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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. 7,322,986

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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")
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1062	French Patent Application 2,717,070 (Pub. Sept. 5, 1995), with certified translation ("Laboureau")
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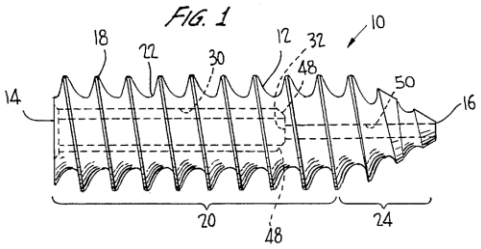
Pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq.*, Smith & Nephew, Inc. ("S&N") and ArthroCare Corp. ("Petitioners") request *inter partes* review of claims 1-6 of U.S. Patent No. 7,322,986 ("the '986 patent").

I. INTRODUCTION

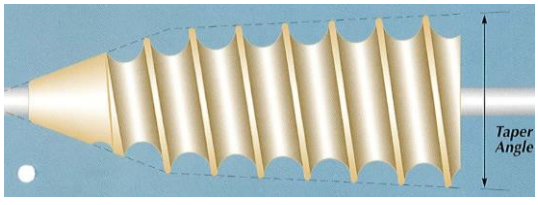
The '986 patent is directed to a method of using an interference screw for anterior cruciate ligament (ACL) reconstruction, which involves drilling tunnels in the tibia and femur where the ACL was formerly attached, and then securing ends of a graft inside the tunnels to replace the ACL. The '986 patent 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 '986 patent concedes, ACL reconstruction using interference screws in this way was conventional. What the specification describes as purportedly 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. Neither a tapered bioabsorbable interference screw with threads along substantially its entire length nor the use of such a screw in ACL reconstruction was new. However, Petitioners need not even establish that, because the claims are directed to subject matter that is broader than what the '986 specification describes as "the invention."

The claims some impose structural requirements on the screw used in the claimed method but a taper is not among them. Patent Owner broadened the claims during prosecution to remove the requirement of a taper. Thus, unlike the claims of the other patents in the family to which the ’986 patent claims priority, the ’986 patent claims are not limited to a tapered screw. Given that the common specification of those “priority” applications describes only a tapered screw, and describes a tapered screw as “the present invention,” the priority applications fail to provide written description support for the claims of the ’986 patent. As a result, the ’986 patent is limited to its actual filing date and is anticipated by the publication of the earliest patent in the family, which is § 102(b) prior art to the ’986 patent. That is the basis for Ground 1.



Even if the Board determines that the ’986 patent is entitled its earliest alleged priority date, neither a bioabsorbable interference screw of the type recited in the claims, nor its use in ACL reconstruction, was new. U.S. Patent No. 5,470,334 (Ex. 1013, “Ross,” Fig. 1 depicted above right), describes ACL reconstruction using such a bioabsorbable interference screw. Ross forms the basis for Grounds 2-3.



A sales brochure from 1995 (three years before the ’986 patent’s alleged earliest

priority date) describes bioabsorbable interference screws a subsidiary of Petitioner S&N commercialized for ACL reconstruction. Ex. 1011 ("Endo-Fix") at 2 (depicted above right). Endo-Fix forms the basis for Grounds 4-6.

Ross and Endo-Fix each renders obvious claim 1 of the '986 patent and most of dependent claims 2-6 even if the '986 patent is entitled to its earliest claimed priority date. One or two (depending on a claim interpretation issue) dependent claims recite specific features of a particular drive socket. Secondary references that disclose that claimed drive socket and provide specific motivation for using it in Ross and Endo-Fix provide the bases for Ground 3 (modifying Ross) and Grounds 5-6 (modifying Endo-Fix).

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. 6,875,216 (of which the '986 patent is a continuation) and 6,629,977 (the '216 patent purports to be a divisional of the '977 patent). Petitioners request that the Board assign a single panel to address these three 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 ’986 patent is available for IPR and that they are not barred or estopped from requesting IPR of the ’986 patent. Arthrex previously asserted the ’986 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*, IPR2012-4, Paper 18 at 15-16 (PTAB Jan. 24, 2013); *Atlanta Gas Light v. Bennett Regulator Guards*, IPR2015-826, 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 '986 patent:

Ground Number and Reference(s)		Claims	Basis
1	The '977 patent	1-6	§ 102(b)
2	Ross	1-2, 5-6	§ 103(a)
3	Ross in view of Hannay	3-4	§ 103(a)
4	Endo-Fix	1-3, 5-6	§ 103(a)
5	Endo-Fix in view of Weiler	1- 2, 5-6	§ 103(a)
6	Endo-Fix in view of Weiler and Hannay	3-4	§ 103(a)

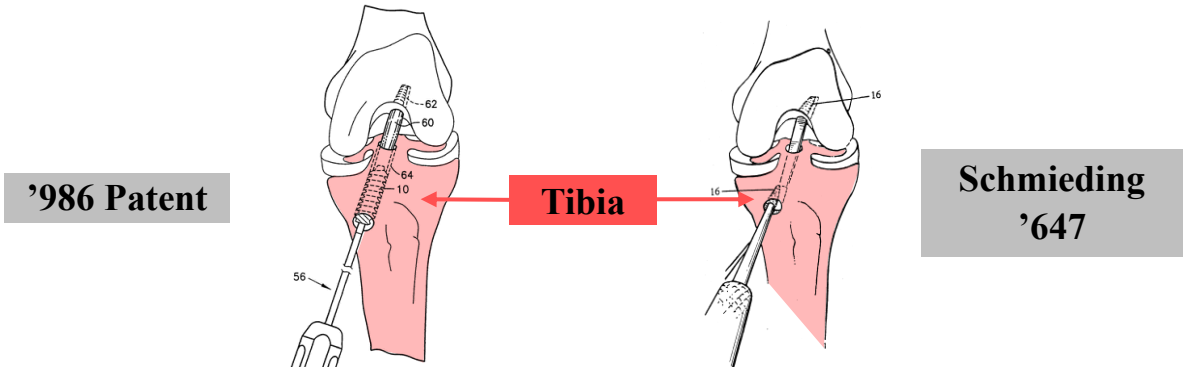
VI. OVERVIEW OF THE '986 PATENT

The '986 patent claims a "method of interference fixation for ACL reconstruction using a bioabsorbable interference screw." Ex. 1003 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. 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 ¶ 30. Performing this procedure

with an interference screw is illustrated in part by Fig. 6 of the '986 patent (below left) and the similar Fig. 2 from prior art U.S. Patent No. 5,211,647 ("Schmieding '647," Ex. 1057, below right) (Beynnon ¶ 34):



Surgeons fixed a graft to the tibia by inserting the graft and an interference screw into the tibial tunnel so that the graft was captured between the screw and the tunnel wall. Ex. 1057 at 2:14-27; Ex. 1021; Beynnon ¶ 34. Bone has a harder outer surface ("cortical bone") and a softer interior ("cancellous bone"). Ex. 1061 at 90; Beynnon ¶ 25. For solid fixation, it was known to have the screw engage the cortical bone when fully seated. Beynnon ¶ 36; *e.g.*, Ex. 1013 (Ross) at 1:24-28; Ex. 1062 at 7:23-34; *cf.* Ex. 1003 at 3:57-4:7. 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 it would protrude from the tunnel, 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 ¶ 38-40. 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 screw 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.

Different types of grafts were known. "Bone block fixation" used a section of the patellar tendon that included blocks of bone on each end that were fixed by the interference screws inside the femur and tibia. Ex. 1020 at 206; Ex. 1018 at 1561-62; Beynnon ¶ 31. "Soft tissue fixation" used sections of hamstring tendons that did not include bone blocks. Ex. 1018 at 1561-62; Beynnon ¶ 31.

B. Summary of the Claims

The '986 patent includes independent claim 1 and dependent claims 2-6. Claim 1 is reproduced below with bracketed letters that precede claim elements (*e.g.*, [a]) and are used throughout as shorthand references for those elements.

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

[pr.2] said elongated threaded body having a proximal end, a distal end, a length for substantially longitudinally filling a tibial tunnel, and a width dimensioned to provide an interference fit in the tibial tunnel,

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

[pr.4] a drive socket disposed within the screw and extending from the proximal end of the elongated threaded body,

[pr.5] wherein the drive socket includes a plurality of radially extending slots configured to receive corresponding radially extending protrusions on a shaft of a screwdriver, 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] turning the screw such that the threads of the screw engage cortical bone in the tunnel,

[c3] said substitute ligament is securely fixed between the threads of the screw and the wall of the tunnel, and

[c4] the bioabsorbable interference screw substantially longitudinally fills the tibial tunnel.

Preamble limitations [pr.1-pr.5] describe an interference screw having features met by Ross and Endo-Fix. Beynnon ¶ 75. The method steps describe the conventional use of these screws in ACL reconstruction. Beynnon ¶ 75.

C. Level of Ordinary Skill in the Art

The ’986 patent has an actual filing date in April 2005 and claims an earliest priority date in November 1999. Ground 1 is based on the ’986 patent not being entitled to a priority date earlier than its April 2005 filing date. The other grounds demonstrate unpatentability even if the ’986 patent is entitled to its earliest claimed

priority date, based on the level of skill a person having ordinary skill in the art ("POSA") possessed in the November 1999 timeframe. A POSA in the interference screw field, to which the '986 patent is directed, would have had (a) an advanced degree in mechanical engineering or the equivalent, or (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 except where otherwise noted, all of Petitioners' constructions are also the proper district court constructions.

A. "proximal end" and "distal end" (claim 1)

The specification uses these terms 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. 1003 at 2:62-65; Beynnon ¶ 76; *see* Ex. 1022 at 658, 1828; Ex. 1023 at 571, 1557 .

B. "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 ¶ 77. Screws having a single helical rib or "thread" are most common. Beynnon ¶ 61, 77.

"Thread" may also refer to "one complete turn of a screw thread," *i.e.*, each turn of a single helical is 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 ¶ 61, 77. 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 ¶ 61, 77. "Threads" in claim 1 refers to this latter usage: multiple complete turns of a helical rib extending in the length-wise direction along the screw. Beynnon ¶ 61, 77. The '986 specification does not show or describe multiple helical ribs and refers to "threads 16 extending substantially from proximal end 20 to distal end 25." Ex. 1003 at 2:64-67, Fig. 1; Beynnon ¶ 62, 77.

C. "radially extending slots" (claim 1)

The BRI of "radially-extending slots" is two or more grooves that extend outwardly from a center axis. Ex. 1022 at 2146 (defining "slot" as "a long and narrow opening or groove"); Ex. 1023 at 1800; Ex. 1025 at 2009; Beynnon ¶ 78.

D. "screw substantially longitudinally fills the tibial tunnel" (claim 1)

The '986 specification nowhere refers to the screw as substantially longitudinally filling the tibial tunnel as recited in claim 1.[1] Beynnon ¶ 79. A similar, but different, disclosure in the specification is that the screw fills all but the top 5-10 mm of the tibial tunnel, which the specification asserts advantageously secures a large portion of the graft against the bone tunnel while engaging cortical bone, and eliminates the purported need for multiple shorter screws. Ex. 1003 at 3:41-51; Beynnon ¶ 79. Dependent claim 6 narrows claim 1 by requiring that the screw occupy all but the top 5-10 mm of the tibial tunnel.

Although a screw that fills all but 5-10 mm of the tunnel must be found to meet the "substantially longitudinally fills the tunnel" limitation in claim 1, this language in claim 1 should be interpreted more broadly or else the "5-10 mm" limitation in dependent claim 6 would be superfluous. *Acumed v. Stryker*, 483 F.3d 800, 806 (Fed. Cir. 2007) (presumption that an independent claim should not be construed to require a limitation of its dependent claim). As claim 6 of the '986 patent and all claims of the related '977 patent demonstrate, the Patent Owner knew how to require the specific "5-10 mm" limitation when it was intended. Claim 1 of the '986 patent must be construed more broadly.

[1] Petitioners reserve the right to argue in litigation that this phrase is indefinite.

Under the BRI, the "substantially longitudinally fills" language should be interpreted to encompass a screw sized to sufficiently fill the tunnel to achieve the only results that the '986 patent describes, *i.e.*, the screw is long enough to engage cortical bone and to secure a sufficiently large portion of the graft against the tibial tunnel to avoid the need for multiple screws. Ex. 1003 at 3:42-51; Beynnon ¶ 79.

E. "tip having a second taper which is greater than the taper of the elongated threaded body" (claim 5)

Claim 5 recites: "a tip having a second taper greater than ***the taper of the elongated threaded body*** of the screw."[2] Claim 5's reference to "the taper of the elongated threaded body of the screw" raises an interpretation issue as there is no antecedent basis for this phrase in claim 1.[3] Beynnon ¶ 87.

The prosecution history reveals that the Patent Owner amended independent claim 9 (which issued as claim 1) to remove a limitation requiring a tapered body and failed to remove the reference to "the taper" from dependent claim 13 (which issued as claim 5). Ex. 1007 at 47-56; *Microsoft v. Proxyconn*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (in determining the BRI of the claims in an IPR the Board should "consult the patent's prosecution history"). The intent to remove the requirement of a tapered body from the claims was reinforced by Patent Owner

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

[3] Petitioners reserve the right to argue in litigation that claim 5 is indefinite.

amending the ’986 patent’s title to remove a reference to the screw being tapered, “to better reflect the invention as claimed.” Ex. 1007 at 104-05.

As filed, claim 13 (which issued as claim 5) did not affirmatively introduce a requirement that the body of the screw have a taper, but merely referred back to the body in the then-pending (but later amended) independent claim to provide context for a tip-related limitation. The subsequent amendment ***removing*** the body taper requirement from the independent claim obviously does not transform the language in dependent claim 5 into an affirmative requirement that the body of the screw have a taper. Thus, the BRI of claim 5, which issued with a language artifact concerning the “taper of the … body” is simply that it requires the screw to have a tip with a taper that would exceed any taper on the body ***if the body had a taper***, but does not affirmatively require that the body have a taper. This broadest reasonable interpretation holds the Patent Owner to its amendments and its statement to the public that the “invention as claimed” is not limited to a screw with a tapered elongated body. Ex. 1007 at 47-56 and 104-05; *see* Beynnon ¶ 87.

F. “body” (claim 1) and “tip” (claim 5)

An interpretation issue arises as to whether the elongated threaded “body” encompasses the entire screw (including the screw’s tip) or excludes the tip. This interpretation impacts certain claimed characteristics of the screw “body” (*e.g.*, threads extending between the proximal and distal ends of the ***body***—*infra* §

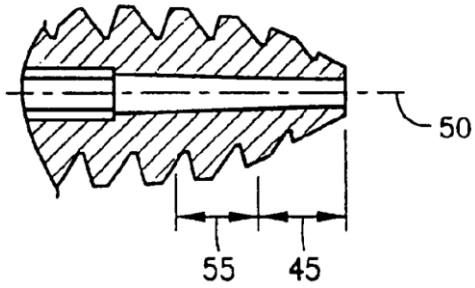
VII.G). However, because the disclosure in the prior art is identical in relevant respects to the disclosure in the '986 patent itself, the claims are unpatentable no matter how the Board resolves this interpretation issue. Beynnon ¶ 81.

Claim 1 does not mention a tip, but claim 5 introduces a requirement that, "the distal end of the screw is provided with a tip having a second taper greater than the taper of the elongated threaded body of the screw." Beynnon ¶ 80. Claim 5 makes clear that the screw has a tip that is distinct from the body for two reasons. Beynnon ¶ 80. First, claim 5 does not recite the body as including the tip—rather, the tip is a separate part of the screw.[4] *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 ¶ 80. Second, the recitation that the tip has a characteristic (taper) different from the taper of the body establishes that it cannot be part of the body, because the tip cannot both be part of the body and have a taper different from the taper of the body. Beynnon ¶ 80.

Construing the "body" of the screw as separate from the "tip" is consistent with the specification, which teaches that the screw has a complex taper as shown in Figs. 1 and 3 (Fig. 3 reproduced right), where "elongated main ***body*** 15" of the

[4] "The distal end of the screw" lacks antecedent basis as the "distal end" recited in claim 1 is of the "body" (not the "screw").

screw 10 (Fig. 1) has a more gradual taper than "initial portion 45" of the screw 10, and where "relatively pointed distal portion 45 forms a nose that provides for ***easy insertion*** of the screw 10 into a bone tunnel." Ex. 1003 at 3:18-20; Beynnon ¶ 56, 81. A POSA would have understood the "relatively pointed distal portion 45" to be the "tip," distinct from the "main body 15." Beynnon ¶ 56-57, 81. This understanding is consistent with claim 5's requirement (already discussed) that the tip have a greater taper than the body. Beynnon ¶ 80.



Thus, the BRI of "body" is the portion of the screw extending from the screw's proximal end and terminating before the "tip." Beynnon ¶ 80. 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 ¶ 80. As noted above, however, all claims are unpatentable even if "body" is construed to encompass the tip and be synonymous with the entire screw. Beynnon ¶ 81.

G. "extending along substantially the entire length of the screw from said proximal end to said distal end" (claim 1)

The preamble of claim 1 recites 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 for substantially longitudinally filling a tibial tunnel, … ***the threads of the screw extending along substantially the entire length of the screw from said proximal end to said distal end***…

The antecedents for "said" proximal and distal ends are the ends of the ***body*** **(**not the screw), and claim 1 is explicit that threads that extend from "said proximal end [of the body] to said distal end [of the body]" extend "along substantially the entire length of the ***screw***." Beynnon ¶ 82. Therefore, the claim structure dictates that threads that extend along the entire body from its proximal to distal end meet the claim's requirement to extend "along substantially the entire length of the screw" even if they terminate before, and do not extend to the tip.[5]

This interpretation is consistent with the specification, as the only embodiment disclosed has threads that terminate before the distal end of the screw. *See* Ex. 1003 at 2:7-12, Fig. 3; Beynnon ¶ 82.

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

[5] Just like a driver who drove "substantially the entire length of the east coast [screw] from Bar Harbor, Maine [proximal end] to Miami [distal end]" drove from Bar Harbor to Miami and not "the entire length of the east coast [screw]."

the petition." 35 U.S.C. § 314(a). All claims would have been obvious over the cited prior art as explained in detail by Dr. Beynnon, a Professor in the Department of Orthopaedics and Rehabilitation at the University of Vermont. Ex. 1008.

IX. GROUNDS OF UNPATENTABILITY OF CLAIMS 1-6

A. Ground 1: The '977 Patent Anticipates Claims 1-6

1. Introduction

The '986 patent is a continuation of Application No. 10/634,807 ("the '807 application," now the '216 patent). The '986 patent and its "parent" applications as filed shared an identical specification, limited to a species of interference screw that was ***tapered***, and a conventional method of ACL reconstruction using that ***tapered*** screw. The specification states that "***[t]he present invention*** … [provides] a ***tapered,*** elongated bioabsorbable interference screw," repeatedly refers to "the present invention" as being a ***tapered*** bioabsorbable interference screw, and refers to the method of ACL reconstruction "of the present invention" as employing a known surgical technique using "the ***tapered*** bioabsorbable interference screw of the present invention." *E.g.*, Ex. 1003 at 1:51-53, 2:21-29; Beynnon ¶ 274-76. The '986 claims were broadened during prosecution to remove reference to the screw being tapered and Patent Owner amended the title of the '986 patent to remove the word "Tapered." Ex. 1007 at 47-56, 104-05. All of the '986 claims are therefore directed to an overly broad genus that includes not only the disclosed tapered species of interference screw, but also a non-tapered species that the

specification explicitly disparages and distinguishes from "the present invention." *E.g.*, Ex. 1003 at 1:51-55; *see* Beynnon ¶ 277.

Unpatentability under § 112 ¶ 1 for lack of written description in the '986 specification is not available as a ground in this proceeding. But determining whether the '986 patent is entitled to an earlier priority date is required to evaluate Ground 1, which is based on unpatentability under § 102. The Board has denied priority under § 120 to a parent application having the same specification as a patent challenged in an IPR where (as here) the parent application failed to support the challenged claims under § 112 ¶ 1. *Infra* § IX.A.2. Given the absence of written description support in the parent applications for the genus claims in the '986 patent, the '986 patent is entitled only to its actual filing date.

The '977 patent issued more than a year before the '986 patent's actual filing date and is § 102(b) prior art that anticipates claims 1-6. Ex. 1001 at [45] (issued Oct. 7, 2003); Ex. 1003 at [22] (filed Apr. 4, 2005). Given that the '977 patent's disclosure is identical to that in the challenged patent, anticipation of claims 1-6 is apparent. As discussed *infra* § IX.A.3, different tests apply so there is no inconsistency in finding the claims anticipated by the specification of the '977 patent but unsupported under § 112 ¶ 1 by the same specification. The '977 patent's disclosure of a tapered species that falls within the broad genus claims of the '986 patent anticipates those claims. *Infra* § IX.A.3.

2. The Alleged Priority Documents Do Not Support Claims 1-6

The ’986 patent is a continuation of the ’807 application (now the ’216 patent), which in turn purports to be a divisional of Application No. 09/711,964 (“the ’964 application,” now the ’977 patent). The ’807 and ’964 applications are referred to herein collectively as the “Earlier Filed Applications” or “EFAs.”

The Board may assess the ’986 patent’s priority claims to the EFAs even though they have the same specification as the ’986 patent. *SAP v. Arunachalam*, IPR2014-414, Paper 11 at 13 (PTAB Aug. 18, 2014) (instituting over objection that assessing priority exceeds Board’s authority); *id.*, Paper 24 at 21 (“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*, IPR2014-833, Paper 14 at 20-22 (PTAB Dec. 3, 2014).

For the ’986 patent to benefit from the filing date of either of the EFAs, “each application in the chain leading back to the earlier application must comply with the written description requirement.” *Lockwood v. Am. Airlines,*107 F.3d 1565, 1571 (Fed. Cir. 1997); 35 U.S.C. § 120. The written description requirement of § 112 ¶ 1 ensures “that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.” *Ariad Pharm. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353-54 (Fed. Cir. 2010) (*en banc*). The written description must

demonstrate that the inventor "possesse[d] the ***full scope*** of the invention." *LizardTech v. Earth Res. Mapping*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005).

The full scope of claims 1-6 encompasses a method of using a genus of screws that includes tapered and ***non-tapered*** screws. *See* Ex. 1003 at claims 1-6; Ex. 1007 at 47-56 (removing "the taper" limitation from the claims); Beynnon ¶ 274. However, a POSA would have understood that the purported invention described in the EFAs was limited to a tapered screw and that "the inventor's contribution to the field of art as described in the patent specification" does not include the use of non-tapered screws. *Ariad Pharm.*, 598 F.3d at 1353-54; Beynnon ¶ 274-76. As "Tapered" in their titles suggests, the EFAs describe only a tapered screw and repeatedly refer to "the ***tapered*** bioabsorbable screw of the present invention" and to the method of ACL reconstruction "of the present invention" as employing a known surgical technique using "the ***tapered*** bioabsorbable interference screw of the present invention." *E.g.*, Ex. 1001 at 1:12-15, 1:52-53, 2:19-29 (citations are to the '977 patent which differs from the EFAs only in the correction of typos and inclusion of patent numbers in the priority claim, *see* Ex. 1005 at 47, 55; Ex. 1006 at 16, 47); Beynnon ¶ 274-76.

The EFAs disparage "***[c]onventional straight-sided*** bioabsorbable interference screws" as providing less "interference fit" than a tapered screw, which allegedly forced a POSA seeking increased fixation to consider a "larger

diameter screw" that was "more difficult to align and insert correctly." *E.g.*, Ex. 1001 at 1:36-42. The EFAs assert that "***[t]he present invention*** overcomes the disadvantages of the [non-tapered] prior art and achieves the foregoing objectives [increased fixation without insertion difficulty] by ***providing a tapered,*** elongated bioabsorbable ***interference screw***." *Id*. at 1:48-50.

The inventor filed an application telling the pubic that his invention was a tapered screw that provided advantages over "straight-sided" screws and then, years later, amended the claims to recite a different "invention" encompassing the straight-sided screws he had earlier disparaged. The newly claimed "invention" lacks written description in the EFAs. *Tronzo v. Biomet*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) (a written description that "specifically distinguishes the prior art as inferior and touts the advantages of the conical shape" of a medical implant cup "make[s] clear that the [written description] discloses *only* conical shaped cups and nothing broader"). The Federal Circuit addressed similar circumstances in *ICU Med. v. Alaris Medical Systems*, 558 F.3d 1368, 1378 (Fed. Cir. 2009):

> ICU's asserted spikeless claims are broader than its asserted spike claims because they do not include a spike limitation; these spikeless claims thus refer to medical valves generically—covering those valves that operate with a spike and those that operate without a spike. But the specification describes only medical valves with spikes. …We reject ICU's contention that the figures and descriptions that include spikes somehow demonstrate that the inventor possessed a medical

valve that operated without a spike. Based on this disclosure, a person of skill in the art would not understand the inventor of the ’509 and ’592 patents to have invented a spikeless medical valve.

Like the claims the Federal Circuit addressed in *ICU*, Arthrex’s “[taper]less claims” in the ’986 patent are broader than its “[tapered] claims” in the related ’216 and ’977 patents because they do not require that the body be tapered. *ICU Med.*, 558 F.3d at 1378; *also Atl. Research Mktg. v. Troy*, 659 F.3d 1345, 1355 (Fed. Cir. 2011) (finding claims to device without a feature to lack written description in specification that only describes the device with the feature). The EFAs describe only interference screws with tapered bodies and disparage and distinguish non-tapered screws from “the present invention.” Beynnon ¶ 274-76. A POSA would not have understood the inventor to have invented a broader genus of interference screw that includes the non-tapered screws the specification distinguishes and disparages. *Tronzo* 156 F.3d at 1159; Beynnon ¶ 276-77. The EFAs fail to provide a written description under § 112, ¶1 for any of claims 1-6.

3. The ’977 Patent Anticipates Claims 1-6

The ’986 patent is not entitled to the earlier dates of the EFAs under § 120 for any of claims 1-6 because the EFAs do not provide written description support for any of those claims. Thus, the ’986 patent is limited to its April 2005 filing date. Ex. 1003 at [22]. The ’977 patent issued in October 2003 (Ex. 1001 at 45) and is prior art under § 102(b). The ’977 patent anticipates claims 1-6 of the ’986

patent. As the Federal Circuit explained, finding that the same disclosure anticipates claims 1-6 but fails to provide written description support for those claims under § 112 ¶ 1 is not inconsistent because the tests differ:

> The CCPA noted in [*In re*] *Lukach*[, 442 F.2d 967, 969-70 (C.C.P.A 1971] that although a patent might contain a disclosure satisfying the written description requirement with respect to the claims in that patent, it could still be section 102(b) prior art as to broader claims of a subsequent application although not containing a disclosure satisfying the section 112 description requirement with respect to the anticipated broader claims. *See id*. at 969-70[]. This apparent anomaly is most likely to occur when the prior art reference discloses a species of a genus sought to be claimed. ... That is exactly what happened in the instant case, and accordingly we see no impermissible anomaly or logical inconsistency in the EIC's rejection.

Chester v. Miller, 906 F.2d 1574, 1577 (Fed. Cir. 1990); *see also Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991).

Claims 1-6 encompass a method of using a genus of screws that includes tapered and non-tapered species. The '977 patent discloses the method using the tapered species. Just as in *In re Lukach*, the '977 patent's disclosure anticipates claims 1-6 even though it does not provide written description support for them.

Given that the disclosures in the '977 and '986 patents are identical, mapping the claims onto the disclosure in the claim chart below is straightforward. *See also* Beynnon ¶ 278. The only interpretation issue warranting discussion

relates to claim 5. For the reasons discussed in § VII.E above, notwithstanding a language artifact lacking antecedent basis, claim 5 (like claims 1-4 and 6) is directed to the overly broad genus including non-tapered screws. Thus, it too is not entitled to the earlier dates of the EFAs and is anticipated by the '977 patent.

U.S. Patent No. 7,322,986	'977 Patent
[pr.1] 1. A method of interference fixation for ACL reconstruction using a bioabsorbable interference screw having an elongated threaded body,	Ex. 1001 at claims 1 and 6, 1:12-15, 2:19-29, Figs. 1, 6.
[pr.2] said elongated threaded body having a proximal end, a distal end, a length for substantially longitudinally filling a tibial tunnel, and a width dimensioned to provide an interference fit in the tibial tunnel,	*Id.* at claims 1 and 6, 2:60-61, 1:31-38, 3:28-30, 3:34-38, 3:41-46, 3:56-58, 4:3-6, 2:62, Figs. 1, 3, 6.
[pr.3] the threads of the screw extending along substantially the entire length of the screw from said proximal end to said distal end, and	*Id.* at claims 1 and 6, 2:4-7, Figs. 1, 6.
[pr.4] a drive socket disposed within the screw and extending from the proximal end of the elongated threaded body,	*Id.* at claim 2, 1:60-63, 2:66-3:6, Figs. 1, 2, 6.
[pr.5] wherein the drive socket includes a plurality of radially extending slots configured to receive corresponding radially extending protrusions on a shaft of a screwdriver, said method comprising the steps of:	*Id.* at claims 2 and 3, 3:1-6, Abstract, 3:52-55, Figs. 1, 2, 5A, 5B.
[a] forming a tunnel in the tibia, said tunnel having a wall;	*Id.* at claims 1 and 6, 1:21-24, 2:19-29, 2:49-51, Fig. 6.
[b] inserting a substitute ligament in the tunnel; and	*Id.* at claims 1 and 6, 1:21-30, 2:19-29, 2:49-51, Fig. 6.
[c1] inserting said bioabsorbable interference screw into the tunnel and	*Id.* at claims 1 and 6, 1:24-30, 2:19-29, 2:49-51, Fig. 6.
[c2] turning the screw such that the threads of the screw engage cortical bone in the tunnel,	*Id.* at claims 1, 2, and 6, 3:42-49, 2:49-51; Fig. 6.
[c3] said substitute ligament is securely fixed between the threads of the screw and the wall of the tunnel, and	*Id.* at claims 1 and 6, 1:21-30, 2:19-29; 3:42-49, 2:49-51; Fig. 6.

[c4] the bioabsorbable interference screw substantially longitudinally fills the tibial tunnel.	*Id.* at claims 1 and 6, 3:34-38, 3:41-46, 2:62, 3:56-58, 4:1-4, 1:56-59, Abstract, Figs. 1, 3, 6.
2. The method of claim 1, wherein the screw is fully cannulated and the method of insertion comprises inserting the cannulated inteference [sic] screw over a guide pin.	*Id.* at claim 6, 2:27-29, 2:10-14, Figs. 1-4.
3. The method of claim 1, wherein the screw has a Delta drive socket and the method of inserting the screw comprises engaging the screw at the proximal end of the screw with a Delta drive screwdriver and rotating the screw into the tunnel.	*Id.* at claim 2, 1:60-65, 2:66-3:8, Figs. 2, 6.
4. The method of claim 3, wherein the Delta drive socket comprises a hexagonally-shaped recess with radially-extending slots in every other annular face.	*Id.* at claim 3, 1:60-63, 2:66-3:10, 3:51-55, Figs. 2, 5A, 5B.
5. The method of claim 1, wherein the distal end of the screw is provided with a tip having a second taper which is greater than the taper of the elongated threaded body of the screw.	*Id.* at claim 4, 3:11-18, Figs. 1, 3.
6. The method of claim 1, wherein the screw, when inserted, occupies all but the top 5-10 mm of a tibial bone tunnel.	*Id.* at claims 1 and 6, 3:34-38, 3:41-46, 2:62, 3:56-58, 4:1-4, 1:56-59, Abstract, Figs. 1, 3, 6.

B. Ground 2: Ross Renders Claims 1-3 and 5-6 Obvious

Ross, issued November 28, 1995 (Ex. 1013 at [45]) and prior art under § 102(b), discloses a bioabsorbable interference screw that meets every element of the screw used in the method of claim 1. Ex. 1013 at 1:10-13; 4:53-5:12, Fig. 2; Beynnon ¶ 279. Ross also describes the use of the screw in conventional ACL reconstruction and explicitly meets most of claim 1's method of use limitations. Ross does not explicitly state that the screw substantially longitudinally fills the tunnel or that it engages cortical bone in the tunnel. However, Ross renders claim 1 obvious under numerous rationales discussed below. Among them, a POSA would have understood Ross to implicitly disclose the limitations that it does not

explicitly disclose, so that claim 1 is anticipated by Ross. *Sony v. HumanEyes Techs.*, IPR2013-219, Paper 16 at 24-25 (PTAB Sept. 23, 2013) ("[A] disclosure that anticipates under 35 U.S.C. § 102 also renders the claim unpatentable under 35 U.S.C. § 103, for anticipation is the epitome of obviousness."); *see also In re Pearson*, 494 F.2d 1399, 1402 (CCPA 1974); *In re Fracalossi*, 681 F.2d 792, 794 (CCPA 1982)"). Alternatively, all the limitations of claim 1 would have been met by the conventional, expected and obvious use of the Ross screw in the conventional ACL reconstruction procedure Ross describes. Beynnon ¶ 279-80.

1. Claim 1

a. [pr.1]

Ross discloses "bioabsorbable interference bone screws particularly useful in securing a ligament in a bone tunnel" via interference fixation, and describes their use in the same conventional ACL reconstruction procedure the '986 patent admits to be known. Beynnon ¶ 281-82; Ex. 1013 at 1:10-13, Title, 6:65-7:20.

The screw has an elongated threaded body, regardless of whether the "body" is construed to include the tip. Ex. 1013 at Fig. 1, 4:27-31("[T]he bone screw 10… includes a longitudinally elongated cylindrical body 12 having… a helical screw thread 18… from proximal end 14 to distal end 16."); Beynnon ¶ 284-86; *supra* § VII.F. The body extends 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 the distal end of the screw, depending on which interpretation of "body" is adopted). Beynnon ¶ 284-86; *supra* § VII.A.

b. [pr.2]

The Ross screw has an elongated body having proximal and distal ends, as discussed in § IX.B.1.a above. The claimed length and width are specified in relation to the tibial tunnel and are discussed separately immediately below.

i. "a length for substantially longitudinally filling a tibial tunnel"

This preamble limitation does not require that the body (or screw) actually substantially fill the tunnel—only that the body have a length "for" doing so. That is to be contrasted with limitation [c1] which recites inserting the screw into the tunnel and limitation [c4] which recites that the entire screw (not just the "body") substantially longitudinally fills the tibial tunnel. As demonstrated in § IX.B.1.f below, Ross implicitly discloses the screw substantially longitudinally filling the tibial tunnel, and alternatively, an obvious use of the Ross screw results in the screw substantially filling the tibial tunnel. A POSA would have understood that the body of the Ross screw therefore has a length "for" doing so no matter how "body" is interpreted, as the Ross screw has a body/tip ratio that is virtually identical to the only embodiment in the '986 patent and has a non-tip body portion that accounts for the vast majority of its length. Beynnon ¶ 289; *supra* § VII.F.

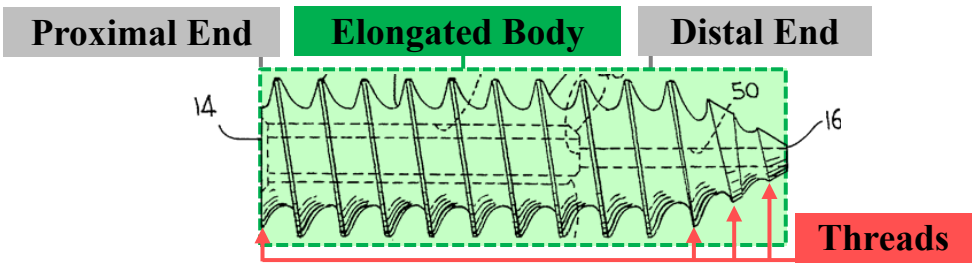
ii. "a width dimensioned to provide an interference fit in the tibial tunnel"

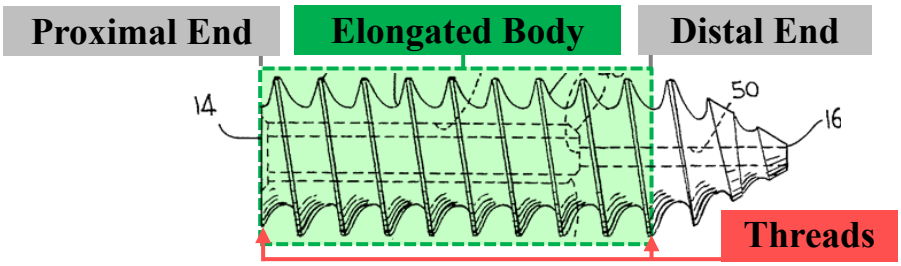
A POSA would have understood "width" to refer to the screw's diameter. Beynnon ¶ 290. Ross describes a "bioabsorbable ***interference bone fixation*** screw" and states that the screw forms an "***interference fit*** between the bone block and the [tunnel] wall," so a POSA would have understood Ross to implicitly disclose the screw as having a diameter or "width" for providing this interference fit. Ex. 1013 at Title, 7:16-20; Beynnon ¶ 290. If Patent Owner argues that interference fit requires that the screw have a diameter that exceeds the diameter of the tunnel, a POSA would have understood Ross to implicitly disclose such a width because it was conventional for interference screws to be sized relative to the tunnel in this way. *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."); Ex. 1026 (Johnson) at 5:10-12 ("A screw having a larger diameter than the screw socket can be used, if even further compaction of the graft socket and bone block is desired."); Ex. 1039 (Arthrex Homepage) ("In the tibia, select a fully threaded screw that is 1 mm larger than the tunnel and graft diameter (i.e., 8 mm tunnel, 8 mm graft = 9 mm screw)."); Beynnon ¶ 290. Indeed, the '986 patent admits that "[b]ioabsorbable interference screws are usually sized so that they are slightly larger tha[n] the diameter of the

tunnel." Ex. 1003 at 1:34-41; Beynnon ¶ 290. If such a width is not considered to be implicitly disclosed by Ross, it would have been obvious to use the Ross screw in the conventional manner by providing the screw with a width that exceeds the diameter of the bone tunnel and is "dimensioned to provide an interference fit in the tibial tunnel." Beynnon ¶ 291; Ex. 1003 at 1:34-35; Ex. 1026 (Johnson) at 5:10-12; Ex. 1039 (Arthrex Homepage); *see also* Ex. 1018 (Frank) at 1564 ("[a]bundant research has shown that… larger screws are slightly better than smaller ones"); Ex. 1035 (Gerich) at 86; Ex. 1034 (Hulstyn) at 419; Ex. 1015 (Weiler) at 123.

c. [pr.3]

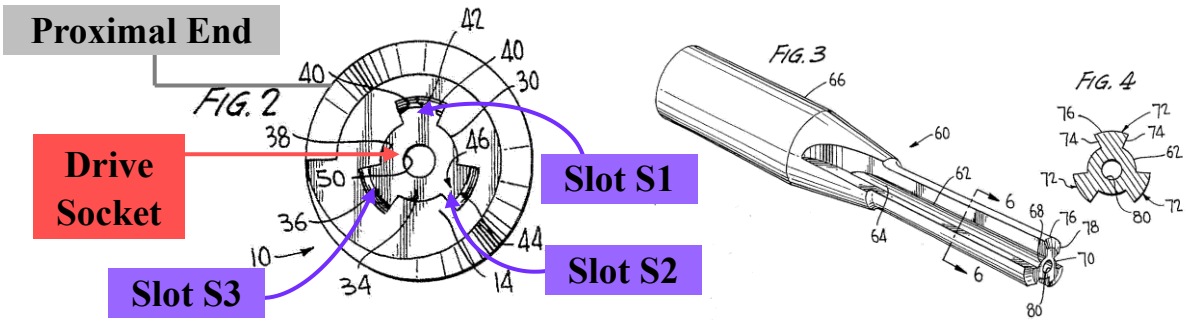
Ross explicitly states that the threads extend along substantially the entire length of the screw and meets this limitation no matter how the interpretation issues discussed in §§ VII.F and VII.G above are resolved. Ex. 1013 at 4:27-31 ("[T]he bone screw 10… includes a longitudinally elongated cylindrical body 12 having… a helical screw thread 18… from proximal end 14 to distal end 16."), Fig. 1; Beynnon ¶ 293-96; (see Fig. 1 annotated below to illustrate how [pr.3] is met under any interpretation of "body" as discussed in § VII.F above).





d. [pr.4] and [pr5]

The Ross screw has a trilobe drive socket disposed within the screw that extends from the proximal end of the elongated threaded body. Ex. 1013 at Fig. 2 (annotated below), 4:50-5:12 ("drive recess 30 includes … three equally spaced lobe openings or chambers 36 radially disposed around cavity 34"); Beynnon ¶ 297. The drive socket lobes are radially extending slots (*i.e.*, grooves that extend outwardly from the center axis of the drive socket) and are nearly identical to those in the only drive socket embodiment in the '986 patent. Ex. 1013 at Fig. 2; Beynnon ¶ 298; *supra* § VII.C. Ross discloses a "driver 60" with matching protrusions ("three lobes 72 disposed radially on shaft 62"). Ex. 1013 at 6:44-50, Fig. 2 (below, left), Figs. 3 & 4 (below right); Beynnon ¶ 298.



e. Method Limitations [a], [b], and [c1-c3]

Ross discloses method limitations, [a], [b], and [c1-c3], Ex. 1013 at 6:65-7:20 (Beynnon ¶ 300):

> [F]or ligament fixation in … replacement of the [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-c3]***.

Ross does not explicitly describe the tibial tunnel screw as being rotated but a POSA would have understood Ross to implicitly disclose that the driver 60 be used to rotate the second screw into interference fit in the tibial tunnel in the same way Ross describes for the screw in the femoral tunnel. Beynnon ¶ 301.

Ross also does not explicitly reference the tibial tunnel screw threads engaging cortical bone, but a POSA would have understood Ross to implicitly disclose this from Ross's reference to the screw providing "an endosteum or endosteal fixation," which a POSA would have understood means that the screw

engages cortical bone when fully seated in the tibial tunnel. Ex. 1013 at 1:24-27; Beynnon ¶ 302. Endosteal fixation refers to fixation with the endosteum, a thin layer of cells on and within cortical bone. Ex. 1047 at 1258; Beynnon ¶ 35, 302. Ross's teaching that the screw engage the endosteum (which results in the screw engaging cortical bone) was consistent with the well-known teachings in the art that a screw engaging harder cortical bone when fully seated would be best secured in the bone tunnel. Beynnon ¶ 36, 148, 302; *see, e.g.*, Ex. 1063 at 397-402. Thus, if Ross is considered to not implicitly disclose cortical bone engagement, it would have been obvious to have the proximal end of the Ross screw engage cortical bone when the screw was fully seated in the tibial tunnel to maximize fixation strength. Beynnon ¶ 302; *cf.* Ex. 1003 at 3:57-4:9 (acknowledging cortical bone engagement with endosteal fixation); *see also* Ex. 1012 (Simon) at 1:4-9.

In addition, step [c2] is also met by the screw threads engaging cortical bone as the screw is being inserted into the tunnel ***before*** it is fully seated. Beynnon ¶ 303. Given that cortical bone is disposed at the opening of the tibial tunnel through which the screw passes during insertion (Ex. 1047 at 1258), a POSA would have understood Ross to implicitly disclose that the screw threads engage cortical bone as the screw is inserted into the tibial tunnel. Beynnon ¶ 303. Alternatively, it would have been obvious to have the Ross screw threads engage cortical bone as the screw is interested into the tibial tunnel. Beynnon ¶ 303.

f. [c4]

As discussed in § VII.D above, the BRI of the screw substantially longitudinally filling the tunnel encompasses a screw that achieves the results described in the ’986 patent, *i.e.*, a screw long enough to engage cortical bone and secure a sufficiently large portion of the graft against the bone tunnel that multiple screws are not needed. Beynnon ¶ 79, 302-303, 306. Ross’s screw is designed to do precisely that. Ex. 1013 at 1:24-28, 6:65-7:20 (describing the use of one screw in the tibial tunnel); Beynnon ¶ 306. Thus, a POSA would have understood Ross to implicitly disclose a screw that “substantially longitudinally fills the tunnel.” Beynnon ¶ 306. Alternatively, the expected, conventional and obvious use of the Ross screw in the ACL reconstruction procedure Ross describes would have resulted in the screw substantially longitudinally filling the tibial tunnel. Beynnon ¶ 306. If this term is interpreted more narrowly, to be limited to the screw filling all but 5-10 mm of the tunnel, it would still be met for the reasons discussed *infra* § IX.B.5 in connection with dependent claim 6. Beynnon ¶ 307.

2. Claim 2

Ross’s screw is fully cannulated—a cannula (drive recess 30 and guide bore 50) extends its entire length. Beynnon ¶ 310. Recess 30 extends “longitudinally from proximal end 14 [of the screw] to end wall 32” and “guide bore or cannulation 50 is … in communication with drive recess 30 and extends

longitudinally from end wall 32 to distal end 16 [of the screw]." Ex. 1013 at 4:54-56; 5:9-12; 3:61-64. Ross describes the screw as being inserted over a guide pin passing through bore 50 and recess 30. *Id*. at 7:10-16 ("[S]crew 10 is inserted via guide bore 50 over a guide wire…."); Beynnon ¶ 186, 310 (explaining that guide wire and guide pin are synonymous). Guide wire insertion is described explicitly only for the femoral tunnel screw, but a POSA would have understood Ross to implicitly disclose that the tibial tunnel screw also is inserted over a guide wire. Alternatively, it would have been obvious to insert Ross's cannulated screw into the tibial tunnel over a guidewire. Beynnon ¶ 311.

3. Claim 3

"Delta" drive socket and screwdriver are coined terms with no known meaning to a POSA and no definition in the specification. Beynnon ¶ 313. In the litigation, Petitioner will ask the court to find these terms indefinite. Under BRI here, the "Delta" drive socket and driver should be construed as covering ***any*** drive socket and driver, including Ross's "drive recess 30" and "rotatable driver 60" (Ex. 1013 at 4:50-53, 6:44-51, Figs. 1-2), given that "Delta" would not have been understood by a POSA as imposing any known limitation on the claimed drive socket or driver. Beynnon ¶ 313. Ross teaches engaging the screw's proximal end with the driver and rotating it during insertion. *Supra* § IX.B.1.e; Beynnon ¶ 314.

4. Claim 5

As discussed in § VII.E above, the BRI of claim 5 requires that the tip have a greater taper than any taper the body may have, but does not affirmatively require a tapered body. Ross's screw has a tip that is tapered more steeply than the body. Ex. 1013 at Fig. 1, 3:46-47 (the screw has "a conically tapered distal end"); Beynnon ¶ 316-18. If claim 5 is interpreted to require that the body have a taper, it would have been obvious to taper the Ross screw body in view of the well-known teachings that tapered screws advantageously allowed insertion torque to increase gradually and increased fixation strength. *See* Beynnon ¶ 319 and the cited references (*e.g.*, Endo-Fix and Simon) disclosing tapered interference screws.

5. Claim 6

As discussed in § IX.B.1.f above, Ross implicitly discloses the screw as substantially longitudinally filling the tibial tunnel. Beynnon ¶ 306, 321. A POSA would have understood that in conventional ACL reconstruction the screw is inserted into the tibial tunnel to a depth just beyond where its proximal end is flush with the "bottom" (away from the knee joint) opening of the tunnel through which the screw is inserted. Beynnon ¶ 322; *e.g.*, Ex. 1021 (Lambert) at 88 (Fig. 6); Ex. 1057 (Schmieding '647) at Fig. 2; Ex. 1052 (Scranton) at 180 (Fig. 10); Ex. 1012 (Simon) at Fig. 32; Ex. 1049 (Bellemans) at 670. A POSA would have understood Ross to implicitly disclose this given Ross's reference to endosteal fixation, which a POSA understood to mean the screw's proximal end engages cortical bone when

fully seated in the tibial tunnel. Ex. 1013 at 1:24-27; Beynnon ¶ 302. Thus, virtually all of the tunnel unfilled as a result of the Ross screw being shorter than the tunnel is at the "top" of the tunnel adjacent the knee joint. Beynnon ¶ 322. While Ross does not explicitly disclose how much of the top of the tunnel would have been unfilled by the screw, claim 6 would have been obvious over Ross for numerous reasons because the numerical requirement that "5-10 mm" be unfilled adds nothing inventive or patentable to the claims beyond what Ross discloses.

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

Ross explicitly discloses the use of its screw for bone block fixation. Ex. 1013 at 6:65-7:20; Beynnon ¶ 324. A POSA understood the Ross screw to also be suitable for soft tissue fixation. Beynnon ¶ 324. The '986 patent acknowledges both bone block and soft tissue fixation to be prior art and it was common for the same types of screws to be used for both procedures. Ex. 1003 at 1:21-30 (admitting both procedures known); Beynnon ¶ 324 (citing Ex. 1030 (Grooms) at 3:50-56 and other references that describe screws used for both procedures).

Procedurally, soft tissue fixation was virtually identical to the bone block fixation Ross describes. Beynnon ¶ 326 (citing numerous references). For example, Corry (Ex. 1048) describes steps [a], [b] and [c1-c3] 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 … tibial tunnel and the screw was

inserted ***[step c1]***. This screw was initially advanced two to three turns with the knee flexed ***[step c2]***. When a firm grip was obtained, the leg was straightened to ensure full extension and then the screw was fully seated ***[step c3]***.").

For soft tissue fixation, Bellemans evidences that a POSA knew that the screw should be "approximately 5 mm shorter than the tibial tunnel length" which maximizes engagement between the screw and the soft tissue graft. Ex. 1049 (Bellemans) at 669-70; Beynnon ¶ 327. This knowledge would have motivated a POSA to choose a size for the Ross screw that filled all but 5 mm of the tibial tunnel for soft tissue fixation. Beynnon ¶ 327. The obvious and conventional use would have seated the screw just inside the bottom of the tibial tunnel so that it would have been the top 5 mm of the tunnel left unfilled. Beynnon ¶ 322, 327-28.

b. No Unexpected Result or Difference In Kind Is Achieved Relative To the Soft Tissue Fixation Art

Patent Owner may seek to swear behind Bellemans. Any such attempt should fail because claim 6 is not limited to a screw with a tapered body. Given that the inventor ***never*** invented the overly broad subject matter claimed (*see supra* § IX.A), Patent Owner cannot show invention of the ***claimed*** subject matter before Bellemans. In addition, even if Patent Owner were to swear behind Bellemans, other patents and publications establish that the conventional and obvious use of the Ross screw in soft tissue fixation would have met step [c4]. Beynnon ¶ 329.

The claims quantify with numerical precision nothing more than the result of

applying well-known, ***common sense*** knowledge to select an appropriately sized screw for the patient. Beynnon ¶ 47, 329; Ex. 1030 (Grooms) at 7:26-30 (for "an ACL procedure … [a] screw … 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 graft integration in the tunnel (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 engaging harder cortical bone would be best secured in the tunnel (*See e.g.*, Ex. 1063 (Amis) at 397-402). Beynnon ¶ 330; *see* Ex. 1038 (Mahony) at 2:11-18 ("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.").

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 ¶ 330-31. 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 ¶ 331. 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 ¶ 333.

The numerical limitation requiring that the top "5-10 mm" of the tibial tunnel be unfilled by the screw recites nothing inventive or patentable because it does not produce an unexpected result or difference in kind from a screw that substantially fills the 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 results the '986 specification asserts are achieved by the screw filling all but the top 5-10 mm of the tibial tunnel —*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. The

’986 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 own 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 as Ross describes. Ex. 1013 at 7:10-20 (describing the use of one screw in each of the femoral and tibial tunnels); Beynnon ¶ 148, 332 (citing numerous references 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, the Ross screw achieved all the advantages the ’986 patent asserts are achieved by filling all but 5-10 mm of the tunnel. *Supra* § IX.B.1.f. Beynnon ¶ 332. The particular claimed 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 conventional and obvious use of the Ross screw in soft tissue fixation and does not render the claims unobvious over Ross. *In re Applied Materials*, 692 F.3d at 1297; Beynnon ¶ 332.

c. The Soft Tissue Fixation Art Taught A Range That Subsumes and Renders Obvious the Claimed Range

Only two simple variables impact how much space is left unfilled by an interference screw inserted in a tibial tunnel: screw length and tunnel length. Beynnon ¶ 334. 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; *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 (a prior art range that overlaps a claimed variable value "provides sufficient motivation to optimize" the variable to have a value in the prior art range). The principle is not limited to composition claims and applies to 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. For soft tissue fixation, the art taught a tibial tunnel 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 3:48-56 (referring to screws "for soft tissue attachment" and identifying 10-40 mm screws as having preferred lengths); Beynnon ¶ 336.

Thus, a POSA following the known teachings to provide the tibial tunnel in

a length of 45 mm for soft tissue fixation, and a bioabsorbable interference screw in a range of 10-40 mm, would have been led to a screw/tunnel pair that would have resulted in the portion of the tibial tunnel unfilled by the screw being within a range of 5-35mm. A POSA would have understood the practical range to be even tighter, as a POSA choosing an "appropriate" screw for a patient would not have chosen a small screw for a large patient. Beynnon ¶ 337; Ex. 1030 (Grooms) at 7:26-30. Nevertheless, the range of 5-35 mm of the tibial tunnel being unfilled a POSA would have been led to by known teachings in the art subsumes the claimed range and renders it *prima facie* obvious. *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. Given the absence of unexpected results or criticality achieved by leaving all but the top "5-10 mm" of the tibial tunnel unfilled, *see supra* § IX.B.5.b, the presumption of obviousness is not overcome and claim 6 would have been obvious over Ross for this additional reason. Beynnon ¶ 338-39.

d. Bone Block Fixation Art Taught Another Range That Subsumes and Renders Obvious the Claimed Range

Claim 6 is also rendered obvious by a conventional and obvious use of the Ross screw in the bone block fixation procedure Ross describes, which has particular sizing considerations for the tibial tunnel as explained in Ex. 1053

(Olszewski) at 13; Beynnon ¶ 340. A POSA knew that the tibial tunnel length for receiving a bone block using known techniques varied from 33-53 mm based on the size of the patient. Ex. 1053 (Olszewski) at 13 (Table 4); Beynnon ¶ 340.

A POSA would have been aware that interference screws for bone block fixation were 25-40 mm 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. A POSA following these known teachings would have had reason to use a 25-40 mm Ross screw in a tibial tunnel within the 33-53 mm range Olszewski describes as conventional for bone block fixation. Beynnon ¶ 340-41. 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. 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 a POSA chose a small screw for use in a large patient. Beynnon ¶ 342.

Thus, a POSA following conventional teachings of screw and tibial tunnel sizes for bone block fixation would have been led to pairings resulting in the amount of the tibial tunnel unfilled by the screw falling in a range of 0-28 mm. Beynnon ¶ 342. 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.

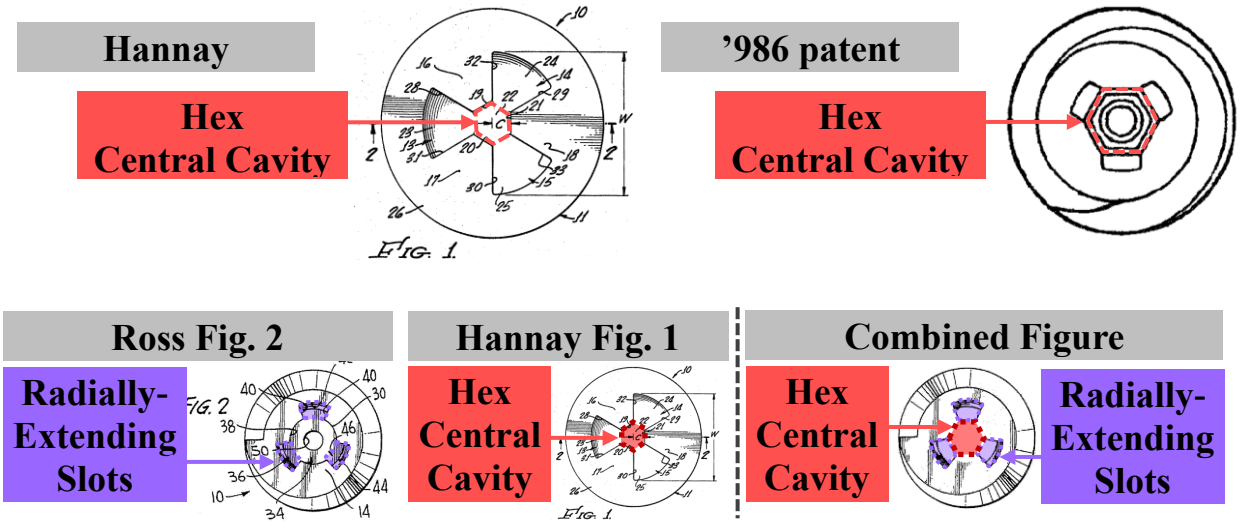
The presumption cannot be overcome. *See supra* § IX.B.5.c.

C. Ground 3: Ross in View of Hannay Renders Claims 3 and 4 Obvious

Claim 3 recites a "Delta" drive socket and driver which, as discussed in § IX.B.3 above, are coined terms, and claim 4 recites the Delta drive socket as comprising a hex-shaped recess with radially-extending slots in every other annular face. Ross does not meet the drive socket requirements in claim 4, nor the Delta drive socket and driver in claim 3 ***if*** the Board interprets "Delta" as limited to the disclosed embodiment. However, the socket/driver interface in the '986 patent was disclosed decades earlier in Hannay (Ex. 1016). Ground 4 is based on a combination (Ross and Hannay) that uses a feature (hex core) of Hannay's drive socket but retains the other features of the Ross screw and meets the other limitations of claims 3-4 in the same way and for the same reasons (discussed in § IX.B above) that Ross does. Beynnon¶ 350.

Hannay, a U.S. patent that issued in 1971 (Ex. 1016 at [45]) and prior art under § 102(b), discloses a drive socket having "three equally spaced individual recesses" like Ross, but a hex (rather than Ross's circular) core. Ex. 1016 at 2:9-17, Fig. 1; Beynnon ¶ 346. Hannay is directed to general screws, but POSAs in the interference screw field routinely looked to other types of screws for ideas on drive socket design. *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.

Substituting Hannay's hex core for Ross's circular core would have been a matter of design choice that would have yielded predictable results, as illustrated below. *KSR Int'l v. Teleflex*, 550 U.S. 398, 416 (2007); Beynnon ¶ 348. In addition, a POSA would have had reasons to improve Ross's trilobe socket by arranging its slots around a hex (rather than circular) core as depicted in Hannay. First, the hex core provides additional socket surfaces that interact with the driver to distribute drive forces and increase drive torque before failure. Beynnon ¶ 347. Second, the hex core allows a hex-shaped driver to insert the screw, affording flexibility if Ross's trilobe driver was unavailable. Beynnon ¶ 347. The '986 patent touts the ability to use a "hex-head screwdriver" as an alternative to the Delta driver as an advantage (Ex. 1003 at 1:63-66) but Hannay taught this decades earlier. Ex. 1016 at Fig. 1 (below showing Hannay's hexagonally-shaped central cavity); Beynnon ¶ 347.



Ross references Hannay among a number of screws with enlarged head and tapered socket designs that present challenges for bioabsorbable screws. Ross at 2:35-51. However, the Ross/Hannay combination is not based on using Hannay's enlarged head or tapered socket, but relies solely on Hannay's teaching of a hex core to modify Ross's circular core. A POSA would have understood the resulting drive interface to improve the ability of the Ross socket to distribute drive forces and to be appropriate for use in a bioabsorbable screw. Beynnon ¶ 348.

Ross's socket modified to use Hannay's hex core is virtually identical to the only embodiment in the '986 specification and discloses claim 3's "Delta" drive socket and driver under any interpretation. See comparison of figures above; Beynnon ¶ 350. The three radially-extending slots are in every other annular face of the hex core, meeting claims 4's requirement. Beynnon ¶ 350.

D. Ground 4: Endo-Fix Renders Claims 1-3 and 5-6 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 (declaration establishing public distribution of Endo-Fix before 1998); *Orion IP v. Hyundai Motor Am.*, 605 F.3d 967, 974-75 (Fed. Cir. 2010) (finding "promotional publication" a printed publication). Endo-Fix discloses a bioabsorbable interference screw for ACL reconstruction that meets every element of the screw in claim 1. Ex. 1011 at 1-2; Beynnon ¶ 352. Endo-Fix does not

explicitly describe all the method steps of claim 1. However, Endo-Fix renders claim 1 obvious under numerous rationales discussed below. Among them, a POSA would have understood Endo-Fix to implicitly disclose the limitations that it does not explicitly disclose, so that claim 1 is anticipated by Endo-Fix. *Sony*, IPR2013-219, Paper 16 at 24-25 ("[A] disclosure that anticipates … also renders the claim unpatentable under 35 U.S.C. § 103"). Alternatively, claim 1 would have been met by a conventional, expected and obvious use of the Endo-Fix screw because, ***as the '986 patent concedes, the recited steps were conventional*** (Ex. 1003 at 1:19-41) and describe the way a POSA would have expected the Endo-Fix screw to be used in ACL reconstruction. Beynnon ¶ 352-53.

1. Claim 1

a. [pr.1]

Endo-Fix discloses an "Interference Screw" of "bioabsorbable material." Ex. 1011 at 1-2; Beynnon ¶ 354. A POSA would have known that an intended use for the Endo-Fix screw was in ACL reconstruction to secure a substitute ligament by interference fixation. Ex. 1011 at 2; Ex. 1003 at 1:24-33 (conceding that it was known to use a bioabsorbable interference screw to secure a graft in a bone tunnel); Beynnon ¶ 355-60 (citing numerous references, including Simon (Ex. 1012 at 4:17-22, 1:19-23) and Ross (Ex. 1013 at 1:10-13, 1:24-28) disclosing methods of graft fixation with bioabsorbable screws).

The Endo-Fix screw has an elongated threaded body, regardless of whether the "body" is construed to include the tip, and describes screws having length (20-30 mm) versus diameter (7-9 mm) proportions that are similar to those disclosed in the '986 patent (length of 35 mm and diameters of 9-12 mm). Ex. 1011 at 2-3; Ex. 1003 at 2:64, 3:21-30; Beynnon ¶ 354, 130-32; *supra* § VII.F. The proximal end of the "body" coincides with the proximal end of the screw, and the distal end of the "body" 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 ¶ 354, 131-32; *supra* § VII.A. Under either interpretation, the Endo-Fix "body" is elongated and threaded. Ex. 1011 at 2; Beynnon ¶ 354, 133, 135.

b. [pr.2]

The Endo-Fix screw has an elongated body with proximal and distal ends, as discussed in § IX.D.1.a above. The claim specifies length and width in relation to the tibial tunnel as discussed separately below.

i. "a length for substantially longitudinally filling a tibial tunnel"

As demonstrated in § IX.D.1.f below, a POSA would have understood Endo-Fix to implicitly disclose this limitation, or alternatively, an obvious use of the Endo-Fix screw would have resulted in the screw body substantially filling the tibial tunnel. A POSA would have understood that the body of the Endo-Fix screw therefore has a length "for" doing so no matter how "body" is interpreted, as the

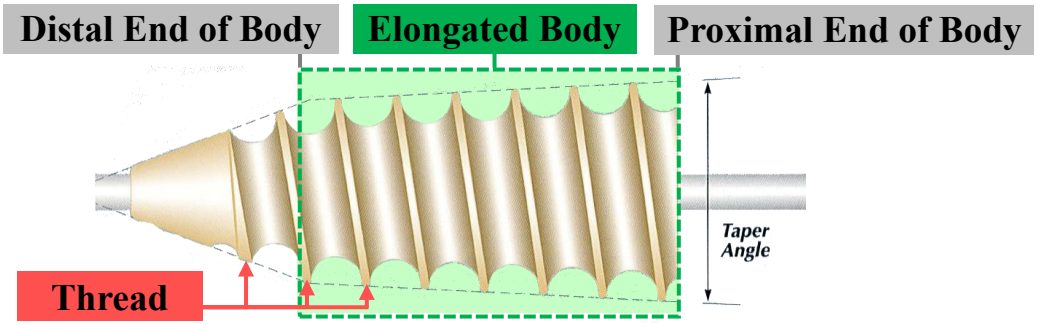
Endo-Fix screw has a body/tip ratio that is virtually identical to the only embodiment in the ’986 patent and has a non-tip body portion that accounts for the vast majority of its length. Beynnon ¶ 363; *supra* § VII.F.

ii. “a width dimensioned to provide an interference fit in the tibial tunnel”

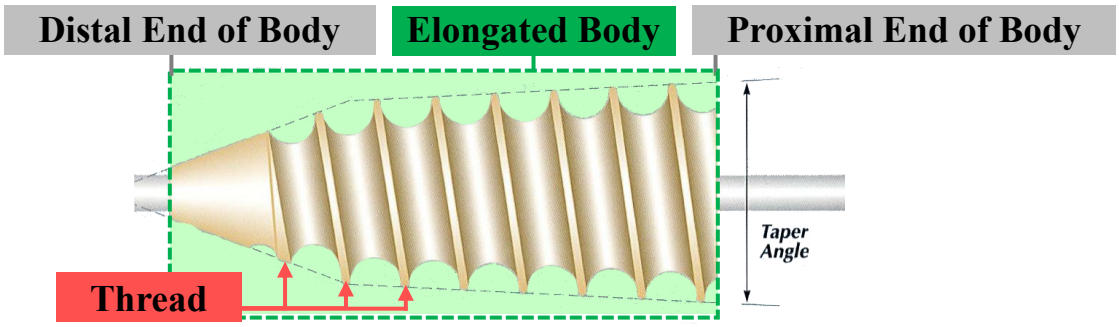
Endo-Fix describes multiple screw sizes, including a 9 mm diameter (“width”) that is identical to a width the ’986 patent states is preferred and necessarily “dimensioned” to provide an interference fit in a tibial tunnel in the same manner as that preferred embodiment. Ex. 1011 at 3; Ex. 1003 at 3:21-23; Beynnon ¶ 364. In addition, a POSA understood that the Endo-Fix screw secured a graft in a tunnel via an interference fit. Beynnon ¶ 364. The ’986 specification asserts that a tapered screw promotes a greater degree of “interference fit” than non-tapered screws by enabling insertion of a screw having a proximal diameter that exceeds the tunnel diameter. Ex. 1003 at 3:29-41. While the claims do not require any degree of “interference fit,” a POSA would have understood the “conically-shaped” Endo-Fix screw to be insertable into a bone tunnel having a diameter smaller than the screw’s proximal end. Beynnon ¶ 365. Indeed, the ’986 patent admits that “[b]ioabsorbable interference screws are usually sized so that they are slightly larger tha[n] the diameter of the tunnel.” Ex. 1003 at 1:34-35; Beynnon ¶ 365. For these reasons, the Endo-Fix screw has a width dimensioned to provide an interference fit in the tibial tunnel. Beynnon ¶ 366.

c. [pr.3]

As discussed in § VII.G above, claim 1 is explicit that threads extending from the proximal end of the ***body*** to the distal end of the ***body*** satisfy the phrase "along substantially the entire length of the screw." As shown in the annotated figure below, the Endo-Fix screw threads extend from the proximal end of the body, past the distal end of the body and onto the tip. Thus, the Endo-Fix screw threads extend "along substantially the entire length of the screw." Ex. 1011 at 2, 3; Beynnon ¶ 367; *supra* § VII.G.

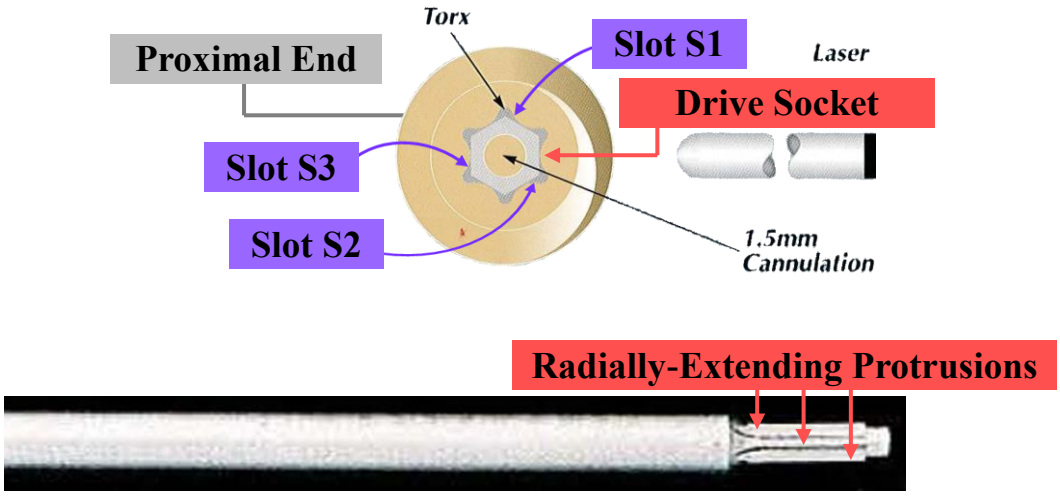


Even if "body" is interpreted to include the "tip" (*supra* § VII.F) the Endo-Fix screw threads extend along substantially the entire length of the screw as illustrated in the annotated figure below because they extend from the screw's proximal end and terminate just prior to the screw's distal end. Beynnon ¶ 368. The distal end of the screw being unthreaded is entirely consistent with the '986 patent specification, as the only disclosed embodiment is a screw that has no thread on its distal end (Fig. 3) and "[p]referably… has a smooth, rounded tip profile so as to minimize abrasion of the graft." Ex. 1003 at 2:7-12; Beynnon ¶ 368.



d. [pr.4] and [pr.5]

Endo-Fix's driver and drive socket have matching "'six-star' Torx " shapes as shown in the annotated figures below. Ex. 1011 at 2-3; Beynnon ¶ 370. The Torx head drive socket is disposed within the screw and extends from the proximal end of the elongated threaded body. Ex. 1011 at 2; Beynnon ¶ 370. The drive socket includes a plurality of radially extending slots (the darker gray grooves at the outer edges of the drive socket in the figure reproduced below) configured to receive radially extending protrusions (annotated below) on the shaft of the driver. Ex. 1011 at 2-3; Beynnon ¶ 371, 171-72; *supra* § VII.C.



e. Method Limitations [a], [b], and [c1-c3]

A POSA would have understood steps [a],[b] and [c1-c3] to be implicitly disclosed by Endo-Fix, because as the evidence cited below establishes, these steps recite nothing more than the conventional and expected use of the Endo-Fix screw to secure a graft in the tibial tunnel during ACL reconstruction. Beynnon ¶ 373-74. Alternatively, the evidence establishes that it would have been obvious to use the Endo-Fix screw in a manner that meets these steps.

First, the '986 patent's admission that it was known to use bioabsorbable "interference screws to secure the graft against the walls of a tunnel drilled through the tibia" is binding on Patent Owner. Ex. 1003 at 1:20-33; *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*, IPR2015-1983, Paper 7 at 6 n.2 (PTAB Mar. 2, 2016). A POSA would have recognized that in these admitted prior art procedures the surgeon inserts the screw into the tibial tunnel by turning the screw using a driver, that the proximal end of the screw engages cortical bone for the reasons discussed in § IX.B.1.e above, and that all of elements [a],[b], and [c1-c3] would have been met. Beynnon ¶ 376-77.

Second, numerous references teach conventional ACL reconstruction procedures for which the Endo-Fix screw was intended and demonstrate the performance of steps [a],[b] and [c1-c3]. A POSA knew the Endo-Fix screw to be

suitable for both soft tissue and bone block fixation. Beynnon ¶ 356-359, 374. Prof. Beynnon cites to numerous references disclosing conventional bone block fixation, including Ross (Ex. 1013). Beynnon ¶ 379-394 (*e.g.*, Exs. 1021, 1054, 1057, 1013, 1042). The way the Ross procedure meets steps [a],[b] and [c1-c3] is discussed in § IX.B.1.e above. Prof. Beynnon also cites numerous references disclosing conventional soft tissue fixation, including Corry. Beynnon ¶ 379-394 (*e.g.*, Exs. 1052, 1058, 1059, 1033, 1041, 1049). The way the Corry procedure meets steps [a],[b] and [c1-c3] is discussed in § IX.B.5 above.

f. [c4]

As discussed in § VII.D above, the BRI of the screw substantially longitudinally filling the tunnel encompasses a screw that achieves the results described in the '986 patent, *i.e.*, a screw long enough to engage cortical bone and secure a sufficiently large portion of the graft against the bone tunnel that multiple screws are not needed. Beynnon ¶ 79, 396. The Endo-Fix screw was designed to do precisely that. Ex. 1011 at 3 (disclosing 20-30 mm lengths); Beynnon ¶ 396. A POSA would have understood Endo-Fix to implicitly disclose a screw that "substantially longitudinally fills the tunnel." Beynnon ¶ 396. Alternatively, the expected, conventional and obvious use of the Endo-Fix screw in the ACL reconstruction procedure for which it was intended would have resulted in the screw substantially longitudinally filling the tibial tunnel. Beynnon ¶ 396-98. If

the Board interprets this term more narrowly to be limited to the screw filling all but 5-10 mm of the tunnel, it would still be met for the reasons discussed in § IX.D.5 below in connection with dependent claim 6. Beynnon ¶ 399.

2. Claim 2

The Endo-Fix screw has a "cannulation, permitting the use of a rigid guide wire" which "helps the surgeon… during insertion." Ex. 1011 at 2, 3 Beynnon ¶ 402. A POSA would have understood Endo-Fix's "rigid guide wire" to be a guide pin, and Endo-Fix to implicitly disclose that its fully cannulated screw be inserted into the tibial tunnel over a guide pin, or alternatively that it would have been obvious to insert the cannulated Endo-Fix screw into a tibial tunnel over a guide pin in ACL reconstruction. Ex. 1013 (Ross) at 6:65-7:20; Ex. 1048 (Corry) at 446-47 (both describing insertion over a guide wire); Beynnon ¶ 186, 402-03.

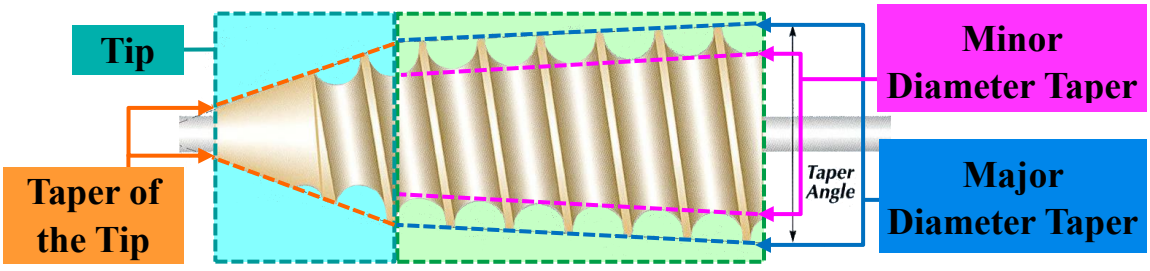
3. Claim 3

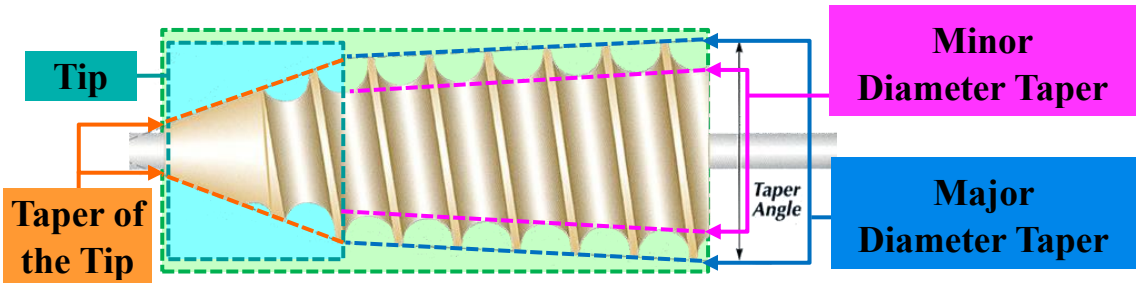
As discussed in § IX.B.3 above, given that "Delta" did not impose any known limitation on the claimed socket or driver, under the BRI in this proceeding, "Delta" drive socket and driver should be construed as covering ***any*** drive socket and driver. Beynnon ¶ 313, 405. If interpreted more narrowly, it must be limited to the only drive socket/driver interface disclosed in the '986 patent—a socket with an inner female hex interface and outer radially-extending slots. Ex. 1003 at 1:63-66, 3:1-12, Fig. 2; Beynnon ¶ 406. Endo-Fix meets either interpretation because its

drive socket has an inner female hex interface and outer radially-extending slots. *See supra* § IX.D.1.d; Ex. 1011 at 2-3; Beynnon ¶ 406. As discussed in § IX.D.1.e. above, a POSA would have understood Endo-Fix to implicitly disclose that the 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. Beynnon ¶ 407. Alternatively, it would have been obvious to use the Endo-Fix screw in this manner. Beynnon ¶ 407-08.

4. Claim 5

The annotated figures below illustrate that the Endo-Fix screw's elongated body is tapered, its distal end has a tip having a greater (*i.e.*, steeper) taper, and renders claim 5 obvious regardless of the interpretation of "body" discussed in § VII.E above. Ex. 1011 at 2; Beynnon ¶ 410. The Endo-Fix body has tapers of both its major (measured at the thread crests) and minor (measured at the thread troughs) diameters, as illustrated below. Ex. 1045 at 1633; Beynnon ¶ 410-12.





5. Claim 6

A POSA would have understood that the Endo-Fix screw substantially filled the tibial tunnel (see *supra* § IX.D.1.f), and that in conventional ACL reconstruction virtually all of the tunnel left unfilled is at the "top" of the tunnel (the portion adjacent the knee joint). *See supra* § IX.B.5; Beynnon ¶ 414-415, *e.g.*, Ex. 1021 (Lambert) at 88 (Fig. 6); Ex. 1057 (Schmieding '647) at Fig. 2; Ex. 1052 (Scranton) at 180 (Fig. 10); Ex. 1012 (Simon) at Fig. 32; Ex. 1049 (Bellemans) at 670. Although Endo-Fix does not disclose down to the millimeter how much of the top of the tibial tunnel would not have been filled by the screw, claim 6 would have been obvious over Endo-Fix for numerous reasons.

Explicit Teaching For Soft Tissue Fixation – Bellemans' teaching 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 ¶ 417.

No Unexpected Result or Difference in Kind – As the evidence discussed above in § IX.B.5.b establishes, the amount of the tibial tunnel filled by the screw

is a result effective variable and the particular requirement that all but the top "5-10 mm" be left 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 the Endo-Fix screw in soft tissue fixation and does not render claim 6 inventive over Endo-Fix. *In re Applied Materials*, 692 F.3d at 1295-97; Beynnon ¶ 419.

Soft Tissue Fixation Range Renders Obvious the Claimed 5-10 mm Range – As established above in § IX.B.5.c, the evidence establishes a known range (5-35 mm) for the portion of tibial tunnel left unfilled by the screw that subsumes the claimed range of 5-10 mm and renders the claimed range *prima facie* obvious, and the presumption of obviousness is not overcome. Beynnon ¶ 421.

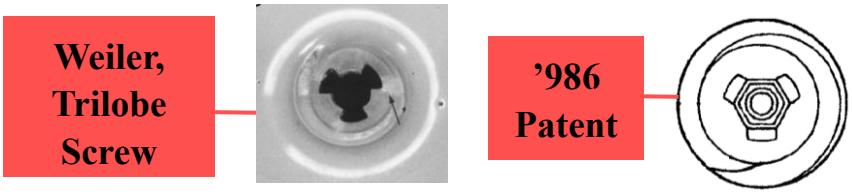
Bone Block Fixation Range Renders Obvious the Claimed 5-10 mm Range – As established above in § IX.B.5.d, for bone block fixation the evidence establishes a known 25-40 mm range of screw lengths and a known range of tibial tunnel lengths of 33-53 mm, resulting in a known range (0-28 mm) for the portion of tibial tunnel left unfilled by the screw that subsumes the claimed range of 5-10 mm and renders the claimed range *prima facie* obvious, and the presumption of obviousness is not overcome. Beynnon ¶ 423.

E. Ground 5: Endo-Fix in View of Weiler Renders Claims 1-2 and 5-6 Obvious

Ground 5 provides an alternative basis for meeting the drive socket

limitations in claims 1-2 and 5-6, as Weiler describes a drive socket that has three radially extending slots that are virtually identical to those in the '986 patent and provides express motivation for using it in place of the Endo-Fix drive socket.

Weiler, published in January 1998 (Ex. 1043) and prior art under § 102(b), describes a study comparing the performance of six different biodegradable interference screws in categories including insertion torque and maximum torque at which the drive socket fails. Ex. 1015 at 119, 125, Figure 4; Beynnon ¶ 208, 209, 213, 426. Among those evaluated is a Linvatec screw with a "trilobe" socket that Weiler identifies as a "Group 3" screw (labeled "C" in Figure 4). Beynnon ¶ 209-10, 427. As shown below, the trilobe socket is the same one disclosed in Ross (assigned on its face to Linvatec). Ex. 1015 Figure 4 at 125 (left); Ex. 1002 at Fig. 2 (right, with numbers and annotations removed); Beynnon ¶ 427.



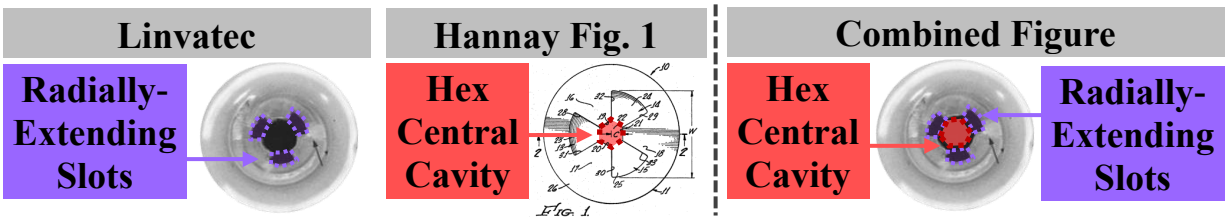
The "trilobe" drive socket screw is compared with an "Acufex" screw (Weiler identifies as Group 6) a POSA would have recognized as the Endo-Fix screw. Ex. 1015 at 121-22, 125; Beynnon ¶ 212, 428. Weiler concluded that the Acufex (Group 6) screw failed at torques that "may present a risk of drive failure during screw insertion" and that torque failure was "highly determined by the drive

design." Ex. 1015 at 126; Beynnon ¶ 214, 428. The trilobe socket (Group 3) withstood significantly higher torque before failure. Ex. 1015 at 126; Beynnon ¶ 215, 428. A POSA would have been motivated by Weiler to modify the Endo-Fix screw to use the trilobe socket to withstand increased torque and address Weiler's concern about "drive failure." Ex. 1015 at 126; Beynnon ¶ 215, 428. A POSA also would have understood that substituting the known trilobe socket for Endo-Fix's torx drive socket would have been a matter of design choice that would have yielded predictable results. *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 ¶ 216-217, 428.

The screw that would have resulted from the combination of Endo-Fix and Weiler would have met the radially extending slot limitation [pr.5] of claim 1 because Weiler's trilobe socket has grooves extending outwardly from a center axis of the drive socket as shown in the Weiler figure reproduced above. Beynnon ¶ 429; Ex. 1015 at 122, 125; *supra* § VII.C. The rest of the Endo-Fix screw and its method of use are not changed in the combination, so the other limitations of claims 1-2 and 5-6 would have been met or rendered obvious by the combination for the same reasons discussed in § IX.D above. Beynnon ¶ 429.

F. Ground 6: Endo-Fix in View of Weiler and Hannay Renders Claims 3 and 4 Obvious

Weiler's trilobe socket does not meet the drive socket in claim 4, or the Delta drive socket in claim 3 ***if*** the Board interprets it as limited to the '986 patent's disclosed embodiment. Beynnon ¶ 431. Ground 6 is a combination of Endo-Fix, Weiler and Hannay that uses Hannay's hex core but retains the other features of the Endo-Fix screw as modified based on Weiler to use a trilobe socket (illustrated below). This combination meets the other limitations of claims 3-4 for the same reasons, discussed in § IX.E above, that the Endo-Fix/Weiler combination does. Beynnon ¶ 431. Weiler's trilobe socket is identical to Ross's and it would have been obvious to modify the core of that socket to use Hannay's hex core for the same reasons discussed in § IX.C above. Beynnon ¶ 433-35. The resulting socket would have met the drive socket and driver limitations of claims 3 and 4 for the same reasons discussed in § IX.C above. Beynnon ¶ 436;



X. CONCLUSION

For the reasons given above, *inter partes* review of U.S. Patent No. 7,322,986 claims 1-6 and the cancellation of those claims is hereby requested.

Dated: March 30, 2016

By/Richard F. Giunta /
Richard F. Giunta, Reg. No. 36,149

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:

Blank Rome LLP
1825 Eye Street NW
Washington DC 20006-5403

Date: March 30, 2016

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