Alphatec Holdings, Inc. and Alphatec Spine, Inc.
v.
NuVasive, Inc.

IPR2019-00361	U.S. Patent No. 8,187,334
IPR2019-00362	U.S. Patent No. 8,631,156
IPR2019-00546	U.S. Patent No. 8,187,334

Petitioners' Presentation

April 3, 2020

Overview of Grounds

Overview of Grounds

The ’334 patent (-0361)		
Ground	**Claims**	**Basis**
1	6-9 and 18	Obvious over Frey, Michelson, and Berry
2	6-9 and 18	Obvious over Brantigan, Baccelli, Berry, and Michelson

The ’334 patent (-0546)		
Ground	**Claims**	**Basis**
1	16	Obvious over Frey, Michelson, and Baccelli
2	16	Obvious over Brantigan, Baccelli, Berry, and Michelson

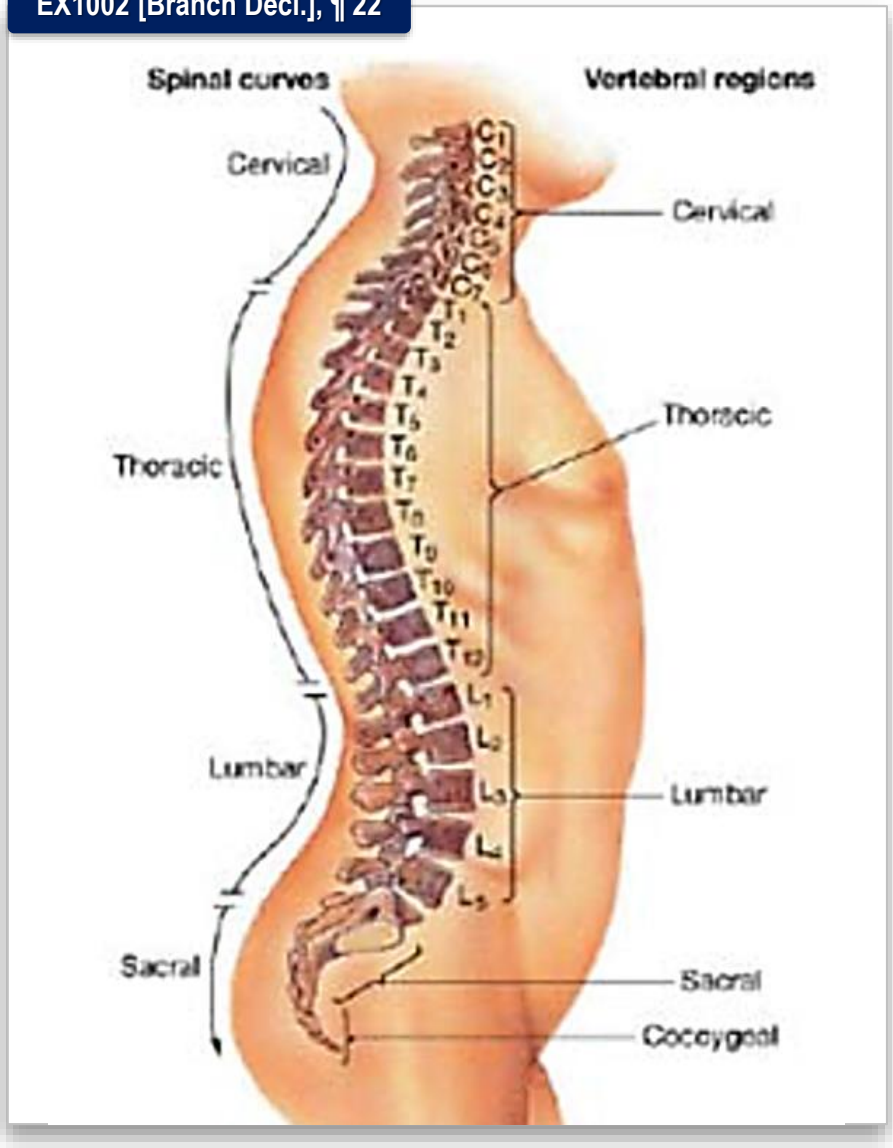
Overview of Grounds

The ’156 patent (-0362)		
Ground	**Claims**	**Basis**
1	1-3, 5, 9, 10, 12-21, 23, 24, and 27	Obvious over Brantigan, Baccelli, and Berry
2	9	Obvious over Brantigan, Baccelli, Berry, and Michelson

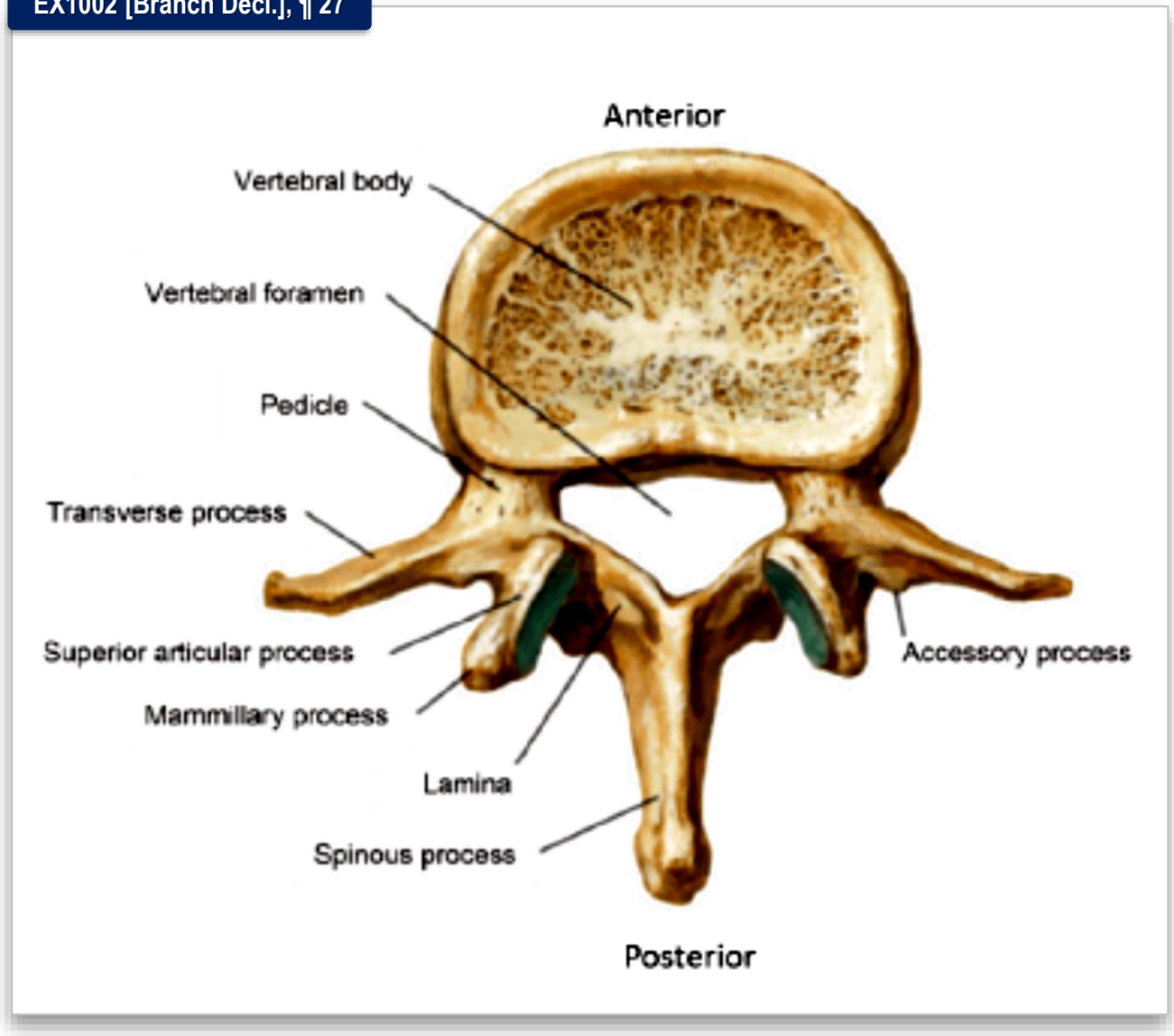
Background

Challenged Claims Directed to Spinal Fusion Implants

EX1002 [Branch Decl.], ¶ 22



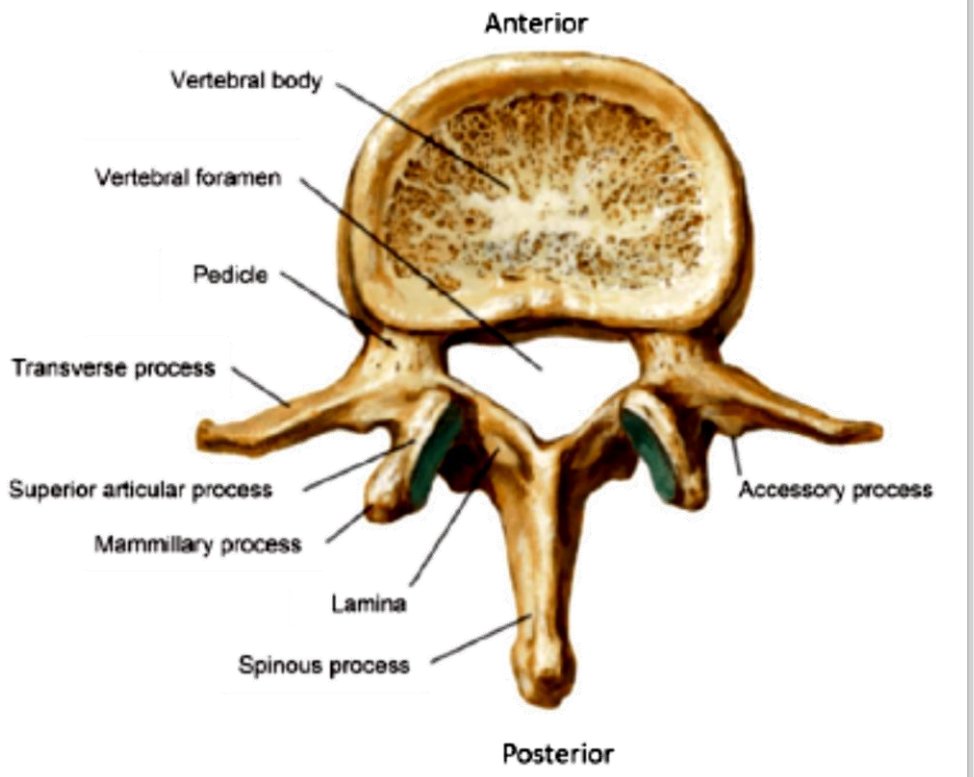
EX1002 [Branch Decl.], ¶ 27



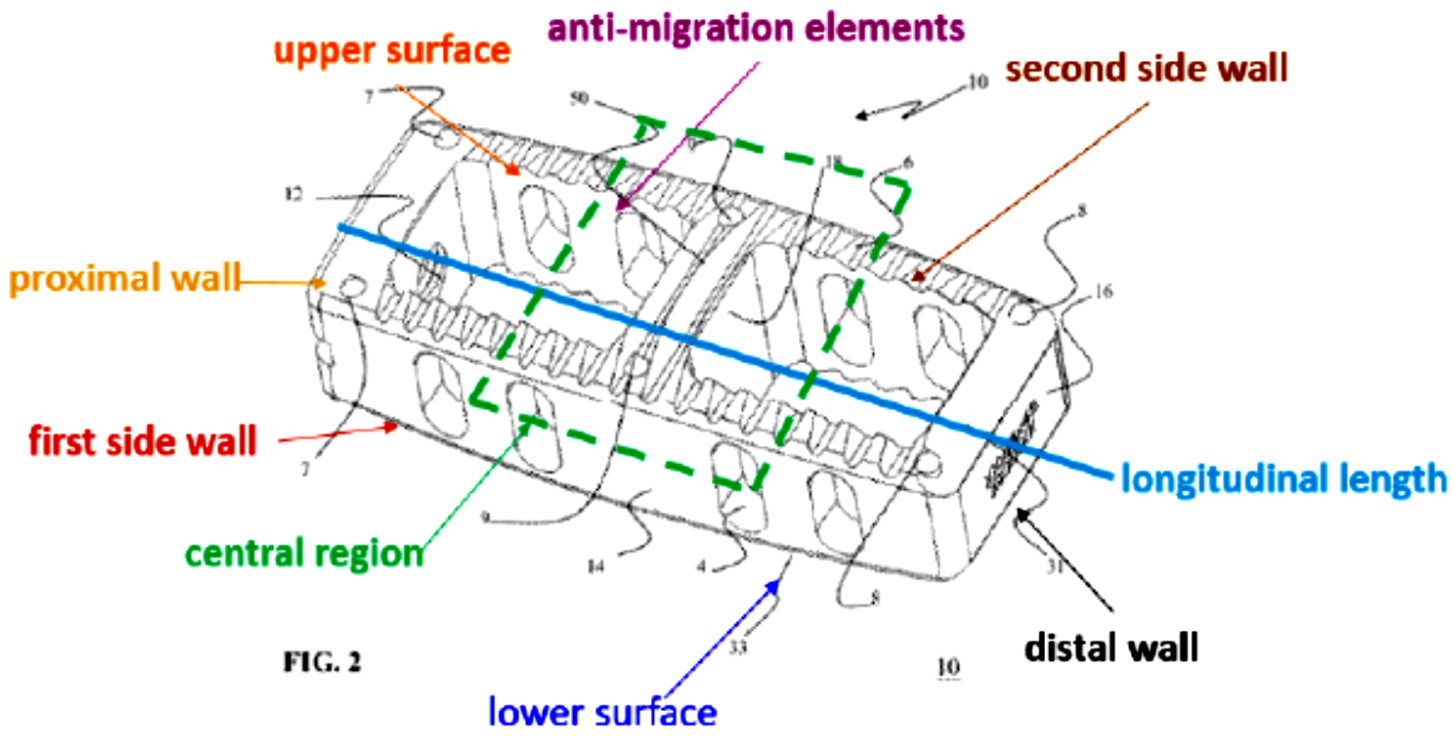
Source: Pet. 47

Challenged Claims Directed to Spinal Fusion Implants

EX1002 [Branch Decl.], ¶ 27



EX1001 ['334 Patent], Fig. 2 (annotated)



Source: Pet., 7, 47

State of the Art

State of the Art

- **Non-bone implants were known**
- Modular implants were known
- Vertebral dimensions were known
- Radiopaque markers were known

Berry Discloses Dimensions for Non-Bone Implants (1987)

EX1022 [Berry], 1

A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae

JAMES L. BERRY, MS, JAMES M. MORAN, DEng, WILLIAM S. BERG, BS, and ARTHUR D. STEFFEE, MD

EX1022 [Berry], 1

ACCURATE 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.

EX1022 [Berry], 1

The current study was undertaken due to a lack of information needed for design projects involving instrumentation for the lumbar and thoracic vertebrae. Direct measurements were made of 27 vertebral dimensions from prepared skeletal components. Radiographs of cadaver specimens were also used to determine the cross-sectional dimensions of the pedicles. Even though some of the measurements duplicate previous studies, they are included for comparative purposes, inasmuch as experimental techniques vary between investigators. Additionally, a wide variability has been reported between demographic groups.[11]

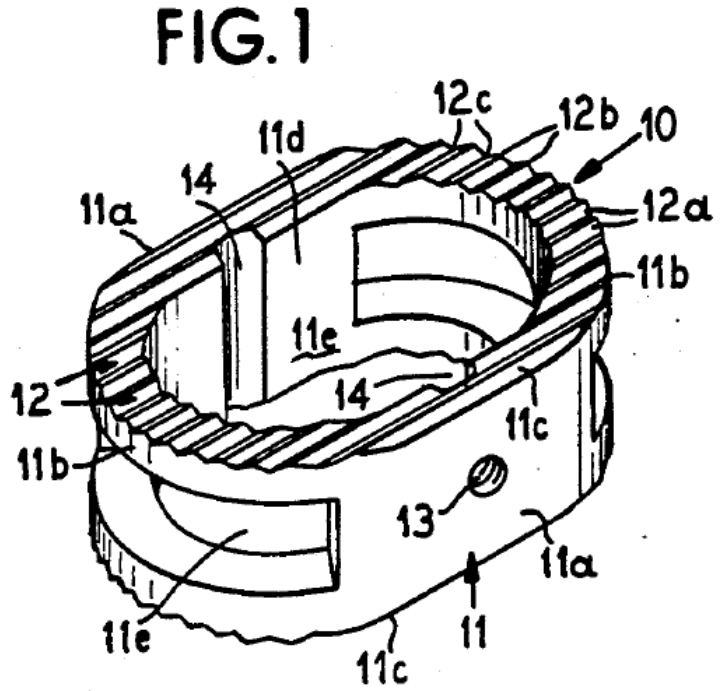
Source: Pet., 12-13

Brantigan Discloses Non-Bone Implants (1993)

EX1007 [Brantigan], 3:9-12

The 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).

EX1007 [Brantigan], Fig. 1



Source: Pet., 15

Michelson Discloses Non-Bone Implants (1999)

EX1032 [Michelson], 6:36-37

The translateral implants of the present invention may be made of an artificial material.

EX1032 [Michelson], Figs. 16, 18

FIG. 18

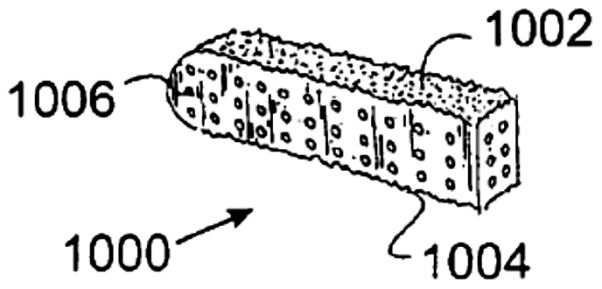
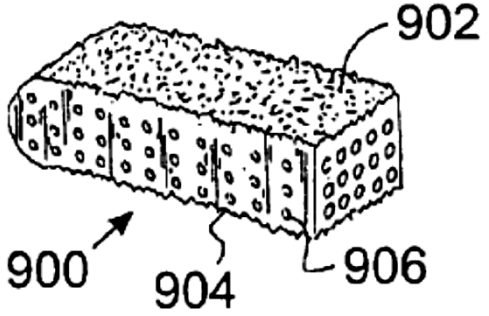


FIG. 16



Source: Pet., 9-12

Frey Discloses Non-Bone Implants (2002)

EX1040 [Frey], [0181]

[0181] The implants described herein can be made from any biocompatible material, including synthetic or natural autograft, allograft or xenograft tissues, and can be resorbable or non-resorbable nature. Examples of tissue materials include hard tissues, connective tissues, demineralized bone matrix and combinations thereof. Further examples of resorbable materials are polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass, and combinations thereof. Further examples of non-resorbable materials are non-reinforced polymers, carbon-reinforced polymer composites, PEEK and PEEK composites; shape-memory alloys; titanium and titanium alloys; cobalt chrome alloys; stainless steel; ceramics; and combinations thereof.

EX1040 [Frey], Fig. 57

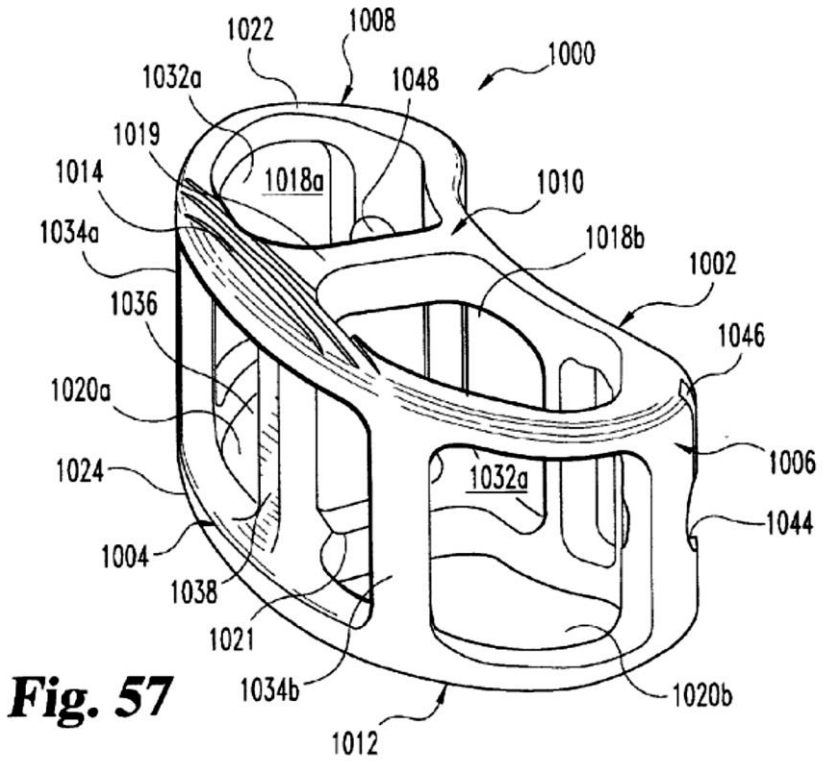


Fig. 57

Source: Pet., 8-9

Patent Owner's State of the Art in Current Proceedings

POR, 13

B. Dr. Branch Presents an Inaccurate Description of the State of the Art

Dr. Branch mischaracterizes the maturity of the field and the timing of developments with respect to non-bone spinal fusion implants. For example, Dr. Branch says that "[b]y the 1990s, the use of non-bone interbody spinal fusion implants had become common place." EX1002, ¶39. This is incorrect. As Dr. Youssef explains, most interbody implants that were available in and around the late-1990's were made of allograft bone. The use of non-bone interbody spinal fusion implants "was still fairly nascent" at the time of the invention. Indeed, Dr.

Source: POR, 13

Patent Owner's Statements in Prior Challenges

EX1038 [IPR2013-00208 McAfee Decl.]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Michelson
U.S. Patent No.: 8,251,997 Attorney Docket No.: 13958-0112IP1
Issue Date: August 28, 2012
Appl. Serial No.: 13/306,583
Filing Date: November 29, 2011
Title: METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE

DECLARATION OF DR. PAUL McAFEE, M.D., M.B.A.

* * *

3. I am not an employee of NuVasive, Inc., but I have been a clinical and research consultant working with Nuvasive over the past 10 years. I am the inventor of the Porous Coated Motion (PCM) cervical disk replacement, and the intellectual property associated with that invention was held by a company named Cervitech Inc., which was acquired by NuVasive in 2009. I have been engaged in the present matter to provide my independent analysis of the issues raised in the above-mentioned *inter partes* review of U.S. Patent No. 8,251,997 ("the '997 patent"). I received no compensation for this declaration

Source: IPR2019-00362 Supp. Sur-Sur-Reply, 2

Patent Owner's Statements in Prior Challenges

EX1038 [IPR2013-00208 McAfee Decl.], ¶ 27

Indeed, by the early 1990's, non-bone "fusion cage" type spinal fusion implants had come on the scene, and numerous different designs were available. *See, e.g.*, U.S. Patent No. 4,501,269 to Bagby (disclosing in 1981 a cylindrical "basket" implant for spinal fusion that included bone chips inside and that included many apertures in the basket so that bone could grow through the implant and create the fusion); U.S. Patent No. 4,878,915 to Brantigan (disclosing in 1987 a rectangular shaped spinal fusion cage); U.S. Patent No. 5,015,247 to Michelson (disclosing in 1988 a threaded cylindrical spinal fusion cage similar in design to the implant later disclosed in the '997 patent); U.S. Patent No. 5,026,373 to Ray et al. (disclosing in 1988 a threaded cylindrical spinal fusion cage); U.S. Patent Nos. 5,489,307 and 5,489,308 (disclosing a threaded spinal implant and methods of implantation through a tubular cannula). Given this context, one of skill in the art as of the early 1990's would have readily known that the lateral access system including a cannula for performing a "fusion" procedure, as disclosed in Jacobson, would be employed to implant a non-bone fusion cage type spinal implant.

Source: IPR2019-00362 Supp. Sur-Sur-Reply, 2

Patent Owner Previously Relied on McAfee (1998)

EX1047 [IPR2013-00208 Reply], 8

Case IPR2013-00208

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

* * *

NUVASIVE 1067 McAfee, *Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine*, SPINE, Vol. 23 (1998)

Source: IPR2109-00362 Supp. Sur-Sur-Reply, 2

McAfee Discloses Non-Bone Implants (1998)

EX1054 [McAfee], Fig. 5

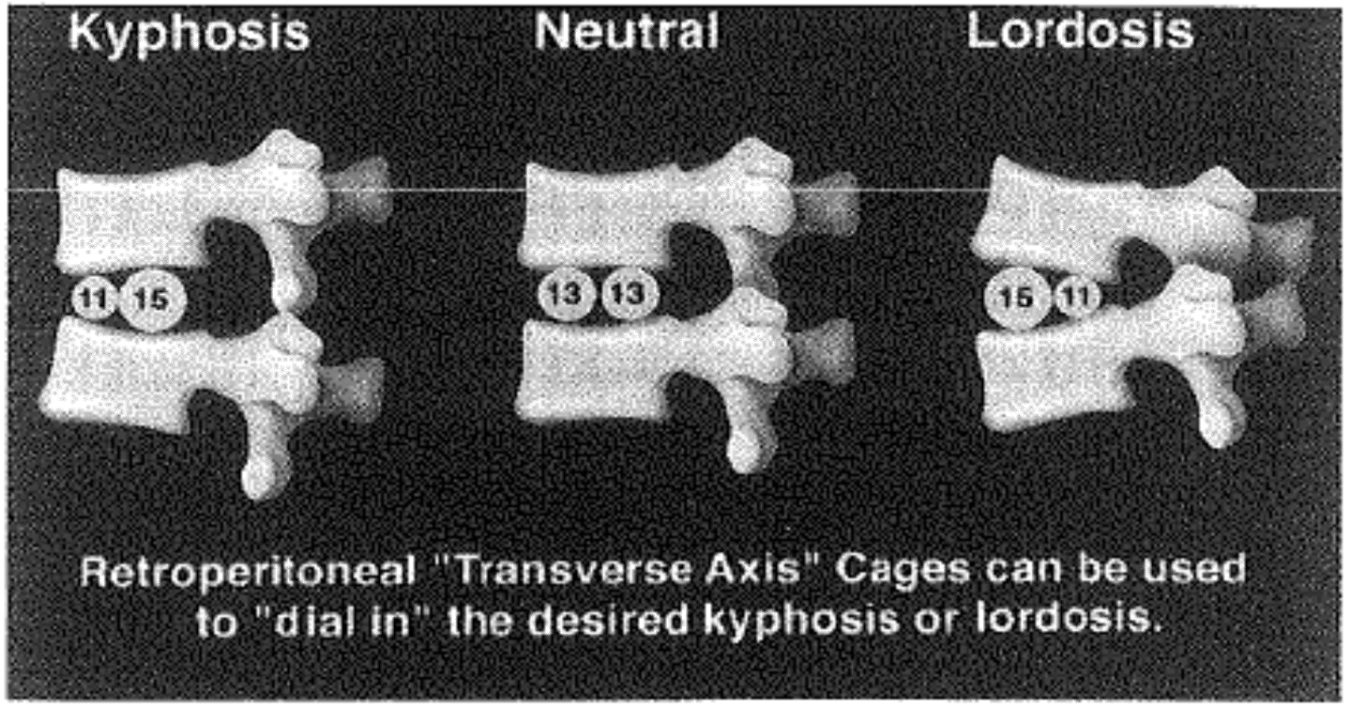


Figure 5. A schematic diagram illustrating how differential sizing of transversely oriented distraction plugs, interbody bone dowels, or fusion cages can "dial in" or adjust the desired amount of lumbar kyphosis or lordosis through a minimally invasive retroperitoneal approach.

Source: Reply, 2; IPR2019-00362 Reply, 2; IPR2019-00546 Reply, 2

Patent Owner Previously Relied on Michelson ‘770 (2001)

EX1038 [IPR2013-00208 McAfee Decl.]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Michelson
U.S. Patent No.: 8,251,997 Attorney Docket No.: 13958-0112IP1
Issue Date: August 28, 2012
Appl. Serial No.: 13/306,583
Filing Date: November 29, 2011
Title: METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE

DECLARATION OF DR. PAUL McAFEE, M.D., M.B.A.

* * *

Third, a later-filed patent of Dr. Michelson – U.S. Patent No. 6,241,770 (‘770 patent) – explains, in its background section, that the implant (I) shown in the ‘997 patent (and thus in the ‘661 patent which has the same specification) “prevents the utilization of the apophyseal rim bone [labeled “AR” in FIG. 1 copied below], located at the perimeter of the vertebral body to support the implants at their trailing end.” *See* ‘770 patent, col. 3, line 57 to col. 4, line 12.

Source: IPR2109-00362 Pet. Supp. Sur-Sur-Reply, 2

Michelson '770 Discloses Non-Bone Implants (2001)

EX1053 [Michelson '770], 2:20-25, 2:33-36

Michelson, Ray, Bagby, Kuslich, and others have taught the use of hollow, threaded perforated cylinders to be placed across a disc space between two adjacent vertebrae in the human spine to encourage interbody spinal fusion by the growth of bone from one vertebra adjacent a disc to the other vertebra adjacent that disc through such implants.

* * *

Such implants now in common use throughout the spine, may be used individually or inserted across the disc space in side-by-side pairs, and may be insertable from a variety of directions.

Source: Reply, 4; IPR2019-00362 Reply, 4; IPR2019-00546, Reply, 4

State of the Art

- Non-bone implants were known
- **Modular implants were known**
- Vertebral dimensions were known
- Radiopaque markers were known

Brantigan Discloses Modular Implants (1993)

EX1007 [Brantigan], 2:4-11

They are also provided in partial (preferably hemi-oval) annular shape to accommodate those surgical procedures where only a portion of the vertebrae or disc is damaged. Two such hemi-oval rings can be used in the posterior lumbar area in side-by-side relation since the dural sac and nerve roots must be retracted to each side in turn as the implant is placed on the opposite side.

Source: Pet., 61-62

Michelson Discloses Modular Implants (1999)

EX1032 [Michelson], 10:48-59

Referring to FIG. **18**, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral **1000**. The spinal fusion implant **1000** is similar to the spinal fusion implant **900**, but has a narrower width such that more than one spinal fusion implant **1000** may be combined in a modular fashion for insertion within the disc space D between the adjacent vertebrae.

Referring to FIG. **19**, 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.

Source: Pet., 41-42

Frey Discloses Modular Implants (2002)

EX1040 [Frey], [0160]

Inserter instrument **1500** also facilitates positioning of the implant in the disc space along a non-linear insertion path. Inserter instrument **1500** can also be used to position multiple implants at various locations in the disc space, and also for insertion of one or more implants from other approaches to the disc space.

Source: Pet., 42-43

Patent Owner's State of the Art in Current Proceedings

POR, 12

Modular interbody fusion implants have been proposed but have not gained traction in the spinal community as compared to single-piece interbody fusion implants. Multipiece implants are more complicated, more invasive, riskier for the patient, and more prone to fail. Petitioner's theorized sequential insertion of pieces into the disc space, moving the pieces around, and assembling them within the disc space all increase risks to patients and make the procedure more invasive, not less invasive.

Source: POR, 12

Patent Owner Previously Relied on McAfee (1998)

EX1054 [McAfee], Fig. 5

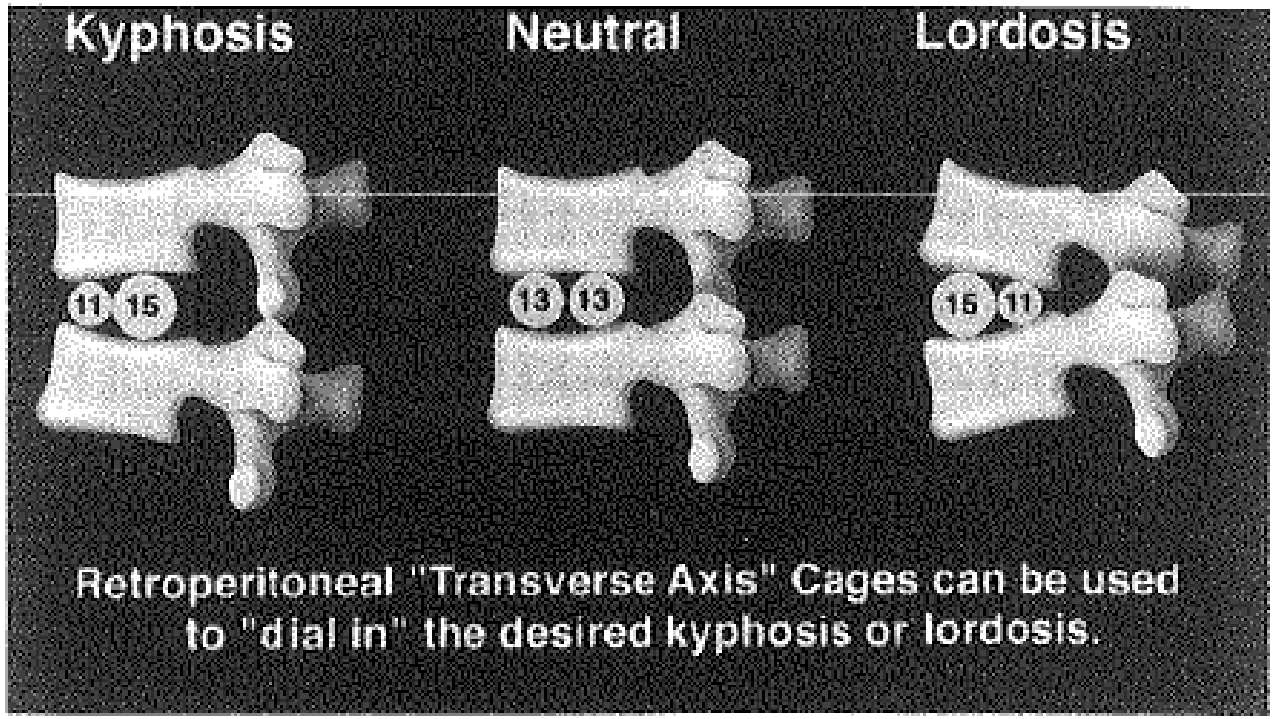


Figure 5. A schematic diagram illustrating how differential sizing of transversely oriented distraction plugs, interbody bone dowels, or fusion cages can "dial in" or adjust the desired amount of lumbar kyphosis or lordosis through a minimally invasive retroperitoneal approach.

Source: Reply, 2; IPR2019-00362 Reply, 2; IPR2019-00546 Reply, 2

Patent Owner Previously Relied on Michelson ‘770 (2001)

EX1053 [Michelson ‘770], Figs. 13B, 14B

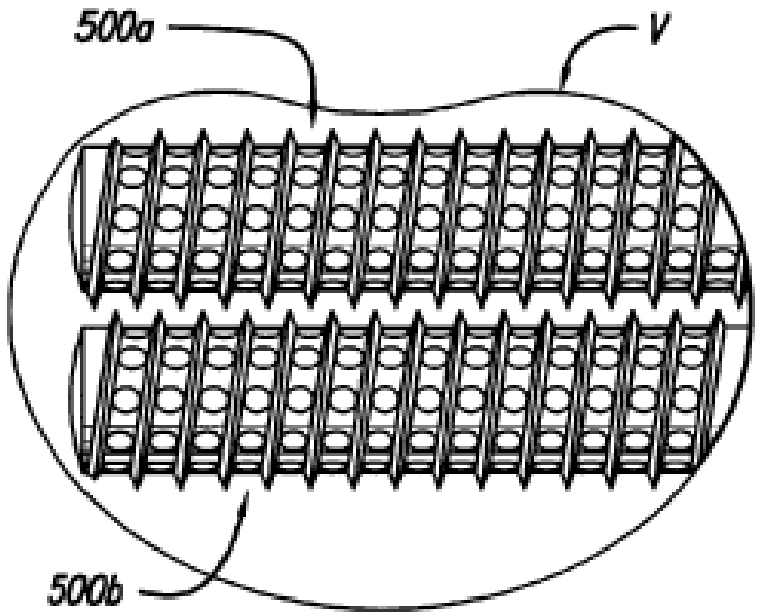


FIG. 13B

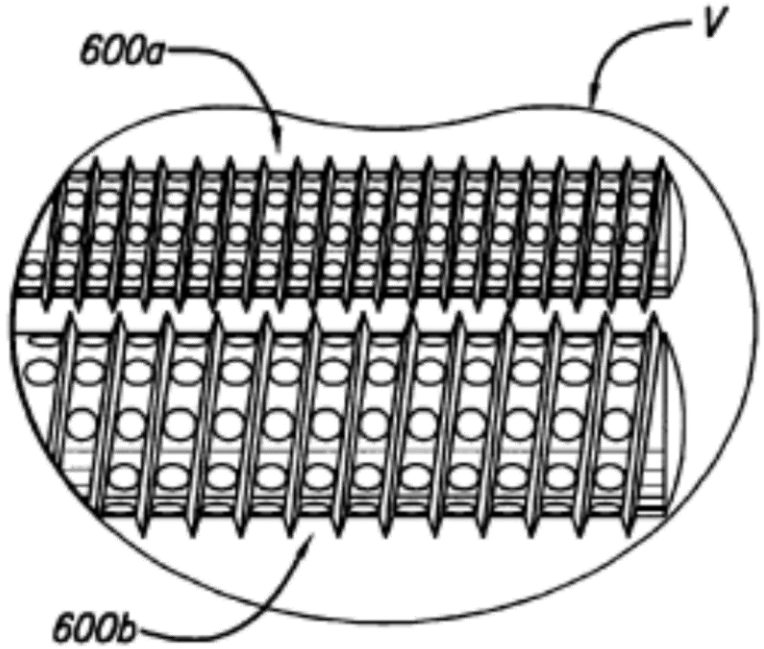


FIG. 14B

Source: Reply, 10-11; Supp. Sur-Sur-Reply, 2; IPR2019-00362 Reply, 12-13; Supp. Sur-Sur-Reply, 2; IPR2019-00546 Supp. Sur-Sur-Reply, 2

State of the Art

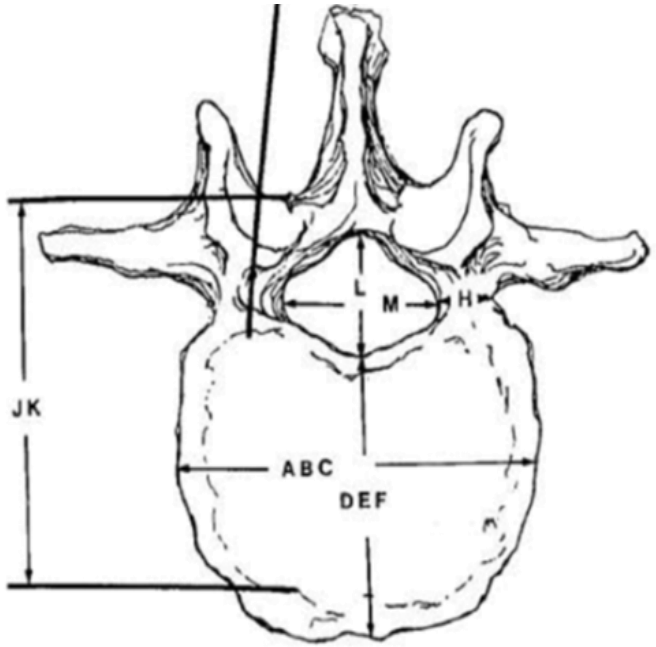
- Non-bone implants were known
- Modular implants were known
- **Vertebral dimensions were known**
- Radiopaque markers were known

Berry Discloses "Direct Dimensional Measurements" (1987)

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	*T2*	*T7*	*T12*	*L1*	*L2*	*L3*	*L4*	*L5*
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0



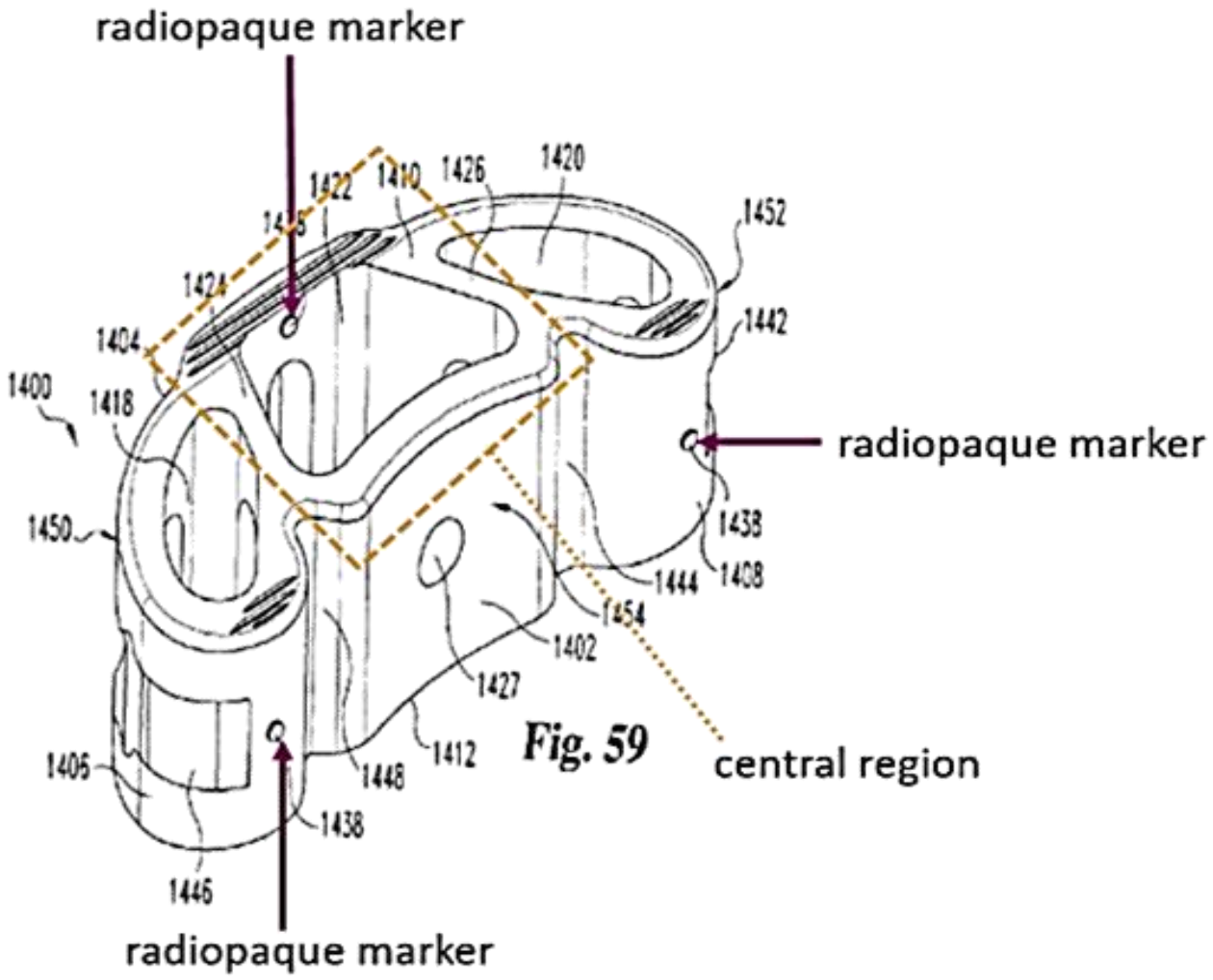
Source: Pet., 13, 40-43

State of the Art

- Non-bone implants were known
- Modular implants were known
- Vertebral dimensions were known
- **Radiopaque markers were known**

Frey Discloses Three Radiopaque Markers (2002)

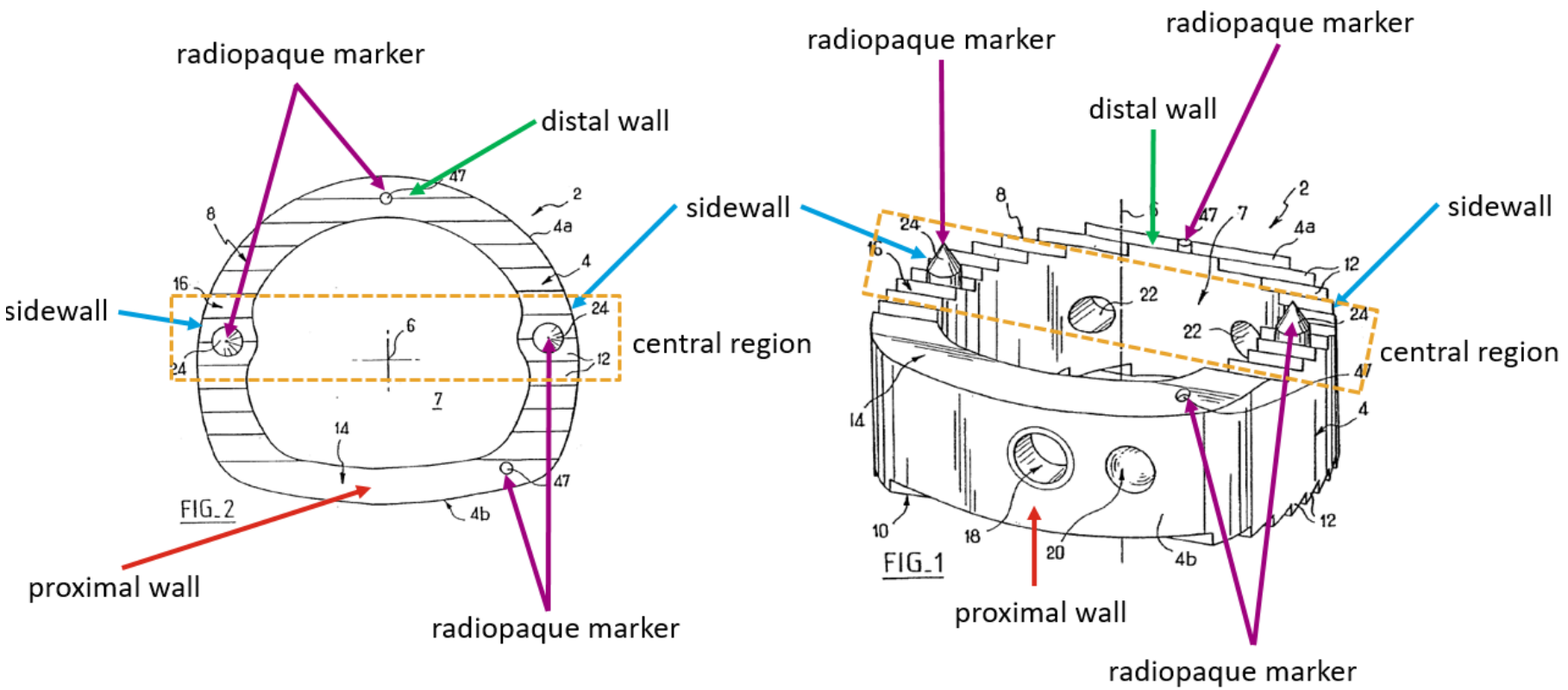
EX1040 [Frey], Fig. 59 (annotated)



Source: Pet., 2

Baccelli Discloses Four Radiopaque Markers (2003)

EX1008 [Baccelli], Figs. 1, 2 (annotated)



Source: Pet., 16

Patent Owner's State of the Art in Current Proceedings

POR, 55

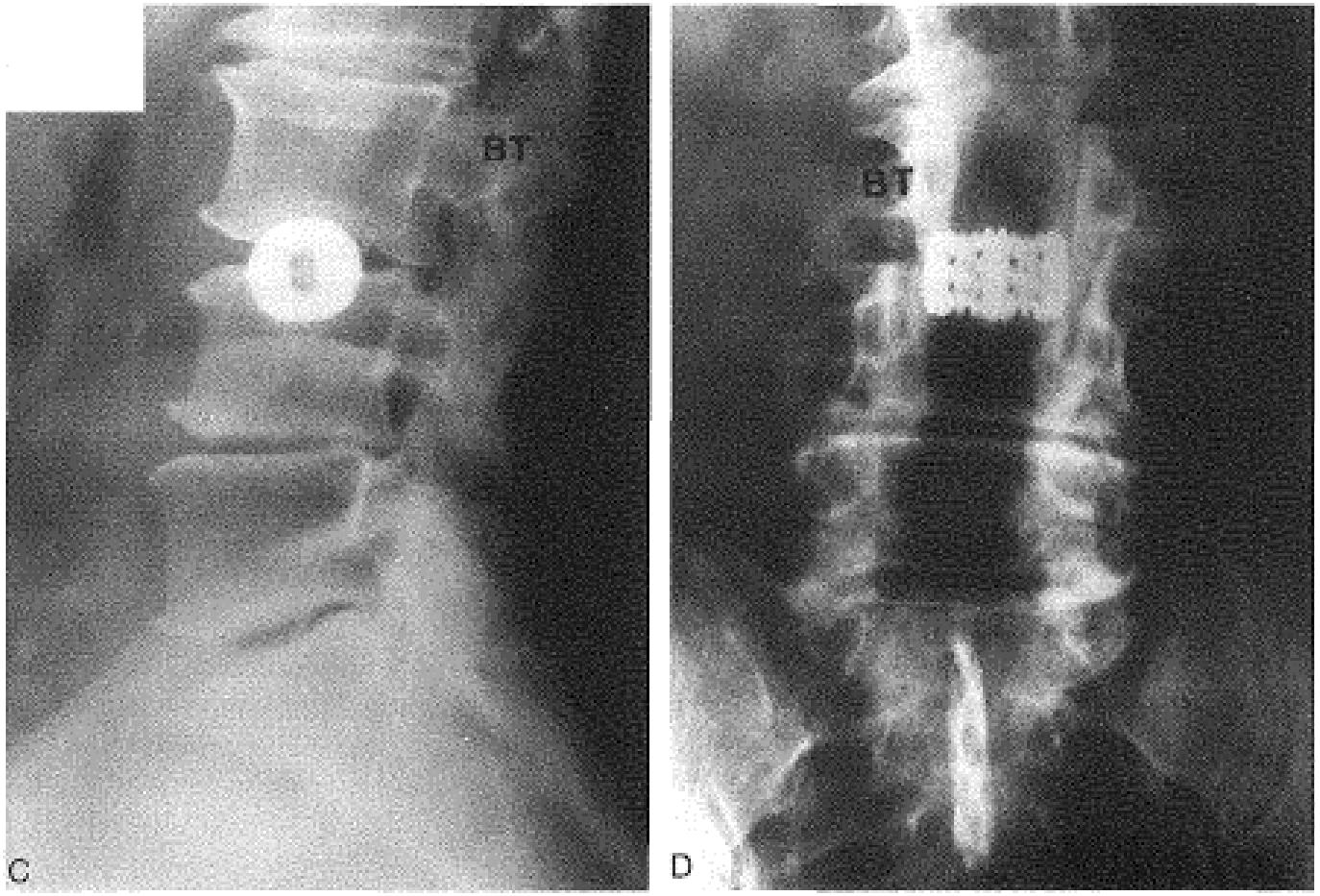
According to the petition, the proposed marker configuration "allow[s] surgeons to align the markers with the spinous process and the lateral ends of the vertebrae." Pet. 45 (citing EX1002, ¶ 199). That is, the petition recycles the same argument that was soundly rejected as impermissible hindsight by the Federal Circuit.

Source: POR, 55

McAfee Discloses X-Rays to Show Implant Position (1998)

EX1054 [McAfee], Fig. 1

Figure 1. This 75-year-old man had back pain and right anterior thigh pain 2 years after he had undergone laminectomies from L3 to SI with a posterolateral fusion from L4 to SI. The lateral **(A)** and anteroposterior **(B)** radiographs show "vacuum disk" sign at L3–L4 with lateral translation of the L3 vertebral body on L4. His characteristic pain was reproduced by an L3–L4 discogram performed by an independent radiologist. Lateral **(C)** and anteroposterior **(D)** radiographs were obtained after the procedure using the endoscopic retroperitoneal approach was performed and a transversely oriented BAK fusion cage was inserted (15 mm in diameter and 24 mm length). The patient's back and right leg pain resolved after surgery.



Source: Reply, 3; IPR2019-00362 Reply, 2-3; IPR2019-00546 Reply, 2-3

IPR2019-00361

‘334 Patent - Ground 1

Overview of Grounds

The ’334 patent (-0361)		
Ground	**Claims**	**Basis**
1	6-9 and 18	Obvious over Frey, Michelson, and Berry

Claim 1 of the '334 Patent Previously Found Invalid

EX1004 [IPR2013-00507 FWD], 13

ORDER

Petitioner has demonstrated, by a preponderance of the evidence, that claims 1–5, 10, 11, 14–17, and 19–28 are unpatentable over Frey and Michelson under 35 U.S.C. § 103(a). Petitioner has not demonstrated, by a preponderance of the evidence, that claim 18 is unpatentable over Frey and Michelson under 35 U.S.C. § 103(a).

EX1005 [Fed. Cir. Op. IPR2013-00507, -00508], 17

CONCLUSION

For the foregoing reasons, we affirm the Board's final written decision in IPR2013-507, invalidating claims 1–5, 10, 11, 14, 15, and 19–28 and upholding claim 18. We vacate the Board's decision in IPR2013-508 and remand for further proceedings regarding claims 16 and 17 in accordance with this opinion.

Source: Pet., 17-21

Claim 1 of the ‘334 Patent Previously Found Invalid

EX1001 [’334 patent]

INTER PARTES REVIEW CERTIFICATE
U.S. Patent 8,187,334 K1
Trial No. IPR2013-00507
Certificate Issued Feb. 22, 2018

1

AS A RESULT OF THE INTER PARTES REVIEW PROCEEDING, IT HAS BEEN DETERMINED THAT:

Claim **18** is found patentable.

Claims **1-5, 10, 11, 14, 15** and **19-28** are cancelled.

* * * * *

Collateral Estoppel Applies to Claim 1

***MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d, 1373, 1376 (Fed. Cir. 2018)**

In the '728 and '615 IPRs, the Board held that claims 1, 17, and 20, involved in this proceeding, were unpatentable. Those decisions have subsequently been affirmed by this court. Both parties agree that those prior decisions, having been affirmed by our court, are binding in this proceeding, as a matter of collateral estoppel, and they could hardly argue otherwise.

[1, 2] It is well established that collateral estoppel, also known as issue preclusion, applies in the administrative context. *See B & B Hardware, Inc. v. Hargis Indus., Inc.*, — U.S. ——, 135 S.Ct. 1293, 1303, 191 L.Ed.2d 222 (2015).

Source: Reply, 6

Previous Petitioner Relied On Different Disclosure For Claim 18

EX1004 [IPR2013-00507 FWD], 10

58. Michelson '661 discloses an implant with a width "in the range of 10 mm to 30 mm." Ex. 1046, 10:31. Even if Michelson '661 discloses an implant with a maximum width of 18 mm (as within the range of 10 mm to 30 mm), Michelson '661 discloses that the length of the implant is "less than the known transverse width W (side to side) of the vertebrae T7 and T8." Ex. 1046, 10:21–23. Petitioner does not assert, or demonstrate sufficiently, that the "known transverse width W (side to side) of the vertebrae T7 and T8" (corresponding to the length of the implant) is greater than 40 mm, as required by claim 18. Nor does Petitioner articulate reasoning, with some rational underpinning, to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified the cited implant to have a length greater than 40 mm.

Prior Petitioner did not:

- cite the same evidence Federal Circuit relied on to invalidate claim 1 for claim 18
- cite Michelson's long-and-narrow modular disclosure for claim 18

Federal Circuit did not:

- address Michelson's long-and-narrow modular disclosure for claim 18
- affirm patentability of claim 18

Source: Pet., 17-21

Federal Circuit Dismissed Claim 18 Cross-Appeals

EX1005 [Fed. Cir. Op. IPR2013-00507, -00508], 8

Medtronic had cross-appealed from the Board's decisions regarding claim 18, but Medtronic later withdrew, and we dismissed, the cross-appeals (Nos. 2015-1674, -1712). The Director of the PTO intervened to defend the Board's rulings against NuVasive's inadequate-process challenges. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

Source: Pet., 21

Federal Circuit Dismissed Claim 18 Cross-Appeals

EX1005 [Fed. Cir. Op. IPR2013-00507, -00508], 15-16

NuVasive relies on the Board's statements finding inadequate Medtronic's showings with respect to claim 18, which requires particular dimensions—namely, a length greater than 40 mm and a maximum width of 18 mm. *See IPR508 Board Decision* at *8; *see also IPR507 Board Decision* at *6. But those statements do not entail a failure of proof of obviousness as to claims lacking the particular dimensional requirements of claim 18. They do not decide more generally that it would not have been obvious to combine "one dimension from one implant with a second dimension from another implant." Resp. & Reply Br. 30–31; *see id.* at 39–40. Nor do they preclude the Board from considering the import of Michelson's Figure 18 after giving NuVasive a full opportunity to submit additional evidence and arguments on that point. *See In re Kumar*, 418 F.3d 1361, 1367–69 (Fed. Cir. 2005).

Source: Pet., 21

Claim 1 Unpatentable Over Frey and Michelson

EX1001 ['334 patent], claim 1

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

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

wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;

wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein said longitudinal length is at least two and half times greater than said maximum lateral width;

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, 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

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

Source: Pet., 17-21; Branch Decl. pgs. 40-56; IPR2019-00546 Pet., 31; Branch Decl. pgs. 40-56

Frey, Michelson, and Berry Render Obvious Claims 6–9, 16, and 18

EX1001 ['334 patent]

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

7. The spinal fusion implant of claim **6**, wherein said medial support is positioned along said central region.

8. 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.

9. The spinal fusion implant of claim **8**, wherein said second fusion aperture is separated from said first fusion aperture by a medial support.

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

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

Dependent claims directed to:

- medial support
- second fusion aperture
- fourth radiopaque marker (claim 16 – IPR2019-00546)
- width of approximately 18 mm

Claims 6–7 and 9: Frey Discloses a "Medial Support"

EX1001 ['334 Patent], claims 6-7

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

7. The spinal fusion implant of claim 6, wherein said medial support is positioned along said central region.

EX1001 ['334 Patent], claim 9

9. The spinal fusion implant of claim 8, wherein said second fusion aperture is separated from said first fusion aperture by a medial support.

EX1040 [Frey], Fig. 55 (annotated)

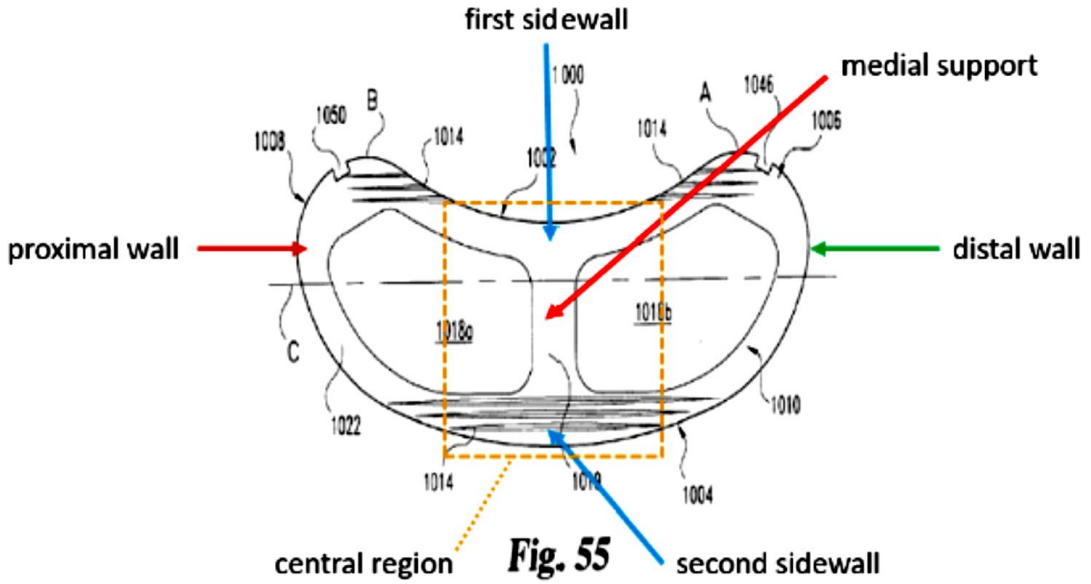


Fig. 55

EX1040 [Frey], Fig. 63 (annotated)

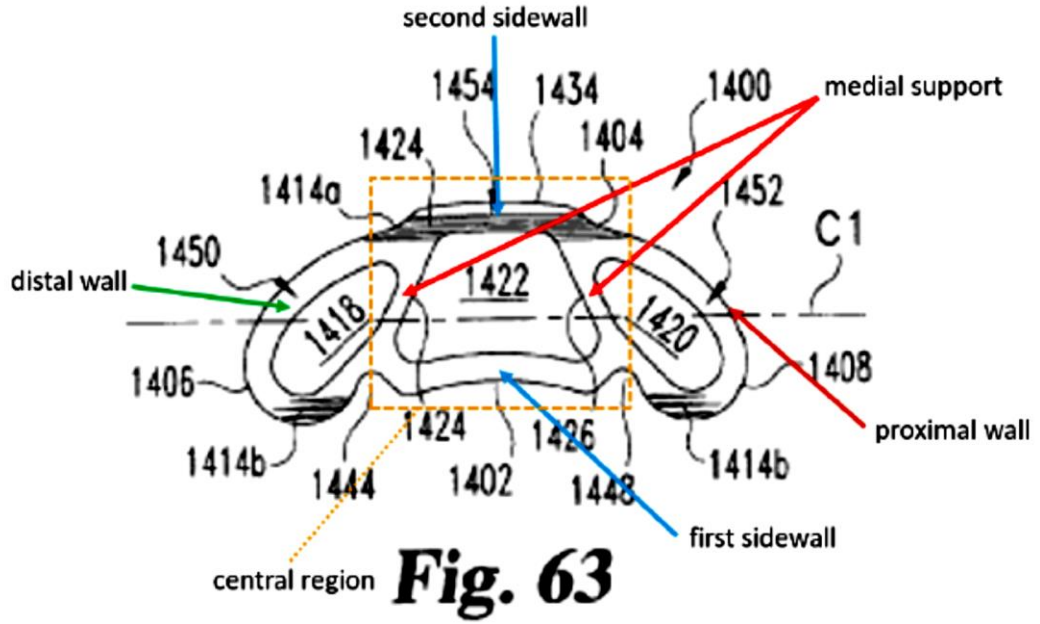


Fig. 63

Source: Pet., 33-36, 38-40

Claims 6–7 and 9: Frey Discloses a "Medial Support"

EX1040 [Frey], [0144]

[0144] In order to promote fusion, the walls and bearing members of implant **1000** are provided with a number of openings. Upper bearing member **1010** includes upper openings **1018***a* and **1018***b* separated by an upper strut **1019**. Lower bearing member **1012** includes lower openings **1020***a* and **1020***b* separated by a lower strut **1021**. An upper bar **1022** forming the perimeter of upper bearing member **1010** has a boomerang shape, and surrounds upper openings **1018***a*, **1018***b* and is connected to strut **1019**.

EX1040 [Frey], [0154]

[0154] In order to provide avenues for bone growth through implant **1400**, the walls of implant **1400** form a number of chambers opening at upper bearing surface **1410** and lower bearing surface **1412**. In particular, leading end portion **1450** includes first chamber **1418** and trailing end portion **1452** includes second chamber **1420**. Middle portion **1454** includes a middle chamber **1422**. A first strut **1424** is located between first chamber **1418** and third chamber **1422** and extends between posterior wall **1402** and anterior wall **1404**. A second strut **1426** is located between second chamber **1420** and third chamber **1422** and extends between posterior wall **1402** and anterior wall **1404**.

Source: Pet., 33-36, 38-40

The '334 Patent Claims Describe "Medial Support"

EX1001 ['334 patent], claims 6-7

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

7. The spinal fusion implant of claim 6, wherein said medial support is positioned along said central region.

"medial support" is *not* "medial plane"

"medial support" *need not* intersect sidewalls "approximately at the midpoint"

"positioned along" does *not* mean "proximate to the midpoint"

Source: Pet., 33-36; Reply, 5-6; POR , 8-9, 51

Claim 1 of the ’334 Patent Defines “Central Region”

EX1001 [’334 Patent], claim 1

wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein said longitudinal length is at least two and half times greater than said maximum lateral width;

“central *region*” has no *midpoint*

Source: Reply 5-6; POR, 8.

Claims 8–9: Frey Discloses "Fusion Aperture"

EX1001 ['334 Patent], claim 8

8. 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.

EX1001 ['334 Patent], claim 9

9. The spinal fusion implant of claim 8, wherein said second fusion aperture is separated from said first fusion aperture by a medial support.

EX1040 [Frey], Fig. 55 (annotated)

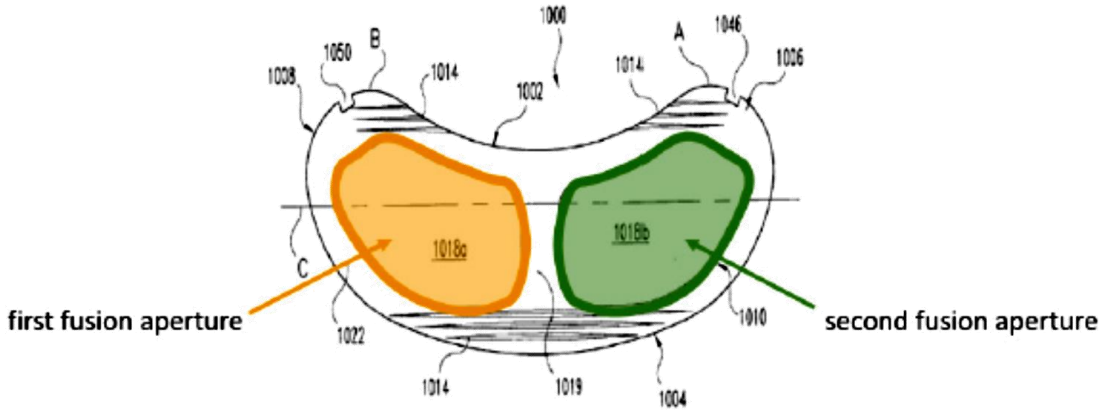


Fig. 55

EX1040 [Frey], Fig. 63 (annotated)

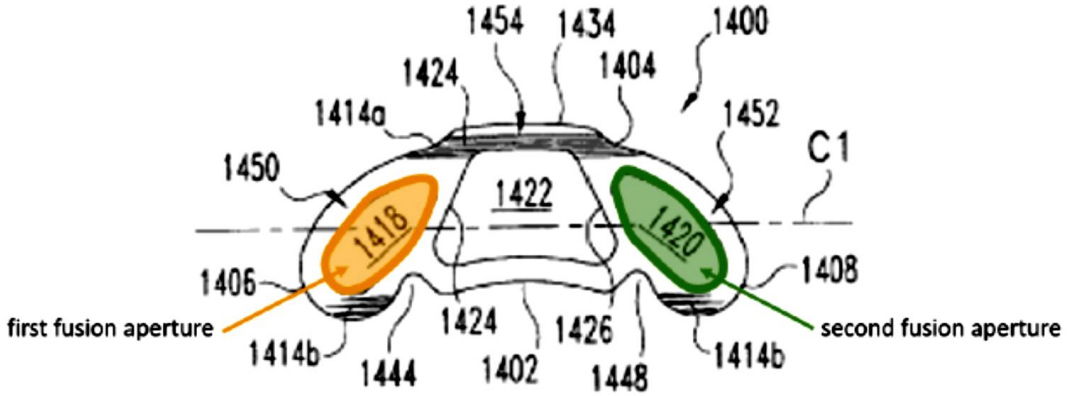


Fig. 63

Source: Pet., 36-40

Claims 8–9: Frey Discloses "Fusion Aperture"

EX1040 [Frey], [0144]

[0144] In order to promote fusion, the walls and bearing members of implant **1000** are provided with a number of openings. Upper bearing member **1010** includes upper openings **1018***a* and **1018***b* separated by an upper strut **1019**. Lower bearing member **1012** includes lower openings **1020***a* and **1020***b* separated by a lower strut **1021**. An upper bar **1022** forming the perimeter of upper bearing member **1010** has a boomerang shape, and surrounds upper openings **1018***a*, **1018***b* and is connected to strut **1019**.

EX1040 [Frey], [0154]

[0154] In order to provide avenues for bone growth through implant **1400**, the walls of implant **1400** form a number of chambers opening at upper bearing surface **1410** and lower bearing surface **1412**. In particular, leading end portion **1450** includes first chamber **1418** and trailing end portion **1452** includes second chamber **1420**. Middle portion **1454** includes a middle chamber **1422**. A first strut **1424** is located between first chamber **1418** and third chamber **1422** and extends between posterior wall **1402** and anterior wall **1404**. A second strut **1426** is located between second chamber **1420** and third chamber **1422** and extends between posterior wall **1402** and anterior wall **1404**.

Source: Pet., 36-40

Patent Owner's "Medial Support" Arguments

EX1040 [Frey], Fig. 59

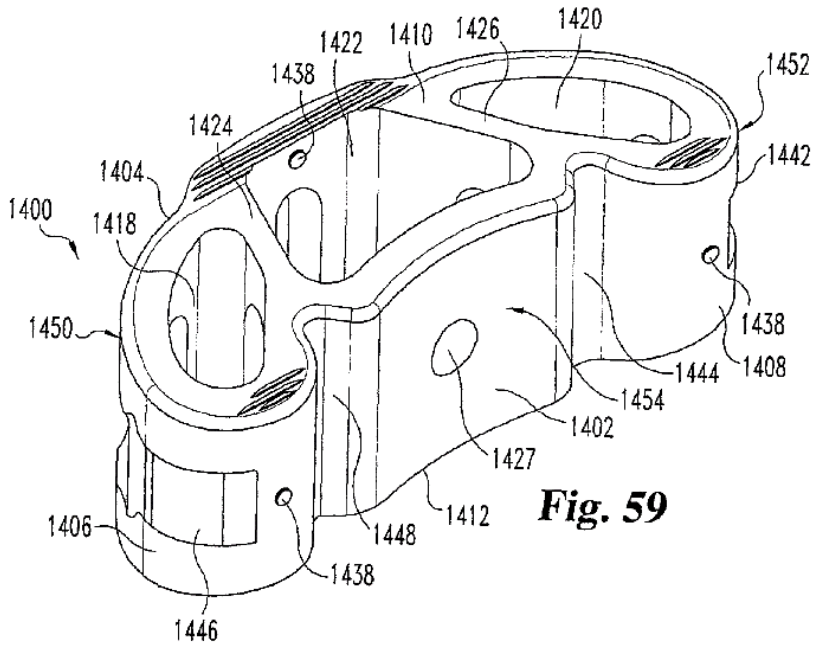


Fig. 59

EX1001 ['334 Patent], claims 6, 7, 9

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

7. The spinal fusion implant of claim **6**, wherein said medial support is positioned along said central region.

* * *

9. The spinal fusion implant of claim **8**, wherein said second fusion aperture is separated from said first fusion aperture by a medial support.

"medial support" *need not* separate fusion apertures from upper and lower surfaces completely

"positioned along" does *not* mean "on a course parallel to the central region"

Source: Pet., 33-36, 38-40; POR 51; Reply, 12-13

Patent Owner's "Fusion Aperture" Arguments

EX1040 [Frey], Fig. 57

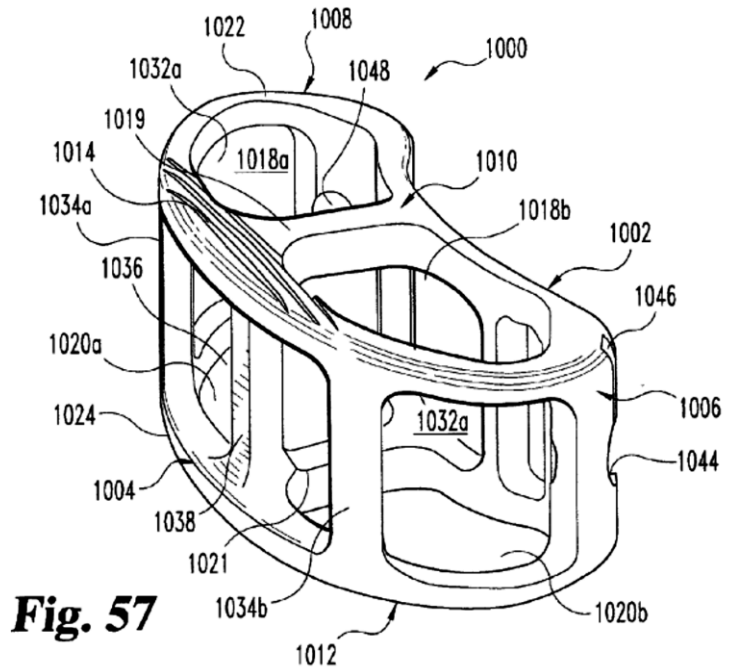


Fig. 57

EX1001 ['334 Patent], claims 1, 8

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, said first fusion aperture having: a longitudinal

* * *

8. 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

"at least a first fusion aperture" means "one or more"

"upper openings 1018a and 1018b" and "lower openings 1020a and 1020b" comprise the claimed "at least a first fusion aperture"

Source: Pet., 36-38; POR, 48; Reply, 11-12

Claim 18: Frey, Michelson, and Berry Disclose Limitations

EX1001 ['334 Patent], claim 18

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

- Frey discloses modular (multiple) implants in the disc space
- Michelson discloses modular, long-and-narrow implants
- Berry discloses vertebral dimensions

Federal Circuit Recognized Michelson's Modularity

EX1005 [Fed. Cir. Op. IPR2013-00507, -00508], 13-14

Medtronic pointed the Board to Figure 18 and the corresponding description as supporting the proposition that Michelson disclosed longer-than-wide implants. Michelson's specification expressly states that the preferred length of embodiment 900 was 42 mm and the preferred width was 26 mm. Michelson, col. 10, lines 42–47. It then states that "spinal fusion implant 1000 is similar to the spinal fusion implant 900, but has a narrower width such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion within the disc space." *Id.*, col. 10, lines 50–55.

Source: Pet., 2-3

Federal Circuit Recognized Michelson's Modularity

EX1005 [Fed. Cir. Op. IPR2013-00507, -00508], 13-14

Figure 18 shows implant 1000, and Figure 19 shows three implant 1000s lined up in the disk space. *Id.*, Figures 18 & 19. Even if Figure 19 were taken as showing only two implants (its point is to show more than one), this is substantial, and anything but speculative, evidence from which to infer that at least one of the set of "narrower" implants must be at most 13 mm wide (at its maximum), which is less than the preferred length (42 mm) divided by 2.5 (16.8 mm).

Source: Pet., 2-3

NuVasive's Argument Re Modularity to Federal Circuit

EX1005 [Fed. Cir. Op. IPR2013-00507, -00508], 16

In particular, NuVasive argues on appeal (1) that a skilled artisan would never have made a long-and-narrow implant for any use other than as a component to be assembled into a single, oversized, modular implant; (2) that, given the state of modular implants at the time of the invention, no one would have tried to make one; and (3) that the boomerang-shaped Frey implant would not have been suitable to be modified to be modular. But NuVasive did not present any meaningful argument to that effect to the Board.

Source: Pet., 17-21

Patent Owner's Argument Re Modularity in Current Proceedings

POR, 12

Modular interbody fusion implants have been proposed but have not gained traction in the spinal community as compared to single-piece interbody fusion implants. Multipiece implants are more complicated, more invasive, riskier for the patient, and more prone to fail. Petitioner's theorized sequential insertion of pieces into the disc space, moving the pieces around, and assembling them within the disc space all increase risks to patients and make the procedure more invasive, not less invasive.

Source: POR, 12

Patent Owner's Expert Dr. Youssef Re Modularity

EX2055 [Youssef Decl.], ¶ 92

92. I understand that Dr. Branch asserts that Michelson's modularity concept involves serial insertion of modules and assembly in the disc space. Specifically, I understand that Dr. Branch envisions inserting a module and then pushing it in the anterior/posterior direction to make room for a second module. Michelson does not disclose such an insertion method. Moreover, serial insertion of pieces to be assembled or placed together in the disc space would be significantly more invasive and less safe compared to use of a single piece implant for at least the reasons mentioned above, and those further explained below.

Source: POR, 36

Patent Owner's Expert Dr. McMillin Re Modularity

EX1051 [McMillin Dep. Tr.], 54:2–17

Q So in particular, I'm going to ask you about the last paragraph -- I'm sorry, the last sentence of that paragraph that says, "Furthermore, I understand that Dr. Branch conflates Brantigan's disclosure regarding the vertically stacked modular embodiment with the nonmodular posterior insertion embodiment."

Did I read that correctly?

A Yes.

Q Why do you say you understand?

A I was informed by counsel of what Dr. Branch asserted. And based on my understanding of that, if he is proposing modular implantation of a corpectomy cage, it would be totally impossible, because you have to put a spline in to hold it together.

Source: Reply, 10

Patent Owner's Argument Against 18 mm Width

POR, 51

As discussed above, neither Frey nor Michelson discloses a maximum lateral width greater than 32 mm or of approximately 18 mm, and a POSA would not have made an implant having a maximum lateral width of approximately 18 mm in view of Frey, Michelson, and Berry. The petition ignores Michelson's dimensions and ignores the space occupied by the annulus fibrosis, both of which confirm that a modular implant having the petition's proposed width would be too large.

Claim 18: Frey Discloses Modular Implants

EX1040 [Frey], [0160]

Inserter instrument **1500** also facilitates positioning of the implant in the disc space along a non-linear insertion path. Inserter instrument **1500** can also be used to position multiple implants at various locations in the disc space, and also for insertion of one or more implants from other approaches to the disc space.

Source: Pet., 42-43

Claim 18: Michelson Discloses Modular Implants

EX1032 [Michelson], 10:48-59

Referring to FIG. **18**, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral **1000**. The spinal fusion implant **1000** is similar to the spinal fusion implant **900**, but has a narrower width such that more than one spinal fusion implant **1000** may be combined in a modular fashion for insertion within the disc space D between the adjacent vertebrae.

Referring to FIG. **19**, 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.

Source: Pet., 40-43

Claim 18: Michelson Discloses Modular Implants

EX1032 [Michelson], 5:34-39

FIG. 19 is a perspective lateral anterior view of a segment of the spinal column with a plurality of the spinal implants of FIG. 18 shown in hidden line inserted from the lateral aspect in a modular fashion in the disc space between two adjacent vertebrae along the transverse width of the vertebrae.

Source: Reply, 10

Claim 18: Michelson Discloses Modular Implants

EX1032 [Michelson], Figs. 16, 18, 19

FIG. 18

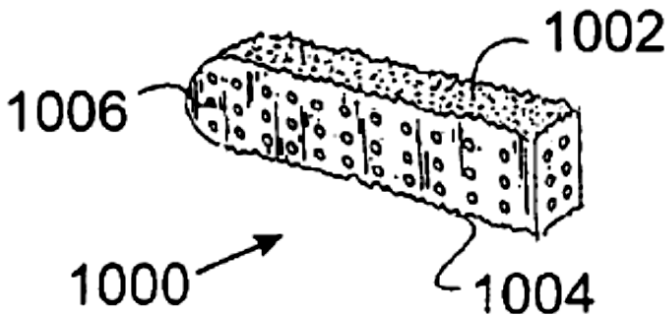


FIG. 16

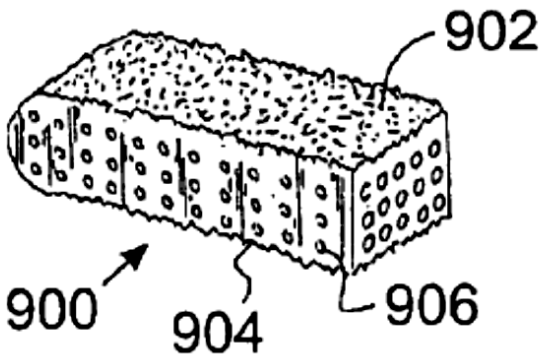
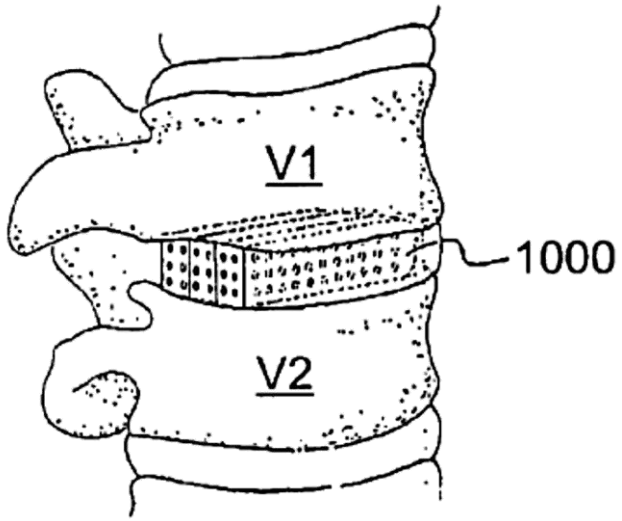


FIG. 19



Source: Pet., 40-43

Claim 18: Michelson's Width "approximates depth of the vertebrae"

EX1032 [Michelson], 10:36-40

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.

Source: Pet., 30

Claim 18: Frey, Michelson, and Berry Disclose Limitations

EX1001 ['334 Patent], claim 18

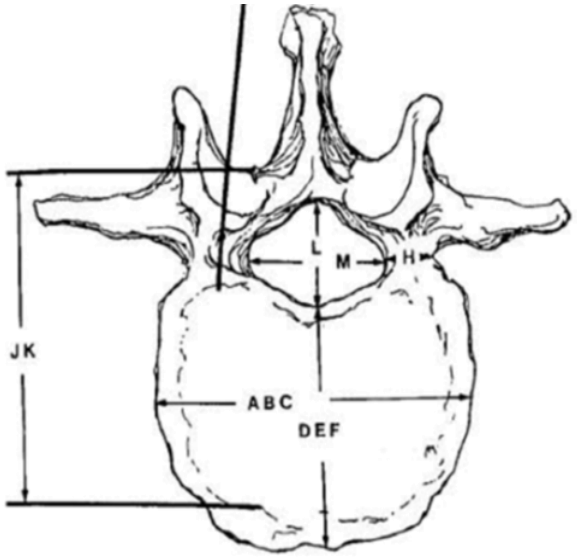
18. The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately 18 mm.

Petitioner never suggested inserting 2 implants each having 18.95 mm width

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	T2	T7	T12	L1	L2	L3	L4	L5
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0



L4-L5 Implant Width Range

L4 (lower ("D")) –> (35.6 – 3.1) / 2 = 16.25 mm*

L5 (upper ("E")) –> (35.1 + 2.8) / 2 = 18.95 mm

Longitudinal Length

L4 (lower ("C")) –> 50.9 – 4.6 = 46.3 mm, which is "at least two and a half times greater than said maximum lateral width" as required by claim 1

*The value "16.15 mm" at Petition 42 should properly be 16.25 mm as calculated above.

Source: Pet., 40-43; Reply, 9-10

Motivation to Combine Frey, Michelson, and Berry

Obviousness Analysis Requires Assessment of Background Knowledge

Pet. Sup. Sur-Sur Reply, 1

"[T]he obviousness 'analysis ***requires*** an assessment of the '…background knowledge possessed by a person having ordinary skill in the art.'" *Koninklijke Philips N.V. v. **Google** LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020) (emphasis in original).

Motivation to Combine: Modular Implants with Vertebral Dimensions

EX1040 [Frey], [0160]

Inserter instrument **1500** also facilitates positioning of the implant in the disc space along a non-linear insertion path. Inserter instrument **1500** can also be used to position multiple implants at various locations in the disc space, and also for insertion of one or more implants from other approaches to the disc space.

EX1032 [Michelson], Fig. 19

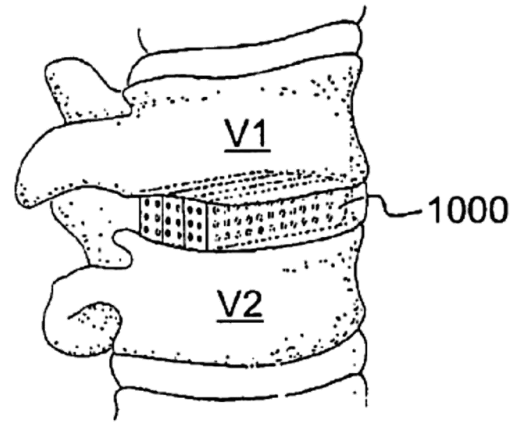


FIG. 19

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	T2	T7	T12	L1	L2	L3	L4	L5
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0

Source: Pet., 30-31

Motivation to Combine: Increased Safety and Decreased Invasiveness

EX1040 [Frey], [0183]

[0183] The above-described instruments and methods have been disclosed with reference to use in substantially open surgical procedures. However, it is contemplated that the implants, instruments and methods may be utilized through guide sleeves or tubes to provided greater protection to adjacent tissues, to reduce the size of access incisions, to provide direct visualization of the surgical site, and/or to provide greater control of the method. The implants, instruments and methods may further be used in combination with disc space preparation and implant insertion through microscopic or endoscopic instruments that provide direct visualization of the surgical site, such as disclosed in U.S. patent application Ser. No. 09/692,932 entitled METHODS AND INSTRUMENTS FOR ENDOSCOPIC INTERBODY SURGICAL TECHNIQUES, filed Oct. 20, 2000, which is incorporated herein by reference in its entirety.

EX1032 [Michelson], 3:61-65

The translateral implants of the present invention are safer to use than implants inserted from the front or the 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.

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.

Source: Pet., 30; Reply, 8-9

Motivation to Combine: Increased Safety and Decreased Invasiveness

Pet., 31

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

Patent Owner's Argument Against Motivation to Combine

POR, 44-45

> Inserting two implants through a single surgical path would result in the first implant blocking the pathway of the second implant. Moving the first implant out of the way to allow the second implant into the disc space would risk damaging the vertebral endplates, particularly in light of the antimigration elements designed to resist posterior and anterior migration. EX1040, ¶¶140, 153.

Source: POR, 44-45

Patent Owner's Expert Dr. Youssef on State of the Art

EX1050, 57:12-22

Q So you're not aware of any -- any peer-reviewed publications regarding side-by-side insertion of implants before 2003; am I correct? Do you need me to read it again? Because I took a long pause.

A I think I got it.

Q All right.

A I'm not familiar with the use of nonbone implants that were placed side by side.

Q Before 2003?

A Before 2003.

Source: Supp. Sur-Sur-Reply, 2; IPR2019-00362 Supp. Sur-Sur-Reply, 2; IPR2019-00546 Supp. Sur-Sur-Reply, 2

Obviousness Analysis Requires Assessment of Background Knowledge

***Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020)**

Although the prior art that can be considered in inter partes reviews is limited to patents and printed publications, it does not follow that we ignore the skilled artisan's knowledge when determining whether it would have been obvious to modify the prior art. Indeed, under 35 U.S.C. § 103, the obviousness inquiry turns not only on the prior art, but whether "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious ... to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Regardless of the tribunal, the inquiry into whether any "differences" between the invention and the prior art would have rendered the invention obvious to a skilled artisan necessarily depends on such artisan's knowledge. *Dow*

Source: Supp. Sur-Sur-Reply, 1

POSAs Aware of Side-By-Side Lateral Insertion of Non-Bone Implants

EX1054 [McAfee], Fig. 5

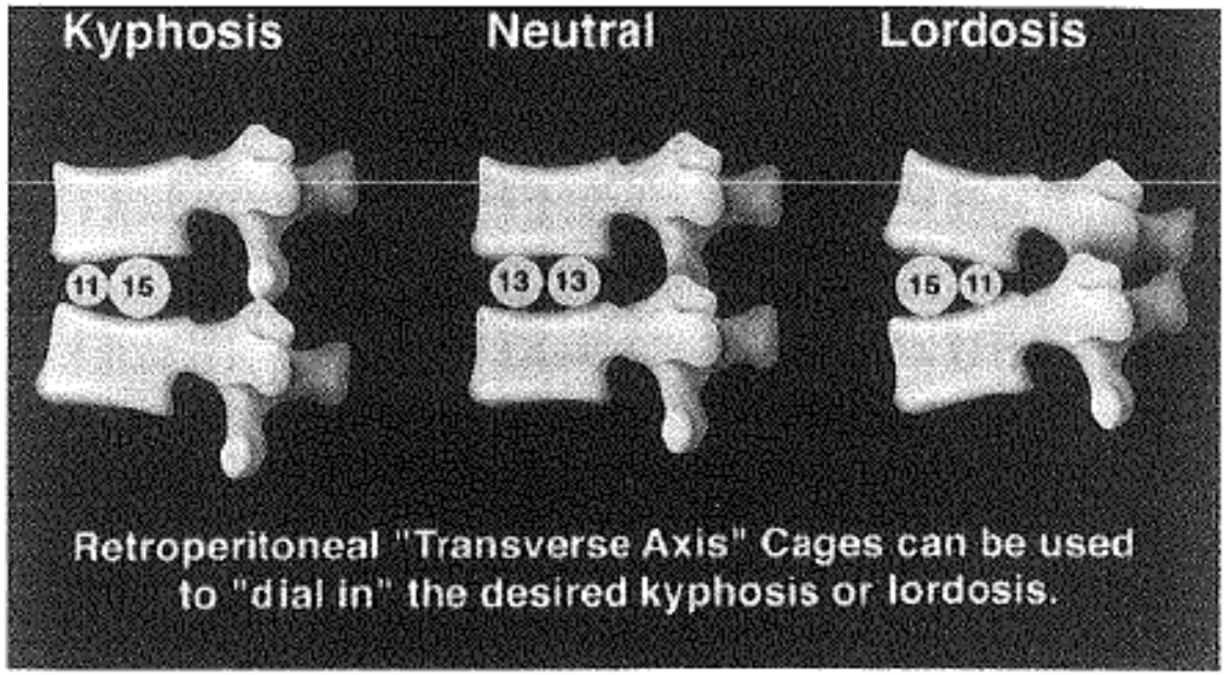
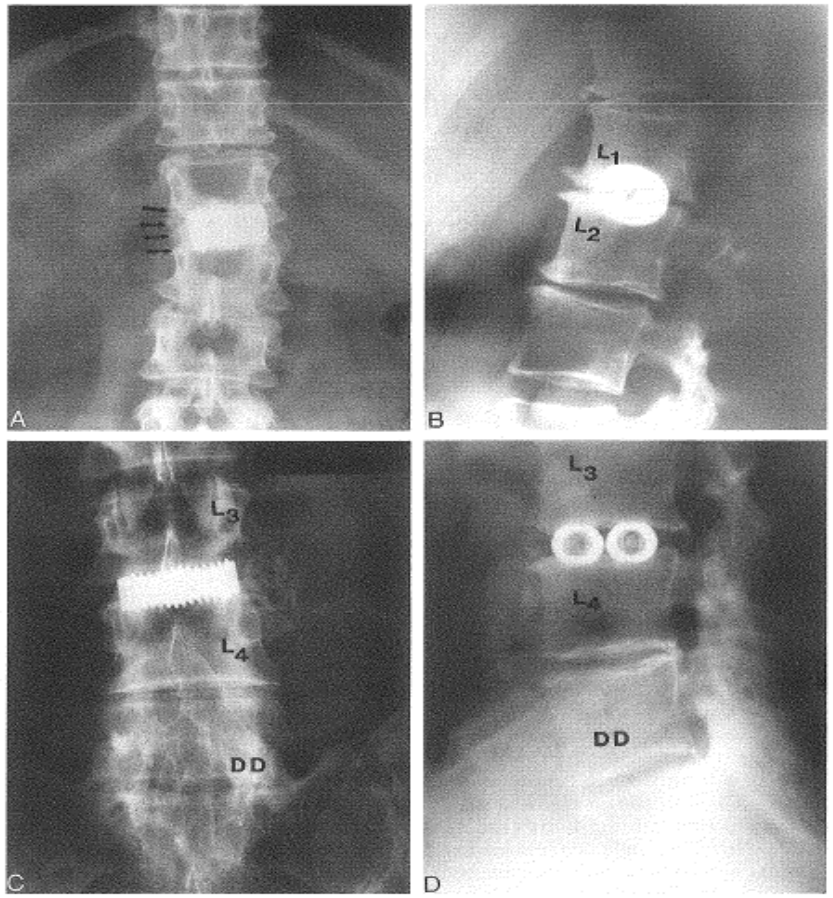


Figure 5. A schematic diagram illustrating how differential sizing of transversely oriented distraction plugs, interbody bone dowels, or fusion cages can "dial in" or adjust the desired amount of lumbar kyphosis or lordosis through a minimally invasive retroperitoneal approach.

EX1054 [McAfee], Fig. 4



Source: Reply, 2

IPR2019-00361

’334 Patent - Ground 2

Overview of Grounds

The ’334 patent (-0361)		
Ground	**Claims**	**Basis**
2	6-9 and 18	Obvious over Brantigan, Baccelli, Berry, and Michelson

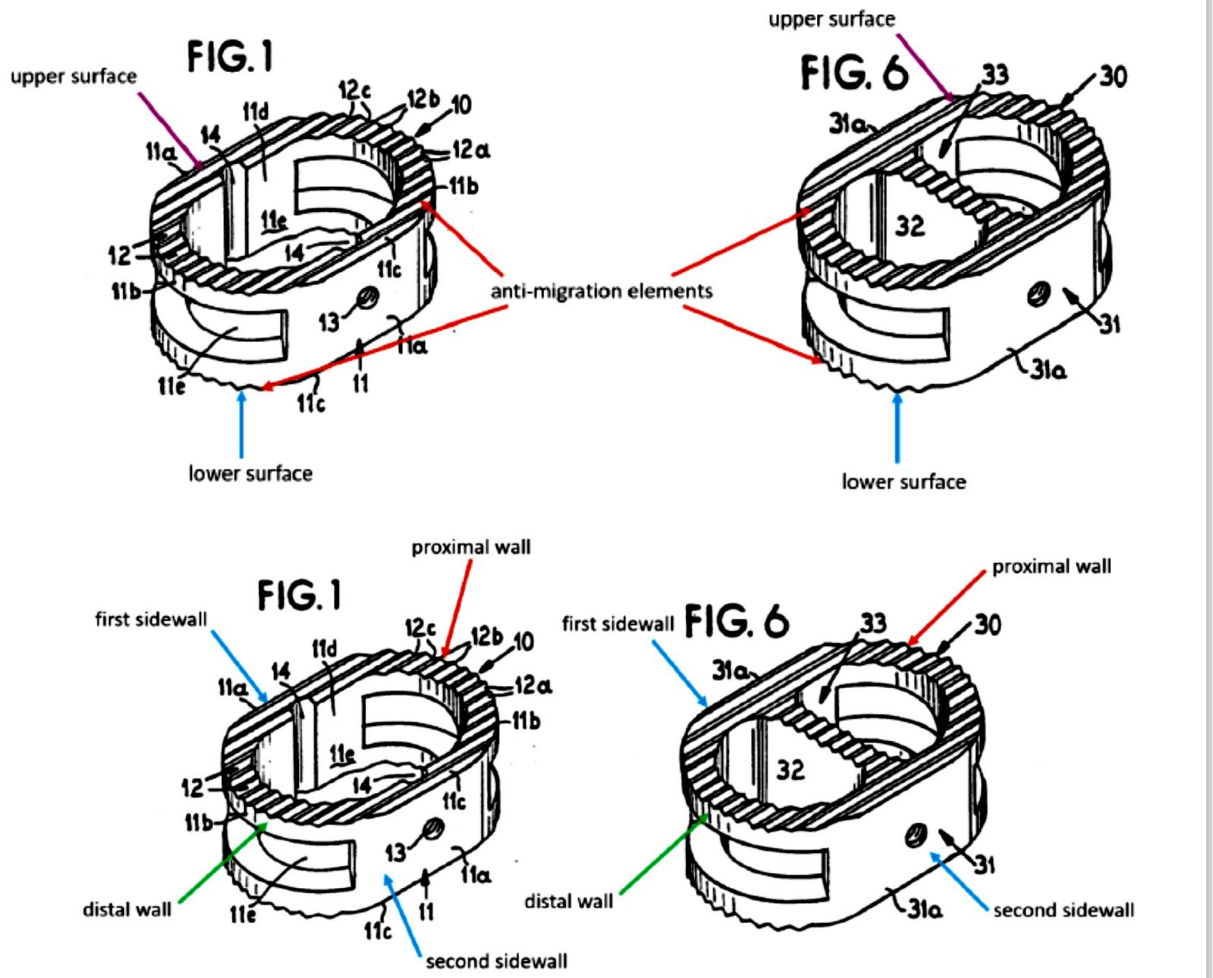
Claim 1: Brantigan Discloses a "Spinal Fusion Implant"

EX1001 ['334 Patent], claim 1

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

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

EX1007 [Brantigan], Figs. 1, 6 (annotated)



Source: Pet., 48-52

Claim 1: Brantigan Discloses a "Spinal Fusion Implant"

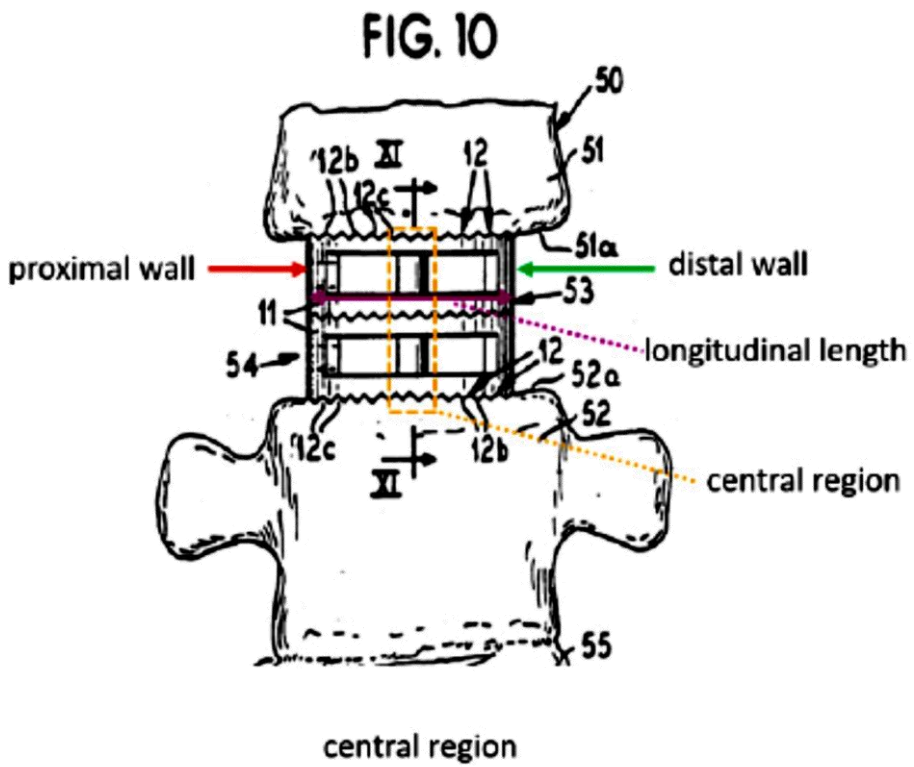
EX1007 [Brantigan], 4:1-14

In FIG. 1, the reference numeral **10** designates generally a vertebrae prosthesis device of this invention composed of rigid biologically acceptable and inactive material, preferably a radiolucent plastics material, inert metal and the like as described above. The device **10** is an oval ring plug **11** generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column. 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. The ends **11***b* have relatively wide and long horizontal peripheral slots **11***e* therethrough preferably extending into the sides **11***a* and communicating with the central aperture **11***d*.

Source: Pet., 48-52

Claim 1: Brantigan Discloses a "Spinal Fusion Implant"

EX1007 [Brantigan], Figs. 1, 6 (annotated)



EX1007 [Brantigan], 3:30-35

The individual plugs or the stack of 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.

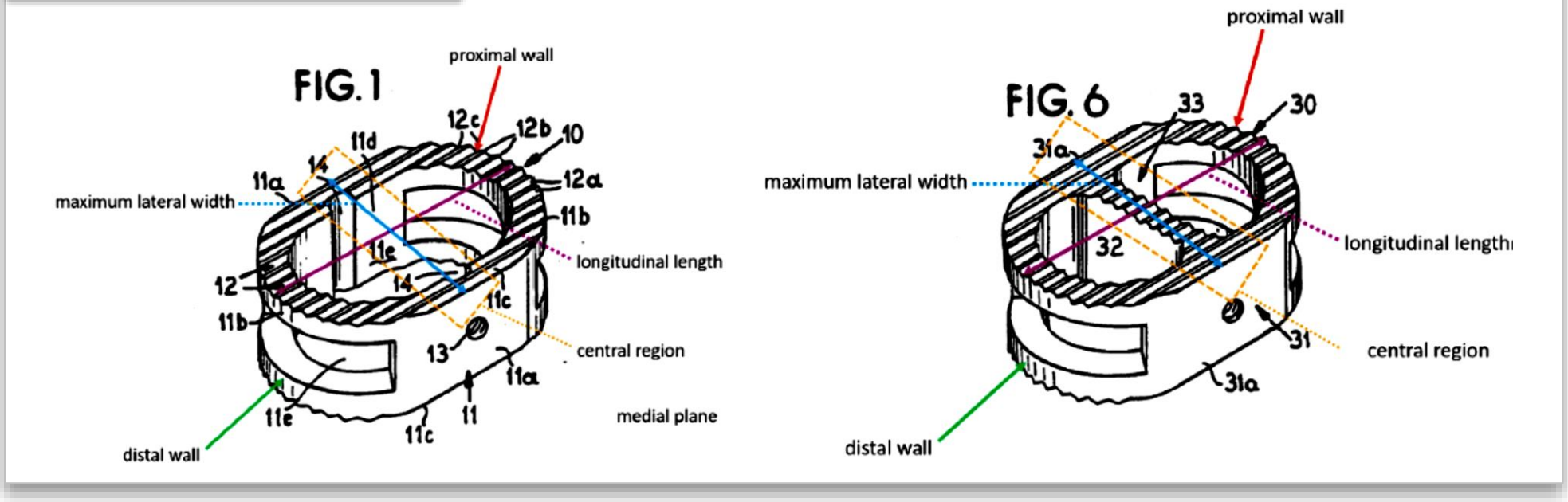
Source: Pet., 56-57, 61-64

Claim 1: Brantigan Discloses Claimed "Central Region"

EX1001 ['334 Patent], claim 1

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

EX1007 [Brantigan], Figs. 1, 6 (annotated)



Source: Pet., 48-52

Claim 1: Brantigan Discloses Claimed "Central Region"

EX1007 [Brantigan], 4:1-14

In FIG. **1**, the reference numeral **10** designates generally a vertebrae prosthesis device of this invention composed of rigid biologically acceptable and inactive material, preferably a radiolucent plastics material, inert metal and the like as described above. The device **10** is an oval ring plug **11** generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column. 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. The ends **11***b* have relatively wide and long horizontal peripheral slots **11***e* therethrough preferably extending into the sides **11***a* and communicating with the central aperture **11***d*.

EX1007 [Brantigan], 5:36-43

Instead of providing a separate bar or plate **15**, as shown in FIG. **6**, a modified device **30** of this invention is a plug **31** of the same oval shape as the plug **11** of FIGS. **1** and **4** but the reinforcing bar **32** of this plug is integral with its side walls **31***a*. The hollow interior **23** of the plug **31** is thus bisected by an integral internal partition **32** forming a pair of side-by-side apertures through the plug adapted to receive bone graft material.

Source: Pet., 48-52

Claim 1: Brantigan, Michelson, and Berry Disclose Claimed Dimensions

EX1001 ['334 Patent], claim 1

wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;

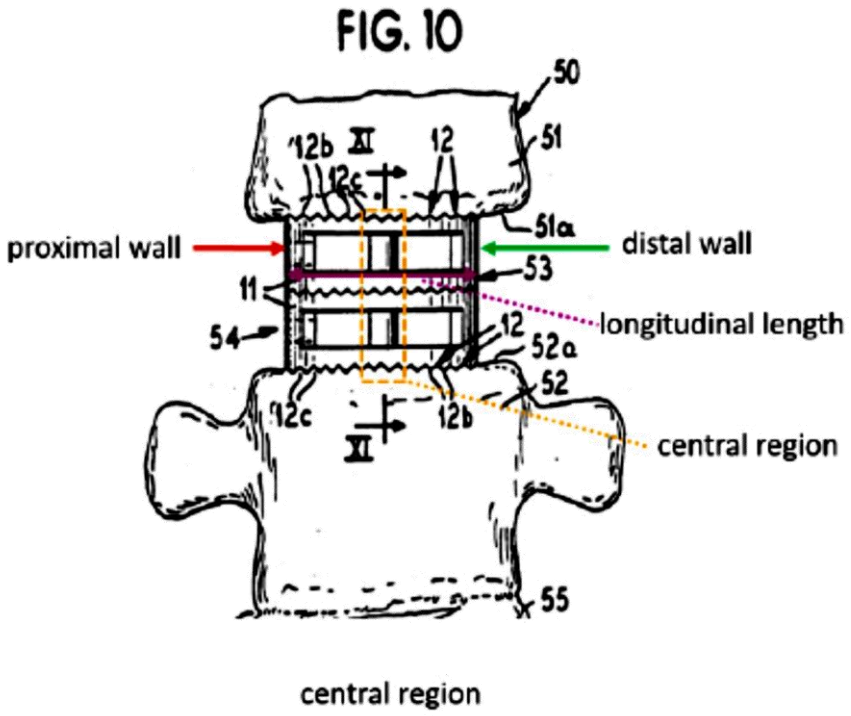
EX1001 ['334 Patent], claim 1

wherein said longitudinal length is at least two and half times greater than said maximum lateral width;

Source: Pet., 56-57, 61-64

Claim 1: Brantigan, Michelson, and Berry Disclose Claimed Dimensions

EX1007 [Brantigan], Figs. 1, 6 (annotated)



EX1007 [Brantigan], 3:30-35

The individual plugs or the stack of 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.

EX1007 [Brantigan], 1:18-21

The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies,

EX1007 [Brantigan], 1:68-2:4

These ring-like prosthetic devices are bottomed on the hard bone faces or end plates of adjacent vertebrae and are generally oval shaped to conform with the general outline perimeter of the vertebrae.

Source: Pet., 56-57, 61-64

Claim 1: Brantigan Discloses Modular Implants

EX1007 [Brantigan], 2:7-11

They are also provided in partial (preferably hemi-oval) annular shape to accommodate those surgical procedures where only a portion of the vertebrae or disc is damaged. Two such hemi-oval rings can be used in the posterior lumbar area in side-by-side relation since the dural sac and nerve roots must be retracted to each side in turn as the implant is placed on the opposite side.

Source: Pet., 61-62

Claim 1: Michelson Discloses Modular Implants

EX1032 [Michelson], 5:34-39

FIG. **19** is a perspective lateral anterior view of a segment of the spinal column with a plurality of the spinal implants of FIG. **18** shown in hidden line inserted from the lateral aspect in a modular fashion in the disc space between two adjacent vertebrae along the transverse width of the vertebrae.

Source: Reply, 10

Claim 1: Michelson Discloses Modular Implants

EX1032 [Michelson], Figs. 16, 18, & 19

FIG. 18

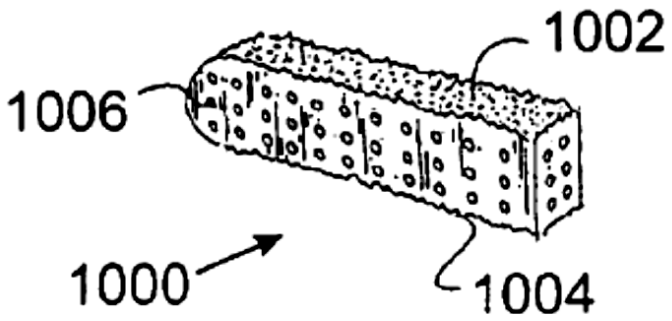


FIG. 16

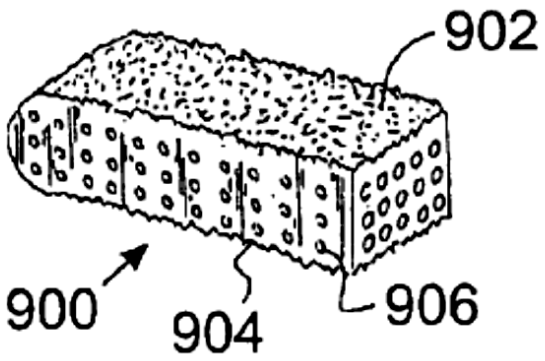
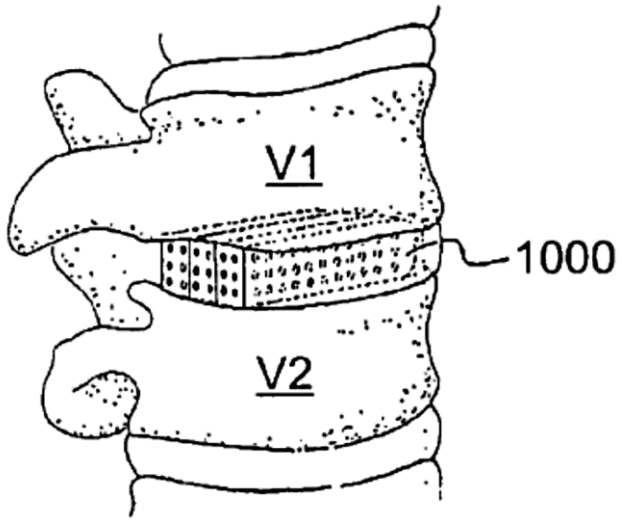


FIG. 19



Source: Pet., 61-62

Claim 1: Michelson's Width "approximates depth of the vertebrae"

EX1032 [Michelson], 10:36-40

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.

Source: Pet., 62

Claim 1: Brantigan, Michelson, and Berry Disclose Claimed Dimensions

EX1001 ['334 Patent], claim 1

wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;

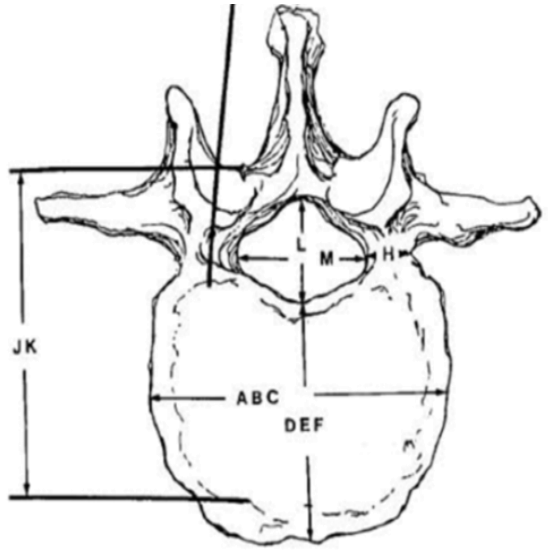
EX1001 ['334 Patent], claim 1

wherein said longitudinal length is at least two and half times greater than said maximum lateral width;

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	T2	T7	T12	L1	L2	L3	L4	L5
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0



L4-L5 Implant Width Range

L4 (lower ("D")) –> (35.6 – 3.1) / 2 = 16.25 mm*

L5 (upper ("E")) –> (35.1 + 2.8) / 2 = 18.95 mm

Longitudinal Length

L4 (lower ("C")) –> 50.9 – 4.6 = 46.3 mm, which is "at least two and a half times greater than said maximum lateral width"

* The value "16.15 mm" at Petition 63 should properly be 16.25 mm as calculated above

Source: Pet., 61-64

Claim 1: Brantigan Discloses Claimed "Fusion Aperture"

EX1001 ['334 Patent], claim 1

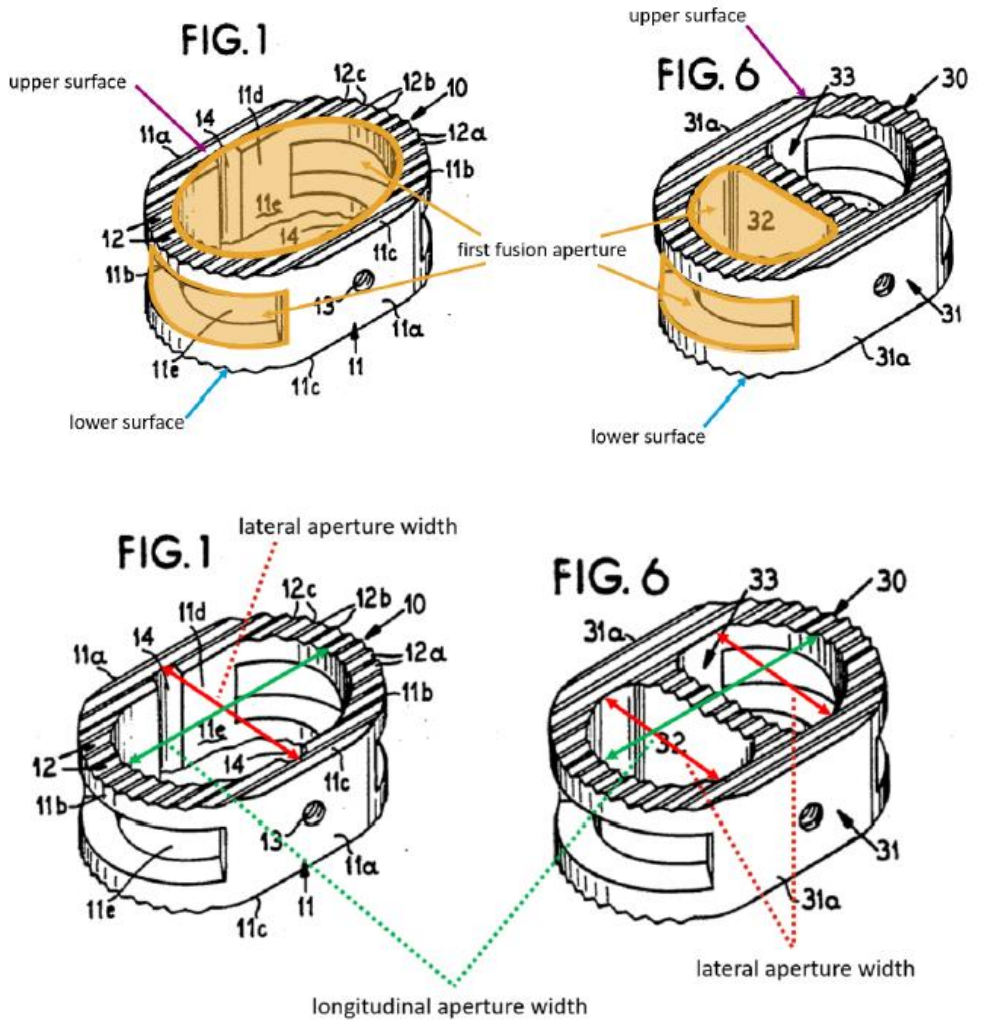
at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length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

POR: Fig. 1 is "unassembled precursor" requiring connecting bar 15

- **Brantigan does not require connecting bar**
- **In any case, aperture length is greater than aperture width**

Source: Pet., 64-66; Reply 14-15

EX1007 [Brantigan], Figs. 1, 6 (annotated)



Brantigan's Implants Do Not Require Connecting Bar 15

EX1007 [Brantigan] claim 10

10. A surgical prosthetic device adapted for fusing together adjoining vertebrae in a vertebral column which comprises a rigid inert annular plug having an interior and sized and shaped to fit opposed end faces of vertebrae in a vertebral column and having top and bottom faces with peaks adapted to bite into the end faces of the adjoining vertebrae and valleys between the peaks to receive bone growth, said plug having a height effective to provide a strut between the vertebrae maintaining a desired disc space, and said plug having a bar intersecting the interior of the plug.

EX1007 [Brantigan] claim 12

12. A prosthetic device seating on hard end plates of vertebrae in a vertebral column while preserving healthy disc tissue between the vertebrae which comprises a rigid inert annular plug generally conforming in shape and size with opposing hard end plates of vertebrae on which it is to be seated, said plug having peripheral side and end walls, top and bottom faces, a central aperture therethrough between the faces, and a peripheral slot therein, said end faces having raised ridges with side walls converging to peaks and valleys between the side walls, said peaks adapted to be bottomed on and bite into the hard end plate faces of vertebrae, tool mounting means in a peripheral wall of the plug, said aperture and slot in the plug adapted to be packed with bone graft material, and said plug being composed of a radiolucent plastics material.

Source: Reply, 14-15

Claim 1: Baccelli Discloses Claimed Markers

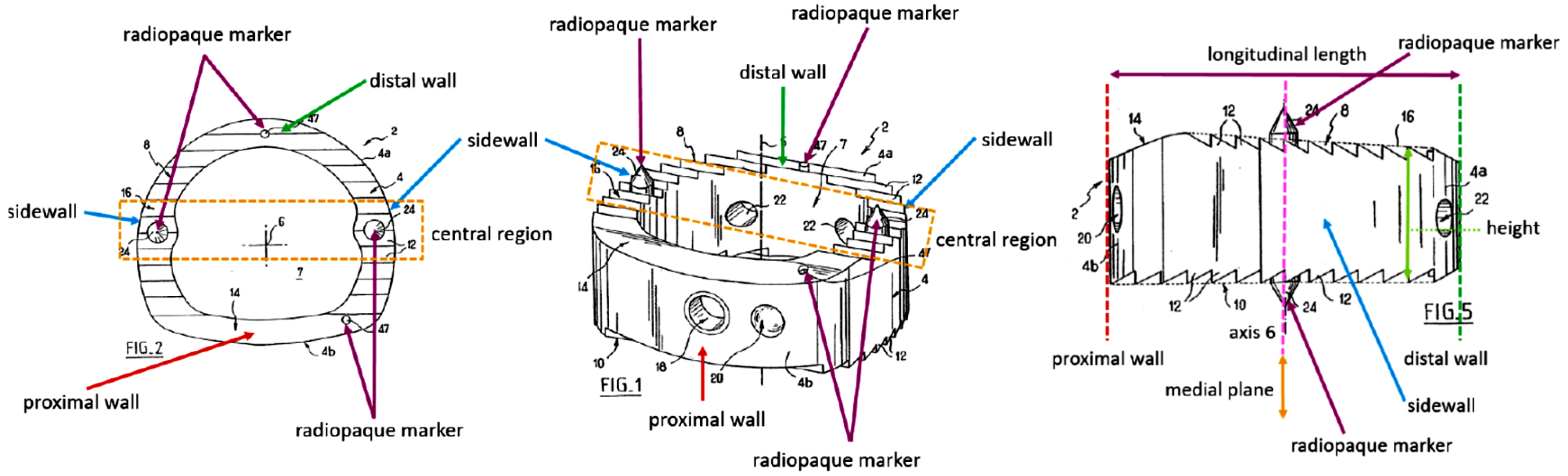
EX1001 ['334 Patent], claim 1

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

Baccelli is not mis-labeled

Longitudinal length defined by insertion

Pet., 45 citing Ex. 1008, Figs. 1–2 (annotated)



Source: Pet., 22-24, 67-70

Federal Circuit: Implant "Length" is "Insertion" to "Trailing" End

EX1019 [Fed. Cir. Op. IPR2013-00206 re Michelson '997 Patent], 5

> [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, the *length* of said implant being greater than the depth of the disc space, . . . [and] the *length* of said implant being greater than the maximum height of said implant.

Id. col. 23 ll. 19–39 (emphases added). Independent claim 17 recites nearly identical language. *Id.* col. 26 ll. 3–24 (claim 17). The "length" is measured laterally, consistent with the direction of the insertion, from the "insertion end" to the "trailing end." *See, e.g.*, *id.* col. 23 ll. 24–26 (claim 1). These appeals principally concern the length of the implant recited in the '997 patent's independent claims.[3]

Source: Pet., 22-24

Patent Owner's Expert Dr. Youssef on Insertion Path

EX1050 [Youssef Dep. Tr.], 23:9-17

Q When the claim language that you reference here says "distal end," what does that mean? Distal to what?

A I think distal to the direction in which the implant is being placed.

Q Okay. And when the claim language uses "proximal end," what does that mean? Proximal to what?

A Proximal to the path of insertion.

Source: Pet., 22-24, Reply, 5

Patent Owner's Expert Dr. McMillin on Insertion Path

EX1051 [McMillin Dep. Tr.], 43:13-20, 44:21-25

Q So by AP implant dimensions in this case, is it your understanding that that also is sometimes referred to as the width of the implant?

A Width is one of those words that can be used in different contexts depending on the type of implant and the direction that you're going. But, yes, in certain cases, that would be the width of the implant.

Q Why would you have to consider the type of implant?

A Sometimes measurements are named differently for different types of an implant. For example, the cervical versus the lumbar.

Source: Pet., 22-24; Reply, 5

Claim 1: Baccelli Discloses Claimed Markers

EX1008 [Baccelli], [0050]

[0050] The cage 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. They could be made of titanium or of titanium alloy. In this case, there are two markers **47** and they are constituted by wires inserted in rectilinear ducts parallel to the axis **6** and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall.

EX1008 [Baccelli], [0051]

[0051] The spikes **24** can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays.

Source: Pet., 67–70

Claims 6–9: Brantigan Discloses Limitations

EX1001 ['334 Patent], claims 6-9

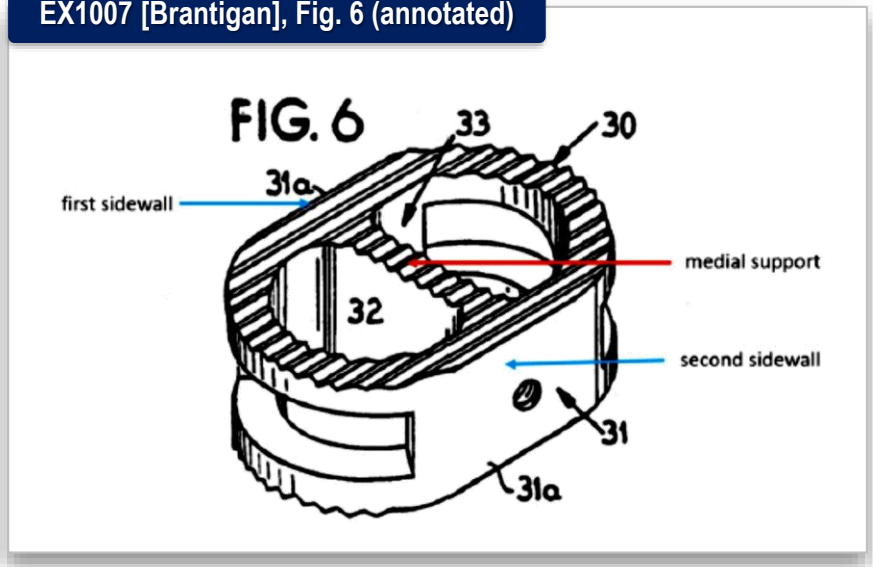
6. The spinal fusion implant of claim **1**, further comprising a medial support extending between the first and second sidewalls.

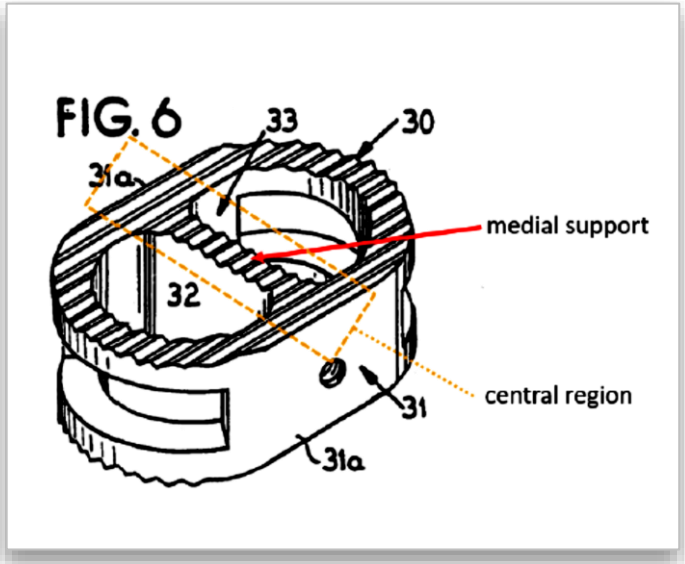
7. The spinal fusion implant of claim **6**, wherein said medial support is positioned along said central region.

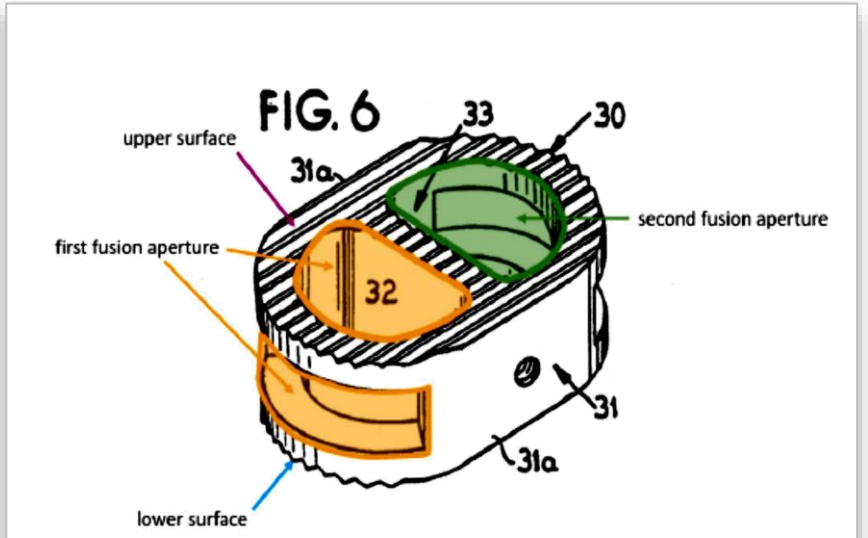
8. The spinal fusion implant of claim **1**, further including a second fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space.

9. The spinal fusion implant of claim **8**, wherein said second fusion aperture is separated from said first fusion aperture by a medial support.

EX1007 [Brantigan], Fig. 6 (annotated)







Source: Pet., 70-73

Claim 18: Brantigan, Michelson, and Berry Disclose Claimed Dimensions

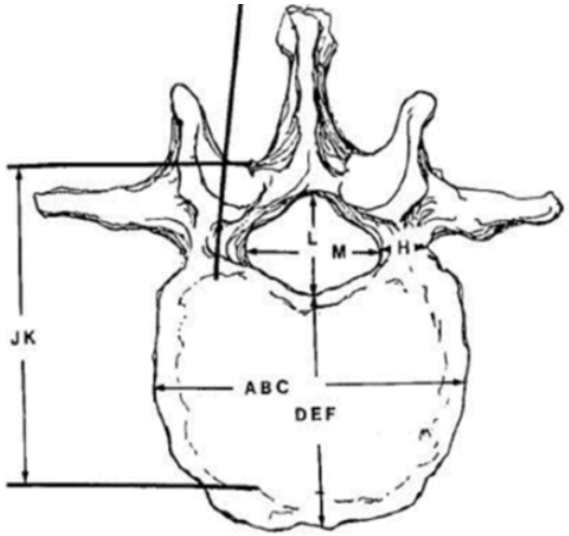
EX1001 ['334 Patent] claim 18

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

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	*T2*	*T7*	*T12*	*L1*	*L2*	*L3*	*L4*	*L5*
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0



L4-L5 Implant Width Range

L4 (lower ("D")) –> (35.6 – 3.1) / 2 = 16.25 mm*

L5 (upper ("E")) –> (35.1 + 2.8) / 2 = 18.95 mm

Longitudinal Length

L4 (lower ("C")) –> 50.9 – 4.6 = 46.3 mm, which is "at least two and a half times greater than said maximum lateral width" as required by claim 1

* The value "16.15 mm" at Petition 74 should properly be 16.25 mm as calculated above

Source: Pet., 73-74

Motivation to Combine Brantigan, Michelson, Baccelli, and Berry

Motivation to Combine: Increased Safety and Decreased Invasiveness

EX1007 [Brantigan], 3:30-35

The individual plugs or the stack of 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.

EX1007 [Brantigan], 7:4-6

Tools such as 73 and 75 may also be replaced with other gripping tools which do not require amounting apertures in the end faces of the plugs.

EX1032 [Michelson], 3:61-65

The translateral implants of the present invention are safer to use than implants inserted from the front or the 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.

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.

Source: Pet., 43-48

Motivation to Combine: Modular Implants with Vertebral Dimensions

EX1007 [Brantigan], 1:18-21

The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies,

EX1032 [Michelson], Fig. 19

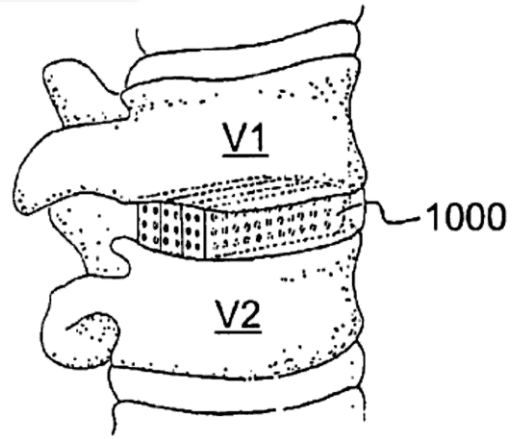


FIG. 19

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	*T2*	*T7*	*T12*	*L1*	*L2*	*L3*	*L4*	*L5*
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0

Source: Pet., 43-48

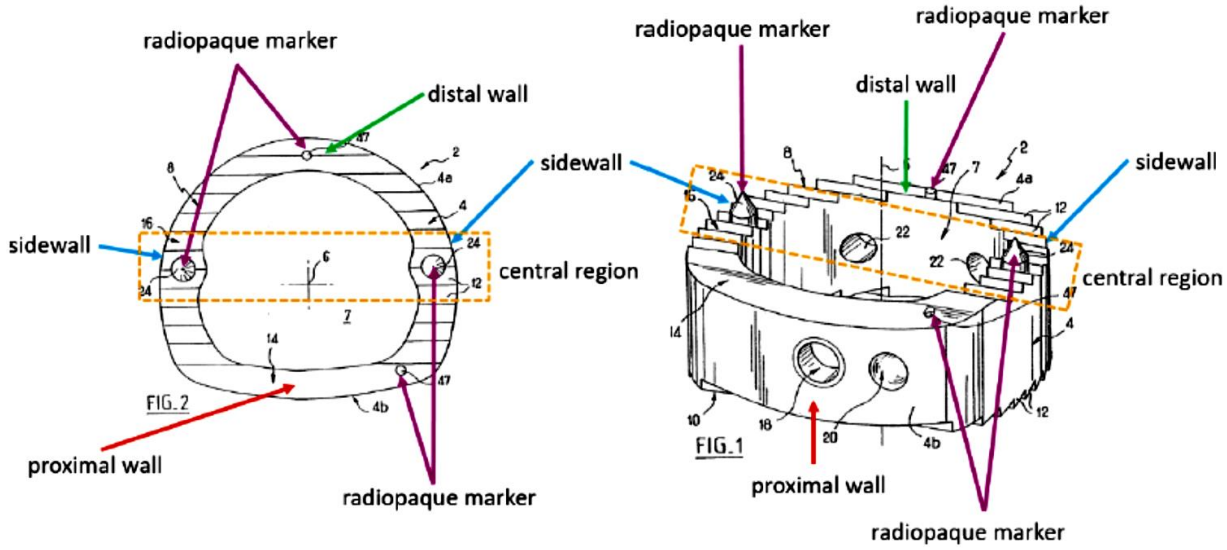
Motivation to Combine: Markers to Identify Implant Position

EX1008 [Baccelli], [0050]

[0050] The cage 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. They could be made of titanium or of titanium alloy. In this case, there are two markers **47** and they are constituted by wires inserted in rectilinear ducts parallel to the axis **6** and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall.

EX1008 [Baccelli], [0051]

[0051] The spikes **24** can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays.



Source: Pet., 43-48

Patent Owner's Argument Against Motivation to Combine

POR, 55

According to the petition, the proposed marker configuration "allow[s] surgeons to align the markers with the spinous process and the lateral ends of the vertebrae." Pet. 45 (citing EX1002, ¶ 199). That is, the petition recycles the same argument that was soundly rejected as impermissible hindsight by the Federal Circuit.

Source: Reply, 2-3

Patent Owner's Expert Dr. Youssef on State of the Art

EX1050, 53:16-25

Q So in paragraph -- in this sentence, you state "Alignment of radiopaque markers with the pedicles and spinous process was not possible with prior art procedures which relied on lateral X-ray; e.g., PLIF and TLIF."

Do you see that?

A I do.

Q So before 2003, did surgeons not know how to do an anterior/posterior X-ray?

A No, they did.

Source: Supp. Sur-Sur-Reply, 2

Patent Owner's Expert Dr. Youssef on State of the Art

EX1050, 54:1-15

Q To your knowledge, has anyone ever inserted a long interbody fusion cage in the lumbar spine laterally and taken an anterior to posterior radiograph and published that before 2003?

A And published that? Can you clarify what you mean?

Q Published in a peer-reviewed publication.

A Oh, I'm -- I can't be specific and accurate, but I would imagine that that's the case.

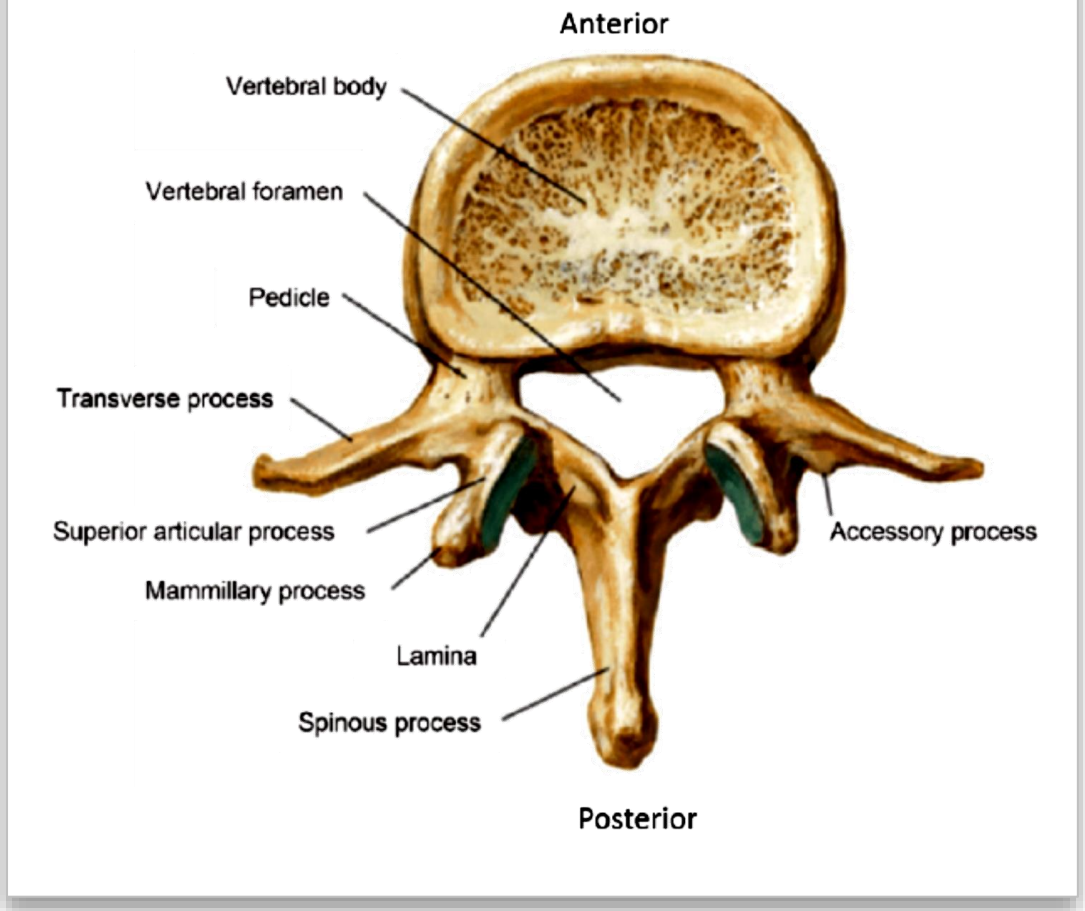
Q Oh, you would imagine that somebody had done that and -- and it was public before 2003?

A Perhaps, yes.

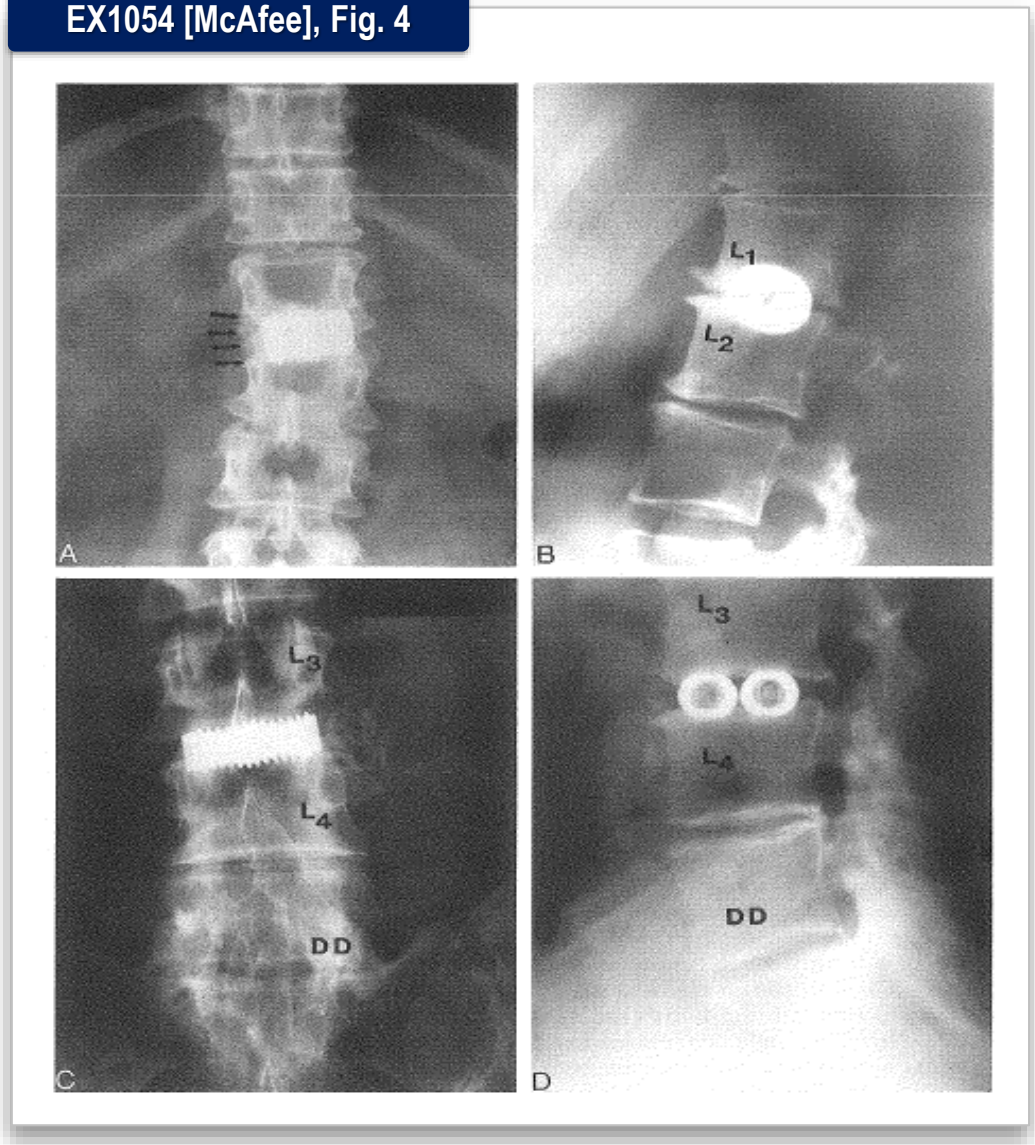
Source: Supp. Sur-Sur-Reply, 2

Marker Argument Not Hindsight: POSAs Knew Benefits

EX1002 [Branch Decl.], ¶ 27



EX1054 [McAfee], Fig. 4



Source: Pet., 43-48, Reply, 2-3

IPR2019-00546

’334 Patent - Grounds 1 and 2

Overview of Grounds

The ’334 patent (-0546)		
Ground	**Claims**	**Basis**
1	16	Obvious over Frey, Michelson, and Baccelli
2	16	Obvious over Brantigan, Baccelli, Berry, and Michelson

Previous Petitioner Relied On Different Disclosure For Claim 16

EX1005 [Federal Circuit Op. IPR2019-00507, -00508], 5

Medtronic's petition in what became IPR508 relied primarily on the Synthes Vertebral Spacer-PR Brochure, Synthes Spine 2002 (SVS-PR), and the Telamon Verte-Stack PEEK Vertebral Body Spacer Brochure and the accompanying Telamon Posterior Impacted Fusion Devic-es Guide 2003 (jointly, Telamon), which teach implants whose lengths are at least 2.5 times their widths. Med-tronic argued that it would have been obvious to modify either SVS-PR or Telamon to have lengths greater than 40 mm, as taught by Michelson. But in the SVS-PR/Telamon petition, unlike the Frey petition, Medtronic did not include an assertion about or citation to material encompassing Michelson's Figure 18.

Board: claim 16 unpatentable

- Federal Circuit remanded for further proceedings

Prior Petitioner did not:

- cite the same evidence Federal Circuit relied on to invalidate claim 1 for claim 16
- cite Michelson's long-and-narrow modular disclosure for claim 16

Federal Circuit did not:

- address Michelson's long-and-narrow modular disclosure for claim 16

Source: Pet., 18-19

Federal Circuit Previously Remanded Claim 16–Parties Settled

EX1005 [Federal Circuit Op. IPR2019-00507, -00508], 17

CONCLUSION

For the foregoing reasons, we affirm the Board's final written decision in IPR2013-507, invalidating claims 1–5, 10, 11, 14, 15, and 19–28 and upholding claim 18. We vacate the Board's decision in IPR2013-508 and remand for further proceedings regarding claims 16 and 17 in accordance with this opinion.

Source: Pet., 1-2

Claim 16 Adds Only A Fourth Marker To Central Region of Claim 1

The ’334 patent (-0361)		
Ground	**Claims**	**Basis**
1	6-9 and 18	Obvious over Frey, Michelson, and Berry
2	6-9 and 18	Obvious over Brantigan, Baccelli, Berry, and Michelson

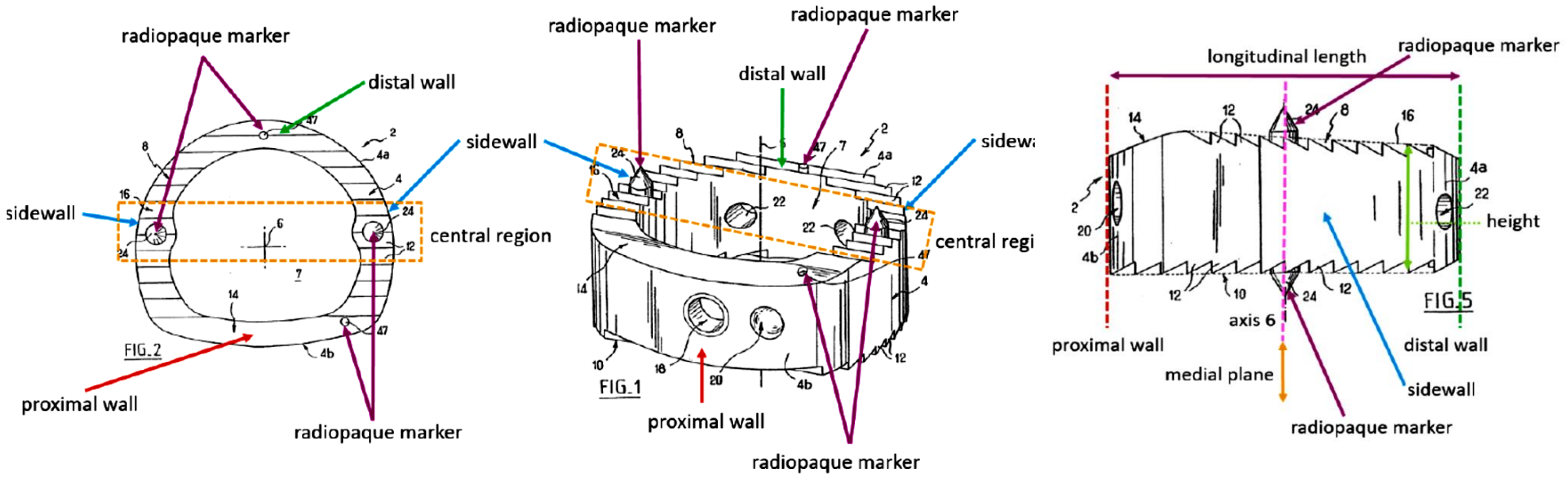
The ’334 patent (-0546)		
Ground	**Claims**	**Basis**
1	16	Obvious over Frey, Michelson, and Baccelli
2	16	Obvious over Brantigan, Baccelli, Berry, and Michelson

Baccelli Discloses Claimed Fourth Marker

EX1001 ['334 Patent], claim 16

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

Pet., 45 citing Ex. 1008, Figs. 1–2 (annotated)



Source: Pet., 63-70

Motivation to Combine:

(1) Frey, Michelson, and Baccelli

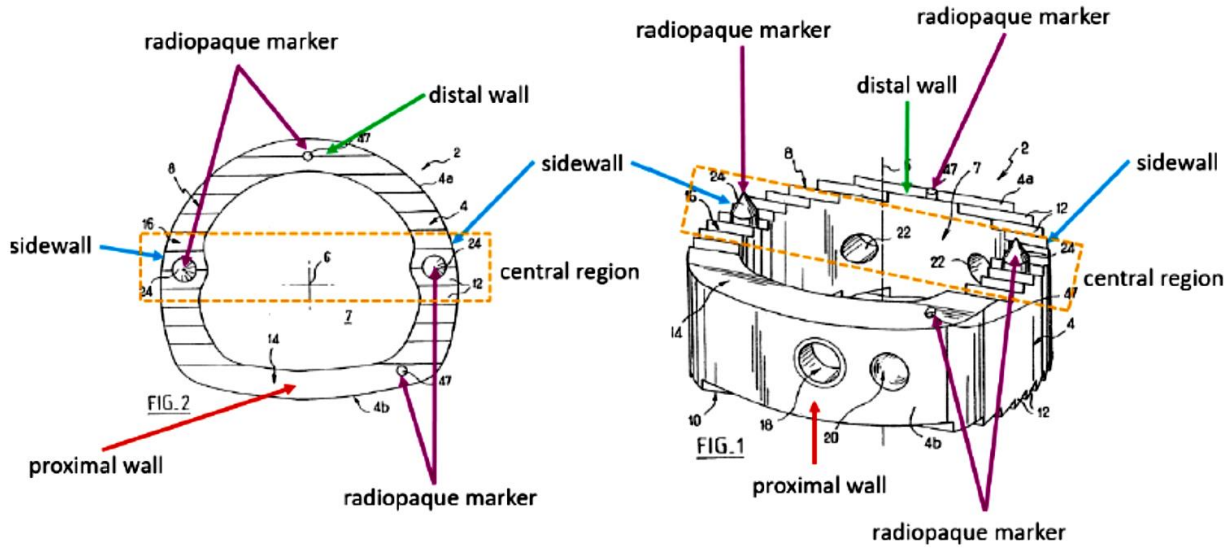
(2) Brantigan, Michelson, Baccelli, and Berry

Motivation to Combine: Modular Implants with Markers

EX1040 [Frey], [0156]

the vertebrae and strength to the body of implant **1400**. A number of radiographic markers **1438** can also be provided in implant **1400** to facilitate X-ray assessment of the locating and positioning of implant **1400** in the patient's body. Such markers are particularly useful for an implant **1400** made from radiolucent material. In the illustrated embodiment,

EX1008 [Baccelli], Figs. 1, 2 (annotated)



EX1032 [Michelson], Fig. 19

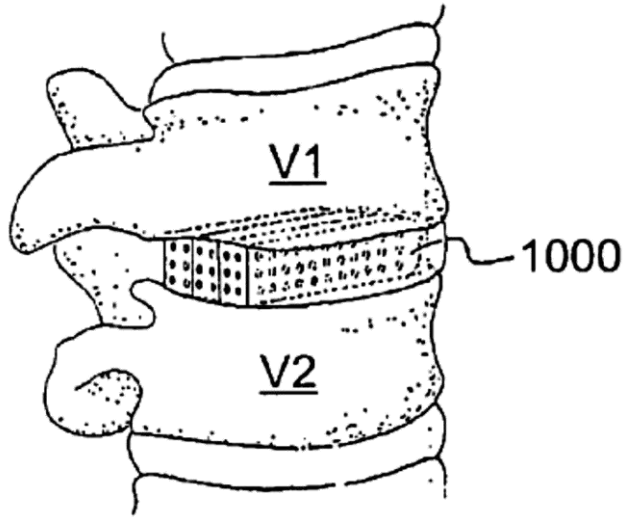


FIG. 19

Source: Pet., 29-31

Motivation to Combine: Modular Implants with Vertebral Dimensions

EX1007 [Brantigan], 1:18-21

The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies,

EX1032 [Michelson], Fig. 19

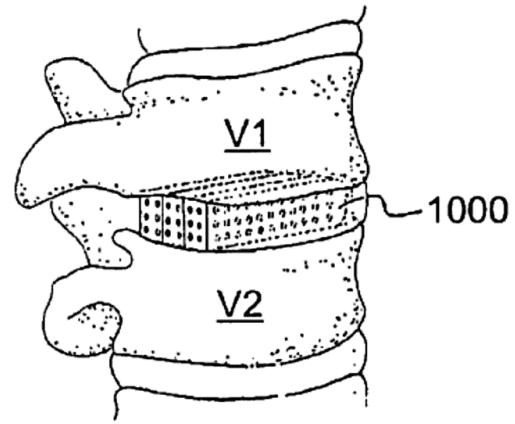


FIG. 19

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	*T2*	*T7*	*T12*	*L1*	*L2*	*L3*	*L4*	*L5*
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0

Source: Pet., 38-42, 54-57

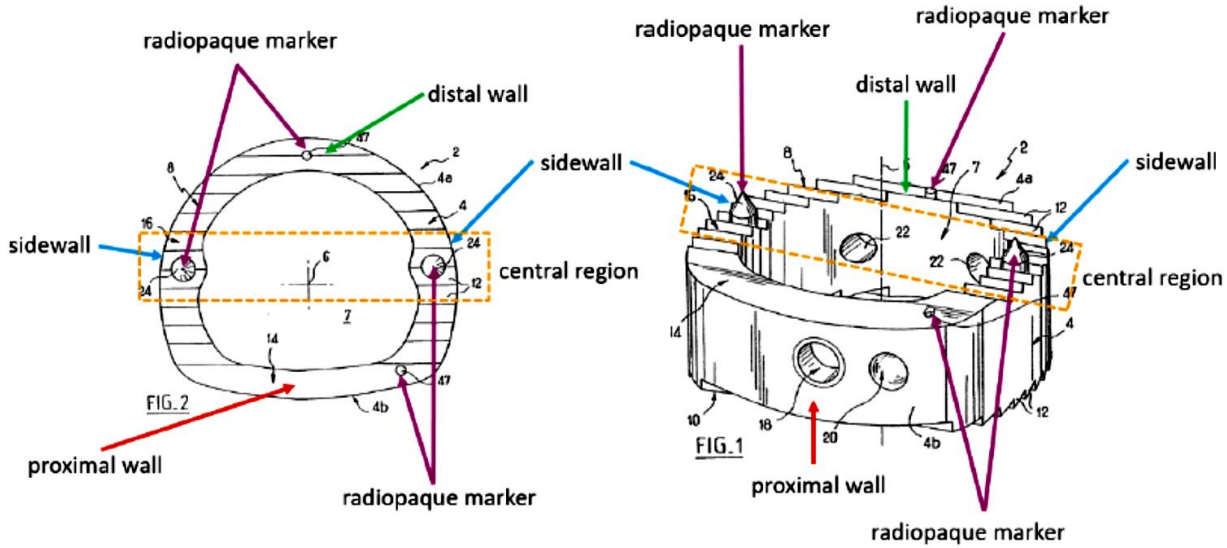
Motivation to Combine: Markers to Identify Implant Position

EX1008 [Baccelli], [0050]

[0050] The cage 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. They could be made of titanium or of titanium alloy. In this case, there are two markers **47** and they are constituted by wires inserted in rectilinear ducts parallel to the axis **6** and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall.

EX1008 [Baccelli], [0051]

[0051] The spikes **24** can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays.



Source: Pet., 38-42

Estoppel Applies

Collateral Estoppel Applies In Administrative Context

Board decisions holding certain claims unpatentable ***"affirmed by [the Federal Circuit], are binding in this proceedings, as a matter of collateral estoppel."***

MaxLinear, Inc. v. CF CRESPE LLC, 880 F.3d 1373, 1376 (Fed. Cir. 2018)

Issue is identical

Claim 1 of the '334 patent invalidated over Frey and Michelson in IPR2013-00507

Issue was actually litigated, and resolution was essential to a final judgment

Patent Owner did not appeal Federal Circuit's affirmance of claim 1 invalidity

Patent Owner had full and fair opportunity to litigate

Patent Owner participated at the Board, Federal Circuit and opted not to appeal to Supreme Court

Equities favor preclusion

Congress intended agencies and courts to issue definitive judgments

B & B Hardware, Inc. v. Hargis Indus., Inc., 575 U.S. 138, 148 (2015)

Sur-reply in IPR2013-00507 would have made no difference because Patent Owner was on notice

Changes in law do not prohibit preclusion

Source: IPR2019-00361 Pet., 32; Reply 6-8; IPR2019-00546 Pet., 31-32; Reply, 6-8

IPR2019-00362

’156 Patent - Ground 1

Overview of Grounds

The ’156 patent (-0362)		
Ground	**Claims**	**Basis**
1	1-3, 5, 9, 10, 12-21, 23, 24, and 27	Obvious over Brantigan, Baccelli, and Berry

‘334 Patent and ‘156 Patent Challenged Claims Substantially Similar

IPR2019-00362 EX1001 [’156 patent], claim 1

What is claimed is:

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

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, a distal wall, a proximal wall, a first sidewall, and a second sidewall generally opposite from the first sidewall, wherein said distal wall, proximal wall, first sidewall, and second sidewall comprise a radiolucent material;

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 said longitudinal length is greater than said maximum lateral width;

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, 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

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.

Dependent claims directed to:

- radiopaque marker orientation
- “receiving aperture” for mounting tool
- width of approximately 18 mm
- PEEK composition
- shape of implant and fusion apertures
- medial support
- anti-migration elements

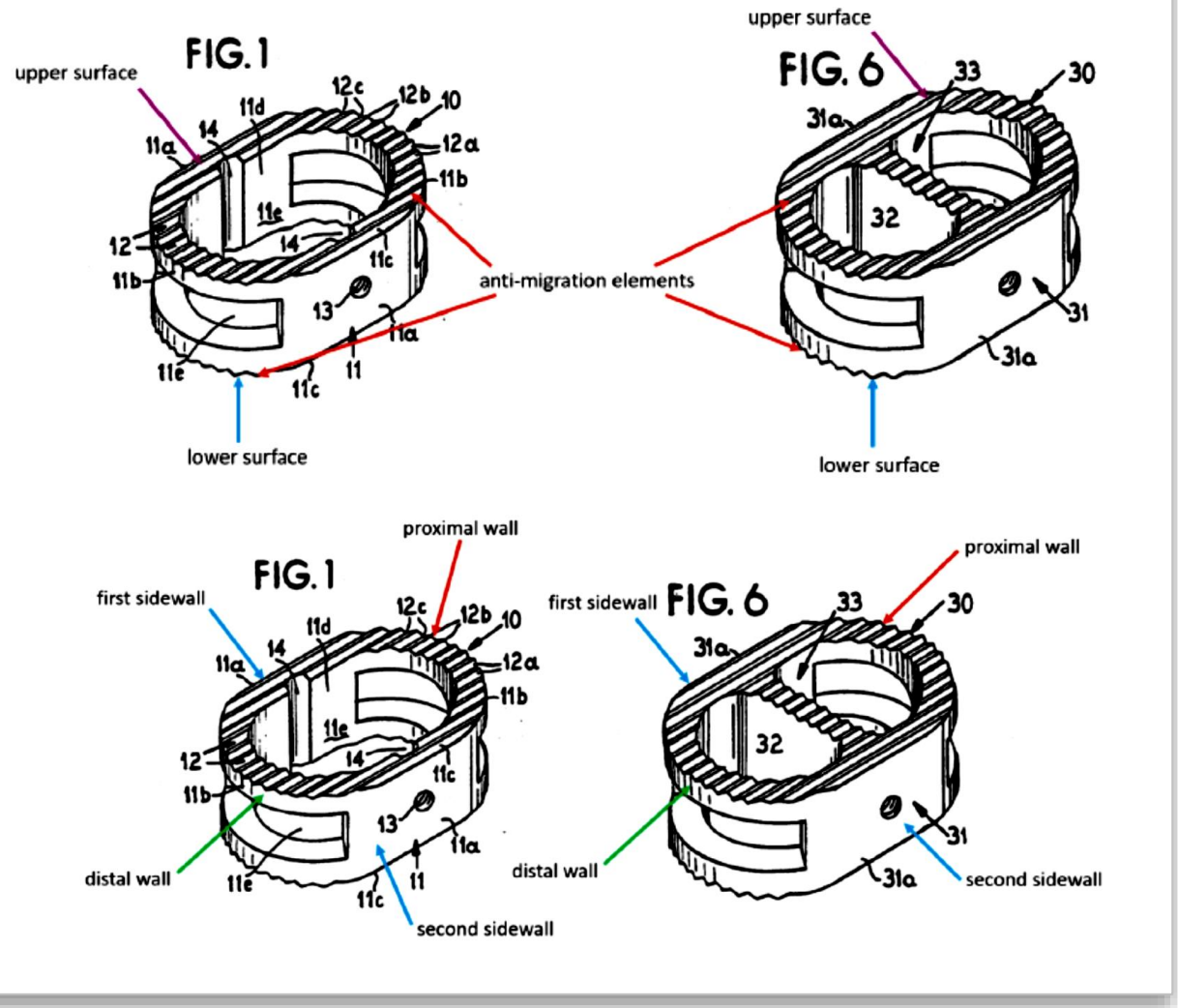
Claim 1: Brantigan "A Spinal Fusion Implant"

EX1001 ['156 Patent], claim 1

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

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, a distal wall, a proximal wall, a first sidewall, and a second sidewall generally opposite from the first sidewall, wherein said distal wall, proximal wall, first sidewall, and second sidewall comprise a radiolucent material;

EX1007 [Brantigan], Figs. 1, 6 (annotated)



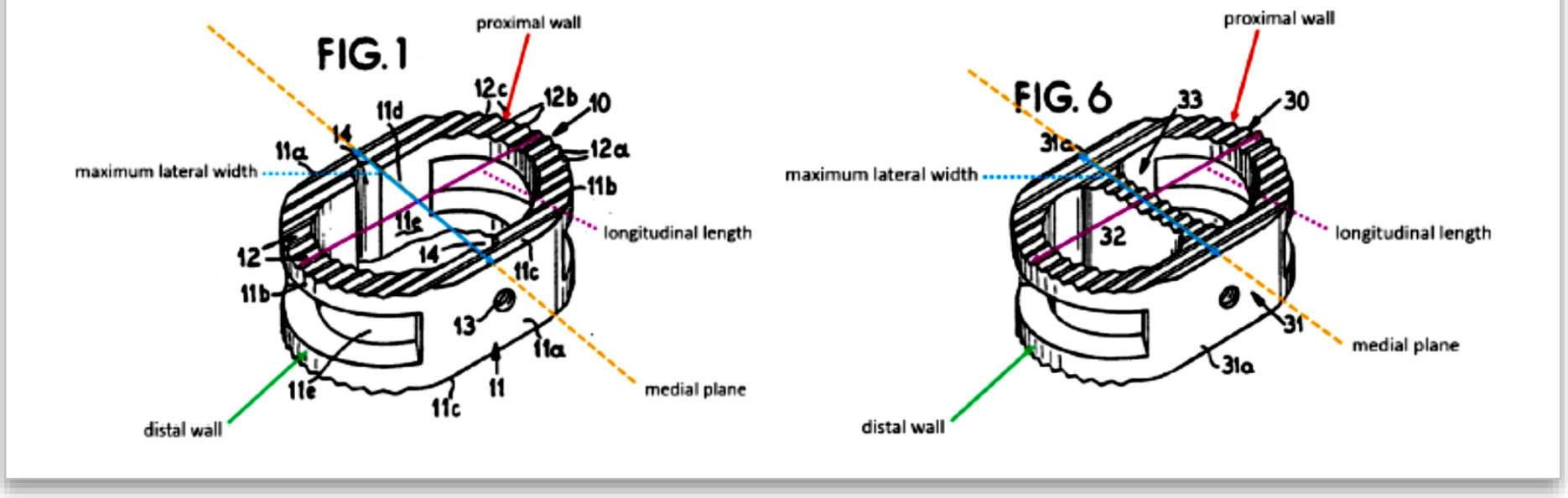
Source: Pet., 33-41

Claim 1: Brantigan Discloses Claimed Dimensions

EX1001 ['156 Patent], claim 1

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 said longitudinal length is greater than said maximum lateral width;

EX1007 [Brantigan], Figs. 1, 6 (annotated)



Source: Pet., 41-44

Claim 1: Brantigan Discloses Claimed Dimensions

EX1007 [Brantigan] 5:30-35

The individual plugs or the stack of 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.

EX1007 [Brantigan], 1:18-21

The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies,

EX1007 [Brantigan], 1:68-2:4

These ring-like prosthetic devices are bottomed on the hard bone faces or end plates of adjacent vertebrae and are generally oval shaped to conform with the general outline perimeter of the vertebrae.

Source: Pet., 56-57, 61-64

Claim 1: Brantigan Discloses Claimed "Fusion Aperture"

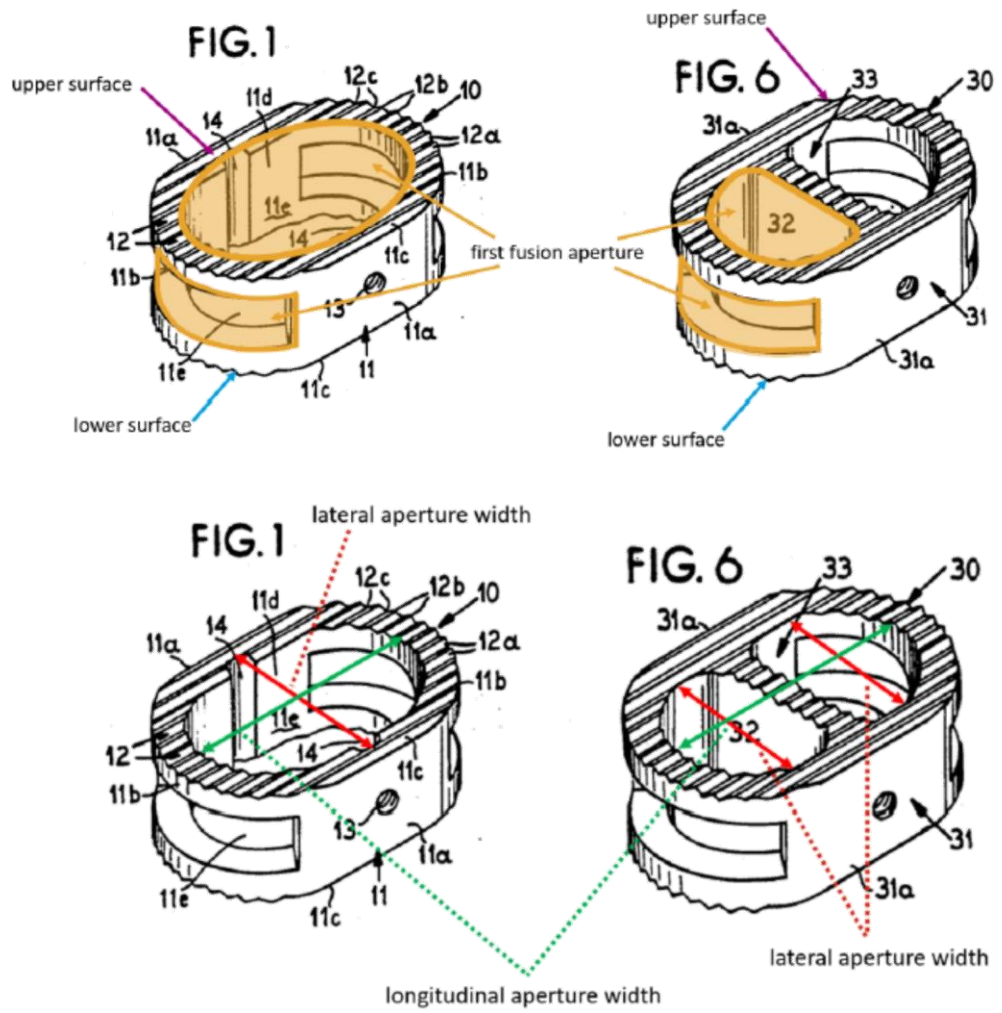
EX1001 ['156 Patent], claim 1

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, 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

POR: Fig. 1 is "unassembled precursor" requiring connecting bar 15

- **Brantigan does not require connecting bar**
- **In any case, aperture length is greater than aperture width**

EX1007 [Brantigan], Figs. 1, 6 (annotated)



Source: Pet., 46-48; POR 17, 28; Reply, 8-10

Claims 1–3: Baccelli Discloses Marker Limitations

EX1001 ['156 Patent], claim 1

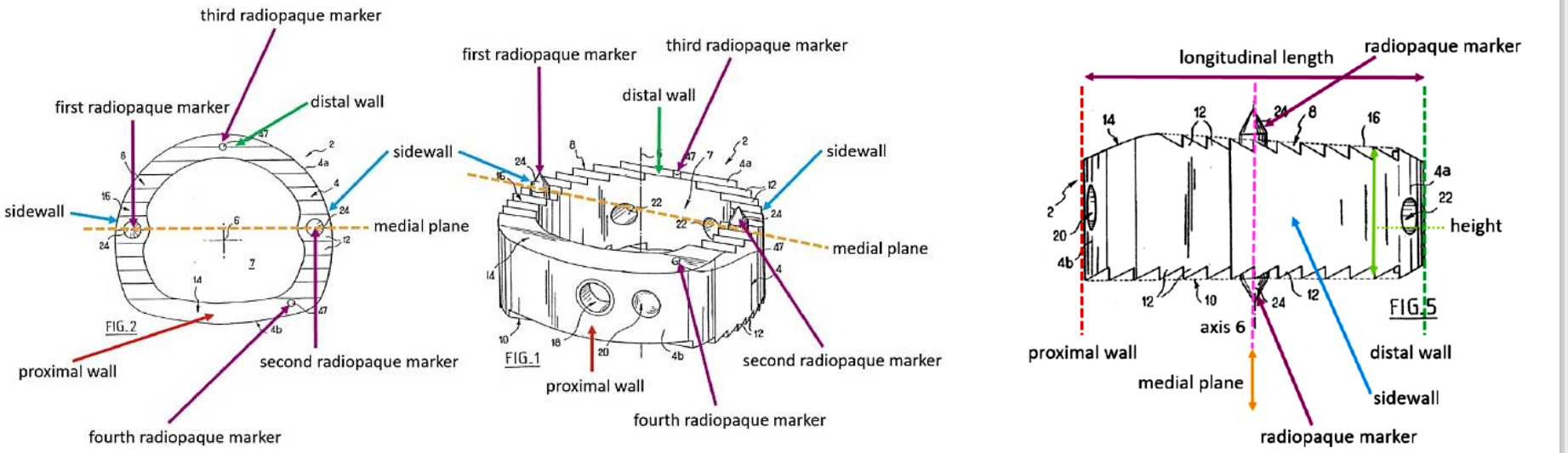
at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said first radiopaque marker extends into said first sidewall at a position proximate to said medial plane, and said second radiopaque marker extends into said second sidewall at a position proximate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

EX1001 ['156 Patent], claims 2–3

2. 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.

3. 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.

EX1008 [Baccelli], Figs. 1–2 (annotated)



Source: Pet., 49-54

Claims 1–3: Baccelli Discloses Marker Limitations

EX1008 [Baccelli], [0050]

[0050] The cage 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. They could be made of titanium or of titanium alloy. In this case, there are two markers **47** and they are constituted by wires inserted in rectilinear ducts parallel to the axis **6** and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall.

EX1008 [Baccelli], [0051]

[0051] The spikes **24** can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays.

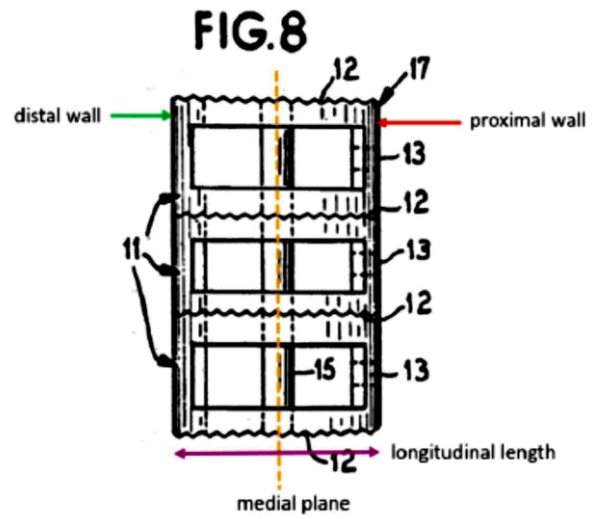
Source: Pet., 49-54

Claim 5: Brantigan and Berry Disclose Claimed Dimensions

EX1001 ['156 Patent], claim 5

5. The spinal fusion implant of claim 1, further including at least one receiving aperture position at said proximal wall wherein said longitudinal length is greater than 40 mm.

EX1007 [Brantigan], Fig. 8



Lumbar longitudinal length is greater than 40 mm

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	T2	T7	T12	L1	L2	L3	L4	L5
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0

Source: Pet., 54-56

Claim 9: Brantigan and Berry Disclose Claimed Dimensions

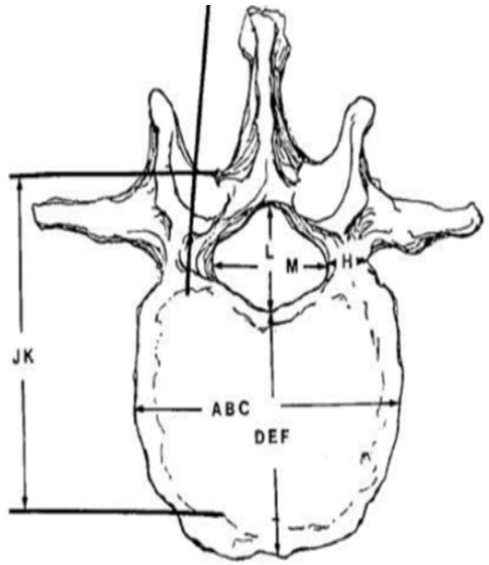
EX1001 ['156 Patent], claim 9

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

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	*T2*	*T7*	*T12*	*L1*	*L2*	*L3*	*L4*	*L5*
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0



EX1007 [Brantigan], 1:68-2:4

These ring-like prosthetic devices are bottomed on the hard bone faces or end plates of adjacent vertebrae and are generally oval shaped to conform with the general outline perimeter of the vertebrae.

Source: Pet., 56

Claims 10, 12–13: Brantigan Discloses Claimed Limitations

EX1001 [‘156 Patent], claims 10, 12, 13

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

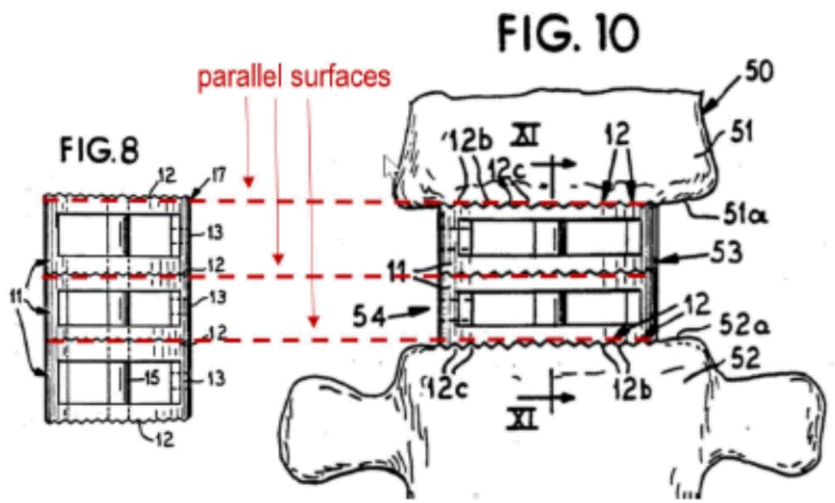
12. The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally parallel to one another.

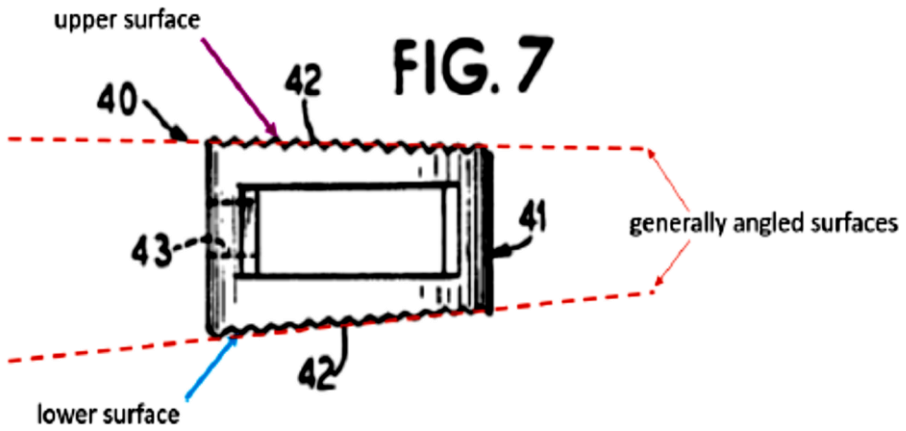
13. The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when said implant is positioned within the interbody space.

EX1007 [Brantigan], 3:9-12

The 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).

EX1007 [Brantigan], Figs. 7, 8, 10 (annotated)





Source: Pet., 57-58

Claim 14–18: Brantigan Discloses Claimed Limitations

EX1001 ['156 Patent], claims 14, 15

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

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

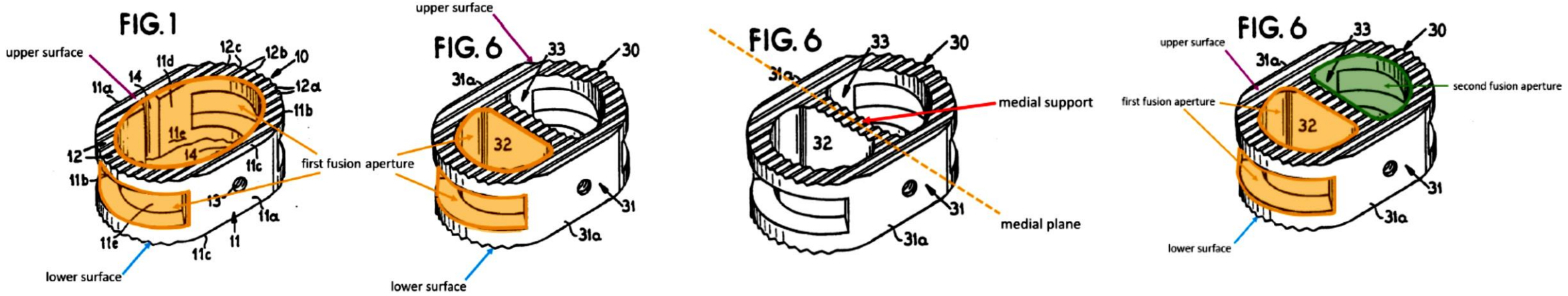
EX1001 ['156 Patent], claims 16-18

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

17. 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.

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

EX1007 [Brantigan], Figs. 7, 8, 10 (annotated)



Source: Pet., 59-62

Claim 19–21: Brantigan and Baccelli Disclose Claimed Limitations

EX1001 ['156 Patent], claims 19-21

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

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

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

EX1008 [Baccelli], [0020]-[0021]

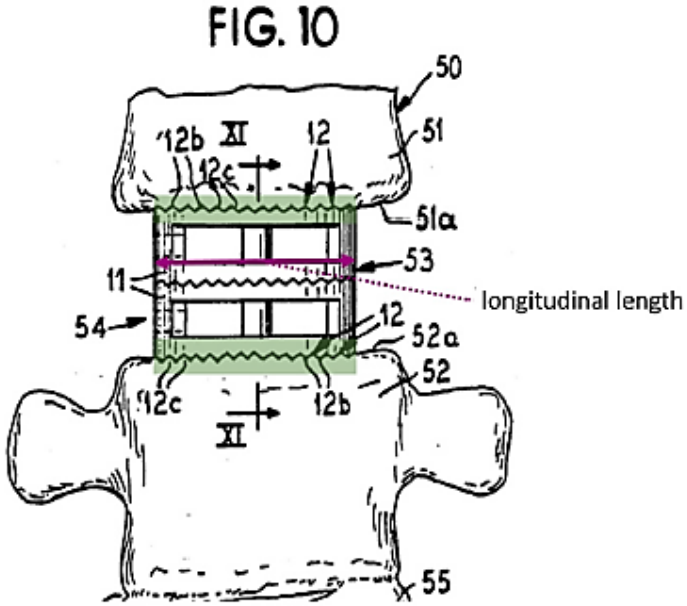
[0020] Advantageously, the implant has at least one spike projecting from one of its main faces, in particular from its toothed face.

[0021] Thus, the spike digs into the vertebral plate and further increases the quality of the anchoring.

EX1007 [Brantigan], 4:15-18

Ridges 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. The valleys 12*c* open at the ends 11*b* of the oval ring plug 11.

EX1007 [Brantigan], Fig. 10 (annotated)



Source: Pet., 63-65

Claims 23–24: Brantigan and Berry Disclose Claimed Limitations

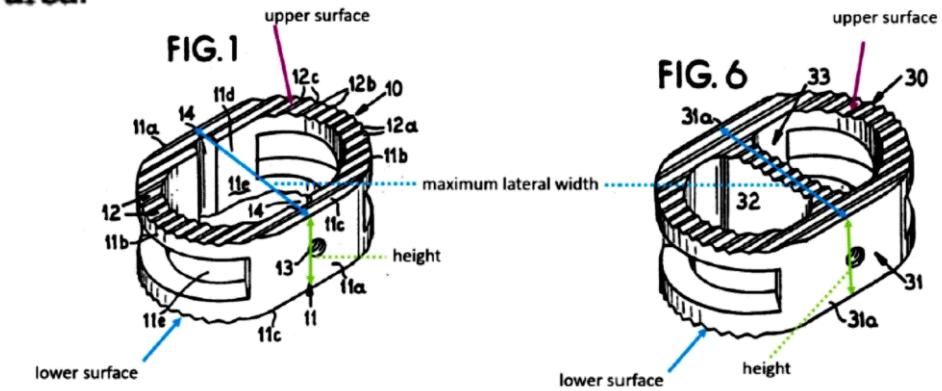
EX1001 [‘156 Patent], claims 23-24

23. 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.

24. 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.

EX1007 [Brantigan], Figs. 1, 6 (annotated), 2:19-22

Each 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.



EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	T2	T7	T12	L1	L2	L3	L4	L5
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0

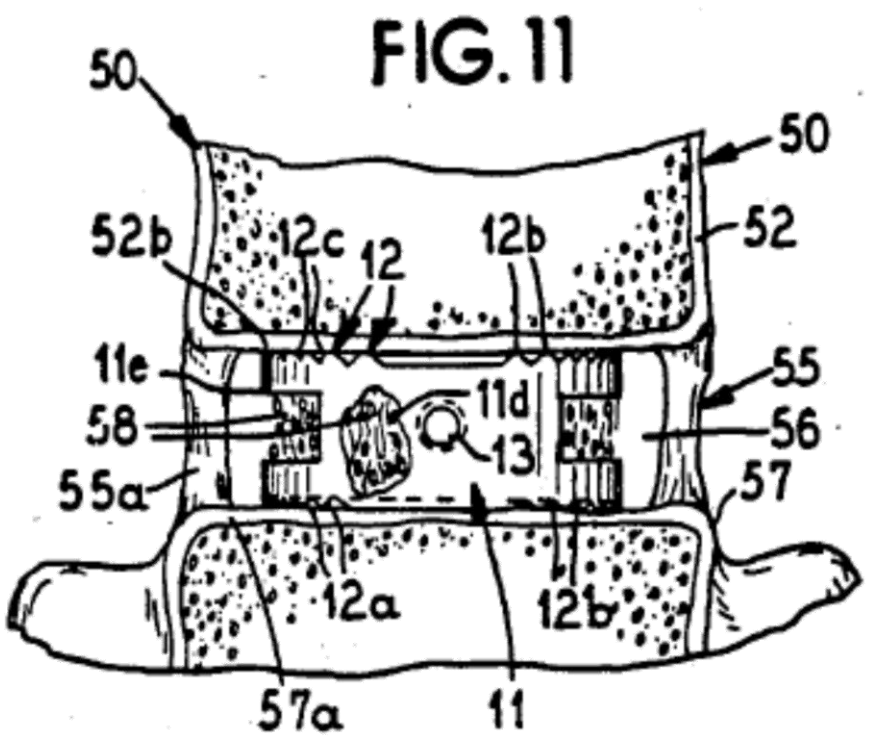
Source: Pet., 66-67

Claim 27: Brantigan Discloses Osteoinductive Material

EX1001 ['156 Patent], claim 27

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

EX1007 [Brantigan], Fig. 11



EX1007 [Brantigan], 2:14-18

The periphery of the oval ring is grooved to accommodate ingrowth of blood capillaries and the open central portion of the ring is preferably packed with bone graft material to facilitate bone ingrowth. Bone graft can also be packed in the grooves.

EX1007 [Brantigan], 6:37-40

As better shown in FIG. 11, 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.

Source: Pet., 68-69

Motivation to Combine Brantigan, Baccelli, and Berry

Motivation to Combine: Implants Sized to Conform with Vertebrae

EX1007 [Brantigan], 3:30-35

The individual plugs or the stack of 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.

EX1007 [Brantigan], 1:18-21

The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies,

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	*T2*	*T7*	*T12*	*L1*	*L2*	*L3*	*L4*	*L5*
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0

Source: Pet., 28-30

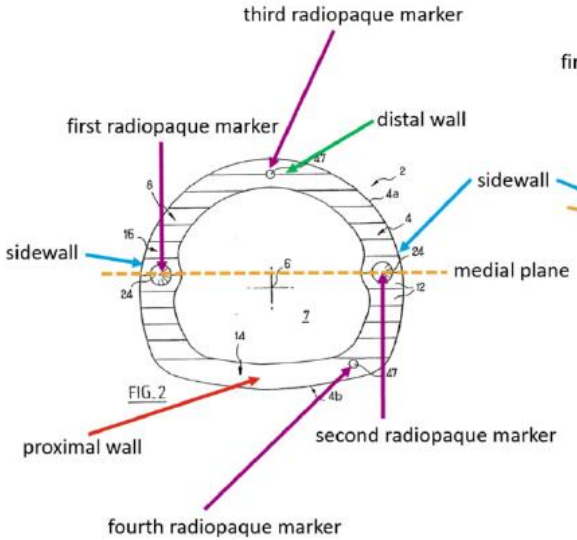
Motivation to Combine: Markers to Identify Implant Position

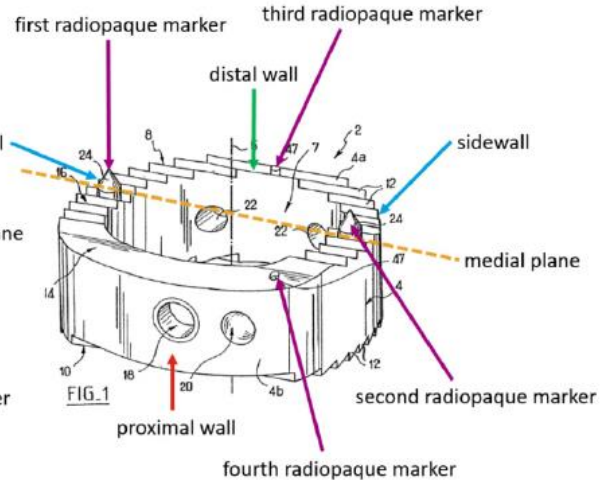
EX1008 [Baccelli], [0050]

[0050] The cage 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. They could be made of titanium or of titanium alloy. In this case, there are two markers **47** and they are constituted by wires inserted in rectilinear ducts parallel to the axis **6** and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall.

EX1008 [Baccelli], [0051]

[0051] The spikes **24** can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays.





Source: Pet., 30-33

IPR2019-00362

’156 Patent - Ground 2

Overview of Grounds

The ’156 patent (-0362)		
Ground	**Claims**	**Basis**
2	9	Obvious over Brantigan, Baccelli, Berry, and Michelson

- Brantigan discloses modular (multiple) implants in the disc space
- Michelson discloses modular, long-and-narrow implants
- Berry discloses vertebral dimensions
- Baccelli discloses claimed markers

Claim 9: Brantigan's Implants Sized to Conform with Vertebrae

IPR2019-00362 EX1001 ['156 Patent], claim 9

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

EX1007 [Brantigan], 1:18-21

The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies,

EX1007 [Brantigan], 1:68-2:4

These ring-like prosthetic devices are bottomed on the hard bone faces or end plates of adjacent vertebrae and are generally oval shaped to conform with the general outline perimeter of the vertebrae.

Source: Pet., 70-75

Claim 9: Brantigan Discloses Modular Implants

EX1007 [Brantigan], 2:4-11

They are also provided in partial (preferably hemi-oval) annular shape to accommodate those surgical procedures where only a portion of the vertebrae or disc is damaged. Two such hemi-oval rings can be used in the posterior lumbar area in side-by-side relation since the dural sac and nerve roots must be retracted to each side in turn as the implant is placed on the opposite side.

Source: Pet., 70-75

Claim 9: Michelson Discloses Modular Implants

EX1032 [Michelson], 10:48-59

Referring to FIG. **18**, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral **1000**. The spinal fusion implant **1000** is similar to the spinal fusion implant **900**, but has a narrower width such that more than one spinal fusion implant **1000** may be combined in a modular fashion for insertion within the disc space D between the adjacent vertebrae.

Referring to FIG. **19**, 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.

Source: Pet., 40-43

Claim 9: Michelson's Width "approximates depth of the vertebrae"

EX1032 [Michelson], 10:36-40

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.

Source: Pet., 30

Claim 9: Berry Discloses "Direct Dimensional Measurements"

IPR2019-00362 EX1001 ['156 Patent], claim 9

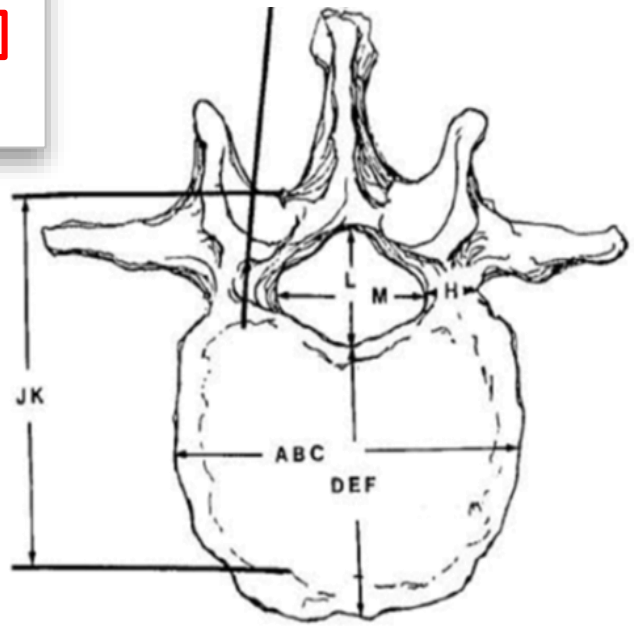
9. The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately 18 mm.

Petitioner never suggested inserting 2 implants each having 18.95 mm width

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	T2	T7	T12	L1	L2	L3	L4	L5
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0



L4-L5 Implant Width Range

L4 (lower ("D")) –> (35.6 – 3.1) / 2 = 16.25 mm*

L5 (upper ("E")) –> (35.1 + 2.8) / 2 = 18.95 mm

*The value "16.15 mm" at Petition 75 should properly be 16.25 mm as calculated above.

Source: Pet., 70-75; Reply 16

Motivation to Combine Brantigan, Baccelli, Berry, and Michelson

Motivation to Combine: Increased Safety and Decreased Invasiveness

EX1007 [Brantigan], 3:30-35

The individual plugs or the stack of 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.

EX1007 [Brantigan], 7:4-6

Tools such as 73 and 75 may also be replaced with other gripping tools which do not require amounting apertures in the end faces of the plugs.

EX1032 [Michelson], 3:61-65

The translateral implants of the present invention are safer to use than implants inserted from the front or the 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.

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.

Source: Pet., 69-70

Motivation to Combine: Modular Implants with Vertebral Dimensions

EX1007 [Brantigan], 1:18-21

The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies,

EX1032 [Michelson], Fig. 19

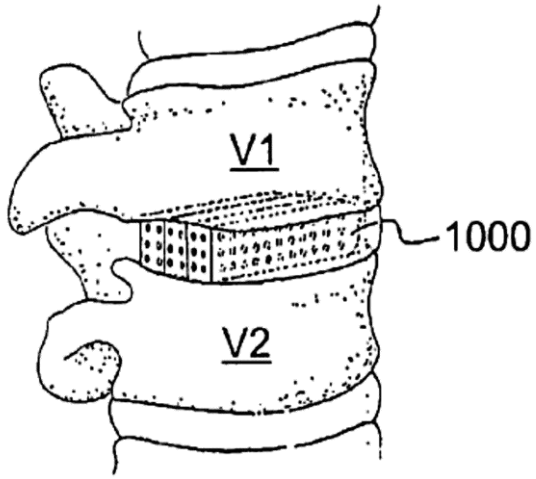


FIG. 19

EX1022 [Berry], Table 1

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	*T2*	*T7*	*T12*	*L1*	*L2*	*L3*	*L4*	*L5*
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B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0

Source: Pet., 28-30

Motivation to Combine: Markers to Identify Implant Position

EX1008 [Baccelli], [0050]

[0050] The cage 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. They could be made of titanium or of titanium alloy. In this case, there are two markers **47** and they are constituted by wires inserted in rectilinear ducts parallel to the axis **6** and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall.

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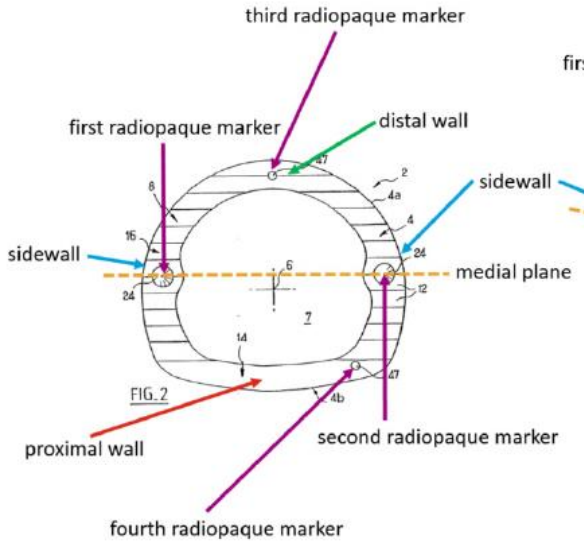

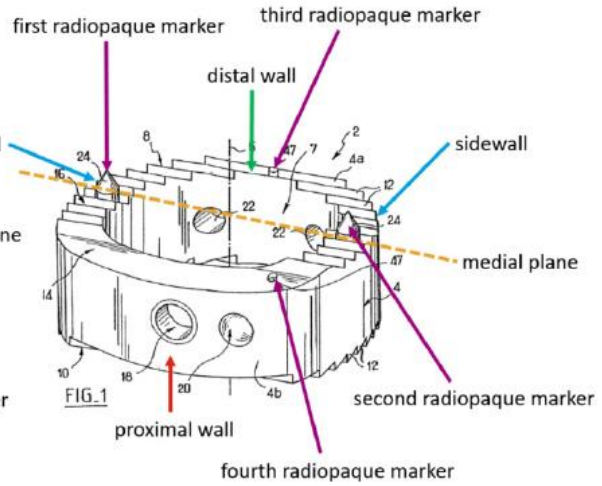

Source: Pet., 30-33

Lack of Nexus Forecloses Secondary Considerations

Objective Indicia Arguments Do Not Establish Non-Obviousness

- Patent Owner relies on several secondary considerations arguments – each lacks nexus
- Development of XLIF and CoRoent XL
  - Success of XLIF is not the same success of CoRoent implant
- Skepticism
  - No evidence that skepticism linked to implant size, rather than access path
- Commercial Success
  - No evidence that implant sales are separate from "success" of unclaimed XLIF features
  - No evidence that implant sales are separate from surgeon education and training
- Copying
  - No evidence of copying
  - "Not every competing product that arguably falls within the scope of the patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent." - *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir 2004)

Source: Reply, 17-20

Dr. Youssef: "XLIF" Comprises Multiple Products

EX2055 [Youssef Decl.], ¶ 84

84. NuVasive made the lateral, trans-psoas approach (*i.e.*, XLIF) possible with a system that includes sequential soft tissue dilation using dilators with directional EMG stimulation electrodes, a three-bladed retractor that minimizes psoas muscle injury, neuromonitoring to detect the location and proximity of the nerves of the lumbar plexus in the psoas muscle and a spinal implant long enough to span the ring apophysis but narrow enough to permit trans-psoas insertion. By developing a platform that integrates these critical elements, NuVasive allowed a surgeon to create a safe lateral surgical corridor that minimizes soft tissue

Source: Reply, 17-20

Mr. Link: "XLIF" Success Due to Surgeon Training

EX1065 [Link Decl.], ¶ 24

NuVasive also implemented the "Marquis Visit Program," or "MVP," at the training center, where visiting surgeons have the opportunity to be trained in the XLIF technique by proctors. Having a central facility for demonstrating and teaching the XLIF technique to surgeons has been instrumental in allowing for the safe and reproducible execution of the XLIF procedure by surgeons across the country. NuVasive also began to provide local lab training for surgeons without convenient access to the San Diego facilities and began to facilitate peer-to-peer interaction through many different venues for surgeons to discuss and observe the XLIF technique.

Source: Reply, 17-20