including a lower distal surface and an upper proximal surface,	The tibial component 10 includes a tibial tray 18 having a tibial plateau 22. The tibial plateau 22 includes an underside (i.e., a lower distal surface) and a planar upper proximal surface. <i>See, e.g.</i> , col. 3, ll. 5-13; Figs. 1, 2.
said proximal surface having either a post or a cavity,	The upper proximal surface of the tibial plateau 22 has a projection 28. <i>See, e.g.,</i> col. 3, ll. 5-13; Figs. 1, 2.
said post or cavity offset from at least one of a medial-lateral centerline and an anterior-posterior centerline of said tibial tray;	The projection 28 is offset in the anterior direction from the anterior-posterior centerline of the tibial tray 18 (i.e., the centerline that separates the anterior and posterior sides). <i>See, e.g.</i> , Figs. 1, 2. Ex. 1005, Erdman Decl., ¶¶ 71-75, 86.
a tibial tray insert engageable with said proximal surface and having a mating second cavity if said tibial tray has a post, or a mating post if said tibial tray has a cavity,	The tibial component 10 includes a bearing 20 (i.e., a tibial tray insert) having a backing surface 46 that engages with the upper surface of the tibial plateau 22. <i>See, e.g.,</i> col. 3, ln. 66-col. 4, ln. 14; Figs. 1, 2. The bearing 20 has a cylindrical shaped opening 38 in which the projection 28 is disposed (i.e., the opening mates with the projection). <i>See, e.g.,</i> col. 3, ll. 29-30; Figs. 1, 2.
said mating post or mating cavity offset from at least one of the medial-lateral centerline and the anterior-posterior centerline of said tibial tray,	The opening 38 is offset in the anterior direction from the anterior-posterior centerline of the tibial tray 18. <i>See, e.g.,</i> Figs. 1, 2. Ex. 1005, Erdman Decl., ¶¶ 71-75, 86.
wherein said mating cavity is adapted to receive at least a portion of said post, or said mating post is adapted to	The opening 38 is cylindrical and engaged with (i.e., is adapted to receive) the projection 28. <i>See, e.g.,</i> col. 3, ll. 29-30, Figs. 1, 2.

be received in at least a portion of said cavity:	
wherein said tibial tray insert rotationally moves with respect to said tibial tray, about said post, when the device is used within the body	The bearing 20 rotationally moves with respect to the plateau 22 of the tibial tray 18 about the projection 28 when the implant is used in the patient's body. <i>See</i> , <i>e.g.</i> , col. 3, ln. 29-col. 4, ln. 14; Fig. 4.
such that the rotation of the tibial tray insert is asymmetric with respect to at least one of the medial-lateral centerline and the anterior-posterior centerline of said tibial tray.	The axis of rotation 40 of the projection 28 is offset in the anterior direction from the anterior-posterior centerline of the tibial tray 18, so the rotation of the bearing 20 is asymmetrical with respect to the anterior- posterior centerline of the tibial tray. Ex. 1005, Erdman Decl., ¶¶ 71-75, 86.
Claim 34	Insall '283 Patent (Ex. 1003)
34. The knee arthroplasty device of claim 31, wherein the tibial tray has a keel with a central axis, and wherein said post or cavity of said tibial tray is offset from the central axis of said keel.	The tibial tray 18 has a distally extending stem 24 (i.e., a keel) with a central axis. <i>See, e.g.</i> , col. 3, ll. 5-13; Figs. 1, 2. The projection 28 of the tibial tray 18 is anteriorly offset from the central axis of the stem 24. <i>See, e.g.</i> , Figs. 1, 2. Ex. 1005, Erdman Decl., ¶¶ 71-75, 87.
Claim 35	Insall '283 Patent (Ex. 1003)
35. The knee arthroplasty device of claim 31, wherein the tibial tray has a keel with a central axis, and wherein said mating post or mating cavity of said tibial tray insert is offset from the central axis of said keel.	The tibial tray 18 has a distally extending stem 24 (i.e., a keel) with a central axis. <i>See, e.g.</i> , col. 3, ll. 5-13; Figs. 1, 2. The opening 38 in the bearing 20 is anteriorly offset from the central axis of the stem 24. <i>See, e.g.</i> , Figs. 1, 2. Ex. 1005, Erdman Decl., ¶¶ 71-75, 88.
Claim 36	Insall '283 Patent (Ex. 1003)
36. The knee arthroplasty	The articular bearing surface 34 of the bearing 20

device of claim 31,	includes a center projection 36 (i.e., a mound). Each
wherein a proximal	discrete portion of the articular bearing surface 34 (i.e.,
surface of said tibial tray	the medial condyle receiver and the lateral condyle
insert includes a mound	receiver) are on either side of the center projection 36.
interposing a medial	See, e.g., col. 3, ll. 22-28; Figs. 1, 4. Ex. 1005, Erdman
condyle receiver and a	Decl., ¶¶ 71-75, 89.
lateral condyle receiver.	

VIII. CONCLUSION

For the foregoing reasons, Petitioners respectfully request the grant of this

Petition and cancellation of claims 15-28 and 31-36 of the Bonutti patent.

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Dated: November 22, 2013

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