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. 2022-00786
Patent No. 9,579,129

_____

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,579,129

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CLAIM LISTING

[24.P] 24. A method for stabilizing a weakened portion of a ligament of a patient's body, the method comprising:

[24.1] a) performing a surgical procedure on the patient's body through a surgical incision proximate the weakened portion of the ligament, the ligament including an upper end at a first side of the weakened portion and a lower end at an opposite second side of the weakened portion;

[24.2] b) securing a first fastener to the upper end and a first bone portion proximate the upper end;

[24.3] c) securing a second fastener to the lower end and a second bone portion proximate the lower end; and

[24.4] d) securing a suture directly to the first and second fasteners and tightening the suture.

25. The method of claim 24, wherein the first bone portion is associated with a first vertebra and the second bone portion is associated with a second vertebra, the ligament of the weakened portion of the ligament being comprised of a spinal ligament.

[26.P] 26. The method of claim 24, further comprising:

[26.1] e) securing a first ligament graft adjacent the upper end in step (b); and

[26.2] f) securing the first ligament graft adjacent the lower end in step (c).

27. The method of claim 26, wherein the first ligament graft spans the weakened portion, the weakened portion comprised of a damaged region.

32. The method of claim 24, wherein the surgical procedure of step (a) is performed on the patient's knee and the first and second bone portions are comprised of bone portions proximate the patient's knee.

33. The method of claim 24, wherein the surgical procedure of step (a) is performed on the patient's elbow and the first and second bone portions are comprised of bone portions proximate the patient's 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 24-27, 32, and 33 of U.S. Patent No 9,579,129 ("the '129 Patent") (Ex. 1001) pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq*. The '129 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 '129 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)

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 ’129 Patent relates to devices and methods for repairing, reconstructing, augmenting, and stabilizing joints of the body. The challenged claims of the ’129 Patent all recite a method for stabilizing a weakened portion of a ligament with three basic steps: (1) securing a first fastener to the upper end of the ligament and a first bone portion; (2) securing a second fastener to the lower end of the ligament and a second bone portion; and (3) securing (and tightening) a suture between the first and second fasteners. Each of these elements, individually and collectively, was well known in the art before the filing of the ’129 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 ’129 Patent teaches (or renders obvious) all of these elements as they are recited in the challenged claims.

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

Petitioner certifies that the ’129 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 ’129 Patent.

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

Petitioner requests (i) review of claims 24-27, 32, and 33 of the ’129 Patent on the grounds set forth below and (ii) that those claims be found unpatentable.

Ground	Claim(s)	Basis for Unpatentability
1	**24, 26, 27, 32**	**Obvious Over Van Kampen**
2	**25, 33**	**Obvious Over Van Kampen in View of Boyce**
3	**24-27, 32**	**Obvious Over Van Kampen in View of Lambrecht**
4	**33**	**Obvious Over Van Kampen in View of Lambrecht in Further View of Boyce**

IV. SUMMARY OF THE '129 PATENT

A. Background of the Technology

The '129 Patent discloses "devices and methods for repairing and stabilizing tissue and implants." Ex. 1001 (the '129 Patent), 1:15-16. In particular, the methods and procedures of the '129 Patent cover repairing, reconstructing, augmenting, and stabilizing joints of the body. *Id*., 1:17-19. Specific methods and procedures are disclosed for repairing and stabilizing the knee and joints of the spine (including intervertebral discs and adjacent bones). *Id*., 1:19-21.

The '129 Patent asserts 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 '129 Patent's stated solution involves repairing, reconstructing, augmenting, and securing tissue or an implant during surgery and "on the way out" after surgery has been performed at an intended operation site. *Id*., 2:56-59. In

particular, the ’129 Patent states that “[h]ard 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. However, repairing, reconstructing, augmenting, and stabilizing joints and tissue was well-known before the filing date if the ’129 Patent, as shown in the references described below.

B. The Claimed Subject Matter

The ’129 Patent contains thirty-three claims, where claims 1, 10, 16, and 24 are independent. This Petition challenges independent claim 24, and claims 25-27, 32, and 33 which depend from claim 24.

Claim 24 is directed to a surgical method for stabilizing a weakened portion of a ligament, such as a missing or torn ligament region 160, a stretched region 154, or a loosened region 152. Figure 9 shows each of these weakened ligament portions. At each region, a first

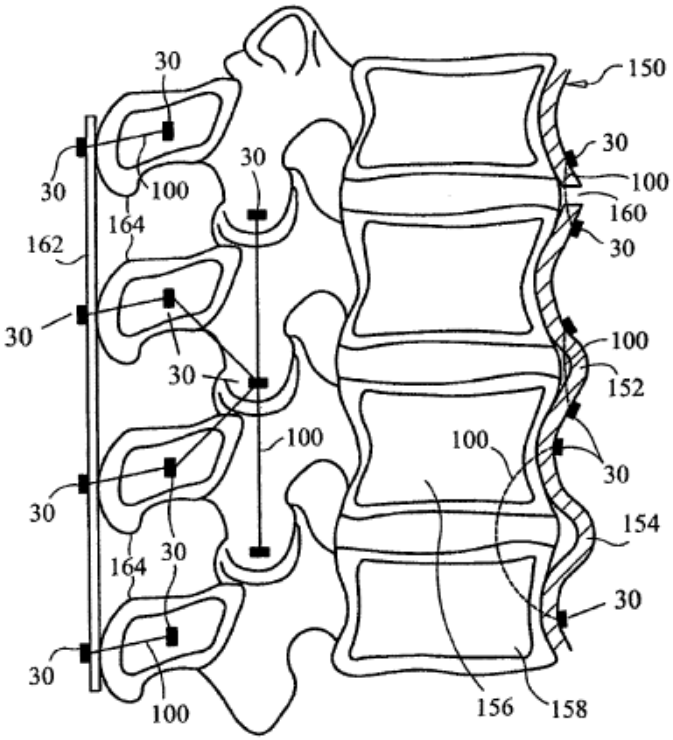


FIG. 9

fastener 30 is positioned on an upper end of the weakened portion and a second fastener 30 on a lower end of the weakened portion. The fasteners 30 are secured to both the upper and lower portions of the weakened ligament 150 and the bone. Suture 100 then connects fasteners 30 to secure the weakened portion of the ligament 150.

Claim 24 recites:

> 24. A method for stabilizing a weakened portion of a ligament of a patient's body, the method comprising:
>
> a) performing a surgical procedure on the patient's body through a surgical incision proximate the weakened portion of the ligament, the ligament including an upper end at a first side of the weakened portion and a lower end at an opposite second side of the weakened portion;
>
> b) securing a first fastener to the upper end and a first bone portion proximate the upper end;
>
> c) securing a second fastener to the lower end and a second bone portion proximate the lower end; and
>
> d) securing a suture directly to the first and second fasteners and tightening the suture.

Dependent claims 25-27, 32, and 33 are directed to various aspects of the surgical method for stabilizing a weakened portion of a ligament recited in independent claim 24. The dependent claims further limit the surgical method of claim 24 to certain regions of the body or disclose incorporating a ligament graft.

C. Prosecution History

U.S. Patent Application No. 14/204,522, which issued as the '129 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 June 21, 2016, the Examiner rejected claims 1, 2, 6-9, 17-23, and 25-34 under 35 U.S.C. §§ 102 and 103 in view of U.S. 6,425,919 to Lambrecht, U.S. 2002/0143329 to Serhan et al., and U.S. 2004/0024457 to Boyce et al. The Examiner allowed claims 11-16 and stated that claims 3-5, 9, 10, and 24 claim allowable subject matter but rejected the claims as being dependent upon a rejected base claim.

To overcome the prior art rejections of independent claims 17 and 25 (issued claims 16 and 24), the Applicant amended the claims to recite "securing a first end of a suture **directly** to the upper end [of the ligament]" and "securing a second end of the suture **directly** to the lower end [of the ligament]." Ex. 1004, 77, 79, 83-84. The Applicant and Examiner agreed during an interview that the cited art references do not disclose securing a suture directly to both a first fastener and a second fastener. *Id.* The Examiner subsequently issued a Notice of Allowance allowing all claims without commenting on the reasons for allowability.

V. PRIOR ART

A. Effective Prior Art Dates

U.S. Patent No. 4,834,752 ("Van Kampen", Ex. 1005) issued May 30, 1989. Van Kampen constitutes prior art to the '129 Patent under pre-AIA 35 U.S.C. § 102(b).

U.S. Patent Publication No. 2004/0024457 ("Boyce," Ex. 1006) was published on February 5, 2004. Boyce constitutes prior art to the '129 Patent under pre-AIA 35 U.S.C. § 102(a) and (e).

U.S. Patent No. 6,425,919 ("Lambrecht," Ex. 1007) issued July 30, 2002. Lambrecht constitutes prior art to the '129 Patent under pre-AIA 35 U.S.C. § 102(b).

B. Overview of Van Kampen

Van Kampen is a patent that 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 '129 Patent, along with over 1000 other prior art references during prosecution, but not applied by the Examiner.

The tissue augmentation device disclosed by Van Kampen 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 anatomical structures connected by the ligament or tendon being augmented. *Id*.

Van Kampen explains that it was well known in the field to provide devices/implants to share the load for a repaired or reconstructed ligament. The reason for load sharing was 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 (without attaching to the ligament) on one side of the joint and to the ligament at the other end, 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 (e.g., there is no augmentation from the point at which the device attaches to the ligament to where the ligament attaches to the bone distal to the device), "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 (without attaching to the ligament) 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, so as to be in parallel with

the ligament and to bear the load; however, to avoid the result of the augmentation device continuing to carry most of the load, part of the augmentation device is made to be biodegradable. *Id*., 2:23-48. In this way, there is augmentation across the entire ligament, but that support diminishes over time as the ligament heals.

In particular, Van Kampen describes that the augmentation device may be made of two strap-like elements secured together through a biodegradable connection element, or a biodegradable fastener is used to attach a terminal portion of the strap-like element to one of the anatomical structures connected by the device, such that the tension across the device is released as the biodegradable connection element degrades. *Id*., 2:23-64. As Van Kampen explains, this 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 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*., 3:20-52.

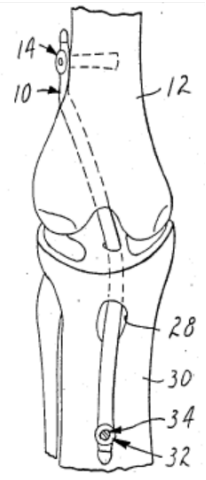


FIG. 1

Van Kampen explains that the fastening mechanisms at both ends of the device affix the device to bone through holes in the biological tissue. Figure 3 shows an embodiment of the device where different fasteners are used at either end. Figure 2 and Figure 4 show two different embodiments of disclosed fasteners. A POSITA would have understood that the methods and device disclosed in Van Kampen could be adopted for augmentation of other ligaments of the knee or ligaments in other areas of the body. Ex 1002, ¶ 48.

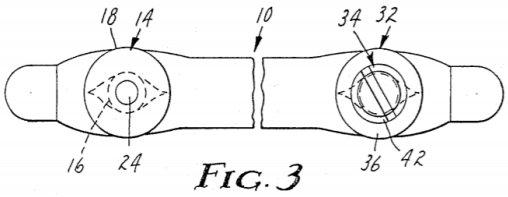
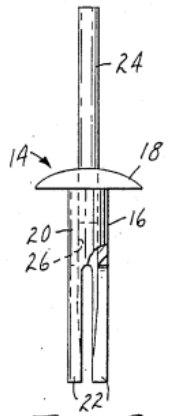
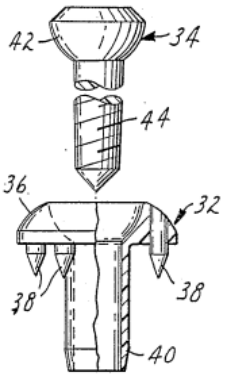


FIG. 3

 FIG. 2	 FIG. 4
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, 3:35-41.	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 three different sources: tissue harvested from elsewhere in the patient, from a donor, or it may be "the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques." Ex. 1005, 4:64-5:8. Van Kampen explains, and a POSITA would have understood, 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, ¶ 50. For both ligament repair and reconstruction, the biological tissue is used in parallel with the augmentation device. Ex. 1005, 2:49-

53, 4:51-53. 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." *Id*., 5:13-21.

Van Kampen teaches that suitable materials for fabricating at least the strap-like member of the augmentation device 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 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.

C. Overview of Boyce

Boyce is a published patent application that discloses an implant for a variety of orthopedic applications. The implant includes a quantity of flexible, elongated elements. Ex. 1006, Abstract, Figs. 1a-1b. During prosecution of 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 joints and ligaments.

Ex. 1004, 104. However, the Examiner did not address other disclosures within Boyce.

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

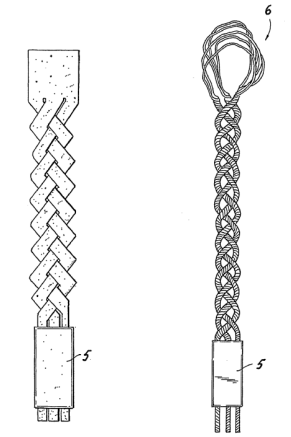


Fig. 1a Fig. 1b

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. 1006, ¶¶ [0002], [0006]. 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 the knee and 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. 1004, 104. The Examiner's conclusion was not refuted by the Applicant.

D. Overview of Lambrecht

Lambrecht is a patent that discloses an implant used to treat spinal injuries, including tears in the annulus fibrosus. Ex. 1007, 1:13-17. The annulus fibrosus is a tough circular exterior of the intervertebral disc including a ring of ligament fibers that encase the inner core of the disc and securely connects to the spinal vertebrae above and below the disc. Ex. 1002, ¶ 56.

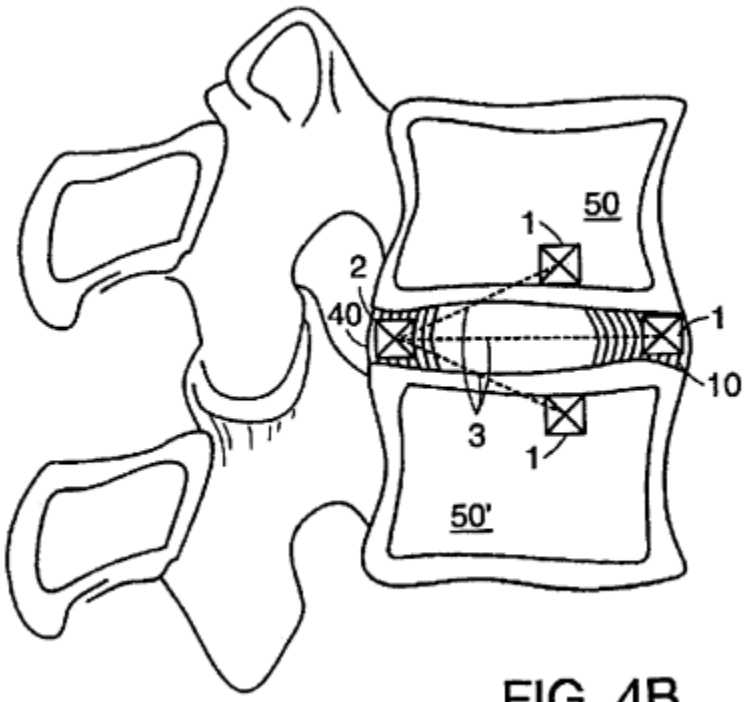


FIG. 4B

In Figure 4B, anchors 1 are affixed in various locations and connected to a support member 2 to support the herniated segment. Ex. 1007, 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. Therefore, a POSITA would have

understood that Figure 4B teaches placing anchors in multiple locations in the vertebral body. Ex. 1002, ¶ 57. Connection member 3 is connected between the anchors and support member 2. Connection member 3 can be one continuous length or several individual strands. Ex. 1007, 12:63-67. A POSITA would have further understood that the anchor locations depicted in Figure 4B are capable of withstanding the tensile forces of connection member 3. Ex. 1002, ¶ 57.

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. 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. The material chosen is preferably adapted to be relatively stiff while in tension, and relatively flexible against all other loads. This allows for maximal mobility of the herniated segment relative to the anchor without the risk of the supported segment moving outside of the pre-herniated borders of the disc. The connection member may be an integral component of either the anchor or support member or a separate component. For example, the connection member and support member could be a length of non-resorbing suture that is coupled to an anchor, and tensioned against the anchor, and sewn to the herniated segment.

Ex. 1007, 11:60-12:12 (emphasis added).

> The anchor and support member can include ***suture***, bone anchors, soft tissue anchors, tissue adhesives, and materials that support tissue ingrowth although other forms and materials are possible. They may be permanent devices or resorbable. Their attachment to a portion of

> FSU and herniated segment must be strong enough to resist the tensional forces that result from repair of the hernia and the loads generated during daily activities.

Id., 11:52-59 (emphasis added).

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

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. "Weakened Portion of a Ligament"

The challenged claims of the '129 Patent recite a method for stabilizing a "weakened portion" of a ligament using fasteners and a suture. Ex. 1001, 34:1-18. The specification explains that these "weakened" ligament portions include regions that are loosened, stretched, missing or torn:

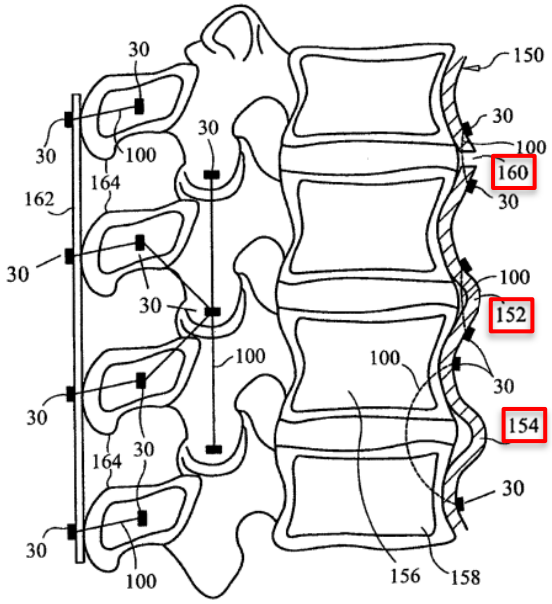


FIG. 9

FIG. 9 shows an anterior longitudinal ligament 150 which has become ***weakened***.

* * *

A fastener 30 is positioned against the ligament 150 adjacent the upper end of a ***loosened region 152*** of the ligament 150. Another fastener 30 is positioned against the ligament 150 adjacent the lower end of the ***loosened region 152***. A suture 100 is positioned through the ligament 150 and through the fasteners 30. The suture 100 is tensioned thereby tightening the ***loosened region 152*** of the ligament 150.

In another embodiment, a fastener 30 is positioned against the ligament 150 above a ***stretched region 154***. Another fastener 30 is placed against the ligament 150 below the ***stretched region 154***. A suture 100 is placed through the ligament 150, adjacent vertebrae 156 and 158, and intervertebral disc 80 in a curved or looped configuration. The suture 100 is tensioned to tighten the ***stretched region 154***.

In a further embodiment represented in FIG. 9, one fastener 30 is positioned against the ligament 150 above a ***missing or torn ligament region 160***. Another fastener 30 is positioned against the ligament 150 below the ***missing region 160***. The suture 100 is positioned through the superior and inferior ends of the ligament 150 at the ***missing or torn***

> ***region 160***. The suture 100 is tensioned between the fasteners 30 causing the ends of the ligament 150 to be drawn together.

Id., 22:27-57 (emphasis added).

Based on the disclosures in the specification, a POSITA would understand the term "weakened portion of a ligament" to mean "a portion of a ligament that is loosened, stretched, missing or torn (either partially or completely)." Ex. 1002, ¶ 32.

B. "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. 1010, 1514. This definition reflects how those of skill in the art understood the term "suture" at the time of filing the '129 Patent. Ex. 1002, ¶¶ 33-34.

This definition is also consistent with the '129 Patent's specification (*see* Ex. 1001, 3:21-31, 4:64-5:11, 13:5-23, 25:1-38, 46-53), and how P Tech described the term in its Complaint in corresponding litigation. In its Complaint, P Tech accused Arthrex's *Internal*Brace™ product of infringing claim 24 of the '129 Patent. Ex. 1008, ¶¶ 85-88. The *Internal*Brace™ includes polyethylene-based FiberTape® secured between two anchors. Ex. 1009, 3.

VII. 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 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 '129 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, securing a suture "directly" to the first and second fasteners. Ex. 1004, 79, 83-84 (distinguishing prior art based on direct attachment of suture to fasteners). Van Kampen shows direct attachment of a suture to the fasteners of the device, as well as all other elements of the challenged claims. Ex. 1005, 3:35-67, Fig. 1.

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).

[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).

D. Grounds of Unpatentability

i. Ground 1: Claims 24, 26, 27, 32 are Obvious Over Van Kampen

1. Claim 24

Claim 24 is obvious under pre-AIA 35 U.S.C. §103 in view of Van Kampen. Specifically, Petitioner believes that Van Kampen discloses and/or suggests all of the limitations of the challenged claims. For instance, to the extent that Van Kampen does not clearly express that the damaged ligament has first and second ends or that the strap-like element constitutes a suture that is tightened between two fasteners, these limitations would have been obvious to a POSITA from the disclosure of Van Kampen. Ex. 1002, ¶ 61.

[24.0] "A method for stabilizing a weakened portion of a ligament of a patient's body, the method comprising:"[2]

To the extent the preamble is deemed limiting, Van Kampen discloses a tissue augmentation device (and method of using the same) used to repair and stabilize a damaged portion of a ligament. Ex. 1005, Abstract ("A tissue augmentation device is disclosed for use in parallel with biological tissue in the repair or reconstruction of ligaments and tendons. … [t]he device is adapted for fixation at each end thereof

[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.

to the anatomical structures connected by the ligament or tendon."), 3:48-61. A POSITA would have used the terms "weakened" and "damaged" similarly as both terms are used to described ligaments that require repair, reconstruction, and/or augmentation. Ex. 1002, ¶ 61. These procedures stabilize the ligament. For example, in an ACL injury, the ligament can be mildly stretched, stretched and partially torn, or completely torn in half. *Id*. As a result, Van Kampen describes and/or suggests the claim limitation.

[24.1] "a) performing a surgical procedure on the patient's body through a surgical incision proximate the weakened portion of the ligament, the ligament including an upper end at a first side of the weakened portion and a lower end at an opposite second side of the weakened portion;"

Van Kampen describes and/or suggests performing standard surgical procedures including placing an incision proximate to a weakened portion of the body that requires repair or reconstruction. *Id*., ¶¶ 62-67; Ex. 1005, 7:51-54. ("In utilizing the device of the invention, standard surgical practices such as incision location, selection of biological tissue and length, method of tissue graft harvest, graft routing and closure are utilized.").

A POSITA would have understood that the placing of an incision proximate to a weakened portion of the body was a standard procedure in the field of orthopedic surgery. Ex. 1002, ¶ 63. Generally, incisions are placed close to the weakened portion of the ligament or in a place that will facilitate easy access around obstructing bone and body tissue. *Id*. A POSITA would have understood both the

aforementioned incision locations to be "proximate" to the weakened portion of the ligament. *Id*.

Van Kampen describes augmentation of damaged ligaments and, in particular, a torn or damaged ACL that is "reapproximated by standard surgical techniques." Ex. 1005, 4:64-5:8. Van Kampen explains that the augmentation device is attached in parallel with the ligament in order to support applied loads of the repaired or reconstructed ligament. *Id*., 4:51-60. A POSITA would have understood that to implant the augmentation device described in Van Kampen, a surgeon would use a surgical incision proximate the weakened ACL. Ex. 1002, ¶ 64.

A POSITA would also understand that the weakened ligament in Van Kampen is the ACL, which extends from an upper end of the joint to an opposite, lower end of the joint. *Id*., ¶ 65. It was understood that ACL repair and reconstructions are generally conducted to ensure a stabilized ligament between the femur and tibia capable of supporting loads. *Id*.; *see also* Ex. 1011. The figure below depicts a standard ACL repair from the Marshall article, referenced in the Van Kampen patent.

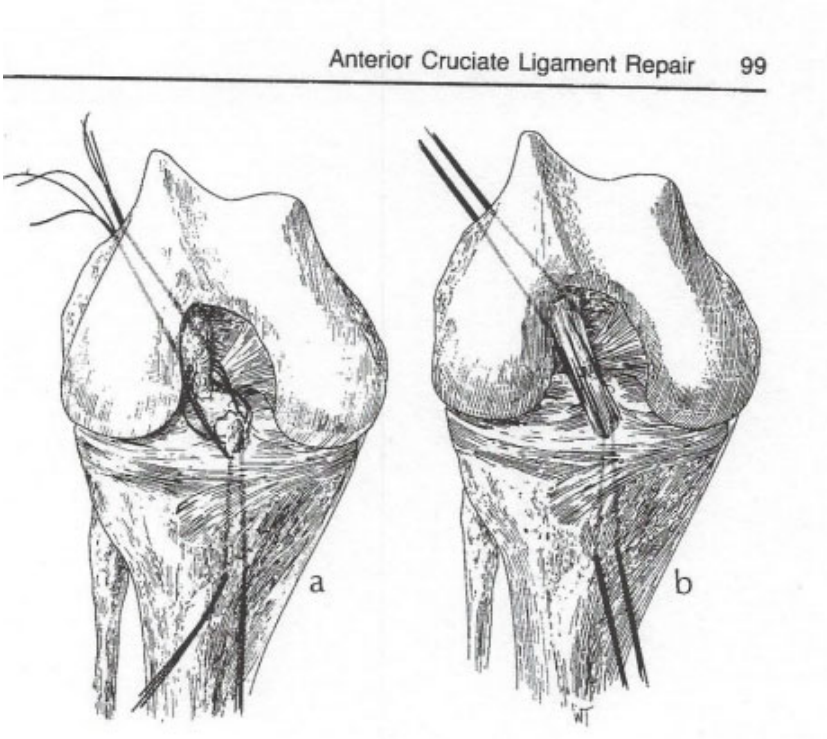


FIG. 1. (a) A midportion tear. Looping sutures are placed in the proximal and distal stumps and exit through bone. (b) When the sutures are drawn tightly, the ligament is reconstituted. Ex. 1011, 99.

A POSITA would also have understood that ligament injuries typically involve a stretch or tear in the ligament between the points at which the ligament is attached to the adjacent bones of the joint. Ex. 1002, ¶ 66. Accordingly, a POSITA would have appreciated, and generally anatomy would have confirmed, that the ligament would have upper and lower ends (e.g., the portions attached to the bone) on the first and second sides of the weakened portion (e.g., the portion stretched and/or torn). *Id*.

A POSITA would have understood that a similar procedure could be used for a tear in ligaments other than the ACL, including ligaments that span other joints in

the body. *Id*., ¶ 67. A POSITA would have appreciated methods similar to those taught by Van Kampen would have been used in regions of the body other than the knee. *Id*. A POSITA would therefore understand standard ligament surgeries, generally, include ligaments with two opposing ends—an upper and lower end. *Id*.

[24.2] "b) securing a first fastener to the upper end and a first bone portion proximate the upper end;"

Van Kampen discloses securing a first fastener (fastener 14) to an upper end of the ligament and a first bone portion proximate to the upper end of the "biological tissue." Ex. 1005, 3:35-47, 4:64-5:8. The biological tissue may be autogenic tissue, allogenic tissue, or the original repaired ligament, particularly in the case of a repair procedure. *Id*., 4:64-5:8. Annotated Figure 1 shows a first fastener of the disclosed augmentation device and a first bone (femur 12) portion proximate to the upper end of the ligament (although the ligament itself is not shown). *Id*., 3:19-23; Ex. 1002, ¶ 68.

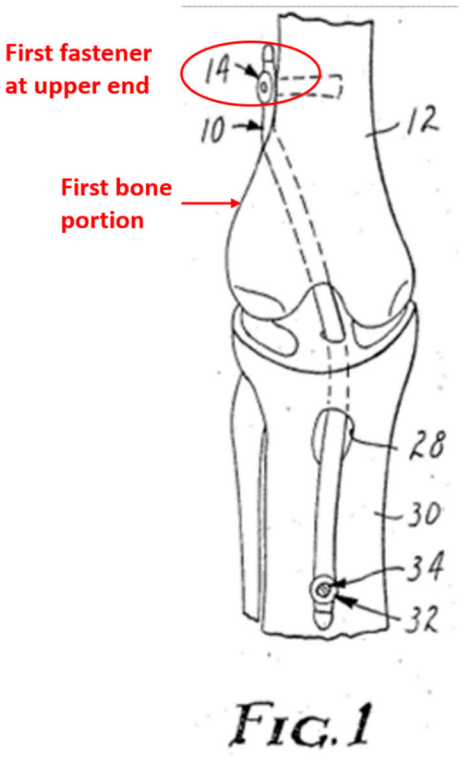


FIG. 1

Van Kampen further explains that the first fastener 14, affixes to both the first bone portion (femur 12) and the upper end of the "biological tissue" when repairing or reconstructing a damaged ligament:

> 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 (emphasis added). In the case of a repair, "the biological tissue used in conjunction with the device of the invention is the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques." *Id.*, 5:4-8. Figure 2 below shows legs 22 and cylindrical portion 20 that are the disclosed component of fastener 14 that is implanted into the bone portion (femur 12).

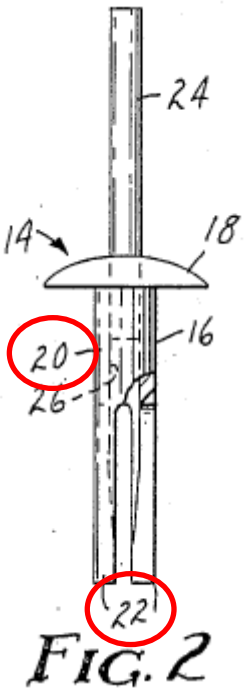


FIG. 2

[24.3] "c) securing a second fastener to the lower end and a second bone portion proximate the lower end; and"

Van Kampen also describes securing a second fastener (bushing 32 and screw 34) to a lower end of the ligament and a second bone portion (tibia 30) proximate to the lower end of the ligament. *See* Ex. 1005, 3:48-52, 3:62-67. Indeed, Van Kampen explains that its procedure is intended to provide support along the entire ligament with a support device that will biodegrade over time to transfer the load to the ligament as it heals. *Id*., 2:23-40, 7:30-41.

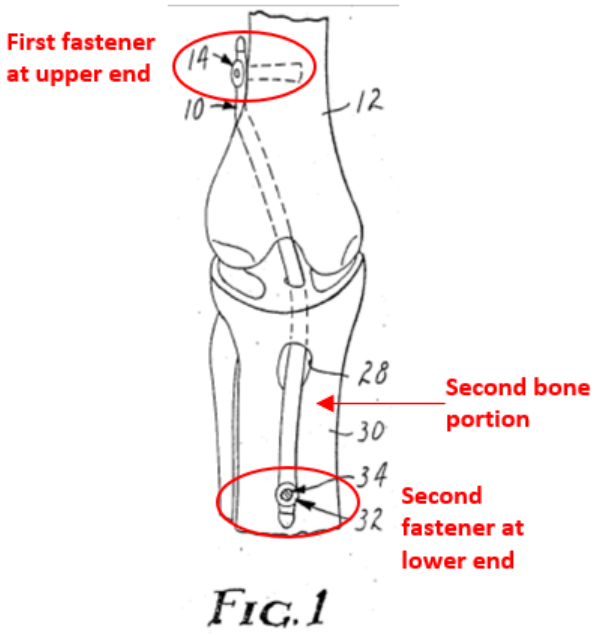


FIG. 1

When repairing or reconstructing a damaged ligament, Van Kampen discloses that a second fastener (bushing 32 and screw 34) affixes to both the tibia and the lower end of the "biological tissue":

> 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 (emphasis added). As stated above, In the case of a repair, "the biological tissue used in conjunction with the device of the invention is the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques." *Id.*, 5:4-8.

Figure 4 shows the second fastener which is comprised of a bushing 32 that is implanted by inserting cylindrical portion 40… into a hole in the tibia" and "[s]crew 34 [that] 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.

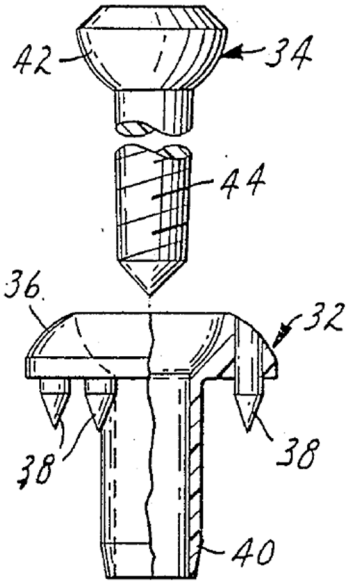
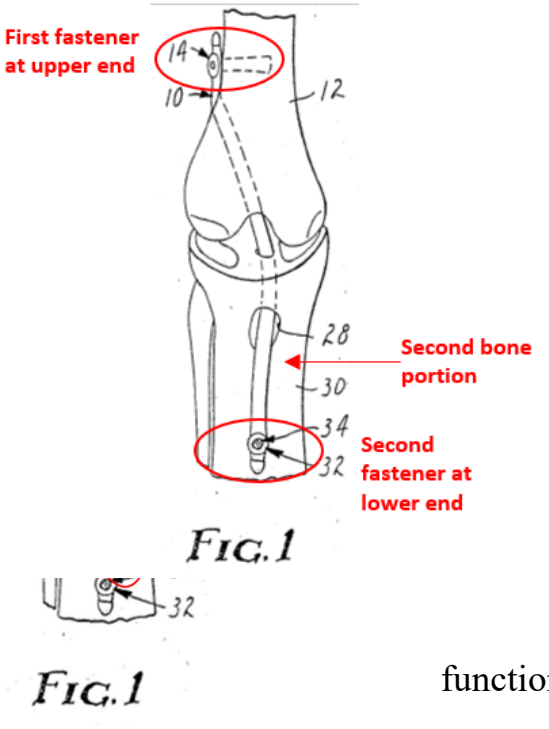


FIG. 4

The described procedure could have been performed on an injured medial collateral ligament ("MCL") which is another ligament that spans the knee joint. Ex. 1002, ¶ 73; *see generally* Ex. 1005, 1:15-24, 2:23-40, 4:66-5:8, 6:16-25, 6:52-55, 7:30-44. A POSITA would have appreciated that the MCL provides more exposed surface area for fastener insertion on the weakened ligament. Ex. 1002, ¶ 73.



[24.4] "d) securing a suture directly to the first and second fasteners and tightening the suture."

Van Kampen describes securing a suture, in the form of a strap-like element, directly to the first and second fasteners and tightening the suture. Ex. 1002, ¶ 74. First, the strap-like element is a suture because it is made of suture material and functions like a suture and, as discussed in more detail below, falls within the definition discussed above in Section VI. Second, the strap-like element connects to first and second fasteners and is tightened. *See* Ex. 1005, 2:55-58, 5:22-29, 8:4-13.

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. This was suture material that was available and widely used in the field of orthopedic surgery in the relevant timeframe and therefore a POSITA

would have understood the disclosed strap-like element is made of suture material. Ex. 1002, ¶ 75.

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, ¶ 76. It was well known in the field of orthopedic surgery that a suture is the material with which two surfaces are kept in apposition and commercially available sutures in the relevant timeframe served this purpose. *Id*. A POSITA would further understand that suture comes in different cross-sectional geometries and sutures with different cross-sectional areas were commercially available at the time of filing the '129 Patent. *Id*. Therefore, a POSITA would have understood the disclosed strap-like element to be a type of suture. *Id*. Accordingly, 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*.

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

> 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.

> The end of augmentation device 10 opposite fastener 14 is affixed to the tibia 30 by bushing 32 and screw 34, as shown in enlarged view in FIG. 3. … 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., 3:49-68.

A POSITA would have understood from Van Kampen that the strap-like element is tightened between the fasteners. Ex. 1002, ¶ 78. The above excerpt explains that the ends of the augmentation device are "securely affixed" to tibia 30 and femur 12, 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. 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 complete functionality of the damaged body part. Ex.

1002, ¶ 78. A POSITA would have understood that for the disclosed strap-like element to act properly as a "total prosthesis" it would be tightened between the fasteners. *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*. If not tightened to the damaged ligament's natural anatomic tension, 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":

> The composite graft thus created is then properly positioned for implantation by the surgeon and securely fastened to the bone by mechanical means of fixation …. 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 pulled tight between the fasteners as described in the claim limitation. Ex. 1002, ¶ 80. The tightening 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.[3] *Id*.

2. Claim 26 - the method of claim 24, further comprising: e) securing a first ligament graft adjacent the upper end in step (b); and f) securing the first ligament graft adjacent the lower end in step (c)

Van Kampen discloses securing a ligament graft adjacent the upper and lower ends of the damaged portion of the ligament. It was known at the time that a ligament repair could involve simply repairing the damaged original ligament, or could also include the use of a graft to reinforce the repaired ligament, sometimes described as an "augmented" repair. *Id*., ¶ 81. When performing an augmented repair, it was common practice to secure a tissue graft adjacent to either end of the repaired portion of the ligament. *Id.*; *see also* Ex. 1011, 98, 100 ("a strip of fascia lata is used in addition to the repair previously described, to act as an additional strut. … The proximal and distal stumps of the ACL are fixed both to bone by the looping stitches and to the fascia lata graft. This then creates a robust solid ligament.").

[3] Patent Owner asserts claim 24 against Arthrex's InternalBrace—a product that does not require "tightening" of the suture after attachment. *See, e.g*. Ex. P to Complaint (attached as Ex. 1009) at 6. Petitioner therefore relies on Patent Owner's implied construction of this limitation having no timing requirement, (i.e. there is no tightening of the suture required ***after*** installation), for this proceeding only.

Van Kampen describes that the augmentation device may be used with the original repaired ligament and with a tissue graft (*see, e.g.*, Ex. 1005, 4:51-5:8), with the graft typically being secured along with the augmentation device to the fasteners used to affix the device to bone:

> The device of the present invention is designed to be used in parallel with biological tissue for the repair or reconstruction of a ligament or tendon. The term "parallel" is not used in the strict geometric sense, but rather in the biomechanical sense of members sharing a common load. The augmentation device and the tissue are used adjacent to one another along their lengths, and there may be inter-twining between the two. Preferably, the augmentation device is sutured or otherwise secured to the tissue along its length. When a free tissue graft such as fascia lata is used, it is preferred to attach the device and the tissue together at each fixation site, e.g., with a common fastener.

Id., 4:51-63.

> If use of a biological graft is preferred surgically for reconstruction, a composite graft is prepared by suturing the device to the graft tissue. … The composite graft thus created is then properly positioned for implantation by the surgeon and securely fastened to the bone by mechanical means of fixation, (e.g., bushings, screws, staples, which need not be biodegradable if a biodegradable connector already exists elsewhere in the device). 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.

Id., 7:62-8:14.

A POSITA would have understood that inter-twining or otherwise securing the augmentation device and graft along the lengths thereof would preferably result in securing the graft to the upper and lower ends as claimed. Ex. 1002, ¶¶ 81-83. A

POSITA would further have understood that securing an augmentation device and a graft along their respective lengths means that the two elements would be connected at the ends. *Id*., ¶ 83. A POSITA would further have understood that Van Kampen teaches (or at the very least suggests) the claim limitation when it discloses a preferred embodiment of securing the augmentation device and graft tissue together at each fixation site. *Id*. At the very least, a POSITA would have found it obvious to install a tissue graft in addition to an augmentation device to a repaired ligament since Van Kampen teaches augmentation of both repaired ligaments in which the damaged ligament was reapproximated and reconstructed ligaments in which a tissue graft is used. *Id*.

3. Claim 27 - the method of claim 26, wherein the first ligament graft spans the weakened portion, the weakened portion comprised of a damaged region.

Van Kampen discloses a ligament graft secured, along with the augmentation device, adjacent to the upper and lower ends of the weakened portion of the ligament to the fasteners secured in bone, as described above for claim 26.

The ligament graft spans the weakened portion of the ligament, where the weakened portion is a damaged region of the ligament. *See* Ex. 1005, 7:30-41 ("the 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 ….”), 1:15-24 (“Current methods for ligament reconstruction often involve tissue transfer procedures, wherein a tissue is transplanted from one part of the body to the site of the damaged ligament in order to reconstruct the damaged ligament. An example of such a procedure in the knee is the reconstruction of the anterior cruciate ligament by using a portion of the patellar tendon. Other tendons such as the semitendinosus tendon, and connective tissues such as fascia lata, are sometimes used to reconstruct the damaged ligament.”). Further, a POSITA would have understood that if a surgeon is performing an augmentation on a particular ligament, the same would be performed because the original ligament is damaged in some way. Ex. 1002, ¶ 85.

Van Kampen discloses an augmentation device that spans the “entire length” of the damaged tissue, (*see* Ex. 1005, 7:30-41), and that “[w]hen a free tissue graft such as fascia lata is used, it is preferred to attach the device and the tissue together at each fixation site, e.g., with a common fastener.” *Id*., 4:51-53. Thus, a POSITA would have understood that when performing an augmented repair according to the teachings of Van Kampen, the grafts that span the entire length of a weakened ligament, including a damaged region of the ligament. Ex. 1002, ¶ 86. A POSITA would have understood that Van Kampen discloses and or suggests this claim limitation. *Id*.

4. Claim 32 - the method of claim 24, wherein the surgical procedure of step (a) is performed on the patient’s knee and

the first and second bone portions are comprised of bone portions proximate the patient's knee

As discussed in regard to claim 24 above, Van Kampen discloses installing the augmentation device to repair or reconstruct a ligament in the knee, by affixing the device to the femur 12 and tibia 30 proximate the knee. *See* Ex. 1005, 3:17-67, Fig. 1. Annotated Figure 1 below further highlights the claim limitation disclosed in Van Kampen where the augmentation device 10 is affixed to the femur 12 and tibia 30 by fastener 14 and bushing 32/screw 34 respectively.

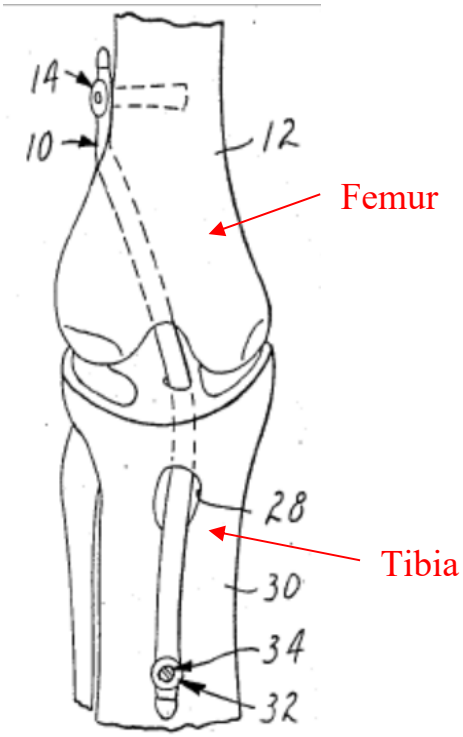


FIG. 1

ii. Ground 2: Claims 25 and 33 are Obvious Over Van Kampen in View of Boyce

Claim 25 recites "the method of claim 24, wherein the first bone portion is associated with a first vertebra and the second bone portion is associated with a second vertebra, the ligament of the weakened portion of the ligament being comprised of a spinal ligament."

Claim 33 recites "the method of claim 24, wherein the surgical procedure of step (a) is performed on the patient's elbow and the first and second bone portions are comprised of bone portions proximate the patient's elbow."

Claims 25 and 33 are obvious under pre-AIA 35 U.S.C. §103 by Van Kampen in view of Boyce.

Overview of the Combination

The combination of Van Kampen and Boyce renders claims 25 and 33 obvious. Van Kampen discloses stabilizing a weakened portion of a ligament by securing a suture to first and second fasteners secured to ligament and bone, as required by independent claim 24 and described above. While Van Kampen does not expressly disclose stabilizing a ligament in the spine (as required by claim 25), or in the elbow (as required by claim 33), it does not limit use of the device to any particular region of the body. 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"). A POSITA would have understood that Van Kampen suggests that the disclosed invention applies to tendons and ligaments that an orthopedic surgeon may encounter when performing surgery on a variety of joints. Ex. 1002, ¶ 90.

Boyce teaches using an orthopedic implant for the treatment of spinal disorders, for the repair and replacement of elbow ligaments, and for the repair and replacement of knee ligaments. Ex. 1006, ¶ [0063]. This further establishes that these types of devices and procedures were known to be used in various joints. 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 and elbow as recited in claims 25 and 33. *Id*.; Ex. 1002 ¶ 91.

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 spine 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 and knee. Ex. 1002, ¶ 92; Ex. 1006, ¶¶ [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 on the spine and elbow. Ex. 1002, ¶ 92. 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*.

Van Kampen and Boyce are both in the same field (ligament repair), and both disclose similar implantation devices used for treating damaged ligaments and tendons. 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*., ¶ 93. First, both disclose similar implantation devices used for treating damaged ligaments and tendons. *Id*. Second, Van Kampen and Boyce disclose the use of implantation devices in the knee. *Id*. Accordingly, it would have been natural for a POSITA to look to Boyce to determine other suitable applications for the device disclosed in Van Kampen. *Id*.

A POSITA would have understood that ligament repair and reconstruction regions in the knee, elbow, and spine were equivalents at the time of the alleged invention of the ’129 Patent. *Id*., ¶ 94. 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 understood that the implantation devices they used in their practice for the spine, knee, 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 '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 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. 1004, 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 VII.B.

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

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

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 spine and the elbow, as disclosed in Boyce. Ex. 1002, ¶ 97. 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 '129 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*., ¶ 98. POSITAs have been using similar techniques to treat and repair weakened ligaments in the body for over 35 years. *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*., ¶ 99. 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 and Boyce are analogous art because they are in the same field as the '129 Patent (Ex. 1001, Abstract, Title) (Ex. 1005, Abstract, Title) (Ex. 1006, Abstract, Title, ¶ [0002]), and all three relate to treating damaged ligaments and tendons. Ex. 1002, ¶ 100.

Claims 25 and 33 are Obvious Over Van Kampen in View of Boyce

> 1. 25. The method of claim 24, wherein the first bone portion is associated with a first vertebra and the second bone portion is associated with a second vertebra, the ligament of the weakened portion of the ligament being comprised of a spinal ligament.
>
> 2. 33. The method of claim 24, wherein the surgical procedure of step (a) is performed on the patient's elbow and the first and second bone portions are comprised of bone portions proximate the patient's elbow.

As discussed above in Ground 1, Van Kampen discloses and/or suggests the claim elements of independent claim 24. However, Van Kampen does not expressly

disclose stabilizing a ligament in the spine ("wherein the first bone portion is associated with a first vertebra and the second bone portion is associated with a second vertebra," as required by claim 25), or in the elbow ("wherein the surgical procedure of step (a) is performed on the patient's elbow and the first and second bone portions are comprised of bone portions proximate the patient's elbow," as required by claim 33). While express disclosure of stabilizing a spine or an elbow is absent, Van Kampen acknowledges that its system is not limited to the knee joint, as discussed above. Indeed, the discussion of knee repairs is only exemplary. Ex. 1005, 3:18-67, Fig. 1. At the time of filing the '129 Patent, a POSITA would have understood that similar treatments could be used in the spine and elbow. Ex. 1002, ¶ 101. 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 and knee. Ex. 1006, ¶¶ [0002], [0063].

As discussed in this Section above, a POSITA would have understood that ligament repair and reconstruction regions in the knee, elbow, and spine were generally equivalent at the time of the alleged invention of the '129 Patent. Ex. 1002, ¶ 102. A POSITA would have used these types of implantation devices interchangeably on various parts of the body. *Id*., ¶¶ 102-03.

A POSITA would have understood that when these devices were used in various ligament repair and reconstruction regions, fasteners could have been used

to secure the two bone portions that proximate the weakened tendon or ligament, as taught in claims 25 and 33. *Id*., ¶ 103.

Thus, a POSITA would have performed Van Kampen's procedure such that the augmentation device would have been connected to adjacent vertebral bones and the ligaments at issue (which could have been, for example, the interspinous ligament or anterior longitudinal ligament). *Id*., ¶ 104. Damage to these spinal ligaments were known to be caused by hyperflexion or extension injuries. *Id*.

Similarly, a POSITA would have performed Van Kampen's procedure such that the augmentation device would have been connected to adjacent bones (humerus and radius) and ligaments (e.g., ulnar collateral ligament) in the elbow joint at issue. *Id*., ¶ 105. The elbow ligaments were known to be damaged by excessive varus or valgus torque, which could be from activity as common as throwing a baseball. *Id*.

iii. Ground 3: Claims 24, 25, 26, 27, 32 are Obvious Over Van Kampen in View of Lambrecht

Claims 24, 25, 26, 27 and 32 are obvious under pre-AIA 35 U.S.C. §103 by Van Kampen in view of Lambrecht.

Overview of the Combination

The combination of Van Kampen and Lambrecht renders claims 24, 25, 26, 27 and 32 obvious. Regarding claim 24, as discussed with respect to ground 1 above, Van Kampen discloses and/or suggests the following limitations to a POSITA:

- [24.0] "A method for stabilizing a weakened portion of a ligament of a patient's body, the method comprising"

- [24.1] "a) performing a surgical procedure on the patient's body through a surgical incision proximate the weakened portion of the ligament, the ligament including an upper end at a first side of the weakened portion and a lower end at an opposite second side of the weakened portion;"

- [24.2] "b) securing a first fastener to the upper end and a first bone portion proximate the upper end;"

- [24.3] "c) securing a second fastener to the lower end and a second bone portion proximate the lower end;"

Claim limitation [24.4] discloses "securing a suture directly to the first and second fasteners and tightening the suture. As discussed in Ground 1 above, Van Kampen discloses a strap-like element of augmentation device 10 attached to fastener 14 and busing 32 that supports the working loads normally supported by the ligament or tendon by acting as a "total prosthesis" for the weakened ligament or tendon. *See* discussion in Ground 1 for [24.4] above. To the extent the Board finds that Van Kampen does not expressly disclose a "suture" or "tightening the suture" between fasteners, Lambrecht discloses these elements. Specifically, it would have been obvious to a POSITA to use the device and methods disclosed in Van Kampen with a suture that is tightened between fasteners, as taught by Lambrecht. Ex. 1002, ¶ 108.

Rationale (Motivation) Supporting Obviousness

A POSITA would have been motivated to combine Van Kampen and Lambrecht. *Id*., ¶ 109. First, Lambrecht discloses an implant utilizing a tensioned suture between two anchors. Ex. 1007, 11:7-21, 11:60-12:12, Fig. 2B, Fig. 4B Second, Van Kampen and Lambrecht both disclose inventions in the field of ligament/joint repair. Ex. 1002, ¶ 109.

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*., ¶ 110. Lambrecht discloses an implant used to treat spinal injuries, including tears in the annulus fibrosus (which is comprised of ligament fibers). Ex. 1007, 1:13-17. The implant of Lambrecht is made up of a suture attached to, and tensioned between, at least two anchors. *Id*., 11:7-21, 11:60-12:12, Fig. 2B, Fig. 4B.

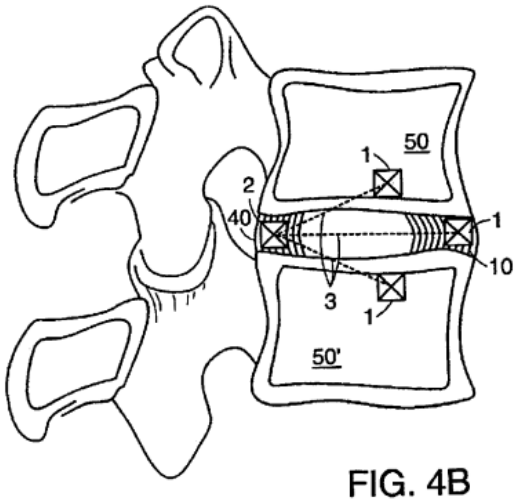


FIG. 4B

Figure 4B above shows fasteners (anchor 1) in bone (vertebral body 50) attached to another fastener (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, ¶ 111. It is was well known at the time of filing the '129 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*. A POSITA would have understood that if the repair or reconstruction procedure of a weakened ligament portion allowed for both fasteners to be placed in bone, it would have produced superior results to do so. *Id*. More 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*., ¶ 112.

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. 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*., ¶ 113. 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, Van Kampen at 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. 1007, 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. Like Van Kampen, Lambrecht teaches the use of tensioned suture that spans the length of the damaged region to provide the requisite support for repair. *Id*., 12:59-67, Fig. 4A, Fig. 4B.

A POSITA would have understood that the use of a suture tightened between the fasteners, as disclosed in Lambrecht, would provide the functionality required of the strap-like element disclosed in Van Kampen. Ex. 1002, ¶ 114. 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 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 VII.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*., ¶ 115. 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*. The tools and methods used for ligament repair at the time of filing the '129 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, 2:26-40. 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.

Analogous Art

Van Kampen and Lambrecht are analogous art, because they are in the same field as the '129 Patent (Ex. 1001, Abstract, Title), (Ex. 1005, Abstract, Title), (Ex. 1007, Abstract, Title, 1:3-17, 5:14-35), and all three relate to treating damaged ligaments. Ex. 1002, ¶ 117.

Claims 24, 25, 26, 27 and 32 are Obvious Over Van Kampen in View of Lambrecht

Claim 24

As already noted, Van Kampen discloses and/or suggests elements [24.0], [24.1], [24.2], and [24.3] of claim 24. To the extent Van Kampen fails to explicitly

teach element [24.4] "d) securing a suture directly to the first and second fasteners and tightening the suture," Lambrecht discloses securing a suture directly to two fasteners and tightening the suture.

First, annotated 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). Lambrecht further discloses connecting member 3 may be comprised of a single or multi-strand suture. Ex. 1007, 11:61-62. Based on this disclosure it would be apparent to a POSITA that Lambrecht discloses suture secured directly to a first and second fastener. Ex. 1002, ¶ 119.

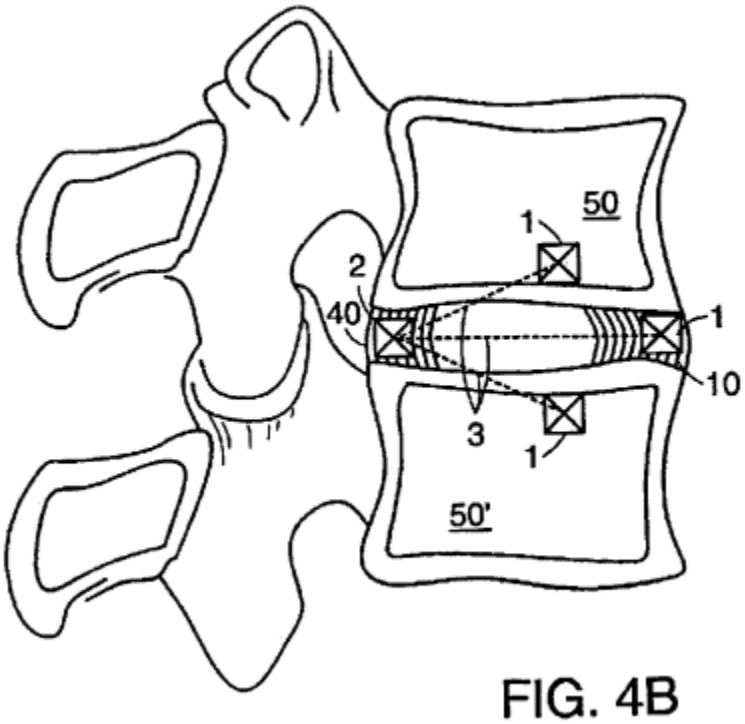


FIG. 4B

Second, Lambrecht teaches tightening 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[5]). Ex. 1007, 11:12-17, 12:35-41, Fig. 4B. Tightening the suture is an obvious step when performing a repair procedure utilizing anchors connected by suture because the tightening step allows for the damaged region to be held securely in its natural anatomic tension. Ex. 1002, ¶ 120.

The Examiner also 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 ligament graft (12, figure 14, column 15 lines 58-63) having a graft length, a superior end portion and an inferior end portion, the ligament graft configured for positioning proximate the ligament such that the superior end portion is positioned at a first side of the ligament and the inferior end portion is positioned at a second side of the ligament (figure 14), the graft length being greater than a distance between a first midpoint of a first vertebra and a second midpoint of the second vertebra associated with the ligament (figure 14); a first fastener (”top” 18) configured for positioning against the superior end portion; a second fastener ("bottom" 18) configured for positioning against the inferior end portion; ***and 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).

[5] 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.

Ex. 1004, 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 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, the suture being tensioned.

Id., 74, 83.

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*. It would have been obvious to a POSITA that the strap-like element in Van Kampen could be tightened between its fasteners, just as taught in Lambrecht. Ex. 1002, ¶ 123. A POSITA would have further known that a tensioned strap would be helpful in supporting the necessary loads required by the ligament augmentation function of Van Kampen. *Id*.

Claim 25

Claim 25 recites "the method of claim 24, wherein the first bone portion is associated with a first vertebra and the second bone portion is associated with a second vertebra, the ligament of the weakened portion of the ligament being comprised of a spinal ligament." Lambrecht teaches the insertion of an implant across two vertebral bodies to treat a damaged spinal region (e.g., the ligament fibers

of the annulus fibrosus). As discussed earlier, Figure 4B shows two fasteners connected by connecting member 3.

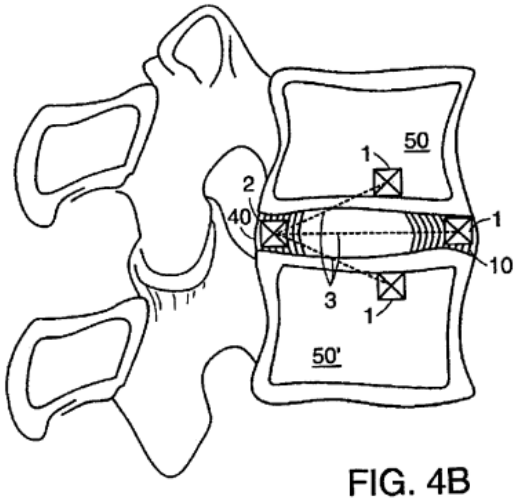


FIG. 4B

While one of the parts of the implant (support 2) in the depicted embodiment of Figure 4B connects to the intervertebral disc rather than the vertebral bone, it would be obvious to a POSITA to connect the anchor to the bone for procedures in which the device is augmenting a spinal ligament such as the anterior longitudinal ligament (*see* Section VII.D.ii above). Ex. 1002, ¶ 125. A POSITA would prefer to connect their anchor points to bone when performing the type of procedure in Van Kampen, in which the augmentation device is intended to bear the anatomical load of a joint. *Id*. A POSITA would find the limitations of claim 25 obvious in light of Van Kampen and Lambrecht. *Id*.

Claims 26, 27 and 32

Van Kampen discloses all of the limitations of claims 26, 27, and 32 for the reasons discussed with respect to Ground 1, above.

iv. Ground 4: Claim 33 is Obvious Over Van Kampen in View of Lambrecht in Further View of Boyce.

As discussed with respect to Ground 3, the combination of Van Kampen and Lambrecht renders obvious claim 24. It would have been obvious to a POSITA to further combine the teachings of Van Kampen and Lambrecht with that of Boyce. *Id*., ¶ 127.

Van Kampen and Lambrecht do not expressly teach repairing or stabilizing a ligament in the elbow; however, both disclosures do not limit the use of the disclosed devices to any particular region of the body. Boyce discloses an implant for repairing or stabilizing a ligament in the elbow in addition to an implant used to treat spinal disorders. Ex. 1006, ¶ [0063]. It would have been natural for a POSITA to look to Boyce deciding which procedures to use on a reconstruction or repair of a ligament in the elbow. Ex. 1002, ¶ 128.

Based on the knowledge of the standard surgical procedures used on elbow ligaments at the time of filing the '129 Patent, a POSITA would have understood that similar applications were known in the art even without the disclosure of Boyce. *Id*., ¶ 129. A POSITA would have found it obvious to combine the teachings of Van Kampen and Lambrecht with Boyce to treat tendon or ligament ailments in the elbow for the reasons described in this Ground as well as Grounds 2 and 3 above. *Id.*

Claim 33 teaches "the method of claim 24, wherein the surgical procedure of step (a) is performed on the patient's elbow and the first and second bone portions

are comprised of bone portions proximate the patient's elbow." Ex. 1001, claim 33. As discussed in Ground 3, the combination of Van Kampen and Lambrecht renders obvious claim 24. The further combination of Boyce with Van Kampen and Lambrecht renders obvious claim 33. Boyce's disclosure of an implant to treat tendon or ligament ailments in the elbow teaches the remaining limitations of claim 33. It would have been obvious to a POSITA that the bone portions disclosed in the claim limitation would necessarily have to be proximate to the elbow when performing a surgical procedure to reconstruct or repair an elbow ligament. Ex. 1002, ¶ 130.

VIII. 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.

IX. CONCLUSION

For the reasons stated above, Petitioner submits that claims 24-27, 32, and 33 of the '129 Patent are unpatentable. Accordingly, Petitioner requests institution of *Inter Partes* Review.

DATED: April 8, 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 8, 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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Date: April 8, 2022

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CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing petition for *inter partes* review contains 12,128 words according to the word processing program used to prepare it.

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