

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ARTHREX, INC.,
Patent Owner.

Case IPR2016-00819
Patent 6,629,977 B1

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 1–6 of U.S. Patent No. 6,629,977 B1 (Ex. 1001, “the ’977 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 1–6 of the ’977 patent.

A. Related Matters

The ’977 patent is related to two other patents for which *inter partes* review has been requested. The ’977 patent is the parent of U.S. Patent 6,875,216, which is the subject of IPR2016-00817. The ’216 patent is a division of the application that matured into the ’977 patent. 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.

B. The '977 Patent

The '977 patent is directed to a method of attaching a substitute ligament for anterior cruciate ligament (ACL) reconstruction using a bioabsorbable interference screw. The method includes the steps of forming a tunnel in the tibia, inserting a substitute ligament in the tunnel, and inserting the bioabsorbable interference screw into the tunnel so that the screw engages cortical bone in the tunnel and substantially longitudinally fills the tunnel to thereby retain the substitute ligament in position.

Figure 6 of the '977 patent is shown below.

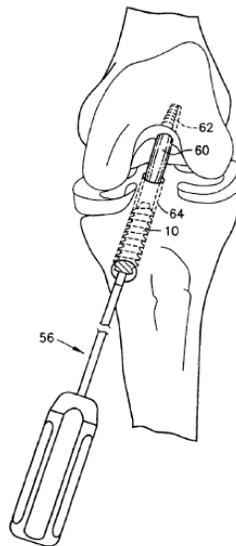


Figure 6 shows screw 10 inserted into tibial tunnel 64.

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, in a preferred embodiment, screw 10 fills all but the top 5–10 mm. of the tunnel. *Id.* at 3:56–4:6.

The disclosed screw used in the disclosed method includes a tapered, bioabsorbable interference fit screw *E.g.*, Ex. 1001, 1:12–15. Figure 1 of the '977 patent is reproduced below:

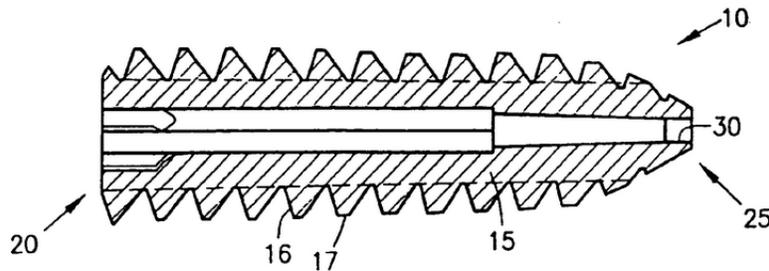


Figure 1 is a cross sectional view of the disclosed screw.

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. 1001, 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 '977 patent is reproduced below:

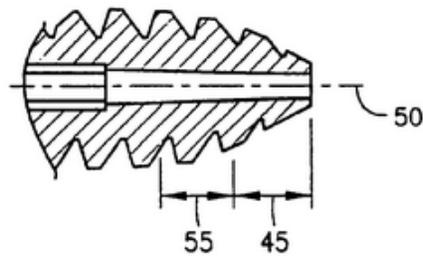


Figure 3 is a cross-sectional view of the distal end of the disclosed screw.

As shown in Figures 1 and 3, screw 10 has a complex taper with an initial portion 45 at an angle of about 27° 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.* 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.

C. Challenged Claims

Petitioner challenges all of the claims, which are claims 1–6. Claims 1 and 6 are independent claims. Claim 1 is representative and is reproduced below.

1. A method of interference fixation for ACL reconstruction using a bioabsorbable interference screw having an elongated threaded body, said elongated threaded body having a proximal end, a distal end, a length and taper, the threads and taper of the screw extending along substantially the entire length of the screw from said proximal end to said distal end, said method comprising the steps of:
forming a tunnel in the tibia, said tunnel having a wall;
inserting a substitute ligament in the tunnel; and
inserting said bioabsorbable interference screw into the tunnel such that said elongated threaded body fills all but 5-10 mm of the tunnel, the threads at the proximal end of the screw engage cortical bone in the tunnel, and said substitute ligament is securely fixed between the threads of the screw and the wall of the tunnel.

D. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–6 of the '977 patent are unpatentable under 35 U.S.C. § 103(a)¹ based on the following four grounds:

References	Claims Challenged
Endo-Fix ²	1, 2, 4–6
Endo-Fix, Weiler ³ and Hannay ⁴	2, 3
Simon ⁵	1, 2, 4–6
Simon and Weiler and Hannay	2, 3

Petitioner also relies on a declaration of Bruce Beynnon, 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 (2016) (upholding the use of the broadest reasonable interpretation

¹ 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.

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

³ 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).

⁴ U.S. Patent 3,575,080, issued April 13, 1971, Ex. 1016.

⁵ U.S. Patent No. 5,891,146, issued April 6, 1999 (Ex. 1012).

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. 10–19) and Patent Owner (Prelim. Resp. 16–23) propose constructions for a number of claim terms. We construe whether the preamble is limiting and we also 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. Preamble

The method steps of claim 1 (forming a tunnel; inserting a ligament; inserting a screw) require a screw having a specific structure (a bioabsorbable interference screw having an elongated threaded body and a specific taper) that are identified and described only by the preamble. *See*

Griffin v. Bertina, 285 F.3d 1029, 1033 (Fed.Cir.2002) (“Consideration of the preamble gives meaning and purpose to the manipulative steps in this case.”). Claim 1 is an example of “the claim drafter choosing to use both the preamble and the body to define the subject matter of the claimed invention. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995) (“when the claim drafter chooses to use *both* the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects.”). The preamble of claim 1 does not merely state an intended use for an invention that is defined in its entirety by the body of the claim. We therefore determine that the preamble of claim 1 limits the claimed invention. *See Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1340 (Fed. Cir. 2003).

Claims 2–5 add additional structure of the screw relating to the drive socket, taper, and cannula.

The format and substance of independent claim 6 is similar to claim 1. Claim 6 recites in the preamble the additional structural feature that screw is “fully cannulated,” which not in claim 1. The body of claim 6 refers to a “guide pin,” which is used with a “fully cannulated” screw. Ex. 1001, 2:10–12 (“The interference screw of the present invention may be optionally provided with a cannulation for insertion over a guide pin.”).

2. Tip Disposed on the Distal End of the Elongated Body.

Dependent claims 4 and 5 recite additional details of the screw structure. Claim 4 recites that the claimed method requires that “the distal end of the screw is provided with a tip having a second taper which is

greater than the taper extending along the substantial length of the body of the elongated threaded body of the screw.” Claim 5 recites that “the tip at the distal end of the screw is smooth and unthreaded.”

Petitioner asserts the claims require “a tip distinct from the body.”
Pet. 12.

Dr. Beynnon 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, ¶¶ 96–98.

Patent Owner states “[w]hether the tip of dependent Claims 4 and 5 is part of the body or not is largely irrelevant to the issues raised in the Petition.” Prelim. Resp. 19.

We look to the claim language itself and the Specification for guidance in interpreting the claims. 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. 1001, 2:52) and an “elongated bioabsorbable interference screw” (*id.* 2:50). 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.

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 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. 1001, 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.* at 3:11–16. As shown in Figures 1 and 3, and as described in the Specification of the ’977 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 claim 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 to 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.* 2:7–9. This suggests the tip is part of the claimed elongated body, not a distinct element.

Claim 4 recites “a tip having a second taper which is greater than the taper extending along the substantial length of the body of the elongated threaded body of the screw.” 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.

For purposes of this Decision, we determine that the broadest reasonable interpretation of the claim, 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 '977 patent claims priority to a provisional patent application filed November 15, 1999. Petitioner asserts the '977 patent is “not entitled to that [priority] date because the provisional describes only the entire screw filling all but 5-10 mm of the tibial tunnel, not the ‘body’ of the screw as claimed.” Pet. 8. Our claim construction discussed above construed the claimed elongated body as co-extensive with the disclosed screw. Based on our construction, we disagree with Petitioner’s argument that the '977 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 '977 patent is November 15, 1999.

C. Obviousness of Claims 1, 2, and 4–6 Based On Endo-Fix

Petitioner argues that claims 1, 2, and 4–6 would have been obvious in view of Endo-Fix. Pet. 46–59.

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. 46. Petitioner relies on the testimony of Paul O’Connor (Ex. 1010) to establish that Endo-Fix is prior art under 35 U.S.C. § 102(b) to the ’977 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. 35. We agree with Patent Owner that it is Petitioner’s burden to establish that Endo-Fix is a printed publication. *Id.* at 36. 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.*

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.

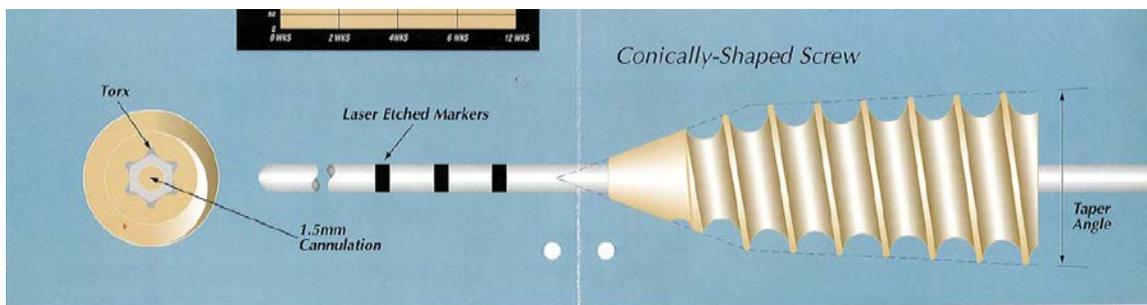
Patent Owner cites (Prelim. Resp. 36) *Toshiba Corp. v. Optical Devices, LLC*, Case IPR2014-01445, Paper 31 at pages 27–28 (Mar. 9, 2016) for support of its position. *Toshiba* determined that the proffered testimony was mere conjecture. As discussed above, we make no such determination on the record 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. 8–9 (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 Claims*

a. *Soft Tissue Fixation*

Patent Owner asserts Endo-Fix is used for bone block fixation while the screw disclosed and claimed in the ’977 patent is for soft tissue fixation. Prelim. Resp. 40–42. Patent Owner also asserts Endo-Fix does not include many claimed features relating to soft tissue fixation.” *Id.* Patent Owner fails, however, to identify any “claimed features” or structure recited in the challenged claims, or any disclosure in the Specification of the ’977 patent,

that limits the challenged claims 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 ’977 patent. Patent Owner also fails to identify persuasive evidence that the Endo-Fix screw is limited to “bone block” fixation.

Moreover, the ’977 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 ’977 patent states in the discussion of the related art:

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. 1001, 1:24–30 (emphasis added). Thus, on the record before us, Patent Owner’s argument that the claims in the ’977 patent are limited to soft tissue fixation, and that the screw in Endo-Fix is limited to bone block fixation, is not supported by any persuasive evidence.

b. Elongated Threaded Body Fills All But 5-10 mm of the Tunnel

The challenged claims all require that the elongated threaded body fills all but 5-10 mm of the tibial tunnel.

Petitioner asserts that background prior art, such as Belleman (Ex. 1049) disclose “that the screw should be “approximately 5 mm shorter than the tibial tunnel length” and “would have motivated a POSA to size the Endo-Fix screw to fill all but 5 mm of the tibial tunnel when used in soft tissue fixation.” Pet. 54 (citing Ex. 1049 at 669-70; Ex. 1008 ¶¶ 324–25, 327,

521). Petitioner also asserts that the precise numerical limitation of the top 5-10 mm unfilled does not produce a new and unexpected result which is different in kind and not merely in degree from the results achieved by the conventional and obvious use of interference screws like the Endo-Fix screw in a soft tissue fixation procedure. Pet. 55 (citing Ex. 1008 ¶ 329–331, 469, 524).

Dr. Beynnon testifies that Belleman explains that “a screw sized to be 5 mm shorter than the tibial tunnel allows for ‘anatomic fixation’ (i.e., fixation of the graft close to the place at the proximal end of the tibial where the ACL used to attach), which provides a variety of benefits.” Ex. 1008 ¶ 327. Dr. Beynnon concludes that a person of ordinary skill “would have known that for soft tissue fixation a screw that is 5 mm shorter than the tibial tunnel offers certain advantages.” *Id.*

Patent Owner asserts correctly “Endo-Fix is completely silent as to whether its device would fill all but the top 5-10 mm of the tibial tunnel.” Prelim. Resp. 42. Patent Owner concludes that “[g]iven the fact that the Endo-Fix screw is for bone block fixation, it would not be that long.” *Id.* As discussed above, we are not persuaded on the current record that Endo-Fix is limited to bone block fixation. Moreover, Dr. Beynnon testifies that a person of ordinary skill “would have known that screw dimensions suitable for bone block fixation would also be suitable for soft tissue fixation.” Ex. 1008 ¶ 144.

Endo-Fix discloses screw diameters of 7 and 9 mm and lengths from 20–30 mm. 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 length screw from the known prior art range for the needs of the particular patient.

Patent Owner does not specifically address dependent claims 2, 4, and 5. Based on the record before us, we are persuaded by Petitioner's evidence and arguments that there is a reasonable likelihood that these claims are unpatentable based on Endo-Fix.

c. Conclusion As To Claims 1, 2, 4–6

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 claims 1, 2, and 4–6 would have been obvious based on Endo-Fix.

*D. Obviousness of Claims 2 and 3 Based On
Endo-Fix, Weiler (Ex. 1015), and Hannay (Ex. 1016)*

Petitioner asserts that claims 2 and 3 would have been obvious based on Endo-Fix, Weiler, and Hannay. Pet. 59–60.

Claims 2 and 3 recite specific details of the drive system of the screw. Endo-Fix discloses a Torx drive. Ex. 1011, 2.

Petitioner relies on Weiler for the disclosure of a “trilobe” drive socket. 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.

Hannay discloses “wrenching means” for threaded fasteners. Ex. 1016, 1:10–14. 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.

According to Petitioner, Weiler and Hannay provide specific motivation to use the claimed drive socket disclosed in Weiler and Hannay in Endo-Fix. Pet. 59.

Patent Owner also asserts that “Endo-Fix *teaches away* from the suggested modification.” Prelim. Resp. 45. 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. 44–45. 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 2 and 3 would have been obvious based on Endo-Fix, Weiler, and Hannay.

Patent Owner asserts that this ground is "redundant." Prelim. Resp. 44. Nothing in our rules prohibits "redundant" grounds. 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, this ground of unpatentability relies on a different facts 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 this ground from consideration.

*E. Obviousness of Claims 1–6 Based On Simon (Ex. 1012)
Alone or in Combination with Weiler and Hannay*

In its asserted Grounds 1 and 2, Petitioner asserts claims 1–6 would have been obvious based on Simon alone or in combination with Weiler. According to Petitioner, “Simon does not explicitly state that threads at the proximal end of the screw engage cortical bone but implicitly discloses this by its teaching of endosteal fixation.” Pet. 20. Petitioner also acknowledges that “Simon also does not explicitly teach that the screw’s elongated body fills all but 5-10 mm of the tibial tunnel.” *Id.* According to Petitioner, “this numerical limitation adds nothing patentable that distinguishes over the method of use.” *Id.*

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. Figures 15 and 18 from Simon are shown below.

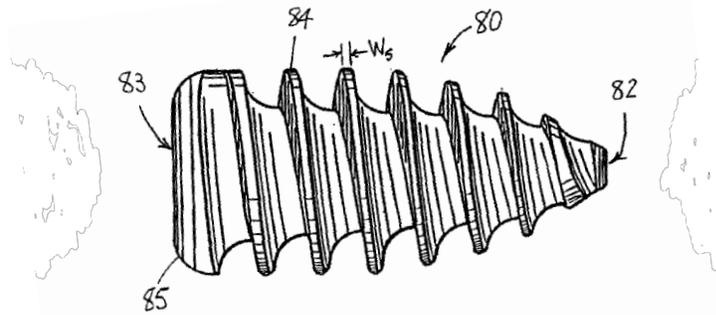


FIG. 15

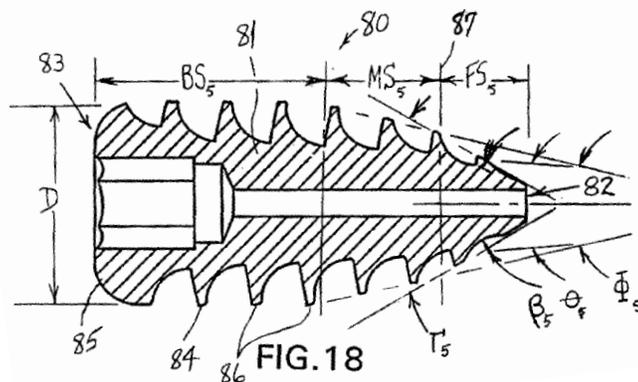


FIG. 18

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 FS₅, a midsection MS₅, and a back section BS₅. *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 FS₅ is greater than the degree of taper in midsection MS₅.

Patent Owner argues that the bone block fixation screw in Simon: does not disclose or suggest the limitation of a screw being inserted into a bone tunnel such that the ligament is “securely fixed between the threads of the screw and the wall of the tunnel,” as recited in Claims 1 and 6. Prelim. Resp. 27. Patent Owner concludes “Petitioners have not demonstrated how Simon teaches securely fixing a graft “between the threads of the screw and the wall of the tunnel,” as claimed. *Id.* at 28.

As discussed above, the challenged claims are not limited to a soft tissue fixation. The phrase “soft tissue” does not appear in the ’977 patent.

Our analysis of claims 2 and 3 regarding the drive socket and the Weiler and Hannay references is the same as above in the context of the ground 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 1–6 would have been obvious based on Simon alone or in combination with Weiler and Hannay.

F. 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 1–6.

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 '977 patent is instituted on the following grounds set forth in the Petition:

Whether claims 1, 2, and 4–6 would have been obvious in view of Endo-Fix;

Whether claims 2 and 3 would have been obvious in view of Endo-Fix, Weiler, and Hannay;

Whether claims 1, 2, and 4–6 would have been obvious in view of Simon; and

Whether claims 2 and 3 would have been obvious in view of Simon, Weiler; and Hannay.

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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