UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALPHATEC HOLDINGS, INC. AND ALPHATEC SPINE, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case No. IPR2019-00546
United States Patent No. 8,187,334

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,187,334

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Alphatec Holdings, Inc. and Alphatec Spine, Inc. (collectively "Petitioner") petition for *Inter Partes* Review under 35 U.S.C. §§ 311–319 and 37 C.F.R., Part 42 of claim 16 of U.S. Patent 8,187,334 (the "'334 patent"). In February 2018, the Director cancelled claims 1–5, 10, 11, 14, 15, and 19–28 under 35 U.S.C. § 318(b). Ex. 1001, Inter Partes Review Certificate; *see also*, Ex. 1004, at 13, Ex. 1005, at 17. As shown herein, Petitioner is reasonably likely to prove the challenged claim unpatentable. Accordingly, Petitioner requests that the Board institute trial and cancel the challenged claim.

I. INTRODUCTION

The claims of the '334 patent are drawn to a radiolucent spinal fusion implant with three radiopaque markers that "has a longitudinal length greater than 40 mm" that is also "at least two and a half times greater than the maximum lateral width." Ex. 1001, cl. 1; Ex. 1004, 5.

In 2016, the Federal Circuit affirmed the Board's finding in IPR2013-00507 (Ex. 1004) that sole independent claim 1 of the '334 patent and eighteen dependent claims (2–5, 10, 11, 14, 15, and 19–28) are invalid. Ex. 1005, 17. In doing so, the Federal Circuit agreed that the combination of U.S. Patent App. Pub. 2002/0165550 A1 to Frey *et al*. ("Frey") (Ex. 1040) in view of U.S. Patent 5,860,973 to Michelson ("Michelson") (Ex. 1032) disclosed a "long-and-narrow" radiolucent spinal fusion implant of non-bone construction with at least three radiopaque markers. Ex. 1005,

14–16. Two of Frey's alternative embodiments—one illustrating three radiopaque markers—are shown below:

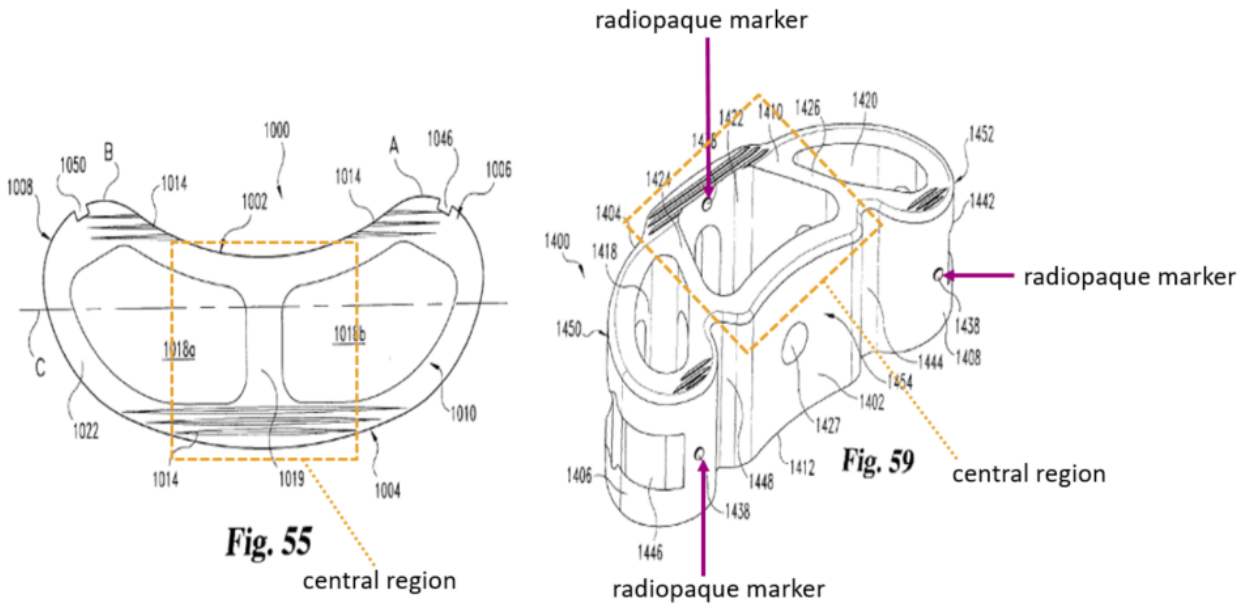
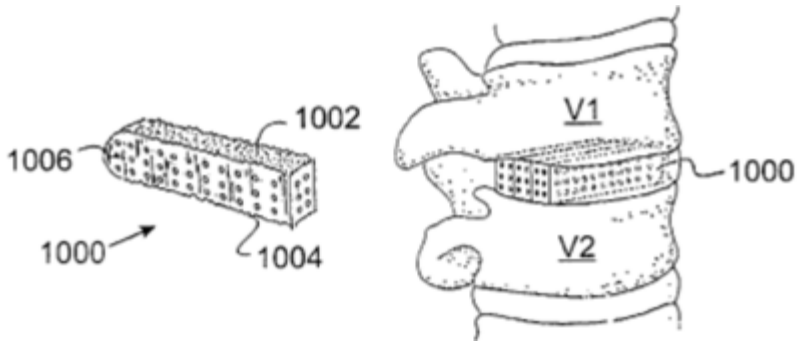


Fig. 55 Fig. 59

Ex. 1040, Figs. 55, 59 (annotated).

With respect to the dimensional limitations of claim 1, the Federal Circuit affirmed the Board's finding that Michelson disclosed "longer-than-wide" implants. Ex. 1005, 14–16. Specifically, the Federal Circuit noted that Michelson "expressly states that the preferred length of embodiment 900 was 42 mm and the preferred width was 26 mm," and "that 'spinal fusion implant 1000 is similar to the spinal fusion implant 900, but has a narrower width such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion within the disc space.'" *Id.*, 14–15. The Michelson long-and-narrow implant is illustrated in Figures 18–19 of that patent:

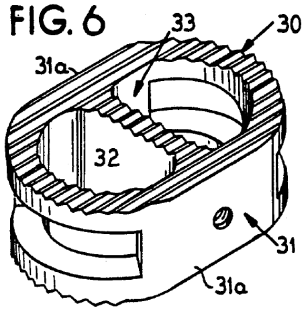


Ex. 1032, 10:50–55, Figs. 18–19. Regarding Figure 19 of Michelson, the Federal Circuit noted that "its point is to show more than one" implant lined up in the disc space. Ex. 1005, 15. Thus, the Federal Circuit affirmed the Board's finding that claims 1–5, 10, 11, 14, 15, and 19–28 of the '334 patent are unpatentable based on "substantial, and anything but speculative, evidence." *Id.*

Presently challenged claim 16 is not patentably distinct from the claims the Board and Federal Circuit deemed invalid based on the combination of Frey and Michelson. This claim is drawn to the spinal fusion implant of invalid claim 1 that additionally has a fourth radiopaque marker positioned in the central region of the implant at a position spaced apart from the third radiopaque marker. Ex. 1001, cl. 16. This limitation is expressly disclosed in Baccelli, as described below.

In addition to Frey, other long-and-narrow radiolucent implants were known in the art prior to the critical date. For example, U.S. Patent 5,192,327 to Brantigan ("Brantigan") (Ex. 1007) issued in March 1993 and, like the '334 patent, discloses a long-and-narrow, radiolucent, spinal fusion implant. Ex. 1007, 3:9–12. Further, Brantigan describes implants for use in the lumbar spine (Ex. 1007, 1:65–68). The

Brantigan implants are "generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column" (*id.*, 4:5–8, 2:2–4), "with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies" (*id.*, 1:20–21).



Id., Fig. 6.

The medial-lateral dimensions (*i.e.*, longitudinal length) of the Brantigan spinal fusion implant and normal vertebral bodies—as widely reported by Berry *et al.*, *A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae*, 12 Spine, 362–367 (1987) (Ex. 1022, "Berry"), for the purpose of "provid[ing] data for implant design"—was greater than 40 mm for the lumbar region. Ex. 1022, Abst., 364, Table 1 (describing the mean longitudinal length of the L1 vertebra as 45.2 mm and the mean longitudinal length of the L5 vertebra as 53.4 mm).

Michelson's disclosure of a long-and-narrow modular implant coupled with the known depth of the human vertebrae in the lumbar region—as reported by Berry—would have motivated a person of ordinary skill in the art ("POSA") to create the long-and-narrow implant of Brantigan in a modular fashion as taught by

Michelson to have a width of approximately 18 mm, which is half the known depth of the lumbar vertebra from front to back as taught by Berry. Ex. 1022, Abst., 364, Table 1. The resulting implant would have a longitudinal length at least two and a half times greater than its maximum lateral width. *See infra* § XI.D.f.

Although Brantigan does not mention using radiopaque markers, using such markers in radiolucent implants was commonplace before March 2004 as disclosed in, for example, U.S. Patent App. Pub. No. 2003/0028249 to Baccelli *et al*. ("Baccelli") (Ex. 1008). Baccelli published in February 2003 and teaches an implant that "can be made of a material that is transparent to X-rays, e.g. out of poly-ether-ether-ketone (PEEK). In which case, the cage can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or the presence of the implant when X-rays are taken during or after the operation." Ex. 1008, [0050]. Baccelli's radiopaque markers may be positioned within any of the implant's four walls, including the central region between the proximal and distal walls of the implant. *Id.*, [0050]–[0051], Figs. 1–4, 8, 9. The radiolucent Baccelli implant with radiopaque markers (denoted "47") and radiopaque spikes (denoted "24") is illustrated in Figure 2 of Baccelli:

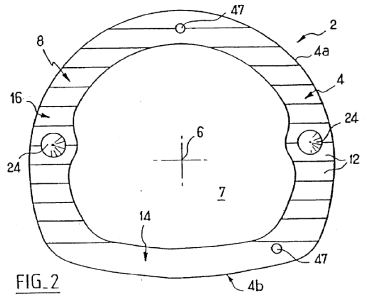


FIG. 2

Id., Fig. 2.

Neither Frey nor Baccelli were cited to or considered by the examiner during prosecution of the ’334 patent. Ex. 1023. And the combinations cited herein were never raised or considered during prosecution or in any prior proceeding for the presently challenged claim. *Id.*; Ex. 1033; Ex. 1034. These combinations render the challenged claim unpatentable.

Petitioner requests the Board institute *inter partes* review and cancel claim 16 of the ’334 patent.

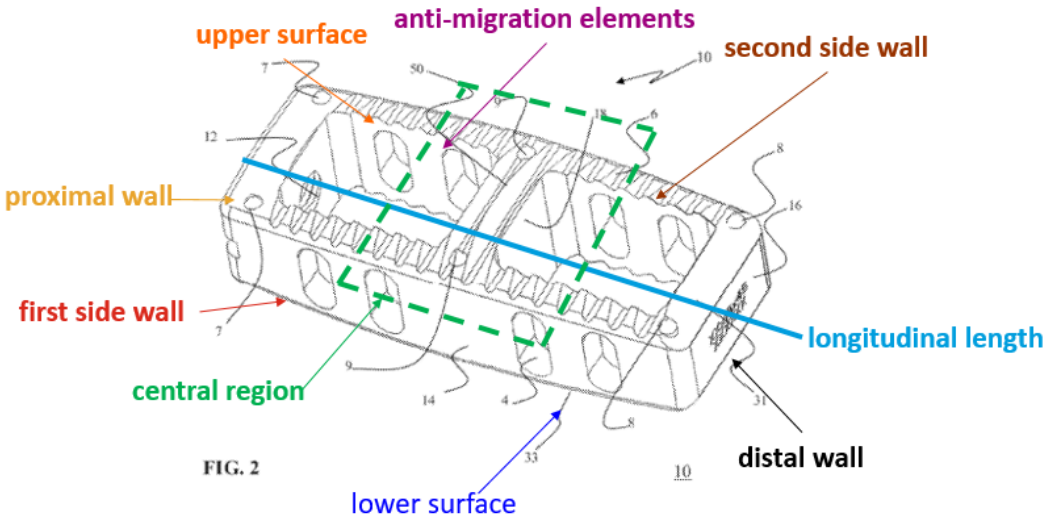
II. PETITIONER’S STANDING

Petitioner certifies that (1) the ’334 patent is available for IPR, (2) none of the parties constituting Petitioner are the Patent Owner, and (3) it is not barred or estopped from requesting IPR. The ’334 patent was first asserted in an amended complaint served on Petitioner on September 13, 2018.

III. THE ’334 PATENT

The ’334 patent describes a spinal fusion system, including a spinal fusion implant and an insertion instrument. Ex. 1001, 5:6–9. The spinal fusion implant is

introduced into the disc space via a lateral approach to the spine or via a posterior, anterior, antero-lateral, or postero-lateral approach, and is made from a radiolucent material, such as PEEK (poly-ether-etherketone). *Id.,* 5:10–15, 5:29–33.



Id., Fig. 2 (annotated).

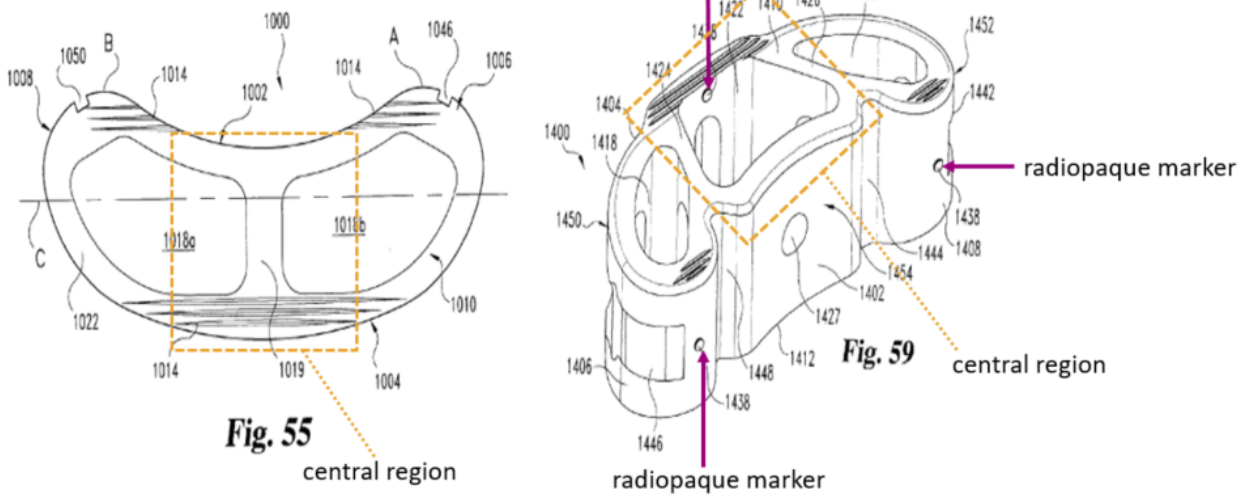
In one embodiment, the spinal fusion implant has a width ranging between 9 and 18 mm and a length ranging between 25 and 45 mm. *Id*., 5:17–19. In another embodiment, the spinal fusion implant includes four pairs of radiopaque markers—described as "spike elements" in the specification: one at least partially positioned in the distal wall, a second at least partially positioned in the proximal wall, a third at least partially positioned in the central region, and a fourth positioned in the central region at a position spaced apart from the third marker. *Id*., cl. 1, 16, 6:27-38; *see also* Fig. 2. The implant sizes and shapes discussed in the '334 patent are no revelation. These implant sizes were described decades earlier in Frey, Michelson,

Brantigan, and Berry. Similarly, the inclusion of four radiopaque markers was also unremarkable because Baccelli previously disclosed a spinal fusion implant having four radiopaque markers positioned in the same locations within the implant as claimed in the '334 patent.

IV. THE PRIOR ART

A. Frey

Frey (Ex. 1040) published in November 2002. Frey discloses a spinal fusion implant that can be made from radiolucent material known as PEEK. Ex. 1040, ¶ [0181]. Frey's implants include a distal wall, a proximal wall, and two sidewalls spanned by a medial support in the central region. *Id.*, ¶ [0151].



Ex. 1040, Figs. 55, 59 (annotated).

Frey's implants have "a length sufficient to span the disc space from the distal portion . . . to the proximal portion" (*id.*, ¶ [0130], Fig. 47), and "may be utilized or modified for use in a variety of surgical applications including, but not limited to, spinal surgery from a unilateral posterior approach, a lateral approach, an oblique approach, and through laparoscopic or endoscopic instruments from any of a variety of angles or approaches to the spine" (*id.*, ¶ [0184]). Frey explicitly "contemplate[s] that disc space D1 can be accessed and prepared…using any other known techniques and instruments and other approaches to the disc space, such as lateral, anterior or antero-lateral approaches, for insertion of implant 1400." *Id.*, ¶ [0150], [0140] (equivalent statement for implant 1000).

Frey's implants have grooves to increase frictional resistance between adjacent vertebrae (*id*., ¶ [0153]), in addition to first and second fusion apertures extending from the top surface to the bottom surface (*id*., ¶ [0154]) configured to hold "[a]ny suitable osteogenetic material" to facilitate bone growth (*id*., ¶ [0182]). Frey's implants include a number of radiopaque markers, and in one example, the radiopaque markers are located in the proximal wall, the distal wall, and the central region of the implant. *Id.*, ¶ [0156], Figs. 59–62 (radiopaque markers denoted "1438").

B. Brantigan

Brantigan (Ex. 1007) issued in March 1993. Patent Owner is no stranger to Brantigan, having relied on it to successfully invalidate claims in a different patent discussing spinal implants. *See* Ex. 1017, 36; Ex. 1018, 35; Ex. 1019, 9–10.

Brantigan discloses spinal fusion implants composed of "rigid biologically acceptable and inactive material, preferably a radiolucent plastics material" for insertion between adjacent vertebrae. Ex. 1007, 4:3–4. Brantigan's implant is "suitable for anterior, posterior or lateral placement in any area of the spine requiring replacement of disc or vertebral body." *Id.*, 2:56–59. It is "generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column." *Id.*, 4:5–8; *see also id.*, Figs. 10–11, 13–14, Abst., 1:18–23, 1:54–56; 1:68–2:4, 2:19–22, 7:29–34.

Patent Owner has made numerous admissions about Brantigan's teachings. Patent Owner conceded that Brantigan "describes an implant that is 'shaped to conform with the general outline perimeter of the vertebrae,' is 'dimensionally similar to normal vertebral bodies,' has 'dimensions in the same ratio as normal vertebral bodies,' and is 'sized to match the height of an average disc.'" Ex. 1035, 49. Patent Owner also admitted that Brantigan discloses "a length substantially greater than the depth of the vertebrae" and "a height for contacting each of the two adjacent vertebrae." *Id.*

Brantigan discloses the same modularity concept Michelson describes. In particular, Brantigan discloses implants that are "preferably hemi-oval" in a partial-annular "shape to accommodate those surgical procedures where only a portion of the vertebrae or disc is damaged." Ex. 1007, 2:4–7. According to Brantigan, "[t]wo such hemi-oval rings can be used in the posterior lumbar area in side-by-side relation." *Id*., 2:7–11. Thus, Brantigan teaches narrowing the width of the implant in the direction of insertion in the same way Michelson teaches. *See, e.g.*, Ex. 1032, 10:50–55.

A POSA, therefore, would have understood Brantigan to teach a longitudinal length greater than 40 mm and a width of approximately 18 mm. Ex. 1002, ¶ 171.

C. Michelson

Michelson (Ex. 1032) issued in January 1999. Michelson describes a spinal fusion implant "dimensioned to fit within the disc space created by removal of the disc material between two adjacent vertebrae." Ex. 1032, 3:35–36. The "implant is inserted from the translateral approach to the spine and has a length that is substantially greater than the depth of the vertebrae and a width that approximates the depth of the vertebrae." *Id.*, 3:37–40. Michelson refers to the laterally-inserted implant as a "translateral spinal fusion implant." *Id.*, 3:1–7. A cross-sectional view of a cylindrical embodiment of Michelson is:

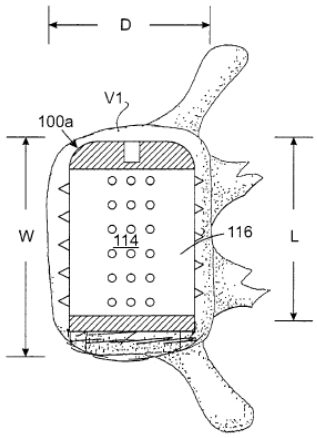


FIG. 4

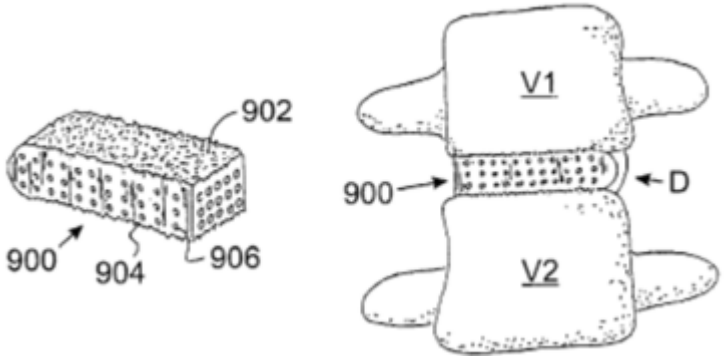
Id., Fig. 4.

Michelson explains, "[t]he dimensions of the translateral spinal fusion implant of the present invention permits a single implant to be inserted by a single procedure into the spine and to engage more of the adjacent vertebrae. As a result, the translateral spinal fusion implant of the present invention has more surface area of contact and thus permits greater stability so as to withstand torque." *Id.*, 3:47–53. Additionally, translateral implants "are safer to use than implants inserted from the front or back as the aorta and vena cava lie anterior to the spine and the dural sac and nerves posteriorly, all of which structures are simply avoided in the lateral approach." *Id.*, 3:56–60.

To maximize safety, Michelson discloses minimally invasive methods of lateral insertion: "the translateral spinal fusion implant of the present invention may be inserted into the disc space through a hollow tube which is engaged to the lateral aspect of the spine through a lateral, anterior, or anterolateral incision making the procedure safe and simple." *Id.*, 3:61–65.

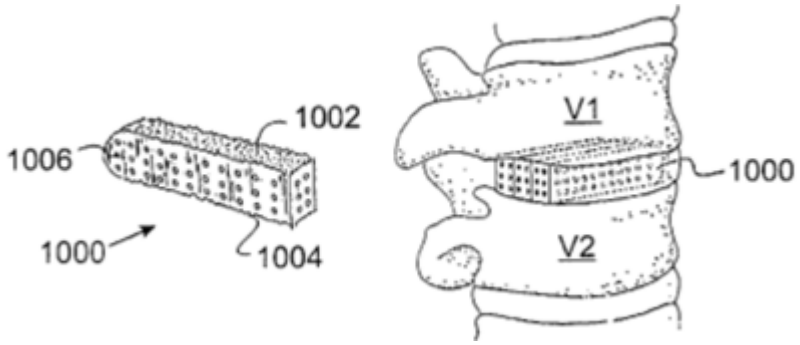
As an alternative to the cylindrical embodiment, Michelson discloses an embodiment that "does not require the removal of any portion of bone from the adjacent vertebrae as the spinal fusion implant 900 fits within the natural disc space between the adjacent vertebrae." *Id.*, 10:6–16. As illustrated below, such a

> spinal fusion implant 900 comprises a rectangular block 901 having a top surface 902 and a bottom surface 904 for engaging the adjacent vertebrae and may be flat or may conform at least in part. The top and bottom surfaces 902 and 904 may comprise any of the surface roughenings described herein for engaging the bone of the adjacent vertebrae to promote firm stability. The spinal fusion implant 900 may be solid or hollow at least in part and have a plurality of openings 906 to allow bone ingrowth. The openings 906 may be present on all surfaces of the implant 900 and may either pass through the entire implant 900, or may be closed bottom wells for holding fusion promoting materials.



Id., 10:19–31, Figs. 16–17.

Michelson further teaches that such implants may have a "narrower width such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion within the disc space."



Id., 10:50–55, Figs. 18–19.

D. Berry

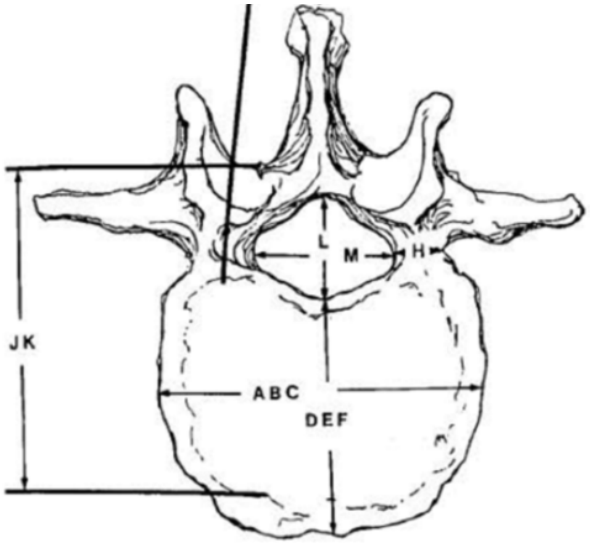
Berry (Ex. 1022) was published in the journal "Spine" in 1987. Berry's study was "undertaken to provide data for implant design." *Id.*, 362.

> [A]ccurate anatomic descriptions of vertebral shape are necessary for the development of implantable devices and spinal instrumentation. The authors' interest in spinal implants and fixation devices resulted in a need for more detailed morphologic and anthropometric data on the vertebrae than could be found in the existing literature.

Id.

Berry measured "major body diameter" (vertebral transverse width) and "minor body diameter" (vertebral depth) at three different points (the superior, *i.e.*, upper, and inferior, *i.e.*, lower, surfaces of the vertebral body, as well as at the

midpoint between them) from 240 different vertebrae. *Id.*, 362–363, Fig. 1; Ex. 1002, ¶ 101.



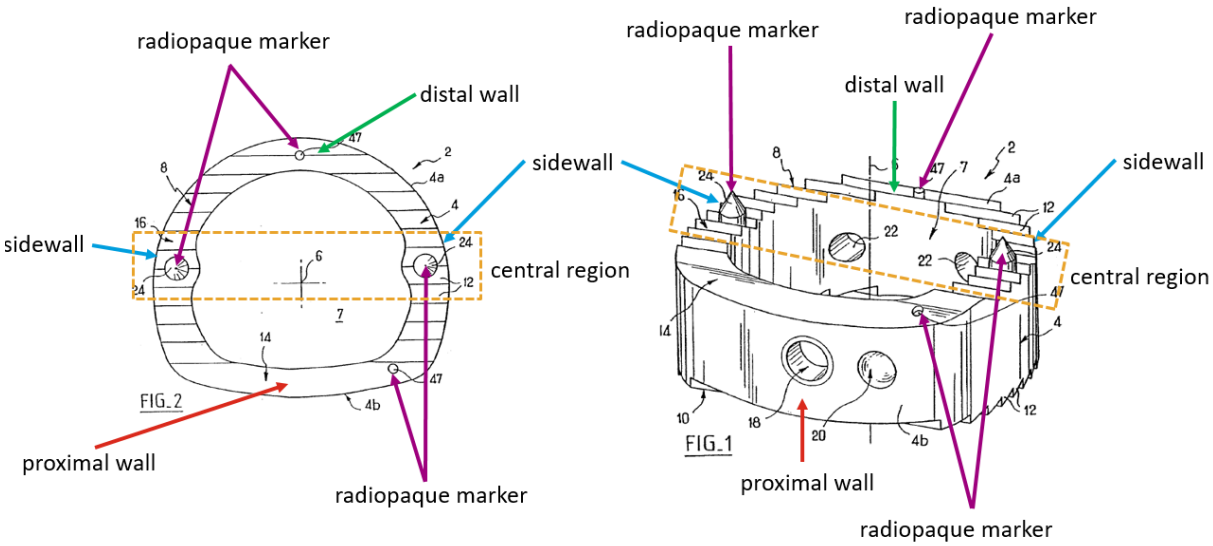
Id., Fig. 1 (excerpted). Berry identified the means and standard deviations associated with dimensions of human vertebrae in the thoracic and lumbar spine. *Id.*, Table 1.

E. Baccelli

Baccelli (Ex. 1008) published in February 2003. Baccelli discloses a spinal fusion implant "made of a material that is transparent to X-rays," like PEEK. Ex. 1008, [0050]. Baccelli discloses a distal wall, a proximal wall, and two sidewalls (*id*., [0033]–[0034]), in addition to upper and lower surfaces that contain anti-migration elements in the form of teeth that "limit[] the ability of the cage to move forwards from its position" after "the cage is put into place between the vertebrae from behind" (*id*., [0045]). Additionally, Baccelli's "implant has a central hole extending from one of the main faces to the other [e.g., from the top to the bottom

surface]" (*id.*, [0012]) that can "receive the [bone] graft that facilitates vertebral bone integration" (*id.*, [0013]).

Baccelli's spinal fusion implant "can have one or more markers 47 included therein . . . to identify the position and/or the presence of the implant when X-rays are taken during or after the operation." *Id.*, [0050], Figs. 1–5, 8, 9. Baccelli also describes how "spikes 24 can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays." *Id.*, [0051]. The four radiopaque markers (24, 47) of Baccelli located in the proximal wall (4b), distal wall (4a), and central region of the side (16, 4) walls are illustrated below:



Id., Figs. 1–2 (annotated); *see also* Figs. 3–5, 8, 9. The two markers positioned in the central region are spaced apart from each other. *Id.*

V. PROSECUTION HISTORY

On March 29, 2005, Patent Owner filed U.S. Patent App. No. 11/093,409, which issued as parent U.S. Patent 7,918,891 (the "'891 patent"). Ex. 1001, 1:6–15. During prosecution of that patent, the examiner rejected the claims as obvious over Michelson in view of U.S. Patent 6,159,211 to Boriani *et al*. ("Boriani") and U.S. Patent 4,349,921 to Kuntz ("Kuntz"), finding that Boriani and Kuntz disclosed radiolucent spinal implant material and Kuntz disclosed a radiopaque marker. Ex. 1020, 245–253. However, because Kuntz did not specify where to place the radiopaque marker, the examiner allowed the claims after amendment to recite "at least three radiopaque markers disposed within the distal, proximal and medial portions of the implant," which Patent Owner contended, neither Boriani nor Kuntz taught. *Id.*, 105–111, 220–231.

The '334 patent was allowed within a year with no substantive rejections. Ex. 1023, 206–214, Ex. 1025, 106–110, Ex. 1013, 191–194. The examiner never had Frey or Baccelli, which disclose a number of radiopaque markers, including at least four radiopaque markers (one at least partially positioned in the distal wall, a second at least partially positioned in the proximal wall, a third at least partially positioned in the central region, and a fourth positioned in the central region at a position spaced apart from the third radiopaque marker) during prosecution, and never considered

these references in view of one another or further in view of Michelson, Brantigan, and Berry.

VI. PREVIOUS CHALLENGES

The ’334 patent has undergone *inter partes* review twice, with the Director cancelling all but one previously challenged claim. In IPR2013-00507, the Board instituted *inter partes* review of claims 1–5, 10, 11, 14, 15, and 18–28. Ex. 1033; Ex. 1004. With the exception of claim 18, the Board found all challenged claims unpatentable under § 103(a) over Frey and Michelson. *Id.,* 13. In IPR2013-00507, the Petitioner did not challenge claim 16 based on the combination of Frey and Michelson. Ex. 1048, 3. Instead, Petitioner challenged claim 16 based on the combination of Frey and Baccelli. *Id*. The Board determined that Petitioner did not establish that there was a reasonable likelihood that claim 16 would have been obvious over the combination of Frey and Baccelli alone because there was insufficient evidence that Frey expressly or inherently discloses an implant that has a longitudinal length greater than 40 mm, as required by claim 1. *Id*., 8-9, 14. In other words, according to the Board, Michelson—and not Frey—disclosed an implant that has a longitudinal length greater than 40 mm. *Id*., 9-12.

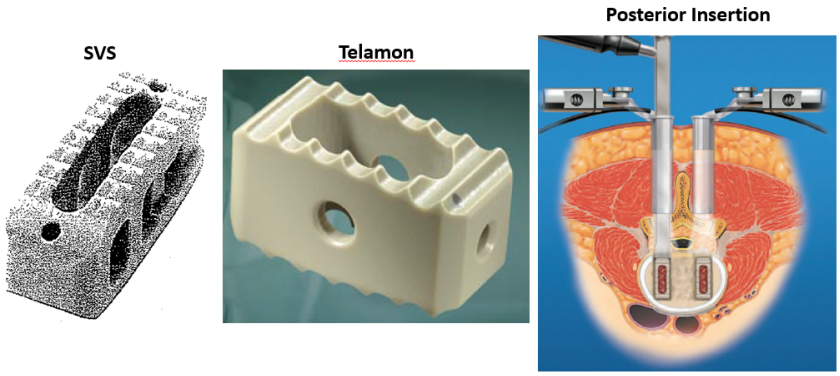
In IPR2013-00508, Medtronic sought *inter partes* review of claims 1–5, 10, 11, and 14–28. Ex. 1034. The Board instituted IPR2013-00508 (Ex. 1031) as well, and with the exception of claim 18, the Board found all challenged claims

unpatentable under § 103(a) over Baccelli, Michelson, and SVS,[1] and separately over Baccelli, Michelson, and Telamon.[2] Ex. 1031, 5, 18.

SVS discloses a radiolucent spinal implant allowing fusion to occur through the implant, measuring 22 mm long by 8 mm wide with two radiopaque markers. Ex. 1009, 1–2. Telamon discloses a radiolucent spinal implant 22–26 mm long by 10 mm wide that includes radiopaque markers. Ex. 1010, 2. Unlike Frey, Michelson, and Brantigan—all of which disclose long implants for lateral insertion (Ex. 1007, 2:56–59; Ex. 1032, 3:1–7; Ex. 1040, ¶ [0184])—SVS and Telamon are designed for posterior insertion (through the patient's back) into the spine and have a length that is less than the depth of the vertebrae:

[1] Synthes Vertebral Spacer–PR Brochure, Synthes Spine 2002 ("SVS", Ex. 1009).

[2] Medtronic Sofamor Danek, Telamon, Verte-Stack PEEK Vertebral Body Spacer, ©2003 Medtronic Sofamor Danek USA, Inc. (Ex. 1010); and Telamon, Posterior Impacted Devices, ©2003 Medtronic Sofamor Danek USA, Inc. (Ex. 1011) (collectively, "Telamon").



Ex. 1009, 1; Ex. 1010, 1; Ex. 1011, 9.

Patent Owner appealed the Board's decisions in IPR2013-00507 and IPR2013-00508, contending that "it did not receive adequate notice of or opportunity to address that reading of Michelson [pertaining to Michelson's Figures 18 and 19] and its consequences for the overall obviousness analysis." Ex. 1005, 3–5. The Federal Circuit disagreed, finding that Medtronic's IPR2013-00507 petition put Patent Owner on notice that Medtronic was relying on particular portions of Michelson to teach the long-and-narrow implant of claim 1 of the '334 patent because

> Medtronic argued that it would have been obvious to modify Frey to have a length greater than 40 mm, as taught by Michelson. But in one brief passage, Medtronic's petition went further. In pointing out that Michelson also teaches many of the '334 limitations, Medtronic stated that "[l]ike Frey, Michelson discloses example lateral fusion implants having an elongated shape" and "dimensions that are longer than wide," ***citing Michelson, col. 10, line 6,***

> ***through col. 11, line 15. J.A. 172. That cited range includes a discussion of Michelson's Figure 18***, which shows an "alternative embodiment . . . 1000 . . . similar to the spinal fusion implant 900, but [which] has a narrower width such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion within the disc space D between the adjacent vertebrae." Michelson, col. 10, lines 48–55.

Id., 5 (emphasis added). In IPR2013-00508, however, the Federal Circuit found that Medtronic's petition had no "assertion about or citation to material encompassing Michelson's Figure 18." *Id.*, 6. On that basis, the Federal Circuit found that "Medtronic's petition did not notify NuVasive of the assertions about the pertinent portions of Michelson that later became critical," and thus, "the Board's ultimate reliance on that material, together with its refusal to allow NuVasive to respond fully once that material was called out, violated NuVasive's rights under the Administrative Procedure Act." *Id.*, 3. The Federal Circuit thus affirmed the Board's final written decision in IPR2013-00507, invalidating claims 1–5, 10, 11, 14, 15, and 19–28. *Id.*, 17. With all but claims 16 and 17 resolved in IPR2013–00507, the Federal Circuit vacated the Board's decision in IPR2013-00508 and remanded for further proceedings regarding claims 16 and 17. *Id*. The parties settled and the IPR was terminated before the Board took any further action. Ex. 1023, 3-5.

VII. IDENTIFICATION OF CHALLENGES

Claim 16 should be canceled in view of the following prior art: Frey (Ex. 1040), Michelson (Ex. 1032), Berry (Ex. 1022), Brantigan (Ex. 1007), and Baccelli (Ex. 1008), which are prior art under pre-AIA § 102. Neither the combination of Frey in view of Michelson and Baccelli, nor the combination of Brantigan in view of Baccelli, Berry, and Michelson was considered during prosecution of the '334 patent or its priority applications, nor were these combinations considered in prior IPR proceedings. This Petition is supported by the testimony of Charles L. Branch, Jr., M.D. (Ex. 1002).

Petitioner presents the following grounds for trial:

- **Ground 1:** Claim 16 is rendered obvious under 35 U.S.C. § 103(a) by Frey in view of Michelson and Baccelli.
- **Ground 2:** Claim 16 is rendered obvious under 35 U.S.C. § 103(a) by Brantigan in view of Baccelli, Berry, and Michelson.

VIII. PATENT OWNER USED BRANTIGAN AND BERRY IN ITS PRIOR CHALLENGES

Patent Owner relied on Brantigan and Berry to invalidate U.S. Patent 8,251,997 to Michelson[3] ("Michelson '997") (Ex. 1021), the parent of Michelson. Michelson '997 claimed, in relevant part, "[i]nserting . . . a non-bone interbody

[3] IPR2013-00206 and IPR2013-208.

intraspinal implant … the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae [and] the length of said implant being greater than the depth of the disc space." Ex. 1019, 4–5 (ellipses in original).

In its petitions for *inter partes* review, Patent Owner represented:

> For example, Brantigan discloses a non-bone spinal implant that can be inserted "laterally" and that meets all limitations of the claimed implant after positioning, including the "length" limitation. Brantigan's implant 11 provides the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections, a maximum height between the bone engaging projections and perpendicular to the length of the implant, and the length of implant being greater than the maximum height of the implant. … In addition, Brantigan's FIG. 10 illustrates a non-bone fusion implant having been inserted laterally into a disc space, and a side-by-side comparison of figures from Brantigan (FIG. 10, which shows laterally inserted implants) and the '997 patent (FIG. 23) illustrates that Brantigan and the '997 patent are similar in lengths when implanted. … FIG. 10 of Brantigan also specifically shows an implant that has been inserted laterally. Indeed, the transverse processes indicate that the view of FIG. 10 is anterior-to-posterior, the tool insertion holes for the implant (on the trailing end)

> are shown in hidden lines on the left side, and the ridges on opposing sides of the implant extend perpendicular to lateral to prevent expulsion laterally (in the direction of insertion).

Ex. 1015, 32–33; Ex. 1014, 24–25 (same); Ex. 1016, 15 (Berry showing a POSA's knowledge in 1995); Ex. 1047, 14–15 (same). Patent Owner proved Michelson '997 unpatentable in view of, *inter alia*, Brantigan. Ex. 1017, 36; Ex. 1018, 35. Using the understanding that as it pertains to spinal fusion implants, length is measured laterally, "consistent with the direction of the insertion, from the 'insertion end' to the 'trailing end,'" the Federal Circuit affirmed. Ex. 1019, 5, 7, 9–10 ("Substantial evidence supports the PTAB's finding that Brantigan teaches an implant that spans substantially the full width of a vertebra;" "[i]n any event, the record belies Warsaw's argument that the Brantigan implants were not designed for lateral implantation.").

Patent Owner unsuccessfully appealed a jury verdict of no invalidity of Michelson under a higher clear error standard. Ex. 1035, 14, 27; Ex. 1046, 2, 5–7. Therein, Patent Owner told the Federal Circuit that "[s]everal references in the 1980s and early 1990s disclosed lateral insertion" (Ex. 1035, 15), including Brantigan. *Id.*,

51, 22. Again, Patent Owner relied on Berry to show a POSA's knowledge in 1995. *Compare* Ex. 1035, 43 *with* Ex. 1022, 364.[4]

Patent Owner's prior positions on Brantigan, Berry, and Michelson are relevant and binding. *Cardpool, Inc. v. Plastic Jungle, Inc.*, 817 F.3d 1316, 1323 (Fed. Cir. 2016) ("where a party successfully urges a particular position in a legal proceeding, it is estopped from taking a contrary position in a subsequent proceeding where its interests have changed"); *Trustees in Bankr. of N. Am. Rubber Thread Co. v. United States*, 593 F.3d 1346, 1354–56 (Fed. Cir. 2010).

IX. GROUNDS FOR TRIAL ARE NOT CUMULATIVE

This is Petitioner's first challenge to claim 16 of the '334 patent. This Petition, and the grounds presented, are not cumulative of previous challenges filed by unrelated parties, without Petitioner's input, relying on different prior art combinations. *See* Ex. 1034, 7; Ex. 1041, 7; Ex. 1042, 8. Petitioner previously filed IPR2019-00361, challenging the validity of claims 6–9 and 18 (but not claim 16) of the '334 patent on December 21, 2018. In the short period of time that has elapsed since then, the Patent Owner has not filed a preliminary response, nor has the Board issued a decision on institution in that proceeding.

[4] Joint Appendix exhibit A17071 is Berry and A17452 is Brantigan. Ex. 1012, 5.

During prosecution, the Examiner never considered the combinations relied upon here, which include (1) Frey in view of Michelson and Baccelli, and (2) Brantigan in view of Baccelli, Berry, and Michelson. Moreover, these combinations were never considered by the Board in any previously filed IPRs challenging claims of the '334 patent. *See supra* § VI.

X. CLAIM CONSTRUCTION UNDER 37 C.F.R. §§ 42.100(b), 42.104(b)(3)

For Petitions filed on or after November 13, 2018, the Board applies "the standard used in federal courts, in other words, the claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), which is articulated in *Phillips*." *See* 83 Fed. Reg. 51340, 51343 (Oct. 11, 2018). Applying *Phillips*, the challenged claims should be given their plain and ordinary meaning. Petitioner submits that no express construction is needed to resolve the issues in this Petition.

XI. DETAILED EXPLANATION UNDER 37 C.F.R. § 42.104(b)

A. The Grounds for Trial Are Based on Prior Art Patents and Printed Publications

For this Petition, the Board need not evaluate whether the '334 patent is entitled to the March 29, 2004 priority date because Petitioner's prior art qualifies as prior art even under this earliest possible filing date.

1. Brantigan is a prior art patent.

Brantigan qualifies as prior art under 35 U.S.C. § 102(b) because it issued as a patent on March 9, 1993, more than one year before the alleged priority date of the '334 patent. Ex. 1007, cover.

2. Michelson is a prior art patent.

Michelson qualifies as prior art under 35 U.S.C. § 102(b) because it issued as a patent on January 19, 1999, more than one year before the earliest claimed priority date of the '334 patent. Ex. 1032, cover.

3. Berry is a prior art printed publication.

Berry is a printed publication because it was disseminated and accessible to those of skill in the art well before March 29, 2004. Patent Owner relied on Berry to show invalidity of Michelson and its parent patent, which had effective filing dates of February 27, 1995. *Supra* § VIII; Ex. 1032, cover; Ex. 1021, cover. Patent Owner also relied on Berry in the District Court and at the Federal Circuit to establish knowledge before 1995. *See, e.g.*, Ex. 1024, 17; Ex. 1035, 43, 49–50.

Independent evidence corroborates Patent Owner's use of Barry as prior art. As evidence of the dissemination and accessibility of Berry, numerous patents and non-patent publications cite Berry. *See, e.g.*, U.S. Patent 5,127,912, which issued July 7, 1992 (Ex. 1028, cover); U.S. Patent 5,514,180, which issued May 7, 1996 (Ex. 1029, 3:40–47); Ex. 1030, 322; Ex. 1036, 5; Ex. 1037, 7. These materials are significantly before March 2004. Accordingly, Berry was a publication that was

familiar and accessible to those in the industry well before March 29, 2004 and thus it constitutes a printed publication under 35 U.S.C. §§ 102(a) & (b).

4. Baccelli is a prior art printed publication.

Baccelli qualifies as prior art under 35 U.S.C. § 102(b) because it was published on February 6, 2003, more than one year before the alleged priority date of the '334 patent. Ex. 1008, cover.

5. Frey is a prior art printed publication

Frey qualifies as prior art under 35 U.S.C. § 102(b) because it was published on November 7, 2002, more than one year before the claimed priority date of the '334 patent. Ex. 1040, cover.

B. Level of Ordinary Skill in the Art

At the time of the invention alleged in the '334 patent, a POSA "would have a medical degree with two to three years' experience performing procedures using interbody spinal fusion implants. Alternatively, a POSA would have a mechanical or biomechanical engineering degree with at least two years' experience working in developing implant devices and associated instruments with significant access to orthopedic surgeons or neurosurgeons." Ex. 1002, ¶ 18. This is based on Dr. Branch's "familiarity teaching and working with those of ordinary skill in the art as of 2004." *Id.*

C. Ground 1: Claim 16 is Rendered Obvious by Frey in View of Michelson and Baccelli.

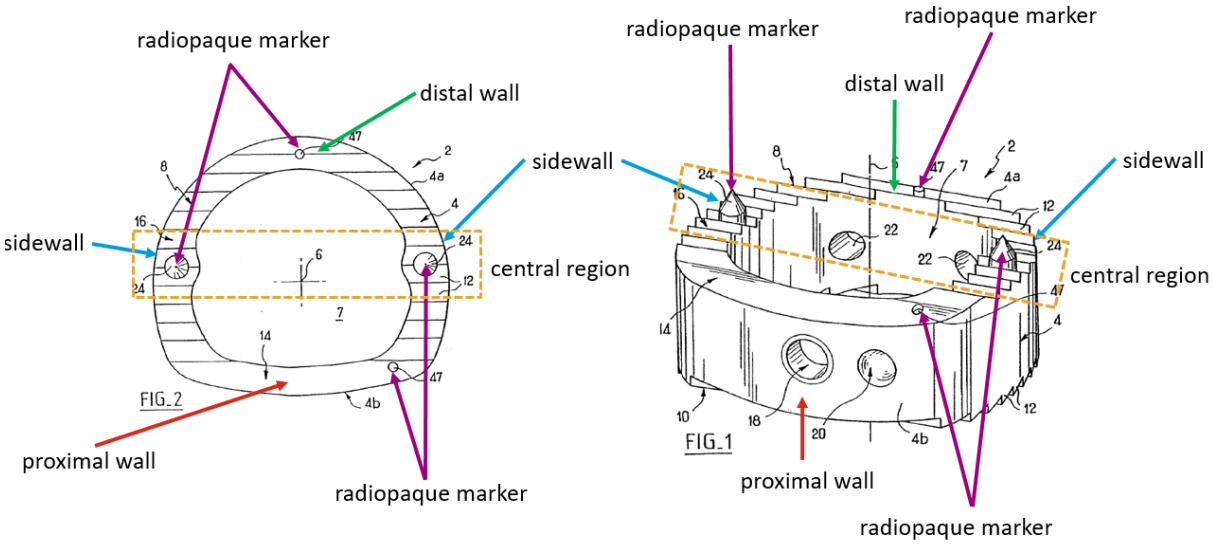
Petitioner requests cancellation of claim 16 because it would have been obvious over Frey in view of Michelson and Baccelli.

1. Motivation to Combine Frey and Michelson with Baccelli

As the Board and Federal Circuit have previously concluded, a POSA would have been motivated to combine Frey and Michelson. Ex. 1005, 14–17; Ex. 1002, ¶¶ 142–143, 147–149.

Frey explains that "[a] number of radiographic markers 1438 can be provided in implant 1400 to facilitate X-ray assessment of the locating and positioning of implant 1400 in a patient's body." Ex. 1040, ¶ [0156]. Notably, Frey does not limit the number of radiographic markers that can be included in the implant. In one example, Frey discloses "markers 1438 are provided at the midline of anterior wall 1404 at the anterior most point defined by offset portion 1434. Markers 1438 are also provided at the posterior-most points of trailing end wall 1408 and leading end wall 1406. Positioning markers 1438 at these locations provides an indication of the anterior and posterior placement of implant 1400 in the disc space, and also an indication of the lateral placement of implant 1400 in the disc space." *Id.*, *see also supra* § IV.E. Frey notes that "[a]lignment of the end wall markers 1438 in a lateral X-ray indicates proper orientation of implant 1400 in the disc space in the A-P direction." Ex. 1040, ¶[0156]; Ex. 1002, ¶ 161.

Baccelli teaches including one or more—and in particular, four— markers in a radiolucent spinal fusion implant. Baccelli's four radiopaque markers are located in each of the implant's walls, with the two markers positioned in the central region spaced apart from each other.



Ex. 1008, Figs. 1–2 (annotated); Figs. 3–5, 8, 9.

Accordingly, Baccelli instructs a POSA to include four radiopaque markers in the implant: one in the distal wall, a second in the proximal wall, a third positioned in the central region, and a fourth maker positioned in the central region at a position spaced apart from the third marker. Following Baccelli, a POSA would have been motivated to include radiopaque markers in all four walls of the radiolucent Frey lateral implant to enable surgeons to visualize the orientation and location of the implant during and after surgery. Ex. 1002, ¶ 161, 166; Ex. 1040, Figs. 55, 59. In particular, and as described in more detail below, a POSA would have found it

obvious to position markers in the middle (*e.g.*, the midline of the anterior wall and the midline of the posterior wall) of Frey's sidewalls, as well as in the leading and trailing ends of the implant, to allow surgeons to align the markers with the spinous process and the lateral ends of the vertebrae. Ex. 1002, ¶ 161. Alignment of markers at the midline of both the anterior and posterior walls in an anterior X-ray indicates proper orientation of the implant in the disc space in the sagittal plane that bisects the patient into left and right through the spinous process. *Id.*

Thus, combining the elements of Frey and Michelson with Baccelli amounts to nothing more than rearranging known mechanical elements to achieve a predictable result. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); Ex. 1002, ¶¶ 143–144, 148–150.

2. Claim 1

As explained above, on February 22, 2018, the Director cancelled claim 1, among others, because the Board determined that all limitations of claim 1 "are taught or suggested by the combination of Frey and Michelson." Ex. 1001, Inter Partes Review Certificate; Ex. 1004, 5, 13. The Federal Circuit affirmed the Board's decision. Ex. 1005, at 17. Thus, Patent Owner is precluded from taking any "action inconsistent with the adverse judgment," including obtaining any claims that are "not patentably distinct from a finally refused or canceled claim." *See* 37 C.F.R. § 42.73(d)(3)(i); *MaxLInear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir.

2018) (citing *B&B Hardware, Inc. v. Hargis Indus., Inc.*, -- U.S. --, 135 S. Ct. 1293 (2015)). Patent Owner is therefore estopped from arguing that claim 1 renders any dependent claim patentable over Frey and Michaelson as those references have been definitively established as rendering claim 1, among others, unpatentable. *The Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) ([I]t is the identity of the issues that were litigated that determine whether collateral estoppel should apply. … If the differences between the unadjudicated patent claims and the adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies.").

The further focus of the discussion of this Ground 1, therefore, will be on the language of claim 16.

3. Claim 16

a. "The spinal fusion implant of claim 1, further comprising a fourth radiopaque marker situated within said implant, said fourth radiopaque marker positioned in said central region at a position spaced apart from said third radiopaque marker."

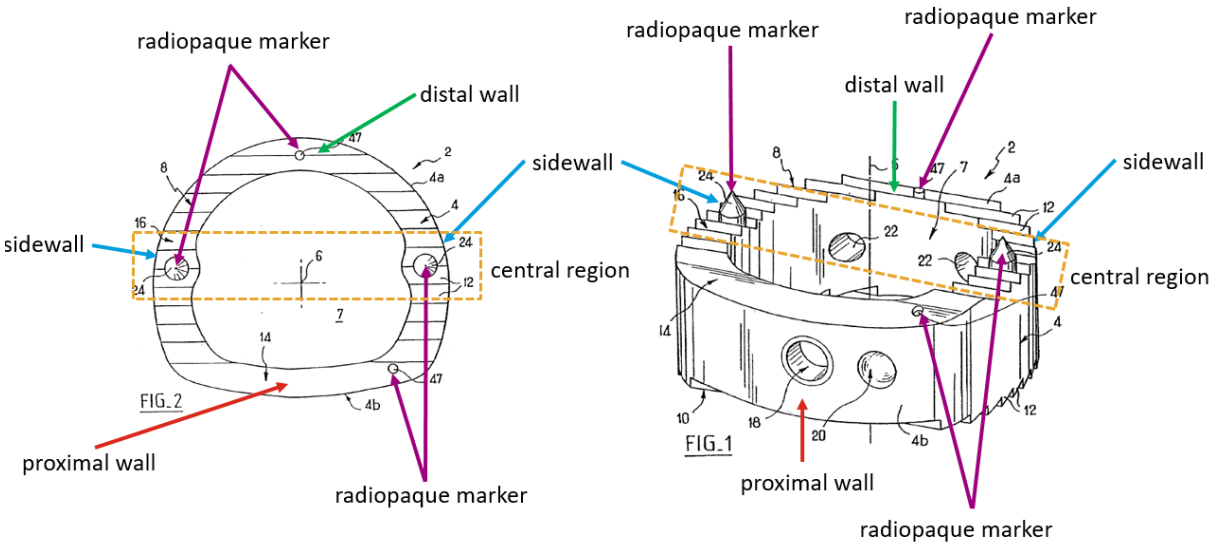
Frey and Michelson render obvious the implant of claim 1. *Supra* § XI.C.2.

Baccelli describes a spinal fusion implant ("cage") that includes four radiopaque markers: one at least partially positioned in the distal wall, a second at least partially positioned in the proximal wall, a third at least partially positioned in the central region, and a fourth positioned in the central region at a position spaced

apart from the third radiopaque marker. Ex. 1002, ¶¶ 162–164; Ex. 1008, [0041], [0050]–[0051]. In particular, Baccelli's spinal fusion implant

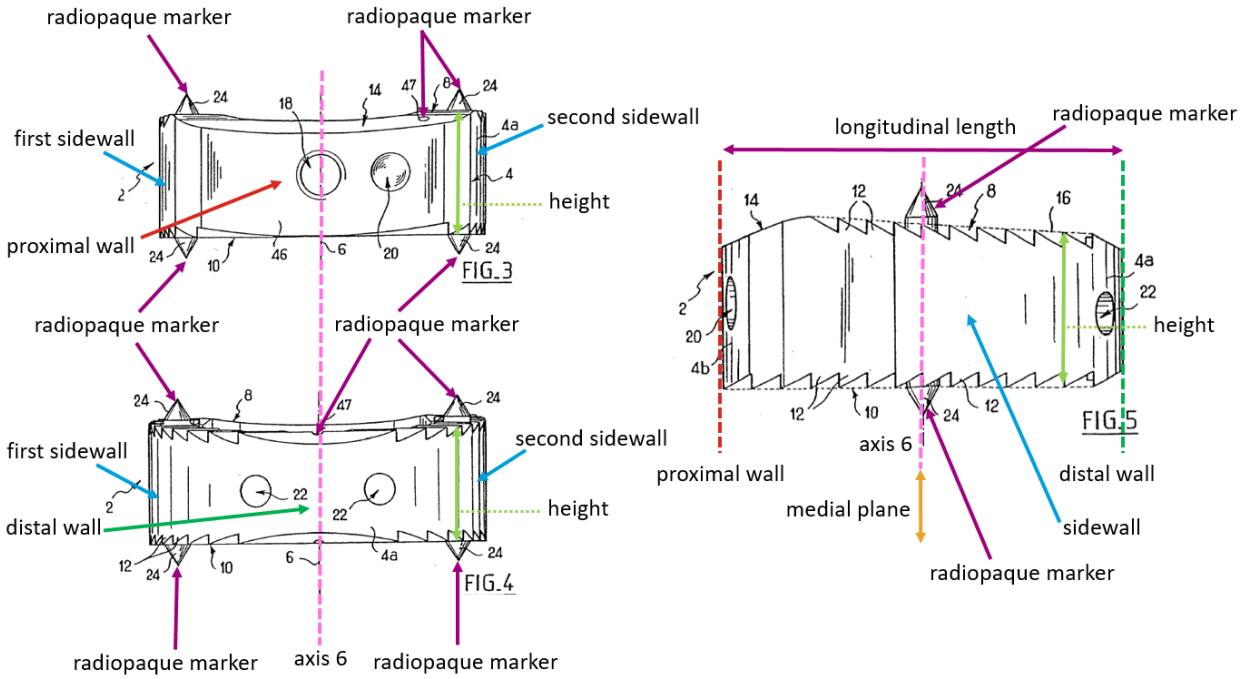
> can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or the presence of the implant when X-rays are taken during or after the operation. They could be made of titanium or of titanium alloy. In this case, there are two markers 47 and they are constituted by wires inserted in rectilinear ducts parallel to the axis 6 and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall. The spikes 24 can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays.

Ex. 1008, [0050]–[0051], Figs. 1–5, 8, 9. Baccelli discloses extending the radiopaque markers (24) and spikes (47) into the proximal and distal walls, as well as the sidewalls in the central region. Ex. 1002, ¶ 163. Thus, Baccelli discloses the fourth radiopaque marker (24) positioned within the implant in the central region at a position spaced apart from the third radiopaque marker. Ex. 1002, ¶ 162.



Ex. 1008, Figs. 1–2 (annotated); *see also* Figs. 3–5, 8, 9.

As illustrated below (annotated Figure 3), Baccelli discloses a proximal wall (4b) including "mounting orifice 18" for "threaded engagement" with "fitting tool 40" as shown in Figures 8 and 9. Ex. 1002, ¶ 165; Ex. 1008, [0044], Figs. 3, 8–9. Baccelli discloses a distal wall (4a) opposite the proximal wall (annotated Figure 4). Ex. 1008, Fig. 4; Ex. 1002, ¶ 165. Baccelli further discloses a first and second sidewall generally opposite the first side walls extending between the proximal and distal walls (annotated Figure 5). Ex. 1002, ¶ 165.



Id., Figs. 3–5 (annotated).

As shown above, Baccelli's radiopaque markers (47) and spikes (24) are oriented parallel to the height of the implant along central axis 6. Ex. 1008, [0041], Figs. 3–5; Ex. 1002, ¶ 165. Baccelli discloses that the radiopaque spikes 24 "are disposed symmetrically to each other about the sagittal midplane," defined as the plane parallel to axis 6 and perpendicular to the front (proximal) wall 4b. Ex. 1008, [0036], [0041], [0050]–[0051], Figs. 3–5; Ex. 1002, ¶ 165. The spikes also "extend in the frontal midplane containing axis 6." Ex. 1008, [0041]; Ex. 1002, ¶ 165. Because the spikes "can be inserted and fixed rigidly in the ducts" (Ex. 1008, [0050]–[0051]), a POSA would have understood that the radiopaque markers extend into the central region including the first and second sidewalls, respectively. Ex. 1002, ¶ 165. Baccelli further explains that "two markers 47 [] are constituted by

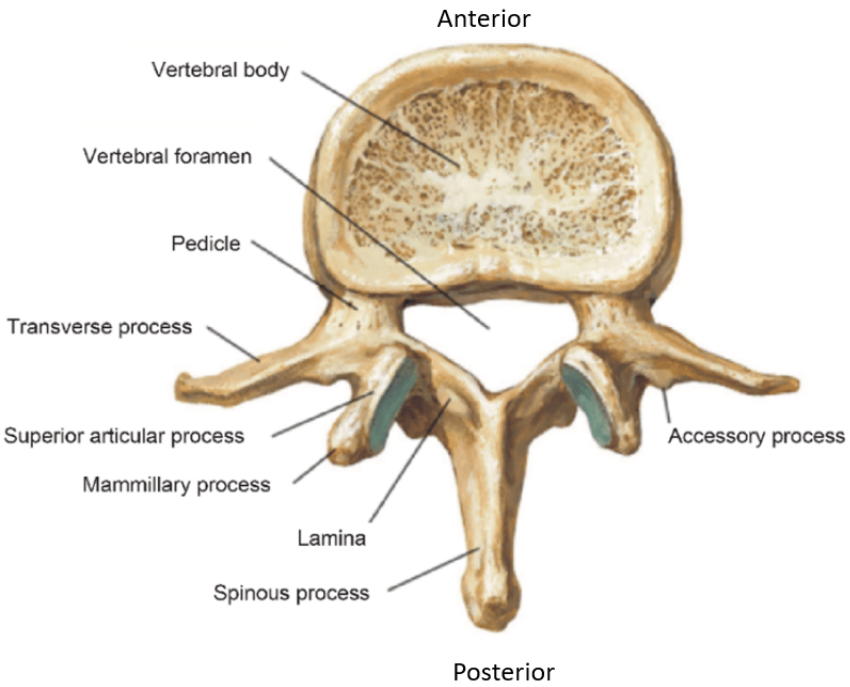
wires inserted in rectilinear ducts parallel to the axis 6 and formed in the wall of the cage." Ex. 1008, [0050]; Ex. 1002 ¶ 165. Because the markers are inserted in rectilinear ducts, the markers extend into the distal wall and proximal wall, respectively. Ex. 1002, ¶ 165.

As described above, Frey describes a number of radiopaque markers in an implant. *Supra* § XI.C.1; Ex. 1040, ¶ [0156]. In one example, Frey explains how "markers 1438 are provided at the midline of anterior wall 1404 at the anterior most point defined by offset portion 1434. Markers 1438 are also provided at the posterior-most points of trailing end wall 1408 and leading end wall 1406. Positioning markers 1438 at these locations provides an indication of the anterior and posterior placement of implant 1400 in the disc space, and also an indication of the lateral placement of implant 1400 in the disc space." *Id.* According to Frey, "[a]lignment of the end wall markers 1438 in a lateral X-ray indicates proper orientation of implant 1400 in the disc space in the A-P direction." *Id.*

Thus, it would have been obvious to a POSA to add a fourth radiopaque marker, like Baccelli teaches, to the Frey implant to give surgeons additional information. Ex. 1002, ¶ 161. For example, with the fourth radiopaque marker a surgeon could evaluate alignment of markers at the midline of both the anterior and posterior walls in an anterior X-ray indicates proper orientation of the implant in the

disc space in the sagittal plane that bisects the patient into left and right through the spinous process. *Id*.

Thus, adding Baccelli's radiopaque markers to Frey's proximal, distal, and side walls would have allowed surgeons to see in an anterior-to-posterior (front) X-ray whether and to what degree the implant is askew relative to the spinous process and the lateral edges of the vertebrae during and after lateral insertion. Ex. 1002, ¶ 166. A lateral (side) X-ray of the same implant would allow the surgeon to identify the position of the posterior sidewall of Frey relative to the posterior edge of the vertebral body (bordering the spinal canal) and the anterior sidewall of Frey relative to the anterior edge of the vertebral body (bordering the aorta and vena cava).



Ex. 1002, ¶ 166.

Accordingly, Frey in view of Michelson and Baccelli renders obvious claim 16. Ex. 1002, ¶ 168.

D. Ground 2: Claim 16 is Rendered Obvious by Brantigan in View of Baccelli, Berry, and Michelson

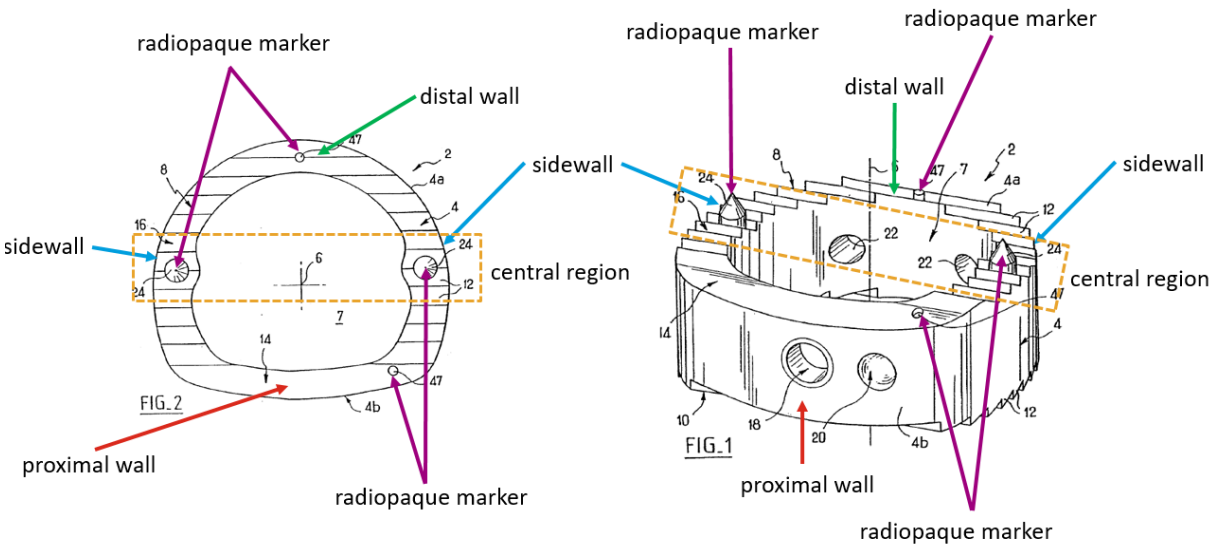
1. Motivation to Combine Brantigan with Baccelli, Berry, and Michelson

A POSA would have been motivated to combine Brantigan with Baccelli, Berry, and Michelson. Brantigan discloses spinal fusion implants for insertion between adjacent vertebrae composed of "rigid biologically acceptable and inactive material, preferably a radiolucent plastics material." Ex. 1007, 4:3–4. Long before the '334 patent, Brantigan disclosed spinal fusion implants that "can be introduced anteriorly, ***laterally*** or posteriorly depending upon conditions and the tool receiving recesses 13 and 23 of the plugs 11 and 21 can thus be positioned to meet the particular type of insertion into the vertebral column." *Id.*, 5:30–35 (emphasis added). Brantigan's implants have "medial-lateral [side to side] and anterior-posterior [front to back] dimensions in the same ratio as normal vertebral bodies" that "conform with the general outline perimeter of the vertebrae" and are "generally shaped and sized to conform with the disc space between adjoining vertebrae." *Id.*, 1:20–21, 2:2–4, 4:6–7. Once inserted laterally into the interbody space, the length of a Brantigan spinal fusion implant spans the full transverse width of the vertebra such that its sidewalls are located along the anterior and posterior portions of the

vertebra. *Id.*, Figs. 8, 10. A POSA would have known the average dimensions of the human vertebrae before March 2004 because that information was reported decades earlier by Berry, for example.

Brantigan's spinal fusion implant is radiolucent and transparent to X-rays. Ex. 1002, ¶ 172; Ex. 1008, [0050]. Brantigan does not, however, mention radiopaque markers in the proximal and distal walls or the central region of the implant. Without radiopaque markers, surgeons would have difficulty identifying the location of the implant during and after surgery. Ex. 1002, ¶ 172.

Baccelli teaches including one or more—and in particular, four— markers in a radiolucent spinal fusion implant. "[B]ecause they are opaque to X-rays," the markers enable surgeons "to identify the position and/or presence of the implant when X-rays are taken during or after the operation." Ex. 1008, [0050]. Baccelli teaches "markers 47" and "spikes 24 [that] can be inserted and fixed rigidly in the ducts formed in the cage" that "too can be made of a material that is radiopaque to X-rays." *Id.*, [0050]–[0051]. Baccelli's four radiopaque markers are located in each of the implant's walls, with the two markers positioned in the central region spaced apart from each other.



Ex. 1008, Figs. 1–2 (annotated); Figs. 3–5, 8, 9.

Accordingly, Baccelli instructs a POSA to include four radiopaque markers in the implant: one at least partially positioned in the distal wall, a second at least partially positioned in the proximal wall, a third at least partially positioned in the central region, and a fourth maker positioned in the central region at a position spaced apart from the third marker. Following Baccelli, a POSA would have been motivated to include radiopaque markers in all four walls of the radiolucent Brantigan lateral implant to enable surgeons to visualize the orientation and location of the implant during and after surgery, including, for example, alignment with the spinous process and the lateral ends of the vertebrae as discussed in more detail below. Ex. 1002, ¶ 173; Ex. 1007, Figs. 8, 10; *infra* § XI.D.3.

Michelson explains the benefits associated with lateral insertion of the Brantigan implant: increased safety, decreased patient discomfort, and increased

structural support that an "oversized" implant provides. Ex. 1032, Abst., 2:19–67, 3:56–4:24, 10:20–59, Figs 18–19; Ex. 1002, ¶ 175. According to Michelson, these benefits can be accomplished by inserting the long-and-narrow implant of Figures 18–19 modularly, allowing a narrower implant to be inserted through a hollow tube, thereby decreasing patient surgical discomfort by reducing incision size. *Id*; Ex. 1032, 10:20–59, Figs. 18–19.

To achieve the benefits of Michelson, a POSA would have been motivated to make Brantigan's laterally-inserted lumbar spinal fusion implants "narrower" for insertion in a modular fashion through a hollow tube to increase patient safety and minimize invasiveness. *Id.*; Ex. 1032, 3:61–65. Coupled with Berry's "direct dimensional measurements" of lumbar vertebrae (Ex. 1022, 364, Table 1), a POSA would have been motivated to reduce the width by half (for example) to make the implants modular, while maintaining the overall length that provides enhanced structural support. *See, e.g.*, Ex. 1032, 10:20–59, Figs. 18–19; Ex. 1002, ¶ 176.

Further, a POSA would have had a reasonable expectation of success to combine Brantigan with Baccelli, Berry, and Michelson to size a long-and-narrow radiolucent interbody implant for lateral insertion, locate the radiopaque markers in the proximal wall, the distal wall, and the central region of the implant, and use an X-ray to determine the location and orientation of the implant because the ability to

see radiopaque markers in a radiolucent implant in an X-ray was known and the consequences were predictable. Ex. 1002, ¶ 177.

2. Claim 1

a. "A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:"

Brantigan discloses "a spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra." Ex. 1002, ¶¶ 178–184.

Brantigan's implants are for spinal fusion: "[s]urgical prosthetic modular implants used singularly or stacked together are provided to support and fuse together adjacent vertebrae." Ex. 1007, Abst., 1:44–47, 1:7–12; Ex. 1002, ¶¶ 96, 181. In particular, Brantigan's "biologically acceptable, but inert rigid annular prosthesis units are provided to support and fuse with adjacent vertebrae in both the cervical, thoracic spine and lumbar portions of a human vertebral column." Ex. 1007, 1:64–68.

Brantigan's implants are constructed of non-bone material. Ex. 1002, ¶ 182. The spinal fusion "implants are preferably made of radiolucent material such as carbon fiber reinforced polymers known commercially as 'Peek', (polyetherether ketone) or 'Ultrapek' (polyether ketone, ether ketone, ketone)." Ex. 1007, 3:9–12; Ex. 1002, ¶ 182.

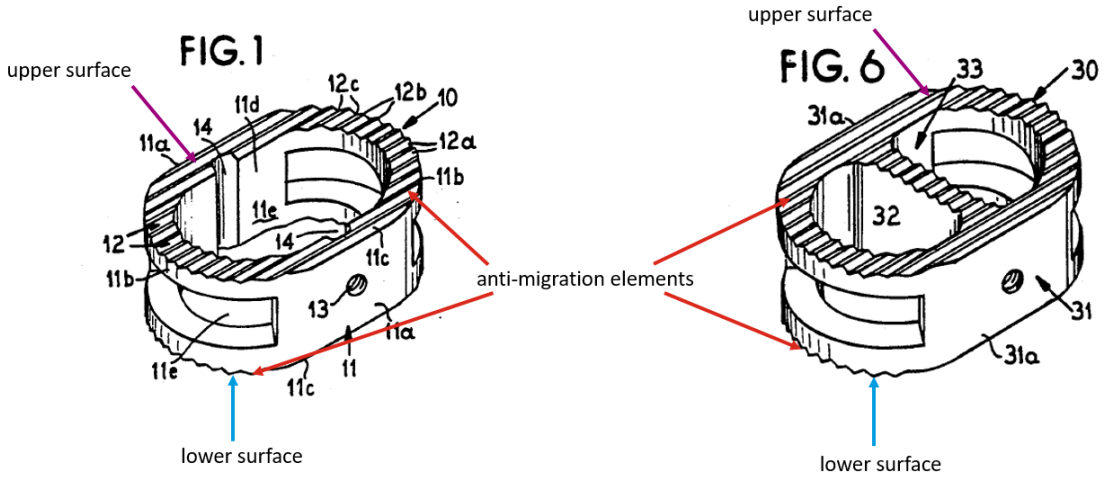
Brantigan's implants are positionable within an interbody space between adjacent vertebra. Ex. 1002, ¶ 181. "The rings are bottomed on the opposing end faces of adjoining vertebrae" and "are supplied in different heights to be used individually to replace a single damaged intervertebral disc." Ex. 1007, 1:18–29, 2:20–23. "To accommodate a myriad of different heights between vertebrae on which the prosthesis ring is to be bottomed, the rings can be supplied in sets of different heights to be stacked to the exact height required for a particular surgical implant." *Id.*, 2:34–38. The height between adjoining vertebrae occupied by the intervertebral disc to be replaced is known as the "interbody space." Ex. 1002, ¶ 32.

Moreover, Patent Owner previously told the Board that "Brantigan's FIG. 10 illustrates a non-bone fusion implant having been inserted laterally into a disc space." Ex., 1015, 32.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 184.

b. "an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space,"

Brantigan's "flat, ridged top and bottom faces" are upper and lower surfaces including anti-migration elements to contact the adjacent vertebra when the implant is positioned within the interbody space:



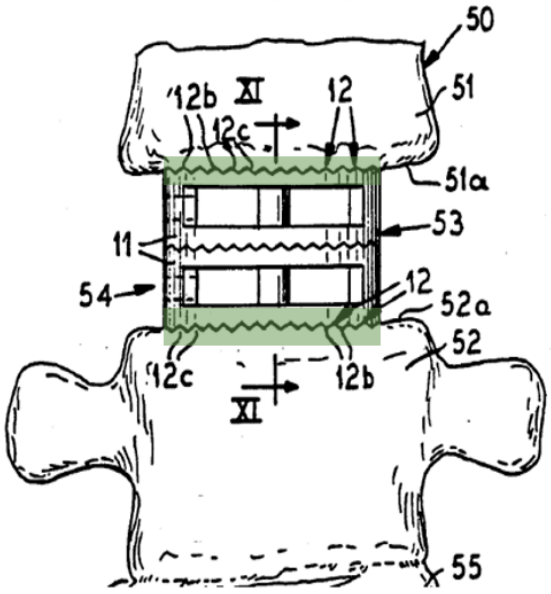
Ex. 1007, Figs. 1 (annotated), 6 (annotated), 4:8–10; Ex. 1002, ¶¶ 186–187.

"The plug 11 has opposed sides 11*a* and ends 11*b*, flat, ridged top and bottom faces 11c and a central upstanding aperture 11*d* therethrough." Ex. 1007, 4:5–10. Brantigan's "[r]idges 12 are formed longitudinally across the end faces 11*c*. These ridges 12 have inclined side walls 12*a* merging at sharp peaks 12*b* and provide valleys 12*c* between the side walls." *Id.*, 4:15–18.

Brantigan explains that "ridges on the exposed end faces of the stacks of plugs will bottom on the hard end faces or end plates of the adjacent vertebrae and the apices or peaks 21b and 22g of these ridges will firmly engage and bite into these faces to prevent slippage." *Id.*, 5:22–26. "[T]he top ridges 12 of the stack are bottomed on and bite into the bottom face or hard end plate of the upper vertebrae 51 while the bottom ridges 12 of the stack are bottomed on and bite into the upper face or hand end plate 52*a*. The ***peaks 12b of the ridges 12 firmly anchor the stack***

to the vertebrae but do not penetrate through the hard faces 51*a* and 52*a* of the vertebrae":

FIG. 10



Id., 6:5–16 (emphasis added), Fig. 10 (annotated).

Brantigan's implants can be used "singly or stacked together between vertebrae," but the anti-migration ridges are present on the upper and lower surfaces regardless of whether the implants are used singly or stacked. *Id.*, 1:14–15, Figs. 6, 8; Ex. 1002, ¶ 191. For this reason, Patent Owner previously told the Board that Brantigan has "opposed surfaces having bone engaging projections" and "a maximum height between the bone engaging projections." Ex. 1014, 24; Ex. 1015, 32–33; Ex. 1002, ¶ 192.

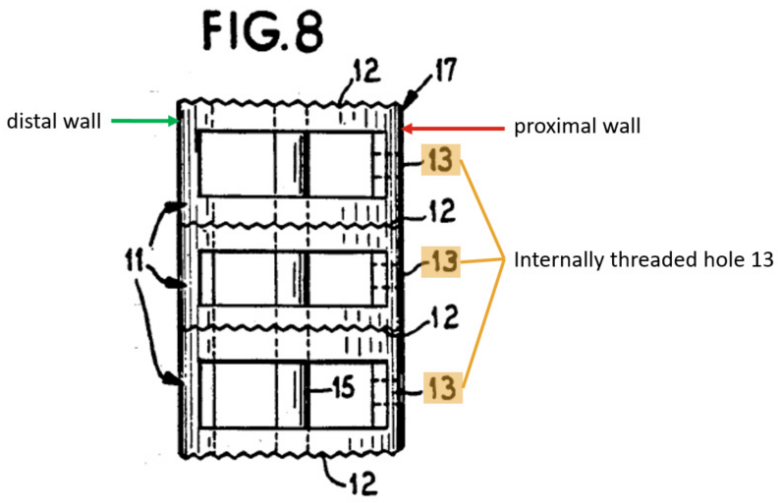
Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 193.

c. "a distal wall, a proximal wall, a first sidewall, and a second sidewall,"

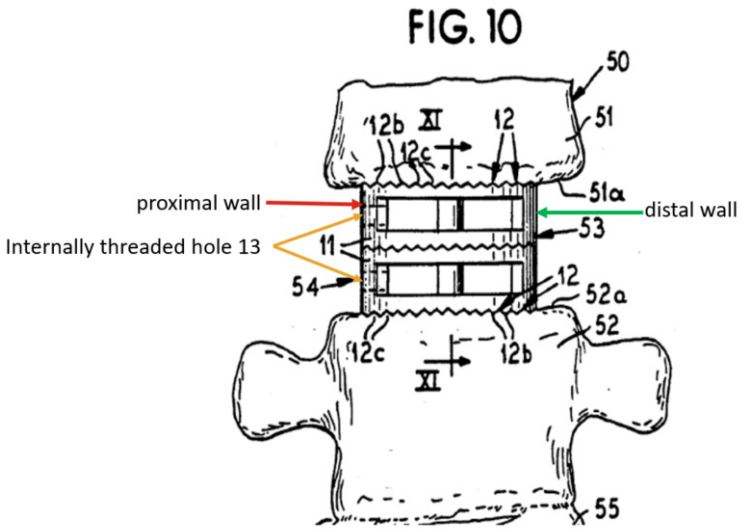
Brantigan discloses distal, proximal, first, and second sidewalls. Ex. 1002, ¶¶ 194–201.

Brantigan's "plugs can be introduced anteriorly, ***laterally***, or posteriorly depending upon conditions and the tool receiving recesses 13 and 23 of the plugs 11 and 21 can thus be positioned to meet the particular type of insertion into the vertebral column." Ex. 1007, 5:30–35 (emphasis added), 2:59–66 (plugs "can be "inserted ... laterally into the vertebral column while mounted on the end of an insertion tool"). "One side wall 11*a* of the plug 11 has an internally threaded hole 13 extending partially through the wall for receiving a mounting tool." *Id.,* 4:20–22. The wall of an implant containing the threaded insertion hole or recess for receiving a mounting tool is referred to as the "proximal wall" or "trailing end" of the implant. Ex. 1002, ¶ 196; Ex. 1019, 5. Opposite the proximal wall is the "distal wall"—the wall of the implant that is inserted into the disc space first, also called the "leading end." Ex. 1002, ¶ 196.

Figure 8 of Brantigan illustrates a stack 17 of plugs 11 with threaded insertion holes 13 in the proximal walls of the implants opposite the distal walls:



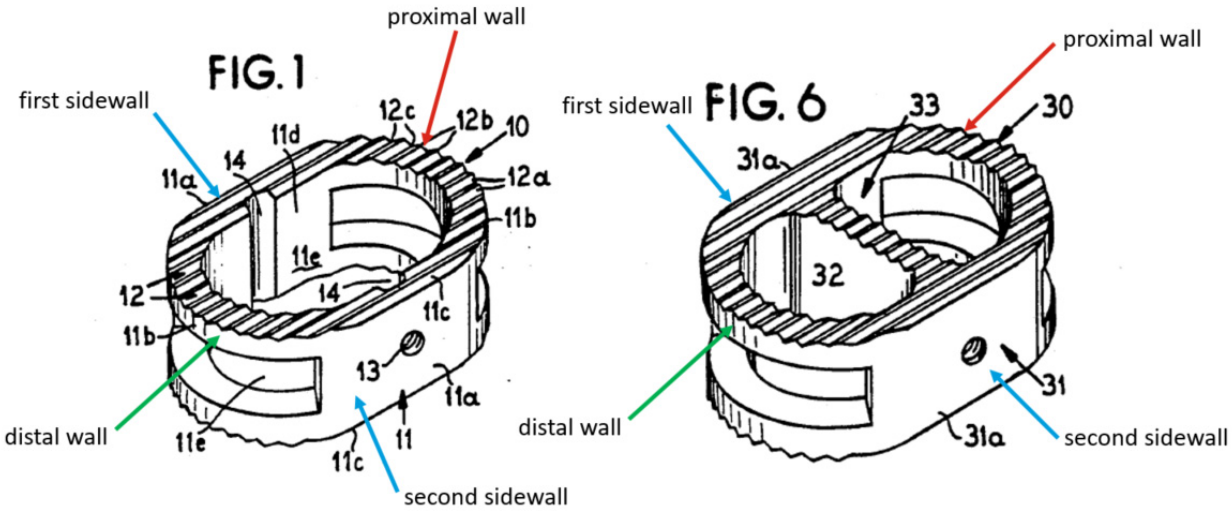
Ex. 1007, Fig. 8 (annotated); Ex. 1002, ¶ 197. The plugs 11 of Figure 8 are shown inserted laterally in the disc space between adjacent vertebrae in Figure 10:



Ex. 1007, Fig. 10 (annotated). As seen above, the threaded insertion holes are visible on the left side of laterally-inserted plug 11. *Id.* In Figure 10, the first sidewall is visible in the anterior portion of the vertebra and extends between the proximal and distal walls. *Id.*, Fig. 10; Ex. 1002, ¶ 198. The second sidewall is not visible in the

figure, but extends between the proximal and distal walls along the posterior portion of the vertebra. Ex. 1002, ¶ 198.

Brantigan further describes the distal, proximal, first, and second sidewalls in greater detail. Ex. 1007, 4:5–10. Brantigan's "opposed sides 11*a*" of the "oval shaped" spinal fusion implants are the first and second sidewalls. *Id.*; Ex. 1002, ¶ 200. Further, Brantigan's second sidewall of the "oval shaped" spinal fusion implant is generally opposite the first sidewall. Ex. 1007, 4:5–10; Ex. 1002, ¶¶ 200–201. Brantigan's "ends 11*b*" are a distal wall and a proximal wall. Ex. 1007, 4:5–10; Ex. 1002, ¶ 200. The following annotated figures illustrate the location of the first and second sidewalls, as well as the distal and proximal walls, when the tool receiving recess 13 is oriented in the proximal sidewall as taught in Figures 8 and 10. *See* Ex. 1007, 5:30–35, 6:61–7:6.



Ex. 1007, Figs. 1 (annotated), 6 (annotated).

Patent Owner relied on these Brantigan disclosures to invalidate Michelson '997: "[T]he transverse processes indicate that the view of FIG. 10 is anterior-to-posterior, the tool insertion holes for the implant (on the trailing end) are shown in hidden lines on the left side, and the ridges on opposing sides of the implant extend perpendicular to lateral to prevent expulsion laterally (in the direction of insertion)." Ex. 1014, 25; Ex. 1015, 33.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 201.

d. "said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;"

Brantigan discloses a distal wall, proximal wall, and first and second sidewalls as explained above. *Supra* § XI.D.2.c.

Brantigan's "implants are preferably made of radiolucent material such as carbon fiber reinforced polymers known commercially as 'Peek', (polyetherether ketone) or 'Ultrapek' (polyether ketone, ether ketone, ketone)." Ex. 1007, 3:9–12; Ex. 1002, ¶ 203.

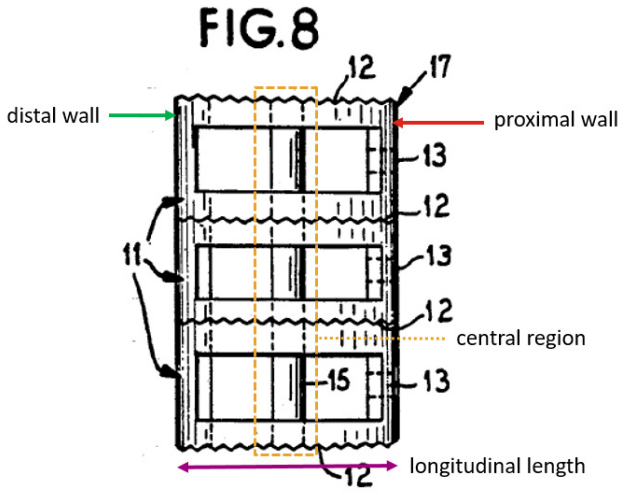
Accordingly, Brantigan discloses this limitation. *Id.*

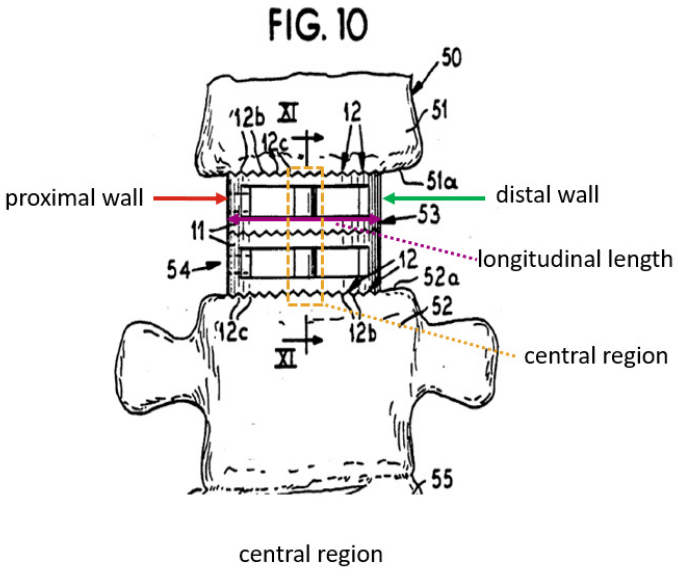
e. "wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall,"

Brantigan discloses a distal wall and a proximal wall. *Supra* § XI.D.2.c.

The following annotated versions of Brantigan Figures 8 and 10 show the longitudinal length of the laterally-inserted Brantigan implant that extends from the

proximal end of the proximal wall (with threaded insertion hole 13) to the distal end of the distal wall:





Ex. 1007, Figs. 8 (annotated), 10 (annotated); Ex. 1002, ¶ 206.

Brantigan further discloses an implant with a longitudinal length that is greater than 40 mm. Ex. 1002, ¶ 204; Ex. 1019, 6–9 (Federal Circuit affirming Brantigan's length is sized to occupy substantially the full transverse width of the vertebral bodies of two adjacent vertebrae). Brantigan's implants are provided for use in the

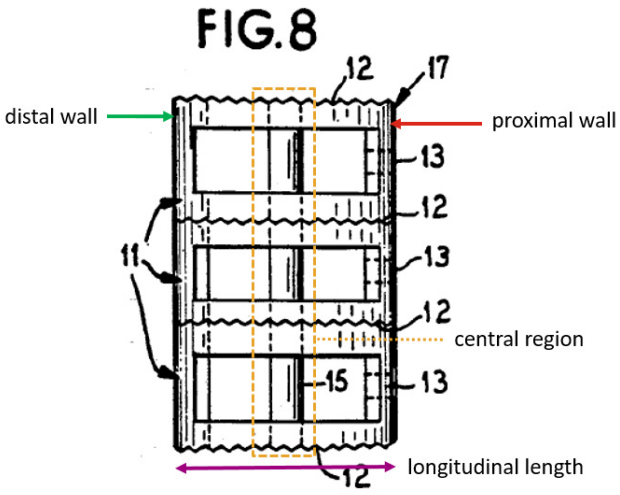
lumbar spine (Ex. 1007, 1:65–68) and are "generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column" (*id.*, 4:5–8, 2:2–4), "with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies" (*id.*, 1:20–21). As Berry disclosed, the longitudinal length would be "greater than 40 mm" for lumbar vertebrae L1 through L5. Ex. 1022, 364, Table 1; Ex. 1002, ¶ 210.

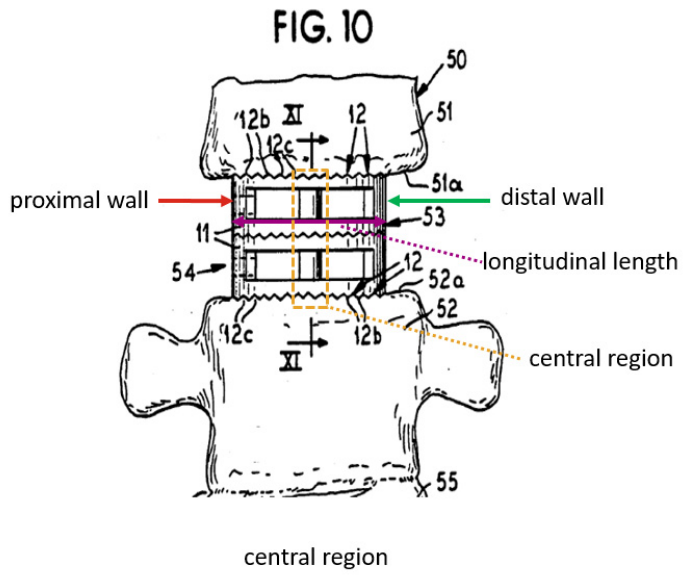
Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 211.

f. "wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall;"

Brantigan discloses a central region that includes portions of the first and second sidewalls positioned centrally between the proximal and distal walls that defines a maximum lateral width between the first and second sidewalls. Ex. 1002, ¶¶ 212–215.

The following annotated versions of Brantigan Figures 8 and 10 show the central region of the implant that includes portions of the first and second sidewalls positioned centrally between the proximal and distal walls:



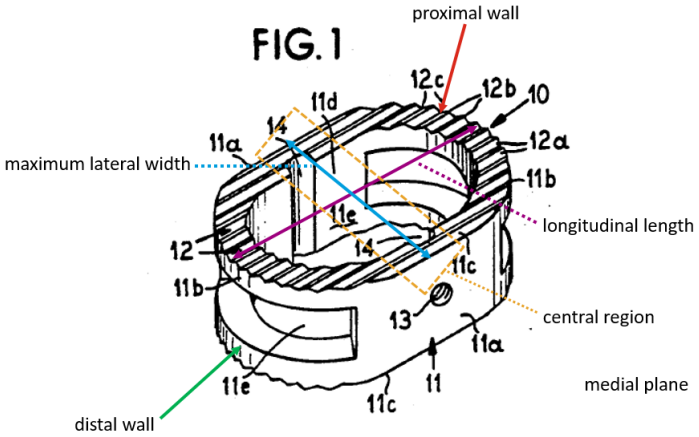


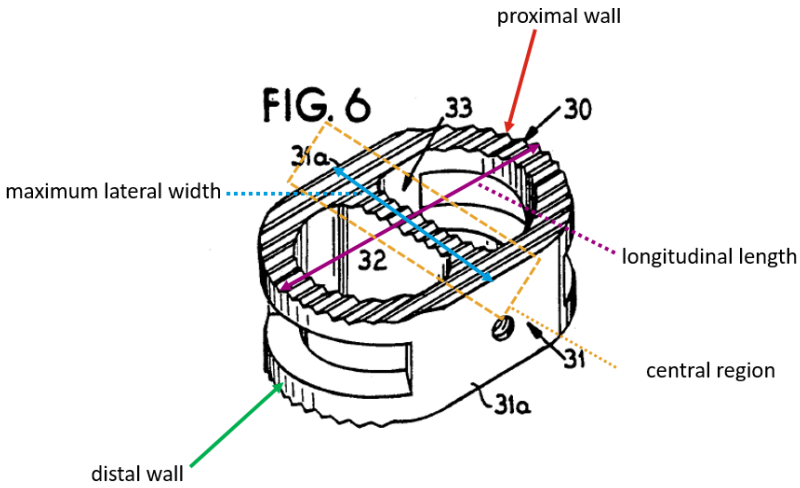
central region

Ex. 1007, Figs. 8 (annotated), 10 (annotated); Ex. 1002, ¶ 213; *see also supra* § XI.D.2.c.

Brantigan further discloses a maximum lateral width extending from the first sidewall to the second sidewall in the central region. Ex. 1002, ¶ 214. As shown above, "the central aperture 11*d* of each plug 11 is separated by the bar 15 into two side-by-side chambers." *Id.* ¶ 214; Ex. 1007, 4:50–53. "Instead of providing a separate bar or plate 15, as shown in FIG. 6 [annotated below], a modified device 30

of this invention is a plug 31 of the same oval shape as the plug 11 of FIGS. 1 [annotated below] and 4 but the reinforcing bar 32 of this plug is integral with its side walls 31*a*. The hollow interior 23 [sic] of the plug 31 is thus ***bisected*** by an integral internal partition 32 forming a pair of side-by-side apertures through the plug." Ex. 1007, 5:36–43 (emphasis added).





Ex. 1007, Figs. 1 (annotated), 6 (annotated); Ex. 1002, ¶ 214. Brantigan, therefore, discloses that connecting bar 15 and reinforcing bar 32 (visible, *e.g.*, in Figure 10) run along the central region positioned generally centrally between the proximal and

distal walls. Ex. 1002, ¶ 215. Because Brantigan discloses implants that "are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies," Brantigan has a maximum lateral width extending from the first sidewall to the second sidewall in the central region that is located centrally between the proximal and distal walls. Ex. 1002, ¶ 215; Ex. 1007, 1:19–21.

Accordingly, Brantigan discloses this limitation. *Id*.

g. "said longitudinal length is at least two and half times greater than said maximum lateral width"

Brantigan discloses an implant with a longitudinal length that is greater than 40 mm. *Supra* § XI.D.2.e; Ex. 1002, ¶ 204; Ex. 1019, 6–9 (Federal Circuit affirming Brantigan's length is sized to occupy substantially the full transverse width of the vertebral bodies of two adjacent vertebrae). Brantigan in view of Berry and Michelson further disclose that the length is at least two and a half times greater than the maximum lateral width. Ex. 1002, ¶¶ 216–227. A POSA would have been motivated to modify the width of the Brantigan implant, which has "medial-lateral and anterior-posterior dimensions in the same ratios as normal vertebral bodies" (Ex. 1007, 1:20–21) according to Michelson's express teaching to make the implant "narrower" so that they "may be combined in a modular fashion for insertion within the disc space D between adjacent vertebrae." Ex. 1032, 10:50–55. A narrower implant for lateral insertion would be easier to fit within the hollow tube Michelson

describes to facilitate insertion into the disc space. *See, e.g.*, Ex. 1032, 3:61–65; Ex. 1002, ¶ 221.

Michelson discloses the same modularity concept Brantigan describes. In particular, Brantigan discloses spinal fusion implants that are "preferably hemi-oval" in a partial-annular "shape to accommodate those surgical procedures where only a portion of the vertebrae or disc is damaged." Ex. 1007, 2:4–7. According to Brantigan, "[t]wo such hemi-oval rings can be used in the posterior lumbar area in side-by-side relation since the dural sac and nerve roots must be retracted to each side in turn as the implant is placed on the opposite side." *Id*., 2:7-11. Thus, Brantigan teaches modifying the width in the direction of insertion of a spinal fusion implant in the same way Michelson teaches. *See, e.g.*, Ex. 1032, 10:50–55.

Both Brantigan and Michelson are directed to, *inter alia*, laterally-inserted implants that are sized to span the full transverse width of the lumbar vertebra. *See* Ex. 1007, 1:18–21, 1:65–68, 2:2–4, 2:55–66, 4:5–8, 5:30–35; Ex. 1032 at 3:1–10, 3:35–53, cl. 1. Michelson further discloses exemplary embodiments: "spinal fusion implant 900" has "a length in the range of 32 mm to 50 mm" and "a width that approximates the depth of the vertebrae." Ex. 1032, 10:32–47. Additionally, Michelson teaches "spinal fusion implant 1000 [that] is similar to the spinal fusion implant 900, but has a narrower width such that more than one spinal fusion implant

1000 may be combined in a modular fashion for insertion within the disc Space D between the adjacent vertebrae." *Id.*, 10:48–59, Figs. 18–19.

Michelson provides a range of preferred dimensions of length, height, and width of spinal fusion implant 900, but does not specify what region of the lumbar spine those dimensions pertain to. Ex. 1002, ¶ 225. Thus, in modifying Brantigan in view of Michelson's long-and-narrow modular teaching for a fusion between L4 and L5, for example, a POSA would have referred to Berry, which teaches "direct dimensional measurements" of human vertebrae. Ex. 1022, 362–364; Ex. 1002, ¶¶ 176, 225. In particular, Berry teaches mean widths ranging from 31.9 mm at L1 to 35.1 mm at L5, half of which as taught by Michelson would be 15.95 mm[5] at L1 and 17.55 mm[6] at L5. Ex. 1022, 362–364, Table 1; Ex. 1002, ¶ 226. Applying the standard deviations reported in Berry, a POSA would have been motivated to modify Michelson's long-and-narrow implants to have widths ranging from 14.1 mm[7] L1 to 18.95 mm[8] for L5. Ex. 1002, ¶ 226. For instance, a POSA performing a fusion between L4 and L5 vertebrae would have modified a Brantigan implant per the

[5] Calculated as 31.9 mm / 2 = 15.95 mm.

[6] Calculated as 35.1 mm / 2 = 17.55 mm.

[7] Calculated as (31.9 mm – 3.7 mm) / 2 = 14.1 mm.

[8] Calculated as (35.1 mm + 2.8 mm) / 2 = 18.95 mm.

teachings of Michelson, to have widths ranging from 16.15 mm to 18.95 mm. Ex. 1022, 364, Table 1; Ex. 1002, ¶ 227. Thus, a POSA would have been motivated to design an L5 spinal fusion implant that was "approximately 18 mm wide." Ex. 1001, cl. 18.; Ex. 1002, ¶ 227. Consistent with Michelson, Berry teaches mean transverse widths of L4 (lower surface) and L5 (upper surface) to be 50.9 mm and 53.4 mm, respectively. Ex. 1022, 364, Table 1; Ex. 1002, ¶ 227. Applying the standard deviations of Berry, an implant for spinal fusion between L4 and L5, therefore, would be at least 46.3 mm in longitudinal length, which is more than two and a half times greater than approximately 18 mm in maximum lateral width. Ex. 1002, ¶ 227.

Accordingly, Brantigan, Berry, and Michelson disclose this limitation. *Id.* ¶¶ 216–227.

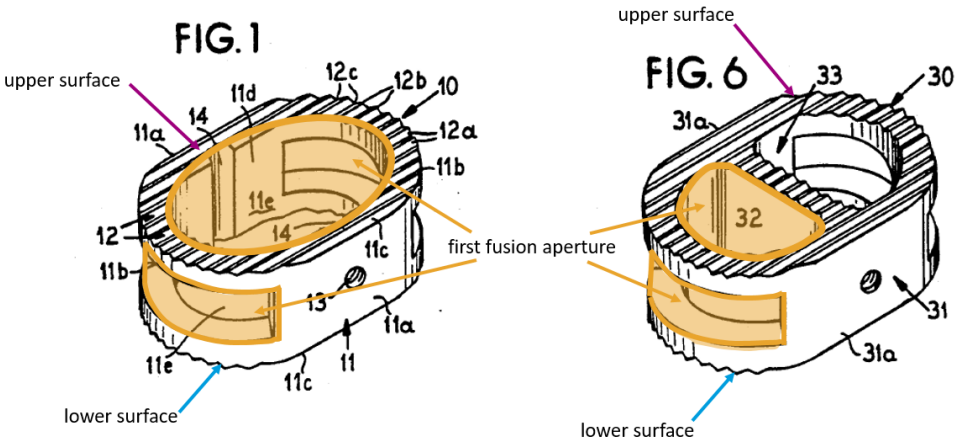
h. "at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space,"

Brantigan discloses an upper surface and a lower surface as explained above. *Supra* § XI.D.2.b.

Brantigan discloses a fusion aperture extending between the upper and lower surfaces that is configured to permit bone growth between adjacent vertebra when the implant is positioned in the interbody space. Ex. 1002, ¶¶ 228–230.

Brantigan's spinal fusion implants have "opposed sides 11*a* and ends 11*b*, flat, ridged top and bottom faces 11*c* and a central aperture 11*d* therethrough." Ex.

1007, 4:8–10, Fig. 1. The following annotation shows the central aperture 11*d* of Brantigan's implant. Ex. 1002, ¶ 229.



Ex. 1007, Figs. 1 (annotated), 6 (annotated).

As Brantigan explains, "the open central portion of the ring is preferably packed with bone graft material to facilitate bone ingrowth." *Id.*, 2:15–17. Bone graft material facilitates bone growth between adjacent vertebrae. Ex. 1002, ¶ 230. Packing the central aperture allows the implants to "receive bone ingrowth which quickly fuses the structure to the bone and forms [sic] a living bone bridge across the fusion area." Ex. 1002, ¶ 230; Ex. 1007, 1:41–43.

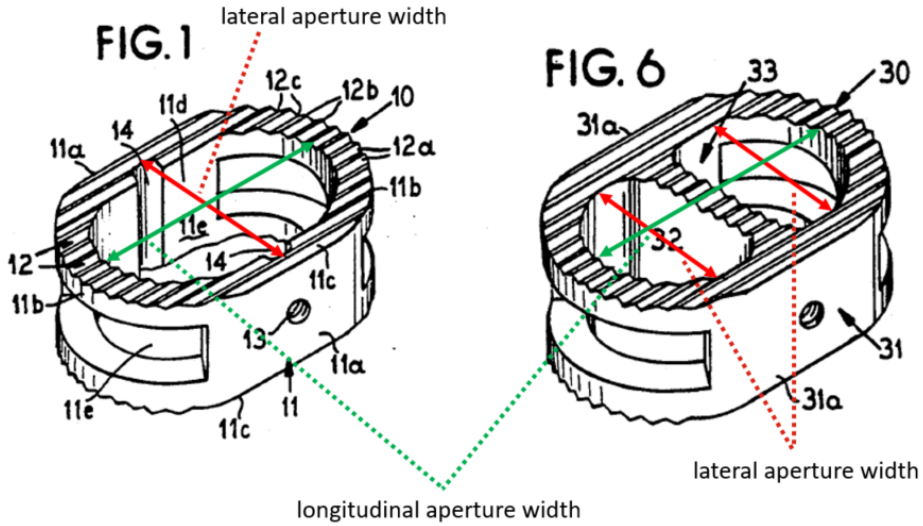
Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 228.

i. "said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and"

Brantigan discloses a first fusion aperture as explained above. *Supra* § XI.D.2.h.

Because Brantigan's oval-shaped implant "conforms generally to the disc space" "with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies," a POSA would have understood the dimensions of Brantigan's central aperture 11*d* would be such that the longitudinal aperture length is greater than the lateral aperture width for any thoracic or lumbar interbody implant. *Supra* § XI.D.2.e, g; Ex. 1002, ¶¶ 231–233; *see also* Ex. 1022, 363–364, Table 1.

The following annotated images of Figures 1 and 6 show the overall shape of the first fusion aperture. In particular, the image depicts "a longitudinal aperture length generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width."



Ex. 1007, Figs.1 (annotated), 6 (annotated); Ex. 1002, ¶ 232.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 233.

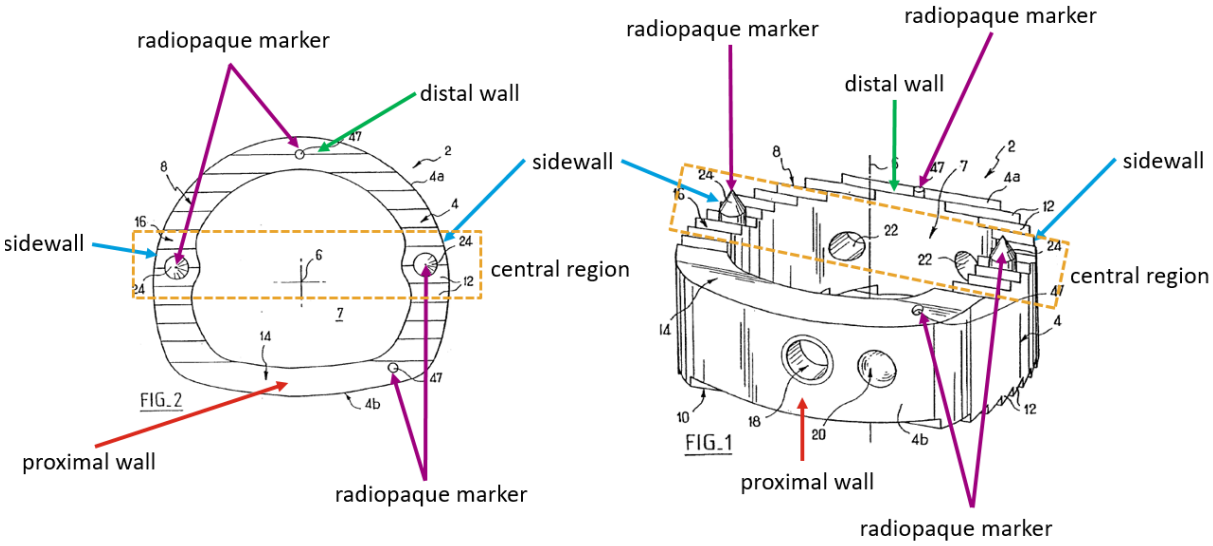
j. "at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region."

Baccelli describes a spinal fusion implant ("cage") that includes at least three radiopaque markers, one in each of the distal, proximal, and two sidewalls. Ex. 1002, ¶ 236; Ex. 1008, [0041], [0050]–[0051]. In particular, Baccelli's spinal fusion implant

> can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or the presence of the implant when X-rays are taken during or after the operation. They could be made of titanium or of titanium alloy. In this case, there

> are two markers 47 and they are constituted by wires inserted in rectilinear ducts parallel to the axis 6 and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall. The spikes 24 can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays.

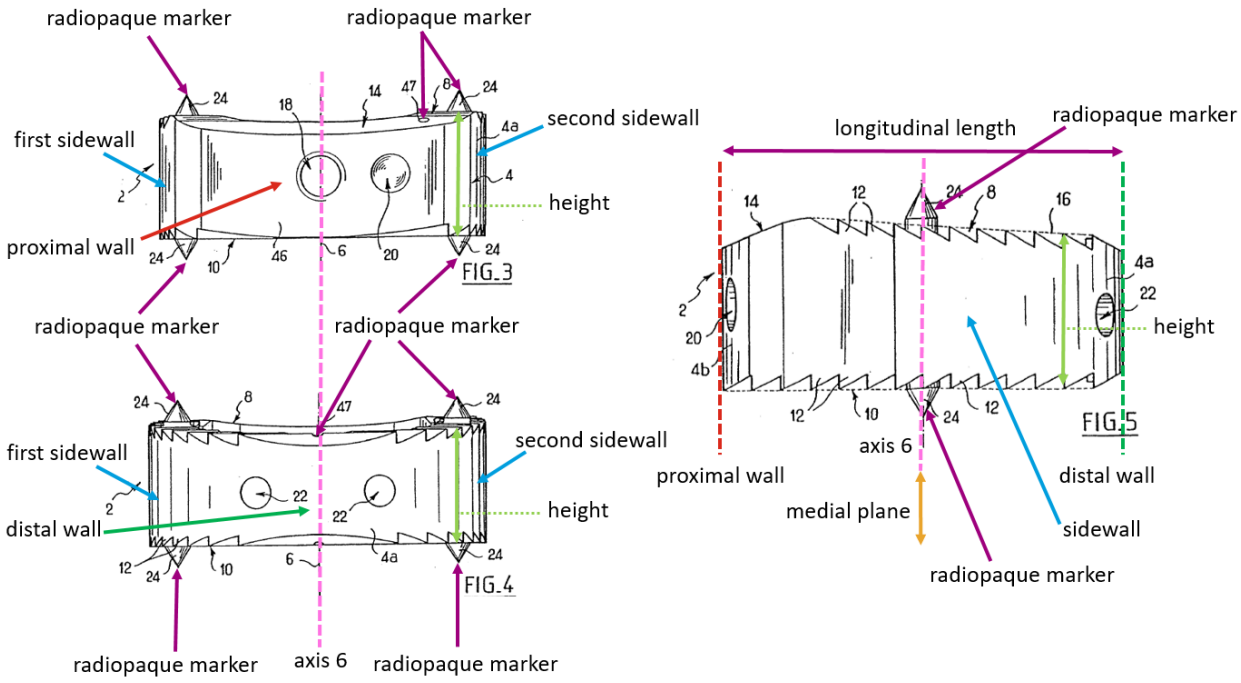
Ex. 1008, [0050]–[0051], Figs. 1–5, 8, 9. Baccelli discloses extending the radiopaque markers (24) and spikes (47) into the proximal and distal walls, as well as the sidewalls in the central region. Ex. 1002, ¶ 237.



Ex. 1008, Figs. 1–2 (annotated); *see also* Figs. 3–5, 8, 9.

As illustrated below (annotated Figure 3), Baccelli discloses a proximal wall (4b) including "mounting orifice 18" for "threaded engagement" with "fitting tool 40" as shown in Figures 8 and 9. Ex. 1002, ¶ 237; Ex. 1008, [0044], Figs. 3, 8–9.

Baccelli discloses a distal wall (4a) opposite the proximal wall (annotated Figure 4). Ex. 1008, Fig. 4; Ex. 1002, ¶ 237. Baccelli further discloses a first and second sidewall generally opposite the first side walls extending between the proximal and distal walls (annotated Figure 5). Ex. 1002, ¶ 237.



Id., Figs. 3–5 (annotated).

As shown above, Baccelli's radiopaque markers (47) and spikes (24) are oriented parallel to the height of the implant along central axis 6. Ex. 1008, [0041], Figs. 3–5; Ex. 1002, ¶ 237. Baccelli discloses that the radiopaque spikes 24 "are disposed symmetrically to each other about the sagittal midplane," defined as the plane parallel to axis 6 and perpendicular to front (proximal) wall 4b. Ex. 1008, [0036], [0041], [0050]–[0051], Figs. 3–5; Ex. 1002, ¶ 237. The spikes also "extend in the frontal midplane containing axis 6." *Id.*, [0041]. Because the spikes "can be

inserted and fixed rigidly in the ducts" (Ex. 1008, [0050]–[0051]), a POSA would have understood that the radiopaque markers extend into the central region including the first and second sidewalls, respectively. Ex. 1002, ¶ 237. Baccelli further explains that "two markers 47 [] are constituted by wires inserted in rectilinear ducts parallel to the axis 6 and formed in the wall of the cage." Ex. 1008, [0050]. Because the markers are inserted in rectilinear ducts, the markers extend into the distal wall and proximal wall, respectively. Ex. 1002, ¶ 237.

Accordingly, Baccelli discloses this limitation. Ex. 1002, ¶ 238.

3. Claim 16

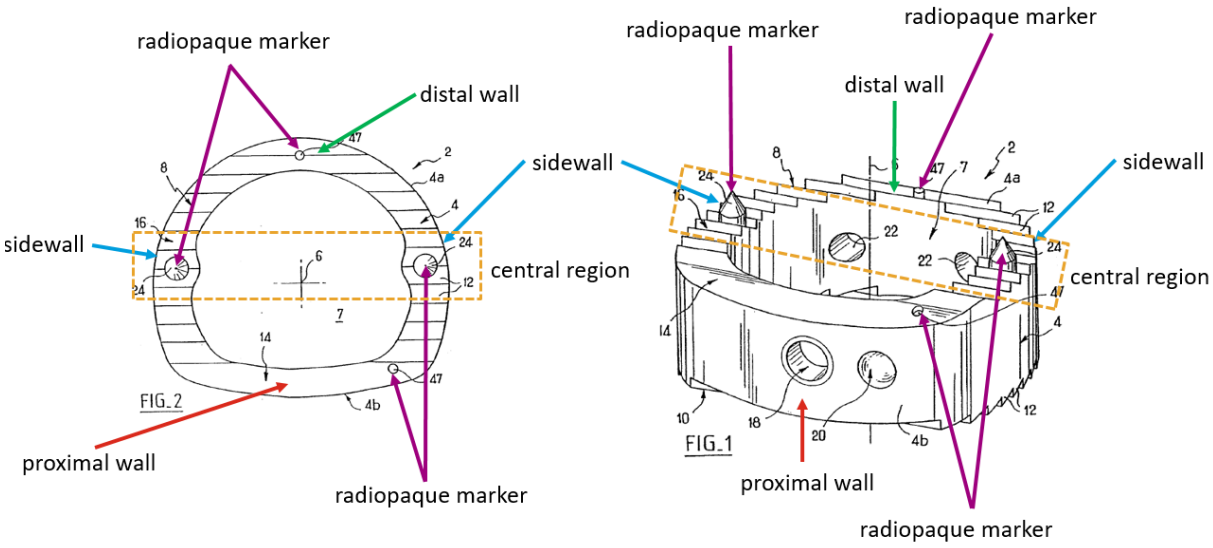
a. "The spinal fusion implant of claim 1, further comprising a fourth radiopaque marker situated within said implant, said fourth radiopaque marker positioned in said central region at a position spaced apart from said third radiopaque marker."

Brantigan in view of Baccelli, Berry, and Michelson renders the implant of claim 1 obvious. *Supra* § XI.D.2.

Baccelli describes a spinal fusion implant ("cage") that includes four radiopaque markers: one at least partially positioned in the distal wall, a second at least partially positioned in the proximal wall, a third at least partially positioned in the central region, and a fourth positioned in the central region at a position spaced apart from the third radiopaque marker. Ex. 1002, ¶ 242; Ex. 1008, [0041], [0050]–[0051]. In particular, Baccelli's spinal fusion implant

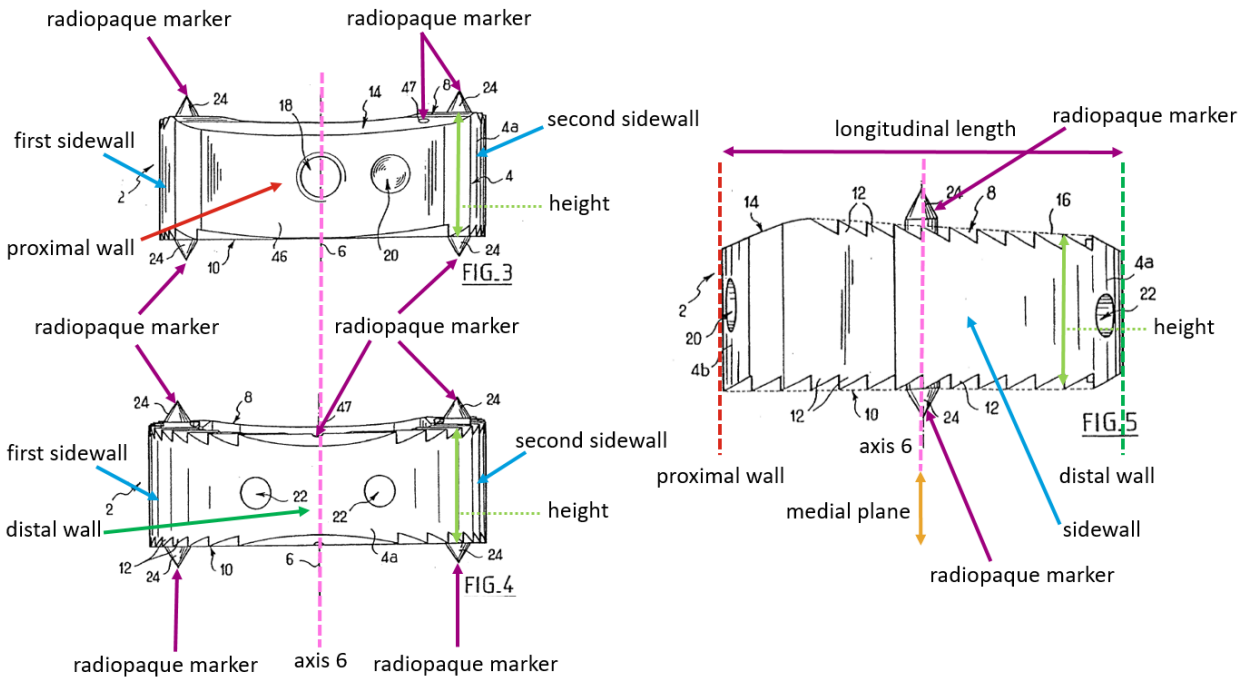
> can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or the presence of the implant when X-rays are taken during or after the operation. They could be made of titanium or of titanium alloy. In this case, there are two markers 47 and they are constituted by wires inserted in rectilinear ducts parallel to the axis 6 and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall. The spikes 24 can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays.

Ex. 1008, [0050]–[0051], Figs. 1–5, 8, 9. Baccelli discloses extending the radiopaque markers (24) and spikes (47) into the proximal and distal walls, as well as the sidewalls in the central region. Ex. 1002, ¶ 241. Thus, Baccelli discloses the fourth radiopaque marker (24) positioned within the implant in the central region at a position spaced apart from the third radiopaque marker. Ex. 1002, ¶ 240.



Ex. 1008, Figs. 1–2 (annotated); *see also* Figs. 3–5, 8, 9.

As illustrated below (annotated Figure 3), Baccelli discloses a proximal wall (4b) including "mounting orifice 18" for "threaded engagement" with "fitting tool 40" as shown in Figures 8 and 9. Ex. 1002, ¶ 243; Ex. 1008, [0044], Figs. 3, 8–9. Baccelli discloses a distal wall (4a) opposite the proximal wall (annotated Figure 4). Ex. 1008, Fig. 4; Ex. 1002, ¶ 243. Baccelli further discloses a first and second sidewall generally opposite the first side walls extending between the proximal and distal walls (annotated Figure 5). Ex. 1002, ¶ 243.

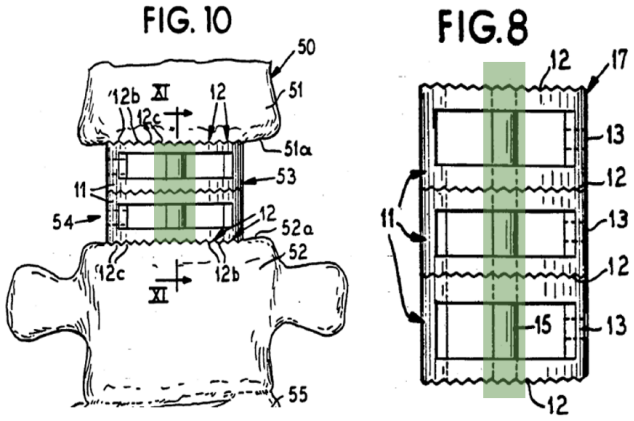


Id., Figs. 3–5 (annotated).

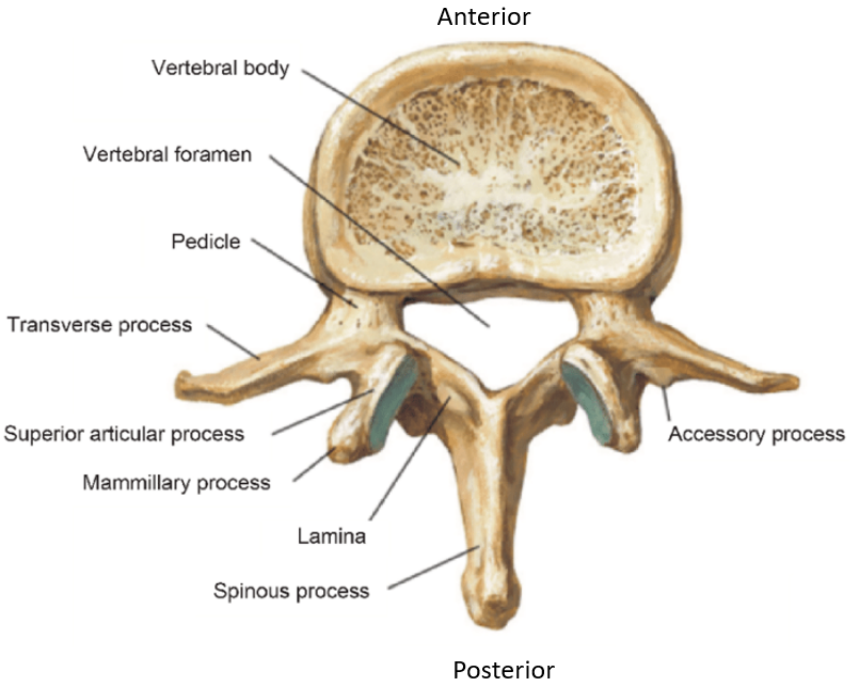
As shown above, Baccelli's radiopaque markers (47) and spikes (24) are oriented parallel to the height of the implant along central axis 6. Ex. 1008, [0041], Figs. 3–5; Ex. 1002, ¶ 243. Baccelli discloses that the radiopaque spikes 24 "are disposed symmetrically to each other about the sagittal midplane," defined as the plane parallel to axis 6 and perpendicular to the front (proximal) wall 4b. Ex. 1008, [0036], [0041], [0050]–[0051], Figs. 3–5; Ex. 1002, ¶ 243. The spikes also "extend in the frontal midplane containing axis 6." *Id.*, [0041]. Because the spikes "can be inserted and fixed rigidly in the ducts" (Ex. 1008, [0050]–[0051]), a POSA would have understood that the radiopaque markers extend into the central region including the first and second sidewalls, respectively. Ex. 1002, ¶ 243. Baccelli further explains that "two markers 47 [] are constituted by wires inserted in rectilinear ducts

parallel to the axis 6 and formed in the wall of the cage." Ex. 1008, [0050]. Because the markers are inserted in rectilinear ducts, the markers extend into the distal wall and proximal wall, respectively. Ex. 1002, ¶ 243.

Because Brantigan does not describe mention radiopaque markers in the proximal and distal walls or the central region of the implant, it would have been difficult for a surgeon to identify the location of the implant during and after surgery. Ex. 1002, ¶ 172. Thus, it would have been obvious to include the four markers Baccelli teaches into the proximal, distal, and sidewalls of the radiolucent lateral Brantigan implant to enable surgeons to visualize the orientation and location of the implant during and after surgery. Ex. 1002, ¶ 173; Ex. 1007, Figs. 8, 10. In particular a POSA would have found it obvious to position markers in the middle (*e.g.*, central region or widest portion) of Brantigan's sidewalls, as well as in the leading and trailing ends of the implant, to allow surgeons to align the markers with the spinous process and the lateral ends of the vertebrae. Ex. 1002, ¶ 173. As illustrated below, rectangular connecting bar 15 runs along the middle of Brantigan and sits directly in front of the spinous process. Ex. 1002, ¶ 174.



Ex. 1007, Figs. 8 (annotated), 10 (annotated). Adding Baccelli's radiopaque markers to Brantigan's proximal, distal, and side walls along connecting bar 15 would have allowed surgeons to see in an anterior-to-posterior (front) X-ray whether and to what degree the implant is askew relative to the spinous process and the lateral edges of the vertebrae during and after lateral insertion. Ex. 1002, ¶ 174. A lateral (side) X-ray of the same implant would allow the surgeon to identify the position of the posterior sidewall of Brantigan relative to the posterior edge of the vertebral body (bordering the spinal canal) and the anterior sidewall of Brantigan relative to the anterior edge of the vertebral body (bordering the aorta and vena cava).



Ex. 1002, ¶ 174.

Accordingly, Brantigan in view of Baccelli, Berry, and Michelson renders obvious claim 16. Ex. 1002, ¶ 245.

XII. THERE ARE NO SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

Petitioner is unaware of any secondary considerations that demonstrate nonobviousness. In IPR2013-00507, Patent Owner offered evidence purportedly to establish "a nexus between NuVasive's CoRoent XL implants and the invention of the '334 patent" to demonstrate commercial success. Ex. 1004, 11–12. The Board explained that the existence of secondary considerations alone—in the absence of nexus—is insufficient to demonstrate non-obviousness. *Id.*, 11. Indeed, despite Patent Owner's offered arguments and information, the Board concluded that

"Patent Owner has not demonstrated that there is a nexus between the merits of the *claimed* invention and the evidence offered. For example, the Patent Owner argues that NuVasive 'pioneered the market for lateral, trans-psoas interbody fusion surgeries,' [], but fails to demonstrate sufficiently that any of the disputed claims recite 'lateral, trans-psoas interbody fusion surgeries.'" *Id.*, 12.

XIII. MANDATORY NOTICES – 37 C.F.R. § 42.8

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

Alphatec Holdings, Inc. and Alphatec Spine, Inc. are the real-parties-in-interest for purposes of this proceeding.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

Patent Owner is currently asserting the '334 patent against Petitioner in *NuVasive, Inc. v. Alphatec Holdings, Inc. et al.*, Case No. 3:18-cv-00347-CAB-MDD (S.D. Cal.), filed on February 13, 2018.

The '334 patent is related to U.S. Patent 8,361,156, which is also asserted in the above-referenced case. Petitioner has filed a Petition for *Inter Partes* Review regarding the '156 patent. *See* IPR2019-00362. Petitioner has also filed a Petition for *Inter Partes* Review of claims 6–9 and 18 of the '334 patent. *See* IPR2019-00361.

Patent Owner previously asserted the '334 patent in *Warsaw Orthopedic, Inc. et al. v. NuVasive, Inc.*, Case No. 3:12-cv-002738-CAB-MDD (S.D. Cal.), filed on August 17, 2012. This case settled on July 27, 2016.

C. Lead and Backup Counsel Under 37 C.F.R. § 42.8(b)(3)

Lead Counsel: Andrew R. Sommer (Reg. #53,932). **Backup Counsel:** Nimalka R. Wickramasekera (*pro hac vice* to be filed) and David P. Dalke (Reg. #40,980).

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Petitioners consent to service by email on the following email addresses:

Alphatec-IPRs@winston.com

XIV. PAYMENT OF FEES – 37 C.F.R. § 42.103

The required fee is being paid through PTABE2E.

XV. CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Board institute *inter partes* review of claim 16 of the '334 patent and cancel this claim as unpatentable.

Date: January 10, 2019

Respectfully submitted,

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Counsel for Petitioner

CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. 42.24(d)

Pursuant to 37 C.F.R. §§ 42.24(a)(i) and 42.24(d), I hereby certify that the number of words in this Petition is 12,955 excluding the Table of Contents, the Table of Authorities, the Mandatory Notices under § 42.8, Certificate of Service, Certificate of Word Count, and Exhibit List.

Date: January 10, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), this is to certify that on January 10, 2019, I caused to be served a true and correct copy of the foregoing "PETITION FOR *INTER PARTES* REVIEW OF CLAIM 16 OF U.S. PATENT NO. 8,187,334" and Exhibits 1001–1005, 1007–1025, 1028–1037, 1040–1042, 1046–1048 by EXPRESS MAIL on the Patent Owner at the correspondence address of record for U.S. Patent No. 8,187,334, as follows:

Correspondence Address:	Fish & Richardson P.C. P.O. Box 1022 Minneapolis, MN 55440-1022
Litigation Counsel:	Paul D. Tripodi, II Wilson Sonsini Goodrich & Rosati 633 West 5th Street, Suite 1500 Los Angeles, CA 90071

Date: January 10, 2019

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