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Paper No. __

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SMITH & NEPHEW, INC. &
ARTHROCARE CORPORATION
Petitioners

v.

ARTHREX, INC.
Patent Owner

_____

Case No. TBD
Patent No. 8,821,541
(Claims 10 & 11)

_____

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *et seq*.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

PETITIONERS' EXHIBITS

Exhibit	Description
1101	U.S. Patent No. 8,821,541 ("the '541 patent")
1102	File History of U.S. Patent No. 8,821,541
1103	Declaration of Mark A. Ritchart
1104	CV of Mark A. Ritchart
1105	U.S. Patent Appl. Pub. No. 2006/0271060 ("Gordon")
1106	U.S. Patent No. 7,322,978 ("West")
1107	U.S. Patent No. 5,464,427 ("Curtis")
1108	U.S. Patent Appl. Pub. No. 2002/0111653 ("Foerster")
1109	U.S. Patent No. 6,656,183 ("Colleran")
1110	U.S. Patent Appl. Pub. No. 2004/0106950 ("Grafton")
1111	U.S. Patent Appl. Pub. No. 2003/0065361 ("Dreyfuss")
1112	U.S. Patent No. 3,716,058 ("Tanner")
1113	Application Ser. No. 11/097,172
1114	Application Ser. No. 10/083,568
1115	Application Ser. No. 09/495,816
1116	Application Ser. No. 11/224,060
1117	Application Ser. No. 60/271,414
1118	Application Ser. No. 60/118,228
1119	Application Ser. No. 60/125,781
1120	Application Ser. No. 60/715,614
1121	*The American Heritage College Dictionary* (3d ed. 2000)

1122	Appendix B, Exhibit 120 to "PLAINTIFF ARTHREX, INC.'S DISCLOSURES OF ASSERTED CLAIMS AND INFRINGEMENT CONTENTIONS AS TO DEFENDANTS SMITH & NEPHEW, INC., AND ARTHROCARE CORP., AND IDENTIFICATION OF DOCUMENT PRODUCTION ACCOMPANYING DISCLOSURE," Civil Action No. 2:15-CV-1047-JRG (E.D. Tex.).
1123	U.S. Food and Drug Administration Guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'
1124	U.S. Patent Appl. Publ. No. 2003/187444 ("Overtaker")
1125	U.S. Patent No. 5,690,676 ("DiPoto")
1126	U.S. Patent Appl. Publ. No. 2002/052629 ("Morgan")
1127	E. Marlowe Goble, et al., *The Development of Suture Anchors for Use in Soft Tissue Fixation to Bone*, THE AMERICAN JOURNAL OF SPORTS MEDICINE (1994)
1128	Stefan Rupp, et al., *Fatigue Testing of Suture Anchors*, THE AMERICAN JOURNAL OF SPORTS MEDICINE (2002)
1129	F. Alan Barber, M.D., et al., *Suture Anchor Failure Strength—An In Vivo Study*, ARTHROSCOPY: THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY (1993)
1130	F. Alan Barber, M.D., et al., *The Ultimate Strength of Suture Anchors*, ARTHROSCOPY: THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY (February 1995)
1131	F. Alan Barber, M.D., et al., *Suture Anchor Strength Revisited*, ARTHROSCOPY: THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY (February 1996)
1132	F. Alan Barber, M.D., et al., *Suture Anchors—Update 2003*, ARTHROSCOPY: THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY (November 2003)
1133	Aaron T. Hecker, et al., *Pull-out Strength of Suture Anchors for Rotator Cuff and Bankart Lesion Repairs*, THE AMERICAN JOURNAL OF SPORTS MEDICINE (1993)

1134	F. Alan Barber, M.D., et al., *Suture Anchors—Update 1999*, ARTHROSCOPY: THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY (October 1999)
1135	Vipool K. Goradia, M.D., et al., *Cyclic Loading of Rotator Cuff Repairs: A Comparison of Bioabsorbable Tacks with Metal Suture Anchors and Transosseous Sutures*, ARTHROSCOPY: THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY (April 2001)
1136	Stephen Burkhart, M.D., et al., *Cyclic Loading of Anchor-Based Rotator Cuff Repairs: Confirmation of the Tension Overload Phenomenon and Comparison of Suture Anchor Fixation with Transosseous Fixation*, ARTHROSCOPY: THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY (December 1997)
1137	U.S. Patent No. 4,632,100
1138	G. Lajtai, et. al., SHOULDER ARTHROSCOPY AND MRI TECHNIQUES (2003)
1139	F. Alan Barber, M.D., et al., *Internal Fixation Strength of Suture Anchors—Update 1997*, ARTHROSCOPY: THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY (June 1997)
1140	U.S. Patent No. 5,824,011
1141	U.S. Patent No. 5,851,219
1142	U.S. Patent No. D331,463
1143	U.S. Patent No. 5,573,548
1144	U.S. Patent No. 5,156,616
1145	U.S. Patent No. 2,243,717
1146	U.S. Patent No. 2,489,870
1147	U.S. Patent No. 5,411,523
1148	U.S. Patent No. 5,236,445
1149	U.S. Patent No. 5,935,129
1150	U.S. Patent No. 5,411,506

Pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq*., Smith & Nephew, Inc. and ArthroCare Corp. ("Petitioners") request *inter partes* review of claims 10 and 11 of U.S. Patent No. 8,821,541 ("the '541 patent") (Ex. 1101).

I. INTRODUCTION

The '541 patent is directed to a suture anchor, which is a medical device used to attach soft tissue to bone. A suture anchor has an anchor body and a structure that secures a suture to the anchor body. The anchor body is driven into bone, and the suture, attached to the anchor body via the suture-securing structure, is tied to a piece of tissue to attach that tissue to the bone at the site of the anchor.

The '541 patent states that prior art suture anchors had suture-securing structures (i.e., eyelets) at their proximal ends, which required "countersinking of the eyelet below the bone surface ... As a result, suture attached to the eyelet is vulnerable to abrasion by the bony rim of the countersunk hole into which the suture anchor is installed." (2:10-16).

The '541 patent discloses two distinct embodiments that purportedly solve this problem. In the first, a suture anchor with a hollow anchor body is disclosed. (3:55-4:29). Rather than having an eyelet extending from its proximal end, the anchor in this embodiment includes a recessed metal pin that extends across the hollow body and around which a tissue securing suture is looped. (4:18-29). The challenged claims are not directed to this embodiment.

Instead, the challenged claims are directed to a second embodiment that purports to improve upon the first. "Rather than having an anchor pin as discussed in the embodiment above," the suture anchor in the second embodiment "has an eyelet shield 9 molded transversely into a distal part 11 of the threaded body 3 of the suture anchor 1." (5:23-26, Figs. 5-8). The molded nature of the eyelet shield "provides greater security to prevent pull-out of the suture from within the suture anchor or from an anchor pin, which could loosen." (5:52-56).

Consistent with this second embodiment, the applicants' original claims sought to cover a suture anchor comprising an anchor body with a central bore and an eyelet shield molded across the bore. Ex. 1102 at 18. As of September 2005, the earliest effective priority date to which claims directed to the second embodiment are entitled, a suture anchor with a central bore and an eyelet shield molded across that bore were known. Accordingly, the Examiner rejected—repeatedly—the applicants' attempts to claim such an anchor.

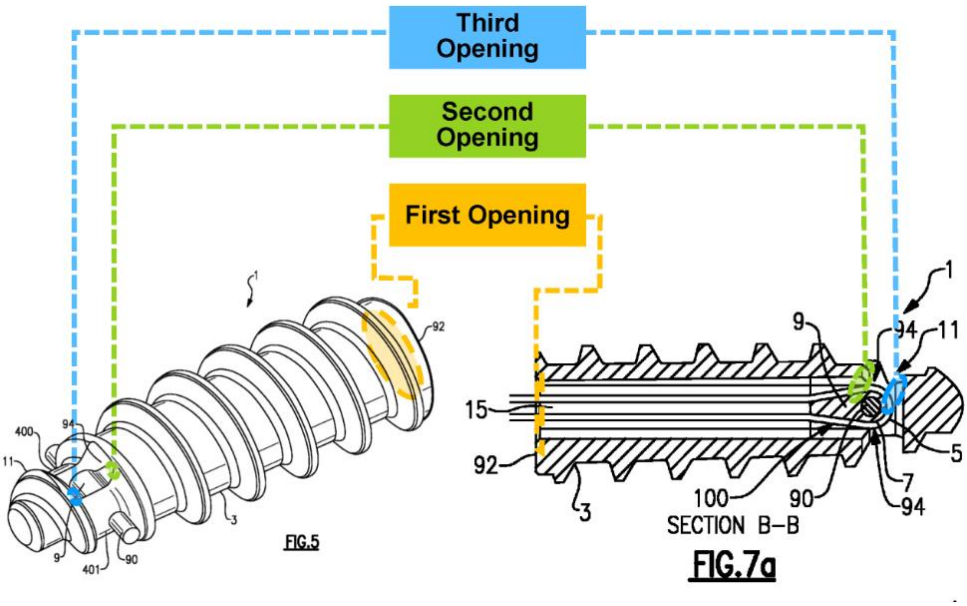
Nearly a decade into prosecution, the applicants introduced for the first time claims that recited a suture anchor with **two** "suture openings" in the anchor body; one at the proximal end of the body that formed an entrance for a suture to enter inside the hollow anchor body, and one formed by a cut-out in the sidewall of the anchor. The only support in the application as filed for the cut-out in the sidewall was the figures, as the written text did not describe this opening as performing any

function or achieving any result and indeed did not reference it at all. To provide support for the second "suture opening," the applicants added language to the original specification and amended the drawings to add a reference character identifying the claimed second "suture opening." *Id.* at 620, 630. The examiner maintained her rejection of pending claims that recited only one suture opening, but allowed those claims that were amended to include more than one opening.

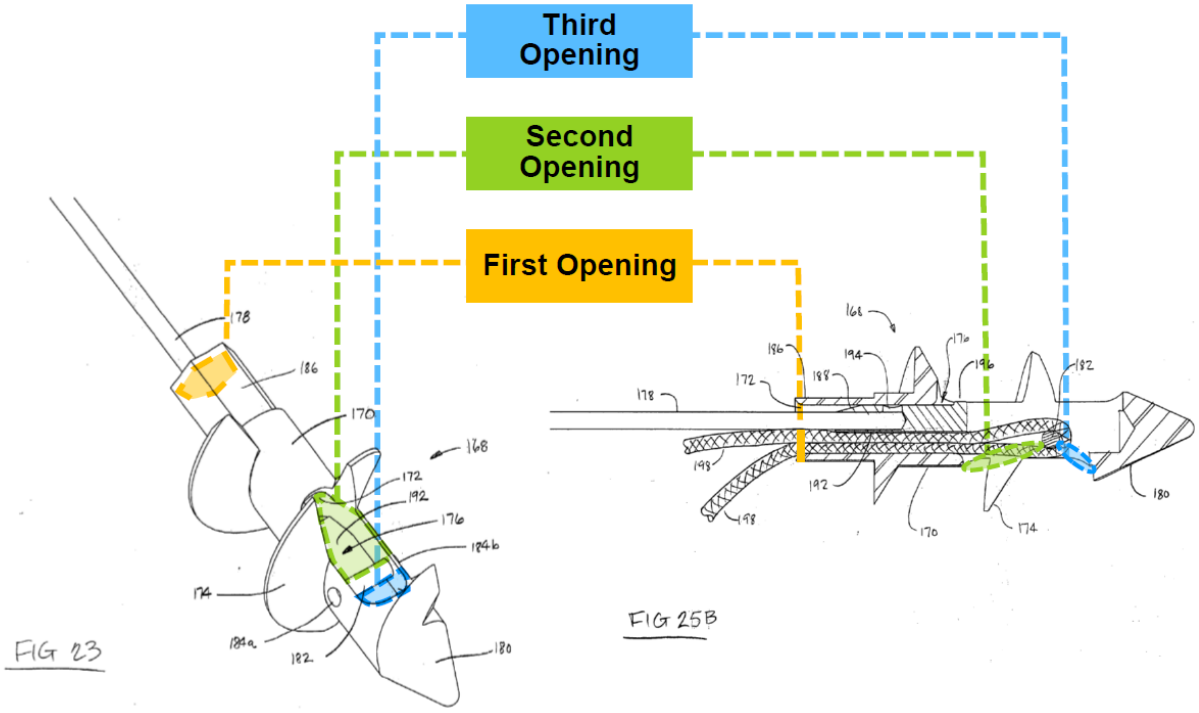
Accordingly, each issued claim of the '541 patent requires at least two "suture openings." Claims 10 and 11 each recites a suture anchor assembly that includes an anchor body, a rigid support extending across a passage within the anchor, and a suture strand supported by the rigid support. Each claim also requires "a first suture opening" that forms an entrance to the passage, and a "second suture opening" that is either "disposed distal of the first suture opening" (claim 10) or "extends from a portion of the anchor body" (claim 11). The claims also recite a "third suture opening … disposed distal of the second suture opening."

Given that it took nearly a decade for the applicants to claim an anchor with more than one "suture opening" and the applicants needed to amend the original disclosure to even identify more than one opening in any of its embodiments, it is not surprising that the patent nowhere states that the second or third openings provide any function or benefit. As shown in annotated Figures 5 and 7a of the

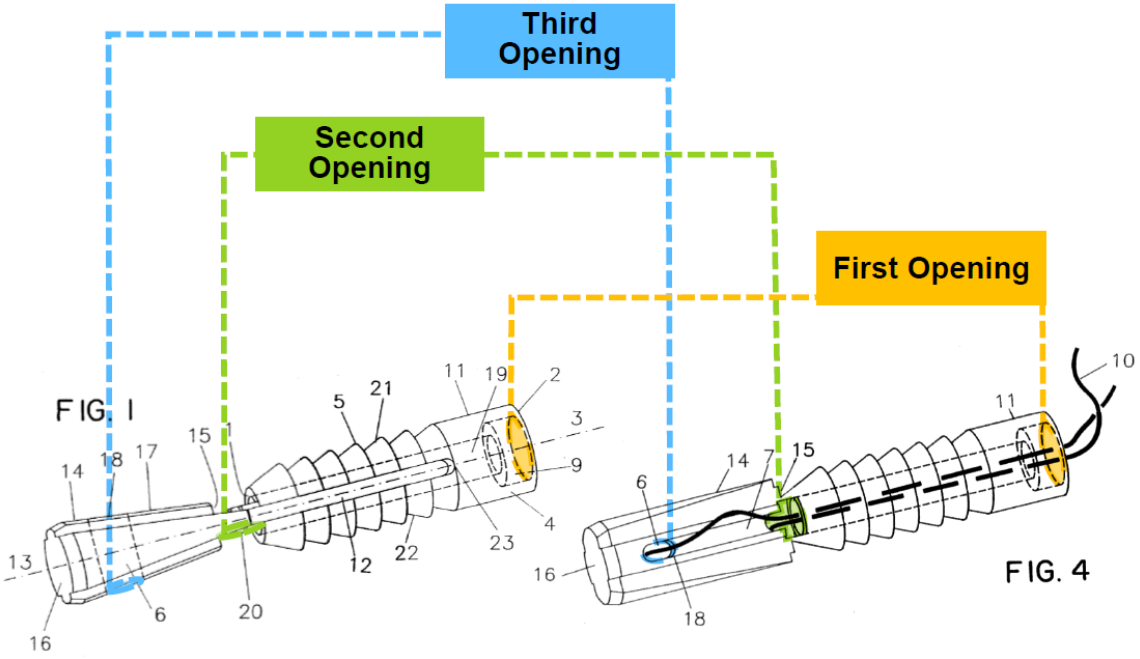
’541 patent below, the second and third suture openings are nothing more than cut-outs in the wall of the anchor body near the eyelet shield (element 9).



Although the claims were allowed only after being amended to require a second or third suture opening, suture anchors with such openings were known before September 2005. Publication No. 2006/0271060 (Ex. 1105, “Gordon”), discloses a suture anchor that includes an anchor body, a passage (i.e., lumen 172) within the body and through which a suture is threaded, and a rigid support (i.e., pulley 182) around which the suture is looped. Gordon ¶ 84. As seen below, just like the suture anchor described in the ’541 patent, the Gordon anchor includes an entrance to the lumen that forms a first suture opening. Also like the anchor described in the ’541 patent, the Gordon anchor has cut-outs in its body near the rigid support, i.e., the pulley. The cut-outs form second and third openings through which the suture is threaded in precisely the same manner as in the ’541 patent.



U.S. Patent No. 5,464,427 (Ex. 1107, "Curtis") also discloses a suture anchor with multiple suture openings. The Curtis anchor comprises a first main body with a passage (i.e., bore 19) and a second conical body that can be pulled into the bore of the main body. Curtis at 2:17-38, claim 1. A suture is threaded through the main body's passage and along channels on the conical body. *Id.* at 2:47-54. It is then looped through a "through-hole" in the conical body and re-threaded back along the channels and through the main body passage. *Id.* As seen below, the Curtis anchor includes a first opening at the proximal end of the body where bore 19 begins, a second opening at the transition between the main body 11 and the conical body 14, and a third opening, i.e., an orifice 18 of the through-hole in the conical body.



Ground 1 demonstrates how claims 10 and 11 would have been obvious over Gordon in view of U.S. Patent No. 7,322,978 (Ex. 1106, "West"), with West being introduced to show the obviousness of extending the helical threads of an anchor all the way to its proximal end (claim 10) and making a rigid suture support integral with an anchor body (claim 11). Ground 2 demonstrates how Curtis anticipates claim 11. Ground 3 demonstrates how claim 10 would have been obvious over Curtis in view of Publication No. 2003/0187444 (Ex. 1124, "Overaker"), with Overaker being introduced to show the obviousness of using helical threads on the body of an expandable suture anchor. Finally, Ground 4 presents an alternative obviousness argument for claim 10 and, by introducing an additional reference that teaches a "driver" similar that taught in the '541 patent, i.e., U.S. Patent No. 5,690,676 (Ex. 1125, "DiPoto"), explains how a POSA would

have found it obvious to use such a driver to insert a suture anchor resulting from the Curtis/Overaker combination discussed in Ground 3, in case the Patent Owner asserts that Curtis does not itself disclose such a driver.

II. MANDATORY NOTICES

A. Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1))

Smith & Nephew, Inc. and its wholly-owned subsidiary ArthroCare Corporation are the real parties-in-interest.

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

A decision in this proceeding could affect or be affected by: (1) Civil Action No. 2:15-cv-01047 (E.D. Tex. filed June 17, 2015) in which Patent Owner ("Arthrex") has asserted the '541 patent and several patents related thereto against Petitioners; (2) IPR Nos. 2016-00505, 2016-00506, 2016-00507, and 2016-00508 in which Petitioners have challenged patents related to the '541 patent; (3) the IPR filed concurrently herewith in which Petitioners are challenging claims 1-9 of the '541 patent, and (4) patents and pending applications related to the '541 patent or one or more applications in its priority chain: U.S. Patent Nos. 8,343,186, 8,801,755, and 8,623,052 and U.S. Patent Application Nos. 14/469,733, 14/698,191 and 14/487,459.

C. Counsel and Service Information (37 C.F.R. § 42.8(b)(3) and (4))

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Powers of attorney are submitted with the Petition. Counsel for Petitioners consents to service of all documents via electronic mail.

III. NOTICE OF FEES PAID

Fees are submitted herewith. If more fees are due during this proceeding, the undersigned authorizes the office to charge Deposit Account No. 23/2825.

IV. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify, pursuant to 37 C.F.R. § 42.104(a), that the '541 patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting *inter partes* review as to the claims identified herein.

V. IDENTIFICATION OF CHALLENGE AND RELIEF REQUESTED

Petitioners request cancellation of claims 10 and 11 of the '541 patent. The table below indicates the references, applicable claims, and basis for each Ground.

GROUND	REFERENCE(S)	CLAIMS	BASIS
1	Gordon and West	10, 11	103(a)

2	Curtis	11	102(b)
3	Curtis and Overaker	10	103(a)
4	Curtis, Overaker and DiPoto	10	103(a)

A. Technology Overview: Suture Anchors

As noted above, a suture anchor is a medical device that is used to secure soft tissue to bone. A suture anchor has two basic components: an anchor body and a suture-securing structure, such as an eyelet. The anchor is fixed in bone, and a suture is attached to the suture-securing structure. Ritchart ¶¶ 27-45 (Ex. 1103). Suture anchors are either tapped or screwed into bone. A screw-in anchor has threads on its exterior that engage with the bone. *Id*. ¶¶ 47-55.

B. Overview of the ’541 Patent and the Challenged Claims

1. The ’541 Patent

Each challenged claim requires an anchor body that includes a “first suture opening,” a “second suture opening” and a “third suture opening” through which a suture is threaded. The ’541 patent describes three distinct embodiments of a suture anchor, but only the second embodiment describes a suture anchor that arguably has second and third “suture openings.” The second embodiment is thus the only embodiment that can support the challenged claims. Ritchart ¶¶ 80-85, 105-08.

In the second embodiment, suture anchor 1 has a bore 15 extending from an opening at its proximal end 92. *Id.* at 5:45-50. Extending across bore 15 is an

"eyelet shield 9 molded transversely into" the anchor body and around which a suture is looped. *Id.* at 5:21-26, Fig. 5 (element 9). According to the patent, because the shield is molded into the body it "provides greater security to prevent pull-out of the suture from within the suture anchor or from an anchor pin, which could loosen." *Id.* at 5:51-56.

Although the patent identifies the shield as the purportedly novel feature of the second embodiment, it also explains in passing that sutures 5, 7 attached to the suture anchor are "threaded into a suture passage 94" that is "on opposing sides of the shield" such that the shield forms a bearing surface around which the sutures "are threaded and disposed." *Id.* at 5:40-50. As discussed below, this language was added to the original specification during prosecution, and the applicants identified suture passage 94 as the written description support for the second suture opening found in the challenged claims. Ex. 1102 at 480, 630.

Two suture passages 94 are shown in Figure 7a. The passages form a path for sutures 5, 7 to travel above and below the eyelet shield 9. The passages are distal to bore 15 and are formed where two cut-outs in the sidewall of the anchor body exist. The passages allow sutures to be threaded through the cut-outs. Ex. 1101 at 5:37-41. Sutures 5, 7 are threaded into the first opening at the proximal end of the anchor body, pass through bore 15 and then into a first suture passage 94 (e.g., the top one in Fig. 7a), loop around eyelet shield 9, and extend

back through a second suture passage 94 (e.g., the bottom one in Fig. 7a), through bore 15 and out through the first opening. *Id.* at 5:37-45.

There are at least four "openings" in the anchor body of Figure 7a through which sutures 5,7 are threaded, and, as explained below, on which the various "openings" of the challenged claims can be read. The first is the opening at the proximal end of the anchor through which the sutures must be threaded in order to enter bore 15. The second and fourth openings are suture passages 94, which create openings through a portion of the anchor body (i.e., its side wall) that respectively allow sutures 5, 7 to exit the anchor body, loop around the eyelet shield, and re-enter the body. The third opening is between the distal end of the eyelet shield and the distal end of the anchor. This third opening extends through the anchor body and allows the suture to loop around the eyelet shield and re-enter the body via the fourth opening. Ritchart ¶ 88.

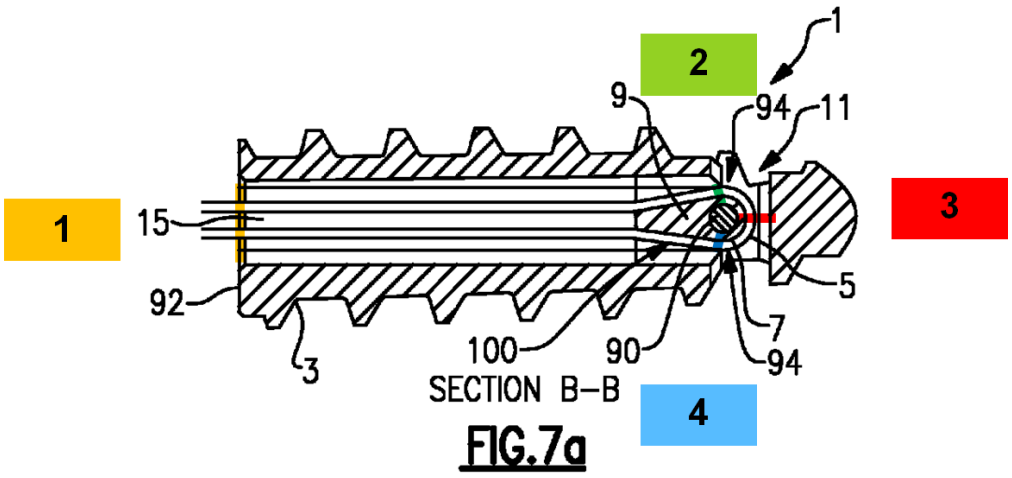


FIG.7a

2. The Challenged Claims

Claim 10 recites an anchor body that includes a "central passage," and claim 11 recites an anchor body that includes a "suture passage." In each case, the claim requires that a "rigid support" extends across the passage and at least one suture strand is threaded into the passage where it is supported by the rigid support. Claim 10 also requires a driver to screw or otherwise insert the anchor into bone.

Claims 10 and 11 both also require first, second, and third "suture openings." The first suture opening reads upon the opening to the passage at the proximal end of the anchor body (i.e., opening 1 above). In claim 11, the second opening "extends through a portion of the anchor body," while in claim 10 it simply must be distal of the first opening. Thus, the second opening reads upon either of the two suture passages 94 shown in Figure 7a (i.e., openings 2 or 4 above). As for the third suture opening, claims 10 and 11 both require that it be distal to the second opening, while claim 10 additionally requires that it be "disposed distal of the rigid support, and claim 11 additionally requires that it "extends through the anchor body." The opening described in the '541 patent that satisfies this description is the opening between the distal end of the eyelet shield and the distal end of the anchor (i.e., opening 3 above).

C. The Prosecution of the '541 Patent

The application that became the '541 patent was filed on September 12, 2006. The original claims were directed to a suture anchor comprising an anchor body with a central bore and an eyelet shield molded at the distal end of the body. Ex. 1102 at 18-21. None of the original claims recited the suture opening elements found in the issued claims. The original claims were all rejected, *id.* at 63-76, and the applicants' subsequent attempts to amend them, *id*. at 86-93, 112-19, 125-33, 166-85, 216-22, 231-36, 271-85, 314-32, were denied eight times, *id.* at 95-107, 122-24, 140-57, 194-206, 227-29, 251-65, 292-304, 472-504.

On January 22, 2014—over seven years into prosecution— the applicants added independent claim 39[1] which recited a suture anchor comprising, *inter alia*, an anchor body with "an opening at the proximal end of the anchor body" and a "suture opening at least partially through the sidewall of the anchor body." Ex. 1102 at 322. The applicants also added several claims that depended from claim

[1] This claim was incorrectly numbered as claim 38 in the January 22, 2014 amendment. The examiner, however, treated what was identified as claim 38 as claim 39, *id*. at 474, and the applicants renumbered their claims accordingly in their next filing, *id*. at 622-629.

39 and which limited the location of the "suture opening" or required "at least one other suture opening." *Id.* at 322-24.

The examiner rejected claim 39 and its dependents as anticipated by both U.S. Patent No. 6,656,183 (Ex. 1109, "Colleran") and U.S. Application Pub. No. 2004/0106950 (Ex. 1110, "Grafton"). Ex. 1102 at 486-93. In doing so, the examiner found that claim 39 was not entitled to a priority date earlier than the filing date of the application because "the parent applications do not teach the anchor body with a rigid member and a suture strand where there is a suture opening at least partially through the sidewall of the anchor body, wherein the at least one suture strand is located in the suture opening." *Id.* at 482. The examiner also rejected certain claims depending from claim 39 under § 112 for lack of written description because the specification did not describe "a second suture opening" or that a suture is "threaded through the two suture openings." *Id.* at 480.

In response, the applicants amended claim 39 and its dependents in an effort to distinguish the claims from Colleran and Grafton. *Id.* at 620, 625-26. The applicants also added claims 55 and 59 which depended from then-pending independent claims 1 and 12, respectively, and introduced to those claims the suture opening limitations found in claim 39 and its dependents. *Id.* at 627-28.

To address the § 112 rejection, the applicants amended the original specification to include the underlined language:

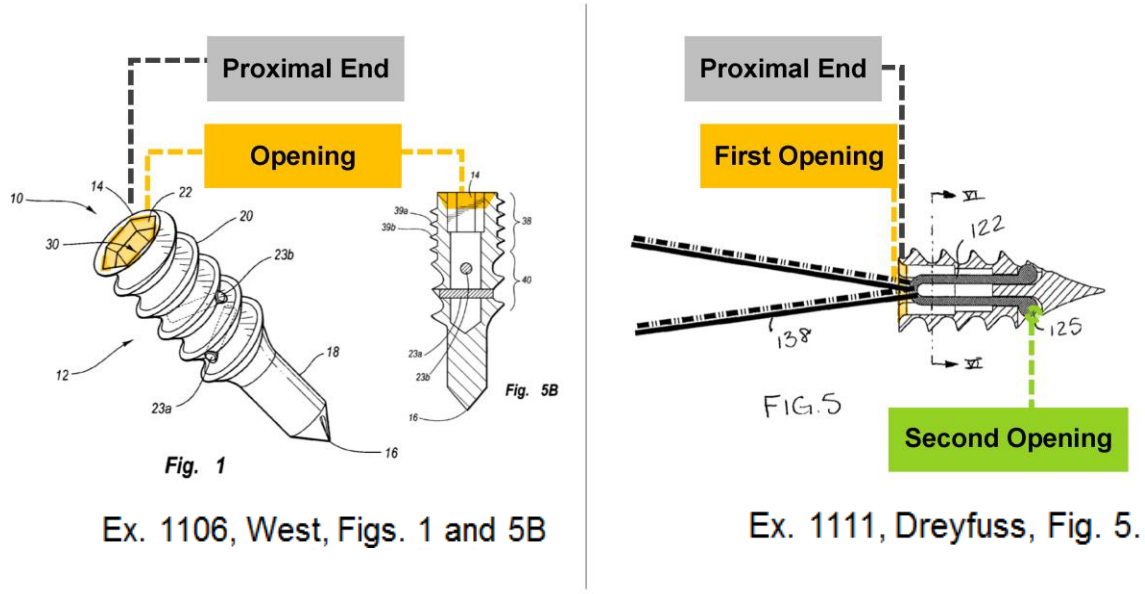
> As illustrated in FIGS. 6-8, two strands of tie-down sutures 5, 7 are threaded around the eyelet shield 9 of the distal end 11of the suture anchor 1 and threaded into a suture passage 94. In one example, there is a suture passage 94 on opposing sides of the shield 9.

Ex. 1102 at 620. The applicants also amended Figure 7a to show the suture "threaded through a suture passage 94." *Id.* at 630, 635. The applicants then identified these disclosures concerning "suture passage 94" as the written description support for "two suture openings." *Id.* at 630.

In the next office action, claim 39 and its dependents were allowed, and claims 55 and 59 were indicated as being allowable if re-written into independent form. *Id.* at 663. The examiner, however, rejected the remaining claims either as anticipated by U.S. Patent No. 7,322,978 ("West") (Ex. 1106) or obvious over Publication. No. 2003/0065361 ("Dreyfuss") (Ex. 1111) in view of U.S. Patent No. 3,716,058 ("Tanner") (Ex. 1112). *Id*. at 656-663. Rather than address the examiner's rejections, the applicants amended the claims to include the subject matter the examiner had indicated as allowable. *Id*. at 707-13. Claim 39 and its dependents thus became issued claims 1-9, while claims 55 and 59 became issued claims 10 and 11.

The "allowable" claims each required that a suture extend through both a first opening at a proximal end of the anchor and a second opening located elsewhere. *Id*. at 625, 627-28. This was evidently the basis for allowance because

West (*see* Figs 1 and 5B – below) had only one opening at its proximal end, and Dreyfuss (see Fig. 5 – also reproduced below), though containing a second "opening" near its distal end, lacked a suture strand that extended through both that second opening and the opening at the anchor's proximal end.



Unlike the references identified during prosecution, the prior art relied upon in this Petition clearly teaches a suture strand disposed in (or threaded through) both first and second openings, as well as the remaining limitations of the challenged claims, as explained in more detail below.

D. The Proper Effective Filing Date of the Challenged Claims

The application that matured into the '541 patent was filed on September 12, 2006. That application purports to be a continuation-in-part of four non-provisional applications—11/097,172 (Ex. 1113); 10/083,568 (Ex. 1114);

09/495,816 (Ex. 1115); and 11/224,060 (Ex. 1116)—and four provisional applications—60/271,414 (Ex. 1117); 60/118,228 (Ex. 1118); 60/125,781 (Ex. 1119); and 60/715,614 (Ex. 1120). As discussed below, and as explained in Mr. Ritchart's accompanying declaration (Ritchart ¶¶ 105-16), only the provisional application filed on September 12, 2005, arguably provides support for the "second suture opening" and "third suture opening" limitations of each challenged claim.

Application No. 11/097,172 (filed April 4, 2005) describes a suture anchor with a central bore across which extends an anchor pin. Ex. 1113 at 8-9, 19 (Fig. 2). The anchor includes a first suture opening, i.e., the entrance to the central bore, through which a suture is threaded, but there are no second or third openings for the suture to pass through. Ritchart ¶ 111. Although this application may support the first (unclaimed) embodiment in the '541 patent, it lacks a second and third suture openings and thus does not provide support for the challenged claims.

Applications Nos. 10/083,568 (filed February 27, 2002) and 60/271,414 (filed February 27, 2001) describe "a push-in suture anchor having suture molded directly into" its body. Ex. 1114 at 3; Ex. 1117 at 2. The anchor is solid and has no suture openings through which a suture is threaded. Ex. 1114 at 16 (Figs. 1 and 2); Ex. 1117 at 6 (Fig. 1). Ritchart ¶ 112. This application may support the third (unclaimed) embodiment in the '541 patent, but not the challenged claims.

Application Nos. 09/495,816 (filed February 2, 2000), 60/118,228 (filed February 2, 1999), and 60/125,781 (filed March 23, 1999) all disclose a "tissue tack" that lacks any sutures, let alone an anchor body having first, second and third "suture openings" of the type claimed. Exs. 1115, 1118, 1119; Ritchart ¶ 113.

Application No. 11/224,060 (filed September 13, 2005) describes a suture anchor with a central passage, i.e., bore 10, but it uses a flexible loop of suture within the passage, not a rigid support, to support a suture. Ex. 1116 at 13, 28 (Fig. 1). Moreover, the suture is threaded only through a first suture opening (i.e., the opening in bore 10), and not through a second or third opening. *Id.* at 28 (Fig. 1); Ritchart ¶ 114. This application cannot support the challenged claims.

Finally, provisional application 60/715,614—filed on September 12, 2005—describes a suture anchor with an eyelet shield and includes figures similar to what would become Figures 5 to 8 of the '541 patent. Ex. 1120 at 4, 7-9 (Figs. 1-4). This provisional application is the only application that arguably provides written description support for the challenged claims; thus, its filing date of September 12, 2005 is the earliest possible priority date for those claims. Ritchart ¶¶ 115-16.

E. Level of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSA") related to the '541 patent would have (a) a master's degree in mechanical engineering or a bachelor's degree in such field 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. Ritchart ¶¶ 24-26. A POSA would have the ability to understand and apply the prior art references discussed herein. *Id.*

VI. CLAIM INTERPRETATION

In this proceeding, claim terms should be given their broadest reasonable interpretation ("BRI") in light of the specification. 37 C.F.R. § 42.100(b). Although the BRI may differ from the proper construction in district court, all of Petitioners' proposed claim constructions would also be proper in district court.

A. "suture opening" – Claims 10 and 11

Under the BRI standard, "suture opening" is "an open space serving as a passage or gap, or a breach or aperture, through which a suture passes."

Other than in the claims, the term "suture opening" does not appear in the '541 patent. During prosecution, the applicants identified the suture passages 94 shown in Fig. 7a as "suture openings." Ex. 1102 at 630. The patent states that sutures can be "threaded into" the suture passages 94. Ex. 1101 at 5:37-41.

The ordinary meaning of "opening" in the context of describing a feature or characteristic of a physical device (such as the suture anchor of the '541 patent) is: "[a]n open space serving as a passage or gap," or "[a] breach or aperture." Ex. 1121 at 956. 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. Ritchart ¶¶ 121-23.

B. "rigid support" – Claims 10 and 11

Under the BRI standard, a "rigid support" is "an inflexible part of the suture anchor that supports a tissue securing suture." The ordinary meaning of "rigid" is "lacking flexibility." Ritchart ¶ 124; Ex. 1121 at 1175. A "support" is something that provides support for something else. Ritchart ¶ 124; Ex. 1121 at 1364. In the context of claims 10 and 11, the "something else" that the rigid support provides support for is a suture strand, i.e., a tissue securing suture. Ritchart ¶ 124.

C. "central passage" – Claim 10

Under the BRI standard, "a central passage" is "a central path, channel, or duct of the anchor body." Other than the claims, the '541 patent does not use the term "central passage." The only instance in which the word "passage" appears is to refer to the suture passages 94 shown in Fig. 7A. Ex. 1101 at 5:37-41.

In the context of describing a feature of a physical device (such as a suture anchor), the ordinary meaning of "passage" is "[a] path, channel, or duct through, over, or along which something may pass." Ex. 1121 at 227, 998; Ritchart ¶ 126. This ordinary meanings is consistent with the claims which require that the claimed "central passage" extend (a) along the longitudinal axis of the anchor

body, (b) from an opening at the proximal end of the anchor body, and (c) through a portion of the anchor body. Ritchart ¶¶ 125-27.

D. "suture passage" – Claim 11

Under the BRI standard, a "suture passage" is "a path, channel, or duct of the anchor body for a suture."

The '541 patent only uses the term "suture passage" to describe the suture passages 94 shown in Fig. 7A. Ex. 1101 at 5:37-41. Indeed, that is the only place in which the patent uses the term "passage" at all, other than in the claims. This usage in the specification is consistent with the ordinary meaning of "passage" noted above. Ex. 1121 at 998; Ritchart ¶¶ 128-29.

E. "branching" – Claims 10 and 11

Under the BRI standard, "branching" means "extending." Other than in the claims, the term "branch" does not appear in any form in the '541 patent.

The term "branching" was introduced during prosecution (Ex. 1102 at 622-23, 625) to distinguish the claims over U.S. Patent No. 6,656,183 (Ex. 1109, "Colleran") and U.S. Application Pub. No. 2004/0106950 (Ex. 1110, "Grafton"). The applicants argued that "Colleran does not disclose a rigid support including a first portion and a second portion that **branch from a first wall portion and a second wall portion**" and, instead, "discloses a winding post 62 that **extends from**

a single wall 61."[2] Ex. 1102 at 632. With respect to Grafton, the applicants argued that "Grafton … does not disclose a 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," and asserted that Grafton instead discloses that a "suture 8 is molded inside the suture body 4 to form an eyelet 20" and that "the eyelet 20 does not include spaced apart portions that branch from wall portions of the suture body." *Id*.

These passages from the file history demonstrate that the term "branching" was introduced simply to make clear that the "rigid support" **extends** across a gap between two opposing, spaced-apart wall portions. Ritchart ¶¶ 130-32.

F. "a rigid support integral with the anchor body to define a single-piece component" – Claim 11

Under the BRI standard, this phrase means "a rigid support formed together with the anchor body as a unitary structure."

The term "integral" does not appear in the '541 patent other than in claim 11. The eyelet shield 9 disclosed in the patent is described only as being "molded transversely" into the distal end of the suture anchor. Ex. 1101 at 5:24-26, 53-54. The patent explains that so forming the eyelet shield "provides greater security to

[2] Unless otherwise noted, bold emphasis added throughout.

prevent pull-out of the suture from the suture anchor or from an anchor pin, which could loosen." *Id*. at 54-56.

This limitation was not found in the originally-filed claims. Instead, it was first introduced during prosecution, Ex. 1102 at 274, 276, in response to a rejection over U.S. Patent Appl. Pub. No. 2002/0052629 (Ex. 1126, "Morgan"). Ex. 1102 at 256-59. With reference to Figs. 6-8 of Morgan (reproduced below), the applicants argued "[t]he retainer 40 and the suture anchor 100 of Figures 6-8 of Morgan et al. do not define a single component, but are instead separate components that are bonded together (paragraph 37)."

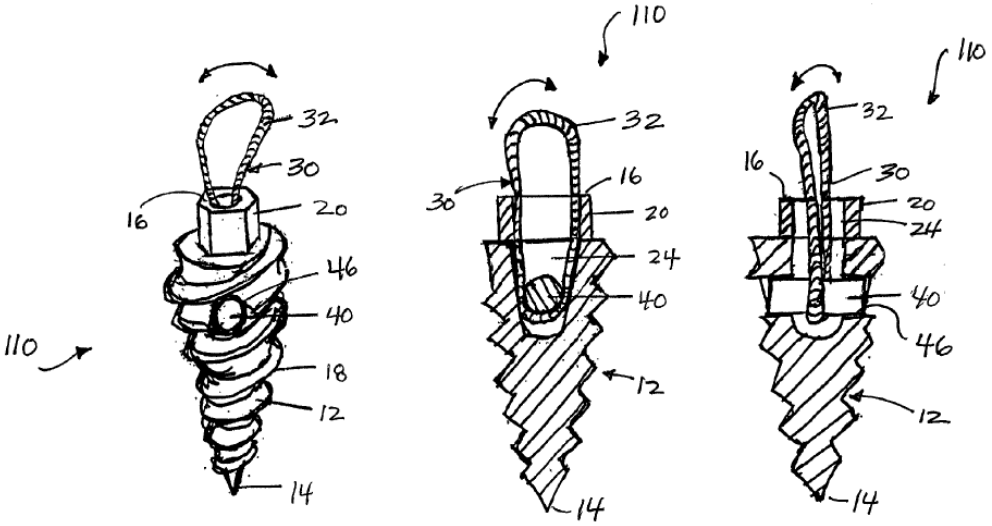


FIG. 6. FIG. 7. FIG. 8

Paragraph [0037] of Morgan to which the applicants referred describes, *inter alia*, securing "the retainer 40 … to an inner surface of the body 12" by "a suitable means such as ultrasonic welding." Ex. 1126 ¶ 37. By these remarks, the applicants thus made clear that the phrase "integral with the anchor body to define

a single-piece component" 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. Ritchart ¶¶ 133-36.

VII. THRESHOLD REQUIREMENT FOR INTER PARTES REVIEW

This Petition and the supporting evidence demonstrate "a reasonable likelihood that petitioner would prevail with respect to at least one of the claims challenged in the petition." 35 U.S.C. § 314(a). All elements of the challenged claims are taught in the prior art and as set forth in the Declaration of Mark Ritchart. Ex. 1103.

VIII. CLAIM-BY-CLAIM EXPLANATION OF GROUNDS FOR UNPATENTABILITY OF CLAIMS 10-11

A. Ground 1: Claims 10 and 11 Would Have Been Obvious Over Gordon in View of West

1. Gordon

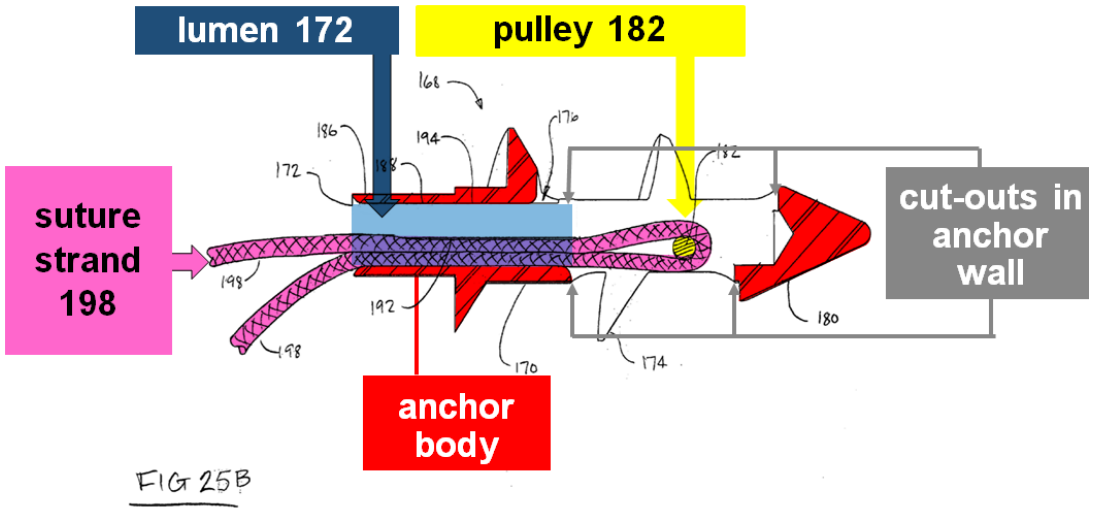
Gordon was filed May 26, 2005, issued on November 30, 2006, and is prior art at least under 35 U.S.C. § 102(e). Gordon discloses a suture anchor that has an anchor body 168 with a hex drive 186 at its proximal end and a nose 180 at its distal end. Gordon ¶ 84, Fig. 23. A lumen 172 begins from an opening in the hex drive, extends through a length of the anchor body, and creates a path along which a suture 198 is threaded. *Id.* ¶¶ 84, 86, Figs. 23, 25A-C; Ritchart ¶ 139.

The suture is threaded into the opening of the lumen at the proximal end of the anchor body (i.e., hex drive 186), passes through the lumen distally, loops

around a pulley 182, and extends back out through the opening at the proximal end of the anchor body. Gordon ¶ 86. To secure the pulley to the anchor body, it is inserted in coaxial holes 184a and 184b through the sides of the body. *Id*. ¶ 84, Fig. 23; Ritchart ¶ 140. Gordon, via its incorporation by reference of Publication No. 2002/0111653 ("Foerster") (Ex. 1108) (*see* Gordon ¶¶ 25, 83), teaches that the pulley can be a "fixed structure" or can alternatively be "formed separately from the anchor body … and inserted in a pair of facing holes." Foerster ¶ 70; Ritchart ¶¶ 188. In the vicinity of the pulley, there are cut-outs in the sidewall of the anchor body. Gordon at Fig. 23; Ritchart ¶ 140.

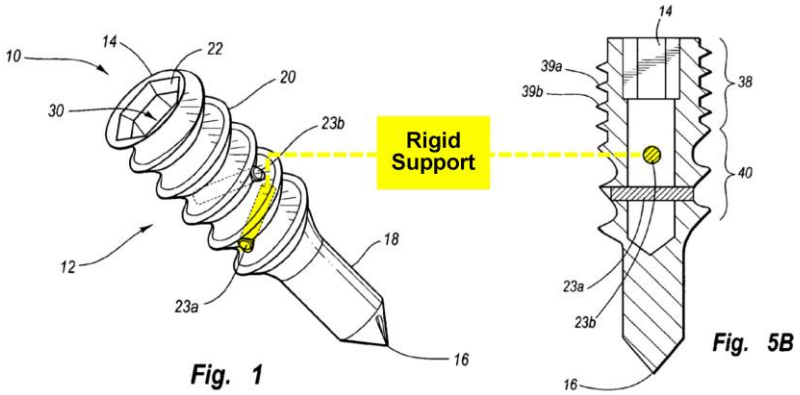
The Gordon suture anchor also includes a "suture locking plug 176." Gordon ¶ 85. To lock suture 198 to the anchor body, a suture lock cable 178 attached to the end of the suture locking plug is pulled in a proximal direction. *Id.* ¶ 87. By pulling the cable proximally, the plug is pulled into and fills the lumen of the anchor body "such that a frictional lock between the lumen 172, plug 176, and the suture 198 is created." *Id.* ¶ 87, Figs. 25A-C; Ritchart ¶ 141. For this Petition, how the suture is locked to the anchor is largely irrelevant.

Below is Figure 25B of Gordon with the suture locking plug 176 and its associated components erased. The figure also includes annotations that identify the various components discussed above and which are relevant to the claim-by-claim analysis that follows.



2. West

West (Ex. 1106) was filed June 22, 2004, issued on January 29, 2008, and is prior art at least under 35 U.S.C. § 102(e). West discloses a suture anchor (referred to as a "bone anchor") comprising a hollow anchor body 12 that houses one or more rigid supports (i.e., pins or posts 23) for looping sutures thereon. West at 5:57-6:55, 7:41-47; Ritchart ¶ 145.



Ex. 1106, West, Figs. 1 and 5B

As seen above, West has a threaded female hex drive socket at its proximal end (rather than an unthreaded male drive head) and teaches that this desirably allows the anchor body to be threaded all the way to its proximal end. West at 1:50-64, 2:59-67, 4:47-51, 5:40-46, 6:14-25, 8:13-17. According to West, "[t]hreading the proximal end of the anchor body provides the bone anchor with the ability to better engage the cortical bone near the surface of the bone." *Id.* at 2:65-67. This design, West explained, was an improvement on "existing bone anchors [that] are not threaded to the proximal end of the anchor" and therefore "do[] not engage the bone near the surface, but only the soft cancellous bone beneath the cortical layer. This feature of existing 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." *Id.* at 1:58-64.

West also teaches that "[a]nchor body 12 is advantageously made from a strong biocompatible material, such as a titanium alloy or stainless steel" (West at 5:31-33), and that in an embodiment the pins within the anchor body are also made from titanium alloy or stainless steel (*id.* at 6:48-50). Consistent with this teaching, West explains that the anchor body and posts can be cast and formed in a die (*id.* at 7:41-43), a process that results in the posts being integral with the anchor body (Ritchart ¶ 147).

3. Combination of Gordon and West

A POSA would have been motivated by West to modify Gordon's suture anchor 168 to replace the male hex drive head 186 with a threaded female hex drive socket as taught by West. Ritchart ¶¶ 162-71. A POSA would have been motivated to make such a modification so as to 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 near the surface of the bone," per West's express teaching. West at 2:65-67; Ritchart ¶¶ 162-66.

Making such a substitution would have involved nothing more than (A) combining prior art elements according to known methods to yield predictable results, (B) substituting one known element for another to obtain predictable results, and/or (C) applying a known technique to improve a similar device in the same way. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-21 (2007).

Moreover, in light of West's disclosure of a suture anchor that includes an anchor body and rigid support created using a casting process, a POSA would have found it obvious to manufacture Gordon's suture anchor by forming the anchor body 170 and pulley 182 (i.e., the "rigid support") using a casting process. West at 5:31-33, 6:48-50, 7:41-43. This implementation would have been consistent with Gordon's teaching, via its incorporation by reference of Foerster (Ex. 1108), that the pulley can be a "fixed structure" (Gordon ¶¶ 25, 83; Ex. 1108 ¶ 70) because the

casting process would have resulted in pulley 182 being "integral" with anchor body 170 and a pulley integral with the anchor body is a "fixed structure." Ritchart ¶ 167.

A POSA would have had several reasons to manufacture Gordon's anchor body and pulley using a casting process that resulted in the pulley being integral with the anchor body.

First, using a casting process to manufacture Gordon's anchor body and pulley out of the same material would minimize the materials used in the anchor and thereby ease the process for getting the suture anchor approved by the FDA for use in patients. Ex. 1123 at 4-8, Ritchart ¶ 169.

Second, it would have been logical to a POSA to manufacture the Gordon anchor using a casting process. Casting was a well-known and accepted technique for creating medical implants by September 2005. West at 7:41-43. Using this well-known technique would have been a simple design choice. Ritchart ¶ 170.

Third, a POSA would have known that creating the Gordon anchor using a casting process would have resulted in the pulley being attached to the anchor body more securely than a pulley that was inserted into apertures in the wall of the anchor and subsequently attached to the body via adhesives. Ritchart ¶ 171. A POSA would have understood that as a medical device intended for use in a human, it was important that the pulley not become unattached from the anchor

body. A POSA would have also known that casting the body and pulley together to form an integral device would have been one obvious way to reduce the likelihood that the pulley separated from the body. Ritchart ¶¶ 171, 210.

The suture anchor that a POSA would have been led to make based upon the teachings of Gordon and West would have been the suture anchor of Gordon modified to use a threaded female drive socket rather than a non-threaded male drive head, and where the anchor body and pulley 182 are cast together in a die to form a single-piece component. Ritchart ¶¶ 162-71.

4. Claim-by-Claim Analysis

a. Independent Claim 10

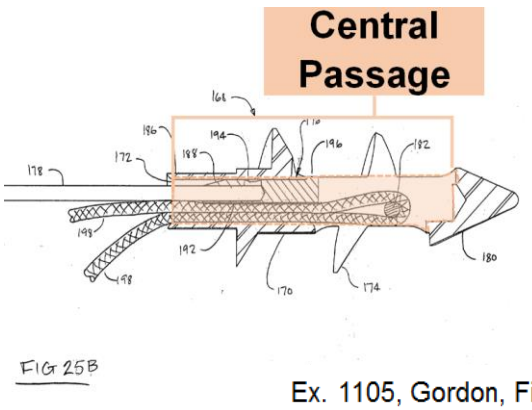
As discussed below and shown in the claim chart that follows, Gordon discloses most, if not all, limitations of claim 10 of the '541 patent. The only feature arguably not expressly disclosed in Gordon is limitation [A3], which requires that "a helical thread defines a perimeter around the proximal end of the anchor body."[3] As the addition of such a feature to a suture anchor was expressly

[3] In describing suture anchor 168, Gordon refers to hex drive 186 and anchor body 170 as different elements. Gordon ¶ 84. Since Gordon's screw threads 184 do "define[] a perimeter around the proximal end of" element 170, which Gordon refers to as its "anchor body," this limitation is arguably met by Gordon alone.

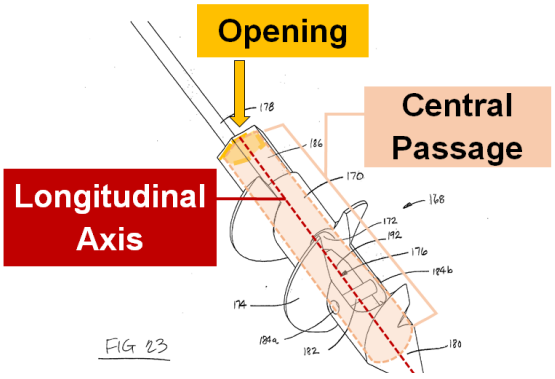
taught by West, a POSA would have found it obvious to modify the Gordon anchor such that it also meets limitation [A3].

Claim 10 also requires an anchor body that has a "central passage." Under the BRI standard, a "central passage" is "a central path, channel, or duct of the anchor body." See § VI.C above. The Gordon anchor body has such a path. Specifically, lumen 172 forms the start of a path that begins with a central opening in hex drive 186 and which extends to a point just proximal of nose 180. Gordon ¶ 84; Ritchart ¶¶ 174-76.

As seen below, the "central passage" disclosed in Gordon extends (a) along the anchor body's longitudinal axis, (b) from an opening at the proximal end of the anchor body, and (c) through a portion of a length of the anchor body.



Ex. 1105, Gordon, Fig. 25B.



Ex. 1105, Gordon, Fig. 23.

Claim 10 further requires that the anchor body has a "first suture opening" at the proximal end of the anchor body, a "second suture opening disposed distal of the first suture opening," and a "third suture opening" that is "disposed distal of the

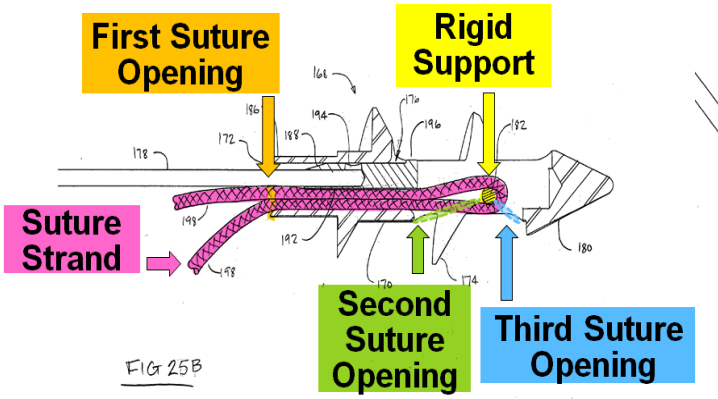
second suture opening" and is also "disposed distal of the rigid support." Under the BRI standard, a "suture opening" is an open space serving as a passage or gap, or a breach or aperture, through which a suture passes." The Gordon anchor body has all three claimed suture openings.

The first suture opening is the entrance to lumen 172 in the center of hex drive 186. Gordon at Figs. 23-25; Ritchart ¶ 177-79. The hex drive 186 is part of the anchor body. Gordon ¶ 84. As seen in Figures 25A-C, the opening in the hex drive is located at the proximal end of the anchor body and is a passage through which a suture passes. Ritchart ¶ 179.

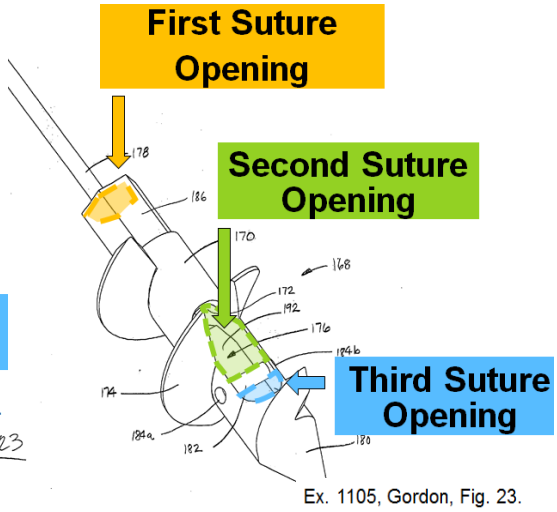
The second suture opening is either of two openings formed by the cut-outs in the anchor wall near pulley 182. Similar to the two suture passages 94 depicted in Figure 7a of the '541 patent, the two openings in Gordon are openings that the cut-outs in the anchor wall create and which allow a suture to be threaded out of the anchor body and around pulley 182 (or the eyelet shield 9 in the '541 patent). *Compare* Gordon at Figs. 23-25 *with* Ex. 1101 at 5:37-41, Fig. 7a (elements 94); Ritchart ¶¶ 180-83. Each such opening in Gordon (like suture passages 94 in the '541 patent) is disposed distal of the first suture opening." Ritchart ¶¶ 180-83.

The third suture opening is the opening through the anchor body between pulley 182 and nose 180. This third opening allows a suture to pass out of one of the second openings, loop around the pulley 182, and pass back into the other of

the second openings. The third opening is "disposed distal of the second suture opening" and is also "disposed distal of the rigid support." Below, the annotated versions of Gordon Figures 23 and 25B show examples of where first, second and third suture openings are disclosed in Gordon.



Ex. 1105, Gordon, Fig. 25B.

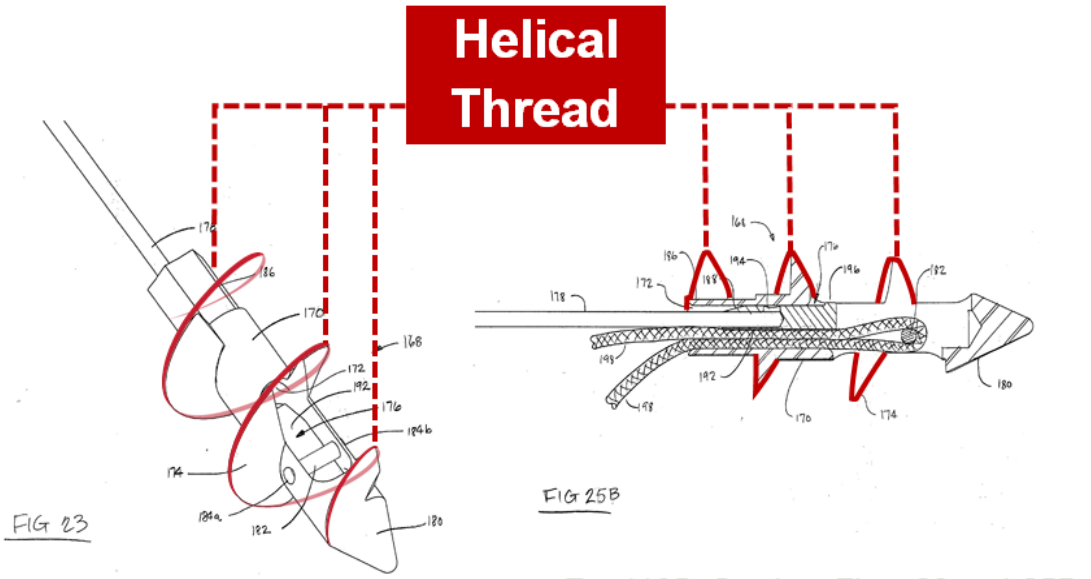


Ex. 1105, Gordon, Fig. 23.

Claim 10 also requires that the suture anchor include a "rigid support." Under the BRI standard, a "rigid support" is "an inflexible part of the suture anchor that supports a tissue securing suture." *See* § VI.B above. Pulley 182 of Gordon is a rigid support. The pulley is fixed to the anchor body via coaxial holes 184a and 184b in the side of the anchor body. Gordon ¶ 84, Fig. 23. The 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. Ritchart ¶¶ 187-88. Pulley 182 is thus a "rigid support" under the BRI.

Claim 10 further requires that the "rigid support" (a) extend across the central passage, and (b) have 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. Under the BRI standard, "branching" means "extending." As it is fixed to the anchor body within holes in the wall of the anchor body, pulley extends from, i.e., branches from, one wall to the other. Gordon ¶ 84, Fig. 23; Ritchart ¶ 189. The first and second "portions" of the pulley are the two halves of the pulley each of which extends from opposing sides of the anchor wall. Ritchart ¶ 189.

As noted above, claim 10 also requires that "a helical thread defines a perimeter around the proximal end of the anchor body." Arguably, this feature is not expressly disclosed by Gordon, because an unthreaded male hex drive 186 extends from the proximal end of Gordon's anchor body 170. As discussed above in § VIII.A.3, however, in light of West's teaching that it is advantageous for a suture anchor to have a helical thread extending to its proximal end, a POSA would have modified Gordon's suture anchor 168 to use a threaded female drive socket so that helical threads extend to the anchor's proximal end. Ritchart ¶¶ 184-85. In the modified Gordon suture anchor, the helical thread defines a perimeter around the proximal end of anchor body 170, as shown in annotated Figs. 23 and 25B below. *Id.*



Ex. 1105, Gordon, Figs. 23 and 25B.

Finally, claim 10 requires a driver with a shaft that "engages the anchor body." Gordon discloses a driver (installation tool 114) including a shaft 118 having a shaft length, wherein shaft 118 engages the anchor body, and the length of the suture strand is greater than the length of shaft 118. Gordon at Figs. 13-14, ¶ 79; Ritchart ¶¶ 194-95.

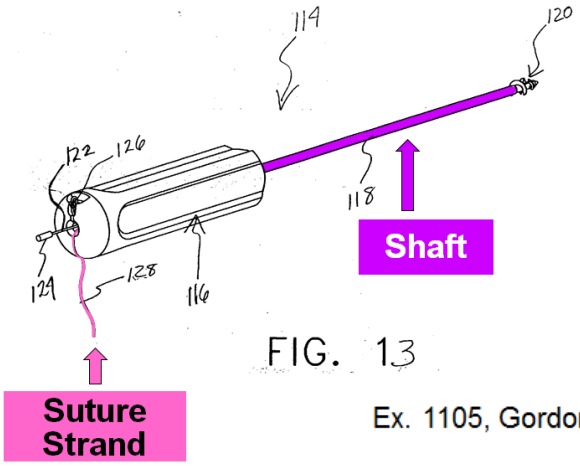
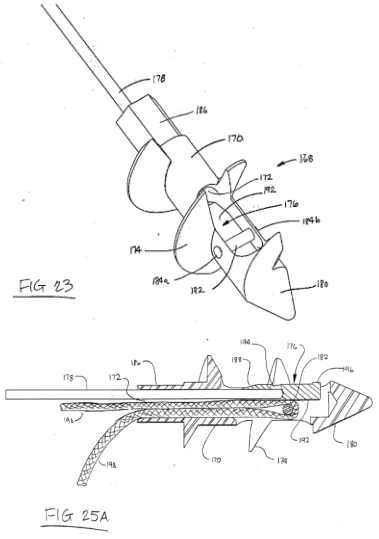


FIG. 13

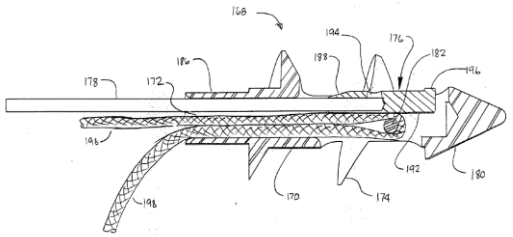
Ex. 1105, Gordon, Fig. 13.

As discussed in § VIII.A.3 *supra*, the suture anchor that a POSA would have been led to implement based on the teachings of West and Gordon would be Gordon's suture anchor 168 modified to use a female drive socket. A POSA would likewise have been led to make the corresponding modification to Gordon's driver (shaft 118) to include a male hex head that mates with the female hex socket formed in the proximal end of anchor body 170 of the modified Gordon suture anchor, as a POSA would readily recognize that a male driver works with a female drive socket and vice versa. Ritchart ¶ 195.

For the reasons discussed above and those identified in the claim chart below, Gordon and West disclose each limitation of claim 10.

CLAIM 10	**GORDON AND WEST**	
10 [pream] A suture anchor assembly comprising:	Gordon at Title ("Threaded Knotless **Suture Anchoring Device** and Method"), ¶¶ 1, 24, 28, 61, 66-67, 84, 86 ("Referring now to FIGS. 25A, 25B, and 25C, there is seen a … **suture anchor 168**…"), Figs. 23-25.	
[A1] 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	Gordon ¶ 84 ("Referring now to FIGS. 23 and 24, there may be seen a knotless suture anchor 168 similar in structure to suture anchor 46 in FIG. 1B, comprising **an anchor body 170, a lumen 172 through anchor body** 170…. The suture anchor 170 further comprises a nose 180… and a hex drive 186."), Figs. 23-25.	

anchor body		
[A2] 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,	Gordon ¶ 84 ("Referring now to FIGS. 23 and 24, there may be seen a knotless suture anchor 168 similar in structure to suture anchor 46 in FIG. 1B, comprising an anchor body 170, a lumen 172 through anchor body 170…."), Figs. 23-25; *see also* figures in [A1]; Ritchart ¶¶ 177-83.	
[A3] wherein a helical thread defines a perimeter at least around the proximal end of the anchor body	West at 2:63-67("Because the driver tool is placed on the interior or the bone anchor, **the anchor body can be threaded to the proximal end**. Threading the proximal end of the anchor body provides the bone anchor with the ability to better engage the cortical bone near the surface of the bone."); *see also id*. at 1:50-64, 2:59-62, 4:47-51, 5:40-46, 6:14-25, 8:13-17; Ritchart ¶¶ 164-66, 184-85.	
[B1] 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	Gordon ¶ 84 ("The suture anchor 170 further comprises a nose 180, **pulley 182**, which is disposed in holes 184a, b...."), ¶ 86 ("Referring now to FIGS. 25A, 25B, and 25C, there is seen … a suture strand 198 that is disposed in the lumen 172 and around the pulley 182."), ¶ 87 ("Now with reference particularly to FIG. 25A, there is clearance between the walls of the lumen 172 and the suture strand 198 that allow the suture strand 198 to move freely within the lumen 172 and around the pulley 182."), Figs. 23-25 (element 182); *see also* figures in [A1]. Ritchart ¶¶ 186-89.	

anchor body	
[B2] wherein the third suture opening is disposed distal of the rigid support	*See* [A2], [B1]; *see also* Ritchart ¶ 190.
[C1] 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	Gordon ¶ 86 ("[A] suture strand 198 that is disposed in the lumen 172 and around the pulley 182."), Figs. 25A-C (element 198).  FIG 25A
[C2] 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.	Gordon ¶ 86 ("[A] suture strand 198 that is disposed in the lumen 172 and **around the pulley 182**."), Figs. 25A-C. Ritchart ¶¶ 192-93.
[D] a driver including a shaft	Gordon ¶ 69 ("In FIG. 3 there is shown a suture anchoring device 50 which comprises a handle actuator 52 attached to

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	an outer tubular shaft 54. An **inner tubular shaft 55** is disposed within the outer tubular shaft 54. **The screw-type anchor 48 is attached to a distal end of the inner shaft 55**."), ¶ 70, ¶ 79 ("Thus, as shown in FIGS. 13 and 14, there is provided a bone anchor installation tool 114, which comprises a handle 116, a shaft 118 extending distally from the handle 116, and a screw-type bone anchor 120 disposed on a distal end of the shaft 118…. A snare loop 126 and **a length of suture 128** are both attached to the bone anchor 120 and **extend proximally through the shaft 118 and handle 116**, as illustrated."), Figs. 3-7, 12-14; Ritchart ¶¶ 194-95

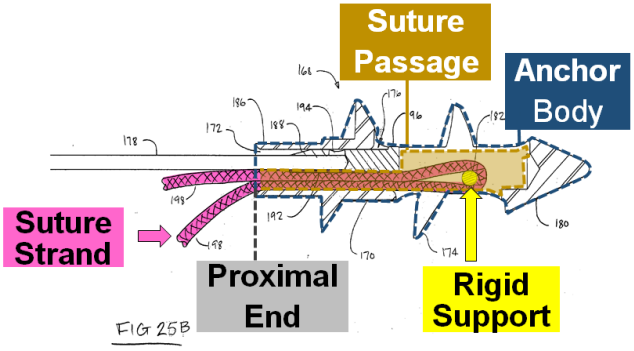
b. Independent Claim 11

Gordon discloses most limitations of claim 11 of the '541 patent. The only feature not expressly disclosed in Gordon is limitation [B1], which requires "a rigid support integral with the anchor body to define a single-piece component." As the formation of such components in that manner was expressly taught by West, a POSA would have found it obvious to modify the Gordon anchor such that it also meets limitation [B1]. Ritchart ¶¶ 167-71, 206-09. The rationale underlying the obviousness of this combination is further explained below.

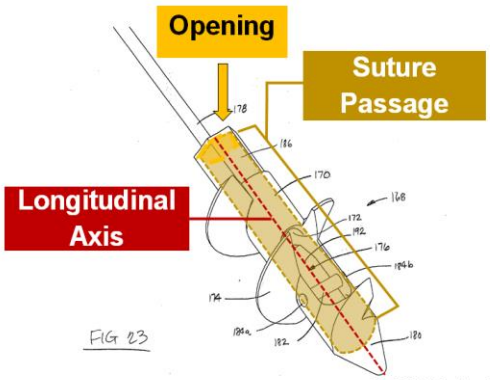
Because claims 10 and 11 are identical in many respects, rather than repeating all of the analysis above concerning claim 10, this Section focuses on the differences between the limitations of claims 10 and 11, as well as the manner in which Gordon/West combination meets the limitations of claim 11 in spite of those differences.

Claim 11 requires an anchor body that has a "suture passage," whereas claim 10 requires the body to have a "central passage." Although very similar, the specific characteristics of the respective elements differ slightly. Under the BRI standard, a "suture passage" is "a path, channel, or duct of an anchor body for a suture." *See* § VI.D above. Gordon discloses an anchor body with such a path. Specifically, lumen 172 forms the start of a path for suture 198 that begins with a central opening in hex drive 186 at the proximal end of the anchor body and which extends to a point just proximal of nose 180. Gordon ¶ 84; Ritchart ¶ 200.

As seen below, the "suture passage" disclosed in Gordon extends (a) about the anchor body's central longitudinal axis, (b) begins at an opening at the proximal end of the anchor body, and (c) extends from that opening at least partially along the length of the anchor body.



Ex. 1105, Gordon, Fig. 25B.



Ex. 1105, Gordon, Fig. 23.

Unlike claim 10, claim 11 requires that "first suture opening" be "encircled by a perimeter of the anchor body," and specifies that the "second suture opening" and the "third suture opening" both "extend[] through a portion of the anchor

body." In spite of these differences, the first, second and third suture openings of claim 11 map to the same openings of Gordon as claim 10.

As for the "first suture opening," i.e., the entrance to lumen 172 in the center of hex drive 186, that opening is encircled by a perimeter of the anchor body (i.e., the perimeter of the hex drive). Ritchart ¶ 202.

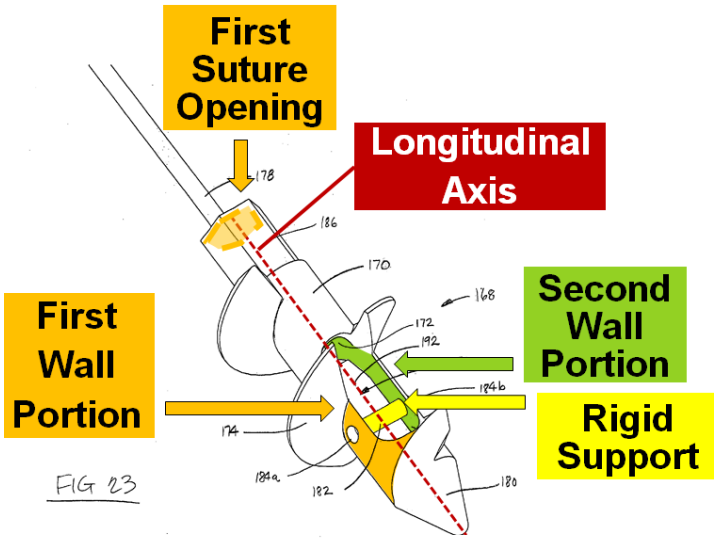
With respect to the "second suture opening," i.e., either of two openings formed by the cut-outs in the anchor wall near pulley 182, similar to the two suture passages 94 depicted in Figure 7a of the '541 patent, the two openings in Gordon are openings that the cut-outs in the anchor wall create and which allow a suture to be threaded out of the anchor body and around pulley 182 (or the eyelet shield 9 in the '541 patent). *Compare* Gordon at Figs. 23-25 *with* Ex. 1101 at 5:37-41, Fig. 7a (elements 94); Ritchart ¶¶ 203-04. Formed by cut-outs in the anchor wall, each opening in Gordon (like suture passages 94 in the '541 patent) "extends through a portion of the anchor body," i.e., the anchor wall. Ritchart ¶¶ 203-04.

Finally, as for the third suture opening, i.e., the opening distal to pulley 182 and proximal to nose 180, it too "extends through the anchor body" because it too is created by cut-outs in the anchor wall. *Id.*

With respect to the "rigid support," claim 11 requires the rigid support to extend across the "suture passage" rather than the "central passage." In addition, unlike claim 10, claim 11 requires that the "rigid support" be spaced axially away

from the opening at the proximal end of the anchor body along its central longitudinal axis.

As seen below, Gordon's rigid support (pulley 182) both extends (i.e., branches) between first and second wall portions of the suture passage and is spaced axially away from the first suture opening (i.e., the entrance to lumen 172 in hex drive 186) along the longitudinal axis of the anchor body. Ritchart ¶ 211-12.



Ex. 1105, Gordon, Fig. 23.

Finally, as noted above, claim 11 requires that the rigid support be "integral with the anchor body to define a single piece component." Under the BRI standard, this phrase means "a rigid support formed together with the anchor body as a unitary structure." *See* § VI.F above. Although this feature is not expressly described in Gordon, a POSA would have found it obvious to form pulley 182 integral with anchor body 170 to define a single-piece component, in view of

West's teaching that, in manufacturing a bone anchor, an anchor body and its posts/pins "can be cast and formed in a die," rather than forming those components separately and then assembling them. West at 7:41-47; Ritchart ¶¶ 205-10.

A POSA would have been motivated to form pulley 182 and anchor body 170 using such a technique at least so as to reduce the number of parts and simplify the process for getting suture anchor 168 approved by the FDA. Ritchart ¶ 208. Moreover, casting was a well-known technique for manufacturing medical devices, and its use in creating the Gordon anchor would have been a simple design choice for a POSA in September 2005. *Id.* ¶ 209. A POSA also would have been motivated to form the rigid support and anchor body as a single piece component to minimize the risk that components would disassociate and become loose within a patient's body, which would be a highly-undesirable result. *Id.* ¶ 210.

B. Ground 2: Claim 11 is anticipated by Curtis

1. Curtis

Curtis (Ex. 1107) issued on November 7, 1995, and is prior art under 35 U.S.C. § 102(b). Curtis discloses an "expanding suture anchor" that includes a main body 11 and a conical body 14 connected via an intermediate portion 20. Curtis at Title, Abstract, 2:16-23, 2:67-3:4, Figs. 1-4.

Prior to inserting the suture anchor into a patient, a suture is threaded through the suture anchor as shown in Fig. 4. To deploy the anchor, the main body

is held using an instrument inserted into connecting means 9 and suture strands 10 are pulled when the anchor is at a desired location within a bone mass. *Id*. at 2:23-28, 2:66-311. Pulling suture strands 10 causes intermediate portion 20 to break, and allows conical body 14 to be pulled within a slot 12 between two legs 21, 22 of the main body. *Id*. at 2:29-33, 3:4-16. Pulling the conical body within slot 12 causes main body 11 to expand (as illustrated in Fig. 5) and become lodged within the bone mass. *Id*. at 2:34-46, 3:12-16; Ritchart ¶¶ 151-52.

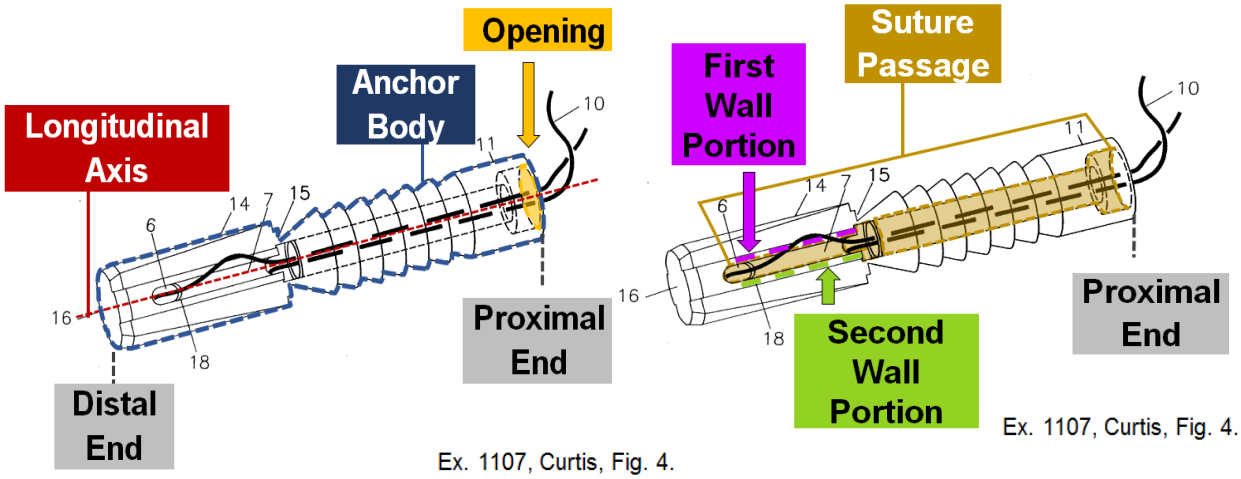
This Ground relies upon the Curtis suture anchor in its single-piece state, i.e., before the intermediate portion 20 is broken, as illustrated, for example, in Figs. 1-4 of Curtis. As illustrated previously (*see* page 5 *supra*), in its single-piece state, Curtis's suture anchor has first, second and third openings, positioned such that a suture 10 can extend into the first opening, pass through the second and third openings so as to loop around the member between channels 7, and extend back out through the first opening.

The structure of the Curtis suture anchor in its single-piece state is similar to devices Patent Owner has asserted are covered by the '541 patent's claims. *E.g.*, *compare* Ex. 1122 at 1 *with* Curtis at Fig. 4.

2. Limitation-by-Limitation Analysis

As discussed below and shown in the claim chart that follows, Curtis discloses each limitation of claim 11 of the '541 patent, and therefore anticipates claim 11. Ritchart ¶¶ 215-36.

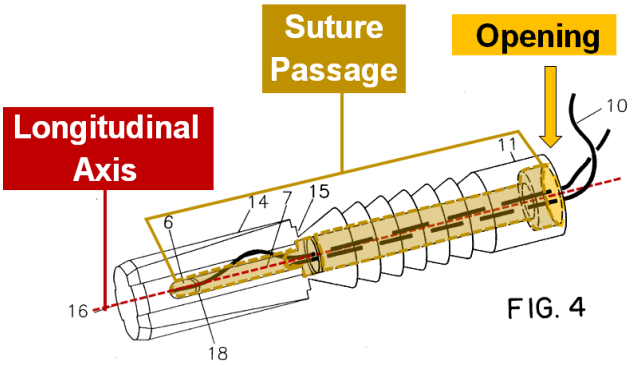
Limitation [A1][4] – The left-hand figure below shows how Curtis's main body 11 and conical body 14 together form an "anchor body" which includes a distal end (i.e., larger base 16 of conical body 14), a proximal end having an opening (i.e., the central hole in rear portion 2), and a central longitudinal axis 3, 13. Curtis at 2:18-19, 2:34-25, 2:66-3:14; Ritchart ¶¶ 217-22. The right-hand figure shows that Curtis's anchor body also has a first wall portion and a second wall portion spaced opposite to the first wall portion, and a suture passage (i.e., bore 19 and channels 7) beginning at the proximal end (i.e., rear portion 2) of anchor body 11, 14. Curtis at Figs. 1-4, 2:16-65, 3:8-10; Ritchart ¶¶ 220-21.



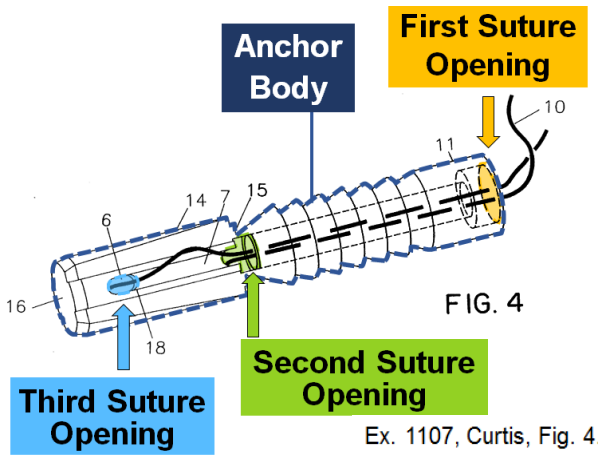
[4] Limitation identifiers correspond to those provided in the claim chart below.

As discussed above in § VI.D, the BRI of "suture passage" is "a path, channel, or duct of an anchor body for a suture." The bore 19 and channels 7 qualify as a "suture passage" under this definition, as they together form a path for suture 10. Curtis at 2:26-28, 2:40-43, 2:47-55, 3:8-10; Ritchart ¶ 222.

Limitations [A2] and [A3] – The annotated figures below identify further details of Curtis's suture passage as well as its first, second and third suture openings. Ritchart ¶¶ 225-29.



Ex. 1107, Curtis, Fig. 4.



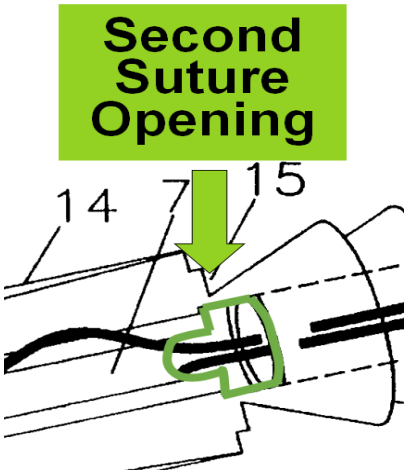
Ex. 1107, Curtis, Fig. 4.

The left-hand figure shows how Curtis's suture passage (i.e., bore 19 and channels 7) extends about central longitudinal axis 3, 13, and how the suture passage extends from the opening located at the proximal end of the anchor body (i.e., the central hole in rear portion 2) and at least partially along a length of anchor body 11, 14. Curtis at Figs. 1-4, 2:22-28, 2:47-59; Ritchart ¶¶ 223-24. The right-hand figure shows how the central hole in Curtis's rear portion 2 is a first suture opening that is encircled by a perimeter of the anchor body (i.e., the

perimeter of the rear portion 2). Curtis at Figs. 1-4. The right-hand figure also shows how a second suture opening (i.e., the space between distal end of bore 19 and passage 24) extends through a portion of anchor body 11, 14, and how a third suture opening (i.e., orifice 18 of through-hole 6) extends through anchor body 11, 14, wherein the third suture opening (i.e., orifice 18) is disposed distal of the second suture opening (i.e., the space between distal end of bore 19 and passage 24). *Id.* at Figs. 1-4, 2:16-65, 3:8-10; Ritchart ¶¶ 225-29.

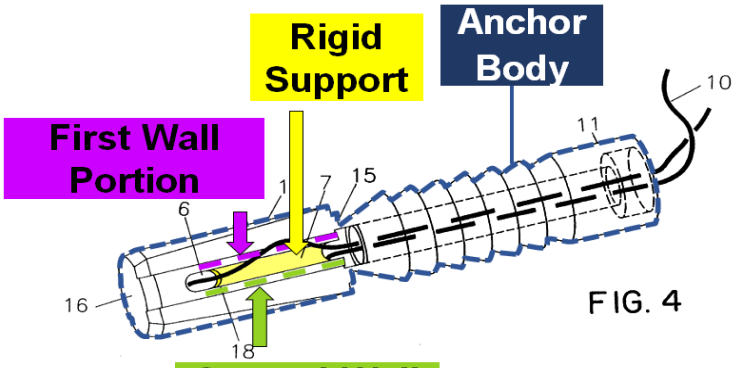
As noted in § VI.A, the BRI of "suture opening" is "an open space serving as a passage or gap, or a breach or aperture, through which a suture passes." The three elements identified above, i.e., central hole in rear portion 2, the space between the distal end of bore 19 and passage 24, and the orifice 18 of through-hole 6, all meet that definition, as they each serve as an aperture through which suture 10 passes. Ritchart ¶ 229.

As shown in the adjacent close-up image, the perimeter of the second suture opening follows along slightly less than half of the circumference of the distal end of bore 19, extends along one leg of intermediate portion 20 toward conical body 14, follows the semicircular shape of passage 24 around to the other leg of intermediate portion 20, and follows that other leg back to beginning of the



circumferential path at the distal end of bore 19. Curtis at Figs. 3-4; Ritchart ¶ 227.

Limitations [B1]-[B3] – As seen below, Curtis discloses the rigid support (i.e., the member between channels 7) claim 11 requires. Ritchart ¶¶ 230-33.



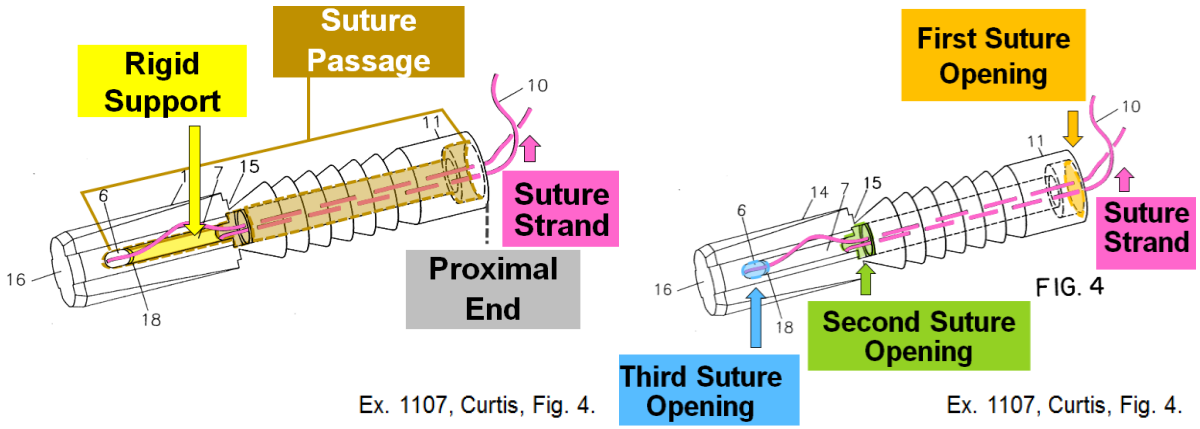
Ex. 1107, Curtis, Fig. 4.

As discussed above in § VI.B, the BRI of "rigid support" is "an inflexible part of the suture anchor that supports a tissue securing suture." The member between the channels 7 qualifies as such a component as a POSA would understand it to be inflexible and it is designed to "support" the suture 10. Curtis at 2:47-3:8, 3:17-19; Ritchart ¶ 231. Moreover, as discussed in § VI.F above, the BRI of "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." The member between channels 7 meets this definition because the **entirety** of Curtis's suture anchor, except for the suture 10, is molded from the same material as a unitary structure, with the main body 14 and the conical body

11 being "temporarily connected coaxially by an intermediate portion 20." Curtis at 2:66-3:4, 3:17-19, claim 1; Ritchart ¶ 231.

As shown above, Curtis's rigid support (i.e., the member between channels 7) extends across the suture passage (i.e., bore 19 and channels 7) and has a first portion and a second portion spaced from the first portion, the first portion branching (i.e., "extending" – *see* § VI.E above) from the first wall portion of the anchor body and the second portion branching from the second wall portion of anchor body 11, 14. Curtis at Figs. 1-4, 2:48-59; Ritchart ¶ 232. Curtis's rigid support (i.e., the member between channels 7) is also spaced axially away from the opening at the proximal end (i.e., the hole in rear portion 2) along central longitudinal axis 3, 13. Curtis at Figs. 1-4, 2:47-59; Ritchart ¶ 233.

Limitations [C1] and [C2]– As shown below, Curtis also discloses the suture strand required by claim 11. Ritchart ¶¶ 234-36.



Ex. 1107, Curtis, Fig. 4. Ex. 1107, Curtis, Fig. 4.

As shown in the left-hand figure, Curtis's suture 10 is threaded into the suture passage (i.e., bore 19 and channels 7), is supported by the rigid support (i.e.,

the member between channels 7), and has ends that extend past the proximal end of the anchor body (i.e., rear portion 2). Curtis at Figs. 2, 4, 2:26-28, 2:40-55, 3:4-8; Ritchart ¶¶ 234-35. The right-hand figure shows how Curtis's suture 10 is disposed in each of the first suture opening (i.e., the hole in rear portion 2), the second suture opening (i.e., the space between distal end of bore 19 and passage 24), and the third suture opening (i.e., orifice 18). Curtis at Figs. 2, 4, :26-28, 2:40-55, 3:4-8; Ritchart ¶ 236.

For the reasons discussed above and those identified in the claim chart below, Curtis discloses each limitation of claim 11.

CLAIM 11	**CURTIS**
11. [pream] A suture anchor assembly comprising:	Curtis at Title ("Expanding Suture Anchor"), Abstract, 2:16-65 ("The **suture anchor** as represented in FIGS. 1-4 consists basically of a first main body 11 and a conical body 14…."), claim 1; Figs. 1-4.
[A1] an anchor body including a distal end, a proximal end having an opening, a central longitudinal axis, a first wall portion, a second wall portion spaced opposite to the first wall portion, and a suture passage beginning at the proximal end of the anchor body,	Curtis at 2:16-17 ("The suture anchor as represented in FIGS. 1-4 consists basically of a first main body 11 and a conical body 14."), 2:18-19 ("The main body 11 has a generally cylindrical shape with a front portion 1, a **rear portion 2** and **a longitudinal axis 3**."), 2:26-28 ("A **central through-going bore 19** extends from the front portion 1 to the rear portion 2 for receiving the two ends of the loop of suture 10."), 2:34-36 ("The second conical body 14 has a smaller base 15, a larger base 16, a curved surface 17 and a **longitudinal axis** 13."), 2:47-51 ("**Two channels 7** are positioned on the curved surface 17 of the conical body 14 and extend from the orifices 18 of the through-hole 6 to the smaller

	base 15. The function of the channels 7 is to take up the suture 10."), 2:66-31, 3:4-10 ("The intermediate portion 20 is provided with a **passage** 24 for allowing space for introduction of the suture 10 between the main body 11 and the conical body 14."). Figs. 1-4, Ritchart ¶¶ 217-22.
[A2] wherein the suture passage extends about the central longitudinal axis, and the suture passage extends from the opening located at the proximal end of the anchor body and at least partially along a length of the anchor body,	Curtis at 2:26-28, 2:47-55 ("A **central through-going bore 19 extends from the front portion 1 to the rear portion** 2 for receiving the two ends of the loop of suture 10…. **Two channels** 7 are positioned on the curved surface 17 of the conical body 14 and **extend from the orifices 18 of the through-hole 6 to the smaller base 15**. The function of the channels 7 is to take up the suture 10--as shown in FIGS. 3 and 4…."), Figs. 1-4; Ritchart ¶¶ 223-24.
[A3] wherein the opening is a first suture opening that is encircled by a perimeter of the anchor body, a second suture opening extends through a portion of the anchor body, and a third suture opening extends through the anchor body, wherein the third suture opening is disposed distal of the second suture opening	Curtis at 2:23-26 ("A central through-going bore 19 extends from the front portion 1 to the rear portion 2 for receiving the two ends of the loop of suture 10."), 2:47-55. ("Two channels 7 are positioned on the curved surface 17 of the conical body 14 and extend from the **orifices** 18 of the through-hole 6 to the smaller base 15. The function of the channels 7 is to take up the suture 10--as shown in FIGS. 3 and 4--after its introduction in the through-hole 6 and to prevent its blocking between the curved surface 17 and the main body 11 (the suture 10 is passed through the through-hole 6 prior to assembly of the anchor), 3:4-10 ("The intermediate portion 20 is provided with a passage 24 for allowing space for introduction of the suture 10 between the main body 11 and the conical body 14."), Figs. 1-4; Ritchart ¶¶ 225-29.
[B1] a rigid support integral with the anchor body to define a single-piece component	Curtis at 2:60-3:8 ("The main body 14 and the conical body 14 may … be – as shown in FIGS. 1-4 – **temporarily connected coaxially by an intermediate portion** 2, which upon applying a certain pulling force to the suture 10 breaks away bringing the conical body in abutment with the main

	body 11 as shown in FIGS 3 and 4. The application of the pulling force occurs by holding the main body 11 with a suitable instrument using the connecting means 9 and pulling the two ends of the loop of suture 10 introduced through the trough [sic – through] hole 6 and the central bore 19."), 3:17-19 ("The suture anchor can be made of any known implant material, e.g. stainless steel or titanium[, and preferably] is made of a resorbable material, e.g. a polylactide."), claim 1; Ritchart ¶¶ 230-31.
[B2] wherein the rigid support extends across the suture passage and has a first portion and a second portion spaced from the first portion, the first portion branching from the first wall portion of the anchor body and the second portion branching from the second wall portion of the anchor body	*See* [B1]*; see also* Curtis at 2:26-28, 47-51 ("A central through-going bore 19 extends from the front portion 1 to the rear portion 2 for receiving the two ends of the loop of suture 10… Two channels 7 are positioned on the curved surface 17 of the conical body 14 and extend from the orifices 18 of the through-hole 6 to the smaller base 15. The function of the channels 7 is to take up the suture 10."); Ritchart ¶ 232.

[B3] the rigid support is spaced axially away from the opening at the proximal end along the central longitudinal axis	*Id*. at Figs. 1-4, 2:48-59; Ritchart ¶ 233.
[C1] at least one suture strand threaded into the suture passage, supported by the rigid support	Curtis at 2:26-28, 2:40-43, 2:47-55, 3:4-8, Figs. 1-4; Ritchart ¶ 234-35.
[C2] having ends that extend past the proximal end of the anchor body, and the at least one suture strand is disposed in the first suture opening, the second suture opening, and the third suture opening.	Curtis at 2:26-28, 2:40-52, Figs. 1-4; Ritchart ¶ 236.

C. Ground 3: Claim 10 Would Have Been Obvious over Curtis in View of Overaker

Curtis was discussed in Ground 2. Publication No. 2003/0187444 ("Overaker") (Ex. 1124) published October 2, 2003, and is prior art under 35 U.S.C. § 102(b).

1. Curtis

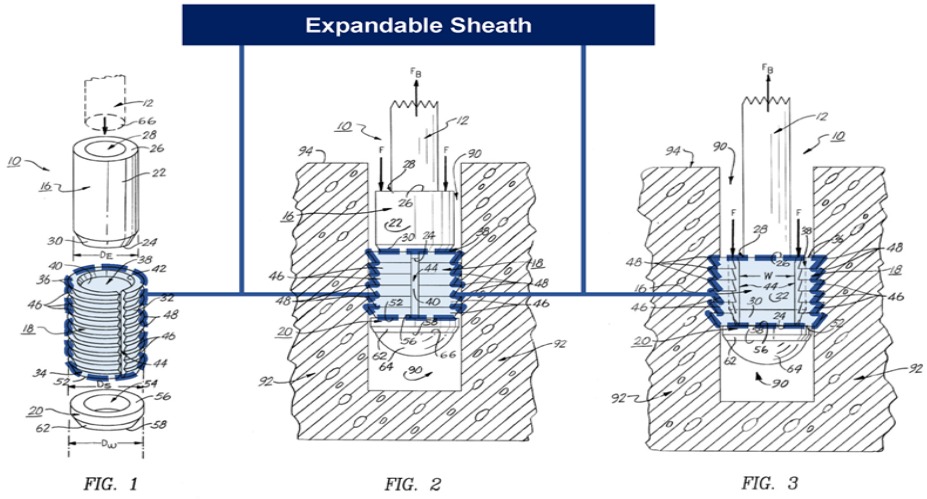
As demonstrated below, Curtis discloses a suture anchor assembly including all limitations of claim 10, except for limitation [A3] which requires that "a helical thread defines a perimeter at least around the proximal end of the anchor body."

Curtis teaches that "[t]he curved surface 4 of the main body 11 is provided with 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." Curtis at 2:20-23. Curtis does not, however, identify what types of protrusions 5 can be employed over its full length. As discussed below, Overaker would have motivated a POSA to modify Curtis's suture anchor to incorporate protrusions in a helical configuration. Ritchart ¶¶ 239-43.

2. Overaker

As illustrated in Figs. 1-3 of Overaker (reproduced below), Overaker describes an expandable anchor similar to that of Curtis except that Overker's expandable sheath 18 expands when an expander member 16 is **pushed** into a

proximal end of the sheath 18, whereas Curtis's main body 11 expands when conical body 14 is **pulled** into a **distal end** of main body 11. Ritchart ¶¶ 155-57.



Overaker's expandable sheath 18 includes ribs 46 along its entire length, including about its proximal end 36, "for engaging the bone tissue within a bone hole opening in which the bone anchoring device 10 is deployed." Overaker ¶ 20. Overaker teaches that, instead of using ribs that are circumferentially aligned, as depicted in Fig. 1, "the ribs 46 could have a helical configuration." *Id.* ¶ 20, claim 10; Ritchart ¶¶ 155-57.

3. Combination of Curtis and Overaker

Overaker discloses that circumferentially aligned ribs on an expandable anchor, like those used with the suture anchor of Curtis, are interchangeable with helical threads. Overaker ¶ 20. In light of Overaker, a POSA would have considered substituting the circumferentially aligned "protrusions" of Curtis, which extend along the full length of the Curtis anchor body (Curtis at 2:18-23), with a

helical thread to be a simple substitution of one known element for securing an anchor to bone for another. Ritchart ¶¶ 242-43. A POSA would have also known that this substitution would have yielded a predictable result, i.e., an expandable anchor with protrusions that facilitate retention of the anchor in bone. *Id*. How such a modification would yield a suture anchor including all of the features of claim 10, including limitation [A3], is explained below.

4. Limitation-by-Limitation Analysis

Curtis discloses most limitations of claim 10 of the '541 patent. The only feature not expressly disclosed in Curtis is limitation [A3] which requires that "a helical thread defines a perimeter at least around the proximal end of the anchor body." As the addition of such a helical thread to an expandable suture anchor was expressly taught by Overaker, a POSA would have found it obvious to modify the Curtis anchor such that it also meets limitation [A3]. Ritchart ¶¶ 256-57.

Because claims 10 and 11 are identical in many respects, rather than repeating all of the analysis above concerning claim 11 vis-à-vis Curtis, this Section focuses on the differences between the limitations of claims 10 and 11 and the manner in which the Curtis/Overaker combination meets the limitations of claim 10 in spite of those differences.

Claim 10 requires an anchor body that has a "central passage," rather than a "suture passage." Although very similar, the specific characteristics of these

respective elements differ slightly. Under the BRI standard, a "central passage" is "a central path, channel, or duct of the anchor body." *See* § VI.C above. The bore 18 and channels 7 of Curtis constitute such a central passage, which extends along longitudinal axis 3, 13 from an opening at the proximal end of the anchor body (i.e., the hole in rear portion 2) through a portion of a length of anchor body 11, 14. Curtis at Figs. 1-4, 2:16-65, 3:8-10; Ritchart ¶¶ 248-50.

Unlike claim 11, claim 10 requires that the "second suture opening" be "disposed distal of the first suture opening," and also requires the "third suture opening" to be "disposed distal of the rigid support." In spite of these difference, the first, second and third suture openings of claim 10 map to the same openings of Curtis as claim 11. Ritchart ¶¶ 251-55.

Specifically, Curtis's anchor body 11, 14 includes a second suture opening (i.e., the space between distal end of bore 19 and passage 24) disposed distal of the first suture opening, and a third suture opening (i.e., orifice 18 of through-hole 6) disposed distal of the rigid support. Curtis at Figs. 1-4, 2:16-65, 3:8-10; Ritchart ¶¶ 251-55.

Claim 10 also differs from claim 11 by requiring "a helical thread [that] defines a perimeter at least around the proximal end of the anchor body." As discussed in SectionVIII.C.3, a POSA would have found it obvious to substitute the circumferentially aligned "protrusions" of Curtis, which extend "over the full

length of the [Curtis] main body" (Curtis at 2:20-23), with a helical thread, at least because Overaker teaches such a substitution. Substituting the protrusions in Curtis's expandable suture anchor for a helical thread would have yielded a helical thread that defines a perimeter at least around the proximal end (rear portion 2) of Curtis's anchor body. Ritchart ¶¶ 242-43, 256-57.

With respect to the "rigid support," claim 10 requires it extends across the "central passage" rather than the "suture passage." Curtis's rigid support (i.e., the member between channels 7) meets this requirement, as it extends (i.e., "branches" – *see* § VI.E) between first and second wall portions of its central passage (i.e., bore 19 and channels 7). Curtis at Figs. 1-4, 2:48-59; Ritchart ¶¶ 258-61.

Finally, unlike claim 11, claim 10 requires "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." A POSA would have interpreted Curtis's disclosure of a "manipulation instrument" that is held by circular connection means 9 (i.e., the central hole in rear portion 2) as implicitly teaching use of a driver including a shaft. Curtis at 2:23-26, 3:4-8; Ritchart ¶¶ 266-69. As such, Curtis teaches that the shaft (of the manipulation instrument) engages the anchor body (via connection means 9). A POSA would also have interpreted Curtis's disclosure of suture 10 having "two ends" that are pulled while holding the suture anchor with the manipulation instrument (Curtis at

2:26-28, 3:4-8), as implicitly disclosing that the suture 10 is longer than the length of the manipulation instrument's shaft. Ritchart ¶¶ 266-69.

If either of these features is found not to be implicitly disclosed by Curtis, it would have been obvious to a POSA to employ a driver and suture with the Curtis suture anchor that met the limitations of claim 10, as discussed below in Ground 4.

D. Ground 4: Claim 10 Would Have Been Obvious Over Curtis in view of Overaker and DiPoto

Curtis and Overaker were discussed above in Grounds 2 and 3. U.S. Patent No. 5,690,676 ("DiPoto") (Ex. 1125) issued on November 27, 1997, and is prior art under 35 U.S.C. § 102(b).

1. Curtis

Curtis the use of a "manipulation instrument" to engage its circular engagement means 9 (Curtis at 2:23-26), and discloses installing the suture anchor by pulling two ends of suture 10 while holding the suture anchor with that instrument. *Id*. at 3:4-8; Ritchart ¶ 271.

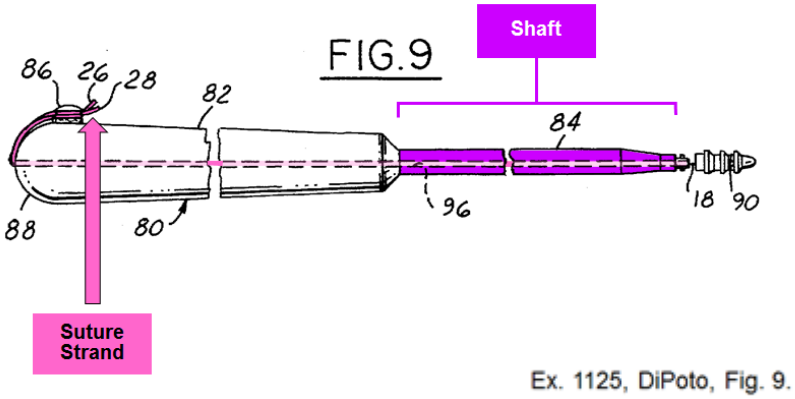
2. Overaker

As noted above, Overaker teaches arranging the ribs on an expandable anchor in a helical configuration. Overaker ¶ 20, claim 10; Ritchart ¶ 272.

3. DiPoto

As seen below, DiPoto discloses a driver 80 used to position a suture anchor in place within a bone. DiPoto at Fig. 9, 6:17-67. The driver has a handle and a

shaft 84 that are cannulated to allow ends of a suture 16 to pass through it and be temporarily held on fixation post 86. *Id*. at 6:17-59. After the driver has set the anchor in place, the ends of the suture are unwound from the fixation post and the driver is removed from the surgical site. *Id*. at 6:49-52; Ritchart ¶¶ 158-60.



Ex. 1125, DiPoto, Fig. 9.

4. Combination of Curtis, Overaker and DiPoto

To the extent the specific "driver" features of limitation 10[D] are deemed not disclosed in Curtis, a POSA would have found it obvious in view of DiPoto to employ a driver having such features together with Curtis's suture anchor. Ritchart ¶¶ 276-77. A POSA would have been motivated to use the driver of DiPoto as the "manipulation instrument" Curtis discloses for engaging the engagement means 9 of Curtis's suture anchor 11, 14, so as to allow a surgeon to accurate place Curtis's suture anchor 11, 14 within a bone cavity, and at the same time temporarily hold the loose ends of Curtis's suture 10. *Id.*

Use of the DiPoto driver device 80 with Curtis's suture anchor 11, 14 would constitute a driver (i.e., DiPoto's driver device 80) including a shaft 84 having a

shaft length, wherein shaft 84 engages anchor body 11, 14, and the suture length of the suture 10,16 is greater than the length of the shaft 84. Such a combination would thus embody the features of limitation 10[D]. Ritchart ¶¶ 276-77.

IX. CONCLUSION

Inter partes review of claims 10 and 11 of the ’541 patent is respectfully requested.

Respectfully submitted,
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CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6(e)(4)

I certify that on April 19, 2016, I will cause a copy of the foregoing document, including any exhibits or appendices referred to therein, to be served via Overnight FedEx upon the attorney of record for the patent at the following address:

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