

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC.,
Petitioner,

v.

P TECH, LLC
Patent Owner.

IPR2022-01066
Patent 10,376,259 B2

Before JEFFREY N. FREDMAN, MICHELLEN. WORMMEESTER, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Arthrex, Inc. (“Petitioner”), on May 31, 2022, filed a Petition to institute *inter partes* review of claims 1–26 (all claims) of U.S. Patent No. 10,376,259 B2 (Ex. 1001, “the ’259 patent”). Paper 2 (“Pet.” or “Petition”). P Tech LLC (“Patent Owner”) did not file a Preliminary Response. On December 2, 2022, the Board instituted an *inter partes* review of all claims of the ’259 patent. Subsequently, Patent Owner filed a Patent Owner Response (Paper 10, “PO Resp.”), Petitioner filed a Reply to the Patent Owner Response (Paper 13, “Pet. Reply”), and Patent Owner filed a Sur-Reply (Paper 17, “PO Sur-Reply”). An oral hearing was held on September 5, 2023. A transcript of the hearing has been entered into the record. Paper 20.

For the reasons that follow, on the full trial record, we conclude that Petitioner has proven by a preponderance of the evidence that claims 1–26 of the ’259 patent are unpatentable.

II. REAL PARTIES-IN-INTEREST

Petitioner identifies Arthrex, Inc. as the real party-in-interest. Pet. xvii. Patent Owner identifies P Tech, LLC as the real party-in-interest. Paper 4.

III. RELATED MATTERS

The Petition states the ’259 patent is “currently involved in the following proceeding: *P Tech, LLC v. Arthrex, Inc.*, Case No. 1-21-cv-00968 (D. Del.).” Pet. xvii. The Petition identifies related IPRs, including *Arthrex, Inc. v. P Tech, LLC*, IPR2022-01043, filed May 23, 2022 and challenging U.S. Patent No. 9,814,453; *Arthrex, Inc. v. P Tech, LLC*, IPR2022-00717,

filed March 31, 2022 and challenging U.S. Patent No. 10,881,440; *Arthrex, Inc. v. P Tech, LLC*, IPR2022-00786, filed April 8, 2022 and challenging U.S. Patent No. 9,279,129; and *Arthrex, Inc. v. P Tech, LLC*, IPR2022-00787, filed April 11, 2022 and challenging U.S. Patent No. 9,999,449. Pet. xvii.

IV. THE '259 PATENT

The '259 patent issued August 13, 2019, from an application filed October 6, 2017. Ex. 1001, codes (45), (22). The '259 patent is a continuation of U.S. 13/871,892 (the "'892 application"), filed April 26, 2013, now U.S. 9,814,453, which is a continuation of U.S. 11/202,294, filed on October 5, 2005, now U.S. 9,463,012. *Id.*, codes (60), (63).

As background, the '259 patent explains that: "physicians use various methods and devices to attach soft tissue to other soft tissue, soft tissue to hard tissue, and hard tissue to other hard tissue. These same or similar techniques and devices are also used to position or fix an implant within the body." Ex. 1001, 1:23–26. The '259 patent teaches "an instrument and method for guiding and positioning various implants within the body. The instrument may provide for the placement of a biocompatible implant within tissue and/or may provide for dynamic and rigid fixation of tissue." *Id.* at 2:63–67.

The '259 patent teaches a "drill system may be used to create a non-linear passage in tissue. The non-linear passage may be formed to go around implants such as an intramedullary rod or prosthesis. The non-linear passage may also allow a physician to avoid critical body parts or tissues such as vessels or organs." Ex. 1001, 6:29–34. The '259 patent alternatively suggests "no drill system may be employed to create a passage in the tissue.

Rather, as described in more detail below, the guide channel may be used to guide and position a self-introducing elongate member.” *Id.* at 6:34–38.

Figure 4 of '259 patent “illustrates a fastener and suture positioned in the hook.” Ex. 1001, 3:57–58.

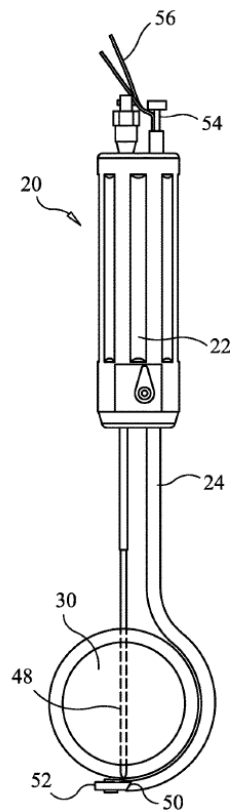


FIG. 4

Figure 4 shows:

With the fastener **52** and suture **56** on the distal end of the flexible pushrod **54**, the pushrod **54** is moved distally through the lumen of the hook **24** until the fastener **52** is positioned generally next to the distal opening of the bone passage **48**, as seen in FIG. 4. The pushrod **54** may be advanced to push the fastener **52** beyond the distal aperture **50** of the hook **24** or may be advanced to position the fastener **52** partially in and partially out of the hook **24**. In the latter configuration, the fastener **52** may be easily withdrawn, if necessary, from the hook **24** by moving the pushrod **54** proximally.

Ex. 1001, 12:49–59.

V. ILLUSTRATIVE CLAIMS

The '259 patent includes claims 1–26, with all claims currently challenged here. Claims 1 and 11 are independent, representative, and reproduced below with bracketed numbering added:¹

1. [1.P] A fastener system comprising:
 - [1.1] a flexible hollow fastener comprised of fibers of a biocompatible polymeric material;
 - [1.2] a flexible elongated fastening member extending through the flexible hollow fastener such that two legs of the flexible elongated fastening member extend from the flexible hollow fastener to enable a user to tension the flexible elongated fastening member,
 - [1.3] wherein at least a portion of the flexible elongated fastening member is fabricated in part with polyethylene; and
 - [1.4] an introducer comprised of a pushrod, the pushrod having a distal portion configured to engage the flexible hollow fastener and position the flexible hollow fastener relative to a body tissue,
 - [1.5] wherein the flexible hollow fastener and flexible elongated fastening member are positioned on the distal end of the pushrod,
 - [1.6] wherein the flexible hollow fastener is configured to deform from a first configuration to a second configuration to secure the flexible hollow fastener and the flexible elongated fastening member when at least one of the two legs of the flexible elongated fastening member are tensioned relative to the body tissue, and
 - [1.7] wherein the flexible elongated fastening member is configured to slide through the flexible hollow fastener under tension when the flexible hollow fastener is in the first configuration and the second configuration.

Ex. 1001, 27:22–47.

¹ For ease of reference, we adopt the bracketed numbering Petitioner uses in the Petition. *See* Pet. xi–xii.

11. [11.P] A deformable fastener system comprising:
- [11.1] a flexible hollow fastener comprised of polymeric biocompatible fibers; and
- [11.2] a flexible elongated fastening member extending through the flexible hollow fastener such that two legs of the flexible elongated fastening member extend from the flexible hollow fastener,
- [11.3] wherein the flexible hollow fastener is configured to deform from a first configuration to a second configuration to secure the flexible elongated fastening member in body tissue as at least one of the two legs of the flexible elongated fastening member portion is tensioned relative to the body tissue, and
- [11.4] wherein the flexible elongated fastening member is configured to slide through the flexible hollow fastener under tension when the flexible hollow fastener is in the first configuration and the second configuration.

Ex. 1001, 28:7–24.

VI. ASSERTED GROUNDS

We instituted trial based on the challenge to the patentability of claims 1–26 of the '259 patent as presented in the Petition based on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)
1	1, 3, 4, 6–8, 10, 11, 13–16, 18–20, 22, 24, 26	103	Fumex ²
2	1, 3, 4, 6–8, 10, 11, 13–16, 18–20, 22, 24, 26	103	Fumex, Grafton ³

² Fumex, U.S. 6,511,498 B1, issued Jan. 28, 2003. Ex. 1004.

³ Grafton, U.S. 2003/0050666 A1, published Mar. 13, 2003. Ex. 1005.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)
3	7, 18	103	Fumex, Bonutti '875 ⁴
4	7, 18	103	Fumex, Grafton, Bonutti '875
5	23, 25	103	Fumex, Bonutti '395 ⁵
6	23, 25	103	Fumex, Grafton, Bonutti '395
7	2, 12	103	Fumex, Stone ⁶
8	2, 12	103	Fumex, Grafton, Stone
9	5, 9, 17, 21	103	Fumex, Stone, To ⁷
10	5, 9, 17, 21	103	Fumex, Grafton, Stone, To

Petitioner also relies on two declarations by Dr. Steve Jordan, in support of the asserted grounds. Ex. 1002; Ex. 1027. Patent Owner relies on a Declaration by Dr. Robert A. Pedowitz. Ex. 2001. Based on the statements of qualifications and curriculum vitae, we find Petitioner's declarant Dr. Jordan qualified to provide technical opinions from the perspective of a person of ordinary skill in the art in this proceeding. *See* Ex. 1001 ¶¶ 2–9. Also based on the statements of qualifications and curriculum vitae, we find 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. *See* Ex. 2001 ¶ 2.

VII. 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. *Graham v. John Deere*

⁴ Bonutti et al., U.S. 5,735,875, issued Apr. 7, 1998. Ex. 1007.

⁵ Bonutti, U.S. 6,238,395 B1, issued May 29, 2001. Ex. 1006.

⁶ Stone et al., U.S. 5,443,482, issued Aug. 22, 1995. Ex. 1010.

⁷ To et al., U.S. 2007/0055206 A1, published Mar. 8, 2007. Ex. 1011.

Co., 383 U.S. 1, 17–18 (1966). The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). 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).

In our Institution Decision we considered these factors and determined based on the record before us that “a person of ordinary skill in the art would have had a medical degree and at least two years of experience performing surgeries with implantable medical devices, such as suture anchors.” Inst. Dec. 9.

Patent Owner agrees with this determination, stating

Patent Owner and Dr. Pedowitz, Patent Owner’s expert, agree with the Board’s analysis at pages 7–9 of the Institution Decision that a POSITA [person of ordinary skill in the art] would have a medical degree and at least two years of experience performing surgeries with implantable medical devices, such as suture anchors. Ex 2001, ¶ 18.

PO Resp. 21. After institution, Petitioner did not dispute our definition and did not further address the level of ordinary skill in the art in the Petitioner’s Reply. *See generally* Pet. 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.

VIII. CLAIM CONSTRUCTION

We interpret claim terms 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) (2020). Thus, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citations omitted) (en banc).

Here, we construe only those claim terms that require analysis to resolve the disputed issues in this *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe 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))); *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy’”).

Three terms are at issue between the parties, “knotless,” “‘a’ or ‘the’ flexible elongated fastening member,” and “secure.” Pet. 21–23; PO Resp. 22–27; Pet. Reply 4–20; PO Sur-Reply 2–16.

A. “A” or “The flexible elongated fastening member”

Independent claim 1 recites the presence of “a flexible elongated fastening member” and further recites a particular fabrication material for it and roles for “the flexible elongated fastening member.” Ex. 1001, 27:22–47.

Patent Owner asserts “[n]othing in the language of the claims, the specification, or the prosecution history necessitate limiting ‘a’ to ‘one.’” Thus, the general rule that ‘a’ means ‘one or more’ applies to the claims of the ‘259 Patent.” PO Resp. 25 (citing *Baldwin Graphic Systems, Inc. v. Siebert, Inc.*, 512 F. 3d 1338, 1342–43 (Fed. Cir. 2008)). Patent Owner asserts

It is not possible for the same fastening member to be both “secure” and to “slide” at the same time. Ex. 1018, 100:22-101:12 (“claim elements 1.6 and 1.7 cannot both be met by a single elongated fastening member, correct? A. Correct”). Indeed, Petitioner calls such a “technical impossibility.” Reply, 8. Thus, given that the language of claim 1 requires “the flexible elongated fastening member” to be both “secure” and “slide” at the same time, it necessarily follows that there must be at least two such fastening members – one that is secure and another that slides when the flexible hollow fastener is in the second configuration.

PO Sur-Reply 4.

Petitioner asserts this argument, i.e., “suggesting that the claims ‘are not limited to a single flexible elongated fastening member’ that is both secure and slidable,” is “legal error.” Pet. Reply 5 (quoting PO Resp., 25).

Petitioner asserts

use of the indefinite “a” cannot “serve to negate what is required by the claim following ‘a.’” [*In re Varma*, 816 F.3d 1352, 1362 (Fed. Cir. 2016).] Using a playful example, the Court explained “[f]or a dog owner to have ‘a dog that rolls over and fetches sticks,’ it does not suffice that he have two dogs, each able to perform just one of the tasks.” *Id.* at 1363.

Pet. Reply 6. Petitioner asserts

Patent Owner’s proposal **requires two** different elongated fastening members to avoid the “slide” vs. “secure” problem, because “a single flexible elongated fastening member cannot

both be ‘secure’ and slide in the second configuration.” POR, 30-31. Accepting Patent Owner’s arguments would mean that that “a” could never refer to a single elongated fastening member because different members would always be required for the two different functions. Logic dictates that a claim construction that requires “a” to mean “at least two” must fail.

Pet. Reply 7.

1. *Analysis*

We begin with the language of claim 1. Claim 1 requires “a flexible elongated fastening member” inside a “hollow fastener” that when tensioned deforms the “hollow fastener” from an original first configuration to a second configuration. Claim 1 further requires that when the “hollow fastener” is in the second configuration under tension “the flexible elongated fastening member” retains the ability to slide through the “hollow fastener.”

The ’259 Specification is permissive of multiple flexible elongated fastening members, generally termed sutures, teaching “the device may allow for the implantation of multiple sutures and fasteners in tissue with little or no repositioning of the device.” Ex. 1001, 4:61–63. The ’259 Specification does disclose a situation where “two passages 162 and 164 may be drilled in tissue, like a fractured bone 166, and two sutures or fastening members may be positioned through the passages, tensioned, and secured.” *Id.* at 18:11–14. But the ’259 Specification is also permissive of a single flexible elongated fastening member where a “suture 56 is looped through or connected with the fastener 52 such that one, two, or more sections, legs, strands, or portions of the suture 56 extend from the fastener 52.” Ex. 1001, 6:44–47. The intrinsic evidence therefore is open to Patent Owner’s interpretation of “a” as “one or more.” Nor does anything in the ’259 Specification supply a clear and manifest disavowal of that meaning.

Turning to the extrinsic evidence, Dr. Jordan, in his initial Declaration, does not state the impossibility of a single secured suture being slidable, stating

In this second position, wherein the anchor is expanded and secured, the suture is still slidable within the sleeve. Like a zip tie, the suture strand can be pulled and slides relative to the sleeve to continue to shrink the loop, slowly increasing the tension of the suture, but once tightened, does not allow the suture to easily slip in the opposite direction to allow the loop to once again widen.

Ex. 1002 ¶ 102. Dr. Jordan also notes that a “POSITA would understand that two separate sutures could be inserted through the flexible anchor and exit through the same orifices.” *Id.* ¶ 202. And when Patent Owner points to the term “impossibility” in Petitioner’s reply, Petitioner actually states “it is clear that the securement of the flexible elongated member and the hollow fastener to one another must still allow some relative movement between the two in order to satisfy [1.7]. Otherwise, the claim would be an invalid technical impossibility.” Pet. Reply 8. Thus, Petitioner and Petitioner’s expert recognize that claim 1 is open to a single flexible elongated fastening member or to more than one flexible elongated fastening members.

“[A]t least in an open-ended ‘comprising’ claim,” . . . “use of ‘a’ or ‘an’ before a noun naming an object” requires that the phrase be construed to mean “‘one or more’ unless the context sufficiently indicates otherwise.” . . . The court has called this the “general rule,” adding that an exception “only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule.”

ABS Global, Inc. v. Cytonome/ST, LLC, 84 F.4th 1034, 1040 (Fed. Cir. 2023) (quoting *Lite-Netics, LLC v. Nu Tsai Capital LLC*, 60 F.4th 1335, 1346 (Fed. Cir. 2023)).

The evidence discussed above supports the plural-allowing meaning in this situation. We agree with Patent Owner that the “general rule” applies and we interpret claim 1 to encompass embodiments with “one or more” flexible elongated fastening members within the flexible hollow fastener.⁸

B. Secure

Independent claim 1 recites the term “secure,” as shown below:

[1.6] wherein the flexible hollow fastener is configured to deform from a first configuration to a second configuration to ***secure*** the flexible hollow fastener and the flexible elongated fastening member when at least one of the two legs of the flexible elongated fastening member are tensioned relative to the body tissue

Ex. 1001, 27:22–47 (emphasis added).

As background to our analysis, we note that this term is at issue because the parties dispute whether Fumex teaches or suggests the claim limitations of [1.6] in claim 1. Specifically, Patent Owner contends “Fumex’s suture *slides* after the sleeve is deformed to its second configuration, so Fumex’s suture is not ‘secured’ as this term is properly construed for the claims of the ‘259 Patent.”⁹ PO Resp. 32. Although we provide this context here, we must—as Patent Owner recognizes—construe the claims independent of whether the Fumex suture is “secure.” *See* PO Sur-Reply 1 (“This IPR has come down to several claim construction arguments which resolve the underlying validity arguments.”). In other words, whether the asserted prior art teaches or suggests a particular claim

⁸ We address the issue of whether the claim permits a single flexible elongated fastening members that is both secure and slidable in Section VIII.B.2.b below.

⁹ *See infra* Section IX.B.1 for a description of the Fumex fastener.

limitation is a separate question to be addressed *after* we construe the claims. Thus, to the extent the parties argue whether the Fumex suture is “secure” in the context of claim construction, we do not address those arguments here. Instead, we first construe the claim term, then we analyze below whether Fumex teaches or suggests the relevant claim limitations.¹⁰

For the reasons discussed below, we construe “secure” to mean “fix, anchor, or attach.”

1. *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 fixation or attachment.’” PO Resp. 27 (quoting Ex. 2001 (Pedowitz Decl. ¶ 47)). 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 26 (quoting Ex. 2006 (Webster’s Dictionary), 4). Patent Owner additionally characterizes “secure” as synonymous with “anchor.” *Id.*; *see also* PO Sur-Reply 9 (“It is unreasonable to consider a suture fixed yet able to slide when they are opposite terms and there is no rationale for making such a broad construction of a term that has ordinary meaning.”). 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 fixation or attachment.” PO Resp. 26 (citing Ex. 1001, 8:50–51, 9:26–27, 13:62–64, 15:31–33, 15:48–50, 20:54–56, 9:62–63).

¹⁰ Our discussion of limitation [1.6] below further addresses the scope of the term “secure.” *See infra* Section IX.D.1.g.

Petitioner argues that Patent Owner’s construction is not supported by the cited dictionary, introduces ambiguity through the use of the term “firmly,” contradicts the intrinsic record, and is inconsistent with the claim language and use of the term “secure” in the field. *See generally* Pet. Reply 4–5, 8–10. Petitioner suggests

the Board could interpret “secure” as encompassing fixing, anchoring, fastening, or attaching, such that the term “to secure the flexible hollow fastener and the flexible elongated fastening member” is met as long as the fastener is offering an anchoring force for the suture even if the suture can be further tensioned (i.e., slide) by the surgeon.

Id. at 8.

2. *Analysis*

We begin with the language of the claims. The term “secure” appears once in claim 1 where limitation [1.6] recites the flexible hollow fastener is configured to deform in order to **secure** the flexible hollow fastener and the flexible elongated fastening member when at least one of the two legs of the flexible elongated fastening member are tensioned relative to the body tissue. Ex. 1001, 27:38–43.

In the context of this use 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. 27. The use above describes anchoring the elongate member consistent with the Specification’s teaching that “suture **56** is tensioned, and the fastener **62** is secured to the suture **56** to thereby approximate the fracture and stabilize the bone **30**.” Ex. 1001, 13:62–64.

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 ’259 patent, “secure” is synonymous with “anchor.” PO Resp. 26 (asserting that “secure . . . is synonymous with ‘anchor’”); Ex. 2001 ¶ 47; Tr. 61:1–2 (Petitioner’s counsel agreeing that in the context of the claimed technology “if construed properly, you can have securement. You can have an anchoring effect.”). 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 fixation or attachment.**” PO Resp. 27 (quoting Ex. 2001 ¶ 47) (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 fixation or attachment,” as well as the parties’ arguments concerning usage of the term “secure” in the art.

a) “*firmly*”

As to inclusion of the term “firmly,” this term adds ambiguity. To explain, we begin by noting that the Specification does not define (or even use) the terms “firm” or “firmly.” Nor does Patent Owner proffer a dictionary definition of “firmly.” Meanwhile, Fumex states

when the loop is tightened by pulling on at least one of the two strands of the thread, the latter is applied against the sleeve and causes its deformation, changing it from a first stretched position to a second position in which it is folded on itself and in which its cross section is increased. . . . By reason of this pressure, the device is then held **firmly** in the hole bored in the bone.

Ex. 1004, 3:1–17 (emphasis added).

In our view, this statement shows the definition of “firmly” can change depending on what is secured, where it is secured, the purpose of the securing because how firmly the device is held will depend on how much tension is applied to the strands of the thread. *See also* Ex. 1018, 81:16–20 (Patent Owner’s expert asking “So how much motion can there be to still be secure?” and answering “It really is a great question. I don't think anybody has defined that and I wouldn't be comfortable answering that.”). Neither party points us to a discussion of these considerations grounded in the intrinsic record.

Perhaps more importantly, we find it unnecessary to include the word “firmly” in order to resolve the disputes pertinent to this Decision. Indeed, Patent Owner identifies that the “term ‘secure’ is defined as ‘to make firm or fast, as by attaching’ by Webster’s Unabridged Dictionary.” PO Resp. 26. In other words, Patent Owner restated its proposed construction of “secure” without including the term “firmly.” *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (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.

b) “so that it cannot be moved at its point of fixation or 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 fixation or attachment.” Patent Owner contends the “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 fixation or attachment.” PO Resp. 26. Patent Owner cites several passages from the

Specification, but fails to explain how they are consistent with the actual language in claim 1.

Specifically, Patent Owner asserts that the Specification points to language regarding movement:

See Ex 1001, 8:50–51, 9:26–27 (“While tension is maintained in the suture, the suture is secured against movement relative to the anchors.”); *Id.*, 13:62–64, 15:31–33, 15:48–50, 20:54–56, 9:62–63 (“When a suture is used it may be secured by connecting a retainer with the suture. . . it may be preferred to secure the suture in place after at least a predetermined tension has been established in the suture”); *Id.*, 9:40–43 (“a retainer member . . . which secures tissue against movement relative to a portion of a bone in a patient’s body”); *Id.*, 10:49–50.

PO Resp. 26.

However, Patent Owner does not reconcile these disclosures or the “cannot be moved language” from the Specification with the actual language recited in claim 1. Claim 1 recites in the final two clauses that

[1.6] wherein the flexible hollow fastener is configured to deform from a first configuration to a second configuration to secure the flexible hollow fastener and the flexible elongated fastening member when at least one of the two legs of the flexible elongated fastening member are tensioned relative to the body tissue, and

[1.7] wherein the flexible elongated fastening member is configured to slide through the flexible hollow fastener under tension when the flexible hollow fastener is in the first configuration and the second configuration.

Ex. 1001, 27:38–47 (emphasis added). As Petitioner notes, claim 1, limitation [1.7] not only permits, but requires, that the flexible elongated fastening member slide through the fastening member when under tension.

Pet. Reply 4, 8.

We recognize Patent Owner's argument that

It is not possible for the same fastening member to be both "secure" and to "slide" at the same time. Ex. 1018, 100:22-101:12 ("claim elements 1.6 and 1.7 cannot both be met by a single elongated fastening member, correct? A. Correct"). Indeed, Petitioner calls such a "technical impossibility." Reply, 8. Thus, given that the language of claim 1 requires "the flexible elongated fastening member" to be both "secure" and "slide" at the same time, it necessarily follows that there must be at least two such fastening members – one that is secure and another that slides when the flexible hollow fastener is in the second configuration.

Sur-Reply 4.

However, this argument does not address the meaning of the term "secure." As noted above, Petitioner does not simply state that this is a technical impossibility but rather asserts "it is clear that the securement of the flexible elongated member and the hollow fastener to one another must still allow some relative movement between the two in order to satisfy [1.7]. Otherwise, the claim would be an invalid technical impossibility."

Pet. Reply 8. Thus, Petitioner is actually arguing that a single flexible hollow fastening member may be secured while still permitting relative movement such as sliding. Nor does it address Dr. Jordan's testimony suggesting that being fixed and sliding was not impossible because "[t]he sutures could still slide in it, even though it was fixed in the bone, as is shown here." Ex. 2002, 18:8–10. As noted previously, Dr. Jordan explains a single secured suture being slidable, stating

In this second position, wherein the anchor is expanded and secured, the suture is still slidable within the sleeve. Like a zip tie, the suture strand can be pulled and slides relative to the sleeve to continue to shrink the loop, slowly increasing the tension of the suture, but once tightened, does not allow the suture to easily

slip in the opposite direction to allow the loop to once again widen.

Ex. 1002 ¶ 102. Dr. Jordan asserts “a POSITA would understand that any amount of slidability of the fastening member within the fastener meets this claim limitation.” *Id.* ¶ 103.

Patent Owner’s expert Dr. Pedowitz states that “a single flexible elongated fastening member cannot both be ‘secure’ and slide in the second configuration.” Ex. 2001 ¶ 66. Dr. Pedowitz acknowledges that Dr. Jordan testified that “[t]he sutures could still slide in it, even though it was fixed in the bone, as is shown here.” Ex. 2002, 18:2–18.” Ex. 2001 ¶ 68.

Dr. Pedowitz also acknowledges regarding the flexible hollow fastening member that “you could make it deliberately out of something slippery. And, of course, if you do that and you make the suture slippery, it might have the advantage of sliding through the sleeve more easily.” Ex. 1018, 125:21–25. While this testimony is not directly addressed to a secured sleeve, it suggests that sliding depends on a variety of factors including the composition of the components and the degree to which the sleeve is secured.

Dr. Pedowitz identifies a number of passages in the Specification that include the words “secure” or “securing” regarding sutures but does not point to a specific teaching that these secured sutures may not slide within a flexible hollow fastener. *See* Ex. 2001 ¶ 46. Dr. Pedowitz’s interpretation of secure is not focused on whether the flexible hollow fastening member is fastened (i.e., secured) to the body tissue but rather is focused on whether the flexible hollow fastening member “cannot be moved relative to its point of fixation or attachment.” *Id.* ¶¶ 47, 65. The plain language of the claim does not require securing the suture relative to the fastener. The phrase “cannot be moved relative to its point of fixation or attachment” is not

recited in claim 1, is not found in a definition in the Specification, and is not even clearly required by the non-limiting cited portions of the Specification.

In sum, we are not persuaded by Patent Owner's argument that the Specification or expert evidence supports inclusion of the term "cannot be moved at its point of fixation or attachment" in the construction of "secure."

Petitioner makes one additional argument against inclusion of this term. As noted above, by including "so that it cannot be moved at its point of fixation or attachment," 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. 30. Petitioner argues that excluding sliding between an elongate member and a fastener contradicts the intrinsic record, because claim 1 explicitly recites an elongate member that slides through the fastener and "must cover 'a' single elongated fastening member, even if it could be 'more than one.'" Pet. Reply 7. Patent Owner responds that "[i]t is unreasonable to consider a suture fixed yet able to slide when they are opposite terms and there is no rationale for making such a broad construction of a term that has ordinary meaning." Sur-Reply 9.

Petitioner has the better argument. Petitioner is correct that claim 1 expressly encompasses "a flexible elongated fastening member" and Patent Owner acknowledged that this reads on "one or more." *See, e.g.*, Ex. 1001, 27:25; PO Resp. 25 ("The general rule that 'a' means 'one or more' applies to the claims of the '259 Patent."). Thus, the language of claim 1 expressly encompasses embodiments with a single flexible elongated fastening member that must be satisfied by the secured and slidable requirements recited within the claim. *In re Varma*, 816 F.3d 1352, 1363 (Fed. Cir. 2016)

(“[U]se of the indefinite ‘a’ cannot ‘serve to negate what is required by the claim following ‘a.’”).

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 fixture or attachment” to the fastener.

3. *Conclusion*

For the reasons discussed above, we construe the term “secure” to mean “fix, anchor, or attach.”

C. Knotless

Independent claim 1 does not recite the term “knotless.” The term “knotless” only appears in dependent claims 7 and 18. To give context to our analysis, we first note that this term is at issue because the parties dispute whether Fumex teaches or suggests the “knotless” limitation in claims 7 and 18.

As above, we first construe the claim term. For the reasons discussed below, we construe “knotless,” as used in reference to a fastener, to mean “a fastener that can be retained in place without tying a knot at the site where the fastener is secured.”

1. *Brief Summary of Parties’ Arguments*

Patent Owner and Dr. Pedowitz assert that a “knotless” fastener is “a fastener that can be retained relative to body tissue without a knot.” PO Resp. 22 (citing Ex. 2001 ¶ 35). Patent Owner asserts a “POSITA would have understood that a ‘knotless fastener’ was not a term of art at the time of

the invention of the ‘259 Patent.” *Id.* (citing Ex. 2001 ¶ 36). Patent Owner asserts they “coined the term ‘knotless’ in describing its fasteners.” *Id.*

Patent Owner asserts

A POSITA would understand the plain and ordinary meaning of “knot” that is consistent with the intrinsic record to be “an interlacing, twining, looping, etc. of a cord, rope, or the like, drawn tight into a knob or lump, for fastening, binding, or connecting two cords together or a cord to something else.”

PO Resp. 24 (citing Ex. 2002 ¶ 41).

Petitioner asserts the “‘259 Patent does not define what makes a hollow fastener ‘knotless.’ In fact, the term ‘knotless’ appears in the specification only once.” Pet 21; Ex. 1001, 11:29–36. Petitioner asserts a “POSITA would have understood the term ‘knotless,’ as used in reference to a fastener, to mean a fastener that can be retained in place without tying a knot at the site where the fastener is secured.” Pet. 23–24. Petitioner explains “a POSITA would have understood ‘knotless’ to refer to the elimination of surgical knot-tying to retain the fastener rather than the elimination of anything that qualifies generally as a ‘knot.’” Pet. Reply 20.

2. *Analysis*

We begin our analysis with the language of the claims. Claim 7 recites “The system of claim 1, wherein the flexible hollow fastener is knotless.” Ex. 1001, 27:61–62. Claim 18, which depends from independent claim 11, recites similar language. Ex. 1001, 28:43–44. The Specification uses the term “knotless” once, stating that “fasteners may be . . . knotless.” Ex. 1001, 11:30–37.

Dr. Pedowitz states that “knotless fastener” was not a term of art (Ex. 2001 ¶ 36), but in response to the question regarding a prior art patent that “it wants to be able to provide that in a way in which the *anchor is*

installed without requiring tying of a knot; correct?,” Dr. Pedowitz acknowledged that this was “[f]or the purposes of achieving the repair of the tissue to the tissue.” Ex. 1018, 33:21–25 (emphasis added). When asked about a patent drawn to “a knotless suture anchor that is suitable for arthroscopic use” where “the surgeon was **not required to tie a knot** in the suture extending from the anchor 1 in order to secure the tissue 30 to the anchor,” Dr. Pedowitz did not identify error in this understanding. Ex. 1018, 34:3–36:1 (emphasis added). Dr. Pedowitz was asked about additional patents which used the term “knotless” and acknowledged that the patents were “talking about the strategy of a way to secure the attachment of soft tissue to bone mass **without tying a knot**.” Ex. 1018, 42:9–11 (emphasis added).

Dr. Jordan disagrees with Dr. Pedowitz and considers “knotless” a term understood by the ordinary artisan, stating, “the Examiner understood a ‘knotless’ fastener to be a fastener such as anchor 30a that could be held in position (i.e., fastened) without the use of a knot.” Ex. 1002 ¶ 44. Dr. Jordan stated “a POSITA would have understood the term ‘knotless,’ as used in reference to a fastener, to mean a fastener that can be retained in place without tying a knot at the site where the fastener is secured in place.” *Id.* ¶ 46. Dr. Jordan, when asked regarding jumbled and looped sutures pushed into a cortical bone hole and then tugged on, whether he would “characterize that jumble of half [hitches] in the suture as a knot in that context?” answered “I wouldn’t characterize it as a knot. I would characterize it as an anchor, much like any configuration that deforms and then becomes in a different shape and can’t passage back out.” Ex. 2002, 40:11–41:9. Dr. Jordan’s testimony demonstrates that Patent Owner’s

proposed dictionary definition of “knot” is broader than the term “knot” as understood in the art, which involves tying. *See* Pet. Reply 20–21, footnote 7.

Patent Owner also asserts that “Petitioner never mentioned the legacy art-specific meaning of ‘knotless suture anchor’ in its Petition, but attempts to adopt it as supporting Petitioner’s construction after Dr. Pedowitz distinguished it. Ex. 2001, ¶ 36.” PO Sur-Reply 12.

We do not find this reasoning persuasive because Patent Owner has not established the necessary predicate that they coined the term “knotless” in the ’259 patent. The standard for “coining a term” or an inventor serving as their own lexicographer in a patent is set forth in *Paulsen*, which states

Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision. “Where an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure” so as to give one of ordinary skill in the art notice of the change.

In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994). When Petitioner and Dr. Jordan point to prior art showing that there was a legacy meaning of “knotless,” and that this meaning of “knotless” differs from Patent Owner’s reliance on a meaning of “knotless” not stated or discussed in the ’259 patent, Petitioner reasonably relies upon the prior art meaning of “knotless.” *See* Ex. 1002 ¶ 46.

On the full trial record, Patent Owner has not identified statements within the Specification which provide notice that the term “knotless” was intended to have a meaning distinct from the use as a fastener in a location without the use of a knot, as understood by Dr. Jordan. Ex. 1002 ¶ 44. And

Dr. Jordan expressly stated that he considered jumbled sutures pressed into a hole and pulled tight as not a knot (*i.e.*, knotless) but rather simply functioning as an anchor. Ex. 2002, 40:11–41:9.

3. *Conclusion*

We therefore interpret the term “knotless” in the context of the fasteners on this trial record as reading on a suture-restraining structure that can be retained in place without tying a knot at the site where the fastener is secured in place.

IX. ANALYSIS

A. Introduction

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17–18. The obviousness inquiry also typically requires an analysis of “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”)). A petitioner cannot prove obviousness with “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Rather, a petitioner must articulate a sufficient reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

We analyze the asserted grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish a preponderance of evidence showing unpatentability of claims 1–26 of the '259 patent.

B. Overview of the Asserted Prior Art

1. *Fumex (Ex. 1004)*

Fumex is a U.S. patent that teaches surgical bone anchoring devices, which require “only the prior boring of a single hole with any wall shape, without requiring tapping, and permitting fixation of organs such as tendons and ligaments, or suspension of the cervix of the uterus, using a surgical thread or a suture thread without the need to use a means of the screw or piton type.” Ex. 1004, 2:3–8.

Fumex teaches the anchoring device “comprises a deformable tubular sleeve, associated with means capable of deforming it between a first stretched position of small diameter and a second folded position of greater diameter.” Ex. 1004, 2:14–17. Fumex teaches the “means capable of deforming the sleeve are made up of a thread passing through the deformable tubular sleeve along its axis and forming a closed loop.” Ex. 1004, 2:25–28. Fumex teaches the “closure of the loop can be obtained by simple crossing of the two strands of the thread, on either side of the deformable sleeve.” Ex. 1004, 2:41–43. Fumex explains that

[B]y exerting a traction on the strands of the thread in diverging directions, the sleeve is folded until it presents approximately the form of a ball which, because its diameter is greater than that of the sleeve, is compressed against the walls of the hole into which the sleeve has been introduced. By reason of this pressure, the device is then held firmly in the hole bored in the bone.

Ex. 1004, 3:10–17.

Figure 1 of Fumex, reproduced below, is “a diagrammatic view of a fixation thread according to the present invention, introduced into a U-shaped sleeve, before tightening and deformation”:

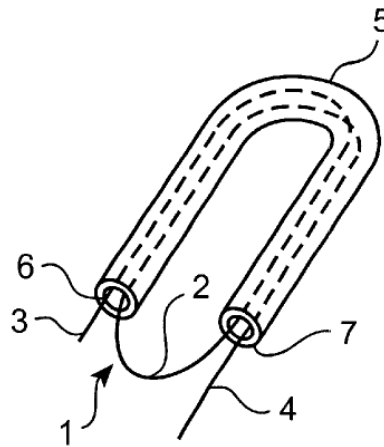


FIG. 1

Figure 1 of Fumex, above, “shows the anchoring device of the present invention, which comprises a suture thread (1) forming, in its middle part, a closed loop (2) which is capable of being tightened by simple traction on one of the two strands (3, 4) of the thread (1).” Ex. 1004, 5:39–43. Figure 1 further shows that the “thread (1) forming the loop (2) passes into the sleeve (5) via its end (6), emerges via the other end (7), once again enters via the end (6) and emerges via the end (7) in such a way as to form a complete loop in the sleeve.” Ex. 1004, 5:44–47.

Figure 5 of Fumex, shown below, depicts “a perspective view of an ancillary instrument permitting semi-automatic positioning of an anchoring device.” Ex. 1004, 5:32–34.

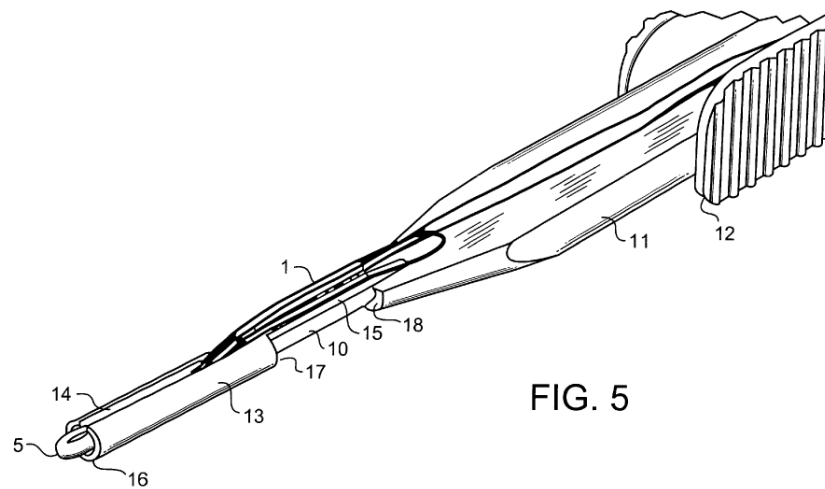


Figure 5 of Fumex shows

After the hole has been bored in the bone using a conventional instrument, the rod (10) bearing the loop-shaped thread (1) and the sleeve (5) is introduced into the hole in such a way that the distal edge (16) abuts against the bone, at the edge of the hole. The rod (10) is then inserted, which results in the sliding of the cylindrical element (13) along the rib (15) until the proximal edge (17) of the cylindrical element (13) comes to bear against the shoulder (18) situated at the base of the rod (10). The sliding distance is determined so as to correspond to the depth of the hole bored in the bone. In this position, the sleeve (5) is entirely inserted in the hole bored in the bone.

Ex. 1004, 6:64–7:8.

2. Grafton (Ex. 1005)

Grafton is a U.S. patent publication that teaches “high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.” Ex. 1005 ¶ 2. Grafton teaches the “preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of

polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.” Ex. 1005 ¶ 6.

3. *Bonutti ’875 (Ex. 1007)*

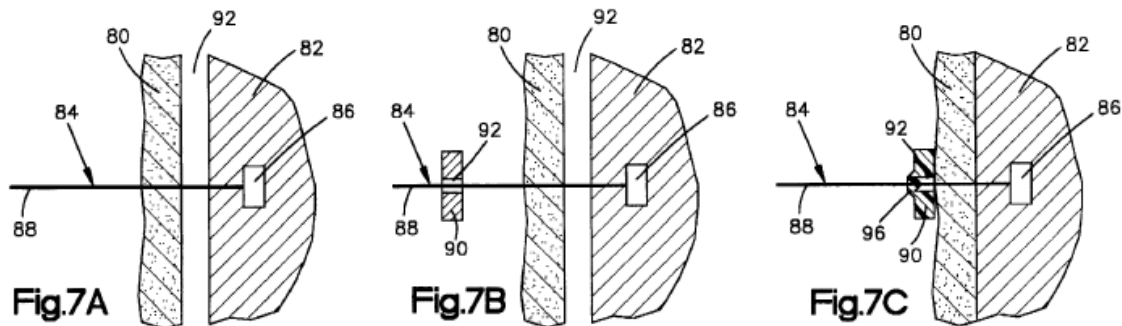
Bonutti ’875 is a U.S. patent that teaches “surgical devices such as implants or suture fastenings.” Ex. 1007, 1:18–19. Bonutti ’875 teaches “heat bonded fastenings for sutures or K-wires, in which a variety of different suture anchors are usable, including expandable distal suture anchors. Such suture fastenings are easier to form and stronger than conventional tied knots.” Ex. 1007, 2:2–5. Bonutti ’875 teaches that it may be

difficult to tie a suture knot to itself or to slide it down through deep tissue in a limited working area . . . mechanical tying or crimping of sutures or K-wires, especially of polymers or biodegradables which are generally smooth, does not produce connections which are as strong as desirable, and suture connections sometimes may come untied as a result.

Ex. 1007, 6:47–57. Bonutti ’875 teaches an embodiment where “surgical connections for holding adjoining tissues together are secured by melting a fastener or anchor on the end of a suture, rather than by tying or by clipping the anchor on the end of the suture.” Ex. 1007, 6:59–62. Bonutti ’875 teaches that advantages of heat bonded fastenings include

a melted anchor provides a stronger bond than the mechanical interlock of a suture knot, because it will not unravel or come apart as a surgical knot may. It takes less time to fasten than it does to tie a suitable knot. There is improved contact between the tissues being joined because of the better suture connection. The straight line suture fastening also avoids buckling of the tissue edges caused by force vectors not extending in the direction of the suture.

Ex. 1007, 7:6–13. Figure 7 of Bonutti '875, reproduced below, depicts a bonded suture fastening:



As illustrated in FIG. 7, two pieces of tissue 80 and 82 are to be joined using a suture 84. A distal anchor 86 is located on the end of the suture 84. The suture is then inserted through the tissues 82 and 80 so that a free end 88 of the suture 84 protrudes at the proximal end. A fastener 90 having an opening 92 therein is slid over the wire 84 and pulled down tight as shown in FIG. 7C to close the gap 94 between the tissues 80 and 82.

The fastener 90 is made of a heat bondable plastic material. (The suture can also be made of heat bondable plastic material which is bonded to secure the connection.) The fastener 90 is then bonded at an area 96 to the protruding free end 88 of the suture 84. In FIG. 7C, it can be seen that the fastener 90 is bonded to the suture 84 without significant deformation of the suture.

Ex. 1007, 7:37–51.

4. *Bonutti '395 (Ex. 1006)*

Bonutti '395 is a U.S. patent publication that teaches a “method of securing sections of a fractured bone. Sections of a fractured bone are held against movement relative to each other by a force transmitting member, such as a suture, which extends through a passage in the bone.” Ex. 1006, 1:36–40.

Figure 5 of Bonutti '395, reproduced below, depicts “the manner in which a suture extends between suture anchors through a nonlinear passage.” Ex. 1006, 2:8–10.

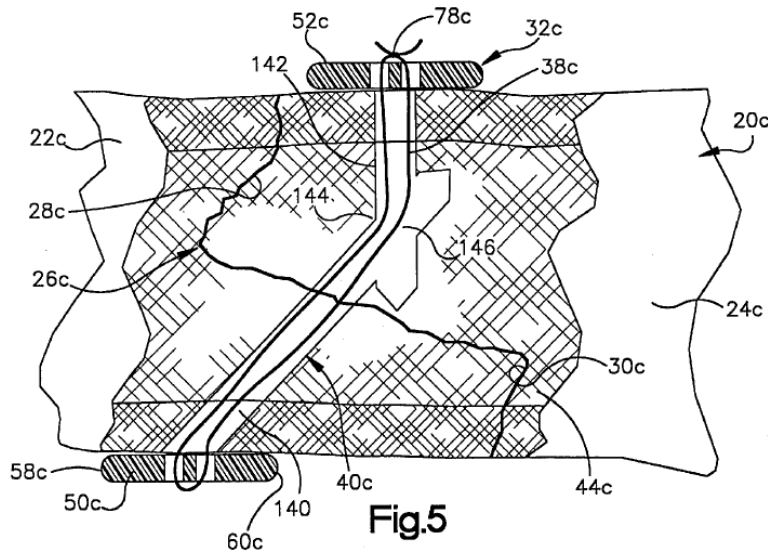


Figure 5 of Bonutti '395 shows a situation where “suture 38c is disposed in a passage 40c having a nonlinear configuration. . . . The flexible suture 38c extends around the bend 144 along a nonlinear path between the suture anchors 50c and 52c.” Ex. 1006, 10:41–48. Bonutti '395 teaches that to position the suture in the nonlinear passage, a “flexible pusher member applies force against the trailing end 60c of the anchor 50c and pushes the anchor around the bend . . . of the passage 40c.” Ex. 1006, 11:27–30.

5. *Stone (Ex. 1010)*

Stone is a U.S. patent that teaches “to provide a device that is designed for endoscopic use and that accommodates multiple suture fixation.” Ex. 1010, 2:12–14. Figure 1 of Stone, reproduced below, depicts a suture anchor assembly.

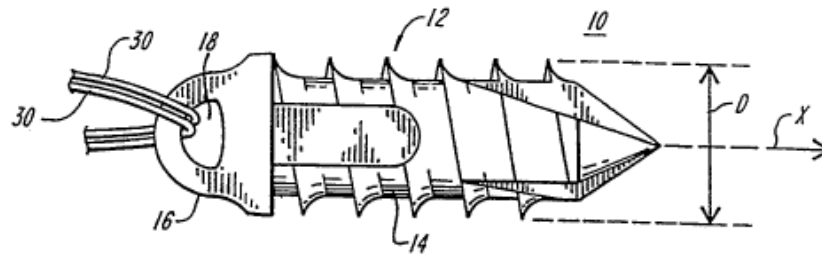


FIG. 1

In the illustrated embodiment of FIG. 1, the top portion 16 includes an eyelet 18 of sufficient size to receive one or more sutures 30. Since sutures are made of different materials and, consequently, are available in a variety of different diameters, the actual size of the eyelet 18 may be of a standard size to accept any suture material or may come in a range of sizes specific to different suture types.

Ex. 1010, 4:34–42.

6. *To (Ex. 1011)*

To is a U.S. patent publication that teaches “devices for delivering tissue anchors that could be used in a variety of procedures, both surgical and percutaneous.” Ex. 1011 ¶ 3. Figure 1, reproduced below, depicts a surgical anchor deployment device where the shaft is rigid:

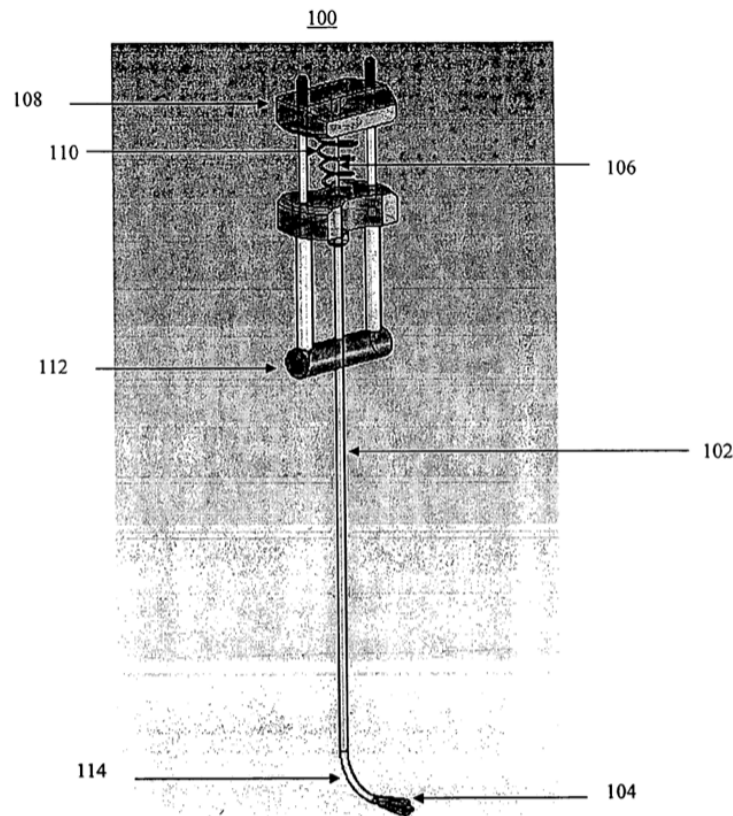


FIG. 1

The mechanism for deploying the anchor distally from the lumen in the variation depicted in FIG. 1 is a plunger (106) slidably disposed within at least a portion of the lumen. In this variation, the device also comprises an actuator for actuating the plunger, shown here as a slidable handle (108) attached to spring (110).

Ex. 1011 ¶ 30. To teaches that the “device may also comprise at least two shafts, so that multiple anchors may be deployed simultaneously. Similarly, a single shaft may be configured to receive at least two anchors therein, for deploying multiple anchors serially or sequentially.” Ex. 1011 ¶ 12. To also teaches a cinching strand that “is used to tighten the slack between the anchors after they are deployed, for example, in order to reduce the

circumference of a valve annulus, hollow body organ, or the like.” Ex. 1011 ¶ 43.

C. Grounds 1, 3, 5, 7, and 9

In these grounds, Petitioner relies upon Fumex alone, or combined with Bonutti ’875, Bonutti ’395, Stone, and/or To in order to render claims 1–26 of the ’259 patent obvious. These grounds are duplicative with grounds 2, 4, 6, 8, and 10 that address the obviousness of claims 1–26 of the ’259 patent but for the inclusion of the Grafton reference, which reference addresses the limitation in independent claim 1 that requires the flexible hollow fastening member is fabricated in part with polyethylene.

Because the asserted grounds that include Grafton address and are dispositive as to all the challenged claims, we need not reach alternative Grounds 1, 3, 5, 7, and 9. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”); *Bos. Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App’x 984, 990 (Fed. Cir. 2020) (nonprecedential) (recognizing that the “Board need not address issues that are not necessary to the resolution of the proceeding” and, thus, agreeing that the Board has “discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims”). Accordingly, we do not reach Petitioner’s arguments that claims 1–26 of the ’259 patent would have been obvious in the absence of the Grafton reference as recited in Grounds 1, 3, 5, 7, and 9.

D. Ground 2: Obviousness over Fumex and Grafton

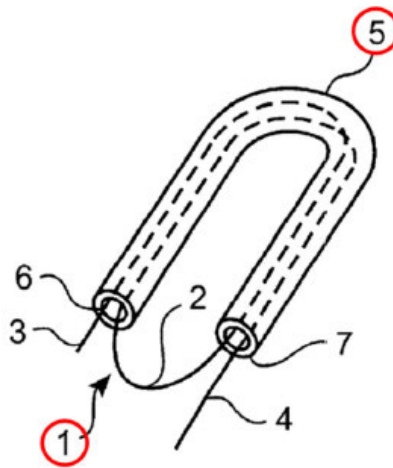
Petitioner contends that claims 1, 3, 4, 6–8, 10, 11, 13–16, 18–20, 22, 24, and 26 of the '259 patent would have been obvious over Fumex and Grafton. Pet. 3. Petitioner provides a detailed analysis of independent claim 1 and then explains where dependent claim limitations of claims 3, 4, 6–8, 10, 11, 13–16, 18–20, 22, 24, and 26 are found within the prior art. Pet. 25–53. Patent Owner responds, asserts specific claim interpretations, and explains why the claims would not have been obvious over Fumex and Grafton. PO Resp. 22–39.

Although Patent Owner challenges only whether Fumex and Grafton teach or suggest limitations in claim elements [1.3], [1.6], and [1.7], for completeness we address each element of claim 1.

1. Analysis of Claim 1

a) Preamble [1.P]: A fastener system comprising

Petitioner asserts, regarding the claim 1 preamble [1.P], that “Fumex describes a fastener system because its surgical bone anchoring system includes a deformable tubular sleeve that can be fastened relative to a hole bored in bone. Ex. 1004, 1:7-10 (‘surgical device for bone anchoring’).” Pet. 25. Petitioner annotates Figure 1 to show the fastener system as depicted below:



Pet. 25 (citing Ex. 1004, Fig. 1; Ex. 1002 ¶¶ 75–76).

Patent Owner neither takes a position on whether the preamble is limiting, nor disputes that Fumex teaches or suggests the preamble. *See generally* PO Resp. We agree with and adopt Petitioner’s undisputed analysis.

b) Limitation [1.1]: a flexible hollow fastener comprised of fibers of a biocompatible polymeric material

Petitioner asserts, as to the recitation in claim 1 [1.1] of “a flexible hollow fastener comprised of fibers of a biocompatible polymeric material,” that

Fumex’s bone anchoring system includes a flexible hollow fastener in the form of flexible, tubular (i.e., hollow) sleeve (5), as shown in Figure 1. Ex. 1004, 5:39-61, 7:21-25 (surgical device for anchoring includes “a deformable tubular sleeve”), Fig. 1. The sleeve can be inserted into a hole bored in a bone and subsequently deformed, causing it to form a ball that bears on an inner surface of a bone, fastening the anchoring system to the bone. Ex. 1004, 5:62-6:22.

Pet 26. Petitioner asserts “[m]aterials suitable for the sleeve include braided metal wire, braided plastic wire, polyester, polyamide, and silicone. *Id.*; Ex. 1002, ¶79.” Pet. 26–27. Petitioner asserts

Fumex discloses an embodiment in which the tubular sleeve (5) is fabricated from “non-absorbable polyester braid.” *Id.*, 4:50-63. Fumex thus describes and/or suggests a unitary hollow fastener fabricated from a plurality of fibers (braid) of polymeric biocompatible material (polyester). *Id.*, 4:50-63, 2:54-65 (sleeve “has the property of being implantable”); Ex. 1002, ¶80.

Pet. 27.

Patent Owner does not dispute that Fumex teaches or suggests limitation [1.1]. *See generally* PO Resp. We agree with and adopt Petitioner’s undisputed analysis.

c) Limitation [1.2]: a flexible elongated fastening member extending through the flexible hollow fastener such that two legs of the flexible elongated fastening member extend from the flexible hollow fastener to enable a user to tension the flexible elongated fastening member

Petitioner asserts, as to the recitation in claim 1 [1.2] of “a flexible elongated fastening member extending through the flexible hollow fastener such that two legs of the flexible elongated fastening member extend from the flexible hollow fastener to enable a user to tension the flexible elongated fastening member,” that

Fumex’s bone anchoring system includes a flexible elongated fastening member—suture (1)—that is passed through the flexible sleeve (5) such that two legs (3, 4), extend from the sleeve. Ex. 1004, 5:38-57, 2:46-49 (“preferably a surgical thread or a suture thread, absorbable or non-absorbable, of the type used to fix or re-attach organs”), Fig. 1.

Pet. 27. Petitioner asserts the “strands (3, 4) of suture thread (1) extending from the sleeve enable a user to tension the suture.” Pet. 28.

Patent Owner does not dispute that Fumex teaches or suggests limitation [1.2]. *See generally* PO Resp. We agree with and adopt Petitioner’s undisputed analysis.

d) Limitation [1.3]: wherein at least a portion of the flexible elongated fastening member is fabricated in part with polyethylene

Petitioner asserts “independent claim 1 (which calls for at least a portion of the suture to be fabricated in part with polyethylene) would have been obvious over Fumex in view of Grafton.” Pet. 48. Petitioner asserts

Fumex discloses a bone anchoring device that includes a hollow, deformable sleeve and a suture thread that is passed through the sleeve prior to implantation. Although Fumex does not expressly disclose a polyethylene thread, it directs the use of any thread “of the type used to fix or re-attach organs.” Section VII.C.1(d), *supra*; Ex. 1004, 2:46-48; Ex. 1002, ¶148.

Pet. 48. Petitioner asserts “Grafton explicitly describes that a suture may be formed of ‘a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester.’ Ex. 1005, Abstract, ¶[0015].” Pet. 48–49.

Petitioner asserts that a “POSITA would have found Grafton’s braided suture to be an obvious choice of suture thread for use in Fumex’s bone anchoring device” because “a suture including polyethylene could have been chosen by a POSITA for applications requiring a relatively higher suture strength. Grafton expressly describes suture strength as being ‘an important consideration in any surgical suture material.’ Ex. 1005, ¶[0004]; Ex. 1002, ¶153.” Pet. 49–50. Petitioner also asserts

Grafton specifically states that the suture is “ideal” for “rotator cuff repair, Achilles [sic] tendon repair, patellar tendon repair, and ACL/PCL reconstruction”—some of the very types of procedures for which Fumex’s bone anchoring device is intended to be used. Ex. 1004, 4:38-41, 1:7-12, 2:1-8; Ex. 1005, ¶[0009]; Ex. 1002, ¶152-53.

Pet. 50.

Petitioner asserts a “POSITA would have had a reasonable expectation of success in combining Fumex’s bone anchoring device with Grafton’s suture thread. Ex. 1002, ¶154.” Pet 51. Petitioner asserts “a POSITA would have expected Grafton’s flexible suture to be as capable of being threaded through Fumex’s flexible sleeve as any other suture. Ex. 1002, ¶¶155-56.” Pet. 51.

Patent Owner asserts that “Fumex fails to describe or suggest that at least a portion of its thread is fabricated with polyethylene as required in claim element [1.3]. For this reason alone, claim 1 is not obvious from Fumex.” PO Resp. 28. Patent Owner does not, however, dispute the obviousness of claim element [1.3] in Ground 2 based on “the combination of Fumex and Grafton due in part to the high suture strength of polyethylene as disclosed by Grafton. Petition, 50, Ex 1002, ¶ 153.” *Id.* at 38–39. We agree with and adopt Petitioner’s undisputed analysis.

e) Limitation [1.4]: an introducer comprised of a pushrod, the pushrod having a distal portion configured to engage the flexible hollow fastener and position the flexible hollow fastener relative to a body tissue

Petitioner asserts, as to the recitation in claim 1 [1.4] of “an introducer comprised of a pushrod, the pushrod having a distal portion configured to

engage the flexible hollow fastener and position the flexible hollow fastener relative to a body tissue,” that

Fumex describes an introducer comprised of a pushrod having a distal portion configured to engage the hollow flexible fastener in the form of an ancillary instrument having a rod 10 with integral handle 11 . . . Ex. 1004, 4:11-18 (“used by introducing the point of the rod of the ancillary instrument, bearing the loop-shaped thread and its sleeve, into the hole bored beforehand in the bone, until the loop is fully engaged in the hole”); 6:48-56. The rod 10 supports and engages with the tubular sleeve 5 (i.e., fastener) to push the sleeve into a hole formed in the tissue. *Id.*, 6:48-56.

Pet. 32. Petitioner asserts “Fumex describes the distal portion of the pushrod as being configured to position the flexible hollow fastener relative to the body tissue.” Pet. 33 (citing Ex. 1004, 2:54–65; Ex. 1002 ¶ 92).

Patent Owner does not dispute that Fumex teaches or suggests limitation [1.4]. *See generally* PO Resp. We agree with and adopt Petitioner’s undisputed analysis.

f) Limitation [1.5]: wherein the flexible hollow fastener and flexible elongated fastening member are positioned on the distal end of the pushrod

Petitioner asserts, as to the recitation in claim 1 [1.5] of “wherein the flexible hollow fastener and flexible elongated fastening member are positioned on the distal end of the pushrod,” that

Fumex describes the flexible hollow fastener (sleeve 5) and flexible elongated fastening member (thread 1 passed through sleeve 5) as being positioned on the distal end because the rod engages with the suture thread and sleeve at the rod’s distal end, as shown in Figure 5. Ex. 1004, Fig. 5, 4:13-18.

Pet. 33–34.

Patent Owner does not dispute that Fumex teaches or suggests limitation [1.5]. *See generally* PO Resp. We agree with and adopt Petitioner's undisputed analysis.

g) *Limitation [1.6]: wherein the flexible hollow fastener is configured to deform from a first configuration to a second configuration to secure the flexible hollow fastener and the flexible elongated fastening member when at least one of the two legs of the flexible elongated fastening member are tensioned relative to the body tissue*

Petitioner asserts, as to the recitation in claim 1 [1.6] “wherein the flexible hollow fastener is configured to deform from a first configuration to a second configuration to secure the flexible hollow fastener and the flexible elongated fastening member when at least one of the two legs of the flexible elongated fastening member are tensioned relative to the body tissue,” that “Fumex describes the flexible hollow fastener (sleeve 5) deforming from a first configuration to a second configuration to secure the flexible hollow fastener and the flexible elongated fastening member (suture thread 1) when the legs of the flexible elongated fastening member are tensioned relative to the body tissue.” Pet. 34. Petitioner cites Fumex as teaching:

At the time of positioning, after introduction of the sleeve and of the thread into the hole bored in the bone, when the loop is tightened ***by pulling on at least one of the two strands of the thread***, the latter is applied against the sleeve and ***causes its deformation, changing it from a first stretched position to a second position in which it is folded on itself and in which its cross section is increased***. More precisely, having folded the sleeve at its middle in such a way that the strands of the thread emerge in the same direction, and having introduced it thus into the hole bored in the bone, by exerting a traction on the strands of the thread in diverging directions, the sleeve is folded until it presents approximately the form of a ball which, because its

diameter is greater than that of the sleeve, is compressed against the walls of the hole into which the sleeve has been introduced. ***By reason of this pressure, the device is then held firmly in the hole bored in the bone.***

Pet. 35 (citing Ex. 1004, 3:1–17). Petitioner explains that

as the suture is tensioned relative to the body tissue, i.e., the bone within the body, the sleeve deforms from a first configuration (“a first folded position”) to a second configuration (“it adopts the shape of a ball”) to secure the sleeve and provide an anchor for the thread as it is tensioned relative to the bone. Ex. 1002, ¶98.

Pet. 36.

Patent Owner asserts “Petitioner and Dr. Jordan allege that Fumex’s single suture is both secure (i.e., anchored by the fastener) and slides in the second configuration with respect to claim elements [1.6] and [1.7].”

PO Resp. 30. Patent Owner asserts

that the plain and ordinary meaning of “secure” that is consistent with the intrinsic record of the ‘259 Patent is “fix, anchor, or attach (something) firmly so that it cannot be moved relative to its point of attachment.” Ex 2001, ¶ 47. Thus, claim element [1.6] requires fixing, anchoring, or attaching (the fastener and the elongated fastening member) firmly so that they cannot be moved relative to their points of fixation or attachment when the fastener is deformed to its second configuration (when “it adopts the shape of a ball” according to Petitioner). Ex 1002, ¶ 98. The flexible hollow fastener (e.g., bone anchor) and flexible elongated fastening member (e.g., suture) are not secured until the fastener is placed in body tissue such as bone. Ex 2001, ¶ 48.

Id. at 30. Patent Owner asserts that “Dr. Jordan explicitly states that, when in the second configuration, suture 1 ‘*could still slide*’ relative to sleeve 5 and the bone hole such that the cortical bone ‘acts as [a] shelf holding the expanded anchor in place.’ Ex 1002, ¶ 102.” *Id.* at 32. Patent Owner asserts “Fumex’s suture *slides* after the sleeve is deformed to its second

configuration, so Fumex's suture is not 'secured' as this term is properly construed for the claims of the '259 Patent." *Id.*

Considering all of the arguments and cited evidence of record, we find that Petitioner shows by a preponderance of the evidence that Fumex teaches or suggests limitation [1.6]. *See* Pet. 34–36. Limitation [1.6] requires deforming the fastener from a first configuration to a second configuration “to **secure** the flexible hollow fastener and the flexible elongated fastening member when at least one of the two legs of the flexible elongated fastening member are tensioned.” Ex. 1001, 27:38–43 (emphasis added). Under our construction of “secure,” limitation [1.6] requires deforming the fastener to “fix, anchor, or attach” the fastener. *See supra* Section VIII.B. As we discuss in more detail below, we find this limitation satisfied by Fumex's teaching that the device is secured to the support (e.g., bone).

As Petitioner's expert notes, Fumex teaches an invention titled “surgical bone anchoring device” that

after introduction of the sleeve and of the thread into the hole bored in the bone, when the loop is tightened by pulling on at least one of the two strands of the thread, the latter is applied against the sleeve and causes its deformation, changing it from a first stretched position to a second position . . . the device is then held firmly in the hole bored in the bone.

Ex. 1004, code (54), 3:1–17; Ex. 1002 ¶¶ 95, 98 (emphasis added). Fumex similarly teaches that after deforming, the anchoring device “increase[s] the phenomenon of anchoring in the spongy substance of the bone, resulting in improved **fastening** of the device of the invention in the bone.” Ex. 1004, 4:35–37 (emphasis added). Dr. Pedowitz acknowledges that when the suture threads are pulled in Fumex, Fumex requires the device to form a ball, and that the “ball sort of be stuck in bone.” Ex. 1018, 69:2–4. The evidence of

record therefore shows that the device of Fumex is a bone anchoring device that is held by or anchored to the bone, satisfying the requirement to “secure” the device when tensioned using the suture threads.

As discussed in more detail in our analysis of limitation [1.7] below, the suture strand in the Fumex anchor is reasonably understood to slide as it is secured. Dr. Jordan states:

As the suture strand is pulled, the anchor’s cross section is increased such that it is larger than the hole in the cortical bone and the cortical bone acts as shelf holding the expanded anchor in place. In this second position, wherein the anchor is expanded and secured, the suture is still slidable within the sleeve.

Ex. 1002 ¶ 102. Dr. Jordan explained “you can deploy the anchor, change the configuration and it’s, thus, fixed or anchored but still slidable. But if you continue to slide within the limits of the loop, at some point it reaches the end and you can’t do it anymore and that’s locked.” Ex. 2002, 27:3–8.

Therefore, after considering all of the arguments and cited evidence of record, we find that Petitioner shows by a preponderance of the evidence that Fumex teaches or suggests limitation [1.6]. We agree with and adopt Petitioner’s analysis.

h) Limitation [1.7]: wherein the flexible elongated fastening member is configured to slide through the flexible hollow fastener under tension when the flexible hollow fastener is in the first configuration and the second configuration.

Petitioner asserts, as to the recitation in claim 1 [1.7] “wherein the flexible elongated fastening member is configured to slide through the flexible hollow fastener under tension when the flexible hollow fastener is in the first configuration and the second configuration,” that

Fumex describes the flexible elongated fastening member (suture thread 1) as being configured to slide through the flexible hollow fastener (sleeve 5) under tension. Ex. 1004, Abstract (“a deformable sleeve (5) which can slide on the thread (1)”), 2:35-45 (“a deformable tubular envelope or sleeve which is able to slide on the thread”), 5:44-48 (sleeve (5) “is made of deformable and compressible material, capable of sliding on the thread”), 7:29-30 (“the deformable tubular sleeve is able to slide on the thread”). Moreover, such sliding is enabled when the sleeve is in the first configuration (“a first folded position”) and the second configuration (“the shape of a ball”) because the suture thread slides under tension relative to the sleeve as the sleeve deforms from the first configuration to the second configuration. Ex. 1004, 4:18-25.

Pet. 36–37.

Petitioner asserts that “Fumex explains that after deformation, ‘the deformable tubular sleeve is able to slide on the thread within the limits of the closed loop.’ *Id.* 7:22-31; Abstract.” Pet. 37. Petitioner further asserts that

Fumex also suggests that the two strands of thread can be secured after the sleeve is deformed (and away from the sleeve) to prevent “loosening.” *Id.*, 4:28-30. This “loosening” indicates slidability in the second configuration, and is consistent with the fact that sleeve lacks any knot to prevent loosening. Ex. 1002, ¶99.

Pet. 37. Petitioner asserts that “[s]ince the specification fails to provide an adequate description of what is meant by slidability of the fastening member, a POSITA would understand that any amount of slidability within the fastener meets this claim limitation. *Id.* ¶103.” Pet. 38.

Patent Owner asserts

in claim 1 of the ’259 Patent, a flexible elongated fastening member is required to meet the limitations of claim [1.6] while a second flexible elongated fastening member is required to meet

the limitations of claim [1.7] since a single flexible elongated fastening member cannot both be “secure” and slide in the second configuration. Ex 2001, ¶ 66.

PO Resp. 30–31. Patent Owner asserts “Fumex’s suture either slides or is fixed with respect to the sleeve but cannot do both, depending upon whether the closed loop of the bone anchor is fully tightened (fixed) or not fully tightened (slides). Ex 2001, ¶ 69.” *Id.* at 33.

Considering all of the arguments and cited evidence of record, we find that Petitioner shows by a preponderance of the evidence that Fumex teaches or suggests limitation [1.7]. *See* Pet. 36–38.

We begin with the language of limitation [1.7] itself, which identifies the slideable component as “the flexible elongated fastening member.” And while Patent Owner asserts the “claims are not limited to a *single* flexible elongated fastening member,” Patent Owner also states that the “general rule that ‘a’ means ‘one or more’ applies to the claims of the ‘259 Patent.”

PO Resp. 25. And as we discussed above, we adopted Patent Owner’s interpretation of the term “a” as encompassing “one or more” flexible elongated fastening members. Thus, limitation [1.7] is interpreted to include both the situation where there is a single flexible elongated fastening member as in Fumex, as well as situations in which there are multiple elongated fastening members.

As to the situation with a single flexible elongated fastening member, Fumex teaches “a thread having a middle part intended to be introduced into the hole bored beforehand, having a closed loop shape, bearing on the loop-shaped part a deformable tubular envelope or sleeve which is *able to slide* on the thread within the limits of the loop.” Ex. 1004, 2:36–41 (emphasis added). Dr. Jordan states:

As the suture strand is pulled, the anchor's cross section is increased such that it is larger than the hole in the cortical bone and the cortical bone acts as shelf holding the expanded anchor in place. In this second position, wherein the anchor is expanded and secured, the suture is still slidable within the sleeve.

Ex. 1002 ¶ 102. Dr. Jordan explained “you can deploy the anchor, change the configuration and it's, thus, fixed or anchored but still slidable. But if you continue to slide within the limits of the loop, at some point it reaches the end and you can't do it anymore and that's locked.” Ex. 2002, 27:3–8.

We recognize that Dr. Pedowitz has stated that “a second flexible elongated fastening member is required to meet the limitations of claim [1.7] since a single flexible elongated fastening member cannot both be ‘secure’ and slide in the second configuration.” Ex. 2001 ¶ 66. However, in answer to the question of “where within the '259 patent is there description of such a suture anchor that has a first suture that is secure and then a second suture that can continue to slide?” Dr. Pedowitz acknowledged that “I don't think that it was specifically called out in the body. I think it was in the language of the claims.” Ex. 1018, 105:12–22. Dr. Pedowitz also responded “correct” to a question stating that at “some point the sleeve becomes what you would consider to be a lump, but there is still some additional tension that can be applied so the suture can continue sliding at least initially once that lump is created.” Ex. 1018, 110:1–5.

The evidence of record supports Petitioner's position that the single flexible elongated fastening member in Fumex may be sufficiently tensioned to anchor or fix the device within bone and still slide, prior to the point at which the flexible elongated fastening member can no longer slide. Therefore, after considering all of the arguments and cited evidence of

record, we find that Petitioner shows by a preponderance of the evidence that Fumex teaches or suggests limitation [1.7].

2. *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 Fumex.

3. *Claims 3, 4, 6, 8, 10, and 24*

We have reviewed Petitioner's unpatentability arguments regarding claims 3, 4, 6, 8, 10, and 24. *See* Pet. 38–47. 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. 34. We are persuaded on the full trial record that Petitioner has shown by a preponderance of the evidence that claims 3, 4, 6, 8, 10, and 24 are unpatentable as obvious over Fumex for the reasons discussed in the Petition. *See* Pet. 38–47.

4. *Claims 11, 13–16, 19, 20, 22, and 26*

Petitioner asserts that claim 11 is obvious over the combination of Fumex and Grafton, arguing:

(a) [11.P] A deformable fastener system comprising:

See limitation [1.P], *supra*; Ex. 1002, ¶121.

(b) [11.1] a flexible hollow fastener comprised of polymeric biocompatible fibers; and

Fumex describes a flexible hollow fastener comprised of polymeric biocompatible fibers. *See* limitation [1.1], *supra*; Ex. 1004, 4:50-63 (sleeve fabricated from braid of polyester, *i.e.*, polymeric biocompatible material); Ex. 1002, ¶122.

(c) [11.2] a flexible elongated fastening member extending through the flexible hollow fastener such that two legs of the flexible elongated fastening member extend from the flexible hollow fastener,

Fumex describes a flexible elongated fastening member extending through the flexible hollow fastener such that two legs of the flexible elongated fastening member extend from the flexible hollow fastener. *See* limitation [1.6], *supra*; Ex. 1002, ¶123.

(d) [11.3] wherein the flexible hollow fastener is configured to deform from a first configuration to a second configuration to secure the flexible elongated fastening member in body tissue as at least one of the two legs of the flexible elongated fastening member portion is tensioned relative to the body tissue, and

Fumex describes the flexible hollow fastener (*i.e.*, sleeve 5) being configured to deform from a first configuration to a second configuration to secure the flexible elongated fastening member in body tissue (*i.e.*, at the distal end of a hole bored in bone). *See* limitation [1.6], *supra*; Ex. 1002, ¶124.

This change in configuration happens as at least one of the suture legs is tensioned relative to the body tissue:

when the loop is tightened *by pulling on at least one of the two strands of the thread*, the latter is applied against the sleeve and *causes its deformation, changing it from a first stretched position to a second position in which it is folded on itself and in which its cross section is increased*.

Ex. 1004, 3:1-17 (emphasis added); Ex. 1002, ¶125.

(e) [11.4] wherein the flexible elongated fastening member is configured to slide through the flexible hollow fastener under tension when the flexible hollow fastener is in the first configuration and the second configuration.

Fumex describes the flexible elongated fastening member being configured to slide through the flexible hollow fastener under tension when the flexible hollow fastener is in the first configuration and the second configuration. *See* limitation [1.7], *supra*; Ex. 1002, ¶126.

Pet. 43–44.

Patent Owner asserts that

Claim element [11.3], like element [1.6], requires fixing, anchoring, or attaching (the fastener *and* the elongated fastening member) firmly so that they cannot be moved relative to their points of attachment when the fastener is deformed to its second configuration (when “it adopts the shape of a ball” according to Petitioner). Ex 2001, ¶ 78, Ex 1002, ¶ 98.

A single flexible elongated fastening member cannot both be “secure” and slide in the second configuration. Ex 2001, 78. It follows that claim 11, like claim 1, requires a flexible elongated fastening member to meet the limitations of claim element [11.3] and requires a second flexible elongated fastening member to meet the limitations of claim element [11.4]. *Id.*

PO Resp. 34–35. Patent Owner asserts “Claims 13–16, 19–20, 22 and 26 depend directly or indirectly from claim 11 and are not obvious for the same reasons provided for claim 11.” *Id.* at 36.

We have reviewed Petitioner’s unpatentability arguments regarding claims 11, 13–16, 19, 20, 22, and 26. *See* Pet. 43–44. Beyond the arguments we already discussed above with respect to elements [1.6] and [1.7] of claim 1 which are identical to those for elements [11.3] and [11.4], Patent Owner did not make any additional arguments for these claims. *See* PO Resp. 35–36. We are persuaded on the full trial record that Petitioner has shown by a preponderance of the evidence that claims 11, 13–16, 19, 20, 22, and 26 are unpatentable as obvious over Fumex and Grafton for the reasons discussed in the Petition. *See* Pet. 43–44.

5. *Claims 7 and 18*

Petitioner asserts “Fumex describes a knotless hollow fastener. The suture is passed through the tubular sleeve such that loop 2 is formed. Ex. 1004, 5:38-57, Fig. 1. However, neither strand 3, 4 extending from the sleeve is passed through the loop to form a knot.” Pet. 40. Petitioner asserts that instead of a knot, “the sleeve is deformed into a ball by ‘exerting a

traction on the strands of the thread in diverging directions,’ anchoring the suture to bone. *Id.*, 3:7-17, 5:38-57.” *Id.* Petitioner asserts that because “a POSITA would have understood ‘knotless’ to refer to the elimination of surgical knot-tying to retain the fastener rather than the elimination of anything that qualifies generally as a ‘knot,’ Fumex would constitute a ‘knotless’ fastener as properly construed.” Pet. Reply 20.

Patent Owner asserts “Fumex does not disclose a flexible hollow fastener that is ‘knotless’ as Patent Owner and Dr. Pedowitz have construed this term in this Proceeding.” PO Resp. 36. Patent Owner asserts that under their claim construction of “knotless,” “Fumex’s suture anchor is knotted because it has looping of a cord (*e.g.*, suture) drawn tight into a knob or lump (*e.g.*, a ball) for fastening the cord to something else (*e.g.*, the sleeve) according to the definition of a knot.” *Id.* at 36–37. Patent Owner asserts “[i]t is the *formation* of this knot that provides the requisite compression force against the sides of a bone passage to form a compression fit to retain the fastener in the bone and anchor the fastener. Ex 1002, ¶ 115, Ex 2001, ¶ 86.” *Id.* at 37.

Patent Owner points to Dr. Jordan’s testimony that “by deforming Fumex’s bone anchor to the second configuration by sliding the suture within the limits of the closed loop, there will be ‘a bigger **knot**’ closer to the cortical bone.” PO Resp. 37 (citing Ex. 2002, 19:21–20:8). Patent Owner also asserts that as discussed for claims 1 and 11, “Fumex fails to describe or suggest claim elements [1.6] or [11.3].” *Id.* at 38.

Considering all of the arguments and cited evidence of record, we find that Petitioner shows by a preponderance of the evidence that Fumex teaches or suggests the “knotless” limitation of claims 7 and 18. *See* Pet. 40–41.

As discussed in the claim interpretation section VIII.C. *supra*, we construe “knotless,” as used in reference to a fastener, to mean “a fastener that can be retained in place without tying a knot at the site where the fastener is secured.”

There is no substantive dispute that the fastener of Fumex does not include tying a knot within the bone. As Dr. Pedowitz notes “since these are anchors that go within bone, it’s literally impossible to tie a knot at the site where the fastener is secured. I don’t know how one would tie a knot within bone.” Ex. 1018, 12:20–23. And Dr. Jordan expressly stated that he considered jumbled sutures pressed into a hole and pulled tight as not a knot (*i.e.*, knotless) but rather simply functioning as an anchor. Ex. 2002, 40:11–41:9. Further, Fumex does not use the term “knot” to refer to the balled up sleeve, but rather states that “when the sleeve is *folded* into a ball shape, as indicated above, the enlargement of its diameter compared to the initial diameter of the sleeve, and the pleated shape of its surface, increase the phenomenon of anchoring.” Ex. 1004, 4:32–35 (emphasis added).

We determine that the term “knot,” which does not even appear in the challenged claims, does not need a construction separate from the construction of “knotless.” We find on the complete trial record that Patent Owner’s proposed position regarding “knot” is unsupported. First, Patent Owner contends that its dictionary definition of “knot” is consistent with the Specification, but fails to adequately explain the basis for this statement. PO Resp. 24 (citing Ex. 1001, 11:36, 15:34–53); *see also* Ex. 2001 (Pedowitz Decl.) ¶ 41, Ex. ¶ 2004, 4. Patent Owner cites column 11, line 36 of the Specification, which merely uses the word “knotless” without any further elaboration. *See id.* Patent Owner also cites column 15, lines 34 through 53.

See id. This portion of the Specification refers to sections of suture that “may be secured with a knot *or* a fastener.” Ex. 1001, 15:34–54 (emphasis added). Patent Owner fails to explain—and we are unable to ascertain—how this paragraph is purportedly consistent with Patent Owner’s proffered dictionary definition of the term “knot.”

Patent Owner appears to rely on the dictionary definition to support an argument that “knots” do not necessarily require tying. Specifically, in calling out the Blackwall hitch, Patent Owner argues that although the dictionary deems it a knot, it “does not involve tying.” PO Resp. 24; Ex. 2001 (Pedowitz Decl.) ¶ 39 (same). However, as Dr. Jordan testifies, in the context of the types of surgeries relevant here, a person of ordinary skill in the art would not have described a hitch as a knot. Specifically, when Dr. Jordan was asked whether a jumble of half-hitches anchored in a bone passage would be characterized as a knot, he responded:

In the traditional sense, I wouldn’t characterize it as a knot. I would characterize it as an anchor, much like any configuration that deforms and then becomes in a different shape and can’t passage back out. But the half [hitches]¹¹ are considered knots, but it’s not the ordinary term for a knot. In the normal practice of surgery that sort of thing has been done and it’s not what we dictate in an operative note as a knot was tied. We would say, the anchor was deployed and fixed to the tissue with resistance or another description, depending on what you do.

Ex. 2002 (Jordan Depo. Tr.), 40:18–41:17. Counsel further asked, “You’d agree, wouldn’t you, that that collection of half [hitches] that kept the suture

¹¹ The deposition transcript uses the phrase “half inches” instead of “half hitches.” Both parties confirmed that “half inches” is a typographical error, and that “half hitches” is the correct term. *See* Tr. 17:11–15, 50:24–51:4. Patent Owner’s counsel explains that a “half hitch” is “a loop that’s drawn tight in a bow.” *Id.* at 51:3–4.

from being pulled from the bone is a knot?,” and Dr. Jordan replied: “Yes. But as I described it, we don’t normally talk about it like that. But I agree, you used what was normally known as a knot to fix the suture to the bone.”¹² *Id.* at 41:19–42:4. In other words, although Dr. Jordan acknowledged that in general parlance a hitch is characterized as a knot, in the context of surgeries like those relevant here, a person of ordinary skill in the art would not have considered a hitch a knot. *See id.*; Reply 18 n.6.

For the above reasons, we find that Patent Owner’s proffered dictionary definition of “knot” is inapt, because it does not represent how the term “knot” as used in the relevant surgical art. “[A] general-usage dictionary cannot overcome art-specific evidence of the meaning’ of a claim term.” *Phillips*, 415 F.3d at 1322 (quoting *Vanderlande Indus. Nederland BV v. Int’l Trade Comm’n*, 366 F.3d 1311, 1321 (Fed. Cir. 2004)). Accordingly, we do not adopt Patent Owner’s proposed dictionary definition of “knot.” Based on our interpretation of “knotless” as drawn to anchors that do not involve tying a knot, we are persuaded on the full trial record that Petitioner has shown by a preponderance of the evidence that claims 7 and 18 are unpatentable as obvious over Fumex and Grafton for the reasons discussed in the Petition. *See* Pet. 40.

¹² Similarly, although Dr. Jordan referred to a “bigger knot” when discussing Fumex, he did not describe Fumex as requiring **tying** of a knot. *See* Ex. 2002 (Jordan Depo. Tr.), 19:21–20:8. Our construction requires elimination of knot-**tying**; it does not encompass the elimination of any structure that could be considered a “knot” in the general sense of the word. *See* Pet. Reply 20–21 n.7; Tr. 16:10–17:10.

E. Ground 4: Obviousness over Fumex, Grafton, and Bonutti '875

Petitioner asserts “Fumex’s bone anchoring device includes a tubular sleeve that is deformed into a ball—and thus fastened—at the distal end of a bone hole without knotting. Ex. 1004, 3:7-17, 5:38-57 . . . Subsequently, the two legs of the suture that extend out of the bone can be knotted. Ex. 1004, 4:28-31; Ex. 1002, ¶164.” Pet. 54. Petitioner asserts that “Bonutti ’875 is directed to suturing body tissue with suture fasteners that are ‘easier to form and stronger than conventional tied knots.’ Ex. 1007, 2:1-28. Such fasteners can be used to secure a suture extending from body tissue. *Id.*, 7:37-44, 8:40-60, Figs. 7A-C, 10.” Pet. 55.

Petitioner asserts a “POSITA would have understood that the suture fastener of Bonutti ’875 could have advantageously replaced the optional suture knot described by Fumex” (Pet. 56) because

Bonutti ’875 describes circumstances in which using a knotless fastener would be advantageous, including: (1) when it would be difficult to tie a knot due to a limited working area, Ex. 1007, 6:47-48; (2) if tying would not produce a strong enough connection and there was a risk of untying, *id.*, 6:53-57; and (3) if buckling of tissue edges due to force vectors was a concern, *id.*, 7:9-14; Ex. 1002, ¶¶165-67.

Pet. 55. Petitioner further asserts a “POSITA would have had a reasonable expectation of success in combining Fumex’s bone anchoring device, including the suture legs that extend from the proximal end of a bone hole, with the suture fastener of Bonutti ’875” because “Bonutti ’875 further discloses that its fasteners can be used with polymeric sutures such as those described by Fumex. Ex. 1007, 3:44-46.” Pet. 57.

Patent Owner asserts “even if a fastener as disclosed in Bonutti ’875 was used with the Fumex bone anchor in forming a construct, the construct

would still include a knot because it includes the Fumex bone anchor knot.”

PO Resp. 40. Patent Owner notes that this ground was “proposed by Petitioner, ‘[t]o the extent that Patent Owner may argue that use of a knot anywhere in the system would preclude the fastener from being ‘knotless’ within the meaning of dependent claims 7 and 18.’ Petition, 54, Ex 1002, 171. Patent Owner does not make such an argument.” PO Resp. 39.

Patent Owner is therefore relying on the same “knotless” argument as discussed above in Ground 2. Based on our interpretation of “knotless” as drawn to fasteners that do not involve tying a knot, we are persuaded on the full trial record that Petitioner has shown by a preponderance of the evidence that claims 7 and 18 are unpatentable as obvious over Fumex, Grafton, and Bonutti ’875 for the reasons discussed in the Petition. *See* Pet. 40.

F. Ground 6: Obviousness over Fumex, Grafton, and Bonutti ’395

Petitioner asserts “Fumex’s bone anchoring device includes a rod that is used to insert the hollow deformable sleeve (including a suture thread passed through the sleeve) into a hole bored in the bone. Ex. 1004, 3:63-66.” Pet. 60. Petitioner asserts that although

Fumex contemplates bone hole shapes beyond simple straight passages, Fumex does not expressly state that the rod is flexible, as would be used when inserting the sleeve and thread through a nonlinear passage. However, flexible pushrods were known in the field of orthopedic surgery at the relevant time and a POSITA would have been familiar them. Ex. 1002, ¶¶179, 181.

Pet 61. Petitioner asserts that “Bonutti ’395’s apparatus includes a flexible pusher member for use in surgical applications in which a suture must be inserted into a nonlinear hole drilled in bone. Ex. 1006, 10:23-12:8.”

Pet. 61. Petitioner asserts that the use of a flexible rod would have been

obvious because “[c]ombining Bonutti ’395 with Fumex could yield, for example, a linear yet flexible rod that could accommodate bored holes having any shape, such as a curved hole or a hole in which two linear passages meet at an angle. Ex. 1002, ¶182.” Pet. 62.

Patent Owner asserts that claims 23 and 25 are “not obvious for the same reasons advanced in Ground 1 with respect to claim element [1.6]” and the “same reasons advanced in Ground 1 with respect to claim element [11.3],” respectively. PO Resp. 42.¹³

These arguments are unavailing, because Petitioner does not rely on Bonutti ’395 to teach or suggest limitations [1.6] and [11.3], and we have already found Fumex teaches these limitations. *See generally* Pet. 60–62.

Based on the entire record, we determine that Petitioner has established that claims 23 and 25 are unpatentable under § 103 as obvious over Fumex, Grafton, and Bonutti ’395.

G. Ground 8: Obviousness over Fumex, Grafton and Stone

Claims 2 and 12 depend from claims 1 and 11, respectively, and recite the system “further comprising at least one additional leg of a flexible elongated fastening member configured to extend from the flexible hollow fastener.” Ex. 1001, 27:48–50, 28:25–27.

Petitioner asserts that “[w]hile Fumex does not limit the number of sutures that can be passed through the flexible sleeve, Fumex does not expressly state that more than one suture is used.” Pet. 66. Petitioner asserts that “Stone recognizes that ‘multiple sutures are often required for soft tissue

¹³ We note that this same argument is applicable to Ground 2, which was analyzed above.

repair’ and discloses a suture anchor assembly specially designed to ‘accommodate[] multiple suture fixation.’ Ex. 1010, 2:3-14.” Pet. 67.

Petitioner asserts that a “POSITA would have found it obvious to apply the teachings of Stone, which specifically describes use of multiple sutures with a bone fastener to Fumex.” because “using multiple sutures is often beneficial depending on the surgical procedure (e.g. reapproximation of soft tissue having a wide footprint), and Stone confirms this understanding..” Pet. 68 (citing Ex. 1002, ¶¶ 199–200; Ex. 1004 at 2:10-11).

Patent Owner repeats the assertion that “claim element [1.6] is missing from Fumex” because “a single flexible elongated fastening member cannot both be ‘secure’ and slide in the second configuration” based on their interpretation of the term “secure.” PO Resp. 44–45 (citing Ex. 2001 ¶¶ 47, 48, 66). Patent Owner asserts that

Petitioner and Dr. Jordan do not indicate how placing two sutures in like manner into Fumex’s bone anchor will “secure” the suture as Patent Owner and Dr. Pedowitz construe that term in this Proceeding to meet claim element [1.6].

For this reason alone, claim 2 is not obvious from Fumex and Stone because the combination lacks claim element [1.6] when Fumex’s bone anchor is in the second (not fully tightened) configuration asserted by Dr. Jordan, yet contains two sutures that slide within the sleeve.

Id. at 47.

Patent Owner also asserts that “[c]laim 2 further requires claim element [2.1] ‘The system . . . further comprising *at least one additional leg of a flexible elongated fastening member configured to extend from the flexible hollow fastener.*’ The emphasized portion of claim element [2.1] is missing from Fumex. Ex 2001, ¶ 111.” PO Resp. 47. Patent Owner asserts “if two sutures are used in Fumex’s anchor, Fumex’s anchor would then

need to accommodate four suture threads in adding another looped suture within the sleeve (5). Ex 2001, ¶ 119.” *Id.* at 48. Patent Owner asserts that a

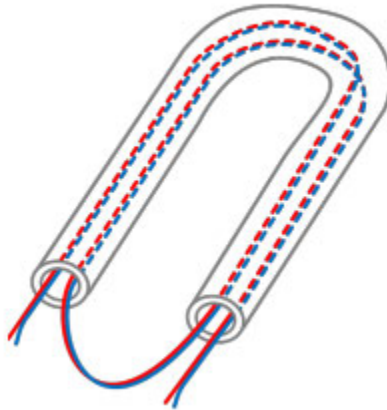
POSITA would have reasonably expected that a second suture, “much like the looped suture” already depicted in Fumex’s figures, would interfere with closure of the loop in the first suture and therefore limit closure to an extent that the principle of operation of the Fumex bone anchor is adversely affected by tangling between the sutures if they are not all pulled at the same time and the same rate. Ex 2001, ¶ 121. For this reason, a POSITA would not have had a reasonable expectation of success in so combining Fumex and Stone to provide multiple sutures in Fumex’s bone anchor having a looped suture. *Id.*

Id. at 49.

Patent Owner’s repetition of the assertions regarding element [1.6] are unavailing, because Petitioner does not rely on Stone to teach or suggest limitation [1.6] and we have already found Fumex teaches this limitation. *See supra.*

As to limitation [2.1], Patent Owner does not challenge Petitioner’s assertion that there would have been a motivation and reason to use two sutures as taught by Stone in the fastener system of Fumex as “often beneficial depending on the surgical procedure.” Ex. 1002 ¶ 200. Rather, Patent Owner disputes whether there would have been a reasonable expectation of success in doing so. We therefore turn to the expert testimony to address the reasonable expectation of success issue.

Dr. Jordan states “two sutures could be looped through the anchor such that the two suture stands run next to one another along their lengths, as shown in the figure below”



Ex. 1027 ¶ 4 (the figure depicts a hollow elongated sleeve with two separate looped threads that run next to each other). Dr Jordan states “a POSITA would understand that the anchor would be dimensioned appropriately and made of suitable material(s) to allow for the anchor to operate as indicated while accommodating two sutures.” Ex. 1027 ¶ 5.

Dr. Pedowitz states a

POSITA would have reasonably expected that a second suture, “much like the looped suture” already depicted in Fumex’s figures, would interfere with closure of the loop in the first suture and therefore limit closure to an extent that the principle of operation of the Fumex bone anchor is adversely affected by tangling between the sutures if they are not all pulled at the same time and the same rate.

Ex. 2001 ¶ 121. In response to the question addressing the use of an additional suture thread asking if a “person of ordinary skill in the art looking at this type of device would understand if they wanted to lower the potential for interference, as you’re discussing, one way that they could do that would be with dimensioning of the components, including both the sleeve and the suture; correct?” Dr. Pedowitz answered “Well. Yeah.”

Ex. 1018, 124:10–17. Dr. Pedowitz also stated “you could make it

deliberately out of something slippery. And, of course, if you do that and you make the suture slippery, it might have the advantage of sliding through the sleeve more easily.” Ex. 1018, 125:21–25. Dr. Pedowitz does state “two different sutures going around the racetrack I think you’d predict that that would be a pretty unreliable construct. But it’s possible to do it and it would have to be tested in the lab to know if it would work. I just don’t think it would work.” Ex. 1018, 127:16–21.

Both experts agree that a fastener system of claim 2 is capable of manufacture. Ex. 1027 ¶ 4, Ex. 1018, 127:16–21. Dr. Jordan asserts that a two suture fastener would reasonably be expected to function. Ex. 1027 ¶ 5. Dr. Pedowitz acknowledges that selection of the suture material for slipperiness would make function more feasible but expects a two suture fastener to be unreliable and require testing. Ex. 1018, 127:16–21. However, Dr. Pedowitz also stated that the tangling concern was focused on the situation where the sutures “are not all pulled at the same time and the same rate.” Ex. 2001 ¶ 121. Dr. Pedowitz therefore implicitly suggests that a fastener system as in Fumex with two sutures where both sutures were pulled at the same time and same rate would not have the tangling concern and would therefore reliably function. This evidence supports a reasonable expectation of success.

Considering all of the arguments and cited evidence of record, we find that Petitioner shows by a preponderance of the evidence that Stone, when combined with Fumex and Grafton, teaches or suggests the use of multiple sutures in the flexible hollow fastener of Fumex with a reasonable expectation of success. *See* Pet. 66–68.

H. Ground 10: Obviousness over Fumex, Grafton, Stone, and To

Petitioner asserts that claims 5, 9, 17, and 21 are unpatentable as obvious over Fumex, Grafton, Stone, and To. Pet. 71–78. Petitioner asserts “Fumex’s bone anchoring system includes a suture that is passed through a flexible sleeve and Stone describes a suture anchor assembly specially designed to accommodate multiple sutures.” Pet. 71. Petitioner asserts

To describes a surgical device for the deployment of tissue anchors that “may be configured to receive at least two anchors therein, for deploying multiple anchors serially or sequentially” and describes that a linking material, such as a suture, may be used to couple multiple anchors together. Ex. 1011 at ¶¶ 12, 13, 55, 56; Ex. 1002, ¶207.

Pet. 71. Petitioner asserts “a cinching strand, or tether (406)/(708) may be connected to the sleeve and anchors as the anchors are deployed.” Pet. 72.

Petitioner asserts that a “POSITA would have found it obvious to fix one of the sutures described in Stone to Fumex’s flexible anchor, and to couple multiple anchors together by attaching one of the legs of a suture to a second anchor, as To suggests” because “a suture fixed to an anchor provides benefits, such as allowing the surgeon to tighten the suture between anchors after the anchors are deployed. Ex. 1011 at ¶43; Ex. 1002, ¶211.” Pet. 73–74.

Patent Owner asserts “[c]laims 5 and 17 are not obvious from the combination of Fumex, Stone and To because the combination is missing claim elements [1.3], [1.6] and [2.1] of claim 5 and claim elements [11.3] and [12.1] of claim 17.” PO Resp. 53. Patent Owner asserts

The teachings of To do not describe “fixing a suture to a flexible bone fastener” as asserted by Dr. Jordan. *Id.* The To publication does not mention anywhere that the anchors are intended for

fixation into bone. In fact, the word “bone” does not appear within the document. The To publication states that “exemplary procedures include repair of heart valves (e.g., mitral, tricuspid, aortic), repair or reduction of sphincters, closure of wounds, and in reducing the circumference of the gastroesophageal junction.” Ex 1011, ¶ 25.

Id. at 54–55. Patent Owner asserts that in To “the anchors are drawn together by a cinching mechanism to decrease the circumference of a soft tissue. This is not analogous to an orthopaedic application of a bone anchor. Ex 2001, ¶ 147.” *Id.* at 55. Patent Owner asserts that “To’s cinching strand would have been completely ineffective in achieving To’s purpose of decreasing the distance between anchors in the context of a bone anchor.” *Id.* at 56. Patent Owner asserts the “To publication describes **multiple** soft tissue **anchors** that are linked via a **single suture**; it does not describe or suggest **a single anchor** connected to **multiple sutures**. Ex 2001, ¶ 143.” *Id.* Patent Owner therefore asserts that a “POSITA would not have considered To as it is not in the same field and is irrelevant to the claimed subject matter. Ex 2001, ¶ 152.” *Id.*

Patent Owner asserts that “claims 9 and 21 require connecting a second fastener to the flexible elongated fastening member.” PO Resp. 59. Patent Owner asserts that a “POSITA would have recognized that if the Fumex anchor is implanted first (anchor 1) and the thread from anchor 1 is to be connected to a Stone bone anchor (anchor 2), then there is no way to properly secure the thread to make the connection.” PO Resp. 59 (citing Ex. 2001 ¶ 157). Patent Owner asserts that

Likewise, a POSITA would have recognized that if a Fumex or Stone bone anchor is implanted first (anchor 1) and the thread from anchor 1 is to be connected to a Fumex bone anchor (anchor 2), then there is no way to properly secure it. *Id.*,

¶ 158. During surgery, a surgeon could not weave a thread coming off of anchor 1 into, through and out of the sleeve of anchor 2 before placement of anchor 2, and could not pull on the strands of anchor 2 to create the balling up mechanism. *Id.*

PO Resp. 60.

Patent Owner's repetition of the assertions regarding elements [1.3], [1.6], [2.1], [11.3] and [12.1] are unavailing, because Petitioner does not rely on To to teach or suggest these limitations and we have already found Fumex, Grafton, and/or Stone teach these limitations. *See supra.*

Claims 5 and 17 recite "wherein the at least one additional leg of flexible elongated fastening member is fixed to the flexible hollow fastener." Ex. 1001, 27:55–57, 28:40–42. Claim 9 recites "connecting a second fastener to at least one leg of the flexible elongated fastening member to secure at least one of the tension in the flexible elongated fastening member and a position of the flexible elongated fastening member." Ex. 1001, 27:65–28:3. Claim 21 recites "connecting a second fastener to the flexible elongated fastening member." Ex. 1001, 28:49–51.

As discussed *supra*, Stone teaches the use of multiple suture threads within a single anchor with an additional leg of a flexible elongated fastening member. Ex. 1027 ¶ 4. To teaches that one use for a second suture thread is "to tighten the slack between the anchors after they are deployed." Ex. 1011 ¶ 43. As Petitioner points out, To's cinching would "be applicable to a Fumex anchor that is connected to a second anchor when one or both anchors are inserted into soft tissue." Pet. Reply 27. That is, claims 5 and 17, dependent from claims 1 and 11, require a fastener meeting the claim limitations but we do not interpret these claims as excluding the combination of the claimed fasteners with other types of fasteners or tissues,

such as situations where a hard tissue like bone is connected to a softer tissue. Indeed, the '259 patent acknowledges the combination of different fasteners, stating the “characteristics and features of the fasteners and fastening methods just described may be combined and integrated with the devices and methods of the present invention.” Ex. 1001, 11:25–28.

Dr. Jordan supports Petitioner’s position, stating “Stone recognizes that ‘multiple sutures are often required for soft tissue repair’ and discloses a suture anchor assembly specially designed to ‘accommodate[] multiple suture fixations.’ Ex. 1010, 2:3–14.” Ex. 1002 ¶ 196. Dr. Jordan also states that it “would have been obvious to connect at least one leg of a suture extending from the fastener to a second fastener (as described in To), known as bridging, in order to support tissue between the anchors and provide additional support for a repair.” Ex. 1002 ¶ 210. Dr. Jordan states “Fumex, Stone, and To are in the same field (securing bone to another organ or tissue using a suture anchor), and a POSITA would have naturally looked to To when considering the nature, characteristics and number of sutures and fasteners to use.” Ex. 1002 ¶ 214.

Dr. Pedowitz states that To is directed towards “soft tissue procedures that do not involve fixation to bone.” Ex. 2001 ¶ 146. Dr. Pedowitz states “a POSITA would have recognized that To’s cinching strand would have been completely ineffective in achieving To’s purpose of decreasing the distance between anchors in the context of a bone anchor.” Ex. 2001 ¶ 148. Dr. Pedowitz states a “POSITA would not look to publications pertaining to intravascular access for cardiac valve repair, or to methods for gastroesophageal sphincter surgery using purse string reduction, as natural

solutions for interconnection of multiple sutures to anchors that are rigidly fixed in bone.” Ex. 2001 ¶ 152.

But in response to the question “if you have a first anchor with suture coming from it in that construct, you can either tie the suture knot or utilize, as you’ve described it, the lateral row in a bridging construct and place that second anchor into bone; correct?” Dr. Pedowitz answered affirmatively “yeah.” Ex. 1018, 143:22–144:1.

“Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Dr. Jordan and Dr. Pedowitz differ on both the field of endeavor and on whether To is pertinent to the particular problem with which the inventor was involved. *See* Ex. 1002 ¶ 214, Ex. 2001 ¶ 152. We find Dr. Jordan’s position more persuasive. In particular, the evidence better supports that the field of endeavor is the slightly broader field of securing bone to another organ or tissue using a suture anchor rather than the narrower field limited to solely securing bones together. This understanding is supported by the ’259 patent itself, which explains that “physicians use various methods and devices to attach soft tissue to other soft tissue, soft tissue to hard tissue, and hard tissue to other hard tissue.” Ex. 1001, 1:23–25. Indeed the ’259 patent identifies the field of endeavor even more broadly under the heading “FIELD” as “apparatus and methods for surgery.” Ex. 1001, 1:14–16. There is no reasonable dispute that all of Petitioner’s cited prior art is drawn

to apparatus for use in surgery, and for attaching tissues to one another. *See* Ex. 1004, 1:7–12, 4:38–43; Ex. 1005 ¶ 9; Ex. 1010, 1:9–27; Ex. 1011 ¶ 2.

Considering all of the arguments and cited evidence of record, we find that Petitioner shows by a preponderance of the evidence that To, when combined with Stone, Fumex, and Grafton, teaches or suggests the multiple anchor and tensioning requirements of claims 5, 9, 17, and 21 with a reasonable expectation of success. *See* Pet. 71–78. We also find these references fall within the same field of endeavor. *See* Ex. 1002 ¶ 214.

X. CONCLUSION

After considering the evidence and arguments presently before us in the complete trial record, we conclude that Petitioner has demonstrated, by a

preponderance of the evidence, that challenged claims 1–26 of the '259 patent are unpatentable.¹⁴

In summary:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not shown Unpatentable
1, 3, 4, 6–8, 10, 11, 13–16, 18–20, 22, 24, 26	103	Fumex ¹⁵		
1, 3, 4, 6–8, 10, 11, 13–16, 18–20, 22, 24, 26	103	Fumex, Grafton	1, 3, 4, 6–8, 10, 11, 13–16, 18–20, 22, 24, 26	
7, 18	103	Fumex, Bonutti '875 ¹⁶		
7, 18	103	Fumex, Grafton, Bonutti '875	7, 18	
23, 25		Fumex, Bonutti '395 ¹⁷		
23, 25		Fumex, Grafton, Bonutti '395	23, 25	

¹⁴ 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, 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 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).

¹⁵ As explained above, we do not reach this alternative ground.

¹⁶ As explained above, we do not reach this alternative ground.

¹⁷ As explained above, we do not reach this alternative ground.

2, 12		Fumex, Stone ¹⁸		
2, 12		Fumex, Grafton, Stone	2, 12	
5, 9, 17, 21		Fumex, Stone, To ¹⁹		
5, 9, 17, 21		Fumex, Grafton, Stone, To	5, 9, 17, 21	
Overall Outcome			1–26	

XI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–26 of U.S. Patent 10,376,259 B2 patent are determined to be unpatentable; and

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

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¹⁸ As explained above, we do not reach this alternative ground.

¹⁹ As explained above, we do not reach this alternative ground.

IPR2022-01066
Patent 10,376,259 B2

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