

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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ARTHREX, INC.  
Petitioner

v.

P TECH, LLC  
Patent Owner

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Case No. IPR2022-01066  
Patent No. 10,376,259

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**PETITION FOR INTER PARTES REVIEW  
OF U.S. PATENT NO. 10,376,259**

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## **PETITIONER’S EXHIBITS**

| <b>Exhibit</b> | <b>Description</b>   |
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| 1001           | U.S. Patent No. 10,376,259 (“’259 Patent”)                                     |
| 1002           | Declaration of Steve E. Jordan, M.D.   |
| 1003           | Curriculum Vitae of Steve E. Jordan, M.D.                                      |
| 1004           | U.S. Patent No. 6,511,498 (“Fumex”)  |
| 1005           | U.S. Patent Publication No. 2003/0050666 (“Grafton”)                           |
| 1006           | U.S. Patent No. 6,238,395 (“Bonutti ’395”)                                     |
| 1007           | U.S. Patent No. 5,735,875 (“Bonutti ’875”)                                     |
| 1008           | Prosecution History of U.S. Application No. 11/202,294                         |
| 1009           | Prosecution History of U.S. Application No. 13/871,892                         |
| 1010           | U.S. Patent No. 5,443,482 (“Stone”)  |
| 1011           | U.S. Patent Application Publication No. 2007/0055206 (“To”)                    |
| 1012           | Prosecution History of U.S. Application No. 15/726,503                         |
| 1013           | U.S. Patent Application Publication No. 2001/0002440 (“Bonutti ’440”)          |
| 1014           | CONMED’s Linvatec Subsidiary Introduces Fourteen New Products (March 10, 2004) |
| 1015           | Herculine Polyethylene Suture (March 13, 2006)                                 |
| 1016           | Smith & Nephew ULTRABRAID Suture (May 7, 2004)                                 |

## **CLAIM LISTING**

- [1.P] 1. 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.
2. The system of claim 1, further comprising at least one additional leg of a flexible elongated fastening member configured to extend from the flexible hollow fastener.
  3. The system of claim 1, wherein the flexible hollow fastener is a suture anchor.
  4. The system of claim 1, wherein the flexible elongated fastening member includes a suture.
  5. The system of claim 2, wherein the at least one additional leg of flexible elongated fastening member is fixed to the flexible hollow fastener.
  6. The system of claim 1, wherein the flexible hollow fastener and flexible elongated fastening member include a similar polymer material.

7. The system of claim 1, wherein the flexible hollow fastener is knotless.
8. The system of claim 1, wherein the flexible hollow fastener is a suture-like structure.
9. The system of claim 5, further comprising 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.
10. The system of claim 1, wherein the flexible hollow fastener and flexible elongated fastening member include a dissimilar polymer material.

[11.P] 11. 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.

12. The system of claim 11, further comprising at least one additional leg of a flexible elongated fastening member configured to extend from the flexible hollow fastener.
13. The system of claim 11, wherein the flexible hollow fastener and flexible elongated fastening member include a dissimilar polymer material.
14. The system of claim 11, wherein the flexible elongated fastening member includes a suture.
15. The system of claim 11, wherein the flexible elongated fastening member includes at least in part one of polyester and polyethylene.

16. The system of claim 11, wherein the flexible hollow fastener and flexible and elongated fastening member include a similar polymer material.
17. The system of claim 12, wherein the at least one additional leg of the flexible elongated fastening member is fixed to the flexible hollow fastener.
18. The system of claim 11, wherein the flexible hollow fastener is knotless.
19. The system of claim 11, wherein the flexible hollow fastener is a suture anchor.
20. The system of claim 11, wherein the flexible hollow fastener is a suture-like structure.
21. The system of claim 17, further comprising connecting a second fastener to the flexible elongated fastening member.
- [22.1] The system of claim 11, further comprising an introducer with a pushrod configured to engage the flexible hollow fastener,

[22.2] wherein flexible hollow fastener and flexible elongated fastening member are positioned on the distal end of the pushrod.

- 23. The system of claim 1, wherein the pushrod is flexible.
- 24. The system of claim 1, wherein the introducer has at least one of a linear configuration and a curved configuration.
- 25. The system of claim 22, wherein the pushrod is flexible.
- 26. The system of claim 22, wherein the introducer has at least one of a linear configuration and a curved configuration.



Pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq.*, Arthrex, Inc. (“Arthrex” or “Petitioner”) requests *inter partes* review (“IPR”) of claims 1-26 of U.S. Patent No. 10,376,259 (“the ’259 Patent”) (Ex. 1001) pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq.* The ’259 Patent is subject to pre-AIA 35 U.S.C. §§ 102 and 103.

## **I. MANDATORY NOTICES**

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

Petitioner certifies that Arthrex, Inc. is the real party-in-interest.

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

The ’259 Patent is currently involved in the following proceeding:

- *P Tech, LLC v. Arthrex, Inc.*, Case No. 1-21-cv-00968 (D. Del.).

The following IPRs challenge the other patents asserted in the above-referenced district court proceeding:

- *Arthrex, Inc. v. P Tech, LLC*, PTAB-IPR2022-01043, filed May 23, 2022 and challenging U.S. Patent No. 9,814,453;
- *Arthrex, Inc. v. P Tech, LLC*, PTAB-IPR2022-00717, filed March 31, 2022 and challenging U.S. Patent No. 10,881,440;
- *Arthrex, Inc. v. P Tech, LLC*, PTAB-IPR2022-00786, filed April 8, 2022 and challenging U.S. Patent No. 9,279,129; and
- *Arthrex, Inc. v. P Tech, LLC*, PTAB-IPR2022-00787 filed April 11, 2022 and challenging U.S. Patent No. 9,999,449.

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

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Service information for lead and backup counsel is provided in the designation of lead and backup counsel, above. Petitioner consents to electronic service by email at the email addresses provided above.

**D. Payment of Fees Under 37 C.F.R. §§ 42.15(a) & 42.103**

The required fees are submitted herewith in accordance with 37 C.F.R. §§ 42.103(a) and 42.15(a). If any additional fees are due during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 22-0261. Any overpayment or refund of fees may also be deposited in this Deposit Account.

## **I. INTRODUCTION**

The '259 Patent is entitled “Deformable Fastener System,” although much of the patent disclosure relates to a “guided positioning ... method and device.” Ex. 1001, Abstract.

The challenged claims of the '259 Patent are directed to fastener systems that include two basic elements: (1) a flexible elongated fastening member (*e.g.*, a suture) that can be used for securing body tissues together, and (2) a flexible, hollow fastener fabricated from biocompatible fibers from which two legs of the fastening member extend, enabling a user to tension the member and deform the fastener from a first configuration to a second configuration. One of the independent claims adds a third element: an introducer that has a pushrod configured to engage the fastener and position it relative to a body tissue.

Each of these claimed elements was known in the art before the filing of the '259 Patent. In particular, U.S. Patent No. 6,511,498 (“Fumex”) discloses and/or suggests the elements recited in the challenged claims, including a flexible hollow fastener (5) and a flexible elongated member (1) with two legs (3, 4), as shown below.

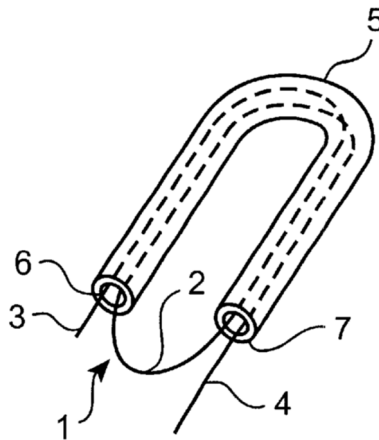


FIG. 1

Ex. 1004, Fig. 1.

Fumex also discloses an introducer having a pushrod (10) for positioning the fastener relative to a body tissue.

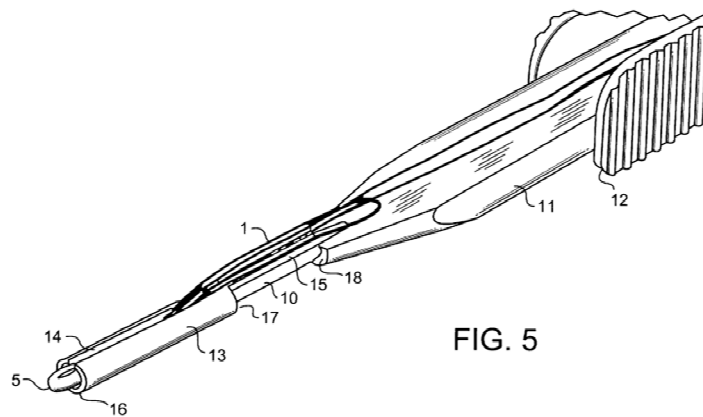


FIG. 5

*Id.*, 6:47-7:5 (“ancillary instrument making it easier to place the anchoring device in a hole ... in a bone.”).

The challenged dependent claims are unpatentable based on Fumex alone or in combination with other prior art.

## **II. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)**

Petitioner certifies that the '259 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting such review. This petition is being filed within one year of Petitioner being served with a complaint alleging infringement.

## **III. IDENTIFICATION OF CHALLENGES UNDER 37 C.F.R. § 42.104(b) AND RELIEF REQUESTED**

### **A. Grounds for the Challenged Claims**

Petitioner requests (i) review of claims 1-26 of the '259 Patent ("Challenged Claims") on the grounds set forth below and (ii) that those claims be found unpatentable.

| <b>Ground</b> | <b>Claim(s)</b>                                    | <b>Basis for Unpatentability</b>  |
|---------------|--|---|
| 1             | 1, 3, 4, 6-8, 10, 11, 13-16, 18-20, 22, 24, and 26 | 35 U.S.C. § 103 as obvious over U.S. Patent No. 6,511,498 ("Fumex")                                   |
| 2             | 1, 3, 4, 6-8, 10, 11, 13-16, 18-20, 22, 24 and 26  | 35 U.S.C. § 103 as obvious over Fumex in view of U.S. Patent Publication No. 2003/0050666 ("Grafton") |
| 3             | 7 and 18   | 35 U.S.C. § 103 as obvious over Fumex in view of U.S. Patent No. 5,735,875 ("Bonutti '875")           |
| 4             | 7 and 18   | 35 U.S.C. § 103 as obvious over Fumex in view of Grafton and Bonutti '875                             |
| 5             | 23 and 25  | 35 U.S.C. § 103 as obvious over Fumex in view of U.S. Patent No. 6,238,395 ("Bonutti '395")           |

|    |                 |  |
|----|-----------------|--|
| 6  | 23 and 25       | 35 U.S.C. § 103 as obvious over Fumex in view of Grafton and Bonutti '395  |
| 7  | 2 and 12        | 35 U.S.C. § 103 as obvious over Fumex in view of U.S. Patent No. 5,443,482 ("Stone")                                   |
| 8  | 2 and 12        | 35 U.S.C. § 103 as obvious over Fumex in view of Grafton and Stone   |
| 9  | 5, 9, 17 and 21 | 35 U.S.C. § 103 as obvious over Fumex in view of Stone and U.S. Patent Application Publication No. 2007/0055206 ("To") |
| 10 | 5, 9, 17 and 21 | 35 U.S.C. § 103 as obvious over Fumex in view of Grafton, Stone, and To  |

#### **B. The Challenges Presented Are Not Cumulative**

The grounds for unpatentability presented in this petition are neither cumulative nor redundant to prosecution of the '259 Patent. Although some of the references were listed on information disclosure statements, none was cited by or otherwise relied on by the Examiner.

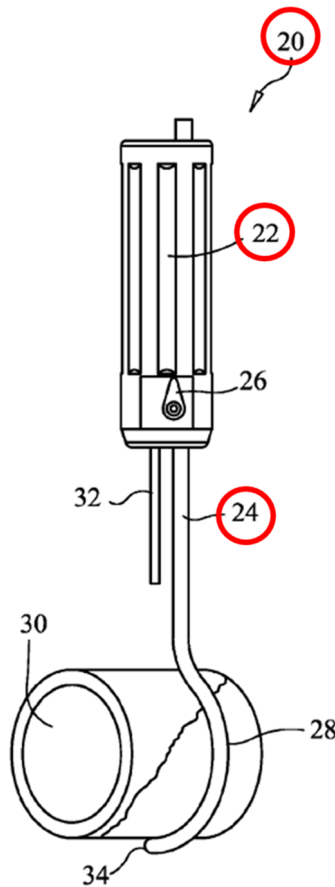
### **IV. SUMMARY OF THE '259 PATENT**

#### **A. Background**

The '259 Patent generally "relates to the guidance and positioning of tissue, an implant, or other surgical devices within the body." Ex. 1001, 1:16-19. The patent acknowledges known techniques and devices for physicians to attach soft tissue to other soft tissue, soft tissue to hard tissue, and hard tissue to other hard tissue, which could also be used to position or fix an implant within the body. *Id.*,

1:23-35. The '259 Patent sought to improve upon guided positioning and fixation of tissue or an implant within the body while accessing the procedure site from a small skin portal. *Id.*, 2:60-63; Ex. 1002, ¶23.

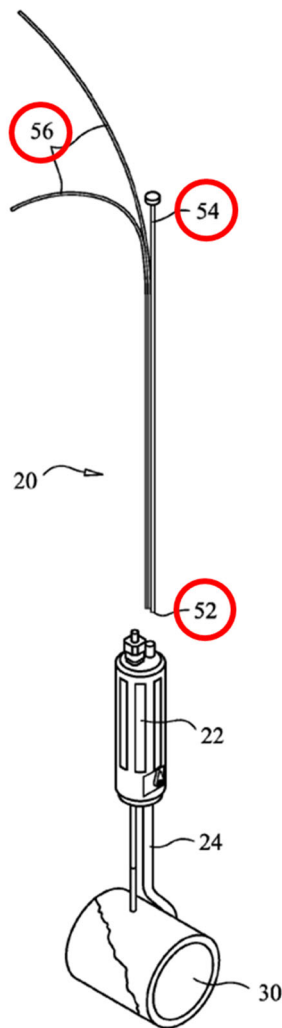
The '259 Patent discloses a guidance device with a cylindrical handle and a hook, as shown in Figure 1. *Id.*, 5:5-17. In operation, a curved portion of the hook is placed around a fractured bone (or other tissue). *Id.*, 6:4-28; Ex. 1002, ¶25.



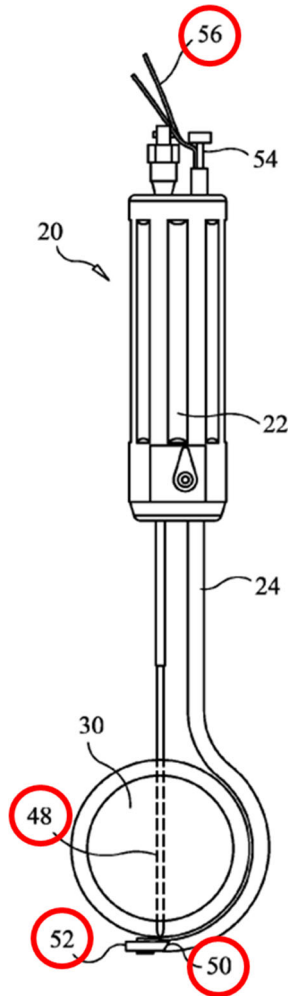
*Id.*, Fig. 1 (annotated).



A suture 56 is looped through a fastener 52 and both are positioned on a pushrod 54. *Id.*, 6:41-47, Fig. 3. The pushrod is then pushed into the hook of the device until the fastener is positioned at the distal opening of the drilled hole in the bone. *Id.*, 12:49-59, Fig. 4; Ex. 1002, ¶24.

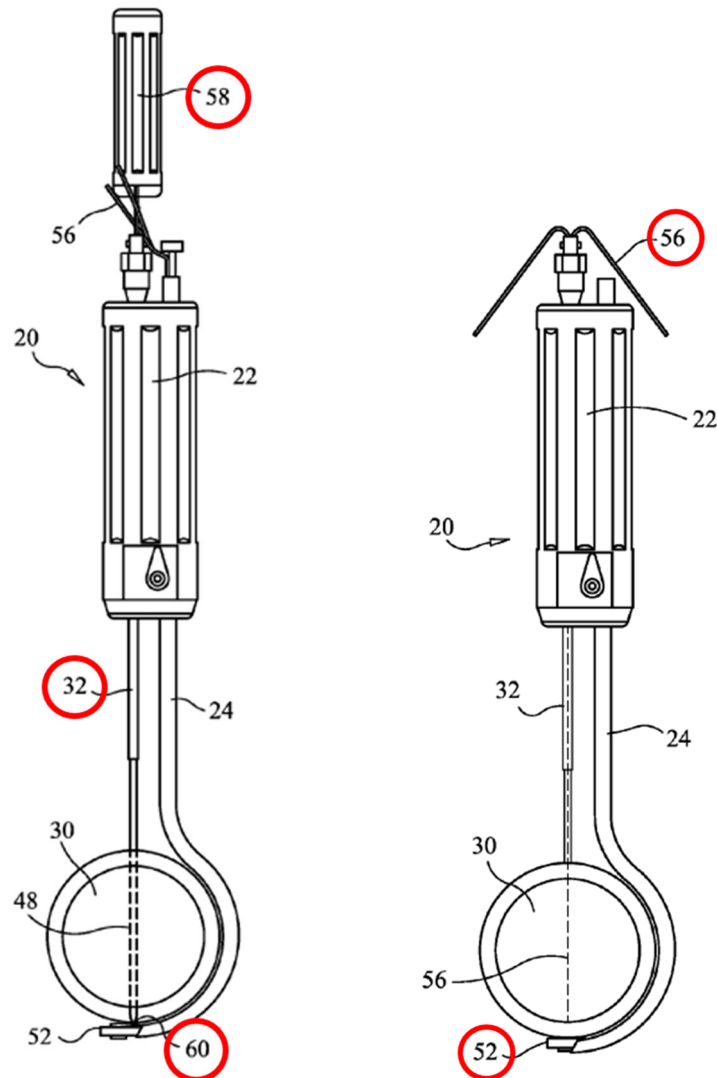


*Id.*, Fig. 3 (annotated).



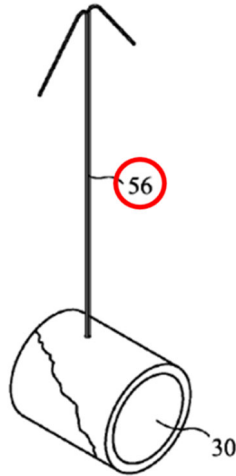
*Id.*, Fig. 4 (annotated to show fastener 52 fully inserted into the device and positioned at distal opening of drilled hole 48, with suture ends 56 extending out of the device); Ex. 1002, ¶26.

Next, a suture claw or grabber 58 is inserted into a guide channel 32 to cause a hook to attach to the suture at the distal end of the fractured bone. *Id.*, 13:10-33, Fig. 5. This allows the suture claw to pull the suture through the guide channel and back out of the device. *Id.*, 13:48-54, Fig. 7.



*Id.*, Figs. 5 (left, annotated to show hook 60 attaching to suture 48), 7 (right, annotated to show fastener 52 and suture ends 56 after suture is pulled through the fractured bone and guide channel); Ex. 1002, ¶28.

From this configuration, the hook instrument can be removed, leaving the suture and the fastener. *Id.*, 13:55-67, Fig. 8. The suture then can be tensioned, causing the fastener to secure the suture to the fractured bone.



*Id.*, Fig. 8 (annotated to show that suture 56 can be tensioned to secure fastener (not shown)); Ex. 1002, ¶29.

While the claims recite, in part, the fastener being a “flexible hollow fastener” that is deformable between different configurations when tensioned, the ’259 Patent offers little details on such features. The only discussion of deformable fasteners appears in a list of options, which itself does not specify the manner of deformation or that the deformable fastener is hollow. *See* Ex. 1001, 11:30-47.<sup>1</sup> Thus, a POSITA would have been left to rely upon what was already known in the field for guidance for these types of devices (such as in Fumex, discussed below).

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<sup>1</sup> Figures 26-28 of the ’259 Patent show drill bits 102 configured to transform into fasteners by expansion of the distal portion of the drill bit after it has been drilled through a fractured bone 112. However, the drill bit is neither hollow nor threaded with another flexible elongated fastening member, as the claims require.

## **B. Claimed Subject Matter**

The '259 Patent contains 26 claims, of which claims 1 and 11 are independent. The only structural elements recited in claim 1 are a flexible hollow fastener, a flexible elongated fastening member, and an introducer with a pushrod. Claim 11 is similar except it does not require an introducer. Dependent claims 2-10 and 12-26 relate to various aspects of the fastener systems recited in the independent claims. Ex. 1002, ¶¶30-31.

## **C. Prosecution History**

The '259 Patent issued on August 13, 2019 from U.S. Application No. 15/726,503 ("the '503 application, which claims priority through U.S. Application No. 13/871, 892 ("the '892 application"), back to U.S. Application No. 11/202,294 ("the '294 application"), filed on October 5, 2005. Ex. 1002, ¶32.

The claims presented during prosecution of the '294 application were directed to a guidance and positioning device and generally did not bear on the suture and fastener claimed in the '259 Patent. Ex. 1008, 4287-89.

During prosecution of the '503 application, the Examiner rejected the claims on various grounds including anticipation and obviousness based on U.S. Patent Nos. 4,898,156 (Gattorna), 5,954,057 (Li), 5,354,298 (Lee), and 3,762,418 (Wasson) and U.S. Patent Publication No. 2003/0167071 (Martin). Ex. 1012, 261-63; Ex. 1002, ¶37.

The Applicant overcame the Examiner's rejections in part by amending the claims to add the claim limitation of a "flexible hollow fastener comprised of fibers of biocompatible polymeric material" and "an introducer comprised of a pushrod."

Ex. 1012 at 246-249. The Applicant also added the claim limitation:

[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, wherein at least a portion of the flexible elongated fastening member is fabricated in part with polyethylene ...

*Id.* After these amendments, the Examiner allowed the claims. Ex. 1002, ¶38.

## **V. PRIOR ART**

U.S. Patent No. 6,511,498 ("Fumex") (Ex. 1004) issued on January 28, 2003.

U.S. Patent No. 2003/0050666 ("Grafton") (Ex. 1005) was published March 13, 2003.

U.S. Patent No. 6,238,395 ("Bonutti '395") (Ex. 1006) issued on May 29, 2001.

U.S. Patent No. 5,735,875 ("Bonutti '875") (Ex. 1007) issued on April 7, 1998.

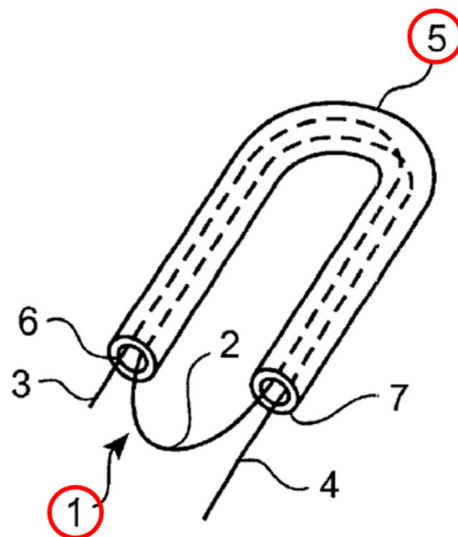
U.S. Patent No. 5,443,482 ("Stone") (Ex. 1010) issued on August 22, 1995.

Thus, these references constitute prior art under pre-AIA 35 U.S.C. § 102(b).

U.S. Patent Application Publication No. 2007/0055206 (“To”) (Ex. 1011) was filed August 10, 2005 and constitutes prior art under pre-AIA 35 U.S.C. § 102(e); Ex. 1002, ¶¶52-58.

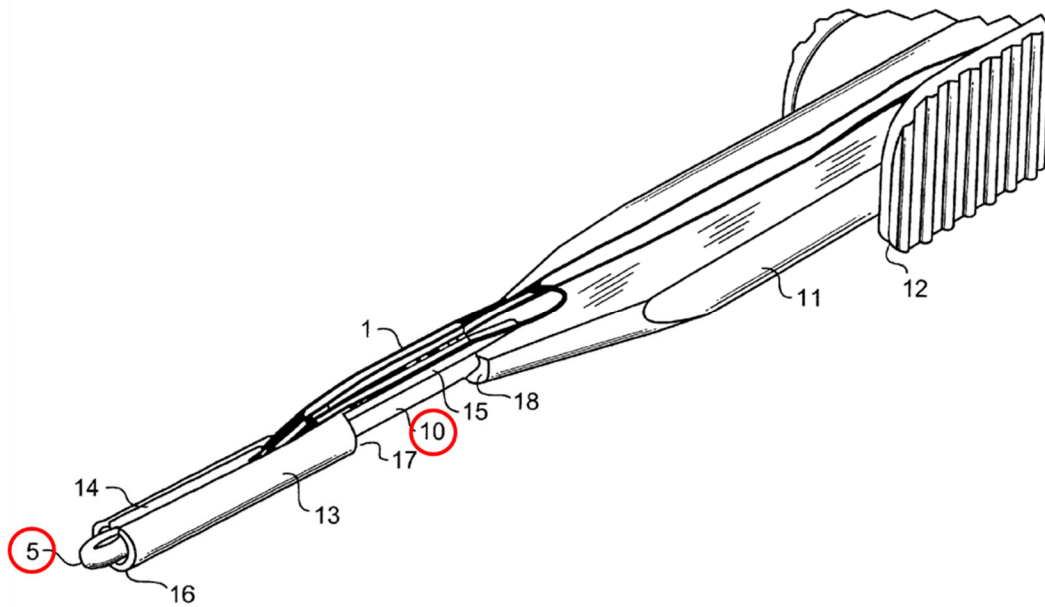
#### A. Overview of Fumex

Fumex describes a surgical bone anchoring system that includes a deformable tubular sleeve. Ex. 1004, 1:7-10 (“surgical device for bone anchoring”), 2:12-18 (“anchoring device ... comprises a deformable tubular sleeve, associated with means capable of deforming it”), 5:62-6:22 (deforming the sleeve causes it to form a ball that bears on an inner surface of a bone), Fig. 1. The bone anchoring system also includes a suture (1) that is passed through the flexible sleeve (5) such that two strands (3, 4) extend from the sleeve. *Id.*; Ex. 1002, ¶59.



*Id.*, Fig. 1 (annotated).

The flexible sleeve and suture can be inserted into a hole in the bone by an introducer having a handle and a rod, as shown in Figure 5 (below). Ex. 1004, 6:48-56. The rod engages with the sleeve, which includes a folded portion of the suture thread, to push these components into the hole. *Id.*, 6:48-56 (“the thread (1) and its sleeve (5) are folded via their center on the free end of the rod (10)”); 3:63-4:2 (“a rod capable of carrying the thread and its sleeve.”); Ex. 1002, ¶60.



*Id.*, Fig. 5 (annotated).

Once inserted, the thread strands can be tensioned to deform the sleeve into a ball that bears on an inner surface of the bone, fastening the anchoring system to the bone:

[T]raction on the strands (3 and 4) of the thread brings about a decrease in the length of the loop (2) until its length becomes equal to that of the sleeve (5). Continuing the traction on the strands of the thread (1), or on only one of the strands while holding the other one still, results ...in compression of the sleeve, whose surface forms undulations because of



the compressibility of the material from which it is made, and ... in tightening of the loop (2).

Ex. 1004, 5:38-57, 2:43-45 (“tubular sleeve can be deformed into a ball by simple traction exerted on at least one strand of the thread”), 3:10-14 (“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”), 5:62-6:22; Ex. 1002, ¶61.

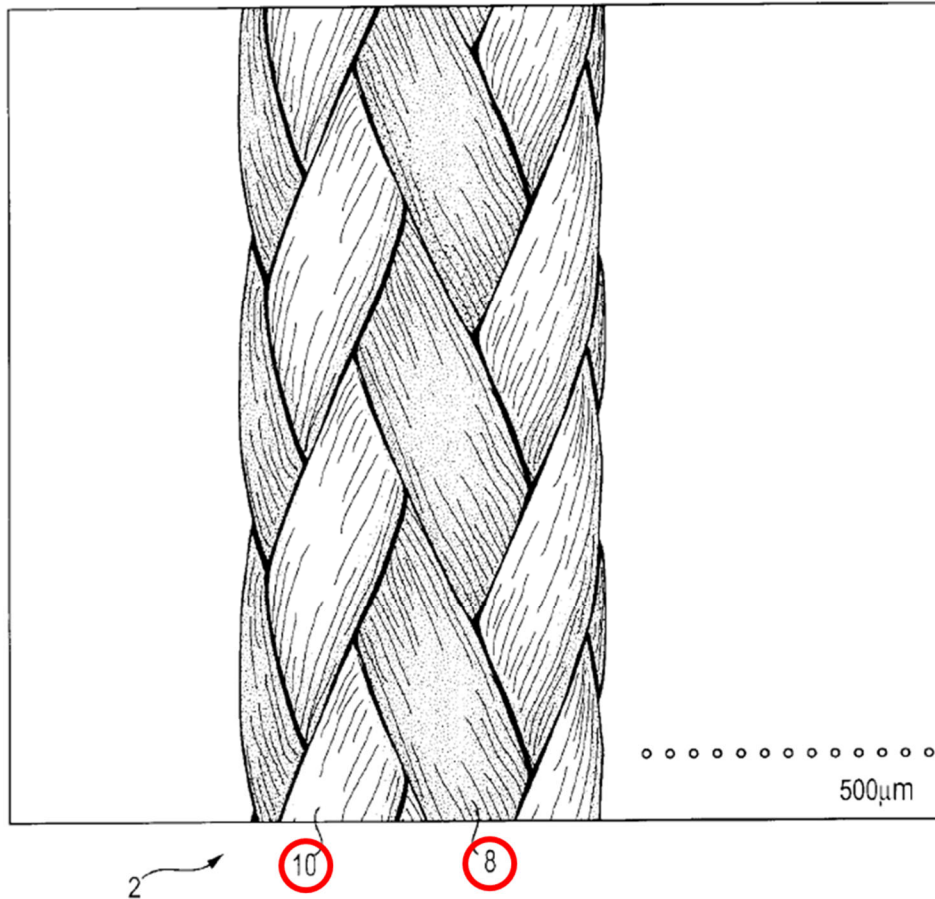
Fumex states that the tubular sleeve “can be made up of a single element or of several elements.” Ex. 1004, 2:66-67. It can be fabricated from “any deformable material, preferably one which has a certain elasticity, which has the property of being implantable, and which is absorbable or non-absorbable.” *Id.*, 2:54-65; Ex. 1002, ¶62.

Similarly, any “surgical thread or suture thread” can be threaded through the flexible sleeve. Ex. 1004, 2:2-9. A thread “used to fix or re-attach organs” such as bone, whether “absorbable or non-absorbable,” is preferred but not necessary. *Id.*, 2:46-48. Fumex also provides two specific examples of suture threads, both of which are synthetic, polymeric, and non-absorbable. *Id.*, 2:46-53 (“a polyester thread such as ... Ercylene®, or a polyamide thread such as Trynil®”); Ex. 1002, ¶63.

## **B. Overview of Grafton**

Grafton describes a high strength surgical suture material. Ex. 1005, ¶[0005]. The material includes “a multifilament cover formed of braided strands

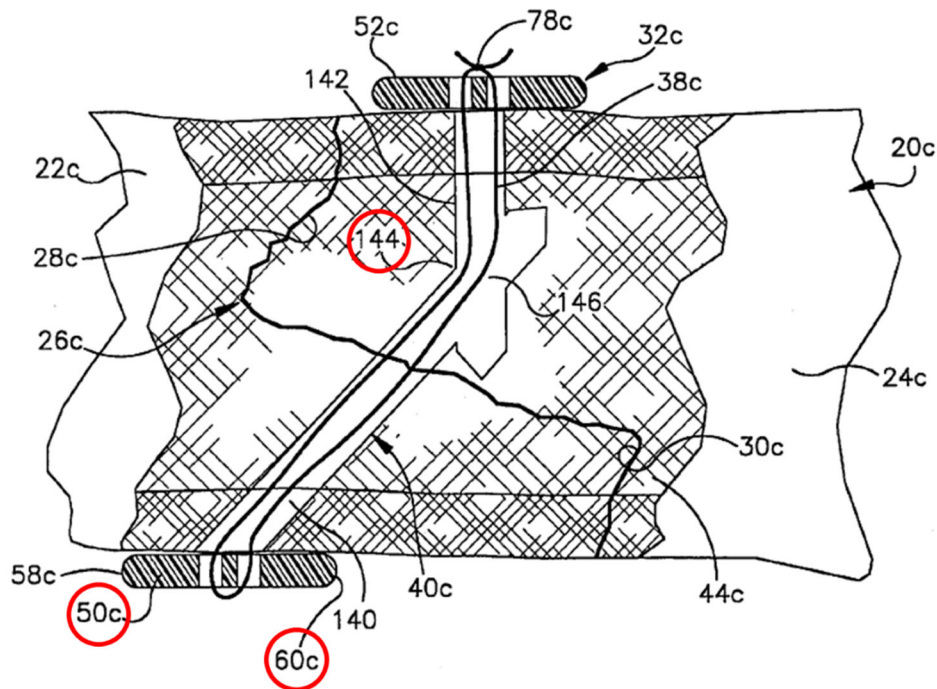
of ultrahigh molecular weight long chain polyethylene and polyester.” *Id.*, Abstract, ¶[0005] (strands of polyethylene and polyester braided together over a core of polyethylene), Fig. 1; Ex. 1002, ¶¶64-65.



Ex. 1005, Fig. 1 (annotated to show strands of polyester 10 and polyethylene 8 braided together).

### C. Overview of Bonutti '395

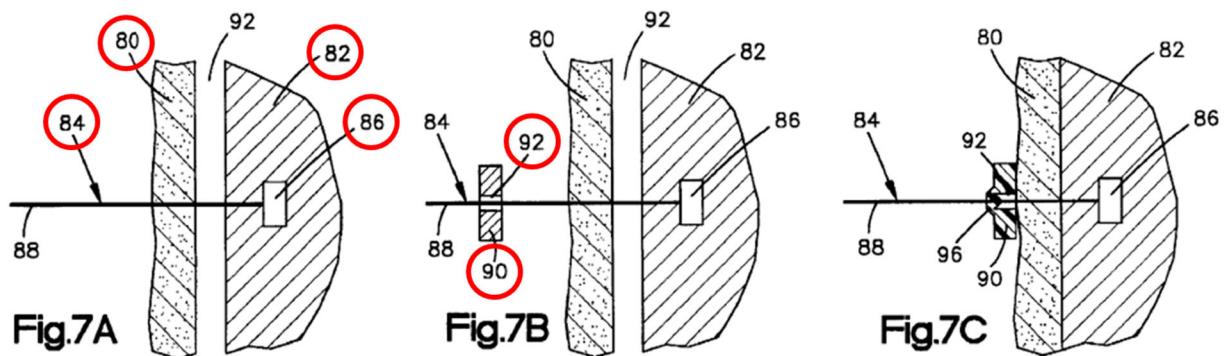
Bonutti '395 describes a flexible push rod for use in applications where a nonlinear hole must be drilled into bone. Ex. 1006, 10:23-12:8 (flexible pusher member applies force against suture anchor to push it around a bend in the passage), Fig. 5.



Ex. 1006, Fig. 5 (annotated to show trailing edge 60c of suture anchor 50c that can be pushed past bend 144 by the flexible pusher (not illustrated)); Ex. 1002, ¶66.

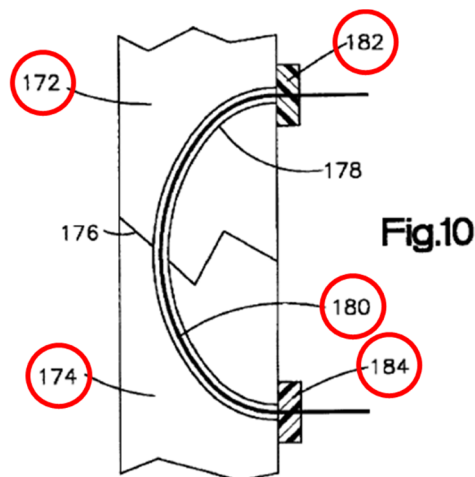
#### D. Overview of Bonutti '875

Bonutti '875 describes a knotless method of suturing body tissue using suture fasteners that are “easier to form and stronger than conventional tied knots.” Ex. 1007, 2:1-28, Figs. 7A-C. As shown in Figure 7A, two pieces of tissue 80, 82 can be joined using a suture 84 attached to a distal anchor 86 that is anchored to tissue 82. *Id.*, 7:37-44. The suture is inserted through the tissues 82 and 80 so that a free end 88 of the suture 84 protrudes at the proximal end, as shown in Figure 7B. *Id.* A fastener 90 with an opening 92 is slid over the suture 84 and pulled down tight to close the gap between the tissues. *Id.*



Ex. 1007, Figs. 7A-7C (annotated to show: in Fig. 7A, suture 84 anchored by distal anchor 86 during surgical repair to join tissues 80 and 82; and in Fig. 7B, fastener 90 including opening 92 with the suture threaded through it); Ex. 1002, ¶67.

As shown in Figure 10, a fastener 182 can secure a suture 180 to a first bone part 172 of a fractured bone, and another fastener 184 can secure the suture to a second bone part 174 of the fractured bone without a knot. *Id.*

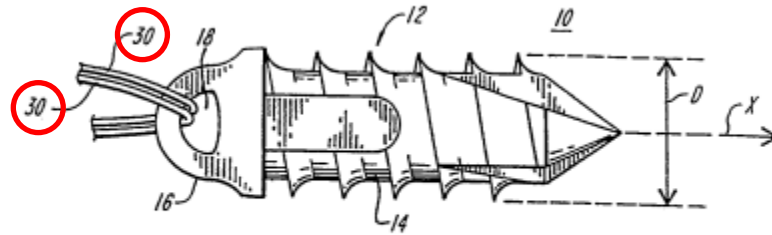


Ex. 1007, Fig. 10 (annotated); Ex. 1002, ¶68.

## E. Overview of Stone

Stone recognizes that “multiple sutures are often required for soft tissue repair.” Ex. 1010, 2:10-11. Stone states “it is an object of the invention to provide

a device that is designed for endoscopic use and that accommodates multiple suture fixation” as shown in Figure 1. *Id.*, 2:3-14.



**FIG. 1**

The top suture/driver portion 16 at the distal end of the assembly 10 is designed both to hold a suture material and to fit the head of a driver device. 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.

*Id.*, 4:32-42; Ex. 1002, ¶69.

#### **F. Overview of To**

To describes a surgical device 100 for the deployment of tissue anchors, comprising a shaft 102 defining a lumen, and a mechanism for deploying the anchor distally from the lumen, as shown in Figure 1. Ex. 1011, ¶29; Ex. 1002, ¶70.

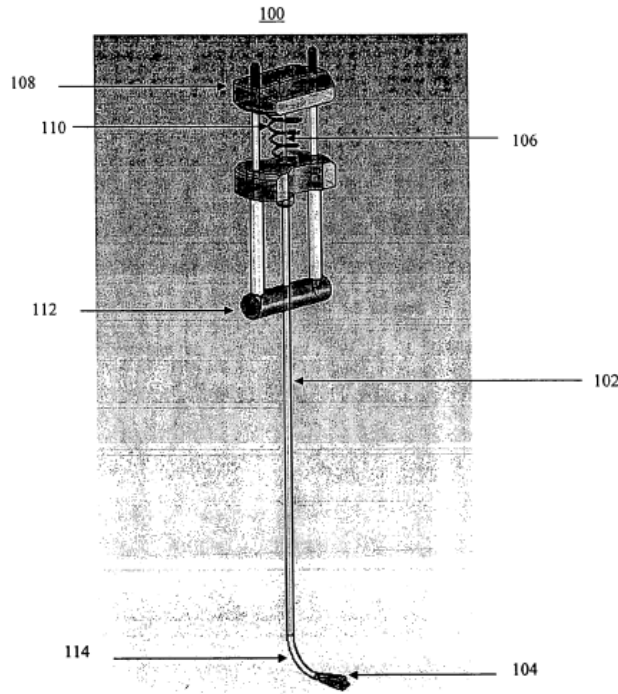
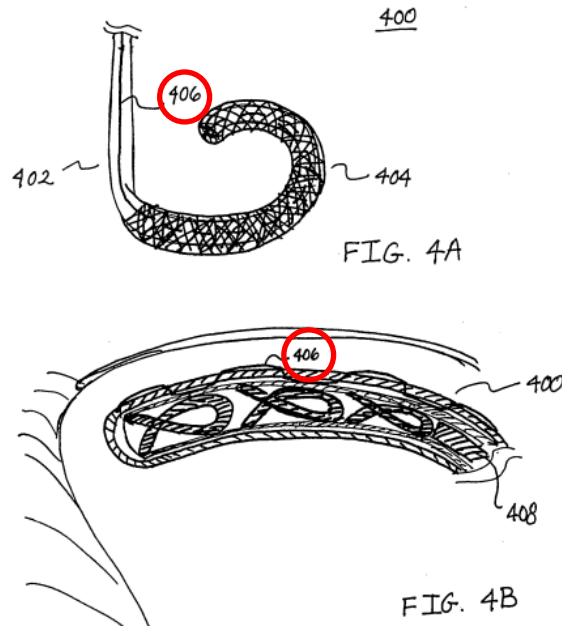


FIG. 1

The device “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. *Id.*, ¶¶12, 13, 55, 56; Ex. 1002, ¶71.



As shown in Figures 4A and 4B, above, a cinching strand, or tether (406) may be included in, and connected to, the anchor or sleeve.

This cinching strand may be made of any suitable material. For example, the cinching strand may be a suture, thread, tether, string, and the like . . . . The cinching strand is connected to the sleeve (404) and 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.

*Id.*, ¶43; Ex. 1002, ¶72.

## VI. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(b)(3)

For the purposes of this Petition, Petitioner states that under any reasonable interpretation of the claims, including the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005) (holding that words of a claim “are generally given their ordinary and customary meaning” as understood by a person

of ordinary skill in the art in question at the time of the invention), all of the limitations of the challenged claims are met in the prior art, as discussed below.

**“flexible hollow fastener is knotless”**

Dependent claims 7 and 18 recite the limitation “wherein the flexible hollow fastener is knotless.”

The '259 Patent does not define what makes a hollow fastener “knotless.” In fact, the term “knotless” appears in the specification only once, in a laundry list of fastener properties purportedly compatible with the deformable fastener system, without any explanation. Ex. 1001, 11:29-36 (“one-piece, Morse taper single piece, multi-component, solid, hollow, polygon-shaped, pointed, locking and unlocking, self-introducing, knotless”); Ex. 1002, ¶40.

The term “knotless,” as used in reference to a fastener, means a suture-restraining structure that can be retained in place without tying a knot at the site where the fastener is secured in place. This is consistent with the specification and prosecution history, as well as how those skilled in the art, including orthopedic surgeons, identified “knotless” fasteners at the relevant time. *Id.*, ¶41.

During prosecution of the related '892 application, the applicant submitted claims to a deformable fastener system including a fastener, a suture extending through the fastener, and an introducer. Ex. 1009, 653-56 (Amendment dated October 23, 2014, claims 6, 27, 28). Dependent claim 6 recited “wherein the



fastener is knotless.” *Id.* (claim 6). The Examiner rejected claim 6, over U.S. Patent Application Publication No. 2001/0002440 (“Bonutti ’440”) (Ex. 1013) in view of another reference. Ex. 1009, 556 (Office Action dated December 2, 2014). Ex. 1002, ¶42.

Specifically, the Examiner found that Figure 6 of Bonutti ’440 shows a knotless fastener. Ex. 1009, 556 (“The fastener is knotless (e.g. Fig. 6).”). Figure 6 of Bonutti ’440 illustrates the insertion of an anchor 30a into body tissue 88a by a shaft 24a of an anchor inserter 20a. As described by Bonutti ’440:

Once the anchor 30a has been moved to the desired depth in the body tissue, the anchor is separated from the shaft 24a. This may be done by merely withdrawing the leading end section 144 of the shaft 24a from the anchor 30a while the anchor remains in the orientation shown in FIG. 6 in the body tissue 88a. It is contemplated that there will be relatively little friction between the outer side surface 120a on the positioning portion 146 of the shaft 24a and the inner side surface 52a. This enables the anchor to be held in position in the body tissue 88a by the resilient force applied against the anchor 30a by the body tissue as the inserter 20a is withdrawn from the anchor.

Ex. 1013 (Bonutti ’440), ¶ [0114]; Ex. 1002, ¶43.

Based on this description and the figure, the Examiner appears to have 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. In the case of anchor 30a, the alternative to a knot was “resilient force applied against the anchor 30a by the body tissue.” *Id.*; Ex. 1002, ¶44.



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. This is consistent with how POSITAs identified “knotless” fasteners at the time of filing the ’259 Patent. Ex. 1002, ¶46.

## **VII. ARGUMENTS**

### **A. Statement of the Law**

The grounds of unpatentability rely on obviousness under 35 U.S.C. § 103. A claim is obvious when “the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103(a); *see KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

### **B. Level of Ordinary Skill in the Art**

A person of ordinary skill in the art (POSITA) would have (1) at least a B.S. or equivalent degree; and (2) at least two years’ experience (i) designing, developing, or testing implantable medical devices, such as suture anchors, or (ii) performing surgeries with implantable medical devices, such as suture anchors. Nevertheless, Petitioner submits that the claims are obvious in view of any reasonable definition of a POSITA. Ex. 1002, ¶50.

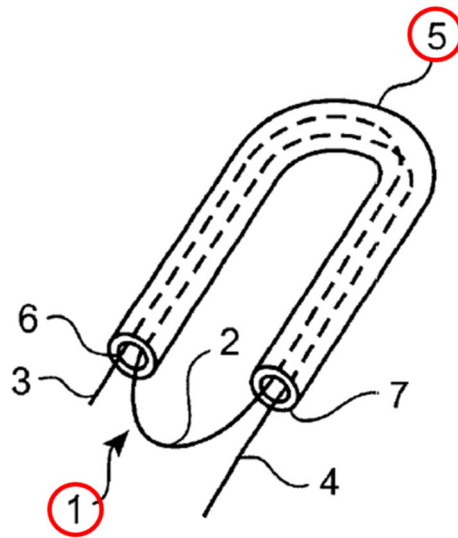
**C. Ground 1: Claims 1, 3, 4, 6-8, 10, 11, 13-16, 18-20, 22, 24, and 26 Are Obvious Over Fumex**

**1. Independent Claim 1**

Independent claim 1 is obvious over Fumex.

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

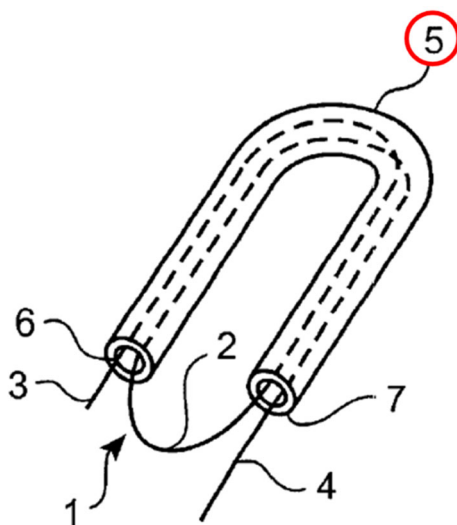
Fumex describes a fastener system because its surgical bone anchoring system includes a deformable tubular sleeve that can be fastened relative to a hole bored in bone. Ex. 1004, 1:7-10 (“surgical device for bone anchoring”), 2:12-18 (“anchoring device ... comprises a deformable tubular sleeve, associated with means capable of deforming it”), 5:62-6:22 (deforming the sleeve causes it to form a ball that bears on an inner surface of a bone).



Ex. 1004, Fig. 1 (annotated); Ex. 1002, ¶¶75-76.

**(b) [1.1] a flexible hollow fastener comprised of fibers of a biocompatible polymeric material;**

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.



Ex. 1004, Fig. 1 (annotated); Ex. 1002, ¶¶77-78.

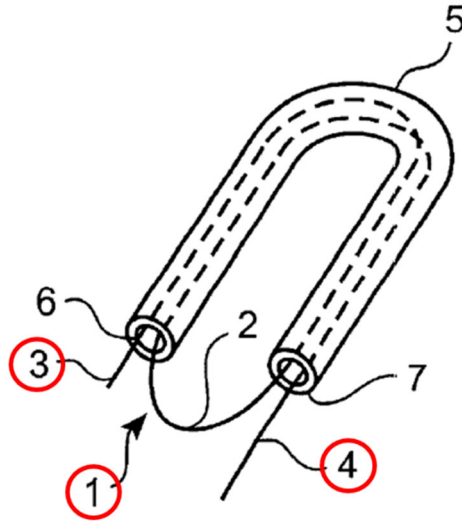
The tubular sleeve, which can be a unitary element or several elements joined together, can be fabricated from “any deformable material, preferably one which has a certain elasticity, which has the property of being implantable, and which is absorbable or non-absorbable.” Ex. 1004, 2:54-67. Materials suitable for

the sleeve include braided metal wire, braided plastic wire, polyester, polyamide, and silicone. *Id.*; Ex. 1002, ¶79.

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.

- (c) **[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,**

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.



Ex. 1004, Fig. 1 (annotated); Ex. 1002, ¶81.

The strands (3, 4) of suture thread (1) extending from the sleeve enable a user to tension the suture:

[T]raction on the strands (3 and 4) of the thread brings about a decrease in the length of the loop (2) until its length becomes equal to that of the sleeve (5). Continuing the traction on the strands of the thread (1), or on only one of the strands while holding the other one still, results, on the one hand, in compression of the sleeve, whose surface forms undulations because of the compressibility of the material from which it is made, and, on the other hand, in tightening of the loop (2).

Ex. 1004, 5:38-57; 2:43-45 (“tubular sleeve can be deformed into a ball by simple traction exerted on at least one strand of the thread”), 3:10-14 (“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”); Ex. 1002, ¶82.

**(d) [1.3] wherein at least a portion of the flexible elongated fastening member is fabricated in part with polyethylene; and**

A POSITA would have understood that Fumex does not limit the suture of its surgical bone anchoring system to being made from any particular material—any “surgical thread or suture thread” is suitable. Ex. 1004, 1:5-10. Preferably, the thread is “the type used to fix or re-attach organs” such as bone. Ex. 1004, 2:46-48, 1:9-10 (“anchoring of suture thread or surgical thread on a bone support”). Fumex provides two specific examples of polymeric threads: “a polyester thread such as ... Ercylene®, or a polyamide thread such as Trynil®.” *Id.*, 2:46-53; Ex. 1002, ¶¶83-84.

While Fumex does not expressly disclose polyethylene suture, it would have been obvious to a POSITA that such suture was not only contemplated by Fumex as a type of surgical or suture thread suitable for Fumex’s bone anchoring device, but would have been as usable in place of the polyester or polyamide threads expressly disclosed by Fumex. Ex. 1002, ¶84.

A POSITA would have recognized that Fumex does not limit its bone-anchoring system to any specific thread materials besides those used for surgical or suture threads. Ex. 1004, 1:8-10, 2:2-8. The only other limitation that Fumex places on thread material, albeit implicitly, is that the thread must be capable of



deforming a tubular sleeve in the manner described by Fumex. Ex. 1004, 5:38-6:22; Ex. 1002, ¶85.

A POSITA also would have recognized that Fumex contemplates a preferable class of suture thread materials, *i.e.*, threads used to fix or re-attach organs, as being particularly suited for the system. Ex. 1002, ¶85. From this class, a POSITA would have known that polyester and polyamide—the two exemplary suture materials specifically disclosed by Fumex—are common synthetic, non-absorbing, suture-appropriate materials. *Id.* A POSITA also would have been familiar with polyethylene as a similar synthetic suture material.<sup>2</sup> *Id.*

A POSITA also would have known that the suture material for a bone anchoring device like Fumex’s could be application-specific, *i.e.*, it could be chosen based on the particular surgical procedure for which the device and suture threads will be used. Ex. 1002, ¶¶86-87. For example, for some procedures, a smooth, monofilament, absorbable suture thread might be sufficient; in other procedures, a braided, high-tensile-strength, non-absorbable suture thread might be

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<sup>2</sup> For example, Linvatec’s Herculine and Smith & Nephew’s ULTRABRAID were examples of polyethylene suture available at the time. Ex. 1014 (Herculine introduced March 10, 2004); Ex. 1015 (“Herculine Polyethylene Suture is nonabsorbable, sterile, single-use, surgical suture”); Ex. 1016 (“ULTRABRAID Suture is a nonabsorbable, sterile, surgical suture composed of either white ultra high molecular weight (UHMW) Polyethylene or white UHMW Polyethylene cobraid with blue monofilament polypropylene”); Ex. 1002, ¶85.

necessary. A POSITA also would have known that, among synthetic, non-absorbing, suture-appropriate materials, the strength of braided polyethylene suture could have been beneficial in surgical procedures where, *e.g.*, a strong repair was needed, tissues being repaired were dense, or a weight-bearing joint was involved. *Id.*

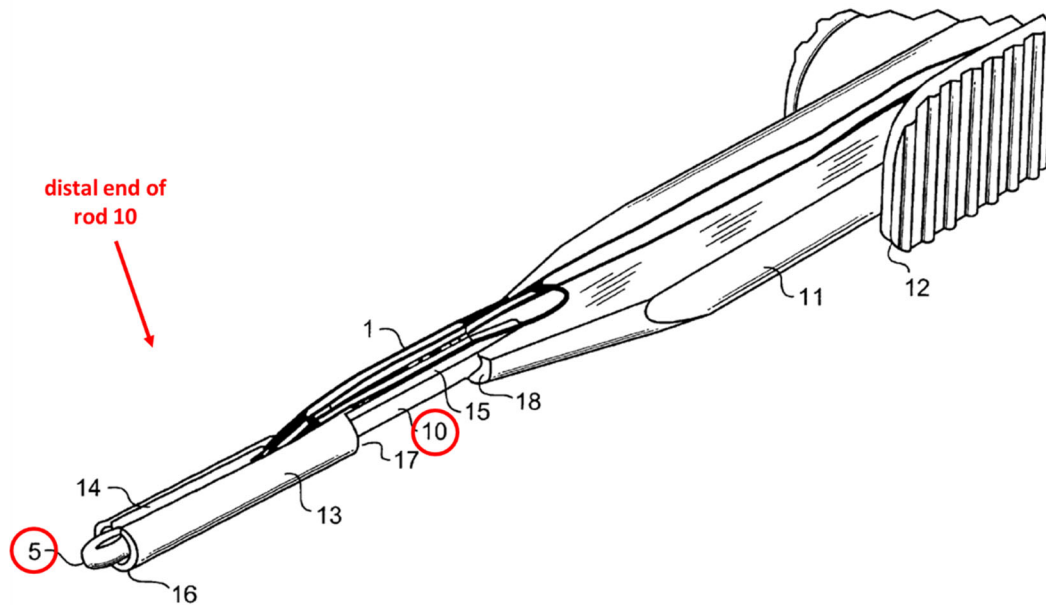
Thus, a POSITA would have known that polyethylene was a common synthetic, non-absorbing, suture-appropriate material, and that polyethylene sutures could (and, depending on the application at hand, should) be used as the surgical or suture thread in Fumex's bone anchoring device. Ex. 1002, ¶87; *see Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004) (POSITA guided by the nature of the problem at hand to select an appropriate one from a known set of components).

Moreover, a POSITA would have recognized that any thread, including a polyethylene suture, would be useful as part of Fumex's bone anchoring device as long as it was sufficiently flexible to be threaded through Fumex's sleeve, as shown in Figure 1. Ex. 1004, 5:38-6:22, Fig. 1. A POSITA thus would have had a reasonable expectation of success using polyethylene thread with Fumex's flexible sleeve. Ex. 1002, ¶88.

Accordingly, limitation [1.3] would have been obvious over Fumex in view of the knowledge of a POSITA.

- (e) **[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,**

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, as shown in Figure 5 (below). 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 (“the thread (1) and its sleeve (5) are folded via their center on the free end of the rod (10)”); 3:63-4:2 (“a rod capable of carrying the thread and its sleeve.”).



*Id.*, Fig. 5 (annotated to show approximate distal end of rod 10 and sleeve 5); Ex. 1002, ¶¶90-91.

Fumex describes the distal portion of the pushrod as being configured to position the flexible hollow fastener relative to the body tissue:

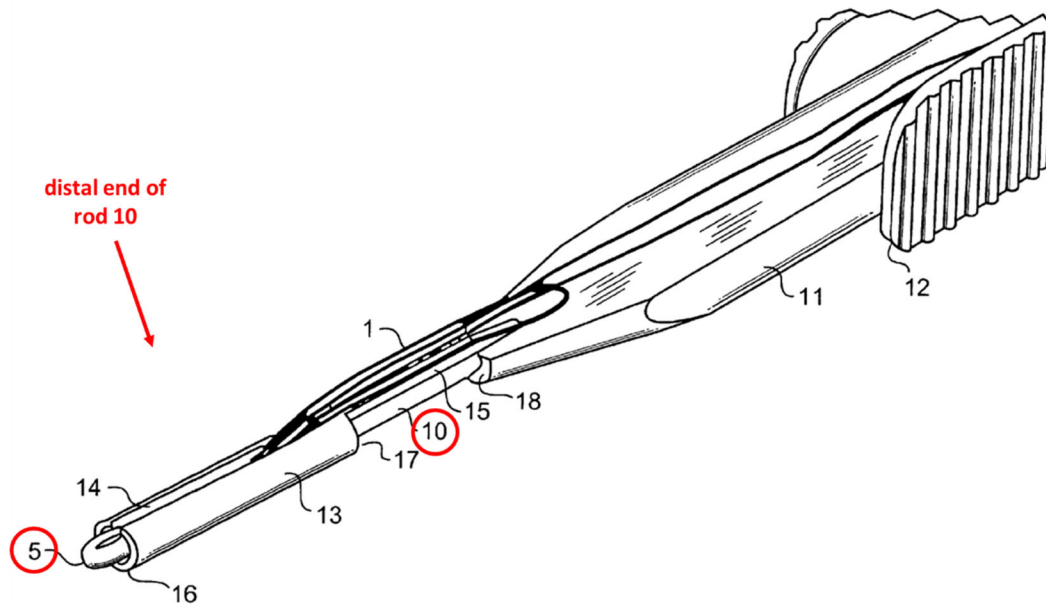
[T]he loop bearing the sleeve is fully introduced into the hole bored in the bone. This sleeve can advantageously be made of any deformable material, preferably one which has a certain elasticity, which has the property of being implantable, and which is absorbable or non-absorbable (for example a braided metal or plastic wire, a tube made of polyester or polyamide, or a tube made of silicone)

Ex. 1004, 2:54-65; Ex. 1002, ¶92.

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

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 (“the point of the rod of the ancillary instrument, bearing the loop-shaped thread and its sleeve”), 6:58-59 (“[t]he rod (10), the sleeve (5) and the thread (1) are enclosed in a cylindrical component (13)”).



*Id.*, Fig. 5 (annotated); Ex. 1002, ¶¶93-94.

- (g) [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

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:

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.**

Ex. 1004, 3:1-17 (emphasis added); Ex. 1002, ¶95.

Fumex describes how this process is achieved using the ancillary instrument:

The device is put into position using [the ancillary instrument]. The method of positioning consists in folding via its center the loop (2) bearing the sleeve (5) in such a way that the two strands of the thread emerge in the same direction, as is shown in FIG. 1, and in introducing it via its center into the hole bored in the bone, then in tightening it by exerting a traction on the strands (3 and/or 4) of the thread (1) in divergent directions. ... The edges (6) and (7) of the sleeve are preferably inserted into the hole under the surface of the cortical bone.

*Id.*, 5:62-6:6; Ex. 1002, ¶96. At this point, the sleeve is in the “first stretched position.” The anchoring process continues by deforming the sleeve into a ball:

When the loop (2) is tightened by pulling on the strand or strands (3) and (4) of the thread, it is narrowed and the flexible sleeve (5) is compressed inside the hole. Then, by further tightening by pulling on the strand (3) of the thread (1), the sleeve (5) is deformed until it adopts the shape of a ball. This ball will be unable to come out of the hole through which it has been introduced into the bone because its diameter has become markedly larger than that of the bored hole. Moreover, this

ball bears on the inner face of the cortical bone or in the spongy bone if it is sufficiently hard.

*Id.*, 6:7-16; Ex. 1002, ¶97.

Thus, 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.

- (h) **[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.**

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 (“it then suffices to exert a traction on one strand of the thread, while slightly holding the other strand still in order to cause tightening of the loop inside the hole in the bone and deformation of the sleeve on the loop until it adopts the shape of a ball, the diameter of which is greater than that of the tubular sleeve before deformation”); 7:14-17 (“the strand (4) of the thread (1) is pulled in such a way as to slide the thread (1) in the sleeve (5) and to deform the latter so that it forms a ball”); Ex. 1002, ¶99. 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. 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.

A POSITA would understand that fixation of the sleeve within the bone occurs before the loop (shown in e.g. Figure 1) is entirely constricted. *Id.* ¶100. In many applications, the hole bored in the bone passes through the hard outer cortical bone and into the inner spongy cancellous bone. *Id.* After insertion, the anchor’s cross section is increased as the suture strand is pulled such that it becomes larger than the hole, thereby holding the anchor in place. *Id.* ¶¶101-102. In this second position, wherein the device is expanded, the suture is still slidable



within the sleeve. *Id.* ¶102. Since 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.

The '259 Patent's specification also fails to provide adequate disclosure of what is meant by a flexible hollow fastener deforming from a first configuration to a second configuration. *Id.* ¶104. However, the closest descriptions in the '259 Patent describe a fastener is "expanded" into another configuration to secure the fastener, which supports this interpretation of Fumex's "second configuration." *Id.* ¶¶105-106 (citing Ex. 1004, 22:59-23:2, 23:16-29).

## **2. Claim 3**

Claim 3, which depends from claim 1, recites "wherein the flexible hollow fastener is a suture anchor." A suture anchor is a device that anchors a suture within a body. Ex. 1001, 6:63-64.

Fumex's tubular sleeve (5) is a suture anchor that anchors thread (1) in a bone hole. Ex. 1004, 2:12-18 ("anchoring device"), 5:62-6:22 (deforming the sleeve causes it to form a ball), 6:7-16 ("ball bears on the inner face of the cortical bone or in the spongy bone if it is sufficiently hard"); Ex. 1002, ¶108.

### 3. Claim 4

Claim 4, which depends from claim 1, recites “wherein the flexible elongated fastening member includes a suture.”

Fumex describes this limitation because the flexible elongated fastening member, *i.e.*, thread (1), is a suture. Ex. 1004, 5:38-57, 2:46-49 (“preferably a surgical thread or a suture thread”), Fig. 1; Ex. 1002, ¶110.

### 4. Claim 6

Claim 6, which depends from claim 1, recites “wherein the flexible hollow fastener and flexible elongated fastening member include a similar polymer material.”

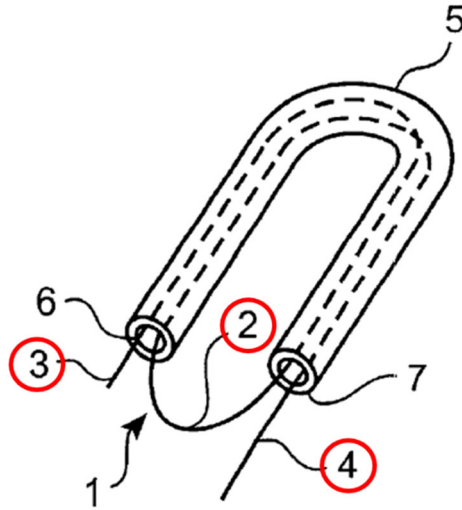
Fumex describes both the flexible hollow fastener (sleeve 5) and the flexible elongated fastening member (thread 1) can be fabricated from polyester. Ex. 1004, 2:46-50 (“a polyester thread”), 2:59-65 (“a tube made of polyester”). Both components also could have been fabricated from polyethylene. *See* Limitation [1.3], *supra* (polyethylene an obvious thread material); Ex. 1004, 2:59-62 (sleeve made of “any deformable material ... which has the property of being implantable, and which is absorbable or non-absorbable”). A POSITA would have recognized that selecting a similar material for both the fastener and the elongated fastening member is nothing more than a simple design choice. Ex. 1002, ¶112. Thus, it

would be obvious that the flexible hollow fastener and elongated fastening member include a similar polymer material. *Id.*

## **5. Claim 7**

Claim 7, which depends from claim 1, recites “wherein the flexible hollow fastener is knotless.” A “knotless” fastener is one that fastens without the use of a knot. *See* Section V.EI, *supra*.

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. Instead, 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 (tensioning the suture causes “compression of the sleeve, whose surface forms undulations because of the compressibility of the material from which it is made”), 6:7-16 (“sleeve (5) is deformed until it adopts the shape of a ball” that is “unable to come out of the hole through which it has been introduced”). Because the sleeve can be fastened without a knot, it is knotless.



*Id.*, Fig. 1 (annotated); Ex. 1002, ¶¶114-15.

## 6. Claim 8

Claim 8, which depends from claim 1, recites “wherein the flexible hollow fastener is a suture-like structure.”

The flexible hollow fastener is suture-like because it is fabricated from a material suitable for an implantable suture and is deformable, *i.e.*, it may bend like a suture. Ex. 1004, 2:59-62 (“any deformable material...which has the property of being implantable, and which is absorbable or non-absorbable”). In fact, Fumex specifically describes a flexible hollow fastener formed of a suture-type material. Ex. 1004, 2:59-67 (explaining the sleeve can be “a tube made of polyester” or “braided plastic wire”); Ex. 1002, ¶117.

## 7. Claim 10

Claim 10, which depends from claim 1, recites “wherein the flexible hollow fastener and flexible elongated fastening member include a dissimilar polymer material.”

As discussed above for limitation [1.3], a POSITA would have found it obvious to use a flexible elongated fastener made from polyethylene. In contrast, Fumex describes a flexible hollow fastener (sleeve 5) fabricated from polyester. Ex. 1004, 2:59-65 (“a tube made of polyester”). Ex. 1002, ¶119.

A POSITA would have understood polyethylene and polyester to be dissimilar (*i.e.*, different) polymer materials. Polyethylene and polyester share physical traits—*e.g.*, both can be biocompatible polymers from which non-absorbable suture can be fabricated—such that the selection of suture made from the two materials may be a design choice driven by the surgical application at hand. Notwithstanding their shared traits, a POSITA would not have considered polyester to be the same as polyethylene. A POSITA would also have recognized that selecting dissimilar materials for the fastener and the elongated fastening member is nothing more than a simple design choice. Ex. 1002, ¶120. Thus, a POSITA would have recognized that a polyethylene flexible elongated fastener and a polyester flexible hollow fastener would include dissimilar polymer materials. *Id.*

## 8. Independent Claim 11

### (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.

## **9. Claim 13**

Claim 13, which depends from claim 11, recites “wherein the flexible hollow fastener and flexible elongated fastening member include a dissimilar polymer material.”

*See* claim 10, *supra*; Ex. 1002, ¶128.

#### **10. Claim 14**

Claim 14, which depends from claim 11, recites “wherein the flexible elongated fastening member includes a suture.”

*See* claim 4, *supra*; Ex. 1002, ¶130.

#### **11. Claim 15**

Claim 15, which depends from claim 11, recites “wherein the flexible elongated fastening member includes at least in part one of polyester and polyethylene.”

Fumex describes this limitation because it expressly discloses a flexible elongated fastening member (*i.e.*, thread 1) fabricated from polyester. Ex. 1004, 2:46-51 (“a polyester thread”). Fumex also describes this limitation because it would have been obvious to a POSITA to use polyethylene to fabricate the flexible elongated fastening member. *See* limitation [1.3], *supra*; Ex. 1002, ¶132.

#### **12. Claim 16**

Claim 16, which depends from claim 11, recites “wherein the flexible hollow fastener and flexible and elongated fastening member include a similar polymer material.”

*See* claim 6, *supra*; Ex. 1002, ¶134.



### **13. Claim 18**

Claim 18, which depends from claim 11, recites “wherein the flexible hollow fastener is knotless.”

*See* claim 7, *supra*; Ex. 1002, ¶136.

### **14. Claim 19**

Claim 19, which depends from claim 11, recites “wherein the flexible hollow fastener is a suture anchor.”

*See* claim 3, *supra*; Ex. 1002, ¶138.

### **15. Claim 20**

Claim 20, which depends from claim 11, recites “wherein the flexible hollow fastener is a suture-like structure.”

*See* claim 8, *supra*; Ex. 1002, ¶140.

### **16. Claim 22**

- (a) [22.1] The system of claim 11, further comprising an introducer with a pushrod configured to engage the flexible hollow fastener,**

*See* limitation [1.4], *supra*.

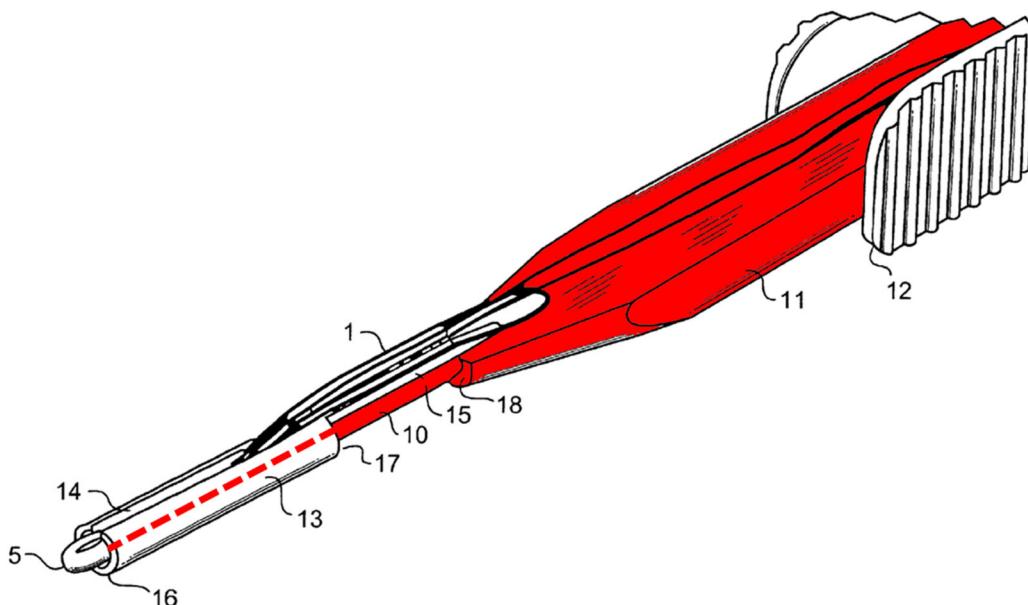
- (b) [22.2] wherein flexible hollow fastener and flexible elongated fastening member are positioned on the distal end of the pushrod.**

*See* limitation [1.5], *supra*.

## 17. Claim 24

Claim 24, which depends from claim 1, recites “wherein the introducer has at least one of a linear configuration and a curved configuration.”

Fumex describes this limitation because the ancillary instrument (*i.e.*, introducer) comprised of rod 10 and handle 11 has a linear configuration. Ex. 1004, Fig. 5, 2:58-60 (“The rod (10), the sleeve (5) and the thread (1) are enclosed in a cylindrical component (13).”); 6:51-7:17.



Ex. 1004, Fig. 5 (annotated) Ex. 1002, ¶144.

## 18. Claim 26

Claim 26, which depends from claim 22, recites “wherein the introducer has at least one of a linear configuration and a curved configuration.”

*See claim 24, supra.*

**D. Ground 2: Claims 1, 3, 4, 6-8, 10, 11, 13-16, 18-20, 22, 24 and 26 Are Obvious over Fumex in View of Grafton**

As an alternative to ground 1, 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.<sup>3</sup>

**1. The Combination of Fumex and Grafton**

**(a) Overview of the Combination**

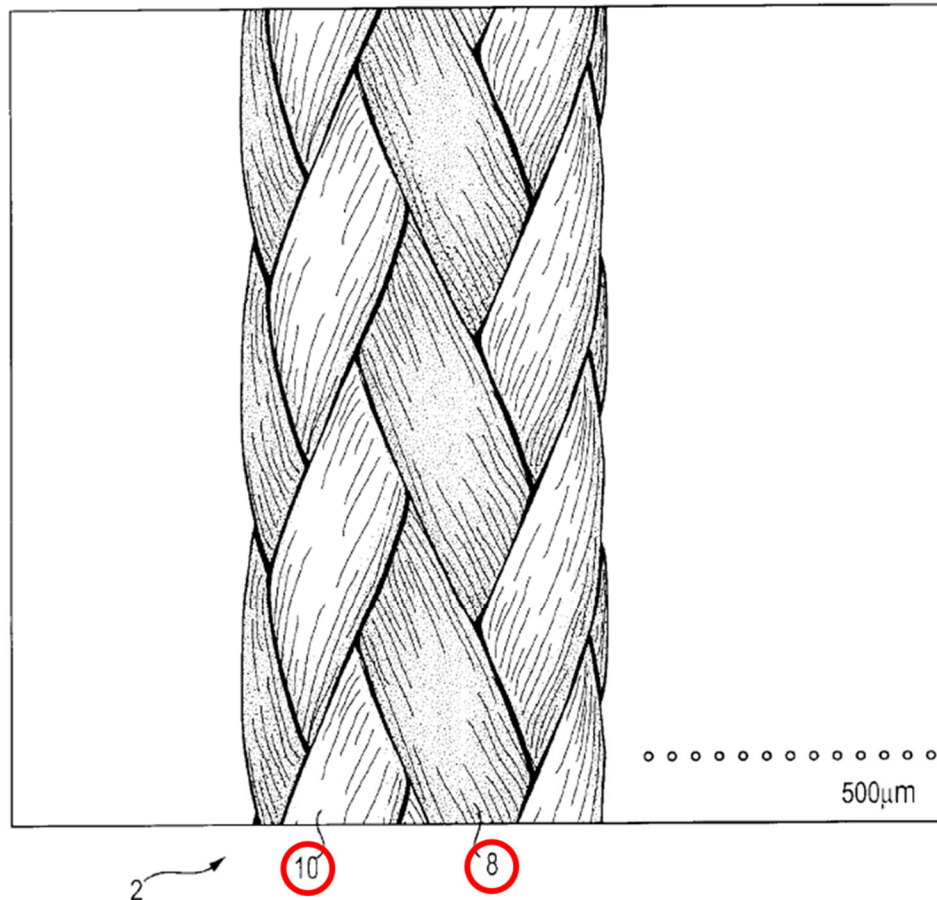
Fumex discloses a bone anchoring device that includes a hollow, deformable sleeve and a suture thread that is passed through the sleeve prior to implantation. Although Fumex does not expressly disclose a polyethylene thread, it directs the use of any thread “of the type used to fix or re-attach organs.”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

As also discussed above, polyethylene sutures were a well-known type of non-absorbable suture threads. To the extent that Patent Owner argues that a POSITA would not have found it obvious to use polyethylene in view of Fumex alone, Grafton explicitly describes that a suture may be formed of “a multifilament cover formed of braided strands of ultra high molecular weight long chain

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<sup>3</sup> Dependent claims 3, 4, 6-8, 10, 11, 13-16, 18-20, 22, 24 and 26 are included due to their respective dependencies on independent claim 1. Except for the teachings of material in Grafton, all other teachings relied upon are as described in Ground 1.

polyethylene and polyester.” Ex. 1005, Abstract, ¶[0015] (strands of polyethylene and polyester braided together over a core of polyethylene), Fig. 1; Ex. 1002, ¶149.



Ex. 1005, Fig. 1 (annotated to show polyester 10 and polyethylene 8 braided together).

Under Ground 2, it would have been obvious to use the braided polyethylene-based suture taught by Grafton as the suture thread in a bone anchoring device as described by Fumex. Ex. 1002, ¶142.

#### **(b) Rationale (Motivation) Supporting Obviousness**

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. Fumex

describes its bone anchoring device as being suitable for many surgical applications, including orthopedic, trauma, gynecological, and cancer surgeries. Ex. 1004, 1:7-12, 2:1-8, 4:38-43. Fumex leaves it to the user to choose any suitable surgical suture thread, as long as it is “of the type used to fix or re-attach organs.” Ex. 1004, 2:46-48. Thus, a POSITA would have understood Fumex to leave it to the user to choose the particular suture. Ex. 1002, ¶¶150-51.

Choosing an appropriate suture for use in Fumex’s system would have been in the wherewithal of a POSITA and driven by the particular application at hand and surgeon preference. Indeed, 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.

Grafton’s braided suture, which “can be attached to a suture anchor” such as Fumex’s deformable sleeve, is described as being “ideally suited for most orthopedic procedures.” Ex. 1005, Abstract. In fact, Grafton specifically states that the suture is “ideal” for “rotator cuff repair, archilles [*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.

**(c) *Graham* Factors**

The level of ordinary skill is as proposed in Section VII.B.

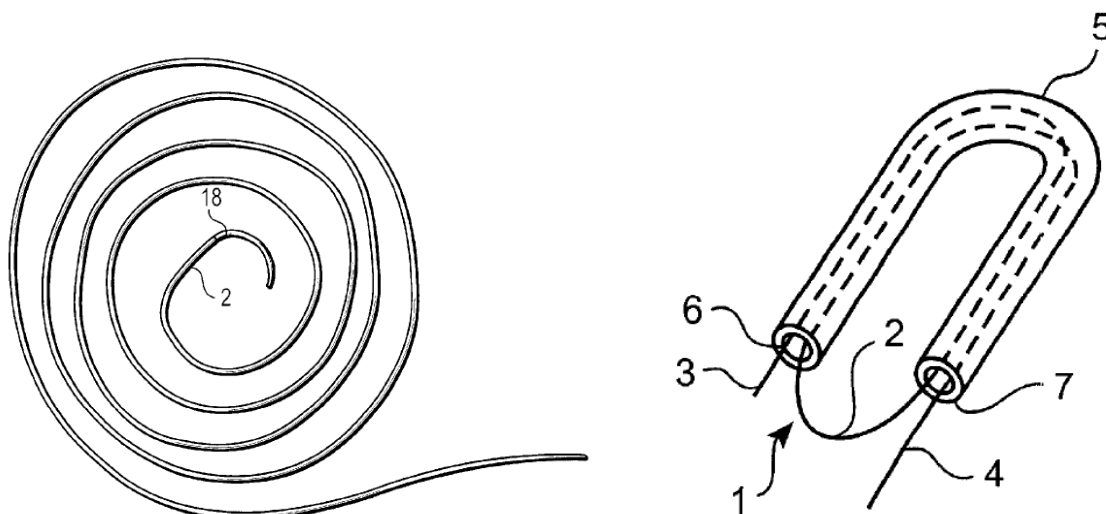
The scope and content of the prior art are discussed throughout this ground and in Section V.

The differences between the prior art and the claims are discussed in the “Overview of the Combination” (Section VII.D.1) and below.

Petitioner is not aware of any secondary considerations that would make an inference of non-obviousness more likely.

**(d) Reasonable Expectation of Success**

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. Grafton expressly states that its thread “can be attached to a suture anchor” like Fumex’s tubular sleeve. Ex. 1005, Abstract. Even without Grafton’s express disclosure of the combination, 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.



Ex. 1005, Fig. 4A (left, Grafton's suture thread); Ex. 1004, Fig. 1 (right, Fumex's flexible sleeve with suture threaded).

### (e) Analogous Art

Fumex and Grafton are in the same field and thus analogous art to the '259 Patent. Ex. 1001, Abstract, 1:13-16; Ex. 1004, Abstract, 1:5-12; Ex. 1005, Abstract. Specifically, all three relate to the surgical anchoring using suture threads. *Id.*; Ex. 1002, ¶157.

### 2. Claim 1

Fumex describes and/or suggests all elements of independent claim 1, but does not explicitly state that “at least a portion of the flexible elongated fastening member is fabricated in part with polyethylene.” *See* Section VII.C.1, *supra*. Fumex does not, however, limit the suture to any particular material, as long as it is suitable to fix and attach organs such as tendons and ligaments. Ex. 1004, 2:46-48, 4:38-41. At the time of the filing of the '259 Patent, polyethylene was a well-known material for use in sutures, and Grafton teaches that a particular suture

fabricated from polyethylene that is designed specifically for the surgical repair of tendons and ligaments. Ex. 1005, ¶¶ [0002], [0009], [0015], Fig. 1; Ex. 1002, ¶158.

A POSITA at the time of the filing of the '259 Patent would have understood that Grafton's suture could easily have been used with the bone anchoring device described by Fumex. In particular, a POSITA would have sought to use the combination in the surgical repair of a tendon or ligament—for example, when suture with high tensile strength was needed. Ex. 1002, ¶159.

### **3. Claims 3, 4, 6-8, 10, 11, 13-16, 18-20, 22, 24 and 26**

Dependent claims 3, 4, 6-8, 10, 11, 13-16, 18-20, 22, 24 and 26 depend from independent claim 1. A POSITA would have found these claims to be obvious over Fumex in view of Grafton for the same reasons the POSITA would have found them to be obvious over Fumex alone. *See* Section VII.C, *supra*.

#### **E. Ground 3: Claims 7 and 18 Are Obvious over Fumex in View of Bonutti '875**

As discussed in Ground 1 (Section VII.C, *supra*), Fumex renders obvious dependent claims 7 and 18, which recite that the flexible hollow fastener is knotless. *See* Sections VII.C.5 (claim 7), VII.C.13 (claim 18), *supra*. Specifically, no knot is used to with respect to anchoring Fumex's tubular sleeve in place. Instead, the sleeve anchors in places by tensioning the suture, thereby deforming the sleeve into a ball. Ex. 1004, 3:7-17, 5:38-57, 6:7-16; Ex. 1002, ¶¶161-62.



Subsequent to anchoring the tubular sleeve, Fumex describes optionally knotting the two legs of the suture that extend from the other end of the hole in the bone “in order to lock the device and prevent its loosening.” Ex. 1004, 4:28-30; Ex. 1002, ¶163.

To 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, the same would have been obvious over Fumex and Bonutti ’875, as discussed below. Specifically, it would have been obvious to use knotless fasteners at both ends of the suture, such that no knotting is needed. Ex. 1002, ¶163.

## **1. The Combination of Fumex and Bonutti ’875**

### **(a) Overview of the Combination**

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 (tension in the suture causes “compression of the sleeve, whose surface forms undulations because of the compressibility of the material from which it is made”), 6:7-16 (“the sleeve (5) is deformed until it adopts the shape of a ball” that is “unable to come out of the hole through which it has been introduced”). Subsequently, the two legs of the suture that extend out of the bone can be knotted. Ex. 1004, 4:28-31; Ex. 1002, ¶164.

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. 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.

It would have been obvious to use the knotless suture fastener described by Bonutti '875 in place of knotting suture legs away from the flexible fastener of Fumex's bone anchoring device. Ex. 1002, ¶167.

**(b) Rationale (Motivation) Supporting Obviousness**

A POSITA would have found that the suture fastener of Bonutti '875 could replace the knotting suture threads when using Fumex's bone anchoring device. After anchoring Fumex's tubular sleeve through deformation, the two legs of the suture extending from the tubular sleeve and out of the hole can be knotted to “lock the device and prevent its loosening.” Ex. 1004, 4:28-31 (suture legs “at the edge of the hole bored in the bone”); Ex. 1002, ¶167.

A POSITA would have understood that the suture fastener of Bonutti '875 could have advantageously replaced the optional suture knot described by Fumex, as Bonutti '875 describes:

- the fastener is “easier to form and stronger than conventional tied knots,” Ex. 1007, 2:4-5;
- “[i]t is difficult to tie a suture knot to itself or to slide it down through deep tissue in a limited working area.” *Id.*, 6:47-48;
- “mechanical tying or crimping of sutures ... 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,” *Id.*, 6:53-57; and
- the fastener “avoids buckling of the tissue edges caused by force vectors not extending in the direction of the suture,” *Id.*, 7:9-14; Ex. 1002, ¶167.

**(c) *Graham* Factors**

The level of ordinary skill is as proposed in Section VII.B.

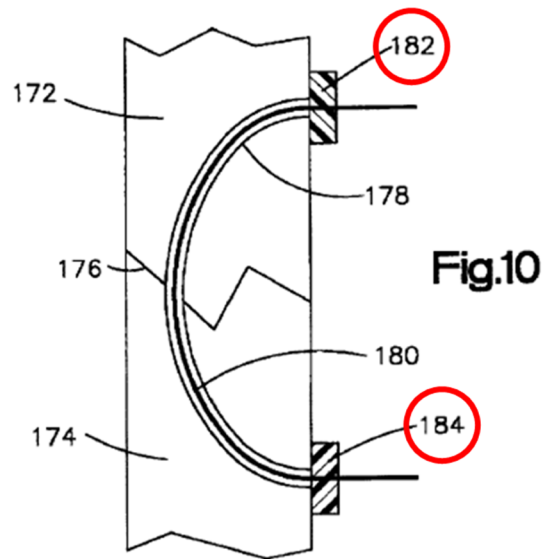
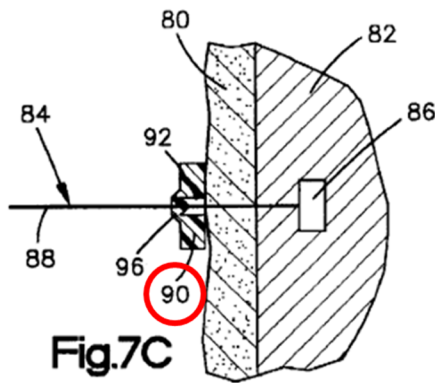
The scope and content of the prior art are discussed throughout this ground and in Section V.

The differences between the prior art and the claims are discussed in the “Overview of the Combination” (Section VII.D.1) and below.

Petitioner is not aware of any secondary considerations that would make an inference of non-obviousness more likely.

**(d) Reasonable Expectation of Success**

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, to fasten those suture legs. Ex. 1002, ¶168. Bonutti expressly describes using its suture fastener in surgical applications like those described in Fumex, including fastening a suture proximal to a distal suture anchor (Figures 7A-C of Bonutti '875) and single-tissue applications (Figure 10 of Bonutti '875). *Id.*, 7:37-44, 8:40-60, Figs. 7A-C, 10. Bonutti '875 further discloses that its fasteners can be used with polymeric sutures such as those described by Fumex. Ex. 1007, 3:44-46. Accordingly, the fastener of Bonutti '875 would have been a replacement for knotted suture legs, as described by Fumex. Ex. 1002, ¶168.



Ex. 1007, Figs. 7A-7C (left, annotated to show fastener 90 in a surgical application involving a distal bone anchor), Fig. 10 (annotated to show fasteners 182 and 184 in a single-tissue (e.g., fractured bone) application); Ex. 1002, ¶168.

### (e) Analogous Art

Fumex and Bonutti '875 are in the same field and thus analogous art to the '259 Patent. Ex. 1001, Abstract, 1:13-16; Ex. 1004, Abstract, 1:5-12; Ex. 1007, Abstract, 1:5-10. Specifically, all three relate to the surgical fastenings using suture threads. *Id.*; Ex. 1002, ¶169.

## 2. Claims 7 and 18

Fumex discloses and/or suggests all elements of independent claims 1 and 11, including disclosing a flexible hollow fastener, which itself is knotless and secured within, e.g., bone. See Section VII.C.1, VII.C.8, *supra*; Ex. 1004, 3:7-17, 5:38-57, 6:7-16. Fumex does note the optional knotting of suture legs at the opposite end of the suture, where they extend from the proximal end of the bone hole. Ex. 1004, 4:28-31. At the time of the filing of the '259 Patent, Bonutti '875

taught an alternative to knotting legs of a suture, namely, the use of a suture fastener. Ex. 1007, 7:37-44, 8:40-60, Figs. 7A-C, 10; Ex. 1002, ¶170-74.

A POSITA at the time of the filing of the '259 Patent would have understood that the suture fastener of Bonutti '875 could easily have been used with the bone anchoring device described by Fumex. A POSITA would have sought to use the combination in surgical applications where, for example, it would be difficult to tie a knot, a fastener would be easier to use, or the fastener would be stronger than a knot. Ex. 1007, 2:4-5, 6:47-48, 6:53-57, 7:9-14; Ex. 1002, ¶170-74.

**F. Ground 4: Claims 7 and 18 are Obvious over Fumex in View of Grafton and Further in View of Bonutti '875**

Dependent claims 7 and 18 recite “wherein the flexible hollow fastener is knotless.” As discussed above in Ground 3, claims 7 and 18 are obvious over Fumex, and Bonutti '875. *See* Section VII.E.2, *supra*.

Under Ground 4, claims 7 and 18 are also obvious over Fumex in view of Grafton and Bonutti '875. This ground is simply a combination of the analyses in Grounds 2 and 3 (Sections VII.D and VII.E, *supra*). The bases for the combinations and manner of combining the references are already articulated in those Grounds. *See* Ex. 1002, ¶¶175-76.

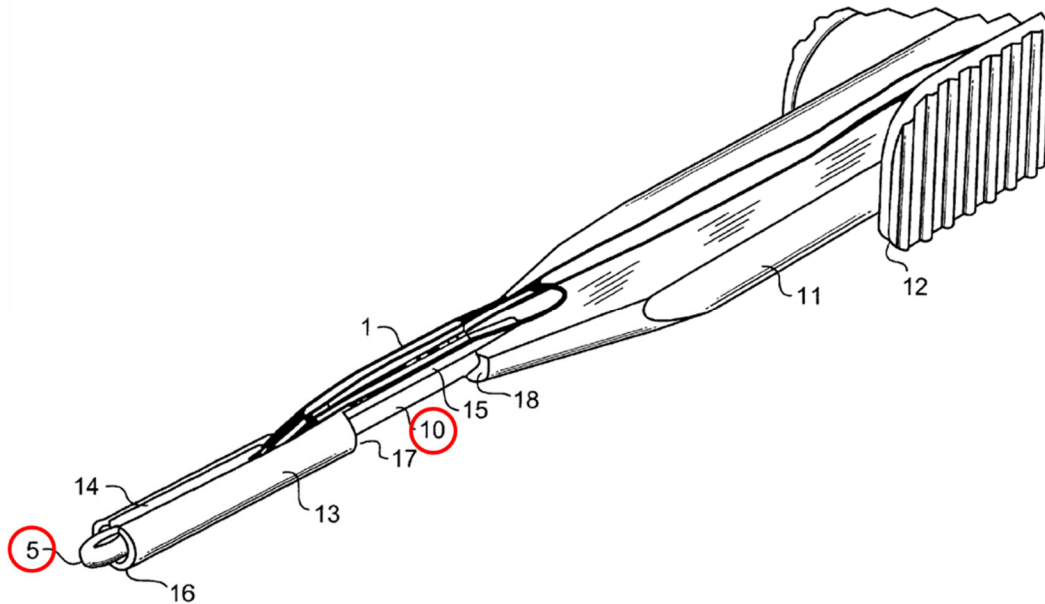
**G. Ground 5: Claims 23 and 25 Are Obvious over Fumex in View of View of Bonutti '395**

Claims 23 and 25, which depend from claims 1 and 22, respectively, recite “wherein the pushrod is flexible.” These claims would have been obvious over Fumex in view of Bonutti ’395.

## 1. The Combination of Fumex and Bonutti '395

### (a) Overview of the Combination

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 (the rod functions to “carry[] the thread and its sleeve for introducing them into the hole bored in the bone”), Fig. 5.



*Id.*, Fig. 5 (annotated); Ex. 1002, ¶178.

Fumex expressly states that the hole can have “any wall shape” and can be bored using any “conventional instrument.” Ex. 1004, 2:1-8, 6:64-65. While

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.

Bonutti '395 describes “securing body tissue to bone.” Ex. 1006, 20-22. 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 (flexible pusher member applies force against suture anchor to push it around a bend in the hole), Fig. 5.

It would have been obvious to use a flexible rod, as described by Bonutti '395, as part of Fumex's bone anchoring device. Specifically, a flexible rod would permit the device to be used in surgical applications in which the hole bored in bone was not linear (*e.g.*, curved or angled). Ex. 1002, ¶¶180-81.

#### **(b) Rationale (Motivation) Supporting Obviousness**

Fumex's bone anchor is intended to be used in surgical applications involving the insertion of the device into bone holes having “any wall shape”—not just linear holes. However, Fumex illustrates a linear rod which, if overly rigid, could not be easily inserted into linear holes. A POSITA would have found it obvious to apply the teachings of Bonutti '395, which describes a nonlinear hole



bored in bone and a flexible pusher member to insert a suture through the hole. Combining 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.

Fumex and Bonutti '395 are in the same field (securing bone to another organ or tissue using a suture anchor), and both disclose surgical devices for implanting a suture into a hole bored in bone. A POSITA would have naturally looked to Bonutti '395 when considering how to configure Fumex's rod for surgical applications requiring the rod to be inserted into a nonlinear hole. This combination does no more than use Bonutti's rod in a known and intended way (*i.e.*, insertion into a hole having any wall shape, as Fumes discloses) to achieve the predictable result of a flexible rod that can accommodate a nonlinear hole. Ex. 1002, ¶183.

### **(c) *Graham* Factors**

The level of ordinary skill is as proposed in Section VII.B.

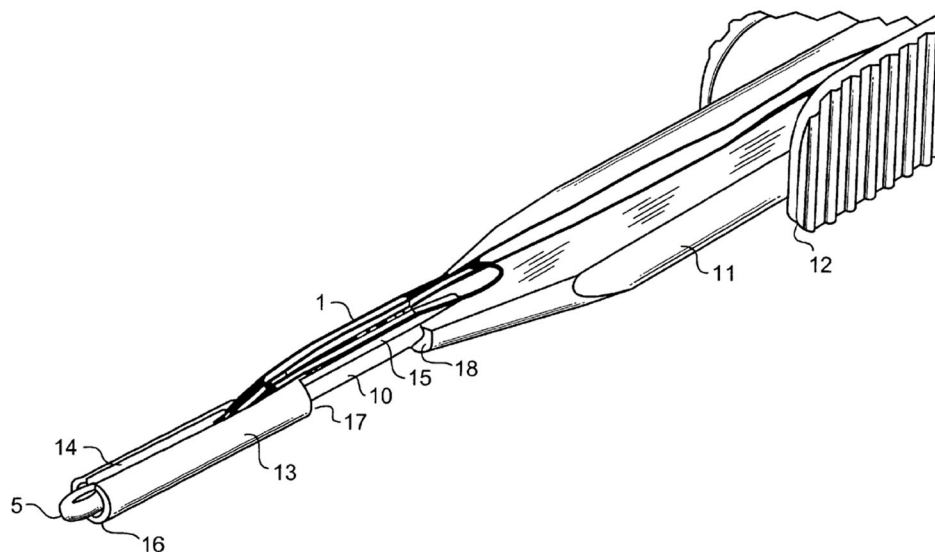
The scope and content of the prior art are discussed throughout this ground and in Section V.

The differences between the prior art and the claims are discussed in the “Overview of the Combination” (Section VII.G.1(a)) and below.

Petitioner is not aware of any secondary considerations that would make an inference of non-obviousness more likely.

**(d) Reasonable Expectation of Success**

A POSITA would have had a reasonable expectation of success in modifying Fumex's rod in this manner. Ex. 1002, ¶184. As shown in Figure 5 of Fumex, the rod is essentially linear prior to insertion, and a flexible rod could have a linear shape when housed within the ancillary instrument. In operation, the rod would extend from the instrument to push the tubular sleeve and suture thread into the hole bored in bone. Ex. 1004, 3:63-4:2 ("rod capable of carrying the thread and its sleeve for introducing them into the hole bored in the bone"), 6:51-7:17 (describing operation of exemplary ancillary instrument). The initially linear rod, once extended beyond the ancillary instrument, would be sufficiently flexible to bend as needed to carry the thread and tubular sleeve through a nonlinear passage.



Ex. 1004, Fig. 5; Ex. 1002, ¶184.

### (e) Analogous Art

Fumex and Bonutti '395 are in the same field and thus analogous art to the '259 Patent. Ex. 1001, Abstract, 1:13-16; Ex. 1004, Abstract, 1:5-12; Ex. 1006, Abstract, 1:20-22. Specifically, all three relate to the surgical anchoring using suture threads. *Id.*; Ex. 1002, ¶185.

### 2. Claim 23 and 25

Fumex discloses and/or suggests all elements of independent claims 1 and 22, including “an introducer comprised of a pushrod,” *see* Section VII.C.1, but does not expressly disclose that the pushrod is flexible, as required by claims 23 and 25. Fumex does not, however, require the insertion rod to be rigid, and in fact expressly contemplates inserting the rod into holes having any wall shape, such as a curved hole or a hole having an angled bend. Ex. 1004, 2:1-8, 6:64-65. At the time of the filing of the '259 Patent, nonlinear holes bored in bone and flexible

rods for inserting sutures into such holes was known, as evidenced by Bonutti '395. Ex. 1006, 10:23-12:8, Fig. 5.

A POSITA at the time of the filing of the '259 Patent would have understood that Fumex's rod could be made flexible, like the flexible pusher member of Bonutti '395, so that Fumex's bone anchoring device could be used in surgical applications in which a rigid, linear rod could not be used to insert the sleeve. For example, the combination could be used in surgical procedures involving nonlinear bone holes. Ex. 1002, ¶¶186-89.

**H. Ground 6: Claims 23 and 25 Are Obvious over Fumex in View of Grafton and Further in View of Bonutti '395**

Dependent claims 23 and 25, which depend from independent claims 1 and 11, respectively, both recite “wherein the pushrod is flexible.” As discussed above in Ground 5, claims 23 and 25 are obvious over Fumex, and Bonutti '395. *See* Section VII.G, *supra*.

Under Ground 6, claims 23 and 25 also are obvious over Fumex in view of Grafton and Bonutti '395. This ground is simply a combination of the analyses in Grounds 2 and 5 (sections VII.D and VII.G, *supra*). The bases for the combinations and manner of combining the references are already articulated in those grounds. Ex. 1002, ¶¶190-92.

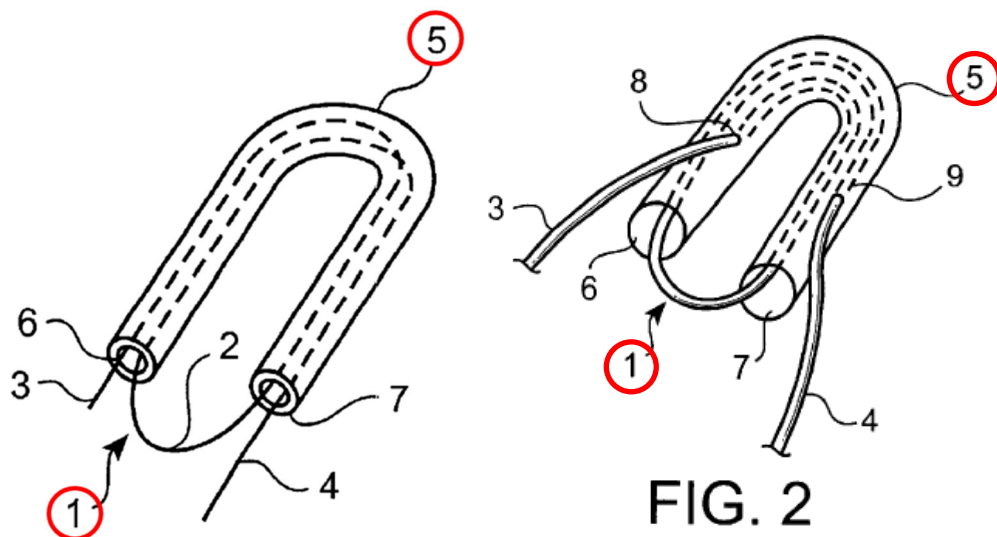
**I. Ground 7: Claims 2 and 12 are Obvious Over Fumex in View of Stone**

Claims 2 and 12, which depend from claims 1 and 11, respectively, further recite “at least one additional leg of a flexible elongated fastening member configured to extend from the flexible hollow fastener.” These claims would have been obvious over Fumex in view of Stone.

**1. The Combination of Fumex and Stone**

**(a) Overview of the Combination**

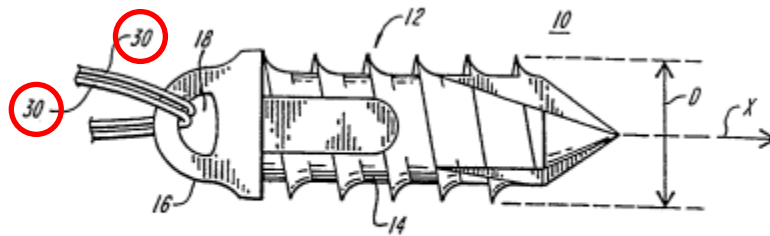
Fumex’s bone anchoring system includes a suture (1) that is passed through a flexible sleeve (5), as shown in Figures 1 and 2 below.



Ex. 1004, Figs. 1, 2 (annotated); Ex. 1002, ¶194.

While 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.

Stone recognizes that “multiple sutures are often required for soft tissue repair” and discloses a suture anchor assembly specially designed to “accommodate[] multiple suture fixation.” Ex. 1010, 2:3-14.



**FIG. 1**

The top suture/driver portion 16 at the distal end of the assembly 10 is designed both to hold a suture material and to fit the head of a driver device. 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*.

*Id.* at 4:32-42 (emphasis added).

It would have been obvious to use multiple sutures described by Stone with the flexible anchor described in Fumex. Ex. 1002, ¶¶195-97.

### **(b) Rationale (Motivation) Supporting Obviousness**

A POSITA would have found it obvious to use multiple sutures in Fumex’s flexible anchor. Fumex’s bone anchor can be used in surgical applications for soft tissue repair, and Stone expressly states that “multiple sutures are often required for soft tissue repair.” Ex. 1004 at 2:10-11. Furthermore, in the description of

“Related Art,” Fumex expressly cites to Stone (U.S. Pat No. 5,443,482) as

describing a known anchoring screw for fixing tissue using a suture:

In other techniques, after a hole has been bored which is able to receive an anchoring piton, the suture thread is passed through the eye of the anchoring piton, then the latter is introduced into the hole by means of a special instrument, and finally the tendon to be fixed is sutured. An example of an anchoring screw for fixing tissues by means of a suture thread is described in the patent U.S. Pat. No. 5,443,482.

Ex. 1004, 1:26-33; Ex. 1002, ¶198.

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.

Ex. 1002, ¶199.

Fumex and Stone are in the same field (securing bone to another organ or tissue using a suture anchor), and a POSITA would have naturally looked to Stone when considering the number and type of sutures used with suture anchors. A POSITA would know that 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. Ex. 1002, ¶200; Ex. 1004 at 2:10-11. The combination of Stone and Fumex does no more than use the two sutures described in Stone in a known and intended way to achieve a predictable result. Ex. 1002, ¶200.

### **(c) *Graham* Factors**

The level of ordinary skill is as proposed in Section VII.B.

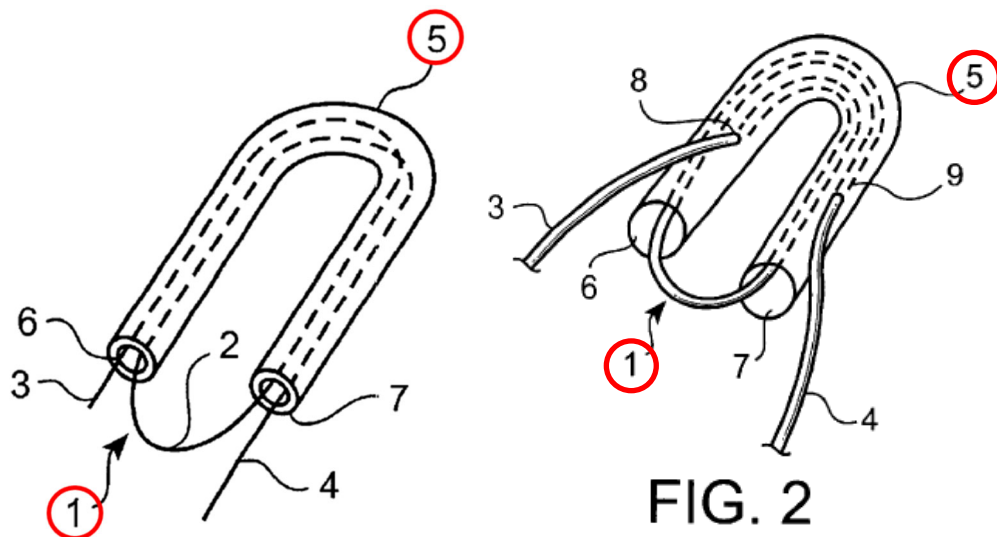
The scope and content of the prior art are discussed throughout this ground and in Section V.

The differences between the prior art and the claims are discussed in the “Overview of the Combination” (Section VII.G.1(a)) and below.

Petitioner is not aware of any secondary considerations that would make an inference of non-obviousness more likely.

#### **(d) Reasonable Expectation of Success**

A POSITA would have had a reasonable expectation of success in using multiple sutures in Fumex’s flexible anchor. As depicted in Figures 1 and 2, Fumex’s flexible anchor (5) is capable of accommodating at least two suture threads, as shown by thread (1) which is looped though the anchor in multiple embodiments.





A POSITA would understand that two separate sutures could be inserted through the flexible anchor and exit through the same or different orifices of the anchor, much like the looped suture is depicted in the alternate embodiments above. Ex. 1002, ¶¶201-202.

**(e) Analogous Art**

Fumex and Stone are in the same field and thus analogous art to the '259 Patent. Ex. 1001, Abstract, 1:13-16; Ex. 1004, Abstract, 1:5-12; Ex. 1010, Abstract. Specifically, all three relate to the surgical anchoring using suture threads. *Id.*; Ex. 1002, ¶203.

**2. Claims 2 and 12**

Fumex discloses and/or suggests all elements of independent claims 1 and 11, *see* Section VII.C.1, but does not expressly disclose at least one additional leg of a flexible fastener extending from the fastener, as required by claims 2 and 12. Fumex does not limit the number of sutures that can be passed through the flexible sleeve, and at the time of the filing of the '259 Patent, using more than one suture with a bone fastener was well-known, as evidenced by Stone. Ex. 1010, 2:3-14; 4:32-42; Fig. 1. A POSITA would have understood that Fumex's flexible anchor could be used with multiple sutures, depending on the surgical application in which it is used, as Stone describes providing benefits for many types of soft tissue repair. Ex. 1002, ¶204; Ex. 1010, 2:3-14.

**J. Ground 8: Claims 2 and 12 are Obvious Over Fumex in View of Grafton and Further in View of Stone**

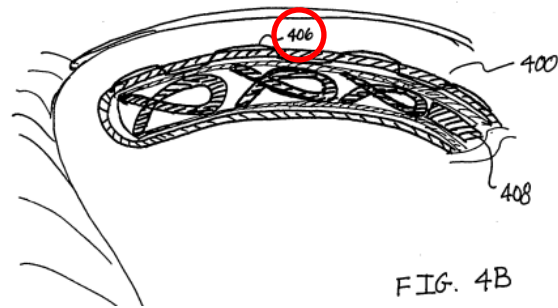
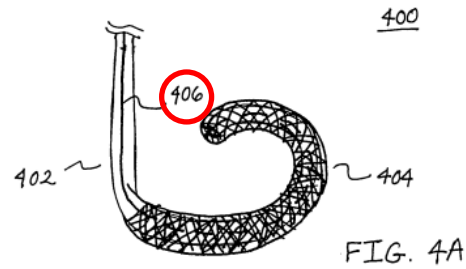
Under Ground 8, claims 2 and 12 also are obvious over Fumex in view of Grafton and Stone. This ground is simply a combination of the analyses in Grounds 2 and 7 (Sections VII.D and VII.I, *supra*). The bases for the combinations and manner of combining the references are already articulated in those grounds. Ex. 1002, ¶¶205-206.

**K. Ground 9: Claims 5, 9, 17, and 21 are Obvious Over Fumex in View of Stone and Further in View of To**

**1. The Combination of Fumex, Stone, and To**

**(a) Overview of the Combination**

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, as described in Ground 7, *supra*. 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.



In addition, a cinching strand, or tether (406)/(708) may be connected to the sleeve and anchors as the anchors are deployed.

***The cinching strand is connected to the sleeve (404) and 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.***

*Id.* at ¶ 43; Ex. 1002, ¶208.

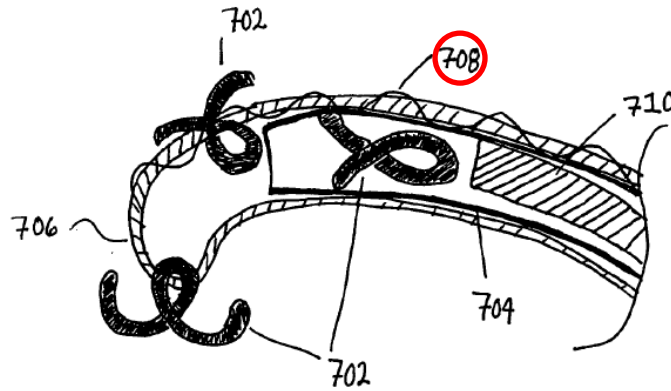


FIG. 7

After all the anchors have been deployed, cinching cable (708) is pulled proximally, to cinch the anchors and sleeve in a purse string fashion.

*Id.* at ¶53; Ex. 1002, ¶208.

It would have been obvious to use the flexible fastener of Fumex and multiple sutures of Stone where one of the sutures is fixed to the fastener, much like To's cinching strand. Ex. 1002, ¶¶209-10. It also would have been obvious to connect at least one leg of one of the sutures extending from the fastener to a second fastener as To describes. *Id.*

#### (b) Rationale (Motivation) Supporting Obviousness

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. To teaches that 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.

While a POSITA would know that using multiple sutures would be beneficial (including from Stone), Stone suggests that the sutures are secured through an eyelet, which the Fumex anchor does not have. A POSITA would understand that there are a limited number of ways to connect sutures to a flexible fastener, and Fumex shows that you can go through the ends of the sleeve as in Figure 1, or through orifices in the body of the sleeve, as in figure 2. Ex. 1004, Figs. 1, 2. A POSITA looking for how to optimize placement of a second suture would look to related art, like To, for how to design an anchor with multiple sutures. To would suggest to a POSITA that one of the sutures can be fixed to the anchor in the same way that To's cinching strand is weaved through the sleeve. Ex. 1002, ¶212.

While Fumex and Stone do not expressly suggest linking multiple anchors together, this practice was well known at the time of the invention, and is expressly taught by To. Ex. 1011 at ¶¶12, 13, 55, 56. A POSITA would have found it obvious to apply the teachings of To, which specifically describes fixing a suture to a flexible bone fastener and linking multiple fasteners together with sutures, to that of Fumex and Stone, as doing so would allow a surgeon to easily tension the

suture to support the tissue between the anchors and provide a wider footprint of support for a repair, like Rotator Cuff repair. Ex. 1002, ¶213.

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. The combination of Fumex, Stone and To does no more than use the fixed suture and connection of multiple anchors as disclosed in To in a known and intended way (*i.e.*, with the flexible anchor disclosed by Fumex) to achieve a predictable result. Ex. 1002, ¶214.

**(c) *Graham* Factors**

The level of ordinary skill is as proposed in Section VII.B.

The scope and content of the prior art are discussed throughout this ground and in Section V.

The differences between the prior art and the claims are discussed in the “Overview of the Combination” (Section VII.G.1(a)) and below.

Petitioner is not aware of any secondary considerations that would make an inference of non-obviousness more likely.

**(d) Reasonable Expectation of Success**

A POSITA would have had a reasonable expectation of success in using a fixed suture in Fumex’s flexible anchor and in connecting multiple anchors

together. A suture could easily have been made to be fixed to the flexible sleeve in Fumes, and nothing in either Fumex or Stone suggest that multiple anchors could not be attached in series with a common suture. Ex. 1002, ¶215.

**(e) Analogous Art**

Fumex, Stone and To are in the same field and thus analogous art to the '259 Patent. Ex. 1001, Abstract, 1:13-16; Ex. 1004, Abstract, 1:5-12; Ex. 1010, Abstract; Ex. 1011, Abstract. Specifically, all relate to the surgical anchoring using suture threads. *Id.*; Ex. 1002, ¶216.

**2. Claim 5**

Claim 5, which depends from claim 2, recites “wherein the at least one additional leg of flexible elongated fastening member is fixed to the flexible hollow fastener.” This claim would have been obvious over Fumex in view of Stone and To.

Fumex and Stone disclose and/or suggest all elements of dependent claim 2, and independent claim 1, *see* Sections VII.C.1, VII.I, but do not expressly disclose at least one additional leg of flexible elongated fastening member is fixed to the flexible hollow fastener, as claim 5 recites. To describes a surgical device for the deployment of tissue anchors that include a cinching strand connected to the anchor that allows a surgeon to tighten the slack between anchors after they are deployed. Ex. 1011 at ¶ 43. A POSITA at the time of the filing of the '259 Patent

would have understood that Fumex's flexible anchor could be used with a fixed suture, as described in To, and doing so would be a simple design choice. Ex. 1002, ¶¶217-18.

### **3. Claim 9**

Claim 9, which depends from claim 5, 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.” This claim would have been obvious over Fumex in view of Stone and To.

Fumex, Stone, and To disclose and/or suggest all elements of dependent claims 5 and 2, and independent claim 1, *see* Sections VII.C.1, VII.K. To also describes connecting a second fastener to one of the legs of the suture extending from a first fastener to secure the tension of the suture. Ex. 1011, ¶¶12, 13, 43, 55, 56. A POSITA at the time of the filing of the '259 Patent would have understood that Fumex's flexible anchor could be used in series, connected by a common suture, as To describes, and doing so would secure the tension and position of the suture between the anchors, while at the same time providing better and wider support for the repair through the use of multiple anchors. Ex. 1002, ¶¶219-20.



#### **4. Claim 17**

Claim 17, which depends from claim 12, recites “at least one additional leg of the flexible elongated fastening member is fixed to the flexible hollow fastener.” See claim 5, *supra*; Ex. 1002, ¶221.

#### **5. Claim 21**

Claim 21, which depends from claim 17, recites “connecting a second fastener to the flexible elongated fastening member.” See claim 9, *supra*; Ex. 1002, ¶222.

#### **L. Ground 10: Claims 5, 9, 17, and 21 are Obvious Over Fumex in View of Grafton and Stone and Further in View of To**

As discussed above in Ground 9, claims 5, 9, 17 and 21 are obvious over Fumex, in view of Stone and To. *See* Section K, *supra*.

Under Ground 10, claims 5, 9, 17 and 21 also are obvious over Fumex in view of Grafton, Stone and To. This ground is simply a combination of the analyses in Grounds 2 and 9 (Sections VII.D and VII.K, *supra*). The bases for the combinations and manner of combining the references are already articulated in those grounds. *See* Ex. 1002, ¶¶223-24.

### **VIII. DISCRETIONARY DENIAL IS NOT APPROPRIATE**

*Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) weighs against exercising discretion in this case. Specifically, factors 1-4 and 6 weigh against denial because in the corresponding litigation, the

Answer was filed on September 22, 2021 with no discovery occurring as of this filing and no current timeline for a trial. Trial is unlikely to occur before a Final Written Decision, and Petitioner plans to seek a stay of the litigation in view of this IPR. Petitioner also challenges claims not identified as being asserted in the corresponding litigation and the merits of the petition are strong.

## **IX. CONCLUSION**

For the reasons stated above, Petitioner submits that claims 1-26 of the '259 Patent are unpatentable. Accordingly, Petitioner requests institution of *inter partes* review.

DATED: May 31, 2022

Respectfully submitted,

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## **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing petition for *inter partes* review, together with all exhibits and other documents filed therewith, was served by Federal Express on May 31, 2022, on the Patent Owner's counsel of record at the U.S. Patent and Trademark Office having the following address:

Stinson LLP (Stinson Leonard Street)  
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St. Louis, MO 63105

Date: May 31, 2022

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**CERTIFICATE OF WORD COUNT**

The undersigned hereby certifies that the foregoing petition for *inter partes* review contains 13,894 words according to the word processing program used to prepare it.

Date: May 31, 2022

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