UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ARTHREX, INC.
Petitioner

v.

P TECH, LLC
Patent Owner

_____

Case No. 2022-00787
Patent No. 9,999,449

_____

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,999,449

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CLAIM LISTING

[1.P] 1. A surgical method for ligament augmentation comprising:

[1.1] securing a first fastener at least partially within a first bone of a joint adjacent a first end of a ligament of the joint, wherein the first end of the ligament is attached to the first bone of the joint before securing the first fastener, and wherein a reinforcement component comprised of a multifilament structure fabricated from polyethylene and polyester is attached directly to the first fastener to anchor the reinforcement component to the first bone; and

[1.2] securing a second fastener at least partially within a second bone of a joint adjacent a second end of the ligament of the joint opposite the first end of the ligament, wherein the second end of the ligament is attached to the second bone of the joint before securing the second fastener, and wherein the reinforcement component is attached to the second fastener to anchor the reinforcement component to the second bone,

[1.3] wherein the reinforcement component extends between the first and second ends of the ligament, and

[1.4] wherein the reinforcement component is tensioned directly between the first and second fasteners.

2. The surgical method for ligament augmentation set forth in claim 1, wherein the reinforcement component extends along the length of the ligament.

3. The surgical method for ligament augmentation set forth in claim 1, wherein the reinforcement component comprises a suture.

4. The surgical method for ligament augmentation set forth in claim 3, wherein the reinforcement component comprises a plurality of sutures.

5. The surgical method for ligament augmentation set forth in claim 1, wherein the first and second bones and the joint are part of a foot.

6. The surgical method for ligament augmentation set forth in claim 1, wherein the first and second bones and the joint are part of a knee.

7. The surgical method for ligament augmentation set forth in claim 1, wherein the first and second bones and the joint are part of a shoulder.

8. The surgical method for ligament augmentation set forth in claim 1, wherein the first and second bones and the joint are part of a spine.

9. The surgical method for ligament augmentation set forth in claim 1, wherein the first and second bones and the joint are part of a hand.

10. The surgical method for ligament augmentation set forth in claim 1, wherein the first and second bones and the joint are part of a hip.

11. The surgical method for ligament augmentation set forth in claim 1, wherein the first and second bones and the joint are part of an elbow.

Pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq.*, Arthrex, Inc.("Arthrex") requests *inter partes* review ("IPR") of claims 1-11 of U.S. Patent No 9,999,449 ("the '449 Patent") (Ex. 1001) pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq*. The '449 Patent is subject to pre-AIA 35 U.S.C. §§ 102 and 103.

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 '449 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);

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 VENABLE LLP 1270 Avenue of the Americas 24th Floor New York, NY 10020 T 212-370-6241 F 212-307-5598 Robert C. Tapparo (Reg. No. 78,896) RCTapparo@Venable.com VENABLE LLP 600 Massachusetts Ave., NW Washington, DC 20001 T 202-344-4439 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.

I. INTRODUCTION

The ’449 Patent relates to methods for repairing, augmenting, and stabilizing joints of the body. The challenged claims of the ’449 Patent all recite a method for ligament augmentation with four basic requirements: (1) securing a first fastener at least partially within a first bone of a joint adjacent a first end of a ligament; (2) securing a second fastener at least partially within a second bone of a joint adjacent a second end of the ligament; and (3) attaching (and tensioning) a reinforcement component made from polyethylene and polyester between the first and second fasteners; (4) wherein the first end of the ligament is attached to the first bone of the joint before securing the first fastener, and the second end of the ligament is attached to the second bone of the joint before securing the second fastener. Each of these elements, individually and collectively, was well known in the art before the filing of the ’449 Patent. As shown below, U.S. Patent No. 4,834,752 (“Van Kampen”) which issued more than a year before the filing date of the ’449 Patent teaches (or renders obvious) all of these elements of the challenged claims.

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

Petitioner certifies that the ’449 Patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR. This petition is being filed within one year of Petitioner being served with a complaint alleging infringement of the ’449 Patent.

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

Petitioner requests (i) review of claims 1-11 of the '449 Patent on the grounds set forth below and (ii) that those claims be found unpatentable.

Ground	Claim(s)	Basis for Unpatentability
1	1-4, 6	Obvious Over Van Kampen in View of Marshall
2	1-4, 6, 8	Obvious Over Van Kampen and Marshall in View of Lambrecht
3	5, 7-11	Obvious Over Van Kampen and Marshall in View of Boyce
4	5, 7, 9-11	Obvious Over Van Kampen, Marshall and Lambrecht in View of Boyce

IV. SUMMARY OF THE '449 PATENT

A. Background of the Technology

The '449 Patent discloses "devices and methods for repairing and stabilizing tissue and implants." Ex. 1001 (the '449 Patent), 1:15-16. In particular, the methods cover repairing, reconstructing, augmenting, and stabilizing joints of the body. *Id*., 1:18-19. Specific methods and procedures are disclosed for repairing and stabilizing the knee and joints of the spine. *Id*., 1:19-21.

The '449 Patent suggests that a problem is created from traditional surgical procedures where tissues, including muscles, ligaments, tendons, cartilage, and bones, are damaged to create the surgical pathway and are not repaired after

surgery. *Id*., 1:25-34. The ’449 Patent’s proposed solution suggests repairing, reconstructing, augmenting, and securing tissue or an implant during surgery and “on the way out” after surgery has been performed. *Id*., 2:56-59. In particular, the ’449 Patent states that “hard and soft tissue at and around the operation site and tissue between the operation site and the skin incision may be compressed and/or rebuilt so that tissue-function may be at least partially restored and the operation region may be stabilized for enhanced healing.” *Id*., 3:6-11.

The Background of the ’449 Patent acknowledges that several elements were already known in the art when the ’449 Patent was filed. First, the ’449 Patent acknowledges that it was known to repair and/or reconstruct damaged tissues, such as tendons. *Id*., 1:40-41, 65-67. Second, the ’449 Patent acknowledges that it was known to use implants during surgical procedures to repair or reconstruct tissue. Ex. 1001, 2:7-20. Third, the ’449 Patent acknowledges that it was known to use fasteners to support necessary components of tissue repair. *Id*., 1:40-49. Fourth, the ’449 Patent acknowledges that it was known to use a flexible member that exists under tension when it resists loading applied during the natural use of a portion of the body. *Id*., 2:35-44.

B. The Claimed Subject Matter

The ’449 Patent contains twelve claims, where claim 1 is the only independent claim, shown in the claim listing above. This Petition challenges claims 1-11.

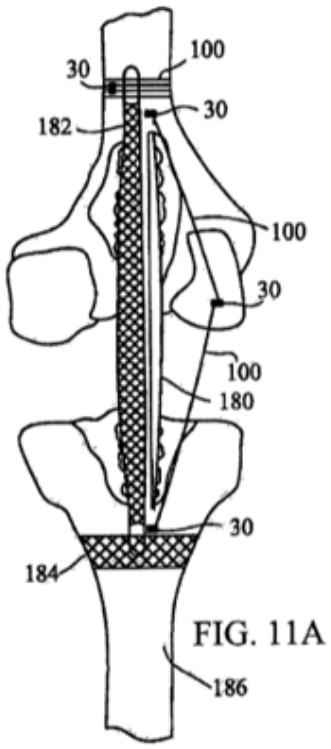

FIG. 11A

Claim 1 is generally directed to a method for ligament augmentation that includes securing a first fastener 30 within a first bone of a joint adjacent a first end of a ligament 180, and securing a second fastener 30 within a second bone of a joint adjacent a second end of ligament 180. A reinforcement component 100 comprised of a multifilament structure fabricated from polyethylene and polyester is connected to the first and second fasteners 30 and tensioned to secure ligament 180. Claim 1 also requires that the first end of ligament is attached to the first bone of the joint before securing the first fastener, and the second end of the ligament is attached to the second bone of the joint before securing the second fastener. The ’449 Patent explains that a ligament may be augmented after it has been repaired or reconstructed. *Id*., 24:31-33.

Dependent claims 2-11 all relate to various aspects of the surgical method for ligament augmentation recited in the independent claim, including limiting the procedure to certain regions of the body.

C. Prosecution History

U.S. Patent Application No. 14/205,442, which issued as the '449 Patent, is a continuation of U.S. Patent Application No. 11/258,795 filed on October 26, 2005 which claims the benefit of U.S. Provisional Patent Application No. 60/622,095, filed October 26, 2004.

In the initial Office Action dated January 30, 2017, the Examiner rejected the claims under 35 U.S.C. §§ 102 and 103 in view of U.S. 2005/0255140 to Hagan et al., U.S. 4,590,928 to Hunt et al., U.S. 6,764,513 to Dowling, and U.S. 5,702,422 to Stone. Ex. 1004, 156-61. In response, the Applicant canceled claims 1-20 and added claims 21-34. *Id*., 126-27. The Applicant argued that the references "fail[] to describe securing a first fastener to a first bone of a joint adjacent a first end of a ligament of the joint, wherein a reinforcement component is attached to the first fastener to anchor the reinforcement component to the first bone." *Id*., 129-30.

The Examiner issued a second Office Action rejecting all claims under 35 U.S.C. §§ 102, 103, and 112. In rejecting claim 21 under § 112, the Examiner stated that it was unclear if "a ligament of the joint opposite the first end of the

ligament" claims "a second ligament different from the 'a first end of a ligament of the joint' in lines 2-3, or is attempting to further define said ligament." *Id*., 106. The Examiner rejected claim 21 under § 102(b) in view U.S. 2002/0120270 to Trieu et al. and in view of U.S. 5,152,790 to Rosenberg et al. The Examiner noted that the implant 51 in U.S. 2002/0120270 and the sutures 46, 46', 74 in U.S. 5,152,790 disclose the claimed reinforcement component. *Id*., 107-08.

In response, the Applicant amended claim 21 to include that "the first end of the ligament is attached to the first bone of the joint before securing the first fastener, and . . . the second end of the ligament is attached to the second bone of the joint before securing the second fastener." *Id*., 75. And to distinguish the cited references, the Applicant amended claim 21 to further claim that the "reinforcement component [is] comprised of a multifilament structure fabricated from polyethylene and polyester [and] is attached directly to the first fastener" and tensioned "directly" between the fasteners. *Id.*, 75. The Examiner issued a Notice of Allowance allowing all claims without providing a reason for their allowance.

D. Prior Art

1. Effective Prior Art Dates

U.S. Patent No. 4,834,752 ("Van Kampen", Ex. 1005) issued May 30, 1989. Van Kampen constitutes prior art under pre-AIA 35 U.S.C. § 102(b).

Marshall et al., "The Anterior cruciate ligament: A technique of repair and reconstruction." Clin. Orthop. Rel. Res. 143:97 ("Marshall," Ex. 1006), was published in the Clinical Orthopaedics and Related Research Journal in 1979. Marshall constitutes prior art under pre-AIA 35 U.S.C. § 102(b).

U.S. Patent No. 6,425,919 ("Lambrecht," Ex. 1008) issued July 30, 2002. Lambrecht constitutes prior art under pre-AIA 35 U.S.C. § 102(b).

U.S. Patent Publication No. 2004/0024457 ("Boyce," Ex. 1007) was published on February 5, 2004. Boyce constitutes prior art under pre-AIA 35 U.S.C. § 102(a) and (e).

2. **Overview of Van Kampen**

Van Kampen discloses a tissue augmentation device for use in parallel with biological tissue in the repair or reconstruction of ligaments and tendons. Ex. 1005, Abstract. Van Kampen was disclosed in the application that became the '449 Patent, along with over 1000 other prior art references during prosecution, but not applied by the Examiner.

The tissue augmentation device is used in parallel with biological tissue in the repair or reconstruction of ligaments or tendons. *Id*., Abstract. The device comprises a "strap-like element" adapted for fixation at each of its ends to the bones connected by the ligament or tendon being augmented. *Id*.

Van Kampen explains that it was well known to provide devices or implants to share the load for a repaired or reconstructed ligament. The reason for load sharing was (and still is) that the repaired or reconstructed ligament needs time to heal before carrying normal loads. *Id*., 1:25-47. Van Kampen describes prior devices for this purpose including the 3M KENNEDY Ligament Augmentation Device ("LAD"). *Id*., 1:37-47. Van Kampen acknowledges that such devices were known to attach to the bone on one side of the joint and to the ligament at the other side, so as to share the load placed on part of the ligament. In that arrangement, however, the entire length of the ligament is not augmented "thus leaving a possible weakness in the unaugmented region." *Id.*, 2:3-9.

Van Kampen also acknowledges that if an augmentation device is connected to bone on both sides of the joint (rather than the bone on one side and only ligament on the other side), and the device is stiffer than the ligament spanning that joint, then the device would carry most of the load. *Id*., 1:60-2:2. Van Kampen proposes a system in which the augmentation device is connected on each side to both the ligament ***and*** the bone, to run in parallel with the ligament and to help bear the load; but to avoid the result of the augmentation device continuing to carry most of the load, part of the augmentation device is designed to be biodegradable. *Id*., 2:23-48. This design allows for augmentation across the entire ligament, but the provided support diminishes over time as the ligament heals.

Van Kampen describes two different designs. In the first design, the augmentation device may be made of two strap-like elements secured together through a biodegradable connection element, and in the second design, a biodegradable fastener is used to attach the strap-like element to one of the anatomical structures connected by the device, so the tension across the device is released as the biodegradable connection element degrades. Including a biodegradable component avoids the need to perform a second surgery to remove or detach a device that provides complete support across the entire ligament but does not biodegrade.

An exemplary embodiment described in Van Kampen is used in the knee for augmentation of the anterior cruciate ligament (ACL), as shown in Figure 1. In this embodiment, the augmentation device 10 is affixed to the femur 12 using fastener 14, extended through tibial tunnel 28, and affixed to the tibia 30 using bushing 32 and screw 34. *Id*., 3:17-52.

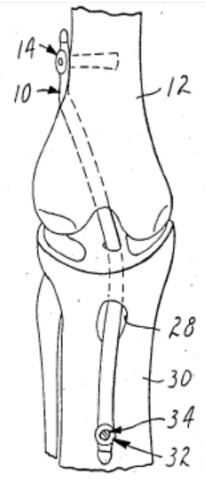

FIG. 1

Van Kampen explains that the fastening mechanisms at both ends of the device attach the device to bone through holes in the biological tissue. A POSITA would have understood that Van Kampen does not limit the use of the device to any particular region of the body and that the methods and device disclosed in Van Kampen could be adopted for the augmentation of other ligaments of the knee or ligaments in other areas of the body. Ex. 1002, ¶ 50; Ex. 1005, 1:15-21 ("[a]n example of such a procedure in the knee"), 2:23-40 ("reconstruction of a ligament or tendon"; "the anatomical structures connected by the ligament or tendon"), 5:9-13 ("selection of the appropriate biological tissue to reconstruct a particular tendon or ligament is well within the level of ordinary skill in the field of orthopedic surgery").

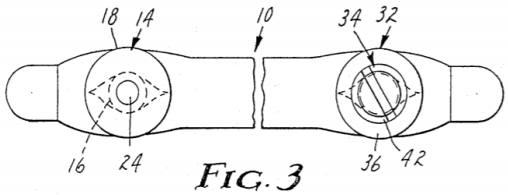

FIG. 3

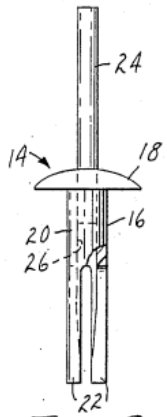

FIG. 2

Fastener 14 is implanted by drilling a hole in the femur 12 which is only slightly larger in diameter than cylindrical portion 20 and deep enough to receive legs 22 and cylindrical portion 20. Legs 22 of the receiver 16 are inserted through the braids of one end of augmentation device 10 and a small hole created in the biological tissue. Ex. 1005, 3:35-40.

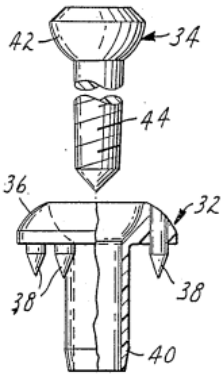

FIG. 4

Bushing 32 is implanted by inserting cylindrical portion 40 through the braids of one end of augmentation device 10 and a small hole created in the biological tissue (See FIG. 1) and then into a hole in the tibia. Screw 34 is then inserted into bushing 32 through head 36 and is bored into the tibia to securely affix augmentation device 10 to the tibia. 30. Ex. 1005, 3:62-67.

The biological tissue used in conjunction with the augmentation device in Van Kampen may be from one of three sources: tissue harvested from elsewhere in the patient, tissue from a donor, or it may be "the [original] damaged ligament or tendon itself which has been reapproximated by standard surgical techniques." Ex. 1005, 4:64-5:8. A POSITA would have understood that Van Kampen explains that scenarios in which a tissue graft is used are typically referred to as ligament "reconstruction," and a scenario wherein the native tissue is reapproximated is

typically referred to as ligament "repair." Ex. 1002, ¶ 51. For both ligament repair and reconstruction, the biological tissue is used in parallel with the augmentation device. *Id.,* 2:49-53. Van Kampen clarifies that "[t]he term 'parallel' is not used in the strict geometric sense, but rather in the biomechanical sense of members sharing a common load." *Id.,* 4:53-56. Van Kampen also discloses an example of known techniques for repair and reconstruction of the ACL as described by Marshall et al. in "The Anterior cruciate ligament: A technique of repair and reconstruction. Clin. Orthop. Rel. Res. 143:97, 1979." (Ex. 1006). *Id*., 5:13-21.

Van Kampen discloses that the device can be made from "polyolefins such as polypropylene, ultrahigh molecular weight polyethylene, and polybutylene; polyesters such as polyester terephthalate; polytetrafluoroethylene; and polyaramid." *Id*., 5:54-61. Van Kampen also explains that "the strap-like element is preferably fabricated from yarns," with braids or weaves of these yarns being preferred. *Id*., 5:62-65.

3. **Overview of Marshall**

Marshall is an article entitled "The Anterior Cruciate Ligament: A Technique of Repair and Reconstruction" published in the Clinical Orthopedics and Related Research Journal in 1979.

Marshall discloses a method for repairing a ligament, such as the ACL, in which sutures are passed through the proximal and distal stumps of the torn

ligament, the sutures are passed through holes drilled in the bone on either side of the ligament, then the sutures are tied down. Specifically, Marshall states:

> A series of sutures are passed in an anterior to posterior direction through the ligament, starting near the attached base and progressing toward the torn end. This places sutures through the entire ligament at varying depths and disseminates the tension to multiple portions of the ligament. In midportion tears these sutures are placed in both proximal and distal stumps. The suture ends are grouped together into 2 groups, keeping the anteriorly and posteriorly exiting sutures separate. These groups are then brought out through separately drilled holes. The individual suture ends are pulled tight to eliminate any slack, and the 2 groups are tied down as one unit. In the case of the midportion tear, when the suture groups are brought out in opposite directions, the torn ends of the ligament are realigned (Fig. l).

Ex. 1006, 98.

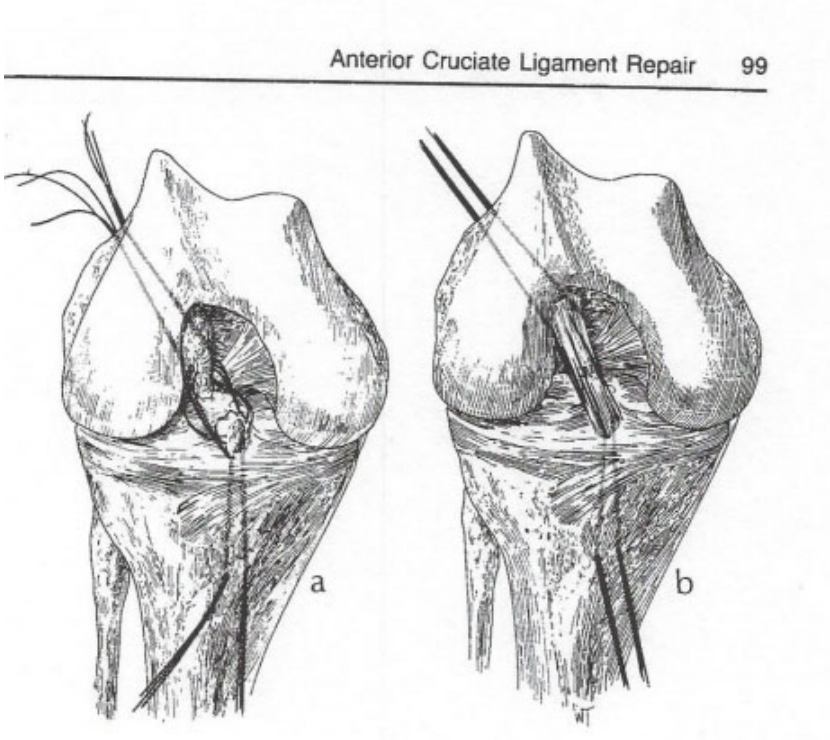

FIG. I. (a) A midportion tear. Looping sutures are placed in the proximal and distal stumps and exit through bone. (b) When the sutures are drawn tightly, the ligament is reconstituted.

Id., 99.

4. **Overview of Lambrecht**

Lambrecht discloses an implant used to treat spinal injuries, including tears in the annulus fibrosus. Ex. 1008, 1:13-17. The annulus fibrosus is a tough circular exterior of the intervertebral disc composed of a ring of ligament fibers that encases the inner core of the disc and securely connects to the spinal vertebrae above and below the disc. Ex. 1002, ¶ 55.

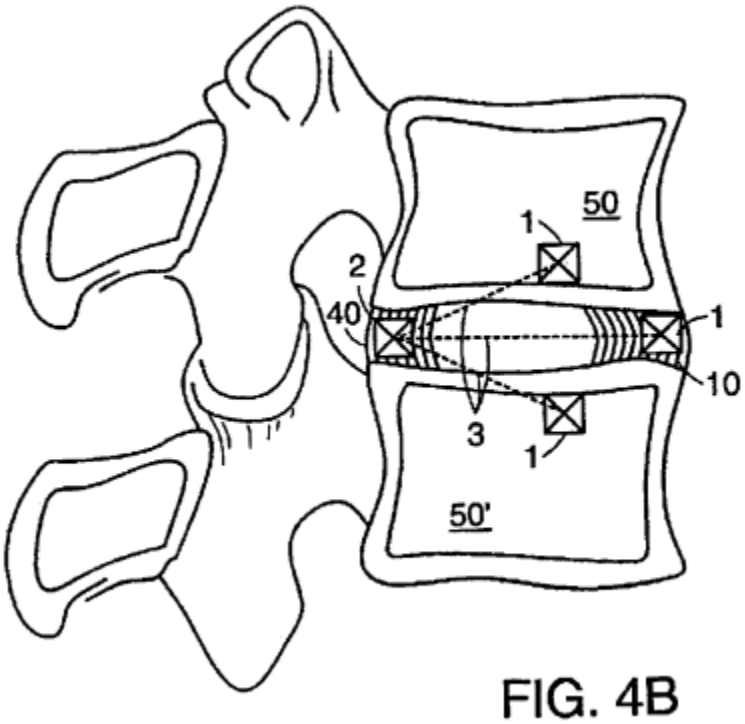

FIG. 4B

In Figure 4B, anchors 1 are affixed in various locations and connected to a support member 2 to support the herniated segment. Ex. 1008, 12:59-63. Figure

4B shows anchor locations in two adjacent vertebrae, superior vertebral body 50 and inferior vertebral body 50'. *Id*, 12:35-41. A POSITA would have understood Figure 4B to illustrate placing anchors in multiple locations in the vertebral body where connection member 3 is connected between the anchors and support member 2 and where connection member 3 can be one continuous length or several individual strands. Ex. 1002, ¶ 56. A POSITA would also have understood that the anchor locations depicted in Figure 4B are capable of withstanding the tensile forces of connection member 3. *Id.*

Lambrecht discloses that the connection member (3) can be made up of a single or multi-strand suture.

> Connection member 3 is also depicted in representative fashion. Member 3 may be in the format of a flexible filament, such as a ***single or multi-strand suture***, wire, or maybe a rigid rod or broad band of material, for example.

Ex. 1008, 11:60-12:12 (emphasis added), 11:52-59; Ex. 1002 ¶ 57.

5. **Overview of Boyce**

Boyce discloses an implant for a variety of orthopedic applications that includes a quantity of flexible, elongated elements. Ex. 1007, Abstract, Figs. 1a-1b. During prosecution of related U.S. Patent No. 9,579,129 ("the '129 patent"), the Examiner applied Boyce to show that the knee and elbow joints and their ligaments are equivalent structures known in the art to spinal ligaments. Ex. 1011. However, the Examiner did not address other disclosures within Boyce.

Figures 1a and 1b below show example implants disclosed in the patent application.

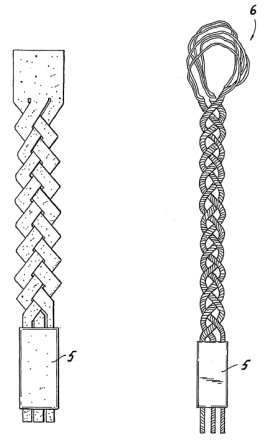

Fig. 1a Fig. 1b

The disclosed implants taught in Boyce can be used for treating spinal disorders, as well as for the treatment of other injuries throughout the body. Ex. 1007, ¶¶ [0002], [0063]. Boyce's disclosed implants may be used for repair or replacement of ligaments or tendons in the hand, elbow, knee, foot, ankle, or any other anatomical location:

> The present invention relates to an implant which is useful for a variety of orthopedic applications. More particularly, the present invention relates to an implant useful for treating bone injuries, defects, etc., such as spinal disorders for which spinal fusion is indicated and the repair or replacement of ligaments, tendons and/or cartilage.

Id., ¶ [0002].

> The implants of this invention can be utilized in a wide variety of orthopedic, neurosurgical and oral and maxillofacial surgical procedures such as the repair of simple and compound fractures and non-unions, external and internal fixations, joint reconstructions such as arthrodesis, general arthroplasty, cup arthroplasty of the hip, femoral and humeral head replacement, femoral head surface replacement and

> total joint replacement, repairs of the vertebral column including spinal fusion and internal fixation, tumor surgery, e.g. deficit filling, discectomy, laminectomy, excision of spinal cord tumors, anterior cervical and thoracic operations, repair of spinal injuries, scoliosis, lordosis and kyphosis treatments, intermaxillary fixation of fractures, mentoplasty, temporomandibular joint replacement, alveolar ridge augmentation and reconstruction, inlay bone grafts, implant placement and revision, sinus lifts, repair of ligaments or tendons in the hand, elbow, knee, foot, ankle or any other anatomical location, etc. These materials can be sutured or stapled in place for anchoring purposes, and serve in guided tissue regeneration or as barrier materials.

Id., ¶ [0063].

The '129 patent's prosecution history shows the Examiner applied Boyce to disclose performing the claimed surgical procedure in both the knee and the elbow. The prosecution history states:

> Boyce et al. discloses a graft members [sic] for stabilizing and repairing ligaments of the body …. In specific, Boyce shows that the knee and elbow joints and their ligaments are equivalent structures known in the art. Therefore, because these two ligament repair regions were art-recognized equivalents at the time the invention was made (see ¶65 of Boyce et al.), one of ordinary skill in the art would have found it obvious to have implemented the general ligament stabilization steps used in the spinal application of Serhan et al. in knee and elbow procedures as taught by Boyce et al.

Ex. 1011, 104. The Examiner's conclusion was not refuted by the Applicant. This Petition applies Boyce in a manner consistent with the prosecution history.

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

For the purposes of this Petition, Petitioner states that under any reasonable interpretation of the claims, including the standard set forth in *Phillips v. AWH*

Corp., 415 F.3d 1303, 1327 (Fed. Cir. 2005) (holding that words of a claim "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art in question at the time of the invention), all of the limitations of the challenged claims are met in the prior art as discussed below. The following constructions are offered for purposes of clarity only.

A. "suture"

The term "suture" is defined in the Stedman's Medical Dictionary as "the material (silk thread, wire, catgut, etc.) with which two surfaces are kept in apposition." Ex. 1012, 1514. This definition reflects how those of skill in the art understood the term "suture" at the time of filing the '449 Patent. Ex. 1002, ¶ 32.

This definition is also consistent with the '449 Patent's specification, which describes sutures being attached to fasteners and tensioned in order to secure the fasteners and articles in relation to one another, and suitable materials for said sutures. Ex. 1001, 13:5-15, 22:27-57, 25:1-10; Ex. 1002, ¶ 33. P Tech accuses Arthrex's InternalBrace™, which includes a FiberTape® component composed of polyethylene secured between two anchors, of infringement in a related litigation. Ex. 1013, 3. The definition of suture presented above is also consistent with P Tech's interpretation of suture, to the extent that P Tech is asserting that FiberTape® is a suture. Ex. 1002, ¶ 34.

VI. ARGUMENTS

A. Statement of the Law

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

B. Level of Ordinary Skill in the Art

A person of ordinary skill in the art (POSITA) would have (1) at least a B.S. or equivalent degree; and (2) at least two years' experience (i) designing, developing, or testing implantable medical devices, such as suture anchors, or (ii) performing surgeries with implantable medical devices, such as suture anchors. Nevertheless, Petitioner submits that the claims are obvious in view of any reasonable definition of a POSITA. Ex. 1002, ¶ 38.

C. The Challenges Presented in This Petition are Not Cumulative to Prosecution of the '449 Patent

While the primary reference upon which this petition is based, Van Kampen, was disclosed in an IDS during prosecution, the reference was not applied by the Examiner. The Applicant disclosed Van Kampen with over 1000 other prior art references, did not highlight which of those references it considered to be of most

significance as recommended by MPEP § 2004,[1] and there is no indication that the relevant features of Van Kampen were considered. Importantly, Van Kampen discloses the subject matter considered allowable by the Examiner—namely, that the "reinforcement component [is] comprised of a multifilament structure fabricated from polyethylene and polyester" and is attached and tensioned "directly" between the fasteners. Ex. 1004, 75.

Because Van Kampen applied against the challenged claims teaches the subject matter deemed missing from the prior art considered during prosecution, these challenges necessarily do not present "the same or substantially the same prior art or arguments previously were presented to the Office" under 35 U.S.C. § 325(d). *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geriite GmbH*, IPR2019-01469, Paper 6 at 8-9 (PTAB Feb. 13, 2020) (precedential).

D. Ground 1: Claims 1-4 and 6 are obvious over Van Kampen in view of Marshall

The combination of Van Kampen and Marshall renders claims 1-4 and 6 obvious.

[1] Citing *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc*., 359 F. Supp. 948, 175 USPQ 260 (S.D. Fla. 1972), aff'd, 479 F.2d 1338, 178 USPQ 577 (5th Cir. 1973) (holding that the Examiner could not have been aware of a material reference buried among a long list of prior art).

1. Claim 1

Claim 1 is obvious under pre-AIA 35 U.S.C. § 103 over Van Kampen in view of Marshall.

Overview of the Combination

Van Kampen teaches each element of claim 1, however, it does not explicitly describe attaching the first end of the ligament to the first bone of the joint before securing the first fastener and attaching the second end of the ligament to the second bone of the joint before securing the second fastener. Van Kampen, however, does disclose that the augmentation device is used in parallel with a damaged ligament or tendon that has been "reapproximated by standard surgical techniques" (Ex. 1005, 4:64-5:8), and explains that Marshall demonstrates examples of such techniques for repair and reconstruction of the ACL. *Id*., 5:13-21.

Marshall describes a technique to repair a torn ACL in which sutures are passed through the proximal and distal ends of the torn ligament, the sutures are also passed through holes drilled in the bone on either side of the ligament, and then the sutures are tied down thereby attaching the first and second ends of the ligament to bone. Ex. 1006, 98-100.

Consequently, a POSITA would have found it obvious to use the methods and device disclosed in Van Kampen to augment a ligament such as the ACL

which has been reapproximated using the technique described in Marshall, as discussed in more detail below. Ex. 1002, ¶ 66.

Rationale (Motivation) Supporting Obviousness

Marshall is explicitly cited in Van Kampen and is described to show known techniques for repair and reconstruction of the ACL. Ex. 1005, 5:13-21. A POSITA would have naturally combined the teachings of Van Kampen and Marshall because the references are in the same field and both disclose methods used for treating damaged tissues, including the ACL ligament. Ex. 1002, ¶ 67. A POSITA would have naturally looked to Marshall when considering a suitable technique for ACL reapproximation. *Id*. The combination does no more than use the methods and device of Van Kampen in conjunction with those described in Marshall in a known way to achieve predictable results since this method to repair ligaments was practiced regularly by surgeons at the time. *Id*.

***Graham* Factors**

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

The **scope and content of the prior art** are discussed throughout the Ground.

The **differences between the prior art and the claims** are discussed in the "Overview of the Combination" and below.

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

Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in using the methods and device of Van Kampen with a reapproximated ACL done in the manner described in Marshall, because such ACL repair was widely practiced in the field before the filing date of the '449 Patent. Ex. 1002, ¶¶ 68-70. The disclosed implants and procedures were already well known in the field, and surgeons were already well versed in these general implants and techniques. *Id*., ¶ 68.

Analogous Art

Van Kampen and Marshall are analogous art, because they are in the same field as the '449 Patent (Ex. 1001, Abstract, Title) (Ex. 1005, Abstract, Title) (Ex. 1006, Title), and all relate to treating damaged tissues, including the ACL ligament. Ex. 1002, ¶ 71.

[1.P] "A surgical method for ligament augmentation comprising:"[2]

To the extent the preamble is deemed limiting, Van Kampen teaches a surgical method for ligament augmentation. Specifically, Van Kampen states "[a]

[2] Petitioner does not assert a position as to whether the claim preambles are limiting and reserves the right to assert either position in this or any other proceeding.

tissue augmentation device is disclosed for use in parallel with biological tissue in the repair or reconstruction of ligaments and tendons. … The device is adapted for fixation at each end thereof to the anatomical structures connected by the ligament or tendon." Ex. 1005, Abstract, 3:48-61; *see also* Ex. 1006, 98-100.

[1.1] "securing a first fastener at least partially within a first bone of a joint adjacent a first end of a ligament of the joint,"

Van Kampen teaches securing a first fastener 14 within a first bone adjacent a first end of a ligament. In the example provided for ligament augmentation in the knee, Van Kampen explains that fastener 14 is implanted into the femur.

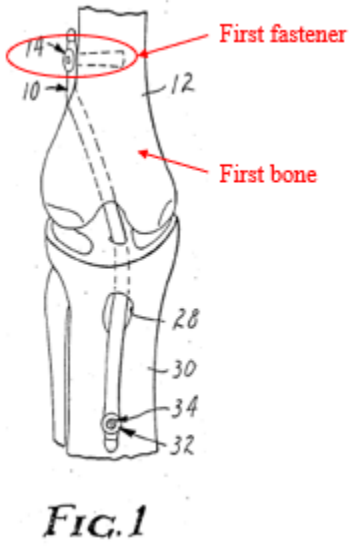

FIG. 1

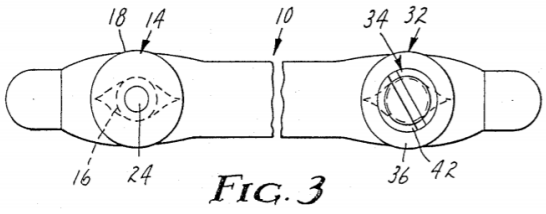

FIG. 3

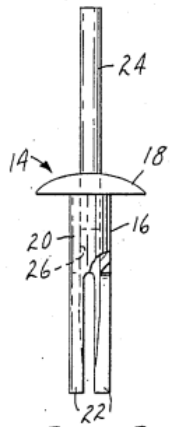

FIG. 2

> Fastener 14 is implanted by drilling a hole in the femur 12 which is only slightly larger in diameter than cylindrical portion 20 and deep enough to receive legs 22 and cylindrical portion 20. Legs 22 of the receiver 16 are inserted through the braids of one end of augmentation device 10 and a small hole created in the biological tissue. This end is shown in closer view in FIG. 3. Legs 22 are then inserted into the hole in the

> femur 12. The receiver 16 is then seated in the hole in the femur 12 by pressure on flanged head 18. Post 24 is then inserted in cylindrical channel 26 through flanged head 18. Post 24 is forced between legs 22 until a secure friction fit is obtained.

Ex. 1005, 3:35-47.

Van Kampen explains that the procedure may include a graft or that "the damaged ligament or tendon itself" may be repaired such that an augmentation device is used in the procedure with the repaired tissue. *Id*., 4:64-5:21, 7:30-33. Van Kampen explains that these techniques were already known at the time, including the use of the 3M Kennedy Ligament Augmentation Device ("LAD") device to augment a damaged ligament. *Id*., 1:36-2:20, 7:33-50. The fastener is placed near the end of the ligament (or replacement tissue), as Van Kampen teaches that the augmentation structure must extend "the entire length," i.e., between both ends of the ligament, as claimed:

> [T]he device of the present invention augments the ***entire length*** of the tissue, and is affixed at both ends to the anatomical structures connected by the ligament or tendon being repaired or reconstructed i.e., in the case of ligament repair or reconstruction the device is affixed to bone at each end . . . . In no event is one end affixed only to the tissue being augmented. It is critical to the practice of the invention that loads are transferred initially from bone through the device to bone . . . with limited transfer through the tissue.

Id., 7:36-50 (emphasis added). Van Kampen also explains that the device is used "in parallel" and "adjacent to" the ligament such that it shares "a common load" with the ligament. *Id*., 4:51-63 ("[t]he augmentation device and the tissue are used

adjacent to one another along their lengths" (emphasis added)). Van Kampen also explains that the fastener may be positioned through one end of the ligament. *Id*., 3:34-42. Even when the fastener is not secured through the end of the ligament, it is still secured near the end of the ligament it is augmenting. *Id*., 2:49-54 ("fixing both ends of such device to the anatomical structures connected by the original ligament or tendon"), Fig. 1; Ex. 1002, ¶ 74. A POSITA would have understood that how close the fastener is to the end of the ligament would depend on factors such as the type of ligament repaired (e.g., ACL vs. MCL), and whether the fastener is being secured directly through the ligament. Ex. 1002, ¶ 74. Accordingly, a POSITA would have understood Van Kampen's fastener 14 to be secured within a first bone (femur) of a joint adjacent a first end of the ligament of the joint. *Id*.

[1.2] "wherein the first end of the ligament is attached to the first bone of the joint before securing the first fastener, and"

Van Kampen teaches that the augmentation device can be used in parallel with a damaged ligament or tendon that has been "reapproximated by standard surgical techniques," or can be used with a graft ligament. Ex. 1005, 4:64-5:8. Van Kampen also discloses an example of known techniques for ACL repair and reconstruction as described by Marshall et al. (Ex. 1006). Ex. 1005., 5:13-21.

A POSITA would have understood that in the case of repairing an original ligament by normal surgical techniques, as described in Van Kampen, the natural

ligament would already be attached in Van Kampen's procedure prior to the insertion of fastener 14. Ex. 1002, ¶ 76. The ligament would be attached/secured in its natural anatomic position, with any partial tear (as an example) having been addressed. *Id*.

Marshall discloses in more detail a method for repairing a ligament in which the first and second ends of a ligament are attached to first and second bones (the bones to which the damaged ligament was originally attached), or portions thereof are more securely attached if the original ligament is being used and intact. Ex. 1006, 98-100. While the repaired or replaced ligament is healing, it was known at the time to provide a suture to take the load of the ligament. Ex. 1005, 2:55-64 ("protect[] from excessive stress"), 6:26-30 (explaining that the device is designed to degrade over time so that "the load is gradually transferred to the tissue"); Ex. 1002, ¶ 77. For example, Marshall describes a technique to repair a torn ACL in which sutures are passed through the proximal and distal stumps of the torn ligament, the sutures are passed through holes drilled in the bone on either side of the ligament, and then the sutures are tied down.

> A series of sutures are passed in an anterior to posterior direction through the ligament, starting near the attached base and progressing toward the torn end. … In midportion tears these sutures are placed in both proximal and distal stumps. The suture ends are grouped together into 2 groups, keeping the anteriorly and posteriorly exiting sutures separate. These groups are then brought out through separately drilled holes. The individual suture ends are pulled tight to eliminate any slack, and the 2 groups are tied down as one unit. In the case of the

midportion tear, when the suture groups are brought out in opposite directions, the torn ends of the ligament are realigned (Fig. l).

Ex. 1006, 98.

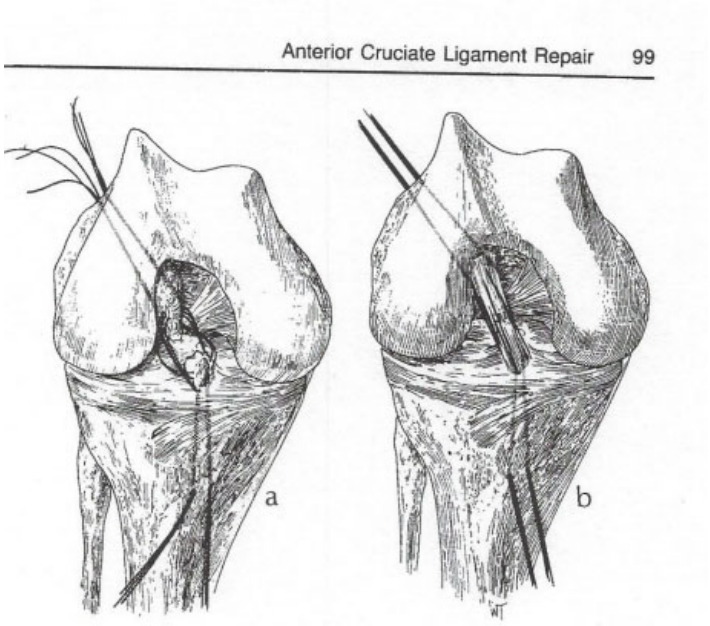

FIG. I . (a) A midportion tear. Looping sutures are placed in the proximal and distal stumps and exit through bone. (b) When the sutures are drawn tightly, the ligament is reconstituted.

Id., 99.

A POSITA would have understood that the first and second ends of the ligament would be attached to the first bone (femur) before the first fastener of Van Kampen was secured when using the augmentation device of Van Kampen to augment a repaired ligament (which may be repaired in a manner described in Marshall). Ex. 1002, ¶ 78. Sutures are used to secure the ligament to the bone in Marshall, as shown in Figure 1(a) above. Ex. 1006, 98 ("The suture ends are grouped together into 2 groups, keeping the anteriorly and posteriorly exiting sutures separate. These groups are then brought out through separately drilled

holes. The individual suture ends are pulled tight to eliminate any slack, and the 2 groups are tied down as one unit."). A POSITA would have understood that the ligament is being put in the anatomically correct position (or a close approximation thereof), and then the augmentation device is being used to aid the replaced or repaired ligament. Ex. 1002, ¶ 78.

In Marshall, the sutures are tied down after attaching the ligament to the bone by eliminating the slack. Ex. 1006, 98. Because the fastener in Van Kampen is being used to attach an augmentation device for a repaired or reconstructed ligament, a POSITA would have appreciated that the fastener would have been secured in place after the ligament is repaired (including being attached). Ex. 1002, ¶ 79. Indeed, the tissue augmentation device in Van Kampen "is adapted for fixation at each end thereof to the anatomical structures connected by the ligament or tendon" (Ex. 1005, 2:32-34), which confirms the ligament is attached to the first bone before the first fastener is inserted. Ex. 1002, ¶ 79; see also Ex. 1005, 5:4-8 ("damaged ligament or tendon itself which ***has been reapproximated*** by standard surgical techniques") (emphasis added).

[1.3] "wherein a reinforcement component comprised of a multifilament structure fabricated from polyethylene and polyester is attached directly to the first fastener to anchor the reinforcement component to the first bone; and"

Van Kampen discloses a reinforcement component in the form of "braided tissue augmentation device 10" (Ex. 1005, 3:17-22), which may be comprised of a multifilament structure fabricated from polyethylene and polyester.

> Materials which are suitable for fabricating the strap-like member … include synthetic polymeric materials which can be formed into high strength yarns. Such polymeric materials include polyolefins such as polypropylene, ultrahigh molecular weight ***polyethylene***, and polybutylene; ***polyesters*** such as polyester terephthalate; polytetrafluoroethylene; and polyaramid.

Id., 5:54-61.

Van Kampen further teaches that "[t]o obtain high strength and flexibility, the strap-like element is preferably fabricated from yarns of the foregoing material. Braids or weaves of these yarns are preferred." *Id*., 5:62-65, 4:1-4 ("augmentation device 10 [] consists of an integral length of braid"). A POSITA would have understood that a component made up of braids or weaves has a "multifilament structure." Ex. 1002, ¶ 81. It was common in orthopedic surgeries to use braided sutures made of polymeric materials. *Id*. The multifilament configuration was and still is well suited for procedures where sutures are implanted within the body (e.g., a ligament augmentation procedure) because multifilament sutures, when tied, hold a knot formation better than monofilament sutures. *Id*. A POSITA would have further understood from Van Kampen that any of the disclosed materials could have been used in the braid or weave, including polyethylene and polyester since these materials are commonly used in orthopedic implants. *Id*.

This is further evidenced by U.S. Patent No. 5,593,425, incorporated by reference into the '449 Patent, which acknowledges that it was known in the field to make sutures from these types of materials:

> Many materials suitable for surgery are made of or incorporate such heat bondable materials. Many biodegradables, polymers such as ***polyethylene***, and composites fall in this class … Composite materials can include reinforced plastics, or polymers which are laminated or layered or reinforced with one or more other materials such as nylon, graphite fibers, Kevlar® fibers, stainless steel fibers, etc. ***Many sutures are made of polymers which are suitable for use herein. Selection of such material is within the ordinary skill of the art***.

Ex. 1009, 3:39-52 (emphasis added).

It would have been obvious to a POSITA to use polyethylene and polyester since these materials were standard options for sutures/straps of the type to be used in Van Kampen's surgical procedure. Ex. 1002, ¶ 83. Moreover, a POSITA would have also understood that a braided design would provide benefits such as higher tensile strength and/or better knot tying properties as compared to a monofilament design. *Id*. A POSITA also would have also known that sutures made up of a combination of polyethylene and polyester provided benefits such as increased strength and resistance to fraying. *Id*; *see also* Exs. 1014, 1015. Braided sutures consisting of both polyethylene and polyester, such as Arthrex's FiberWire®, made of a multi-stranded ultra-high molecular weight polyethylene (UHMWPE) core with a polyester and UHMWPE braided jacket, were known and commercially available before the priority date of the '449 Patent. *Id*. Therefore,

combining polyethylene and polyester in a braided fashion would have been known to provide a product that would be strong and easy to use with a knotless fastener. *Id*.

Finally, Van Kampen also teaches attaching the reinforcement component directly to the first fastener to anchor it to the femur.

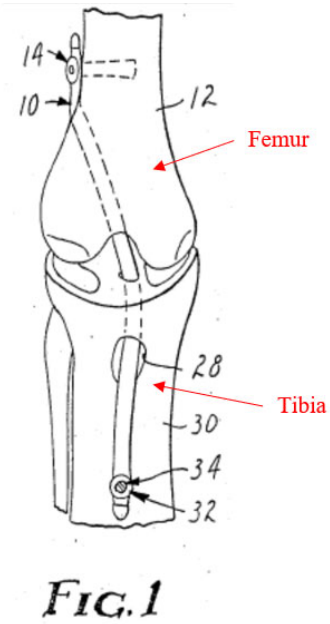

FIG. 1

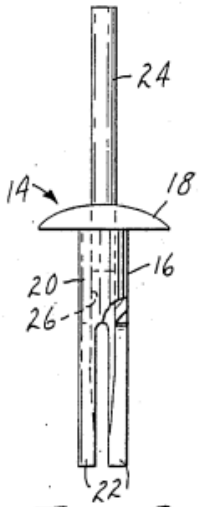

FIG. 2

> Fastener 14 is implanted by drilling a hole in the femur 12 which is only slightly larger in diameter than cylindrical portion 20 and deep enough to receive legs 22 and cylindrical portion 20. Legs 22 of the receiver 16 are inserted through the braids of one end of augmentation device 10 and a small hole created in the biological tissue.

Ex. 1005, 3:35-40.

[1.4] "securing a second fastener at least partially within a second bone of a joint adjacent a second end of the ligament of the joint opposite the first end of the ligament,"

Van Kampen teaches securing a second fastener within a second bone adjacent a second end of a ligament of a joint. In the example provided for ACL augmentation, Van Kampen teaches that busing 32 is implanted into the tibia.

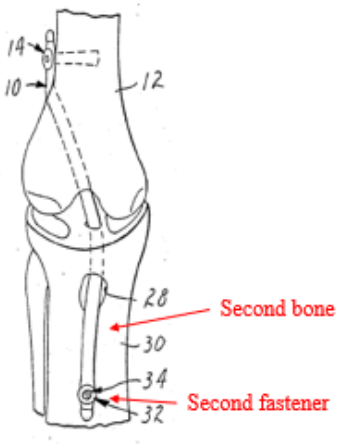

FIG. 1

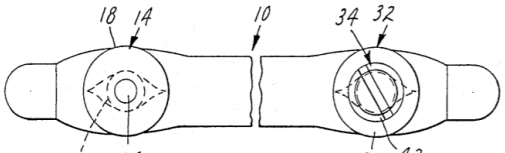

FIG. 3

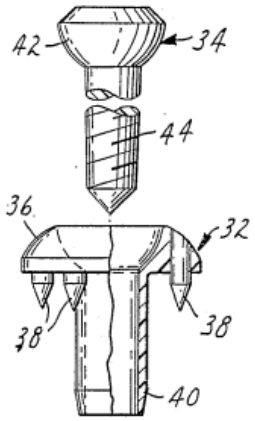

FIG. 4

> Bushing 32 is implanted by inserting cylindrical portion 40 through the braids of one end of augmentation device 10 and a small hole created in the biological tissue (See FIG. 1) and then into a hole in the tibia. Screw 34 is then inserted into bushing 32 through head 36 and is bored into the tibia to securely affix augmentation device 10 to the tibia. 30.

Id., 3:62-67.

As discussed above for claim [1.1], Van Kampen explains that the damaged tissue being augmented may be "the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques" as well as the use of a graft ligament. *Id*., 4:64-5:8. Further, Van Kampen teaches that the augmentation structure must extend "the entire length," i.e., "between the first and second ends" of the ligament as claimed:

> [T]he device of the present invention augments the ***entire length*** of the tissue and is affixed at both ends to the anatomical structures connected by the ligament or tendon being repaired or reconstructed i.e., in the case of ligament repair or reconstruction the device is affixed to bone at each end.

Id., 7:36-50 (emphasis added). Thus, a POSITA would have understood that Van Kampen's second fastener would be placed "adjacent" an end of the ligament. Indeed, the very point of the device is for it to be used "in parallel" with the ligament such that it shares "a common load" with the ligament. *Id*., 4:51-63 ("[t]he augmentation device and the tissue are used ***adjacent*** to one another along their lengths" (emphasis added)). Accordingly, a POSITA would have understood Van Kampen's second fastener to be secured within a second bone (tibia) of a joint adjacent a second end of the ligament of the joint. Ex. 1002, ¶ 86.

[1.5] "wherein the second end of the ligament is attached to the second bone of the joint before securing the second fastener, and"

As discussed above for claim [1.2], Marshall discloses a method for repairing a ligament in which the first and second ends of a ligament are attached to first and second bones. A POSITA would have understood that when using the augmentation device of Van Kampen to augment a repaired ligament (which may be a manner described in Marshall), the first and second ends of the ligament would be attached to the femur and tibia such that the ligament was under its natural anatomic tension before the augmentation device of Van Kampen was

installed. Ex. 1002, ¶ 87; Ex. 1006, 98. A POSITA would have understood to attach the first and second ends of the ligament so that the ligament is restored to its natural anatomic tension prior to augmenting or reinforcing the joint. Ex. 1002, ¶ 87. A POSITA would have further understood that restoring the ligament to its natural anatomic tension eliminates the potential for stress shielding when the augmentation device is installed. *Id*. In Marshall, the sutures are tied down after tensioning the ligament to its natural anatomic tension and attaching the ligament to the bone. Ex. 1006, 98; Ex. 1002, ¶ 87. The second fastener in Van Kampen is being used to attach an augmentation device for a repaired or reconstructed ligament, and therefore, a POSITA would have appreciated that the fastener would have been secured in place after the ligament is repaired (including being attached). Ex. 1002, ¶ 87. Indeed, the tissue augmentation device in Van Kampen "is adapted for fixation at each end thereof to the anatomical structures connected by the ligament or tendon," (Ex. 1005, 2:32-24), which suggests that the ligament has already been attached to the second bone before the second fastener is inserted. Ex. 1002, ¶ 87.

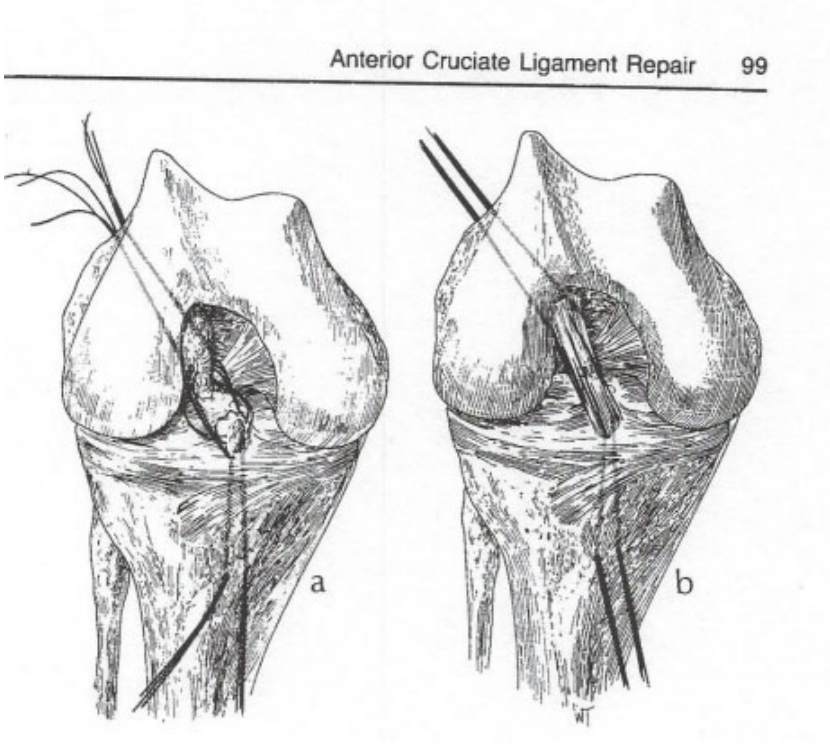

FIG. I. (a) A midportion tear. Looping sutures are placed in the proximal and distal stumps and exit through bone. (b) When the sutures are drawn tightly, the ligament is reconstituted.

Ex. 1006, 99.

[1.6] "wherein the reinforcement component is attached to the second fastener to anchor the reinforcement component to the second bone,"

Van Kampen teaches attaching the reinforcement component (10) to the second fastener (34) to anchor it to the tibia 30.

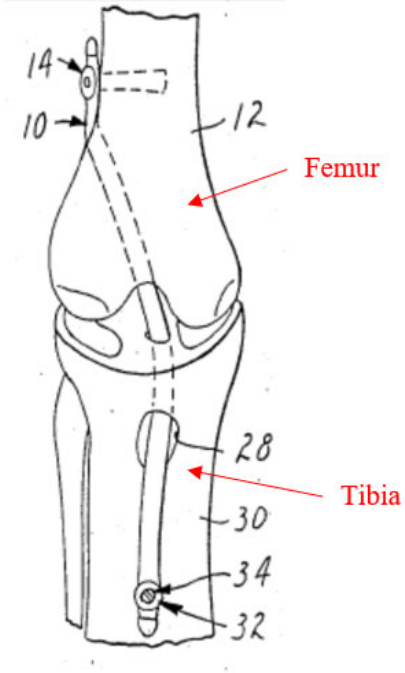

FIG. 1

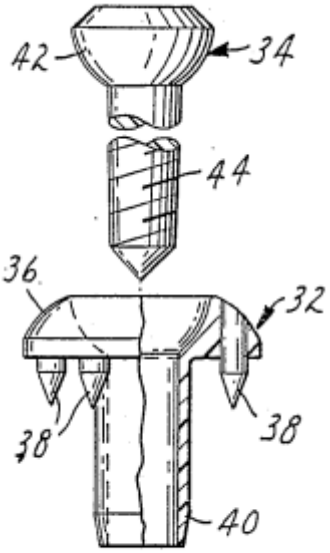

FIG. 4

> Bushing 32 is implanted by inserting cylindrical portion 40 through the braids of one end of augmentation device 10 and a small hole created in the biological tissue (See FIG. 1) and then into a hole in the tibia. Screw 34 is then inserted into bushing 32 through head 36 and is bored into the tibia to securely affix augmentation device 10 to the tibia 30.

Ex. 1005, 3:62-67.

A POSITA would have understood that the purpose of the first and second fasteners is to anchor the augmentation device in place. Ex. 1002, ¶ 89. Such procedures were known in the art even before the filing date of Van Kampen, as Van Kampen acknowledges with reference to the prior use of the LAD device. *Id.*; *see also* Ex. 1005, 1:36-2:20.

[1.7] "wherein the reinforcement component extends between the first and second ends of the ligament, and"

As established above, Van Kampen teaches that the reinforcement component (10) extends between the first and second ends of the ligament.

> A tissue augmentation device is disclosed for use in parallel with biological tissue in the repair or reconstruction of ligaments and tendons. … The device is adapted for fixation at each end thereof to the anatomical structures connected by the ligament or tendon.

Id., Abstract.

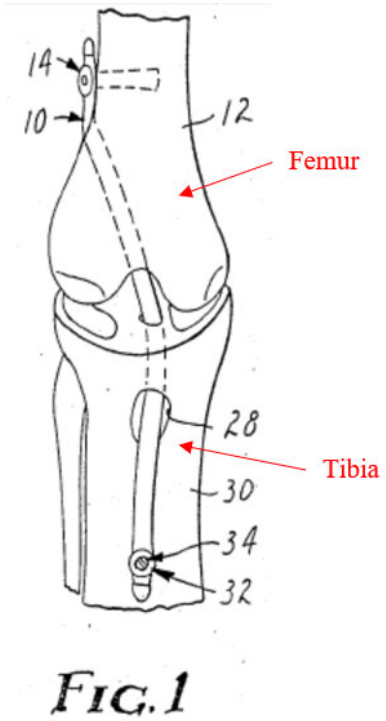

FIG. 1

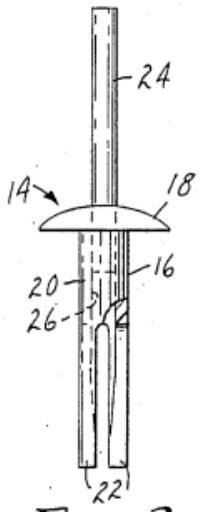

FIG. 2

> Referring now to FIG. 1, a braided tissue augmentation device 10 of this invention is shown implanted in a knee. Device 10 has a tissue graft (not shown) sutured along its length. Device 10 is affixed to the femur 12 by an expandable fastener 14 which is shown in greater detail in FIG. 2.

Id., 3:17-23. Van Kampen also teaches that the strap-like augmentation device must extend "the entire length," i.e., "between the first and second ends" of the ligament as claimed:

> [T]he device of the present invention augments the ***entire length*** of the tissue and is affixed at both ends to the anatomical structures connected by the ligament or tendon being repaired or reconstructed i.e., in the case of ligament repair or reconstruction the device is affixed to bone at each end . . . It is critical to the practice of the invention that loads are transferred initially from bone through the device to bone . . . with limited transfer through the tissue.

Id., 7:36-50 (emphasis added).

Because the Van Kampen strap-like element extends along the entire length of the ligament, a POSITA would have understood that it extends between the first and second ends of that ligament. Ex. 1002, ¶ 91. Furthermore, a POSITA would have found it obvious that where the device is intended to augment the entire ligament, bear the load of the ligament, and attach through the ligament to the bone, the same extends from one end of the ligament to the other. *Id*.

[1.8] "wherein the reinforcement component is tensioned directly between the first and second fasteners."

Van Kampen teaches that the reinforcement component is tensioned directly between the first and second fasteners. Van Kampen teaches that augmentation device 10 (the strap-like element) is directly attached to fastener 14 and to bushing 32/screw 34 (the first and second fasteners).

> Fastener 14 is implanted by drilling a hole in the femur 12 …. Legs 22 of the receiver 16 are inserted through the braids of one end of augmentation device 10 and a small hole created in the biological tissue. ... Legs 22 are then inserted into the hole in the femur 12. The receiver 16 is then seated in the hole in the femur 12 by pressure on flanged head 18. Post 24 is then inserted in cylindrical channel 26 through flanged head 18. Post 24 is forced between legs 22 until a secure friction fit is obtained.

Ex. 1005, 3:35-47.

> The end of augmentation device 10 opposite fastener 14 is affixed to the tibia 30 by bushing 32 and screw 34 … Bushing 32 is implanted by inserting cylindrical portion 40 through the braids of one end of augmentation device 10 and a small hole created in the biological tissue [] and then into a hole in the tibia. Screw 34 is then inserted into bushing 32 through head 36 and is bored into the tibia to securely affix augmentation device 10 to the tibia 30.

Id., 3:49-67.

A POSITA would have understood from Van Kampen that the strap-like element is tensioned between the fasteners. Ex. 1002, ¶ 93. In the excerpts above, Van Kampen explains that the ends of the augmentation device are "securely affixed" to the tibia and femur, and throughout the specification, Van Kampen explains that the augmentation device supports the working loads normally supported by the ligament. Ex. 1005, 2:22-37, 4:51-56, 5:44-53, 7:46-50, 1:48-64. Van Kampen describes the augmentation device as a "total prosthesis" for the damaged ligament. *Id*., 2:55-58, 5:22-29. A POSITA would have understood the term "total prosthesis" refers to an implant that performs the total functionality of the damaged body part the prosthesis replaces. Ex. 1002, ¶ 93. A POSITA would

have understood that the disclosed strap-like element would be tightened between the fasteners to act properly as a "total prosthesis." *Id*. This is because healthy ligaments are in tension and for the strap-like element to supplement the natural anatomical function, it would need to be tightened to the damaged ligament's natural anatomic tension. *Id*. Otherwise, it would not be supporting the load in a way that allows for the damaged ligament to heal. *Id*.

Additionally, Van Kampen explains that a composite graft made up of the biological graft sutured to the augmentation device may be used, and when this graft is used, it must be "tensioned appropriately":

> In the case of the reconstruction of the anterior cruciate ligament, the composite graft may first be affixed to the femur, then routed and ***tensioned appropriately*** for subsequent fixation to the tibia.

Ex. 1005, 8:4-13 (emphasis added).

Based on a POSITA's understanding of "total prosthesis" and the disclosures in Van Kampen, a POSITA would recognize that the strap-like element of the augmentation device would have been tensioned between the fasteners as described in the claim limitation. Ex. 1002, ¶ 95. The tensioning of the strap-like element is necessary to perform the desired functionality taught by Van Kampen, and any POSITA would have understood that the strap-like element is under tension. *Id*.

2. Claim 2 - The surgical method for ligament augmentation set forth in claim 1, wherein the reinforcement component extends along the length of the ligament

Van Kampen teaches that the ligament augmentation device extends along the length of the ligament. Van Kampen states that the device is used "in parallel with biological tissue in the repair or reconstruction of ligaments and tendons." Ex. 1005, Abstract. "The device comprises at least one strap-like element formed of a stable biocompatible material and a biodegradable element connected in series with the strap-like element. The device is adapted for fixation at each end thereof to the anatomical structures connected by the ligament or tendon." *Id*. The device also extends the "entire length" of the ligament:

> [T]he device of the present invention augments the ***entire length*** of the tissue and is affixed at both ends to the anatomical structures connected by the ligament or tendon being repaired or reconstructed … In no event is one end affixed only to the tissue being augmented. It is critical to the practice of the invention that loads are transferred initially from bone through the device to bone [] with limited transfer through the tissue.

Id., 7:36-50 (emphasis added).

3. Claim 3 – The surgical method for ligament augmentation set forth in claim 1, wherein the reinforcement component comprises a suture

Van Kampen discloses a reinforcement component that comprises a suture. Van Kampen explains that the strap-like element of augmentation device 10 may "consist[] of an integral length of braid" (*id.*, 4:1-2), and may be fabricated from "polyolefins such as polypropylene, ultrahigh molecular weight polyethylene, and

polybutylene; polyesters such as polyester terephthalate; polytetrafluoroethylene; and polyaramid," preferably fabricated from braids or weaves of yarns made of these materials. *Id*., 5:54-65. In the field of orthopedic surgery, this was suture material that was available and widely used in the relevant timeframe, and therefore a POSITA would have understood the disclosed strap-like element is made of suture material. Ex. 1002, ¶ 97.

Van Kampen also explains that "the term 'strap-like' is used broadly to connote flexibility, and although the preferred embodiment is flat in cross-section, any cross-sectional geometry may be used." Ex. 1005, 5:33-36. A POSITA would have further understood that the strap-like element functioned as a suture to keep two surfaces in apposition of each other. Ex. 1002, ¶ 98. It was well known in the field of orthopedic surgery that a suture is the material with which two surfaces are kept in apposition. *Id*. Commercially available sutures in the relevant timeframe served this purpose. *Id*. A POSITA would have further understood that suture comes in different cross-sectional geometries. *Id*. Sutures with different cross-sectional areas were commercially available at the time of filing the '449 Patent. *Id*. Therefore, a POSITA would have understood the disclosed strap-like element to be a type of suture. *Id*. In any event, Van Kampen describes that variations may be used, which a POSITA would have understood could have been any suture that could handle the load in the relevant joint. *Id*.

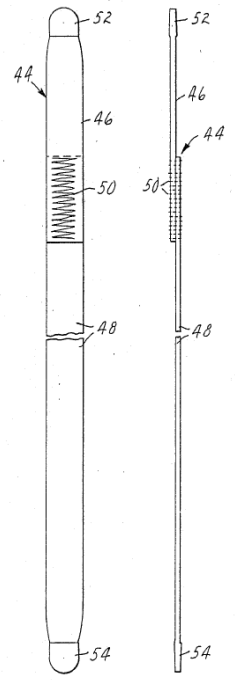

FIG. 5 FIG. 6

Van Kampen also discloses an alternate embodiment shown in Figures 5 and 6, wherein the ligament augmentation device (44) is constructed of two strap-like elements (46 and 48) constructed from bundles of polypropylene filaments that are overlapped and sewn together using biodegradable suture 50. Ex. 1005, 4:1-11; 4:15-25; 7:55-61; 8:16-38. A POSITA would have understood that this alternate embodiment discloses a reinforcement component that compromises a suture through its disclosure of suture 50, or either of the strap-like elements 46 and 48. Ex. 1002, ¶ 99.

4. Claim 4 – The surgical method for ligament augmentation set forth in claim 3, wherein the reinforcement component comprises a plurality of sutures

For the reasons described above for claim 3, Van Kampen discloses a ligament augmentation device comprising a plurality of sutures. A POSITA would have understood that the embodiment shown in Figures 5 and 6 discloses or renders obvious a reinforcement component comprising a plurality of sutures through its disclosure of the multiple stitches of suture 50, or the combination of any of suture (50) and the two strap-like elements (46 and 48). Ex. 1002, ¶ 100.

5. Claim 6 – The surgical method for ligament augmentation set forth in claim 1, wherein the first and second bones and the joint are part of a knee

Van Kampen discloses the surgical method for ligament augmentation as described above in claim 1. The augmentation device shown in Van Kampen Figure 1 depicts a knee joint including femur 12 and tibia 30. Ex. 1002, ¶ 101.

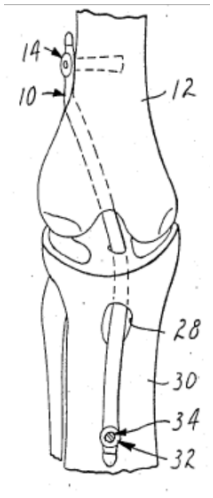

FIG. 1

> Referring now to FIG. 1, a braided tissue augmentation device 10 of this invention is shown implanted in a knee. Device 10 has a tissue graft (not shown) sutured along its length. Device 10 is affixed to the femur 12 by an expandable fastener 14 which is shown in greater detail in FIG. 2.

Ex. 1005, 3:17-23; *see also* 3:47-51; Ex. 1002, ¶¶ 102-103.

E. Ground 2: Claims 1-4, 6 and 8 are Obvious Over Van Kampen in View of Marshall in Further View of Lambrecht

Claims 1-4, 6, and 8 are obvious under pre-AIA 35 U.S.C. §103 by Van Kampen in view of Marshall and Lambrecht. Ex. 1002, ¶ 104.

As discussed with respect to Ground 1, Van Kampen and Marshall teach claim elements [1.1]-[1.8] for the reasons described above. Van Kampen discloses a strap-like element of augmentation device 10 attached to fastener 14 and bushing 32/screw 34 that supports the working loads normally supported by the ligament or tendon by acting as a "total prosthesis" for the weakened ligament or tendon. To the extent the Board finds that Van Kampen alone does not expressly disclose that a reinforcement component is tensioned between the fasteners, Lambrecht teaches this element. Specifically, it would have been obvious to a POSITA to use the device and methods disclosed in Van Kampen with a reinforcement component that is tightened between fasteners, as taught by Lambrecht. *Id*. ¶¶ 105-06.

Rationale (Motivation) Supporting Obviousness

A POSITA would have been motivated to combine Van Kampen and Lambrecht. *Id*. ¶ 107. First, Lambrecht discloses an implant utilizing a tensioned

suture between two anchors. Second, Van Kampen and Lambrecht are both disclosed inventions in the field of ligament/joint repair. *Id*.

A POSITA would have found it obvious to use the device and methods disclosed in Van Kampen with a suture that is tightened between fasteners. *Id*., ¶ 108. Lambrecht discloses an implant used to treat spinal injuries, including tears in the annulus fibrosus which is comprised of ligament fibers. *Id.*; Ex. 1008, Lambrecht, 1:13-17. The implant of Lambrecht is made up of a suture attached to, and tensioned between, at least two anchors. Ex. 1008, 11:7-21, 11:60-12:12, Fig. 2B, Fig. 4B.

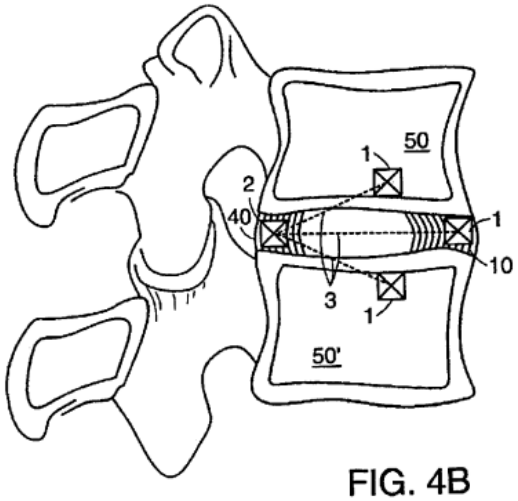

FIG. 4B

Figure 4B above shows fasteners (anchor 1) in bone (vertebral body 50) attached to another anchor (support member 2) by tensioned suture (connection member 3). A POSITA would have understood that while support member 2 may not be attached to bone in the depicted embodiment of Figure 4B, it would have been obvious to place the second fastener in bone given that anchor 1 is attached to

bone. Ex. 1002, ¶ 109. In fact, it is was well known at the time of filing the '449 Patent that placing an anchor in bone results in a more secure anchor than placing an anchor in other bodily material and therefore bone is a preferred anchor location. *Id*. If the repair or reconstruction procedure of a weakened ligament portion allowed for both fasteners to be placed in bone, a POSITA would have done so knowing it would produce superior results. *Id*. Specifically, support member 2 is used to support a bulge in an intervertebral disc, but a POSITA would have understood that such a device could be used to support spinal ligaments when no bulge is present. *Id*. In any event, Van Kampen already describes the features of claim 24, and reliance on Lambrecht simply establishes that when fasteners and sutures were used to span a joint, the same were known to be used under tension. *Id*.

A POSITA would have found it obvious to combine the device and methods disclosed in Van Kampen with the tensioned suture disclosed in Lambrecht to produce a predictable outcome. *Id*., ¶ 110.

Van Kampen and Lambrecht both disclose inventions in the field of ligament repair and both disclose similar implantation devices and methods used for treating damaged ligaments. *Id.*, ¶ 111. A POSITA would have naturally looked to Lambrecht when considering suitable materials and designs for the strap-like element and methods of application for the device disclosed in Van Kampen.

Id. Van Kampen explains that the disclosed device supports working loads normally supported by the ligament or tendon and that the device acts as a "total prosthesis" for the damaged ligament or tendon. Ex. 1005, 2:32-37, 4:51-56, 5:44-53, 7:46-50, 2:55-58, 5:22-29. Lambrecht discloses a connection member 3 comprised of a single or multi-strand suture. Ex. 1008, 11:61-62. Lambrecht further discloses a suture (connection member 3) maintained under tension between two fasteners (anchor 1 and support member 2*). Id.*, 11:12-17, 12:35-41, Fig. 4B. Similar to Van Kampen, Lambrecht teaches the use of a tensioned suture that spans the length of the damaged region to provide the requisite support for repair. *Id*., 12:59-67, Figs. 4A-4B.

A POSITA would have understood that Lambrecht's disclosed use of a suture tightened between the fasteners would provide the functionality required of the strap-like element disclosed in Van Kampen. Ex. 1002, ¶ 112. It is well known in the art that tightening of a suture, as disclosed in Lambrecht, provides for support of the damaged area. *Id*. Additionally, a POSITA would have understood that the combination of these disclosed inventions would do no more than use the device and methods of Van Kampen in a known way to achieve predictable results. *Id*. For these reasons, a POSITA, having reviewed Van Kampen, would have naturally looked to Lambrecht to understand that sutures attached to fasteners (particularly when spanning a joint) would be tightened to provide tension. *Id*.

***Graham* Factors**

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

The **scope and content of the prior art** are discussed throughout the Ground.

The **differences between the prior art and the claims** are discussed in the "Overview of the Combination" and below.

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

Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in using the methods and device of Van Kampen with a suture tensioned between fasteners, as disclosed in Lambrecht. *Id*., ¶ 113-15. As previously discussed, both disclosures teach the use of a tensioned suture spanning the length of a damaged region to repair the damaged region. This was and still is a common method of repairing damaged ligaments and tendons in the body. *Id*., ¶ 115. The tools and methods used for ligament repair at the time of filing the '449 Patent generally employed the use of tensioned suture in a predictable manner. *Id*. A POSITA would have found it obvious to combine these two disclosures for the repair or reconstruction of a damaged ligament. *Id*.

Van Kampen discloses a strap element that supports "working loads". Ex. 1005, 2:32-40. A POSITA would have understood that a "working load" is the load that was previously borne by the ligament that the disclosed strap element is tensioned in order to support this load. Ex. 1002, ¶ 116. Lambrecht similarly teaches tensioning a suture-like device between fasteners. A POSITA would have had a reasonable expectation of success in using the methods and device of Van Kampen with a suture tensioned between fasteners, as disclosed in Lambrecht. *Id*. A POSITA would have been able to make the necessary modifications to the device and methods of Van Kampen to implement this combination. *Id*.

Analogous Art

Van Kampen, Marshall, and Lambrecht are analogous art, because they are in the same field as the '449 Patent (Ex. 1001, Title) (Ex. 1005, Abstract, Title) (Ex. 1008, Abstract, Title, 1:11-17, 5:14-35), and all three relate to treating damaged tissues. Ex. 1002, ¶ 117.

1. **Claim 1**

Van Kampen and Marshall teach claim elements [1.0]-[1.7] as discussed in Ground 1 above. To the extent Van Kampen and Marshall fail to teach the tensioning of claim [1.8] ("wherein the reinforcement component is tensioned directly between the first and second fasteners"), Lambrecht discloses tensioning a suture between two fasteners.

First, Figure 4B teaches securing suture directly to, and among, various fasteners. Connecting member 3 connects the first fastener (anchor 1) and the second fastener (support member 2). Ex. 1008, 12:31-67, Fig. 4B. Lambrecht further discloses connecting member 3 may be comprised of a single or multi-strand suture. *Id*., 11:61-62. Based on this disclosure, it would have been apparent to a POSITA that Lambrecht discloses a suture secured directly to a first and second fastener. Ex. 1002, ¶¶ 118-119.

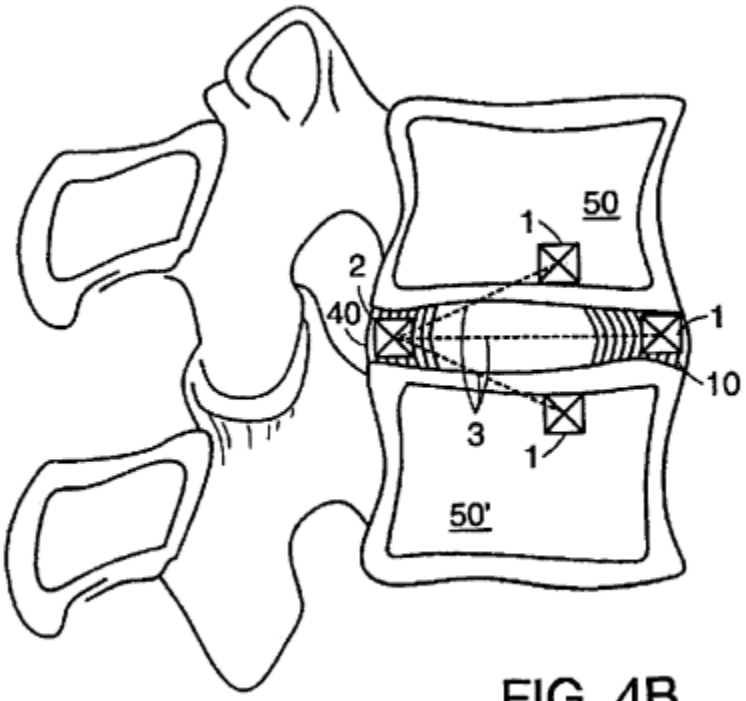

FIG. 4B

Second, Lambrecht teaches tensioning the suture connected to fasteners. Specifically, it teaches suture (connection member 3) maintained under tension between two fasteners (anchor 1 and support member 2 or different anchors 1,

depending on the procedure[3]). Ex. 1008, 11:12-17, 12:35-41, Fig. 4B. Tensioning the suture is an obvious step when performing a repair procedure utilizing anchors connected by suture, because the tensioning step allows for the damaged region to be held securely in its natural anatomic tension. Ex. 1002, ¶ 120.

The Examiner who handled the application that ultimately issued as the related '129 patent determined that Lambrecht discloses a suture attached to, and tensioned between fasteners:

> Lambrecht disclose [sic] a system for stabilizing a ligament (figure14). The system includes … ***a suture (14) secured to at least one of the first and the second fasteners in an implanted configuration, the suture being tensioned*** (column 11, line 52-59).

Ex. 1011, 97 (emphasis added).

The Applicant responded to the rejection of claim 1 based on Lambrecht by amending the claim to include the additional underlined limitation:

> a suture secured to at least one of the first and the second fasteners in an implanted configuration <u>and configured for extending through the superior end portion, the ligament, the first vertebra, the intervertebral disc, the second vertebra, and the inferior end portion</u>, the suture being tensioned.

Id., 74, 83.

[3] A POSITA would have appreciated that Lambrecht's teaching of tightening a suture between fasteners could be used regardless of whether the system attached to a bulging disc or simply spanned two bones. Ex. 1002, ¶ 120.

The Applicant did not refute the Examiner's assertion that at the time of filing, it was known in the art to tension a suture connected to fasteners, as taught in Lambrecht. *Id*. A POSITA would have found it obvious that the strap-like element in Van Kampen could be tensioned between its fasteners, just as taught in Lambrecht, and a POSITA would have known that a tensioned strap would be helpful in supporting the necessary loads required by the ligament augmentation function of Van Kampen. Ex. 1002, ¶ 123.

2. **Claim 2**

Van Kampen and Marshall disclose all of the limitations of claim 2 for the reasons discussed with respect to Ground 1, claim 2 above.

3. **Claim 3**

To the extent Van Kampen and Marshall fail to disclose that "the reinforcement component comprises a suture" as recited in Ground 1, claim 3, Lambrecht discloses that the reinforcement component is preferably a suture. For example, "[m]ember 3 may be in the format of a flexible filament, such as a single or multi-strand suture, wire, or maybe a rigid rod or broad band of material." Ex. 1008, 11:61-63. It was also common to tension a single or multi-strand suture between two anchors. Ex. 1002, ¶ 125.

4. **Claim 4**

To the extent Van Kampen and Marshall fail to disclose that "the reinforcement component comprises a plurality of sutures" as recited in Ground 1,

claim 4, a POSITA would understand that Lambrecht discloses or suggests to a POSITA that the reinforcement component may comprise a plurality of sutures. *Id*. ¶ 126. For example:

> [m]ember 3 may be in the format of a flexible filament, such as a single or multi-strand suture, wire, or maybe a rigid rod or broad band of material. Suture, wire, or maybe a rigid rod or broad band of material, for example. The connection member can further include suture, wire, pins, and woven tubes or webs of material. It can be constructed from a variety of materials, either permanent or resorbable, and can be of any shape suitable to fit within the confines of the intervertebral disc space.

Ex. 1008, 11:61-12:1; Ex. 1002, ¶ 126.

5. **Claim 6**

Van Kampen and Marshall disclose all of the limitations of claim 6 for the reasons discussed with respect to Ground 1, claim 6 above.

6. **Claim 8**

Claim 8 depends on claim 1 and adds that the first and second bones and the joint are part of a spine. Lambrecht discloses a system used to treat spinal injuries, including tears in the annulus fibrosus. Ex. 1008, 1:13-17. Similar to Van Kampen, the Lambrecht system is made up of a connection member (3) attached to, and tensioned between, at least two anchors (1) and (2) secured to vertebrae in the spine as shown in Figure 4B.

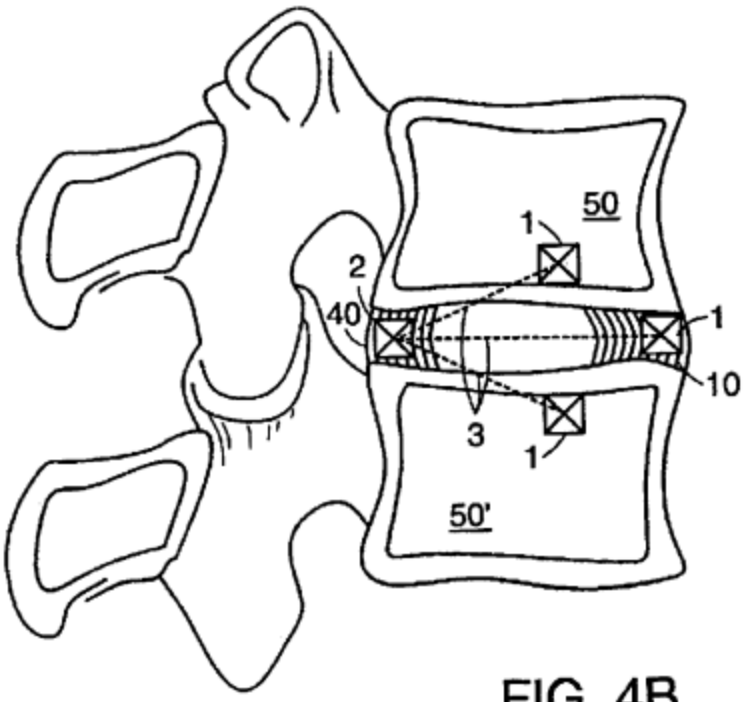

FIG. 4B

> As shown in FIGS. 4A and 4B, anchor 1 can be a single anchor in any of the shown locations, or there can be multiple anchors 1 affixed in various locations and connected to a support member 2 to support the herniated segment. Connection member 3 can be one continuous length that is threaded through all the sited anchors and the support member, or it can be several individual strands of material each terminated under tension between an anchor and one or more support members.

Id., 12:59-67. Van Kampen also makes clear that its device may be used on the ligaments and tendons of other joints of the body. Ex. 1005, 2:23-40 ("reconstruction of a ligament or tendon"; "the anatomical structures connected by the ligament or tendon"), 5:9-13 ("selection of the appropriate biological tissue to reconstruct a particular tendon or ligament is well within the level of ordinary skill in the field of orthopedic surgery"). For the reasons provided above regarding claim 1, it would have been obvious to combine the teachings of Van Kampen and

Marshall with Lambrecht, and to utilize the methods of Van Kampen and Marshall in the spine, as taught by Lambrecht. Ex. 1002, ¶ 128.

F. Ground 3: Claims 5, 7-11 are Obvious Over Van Kampen in View of Marshall and Boyce

Claims 5, 7-11 are obvious under pre-AIA 35 U.S.C. §103 by Van Kampen in view of Marshall in further view of Boyce. *Id.*, ¶ 129.

Overview of the Combination

Van Kampen and Marshall teach all elements of claim 1, as described in Ground 1. To the extent that Van Kampen does not expressly disclose augmenting a ligament in the foot (claim 5), shoulder (claim 7), spine (claim 8), hand (claim 9), hip (claim 10), or elbow (claim 11), it does not limit the use of the device to any particular region of the body. Ex. 1005, 1:15-21, 2:23-40, 5:9-13. A POSITA would have understood that Van Kampen suggests that the disclosed invention applies to tendons and ligaments that an orthopedic surgeon might encounter when performing surgery on a variety of joints. Ex. 1002, ¶ 130.

Boyce teaches using an orthopedic implant for the treatment of spinal disorders, and for the repair and replacement of hand, elbow, knee, foot, and ankle ligaments. Ex. 1007, ¶ [0063]. Boyce shows that these types of devices and procedures could be used in various joints. Ex. 1002, ¶ 131. Indeed, like Van Kampen, Boyce teaches the use of implants for the knee, but unlike Van Kampen,

Boyce further teaches the use of the similar implants in the spine, hand, elbow, and foot as found in claims 5 and 7-11. Ex. 1007, ¶ [0063].

Rationale (Motivation) Supporting Obviousness

A POSITA would have found it obvious to use the device and methods disclosed in Van Kampen to stabilize or repair ligaments throughout the body, including ligaments in the foot, shoulder, spine, hand, hip, and elbow not only in view of Van Kampen itself, but in further view of Boyce's disclosure of using such procedures to treat the joints of the spine, elbow, knee, ankle, hand, and foot, "or any other anatomical location." Ex. 1002, ¶ 129; Ex. 1007, ¶¶ [0002], [0063]. A POSITA would have found it obvious to combine the teachings of Van Kampen's device, capable of use on a variety of ligaments in the body, with Boyce's description of performing similar procedures throughout the body. Ex. 1002, ¶ 132. A POSITA would expect predictable outcomes from this combination inasmuch as these techniques were known to be useful for various joints in which ligaments were damaged. *Id*.

A POSITA would have looked to both Van Kampen and Boyce when researching methods in the field of ligament repair and reconstruction, and would have been motivated to combine the two disclosures. *Id*., ¶ 133. First, both disclose similar implantation devices used for treating damaged ligaments and tendons. Second, Van Kampen and Boyce disclose the use of implantation devices

in the knee. It would have been natural for a POSITA to look to Boyce to determine other suitable applications for the device disclosed in Van Kampen because of this overlap in disclosure. *Id*.

A POSITA would have understood that ligament repair and reconstruction regions in the knee, foot, shoulder, spine, hand, hip, and elbow were equivalents at the time of the alleged invention of the '449 Patent. *Id*., ¶ 134. It is known in the field that implantation devices with similar applications can be used interchangeably on various parts of the body. *Id*. A POSITA would have further understood that the implantation devices they used in their practice for the knee, foot, shoulder, spine, hand, hip, and elbow could have been used interchangeably, and would have done nothing more than yield predictable results in different parts of the body. *Id*.

The Examiner who handled the application that ultimately issued as the related '129 patent also recognized that ligament repair regions in the knee, elbow, and spine were equivalents:

> Boyce et al. discloses a graft members [sic] for stabilizing and repairing ligaments of the body (figures 1 A and 1 B, ¶65[4]). In specific Boyce shows that the knee and elbow joints and their ligaments are equivalent structures known in the art. Therefore, because these two ligament repair regions were art-recognized equivalents at the time the invention was made (see ¶65 of Boyce et al.), one of ordinary skill in the art would

[4] This is an apparent typo as Boyce only contains 64 paragraphs. It is believed that Examiner meant to cite Paragraph 63 of Boyce, which directly supports the statements made in the Office Action.

> have found it obvious to have implemented the general ligament stabilization steps used in the spinal application of Serhan et al. in knee and elbow procedures as taught by Boyce et al.

Ex. 1011, 104. The Applicant did not refute this conclusion when responding to the rejection. *Id*., 84.

***Graham* Factors**

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

The **scope and content of the prior art** are discussed throughout the Ground.

The **differences between the prior art and the claims** are discussed in the "Overview of the Combination" and below.

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

Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in using the methods and device of Van Kampen throughout the body, including in the foot, shoulder, spine, hand, hip, and elbow, as disclosed in Boyce. Ex. 1002, ¶ 137. The disclosed implants and procedures were already well known in the field. *Id*. And the techniques and materials used to repair one joint were known to be applicable for use in other joints. *Id*. At the time of filing the '449 Patent, a POSITA would have understood the combination of the Van Kampen and Boyce would have

yielded predictable results. *Id*. Indeed, surgeons were already well versed in these general implants and techniques. *Id*.

A POSITA would expect that they can use similar ligament repair methods and devices in similar ligament repair regions in the body and yield predictable results. *Id*., ¶ 138. POSITA's had been using similar techniques to treat and repair weakened ligaments in the body for years before the '449 Patent was filed. *Id*. The art has been predictable since that timeframe such that orthopedic surgeons have continuously used the same methods and devices to treat spinal disorders and repair or reconstruct ligaments in the elbow and the knee while continuously producing predictable results. *Id*.

It would have been obvious to a POSITA to combine these similar methods and devices to produce suitable results in all similar ligament repair and reconstruction regions. *Id*., ¶ 139. A POSITA would have been able to also combine the device and methods of Van Kampen and Boyce to implement this Ground. *Id*.

Analogous Art

Van Kampen, Marshall, and Boyce are analogous art, because they are in the same field as the '449 Patent (Ex. 1001, Title) (Ex. 1005, Abstract, Title) (Ex. 1006, Title) (Ex. 1007, Abstract, Title, ¶ [0002]), and all relate to treating damaged ligaments and tendons. Ex. 1002, ¶ 140.

Claims 5 and 7-11 are Obvious Over Van Kampen in View of Marshall in Further View of Boyce

As discussed above in Ground 1, Van Kampen and Marshall describe and/or suggest all elements of claim 1, but Van Kampen and Marshall do not expressly state that the first and second bones and the joint are "part of a foot" as recited in claim 5; "part of a shoulder" as recited in claim 7, "part of a spine" as recited in claim 8, "part of a hand" as recited in claim 9, "part of a hip" as recited in claim 10, or "part of an elbow" as recited in claim 11. While express disclosure of stabilizing these areas of the body is absent, Van Kampen acknowledges that its system is not limited to the knee, as discussed above. Indeed, the discussion of knee repairs is only exemplary.

At the time of filing the '449 Patent, a POSITA would have understood that similar treatments could be used throughout the body, including in the foot, shoulder, spine, hand, hip, and elbow. Ex. 1002, ¶¶ 141-52. For example, Boyce teaches using an orthopedic implant for the treatment of spinal disorders, as well as for the repair and replacement of ligaments in the elbow, knee, foot, hand, and ankle, "or any other anatomical location." Ex. 1007, ¶¶ [0002], [0063]. A POSITA would also have been able to make any necessary modifications to the device or methods disclosed in Van Kampen and Marshall to implement a similar repair to a ligament in the foot, shoulder, spine, hand, hip, and elbow. Ex. 1002, ¶ 141-52.

As discussed above, it is known in the field that implantation devices with similar applications can be used interchangeably on various parts of the body. Ex. 1002, ¶ 134. A POSITA would have understood that the implantation devices they used in their practice for the knee, foot, shoulder, spine, hand, hip, and elbow could have been used interchangeably, and would have done nothing more than yield predictable results in different parts of the body. *Id*. A POSITA would therefore have understood that ligament repair and reconstruction regions in the knee, foot, shoulder, spine, hand, hip, and elbow were generally equivalent at the time of the alleged invention of the '449 Patent. *Id.*, ¶¶ 141-52. For example, during prosecution, the Examiner recognized that ligament repair regions in the knee, elbow, and spine were equivalents—a conclusion that the Applicant did not refute. Ex. 1011, 104, 84.

A POSITA would have used these types of implantation devices interchangeably on various parts of the body, including in the foot, shoulder, spine, hand, hip, and elbow, as recited in claims 5, 7, 8, 9, 10, and 11, respectively. Ex. 1002, ¶¶ 141-52. In fact, as only one example, acromioclavicular joint repair and reconstruction in the shoulder were common surgeries of this type and were performed using this method prior to the filing date of the '449 Patent. *Id*., ¶ 144. It therefore would have been obvious to a POSITA to use the device and methods disclosed in Van Kampen to augment ligaments wherein the first and second bones

and the joint are "part of a foot" as recited in claim 5; "part of a shoulder" as recited in claim 7, "part of a spine" as recited in claim 8, "part of a hand" as recited in claim 9, "part of a hip" as recited in claim 10, and "part of an elbow" as recited in claim 11. *Id*., ¶¶ 141-52.

G. Ground 4 – Claims 5, 7, and 9-11 are Obvious Over Van Kampen in View of Marshall in Further View of Lambrecht in Further View of Boyce

Claims 5, 7, and 9-11 are obvious under pre-AIA 35 U.S.C. §103 by Van Kampen in view of Marshall in further view of Lambrecht and Boyce.

A POSITA would have been motivated to combine Van Kampen, Marshall, Lambrecht, and Boyce, and would have had a reasonable expectation of success in doing so, for the reasons described above in Grounds 2 and 3. Ex. 1002, ¶ 154.

As discussed with respect to Ground 2 above, to the extent that Van Kampen and Marshall do not teach or render all limitations of independent claim 1 obvious, the combination of these two references and Lambrecht describe and/or suggest all elements of claim 1 for the reasons described above. *Id*., ¶ 155.

A person having ordinary skill in the art would be motivated by the teachings of Boyce, as described above for Ground 3, to utilize these combined reference teachings in the various anatomical applications discussed in claims 5, 7, and 9-11. *Id*., ¶ 156. Namely, applying the combined procedure of Van Kampen, Marshall, and Lambrecht as discussed above for Ground 2 to the foot, shoulder,

hand, hip, and elbow would have been within the knowledge of an ordinarily skilled artisan, who would have been motivated to apply these reinforcement procedures to other anatomical applications as evidenced by the teachings of Boyce. *Id*.

1. **Claim 5**

Van Kampen, Marshall, and Lambrecht in view of Boyce disclose all the limitations of claim 5 for the reasons discussed with respect to Grounds 2 and 3 above.

2. **Claim 7**

Van Kampen, Marshall, and Lambrecht in view of Boyce disclose all the limitations of claim 7 for the reasons discussed with respect to Grounds 2 and 3 above.

3. **Claim 9**

Van Kampen, Marshall, and Lambrecht in view of Boyce disclose all the limitations of claim 9 for the reasons discussed with respect to Grounds 2 and 3 above.

4. **Claim 10**

Van Kampen, Marshall, and Lambrecht in view of Boyce disclose all the limitations of claim 10 for the reasons discussed with respect to Grounds 2 and 3 above.

5. Claim 11

Van Kampen, Marshall, and Lambrecht in view of Boyce disclose all the limitations of claim 11 for the reasons discussed with respect to Grounds 2 and 3 above.

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

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) weighs against exercising discretion in this case. Specifically, factors 1-4 and 6 weigh against denial because in the corresponding litigation, the Answer was filed on September 22, 2021 with no discovery occurring as of this filing and no current timeline for a trial. Trial is unlikely to occur before a Final Written Decision, and Petitioner plans to seek a stay of the litigation in view of this IPR. Petitioner also challenges claims not identified as being asserted in the corresponding litigation and the merits of the petition are strong.

VIII. CONCLUSION

For the reasons stated above, Petitioner submits that claims 1-11 of the '449 Patent are unpatentable. Accordingly, Petitioner requests institution of *Inter Partes* Review.

DATED: April 11, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing petition for *inter partes* review, together with all exhibits and other documents filed therewith, was served by Federal Express on April 11, 2022, on the Patent Owner's counsel of record at the U.S. Patent and Trademark Office having the following address:

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CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing petition for *inter partes* review contains 13,829 words according to the word processing program used to prepare it.

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