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. IPR2019-00362
United States Patent No. 8,361,156

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,361,156

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

TABLE OF EXHIBITS

PETITIONER'S EXHIBIT LIST	
Exhibit No.	**Brief Description**
1001	U.S. Patent No. 8,361,156 to Curran *et al*. ("'156 patent")
1002	Declaration of Charles L. Branch, Jr., M.D.
1003	*Curriculum Vitae* of Charles L. Branch, Jr., M.D.
1004	IPR2013-00506, Final Written Decision, Paper No. 47 ("IPR506 FWD")
1005	*In re: NuVasive, Inc*., No. 2015-1670, Opinion, (Fed. Cir. Dec. 7, 2016) ("IPR2013-00506 CAFC Opinion")
1006	IPR2013-00506, Judgment Granting Joint Motion to Terminate after Remand from the Court of Appeals for the Federal Circuit, Paper No. 57
1007	U.S. Patent No. 5,192,327 to Brantigan ("Brantigan")
1008	U.S. Patent App. Pub. No. 2003/0028249 to Baccelli *et al*. ("Baccelli")
1009	Synthes Vertebral Spacer-PR Brochure ("SVS-PR")
1010	Telamon Verte-Stack PEEK Vertebral Body Spacer Brochure ("Telamon Brochure")
1011	Telamon Implantation Guide ("Telamon Guide")
1012	*Warsaw Orthopedic, Inc. v. NuVasive, Inc.,* No. 2013-1576, -1577, Joint Appendix, Docket No. 52-1 (Fed. Cir. June 16, 2014)
1013	Prosecution History of the '156 patent, U.S. App. No. 13/441,092
1014	IPR2013-00208, Corrected Petition for *Inter Partes* Review of United States Patent No. 8,251,997, Paper No. 5 ("IPR208 Petition")
1015	IPR2013-00206, Corrected Petition for *Inter Partes* Review of U.S. Patent No. 8,251,997, Paper No. 5 ("IPR206 Petition")
1016	IPR2013-00206, Petitioner's Reply to Patent Owner's Response, Paper No. 43, ("IPR206 Reply")
1017	IPR2013-00206, Final Written Decision, Paper No. 65 ("IPR206 FWD")
1018	IPR2013-00208, Final Written Decision, Paper No. 62 ("IPR208 FWD")
1019	*In re: Warsaw Orthopedic, Inc.*, Nos. 2015-1050, 2015-1058 (Fed. Cir. Aug. 9, 2016) ("IPR208 CAFC opinion")

PETITIONER'S EXHIBIT LIST	
Exhibit No.	**Brief Description**
1020	Prosecution History of U.S. Patent No. 7,918,891, U.S. App. No. 11/093,409
1021	U.S. Patent No. 8,251,997 to Michelson ("Michelson '997")
1022	Berry *et al.* "A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae," 12 SPINE, 362–367 (1987) ("Berry")
1023	Prosecution History of U.S. Patent No. 8,187,334, U.S. App. No. 13/079,645
1024	*Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, No. 3:08-cv-1512 CAB-MDD, NuVasive Inc.'s Memorandum of Points and Authorities in Support of its Renewed Motion for Judgment as a Matter of Law or a new Trial, Docket No. 407-1 (S.D. Cal. Oct. 27, 2011) ("*Warsaw* JMOL")
1025	Prosecution History of U.S. Patent No. 8,246,686, U.S. App. No. 13/440,062
1026	U.S. Provisional Patent App. No. 60/557,536, filed March 29, 2004
1027	RESERVED
1028	U.S. Patent No. 5,127,912 to Ray *et al*.
1029	U.S. Patent No. 5,514,180 to Heggeness *et al*.
1030	Amonoo-Kuofi, "Age-Related Variation in the Horizontal and Vertical Diameters of the Pedicles of the Lumbar Spine," 186 J. ANAT., 321–328 (1995)
1031	IPR2013-00506 Decision to Institute, Paper No. 9
1032	U.S. Patent No. 5,860,973 to Michelson ("Michelson '973")
1033	IPR2013-00504, Decision Denying Institution, Paper No. 8
1034	IPR2013-00506, Petition, Paper No. 1
1035	*Warsaw Orthopedic, Inc. v. NuVasive, Inc.,* No. 2013-1576, -1577, NuVasive's Opening Brief, Docket No. 33 (Fed. Cir. Feb. 3, 2014)
1036	Panjabi *et al*., "Complexity of the Thoracic Spine Pedicle Anatomy," 6 EUR. SPINE J., 19–24 (1997)
1037	Kopperdahl *et al*., "Yield Strain Behavior of Trabecular Bone," 31 J. BIOMECHANICS, 601–608 (1998)
1038	IPR2013-00208, Declaration of Dr. Paul McAfee, M.D., M.B.A., Paper No. 1001
1039	*NuVasive Inc. v. Medtronic, Inc*., No. 2015-1670, Corrected NuVasive's Opening Brief, Docket No. 19 (Fed. Cir. July 23, 2015)
1040	U.S. Patent Application No. 2002/0165550 to Frey *et al*.
1041	IPR2013-00504, Petition, Paper No. 3

PETITIONER'S EXHIBIT LIST	
Exhibit No.	**Brief Description**
1042	IPR2014-00487, Petition, Paper No. 1
1043	IPR2013-00506, Patent Owner Response, Paper No. 21
1044	IPR2014-00487, Decision Denying Institution, Paper No. 8
1045	RESERVED
1046	*Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, No. 2013-1576, 2013-1577, Opinion, Docket No. 77 (Fed. Cir. March 2, 2015)
1047	IPR2013-00208, Petitioner's Reply to Patent Owner's Response, Paper No. 40

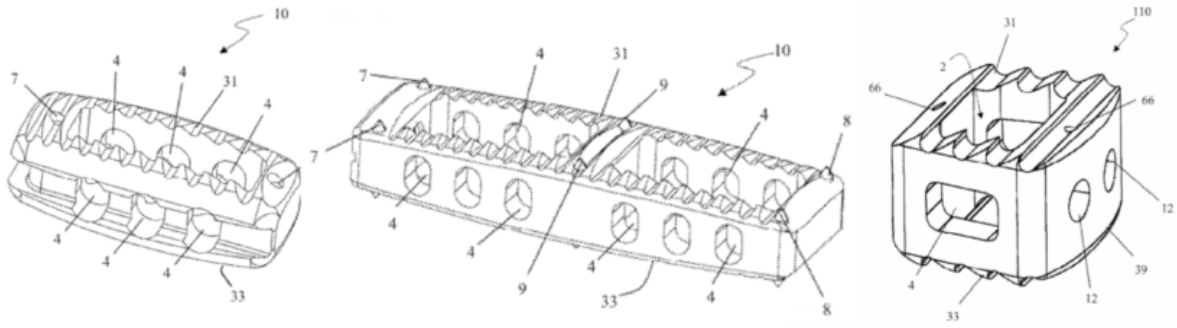
Alphatec Holdings, Inc. and Alphatec Spine, Inc. (collectively "Petitioner") petition for *Inter Partes* Review under 35 U.S.C. §§ 311–319 and 37 C.F.R., Part 42 of claims 1–3, 5, 9–10, 12–21, 23–24, and 27 of U.S. Patent 8,361,156 (the "'156 patent"). As shown herein, Petitioner is reasonably likely to prove these challenged claims unpatentable. Accordingly, Petitioner requests that the Board institute trial and cancel all challenged claims.

I. INTRODUCTION

Spinal fusion procedures for treating, for example, chronic back or neck pain, generally involve removing some or all of the diseased or damaged intervertebral disc and inserting one or more intervertebral implants into the disc space. Ex. 1001, 1:27–37. The '156 patent is directed to generic spinal fusion implants of non-bone construction that purportedly "overcome" the drawbacks of the prior art in that it is not supply limited (as with allograft [cadaver bone]) and does not require harvesting bone from the patient (as with autograft)." Ex. 1001, 2:2–6. Beyond being made of non-bone construction, the '156 patent identifies no additional benefits over the prior art. *Id.,* 1:16–3:24. Nor does the '156 patent discuss the numerous prior art implants of non-bone construction known well before the earliest claimed filing date of the '156 patent.

The '156 patent instead describes and claims features that were found in prior art non-bone implants well before March 2004. There was nothing new in the '156

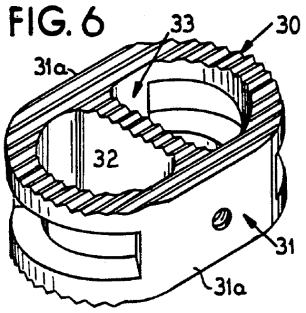
patent. For example, the '156 patent claims a spinal fusion implant having four walls (a distal wall, a proximal wall, and two side walls), upper and lower surfaces including anti-migration elements to contact the vertebrae when the implant is positioned in the intervertebral space, at least one fusion aperture extending between the upper and lower surfaces that allows a boney bridge to form through the spinal fusion implant, and a length that is greater than a maximum lateral width of the implant along its midpoint. Ex. 1001, 12:31–67. Exemplary shapes and sizes of the claimed implant are illustrated in Figures 18, 20, and 22.



The '156 patent further indicates that "when the spike elements are provided having radiodense characteristics and the implant is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant during implantation and/or the placement of the implant after implantation." *Id.*, 3:4–10.

The '156 patent claims only what was old and obvious. U.S. Patent 5,192,327 to Brantigan ("Brantigan") (Ex. 1007) issued in March 1993 and, like the '156

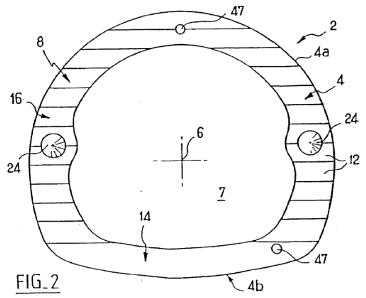
patent, discloses spinal fusion implants "preferably made of radiolucent material such as carbon fiber reinforced polymers known commercially as 'Peek', (polyetherether ketone) or 'Ultrapek' (polyether ketone, ether ketone, ketone)." Ex. 1007, 3:9–12. Also like the '156 patent, Brantigan discloses a spinal fusion implant having a distal wall, a proximal wall, and two side walls, upper and lower surfaces including anti-migration elements, at least one fusion aperture extending between the upper and lower surfaces, and a length that is greater than a maximum lateral width of the implant along its midpoint. One of Brantigan's embodiments is:



Ex. 1007, Fig. 6.

Although Brantigan does not mention using radiopaque markers, the use of such markers had become commonplace by March 2004. For example, U.S. Patent App. Pub. No. 2003/0028249 to Baccelli *et al*. ("Baccelli") (Ex. 1008), published in February 2003, 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 along the medial plane that bisects the length of the implant from distal to proximal end. *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:



Ex. 1008, Fig. 2.

The Patent Office allowed the challenged claims of the '156 patent because the examiner did not believe that the prior art disclosed or rendered obvious "a spinal fusion implant with a longitudinal length that is greater than the maximum width and with two radiopaque markers parallel to an implant height, in the sidewalls of the implant." Ex. 1013, 193; *infra* § V. Baccelli, however, was never cited to or otherwise considered by the examiner, nor was the combination of Brantigan in view of Baccelli. That combination—along with other prior art in this petition—renders the challenged claims unpatentable.

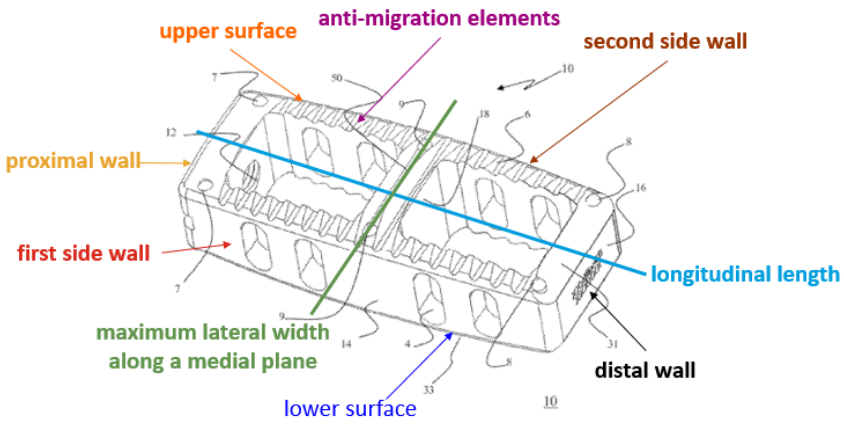
Petitioner therefore requests the Board institute *inter partes* review and cancel claims 1–3, 5, 9–10, 12–21, 23–24, and 27 of the '156 patent.

II. PETITIONER'S STANDING

Petitioner certifies that (1) the '156 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 '156 patent was first asserted in a complaint served on Petitioner on February 16, 2018.

III. THE '156 PATENT

The '156 patent describes "a spinal fusion implant of non-bone construction" that can be positioned in the interbody space between a first and second vertebrae. Ex. 1001, Abst., 12:33–34. One embodiment of the claimed spinal fusion implant is illustrated below:



Ex. 1001, Fig. 2 (annotated).

At times, Patent Owner has suggested that the '156 patent is narrower than the claims. Ex. 1039, 13. The '156 patent refers to "a lateral (trans-psoas) approach

to the spine," but adds that "posterior, anterior, antero-lateral, and postero-lateral" approaches may be used "without departing from the scope of the present invention (depending upon the sizing of the implant 10)." Ex. 1001, 5:29–35. The claimed implant may also "be provided in any number of suitable shapes and sizes depending upon the particular surgical procedure or need" and "may be dimensioned for use in the cervical and/or lumbar spine without departing from the scope of the present invention." *Id.,* 2:12–17, 12:21–26 (also suitable for thoracic spine). Nothing in the claims limits them to a lateral implant.

The '156 patent provides exemplary sizes following common knowledge of spinal anatomy: for lumbar use the implant is larger, having "a width ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 25 and 45 mm," and for cervical use it is smaller, having "a width about 11 mm, a height ranging between 5 and 12 mm, and a length about 14 mm." *Id.,* 2:17–25. The implant sizes and shapes discussed in the '156 patent are no revelation. These dimensions were widely-reported nearly two decades earlier by Berry *et al. A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae*, 12 SPINE, 362–367 (1987) ("Berry"), an often-cited study of "selected human vertebrae undertaken" for the purpose of "provid[ing] data for implant design." Ex. 1022, Abst., 364.

The ’156 patent says the claimed implants may have “any number of additional features for promoting fusion.” Ex. 1001, 2:26–28. These include:

- “apertures extending between the upper and lower vertebral bodies which allow a boney bridge to form through the spinal fusion implant,” *id.*, 2:28–30;
- “anti-migration features to prevent spinal fusion implant from migrating or moving from the disc space after implantation,” (e.g., “angled teeth formed along the upper and/or lower surfaces of the spinal fusion implant and/or spike elements disposed partially within and partially outside the upper and/or lower surfaces of the spinal fusion implant”), *id.*, 2:41–48; and
- “any number of features for enhancing the visualization of the implant during and/or after implantation into a spinal target site,” such as, “spike elements used for anti-migration, which may be manufactured from any of a variety of suitable materials, including but not limited to a metal, ceramic, and/or polymer material, preferably having radiopaque characteristics.” *Id.,* 2:54–3:62.

While the ’156 patent acknowledges that autologous and allograft bone grafts were “widely used for intervertebral implant[s] for lumbar fusion,” (*id.*, 1:38–39), it

does not acknowledge any of the dozens of non-bone spinal fusion implants known to those of skill in the art. Some art teaching such implants are discussed below.

IV. THE PRIOR ART

A. 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 for insertion between adjacent vertebrae composed of "rigid biologically acceptable and inactive material, preferably a radiolucent plastics material." 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 concedes 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,

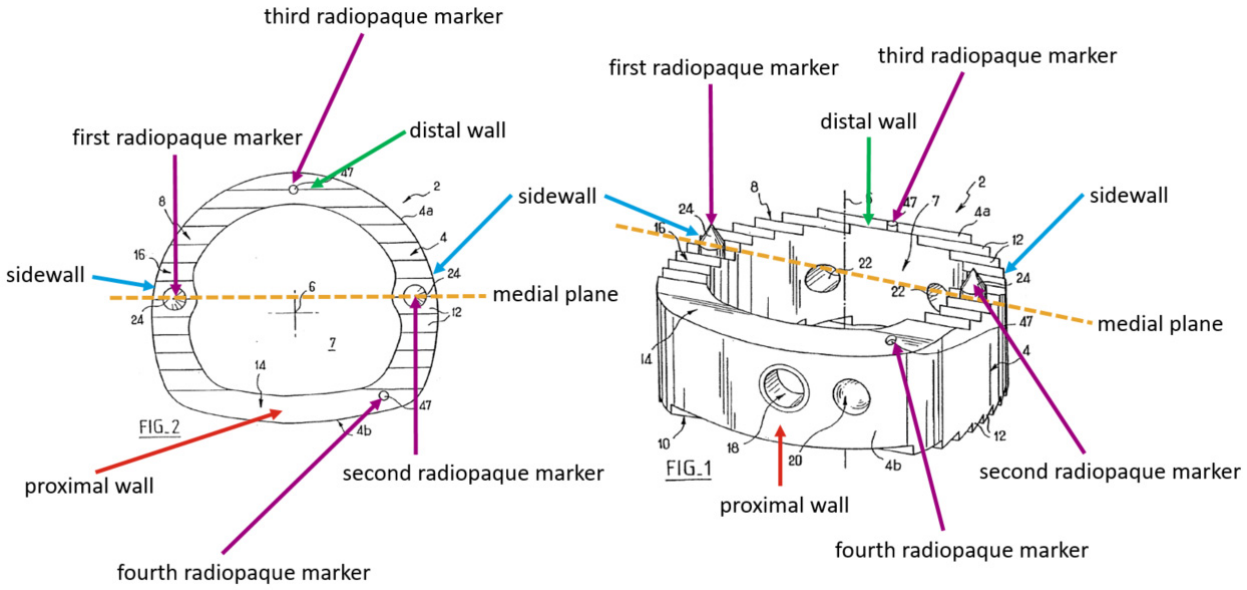
49. Patent Owner also admits Brantigan's implant would have "a length substantially greater than the depth of the vertebrae" and "a height for contacting each of the two adjacent vertebrae." *Id.* A person having ordinary skill in the art ("POSA"), therefore, would have understood Brantigan to teach a longitudinal length greater than the maximum lateral width of the implant, including a length greater than 40 mm and a width of approximately 18 mm. Ex. 1002, ¶¶ 165-175, 202, 209-211.

B. Baccelli

Baccelli (Ex. 1008) was filed in April 2002 and published in February 2003. Baccelli discloses a spinal fusion implant that "can be made of a material that is transparent to X-rays," like PEEK. Ex. 1008, [0050]. Baccelli's implant includes 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 explains that the 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. In addition to markers, 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 (4b), distal (4a), and side (16, 4) walls are illustrated below:



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

C. Berry

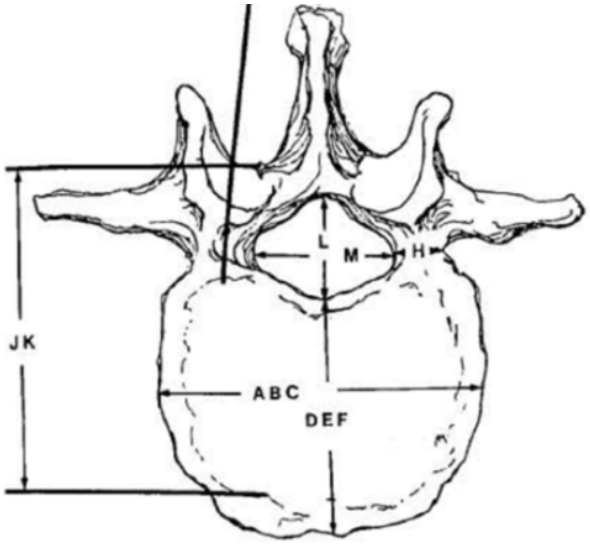
Berry was published in the Journal "Spine" in 1987. (Ex. 1022.) The study discussed in Berry was "undertaken to provide data for implant design." *Id.*, 362.

> [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 and inferior surfaces of the vertebral body, as well as at the midpoint between them) from 240 different vertebrae. *Id.*, 362–363, Fig. 1; Ex. 1002, ¶¶ 102, 169-172.



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.

D. Michelson '973

U.S. Patent 5,860,973 to Michelson ("Michelson '973") (Ex. 1032) was filed in October 1996 and issued in January 1999. Michelson '973 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 '973 refers to such a laterally-inserted implant as a "translateral spinal fusion implant." *Id.*, 3:1–7. A cross-sectional view of a cylindrical embodiment of Michelson '973 is:

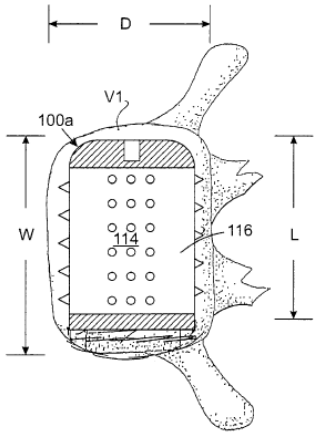


FIG. 4

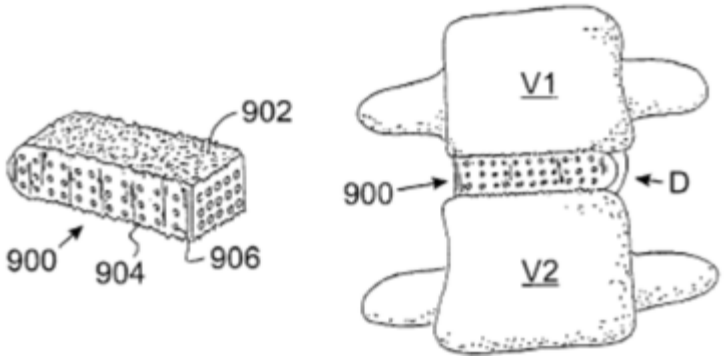
Id., Fig. 4.

Michelson '973 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, Michelson '973 teaches that 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 of the lateral approach to the spine, Michelson '973 discloses a minimally invasive method of 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.

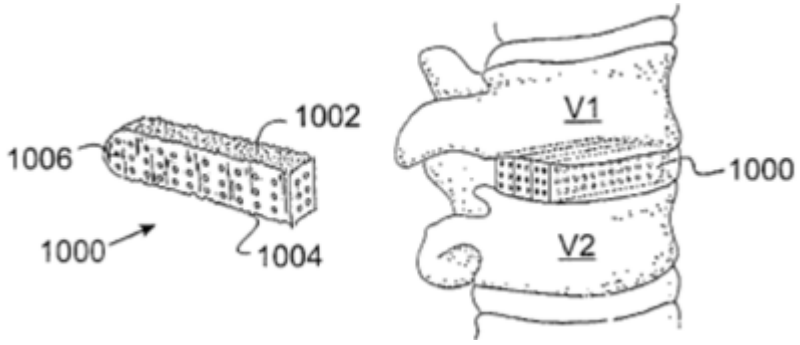
As an alternative to the cylindrical embodiment, Michelson '973 discloses an embodiment that "does not require the removal of any portion of bone from the adjacent vertebrae as the spinal fusion implant 900 fits within the natural disc space between the adjacent vertebrae." *Id.*, 10:6–16. As illustrated 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.

Additionally, as illustrated below, Michelson '973 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.

V. PROSECUTION HISTORY

Through a series of continuations, the '156 claims priority to Provisional App. No. 60/557,536 (the "Provisional"), filed March 29, 2004. The sole independent claim requires a spinal fusion implant having a "longitudinal length [that] is greater than said maximum lateral width." Ex. 1001, 12:45–51. This feature is absent from the Provisional. The Provisional disclosed only the following dimensions: for

lumbar, "a length ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a width ranging between 25 and 45 mm," and for cervical, "a length about 11 mm, a height ranging between 5 and 12 mm, and a width about 14 mm." Ex. 1026, 4:18–5:2, 11:12–14, 20:11–14. While dependent claims 5–8 and 9 of the '156 patent require a length of 40 mm and a maximum width of approximately 18 mm, these measurements are not disclosed in the Provisional.

Finally, to the extent Patent Owner contends that the '156 patent is limited to spinal implants for "a lateral (trans-psoas) approach to the spine" (Ex. 1001, 5:29–35, 11:58–63)—and it is not—this disclosure is also not in the Provisional.

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. In that application, Patent Owner added new matter. Ex. 1020, 1234 [4:16–21] (new lengths), 1241 [11:15–18] (new lengths), 1242 [12:2–5] (new "lateral (trans-psoas)"), 1249 [19:7–9] (new lengths), 1254–55 [24:20–25:16] (new lengths, new "lateral (trans-psoas)," and new "enhanced visualization features of the implants"), Figures 18–23 (newly added).

During prosecution of the '891 patent, the examiner rejected the claims as obvious over Michelson '973 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 '156 patent and its other parents (U.S. Patent 8,187,334 and 8,246,686) were allowed within a year with no substantive rejections. Ex. 1023, 206–214, Ex. 1025, 106–110, Ex. 1013, 191–194. The examiner never had Baccelli, which discloses four radiopaque markers, one in each wall of the radiolucent implant, during prosecution of the '156 patent or its parents, and, thus, never considered the combination of Brantigan in view of Baccelli, Berry, or Michelson '973.

VI. PREVIOUS CHALLENGES

The '156 patent has undergone *inter partes* review. In 2013, Medtronic, Inc. ("Medtronic") sought *inter partes* review of claims 1–14, 19, 20, and 23–27 of the '156 patent—IPR2013-00504 and IPR2013-00506. The Board instituted IPR2013-00506 (Ex. 1031), finding the challenged claims unpatentable under § 103(a) over:

Claims	References
1–4, 7, 8, 10–14, 19, 20, 23, 24, 26, and 27	SVS[1] and Baccelli[2]
5, 6, and 9	SVS, Baccelli, and Michelson[3]
25	SVS, Baccelli, and Telamon[4]
1–4, 7, 10–14, 19, 20, and 23–27	Telamon and Baccelli
5, 6, 8, and 9	Telamon, Baccelli, and Michelson

Ex. 1004, 5, 19–20.

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

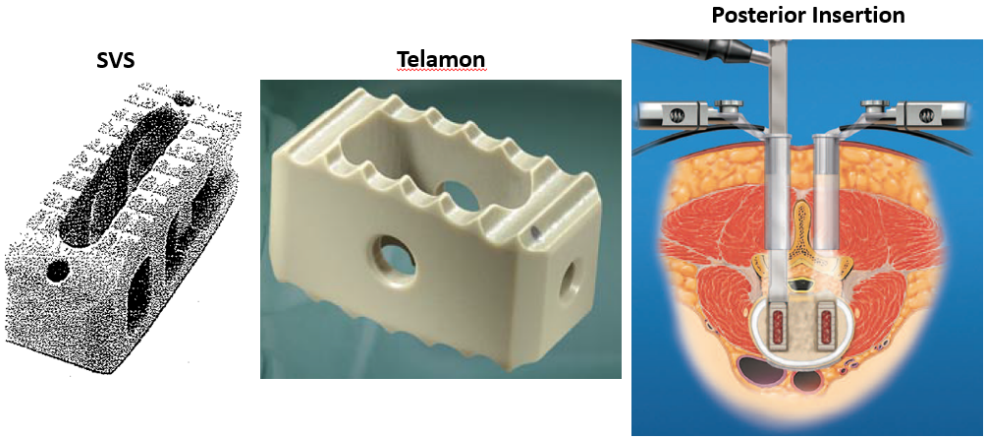
[1] Synthes Vertebral Spacer–PR Brochure, Synthes Spine 2002 ("SVS", Ex. 1009).

[2] Ex. 1008

[3] Ex. 1032

[4] 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").

10 mm wide that includes radiopaque markers. Ex. 1010, 2. SVS and Telamon are designed for posterior insertion (through the patient's back) into the spine:



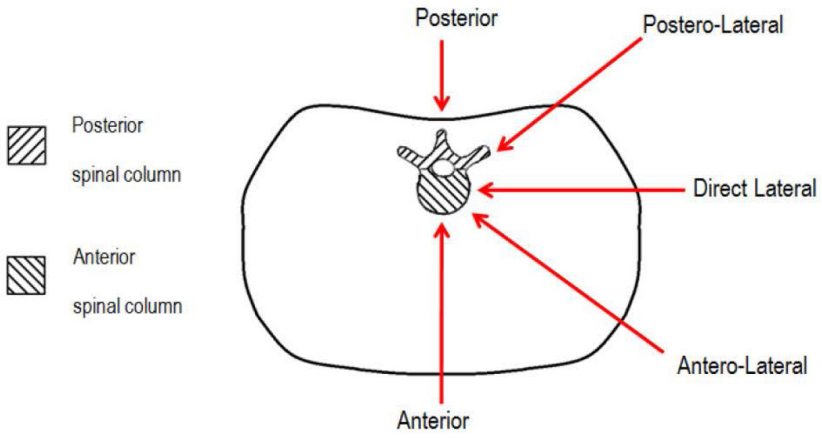
Ex. 1009, 1; Ex. 1010, 1; Ex. 1011, 9.

In its Final Written Decision, the Board agreed that a POSA would have been motivated to modify SVS and Telamon, in light of Baccelli, to place radiopaque markers in the middle of the implant "to provide additional information regarding the location and/or orientation of an implant, both during and after implantation." Ex. 1004, 9, 23.

Patent Owner appealed. Medtronic opposed, but settled with Patent Owner before oral argument and withdrew. Ex. 1005, 3; Ex. 1006, 2. The Patent Office intervened and participated at oral argument. Ex. 1005, 3.

Although the '156 patent describes an implant that "may be introduced in any of a variety of approaches, such as posterior, anterior, antero-lateral, and postero-lateral, without departing from the scope of the present invention" (Ex. 1001, 5:29–35), Patent Owner argued on appeal that "[t]he spinal fusion implants claimed in the

’156 patent are designed for insertion using such a ***lateral*** trans-psoas approach [i.e., entering through the patient’s side for insertion into the spine] based, in part, on the placement of radiopaque markers in specific positions that a surgeon can use to determine whether the implant is correctly placed in the disc space” (Ex. 1039, 13 (emphasis added)). Patent Owner previously used the following illustration to show the “approaches to the spine [that] were known and used before” 1995:



Ex. 1038, 6–7. According to Patent Owner, “[t]he location of the markers in the medial plane enables surgeons to properly visualize both the orientation and location of ***laterally-inserted*** implants.” Ex. 1039, 14 (emphasis added). That is because with “two radiopaque markers in the medial plane [of a laterally-inserted implant], a surgeon can align both markers with the spinous process to better align the implant as it is positioned laterally across the disc space. Having two radiopaque markers also allows a surgeon to see in an anterior-to-posterior x-ray view whether the implant is askew and the degree to which the implant is askew.” *Id.*, 39.

None of this is disclosed in the '156 patent, which is not limited to lateral implants. Nevertheless, Patent Owner emphasized that "these uses were not disclosed in the cited prior art references." *Id.* In doing so, Patent Owner distinguished the cited art based on its posterior insertion: "prior art implants designed for implantation through either an anterior or posterior approach, which if they provided radiopaque markers, typically placed the markers in the proximal and distal walls, rather than in the middle of the implant." *Id.,* 15, *see also id.*, 17 ("disclosed implants were designed for posterior or anterior insertion").

According to Patent Owner, "[n]one of the cited art describes any reason to add a pair of radiopaque markers to the medial plane of Telamon, SVS-PR, or any posterior implant, nor do any of the cited references identify what additional information would be provided by such medial plane markers (beyond the information provided by those markers already present in the Telamon and SVS-PR)." *Id.*, 24–25, *see also* 17–19, 40–41. Thus, Patent Owner argued that the Board articulated no motivation to modify ***posteriorly-inserted*** SVS and Telamon, in light of Baccelli, to place radiopaque markers in the middle of the implant. *Id.*, 45–46.

On appeal, the Federal Circuit did not limit the claims to lateral implants, but instead noted "the PTAB never articulated why the additional information would benefit a PHOSITA when implanting a posterior lumbar interbody fusion implant, such as the implants disclosed by the SVS-PR brochure and the Telamon references"

and remanded for additional findings and explanations regarding motivation to combine. Ex. 1005, 12–13. The parties settled and the Board dismissed IPR2012-00506 before considering additional arguments. Ex. 1006, 2. Unlike the art cited in the previous challenge, the art used here discloses laterally-inserted implants.

In IPR2012-00504, Medtronic challenged the same claims based on U.S. Patent App. Pub. 2002/0165550 A1 to Frey *et al*. ("Frey") (Ex. 1040). The Board denied the petition because Medtronic did "not explain how the maximum lateral width of the implant is along a medial plane that is generally perpendicular to the longitudinal length." Ex. 1033, 8. Medtronic's annotation of Frey is:

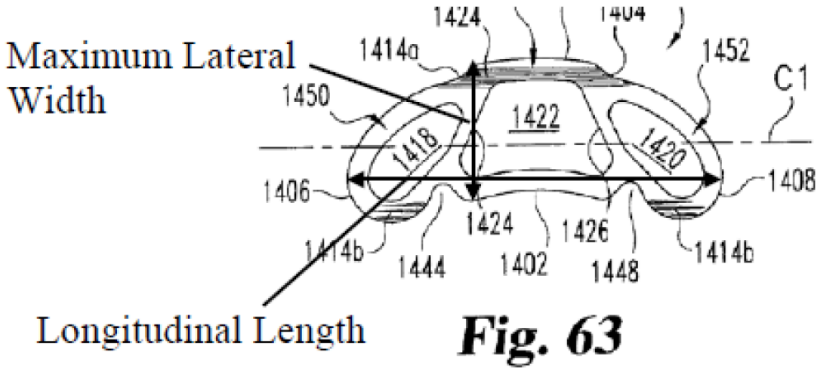


Fig. 63

Id., 7. Medtronic filed IPR2014-00487 to remedy deficiencies in IPR2013-00504, but the Board declined to institute trial because it was "essentially a duplicate of its previously denied petition in the '504 IPR." Ex. 1044, 5, 7.

VII. IDENTIFICATION OF CHALLENGES

Claims 1–5, 9–10, 12–21, 23–24, and 27 should be canceled in view of the following prior art: Brantigan (Ex. 1007), Baccelli (Ex. 1008), Berry (Ex. 1022),

and Michelson ’973 (Ex. 1032), which are prior art under pre-AIA § 102. Neither Baccelli nor the combination of Brantigan in view of Baccelli, Berry, and/or Michelson ’973 was considered during prosecution of the ’156 patent or its parent 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:** Claims 1–3, 5, 9–10, 12–21, 23–24, and 27 are rendered obvious under 35 U.S.C. § 103(a) by Brantigan in view of Baccelli and Berry.
- **Ground 2:** Claim 9 is rendered obvious under 35 U.S.C. § 103(a) by Brantigan in view of Baccelli, Berry, and Michelson ’973.

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[5] (“Michelson ’997”) (Ex. 1021), the parent of Michelson ’973. Michelson ’997 claimed, in relevant part, “[i]nserting . . . a non-bone interbody 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]

[5] IPR2013-00206 and IPR2013-208.

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 state of art 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 '973 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.[6]

Patent Owner's prior positions on Brantigan, Berry, and Michelson '973 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 the '156 patent claims. 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. For example, the Board never considered Brantigan, which Patent Owner admits describes a lateral implant with a length that spans the transverse width of the vertebra. Moreover, the Board never considered Brantigan in view of Baccelli, Berry, or Michelson. Additionally, none of the references relied upon in this Petition were applied during prosecution.

[6] Joint Appendix exhibit A17071 is Berry, and Joint Appendix exhibit A17452 is Brantigan '327. Ex. 1012, 5.

Indeed, Baccelli, which discloses four radiopaque markers—two in the middle of the sidewalls—was not even cited during prosecution. Finally, the prior IPRs did not address challenged claims 15–18 and 21. The Board should resolve the non-cumulative issues presented herein. *See Becton Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper No. 8, 17–18 (P.T.A.B. Dec. 15, 2017).

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 '156 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 '156 patent. Ex. 1007, cover.

2. 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 '156 patent. Ex. 1008, 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 '973 and '997, 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 USC §§ 102(a) & (b).

4. Michelson '973 is a prior art patent.

Michelson '973 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 '156 patent. Ex. 1032, cover.

B. Level of Ordinary Skill in the Art

At the time of the invention alleged in the '156 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: Claims 1-3, 5, 9–10, 12-21, 23–24, and 27 are rendered obvious by Brantigan in view of Baccelli and Berry

1. Motivation to Combine Brantigan with Baccelli and Berry

A POSA would have been motivated to combine Brantigan with Baccelli and Berry. With one exception, Brantigan discloses all elements recited in the challenged claims. 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 '156 patent did, Brantigan disclosed that its spinal fusion implants "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.

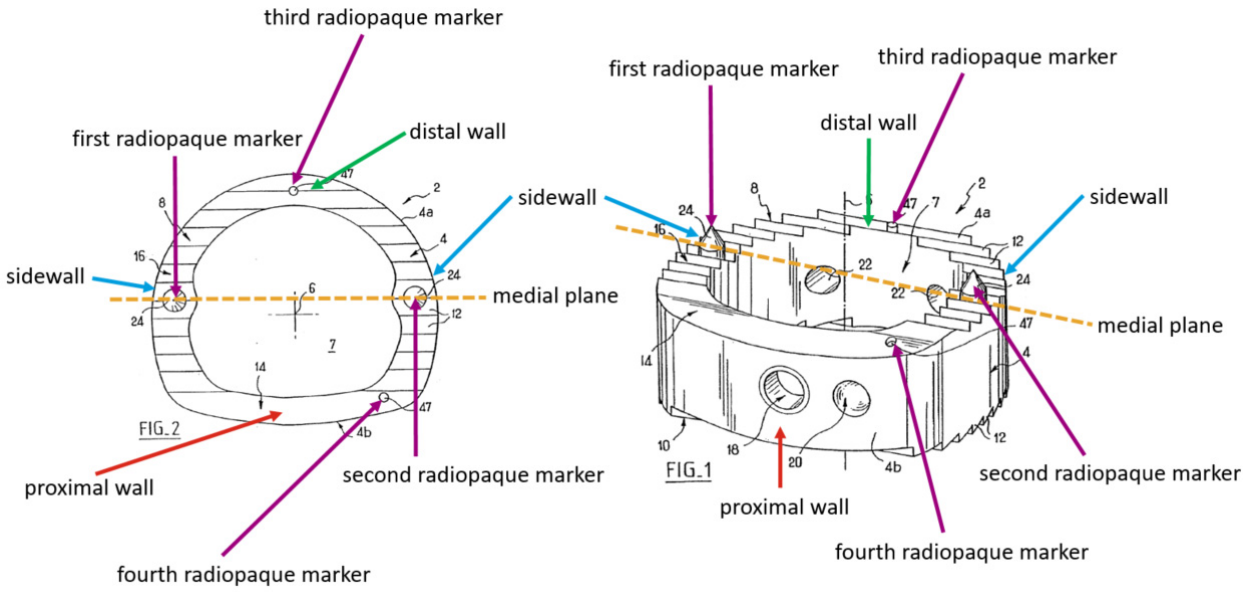
Once inserted laterally into the interbody space, Brantigan's length spans the full transverse width of the vertebra such that its sidewalls are located along the anterior and posterior portions of the vertebra. *Id.*, Figs. 8, 10. A POSA would have known the average length and width of human vertebrae before March 2004 because that information was reported decades earlier by Berry, for example. Berry measured 27 different dimensions from thoracic and lumbar vertebrae from 30 human skeletons and reported means and standard deviations associated with those measurements. Ex. 1022, 362–364. Berry did so recognizing that "accurate anatomic descriptions of vertebral shape are necessary for the development of

implantable devices and spinal instrumentation." *Id.*, 362. Thus, a POSA would have been motivated to turn to Berry when developing the implants of Brantigan.[7]

Because Brantigan teaches a spinal fusion implant that is radiolucent, it is transparent to X-rays. Ex. 1002, ¶ 123; Ex. 1008, [0050]. Brantigan does not, however, mention radiopaque markers in the middle of the implant sidewalls. Without radiopaque markers, surgeons would have difficulty identifying the position and presence of the implant during and after surgery. Ex. 1002, ¶ 123.

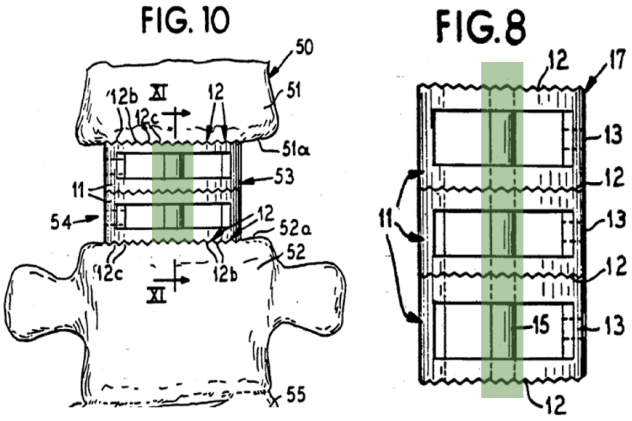
Baccelli teaches the inclusion of one or more markers in a radiolucent spinal fusion implant. "[B]ecause they are opaque to X-rays," the markers enable surgeons "to identify the position and/or presence of the implant when X-rays are taken during or after the operation." Ex. 1008, [0050]. Baccelli teaches "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.*, [0051]. The '156 patent's text is so similar to Baccelli it may well have borrowed this concept. *See* Ex. 1001, 2:56–62. Baccelli teaches four radiopaque markers, one located in each of Baccelli's walls.

[7] Petitioner contends that Berry merely reflects knowledge that would have been available to and within the purview of a POSA, but to avoid Patent Owner challenging that proposition, Petitioner applies Berry in this ground.

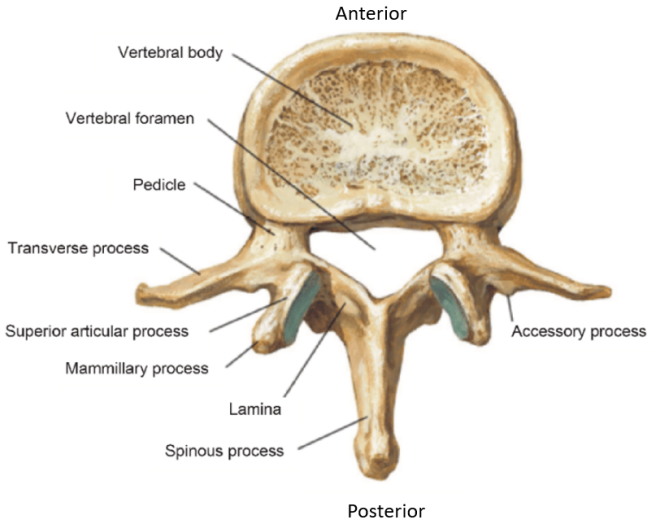


Ex. 1008, Figs. 1–2 (annotated); *see also* Figs. 3–5, 8, 9.

Accordingly, Baccelli instructs a POSA to include radiopaque markers in the middle of the sidewalls of the implant relative to the direction in which the implant is inserted. Following Baccelli, a POSA would have been motivated to include the radiopaque markers of Baccelli in the anterior and posterior sidewalls of the radiolucent Brantigan lateral implant to enable surgeons to visualize the orientation and location of the implant during and after surgery. Ex. 1002, ¶¶ 122–126, 257, Ex. 1007, Figs. 8, 10. In particular, a POSA have found it obvious to position two markers in the middle (widest portion) of Brantigan's sidewalls to allow surgeons to align the markers with the spinous process during and after the implant is inserted laterally. As illustrated below, rectangular connecting bar 15 runs along the medial plane of Brantigan and sits directly in front of the spinous process. Ex. 1002, ¶ 125.



Ex. 1007, Figs. 8 (annotated), 10 (annotated). Adding Baccelli's radiopaque markers to Brantigan's sidewalls 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 during and after lateral insertion. Ex. 1002, ¶ 125. A lateral (side) X-ray of the same implant would allow the surgeon 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, ¶ 125.

Further, a POSA would have had a reasonable expectation of success to combine Brantigan with Baccelli and Berry to size a radiolucent interbody implant for lateral insertion, locate the radiopaque markers in the middle of the anterior and posterior sidewalls "at the medial plane of the implant" as the Board previously concluded, and use an X-ray to determine the location and spatial 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—*i.e.*, surgeons had a reasonable expectation that they would be able tell how the otherwise translucent implant was arranged inside the patient. Ex. 1004, 13; Ex. 1002, ¶ 126. The use of such. Ex. 1002, ¶ 126.

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, ¶¶ 129-135.

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 ("especially well suited for

anterior cervical and lumbar fusion"), 1:7–12; Ex. 1002, ¶¶ 130-131. 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, ¶ 133. 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. Carbon fiber reinforced polymers, such as PEEK, are well-known non-bone materials. Ex. 1002, ¶ 133.

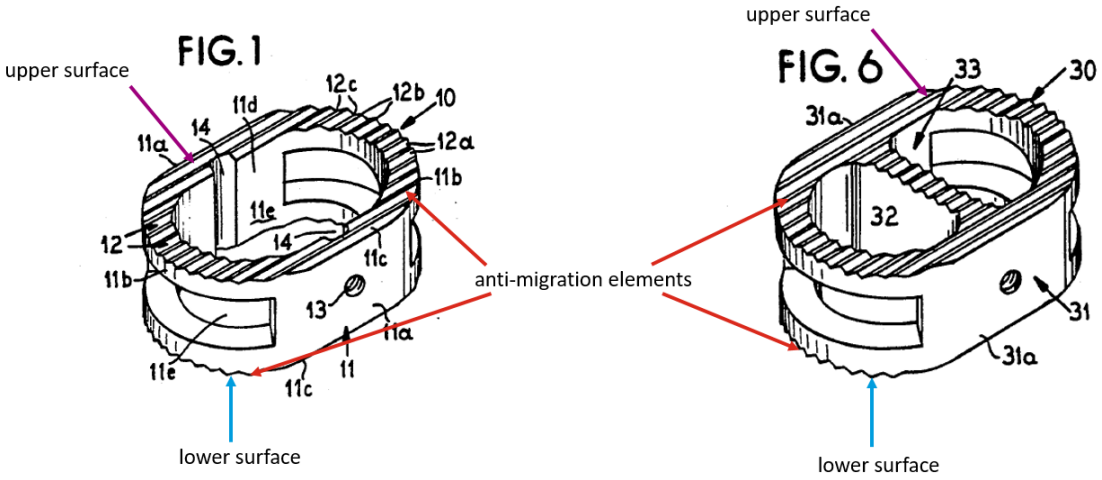
Brantigan's implants are positionable within an interbody space between adjacent vertebra. *Id.*, ¶¶ 130-132. "The rings are bottomed on the opposing end faces of adjoining vertebrae" and "are supplied in different heights to be used individually to replace a single damaged intervertebral disc." Ex. 1007, 1:18–29, 2:20–23 ("Each of the oval implants is sized to match the height of an average disc."). "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, ¶¶ 30, 131.

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, ¶ 135.

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:



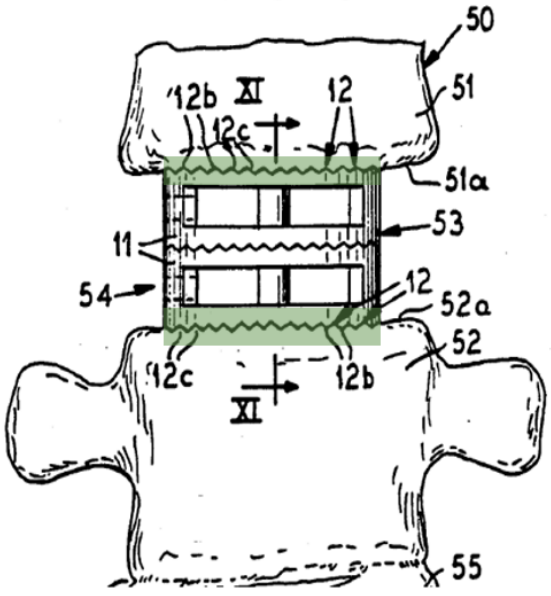
Ex. 1007, Figs. 1 (annotated), 6 (annotated), 4:8–10; Ex. 1002, ¶¶ 137-138.

"The plug 11 has opposed sides 11*a* and ends 11*b*, flat, ridged top and bottom faces 11c and a central 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 (emphasis added). "[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 discloses spinal fusion implants that can be used "singly or stacked together between vertebrae." *Id.*, 1:14–15. The anti-migration ridges are present on the upper and lower surfaces regardless of whether the implants are used singly or stacked. Ex. 1002, ¶ 142; *compare* Ex. 1007, Figs. 6, 8. 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, ¶ 143.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 144.

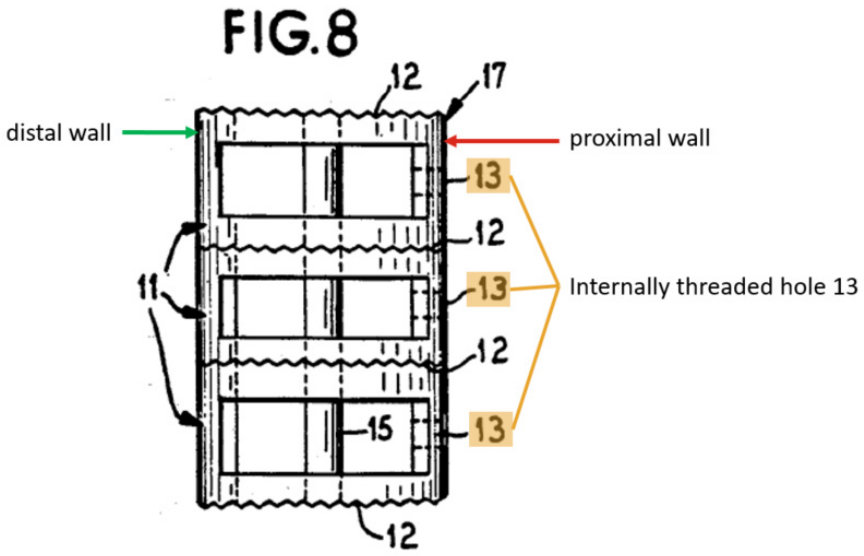
c. "a distal wall, a proximal wall, a first sidewall, and a second sidewall generally opposite from the first sidewall,"

Brantigan discloses distal, proximal, first, and second sidewalls, where the second sidewall is generally opposite the first sidewall. *Id.*, ¶¶ 145-152.

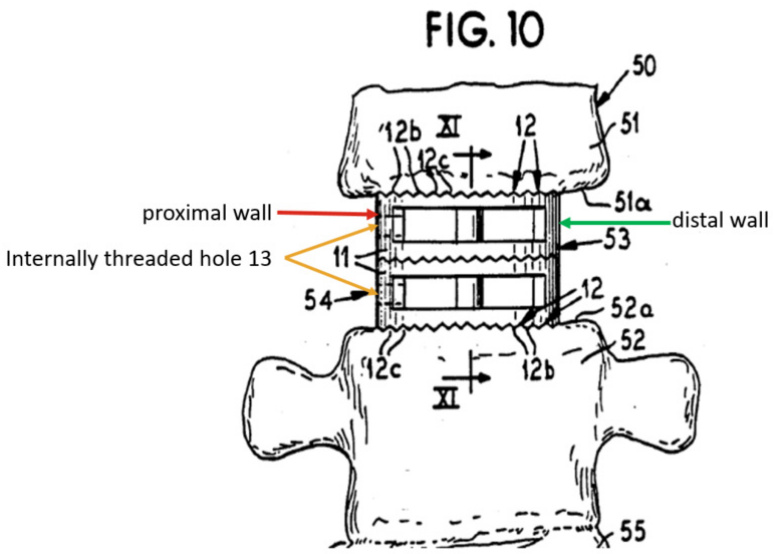
Brantigan's "plugs can be introduced anteriorly, ***laterally***, or posteriorly depending upon conditions and the tool receiving recesses 13 and 23 of the plugs 11 and 21 can thus be positioned to meet the particular type of insertion into the vertebral column." Ex. 1007, 5:30–35 (emphasis added), 2:59–66 (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, ¶ 147, 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" of the implant. Ex. 1002, ¶ 147.

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, ¶ 148. The plugs 11 of Figure 8 are shown inserted laterally in the disc space between adjacent vertebrae in Figure 10:

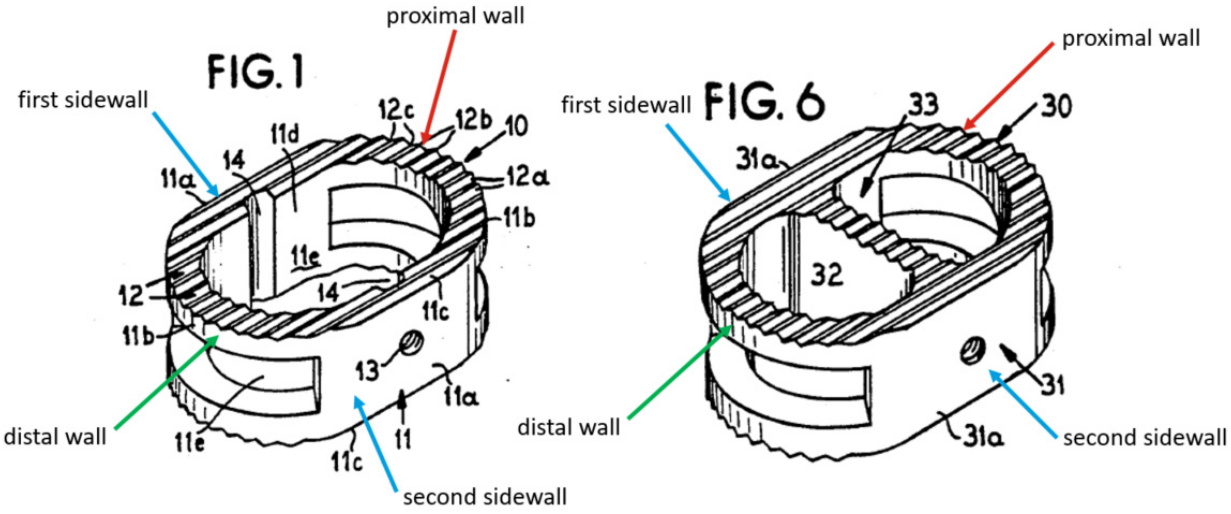


Ex. 1007, Fig. 10 (annotated). As seen above, the threaded insertion holes are visible on the left side of laterally-inserted plug 11. *Id.*

Brantigan further discloses a first sidewall and a second sidewall generally opposite the first sidewall. In Figure 10 above, 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, ¶ 149. 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, ¶ 149.

Brantigan further describes the distal, proximal, first, and second sidewalls in greater detail: "The plug 11 has opposed sides 11*a* and ends 11*b*, flat, ridged top and bottom faces 11*c* and a central upstanding aperture 11*d* therethrough." 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, ¶ 151. 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 ¶ 152. Brantigan's "ends 11*b*" are a distal wall and a proximal wall. Ex. 1007, 4:5–10; Ex. 1002, ¶ 151. The following, annotated figures 1 and 6 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 per Figures 8 and 10, consistent with Brantigan's teaching that tool receiving recesses can be positioned to meet the particular type of insertion into the vertebral column. *See* Ex. 1007, 5:30–35, 6:61–7:6 (varying type and location of insertion receiving apertures and tools depending on insertion direction).



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

Patent Owner relied on these disclosures in Brantigan 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, ¶ 152.

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

Brantigan discloses a distal wall, proximal wall, and first and second sidewalls as explained above. *Supra* § XI.C.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, ¶¶ 154-155.

Accordingly, Brantigan discloses this limitation. *Id.*

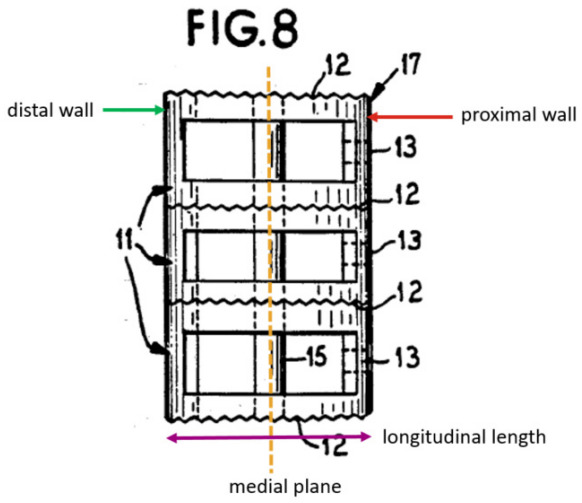
e. "wherein said implant has a longitudinal length extending from a proximal end of said proximal wall to a distal end of said distal wall, said implant has a maximum lateral width extending from said first sidewall to said second sidewall along a medial plane that is generally perpendicular to said longitudinal length, and"

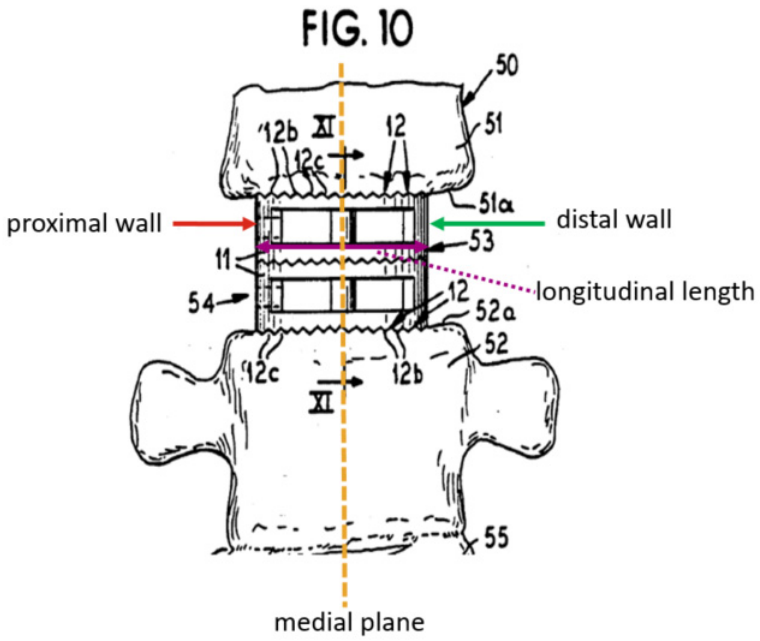
Brantigan discloses a distal wall, proximal wall, and first and second sidewalls as explained above. *Supra* § XI.C.2.c.

Brantigan further discloses an implant with a longitudinal length extending

from a proximal end of the proximal wall to a distal end of the distal wall. Ex. 1002, ¶ 158; Ex. 1019, 6–9 (Federal Circuit affirming Brantigan has a length sized to occupy substantially the full transverse width of the vertebral bodies of two adjacent vertebrae).

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:

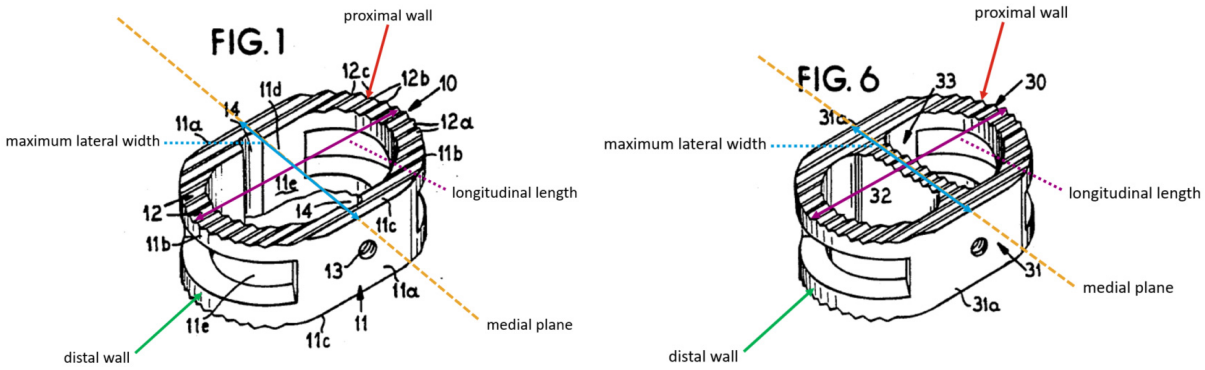




Ex. 1007, Figs. 8 (annotated), 10 (annotated); Ex. 1002, ¶ 158; *see also supra* § XI.C.2.c.

Brantigan further discloses a maximum lateral width extending from the first sidewall to the second sidewall along a medial plane generally perpendicular to the longitudinal length. Ex. 1002, ¶ 160-162. As shown above, "the central aperture 11d of each plug 11 is separated by the bar 15 into two side-by-side chambers." *Id.* ¶¶ 160-162, 241; 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 31a. 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." *Id.*, 5:36–43 (emphasis

added).



Ex. 1007, Figs. 1 (annotated), 6 (annotated); Ex. 1002, ¶¶ 160-162. Brantigan, therefore, discloses that connecting bar 15 and reinforcing bar 32 (visible, e.g., in Figure 10) run along the medial plane that is generally perpendicular to the longitudinal length. Ex. 1002, ¶¶ 160-162. 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 along a medial plane that is generally perpendicular to the longitudinal length. Ex. 1002, ¶ 163; Ex. 1007, 1:19–21.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 163.

f. "said longitudinal length is greater than said maximum lateral width;"

Brantigan discloses a longitudinal length and a maximum lateral width as explained above. *Supra* § XI.C.2.e.

Brantigan's "oval ring plug 11 [is] generally shaped and sized to conform with

the disc space between adjoining vertebrae in a vertebral column." Ex. 1007, 4:5–8, 2:2–4 (implants are "generally oval shaped to conform with the general outline perimeter of the vertebrae"). Further, Brantigan discloses plugs that "are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies." *Id.*, 1:19–21.

The size of the disc space varies along the human spine—the medial-lateral and anterior-posterior dimensions of the disc space are different for thoracic and lumbar vertebrae. Ex. 1002, ¶ 167. Brantigan's implants "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, 1:65–68.

Well before 2004, the average medial-lateral and anterior-posterior dimensions of the human thoracic and lumbar spine where known. Berry, for example, conducted "a morphometric study of selected human vertebrae undertaken to provide data for implant design." Ex. 1022, 362. In particular, Berry measured "major body diameter" (vertebral transverse width) and "minor body diameter" (vertebral depth) at three different points from 240 different vertebrae. *Id.*, 362–363, Fig. 1; Ex. 1002, ¶ 169. Berry determined the means and standard deviations associated with these dimensional data. Ex. 1022, Table 1. As reflected in Table 1 of Berry, a POSA would have known well before 2004 that the vertebral transverse width would be greater than the vertebral depth for all of Brantigan's thoracic or

lumbar implants, which "are preferably oval shaped with medial-lateral [*i.e.*, longitudinal length] and anterior-posterior [*i.e.*, maximum lateral width] dimensions in the same ratio as normal vertebral bodies." Ex. 1007, 1:19–21; Ex. 1022, Table 1; Ex. 1002, ¶¶ 174-175.

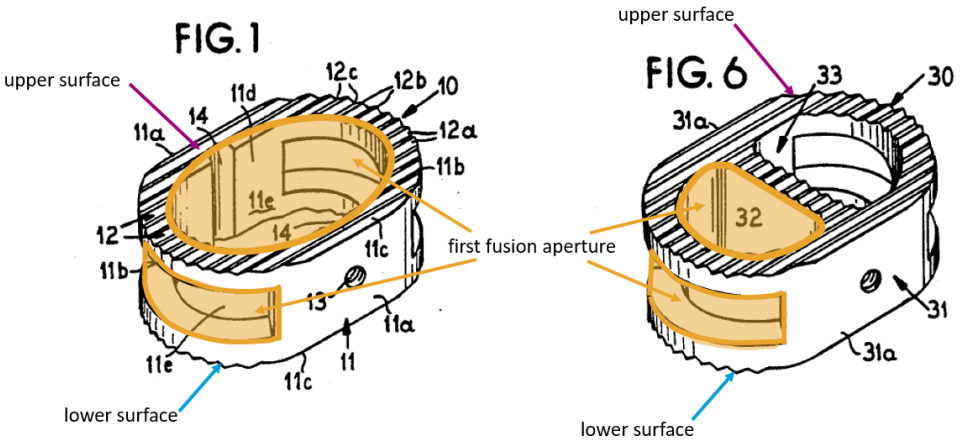
Accordingly, Brantigan discloses this limitation. *Id*.

g. "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.C.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, ¶¶ 176-181.

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, ¶ 177.



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, ¶ 179. 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." *Id.*, ¶¶ 177-180, 241; Ex. 1007, 1:41–43.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 181.

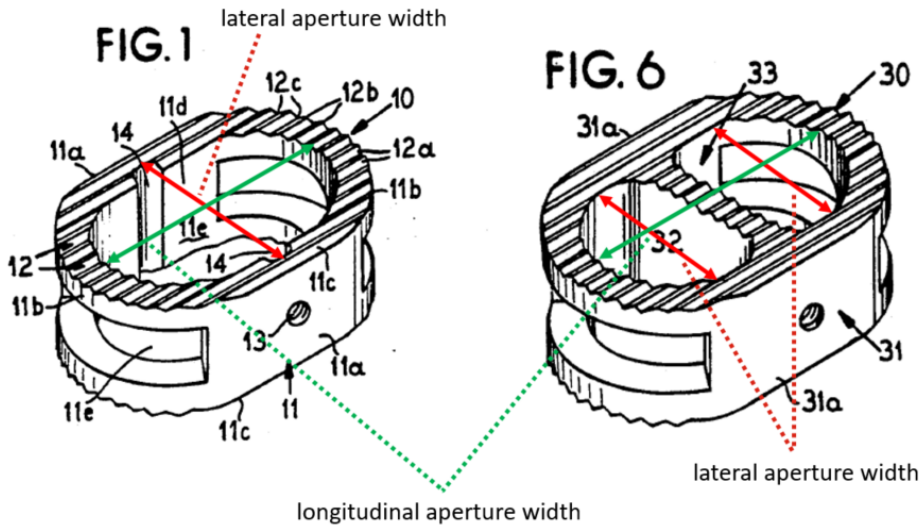
h. "said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral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

Brantigan discloses a first fusion aperture as explained above. *Supra* § XI.C.2.g.

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.C.2.f; Ex. 1002, ¶ 182; *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, ¶ 183.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 185.

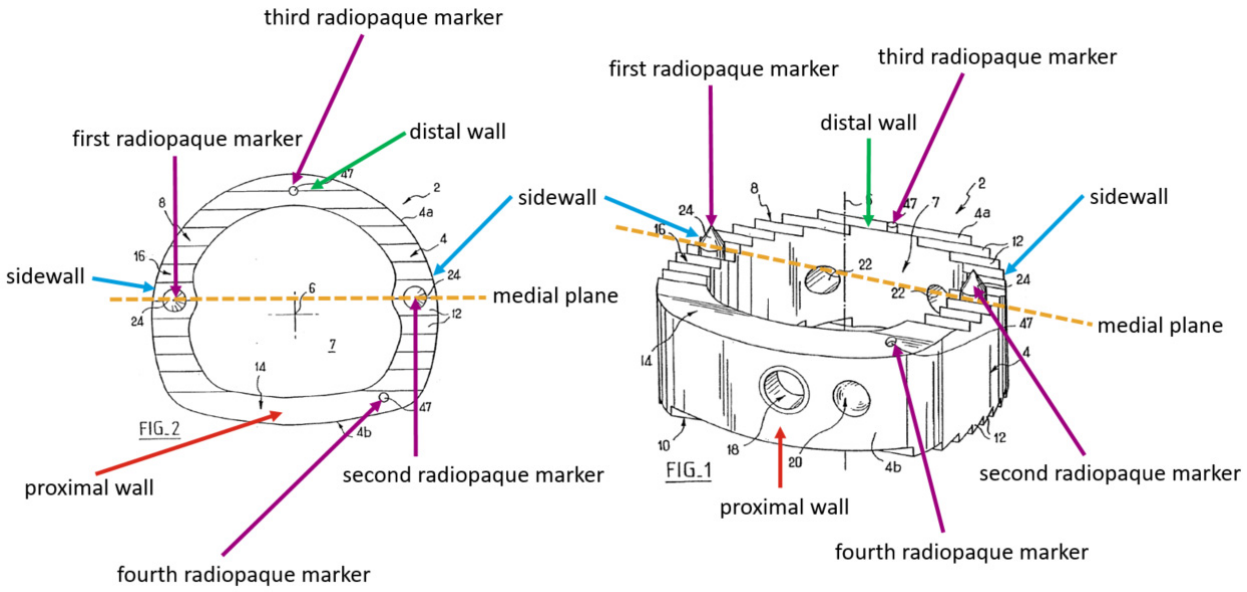
i. "at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said first radiopaque marker extends into said first sidewall at a position proximate to said medial plane, and said second radiopaque marker extends into said second sidewall at a position proximate to said medial plane."

Baccelli describes a spinal fusion implant ("cage") that includes "at least first and second radiopaque markers." Ex. 1002, ¶ 187; Ex. 1008, [0041], [0050]–[0051]. In particular, Baccelli's spinal fusion implant

> has spikes 24, in this case four such spikes, i.e., two associated with each of the main faces 8 and 10. Each spike has a pointed end and it projects from the associated main face. The two spikes on each face are disposed symmetrically to each other about the sagittal midplane. In addition, they extend in the frontal midplane containing the axis 6.

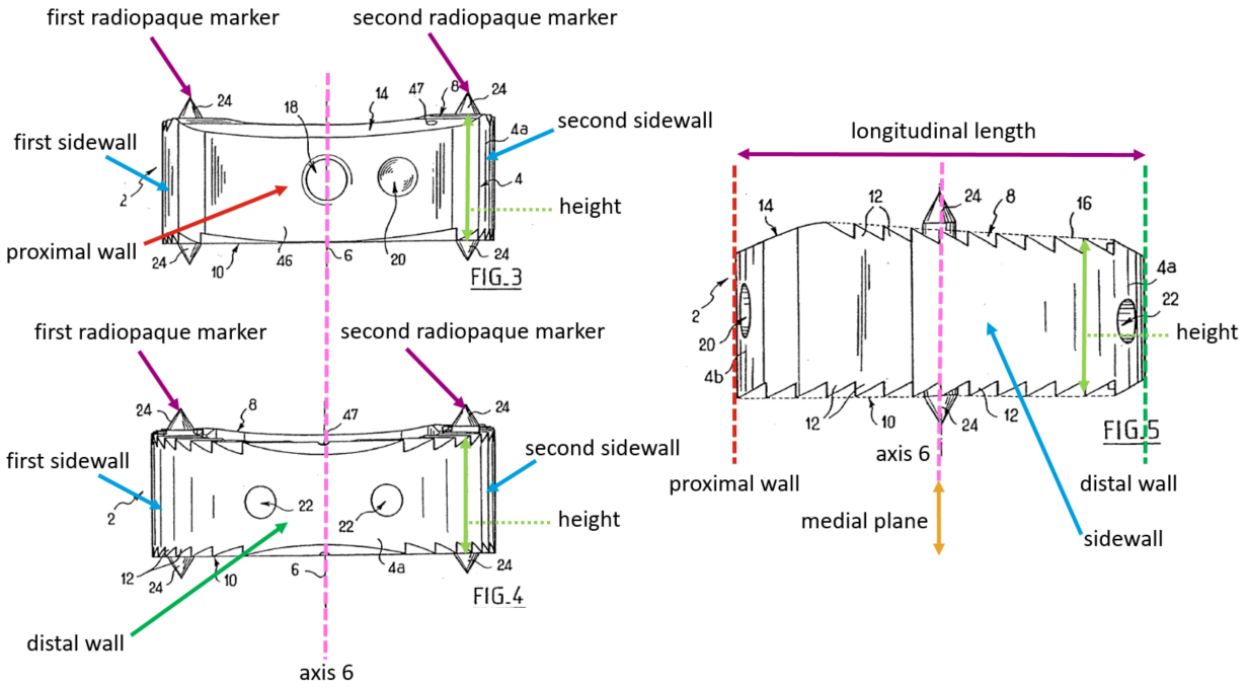
Ex. 1008, [0041], Figs. 1–5, 8, 9. Baccelli also explains that the spikes 24 "can be made of a material that is opaque to X-rays." Ex. 1008, [0051].

Baccelli discloses extending the radiopaque markers (24) into the first and second sidewalls at a position proximate to the medial plane. Ex. 1002, ¶ 189.



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, ¶ 191; 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, ¶ 191. 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, ¶ 191.



Id., Figs. 3–5 (annotated).

As shown above, Baccelli's radiopaque markers (spikes 24) are oriented parallel to the height of the implant in the sidewalls along central axis 6. Ex. 1008, [0041], Figs. 3–5; Ex. 1002, ¶ 192. Baccelli discloses that the radiopaque markers "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, ¶ 192. The spikes also "extend in the frontal midplane containing axis 6." *Id.*, [0041]. Accordingly, as shown in the illustrations, the first radiopaque marker extends into the first sidewall at a position proximate to said medial plane, and the second radiopaque marker extends into the second sidewall at a position proximate to said medial plane. Ex. 1002, ¶¶ 192-193. 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 first and second sidewalls, respectively. Ex. 1002, ¶¶ 192-193.

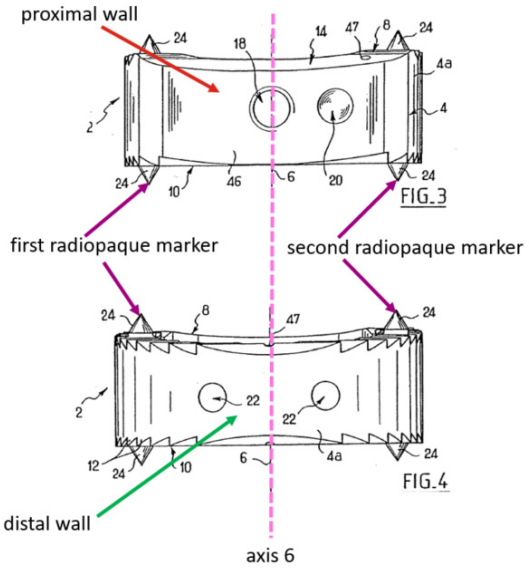
Accordingly, Baccelli discloses this limitation. *Id.*

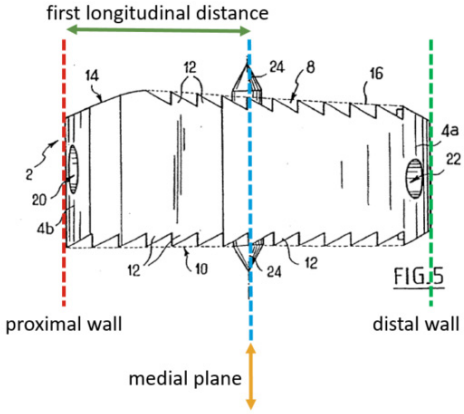
3. Claim 2

a. "The spinal fusion implant of claim 1, wherein the first and second radiopaque markers are substantially equally spaced apart from said proximal end of said proximal wall by a first longitudinal distance."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2.

Further, as shown below, Baccelli's first and second radiopaque markers are substantially equally spaced apart from the proximal end of the proximal wall by a longitudinal distance. Ex. 1002, ¶ 195.





Ex. 1008, Figs. 3–5 (annotated); *see also* Figs. 1, 8, 9. Baccelli explains that the radiopaque markers are situated on the mid-sagittal plane, substantially equidistant

from the proximal wall. Ex. 1008, ¶¶ [0041]; [0036]. The mid-sagittal plane is the sagittal plane that vertically bisects the human body. Ex. 1002, ¶ 196.

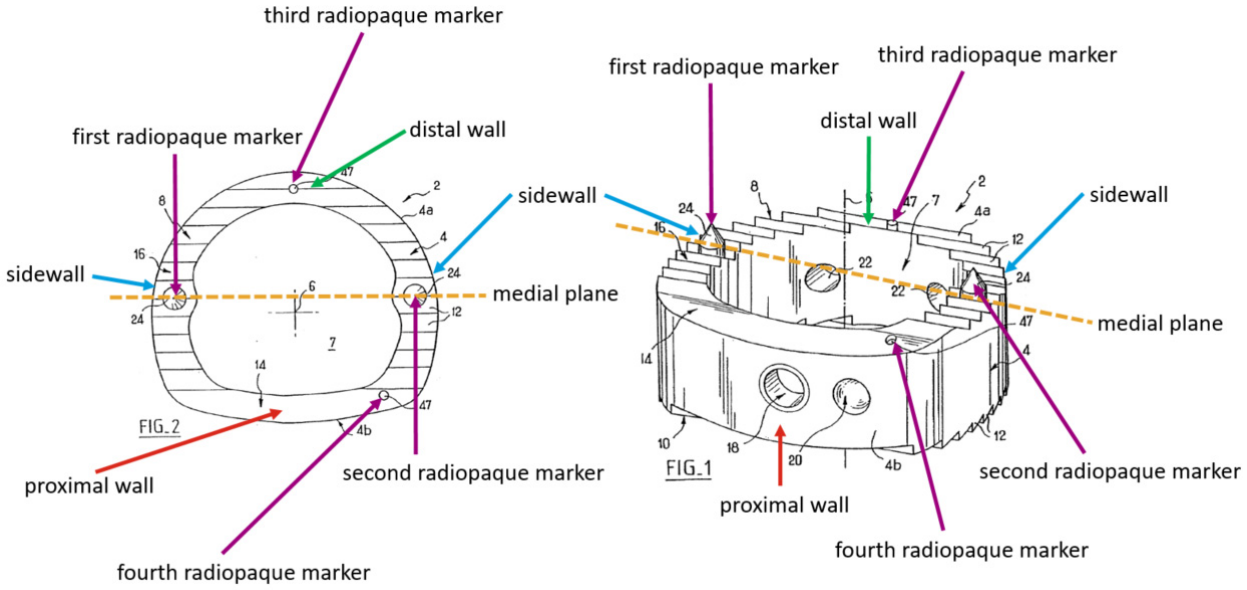
Accordingly, Baccelli discloses this limitation. *Id.*, ¶ 197.

4. Claim 3

a. "The spinal fusion implant of claim 1, further comprising a third radiopaque marker that extends into said distal wall, and a fourth radiopaque marker that extends into said proximal wall."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2.

Baccelli further discloses third and fourth radiopaque markers:



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

Baccelli 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." *Id.*, [0050].

Because the markers are inserted in rectilinear ducts, the markers extend into the distal wall and proximal wall, respectively. Ex. 1002, ¶ 200.

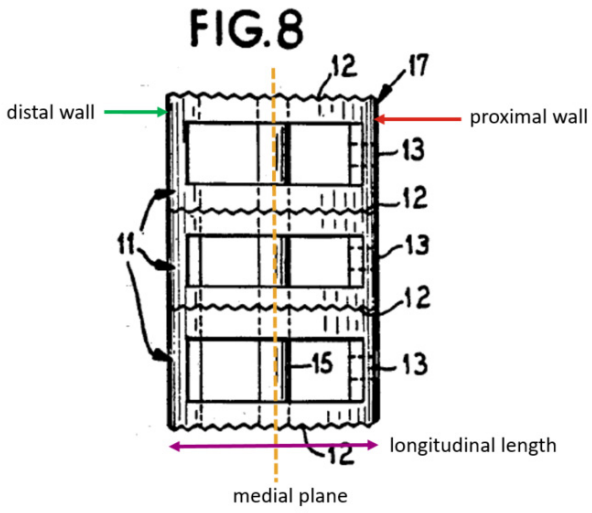
Accordingly, Baccelli discloses this limitation. *Id.*, ¶ 201.

5. Claim 5

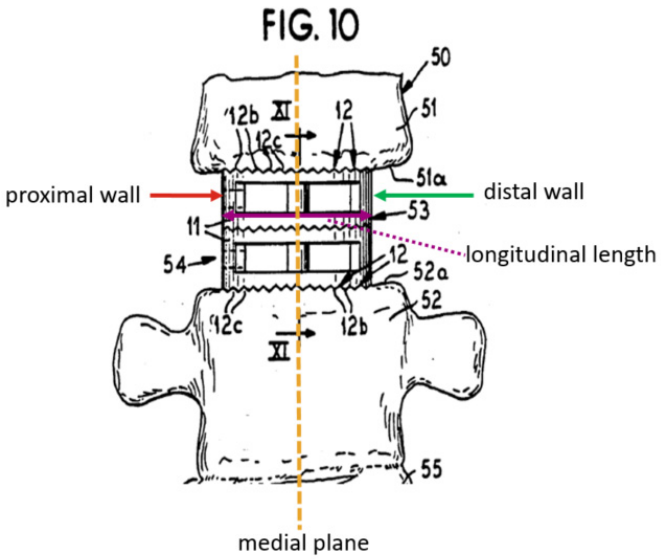
a. "The spinal fusion implant of claim 1, further including at least one receiving aperture position at said proximal wall"

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2.

Brantigan discloses that "[o]ne side wall 11*a* of the plug 11 has an internally threaded hole 13 extending partially through the wall for receiving a mounting tool." Ex. 1007, 4:20–22. Brantigan further states that "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.*, 5:32–35. Brantigan Figure 8 illustrates a stack 17 of plugs 11 with threaded insertion holes 13 in the proximal walls:



Id., Fig. 8 (annotated); Ex. 1002, ¶ 205. 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 in Figure 10, the threaded insertion holes are visible on the left (proximal) side of laterally-inserted plug 11. *Id;* Ex. 1002, ¶ 205.

Accordingly, Brantigan discloses this limitation. *Id.*, ¶¶ 202-208, 211.

b. "wherein said longitudinal length is greater than 40 mm."

Brantigan's implants are "generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column," (Ex. 1007, 4:5–8) "with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies" (*id.*, 1:20–21). *See supra* § XI.C.2.f; Ex. 1007, 2:2–4. Brantigan's implants are provided for use in the thoracic and lumbar spine. Ex. 1007, 1:65–68.

As disclosed in Berry, the longitudinal length would be "greater than 40 mm" for thoracic vertebrae T12 and lumbar vertebrae L1 through L5. Ex. 1022, 364,

Table 1; Ex. 1002, ¶¶ 209-210.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶¶ 209-211.

6. Claim 9

a. "The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately 18 mm."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2.

Brantigan's implants are "generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column," (Ex. 1007, 4:5–8) "with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies" (*id.*, 1:20–21), and "are generally oval shaped to conform with the general outline perimeter of the vertebrae" (*id.*, 2:2–4). S*ee supra* § XI.C.2.f.

A POSA would have been aware of Berry's "direct dimensional measurements" of human vertebrae and would have known that a Brantigan implant positionable within the interbody space at T2 would have a longitudinal length of approximately 29.8 mm and a lateral width of approximately 18.1 mm. Ex. 1002, ¶¶ 174, 213-214; Ex. 1022, 362, 364, Table 1.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 215.

7. Claim 10

a. "The spinal fusion implant of claim 1, wherein said radiolucent material comprises PEEK."

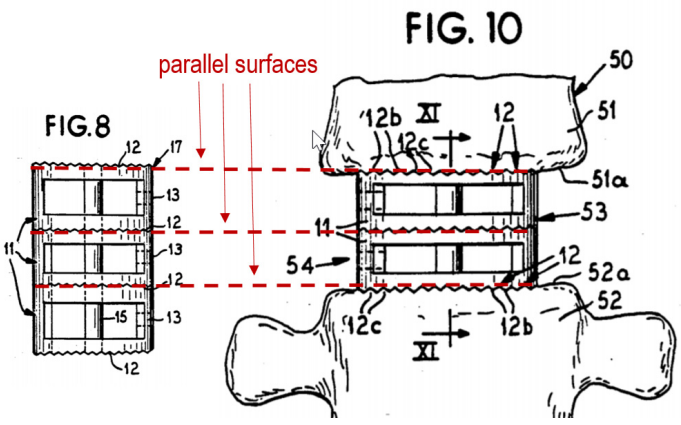
Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. Further, Brantigan's "implants are preferably made of radiolucent material," such as "'Peek', (polyetherether ketone) or 'Ultrapek' (polyether ketone, ether ketone, ketone)." Ex. 1007, 3:9–12; Ex. 1002, ¶ 217.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 218.

8. Claim 12

a. "The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally parallel to one another."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. Further, Brantigan teaches devices that "are uniform in thickness or height across their length." Ex. 1007, 5:48–49. As shown below, the upper and lower surfaces of one Brantigan embodiment are generally parallel to one another.



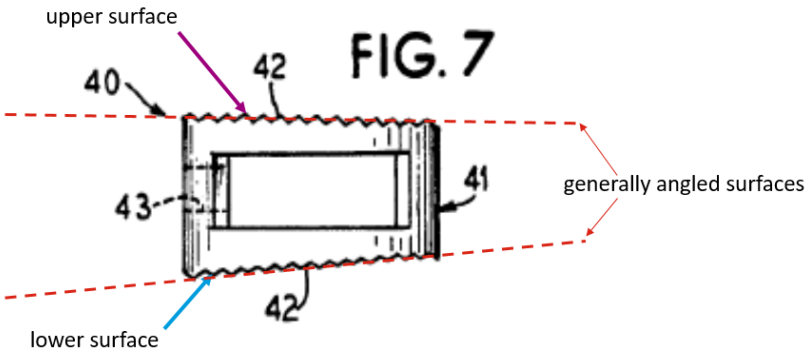
Id., Figs. 8 (annotated), 10 (annotated excerpt).

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶¶ 220-222.

9. Claim 13

a. "The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when said implant is positioned within the interbody space."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. Brantigan further discloses one embodiment that "is tapered to be higher or thicker at its anterior end than at its posterior end":



Ex. 1007, 5:50–52, Fig. 7 (annotated).

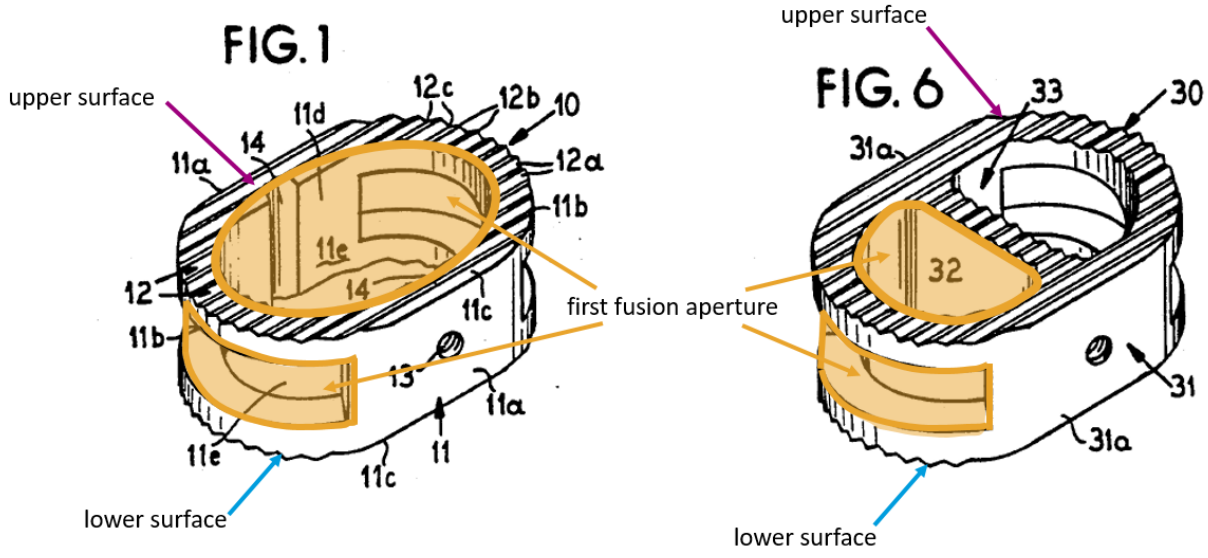
For example, "the trailing end could be 12 mm in height while the leading end reduced to 9 mm in height." *Id.*, 5:55–57; Fig. 7. Further, "[t]he ridged faces 42 of the tapered plugs 41 will interdigitate and the exposed end faces of these ridges will be inclined or tapered to suit surgical application in spaces where the adjacent vertebrae are wider at one end than at the other." *Id.*, 5:65–6:1. Such a taper is designed to correspond to lordosis of the lumbar spine when the implant is positioned in the interbody space. Ex. 1002, ¶¶ 224-225.

Accordingly, Brantigan discloses this limitation. *Id.*, ¶ 226.

10. Claim 14

a. "The spinal fusion implant of claim 1, wherein said first fusion aperture is one of generally rectangular and generally oblong in shape."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. Brantigan implants "are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies." Ex. 1007, 1:19–21. Brantigan's first fusion aperture, like the implant, has two longer parallel sides (length) and two shorter curved sides (width) and is "generally rectangular and generally oblong in shape." Ex. 1002, ¶ 228.



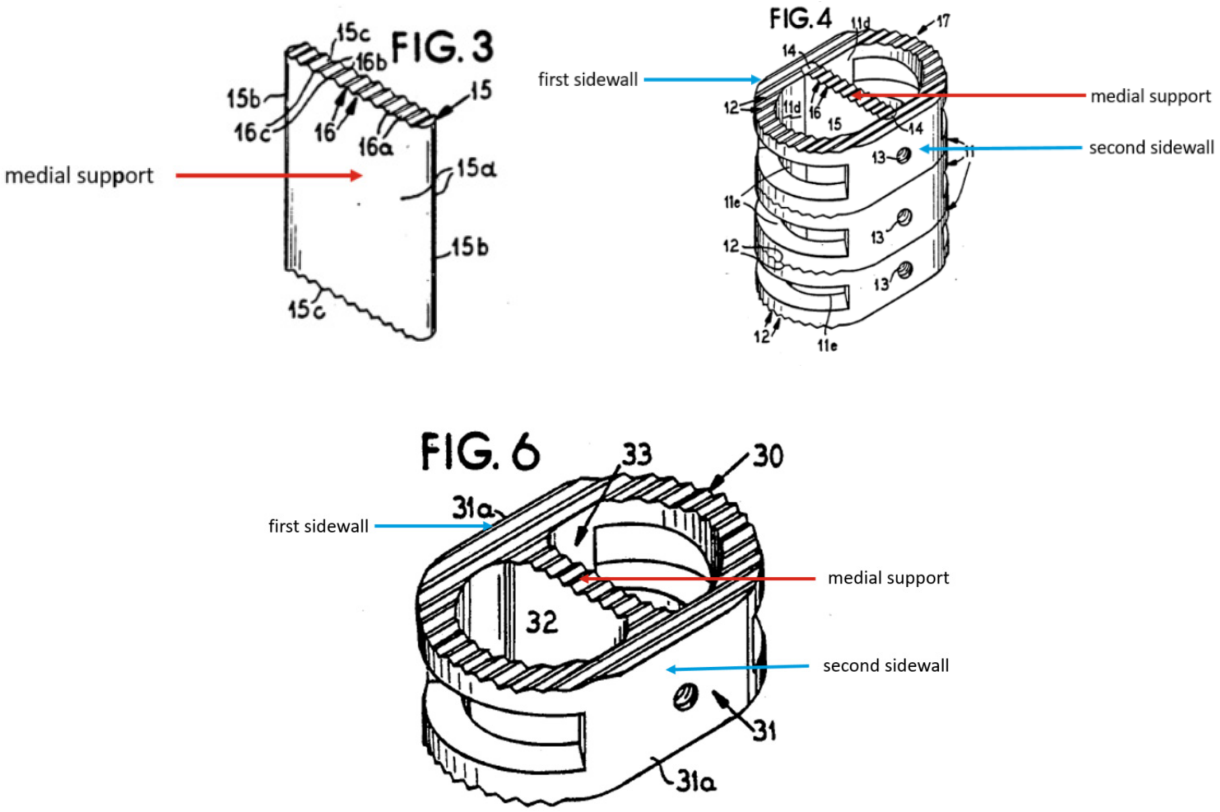
Ex. 1007, Figs. 1 (annotated), 6 (annotated).

Accordingly, Brantigan discloses this limitation. *Id.*, ¶ 229.

11. Claim 15

a. "The spinal fusion implant of claim 1, further comprising a medial support extending between the first and second sidewalls."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. Brantigan discloses embodiments bisected by connecting bar 15 and integral partition 32:



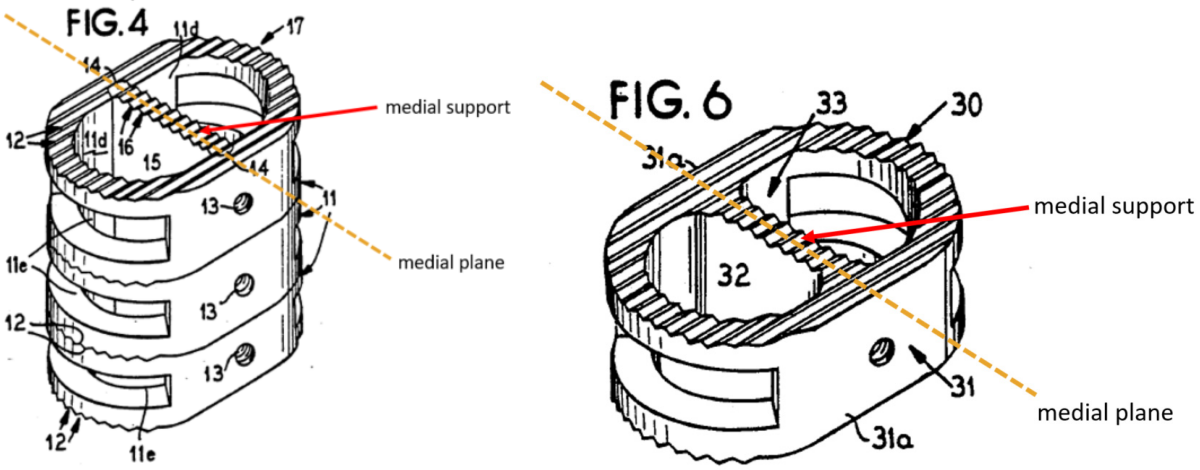
Ex. 1007, 4:23–27, 4:50–53, 5:36–43, Figs. 3, 4 (annotated), 6 (annotated); Ex. 1002, ¶ 233.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 234.

12. Claim 16

a. "The spinal fusion implant of claim 15, wherein said medial support is positioned along said medial plane."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. As further described above for claim 15, and as illustrated in the following annotated figure, Brantigan discloses spinal fusion implants in which the "medial support is positioned along said medial plane." Ex. 1002, ¶¶ 236-237.



Ex. 1007, Figs. 4 (annotated), 6 (annotated).

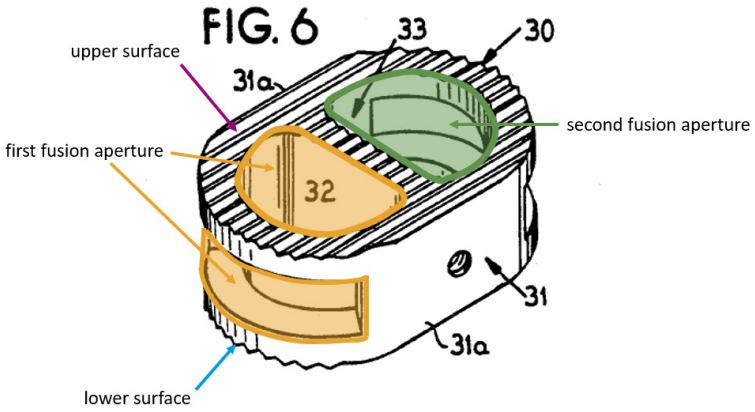
Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 238.

13. Claim 17

a. "The spinal fusion implant of claim 1, further including a second 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 in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. As described above for claim 15, the central aperture of Brantigan's

implant "is separated by the bar 15 into two side-by-side chambers which are easily packed with bone graft material to expedite the fusion of the prosthesis device in the spinal column" or is "bisected by an integral internal partition 32 forming a pair of side-by-side apertures through the plug adapted to receive bone graft material." Ex. 1007, 4:50–53; 5:36–43, Fig. 6. In both embodiments, the aperture extends through the upper and lower surfaces:



Ex. 1007, Fig. 6 (annotated). The side-by-side chambers allows the spinal fusion implant "to be packed with bone graph material" to "form[] a living bone bridge across the fusion area." Ex. 1007, 1:42–43, 8:38–53.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶¶ 240-242.

14. Claim 18

a. "The spinal fusion implant of claim 17, wherein said second fusion aperture is separated from said first fusion aperture by a medial support."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. As explained for claim 17 above, the "connecting bar 15" that forms

the "side-by-side chambers" and the "integral partition 32" that forms the "side-by-side apertures" disclosed in Brantigan is a medial support. Ex. 1002 at ¶ 244; Ex. 1007, 4:23–27, 4:50–53, 5:36–43, Figs. 3–4, 6.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 245.

15. Claim 19

a. "The spinal fusion implant of claim 1, wherein said anti-migration elements of said upper surface comprise a plurality of ridges."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. Brantigan discloses "[r]idges 12 [] 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." Ex. 1007, 4:15–18. "The 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 21*b* and 22*g* of these ridges will firmly engage and bite into these faces to prevent slippage." *Id.*, 5:22–26.

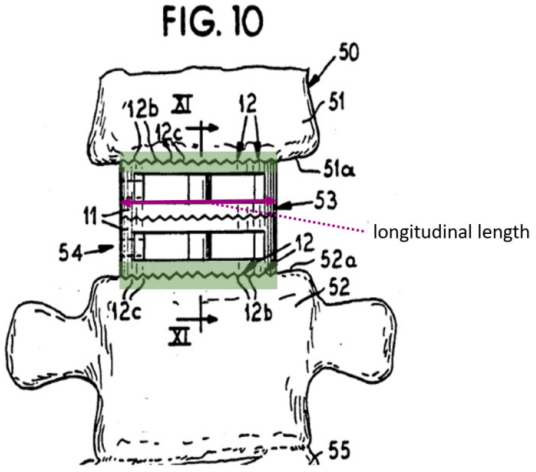
Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶¶ 247-249.

16. Claim 20

a. "The spinal fusion implant of claim 19, wherein said plurality of ridges extend generally perpendicular to said longitudinal length."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. As explained above for claim 19 and illustrated below, Brantigan

discloses the claimed ridges that extend generally perpendicular to the longitudinal length of the implant. *See* Ex. 1007, Fig. 10; Ex. 1002, ¶ 251.



Ex. 1007, Fig. 10 (annotated excerpt).

Patent Owner previously told the Board that Figure 10 "shows an implant that has been inserted laterally… 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, ¶¶ 251-253.

17. Claim 21

a. "The spinal fusion implant of claim 1, wherein said anti-migration elements of said upper surface comprise spike elements."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2.

Brantigan discloses spinal fusion implants that improved the "art of interbody

fusion" "without cutting grooves or channels into the vertebrae" to minimize implant migration after surgery. Ex. 1002, ¶ 255; Ex. 1007, 1:44–47. Indeed, Brantigan's "devices do not require anchoring screws or penetration through the hard faces of the vertebrae" for proper implantation. Ex. 1002, ¶ 255; Ex. 1007, 7:23–25. As an alternative to these invasive techniques, Brantigan developed implants with ridges that "firmly anchor" the implant "to the vertebrae but do not penetrate through the hard faces 51*a* and 52*a* of the vertebrae." Ex. 1002, ¶ 255; Ex. 1007, 6:14–16.

Consistent Brantigan's approach to anchor, rather than invasively fix, the implant, Baccelli discloses an improvement "that ensures even better anchoring" than known implants such as Brantigan that have "mutually parallel elongate teeth on both main faces." Ex. 1008, [0002]–[0003]. In particular, Baccelli discloses "at least one spike projecting from one of its main faces" that "digs into the vertebral plate and further increases the quality of the anchoring," even when the implant already has ridges or teeth. *Id.*, [0020]–[0021]. As described above, Baccelli further teaches that such spikes "can be made of a material that is opaque to X-rays." *Id.*, [0051]; *supra* § XI.C.3.

Thus, Baccelli discloses a spinal fusion implant with anti-migration elements of the upper surface that include spike elements. Ex. 1002, ¶ 256; *see also supra* §§ XI.C.2.i, XI.C.3, XI.C.4. Further, a POSA would have been motivated to include Baccelli's spike in Brantigan's implant to both prevent implant migration after

insertion and enhance visualization to determine proper orientation using X-rays during and after surgery. Ex. 1002, ¶ 257.

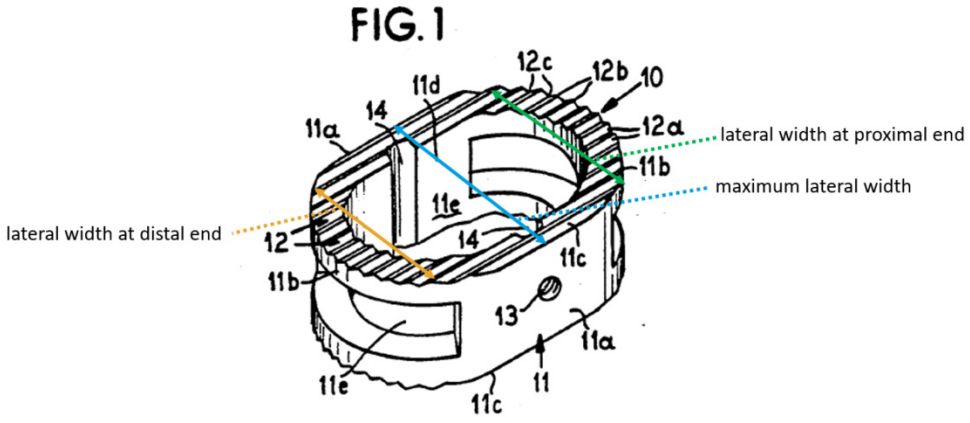
Accordingly, Baccelli discloses this limitation. *Id.*, ¶ 258.

18. Claim 23

a. "The implant of claim 1, wherein said maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2.

As described above, Brantigan's spinal fusion implant is "preferably oval shaped." Ex. 1007, 1:19, *see also* Fig. 6; *supra* § XI.C.2.c. A POSA would have understood that the maximum lateral width of an oval-shaped implant is greater than the lateral width of either the distal end of the distal wall, or the proximal end of the proximal wall where the sidewalls become rounded. Ex. 1002, ¶ 260.



Ex. 1007, Fig. 1 (annotated).

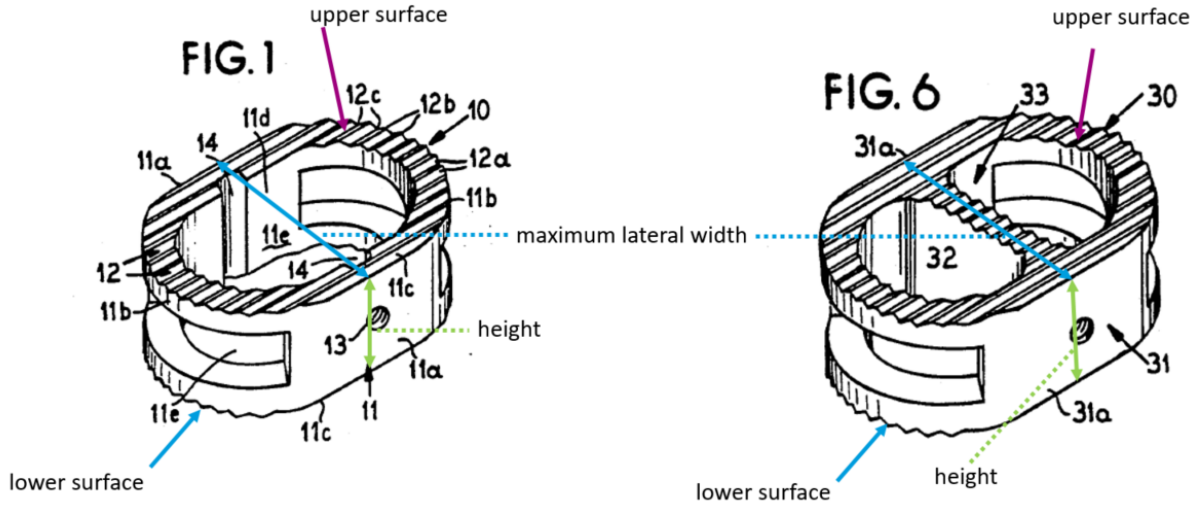
Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 261.

19. Claim 24

a. "The implant of claim 1, wherein said implant has a height extending from said upper surface to said lower surface, wherein said maximum lateral width is greater than said height."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. Brantigan also discloses that "[e]ach of the oval implants is sized to match the height of an average disc and thus, can vary from 10 to 15 mm for the lumbar area and from 7-11 mm for the cervical area." Ex. 1007, 2:19–22.

The following annotated images illustrate the height of the Brantigan spinal fusion implants, which extends from the upper surface to the lower surface. The images also illustrate the maximum lateral width, which, as described below, is greater than the height.



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

As explained above in claim 1(e), Brantigan's implants are "generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column." Ex. 1007, 4:5–8, 1:19–21.

Berry teaches that the maximal lateral width of implants sized and shaped for the lumbar spine (corresponding to the depth of the disc space) would range from 31.9 mm to 35.1 mm. Ex. 1002, ¶ 266; Ex. 1022, 364, Table 1. Brantigan's lumbar implants range from 10 to 15 mm high. Ex. 1007, 2:19–22. Thus, a POSA following the teachings of Brantigan to size the implant to conform with the disc space would have been motivated to modify the Brantigan lumbar implant having a height of 10 to 15 mm to have the width of Berry from 31.9 mm to 35.1 mm, thus having a maximum lateral width that is greater than the height of those implants.

Accordingly, Brantigan discloses this limitation. Ex. 1002, ¶ 268.

20. Claim 27

a. "The spinal fusion implant of claim 1, further comprising an osteoinductive material positioned with said first fusion aperture."

Brantigan in view of Baccelli and Berry render the implant of claim 1 obvious. *Supra* § XI.C.2. Brantigan further explains that "the open central portion of the ring is preferably packed with bone graft material to facilitate bone ingrowth." Ex. 1007, 2:15–17; *see also* FIG. 11, 6:37–40 ("the hollow interior 11*d* and the slots 11*e* of the plug 11 are packed with bone graft material 58 which can be conveniently harvested

from the iliac crests of the patient's pelvic bone."); Ex. 1002, ¶ 270. Bone graft material—whether harvested from the patient's pelvic bone or taken from other sources—promotes bone growth and, thus, is "osteoinductive material." Ex. 1002, ¶¶ 270-271.

Accordingly, Brantigan discloses this limitation. *Id.*, ¶ 272.

D. Ground 2: Claim 9 is rendered obvious by Brantigan, Baccelli, Berry, and Michelson '973.

1. Motivation to combine Brantigan, Berry, Baccelli, and Michelson '973.

Brantigan discloses lateral insertion of a spinal fusion implant. *See supra* §§ IV.a, VIII. Michelson '973 explains the benefits associated with such lateral insertion: increased safety, decreased patient discomfort, and increased structural support that an "oversized" implant provides. Ex. 1032, Abst., 2:19–67, 3:56–4:24; Ex. 1002, ¶¶ 113-115. According to Michelson '973, these benefits can be accomplished by inserting the "oversized" implant modularly, allowing a narrower implant to be inserted through a hollow tube, thereby decreasing patient surgical discomfort by reducing incision size. *Id*.

To achieve the benefits of Michelson '973, 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. Coupled with Berry's "direct dimensional

measurements" of lumbar vertebrae (Ex. 1022, 364, Table 1),[8] 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, 3:50–55 (describing how a translateral spinal fusion implant having a length that is substantially greater than the depth of the vertebrae and a width that approximate the depth of the vertebrae "has more surface area of contact and thus permits greater stability so as to withstand torque"). Further, a. Ex. 1002, ¶¶ 277-284.

2. Claim 9

a. "The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately 18 mm."

Brantigan, Baccelli, and Berry render the spinal fusion implant of claim 1 obvious. *Supra* § XI.C.2.

In addition to disclosing cylindrical translateral spinal fusion implants, Michelson '973 describes an alternative:

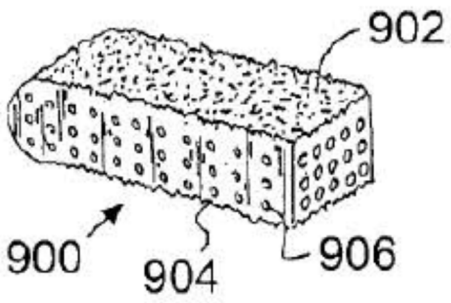
> spinal fusion implant 900 [that] comprises a rectangular block 901 having a top surface 902 and a bottom surface

[8] Petitioner contends that Berry merely reflects knowledge that would have been available to and within the purview of a POSA, but to avoid Patent Owner challenging that proposition, Petitioner applies Berry in this ground.

> 904 for engaging the adjacent vertebrae and may be flat or conform at least in part. The top and bottom surfaces 902 and 904 maybe comprise any of the surface roughenings described herein for engaging the bone of the adjacent vertebra 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.

Ex. 1032, 10:19–31; *see also* Fig. 16.

FIG. 16



Id., Fig. 16.

Michelson ’973 illustrates spinal fusion implant 900 “implanted from the lateral aspect of the spine in the disc space D between two adjacent vertebrae V, V_1 and V_2 along the transverse width of the adjacent vertebrae V_1 and V_2. The spinal

fusion implant 900 has a height that is substantially equal to the height of the disc space D, a length that is greater than one half the transverse width W of the vertebrae and a width that approximates the depth of the vertebrae." *Id.*, 10:32–41; *see also* Fig. 17 below.

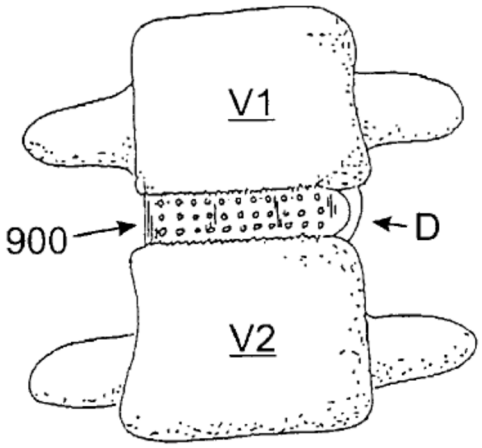


FIG. 17

Id., Fig. 17.

Michelson '973 also describes "spinal fusion implant 1000 [which] 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 adjacent vertebrae." *Id.*, 10:50–55. In particular, Michelson '973 discloses "a plurality of spinal fusion implants 1000 are shown combined in a modular fashion inserted in the disc space D from the lateral aspect of the spine and along the transverse width of the vertebrae V_1 and V_2." *Id.*, 10:56–59; *see also* Fig. 19 below.

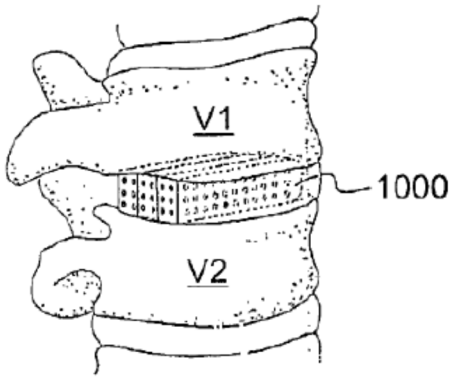


FIG. 19

Id., Fig. 19.

Michelson '973 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 retraced 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 '973 teaches. *See, e.g.*, Ex. 1032, 50–55.

Michelson '973 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. Therefore, a POSA designing an implant for fusion between L4 and L5 would have been motivated to further rely on Berry's

dimensional data, which Berry provided to facilitate implant design. Ex. 1002, ¶ 281; Ex. 1022, 362, 364, Table 1; Ex. 1032, 10:42–47.

At least as of March 2004, POSAs would have understood the inherent variability of the segmental lordosis, and anatomic dimensions over the course of the lumbo-sacral spine. Ex. 1002, ¶ 282. Thus, POSAs would have understood that implants would need to accommodate this variability and not be specific to a given level in the vertebral column, unless that was a specific intent of the inventor, *i.e*. an implant specific to L5-S1 which has the greatest height and lordosis. *Id.*

Thus, 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 '973'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, ¶283.

To size the narrow implant, a POSA would have turned to Berry, which teaches mean widths ranging from 31.9 mm at L1 to 35.1 mm at L5, and based on the teachings in Brantigan, would have made the implants half that width, which

would be 15.95 mm[9] at L1 and 17.55 mm[10] at L5. Ex. 1022, 364, Table 1; Ex. 1022, ¶ 284. Considering Berry's standard deviation, a POSA would have been motivated to modify Brantigan's implants to have widths between 14.1 mm[11] L1 to 18.95 mm[12] for L5. Ex. 1002, ¶ 284. A POSA performing a fusion between adjacent L4 and L5 vertebrae, for example, would have had a reasonable expectation of success in modifying a Brantigan implant per the teachings of Michelson '973, to have widths ranging from 16.15 mm to 18.95 mm for a lumbar fusion. Ex. 1022, 364. Thus, a POSA would have been motivated to design an L5 spinal fusion implant that was "approximately 18 mm wide." Ex. 1002, ¶ 284.

Accordingly, Michelson '973 discloses this limitation. Ex. 1002, ¶¶ 275–285.

XII. THERE ARE NO SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

Petitioner is unaware of any secondary considerations that demonstrate nonobviousness. In IPR2013-00506, Patent Owner offered evidence purportedly to establish "a nexus between NuVasive's CoRoent XL implants and the invention of

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

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

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

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

the ’156 patent” to demonstrate commercial success. Ex. 1004, 20–22 (citing Ex. 1043, 65). The Board explained that the existence of secondary considerations alone—in the absence of nexus—is insufficient to demonstrate non-obviousness. *Id*. 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,’ ([Ex. 1043, 65]), but fails to demonstrate sufficiently that any of the disputed claims recite ‘lateral, trans-psoas interbody fusion surgeries.’” *Id.*, 22.

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 ’156 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 ’156 patent is related to U.S. Patent 8,187,334, which is also asserted in the above-referenced case. Petitioner will file a Petition for *Inter Partes Review* regarding the ’334 patent. *See* IPR2019-00361.

Patent Owner previously asserted the ’156 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 claims 1, 2–5, 9, 10, 12–24, and 27 of the ’156 patent and cancel those claims as unpatentable.

Date: December 13, 2018

Respectfully submitted,

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Counsel for Petitioners

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 13,782 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: December 13, 2018

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 December 13, 2018, I caused to be served a true and correct copy of the foregoing "PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1–3, 5, 9–10, 12–21, 23–24, and 27 OF U.S. PATENT NO. 8,361,156" and Exhibits 1001-1026, 1028-1044, and 1046-1047 by EXPRESS MAIL on the Patent Owner at the correspondence address of record for U.S. Patent No. 8,361,156, 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: December 13, 2018

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