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 8,435,294

Issue Date: May 7, 2013

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- '294" – U.S. Patent No. 8,435,294 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 8,435,294
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, to find and cancel Claims 6-11, 13 and 16-18 of U.S. Patent No. 8,435,294, entitled "Devices, Systems and Methods for Material Fixation," issued May 7, 2013 (Serial No. 12/634,581, filed December 9, 2010) (" the '294 patent"), assigned to Cayenne Medical, Inc. The '294 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 '294 patent, Petitioner also concurrently submits a Petition for *Inter Partes* Review of 7,651,528 ("the '528 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 '294 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 this Petition for *Inter Partes* Review is submitted herewith. Claims 6-9, 11, 13, and 16-18 of the '294 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 '294 patent is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting *Inter Partes* Review challenging the claims of the '294 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 '294 patent by Cayenne. *See* Exs. 1002-1003.

B. Level of Ordinary Skill in the Art

The '294 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 6-11, 13, and 16-18 are found unpatentable and cancelled from the '294 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 6-11, 13 and 16-18 of U.S. Patent No. 8,435,294 to Montgomery et al. ("the '294 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)	6-11, 13, and 16-18
2	U.S. Patent No. 6,887,271	35 U.S.C. § 102(b)	6-11, 13, and 16-18
3	WO 02/32345 A3	35 U.S.C. § 102(b)	6-11, 13, and 16-18
4	WO 02/32345 A3 in view of EP 1 066 805 A2 or U.S. Patent No. 6,887,271	35 U.S.C. § 103(a)	6-11, 13 and 16-18

Petitioner contends that Claims 6-11, 13, and 16-18 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 art qualify as prior art against the ‘294 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 ‘294 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

While the Justin ‘271 patent was of record during prosecution of the application that issued as the ‘294 patent, neither EP ‘805, nor WO ‘345 was of record. The Justin ‘271 patent was relied upon by the examiner as a secondary reference in a rejection during prosecution of the application that issued as the ‘294 patent.

The arguments made herein regarding any art mentioned in the prosecution history of the ‘294 patent were not made during the prosecution of the patent

application. The Justin '271 patent is being applied in a different manner than utilized by the Examiner.

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 '294 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 '294 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 '294 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 '294 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 1327. This standard does not apply to the *inter partes* review. *See generally In re Cuozzo Speed Techs, 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 '294 PATENT (EX 1001)

A. Background of '294 Patent

The '294 patent generally relates to devices, systems and methods for material fixation (Ex. 1001). (Col. 1, lines 18-19). 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 19-22). In the specification of the '294 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. 3, lines 2-16). The various embodiments disclosed in the ‘294 patent include include a substantially non-cylindrical shape having a substantially non-circular cross-section to enable compression of the graft directly against the bone and securing the anchor within the bone tunnel. The substantially non-cylindrical shape applies differential forces to compress the graft against the bone tissue. In addition, the substantially non-cylindrical 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 45-57).

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. 4, lines 3-17). 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 28-30).

B. Prosecution History of the ‘294 Patent

The file history of the ‘294 patent was obtained by Petitioner from the USPTO PAIR database and is found at Exhibit 1008.

The ‘294 patent issued from Application No. 12/634,581 (“ the ‘581 application”), filed on December 9, 2009. The ‘581 application is a continuation of Application No. 11/281,566 filed on November 18, 2005, issued as U.S. Patent No. 7,651,528. The ‘581 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. (Exhibit 1008, pp. 10-81)

The ‘581 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. 77-80).

By Preliminary Amendment filed on January 30, 2012, Patentees cancelled all of the original claims, *i.e.*, Claims 10-20 and added new Claims 21-41. (Exhibit 1008, pp. 199-204). In the remarks section of the Amendment, the Patentees indicated that the specification was amended to update the priority claims. No reason was given for the cancellation of Claims 10-20 and replacement with new Claims 21-41. (Exhibit 1008, p. 205).

In the non-final rejection mailed on February 8, 2012, the Examiner rejected all of the pending claims, *i.e.*, Claims 21-41. (Exhibit 1008, pp. 211-220). Claims Claims 21-41 were first rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1-18 of U.S. Patent No. 7,651,528. In addition, Claims 28-36 and 39-41 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Patent No. 7,879,094. Claims 21-27 and 37-38 were rejected under 35 U.S.C. § 102(e) as being anticipated by Martinek (U.S Patent No. 7,037,324). Claims 28-36 and 39-41, which ultimately issued as Claims 6-11, 13 and 16-18 of the ‘294 patent being challenged herein, were rejected under 35

U.S.C. § 102(b) as being anticipated by Li U.S. Patent No. 5,702,215 ("the Li '215 patent").

The Examiner asserted that the Li '215 patent disclosed a material fixation system that included an implant placeable in a space defined by bone, the implant comprising a body having a distal end and a proximal end and a first member on the body which is expandable outwardly; and a second member on the body which is disposed axially from the first member and is expandable outwardly. The Examiner asserted that the method Claims 39-41 would have been inherently carried out in the operation of the device in Claim 28. Id.

In response, Patentees amended Claim 28 (issued as Claim 6) to include a body having "a longitudinal axis" and further define the first and second member to be moveably expandable outwardly. Claim 28 was further amended to include the element "a distal end of said body comprising a space for receiving soft tissue therethrough, said space being defined by surfaces of said body which are oriented both generally parallel to said longitudinal axis and generally transverse to said longitudinal axis." Claim 28 was further amended to require "a deployment device which is moveable in a generally axial direction to deploy at least one of

said of first and second members." The method of Claim 39 (issued as independent Claim 16) was also amended to define the implant as "having a longitudinal axis extending from a distal end from the implant to a proximal end of the implant." In addition, the second member was further defined as in a axially space relationship from the first member. Lastly, Claim 39 was amended to include the element "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." (Exhibit 1008, pp. 255-262).

In the Remarks section of the Amendment, Patentees argued that the Li '215 patent disclosed a retractable fixation device for securing two portions of a fractured bone together until the bone has healed. Patentees further argued that, since the Li '215 patent does not contemplate anchoring soft tissue, there is no disclosure of the element of a distal end of the body of the device having a space for receiving soft tissue therethrough. Patentees also argued that the Li '215 patent failed to disclose or suggest the deployment device. Similarly, with regard to Claim 39, Patentees maintained that, since the Li '215 patent does not disclose or suggest anything regarding soft tissue, the element of the first and second

members compressing the soft tissue against adjacent bone is not disclosed. Patentees also filed a Terminal Disclaimer. Id.

A second non-final Office Action was mailed on July 9, 2012 rejecting all of the pending claims, *i.e.*, Claims 21-28 and 30-41. (Exhibit 1008, pp. 273-280). Claim 29 was cancelled in the previous Amendment. More specifically, the Examiner asserted that Claims 23, 27, 28, and 30-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Levy (U.S. Patent No. 6,554,833) in view of Justin (U.S. Patent No. 6,887,271). The Examiner argued that Levy discloses all of the claim limitations such as a body, a first member that is moveably expandable outwardly, a second member that is moveably expandable outwardly, and a deployment device that is moveable in a generally axial direction to deploy at least of the first and second members and a plurality of arms that expand and pivot to engage bones.

The Examiner conceded that Levy did not teach a distal tip about which soft tissue may be looped, the distal end comprising a space for receiving soft tissue therethrough, the space being defined by surfaces of the body which are oriented both generally parallel to the longitudinal axis and generally transverse to the

longitudinal axis. However, the Examiner asserted that these elements were disclosed in Justin et al. Id.

Patentees filed an Amendment in response further amending Claim 28 to include the element, "said second member being of a substantially different construction then said first member." In the Remarks portion of the Amendment, Patentees argued that, since Levy not at all concerned with the attachment of soft tissue to bone, there would have been no motivation to apply the teachings of Justin to modify the Levy device. Patentees argued that the only motivation asserted by the Examiner is that Justin is "similar art." However, Patentees argued argued that other than both references being in the field of orthopedics, they are totally dissimilar because Levy is concerned with securing two fractured pieces of both together, while Justin is concerned with attaching soft tissue to bone. Thus, Patentees argued that a practitioner in the field would never use the two types of anchors together. In addition, regarding independent Claim 28, Patentees urged that the second member of Levy is of substantially the same construction as the first member of Levy. Patentees provide no indication for support in the spec for

the phrase "substantially different construction" nor does the specification contain any definition. (Exhibit 1008, pp. 334-346).

A Notice of Allowance was mailed on January 11, 2013. (Exhibit 1008, pp. 352-356). No explanation was given by the Examiner as to the patentability of the claims. The Issue Fee was timely paid on April 5, 2013 (Exhibit 1008, pp. 367-369) and the patent issued on May 7, 2013 as U.S. Patent No. 8,435,294. (Exhibit 1008, pp. 375).

C. Construction of the '294 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 its face.

1. Claims 6 and 16 - "implant"

The term "implant" is used in independent Claims 6 and 16 but is not expressly defined in the '294 patent. However, the '294 patent does disclose "implant embodiments of the present invention." (Col. 8, line 25). 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 30-32). In addition, Figs. 48A-48D are described as disclosing an "implant." (Col. 23, line 7). Thus, the proper construction of "implant" is "an object surgically placed in the body."

2. Claims 6 and 16 - "having a longitudinal axis, a distal end, and a proximal end"

The element of "having a longitudinal axis, a distal end, and a proximal end" set forth in Claim 6 of the '294 patent is not expressly defined in the specification. Referring to Figs. 11A-11C, the specification does refer to the ACL 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 37-38). Thus, the distal end, is generally referred to as the 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 64-66). Thus, the proper construction for "having a longitudinal axis, a distal end, and a proximal end" is "a structure having an axis along its length having a first leading end opposed to a second end."

3. Claims 6 and 16 - “a first member”

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 44-53). Thus, “a first member on said body” should be construed as “a distinct portion of the body.”

4. Claim 6 - “moveably expandable outwardly”

The term “moveably expandable outwardly” is not defined or referred to in the specification. The term “moveably” was added to Claim 6 in an Amendment during the prosecution of the application. The specification 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 39-43). Thus, the proper construction of

of the term "moveably expandable outwardly" is "capable of being moved or deformed in an outward direction away from the longitudinal axis of the body."

5. Claim 6 and 16 - "a second member on said body which is disposed axially from said first member"

The term "a second member on said body which is disposed axially from said first member" as set forth in claim 6 is not defined in the specification. However, in describing Figs. 14A-14B, the specification 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 second member on said body which is disposed axially from said first member" is "a second portion of the body which is located at a different position from the first member in a direction defined by the longitudinal axis of the body." Claim 16 which states "a second member disposed on said implant in axially spaced relationship from the first member" should have the same construction.

6. Claim 6 - "a substantially different construction"

The term "a substantially different construction" is not described or defined in the specification and was added by Patentees in an Amendment to avoid the prior art. No support was provided by the Patentees when making the amendment.

amendment. More specifically, in Applicants' Amendment, it was argued "both of of the expandable members [of the prior art] are shown and disclosed as having a substantially identical construction." Accordingly, in order to avoid this prior art, Applicants added the limitation of requiring that the first and second members must be of "substantially different construction." Therefore, the proper construction of the term "a substantially different construction" is "more than a minor difference in shape or chemical composition."

7. Claim 6 - "a distal end of said body comprising a space for receiving soft tissue therethrough"

The phrase "a distal end of said body comprising a space for receiving soft tissue therethrough" is not defined in the specification. In describing Figs. 11A - 11C, the specification states that "the ACL graph strands 113 are looped around the distal end of the direct anchor." (Col. 15, lines 37-38). In addition, referring to Figs. 17A-C, the specification states "The tendon segment 173 loops around the distal end of the substantially non-cylindrical direct anchor 71 and fits within the opposing grooves." (Col. 16, lines 64-66). In describing the embodiment in Fig. 20A, the specification indicates that "loops 204 are connected to the distal end 203 or pass through the central lumen where they connect to other component of the

anchor 201 or are incorporated as one or more snares in the deployment instrument." (Col. 17, lines 39-42). Thus, the proper construction of the term "a distal end of said body comprising a space for receiving soft tissue therethrough" is "an empty area defined by at least a portion of the distal end through which soft tissue can be received."

8. Claim 6 - "surfaces of said body which are oriented both generally parallel to said longitudinal axis and generally transverse to said longitudinal axis"

The phrase "surfaces of said body which are oriented both generally parallel to said longitudinal axis and generally transverse to said longitudinal axis" is not defined or described in the specification. The word "longitudinal" appears nowhere in the specification. Neither do the words "parallel" or "transverse." The The various embodiments in the specification generally show a structure having an axis along its length. Therefore, the proper construction of the phrase "surfaces of of said body which are oriented both generally parallel to said longitudinal axis and generally transverse to said longitudinal axis" means "at least one surface having at least a portion generally parallel to the longitudinal axis of the body and

at least one surface having at least a portion generally in a direction across the longitudinal axis of the body."

9. Claim 6 - "a deployment device which is moveable in a generally axially direction"

Throughout the specification, the deployment device is described as a device which causes deployment of the first and/or second members of the recited implant. Deployment, as described below, means to cause the first or second member to move away from the longitudinal axis of the body.

10. Claims 6 and 16 - "to deploy"

The specification does not specifically refer to the deployment of the first and second members. 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 32-34). Thus, the proper construction of the term "to deploy" is "to cause the first or second member to move away from the longitudinal axis of the body."

11. Claim 9 - "wherein said member first comprises an arm which is pivotable outwardly"

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 49-52). In describing Figs. 49A and B, 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 16-20). Thus, the proper construction of the phrase "wherein said member first comprises an arm which is pivotable outwardly" is "wherein the first member is in the form of or includes a portion extending from the body having an unsupported terminal end capable of moving in a direction away from the longitudinal axis of the body."

12. Claims 9 and 16 - "to engage 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 extensions 224 being "expanded radially outward into engagement with this bone surface thereby securing the direct anchor 221 to the bone." (Col. 18, lines 21-

21-24). Thus, the proper construction of the phrase "to engage bone" is "to press against the adjacent bone to positionally fix the body to the bone."

13. Claim 16 - "compresses the soft tissue between said one of said first and second members and adjacent bone"

Throughout the specification, patent owners describe compressing soft tissue, such as a tendon, between one of the members of the implant and the adjacent bone. For example, in describing Figs. 3A-C, the Applicants state that the anchor "is able to expand into the radially enlarged orientation during deployment, ensuring the direct anchor compresses the tendon against the bone surface defined by the drilled hole." (Col. 13, lines 50-53). In describing Figs. 11A-C, the Applicants state, "the direct bone anchor 71 compresses the tendon 113 against the surface of the femur 111 defined by the drill hole 112 and engages the securing extension of the direct anchor 71 against the bone surface to ensure the tendon 113 is secured in place as tension is applied." (Col. 15, lines 41-46). Thus, the proper construction of the phrase "compresses the soft tissue between said one of said first and second members and adjacent bone" is "one of the first or second members exerts a force on the soft tissue in a direction away from the longitudinal axis of the body against the adjacent bone."

VI. EACH GROUND PROVIDES MORE THAN A REASONABLE LIKELIHOOD THAT EACH CHALLENGED CLAIM OF THE‘294 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 Gerke et al. [Claims 6-11, 13 and 16-18]

EP 1 066 805 A2 to Gerke et al. (“EP ‘805”) includes each of the elements in Claims 6-11, 13 and 16-18 and, therefore, anticipates these claims under 35 U.S.C. § 102(b).

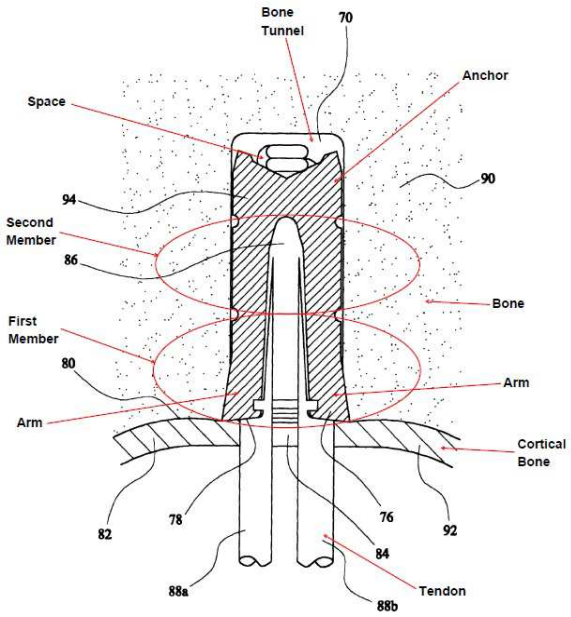


FIG. 3

With regard to claim 6, EP ‘805 discloses an implantable bone anchor 2, 76 insertable into a bore hole 70 formed in the bone for attaching a ligament or tendon secured thereto. (Fig. 3; Col. 2, lines 19-24; Col. 9, lines 9-14.)

Claim 6 defines a fixation system that includes an implant which is placeable in a bone space. The implant includes a body having a longitudinal axis, a distal end and a proximal end. The EP ‘805 discloses that the anchor 2 has a proximal end 6 and a distal end 4. (Fig. 1(c); Col. 7, lines 14-17.) The anchor has a longitudinal axis.

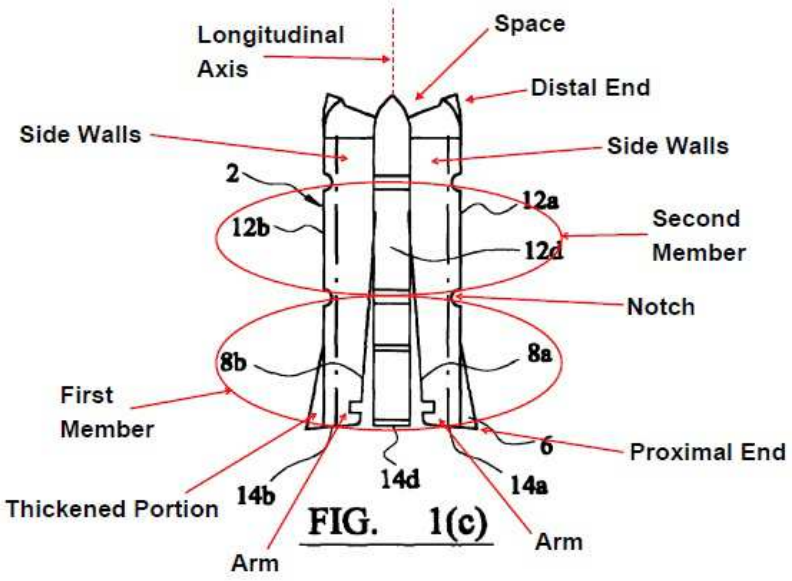


FIG. 1(c)

Claim 6 further defines a first member on the body which is moveably expandable outwardly. EP '805 discloses that the anchor includes a plurality of legs 20, 22, 24 and 26 joined at the distal end 4. (Col. 7, lines 11-13.) At least one of the legs has a portion extending from the proximal end, *e.g.*, 14b, up into a medially disposed notch as shown in Fig. 1(c). This distinct portion of the anchor body forms a first member.

The first member is capable of being moved in an outward direction away from the longitudinal axis of the body. *See* Col. 8, lines 10-12 "(this causes the

legs 20-26 to splay outwardly. . . ," Col. 9, lines 27-32 ("to cause the proximal end 78 of the bone anchor 76 to expand radially.").

The claim further defines a second member on the body which is disposed axially from the first member. The second member includes the portion of the legs 20-26 between the medially disposed notch and a distally located second notch formed on the legs. The second member is located at a different position from the first member in a direction defined by the longitudinal axis of the body. Figure 1(c). Therefore, the second member is disposed axially from the first member. The second member is a separate and distinct portion of the anchor.

Claim 6 further defines that the second member is moveable expandable outwardly. During securement of the bone anchor, the entire portion of the legs would expand outwardly, especially upon insertion of a peg 50. (Col. 4, lines 44-47; Col. 6, lines 21-30; Col. 8, lines 7-18 and Col. 9, lines 27-32). The peg 50 expands the legs outwardly to help retain the anchor within the bone and to keep tension on the soft tissue.

The claim also defines that the second member is of a substantially different construction than the first member. The proximal portion of the leg which

constitutes the first member has a significantly different size and shape than the second member. This is clearly shown in Figs. 1(c)-(f) of EP ‘805. Specifically, the first member includes a thickened portion 32 and bottom surface 14 which is urged against the inside surface of cortical bone. (Fig. 1(d), Col. 8, lines 11-15). Such a thickened portion is not found on the second member. The first member also has a bottom surface 14 not found in the second member.

As recited in claim 6, EP ‘805 also discloses a distal end of the body comprising a space for receiving soft tissue therethrough. EP ‘805 includes an empty space, or recess, defined by a portion of the distal end through which soft tissue can be received. (Col. 3, lines 53-57; Col. 7, lines 38-41.) This is depicted in Figs. 1(a), 1(c) and 3. Col. 7, lines 52-56 expressly states that “due to the shape of the bone anchor, described, two constructive ligaments or tendons may be located crosswise over the distal end 4 of the bone anchor.

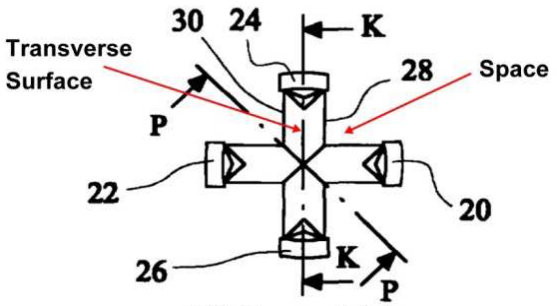


FIG. 1(a)

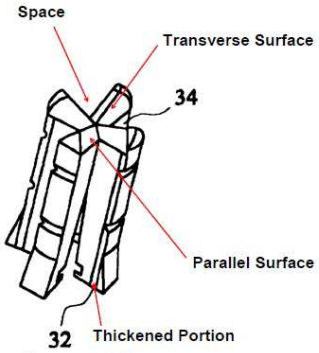


FIG. 1(d)

Claim 6 further defines that the space is defined by surfaces of said body which are oriented both generally parallel to said longitudinal axis and generally transverse to the longitudinal axis. This claimed feature is illustrated in Figs. 1(a) and 1(d) set forth above. The upper end of the walls that form the recess space are generally parallel to the longitudinal axis of the anchor as shown in Fig. 1(d). The top ends of the walls are transverse to the longitudinal axis as shown in Fig. 1(a).

Claim 6 further defines a deployment device which is moveable in a generally axially direction to deploy at least one of the first and second members. As set forth in EP ‘805, peg 50 is received within a peg receiving cavity 10 (Col. 8, lines 30-34). In Col. 8, lines 28-49, the reference discloses that the axially inserting the peg 50 in to the peg receiving cavity 10 forces the legs outwardly to

the radially extent to which they are designed. (Col. 8 lines 7-18; Col. 9, lines 27-27-32.) Accordingly, the peg is a deployment device which moves both of the first and second members away from the longitudinal axis of the body.

With regard to claim 7, this claim requires that the second member is disposed distally of the first member. This is clearly shown in Figs. 1(c) and Fig. 3 of EP ‘805. The portion of the leg constituting the second member is located closer to the distal end than the first member.

With regard to claim 8, the second member disclosed in EP ‘805 is proximal to the distal end 112 as shown in Figs. 1(c) and 3.

With regard to claim 9, in the anchor of EP ‘805, the first member extends outwardly and has an unsupported terminal end, thereby forming an arm. The proximal end pivots outwardly to engage bone disclosed in EP ‘805. (Col. 8, lines 10-15 and 46-49; Col. 9, lines 27-32.)

With regard to claim 10, in EP’805, the arm is pivotable outwardly especially upon insertion of the peg 50. The distal end of the arm is attached to the anchor body. The proximal end of the arm includes outwardly thickened portions 32 that engage the bone. (Fig. 3; Col. 5, lines 1-5; Col. 8, lines 10-15.)

Claim 11 adds that the first member comprises a plurality of arms. In EP'805, the anchor 2 includes plurality of legs 20, 22, 24 and 6. Each leg includes a proximal portion forming a first member. Figure 1(c); Column 8 lines 10-12. Each first member is in the form of an arm. Therefore, EP '805 discloses a plurality of first arms.

With regard to claim 13, the peg 50, also referred to as a wedge means or expansion tool, is axially inserted into peg receiving cavity 10, the legs which include the first and second members are pivoted outwardly. (Col. 6, lines 22-30; Fig. 3; Col. 8, lines 7-11 and 34-49.)

With regard to claim 16, 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 15-18; 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 15-18.) Soft tissue such as

ligaments or tendons may be positioned cross wise 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. (Col. 6 lines 2-6; Fig. 3.)

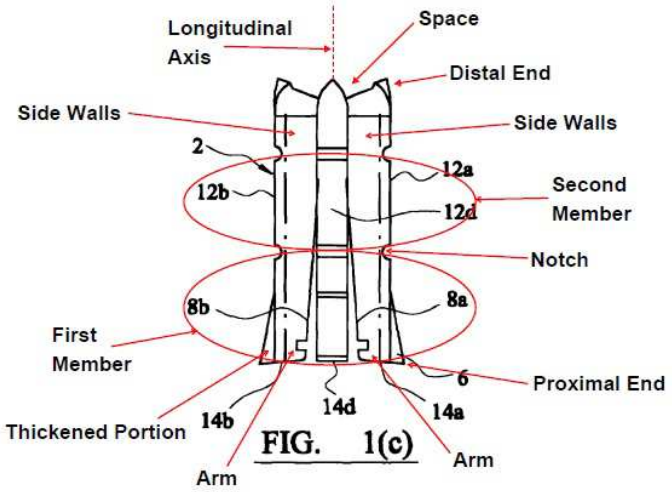


FIG. 1(c)

The anchor includes a first member including the bottom half of one of legs 20-26 including the thickened radially outermost portion 32 and bottom surface 14, up to medially disposed notch. (Figs.1(c), annotated above, and 1(d).) EP ‘805 also discloses that the legs 20, 22, 24, and 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. It also causes the bottom

surface of the first member to come into "the plane of the inside surface of the cortical bone providing a flat base for anchoring against the bone." (Fig. 3; Col. 8, 8, lines 10-18; Col.. 9, lines 30-32.)

EP '805 further discloses a second member including the portion of the legs between the medially disposed second notch and a third notch formed on the leg. (Fig. 1(c).) 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; 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 is advantageous to use the anchor to compress the soft tissue and the bone. The references 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; lines 30-34.)

With regard to claim 17, 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 18, in EP ‘805 the second member is disposed closer to the distal end than the first member, as shown in Fig. 1(c).

Accordingly, claims 6-11, 13 and 16-18 are invalid under 35 U.S.C. § 102(b) in view of EP ‘805.

B. Ground 2: § 102(b) – Justin '271 patent [Claims 6-11, 13 and 16-18]

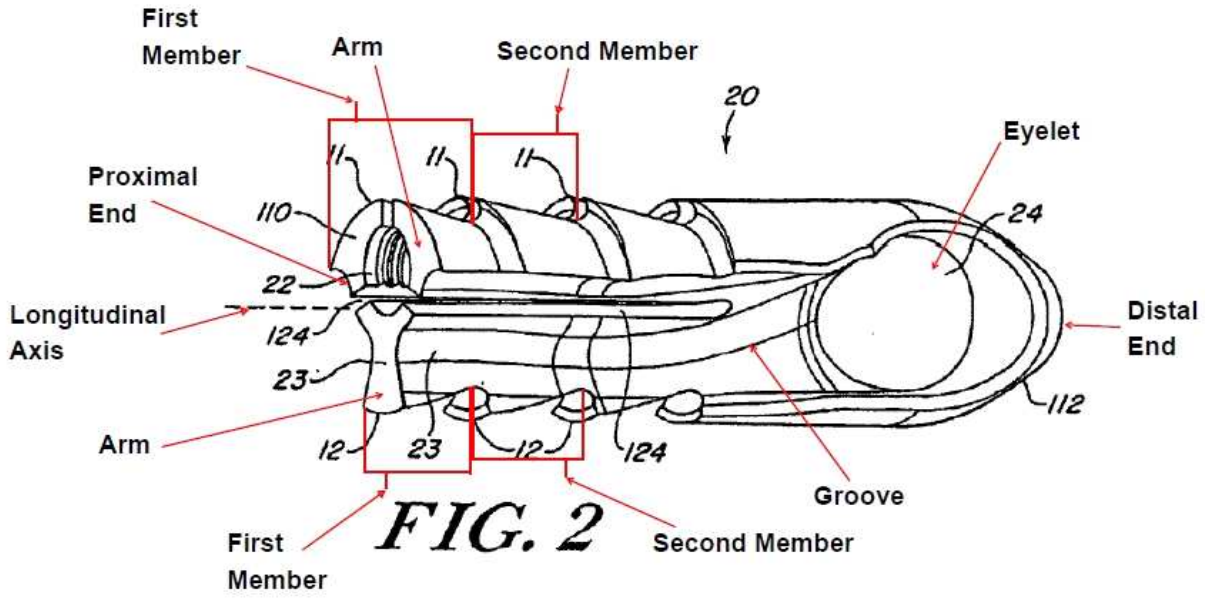


FIG. 2

With regard to claim 6, the Justin '271 patent discloses a fixation member 20 which is inserted within a patient's body in a space defined by bone. (Col. 2, lines 24-26; Col. 3, lines 52-55.)

The fixation member 20 has a longitudinal axis with a proximal end 110 and a distal end 112. (Fig. 2; Col. 3, lines 56-61.) The fixation member has a body which has a first member thereon. The first member includes a distinct proximal portion including a flat end surface and fins 11 and 12 located on the extremity of

the fixation member. The first member is moveable expandably outwardly away from the longitudinal axis of the body. (Fig. 2; Col. 4, lines 37-43; Col. 5, lines 1-1-5.)

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 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 the grooves, is expandable outwardly away from the longitudinal axis of the body Col. 5, lines 4-8. The fixation member 20 expands so as to force graft material pressed between grooves 23 and the bone tunnel wall into even more intimate contact therewith. (Col. 5, lines 4-8.)

The shape and configuration of the second member is significantly different from the shape and configuration of the first member. The first member includes

the proximal end having a flat end surface, which is not found in the second member. (Figs. 2 and 2A.)

The distal end of the body includes an eyelet 24 defining a space for receiving soft tissue. As set forth in the Justin '271 patent the graft material can be passed through the eyelet. (Col. 3, lines 62-65.) This feature is also shown in Figs. 1 and 2B.

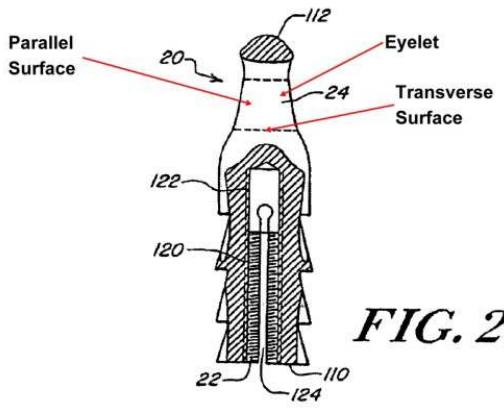


FIG. 2B

Claim 6 defines the space as being defined by surfaces of the body which are oriented both generally parallel to the longitudinal axis and generally transverse to the longitudinal axis. As shown in the Justin '271 patent, the eyelet 24 has a portion which extends transverse to the longitudinal axis of the fixation

member body and also has portions which extend parallel to the fixation member body. (Figs. 2 and 2B.)

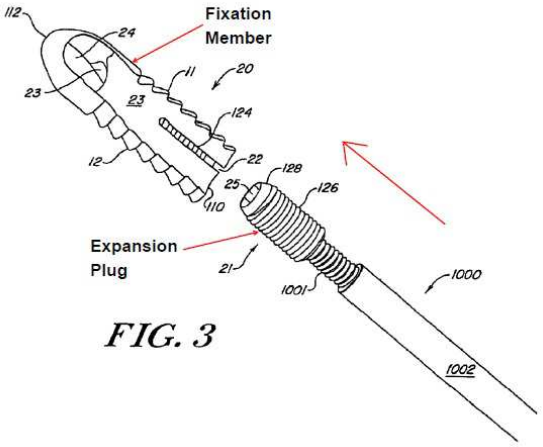


FIG. 3

The ‘271 patent discloses an expansion plug 21 which acts as a deployment device and it is moveable in the axial direction to force the first and second members outwardly away from the longitudinal axis of the fixation member body. (Col. 5, lines 49-52; Col. 4, line 64 through line 8.)

The first and second members are separated from each other in a direction along the longitudinal axis of the fixation member as shown in Fig. 2 of the Justin ‘271 patent. The second member is closer to the distal end. Fig. 2.

With regard to claim 7, this claim requires that the second member is disposed distally of the first member. This feature is clearly shown in the Justin

‘271 patent Fig. 2. The portion of the body constituting the second member is located closer to the distal end than the first member.

With regard to claim 8, the second member is proximal to the distal end 112 as shown in Fig. 2.

With regard to claim 9, the first member comprises an arm which is pivotable outwardly and has a portion adapted to engage bone. The first member includes an element that extends outwardly from the body having and unsupported end. Therefore, the element constitutes an arm. Fig. 2. The arm includes a fin 11/12, which is engagable with the bone. The ‘271 patent describes fins 11 and 12 as digging into the walls of the bone tunnel. (Col. 4, lines 40-45.) The ‘271 patent also describes that the bone engaging elements 11 and 12 move in opposed directions to force the bone engaging elements into engagement contact with the bone tunnel wall to lock the fixation member in place within the bone tunnel. (Col. 5, lines 1-5.)

With regard to claim 10, the arm is pivotable outwardly upon insertion of the expansion plug 21 and attached to the body to allow pivoting at the distal end

thereof. The proximal end of the arm includes engaging elements 11 and 12 that engage the bone. (Figs. 2 and 3; Col. 4, lines 60-66; Col. 5, lines 1-5.)

With regard to claim 11, the first member is defined as including a plurality of arms. The first member is divided by a slot 124 forming two separate arms. Both arms have bone engaging members 11 and 12. (Fig. 2; Col. 4, lines 51-56.)

With regard to claim 13, the expansion plug 21 moves the first and second members outwardly away from the longitudinal axis. (Col. 4, line 65 through Col. 5, line 8; Col. 5, lines 47-53.) As the expansion plug 21 is advanced into the fixation member 20, the expansion slot 124 permits the fixation member to expand outwardly so that the bone engaging elements 11 and 12 located along the length of the first and second members are forced into engagement with the bone. (Col. 4, line 51 through Col. 5, line 5.)

With regard to claim 16, the Justin ‘271 patent recites an expanding ligament graft fixation system and method. The ‘271 patent discloses a method of anchoring soft tissue to bone using the fixation member 20. (Col. 2, lines 24-26; Col. 3, lines 52-55.) The recited system includes a fixation member 20 and an expansion plug 21 positioned at a proximal end of the fixation member. The ‘271

patent further teaches 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.

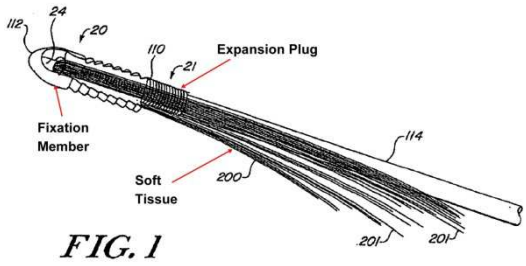


FIG. 1

The '271 patent further discloses placing the soft tissue on an implant. (Fig. 1; 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. (Fig. 1; Col. 3, lines 60-64.)

The fixation member 20 has a longitudinal axis extending from a distal end 112 to a proximal end 110 as shown in Figs. 1 and 2. (Col. 3, lines 56-61.)

The fixation member 20 is disposed in a space located within a bone tunnel of a patient's body. (Col. 3, lines 52-55.) The fixation member fixes soft tissue graft material within a bone tunnel to replace damaged ligamentary material. (Col. (Col. 6, line 61 through Col. 7, line 12.)

The fixation member 20 includes a first member which includes a distinct proximal portion of the fixation member. (*See* annotated Fig. 2 above). As set forth in the Justin '271 patent, fins 11 and 12 are moved outwardly away from the longitudinal axis of the body and into engagement with the adjacent bone. (Col. 4, lines 37-43.) The bone engaging elements 11 and 12 dig into the walls of the bone tunnel after expansion of the fixation element. (Col. 4, lines 37-43.)

The fixation member 20 includes a second member having fins 11 and 12. The second member is spaced from the first member in an axial direction. The second member also includes grooves 23. (Col. 5, lines 4-8.) The fins portion of the second member engages bone. (Fig. 2; Col. 4, lines 40-42; Col. 4, line 60 through Col. 5, line 8.) In addition, as shown in Figs. 1 and 2, the grooves have a portion disposed at a different axial location than their proximally located fins 11 and 12.

An expansion plug 21 is insertable into the fixation member. Such insertion results in the deployment of both the first and second members outwardly away from the longitudinal axis of the fixation member. (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. (Col. 5, lines 4-8.)

With regard to claim 17, 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 and in a direction away from the longitudinal axis. (Fig. 3; Col. 5, lines 1-8 and 42-53; Col. 7, lines 2-7.)

With regard to claim 18, the second member of the Justin ‘271 patent is disposed distally to the first member. (Figs. 2, 2B and 3.)

Accordingly, claims 6-11, 13 and 16-18 are invalid under 35 U.S.C. § 102(b) in view of the Justin ‘271 patent.

C. Ground 3: § 102(b) - WO '345 [Claims 6-11, 13 and 16-18]

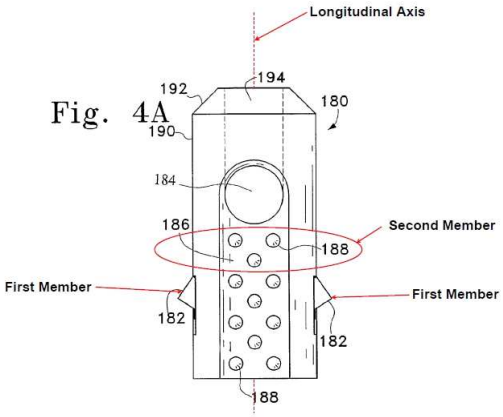


Fig. 4A

With regard to claim 6, WO '345 discloses an intraosseous anchor 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.) The body includes a first member 182 in the form of rotating barbs which are extendable outwardly. The barbs are hinged so that they rotate away from the longitudinal axis of the body. (Fig. 4D; Page 11, lines 11-13; page 11 line 26 to Page 12, line 3.)

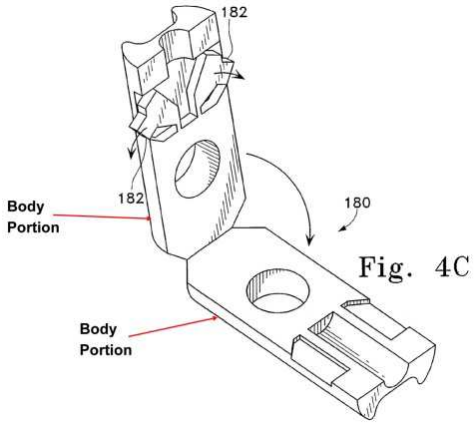


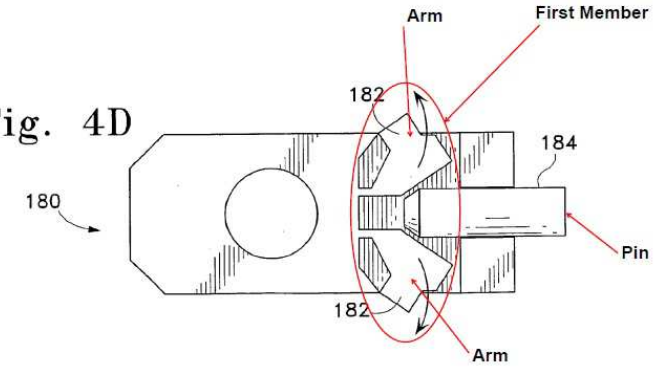
Fig. 4C

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 barbs are spaced axially from the first member. As shown in Fig. 4C, the body has two portions hinged at a distal end. Each portion of the body has the soft tissue barbs 186. When a pin 184 is inserted into the body, the two body portions would tend to expand outwardly away from the longitudinal axis in order to compress the soft tissue against the bone. Page 1, lines 7-9. The second member has a substantially different shape and configuration than the first member in that the second member does not include the rotating barbs. (Fig. 4A.)

The anchor 180 has a cross passageway 184 for receiving the soft tissue therethrough. (Page 11, lines 14-15.) The passageway has surfaces which are

oriented both generally parallel to the longitudinal axis and generally transverse to the longitudinal axis. (Fig. 4A and 4C.)

Fig. 4D



Pin 184 is a deployment device and is axially insertable into the anchor body. Such movement drives the rotating barbs outwardly away from the longitudinal axis of the body. (Page 11, lines 11-13, Fig. 4D; page 11 line 26 to Page 12, line 3.)

With regard to claims 7 and 8, the second member includes barbs 188 and a recess 186 that are disposed distally of the rotating barbs 182. (Fig. 4A.) The second member is proximal to the distal end.

With regard to claim 9, the rotating barbs each have an arm which pivotable outwardly from the body. (Page 11, lines 11-13; Fig. 4D; page 11 line 26 through

page 12, line 3.) The barbs dig into bone to secure the anchor in place. (Page 12, 12, lines 1-3.)

With regard to claim 10, each rotating barb has a distal end attached to the body and which allows the barb to pivot. Fig. 4C and 4D. A proximal end of the barb pivots outwardly and engages bone. (Page 12, lines 1-3.)

With regard to claim 11, the anchor has two rotating barbs 182. (Fig. 4A.)

With regard to claim 13, the insertion of the pin into the anchor body will cause the rotating barbs 182 to rotate outwardly. (Page 11, line 26 through page 12, line 3). In addition, the insertion of the pin will tend to urge the two body portions apart. WO '345 discloses that it is desirable to press the soft tissue against the bone to accelerate growth of the soft tissue and attachment to the bone. (Page 1, lines 7-9.)

With regard to claim 16, WO '345 discloses an intraosseous anchor for securing soft tissue such as a tendon in a cavity formed in a bone. (Page 1, lines 4-4-7) The anchor 180 has a body and a longitudinal axis with a distal and proximal proximal end. (Fig. 4A.) The body includes a first member 182 in the form of rotating barbs which are extendable outwardly. The barbs are hinged so that they

rotate away from the longitudinal axis of the body to engage adjacent bone. (Fig. 4D; Page 11, lines 11-13; page 11 line 26 to Page 12, line 3.)

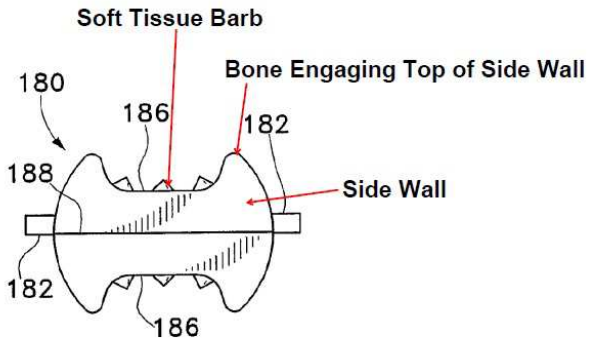


Fig. 4B

The body has a second member including a plurality of soft tissue barbs 188 disposed in an exterior cavity 186. The soft tissue barbs are spaced axially from the first member. As shown in Fig. 4C, the body has two portions hinged at a distal end. Each portion of the body has the soft tissue barbs 186. When a pin 184 184 is inserted into the body, the two body portions would tend to expand outwardly in order to engage bone and to compress the soft tissue against the bone. (Page 1, lines 7-9.) The outermost portion of the walls defining the recess

186 will engage bone as the two body portions expand outwardly upon insertion of the pin 184. (Fig. 4B.)

Deployment of the second member presses the soft tissue against the bone to accelerate growth by the soft tissue. (Page 1, lines 7-9.)

With regard to claim 17, the deployment of the first and second members is achieved by inserting a pin 184 into the anchor body. (Fig. 4C; page 11, line 24 through page 12, line3.)

With regard to claim 18, the second member includes soft tissue barbs 188 and a recess 186 that are disposed distally of the rotating barbs 182. (Fig. 4A.)

Accordingly, claims 6-11, 13 and 16-18 are invalid under 35 U.S.C. § 102(b) in view of WO ‘345.

D. Ground 4: § 103(a) - WO ‘345 in View of Either EP ‘805 or the Justin ‘271 patent [Claims 6-11, 13 and 16-18]

Section VI. C. above is incorporated by reference to show that each of the elements of claims 6-11, 13, and 16-18 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 6 and 16, both EP ‘805 and the Justin ‘271 patent teach the use of a

tapered member for deploying first and second members outwardly. Thus, claims 6-11, 13 and 16-18 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 (page 1, lines 7-9; page 9, lines 13-16), and also to engage adjacent bone. (Page 11 line 25 through page 12, line 3.) Such a teaching is also found in both EP ‘805 and the Justin ‘271 patent. For example, EP ‘805 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. (Col. 8, lines 28-34; *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 for engagement to adjacent bone. (Col. 8 lines 34-49.)

The Justin ‘271 patent teaches that the fixation member expands to fix the graft material to the interior of the bone tunnel. (Col. 4, lines 4-8.) Engagement with the adjacent bone by the first and second members is also taught in the Justin ‘271 patent. (Fig. 2; Col. 4, lines 37-43; Col. 4, line 60 through 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. (Col. 8, lines 46-49.) It would have been obvious to one skilled in the art 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.

The Justin ‘271 patent 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 modify the WO ‘345 anchor 180 of to use a tapered expansion member as in the Justin ‘271 patent 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.

Accordingly, claims 6-11, 13 and 16-18 are invalid under 35 U.S.C. § 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 6			
A material fixation system, comprising an implant which is placeable in a space defined by bone, said implant comprising:	bone anchor 2, 76, Fig. 1(d), 3	Col. 2, lines 24-26 and Col. 3, lines 52-55	Page 1, lines 4-7.
a body having a longitudinal axis, a distal end, and a proximal end;	Fig. 1(c); Col. 7, lines 14-17	Fig. 2; Col. 3, lines 56-61.	Fig. 4A.
a first member on said body	Col. 7, lines 11-13; Figs. 1 (c) and 1(d)	Fig. 2; Col. 4, lines 37-43; Col. 5, lines 1-5.	Fig. 4D; Page 11, lines 11-13; and Page 11 line 26 to Page 12, line 3.
which is movably expandable outwardly;	Col. 8 lines 7-18. Col. 9, lines 27-32	Col. 4, lines 37-43; Col. 5, lines 1-5.	Fig. 4D; Page 11, lines 11-13; and Page 11 line 26 to Page 12, line 3.
a second member on said body which is disposed axially from said first member and is also movably expandable outwardly	Fig. 1(c). Col. 4, lines 44-47; Col. 6, lines 21-30; Col. 8, lines 7-18 and Col. 9, lines 27-32.	Fig. 2; Col. 5, lines 4-8	Fig. 4C; Page 1, lines 7-9.
said second member being of a substantially	Fig. 1(c)-(f); Col. 8, lines 11-15.	Figs. 2 and 2A.	Fig. 4A

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different construction than said first member;			
a distal end of said body comprising a space for receiving soft tissue therethrough	Figs. 1(a), 1(c) , 3. Col. 3, lines 53-57; and Col. 7, lines 38-41; Col. 7, lines 52-56.	Figs. 1 and 2B; Col. 3, lines 62-65.	Page 11, lines 14-15
said space being defined by surfaces of said body which are oriented both generally parallel to said longitudinal axis and generally transverse to said longitudinal axis; and	Fig. 1 (a), 1(d)	Figs. 2 and 2B;	Fig. 4A and 4C.
a deployment device which is moveable in a generally axial direction to deploy at least one of said first and second members.	Col. 8, lines 7-18. Col. 8, lines 28-49; Col. 9, lines 27-32	Col. 5, lines 49-52; Col. 4, line 64 through Col. 5, line 8.	Page 11, lines 11-13, Fig. 4D; and Page 11 line 26 to Page 12, line 3.
CLAIM 7			
said second member is disposed distally of said first member	Figs. 1(c) and 3	Fig. 2	Fig. 4A.
CLAIM 8			
said second member is proximal to said distal	Figs. 1(c) and 3.	Fig. 2	Fig. 4A.

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end.			
CLAIM 9			
said first member comprises an arm which is pivotable outwardly, said arm having a portion which is adapted to engage bone to anchor the body to the bone.	Fig. 3; Col. 8, lines 10-18 and 46-49; Col. 9, lines 27-32	Fig. 2; Col. 4, lines 40-45; Col. 5, lines 1-5.	Page 11, lines 11-13, Fig. 4D; Page 11 line 26 to Page 12, line 3; and Page 12, lines 1-3.
CLAIM 10			
a distal end of the arm is attached to the body, and comprises the pivoting end, and a proximal end of the arm pivots outwardly and comprises the portion which is adapted to engage bone.	Fig. 3; Col. 5, lines 1-5; Col. 8, lines 10-15.	Fig. 2 and 3; Col. 4, lines 40-45 and 60-66; Col. 5, lines 1-5.	Fig. 4C and 4D. Page 12, lines 1-3.
CLAIM 11			
said first member comprises a plurality of said arms	Fig. 1(c); Col. 8 lines 10-12.	Fig. 2; Col. 4, lines 51-56.	Fig. 4A.
CLAIM 13			
said deployment device deploys both said first and second members	Col. 6, lines 22-30; Fig. 3; Col. 6, lines 22-30; Fig. 3; Col. 8, lines 7-11 and 34-49.	Col. 4, line 65 through Col. 5, line 8; Col. 5, lines 47-53.	Page 1, lines 7-9. Page 11, line 26 through page 12, line 3.

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CLAIM 16			
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.	Page 1, lines 4-7.
having a longitudinal axis extending from a distal end of the implant to a proximal end of the implant, and	Figs. 1(c) and 3; Col. 7, lines 15-18.	Fig. 2; Col. 3, lines 56-61.	Fig. 4A.
disposing the implant within a space at a desired location within a portion of bone;	Col. 6 lines 2-6, Fig. 3.	Col. 3, lines 52-55; Col. 6, line 61 through Col. 7, line 12.	Page 1, lines 4-7.
deploying a first member on said implant outwardly to engage adjacent bone; and	Figs. 1 (c) and 1(d).; Col. 8, lines 10-18, FIG. 3. Fig. 3, Col. 9, lines 30-32.	Figs. 1 and 2; Col. 4, lines 37-43; Col. 5, lines 4-8.	Fig. 4D; Page 11, lines 11-13; and Page 11 line 26 to 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;	Col. 6, lines 22-30; Fig. 3. Col. 8, lines 7-11; and Col. 8 lines 34-49.	Figs. 1 and 2; Col. 5, lines 4-8.	Figs. 4B and 4C; Page 1, lines 7-9.
wherein the outward deployment of one of said first and second	Col. 4, lines 44-44-47, and Col. 8, lines 19-27 and	Col. 4, lines 1-7; Col. 4, line 60 through Col. 5	Page 1, lines 7-9.

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members compresses the soft tissue between said one of said first and second members and adjacent bone.	30-34.	line 8.	
CLAIM 17	.		
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. 4C; page 11, line 24 through page 12, line3.	Page 1, lines 1-3
CLAIM 18			
wherein said second member is disposed distally of said first member.	Fig. 1(c)	Figs. 2, 2b and 3.	Fig. 4A

VII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *Inter Partes* Review of Claims 6-11, 13 and 16-18 of U.S. 8,435,294, followed by a grant of this Petition rejecting Claims 6-11, 13 and 16-18 of the '294 patent on the grounds detailed herein.

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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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