Paper 9 Entered: February 26, 2014

### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC. Petitioner

v.

BONUTTI SKELETAL INNOVATIONS, LLC Patent Owner

> Case IPR2013-00605 Patent 7,749,229 B1

Before WILLIAM V. SAINDON, MICHAEL R. ZECHER, and RICHARD E. RICE, *Administrative Patent Judges*.

RICE, Administrative Patent Judge.

DECISION Institution of *Inter Partes* Review 37 C.F.R. § 42.108

> S&N EXHIBIT 1027 S&N v. BSI IPR2013-00629

# I. INTRODUCTION

Smith & Nephew, Inc. ("Petitioner") filed a petition (Paper 3, "Pet.") requesting an *inter partes* review of claim 23 of U.S. Patent No. 7,749,229 B1 (Ex. 1001, "the '229 Patent"). The owner of the '229 Patent, Bonutti Skeletal Innovations LLC ("Patent Owner"), did not file a preliminary response. We have jurisdiction under 35 U.S.C. § 314.

The standard for instituting an *inter partes* review is set forth in 35 U.S.C.

§ 314(a), which provides as follows:

THRESHOLD -- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

We determine that the information presented in the petition establishes that there is a reasonable likelihood that Petitioner would prevail in its challenge of claim 23 of the '229 Patent as unpatentable. Accordingly, pursuant to 35 U.S.C. § 314, we institute an *inter partes* review for claim 23 of the '229 Patent.

# A. Related Proceeding

The '229 Patent is involved in co-pending litigation styled *Bonutti Skeletal Innovations LLC v. Smith & Nephew, Inc.*, D. Del. Case No. 12-1111-GMS. Pet. 1.

#### B. The '229 Patent

The '229 Patent, titled "Total Knee Arthroplasty Through Shortened Incision," issued on July 6, 2010, based on U.S. Patent Application Serial No. 11/170,969, filed on June 30, 2005. The '229 Patent is a continuation of U.S. Patent Application Serial No. 10/191,751 ("the '751 Application"), filed on July 8, 2002. The '751 Application is a continuation-in-part of U.S. Patent Application Serial No. 09/976,396, filed Oct. 11, 2001, and a continuation-in-part of U.S. Patent Application Serial No. 09/941,185 ("the '185 Application"), filed Aug. 28, 2001. The '751 Application is also a continuation-in-part of a number of earlierfiled applications that are not relevant to our decision.

The '229 Patent uses the term "total knee arthroplasty" in claim 23 and the abstract. Claim 23 recites "[a] method of performing *total knee arthroplasty* through a primary incision having a length of less than thirteen (13) centimeters . . . ." (Emphasis added).

The abstract of the '229 Patent states that "[a] method is provided for performing *total knee arthroplasty*." Ex. 1001, Abstr. 1 (emphasis added). The abstract states that the method includes "making a primary incision," "cutting medial and lateral condyles of the femur of the leg," "moving a femoral component of a total knee implant through the primary incision," and "positioning the femoral component with respect to the . . . femoral cut surface." *Id.* at Abstr. 2-8. The abstract also states that "[t]he primary incision has a length of less than thirteen (13) centimeters." *Id.* at Abstr. 8-9.

The term "total knee arthroplasty" does not appear in the specification other than the claims. Rather, the specification uses, interchangeably, the terms "total

knee joint replacement," "total knee replacement," and "full knee replacement" (all being hereinafter referred to as "total knee replacement"). *See, e.g., id.* at 1:47, 58; 11:22-28; 37:14-15.

The specification describes a method for performing total knee replacement through an incision of less than 13 centimeters. *See, e.g., id.* at 14:54-61; 18:40-44; 26:26-34; 30:26-28; 49:2-19, 44-57;105:47-55. As described, the method requires cutting and shaping both the femoral and tibial sides of the knee joint, and installing an implant comprising femoral and tibial components. *See, e.g., id.* at 30:26-28; 31:48–32:37. Total knee replacement may, or may not, involve work on the patella. *See id.* at 29:59–30:7.

The specification describes making a cut across anterior portions of the lateral and medial condyles of the femur, such that the anterior portion of the lateral and medial epicondyles are cut away and flat anterior cut surface 182 is disposed on distal end portion 124 of femur 126. *See id.* at 20:21-23; 22:4-7; figs. 13, 14, & 15.

After making the anterior cut, distal resection guide 186 is positioned on flat anterior cut surface 182 (*see, e.g., id.* at 23:8-9; figs 16 & 17), and distal femoral cut is made by moving saw blade 170 along guide surface 202 of the resection guide (*see, e.g., id.* at 23:57-59; figs. 17 & 18). "When the distal femoral cut is completed, a flat distal end surface **209** extends across the distal end of the femur **126**," and "[t]he trochlear groove of the femur extends through the distal end surface **209**." *Id.* at 24:34-35, 41-42; figs. 17 & 18.



Figures 17 and 18 of the '229 Patent is reproduced below:

Figures 17 and 18 depict the manner in which the distal femur cut is made.

The method of total knee replacement described in the specification, therefore, involves cutting and shaping the two condyles of the femur and the distal end portion of the femur. *See, e.g., id.* at 20:18-25; 24:34-42; figs. 13 & 17; *see also id.* at 75:45-46 (explaining that, in contrast with total knee replacement, "[w]hen a partial knee replacement is to be made, only one of the two condyles . . . is cut"). The method of total knee replacement described in the specification also involves cutting and shaping the proximal end portion of the tibia. *See, e.g., id.* at 27:19-30; fig. 21. After the femoral and tibial cuts have been made, and any work on the patella has been performed, a tibial component is mounted on the proximal

end portion of the tibia, and a femoral component is mounted on the distal end portion of the femur. *See, e.g., id.* at 30:26-28; 31:48–32:37; 96:39-52.

#### *C. Claim* 23

Claim 23 is the only claim challenged in this proceeding, and it is

reproduced below:

23. A method of performing total knee arthroplasty through a primary incision having a length of less than thirteen (13) centimeters, comprising the steps of:

making a primary incision of less than thirteen (13) centimeters near the knee joint of a leg of a patient, and carrying out the further steps, through the primary incision, of

cutting medial and lateral condyles, and the trochlear groove of the femur of the leg to create at least one femoral cut surface;

moving a single femoral component of a total knee implant operative to replace the entire articulating surfaces of the medial and lateral condyles and the trochlear groove, through the primary incision; and

positioning the femoral component with respect to the at least one femoral cut surface.

#### D. References Relied Upon

Petitioner relies upon the following references:

Lacey '483	US 4,502,483	Mar. 5, 1985 (filed Mar. 9, 1983)	Ex. 1003
Engh '209	US 6,482,209 B1	Nov. 19, 2002 (filed June 14, 2001)	Ex. 1005

Dow Corning Wright, *Lacey Condylar Total Knee System Surgical Procedure* (hereinafter "the Lacey Guide") (Ex. 1004).

Stryker Howmedica Osteonics, Scorpio Single Axis Total Knee System – Passport Total A.R. Total Knee Instruments – Passport A.R. Surgical Technique ("the Scorpio Guide") (Ex. 1006).

Smith & Nephew, *Profix Total Knee System Primary Procedure* ("the Profix Guide") (Ex. 1020).

#### E. The Alleged Grounds of Unpatentability

Petitioner challenges claim 23 of the '229 Patent based on the alleged grounds of unpatentability set forth in the table below:

Reference(s)	Basis	Challenged
		Claim
Lacey '483	§ 102	23
Lacey '483	§ 103	23
Lacey Guide	§ 102	23
Lacey Guide	§ 103	23
Lacey '483 and the Lacey Guide	§ 103	23
Lacey '483 and the Scorpio	§ 103	23
Guide		
Engh '209	§ 103	23
Engh '209 and Profix Guide	§ 103	23

#### II. ANALYSIS

#### A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial

Practice Guide, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012). Applying this standard, we construe the following claim terms or phrases recited in claim 23.

# 1. performing total knee arthroplasty through a primary incision having a length of less than thirteen (13) inches

The preamble of claim 23 recites, "[a] method of performing tota1 knee arthroplasty through a primary incision having a length of less than thirteen (13) centimeters." Petitioner does not state explicitly that the preamble of the '229 Patent is entitled to patentable weight and, therefore, constitutes a claim limitation. However, Petitioner treats the preamble as a claim limitation when it argues that "Engh '209 discloses a method of 'performing total knee arthroplasty through a primary incision having a length of less than thirteen (13) centimeters,' as recited in the preamble . . . ." Pet. 48-49 (referencing Ex. 1005, 8:53-59, fig. 2; Ex. 1002 ¶ 70).

"In general, a preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). "[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Id.* at 808-09 (citing *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375 (Fed.Cir.2001)). Here, the preamble clearly was relied on during prosecution to distinguish the prior art. *See* Ex. 1011 (Resp. to Office Action filed May 8, 2008), at 7) ("Caspari [U.S. Patent No.").

5,395,376] does not address the problem of performing a total knee replacement through a reduced size incision.").

Accordingly, we construe the preamble of claim 23 as a claim limitation that requires performing total knee arthroplasty through a primary incision having a length of less than 13 centimeters.

#### 2. total knee arthroplasty

Petitioner contends that the term "total knee arthroplasty" should be construed as "resurfacing the medial and lateral femoral condyle and the associated tibial plateau." Pet. 8 (citing Ex. 1001, 96:39-47). The portion of the specification upon which Petitioner relies states as follows:

In general, prior art knee prostheses for partially or totally replacing a knee joint include a femoral component for attachment to the distal end of the femur and a tibial component for attachment to the proximal end of the tibia. The tibial component typically includes a base or tray that is implanted in the tibia and an insert or meniscal plate placed on the face of the tray for articulating with the condyles of the femoral component. The tray often includes a keel or stem that inserts in the tibia to provide stability.

Ex. 1001, 96:39-47. Petitioner also states that the '229 Patent sometimes refers to "total knee arthroplasty" as "total knee replacement." Pet. 8.

We agree with Petitioner that the terms "total knee arthroplasty" and "total knee replacement" are used interchangeably in the '229 Patent, because the abstract describes "total knee arthroplasty" in a manner that is consistent with the description of "total knee replacement" in the specification. *See* section I. B *supra*. We note that interpreting "total knee arthroplasty" to mean "total knee replacement" is consistent with the ordinary meaning of "arthroplasty" as "plastic surgery of a joint: the operative formation or restoration of a joint." WEBSTER'S

THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED 123 (1971). Further, we credit the testimony of Plaintiff's expert, Dr. Mabrey, on this point. *See* Ex. 1002 (Mabrey Decl.), ¶ 14 ("The challenged claim of the ['229 Patent] relates to a method for knee surgery, specifically total knee arthroplasty ('TKA') or, sometimes, total knee replacement.").

We do not agree, however, that "total knee replacement," as used in the '229 Patent, means "resurfacing" the medial and lateral femoral condyles and the associated tibial plateau, as Petitioner contends. *See* Pet. 8. In particular, the proposed claim construction is overly broad, because it encompasses any form of "resurfacing," including, for example, "biological resurfacing." The specification indicates clearly that biological resurfacing is only an aspect of, and is distinct from, total knee replacement. *See, e.g.*, Ex. 1001, 4:43-47.

We construe "total knee arthroplasty," consistent with the specification of the '229 Patent, to mean a surgical procedure that involves cutting and shaping the two condyles of the femur, the distal end portion of the femur, and the proximal end portion of the tibia, and installing a knee implant having femoral and tibial components. *See, e.g., id.* at 30:26-28; 31:48–32:37; 75:45-46; 96:39-47.

#### *3. a single femoral component*

Claim 23 recites the step of "moving a single femoral component of a total knee implant operative to replace the entire articulating surfaces of the medial and lateral condyles and the trochlear groove, through the primary incision." (Emphasis added).

Petitioner argues implicitly that the italicized portion of the claim language quoted above requires the entire femoral side of the total knee implant to be in the

form of a single piece, as opposed to an assembly of separate portions. Pet. 50, 52-53. Petitioner relies on this implicit claim construction to argue that a person of ordinary skill in the art predictably would have substituted "a single femoral component" for "the separate femoral components," as taught by Engh '209. *Id.* Petitioner also argues that "Engh '209 recognizes that in 'traditional total knee replacements, the femoral component is generally a *unitary piece* and the tibial component is a unitary piece." *Id.* at 49 (quoting Ex. 1005, 5:14-16, Ex. 1002 ¶ 73) (emphasis added).

We agree that "a single femoral component" refers to a single piece or portion of the femoral component of a total knee implant. However, contrary to Petitioner's argument, nothing in the claim language requires the entire femoral side of a total knee implant to consist of just a single piece or unitary body. *See* Pet. 50, 52-53. Further, Petitioner's implicit construction would be inconsistent with the specification of the '229 Patent, which teaches the benefit of using an assembly of separate portions, or a plurality of femoral components, to form the femoral side of a total knee plant. *See, e.g.,* Ex. 1001 49:2-5 ("In order to enable surgery . . . to be conducted through an incision **114** of relatively small size, the implant may advantageously be formed in two or more portions."); *id.* at 49:44-46 ("In the embodiment of the invention illustrated in FIG. 40, the femoral component **290** of an implant is formed as two separate portions 572 and 574."); *id.* at 99:17-19 ("In order to facilitate insertion of femoral component **1224** through a minimally invasive lateral or medial incision, femoral component **1224** can be made modular."); figs. 40 & 87.

Consistent with the specification of the '229 Patent, the broadest reasonable construction of "a single femoral component of a total knee implant operative to replace the entire articulating surfaces of the medial and lateral condyles and the trochlear groove" is a single piece or portion of the femoral component of a total knee implant that functions to replace the entire articulating surfaces of the medial and lateral condyles and the medial and lateral condyles and the trochlear groove.

#### 6. Other Terms

All other terms recited in claim 23 are given their ordinary and customary meaning, as would be understood by one with ordinary skill in the art, and need not be construed explicitly at this time.

#### B. Alleged Grounds of Unpatentability

As noted above, Petitioner alleges that claim 23 is unpatentable over (1) Lacey '483; (2) the Lacey Guide; (3) Lacey '483 and Lacey Guide; (4) Lacey '483 and the Scorpio Guide; (5) Engh '209; and (6) Engh '209 and the Profix Guide. In light of the arguments and supporting evidence submitted with the petition, Petitioner has established a reasonable likelihood that it would prevail in its challenge of claim 23 as unpatentable for the reasons explained below.

1. Grounds of unpatentability based on the Lacey Guide

Petitioner alleges that the Lacey Guide "was submitted to the PTO prior to 1985[,] and is identified as a reference cited in issued patents 4,567,886; 4,979,957; 4,979,957 [sic]; and 4,474,177." Pet. 3 n. 3. The earliest of these patents, U.S. Patent No. 4,474,177, issued on October 2, 1984. At this stage of the proceeding, we will treat the Lacey Guide as prior art to the '229 Patent under

#### 35 U.S.C. § 102(b).

Petitioner alleges, *inter alia*, that the Lacey Guide "makes obvious" the limitations of claim 23. Pet. 42-43. In support of its position, Petitioner relies on the declaration of its expert, Dr. Mabrey. *See id.* at 40-43; Ex. 1002, ¶¶ 61-64.

Dr. Mabrey testifies that the Lacey Guide "discloses a method of 'performing total knee arthroplasty through a primary incision having a length of less than thirteen (13) centimeters,' as recited in the preamble." Ex. 1002, ¶ 61. Dr. Mabrey further testifies that the Lacey Guide "describes and illustrates the surgical procedure for a 'Lacey condylar total knee surgical procedure," in which "[a]n anterior 5-6 inch [i.e., 12.7 - 15.2 centimeter] midline incision is made with the knee flexed to 90 degrees." Ex. 1002, ¶ 47 (quoting Ex. 1004, p. 2).

The Lacey Guide discloses cutting and shaping the two condyles of the femur (Ex. 1004, p. 8), the distal end portion of the femur (*id.*), and the proximal end portion of the tibia (*id.* at 9), and installing a knee implant having femoral and tibial components (*id.* at 11). For purposes of this decision, based on the evidence discussed in detail below, we are persuaded that the Lacey Guide discloses performing all of the steps of the Lacey condylar total knee surgical procedure through a primary incision having a length of less than 13 centimeters.

Dr. Mabrey also testifies that the Lacey Guide discloses the steps of (a) "making a primary incision of less than thirteen (13) centimeters near the knee joint of a leg of a patient, and carrying out the further steps, through the primary incision," and (b) "cutting medial and lateral condyles, and the trochlear groove of the femur of the leg to create at least one femoral cut surface," as recited in claim 23. Ex. 1002, ¶¶ 61, 62.

Figures (A) and (B), as set forth in paragraph 47 of the Mabry declaration, are reproduced below:



Figures (A) and (B) are figures reproduced from the Lacey Guide. Figure (A) illustrates the anterior midline incision (Ex. 1004, p. 2), and Figure (B) illustrates the cut surfaces of the femur (*id.* at p. 8).

Dr. Mabrey points to Figure (B) as evidence that the Lacey Guide "describes and illustrates that the medial and lateral condyles and the trochlear groove of the femur are cut to accommodate a new implant." *Id.* ¶ 62 (comparing Fig. (B) with Ex. 1001, fig. 22).

Dr. Mabrey testifies that the Lacey Guide also discloses the steps of (c) "moving a single femoral component of a total knee implant operative to replace the entire articulating surfaces of the medial and lateral condyles and the trochlear groove, through the primary incision" and (d) "positioning the femoral component with respect to the at least one femoral cut surface," as recited in claim 23. *Id.* ¶ 63. Dr. Mabrey opines that "[o]ne skilled in the art would understand from the disclosure that the implant is placed on the distal end of the femur through the incision described previously." *Id.* 

A figure from Dr. Mabrey's declaration (in  $\P$  47) is reproduced below:



This figure, which is reproduced from the Lacey Guide (Ex. 1004, p. 11) with annotations by Dr. Mabrey, depicts a single femoral component.

We are persuaded that the femoral component depicted in the figure above, which is reproduced from the Lacey Guide, satisfies the requirement of claim 23 for "a single femoral component of a total knee implant operative to replace the entire articulating surfaces of the medial and lateral condyles and the trochlear groove."

For the foregoing reasons, Petitioner has established a reasonable likelihood that it would prevail in its challenge of claim 23 as unpatentable over the Lacey Guide.

#### 2. Grounds of unpatentability based in part on Lacey '483

Petitioner asserts that Lacey '483 has a filing date of March 9, 1983, and is prior art to the '229 Patent under 35 U.S.C. § 102(b). Pet. 3. Petitioner alleges, *inter alia*, that claim 23 is unpatentable as obvious over: (1) Lacey '483;

(2) Lacey '483 and the Lacey Guide; and (3) Lacey '483 and the Scorpio Guide.Pet. 44-48. Our analysis below focuses on Petitioner's alleged ground of unpatentability based on obviousness over Lacey '483 and the Lacey Guide.

Lacey '483 discloses a method and apparatus for shaping the distal surface of a femur to receive a distal femoral prosthesis. Ex. 1003, 2:21-22. First, "[a]n anterior 5" to 6" (127 mm to 152 mm) midline incision is made with the knee flexed to 90 degrees." *Id.* at 7:54-58. If a total knee replacement is being performed, Lacey '483 discloses cutting and shaping the proximal end portion of the tibia before cutting and shaping the distal end portion of the femur. *Id.* at 7:65– 8:1. Lacey '483 states: "If a proximal tibial prosthesis is to also be implanted *as in total knee implant surgery*, the proximal tibial surface may preferably . . . be shaped to receive that proximal tibial prosthesis in the manner typically employed for such a prosthesis." *Id.* (emphasis added). Lacey '483 further discloses that "[t]he tibial surface should be prepared such that the tibial prosthesis will properly align and cooperate with the distal femoral prosthesis which is attached to the distal femoral surface being shaped in accordance with the method of the present invention." *Id.* at 8:1-6 (emphasis added). After the proximal tibial surface has been shaped, the distal femur is shaped. *Id.* at 8:7-9:62; figs. 13-17.

Figure 17 of Lacey '483 is reproduced below:



Figure 17 depicts the shaped femoral surface.

As illustrated in Figure 17, Lacey '483 discloses "cutting medial and lateral condyles, and the trochlear groove of the femur of the leg to create at least one femoral cut surface," as recited in claim 23. *See* Pet. 30-31 (citing Ex. 1003, 9:56-61; Fig. 17); Ex. 1002, ¶ 56.

We are persuaded that Lacey '483 discloses "performing total knee arthroplasty through a primary incision having a length of less than thirteen (13) centimeters," as recited in the preamble of claim 23. Pet. 37, 39, 44 n. 9 (citing Ex. 1003, 2:20-38; 7:26-34, 56-58; figs. 13-15); *see* Ex. 1002 (Mabrey Decl.), ¶¶ 55, 59. We are also persuaded that Lacey '483 discloses "cutting medial and lateral condyles, and the trochlear groove of the femur of the leg to create at least one femoral cut surface." *See* Pet. 37-38 (citing Ex. 1003, fig. 17 Ex. 1002, ¶ 56).

As discussed above, the Lacey Guide discloses the limitations of "moving a single femoral component of a total knee implant operative to replace the entire articulating surfaces of the medial and lateral condyles and the trochlear groove, through the primary incision" and "positioning the femoral component with respect

to the at least one femoral cut surface," as recited in claim 23. Petitioner contends that the Lacey Guide remedies any deficiencies in Lacey '483 with respect to these limitations. Pet. 44, 47-48.

Petitioner argues that a person of ordinary skill in the art would have been motivated to combine the teachings of Lacey '483 with the known femoral prosthesis taught by the Lacey Guide, because the combination would have been "no more than the predictable application of a known technique—implanting a femoral prosthesis—with known prostheses to yield the predictable outcome of a successful TKA [total knee arthroplasty] performed through a small incision." *Id.* at 46 (citing Ex. 1002, ¶ 68). Petitioner's reasoning is persuasive, and we note that Lacey '483 teaches that "[d]istal femoral prostheses are well known to those skilled in the art," and that:

[i]t is well within the ability of those skilled in the art to construct guide instruments in accordance with the . . . description [set forth in the specification of Lacey '483] which meet the specific design requirements to produce a shaped distal femoral surface for a particular distal femoral prosthesis.

Ex. 1003, 7:26-34. For purposes of this decision, therefore, we are persuaded that Petitioner has provided an articulated reason with a rational underpinning that explains why a person of ordinary skill would have had reason to combine the teachings of Lacey '483 and the Lacey Guide.

For the foregoing reasons, Petitioner has established a reasonable likelihood that it would prevail in its challenge of claim 23 as unpatentable over Lacey '483 and the Lacey Guide.

3. Grounds of unpatentability based in part on Engh '209

Petitioner asserts that Engh '209 has a filing date of June 14, 2001, and is prior art to the '229 Patent under 35 U.S.C. § 102(e). Pet. 3.

During prosecution of the '229 Patent, the Examiner found that the claimed subject matter was first disclosed in the '185 Application (the great grandparent of the application from which the '229 Patent issued), which was filed on August 28, 2001. Ex. 1013 (Office Action mailed May 15, 2008), p. 2. For the purpose of antedating Engh '209, therefore, the inventor submitted an Affidavit of Prior Invention Pursuant To 37 C.F.R. § 1.131, which stated that "[t]he date I conceived of my invention and conveyed same to my registered representative, as evidenced by 'Exhibit B', was prior to June 14, 2001." Ex. 1015, p. 2. Exhibit B to the affidavit is simply a one-page printout of the "Properties" dialog box corresponding to the document that Petitioner filed on August 28, 2001, as the '185 Application. Id. at 1-2; Ex. 1017. The "Properties" dialog box does not constitute sufficient and credible evidence that Petitioner was in possession of the subject matter of the '185 Application prior to its filing date (August 28, 2001), much less prior to June 14, 2001. Ex. 1017. On this record, the affidavit is insufficient to antedate Engh '209, because nothing in the affidavit, including Exhibit B thereto, corroborates the inventor's testimony that he conceived of the invention of the '229 Patent prior to June 14, 2001. See Pet. 27-28; see also Mahukar v. C.R. Bard, Inc., 79 F.3d 1572, 1577 (Fed. Cir. 1996) (An inventor's testimony, standing alone, is insufficient to prove conception, as some form of corroboration is required.).

Petitioner asserts that claim 23 is unpatentable as obvious over Engh '209. Pet. 48-52. Petitioner asserts, alternatively, that claim 23 is unpatentable as obvious over Engh '209 and the Profix Guide. *Id.* at 52-58. Our analysis below focuses on Petitioner's alleged ground of unpatentability based on obviousness over Engh '209.

Engh '209 discloses that, typically, surgeons perform total knee replacement through a primary incision having a length of less than 13 centimeters. Engh '209 states that "[t]he incision **40** must be large enough to expose the entire knee joint articular surfaces with the patella subluxed or dislocated" and that, "[a]dditionally, the incision must accommodate insertion of components that fully cover the end of the femur, the top of the tibia and the undersurface of the patella." Ex. 1005, 8:57-62. More particularly, as to the size of the incision, Engh '209 states that "the conventional midline incision **40** for a total knee replacement surgery . . . [t]ypically . . . is roughly 8 to 15 centimeters in length." *Id.* at 8:53-57, fig. 2.

As such, we are persuaded that Engh '209 discloses: "performing total knee arthroplasty through a primary incision having a length of less than thirteen (13) centimeters" and, further, "making a primary incision of less than thirteen (13) centimeters near the knee joint of a leg of a patient, and carrying out the further steps, through the primary incision," as recited in claim 23 of the '229 Patent. Pet. 48-49.

We are also persuaded, on the present record, that that Engh '209 discloses "cutting medial and lateral condyles, and the trochlear groove of the femur of the leg to create at least one femoral cut surface," as required by claim 23. *Id.* at 49. As Petitioner points out, "Engh '209 recognizes that '[t]ypically, a total knee joint

replacement involves replacing the articular surfaces of the lateral femoral condyle 12, the medial femoral condyle 14, the medial tibial condyle 30 and the lateral tibial condyle 32." *Id.* (citing Ex. 1005, 8:43-46; Ex. 1002, ¶ 71). In addition, Engh '209 discloses sculpting the distal end of the femur to form flat anterior and posterior surfaces, a flat end surface normal to the anterior and posterior surfaces, and angled flat surfaces joining these surfaces (Ex. 1005, 2:2-7), and sculpting the proximal end of the tibia to form a generally upwardly-facing bearing surface that articulates with the condylar surfaces of the femoral prosthesis (*id.* at 2:8-13).

We are persuaded that Engh '209 also discloses "moving a single femoral component of a total knee implant operative to replace the entire articulating surfaces of the medial and lateral condyles and the trochlear groove, through the primary incision" and "positioning the femoral component with respect to the at least one femoral cut surface," as required by claim 23. Pet. 49-50. With respect to the "single femoral component" requirement, Engh '209 discloses that "[i]n traditional total knee replacements, the femoral component is generally a unitary piece and the tibial component is a unitary piece." Ex. 1005, 5:14-16.

For the foregoing reasons, we are persuaded that Engh '209 discloses all of the limitations of claim 23. Accordingly, Petitioner has established a reasonable likelihood that it would prevail in its challenge of claim 23 as unpatentable over Engh '209.

#### C. Remaining Grounds of Unpatentability

Petitioner contends that claim 23 is unpatentable as anticipated under 35 U.S.C. § 102 by (1) Lacey '483 and (2) the Lacey Guide, and that claim 23 is unpatentable as obvious under 35 U.S.C. § 103 over (3) Lacey '483, (4) Lacey '483 and the Scorpio Guide, and (5) Engh '209 and the Profix Guide. Those grounds of unpatentability are redundant to the grounds of unpatentability on which we initiate an *inter partes* review. Accordingly, we do not authorize an *inter partes* review on any of those grounds of unpatentability. *See* 37 C.F.R. § 42.108(a).

#### III. CONCLUSION

For the forgoing reasons, we determine that there is a reasonable likelihood that Petitioner would prevail in its challenge of claim 23 of the '229 Patent as unpatentable. However, we have not made a final determination on the patentability of the challenged claim.

#### IV. ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to claim 23 of the '229 Patent on the following grounds of unpatentability:

- 1. Under 35 U.S.C. § 103(a) as obvious over the Lacey Guide;
- Under 35 U.S.C. § 103(a) as obvious over Lacey '483 and the Lacey Guide; and

3. Under 35 U.S.C. § 103(a) as obvious over Engh '209;

FURTHER ORDERED that that no other grounds of unpatentability are authorized for the *inter partes* review as to claim 23 of the '229 Patent;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(d) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial on the grounds of unpatentability authorized above; the trial commences on the entry date of this decision;

FURTHER ORDERED that an initial conference call with the Board is scheduled for 2:00 PM Eastern Time on March 20, 2014; the parties are directed to the Office Trial Practice Guide (Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48765-66 (Aug. 14, 2012)) for guidance in preparing for the conference call, and should be prepared to discuss any proposed change to the Scheduling Order entered concurrently herewith and any motion the parties intend to file.

For PETITIONERS:

David L. Cavanaugh Jacob S. Oyloe WILMER CUTLER PICKERING HALE and DORR LLP <u>david.cavanaugh@wilmerhale.com</u> jocob.oyloe@wilmerhale.com

For PATENT OWNER:

Cary Kappel William Gehris DAVIDSON, DAVIDSON & KAPPEL, LLC <u>ckappel@ddkpatent.com</u> wgehris@ddkpatent.com