

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC.,
Petitioner,

v.

P TECH, LLC,
Patent Owner.

IPR2022-00787
Patent 9,999,449 B2

Before SHERIDAN K. SNEDDEN, MICHELLE N. WORMMEESTER,
and CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

WORMMEESTER, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Arthrex, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 1–11 of U.S. Patent No. 9,999,449 B2 (Ex. 1001, “the ’449 patent”). P Tech, LLC (“Patent Owner”) did not file a preliminary response. We have jurisdiction under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” For the reasons that follow, we institute an *inter partes* review as to all challenged claims of the ’449 patent based on all grounds presented.

II. BACKGROUND

A. Related Proceedings

The parties identify one related federal district court case involving the ’449 patent, *P Tech, LLC v. Arthrex, Inc.*, Case No. 1-21-cv-00968 (D. Del.). Pet. x; Paper 4, 2 (Mandatory Notices of the Patent Owner). The parties also identify two *inter partes* review proceedings involving other patents asserted in the district court case, namely, IPR2022-00717 and IPR2022-00786. Pet. x; Paper 4, 2.

B. The ’449 Patent

The ’449 patent describes augmenting joints of the body, such as the knee. Ex. 1001, 1:15–21. For example, the ’449 patent describes ligament augmentation. *See id.* at 24:28–26:35. Ligaments are soft tissue in or around a joint that hold the joint together while also controlling movements of the joint. *Id.* at 21:52–55. Ligament augmentation reinforces or

supplements natural ligaments, including those that have been repaired or reconstructed. *Id.* at 24:30–49.

To illustrate, Figure 11A of the '449 patent is reproduced below.

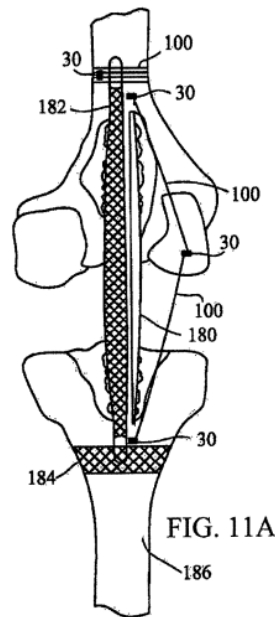


Figure 11A shows the augmentation of ligament 180. Ex. 1001, 8:34–35. A fastener 30 is placed near one end of ligament 180, while another fastener 30 is placed near the opposite end of ligament 180. *Id.* at 24:60–64. Two sutures 100, each of which is placed at an angle to ligament 180, are secured at their ends to fasteners 30 and tensioned between the fasteners. *See id.* at 24:64–25:4, Fig. 11A. This allows for “multiple-direction augmentation.” *Id.* at 25:5–7.

Tissue graft 182, which extends in a direction parallel to ligament 180, also is used to augment ligament 180. *Id.* at 25:8–13. The ends of graft 182 may be anchored to bone, ligament, or other tissue. *Id.* at 25:13–16. For example, as shown toward the top of Figure 11A, a fastener 30 is placed against tissue that is adjacent to graft 182, and a suture 100 is wrapped around graft 182 and the tissue multiple times to form

a band. *Id.* at 25:20–24. As shown toward the bottom of Figure 11A, graft 182 also is secured to tissue (bone 186) using band 184, which is wrapped around graft 182 and bone 186. *Id.* at 25:29–33. Alternatively, one fastener may be placed in or against the graft, while another fastener may be placed in or against adjacent tissue, and the ends of a suture are secured to the fasteners and tensioned between them. *Id.* at 25:16–20.

C. Illustrative Claim

Petitioner challenges claims 1–11 of the '449 patent. Claim 1 is independent and illustrative of the claims under challenge:

1. A surgical method for ligament augmentation comprising:
 - 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
 - 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,
 - wherein the reinforcement component extends between the first and second ends of the ligament, and
 - wherein the reinforcement component is tensioned directly between the first and second fasteners.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–11 of the ’449 patent on the following four grounds. Pet. 2, 21–57.

Claims Challenged	35 U.S.C. § ¹	References/Basis
1–4, 6	103	Van Kampen, ² Marshall ³
1–4, 6, 8	103	Van Kampen, Marshall, Lambrecht ⁴
5, 7–11	103	Van Kampen, Marshall, Boyce ⁵
5, 7, 9–11	103	Van Kampen, Marshall, Lambrecht, Boyce

In support of its arguments, Petitioner relies on a Declaration of Dr. Steve E. Jordan, M.D. (Ex. 1002).

III. DISCUSSION

A. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Petitioner contends:

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the ’449 patent issued claims the benefit of priority to an application that was filed before this date, the pre-AIA version of § 103 applies.

² Van Kampen, U.S. Patent No. 4,834,752, issued May 30, 1989 (Ex. 1005).

³ John L. Marshall et al., *The Anterior Cruciate Ligament: A Technique of Repair and Reconstruction*, in 143 CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 97–106 (Marshall R. Urist, ed., 1979) (Ex. 1006).

⁴ Lambrecht, U.S. Patent No. 6,425,919 B1, issued July 30, 2002 (Ex. 1008).

⁵ Boyce et al., U.S. Publ’n No. 2004/0024457 A1, published Feb. 5, 2004 (Ex. 1007).

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.

Pet. 19 (citing Ex. 1002 ¶ 38).

Factors pertinent to determining the appropriate level of skill in the art include:

(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. . . . The patent's purpose can also be informative.

Best Medical Int'l, Inc. v. Elekta Inc., 46 F.4th 1346, 1353 (Fed. Cir. 2022) (citations omitted). In support of its proposal, Petitioner presents no argument or evidence relating to these factors, but instead simply cites Dr. Jordan's testimony. *See* Pet. 19. Dr. Jordan states that he determined the appropriate level of skill in the art based on his "education, experience, and knowledge of problems encountered in the field," but also provides no analysis of the relevant factors. Ex. 1002 ¶ 38.

On this record, we do not find Petitioner's proposed level of ordinary skill in the art to be supported by the factors listed above. Petitioner's proposal allows for at least two years of experience "designing, developing, or testing implantable medical devices," *or* "performing surgeries with implantable medical devices." Critically, Petitioner's proposal does not require that a person of ordinary skill in the art have experience performing surgeries with implantable medical devices. The record, however, indicates a decidedly surgical focus in the cited prior art and challenged patent.

For example, Van Kampen relates to “methods and devices for augmenting or reinforcing biological tissue used in the repair or reconstruction of ligaments or tendons,” and Marshall is a research article on “the difficult technical aspects of both primary repairs and secondary reconstructions of ACL lesions,” where ACL refers to the anterior cruciate ligament in the knee. Ex. 1005, 1:10–12; Ex. 1006, 97. Boyce 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.” Ex. 1007 ¶ 2. Lambrecht relates to “the surgical treatment of intervertebral (IV) discs in the lumbar, cervical, or thoracic spine.” Ex. 1008, 1:12–16. The inventor of the ’449 patent is a surgeon. *Arthrex, Inc. v. P Tech, LLC*, IPR2022-00786, Exhibit 1008 ¶¶ 6, 9, 10 (PTAB Apr. 11, 2022) (district court complaint discussing inventor).⁶ The challenged patent relates to “devices and methods for repairing, reconstructing, augmenting, and stabilizing joints of the body.” Ex. 1001, 1:15–21.

In view of pertinent factors including the educational level of the inventor, the types of problems encountered in the art and prior art solutions to those problems, the educational level of active workers in the field, and the ’449 patent’s purpose, we find the portion of Petitioner’s proposal that encompasses a person having a B.S. degree (or equivalent) and at least two years of experience designing, developing, or testing implantable medical devices—without any surgical experience—to be unsupported.

⁶ As discussed above, IPR2022-00786 is a proceeding that involves another patent asserted in the related district court case. *See supra* Part II.A.

Accordingly, for purposes of this Decision, we find that a person of ordinary skill in the art would have had a medical degree and at least two years of experience performing surgeries with implantable medical devices, such as suture anchors. In subsequent briefing, the parties are encouraged to address the impact, if any, of the level of ordinary skill in the art on the obviousness analyses at issue in this proceeding. Any final determination pertaining to the level of ordinary skill in the art will be made on the full trial record.

B. Claim Construction

In an *inter partes* review proceeding, we construe a claim of a patent “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” *See* 37 C.F.R. § 42.100(b) (2019). That standard involves construing claims in accordance with the ordinary and customary meaning of such claims as would have been understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc).

Petitioner proposes a construction of the claim term “suture.” Pet. 18. For purposes of this Decision, we conclude that no claim term requires express interpretation at this time to resolve any controversy in this proceeding. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

C. Obviousness over Van Kampen and Marshall

Petitioner asserts that claims 1–4 and 6 of the '449 patent would have been obvious over Van Kampen and Marshall. Pet. 20–46. For the reasons explained below, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on this ground.

1. Overview of Asserted Prior Art

We start with an overview of the asserted prior art, Van Kampen and Marshall.

a. Van Kampen

Van Kampen describes a tissue augmentation device for augmenting biological tissue used in ligament repair or reconstruction. Ex. 1005, 1:10–12, 2:23–32. To illustrate, Figure 1 of Van Kampen is reproduced below.

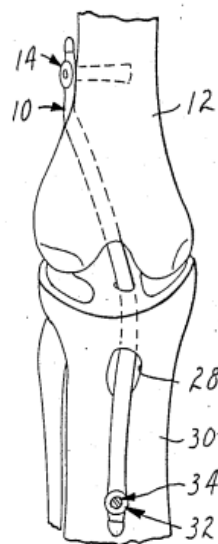


FIG. 1

Figure 1 shows a knee with braided tissue augmentation device 10 in place. *Id.* at 3:1–2, 3:18–19. Device 10 is attached at one end to femur 12 by

inserting legs of fastener 14 through braids at the end of device 10 and a hole that has been drilled in femur 12. *Id.* at 3:20–22, 3:34–41. Device 10 extends from fastener 14 through tibial tunnel 28, and is attached at the other end to tibia 30 by inserting a cylindrical portion of bushing 32 through braids at the end of device 10 and a hole in tibia 30. *Id.* at 3:47–52, 3:62–65. Screw 34 is inserted into bushing 32 and bored into tibia 30 to secure device 10 to tibia 30. *Id.* at 3:66–68.

Device 10 has biological tissue sutured along its length. Ex. 1005, 3:19–20, 4:51–60. In the case of ligament repair, the tissue may be the damaged ligament itself. *Id.* at 5:4–8. Van Kampen explains that, in the early post-operative healing period, tissue loses strength because its normal blood supply is disrupted by the surgery. *Id.* at 1:25–30. The tissue eventually regains its strength, but, until then, the tissue must be protected from carrying normal loads. *Id.* at 1:30–34. Thus, device 10 has sufficient mechanical properties to support the working loads normally supported by the ligament. *Id.* at 2:23–37, 5:22–25, 5:43–49, 6:16–25. Device 10 will gradually lose some of its load-bearing capability after implantation, thereby gradually transferring increased loads to the tissue. *Id.* at 1:37–40, 6:16–25.

b. Marshall

Marshall is an article that discusses “the difficult technical aspects of both primary repairs and secondary reconstructions of ACL lesions alone,” where ACL refers to the anterior cruciate ligament. Ex. 1006, 97. Regarding primary repairs, Marshall describes passing a series of sutures in an anterior to posterior direction through the ligament, starting near the attached base and progressing toward the torn end. *Id.* at 98. For

midportion tears, the sutures are placed in proximal and distal stumps. *Id.* The suture ends are divided into two groups, keeping the anteriorly and posteriorly exiting sutures separate. *Id.* The groups of sutures are brought out through separately drilled holes, and the suture ends are pulled tightly to eliminate slack. *Id.* The torn ends of the ligament are thus realigned. *Id.*

To illustrate, Figure 1 of Marshall is reproduced below.

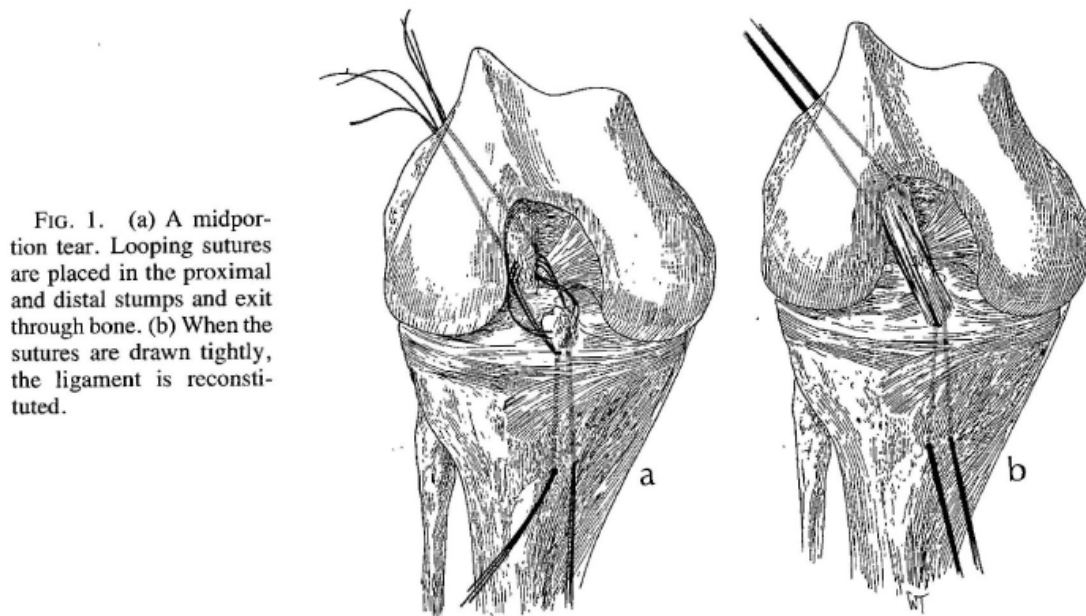


Figure 1 of Marshall shows a midportion tear in the ligament. Ex. 1006, 99. The left-hand view of Figure 1, designated by the letter “a,” shows looping sutures that are placed in proximal and distal stumps and exit through bone. *Id.* The right-hand view of Figure 1, designated by the letter “b,” shows that the ligament is reconstituted when the sutures are drawn tightly. *Id.*

2. Analysis

Turning now to the claims, we discuss independent claim 1 in detail. Claim 1 recites a surgical method with various limitations. We address the preamble and recited limitations in turn.

a. Preamble

The preamble of claim 1 recites “[a] surgical method for ligament augmentation.” Petitioner contends that, “[t]o the extent the preamble is deemed limiting, Van Kampen teaches a surgical method for ligament augmentation.” Pet. 23. As support, Petitioner directs us to where Van Kampen describes using its tissue augmentation device “in parallel with biological tissue in the repair or reconstruction of ligaments,” where “[t]he device is adapted for fixation at each end thereof to the anatomical structures connected by the ligament.” *Id.* at 22–23 (quoting Ex. 1005, code (57)).

Although we do not determine whether the preamble is limiting at this stage of the proceeding, we are persuaded based on Petitioner’s argument and evidence that Petitioner has shown sufficiently for purposes of this Decision that Van Kampen teaches the subject matter of the preamble.

b. Limitation 1.1: “securing a first fastener”

Claim 1 recites “securing a first fastener at least partially within a first bone of a joint adjacent a first end of a ligament of the joint.” For this limitation, which Petitioner designates as limitation 1.1, Petitioner provides an annotated version of Figure 1 of Van Kampen, which is reproduced below. Pet. 24.

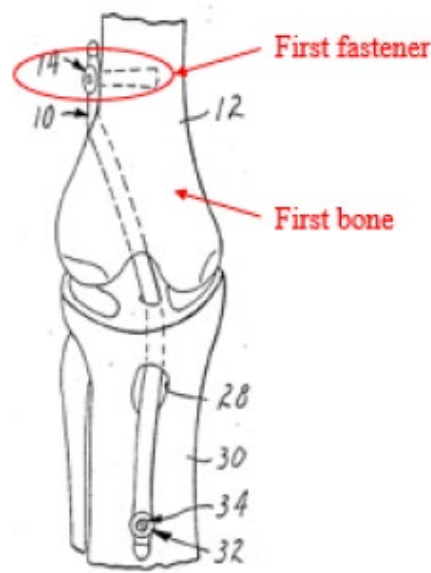


FIG. 1

Figure 1 of Van Kampen, as annotated by Petitioner, shows tissue augmentation device 10 implanted in a knee. *See* Ex. 1005, 3:17–19.

Petitioner directs us to Van Kampen’s teaching that device 10 is “used in parallel with biological tissue for the repair or reconstruction of a ligament or tendon,” where “device [10] and the tissue are used adjacent to one another along their lengths,” and “device [10] is sutured or otherwise secured to the tissue along its length.” *Id.* at 4:51–60 (cited by Pet. 25).

Petitioner also directs us to where Van Kampen teaches that, for ligament or tendon repair, “the biological tissue . . . is the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques.” *Id.* at 5:4–8 (cited by Pet. 25).

Petitioner identifies Van Kampen’s fastener 14 as a “first fastener,” Van Kampen’s femur 12 as a “first bone,” and Van Kampen’s biological tissue, namely, the damaged ligament itself, as a “ligament.” *See* Pet. 24–25. As support, Petitioner further directs us to where Van Kampen teaches

that “[f]astener 14 is implanted by drilling a hole in the femur 12,” and that legs of fastener 14 “are inserted through the braids of one end of augmentation device 10 and a small hole created in the biological tissue,” and then “into the hole in the femur 12.” Pet. 24–25 (quoting Ex. 1005, 3:35–42). Petitioner additionally points to Van Kampen’s teaching that device 10 “augments the *entire length* of the tissue and . . . is affixed to bone at each end.” *Id.* at 25 (quoting Ex. 1005, 7:36–41 (emphasis added by Petitioner)). Petitioner contends that Van Kampen’s “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.” *Id.*

Based on Petitioner’s argument and evidence, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that Van Kampen teaches limitation 1.1 of claim 1.

c. Limitation 1.2: “first end of the ligament”

In connection with the step of “securing a first fastener,” claim 1 further limits the recited first end of the ligament. Specifically, claim 1 recites “wherein the first end of the ligament is attached to the first bone of the joint before securing the first fastener.” For this limitation, designated by Petitioner as limitation 1.2, Petitioner relies on Marshall. As discussed above, “the damaged ligament . . . which has been reapproximated by standard surgical techniques” corresponds to the recited ligament. Based on the declaration testimony of Dr. Jordan, “a scenario wherein the native tissue is reapproximated is typically referred to as ligament ‘repair.’” Ex. 1002 ¶ 51 (cited by Pet. 11–12). Petitioner points to Marshall as “disclos[ing] 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.” *Id.* at 27 (citing Ex. 1006, 98–100).

In particular, Petitioner asserts that Marshall describes “a technique to repair a torn ACL in which sutures are passed through the proximal and distal stumps (ends) 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.” Pet. 27 (citing Ex. 1006, 98). To illustrate, Figure 1 of Marshall is reproduced below.

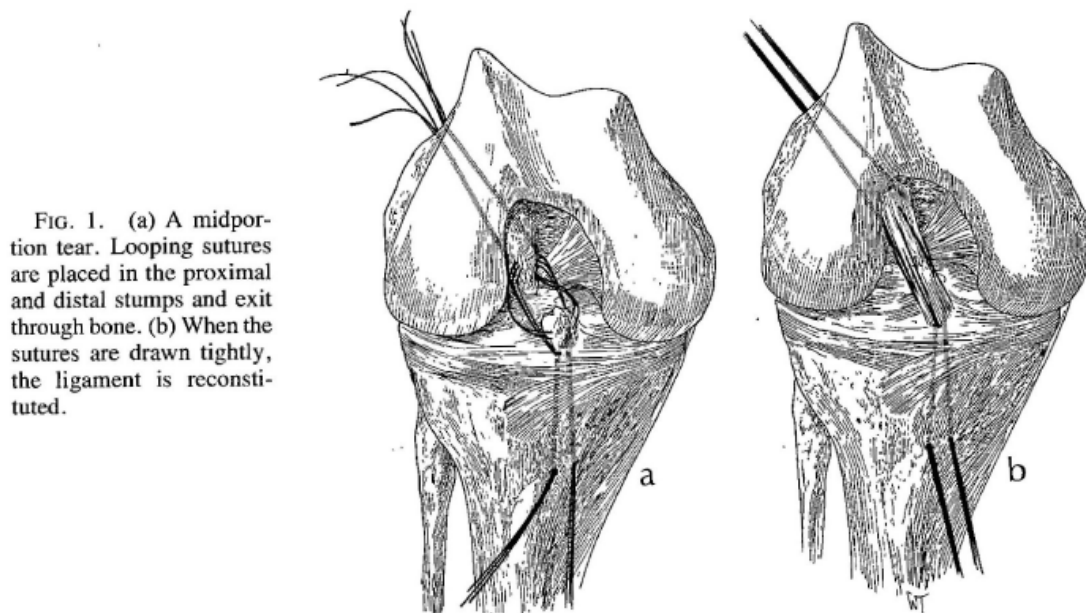


Figure 1 of Marshall shows a midportion tear in the ligament. Ex. 1006, 99. The left-hand view of Figure 1 shows looping sutures that are placed in proximal and distal stumps and exit through bone. *Id.* The right-hand view of Figure 1 shows that the ligament is reconstituted when the sutures are drawn tightly. *Id.* Petitioner contends that, “[b]ecause the fastener in Van

Kampen is being used to attach an augmentation device for a repaired or reconstructed ligament, a [person of ordinary skill in the art] would have appreciated that the fastener would have been secured in place after the ligament is repaired,” for example, “in a manner described in Marshall.” Pet. 28–29. In support of this contention, Petitioner reiterates that the damaged ligament in Van Kampen “has been reapproximated.” *Id.* at 29 (citing Ex. 1005, 5:4–8). Petitioner adds that “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.” Pet. 29. Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* (citing Ex. 1002 ¶ 79).

Based on Petitioner’s argument and evidence, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that the proposed combination of Van Kampen and Marshall teaches limitation 1.2 of claim 1. On this record, we also are persuaded that Petitioner’s proffered reasoning for combining the teachings of Van Kampen and Marshall is sufficient to support institution. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”); Ex. 1005, 5:4–8 (“[T]he biological tissue used in conjunction with the device . . . is the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques.”); Ex. 1002 ¶ 51 (“[A] scenario wherein the native tissue is reapproximated is typically referred to as ligament ‘repair.’”); Pet. 27 (“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.”).

d. Limitation 1.3: “reinforcement component”

Also in connection with the step of “securing a first fastener,” claim 1 further recites “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.” For this limitation, designated by Petitioner as limitation 1.3, Petitioner identifies Van Kampen’s tissue augmentation device 10 as a “reinforcement component.” Pet. 30. Device 10 has “a strap-like element which provides permanent augmentation of the tissue.” Ex. 1005, 5:22–25. Petitioner directs us to where Van Kampen teaches that “[m]aterials which are suitable for fabricating the strap-like member . . . generally include synthetic polymeric materials which can be formed into high strength yarns,” including, for example, “ultra high molecular weight polyethylene” and “polyesters.” Pet. 30 (quoting Ex. 1005, 5:54–61) (emphases omitted). Petitioner further directs us to where Van Kampen teaches that “the strap-like element is preferably fabricated from yarns of [such] material[s],” and that “[b]raids or weaves of these yarns are preferred.” *Id.* (quoting Ex. 1005, 5:62–65) (alterations added). Petitioner contends that an ordinarily skilled artisan “would have understood that a component made up of braids or weaves has a ‘multifilament structure.’” *Id.* Petitioner also contends that an ordinarily skilled artisan “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.* Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* (citing Ex. 1002 ¶ 81); *see also id.* at 31–32 (citing Ex. 1002 ¶ 83).

Petitioner additionally directs us again to where Van Kampen teaches that “[f]astener 14 is implanted by drilling a hole in the femur 12,” and that legs of fastener 14 “are inserted through the braids of one end of augmentation device 10 and a small hole created in the biological tissue.” Pet. 32 (quoting Ex. 1005, 3:35–40). According to Petitioner, this “teaches attaching the reinforcement component directly to the first fastener to anchor it to the femur.” *Id.* As discussed above, Van Kampen’s fastener 14 corresponds to the recited first fastener, and Van Kampen’s femur 12 corresponds to the recited first bone. *See supra* Part III.C.2.b.

Based on Petitioner’s argument and evidence, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that Van Kampen teaches limitation 1.3 of claim 1.

e. Limitation 1.4: “securing a second fastener”

Claim 1 further recites “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.” For this limitation, designated by Petitioner as limitation 1.4, Petitioner provides another annotated version of Figure 1 of Van Kampen, which is reproduced below. Pet. 32–33.

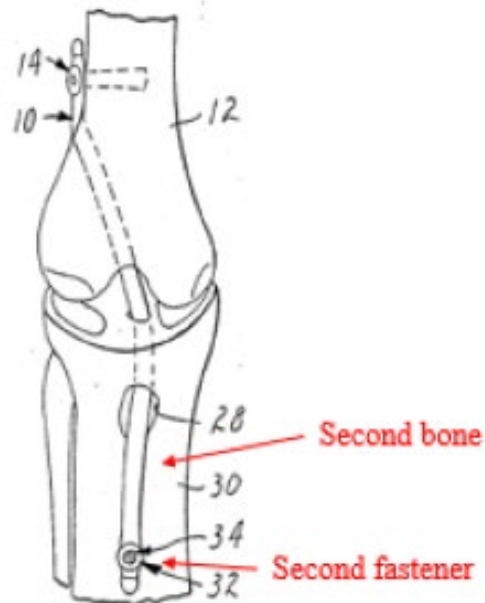


FIG. 1

Figure 1 of Van Kampen, as annotated by Petitioner, shows tissue augmentation device 10 implanted in a knee. *See* Ex. 1005, 3:17–19. As annotated Figure 1 shows, Petitioner identifies Van Kampen’s bushing 32 and screw 34 together as a “second fastener,” and tibia 30 as a “second bone.” Pet. 33; *see also id.* at 36. To support its position, Petitioner directs us to where Van Kampen teaches that “[b]using 32 is implanted by inserting cylindrical portion 40 [of bushing 32] 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,” and that “[s]crew 34 is then inserted into bushing 32 . . . and is bored into the tibia to securely affix augmentation device 10 to the tibia 30.” *Id.* (quoting Ex. 1005, 3:62–67). Petitioner additionally points to Van Kampen’s teaching that device 10 “augments the *entire length* of the tissue and . . . is affixed to bone at each end.” *Id.* at 34 (quoting Ex. 1005, 7:36–41 (emphasis added by Petitioner)).

As discussed above, Van Kampen’s biological tissue, namely, the damaged ligament itself, corresponds to the recited ligament. Petitioner contends that an ordinarily skilled artisan thus “would have understood that Van Kampen’s second fastener would be placed ‘adjacent’ an end of the ligament.” *Id.*

Based on Petitioner’s argument and evidence, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that Van Kampen teaches limitation 1.4 of claim 1.

f. Limitation 1.5: “second end of the ligament”

In connection with the step of “securing a second fastener,” claim 1 further limits the recited second end of the ligament. Specifically, claim 1 recites “wherein the second end of the ligament is attached to the second bone of the joint before securing the second fastener.” For this limitation, designated by Petitioner as limitation 1.5, Petitioner relies again on Marshall and refers to its discussion regarding limitation 1.2. Pet. 34. In its discussion of limitation 1.2, Petitioner points to Marshall as “disclos[ing] 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.” Pet. 27 (citing Ex. 1006, 98–100). As discussed above, the damaged ligament that has been reapproximated in Van Kampen corresponds to the recited ligament, and the scenario where a ligament is reapproximated refers to ligament repair. *See supra* Part III.C.2.c (citing Ex. 1002 ¶ 51).

Referring to Marshall's description of ligament repair in particular, Petitioner asserts that "the sutures are tied down after tensioning the ligament to its natural anatomic tension and attaching the ligament to the bone." Pet. 35. To illustrate, Figure 1 of Marshall is reproduced below.

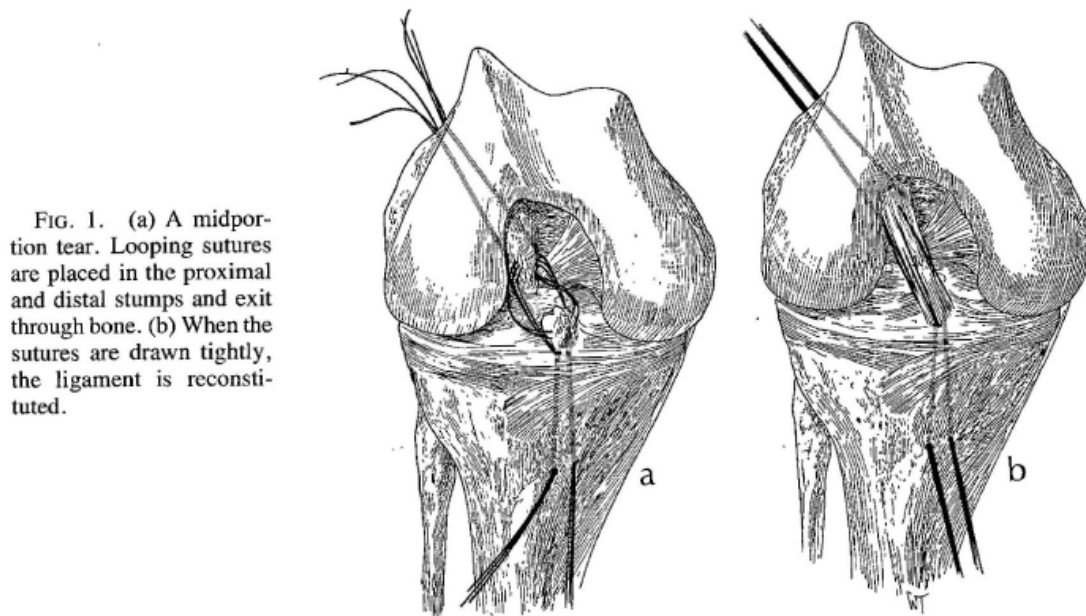


Figure 1 of Marshall shows a midportion tear in the ligament. Ex. 1006, 99. The left-hand view of Figure 1 shows looping sutures that are placed in proximal and distal stumps and exit through bone. *Id.* The right-hand view of Figure 1 shows that the ligament is reconstituted when the sutures are drawn tightly. *Id.* Petitioner contends that "[t]he second fastener in Van Kampen is being used to attach an augmentation device for a repaired or reconstructed ligament, and therefore, a [person of ordinary skill in the art] would have appreciated that the fastener would have been secured in place after the ligament is repaired (including being attached)." Pet. 35. Petitioner adds that "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–[3]4), which suggests that the ligament

has already been attached to the second bone before the second fastener is inserted.” *Id.* at 35.⁷ Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* at 34–35 (citing Ex. 1002 ¶ 87).

Based on Petitioner’s argument and evidence, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that the proposed combination of Van Kampen and Marshall teaches limitation 1.5 of claim 1. On this record, we also are persuaded that Petitioner’s proffered reasoning for combining the teachings of Van Kampen and Marshall is sufficient to support institution.

g. Limitations 1.6, 1.7, and 1.8: “reinforcement component”

The final recitations of claim 1 further limit the reinforcement component discussed above (*see supra* Part III.C.2.d). For example, in connection with the step of “securing a second fastener,” claim 1 recites “wherein the reinforcement component is attached to the second fastener to anchor the reinforcement component to the second bone.” For this limitation, designated by Petitioner as limitation 1.6, Petitioner directs us to where Van Kampen teaches that “[b]ushing 32 is implanted by inserting cylindrical portion 40 [of bushing 32] 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,” and that “[s]crew 34 is then inserted into bushing 32 . . . and is bored into the tibia to securely affix augmentation device 10 to the tibia 30.” Pet. 37 (quoting Ex. 1005, 3:62–

⁷ Petitioner cites “Ex. 1005, 2:32–24,” but this appears to be a typographical error. The quoted language appears at Exhibit 1005, column 2, lines 32 through 34.

67). As discussed above, Van Kampen's augmentation device 10 corresponds to the recited reinforcement component, Van Kampen's bushing 32 and screw 34 together correspond to the recited second fastener, and tibia 30 corresponds to the recited second bone. *Id.* at 33, 36.

Claim 1 also recites "wherein the reinforcement component extends between the first and second ends of the ligament." For this limitation, designated by Petitioner as limitation 1.7, Petitioner directs us again to where Van Kampen teaches that its device 10 "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," that is, "in the case of ligament repair or reconstruction the device is affixed to bone at each end." Pet. 39 (quoting Ex. 1005, 7:36–41) (emphasis added by Petitioner). As discussed above, device 10 has "a strap-like element which provides permanent augmentation of the tissue." Ex. 1005, 5:22–25. Petitioner contends that "[b]ecause the Van Kampen strap-like element extends along the entire length of the ligament, a [person of ordinary skill in the art] would have understood that it extends between the first and second ends of that ligament." Pet. 39. Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* (citing Ex. 1002 ¶ 91).

Lastly, claim 1 recites "wherein the reinforcement component is tensioned directly between the first and second fasteners." For this limitation, designated by Petitioner as limitation 1.8, Petitioner contends that "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)." Pet. 39–40 (citing Ex. 1005, 3:35–47, 3:49–68). As discussed above, Van Kampen teaches that the legs of fastener 14 are

inserted through the braids of one end of augmentation device 10, and that the cylindrical portion of bushing 32 is inserted through the braids of the other end of augmentation device 10. Ex. 1005, 3:37–40, 3:62–65 (cited by Pet. 40).

Petitioner further contends that an ordinarily skilled artisan “would have understood from Van Kampen that the strap-like element is tensioned between the fasteners” because “the ends of the augmentation device are ‘securely affixed’ to the tibia and femur,” as discussed above, and “Van Kampen explains that the augmentation device supports the working loads normally supported by the ligament.” Pet. 40. As support, Petitioner directs us to where Van Kampen teaches that the “strap-like element [is] formed of a stable biocompatible material having sufficient mechanical properties to support at least the working loads normally supported by the ligament.” Ex. 1005, 2:23–30 (cited by Pet. 40). Petitioner also points us to Van Kampen’s teaching that its augmentation device “provide[s] a temporary total prosthesis for the ligament.” *Id.* at 5:22–29 (cited by Pet. 40). According to Petitioner, an ordinarily skilled artisan “would have understood that the disclosed strap-like element would be tightened between the fasteners to act properly as a ‘total prosthesis,’” and that “[t]his 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.” Pet. 41. Petitioner adds that, “[o]therwise, it would not be supporting the load in a way that allows for the damaged ligament to heal.” *Id.* Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* at 40–41 (citing Ex. 1002 ¶ 93); *see also id.* at 41 (citing Ex. 1002 ¶¶ 93, 95). On this record, Petitioner’s contention in this

regard is consistent with Van Kampen’s teaching that “the strap-like element must have sufficient tensile strength to carry the working loads normally carried by the ligament . . . being repaired or reconstructed and low flexural rigidity so as to be flexible enough to prevent interference with the normal movement of the muscular or skeletal structures connected by the device.” Ex. 1005, 5:43–49 (cited by Pet. 40).

Based on Petitioner’s argument and evidence, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that Van Kampen teaches limitations 1.6, 1.7, and 1.8 of claim 1.

3. Summary

In view of the foregoing, we determine that Petitioner has demonstrated a reasonable likelihood of showing that claim 1 would have been obvious over Van Kampen and Marshall. Claims 2–4 and 6 depend from claim 1. Having reviewed Petitioner’s arguments asserting that claims 2–4 and 6 would have been obvious over Van Kampen and Marshall, (*see* Pet. 42–46), we also determine that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertions as to these dependent claims.

D. Obviousness over Van Kampen, Marshall, and Boyce

Petitioner asserts that claims 5 and 7–11 of the ’449 patent would have been obvious over Van Kampen, Marshall, and Boyce. Pet. 57–64. For the reasons explained below, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on this ground.

We provided an overview of Van Kampen and Marshall above. *See supra* Part III.C.1. Before addressing Petitioner’s analysis, we additionally provide an overview of Boyce.

1. Boyce

Boyce describes implants useful for “the repair or replacement of ligaments, tendons and/or cartilage.” Ex. 1007 ¶ 2. The implants are made from flexible elongated elements, such as bone, tendons, ligaments, or synthetic polymeric fibers. *Id.* ¶ 25. The elongated elements are aligned along their longitudinal axis to provide, for example, woven, knitted, braided, or twisted structures. *Id.* ¶¶ 10, 20. To illustrate, Figures 1A and 1B are reproduced below.

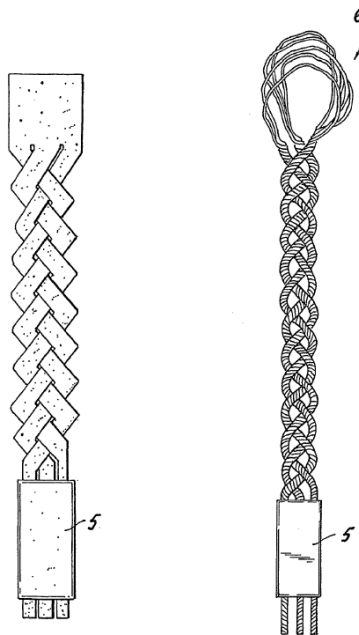


Fig. 1a

Fig. 1b

Figure 1A shows an elongated section of bone that has been cut to provide three elongated elements arranged in a braid, and Figure 1B shows elongated elements formed into yarns that are arranged in a braid. *Id.* ¶ 24. The

elongated elements have “connective tissue-healing activity,” which means they have “the ability . . . to participate in the repair, regeneration, healing, etc., of connective tissue, e.g., bone, ligament, tendon or cartilage.” *Id.* ¶ 15. The implants comprising the elongated elements can be used in various surgical procedures, including the repair of the vertebral column as well as the repair of ligaments or tendons in the spine, hand, elbow, knee, foot, and ankle. *Id.* ¶ 63.

2. Analysis

We turn now to the claims. Each of claims 5 and 7–11 depends directly from claim 1. As discussed above, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that its proposed combination of Van Kampen and Marshall teaches all the limitations of claim 1, including a “first bone,” a “second bone,” and a “joint.” *See supra* Part III.C. Dependent claims 5 and 7–11 further limit these claim elements. Specifically, claim 5 requires that the first and second bones as well as the joint are part of a foot; claim 7 requires that they are part of a shoulder; claim 8 requires that they are part of a spine; claim 9 requires that they are part of a hand; claim 10 requires that they are part of a hip; and claim 11 requires that they are part of an elbow.

For these limitations, Petitioner acknowledges that an express disclosure regarding “stabilizing these areas of the body is absent” in Van Kampen,” but at the same time notes that Van Kampen “does not limit the use of [its] device to any particular region of the body.” Pet. 57, 62 (citing Ex. 1005, 1:15–21, 5:9–13); *see also* Ex. 1005, 5:9–13 (“The selection of the appropriate biological tissue to reconstruct or repair a particular tendon or

ligament is well within the level of ordinary skill in the field of orthopedic surgery and does not form part of the present invention.”). Petitioner thus relies additionally on Boyce, asserting that “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.’” Pet. 62 (citing Ex. 1007 ¶¶ 2, 63). Petitioner contends that an ordinarily skilled artisan “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.” *Id.* at 58.

As support, Petitioner asserts that Van Kampen and Boyce “disclose similar implantation devices used for treating damaged ligaments and tendons.” Pet. 58. Petitioner also asserts that, “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.” *Id.* at 57–58 (citing Ex. 1005, 2:23–40; Ex. 1007 ¶¶ 2, 63). Petitioner points to Van Kampen’s characterization of its discussion of ligament reconstruction in the knee as “[a]n example,” and further asserts that “[i]t would have been natural for a [person of ordinary skill in the art] to look to Boyce to determine other suitable applications for the device disclosed in Van Kampen because of this overlap in disclosure.” *Id.* at 57, 59 (citing Ex. 1005, 1:15–21). Petitioner adds that the ordinarily skilled artisan “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,” and “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.” *Id.* at 59, 62. Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* at 58–64 (citing Ex. 1002 ¶¶ 129, 132–134, 137–152).

Based on Petitioner’s argument and evidence, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that the proposed combination of Van Kampen, Marshall, and Boyce teaches or suggests the recited limitations of claims 5 and 7–11. On this record, we also are persuaded that Petitioner’s proffered reasoning for using Van Kampen’s device in the treatment of a ligament in a foot, a shoulder, a spine, a hand, a hip, or an elbow as taught or suggested by Boyce is sufficient to support institution.

3. *Summary*

In view of the foregoing, we determine that Petitioner has demonstrated a reasonable likelihood of showing that claims 5 and 7–11 would have been obvious over Van Kampen, Marhsall, and Boyce.

E. Remaining Grounds

Petitioner asserts that claims 1–4, 6, and 8 of the ’449 patent would have been obvious over Van Kampen, Marshall, and Lambrecht. Pet. 46–57. Petitioner also asserts that claims 5, 7, and 9–11 would have been obvious over Van Kampen, Marshall, Lambrecht, and Boyce. *Id.* at 64–66. As discussed above, Petitioner has already demonstrated a reasonable likelihood that it will prevail on its asserted ground of obviousness over Van Kampen and Marshall as well as its asserted ground of obviousness over

Van Kampen, Marshall, and Boyce. *See supra* Parts III.C, III.D.

Accordingly, we institute trial on all challenged claims and all asserted grounds of unpatentability, including the grounds based additionally on *Lambrecht*. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) (holding that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition); Patent Trial and Appeal Board, Consolidated Trial Practice Guide, 5 (Nov. 2019), available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf> (“In instituting a trial, the Board will either (1) institute as to all claims challenged in the petition and on all grounds in the petition, or (2) institute on no claims and deny institution. The Board will not institute on fewer than all claims or all challenges in a petition.”).

IV. CONCLUSION

For the foregoing reasons, Petitioner has demonstrated on the record before us a reasonable likelihood that it will prevail in showing that claims 1–11 of the ’449 patent are unpatentable. We have not, however, made a final determination with respect to the patentability of these claims.

V. ORDER

For the reasons given, it is

ORDERED that *inter partes* review is instituted as to all the challenged claims of the ’449 patent, namely, claims 1–11, based on all the grounds presented in the Petition:

- A. Obviousness under 35 U.S.C. § 103 of claims 1–4 and 6 over Van Kampen and Marshall;

- B. Obviousness under 35 U.S.C. § 103 of claims 1–4, 6, and 8 over Van Kampen, Marshall, and Lambrecht;
- C. Obviousness under 35 U.S.C. § 103 of claims 5 and 7–11 over Van Kampen, Marshall, and Boyce; and
- D. Obviousness under 35 U.S.C. § 103 of claims 5, 7, and 9–11 over Van Kampen, Marshall, Lambrecht, and Boyce; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial will commence on the entry date of this Decision.

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