

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*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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”). We instituted a trial to determine whether: (1) claims 1–11, 14–17, 19, and 20 are unpatentable over Meridew¹ taken with either Pietrzak² or Goble;³ (2) claims 12 and 13 are unpatentable over Meridew, Pietrzak or Goble, and Fucci⁴ or Schmieding;⁵ and (3) claim 18 is unpatentable over Meridew, Pietrzak or Goble, and Anspach.⁶ See Paper 7, 27 (“Institution Decision” or “Inst. Dec.”).⁷ After institution of trial, Patent Owner, KFx Medical, LLC (“Patent Owner”), filed a Patent Owner Response (Paper 9, “PO Resp.”), and Petitioner filed a Reply (Paper 11, “Pet. Reply”). Patent Owner further filed a Motion for Observations on Cross-Examination (Paper 13), and Petitioner

¹ U.S. Patent No. 7,976,565 B1 (issued July 12, 2011) (Ex. 1005, “Meridew”).

² U.S. Patent No. 5,527,342 (issued June 18, 1996) (Ex. 1007, “Pietrzak”).

³ U.S. Patent No. 5,141,520 (issued Aug. 25, 1992) (Ex. 1008, “Goble”).

⁴ U.S. Patent No. 5,827,291 (issued Oct. 27, 1998) (Ex. 1019, “Fucci”).

⁵ U.S. Patent No. 6,511,499 B2 (issued Jan. 28, 2003) (Ex. 1020, “Schmieding”).

⁶ U.S. Patent No. 5,741,282 (issued Apr. 21, 1998) (Ex. 1021, “Anspach”).

⁷ As we noted in the Decision on Institution (*id.* at 14), although Petitioner initially styled the pertinent ground of unpatentability as being collectively over “Meridew in view of Pietrzak or Goble, Fucci or Schmieding, and Anspach,” we understood Petitioner to be applying the references to the claims in the more refined manner we state here.

filed a Response to Patent Owner's Motion for Observations (Paper 21). Petitioner also filed a Motion to Exclude Evidence (Paper 18), Patent Owner filed an Opposition to the Motion (Paper 20), and Petitioner filed a Reply (Paper 22). Oral argument was conducted on November 8, 2017. Paper 26 ("Tr.").⁸

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.

⁸ We held a combined hearing for this case as well as related *inter partes* review IPR2016-01698. Many of the substantive issues are present in both cases and, as such, the parties' statement at the hearing are applied to each of the cases as appropriate.

Figures 11–13 of the '226 patent are reproduced below:⁹

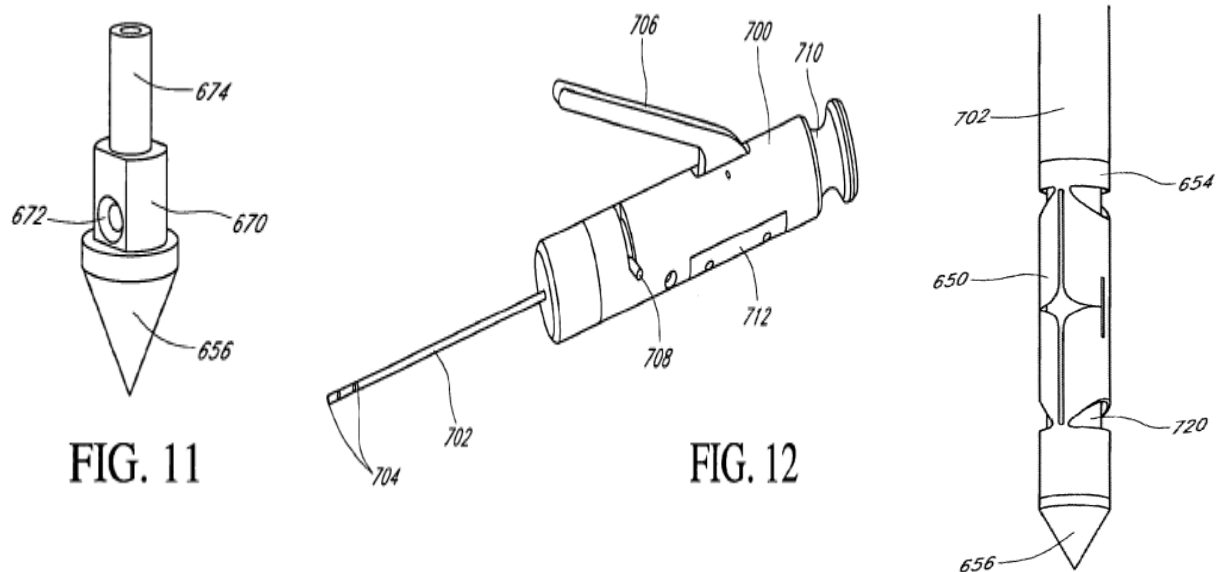


Figure 11 shows a piercing bone anchor tip; Figure 12 shows an inserter for inserting a piercing bone anchor into bone; and Figure 13 shows the interface between a piercing bone anchor and an anchor inserter. *Id.* at 3:38–42. A piercing bone anchor includes: (1) anchor inserter attachment structure 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 inserter may be

⁹ Figure 13 is not labeled but is the rightmost figure reproduced.

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:

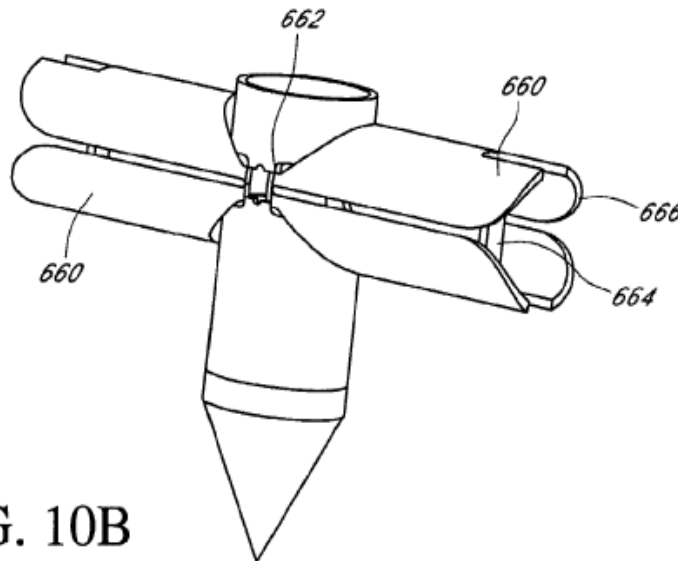


Figure 10B depicts a piercing bone anchor in a deployed state. *Id.* at 3:36–37. In that deployed state, cylinder 650 (not numbered in Figure 10B) collapses into a configuration in which lateral wings 660 of the cylinder are positioned to prevent removal the anchor from the bone. *Id.* at 10:25–30.

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.

Ex. 1001, 14:30–51, 15:1–32.

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).

In the Institution Decision, we determined that all claims terms should be given their ordinary and customary meaning. Inst. Dec. 10. We addressed specifically the meaning of the terms (1) “constant diameter along its length” (claims 1, 9, and 15); (2) “bone-piercing tip . . . comprising a pointed tip” (claims 1, 9, and 15); and (3) “inner tube” (claims 9 and 15). *Id.* at 9–11. In particular, we rejected Petitioner’s contention that “constant diameter along its length” should be broadly construed as encompassing a constant diameter along only “a portion of” the claimed lengths and that “pointed tip” encompasses tapered tips that can be blunt tips. *Id.* at 9–10. We also agreed with Patent Owner that in the context of the ’226 patent, a tube is something that is hollow, and we therefore construed “inner tube” as an inner structure that is hollow. *Id.* at 10.

Neither party contends that any claim term has a special meaning, nor does either party dispute the claim constructions of the above-noted terms that were set forth in the Institution Decision. We determine that it is not necessary for purposes of this Final Written Decision to revisit them. We resolve any remaining claim construction disputes in the context of the parties’ arguments regarding the prior art.

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness.¹⁰ *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We analyze the asserted ground of unpatentability in accordance with those principles.

C. Level of Ordinary Skill in the Art

Relying on its expert Dr. Steve E. Jordan, Petitioner contends that a person having ordinary skill in the art “related to the ’226 patent would have (1) at least a B.S. or equivalent degree; and (2) at least two years’ experience designing, developing, testing, or performing surgeries with implantable medical devices.” Pet. 13 (citing Ex. 1027 ¶ 28 (the “Jordan Declaration”)). Patent Owner does not address Petitioner’s assessment of the level of ordinary skill in the art in its Preliminary Response or Response, or argue for a different assessment. Patent Owner’s expert, Dr. Jonathan Ticker, does not address Petitioner’s proposal, but does set forth his own assessment of the appropriate level of ordinary skill in the art:

Based on my review of the ’226 patent along with my knowledge and experience, it is my opinion that a person of ordinary skill in the relevant art as of the ’226 patent’s effective filing date would be an orthopedic surgeon with 2–5 years of clinical experience beyond the residency level. Alternatively, the person of ordinary skill could have less medical training but

¹⁰ The parties have not presented any objective evidence of non-obviousness.

significant experience in designing and developing orthopedic implants, in which case the person would also have experience observing the use of implants in the operating room and lab.

Ex. 2005 ¶ 11 (the “Ticker Declaration”).

Neither party directly addresses the proposed level of ordinary skill in the art of the other party, or argue that adopting one or the other proposal determines the outcome of any issue in the case. We also see little substantive difference between the two proposals, and do not believe adopting one or the other party’s proposals would cause us to make any different findings or come to any different conclusions in the case.

Nevertheless, we decline to adopt Petitioner’s proposal because it fails to identify any particular B.S. degree, and would seemingly include as one of ordinary skill in the art a person with any B.S. degree coupled with two years of undefined “testing” experience. We read Patent Owner’s proposal as including one with “significant experience in designing and developing orthopedic implants,” but not necessarily an M.D. or an orthopedic surgeon. We view that standard as more appropriate in the context of the ’226 patent than Petitioner’s standard, and we therefore adopt Patent Owner’s standard as our own. We also observe that the prior art of record reflects the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

D. Obviousness of Claims 1–11, 14–17, 19, and 20 Based on Meridew and Goble or Pietrzak

Petitioner contends that Meridew, in combination with either Goble or Pietrzak, renders obvious claims 1–11, 14–17, 19, and 20. Pet. 18–39, 44–49. We have reviewed Petitioner’s explanation identifying where each

limitation allegedly appears in Meridew, Goble, and Pietrzak, along with the testimony of Petitioner's declarant, Dr. Jordan. *Id.*; Ex. 1027 ¶¶ 60–122, 142–153. We have also reviewed Patent Owner's assertions and evidence as to why Petitioner's explanations and evidence are deficient. PO Resp. 8–32.

1. Overview of Prior Art

a. Overview of Meridew

Meridew is titled “Expanding Suture Anchor Having an Actuator Pin.” Ex. 1005, Title. Meridew summarizes its invention as “[a] method and apparatus for reattaching soft tissue to a pre-selected boney structure using an expanding suture anchor.” *Id.* at 1:32–35. Meridew's Figures 1 and 2 are reproduced below:

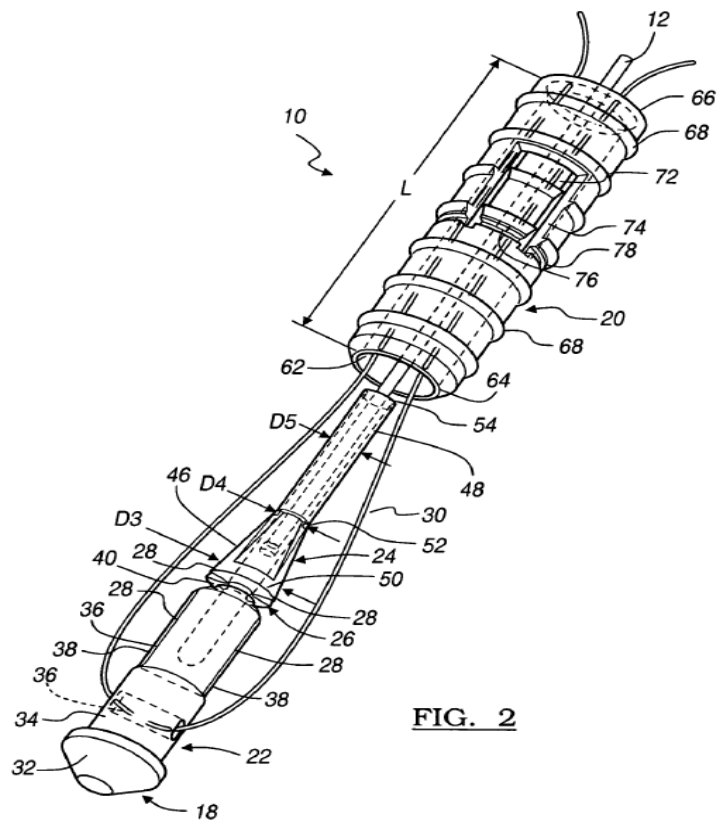
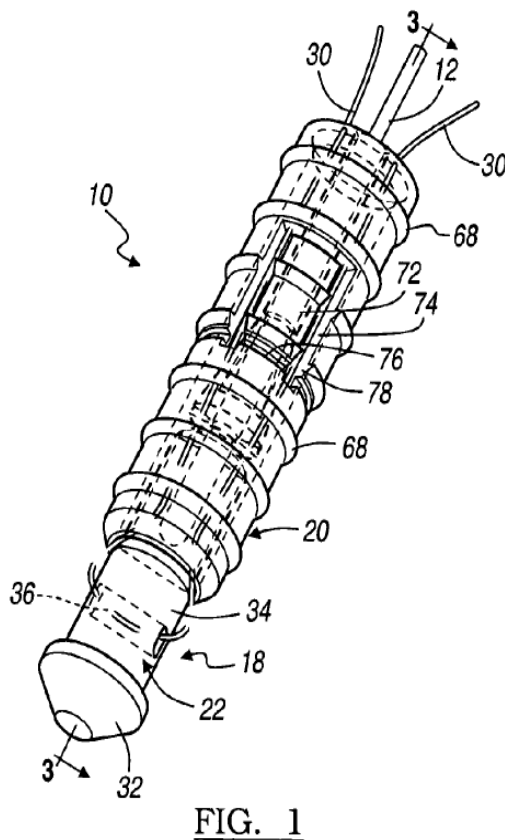
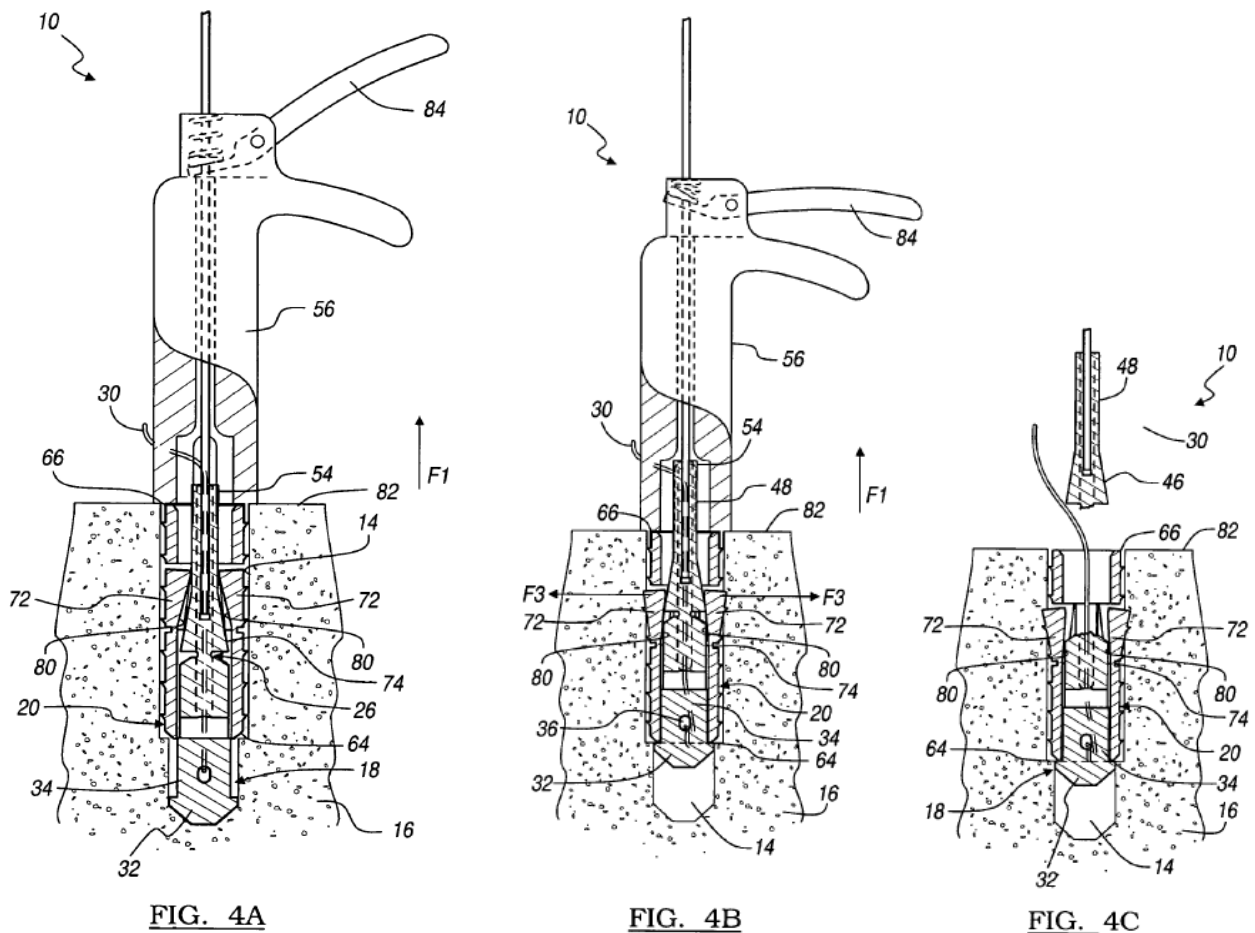


Figure 1 depicts expanding suture anchor 10 having actuator pin 12.

Id. at 2:13–14; 55–56. Figure 2 illustrates an exploded view of suture 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^[11] 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.

b. 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:

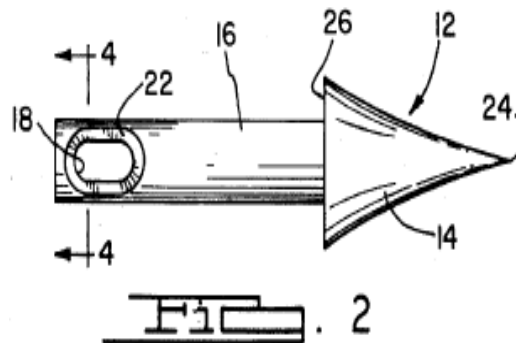


Figure 2 illustrates a side elevational view of an “apparatus for securing soft tissues, tendons and ligaments to bone” according to an

¹¹ Force F2 appears to be labeled “F3” in Figure 4B.

embodiment of the invention. *Id.* at 3:5–7. 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.

c. Overview of Goble

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

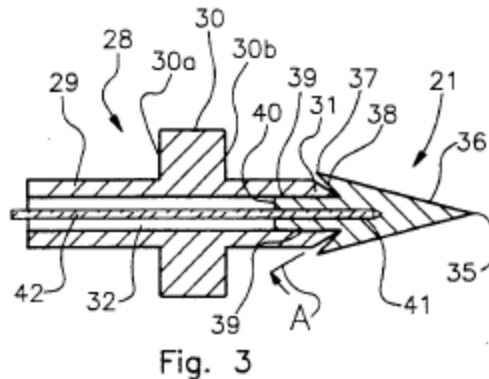


Figure 3 shows “an enlarged profile sectional view of a first embodiment of a harpoon suture anchor of the present invention[.]” *Id.* at 3:49–51. Goble describes suture anchor mount 28 and suture anchor 21 that incorporates “a pointed forward end 35 . . . for penetrating a bone 33 surface.” *Id.* at 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.

2. *Discussion – Claims 1–11, 14–17, 19, and 20*

a. *Whether the Combination of References Discloses All of the Claim Limitations*

Petitioner argues that Meridew discloses all of the limitations of claims 1–11, 14–17, 19, and 20 with the exception of a bone-piercing tip having a pointed tip (required by all claims) and piercing the bone by tapping on the inserter with a hammer (required by dependent claim 20). *See* Pet. 44–50; *see also id.* at 18–39. Petitioner argues that both Goble and Pietrzak disclose the claimed bone piercing pointed tip and tapping an inserter with a hammer to pierce bone. *Id.* at 44–46, 49–50. Petitioner also contends that one of ordinary skill in the art would have been motivated to modify Meridew in view of Goble and Pietrzak for a number of reasons. *Id.* at 46–48. With the exception of certain limitations found in claims 9–14, Patent Owner does not generally dispute Petitioner’s assertion that the combination of Meridew with either Goble or Pietrzak discloses all of the limitations of claims 1–11, 14–17, 19, and 20. PO Resp. 8–33, 42–47. Instead, Patent Owner focuses on whether a person of ordinary skill in the art would have sought to combine Meridew with Goble or Pietrzak. *Id.* at 8–33.¹²

i. *Claims 1–8*

With respect to independent claim 1, we find that Meridew discloses all of the limitations with the exception of the “bone-piercing tip that comprises . . . a distal portion comprising a pointed tip configured to pierce through bone.” Claim 1 begins by claiming “[a] bone implant, comprising: a

¹² Patent Owner waived any arguments for patentability not raised in the Patent Owner Response. Paper 8, 6.

substantially hollow cylinder.” We find that Meridew discloses sleeve 20 and suture receiving portion 22 that together form a “bone implant,” and sleeve 20 discloses the claimed “substantially hollow cylinder.” Ex. 1005, Abstract, 2:61–62, 4:31, Fig. 4C; Ex. 1027 ¶¶ 63–64; Pet. 19. With respect to the limitation requiring the cylinder to comprise “bone-engaging protrusions configured to prevent removal of the implant from the bone,” we find that Meridew discloses securement devices 68 on external surface 70 of sleeve 20 that aids in engagement of the suture anchor in the bone. *Id.* at 4:31–38; Pet. 19.

With respect to the claimed “tip that comprises . . . a distal portion . . . having a maximum diameter at its proximal end,” we find that Meridew discloses tip 32 having a distal portion that, due to its taper, includes a maximum diameter at its proximal end. Ex. 1005, Fig. 4A–4C; Ex. 1027 ¶ 65; Pet. 19, 21. With respect to the claimed “medial portion comprising a transverse suture aperture and having a constant diameter along its length that is smaller than the distal portion maximum diameter,” we find that Meridew discloses cylindrical body 34 with suture aperture 36 and a diameter less than the maximum diameter of tip 32. Ex. 1005, Fig. 3A; Ex. 1027 ¶ 66; Pet. 19, 21. With respect to the claimed “proximal portion having a constant diameter along its length that is smaller than the medial portion diameter and configured to couple to an inserter,” we find that Meridew discloses cylindrical body 34 with a proximal end having a constant diameter smaller than the diameter of the medial portion. Ex. 1005, Figs. 3A and 4A; Ex. 1027 ¶ 67; Pet. 19, 21. We also find that Meridew discloses proximal end of cylindrical body 34 configured to couple to an inserter at breakaway section 26. Ex. 1005, Figs. 3A and 4A; Ex. 1027 ¶ 68;

Pet. 19, 21–22.

With respect to the limitation requiring a proximal portion of the tip “configured to be positioned within a distal portion of the substantially hollow cylinder and not extend[ing] to a proximal end of the substantially hollow cylinder,” we find that Meridew discloses the proximal portion of suture receiving portion 22 positioned within sleeve 20 (the claimed “cylinder”), without extending to a proximal end of sleeve 20. Ex. 1005, Fig. 4C; Ex. 1027 ¶ 69; Pet. 22–23. With respect to the claimed tip having “a length that is shorter than the length of the substantially hollow cylinder,” we find that Meridew discloses suture receiving portion 22 having a length, after broken-away at section 26, which is shorter than the length of sleeve 20. Ex. 1005, Figs. 4C, 5A, 5B; Ex. 1027 ¶ 70; Pet. 23. With respect to the claimed cylinder having “an inner diameter that is smaller than the bone-piercing tip distal portion maximum diameter,” we find that Meridew discloses sleeve 20 (the claimed “cylinder”) with an inner diameter smaller than the maximum diameter of tip 32. Ex. 1005, Fig. 4C; Ex. 1027 ¶ 71; Pet. 23–24.

With respect to the limitation requiring “a bone-piercing tip that comprises a distal portion comprising a pointed tip configured to pierce through bone,” we find that Goble discloses a suture anchor having body 36 that tapers to pointed end 35 configured to pierce through bone. Ex. 1008, 1:32–47, 2:21–31, 5:25–27, Fig. 3; Ex. 1027 ¶ 145; Pet. 45. Similarly, we find that Pietrzak discloses a suture anchor with a pointed end configured to pierce through bone. Ex. 1007, 2:45–50, Fig. 1; Ex. 1027 ¶ 144; Pet. 44–45.

Claims 2–8 depend directly or indirectly from claim 1. Claim 2 requires a “cylindrical” proximal portion. We find that Meridew discloses a

cylindrical, proximal portion of cylindrical body 34 that meets this limitation. Ex. 1005, Fig. 2; Ex. 1027 ¶ 72; Pet. 24.

Claim 3 requires “a suture coupled to the bone-piercing tip and extending through the substantially hollow cylinder.” We find that Meridew discloses suture 30 coupled to suture receiving portion 22 and extending through sleeve 22 (the claimed “cylinder”). Ex. 1005, Figs. 4C, 5A, 5B; Ex. 1027 ¶ 73; Pet. 24.

Claim 4 requires suture “threaded through the suture aperture.” We find that Meridew discloses suture threaded through suture aperture 36. Ex. 1005, Fig. 3A; Ex. 1027 ¶ 74; Pet. 24.

Claim 5 requires “a wall of the substantially hollow cylinder is deformable under axial stress.” We find that Meridew discloses sleeve 20 deforming at hinges 76 such that expanding members 72 extend outward when placed under axial stress as shown in Figure 4B. Ex. 1005, 4:48–51, 5:8–17, Figs. 3, 4B; Ex. 1027 ¶ 75; Pet. 25.

Claim 6 requires a bone-piercing tip “positioned distally of the substantially hollow cylinder.” We find that Meridew discloses tip 32 positioned distally of sleeve 20 (the claimed “cylinder”). Ex. 1005, Figs. 4C, 5A, 5B; Ex. 1027 ¶ 76; Pet. 25–26.

Claim 7 requires a bone-piercing tip that “contacts the substantially hollow cylinder.” We find that Meridew discloses suture receiving portion 22 in contact with sleeve 20 (the claimed “cylinder”). Ex. 1005, Figs. 3A; Ex. 1027 ¶ 77; Pet. 26.

Finally, claim 8 requires that the substantially hollow cylinder is “configured to prevent easy removal of the implant from bone.” We find that Meridew discloses expanding members 72 which expand to lock into

bone. Ex. 1005, 4:31–51; Ex. 1027 ¶ 77; Pet. 26.

Based on the foregoing, we find that the Meridew, in combination with either Goble or Pietrzak, discloses all of the limitations of claims 1–8.

ii. Claims 9–11

Independent claim 9 contains several limitations that are identical to, or nearly identical to, several limitations in claim 1, and our analysis above in the context of claim 1 applies to those limitations of claim 9.

Accordingly, we find that Meridew discloses “a substantially hollow cylinder having bone-engaging protrusions,” a “tip comprising a distal portion . . . , a medial portion, and a proximal portion,” the various requirements of the diameters of the portions of the tip, the length of the tip “shorter than the length of the substantially hollow cylinder,” and “the substantially hollow cylinder has an inner diameter that is smaller than the bone-piercing tip distal portion maximum diameter” for the reasons provided above in the context of claim 1. See Ex. 1027 ¶¶ 79–94; Pet. 26–32. We also find that both Goble and Pietrzak disclose the claimed “bone-piercing tip comprising a distal portion having a pointed tip” for the reasons provided above in the context of claim 1. See Ex. 1027 ¶¶ 144–145; Pet. 44–46.

With respect to claim 9’s reference to an “inserter and bone implant combination,” we find that Meridew discloses actuator gun 56 that forms part of an inserter, and sleeve 20 and suture receiving portion 22 that form a bone implant. Ex. 1005, 3:37–57, Figs. 2, 3, 4A; Ex. 1027 ¶ 79; Pet. 26. With respect to the limitation requiring an inserter comprising “a handle, an outer sleeve coupled to the handle and fixed relative to the handle,” we find that Meridew discloses actuator gun 56 (inserter) that includes a handle and an outer sleeve (shown in cross section in Figure 4A) fixed relative to the

handle. Ex. 1005, 3:37–57, Fig. 4A; Ex. 1027 ¶¶ 81–82; Pet. 26–27. With respect to the limitation requiring “an inner tube disposed within the outer sleeve,” we find that Meridew discloses end section 24, which includes tapered portion 46 and annular body 48, which together form central bore 58 that receives actuator pin 12 therein. Ex. 1005, 3:56–58, Figs. 2, 4A, 4B; Ex. 1027 ¶ 83; Pet. 27–28. End section 24, being hollow due to central bore 58, forms the claimed “inner tube,” with annular body 48 extending within the outer sleeve of gun 56. *Id.* With respect to the limitation requiring “a bone implant coupled to the inserter,” we find that Meridew discloses its implant, a combination of sleeve 20 and suture receiving portion 22, coupled to Meridew’s inserter. Ex. 1005, Abstract; Ex. 1027 ¶ 84; Pet. 28.

With respect to the limitation requiring “the proximal portion of the bone piercing tip . . . removably coupled to the inserter,” we find that Meridew discloses suture receiving portion 22 removably coupled to end section 24 (part of the inserter) via breakaway portion 26. Ex. 1005, Fig. 2; Ex. 1027 ¶ 91; Pet. 30–31. Regarding the limitation requiring “a distal end of the outer sleeve . . . flush with an open, proximal end of the substantially hollow cylinder,” we find that Meridew discloses the distal end of the outer sleeve of gun 56 flush with the open, proximal end of sleeve 20 (the claimed “cylinder”). Ex. 1005, Fig. 4A; Ex. 1027 ¶ 94; Pet. 31–32.

Claim 9 also requires “a portion of the inner tube extends distally through the substantially hollow cylinder and contacts the bone-piercing tip.” Petitioner, relying on Meridew’s Figure 2, contends that a portion of end section 24 (the claimed “inner tube”) extends through sleeve 20 (the claimed “cylinder”). Pet. 30 (citing Ex. 1027 ¶ 90). Patent Owner contends that Petitioner previously identified end section 24 as the claimed inner tube

and suture receiving portion 22 as the claimed “bone-piercing tip.” PO Resp. 42–44. Patent Owner argues that end section 24 cannot “contact” suture receiving portion 22 as required by claim 8 because the two parts are “separated by breakaway section 26.” *Id.* at 44 (citing Ex. 1005, 2:63–66, Figs. 2, 4A). Petitioner responds, arguing that the claim does not require “direct contact” and Meridew’s “end section and suture receiving portion are joined at the breakaway section . . . , and thus ‘contact’ one another.” Pet. Reply 23. Petitioner also argues that even if the claim does require direct contact, Meridew discloses direct contact because “the ‘breakaway section’ is not a true separate structure—it is part of the end section and the suture receiving portion.” *Id.* at 23–24 (citing Ex. 1030 ¶ 72). Petitioner asserts that Meridew’s end section and suture receiving portion are not only in direct contact with one another, they are attached to one another, and the breakaway section merely “facilitates fracture or breakage of the two pieces apart upon application of a force.” *Id.* at 24.

We need not decide whether Petitioner’s broader proposed construction of “contact,” which does not require direct contact, has merit, because we find that Meridew discloses direct contact between end section 24 and suture receiving portion 22. As Petitioner points out, and we agree, breakaway section 26 is not a “true separate structure,” as all three of the end section 24, suture receiving portion 22, and breakaway section 26 are integral with one another prior to breakage. Pet. Reply 23–24; Ex. 1005, Figs. 3, 4A; *see also id.* at 2:63–3:6 (describing insert 18 as including suture receiving portion 24 and end section 22, and with “insert 18 . . . generally insert molded from a resorbable material”); Ex. 1030 ¶ 72. Breakaway section 26 appears as a narrow neck between the two wider adjacent portions

of insert 18. Ex. 1005, Figs. 3, 4A. Although Meridew names and describes this connecting structure and its function in some detail, the importance of its function does not determine whether Meridew discloses the “contact” limitation—i.e., whether any portion of Meridew’s end section 24 contacts suture receiving portion 22. As such, breakaway section 26 need not be viewed as a separate structure and instead can be viewed reasonably as part of end section 24, part of suture receiving portion 22, or part of both, and in all three approaches end section 24 is in direct contact with suture receiving portion 22. See Pet. Reply 23–24; Ex. 1030 ¶ 72.¹³

Claims 10, 11, and 14 depend from claim 9. Claim 10 requires the inner tube of claim 9 be “configured to move axially relative to the outer sleeve.” We find that Meridew discloses end section 24 configured to move axially relative to the outer sleeve of Meridew’s inserter. Ex. 1005, 4:61–5:17; Ex. 1027 ¶ 95; Pet. 32.

Claim 11 requires “a suture coupled to the bone implant.” We find that Meridew discloses suture 30 coupled to suture receiving portion 22. Ex. 1005, Figs. 1–6; Ex. 1027 ¶ 96; Pet. 31.

Based on the foregoing, we find that the Meridew, in combination with either Goble or Pietrzak, discloses all of the limitations of claims 9–11.

¹³ Notably, after breakage occurs, Meridew describes the result as end section 24 and suture receiving portion 22 “severed” from one another without mentioning a third, breakaway structure, which supports our finding that, prior to breakage, the two structures are in contact with one another. Ex. 1005, 3:2–5; *see also id.* at 3:34–36 (“The fracturing of the breakaway section 26 detaches the suture receiving portion 22 from the end section 24 of the insert 18.”).

iii. Claim 14

Claim 14 depends from claim 9 and adds the feature that the substantially hollow cylinder “is not rotatable relative to the inner tube.” Ex. 1005, 15:43–44. Petitioner contends that as shown, for instance, in Meridew’s Figure 4B, sleeve 20 is not rotatable. Pet. 32; Ex. 1027 ¶ 97.

Patent Owner disagrees with Petitioner. To that end, Patent Owner contends the following:

According to Petitioner, the claimed “substantially hollow cylinder” is Meridew’s sleeve 20, and the claimed “inner tube” is the end section 24 of Meridew’s insert 18. *E.g.*, Pet. at 30 (addressing element 9[c]). Thus, for claim 14 to be satisfied, sleeve 20 must not be rotatable relative to end section 24. However, Meridew never suggests that these components are not rotatable. To the contrary, Meridew shows that sleeve 20 has a rounded inner surface and end section 24 has a rounded outer surface. *E.g.*, Ex. 1005, Fig. 2. A skilled artisan would therefore expect these two components to be rotatable relative to each other.

PO Resp. 46 (citing Ex. 2005 ¶ 88).

Petitioner counters that “[Patent Owner’s] expert testified the cylindrical body is wedged into the wings of the ‘substantially hollow cylinder’ and is not rotatable once in this wedged position.” Pet. Reply 24–25 (citing Ex. 1029, 97:6–98:1; Ex. 1030 ¶ 73). Petitioner, thus, contends that Patent Owner’s argument should be dismissed. *Id.* at 25.

We conclude that Petitioner makes out a more persuasive case. Both parties’ declarants (i.e. Dr. Jordan and Dr. Ticker) are seemingly in agreement that in the deployed position shown in Figure 4B, cylindrical body 34 is “wedged” into sleeve 20 such that sleeve 20 does not rotate. *See* Ex. 1029, 97:6–98:1; Ex. 1030 ¶ 73. That sleeve 20 is in such a wedged

position in which it does not rotate reasonably and readily conveys that it does not rotate relative to end section 24 (i.e., the inner tube). Accordingly, we conclude that Petitioner has shown by a preponderance of the evidence Meridew taken with either Goble or Pietrzak discloses all the limitations of claim 14.

iv. Claims 15–17, 19, and 20

Independent method claim 15 claims “[a] method of fixating a bone implant within bone, comprising: providing a bone implant.” Ex. 1001, 15:45–46. We find that Meridew discloses a method of fixating a bone implant that includes sleeve 20 and suture receiving portion 22 within bone 16. Ex. 1005, Abstract, Figs. 4A–4C; Ex. 1027 ¶ 98; Pet. 33. Claim 13 includes a number of requirements for the claimed “bone implant,” all of which were already addressed in the context of claim 1. Ex. 1001, 15:46–16:3–21 (claiming implant having “substantially hollow cylinder,” “bone-piercing tip” with medial and proximal portions with various requirements, the length of the tip is shorter than the length of the cylinder, and the cylinder has an inner diameter smaller than the tip distal portion maximum diameter); *see also* Pet. 33–36 (referring back to analysis for correlating limitations in claim 1). Similarly, claim 15 requires “providing an inserter” having requirements the same as those discussed above in the context of claim 9. Ex. 1003, 16:22–26 (claiming an inserter having a “handle,” “outer sleeve,” “inner tube within the outer sleeve,” and bone implant “coupled to” the inserter); *see also* Pet. 36–37 (referring back to analysis for correlating limitations in claim 9). Accordingly, we find that the combination of Meridew with either Goble or Pietrzak discloses those limitations for the reasons discussed above in the context of claims 1 and 9.

Claim 15 also requires: “a suture material [that] passes through the suture aperture of the bone implant,” and we find that Meridew discloses suture 30 coupled to and extending through the aperture 36 of suture receiving portion 22. Ex. 1005, Figs. 1–6; Ex. 1027 ¶ 115; Pet. 36–37. With respect to the limitation requiring “piercing bone with the bone piercing tip,” we find, as we did with respect to a similar limitation in claim 1, that both Goble and Pietrzak disclose suture anchors that taper to pointed ends configured to pierce through bone. Ex. 1007, 2:45–50, Fig. 1; Ex. 1008, 1:32–47, 2:21–31, 5:25–27, Fig. 3; Ex. 1027 ¶¶ 144–145; Pet. 44–49. With respect to the limitation requiring “moving the inner tube axially relative to the outer sleeve,” we find that Meridew discloses such axial movement of end section 24 relative to the outer sleeve of gun 56. Ex. 1005, 4:61–5:17; Ex. 1027 ¶ 117; Pet. 37. Finally, with respect to the limitations requiring “detaching the bone implant from the inserter; and withdrawing the inserter from the bone, such that the suture material and the bone implant remain within the bone,” we find that Meridew discloses breaking away end section 24 from the implant, leaving suture 30, sleeve 20, and suture receiving portion 22 in bone. Ex. 1005, 3:24–5:17, Figs. 4A–4C; Ex. 1027 ¶ 118; Pet. 37–38.

Claim 16 depends from claim 15 and further requires: “the outer sleeve holds a proximal end of the bone implant steady during insertion.” Petitioner contends that Meridew’s Figure 4B discloses the outer sleeve of gun 56 holding the proximal end of sleeve 20 steady during insertion. Pet. 38 (citing Ex. 1027 ¶ 120). Patent Owner argues that Meridew’s Figure 4B does not depict insertion, which occurs prior to use of gun 56 (and therefore the outer sleeve). PO Resp. 48 (quoting Ex. 1005, 4:52–63). Patent Owner

further contends that “insertion” cannot be read so broadly that it encompasses “deployment” of Meridew’s retaining features. *Id.* at 49. In response, Petitioner argues that Patent Owner makes an artificial distinction between “insertion” and “deployment” not supported by the ’226 patent, and that “insertion” includes “deployment.” Pet. Reply 25. Petitioner also contends that Meridew’s gun 56, or the alternative actuator gun disclosed in Figure 4D, can be used to hold the anchor steady during insertion prior to deployment. *Id.* at 25–26.

We agree with Petitioner that the phrase “during insertion” in claim 16 does not exclude deployment of the anchor. Instead, “during insertion” encompasses the actions necessary to insert the anchor and leave the anchor in the bone, which includes deployment of the anchor. The ’226 patent uses the terms “insertion” and “deployment” in different ways, but does not state that “insertion” begins and ends with the initial introduction of the anchor into bone. Instead, the ’226 patent specification supports a broader reading by describing use of an “inserter” to both introduce the anchor into the bone and deploy the anchor. Ex. 1001, 11:16–64 (describing the “inserter” used to drive anchor 704 into bone and to deploy the anchor, with withdrawal of the inserter occurring only after deployment and “detachment of the anchor inserter from the anchor 704”). Patent Owner’s reading creates unnecessary tension with the ’226 patent specification because the specification describes the “inserter” as necessary to deploy the anchor. *See id.* Reading “during insertion” to include the functions performed by the “inserter” described in the specification, including deployment, remains more consistent with the usage in the specification. We therefore decline to adopt Patent Owner’s position that “during insertion” refers only to the initial introduction of the

anchor into bone, and excludes subsequent steps such as deployment.

Patent Owner does not argue that Meridew fails to disclose the limitation if “during insertion” includes deployment, and we find that Meridew discloses use of the outer sleeve of gun 56 to hold the proximal end of sleeve 20 steady during insertion of the anchor. *See* Ex. 1005, Fig. 4B; Ex. 1027 ¶ 120; Pet. 38; Pet. Reply 24–25. Moreover, we agree with Petitioner that even if “during insertion” is limited to the initial introduction of the anchor into bone and excludes deployment, both gun 56 in Figure 4B and the alternative embodiment disclosed in Figure 4D disclose structures capable of holding the anchor steady during initial introduction of the anchor. Ex. 1005, Figs. 4B, 4D; Ex. 1030 ¶¶ 53–60, 74–75; Pet. Reply 25–26.

Claim 17 depends from claim 13 and further requires: “the inner tube pushes against the bone-piercing tip while piercing bone with the bone-piercing tip.” We find that Meridew, as modified by Goble or Pietrzak, accounts for the bone-piercing tip, and discloses end section 24 (part of which forms the claimed inner tube) pushing against suture receiving portion 22 when piercing bone. Ex. 1005, Fig. 4B; Ex. 1027 ¶ 121; Pet. 38.

Claim 19 depends from claim 15 and further requires “moving the inner tube axially relative to the outer sleeve moves the distal portion of the bone-piercing tip closer to a proximal end of the substantially hollow cylinder.” We find that Meridew discloses axial movement of end section 24 (the claimed “inner tube”) relative to the outer sleeve moves the distal portion of suture receiving portion closer to the proximal end of sleeve 20 (the claimed “cylinder”). Ex. 1005, 4:61–5:17, Figs. 4A–4C; Ex. 1027 ¶ 122; Pet. 38–39.

Claim 20 depends from claim 15 and further requires “piercing bone with the bone-piercing tip comprises tapping on the inserter with a hammer.” We find that both Goble and Pietrzak disclose tapping on their respective handles with a hammer. Ex. 1007, 7:25–53; Ex. 1008, 2:9–15; Ex. 1027 ¶ 152; Pet. 49–50.

Based on the foregoing, we find that the Meridew, in combination with either Goble or Pietrzak, discloses all of the limitations of claims 15–17, 19, and 20.

b. Whether One of Ordinary Skill in the Art Would Have Combined the References As Asserted By Petitioner

Petitioner contends that it would have been obvious to one of ordinary skill in the art to modify Meridew by adding the pointed, bone-piercing tips of either Goble or Pietrzak for three reasons. Pet. 46–48. First, Petitioner asserts that “[t]here is a teaching, suggestion, or motivation in the prior art that would have led one to combine the prior art teachings to arrive at the claimed invention.” *Id.* at 46. More specifically, Petitioner relies on Meridew’s statement that the tip could take any desired shape and could be an impacting tip, which includes pointed tips. *Id.* According to Petitioner, use of a pointed, impacting tip avoids the need to pre-drill a hole in the bone, and therefore provides advantages over the approach taken in Meridew. *Id.*

Second, Petitioner asserts that the claimed combination “is merely the result of prior art elements combined according to known methods to yield predictable results.” *Id.* at 47. Petitioner argues that the pointed tips of Goble and Pietrzak predictably would perform the same function in Petitioner’s proposed combination with Meridew as they do independently. *Id.*

Third, Petitioner asserts that that the “claimed invention is merely a known technique applied to a similar device in the same way.” *Id.* at 47–48. According to Petitioner, Goble and Pietrzak are comparable to Meridew—all three references disclose suture anchors—and were improved by the addition of pointed tips that would also improve Meridew with predictable results. *Id.* at 45–46.¹⁴

Patent Owner argues that the pointed tips of Goble and Pietrzak are incompatible with Meridew’s retraction mechanism because the addition of the pointed tips prevent retraction. PO Resp. 8–13. According to Patent Owner, one of ordinary skill in the art would recognize the incompatibility of the pointed tips with Meridew, which relies on a pre-drilled hole to remove bone material prior to insertion. *Id.* at 13–14. Patent Owner argues that omitting Pietrzak’s collar from the combination does not solve the problem because the pointed tip itself would prevent retraction if added to Meridew. *Id.* at 14–21. Patent Owner also argues that removing the pre-drilled hole from Meridew results in the loss of important benefits. *Id.* at 21–22.

Patent Owner further disputes Petitioner’s stated reasons for making the proposed modification to Meridew, relying again on the pointed tips of Goble and Pietrzak preventing retraction. *Id.* at 23–25. For example, Patent Owner argues that Meridew’s anchor would not perform the same function

¹⁴ Petitioner also argues, in the context of dependent claim 20, that it would have been obvious to tap Meridew’s modified inserter with a hammer, as disclosed by Goble and Pietrzak, because Meridew contemplates an “impacting tip” and doing so merely involves applying a known technique to a similar device in the same way. Pet. 49–50 (citing Ex. 1027 ¶¶ 152–153).

after the modification due to the pointed tips tendency to prevent retraction. *Id.* For the same reason, Patent Owner alleges there would be no expectation of success and the modification would not improve Meridew. *Id.* at 26.

Patent Owner also contends that Meridew's design does not lend itself to impact-driven insertion because Meridew's actuator pin and sleeve would likely break if struck with a hammer. *Id.* at 27–30. Patent Owner lastly alleges that Meridew's alternative embodiment disclosed in Figure 4D, which may lend itself to impact with a hammer, lacks the claimed “outer sleeve.” *Id.* at 31–33.

After reviewing the parties' arguments, including the relevant expert testimony, we find that one of ordinary skill in the art would have been motivated to add the pointed tips of either Goble or Pietrzak to Meridew in order to avoid the need to have a drill a hole prior to insertion of the anchor. We start by noting that although Meridew discloses in its figures a conical tip with a flat end, Meridew expressly recognizes the possible use of an “impacting tip”:

Although the following description is related generally to a suture anchor that can be positioned in a pre-drilled hole, that is a hole provided in a boney structure for acceptance of the suture anchor, it will be understood that a suture anchor including an impacting tip or self-drilling thread may be provided as well.

Ex. 1005, 2:44–49 (emphasis added). “Impacting tips” would be understood by the ordinary artisan as including pointed tips such as those Goble and Pietrzak disclose. Ex. 1007, 2:45–50, Fig. 1; Ex. 1008, 1:32–47, 2:21–31, 5:25–27, Fig. 3. Accordingly, Meridew, itself, in the passage quoted above, suggests the use of impacting tips, the kind of tips Goble and

Pietrzak disclose, and suggests doing so will remove the need for the pre-drilled hole contemplated by the remainder of its detailed description. The passage directly supports Petitioner’s argument that the prior art provides a teaching, suggestion, or motivation to make the proposed modification, and that avoiding the need for pre-drilled holes provides advantages over the approach taken in the remainder of Meridew’s disclosure. Pet. 46; Ex. 1027 ¶¶ 147–148. Goble and Pietrzak also make explicit that adding 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 a 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”). Meridew’s passage, as well Goble and Pietrzak’s teaching of pointed tips to avoid pre-drilled holes, all support Petitioner’s argument that its proposed combination uses known methods to yield predictable, advantageous results already taught and obtained in the relevant prior art. Pet. 47; Ex. 1027 ¶ 149.

Patent Owner attempts to downplay the significance of Meridew’s passage by arguing that Meridew does not explain how to implement the impacting tip and does not enable this embodiment. PO Resp. 13 n.1; Tr. 32:2–7 (arguing that Meridew is not enabling on this point). Patent Owner’s argument may be appropriate in an anticipation context, where a specific, enabling reference to a pointed impacting tip may be required. But the passage remains highly relevant in an obviousness analysis based on a combination broadly contemplated by the primary reference at issue. Patent Owner also fails to acknowledge that the passage directly undermines Patent

Owner's argument that Meridew's primary embodiment, and reliance on the pre-drilled hole, was essential and not amenable to a modification that would remove the need for a pre-drilled hole. PO Resp. 21–22. Instead, Meridew expressly suggests a way to avoid the pre-drilled hole. Ex. 1005, 2:44–49.

We are also not persuaded by Patent Owner's primary argument—that one would not modify Meridew in the manner proposed because doing so would prevent retraction of the anchor contemplated by Meridew's design. PO Resp. 8–13. First, the argument assumes that Petitioner's proposed combination requires adding not only the pointed tips of Goble and Pietrzak, but also Goble's suture anchor skirt and Pietrzak's collar member 20, which help prevent retraction. *Id.*; Ex. 1007, 4:60–66, Fig. 1; Ex. 1008, 5:62–6:3, 7:39–49 (describing skirt “flexing into and anchoring into” bone materials), Fig. 11; Ex. 1030 ¶¶ 29–30. As Petitioner points out, its proposed modification of Meridew contemplates adding the pointed tips of Goble and Meridew, and nothing else. Pet. Reply 3, 6. One of ordinary skill in the art would not view Goble's skirt or Pietrzak's collar as required when adding a pointed tip, as Meridew, itself, suggests adding an “impacting tip” without suggesting the addition of any other structure to accommodate such a tip. Ex. 1005, 2:44–49. Patent Owner's arguments based on structure in Goble and Pietrzak not included in the proposed combination, therefore, miss the mark.

Second, when Patent Owner does acknowledge that perhaps Petitioner proposes to add only the pointed tips from Goble and Pietrzak, Patent Owner makes speculative claims that the resulting combination would still prevent retraction. PO Resp. 14–21. Patent Owner's arguments on this point lack adequate support. Patent Owner does not direct us to any teaching in Goble

or Pietrzak that suggests the use of a pointed tip alone prevents retraction. *See id.* Nor does Patent Owner point to any teaching in Meridew suggesting that its protrusions, without the aid of a pre-drilled hole, would prevent retraction, or that the benefits of the pre-drilled hole are so critical that they teach away from removing the pre-drilled hole. *See id.*; *see also id.* at 21–22. Instead, Meridew itself at least implicitly suggests the opposite by suggesting the use of an impacting tip without a pre-drilled hole. Ex. 1005, 2:44–49. Moreover, even if Patent Owner correctly asserts that the addition of a pointed tip to Meridew, combined with Meridew’s protrusions and the lack of a pre-drilled hole, produces some resistance to retraction, that does not establish that one of ordinary skill in the art would not make the proposed modification. As Petitioner points out, Patent Owner does not quantify the additional force needed to overcome the alleged resistance to retraction, or adequately explain how one would be unable to overcome whatever additional force may be required using Meridew’s gun 56. Pet. Reply 11–14; Ex. 1030 ¶¶ 44–47.

Furthermore, Patent Owner’s argument that Meridew’s design does not lend itself to impact-driven insertion for a number of reasons lacks support. PO Resp. 27–33. Again, Meridew, itself, undermines Patent Owner’s argument by suggesting use of its structure with an impacting tip and without the need for a pre-drilled hole. *See* Ex. 1005, 2:44–49. Further, Patent Owner’s allegation that Meridew’s parts, such as its pin made from surgical steel, might break or not work properly if hammered, amounts to speculation in light of Meridew’s teaching of use without a pre-drilled hole and “forcing” its anchor through bone. *See id.* at 2:44–49, 3:14–15, 3:66–4:2; Ex. 1030 ¶¶ 53–59; Pet. Reply 16–17.

Finally, Patent Owner does not argue that the embodiment of Meridew's Figure 4D does not lend itself to impact-driven insertion, and the inclusion of another inserter with a head seemingly ready for impact generally supports the notion that Meridew's disclosures should be read as able to be impact driven, rather than the other way around as proposed by Patent Owner. Ex. 1005, Fig. 4D; PO Resp. 31–33; Pet. Reply 18 (citing Ex. 1029, 57:3:18; Ex. 1030 ¶ 60).

3. Conclusion – Claims 1–11, 14–17, 19, and 20

After review of the arguments and evidence as a whole, including weighing of the respective expert testimony, we conclude that Petitioner provided adequate reasoning and evidence to establish that a skilled artisan would have modified Meridew's tips to incorporate a pointed tip. *See* Pet. 43–46; Pet. Reply 2–18. Indeed, an ordinary 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 Goble or Pietrzak. *See KSR*, 550 U.S. at, 421 (“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.”).

We conclude that Petitioner has shown by a preponderance of the evidence that claims 1–11, 14–17, 19, and 20 would have been obvious in view of Meridew and Goble as well as Meridew and Pietrzak.

*E. Obviousness of Claims 12 and 13 Based on Meridew, Goble
or Pietrzak, and Fucci or Schmieding*

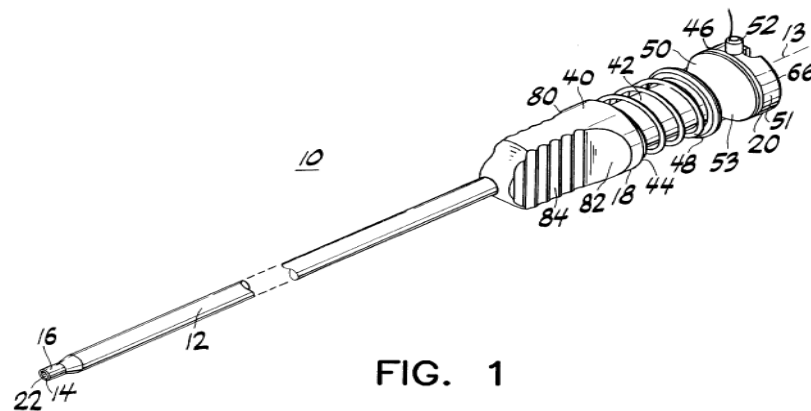
Claim 12 depends from claim 11, which depends from claim 9. Claim 13 depends from claim 12. Claim 12 adds the feature of a suture that “extends through an axial bore in the inner tube and an axial bore in the handle of the inserter.” Ex. 1001, 15:37–39. Claim 13 further adds that “the suture exits the inserter through a hole in a proximal end of the handle.” *Id.* at 15:40–42.

Petitioner contends that Meridew, in combination with either Goble or Pietrzak, and further in combination with either Fucci or Schmieding, renders obvious claims 11 and 12. Pet. 39–42, 48–49. We have reviewed Petitioner’s explanation identifying where each limitation allegedly appears in the references, along with the testimony of Petitioner’s declarant, Dr. Jordan. *Id.*; Ex. 1027 ¶¶ 125–127, 132–136, 150. We have also reviewed Patent Owner’s assertions and evidence as to why Petitioner’s explanations and evidence are deficient. PO Resp. 33–42.

1. Overview of Prior Art

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:

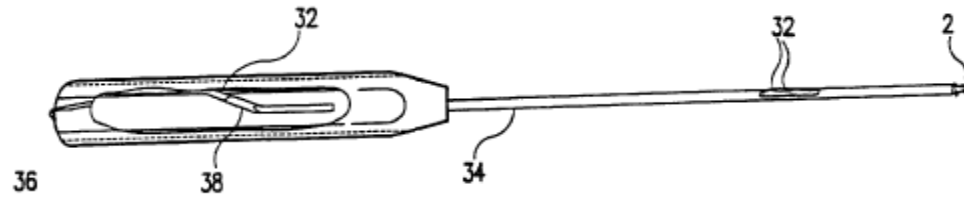


FIG.4

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.

2. Discussion – Claims 12 and 13

In the Petition, Petitioner asserts that “[w]hen modified by *Fucci* or *Schmieding*, for example, *Meridew* will include” the features of claims 12 and 13. Pet. 39–40. Petitioner then points to disclosures in *Fucci* and *Schmieding* allegedly disclosing the claimed features, such as suture coupled to bone implants and anchors and then routed through the middle of the respective inserters and out a hole in the end of the handle of the inserter. *Id.* (citing Ex. 1027 ¶¶ 125–127). 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). Petitioner also asserts that the suture-holding arrangements of *Fucci* and *Schmieding* “would perform their same function in *Meridew* as they do separately.” *Id.* at 42 (citing Ex. 1027 ¶¶ 135–136).

Patent Owner argues that Petitioner has failed to set forth sufficient evidence to establish that its proposed combination would satisfy the limitations of claims 12 and 13 because the Petition and accompanying expert declaration fail to cite any evidence or identify appropriate structures in the resulting combination. PO Resp. 34–35. Patent Owner also argues that “a skilled artisan would have had no reason to make the modification Petitioner suggests.” *Id.* at 34. According to Patent Owner, Petitioner’s stated reason for the combination—to hold the suture in tension—makes no sense in Meridew where the actuator pin already provides the necessary stable attachment. *Id.* at 35–36 (citing Ex. 1005, 1:21–24, 5:52–59; Ex. 2005 ¶ 73), 40–41. Patent Owner also alleges that the tension proposed by Petitioner will actually prevent Meridew’s device from deploying as intended. *Id.* at 36–37 (citing Ex. 1005, 5:8–17; Ex. 2005 ¶¶ 74–76), 42.

Patent Owner then contends that even if the sutures were useful to hold Meridew’s anchor in place, there would be no reason to route the suture through the inner tube (Meridew’s central bore 58 in end section 24) because actuator pin 12 already occupies central bore 58, and adding space for sutures undermines the function of the pin. *Id.* at 37–40. Patent Owner also argues that a skilled artisan would not modify Meridew to route the suture through central bore 58 when Meridew already provides for exterior grooves 28 to accommodate the suture. *Id.* at 40 (citing Ex. 1005, 3:10–12; Ex. 2005 ¶ 82). According to Patent Owner, Petitioner’s proposed modification would not have been obvious because it provides no benefits beyond Meridew’s design and is, on balance, not desirable. *Id.*

In response, Petitioner argues that the presence of the actuator pin does not render the use of sutures to create additional support unnecessary.

Pet. Reply 19–20. Petitioner next argues that the addition of suture under tension would not prevent deployment of Meridew’s anchor or cause premature deployment because a skilled artisan would apply an appropriate amount of tension. *Id.* at 20–21. With regard to routing the suture through the bore, Petitioner contends that that Meridew’s end section includes enough empty space in the axial bore to accommodate suture, and that Meridew’s grooves 28 “can be extended and enclosed to accommodate suture in the axial bore.” *Id.* at 22 (citing Ex. 1030 ¶¶ 68–70). Petitioner also argues that Patent Owner’s expert “acknowledges that enclosing suture completely as opposed to partially in grooves provides the added benefit of additional suture security.” *Id.* (citing Ex. 1029, 51:6–52:1, 53:23–54:23). Finally, Petitioner argues that a skilled artisan “could easily widen the diameter of the axial bore” to accommodate suture and would have recognized advantages of doing so over routing the suture through the existing grooves. *Id.* at 22–23.

After review of the parties’ arguments and evidence, including weighing the relevant expert testimony, we are not persuaded that Petitioner met its burden of establishing that one of ordinary skill in the art would have made the proposed combination in the manner Petitioner suggests. The Petition, itself, as well as the accompanying expert declaration, are largely silent regarding how, exactly, Petitioner proposes to route the suture in the proposed combination, and why the suture would be routed in a manner consistent with claims 12 and 13. *See* Pet. 39–42; Ex. 1027 ¶¶ 125–130, 134–136. The original expert declaration does describe the “[m]odification of Meridew in view of Fucci or Schmieding,” but then refers to routing suture “through the inner shaft 19 and driver 100,” which Meridew does not

disclose. Ex. 1027 ¶ 125; PO Resp. 34–35. In its Reply and accompanying expert declaration, Petitioner sets forth two different approaches to routing the suture—one through the axial bore of end section 24 and another by enclosing Meridew’s grooves. Pet. Reply 21–23; Ex. 1030 ¶¶ 68–70.

Petitioner’s arguments largely miss the mark because they focus on what one of ordinary skill in the art *could* do to modify Meridew in a manner that meets the requirements of claims 12 and 13, without adequately explaining *why* one of ordinary skill in the art *would* make the modifications. *See Personal Web Techs. LLC v. Apple, Inc.*, 848 F.3d 987, 993–94 (Fed. Cir. 2017) (finding that a skilled artisan would have understood that prior art could be combined insufficient; “it does not imply motivation to pick out those two references and combine them to arrive at the claimed invention”). For example, regarding routing suture through the axial bore, Petitioner contends that even though actuator pin occupies the same bore, the bore provides enough room to accommodate suture, or could be widened if necessary to do so. Pet. Reply 22. That argument ignores the fact that axial bore 58 forms around actuator pin 12, and adding additional structure between the pin and axial bore wall, or expanding that space to accommodate the suture, would undermine or weaken the fit of the bore around the pin. PO Resp. 39–40; Ex. 1005, 3:59–66, 5:52–59; Ex. 2005 ¶¶ 80–82. Petitioner does not explain adequately why one of ordinary skill in the art would make that modification in light of the negative consequences of doing so when Meridew already provides grooves 28 to route the suture. *See id.* Indeed, that Meridew viewed grooves 28 as necessary despite the presence of axial bore and actuator pin 12 does not aid Petitioner’s view that a skilled artisan, nevertheless, would simply have

disregarded those grooves.

On balance, we credit the testimony of Patent Owner's expert, and find that Petitioner has not adequately established why routing the sutures through the same central bore 58 occupied by actuator pin 12 would have been obvious. *See* Ex. 2005 ¶¶ 72–87.

Regarding Petitioner's proposal to enclose grooves 28, Petitioner submits that such an approach promotes "additional suture security" and that Patent Owner's expert agrees. *Pet. Reply* 22. As noted above, this theory was not included in the Petition or accompanying expert declaration. The subject came up, perhaps for the first time, during a deposition of Patent Owner's expert on July 29, 2017, prior to submission of Petitioner's Reply Brief and accompanying expert declaration but after Patent Owner submitted its Patent Owner Response and accompanying expert declaration. *See Reply Br.* 26 (Reply Brief dated Aug. 16, 2017); Ex. 1029, 1 (deposition dated July 29, 2017); Ex. 1030, 34 (Dr. Jordan expert declaration in support of Petitioner dated Aug. 16, 2017); PO Resp. 53 (dated May 24, 2017)); Ex. 2005 (Dr. Ticker expert declaration in support of Patent Owner dated May 23, 2017). A portion of the testimony cited by Petitioner appears below:

Q. And it would be easier to retain suture strands in grooves 28 if grooves were fully enclosed, correct?

A. Not necessarily.

Q. But you would agree with me that if grooves 28 fully enclosed suture legs, they wouldn't be loose, as shown in Figure 2?

A. They could not be loose if they were within an enclosed channel.

Q. So it could be desirable to retain sutures in an enclosed channel, correct?

A. It could be.

Q. Is there also a chance that when this Meridew anchor is deployed, the suture could get pinched against the anchor body?

A. I don't think so.

Ex. 1029, 54:12–55:2. As an initial matter, this testimony does not amount to an admission that completely enclosing Meridew's grooves 28 provides the added benefit of additional suture security, or that one of ordinary skill in the art would have been motivated to make Petitioner's proposed modification. *See* Pet. Reply 22. The testimony merely suggests that it "could" be desirable to enclose the sutures, but it was "[n]ot necessarily" an easier way to retain suture strands compared to leaving the sutures in open grooves 28, and the expert did not think there was a chance of pinching the sutures using Meridew's unmodified design. Ex. 1029, 54:12–55:2.

More importantly, Petitioner cannot use this testimony, extracted by leading questions by Petitioner's counsel, as a basis to justify a new theory in a Reply Brief and accompanying expert declaration for the first time. *See* 37 C.F.R. § 42.23(b) ("A reply may only respond to arguments raised in the corresponding opposition, patent owner preliminary response, or patent owner response."). If that were the case, Petitioner Reply Briefs could skirt the rule against adding new theories and arguments in Reply for the first time by first questioning Patent Owner's expert regarding the theory at deposition. "It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify 'with particularity' the 'evidence that supports the ground for the challenge to each claim.'" *Intelligent Gio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (quoting 35 U.S.C. § 312(a)(3)). Here, Petitioner's new theory and accompanying evidence were not made as a

legitimate response to Patent Owner's arguments, which never addressed enclosing Meridew's grooves 28. As such, Patent Owner has not had a fair and meaningful opportunity to address Petitioner's new theory. *See* Tr. 39:4–8 (counsel for Patent Owner alleging that new statements in expert's reply declaration are conclusory and an attempt to fill gaps in Petition). Accordingly, we decline to consider the merits of Petitioner's untimely argument that one of ordinary skill in the art would have found it obvious to route the suture through modified, enclosed grooves of Meridew.

We conclude that Petitioner has not shown by a preponderance of the evidence that claims 12 and 13 would have been obvious in view of Meridew and Goble or Pietrzak, in combination with either Fucci or Schmieding.

F. Obviousness of Claim 18 Based on Meridew, Goble or Pietrzak, and Anspach

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. Pet. 49 (incorporating arguments made at Pet. 42–43).

Anspach discloses a “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. To support the combination, Petitioner argues 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 does not address claim 18 in the Patent Owner Response, apart from the arguments already discussed above regarding the combination of Meridew with Goble and Pietrzak.

We find that Anspach discloses piercing soft tissue with a bone-piercing tip as alleged by Petitioner. Ex. 1021, 5:34–36, Fig. 9; Ex. 1027 ¶ 136; Pet. 42–43. We also find that one of ordinary skill in the art would have been motivated to modify further Meridew, in combination with Goble or Pietrzak, because (1) the modification involved applying a known technique (piercing soft tissue with a sharp tip) to a similar device in the same way, and (2) the results would have been predictable to one of ordinary skill in the art. Ex. 1027 ¶¶ 137, 140–141; Pet. 42–43.

We conclude that Petitioner has shown by a preponderance of the evidence that claim 18 would have been obvious in view of Meridew, Goble, and Anspach as well as Meridew, Pietrzak, and Anspach.

G. Petitioner’s Motion to Exclude

Petitioner seeks to exclude an “experiment” allegedly conducted by Patent Owner’s counsel at the deposition of Petitioner’s expert, as well as related testimony and exhibits. Paper 18, 1–2. Petitioner describes the problematic questioning as “a demonstration which consisted of [Patent Owner’s counsel] hammering two pointed tips of [Petitioner’s] suture anchors into a foam block.” *Id.* at 2. Petitioner argues, among other things, that the experiment was not conducted according to the Federal Rules of Evidence, the foam block used in the experiment was not authenticated, the experiment amounts to attorney argument improperly presented at this late stage of the proceedings, and the experiment is irrelevant to the obviousness

issues in this proceeding. *Id.* at 4–12; *see also* Paper 22, 1–5 (Petitioner arguing in Reply that the challenged testimony is irrelevant and the foam block was not properly authenticated).

Patent Owner describes the demonstration as attempting to illustrate the difference in resisting retraction of a spear and an awl from a foam block. Paper 20, 1. Patent Owner contends that Petitioner incorrectly assumes that “the demonstration was offered as a scientific experiment.” *Id.* at 2. Patent Owner argues that the testimony related to the demonstration complies with the Federal Rules of Evidence and rules governing *inter partes* proceedings. *Id.* at 4–5. Patent Owner also contends, among other things, that the foam block used in the demonstration was authenticated, that the questioning was within the scope of the expert’s Reply Declaration, and the demonstration and related documents are relevant. *Id.* at 6–15.

We note that none of the testimony or evidence at issue was relied on for any determination in this case. Patent Owner’s demonstration sought to undermine Petitioner’s arguments regarding obviousness based on a modification of Meridew with the pointed tips of Goble and Pietrzak. *See* Paper 20, 12–14. After considering this evidence and testimony purportedly in Patent Owner’s favor, we have concluded, as discussed above, that Petitioner established by a preponderance of the evidence that a number of claims are unpatentable based on proposed modification of Meridew with the pointed tips of Goble and Pietrzak. Accordingly, whether this testimony and evidence is excluded would have no effect on the outcome of this proceeding or on any aspect of the present Decision. As a result, we *dismiss* Petitioner’s Motion to Exclude as moot.

III. CONCLUSION

Having carefully considered the record before us, we determine that Petitioner has shown by a preponderance of the evidence that (1) claims 1–11, 14–17, 19, and 20 would have been obvious based on a combination of Meridew and Goble or a combination of Meridew and Pietrzak, and (2) claim 18 would have been obvious based on a combination of Meridew, Goble, and Anspach or a combination of Meridew, Pietrzak, and Anspach. Petitioner, however, has not shown by a preponderance of the evidence that claims 12 and 13 are unpatentable.

IV. ORDER

It is

ORDERED that claims 1–11 and 14–20 are held unpatentable under 35 U.S.C. § 103;

FURTHER ORDERED that claims 12 and 13 are not held unpatentable based on the record in this proceeding;

FURTHER ORDERED that Petitioner’s Motion to Exclude (Paper 18) is *dismissed* as moot; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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