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Paper No. 27
Date: October 13, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC.,
Petitioner,

v.

P TECH, LLC,
Patent Owner.

IPR2022-00717
Patent 10,881,440 B2

Before SHERIDAN K. SNEDDEN, MICHELLE N. WORMMEESTER, and CYNTHIA M. HARDMAN, *Administrative Patent Judges.*

HARDMAN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–20 (all claims) of U.S. Patent No. 10,881,440 B2 ("the '440 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e) (2018). Having reviewed the parties' arguments and cited evidence, for the reasons discussed below, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–20 are unpatentable.

A. Procedural History

Petitioner Arthrex, Inc. filed a Petition for *inter partes* review of claims 1–20 of the '440 patent. Paper 1 ("Pet."). Patent Owner P Tech, LLC did not file a Preliminary Response. In view of the then-available preliminary record, we instituted an *inter partes* review. Paper 6 ("Inst. Dec.").

After institution, Patent Owner filed a Response. Paper 13 ("PO Resp."). Petitioner filed a Reply. Paper 19 ("Reply"). Patent Owner filed a (corrected) Sur-reply. Paper 24 ("Sur-reply").

On July 20, 2023, we held an oral hearing, the transcript of which is of record. Paper 26 ("Tr.").

B. Real Parties in Interest

Petitioner and Patent Owner each identify themselves as the real party in interest. Pet. xii; Paper 4 (Patent Owner Mandatory Notices), 2.

C. Related Matters

The parties identify *P Tech, LLC v. Arthrex, Inc.*, Case No. 1-21-cv-00968 (D. Del.), filed June 30, 2021, as a related matter. Pet. xii; Paper 4, 2.

Patent Owner also identifies as related matters IPR2022-00786 and IPR2022-00787, which respectively concern U.S. Patent Nos. 9,579,129 and 9,999,449, both of which are also assigned to Patent Owner and which have also been asserted against Petitioner in Civil Action No. 1-21-cv-00968. Paper 4, 2.

D. The '440 patent (Ex. 1001)

The '440 patent, titled "Fixation Systems and Methods," relates to fixation of damaged tissues in a patient's body.[1] Ex. 1001, code (54), 1:15–19. Per the Specification, fractures near a joint may include small bone fragments attached to soft tissue, which are not addressed when using traditional surgical techniques. *Id.* at 1:27–36. The Specification identifies "a need for a system to repair traditionally unsecured soft tissue fragments thereby stabilizing soft and hard tissue fragments together as a unit." *Id.* at 1:65–67. The '440 patent purports to meet this need by using a system that includes a deformable suture material and fasteners to increase stability by capturing a bone fragment and by allowing "closure [of a] fracture with a desired compression." *Id.* at 1:67–2:6.

The Specification describes exemplary systems that include fixation devices for securing first and second body tissue portions of a fracture. *Id.*

[1] The '440 patent claims priority to a continuation application and a provisional application, which were filed March 15, 2013, and January 5, 2013, respectively. Ex. 1001, codes (63), (60). Petitioner assumes that the challenged claims are entitled to claim priority to these dates. Pet. 8. Patent Owner does not take a position on priority date. *See generally* PO Resp. For purposes of this Decision, we assume that the challenged claims are entitled to claim priority to January 5, 2013.

at 2:15–27. One exemplary system is depicted in Figure 42, reproduced below.

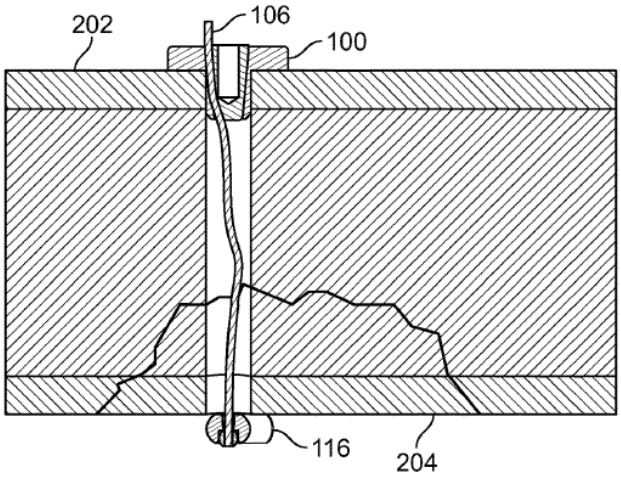


FIG. 42

Figure 42 of the '440 patent, reproduced above, is a side section view of a system that includes a fixation device positioned with respect to a tissue fracture. Ex. 1001, 4:49–51, 4:56–57, 16:50–51. The system includes fixation device 100 and fastener 116 for securing "elongate member 106 to repair a fracture of hard and/or soft tissue,"[2] such as tissue 202 and tissue 204. *Id.* at 16:51–54.

In operation, "[t]o secure tissue 202 and tissue 204 relative to each other, a cutting instrument . . . may be urged into and/or through tissues 202 and 204 from a proximal area to a distal area thereby creating a passage." *Id.* at 16:58–63. Fixation device 100 includes a base component having a passage therein for accepting an insert component, and both components are positioned within the passage of the tissues as shown in Figure 42. *Id.* at 2:17–19. The insert component is positioned within at least a portion of the

[2] Throughout this Decision, we omit bolding of reference numbers in quotations from the challenged patent and prior art references.

passage of the base component, as further described below, and elongate member 106 is positioned between the two components and through tissues 202, 204. *Id.* at 2:20–23. Elongate member 106 is then "tensioned and pinched between the base component and insert component or within the passage of the insert component, for example, to secure the first and second body tissue portions." *Id.* at 2:23–27.

Figure 4, reproduced below, is a schematic view of an exemplary fixation device.

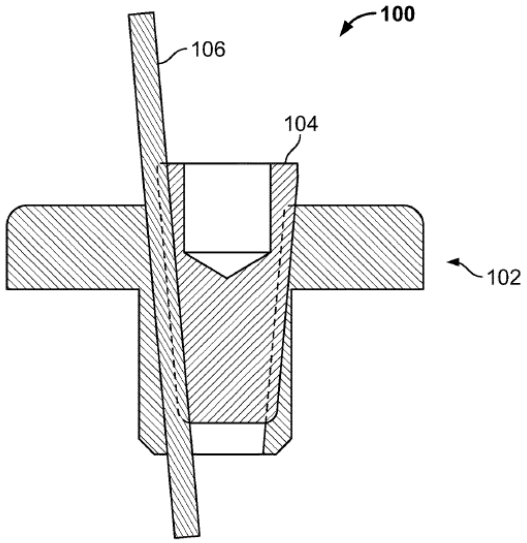


FIG. 4

Figure 4 of the '440 patent, reproduced above, is a front section view of a fixation device. Ex. 1001, 3:24–27, 3:31–32. Fixation device 100 includes base component 102 having "a passage through all or any portion of its length," and is "configured to directly contact and/or fit into the body tissue." *Id.* at 13:4–8. "Insert component 104 may be secured in the passage of base component 102 to secure elongate member 106 with respect to body tissue and/or additional fixation devices." *Id.* at 2:22–25. "Elongate

member 106 may be secured with mechanical features, press fitting, screwing, crimping, squeezing, melting, thermal or ultrasonic joining, gluing, or any other method disclosed herein." *Id.* at 13:25–28.

Figure 84, reproduced below, depicts an exemplary fastener.

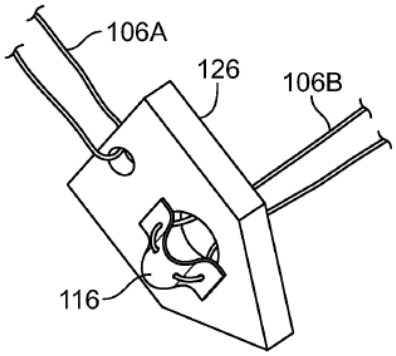


FIG. 84

Figure 84 of the '440 patent, reproduced above, is an isometric view of a two-component fastener. Ex. 1001, 6:15–17, 6:22–23. Fastener 116 is depicted in an interlocking embodiment in which component 126 is connected to both elongate member 106A and elongate member 106B, by way of first and second bores in component 126. *Id.* at 21:20–26. "In use, fastener 116 is configured to pass through the bore of component 126 while in a first configuration (FIG. 83), then elongate member 106B may be tensioned to deform fastener 116 to a second configuration (FIG. 84)." *Id.* at 21:29–33. "The second configuration of fastener 116 may obstruct movement of fastener 116 through the second [bore] thereby securing elongate member 106B relative to elongate member 106A." *Id.* at 21:33–36. The Specification discloses that "[f]asteners 116 may be deployed on the articular surface," "may include a woven, mesh, scaffold, collagen, or any other synthetic or biologic material that encourages tissue growth to repair a

tissue defect," and "may be secured to the articular cartilage surface by the attachment of an elongate member 106 and/or fixation device 100." *Id.* at 22:27–35. The cartilage surface can be that of a humeral head of a shoulder joint. *Id.* at 18:39–44.

E. The Challenged Claims

Petitioner challenges all twenty claims of the '440 patent. Claims 1, 10 and 15 are independent. Claim 1, reproduced below with bracketed numbering added,[3] is illustrative:

> 1. [1.P] A method for securing body tissues comprising:
>
> [1.1] inserting a flexible fastener having a passage into a passage in a first bone portion, wherein an elongate member extends through the fastener passage, such that at least two legs of the elongate member extend from the fastener and outside the passage in the first bone portion;
>
> [1.2] deforming the fastener from a first configuration to a second configuration to secure the fastener and the elongate member when tensioning at least one of the legs of the elongate member;
>
> [1.3] passing at least one of the legs of the elongate member over at least one tissue;
>
> [1.4] passing at least one of the legs of the elongate member through a bore in a first component of a two component knotless fixation device;
>
> [1.5] inserting the two component knotless fixation device into a passage in a second bone portion; and

[3] For ease of reference, we adopt the bracketed numbering Petitioner uses in the Petition at pages vi–xi. For clarity, we note that in the argument section of the Petition, Petitioner used different designations for the claim elements. *See, e.g.*, Pet. 20–35. Most relevant here, the Petition sometimes refers to limitations [1.2] and [1.6] as limitations [1.3] and [1.7], respectively. *Compare* Pet. vi, *with* Pet. 26, 32.

> [1.6] securing the at least one leg of the elongate member when both the first and second components of the two component knotless fixation device are positioned in the passage in the second bone portion, wherein the elongate member presses against an external surface of the second component of the two component fixation device.

Ex. 1001, 30:33–57.

Independent claims 10 and 15 are similar to claim 1, but differ in a few ways, including requiring that the claimed method uses an additional component, i.e., an allograft collagen matrix scaffold in claim 10, and at least one of a scaffold, mesh, graft, and matrix in claim 15. *Id.* at 31:11–39, 32:8–29.

Challenged dependent claims 2–9 depend directly from claim 1 and add additional features. For example, claim 3 further requires that "the elongate member is at least one of a suture and a cable."[4] *Id.* at 30:60–61. Claim 6 further requires that "at least one of the two components comprising the fixation device is comprised of at least one of PEEK, PLLA, and titanium." *Id.* at 31:1–3.

Challenged dependent claims 11–14 depend directly from claim 10, and add limitations similar to those of claims 2–4 and 6. *Id.* at 31:40–32:7.

Challenged dependent claims 16–20 depend directly from claim 15, and add limitations similar to those of claims 2–4, 6, and 11. *Id.* at 32:30–40.

[4] Like Patent Owner, for simplicity we use the terms "elongate member" and "suture" interchangeably herein. *See* Sur-reply 1.

F. The Asserted Grounds of Unpatentability

We instituted trial based on the following grounds of unpatentability:

Ground	Claim(s) Challenged	35 U.S.C. §[5]	Reference(s)/Basis
1	1–5, 7, 9, 15–19	§ 103(a)	Stone[6]
2	6, 20	§ 103(a)	Stone, Dhawan[7]
3	5, 8, 10–13	§ 103(a)	Stone, Barber[8]
4	14	§ 103(a)	Stone, Dhawan, Barber
5	1–4, 6, 7, 9, 15–20[9]	§ 103(a)	ElAttrache,[10] Stone

[5] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended several provisions of 35 U.S.C., including § 103. Because the January 5, 2013, priority date we apply herein for the challenged claims (*see supra* n.1) is before the effective date of the applicable AIA amendments, we refer to the pre-AIA version of 35 U.S.C. § 103.

[6] Stone et al., U.S. Patent No. 7,905,903 B2, issued March 15, 2011 ("Stone," Ex. 1005).

[7] Dhawan et al., *Complications of Bioabsorbable Suture Anchors in the Shoulder*, 40 THE AMERICAN JOURNAL OF SPORTS MEDICINE 6:1424–30, June 2012 ("Dhawan," Ex. 1006).

[8] Barber et al., *Ultimate Tensile Failure Loads of a Human Dermal Allograft Rotator Cuff Augmentation*, 42 ARTHROSCOPY: THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY 1:20–24, January 2008 ("Barber," Ex. 1007).

[9] Although the Petition indicates that claim 5 is challenged under Ground 5 (*see, e.g.*, the chart on page 3 of the Petition and the heading and introductory paragraph on page 56 of the Petition), the Petition does not provide argument for claim 5 under this Ground. *See* Inst. Dec. 9 n.8. Accordingly, we exclude claim 5 from this Ground.

[10] ElAttrache et al., U.S. Patent App. Pub. No. 2007/0191849 A1, published August 16, 2007 ("ElAttrache," Ex. 1009).

Ground	Claim(s) Challenged	35 U.S.C. §[5]	Reference(s)/Basis
6	8, 10–14	§ 103(a)	ElAttrache, Stone, Barber

Inst. Dec. 9–10, 51; Pet. 3. Petitioner supports its contentions with the Declaration of Steve E. Jordan, M.D. (Ex. 1002), among other evidence. Patent Owner supports its contentions with the Declaration of Robert A. Pedowitz, M.D., Ph.D. (Ex. 2001), among other evidence.

II. ANALYSIS

A. Legal Standards

"In an [inter partes review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review). To prevail, Petitioner must demonstrate unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e).

A claim is unpatentable as obvious under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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) (2006); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) any

objective indicia of nonobviousness.[11] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). An obviousness determination requires finding a reason to combine accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR*, 550 U.S. at 419–20.

B. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art (sometimes abbreviated herein as "POSITA"). *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Factors pertinent to determining the appropriate level of skill in the art include:

> (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. . . . The patent's purpose can also be informative.

Best Med. Int'l, Inc. v. Elekta Inc., 46 F.4th 1346, 1353 (Fed. Cir. 2022) (citations omitted). After considering the above factors and Petitioner's proposed level of skill in the art, for purposes of our Institution Decision, we defined a person of ordinary skill in the art as someone having a medical degree and at least two years of experience performing surgeries with implantable medical devices, such as suture anchors. Inst. Dec. 12.

[11] Patent Owner does not present any objective indicia of nonobviousness.

Patent Owner and its declarant Dr. Pedowitz agree with our analysis and employ our definition of a person of ordinary skill in the art. PO Resp. 21; Ex. 2001 (Pedowitz Decl.) ¶ 18. After institution, Petitioner did not dispute our definition. *See generally* Reply. Accordingly, we maintain our definition of a person of ordinary skill in the art as someone having a medical degree and at least two years of experience performing surgeries with implantable medical devices, such as suture anchors.

Based on their statements of qualifications and curricula vitae, we find Petitioner's declarant Dr. Jordan and Patent Owner's declarant Dr. Pedowitz qualified to provide technical opinions from the perspective of a person of ordinary skill in the art in this proceeding. Ex. 1002 (Jordan Decl.) ¶¶ 2–9 (Dr. Jordan's statement of qualifications); Ex. 1003 (Dr. Jordan's curriculum vitae); Ex. 2001 (Pedowitz Decl.) ¶ 2 (Dr. Pedowitz's statement of qualifications), Appendix A (Dr. Pedowitz's curriculum vitae).

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention" and "after reading the entire patent" and its prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 1321 (Fed. Cir. 2005) (en banc). Although extrinsic evidence including

expert and inventor testimony, dictionaries, and learned treatises can be consulted, extrinsic evidence is less significant than the intrinsic record. *Id.* at 1312–17. Usually, the specification is dispositive, and is the single best guide to the meaning of a disputed term. *Id.* at 1315.

Petitioner addresses two terms, "passage" and "allograft collagen matrix scaffold." Pet. 15–17. Petitioner also presents arguments based on Patent Owner potentially arguing that the claimed steps must be performed in order. *See, e.g.*, *id.* at 27, 31. Patent Owner addresses two terms, "passage" and "secure" [or "securing"]. Below we construe the terms "passage" and "secure"/"securing."

We determine that we need not construe "allograft collagen matrix scaffold" or any other claim term. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) ("The Board is required to construe 'only those terms . . . that are in controversy, and only 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)). Additionally, because Patent Owner did not argue that the claimed steps must be performed in order, we determine that we need not address that issue.

1. "passage"

Independent claim 1 recites "a passage in a first bone portion." Ex. 1001, 30:34–35. Independent claims 10 and 15 recite similar limitations, namely "a passage in first portion of a humeral head" (claim 10), and "a first passage in first portion a bone" (claim 15). *Id.* at 31:13–14, 32:10–11. In our Institution Decision, we found that a portion of Petitioner's proposed construction of "passage" was consistent with the Specification (i.e., "an opening into which something can be placed"), but

that Petitioner's further position that the opening "must go all the way through the bone" was inconsistent with the intrinsic record. Inst. Dec. 13–18.

Patent Owner and its declarant Dr. Pedowitz agree with our analysis and employ our construction of "passage." PO Resp. 22–23; Ex. 2001 (Pedowitz Decl.) ¶¶ 34–36. After institution, Petitioner did not dispute our construction. *See generally* Reply. Accordingly, for the reasons discussed in our Institution Decision, we maintain our construction of "passage" as meaning "an opening into which something can be placed." *See* Inst. Dec. 13–18.

2. "secure"/"securing"

Independent claim 1 recites the terms "securing" and "secure," as shown below:

> 1. [1.P] A method for **securing** body tissues comprising:
>
> . . .
>
> [1.2] deforming the fastener from a first configuration to a second configuration to **secure** the fastener and the elongate member when tensioning at least one of the legs of the elongate member . . . ; and
>
> [1.6] **securing** the at least one leg of the elongate member when both the first and second components of the two component knotless fixation device are positioned in the passage in the second bone portion, wherein the elongate

> member presses against an external surface of the second component of the two component fixation device.

Ex. 1001, 30:33–57 (emphasis added). Independent claims 10 and 15 contain similar recitations of the terms "secure" and "securing."[12] *Id.* at 31:11–39, 32:8–29. Prior to institution, neither party raised this term for construction.

To give context to our analysis, we first note that this term is at issue because the parties dispute whether Stone teaches or suggests claim limitations [1.2] and [1.6]. Specifically, Patent Owner contends Stone's elongate member (strand or suture 120) can slide relative to the fastener (sleeve 100), and thus the elongate member not "secure" under its proposed construction.[13] PO Resp. 27, 34. Although we provide this context here, we must—as Patent Owner recognizes—construe the claims independent of whether Stone's suture is "secure." *See* Sur-reply 2 ("Whether Stone's suture is 'secured' . . . should be determined once the claim terms are properly construed . . . ."). In other words, whether the asserted prior art teaches or suggests a particular claim limitation is a separate question to be addressed *after* we construe the claims. Thus, to the extent the parties argue whether Stone's suture is "secure" in the context of claim construction, we do not address those arguments here. Instead, we first construe the claim

[12] Accordingly, we address claim 1 as representative of independent claims 1, 10, and 15.

[13] *See infra* Section II.D.1 for a description of Stone's fastener.

term, then we analyze below whether Stone teaches or suggests the relevant claim limitations.[14]

For the reasons discussed below, we construe "secure" to mean "fix, anchor, or attach," and "securing" to mean "fixing, anchoring, or attaching."

a) Brief Summary of Parties' Arguments

Patent Owner argues that "the plain and ordinary meaning of 'secure' that is consistent with the intrinsic record is 'fix, anchor, or attach (something) firmly so that it cannot be moved at its point of attachment.'" PO Resp. 24–25 (quoting Ex. 2001 (Pedowitz Decl.) ¶ 42). Patent Owner bases this construction on a dictionary definition of "secure," which defines the term as meaning "to make firm or fast, as by attaching." *Id.* at 23–24 (quoting Ex. 2007 (Webster's Dictionary), 4; citing Ex. 2001 (Pedowitz Decl.) ¶ 40). Patent Owner additionally characterizes "secure" as synonymous with "anchor." *Id.* (citing Ex. 2001 (Pedowitz Decl.) ¶ 40; Ex. 2002 (Jordan Depo. Tr.), 13:6–10); *see also* Sur-reply 8 ("'Secure' is synonymous with 'anchor' when used as a verb."). Patent Owner further argues that "[t]he Specification indicates that tissue or an elongate member is secured by fixing or attaching it so that the tissue or elongate member cannot be moved relative to its point of attachment." PO Resp. 24 (citing Ex. 1001, 8:58–61, 13:25–28, 20:25–40, 25:53–62); Sur-reply 2 (citing Ex. 1001, 13:49–50).

Petitioner argues that Patent Owner's construction is not supported by the cited dictionary, introduces ambiguity through the use of the term

[14] Our discussion of limitations [1.2] and [1.6] below contains further addresses the scope of the terms "secure"/"securing." *See infra* Sections II.E.1.c, II.E.1.g, II.I.2.c, and II.I.2.g.

"firmly," contradicts the intrinsic record, and is inconsistent with the claim language and use of the term "secure" in the field. *See generally* Reply 2–8. Petitioner does not offer a different construction; it instead contends that no construction is necessary. *Id.* at 7–8.

b) Analysis

We begin with the language of the claims. The term "secure" (or "securing") appears three times in claim 1: (i) the preamble ([1.P]) recites "[a] method for **securing** body tissues;" (ii) limitation [1.2] recites deforming a fastener from a first configuration to a second configuration "to **secure** the fastener and the elongate member;" and (iii) limitation [1.6] recites **securing** at least one leg of the elongate member, wherein the elongate member presses against an external surface of the second component of the two component fixation device. Ex. 1001, 30:33–57.

In the context of these three uses of the term, we agree with the first part of Patent Owner's proposed construction (i.e., defining "secure" as "fix, anchor, or attach"), because it is consistent with the language of the claims. *See* PO Resp. 24–25. Use (i) above, "[a] method for **securing** body tissues," describes attaching body tissues. Use (ii) above, when considered in the context of the claim as a whole, describes anchoring the fastener and elongate member in a first bone passage. Use (iii) above describes anchoring the elongate member in a second bone passage.

Equating "secure" with "fix" and "attach" is also consistent with Patent Owner's cited dictionary definition, which defines "secure" as meaning "to make firm or fast, as by attaching." PO Resp. 23–24 (quoting Ex. 2007 (Webster's Dictionary), 4. Additionally, the parties agree that in the context of the '440 patent, "secure" is synonymous with "anchor."

PO Resp. 23–24 (asserting that "secure . . . is synonymous with 'anchor'"); Ex. 2001 (Pedowitz Decl.) ¶ 40 (same); Tr. 10:17–12:17 (Petitioner's counsel agreeing that in the context of the claimed technology, secure means anchor). Accordingly, construing "secure" to mean "fix, anchor, or attach" is consistent with the plain language of the claims and the proffered dictionary definition.

Patent Owner's proposed construction, however, additionally recites that the fixing, anchoring, or attaching (of something) is done "**firmly** so that it **cannot be moved at its point of attachment**." PO Resp. 24–25 (quoting Ex. 2001 (Pedowitz Decl.) ¶ 42) (emphasis added). Below we address Patent Owner's proposed inclusion of the terms "firmly" and "so that it cannot be moved at its point of attachment," as well as the parties' arguments concerning usage of the term "secure" in the art.

(1) "firmly"

As to inclusion of the term "firmly," we agree with Petitioner that this term "adds ambiguity." Reply 3. To explain, we begin by noting that the Specification does not define (or even use) the terms "firm" or "firmly." On Sur-reply, Patent Owner contends that "[a] POSITA would understand 'firmly' to be 'secure under the type of loads that would be anticipated *in vivo*.'" Sur-reply 3 (citing Ex. 1018 (Pedowitz Depo. Tr.), 46:20–25). In our view, this statement confirms Petitioner's point about adding ambiguity. The definition of "firmly" can change depending on what is secured, where it is secured, the purpose of the securing, and the loads a person of ordinary skill in the art would anticipate *in vivo* in the relevant scenario. *See also* Tr. 12:3–25 (Petitioner's counsel discussing how "firmly" relates to considerations that are "outside [the] scope of the claim"). Neither party

points us to a discussion of these considerations grounded in the intrinsic record.

More importantly, we find it unnecessary to include the word "firmly" in order to resolve the disputes pertinent to this Decision. Indeed, Patent Owner itself contends that "[i]f an object is fixed, anchored or attached so it cannot be moved at its point of attachment, it is secure." Sur-reply 4. In other words, Patent Owner restated its proposed construction of "secure" without including the term "firmly" or the concept of the anticipated *in vivo* load, thus demonstrating that the term "firmly" is unnecessary here. *See Realtime Data, LLC*, 912 F.3d at 1375 (stating that the Board need construe terms "only to the extent necessary to resolve the controversy"). For these reasons, we do not include "firmly" in our construction.

(2) "so that it cannot be moved at its point of attachment"

We now turn to the portion of Patent Owner's proposed construction that recites "so that it cannot be moved at its point of attachment." Patent Owner contends that "specifying a point of attachment in the definition is based on the '440 specification's teachings." Sur-reply 2. Patent Owner cites several passages from the Specification, but fails to explain how they support its proposed construction. PO Resp. 24. Nevertheless, we address each cited passage in turn, to determine whether we can divine how the passages support Patent Owner's proposed inclusion of the phrase "so that it cannot be moved at its point of attachment" in its construction of "secure."

Patent Owner first cites a sentence reading: "Fixation [of fracture fragments] may be achieved by securing to the tendon or ligament portion." PO Resp. 24 (quoting Ex. 1001, 8:58–61). This statement addresses

securing (or fixing) fracture fragments to a tendon or ligament, but Patent Owner does not explain, and we do not discern, how this statement specifically addresses whether the fragments "cannot be moved at [their] point of attachment."

Next, Patent Owner cites a sentence reading: "Elongate member 106 may be secured with mechanical features, press fitting, screwing, crimping, squeezing, melting, thermal or ultrasonic joining, gluing, or any other method disclosed herein." *Id.* (quoting Ex. 1001, 13:25–28). This sentence address *how* to secure an elongate member, but like the passage we address above, Patent Owner does not explain, and we do not discern, how this statement specifically addresses whether the elongate member is secured "so that it cannot be moved at its point of attachment."

Patent Owner's next citation reads: "Fastener 116 may include flexible, bendable and/or deformable configurations for securing elongate member 106. . . . Fastener 116 may include . . . any other shapes configured to resist movement of elongate member 106 with respect to tissue." PO Resp. 24 (quoting Ex. 1001, 20:25–40). The first quoted sentence gives no insight into whether the fastener and elongate member, once secured, can still move relative to each other. The second quoted sentence references "resist[ing] movement," but in context, it explains that the shape of the fastener may resist movement of the elongate member *relative to tissue*. This does not support Patent Owner's proposed construction, which is intended to capture a suture that cannot be moved at its point of attachment *relative to the fastener or sleeve* (not *relative to tissue*, as stated in the quote). *See, e.g.*, Sur-reply 13 (arguing that "Stone's deformation does not

secure the strand" because "it is not fixed, anchored or attached and has no point of attachment *relative to the sleeve*") (emphasis added).

Patent Owner next cites a passage that reads:

> [F]ixation device 100 **may** include a tortuous path to secure elongate member 106. . . . Elongate member 106 **may** be forced into or clamped between a tortuous path between the projections base component 102 and insert component 104. This **may** also apply friction to elongate member 106 thereby resisting motion. Fixation device 100 **could be** secured by mechanical interference of the projections, mechanical interlock, Morse taper, vibratory or thermal joining, or any other attachment feature disclosed herein.

Ex. 1001, 25:53–62 (cited at PO Resp. 24) (emphasis added). Again Patent Owner does not explain, and we do not discern, how this passage suggests that something described as "secure" necessarily "cannot be moved at its point of attachment." The first two sentences and the last sentence discuss *how* a material may be secured, but fail to address whether the material "cannot be moved at its point of attachment." The third sentence references "resisting motion," but "resisting motion" does not necessarily equate to "cannot be moved."

Finally, Patent Owner cites a statement that reads: "elongate member 106 may be secured at any point along its length." Sur-reply 2 (citing Ex. 1001, 13:49–50). This statement addresses where the elongate member can be secured, but does not specifically address whether, once "secured," it "cannot be moved at its point of attachment."

In sum, we are not persuaded by Patent Owner's argument that the Specification supports inclusion of the term "cannot be moved at its point of

attachment" in the construction of "secure." Petitioner makes two additional arguments against inclusion of this term. We address each argument in turn.

First, as noted above, by including this term, Patent Owner seeks to exclude from the scope of the challenged claims an elongate member (or suture) that can slide relative to the fastener (or sleeve). *See, e.g.*, PO Resp. 27. Petitioner argues that excluding sliding between an elongate member and a fastener contradicts the intrinsic record, because the Specification explicitly states that the elongate member may slide through the fastener. Reply 3 (citing Ex. 1001, 20:25–35, 17:28–30, 29:48–56). Patent Owner responds that "none of Petitioner's citations are to a secure suture that slides." Sur-reply 4–5. Patent Owner also appears to suggest that to the extent the Specification does disclose a secure suture that slides, "a patentee can and often does claim fewer embodiments than are disclosed." *Id.* at 8.

Petitioner has the better argument. Petitioner is correct that the Specification expressly states that the suture may slide inside the fastener. *See, e.g.*, Ex. 1001, 20:27–30 (with reference to Figures 67–80, the Specification states that "[e]longate member 106 may pass, *slide*, and/or be tensioned through all or one or more portions of fastener 116") (emphasis added).

The Specification also suggests that even sutures described as "secure" can still slide. For example, with reference to Figures 67–80, the Specification states: "Fastener 116 may include flexible, bendable, and/or deformable configurations for **securing** elongate member 106." *See id.* at 20:25–27. Figures 67–80 depict a suture laced through a fastener in a variety of ways. Figure 73, which we reproduce below, shows one example:

FIG. 73

Figure 73 shows suture 106 laced through fastener 116. *See id.* at 20:41–46. In use, the fastener deforms as shown in Figure 84, which we reproduce below:

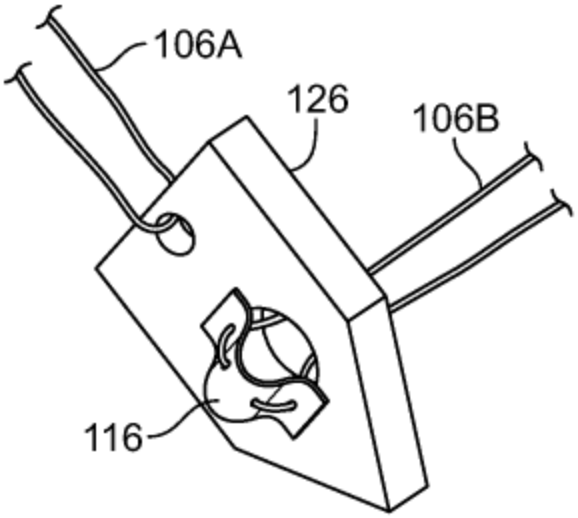


FIG. 84

Figure 84 shows fastener 116 and suture 106 inserted into a hole in component 126. *See id.* at 21:20–36. Fastener 116 is in a deformed state, such that it cannot pass through the hole. *See id.* at 21:33–36; Sur-reply 5 (explaining that Figure 84 shows the fastener of Figure 73 in a deformed state).

We agree with Petitioner that "[i]n Figs. 73 and 84, the elongate member is threaded through the fastener with nothing preventing it from being pulled through the fastener in either configuration." Reply 8–9. Dr. Pedowitz conceded that in these Figures, "it's possible that the suture would slide within the device." Ex. 1018 (Pedowitz Depo. Tr.), 14:6–18; Reply 9. Yet the Specification describes the fastener in this embodiment as having a "deformable configuration[] for **securing** elongate member 106." Ex. 1001, 20:25–27. In other words, the Specification describes this fastener as securing the elongate member, even though Dr. Pedowitz concedes the suture can still slide. This undermines Patent Owner's attempt to exclude sliding sutures from the scope of the claims.

Patent Owner appears to suggest that Dr. Pedowitz did not concede that the suture could slide, but "merely stated he could not tell *from the drawing alone*" whether the suture would slide after the fastener deforms. Sur-reply 5 (citing Ex. 1018 (Pedowitz Depo. Tr.), 11:20–12:10, 13:8–14:18, 94:3–14, 95:1–17, 97:9–25). Patent Owner's argument is unavailing. Dr. Pedowitz did not point to any other portion of the Specification indicating that a "secure" suture is prevented from sliding. Rather, in the testimony Patent Owner cites, Dr. Pedowitz again acknowledges that in Figure 84, the suture may slide or not, depending for example on the friction between the suture and fastener. *See, e.g.*, Ex. 1018 (Pedowitz Depo. Tr.), 13:15–18 ("[A] suture could be designed and the fixator could be designed to slide relative to one another or they could be designed to not slide past one another."), 95:1–17 (in response to the question "What is actually causing this embodiment shown in figure 84 to not be possible to slide," Dr. Pedowitz answers "I guess in a sense it's the friction created between the

suture and the device 116 or it's the interaction between the suture and itself"). Patent Owner does not point to any portion of the Specification indicating that a secure suture is one that does not slide between the suture and the fastener. Accordingly, we agree with Petitioner that construing "secure" in a manner that would exclude sliding between an elongate member and a fastener contradicts the intrinsic record.

Petitioner's second argument against inclusion of the term "cannot be moved at its point of attachment" in the construction of "secure" relates to Patent Owner's assumption that "'securing' refers to the suture being secure relative to the fastener or fixation device." Reply 7. According to Petitioner, "[t]hat is not specified in the claims." *Id.* Patent Owner disputes this argument, contending that "claim element [1.2] conveys that the suture is secure relative to the fastener." Sur-reply 9.

We again find that Petitioner has the better argument. The plain language of the claim does not require securing the suture relative to the fastener. Claim 1 recites a method that includes, in limitation [1.2], deforming the fastener "to secure the fastener ***and*** the elongate member." Ex. 1001, 30:40–43 (emphasis added). Patent Owner improperly reads as deforming the fastener "to secure the fastener ***to*** the elongate member."

The Specification also does not require reading the claim as Patent Owner contends. *See* Sur-reply 8–9 (citing Ex. 1001, 13:52–55, 16:13–17, 20:25–27). To be sure, the Specification teaches securing the elongate member relative to the fastener, e.g., stating: "All or any portion of base component 102, insert component 104, and/or elongate member 106 ***may deform relative to each other***, for example, to secure elongate member

106."[15] Ex. 1001, 13:52–55. But the Specification also teaches securing the elongate member relative to body tissue: "[i]nsert component 104 may be secured in the passage of base component 102 ***to secure elongate member 106 with respect to body tissue*** and/or additional fixation devices." *Id.* at 13:22–25 (emphasis added). The Specification also describes, in connection with Figure 84, securing elongate member 106B relative to elongate member 106A, even though elongate members 106A and 106B have no point of attachment to each other. *See id.* at 21:33–36 ("The second configuration of fastener 116 may obstruct movement of fastener 116 through the second hol[e] thereby ***securing*** elongate member 106B relative to elongate member 106A.") (emphasis added). The breadth of these teachings undermines Patent Owner's proposal to narrow the claim to require securing the fastener ***to*** the elongate member.

On balance, given the breadth of the Specification and the plain language of the claims, we do not find support in the intrinsic record for reading in Patent Owner's proposed requirement that the elongate member be fixed, anchored, or attached to the fastener such "that it cannot be moved at its point of attachment" to the fastener.

(3) Usage in the Field

Petitioner argues that Patent Owner's proposed construction is inconsistent with "how the term secure is used in the field." Reply 4–5. Petitioner explains that "Stone explicitly and repeatedly states that its arrangement (which Patent Owner attempts to distinguish with its definition) 'secures' its elongate member (120) to the fastener (100) and fixation device

[15] The fastener here is base component 102 and insert component 104.

(200d)." *Id.* (citing Ex. 1005 (Stone), 1:36–37 ("a method for securing a strand to a plurality of anchors"), 1:45–52, 3:37–44, 3:52–55, 4:34–39, 4:52–56, 5:43–47, 5:56–59, 5:65–6:14, 6:20–23, 6:33–36, 6:62–65, 7:17–20, claim 1). Petitioner argues that "[i]t strains logic to accept that the ordinary meaning of secure excludes Stone's arrangement where Stone repeatedly states that the same is for 'securing.'"[16] *Id.* at 5.

Patent Owner responds that "Stone uses the term differently than its ordinary meaning." Sur-reply 8. As support, Patent Owner cites Dr. Pedowitz's testimony asserting that the term "secure" "has a different meaning in Stone," given that Stone's suture can slide in the sleeve. *Id.* (citing Ex. 1018 (Pedowitz Depo. Tr.), 110:11–111:24).

Petitioner has the better position. Patent Owner does not support its argument with any citation to Stone, e.g., evidencing that Stone intended to act as its own lexicographer with respect to the word "secure." *See, e.g.*, *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (2012) ("To

[16] In addition to arguing that Patent Owner's proposed construction is inconsistent with Stone's use of the term "secure," Petitioner argues that the construction is inconsistent with Patent Owner's "own prior usage of 'secure'" in claim 1 of U.S. Patent No. 10,376,259 (Ex. 1020; "'259 patent"). *See* Reply 5–6. Petitioner is correct that "[t]he '259 patent's *specification* is incorporated by reference in the '440 patent" (via incorporation of the '259 patent's grandparent application). *See* Reply 5–6 (emphasis added); *see also* Ex. 1001, 25:2–8 (incorporating by reference U.S. Patent Appl. Publ. No. 2007/0088362 (Ex. 1019)). But the *claims* of the '259 patent are *not* incorporated by reference into the '440 patent, and thus are not "part of the intrinsic record" of the '440 patent, as Petitioner contends. *See* Tr. 16:14–17:5. Petitioner's argument relies solely on claim 1 of the '259 patent, not on any portion of its specification. On this record, we decline to construe the claims of the '259 patent, which is not at issue in the proceeding and is not related to the '440 patent.

act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning."). Instead, Patent Owner and Dr. Pedowitz resort to circular logic. Dr. Pedowitz assumes that the term "secure" excludes a suture that slides in the sleeve, and opines that because Stone's suture slides in the sleeve, Stone must be using a unique definition of the word "secure."

Patent Owner does not persuade us that Stone uses the term "secure" in a way contrary to its plain meaning. Instead, we agree with Petitioner that Stone demonstrates that Patent Owner's proposed construction is inconsistent with the plain meaning of the term "secure" as understood by a person of ordinary skill in the art. *See* Reply 4–5.

c) Conclusion

For the reasons discussed above, we construe the term "secure" to mean "fix, anchor, or attach," and the term "securing" to mean "fixing, anchoring, or attaching."

D. Overview of Asserted Prior Art

1. Stone (Ex. 1005)

Stone, titled "Method for Tissue Fixation," teaches "a versatile tissue fixation method that can be used with various bone anchors or other implantable fixation members to attach soft tissue to bone or any tissue to other tissue." Ex. 1005, code (54), 1:19–22. Stone issued on March 15, 2011, and thus we understand that Stone is prior art. *Id.* at code (45).

Stone discloses that its "method includes passing a strand having first and second ends through a flexible sleeve, passing the sleeve through the aperture of the fixation member in a first direction, tensioning the strand, and moving the sleeve in a second direction different than the first direction

to secure the sleeve to the fixation member without tying the strand on the fixation member." *Id.* at 1:29–35. Stone discloses that its method can be used for rotator cuff reconstruction and includes "fastening tendons, grafts, or strands of fibrous tissue and bone." *Id.* at 2:37–43.

We reproduce below Stone Figure 1.

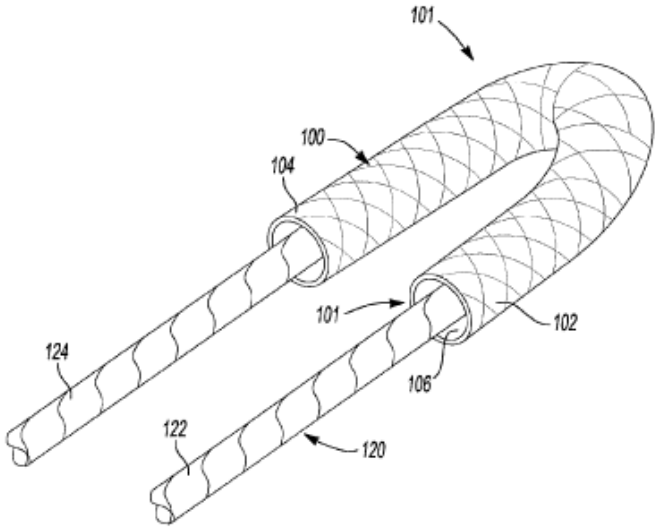


Fig-1

Stone Figure 1 is a perspective view of connector device 101. Ex. 1005, 1:64. The device, used for attaching soft tissue to bone, includes flexible tubular sleeve 100 having inner bore 106 between two open ends (102 and 104). *Id.* at 2:46–51. Strand 120 passes through bore 106 such that first strand end 122 and second strand end 124 exit first open end 102 and second open end 104 of sleeve 100, respectively. *Id.* at 3:1–7. Sleeve 100 has a generally flaccid shape that can be manipulated or deformed into different

configurations such as a "bunched-up" or a "ball-like" configuration.[17] *Id.* at 2:57–67.

Figure 3, reproduced below, depicts the connector device of Stone Figure 1 in use, having a second configuration other than the flaccid shape.

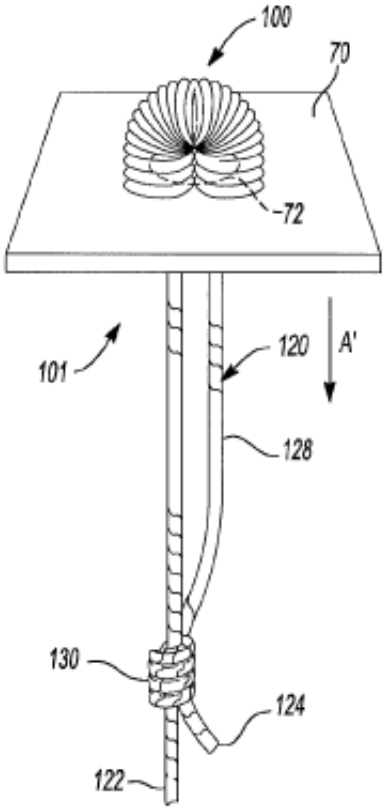


Fig-3

Stone Figure 3 is a perspective view of a connector device engaged with an aperture of support 70. Ex. 1005, 2:10–11. Prior to engagement, sleeve 100 with strand 120 is folded and pushed through orifice 72 of support 70. *Id.* at 3:28–36. Strand ends 122, 124 can be connected with knot 130, such as a

[17] Stone's sleeve fastener with suture was commercialized as the JuggerKnot soft anchor. *See* Pet. 10; PO Resp. 55.

slipknot, to form strand loop 128. *Id.* By pulling on one of strand ends 122, 124 in direction A' (downward), tension causes sleeve 100 to change configuration to a "bunched-up" or "ball-like" configuration, which cannot pass through orifice 72 so that strand 120 is secured on support 70. *Id.* at 3:37–43. Support 70 "can be soft tissue, bone, implant, anchor or other threaded or unthreaded implant fixation member." *Id.* at 4:4–6.

We reproduce Stone Figure 8 below.

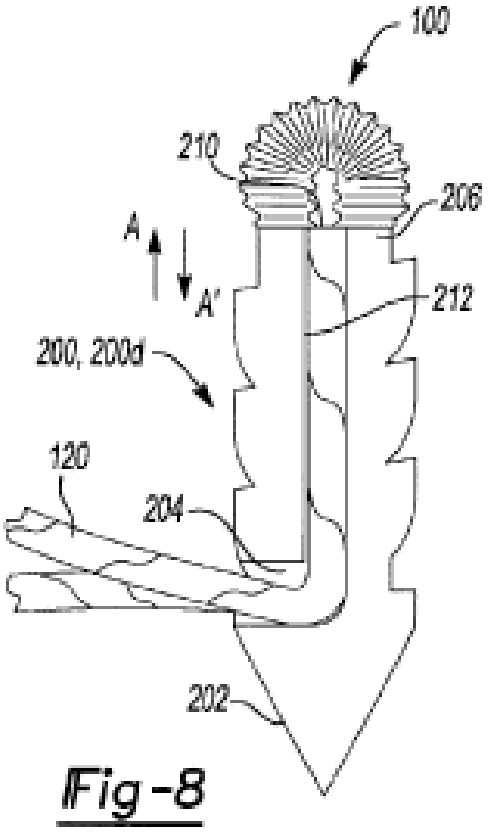


Fig -8

Stone Figure 8 is a side view of the connector device of Figure 1, together with an exemplary fixation member or anchor 200. Ex. 1005, 2:24–25. Fixation member 200 can be in the form of "an externally threaded suture anchor 200d," having bore 212 extending to eyelet 204. *Id.* at 5:35–39. Sleeve 100 is passed through eyelet 204 and bore 212 in direction of arrow

A (upward) such that strand 120 passes through bore 212 and exits eyelet 204 at the bottom of the fixation member, while sleeve 100 (which carries strand 120) exits through aperture 210 at the top of the fixation member. *Id.* at 5:39–43. As strand ends 122, 124 are pulled away from fixation member 200 in the direction of arrow A' (downward), sleeve 100 is secured against the top of the fixation member in a "bunched-up" or ball-like" configuration. *Id.* at 5:43–47.

We reproduce Stone Figure 9 below.

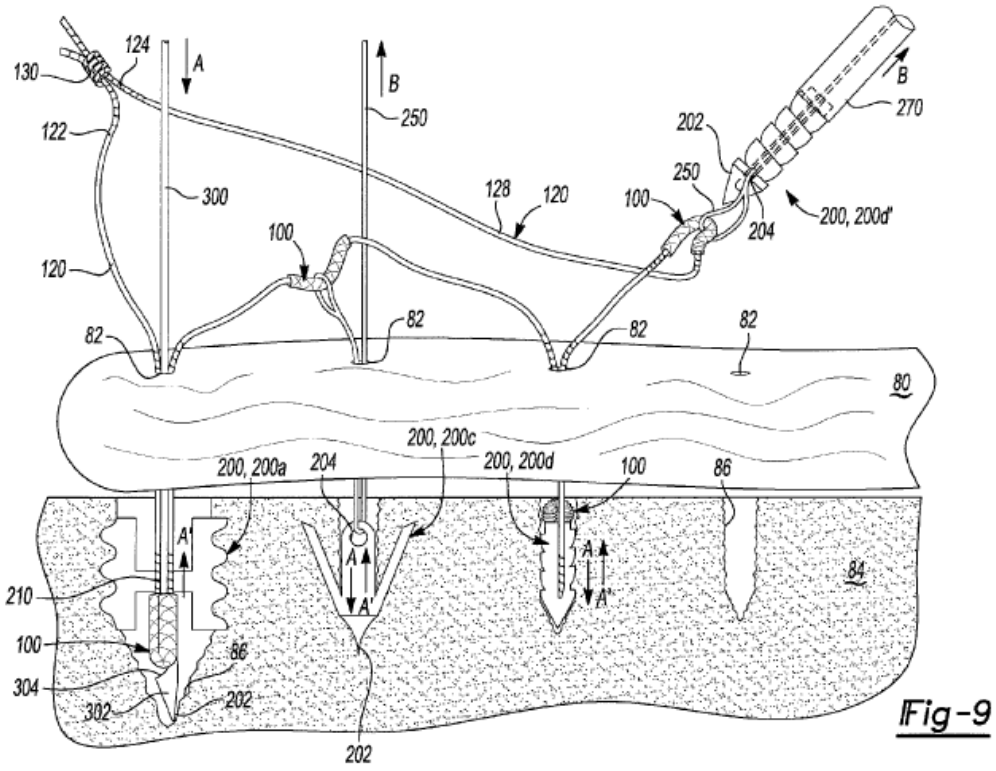


Fig-9

Stone Figure 9 shows "an exemplary method of using a series of interconnected connector devices for securing soft tissue to bone." Ex. 1005, 2:26–27. A series of sleeves 100 are strung along a single loop 128 of strand 120 without having knots other than single slipknot 130, which couples strand ends 122, 124. *Id.* at 5:60–63. Sleeves 100 are inserted into

bores 86 of bone 84 and anchored by various fixation members 200 to attach soft tissue 80 to bone 84. *Id.* at 5:63–6:5. Stone also discloses that "one or more fixation members 200 can be omitted, such that the sleeve 100 is secured directly in a bone bore 86, without using a fixation member 200." *Id.* at 6:2–4.

Fixation member 200 can be inserted through opening 82 in soft tissue 80 and into bone bore 86. *Id.* at 6:43–46. In a repair procedure such as a rotator cuff repair, one of strand ends 122, 124 is pulled to tighten loop 128 to secure sleeves 100 in fixation members 200, such that tying individual knots for each respective sleeve and fixation member is unnecessary. *Id.* at 6:63–7:5. In Figure 9, the right-most fixation member 200 that is positioned within bone bore 86 exemplifies how suture anchor 200d (the Figure 8 embodiment) can be used.

2. Dhawan (Ex. 1006)

Dhawan is titled "Complications of Bioabsorbable Suture Anchors in the Shoulder." Ex. 1006, 1424. It evaluates composites such as polyetheretherketone (PEEK) for suture anchors as to whether they are safe and consistent for securing soft tissue to bone in and about the shoulder. *Id.* at 1424 (Abstract). Dhawan notes that "metallic anchors for soft tissue fixation in and about the shoulder" have "demonstrated complications." *Id.* at 1425. Thus, Dhawan investigates bioabsorbable suture anchors made of different materials, including polylactic acid enantiomers (PLLA), for their degradation time and possible surgical complications. *Id.* at 1425–26. Dhawan notes that although PEEK is not bioabsorbable, it is biologically inert such that it can also be "used as a material for manufacturing orthopaedic implants." *Id.* at 1426. Dhawan concludes from its studies that

bioabsorbable suture anchors "provide a safe and mechanically stable implant, allowing arthroscopic surgeons to reliably repair soft tissue to bone in and around the shoulder." *Id.* at 1429.

3. Barber (Ex. 1007)

Barber, titled "Ultimate Tensile Failure Loads of a Human Dermal Allograft Rotator Cuff Augmentation," examines tendon repairs "with and without human dermal allograft augmentation." Ex. 1007, 20 (Abstract). Barber examines GraftJacket, a human dermal allograft from Wright Medical Technology, for failure characteristics and ultimate failure load. *Id.* Although Barber notes certain weaknesses in its studies, it concludes that its "examination of the failure characteristics and ultimate failure load of supraspinatus tendon tears augmented with GraftJacket supported the study hypothesis that a human dermal allograft would significantly increase the strength of a repaired tendon." *Id.* at 23.

4. ElAttrache (Ex. 1009)

ElAttrache is titled "Method for Double Row Fixation of Tendon to Bone" and "relates to . . . an improved method of attaching tissue to bone, such as rotator cuff repair." Ex. 1009, code (54), ¶ 2. ElAttrache explains that knot tying in arthroscopic surgery can be tedious and time-consuming. *Id.* ¶ 4. ElAttrache purports to resolve this problem by providing a method for securing soft tissue to bone that does not require multiple suture knots. *Id.* ¶ 5.

An exemplary method is depicted in ElAttrache Figure 15, reproduced below.

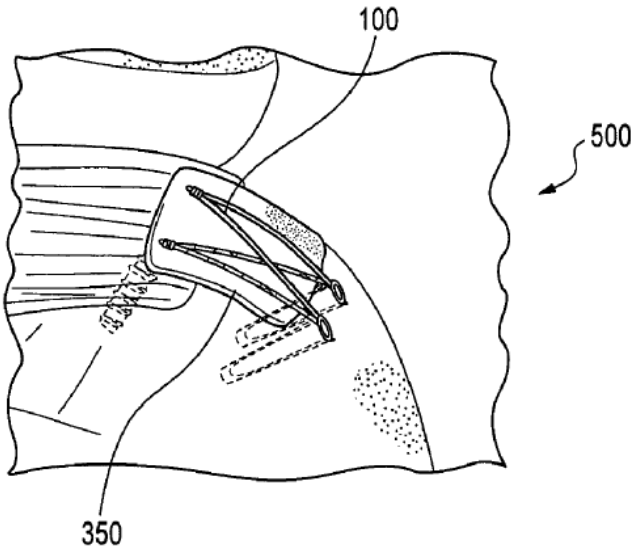


FIG. 15

ElAttrache Figure 15 shows shoulder tendon repair system 500, which comprises a medial row of suture anchors on the left, and a lateral row of suture anchors on the right, which are connected by a suture. Ex. 1009 ¶ 23. "The repair consists of a tied medial row constructed with at least one suture anchor combined with knotless lateral fixation using at least one knotless fixation device," e.g., a Push Lock or SwiveLock anchor.[18] *Id.* ¶ 25. ElAttrache's method includes:

> (i) providing a first medial row constructed with a first plurality of fixation devices, at least one of the first plurality of fixation devices being an anchor; (ii) providing a second lateral row constructed with a second plurality of fixation devices, at least one of the second plurality of fixation devices being a knotless fixation device; and (iii) providing a structure comprising an element selected from the group consisting of suture, tape and allograft/biological component, and extending the structure

[18] ElAttrache's method is commercially known as the SutureBridge double row repair. *See* Ex. 1002 (Jordan Decl.) ¶ 152; Ex. 2001 (Pedowitz Decl.) ¶ 132.

over the soft tissue so that the structure is secured in place by the anchors.

Id. ¶ 7.

Figure 13, reproduced below, is an exemplary fixation device.

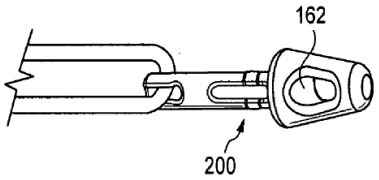


FIG. 13

Figure 13 shows an enlarged side view of a swivel anchor implant. Ex. 1009 ¶ 21. Swivel anchor implant 200 (e.g., a SwiveLock anchor, sold by Arthrex) can be used for a knotless method of attaching tissue to bone. *Id.* ¶ 37. Such anchor implants "minimize or eliminate the need to tie knots" and provide "secure fixation of suture constructs—the secure suture construct results from the suture being pushed into a pilot hole on the lateral row and held tightly by an anchor[]." *Id.* ¶ 40.

E. Ground 1 – Alleged Obviousness Over Stone (Claims 1–5, 7, 9, 15–19)

For Ground 1, Petitioner asserts that claims 1–5, 7, 9, and 15–19 are unpatentable as obvious over Stone. Pet. 20–41. Patent Owner opposes. PO Resp. 25–38.

For the reasons explained below, we find that Petitioner has established by a preponderance of the evidence that claims 1–5, 7, 9, and 15–19 are unpatentable as obvious over Stone. We begin by analyzing the parties' arguments in the context of claim 1, then move to the remaining claims challenged in this ground.

1. Analysis of Independent Claim 1

Below we provide an overview of Petitioner's showing as to how claim 1 is unpatentable as obvious over Stone, and we address Patent Owner's rebuttal thereto. Although Patent Owner challenges only whether Stone teaches or suggests limitations [1.2] and [1.6], for completeness we address each element of claim 1.

(a) *Preamble [1.p]: A method for securing body tissues comprising:*

Petitioner contends that the preamble is not limiting, but to the extent it is, Stone teaches a method for securing body tissues. Pet. 20. Patent Owner neither takes a position on whether the preamble is limiting, nor disputes that Stone teaches or suggests the preamble. *See generally* PO Resp.

Generally, a preamble does not limit a claim. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). We need not decide whether the preamble here is limiting, because even assuming it is, Petitioner demonstrates by a preponderance of the evidence that Stone discloses a method for securing body tissues. *See* Pet. 20–21; Ex. 1005 (Stone), 1:19–20 (disclosing a "tissue fixation method"), 2:46–47 (illustrating a device "that can be used for attaching soft tissue to bone").

(b) *Limitation [1.1]: inserting a flexible fastener having a passage into a passage in a first bone portion, wherein an elongate member extends through the fastener passage, such that at least two legs of the elongate member extend from the fastener and outside the passage in the first bone portion;*

Petitioner demonstrates by a preponderance of the evidence that Stone teaches or suggests the claimed "flexible fastener having a passage," via its

disclosure of connector device 101. *See* Pet. 21. We reproduce Stone Figure 1 below:

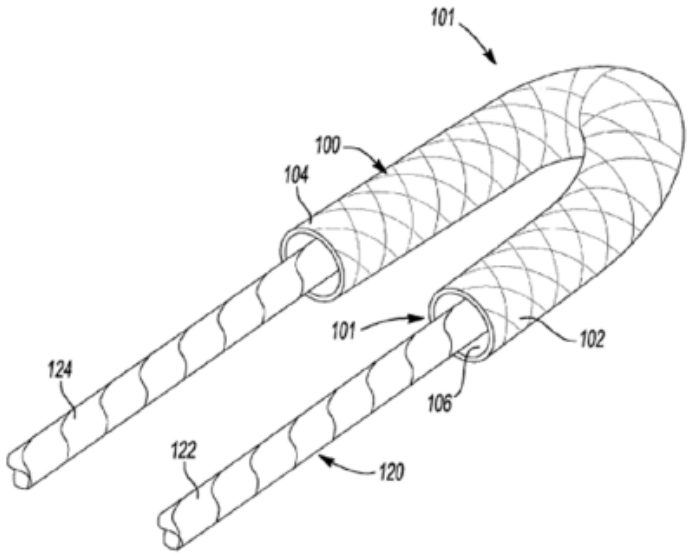


Fig-1

Stone Figure 1 above illustrates connector device 101, which comprises a flexible fastener (sleeve 100) having a passage (inner bore 106). *See* Pet. 21–22; Ex. 1005 (Stone), 2:48–67; Ex. 1002 (Jordan Decl.) ¶ 58.

Petitioner also demonstrates that sleeve 100 has fastening capability, based on its ability to change shape under tension. *See* Pet. 23–24; Ex. 1002 (Jordan Decl.) ¶¶ 44–47, 60. We reproduce Stone Figures 2 and 3 below:

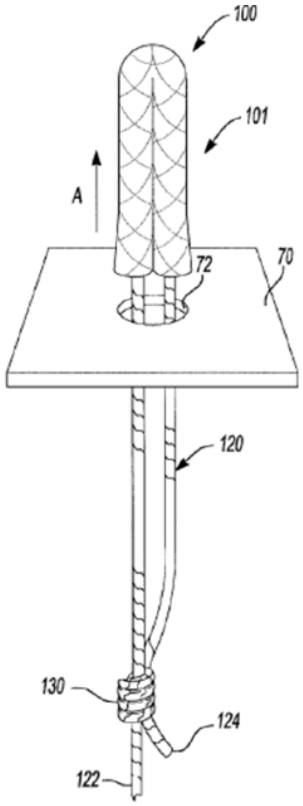


Fig-2

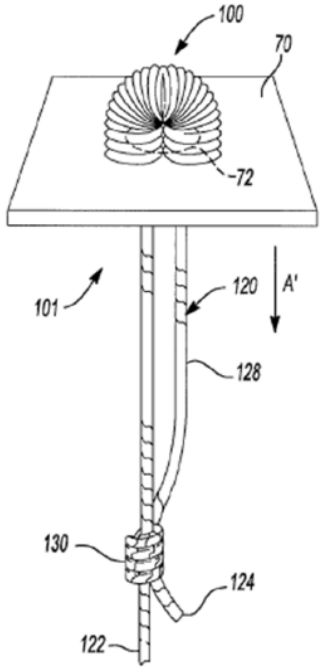
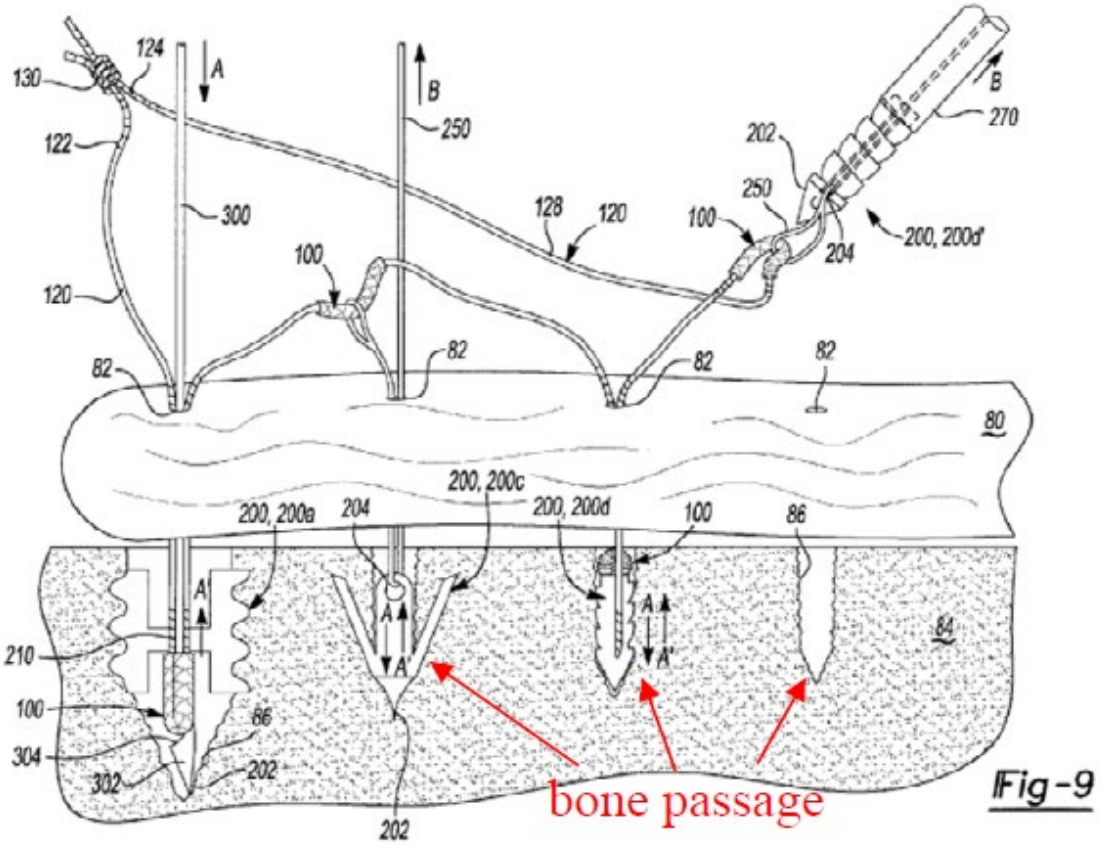


Fig-3

Stone Figures 2 and 3 above illustrate Stone's sleeve 100 inserted through aperture 72, which can be in bone, before and after tensioning. Pet. 23–24; Ex. 1005 (Stone), 4:4–6 (teaching that support 70 "can be soft tissue, bone," or other fixation members); Ex. 1002 (Jordan Decl.) ¶ 59. Stone explains that pulling on one of the strand ends 122, 124 causes sleeve 100 to "change configuration, bunching up from a folded and/or flaccid configurate to a bunched-up, ball-like configuration that cannot pass through orifice 72, such that the strand 120 can be secured on the support 70." Ex. 1005 (Stone), 3:37–43. "[S]trand 120 can still slide relative to the sleeve 100 and the orifice 72, therefore the orifice 72 can act effectively as an anchor eyelet." *Id.* at 4:1–3; Ex. 1002 (Jordan Decl.) ¶¶ 45, 47, 60.

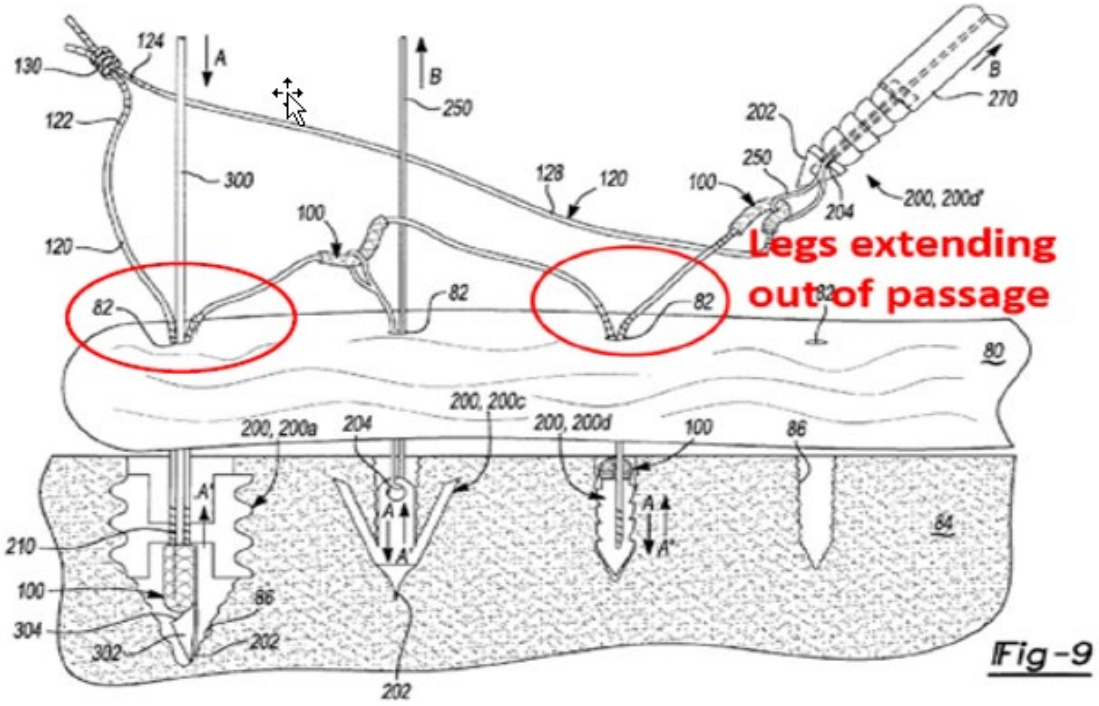
Petitioner further demonstrates that Stone teaches or suggests inserting the flexible fastener (sleeve 100) into a passage in a first bone portion. Pet. 22–23; Ex. 1005 (Stone) Figs. 2, 3, 9. Below we reproduce Petitioner's annotated version of Stone Figure 9:



Pet. 22. As shown in Petitioner's annotated version of Stone Figure 9 above, Stone illustrates a fixation method employing several bone passages (labeled with red text). To secure strand 120, flexible sleeve 100 can be inserted into a bone passage, either alone as depicted in Figures 2 and 3 (reproduced *supra*), or in combination with fixation member 200, as depicted in annotated Figure 9 above. *Id.* at 22–23. As shown in annotated Figure 9 above, fixation member 200 can take a variety of forms, including "an externally threaded open-ended tubular member 200*a*" (depicted in the

leftmost bone passage), a "harpoon-type anchor 200*c* having a pointed anchoring tip 202" (depicted in the second bone passage from the left), or "an externally threaded suture anchor 200*d*" (depicted in the third bone passage from the left). Ex. 1005 (Stone), 4:41–44, 5:21–23, 5:35–39; *see also id.* at 4:4–8, 4:34–5:50, 7:36–40, Figs. 5–8.

Petitioner also persuasively demonstrates that Stone Figure 1 (reproduced *supra*) depicts two legs of an elongate member (strand 120) extending through the passage in the flexible fastener (sleeve 100). The legs of the elongate member (strand 120) extend from the first bone portion. For example, in Stone Figures 2 and 3 reproduced *supra*, ends 122, 124 of strand 120 extend outside orifice 72 of support 70, which can be a bone bore. *Id.* at 25; Ex. 1002 (Jordan Decl.) ¶ 64. This can also be seen in Stone Figure 9. We reproduce below a second annotated version of Stone Figure 9 (different than the annotated Figure 9 reproduced above):



Pet. 26. In Petitioner's annotated version of Stone Figure 9 reproduced above, it can be seen that following insertion of the flexible fastener (sleeve 100) into bone bores 86, the legs of strand 120 extend through sleeve and outside of the bone bores (see red circles). Ex. 1002 (Jordan Decl.) ¶¶ 62–63.

Patent Owner does not dispute that Stone teaches or suggests limitation [1.1]. *See generally* PO Resp.

> (c) *Limitation [1.2]: deforming the fastener from a first configuration to a second configuration to secure the fastener and the elongate member when tensioning at least one of the legs of the elongate member;*

With reference to Stone Figure 3 reproduced *supra*, Petitioner argues that pulling the legs of Stone's elongate member (strand 120) causes the fastener (sleeve 100) to "change configuration" or "bunch up," such that the fastener and elongate member are secured. Pet. 26–28; Ex. 1002 (Jordan Decl.) ¶¶ 65, 67. In the bunched-up configuration, "strand 120 [is] secured on the support 70 . . . [and] sleeve 100 cannot pass through the orifice 72 in the direction of the arrow A' [downward]." Ex. 1005 (Stone), 3:37–55; Pet. 26–28; Ex. 1002 (Jordan Decl.) ¶¶ 47, 65. Petitioner notes that the very purpose of Stone's design is to "secur[e] a strand to a plurality of anchors for a surgical procedure." Reply 11 (quoting Ex. 1005 (Stone), 1:36–37); *see also id.* (citing Ex. 1005 (Stone), 3:52–55 ("The strand ends 122, 124 and the sleeve 100 remain on opposite sides of the orifice 72, and the legs 103, 105 provide additional resistance for securing the strand 120 to the support 70."), 4:13–15 ("[T]he connector device 101 can be used as a versatile suture lock that is easy to use, avoids knot-tying, and saves time during the surgical procedure."), 5:56–6:36).

Patent Owner argues that Stone does not teach or suggest limitation [1.2] because Stone's elongate member (strand 120) can slide relative to the fastener (sleeve 100) and thus is not "secure" under Patent Owner's proposed construction of that term. *See, e.g.*, PO Resp. 27 (citing Ex. 2001 (Pedowitz Decl.) ¶ 59; Ex. 1005 (Stone), 3:62–4:3); Sur-reply 10–11 ("Under PO's proposed definition of 'secure,' . . . Stone's suture moves freely after deformation of the sleeve 100 by design so the suture is not fixed, anchored or attached and has no point of attachment to the sleeve 100.").

Considering all of the arguments and cited evidence of record, we find that Petitioner shows by a preponderance of the evidence that Stone teaches or suggests limitation [1.2]. *See* Pet. 26–28. Limitation [1.2] requires deforming the fastener "to ***secure the fastener and the elongate member***." Ex. 1001, 30:40–43 (emphasis added). Under our construction of "secure," limitation [1.2] requires deforming the fastener to fix, anchor, or attach the fastener and the elongate member. *See supra* Section II.C.2. The claim language does not specify to what the fastener and elongate member must be secured. As we discuss in more detail below, we find this limitation satisfied by Stone's teaching that the strand and sleeve are secured to the support (e.g., bone).

First, Stone teaches that deforming the fastener (sleeve 100) ***secures the fastener***. Specifically, Stone teaches that after sleeve 100 is tensioned to the bunched-up configuration, it "cannot pass through the orifice," meaning that it is anchored in the orifice. Ex. 1005 (Stone), 3:50–52; *see also* Ex. 1002 (Jordan Decl.) ¶ 60 ("[A] POSITA would understand that the flexible sleeve 100 operates as a fastener when it is tensioned and thereby

deformed into a shape that prevents removal from a bone passage."), ¶ 65 (opining that a person of ordinary skill in the art would understand Stone to be teaching "flexible members that changed configuration and thereby created a locking functionality").

Second, Stone expressly teaches that deforming the fastener (sleeve 100) ***secures the elongate member*** (strand 120). Specifically, Stone teaches that tensioning the sleeve to the bunched-up configuration causes strand 120 to be "***secured*** on the support 70." Ex. 1005 (Stone), 3:37–43 (emphasis added); Ex. 1002 (Jordan Decl.) ¶ 65. Stone notes that "strand 120 can still slide relative to the sleeve 100 and the orifice 72, [and] therefore the orifice 72 can act effectively as an anchor eyelet." Ex. 1005 (Stone), 3:62–4:3 (emphasis added). In this way, although the elongate member can slide relative to the sleeve, Stone teaches that it is anchored vis-à-vis the support (e.g., bone). *See also id.* at 7:17–20 ("the connector device 101 including one or more sleeves 100 can be [used] to secure a strand 120, such as a suture to soft tissue 80 or bone"), claim 1 (teaching a "method for securing a strand to a bone"); *see also* Reply 10–11 ("Stone explains that the very purpose of its design is to 'secur[e] a strand to a plurality of anchors for a surgical procedure.'") (quoting Ex. 1005 (Stone), 1:36–37).

Patent Owner's only argument for why Stone fails to teach limitation [1.2] is because Stone's suture can slide relative to the sleeve. *See* PO Resp. 7. However, as discussed above, we reject Patent Owner's proposed claim construction, and its related contention that a suture that slides relative to the fastener is not "secure" as claimed. *See supra* Section II.C.2.

Although we reject Patent Owner's proposed construction of "secure" and conclude that Petitioner shows by a preponderance of the evidence that Stone teaches or suggests limitation [1.2] under the correct construction, for completeness we address Petitioner's arguments that even under Patent Owner's proposed construction, Stone teaches or suggests limitation [1.2].

First, even if Patent Owner were correct that a suture that slides relative to the fastener is not "secure," we would still find that Stone teaches limitation [1.2]. This claim limitation allows for the securing to occur when tensioning ***at least*** one suture leg. Reply 9; Ex. 1001, 30:40–43. Stone teaches that the fastener (sleeve 100) may be deformed by pulling ***both*** suture legs, i.e., strand ends 112 and 124. Reply 9; Ex. 1005 (Stone), 5:28–31 ("strand ends 122, 124 can be pulled . . . such that the sleeve 100 is held against the body 218 in a bunched-up (ball or bell-like) configuration"), 5:43–47 ("The strand ends 122, 124 can be pulled away from the fixation member 200 in the direction of arrow A', such that the sleeve 200 can be secured against the proximal end 206 in a bunched-up (ball or bell like) configuration."). We agree with Petitioner that "when both legs of Stone's strand 120 are tensioned strand 120 will not slide." Reply 9. Patent Owner's declarant Dr. Pedowitz also agreed. When asked, "if you pulled on both strands at that moment, it would be secure?," he answered, "[a]t that moment, that's true." Ex. 1018 (Pedowitz Depo. Tr.), 113:20–114:2; Reply 9.[19]

[19] Patent Owner argues that we should ignore Petitioner's argument premised on pulling both legs of Stone's strand because it is not in the Petition. Sur-reply 3. We disagree that this argument is untimely. First, the Petition expressly discusses tensioning Stone's strand by pulling both legs. *See* Pet. 27–28 ("the leg**s** of strand 120 would be pulled to deform sleeve

Second, Petitioner argues that Dr. Pedowitz admitted that "Stone's sleeve 100 and strand 120 would be secure . . . if a knot were used," and that "a POSITA would have used a knot with Stone's fastener." Reply 10 (citing Ex. 1018 (Pedowitz Depo. Tr.), 51:3–52:20, 103:5–19, 105:2–107:8). We are not persuaded by Petitioner's argument because the cited testimony does not clearly make the alleged admissions. For example, at page 51, Dr. Pedowitz explains that he is describing a "*current* commercial example" of Stone, not the prior art Stone reference or a contemporaneous commercial example of Stone. Ex. 1018 (Pedowitz Depo. Tr.), 51:10–17 (emphasis added). At page 105, Dr. Pedowitz testifies that if a surgeon were to use a "nonsliding knot," "it would be contrary to the Stone patent which requires sliding." *Id.* at 105:2–15. On this record, Petitioner fails to explain, and we are unable to adequately discern, how Dr. Pedowitz's testimony constitutes an alleged admission that "a POSITA would have used a knot with Stone's fastener." Reply 10.

After considering all of the arguments and cited evidence of record, we find that Petitioner shows by a preponderance of the evidence that Stone teaches or suggests limitation [1.2].

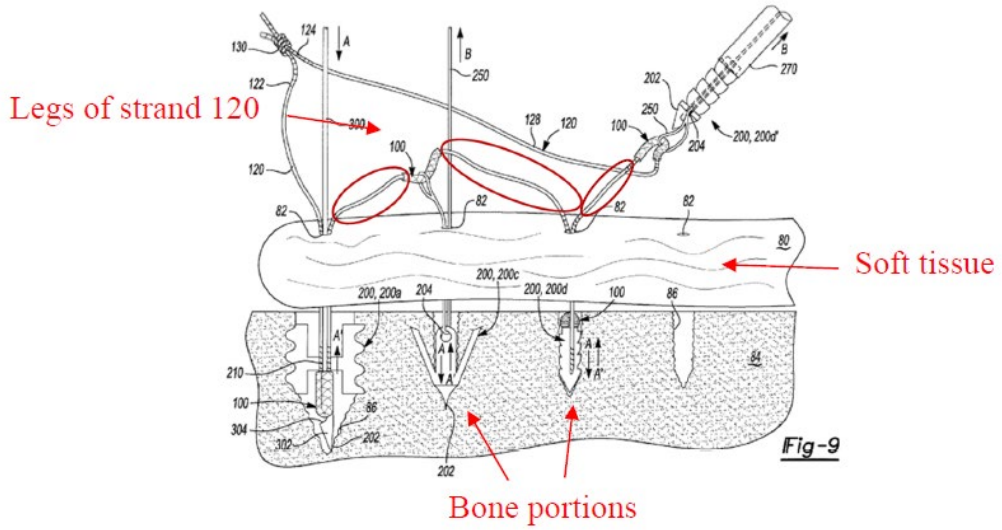
100") (emphasis added). Second, the argument responds to Patent Owner's proposed construction of "secure," which Patent Owner first offered post-institution. Under these circumstances, Petitioner is permitted to proffer additional argument and evidence in its Reply to respond to the proposed construction. *See Axonics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1382 (Fed. Cir. 2023) ("[A] petitioner is entitled under the APA to respond to new claim construction arguments made by a patent owner.").

(d) *Limitation [1.3]: passing at least one of the legs of the elongate member over at least one tissue;*

Petitioner persuasively demonstrates that Stone teaches or suggests this limitation. Stone teaches that a series of flexible fasteners (sleeves 100) can be used together with a single strand 120:

> Referring to FIGS. 4 and 9, a series of sleeves 100 can be strung along a single loop or chain 128 of the strand 120 without other knots except a single slipknot 130 coupling the strand ends 122, 124. Each sleeve 100 can be inserted in a corresponding prepared bone bore 84 or in a corresponding fixation member 200 to attach soft tissue 80 to a bone 84.

Ex. 1005 (Stone), 5:60–6:5.[20] Dr. Jordan explains that this would be useful in a surgery requiring multiple anchor fixations. Ex. 1002 (Jordan Decl.) ¶ 68. In such a scenario, the elongate member (strand 120) would pass over tissue. To demonstrate, we reproduce below a third annotated version of Stone Figure 9:



[20] As Dr. Jordan explains, although Stone refers to "bone bore 84," this appears to be a typographical error, where "bone bore 86" is intended. Ex. 1002 (Jordan Decl.) ¶ 59 n.2.

Pet. 28. As can be seen in Petitioner's third annotated version of Stone Figure 9 reproduced above, when using a series of flexible fasteners (sleeves 100), the legs of elongate member (strand 120) are passed over soft tissue 80 (see red circles). *See id.* at 28–29; Ex. 1002 (Jordan Decl.) ¶¶ 66–68.

Patent Owner does not dispute that Stone teaches or suggests limitation [1.3]. *See generally* PO Resp.

(e) *Limitation [1.4]: passing at least one of the legs of the elongate member through a bore in a first component of a two component knotless fixation device;*

Petitioner persuasively demonstrates that Stone teaches or suggests this limitation. Pet. 29. Petitioner shows that the two-component knotless fixation device recited in limitation [1.4] corresponds to the combination of Stone's flexible fastener (sleeve 100) (the first component) and fixation member 200 (the second component). *Id.*; Ex. 1002 (Jordan Decl.) ¶ 69. Stone Figure 9 depicts passing one of the legs (122, 124) of the elongate member (strand 120) through a bore in the flexible fastener (sleeve 100), which is the first component of the two-component knotless fixation device. Pet. 29; *see also* Ex. 1005 (Stone), 2:48–49 ("a flexible tubular sleeve 100 having an inner bore"), 3:3–5 ("strand 120 can pass axially through the bore 106 of the sleeve 100"); Ex. 1002 (Jordan Decl.) ¶¶ 69, 71. This step can be performed before or after implantation of fixation member 200 into the bone. Pet. 31; Ex. 1005 (Stone), 6:54–61.

Patent Owner does not dispute that Stone teaches or suggests limitation [1.4]. *See generally* PO Resp.

(f) *Limitation [1.5]: inserting the two component knotless fixation device into a passage in a second bone portion; and*

Petitioner persuasively demonstrates that Stone teaches or suggests this limitation. Pet. 31–32. For example, in Stone Figure 9, fixation member 200d is already in place in the third bone bore (from left to right), and another fixation member 200d is outside of the fourth bone bore, about to be inserted. *Id.*; Ex. 1005 (Stone), 6:39–46; Ex. 1002 (Jordan Decl.) ¶¶ 72, 73.

Patent Owner does not dispute that Stone teaches or suggests this limitation. *See generally* PO Resp.

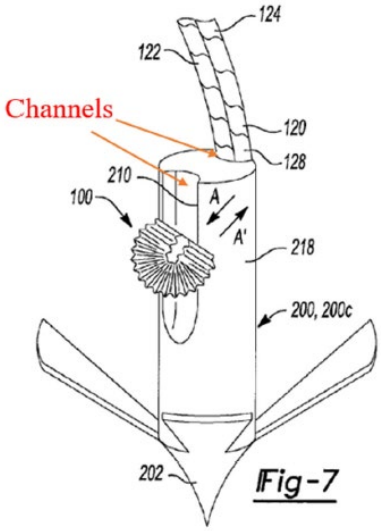
(g) *Limitation [1.6]: securing the at least one leg of the elongate member when both the first and second components of the two component knotless fixation device are positioned in the passage in the second bone portion, wherein the elongate member presses against an external surface of the second component of the two component fixation device.*

Petitioner asserts two distinct ways that Stone teaches or suggests this limitation, based on Stone's teaching the fastener can be deformed either before or after fixation member 200d is implanted. Pet. 32–35; Ex. 1005 (Stone), 6:54–61; Ex. 1002 (Jordan Decl.) ¶ 75.

The first way Petitioner asserts Stone teaches or suggests limitation [1.6] is based on deformation of the fastener before implantation of fixation member 200d. In this embodiment, Petitioner contends that after deformation of the fastener outside of the body and implantation of the construct in the body, the ends of suture strand 120 will be secured because they will be pinned between the threads on the external surface of fixation member 200d and the bone passage. Ex. 1002 (Jordan Decl.) ¶ 75; Pet. 33;

Reply 14–15 (explaining that in Stone's device, "both legs are pressed between the outside surface of fixation member 200d and the passage in the bone when implanted").

The second way Petitioner asserts Stone teaches or suggests limitation [1.6] is based on deformation of the fastener after implantation of fixation member 200d. In this embodiment, after implantation, the surgeon must still be able to pull the suture legs to achieve deformation of the fastener. As such, Petitioner argues that a person of ordinary skill in the art would have understood that fixation member 200d would have an external channel in which the legs of the elongate member (strand 120) would sit, such that the suture legs could be pulled without getting caught in the threading of fixation member 200d. *See* Pet. 34. Such a channel is shown in Petitioner's annotated version of Stone Figure 7, reproduced below:



Pet. 34; Ex. 1002 (Jordan Decl.) ¶ 75. Stone Figure 7, reproduced above, depicts fixation member 200c, with an annotation pointing to two external channels, one of which has suture legs 122, 124 residing in, and extending from, the channel. Petitioner argues that when fixation member 200d

includes a channel and is implanted, "[t]he legs of the elongate member are secured by a normal force created by the channel formed in the body of fixation member 200d and the wall of the bone hole pressing against the elongate member (strand 120), as well as by the deformation of sleeve 100." Pet. 34; Ex. 1002 (Jordan Decl.) ¶ 75.

We analyze each alternative in turn.

(1) Deformation of the Fastener Before Implantation

As to Petitioner's arguments based on deformation of the fastener before implantation, Patent Owner disputes that the suture will be pinned between bone passage and the threads on fixation member 200d. This is because, Patent Owner contends, fixation member 200d must always have an external channel: "[t]here are not two different versions of the fixation device 200d depending upon whether the sleeve 100 is deformed before or after the fixation device is implanted." PO Resp. 35; Ex. 2001 (Pedowitz Decl.) ¶ 77. Patent Owner argues that an external channel precludes "securing" the suture as required by limitation [1.6], yet a channel is necessary because without it, "the strand ends would get caught in the external threads of fixation member 200d and could not be pulled to tension the sleeve 100 and/or slide to remove slack from single loop 128 of strand 120 as required by Stone." PO Resp. 31–32; Ex. 2001 (Pedowitz Decl.) ¶ 69. Patent Owner and Dr. Pedowitz contend that Stone Figure 9 depicts the external channel in fixation member 200d. PO Resp. 31; Ex. 2001 (Pedowitz Decl.) ¶ 69.

Patent Owner does not persuade us that a person of ordinary skill in the art would have understood Stone to teach or suggest that fixation

member 200d necessarily has an external channel. To explain, we first discuss fixation member 200d with reference to Stone Figure 8 (reproduced below):

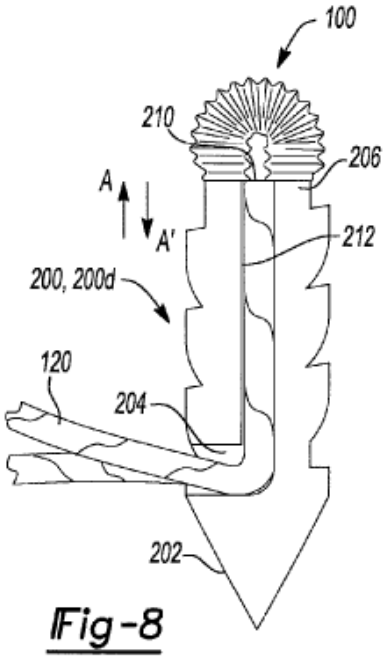
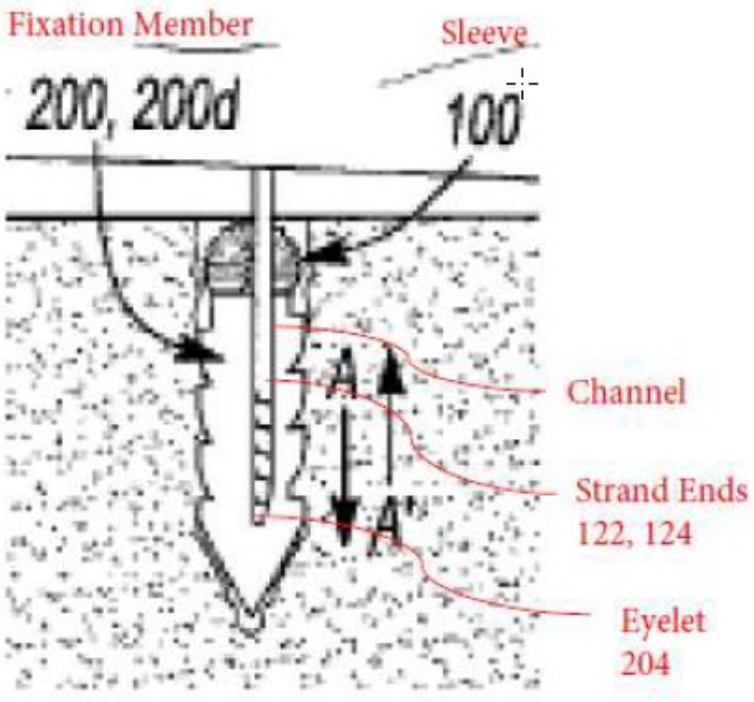


Fig-8

Stone Figure 8 depicts fixation member 200d. Ex. 1005 (Stone), 5:35–59. Stone does not describe this fixation member as having an external channel; instead, it describes it only as having external threads. *Id.* at 5:35–39. Patent Owner and Dr. Pedowitz acknowledge Figure 8 does not depict an external channel, but contend that Figure 8 is a cross-section, and the channel is visible in the side view shown in Stone Figure 9. PO Resp. 31; Ex. 2001 (Pedowitz Decl.) ¶ 69. We reproduce below Patent Owner's annotated excerpt of Stone Figure 9:



PO Resp. 32; Ex. 2001 (Pedowitz Decl.) ¶ 69. In Patent Owner's annotated excerpt of Stone Figure 9, Patent Owner adds labels for what it contends are eyelet 204, strand ends 122, 124, and the external channel on fixation member 200d.

We are not persuaded by Patent Owner's argument that Stone requires that fixation member 200d necessarily has an external channel. First, Stone does not describe this device as having a channel. Second, Figure 9 is equivocal. What Patent Owner labels as a channel may be a channel, or it may just be the strand ends exiting out of eyelet 204 and extending up the device and out of the body. Indeed, Patent Owner's annotation of Figure 9 suggests that there is an external channel engaged with eyelet 204, but that is not consistent with the purported cross-section in Figure 8, which depicts external threads, not an external channel, outside of eyelet 204. Although we agree with Petitioner that a person of ordinary skill in the art would have

used a channel in fixation member 200d if needed, this does not mean that Stone necessarily teaches or requires such a channel. *See KSR Int'l Co.*, 550 U.S. at 418, 421 (holding that an obviousness analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ," and "[a] person of ordinary skill is . . . a person of ordinary creativity, not an automaton").

Patent Owner's other theory for why fixation member 200d must necessarily have an external channel (where the channel precludes "securing" the suture as required by limitation [1.6]) is also unavailing. Patent Owner contends that a channel is required in order to "remove slack when the strand end 122 or 124 is pulled to tighten single loop 128." PO Resp. 31–32, 35; Ex. 2001 (Pedowitz Decl.) ¶¶ 69, 78. Patent Owner is referring to Stone's Figure 9 embodiment, which describes tensioning multiple fixation members using a single suture loop secured with a slipknot. *See* Ex. 1005 (Stone), 6:62–7:2.

We agree with Petitioner that this is merely an exemplary embodiment described in Stone, whereas Patent Owner's arguments improperly assume that Stone is limited to this example. *See* Reply 15–16. In other words, in arguing that "Stone's strand must move freely through all of its sleeves 100 and fixation members 200 **by design** to be able to position the sliding knot within the patient's body," Patent Owner reads Stone too narrowly. Sur-Reply 13. Stone is not limited to an embodiment that requires tightening suture in multiple fasteners by using a single suture loop with a slipknot; it is merely one described embodiment. *See* Ex. 1005 (Stone), 2:31–33 ("The following description is merely exemplary in nature and is in no way intended to limit the scope of the present teachings, applications, or uses.");

id. at 5:47–50 ("The fixation member 200d ***can also*** be used in a single loop 128 with multiple similar or different fixation members 200 for attaching soft tissue 80 to bone 84 in multiple locations, as illustrated in FIG. 9.") (emphasis added). Stone also depicts using individual knots with individual fasteners, as well as using knots other than slipknots. *See id.* at Fig. 2, 2A, 3, and 3A (depicting individual knots with individual fasteners), 3:33–35 ("The strand ends of 122, 124 can be connected with a knot 130, *such as* slipknot . . . .") (emphasis added); *see also* Tr. 20:4–12 (discussing Stone's teachings regarding use of individual knots), 24:11–24 (discussing Stone's teachings regarding knots other than slipknots). Dr. Pedowitz agreed that if a surgeon were to perform Stone's Figure 9 method but with a knot other than a slipknot, there would be no need for the suture to slide relative to fixation member 200d. Ex. 1018 (Pedowitz Depo. Tr.), 105:2–107:12.

In sum, Stone nowhere describes fixation member 200d as having an external channel. Stone does depict a channel in fixation member 200c (*see* Stone Figure 7) which a person of ordinary skill in the art would have understood could be used with other fixation members as needed, but Patent Owner does not persuade us that Stone necessarily teaches that fixation member 200d has or always requires a channel. Nor do we agree with Patent Owner that Stone's methods necessarily require a channel, e.g., to remove slack, because the method described in connection with Stone Figure 9 is merely exemplary.

In view of the above discussion, we agree with Petitioner that when deformation of the fastener take places before fixation member 200d is implanted, the ends of suture strand 120 will be secured because they will be pinned (or fixed or anchored) between the threads on the external surface of

fixation member 200d and the bone passage. Pet. 34; Ex. 1005 (Stone), 6:54–61; Ex. 1002 (Jordan Decl.) ¶ 75.

(2) Deformation of the Fastener After Implantation

As to Petitioner's arguments based on deformation of the fastener after implantation, Patent Owner argues that strand 120 is not "secured" because "[t]he fixation device with a channel would allow the strand ends 122, 124 to still slide after implantation as required by Stone, and this is what is depicted in . . . [Stone] FIG. 9." PO Resp. 35; Ex. 2001 (Pedowitz Decl.) ¶¶ 67, 72, 75, 78.

In response, Petitioner acknowledges that although the channel in this embodiment may allow for some movement of strand 120, the amount of friction would be determined by the depth of the channel, such that the strand can still be secured between the channel and the wall of the bone hole. Reply 14–15; Ex. 1018 (Pedowitz Depo. Tr.), 101:2–8 (Dr. Pedowitz acknowledging that the amount of friction between the suture and the bone will depend on the depth of the channel on fixation member 200d). Petitioner also argues that the strand is secure in the fixation device via contact resistance, because the strand makes three U-turns in the device, thereby fixing the strand to the device. Reply 13 (citing Ex. 1018 (Pedowitz Depo. Tr.), 99:15–100:6, acknowledging that using sleeve 100 in combination with fixation device 200d provides more friction than using sleeve 100 alone). This is demonstrated in Petitioner's annotated version of Stone Figure 8, which we reproduce below:

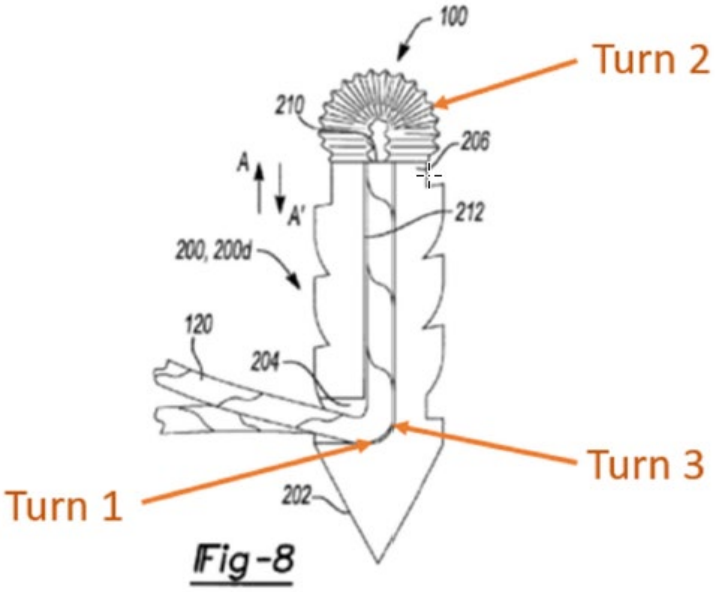


Fig-8

Reply 13. Petitioner supports its argument by pointing to the '440 patent's teaching that the fixation device "may include a tortuous path to secure elongate member," to "apply friction to elongate member 106 thereby resisting motion." Ex. 1001, 25:53–58, Fig. 112; Reply 14.

We find that Petitioner shows by a preponderance of the evidence that Stone teaches or suggests limitation [1.6]. Stone teaches that the strands (which are inside sleeves 100) are secure to the fixation member even before a single loop is tightened: "After all the sleeves 100 have been *secured* to the corresponding fixation members 200, the single loop 128 is tightened by pulling one of the strand ends 122, 124 relative to slipknot 130." Pet. 32 (quoting Ex. 1005 (Stone), 6:62–7:2). The strand is secure in the fixation device via the three U-turns it makes in the device. Reply 13–14; Ex. 1018 (Pedowitz Depo. Tr.), 99:15–100:6 (acknowledging that using sleeve 100 in combination with fixation device 200d provides more friction than using sleeve 100 alone). The U-turns "create contact resistance in order to secure the elongate member in place." Reply 14. This is akin to the "tortuous

path" taught in the '440 patent, which is said to "apply friction to elongate member 106 thereby resisting motion." Ex. 1001, 25:53–58, Fig. 112; Reply 14.

Patent Owner responds to this argument by contending that the "'440 Patent's FIG. 4 can secure the suture more firmly than does Stone's fixation member 200d." PO Resp. 14. We find that this argument is not responsive to Petitioner's arguments regarding the effect of the U-turns, because Figure 4 of the '440 Patent does not depict similar U-turns or a tortuous path for the suture. *See* Ex. 1001, Fig. 4; *see also* PO Resp. 6 (describing '440 patent Fig. 4).

Petitioner further shows that Stone teaches or suggests the "wherein" clause of limitation [1.6] (i.e., "wherein the elongate member presses against an external surface of the second component of the two component fixation device"), because the strand presses against the channel of the fixation device and the wall of bone hole 86. *See* Pet. 33. This is depicted in Petitioner's fourth annotated version of Stone Figure 9, which we reproduce below:

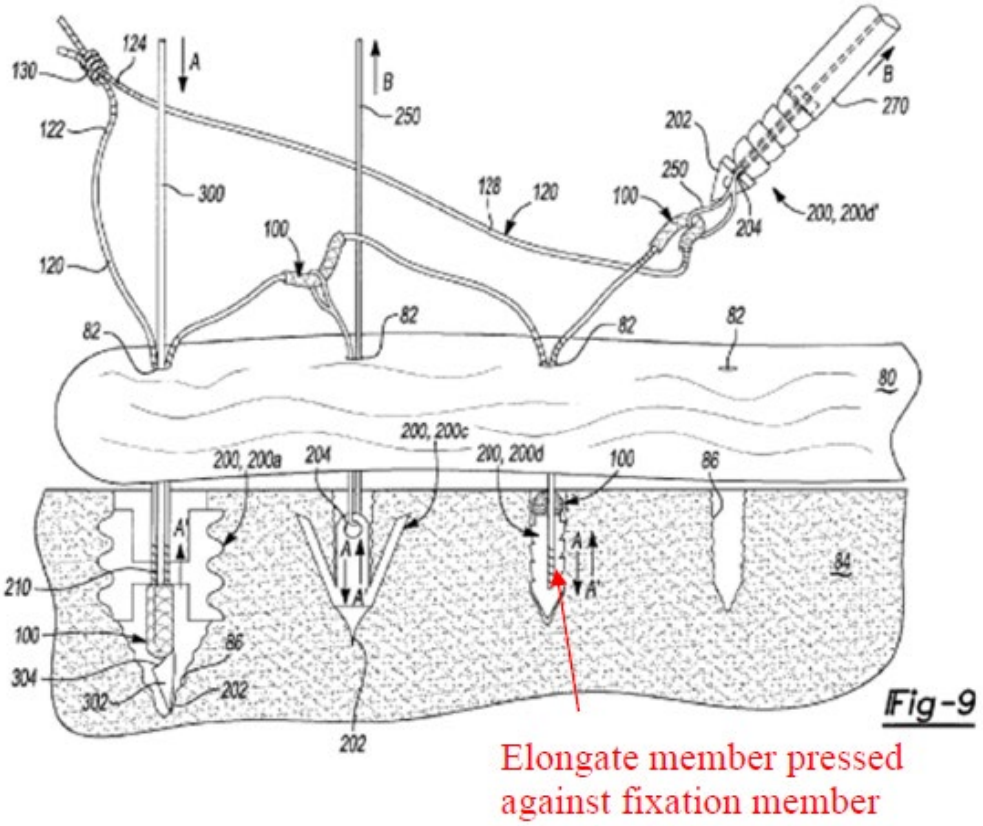


Fig-9

Id. In Petitioner's fourth annotated version of Stone Figure 9, Petitioner adds a red arrow pointing to fixation member 200d inserted into bone bore 86, with a label reading "Elongate member pressed against fixation member." *Id.* Dr. Jordan explains that when fixation member 200d includes a channel and is implanted, "[a] normal force created between the channel formed in the body of fixation member 200d and elongate member (strand 120) coupled with the deformed sleeve (100) secures the legs of the elongate member." Ex. 1002 (Jordan Decl.) ¶ 75; Pet. 34; Reply 14–15; Ex. 1018 (Pedowitz Depo. Tr.), 101:2–8. This arrangement teaches or suggests the wherein clause, i.e., "wherein the elongate member presses against an external surface of the second component of the two component fixation device."

Patent Owner's rebuttal arguments focus on the strand not being secure relative to the sleeve, because it always slides in the sleeve. *See* PO Resp. 35–36; Sur-reply 14–15. Patent Owner's arguments are unavailing, because our construction does not preclude sliding between the suture and the sleeve, nor does it require that the suture "cannot be moved at its point of attachment." *See supra* Section II.C.2. Patent Owner does not argue or demonstrate that the friction that secures or fixes the suture between the channel and the bone hole would have prevented pulling the suture to deform the fastener after implantation.

In view of the above, we find that Petitioner shows by a preponderance of the evidence that Stone teaches or suggests limitation [1.6].

(h) *Conclusion for Claim 1*

Based on the entire record, we determine that Petitioner has established that claim 1 is unpatentable under § 103 as obvious over Stone.

2. Claims 2–5, 7, 9, and 15–19

We have reviewed Petitioner's unpatentability arguments regarding claims 2–5, 7, 9, and 15–19. *See* Pet. 35–41. Beyond the arguments we already discussed above with respect to claim 1, Patent Owner did not make any additional arguments for these claims. *See* PO Resp. 36–38. We are persuaded on the full trial record that Petitioner has shown by a preponderance of the evidence that claims 2–5, 7, 9, and 15–19 are unpatentable as obvious over Stone, for the reasons discussed in the Petition. *See* Pet. 35–41.

F. Ground 2 – Alleged Obviousness Over Stone and Dhawan (Claims 6, 20)

For Ground 2, Petitioner asserts that claims 6 and 20 are unpatentable as obvious over Stone and Dhawan. Pet. 41–46. Claims 6 and 20 recite that the fixation device comprises at least one of PEEK, PLLA, and titanium. Ex. 1001, 31:1–3, 32:38–40. Petitioner argues that although Stone does not expressly teach that the fixation member can be made of PLLA or PEEK, a person of ordinary skill in the art would have been motivated to use these materials with a reasonable expectation of success, because they were well-known, commercially available materials for suture anchors, and Dhawan expressly touts the strength and safety of using them when repairing soft tissue to bone. Pet. 42, 45; Ex. 1002 (Jordan Decl.) ¶¶ 100–15.

Beyond the arguments already discussed above with respect to Ground 1, Patent Owner argues that Dhawan does not disclose the "securing" limitations (i.e., limitations [1.2], [1.6], [10.2], and [10.6]) that it contends are missing from Stone. *See* PO Resp. 39–40. This argument is unavailing, because Petitioner does not rely on Dhawan as teaching or suggesting these limitations. *See generally* Pet. 41–46.

Based on the entire record, we determine that Petitioner has established that claims 6 and 20 are unpatentable under § 103 as obvious over Stone and Dhawan, for the reasons provided in the Petition. *See* Pet. 41–46.

G. Ground 3 – Alleged Obviousness Over Stone and Barber (Claims 5, 8, 10–13)

For Ground 3, Petitioner asserts that claims 5, 8, and 10–13 are unpatentable as obvious over Stone and Barber. Pet. 46–55.

Dependent claim 5 depends from claim 1 and recites that the involved tissue is a rotator cuff tendon and the first and second bone portions are portions of a humeral head. Ex. 1001, 30:64–67. Petitioner demonstrates that Stone teaches using its devices and methods for rotator cuff repair. Pet. 47; Ex. 1005 (Stone), 7:3–6, 2:41–44. Petitioner explains that a surgeon performing Stone's procedure for a rotator cuff repair would have passed the elongate member (strand 120) through the rotator cuff tendon and secured it at multiple points on the humeral head, as taught by Barber. Pet. 50 (citing Ex. 1007 (Barber), 20–21, Fig. 2; Ex. 1002 (Jordan Decl.) ¶¶ 128–29).

Dependent claim 8 depends from claim 1 and recites that the method further comprises "stabilizing an allograft collagen matrix scaffold." Ex. 1001, 31:7–8. Independent claim 10 recites a method similar to that recited in claim 1, but (1) instead of reciting first and second bone portions, it recites a first and second portion of a humeral head; and (2) it includes additional limitations directed to an allograft collagen matrix scaffold. *See id.* at 31:11–39. Dependent claims 11–13 depend from claim 10 and inherit the limitations of claim 10, including those directed to the allograft collagen matrix. *See id.* at 31:40–32:4.

In brief, Petitioner asserts that Stone teaches or suggests all limitations of claims 8 and 10–13, except an "allograft collagen matrix scaffold." Pet. 46–47. According to Petitioner, Stone teaches that its devices and methods can be used for securing grafts to tissue, but does not detail the type of grafts that can be used. *Id.* at 47 (citing Ex. 1005 (Stone), 7:3–6, 2:41–44). Petitioner asserts that a person of ordinary skill in the art would have looked to Barber, which describes a study that "examine[d] the failure mode of supraspinatus tendon repairs with and without human dermal allograft

augmentation." *Id.* at 48 (quoting Ex. 1007 (Barber), 20). In view of Barber's conclusion that "a human dermal allograft significantly increases the strength of the repaired tendon" and "can be expected to significantly increase the initial strength of a rotator cuff repair," Petitioner asserts that a person of ordinary skill in the art looking to improve Stone's methods would have used GraftJacket (a human dermal allograft) to achieve the increased strength of the tendon and repair as taught by Barber, with a reasonable expectation of success. *Id.* at 48 (quoting Ex. 1007 (Barber), 20), 49; Ex. 1002 (Jordan Decl.) ¶¶ 116–45.

Beyond the arguments already discussed above with respect to Ground 1, Patent Owner additionally argues that Barber does not disclose the "securing" limitations (i.e., limitations [1.2] and [1.6]) that it contends are missing from Stone. *See* PO Resp. 40–41, 42–43. This argument is unavailing, because Petitioner does not rely on Barber as teaching or suggesting these limitations. *See generally* Pet. 46–55.

As to claims 10–13, Patent Owner disputes that a person of ordinary skill in the art "would have found it obvious to use Barber's allograft collagen matrix scaffold as the graft to carry out procedures disclosed by Stone." PO Resp. 41; Ex. 2001 (Pedowitz Decl.) ¶ 100. Patent Owner contends that Barber's graft "enhanced biomechanical characteristics when it was fixed with multiple mattress sutures for a rotator cuff repair *in vitro*," but a person of ordinary skill in the art "would have understood that those data could not be extrapolated to other fixation methods, especially knotless suture bridging techniques, *in vivo*." PO Resp. 41; Ex. 2001 (Pedowitz Decl.) ¶ 100.

Neither Patent Owner nor Dr. Pedowitz explains why a person of ordinary skill in the art would have understood that Barber's data "could not be extrapolated to other fixation methods," thus rendering the basis for this argument unclear. PO Resp. 41; Ex. 2001 (Pedowitz Decl.) ¶ 100. To the extent Patent Owner is arguing that "Barber's teachings could not be 'extrapolated' to actual surgeries because Barber involves an *in vitro* (cadaver) study," we agree with Petitioner that this argument is unavailing. Reply 27. As will be discussed in connection with Ground 5, Patent Owner's argument regarding a person of ordinary skill in the art's purported lack of motivation to combine ElAttrache and Stone relies on cadaver studies. *See supra* Section II.I.2.b.1 (discussing Ex. 2004 (Mall); Ex. 2005 (Busfield); Ex. 2009 (Leek)). This demonstrates that it would be inappropriate to set aside cadaver studies merely because they are performed *in vitro* and not *in vivo*.

To the extent Patent Owner is arguing that a person of ordinary skill in the art would have understood that GraftJacket's enhanced biomechanical characteristics could be achieved only in connection with mattress sutures (as used in Barber), or would not work with knotless suture bridging techniques like that depicted in Stone, this argument is unavailing. Dr. Jordan explains three scenarios where the GraftJacket is known to be "particularly useful": (1) to add thickness to repaired tissue and thereby strengthen the repair; (2) to strengthen and augment the healing of compromised tissue; (3) to connect two existing sections of tissue separated by a gap. Ex. 1002 (Jordan Decl.) ¶ 119. Patent Owner does not point us to anything in the record suggesting that the utility of the GraftJacket in these scenarios could be achieved only with mattress sutures or would have

depended on the type of sutures used. Indeed, Dr. Jordan demonstrates that GraftJacket was a commercially available product that was used not only in rotator cuff repairs, but in other types of surgeries as well. *See id.* ¶¶ 118, 124; *see also* Ex. 1008 (Lee), 151 (utilizing GraftJacket in a chronic Achilles tendon rupture). The general availability of GraftJacket undermines Patent Owner's argument that a person of ordinary skill in the art would have understood that its benefits were applicable only in the fixation method tested in Barber.

Based on the entire record, we determine that Petitioner has established that claims 5, 8, and 10–13 are unpatentable under § 103 as obvious over Stone and Barber, for the reasons provided in the Petition. *See* Pet. 46–55.

H. Ground 4 – Alleged Obviousness Over Stone, Barber, and Dhawan (Claim 14)

For Ground 4, Petitioner asserts that claim 14 is unpatentable as obvious over Stone, Barber, and Dhawan. Pet. 55–56. Claim 14 depends from independent claim 10, and recites that the fixation device comprises "at least one of PEEK, PLLA, and titanium." Ex. 1001, 32:5–7. Similar to its arguments for Ground 2, Petitioner asserts that in view of Dhawan, a person of ordinary skill in the art would have been motivated to make Stone's fixation member using PEEK or PLLA. Pet. 56; Ex. 1002 (Jordan Decl.) ¶ 146.

We determine on this record that Petitioner demonstrates that claim 14 would have been obvious over Stone, Barber, and Dhawan, for the reasons provided in the Petition. *See* Pet. 55–56.

Beyond the arguments already discussed above with respect to Ground 1, Patent Owner argues that Dhawan and Barber do not disclose the "securing" limitations (i.e., limitations [10.2] and [10.6]) that it contends are missing from Stone. *See* PO Resp. 43–44. This argument is unavailing, because Petitioner does not rely on Dhawan or Barber to teach or suggest limitations [10.2] and [10.6]. *See generally* Pet. 56.

Based on the entire record, we determine that Petitioner has established that claim 14 is unpatentable under § 103 as obvious over Stone, Barber, and Dhawan.

I. Ground 5 – Alleged Obviousness Over ElAttrache and Stone (Claims 1–4, 6, 7, 9, 15–20)

For Ground 5, Petitioner asserts that claims 1–4, 6, 7, 9, and 15–20 are unpatentable as obvious over ElAttrache and Stone.[21] Pet. 56–73. Patent Owner opposes. PO Resp. 44–68.

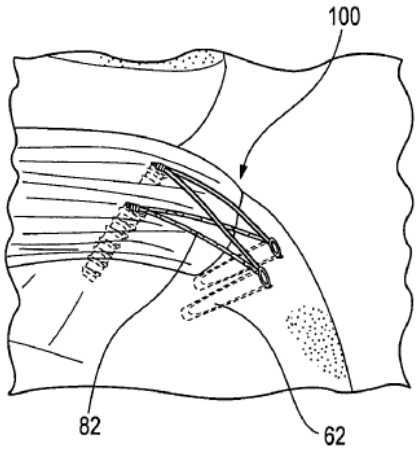
For the reasons explained below, we find that Petitioner has established by a preponderance of the evidence that claims 1–4, 6, 7, 9, and 15–20 are unpatentable as obvious over ElAttrache and Stone. We begin with a brief overview of Petitioner's asserted combination of ElAttrache and Stone. We then analyze the parties' arguments in the context of claim 1, before moving to the remaining claims challenged in this ground.

1. Brief Overview of the Asserted Combination

Like Stone, ElAttrache teaches a suture-based tissue repair method that reduces knot-tying, where multiple fixation devices are connected

[21] As we explain above (*see* n.9), Petitioner did not argue the alleged unpatentability of claim 5 in connection with Ground 5.

between one shared suture strand. Ex. 1009 (ElAttrache) ¶ 33. We reproduce ElAttrache Figure 10 below.



Id. at Fig. 10; Pet. 58. ElAttrache Figure 10 shows a "criss cross suturing arrangement 82 . . . having double rows of fixation devices." Ex. 1009 (ElAttrache) ¶ 36. "The repair consists of a tied medial row constructed with a least one suture anchor combined with knotless lateral fixation using a least one knotless fixation device." *Id.* ¶ 25.

Petitioner asserts that, consistent with ElAttrache and Stone's shared goals of reducing knot tying during surgery, a person of ordinary skill in the art would have been motivated to substitute ElAttrache's tied medial row suture anchors with Stone's knotless fasteners, i.e., elongate member (strand 120) and flexible fastener (sleeve 100). Pet. 56–57. In this combination, the medial row of fasteners (i.e., the fasteners on the left of Figure 10 above) would have used Stone's fasteners, and the lateral row (i.e., the righthand row) would have used ElAttrache's knotless, screw-in anchors (e.g., SwiveLock). *See id.* at 58–59, 57 n.8.

Petitioner contends that a person of ordinary skill in the art would have been motivated to make this substitution because both Stone and

ElAttrache teach repairing tissue by anchoring suture to bone, and using Stone's knotless fasteners would have improved ElAttrache's method by eliminating all knot-tying from the procedure. Pet. 60–61; Ex. 1002 (Jordan Decl.) ¶¶ 147–58; Ex. 1005 (Stone), 4:7–20, 6:65–7:15; Ex. 1009 (ElAttrache) ¶¶ 4, 5, 26. Petitioner further contends that this would have been a simple substitution of one known element for another, with predictable results. Pet. 60; Ex. 1002 (Jordan Decl.) ¶¶ 155–57. Petitioner also contends that "surgeons were [already] using similar methods together in practice." Pet. 58; Ex. 1002 (Jordan Decl.) ¶¶ 153, 155 (discussing a double row rotator cuff repair performed by a Dr. Patrick, utilizing JuggerKnot anchors in the medial row and SwiveLock anchors in the lateral row); Ex. 1017 (video of Dr. Patrick's double row rotator cuff repair).

2. Analysis of Independent Claim 1

Patent Owner disputes that a person of ordinary skill in the art would have substituted the knotted suture in ElAttrache's medial row with Stone's knotless suture anchors, with a reasonable expectation of success. *See* PO Resp. 51–67. We address these arguments in the section below regarding limitation [1.1]. Patent Owner also disputes that the proposed combination teaches or suggests limitation [1.2]. *See id.* at 48–50. We also address this argument below. For completeness, we also address the remaining limitations of claim 1, which Patent Owner does not dispute.

(a) *Preamble [1.p]: A method for securing body tissues comprising:*

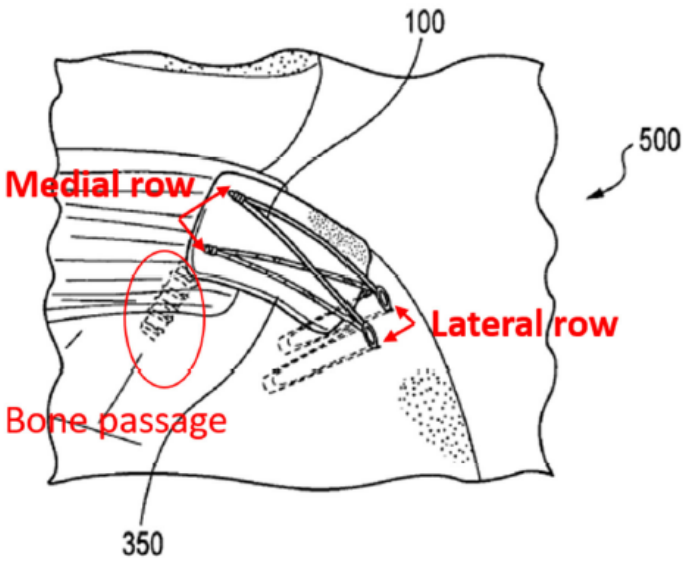
Petitioner contends that to the extent the preamble is not limiting, both Stone and ElAttrache teach methods for securing body tissue. Pet. 62. Patent Owner neither takes a position on whether the preamble is limiting,

nor disputes that Stone and ElAttrache teach or suggest the preamble. *See generally* PO Resp.

We need not decide whether the preamble is limiting, because Petitioner sufficiently demonstrates that Stone and ElAttrache both disclose methods for securing body tissues. *See* Pet. 62; Ex. 1005 (Stone) 1:19–20, 2:46–47; Ex. 1009 (ElAttrache), code (57), ¶¶ 2, 7.

> (b) *Limitation [1.1]: inserting a flexible fastener having a passage into a passage in a first bone portion, wherein an elongate member extends through the fastener passage, such that at least two legs of the elongate member extend from the fastener and outside the passage in the first bone portion;*

For context, we reproduce below Petitioner's annotated version of ElAttrache Figure 15:



Pet. 63. Petitioner's annotated version of ElAttrache Figure 15 depicts a rotator cuff repair, with labels pointing to the medial row and lateral row of fasteners inserted into bone passages. *See* Ex. 1009 (ElAttrache) ¶ 23. Petitioner argues that a person of ordinary skill in the art would have

modified ElAttrache's method by substituting the knotted anchors in ElAttrache's medial row, which are inserted into a first bone portion, with Stone's flexible fasteners (sleeves 100), for the reasons discussed above. *See* Pet. 63; Ex. 1002 (Jordan Decl.) ¶ 161.

Petitioner cites its arguments for Ground 1 to explain how Stone teaches or suggests the fastener and elongate member recited in limitation [1.1]. *See* Pet. 63–64; Ex. 1002 (Jordan Decl.) ¶ 161. Petitioner additionally notes that the suture legs would extend from the medial row fasteners and outside of the bone bores, as recited in limitation [1.1]. *Id.* (citing Ex. 1009 (ElAttrache) ¶ 32 ("suture tails 40 will be draped over the lateral aspect of the tendon 34 and will be held in place with two knotless fixation devices")); *see also* Ex. 1002 (Jordan Decl.) ¶ 162.

Patent Owner does not dispute that the proposed combination, if made, would have taught or suggested limitation [1.1]. *See generally* PO Resp. Patent Owner does dispute, however, that a person of ordinary skill in the art would have been motivated to substitute the knotted corkscrew anchors ElAttrache teaches for use in the medial row with Stone's knotless flexible fasteners, with a reasonable expectation of success. *See id.* at 51–67; Ex. 2001 (Pedowitz Decl.) ¶¶ 126–54. This is because, Patent Owner argues, a person of ordinary skill in the art "would have understood that it was essential to create medial suture knots as emphasized by ElAttrache, and that it would be best to avoid the knotless, flexible fastener described by Stone in the medial row of a double row rotator cuff repair." PO Resp. 51; Ex. 2001 (Pedowitz Decl.) ¶ 126.

More particularly, Patent Owner argues the following three reasons why a person of ordinary skill in the art would not have substituted ElAttrache's knotted corkscrew anchors with Stone's knotless fasteners:

> (1) the combined teachings of ElAttrache and Stone would not have suggested the substitution of knotless suture bridging for fixation (tying) of ElAttrache's medial row to a POSITA;
>
> (2) the state of the art at the time of the invention, including a study funded by Petitioner, advised maintaining medial row knots to provide medial fixation; and
>
> (3) a knotless medial row was more likely to cut into the tendon and cause repair failure, showing that a POSITA would not have had a reasonable expectation of success.

PO Resp. 51–52; Ex. 2001 (Pedowitz Decl.) ¶ 128. Below, we address Patent Owner's first and second arguments together; we then turn to the third argument.

(1) Whether the Art Suggested the Proposed Substitution and Whether Medial Row Knots Were State of the Art

Patent Owner argues that a person of ordinary skill in the art would have lacked motivation to substitute ElAttrache's medial row knotted corkscrew anchors with Stone's knotless flexible fasteners. As background, Patent Owner explains that ElAttrache teaches a surgical method designed to "enhance footprint compression and allow for accelerated tendon healing to bone." PO Resp. 52 (quoting Ex. 1009 (ElAttrache) ¶ 25). According to Patent Owner, this method involves using a tied medial row and a knotless lateral row, and a person of ordinary skill in the art would have understood that "the tied medial row is *necessary*" to achieve ElAttrache's goals. *Id.*;

Ex. 2001 (Pedowitz Decl.) ¶¶ 129, 132, 140, 145–46. This is because, Patent Owner contends, as compared to knotless constructs, medial knots better secure the tendon and compress it against the footprint, which minimizes gap formation and promotes healing. *See, e.g.*, PO Resp. 55,[22] 60–61; Ex. 2001 (Pedowitz Decl.) ¶¶ 134, 140–46. Patent Owner asserts that at the time of the invention, there was a consensus in the art that tying knots in the medial row sutures improved the repair. PO Resp. 61–62 (citing Ex. 2001 (Pedowitz Decl.) ¶¶ 143–44; Ex. 2005 (Busfield), 906; Ex. 2004 (Mall), 377).

After considering the arguments and cited evidence of record, we determine that Petitioner demonstrates by a preponderance of the evidence that a person of ordinary skill in the art would have been motivated to substitute ElAttrache's medial row knotted corkscrew anchors with Stone's knotless flexible fasteners, as discussed in the Petition. A reason to combine can be found in "any need or problem known in the field of endeavor at the time of invention and addressed by the patent." *KSR*, 550 U.S. at 420–21. Petitioner demonstrates that Stone and ElAttrache are both directed to securing tissue to bone, and that a person of ordinary skill in the art would have understood that Stone's flexible fastener and ElAttrache's two component knotless fixation device could have been used together in a

[22] On page 55 and other pages of the Patent Owner response, Patent Owner cites Exhibit 1017, with pinpoint citations to certain time stamps. *See, e.g.*, PO Resp. 55 (citing "Ex. 1017, time 11:15-11:23"). Exhibit 1017 is a printout from www.youtube.com; it is not a video. Exhibit 1012 is a video, but it was filed in four parts, and no part appears to contain timestamps that correspond to Patent Owner's citation. Accordingly, Patent Owner's intended citations to Exhibit 1017 are unclear.

double row rotator cuff repair. *See* Pet. 57–58; Ex. 1002 (Jordan Decl.) ¶ 149 (opining that given the similarity of the ElAttrache and Stone methods for securing tissue to bone, a person of ordinary skill in the art would have "look[ed] at both disclosures when determining the best methods for securing soft tissue to bone for repair or reconstruction"); *see also id.* ¶¶ 147–56.

Petitioner further demonstrates that a person of ordinary skill in the art would have been motivated to make this combination to eliminate all knot-tying from the procedure. *See* Pet. 60; Ex. 1002 (Jordan Decl.) ¶ 149 (opining that a person of ordinary skill in the art would have seen "benefits with the knotless, flexible design of [Stone's] fasteners for use in the medial row"), 154 (opining that a person of ordinary skill in the art would have wanted to eliminate knot tying). Both ElAttrache and Stone recognize the benefits of eliminating knot-tying. *See* Pet. 60–61; Ex. 1005 (Stone), 1:50–52, 4:7–20, 6:65–7:15, 7:35–38; Ex. 1009 (ElAttrache) ¶¶ 4, 5, 26. Similarly, both of the parties' declarants recognize the benefits of eliminating knot-tying. *See* Ex. 1002 (Jordan Decl.) ¶¶ 70, 154; Ex. 1018 (Pedowitz Depo. Tr.), 75:13–76:1 (discussing how a knotless procedure is potentially more surgically efficient), 129:6–130:6 (discussing the challenges of knot-tying and the benefit of "an alternative strategy for those that either can't or don't want to tie good knots"). Thus, Petitioner demonstrates that a person of ordinary skill in the art would have had a reason to replace ElAttrache's knotted corkscrew anchors with Stone's sleeves, i.e., this change would have resulted in the advantage of eliminating the time-consuming and potentially difficult procedure of knot-tying during surgery. *See, e.g.*, *Cablz, Inc. v. Chums, Inc.*, 708 F. App'x 1006, 1013

(Fed. Cir. 2017) (affirming obviousness where replacing one eyewear retainer with another would have been "a matter of simple substitution that would result in an eyeglass retainer with certain advantages").

To buttress its arguments, Petitioner asserts that its proposed combination was actually performed in the prior art. In support of this argument, the Petition cites two pieces of evidence: (1) a video showing a surgeon, Dr. Patrick, performing a double row rotator cuff repair using Stone's flexible fasteners (JuggerKnots) in the medial row and ElAttrache's two-component anchors (SwiveLocks) in the lateral row; and (2) Figure 22 of the JuggerKnot brochure (Ex. 1013), which also shows a double row rotator cuff repair using JuggerKnots in the medial row. *See* Pet. 58–60; Ex. 1002 (Jordan Decl.) ¶¶ 153, 155 (discussing Ex. 1012 (video)); Ex. 1013 (JuggerKnot brochure), Fig. 22).

Patent Owner correctly points out that the video and brochure do not represent Petitioner's proposed combination, because both of the depicted surgeries used knots in the medial row, whereas Petitioner's combination requires elimination of all knots. *See* PO Resp. 55–56, 58–60. We find that at best, the video and brochure demonstrate that a person of ordinary skill in the art would have been motivated to modify ElAttrache's method by using Stone's flexible fasteners (JuggerKnots) in the medial row. *See, e.g.*, Ex. 1018 (Pedowitz Depo. Tr.), 125:20–126:6 (agreeing that Dr. Patrick used JuggerKnots in the medial row and SwiveLocks in the lateral row), 54:17–20 (same); Reply 18–19. However, we agree with Patent Owner that these references do not fully align with Petitioner's arguments, given their use of medial row knots.

On Reply, Petitioner asserts that "even if knots were included on the medial row, the combination would still fall within the scope of the claims," because "[t]he claims do not preclude using knots with the flexible fastener." Reply 21. While it is true the claims do not preclude using knots with the flexible fastener, the combination Petitioner proffers in the Petition expressly requires eliminating knot tying in the medial row. *See, e.g.*, Pet. 60 ("This combination would provide a benefit over the technique described in ElAttrache by eliminating all knot-tying from the procedure, including the medial row of fixation, which both references and a POSITA recognize as beneficial."). We agree with Patent Owner that "Petitioner cannot now change its combination in Reply to *include* medial row knots." Sur-reply 17, 21. As explained in our Trial Practice Guide,[23] in a reply brief, a party is not permitted to "proceed in a new direction with a new approach as compared to the positions taken in a prior filing," as Petitioner attempts to do here. Trial Practice Guide, 74; *see also* 37 C.F.R. § 42.23(b); *Intelligent Bio-Sys., Inc.*, 821 F.3d at 1369 (noting that the initial petition must identify "with particularity the evidence that supports the grounds for the challenge to each claim") (internal citations omitted). Accordingly, we will not consider Petitioner's new arguments asserting obviousness based on using Stone's flexible fasteners with medial row knots.

Patent Owner argues that the art taught away from replacing ElAttrache's knotted medial row with a knotless construct. PO Resp. 60–63. According to Patent Owner, there was a "consensus in the art" that tying

[23] PTAB Consolidated Trial Practice Guide (Nov. 2019), *available at* https://www.uspto.gov/about-us/news-updates/consolidated-trial-practice-guide-november-2019.

knots in the medial row "improved the repair." *Id.* at 61–63, 65; *see also, e.g.*, Ex. 2001 (Pedowitz Decl.) ¶ 143; Ex. 2005 (Busfield), 904; Ex. 2004 (Mall), 377; Ex. 2009 (Leek), S130. We find Patent Owner's arguments unavailing.

Prior art teaches away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). "[T]he prior art could contain one reference suggesting a combination and others critiquing or otherwise discouraging the same." *Arctic Cat Inc. v. Bombardier Recreational Products Inc.*, 876 F.3d 1350, 1360 (Fed. Cir. 2017). "[I]t is error to fail to consider the entirety of the art." *Id.*

To show the state of the art, Patent Owner and Dr. Pedowitz largely rely on two references, Busfield (Exhibit 2005) and Mall (Exhibit 2004), both of which discuss studies comparing the use of knots in the medial row to a knotless version of the procedure. *See* Reply 22; PO Resp. 60–63. Petitioner additionally cites Exhibit 2009 (Leek), when discussing the state of the art. *See* Reply 22–25. We address each of these three references, in chronological order.

First, Busfield, a 2008 paper, discusses a study funded by Petitioner that compares double row fixation with SutureBridge on cadaveric shoulders with and without medial row knots. Ex. 2005 (Busfield), 901. Busfield explains:

> Rotator cuff repair constructs have recently been marketed that presumably allow for a technically easier and faster surgery from elimination of any knot tying. The purpose of this study

> was to determine the biomechanical importance of medial row knot fixation in the SutureBridge with PushLocks (Arthrex) construct.

Id. at 902. Busfield reports that "a knotless medial row compromises the construct leading to greater gapping and failure at lower loads," and concludes that "[d]ouble-row fixation suture-bridging techniques, based on this study model, should not be performed without suture knots in the medial row." *Id.* at 901, 906.

Next is a 2010 paper, Leek, which is co-authored by Patent Owner's declarant, Dr. Pedowitz. *See* Ex. 2009 (Leek), S127. Leek "investigate[s] the importance of medial-row knot tying to mechanical stability in a double-row rotator cuff repair by comparing a knotless construct with transtendon anchor passage versus a similar construct implementing medial knots." *Id.* at Abstr. Leek concludes: "Our data suggest that creation of medial knots increases construct stiffness and stability in arthroscopic double-row cuff repair. . . . Medial knots create increased mechanical stability that theoretically may improve rotator cuff healing." *Id.* The paper notes, however, that "[t]his mechanical advantage must be weighed against surgical efficiency, with consideration given to factors such as tissue quality." *Id.*

Finally, Mall is a 2013 systematic review of five studies to determine whether tying the medial-row sutures provides added stability during biomechanical testing of a transosseous-equivalent rotator cuff repair. *See* Ex. 2004 (Mall), Abstr. Mall teaches that "the biomechanical factors ultimate load, stiffness, gap formation, and contact area are significantly improved when medial knots are tied as part of a transosseous-equivalent

suture bridge construct compared with knotless constructs," but indicates that "this has not been definitively proven to translate to improved healing rates clinically." *Id.*

Collectively, these references indicate that as compared to knotless constructs, tying medial knots improved biomechanical factors (ultimate load, stiffness, gap formation, and contact area). *See* Ex. 2004 (Mall), Abstr.; Ex. 2005 (Busfield), 905, 906; Ex. 2009 (Leek), S127. Busfield in particular advocates for tying knots in the medial row. Ex. 2005 (Busfield), 906. Nevertheless, the entirety of the art is not as unequivocally supportive of medial row knots as Patent Owner would have us believe. *See* Reply 24 ("Patent Owner overstates those studies."). This is demonstrated by Mall, which was accepted on November 6, 2012, but published in February 2013 (just one month after the January 5, 2013, priority date). Ex. 2004 (Mall), 377; Reply 24.

Of the three references, Mall published closest in time to the January 5, 2013, priority date. Mall indicates that "[d]ebate on the utility of tying the medial row continues among surgeons performing arthroscopic rotator cuff repairs." Ex. 2004 (Mall), 377. Mall explains that "[p]roponents of tying the medial row stress the importance and the improvement of strength of the construct, whereas advocates for the knotless repairs claim no difference in repair strength or clinical outcomes and emphasize the possibility of reduced irritation of the medial knot within the subacromial space." *Id.* Mall's statements indicate that as of the priority date, both knotted and knotless techniques were in use and had their proponents and relative advantages. Reply 22–23, 25.

Mall concludes by calling for "[f]urther studies comparing the clinical healing rates and functional outcomes between medial knotted and knotless repair techniques." Ex. 2004 (Mall), 384; Reply 24. In other words, although Mall recognizes that tying knots in the medial row provides some biomechanical advantages, it nevertheless calls for additional comparative studies, indicating that biomechanical advantages were not the whole story. Leek similarly recognizes that the increased mechanical stability associated with medial knots "***theoretically*** may improve rotator cuff healing," but states that "[t]his mechanical advantage must be weighed against surgical efficiency[24] with consideration given to factors such as tissue quality." Ex. 2009 (Leek), 127 (emphasis added); Reply 25.

It is not necessary to show that a combination is "the *best* option, only that it be a *suitable* option." *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1197–98 (Fed. Cir. 2014). "[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). "Instead, the benefits, both lost and gained, should be weighed against one another." *Id.* This is the situation here. The art teaches that both knotted and knotless medial rows were being used and had their relative advantages. And although tying knots in the medial row provides some biomechanical advantages, knotless procedures also provide advantages, e.g., surgical efficiency. *See, e.g.*, Ex. 2009 (Leek), 127. As such, we do not find that the prior art teaches away, as Patent Owner argues.

[24] "[S]urgical efficiency refers to the speed/ease of the surgery and that tying knots arthroscopically was difficult." Reply 25; Ex. 1018 (Pedowitz Depo. Tr.), 75:13–76:2, 133:7–14.

In fact, the record reflects that some surgeons were performing double row rotator cuff repairs using knotless medial rows. For example, Dr. Pedowitz acknowledged that at the time of the invention, surgeons were actually performing double-row, knotless procedures. *See* Reply 23; Ex. 1018 (Pedowitz Depo. Tr.), 65:1–12, 76:22–77:15 (acknowledging that his co-authors/fellow surgeons had "probably observed me and other surgeons doing both varieties [knotted and knotless] of the surgery"), 80:23–81:8 (indicating that as of 2014, "people were still doing . . . double row . . . knotless" procedures), 139:3–10 (asserting that the double row knotless technique was "[m]ore than theoretically [possible], they actually were possible"), 140:7–14 (agreeing that "knotted and knotless double row repairs were known"), 143:4–9 (agreeing that a surgeon could perform a double row knotless surgery "and it could work out fine"). Even if knotted medial rows were superior as Patent Owner contends, "[a] known or obvious composition [or method] does not become patentable simply because it has been described as somewhat inferior to some other product [or method] for the same use." *Gurley*, 27 F.3d at 553.

In sum, we agree with Petitioner that a person of ordinary skill in the art would have been motivated to combine ElAttrache and Stone in the manner it proposes, and that the "combination would provide a benefit over the technique described in ElAttrache by eliminating all knot-tying from the procedure." Pet. 60. Indeed, the evidence shows that surgeons were using similar methods in practice. *Id.* at 58. As noted above, Dr. Patrick performed a double row rotator cuff repair using JuggerKnot anchors in the medial row and SwiveLock anchors in the lateral row. *See* Ex. 1002 (Jordan Decl.) ¶¶ 153, 155; Ex. 1018 (Pedowitz Depo. Tr.), 125:20–126:6, 54:17–

20; Reply 18–19. The JuggerKnot brochure similarly depicts a double row rotator cuff repair using JuggerKnot anchors in the medial row. Pet. 59–60, 63; Ex. 1013 (JuggerKnot brochure), 7–10; Ex. 1002 (Jordan Decl.) ¶¶ 45–46, 161 n.6. Even though both Dr. Patrick and the brochure used medial row knots, their use of JuggerKnots in the medial row still supports Petitioner's contention that "a POSITA would have understood that the flexible fasteners shown in Stone (sleeve 100) can be used for th[e] medial row of anchors." Pet. 63.

In view of the above, we agree with Petitioner that its proposed combination of ElAttrache and Stone "amounts to an arrangement of old elements in a known way with each performing the same function it had been known to perform," "yield[ing] no more than a POSITA would expect from such an arrangement." Pet. 61–62; Ex. 1002 (Jordan Decl.) ¶¶ 156–57. Additionally, for the reasons discussed above, on this record we find Patent Owner's teaching away and state of the art arguments to be unavailing. We conclude that Petitioner has adequately established a reason to combine ElAttrache and Stone (e.g., for surgical efficiency associated with not having to tie knots). *See, e.g.*, Pet. 60; Reply 25.

(2) Reasonable Expectation of Success

Petitioner argues that a person of ordinary skill in the art would have had a reasonable expectation of success in using Stone's flexible fasteners in ElAttrache's method because this combination "amounts to an arrangement of old elements in a known way with each performing the same function it had been known to perform," and "it yields no more than a POSITA would expect from such an arrangement." Pet. 61–62; Ex. 1002 (Jordan Decl.) ¶¶ 156–57.

Patent Owner argues that a person of ordinary skill in the art would not have had a reasonable expectation of success in making Petitioner's proposed combination, because they would have expected the combination "to impair the biomechanics of the construct such that the repair would be more likely to fail." PO Resp. 64; *see also id.* at 63–67; Ex. 2001 (Pedowitz Decl.) ¶¶ 147–49. Patent Owner explains that one of the most common ways ElAttrache's method fails is when the suture cuts through the tendon, and the use of a medial knot provides load-sharing capacity that mitigates this risk. PO Resp. 64–65 (citing Ex. 2004 (Mall), 382; Ex. 2009 (Leek), S129–30; Ex. 2001 (Pedowitz Decl.) ¶ 151). Patent Owner also argues that a person of ordinary skill in the art would have expected the proposed substitution to impair the biomechanics because the knotless medial row would not provide the footprint compression achieved with a knotted medial row. *Id.* at 66 (citing Ex. 2001 (Pedowitz Decl.) ¶ 152).

Patent Owner's arguments are unavailing. As an initial matter, we note that although Mall and Leek report that constructs can fail when suture cuts through the tendon, they found "no significant difference or tend toward a mode of failure in either [the knotted or knotless] group." Ex. 2009 (Leek), S129; *see also* Ex. 2004 (Mall), 382 (repeating same)). This undercuts Patent Owner's suggestion that as compared to a knotted medial row, a knotless medial row would have been more likely to fail due to suture cutting through the tendon.

Additionally, we agree with Petitioner that Patent Owner's reasonable expectation of success arguments are not tied to the language of the claims. Reply 25. "The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations ***of the***

claimed invention." *Intelligent Bio-Sys., Inc.*, 821 F.3d at 1367 (emphasis added). Patent Owner's arguments posit a lack of reasonable expectation of success because medial row knotting has "improved healing/outcomes relative to the knotless version." Reply 25. The claims, however, do not recite any limitations directed to improved healing or outcomes of a knotless construct versus a knotted construct.

On this point, Patent Owner argues that "securing body tissue" is a claim requirement, and Dr. Pedowitz explained that the knotted medial row provides "a short term expectation that it's a *more secure* repair." Sur-reply 23 (quoting Ex. 1018 (Pedowitz Depo. Tr.), 143:23–144:4) (emphasis added). But again, the cited testimony from Dr. Pedowitz is making a comparison; he states that the knotted repair would be "more secure" than the knotless repair. Ex. 1018 (Pedowitz Depo. Tr.), 143:23–144:4. Comparatively better performance is not recited in the claim and thus is not pertinent to the reasonable expectation of success analysis. Indeed, the same question and answer indicates that Dr. Pedowitz agreed that a surgeon could do the repair either way, thus supporting a reasonable expectation of success for the knotless version of the repair. *See id.*

Patent Owner argues that "the mere fact that studies were being done on both knotless and knotted options as Petitioner argues is not sufficient to establish a reasonable expectation of success in the combination." PO Resp. 24 (citing *Cumberland Pharms. Inc. v. Mylan Inst. LLC*, 846 F.3d 1213, 1222 (Fed. Cir. 2017)); *see also id.* at 21 (arguing that Mall depicted studies performed on a piece of rubber, not a human tendon). This mischaracterizes the record by suggesting that knotless repairs were merely being studied in the lab (e.g., using cadavers or rubber), as opposed to

having been actually performed. As discussed above, the record shows that knotless repairs were not only performed in the context of research studies, but were actually being performed *in vivo*. *See, e.g.*, Ex. 1018 (Pedowitz Depo. Tr.), 65:1–12, 80:23–81:8, 139:3–10. But even if the knotless option had only been performed in a research setting, this would not preclude us from finding a reasonable expectation of success. Dr. Pedowitz agreed that "[a] surgeon could perform the knotless version and it could work out fine for that patient." *Id.* at 143:4–9. This testimony supports a reasonable expectation of success. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) ("[O]nly a reasonable expectation of success, not a guarantee, is needed.").

In view of the above, we determine that Petitioner has established a reasonable expectation of success by a preponderance of the evidence.

(3) Conclusion

In view of the above, Petitioner persuasively shows that the combination of ElAttrache and Stone teaches or suggests limitation [1.1], and that a person of ordinary skill in the art would have been motivated to eliminate all knot tying by substituting ElAttrache's knotted medial suture anchors in the medial row with Stone's knotless suture anchors, with a reasonable expectation of success.

(c) *Limitation [1.2]: deforming the fastener from a first configuration to a second configuration to secure the fastener and the elongate member when tensioning at least one of the legs of the elongate member;*

As it did for Ground 1, Petitioner argues that Stone teaches or suggests this limitation. *See* Pet. 64 (cross-referencing arguments in the Petition made for Ground 1, limitation [1.2]). Patent Owner repeats the

same arguments we discussed above in connection with Ground 1, i.e., Stone does not teach or suggest the "secur[ing]" recited in limitation [1.2] because "Stone's elongate member (strand 120) is not fixed, anchored or attached so that it cannot be moved relative to sleeve 100." PO Resp. 49–50; *see also id.* at 50 ("[A] POSITA would understand that Stone's suture strand 120 would *still slide* relative to Stone's sleeve 100 in ElAttrache's medial row *after* the sleeve is deformed."); Ex. 2001 (Pedowitz Decl.) ¶¶ 122–25.

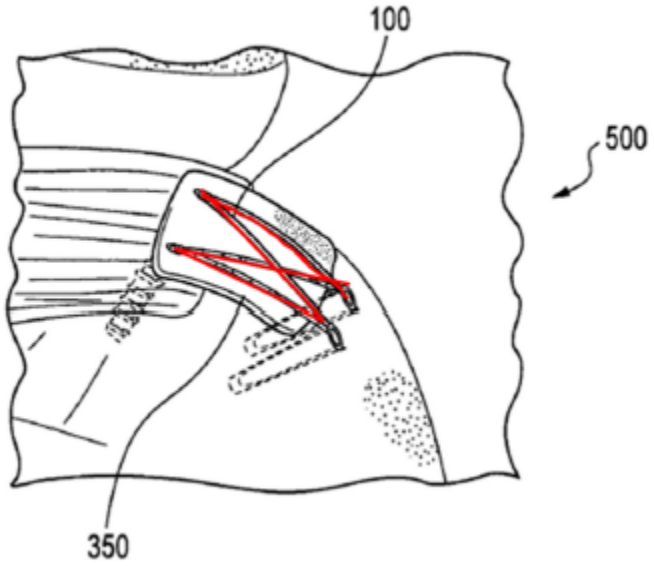
On Reply, Petitioner argues that Patent Owner's theory that a person of ordinary skill in the art would have tied knots in the medial row eviscerates Patent Owner's arguments on this limitation, because Dr. Pedowitz allegedly admitted that the use of knots in the medial row would result in a "secure" connection. Reply 26–27. As discussed in the previous section (II.I.2.b.1), we will not consider Petitioner's unpatentability arguments based on using Stone's flexible fasteners with medial row knots, because Petitioner did not make such arguments in the Petition.

For the same reasons discussed above, we find Patent Owner's arguments on limitation [1.2] unavailing, and instead find that Petitioner persuasively shows that Stone teaches or suggests this limitation. *See supra* Section II.E.1.(c).

(d) *Limitation [1.3]: passing at least one of the legs of the elongate member over at least one tissue;*

Petitioner cites its arguments for Ground 1, limitation [1.3] to address how Stone teaches or suggests this limitation, and additionally asserts that "when performing the bridging technique disclosed in ElAttrache, at least one of the legs of the elongate member (Stone's strand 120) is passed over at

least one tissue from the medial row of fixation to the lateral row," as shown in the annotated version of ElAttrache Figure 15 reproduced below:



Pet. 64–65. In Petitioner's annotated version of ElAttrache Figure 15 above, Petitioner highlights in red the suture that extends between the medial row of fixation members (on the left) to the lateral row of fixation members (on the right). *Id.*; *see also* Ex. 1009 (ElAttrache) ¶ 32; Ex. 1002 (Jordan Decl.) ¶¶ 165–66. Petitioner explains that in the proposed combination, the suture would come from the flexible fastener in the medial row of fixation, and would pass over tissue to the lateral row anchors. Pet. 64; Ex. 1002 (Jordan Decl.) ¶ 166.

Patent Owner does not dispute that Stone and ElAttrache teach or suggest this limitation. *See generally* PO Resp.

In view of the above, Petitioner persuasively shows that the combination of ElAttrache and Stone teaches or suggests limitation [1.3].

(e) *Limitation [1.4]: passing at least one of the legs of the elongate member through a bore in a first component of a two component knotless fixation device;*

Petitioner shows that ElAttrache teaches a two-component knotless fixation device, where the first component is the swivel anchor implant 200 ("SwiveLock"), and the second component is screw 90. Pet. 65; Ex. 1009 (ElAttrache), Figs. 11–13, ¶¶ 38–39. Petitioner explains that when ElAttrache's bridging technique is performed, one of the legs of the elongate member (Stone's strand 120) is passed from the fasteners in the medial row through a bore (eyelet 162) in swivel anchor implant 200 in a lateral row. *Id.* (citing Ex. 1009 (ElAttrache) ¶¶ 32, 33, 37, 39; Ex. 1002 (Jordan Decl.) ¶ 167).

Patent Owner does not dispute that ElAttrache teaches or suggests limitation [1.4]. *See generally* PO Resp.

In view of the above, Petitioner persuasively shows that ElAttrache teaches or suggests limitation [1.4].

(f) *Limitation [1.5]: inserting the two component knotless fixation device into a passage in a second bone portion; and*

Petitioner demonstrates that ElAttrache teaches or suggests this limitation. Pet. 66–67. ElAttrache describes preparing two pilot bone holes (60) in the lateral row for receiving suture and the two-component knotless fixation devices, and both components of the knotless fixation device are then inserted into the bone passage. *Id.*; *see also* Ex. 1009 (ElAttrache) ¶ 32, Fig. 15; Ex. 1002 (Jordan Decl.) ¶ 168.

Patent Owner does not dispute that the ElAttrache teaches or suggests limitation [1.5]. *See generally* PO Resp. In view of the above, Petitioner persuasively shows that ElAttrache teaches or suggests this limitation.

> (g) *Limitation [1.6]: securing the at least one leg of the elongate member when both the first and second components of the two component knotless fixation device are positioned in the passage in the second bone portion, wherein the elongate member presses against an external surface of the second component of the two component fixation device.*

Petitioner persuasively demonstrates that ElAttrache teaches or suggests this limitation. ElAttrache teaches that the leg of the elongate member (Stone's suture strand 120) coming from the flexible fastener (Stone's sleeve 100 in the medial row) is secured when the two components of the ElAttrache SwiveLock device are positioned in the passage in the second bone portion (i.e., the lateral row). Pet. 67–68; Ex. 1009 (ElAttrache) ¶ 40. Petitioner explains that in this construct, Stone's strand 120 is placed at the bottom of the bone bore in the aperture 162 of the first component of the SwiveLock, and extends up the side of the bone bore, pressing against an external surface of the second component (screw 90) of the SwiveLock. Pet. 68; Ex. 1002 (Jordan Decl.) ¶ 169. The suture legs come out of the bone bore surface and "are then cut flush using a suture cutter." Ex. 1009 (ElAttrache) ¶ 36; Pet. 68.

Patent Owner does not dispute that the ElAttrache teaches or suggests limitation [1.6]. *See generally* PO Resp.; Reply 27. In view of the above, Petitioner persuasively shows that ElAttrache teaches or suggests this limitation.

(h) *Conclusion for Claim 1*

Based on the entire record, we determine that Petitioner has established by a preponderance of the evidence that claim 1 is unpatentable under § 103 as obvious over ElAttrache and Stone.

3. Claims 2–4, 6, 7, 9, and 15–20

We have reviewed Petitioner's contentions regarding claims 2–4, 6, 7, 9, and 15–20. *See* Pet. 68–73; Ex. 1002 (Jordan Decl.) ¶¶ 170–92. Beyond the arguments we already discussed above with respect to claim 1, Patent Owner did not make any additional arguments for these claims. *See* PO Resp. 67–68.

We are persuaded on the full trial record that Petitioner has shown by a preponderance of the evidence that claims 2–4, 6, 7, 9, and 15–20 are unpatentable as obvious over ElAttrache and Stone, for the reasons discussed in the Petition. *See* Pet. 68–73.

J. Ground 6 – Alleged Obviousness Over ElAttrache, Stone, and Barber (Claims 8, 10–14)

For Ground 6, Petitioner asserts that claims 8 and 10–14 are unpatentable as obvious over ElAttrache, Stone, and Barber. Pet. 73–74. As discussed above in connection with Ground 3, these claims all include a limitation directed to "an allograft collagen matrix scaffold."

In brief, Petitioner asserts that both Stone and ElAttrache teach that their devices and methods can be used to secure grafts to tissue, but do not specifically teach that the graft can be "an allograft collagen matrix scaffold." *Id.* (citing, *e.g.*, Ex. 1009 (ElAttrache) ¶¶ 43–44). Petitioner asserts that Barber teaches use of GraftJacket (an allograft collagen matrix scaffold), and that a person of ordinary skill in the art would have

recognized that the GraftJacket constitutes a simple substitution of one known element (the grafts disclosed in Stone and Barber) with another known element (GraftJacket), with predicable results. *See id.* (citing, e.g., Grounds 3 and 5); Ex. 1002 (Jordan Decl.) ¶¶ 193–95.

Beyond the arguments already discussed above with respect to Grounds 1 and 5, Patent Owner argues that Barber does not disclose the "securing" limitations (i.e., limitations [1.2], [1.6], [10.2], and [10.6]) that it contends are missing from Stone.[25] *See* PO Resp. 69, 70. This argument is unavailing because Petitioner does not rely on Barber to teach or suggest these limitations. *See generally* Pet. 73–74.

We are persuaded on the full trial record that Petitioner has shown by a preponderance of the evidence that claims 8 and 10–14 are unpatentable as obvious over ElAttrache, Stone, and Barber, for the reasons discussed in the Petition. Pet. 73–74.

III. CONCLUSION[26]

Based on the information presented, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–20 are unpatentable.

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[25] Although Patent Owner disputed Petitioner's arguments in Ground 3 regarding Barber with respect to claim 10, it does not do so here with respect to Ground 6.

[26] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent

In summary:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–5, 7, 9, 15–19	103	Stone	1–5, 7, 9, 15–19	
6, 20	103	Stone, Dhawan	6, 20	
5, 8, 10–13	103	Stone, Barber	5, 8, 10–13	
14	103	Stone, Dhawan, Barber	14	
1–4, 6, 7, 9, 15–20	103	ElAttrache, Stone	1–4, 6, 7, 9, 15–20	
8, 10–14	103	ElAttrache, Stone, Barber	8, 10–14	
Overall Outcome			1–20	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1–20 of U.S. Patent No. 10,881,440 B2 are unpatentable; and

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

Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

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