

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SMITH & NEPHEW, INC. and  
ARTHROCARE CORP.,  
Petitioner,

v.

ARTHREX, INC.,  
Patent Owner.

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Case IPR2016-00817  
Patent 6,875,216 B2

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Before WILLIAM V. SAINDON, BARRY L. GROSSMAN, and  
TIMOTHY J. GOODSON, *Administrative Patent Judges*.

GROSSMAN, *Administrative Patent Judge*.

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

## I. INTRODUCTION

Smith & Nephew, Inc. and ArthroCare Corp. (jointly “Petitioner”) request an *inter partes* review of claims 1–7 of U.S. Patent No. 6,875,216 B2 (Ex. 1002, “the ’216 patent”). Paper 2 (“Petition” or “Pet.”). Arthrex, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” “The ‘reasonable likelihood’ standard is a somewhat flexible standard that allows the Board room to exercise judgment.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765 (Aug. 14, 2012).

Upon consideration of the Petition and Patent Owner’s Preliminary Response, we institute an *inter partes* review on claims 1–7 of the ’216 patent.

### *A. Related Matters*

The ’216 patent is related to two other patents for which *inter partes* review has been requested. The ’216 patent is a division of U.S. Patent No. 6,629,977, which is the subject of IPR2016-00819. Also, U.S. Patent No. 7,322,986, which is the subject of IPR2016-00818, is a continuation of the ’216 patent.

The ’977, ’216, and ’986 patents have been asserted by Patent Owner in the U.S. District Court for the Eastern District of Texas in *Arthrex, Inc. v.*

*Smith & Nephew, Inc.*, Civil Action No. 2:2015-cv-01047. Pet. 4; Paper 5, 1–2.

*B. The '216 Patent*

The '216 patent is directed to a tapered, bioabsorbable interference screw for anterior cruciate ligament (ACL) reconstruction. *E.g.*, Ex. 1002, 1:13–16. Figure 1 of the '216 patent is reproduced below:

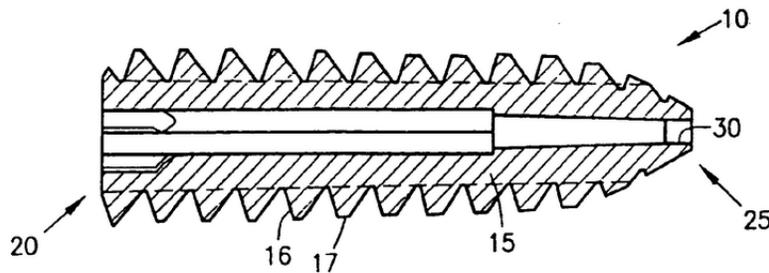


Figure 1 is a cross sectional view of the disclosed screw.

As shown in Figure 1, screw 10 includes main body portion 15, proximal end 20, and distal end 25. *Id.* at 2:60–61. Screw 10 preferably is provided with cannula 30.

Elongated socket 35 (*see* Figure 2) is provided on proximal end 20 of screw 10 and is configured to receive screwdriver 56. Ex. 1002, 2:66–3:1. Socket 35 has radially-extending slots 40 that receive correspondingly-shaped protrusions 42 (*see* Figure 5B) on screwdriver 56 when installing screw 10. *Id.* at 3:2–6. Socket 35 and slots 40 permit increased torque when installing screw 10 while minimizing the problem of stripping the drive portion of the screw 10. *Id.* at 3:6–8.

Figure 3 of the '216 patent is reproduced below:

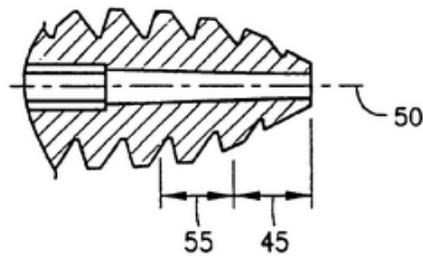


Figure 3 is a cross-sectional view of the distal end of the disclosed screw.

As shown in Figures 1 and 3, screw 10 has a complex taper with an initial portion 45 at an angle of about  $27^\circ$  with respect to the longitudinal axis 50, an intermediate portion 55 at an angle of about  $12^\circ$  angle with respect to axis 50, and an elongated main body 15 with a more gradual taper. *Id.* at 3:11–16. The resulting pointed distal portion 45 forms a nose that provides for easy insertion of the screw 10 into a bone tunnel, such as tibial tunnel 64, shown in Figure 6. *Id.* at 3:16–18. As described in the patent, the tapered body of the screw permits use of a smaller tunnel, as compared with non-tapered bone screws. *Id.* at 3:29–31. In a preferred form of the disclosed screw, screw 10 promotes about a 1.5 mm interference fit with the bone tunnel; *i.e.*, the diameter of the proximal end 20 of main body 15 of screw 10 is 1.5 mm larger than the diameter of the bone tunnel. *Id.* at 3:34–36. Screw 10 is configured to be sufficiently long so as to fill all but the top 5–10 mm of tibial bone tunnel 64. *Id.* at 3:40–41.

Figure 6 of the '216 patent is shown below.

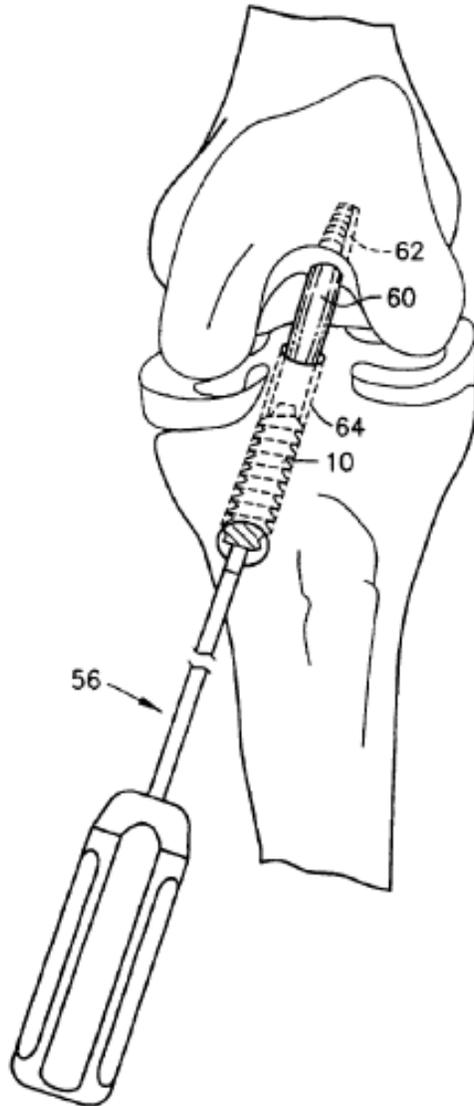


Figure 6 shows screw 10 inserted into tibial tunnel 64.

In use, and as shown in Figure 6, one end of ligament graft 60 is secured in femoral socket 62. The opposite end of the graft extends through tibial tunnel 64 and is retained in the tibial tunnel by driving screw 10 in the tibial tunnel against graft 60 to the level of the anterior cortex in the distal portion of the tibial tunnel, such that screw 10 fills all but the top 5–10 mm. of the tunnel. *Id.* at 4:1–11.

*C. Challenged Claims*

Petitioner challenges all of the claims, which are claims 1–7. Claim 1 is the sole independent claim and is reproduced below.

1. A bioabsorbable interference screw for ACL reconstruction, comprising:
  - an elongated threaded body having a proximal end, a distal end, a length of about 35 mm. and a taper, the threads and the taper of the elongated threaded body extending along substantially the entire length of the elongated threaded body, the proximal end of the screw being configured to provide an interference fit of up to 1.5 mm. in a bone tunnel;
  - a tip disposed of the distal end of the elongated body, the tip being threaded and having a taper which is greater than the taper of the elongated threaded body so as to be easily insertable in a bone tunnel; and
  - a drive socket disposed within the screw and extending from the proximal end of the elongated threaded body, wherein the drive socket has radially-extending slots for receiving a driver having three radially-extending protusions corresponding to the slots.

*D. Prior Art and Asserted Grounds*

Petitioner asserts that claims 1–7 of the '216 patent are unpatentable under 35 U.S.C. § 103(a)<sup>1</sup> based on the following five grounds:

<b>References</b>	<b>Claims Challenged</b>
Endo-Fix <sup>2</sup>	1–7
Endo-Fix and Weiler <sup>3</sup>	1–7
Simon <sup>4</sup>	1–7
Simon and Weiler	1–7
EP '459 <sup>5</sup>	1–7

Petitioner also relies on a declaration of Bruce Beynon, Ph.D (Ex. 1008).

II. ANALYSIS

*A. Claim Construction*

We interpret the claims of an unexpired patent using the broadest reasonable interpretation in light of the specification of the patent. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46

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<sup>1</sup> The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 296–07 (2011), took effect on September 16, 2012. Because the application for the patent at issue in this proceeding has an effective filing date before that date, we refer to the pre-AIA versions of the statute.

<sup>2</sup> Acufex Sales Brochure, “An Absorbable Interference Screw ... the difference is Acufex” (copyright claimed as 1995) (“Endo-Fix”) (Ex. 1011).

<sup>3</sup> Andreas Weiler et al., “Biodegradable Interference Screw Fixation Exhibits Pull-Out Force and Stiffness Similar to Titanium Screws,” 26(1) Am. J. Sports Med. 119 (copyright claimed as 1998) (“Weiler”) (Ex. 1015).

<sup>4</sup> U.S. Patent No. 5,891,146, issued April 6, 1999 (Ex. 1012).

<sup>5</sup> European Pat. App. EP1,101,459, published May, 23, 2001 (“EP '459 Application”) (Ex. 1014).

(2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Although our claim interpretation cannot be divorced from the specification, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (citing *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language; *see SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner (Pet. 9–16) and Patent Owner (Prelim. Resp. 19–27) propose constructions for a number of claim terms. We determine that only one phrase requires specific construction for purposes of this Decision, as discussed below. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

*1. “a tip disposed of the distal end of the elongated body.”*

Independent claim 1 recites a screw having “an elongated threaded body” and “a tip disposed of the distal end of the elongated body.” Ex. 1002, 4:20–30. Petitioner asserts the claims require “a tip distinct from the body.” Pet. 10. According to Petitioner, the broadest reasonable

construction of the terms “tip” and “body” in the disputed phrase “a tip disposed of the distal end of the elongated body” is:

the [ ] “tip” is the portion of the screw that starts at the screw’s distal end, increases in diameter proximally, and terminates where the taper of the screw changes to a lesser taper. The [ ] “body” is the portion of the screw extending from the screw’s proximal end and terminating before the tip.

*Id.* at 11 (citations to Ex. 1008 ¶ 58 omitted). Dr. Beynon testifies that a person of ordinary skill in the relevant technology would have understood that the “body” and “tip” are “distinct” parts of the claimed screw. Ex. 1008, ¶ 54–58.

Patent Owner takes a different view of the meaning of the disputed phrase. According to Patent Owner, the broadest reasonable interpretation of the disputed phrase is that “the ‘body’ *includes* the ‘tip’.” Prelim. Resp. 21. For purposes of this Decision, we agree with Patent Owner.

We look to the claim language itself and the Specification for guidance in interpreting the disputed phrase. The antecedent basis for the term “the elongated body” in the disputed phrase “a tip disposed of the distal end of the elongated body” is in the immediately preceding clause of claim 1, which recites “an elongated threaded body having a proximal end, a distal end, a length of about 35 mm. and a taper.” Thus, we first determine the construction of the claimed “elongated threaded body.”

In the Summary of the Invention, the Specification refers to an “elongated threaded screw” (Ex. 1002, 2:53) and an “elongated bioabsorbable interference screw” (*id.* 2:51). This suggests that reference to an “elongated threaded body” in the claims is a reference to the entire screw and not just a portion of the screw as proposed by Petitioner. We note that

the preamble refers to a “bioabsorbable interference” screw. Thus, the words “elongated” and “threaded,” modifying the word “body,” in the claim add specific limitations to the “body” that are consistent with the description of the entire screw in the Summary of the Invention. This also suggests that the recited “elongated threaded body” represents the claimed screw from end to end.

The Specification also states that “[s]crew 10 is provided in a preferred length of 35 mm, with threads 16 extending substantially from proximal end 20 to distal end 25.” *Id.* at 2:62–64. This description of “screw 10” is consistent with the claimed structure of the “elongated threaded body” in claim 1, which recites “a length of about 35 mm. This also suggests that the recited “elongated threaded body” represents the claimed screw from end to end.

The Specification refers to screw 10 having “a main body portion 15, a proximal end 20 and a distal end 25.” Ex. 1002, 2:60–61. As shown in Figure 1, the arrows indicating the proximal and distal ends point generally to end regions of screw 10, not end regions of main body portion 15. This suggests that proximal end 20 and distal end 25 are ends of screw 10, not ends of main body 15.

The Specification refers to three distinct portions of screw 10: (1) an “initial portion 45; (2) an “intermediate portion 55;” and (3) an “elongated main body 15.” *Id.* 3:11–16. As shown in Figures 1 and 3, and as described in the Specification of the ’216 patent, screw 10 has a complex taper with an initial portion 45 at an angle of about 27° with respect to the longitudinal axis 50, an intermediate portion 55 at an angle of about 12° angle with respect to axis 50, and an elongated main body 15 with a more gradual taper.

*Id.* The disputed claim phrase does *not* use the word “main” in identifying the claimed “body.” This suggests the disclosed “elongated main body 15” is *not* co-extensive with the claimed “elongated threaded body” forming screw 10.

Turning specifically to the disputed phrase and the word “tip,” the only reference to the “tip” of the screw in the Specification is in the Summary of the Invention, which states “[p]referably, the distal end of the screw, the end closest to the joint, has a smooth, rounded tip profile so as to minimize abrasion with the graft.” *Id.* 2:8–10. This suggests the tip is part of the claimed elongated body, not a distinct element.

Claim 1 also recites “a tip . . . having a taper which is greater than the taper of the elongated threaded body.” The elongated threaded body, does not have a single taper. As disclosed, it has a “complex taper,” with the tip tapered more than the remainder of the body. We do not interpret this as requiring the tip to be a distinct element. The elongated body is, as disclosed, a single element with a complex taper, having a tip on its distal end.

“Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.”

*Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (citations omitted).

For purposes of this Decision, we determine that the broadest reasonable interpretation of the claim, and the construction that most

naturally aligns with the '216 patent's description of the claimed screw, in light of the Specification and other evidence before us, is that the tip and body are *not* distinct elements. The tip is merely a more tapered portion of the tapered body.

Our claim construction determination is a preliminary determination. It does not preclude the parties from arguing their proposed constructions of the claims during trial. Indeed, the claim construction issues discussed in the Petition, Preliminary Response, and this Decision put the parties on notice that claim construction, in general, is an issue to be addressed at trial.

### *B. Priority Claim*

The '216 patent claims priority to a provisional patent application filed November 15, 1999. Petitioner asserts “[t]he provisional and [intervening] '977 patent each discloses only a 35 mm long screw, not a 35 mm long ‘body’ as claimed in the '216 patent.” Pet. 8. Our claim construction discussed above construed the claimed 35 mm elongated body as co-extensive with the disclosed 35 mm screw. Based on our construction, we disagree with Petitioner's argument that the '216 claims are not entitled to the priority date of the provisional application for the reason asserted by Petitioner. Thus, for purposes of this Decision, the priority date of the '216 patent is November 15, 1999.

### *C. Obviousness of Claims 1–7 Based On Endo-Fix*

Petitioner argues that claims 1–7 would have been obvious in view of Endo-Fix. Pet. 16–37.

Section 103(a) precludes issuance of a patent when “the differences between the subject matter sought to be patented and the prior art are such

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a). In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Court set out a framework for applying the statutory language of § 103:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

*Id.*, at 17–18. Secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others also are considered. *Id.* at 18. “While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls.” *KSR Int’l. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007).

The Supreme Court has made clear that we apply “an expansive and flexible approach” to the question of obviousness. *Id.* at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.* at 417. To reach this conclusion, however, requires more than a mere showing that the prior art includes references covering each separate limitation in a claim under examination. *Id.* at 418 (“a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art”). “Rather, obviousness requires the additional showing that a person of ordinary skill at

the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011).

Against this general background, we consider the references, other evidence, and arguments on which the parties rely.

*1. Scope and Content of the Prior Art*

*a. Endo-Fix (Ex. 1011)*

According to Petitioner, Endo-Fix is a sales brochure that Acufex (a division of Smith & Nephew) distributed before 1998. Pet. 16. Petitioner relies on the testimony of Paul O’Connor to establish that Endo-Fix is prior art under 35 U.S.C. § 102(b) to the ’216 patent. *Id.*

Mr. O’Conner is currently employed at Smith & Nephew and has been employed at Smith & Nephew, Inc. since April 1997. Ex. 1010 ¶ 1. In the 1997–1999 timeframe, as part of his regular duties, Mr. O’Conner testifies that he “became familiar with product brochures that were available and distributed to the public regarding certain products from Acufex and Smith & Nephew. *Id.* Mr. O’Conner testifies that “[t]he Endo-Fix Brochure was widely distributed to medical professionals (i.e., surgeons, clinicians, researchers, administrators, associated staff, and others) before November 1998.” *Id.* at ¶ 5. Mr. O’Conner also testifies that the brochure was distributed “without any obligation or expectation of confidentiality.” *Id.* at ¶ 6.

Patent Owner asserts “[t]he alleged prior art status of Endo-Fix is not so simple that it can be resolved with a mere conclusory statement.” Prelim.

Resp. 29. We agree with Patent Owner that it is Petitioner's burden to establish that Endo-Fix is a printed publication. *Id.* at 30. We disagree with Patent Owner, however, that, on the record before us, Mr. O'Conner's testimony is not substantiated with any specific statement of fact, or that it is "conclusory" or "mere conjecture." *Id.* at 30.

Mr. O'Conner testifies: "I am familiar with the Endo-Fix Brochure. I became familiar with the Endo-Fix Brochure before November 1998. Exhibit 1011 is [a] true, correct, accurate, and complete copy of the Endo-Fix Brochure." Ex. 1010 ¶ 3. These are specific statements of fact. Mr. O'Conner also testifies that the Endo-Fix Brochure "was widely distributed" prior to November 1998. *Id.* at ¶ 5. This is a specific statement of fact that is neither conclusory nor conjecture.

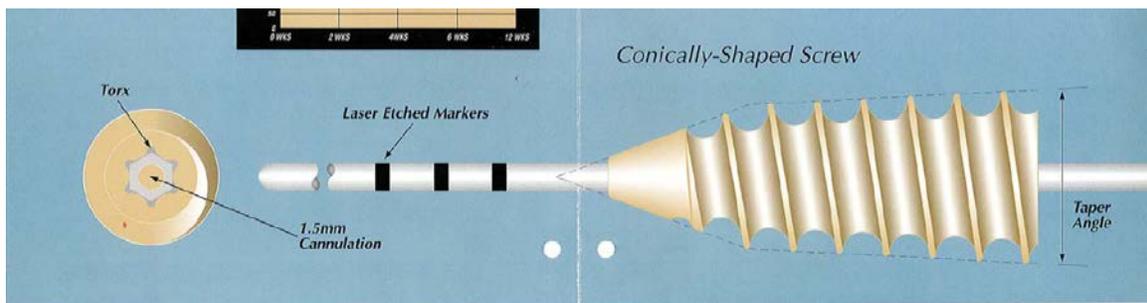
Patent Owner cites *Toshiba Corp. v. Optical Devices, LLC*, Case IPR2014-01445, Paper 31 at pages 27–28 (Mar. 9, 2016) for support of its position. *Toshiba* determined that the proffered testimony was mere conjecture. As discussed above, we make no such determination on the record before us.

Moreover, *Toshiba* was a final written decision, following a completed trial, not an initial decision instituting the start of a trial. Our review of the Petition under 35 U.S.C. § 314 is not to determine whether an asserted fact is indisputable. Our review is to determine whether the totality of the information presented in the Petition and Preliminary Response "shows that there is a reasonable likelihood that the petitioner would prevail" in establishing that a challenged claim is unpatentable. If Patent Owner questions the factual basis of Mr. O'Conner's testimony, Patent

Owner has an opportunity to cross-examine Mr. O’Conner during the trial in accordance with the applicable rules governing an *inter partes* review.

Based on the record before us, for purposes of this Decision, we determine that Endo-Fix is available as a reference. Thus, we proceed to the merits of Petitioner’s assertion that the challenged claims would have been obvious in view of Endo-Fix.

Endo-Fix is a three page document, including its cover, that illustrates and describes an absorbable, conically-shaped, interference screw. Ex. 1011, p. 2. An illustration of the screw from Endo-Fix is shown below.



An illustration from Endo-Fix of a conically-shaped screw with a slotted drive socket.

As shown in the Endo-Fix illustration, Endo-Fix discloses a screw having a complex taper, where the angle at the tip is greater than the angle of the main body. *Id.* The disclosed screw was available in either a 7 mm or 9 mm diameter, with each diameter available in lengths of either 20, 25, or 30 mm. *Id.* at 3. The diameter is measured at the proximal or socket end of the screw. Ex. 1008 ¶ 158 (“Endo-Fix discloses a screw with a 9 mm diameter, which a POSA would have understood to disclose a screw with a 9 mm diameter at the drive socket.”).

## 2. Level of Skill

The level of skill in the art is “a prism or lens” through which we view

the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (“the level of skill in the art is a prism or lens through which a judge, jury, or the Board views the prior art and the claimed invention”).

Petitioner proposes that a person of ordinary skill would have had (a) an advanced degree in mechanical engineering or the equivalent, (b) a bachelor’s degree in such a field along with two or more years of experience designing interference screws, or (c) a medical degree and two or more years of experience performing surgeries that involve interference screws and/or advising engineers on interference screw design. Pet. 9 (citing Ex. 1008 ¶ 17).

Patent Owner does not state a proposed level of skill.

For purposes of this Decision, we determine that it is not necessary to establish a specific level of skill. The prior art itself reflects an appropriate level of skill. *Okajima*, 261 F.3d at 1355.

### *3. Differences Between the Prior Art and Claim 1*

Petitioner asserts two arguments based on whether the claims are interpreted with the tip as a distinct element from the body (Pet. 17) or whether the body includes the tip (*id.* at 28). Based on our claim construction that the body includes the tip, we consider this asserted alternative.

#### *a. Body Length of About 35 mm*

According to Petitioner, Endo-Fix “meets every limitation of claim 1 except the requirement that the ‘body’ have a ‘length of about 35 mm.’” Pet. 17 (citing Ex. 1008 ¶ 125). Petitioner asserts several reasons why “it

would have been obvious to modify the Endo-Fix screw so that it had a length of about 35 mm” instead of the 20–30 mm length disclosed in Endo-Fix. *Id.* at 29. Petitioner asserts: “merely modifying a device’s size is not ‘invention’,” particularly because the ’216 patent does not describe any criticality or unexpected result associated with a screw having a particular length of about 35 mm.” *Id.* Petitioner also asserts numerous background references that disclose interference screws of about 35 mm. *Id.* (citing numerous prior art references). These background references establish the general information that would have been known to a person of ordinary skill. Additionally, Petitioner asserts “screw length was a result-effective variable,” that “would have been a matter of ordinary experimentation” for a person of ordinary skill to arrive at the claimed length. *Id.* at 30 (citing Ex. 1008 ¶¶ 149–52).

Patent Owner asserts “[t]he ’216 Patent establishes that the claimed length is *critical*” (Prelim. Resp. 41), but fails to cite persuasive evidence to support this statement. We note that in the proceedings leading to the issuance of the ’216 patent, the Examiner did *not* mention the 35 mm length as a reason for allowing the application to issue. *See* Ex. 1006, p. 61. Indeed, the Examiner stated “it would have been an obvious matter of design choice to size the screw length to adequately fix the ligament within the tunnel.” *Id.* at 41.

Based on the record before us, we are persuaded for purposes of institution that it would have been obvious to a person of ordinary skill to size the Endo-Fix screw to a length of about 35 mm.

*b. An Interference Fit of Up To 1.5 mm*

Endo-Fit does not expressly disclose an interference fit of 1.5 mm. Endo-Fit does disclose, however, a tapered screw diameter of 7 or 9 mm. Ex. 1011, 3. The '216 patent discloses tapered screws with a tip or distal diameter ranging from 7.5–9.5 mm. and a socket or proximal diameter of diameter ranging from 9–12 mm. Ex. 1002, 3:19–26. Petitioner asserts that because Endo-Fix discloses a tapered screw with a proximal diameter of 9 mm, one of the '216 patents preferred sizes, a person of ordinary skill “would have understood the Endo-Fix proximal diameters to be ‘configured’ to exceed (by 1.5 mm or less) the diameters of bone tunnels of numerous sizes.” Pet. 24 (citing Ex. 1008 ¶ 158).

Dr. Beynnon testifies that a person of ordinary skill “would have understood that the Endo-Fix screw’s proximal end to be configured to provide ‘an interference fit of up to 1.5 mm in a bone tunnel’ in the same manner as a preferred embodiment in the '216 patent.” Ex. 1008 ¶ 158. Dr. Beynnon reasons that, because Endo-Fix discloses a tapered screw that is “inserted with a torque that increases gradually,” a person of ordinary skill:

would have understood that the taper allows the screw to be inserted into a tunnel with a diameter than is larger than the diameter of the tip of the screw (where insertion torque would be relative low) but smaller than the diameter of proximal end of the screw (where the screw would increase the diameter of the tunnel and insertion torque would be at a peak).

*Id.* at ¶ 159. This “understanding,” however, does not explain or provide facts or data to support why a person of ordinary skill would have selected a specific interference fit of “up to 1.5 mm,” as recited in the claims. Dr. Beynnon supports his opinion by relying on the '216 patent specification,

which acknowledges that “[b]ioabsorbable interference screws are usually sized so that they are slightly larger than the diameter of the tunnel.” *Id.* (citing Ex. 1002 at 1:33-35). Dr. Beynnon does not explain why this statement from the patent suggests an interference fit of up to 1.5 mm.

Thus, it is Petitioner’s position that because both the claimed screw and the screw in Endo-Fix both have a proximal diameter of 9 mm, both screws must be configured to have an interference fit of up to 1.5 mm when inserted into the same bone tunnel, as recited in the challenged claims.

Screw diameter, alone, does not establish whether a fit is or is not an interference fit, and, if it is, the amount or degree of interference. It is the combination of the screw diameter *and* the bone tunnel diameter that establishes whether there is an interference fit of “up to 1.5 mm.” As explained in the Specification, as screw 10 advances through a bone tunnel, the screw dilates bone outwardly around the bone tunnel and creates an interference fit between screw 10 and bone tunnel 64. Ex. 1002, 3:27–29. According to the Specification, the tapered body of the screw permits use of a smaller tunnel, compared to non-tapered bone screws. *Id.* at 3:29–31. In the disclosed preferred embodiment, interference screw 10 “promotes about a 1.5 mm interference fit; i.e., the diameter of the proximal end 20 of the screw 15 [sic, 10] is 1.5 mm larger than the diameter of the bone tunnel.” *Id.* at 3:33–36. Using a screw with proximal diameter of 9 mm, as recited for example in claim 4, a 1.5 mm interference fit requires a bone tunnel having a diameter of 7.5 mm. Thus, the amount of interference fit is determined by the diameter of the proximal end of screw 10 *and* the diameter of the bone tunnel.

Claim 1 is directed to a screw, not a method or using or inserting a screw and not to a screw in combination with a bone tunnel.<sup>6</sup> Endo-Fix discloses a substantially similar screw, which if used in the same environment as the claimed screw would result in the same interference fit of up to 1.5 mm.

Thus, on the record before us, we are persuaded for purposes of institution that Endo-Fix discloses a screw diameter within the range of screw diameters that the '216 patent states is “configured to provide an interference fit of up to 1.5 mm. in a bone tunnel.”

*c. Soft Tissue Fixation*

Patent Owner asserts Endo-Fix “is used for bone block fixation” while the screw disclosed and claimed in the '216 patent “is for soft tissue fixation.” Prelim. Resp. 34. Patent Owner also asserts Endo-Fix “does not—and would not—include many claimed features relating to soft tissue fixation.” *Id.* Patent Owner fails, however, to identify any “claimed features” or structure recited in claim 1, or any disclosure in the Specification of the '216 patent, that limits claim 1 to soft tissue fixation and which are not disclosed in Endo-Fix. We note that the phrases “soft tissue” or “soft tissue fixation” do not appear in the '216 patent. Patent Owner also fails to identify persuasive evidence that the Endo-Fix screw is limited to “bone block” fixation.

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<sup>6</sup> Related patent 6,629,977, which is the subject of IPR2016-00818, claims a method of interference fixation for ACL reconstruction using a bioabsorbable interference screw. Related patent 6,629,977, which is the subject of IPR2016-00819, also claims a method of interference fixation for ACL reconstruction using a bioabsorbable interference screw.

Moreover, the '216 patent suggests that bioabsorbable screws, such as recited in the challenged claims, and as disclosed in Endo-Fix, are used *without* a bone block. The '216 patent states:

A strong graft attachment is obtained by using a metal interference screw to wedge a graft bone block to the wall of a graft tunnel formed through the bone, as disclosed in U.S. Pat. No. 5,211,647 to Schmieding [*see* Ex. 1057]. *If a bioabsorbable interference screw is used, the graft is often wedged directly against the bone by the screw, without a bone block.*

Ex. 1002, 1:25–31 (emphasis added). Thus, on the record before us, Patent Owner's argument that the claims are limited to soft tissue fixation, and that the screw in Endo-Fix is not so limited, is not supported by any persuasive evidence.

*d. Threaded Along "Substantially the Entire Length"*

Patent Owner also asserts that the Endo-Fix screw is not threaded along "substantially the entire length," as required by claim 1. Prelim. Resp. 35–36. Petitioner asserts the threads extend along the main body and "onto" the tip of the Endo-Fix screw, which, according to Petitioner, is substantially the entire length of the Endo-Fix screw. Pet. 31 (citing Ex. 1008 ¶ 156). Patent Owner responds that "Petitioners' position allows for a tip that is largely unthreaded, which does not comport with the claim language." Prelim. Resp. 36.

The Specification states that threads 16 extend substantially from proximal end 20 to distal end 25. Ex. 1002, 2:63–64. The only reference to the "tip" of the screw in the Specification is in the Summary of the Invention, which states "[p]referably, the distal end of the screw, the end closest to the joint, *has a smooth, rounded tip profile so as to minimize*

*abrasion with the graft.*” *Id.* 2:8–10 (emphasis added). Thus, based on the Specification, it is reasonable that the disclosed and claimed invention may have a “smooth, rounded tip profile,” as disclosed in Endo-Fix, and still meet the claim limitation of threads “extending along substantially the entire length of the elongated threaded body.” Thus, for purposes of this Decision, we are persuaded that the threads on the Endo-Fix screw extend substantially the entire length of the screw.

*e. Conclusion As To Claim 1*

Accordingly, based on the record before us and the analysis above, we are persuaded that there is a reasonable likelihood that Petitioner will prevail in establishing that claim 1 would have been obvious based on Endo-Fix.

*4. Claims 2–7*

Claims 2–7 each depend from claim 1.

Claim 2 recites “the drive socket has a taper corresponding to the taper of the elongated threaded body.” Patent Owner states, correctly, that “Endo-Fix is completely silent as to whether its drive socket is tapered.” Prelim. Resp. 45. Indeed, Petitioner recognizes that “Endo-Fix does not disclose its drive socket as tapered.” Pet. 32. Petitioner asserts, however, that “it was well known to provide a tapered screw with a drive socket having a corresponding taper to maintain the thickness and strength of the screw wall in the drive socket area.” *Id.* (citing Ex. 1008 ¶ 175). Dr. Beynnon testifies that a person of ordinary skill “would have known about the well-known teachings of tapered drive sockets and would have had reason to use a tapered drive socket. Ex. 1008 ¶ 175.

In the Petition, Petitioner cites and discusses three references to support Petitioner's position that it was well-known to provide a tapered bioabsorbable screw with a correspondingly tapered drive socket to maintain a constant wall thickness for the screw. Pet. 32–33. Petitioner cites and discusses Stellin (Ex. 1040), Hannay (Ex. 1016), and Rieser (Ex. 1041) as evidence of its position. Although cited as background information to establish what was known to a person of ordinary skill at the relevant time, Petitioner relies on, and argues, each of these asserted references as a critical component of why, in Petitioner's view, the challenged claim is not patentable. Accordingly, we consider these three references as references Petitioner reasonably could have raised as part of the asserted grounds of unpatentability in this *inter partes* review.

Stellin discloses screws having a recess or socket in the head to receive a screw driver, “known as the internal wrenching type.” Ex. 1040, 1:1–4. We have not been directed to any evidence that the screw in Stellin is a bioabsorbable interference screw intended to be used for ACL reconstruction. Nonetheless, it is still relevant. *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (“When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.”) Stellin discloses that hexagon sockets are seldom used in certain screws “due to the fact that the thickness of metal around the socket becomes thinner and weaker as the head tapers inwardly of the screw axis.” *Id.* at 1:17–22. Stellin solves this problem by providing a socket that also is tapered inwardly, “so that the metal thickness around the socket remains socket constant and the liability of breakage is practically eliminated.” *Id.* 1:22–26.

Hannay discloses “wrenching means” for threaded fasteners. Ex. 1016, 1:10–14. We have not been directed to any evidence that the screw in Hannay is a bioabsorbable interference screw intended to be used for ACL reconstruction. Hannay discloses a tapered socket corresponding to the tapered walls of the screw head “assuring a full thickness of material beneath all sections of the recess.” *Id.* at 2:30–35.

Rieser discloses a screw used for bicortical tibial fixation of anterior cruciate ligament grafts. Ex. 1041, 1:10–15. Rieser discloses using interference screw fixation, with the interference screws having a hex socket for receiving a hex-head screwdriver. *Id.* at 2:25–28. The hex socket extends substantially the length of the screw to optimize the distribution of insertion torque along the length of the screws. *Id.* at 2:28–30. In order to maintain wall thickness, “the hex socket is tapered in correspondence with the tapered outer profile of the device.” *Id.* at 2:30–32.

Based on the disclosures in Stellin, Hannay, and Rieser, we are persuaded, for purposes of this Decision, that a person of ordinary skill would have recognized the benefits of a drive socket having a taper corresponding to the taper of the elongated screw body. Accordingly, there is a reasonable likelihood that Petitioner will prevail in establishing that claim 2 would have been obvious based on Endo-Fix.

Claim 3 recites the screw is fully cannulated for receiving a guide pin. The Endo-Fix screw is “cannulated” with a “1.5 mm cannulation.” Ex. 1011, p. 2. Endo-Fix discloses that “cannulation” permits “the use of a rigid guide wire,” which helps the surgeon achieve parallel screw placement and “may minimize wire capture or breakage during screw insertion.” *Id.* at p. 3. Patent Owner does not address the merits of the proposed ground

against claim 3. For the reasons asserted by Petitioner (Pet. 34), there is a reasonable likelihood that Petitioner will prevail in establishing that claim 3 would have been obvious based on Endo-Fix.

Claims 4–7 recite specific dimensions establishing the amount of “taper” of the claimed screw. Claims 4–6 recite specific dimensions that establish a 1.5 mm taper. Claim 4, for example, recites that the screw tapers from a diameter of 9 mm at the drive socket to a diameter of 7.5 mm at the tip. Claim 6 recites that the screw tapers from a diameter of 11 mm at the drive socket to a diameter of 9.5 mm at the tip. Claim 7, however, recites a 2.5 mm taper, wherein the screw tapers from a diameter of 12 mm at the drive socket to a diameter of 9.5 mm at the tip.

Endo-Fix discloses screw diameters of 7 mm and 9 mm (Ex. 1011, p. 3) and a complex taper for the screw (*id.* at p. 2), but does not provide specific dimensions concerning the amount of taper.

According to Petitioner, the ’216 patent does not describe any “criticality or unexpected result” of any of the specific dimensions recited in the claims. Pet. 34 (citing Ex. 1008 ¶ 192). Petitioner asserts that describing and claiming four different sizes “reinforces that none provides a critical benefit or unexpected result.” *Id.* Dr. Beynon concludes that a person of ordinary skill in the relevant technology “would have known that interference screws could be, and in fact were, provided in a range of diameters and tapers encompassing the claimed diameters and tapers, and a POSA would have had reason to use those diameters and tapers with the Endo-Fix screws.” Ex. 1008 ¶ 193 (citing background references Exs. 1026,

1028, 1029, and 1030)<sup>7</sup>. Based on this information, Dr. Beynnon concludes that claims 4–7 would have been obvious in view of Endo-Fix. *Id.* at ¶ 192. Neither Dr. Beynnon nor Petitioner direct us to any evidence that the background references on which Dr. Beynnon relies are tapered screws, as recited in the claims.

Patent Owner asserts that the dimensions are “critical” to the claimed invention. Prelim. Resp. 47. As evidence of the asserted criticality, Patent Owner argues that “[t]he claimed interference fit provides 28% more pull out strength relative to the prior art.” *Id.* (citing Ex. 1002, 3:39-40). The context of the cited disclosure, however, establishes that it is the *taper* that is critical to the alleged increased pull out strength, *not* the *specific dimensions* or amount of taper, or the fact that there is an “interference fit”.

The ’216 patent discloses that as tapered screw 10 advances through a bone tunnel, the screw dilates bone outwardly around the bone tunnel and creates an interference fit with the bone. Ex. 1002, 3:27–29. The Specification makes clear, however, that typical bone screws, which are not tapered, also provide an interference fit. *Id.* 3:36–38 (“Typical bone screws, which are not tapered, provide a maximum of 1.0 mm interference fit.”). Thus, it is not the interference fit itself that provides the increased pull out strength. The Specification merely points out that a 1.5 mm interference fit is stronger than a 1.0 mm interference fit. The feature that enhances pull out strength, according to the Specification, is that the: “tapered body of the

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<sup>7</sup> Although cited as background information to establish what was known to a person of ordinary skill at the relevant time, we consider these references as references Petitioner reasonably could have raised as part of this *inter partes* review.

screw permits the use of a smaller tunnel, as compared with non-tapered bone screws. The taper also causes a wedge effect that allows a large-diameter screw to be used in relation to the bone tunnel and graft size.”

*Id.* at 3:29–33.

Endo-Fix clearly discloses a tapered screw and thus will realize the all the benefits attributed to tapered screws. Endo-Fix discloses screw diameters of 7 and 9 mm. The background prior art of record establishes that non-tapered screws having outer diameters between 5–13 mm are well-known and that specific selections are based on the needs of individual patients. *E.g.*, Ex. 1026, 3:56–58, 4:9–11. As the Supreme Court reminds us, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR*, 550 U.S. at 421. On the record before us, it would have been obvious to such a person based on Endo-Fix to choose the proper diameter screw from the known prior art range for the needs of the particular patient.

Accordingly, for purposes of this Decision, we are persuaded that there is a reasonable likelihood that Petitioner will prevail in establishing that claims 4–7 would have been obvious based on Endo-Fix.

*D. Obviousness of Claims 1–7 Based On Endo-Fix and Weiler (Ex. 1015)*

Petitioner asserts that claims 1–7 would have been obvious based on Endo-Fix and Weiler. Pet. 37–40. Petitioner relies on Weiler for the disclosure of a “trilobe” drive socket. Weiler is cited to address the claims *if* claim 1 is construed to be limited to a drive socket with only three slots for receiving only three protrusions. Pet. 37. According to Petitioner, “Weiler would have given a [person of ordinary skill in the art] reason to modify the

Endo-Fix drive socket with Weiler’s ‘trilobe’ configuration.” *Id.* at 37–38 (citing Ex. 1008 ¶ 208). Petitioner concludes claims 1–7 would have been obvious over Endo-Fix in view of Weiler. *Id.* at 38–39. Dr. Beynnon’s testimony supports Petitioner’s position. Ex. 1008 ¶¶ 207–208.

Weiler is an article that was published in The American Journal of Sports Medicine. Weiler presents the results of a research study of the properties of various bioabsorbable interference screws. Ex. 1015, p. 119. The study compared biomechanical data for six different biodegradable interference screws, consisting of five different polymers, with a conventional titanium screw in a standardized model. *Id.*, Abstract. Seventy proximal calf tibias were used to determine maximal pull-out force, stiffness of fixation, and insertion torque for interference screw fixation of bone-tendon-bone grafts. *Id.* Additionally, maximal torque at failure was determined. *Id.* Data were analyzed with respect to aspects of screw design, such as drive and thread shape. *Id.* In sum, it was a sophisticated analysis of the best drive design to install a biodegradable interference screw. *Id.* at 126 (“We have shown that torque at failure is highly determined by the drive design.”). It also reflects the detailed information available to a person of ordinary skill in the relevant technology.

Dr. Beynnon testifies that among the screws tested in Weiler were screws with a “trilobe” drive socket, which has three slots for receiving a driver with three protrusions. Ex. 1008, ¶ 208. According to Dr. Beynnon’s testimony, “Weiler explains that the trilobe socket outperformed the screws with a Torx drive socket with regard to the amount of torque required to break the screw when it is fully seated in a tunnel (i.e., ‘maximal torque at

failure’). *Id.* (citing Ex. 1015 at 121, 124). Endo-Fix discloses a Torx drive socket. Ex. 1011, p. 2.

Petitioner asserts a person of ordinary skill “would have been motivated by Weiler to modify the Endo-Fix screw to use the trilobe socket to increase the torque that could be applied to the screw during insertion and address Weiler’s concern that the Endo-Fix design may result in “drive failure during screw insertion.” Pet. 39 (citing Ex. 1015 at 126; Ex. 1008 at ¶ 215).

Patent Owner asserts that “Weiler does not cure the deficiencies in Endo-Fix.” Prelim. Resp. 49. Based on the evidence before us and our analyses above, we disagree.

Patent Owner also asserts that the asserted Ground 2 is “vertically redundant” of Ground 1 “and should be dismissed.” *Id.* Under our rules, we have the discretionary authority to institute an *inter partes* review on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim. 37 C.F.R. § 42.108(a). We also have the discretionary authority at any time prior to institution of *inter partes* review, to deny some or all grounds for unpatentability for some or all of the challenged claims. *Id.*, § 42.108(b). *See Shaw Indus. Grp., Inc. v. Automated Creel Sys., Inc.*, 817 F.3d 1293, 1298 (Fed. Cir. 2016) (“We can see benefit in the PTO having the ability to institute IPR on only some of the claims and on only some of the proposed grounds, particularly given the Board’s statutory obligation to complete proceedings in a timely and efficient manner.”). In this proceeding, Ground 2, based on Endo-Fix and Weiler, relies on different references to establish different facts than Ground 1, based on Endo-Fix alone. Ground 2 also relies on a different rationale for

the proposed modification of the Torx drive in Endo-fix. Having discretion not to institute a trial in the circumstances of this proceeding also means the Board has discretion to institute trial. We determine not to exclude Ground 2 from consideration.

Patent Owner also asserts that “Endo-Fix *teaches away* from the suggested modification.” Prelim. Resp. 50. As pointed out by Patent Owner, Endo-Fix discloses that the Torx head “affords a more efficient transmission of torque than the more conventional hex head designs.” *Id.* (quoting Ex. 1011, p. 2).

*In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) states that the general rule to determine whether a reference “teaches away” is when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant. *Id.*

The fact that Endo-Fix discloses that a Torx head “affords a more efficient transmission of torque *than the more conventional hex head designs*” (Ex. 1011, p. 2) does not teach away from substituting the “trilobe” drive socket, disclosed in Weiler, for the Torx drive socket disclosed in Endo-Fix. There is no evidence that a trilobe design is a “conventional hex head” design. In light of the disclosure that screws with a trilobe socket outperformed screws with a Torx drive and screws with a hexagonal drive in maximal torque at failure (Ex. 1015 at 121, 124; Ex. 1008, ¶ 208), there is

no persuasive evidence that the “trilobe” design is unlikely to be productive in establishing a stronger, more efficient transmission of torque than a Torx design. Indeed, the evidence is to the contrary. Accordingly, Endo-Fix does not teach away from using a “trilobe” design.

Patent Owner also asserts that the Petition incorporates by reference substantial material from Dr. Beynnon’s declaration, which, according to Patent Owner, “is improper.” Prelim. Resp. 50. On the specific facts before us, we disagree. The Petition itself includes argument and explanation of the evidence and Petitioner’s position. It relies on Dr. Beynnon’s Declaration for evidentiary support. In the Declaration, Dr. Beynnon provides a comprehensive, detailed analysis of the evidence to support his opinions. His Declaration testimony is not, and need not be, limited to a verbatim or paraphrased repetition of the Petition. We also note that we have not cited or relied on substantial portions of Dr. Beynnon’s Declaration.

Considering the information presented in the Petition and Preliminary Response, and based on the analyses above, we are persuaded that there is a reasonable likelihood that Petitioner will prevail in establishing that claims 1–7 would have been obvious based on Endo-Fix and Weiler.

*E. Obviousness of Claims 1–7 Based On Simon (Ex. 1012)  
Alone or in Combination with Weiler*

Petitioner asserts claims 1–7 would have been obvious based on Simon alone or in combination with Weiler. Pet. 40–58. According to Petitioner, “Simon discloses every limitation of claim 1 of the ’216 patent, except the limitation that the ‘body’ have a ‘length of about 35 mm.’” *Id.* at 40–41 (citing Ex. 1008 ¶ 221); *see also id.* at 50 (“Simon does not describe the body of the screw as being about 35 mm long.”). Petitioner also

concedes, however, that “Simon does not disclose any specific screw diameters,” and thus does not disclose “an interference fit of up to 1.5 mm,” as required by the challenged claims.

Petitioner “focuses on the ‘sixth embodiment [in Simon],’ which is depicted in Figs. 19–22.” *Id.* at 40. We briefly describe below the scope and content of Simon.

Simon discloses “an orthopedic interference screw for compression anchoring a bone graft in a bore formed in a bone mass.” Ex. 1012, 2:26–27. Simon discloses that the sixth embodiment shown in Figures 19–22, on which Petitioner focuses, is very similar to the fifth embodiment shown in Figures 15-18, except that the interference screw 90 of the sixth embodiment is longer than the screw 80 in the fifth embodiment. *Id.* at 2:13–16. Because the fifth embodiment is described in the Specification in more detail than the sixth embodiment, we illustrate below, and generally describe, the fifth embodiment, shown in Figures 15 and 18. We also note that all the embodiments in Simon are related. *See* Ex. 1008 ¶ 222.

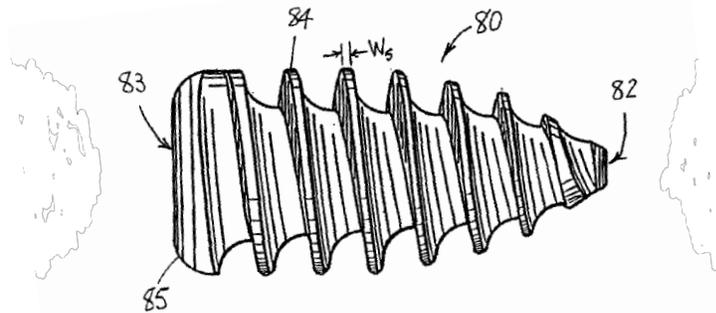


FIG. 15

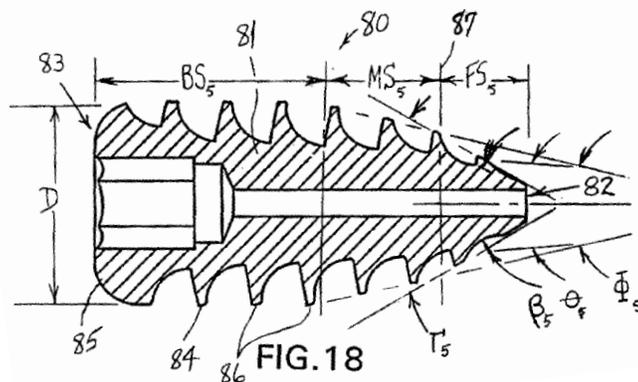


FIG. 18

Figure 15 (front view) and Figure 18 (sectional view)  
of the interference screw in Simon

As shown and described in Simon, screw 80 has a cannulated or a non-cannulated biocompatible body B5 with elongated root portion 81 with a circular cross-sectional shape. Ex. 1012, 6:39–43. Root portion 81 includes three sections: a front section FS<sub>5</sub>, a midsection MS<sub>5</sub>, and a back section BS<sub>5</sub>. *Id.* at 6:43–45. The root portion 81 also includes a front or tip end 82 and a back or head end 83. *Id.* at 6:45–46. A thread 84 is formed over substantially the entire root section 81 from the tip end 82 to the back end 83. *Id.* at 6:46–48. As shown particularly in Figure 18, the degree of taper in front section FS<sub>5</sub> is greater than the degree of taper in midsection MS<sub>5</sub>.

Substantially similar to Petitioner’s assertions with respect to Endo-Fix discussed above, Petitioner asserts it would have been obvious to a person of ordinary skill to provide the Simon screw in a length of 35 mm. Pet. 49. According to Petitioner, a person of ordinary skill “would have understood that the Simon screw is not limited to any particular size and can be provided in any suitable length, including any known interference screw length. *Id.* (citing Ex. 1008 ¶ 232).

Petitioner also asserts that a person of ordinary skill “would have understood that regardless of what diameter is chosen for the proximal end of Simon’s screw, the screw could have been used in a bone tunnel of a diameter smaller than the proximal end of the screw by 1.5 mm or less.” *Id.* at 44–45 (citing Ex. 1008 ¶ 239). Similar to the assertions discussed above on the grounds based on Endo-Fix, Petitioner asserts a person of ordinary skill “would have understood that the proximal end of the Simon screw is ‘configured’ to exceed the diameter of a bone tunnel by 1.5 mm or less. *Id.* at 45 (citing Ex. 1008 ¶ 239).

Petitioner relies on Weiler based on the same analysis discussed above in the asserted ground based on Endo-Fix and Weiler. *Id.* at 5658.

Patent Owner asserts that the asserted unpatentability based on Simon is “horizontally redundant,” “vertically redundant,” “cumulative,” and “limited to bone block fixation.” Prelim. Resp. 51–52. Patent Owner also argues that the bone block fixation screw in Simon: does not disclose or suggest a 1.5 mm interference fit with the bone tunnel (*id.* at 54); and does not disclose or suggest the “critical” 35 mm length if the screw (*id.* at 55–58). Patent Owner also asserts that the Petition “improperly [relies] on Beynnon—their expert—to explain what the prior art discloses.” *Id.* at 57.

We have addressed substantially the same assertions by Patent Owner above in our analysis of the grounds of unpatentability based on Endo-Fix.

Considering the information presented in the Petition and Preliminary Response, and based on the analyses above, we are persuaded that there is a reasonable likelihood that Petitioner will prevail in establishing that claims 1–7 would have been obvious based on Simon alone or in combination with Weiler.

*F. Obviousness Based On EP '459 (Ex. 1014)*

Petitioner asserts that claims 1–7 would have been obvious based on EP '459. Pet. 58–60. It is Petitioner's position that none of the applications in the chain to which the '216 patent claims priority "disclose a 35 mm "body"; each discloses only a 35 mm screw (including both the body and the tip)." Pet. 58. Petitioner concludes that "the '216 patent claims, which all require a 35 mm body, are entitled only to the actual filing date of the '216 patent, August 6, 2003." *Id.*

Based on our claim construction analysis above, the claims are not limited to a 35 mm "body," which Petitioner has asserted is the disclosed "main body 15," as argued by Petitioner. As discussed above, the claimed "elongated body" is, as disclosed, a single element with a complex taper, having a tip on its distal end with a total length of 35 mm. As discussed above, we disagree with Petitioner's argument that the '216 claims are not entitled to the priority date of the provisional application. Thus, for purposes of this Decision, the priority date of the '216 patent is November 15, 1999. EP '459, published on May 23, 2001, is not available as a

reference against the '216 patent. Accordingly, there is *not* a reasonable likelihood that Petitioner will prevail on this asserted ground.

### *G. Conclusion*

For the foregoing reasons, upon review of the arguments and evidence in the Petition and Preliminary Response, we conclude that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to the obviousness challenges to at least one of claims 1–7 based on Endo-Fix, Endo-Fix and Weiler, Simon, or Simon and Weiler. We further conclude that Petitioner has *not* demonstrated a reasonable likelihood that it would prevail in the obviousness challenge to claims 1–7 based on EP '459.

This is a decision to institute an *inter partes* review under 35 U.S.C. § 314. Our factual findings and conclusions at this stage of the proceeding, including claim constructions, are preliminary, and based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial.

### III. ORDER

In view of the foregoing, it is hereby:

ORDERED that *inter partes* review of the '216 patent is instituted on the following grounds set forth in the Petition:

Whether claims 1–7 would have been obvious in view of Endo-Fix;

Whether claims 1–7 would have been obvious in view of Endo-Fix and Weiler;

Whether claims 1–7 would have been obvious in view of  
Simon; and

Whether claims 1–7 would have been obvious in view of Simon  
and Weiler;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37  
C.F.R. § 42.4, *inter partes* review shall commence on the entry date of this  
Order, and notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the grounds  
identified above.

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