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Paper No. __

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SMITH & NEPHEW, INC. &
ARTHROCARE CORPORATION
Petitioners

v.

ARTHREX, INC.
Patent Owner

_____

Case No. TBD
Patent No. 6,875,216

_____

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *et seq.*

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1062	French Patent Application 2,717,070 (Pub. Sept. 5, 1995), with certified translation ("Laboureau")
1063	Andrew A. Amis, *The Strength of Artificial Ligament Anchorages*, 70-B(3) J. Bone & Joint Surgery 397 (May 1988) ("Amis")

Pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq.*, Smith & Nephew, Inc. ("S&N") and ArthroCare Corp. ("Petitioners") request *inter partes* review of claims 1-7 of U.S. Patent No. 6,875,216 ("the '216 patent").

I. INTRODUCTION

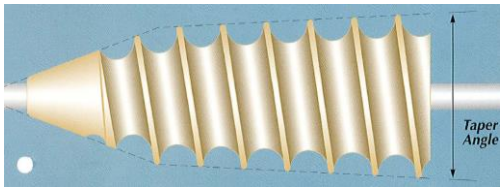
The '216 patent (Ex. 1002) is directed to a bioabsorbable interference screw for use in anterior cruciate ligament (ACL) reconstruction. ACL reconstruction involves drilling "bone tunnels" in the femur and tibia with openings at the knee joint where the ACL was formerly attached, and then securing a graft inside those bone tunnels to replace the ACL. An interference screw is inserted into each bone tunnel and secures the graft in the tunnel via an "interference fit."

The '216 patent asserts that prior art non-tapered interference screws were deficient in the degree of fixation provided. They were said to achieve only "an interference fit of about 1 mm., *i.e.*, about 1 mm. of bone is dilated as the screw is inserted into the bone tunnel." Ex. 1002 at 1:38-40. The '216 patent states that larger diameter screws increased fixation but were "more difficult to align and insert correctly," creating a need for a screw that "provides for increased dilation and interference fit without increased difficulty of insertion." *Id.* at 1:36-46.

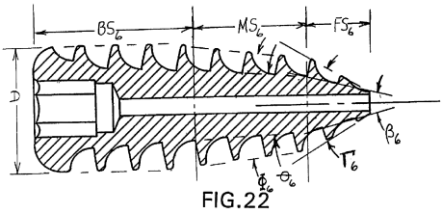
The '216 patent allegedly satisfied this need "by providing a ***tapered***, elongated bioabsorbable interference screw, the taper of the screw extending along

substantially the entire length of the elongated threaded screw." *Id.* at 1:49-53.[1] The '216 patent asserts that the screw's taper "promotes about a 1.5 mm interference fit; *i.e.*, the diameter of the proximal end … of the screw … is 1.5 mm larger than the diameter of the bone tunnel." *Id.* at 3:34-37.

Despite the '216 patent's contrary suggestion, tapered bioabsorbable interference screws configured to provide such an "interference fit" were known. A subsidiary of Petitioner S&N sold such screws, marketed under the name Endo-Fix, years before the '216 patent's alleged priority date. Ex. 1011 at 3. Grounds 1 and 2 are based on the 1995 Endo-Fix Brochure ("Endo-Fix"). Ex. 1011 at 2:



Grounds 3-4 are based on U.S. Patent 5,891,146 (Ex. 1012, "Simon"), which also discloses a tapered bioabsorbable interference screw. Ex. 1012 at Fig. 22:

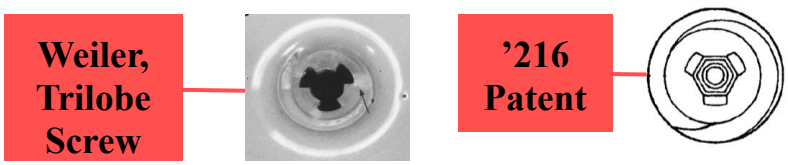


The '216 patent claims all require a screw ***body*** "about 35 mm" long—even though the specification only discloses 35 mm as the length of the entire screw

[1] Unless otherwise noted, all emphasis is added.

including both body and tip (*i.e.*, not just the body). The specification also fails to describe any benefit, let alone an unexpected result or difference in kind, of this particular length as there was none. Ex. 1002 at 2:62; Beynnon ¶ 148. Although Endo-Fix and Simon, like the '216 patent itself, do not disclose a 35 mm body, interference screws in a range of body lengths, including 35 mm, were known. Beynnon ¶ 138-147. It would have been obvious to provide the Endo-Fix screw, the Simon screw, or any other interference screw, with a 35 mm body.

The '216 patent claims all require a drive socket having "radially-extending slots for receiving a driver having three radially-extending protrusions corresponding to the slots." In co-pending litigation, Patent Owner asserts that the claims cover sockets with three ***or more*** slots. If Patent Owner is held to that position as the broadest reasonable interpretation (BRI) in this proceeding, then Endo-Fix and Simon both satisfy the requirement. If the claims are interpreted to require drive sockets having ***only*** three slots, such sockets were known to be effective for use in interference screws. Weiler (Ex. 1015) studied drive sockets for bioabsorbable interference screws and concluded that a "trilobe" socket withstood more torque than the sockets Endo-Fix and Simon disclosed. Weiler's tri-lobe socket is nearly identical to Fig. 2 of the '216 patent (excerpt):



As described in Grounds 2 and 4, a person of ordinary skill in the art ("POSA") would have been motivated by Weiler to modify the drive sockets of Endo-Fix and Simon to use a "trilobe" design to withstand greater insertion torque.

II. MANDATORY NOTICES

A. Real Party-In-Interest

Smith & Nephew, Inc. and ArthroCare Corp. are the real parties-in-interest.

B. Related Matters

A decision in this proceeding could affect or be affected by the following:

(1) Petitioners are simultaneously filing petitions for *inter partes* review of U.S. Patents Nos. 7,322,986 (a continuation of the '216 patent) and 6,629,977 (the '216 patent is alleged to be a divisional of the '977 patent). Petitioners request that the Board assign a single panel to address the three *inter partes* review petitions because there are common issues and prior art across them.

(2) Patent Owner is currently asserting the '216, '986 and '977 patents against Petitioners in federal district court (E.D. Tex., Case No. 2:15-cv-01047).

C. Counsel and Service Information

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Powers of attorney are submitted with this Petition. Counsel for Petitioners consents to service of all documents via electronic mail.

III. NOTICE OF FEES PAID

Fees are submitted herewith. If more fees are due during this proceeding, the undersigned authorizes the Office to charge Deposit Account No. 23/2825.

IV. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify, pursuant to 37 C.F.R. § 42.104(a), that the '216 patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting *inter partes* review as to the '216 patent claims. Arthrex previously asserted the '216 patent against Petitioners, but that action was dismissed without prejudice and does not give rise to a statutory bar under 35 U.S.C. § 315. *Macauto USA v. BOS GmbH*, IPR2012-00004, Paper 18 at 15-16 (PTAB Jan. 24, 2013); *Atlanta Gas Light v. Bennett Regulator Guards*, IPR2015-00826, Paper 12 at 12-14 (PTAB Sept. 1, 2015).

V. IDENTIFICATION OF CHALLENGE AND RELIEF REQUESTED

Petitioners request cancellation of claims 1-7 of the '216 patent:

Ground Number and Reference(s)		Claims	Basis
1	Endo-Fix	1-7	§ 103(a)
2	Endo-Fix in view of Weiler	1-7	§ 103(a)
3	Simon	1-7	§ 103(a)
4	Simon in view of Weiler	1-7	§ 103(a)
5	EP 1,101,459 ("EP '459 Application")	1-7	§ 103(a)

VI. OVERVIEW OF THE '216 PATENT

The '216 patent concerns "fixation of a substitute anterior cruciate ligament [ACL] using a tapered bioabsorbable interference screw." Ex. 1002 at 1:13-16.

A. Technology Overview

The ACL connects the tibia (*i.e.*, shinbone) and femur (*i.e.*, thighbone) and stabilizes the knee. Ex. 1017; Beynnon ¶ 21. Ruptures or tears of the ACL are common. Ex. 1017; Beynnon ¶ 23. By the late 1990s, before the alleged invention, ruptured ACLs were often reconstructed using a replacement tissue graft. Ex. 1018 at 1561; Ex. 1019 at 259; Beynnon ¶ 31.

ACL reconstruction typically involved drilling bone tunnels in the femur and tibia with openings at the knee joint and then securing a graft inside both tunnels. Ex. 1020 at 219-21; Beynnon ¶ 30. Surgeons had several choices for the graft. Beynnon ¶ 31. "Bone block fixation" involved using a section of the patellar tendon (*i.e.*, the tendon connecting the patella/kneecap to the tibia), which includes sections of bone on either end to aid in fixation inside the bone tunnels. Ex. 1018

at 1561-62; Beynnon ¶ 31. "Soft tissue fixation" used sections of hamstring tendons without bone blocks. Ex. 1018 at 1561-62; Beynnon ¶ 31. Fixation of a graft using an interference screw was achieved by inserting the graft and screw into the bone tunnel so that the screw pressed the graft against the tunnel wall and secured the graft in the tunnel via "interference fit." Ex. 1021 at 87; Beynnon ¶ 32.

Early interference screws were metal, but bioabsorbable plastic interference screws were introduced in the early 1990s. Ex. 1020 at 208; Beynnon ¶ 38-40. Plastic was weaker than metal, which drove design changes, including slotted drive sockets that increased the torque that could be applied without breaking the plastic, and tapered bodies that decreased the torque needed to insert the screw into a bone tunnel. Ex. 1015 at 120-121; Ex. 1011 at 2; Beynnon ¶ 42-46.

B. Summary of the Claims

The '216 patent includes independent claim 1 and dependent claims 2-7. Claim 1 is reproduced below with letters in brackets preceding the claim elements (*e.g.*, "[a1]") that are used herein as shorthand references for those elements. "Protusions" (sic) in claim element [c2] is corrected to "protrusions" throughout.

[pr.] A bioabsorbable interference screw for ACL reconstruction, comprising:

[a1] ***an elongated threaded body*** having a proximal end, a distal end, a length of about 35 mm. and a taper, **[a2]** the threads and the taper of the elongated threaded body extending along

substantially the entire length of the elongated threaded body, **[a3]** the proximal end of the screw being configured to provide an interference fit of up to 1.5 mm in a bone tunnel;

[b1] ***a tip*** disposed of the distal end of the elongated body, **[b2]** 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

[c1] ***a drive socket*** disposed within the screw and extending from the proximal end of the elongated threaded body, **[c2]** wherein the drive socket has radially-extending slots for receiving a driver having three radially-extending protusions [sic] corresponding to the slots.

Claim 1 thus recites a bioabsorbable interference screw comprising: a body, a tip, and a drive socket. Beynnon ¶ 52. Elements [a1], [a2], and [a3] recite features of the body; elements [b1] and [b2] recite features of the tip; and elements [c1] and [c2] recite features of the drive socket. Beynnon ¶ 52.

C. Level of Ordinary Skill in the Art

The ’216 patent claims priority through the ’977 patent to a provisional filed November 15, 1999. The provisional and ’977 patent each discloses only a 35 mm long screw, not a 35 mm long “body” as claimed in the ’216 patent. As a result, the ’216 claims are not entitled to an earlier priority date and are limited to the actual filing date (August 6, 2003) of the ’216 patent. Nevertheless, this Petition evaluates the patentability of the claims based on the level of skill a POSA had in

the November 1999 timeframe, because the claims are unpatentable even if the Board determines that the ’216 patent is entitled to that earlier priority date. A POSA in the interference screw field, to which the ’216 patent is directed, 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. Beynnon ¶ 17.

VII. CLAIM INTERPRETATION

Each claim term should be given its broadest reasonable interpretation consistent with the specification. 37 C.F.R. § 42.100(b). This construction may be different from the proper construction in district court, but except where otherwise noted, all of Petitioners’ constructions are also the proper district court constructions.

A. “proximal end” and “distal end” (claim 1)

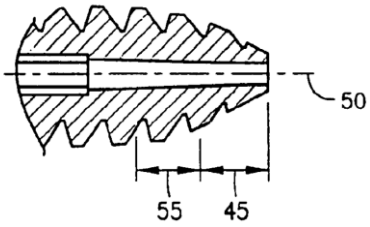
Claim 1 requires that the screw body have proximal and distal ends. These terms have customary meanings, with the proximal end being the end nearest the practitioner and the distal end being the end furthest from the practitioner while the screw is being inserted. Beynnon ¶ 53; Ex. 1022 at 658, 1828; Ex. 1023 at 571, 1557. Those meanings are consistent with the usage in the specification of the

’216 patent. Ex. 1002 at 2:60-66; Beynnon ¶ 53.

B. “tip” and “body” (claim 1)

Claim 1 separately recites the screw as comprising a “body” and a “tip disposed of” the body and having “a taper which is greater than” the taper of the body. The claim structure thus requires a tip distinct from the body because the body and tip are recited separately, and because the tip cannot have a different taper from the body if it is part of the body. *Becton, Dickinson v. Tyco Healthcare*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (“Where a claim lists elements separately, ‘the clear implication of the claim language’ is that those elements are ‘distinct component[s]’ of the patented invention.”); Beynnon ¶ 54-58. The tip “disposed of” the body confirms that they are separate portions of the screw, because “disposed” means “arranged” and “of” is “used to indicate … separation.” Ex. 1022 at 654; Ex. 1023 at 568, 1343; Beynnon ¶ 54.

Construing the tip as separate from the body is consistent with the ’216 patent specification, which teaches that the screw has a complex taper as shown in Figs. 1 and 3 (Fig. 3 reproduced below), where “elongated main ***body*** 15” (Fig. 1) has a more gradual taper than “initial portion 45,” and where “relatively pointed distal portion 45 forms a nose that provides for ***easy insertion*** of the screw 10 into a bone tunnel.” Ex. 1002 at 3:11-18; Beynnon ¶ 56.



A POSA would have understood the "relatively pointed distal portion 45" of the screw to be the "tip," distinct from the "main body 15." Beynnon ¶ 56-57. Accordingly, the BRI of "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. Beynnon ¶ 58. The BRI of "body" is the portion of the screw extending from the screw's proximal end and terminating before the tip. Beynnon ¶ 58.

Claim 1 requires that the "body" (exclusive of "tip") be "about 35 mm" long. In litigation, Patent Owner has accused of infringement screws that are about 35 mm in ***total*** length—inclusive of tip and body. Ex. 1024 at 3. Although Petitioners believe such an interpretation is improper for the reasons discussed above (even under a district court claim construction), this Petition demonstrates that all claims are unpatentable even if the tip is considered part of the body for purposes of meeting the claimed 35 mm length requirement.

C. "the tip being threaded" (claim 1)

Under the BRI, "the tip being threaded" requires that at least a portion of a thread extends over at least a portion of the tip. Beynnon ¶ 60.

D. "threaded body having … a taper" (claim 1)

Threaded screws have a major diameter from crest to crest of the threads and a minor diameter from trough to trough of the threads (at the root of the screw). Beynnon ¶ 61. A screw can taper in its major diameter, minor diameter, or both. Ex. 1022 at 2339 (defining "taper" as a "gradual diminution of thickness, diameter, or width in an elongated object"); Ex. 1023 at 1943 Ex. 1045 (Machinery's Handbook) at 1633; Beynnon ¶ 61. The claims do not limit the type of taper, and tapering either the major or minor diameter would achieve the benefits that the '216 specification states are achieved by tapering the screw. Beynnon ¶ 61-62. Thus, under the BRI, the "threaded body having … a taper" requires that the major and/or minor diameter of the body decreases along the length of the "body." Beynnon ¶ 61.

E. "proximal end of the screw being configured to provide an interference fit of up to 1.5 mm" (claim 1)

The specification describes the screw as dilating bone outwardly around the bone tunnel to create an interference fit and explicitly defines what "1.5 mm interference fit" means—"*i.e.*, the diameter of the proximal end 20 of the screw 15 is 1.5 mm larger than the diameter of the bone tunnel." Ex. 1002 at 3:28-36; Beynnon ¶ 64. Claim 1 recites interference fit of "***up to*** 1.5 mm." During prosecution, Patent Owner broadened the claims, which previously recited an "interference fit of more than 1 mm and up to 1.5 mm," to remove the 1 mm lower

limit. Ex. 1006 at 17. Thus, claim 1 limits the maximum "interference fit" (defined as the amount by which the diameter of the screw's proximal end exceeds the tunnel diameter) the proximal end of the screw must be configured to have but imposes no lower limit. Beynnon ¶ 64. Therefore, a POSA would have understood "proximal end of the screw being configured to provide an interference fit of up to 1.5 mm" to be met by a screw with a proximal end having a diameter that exceeds the diameter of the tunnel by no more than 1.5 mm. Beynnon ¶ 64.

F. "the drive socket has radially-extending slots for receiving a driver having three radially-extending protrusions corresponding to the slots" (claim 1)

Although claims in litigation are interpreted according to the Federal Circuit's *Phillips* framework, the Federal Circuit recently confirmed that claims are interpreted more broadly in IPR proceedings using the BRI. *In re Cuozzo Speed Techs.*, 793 F.3d 1268, 1275-79 (Fed. Cir 2015), *pet. cert. granted*, 136 S. Ct. 890 (Jan. 15, 2016); *see also Cheetah Omni v. Samsung Elecs. Am.*, 2009 WL 5196721, at *3 (E.D. Tex. Dec. 21, 2009) (adopting claim construction narrower than that applied by the Patent Office).

The BRI of claim 1 is that it covers a drive socket with ***three or more*** grooves extending outwardly from a center axis of the socket to receive three or more radially extending protrusions. Ex. 1022 at 1871, 2146 (defining "slot" as "a long and narrow opening or groove"); Ex. 1023 at 1591-92, 1800 Ex. 1025 at

2009; Beynnon ¶ 65. Claim 1 uses the open-ended transition "comprising" and, on its face, contains no upper limit on the number of grooves so long as the screw has three "for receiving a driver having three radially-extending protrusions." Patent Owner has accused of infringement devices with more than three grooves. Patent Owner should be held to that position as "reasonable" here because it would be unfair for Patent Owner to accuse such devices of infringing without facing, in this proceeding, prior art containing identical disclosures. If Patent Owner wishes a narrower construction, it can seek leave to amend the claims. *In re Cuozzo*, 793 F.3d at 1276 (noting that BRI "serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified") (internal quotation omitted). Thus, although a narrower construction should apply in district court for reasons briefly explained below, the BRI of claim 1 covers screws with three ***or more*** slots (grooves).

Under the claim construction standards that apply in district court, the claims should be interpreted to exclude drive sockets for receiving drivers having more than three radially-extending protrusions. The '216 patent specification discloses only sockets with three grooves, and Patent Owner disclaimed sockets with more than three grooves during prosecution of the '216 patent's parent application. Those facts are weightier in district court than in this proceeding, given the absence in district court of a bias toward the "broadest reasonable interpretation."

G. "the drive socket has a taper corresponding to the taper of the … body" (claim 2)

The BRI of this limitation requires that the drive socket taper at the same angle as the body tapers in the area of the drive socket. Beynnon ¶ 67.

H. "diameter … at the drive socket" (claims 4-7)

The BRI of "diameter … at the drive socket" is a diameter of the screw as measured at any point along the drive socket. Beynnon ¶ 70.

I. "diameter… at the tip" (claims 4-7)

The BRI of "diameter… at the tip" (claims 4-7) is a diameter of the screw as measured at any point along the "tip." Beynnon ¶ 71.

J. "threads" (claim 1)

Claim 1 introduces a threaded body and then refers to "the threads" (plural). The term "thread" has two meanings in the screw art. "Thread" may refer to "the projecting helical rib of a screw" so that a single thread may make multiple turns as it extends along the length of the screw. Ex. 1022 at 2381, 2041; Ex. 1023 at 1723; Beynnon ¶ 63. While some screws have multiple helical ribs, it is most common for a screw to have only one. Beynnon ¶ 63.

"Thread" may also refer to "one complete turn of a screw thread," *i.e.*, each turn of a single helical rib is sometimes referred to as a thread so that a screw with a single helical rib may be considered to have multiple threads. Ex. 1022 at 2381, 2041; Beynnon ¶ 63. An example of this usage of "thread" is when screws are

characterized by "threads per inch." Ex. 1026 (Johnson) at 3:29-32, 3:56-57; Beynnon ¶ 63. The reference in claim 1 to multiple "threads" refers to multiple complete turns of a projecting helical rib extending in the length-wise direction along the screw. Beynnon ¶ 63. This is consistent with the specification of the '216 patent, which does not show or describe multiple helical ribs and refers to "threads 16 extending substantially from proximal end 20 to distal end 25." Ex. 1001 at 2:64-67, Fig. 1; Beynnon ¶ 63.

VIII. THRESHOLD REQUIREMENT FOR *INTER PARTES* REVIEW

This Petition and the supporting evidence demonstrate "a reasonable likelihood that petitioner would prevail with respect to at least one of the claims challenged in the petition." 35 U.S.C. § 314(a). All of the '216 patent claims would have been obvious over the prior art relied upon in this Petition, as explained in detail by Dr. Beynnon, a Professor in the Department of Orthopaedics and Rehabilitation at the University of Vermont ("Beynnon," Ex. 1008).

IX. CLAIM-BY-CLAIM EXPLANATION OF GROUNDS FOR UNPATENTABILITY OF CLAIMS 1-7

A. Ground 1: Endo-Fix Renders Claims 1-7 Obvious

Endo-Fix is a sales brochure that Acufex (a division of S&N) distributed before 1998. It is prior art under 35 U.S.C. § 102(b). Ex. 1010 (O'Connor Decl.); *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974-75 (Fed. Cir. 2010) ("promotional publication" was a printed publication). Endo-Fix discloses a

tapered bioabsorbable interference screw for ACL reconstruction that has a slotted drive socket and meets every limitation of claim 1 except the requirement that the "body" have a "length of about 35 mm." Beynnon ¶ 125. As explained below, claims 1-7 would have been obvious over Endo-Fix regardless of whether the tip is considered part of, or separate from, the body. Beynnon ¶ 125-26.

1. Claim 1 Is Unpatentable If "Body" Is Separate from "Tip"

a. "[pr.] A bioabsorbable interference screw for ACL reconstruction, comprising:"

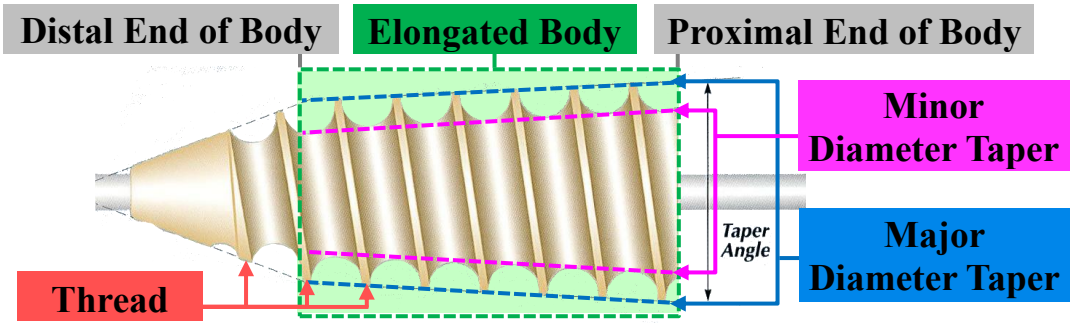
Endo-Fix discloses an "Interference Screw," made from a "bioabsorbable material." Ex. 1011 at 1-2; Beynnon ¶ 127. If "for ACL reconstruction" is considered limiting rather than a statement of intended use,[2] a POSA would have understood Endo-Fix to disclose a screw for ACL reconstruction based on Endo-Fix's disclosure of fixing a graft. Ex. 1011 at 2; Beynnon ¶ 128-29.

b. "[a1] an elongated threaded body having a proximal end, a distal end, … and a taper,"

Endo-Fix discloses an elongated threaded body (green dashed box) having a proximal end, a distal end, and a taper of both the major and minor diameters (magenta and blue dashed lines), shown below. Ex. 1011 at 2; Beynnon ¶ 130-31, 133-35. The "body" is the portion of the screw extending from the proximal end

[2] Patent Owner maintains that this language is not limiting. Ex. 1024 at 2.

of the screw and terminating before the "tip." Beynnon ¶ 131; *see supra* §§ VII.A, VII.B.



c. "[a1] an elongated threaded body having … a length of about 35 mm"

Endo-Fix describes screws with overall lengths of 20, 25 and 30 mm but does not disclose a 35 mm body length. At least four distinct reasons exist why the 35 mm limitation adds nothing patentable to the claims, and why it would have been obvious to implement the Endo-Fix screw with a 35 mm body length.

Size Not Patentable **–** Courts have long recognized that merely changing the size of a device is not patentable. *Powers-Kennedy Contracting v. Concrete Mixing & Conveying*, 282 U.S. 175, 185 (1930) ("[A] mere change in proportion would involve no more than mechanical skill and would not amount to invention."); *Ex Parte Asiatico*, No. 2012-003942, 2015 WL 1522469, at *2 (PTAB Mar. 31, 2015) ("[I]t is well established that size is not ordinarily a patentable feature."). This common-sense rule applies with particular force here because the '216 patent does not describe any criticality or unexpected result

associated with a screw body having any particular length—let alone 35 mm. Beynnon ¶ 148. The '216 patent does not even disclose a ***body*** (exclusive of tip) of 35 mm. The '216 patent states only that the entire screw can be 35 mm long, without describing any criticality or unexpected result that flows from that length. Ex. 1002 at 2:62; *see also* Beynnon ¶ 148. Thus, the '216 patent fails to support a conclusion that 35 mm is patentably distinct from any other body length.

Numerical Value Subsumed By Prior Art – When the prior art discloses a range of values that encompasses a numerical value recited in a claim, a *prima facie* case of obviousness is established and the claimed numerical value can only render the claim patentable if the inventor demonstrates that it provides unexpected beneficial results or a difference in kind. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) ("A *prima facie* case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art."); *Ormco v. Align Tech.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) ("Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness."); *In re Applied Materials*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (citing *Peterson*) (holding when the prior art teaches a range of values that overlap the claimed value, the "overlap itself provides sufficient motivation to optimize" the variable to have a particular value in the prior art's disclosed range). This principle applies regardless of the nature of the numerical value limitation. *E.g.*,

Ormco, 463 F.3d at 1311 (concerning a claimed time range); *In re Applied Materials*, 692 F.3d at 1295 (concerning size dimensions of a claimed variable).

Although Endo-Fix discloses screws that were 20 mm, 25mm and 30 mm long (Ex. 1011 at 3), a POSA knew that interference screws were provided in a range of sizes that included screw and body lengths of 35 mm. Beynnon ¶ 138-47. Johnson (published in 1996) discloses bioabsorbable interference screws ranging from "25 to 40 mm long," the latter having a body length of ***almost exactly 35 mm***. Ex. 1026 at 1:14-28, 3:55-58 (40 mm screw with 4.7 mm tip; body length of 35.3 mm); Beynnon ¶ 140. By 1996, at least four companies had made 40 mm interference screws. Ex. 1020 at 210; Ex. 1027 at 778; Ex. 1028 at 2-3; Ex. 1029 at 2-3; Beynnon ¶ 143. Other references disclose an even wider range, with body lengths of 35 mm squarely in the middle. For example, Grooms discloses a range of screws of 8 mm to 70 mm (preferably 10 mm to 40 mm) in length, (Ex. 1030 at 3:48-54, 2:9-11); Thramann discloses 15-60 mm interference screws (Ex. 1031 at 1:14-22, 8:51-53); Sgaglione discloses 15-40 mm interference screws (Ex. 1020 at 210); Petitioner's RCI FDA submission discloses 25-50 mm interference screws (Ex. 1029 at 3); and Stadelmaier discloses 40 mm interference screws from Petitioners (Ex. 1027 at 778). Beynnon ¶ 143. While some of these references disclose metal interference screws for ACL procedures, a POSA would have

understood that desirable lengths were the same for bioabsorbable and metal interference screws. Ex. 1032 at 241; Ex. 1033 at 29; Beynnon ¶ 144.

The overlap between the range of body lengths in the prior art and the claimed 35 mm body length renders 35 mm presumptively obvious, with nothing (*e.g.*, no alleged criticality or unexpected results) to rebut the presumption. *In re Peterson*, 315 F.3d at 1329; *Ormco*, 463 F.3d at 1311; *In re Applied Materials*, 692 F.3d at 1295; Beynnon ¶ 148. Patent Owner may argue that a screw with a 35 mm length body would eliminate the "need for multiple, shorter interference screws" as it may fill "all but the top 5-10 mm" of the tibia tunnel, and provide some other alleged benefits (Ex. 1002 at 3:41-51), but this argument is a straw-man. As shown immediately above, screws with 35 mm bodies—and longer—were known in the art and had these same benefits. Beynnon ¶ 138-48. Further, given the different anatomy of different patients, Patent Owner has no evidence that a screw with a 35 mm length body would actually achieve the stated goal of filling all but the top 5-10 mm of the tibial tunnel for all patients. Beynnon ¶ 148.

***Result Effective Variable Obvious* –** When a claimed value relates to a variable known to be result-effective (*i.e.*, to impact how the claimed invention performs), it would have been obvious for a POSA to perform routine experiments to determine what value(s) achieve effective results. *In re Applied Materials*, 692 F.3d at 1295-96 ("'[D]iscovery of an optimum value of a result effective variable ..

is ordinarily within the skill of the art.'" (quoting *In re Boesch*, 617 F.2d 272, 276 (C.C.P.A. 1980)); *id.* at 1297 ("A recognition in the prior art that a property is affected by the variable is sufficient to find the variable result-effective.").

A POSA knew that screw (and hence body) length was a result-effective variable because: (a) longer screws provide stronger fixation and faster integration of the graft in the tunnel (Ex. 1034 (Hulstyn) at 419; Ex. 1035 (Gerich) at 86; Ex. 1027 (Stadelmaier) at 779 (noting "the pull-out strength of the longer [40 mm] screw would significantly exceed that of the traditional shorter [25 mm] screw"); Ex. 1036 (Weiler AANA) at 548-49; Ex. 1037 (Pinczewski) at 642-43), and (b) a screw that is too long risks protruding from the tibial tunnel, which could cause pain and tissue damage (Ex. 1020 (Sgaglione) at 213; Ex. 1038 (Mahony) at 2:11-18). Beynnon ¶ 149. As Mahony (Ex. 1030) explained, "[t]he screw which is used to affix the bone graft in place must be long enough to have adequate purchase against the bone graft but short enough so that any portion extending beyond the surface of the tibia or femur when the screw is tightened is minimized and preferably eliminated." Ex. 1038 (Mahony) at 2:11-18; Beynnon ¶ 150. Given these known factors and the relatively narrow range of potential lengths, it would have been a matter of ordinary experimentation for a POSA to arrive at the claimed length. Beynnon ¶ 150-52. *In re Applied Materials*, 692 F.3d at 1295-96.

Specific Motivation – The teaching in the art that longer interference screws provided better fixation alone would have rendered a 35 mm body length obvious over Endo-Fix. A POSA's knowledge of longer interference screws (including Johnson's 40 mm interference screw with the 35.3 mm body) and the benefits they provided would have given a POSA reason to lengthen the Endo-Fix screw to have a longer (including a 35 mm) body. Beynnon ¶ 153. Where, as here, a POSA would have had a reason to try "a finite number of identified, predictable solutions," and would have had a reasonable expectation of success (here, with respect to a body length of 35 mm) the claim would have been obvious. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Beynnon ¶ 153.

d. "[a2] the threads and the taper of the elongated threaded body extending along substantially the entire length of the elongated threaded body,"

As illustrated by the annotated figure from Endo-Fix in § IX.A.1.b above, both the threads and the taper of the Endo-Fix screw extend along the entire length of the elongated threaded body. Ex. 1011 at 2-3; Beynnon ¶ 155.

e. "[a3] the proximal end of the screw being configured to provide an interference fit of up to 1.5 mm in a bone tunnel;"

As discussed in § VII.E above, this limitation is met by a screw with a proximal end having a diameter "configured" to exceed the bone tunnel diameter by up to 1.5 mm. Endo-Fix discloses screws with proximal ends having diameters

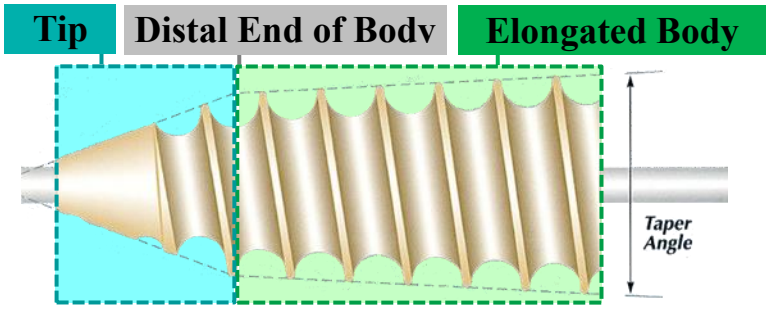
of 7 mm and 9 mm. Ex. 1011 at 2-3; Beynnon ¶ 158. A 9 mm diameter at the proximal end is one of the "preferred" sizes described by the '216 patent, so Endo-Fix describes a screw having a proximal end "configured" in precisely the manner the '216 specification describes as preferred. Ex. 1002 at 3:19-21; Beynnon ¶ 158. A POSA 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. Beynnon ¶ 158. Given that claim 1 is not a method claim requiring use of a screw having a proximal end diameter greater than the diameter of a tunnel in which the screw is inserted, under the BRI applicable in this proceeding, nothing further is required to meet this limitation. Beynnon ¶ 158.

A POSA would have known that tapering the body of the Endo-Fix screw facilitated inserting the screw into spaces or bone tunnels having a diameter smaller than the diameter at the screw's proximal end. Ex. 1011 at 2; Beynnon ¶ 159. In addition, as the '216 patent's specification admits, it was known that "[b]ioabsorbable interference screws are usually sized so that they are slightly larger tha[n] the diameter of the tunnel." Ex. 1002 at 1:33-35; *see Riverwood Int'l v. R.A. Jones & Co.*, 324 F.3d 1346, 1354 (Fed. Cir. 2003) ("Valid prior art may be created by the admissions of the parties."); *LG Elecs. v. Core Wireless Licensing*, IPR2015-01983 Paper 7 at 6 n.2 (PTAB Mar. 2, 2016); Beynnon ¶ 159. Other evidence confirms that it was known to insert an interference screw into a smaller

diameter bone tunnel. Ex. 1026 at 3:56-58, 4:16-18, 6:63-67 (using a bone tunnel up to 11 mm wide and an interference screw up to 13 mm wide); Ex. 1039 (Patent Owner's website in 1998 recommended that a bioabsorbable screw be "1 mm larger than the tunnel."); Beynnon ¶ 159. Thus, under the BRI, the Endo-Fix screw's proximal end was "configured" to have a diameter that exceeds, by 1.5 mm or less, the diameter of a bone tunnel. Beynnon ¶ 160.

f. "[b1] a tip disposed of the distal end of the elongated body,"

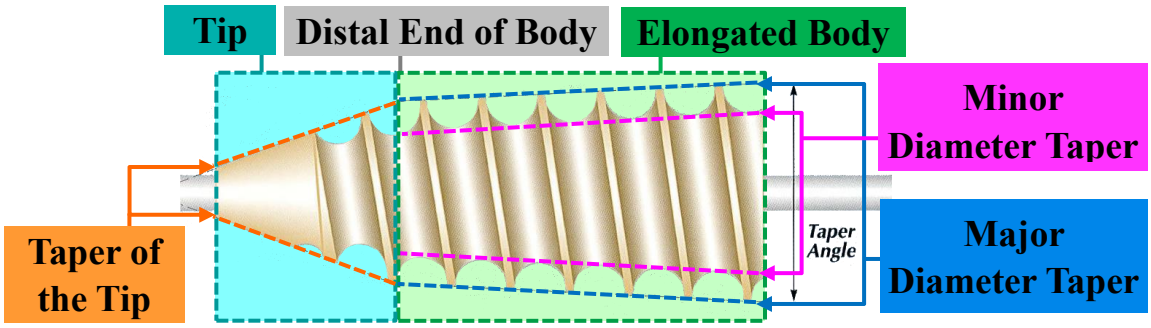
Endo-Fix discloses a tip disposed of the distal end of the elongated body. A POSA would have understood that the tip of the Endo-Fix screw is the portion of the screw that starts at the screw's distal end, increases in diameter proximally, and terminates where the taper of the screw changes to a lesser taper. Ex. 1011 at 2; Beynnon ¶ 161; *see supra* § VII.B. The tip is illustrated below in the blue box.



g. "[b2] 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"

The tip of the Endo-Fix screw is threaded because the thread extends onto the tip. Ex. 1011 at 2; Beynnon ¶ 167; *see supra* § VII.C. As shown in the

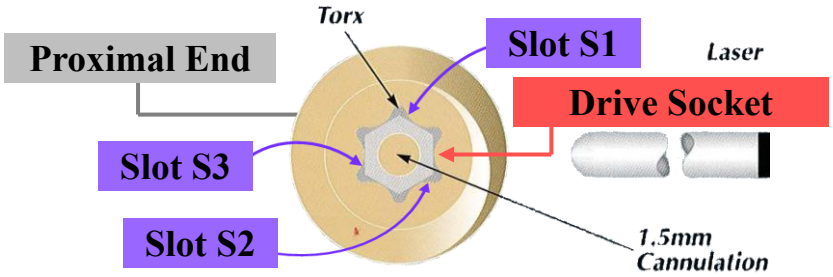
annotated figure below, the tip has a greater (*i.e.*, steeper) taper than the elongated threaded body. Beynnon ¶ 164. A POSA would have understood the Endo-Fix screw's "conical design" to make the screw "easily insertable"[3] in the same way the "relatively pointed distal portion 45 … provides for easy insertion of the screw" in the '216 patent. Ex. 1002 at 3:16-18; Beynnon ¶ 166. The tapered tip facilitates guiding the screw into the bone tunnel, and also beneficially allows the insertion torque to be relatively low initially and to increase gradually. Beynnon ¶ 166. The features of element [b2] are shown on the annotated figure below.



h. "[c1] a drive socket disposed within the screw and extending from the proximal end of the elongated threaded body,"

The Endo-Fix screw has a "Torx head" drive socket disposed within the screw and extending distally from the proximal end of the elongated threaded body. Ex. 1011 at 2; Beynnon ¶ 169. The Torx head drive socket at the proximal end is depicted in the annotated Endo-Fix figure below. Beynnon ¶ 169, 171.

[3] Petitioners reserve the right to argue in court that "easily insertable" is indefinite.



i. "[c2] wherein the drive socket has radially-extending slots for receiving a driver having three radially-extending protrusions corresponding to the slots."

Endo-Fix's driver and drive socket have matching "'six-star' Torx head" shapes. Ex. 1011 at 2; Beynnon ¶ 171. The driver is shown in the Endo-Fix figure reproduced below and annotated to show three of the six radially-extending protrusions. Ex. 1011 at 3. The drive socket includes six slots that are shown as darker gray grooves at the outer edges of the drive socket in the figure reproduced above in connection with element [c1], and are configured to receive the driver's six protrusions. Beynnon ¶ 171. Under the BRI standard, any three of Endo-Fix's six slots (*e.g.*, slots S1-S3 in the annotated drawing above in connection with element [c1]) meet the slot requirement and any three of the driver protrusions meet the radially-extending protrusions requirement. Beynnon ¶ 171; *see supra* § VII.F.

j. Conclusion: If "Body" Is Separate from "Tip"

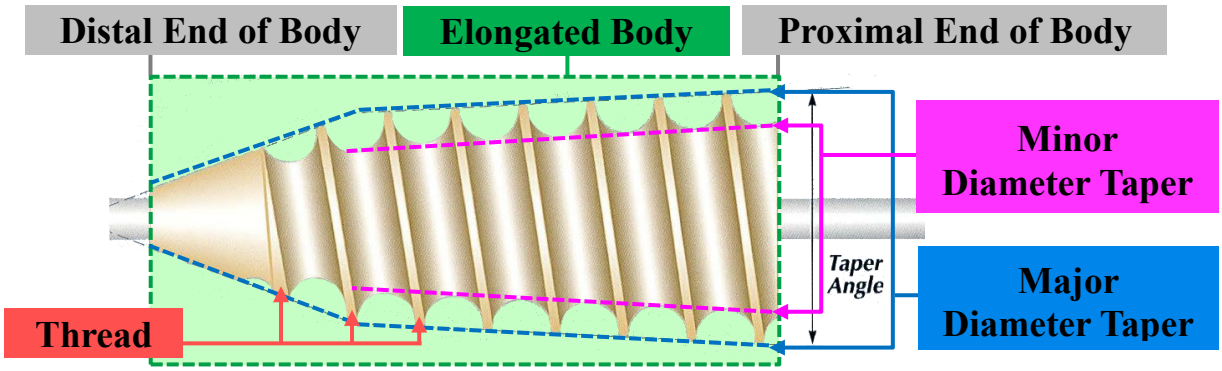
For the foregoing reasons, claim 1 would have been obvious over Endo-Fix if "body" is interpreted to be separate from the "tip." *See infra* § VII.B.

2. Claim 1 Is Unpatentable If "Body" Includes the "Tip"

Given that elements [pr.], [a3], [c1], and [c2] are unaffected by the interpretation of "body," those elements are disclosed by Endo-Fix for the reasons discussed in § IX.A.1 above. Elements [a1], [a2], [b1], and [b2], which are affected by the interpretation of "body," are addressed below.

a. "[a1] an elongated threaded body having a proximal end, a distal end, a length of about 35 mm. and a taper,"

For the same reasons discussed in § IX.A.1 above, Endo-Fix discloses a screw with an elongated threaded body having a proximal end, a distal end, and a taper. Even if the Board interprets "body" to include the "tip," then the distal end of the screw is the "distal end" of the body and the body length is the screw length. Beynnon ¶ 132; *see supra* § VII.A. The "proximal end" is unchanged. Beynnon ¶ 130; §§ VII.A, VII.B. The "body" (*i.e.*, screw) is elongated, threaded, and has a taper (*e.g.*, the body tapers at a first taper from the proximal end and changes to a second taper before reaching the distal end). Beynnon ¶ 133-35; *see also supra* § VII.D. The features of element [a1] are shown on the annotated figure from Endo-Fix below. Beynnon ¶ 132.



Endo-Fix discloses a screw (and hence a "body" under an interpretation in which the body includes the tip) that is 20 mm, 25 mm or 30 mm in length. For the same reasons already described in § IX.A.1.c above, it would have been obvious to modify the Endo-Fix screw so that it had a length of about 35 mm instead.

First, merely modifying a device's size is not "invention." *Powers-Kennedy*, 282 U.S. at 185. The '216 patent does not describe any criticality or unexpected result associated with a screw having a particular length of "about 35 mm." Beynnon ¶ 47, 148. Thus, the '216 patent fails to support a conclusion that 35 mm is patentably distinct from any other body length.

Second, a POSA knew that interference screws were provided in a range of lengths, with 35 mm within the range. Beynnon ¶ 138-47. Johnson discloses bioabsorbable interference screws ranging from "25 to 40 mm long" (Ex. 1026 at 3:51-58); Grooms discloses 8-70 mm interference screws (Ex. 1030 at 3:48-54, 2:9-11); Thramann discloses 15-60 mm interference screws (Ex. 1031 at 1:14-22, 8:51-53); Sgaglione discloses 15-40 mm interference screws (Ex. 1020 at 210);

and Petitioner's RCI FDA submission discloses 25-50 mm interference screws (Ex. 1029 at 3). The overlap between the range of screw lengths in the prior art and the claimed length of 35 mm renders 35 mm presumptively obvious, with nothing (*e.g.*, no alleged criticality or unexpected results) to rebut the presumption. *In re Peterson*, 315 F.3d at 1329; *Ormco*, 463 F.3d at 1311; *In re Applied Materials*, 692 F.3d at 1295; Beynnon ¶ 148.

Third, as discussed in § IX.A.1.c above, a POSA knew that screw length was a result-effective variable, with longer screws being more effective so long as they were not so long that they protruded from the tunnel. Beynnon ¶ 149-50. Given the known factors to consider and the narrow range of potential lengths, it would have been a matter of ordinary experimentation for a POSA to arrive at the claimed length. Beynnon ¶ 150-52. *In re Applied Materials*, 692 F.3d at 1295-96.

Fourth, the belief in the art that longer interference screws provided better fixation and integration alone would have rendered a 35 mm length obvious over Endo-Fix's 30 mm screw. A POSA's knowledge of longer interference screws (*see supra* § IX.A.1.c) would have given a POSA reason to lengthen the Endo-Fix screw, including to 35 mm. Beynnon ¶ 153. Where, as here, a POSA would have had a reason to try "a finite number of identified, predictable solutions," and would have had a reasonable expectation of success (here, with respect to a screw length of 35 mm) the claim is obvious. *KSR*, 550 U.S. at 421; Beynnon ¶ 153-54.

b. "[a2] the threads and the taper of the elongated threaded body extending along substantially the entire length of the elongated threaded body,"

Endo-Fix discloses threads along substantially a screw's entire length, the threads extend from the proximal end onto the tip, and the entire screw is tapered. Ex. 1011 at 2; Beynnon ¶ 156. The threads and taper are shown in the annotated figure in § IX.A.1.c above in connection with element [a1].

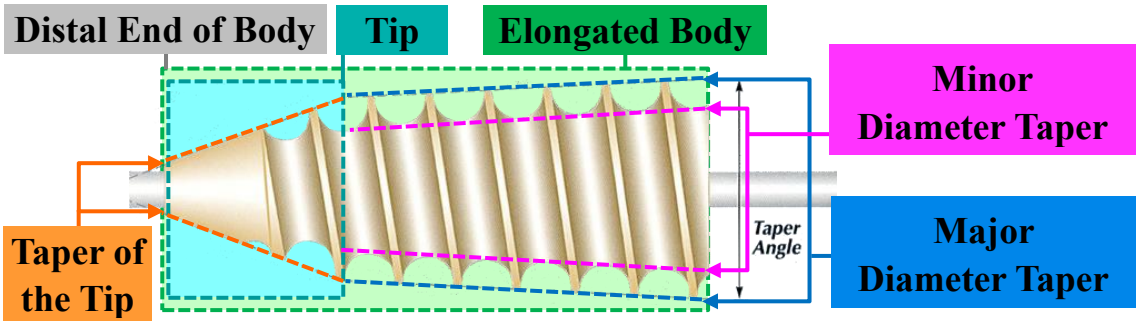
c. "[b1] a tip disposed of the distal end of the elongated body,"

As discussed in § VII.B above, the tip should be interpreted as distinct from the body. If the Board interprets the "body" to include the "tip," the "tip" remains at the distal end of the screw and is disclosed by Endo-Fix. Beynnon ¶ 162. The tip is illustrated in the annotated figure below in connection with element [b2].

d. "[b2] 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"

As discussed in section § VII.B above, the requirement that the tip's taper be greater than the taper of the elongated body supports an interpretation that the tip is distinct from the body. Even if the Board interprets the "body" as including the "tip," the taper of the Endo-Fix screw tip is greater (*i.e.*, steeper) than the taper of the more proximal portion of the body that is not the tip. Ex. 1011 at 2; Beynnon ¶ 165. The other limitations of element [b2] are met in the same manner discussed

in § IX.A.1.g above, and all of the limitations of element [b2] are met as shown on the annotated Endo-Fix figure below. Beynnon ¶ 165.



e. Conclusion: If "Body" Includes the "Tip"

For the foregoing reasons, claim 1 would have been obvious to a POSA over Endo-Fix, even if the "body" is interpreted as including the "tip."

3. Claim 2: "The bioabsorbable interference screw of claim 1, wherein the drive socket has a taper corresponding to the taper of the elongated threaded body."

Endo-Fix does not disclose its drive socket as tapered, but 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. Beynnon ¶ 175. For example, Stellin (Ex. 1040) discloses a tapered screw in which "the socket … is tapered inwardly … so that the metal thickness around the socket remains constant and the liability of breakage is practically eliminated." Ex. 1040 at 1 (left col. at 15-27), Figs. 4, 22; *see also* Ex. 1016 (Hannay) at 2:25-35 (the tapered socket "assur[es] a full thickness of material beneath all sections of the recess"); Ex. 1041 (Rieser) at 2:31-35, 2:48-55 (explaining that wall thickness

of a bioabsorbable interference screw is maintained by tapering the drive socket "in correspondence with the tapered outer profile of the device"); Beynnon ¶ 176-80. Stellin and Hannay are § 102(b) prior art and Rieser is § 102(e) prior art.

A POSA would have been motivated by the well-known benefit of a tapered drive socket to modify the Endo-Fix screw so that its drive socket has the same taper as the body of the screw in the drive socket area to maintain constant wall thickness and strength of the screw. *Randall Mfg. v. Rea*, 733 F.3d 1355, 1363 (Fed. Cir. 2013) ("[I]t is hard to see why one of skill in the art would not have thought to modify [prior art] to include this [known] feature—doing so would allow the designer to achieve the other advantages of the [prior art] assembly while using a [feature] that was very familiar in the industry."); Beynnon ¶ 176-82.

Modifying Endo-Fix to use a tapered drive socket would have been nothing more than "simple substitution of one known element for another," "combining previously known elements," and "the predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417-18 ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability."); Beynnon ¶ 182. Accordingly, claim 2 would have been obvious over Endo-Fix in light of the knowledge of a POSA of the well-known benefits of a tapered drive socket. Beynnon ¶ 183-84.

4. Claim 3: "The bioabsorbable screw of claim 1, wher[ei]n the screw is fully cannulated for receiving a guide pin."

The Endo-Fix screw is fully cannulated for receiving a guide pin. Ex. 1011 at 2-3 ("designed with a 1.5 mm (0.06") cannulation, permitting the use of a rigid guide wire"); Beynnon ¶ 187-88. A POSA would have understood that Endo-Fix's "rigid guide wire" is a guide pin. Beynnon ¶ 186; *see also* Ex. 1022 at 1009 (defining "guide pin" as "a pin or peg for aligning a tool or die properly with the work"). Claim 3 would have been obvious over Endo-Fix. Beynnon ¶ 189.

5. Claims 4-7: "The bioabsorbable interference screw of claim 1, wherein the screw tapers from a diameter of [x] mm. at the drive socket to a diameter of [less than x] at the tip."

Claims 4-7 depend from claim 1 and add diameters for the screw at its "drive socket" and "tip." The '216 patent states that the screw can be "preferably provided in four sizes" and discloses the specific combinations of tip and socket diameters recited in claims 4-7. Ex. 1002 at 3:19-27. All are consistent with tapered screws because the diameters at the tip are less than those at the drive socket (by 1.5 mm for claims 4-6 and by 2.5 mm for claim 7). The '216 patent does not describe any criticality or unexpected result of any of these value pairs. Beynnon ¶ 192. Indeed, the '216 patent's description of four different sizes as all being "preferred" reinforces that none provides a critical benefit or unexpected result. Beynnon ¶ 192. Claims 4-7 are thus obvious over Endo-Fix.

First, merely modifying a device's size is not an "invention." *Powers-*

Kennedy, 282 U.S. at 185. The '216 patent does not describe any criticality or unexpected result associated with any particular socket and tip diameters for the interference screw—let alone the particular diameters recited in claims 4-7. Beynnon ¶ 192. The '216 patent fails to support a conclusion that the claimed diameters are patentably distinct from any other diameters.

Second, a POSA knew that interference screws were provided in a range of socket and tip diameters that overlapped and subsumed the claimed diameters. *E.g.*, Ex. 1026 (Johnson) at 3:56-58 ("outer diameter … can be 5, 7, 9, 11 or 13 mm"); Ex. 1030 (Grooms) at 3:48-51 ("the bone screw may have a diameter between about 4 mm and about 12 mm, for ACL implant fixation"); Beynnon ¶ 193. Rego discloses an interference screw with a taper of 1-10 degrees to ensure that "insertional torque commences gradually and is lowest at the distal region." Ex. 1042 at 3:22-24; 4:40-47; Beynnon ¶ 195. Endo-Fix teaches a 9 mm screw, which a POSA would have understood to be the maximum diameter of the screw at the drive socket. Ex. 1011 at 2; Beynnon ¶ 195. Endo-Fix does not specify the degree of taper, but if a 1° taper as taught by Rego was used with an Endo-Fix screw having a 9 mm outer diameter and a body with a 35 mm length, *see* § IX.A.2.a above, the tip's proximal end would have a diameter of about 7.5 mm—as recited in claim 4. Beynnon ¶ 195. This is but one example, as the prior art discloses other diameters and resulting tapers that overlap with and subsume the

diameters recited in all of claims 4-7, thus rendering all the claimed diameter pairs presumptively obvious. Beynnon ¶ 194-200; *In re Peterson*, 315 F.3d at 1329; *Ormco*, 463 F.3d at 1311; *In re Applied Materials*, 692 F.3d at 1295. There is no criticality or unexpected results of any of the claimed diameter pairs to rebut the presumption. While the '216 patent describes a purported benefit of a tapered screw promoting an "interference fit" of 1.5 mm (3:27-40), none of the diameters pairs recited in claims 4-7 guarantees such an interference fit; and, conversely, such an interference fit can be achieved by many screw sizes not recited in claims 4-7. The "interference fit" described in the specification does not establish the patentability of any of the diameter pairs recited in claims 4-7. Beynnon ¶ 192.

Third, a POSA knew that socket and tip diameter, and a resulting taper, were result-effective variables that impacted fixation strength and insertion torque, the latter of which is important to limit for relatively weak bioabsorbable screws. Ex. 1034 (Hulstyn) at 419 (noting "higher insertional torques with increasing diameter"); Ex. 1015 (Weiler) at 123 (noting relationship between insertion torque and pull-out force for some screws), 126 (noting that screws fail at some amount of insertion torque); Ex. 1035 (Gerich) at 86 (finding grafts fixed with a 9 mm diameter screw to be significantly stronger than grafts fixed with a 7 mm diameter screw); Ex. 1011 at 2 ("conical design safeguards against screw fragmentation" because torque "increases gradually"). Beynnon ¶ 201-02. A POSA knew that

screw diameters could be varied to strike a desired balance between insertion torque and pull-out strength. Beynnon ¶ 203. Given the known factors to consider, and the relatively narrow range of potential socket and tip diameters, it would have been a matter of ordinary experimentation for a POSA to arrive at the claimed values. Beynnon ¶ 203. *In re Applied Materials*, 692 F.3d at 1295-96.

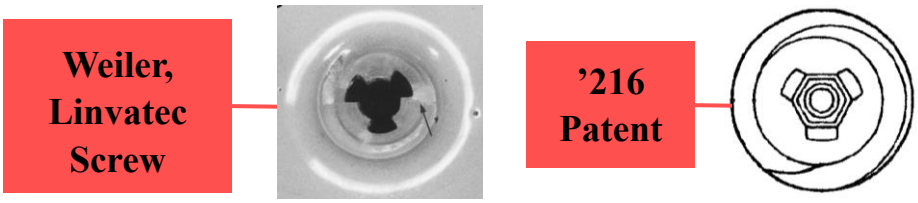
Fourth, where, as here, a POSA would have had a reason to try "a finite number of identified, predictable solutions," and would have had a reasonable expectation of success (here, with respect to socket and tip diameters of, respectively: 9 mm and 7.5 mm; 10 mm and 8.5 mm; 11 mm and 9.5 mm; and 12 mm and 9.5 mm) the claims would have been obvious. *KSR*, 550 U.S. at 421. Beynnon ¶ 205. Therefore, each of claims 4-7 would have been obvious over Endo-Fix in view of the knowledge of a POSA. Beynnon ¶ 190-206.

B. Ground 2: Endo-Fix In View of Weiler Renders Claims 1-7 Obvious

Weiler (Ex. 1015) was published in January 1998 (Ex. 1043), and is prior art to the '216 patent under 35 U.S.C. § 102 (b). As discussed in more detail below, Weiler discloses and describes advantages of a "trilobe" drive socket that includes only three slots for receiving only three driver protrusions and meets element [c2] even if the Board construes claim 1 to be limited to a drive socket with only three slots for receiving only three protrusions. Beynnon ¶ 207. Weiler would have given a POSA reason to modify the Endo-Fix drive socket with Weiler's "trilobe"

configuration. Beynnon ¶ 208. Thus, claims 1-7 would have been obvious over Endo-Fix in view of Weiler. Beynnon ¶ 207.

Weiler describes a study of six different biodegradable interference screws to compare performance in a number of categories, including insertion torque and maximum torque at which various types of drive sockets failed. Ex. 1015 at 119, 125, Figure 4; Beynnon ¶ 209. Among the screws evaluated was a Linvatec screw with a "trilobe" socket that Weiler identifies as a "Group 3" screw (labeled "C" in Fig. 4). Beynnon ¶ 210. As shown below, the trilobe socket has three grooves that extend outwardly from the center axis of the drive socket and are nearly identical to the three slots in the only drive socket embodiment in the '216 patent. Beynnon ¶ 210-11; Ex. 1015 Figure 4 at 125 (left); Ex. 1002 at Fig. 2 (right, with some reference characters and annotations removed).



Weiler compared the Linvatec "trilobe" drive socket screw to an "Acufex" screw (which Weiler identifies as a "Group 6" screw) that a POSA would have recognized as the screw described in Endo-Fix. Ex. 1015 at 121-22, 125; Beynnon ¶ 212. Weiler states that the Acufex/Endo-Fix screw (Group 6) failed at torques that "may present a risk of drive failure during screw insertion" and that torque

failure was "highly determined by the drive [and socket] design." Ex. 1015 at 126; Beynnon ¶ 214. In contrast, the trilobe socket (Group 3) withstood significantly higher torque before failure. Ex. 1015 at 126; Beynnon ¶ 215. A POSA 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." Ex. 1015 at 126; Beynnon ¶ 215.

Furthermore, Weiler reveals that numerous drive socket configurations were known, including a three-slot configuration. Beynnon ¶ 217. A POSA would have understood that any of these known drive sockets could have been used for the Endo-Fix screw, and that substituting the known trilobe socket described in Weiler for the Torx drive socket of Endo-Fix would have been a matter of design choice that would have yielded predictable results. *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008); *KSR*, 550 U.S. at 416 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.") (citation omitted). Beynnon ¶ 217. This provides an additional independent reason to modify Endo-Fix based on Weiler.

The interference screw to which a POSA would have been led by using the trilobe drive socket of Weiler in Endo-Fix would have met most of the elements of

claims 1-7 (*i.e.*, elements [pr.], [a1], [a2], [a3], [b1], and [b2] of claim 1, and all the elements of claims 2-7) in precisely the same manner as Endo-Fix alone does as discussed above in § IX.A in connection with Ground 1. Beynnon ¶ 218. The trilobe drive socket of Weiler would have met element [c1] because it is "a drive socket disposed within the screw and extending from the proximal end of the elongated threaded body." Beynnon ¶ 218; *see also supra* § VII.F. Additionally, the drive socket of Weiler would also have met element [c2], even if the Board construes claim 1 to be limited to only three slots. Beynnon ¶ 218. With respect to claim 2, which requires a tapered socket, it would have been obvious to taper the socket in the Endo-Fix/Weiler combination for the same reasons discussed in § IX.A.3 above regarding the Endo-Fix socket. Beynnon ¶ 218. Thus, claims 1-7 would have been obvious over Endo-Fix in view of Weiler, even under a narrower interpretation of "radially-extending slots" in claim 1. Beynnon ¶ 220.

C. Ground 3: Simon Renders Claims 1-7 Obvious

Simon (Ex. 1012) is a U.S. Patent that issued on April 6, 1999, and is prior art to the '216 patent under 35 U.S.C. § 102(b), if the Board finds that the '216 patent is not entitled to the priority date of the provisional (*see supra* § VI.C), and under § 102(a) and (e) otherwise. Simon discloses a tapered bioabsorbable interference screw for ACL reconstruction and has a slotted drive socket. *Id.* at 1:5-9, 1:36-41, 4:17-22. Simon discloses every limitation of claim 1 of the '216

patent, except the limitation that the "body" have a "length of about 35 mm." Beynnon ¶ 221. Claim 1 would have been obvious over other embodiments disclosed in Simon, but this Petition focuses on the "sixth embodiment," which is depicted in Figs. 19-22. As described in § VII.B above, Arthrex may dispute whether the "tip" is part of or separate from the "body." Below, Petitioners show that claims 1-7 would have been obvious over Simon regardless.

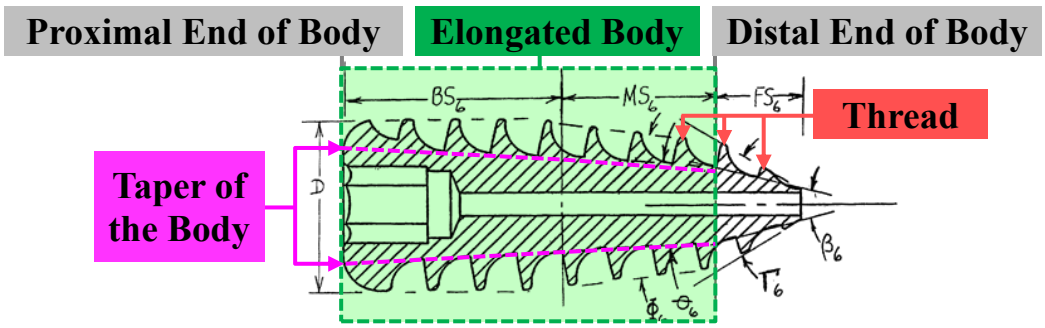
1. Claim 1 is Unpatentable If "Body" Is Separate from "Tip"

a. "[pr.] A bioabsorbable interference screw for ACL reconstruction, comprising:"

Simon discloses "an orthopedic interference screw for use in ACL reconstruction" that is made from a "bio-absorbable material." Ex. 1012 at 1:36-41, 2:25-27, 4:17-22; Beynnon ¶ 224; *see also* Ex. 1012 at 6:40-43, 7:13-16.

b. "[a1] an elongated threaded body having a proximal end, a distal end,… and a taper,"

Simon's Fig. 22 is annotated below to show the elongated body (boxed with the green dashed line), the proximal end of the body, the distal end of the body, the thread, and the taper (indicated with magenta dashed lines). Beynnon ¶ 226.



The "body" is the portion of the screw extending from the proximal end of the screw and ending before the "tip." Ex. 1012 at Figs. 19, 22; Beynnon ¶ 226; *see supra* §§ VII.A, VII.B. The body is elongated, tapered (*e.g.*, the minor or "root" diameter decreases gradually along the MS and BS sections as shown in magenta in the annotated drawing above), and threaded (*i.e.*, the thread extends along the body). Ex. 1012 at 2:27-30 (the "screw thread is formed over substantially all of [the screw]"), 3:54-57 (describing a "root taper angle" along the body), 6:40-43 (describing the fifth embodiment screw's "elongated root portion"), 7:13-16 (explaining that the sixth embodiment is "very similar to the fifth embodiment"), Figs. 19, 22; Beynnon ¶ 228-30.

c. "[a1] an elongated threaded body having… a length of about 35 mm"

Simon does not disclose any specific screw or body length. Beynnon ¶ 232. A POSA would have understood that this is because the Simon screw is not limited to any particular size and can be provided in any suitable length, including any known interference screw length. Beynnon ¶ 232. As with the Endo-Fix screw discussed in § IX.A.1.c above, it would have been obvious to a POSA to provide the Simon screw with a 35 mm body length for numerous reasons. Beynnon ¶ 232.

First, identifying a particular size for the screw body is not patentable. *Powers-Kennedy*, 282 U.S. at 185 ("[A] mere change in proportion would involve no more than mechanical skill and would not amount to invention."); *Ex Parte*

Asiatico, 2015 WL 1522469, at *2 ("[I]t is well established that size is not ordinarily a patentable feature."). Beynnon ¶ 47.

Second, the length of the screw body is a result-effective variable and it would have been a matter of ordinary experimentation for a POSA to arrive at the claimed body length. *See supra* § IX.A.1.c; *In re Applied Materials*, 692 F.3d at 1295-96 ("'[D]iscovery of an optimum value of a result effective variable... is ordinarily within the skill of the art.'" (quotation omitted)); Beynnon ¶ 233.

Third, a POSA would have had reason to implement the Simon screw with a 35 mm body length because 35 mm was one of a relatively narrow range of appropriate body lengths. *See supra* § IX.A.1.c; *KSR*, 550 U.S. at 421 (trying "a finite number of identified, predictable solutions" with a reasonable expectation of success is obvious), 417 (finding obvious the use of a known technique to improve a similar device); Beynnon ¶ 234.

Fourth, the prior art discloses a range of screw body lengths that overlaps with and subsumes the claimed 35 mm body length, rendering the claimed length *prima facie* obvious, and the presumption of obviousness is not rebutted given that the prior art did not teach away from a 35 mm body, this length was not "critical," and did not "produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art." *In re Applied Materials*, 692 F.3d at 1297 (citation omitted); *see supra* § IX.A.1.c; Beynnon ¶ 235.

The ’216 patent’s specification identifies no unexpected property of a screw with a 35 mm body. Beynnon ¶ 148, 235. The beneficial results of a longer screw securing a larger portion of the ligament were well known in the art, and filling all but 5-10 mm of the tibial tunnel is not ensured by the claimed 35 mm body length and requires matching the screw length to the size of the tunnel. Beynnon ¶ 148, 235; *see supra* § IX.A.1.c. The presumption of obviousness is not overcome. *Id*.

d. “[a2] the threads and the taper of the elongated threaded body extending along substantially the entire length of the elongated threaded body,”

Simon discloses (*e.g.*, Fig. 22) that the threads and the taper both extend along substantially the entire length of the elongated threaded body. Ex. 1012 at 2:27-30 (“screw thread is formed over substantially all of” the screw), 3:54-57 (describing a “root taper angle” along the body), Figs. 19, 22; Beynnon ¶ 237.

e. “[a3] the proximal end of the screw being configured to provide an interference fit of up to 1.5 mm in a bone tunnel;”

As discussed in § VII.E above, this limitation is met by a screw with a proximal end having a diameter “configured” to exceed the diameter of a bone tunnel by any amount up to 1.5 mm. Simon does not disclose any specific screw diameters. However, a POSA 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. Beynnon ¶ 239. Given that claim 1 is not a method claim, nothing further is required to meet this limitation under the BRI. Beynnon ¶ 239; *see supra* § VII.E. Thus, a POSA 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. Beynnon ¶ 239.

Furthermore, as discussed in § IX.A.1.e above, the '216 patent's specification and other evidence establishes that it was known that "[b]ioabsorbable interference screws are usually sized so that they are slightly larger tha[n] the diameter of the tunnel." Ex. 1002 at 1:33-35; Beynnon ¶ 240. A POSA also would have understood that tapering Simon's screw facilitated insertion into spaces or bone tunnels having a diameter smaller than the screw's proximal end and allowed for "compression anchoring a bone graft in a bore formed in a bone mass." Ex. 1012 at Abstract; Beynnon ¶ 240. A POSA would have understood the proximal end of Simon's screw to be "configured," under the BRI, to have a diameter that exceeds the diameter of a bone tunnel for these additional reasons. Beynnon ¶ 241.

f. "[b1] a tip disposed of the distal end of the elongated body,"

A POSA would have understood Simon's front section FS_6 to be a tip disposed of the distal end of the elongated body because it starts at the screw's distal end, increases in diameter proximally, and terminates where the taper of the

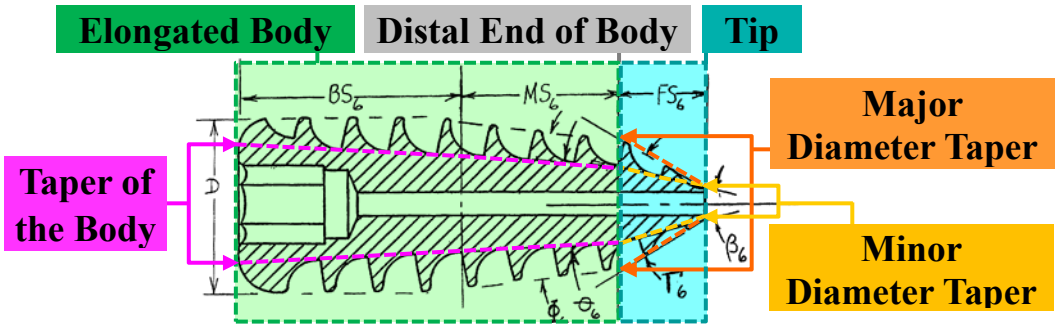
screw changes (at the transition to middle section MS_6) to a lesser taper. Ex. 1012 at Fig. 22; Beynnon ¶ 242; *see supra* § VII.A.

g. "[b2] 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"

Simon's tip is threaded because the thread extends onto the tip. Ex. 1012 at 6:51-53 ("The screw thread 84… in the front section FS_5"), 7:13-14, Figs. 19, 22; Beynnon ¶ 248; *see supra* § VII.C. As shown in Fig. 22 reproduced below, Simon's tip has a taper (of both the root and the major thread diameter) that is greater (*i.e.*, steeper) than the taper of the elongated threaded body. Ex. 1012 at 6:49-51[4] (describing the fifth embodiment: "[T]he front section FS_5… is uniformly tapered… in the range of 30° to 40°."), 4:42-43 (describing the third embodiment: "the root taper angle θ_2 is 6°"), 7:3-6 (BS_5 is same as the back section in the third embodiment), 7:13-16 (explaining that the sixth embodiment is a longer version of the fifth embodiment), Figs. 19, 22; Beynnon ¶ 245. A POSA would have understood that the tapered tip makes the screw easily insertable in a bone tunnel because the tip guides the screw into the tunnel and requires less torque to advance the screw into the tunnel. Ex. 1012 at 5:19-22, 8:31-34;

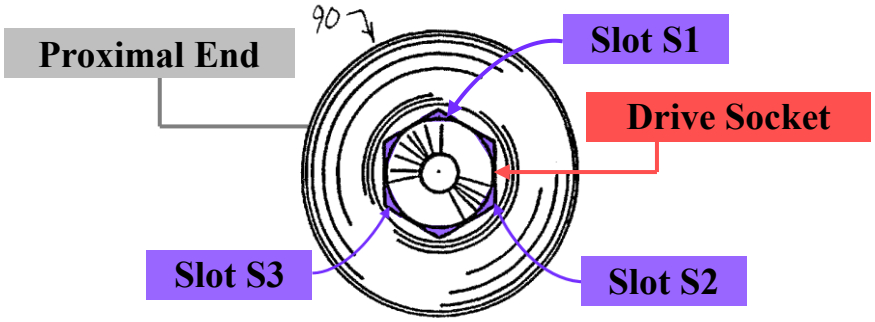
[4] Citations to front section FS_5 of the fifth embodiment of Figs. 15-18 apply to the "very similar" sixth embodiment of Figs. 19-22. Ex. 1012 at 7:13-25.

Beynnon ¶ 247. Simon's Fig. 22 is annotated below to show the tip with a root taper (indicated with the yellow dashed lines) and a crest taper (indicated with the orange dashed lines) that is greater than the root taper of the elongated body (indicated with the magenta dashed lines). Beynnon ¶ 245.



h. "[c1] a drive socket disposed within the screw and extending from the proximal end of the elongated threaded body,"

Simon's drive socket (shown in Figs. 20 and 22 and described in connection with Simon's "second embodiment" that employs the same drive socket as the sixth embodiment) is disposed within the screw and extends from the proximal end of the elongated body. Ex. 1012 at 4:57-58; Beynnon ¶ 250. Fig. 20 is reproduced below and annotated to show slots highlighted in purple. Beynnon ¶ 250, 252.



i. "[c2] wherein the drive socket has radially-extending slots for receiving a driver having three radially-extending protrusions corresponding to the slots."

The six corners of Simon's hex drive socket (highlighted in purple in the figure above in connection with element [c1]) are radially extending slots, as a POSA would have understood them to be grooves in the drive socket that extend outwardly from a center axis of the drive socket. Beynnon ¶ 252; *see supra* § VII.F. The hex drive socket receives a matching driver with six corresponding protrusions. Ex. 1012 at 5:42-44 (disclosing "a tool 56 having a hex-shaped driving end thereon which is receivable into the respective hex-shaped socket"); Beynnon ¶ 252.

As discussed in § IX.A.1.i above, if the Board holds Patent Owner to its litigation position that the claims are broad enough to cover drive sockets with more than three slots to receive more than three protrusions under the BRI, then Simon discloses element [c2]. If claim 1 is interpreted as excluding drive sockets with more than three slots to receive more than three protrusions, the claims are obvious over Simon in view of Weiler for the reasons stated in Ground 4.

j. Conclusion: If "Body" Is Separate from "Tip"

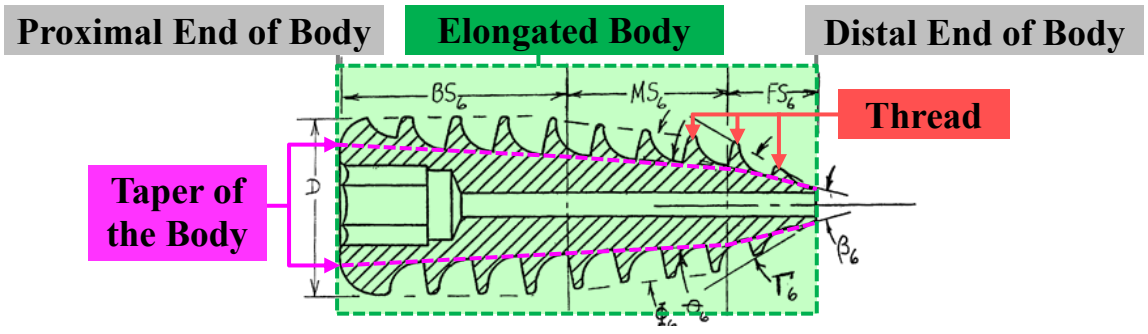
For the foregoing reasons, claim 1 would have been obvious over Simon when interpreting the "body" as separate from the "tip."

2. Claim 1 is Unpatentable If "Body" Includes the "Tip"

Elements [pr.], [a3], [c1], and [c2] are unaffected by the interpretation of "body" and met by Simon for the reasons discussed in § IX.C.1 above. Elements [a1], [a2], [b1], and [b2], are affected by the interpretation of "body" and met as shown below.

a. "[a1] an elongated threaded body having a proximal end, a distal end, a length of about 35 mm. and a taper,"

For the same reasons discussed in § IX.C.1 above, Simon discloses a screw with an elongated threaded body having a proximal end, a distal end, and a taper. If the Board interprets "body" to include the "tip," then the distal end of the "tip" is the "distal end" of the body and of the screw, and the body length is the screw length. Beynnon ¶ 227; *see supra* § VII.A. The "proximal end" is unchanged, and the "body" is the entire screw. Beynnon ¶ 225; *see supra* § VII.A, § VII.B. The "body" is elongated, threaded (*i.e.*, threads extend along the body) and has a taper (*e.g.*, the minor diameter decreases gradually along the screw). Ex. 1012 at Figs. 19, 22 (annotated below); Beynnon ¶ 228-30.



Simon does not describe the body of the screw as being about 35 mm long. For reasons similar to those discussed in § IX.C.1.c above, it would have been obvious to a POSA to provide the Simon screw in a length of 35 mm. A POSA 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. Beynnon ¶ 232. It would have been obvious to a POSA to provide the Simon screw in a 35 mm length for numerous reasons. Beynnon ¶ 232.

First, reciting a particular size for the screw does not render the claims patentable. *Powers-Kennedy*, 282 U.S. at 185 ("[A] mere change in proportion would involve no more than mechanical skill and would not amount to invention."); *Ex Parte Asiatico*, 2015 WL 1522469, at *2. Beynnon ¶ 47.

Second, given that the prior art discloses a range of screw lengths that overlaps with and subsumes the claimed 35 mm length, the claimed length is *prima facie* obvious, and the presumption of obviousness is not rebutted given that the prior art did not teach away from a 35 mm screw, this length was not "critical" and did not "produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art." *In re Applied Materials*, 692 F.3d at 1297 (citation omitted); *see supra* § IX.A.1.c; Beynnon ¶ 235.

The '216 patent's specification identifies no unexpected property of a screw with a 35 mm length. Beynnon ¶ 148, 235. The beneficial results of a longer

screw securing a larger portion of the ligament were well known in the art, and filling all but 5-10 mm of the tibial tunnel is not ensured by the claimed 35 mm screw length but instead requires matching the screw length to the size of the tunnel. *See* § IX.A.1.c *supra*; Beynnon ¶ 148, 235. The presumption of obviousness is not overcome. *See supra* § IX.A.1.c.

Third, a POSA would have known that the length of the screw body is a result-effective variable and it would have been a matter of ordinary experimentation for a POSA to arrive at the claimed screw length. *See supra* § IX.A.1.c ; *In re Applied Materials*, 692 F.3d at1295-96; Beynnon ¶ 233.

Fourth, a POSA would have had reason to implement the Simon screw with a 35 mm length as one of a relatively narrow range of appropriate body lengths. *See supra* § IX.A.1.c; *KSR*, 550 U.S. at 421 (finding obvious trying "a finite number of identified, predictable solutions" with a reasonable expectation of success); Beynnon ¶ 234.

b. "[a2] the threads and the taper of the elongated threaded body extending along substantially the entire length of the elongated threaded body,"

Simon's threads extend along substantially the entire length of the body (*i.e.*, of the screw). Ex. 1012 at Figs. 19, 22; Beynnon ¶ 238; *see supra* § IX.C.1.d. Simon's taper extends along substantially the entire length of the body (*i.e.*, of the screw), and is a complex taper like the embodiment of the '216 patent (Ex. 1002 at

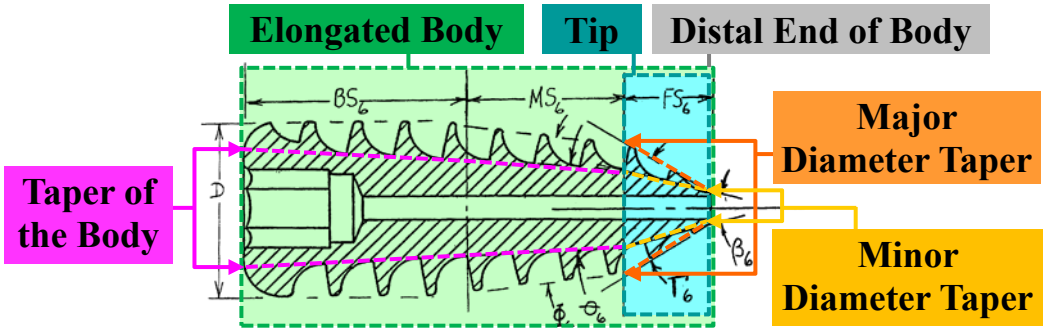
3:11-18) in that different taper angles extend over different sections of the screw. Ex. 1012 at Figs. 19, 22; Beynnon ¶ 238; *see supra* § IX.C.1.d.

c. "[b1] a tip disposed of the distal end of the elongated body,"

If "body" is interpreted as including the "tip," the "tip" is the distal end of the body so this limitation is met by Simon. Beynnon ¶ 243. The tip is illustrated in § IX.C.2.d below, in connection with element [b2].

d. "[b2] 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"

As discussed in section § VII.B above, the requirement that the tip taper be greater than the taper of the elongated body supports the tip being distinct from the body. However, if the Board interprets the "body" as including the "tip," the taper of Simon's tip is greater (*i.e.*, steeper) than the taper of the other portions of the body. Ex. 1012 at Figs. 19, 22; Beynnon ¶ 246. The other limitations of element [b2] are met in the same manner discussed in § IX.A.1.g above. Simon's Fig. 22 is annotated below to show the tip with a root taper (indicated with the yellow dashed lines) and a crest taper (indicated with the orange dashed lines) that is greater than the root taper of the elongated body (indicated with the magenta dashed lines).



e. Conclusion: If "Body" Includes the "Tip"

For the foregoing reasons, claim 1 would have been obvious to a POSA over Simon if the "body" is interpreted as including the "tip."

3. Claim 2: "The bioabsorbable interference screw of claim 1, wherein the drive socket has a taper corresponding to the taper of the elongated threaded body."

Simon discloses a drive socket, but does not describe the drive socket as tapering. Beynnon ¶ 255. As discussed in § IX.A.3 above and demonstrated by the evidence cited therein, it was well known to provide a tapered screw with a drive socket that had a corresponding taper to maintain the thickness and strength of the screw wall in the area of the drive socket. Beynnon ¶ 175-183, 255. A POSA would have been motivated by this well-known teaching to modify the Simon screw to include a drive socket that tapers along with the body of the screw to maintain constant screw wall thickness in the area of the drive socket. Beynnon ¶ 181, 255; *see supra* § IX.A.3 and the caselaw cited therein. In addition, modifying Simon to use a tapered drive socket would have been nothing more than a "simple substitution of one known element for another," the result of "combining

previously known elements," and "the predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417-18; *Randall Mfg.*, 733 F.3d at 1363; Beynnon ¶ 256. For the foregoing reasons, claim 2 would have been obvious over Simon in light of the knowledge of a POSA. Beynnon ¶ 257.

4. Claim 3: "The bioabsorbable screw of claim 1, wherien [sic] the screw is fully cannulated for receiving a guide pin."

The Simon screw is fully cannulated for receiving a guide pin. Ex. 1012 at 2:16-22 ("[T]he screws [are] cannulated to facilitate installation of the respective screws utilizing a guide wire…."), Fig. 22; Beynnon ¶ 258. A POSA would have understood that "guide wire" and "guide pin" are synonymous and that Simon's "guide wire" is a guide pin. Beynnon ¶ 186, 255; *see* Ex. 1022 at 1009 (defining "guide pin" as "a pin or peg for aligning a tool or die properly with the work"). Claim 3 would have been obvious over Simon. Beynnon ¶ 239.

5. Claims 4-7: "The bioabsorbable interference screw of claim 1, wherein the screw tapers from a diameter of [x] mm. at the drive socket to a diameter of [less than x] mm. at the tip."

Claims 4-7 depend from claim 1 and each adds specific diameter measurements for the claimed screws at their "drive sockets" and at their "tips." As discussed in § IX.A.5 above, the '216 patent states that the screw can be "preferably provided in four sizes" and recites different combinations of diameters for the screw at the tip and socket, but does not describe any criticality or any

unexpected result of having the tapered screw's diameters at the tip and drive socket take any of these particular values. Beynnon ¶ 192, 260. Each of claims 4-7 would have been obvious to a POSA in view of Simon for numerous reasons. Beynnon ¶ 265-66.

First, merely modifying a device's size is not an "invention." *Powers-Kennedy*, 282 U.S. at 185. The '216 patent does not describe any criticality or unexpected result associated with any particular socket and tip diameters for the interference screw—let alone the particular diameters recited in claims 4-7. Beynnon ¶ 192. Thus, the '216 patent fails to support a conclusion that the claimed diameters are patentably distinct from any other diameters.

Second, as discussed in § IX.A.5 above, the prior art discloses a range of diameters and resulting tapers that overlap with and subsume the claimed diameters, thereby rendering the claimed diameters *prima facie* obvious. *In re Peterson*, 315 F.3d at 1329 ; *In re Applied Materials*, 692 F.3d at 1295; *e.g.*, Ex. 1026 (Johnson) at 3:56-58; Ex. 1030 (Grooms) at 3:48-51; Ex. 1042 at 3:22-24; 4:40-47; Beynnon ¶ 261. As further discussed in § IX.A.5 above, that presumption of obviousness is not overcome.

Third, as discussed in § IX.A.5 above, a POSA would have known that the diameters, and the tapers they create, are result-effective variables, so that it would have been nothing more than routine experimentation to find optimal values for

them in Simon's tapered screw. *In re Applied Materials*, 692 F.3d at1295-96; *In re Boesch*, 617 F.2d at 276; *e.g.*, Ex. 1035 (Gerich) at 86; Ex. 1034 (Hulstyn) at 419; Ex. 1015 (Weiler) at 123; Beynnon ¶ 263.

In view of the foregoing, each of claims 4-7 would have been obvious over Simon as viewed with the general knowledge of a POSA. Beynnon ¶ 266.

D. Ground 4: Simon in View of Weiler Renders Claims 1-7 Obvious

As discussed in § IX.B above, Weiler describes advantages of a trilobe drive socket that meets element [c2] even if claim 1 is construed to be limited to a drive with only three slots for receiving only three protrusions. Weiler compared the "trilobe" drive socket with an Arthrex screw having a "hexagonal drive" socket (Weiler identifies as Group 1) of the type disclosed by Simon. Ex. 1015 at 121-122; Figure 1B; Beynnon ¶ 268. Weiler concluded that the screw with hex drive socket (Group 1) failed at the driver-screw interface (see Figure 4 A) at torques that "may present a risk of drive failure during screw insertion" and that torque failure was "highly determined by the drive design." Ex. 1015 at 125-126; Beynnon ¶ 269. The trilobe socket (Group 3) withstood significantly higher torque before failure. Ex. 1015 at 126; Beynnon ¶ 269. Because Simon uses a hex drive socket like the Arthrex Group 1 screw (Ex. 1012 at 4:57-58, Figs. 20, 22; Ex. 1015 at 122), a POSA would have expected the trilobe socket to improve Simon's hex drive socket. Beynnon ¶ 269-70. Therefore, Weiler would have motivated a POSA

to modify Simon's hex drive socket to use the trilobe socket to increase the insertion torque that could be applied to the screw and address Weiler's concerns about "drive failure during screw insertion." Ex. 1015 at 126; Beynnon ¶ 269-270.

In addition, Weiler shows that numerous socket configurations were known, including the three-slot configuration recited in claim 1. Beynnon ¶ 270. A POSA would have understood that any of these known sockets could have been used in the Simon screw, and that substituting the known trilobe socket of Weiler for the hex socket of Simon would have been a matter of design choice that would yield predictable results. Beynnon ¶ 217, 270; *see supra* § IX.B and the cases cited therein. This provides an additional reason for modifying Simon based on Weiler.

An interference screw that a POSA would have been led to by substituting the trilobe drive socket of Weiler for Simon's hex drive socket would have met most of the elements of claims 1-7 (*i.e.*, elements [pr.], [a1], [a2], [a3], [b1], and [b2] of claim 1, and all the elements of claims 2-7) in precisely the same manner as Simon alone meets them as discussed in § IX.A above in connection with Ground 3. Beynnon ¶ 271. Elements [c1] and [c2] would have been met by the trilobe drive socket, which would have met element [c1] because it is "a drive socket disposed within the screw and extending from the proximal end of the elongated threaded body." Beynnon ¶ 271; *supra* § VII.F. The trilobe drive socket also would have met element [c2], regardless of whether the Board construes claim 1 to

require slots to receive only three radially-extending protrusions or three or more such protrusions. Beynnon ¶ 271. With respect to claim 2, which requires a tapered socket, it would have been obvious to taper the socket in the Simon/Weiler combination for the same reasons discussed in § IX.C.3 above re the Simon socket. Beynnon ¶ 271. For the foregoing reasons, claims 1-7 would have been obvious over Simon in view of Weiler.

E. Ground 5: EP '459 Application Renders Claims 1-7 Obvious

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). Beynnon ¶ 272. Accordingly, 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. *See LizardTech v. Earth Res. Mapping,* 424 F.3d 1336, 1345 (Fed. Cir. 2005) (the specification "must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, *i.e.*, that the patentee invented what is claimed"); *SAP Am. v. Arunachalam*, IPR2014-00414, Paper 11 at 13 (PTAB Aug. 17, 2015) (instituting over objection that assessing priority exceeds the Board's authority); *id.*, Paper 24 at 21 (Aug. 17, 2015) ("A review of the disclosure for purposes of identifying the priority date for the claimed subject matter is appropriate and within the scope of *inter partes* review."); *FedEx v. IpVentures,*

IPR2014-00833, Paper 14 at 20-22 (PTAB Dec. 3, 2014). The EP '459 application published on May 23, 2001 and is § 102(b) prior art to the '216 patent. Ex. 1014 at [43]. As shown in the claim chart below, that application, which shares a specification with the '216 patent, expressly discloses all elements of the claims of the '216 patent, except a 35 mm "body." Beynnon ¶ 273. For the reasons stated above in section IX.A.1.c, a 35 mm body would have been obvious to a POSA. Beynnon ¶ 273.

U.S. Patent No. 6,875,216	**EP '459 Application**
[pr.] 1. A bioabsorbable interference screw for ACL reconstruction, comprising:	*E.g.*, Ex. 1014 at (57), [0009-10], [0014], and claim 1.
[a1] an elongated threaded body having a proximal end, a distal end, a length of about 35 mm. and a taper,	*E.g.*, *id.* at Fig. 1, [0014], [0016], and claim 1.
[a2] the threads and the taper of the elongated threaded body extending along substantially the entire length of the elongated threaded body,	*E.g.*, *id.* at Fig. 1, [0014], and claim 1.
[a3] the proximal end of the screw being configured to provide an interference fit of up to 1.5 mm. in a bone tunnel;	*E.g.*, *id.* at [0018], [0021], and claim 1.
[b1] a tip disposed of the distal end of the elongated body,	*E.g.*, *id.* at Figs. 1 and 3, [0016], and claim 1.
[b2] 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	*E.g.*, *id.* at Figs. 1 and 3, [0016], and claim 1.
[c1] a drive socket disposed within the screw and extending from the proximal end of the elongated threaded body,	*E.g.*, *id.* at Figs. 1 and 2, [0015], and claim 1.

U.S. Patent No. 6,875,216	EP '459 Application
[c2] wherein the drive socket has radially-extending slots for receiving a driver having three radially-extending protrusions corresponding to the slots.	*E.g.*, *id.* at Figs. 1 and 2, [0015], and claims 1 and 2.
2. The bioabsorbable interference screw of claim 1, wherein the drive socket has a taper corresponding to the taper of the elongated threaded body.	*E.g.*, *id.* at Figs. 1, 2, 5A, and 5B, [0015], [0020], and claim 3.
3. The bioabsorbable screw of claim 1, wherien [sic] the screw is fully cannulated for receiving a guide pin.	*E.g.*, *id.* at Fig. 1, [0008], [0010], and claim 4.
4. The bioabsorbable interference screw of claim 1, wherein the screw tapers from a diameter of 9 mm. at the drive socket to a diameter of 7.5 mm. at the tip.	*E.g.*, *id.* at [0017] and claim 5.
5. The bioabsorbable interference screw of claim 1, wherein the screw tapers from a diameter of 10 mm. at the drive socket to a diameter of 8.5 mm. at the tip.	*E.g.*, *id.* at [0017] and claim 6.
6. The bioabsorbable interference screw of claim 1, wherein the screw tapers from a diameter of 11 mm. at the drive socket to a diameter of 9.5 mm. at the tip.	*E.g.*, *id.* at [0017] and claim 7.
7. The bioabsorbable interference screw of claim 1, wherein the screw tapers from a diameter of 12 mm. at the drive socket to a diameter of 9.5 mm. at the tip.	*E.g.*, *id.* at [0017] and claim 8.

X. CONCLUSION

Inter partes review and cancellation of claims 1-7 of U.S. Patent No. 6,875,216 under 35 U.S.C. § 311 and 37 C.F.R. § 42.101 is requested.

Dated: March 30, 2016

/Richard F. Giunta /
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CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6 (e)(4)

I certify that on March 30, 2016, I will cause a copy of the foregoing document, including any exhibits or appendices referred to therein, to be served via Priority Overnight FedEx upon the attorney of record for the patent at the following address:

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Dated: March 30, 2016

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