UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDSHAPE, INC.
Petitioner

v.

CAYENNE MEDICAL, INC.
Patent Owner

Case No. Unassigned

U.S. Patent 7,651,528

Issue Date: January 26, 2010

Title: Devices, Systems and Methods for Material Fixation

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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APPENDIX OF EXHIBITS

Exhibit Number	Exhibit Description
1001	"Montgomery- '528" – U.S. Patent No. 7,651,528 to Montgomery et al.
1002	Complaint filed in *Cayenne Medical, Inc. v. MedShape, Inc*., Case No. 2:14-CV-00451
1003	Affidavit of Service Filed in *Cayenne Medical, Inc. v. MedShape, Inc*., Case No. 2:14-CV-00451
1004	Declaration of Geoffrey Higgs, M.D.
1005	European Patent Application EP 1 066 805 A2 to Gerke et al.
1006	U.S. Patent No. 6,887,271 to Justin et al.
1007	International Publication No. WO 02/32345 A3 to Jacobs et al.
1008	File History of 7,651,528
1009	Patent holder Cayenne Medical Inc.'s Opening Claim Construction Brief

I. THE PETITION

Petitioner, real party-in-interest MedShape, Inc. hereby petitions the Patent Trial and Appeal Board (the "Board" or the "PTAB") of the United States Patent and Trademark Office ("PTO"), pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.1 *et seq*., to institute an *inter partes* review and to find and cancel Claims 12-18 of U.S. Patent No. 7,651,528, entitled "Devices, Systems and Methods for Material Fixation," issued January 26, 2010 (Serial No. 11/281,566, filed November 18, 2005) ("the '528 patent"), assigned to Cayenne Medical, Inc. The '528 patent is submitted herewith as Exhibit 1001. There is a reasonable likelihood that Petitioner will prevail with respect to at least one claim challenged in this petition.

II. MANDATORY NOTICES

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this petition.

A. Real party-in-interest

Pursuant to 37 C.F.R. § 42.8(b)(1) Petitioner, MedShape, Inc. ("MedShape"), a corporation, organized and existing under the laws of the State of Georgia, is the sole real party-in-interest.

B. Related matters (37 C.F.R. § 42.8(b)(2))

Cayenne has asserted two patents – U.S. Patent Nos. 8,435,294 and 7,651,528 in a lawsuit captioned *Cayenne Medical, Inc. v. MedShape, Inc.* Case No. 2:14-CV-00451 (HRH) (D. Ariz.). The litigation is presently ongoing. In addition to the instant Petition relating to the '528 patent, Petitioner also concurrently submits a Petition for *Inter Partes* Review of 8,435,294 ("'294" patent") owned by Cayenne Medical, Inc.

C. Counsel (37 C.F.R. §§ 42.8(b)(3) and 42.10(a))

Petitioner designates the following individuals as its lead counsel and back-up lead counsel:

Lead Counsel	Back-up Lead Counsel
Anthony E. Bennett	James F. Harrington
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D. Service information (37 C.F.R. §42.8(b)(4))

Service on Petitioner may be made electronically by using all the following two email addresses together in providing service: aebdocket@hbiplaw.com and jfhdocket@hbiplaw.com. Service on Petitioner may be made by Postal Mailing or

or Hand-delivery addressed to Lead and Back-up Lead Counsel at the following address, but electronic service above is requested:

Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, New York 11791

This document, together with all exhibits referenced herein, has been served on the patent owner at its principal place of business at 16597 North 92nd Street, Suite 101, Scottsdale, Arizona 85260 as well as the correspondence address of record for the '528 patent: Donald E. Stout, Esq.; Stout, Axa & Buyan, LLP, 4 Venture, Suite 300, Irvine, CA 92618.

III. PAYMENT OF FEES

Pursuant to 37 C.F.R. §§ 42.103 and 42.15(a), the requisite filing fee of $23,000 (request fee of $9,000 and post-institution fee of $14,000) for a Petition for *Inter Partes* Review is submitted herewith. Claims 12-18 of the '528 patent are being reviewed as part of this Petition. The undersigned further authorizes payment from Deposit Account No. 08-2461 for any additional fees or refund that may be due in connection with the Petition.

IV. ADDITIONAL REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner hereby certifies that the '528 patent is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting *Inter Partes* Review challenging the claims of '528 patent on the grounds identified herein. This Petition is timely filed under 35 U.S.C. §315(b) because it is filed within one year of the service of the Complaint alleging infringement of the '528 patent by Cayenne. *See* Exs. 1002-1003.

B. Level of Ordinary Skill in the Art

The '528 patent claims priority to a provisional application filed on November 18, 2004. A person of ordinary skill in the art in November 2004 would be a person with a Bachelor of Science degree in mechanical engineering with at least two years of practical or post-graduate work in the area of implantable orthopaedic medical devices, or a person having graduated with a medical degree from an accredited medical school with experience in using anchor devices for attaching soft tissue to bone.

C. Identification of Challenge and Relief Requested (37 C.F.R. § 42.104(b) and 37 C.F.R. § 42.22(a)(1))

The precise relief requested by Petitioner is that Claims 12-18 are found unpatentable and cancelled from the '528 patent.

1. Claims for which Inter Partes Review is Requested(37 C.F.R. §42.104(b)(2))

Petitioner requests *Inter Partes* Review of claims 12-18 of the '528 patent.

2. Specific Statutory Grounds on which the Challenge is Based (37 C.F.R. § 42.104(b)(2))

The specific statutory grounds for the challenge are as follows:

Ground	Reference(s)	Basis	Claims Challenged
1	EP 1 066 805 A2	35 U.S.C. § 102(b)	12-18
2	U.S. Patent No. 6,887,271	35 U.S.C. § 102(b)	12-18
3	WO 02/32345 A3	35 U.S.C. § 102(b)	12-18
4	WO '345 in view of EP '805 or US `271	35 U.S.C. § 103(a)	12-18

Petitioner contends that Claims 12-18 are unpatentable under 35 U.S.C. §§ 102 and/or 103, with the following prior art references being cited in support of the challenge: EP 1 066 805 A2 (EP '805), U.S. Patent No. 6,887,271 ("the Justin

‘271 patent”), and WO 02/32345 A3 (WO ‘345). All the foregoing art qualify as prior art against the ‘528 patent under 35 U.S.C. § 102.

The references set forth in the table below were all published before November 18, 2003, which is more than one year prior to the earliest possible priority date of November 18, 2004 of the ‘528 patent.

§ 102(b) Reference	Publication Date	Exhibit No.
EP 1 066 805 A2	January 10, 2001	1005
U.S. Patent No. 6,887,271	April 3, 2003	1006
WO 02/32345	April 25, 2002	1007

None of the references forming the basis for this Petition were relied on by the examiner during the prosecution of the ‘528 patent.

D. Claim Construction - Broadest Reasonable Interpretation (“BRI”) (37 C.F.R. § 42.104(b)(3))

In an *inter partes* review, claim terms are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012). The patent claim terms are also given their

ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Therefore, the claim terms in the '528 patent should be interpreted according to their broadest reasonable construction in light of the specification and should also be given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure.

The following discussion proposes constructions of terms in the challenged claims under the broadest reasonable construction standard. Any claim terms not included in the following discussion are to be given their broadest reasonable interpretation in light of the specification as commonly understood by those of ordinary skill in the art. (M.P.E.P. § 2111.01(I)). Should the patent owner, in order to avoid the prior art, contend that the claims have a construction different from their broadest reasonable interpretation, the appropriate course is for the patent owner to seek to amend the claims to expressly correspond to its contentions in this proceeding. *See* 77 Fed. Reg. 48764 (Aug. 14, 2012). Any

such amendment would only be permissible if the proposed amended claims comply with 35 U.S.C. § 112.

Also, for the '528 patent inventors to act as their own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). If a feature is not necessary to give meaning to what the '528 patent inventors mean by a claim term, it would be "extraneous" and should not be read into the claim. *Renishaw PLC*, 158 F.3d at 1249; *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988). The construction that stays true to the claim language and most naturally aligns with the inventors' description is likely the correct interpretation. *See Renishaw PLC*, 158 F.3d at 1250.

Petitioner's position regarding the scope of '528 patent claims should not be taken as an assertion regarding the appropriate claim scope in other adjudicative forums where a different claim interpretation standard may apply, *e.g.*, in a patent infringement action. Moreover, Petitioner reserves all of its rights to further challenge any of the claim terms herein under 35 U.S.C. § 112, including by

arguing that the terms are not definite, supported by the written description, and/or enabled. Further, as Petitioner is precluded from presenting challenges under 35 U.S.C. § 112 in an *inter partes* review, Petitioner's arguments in this Petition, or lack of arguments on any of these grounds, should not be interpreted as waiving or conflicting with arguments available in other forums under 35 U.S.C. § 112.

Petitioner notes that the interpretation recommended in Section V subsection C is at times similar to the construction the patent holder Cayenne proposed in its Opening Claim Construction Brief in the corresponding litigation. (Exhibit 1009). The claim construction in a litigation can be narrower than in an *inter partes* review because it is performed in view of both the intrinsic and extrinsic record. *Philips v. AWH Corp.*, 415 F.3d, 1303 (Fed. Cir. 2005). In addition, if the claim is still ambiguous in view of the relevant evidence during a litigation, it should construed to preserve the validity. Id. at p. 1327. This standard does not apply to the *inter partes* review. *See generally In re Cuozzo Speed Techs, LLC*, No. 2014-1301 (Fed. Cir. Feb. 4, 2015). Thus, while Petitioner's proposed claim construction in the corresponding litigation can be more narrow than recommended herein, Cayenne's proposed claim construction in

connection with this Petition should not be more narrow than what is proposed in its Opening Claim Construction Brief. (Exhibit 1009).

V. SUMMARY OF THE '528 PATENT (EX 1001)

A. Background of '528 Patent

The '528 patent generally relates to devices, systems and methods for material fixation (Ex. 1001). (Col. 1, lines 14-15). More specifically, the purported invention relates to techniques that can be used to firmly hold a soft tissue or graft against bone tissue within a bone tunnel. (Col. 1, lines 15-18). In the specification of the '528 patent, Patentees expressly state that, although the tendon to bone example is used throughout the disclosure for the sake of simplicity, the invention is applicable to any soft material to hard material fixation. (Col. 2, line 65 - Col. 3 line 11). The various embodiments disclosed in the '528 patent enable compression of the graft directly against the bone and securing the anchor within the bone tunnel. In addition, the anchor embodiments urge the graft directly against the bone tissue while engaging the bone tissue directly to prevent dislodgment of the anchor relevant to the bone. (Col. 3, lines 40-52).

According to the Patentees, the embodiments of the invention allow direct fixation of the tendon within the bone tunnel without a pull-through stitch needed to seat the tendon in the bone tunnel and hold tension during fixation. Patentees also assert that the invention provides direct tendon to bone compression, which facilitates healing, and provides a single point of fixation which allows for more isometric graft positioning. (Col. 3, line 65 - Col. 4 line 11) Patentees also state that there is no tendon compromise because there is no cutting of the graft with screw threads, and no cutting of the sutures with screw threads as is seen with methods of the prior art. (Col. 4, lines 23-25).

B. Prosecution History of the ‘528 Patent

The file history of the ‘528 patent, as obtained by Petitioner from the USPTO PAIR database, is found at Exhibit 1008.

The ‘528 patent issued from Application No. 11/281,566 (“ the ‘566 application”), filed on November 18, 2005. The ‘566 application claims priority to Provisional Application No. 60/628,774 filed on November 18, 2004 and Provisional Application No. 60/671,510 filed on April 15, 2005.

The ‘566 application was originally filed with 20 claims. The original claims broadly related to a device for connecting a soft material to a hard material, the device comprising a substantially non-cylindrical anchor that secures the soft material thereto, the anchor adapted to stably attach to a hard material. Corresponding system and method claims were also provided. (Exhibit 1008, pp. 64-67).

On July 17, 2007, the Examiner rejected all of the pending claims, *i.e.*, Claims 1-20. (Exhibit 1008, pp. 145-149). Claims 1-10, 12-17, 19, and 20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Colleran et al. (6,656,183). The Examiner asserted that Colleran, as best seen in Fig. 1, discloses an anchor that secures soft tissue to the bone. The anchor includes a wall (31) that moves from an initial to a secondary configuration when the anchor is wedged within the bone. The device further includes a tab/wedge (2). The Examiner further asserted that the functional language used in the claims fails to overcome the Colleran device.

Claims 11 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatenable over Colleran et al. in view of Bonnuti (2003/0204204). The

Examiner acknowledged that Colleran did not teach a delivery device. However, the Examiner asserted that Bonnuti, in a similar art, discloses the use of a delivery instrument to insert and anchor into bone.

In response to the Office Action, Patentees cancelled all of the pending claims, *i.e.*, Claims 1-20, and provided new Claims 21-41 through new counsel. In the Remarks section of the Amendment, it was generally stated, "Patentees respectfully submit that new Claims 21-41 are allowable over the prior art of record." No further argument was made as to how the newly submitted claims avoided the cited art. (Exhibit 1008, pp. 155-160).

A final Office Action was issued on May 5, 2008 again rejecting all of the pending claims, *i.e.*, Claims 21-41 (Exhibit 1008, pp. 199-206). Claims 21-41 were rejected under 35 U.S.C. §102(b) as being anticipated by McDevitt et al. (5,935,129). With respect to Claim 21 and 28, the Examiner asserted that McDevitt et al. disclosed a material fixation system comprising an implant placeable in a space defined by bone having first and second members as set forth in the claims, wherein proximal movement of the second member actuates the first member to expand outwardly to engage the bone, thereby securing the implant in

place. The Examiner further asserted that dependent Claims 2-27 and 29-36 were also disclosed by McDevitt et al. With respect to the method Claims 37-41, the Examiner asserted that the steps as set forth would have been inherently carried out in operation of the disclosed device.

Claims 21-41 were also rejected under 35 U.S.C. § 102(b) as being anticipated by Lee et al. (5,480,403). The Examiner made the same rejection as set forth in connection with McDevitt et al.

Claims 21-41 were further rejected under 35 U.S.C. § 102(e) as being anticipated by Stewart et al. (7,201,754) making the similar argument as that in connection with McDevitt and Lee.

Patentees filed a Response amending Claim 21 and cancelling Claims 24, 37, and 38 (Exhibit 1008, pp. 217-224). Claim 39, which ultimately issued as Claim 12 in the ‘528 patent was not amended.

In the Remarks section, with regard to Claim 39, Patentees argued that the claim was not anticipated by McDevitt et al. because the claim recited the steps of deploying a first member on an implant outwardly to engage adjacent bone and deploying a second member disposed on the implant axially from the first member

outwardly to engage adjacent bone. The Patentees asserted that the Examiner ignored the limitation that the second member, as well as the first member, is expandable outwardly. Patentees argued that the method was neither taught or suggested by McDevitt which only disclosed engagement of adjacent bone by member 4. Patentees similarly argued that the Lee reference did not anticipate Claim 39 since it failed to disclose that the second member 110 is expandable outwardly to engage bone. Patentees made the same argument with regard to the Stewart reference.

A non-final Office Action was mailed on September 2, 2008 rejecting all of the pending claims, *i.e.*, Claims 21-23, 25-36, and 39-41 (Exhibit 1008, pp. 228-232). The claims were rejected under 35 U.S.C. § 102(b) as being anticipated by Curtis et al. (5,464,427). The Examiner argued that Curtis et al. disclosed all of the elements of the material fixation system set forth in independent Claims 21 and 28. With regard to Claims 37-41, the Examiner asserted that the method steps, as set forth, would have inherently been carried out in the operation of the device of Claims 21 and 28.

In response, Patentees filed a third Amendment (Exhibit 1008, pp. 241-250) amending Claims 21, 28 and 39. Patentees also added new Claims 42-46 which depend from Claim 39. Claim 39 was amended to further define the implant as "having a longitudinal axis extending from a distal end of the implant to a proximal end of the implant." Claim 39 was also broadened to refer to the engagement of "material" instead of "bone."

In the Remarks section of the Amendment, with regard to Claim 39, the Patentees asserted that Curtis failed to disclose or suggest placing soft tissue on the implant 11, 14. Rather, Curtis only disclosed a suture anchoring method. Patentees argued that a suture cannot be construed as soft tissue. Patentees further further argued that Claim 39 recites a step of deploying a first member on said implant outward to engage adjacent material. Patentees acknowledged the outward deployment of legs 21, 22 of Curtis by proximal movement of the conical body 14 could be construed as meeting this limitation. However, Patentees argued argued that a further step is recited of "deploying a second member, disposed on said implant in axially spaced relationship from the first member, outwardly to

engage adjacent material", and maintained that no such second member is disclosed in Curtis.

On June 9, 2009, the Examiner issued a final Office Action rejecting Claims 28-36 and 39-46 (Exhibit 1008, pp. 256-262). Claims 21-23 and 27 were deemed allowable. Claims 28-36 were rejected under 35 U.S.C. § 102(b) as being anticipated by Li (5,702,215). Claims 39-41 and 44-46 were rejected under 35 U.S.C. § 102(b) as being anticipated by Adams (6,113,609).

The Examiner asserted that Adams disclosed a method of anchoring soft tissue to bone by placing the soft tissue on an implant having a longitudinal axis extending from a distal end of the implant to a proximal end of the implant, and disposing the implant within a space at a desired location within a patient's body; deploying a first member (40), disposed on the implant outwardly to engage adjacent material; and deploying a second member (30) disposed on the implant in axially spaced relationship from the first member outwardly to engage adjacent material; wherein each of the deploying steps are performed by moving a deployment device (54) in generally axially direction, the soft tissue comprising a

tendon, a graph and the first member comprising a hinged arm and a wedge is moved axially to pivot the hinged arm outwardly.

In response, Patentees filed a fourth Amendment amending independent Claim 28 directed to a material fixation system, and independent Claim 39, which ultimately issued as Claim 12 (Exhibit 1008, pp. 274-281). Claim 39 was amended to again specify that the first and second members engage bone. In addition, Claim 39 was amended to add the phrase "wherein the outward deploying of one of said first and second members compresses the soft tissue between said one of said first and second members and adjacent bone." This element was incorporated from dependent Claim 43 which was cancelled.

In the Remarks section of the Amendment, with regard to Claim 39, Patentees noted that Claim 39 had been amended to recite that the outward deployment of one of the first and second members compresses the soft tissue between the said one of the first and second members and adjacent bone. Patentees argued that Adams discloses a wholly unrelated implantable fastening system for securing layers of tissue together to treat GERD. Patentees concluded that, since Claim 39 has been amended to clearly recite that the method is for

anchoring soft tissue to bone, it is clear that Adams did not disclose or suggest the claimed method. Notably, Patentees did not argue that Adams failed to disclose a first and second member which are expandable outwardly.

A Notice of Allowance was mailed on November 23, 2009. (Exhibit 1008, pp. 374-380). The Notice of Allowability indicated that Claims 21-23, 27, 28, 30-35, 39-42 and 44-46 were allowed, corresponding to Claims 1-18 of the '528 patent. The Notice of Allowability also included an Examiner's Amendment in which Claim 28 was amended to specify that both the first and second members have "a substantially outermost contacting portion when said [first or second] member is expanded outwardly for contacting adjacent soft tissue or bone." Claim 28 was also amended to specify that the wedge is moved in an axial direction "relative to said first and second members." Lastly, Claim 28 was amended to add the phrase "wherein the substantially outermost contacting portion of the first member and the substantially outmost contacting portion of the second member are at axially different locations along said body."

Claim 39, which issued as Claim 12, was amended to specify that the first member on the implant is deployed outwardly to engage adjacent bone "with a

substantially outermost contacting portion of the first member at a first axial location." The second member was amended to specify that it is deployed outwardly to engage adjacent bone "with a substantially outermost contacting portion of the second member at a second axially location which is different than said first axially location." Accordingly, Patentees were able to gain allowance of the claims simply by specifying that the first and second members engage the bone at different locations. This element, however, was disclosed in the prior art.

The Issue Fee was timely paid on December 9, 2009 (Exhibit 1008, pp. 407-409) and the patent issued on January 26, 2010 as U.S. Patent No. 7,651,528. (Exhibit 1008, pp. 412).

C. Construction of the '528 patent Claim Terms

As discussed above, a claim in *inter partes* review is given the "broadest reasonable construction in light of the specification. *See* 37 C.F.R. § 42.100(b).

Petitioner sets forth herein its recommended interpretation of certain claim terms, the scope of which are unclear on their face.

1. Claim 12 - “implant”

The term “implant” is used in independent Claim 12. The term “implant” is not expressly defined in the ‘528 patent. However, the ‘528 patent does disclose “implant embodiments of the present invention.” (Col. 8, lines 18-19). The specification then further describes “[d]irect anchor embodiments [that] include uniquely shaped implants that hold a tendon or other soft tissue, and fix it directly to the bone.” (Col. 8, lines 23-25). In addition, Figs. 48A to 48D are described as disclosing an “implant.” (Col. 22 line 66). Thus, the proper construction of “implant” is “an object surgically placed in the body.”

2. Claim 12 - “having a longitudinal axis extending from a distal end of the implant to a proximal end of the implant”

The element of “having a longitudinal axis extending from a distal end of the implant to a proximal end of the implant” set forth in Claim 12 of the ‘528 patent is not expressly defined in the specification. Referring to Figs. 11A - 11C, the specification does refer to the ACL graph strands 113 being “looped around the distal end of the direct anchor 71 and inserted through the bone hold 112 of the femur 111.” (Col. 15, lines 29-31). Thus, the distal end, is generally referred to as as the lead end being inserted into the bone. Similarly, referring to Figs. 17A -

17C, the specification refers to the tendon segment 173 looping around "the distal end of the substantially non-cylindrical direct anchor 71." (Col. 16, lines 56-57). Thus, the proper construction for "a body having a longitudinal axis extending from a distal end of the implant to a proximal end of the implant" is "a structure having an axis along its length having a first leading end opposed to a second end."

3. Claim 12 - "deploying"

The specification does not specifically refer to deploying the first and second members as set forth in Claim 12. The specification does, however, refer generally to the deployment of the implant device. For example, the specification states: "Anchor deployment results in compression of the anchor against the surrounding bone, and also compresses the tendon against the bone." (Col. 10, lines 25-27). Claim 12 refers to deploying both the first and second members. Thus, the proper construction of the term "deploying" is "causing the first and second member to move away from the longitudinal axis of the body."

4. Claim 12 - "a first member on said implant"

The term "member" is not defined or referred to anywhere in the specification, only the claims. However, the specification broadly refers to different portions of the body. For example, referring to Figs. 3A-3C, patentees describe clover leaf extensions having one end 32 that is flared to engage bone, and a mid-section 33 that is not flared to ensure the body is able to radially expand during deployment thereby compressing the tendon against the bone. (Col. 13, lines 36-45). Thus, "a first member on said implant" should be construed as "a distinct portion of the implant."

5. Claim 12 - "outwardly to engage adjacent bone"

Throughout the specification, the patent owner describes extensions or arms that expand radially outward to engage the surface of the bone thereby anchoring to the bone. For example, in describing Figs. 22A-D, the patent owners describe "butterfly" extensions 224 being "expanded radially outward into engagement with this bone surface thereby securing the direct anchor 221 to the bone." (Col. 18, lines 13-16). The specification also discloses that "the direct anchor can incorporate expandable arms that compress the tendon or other soft tissue directly

against the bone while directly contacting the bone to provide anchoring of the implant." (Col. 8, lines 32-36). Thus, the proper construction of the phrase "outwardly to engage adjacent bone" is "in an outward direction away from the longitudinal axis of the implant to press against the bone."

6. Claim 12 - "substantially outermost contacting portion"

The phrase "substantially outermost contacting portion" as used in Claim 12 is not set forth in the specification. In describing Fig. 39A - 39F, the specification states that "[t]he lateral arms 397 directly contact the bone surface and can have various protrusions or extensions 398 that anchor the implant 391 into the bone." (Col. 21, lines 33-36). Similarly, in describing Figs. 49A - 49B, the specification explains the "arms 494 may include tabs 495 that assist in the securing of the anchor portion 492 within a bone hole." Thus, the proper construction of "substantially outermost contacting portion" is "the exterior surface of the implant that contacts the bone."

7. Claim 12 - "a second member disposed on said implant in axially spaced relationship from the first member"

The term "a second member disposed on said implant in axially spaced relationship from the first member" is not defined or referred to anywhere in the

specification. However, in describing Figs. 14A - 14B, the specification describes describes "the expansion shaft 144 continues to move axially further expanding the direct anchor 143." (Col. 16, lines 19-20). Thus, the proper construction of "a "a second member disposed on said implant in axially spaced relationship from the first member" is "a second portion of the implant which is located at a different position from the first member in a direction defined by the longitudinal axis of the implant."

8. Claim 18 - "hinged arm"

The term "hinged arm" is not defined in the specification. The specification does describe, however, "pivoting." The specification states, "Some classes of anchors are substantially symmetrical but have the characteristic of expanding wall portions or pivoting arms that aid in the press fit of the anchor within a hole in a bone." (Col. 8, lines 42-45). In describing Figs. 49A and 49B, the specification describes "a pair of pivoting arms 494" and that such arms "may include tabs 495 that assist in the securing of the anchor portion 492 within a hole." (Col. 23, lines 9-12). Thus, the proper construction of the phrase "hinged arm" is "an element attached to one end that can pivot about the attachment."

9. Claim 18 - "wedge"

The term "wedge" is described in the specification in a number of different embodiments. For example, in describing Figs. 39A - 39F, Patentees refer to a "wedge piece component 395 of the implant" that "includes a taper design." (Col. 21, lines 40-41). The wedge expands the outer anchor arms radially as it is advanced distally. (Col. 21, lines 40-44). In describing Figs. 49A and 49B, Patentees refer to a "separating wedge 496. . . shaped to fit and separate the pair of pivoting arms 494…." (Col. 23, lines 11-12). Thus, the proper construction of the term "wedge" is "an object that tapers from a thick portion to a thinner portion."

VI. EACH GROUND PROVIDES MORE THAN A REASONABLE LIKELIHOOD THAT EACH CLAIM OF THE '528 PATENT IS UNPATENTABLE

Provided below are detailed discussions of each ground for claim invalidation, with relevant figures from the prior art, and claim charts for Grounds 1-4. In support of the invalidity arguments submitted herewith, Petitioner relies upon the Declaration of Dr. Geoffrey Higgs (Exhibit 1004) and the opinions and analysis set forth therein.

Petitioner notes that all the prior art cited herein may be combined with each other, and should not be limited by the way Petitioner has organized the grounds and prior art citations herein. Thus, absence of an entry in any claim chart is not an admission that the particular prior art does not disclose and/or possess that element. Petitioner expressly reserves the right to present arguments, if applicable, that the particular prior art does disclose and possess same.

A. Ground 1: §102(b) – EP 1 066 805 A2 to EP '805 [Claims 12-18]

EP 1 066 805 A2 to Gerke et al. ("EP '805") includes each of the elements in Claims 12-18 and, therefore, anticipates these claims under 35 U.S.C. § 102(b).

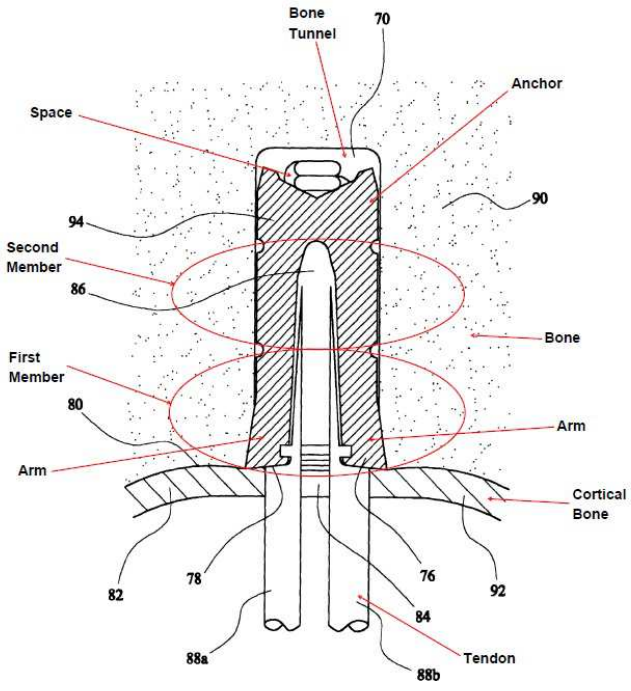
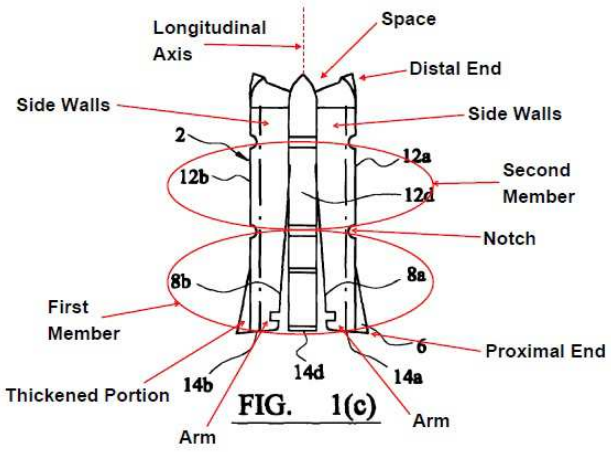


FIG. 3

With regard to claim 12, EP ‘805 is directed to a bone anchor insertable into a bore hole formed in the bone for attaching a ligament or tendon secure thereto. EP ‘805 explicitly discloses a material fixation system comprising bone anchor 2, 76 which is placeable in a hole 70 formed in a bone. (Fig. 3; Col. 2, lines 19-26; Col. 7, lines 52-56; Col. 9, lines 9-14).



The bone anchor has a longitudinal axis as shown in Figs. 1(c) and 3 with a distal end 4 and a proximal end 6. (Col. 7, lines 14-18). Soft tissue such as ligaments or tendons may be positioned crosswise over the distal end of the anchor as described in EP '805 (Col. 7, lines 52-56).

EP '805 discloses that the anchor is placed within a bore hole formed in the bone and mounted on the inside surface of the cortical bone. (Fig. 3; Col. 6, lines 2-6).

The anchor 2, 76 has a first member which is a distinct portion of the anchor including the bottom portions of legs 20, 22, 24, 26, including the thickened radially outermost portions 32 and bottom surface 14, up to medially disposed notches. *See* annotated Fig. 1(c) above; Figs. 1(c) and 1(d). EP '805 discloses

that the legs 20-26, which include the first member are splayed outwardly away from the longitudinal axis to urge the legs into firm engagement against the bone at a first axial location. (Fig. 3; Col. 6, lines 21-30; Col. 8, lines 7-18 and Col. 9, lines 27-32). This also causes an outermost surface including the bottom surface of the legs to come into plane of the inside surface of the cortical bone providing a flat base for anchoring against the bone. Id.

EP '805 also discloses a second member including the portion of the legs 20-26 between the medially disposed notch and a distally located second notch formed on the legs. *See* annotated Fig. 1(c) above. This second member is disposed at a different axial location than the first member. The second member is a separate and distinct portion of the anchor. The second member is deployed outwardly away from the longitudinal axis of the anchor when the peg 50 is inserted in the peg receiving cavity 10. (Col. 6, lines 22-30; Fig. 3. Col. 8, lines 7-11; and Col. 8, lines 34-49). The outermost surface of the second member will engage adjacent bone at an axial location different from the first axial location contacted by the first portion. (Fig. 3; Col. 8, lines 7-11).

EP ‘805 discloses that it as advantageous to use the anchor to compress the soft tissue and the bone. This reference further discloses that tendon profile 40 may be urged radially outwardly into the bore hole and cortical bone at the outlet causing a greater likelihood of graft fixation. (Col. 4, lines 44-47; Col. 8, lines 19-27 and 30-34). The first and second members include side walls that guide the soft tissue and urge it against the wall of the bone hole. (Col. 2, line 54, Col. 3, lines 1).

With regard to claim 13, EP ‘805 discloses using a peg 50 which widens as it extends from the distal to proximal end as shown in Fig. 2(a). The peg is insertable into a cavity 10 which extends along the longitudinal axis of the anchor. Insertion of the peg into the cavity along the axial direction causes the first and second members to move outwardly away from the longitudinal axis of the anchor. The peg forces the legs including the first and second members outwardly to the radial extent to which they were designed. (Col. 8, lines 47-49).

With regard to claim 14, the second member is disposed closer to the distal end than the first member, as shown in Fig. 1(c).

With regard to claim 15, the adjacent material is bone as shown in Fig. 3 of EP ‘805.

With regard to claim 16, EP ‘805 discloses that the soft tissue is tendon material. (Col. 5, line 58 through Col. 6, line 1).

With regard to claim 17, EP ‘805 discloses that the soft tissue is a graft. (Col. 5, line 58 through Col. 6, line 1).

With regard to claim 18, the distal end of one of the legs constitutes an arm in that is extends outwardly and has an unsupported terminal end. The arm can pivot outwardly to engage bone as set forth, for example, in EP ‘805 at Col. 8, lines 10-15 and 46-49. The peg 50 is a tapered member which forms a wedge to force the legs outwardly. At Col. 8, lines 10-15 and 46-49, EP ‘805 describes the peg as a wedge means or expansion tool that pivots the legs radially outwardly.

Accordingly, claims 12-18 are invalid under 35 U.S.C. § 102(b) in view of EP ‘805.

B. Ground 2: §102(b) – U.S. Patent No. 6,887,271 [Claims 12-18]

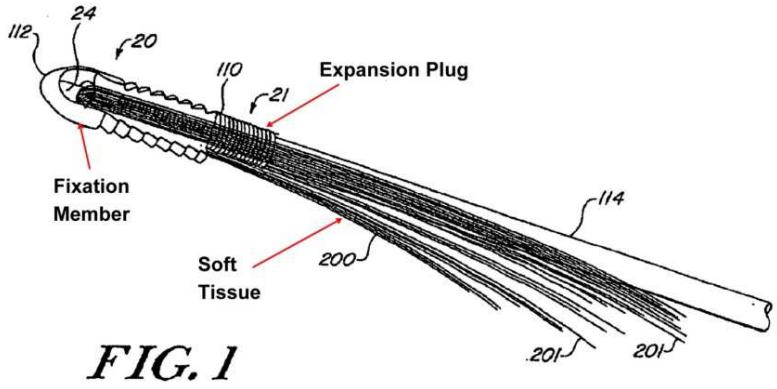


FIG. 1

With regard to claim 12, the Justin '271 patent is directed to an expanding ligament graft fixation system and method. The device includes a fixation member 20 and an expansion plug 21 positioned at a proximal end of the fixation member. The Justin '271 patent discloses that it is desirable to firmly press graft material against the walls of the bone tunnel in order to enhance the fixation of the material to the bone. (Col. 5, lines 4-8).

The Justin '271 patent discloses a method of anchoring soft tissue to bone using the fixation member 20. (Col. 2, lines 24-26 and Col. 3, lines 52-55).

The Justin '271 patent further discloses placing the soft tissue on an implant as shown in Fig. 1 and set forth in Col. 3, lines 60-64. A graft material holding

element in the form of an eyelet 24 is located proximate to a distal end 112 of the fixation member. The graft material 200 can be passed through the eyelet 24 so that two ends 201 of the graft trail fixation member 20 proximally. (Col. 3, lines 60-64).

The fixation member 20 of the Justin ‘271 patent has a longitudinal axis extending from a distal end 112 to a proximal end 110 as shown in Figs. 2 and 3. (Col. 3, lines 56-61).

The fixation member of the Justin ‘271 patent is also disposed in a space located within a bone tunnel of a patient’s body. As set forth in Col. 3, lines 52-55, the implant of the Justin ‘271 patent is useful for fixing soft tissue graft material within a bone tunnel to replace damaged ligamentary material and to restore function to a portion of a patient’s body. Col. 6, line 61 through Col. 7, line 12. The Justin ‘271 patent further describes how the device is placed within a patient’s body.

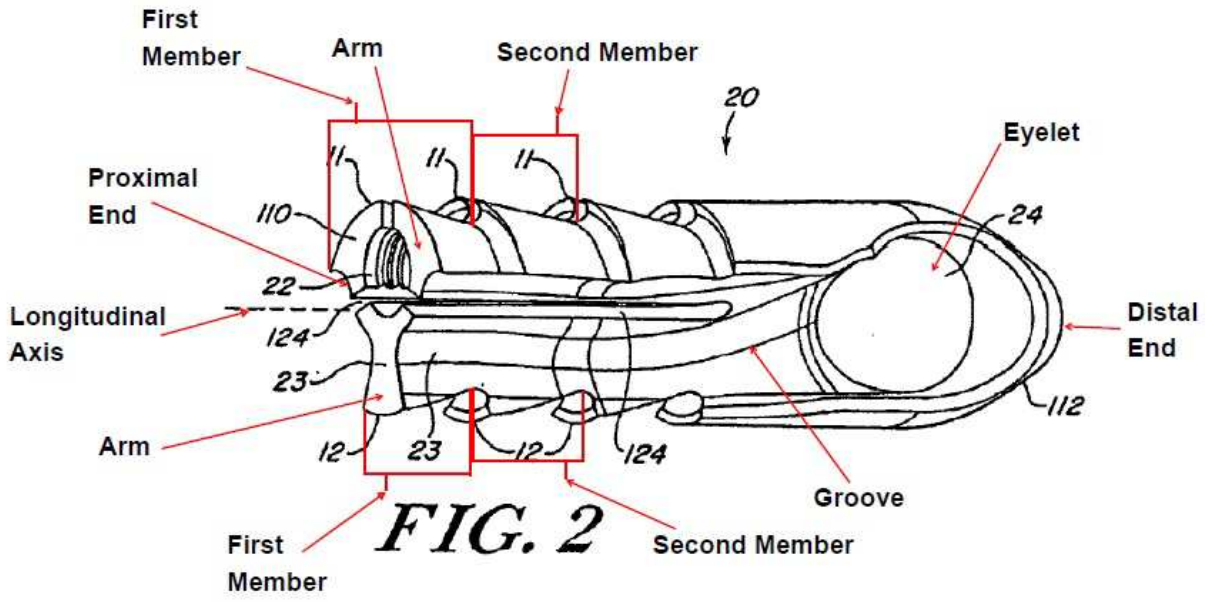


FIG. 2

The fixation member has a first member which includes the distinct proximal portion including the flat end surface and fins 11 and 12 located on the extremity of the anchor as shown in Figs. 2 and 3. These fins are moved outwardly away from the longitudinal axis of the body and into engagement with the adjacent bone. (Fig. 2; Col. 4, lines 37-43). The bone engaging elements or fins 11 and 12 dig into the walls of the bone tunnel after expansion of the fixation element. Id.

The first member extends axially from the flat end surface to a second member. With further reference to annotated Figure 2 shown above, the first

member extends axially from the flat end surface and most proximal set of fins 11/12 of the fixation member to the beginning of the second member. The second member is the portion of the fixation member that begins at the second set of fins 11/12 located distally from the first set of fins 11/12. The second member is a distinct portion of the fixation member. The second member is located on the body closer to the distal end than the first member. (Fig. 2). The second member includes fins 11 and 12, as well as a portion of the grooves 23 which are displaced axially from the first member. (Col. 5, lines 4-8). The second member, including including the grooves, is expandable outwardly away from the longitudinal axis of the body (Col. 4, lines 2-6; Col. 5, lines 4-8 and 48-52). The fins portion of the second member constitutes an outermost contacting portion of the second member, and it engages bone. (Fig. 2; Col. 4, lines 40-42; Col. 4, line 60 through Col. 5, line 8.)

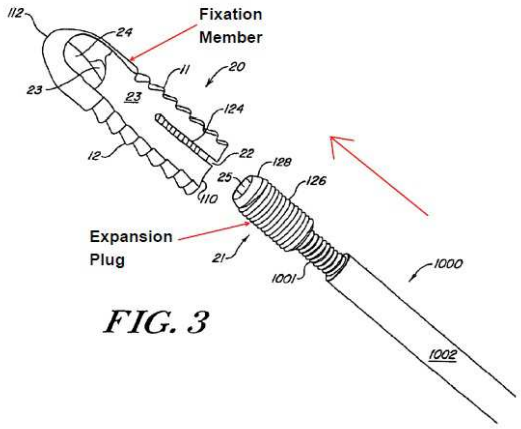


FIG. 3

An expansion plug 21 is insertable into the fixation member resulting in the movement of both the first and second members outwardly away from the longitudinal axis, thereby deploying the first and second members. (Fig. 3, Col. 4, lines 1-7; Col. 4, line 60 through Col. 5, line 8).

When the fixation member 20 is expanded, the graft material is pressed between grooves 23 and the bone tunnel into even more intimate contact therewith as described in Col. 5, lines 4-8. Accordingly, at least one of the first and second members compresses the soft tissue against the adjacent bone.

With regard to claim 13, the expansion plug 21 of the Justin ‘271 patent forms a deployment device which upon movement in the axial direction causes the

first and second members to expand radially outwardly in a direction away from the longitudinal axis. (Fig. 3; Col. 5, lines 42-52; and Col. 7, lines 2-7.)

With regard to claim 14, the second member of the Justin ‘271 patent is disposed distally to the first member as shown in Figs. 2, 2B and 3.

With regard to claim 15, in the Justin ‘271 patent, the adjacent material includes bone as set forth in Col. 4, lines 37-43.

Claim 16 requires that the soft tissue comprises tendon. The Justin ‘271 patent describes ligaments, tendons and other soft tissues as ligamentary material referred to as grafts. (Col. 1, lines 30-35.)

With regard to claim 17, this claim defines the soft tissue as a graft. The Justin ‘271 patent discloses that the soft tissue may be a graft. (Col. 1, lines 30-35).

With regard to claim 18, the Justin ‘271 patent discloses the first member includes the distal end of the anchor extend extending from the body and unsupported at one end. (Fig. 2). Therefore, the first member comprises an arm. (See annotated Fig. 2 above). The expansion plug has a distal tapered region 128, Col. 6, line 48 which engages the opening 22 on the fixation element. (Fig. 3, Col.

Col. 6, lines 45-51). When the expansion plug 21 is inserted axially into the opening 22, the expansion plug acts as a wedge and moves the arm radially outwardly. (Col. 4, line 65 through Col. 5, line 5).

Accordingly, claims 12-18 are invalid under 35 U.S.C. § 102(b) in view of the Justin ‘271 patent.

C. Ground 3: §102(b) – WO ‘345 [Claims 12-18]

With regard to claim 12, WO ‘345 discloses an intraosseous anchor and method for securing soft tissue such as a tendon in a cavity formed in a bone. (Page 1, lines 4-7). The device presses the soft tissue against the bone to accelerate growth by the soft tissue. (Page 1, lines 7-9). The anchor 180 has a body and a longitudinal axis with a distal and proximal end. (Fig. 4A).

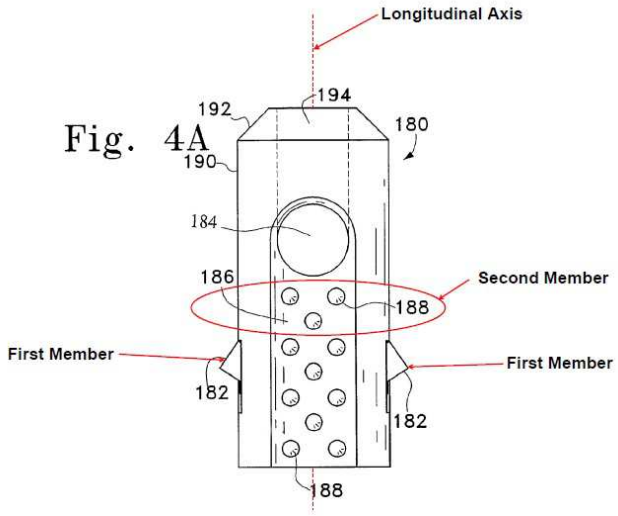


Fig. 4A

The anchor 180 has a cross passageway 184 for receiving the soft tissue therethrough. (Page 11, lines 14-15). The anchor is placed within a bone opening. (Page 2, lines 7-8).

The anchor body includes a first member in the form of rotating barbs 182 which are extendable outwardly away from the longitudinal axis of the anchor body. The barbs form outermost contacting portions. (Fig. 4A). The barbs are hinged so that they rotate away from the longitudinal axis of the body and the outermost portions dig into the bone at a first axial location. (Fig. 4D; Page 11, lines 11-13; and Page 11 line 26 through page 12, line 3).

The body has a second member including a distinct portion having a plurality of soft tissue barbs 188 disposed in an exterior cavity 186. (*See* annotated Fig. 4A above). The soft tissue barbs 188 are spaced axially from the first member.

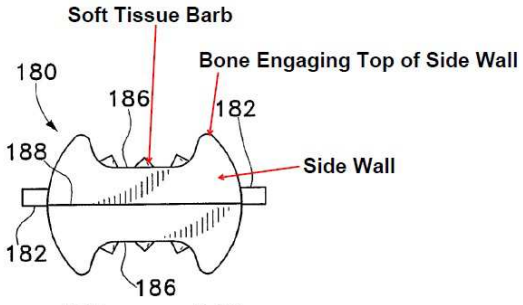


Fig. 4B

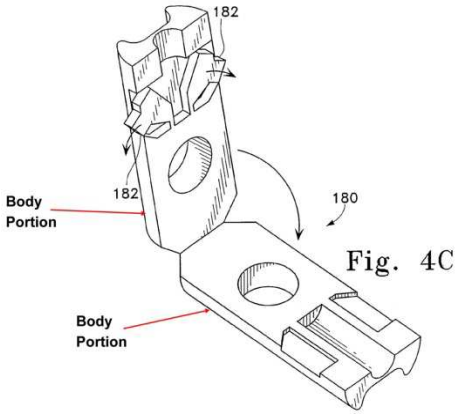


Fig. 4C

As shown in Fig. 4C, the body has two body portions hinged at a distal end. Each portion of the body has the soft tissue barbs 186. *See* annotated Fig. 4B above. When a pin 184 is inserted into the body, the two body portions would expand outwardly away from the longitudinal axis in order engage bone and to compress the soft tissue against the bone. (Fig. 4C; Page 1, lines 6-10). WO '345 '345 teaches that it is desirable to compress the soft tissue against the bone, and outward deployment of the two body portions would achieve this. Upstanding walls defining the recess 186 will engage bone as the two body portions expand

outwardly. Fig. 4B. The engagement of the bone by an outermost contacting portion of the second member occurs at an axial location different than the first axial location. (Fig. 4A).

Pin 184 is axially insertable into the anchor body. Such movement drives the body portions apart and compresses the soft tissue between the second member and the adjacent bone. (Fig. 4D; Page 11, lines 11-13; and Page 11 line 26 through page 12, line 3).

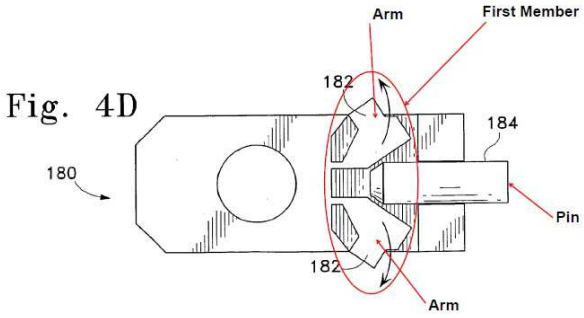


Fig. 4D

With regard to claim 13, the movement of the pin in the axial direction into the body caused the first member rotating barbs outwardly away from the longitudinal axis of the body. It also deploys the second member by moving the body portions apart. (Page 11, lines 11-13, Fig. 4D; and Page 11 line 26 through page 12, line 3, Fig. 4C). This outward deployment of the soft tissue barbs

compresses the soft tissue between at least the second member and the adjacent bone.

With regard to claim 14, the second member of WO ‘345 is disposed distally to the first member as shown in Fig. 4A.

With regard to claim 15, WO ‘345 teaches that the adjacent material includes bone. (Page 11, line 24 through page 12, line 3).

Challenged claim 16 requires that the soft tissue comprises tendon. WO ‘345 describes soft tissue as tendon or ligament. (Page 6, lines 10-11; Page 8 lines 1-3).

With regard to claim 17, this claim defines the soft tissue as a graft. WO ‘345 describes the tissue as a soft tissue graft. (Page 8, lines 10-12).

With regard to claim 18, WO ‘345 the first member includes rotating barbs forming arms that are pivotally secured to the body. (Fig. 4A). The movement of of the pin 184 having a tapered front end into the body acts as a wedge to drive the arms outwardly away from the longitudinal axis of the body. (Fig. 4D; Page 11, line 26 through Page 12, line 3). The pin also deploys the second member by

moving the two body portions apart. (Figs. 4C and 4D; Page 11, lines 11-13, Fig. 4D; page 11 line 26 through page 12, line 3).

D. Ground 4: §103(a) - WO '345 in View of Either EP '805 or the Justin '271 Patent [Claims 12-18]

Section VI. C. is incorporated by reference to show that each of the elements of claims 12-18 is found in WO '345. However, should the pin 184 of WO '345 be found not to deploy the second member outwardly as set forth in claim 12, both EP '805 and the Justin '271 patent teach the use of a tapered member for deploying first and second members outwardly. Thus, the claims are obvious over the combination of references.

WO '345 teaches that it is desirable for the second member to be deployed or expanded outwardly. In WO '345, outward deployment/expansion is used to press the soft tissue against the bone to accelerate tissue growth, WO '345 Page 1, lines 7-9; Page 9, lines 13-16, and also to engage adjacent bone, Page 11 line 25 to Page 12, line 3. This teaching is also found in both EP '805 and Justin '271. EP '805 at Col. 8, lines 28-34 teaches that the tendon profile is urged radially

outwardly into the bone hole and cortical bone at the outlet causing greater likelihood of graft fixation. See also, Fig. 3;Col. 6, lines 22-30; Col. 8, lines 7-11.

EP ‘805 further teaches that the deployed first and second members engage adjacent bone. Col. 8 lines 34-49 for engagement to adjacent bone. Justin ‘271 teaches that the fixation member expands to fix the graft material to the interior of the bone tunnel. Justin ‘271 Col. 4, lines 4-8. Engagement with the adjacent bone by the first and second members is also taught in Justin ‘271. Fig. 2; Col. 4, lines 40-42; Col. 4, line 60 to Col. 5, line 8.

EP ‘805 teaches using a tapered peg 50 insertable into a peg receiving cavity. The peg helps to force the legs outwardly to the radial extent to which they were designed. EP ‘805 Col. 8, lines 46-49. It would be obvious to one skilled in the art at the time of the invention to modify WO ‘345 to use a tapered member as in EP ‘805 in order to force the hinged body portions apart to press the soft tissue against the bone to accelerate tissue growth and to engage the bone to fix the anchor in place.

Justin teaches inserting an expansion plug 21 having tapered end into a plug receiving opening 22 to expand the fixation member 20. Col. 5, lines 42-53.

It would be obvious to one skilled in the art at the time of the invention to modify the WO ‘345 anchor 180 of to use a tapered expansion member as in Justin ‘271 in order to force the hinged body portions apart to press the soft tissue against the bone to accelerate tissue growth and to engage bone to fix the anchor in place.

Therefore, Claims 12-18 are invalid under § 103(a) over WO ‘345 in view of either EP ‘805 or the Justin ‘271 patent.

E. CLAIM CHART

CLAIM LANGUAGE	EP 1 066 805	6,887,271	WO 02/032345
CLAIM 12			
A method of anchoring soft tissue to bone, comprising placing the soft tissue on an implant:	Fig. 3; Col. 2, lines 19-26; Col. 7, lines 52-56; Col. 9, lines 9-14.	Col. 2, lines 24-26 and Col. 3, lines 52-55 and 60-64.	Page 1, lines 4-7.
having a longitudinal axis extending from a distal end of the implant to a proximal end of the implant	Fig. 1(c) and 3; Col. 7, lines 14-18.	Figs. 2 and 3; Col. 3, lines 56-61.	Fig. 4A.

CLAIM LANGUAGE	EP 1 066 805	6,887,271	WO 02/032345
deploying a first member on said implant outwardly	Figs. 1 (c), 1(d), and 3; Col. 6, lines 21-30; Col. 8, lines 17-18, Fig.3. Fig. 3, Col. 9, lines 27-32.	Figs. 2 and 3; Col. 4, lines 37-43; Col. 5, lines 4-8.	Fig. 4D; Page 11, lines 11-13; and Page 11 line 26 through page 12, line 3.
to engage adjacent bone with a substantially outermost contacting portion of the first member at a first axial location	Fig., 3; Col. 6, lines 21-30; Col. 8, lines 7-18 and Col. 9, lines 27-32.	Fig. 2; Col. 4, lines 37-43.	Page 11, lines 11-13; and Page 11 line 26 through page 12, line 3
deploying a second member, disposed on said implant in axially spaced relationship from the first member, outwardly to engage adjacent bone	Fig. 3; Col. 6, lines 22-30; Col. 8, lines 7-11; and Col. 8 lines 34-49.	Fig. 2; Col. 4, lines 40-42; Col. 4, line 60 through Col. 8.	Fig. 4C; Page 1, lines 6-10.
with a substantially outermost contacting portion of the second member	Fig. 3; Col. 8, lines 7-11.	Col. 4, lines 40-42; Figs. 1 and 2.	Fig. 4B
at a second axial location which is different than said first axial location;	Fig. 3.	Figs. 1 and 2.	Fig. 4A

CLAIM LANGUAGE	EP 1 066 805	6,887,271	WO 02/032345
wherein the outward deployment of one of said first and second members compresses the soft tissue between said one of said first and second members and adjacent bone.	Col. 4, lines 44-47, and Col. 8, lines 19-27 and 30-34; Col. 2, line 54 and Col. 3, lines 1.	Fig. 3, Col. 4, lines 1-7; Col. 4, line 60 through Col. 5 line 8; Col. 5, lines 4-8	Col. 5, lines 4-8.
CLAIM 13			
wherein each of said deploying steps are performed by moving a deployment device in a generally axial direction.	Fig. 2(a); Col. 8, lines 47-49	Fig. 3; Col. 5, lines 42-52; and Col. 7, lines 2-7	Page 11, lines 11-13, Fig. 4D; and Page 11 line 26 through page 12, line 3, Fig. 4C.
CLAIM 14			
wherein said second member is disposed distally of said first member.	Fig. 1(c).	Figs. 2, 2B and 3	Fig. 4A.
CLAIM 15			
wherein said adjacent material comprises bone.	Fig. 3	Col. 4, lines 37-43	Page 11, line 24 through page 12, line 3

CLAIM LANGUAGE	EP 1 066 805	6,887,271	WO 02/032345
CLAIM 16			
wherein the soft tissue comprises a tendon.	Col. 5, line 58 through Col. 9, line 1.	Col. 1, lines 30-35	Page 6, lines 10-11; Page 8 lines 1-3.
CLAIM 17			
wherein the soft tissue comprises a graft.	Col. 5, line 58 through Col. 6, line 1.	Col. 1, lines 30-35	Page 8, lines 10-12
CLAIM 18			
wherein the first member comprises a hinged arm, and a wedge is moved axially to pivot the hinged arm outwardly.	Col. 8, lines 10-15 and 46-49; Col. 8, lines 10-15 and 46-49.	Fig. 3, Col. 6, lines 45-51; Col. 4, line 65 through Col. 5, line 5	Page 11, lines 11-13, Fig. 4D; and Page 11 line 26 through page 12, line 3, Fig. 4C.

VII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *Inter Partes* Review of Claims 12-18 of U.S. 7,651,528, followed by a grant of this Petition rejecting Claims 12-18 of the ‘528 patent on the grounds detailed herein.

Dated: March 5, 2015 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of March 2015, the foregoing PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ*., including Exhibits, were served pursuant to 37 C.F.R. §§ 42.6 and 42.105, via Federal Express®, next day delivery, on the following:

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