UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

ARTHREX, INC.
Petitioner

v.

P TECH, LLC
Patent Owner

_____

Case No. IPR2022-01043
Patent No. 9,814,453

_____

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,814,453

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

PETITIONER'S EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 9,814,453 ("'453 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 Application 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	*P Tech, LLC v. Arthrex, Inc.*, Case No. 1:21-cv-968-LPS, Document 1-14 (Complaint Exhibit N) (June 30, 2021)
1011	CONMED's Linvatec Subsidiary Introduces Fourteen New Products (March 10, 2004)
1012	Herculine Polyethylene Suture (March 13, 2006)
1013	Smith & Nephew ULTRABRAID Suture (May 7, 2004)
1014	Hospital Pharmacy Mission of the Hospices Civils de Lyone at the Ali Abad Hospital in Kabul (excerpt) (July 16, 2004)
1015	Sworn English Translation of Exhibit 1014
1016	U.S. Patent No. 5,718,717 ("Bonutti '717")
1017	U.S. Patent Application Publication No. 2001/0002440 ("Bonutti '440")

CLAIM LISTING

[1.P] 1. A deformable fastener system comprising:

[1.1] a flexible hollow fastener fabricated solely from a plurality of biocompatible fibers;

[1.2] a suture extending through the hollow fastener such that two legs of the suture extend from the hollow fastener to enable a user to tension the suture,

[1.3] wherein at least a portion of the suture is fabricated with polyethylene; and

[1.4] an introducer having a pushrod configured to engage the fastener and position the fastener relative to a body tissue,

[1.5] wherein the hollow fastener and suture are positioned on the distal end of the pushrod, and

[1.6] wherein the hollow fastener is configured to deform from a first configuration to a second configuration to provide an anchor for the suture as the suture is tensioned relative to the body tissue; and

[1.7] wherein the hollow fastener includes a polymeric material.

2. The system of claim 1, wherein the suture includes at least a portion of polyester.

3. The system of claim 1, wherein the hollow fastener is knotless.

4. The system of claim 1, wherein the suture is positionable through proximal and distal portions of body tissue.

5. The system of claim 1, wherein the pushrod is flexible.

6. The system of claim 1, wherein the introducer has at least one of a linear configuration and a curved configuration.

7. The system of claim 1, wherein the distal portion of the introducer is configured to penetrate an imperforate surface of the body.

[8.P] 8. A deformable fastener system comprising:

[8.1] a suture;

[8.2] a flexible hollow fastener fabricated solely from a plurality of fibers comprised of a biocompatible polymeric material,

[8.3] wherein at least a portion of the suture extends through the hollow fastener such that two legs of the suture extend from the hollow fastener to enable a user to tension the suture

[8.4] to deform the hollow fastener from a first configuration to a second configuration to anchor the suture within the body; and

[8.5] an introducer with a pushrod configured to engage the fastener,

[8.6] wherein the hollow fastener and suture are positioned on the distal end of the pushrod.

9. The system of claim 8, wherein the suture is at least one of braided and interlaced.

10. The system of claim 8, wherein the suture includes polyethylene.

11. The system of claim 8, wherein the suture includes at least a portion of polyester.

12. The system of claim 8, wherein the pushrod is flexible.

13. The system of claim 8, wherein the introducer has at least one of a linear configuration and a curved configuration.

[14.P] 14. A method of using a deformable fastener system, said method comprising:

[14.1] inserting a deformable hollow fastener into a passage in a bone,

[14.2] the deformable hollow fastener being flexible and fabricated solely from a plurality of flexible biocompatible fibers, and

[14.3] having a suture extending through the deformable hollow fastener such that two legs of the suture extend from the deformable hollow fastener to enable a user to tension the suture,

[14.4] wherein the deformable hollow fastener and suture are positioned on the distal end of a pushrod during insertion;

[14.5] tensioning the suture to anchor the deformable hollow fastener into the bone;

[14.6] deforming the deformable hollow fastener from a first configuration to a second configuration in the bone; and

[14.7] wherein inserting a deformable hollow fastener further comprises inserting a deformable hollow fastener that includes a polymeric material.

15. The method of claim 14, wherein inserting a deformable hollow fastener having a suture further comprises inserting a deformable hollow fastener having a suture that is at least one of braided and interlaced.

16. The method of claim 14, wherein inserting a deformable hollow fastener having a suture further comprises inserting a deformable hollow fastener having a suture that includes at least one of polyethylene and polyester.

17. The method of claim 14, wherein inserting a deformable hollow fastener further comprises inserting a deformable hollow fastener with a pushrod that is flexible.

18. The method of claim 14, wherein inserting a deformable hollow fastener further comprises inserting a deformable hollow fastener with an introducer that has at least one of a linear configuration and a curved configuration.

19. The system of claim 8, wherein the hollow fastener is knotless.

20. The method of claim 14, wherein inserting a deformable hollow fastener further comprises inserting a deformable hollow fastener that is knotless.

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 1-20 of U.S. Patent No 9,814,453 ("the '453 Patent") (Ex. 1001) pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq.* The '453 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 '453 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*, IPR2022-00717 (PTAB) (filed March 31, 2022) (challenging U.S. Patent No. 10,881,440);
- *Arthrex, Inc. v. P Tech, LLC*, IPR2022-00786 (PTAB) (filed April 8, 2022) (challenging U.S. Patent No. 9,279,129); and
- *Arthrex, Inc. v. P Tech, LLC*, IPR2022-00787 (PTAB) (filed April 11, 2022) (challenging U.S. Patent No. 9,999,449).

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

Lead Counsel	Backup Counsel
Megan S. Woodworth (Reg. No. 53,655) *mswoodworth@venable.com* VENABLE LLP 600 Massachusetts Ave., NW Washington, DC 20001 T 202-344-4507 F 202-344-8300	Justin J. Oliver (Reg. No. 44,986) *jjoliver@venable.com* VENABLE LLP 600 Massachusetts Ave., NW Washington, DC 20001 T 202-721-5423 F 202-344-8300 Robert E. Bugg (Reg. No. 65,949) *rebugg@venable.com* Seth E. Boeshore (Reg. No. 63,049) *sboeshore@venable.com* VENABLE LLP 1270 Avenue of the Americas 24th Floor New York, NY 10020 T 212-370-6241 F 212-307-5598 Joseph B. Cahill (Reg. No. 80,691) *jbcahill@venable.com* VENABLE LLP 600 Massachusetts Ave., NW Washington, DC 20001 T 202-344-4201 F 202-344-8300

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.

II. INTRODUCTION

The ’453 Patent relates to deformable fastener systems for securing tissue within the body, particularly fractured, incised, or torn tissue. Specifically, tissues are held together by a fastening member, such as a suture, which extends through the tissues. On at least one end, a fastener is used to hold the fastening member in place, such that tensioning the fastening member (*e.g.*, suture) pulls the pieces together.

The challenged claims of the ’453 Patent all include three basic elements: (1) a flexible hollow fastener fabricated solely from biocompatible polymeric fibers; (2) a suture extending through the hollow fastener so that two legs of the suture extend from the fastener, enabling a user to tension the suture and deform the fastener from a first configuration to a second configuration; and (3) an introducer having a pushrod configured to engage the fastener and position it relative to tissue. Two of the three independent challenged claims recite deformable fastener systems having these basic elements, while the third recites a method of using such a deformable fastener system.

Each claimed element was well known in the art before the filing of the ’453 Patent. In particular, U.S. Patent No. 6,511,498 (“Fumex”) teaches and/or suggests all elements recited in the independent challenged claims. Fumex was not considered by the Patent Office in deciding to allow the claims.

Beyond the independent claims, the challenged dependent claims are unpatentable based either solely on Fumex or in combination with other prior art. As that art is applied, all challenged claims of the ’453 Patent are unpatentable.

III. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the ’453 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 of the ’453 Patent.

IV. 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 1-20 of the ’453 Patent (“Challenged Claims”) on the grounds set forth below and (ii) that those claims be found unpatentable.

Ground	Claim(s)	Basis for Unpatentability
1	8, 9, 11, 13-16, and 18-20	35 U.S.C. § 102 as anticipated by Fumex
2	1, 3, 4, 6-11, 13-16, and 18-20	35 U.S.C. § 103 as obvious over Fumex
3	1-4, 6, 9, 10, and 15	35 U.S.C. § 103 as obvious over Fumex and Grafton

4	5, 12, and 17	35 U.S.C. § 103 as obvious over Fumex and Bonutti ’395
5	5	35 U.S.C. § 103 as obvious over Fumex, Grafton, and Bonutti ’395
6	3, 19, and 20	35 U.S.C. § 103 as obvious over Fumex and Bonutti ’875
7	1 and 7	35 U.S.C. § 103 as obvious over Bonutti ’717 and Fumex
8	1 and 7	35 U.S.C. § 103 as obvious over Bonutti ’717, Fumex, and Grafton

B. The Challenges Presented Are Not Cumulative

The grounds for unpatentability presented in this petition are neither cumulative nor redundant to prosecution of the ’453 Patent. Although some of the references were listed on information disclosure statements, none was cited by or otherwise relied on by the Examiner.

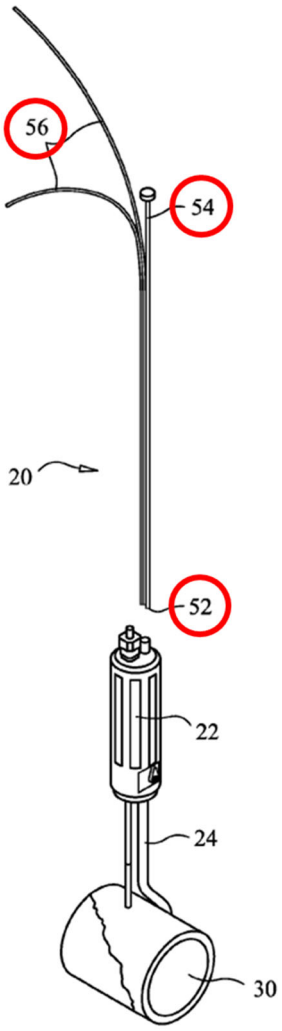
V. SUMMARY OF THE ’453 PATENT

A. Background

The ’453 Patent “relates to the guidance and positioning of tissue, an implant, or other surgical devices within the body.” Ex. 1001, 1:13-16. The patent acknowledges known techniques/devices for physicians to attach tissue to tissue, and that these techniques or devices could be used to position or fix an implant within the body. *Id.*, 1:20-32. The patent purports to improve upon guided

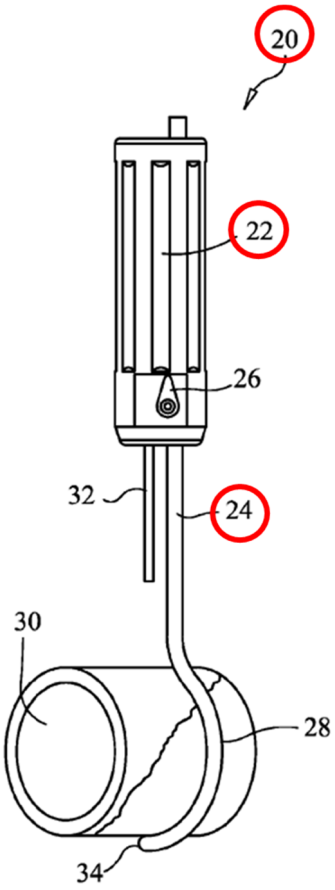
positioning, as well as fixation of tissue/implants within the body while accessing the procedure site from a small skin portal. *Id.*, 2:53-56; Ex. 1002, ¶25.

The fixation device described by the ’453 Patent includes suture 56 that is looped through deformable fastener 52 prior to implantation. Ex. 1001, 6:36-42, Fig. 3. The suture and fastener then are positioned on pushrod 54. *Id.*



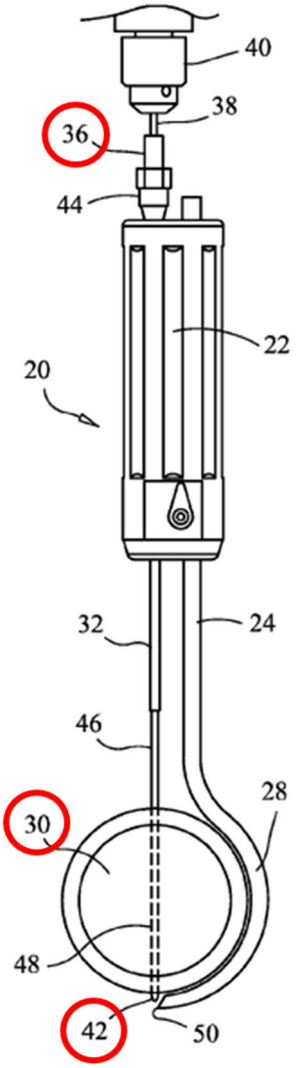
Id., Fig. 3 (annotated).

To prepare the tissue for insertion of the suture and fastener, a guidance and positioning device 20 that includes cylindrical handle 22 and hook 24 is inserted. *Id.*, 5:2-14, Fig. 1.



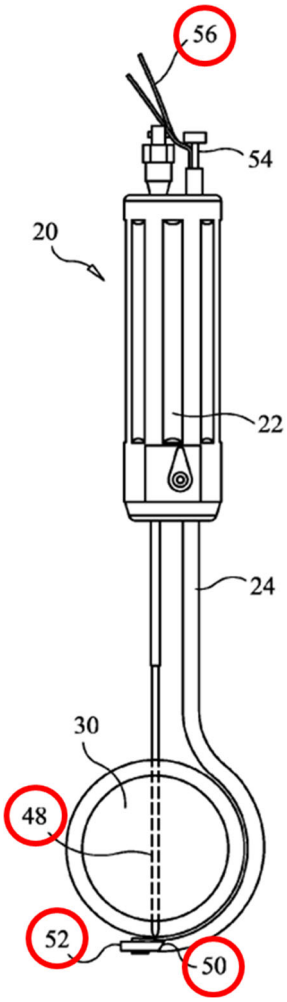
Id., Fig. 1 (annotated).

Next, drill system 36 is used to drive bit 42 to create a hole through the tissue. *Id.*, 5:66-6:23, Fig. 2.



Id., Fig. 2 (annotated); Ex. 1002, ¶¶26-28.

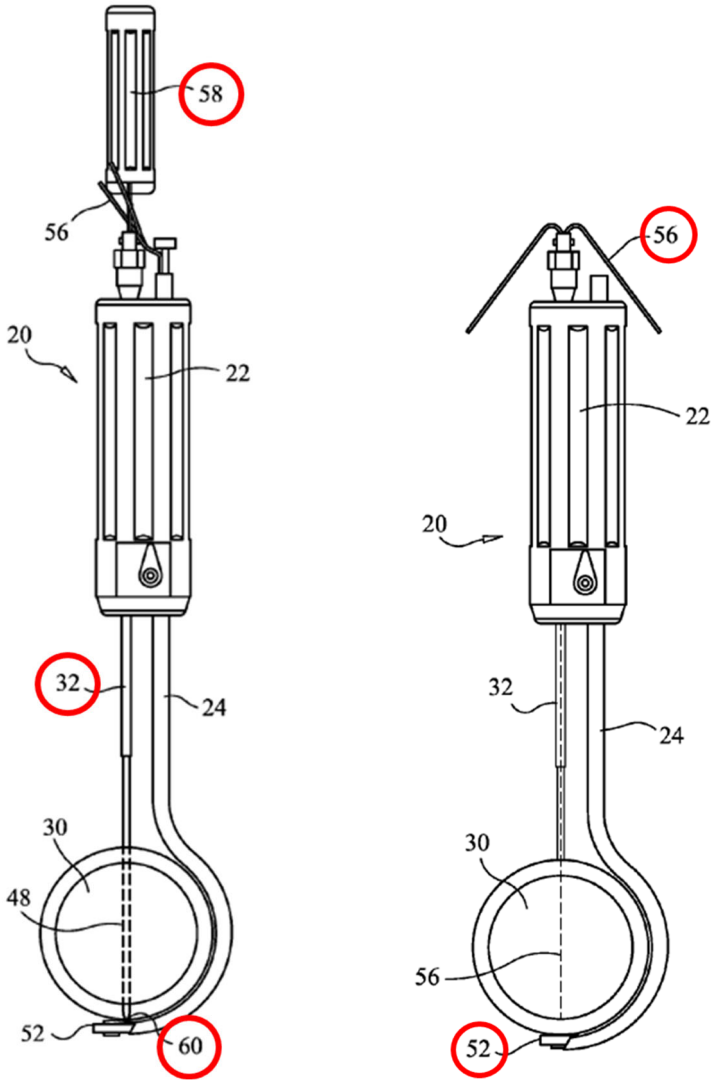
With the hole drilled, pushrod 54 can push fastener 52 through the hook to be positioned at the distal opening of the drilled hole, beyond distal aperture 50 of the hook. Ex. 1001, 12:48-58, Fig. 4.



Id., Fig. 4 (annotated); Ex. 1002, ¶28.

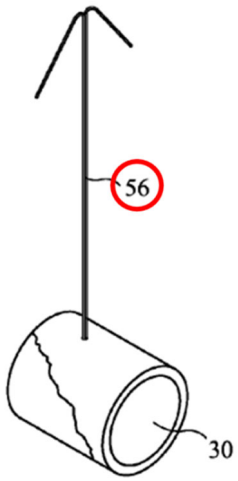
The ’453 Patent does not illustrate fastener 52 being a flexible hollow fastener. The only mention of the fastener being “hollow” appears in a laundry list of possible options, which separately mentions “hollow” and “threaded.” Ex. 1001, 11:29-36.

After fastener 52 is in place and pushrod 54 is removed, suture claw 58 or grabber is inserted through the drilled hole to cause hook 60 to attach to the suture 56 to fastener 52 at the distal end of the fractured bone. *Id.*, 13:9-52, Figs. 5, 7.



Id., Figs. 5 (left, annotated), 7 (right, annotated); Ex. 1002, ¶¶29-30.

From this configuration, the guidance and positioning device 20 can be removed, leaving just suture 56 and fastener 52. Ex. 1001, 13:23-64, Fig. 8. The suture then can be tensioned, causing the fastener to secure the suture to the fractured bone.



Id., Fig. 8 (annotated); Ex. 1002, ¶31.

In this manner, the fractured bone can be secured during healing. As established below, such procedures/devices were known in the field prior to the filing date of the '453 Patent.

B. Claimed Subject Matter

The '453 Patent contains twenty claims, of which claims 1, 8, and 14 are independent. Independent claim 8 recites:

> A deformable fastener system comprising:
>
> a suture;
>
> a flexible hollow fastener fabricated solely from a plurality of fibers comprised of a biocompatible polymeric material, wherein at least a portion of the suture extends through the hollow fastener such that two legs of the suture extend from the hollow fastener to enable a user to tension the suture to deform the hollow fastener from a first configuration to a second configuration to anchor the suture within the body; and
>
> an introducer with a pushrod configured to engage the fastener, wherein the hollow fastener and suture are positioned on the distal end of the pushrod.

Notably, the only structural elements recited in the claim are a suture, a fastener, and an introducer with a pushrod.

Independent claim 1 includes many of the same limitations as claim 8. The primary difference between them is that claim 1 requires a portion of the suture to be polyethylene. Independent claim 14 recites a method for using a deformable fastener system having essentially the same limitations as claim 8. Ex. 1002, ¶¶32-34.

C. Prosecution History

The ’453 Patent issued from U.S. Application No. 13/871,892 (“the ’892 application”), which is a continuation of U.S. Application No. 11/202,294 (“the ’294 application”).

The claims presented in the ’294 application were directed to a guidance and positioning device and generally did not bear on the suture and fastener claimed in the ’453 Patent. Ex. 1008; Ex. 1002, ¶35.

In the ’892 application, the Examiner initially rejected the claims on various grounds, including anticipation and obviousness. Ex. 1009, 1367-74. To overcome these rejections, the applicant amended the claims to add limitations of “a suture extending through a portion of the fastener” and “the fastener is configured to deform to and provide an anchor for the suture as the suture is tensioned.” *Id.*, 854-57, 859-63. After a subsequent, similar rejection, the applicant further amended the

claims to specify that "two legs of the suture extend from the fastener to enable a user to tension the suture." *Id.*, 653-58; Ex. 1002, ¶¶36-37.

In subsequent actions, the Examiner made additional rejections based on new prior art. Ex. 1009, 247-54. To overcome these rejections, the applicant added the limitation of "wherein the hollow fastener and suture are positioned on the distal end of the pushrod." *Id.*, 227-38.

After an Examiner interview, a limitation that the hollow fastener included "a polymeric material" was added and the application was allowed. *Id.*, 854-64; Ex. 1002, ¶38.

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) ("ordinary and customary meaning"), all limitations of the challenged claims are met in the prior art as discussed below.

A. "Passage"

Independent claim 14 includes a step of "inserting a deformable hollow fastener into a passage in a bone."

In each embodiment in the '453 Patent, a fastener is applied at the distal opening of a passage that traverses the entire bone. *See, e.g.*, Ex. 1001 Figs. 2, 4, 5, 7-9. However, in the related proceeding, Patent Owner asserts that the '453 Patent

claims cover a procedure that includes placing a fastener at or in a bone hole that does not go all the way through the bone. Ex. 1010, 4-6. Accordingly, Patent Owner's apparent construction of "passage" would encompass any opening in a bone into which a device can be inserted, including "passages" that do not go all the way through the bone. Thus, Patent Owner appears to construe "passage" simply as "an opening into which something can be placed."

For purposes of this proceeding only, this petition applies Patent Owner's apparent construction in the related proceedings. *See NEC Display Solutions of America, Inc. v. Ultravision Tech.*, IPR2019-01123, Paper No. 7, 12-14 (P.T.A.B. Dec. 2, 2019).

B. "Knotless" Fastener

Claims 3 and 19 recite the limitation "wherein the hollow fastener is knotless." Claim 20 recites a similar limitation of "a deformable hollow fastener that is knotless."

The '453 Patent specification uses the term "knotless" only once in a laundry list of fastener options, but does not define it. Ex. 1001, 11:29-36. 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. Ex. 1002, ¶¶40-48.

VII. PRIOR ART

A. Effective Filing Dates

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.

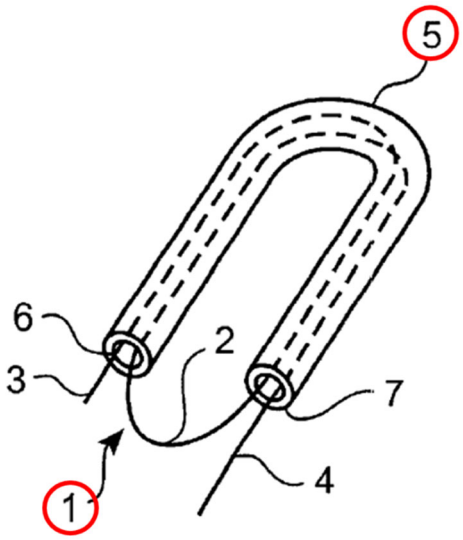
U.S. Patent No. 5,718,717 ("Bonutti '717") (Ex. 1016) issued on February 17, 1998.

Thus, each reference constitutes prior art under pre-AIA 35 U.S.C. § 102(b).

B. Overview of Fumex

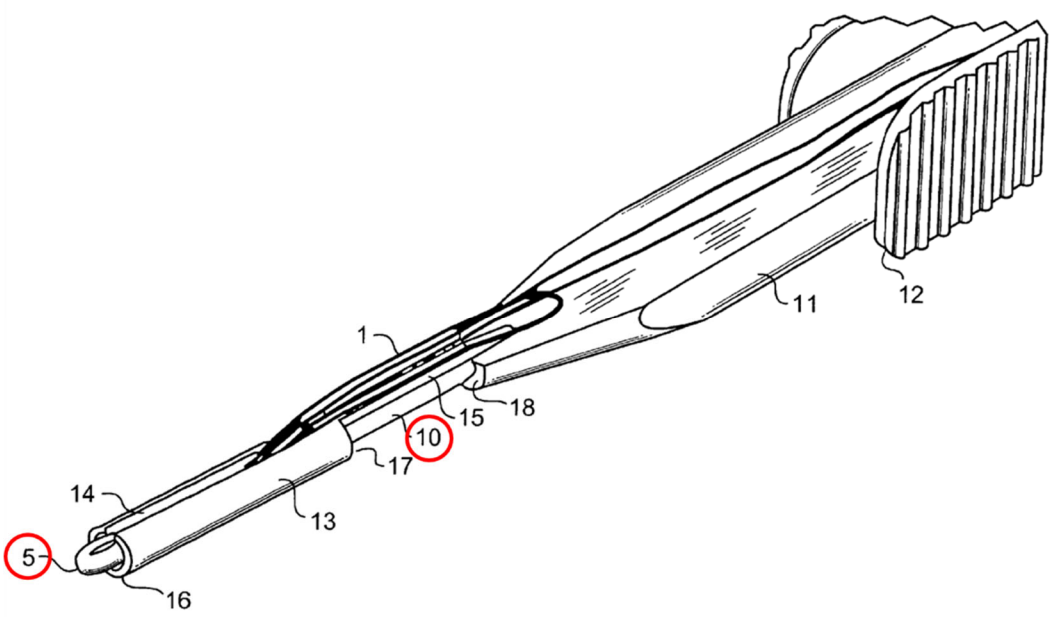
Fumex describes a surgical bone anchoring system that includes a deformable tubular sleeve for fastening to a hole bored in bone. Ex. 1004, 1:7-12 ("surgical device for bone anchoring"), 2:12-18 ("anchoring device…can be used in combination with a hole bored in the bone support, and it comprises a

deformable tubular sleeve"), 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 system includes suture thread 1 that is passed through flexible sleeve 5 such that two strands extend from the sleeve.



Id., Fig. 1 (annotated); Ex. 1002, ¶60.

The flexible sleeve and suture can be inserted into the hole in the bone by an ancillary instrument having a handle and a rod. Ex. 1004, 6:47-56, Fig. 5. The rod engages with the sleeve and suture passed through it to push them into the hole. *Id.*, 6:47-56 ("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); Ex. 1002, ¶61.

Once inserted into the hole in the bone, the thread strands extending from the hole 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 ….

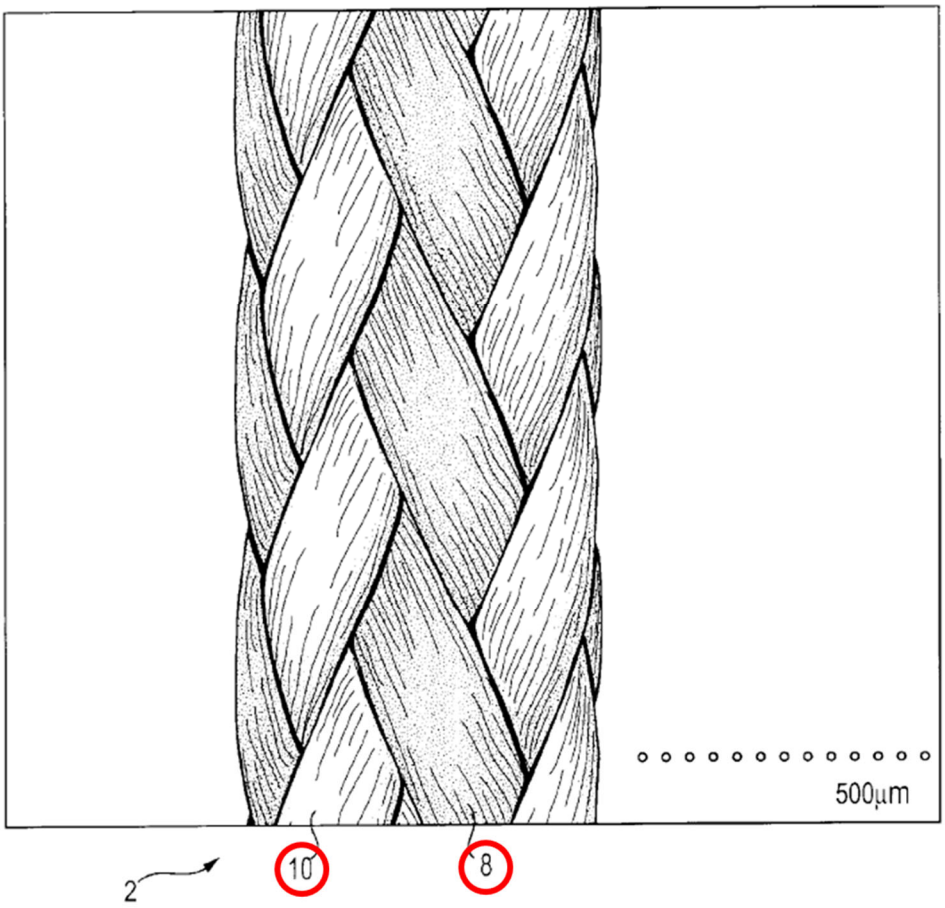
Ex. 1004, 5:38-57, 2:42-45 ("tubular sleeve can be deformed into a ball by simple traction exerted on at least one strand"), 3:10-14 ("by exerting a traction on the strands of the thread in diverging directions, the sleeve is folded until it presents approximately the form of a ball"), 5:62-6:22; Ex. 1002, ¶62.

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." *Id.*, 2:54-65. Examples of sleeve materials include braided metal or plastic wire, polyester, polyamide, and silicone. *Id.*, 2:54-65; Ex. 1002, ¶63.

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. Ex. 1004, 2:46-48, 1:9-10 ("anchoring of suture thread or surgical thread on a bone support"). Fumex provides two examples of suture threads, both of which are synthetic, polymeric, and non-absorbable. *Id.*, 2:46-53 ("a polyester thread such as the one marketed under the brand name Ercylene®, or a polyamide thread such as Trynil®"); Ex. 1002, ¶64.

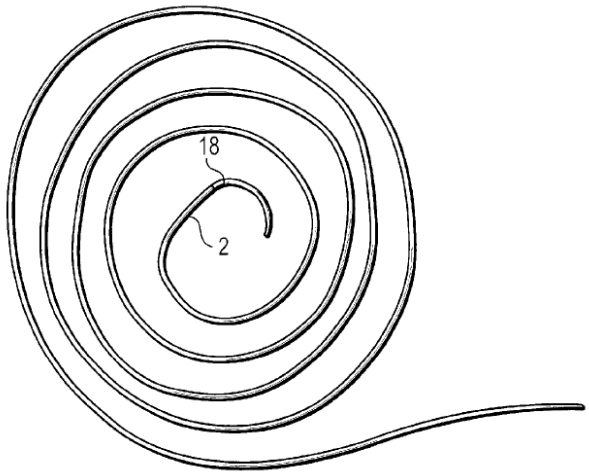
C. Overview of Grafton

Grafton describes high strength surgical suture. Ex. 1005, ¶[0005]. The suture 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), [0006], Fig. 1.



Id., Fig. 1 (annotated to show strands of polyester 10 and polyethylene 8 braided together); Ex. 1002, ¶65.

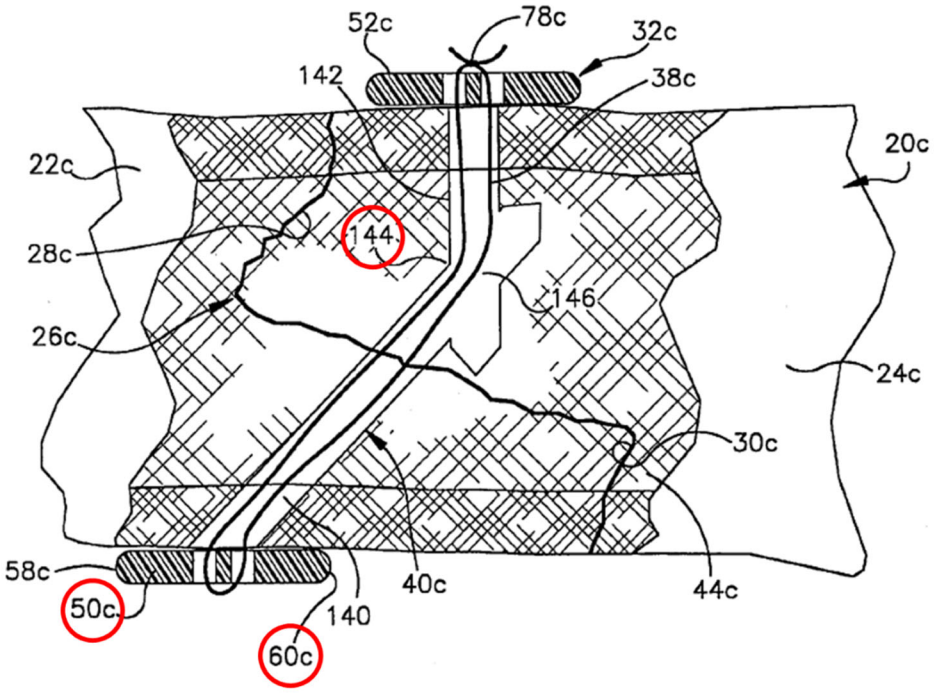
Grafton's suture can be rolled into a coil and thus is sufficiently flexible for use as surgical suture in applications where the suture must be threaded through, for example, a flexible fastener. Ex. 1005, Fig. 4A.



Id., Fig. 4A; Ex. 1002, ¶66.

D. Overview of Bonutti ’395

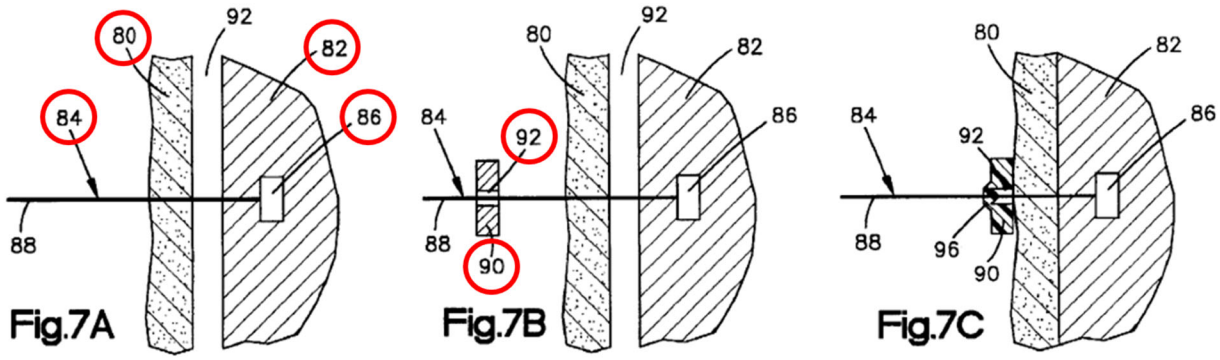
Bonutti ’395 describes a flexible push rod for use with a nonlinear hole drilled into bone. Ex. 1006, 10:23-12:8 (flexible pusher member applies force against suture anchor to push it around a bend in the passage), Fig. 5.



Id., 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, ¶67.

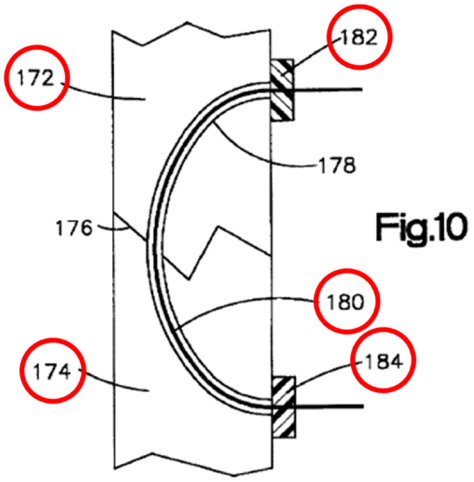
E. Overview of Bonutti '875

Bonutti '875 describes a 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. Two pieces of tissue 80 and 82 are joined using a suture 84 attached to a distal anchor 86 that is anchored to tissue 82. *Id.*, 7:37-44, Fig. 7A. Suture 84 is inserted through the tissues 82 and 80 so that free end 88 of suture 84 protrudes at the proximal end. *Id.*, Fig. 7B. Fastener 90 having opening 92 is slid over wire 84 and pulled down tight, to close the gap between the tissues. *Id.*, Fig. 7C.



Id., Figs. 7A-7C (annotated); Ex. 1002, ¶68.

Bonutti '875 describes several different applications for its suture fasteners, including securing a suture to a single tissue (*e.g.*, a fractured bone). Ex. 1007, 8:40-60, Fig. 10. For example, fastener 182 can secure suture 180 to first bone part 172 of a fractured bone, and another fastener 184 can secure the suture to second bone part 174 of the fractured bone without a knot. *Id.*, Fig. 10.



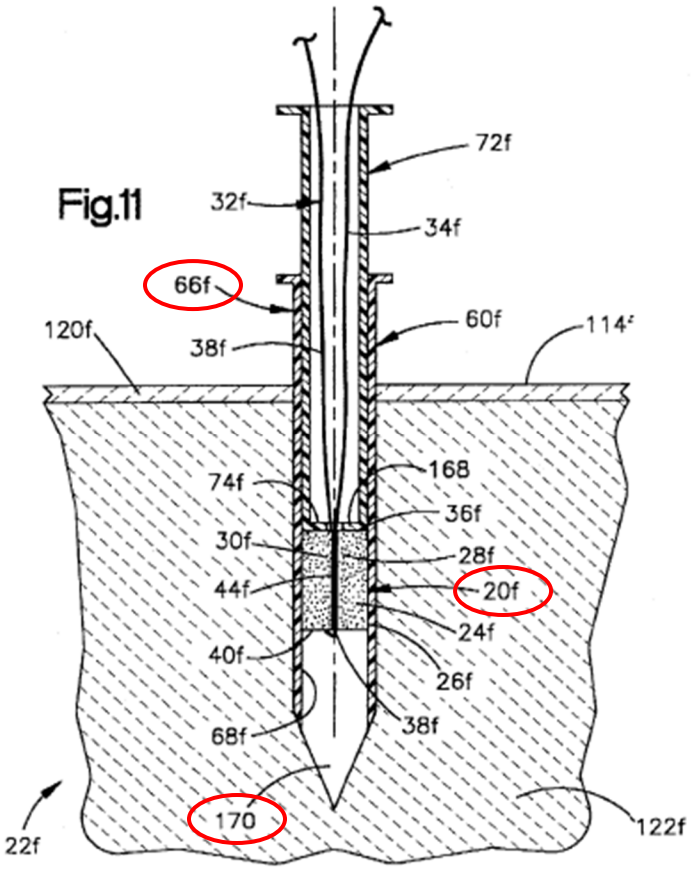
Ex. 1007, Fig. 10 (annotated); Ex. 1002, ¶69.

F. Overview of Bonutti '717

Bonutti '717, which is referenced in the '453 Patent, describes a suture anchor that when inserted into body tissue expands to retain the suture anchor with

suture ends extending from the anchor. Ex. 1016, 1:24-26, 2:45-48. The suture anchor may be used in hard or soft tissue at various locations in the body, including bone. *Id*., 4:45-54; Ex. 1002, ¶70.

Bonutti ’717 describes an inserter assembly for positioning the suture anchor in body tissue. Ex. 1016, 12:5-14:64, Fig. 11. The suture anchor 20f is positioned in cylindrical outer sleeve 66f of the syringe-like inserter assembly 60f. The outer sleeve has a pointed leading end portion 170 configured to penetrate body tissue and position the suture anchor. The inserter assembly also includes cylindrical inner sleeve 72f, which is telescopically engaged with outer sleeve 66f and includes leading end portion 76f as bearing surface against suture anchor 20f. *Id.*, 12:45-64.



Id., Fig. 11 (annotated); Ex. 1002, ¶71.

To insert the suture into body tissue, outer sleeve 66f is forced into the tissue to the desired depth. *Id.*, 13:14-36. Next, inner sleeve 72f is pressed downward to move the compressed suture anchor 20f to the leading end portion 170. *Id.* Then, outer sleeve 66f is moved upward while inner sleeve 72f is held stationary. *Id.* This causes suture anchor 20f to be ejected from outer sleeve 66f into the tissue. Once ejected, the anchor expands and the inner and outer sleeves are withdrawn. *Id.*; Ex. 1002, ¶72.

VIII. ARGUMENTS

A. Statement of the Law

Ground 1 relies on anticipation under 35 U.S.C. § 102. A claim is anticipated when "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The remaining grounds 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 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. Ex. 1002, ¶52.

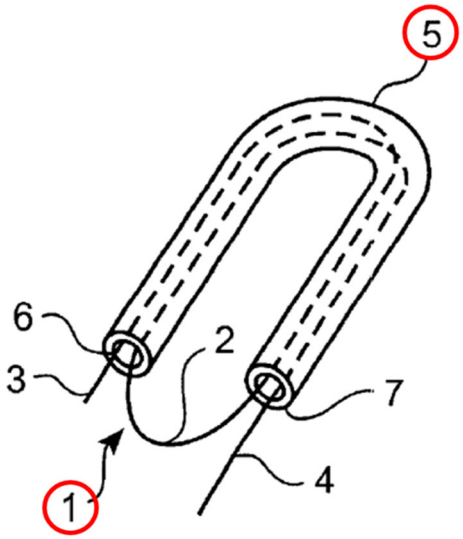
C. Ground 1: Claims 8, 9, 11, 13-16, and 18-20 Are Anticipated by Fumex

1. Independent Claim 8

Fumex discloses all limitations of independent claim 8.

(a) [8.p] *A deformable fastener system comprising*:

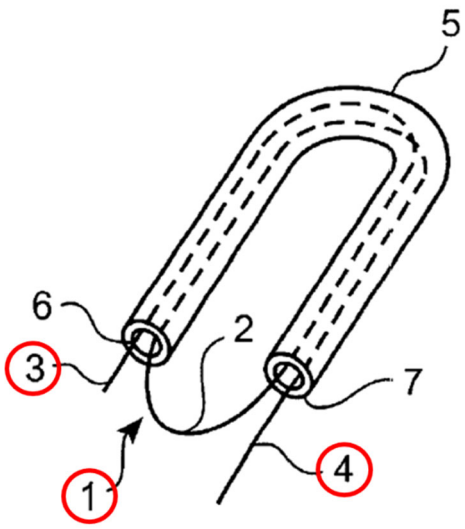
Fumex describes a deformable fastener system because its surgical bone anchoring system (*see, e.g.*, Figure 1) includes deformable tubular sleeve 5 that can be fastened to a hole bored in bone. Ex. 1004, 1:7-10 ("surgical device for bone anchoring"), 2:12-18 ("anchoring device…can be used in combination with a hole bored in the bone support, and it 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).



Id., Fig. 1 (annotated); Ex. 1002, ¶76.

(b) [8.1] *a suture*;

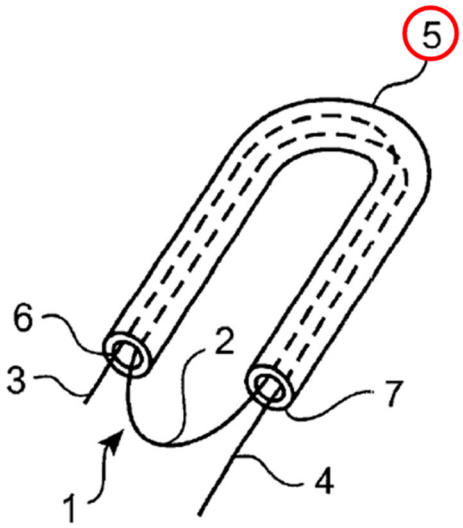
Fumex's bone anchoring system includes suture 1 that passes through the flexible sleeve such that two strands (3, 4) extend from the sleeve. Ex. 1004, 5:38-57, 2:46-49 ("preferably a surgical thread or a suture thread, absorbable or non-absorbable, of the type used to fix or re-attach organs"), Fig. 1.



Id., Fig. 1 (annotated); Ex. 1002, ¶77.

(c) [8.2] ***a flexible hollow fastener fabricated solely from a plurality of fibers comprised of a biocompatible polymeric material,***

Fumex's describes a flexible hollow fastener in the form of flexible, tubular (*i.e.*, hollow) sleeve 5. Ex. 1004, 5:39-61, 7:21-25 (surgical device for anchoring includes "a deformable tubular sleeve"), Fig. 1. The sleeve is 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. *Id.*, 5:62-6:22. Thus, it is a fastener.



Id., Fig. 1 (annotated); Ex. 1002, ¶¶78-81.

The tubular sleeve 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, ¶80.

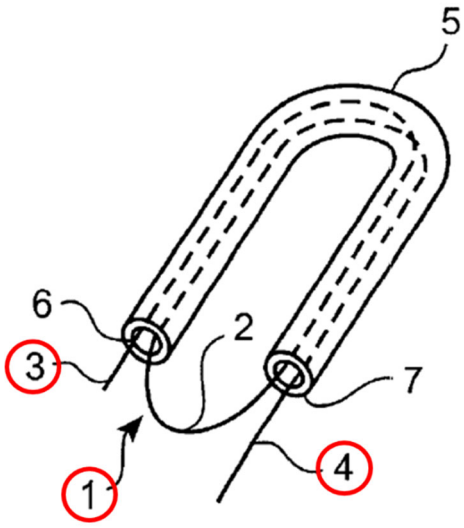
Fumex discloses an embodiment in which tubular sleeve 5 is fabricated from a "non-absorbable polyester braid." Ex. 1004, 4:50-63. Fumex thus describes a unitary hollow fastener fabricated solely from a plurality of fibers (braid) of polymeric biocompatible material (polyester).[1] *Id.*, 4:50-63, 2:54-65 (sleeve "has the property of being implantable"); Ex. 1002, ¶81.

---

[1] To the extent that Fumex does not expressly state that sleeve is the sleeve in this embodiment is fabricated ***solely*** from non-absorbable polyester braid or another polymeric biocompatible material, it would have been obvious to a POSITA, as discussed in Ground 2 below (Section VIII.D.1).

(d) **[8.3]** ***wherein at least a portion of the suture extends through the hollow fastener such that two legs of the suture extend from the hollow fastener to enable a user to tension the suture …***

Fumex describes at least a portion of the suture extending through the hollow fastener because the suture thread is passed through sleeve 5 such that two legs (3, 4) extend from the sleeve. Ex. 1004, 5:38-61, Fig. 1.



Id., Fig. 1 (annotated); Ex. 1002, ¶82.

Moreover, the strands of suture thread extending from the sleeve enable a user to tension (*i.e.*, apply traction to) 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 … in compression of the sleeve ….

Ex. 1004, 5:38-57, 2:43-45 ("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, ¶83.

(e) [8.4] … *to deform the hollow fastener from a first configuration to a second configuration to anchor the suture within the body; and*

Fumex describes the hollow fastener deforming from a first configuration to a second configuration as the suture is tensioned, causing the suture to be anchored within the body:

> 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).

Fumex further 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. At this point, the sleeve is in the "first stretched position." The anchoring process continues by further 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.

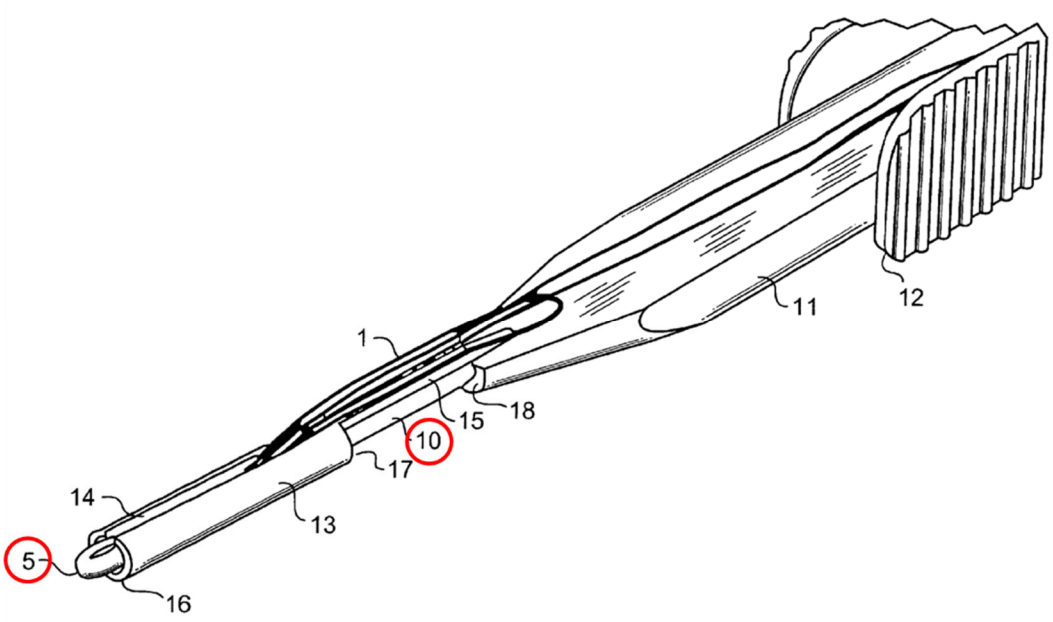
Id., 6:7-16.

As the passages above make clear, as the suture is tensioned relative to the bone within the body, the sleeve deforms from a first configuration ("a first stretched position") to a second configuration ("a second position in which it is folded on itself") to provide an anchor for the thread. Ex. 1002, ¶¶84-87.

(f) [8.5] ***an introducer with a pushrod configured to engage the fastener,***

Fumex describes an introducer having a pushrod configured to engage the fastener in the form of an ancillary instrument having a rod 10 with integral handle 11, as shown in Figure 5. 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 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.").

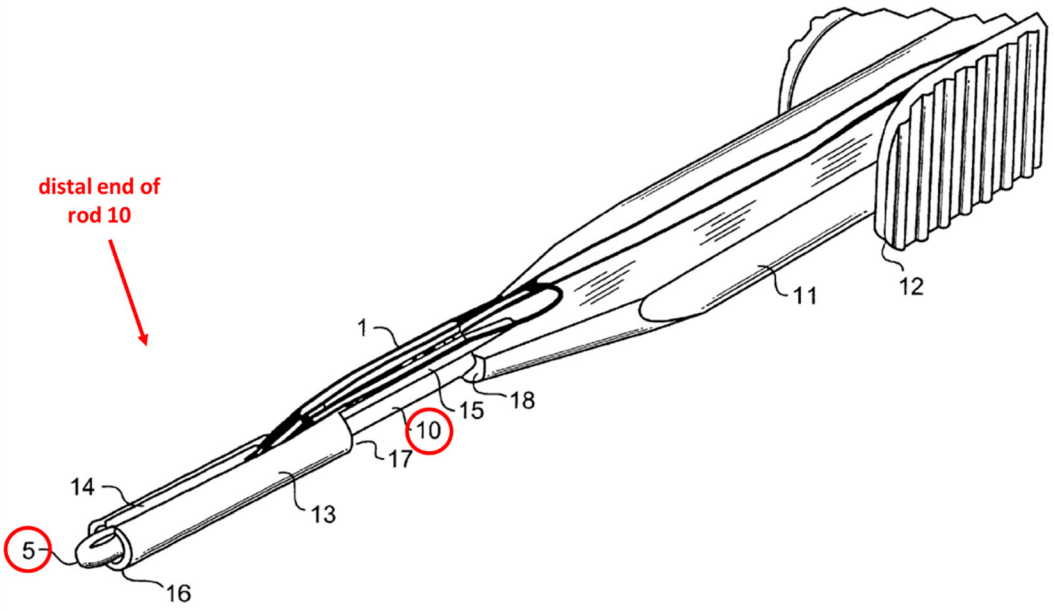


Id., Fig. 5 (annotated to highlight engagement between rod 10 and sleeve 5); Ex. 1002, ¶¶88-89.

(g) [8.6] ***wherein the hollow fastener and suture are positioned on the distal end of the pushrod.***

Fumex describes the hollow fastener (sleeve 5) and suture (thread 1) as being positioned on the distal end of the pushrod 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, ¶90.

2. Claim 11

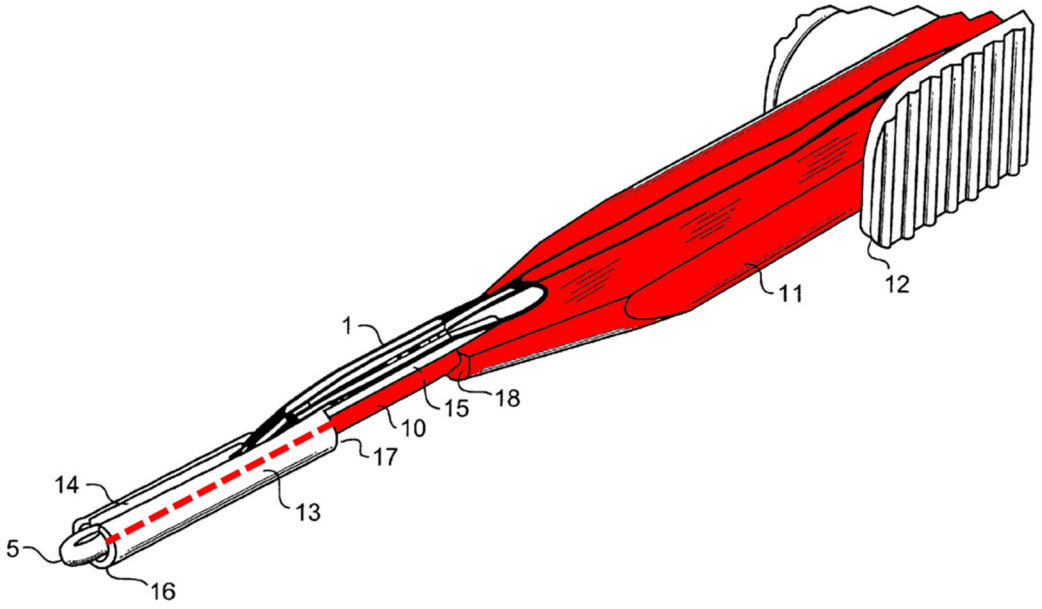
Claim 11, which depends from independent claim 8, recites "wherein the suture includes at least a portion of polyester."

Fumex specifically states that the suture can be made from polyester thread. Ex. 1004, 2:46-53 ("a polyester thread such as the one marketed under the brand name Ercylene®"); Ex. 1002, ¶92.

3. Claim 13

Claim 13, which depends from independent claim 8, 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, 6:58-60 ("The rod (10), the sleeve (5) and the thread (1) are enclosed in a cylindrical component (13)."), 6:51-7:17 (describing operation of exemplary ancillary instrument).



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

4. Independent Claim 14

Independent claim 14 recites a method of using the deformable fastener system of independent claim 8, which is anticipated by Fumex. Moreover, the '453 Patent does not disclose any new use for such a system. In fact, Fumex describes using its bone anchoring system in the same way as claim 14 recites, as discussed below. Ex. 1002, ¶95.

(a) [14.p] ***A method of using a deformable fastener system, said method comprising:***

Fumex describes a method of using its bone anchoring device, which is a deformable fastener system. *See* limitation [8.p], *supra*; Ex. 1004, 6:44-7:20 ("anchoring device described above is put into position effectively using an ancillary instrument"); Ex. 1002, ¶96.

(b) [14.1] ***inserting a deformable hollow fastener into a passage in a bone,***

Fumex describes a deformable hollow fastener in the form of flexible, tubular sleeve 5. *See* limitation [8.2], *supra*. Fumex also describes inserting the sleeve into a passage in a bone:

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

Ex. 1004, 6:64-7:8 (emphasis added); Ex. 1002, ¶97.

(c) [14.2] ***the deformable hollow fastener being flexible and fabricated solely from a plurality of flexible biocompatible fibers, and***

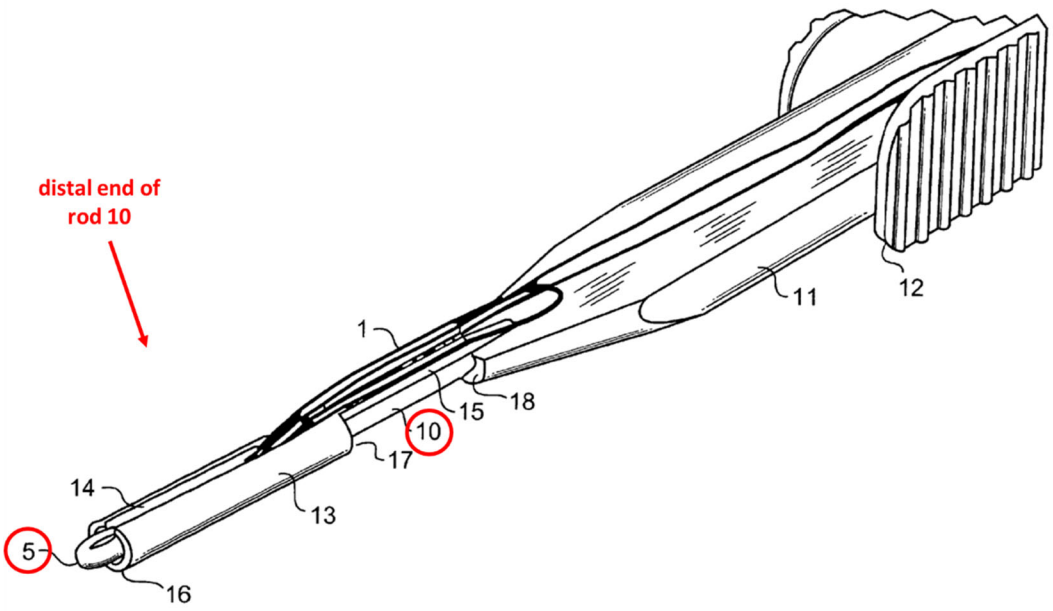
See limitation [8.2], *supra*; Ex. 1002, ¶98.

(d) [14.3] ***having a suture extending through the deformable hollow fastener such that two legs of the suture extend from the deformable hollow fastener to enable a user to tension the suture,***

See limitations [8.1], [8.3], *supra*; Ex. 1002, ¶99.

(e) [14.4] ***wherein the deformable hollow fastener and suture are positioned on the distal end of a pushrod during insertion;***

See limitations [8.2], [8.5], [8.6], *supra*. Specifically, Fumex's hollow fastener (sleeve 5) and suture (thread 1) are positioned on the distal end of the pushrod because they engage with the rod at its distal end. 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)"). This positioning of sleeve 5 and suture 1 relative to rod 10 is maintained during insertion. *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); Ex. 1002, ¶¶100-101.

(f) [14.5] *tensioning the suture to anchor the deformable hollow fastener into the bone;*

See limitations [8.4], [8.5], [8.6], *supra*. Further, Fumex states that tensioning the sleeve via the thread strands causes the sleeve to deform and anchor itself in bone:

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

Ex. 1004, 3:10-17 (emphasis added); Ex. 1002, ¶¶102-103.

(g) [14.6] *deforming the deformable hollow fastener from a first configuration to a second configuration in the bone; and*

See limitation [8.4], *supra*; Ex. 1002, ¶104.

(h) [14.7] *wherein inserting a deformable hollow fastener further comprises inserting a deformable hollow fastener that includes a polymeric material.*

See limitation [8.2], *supra*. Fumex describes the sleeve as being made 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, 2:54-65. Examples include several polymeric materials: polyester, polyamide, and silicone. Ex. 1004, 2:54-65; Ex. 1002, ¶¶105-106.

5. Claim 16

Claim 16, which depends from independent claim 14, recites that the inserting step (limitation [14.1]) further comprises inserting a deformable hollow fastener having a suture that includes at least one of polyethylene and polyester.

Fumex describes this limitation because the suture can be made from "a polyester thread, such as the one marketed under the brand name Ercylene®." Ex. 1004, 2:49-51; Ex. 1002, ¶108.

6. Claim 18

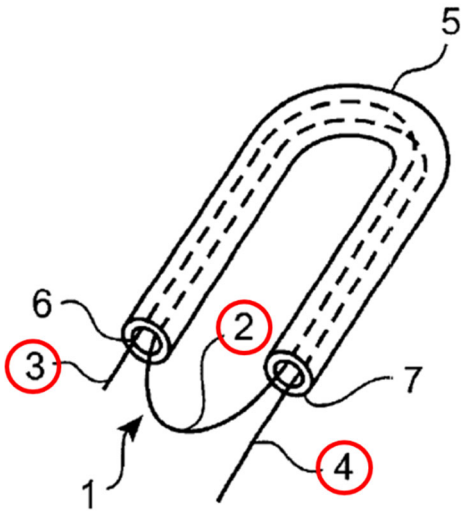
Claim 18, which depends from independent claim 14, recites "wherein inserting a deformable hollow fastener further comprises inserting a deformable hollow fastener with an introducer that has at least one of a linear configuration and a curved configuration."

Fumex describes this limitation. *See* claim 13, supra; Ex. 1002, ¶110.

7. Claim 19

Claim 19, which depends from independent claim 8, recites "wherein the hollow fastener is knotless." A "knotless" fastener is one that fastens without the use of a knot. *See* Section VI.B, *supra*; Ex. 1002, ¶112.

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, ¶113.

8. Claim 20

Claim 20, which depends from independent claim 14, recites "wherein inserting a deformable hollow fastener further comprises inserting a deformable hollow fastener that is knotless."

Fumex describes this limitation. *See* claim 19, *supra*; Ex. 1002, ¶115.

D. Ground 2: Claims 1, 3, 4, 6-11, 13-16, and 18-20 Are Obvious over Fumex

1. Independent Claims 8 and 14 (and Dependent Claims 9, 11, 13, 15, 16, and 18-20)[2]

As discussed in Ground 1, Fumex discloses the limitations of independent claims 8 and 11, including a deformable hollow fastener fabricated from a plurality of biocompatible fibers. *See* Sections VIII.C.1 and VIII.C.2, *supra*. Fumex further

[2] These claims depend from either independent claim 8 or 14.

discloses the use of a biocompatible material because it describes an exemplary sleeve fabricated from "non-absorbable polyester braid"—a biocompatible material. Ex. 1004, 4:50-63, 2:54-65 (sleeve "has the property of being implantable"); Ex. 1002, ¶118.

To the extent Fumex does not expressly require its sleeve to be "fabricated solely from a plurality of fibers comprised of a biocompatible material," as independent claims 8 and 14 recite, a POSITA would have found the same obvious from Fumex. Ex. 1002, ¶119.

First, flexible hollow fasteners fabricated from biocompatible polymer materials, such as Fumex's sleeve, were known at the time the '453 Patent was filed. It was understood in the field of orthopedic surgery at the relevant time that materials used to fabricate components implanted in the body should be biocompatible; otherwise, the health of the patient could be negatively affected. Because Fumex discloses the use of polymeric fibers, among other materials, to fabricate its sleeve, it would have been obvious to a POSITA to fabricate the sleeve solely from a plurality of biocompatible polymeric fibers (or to select any of the materials described in Fumex or otherwise known in the field). Ex. 1002, ¶120.

Second, a POSITA would have understood Fumex as instructing fabrication of the sleeve solely from a plurality of biocompatible fibers, which was a common material composition for these types of components at the time. Fumex states that

the tubular sleeve "can be made up of a single element," which itself suggests a unitary body of a single type of material. Ex. 1004, 2:66-67. The disclosure further provides multiple examples of single-material sleeves: "a tube made of polyester or polyamide, or a tube made of silicone." *Id.*, 2:64-65. Additionally, a POSITA would have recognized Fumex's sleeve embodiment consisting solely of polyester. *Id.*, 4:56-57 ("[T]ests were conducted on two series of devices made up of sleeves of ***non-absorbable polyester braid***." (emphasis added)). Therefore, based on Fumex and what was known in the field of orthopedic surgery at the time of filing the '453 Patent, it would have been obvious to fabricate Fumex's sleeve solely from a plurality of biocompatible fibers. Ex. 1002, ¶121.

Accordingly, it would have been obvious to a POSITA that Fumex's disclosure of a plurality of fibers—in the form of a non-absorbable polyester braid, Ex. 1004, 4:50-63—suggests the use of a sleeve fabricated solely from a plurality of fibers comprised of biocompatible materials.

2. Independent Claim 1

As discussed below, each limitation of independent claim 1 is disclosed and/or suggested by Fumex. Of note, limitation [1.3] calls for at least a portion of the suture to be polyethylene. While not explicitly disclosed by Fumex, this limitation would have been obvious to a POSITA based on their education,

experience, and general knowledge of the art. Claim 1 thus is obvious in view of Fumex.

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

See limitation [8.p], *supra*; Ex. 1002, ¶123.

(b) [1.1] ***a flexible hollow fastener fabricated solely from a plurality of biocompatible fibers;***

See limitation [8.2], *supra*. To the extent Fumex does not expressly describe fibers that are biocompatible, or that a fastener would be fabricated "solely" from a plurality of such fibers, a fastener fabricated solely from a plurality of biocompatible fibers would have been obvious to a POSITA for the same reasons as discussed above in connection with independent claims 8 and 14. *See* Section VIII.D.1, *supra*. Specifically, Fumex describes: (1) several types of materials available in biocompatible form for fabricating the implantable sleeve, Ex. 1001, 2:54-65 (braided metal wire, braided plastic wire, polyester, polyamide, and silicone); (2) the use of biocompatible materials, Ex. 1004, 2:62 ("property of being implantable"), 1:57-63 (cautioning against "allergenic" or "carcinogenic" materials); and (3) a sleeve fabricated from a plurality of fibers, *i.e.*, non-absorbable polyester braid, without the suggestion of any other material being used. Ex. 1002, ¶¶124-125.

(c) [1.2] *a suture extending through the hollow fastener such that two legs of the suture extend from the hollow fastener to enable a user to tension the suture,*

See limitations [8.1], [8.3], *supra*; Ex. 1002, ¶126.

(d) [1.3] *wherein at least a portion of the suture is fabricated 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, whether "absorbable or non-absorbable." 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. *Id.*, 2:46-53 ("a polyester thread such as the one marketed under the brand name Ercylene®, or a polyamide thread such as Trynil®"); Ex. 1002, ¶128.

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, ¶¶128-33.

A POSITA would have recognized that Fumex generally does not limit its system to any specific suture besides those used for surgical or suture threads. Ex.

1004, 1:8-10, 2:2-8; Ex. 1002, ¶128. The only other limitation that Fumex places on suture, albeit implicitly, is that it must be capable of deforming a tubular sleeve in the manner described by Fumex. Ex. 1004, 5:38-6:22; Ex. 1002, ¶¶128-29.

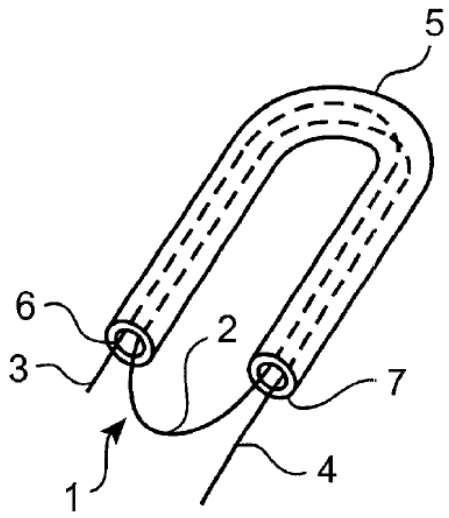
A POSITA also would have recognized that Fumex contemplates a preferable class of suture materials, *i.e.*, absorbable or non-absorbable threads used to fix or re-attach organs, as being particularly suited for the system. Ex. 1002, ¶129. From this preferable class, a POSITA would have known from his or her education, experience, and general knowledge of the art that polyester and polyamide—the two exemplary 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 material. *Id.* For example, Linvatec's Herculine and Smith & Nephew's ULTRABRAID were examples of polyethylene suture available at the time. Ex. 1011 (Herculine introduced March 10, 2004); Ex. 1012 ("Herculine Polyethylene Suture is nonabsorbable, sterile, single-use, surgical suture"); Ex. 1013 ("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, ¶129.

A POSITA would have known from his or her education, experience, and general knowledge of the art that the suture material used for Fumex's system

could be application-specific; *i.e.*, it could be chosen based on the particular surgical procedure for which the device. Ex. 1002, ¶¶129-31. 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 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 suture could be used as the surgical or suture thread in Fumex's bone anchoring device. Ex. 1002, ¶¶127-31; *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 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. 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, ¶132.



Ex. 1004, Fig. 1; Ex. 1002, ¶132.

Accordingly, limitation [1.3] would have been obvious over Fumex, taking into account the knowledge of a POSITA.

(e) [1.4] ***an introducer having a pushrod configured to engage the fastener and position the fastener relative to a body tissue,***

See limitation [8.5], *supra*; Ex. 1002, ¶134.

Fumex further describes that the pushrod is configured to position the fastener relative to a body tissue:

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

Ex. 1004, 6:64-7:7, 3:63-4:2 ("a rod capable of carrying the thread and its sleeve for introducing them into the hole bored in the bone"), 4:13-18 ("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"); Ex. 1002, ¶134.

(f) [1.5] *wherein the hollow fastener and suture are positioned on the distal end of the pushrod, and*

See limitation [8.6], *supra*; Ex. 1002, ¶135.

(g) [1.6] *wherein the hollow fastener is configured to deform from a first configuration to a second configuration to provide an anchor for the suture as the suture is tensioned relative to the body tissue; and*

See limitation [8.4], *supra*; Ex. 1002, ¶136.

(h) [1.7] *wherein the hollow fastener includes a polymeric material.*

See limitation [8.2], *supra*; Ex. 1002, ¶137.

3. Claim 3

Claim 3, which depends from independent claim 1, recites "wherein the hollow fastener is knotless."

Fumex describes this limitation. *See* claim 19, *supra*; Ex. 1002, ¶139.

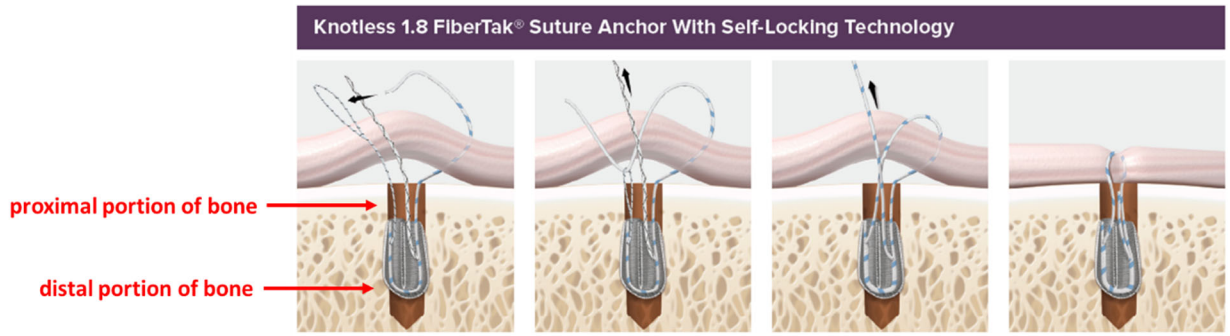
4. Claim 4

Claim 4, which depends from independent claim 1, recites "wherein the suture is positionable through proximal and distal portions of body tissue."

Fumex describes and/or suggests this limitation. Fumex's tubular sleeve, including the suture passed through it, is inserted into a hole bored from the outer (proximal) surface of a bone. Ex. 1004, 6:64-65, 6:4-6 ("The edges…of the sleeve are preferably inserted into the hole under the surface of the cortical bone."). The suture thus is positionable at the outer (proximal) surface of the bone—the outer "entrance" of the hole bored in cortical bone. The suture subsequently is positionable at a distal portion of the bone because after being fully inserted and tensioned, the sleeve is deformed into a ball by tension on the suture, causing both the sleeve and suture to be positioned at an inner (distal) portion of the bone—the inner "exit" of the hole bored in cortical bone. *Id.*, 6:4-6 ("The edges…of the sleeve are preferably inserted into the hole under the surface of the cortical bone."), 6:15-16 ("ball bears on the inner face of the cortical bone"), 1:7-11 ("a surgical device permitting simple and effective anchoring of suture thread or surgical thread on a bone support"); Ex. 1002, ¶141.

Furthermore, in the related proceeding, Patent Owner has accused Petitioner's FiberTak Soft Anchor of infringing the '453 Patent. Ex. 1010. Like Fumex's bone-anchoring device, the accused anchor is positionable at the outer (proximal) surface of a hole bored in cortical bone and subsequently positionable at an inner (distal) portion of the bone after being inserted and tensioned. *Id.*, 4-5 (figure below). In particular, the anchor (including suture) is set by:

- drilling a hole through the cortical bone, *id.*, 5 ("Create a bone socket for the anchor by advancing the drill");
- positioning the anchor and suture through the entrance of the cortical bone hole (proximal portion), *id.*, 5 ("Insert the anchor through the spear and into bone by gentle impaction"); and
- fully inserting the anchor into cancellous bone, *id.*, 5 ("gentle impaction until the inserter handle is flush with the back of the spear"), 4 (figure showing position of fully inserted anchor). Ex. 1002, ¶142.



Ex. 1010, 4 (annotated); Ex. 1002, ¶142.

Accordingly, the application of Fumex to claim 4 set forth above aligns with Patent Owner's own view of the claim's scope, particularly the term "positionable through proximal and distal portions of body tissue." Ex. 1002, ¶¶142-43.

5. Claim 6

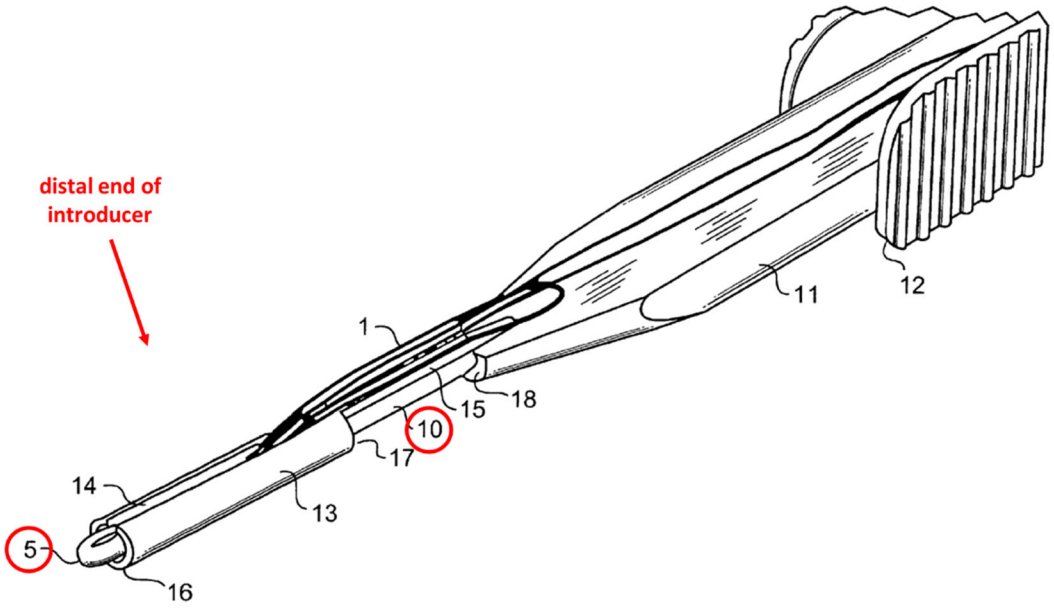
Claim 6, which depends from independent claim 1, recites "wherein the introducer has at least one of a linear configuration and a curved configuration."

Fumex describes this limitation. *See* claim 13, *supra*; Ex. 1002, ¶145.

6. Claim 7

Claim 7, which depends from independent claim 1, recites "wherein the distal portion of the introducer is configured to penetrate an imperforate surface of the body."

Figure 5 of Fumex shows an introducer having a pushrod 10 that engages the suture and flexible sleeve 5 at its distal end. Ex. 1004, Fig. 5, 4:13-18, 6:50-7:10. Although the rod's distal end is not visible in Figure 5, Fumex describes it as being pointed. *Id.*, 4:13-25 ("the point of the rod"). Fumex also describes it as being sufficiently rigid to carry the suture and sleeve through a hole bored in bone "with any wall shape, without requiring tapping." *Id.*, 2:1-4; 3:63-66. Therefore, by virtue of being rigid and pointed, the distal end of rod 10 is "configured to penetrate an imperforate surface of the body," as recited in claim 7.



Ex. 1004, Fig. 5 (annotated); Ex. 1002, ¶147.

Although several Fumex embodiments focus on placing the inserter into a pre-drilled hole, a POSITA would have understood that the introducer of Fumex would be configured to penetrate certain imperforate surfaces of the body, including metaphyseal bone or other body tissues, in applications where a pre-drilled hole was not required. Ex. 1002, ¶148. This is consistent with other teachings of Fumex, which describe using the introducer and sleeve in "fixation of organs such as tendons and ligaments, or suspension of the cervix," (Ex. 1004 at 2:5-8) or "in the spongy substance of the bone," (*id.* at 4:34-35), in which a hole could be drilled in the harder cortical layer of the bone, and then the introducer itself could be used to penetrate the imperforate surface of the spongier, cancellous bone underneath. Ex. 1002, ¶¶148-52.

7. Claim 9

Claim 9, which depends from independent claim 8, recites "wherein the suture is at least one of braided and interlaced."

As discussed in connection with limitation [1.3], *supra*, any type of surgical or suture threads may be used with Fumex's system, as long as it is capable of deforming a tubular sleeve. While Fumex does not expressly disclose braided suture, a POSITA would have been familiar with such suture, which was known and readily available at the time, including braided polymer fiber products such as Herculine, ULTRABRAID, and Ethicon. Exs. 1011-1013; Ex. 1002, ¶¶154-55.

A POSITA would have known from his/her experience and general knowledge that braided suture could be used for orthopedic surgeries, including applications involving tissue anchoring devices like Fumex's. Ex. 1002, ¶¶156-58. As discussed above in connection with limitation [1.3], *supra*, suture choice could be driven by surgical application. Braided suture was known to be advantageous for the orthopedic surgery applications contemplated by Fumex. Ex. 1011 (Herculine "provides superior fixation for soft tissue repairs"); Ex. 1012 (Herculine indicated for use in approximation and/or ligation of soft tissues for orthopedic surgeries). Because any sufficiently flexible suture could be used in Fumex's bone anchoring device, a POSITA would have had a reasonable expectation of successfully using braided suture together with Fumex's flexible sleeve.

Accordingly, claim 9 would have been obvious over Fumex.

8. Claim 10

Claim 10, which depends from independent claim 8, recites "wherein the suture includes polyethylene." Thus, with respect to the limitations related to the claimed suture, claim 10 is similar to independent claim 1. Accordingly, claim 10 is obvious for the same reasons set forth with respect to independent claim 1. *See* limitation [1.3], *supra*; Ex. 1002, ¶160.

9. Claim 15

Claim 15, which depends from independent claim 14, recites "wherein inserting a deformable hollow fastener having a suture further comprises inserting a deformable hollow fastener having a suture that is at least one of braided and interlaced."

This limitation is obvious in view of Fumex. *See* claim 9, *supra*; Ex. 1002, ¶162.

E. Ground 3: Claims 1-4, 6, 9, 10, and 15 Are Obvious over Fumex and Grafton

1. Claims 1, 3, 4, 6, and 10[3]

As an alternative to the unpatentability arguments set forth in Ground 2, independent claim 1 (which calls for at least a portion of the suture to be fabricated

---

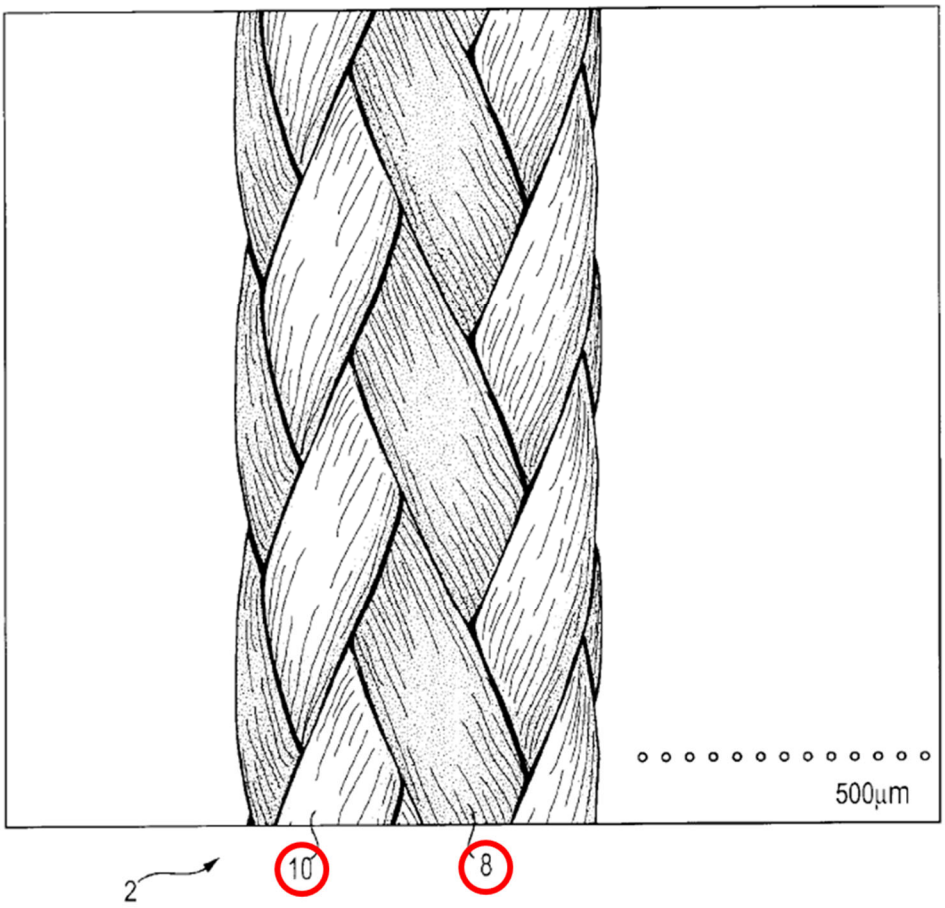
[3] Dependent claims 3, 4, and 6 are included due to their respective dependencies on independent claim 1.

from polyethylene) and dependent claim 10 (which calls for the suture to include polyethylene) would have been obvious over Fumex and Grafton.

(a) Overview of the Combination

Fumex's bone anchoring device includes a hollow, deformable sleeve and a surgical or suture thread that is passed through the sleeve prior to implantation. Once threaded, the device is inserted into a hole bored in the bone and deformed into a bone anchor by tensioning the thread. While Fumex does not expressly disclose a polyethylene thread, it directs the use of any absorbable or non-absorbable thread "of the type used to fix or re-attach organs." Ex. 1004, 2:46-48; Ex. 1002, ¶164.

Polyethylene was a known, non-absorbable suture material, and Grafton describes a suture that includes "a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester." Ex. 1005, Abstract, ¶¶[0005] (strands of polyethylene and polyester braided together over a core of polyethylene), [0006], Fig. 1; Ex. 1002, ¶¶164-65.



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

Under Ground 3, it would have been obvious to use the braided polyethylene-based suture taught by Grafton in the bone anchoring device described by Fumex.

(b) Rationale (Motivation) Supporting Obviousness

A POSITA would have found Grafton's braided suture to be an obvious choice of suture 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 permits the use of any suitable suture thread, as long as it is "of the type used to fix or re-attach organs." Ex. 1004, 2:46-48. A POSITA would have understood Fumex to leave it to the user to choose the particular suture. Ex. 1002, ¶167.

Choosing an appropriate suture for use in Fumex's system would have been driven by the particular application at hand. Indeed, a suture including polyethylene could have been chosen by a POSITA for applications requiring a relatively higher suture strength. Indeed, Grafton expressly describes suture strength as being "an important consideration in any surgical suture material." Ex. 1005, ¶[0004]; Ex. 1002, ¶¶167-69.

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 intended for Fumex's bone anchoring device. Ex. 1004, 4:38-41 ("the device and the ancillary positioning instrument according to the present invention are most particularly intended for reparative surgery of ligaments and tendons"), 1:7-12, 2:1-8; Ex. 1005, ¶[0009].

(c) *Graham* Factors

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

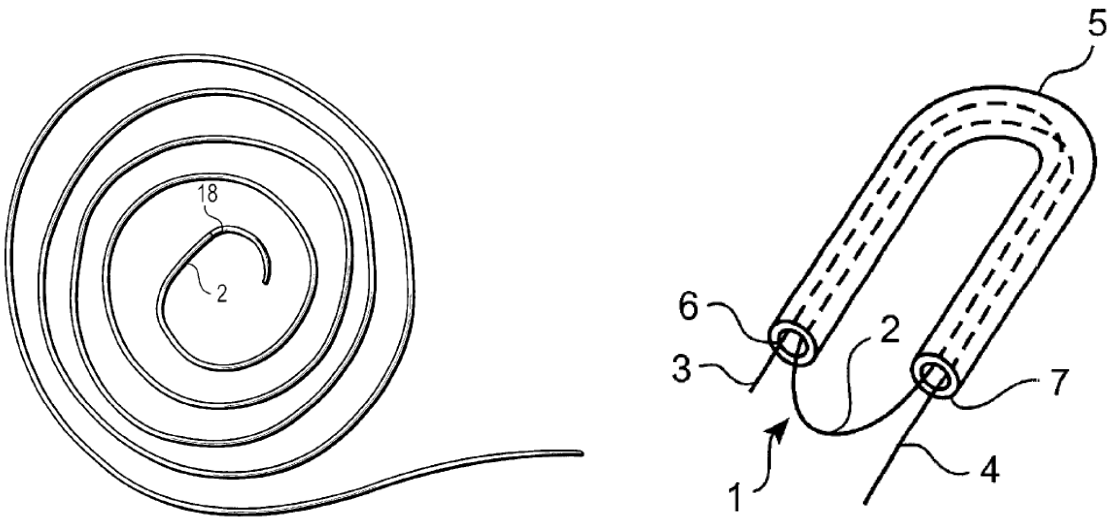
The scope and content of the prior art are discussed throughout this Ground and in Section VII.

The differences between the prior art and the claims are discussed in the "Overview of the Combination" (Section VIII.E.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

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, ¶¶170-72.



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

The art was relatively predictable in the relevant timeframe. Accordingly, a POSITA would have had a reasonable expectation of success. Ex. 1002, ¶¶170-72.

(e) Analogous Art

Fumex and Grafton are analogous art to the '453 Patent. They are in the same field as the '453 Patent. Ex. 1001, Abstract, 1:13-16; Ex. 1004, Abstract, 1:5-12; Ex. 1005, Abstract, ¶[0002]. Specifically, all three relate to surgical anchoring using suture threads. *Id*.; Ex. 1002, ¶173.

(f) Claims 1 and 10 Are Obvious Over Fumex and Grafton

Fumex describes and/or suggests all elements of independent claim 1 and dependent claim 10 except for express disclosures of "at least a portion of the suture is fabricated with polyethylene" (claim 1) or "the suture includes polyethylene" (claim 10). 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 relevant time, polyethylene was a known material for use in sutures, and Grafton teaches 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, ¶174.

A POSITA at the time of the filing of the '453 Patent would have understood that Grafton's suture could be 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, ¶175.

(g) Claims 3, 4, and 6

Claims 3, 4, and 6 depend from independent claim 1. A POSITA would have found them obvious for the same reasons as discussed above, in connection with claim 1, and in Ground 2, in connection with the respective dependent claims. Ex. 1002, ¶176.

2. Claim 2

Claim 2, which depends from independent claim 1, recites that the suture includes at least a portion of polyester. In conjunction with claim 1, which calls for at least a portion of the suture to be fabricated with polyethylene, dependent claim

2 requires a suture that includes both a polyester portion and a polyethylene portion. Ex. 1002, ¶178.

While Fumex does not explicitly describe a suture that is fabricated from polyester and polyethylene portions, Grafton's suture includes both polyester and polyethylene portions. Ex. 1005, ¶¶[0005] (strands of polyethylene and polyester braided together over a core of polyethylene), [0006], Fig. 1.

It would have been obvious to a POSITA to combine Grafton with Fumex for at least the reasons discussed above in Section VIII.E.1, *supra*. In particular, Grafton's suture provides high tensile strength and is suitable for surgical applications involving the repair of tendons and ligaments. Ex. 1002, ¶178.

3. Claims 9 and 15

As discussed in Section VIII.D, *supra*, Fumex discloses and/or suggests all limitations of claims 9 and 15, including the use of braided suture in Fumex's bone anchoring system.

As an alternative to those unpatentability arguments, claims 9 and 15 would have been obvious over Fumex and Grafton for at least the reasons discussed above in connection with claim 1. Specifically, the combination of Grafton's braided suture with Fumex's flexible hollow fastener would have met the limitations of these claims. Ex. 1002, ¶180.

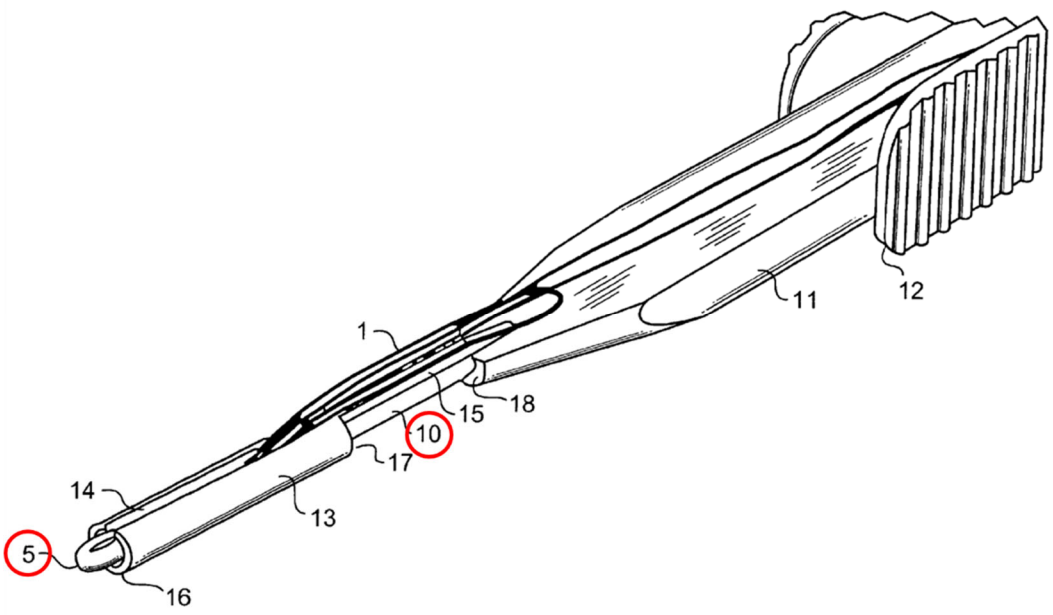
F. Ground 4: Claims 5, 12, and 17 Are Obvious over Fumex and Bonutti '395

1. Claim 5

Claim 5, which depends from independent claim 1, recites "wherein the pushrod is flexible." This claim would have been obvious over Fumex and Bonutti '395.

(a) Overview of the Combination

Fumex's bone anchoring device includes a rod 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, ¶182.

Fumex thus describes a hole being bored into bone prior to insertion of the sleeve, suture, and rod. 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 might be needed, for example, when inserting the sleeve and thread into 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, ¶183.

Bonutti '395 describes "securing body tissue to bone." Ex. 1006, 1:20-22. Bonutti '395's apparatus includes a flexible pusher member for use in surgical applications where a suture must be inserted into a nonlinear hole drilled in bone. *Id*., 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 or other tissue was not linear (*e.g.*, curved or angled). Ex. 1002, ¶¶183-85.

(b) Rationale (Motivation) Supporting Obviousness

Fumex's bone anchor is intended to be used in surgical applications involving the insertion of the device into holes bored in bone 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 specifically describes not only a nonlinear hole bored in bone, but also the use of a flexible pusher member to insert a suture through a bend in that hole. Combining Bonutti ’395 with Fumex could yield, for example, a linear yet flexible rod that could accommodate bored holes that have any wall shape, such as a curved hole or a hole in which two linear passages meet at an angle. Ex. 1002, ¶186.

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 that require the rod to be inserted into a nonlinear hole. The combination of Bonutti ’395 and Fumex does no more than use Fumex’s rod in a known and intended way (*i.e.*, insertion into a hole having any wall shape, as disclosed by Fumex) to achieve the predictable result of a flexible rod that can accommodate a nonlinear hole, as described by Bonutti ’395. Ex. 1002, ¶187.

(c) *Graham* Factors

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

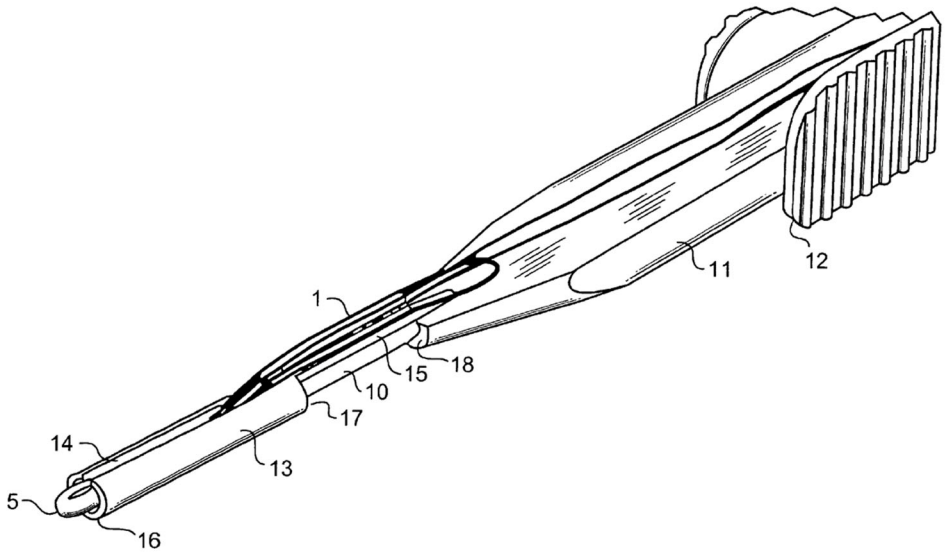
The scope and content of the prior art are discussed throughout this Ground and in Section VII.

The differences between the prior art and the claims are discussed in the "Overview of the Combination" (Section VIII.F.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 reasonably expected to successfully modify Fumex's rod in this manner. Ex. 1002, ¶188. 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 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, ¶188.

(e) Analogous Art

Fumex and Bonutti ’395 are analogous art to the ’453 Patent. They are in the same field as the ’453 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. *Id*.; Ex. 1002, ¶189.

(f) Claim 5 Is Obvious over Fumex and Bonutti ’395

Fumex discloses and/or suggests all elements of independent claim 1, including “an introducer having a pushrod,” *see* Section VIII.D.2, but does not expressly disclose a flexible pushrod, as required by claim 5. Fumex does not, however, require the rod to be rigid. In fact, it leaves open the possibility for a flexible rod by expressly contemplating 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 relevant time, nonlinear holes bored in bone and flexible rods for

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

A POSITA at the time the '453 Patent was filed would have understood that Fumex's rod could be made flexible, like the pusher member of Bonutti '395, so that Fumex's sleeve 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, ¶191.

2. Claims 12 and 17

Claim 12, which depends from independent claim 8, recites "wherein the pushrod is flexible." Similarly, claim 17, which depends from independent claim 14, recites "wherein inserting a deformable hollow fastener further comprises inserting a deformable hollow fastener with a pushrod that is flexible."

Fumex discloses and/or suggests all elements of independent claims 8 and 14, including "an introducer with a pushrod" (claim 8) and "a pushrod" (claim 14). *See* Sections VIII.C.1 and 4, *supra*. Fumex does not expressly disclose that the pushrod is flexible, as required by claims 12 and 17. However, these claims would have been obvious over Fumex and Bonutti '395. *See* claim 5, *supra*; Ex. 1002, ¶¶193, 195.

G. Ground 5: Claim 5 Is Obvious over Fumex, Grafton, and Bonutti ’395

As discussed above in Ground 4, claim 5, which recites “wherein the pushrod is flexible,” is obvious over Fumex and Bonutti ’395.

Under Ground 5, claim 5 also is obvious over the combination of Fumex and Grafton (which discloses and/or suggests all elements of independent claim 1, as discussed in Ground 3) further combined with Bonutti ’395, for the same reasons that the claim would have been obvious over Fumex and Bonutti ’395. *See* Ex. 1002, ¶¶197-99.

H. Ground 6: Claims 3, 19, and 20 Are Obvious Over Fumex and Bonutti ’875

As discussed in Grounds 1 and 2 (Sections VIII.C and VIII.D, *supra*), Fumex discloses and/or suggests the limitations of dependent claims 3, 19, and 20, including a deformable hollow fastener that is knotless. *See* Sections VIII.C.7, VIII.C.8, and VIII.D.3, *supra*. Specifically, no knot is used to form an anchor from the tubular sleeve. Instead, the sleeve forms an anchor by tensioning the suture, thereby deforming the sleeve into a ball. Ex. 1004, 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 (“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”).

The process of deforming Fumex's tubular sleeve into a ball (*i.e.*, a suture anchor) at the distal edge of the hole bored in bone does not involve any knotting of the sleeve or suture at the fastening site. Subsequent to anchoring the sleeve with the suture therethrough, Fumex describes optionally knotting the two legs of the suture that extend from the sleeve and through the hole. Ex. 1004, 4:28-31 (suture legs "can be knotted, at the edge of the hole bored in the bone, in order to lock the device and prevent its loosening"). However, this occurs not in association with Fumex's tubular anchor, which is secured by the ball shape at the distal end of the hole in bone, but outside the bone hole. Ex. 1002, ¶¶201-202.

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 3, 19, and 20, 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, ¶203.

1. Claim 3

Claim 3, which depends from independent claim 1, recites "wherein the hollow fastener is knotless." This claim would have been obvious over Fumex and Bonutti '875.

(a) Overview of the Combination

As discussed, 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, 6:7-16. Subsequently, the two legs of the suture that extend out of proximal side of the bone can be knotted. Ex. 1004, 4:28-31; Ex. 1002, ¶204.

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, ¶205.

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, ¶206.

(b) Rationale (Motivation) Supporting Obviousness

A POSITA would have found the suture fastener of Bonutti '875 to be an obvious alternative to knotting suture threads when using Fumex's bone anchoring device. Fumex's tubular sleeve is anchored at the distal end of a hole bored in bone. That anchoring occurs by deformation rather than knotting. Ex. 1004, 3:7-17, 5:38-57, 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"). However, at the other end, the two legs of the suture extend from the tubular sleeve and through the proximal end of the hole. Ex. 1004, 4:28-31. Fumex states that knotting the legs may be used to "lock the device and prevent its loosening." *Id.*; Ex. 1002, ¶207.

A POSITA would have understood that the suture fastener of Bonutti '875 could have advantageously replaced the suture knot described by Fumex. Bonutti '875 provides reasons to use its fastener rather than a suture knot, including:

- 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, ¶208.

(c) *Graham* Factors

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

The scope and content of the prior art are discussed throughout this Ground and in Section VII.

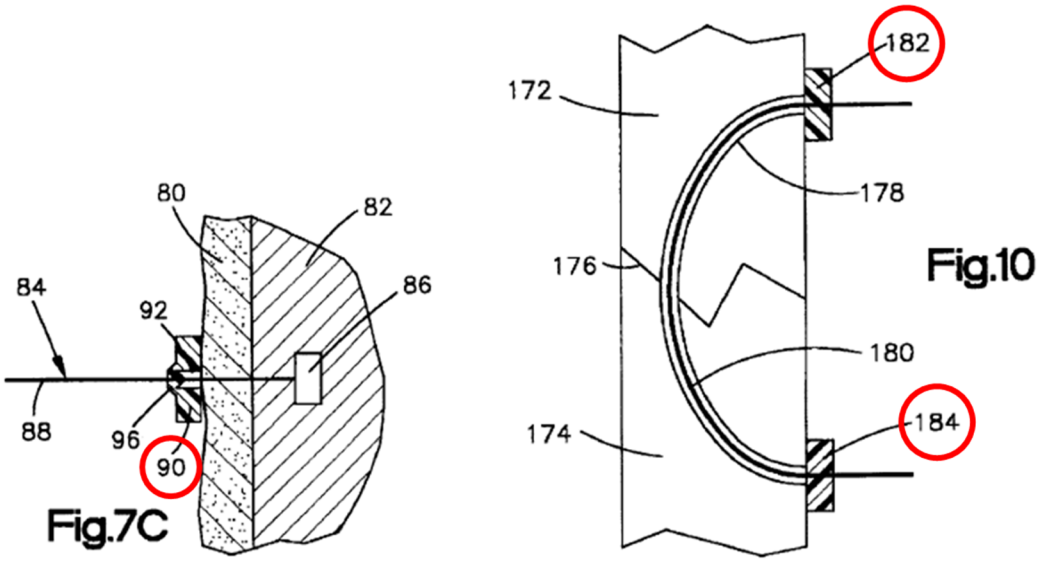
The differences between the prior art and the claims are discussed in the "Overview of the Combination" (Section VIII.E.1(a)) and below.

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 reasonably expected to successfully combine 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. Bonutti '875 expressly describes using its suture fastener in

surgical applications like those described in Fumex, including fastener 90 used to fasten a suture proximal to a distal suture anchor (Figure 7C of Bonutti '875) and fasteners 182, 184 used in the single-tissue application of a fractured bone (Figure 10). Ex. 1007, 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. *Id.*, 3:44-46. Accordingly, the fastener of Bonutti '875 would have been a replacement for the knotted suture legs described by Fumex. Ex. 1002, ¶209.



Ex. 1007, Fig. 7C (left, annotated), Fig. 10 (right, annotated); Ex. 1002, ¶209.

The art was relatively predictable in the relevant timeframe. Moreover, to the extent any modification to the fastener of Bonutti '875 was needed to use it with Fumex's bone anchoring device, a POSITA would have been able to make such modification. Ex. 1002, ¶209.

(e) Analogous Art

Fumex and Bonutti ’875 are analogous art to the ’453 Patent. They are in the same field as the ’453 Patent. Ex. 1001, Abstract, 1:13-16; Ex. 1004, Abstract, 1:5-12; Ex. 1007, Abstract, 1:16-19. Specifically, all three relate to the surgical fastenings using suture threads. *Id*.; Ex. 1002, ¶210.

(f) Claim 3 Is Obvious Over Fumex and Bonutti ’875

Fumex discloses and/or suggests all elements of independent claim 1, including disclosing a hollow fastener, which itself is knotless. *See* Ground 2 (Section VIII.D.2), *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. Thus, Fumex does not expressly state that no knot would be used anywhere in the system, should Patent Owner allege such a construction for the limitation of “the hollow fastener is knotless.” Nevertheless, at the time of the filing of the ’453 Patent, Bonutti ’875 taught an alternative to knotting suture legs, namely, the use of a suture fastener. Ex. 1007, 7:37-44, 8:40-60, Figs. 7A-C, 10; Ex. 1002, ¶212.

A POSITA at the time of the filing of the ’453 Patent would have understood that the suture fastener of Bonutti ’875 could have been used with the bone anchoring device described by Fumex. In particular, 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, 6:47-49, 6:53-57, 7:9-14; Ex. 1002, ¶213.

2. Claim 19

Claim 19, which depends from independent claim 8, recites "wherein the hollow fastener is knotless."

Fumex discloses and/or suggests all elements of independent claim 8, including "a flexible hollow fastener," *see* Sections VIII.C.1, VIII.D.1, *supra*. To the extent that Fumex does not expressly disclose that the fastener is knotless, as required by claim 19, the claim would have been obvious over Fumex and Bonutti '875. *See* claim 3, *supra*; Ex. 1002, ¶215.

3. Claim 20

Claim 20, which depends from independent claim 14, recites "a deformable hollow fastener that is knotless."

Fumex discloses and/or suggests all elements of independent claim 14, including "a deformable hollow fastener," *see* Sections VIII.C.4, VIII.D.1, *supra*. To the extent that Fumex does not expressly disclose that the fastener is knotless, as required by claim 20, the claim would have been obvious over Fumex and Bonutti '395. *See* claim 3, *supra*; Ex. 1002, ¶217.

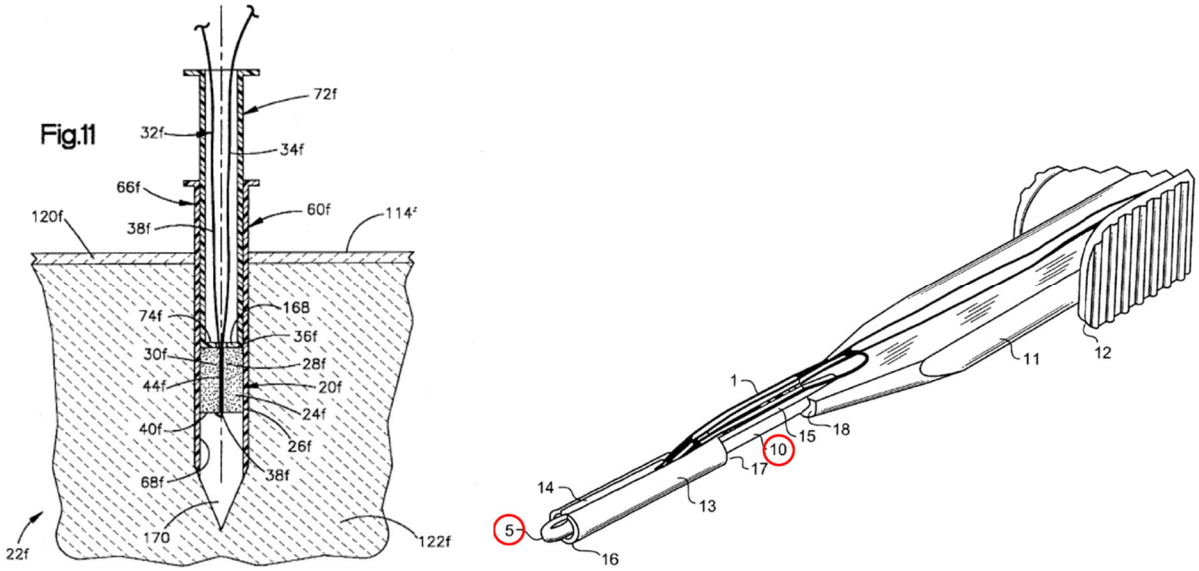
I. Ground 7: Claims 1 and 7 Are Obvious over Bonutti ’717 and Fumex

Fumex discloses and/or suggests all limitations of independent claim 1 and dependent claim 7. *See* Section VIII.D *supra*. These claims also would have been obvious over Bonutti ’717 and Fumex.

1. Claim 1

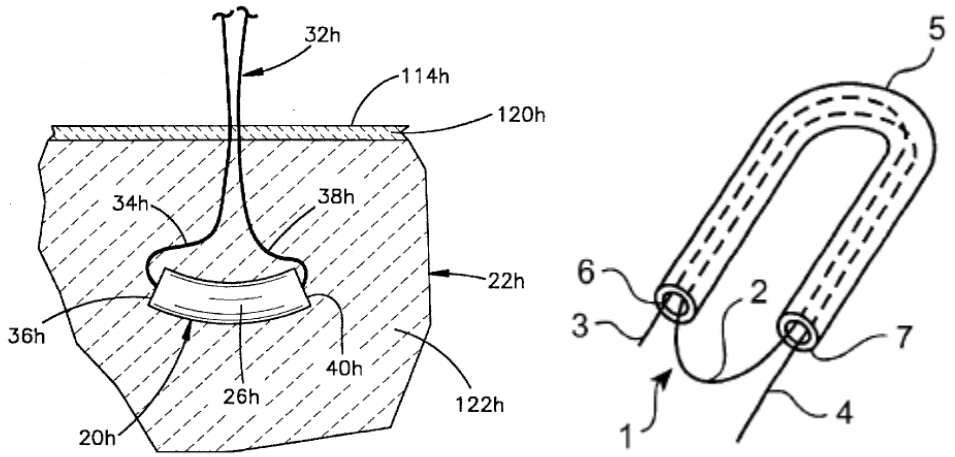
(a) Overview of the Combination

Bonutti ’717 discloses inserter assembly 60f (shown below left) that can be used to introduce an expandable suture anchor within body tissue. As discussed, Fumex also describes an inserter assembly that introduces an expandable suture anchor (*i.e.*, flexible sleeve 5) within body tissue (shown below right). *See* Section VIII.C.1, *supra*; Ex. 1002, ¶219.



Ex. 1016, Fig. 11; Ex. 1004, Fig. 5.

Both inserter assemblies use an outer tube (sleeve 66f in Bonutti ’717 and cylindrical component 13 in Fumex) to control the insertion position and depth of the suture anchor. Ex. 1016, 13:14-36; Ex. 1004, 6:64-7:17. Both also use the tube to hold the suture anchor in a compressed configuration for insertion. Both use an axial inner shaft (inner sleeve 72f or rod 10 in Fumex) to push the suture anchor through the outer tube and into the body tissue. And both describe similar suture anchors that expand once ejected from the outer tube, as shown below. Ex. 1002, ¶220.



Ex. 1016, Fig. 13; Ex. 1004, Fig. 1.

Bonutti ’717 differs from Fumex in that Bonutti ’717 explains that the assembly may penetrate the body tissue without the need for creating an opening in advance. A POSITA would have recognized that Fumex’s flexible sleeve could be used with Bonutti ’717’s self-penetrating inserter assembly. Ex. 1002, ¶221.

(b) Rationale (Motivation) Supporting Obviousness

Bonutti ’717 describes an inserter assembly for expandable suture anchors. Ex. 1016, 1:24-26, 2:45-48, Fig. 11. The inserter assembly generally works by ejecting suture anchors into body tissue, where the anchor expands to secure itself in place. *Id.*, 13:14-36. Bonutti ’717 describes a number of different expandable anchors that can be used with its assembly. *Id.*, 13:14-36, 16:28-17:26. Ex. 1002, ¶222.

Fumex’s flexible sleeve is another expandable suture anchor that could be delivered by Bonutti ’717’s inserter assembly. Specifically, Fumex’s flexible sleeve would be compressed into a folded position (as shown in Figure 5 of Fumex) when inside the outer sleeve 66f and expand into an uncompressed state after being ejected. Subsequently, the flexible sleeve is deformed into a ball by tensioning the suture, further increasing the diameter of the anchor and securing it in tissue, as Fumex describes. *Id.*, ¶223.

A POSITA would have recognized that Fumex’s flexible sleeve was one of multiple suture anchors that could be used with Bonutti ’717’s inserter assembly. The selection of a particular suture anchor would have been a simple design choice. *Id.*, ¶224.

A POSITA would have naturally looked to Fumex when considering suture anchors for use with Bonutti ’717’s inserter assembly or, *vice versa*, inserter

assemblies for use with Fumex's flexible sleeve. The combination of Bonutti '717 and Fumex does no more than use Fumex's flexible sleeve as intended, but with the inserter assembly of Bonutti '717. *Id.*, ¶225.

(c) *Graham* Factors

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

The scope and content of the prior art are discussed throughout this Ground and in Section VII.

The differences between the prior art and the claims are discussed in the "Overview of the Combination" (Section VIII.F.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 a reasonable expectation of success in using Fumex's flexible sleeve in Bonutti '717's inserter. Ex. 1002, ¶226. In operation, the inner sleeve 72f of Bonutti '717 would push the flexible sleeve and suture out of the leading end portion 170 of outer sleeve 66f once at the appropriate tissue depth. The inner sleeve would require minimal modification, if any, to accommodate the folded flexible sleeve shape. Ex. 1002, ¶226.

(e) Analogous Art

Bonutti '717 and Fumex are in the same field as the '453 Patent. Ex. 1001, Abstract, 1:13-16; Ex. 1004, Abstract, 1:5-12; Ex. 1016, Abstract, Fig. 11.

Specifically, all three relate to the insertion of suture anchors into the body. *Id*.; Ex. 1002, ¶227.

(f) Claim 1 Is Obvious over Bonutti ’717 and Fumex

(1) [1.p] A deformable fastener system comprising:

Bonutti ’717 and Fumex describe deformable fasteners (suture anchors) implanted using inserters. Ex. 1016, 1:5-7 (“a suture anchor which is capable of expanding in a patient's body to enable the anchor to withstand relatively large pull-out forces”), 13:14-36, Fig. 11; (a)Ex. 1002, ¶228; *see* Section VIII.C.1(a), *supra*.

(2) [1.1] a flexible hollow fastener fabricated solely from a plurality of biocompatible fibers;

See Section VIII.C.1(c), *supra*. A POSITA would have understood that Fumex’s sleeve could be inserted into the body with inserter assembly of Bonutti ’717, and that using Fumex’s flexible sleeve in this manner was a simple design choice relating to the type of expandable anchor to be used. Ex. 1002, ¶¶229-30.

(3) [1.2] a suture extending through the hollow fastener such that two legs of the suture extend from the hollow fastener to enable a user to tension the suture, …

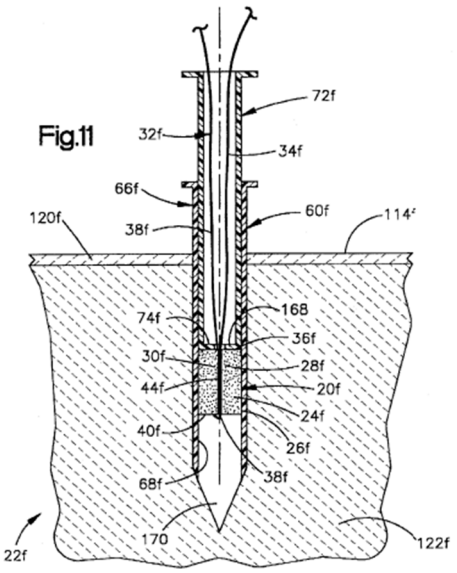
See Sections VIII.C.1(b) and (d), *supra*; Ex. 1002, ¶231.

(4) [1.3] wherein at least a portion of the suture is fabricated with polyethylene; and

See Section VIII.D.2(d), *supra*; Ex. 1002, ¶232.

(5) [1.4] an introducer having a pushrod configured to engage the fastener and position the fastener relative to a body tissue,

Bonutti '717 discloses an introducer (*i.e.*, inserter assembly 60f) having a pushrod (inner sleeve 72f) configured to engage a suture anchor (such as Fumex's flexible sleeve) and position it relative to body tissue.



Ex. 1016, Fig. 11; Ex. 1002, ¶233.

(6) [1.5] wherein the hollow fastener and suture are positioned on the distal end of the pushrod, and

Bonutti '717 discloses a suture anchor (such as Fumex's hollow, flexible sleeve) and suture being positioned on the distal end of the pushrod because the inner sleeve 72f engages with the suture thread and sleeve at the rod's distal end, as shown in Figure 11 above. Ex. 1002, ¶234.

(7) [1.6] wherein the hollow fastener is configured to deform from a first configuration to a second configuration to provide an anchor for the suture as the suture is tensioned relative to the body tissue; and

See Section VIII.C.1(e), *supra*; Ex. 1002, ¶235.

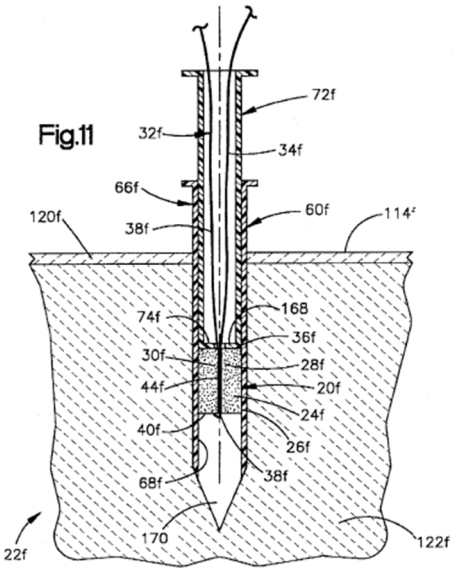
(8) [1.7] wherein the hollow fastener includes a polymeric material.

See Section VIII.C.1(c), *supra*; Ex. 1002, ¶236.

2. Claim 7

Claim 7 recites "wherein the distal portion of the introducer is configured to penetrate an imperforate surface of the body."

Bonutti '717 describes that the "pointed configuration of the leading end portion 170 … enables the leading end portion … to form an opening in an imperforate outer side surface 114f of the patient's body tissue 22f." Ex. 1016, 13:3-26, Fig. 11; Ex. 1002, ¶238.



Ex. 1016, Fig. 11.

J. Ground 8: Claims 1 and 7 Are Obvious over Bonutti ’717, Fumex, and Grafton

As discussed above in Ground 7, claims 1 and 7 are obvious over Bonutti ’717 and Grafton. Under Ground 8, claims 1 and 7 also are obvious over the combination of Bonutti ’717, Fumex, and Grafton

Ground 3 establishes the reason for and manner of combining Grafton with Fumex (the combination of which discloses and/or suggests all limitations of the flexible hollow fastener and suture recited in claim 1) and Ground 7 establishes the reason for and manner of combining Fumex with Bonutti ’717 (the combination of which discloses and/or suggests the limitations of the introducer recited in claims 1 and 7). Thus, the combination of Bonutti ’717, Fumex, and Grafton has already been established above in Grounds 3 and 7. Ex. 1002, ¶¶239-40.

IX. THE BOARD SHOULD INSTITUTE UNDER 35 U.S.C. § 314

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper No. 11 (P.T.A.B. 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.

X. CONCLUSION

For the reasons stated above, Petitioner submits that claims 1-20 of the '453 Patent are unpatentable.

DATED: May 23, 2022

Respectfully submitted,

By: /Megan S. Woodworth/
Reg. No. 53,655
VENABLE LLP
600 Massachusetts Ave., NW
Washington, DC 20001
T 202-344-4507
F 202-344-8300

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 23, 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)
7700 Forsyth Boulevard, Suite 1100
St. Louis, MO 63105

Date: May 23, 2022

/Megan S. Woodworth/
Reg. No. 53,655
VENABLE LLP
600 Massachusetts Ave., NW
Washington, DC 20001
T 202-344-4507
F 202-344-8300

CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing petition for *inter partes* review contains 13,987 words according to the word processing program used to prepare it.

Date: May 23, 2022

/Megan S. Woodworth/
Reg. No. 53,655
VENABLE LLP
600 Massachusetts Ave., NW
Washington, DC 20001
T 202-344-4507
F 202-344-8300