Trials@uspto.gov
Tel: 571-272-7822

Paper 11
Entered: August 2, 2016

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 IPR2016-00506
Patent 8,623,052 B2

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

GROSSMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Smith & Nephew, Inc. and ArthroCare Corp. (jointly "Petitioner") request an *inter partes* review of claims 1–18 of U.S. Patent No. 8,623,052 B2 (Ex. 1001, "the '052 patent"). Paper 2 ("Petition" or "Pet."). Arthrex, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition and Patent Owner's Preliminary Response, we institute an *inter partes* review on all challenged claims of the '052 patent.

Our factual findings and conclusions at this stage of the proceeding, including claim constructions, are preliminary, and based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial.

A. Related Matters

The '052 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. Pet. 5; Paper 6, 1. There are several related petitions for *inter partes* review: IPR2015-00505 (involving U.S. Patent No. 8,343,186, from which the '052 patent claims priority), and IPR2016-00507 and 508 (involving U.S. Patent No. 8,801,755, which claims priority from

the ’052 patent). Pet. 5; Paper 6, 1. There are also a number of related patents and patent applications not presently at issue. Pet. 5; Paper 6, 1–2.

B. The ’052 Patent

The ’052 patent is directed to a suture anchor having a transverse anchor pin inside the body of the anchor. Ex. 1001, 2:16–19. Figure 6 of the ’052 patent is reproduced below:

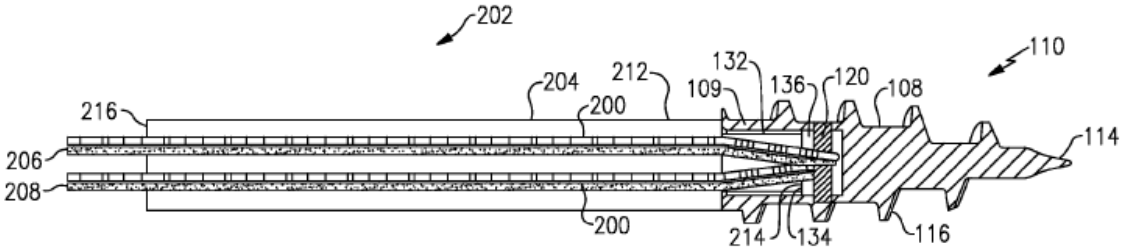

FIG.6

Figure 6 is a cross sectional view of a suture anchor showing a driver inserted into the surgical anchor.

As shown in Figure 6, suture strands 200 are threaded around anchor pin 120 in suture anchor 110. Ex. 1001, 4:35–36. Ends 206 and 208 of suture strands 200 are threaded through cannula 204 in hex driver 202, extending from distal end 214 through proximal opening 216. *Id.* at 4:36–39. Distal end 214 of hex driver 202 is inserted into the proximal end of the anchor 110. *Id.* at 4:39–40. In use, hex driver 202 is rotated to drive anchor 110 into the bone until the proximal surface of the anchor 110 is flush with the surface of the bone. *Id.* at 4:43–45.

C. Challenged Claims

Petitioner challenges claims 1–18. Claims 1 and 10 are independent claims and substantially are identical.[1] Claim 1 is reproduced below.

> 1. A suture anchor assembly comprising:
> an anchor body having a distal end, a proximal end, a length extending along a central longitudinal axis of the anchor body, and an internal central cavity, wherein the internal central cavity extends about the central longitudinal axis, extends at least partially along the length of the anchor body and extends from an opening located at the proximal end of the anchor body, wherein an external helical thread extends at least partially around the internal central cavity;
> a rigid member fixed by the anchor body against relative movement along the central longitudinal axis of the anchor body, wherein the rigid member extends across the internal central cavity, wherein the rigid member has a first dimension that is generally parallel to the central longitudinal axis of the anchor body and a second dimension that is generally perpendicular to the central longitudinal axis of the anchor body, and the second dimension is longer than the first dimension;
> at least one tissue securing suture looped over the rigid member, wherein the at least one tissue securing suture includes a first end and a second end that extend out of the opening located at the proximal end of the anchor body; and
> a driver having a cannula, wherein the cannula has a distal opening and a proximal opening, the

[1] For example: claim 1 recites "a rigid member," claim 10 recites "a rigid support;" claim 1 recites a "central longitudinal axis," claim 10 recites a "longitudinal axis."

> driver engaging the anchor body through a portion of the internal central cavity, and wherein the first end and the second end of the at least one tissue securing suture extend out of the proximal opening of the cannula.

D. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–18 of the '052 patent are unpatentable under 35 U.S.C. § 103 on the following grounds:

References	**Claims Challenged**
Dreyfuss[2] and Foerster[3]	1–18
Dreyfuss and Goble '397[4]	1–18
Morgan[5] and Dreyfuss	1–18
Pierson[6] and Goble '523[7]	1–18

Petitioner also relies on a 280 page declaration of Mark A. Ritchart (Ex. 1003), the president of a medical device company (*id.* ¶ 2).

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.

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[2] U.S. Pub. No. 2003/0065361 A1, published Apr. 3, 2003 (Ex. 1006).

[3] U.S. Patent No. 7,090,690 B2, issued Aug. 15, 2006, filed Nov. 19, 2002 (Ex. 1009).

[4] U.S. Patent No. 5,702,397, issued Dec. 30, 1997, (Ex. 1010).

[5] U.S. Pub. No. 2002/0052629, published May 2, 2002 (Ex. 1005).

[6] U.S. Patent No. 6,648,903 B1, issued Nov. 18, 2003, filed Sept. 8, 1998 (Ex. 1007).

[7] U.S. Patent No. 5,411,523, issued May 2, 1995, (Ex. 1008).

§ 42.100(b); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Although our claim interpretation cannot be divorced from the specification, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (citing *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language; *see SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes constructions for a number of terms, "an internal central cavity," "cavity," "longitudinal axis," "rigid member," "rigid support," and "cannula." Pet. 11–12. Patent Owner offers its constructions of these terms, but also argues that the terms are not a source of dispute in the prior art and do not need a construction. Prelim. Resp. 9–14. We agree with Patent Owner that none of these terms require construction at this time. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Accordingly, we do not adopt an express claim construction of any claim term in this Decision.

Our claim construction determination is a preliminary determination. It does not preclude the parties from arguing their proposed constructions of the claims during trial. Indeed, the claim construction issues discussed in the Petition and Preliminary Response put the parties on notice that claim construction, in general, is an issue to be addressed at trial.

B. Obviousness of Claims 1–18 Based On Dreyfuss and Foerster

Petitioner argues that claims 1–18 would have been obvious in view of Dreyfuss and Foerster. Pet. 13–29.

Section 103(a) precludes 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." 35 U.S.C. § 103(a). In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Court set out a framework for applying the statutory language of § 103:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Id., at 17–18. Secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others also are considered. *Id.* at 18. "While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls." *KSR Int'l. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007).

The Supreme Court has made clear that we apply "an expansive and flexible approach" to the question of obviousness. *Id.* 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, requires more than a mere showing that the prior art includes references covering each separate limitation in a claim under examination. *Id.* at 418 ("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"). "Rather, obviousness requires the additional showing 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." *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011).

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. Dreyfuss

Dreyfuss relates to a suture anchor having an internal suture loop for anchoring the suture to bone during arthroscopic surgery. Ex. 1006 ¶ 3. Figure 5 of Dreyfuss is reproduced below:

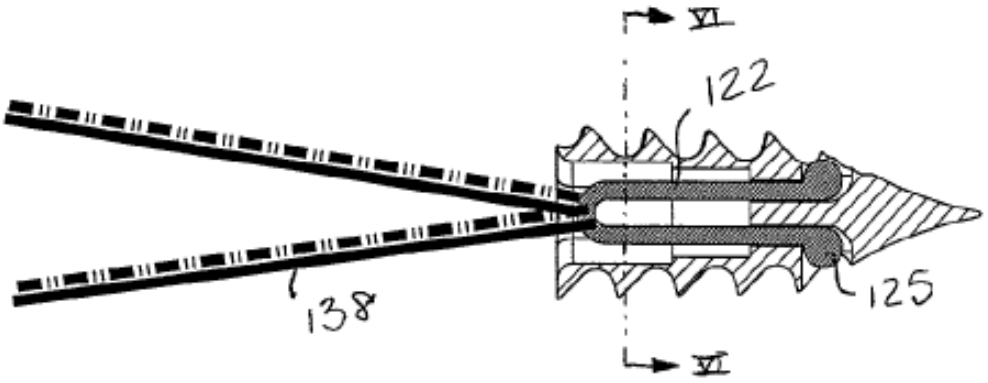

FIG. 5

Figure 5 is a cross sectional view of the suture anchor. *Id.* ¶ 24. A loop of suture 122 is disposed inside the body of the suture anchor. *Id.* ¶ 35. The ends of suture loop 122 are tied in knots 125 and inserted into apertures, which prevent suture loop 122 from being pulled through, into the interior of the anchor. *Id.* ¶ 37. Suture anchors are distributed to surgeons with one or more strands of suture 138 prethreaded through suture loop 122. *Id.* ¶ 43.

b. Foerster

Foerster describes devices for axially anchoring suture, which attaches soft tissue to adjacent bone structure. Ex. 1009, Abstract. Figure 4 of Foerster is shown below:

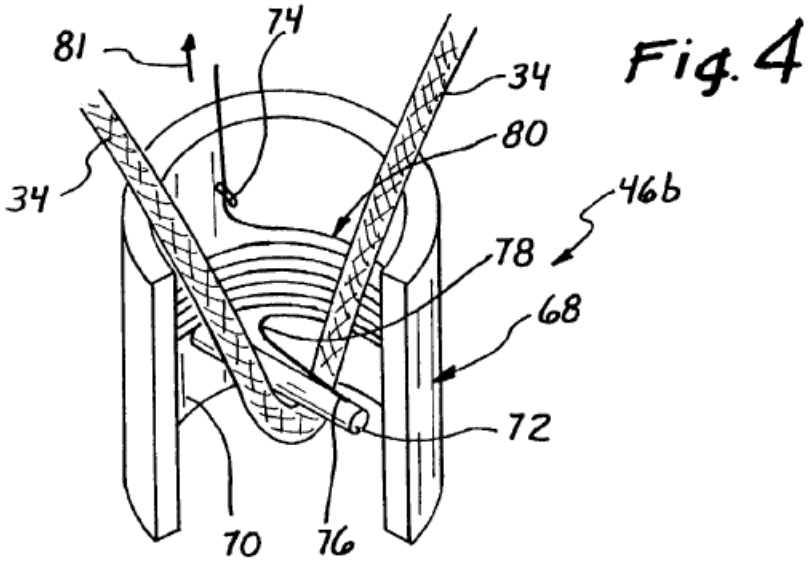

Fig. 4

Figure 4 shows a perspective view of suture anchoring device 46b, which includes cylindrical insert 68 and "suture return member or primary pin 72" disposed across the inner diameter of insert 68. *Id.* at 9:23–29. Suture length 34 is wrapped around primary pin 72. *Id.* at 9:39–41. Suture 34 is tensioned and therefore moved axially about primary pin 72 in order to pull the soft tissue toward the bone. *Id.* at 9:41–44. Monofilament fiber 78 is then pulled in the direction of arrow 81, which causes monofilament fiber 78 to wrap tightly around suture 34, locking it in place lengthwise. *Id.* at 9:44–52.

2. Level of 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) ("the level of skill in the art is a prism or lens through which a judge, jury, or the Board views the prior art and the claimed invention").

Petitioner proposes that a person of ordinary skill would have either (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. Pet. 10 (citing Ex. 1003 ¶ 12).

Patent Owner does not state a proposed level of skill.

For purposes of this Decision, we determine that it is not necessary to establish a specific level of skill. The prior art itself reflects an appropriate level of skill. *Okajima*, 261 F.3d at 1355.

3. Analysis

According to Petitioner,

> the only difference between the solutions of Dreyfuss and the '052 patent is that Dreyfuss uses a 'suture loop disposed inside the body of the suture anchor' (Dreyfuss ¶ 15), while the '052 patent recommends a 'transverse anchor pin disposed inside the body of the suture anchor' (Ex. 1001 at 2:16-19).

Pet. 14.

Petitioner contends that it would have been obvious to a person of ordinary skill to replace Dreyfuss's suture loop 122 with Foerster's pin 72. *Id.* at 15 (citing Ex. 1003, ¶¶ 148-49. According to Petitioner, this modification would have been a simple substitution of one known design for securing a suture to an anchor for another that would yield a predictable result. *Id.* Petitioner further asserts that a skilled artisan would have been motivated to make this substitution: (1) to reduce complexity and manufacturing cost (*id.* at 15–16 (citing Ex. 1003 ¶ 152)); (2) to streamline the regulatory approval process (*id.* at 16 (citing Ex. 1003 ¶¶ 153–154));

(3) to gain performance advantage because a smooth pin creates less friction than a suture loop (*id.* at 17 (citing Ex. 1003 ¶ 155)); and (4) because a pin could withstand more tension than a suture loop (*id.* (citing Ex. 1003 ¶ 156)).

Patent Owner argues that Petitioner fails to provide a reason why a skilled artisan would have incorporated coaxial apertures into Dreyfuss. Prelim. Resp. 24–26. On this issue, Petitioner cites to the testimony of Mr. Ritchart that apertures were a known structure for securing a pin to a suture anchor. *See* Pet. 17 (citing Ex. 1003 ¶¶ 160–163). [8] Mr. Ritchart discusses two exemplary prior art references that teach coaxial holes in anchor bodies through which pins are inserted and secured. Ex. 1003 ¶ 161 (citing Ex. 1043 ¶ 110; Ex. 1005 ¶ 37). Patent Owner argues that Mr. Ritchart's reliance on these two additional references is improper because the asserted ground includes only Dreyfuss and Foerster. Prelim. Resp. 25. This argument is not persuasive because "[a]rt can legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness." *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015) (citing *Randall Mfg. v.*

[8] Patent Owner argues that Mr. Ritchart's declaration should be disregarded because he is biased by his affiliation with Petitioner ArthroCare Corporation and because his status as an inventor of Foerster colors his view of what is disclosed in that reference. *See* Prelim. Resp. 20–22. On the current record, we disagree with Patent Owner that the entirety of Mr. Ritchart's testimony is entitled to no weight. We have considered Patent Owner's arguments and given the testimony of Mr. Ritchart the appropriate weight in rendering this Decision. After institution of trial, Patent Owner will have the opportunity to cross-examine Mr. Ritchart and present additional argument why his testimony is unreliable.

Rea, 733 F.3d 1355, 1362–63 (Fed. Cir. 2013)). Moreover, as Mr. Ritchart correctly notes, one of the exemplary references he cites is expressly incorporated by reference into Foerster. *See* Ex. 1003 ¶ 161; Ex. 1009, 8:4–8.

Next, Patent Owner argues that the proposed modification would render Dreyfuss unsatisfactory for its intended purpose because it eliminates the ability to rethread the anchor. Prelim. Resp. 26–27 (citing Ex. 1006 ¶ 44). The cited paragraph in Dreyfuss describes that "[*o*]*ptionally*, or *if* it becomes necessary due to the pre-threaded suture strands being accidentally removed from the suture loop, the user *may* be required to thread or re-thread the suture strands through the suture loop." Ex. 1006 ¶ 44 (emphasis added). Thus, based on the record, the ability to rethread is an optional or potential feature, not a "critical" feature, as asserted by Patent Owner (*id.* at 26). Dreyfuss goes on to describe that coating the ends of the suture strand or using a tool may facilitate threading suture strands through the suture loop. Ex. 1006 ¶ 44. On the current record, Patent Owner does not persuade us that rethreading the anchor is the intended or critical purpose of Dreyfuss. Dreyfuss describes that suture anchors are preferably distributed with suture strands 138 already threaded. *Id.* ¶ 43. The ability to re-thread the anchor is an optional feature that may become necessary in the event of accidental removal. *Id.* ¶ 44. Moreover, Patent Owner's assertion that the proposed modification "eliminates the ability to rethread the anchor" is supported only by attorney argument. Prelim. Resp. 26. On the current record, we are not convinced that placing anchor pin 72 at the position asserted by Petitioner would make it impossible to re-thread suture strands

138 into the anchor, particularly if one were to use stiffening agents or tools as suggested by Dreyfuss. Ex. 1006 ¶ 44.

Patent Owner also contests the adequacy of Petitioner's stated reasons for combining Dreyfuss and Foerster. Prelim. Resp. 27–34. Patent Owner argues that Petitioner fails to provide any support for their assertion that the proposed combination would reduce the complexity and cost of manufacturing compared to Dreyfuss. *Id.* at 27–29. We disagree that Petitioner's assertion is unsupported. With citation to the testimony of Mr. Ritchart, Petitioner describes the steps that are necessary to manufacture an anchor with suture loop 122 as shown in Dreyfuss:

> Manufacturing the Dreyfuss anchor requires (1) forming two longitudinal passageways 126 in the anchor body; (2) threading the ends of the suture that comprises suture loop 122 through the proximal opening of the anchor body and the passageways; (3) ensuring that the suture loop apex is within the bore; and (4) fixing the ends of the suture loop to the anchor body, either by knotting and sealing each end and fitting the knots into apertures in the wall of the anchor body or by crimping the anchor body to hold the ends in place.

Pet. 15–16 (citing Ex. 1003 ¶ 151; Ex. 1006 ¶¶ 33–42). Petitioner contrasts that process with making an anchor having a pin, which "only requires creating two coaxial apertures in the side of the anchor, inserting the pin through them, and affixing it, e.g., by welding." *Id.* at 16 (citing Ex. 1003 ¶ 152). In view of this explanation and the supporting testimony of Mr. Ritchart, Petitioner has made a sufficient threshold showing that reducing

manufacturing complexity would have motivated a skilled artisan to combine Dreyfuss and Foerster as proposed.[9]

Based on the current record, Petitioner has demonstrated a reasonable likelihood of showing that claim 1 would have been obvious over Dreyfuss and Foerster.

C. Obviousness of Claims 1–18 Based On Dreyfuss and Goble '397

Petitioner asserts that claims 1–18 would have been obvious over Dreyfuss and Goble '397. Pet. 30–38.

1. Goble

Goble '397 describes a bone anchor for arthroscopic procedures to mount a ligament under tension at variable lengths in a tunnel section formed through a bone. Ex. 1010, Abstract. Figure 23 is reproduced below:

[9] Patent Owner also challenges the other three reasons Petitioner articulates for combining Dreyfuss and Foerster. *See* Prelim. Resp. 29–34. However, having found that Petitioner's stated rationale of simplifying manufacturing provides a sufficient reason to combine for purposes of establishing a reasonable likelihood of success, it is unnecessary to consider Petitioner's other asserted reasons for the combination. These other rationales remain part of Petitioner's asserted ground and are not excluded from trial.

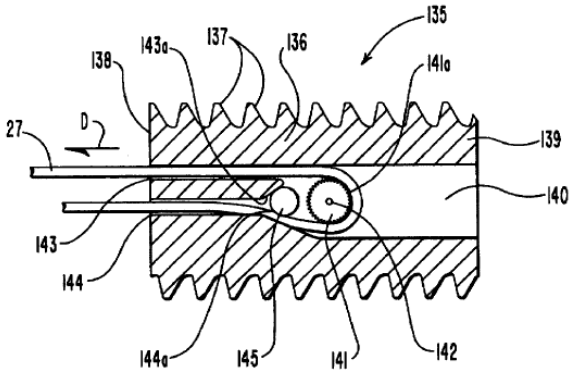

FIG. 23

Figure 23 is a side elevation longitudinal section of a bone anchor having "a turn back locking device with a suture turned back upon itself after passage around a fixed or rotating pulley which may be geared and across a lock ball." *Id.* at 6:35–40. Gear 141 is mounted to axle 142, which can be arranged to turn in only one direction. *Id.* at 11:66–12:2. Suture 27 is fitted through first hole 143 and passes around pulley 141 and back across lock ball 145. *Id.* at 12:7–10. Suture locking is provided by lock ball 145 and pulley 141. *Id.* at 12:18–19. According to Goble '397, "the lock ball and seat or the gear arranged to turn in one direction only each can alone function to lock the suture 27 in anchor 135." *Id.* at 12:20–22.

2. Analysis

In this asserted ground of unpatentability, Petitioner asserts that it would have been obvious to replace Dreyfuss's suture loop 122 (described above) with the gear assembly of Goble '397. Pet. 30. According to Petitioner, a skilled artisan would have had reason to do so in order to obtain the advantage that Goble '397 teaches its gear assembly provides: restricting suture movement to one direction. *Id.* at 31 (citing Ex. 1010, 12:14–22). Petitioner asserts, with citation to Mr. Ritchart's declaration, that "[b]y

holding the suture and tissue in place, the gear assembly allows the surgeon to move the soft tissue without needing to maintain constant tension on the suture." *Id.* (citing Ex. 1003 ¶¶ 240–53).

Petitioner also asserts that in modifying the Dreyfuss anchor to replace suture loop 122 with the gear assembly of Goble '397, a person of ordinary skill "would have made the same modifications" discussed in Petitioner's Ground 1, combining Dreyfuss and Foerster, "resulting in suture 138 being threaded around the gear assembly, which would be situated in the cylindrical bore 136. *Id.* at 32 (citing Ex. 1003 ¶¶ 254–62).

Patent Owner argues that Petitioner's stated reasoning for the combination is "conclusory" because Petitioner does not explain why the proposed combination uses pulley and axle diameters that are different than the diameters in Goble '397. Prelim. Resp. 36. Patent Owner also asserts there is no evidence that it would have been obvious to use coaxial apertures to attach the pulley. Prelim. Resp. 37. Patent Owner asserts:

> The Petition itself does not provide any reasoning for incorporating coaxial apertures with respect to Ground 2, but cites to six pages of the Ritchart Declaration to do so. Petition, p. 32 citing Ex. 1003 ¶¶ 254-262. This is an improper incorporation by reference of the Ritchart Declaration into the Petition.

Id. We disagree.

Petitioner's argument and evidence as to why it would be obvious to use coaxial apertures, and Patent Owner's criticisms of that argument and evidence, are essentially the same as in the ground based on Dreyfuss and Foerster. Moreover, Petitioner further explains the proposed modifications and provides an illustration of the proposed modification (Pet. 32) and a

detailed analysis using claim charts for the proposed modification (*id.* at 32–35). Based on our analysis above, Petitioner has made a sufficient threshold showing that it would have been obvious to use coaxial apertures to attach the gear assembly.

Patent Owner also argues that the proposed modification is not a simple substitution because pulley 141 and axle 142 of Goble '397 do not perform the same function as the suture loop 122 in Dreyfuss. Prelim. Resp. 38–39. Patent Owner also argues that the proposed combination would change the principle of operation of Dreyfuss because only one end of suture would attach to tissue in the proposed modification instead of two. *Id.* at 40–42.

Although we agree with Patent Owner that the proposed combination would have some differences in operation compared to unmodified Dreyfuss, we are not persuaded, on the current record, that these differences undermine the obviousness of the proposed combination. Specifically, we are not convinced that the differences Patent Owner identifies amount to "a

change in the basic principle under which the [Dreyfuss] construction was designed to operate." *Id.* at 42 (quoting MPEP § 2143.01(VI)). [10]

Indeed, the testimony of Mr. Ritchart address the trade-offs involved in modifying Dreyfuss. Mr. Ritchart testifies that although the unidirectional gear assembly is in some respects more complicated than a simple pin, "a POSA would have understood that the benefits achieved with the gear assembly would have outweighed the additional manufacturing and assembly costs for some users and would have provided a design choice option for users who are willing to pay more for additional functionality." Ex. 1003 ¶ 253. This testimony is consistent with legal precedent. "A given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (citation omitted). "The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and

[10] The Foreword of the MPEP, ninth edition, July 2015 revision, states (emphasis added):

> This Manual is published to provide U.S. Patent and Trademark Office (USPTO) patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the USPTO. It contains instructions to examiners, as well as other material in the nature of information and interpretation, and *outlines the current procedures which the examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application. The Manual does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.*

gained, should be weighed against one another." *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000).

Patent Owner next argues that the proposed combination makes Dreyfuss unsatisfactory for its intended purpose because it prevents re-threading of the suture. Prelim. Resp. 42–43. As we discussed above, we are not persuaded that rethreading the anchor is the intended purpose of Dreyfuss, nor that the proposed combination eliminates the ability to rethread the anchor.

Based on the current record, Petitioner has demonstrated a reasonable likelihood of showing that claim 1 would have been obvious over Dreyfuss and Goble '397.

D. Obviousness of Claims 1–18 Based On Morgan and Dreyfuss

Petitioner asserts that claims 1–18 would have been obvious over Morgan and Dreyfuss. Pet. 38–50.

1. Morgan

Morgan is directed to an anchor for securing soft tissue to bone. Ex. 1005, Abstract. Morgan states that known anchors "are fairly time consuming and complicated to fasten the soft tissue against the bone mass." *Id.* ¶ 7. Morgan seeks "to provide a suture anchor that simplifies the operation process. . . . Preferably, the suture anchor will be provided with an eyelet that is movable with respect to the anchor in order to simplify the process of attaching a suture to the eyelet." *Id.* ¶ 8; *see also id.* ¶ 10 ("The continuous suture loop of the anchor provides strength and a flexible eyelet, which can ease the process of threading a suture through the eyelet during a surgical procedure."). Figures 6–8 of Morgan are reproduced below:

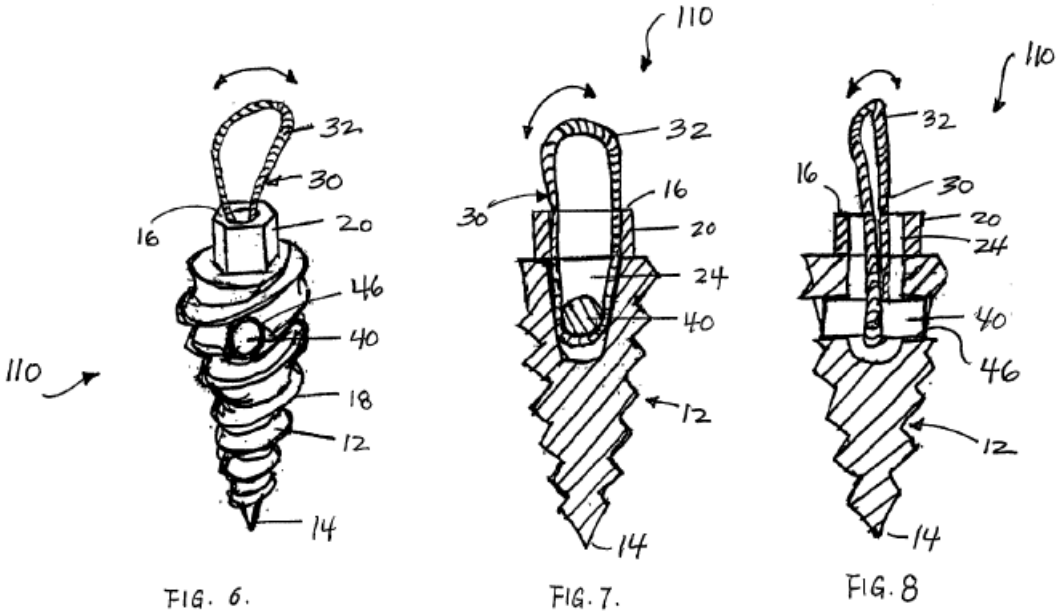

Figure 6 is a perspective view, and Figures 7 and 8 are sectional views, of suture anchor 110. *Id.* ¶¶ 21–23. Suture anchor 110 includes bore 46 that extends laterally within body 12. *Id.* ¶ 37. Retainer 40 is received in bore 46. *Id.* "Preferably, the suture loop 30 is not bonded to either of the body 12 or the retainer 40, such that the loop 30 is movable between the retainer 40 and the inner surface of the bore 24, in order to reduce stress on the suture loop 30." *Id.*

2. Analysis

Relying on Dreyfuss's teaching that countersinking suture anchors below bone surface avoids abrasion of tissue by the eyelet, Petitioner asserts that a skilled artisan would have known that Morgan required countersinking to prevent tissue abrasion by its male drive head and suture loop eyelet. Pet. 39. Then, because Dreyfuss teaches that countersinking can lead to abrasion of the suture against the bony rim of the countersunk hole, Petitioner asserts that a skilled artisan would have had reason to modify Morgan to a recessed suture-securing structure, like Dreyfuss. *Id.* Petitioner

then asserts that although Morgan's suture loop eyelet provides for attachment of the suture to the anchor after it is installed, Dreyfuss's pre-threaded anchor would eliminate the need to separately attach suture at all. *See id*. at 41. Accordingly, Petitioner asserts it would have been obvious to convert Morgan's suture loop eyelet to a pre-threaded suture. *See id.*

Patent Owner argues that "elimination of the suture loop in either Dreyfuss or Morgan simply results in the loss of an important benefit, not in a reason to make the modification." Prelim. Resp. 46. Patent Owner concludes "the proposed modification would amount to 'a substantial reconstruction and redesign of the elements shown in [Morgan] as well as a change in the basic principle under which the [primary reference] construction was designed to operate' and therefore the proposed modification does not render the claims prima facie obvious." *Id.* at 47 (citing MPEP § 2143.01(VI)).

Dreyfuss and Morgan both use suture loops. Ex. 1006, Fig. 5; Ex. 1005, Fig. 1. Dreyfuss's loop stays within the body of the suture anchor (Ex. 1006, Abstract), whereas Morgan's loop extends outside the body of the suture anchor (Ex. 1005, Abstract). In Petitioner's proposed combination, however, no suture loop is found. On the surface, Petitioner's proposed combination simply replaces the loop in Morgan with suture. In effect, however, Petitioner's proposed combination removes a structure present in both prior art references, but does not explain sufficiently why a person of ordinary skill in the art would have considered it obvious to remove that feature, given that neither reference teaches to remove the loop or teaches a structure without a loop.

Petitioner asserts that Dreyfuss "would have given a POSA reason to pre-thread the Morgan anchor, eliminating the primary benefit of suture loop 30, and thus leading a POSA to use retainer 40 of Morgan itself as the suture securing structure." Pet. 40 (citing Ex. 1003¶¶ 350-54).

Mr. Ritchart testifies that a person of ordinary skill in the art considering how to modify Morgan in view of Dreyfuss as having the ability to pursue two options:

> (1) shorten suture loop 32 such that its apex did not extend beyond hexagonal bore 132 or (2) eliminate suture loop 32 and pass the tissue securing suture directly around retainer 40.

Ex. 1003 ¶ 352. However, only the first option, which corresponds to the teaching of Dreyfuss, is supported by evidence of record for this ground. The second option identified by Mr. Ritchart is not the option disclosed in Dreyfuss. Mr. Ritchart explains his opinion that "a POSA would have eliminated suture loop 32 and would have directly attached the tissue securing suture (*e.g.*, suture 138 of Dreyfuss) to retainer 40. Such a modification would have simplified the modified suture anchor by removing a component (suture loop 32) that had become redundant and unnecessary." *Id.* at 354. Mr. Ritchart offers no additional facts or data to support his conclusion. On the present record, we are not persuaded 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 structure in the challenged claims.

Accordingly, we are not persuaded that Petitioner has shown a reasonable likelihood of success of prevailing on this ground.

E. Obviousness of Claims 1–18 Based On Pierson and Goble '523

Petitioner asserts that claims 1–18 would have been obvious over Pierson and Goble '523. Pet. 49–58.

1. Pierson

Pierson describes a "medical tensioning cable system [that] provides dynamic tensioning to maintain high tension in a fixation system despite tissue shifting, cable slippage, or other inadvertent loss of tension." Ex. 1007 Abstract. Figures 9A and 9B of Pierson are reproduced below:

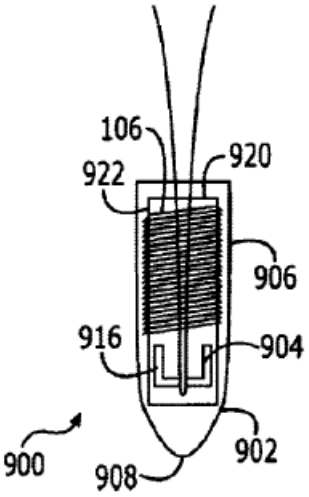

FIG. 9A

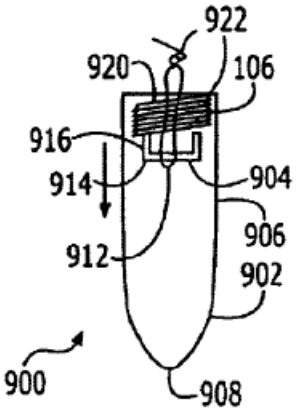

FIG. 9B

These figures illustrate an in-line tensioning system that includes securing component 902, attachment component 904, and biasing mechanism 106. *Id.* at 2:29–30. Securing component 902 is a hollow cylinder that engages bone. *Id.* at 6:66–7:3. "The attachment component 904 may comprise any suitable mechanism for attaching the suture or wire 102 to the anchor component 900." *Id.* at 7:16–19. In the embodiment depicted in Figures 9A and 9B,

> attachment component 904 comprises a pin 912 slidably disposed within the hollow interior of the securing component 902. For example, the pin 912 suitably comprises a cross-member 914 oriented across the diameter of the hollow interior of the securing component 902. The cross-member 914 is connected to a pair of guide posts 916 slidably disposed within a pair of guide channels 918 formed in the interior surface of the securing component 902. The suture or wire 102 may be connected to or wrapped around the cross-member 914, and the pin 912 may slide along the axial length of the securing component 902 while maintaining its orientation across the securing component 902.

Id. at 7:19–31. "To provide dynamic tensioning, the biasing mechanism 106 is connected to the securing component 902 and the attachment component 904 to take up any slack that may develop in the cable or suture 102." *Id.* at 6:59–63. In Figures 9A and 9B, biasing mechanism 106 includes compressed helical spring 920 that engages posts 916 of pin 912. *Id.* at 8:1–6. "Consequently, as slack develops in the suture, [] the spring 920 forces the attachment component 904 deeper into the securing component 902, thus removing slack." *Id.* at 8:6–9.

2. Goble '523

Goble '523 is directed to a suture anchor and driver for use in a surgical procedure to secure a suture onto a bone surface. Ex. 1008, Abstract. Figure 1 is reproduced below:

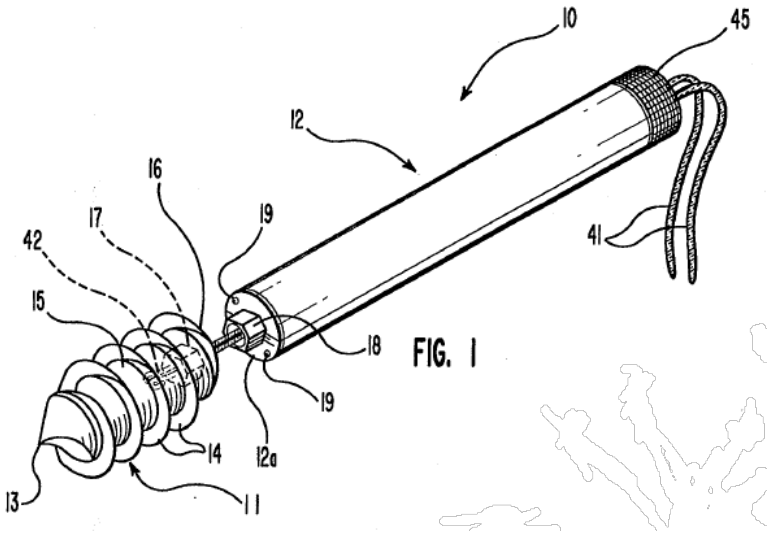

FIG. 1

Figure 1 shows anchor 11 and driver 12. *Id.* at 4:12–13. Driver 12 is open longitudinally such that suture 41 can run through it. *Id.* at 6:19–24. Driver 12 includes driver extension 18 that seats in opening 17 of anchor 11 and engages with the sides of opening 17 such that turning driver 12 about its longitudinal axis causes the anchor 11 to turn about its longitudinal axis. *See id.* at 4:46–59.

3. Analysis

Petitioner asserts that it would have been obvious to use the drive socket of Goble '523 to screw Pierson's anchor into bone. Pet. 51.

Independent claims 1 and 10 each require a rigid member (claim 1) or rigid support (claim 10) that is fixed against relative movement along the longitudinal axis of the anchor body.

Petitioner contends that the proposed combination of references would satisfy the limitation in the challenged claims of a rigid member/support that is fixed against relative movement. *Id.* at 53, 55 (claim chart, [B1]. In particular, Petitioner focuses on Pierson's disclosure that the attachment

component "may comprise any suitable mechanism for attaching the suture." *Id.* at 53 (quoting Ex. 1007, 7:16–19). Based on this teaching, Petitioner asserts that a skilled artisan "would have understood that attachment component 904 could be fixed by the anchor against relative movement along the longitudinal axis." *Id.* (citing Ex. 1003 ¶¶ 458-62). [11]

Pierson discloses that attachment component 904 "may comprise any suitable mechanism for attaching the suture or wire 102 to the anchor component 900." Ex. 1007, 7:16-19. Pierson explains that in the embodiment disclosed and illustrated attachment component 904 comprises pin 912 *slidably disposed* within the hollow interior of the securing component 902. *Id.* at 7:19–21. Suture 102 may be connected to or wrapped around cross-member 914, and *pin 912 may slide along the axial length of the securing component 902* while maintaining its orientation across the securing component 902. *Id.* at 7:27–31. Pierson also discloses that alternatively, attachment component 904 may be a piston *slidably disposed* within the hollow interior of securing component 902. *Id.* at 7:32–34.

Patent Owner asserts Petitioner's proposed modification "fails to account for each and every element in the claims." Prelim. Resp. 51–54. Specifically, Patent Owner asserts attachment component 904 in Pierson

[11] As discussed above, we evaluate Petitioner's assertion to determine whether a challenged claim, as a whole, would have been obvious to a person of ordinary skill based on the evidence presented and argued. Because Petitioner's challenge is under § 103, we understand Petitioner to be asserting this statutory standard. Whether a person of ordinary skill "would have understood" that attachment component 904 in Pierson "could be fixed" by the anchor is not the standard we have used.

cannot be the recited "rigid member" and "rigid support" required by claims 1 and 10, respectively, because attachment component 904 is not fixed against relative movement along the longitudinal axis of the anchor body, as recited in claims 1 and 10. Prelim. Resp. 52. According to Patent Owner, in Pierson, attachment component 904 moves axially with biasing mechanism 106 to accommodate for slack in suture 102, as shown in the different axial positions of attachment component 904 in Figures 9A and 9B of Pierson. *Id.* We agree.

As summarized above, Pierson expressly teaches that attachment component 904 is "slidably disposed" within securing component 902 such that "pin 912 may slide along the axial length of the securing component." Ex. 1007, 7:20, 29–31. The ability of attachment component 904 to move axially within securing component 902 allows it to respond to biasing mechanism 106, thereby providing the dynamic tensioning that is the stated goal of Pierson and the entire reason much of the structure is present. *See id.* at 6:59–63, 1:49–63.

Mr. Ritchart testifies that a person of ordinary skill "would have understood [Pierson's] disclosure to mean that Pierson's anchor was not limited to embodiments in which the attachment component was slidably disposed." Ex. 1003 ¶ 459. Mr. Ritchart relies on Morgan (Ex. 1043), which is not cited by Petitioner in this asserted ground of unpatentability, to conclude that a person of ordinary skill "would have interpreted Pierson to disclose a rigid member (i.e., attachment component 904) that was fixed by the anchor body against relative movement along the central longitudinal axis of the anchor body." *Id.* Thus, Mr. Ritchart opines that Pierson's slidable component 904 could be fixed. We acknowledge this testimony but

give it little weight in light of Pierson's disclosure only of slidable structures for component 904 and Petitioner's failure to assert any argument based on Morgan. Moreover, this testimony does not explain persuasively why a skilled artisan would choose to use a fixed pin instead of a sliding attachment component, or how that could be done without eliminating the dynamic tensioning feature that is the core of Pierson's disclosure.

Thus, for purposes of this Decision, based on the record before us, we determine that Petitioner has not explained sufficiently why it would have been obvious to modify the slidable member of Pierson, and associated structure, to have a rigid member/support that is fixed against relative movement along the longitudinal axis of the anchor body, as recited in the challenged claims.

Accordingly, based on the current record, Petitioner has not demonstrated a reasonable likelihood of showing that the challenged claims would have been obvious over Pierson and Goble '523.

F. Conclusion

For the foregoing reasons, upon review of Petitioner's analysis and supporting evidence, as well as the arguments presented in the Preliminary Response, we conclude that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to the obviousness challenges to at least one of claims 1–18 based on Dreyfuss and Foerster, and also based on Dreyfuss and Goble '397. We further conclude that Petitioner has not demonstrated a reasonable likelihood that it would prevail in the obviousness challenge to claims 1–18 based on Morgan and Dreyfuss, or based on Pierson and Goble '523

This is a decision to institute an *inter partes* review under 35 U.S.C. § 314. The Board has not made a final determination on the patentability of the challenged claims.

III. ORDER

In view of the foregoing, it is hereby:

ORDERED that *inter partes* review of the '052 patent is instituted on the following grounds set forth in the Petition:

Whether claims 1–18 would have been obvious in view of Dreyfuss and Foerster; and

Whether claims 1–18 would have been obvious in view of Dreyfuss and Goble '397;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the grounds identified above.

FOR PETITIONER:

Randy J. Pritzker
Michael N. Rader
Richard F. Giunta
Wolf, Greenfield & Sacks, P.C.
RPritzker-PTAB@wolfgreenfield.com
MRader-PTAB@wolfgreenfield.com
RGiunta-PTAB@wolfgreenfield.com

FOR PATENT OWNER:

Anthony P. Cho
John E. Carlson
Brian S. Tobin
Quincy J. Harrison
Carlson, Gaskey & Olds, P.C.
acho@cgolaw.com
jcarlson@cgolaw.com
btobin@cgolaw.com
qharrison@cgolaw.com