UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner

v.

BONUTTI SKELETAL INNOVATIONS LLC,
Patent Owner

Case No.: IPR2015-_____
U.S. Patent No. 8,795,363
Issued: August 5, 2014
Application No: 13/847,325
Filed: March 19, 2013

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,795,363

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

LIST OF EXHIBITS

EX1015 Lane JD, Jr., Moore ES, Jr. Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area. Ann Surg. Mar 1948;127(3):537-551

EX1016 Panjabi MM, Goel V, Oxland T, Takata K, Duranceau J, Krag M, Price M. Human lumbar vertebrae. Quantitative three-dimensional anatomy. Spine (Phila Pa 1976). 1992 Mar;17(3):299-306.

EX1017 Scranton PE Jr. Results of arthrodesis of the tarsus: talocalcaneal, midtarsal, and subtalar joints. Foot Ankle. 1991 Dec;12(3):156-64

EX1018 Troyanovich SJ, Cailliet R, Janik TJ, Harrison DD, Harrison DE. Radiographic mensuration characteristics of the sagittal lumbar spine from a normal population with a method to synthesize prior studies of lordosis. J Spinal Disord. 1997 Oct;10(5):380-6

EX1019 Wagner PC, Bagby GW, Brant BD, Gallina A, Ratzlaff M, Sande R. Surgical stabilization of the equine cervical spine. Vet Surg 1979 8:7-12

EX1020 Weiner BK, Fraser RD. Spine update lumbar interbody cages. Spine. 1998 Mar 1; 23(5):634-40

EX1021 Claim Chart – Claims 1, 2, 14, 44, 47 and 53 vs. French Application No. 2,747,034 and International (PCT) Application Publication No. WO 97/20526

EX1022 *Bonutti Skeletal Innovations, LLC v. Globus Medical Inc.*, U.S. District Court for the Eastern District of Pennsylvania, Civil Action no. 14-cv-6650-WY – Bonutti Skeletal's Disclosure of Asserted Claims and Infringement Contentions

I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, the undersigned, on behalf of and representing Petitioner Globus Medical, Inc. ("Globus" or "Petitioner") hereby petitions for *inter partes* review of claims 1, 2, 14, 44, 47 and 53 of U.S. Patent No. 8,795,363, titled "Wedge Apparatus For Use In Operating On A Bone" ("the '363 patent"), issued to Peter M. Bonutti and assigned to Bonutti Skeletal Innovations LLC ("Bonutti"). The '363 patent is attached as **EX1001**.

The invention of the '363 patent is not new. Rather, the claimed invention encompasses known implantable orthopedic devices for use in association with and affecting the spatial relationship of bones in a patient's body. In this regard, the challenged claims of the '363 patent describe the invention having features that are well-known and/or inherent in the prior art orthopedic implant devices.

For the reasons set forth herein, Petitioner asserts that all of the challenged claims are unpatentable. The grounds for unpatentability presented in detail, below, demonstrate how each of claims 1, 2, 14, 44, 47 and 53of the '363 patent is anticipated and/or obvious in view of the prior art. Evidentiary support for Petitioner's conclusions is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. **EX1006.**[1] Dr. Ochoa is an expert with over 25 years of experience in the area

[1] Sometimes referred to herein as **"**Ochoa Decl."

of design and development of orthopedic medical devices, surgical instruments and techniques, as well as biomechanics, and engineering biomaterials. Dr. Ochoa's declaration establishes that each of the challenged claims is anticipated or rendered obvious in view of the prior art and confirms all of Petitioner's assertions of unpatentability.

Petitioner submits that this Petition demonstrates a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. 35 U.S.C. §314(a). Accordingly, Petitioner respectfully requests that this Petition be granted and that claims 1, 2, 14, 44, 47 and 53 of the '363 patent be reviewed and held unpatentable.

II. FORMALITIES

A. Mandatory Notices

1. Real Party in Interest (37 C.F.R. § 42.8(b)(1))

Globus Medical, Inc. ("Globus") is the real party-in-interest.

2. Designation of Lead and Backup Counsel (37 C.F.R.§ 42.8(b)(3))

Lead Counsel	Backup Counsel
George D. Moustakas (Reg. No. 44,425) HARNESS, DICKEY & PIERCE, P.L.C. 5445 Corporate Dr., Suite 200 Troy, MI 48098 248-641-1600 (telephone) 248-641-0270 (facsimile) gdmoustakas@hdp.com	David P. Utykanski (Reg. No. 39,052) HARNESS, DICKEY & PIERCE, P.L.C. 5445 Corporate Dr., Suite 200 Troy, MI 48098 248-641-1600 (telephone) 248-641-0270 (facsimile) dutykanski@hdp.com

3. Notice of Service (37 C.F.R. § 42.8(b)(4))

Please direct all correspondence to lead counsel at the above address. Petitioner consents to email service at the above-referenced email addresses.

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

Petitioner states that the '363 patent is asserted in *Bonutti Skeletal Innovations, LLC v. Globus Medical Inc.*, U.S. District Court for the Eastern District of Pennsylvania, Civil Action no. 14-cv-6650-WY ("the Pending Litigation"). Petitioner is a party to the Pending Litigation. Notably, in the Pending Litigation, Bonutti has accused certain of Globus's spinal implant devices of infringing the challenged claims of the '363 patent. *See* **EX1022.**

Concurrently with this petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 8,486,066 ("the '066 patent"). The '066 patent is related to the '363 patent through continuation practice, and claims subject matter nearly identical to the '363 patent. Petitioner understands that the '363 patent and the '066 patent are commonly owned by Bonutti Skeletal Innovations LLC.

Moreover, Petitioner is concurrently filing Petitions for *inter partes* review of U.S. Patent Nos. 6,099,531 ("the '531 patent"); 6,423,063 ("the '063 patent"); and 7,001,385 ("the '385 patent"). The '531, '063 and '385 patents are related to each other through continuation practice and, although not formally related to the '066 patent, they are directed to subject matter similar to that of the '066 patent.

Petitioner understands that the '531, '063 and '385 patents are likewise commonly owned by Bonutti Skeletal Innovations LLC.

B. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that (1) the '363 patent is available for *inter partes* review; and (2) Petitioner is not barred or estopped from requesting *inter partes* review of any claim of the '363 patent on the grounds identified in this Petition. It should be noted that, in this regard, service of the Summons and Complaint issued in the Pending Litigation was made on Petitioner on December 30, 2014. Consequently, Petitioner is not time barred by the Pending Litigation to bring this Petition.

C. Procedural Statements

This Petition is filed in accordance with 37 C.F.R. § 42.106(a). A Power of Attorney (37 C.F.R. § 42.10(b)) and Exhibit List (37 C.F.R. § 42.63(e)) are filed concurrently with this Petition. The fee is being paid via Deposit Acct. No. 08-0750. The United States Patent and Trademark Office is authorized to charge any fee deficiency, or credit any overpayment, to Deposit Acct. No. 08-0750.

III. U.S. PATENT NO. 8,795,363 ("THE '363 PATENT") (EX1001)

The '363 patent issued on August 5, 2014, on an application filed on Mar 19, 2013. The '363 patent is a continuation of U.S. Patent No.8,690,944, filed on October 30, 2007, which is a continuation of U.S. Patent No. 8,486,066, filed on

May 15, 2003, which is a continuation of U.S. Patent No. 6,575,982, filed May 5, 2000 which, in turn, is a continuation of U.S. Patent No. 6,086,593, filed June 30, 1998. The earliest priority date for the '363 patent is June 30, 1998.

A. The '363 Patent Specification and Claims

The '363 patent is directed to an implantable spacer (*e.g.,* a wedge member) for use in association with bones in a patient's body, *e.g.,* to change special relationships in and between bones to correct defects. The challenged claims, however, encompass known implantable orthopedic devices for use in association with and affecting the spatial relationship of bones in a patient's body and are unpatentable. The '363 patent issued with 85 claims, of which only claims 1, 2, 14, 44, 47 and 53 are at issue in this Petition. Claim 1 is independent, and each of claims 2, 14, 44, 47 and 53 is dependent either directly or indirectly from claim 1.

The written description and drawings of the '363 patent describe various embodiments of an implantable spacer device. The apparatus of the challenged claims, however, is a wedge member 36d having a large central opening 134 through which bone may grow. **EX1001 at 14:39-40**. The opening 134 extends between upper and lower major side surfaces 68d and 70d and is configured so that the upper and lower major side surfaces 68d and 70d engage an outer layer 80d of hard cortical bone. ***Id.*** **at 14:40-46**. The opening 134 enables the core 90d of soft cancellous bone to easily grow through the wedge member 36d. ***Id.*** **at 14:48-50**.

Material 130d (FIG. 11) for promoting a growth of bone can be included in the opening 134. ***Id.*** **at 14:50-52**. The opening 134 has a configuration which is similar to but smaller than the overall configuration of the wedge member 36d. ***Id.*** **at 14:59-61.** The side surface 138 of the opening 134 is spaced from the outer side surface 50d by a distance which is greater than the thickness of the outer layer 80d of hard cortical bone. ***Id.*** **at 15:1-3**. Mounting strips 60d, 62d and 64d abut the outer side surface 94d of the bone and suitable fasteners 58d can then be utilized to connect the wedge member 36d with the upper end portion 30d and the lower portion 32d of the bone 22d. ***Id.*** **at 15:17-21**.

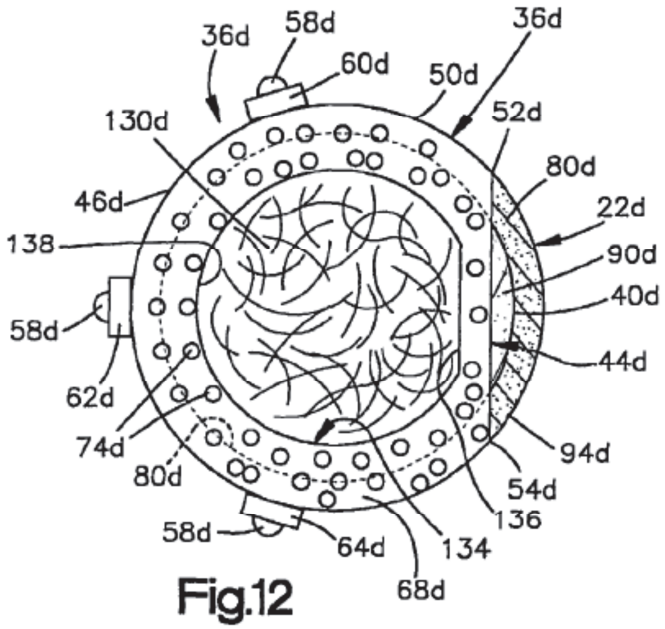


Fig.12

The apparatus is best understood with reference to FIGs. 11 and 12. A wedge member 36d has a thin edge 44d and a thick edge 46d. An outer side surface 50d extends between opposite ends 52d and 54d (FIG. 12) of the thin edge 44d. The outer side surface 50d has a configuration which corresponds to the configuration of an outer side surface 94d of a bone 22d (FIG. 11). The wedge member 36d has flat upper and lower major side surfaces

68d and 70d which are skewed at an acute angle relative to each other and extend between the thin edge 44d and the thick edge 46d of the wedge member 36d. ***Id.*** **at 13:64-14:7**. Mounting strips 60d, 62d, and 64d on the wedge member 36d are

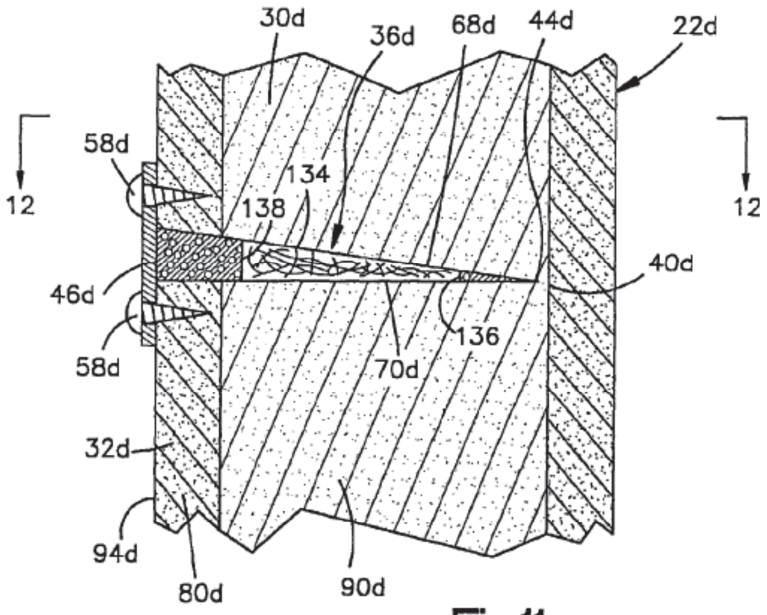


Fig.11

configured to move into abutting engagement with the outer side surface 94d of the bone 22d (FIG. 12). The mounting strips 60d, 62d, and 64d are fixedly connected with the upper end portion 30d and lower portion 32d of the bone 22d by suitable fasteners 58d. The fasteners 58d retain the wedge member 36d against movement from a position in which the side surface 50d is aligned with the outer side surface 94d of the bone 22d. ***Id.*** **at 14:18-26.** the wedge member 36d has a large central opening 134 through which bone may grow. The opening 134 extends between upper and lower major side surfaces 68d and 70d of the wedge member 36d. The opening 134 is configured in such a manner that the upper and lower major side surfaces 68d and 70d of the wedge member 36d engage an outer layer 80d of hard cortical bone throughout movement of the wedge member 36d into the slot formed in the bone 22d. ***Id.*** **at 14:38-46**. Suitable fasteners 58d can be utilized to connect

the wedge member 36d with the upper end portion 30d and the lower portion 32d of the bone 22d. ***Id.* at 15:19-21**.

B. The '363 Patent Prosecution History (EX1002)

The continuation application leading to the '363 patent, Serial No. 13/847,325, was filed on March 19, 2013. Prosecution before the U.S. Patent and Trademark Office for the application leading to the '363 patent encompassed only a single restriction requirement and a single substantive office action. In response to the restriction requirement, the Applicant elected the species identified in Figures 11 and 12 for continued prosecution. *See*, Prosecution History, Response to Election Requirement dated September 16, 2013, **EX1002 at page 130.**

In the March 2014 Amendment responding to the single Office Action, the applicant amended then pending claim 1 to include the limitation that "the body width being greater than the body length" as recited in dependent claim 2 and identified as allowable subject matter by the Examiner.[2] *See*, Prosecution History, Amendment dated March 20, 2014, ***Id*. at pages 64 and 76.** The Applicant further added new claims, of which claims 47-57 depending ultimately depended from claim 1.[3] Subsequent to the Amendment, a Notice of Allowance was issued on June 23, 2014.

---

[2] Claim 1, as amended during prosecution, appears as claim 1 of the '363 patent which is at issue in this Petition.

[3] Three of the claims added in the March 20, 2014 Amendment correspond to claims 44, 47 and 53, which are at issue in this Petition.

IV. THE PERSON HAVING ORDINARY SKILL IN THE ART AND THE STATE OF THE ART

As established in the Declaration of Dr. Ochoa (**EX1006** at ¶ 18), a person having ordinary skill in the art (PHOSITA) of the '363 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience. The experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. Alternatively, a PHOSITA could have an advanced degree, in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

V. CLAIM CONSTRUCTION

The claims of the '363 patent are to be given their broadest reasonable construction in light of the '363 patent's specification as understood by a person having ordinary skill in the art. 37 C.F.R. § 42.100(b).

The standard for claim construction in the United States Patent and Trademark Office is different than the standard used in litigation in the U.S. District Courts. *In re Am Acad. Of Sci. Tech Ctr.*, 367 F.3d 1359, 1364, 1369 (Fed. Cir. 2004); M.P.E.P. § 2111. Petitioner, therefore, expressly reserves the right to argue a different claim construction in a different forum for any term in the '363

patent, as appropriate in that proceeding.

VI. THE PRIOR ART RELIED UPON IN THIS PETITION

A. French Patent Application No. FR 2,747,034 to Benezech et al. ("the FR'034 application" or "Benezech") (EX1003)[4]

French Patent Application No. FR 2,747,034 to Benezech et al., entitled "Intersomatic Setting and Fusion System," published October 10, 1997. The FR'034 application is prior art to the '066 patent under 35 U.S.C. § 102(a) because it is a printed publication in the U.S. or a foreign country before the invention of the '363 patent. The FR'034 application was neither disclosed by the patent applicant nor cited, referred to, or relied on by the Examiner during the prosecution of the application leading to the '363 patent.

B. International (PCT) Application Publication No. WO 1997/20526 to Bray ("the '526 publication" or "Bray") (EX1005)

International (PCT) Application Publication No. WO 1997/20526 to Bray, entitled "Anterior Stabilization Device," published June 12, 1997. Bray is prior art to the '363 patent under 35 U.S.C. § 102(b) because it is a printed publication more than one year prior to the date of the application for the '363 patent in the United States. Bray was not disclosed during the prosecution of the '363 patent; however, U.S. Patent no. 5,888,223 which shares a common priority document (*i.e.,* U.S. Provisional application No. 60/008,365) and appears to include a written

[4]A certified English translation of the specification of the FR'034 application is attached as **EX1004**.

description and drawings which are substantially the same as Bray, was disclosed by the patent applicant during the prosecution of the application leading to the '363 patent, but was not referred to or relied on by the Examiner during the prosecution.

VII. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. §42.22(a))

Petitioner seeks, by this Petition, a final, written decision that challenged claims 1, 2, 14, 44, 47 and 53 of the '363 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. Of the challenged claims, only claim 1 is independent; claims 2, 14, 44, 47 and 53 all ultimately depend from claim 1.

A specific listing of Petitioner's asserted grounds for unpatentability, a comparison of the prior art to the challenged claims, and the supporting testimony from Petitioner's technical expert, Dr. Ochoa, follows below.

In summary, and as established by the declaration of Dr. Ochoa, claims 1, 2, 14, 44, 47 and 53 are unpatentable as obvious under 35 U.S.C. § 103 over the FR'034 application in view of Bray (the '526 publication) (**EX1006 at ¶¶ 30-81**).

VIII. IDENTIFICATION OF GROUNDS FOR UNPATENTABILITY (37C.F.R. § 42.104(b))

This petition presents the following Grounds of unpatentability:

- Ground 1: Claims 1, 2, 14, 44, 47 and 53 are unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (**EX1003**) in view of the '526 publication (**EX1005**).

A. Ground 1: Claims 1, 2, 14, 44, 47 and 53 are unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (EX1003) in view of the '526 publication

The FR'034 application discloses a system for intersomatic fusion and setting of vertebrae. **EX1004 at Abstract**. The system includes at least one open internal cage arranged for receiving spongy bone or bone substitute and is designed to be interposed between two vertebrae during diskectomy. ***Id.* at 1:1-9; FIGs. 1 and 2**. A cage (1, 1A) includes on its anterior face (5, 5A) an external element forming a plate (12, 12A) extending in a plane substantially perpendicular to the insertion plane of the cage, and has at each of its ends an anchor device adapted for anchoring to at least two adjacent vertebrae to be secured to each other by the cage. ***Id.* at 3:11-17 and FIG. 2**. The cage can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. ***Id.* at 3:3-5; 4:8-11**. The characteristics or features taught in the FR'034 application would have been readily identified by a PHOSITA and understood to present one of various design configurations achievable without changing the principle of operation of the spinal implant device. The systems of the invention are preferably made of titanium alloy or an equivalent material. ***Id.* at 6:3-5.** The cage is made of metal or biocompatible plastics. ***Id.* at 2:4-5**.

The cage and plate of the implant device of the FR'034 application possess various characteristics or features that are intrinsic to the geometric configuration

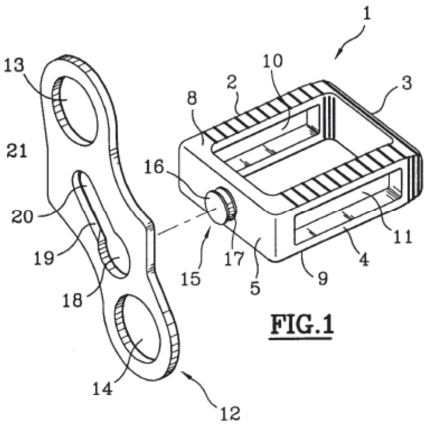
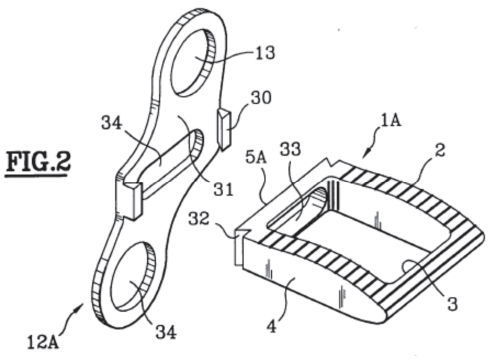
of the device, as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae and the cage (i.e., body), can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 3:3-5; 5:1-3; EX1006 Ochoa Decl. at ¶33.** A PHOSITA would have recognized and understood from the FR'034 application this configuration of the cage as being consistent with a spinal implant that is intended for use to restore a desired anatomical relationship between vertebrae, e.g., the natural lordosis of the lumbar spine. **EX1006 Ochoa Decl. at ¶¶30, 34-35 and 55.**

The '526 publication discloses an interbody fusion device (e.g., a spinal implant device) for use in a spinal fusion surgical procedure that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) in the intervertebral space between a first and second bones (*i.e.*, vertebrae) at an intervertebral joint. ***Id*. at ¶65.** The device is described as a generally oval shaped interbody cage defining a hollow interior for receiving bone graft or bone substitute material that is intended to be placed into the intervertebral space after to fix the spatial relationship of the vertebral bodies to achieve stabilization and/or bone fusion. **EX1004 at 1:5-10; EX1006 Ochoa Decl. at ¶65.**

A PHOSITA would have understood that the spinal implant taught in the

FR'034 application, when considered in combination with the spinal implant taught in the '526 publication, renders obvious claims 1, 2, 14, 44, 47 and 53 of the '363 patent. The claim charts and accompanying analysis, below, evidence this conclusion.

1. Claim 1

'363 patent Claim 1 vs. FR'034 Application and '526 publication
An implantable device for use in association with bones in a patient's body, the implantable device comprising:
The FR'034 application (**EX1003**) discloses: • The FR'034 application discloses a spinal implant device for use in spinal fusion surgical procedures that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1006 Ochoa Decl. at ¶30.** • The system includes at least one open internal cage arranged for receiving spongy bone or bone substitute and is designed to be interposed between two vertebrae during a diskectomy. **EX1004 at 1:1-9** and, *see, e.g.*, **FIGs. 1** and **2**. • The system is made either in the form of an internal cage and an external plate including devices for assembling the plate to the cage (e.g., FIG. 2) or in the form of a single piece cage-and-plate unit (e.g., FIG. 3). ***Id.*** **at 2:9-12.** • The spinal implant device includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1006 Ochoa Decl. at ¶30.**    FIG.1    FIG.2

- The FR'034 application discloses an implantable device (the spinal implant) for use in association with bones (vertebrae) in a patient's body. **EX1006 Ochoa Decl. at ¶35.**

The '526 publication (Bray) (**EX1005**) discloses:

- Bray discloses a spacer (e.g., a spinal implant device) for use in spinal fusion surgical procedures that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1006 Ochoa Decl. at ¶65.**
- Bray discloses an implantable device (the spinal implant) for changing the spatial relationship between first and second bones (vertebrae) in a patient's body. ***Id*. at ¶¶65 and 69.**
- The spacer (spinal implant) is placed on the anterior surface and in the intervertebral space of two adjacent vertebral bodies to thereby fix the spatial relationship of the vertebral bodies to achieve stabilization and/or bone fusion. **EX1005 at 1:5-10**.
- The spacer is designed to be manufactured as a kit with multiple sized spacers and retaining plates present in the kit as well as multiple lordotic, kyphotic and scoliotic spacers. Thus, a surgeon who is performing an anterior fixation surgery can isolate the anterior spine using well known surgical techniques and place an appropriate sized and shaped spacer from the kit into the intervertebral space of two adjacent vertebrae. If the 35 spacer used is too large, too small, or the wrong shape that spacer can be removed and replaced with a spacer of a more appropriate size and shape. ***Id.* at 9:30-36.**
- *See, e.g.,* ***Id.* at FIGs. 1a, 1c**, and **10,** below.

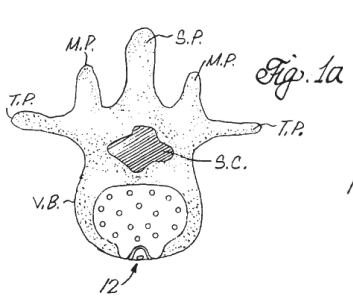


Fig. 1a

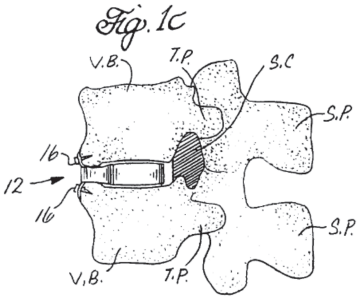


Fig. 1c

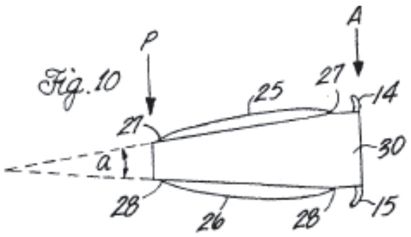


Fig. 10

The FR'034 application discloses a spinal implant device for use in spinal fusion surgical procedures that changes the spatial relationship (*e.g.*, restores a

desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1006 Ochoa Decl. at ¶ 30**. The spinal implant device includes two primary components: a "cage" (i.e., a body) and a "plate" (i.e., a mounting strip). ***Id.***

The preamble of claim 1 merely states the intended use of the invention and does not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction.[5]

To the extent that the preamble limits the claim, a PHOSITA would have recognized that the FR'034 application discloses *an implantable device* (the spinal implant) *for use in association with bones* (vertebrae) *in a patient's body*, as recited in the claims. **EX1006 Ochoa Decl. at ¶ 35**.

The '526 publication discloses an interbody fusion device (e.g., a spinal implant device) for use in a spinal fusion surgical procedure that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) in the intervertebral space between a first and second bones (*i.e.*, vertebrae) at an intervertebral joint. ***Id*. at ¶ 65**. The device is described as a generally oval shaped interbody cage defining a hollow interior for receiving bone graft or bone substitute material that is intended to be placed into the intervertebral space after to fix the spatial relationship of the vertebral bodies to achieve

[5] *Pitney Bowes, Inc. v. Hewlett-Packard Co.,* 182 F.3d 1298, 1305, 51 U.S.P.Q.2d 1161, 1165 (Fed. Cir. 1999); M.P.E.P. § 2111.02.

stabilization and/or bone fusion. **EX1005 at 1:5-10; EX1006 Ochoa Decl. at ¶65.** A PHOSITA would have recognized that the'026 publication discloses *an implantable device* (the spinal implant) *for use in association with bones* (vertebrae) *in a patient's body*, as recited in the claims. **EX1006 Ochoa Decl. at ¶ 65**.

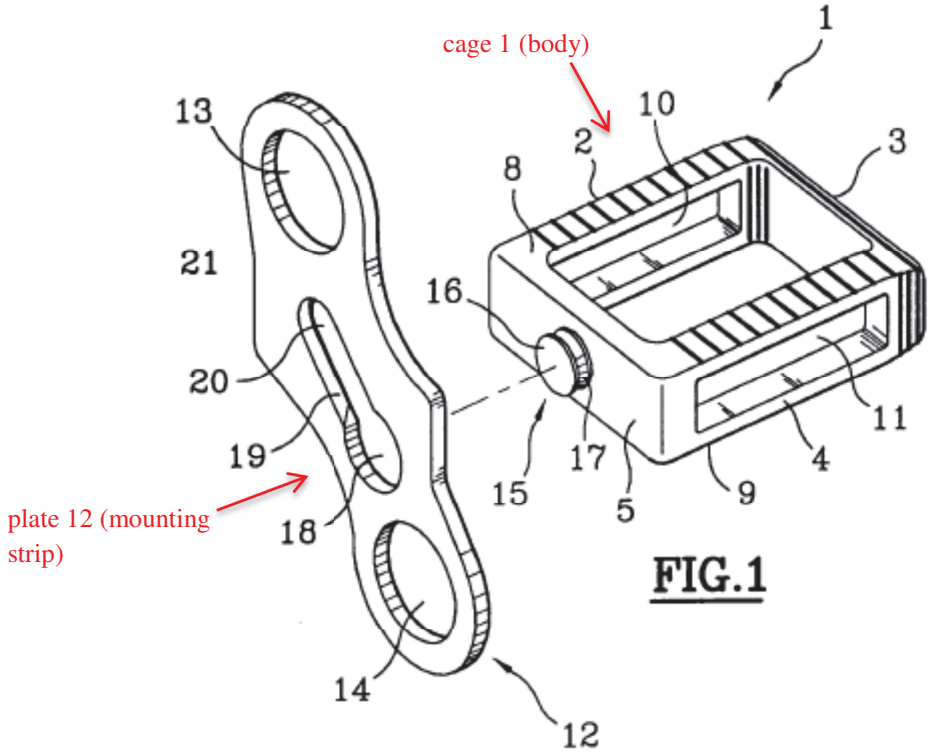
A PHOSITA would have been motivated to look to the teachings of the FR'034 application, the '526 publication, and other prior art disclosing implantable orthopedic devices for use in association with bones in a patient's body (e.g., for changing the spatial relationship of bones in the human body) when considering improvements to the design of such devices. ***Id.*** **at ¶68.**[6]

Further, a PHOSITA would have been motivated to apply the teachings of the '526 publication to those of the FR'034 application because both the FR'034 application and the '526 publication disclose implantable orthopedic devices for use in a spinal fusion surgical procedures that change the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint in a patient. ***Id.*** **at ¶69.**[7]

---

[6] *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 420-21 (2007) (a person of ordinary creativity is not an automaton and in many cases will be able to fit the teachings of multiple patents together like pieces of a puzzle).

[7] *KSR*, 550 U.S. at 417 (if a PHOSITA would recognize that a technique would improve similar devices in the same way, using the technique is obvious).

a body constructed of a polymeric material including
The FR'034 application (**EX1003**) discloses: • The spinal implant device includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1006 Ochoa Decl. at ¶30.** • *See*, *e.g.*, **EX1004 at FIG. 1**, as labeled below.    FIG.1 • The "cage" (body) is made of metal or biocompatible plastics material. ***Id.* at 2:4-5; 6:3-5.** • The FR'034 application discloses a spinal implant having a body constructed of a polymeric material. **EX1006 Ochoa Decl. at ¶34.**

The FR'034 application discloses that the implant device includes a body in the form of a cage (1A) that may be made of biocompatible plastics. **EX1004 at 2:4-5; 6:3-5.** It was well-known in the art at the time of invention to use polymeric materials for constructing spinal implants because such materials have advantages for medical imaging of the fusion mass. **EX1006 Ochoa Decl. at ¶ 36.**

Consequently, a PHOSITA would have understood that the FR'034 application discloses a spinal implant having a body constructed of a polymeric material, as recited in the claims. ***Id.***

a trailing end portion, a leading end portion having a leading end, a first side surface, a second side surface, an upper surface and a lower surface,
The FR'034 application (**EX1003**) discloses: • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**. • The anterior face and posterior face of the cage are of heights that are determined so as to conserve an appropriate intervertebral space. ***Id.*** **at 3:3-5**. • The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae. **EX1006 Ochoa Decl. at ¶33.** • The "cage" (body) is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. ***Id*.** • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. ***Id*. at ¶31.** • *See*, *e.g.,* **EX1004 at FIG. 1**, as labeled below.

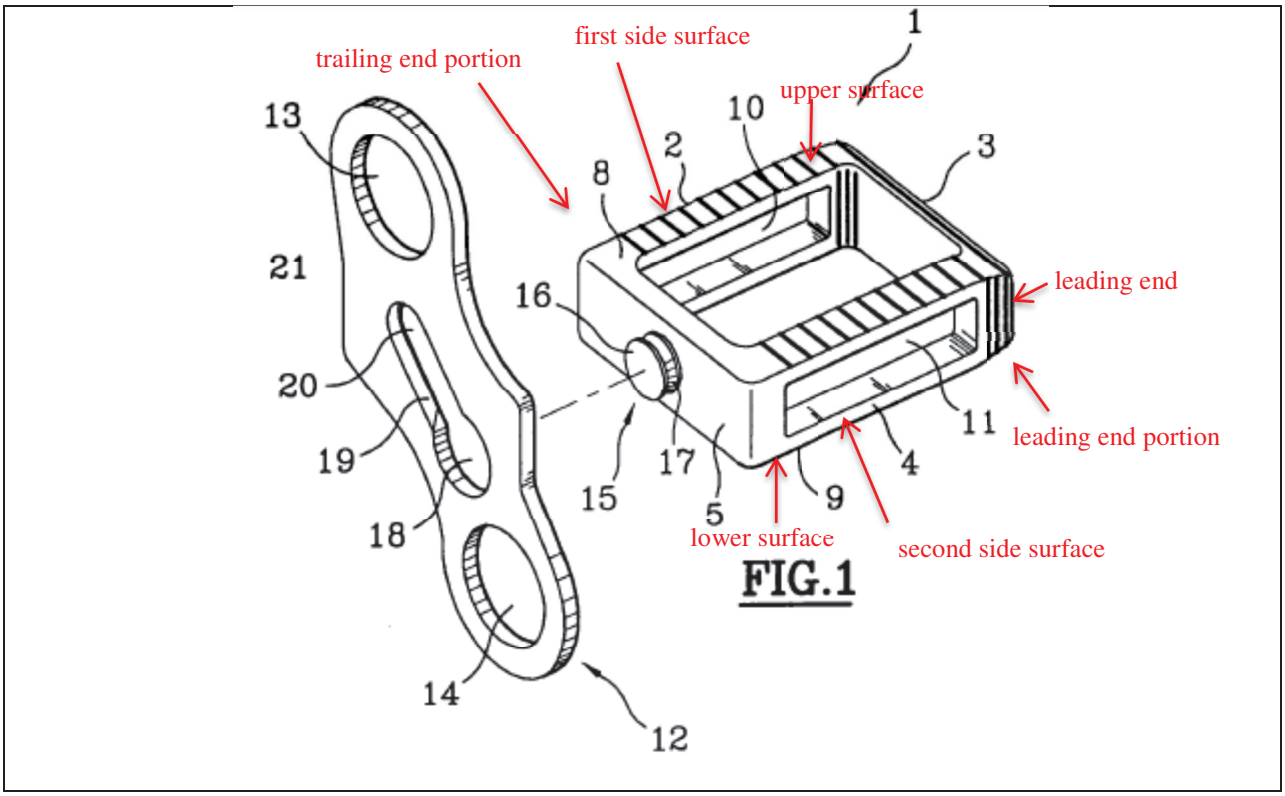


FIG.1

The cage of the implant device of the FR'034 application possesses various characteristics or features that are intrinsic to the geometric configuration of the device, as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae and the cage (i.e., body), can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 3:3-5; 4:8-11; 5:1-3; EX1006 Ochoa Decl. at ¶33.**

A PHOSITA would have understood that the spinal implant disclosed in the FR'034 application would have been suitable for implantation through an anterior approach. **EX1006 Ochoa Decl. at ¶37.** When implanted using an anterior

approach, a PHOSITA would have understood that the posterior face (“ posterior face 3”) would be a leading end located at the leading end portion of the body and the anterior or front face (“anterior face 5”) would be located at the trailing end portion of the of the body. ***Id.*** Therefore, a PHOSITA would have understood that the FR’034 application discloses the body having *a trailing end portion* and *a leading end portion having a leading end*, as recited in the claims. ***Id*.**

A PHOSITA would have also understood that the body of the FR’034 application spinal implant includes opposite side walls (“side walls 2 and 4”) each including a side surface. ***Id.*** **at ¶39.** A PHOSITA would have recognized, then, that the FR’034 application discloses the body having *a first side surface* and *a second side surface,* as recited in the claims. ***Id.***

Further, a PHOSITA would have understood that the body of the spinal implant includes top and bottom faces (“faces 8 and 9”). ***Id.*** **at ¶40.** The top and bottom faces provide the supporting surfaces for the adjacent bone when the body is inserted between two vertebrae. ***Id.*** A PHOSITA would have recognized that the FR’034 application discloses the body having *an upper surface* and *a lower surface,* as recited in the claims. ***Id.***

the body further including a central opening extending through the upper surface and the lower surface,
The FR’034 application (**EX1003**) discloses: • The system includes at least one open internal “cage” (body). **EX1004 at 1:1-9**.

- The "cage" (body) has top and bottom open faces. ***Id.*** **at 2:7-8** and **2:26-3:2**.
- The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.**
- *See, e.g.*, **EX1004 at FIG. 1**, as labeled below.

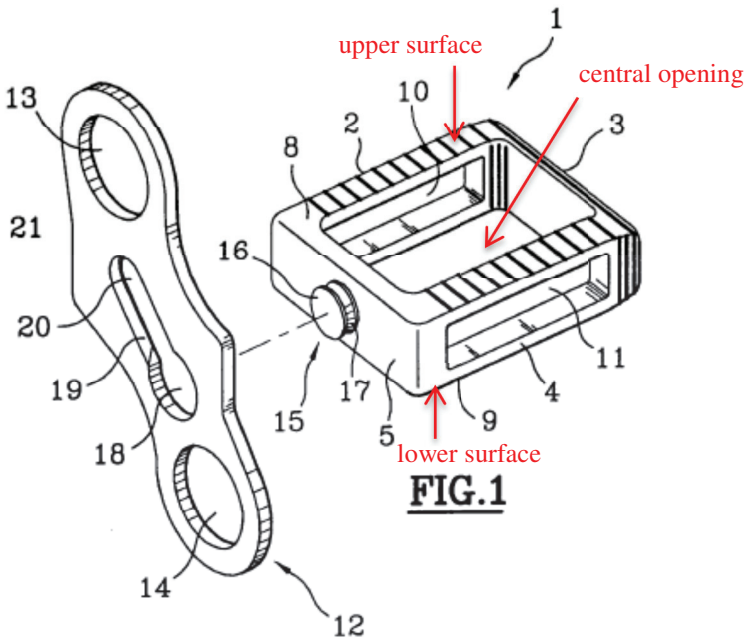


FIG.1

The FR'034 application discloses that the device has an open internal body that is designed to receive graft materials. **EX1004 at 1:1-9, 2:7-8** and **2:26-3:2; EX1006 Ochoa Decl. at ¶57.** The central opening extends vertically through the upper and lower surfaces ("top and bottom faces 8 and 9") and opens towards successive vertebrae. ***Id.*** A PHOSITA would have known and understood that the large, vertical opening would provide the opportunity to incorporate a large volume of graft material within the cage and create a large surface area of contact between the endplate and graft, thus providing an excellent milieu for arthrodesis. **EX1006 Ochoa Decl. at ¶57.** A PHOSITA would have understood that the

FR'034 patent discloses the body *including a central opening formed in the body and extending generally vertically through the upper surface and the lower surface*, as recited in the claims. ***Id.***

the central opening having
an internal surface including an internal leading surface, a first internal side surface and a second internal side surface,
a first depth defined between the leading end and the internal leading surface,
a first spacing defined between the first side surface and the first internal side surface and a second spacing defined between the second side surface and the second internal side surface,
the first spacing being substantially the same as the second spacing and the first depth being less than the first spacing,

The FR'034 application (**EX1003**) discloses:

- The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**.
- The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.**
- *See*, *e.g.,* **EX1004 at FIG. 1**, as labeled below.

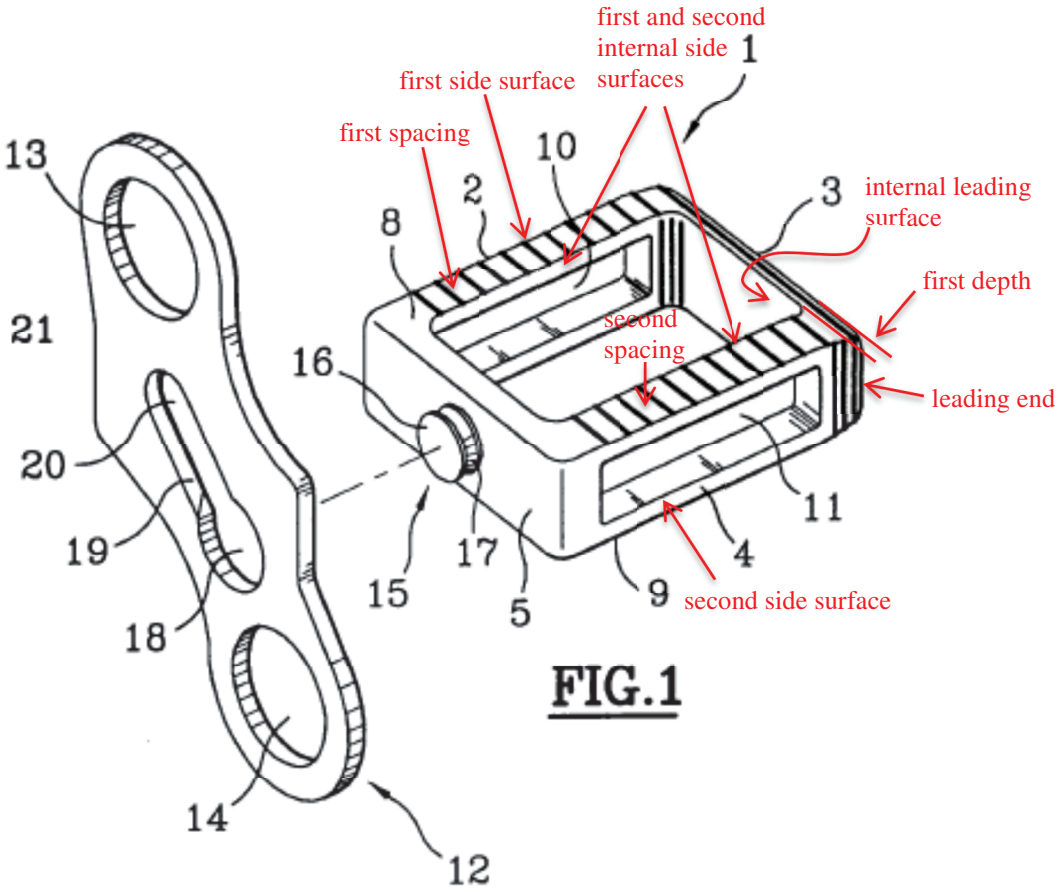


FIG.1

The cage of the implant device of the FR'034 application possesses various characteristics or features that are intrinsic to the geometric configuration of the device, as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** A PHOSITA would have understood that the body ("cage 1") of the FR'034 application spinal implant has an anterior wall, a posterior wall, and side walls that

form a parallelepiped having a generally wedge shape. **EX1004 at 2:4-8, 2:27-3:2, FIG. 1** and **EX1006 Ochoa Decl. at ¶58.** A PHOSITA would have recognized that the graft materials would be held in the central opening defined by the interior surface of each of these walls. **EX1006 Ochoa Decl. at ¶58.** A PHOSITA would, therefore, have understood that the FR'034 application discloses a *central opening having an internal surface including an internal leading surface, a first internal side surface and a second internal side surface,* as recited in the claims. ***Id.***

A PHOSITA would have also understood that the spacings between each of the side surfaces and their respective internal side surfaces would define the widths of each of the side walls of the body. **EX1004 at FIG. 1** and **EX1006 Ochoa Decl. at ¶58.** A PHOSITA would therefore have recognized that the FR'034 application discloses *a first spacing defined between the first side surface and the first internal side surface and a second spacing defined between the second side surface and the second internal side surface,* as recited in the claims. **EX1006 Ochoa Decl. at ¶58.**

Similarly, a PHOSITA would have recognized that the width of the posterior wall would be defined by the distance between the leading end and the internal leading surface. ***Id.*** **at ¶59.** A PHOSITA would, therefore, have understood that the FR'034 application discloses *a first depth defined between the leading end and the internal leading surface,* as recited in the claims. **EX1004 at FIG. 1** and **EX1006 Ochoa Decl. at ¶59.**

A PHOSITA would have understood that the relative dimensions of the cage walls and interior graft chamber of the device of the FR‘034 application may be configured having a variety of different geometries. **EX1004 at 4:8-11** and **EX1006 Ochoa Decl. at ¶60.** It would also have been recognized by a PHOSITA that a preferred approach for implanting the device would be through an anterior approach, and as such the device would be implanted on the center line of the disc space. **EX1006 Ochoa Decl. at ¶60.** Because of the resulting symmetry in placement and loading, a PHOSITA would have understood that the lateral loaded portions of the device would be constructed symmetrically. ***Id.*** Moreover, and while recognizing that the drawings may not be to scale, the relative sizes and proportions observable in the figures of the FR’034 application (e.g., FIG. 1) make clear that the first spacing and second spacing are substantially the same. ***Id.*** Consequently, a PHOSITA would have understood that the FR’034 application discloses *the first spacing being substantially the same as the second spacing,* as recited in the claims. ***Id.*** Moreover, for at least the reasons noted above, *e.g.*, symmetry in placement and loading of the device, a PHOSITA would have considered such a configuration an obvious and preferred design choice. ***Id.***

Understanding that the body (“cage 1”) disclosed in the FR’034 application could have various dimensions in height, width and depth, **EX1004 at 4:8-11** and **EX1006 Ochoa Decl. at ¶61,** a PHOSITA would have recognized there are many

potential configurations for the posterior wall of the cage of the device. ***Id.*** While the claims calls for *the first depth being less than the first spacing,* there is no motivation or benefit of this configuration described in the specification. **EX1006 Ochoa Decl. at ¶61.** It is of note that prior art devices may omit the use of a posterior wall altogether. ***Id.*** Moreover, and while recognizing that the drawings may not be to scale, the relative sizes and proportions observable in the figures of the FR'034 application (*e.g.,* FIG. 1), however, make clear that the distance between the leading end and the internal leading surface is less than the width the side walls (*i.e.,* first and second spacings). ***Id.*** Thus, a PHOSITA would have understood that the FR'034 application discloses *the first depth being less than the first spacing,* as recited in the claims. ***Id.*** Further, a PHOSITA would have considered such a configuration an obvious matter of design choice. ***Id.***

a body width defined between the first side surface and the second side surface and a body length defined between the leading end and a trailing end of the trailing end portion, *the body width being greater than the body length; and*
The FR'034 application (**EX1003**) discloses: • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**. • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** • *See*, *e.g.,* **EX1004 at FIG. 1**, as labeled below.

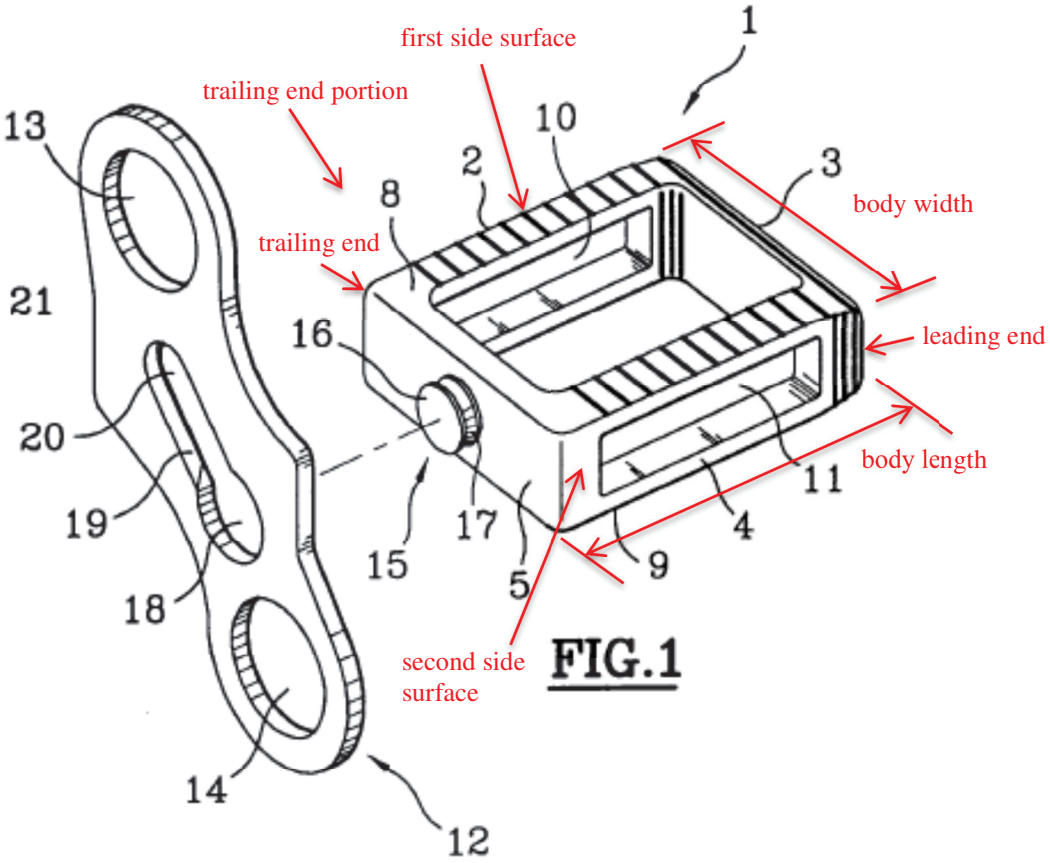


FIG.1

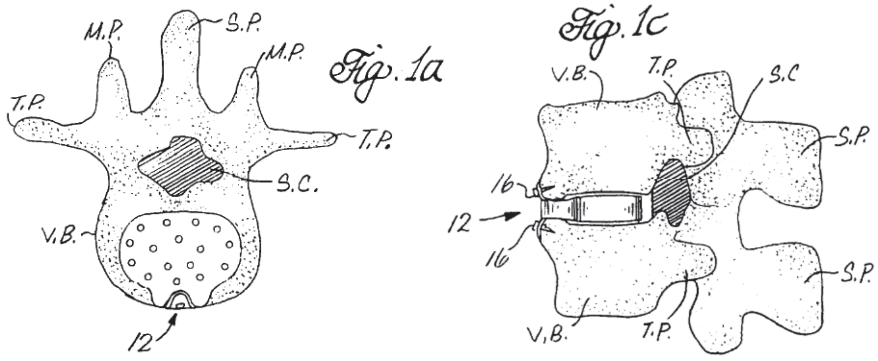
- The width of the body of the device can be greater than the length of the body. **EX1006 Ochoa Decl. at ¶¶44 and 67.**

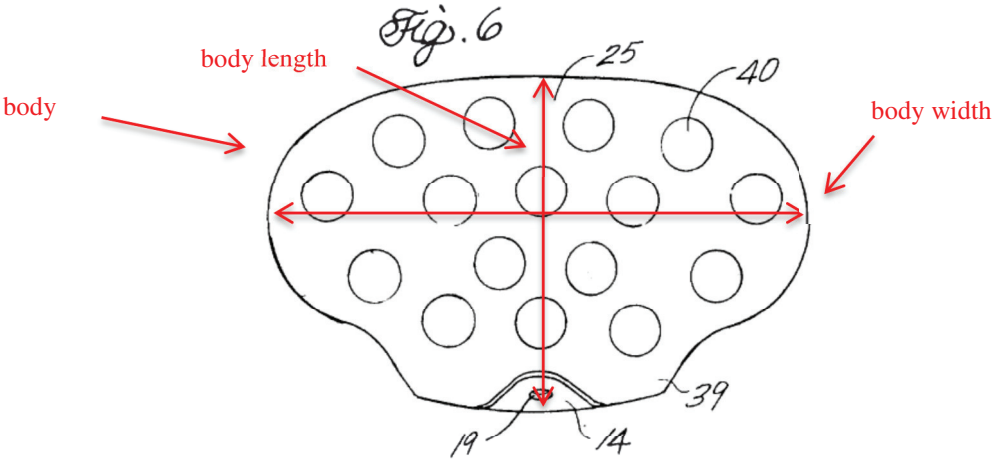
The '526 publication (Bray) (**EX1005**) discloses:

- Bray discloses a spacer (e.g., a spinal implant device) for use in spinal fusion surgical procedures that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1006 Ochoa Decl. at ¶65.**
- Bray discloses an implantable device (the spinal implant) for use in association with bones (vertebrae) in a patient's body. ***Id.***
- The spacer (spinal implant) is placed on the anterior surface and in the intervertebral space of two adjacent vertebral bodies to thereby fix the spatial relationship of the vertebral bodies to achieve stabilization and/or bone fusion. **EX1005 at 1:5-10**.
- The device is sized according to the particular intervertebral disk which it replaces… Spacers designed for lumbar use typically have … a lateral width of from about 26 to 32 mm and an anterior-posterior width [*i.e.*, a

length] of from about 22 to 30 mm. ***Id.*** **at 3:27-36**.

- *See, e.g.,* ***Id.*** **at FIGs. 1a, 1c** and **6**, as labeled below.





- The width of the body of the device is greater than the length of the body. **EX1006 Ochoa Decl. at ¶66.**

The cage of the implant device of the FR'034 application possesses various characteristics or features that are intrinsic to the geometric configuration of the device, as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** A PHOSITA would have understood that the body of the spinal implant of the FR'034 application includes opposite side walls ("side walls 2 and 4") each including a side surface. ***Id.*** **at ¶39.** Additionally, a PHOSITA would have understood that the FR'034 application discloses that the body is a parallelepiped

having a generally wedge shape and could have various dimensions in width and depth. **EX1004 at 2:26-3:2; 4:8-11; EX1006 Ochoa Decl. at ¶38.** Thus, A PHOSITA would have recognized that the FR'034 application discloses that the body has *a body width defined between the first side surface and the second side surface* and *a body length defined between the leading end and a trailing end of the trailing end portion,* as recited in the claims. **EX1006 Ochoa Decl. at ¶41.**

Although the FR'034 application does not expressly disclose that the width of the body is greater than its length, a PHOSITA would have understood from the FR'034 application that the shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae and the cage (i.e., body), can have various dimensions in height, in width, and in depth, and may also be given a preferred anatomical shape. **EX1004 at 3:3-5; 4:8-11; 5:1-3 EX1006 Ochoa Decl. at ¶33.** Thus, a PHOSITA would have understood from the FR'034 application that the width of the body of the spinal implant can be greater than the length of the body. **EX1006 Ochoa Decl. at ¶44.**

It would have also been known to a PHOSITA that the width of a vertebral endplate is greater than its depth (*i.e.,* length). For example, it would have been known to a PHOSITA that in the lumbar spine, the ratio between width and depth ranges from approximately 1.2:1 to 1.5:1. ***Id.*** A PHOSITA would have, therefore, recognized that a cage having a width greater than its depth (i.e., length), would

advantageously optimize the footprint of the cage implanted in the intervertebral space, thus maximizing the available area for bone growth, and loading the stronger peripheral bone of the vertebral endplate while reducing subsidence of the cage. ***Id.*** A PHOSITA would have understood that the resulting shape would be better adapted to the intervertebral space defined by two adjacent vertebrae. ***Id.***

Knowing these benefits, a PHOSITA would have been motivated to design the cage of the implant of the FR'034 application having a width greater than its depth (i.e., length) so that the implant would achieve a preferred anatomical shape that is optimized to the intervertebral space. ***Id.*** **at ¶45.** Moreover, a PHOSITA would have deemed such a consideration as an obvious matter of design choice that would have yielded a predictable and desired effect in the resulting design[8] and would not have changed the principle of operation of the spinal implant of the FR'034 application.[9] ***Id.*** **at ¶46.** A PHOSITA would have understood that the resulting device would have a body having a *body width being greater than the body length,* as recited in the claims. ***Id.*** **at ¶47.**

Further, a PHOSITA would have understood that the device of the '526

[8] *KSR*, 550 U.S. at 416 (the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results).

[9] *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2008) (a claimed invention is likely to be obvious if it is a combination of known prior art elements that would reasonably have been expected to maintain their respective properties or functions after they have been combined).

publication is sized according to the particular intervertebral disc which it replaces. ***Id.*** **at ¶66.** The '526 publication teaches that the vertebral body is generally oval shaped with a weak central area and a stronger outer ring of cortical bone. **EX1005 at 1:5-10; EX1006 Ochoa Decl. at ¶66.** The '526 publication further teaches that use of an oval shaped spacer (i.e. having *body width being greater than the body length*) utilizes the stronger areas of the vertebral body for support. **EX1005 at 5-27-35; EX1006 Ochoa Decl. at ¶66.** For example, preferred widths of 26, 28, 30 and 32 mm and preferred lengths of 22, 24, 26, 28 and 30 mm are recommended for lumbar spacers. ***Id.***

A PHOSITA would have recognized by that the porous superior ("25") and inferior walls of the cage ("26") of the implant device of the '526 publication are analogous to the top and bottom faces ("faces 8 and 9") of the cage of the device of the FR'034 application. **EX1006 Ochoa Decl. at ¶70.** The superior and inferior surfaces of each cage interact with the adjacent vertebral endplates offering both mechanical support and providing open surfaces for bone growth into the enclosed graft material. ***Id.*** Therefore, the applicability and advantages of optimizing the width and length of the cage body to maximize surface area and while interacting with the relatively stronger peripheral bone as taught in the '526 publication would have been readily apparent to a PHOSITA with respect to the device of the FR'034 application. ***Id.***

A PHOSITA, therefore, would have been motivated in view of the combined teachings of the FR'034 application and the '526 publication to configure the interbody cage of the FR'034 application with a *body width being greater than the body length* in order to provide a large surface area for contact with the bone of the endplates while utilizing the relative strong bone of the outer periphery of the endplate for support. ***Id.*** **at ¶71.** A PHOSITA would have considered such a modification an obvious design choice that would have yielded a predictable effect in the resulting design[10] and would not have changed the principle of operation of the spinal implant of the FR'034 application.[11] ***Id.*** **at ¶72.** A PHOSITA would have understood that the product resulting from the combined teachings of the FR'034 application and the '526 publication would have produced a spinal implant wherein the body length and width are configured with the *body width being greater than the body length,* as recited in the claims. ***Id.*** **at ¶73.**

a first mounting strip constructed of a metallic material connected to the trailing end portion, *a first screw hole and a second screw hole extending through the first mounting strip.*
The FR'034 application (**EX1003**) discloses: • The spinal implant device includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1006 Ochoa Decl. at ¶30.** • The cage carries on its anterior face an external strap-forming element ("plate") extending in a plane that is substantially perpendicular to the insertion plane of the cage, on either side thereof, and having at each of its

[10] *See,* footnote 8, *supra.*
[11] *See,* footnote 9, *supra.*

ends anchor devices for anchoring to at least two adjacent vertebrae in order to connect them together via the cage. **EX1004 at 3:11-17**.

- The anchor device for anchoring the plate 12 on the vertebrae, after the cage 1 has been fixed make use of pedicular screws passing through corresponding holes 13 and 14 formed through the ends of the strap 12. ***Id.* at 5:10-15.**
- The systems of the invention are preferably made of titanium alloy or an equivalent material. ***Id.* at 6:3-5**.
- *See*, *e.g.*, ***Id.* at FIG. 1**, as labeled below.

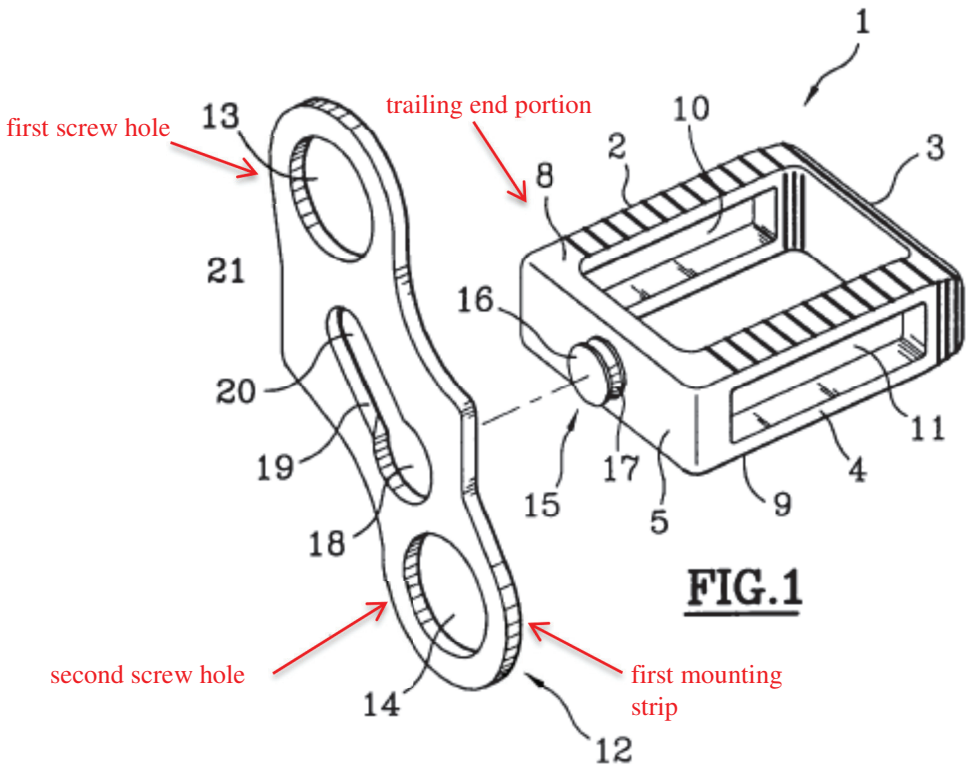


FIG.1

A PHOSITA would have understood that the spinal implant disclosed in the FR'034 application includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1006 Ochoa Decl. at ¶¶30 and 63.** The mounting strip is carried on the anterior face of the body at the trailing end portion and is configured to include screw holes ("fixing holes 13 and 14"). ***Id.* at ¶62** and

EX1004 at 3:11-17 and **5:10-15.**

A PHOSITA would have understood that at the time of invention, a common method for fixing a plate to a bone was through the use of a bone screw. **EX1006 Ochoa Decl. at ¶62.** Further, a PHOSITA would have understood that titanium alloy is a preferred biocompatible metal with favorable mechanical properties for use in orthopedic plates and screws, ***Id.***, and that the FR'034 application expressly discloses that titanium alloy as a preferred material. **EX1004 at 6:3-5.**

Therefore, a PHOSITA would have understood that the FR'034 patent discloses *a first mounting strip constructed of a metallic material connected to the trailing end portion*, and *a first screw hole and a second screw hole extending through the first mounting strip,* as recited in the claims. **EX1006 Ochoa Decl. at ¶62.**

In summary, and as confirmed by Dr. Ochoa, the FR'034 application in view of the '526 publication renders claim 1 unpatentable as obvious under 35 U.S.C. § 103(a).

2. Claim 2

'363 patent Claim 2 vs. FR'034 Application and '526 publication
The implantable device of claim 1, wherein *the trailing end portion defines a first thickness and the leading end portion defines a second thickness,* *the first thickness being greater than the second thickness.*
The FR'034 application (**EX1003**) discloses:

- *See* claim 1, above.
- The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**.
- The anterior face and posterior face of the cage are of heights that are determined so as to conserve an appropriate intervertebral space. ***Id.*** **at 3:3-5**.
- The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae. **EX1006 Ochoa Decl. at ¶33.**
- The "cage" (body) is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. ***Id.***
- The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. ***Id.*** **at ¶31.**
- *See*, *e.g.,* **EX1004 at FIGs. 1** and **2**, as labeled below.

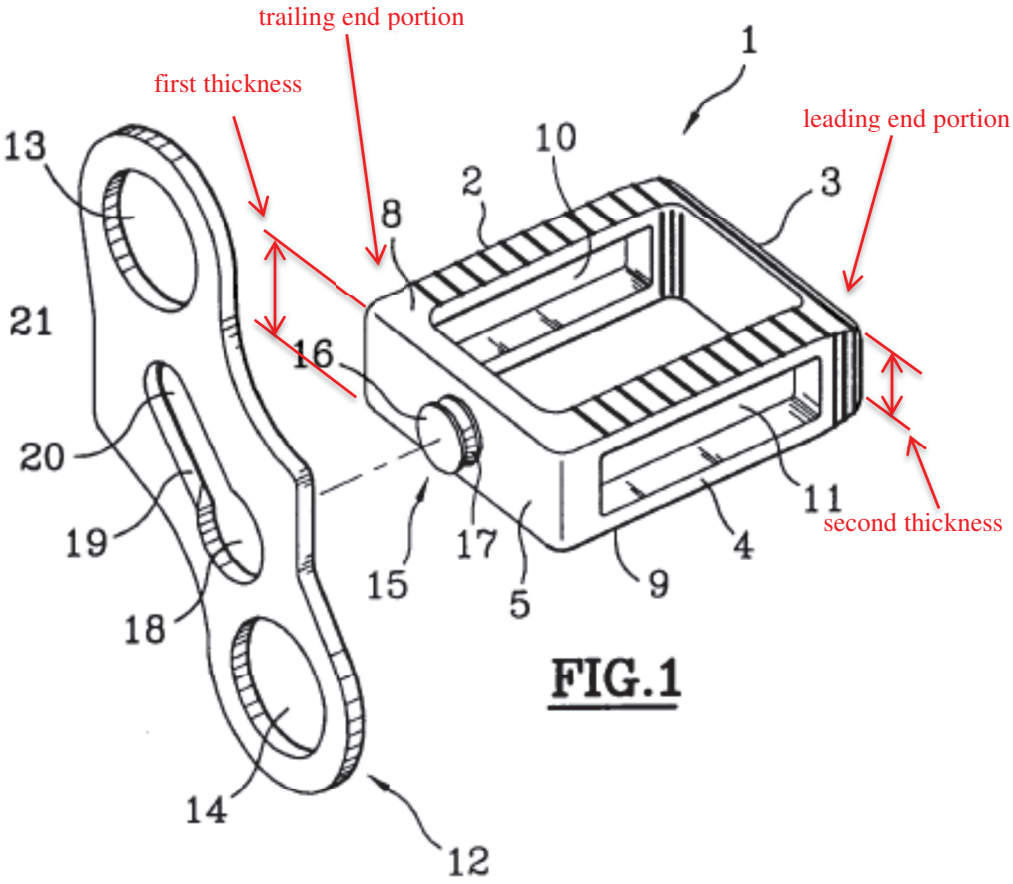
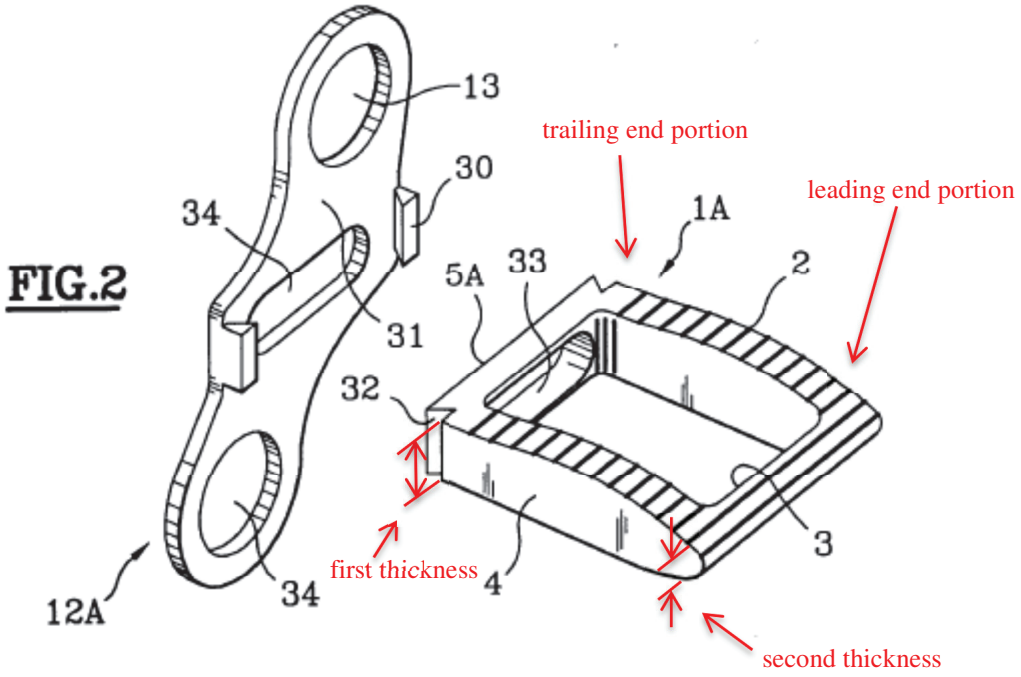
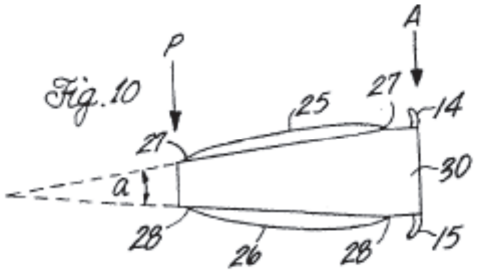


FIG.1



The '526 publication (Bray) (**EX1005**) discloses:

- Bray discloses a spacer (e.g., a spinal implant device) for use in spinal fusion surgical procedures that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1006 Ochoa Decl. at ¶65.**
- The dimensions of the intervertebral spacer vary depending on the intended use of the spacers, having small spacers for the cervical spine, medium spacer for the thoracic spine, and large spacers for the lumbar spine. A spacer 30with a lordotic angle, a, is illustrated in FIG. 10. The lordotic angle extends from a smaller posterior surface, P, to a larger anterior surface, A. The angle, a, can range from about 1° to about 45°. **EX1005 at 8:19-21, 31-36** and **FIG. 10**.



The cage of the implant device of the FR'034 application possesses various characteristics or features that are intrinsic to the geometric configuration of the device, as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae and the cage (i.e., body), can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 3:3-5; 4:8-11; 5:1-3; EX1006 Ochoa Decl. at ¶33.** A PHOSITA would have understood that the FR'034 application discloses that the anterior face and posterior face of the body are of heights that are dimensioned to conserve an appropriate intervertebral space. **EX1006 Ochoa Decl. at ¶¶54-55.**

A PHOSITA would have understood that to achieve the desired fit in the intervertebral space of the lumbar spine and correct for the natural lordotic angle of the vertebral space, the body of the implant would require a thicker anterior or trailing portion and a thinner posterior or leading portion, as is illustrated in the FR'034 application. ***Id.*** **at ¶55.** A PHOSITA would have understood that the FR'034 application discloses that the body has a first thickness at its anterior or trailing end portion and a second thickness at its posterior or leading end portion, the anterior thickness being greater than the posterior thickness. ***Id.*** **at ¶54** and **EX1004 at FIG. 1.** Therefore, a PHOSITA would have understood that the FR'034 application discloses *the trailing end portion defines a first thickness and*

the leading end portion defines a second thickness, the first thickness being greater than the second thickness, as recited in the claims. **EX1006 Ochoa Decl. at ¶54.** Moreover, for at least the reasons noted above, *e.g.*, to achieve the desired fit in the intervertebral space of the lumbar spine and correct for the natural lordotic angle of the vertebral space, a PHOSITA would have considered such a configuration an obvious and preferred design choice. ***Id.***

Further, a PHOSITA would have understood from the '526 publication that the dimensions of the spinal implant may vary depending on its intended use. **EX1005 at 8:19-21; EX1006 Ochoa Decl. at ¶74.** A PHOSITA would have understood that the '526 publication teaches a lordotic spacer with an acute angle of about 1° to about 45° for use in the lumbar spine. **EX1005 at 8:31-36; EX1006 Ochoa Decl. at ¶74.** Further, a PHOSITA would understand that the resulting spacer extends from a smaller (leading) posterior thickness to a larger (trailing) anterior thickness. **EX1006 Ochoa Decl. at ¶74.**

A PHOSITA would have been motivated to look to the teachings of the FR'034 application, the '526 publication, and other prior art disclosing implantable orthopedic devices for use in association with bones in a patient's body (e.g., for changing the spatial relationship of bones in the human body) when considering improvements to the design of such devices. ***Id.*** **at ¶75.** A PHOSITA would have been motivated to apply the teachings of the '526 publication to those of the

FR'034 application because both the FR'034 application and the '526 publication disclose implantable orthopedic devices for use in a spinal fusion surgical procedures that change the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint in a patient. ***Id.* at ¶76.**

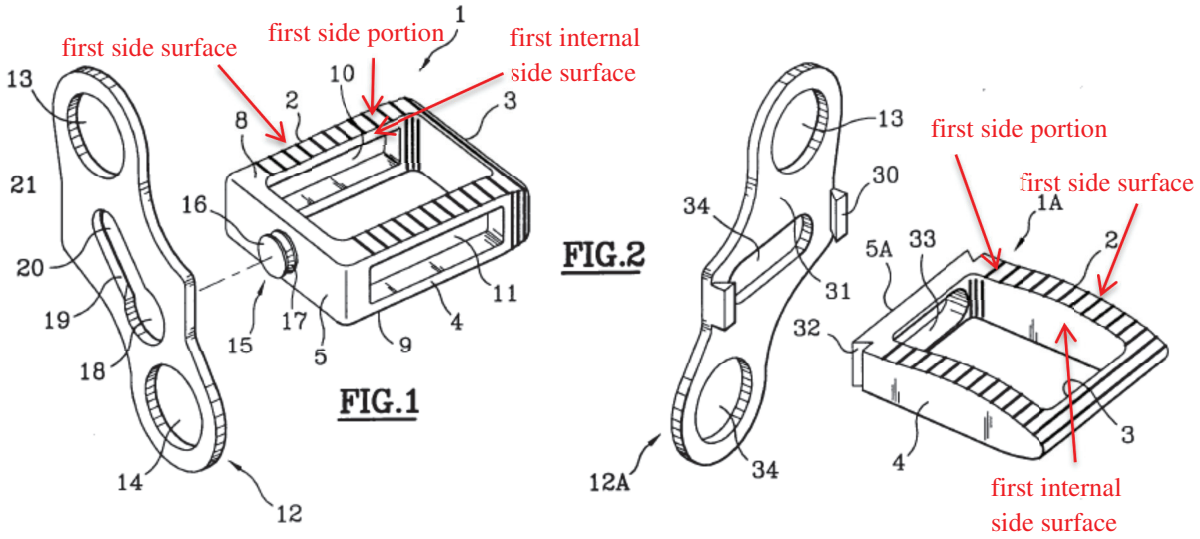
Thus, A PHOSITA would have understood that the product resulting from the combined teachings of the FR'034 application and the '526 publication would have produced a spinal implant *wherein the trailing end portion defines a first thickness and the leading end portion defines a second thickness, the first thickness being greater than the second thickness*, as recited in the claims. ***Id.* at ¶80.**

3. Claim 14

'363 patent Claim 14 vs. FR'034 Application and '526 publication
The implantable device of claim 1, wherein *the body includes a first side portion between the first side surface and the first internal side surface, the first side portion constructed of a solid, continuous polymeric material.*
The FR'034 application (**EX1003**) discloses: • *See* claim 1, above. • The "cage" (body) is made of metal or biocompatible plastics material. **EX1004 at 2:4-5; 6:3-5** and **EX1006 Ochoa Decl. at ¶36.** • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**. • The cage 1A [FIG. 2] does not have the lateral openings as in the cage 1 [FIG. 1]. ***Id.* at 4:22-24**. • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in

the figures. **EX1006 Ochoa Decl. at ¶31.**

- *See*, *e.g.,* **EX1004 at FIGs. 1** and **2**, as labeled below**.**



- The cage (body) of the device includes a first side portion between the first side surface and the first internal side surface. **EX1006 Ochoa Decl. at ¶50.**
- The first side portion of the cage (body) is constructed of a solid, continuous polymeric material. ***Id*.**

The cage of the implant device of the FR'034 application possesses various characteristics or features that are intrinsic to the geometric configuration of the device, as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** A PHOSITA would have understood that the body of the FR'034 application is a parallelepiped having a generally wedge shape and could have various dimensions in width and depth. **EX1004 at 2:26-3:2.** The open cage body is designed to receive graft material via openings in the top and bottom faces, through lateral openings in the side walls ("side walls 2 and 4") and/or through an anterior opening. **EX1006 Ochoa Decl. at ¶48** and **EX1004 at FIGs. 1** and **2.** A PHOSITA

would have recognized that the openings in the upper and lower surfaces were necessary to create a large surface area of contact between the endplate and graft, thus provide an excellent milieu for arthrodesis. **EX1006 Ochoa Decl. at ¶57.** A PHOSITA would have understood that additional openings for packing graft material into the cage would be optional depending on the surgical approach and could include openings or slots in either the lateral walls or the anterior face, as illustrated in Figure 1 and Figure 2. ***Id.*** **at ¶49.**

A PHOSITA would have also understood that the features of the several embodiments of the spinal implant device disclosed in the FR'034 application were readily combinable in different variations. ***Id.*** **at ¶51.** In this regard, for example, features of the cages 1, 1A such as the slots 10, 11 and 33 for providing access for packing graft material in the open internal cage, or the means for attaching the mounting strap 12, 12A to the body, or its shape or profile, could be easily interchanged with one another. ***Id.***

A PHOSITA would have, therefore, recognized that the cage of the embodiment of the device shown in Figure 1 could be adapted to include the dovetail locking mechanism for the mounting strap of the embodiment of the device shown Figure 2. ***Id.*** A PHOSITA would have understood that such a modification would allow bone graft to be placed through an anterior opening in the cage and obviate the need for lateral openings in the side walls. ***Id.*** As a result,

the strength of the side walls of the cage would be increased, while providing improved containment of the graft material within the cage. ***Id.*** A PHOSITA, therefore, would have been motivated to construct the body of the device to include *a first side portion between the first side surface and the first internal side surface, the first side portion constructed of a solid, continuous polymeric material,* as recited in the claims. ***Id.*** **at ¶52.** Moreover, a PHOSITA would have deemed such a modification as an obvious matter of design choice that would have yielded a predictable and desired effect in the resulting design.[12] ***Id.*** **at ¶53.**

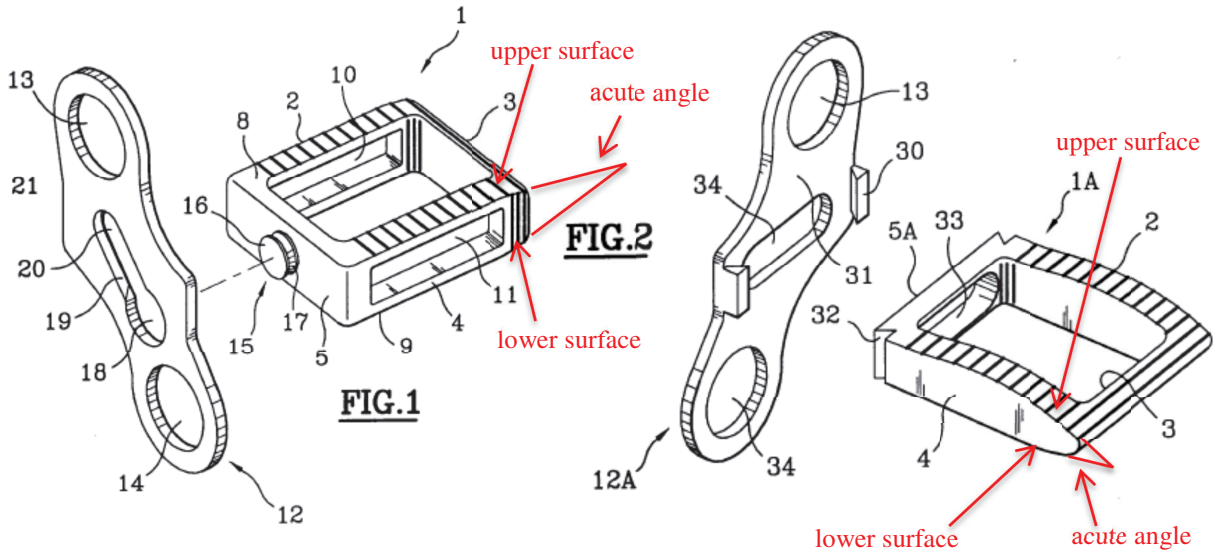
4. Claim 44

'363 patent Claim 44 vs. FR'034 Application and '526 publication
The implantable device of claim 1, wherein the upper and lower surfaces define an acute angle.
The FR'034 application (**EX1003**) discloses: • *See* claim 1, above. • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**. • The anterior face and posterior face of the cage are of heights that are determined so as to conserve an appropriate intervertebral space. ***Id.*** **at 3:3-5**. • The profile and shape of the cage 1A of FIG. 2 enable the overall device to fit perfectly in the intervertebral space. ***Id.*** **at 5:1-3.** • The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae. **EX1006 Ochoa Decl. at ¶33.** • The "cage" (body) is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. ***Id*.** • The "cage" (body) possesses various characteristics or features that are

[12] *See* footnote 8, *supra*.

intrinsic to the geometric configuration of the device as clearly illustrated in the figures. ***Id*. at ¶31.**

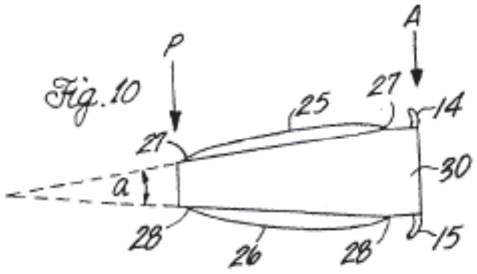
- *See*, *e.g.,* **EX1004 at FIGs. 1** and **2**, as labeled below.



- The device has an acute angle between the upper and lower surfaces of the body. **EX1006 Ochoa Decl. at ¶56.**

The '526 publication (Bray) (**EX1005**) discloses:

- Bray discloses a spacer (e.g., a spinal implant device) for use in spinal fusion surgical procedures that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1006 Ochoa Decl. at ¶65.**
- The dimensions of the intervertebral spacer vary depending on the intended use of the spacers, having small spacers for the cervical spine, medium spacer for the thoracic spine, and large spacers for the lumbar spine. A spacer 30with a lordotic angle, a, is illustrated in FIG. 10. The lordotic angle extends from a smaller posterior surface, P, to a larger anterior surface, A. The angle, a, can range from about 1° to about 45°. **EX1005 at 8:19-21, 31-36** and **FIG. 10**.



The cage of the implant device of the FR'034 application possesses various characteristics or features that are intrinsic to the geometric configuration of the device, as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae and the cage (i.e., body), can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 3:3-5; 4:8-11; 5:1-3; EX1006 Ochoa Decl. at ¶33.** A PHOSITA would have understood that the FR'034 application discloses that the anterior face and posterior face of the body are of heights that are dimensioned to conserve an appropriate intervertebral space. **EX1006 Ochoa Decl. at ¶¶54-55.**

A PHOSITA would have understood that to achieve the desired fit in the intervertebral space of the lumbar spine and correct for the natural lordotic angle of the vertebral space, the body of the implant would require a thicker anterior or trailing portion and a thinner posterior or leading portion, as is illustrated in FIGs. 1 and 2 the FR'034 application. ***Id.*** **at ¶55; EX1004 at FIGs. 1** and **2.**

It had been documented, and would have been known to a PHOSITA at the time of invention that the average angle of the intervertebral disc space varies between approximately 5 and 15 degrees in the lumbar spine. **EX1006 Ochoa Decl. at ¶56.** Although a specific angle is not disclosed in the FR'034 application, a PHOSITA would have nevertheless understood from the entirety of the

disclosure of the FR'034 application that the angle between the top and bottom faces ("faces 8 and 9") would vary between approximately 5 and 15 degrees in order to fit within and conserve an appropriate intervertebral space in the lumbar spine (i.e. restore lumbar lordosis).[13] ***Id.*** Moreover, and while recognizing that the drawings may not be to scale, the relative sizes and proportions observable in the figures of the FR'034 application (e.g., Figures 1 and 2) make clear that the upper and lower surfaces are configured to define an acute angle at the leading end. ***Id.*** A PHOSITA would understand that this acute angle at the leading end would also have the benefit of easing insertion of the device into the intervertebral space. ***Id.*** Therefore, a PHOSITA would have understood that the FR'034 application discloses upper and lower surfaces that are configured to *define an acute angle,* as recited in the claims. ***Id.*** Moreover, for at least the reasons noted above, *e.g.*, conserve an appropriate intervertebral space in the lumbar spine, a PHOSITA would have considered such a configuration an obvious and preferred design choice. ***Id.***

Further, a PHOSITA would have understood from the '526 publication that the dimensions of the spinal implant may vary depending on its intended use. **EX1005 at 8:19-21; EX1006 Ochoa Decl. at ¶74.** The applicability and advantages of supplying appropriately sized and shaped spacers, including lordotic

[13] FR'034 Application, 3:3-5, 5:1-3.

and kyphotic spacers as taught in '526 publication would have been readily apparent to a PHOSITA with respect to the device of the FR'034 application. ***Id.*** **at ¶77.** When implanted using an anterior approach, a PHOSITA would have understood that achieving the desired fit in the intervertebral space of the lumbar spine would require the body of the implant to have a thicker anterior (trailing) portion and a thinner posterior (leading) portion. ***Id.*** **at ¶78.**

It would have been recognized by a PHOSITA that the superior (25) and inferior (26) walls of the spacer in the '526 publication are analogous to the top and bottom faces ("faces 8 and 9") of the cage of the FR'034 application. ***Id.*** **at ¶77.** The superior and inferior surfaces of each cage interact with the adjacent vertebral endplates offering both mechanical support and providing open surfaces for bone growth into the enclosed graft material. ***Id.***

As mentioned, it had been documented, and would have been known to a PHOSITA at the time of invention that the average angle of the intervertebral disc space varies between approximately 5 and 15 degrees in the lumbar spine. ***Id.*** **at ¶78.** A PHOSITA would have understood that the '526 publication teaches a lordotic spacer with an acute angle of about 1° to about 45° for use in the lumbar spine. **EX1005 at 8:31-36** and **FIG. 10; EX1006 Ochoa Decl. at ¶74.**

A PHOSITA would have been motivated to look to the teachings of the FR'034 application, the '526 publication, and other prior art disclosing implantable

orthopedic devices for use in association with bones in a patient's body (e.g., for changing the spatial relationship of bones in the human body) when considering improvements to the design of such devices. **EX1006 Ochoa Decl. at ¶75.** A PHOSITA would have been motivated to apply the teachings of the '526 publication to those of the FR'034 application because both the FR'034 application and the '526 publication disclose implantable orthopedic devices for use in a spinal fusion surgical procedures that change the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint in a patient. ***Id.*** **at ¶76.**

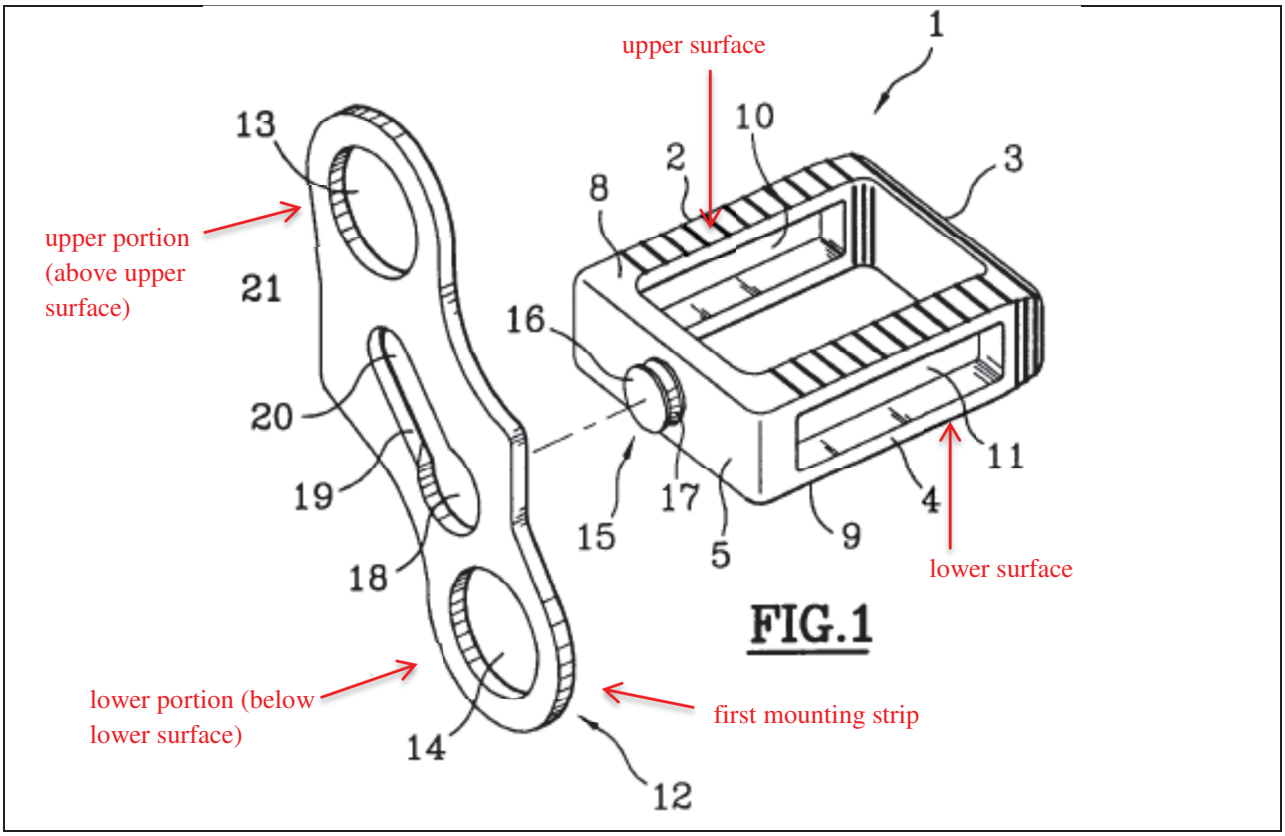
A PHOSITA, therefore, would have been motivated in view of the combined teachings of the FR'034 application and the '526 publication to configure the interbody cage of the FR'034 application as a lordotic cage *wherein the upper and lower surfaces define an acute angle* in order to correct for the natural lordotic angle of the intervertebral space. ***Id.*** **at ¶78.** A PHOSITA would have considered such a modification an obvious design choice that would have yielded a predictable effect in the resulting design[14] and would not have changed the principle of operation of the spinal implant FR'034 application.[15] ***Id.*** **at ¶79.** A PHOSITA would have understood that the product resulting from the combined teachings of the FR'034 application and the '526 publication would have produced

[14] *See* footnote 8, *supra.*
[15] *See* footnote 9, *supra.*

a spinal implant *wherein the upper and lower surfaces define an acute angle*, as recited in the claims. ***Id.*** **at ¶80.**

5. Claim 47

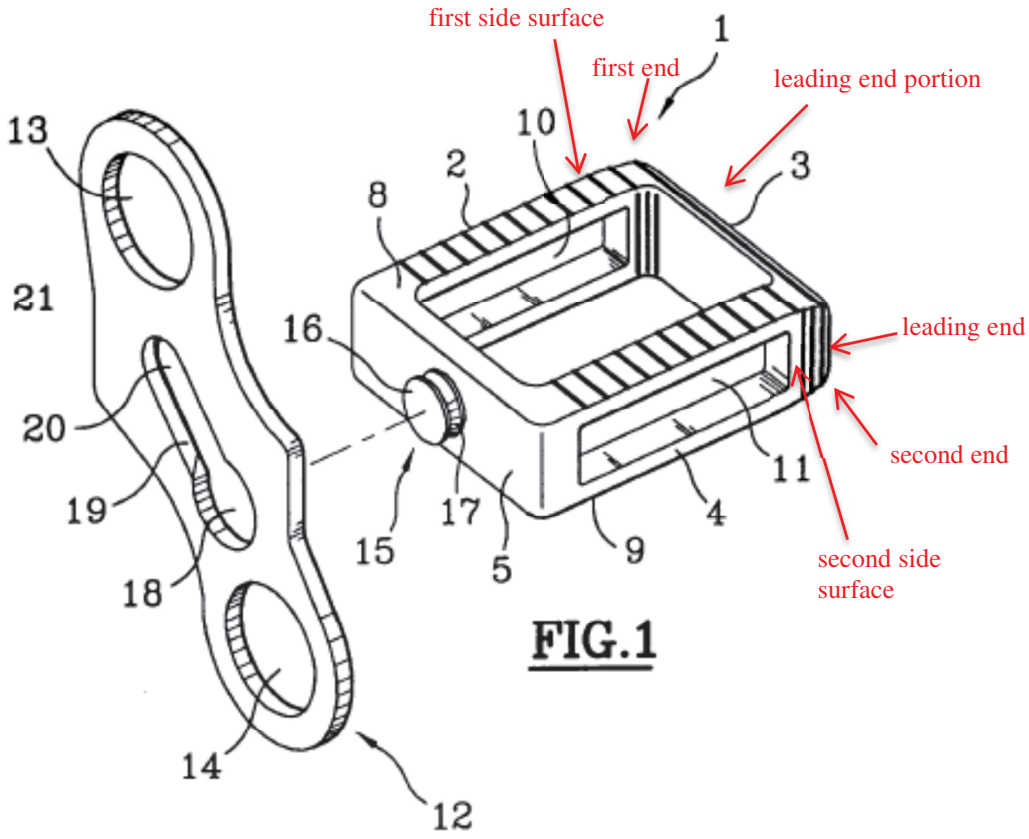
'363 patent Claim 47 vs. FR'034 Application and '526 publication
The implantable device of claim 1, wherein the first mounting strip includes an upper portion extending above the upper surface and a lower portion extending below the lower surface in a mounted configuration.
The FR'034 application (**EX1003**) discloses: • *See* claim 1, above. • The spinal implant device includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1006 Ochoa Decl. at ¶63.** • The cage carries on its anterior face an external strap-forming element ("plate") extending in a plane that is substantially perpendicular to the insertion plane of the cage, on either side thereof, and having at each of its ends anchor devices for anchoring to at least two adjacent vertebrae in order to connect them together via the cage. **EX1004 at 3:11-17**. • *See*, *e.g.,* ***Id.*** **at FIG. 1**, as labeled below.

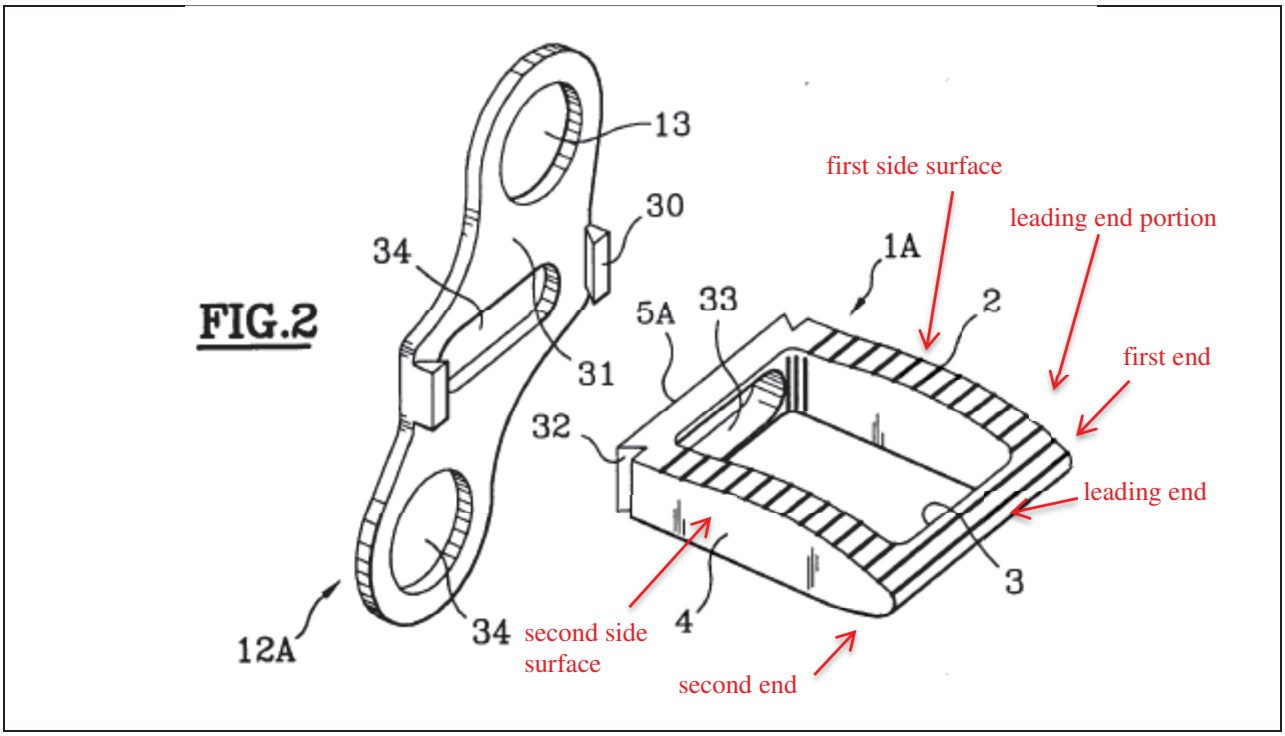


A PHOSITA would have understood that the spinal implant disclosed in the FR'034 application includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1006 Ochoa Decl. at ¶¶30 and 63.** A PHOSITA would have understood that the plate 12 disclosed in the FR'034 application extends upwards and downwards from the cage for anchoring to the cephalad (upper) and caudal (lower) vertebrae. **EX1004 at 3:11-17** and **FIG. 1; EX1006 Ochoa Decl. at ¶63.** Therefore, a PHOSITA would have understood that the FR'034 application discloses that the *mounting strip includes an upper portion extending above the upper surface and a lower portion extending below the lower surface in a mounted configuration,* as recited in the claims. **EX1006 Ochoa Decl.**

at ¶63.

6. Claim 53

'363 patent Claim 53 vs. FR'034 Application and '526 publication
The implantable device of claim 1, wherein the first side surface connects to the leading end at a first opposite end and the second side surface connects to the leading end at a second opposite end, the leading end portion being generally straight between the first and second opposite ends.
The FR'034 application (**EX1003**) discloses: • *See* claim 1, above. • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** • *See*, *e.g.,* **EX1004 at FIGs. 1** and **2**, as labeled below.    **FIG.1**



The cage of the implant device of the FR'034 application possesses various characteristics or features that are intrinsic to the geometric configuration of the device, as clearly illustrated in the figures. **EX1006 Ochoa Decl. at ¶31.** A PHOSITA would have understood that the body of the FR'034 application spinal implant has an anterior wall, a posterior wall, and side walls that form a parallelepiped having a generally wedge shape. **EX1004 at 2:4-8, 2:27-3:2, FIGs. 1** and **2; EX1006 Ochoa Decl. at ¶58.** A PHOSITA would have recognized that the graft materials would be held in the central opening defined by the interior surface of each of these walls. ***Id.*** A PHOSITA would, therefore, have understood that the FR'034 application discloses *the first side surface connects to the leading end at a first opposite end* and *the second side surface connects to the leading end*

at a second opposite end, as recited in the claims. ***Id.*** **at ¶42.**

Further, a PHOSITA would have understood that the leading end ("posterior face 3") of the body ("cage 1") of the FR'034 application spinal implant is generally straight from one end to the other. ***Id.*** **at ¶43.** Thus, a PHOSITA would have recognized that the FR'034 application discloses a *leading end portion being generally straight between the first and second opposite ends,* as recited in the claims. ***Id.***

In summary, and as confirmed by Dr. Ochoa, claims 1, 2, 14, 44, 47 and 53 are unpatentable as obvious under 35 U.S.C. § 103(a) over the FR'034 application in view of the '526 publication.

IX. CONCLUSION

Petitioner has demonstrated in this Petition that claims 1, 2, 14, 44, 47 and 53 of the '363 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '363 patent.

Dated: June 4, 2015

By: / George D. Moustakas /

George D. Moustakas, Reg. No. 44,425
(gdmoustakas@hdp.com)
David P. Utykanski, Reg. No. 39,052
(dutykanski@hdp.com)
Harness, Dickey & Pierce, PLC
5445 Corporate Dr., Suite 200
Troy, MI 48098
Telephone: (248) 641-1600
Facsimile: (248) 641-0270

Attorneys for Petitioner,
Globus Medical, Inc.

CERTIFICATION OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, this is to certify that I caused a true and correct copy of the PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,795,363 (and accompanying Exhibits **EX1001-EX1022**) to be served via FedEx, next day delivery, on patent owner at the following correspondence address of record for the subject patent, on this 4th day of June, 2015:

Panitch Schwarz Belisario & Nadel LLP
One Commerce Square
2005 Market Street, Suite 2200
Philadelphia, PA 19103

A copy of this Petition and the associated Exhibits was also served via FedEx, next day delivery, on lead counsel of record in the related action in the United States District Court for the Eastern District of Pennsylvania:

John M. Desmarais
Laurie Stempler
Kevin K. McNish
Desmarais LLP
230 Park Avenue
New York, NY 10169

By: / George D. Moustakas /

George D. Moustakas, Reg. No. 44,425
(gdmoustakas@hdp.com)
David P. Utykanski, Reg. No. 39,052
(dutykanski@hdp.com)
Harness, Dickey & Pierce, PLC
5445 Corporate Dr., Suite 200
Troy, MI 48098
Telephone: (248) 641-1600;
Fax: (248) 641-0270

Attorneys for Petitioner,
Globus Medical, Inc.