

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC.,
Petitioner,

v.

KFX MEDICAL, LLC,
Patent Owner.

Case IPR2016-01697
Patent 9,044,226 B2

Before LORA M. GREEN, JOSIAH C. COCKS, and
RICHARD H. MARSCHALL, *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

DECISION
Instituting *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Summary

Petitioner, Arthrex, Inc. (“Petitioner”), filed a Petition (Paper 1, “Pet.”) to institute an *inter partes* review of claims 1–20 of U.S. Patent No. 9,044,226 B2 (Ex. 1001, “the ’226 patent”). Patent Owner, KFx Medical, LLC (“Patent Owner”), filed a Preliminary Response. Paper 6, “Prelim. Resp.”

An *inter partes* review may not be instituted unless the information presented in the Petition shows “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); see 37 C.F.R. § 42.108. For the reasons set forth below, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail in showing the unpatentability of claims 1–20. Accordingly, we institute an *inter partes* review as to those claims.

B. Related Matters

Petitioner and Patent Owner identify the following proceeding in the U.S. District Court for the District of New Jersey as a related matter: *Arthrex, Inc. v. Joseph Tauro et al.*, No: 3:15-cv-06580-PGS-LHG. Pet. 3; Paper 4, 1. Patent Owner also identifies an *inter partes* review involving U.S. Patent No. 8,926,663 (IPR2016-01698) as a related matter. Paper 4, 1.

C. The ’226 patent

The ’226 patent is titled “System and Method for Attaching Soft Tissue to Bone.” Ex. 1001, Title. The ’226 patent summarizes its disclosed invention as follows:

The present invention is particularly suited for use in arthroscopic procedures, including but not limited to rotator cuff surgery. More broadly, it can be used in any procedure in which it is desired to fix a suture to a solid object without tying of knots, including not only arthroscopic procedures, but also open surgery, and can be used for such diverse purposes as bladder neck suspension, tendon and ligament affixation or repair, prosthetic attachment, and rotator cuff repair.

Id. at 1:52–59.

Figures 11–13 of the '226 patent are reproduced below:

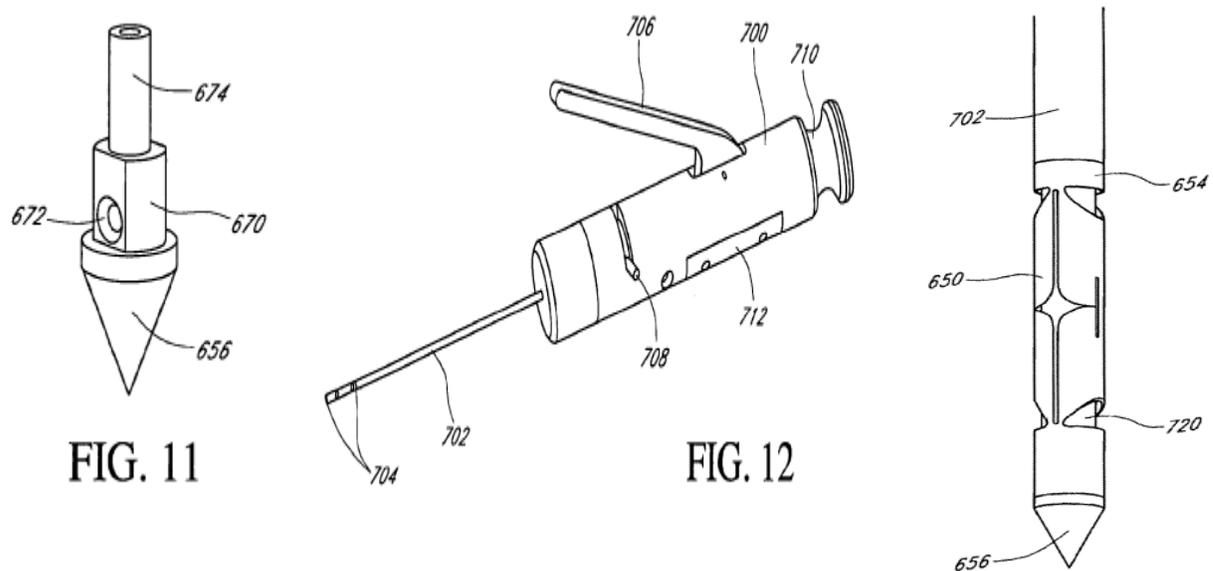


Figure 11 shows a piercing bone anchor tip; Figure 12 shows an inserter for inserting a piercing bone anchor into bone; and Figure 13 shows the interface between a piercing bone anchor and an anchor inserter. *Id.* at 3:38–42. A piercing bone anchor includes: (1) anchor inserter attachment structure 674, which forms a proximal portion of the anchor; (2) structure 670 with suture aperture 672, which forms a medial portion; and (3) anchor tip 656, which constitutes a distal portion. *Id.* at 10:45–11:3. Piercing bone anchor 704 also includes hollow cylinder 650, which facilitates attachment

of the bone anchor to outer sleeve 702 of the inserter. *Id.* at 11:16–24. Hollow cylinder 650 surrounds inner tube 720 of the inserter, which provides structural reinforcement of anchor 704 and pushes against anchor tip 656 when the anchor is driven into bone. *Id.* at 11:32–34. Once the bone anchor is driven into bone, deployment lever 706 of the insert may be pressed to deploy and detach 704. *Id.* at 11:9–10.

The '226 patent further explains the following regarding inner tube 720:

The inner tube 720 may be fixed relative to the handle 712 and outer sleeve 702 during insertion, however, during deployment of the anchor 704, the inner tube 720 may be released by switching safety switch 708 so that the inner tube 720 can move axially relative to the outer sleeve 702 while the anchor cylinder 650 collapses.

Id. at 11:34–40.

Figure 10B of the '226 patent is reproduced below:

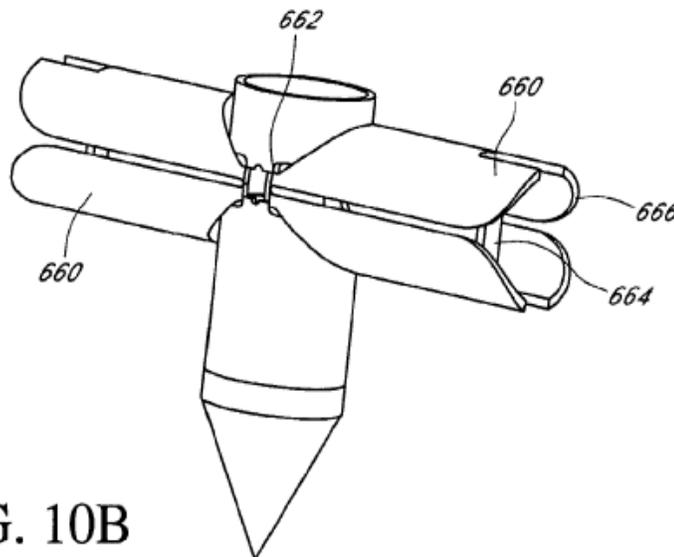


Figure 10B depicts a piercing bone anchor in a deployed state. *Id.* at 3:36–37. In that deployed state, cylinder 650 (not numbered in Figure 10B) collapses into a configuration in which lateral wings 660 of the cylinder are positioned prevent removal the anchor from the bone. *Id.* at 10:25–30.

D. Claims

Claims 1, 9 and 15 are independent. Claims 2–8, 10–14, and 16–20 ultimately depend from one of those independent claims. Claim 1 is drawn to a “bone implant.” Claim 9 is directed to “[a]n inserter and bone implant combination.” Claim 15 recites a method of fixating a bone implant within bone that corresponds to claim 9. Claims 1 and 9 are illustrative and are reproduced below:

1. A bone implant, comprising:
 - a substantially hollow cylinder; and
 - a bone-piercing tip that comprises
 - a distal portion comprising a pointed tip configured to pierce through bone and having a maximum diameter at its proximal end,
 - a medial portion comprising a transverse suture aperture and having a constant diameter along its length that is smaller than the distal portion maximum diameter, and
 - a proximal portion having a constant diameter along its length that is smaller than the medial portion diameter and configured to couple to an inserter, wherein the proximal portion of the bone-piercing tip is configured to be positioned within a distal portion of the substantially hollow cylinder and not extend to a proximal end of the substantially hollow cylinder, wherein the bone-piercing tip has a length that is shorter than the length of the substantially hollow cylinder, and
 - wherein the substantially hollow cylinder has an inner diameter that is smaller than the bone piercing tip distal portion maximum diameter.

9. An inserter and bone implant combination, comprising:
- an inserter, comprising:
 - a handle,
 - an outer sleeve coupled to the handle and fixed relative to the handle, and
 - an inner tube disposed within the outer sleeve; and
 - a bone implant coupled to the inserter, the bone implant comprising:
 - a substantially hollow cylinder, and
 - a bone-piercing tip comprising a distal portion having a pointed tip, a medial portion having a suture aperture, and a proximal portion, wherein the pointed tip has a maximum diameter at its proximal end, the medial portion has a constant diameter along its length that is smaller than the distal portion maximum diameter, and the proximal portion has a constant diameter along its length that is smaller than the medial portion diameter;
 - wherein a portion of the inner tube extends distally through the substantially hollow cylinder and contacts the bone piercing tip,
 - wherein the proximal portion of the bone piercing tip is configured to be positioned within a distal portion of the substantially hollow cylinder and not extend to a proximal end of the substantially hollow cylinder and is removably coupled to the inserter,
 - wherein the length of the bone-piercing tip is shorter than the length of the substantially hollow cylinder, wherein the substantially hollow cylinder has an inner diameter that is smaller than the bone-piercing tip distal portion maximum diameter, and wherein a distal end of the outer sleeve is flush with an open, proximal end of the substantially hollow cylinder.

E. The Prior Art

Petitioner relies on the following prior art references:

Reference	Date	Exhibit No.
U.S. Patent 7,976,565 B1 issued to Meridew (“Meridew”)	July 12, 2011	1005
U.S. Patent Application Publication No. 2004/0093031 A1 issued to Burkhardt et al. (“Burkhardt”)	May 13, 2004	1006
U.S. Patent No. 5,527,342 issued to Pietrzak et al. (“Pietrzak”)	June 18, 1996	1007
U.S. Patent No. 5,141,520 issued to Goble et al. (“Goble”)	Aug. 25, 1992	1008
U.S. Patent No. 5,827,291 issued to Fucci et al. (“Fucci”)	Oct. 27, 1998	1019
U.S. Patent No. 6,511,499 B2 issued to Schmieding et al. (“Schmieding”)	Jan. 28, 2003	1020
U.S. Patent No. 5,741,282 issued to Anspach, III et al. (“Anspach”)	Apr. 21, 1998	1021

F. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–20 based on the following grounds:

Ground No.	Reference(s)	Basis	Challenged Claims
1	Meridew	§ 102	1–11, 14–17, and 19
2	Meridew and Fucci or Schmieding	§ 103	3, 4, 12, and 13

Ground No.	Reference(s)	Basis	Challenged Claims
3	Meridew and Anspach	§ 103	18
4	Meridew, Pietrzak or Goble, Fucci or Schmieding, and Anspach	§ 103	1–20
5	Burkhart and Pietrzak or Goble	§ 103	1, 2, 5–11, 14–17, 19, and 20
6	Burkhart, Pietrzak or Goble, and Fucci or Schmieding	§ 103	3, 4, 12, and 13
7	Burkhart, Pietrzak or Goble, and Anspach	§ 103	18

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, a claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Consistent with the broadest reasonable construction, claim terms are presumed to have their ordinary and customary meaning as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Here, neither party contends that any claim term should be afforded a meaning other than its ordinary and customary one. Petitioner proposes

express construction of such meaning for certain claim terms/phrases. *See* Pet. 13–18. For purposes of this Decision, we need only address explicitly the construction of three claim phrases/terms: (1) “constant diameter along its length” (claims 1, 9, and 15); and (2) “bone-piercing tip . . . comprising a pointed tip” (claims 1, 9, and 15); and (3) “inner tube” (claims 9 and 15).

1. *“constant diameter along its length”*

Each of claims 1, 9, and 15 requires a medial portion and a proximal portion associated with a bone-piercing tip. Each of those portions is required to have “a constant diameter along its length.” According to Petitioner, that requirement should be construed broadly as encompassing a constant diameter along only “a portion of” the lengths of the proximal and medial portions. Petitioner, however, provides no meaningful explanation as to why the broadest reasonable interpretation of the pertinent phrase should, in effect, insert the term “a portion of” in front of the word “length.” It is apparent from the claim language, itself, that each of the medial and proximal portions must have a length, and that such length has a constant diameter along its extent.

Thus, although we agree with Petitioner (Pet. 15) that the “along its length” language does not limit the claims to details of the embodiment shown at Figure 11 of the ’226 patent, that does not justify a construction that permits a constant diameter of the medial and proximal portions that is something regarded as less than along their entire length.

2. *“pointed tip”*

Claims 1, 9, and 15 require a “bone-piercing tip” having a distal portion with a “pointed tip.” According to Petitioner, the term “pointed” means “having a sharpened or tapered tip or end,” and that “[a] tip can be

‘tapered’ and still have a blunted or softened terminal end.” Pet. 15–16. Thus, Petitioner is of the view that a tip remains “pointed” even if it has a “blunted or softened terminal end.” That construction is unreasonable. Petitioner’s contorted position that construction of the term “tapered,” which is not a claim term, infuses a meaning of “pointed tip” as encompassing a tip that is blunted, and thus clearly not pointed, cannot be correct. A blunted tip is essentially the opposite of a pointed tip. Petitioner’s position is contrary to the ordinary meaning of “pointed,” and also is inconsistent with the Specification of the ’226 patent, which discloses pointed tips lacking a blunted or softened terminal end in the embodiments covered by the claims of the ’226 patent. *See, e.g.*, Ex. 1001, Figs. 10A, 10B, 11, and 13. We, thus, do not adopt Petitioner’s construction of the term “pointed tip,” but determine that, for purposes of this Decision, we need not make express the construction of that term.

3. “*inner tube*”

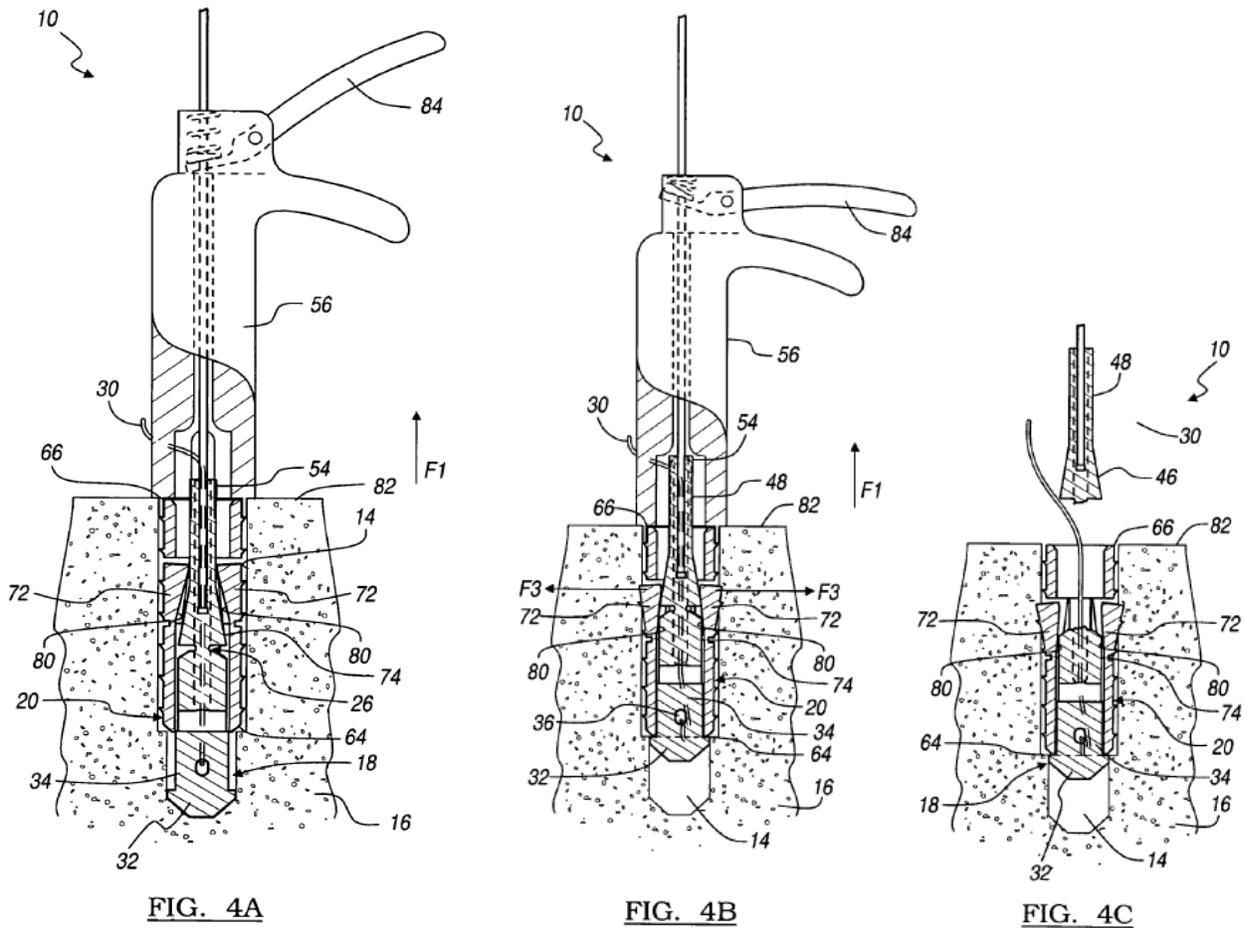
Petitioner provides no express construction of the claim term “inner tube.” Pointing to a dictionary definition (Ex. 2004), Patent Owner contends that a “tube” must be a “hollow” structure. Prelim. Resp. 27. Patent Owner also notes that the Specification of the ’226, in discussing inner tubes, describes structures that are hollow. *Id.* at 27–28. We agree with Patent Owner that in the context of the ’226 patent, a tube is something that is hollow. Thus, we construe “inner tube” as an inner structure that is hollow.

4. *Remaining claim terms*

We have given all claim terms, including those discussed above, their ordinary and customary meaning. We determine that it is not necessary to address or make express that meaning for any other claim term of the ’226

anchor 10. *Id.* at 2:15. Suture anchor 10 includes insert 18 molded to actuator pin 12 and partially disposed in sleeve 20. *Id.* at 2:61–62. Insert 18 includes suture receiving portion 22, with tip 32 and cylindrical body 34, and end section 24 displaced from portion 22 by breakaway section 26. *Id.* at 2:64–66; 3:12–13.

Meridew's Figures 4A–4C are reproduced below:



Figures 4A–4C are “environmental view[s]” of the suture anchor in use. *Id.* at 2:21–25. As shown Figures 4A–4C, suture anchor 10 is inserted into “pre-drilled hole 14” in bony structure 16. *Id.* at 4:52–56. Squeezing trigger 84 of actuation gun 56 applies retractive force F1 to actuator pin 12.

Id. at 4:60–62. Meridew further explains the following:

The application of the retractive force F1 causes the insert 18 to displace rearwardly with respect to the sleeve 20 as illustrated in FIG. 4B. This rearward displacement causes the tapered portion 46 to apply a force F2 to the tapered interior bearing surface 80 of the expanding members 72 of the sleeve 20. As the insert 18 continues to move rearward, the tapered portion 46 applies an increasingly greater force F2^[1] to the tapered interior bearing surface 80 of the expanding members 72 until the expanding members 72 are engaged with the boney structure 16.

Id. at 5:8–17. Once expanding member 72 is fully engaged with boney structure 16, subsequent application of retractive force F1 causes breakaway section 26 to fracture as shown in Figure 4C. *Id.* at 5:18–23.

2. Discussion – Grounds 1–3 Based on Meridew

For ground 1, Petitioner argues that claims 1–11, 14–17, and 19 are anticipated by Meridew. For grounds 2 and 3, Petitioner asserts that claims 3, 4, 12, 13, and 18 would have been obvious based on Meridew. Grounds 1–3 all rest on Petitioner’s proposed interpretation of “pointed tip” as encompassing a tip that is blunted. As discussed above in connection with our claim construction, we decline to adopt Petitioner’s proposed interpretation. According to Petitioner, Meridew’s tip 32, shown for instance in Figures 1, 2, and 4A–4C reproduced above, is a pointed tip. *See, e.g.*, Pet. 19–21. We agree with Patent Owner, however, that it is clear from those figures that tip 32 includes a flattened end portion. *See* Prelim. Resp. 22. That flattened end portion is not a “pointed tip.” We are cognizant that Meridew generally contemplates a possibility of some undescribed

¹ Force F2 appears to be labeled “F3” in Figure 4B.

“impacting tip” that may be employed with a suture anchor. *See* Ex. 1005, 2:47–49. Meridew, however, provides no detail of the structure of an “impacting tip,” or further mention of such a tip. Patent Owner’s grounds 1–3 also are not premised on any modification of Meridew. Based on this record, we find that Meridew does not expressly or inherently disclose the “pointed tip” required by all of the claims of the ’226 patent.

For at least the reasons noted above, we are not persuaded that Petitioner has made an appropriate showing in its Petition of a reasonable likelihood of success in connection with grounds 1–3 based on Meridew.

C. Ground 4 – Obviousness Based on Meridew

Petitioner proposes an alternative ground to claims 1–20 based on Meridew. Although Petitioner initially styles the proposed ground applied to claims 1–20 as being collectively over “Meridew in view of Pietrzak or Goble, Fucci or Schmieding, and Anspach” (Pet. 18), Petitioner refines the statement of the ground in justifying its merits. In particular, Petitioner applies the references as follows: (1) claims 1–11, 14–17, 19, and 20 are rendered unpatentable over Meridew in view of Pietrzak or Goble (*id.* at 44, 49–50); (2) claims 12 and 13 are rendered unpatentable over Meridew, Goble or Pietrzak, and Fucci or Schmieding (*id.* at 48–49); and (3) claim 18 is rendered unpatentable over Meridew, Goble or Pietrzak, and Anspach (*id.* at 49). Accordingly, we consider the claims in the above-noted groupings.

1. Claims 1–11, 14–17, 19, and 20

Here, the basis of Petitioner’s alternative ground involving Meridew is premised on the position that even if Meridew’s tip 32 is not considered to be “pointed,” such a tip is accounted for when taking Meridew’s teachings along with those of either Pietrzak or Goble.

a. Overview of Pietrzak

Pietrzak is titled “Method and Apparatus for Securing Soft Tissues, Tendons and Ligaments to Bone.” Ex. 1007, Title. Pietrzak’s Figure 2 is reproduced below:

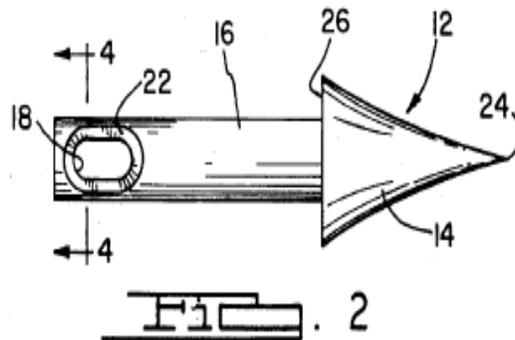


Figure 2 illustrates a side elevational view of “the apparatus for securing soft tissues, tendons and ligaments to bone” according to an embodiment of the invention. *Id.* at 3:1–4. Pietrzak describes suture anchor 10 with spear member 12 having cone-shaped head portion 14 that comes to “point 24 which is suitable for piercing and being driven into bone.” *Id.* at 5:1–23. Pietrzak sets forth that an object of the invention “is to provide a method and apparatus to secure a suture to bone without the need to pre-drill the bone nor require the use of a drill to install the anchor.” *Id.* at 2:45–49.

b. Overview of Goble

Goble is titled “Harpoon Suture Anchor.” Ex. 1008, Title. Goble’s Figure 3 is reproduced below:

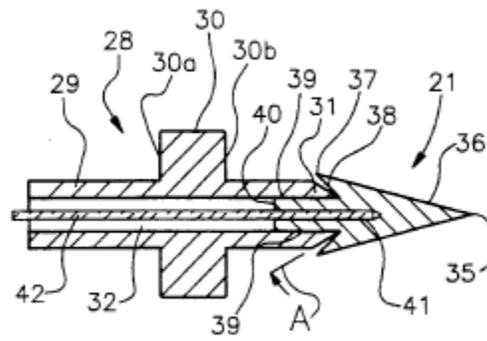


Fig. 3

Figure 3 shows “an enlarged profile sectional view of a first embodiment of a harpoon suture anchor of the present invention[.]” *Id.* at 3:49–51. Goble describes suture anchor mount 28 and suture anchor 21 that incorporates “a pointed forward end 35 . . . for penetrating a bone 33 surface.” *Id.* at 5:15–27 (bone surface 33 not shown in Figure 3). Goble describes that an “object of the present invention is to provide a suture anchor that can be installed in a bone that does not require a prior site preparation.” *Id.* at 2:20–23.

c. Discussion – Meridew and Pietrzak or Goble

In connection with the above-noted ground, Petitioner lays out in detail where all the features of claims 1–11, 14–17, 19, and 20 are found in Meridew with a proposed modification of tip 32 so as to account for the feature of a bone-piercing tip having a pointed tip. *See* Pet. 19–39, 44–50. Specifically, Petitioner contends that it would have been obvious to implement the pointed tip portions of the suture anchors of either Pietrzak or Goble into the suture anchor of Meridew. Pet. 44–48.

Although Meridew’s tip 32 does not form a pointed tip, the tips disclosed by Pietrzak and Goble do form pointed tips that fall within the scope of “pointed tip” in the claims of the ’226 patent. Petitioner sets forth

several reasons why it would have been obvious to modify the blunted end with the pointed ends of either Pietrzak or Goble. *Id.* at 44–48. Based on the current record and for purposes of this Decision, we adopt those reasons as our own.

As Petitioner points out, Meridew generally recognizes the possible use of an “impacting tip.” *Id.* at 43; Ex. 1005, 2:47–49. Further, it is apparent from each of Pietrzak and Goble that the tip of a suture anchor may be configured with a pointed tip that is operable to pierce bone. *See* Ex. 1007, 5:1–23; Ex. 1008, 5:15–27. Pietrzak and Goble also make explicit that such a pointed tip, and its associated bone-piercing ability, provides a benefit in eliminating the need to provide prior site preparation, such as the need to pre-drill a hole in the bone. *See* Ex. 1007, 2:45–49 (seeking “to secure suture to bone without the need to pre-drill the bone”); Ex. 1008, 2:20–23 (setting goal of providing suture anchor that can be installed without “a prior site preparation”). As discussed above, Meridew contemplates a pre-drilled hole prior to the use of the anchor. Ex. 1005, 4:52–56.

Accordingly, by providing a tip that removes the need for a pre-drilled hole, both Pietrzak and Goble provide an alternative, pointed tip design with an advantage over the tip used in Meridew. On that record before us, there is adequate reason presented in the Petition that a skilled artisan would have modified Meridew’s tips to incorporate a tip understood as one that is bone-piercing with a pointed tip. Indeed, a skilled artisan seeking to eliminate the necessity of pre-drilling a hole in the bone has good reason to pursue the known, viable options that are conveyed by the prior art to facilitate such pursuit, i.e., implementing the pointed tips of either Pietrzak or Goble. *See*

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007) (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”)

Patent Owner also argues that the feature of claims 1, 9, and 15 directed to a “proximal portion having a constant diameter along its length that is smaller than the medial portion diameter” distinguishes those claims over the prior art. Prelim. Resp. 30–33. Petitioner identifies the portions of Meridew’s suture anchor that Petitioner believes corresponds to the claimed medial portion and distal portion. *See, e.g.*, Pet. 19, 21, 22. In considering those identified portions as shown, in Meridew’s Figure 2, we are satisfied, as this time, that Petitioner has made an adequate showing that Meridew discloses the claimed “proximal portion.”

With respect to claims 9–20, Patent Owner contends that Meridew does not disclose an inserter that includes an “inner tube” as required by those claims. Prelim. Resp. 23–28. In accounting for that feature, Petitioner relies on Meridew’s end section 24, which includes tapered portion 46 and annular body 48. Pet. 27. The end section and associated tapered portion and annular body are identified, for instance, in Meridew’s Figures 2 and 4C (reproduced *supra*). Tapered portion 46 and annular body 48 are described as forming central bore 58 that receives actuator pin 12 therein. Ex. 1005, 3:56–58.

Patent Owner argues that end section 24 (including tapered portion 46 and annular body 48) is not an “inner tube” of the inserter because it is

“actually part of the suture anchor and therefore cannot be part of the claimed inserter.” Prelim. Resp. 23. According to Patent Owner, end section 24, as well as the end section’s tapered portion 46 and annular body 48, are “all part of insert 18, which is part of suture anchor 10” and, therefore, “cannot also be part of the claimed inserter. *Id.* at 26. We disagree. Although end section 24 is initially associated with insert 18, once the insert is implanted within a bone, the end section is compelled, via retractive force F1 provided by actuator gun 56, to separate from insert 18 via breakaway section 26 and is removed from the bone via operation of actuator gun 56. Ex. 1005, 3:24–36. At this time, we are persuaded that because end section 24 is removed along with the inserter device formed by actuator gun 56, and does not remain implanted within bone, the end section is regarded reasonably as a part of the inserter, rather than part of the suture anchor as alleged by Patent Owner. Indeed, the primary function of end section 24 appears to be facilitating insertion of insert 18 into a bone.

Patent Owner also argues that Meridew’s tapered portion 46 and annular body 48 do not form a tube because they are not hollow. Prelim. Resp. 28. That argument is without merit. As noted above, the tapered portion and annular body together form central bore 58, and, thus, constitute a structure that is hollow.

Lastly, with respect to claims 15–20, Patent Owner contends that Meridew fails to teach a bone implant that is “coupled to a distal end of the inserter” as recited in claim 15. Prelim. Resp. 28. The premise of that contention is that components that are initially attached to insert 18, such as end section 24, but that ultimately are removed by operation of actuator 56, nevertheless, must be considered part of an implant rather than an inserter.

Id. at 28–30. For purposes of this Decision, we do not agree with Patent Owner, and conclude, at this time, that portions of Meridew’s insert 18 that are removed along with actuator 56 are viewed reasonably as part of an inserter.

For the reasons given above, we are satisfied, on the present record, that Petitioner has shown that the combination of Meridew with either Pietrzak or Goble discloses all of the limitations of claims 1–11, 14–17, 19, and 20. We have considered Patent Owner’s additional arguments against the combination of Meridew with either Pietrzak or Goble and are not persuaded that institution should be denied for the reasons stated by Patent Owner. *See* Prelim. Resp. 44–49. We are satisfied, on the present record, that Petitioner has shown a reasonable likelihood of success in its challenge that claims 1–11, 14–17, 19, and 20 are unpatentable over Meridew taken with either Pietrzak or Goble.

2. Claims 12 and 13

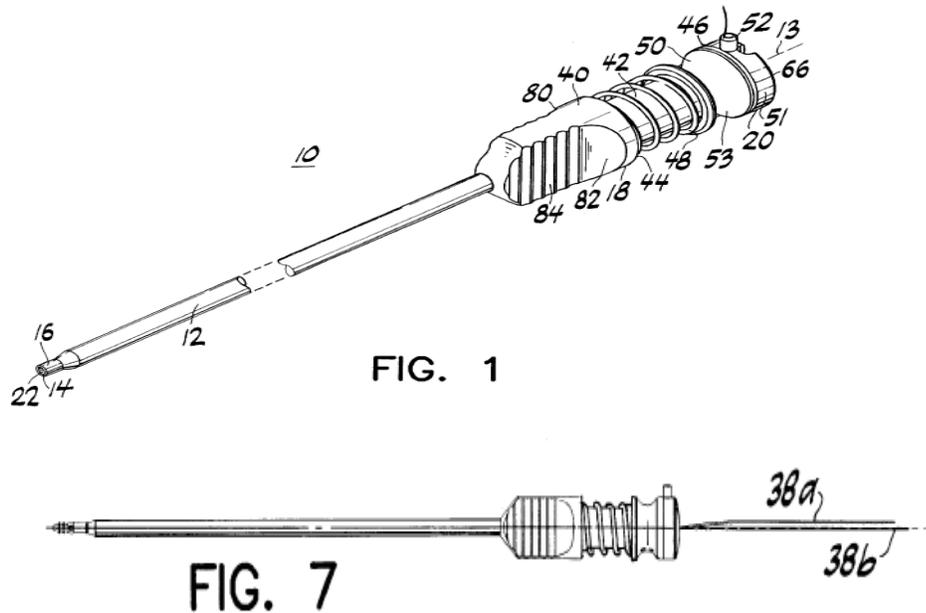
Claims 12 depends from claim 11, which depends from claim 9. Claim 13 depends from claim 12. Claim 12 adds the feature of a suture that “extends through an axial bore in the inner tube and an axial bore in the handle of the inserter.” Claim 13 further adds that “the suture exits the inserter through a hole in a proximal end of the handle.”

Petitioner contends that although such features are absent from Meridew, claims 12 and 13 would have been obvious when Meridew’s teachings are considered along with those of either Fucci or Schmieding. Pet. 48–49 (incorporating analysis from pages 39–42).

a. Overview of Fucci

Fucci is titled “Suture Anchor Driver with Suture Retainer.”

Ex. 1019, Title. Fucci's Figures 1 and 7 are reproduced below:



Figures 1 and 7 depict a suture anchor driver according to Fucci's invention. As shown in Figure 1, driver 10 includes drive shaft 12 extending to distal end 16, and handle portion 18 at proximal end 20. *Id.* at 4:26–30. Throughbore 22 extends from distal end 16 to proximal end 20. *Id.* at 4:30–31. As illustrated in Figure 7, suture ends 38a and 38b of suture 38 (not numbered) “are passed through bore 22 of the cannulated driver from the distal tip 16 and out of the proximal end 20.” *Id.* at 5:27–30. Fucci describes that driver 10 is intended for use with implants such as anchor 30 or anchor 30a (not shown in Figures 1 and 7 above), and that the driver “captures and secures either implant to itself by means of tension translated to the implant via suture 38 that is passed through the eyelet of the implant.” *Id.* at 4:47–51.

b. Overview of Schmieding

Schmieding is titled “Corkscrew Suture Anchor.” Ex. 1020, Title.

Schmieding's Figure 4 is reproduced below:

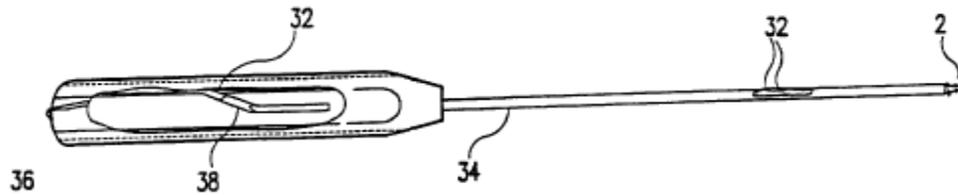


FIG.4

Figure 4 shows a side view of a suture anchor assembly according to an embodiment of Schmieding's invention. The suture anchor assembly includes pieces of suture 32 extending within driver 34 and within a handle portion of the assembly and wraps around cleat 36. *See id.* at 4:45–47. Schmieding sets forth that “[t]ension on the suture aids in retaining the suture anchor in the distal end of the driver.” *Id.* at 4:47–49.

c. Discussion – Meridew (as modified by Goble or Pietrzak) and Fucci or Schmieding

Petitioner contends that in light of the teachings of either Fucci or Schmieding, a person of ordinary skill in the art would have recognized that in connection with a suture anchor assembly, such as that of Meridew, suture may be arranged within the assembly such that it extends from a suture anchor to, and through, a hole in the proximal end of a handle. Pet. 39–42.

According to Petitioner, a skilled artisan would have configured the handle of Meridew's suture anchor assembly, and associated suture, in the manner required by claims 12 and 13 “in order to hold the eyelet implant in place under tension which increases the ease of insertion, as taught by Fucci or

Schmieding.” Pet. 42 (citing Ex. 1027 ¶ 134).² Petitioner also is of the view that the suture holding arrangements of Fucci and Schmieding “would perform their same functions when incorporated into the *Meridew* anchor as they do alone.” *Id.* (citing Ex. 1027 ¶¶ 135–136).

Patent Owner urges that Petitioner has not advanced any “reasonable rationale” for the proposed combination of Meridew and either Fucci or Schmieding on the theory that the back portion of Meridew’s handle “houses necessary functional components,” and that incorporation of Fucci or Schmieding’s teachings would require that Meridew’s handle “have to be significantly redesigned.” Prelim. Resp. 39–43.

We have considered Patent Owner’s preliminary arguments pertaining to claims 12 and 13. Patent Owner does not dispute that the features of claims 12 and 13 are known in the art of suture anchors. At this initial stage, we are satisfied that Petitioner has made a sufficient showing to warrant institution of *inter partes* review of those claims based on Meridew and either Fucci or Schmieding. In particular, to the extent that some redesign of Meridew may be necessary in light of Fucci or Schmieding’s teachings, it is not apparent that such redesign would be beyond the ordinary skill of a skilled artisan. Based on the teachings of Fucci or Schmieding, and in crediting, at this time, the testimony of Petitioner’s declaration, R. Jordan (Ex. 1027), we are persuaded that Petitioner has shown a reasonable

² Although characterized as relating to “Ground 3,” these portions of the Petition and Dr. Jordan’s testimony here, and below, are referenced at page 48–49 of the Petition in connection with the ground identified as “Ground 4.”

likelihood of success in its challenge to claims 12 and 13 based on Meridew and either Fucci or Schmieding.

3. *Claim 18*

Claim 18 depends from claim 15 and adds a step of “piercing soft tissue with the bone-piercing tip.” Petitioner relies on Anspach in combination with Meridew to account for that additional step. Anspach is titled “Soft Tissue Fastener Device.” Ex. 1021, Title. Anspach describes that the use of its device during a surgical procedure and during such procedure “soft tissue is pierced.” *Id.* at 2:3–6. Petitioner urges that Meridew and Anspach are generally similar devices and that, in light of the teachings of Anspach, a person of ordinary skill in the art would have appreciated that a suture anchor having a pointed bone-piercing tip, such as that suggested by Meridew and either Goble or Pietrzak, may be employed to pierce soft tissue with predictable results. Pet. 42–43 (citing Ex. 1027 ¶¶ 137, 140–141)).

Patent Owner disagrees with Petitioner. In particular, Patent Owner is of the view that Anspach and Meridew are not similar devices, and that Anspach’s approach of piercing tissue would not apply to Meridew’s device. Prelim. Resp. 43–44. Patent Owner also contends that any combination of Anspach and Meridew would necessitate that “substantial redesign” Meridew that undercuts Petitioner’s obviousness position. *Id.*

At this time, we are persuaded to institute *inter partes* review of claim 18 based on Petitioner’s Ground 4. It is apparent from the record at hand that surgical techniques involving the fastening or anchoring of structures to bone are understood to employ bone-piercing tips and piercing of soft tissue. Patent Owner also does not explain why even if the implementation of

Anspach's teachings onto Meridew's assembly requires some redesign, that any such redesign extends beyond an ordinary artisan's skill. In light of the current record, we are persuaded to institute inter partes review of claim 18 based on Petitioner's Ground 4.

D. Grounds 5–7 Based on Burkhart

Petitioner proposes alternative grounds to claims 1–20 based on Burkhart. Pet. 18. Burkhart is titled “Graft Fixation Using a Plug Against Suture.” Ex. 1006, Title. Although, like Meridew, Burkhart describes a tool and practice of securing soft tissue to bone, Burkhart takes a difference approach than Meridew. For instance, Burkhart's tool employs various configuration of eyelet's through which suture is threaded. *See, e.g.*, Ex. 1006, Figs. 4, 10, 11 (elements 50, 55, 250, 255). It is manifest that those structures are not bone-piercing tips and do not have pointed tips. Burkhart, unlike Meridew, provides no contemplation of incorporating any such pointed tip or impacting tip in lieu of those structures. Although Petitioner contends that combining Burkhart's teachings with either Pietrzak or Goble accounts for the required tip, we are skeptical that Petitioner's proposed “result” of that combination is one that a skilled artisan reasonably would have derived based on the teachings of the relevant prior art. *See* Pet. 51.

As Patent Owner notes, Burkhart contemplates manipulating the sutures after inserting the implant device into a pilot hole, with the sutures residing on the outside of the device. Prelim. Resp. 49–50; see also Ex. 1006, ¶¶ 27–28, Figs. 4–5. Only after the tensioning of the suture does Burkhart contemplate impacting the interference device into the pilot hole, locking the implant with the sutures in place. Ex. 1006, ¶ 28, Fig. 7. Patent Owner correctly points out that the interference device of Burkhart

“becomes superfluous” by modifying Burkhart with the pointed tips of Pietrzak or Goble, given that the pointed tips form an interference fit with surrounding bone upon insertion. Prelim. Resp. 50–54. Petitioner also fails to explain how the procedure of Burkhart, initially requiring insertion of the anchor without an interference fit to allow manipulation of the sutures, can be performed using pointed tips that form an interference fit upon insertion. Based on these deficiencies, we are not persuaded that Petitioner has established a reasonable likelihood of success in prevailing on Grounds 5–7.

Further, with respect to claims 9–22 and as discussed above, those claims require an “inner tube,” and that such tube in the context of the ’226 patent must be hollow. We agree with Patent Owner that it is not apparent that shank 19 of Burkhart, on which Petitioner relies to account for such a tube, is hollow. *See* Prelim. Resp. 33–35. In that respect, there is no suggestion in Burkhart that any component is intended to extend through that shank. For instance, all of Burkhart’s disclosed embodiments show suture that is external to Burkhart’s suturing tool.

Petitioner relies on other prior art in combination with Burkhart, but does not rely on that art to address the deficiencies we note above in Burkhart. Based on the foregoing, we do not institute *inter partes* review on any of Petitioner’s Grounds 5–7 based on Burkhart.

III. CONCLUSION

Having evaluated the Petition, its underlying supporting evidence, and Patent Owner’s Preliminary Response, we determine that Petitioner has shown a reasonable likelihood of success in its challenge to claims 1–20 based on Meridew, Pietrzak or Goble, Fucci or Schmieding, and Anspach.

At this stage of the proceeding, the Board has not made a final

determination as to the construction of any claim term or the patentability of claims 1–20 of the '226 patent.

IV. ORDER

It is ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted to determine whether claims 1–20 are unpatentable based on Meridew, Pietrzak or Goble, Fucci or Schmieding, and Anspach;

FURTHER ORDERED that *inter partes* review is not instituted in this proceeding on any other grounds; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial. The trial will commence on the entry date of this decision.

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For PETITIONER:

Anthony P. Cho
Timothy J. Murphy
John M. Siragusa
Brian S. Tobin
acho@cgolaw.com
tmurphy@cgolaw.com
jsiragusa@cgolaw.com
btobin@cgolaw.com

CARLSON, GASKEY & OLDS, P.C.
400 West Maple Road, Suite 350,
Birmingham, MI 48009

For PATENT OWNER:

Joseph F. Jennings
Bridget A. Smith
2jfi@knobbe.com
2bzs@knobbe.com
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, Fourteenth Floor
Irvine, CA 92614