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Paper 42
Entered: October 16, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC. and
ARTHROCARE CORP.,
Petitioner,

v.

ARTHREX, INC.,
Patent Owner.

Case IPR2016-00918
Patent 8,821,541 B2

Before WILLIAM V. SAINDON, BARRY L. GROSSMAN, and TIMOTHY J. GOODSON, *Administrative Patent Judges*.

GROSSMAN, *Administrative Patent Judge*.

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

Incorporating Decision on
PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

I. INTRODUCTION

Petitioner requested an *inter partes* review of claims 10 and 11 of U.S. Patent No. 8,821,541 B2 (Ex. 1101, "the '541 patent"). Paper 2 ("Petition" or "Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp."). Claims 10 and/or 11 were challenged under four separate and distinct grounds. Pet. 8–9. We instituted review on three of the four grounds. Paper 9, 14 ("Dec. Inst."). We instituted a trial on the following grounds:

1. Whether claims 10 and 11 would have been obvious under 35 U.S.C. § 103(a)[1] in view of Gordon[2] and West[3];

2. Whether claim 11 is anticipated under 35 U.S.C. § 102(b) by Curtis[4]; and

3. Whether claim 10 would have been obvious under 35 U.S.C. § 103(a) in view of Curtis, Overaker[5], and DiPoto[6].

Patent Owner filed a Response to the Petition (Paper 15, "PO Resp."),

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[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 296–07 (2011), took effect on September 16, 2012. Because the application for the patent at issue in this proceeding has an effective filing date before that date, we refer to the pre-AIA versions of the statute.

[2] U.S. Pub. No. 2006/0271060 A1, published Nov. 30, 2006, Filed May 26, 2006 (Ex. 1105).

[3] U.S. Patent No. 7,322,978 B2, issued Jan. 29, 2008, filed June 22, 2004 (Ex. 1106).

[4] U.S. Patent No. 5,464,427, issued Nov. 7, 1995 (Ex. 1107).

[5] U.S. Pub. No. 2003/0187444 A1, pub. Oct. 2, 2003, filed Mar. 29, 2002 (Ex. 1124).

[6] U.S. Patent No. 5,690,676, issued Nov. 25, 1997 (Ex. 1125).

and Petitioner filed a Reply (Paper 19, "Pet. Reply").

Petitioner submitted 77 exhibits, including demonstratives used at the hearing (Exs. 1101–1170, 1172–1178). Paper 36. Patent Owner submitted 52 exhibits, including demonstratives used at the hearing (Exs. 2001–2043, 2045–2053). Paper 31.

Patent Owner filed a Motion to Exclude Certain Evidence. Paper 32. Petitioner filed an Opposition to the Motion to Exclude. Paper 35. Patent Owner Filed a Reply. Paper 35.

A hearing was held July 19, 2017. Paper 38 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. We enter this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Petitioner has the burden of proving unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e). Based on the findings and conclusions below, we determine that Petitioner has met its burden to establish that claims 10 and 11 are unpatentable.

We deny Patent Owner's Motion to Exclude as moot.

A. Related Matters

As required by 37 C.F.R. § 42.8, the parties informed us that the '541 patent has been asserted in the U.S. District Court for the Eastern District of Texas, *Arthrex, Inc. v. Smith & Nephew, Inc.*, Civil Action No. 2:2015-cv-01047 (E.D. Tex. Filed June 17, 2015) Pet. 7; Paper 5, 2. In its Response, Patent Owner informed us of a change in the status of this litigation. Patent Owner stated that:

> Since the institution of this *Inter Partes* Review, the District Court for the Eastern District of Texas entered judgment (Ex. 2030) holding challenged claims 10 and 11 of U.S. Patent

> 8,821,541 ("the '541 Patent") willfully infringed by Petitioners and valid over the *Gordon*, *West* and *Curtis* prior art asserted against the '541 Patent here.

PO Resp. 6. Patent Owner's Response was filed January 13, 2017. Exhibit 2030, cited by Patent Owner, is a one-page Judgment from the District Court, entered December 12, 2016, stating, in part, that "[c]laims 10 and 11 of the '541 Patent . . . are found not invalid." Ex. 2030. The Judgment was entered following a jury verdict. Ex. 3001. Patent Owner, however, has not directed us to any evidence in this *inter partes* review proceeding supporting its assertion that the evidence and arguments before the District Court were the same evidence and arguments asserted by Petitioner in this *inter partes* review proceeding.

Following the jury verdict, all claims and counterclaims asserted between Plaintiff Arthrex, Inc. (Patent Owner in this *inter partes* review) and Defendants Smith & Nephew, Inc. and ArthroCare Corp. (Petitioners in this *inter partes* review) were dismissed with prejudice. Ex. 3002 ("Dismissal"). The Dismissal was based on a Joint Stipulated Motion for Dismissal with Prejudice filed by the parties on February 13, 2017. Ex. 3003. The Joint Stipulated Motion was filed while post-trial motions were pending. *See e.g.*, Ex. 3004, 10. (Sealed Motion – Defendants' Renewed Motion for Judgment as a Matter of Law, or in the Alternative, for a New Trial, as to Patent Invalidity by ArthroCare, Corp., Smith & Nephew, Inc., District Court docket entry No. 328, entered January 9, 2017). Thus, the Judgment from the District Court entered December 12, 2016 (Exhibit 2030) effectively was replaced by the Dismissal entered February 13, 2017 (Ex. 3002).

At the July 19, 2017 hearing, approximately five months after the February 13, 2017 settlement and dismissal in the District Court, Counsel for Patent Owner referred to the District Court Judgment but failed to inform us that the Judgment entered December 12, 2016 (Exhibit 2030) effectively was replaced by the Dismissal entered February 13, 2017 (Ex. 3002). *See* Tr. 53:10–12 ("I will say that we do have a judgment from the court in Texas . . .").

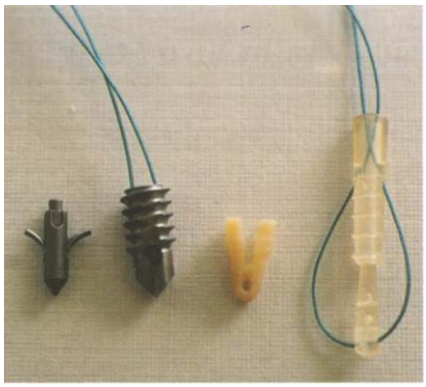
There are several related petitions for *inter partes* review: IPR2016-00505 (involving U.S. Patent No. 8,343,186, the parent of the '541 patent), IPR2016-00506 (involving U.S. Patent No. 8,623,052, a child of the '186 patent), and IPR2016-00507 and 508 (involving U.S. Patent No. 8,801,755, a child of the '052 patent). Pet. 7; Paper 5, 1. All four of these related proceedings were terminated as a result of a settlement. *See, e.g.*, *Smith & Nephew, Inc. et al v. Arthrex, Inc.*, IPR2016-00505, Order Granting Joint Motion to Terminate (PTAB Oct. 19, 2016) (Paper 18).

There are also a number of related patents and patent applications not presently at issue. Pet. 7; Paper 5, 2.

B. The '541 Patent

The '541 patent discloses and claims a suture anchor. A suture anchor is a medical-grade device that mechanically reattaches soft tissue, such as tendons and ligaments, to its supporting bone. Ex. 1101, 1:32–33; Ex. 2010 ¶ 47. Suture anchors are a sophisticated, nuanced, and highly developed medical technology. *Id.* at 1:40–57; *see also id.* at 2–4 (listing under "References Cited" 3 pages, with 2 columns per page, of U.S. and foreign patent documents and other publications).

In general use, all suture anchors perform a similar function: one end of the anchor is screwed into or otherwise connected to the supporting bone; suture material is threaded through or otherwise attached to the anchor; and the suture material is connected to the soft tissue. Ex. 1103 ¶ 33, 44. In general, all suture anchors also have a similar structure: a mechanism for holding the suture anchor in the bone, such as threads or barbs; and a mechanism for attaching the suture material to the anchor, such as suture passages, connecting posts, or frictional locks. *See id.* at ¶¶ 39–43 (illustrating and discussing numerous prior suture anchor designs). Four such exemplary prior art suture anchors are shown below.



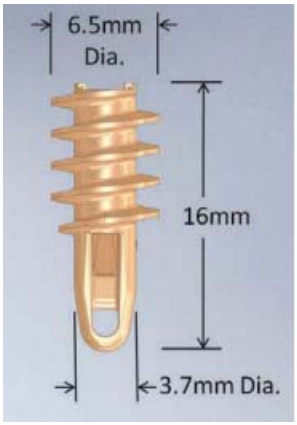
Excerpt from Ex. 1103 ¶ 39 showing four prior art suture anchors.

The following illustration shows a commercially available implanted suture anchor using sutures to connect soft tissue to bone. *See* Ex. 1158, 2.[7]

[7] Ex. 1158 is a brochure illustrating a Smith & Nephew SpeedScrew suture anchor. It is cited to illustrate a suture anchor in use. It is not cited to illustrate features of the claimed invention. We have not been directed to any evidence in the record before us of any similar illustration for a commercial product sold by Patent Owner that illustrates the claimed invention in use.

Illustration from Ex. 1158, 2 showing an implanted suture anchor connecting soft tissue to bone.

The suture anchor used in the illustration above is shown in the two illustrations below.



Commercial suture anchor. Ex. 1158, 3.[8]

Commercial suture anchor threaded with suture mounted on implantation device. Ex. 1158, 1.

We now turn to the suture anchor disclosed in the '541 patent.

The '541 patent discloses three distinct embodiments. A first embodiment is illustrated in Figures 1–4 (*e.g.*, Ex. 1101, 2:53–67); a second embodiment is illustrated in Figures 5–8 (*e.g.*, *id.* at 2:1–10); and a third

[8] *See also* Ex. 2010 ¶ 86 (showing images of two products commercialized by Patent Owner on top of a U.S. penny to show relative size of a suture anchor).

embodiment is illustrated in Figures 9–12 (*e.g.*, *id.* at 11–18).

Petitioner asserts, without dispute by Patent Owner, that the challenged claims are directed only to the second embodiment, disclosed in Figures 5–8 and the related text of the Specification. *E.g.*, Pet. 2 ("the challenged claims are directed to a second embodiment," citing "Figs. 5–8"); *see also* PO Resp. 9–10 (acknowledging that claims 10 and 11 do not read on the first embodiment).

Challenged claims 10 and 11 each recite first, second, and third suture openings. *See* Ex. 1101, 8:3–7; 8:38–44. As explained below, the second embodiment is the only embodiment with first, second, and third suture openings, as claimed.

The first embodiment is disclosed in Figures 1–4. *E.g.*, *id.* at 3:31–33 ("FIG. 1 illustrates a suture anchor according to a first preferred embodiment"). The first embodiment describes a suture anchor that includes central cylindrical bore 136 that mates with central "polygonally shaped bore 134" to form a single continuous bore. *E.g.*, *id.* at 3:55–4:10. Anchor pin 120 extends across the central bore and is supported within diametrically opposite bores 118 formed in anchor body 108. *E.g.*, *id.* at 4:14–17. One or more sutures are threaded into the central bore 134/136 and loop around anchor pin 120, as shown in Figure 4a. *Id.* at 4:21–23. The suture enters and exits anchor body 108 through proximal opening 112 (*see* Fig. 3), "polygonally shaped bore 134" (Ex. 1101, 3:55–60), and cylindrical bore 136 (*id.* at 4:5–10). *See also id.* at Figs. 4a and 4c (showing the suture entering and exiting through the central bore). Opening 112 is the outer edge or lip of bore 134, and bore 134 mates with bore 136. Thus, there is only a single opening in anchor body 108, which is the central bore formed

by opening 112 and bores 134, 136. This first embodiment does not have first, second, and third suture openings, as recited in challenged claims 10 and 11.

The third embodiment is a push-in suture anchor having suture molded directly into its body. Ex. 1101, 6:9–12. The anchor is solid and has no suture openings through which a suture is threaded. *See id.* at Fig. 10. Thus, this third embodiment does not have first, second, and third suture openings, as recited in challenged claims 10 and 11.

Figure 5, shown below, illustrates the second embodiment of a suture anchor according to the disclosed invention.

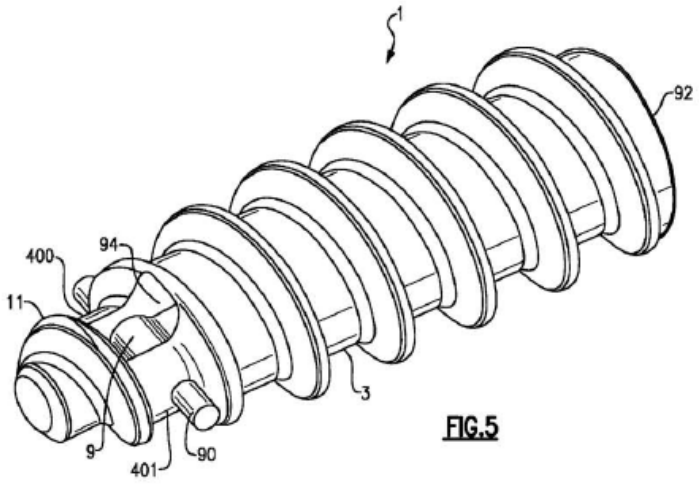


FIG.5

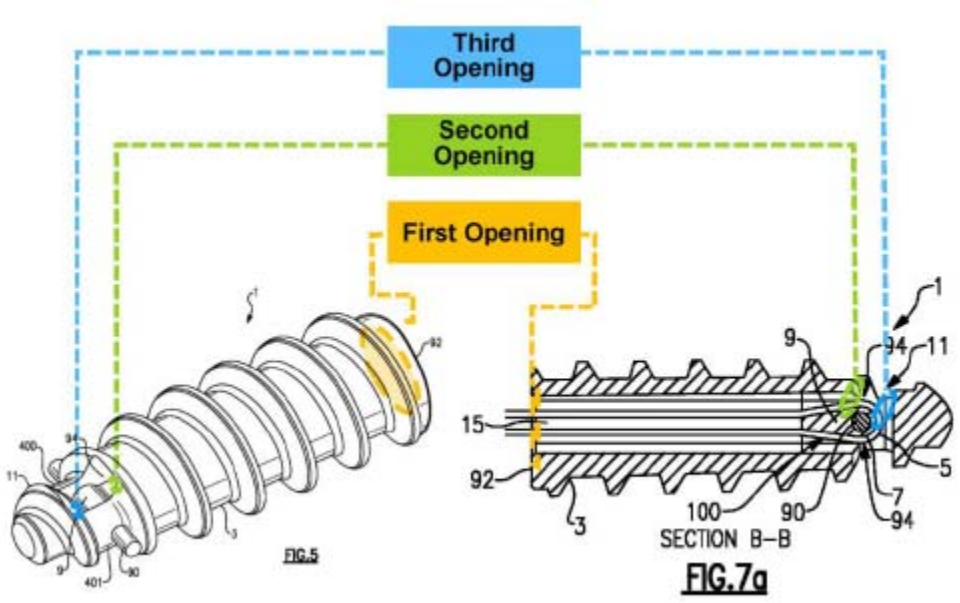
Fig. 5 of the ’541 patent is a perspective view of a suture anchor.

As shown in Figure 5, suture anchor 1 includes threaded body 3. Rigid support or eyelet shield 9 is molded transversely into distal part 11 of threaded body 3. Eyelet shield 9 can include a length of suture 90 molded into threaded body 3. Ex. 1101, 5:18–31. As explained in the Specification, rather than having an anchor pin 120, as discussed in the first embodiment above, suture anchor 1 in the second embodiment has eyelet shield 9 molded

transversely into distal part 11 of threaded body 3. *Id.* at 5:23–26. "Eyelet shield 9 is shown as a bar." *Id.* at 5:26–27.

In the disclosed second embodiment, two strands of sutures 5, 7 are threaded around eyelet shield 9 and threaded into suture passage 94. *Id.* at 5:37–39. Suture passage 94 may be on opposing sides of shield 9. *Id.* at 5:40–41, Figure 7a.

Petitioner provides the following annotated versions of Figures 5 and 7a of the '541 patent, illustrating the first second and third openings recited in the challenged claims:



Pet. 4. The annotations identify three openings through which suture passes. The first opening is bore 15 or opening 92. Ex. 1101, 5:42–48 ("The bore 15 extends from the proximal end 92 of the suture anchor 1 to a location roughly halfway along the anchor body 1. . . . the bore 15 has an opening at the proximal end 92 of the suture anchor"). The second and third openings are suture passages 94 on opposing sides of shield 9.

Shield 9 provides a bearing surface around which sutures are threaded. *Id.* at 5:41–42. Sutures are threaded through central bore 15 (*see* Figs. 7a and 8) and disposed about shield 9, with suture ends 306 and 308 extending out of proximal end 92 of anchor 1. *Id.* at 5:42–45; *see* Fig. 7b. Bore 15 has an opening at proximal end 92, with the opening shaped to accommodate driver 300 for driving the suture anchor. *Id.* at 5:47–50.

C. Challenged Claims

Petitioner challenges independent claims 10 and 11. Claim 10 is reproduced below.

> 10. A structure anchor assembly comprising an anchor body including a longitudinal axis, a proximal end, a distal end, and a central passage extending along the longitudinal axis from an opening at the proximal end of the anchor body through a portion of a length of the anchor body, wherein the opening is a first suture opening, the anchor body including a second suture opening disposed distal of the first suture opening, and a third suture opening disposed distal of the second suture opening, wherein a helical thread defines a perimeter at least around the proximal end of the anchor body;
>
> a rigid support extending across the central passage, the rigid support having a first portion and a second portion spaced from the first portion, the first portion branching from a first wall portion of the anchor body and the second portion branching from a second wall portion of the anchor body, wherein the third suture opening is disposed distal of the rigid support;
>
> at least one suture strand having a suture length threaded into the central passage, supported by the rigid support, and threaded past the proximal end of the anchor body, wherein at least a portion of the at least one suture strand is disposed in the central passage between the rigid support and the opening at the proximal end, and the at least

> one suture strand is disposed in the first suture opening, the second suture opening, and the third suture opening; and
>
> a driver including a shaft having a shaft length, wherein the shaft engages the anchor body, and the suture length of the at least one suture strand is greater than the shaft length of the shaft.

Ex. 1101, 7:58–8:28.

Independent claim 11 is similar to claim 10. There are three substantive differences between claims 10 and 11:

(1) Claim 10 recites a "helical thread" around the proximal end of the anchor body (*id.* at 8:7–8); claim 11 does not recite a "helical thread;"

(2) Claim 11 recites that the "rigid support" is "integral with the anchor body" (*id.* at 8:45); claim 10 does not recite an "integral" relationship between the rigid support and anchor body;

(3) Claim 11 does not recite the "driver" recited in the last clause of claim 10.

II. ANALYSIS

A. Claim Construction

We interpret the claims of an unexpired patent using the broadest reasonable interpretation in light of the specification of the patent. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). The correct inquiry in giving a claim term its broadest reasonable interpretation in light

of the specification is "an interpretation that corresponds with what and how the inventor describes his invention in the specification, *i.e.*, an interpretation that is 'consistent with the specification.'" *In re Smith Int'l, Inc.*, No. 2016-2303, 2017 WL 4247407, at *5 (Fed. Cir. Sept. 26, 2017). The broadest *reasonable* interpretation differs from the "broadest *possible* interpretation." *Id.* Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We are careful, however, not to cross that "fine line" that exists between properly construing a claim in light of the specification and improperly importing into the claim a limitation from the specification. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998) ("We recognize that there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.").

Petitioner proposes constructions for the terms, "suture opening," "rigid support," "central passage," "suture passage," "branching from," and "a rigid support integral with the anchor body to define a single-piece component." Pet. 19–24. Patent Owner agrees that construing several of these terms "is necessary to resolve the controversy." PO Resp. 8; *see also id.* at 8–17 (proposing constructions for the terms "rigid support," "branching from," and "rigid support integral" proposed by Petitioner, as well as the term "helical thread").

We did not specifically construe any claim terms in our Decision to Institute. Dec. Inst. 6.

Because claim construction is based on how a term would be understood by a person of ordinary skill in the art, we first determine the ordinary skill level.

1. Level of Ordinary Skill

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Factors pertinent to a determination of the level of ordinary skill in the art include: (1) educational level of the inventor; (2) type of problems encountered in the art: (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology, and (6) educational level of workers active in the field. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed.Cir.1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, these factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art. *Daiichi Sankyo Co. Ltd, Inc. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). Additionally, the Supreme Court informs us that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Neither party presents a detailed evidentiary showing of factors typically considered in determining the level of ordinary skill.

Petitioner asserts that a person of ordinary skill in the relevant technology would have had "(a) a master's degree in mechanical engineering or a bachelor's degree in mechanical engineering along with two or more years of experience designing suture anchors; or (b) a medical degree and several years of experience performing surgeries that involve suture anchors and/or advising engineers on suture anchor design." Pet. 18–19 (citing Ex. 1103 ¶¶ 24-26). Exhibit 1103 is a 152 page declaration from Mark A. Ritchart.[9] Mr. Ritchart's declaration testimony merely repeats the level of skill asserted by Petitioner without any analysis or discussion of the underlying facts or data on which his opinion is based. We give his testimony some, but little, evidentiary weight. 37 C.F.R. § 42.65(a).

Patent Owner does not assert a level of ordinary skill to apply in this proceeding, nor does Patent Owner comment on Petitioner's proposed level of ordinary skill.

At the hearing, Counsel for Petitioner stated his understanding that "there is no dispute over the [ordinary level of skill] standard that, as we set forth in pages 18 and 19 of our petition, that is the standard." Tr. 28:19–22. Counsel for Patent Owner did not dispute at the hearing that the parties agree

[9] Mr. Ritchart holds a degree in mechanical engineering. He has been involved in all aspects of designing and testing suture anchors since at least 1993. *Id.* ¶ 4. He also served as the President and Chief Technology Officer of Opus Medical, Inc., a medical device company that designed, manufactured and marketed soft-tissue-to-bone and tissue-to-tissue repair systems, including suture anchors. *Id.* ¶ 3. Mr. Ritchart is a named inventor on numerous patents related to medical devices, including suture anchors. *Id.* ¶ 4. We determine that Mr. Ritchart is qualified as an expert by his knowledge, skill, experience, training, and education to testify in the form of an opinion in this proceeding. Fed. R. Evid. 702.

on Petitioner's proposed level of ordinary skill. *See also* Ex. 2010 ¶ 9 (testimony of Patent Owner's expert Dr. Ken Gall, Ph.D., testifying that "I qualify for the POSA standard set forth by Petitioners.").

In determining a level of ordinary skill, we may also look to the prior art, which may reflect an appropriate skill level. *Okajima*, 261 F.3d at 1355.

Based on the record before us, we adopt Petitioner's proposed level of skill. A person of ordinary skill in the relevant technology would have had (a) a master's degree in mechanical engineering or a bachelor's degree in mechanical engineering along with two or more years of experience designing suture anchors; or (b) a medical degree and several years of experience performing surgeries that involve suture anchors and/or advising engineers on suture anchor design.

We now turn to construction of disputed claim terms.

2. Suture Opening

Petitioner asserts that the broadest reasonable interpretation of "suture opening" is "an open space serving as a passage or gap, or a breach or aperture, through which a suture passes." Pet. 19. Patent Owner does not propose a specific construction for this term, nor does Patent Owner comment on Petitioner's proposed construction.

a. The Claims

The claim construction inquiry "begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998) (citations omitted). "[T]he resulting claim interpretation must, in the end, accord with the words chosen by the

patentee to stake out the boundary of the claimed property." *Id.* Thus, we begin with the words of the claims.

The term "suture opening" is used numerous times throughout both claims 10 and 11. For example, Claim 10 recites distinct "first," "second," and "third" suture openings:

> an anchor body including a longitudinal axis, a proximal end, a distal end, and a central passage extending along the longitudinal axis from an opening at the proximal end of the anchor body through a portion of a length of the anchor body, wherein the opening is *a first suture opening*, the anchor body including *a second suture opening* disposed distal of the first suture opening, and *a third suture opening* disposed distal of the second suture opening,

Ex. 1101, 7:58–8:7 (emphases added). Claim 11 recites these same three distinct "first," "second," and "third" suture openings. *Id.* at 8:38–44, 57–59. Although the first, second, and third suture openings are important elements in issued claims 10 and 11, they are not an emphasized element in the Specification. Other than in the claims, the term "suture opening" does not appear in the '541 Specification.

b. The Specification

Although the written description does not use the term "suture opening," it refers twice to "suture passages 94." *Id.* at 5:37–41 (". . . sutures 5, 7 are threaded around the eyelet shield 9 of the distal end 11 of the suture anchor 1 and threaded into a *suture passage* 94. In one example, there is a *suture passage* 94 on opposing sides of the shield 9." (emphases added)). The written description provides no structural or functional distinction between a "passage" and an "opening."

Petitioner equates "suture openings" with the disclosure of "suture passages." Pet. 19–20 ("The patent's description of suture passages 94 is consistent with that ordinary meaning, and the remainder of the patent contains no disclosure or description that would compel a narrower meaning of the term 'opening' as it is used in the claims." (citing Ex. 1103 ¶¶ 121–23)). Mr. Ritchart essentially repeats Petitioner's argument without any additional analysis.

In construing the claims, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw*, 158 F.3d at 1250. Thus, Petitioner's assertion that the claimed "openings" are disclosed by passages 94 has some evidentiary support.

Claim 11, however, uses both the term "suture openings" (*id.* at 8:38–44) and "suture passages" (*id.* at 8:38–44). This suggests that the term "suture opening" has a meaning separate and distinct from the term "suture passage." This is based on "the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1369 (Fed. Cir. 2007) (quoting *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971–72 (Fed.Cir.1999)); *see also Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." (citations omitted)). The preference for giving meaning to all terms, however, is not an inflexible rule that supersedes all other principles of claim construction. *SimpleAir, Inc. v. Sony Ericsson Mobile Commc'ns AB*, 820 F.3d 419, 429 (Fed. Cir. 2016).

The prosecution history, which we discuss below, sheds some light on this issue.

c. Prosecution History

The proceedings in the Patent and Trademark Office suggest that Applicants used the terms "suture opening" and "suture passage" interchangeably. During prosecution, Applicants identified suture passages 94 shown in Fig. 7a as "suture openings." Pet. 19 (citing Ex. 1102 at 630)

An Amendment submitted on May 21, 2014 (Ex. 1102, 617–633) laid the substantial foundation for the eventually issued claims. In this amendment, new application claims 55 and 59 were submitted, which eventually became patent claims 10 and 11, respectively. *Id.* at 627–628; *see also id.* at 727 (showing the concordance between the application ("Original") claims and the issued ("Final") claims). In the May 21 amendment, Applicants also amended application paragraph 46 to add two references to "*suture passage 94*." Ex. 1102, 620 (emphasis added). These are the same two references to "suture passages 94" that now appear in the issued patent. *See* Ex. 1101, 5:37–41. As filed, neither application paragraph 46, nor any other portion of the written description, referred to suture passages 94. *See, e.g.*, Ex. 1102, 9–10.

The May 21 amendment also amended Figures 5 and 7a "to show suture strands 5 and 7 threaded through a suture passage 94." *Id.* at 630. The drawings as filed did *not* include reference numeral 94. *See Id.* at 29–33, 36–43. In describing these drawing changes, Applicants stated "[r]egarding claims 43 to 44, two *suture openings 94* are shown in Figure

7A. Figures 7a[10] and 7b show the path of claim 44." *Id.* at 630 (emphasis added).

Regarding a rejection under Section 112[11], Applicants also stated that "[r]egarding claim 43–44, Figure 7A shows two suture *openings*. The *suture openings 94* are disclosed in paragraph 46." *Id.* (emphasis added). Here, Applicants interchange the word "openings" for "passages" in describing element 94. Amended application claim 43 recited first, second, and third "suture openings." *Id.* at 626. Amended application claim 44 recited first and second "suture openings." Ex. 1102 at 630. It is these suture openings that Applicants asserted were illustrated by suture passages/openings 94.

"The very nature of words would make a clear and unambiguous claim a rare occurrence." *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 396 (Ct. Cl. 1967). Using different words for the same element compounds the difficulties of claim interpretation.

d. Construction of "Suture Opening"

Based on our analysis above, including the claims, written description, and prosecution history, we conclude that the terms "suture opening" and "suture passage" represent a distinction without a substantive difference.

[10] The issued '541 patent, like these quoted sentences, refers to both "Figure 7a" (*see* Ex. 1101, drawing figures) and to "Figure 7A" (*see id.* at 3:4–5, 5:66).

[11] The Office Action mailed February 21, 2014, to which Applicants were responding, rejected claims 42–44 under 35 U.S.C. § 112, first paragraph, because "[c]laims 42–44 recite a second suture opening which is not found in the original disclosure therefore it is considered new matter." The Examiner did not repeat this rejection in subsequent Office Actions.

We determine that the broadest reasonable interpretation of both terms is a space through which a suture passes.

3. Rigid Support

Claims 10 and 11 each recite "a rigid support." Ex. 1101, 8:9, 8:45.

Petitioner asserts that the broadest reasonable interpretation of the term "rigid support" is "an inflexible part of the suture anchor that supports a tissue securing suture." Pet. 20 (citing Ex. 1103, the testimony of its expert Mr. Ritchart).

Patent Owner appears generally to agree with Petitioner's proffered construction. PO Resp. 9 ("Patent Owner's expert agrees with Petitioner's expert regarding the broadest reasonable construction for the term 'rigid support.'"). This apparent agreement, however, is based on Patent Owner's inaccurate summary of its expert's, Dr. Ken Gall's, testimony[12]. Patent Owner asserts "Dr. Gall explains that a 'rigid support' as that term is used in claims 10 and 11 requires an inflexible structure that withstands the loading on the sutures used to secure tissue after the anchor has been implanted in the patient." *Id.* (citing Ex. 2010 ¶¶ 103–106). In fact, Dr. Gall did not provide any such explanation or opinion concerning the construction of the

[12] Dr. Gall is Chair of the Mechanical Engineering and Materials Science Department at Duke University and a Professor of Orthopedic Surgery in the School of Medicine. Ex. 2010 ¶ 3. He has a Ph.D. in mechanical engineering. *Id.* His publications include peer-reviewed journal articles on the mechanics of suture anchors. *Id.* at ¶ 4. Dr. Gall also has experience in the commercialization of orthopedic medical devices, including a suture anchor. *Id.* at ¶ 6. We determine that Dr. Gall is qualified as an expert by his knowledge, skill, experience, training, and education to testify in the form of an opinion in this proceeding. Fed. R. Evid. 702.

term "rigid support" at the cited paragraphs of Exhibit 2010 on which Patent Owner relies to support its argument.

Paragraph 103 of Dr. Gall's testimony summarizes Petitioner's proposed construction of the term "rigid support." Ex. 2010 ¶ 103. Dr. Gall does not state in this paragraph any opinion as to whether he agrees or disagrees with Petitioner's proposed construction, whether he agrees or disagrees with Mr. Ritchart's declaration testimony concerning the construction of "rigid support," nor does he provide his own opinion on the construction of the term "rigid support." *Id.*

Paragraph 104 of Dr. Gall's testimony summarizes excerpts from Mr. Ritchart's deposition testimony. *Id.* at ¶ 104. Dr. Gall does not state in this paragraph any opinion as to whether he agrees or disagrees with Mr. Ritchart's deposition testimony, whether he agrees or disagrees with Mr. Ritchart's declaration testimony concerning the construction of "rigid support," nor does he provide his own opinion on the construction of the term "rigid support." *Id.*

Paragraph 105 of Dr. Gall's testimony summarizes his understanding of Petitioner's Exhibit 1136. *Id.* at ¶ 105. Exhibit 1136 is a five page article titled "Cyclic Loading of Anchor-Based Rotator Cuff Repairs: Confirmation of the Tension Overload Phenomenon and Comparison of Suture Anchor Fixation With Transosseous Fixation." Ex. 1136, 1. Dr. Gall does not state in Paragraph 105 of his testimony any opinion as to whether he agrees or disagrees with Petitioner's proposed construction of "rigid support," whether he agrees or disagrees with Mr. Ritchart's declaration testimony concerning the construction of "rigid support,", nor does he provide his own opinion on the construction of this term. Ex. 2010 ¶ 105.

Paragraph 106 of Dr. Gall's testimony summarizes trial testimony in a district court of "Petitioners' expert Dr. McAllister" regarding the "Curtis support." *Id.* at ¶ 106 (citing Ex. 2012, 1268:1-13). Dr. Gall does not state in Paragraph 106 of his testimony whether he agrees or disagrees with Petitioner's proposed construction of "rigid support" in this *inter partes* review, whether he agrees or disagrees with Mr. Ritchart's declaration testimony concerning the construction of "rigid support,", nor does he provide his own opinion on the construction of this term. *Id.*

Whether the experts agree or not, Patent Owner asserts a slightly different construction of the term "rigid support" than asserted by Petitioner. According to Patent Owner, the broadest reasonable interpretation of the term "rigid support" is "an inflexible, or *stiff* part that *bears the loading* on the tissue securing suture." PO Resp. 9 (emphases added). The only evidence cited by Patent Owner to support its asserted construction is the testimony of Dr. Gall in paragraphs 103–106 of his Declaration (Ex. 2010), discussed above. *Id.* As discussed above, the cited testimony is not persuasive evidence supporting Patent Owner's asserted construction of the term "rigid support."

In its Reply, Petitioner asserts that "[t]he parties agree 'rigid support' is an 'inflexible part of the suture anchor' that supports the suture." Pet. Reply 5. It is Petitioner's position that the parties "disagree about whether it [the rigid support] *alone* must bear the *full load* on the suture *at all times* (Arthrex's [Patent Owner's] position), or simply bear some load on the suture at any time (S&N's [Petitioner's] position)." *Id.* (emphasis added). Petitioner, however, has not directed us to any persuasive evidence supporting Petitioner's characterization of Patent Owner's position. We

have not been directed to any persuasive evidence that Patent Owner argues that the rigid support *alone* must bear the *full load* on the suture *at all times*. In this proceeding, Patent Owner has asserted that the meaning of the term the term "rigid support" is "an inflexible, or stiff part that bears the loading on the tissue securing suture." PO Resp. 9; *see also* Ex. 1165 ¶ 27 (testimony of Petitioner's expert Alexander H. Slocum, Ph.D.[13], testifying that in the Patent Owner Response, Patent Owner "argues that the BRI of 'rigid support' is 'an inflexible, or stiff part that bears the loading on the tissue securing tissue" (citing PO Resp. 9)).

At the hearing, Counsel for Patent Owner appeared to agree with Petitioner's construction of the term "rigid support." Tr. 55:13–17 ("When I looked at these claim constructions [on slide 10 of Patent Owner's demonstrative exhibits [Ex. 2053)]] and read them over and over again, I didn't discern much of a difference, if any."); *see also id.* at 56:13–59:12 (Patent Owner's discussion of claim construction concluding, for the term "rigid support," that "I don't know if there's much of a difference in terms of the construction").

[13] Dr. Slocum is a Professor of Mechanical Engineering at the Massachusetts Institute of Technology ("MIT"). Ex. 1165 ¶ 3. He received his Bachelor's, Master's, and Ph.D. degrees in Mechanical Engineering from MIT. *Id.* Dr. Slocum has approximately 30 years of experience in casting and molding. *Id.* at ¶ 6. He has published several articles and received many patents directed to designs and processes for casting and molding various components. *Id.* He also has designed molds for forming components through molding and casting, ranging in size from fractions of a millimeter (e.g., medical devices, razor blade edges) to meters in diameter. *Id.* We determine that Dr. Slocum is qualified as an expert by his knowledge, skill, experience, training, and education to testify in the form of an opinion in this proceeding. Fed. R. Evid. 702.

We interpret the term "rigid support" in light of the Specification, which is a basic tool in reaching a proper claim construction. *In re Smith Int'l.*, 2017 WL 4247407, at *5 ("The correct inquiry . . . is an interpretation that corresponds with what and how the inventor describes his invention *in the specification*, *i.e.*, an interpretation that is '*consistent with the specification*.'") (emphases added); *Retractable Techns., Inc. v. Becton, Dickinson & Co*., 653 F.3d 1296, 1305 (Fed. Cir. 2011) ("In reviewing the intrinsic record to construe the claims, we strive to capture the scope of the actual invention, rather than strictly limit the scope of claims to disclosed embodiments or allow the claim language to become divorced from what the specification conveys is the invention."). This focus on the Specification helps to avoid what has been called "the curse of . . . claims divorced from the written description." *Retractable Techns.*, 653 F.3d at 1311 (Plager, Circuit Judge, concurring). Before considering the Specification, however, we start with the actual words of the claim. *Renishaw*, 158 F.3d at 1248.

a. The Claims

Claim 10 recites the location and function of the rigid support as "a rigid support extending across the central passage . . . [with] at least one suture strand having a suture length threaded into the central passage, supported by the rigid support." Ex. 1101, 8:9, 8:16–17.

Claim 11 similarly recites "a rigid support integral with the anchor body to define a single-piece component, wherein the rigid support extends across the suture passage . . . [with] at least one suture strand threaded into the suture passage, supported by the rigid support." *Id.* at 8:45–47, 8:54–55.

Thus, the recited objective of the "rigid support" is to support a strand of suture.

b. The Specification

The term "rigid support" is used only in the claims. It is not used in the Specification.

In the first disclosed embodiment, the structure that supports the strands of suture is metal anchor pin 120. Ex. 1101, 4:21–23 ("One or more sutures 200 are *secured to the anchor* by looping the suture(s) around metal anchor pin 120 as shown in FIG. 4a"). Thus, the rigid support must support the sutures so that they are *secured* to the anchor.

In the third embodiment, the suture strands are molded into the body of the anchor, and thus do not have a separate support equivalent to anchor pin 120 or eyelet shield 9.

In the second disclosed embodiment, rather than having anchor pin 120 as a rigid support for supporting suture strands, as discussed above, suture anchor 1 has eyelet shield 9 molded transversely into a distal part 11 of the threaded body 3. Ex. 1101, 5:23–26. Shield 9 provides a bearing surface around which sutures 5, 7 are threaded and disposed. *Id.* at 5:41–42. As explained in the Specification:

> The eyelet shield 9 resists suture cut-[sic]. Further, the shield 9 *provides the strength necessary to secure the sutures* 5, 7. In addition, because the eyelet shield is molded transversely into the distal end of the suture anchor, this provides greater security *to prevent pull-out of the suture from within the suture anchor* or from an anchor pin, which could loosen. The eyelet shield also prevents the suture from fraying.

Id. at 5:51–57 (emphasis added). Thus, eyelet shield 9, the claimed rigid support, "provides the strength necessary to secure the sutures." *Id.* at 5:51–52.

Counsel for Patent Owner acknowledged that nothing in the Specification or claims establishes how rigid or flexible the rigid support may be. Tr. 63:19–64:1.

c. Construction of "Rigid Support"

We determine that the construction of the term "rigid support" that stays true to the claim language, most naturally aligns with the patent's written description of the invention, and is consistent with the other evidence discussed above is the construction proposed by Petitioner – an inflexible part of the suture anchor that supports a tissue securing suture.

4. Central Passage

The term "central passage" is recited only in claim 10. Petitioner asserts that the broadest reasonable interpretation of this term is "a central path, channel, or duct of the anchor body." Pet. 20. For evidentiary support, Petitioner relies on the declaration testimony of Mr. Ritchart (Ex. 1103) and a dictionary definition (Ex. 1121). *Id.* at 20–21. Because the proposed interpretation uses the word "central" to define a "central passage," Petitioner essentially is asserting a construction of the word "passage." Patent Owner does not assert a construction for this term, nor does Patent Owner comment on the construction proposed by Petitioner.

a. The Claims

Claim 10 refers to a "central passage" four times. It recites:

> (1) "an anchor body including a longitudinal axis, a proximal end, a distal end, and a *central passage* extending along the longitudinal axis from an opening at the proximal end of the anchor body through a portion of a length of the anchor body" (Ex. 1101,

7:59–8:3 (emphasis added));

(2) "a rigid support extending across the *central passage*" (*id.* at 8:9 (emphasis added));

(3) "at least one suture strand having a suture length threaded into the *central passage*" (*id.* at 8:16–17 (emphasis added)); and

(4) "wherein at least a portion of the at least one suture strand is disposed in the *central passage* between the rigid support and the opening at the proximal end" (*id.* at 8:19–21 (emphasis added)).

b. The Specification

The term "central passage" does not appear in the Specification. The written description of the first embodiment refers to a "central opening" at the proximal end of the anchor. Ex. 1101, 3:62.

The word "passage" appears only twice in the Specification, referring to "passage 94" disclosed in the context of the second embodiment. *Id.* at 5:39–41. The Specification also states that sutures 5, 7 are threaded through bore 15, are disposed about shield 9, and have ends 306 and 308 that extend out of proximal end 92 of the anchor 1. *Id.* at 5:42–45; *see* Figures 7a and 7b, Bore 15 extends from proximal end 92 of suture anchor 1 to a location roughly halfway along anchor body 1. *Id.* at 5:45–47; *see* Figures 7a and 8.

c. Construction of "Central Passage"

We determine that the construction of the term "central passage" that stays true to the claim language, most naturally aligns with the patent's written description of the invention, and is consistent with the other evidence discussed above is a pathway through the center of the anchor body. The additional claim language in claim 10 locates the central passage along the

longitudinal axis of the anchor body extending from a proximal end opening through a portion of the anchor body. *See id.* at 8:1–3.

5. Suture Passage

The term "suture passage" appears only in claim 11. *E.g., see* Ex. 1101, 8:33–35. In our analysis of the term "suture opening" we determined that the terms "suture opening" and "suture passage" represent a distinction without a substantive difference. We determined that the broadest reasonable interpretation of both terms is a space through which a suture passes.

6. Branching

Claims 10 and 11 each recite first and second portions of the claimed rigid support "branching" from first and second wall portions of the anchor body, respectively. Petitioner asserts the broadest reasonable interpretation of this "branching" term is "extending." Pet. 21.

Patent Owner takes a contrary position. According to Patent Owner, the correct construction of the "branching" limitation is "continuous with the anchor body and the branching first and second portions of the rigid support spread out or diverge from the respective wall portions." PO Resp. 14. Patent Owner argues that Petitioner's proposed construction is wrong because claim 10 already recites "a rigid support *extending* across the central passage." PO Resp. 12. According to Patent Owner, if "branching" simply means "extending" across a gap then the "extending across a passage" clause in claim 10 becomes redundant, and thus superfluous. *Id.* Patent Owner asserts that a claim construction that makes a limitation superfluous or redundant is not proper. *Id.*

Petitioner argues that interpreting "branching to require the rigid support to be "continuous" is "inconsistent with the intrinsic evidence and Arthrex's prior positions." Pet. Reply 3. According to Petitioner, if the rigid support is "continuous" with the anchor body, as recited in both claims 10 and 11, the additional recitation in claim 11 that the rigid support also is "integral with the anchor body" (Ex. 1101, 8:45) becomes redundant and thus superfluous. Tr. 39, 14–16 ("in our opinion, their construction would render the integral limitation of Claim 11 entirely superfluous.").

Thus, the only agreement between the parties is that a claim construction that renders a claim term redundant and superfluous is neither correct nor reasonable.

We evaluate these issues and arguments by starting with the language of the claims.

a. The Claims

Claim 10 recites:

> a rigid support *extending across* the central passage, the rigid support having a first portion and a second portion spaced from the first portion, the first portion *branching from* a first wall portion of the anchor body and the second portion *branching from* a second wall portion of the anchor body.

Ex. 1101, 8:9–14 (emphasis added). Claim 11 is similar, but additionally recites that the rigid support is "integral with the anchor body to define a single-piece component." *Id.* at 8:45–46. Thus, claims 10 and 11 each require the rigid support to have first and second portions that "branch" from first and second wall portions of the anchor body, respectively. Claims 10 and 11 also each require the rigid support to extend across the central or suture passage. *Id.* at 8:9, 8:47.

Patent Owner misconstrues Petitioner's proposed construction. Petitioner's construction is more limited than argued by Patent Owner. Petitioner is asserting simply that the term "'branching' means 'extending.'" Pet. 21. Thus, under Petitioner's construction, the first and second portions of the rigid support branch or *extend from* first and second wall portions of the anchor body. Claim 10 and 11 also recites that the first and second portions of the rigid support *extend across* the central or suture passage. These two terms are neither redundant nor superfluous, as explained by counsel for Petitioner:

> JUDGE SAINDON: Counsel, let me ask you this.
>
> So if you have a hollow cylinder, *branching means* it's coming out from. Under your construction here, *extending across means* the two branches connect?
>
> MR. SPEED: Right.
>
> JUDGE SAINDON: And *integral means* formed all from the same material?
>
> MR. SPEED: Exactly.
>
> JUDGE SAINDON: Okay.
>
> MR. SPEED: So you could have a pin that branches from one wall to another and extends across the entire center of the hollow cylinder. You could conceivably have a pin that only extends partially across or something along those lines.
>
> JUDGE SAINDON: Okay. So that's what across adds[, it's] that they're connected as opposed to not?
>
> MR. SPEED: Right. Exactly.

Tr. 37, 5–20 (emphases added).

b. The Specification

The Specification does not use the term "branching from," "branching," "branch," or a similar word in describing the relationship of the rigid support to the walls of the anchor body. The written description also does not refer to first and second portions of the rigid support or first and second wall portions. Indeed, neither party directs us to any persuasive evidence in the written description supporting their position.

Regarding the first disclosed embodiment, the written description states "[t]wo longitudinal, diametrically opposite apertures 118 are formed in anchor body 108, the apertures 118 supporting a metal transverse anchor pin 120 which extends across cylindrical bore 136." Ex. 1101, 4:14–17. Anchor pin 120 is the claimed rigid support in this embodiment. The only disclosed relationship between anchor pin 120 and the walls of anchor body 108 is that anchor body 120 is supported by opposing apertures 118 in the anchor body walls.

Regarding the second disclosed embodiment, as discussed above, anchor pin 120 is replaced with eyelet shield 9 "molded transversely into" anchor body 3. *Id.* at 5:23–26. There is no disclosure of eyelet shield 9 having first and second portions. The only disclosed relationship between eyelet shield 9 and the walls of the anchor body is that shield 9 is "molded into" anchor body 3. *Id.* at 5:30.

Figures 1–8 illustrate the rigid support (120 or 9) that extends from opposing side walls of the anchor body, and also extends across the central passage or suture passage i.e., bore 134 or bore 15).

c. Prosecution History

The reference to "branching" and the claim language about first and second portions of the rigid support and anchor body walls first appeared in claims in an amendment submitted on May 21, 2014, responding to an Office Action mailed February 21, 2014. Ex. 1102, 617–636. In this amendment, the Specification was supplemented extensively. *Id.* at 618–621. The pending claims also were amended extensively, some claims were cancelled, and new claims 50–67 were added. *Id.* at 622–629. Pending application claims 1 (*id.* at 622), 12 ((*id.* at 623), and 39 (*id.* at 625) were amended to include the "branching" and first and second portion language.

In arguing that the amended claims were not anticipated by the Colleran reference (Ex. 1109), Applicants argued that "Colleran discloses a winding post 62 [a rigid support] that extends from a *single wall* 61." Ex. 1102, 632 (emphasis added). Colleran discloses winding post 62 that extends from wall 61. Ex. 1109, 5:8–9, *see* in Figs. 2A, 2D. As shown, post 62 is cantilevered from wall 61. *See* PO Resp. 11 ("That argument was based on the fact that Colleran's winding post 62 is cantilevered from a single wall 61."). Thus, the argued distinction is the difference between a rigid support that extends from *one* wall portion versus a claimed structure that extends from *two* wall portions. This asserted distinction does not require that the broadest reasonable interpretation of the disputed claim language is that the rigid support is "continuous" with the walls, as proposed by Patent Owner's construction.

In arguing that the claims were not anticipated by the Grafton reference (Ex. 1110), Applicants argued that a suture "molded inside the suture body" to form an eyelet, as disclosed in Grafton, was not a structure

that included portions of a rigid body branching from wall portions, as recited in the claims. Ex. 1102, 632; *see also* Ex. 1110, ¶ 24 (disclosing that "a strand of suture 8 [is] molded into the anchor body 4 during manufacture"). This asserted distinction also does not require that the broadest reasonable interpretation of the disputed claim language is that the rigid support is "continuous" with the walls, as proposed by Patent Owner's construction.

Applicants also argued the Dreyfuss reference[14] did not disclose a structure that included portions of a rigid body branching from wall portions, as recited in the claims. Ex. 1102, 632–633. Applicants simply stated this conclusion without further elaboration.

d. Construction of "Branching"

We determine that the construction of the term "branching" that stays true to the claim language, most naturally aligns with the patent's written description of the invention, and is consistent with the other evidence discussed above is simply "extending."

[14] For reasons not explained in the materials filed by Petitioner, the Dreyfuss reference submitted by Petitioner as an exhibit in this proceeding (Ex. 1111) is U.S. Patent App. Pub. No. 2003/0065361. *See, e.g.*, Paper 33, 2. The Dreyfuss reference applied by the Examiner, however, was U.S. Patent No. 6,652,563, the patent that issued from U.S. Patent App. Pub. No. 2003/0065361. Ex. 1102, 494 ("Claims 1, 12, 13, 22, 24, and 28-37 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over *Dreyfuss (6,652,563)* in view of Grafton et al. (5,964,783)." (emphasis added)). We have added the Dreyfuss patent to our record as Ex. 3005.

7. Integral to Define a Single-Piece Component

We addressed the construction of the term "rigid support" above. Claim 11 recites that the claimed "rigid support" is "integral with the anchor body to define a single-piece component." Ex. 1101, 8:45–46. Claim 10 does *not* have a similar limitation. We now address the construction of an "integral . . . single-piece component."

Petitioner asserts that the broadest reasonable interpretation of the phrase "a rigid support integral with the anchor body to define a single-piece component is "a rigid support formed together with the anchor body as a unitary structure." Pet. 22. Petitioner relies on the prosecution history for evidentiary support, asserting that the Applicants argued that this phrase "cannot cover separately formed components that are somehow joined together, even by ultrasonic welding, and instead requires the stated elements to be formed as a unitary structure." *Id.* at 23–24 (citing Ex. 1103 ¶¶ 133-36). The cited testimony of Mr. Ritchart merely repeats Petitioner's argument.

Patent Owner agrees with Petitioner's proposed construction and prosecution history analysis (PO Resp. 16–17).

Accordingly, we adopt the agreed upon construction. The phrase "a rigid support integral with the anchor body to define a single-piece component" means a rigid support formed together with the anchor body as a unitary structure.

8. Helical Thread

Claim 10 recites that "a helical thread defines a perimeter at least around the proximal end of the anchor body." Ex. 1101, 8:7–8. Claim 11 does *not* include the "helical thread" term.

Mr. Ritchart testifies as to the basic types of insertion and fixation mechanisms used in suture anchors at the time of the claimed invention. Ex.1103 ¶¶ 46–58. These included screw-type anchors, which used helical threads, "much like the threads of a wood screw" (*id.* at ¶¶ 47–55); tap-in anchors, which are tapped into a predrilled hole in the bone with a hammer or by hand (*id.* at ¶¶ 56–57); and other anchors, which used a toggle-bolt design inserted into a pre-drilled hole in the bone, and a portion of the anchor rotated to lock the suture anchor within the bone hole (*id.* at ¶ 58).

a. Patent Owner's Proposal

Patent Owner proposes that the term "helical thread" should be interpreted to require a helical ridge or raised surface that *facilitates rotary insertion of the anchor body into bone* and serves to retain the anchor in bone. PO Resp. 15 (citing Ex. 2010 ¶ 119 (emphasis added)). The cited testimony of Dr. Gall is that "'[t]hread' is understood by those skilled in the art as an inclined surface that facilitates advancing one object (e.g., a screw) into another (e.g., a hole) using a relative rotary motion to achieve longitudinal displacement." Ex. 2010 ¶ 119. Dr. Gall concludes that the term "helical thread" means "a helical ridge or raised surface that facilitates rotary insertion of the anchor body into bone and serves to retain the anchor in bone." *Id.* at ¶120.

Dr. Gall also testifies that he has reviewed the Oxford Dictionary (Ex. 2008) and the Machinery Handbook (Ex. 2009) definitions of "thread",

which he found to be "consistent with my understanding of how a POSA interprets that term." Ex. 2010 ¶ 118.

Relevant to the claimed technology, the Oxford Dictionary defines thread as "*a spiral ridge* on the outside of a *screw or bolt* or on the inside of a hole to allow two parts to be *screwed* together." Ex. 2008 (emphases added).

The Machinery Handbook defines thread as "a portion of a *screw thread* encompassed by one pitch." Ex. 2009 (emphasis added).

b. Petitioner's Proposal

Petitioner agrees that "'helical thread' means a 'helical ridge or raised surface' that 'serves to retain the anchor in bone,' but [Petitioner] disagrees with [Patent Owner's] assertion that it must 'facilitate rotary insertion.'" Pet. Reply 1. Petitioner also relies on dictionary definitions (*Id.* at 2 (citing Ex. 2009 and Exhibit 1155, 338)) and the declaration testimony of Dr. Slocum. *Id.* at 3 (citing Ex. 1165 ¶¶ 34–57).

The definition in Exhibit 2009, the Machinery Handbook, is stated above ("a portion of a screw thread encompassed by one pitch."). The cited page (338) of Exhibit 1155 is a dictionary definition of "screw thread." It defines "screw thread" as "[t]he ridge on the surface of a cylinder or cone produced by forming *a continuous helical or spiral groove* of uniform section and such that the distance between two corresponding points on its contour measured parallel to the axis is proportional to their relative angular displacement about the axis." Ex. 1155, 338 (emphasis added).

These various dictionary definitions suggest that, in the context of the relevant technology, the word "thread" is generally understood to suggest a spiral or helical thread of a screw. Although dictionaries may be helpful in

claim interpretation in some cases, the use of a dictionary definition can conflict with a correct claim construction because "there may be a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all *possible* definitions for particular words. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (emphasis added). The broadest *reasonable* interpretation differs from the "broadest *possible* interpretation." *In re Smith Int'l.*, No. 2016-2303, slip op. at 13.

Dr. Slocum's testimony on behalf of Petitioner relies on the dictionaries cited above and other dictionaries. Ex. 1165 ¶¶ 54–57. He also relies on three prior art patents. *Id.* at 34–53. Dr. Slocum concludes that although "a helical thread may be used to facilitate rotary insertion of an anchor body into bone, the BRI of helical thread is not limited to that particular function." Ex. 1165 ¶ 36. Dr. Slocum states that it was "known in the art that *helical* threads were appropriate for use with suture anchors that were *not rotated* into bone." *Id.* (emphasis added).

(1) Dr. Slocum's Review of Prior Patents

Dr. Slocum testified about three prior art patents that he states support his opinion that "it was "known in the art that helical threads were appropriate for use with suture anchors that were not rotated into bone." The three patents are Curtis (Ex. 1107), McDevitt (Ex. 1149), and Nicholson (Ex. 1161). We discuss Dr. Slocum's analysis of these three patents below.

Curtis (Ex. 1107) is asserted as a reference in this proceeding. Curtis is discussed in detail below in Section II.C.1. Curtis discloses a suture anchor that "presses" protrusions or barbs into bone to thereby fix the anchor in the bone. Ex. 1107, 2:34–38. Dr. Slocum (Petitioner's expert) testifies

that he agrees with Dr. Gall (Patent Owner's expert) that Curtis discloses anchors that "are intended to be inserted, *not rotated*, into a bone hole." Ex. 1165 ¶ 40 (emphasis added). Dr. Slocum notes that although Curtis is *not* rotated, Curtis discloses the use of "protrusions" that may be "*threads* or barbs." *Id.* at ¶ 41 (citing Ex. 1107, claim 7 (emphasis added)).

Curtis discloses "protrusions 5, in the form of barbs distributed over the full length of the main body to facilitate retention of the suture anchor in cortical bone or cortical and cancellous bone." Ex. 1107, 2:20–23. The written description in Curtis does *not* disclose that the "protrusions" can take any form other than "barbs." The written description does not mention "threads." Nonetheless, claim 7 in Curtis claims that the "protrusions" recited in claim 6 are "threads or barbs." *Id.* t 4:9-12. Neither the drawings nor the written description in Curtis show or describe protrusions, whether considered to be threads or barbs, that are "helical," as recited in challenged claim 10 of the '541 patent.

As described above, the cited dictionary definitions suggest that a person of ordinary skill would understand that the word "thread" in Curtis' claim 7 is a spiral or helical thread.

Thus, we find that Curtis supports Dr. Slocum's opinion that it was known in the art that *helical* threads were appropriate for use with suture anchors that were pressed, *not rotated*, into bone.

Dr. Slocum also testifies that the McDevitt patent (Ex. 1149), which is "a two part device with an interior stem (2) and an outer or expanding sleeve (4)" (Ex. 1165 ¶ 44), and uses "protrusions" in the form of "threads" (*id.* at ¶ 45) to secure the anchor in a "predrilled bone hole" (*id.* at ¶ 46). We note that McDevitt discloses that the anchoring element 4, which is the

expanding sleeve, may have "protrusions 53 that may take the form of ribs, *threads*, a plurality of raised points or other shapes." Ex. 1149, 6:39–42 (emphasis added). According to Dr. Slocum, the McDevitt patent "is secured in the bone hole when the stem is pulled proximally drawing the larger diameter portion of the stem into the sleeve thereby forcing the sleeve to expand into contact with the surrounding bone." *Id.* at ¶ 44.

As discussed above, the cited dictionary definitions suggest that a person of ordinary skill would understand that the word "thread" in McDevitt is a spiral or helical thread.

Thus, we find that McDevitt also supports Dr. Slocum's opinion that it was known in the art that *helical* threads were appropriate for use with suture anchors that were not rotated into bone.

Dr. Slocum states that Nicholson (Ex. 1161) discloses an expandable suture anchor that uses screw threads to engage the bone. Ex. 1165 ¶ 51. As summarized by Dr. Slocum, Nicholson states that "*the threads are not used for turning the expandable member into the bore*." *Id.* (citing Ex. 1161, 18:39-40 (emphasis added)). Rather than turning the screw threads to facilitate engagement of bone, the screw threads "facilitate deformation of the outer portion of the member [only after] the member is expanded within the bone hole." *Id.* (citing Ex. 1161 at 18:39-46.).

Thus, we find that Nicholson supports Dr. Slocum's opinion that it was known in the art that *helical* screw threads were appropriate for use with suture anchors that were not rotated into bone.

Based on this analysis, Dr. Slocum opines that a person of ordinary skill in the relevant technology would understand that the "*helical thread*"

recited in claim 10 "need not facilitate rotational insertion of an anchor into bone." *Id.* at ¶ 53 (emphasis added). We agree with this analysis.

Neither Petitioner nor Dr. Slocum discuss the Specification of the '541 patent in their claim construction analysis of "helical thread."

We turn to the claim language and the Specification for guidance in completing our interpretation of the term "helical thread."

c. The Claim

Claim 10 does not refer to "rotary insertion." It does, however, refer to a structural feature that facilitates insertion. Specifically, claim 10 recites "a driver including a shaft having a shaft length" that engages the anchor body. Ex. 1101, 8:25–26. Claim 10 does not recite the purpose or function of the driver. To understand the purpose or function of the claimed driver, we turn to the written description in the Specification.

d. The Specification

The phrase "helical thread" or the word "helical" does not appear in the written description. Figures 1 and 5, however, shown below, clearly illustrate a thread that is helical.

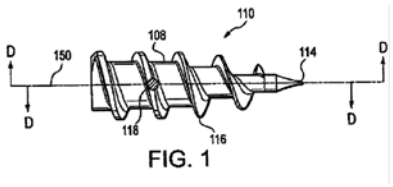


FIG. 1

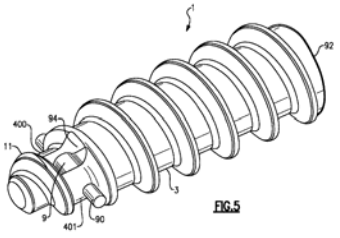


FIG.5

Figures 1 and 5 of the '541 patent illustrating a helical thread around the perimeter of a suture anchor body.

The helical thread shown in Figures 1 and 5 illustrate one form of retaining the anchor in bone. An alternative embodiment, shown in Figures

9–12, discloses "a push-in suture anchor 20" as an alternative to rotary insertion using helical threads. *Id.* at 6:9–10.

As explained in the written description, suture anchor 110, shown in Figure 1, is installed using driver 202 "to drive the anchor into bone." Ex. 1101, 4:11–13. The written description also states that "driver 202 is *rotated* to drive the anchor 110 into the bone until the proximal surface of the anchor 110 is flush with the surface of the bone." *Id.* at 5:3–5 (emphasis added). As an alternative retaining structure, the suture anchor "need not be formed as a threaded device, but can also be formed as a tap-in type anchor." *Id.* at 4:35–37. Thus, the Specification, like Mr. Ritchart's testimony discussed above, draws a distinction between a screw-type anchor with helical threads, and a tap-in type anchor.

A similar description is provided for retaining suture anchor 1, shown in Figure 5. Suture anchor 1 is installed using driver 300. *Id.* at 5:64. The distal end of driver 300 is inserted into proximal end 92 of anchor 1, and driver 300 is *rotated* to drive anchor 1 into the bone until the proximal surface of anchor 1 is flush with the surface of the bone. *Id.* at 6:4–8. The same alternative retaining structure is disclosed for suture anchor 1 in Figure 5. *Id.* at 5:58–62 ("the suture anchor also need not be a threaded device, but can also be formed as a tap-in type anchor.").

In light of the alternative "tap-in" insertion disclosed in the Specification, and the substantial evidence discussed above from Dr. Slocum regarding threaded anchors that are *not* inserted by a rotary motion, we are not persuaded that the "rotational" driver disclosed in the Specification should be read into the claim term "helical thread" to require rotary insertion of the claimed anchor. Various drivers were known in the art. Curtis,

discloses the use of a "manipulation instrument" for installing the suture anchor, but does not provide details about its use or structure. Ex. 1107, 2:23–26. Non-rotary drivers were known in the art for inserting anchors. *See* DiPoto, Ex. 1125, 6:12–16 ("The anchor 16 is then forced axially into the hole by, for example, the surgeon tapping on the end of the driver with a mallet or the like. It is not necessary to rotate the assembly in order to install it in position."). DiPoto (Ex. 1125) is discussed in detail in Section II.D.2 below.

In accord with settled practice, "we construe the claim as written, not as the patentees wish they had written it." *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F. 3d 1371, 1374 (Fed. Cir. 2004).

e. Construction of "Helical Threads"

We determine that the construction of the term "helical threads" that stays true to the claim language, most naturally aligns with the patent's written description of the invention, and is consistent with the other evidence discussed above is the construction proposed by Petitioner – a helical ridge or raised surface that serves to retain the anchor in bone.

9. Summary of Claim Constructions

The following is a summary of our claim constructions:

"suture opening" and "suture passage" – a space through which a suture passes;

"rigid support" – an inflexible part of the suture anchor that supports a tissue securing suture;

"central passage" – a pathway through the center of the anchor body;

"branching" – extending;

a rigid support "integral with the anchor body to define a single-piece component" – a rigid support formed together with the anchor body as a unitary structure; and

"helical threads" – a helical ridge or raised surface that serves to retain the anchor in bone.

We now address the grounds of unpatentability on which we instituted trial.

B. Obviousness in View of Gordon and West (Claims 10 and 11)

Petitioner asserts that the subject matter of claims 10 and 11 would have been obvious to a person of ordinary skill in the art in view of Gordon and West. Pet. 24–43.

Section 103(a) "forbids issuance" of a patent when "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." *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) when available, secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); see *KSR*, 550 U.S. at 407 ("While the sequence of these questions might be reordered in any particular case, the [Graham] factors continue to define the inquiry that controls."). The Court in *Graham* explained that these factual

inquiries promote "uniformity and definiteness," for "[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context." *Id.* at 18.

The Supreme Court made clear that we apply "an expansive and flexible approach" to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id*. at 417. To reach this conclusion, however, it is not enough to show merely that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc*., 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention "would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention." *Id*.

Moreover, in determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Litton Indus. Products, Inc. v. Solid State Systems Corp*., 755 F.2d 158 (Fed. Cir. 1985) ("It is elementary that the claimed invention must be considered as a whole in deciding the question of obviousness."); *see also Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1537 (Fed. Cir. 1983) ("the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious. Consideration of differences, like each of the findings set forth in Graham, is but an aid in reaching the ultimate determination of whether the claimed invention as a

whole would have been obvious.").

"A reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect." *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).

As a factfinder, we also must be aware "of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *KSR*, 550 U.S. at 421. This does not deny us, however, "recourse to common sense" or to that which the prior art teaches. *Id.*

Against this general background, we consider the references, other evidence, and arguments on which the parties rely.

1. Scope and Content of the Prior Art

a. Gordon (Ex. 1105)

Gordon discloses devices and methods for securing sutures to a bone anchor without the requirement of knot tying. Ex. 1105 ¶ 24. The disclosed knotless anchor includes a bone engaging mechanism, a suture tensioning mechanism, and a suture locking mechanism. *Id.* at ¶ 26.

The bone engaging mechanism includes a helical threaded surface on its distal end that is rotatable to engage adjacent bone. *Id.* at ¶ 31. Figure 23 from Gordon is shown below.

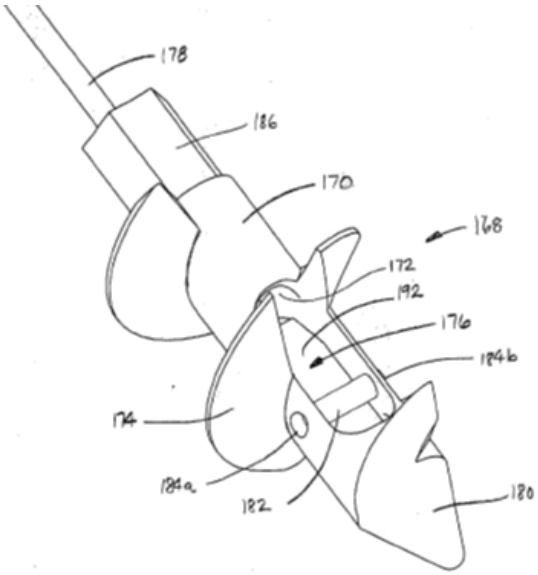


Figure 23 from Gordon is a perspective view of a suture anchor. As shown, the suture anchor includes anchor body 170 and a "lumen" or bore 172 formed through anchor body 170. Ex. 1105 ¶ 84. Bore 172 is shown more clearly in Figure 25A, which is reproduced below.

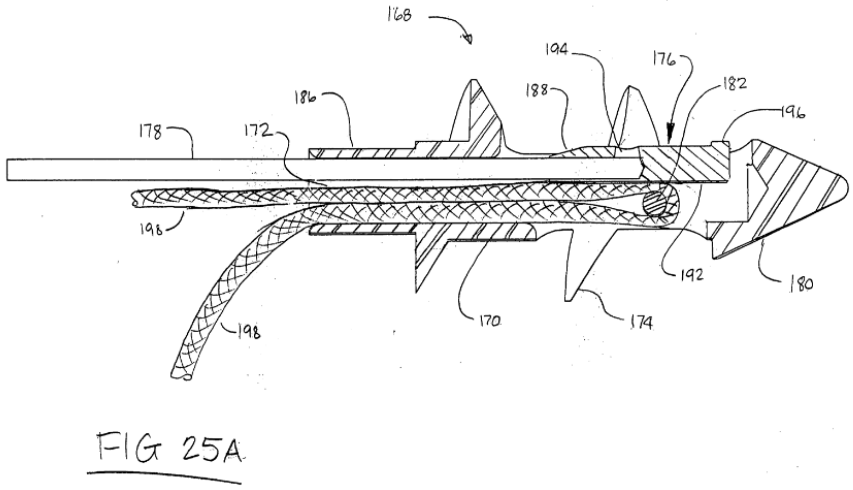


Figure 25A from Gordon is a cross-sectional view of the suture anchor shown in Figure 23.

As shown in the figures above, the Gordon suture anchor includes screw threads 174, "suture locking plug" 176, and "suture lock cable" 178. *Id.* Suture anchor body 170 also includes "pulley" 182. *Id.* Pulley 182 is

disposed in holes 184a and 184b (*see* Fig. 23). Gordon does not elaborate further on the specific structure of pulley 182. Further elaboration of the pulley structure is provided, however, in then pending patent application No. 09/781,793, which Gordon incorporates by reference. *Id.* at ¶¶ 25, 83. This application was published as U.S. Pub. No. 2002/0111653 ("Foerster"), which is Exhibit 1108 in this proceeding.

Foerster, incorporated by reference into Gordon, discloses a suture pulley fixed with respect to the anchor body such that a length of suture may be introduced into the lumen from the proximal end, looped around pulley, and passed out of lumen through the proximal end. Ex. 1108 ¶ 22. The suture pulley may be "*formed in*" a sidewall of the lumen. *Id.* at ¶ 24 (emphasis added). Where the anchor body is tubular, the suture pulley is desirably disposed at a distal end of the tubular body as a rod transverse to the lumen axis. *Id.* The rod may rotate with respect to the anchor body, or may be fixed. *Id.* Instead of a rod, the pulley may comprise a bridge formed between two spaced apertures at the distal end of the tubular body. *Id.*

Foerster, incorporated by reference into Gordon, discloses specifically that pulley 70 "comprises a pin oriented transversely to the axis of the suture anchor 46 and located along a sidewall thereof." Ex. 1108 ¶ 70. As shown in Figure 4A of Foerster, pin 70 may span axial slot 100 or lumen in a sidewall of anchor body 54. *Id.* Foerster also discloses that, alternatively, two axially spaced holes with chamfered or rounded edges may be formed in the sidewall of the anchor body 54 through which the free ends 34a, 34b can be threaded. *Id.* Foerster also discloses that pin-type pulley 70 can be formed separately from anchor body 54, and then be inserted within a pair of facing holes in the edges of the slot or lumen 100 so that pin-type pulley 70

rotates within the holes, thus reducing friction between the free ends 34a, 34b and the pulley. *Id.*

Returning to the Gordon reference, Gordon discloses that a driver, such as hex drive 186, is used to screw suture anchor 168 into bone for the purpose of creating a suture attachment point. Ex. 1105 ¶ 84. Screw threads 174 retain suture anchor 168 in the bone. *Id.*

The suture material, shown as suture strand 198, is threaded in lumen or bore 172 and around pulley 182. Ex. 1105 ¶ 86. As shown in Figure 25A, there is clearance between the walls of lumen 172 and suture strand 198 that allow suture strand 198 to move freely within lumen 172 and around the pulley 182. *Id.* at ¶ 87.

The next step in Gordon is to provide tension to the suture strand using the suture tensioning mechanism. In this step, the suture may be "tensioned" to approximate the soft tissues to be attached to the bone. *Id.* The tensioning step involves the surgeon tensioning the suture "in order to approximate the tendon 22 to the adjacent bone." *Id.* at ¶ 74; *see also id.* at ¶ 75 ("thus cinching the suture in order to tension it and therefore approximate the tendon 22 to the bone 26"). When the suture is cinched to a desired level, the "suture cinching mechanism" will "maintain the suture tension." *Id.* at ¶ 75. Thus, a tension load is applied and maintained on the pulley.

The next step is to lock the suture stands in place with the suture locking mechanism. Suture locking plug 176 includes tapered locking surface 192 (*see* Figs. 25A, B, C), weld hole 194, and travel stop 196. Ex. 1105 ¶ 85. Suture lock cable 178 is inserted into locking plug 176 so that the distal end of cable 178 is visible through weld hole 194. *Id.* Suture lock

cable 178 and locking plug 176 may be joined together using a weld in weld hole 194 or by other suitable means. *Id.* As described below, however, the connection between lock cable 178 and locking plug 176 is breakable; the two parts separate on actuation of the suture locking mechanism.

The suture locking mechanism is actuated by pulling on suture lock cable 178. *Id.* The suture locking plug is movable within the lumen from a first position to a second position. The suture locking plug does *not* interfere with axial movement of the length of suture in the first position and does interfere with axial movement of the length of suture in the second position, by compressing the length of suture against the anchor body.

As shown in figure 25B, when actuated, locking plug 176 is forced into the lumen 172. At this point, tapered locking surface 192 is in intimate contact with suture strand 198. *Id.* Locking plug 176 fills lumen 172 such that a frictional lock between lumen 172, plug 176, and suture 198 is created. *Id.*

As indicated in Figure 25C by the absence of suture lock cable 178, cable 178 includes a point of tensile weakness permitting it to be detached from the locking plug. Once actuated and pulled as described above, suture lock cable 178 is no longer attached to plug 176. Ex. 1105 ¶ 88. The frictional force between lumen 172, plug 176, and suture 198 overcomes the tensile strength of the weld or other attachment, described above, between lock cable 178 and plug 176. *Id.* This leaves knotless suture anchor 168 and suture 198 in place, securing the tissues. *Id.* Travel stop 196 is disposed on plug 176 to prevent it from being pulled completely through lumen 172. *Id.*

b. West (Ex.1106)

Figure 1 of West is shown below.

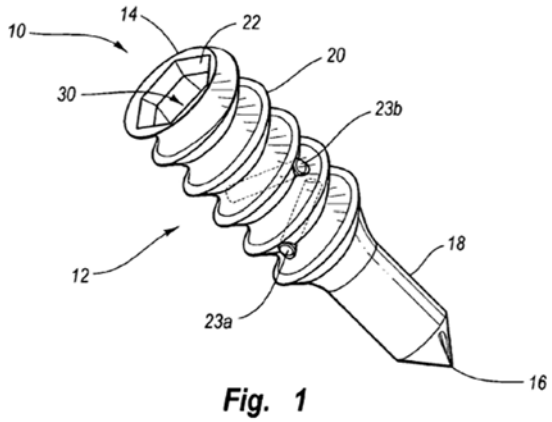


Fig. 1

Figure 1 from West is a perspective view of a suture anchor.

As shown in Figure 1, West discloses suture anchor 10 having hollow anchor body 12 that extends between proximal end 14 and a distal end 16. Ex. 1106, 4:39–41. Distal end 16 has a non-threaded portion that forms stabilizing extension 18 that prevents lateral movement of anchor body 12 within bone tissue. *Id.* at 4:41–44. Anchor body 12 also has a threaded portion, which includes threads 20 for engaging bone tissue. *Id.* at 4:44–46.

Proximal end 14 includes opening 30, which provides access to hollow interior bone 30 of anchor body 12. *Id.* at 4:4447–48. Hex socket 22 is formed in bore 30, which allows suture anchor 10 to be driven into a bone using a hex driver. *Id.* at 4:48–51.

Transverse pins 23a and 23b are disposed through anchor body 12 and provide attachment points for sutures. *Id.* at 4:53–55. Pins 23a and 23b are *formed or inserted in* anchor body 12 lying across bore 30. *Id.* at 5:58–60 (emphasis added). West discloses that in manufacturing bone anchor 10,

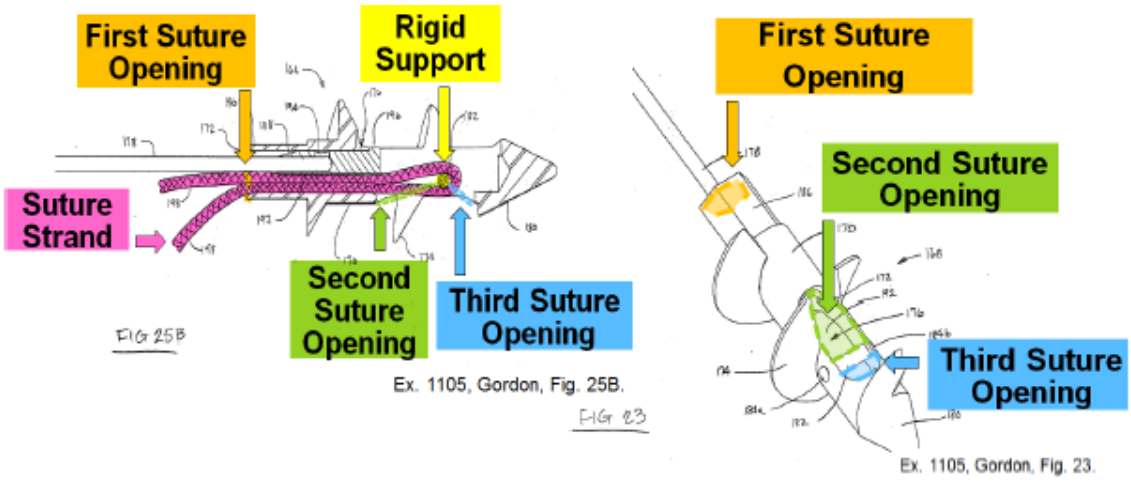
> anchor body 12 and posts 23 can be *cast and formed in a die*. *Alternatively* anchor body 12 can be cast or formed and posts 23a and 23b *inserted later*. For instance, anchor body 12 can be cast and formed from PLLA. Anchor body 12 can then be drilled to prepare holes for stainless steel pins 23a and 23b.

Id. at 7:41–47 (emphases added). The alternative option described in the second sentence, that the pins are "inserted later," suggests that the primary option, described in the first sentence, does *not* have the pins inserted later.

Pins 23a and 23b are placed below hex socket 22 so a hex driver can be inserted without hitting the pins. *Id.* at 6:20–22. An advantage of this position for the pins is that forces applied by sutures 36 are transferred to a more central location within anchor body 12, and thus these forces are less likely to cause anchor 10 to become loosened or dislodged. *Id.* at 6:17–20. Although West discloses and illustrates the use of two pins, West also discloses more or fewer pins may be used depending on the required number of sutures and/or the space available within bore 30 for placing more sutures. *Id.* at 6:26–36.

2. Differences Between the Claimed Subject Matter and the Prior Art

Petitioner asserts that Gordon discloses a suture anchor having an anchor body with a central passage, a rigid support for the suture, a suture, and three openings, as depicted in Petitioner's annotated versions of Figures 25B and 23 of Gordon, reproduced below:



Pet. 33. Petitioner's annotated version of Figure 25B depicts a cross section of Gordon's anchor. Petitioner's annotated version of Figure 23 depicts a perspective view of Gordon's anchor.

According to Petitioner, two claim elements are missing from Gordon. The first missing element is helical threads defining a perimeter at least around the proximal end of the anchor body. Pet. 28. In Gordon, the proximal end of the anchor body is a male drive head, precluding the presence of threads at the proximal end. *Id.*; *see, e.g.*, Ex. 1105, Fig. 23. Petitioner asserts that substituting an internal hex drive socket, as shown in West, would allow for the presence of threads on the proximal end, and would have been a known and predictable substitution. Pet. 28. Further, the socket in West "provides the bone anchor with the ability to better engage the cortical bone near the surface of the bone," due to the extra threads. Ex. 1106, 2:65–67; Ex. 1103 ¶¶ 162–166.

The second missing element, according to Petitioner, is to manufacture Gordon using a casting process, such as to make the rigid support (the pin around which the suture is threaded) an integral component of the anchor body. Pet. 28–30. This identified difference is relevant only to claim 11, which recites that the rigid support is "integral with the anchor body to define a single-piece component." Petitioner asserts it would have been obvious to manufacture Gordon's suture anchor by forming anchor body 170 and pulley 182 in Gordon (i.e., the asserted "rigid support") using a casting process. *Id.* at 28. According to Petitioner, the "casting process" would have resulted in pulley 182 being "integral" with anchor body 170 and a pulley integral with the anchor body as a "fixed structure." *Id.* at 29 (citing Ex. 1103 ¶ 167).

We note, however, that claim 11 does not recite or otherwise refer to a "casting process." It recites only "a rigid support integral with the anchor body to define a single-piece component." Ex. 1101, 8:45–46. The only reference to casting in the Specification is that "[i]n manufacturing the suture anchor 110 in accordance with the present invention, the anchor body 108 is cast in a die, with the bores, passageways and apertures described above either being formed during the casting process or formed afterwards." *Id.* 4:42–46.

According to Petitioner, West describes a similar anchor body having pins over which sutures are threaded, and that West describes making the anchor using a casting process. *Id.* at 28–29. Petitioner also asserts that this implementation is consistent with Gordon because Gordon incorporates Foerster, which describes how a pulley (like Gordon) may be a "fixed structure." *Id.*

Concerning a rationale for the proposed modifications, Petitioner asserts several other reasons to cast the structures, because it would minimize the materials used (allegedly useful in FDA approvals), because casting was well known, and because this would be more secure than an attached support. *Id.* at 29–30 (citing Ex. 1103 ¶¶ 169–171, 210).

Patent Owner takes a different view of the scope and content of the asserted references, the differences between the asserted references and the claimed invention, and the asserted reasons for combining the references, which we address in detail below.

3. Discussion

a. Helical Threads Around the Proximal End (Claim 10)

Claim 10 recites that "a helical thread defines a perimeter at least around the proximal end of the anchor body." According to Petitioner, "[t]he only feature [recited in claim 10] arguably not expressly disclosed in Gordon" is the "helical thread" limitation. Pet. 30.[15]

To provide screw threads at the proximal end requires an internal hex drive, as disclosed in West, rather than an external hex drive as disclosed in Gordon. *See* Ex. 2010 ¶ 162 (Petitioners' proposed modification "seeks to replace the external hex drive 186 from Gordon with an internal hex socket 22 from West. Petitioners make this modification in order to incorporate the threads 20 from West at the proximal end of the anchor 168 in Gordon." (citations omitted)).

The benefits of having a proximal end socket are known. The background portion of West explains:

> Bone anchors can fail for various reasons. One reason is that existing bone anchors are not threaded to the proximal end of the anchor where the anchor meets the surface of the bone in the hard cortical bone region. In existing bone screws, the proximal end is not threaded because the driver tool used to insert the bone anchor fits over a hex shaped protrusion. The hex protrusion cannot extend above the bone surface so the screw is driven into the bone until the protrusion is below the surface. Since the protrusion has no threads, the bone anchor does not engage the bone near the surface, but only the soft cancellous bone beneath the cortical bone layer. This feature of existing

[15] Petitioner also asserts that "this limitation is arguably met by Gordon alone" (Pet. 30, fn3) but, nonetheless, challenges patentability of claim 10 in this ground only based on Gordon and West.

> bone anchors is very problematic because it prevents a practitioner from placing the threads of the bone anchor in the harder cortical bone, which is near the bone surface.

Ex. 1106, 1:50–64.

Patent Owner asserts Gordon is limited to inserting the suture anchor in "cancellous bone" completely below the "cortical bone" surface. PO Resp. 19. Cortical bone is the tough, dense outer layer of bone, whereas cancellous bone is the less dense, airy and somewhat vascular interior of the bone. Ex. 1105 ¶ 10. There is a clear demarcation between the cortical bone and cancellous bone; the cortical bone presents a hard shell over the less dense cancellous bone. *Id*. Patent Owner's clear implication is that there is no reason for Gordon to have threads around the proximal end of the anchor body.

We note that the '541 patent does not mention the word "cortical" or "cancellous" in the Specification or claims. The '541 patent written description refers only to "bone." E.g., Ex. 1101, 1:25–26 ("The present invention relates to an apparatus for anchoring surgical suture to bone."). The '541 patent does not differentiate between cortical and cancellous bone. The word "bone" does not appear in either claim 10 or 11.

The patentability issue presented is not solely on what Gordon or West discloses or requires individually. The patentability issue is whether claim 10 would have been obvious based on the combined teachings of Gordon and West.

Gordon and West each disclose a "suture anchor" assembly, which is what is claimed. Gordon and West also each disclose the use of screw threads to retain the suture anchor in bone; they each disclose the use of a suture strand threaded through a central passage of the anchor body; they

each disclose use of a driver for inserting the screw anchor; and they each disclose a structure for supporting the suture strand within the anchor body.

Patent Owner's criticism of the proposed combination fails to consider that the determination of whether a claimed invention would have been obvious is based on what the combined teachings of the references would have suggested to those of ordinary skill in the art. *MCM Portfolio LLC v. Hewlett-Packard Co*., 812 F.3d 1284, 1294 (Fed. Cir. 2015) ("[W]e have consistently held, as the Board recognized, that '[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; *nor is it that the claimed invention must be expressly suggested in any one or all of the references*. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.'" (citations omitted; emphasis added)).

Moreover, *KSR* does not require that a combination only unite old elements without changing their respective functions. *KSR*, 550 U.S. at 416. Instead, *KSR* teaches that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id*. at 421. And it explains that the ordinary artisan recognizes "that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id*. at 420. The rationale of *KSR* does not support a theory that a person of ordinary skill can only perform combinations of a puzzle element A with a perfectly fitting puzzle element B. *ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1219 (Fed. Cir. 2016). To the contrary, *KSR* instructs that the obviousness inquiry requires a flexible approach. *KSR*, 550 U.S. at 415.

When we apply this flexible approach to the evidence discussed above, we find that the combination of Gordon and West would have resulted in no more than a predictable result. *Id.* at 417 ("a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.").

Also, we consider the proposed combination from the viewpoint of a person of ordinary skill in the relevant technology. Here, that person is highly educated and skilled; an engineer or a medical doctor. The evidence does not support that such a highly skilled person would ignore a disclosure based on whether it was directed primarily to a suture anchor for cortical bone or a suture anchor for cancellous bone. Both are suture anchors, as is the claimed invention. We are persuaded that a suture anchor designer of ordinary skill and creativity, facing the wide range of needs and design options known in this technological field, would have found it would have been obvious, based on the disclosure in West, to provide Gordon with helical threads that a define a perimeter at least around the proximal end of the anchor body, as recited in claim 10.

b. Rigid Support

Patent Owner asserts that "the rigid support of claim 10 is missing from Petitioners' proposed combination because Gordon's pulley is not a rigid support as required by claim 10. Without that in the proposed combination, Claim 10 cannot be considered obvious." PO Resp. 21. Patent Owner asserts two reasons why the claimed rigid support is missing from Gordon.

First, Patent Owner asserts that Gordon's pulley 182 does not meet the "branching" requirement of claim 10. *Id.* We disagree.

Patent Owner acknowledges that Gordon's pulley 182 "extends across the central passage (lumen 172) and has a first portion (one end of pulley 182) and a second portion spaced from the first portion (the other end of pulley 182)." *Id.* Patent Owner asserts, however, that "[s]imply extending across a gap is not enough to satisfy the more specific claim language." *Id.* at 22 (citing Ex. 2010 ¶¶ 115-16). In our claim construction of the term "branching," we reached a contrary determination. We found that "branching" means "extending." Applying this construction to Patent Owner's recognition that Gordon's pulley 82 extends across the central passage defined by lumen 172 establishes that Gordon's pulley or rigid support meets the requirements for the claimed "branching" of the rigid support from sidewalls of the anchor body.

Second, Patent Owner asserts that Gordon's pulley 182 does not, in fact, support any load placed on it by the suture. PO Resp. 24. According to Patent Owner, after Gordon's anchor is installed, locking plug 176 clamps and frictionally locks the suture strand in place. *Id.* Patent Owner asserts that this results in the portion of suture that is looped around pulley 182 being isolated from any load on the suture. *Id.* We disagree. Pulley 182 is *not* isolated from *any* load on the suture.

Based on the clear disclosure in Gordon, discussed above, the suture in Gordon is placed under tension in order to approximate the tension existing when a tendon is connected to the adjacent bone, and this tension is maintained on the pulley. Ex. 1105 ¶¶ 74–75; *see also id.* ¶ 87 (describing that in the configuration in which suture strand 198 has been positioned around pulley 182, "the suture may be tensioned as previously described to

approximate the soft tissues to be repaired to the bone or other tissues."). Thus, the pulley clearly is able to support this load.

We defined "rigid support" to mean an inflexible part of the suture anchor that supports a tissue securing suture. We also explained that by including the phrase "tissue securing," the adopted construction recognizes the fundamental purpose of the disclosed and claimed invention is to mechanically reattach soft tissue to its supporting bone. Thus, the support provided to the suture is support sufficient for that suture to secure tissue to bone. This is the tension or load applied to pulley 182 in Gordon – a load that approximates the load sufficient to secure tissue to bone.

The experts disagree as to whether Gordon's pulley does, or does not, provide support sufficient for the suture to secure tissue to bone.

Petitioner's expert, Mr. Ritchart testified that Gordon's pulley "is inflexible *in order to keep a suture in a fixed position* and to withstand the *cyclical* loads placed upon the pulley after the anchor has been installed in a patient. He concluded that pulley 182 is thus a "rigid support" under the BRI." Ex. 1103 ¶ 187 (emphasis added). We note that the claims do not recite any requirement that the rigid support is the structure that keeps a suture in a *fixed* position or that the rigid support withstand *cyclical* loads.

Patent Owner's expert, Dr. Gall, is of the opinion that "[t]he pulley 182 in Gordon is *not intended to bear any load* from the suture to secure the suture and soft tissue after the locking plug has been installed." Ex. 2010 ¶ 159 (emphasis added). Dr. Gall explains that "[t]his is the result of the locking plug 176 clamping and frictionally locking the suture against the inside of the anchor body in a position between the pulley and the tissue that

is being secured by the suture." *Id.* (citing Ex. 1105, ¶ 87). Dr. Gall concludes that "pulley 182 is not a 'rigid support.'" *Id.*

As explained above, Gordon discloses that the suture looping around pulley 182 is placed and maintained in tension to approximate the load between the tissue and bone. Thus, it is not accurate to state that pulley 182 in Gordon does not bear any load.

Thus, we agree with Petitioner that Gordon discloses a rigid support as claimed.

c. Integral (Claim 11)

Claim 11 recites "a rigid support integral with the anchor body to define a single-piece component." We construed this to mean a rigid support formed together with the anchor body as a unitary structure.

Patent Owner asserts that pulley 182 in Gordon is a separate piece attached to anchor body 170 and, therefore, is not integral with the anchor body to define a single-piece component. PO Resp. 36. Petitioner relies on West's disclosure that West's "anchor body 12 and posts 23 can be cast and formed in a die." Pet. 42–43 (citing Ex. 1106, 7:41-43; Ex. 1103, ¶¶ 205-10.

As stated above, West states clearly that "[i]n manufacturing bone anchor 10, in accordance with the present invention, anchor body 12 and posts 23 can be cast and formed in a die. Alternatively anchor body 12 can be cast or formed and posts 23a and 23b inserted later." This presents two clear alternatives – form anchor body 12 and posts 23 together, *i.e.*, as an integral component, or, alternatively, create them as separate components and insert the posts after the body is formed. Forming them integrally is consistent with the disclosure in Foerester, incorporated into Gordon, that

the suture pulley may be "*formed in*" a sidewall of the lumen. Ex. 1108 ¶ 24 (emphasis added).

Thus, we determine that West suggests that pulley 182 of Gordon can be formed integral with the suture anchor body, as recited in claim 11.

d. Rationale

Petitioner asserts that it would have been obvious to a person of ordinary skill to modify Gordon's suture anchor 168 to replace the external hex drive head 186 of Gordon with an internal hex drive socket, as taught by West. Pet. 28 (citing Ex. 1103 ¶¶ 162-71). The reason why this change would be made, according to Petitioner, is because it would allow Gordon's screw threads 174 to extend all the way to the proximal end of anchor body 170 and thus provide the bone anchor with the ability to better engage the cortical bone. *Id.* (citing Ex. 1106, 2:65-67). As we discussed above, West discloses the benefits of having a proximal end socket. *See* Ex. 1106, 1:50–64.

West also discloses the option of forming the rigid support, that is the pulley in Gordon or pins in West, integral with the body, or inserting the pins in the body after the body is formed. Choosing the preferred option would have been an obvious choice of the designer.

Patent Owner asserts that "the legally required rationale for the combination is missing." PO Resp. 21. According to Patent Owner, the proposed modification would interfere with Gordon's intended operation and result; there is no reasonable expectation of success; and there is no benefit to making the modification. *Id.* This assertion is based, in part, on Patent Owner's argument that Gordon is intended to be secured in the

cancellous bone, not cortical bone. This argument is not persuasive for reasons we have addressed above.

Patent Owner also argues that Gordon could not function if modified as proposed. *Id.* at 26–34. As we stated above, whether a claimed invention would have been obvious is based on what the combined teachings of the references would have suggested to those of ordinary skill in the art. *MCM Portfolio*, 812 F.3d at 1294. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. *Id.* Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *Id.* Moreover, a person of ordinary skill and creativity would recognize that familiar items may have obvious uses beyond their primary purposes, *KSR*, 550 U.S. at 420.

We recognize that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known. *Id.* at 418–419; *see also Metalcraft of Mayville, Inc. v. The Toro Company*, 848 F.3d 1358, 1367 (Fed. Cir. 2017) (holding it is not enough "to merely demonstrate that elements of the claimed invention were independently known in the prior art. Often, every element of a claimed invention can be found in the prior art."). For this reason, it is necessary to identify "why" a person of ordinary skill would have selectively gleaned some elements or structure from the

references relied on to come up with the limitations in the challenged claims. *Metalcraft v. Toro*, at 1366 ("In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason why a person of skill in the art would have made the combination.").

Here, as discussed above, West provides a persuasive rationale for "why" the proposed features would have been combined.

Before determining patentability of under Section 103, we consider the objective evidence presented by Patent Owner.

e. Objective Evidence

Patent Owner asserts that "secondary considerations" establish that the claims 10 and 11 would not have been obvious. PO Resp. 65–69.

Objective indicia of non-obviousness play an important role as a guard against the statutorily proscribed hindsight reasoning in the obviousness analysis. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). "[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). "[E]vidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." *Id*. at 1538. "For objective evidence . . . to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re Kao,* 639 F.3d 1057, 1068 (Fed. Cir. 2011) (quoting *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010)) (emphasis omitted) (internal quotation marks omitted).

Patent Owner offers evidence it asserts shows objective evidence of non-obviousness in the form of copying by competitors (PO Resp. 65–68), licensing (*id.* at 68–69), and commercial success (*id.* at 69).

(1) Copying

Patent Owner asserts seven competitors introduced suture anchors having the combination of features in the challenged claims after Patent Owner began selling its patented anchors: PO Resp. 65. To support its assertion, Patent Owner provides a chart comparing a figure from the '541 patent to pictures of alleged "copied designs." *Id.* at 66–67 (citing Ex. 2014). Exhibit 2014 is a claim chart comparing the alleged products that copied the '541 patented invention to claims 10 and 11. There is no identification of the source of this chart or the authenticity of the products identified on the chart.

Patent Owner states that each of the copied designs includes first, second, and third suture openings, threads to a proximal end, and a rigid support integral with the anchor body. *Id.* at 67 (citing "Gall ¶__." [sic]). Patent Owner also states there is a nexus (*id.*) but provides no evidence to support this argument. *Garrido v. Holt*, 547 F. App'x 974, 979 n.3 (Fed. Cir. 2013) (citing *In re Schulze*, 346 F.2d 600, 602 (CCPA 1965) ("Argument in the brief does not take the place of evidence in the record.")).

Moreover, for copying to be effective in showing non-obviousness, there must be more than simply a competing version of the product. *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Not every competing product that arguably falls within the scope of a patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent."). Evidence of

copying can be particularly persuasive when a competitor had tried and failed to introduce a competing product until the patented product became available. *Vandenberg v. Dairy Equipment Co., a Div. of DEC Int'l, Inc.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984). We have no such evidence in this case.

Merely offering competing products or alleging infringement are not signs of non-obviousness. *Wyers*, 616 F.3d at 1246. The secondary consideration of copying is very specific—"evidence of efforts to replicate a specific product." *Id.* This specifically is not evidence of efforts to provide a competing product or evidence of a product having the same features, or we would be reading out the crux of the basis for the court's reasoning in *Wyers*, that "[n]ot every competing product that arguably falls within the scope of a patent is evidence of copying." *Id.* Patent Owner's timeline of when competing products were introduced (PO Resp. 68) is not persuasive evidence of copying because the timeline does not indicate that the later introduced competing products were intended to replicate the subject matter of the '541 patent. Indeed, the timeline could just as readily support the notion that the competing products were intended to replicate features from Gordon (*see* Ex. 1105, Fig. 23) or other suture anchors (*see* Ex. 1103 ¶¶ 39–43 (illustrating and discussing numerous prior suture anchor designs)).

Here, we have no evidence of a nexus or of efforts to replicate a specific product. Thus, the evidence on which Patent Owner relies has no probative weight of copying.

(2) Licensing

Patent Owner argues we should "infer" from the fact that one license to Parcus Medical has been granted under the '541 patent that the one

license "was taken based on the merits of the claimed invention." PO Resp. 68. Again, Patent Owner provides no evidence to support this argued inference. Petitioner states Parcus's CEO testified that the license was executed to resolve litigation and "ninety-five percent" of the motivation was to avoid legal fees. Pet. Reply 31 (citing Ex. 1169).

Here, we have no evidence of a nexus of the one license to claims 10 and 11 of the '541 patent. Thus, the evidence on which Patent Owner relies has no probative weight of copying.

(3) Commercial Success

Patent Owner asserts the "'541 Anchors" were commercially successful. PO Resp. 69 (citing Ex. 2029 and "Ex. 2025, ¶#-#." [sic]). Exhibit 2029 is a Declaration of Christopher Holter, Patent Owner's Senior Director of Commercial Finance that reports quarterly sales data for certain product codes. No market share information is included, and there is no illustration or description of the products. Exhibit 2025 is a Declaration of Christopher Vellturo, a consultant retained by Patent Owner to "provide summaries and charts of sales data (as provided to [him] by Arthrex) for Arthrex suture anchor products made under U.S. Patent No. 8,821,541 (Claims 10 and 11)." Ex. 2025 ¶ 2. The graph and chart in Mr. Vellturo's declaration list the products that he "understand[s] . . . practice the '541 patent," but there is no depiction or description of those products, nor is there any analysis or explanation of why those products embody claims 10 or 11 of the '541 patent. *Id.* at 17–18. The only "[s]ource" listed for Mr. Vellturo's chart and graph is "Holter Declaration, Exhibit 1." *Id.*

Patent Owner also asserts "a nexus should be presumed because each of the '541 Anchors at issue are coextensive with at least one of claims 10

and 11." PO Resp. 69. But Patent Owner does not point us to evidence or explanation supporting its contention that the anchors embody claim 10 or 11 of the '541 patent. We have not been directed to persuasive evidence of any nexus between the Patent Owner's sales and the patented invention. Accordingly, the evidence of commercial success has no probative weight.

4. Conclusion Regarding Patentability of Claims 10 and 11 Based On Gordon and West

Based on the evidence and analysis above, we determine that a preponderance of the evidence establishes that claims 10 and 11 would have been obvious based on Gordon and West.

C. Anticipation by Curtis (Claim 11)

Petitioner asserts that claim 11 is anticipated by Curtis. Pet. 43–52.

> [U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.

Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008); *see also Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co*., 868 F.2d 1226, 1236 (Fed. Cir. 1989).

1. Curtis (Ex. 1107)

Curtis is titled "Expanding Suture Anchor." Ex. 1107. Figures 2 and 3 (annotated) from Curtis are shown below.

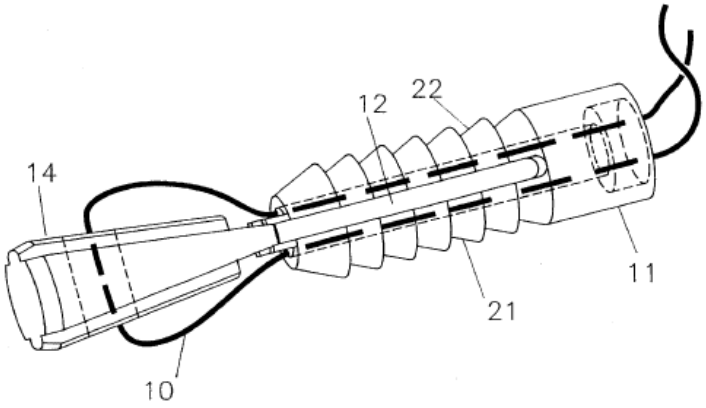


Figure 2 from Curtis is a perspective view of an expanding suture anchor after introduction of the suture.

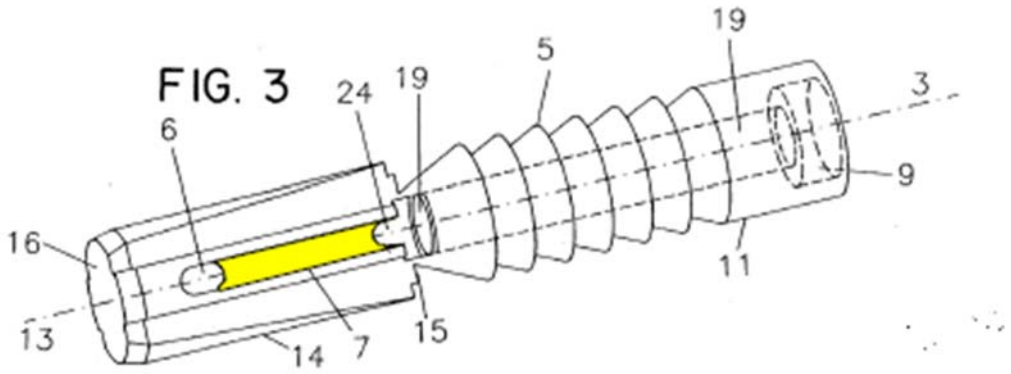


Figure 3 (annotated) from Curtis is a perspective view of the expanding suture anchor according to Figure. 1 rotated by 90°.

The disclosed suture anchor has a main body (11) and a conical body (14). *Id.* at Abstract; 2:16–17. Main body 11 is provided with protrusions 5, in the form of barbs or threads, distributed over the full length of the main body to facilitate retention of the suture anchor in cortical bone or cortical and cancellous bone. *Id.* at 2:20–23; claim 7 (4:11–12).

Main body 11 and conical body 14 may be either two distinct parts or, as shown in Figures 1 to 4, *temporarily* connected coaxially by an intermediate portion 20. Ex. 1107, 2:66–3:1. If temporarily connected, the two body parts are separated when inserted into bone. In use, as shown in Figure 5, main body 11 separates from conical body 14 at intermediate portion 20 so that conical body 14 enters slot 12, expands legs 21, 22 of main body 11, and thereby presses the protrusions or barbs into bone to thereby fix the anchor in the bone. *Id.* at 2:34–38.

Petitioner's argument is based on the one-piece configuration of the suture anchor *prior* to fixation in the bone. Pet. 44.

As shown in Figure 3, "through-hole" 6 is transverse to longitudinal axis 13·of conical body 14. Ex. 1107 2:40–42. Through-hole 6 is intended to receive a suture strand threaded through it. *Id.*

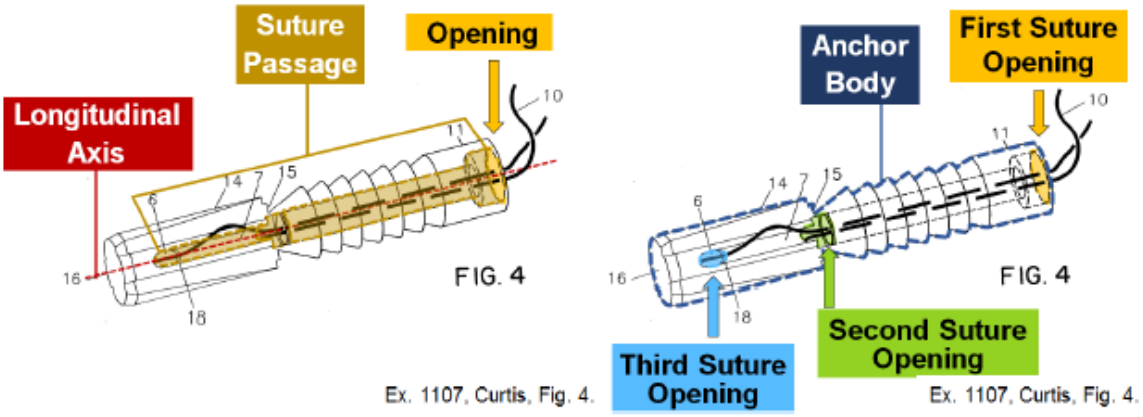
Two channels 7 are positioned on curved surface 17 of conical body 14. *Id.* at 2:47–48. Channels 7 extend from through-hole 6 to base 15. Channels 7 provide a recessed area to house suture 10 when the two bodies are assembled, as described above. Because there is a channel on opposing side of conical body 14, the inner surface of each channel defines a web or bridge, somewhat like an I-beam, between the two channels. This web or bridge is highlighted in the annotated Figure 3 above.

2. Discussion

Patent Owner asserts two reasons why claim 11 is not anticipated by Curtis: (1) Curtis does not have a "rigid support integral with the anchor body to define a single-piece component" as required by claim 11 (PO Resp. 45–51); and (2) Curtis discloses a "multiple piece anchor" (*id*. 51–57).

a. Rigid Support

Petitioner provides the following annotated versions of Figure 4 of Curtis to show most of the claimed features.



Pet. 46; *see also* Pet. 50–52 (providing a claim chart identifying each element in claim 11 and the corresponding structure in claim 11).

As shown by the dotted blue outline in the Figure above on the right, in its assembled state, Petitioner regards the anchor body as a single element. This single element has a first part 11 and a second part 14 that are connected temporarily, as described above.

The structure Petitioner identifies as the "rigid support" in claim 11 is the web or bridge discussed above and shown in the annotated Figure 3 above. Pet. 44 (suture "loop[s] around the member between channels 7"); *id.* at 48 ("Curtis discloses the rigid support (i.e., the member between channels 7)"). Petitioner also provides the following annotated Figure 4 from Curtis identifying the rigid support.

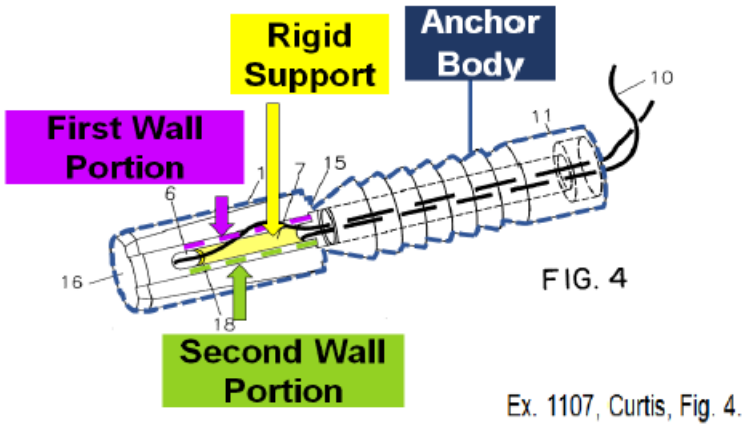


Figure 4 from Curtis annotated by Petitioner.

Id. at 48. As shown in annotated Figure 3 above and also in Petitioner's annotated Figure 4, the web or bridge also extends from the walls of conical body 14. Petitioner also relies on the testimony of Mr. Ritchart, which supports Petitioner's argument. *Id.* (citing Ex. 1103 ¶¶ 230–233).

At the hearing, Petitioner's Counsel stated: "If we take a look at Slide 10, the petition demonstrates this rigid support is met in Curtis by the portion of the conical body, 14, through which the suture is threaded and disposed. That's highlighted in yellow in the petition as reproduced here on Slide 10." Tr. 5:19–23. Slide 10 contained a reproduction of page 48 of the Petition and the Figure reproduced above showing the rigid support highlighted in yellow. Ex. 1178, slide 10.

Patent Owner argues that Curtis does not have a rigid support integral with the anchor body to define a single-piece component. PO Resp. 47. According to Patent Owner, "Curtis' anchor is flexible in a way that leaves it unable to satisfy the rigid support claim language. *Id.* Patent Owner reaches this conclusion based on the assertion that "the Curtis anchor's intermediate portion 20 'breaks away' in response to a 'certain pulling force to the suture

10.'" *Id.* Patent Owner does not persuasively refute Petitioner's position, which is that the web or bridge material defined by channels 7 corresponds to the claimed "rigid support." Petitioner makes clear that intermediate portion 20 in Curtis is not part of the "rigid support" in Curtis. Pet. Reply 27 (citing Ex. 1165 ¶¶ 233-234).

We are persuaded by the evidence that the web or bridge material between the channels 7 is a rigid support integral with the conical body to define a single-piece component.

b. Multiple Piece Anchor

Patent Owner argues that Curtis is a multiple piece anchor, not a single piece anchor. PO Resp. 51. This argument is related to the requirement that the "rigid support" be integral with the side wall of the anchor body.

Patent Owner asserts, correctly, that the Curtis anchor is "assembled" into the two piece condition shown in Figure 5 when inserted into bone for supporting suture to hold tissue in a desired position." *Id.* at 47. Patent Owner's logic appears to be that if the anchor body is in two pieces, the rigid support in conical body 14 cannot be integral with the entire body. Patent Owner relies on the testimony of Dr. Gall for support. PO Resp. 51 (citing Ex. 2010 ¶¶ 200–204. Dr. Gall's testimony is that because main body 11 and conical body 14 are only temporarily connected, that means that the web or bridge material defined by channels 7 cannot be a rigid support integral with the anchor body, as recited in claim 11. Ex. 2010 ¶ 201. His opinion is that "'[t]emporary connections' and 'breaking' do not dictate the two components are integrally formed." *Id.*

Petitioner's position, however, is that the structure that anticipates claim 11 is the one-piece suture anchor that exists prior to being inserted in the bone. Pet. 44. The web or bridge material in Curtis is always integral with conical body 14. When conical body 14 and main body 11 are connected, they form a single body unit. The web or bridge material is integral with this single body unit.

Patent Owner has not directed us to any persuasive argument or evidence that establishes that the broadest reasonable interpretation of claim 11 is limited to an installed suture anchor. We recognize that there are differences, when installed in a bone, between Curtis and the claimed invention. When manufactured, however, and prior to installation, the one-piece configuration shown in Figures 1–4 of Curtis is a "suture anchor assembly" that has a rigid support integral with the suture body, as recited in claim 11. There is no persuasive evidence that a temporary attachment of the two Curtis body parts precludes the rigid support from being "integral with the anchor body."

Thus, we conclude that a preponderance of the evidence establishes that Curtis anticipates claim 11.

D. Curtis, Overaker, and DiPoto (Claim 10)

Claim 10 recites both a "helical thread" and a "driver."

Petitioner asserts that claim 10 would have been obvious based on Curtis, Overaker, and DiPoto. Pet. 53–60.

First we consider the scope and content of the prior art. Curtis has been discussed above.

1. Overaker (Ex. 1124)

Overaker describes an expandable suture anchor similar to that of Curtis. Pet. 53–54 (citing Ex. 1103 ¶¶ 155-57). As shown in Figure 1, outer wall surface 32 of sheath 8 includes a plurality of engagement ribs 46. Ex. 1124 ¶ 20. Each rib 46 has an engagement edge 48 for engaging the bone tissue within a bone hole opening in which the bone anchoring device 10 is deployed, as shown in Figure. 3. *Id.* As shown in Figure 1, ribs 46 are circumferentially aligned, as well as being transversely aligned relative to slot 44. *Id.* Alternatively, Overaker discloses that "*ribs 46 could have a helical configuration*." *Id.* (emphasis added).

2. DiPoto (Ex. 1125)

DiPoto discloses driver 80 used to position a suture anchor in place within a bone. Ex. 1125, 6:17–23; Fig. 9. Driver 80 engages the suture anchor and has a handle and shaft 84 that are cannulated to allow ends of suture 16 to pass through it and be held temporarily on fixation post 86. *Id*.

After the hole in the bone or tissue is formed by drilling, anchor 16 is "snapped" into position on the end of the shaft of the driver. *Id*. at 6:5–16. The anchor and driver assembly is moved into position by the surgeon. *Id.* The anchor is then forced axially into the hole by, for example, the surgeon tapping on the end of the driver with a mallet or the like. *Id.* "It is not necessary to rotate the assembly in order to install it in position." *Id.* at 6:14–16.

3. Differences Between the Claimed Subject Matter and the Prior Art

Petitioner acknowledges that Curtis does not disclose helical threads, as recited in claim 10. Pet. 53 ("Curtis does not, however, identify what

types of protrusions 5 can be employed over its full length."). Curtis also discloses the use of a "manipulation instrument" for installing the suture anchor, but does not provide details about its use or structure.

Overaker discloses that helical threads are an option for use on an expansion-type suture anchor.

DiPoto discloses a "manipulation instrument," a driver, for installing a suture anchor without rotary motion.

4. Discussion

Petitioner asserts that Curtis does not disclose the claimed helical threads of claim 10, but that Overaker does. Pet. 53–54. Petitioner asserts modifying Curtis's barbs to be helical as shown in Overaker would have been a known substitution and option available to a suture anchor designer, and that using this option provides the predictable result of retaining the anchor in bone. *Id.* at 54–55.

Petitioner also asserts that a person of ordinary skill would have been motivated to use the driver of DiPoto as the "manipulation instrument" disclosed in Curtis. This known option allows a surgeon to accurately place Curtis's suture anchor within a bone cavity. *Id.* DiPoto's driver is fully consistent with Curtis and Overaker because all three suture anchors are push-in type anchors; they are not rotated into engagement. DiPoto discloses specifically that it is *not* necessary to rotate the suture anchor assembly using the DiPoto driver in order to install the suture anchor in position." Ex. 1125, 6:14–16.

Patent Owner argues that Petitioners' proposed combination of Curtis, Overaker, and DiPoto (1) does not have the required helical thread at the

proximal end of the anchor body; (2) does not provide a workable result so it cannot be made, (3) does not yield a predictable result, and (4) there is no reason for the proposed combination. PO Resp. 57.

Regarding the helical thread at the proximal end limitation in claim 10, Petitioner asserts that Patent Owner ignores Curtis's explicit statements that protrusions 5 are "distributed over the full length of the main body" (Ex. 1107,2:20–23) and retain the "anchor in cortical bone," (*id.*), both of which require protrusions at the proximal end. Pet. Reply 28 (citing Ex. 1165 ¶¶ 240-243), Ex. 1103 ¶¶ 256-257. Notwithstanding the illustrations in Curtis, the disclosure clearly suggests to a person of ordinary skill to use protrusions over the "full length" of the suture body.

It is also beyond reasonable dispute that Overaker discloses the use of helical threads to retain an expansion-type suture anchor. Ex. 1124 ¶ 20 ("Alternatively, the ribs 46 could have a helical configuration.").

Helical threads over the full length of the suture anchor body are a known design option. It would have been obvious to a person of ordinary skill and creativity to choose the preferred option for the task at hand. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417. There is no persuasive evidence that the proposed changes in Curtis exceed the skill level of our highly skilled person of ordinary skill.

Patent Owner speculates, without citation of evidence, that using a threaded engagement in Curtis "*could* interfere with the ability of the legs to splay, thereby interfering with the intended operation of the anchor." PO

Resp. 61 (emphasis added). Patent Owner relies on the testimony of Dr. Gall. *Id.* at 61–62 (citing Ex. 2010 ¶¶ 220–221). Dr. Gall merely repeats Petitioner's argument without any additional facts or data on which the opinion is based. Thus, it is entitled to little if any probative weight. 37 C.F.R. 42.65(a). There is no persuasive evidence that the proposed helical thread would interfere with the ability of legs in Curtis to splay into engagement with adjacent bone any more so than the existing protrusions 5 disclosed in Curtis.

Patent Owner also argues that there is no reason for the proposed modifications. The references themselves suggest design options available to a person of ordinary skill. There is no persuasive evidence that use of known helical threads and drivers, as broadly recited in claim 10, is beyond the skill and creativity of a person with degrees in engineering or medicine, and also having experience designing suture anchors.

Patent Owner argues that there is no reason to use the driver from DiPoto with the anchor in Curtis because Curtis is a "push-in style anchor." PO Resp. 63. The driver in DiPoto is disclosed specifically for use with push-in style anchors. Ex. 1125 6:12–16 ("The anchor 16 is then forced axially into the hole by, for example, the surgeon tapping on the end of the driver with a mallet or the like. It is not necessary to rotate the assembly in order to install it in position.").

5. Secondary Considerations

Our analysis above in Section II.B.3.e. applies equally to this asserted ground of patentability.

6. Conclusion Regarding Patentability of Claim 10 Based On Curtis, Overaker, and DiPoto

Based on the evidence and analysis above, we determine that a preponderance of the evidence establishes that claim 10 would have been obvious based on Curtis, Overaker, and DiPoto.

III. PATENT OWNER'S MOTION TO EXCLUDE CERTAIN EVIDENCE

Patent Owner moves to exclude Paragraph 119 of Dr. Slocum's Declaration, Ex. 1165, because Dr. Slocum failed to produce test data inconsistent with his opinion. Mot. Excl. 1. Patent Owner also moves to exclude Exhibit 1170 and corresponding ¶ 100 of the Dr. Slocum's declaration under FRE 401, 402 and 901. *Id.* at 3. Exhibit 1170 is a website relied on by Dr. Slocum.

We deny the Motion as moot. We have not relied on or cited the evidence Patent Owner seeks to exclude. Moreover, the Board acts as both the gatekeeper of evidence and as the weigher of evidence. Rather than excluding evidence that is allegedly confusing, misleading, and/or irrelevant, we will simply not rely on it or give it little weight, as appropriate, in our analysis. Similar to a district court in a bench trial, the Board, sitting as a non-jury tribunal with administrative expertise, is well positioned to determine and assign appropriate weight to evidence presented, including giving it no weight. *See, e.g.*, *Donnelly Garment Co. v. NLRB*, 123 F.2d 215, 224 (8th Cir. 1941) ("One who is capable of ruling accurately upon the admissibility of evidence is equally capable of sifting it accurately after it has been received . . . .").

Thus, in this *inter partes* review, the better course is to have a complete record of the evidence to facilitate public access as well as appellate review.

IV. ORDER

In view of the foregoing, it is hereby:

ORDERED that claims 10 and 11 of the ’541 patent have been shown by a preponderance of the evidence to be unpatentable on the basis they would have been obvious under 35 U.S.C. § 103 in view of Gordon and West;

FURTHER ORDERED that claim 11 of the ’541 patent has been shown by a preponderance of the evidence to be unpatentable on the basis that it is anticipated under 35 U.S.C. § 102 by Curtis;

FURTHER ORDERED that claim 10 of the ’541 patent has been shown by a preponderance of the evidence to be unpatentable on the basis it would have been obvious under 35 U.S.C. § 103 in view of Curtis, Overaker, and DiPoto;

FURTHER ORDERED that Patent Owner’s Motion to Exclude is dismissed as moot; and

FURTHER ORDERED that this is a Final Written Decision under 35 U.S.C. § 318(a), and that parties to the proceeding seeking judicial review of the decision under 35 U.S.C. § 319 must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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