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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. 6,629,977

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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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1060	Donald T. Reilly et al., *The Mechanical Properties of Cortical Bone*, 56-A(5) J. Bone & Joint Surgery 1001 (July 1974) ("Reilly")
1061	R. Van Audekercke & M. Martens, *Mechanical Properties of Cancellous Bone, in* Natural Living Biomaterials (Boca Raton, Fla. CRC Press. 1984) ("Van Audekercke")
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 1-6 of U.S. Patent No. 6,629,977 ("the '977 patent").

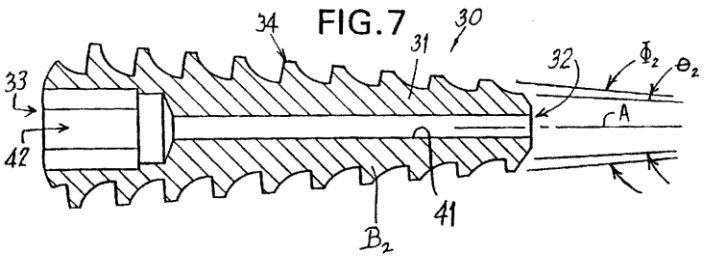
I. INTRODUCTION

The '977 patent (Ex. 1001) is directed to a method of using an interference screw for anterior cruciate ligament (ACL) reconstruction, which involves drilling tunnels in the tibia and femur where the ACL was formerly attached, and then securing the ends of a graft inside the tunnels to replace the ACL. The '977 patent claims cover a method of securing the graft in the "tibial tunnel" with an interference screw that is inserted into the tunnel and secures the graft therein via an "interference fit."

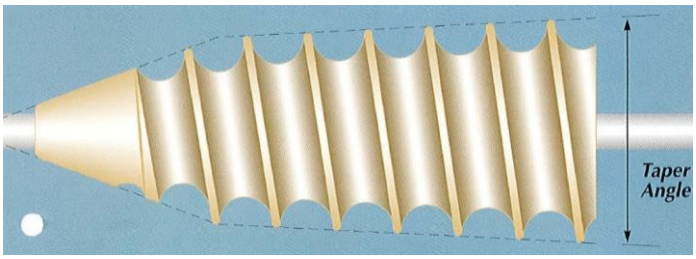
As the '977 patent concedes, ACL reconstruction using interference screws in this way was conventional. What the specification describes as purportedly being novel is a particular type of interference screw (*i.e.*, a tapered bioabsorbable interference screw with threads along substantially its entire length), and the use of that "new" screw in conventional ACL reconstruction. However, neither a tapered bioabsorbable interference screw with threads along substantially its entire length nor its use in ACL reconstruction was new.

U.S. Patent 5,891,146 (Ex. 1012, "Simon") describes ACL reconstruction using a tapered bioabsorbable interference screw with threads along substantially

its entire length and forms the basis for Grounds 1-2. Ex. 1012 at Fig. 7:



A sales brochure from 1995 (three years before the earliest alleged priority date of the ’977 patent) describes screws that a subsidiary of Petitioner S&N commercialized for use in ACL reconstruction. Ex. 1011 (“Endo-Fix”). Endo-Fix describes a tapered bioabsorbable interference screw with threads along substantially its entire length and forms the basis for Grounds 3-4. *Id*. at 2:



The Simon (Grounds 1-2) and Endo-Fix (Grounds 3-4) screws were used in the conventional ACL reconstruction procedure recited in the ’977 claims. Each renders obvious both of the independent claims of the ’977 patent and most of the dependent claims. One or two (depending on a claim interpretation issue) dependent claims recite specific features of a particular drive socket disclosed in the ’977 patent. That drive socket was known. Secondary references that disclose the claimed drive socket and provide motivation for using it in Simon and Endo-Fix provide the bases for Grounds 2 and 4.

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 concurrently filing petitions for *inter partes* review of U.S. Patent Nos. 6,875,216 (which purports to be a divisional of the '977 patent) and 7,322,986 (a continuation of the '216 patent). For efficiency and consistency, Petitioners request that the Board assign a single panel to address these three IPR 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 - § 42.8(b)(3) and (4)

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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 additional fees are due during this proceeding, the Office is authorized to charge Deposit Account No. 23/2825.

IV. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify (37 C.F.R. § 42.104(a)) that the '977 patent is available for IPR and that they are not barred or estopped from requesting IPR of the '977 patent. Arthrex previously asserted the '977 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. *See, e.g.*, *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 1-6 of the '977 patent as follows:

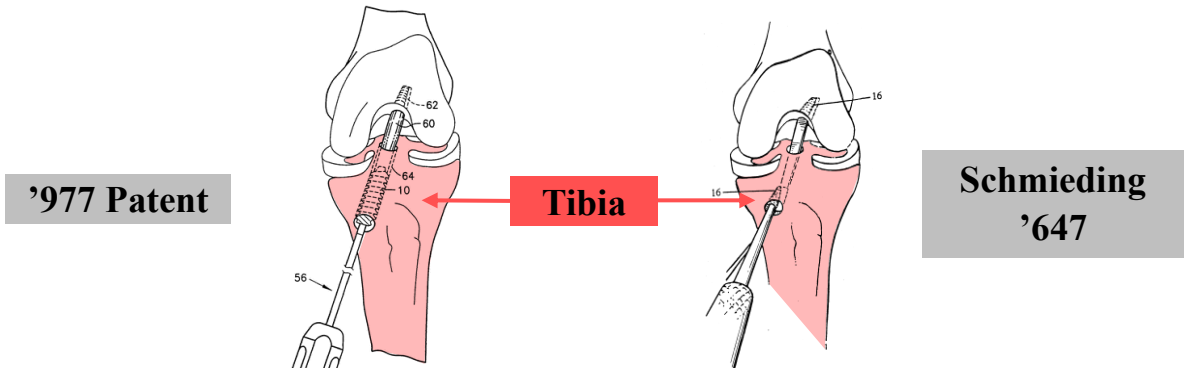
Ground Number and Reference(s)		Claims	Basis
1	Simon	1-2, 4-6	§ 103(a)
2	Simon in view of Weiler and Hannay	2-3	§ 103(a)
3	Endo-Fix	1-2, 4-6	§ 103(a)
4	Endo-Fix in view of Weiler and Hannay	2-3	§ 103(a)

VI. OVERVIEW OF THE '977 PATENT

The '977 patent claims all recite a "method of interference fixation for ACL reconstruction using a bioabsorbable interference screw." Ex. 1001 at claim 1.

A. History of the Technology

Injuries to the ACL, a ligament connecting the tibia and femur, are common. Ex. 1017; Beynnon ¶ 21, 23. By the late-1990s, before the alleged invention, ruptured ACLs were often reconstructed using a replacement graft of biological tissue. Ex. 1018 at 1561-62; Beynnon ¶ 31. ACL reconstruction typically involved drilling holes in the femur and tibia at the knee joint where the ACL was attached and then securing a graft inside those holes. Ex. 1020 at 219-21; Beynnon ¶ 31. One way of performing this procedure is illustrated in part by Fig. 6 of the '977 patent (below left) and similar Fig. 2 from prior art U.S. Patent No. 5,211,647 ("Schmieding '647," Ex. 1057, below right) (Beynnon ¶ 34):



In the procedure illustrated above, surgeons fixed the graft to the tibia by inserting the graft and an interference screw into the tibial tunnel so that the graft was captured via an "interference fit" between the screw and the tunnel wall. Ex. 1057 at 2:14-27, 3:63-66; Ex. 1021 at 87; Beynnon ¶ 34. Conventional interference screws had a cannula extending therethrough that enabled the screw to

be passed over a guide wire to guide the screw to the proper position and at the proper orientation to enter the tibial tunnel. Ex. 1020 at 207-08; Beynnon ¶ 37.

Bone has a hard outer surface ("cortical bone") and a softer interior ("cancellous bone"). Ex. 1061 at 90; Beynnon ¶ 26. For solid fixation, it was known to have the fully seated screw engage the cortical bone. Beynnon ¶ 36; *e.g.*, Ex. 1013 at 1:24-28; Ex. 1062 at 7:23-34; *cf.* Ex. 1001 at 3:56-4:6. It was also known that longer screws could provide better fixation, but that the screw should not be longer than the tibial tunnel or else the screw would protrude, causing pain and complications. Beynnon ¶ 36; *e.g.*, Ex. 1038 at 2:11-18; Ex. 1020 at 213.

Early interference screws were metal, but bioabsorbable plastic screws were introduced in the early 1990s. Ex. 1020 at 208; Beynnon ¶ 38-39. Bioabsorbable plastic was weaker than metal, which drove design innovations, including slotted drive sockets that allowed more torque to be applied without breaking the plastic, and tapered bodies that decreased the torque needed to insert the screw in a bone tunnel. Ex. 1015 at 120-121; Ex. 1011 at 2; Beynnon ¶ 42-46.

Surgeons had choices. Beynnon ¶ 31. "Bone block fixation" used a section of the patellar tendon (which connects the kneecap to the tibia) that included plugs or "blocks" of bone on both ends. Ex. 1018 at 1561-62; Beynnon ¶ 31. Interference screws wedged the bone blocks against the tunnel walls inside the femur and tibia to create the interference fit that fixed the graft. Ex. 1021 at 87;

Beynnon ¶ 32. "Soft tissue fixation" used sections of hamstring tendons that did not include bone blocks so that soft graft tissue was captured directly between the screw and the tunnel walls and secured by the interference fit between the screw and the bone tunnel. Ex. 1052 at 178-80; Ex. 1050 at 774-77; Beynnon ¶ 31.

B. Summary of the Claims

The '977 patent includes independent claims 1 and 6 and dependent claims 2-5. Claim 6 is reproduced below with bracketed letters that precede claim elements (*e.g.*, [a]) and are used throughout as shorthand references for those elements. Claim 1 is identical to claim 6 except that [pr. 1] in claim 1 does not require that the screw be "fully cannulated," and claim 1 does not include limitation [c2] requiring that the screw be inserted "over a guide pin." Beynnon ¶ 90. Thus, demonstrating that claim 6 would have been obvious necessarily establishes the obviousness of claim 1 as well.

[pr.1] A method of interference fixation for ACL reconstruction using a fully cannulated bioabsorbable interference screw having an elongated threaded body,

[pr.2] said elongated threaded body having a proximal end, a distal end, a length and taper,

[pr.3] 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:

[a] forming a tunnel in the tibia, said tunnel having a wall;

[b] inserting a substitute ligament in the tunnel; and

[c1] inserting said bioabsorbable interference screw into the tunnel and

[c2] over a guide pin such that

[c3] said elongated threaded body fills all but 5-10 mm of the tunnel,

[c4] the threads at the proximal end of the screw engage cortical bone in the tunnel, and

[c5] said substitute ligament is securely fixed between the threads of the screw and the wall of the tunnel.

Preamble limitations [pr.1-pr.3] describe an interference screw having specific features. As demonstrated by Simon and Endo-Fix, such screws were known. Beynnon ¶ 91. Method steps [c1-c5] describe the conventional use of such screws in performing ACL reconstruction. Beynnon ¶ 91.

C. Level of Ordinary Skill in the Art

The ’977 patent claims priority to a provisional filed in November 1999, but is not entitled to that 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. *See* § IX.A.1.e below. Nevertheless, the grounds all demonstrate the unpatentability of the claims even if the ’977 patent is entitled to its earliest priority date, based on the level of skill a person of ordinary skill in the art (“POSA”) possessed in the November 1999 timeframe. A POSA in the interference screw field, to which the ’977 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 ("BRI") consistent with the specification. 37 C.F.R. § 42.100(b). This construction may be different from the proper construction in district court, but unless otherwise noted, all of Petitioners' constructions are also the proper district court constructions.

A. "proximal end" and "distal end" (Claims 1 and 6)

These terms are used in their customary way, with the "proximal end" being the end nearest (proximate) the practitioner and the "distal end" being the opposite end furthest from the practitioner during insertion. Ex. 1001 at 2:62-65; Beynnon ¶ 53, 92; see Ex. 1022 at 658, 1828; Ex. X65 at 571, 1557.

B. "threads" (Claims 1 and 6)

Claims 1 and 6 each 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. X65 at 1723; Beynnon ¶ 63, 93. While some screws have multiple helical ribs, screws with a single helical thread

are far more common. Beynnon ¶ 63, 93.

"Thread" may also refer to "one complete turn of a screw thread," *i.e.*, each complete turn of a single helical may be referred to as a separate "thread." Ex. 1022 at 2381, 2041; Ex. X65 at 1723; Beynnon ¶ 63, 93. Thus, a screw with a single helical rib may be considered to have multiple threads. An example of this usage is when a screw is characterized by its number of "threads per inch." Ex. 1026 (Johnson) at 3:29-32, 3:56-57; Beynnon ¶ 63, 93. "Threads" in claims 1-6 refer to multiple complete turns of a helical rib extending in the length-wise direction along the screw. Beynnon ¶ 63, 93. This is consistent with the '977 specification, which does not disclose multiple helical ribs and refers to "threads 16 extending substantially from proximal end 20 to distal end 25." Ex. 1001 at 2:62-65, Fig. 1; Beynnon ¶ 63, 93.

C. "taper" (Claims 1 and 6)

The claims refer to the screw and its elongated body as having a "taper." The diameter of a threaded screw can be measured from crest-to-crest of the threads (referred to as the "major diameter") and at the "root" of the screw from trough-to-trough of the threads (referred to as the "minor diameter"). A POSA understood that a screw (or portion thereon) 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. X65 at 1943; Ex. X67 at

1633; Beynnon ¶ 61-63, 94. The claims do not limit the type of taper. Beynnon ¶ 61-63, 94. Thus, the screw or elongated body having a "taper" requires that the major and/or minor diameter of the screw (or body) vary gradually along the length of at least a portion of the screw (or body). Beynnon ¶ 61-63, 94.

D. "body" (Claims 1, 4, and 6) and "tip" (Claims 4 and 5)

An interpretation issue arises as to whether the "body" encompasses the entire length of the screw or refers to a portion of the screw other than a "tip" of the screw. This question impacts certain requirements that the claims impose on the "body" of the screw. For example, claims 1 and 6 require threads and a taper extending between the proximal and distal ends of the "body" (*supra* § VII.E), and also require the "body" to fill all but 5-10 mm of the tibial tunnel.

For the reasons discussed below, the proper interpretation—driven by the structure of the '977 patent claims—is that the screw includes a "tip" that is distinct from the "body." Thus, the "body" does ***not*** encompass the entire length of the screw.[1] In this respect, the '977 patent claims are similar to the claims of the related '216 and '986 patents in which, as explained in Petitioners' concurrent IPR petitions for those two patents, the "body" and "tip" are likewise distinct parts of

[1] Given that the disclosure in both Simon and Endo-Fix is commensurate with what the '977 specification describes, the claims are unpatentable under each ground no matter how the Board resolves this interpretation issue. Beynnon ¶ 95.

the screw. However, for reasons discussed below, the question of how much of the distal portion of the screw constitutes the "tip" (distinct from the "body") must be resolved differently for the '977 patent than for the related '216 and '986 patents because Patent Owner used the term "tip" differently in the '977 patent claims. Beynnon ¶ 95.

Neither independent claim in the '977 patent recites the screw as having a tip, but dependent claims 4-5 do introduce a tip. Claim 4 recites "***the distal end of the screw is provided with a tip*** having a second taper greater than the taper extending along the substantial length of the elongated threaded body of the screw."[2] Claim 5 (which depends from claim 4) recites the tip as being "smooth and ***unthreaded***." Beynnon ¶ 96.

Claims 4 and 5 make clear that, as in the '216 and '986 patents, the screw has a tip that is distinct from the body. First, claim 4 does not recite the body as including the tip—rather, it recites the tip as another part "of the screw." *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 ¶ 96. In addition, claim 5 requires that the tip be "unthreaded." By contrast, as demonstrated below, claim 1 requires that the "body" be threaded along its entire

[2] Emphasis is added throughout this Petition unless otherwise noted.

length. The "***unthreaded tip***" thus cannot be part of the ***fully threaded "body***." Beynnon ¶ 97.

The preambles of claims 1 and 6 both recite 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***,

As the language bolded above shows, the antecedents for "said" proximal and distal ends are the proximal and distal ends of the ***body***, not the screw. As also shown in bold, claim 1 requires that the threads extend from "said proximal end [of the body] to said distal end [of the body]." Beynnon ¶ 97. By definition, the "unthreaded" tip recited in claim 5 cannot be part of a body that is completely threaded from end to end.

For all of the above reasons, the "body" and "tip" should be construed to be different and distinct parts of the screw; in other words, the "body" is ***not*** synonymous with the "screw." As noted above, this aspect of the claim construction is identical in the '216 and '986 patents, the claims of which also require, by their structure, that the "body" and "tip" be different and distinct parts of the screw. However, the structure of the '977 patent claims does dictate one

difference in construction relative to the claims of the ’216 and ’986 patents.

In particular, the portion of the screw that constitutes the “tip” is different in the claims of the ’977 patent because of the requirement, in claim 5 of the ’977 patent, that the tip be “unthreaded.” This requirement is ***directly contrary*** to the requirement in every claim of the ’216 patent (Ex. 1002) that the tip be “threaded.” The specification shared between the ’977 and ’216 patents does not describe alternate embodiments—one with a threaded tip and one with an unthreaded tip—but rather only the single screw configuration shown in Figs. 1-4 that has a “complex taper” where “elongated main body 15” 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.” *Id*. at 3:18-20; Beynnon ¶ 100. The “unthreaded tip” claimed in the ’977 patent and the “threaded tip” claimed in the ’216 patent both must be construed to read on this same embodiment given that it is not just a preferred embodiment, but the ***only*** embodiment disclosed in the shared specification of these patents. *Accent Packaging v. Leggett & Platt*, 707 F.3d 1318, 1326 (Fed. Cir. 2013) (reversing claim construction that excluded the preferred embodiment).

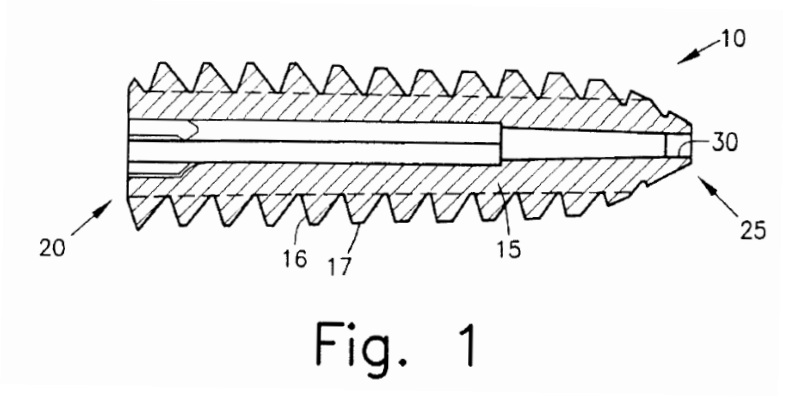


Fig. 1

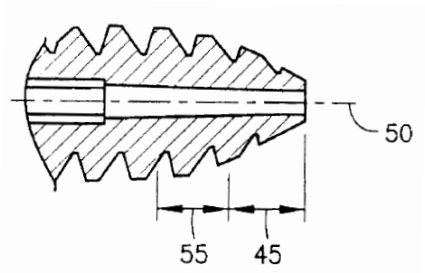


Fig. 3

While a POSA would have otherwise understood the "relatively pointed distal portion 45," with its sharp taper, to be a "tip"[3] distinct from the "main body 15" with a lesser taper, that cannot be the BRI for "tip" in the '977 patent because claim 5 of the '977 patent requires that the tip be "unthreaded" and the distal portion 45 is threaded. Beynnon ¶ 99; *Phillips v. AWH*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) ("[T]he usage of a term in one claim can often illuminate the meaning of the same term in other claims."); *Forest Labs. v. Abbott Labs.*, 239 F.3d 1305, 1310 (Fed. Cir. 2001) ("We also construe independent claims consistently with the claims that depend from them."); *Alcon Research v. Apotex*, 687 F.3d 1362, 1367 (Fed. Cir. 2012) (construing independent claim term based on the scope of the dependent claim).[4]

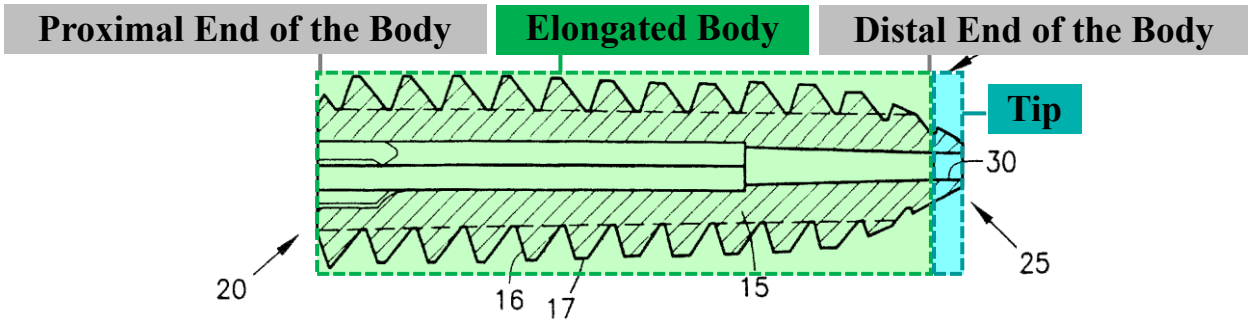
[3] The "threaded tip" in the '216 patent reads on the distal portion 45.

[4] While it is unusual to construe the same term differently in different patents in the same family, Patent Owner's inconsistent use of "tip" compels that result. *AK*

While the ’977 specification is not explicit about what portion of the screw the term “tip” refers to, *see* Ex. 1001 at 1:52-56; 2:7-10 and 3:19-27; Beynnon ¶ 101, the “unthreaded tip” recited in claim 5 must be construed to cover ***some*** structure described in the specification. *Accent Packaging*, 707 F.3d at 1326 (reversing claim construction that excluded the preferred embodiment). In the only embodiment disclosed in the ’977 specification, threads extend almost the entire length of the screw. The portion at the distal end of the screw after the last thread revolution (*see* Fig. 1 annotated below) is the only unthreaded portion of the screw. Thus, to be consistent with claim 5’s requirement that the tip be “unthreaded,” a POSA would have understood the BRI of “tip” to read on such a portion; in other words, the “tip” covers only the portion of the screw that starts at the screw’s distal end, increases in diameter proximally, and terminates where the threads begin. *Forest Labs.*, 239 F.3d at 1310 (dependent claim should not be construed to be inconsistent with the claim from which it depends); Beynnon ¶ 100-01. The BRI

Steel v. Sollac & Ugine, 344 F.3d 1234, 1243 (Fed. Cir. 2003) (“[W]e have interpreted differently two similar claims supported by the same specification … our differing constructions of the two patents’ claims is compelled by all of the relevant facts.”); *Wilson Sporting Goods v. Hillerich & Bradsby*, 442 F.3d 1322, 1327-28 (Fed. Cir. 2006) (holding that the claim term “gap” had different meanings in different claims based on those claims’ different contexts).

of "body," in turn, is the portion of the screw extending from the screw's proximal end and terminating before the "tip." Beynnon ¶ 101.



E. "the threads and taper of the screw extending along substantially the entire length of the screw from said proximal end to said distal end" (Claims 1 and 6)

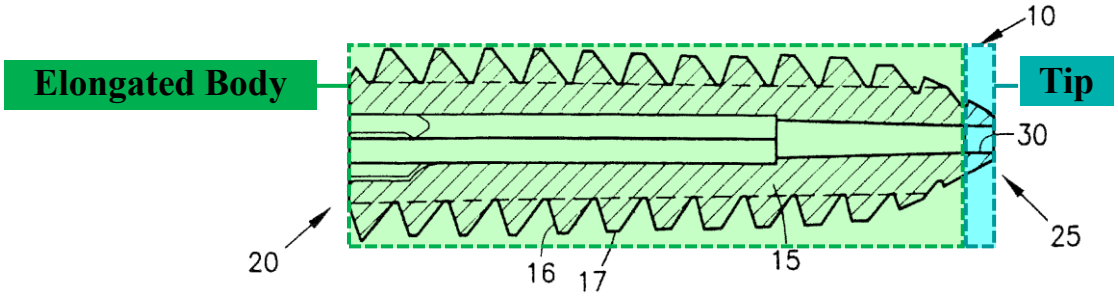
Referring again to the preambles of claims 1 and 6, both recite using:

> 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:

As demonstrated in § VII.D above, the antecedents for "said" proximal and distal ends are the proximal and distal ends of the ***body***, not the screw. As shown in bold, both independent claims are explicit that threads and a taper extending from "said proximal end [of the body] to said distal end [of the body]" extend

"along substantially the entire length of the ***screw***."[5] Beynnon ¶ 102. Therefore, the claim structure dictates that threads and a taper that extend along the entire ***body*** from its proximal end to its distal end are deemed to also meet the requirement to extend "along substantially the entire length of the screw" even if they terminate before, and do not extend onto, the tip.

This interpretation is consistent with the specification, as the only embodiment has threads that extend along the entire length of the body but terminate before, and do not extend to, the distal end of the screw. *See* Ex. 1001 at 2:4-9; Beynnon ¶ 103. This interpretation is also consistent with the "tip" being only the portion of the screw distal to final thread revolution (§ VII.D above) because the "tip" is short and the "body" extends along substantially the entire length of the screw as show in annotated Fig. 1 below. Beynnon ¶103.



[5] Just like a statement that a driver drove "substantially the entire length of the east coast [screw] from Bar Harbor, Maine [proximal end] to Miami, Florida [distal end]" would be understood to indicate that the driver drove from Bar Harbor to Miami and not "the entire length of the east coast [screw]."

This interpretation is also consistent with dependent claim 5 which depends from claim 1 and must be interpreted consistently with it. *See* case cites in § VII.D above. Beynnon ¶ 103. Claim 5 requires that the "tip at the distal end of the screw is … unthreaded." For claim 5 to be consistent with claim 1, a screw with an "unthreaded" tip (shown in teal above) must nevertheless be considered to have threads "extending along substantially the entire length of the screw" (claim1).

VIII. THRESHOLD REQUIREMENT FOR *INTER PARTES* REVIEW

This Petition and 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 the claims would have been obvious over the prior art relied upon herein as explained in detail by Dr. Beynnon, a Professor in the Department of Orthopaedics and Rehabilitation at the University of Vermont. Ex. 1008.

IX. CLAIM-BY-CLAIM EXPLANATION OF GROUNDS FOR UNPATENTABILITY OF CLAIMS 1-6

A. Ground 1: Simon Renders Claims 1-2 and 4-6 Obvious

Simon is a U.S. patent that is prior art to the '977 patent under 35 U.S.C. § 102(b) if the Board agrees that the '977 patent is not entitled to the earlier filing date of the provisional application it references (see § VI.C *supra*), or under § 102(a) and (e) if the '977 patent is granted the benefit of the provisional's earlier filing date. Ex. 1012. Simon discloses a fully cannulated, tapered bioabsorbable

interference screw that meets every element of the screw in claims 1 and 6. Ex. 1012 at 1:5-9, 1:36-41, 4:17-22; Beynnon ¶ 438. Simon discloses numerous embodiments that each renders the claims obvious under numerous rationales. The "second embodiment" shown in Figs. 5-9 is used illustratively and consistently below to demonstrate the obviousness of the claims. Beynnon ¶ 439.

Simon describes the use of the screw in conventional ACL reconstruction and explicitly meets most of the method of use limitations in claims 1-6. 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 as discussed below. Simon also does not explicitly teach that the screw's elongated body fills all but 5-10 mm of the tibial tunnel, but this numerical limitation adds nothing patentable that distinguishes over the method of use that Simon describes for the reasons discussed below. In addition, numerous patents and/or printed publications cited below establish that both of these limitation would have been met by an obvious use of the Simon screw in the conventional ACL reconstruction procedure Simon describes. Beynnon ¶ 438.

1. Claims 1 and 6

Claim 6 includes every limitation of claim 1 and adds the recitation to [pr.1] that the screw is "fully cannulated" and limitation [c2] requiring that the screw be inserted into the tunnel "over a guide pin." The claim 6 language that is absent

from claim 1 is italicized in the headings for [pr.1] and [c2] below.

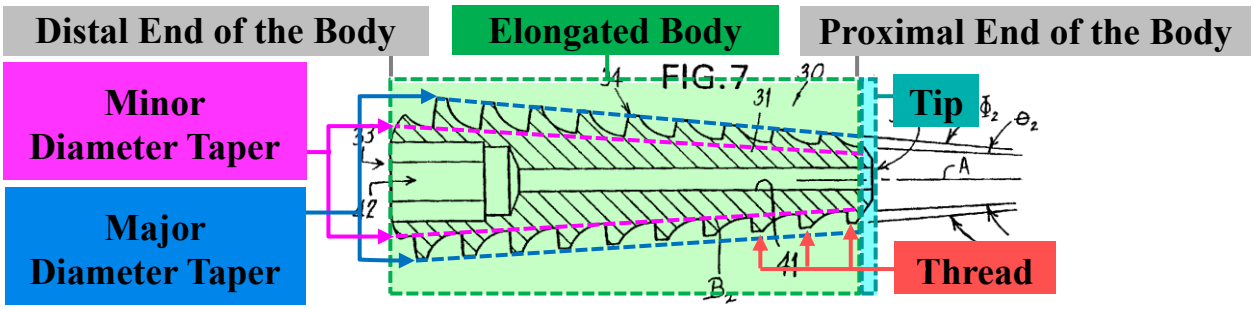
a. "[pr.1] A method of interference fixation for ACL reconstruction using a *fully cannulated* bioabsorbable interference screw having an elongated threaded body,"

Simon discloses a bioabsorbable "orthopedic interference screw for use in ACL reconstruction." Ex. 1012 at 1:5-9, 1:33-41, 4:17-22, 4:66-5:2, 4:25-26; Beynnon ¶ 442. The Simon screw is fully cannulated. Ex. 1012 at 2:16-22 ("[T]he screws [are] cannulated to facilitate installation of the respective screws utilizing a guide wire…."), 4:51-52, Fig. 7; Beynnon ¶ 443. Simon describes the use of the screw in conventional ACL reconstruction. Ex. 1012 at 1:12-28, 5:2-18, 5:33-44; Beynnon ¶ 444; *supra* § IX.C.1.a. The screw has an elongated body as discussed below in connection with [pr.2].

b. "[pr.2] said elongated threaded body having a proximal end, a distal end, a length and taper,"

Simon discloses an elongated threaded body having a proximal end, a distal end, and a taper. Beynnon ¶ 447-53. The body's proximal end is the proximal end of the screw and the body's distal end is where the body ends and the tip begins. Ex. 1012 at Figs. 6-7; Beynnon ¶ 448; *see supra* §§ VII.A. The body is elongated, tapered in both major and minor ("root") diameters which vary gradually along the body (and the entire screw), and threaded (*i.e.*, the helical thread extends along the body and creates multiple turns or "threads"). Ex. 1012 at Figs. 6-7, 4:25-27

(second embodiment: "The screw 30 has a biocompatible body B_2 with an elongated root portion 31 with a circular cross-sectional shape. … A thread 34 is formed over substantially the entire root section 31 from the tip end 32 to the back end 33. … In this particular embodiment, the root portion 31 … is uniformly tapered at a root taper angle θ_2 that is in the range of 5.8° to 6.2°. … In a preferred embodiment, the root taper angle θ_2 is 6° and the crest taper angle Φ_2 is 11.4°."); Beynnon ¶ 451-52. Simon's Fig. 7 shows the threads, root taper angle θ_1 and crest taper angle Φ_1 and is annotated below to identify the elongated body (boxed with the green dashed line) and its proximal and distal ends. § VII.D above; Beynnon ¶ 449.



c. "[pr.3] the threads and taper of the screw extending along substantially the entire length of the screw from said proximal end to said distal end, and"

Simon's threads and taper extend along substantially the entire length of the screw, see § VII.E above, because they extend from the "proximal end" of the body (which is also the proximal end of the screw) to the "distal end" of the body (which is either where the "body" ends and the "tip" begins, or is the distal end of

the screw, depending on which interpretation of "body" is adopted. Beynnon ¶ 454; *see supra* §VII.D. Indeed, given that Simon discloses a screw (*e.g.*, Fig. 2) where the tapers (both crest and root) and threads extend along the entire screw from the "tip end 12 to the back end 13," Simon necessarily meets element [pr.3] under any interpretation of "body" or "substantially the entire length of the screw." Ex. 1012 at Figs. 1-2, 4:25-42 ("A thread 34 is formed over substantially the entire root section 31 from the tip end 32 to the back end 33. In this particular embodiment, the root portion 31 … is uniformly tapered…."); Beynnon ¶ 454; *see supra* § VII.D and § VII.E.

d. Method Limitations [a], [b], [c1], *[c2]*, [c4], and [c5]

Simon discloses the use of the bioabsorbable screw in its second embodiment for an ACL reconstruction procedure that meets limitations [a], [b], [c1-c2] and [c4-c5]. Ex. 1012 at 1:15-35, 5:33-44 (quoted below with disclosed claim elements in brackets) (Beynnon ¶ 456):

> Medical procedures have developed over the years to enable in ACL reconstruction, the substitution of a ligament or graft and attaching both ends thereof to the distal femur or proximal tibia to facilitate regrowth and permanent attachment. One method for increasing the strength of the graft attachment comprises wedging an interference screw between a graft bone block and an interior wall of a bore (osseous tunnel) formed through the bone mass. **[a, b, c1]** … [I]t is essential that the interference screw so utilized in the medical

> procedure have sufficient strength to resist the tendencies for the replacement ligament (graft) to pull out of the osseous tunnels formed in the bone mass. **[c5]** … [A] need remains for a high strength interference screw for use in surgical procedures, such as ACL reconstruction. …
>
> It will become important for the surgeon to become familiar with the use of two differing interference screws in practicing, for example, ACL reconstruction and effecting a compression anchoring of the bone graft 51 in the osseous tunnels formed in the femur and the tibia. **[a, b and c1]** … [I]t will be a familiar practice for the surgeon to use a guide wire 54 such as is schematically illustrated in FIG. 32 in facilitating an insertion of the screw into the respective femur and tibia **[c2]** utilizing a tool 56 having a hex-shaped driving end thereon which is receivable into the respective hex-shaped socket 22 and 42.

While Simon does not explicitly state that threads at the proximal end of the screw engage cortical bone, a POSA would have understood Simon's reference to "endosteal fixation" to implicitly disclose that the screw engages cortical bone when fully seated in the tibial tunnel. Ex. 1012 (Simon) at 1:4-9, 2:7-16, 2:34-38; Beynnon ¶ 35, 457; Ex. 1047 at 1258. Endosteal fixation (which is in the title of the '977 patent) refers to fixation with the endosteum, a thin layer of cells separating cortical bone from cancellous bone. Ex. 1047 at 1258; Beynnon ¶ 35-36, 457. Simon's teaching that the screw should engage the endosteum (which necessarily engages cortical bone) was consistent with the well-known common

sense teachings in the art that a screw engaging harder cortical bone when fully seated would be best secured in the bone tunnel. Beynnon ¶ 36, 457; *see, e.g.*, Ex. 1063 (Amis) at 397-402. Thus, a POSA would have understood Simon to implicitly disclose engagement of the proximal end of the screw with cortical bone, or alternatively it would have been obvious to perform the procedure Simon describes in a manner that would have resulted in threads at the proximal end of the Simon screw engaging cortical bone when the screw was fully seated in the tibial tunnel to maximize fixation strength. Beynnon ¶ 457; *cf.* Ex. 1001 at 3:56-4:6 (acknowledging cortical bone engagement with endosteal fixation); Ex. 1012; *see also* Ex. 1013 (Ross) at 1:24-28.

In addition, step [c4] does not require cortical bone engagement when the screw is fully seated, and is broad enough under the BRI to be met by threads at the proximal end of the screw engaging cortical bone as the screw is being inserted into the tunnel before it is fully seated. Beynnon ¶ 303, 458. Given that cortical bone is disposed at the opening into the tibial tunnel through which the screw passes during insertion, the only way threads at the proximal end of the screw would ***not*** engage cortical bone during insertion would be if the screw was only partially inserted so that its proximal end never entered the tibial tunnel and protruded from it. Beynnon ¶ 303, 458. A POSA understood that a protruding screw could cause pain and other complications. Beynnon ¶ 303, 458; Ex. 1020

(Sgaglione) at 213 (proximal end of screw should not protrude from tunnel). A POSA would have known that the screw should be inserted fully into the tunnel, which would necessarily result in threads at the proximal end of the screw engaging cortical bone at the tunnel opening during insertion even if the surgeon chose (against convention) to continue to turn the screw more deeply into the tunnel so that threads at the proximal end of the screw did not engage cortical bone when the screw was fully seated in the tunnel. Beynnon ¶ 303, 458. For this additional reason, a POSA would have understood Simon to implicitly disclose step [c4], or alternatively, that the conventional and obvious insertion of the Simon screw into a tibial tunnel would have met step [c4]. Beynnon ¶ 303, 458.

Method steps [a], [b], [c1-c2] and [c4-c5] describe nothing more than well-known conventional ACL reconstruction. Beynnon ¶ 459. Thus, in addition to the specific teachings in Simon, a POSA would have understood that all of these method steps would have been met by the conventional and obvious use of the Simon screw in securing a graft in the tibial tunnel during ACL reconstruction based on the general knowledge in the art. *Infra* § IX.C.1.d. (and the evidence cited therein); Beynnon ¶ 460

For the foregoing reasons, a POSA would have understood each of steps [a], [b], [c1-c2] and [c4-c5] to be disclosed (explicitly or implicitly) by Simon, or alternatively, that these steps all would have been met by an obvious use of the

Simon screw in the procedure Simon describes to secure a graft in the tibial tunnel during conventional ACL reconstruction. Beynnon ¶ 461.

e. "[c3] said elongated threaded body fills all but 5-10 mm of the tunnel"

The requirement in claims 1 and 6 that the screw ***body*** fill all but "5-10 mm" of the tibial tunnel adds nothing inventive or patentable to the claims. The limitation does not even accurately recite the inventor's alleged contribution as disclosed in the specification, which only describes the ***entire screw***—not just its body—as filling all but the top 5-10 mm of the tunnel. Ex. 1001 at 3:41-50, 4:1-4; Beynnon ¶ 462. This limitation fails to render the claims unobvious over Simon for several independent reasons, and under several different obviousness rationales, discussed below.

i. Soft Tissue Art Explicitly Taught Filling All But 5 mm of the Tunnel

Simon explicitly discloses the use of its screw for bone block fixation. Ex. 1012 at 1:4-8, 1:19-23, 4:66-5:18; Beynnon ¶ 324, 464. However, a POSA would have understood that the Simon screw was also suitable for use in soft tissue fixation. Beynnon ¶ 464. The '977 patent acknowledges both bone block and soft tissue fixation to be prior art, and it was common for the same type of interference screw to be used for both procedures. Ex. 1001 at 1:21-30 (admitting that both procedures were known); Beynnon ¶ 324, 464 (citing Ex. 1030 (Grooms) at 3:50-

56 and other references that describe screws used for both procedures).

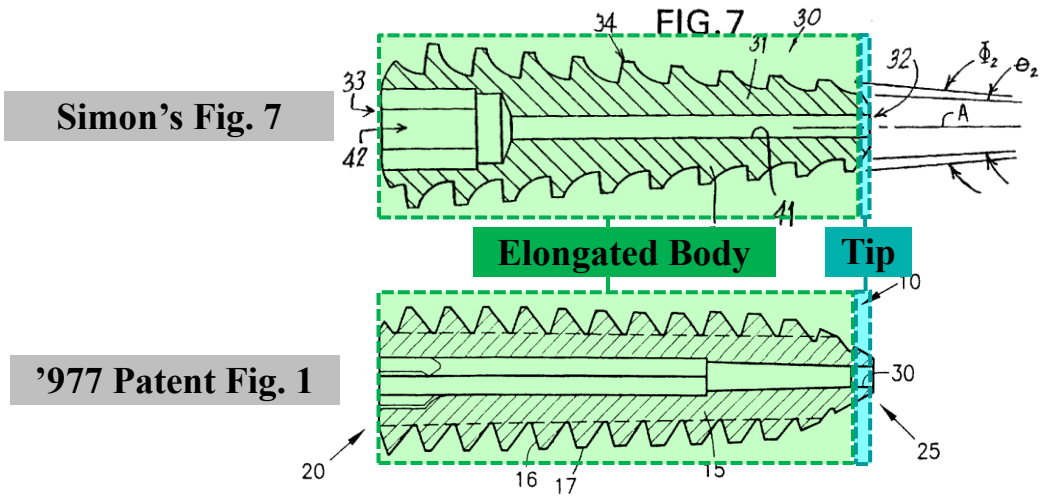
The soft tissue fixation procedure was virtually identical to the bone block fixation procedure that Simon describes in the excerpt cited at length above. *See supra* § IX.1.d; Beynnon ¶ 324, 326, 465 (citing Ex. 1052 (Scranton); Ex. 1058 (Palmeri); Ex. 1059 (Jomha); Ex. 1041 (Rieser); Ex. 1049 (Bellemans); and Ex. 1048 (Corry)). As one example, Corry (Ex. 1048) describes steps [a], [b], [c1-c2] and [c4-c5] for a soft tissue procedure at 446-447 ("The tibial tunnel was created …**[step a]** …The graft was then passed into the knee **[step b]**. …A guide pin was then inserted along the posterior aspect of the tibial tunnel and the screw was inserted **[steps c1 and c2]**. This screw was initially advanced two to three turns with the knee flexed. When a firm grip was obtained, the leg was straightened to ensure full extension and then the screw was fully seated **[steps c4 and c5]**."); Beynnon ¶ 326, 465. The screw engages directly with the graft's soft tissue because the graft has no bone block. Beynnon ¶ 31, 326, 465.

For soft tissue fixation, Bellemans explicitly teaches that the screw should be "approximately 5 mm shorter than the tibial tunnel length" to maximize engagement between the screw and the soft tissue graft. Ex. 1049 (Bellemans) at 669-70; Beynnon ¶ 327, 466. This knowledge would have motivated a POSA to choose a size for the Simon screw that filled all but 5 mm of the tibial tunnel when the Simon screw was used in a soft tissue fixation procedure. Beynnon ¶ 469.

Bellemans, like the ’977 specification, discusses the ***screw*** filling all but 5 mm of the tibial tunnel. Ex. 1001 at 1:56-59, 3:41-42. As the ’977 patent specification only discloses the ***screw*** (not just its body) filling all but 5-10 mm of tunnel, Patent Owner cannot plausibly argue that any distinction between the “body” of the screw, rather than the entire screw, filling all but 5-10 mm of the tibial tunnel as required by the claims of the ’977 patent provides a patentable distinction over the prior art. Indeed, as shown by the comparison of the figures below, Simon’s “second embodiment” is virtually identical to the only embodiment in the ’977 patent in terms of how much of the distal end of the screw extends beyond the last turn of the thread and is provided as an “unthreaded tip” (highlighted in teal in the figures). Therefore, when the entire Simon screw fills all but 5 mm of the tibial tunnel, the ***body*** of the Simon screw would fill all but 5-10 mm of the tibial tunnel in the exact same manner as the body of the only embodiment disclosed in the ’977 patent. Beynnon ¶ 467.

In addition, the body of the Simon screw must be interpreted as including all but the unthreaded portion at the distal end of the screw (highlighted in Fig. 7 reproduced below) for the reasons discussed in § VII.D above. The unthreaded tip is very short and accounts for little of the screw’s length. Beynnon ¶ 467. Thus, when the entire Simon screw is sized to fill all but 5 mm of the tibial tunnel, the body would fill only slightly less, resulting in the amount of the tibial tunnel

unfilled by the "body" being in the claimed 5-10 mm range. Beynnon ¶ 467.



ii. No Unexpected Result or Difference In Kind Is Achieved Relative To The General Teachings In the Soft Tissue Fixation Art

Patent Owner may seek to swear behind Bellemans. Any such attempt should fail at a minimum because claims 1-6 refer to the "body" (not the entire screw) as filling all but 5-10 mm of the tibial tunnel and are not commensurate in scope with the inventor's alleged "invention." *See* Ex. 1004 (Provisional) ("The tapered ***screw of the present invention*** fills all but the top 5-10mm of the tibial tunnel."). Given that the inventor ***never*** invented the claimed subject matter, Patent Owner cannot show an invention date before Bellemans.

In addition, the knowledge possessed by a POSA (as evidenced by patents and printed publications) that would have led to the use of a screw sized to fill all but 5-10 mm of the tibial tunnel for soft tissue fixation went far beyond Bellemans' explicit suggestion. Beynnon ¶ 470. Thus, even if Patent Owner were to swear

behind Bellemans, other teachings in the art establish that the conventional and obvious use of the Simon screw in soft tissue fixation would have met step [c3].

The claims quantify with numerical precision nothing more than the result of applying well-known, straightforward, ***common sense*** knowledge possessed by a POSA to select an appropriately sized screw for the patient. Beynnon ¶ 470, 329-331, 149; Ex. 1030 (Grooms) at 7:26-30 (for "an ACL procedure … [a] screw of this invention having the appropriate dimensions is selected by the surgeon, based on the needs of the particular patient"). In choosing an "appropriate" screw for a particular patient and procedure (which together establish the tibial tunnel length), a POSA would have been guided by several known considerations: (a) longer screws were believed to create stronger initial graft fixation and faster integration of the graft in the tunnel (Ex. 1027 (Stadelmaier) at 779); Ex. 1036 (Weiler AANA) at 548-49; Ex. 1037 (Pinczewski) at 642-43); (b) the screw should not be longer than the tunnel or it could protrude and cause pain and tissue damage (Ex. 1020 (Sgaglione) at 213); and (c) a screw would be best secured in the bone tunnel by engaging harder cortical bone (*see*, *e.g.*, Ex. 1063 (Amis) at 397-402). Beynnon ¶ 330, 470; *see* Ex. 1038 (Mahony) at 2:11-18 (for bone block fixation "The screw… 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. Therefore,

the surgeon must have available screws in several lengths to be able to select ones having the proper length.").

These teachings demonstrate that the relative sizes of the screw and tibial tunnel and the amount of the tunnel left unfilled were known to be result-effective. Beynnon ¶ 470. Applying this knowledge, a POSA would have been led to a long screw to maximize fixation but not longer than the tibial tunnel, and to perform routine experimentation to determine specific value(s) for the screw and tunnel lengths that achieve these desired results. Beynnon ¶ 470. Thus, the specific value of 5-10 mm of the tibial tunnel left unfilled would have been obvious. *In re Applied Materials*, 692 F.3d 1289, 1295-97 (Fed. Cir. 2012) ("'[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."). Beynnon ¶ 470.

The particular numerical limitation requiring that all but "5-10 mm" of the tibial tunnel be unfilled by the screw body recites nothing inventive or patentable because it does not produce an unexpected result or difference in kind from a screw (or body) that substantially fills the tibial tunnel but leaves, for example, 4 mm or 11 mm unfilled. *In re Applied Materials*, 692 F.3d at 1297 (claimed invention that 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" was obvious).

The specification describes ***no*** benefit achieved by having the ***body*** of the screw (as opposed to the entire screw) fill all but 5-10 mm of the tibial tunnel, let alone one that was unexpected or different in kind from the results achieved by following the well-known teachings in the art. Ex. 1001 at 3:41-50; 4:1-4; Beynnon ¶ 148, 332, 470. The results the '977 specification asserts are achieved by filling all but the top 5-10 mm of the tibial tunnel with the ***screw*** (not just the body)—*i.e.*, securing a large portion of the graft, engaging cortical bone, and avoiding the need for multiple screws—were known, expected, and no different in kind than the benefits of using a screw that substantially fills the tunnel but leaves a few millimeters more or less unfilled. Ex. 1003 at 3:42-51; Beynnon ¶ 148, 332, 470. Indeed, the '977 patent's assertion that using a "sufficiently long" screw eliminates "the need for multiple, shorter interference screws in a bone tunnel" knocks down a straw man of the drafter's creation. Although some references disclosed the use of multiple screws, it was far more typical to use only a single interference screw in the tibial tunnel. Beynnon ¶ 148, 332, 470 and the numerous references cited therein describing the use of a single interference screw. *E.g.*, Ex. 1021 (Lambert) at 88 (Fig. 6); Ex. 1057 (Schmieding '647) at Fig. 2; Ex. 1026 (Johnson) at Fig. 4; Ex. 1052 (Scranton) at 180; Ex. 1049 (Bellemans) at 670.

When inserted into a tibial tunnel in the way Simon describes, the Simon

screw achieved all the advantages that the ’977 patent asserts are achieved by filling all but 5-10 mm of the tunnel. Beynnon ¶ 148, 332, 470. The particular numerical limitation does not “produce a new and unexpected result which is different in kind and not merely in degree from the results” achieved by the expected use of the Simon screw in soft tissue fixation and does not render the claims nonobvious over Simon. *In re Applied Materials*, 692 F.3d at 1297; Beynnon ¶ 148, 332, 470.

iii. The Soft Tissue Fixation Art Taught A Range That Subsumes and Renders Obvious the Claimed 5-10 mm Range

Only two simple variables influence how much space is left unfilled in the tibial tunnel after an interference screw is inserted: screw length and tunnel length. Both were known to have a small range of suitable values, resulting in a small range of possible “unfilled” tunnel space that subsumes the claimed 5-10 mm range and renders it *prima facie* obvious. Beynnon ¶ 334-337, 473; *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 at 1295 (explaining that when the prior art teaches a range of values that overlap the claimed value for a variable, the “overlap itself provides sufficient motivation to optimize” the variable to have a particular value in the prior art’s disclosed range). The principle applies to

composition claims and claims with other types of numerical limitations. *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).

Tunnel Length – Conventional tibial tunnels varied in length depending upon the size of the patient, the drilling technique used, and whether a soft tissue or bone block procedure was used. Ex. 1053 (Olszewski) at 13; Ex. 1052 (Scranton) at 180 (describing 45 mm tibial tunnel length for soft tissue fixation); Ex. 1048 (Corry) at 446, 447 (same); Beynnon ¶ 335, 473. For soft tissue fixation, the art taught at least a tibial tunnel length of 45 mm. *Id*.

Screw Length – The prior art taught a range of sizes for interference screws, including 10-40 mm for soft tissue fixation. Ex. 1030 (Grooms) at 3:50-56 (screws "for soft tissue attachment" have preferred length of 10-40 mm); Beynnon ¶ 336, 473.

A POSA following the known teachings to use a 45 mm long tibial tunnel for soft tissue fixation and a 10-40 mm screw would have been led to a screw and tunnel pair that would have resulted in the portion of the tibial tunnel unfilled by the screw being within a range of 5-35mm, which subsumes the claimed range and renders it *prima facie* obvious. Beynnon ¶ 337, 473. *In re Applied Materials*, 692 F.3d at 1295; *Ormco*, 463 F.3d at 1311.

The presumption of obviousness can only be overcome by a showing that

the claimed range of 5-10 mm provided unexpected results or achieved a difference in kind and not simply in degree. *In re Applied Materials*, 692 F.3d at 1297 (claimed invention that 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" was obvious). Given the absence of unexpected results or criticality achieved by leaving all but "5-10 mm" of the tibial tunnel unfilled by the screw, see § IX.A.1.e.ii above), the presumption of obviousness is not overcome and claim 6 would have been obvious over Simon for this additional reason.

The prior art ranges discussed above raise a presumption that the ***screw*** filling all but 5-10 mm of the tibial tunnel was obvious. For three reasons discussed in § IX.A.1.e.i above, the claimed reference to the ***body*** (rather than the entire screw) filling all but 5-10 mm of the tibial tunnel does not patentably distinguish over these teachings. First, given that the '977 patent specification only discusses the ***screw*** (not just its body) filling all but 5-10 mm of tunnel, Patent Owner cannot demonstrate that any distinction between the "body" of the screw, rather than the entire screw, filling all but 5-10 mm of the tibial tunnel provides a patentable distinction over the prior art. Beynnon ¶ 467, 474. Second, Simon discloses this "invention" to the same extent as the '977 patent because Simon's "second embodiment" is virtually identical to the only embodiment in the '977 patent in terms of how much of the distal end of the screw extends beyond the last

turn of the thread and is provided as an "unthreaded tip." Beynnon ¶ 467, 474. Third, given that it would have been obvious to provide the Simon screw in any of a range of sizes that would have resulted in all but 5-10 mm of the tibial tunnel being unfilled by the entire screw, and given that the body would fill only slightly less of the tibial tunnel than the entire screw, obvious size choices for the Simon screw (*e.g.*, one that left only 5 mm of the tibial tunnel unfilled by the entire screw) would have resulted in the amount of the tibial tunnel unfilled by the "body" falling within the claimed 5-10 mm range because the amount left unfilled by the body would be only slightly larger and would not have exceeded 10 mm. Beynnon ¶ 468, 474.

iv. The Bone Block Fixation Art Taught Another Range That Subsumes and Renders Obvious the Claimed 5-10 mm Range

The claims are also rendered obvious by Simon because a conventional and obvious use of Simon's screw in the bone block fixation procedure Simon describes would have resulted in the claimed 5-10 mm limitation being met. In bone block fixation, a bone block at the end of the graft is secured in the tunnel via interference fit with the screw. Beynnon ¶ 340, 476. This results in particular sizing considerations for the tibial tunnel as explained in Olszewski. Ex. 1053 at 13; Beynnon ¶ 340, 476. A POSA would have known that the tibial tunnel length for receiving a bone block using known techniques varied based on the patient's

anatomy (*e.g.*, the size of the patient) and could be between 33 mm and 53 mm. Ex. 1053 (Olszewski) at 13 (Table 4); Beynnon ¶ 340, 476.

A POSA was aware of teachings that the interference screw used in bone block fixation should be 25-40mm long. Ex. 1026 (Johnson) at 1:14-28, 3:51-58 (describing "25 to 40 mm long" bioabsorbable interference screws for bone block fixation); Beynnon ¶ 341, 476. Thus, a POSA following these known teachings would have had reason to use the Simon screw in a length of 25-40 mm and in a tibial tunnel within the 33-53 mm range Olszewski describes as conventional for bone block fixation. Beynnon ¶ 340-41, 476. Using screw and tunnel sizes at the low ends of the ranges would have left 8 mm of the tibial tunnel unfilled (25 mm screw/33 mm tunnel) and at the high ends would have left 13 mm unfilled (40 mm screw/53 mm tunnel). Beynnon ¶342, 476. Other combinations would have left as little as 0 mm unfilled (*e.g.*, 40 mm screw/40 mm tunnel) or a maximum of 28 mm unfilled in the unlikely event that a POSA chose a small screw at the low end of the range for use in a large patient. Beynnon ¶342, 476; *see* Ex. 1038 (Mahony) at 2:11-18 (for bone block fixation: "The screw … 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. Therefore, the surgeon must have available screws in several lengths to be able to select ones having the proper length.").

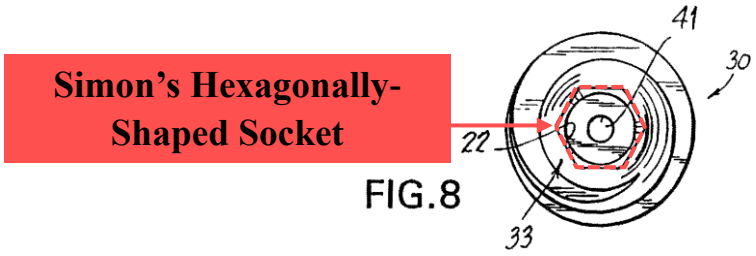
Thus, a POSA following conventional teachings relating to screw and tibial tunnel size for bone block fixation would have been led to pairings resulting in the amount of the tibial tunnel being unfilled by the screw falling in a range of 0-28 mm. Beynnon ¶342, 477. This subsumes the claimed range of 5-10 mm, rendering the claimed range *prima facie* obvious. *In re Applied Materials*, 692 F.3d at 1295; *Ormco*, 463 F.3d at 1311. The presumption of obviousness cannot be overcome because the claimed range of "5-10 mm" unfilled by the screw provided no unexpected results or a difference in kind. *See supra* §IX.A.1.e.ii.

For the same three reasons discussed in § IX.A.1.e.iii above, the claimed reference to the body (rather than the entire screw) filling all but 5-10 mm of the tibial tunnel does not patentably distinguish over these teachings. Beynnon ¶ 477.

2. Claim 2

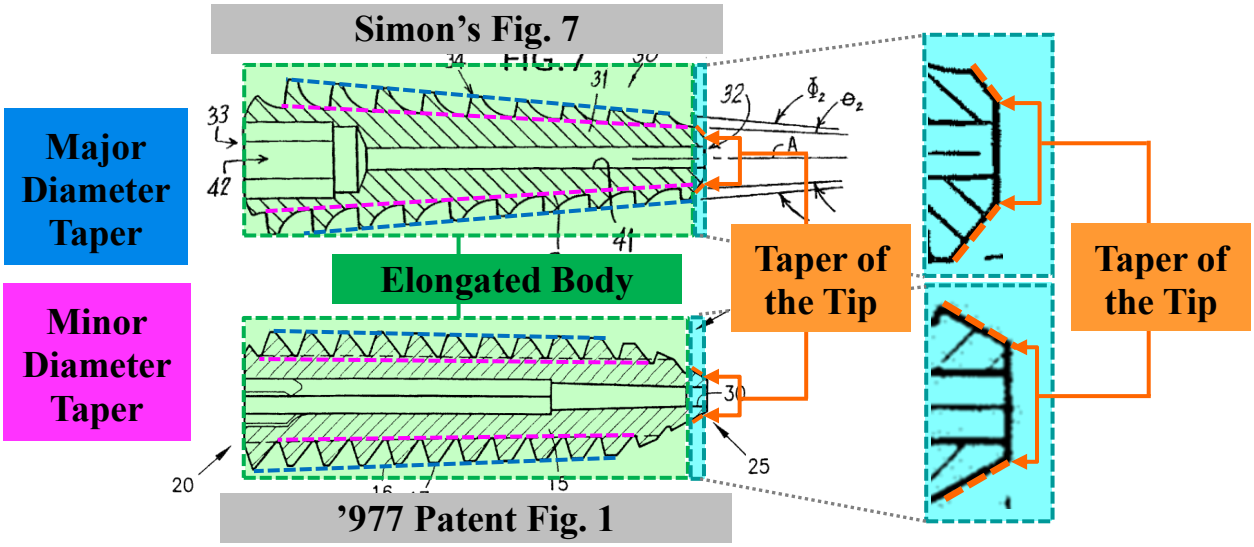
"Delta drive socket" is a coined term that is undefined in the specification and had no known meaning to a POSA. Beynnon ¶ 313, 480. In the litigation, Petitioner will ask the court to find this limitation indefinite. However, under the BRI in this proceeding, the "Delta" drive socket should be construed as covering ***any*** drive socket, given that "Delta" would not have been understood by a POSA as imposing any known limitation on the claimed drive socket. Beynnon ¶ 313, 480. Simon has a "hexagonally shaped [drive] socket 42 formed in the [proximal] head end 33" (Fig. 3, below) that is engaged by a driver 56 "for effecting a rotative

driving of the screw 30." Ex. 1012 at 4:55-60, Figs. 7, 8, 32; Beynnon ¶ 480-81.

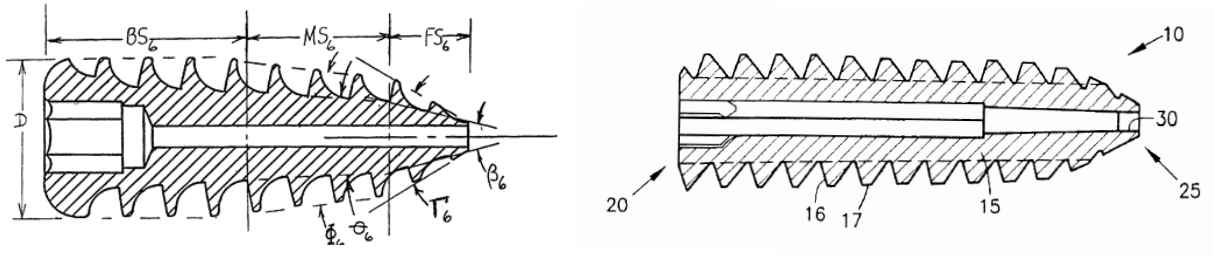


3. Claim 4

The screw's tip must be interpreted to include only the unthreaded portion at the screw's distal end for reasons discussed in § VII.D above. As illustrated by the comparison below, Simon's "second embodiment" has an "unthreaded" distal tip in precisely the same manner as the only embodiment disclosed in the '977 patent (both are highlighted below), and the distal tip has a taper (illustrated in orange below) that is greater (*i.e.*, steeper) than the root taper angle θ_1 and crest taper angle Φ_1 along the substantial length of the body. Beynnon ¶ 483. Thus, claim 4 would have been obvious over Simon's "second embodiment." Beynnon ¶ 483.



If the Board construes the tip to require a longer portion of the screw (*i.e.*, that extends more proximally from the distal end), Simon discloses a "sixth embodiment" in Figs. 19-22 that has a complex taper in which both the root and major thread diameter at a "front section" taper more aggressively than along the "middle" and "back" sections of the elongated threaded body. Ex. 1012 at 6:49-51 (front section FS_5 has root taper of 30° to 40° and crest taper of 55° to 65°), 6:49-60, 7:13-25 (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), 7:17-26 (middle section MS_6 has a root taper angle θ_6 of 6° and a crest taper angle Φ_6 of 11°); Beynnon ¶ 484. The back section BS_6 has the same root taper angle θ_6 as the middle section MS_6. Ex. 1012 at 7:19-22, 7:3-6, 6:7-9, 4:41-42; Beynnon ¶ 484. Simon's Fig. 22 is compared with the '977 patent's Fig. 1 below. Beynnon ¶ 484. Simon's "sixth embodiment" meets the other limitations of claim 1 (from which claim 4 depends) for the same reasons as the "second embodiment," except that in the sixth embodiment only the minor (root) diameter taper extends along the entire length of the screw body whereas the "second embodiment" has a taper of both its major and minor diameters along the entire length of the body. Beynnon ¶ 485. The sixth embodiment provides an additional or alternate basis for finding claim 4 obvious over Simon. Beynnon ¶ 485.



4. Claim 5

As illustrated by the highlighting in the annotated figure above in connection with claim 4, Simon's "second embodiment" has a distal end that looks just like the only embodiment in the '977 patent, *i.e.*, it has a short portion at the distal end that is unthreaded. Simon's "sixth" embodiment also looks just like the only '977 embodiment—it has a complex taper that is more aggressive near the distal end of the screw and threads extending to almost the distal end of the screw. Given that the reference to the tip being unthreaded must be interpreted as reading on the only embodiment in the '977 patent under BRI, see § VII.D above, claim 5 must be interpreted as requiring that the tip include only the portion of the screw that starts at the screw's distal end, increases in diameter proximally, and terminates where the threads begin. The first and sixth embodiments in Simon each meets the "smooth and unthreaded" tip requirement in the same way the only disclosed embodiment of the '977 patent does. Beynnon ¶ 486.

B. <u>Ground 2</u>: Simon in View of Weiler and Hannay Renders Claims 2-3 Obvious

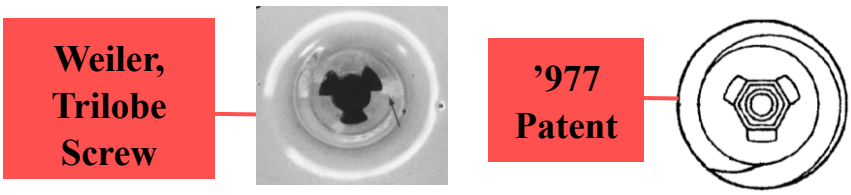
Ground 2 provides an alternative basis for meeting claim 2's "Delta" drive

socket if it is interpreted narrowly to cover the only embodiment disclosed in the ’977 patent, and also meets the drive socket limitations in claim 3. The drive socket disclosed in the ’977 patent and recited in claim 3 employs a hexagonal shaped recess with radially extending slots in every other annular face. The prior art provides specific motivation to use this type of known drive socket in Simon.

Weiler, published in January 1998 (Ex. 1043) and prior art under § 102(b), describes a study comparing the performance of different biodegradable interference screws in a number of categories. Beynnon ¶ 208-09, 488. Among the screws tested was an Arthrex screw having a “hexagonal drive” socket (identified as Group 1 in Weiler) of the type disclosed by Simon. Ex. 1015 at 121-122, 124-126, Figure 1B; Beynnon ¶ 268, 489. Weiler concluded that the hex drive socket failed at the driver/socket interface 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, 489.

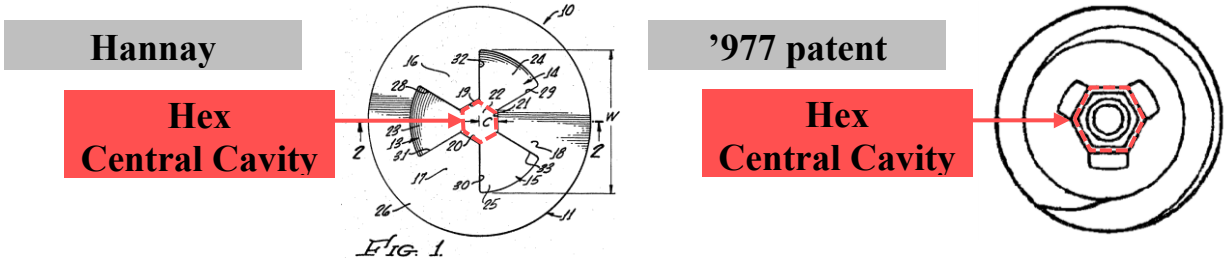
Weiler discloses that a Linvatec screw with a “trilobe” socket (identified as a “Group 3” screw and labeled “C” in Figure 4) withstood significantly higher torque before failure than the hex socket. Ex. 1015 at 126; Beynnon ¶ 209-11, 488, 490. Simon uses a hex drive socket like the Arthrex Group 1 screw (Ex. 1012 at 4:57-58, Figs. 6, 8, 20, 22; Ex. 1015 at 122). Therefore, a POSA would have been motivated by Weiler to modify Simon’s hex drive socket to use a trilobe socket to

increase the insertion torque that could be applied to the screw before breakage and address Weiler's concerns about a hex socket (like Simon's) experiencing "drive failure during screw insertion." Ex. 1015 at 126; Beynnon ¶ 269, 489. As shown below, the trilobe socket in Weiler has three grooves extending outwardly from the center axis of the drive socket that are nearly identical to those in the only drive socket embodiment in the '977 patent. Ex. 1015 at 125 (Fig. 4, left); Ex. 1001 at Fig. 2 (right, with numbers and annotations removed); Beynnon ¶ 490.



The trilobe socket in Weiler has a circular (rather than a hex) core about which the three lobes extend. However, trilobe drive sockets with a hex core were known. Hannay, a U.S. patent that issued in 1971 (Ex. 1016 at [45]) and prior art under § 102(b), discloses a drive socket having a hex core with three radially extending slots ("three equally spaced individual recesses") in every other annular face. Ex. 1016 at 2:9-17, Fig. 1; Beynnon ¶346, 491. Hannay is directed to general screws, but POSAs in the interference screw field routinely looked to other types of screws for drive socket design ideas. *E.g.*, Ex. 1042 (Rego) at 4:6-10; 5:9-16 (referring to Reiland (Ex. 1056), a decades old patent concerning general screws); Beynnon ¶ 349, 493. Hannay disclosed the same drive socket

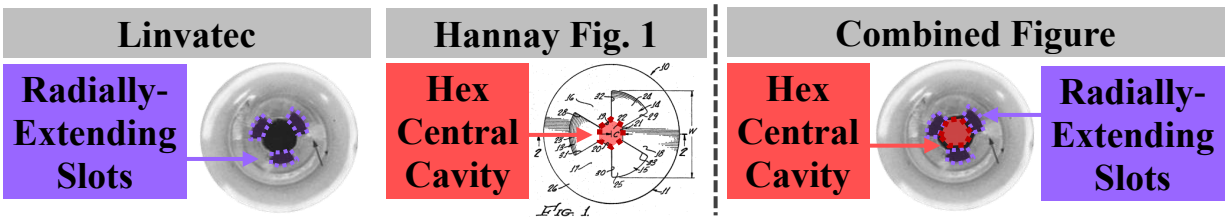
configuration described and claimed in the '977 with a hexagonal recess (shown in the dotted red line below) and radially extending slots in every other annular face. Beynnon ¶ 346, 491.



Substituting Hannay's hex core for the circular core in the trilobe socket of Weiler would have been a matter of design choice that would have yielded predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); Beynnon ¶ 493. In addition, a POSA would have had reason to improve Weiler's trilobe socket by arranging its slots around a hex (rather than circular) core as depicted in Hannay for two reasons. First, the hex core provides additional socket surfaces that interact with the driver to distribute drive forces and increase drive torque before failure. Beynnon ¶ 492. Second, the hex core allows a hex-shaped driver to insert the screw, affording flexibility if the specialized (trilobe) driver was unavailable. Beynnon ¶ 492. The '977 patent touts the ability to use a "hex-head screwdriver" as an alternative to the specialized (Delta) driver as an advantage (Ex. 1003 at 1:63-66), but Hannay taught this decades earlier. Beynnon ¶ 492.

As shown below, Weiler's trilobe socket modified (based on Hannay) to use a hex core is virtually identical to the only embodiment in the '977 specification

and discloses claim 2's Delta drive socket under any interpretation. Beynnon ¶ 493-94. The three radially-extending slots are in every other annular face of the hex core, meeting claims 3's requirement. Beynnon ¶ 494. The rest of the Simon screw and its method of use are not changed in the combination, so the combination meets or renders obvious the other limitations of claims 1-3 in the same way that Simon does. Beynnon ¶ 494; *supra* § IX.A.



C. Ground 3: Endo-Fix Renders Claims 1-2 and 4-6 Obvious

Endo-Fix is a sales brochure that Acufex (a division of petitioner S&N) distributed to medical professionals before 1998 and is prior art under 35 U.S.C. § 102(b). Ex. 1010 (establishing public distribution of Endo-Fix before 1998); *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974-75 (Fed. Cir. 2010) (finding "promotional publication" a printed publication). Beynnon ¶ 125, 496. Endo-Fix discloses a fully cannulated bioabsorbable interference screw for ACL reconstruction that meets every element of the screw in claims 1 and 6. Ex. 1011 at 1-2; Beynnon ¶ 496. Endo-Fix does not explicitly describe all the claimed method steps. However, as the '977 patent concedes and, as numerous patents and printed publications cited below establish, those steps were conventional. A POSA

would have understood that all the method steps except [c3] were implicitly disclosed by Endo-Fix, and that the known and obvious use of the Endo-Fix screw in conventional ACL reconstruction would have met all the method steps including [c3]. Ex. 1001 at 1:21-30; Beynnon ¶ 496-97.

1. Claims 1 and 6

Claim 6 includes every limitation of claim 1 and adds the recitation that the screw is "fully cannulated" to [pr.1] and the limitation [c2] requiring that the screw be inserted into the tunnel "over a guide pin." The claim 6 language absent from claim 1 is italicized in the headings for [pr.1] and [c2] below.

a. "[pr.1] A method of interference fixation for ACL reconstruction using a *fully cannulated* bioabsorbable interference screw having an elongated threaded body,"

Endo-Fix discloses an "Interference Screw" of "bioabsorbable material." Ex. 1011 at 1-2; Beynnon ¶ 127, 499. A POSA would have known that the Endo-Fix screw was to be used in ACL reconstruction to secure a substitute ligament in the tibial tunnel by interference fixation. Ex. 1011 at 2; Beynnon ¶ 355, 402, 500. As the '977 patent concedes, it was known to use a bioabsorbable interference screw to secure a graft in the tibial tunnel. Ex. 1001 at 1:21-31; Beynnon ¶ 356-59, 500.

The Endo-Fix screw is fully cannulated (a cannula extends through its entire length) and has an elongated body as discussed below in connection with [pr.2].

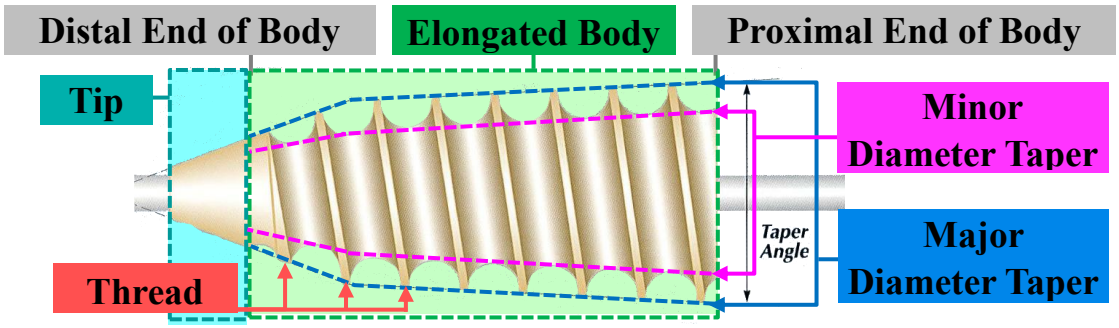
Ex. 1011 at 3, 2 (pointing out a "1.5 mm cannulation"); Beynnon ¶ 499.

b. "[pr.2] said elongated threaded body having a proximal end, a distal end, a length and a taper,"

The Endo-Fix screw's elongated threaded body has proximal and distal ends, a length, and a taper, as illustrated by the annotated figure below. Ex. 1011 at 2 (annotations include a green dashed line to show the elongated body and blue and magenta dashed lines to show the taper); Beynnon ¶ 502-07. The Endo-Fix screw tapers on both its major diameter (measured at the crests of the threads as shown in the annotated figure below) and its minor diameter (measured at the thread troughs). Beynnon ¶ 505. The proximal end of the "body" is the larger diameter end of the screw, and the distal end of the "body" is where the body ends and the "tip" begins. Beynnon ¶ 502-3; *see supra* §§ VII.A, VII.D. If the Board were to construe the body as including the tip, all of these limitations are also met, as the distal end of the "body" would simply be the distal end of the screw. Beynnon ¶ 502-03.

While Endo-Fix does not explicitly state that the body is elongated, a POSA would have understand that to be the case regardless of whether "body" is construed to include the tip. Beynnon ¶ 506; *supra* § VII.D. Indeed, Endo-Fix describes screws having length versus diameter proportions (diameters of 7-9 mm and lengths of 20-30 mm) that are similar to those disclosed in the '977 patent (diameters of 9-12 mm and length of 35 mm). Ex. 1011 at 2-3; Ex. 1001 at 2:62,

3:19-27; Beynnon ¶ 506.



c. "[pr.3] the threads and taper of the screw extending along substantially the entire length of the screw from said proximal end to said distal end, and"

As shown in the annotated figure above in connection with [pr.2], the Endo-Fix screw tapers along the entire length of the screw. The threads extend the entire length of the body from the proximal end of the screw to the unthreaded tip terminating just prior to the screw's distal end. Ex. 1011 at 2-3; Beynnon ¶ 508. As discussed in § VII.E above, claims 1 and 6 are explicit that threads (and a taper) extending from the proximal end to the distal end of the ***body*** must be considered to extend "along substantially the entire length of the screw." Thus, the Endo-Fix screw threads extend "along substantially the entire length of the screw" as claimed. Beynnon ¶ 508.

If the body of the screw is interpreted as including the tip, these limitations are still met. *See* § VII.D *above*. The taper extends along the entire length of the screw and the threads extend to the distal end of the screw where there is an unthreaded tip. Beynnon ¶ 509. This is precisely what is shown and claimed (see

claim 5) in the '977 patent, so claims 1 and 6 must be interpreted to cover such a screw. Beynnon ¶ 509; *see supra* § VII.D.

d. Method Limitations [a], [b], [c1], *[c2]*, [c4], and [c5]

A POSA viewing Endo-Fix would have understood that an expected use for it was in conventional ACL reconstruction, and therefore that steps [a],[b], [c1-c2] and [c4-c5] were implicitly disclosed by Endo-Fix as they recite nothing more than the conventional steps of using an interference screw like Endo-Fix to secure a graft in the tibial tunnel during ACL reconstruction. Beynnon ¶ 373, 376-77, 512. *In re Preda*, 401 F.2d 825, 826 (CCPA 1968) ("[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom."). Alternatively, steps [a],[b], [c1-c2] and [c4-c5] would have been performed in an obvious use of the Endo-Fix screw to secure a graft in the tibial tunnel during conventional ACL reconstruction. Beynnon ¶ 374-93, 402, 513. A POSA would have understood Endo-Fix to disclose that the cannulated screw be inserted over a guide pin, or alternatively this would have been an obvious way to use Endo-Fix's cannulated screw in ACL reconstruction. Ex. 1011 at 2-3 ("a 1.5 mm… cannulation, permitting the use of a rigid guide wire. This helps the surgeon… during insertion."); Ex. 1013 (Ross) at 6:65-7:20; Ex. 1048 (Corry) at 446-47 (both describing screw insertion over a guide wire);

Beynnon ¶ 402-03, 514 (guide wire and guide pin are synonymous).

Patents and publications corroborate Prof. Beynnon's testimony that steps [a], [b], [c1-c2] and [c4-c5] describe conventional ACL reconstruction using a cannulated interference screw like the Endo-Fix screw. Beynnon ¶ 515. First, the '977 patent admits that it was known to use bioabsorbable "interference screws to secure the graft against the walls of a tunnel drilled through the tibia." Ex. 1001 at 1:21-31. This admitted prior art meets elements [a], [b], [c1-c2] and [c4-c5]. *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). A POSA would have recognized that in the typical, or obvious, implementation of these admitted prior art procedures the surgeon inserts the screw into the tibial tunnel over a guide pin and by turning the screw, as the screw turns its threads engage cortical bone at the opening of the tunnel, and all of elements [a],[b], [c1-c2] and [c4-c5] would have been met. Beynnon ¶ 375, 515.

Second, numerous prior art references discussed below teach variations of the conventional ACL reconstruction procedures for which the Endo-Fix screw was intended and demonstrate the performance of steps [a], [b] and [c1-c2] and [c4-c5]. A POSA would have understood the Endo-Fix screw to be suitable for both bone block and soft tissue fixation. Beynnon ¶ 357-59, 516.

Bone Block Fixation – Prof. Beynnon cites numerous references disclosing conventional bone block fixation, including Ex. 1013 (Ross), Ex. 1021 (Lambert), Ex. X41 (Kurosaka), Ex. 1057 (Schmieding '647), Ex. 1026 (Johnson), Ex. 1012 (Simon), and Ex. 1042 (Rego). Beynnon ¶ 379-86, 403, 516. The way in which the Simon procedure meets these method steps is described in § IX.A.1.d above. As another example, Ross (Ex. 1013) describes steps [a], [b], [c1-c2] and [c4-c5]. Ex. 1013 at 6:65-7:20 (quoted below) (Beynnon ¶ 300-01, 516):

> [F]or ligament fixation in … replacement of the anterior cruciate ligament [ACL] … bone tunnels are formed, respectively, in the proximal tibia **[step a]** and distal femur. A ligament, either graft or prosthetic, having bone blocks at its ends is passed … through the tibial tunnel to position a bone block in the femoral and tibial tunnels **[step b]**. ...Bone screw 10 is inserted via guide bore 50 over a guide wire positioned in the femoral bone tunnel between the bone block positioned therein and the tunnel wall. … Driver 60 is rotated to drive bone screw 10 into interference fit between the bone block and the wall of the femoral bone tunnel. With the ligament held in tension, a second bone screw 10 is inserted to secure the remaining bone block with respect to the wall of the tibial bone tunnel. **[steps c1-c2 and c4-c5]**.

Although Ross describes more detail about screw insertion into the femoral tunnel (*e.g.*, referring to insertion over a guide wire and rotating the driver to drive the bone screw into the tunnel), a POSA would have understood Ross to teach that the

second screw be inserted into the tibial tunnel in the same manner. Beynnon ¶ 516.

Soft Tissue Fixation – Prof. Beynnon also cites numerous references disclosing conventional soft tissue fixation, including Ex. 1052 (Scranton); Ex. 1058 (Palmeri); Ex. 1059 (Jomha); Ex. 1041 (Rieser); Ex. 1049 (Bellemans); and Ex. 1048 (Corry); Beynnon ¶ 387092, 403, 516. As one example, Corry (Ex. 1048) describes steps [a], [b], [c1-c2] and [c4-c5]. Ex. 1048 at 446-447 ("The tibial tunnel was created using a drill guide **[step a]**. …The graft was then passed into the knee **[step b].** …A guide pin was then inserted along the posterior aspect of the tibial tunnel and the screw was inserted **[steps c1 and c2]**. This screw was initially advanced two to three turns with the knee flexed **[step c4]**. When a firm grip was obtained, the leg was straightened to ensure full extension and then the screw was fully seated **[step c5]**."); Beynnon ¶ 326, 516.

A POSA understood that in its conventional and obvious use, threads at the proximal end of the Endo-Fix screw engage cortical bone when fully seated in the tibial tunnel, and alternatively, during insertion which is all that is required to meet step [c4] for the reasons discussed in § IX.A.1.d above. Beynnon ¶ 376-77, 517.

Thus, a POSA understood steps [a], [b], [c1-c2] and [c4-c5] to be implicitly disclosed by Endo-Fix, or alternatively, that each of these steps would have been met by an obvious use of the Endo-Fix screw. Beynnon ¶518-19.

e. "[c3] said elongated threaded body fills all but 5-10 mm of the tunnel"

As discussed in § IX.A.1.e above, the numerical limitation in claims 1 and 6 requiring that "5-10 mm" of the tibial tunnel be unfilled by the ***body*** does not accurately recite the inventor's alleged contribution as disclosed in the specification and adds nothing inventive or patentable to the claims. Ex. 1001 at 3:41-50, 4:1-4; Beynnon ¶ 462, 520. This limitation fails to render the claims unobvious over Endo-Fix for several independent reasons, and under several different obviousness rationales, discussed below.

Explicit Teaching For Soft Tissue Fixation to Fill All But 5 mm – Bellemans' teaching that the screw should be "approximately 5 mm shorter than the tibial tunnel length" 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. Ex. 1049 at 669-70; Beynnon ¶ 324-25, 327, 521. The claim to the body (rather than the entire screw) filling all but 5-10 mm of the tibial tunnel does not patentably distinguish over Endo-Fix for two reasons. First, given that the '977 patent specification only discusses the ***screw*** (not just its body) filling all but 5-10 mm of tunnel, Patent Owner cannot demonstrate that any distinction between the "body" of the screw, rather than the entire screw, filling all but 5-10 mm of the tibial tunnel provides a patentable distinction over Endo-Fix. Second, given that it would have been obvious to provide the Endo-Fix screw in any of a range of sizes

that would have resulted in all but 5-10 mm of the tibial tunnel being unfilled by the entire screw, and given that the body would fill slightly less of the tunnel than the entire screw since the tip must be construed to cover only the unthreaded distal portion of the Endo-Fix screw, obvious size choices for the Endo-Fix screw (*e.g.*, one that left only 5 mm of the tibial tunnel unfilled by the entire screw) would have resulted in the amount of the tibial tunnel unfilled by the "body" falling within the claimed 5-10 mm range because the amount left unfilled by the body would be only slightly larger than the amount left unfilled by the entire screw and would not have exceeded 10 mm. *Supra* § VII.D; Beynnon ¶ 462, 522.

No Unexpected Result or Difference in Kind – As the evidence discussed in § IX.A.1.e.ii above establishes, the amount of the tibial tunnel filled by the screw is a result effective variable and the precise numerical limitation of all but 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 and does not render the claims inventive over Endo-Fix. *In re Applied Materials*, 692 F.3d at 1295-97; Beynnon ¶ 329-331, 469, 524.

Soft Tissue Fixation Range Renders Obvious the Claimed 5-10 mm Range – The evidence cited in § IX.A.1.e.iii above establishes a known 10-40 mm range of screw lengths and a known tibial tunnel size of 45 mm for soft tissue fixation,

resulting in a known range (5-35 mm) for the unfilled portion of tunnel that subsumes and renders the claimed 5-10 mm range *prima facie* obvious. This presumption is not overcome. *Supra* § IX.A.1.e.iii. Claim 6 would have been obvious over Endo-Fix for this additional reason. Beynnon ¶ 335-37, 473, 527.

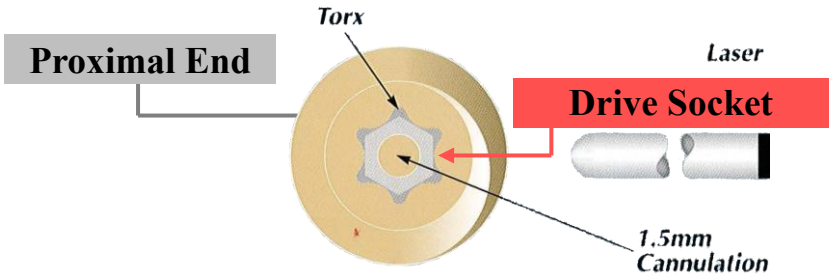
Bone Block Fixation Range Renders Obvious the Claimed 5-10 mm Range – As established in § IX.A.1.e.iv above, for bone block fixation the evidence establishes a known 25-40 mm range of screw lengths and a known range of tibial tunnel lengths of 33-53 mm, resulting in a known range (0-28 mm) for the portion of tunnel left unfilled by the screw that subsumes the claimed range of 5-10 mm and renders the claimed range *prima facie* obvious. The presumption of obviousness is not overcome. § IX.A.1.e.iii. Claim 6 would have been obvious over Endo-Fix for this additional reason. Beynnon ¶ 340-44, 475, 530.

The prior art ranges discussed above for bone block and soft tissue fixation raise a presumption that the ***screw*** filling all but 5-10 mm of the tibial tunnel was obvious. The claimed reference to the body (rather than the screw) filling all but 5-10 mm of the tibial tunnel does not patentably distinguish over these teachings for the two reasons discussed above: (1) Patent Owner cannot demonstrate that any distinction between the "body" of the screw, rather than the entire screw, filling all but 5-10 mm of the tibial tunnel provides a patentable distinction over the prior art given that the "body" filling all but 5-10 mm of the tunnel is not even disclosed in

the ’977 patent and (2) obvious size choices for the Endo-Fix screw (*e.g.*, one that left only 5 mm or even less of the tibial tunnel unfilled by the entire screw) would have resulted in the amount of the tibial tunnel unfilled by the “body” falling in the claimed 5-10 mm range. Beynnon ¶ 148, 332, 473, 475, 527, 530.

2. Claim 2

As discussed in § IX.A.2 above, the claimed “Delta” drive socket should be construed under BRI to cover ***any*** drive socket, given that “Delta” would not have been understood by a POSA as imposing any known limitation on the claimed drive socket. Beynnon ¶ 313, 534. Endo-Fix has a drive socket at its proximal end as shown in the figure reproduced below. Ex. 1011 at 2-3; Beynnon ¶ 534. As discussed in § IX.C.1.d above, a POSA would have understood that the expected and obvious use of the Endo-Fix screw in ACL reconstruction involved engaging the drive socket at the screw’s proximal end with a driver and using the driver to rotate the screw into the tunnel. *E.g.*, Ex. 1013 (Ross) at 6:65-7:20, Fig. 5; Ex. 1011 at 2-3; Beynnon ¶ 536-37.

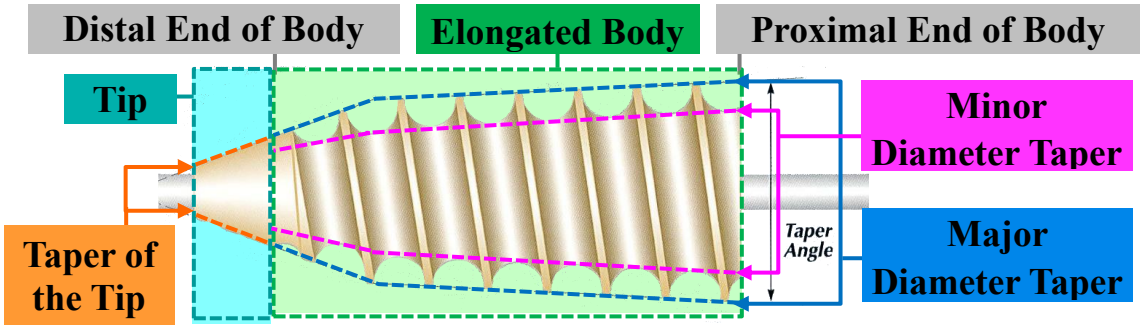


If “Delta drive socket” is interpreted more narrowly, a question arises as to

what features of the drive socket disclosed in the '977 patent are to be read into claim 2 and which are not. If "Delta" drive socket is interpreted to require a socket with an inner female hexagonal interface and outer radially-extending slots as disclosed in the '977 patent (Ex. 1001 at 1:60-66, 2:66-3:10, Fig. 2), such a socket is disclosed by Endo-Fix. Ex. 1011 at 2-3; Beynnon ¶ 535. If "Delta" drive socket is interpreted to require more of the characteristics of the only drive socket disclosed in the '977 patent, the Delta drive socket would still be met by the combination in Ground 4.

3. Claim 4

As shown in the annotated figure below, the Endo-Fix screw's elongated body is tapered, and the screw's distal end has a tip having a greater (*i.e.*, steeper) taper than the taper extending along the substantial length of the body of the elongated threaded body. Ex. 1011 at 2; Beynnon ¶540. The screw body has tapers of both its major diameter (measured at the crests of the threads as shown in the annotated figure below) and its minor diameter (measured at the thread troughs). Beynnon ¶ 540.



4. Claim 5

The annotated figure immediately above shows that the tip at the distal end of the Endo-Fix screw is smooth and unthreaded. *Supra* § VII.D; Beynnon ¶ 542.

D. Ground 4: Endo-Fix in View of Weiler and Hannay Renders Claims 2-3 Obvious

Ground 4 provides an alternative basis for meeting the "Delta" drive socket in claim 2 if it is interpreted narrowly to cover the only embodiment disclosed in the '977 patent, and meets the specific drive socket limitations in claim 3 relating to a hex shaped recess with radially extending slots in every other annular face. Weiler and Hannay provide specific motivation to use this type of known drive socket in Endo-Fix for the same reasons discussed in § IX.B above.

The Weiler study discussed in § IX.B above also evaluated an "Acufex" screw (identified as Group 6), which a POSA would have recognized as the screw described in Endo-Fix, and determined that it failed at torques that "may present a risk of drive failure during screw insertion." Ex. 1015 at 121-22, 125-26; Beynnon ¶ 208-09, 213-14, 545. Weiler found that the Linvatec "trilobe" socket discussed in § IX.B above withstood higher torque than the Endo-Fix/Acufex screw before failure. Ex. 1015 at 126; Beynnon ¶ 209-10, 212, 215, 546. Therefore, a POSA would have been motivated by Weiler to modify the Endo-Fix drive socket to use a trilobe socket to withstand increased torque. Ex. 1015 at 126; Beynnon ¶ 215, 546.

Substituting Hannay's hex core for the circular core in Weiler's trilobe

socket would have been a matter of design choice that would have yielded predictable results, particularly given that Endo-Fix already had a hex core. *KSR*, 550 U.S. at 416; Beynnon ¶ 216-18, 546-47. In addition, a POSA would have had the two reasons discussed in § IX.B above to improve Weiler's trilobe socket by arranging its slots around a hex core as taught by Hannay (*i.e.*, to provide additional socket surfaces to increase drive torque and also allow insertion by a hex-shaped driver). Beynnon ¶ 548-50. As shown in § IX.B above, Weiler's trilobe socket modified to have a hex core is virtually identical to the only embodiment in the '977 specification and discloses claim 2's Delta drive socket under any interpretation. Beynnon ¶ 346, 548. The three radially-extending slots are in every other annular face of the hex core, meeting claim 3. Beynnon ¶ 551. The remainder of the Endo-Fix screw and its method of use are unchanged in the combination, so the combination meets the other limitations of claims 1-3 in the same way Endo-Fix does. Beynnon ¶ 552; *supra* § IX.C.

X. CONCLUSION

For the foregoing reasons, *inter partes* review of U.S. Patent No. 6,629,977 claims 1-6 and the cancellation of those claims is hereby requested.

Dated: March 30, 2016

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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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