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. 8,486,066
Issued: July 16, 2013
Application No: 10/438,705
Filed: May 15, 2003

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EX1024 Claim Chart – Claims 1, 2, 3, 8, 13, and 18 vs. French Patent Application No. 2,747,034; Claims 9 and 10 vs. FR '034 and U.S. Patent No. 5,669,909; and Claims 16 and 17 vs. FR '034 and U.S. Patent No. 5,397,364

EX1025 *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, 3, 8, 9, 10, 13, 16, 17 and 18 ("the challenged claims") of U.S. Patent No. 8,486,066, entitled "Spacer" ("the '066 patent"), issued to Peter M. Bonutti and assigned to Bonutti Skeletal Innovations LLC ("Bonutti"). The '066 patent is attached as **EX1001.**

The invention of the '066 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 '066 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, 3, 8, 9, 10, 13, 16, 17 and 18 of the '066 patent is 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. **EX1009.**[1] Dr. Ochoa is an expert with over 25 years of experience in the area of design and development of orthopedic medical devices, surgical instruments and

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

techniques, as well as biomechanics, and engineering biomaterials. Dr. Ochoa's declaration establishes that each of the challenged claims is 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, 3, 8, 9, 10, 13, 16, 17 and 18 of the '066 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))

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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 '066 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 '066 patent. *See* **EX1025.**

Concurrently with this petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 8,795,363 ("the '363 patent"). The '363 patent is related to the '066 patent through continuation practice, and claims subject matter nearly identical to the '066 patent. Petitioner understands that the '066 patent and the '363 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 '066 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 '066 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. 8,486,066 ("THE '066 PATENT") (EX1001)

The '066 patent issued on July 16, 2013, on an application filed on May 15, 2003. The '066 patent is a continuation of U.S. Application Serial No. 09/566,070, filed May 5, 2000 issued as U.S. Patent No. 6,575,982, which is a continuation of

U.S. Application Serial No. 09/109,126, filed June 30, 1998, issued as U.S. Patent No. 6,086,593. Thus, the earliest priority date for the '066 patent is June 30, 1998.

A. The '066 Patent Specification and Claims

The '066 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 spatial 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 '066 patent issued with 32 claims, of which only claims 1-3, 8-10, 13 and 16- 18 are at issue in this Petition. Claim 1 is independent, and each of claims 2, 3, 8-10, 13 and 16-18 is dependent either directly or indirectly from claim 1.

The written description and drawings of the '066 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**.

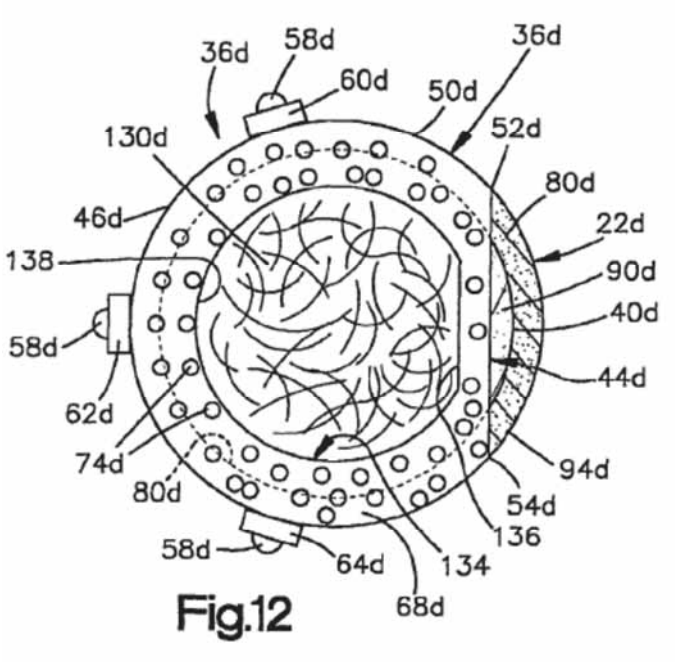


Fig.12

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 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

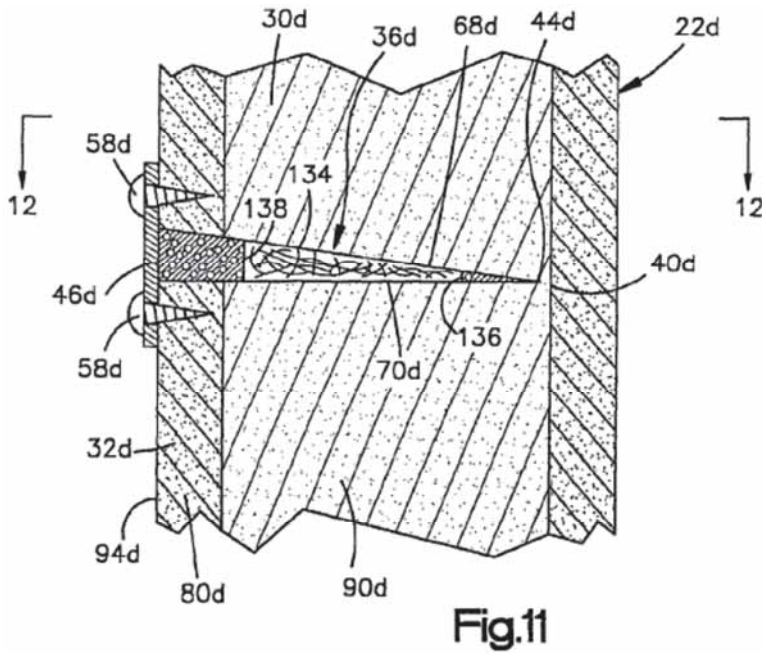


Fig.11

of the bone 22d. ***Id.*** **at 15:19-21**.

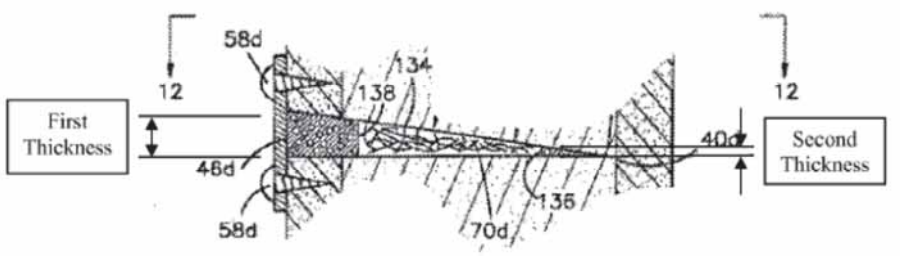
B. The '066 Patent Prosecution History (EX1002)

The continuation application leading to the '066 patent, Serial No. 10/438,705, was filed on May 15, 2003. The prosecution of the application before the U.S. Patent and Trademark Office for the application leading to the '066 patent spanned more than 10 years in which 9 Office Actions were issued, 1 Appeal was filed, 3 Requests for Continued Examination (RCEs) were filed, and multiple Examiner interviews were conducted.

More than nine years into prosecution and after the third RCE, the applicant filed an Amendment in response to a non-final Office Action on December 13, 2012 (hereafter, "the Amendment") (**EX1003**). In the Amendment, the applicant cancelled all of the pending claims and added an entirely new claim set having claims 54-89. ***Id.***

In the Amendment, the applicant conceded that words and phrases found in the new claims 54-89 were not recited in the originally filed specifications of any of the family applications, but that one of ordinary skill in the art, upon reading the entirety of the originally-filed specifications and drawings, would understand that the applicant was in possession of the apparatus assembly and structure recited in the new claims 54-89**.** ***Id.*** **at 7-8**. The applicant then identified the limitations of

the new claims by overlaying them onto FIGs. 11 and 12 of the '066 patent, *e.g.*, as shown at left. ***Id.*** **at 9, 11, 12 and 14**.



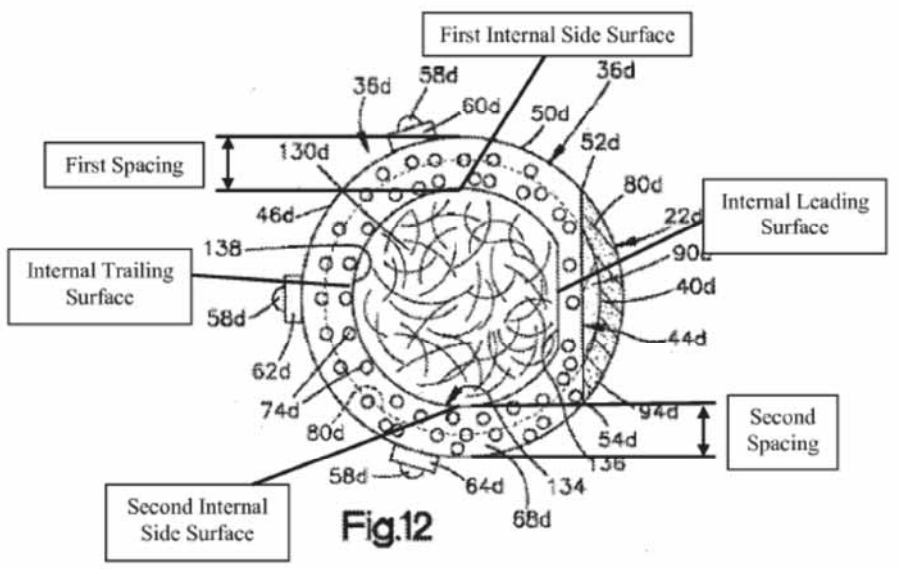


Fig.12

Further, in the Amendment the applicant also stated that the addition of the metallic mounting strip and the polymeric body overcame the anticipation rejections based on the cited references Henderson (U.S. Patent no. 6,066,175) and Koshino (U.S. Patent no. 5,766,251).

After an April 25, 2013 interview, an Examiner's amendment to the independent claims was made adding the limitations of "a thin end portion defining a thin end axis that extends between opposite ends" and "the internal leading surface including a substantially linear portion extending substantially parallel to the thin end axis between a first and a second end, the internal leading surface defining an internal leading height that is substantially constant between the first end and the second end." *See,* Applicant-Initiated Interview Summary dated April

25, 2013 (**EX1004**). The ‘066 patent was thereafter allowed.

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

As established in the Declaration of Dr. Ochoa (**EX1009** at ¶ xx), a person having ordinary skill in the art (PHOSITA) of the ‘066 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 ‘066 patent are to be given their broadest reasonable construction in light of the ‘066 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 '066 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") (EX1005)[2]

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 '066 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 '066 patent.

B. U.S. Patent No. 5,669,909 to Zdeblick et al. ("the '909 patent" or "Zdeblick") (EX1007)

U.S. Patent No. 5,669,909 to Zdeblick et al., entitled "Interbody Fusion Device and Method for Restoration of Normal Spinal Anatomy," issued September 23, 1997 on an application filed March 30, 1995. Zdeblick is prior art to the '066 patent under 35 U.S.C. § 102(e)(2) because it is a patent granted on an application for patent by another filed in the United States before the invention by the

[2]An English translation of the specification of the FR'034 application is attached as **EX1006**.

applicant of the ‘066 patent. Zdeblick was disclosed by the applicant to the Patent Office during the prosecution of the application leading to the ‘066 patent, but was not referred to or relied on by the Examiner during the prosecution.

C. U.S. Patent No. 5,397,364 to Kozak et al. (“the ‘364 patent” or “Kozak”) (EX1008)

U.S. Patent No. 5,397,364 to Kozak et al., entitled “Anterior Interbody Fusion Device,” issued March 14, 1995. Kozak is prior art to the ‘066 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 ‘066 patent in the United States. Kozak was disclosed by the applicant to the Patent Office during the prosecution of the application leading to the ‘066 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, 3, 8, 9, 10, 13, 16, 17 and 18 of the ‘066 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. Of the challenged claims, only claim 1 is independent; claims 2, 3, 8, 9, 10, 13, 16, 17 and 18 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, the FR'034 application renders claims 1, 2, 3, 8, 13and 18 unpatentable as obvious under 35 U.S.C. § 103 (**EX1009 at ¶¶ 30- 58**); claims 9 and 10 are unpatentable as obvious under 35 U.S.C. § 103 over the FR'034 application in view of Zdeblick (***Id.* at ¶¶ 59- 70**); and claims 16 and 17 are unpatentable as obvious under 35 U.S.C. § 103 over the FR'034 application in view of Kozak (***Id.* at ¶¶ 71-83**).

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, 3, 8, 13 and 18 are unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (**EX1005**).
- Ground 2: Claims 9 and 10 are unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (**EX1005**) in view of Zdeblick (**EX1007**).
- Ground 3: Claims 16 and 17 are unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (**EX1005**) in view of Kozak (**EX1008**).

A. Ground 1: Claims 1, 2, 3, 8, 13 and 18 are unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (EX1005).

The FR'034 application discloses a system for intersomatic fusion and setting of vertebrae. **EX1006 at Abstract**. The system includes at least one open internal cage arranged for receiving spongy bone or bone substitute and is designed

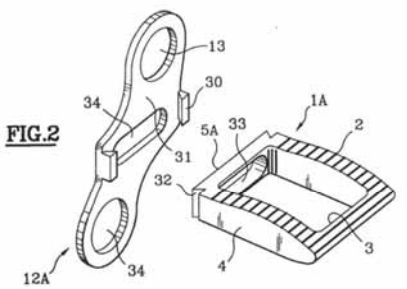
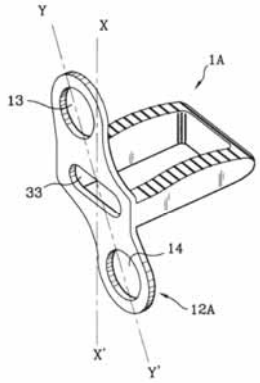
to be interposed between two vertebrae during diskectomy. ***Id.* at 1:1-9; FIGs. 1 and 2**. A cage (1, 1A) includes on its anterior face (5, 5A) an external element forming a plate (12, 12A) extending in a plane substantially perpendicular to the insertion plane of the cage, and has at each of its ends 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 implant of the FR'034 patent. **EX1009 at ¶32.**

The systems of the invention are preferably made of titanium alloy or an equivalent material. **EX1006 at 6:3-5.** The cage is made of metal or biocompatible plastics. ***Id.* at 2:4-5**.

A PHOSITA would have understood that the spinal implant for use during spinal fusion including a cage (*i.e.,* a body) having an internal opening that can be packed with bone graft and a plate that is used to secure fixation of the cage to the adjacent vertebral bodies taught in the FR'034 application renders obvious claims 1, 2, 3, 8, 13 and 18 of the '066 patent. The claim charts and accompanying analysis, below, evidence this conclusion.

1. Claim 1

Claim 1 is directed to an apparatus for use in association with bones in a patient. Claim 1 is obvious over the FR'034 application, as follows:

'066 patent Claim 1 vs. FR'034 Application
An apparatus assembly for use in association with bones in a patient's body, the apparatus assembly comprising:
The FR'034 application (**EX1005**) 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. **EX1009 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. **EX1006 at 1:1-9** and, *see,* **FIGs. 2** and **3**. • 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). **EX1009 Ochoa Decl. at ¶30.**  FIG.2  FIG.3 • The FR'034 application discloses an apparatus assembly (the spinal implant) for use in association with bones (vertebrae) in a patient's body. **EX1009 Ochoa Decl. at ¶35.**

The FR'034 application discloses a spinal implant device for use in spinal

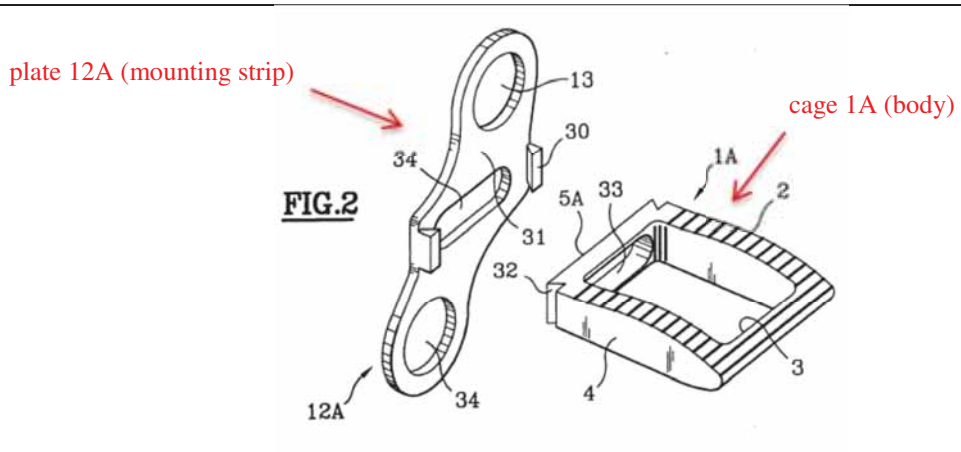
fusion surgical procedures that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1009 Ochoa Decl. at ¶ 30**. The spinal implant device includes two primary 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.[3]

To the extent that the preamble limits the claim, a PHOSITA would have recognized that the FR'034 application discloses *an apparatus assembly* (the spinal implant) *for use in association with bones* (vertebrae) *in a patient's body*, as recited in the claims. **EX1009 Ochoa Decl. at ¶ 35.**

a body constructed of a polymeric material including
The FR'034 application (**EX1005**) discloses: • The spinal implant device includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1009 Ochoa Decl. at ¶30.** • *See*, *e.g.,* **EX1006 at FIG. 2**, as labeled below. • The "cage" (body) is made of metal or biocompatible plastics material. ***Id.* at 2:4-5; 6:3-5.**

[3] *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.



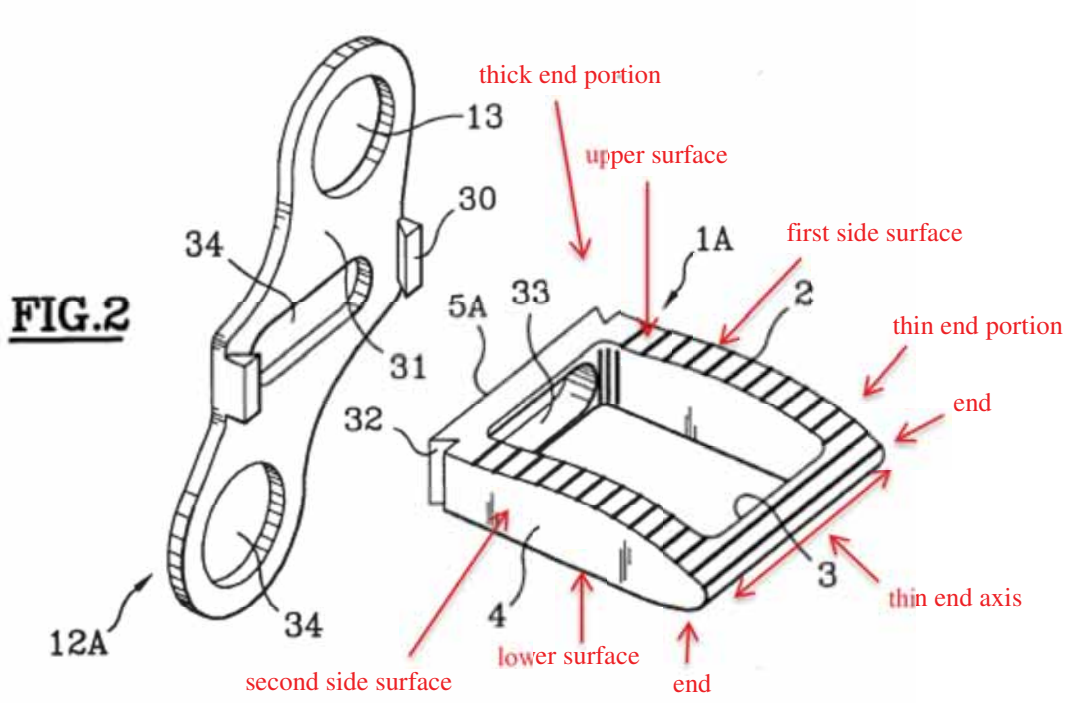
- The FR'034 application discloses a spinal implant having a body constructed of a polymeric material. **EX1009 Ochoa Decl. at ¶36.**

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. **EX1006 at 2:4-5; 6:3-5** and **EX1009 Ochoa Decl. at ¶36.** 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. ***Id.*** 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 thick end portion, a thin end portion defining a thin end axis that extends between opposite ends, a first side surface, a second side surface, an upper surface and a lower surface,
The FR'034 application (**EX1005**) discloses: • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1006 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. **EX1009 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. **EX1009 Ochoa Decl. at ¶33.**
- The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1009 Ochoa Decl. at ¶31.**
- *See*, *e.g.,* **EX1006 at FIG. 2**, as labeled below.



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. **EX1009 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. **EX1006 at 3:3-5; 4:8-11; 5:1-3; EX1009 Ochoa Decl. at ¶33.** As such, the cage is generally wedge-shaped, from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. **EX1009 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 the natural lordosis between vertebrae of the lumbar spine. ***Id.*** **at ¶37.** A PHOSITA would have, therefore, understood that the FR'034 application discloses a spinal implant having a body with *a thick end portion* and *a thin end portion*, as recited in the claims. ***Id.***

Similarly, a PHOSITA would have recognized that the thin end portion extends laterally across the body between opposite ends along a thin end axis. ***Id.*** **at ¶38.** Thus, a PHOSITA would have understood that the FR'034 application discloses that the body has *a thin end axis that extends between opposite ends*, as recited in the claims. ***Id.***

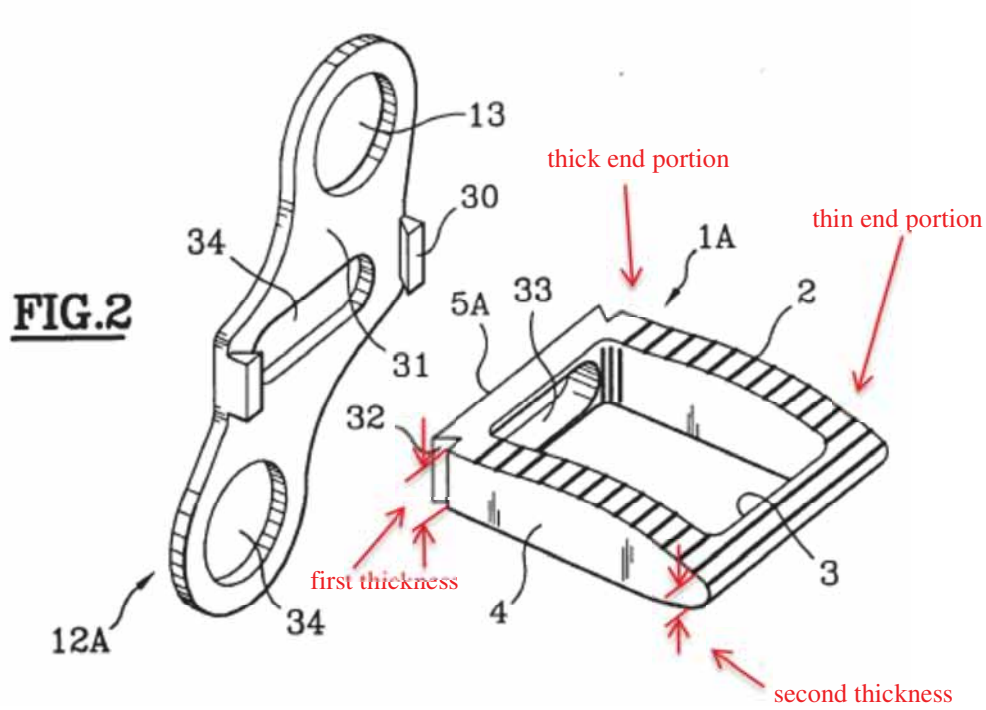
The FR'034 application also discloses that the spinal implant includes opposite side walls ("side walls 2 and 4") each including a side surface. **EX1006 at 2:26-3:2** and **FIG. 2; EX1009 Ochoa Decl. at ¶39.** A PHOSITA would have recognized that the FR'034 application discloses *a first side surface* and *a second side surface*, as recited in the claims. ***Id.***

In addition, the FR'034 application discloses that the spinal implant includes top and bottom faces ("faces 8 and 9"). **EX1006 at 2:26-3:2** and **FIG. 2; EX1009 Ochoa Decl. at ¶40.** The top and bottom faces provide the supporting surfaces for the adjacent bone when the body is inserted between two vertebrae. **EX1009 Ochoa Decl. at ¶40.** A PHOSITA would have recognized that the FR'034 application discloses *an upper surface* and *a lower surface*, as recited in the claims. ***Id.***

As demonstrated and supported by the claim charts, a PHOSITA would have recognized that the FR'034 application clearly illustrates in its figures that the body (*i.e.*, cage) of the spinal implant has the features of *a thick end portion, a thin end portion defining a thin end axis that extends between opposite ends, a first side surface, a second side surface, an upper surface and a lower surface,* as recited in the claims. **EX1009 Ochoa Decl. at ¶¶37-40.**

the thick end portion having a first thickness and the thin end portion having a second thickness, the first thickness being greater than the second thickness,
The FR'034 application (**EX1005**) discloses: • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1006 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. **EX1009 Ochoa Decl. at ¶33.**

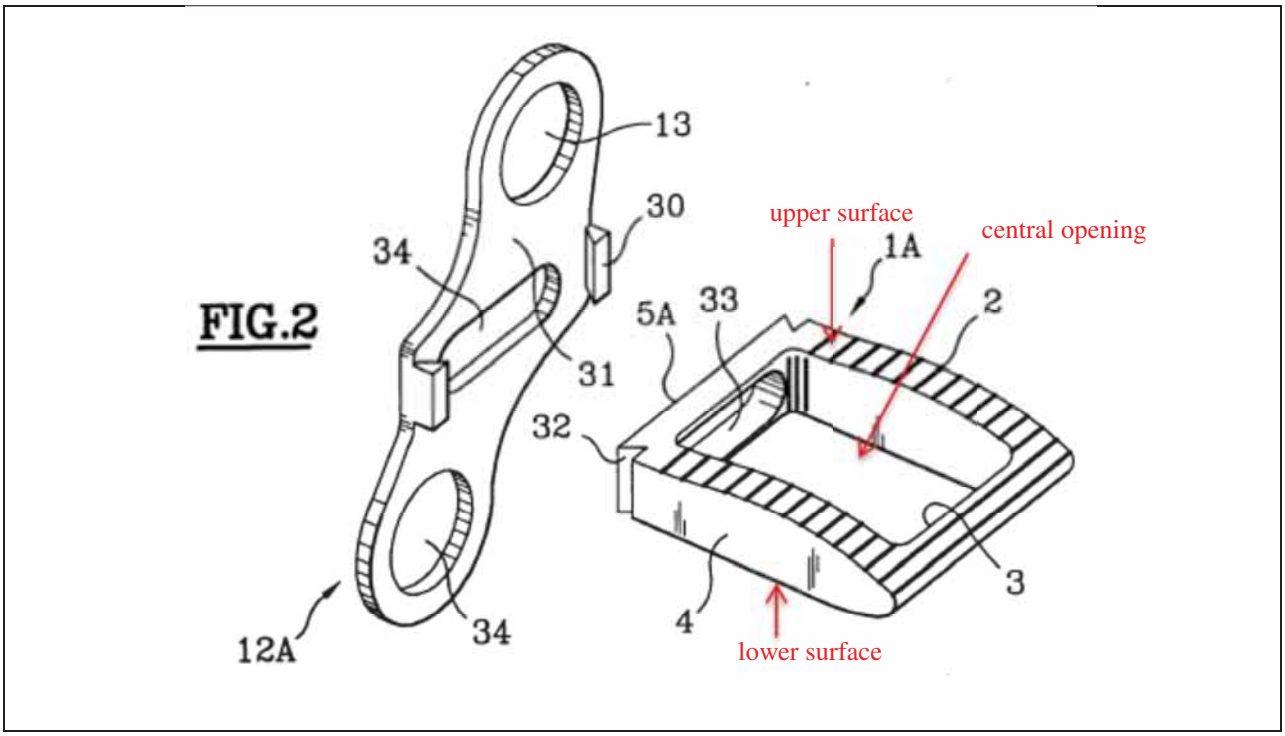
- The "cage" (body) is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. **EX1009 Ochoa Decl. at ¶33.**
- The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1009 Ochoa Decl. at ¶31.**
- *See*, *e.g.,* **EX1006 at FIG. 2**, as labeled below.



The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1006 at 4:8-11.** Moreover, a PHOSITA would have understood that the FR'034 application illustrates the thickness of the anterior thick end portion the body is greater than the thickness of the posterior thin end portion of the body. **EX1009 Ochoa Decl. at ¶42.** FIG. 2 illustrates the spinal implant device with an anterior thick end portion having a first thickness and a posterior thin end portion having a second thickness,

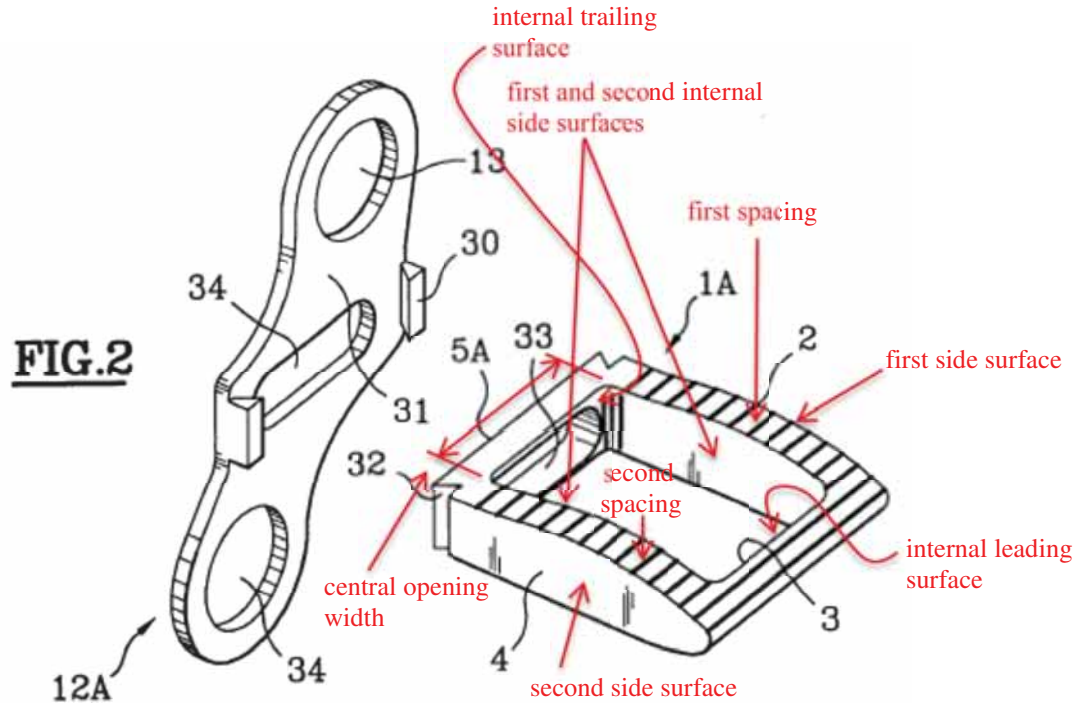
the thickness of the anterior end being greater than the thickness of the posterior end. ***Id.*** The FR'034 application discloses that the body of the spinal implant is dimensioned to conserve an appropriate intervertebral space and may have a profile and shape to enable it to fit perfectly in the intervertebral space. **EX1006 at 3:3-5** and **5:1-3; EX1009 Ochoa Decl. at ¶42.** A PHOSITA would have understood, therefore, 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 have a thicker anterior or trailing portion and a thinner posterior or leading portion, as is illustrated in FIG. 2. **EX1009 Ochoa Decl. at ¶41.** Consequently, a PHOSITA would have understood that the FR'034 patent discloses *the thick end portion* (of the body) *having a first thickness and the thin end portion having a second thickness, the first thickness being greater than the second thickness*, as recited in the claims. ***Id.*** **at ¶41.**

the body further including a central opening formed in the body and extending generally vertically through the upper surface and the lower surface,
The FR'034 application (**EX1005**) discloses: • The system includes at least one open internal "cage" (body). **EX1006 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. **EX1009 Ochoa Decl. at ¶31.** • *See, e.g.*, **EX1006 at FIG. 2**, as labeled below.



The FR'034 application discloses that the device has an open internal body that is designed to receive graft materials ("cage 1A"). **EX1006 at 1:1-9, 2:7-8** and **2:26-3:2; EX1009 Ochoa Decl. at ¶46.** 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. **EX1009 Ochoa Decl. at ¶46.** A PHOSITA would have understood that the FR'034 patent discloses a *body further 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, an internal trailing surface, a first internal side surface and a second internal side surface,* *a central opening width defined between the first and second internal side surfaces,* *wherein the first internal side surface is spaced from the first side surface at a first spacing and the second internal side surface is spaced from the second side surface at a second spacing,*
The FR'034 application (**EX1005**) discloses: • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1009 Ochoa Decl. at ¶31.** • *See*, *e.g.,* **EX1006 at FIG. 2**, as labeled below.    FIG.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. **EX1009 Ochoa Decl. at ¶31.** A PHOSITA would have understood that

the body ("cage 1A") of the spinal implant disclosed and illustrated in the FR'034 application has an anterior wall, a posterior wall, and side walls that form a parallelepiped having a generally wedge shape. ***Id*. at ¶47.** A PHOSITA would have understood that the graft materials would be held captive by the central opening defined by the interior surface of each of these walls. ***Id.*** A PHOSITA would, therefore, have recognized that the FR'034 application discloses the central opening having *an internal surface including an internal leading surface, an internal trailing surface, a first internal side surface and a second internal side surface*, as recited in the claims. ***Id.***

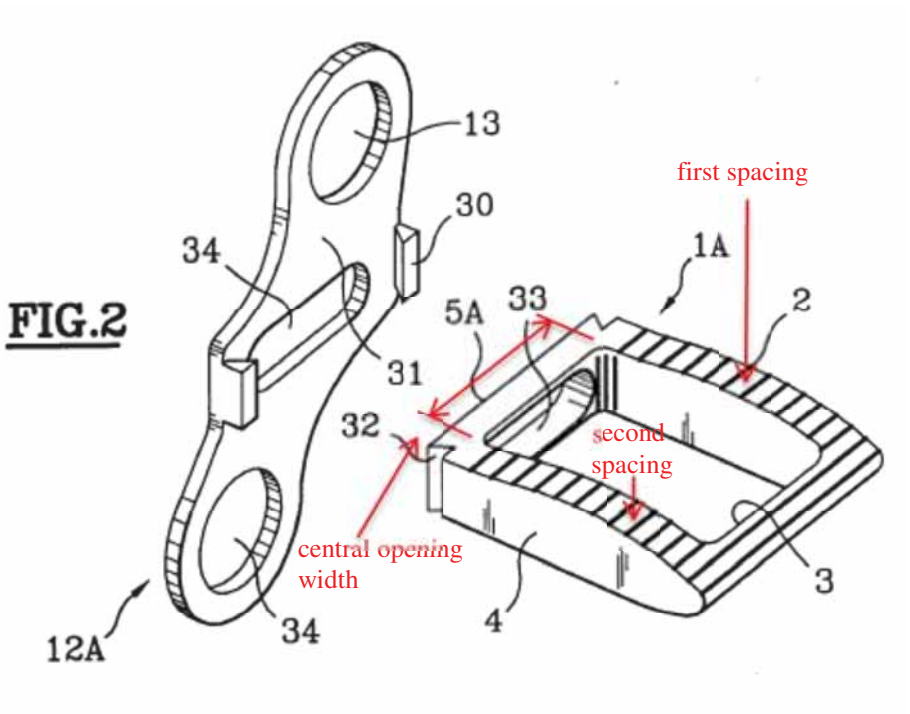
Similarly a PHOSITA would also have recognized that the central opening width is *defined between the first and second internal side surfaces*, as recited in the claims. ***Id.***

Further, 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. **EX1009 Ochoa Decl. at ¶48.** A PHOSITA would therefore have recognized that the FR'034 application discloses that *the first internal side surface is spaced from the first side surface at a first spacing and the second internal side surface is spaced from the second side surface at a second spacing*, as recited in the claims. ***Id.***

the central opening width being greater than a sum of the first spacing and the second spacing,

The FR'034 application (**EX1005**) discloses:

- The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1006 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. **EX1009 Ochoa Decl. at ¶31.**
- *See*, *e.g.,* **EX1006 at FIG. 2,** as labeled below.



As discussed, the FR'034 application discloses an open internal body that is designed to receive graft materials ("cage 1A"). **EX1006 at 1:1-9, 2:7-8** and **2:26-3:2; EX1009 Ochoa Decl. at ¶49.** The cage can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1006 at 4:8-11.** A PHOSITA would have understood that an open internal body would be configured to maximize the volume of material available for graft

materials and minimize the wall thickness of the body while still maintaining the structural integrity of the device. **EX1009 Ochoa Decl. at ¶49.** This would create a large surface area of contact between the endplate and graft, thus providing an excellent milieu for arthrodesis. ***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. 2) make clear that the width of the opening in the body ("cage 1A") is greater than the sum of the widths of the first and second side walls. ***Id.*** A PHOSITA would have understood that the FR'034 patent discloses a *central opening width being greater than a sum of the first spacing and the second spacing*, as recited in the claims. ***Id.*** Moreover, for at least the reasons noted above, *e.g.,* creating a large surface area of contact between the endplate and graft, a PHOSITA would have considered such a configuration an obvious and preferred design choice. ***Id.***

the internal leading surface including a substantially linear portion extending substantially parallel to the thin end axis between a first end and a second end, the internal leading surface defining an internal leading height that is substantially constant between the first end and the second end; and
The FR'034 application (**EX1005**) discloses: • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1009 Ochoa Decl. at ¶31.** • *See*, *e.g.,* **EX1006 at FIG. 3**, as labeled below. The embodiment of FIG. 3 differs from that of FIG. 2 in that it is made as a single piece. ***Id.*** **at 5:4-5.**

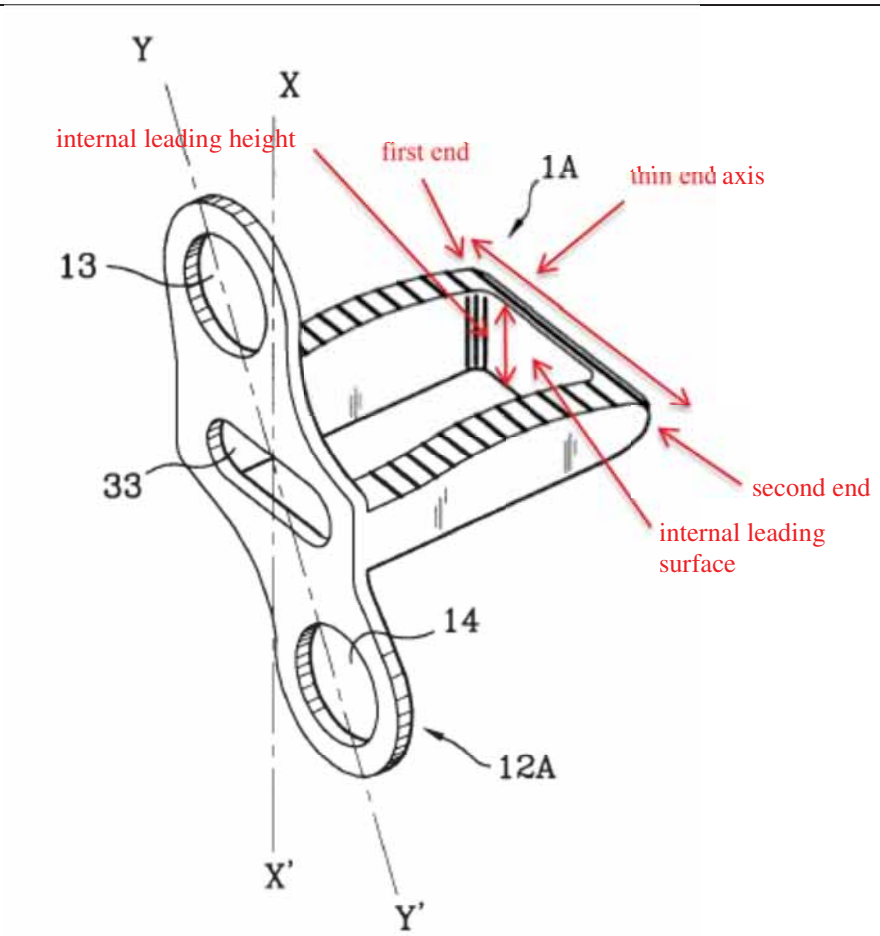


FIG.3

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. **EX1009 Ochoa Decl. at ¶50.** Thus, the interior face of the posterior end of the body ("cage 1A") is *the internal leading surface*. ***Id.*** As noted 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. ***Id.*** **at ¶31;** *and see*, *e.g.,* **EX1006 at FIG. 3** (the embodiment of FIG. 3 differs from that

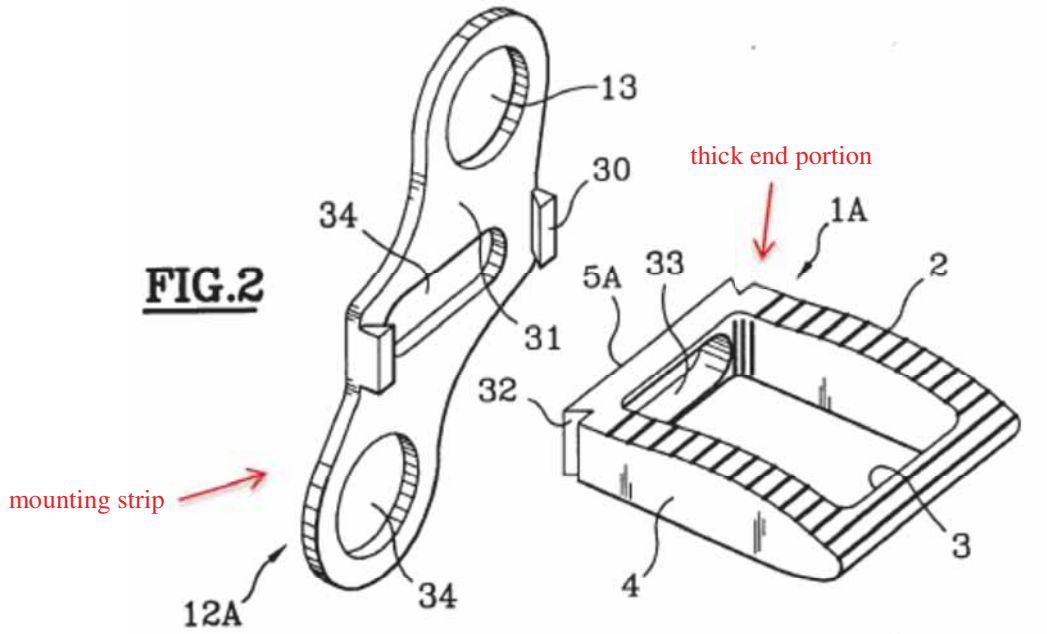
of FIG. 2 in that it is made as a single piece. ***Id.* at 5:4-5.**) A PHOSITA would have understood that the internal leading surface of the spinal implant is planar and includes a *substantially linear portion.* **EX1009 Ochoa Decl. at ¶50.** A PHOSITA would have further understood that the internal leading surface extends substantially parallel to the *thin end axis* between opposite ends. ***Id.*** Therefore, a PHOSITA would have recognized that the FR'034 application discloses an *internal leading surface including a substantially linear portion extending substantially parallel to the thin end axis between a first end and a second end*, as recited in the claims. ***Id.***

Moreover, a PHOSITA would have understood that the interior face of the posterior end of the body ("cage 1A") does not vary in height across the width of the body. **EX1009 Ochoa Decl. at ¶51.** Consequently, a PHOSITA would have understood that the FR'034 application discloses *the internal leading surface defining an internal leading height that is substantially constant between the first end and the second end*, as recited in the claims. ***Id.***

a mounting strip connected to the thick end portion, the mounting strip constructed of a metallic material.
The FR'034 application (**EX1005**) discloses: • The spinal implant device includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1009 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 ends anchor devices for anchoring to at least two adjacent vertebrae in order

to connect them together via the cage. **EX1006 at 3:11-17**.

- The anchor device for anchoring the plate 12A on the vertebrae, after the cage 1A has been fixed make use of pedicular screws passing through corresponding holes 13 and 14 formed through the ends of the strap 12A. ***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. 2**, as labeled below.



A PHOSITA would have understood that the spinal implant disclosed in the FR'034 application device includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1009 Ochoa Decl. at ¶30.** The mounting strip is carried on the anterior face of the body at the thick end portion. ***Id.* at ¶55** and **EX1006 at 3:11-17.** A PHOSITA would have understood that titanium alloy is a preferred biocompatible metal with favorable mechanical properties for use in orthopedic plates and screws, **EX1009 Ochoa Decl. at ¶55,** and that the FR'034

application discloses that titanium alloy as a preferred material. **EX1006 at 6:3-5.** Therefore, a PHOSITA would have understood that the FR'034 patent discloses *a mounting strip connected to the thick end portion, the mounting strip constructed of a metallic material*, as recited in the claims. **EX1009 Ochoa Decl. at ¶55.**

In summary, and as confirmed by Dr. Ochoa, the FR'034 application renders claim 1 obvious and unpatentable under 35 U.S.C. § 103.

2. Claims 2 and 3

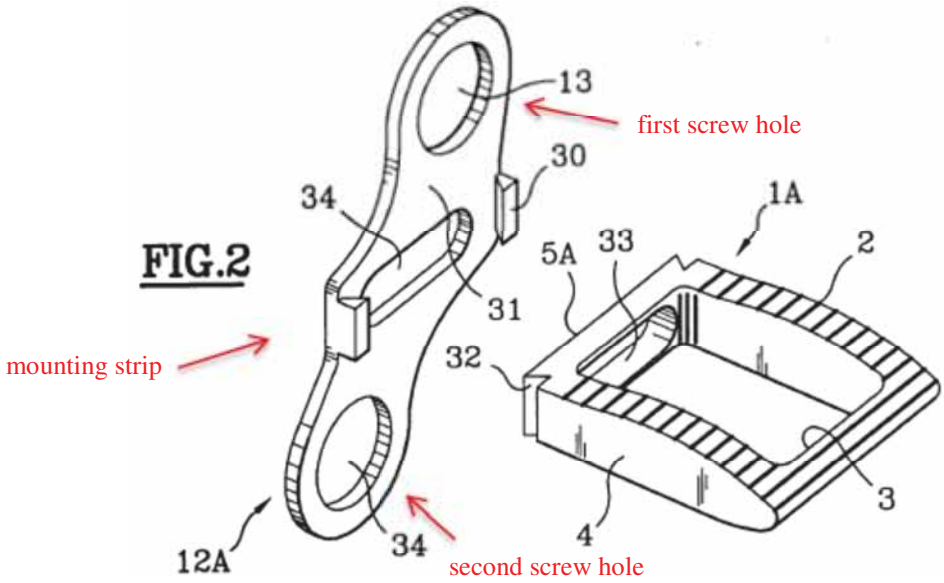
Dependent claim 2 of the '066 patent depends from independent claim 1, and dependent claim 3 depends from claim 2. Claims 2 and 3 further describe the apparatus of claim 1 as including first (claim 2) and second (claim 3) screws used in conjunction with the mounting strip. Claims 2 and 3 are rendered obvious by the FR'034 application, as follows:

'066 patent Claim 2 vs. FR'034 Application
The apparatus assembly of claim 1, further comprising: *a first screw having a head and a threaded shaft; and* *a first screw hole extending through the mounting strip,* *the head configured for engagement with the mounting strip proximate the first screw hole and* *the threaded shaft configured in a mounted configuration to engage cortical bone of the bones.*
'066 patent Claim 3 vs. FR'034 Application
The apparatus assembly of claim 2, further comprising: *a second screw having a head and a threaded shaft; and* *a second screw hole extending through the mounting strip,* *the head of the second screw configured for engagement with the mounting strip proximate the second screw hole and*

the threaded shaft of the second screw configured in the mounted configuration to engage cortical bone of the bones.

In regard to claims 2 and 3, the FR'034 application (**EX1005**) discloses:

- *See* claim 1, above.
- 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. **EX1006 at 3:11-17**.
- The anchor device for anchoring the plate 12A on the vertebrae, after the cage 1A has been fixed make use of pedicular screws passing through corresponding holes 13 and 14 formed through the ends of the strap 12A. ***Id.* at 5:10-15.**
- The spinal implant is anchored to the vertebrae by pedicular screws passing through holes in the "plate" (mounting strip). **EX1009 Ochoa Decl. at ¶57.**
- *See*, *e.g.,* **EX1006 at FIG. 2**, as labeled below.



- The FR'034 application discloses a first screw having a head and threaded shaft and a first screw hole extending through the mounting strip. **EX1009 Ochoa Decl. at ¶56.**
- The FR'034 application discloses that the head of the screw would be configured for engagement with the mounting strip proximate the first screw hole and the threaded shaft configured in a mounted configuration to engage cortical bone of the bones. **EX1009 Ochoa Decl. at ¶57.**

The FR'034 application discloses the use of pedicular screws passing through holes 13 and 34 to anchor the plate 12, 12A to at least two adjacent vertebrae. **EX1006 at 5:10-15; EX1009 Ochoa Decl. at ¶56.** A PHOSITA would have known that a common method for fixing a plate to a bone was through the use of a bone screw. **EX1009 Ochoa Decl. at ¶56.** A PHOSITA at would have understood that pedicular screws included headed screws with a threaded shaft. ***Id.*** A PHOSITA would have understood that, typically, the threaded shaft of the bone screw would be advanced into the bone until the head of the screw engaged the plate. ***Id.*** Further advancement of the screw would force the head of the screw to bear down on the plate providing compression of the plate against the bone and thus stabilizing the construct. ***Id.*** Thus, a PHOSITA would have understood that the FR'034 patent discloses *a first screw* and *second screw* that *have a head and threaded shaft* as well as *a first and second screw hole extending through the mounting strip*, as recited in the claims. ***Id.***

The phrases in claims 2 and 3 that the head of the screw is *"configured for engagement with the mounting strip proximate the first [second] screw hole,"* and the shaft is *"configured in a mounted configuration to engage cortical bone of the bones"* are recitations of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and, therefore, is not material to

patentability. As such, this language carries no patentable weight.[4]

However, to the extent that this language limits the claims, the FR'034 application discloses these limitations. A PHOSITA would have understood that to anchor the plate 12, 12A to at least two adjacent vertebrae, as disclosed in the FR'034 application, the threads of the pedicular screws passing through holes 13 and 14 in the plate 12, 12A would engage a combination of cortical and cancellous bone in the vertebrae. **EX1009 Ochoa Decl. at ¶57.** Additionally, stated above, a PHOSITA would have recognized that the heads of the screws would interact with the plate to compress the plate against the bone to stabilize the construct. ***Id.*** Therefore, a PHOSITA would have understood that the FR'034 application discloses that the heads of the screws are *configured for engagement with the mounting strip proximate the first screw hole* and *the threaded shaft configured in a mounted configuration to engage cortical bone of the bones*, as recited in the claims. ***Id.***

Consequently, and as supported by Dr. Ochoa, the FR'034 application renders claims 2 and 3 obvious and unpatentable under 35 U.S.C. § 103.

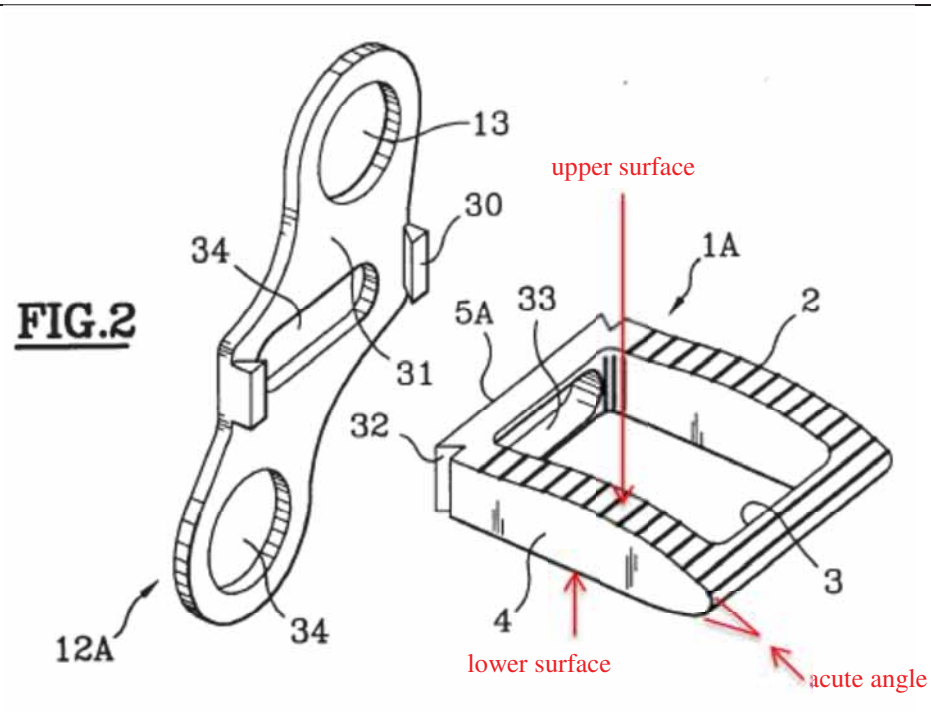
3. Claim 8

Dependent claim 8 of the '066 patent depends directly from independent

[4] *In re Schreiber,* 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart,* 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); *and In re Danly,* 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

claim 1. Claim 8 further describes the geometry of the body of the apparatus of claim 1 as the upper and lower surfaces defining an acute angle. Claim 8 is rendered obvious by the FR'034 application, as follows:

'066 patent Claim 8 vs. FR'034 Application
The apparatus assembly of claim 1, wherein the upper and lower surfaces define an acute angle.
The FR'034 application (**EX1005**) 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. **EX1006 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. **EX1009 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. **EX1009 Ochoa Decl. at ¶33.** • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1009 Ochoa Decl. at ¶31.** • *See*, *e.g.,* **EX1006 at FIG. 2**, as labeled below.



- The device has an acute angle between the upper and lower surfaces of the body. **EX1009 Ochoa Decl. at ¶42**.

As discussed, *supra*, a PHOSITA would have recognized and understood from the FR'034 application that the cage of the implant device possesses various characteristics or features that are intrinsic to the geometric configuration of the device, as clearly illustrated in the figures. **EX1009 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. **EX1006 at 3:3-5; 4:8-11; 5:1-3; EX1009 Ochoa Decl. at ¶33.** As such, the cage is generally wedge-shaped, from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. **EX1009 Ochoa Decl.**

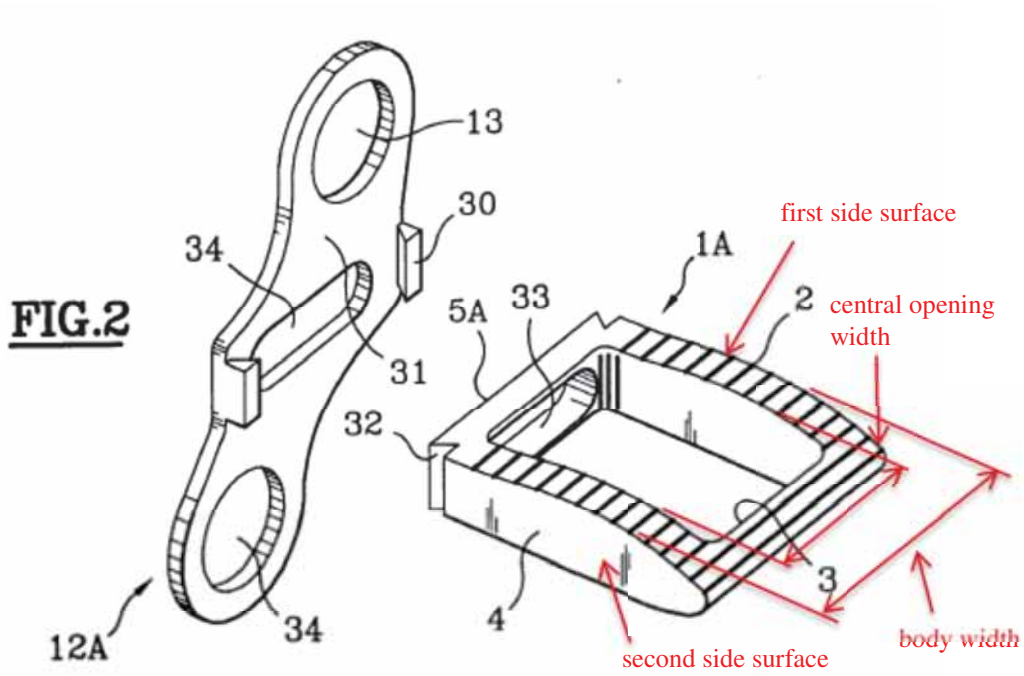
at ¶33. A PHOSITA would have recognized and understood from the FR'034 application this configuration of the cage as being consistent with a spinal implant that is intended for use to restore the natural lordosis between vertebrae of the lumbar spine. ***Id.*** **at ¶37.** It had been documented, and would have been known to a PHOSITA at the time of invention, that the average angle of the intervertebral disc space is an acute angle that varies between approximately 5 and 15 degrees in the lumbar spine. ***Id.*** **at ¶42.** Moreover, and while recognizing that the drawings may not be to scale, the relative size and shape observable in the figures of the FR'034 application (e.g., Figure 2) make clear that the upper and lower surfaces are configured to define an acute angle. ***Id.*** A PHOSITA would have, therefore, understood that the FR'034 patent 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.,* to restore the natural lordosis between vertebrae, a PHOSITA would have considered such a configuration an obvious and preferred design choice. ***Id.***

As supported by the declaration of Dr. Ochoa, the FR'034 application renders claim 8 obvious and unpatentable under 35 U.S.C. § 103.

4. Claim 13

Dependent claim 13 depends directly from independent claim 1 and further defines certain geometric characteristics of the apparatus. Claim 13 is rendered

obvious by the FR'034 application, as follows:

'066 patent Claim 13 vs. FR'034 Application
The apparatus assembly of claim 1, wherein the body defines a body width between the first side surface and the second side surface, the central opening width being greater than one half the body width.
The FR'034 application (**EX1005**) 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. **EX1006 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. **EX1009 Ochoa Decl. at ¶31.** • *See*, *e.g.,* **EX1006 at FIG. 2,** as labeled below. 

As discussed, *supra*, a PHOSITA would have recognized and understood from the FR'034 application that the cage of the implant device possesses various characteristics or features that are intrinsic to the geometric configuration of the

device, as clearly illustrated in the figures. **EX1009 Ochoa Decl. at ¶31.** A PHOSITA would have understood that the body ("cage 1A") of the FR'034 application spinal implant disclosed in the FR'034 application includes opposite side walls ("side walls 2 and 4") each including a side surface with the body contained between the walls. **EX1009 Ochoa Decl. at ¶52.** Thus, a PHOSITA would have recognized that the FR'034 application discloses *a body width between the first side surface and the second side surface*, as recited in the claims. ***Id.***

Further, a PHOSITA would have understood that the implant device of the FR'034 application discloses an open internal body designed to receive graft materials ("cage 1A"). **EX1009 Ochoa Decl. at ¶53.** A PHOSITA would have understood that the open internal body would be configured to maximize the volume and exposed surface are available for graft materials and minimize the wall thickness of the body while still maintaining the structural integrity of the device. ***Id.*** This would create a large surface area of contact between the endplate and graft, thus providing an excellent milieu for arthrodesis. ***Id.*** Moreover, and while recognizing that the drawings may not be to scale, the relative size and proportions observable in the figures of the FR'034 application (e.g., FIG. 2) make clear that the width of the opening in the body is greater than one-half of the width of the body. ***Id.*** A PHOSITA would have, therefore recognized and understood that the FR'034 application discloses that the body *defines a body width between the first*

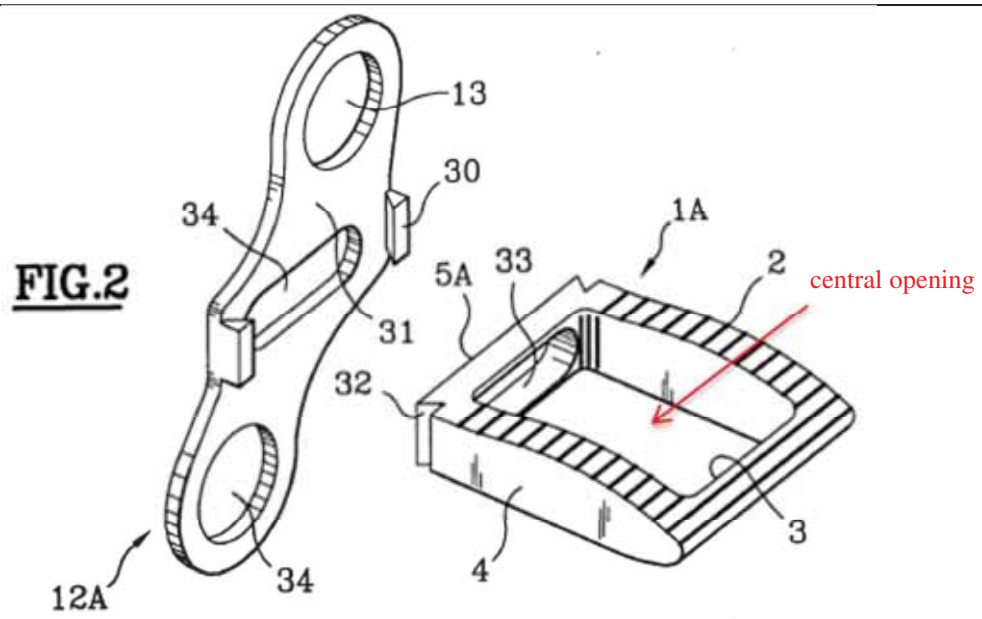
side surface and the second side surface, the central opening width being greater than one half the body width. ***Id.*** Moreover, for at least the reasons noted above, to maximize the volume and exposed surface are available for graft materials, a PHOSITA would have considered such a configuration an obvious and preferred design choice. ***Id.***

Claim 13 is rendered unpatentable under 35 U.S.C. § 103 by the FR'034 application, as supported by the declaration of Dr. Ochoa.

5. Claim 18

Dependent claim 18 depends directly from independent claim 1 and further describes the purpose of the central opening in the body of the apparatus. Claim 18 is rendered obvious by the FR'034 application, as follows:

'066 patent Claim 18 vs. FR'034 Application
The apparatus assembly of claim 1, wherein the central opening is configured to be filled with bone growth inducing material for promoting growth of bone through the central opening.
The FR'034 application (**EX1005)** discloses: • *See* claim 1, above. • 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. The system is capable of installing a bone graft or material encouraging fusion between the two vertebrae concerned. **EX1006 at 1:1-9** and, *see, e.g.*, **FIG. 2**, as labeled below.



- The cage is designed to receive spongy bone or bone substitute material via its top and bottom open faces and/or via a front opening. ***Id.*** **at 2:7-8** and **2:26-32**.
- The spongy bone or other bone substitute can be put into place either before or after the cage has been positioned between the vertebrae. ***Id.*** **at 4:12-14.**
- The anterior face 5A of the cage-and-plate unit has an oblong slot 33 so as to enable spongy bone to be inserted frontally into the cage portion after the cage-and-plate unit has been put into place. ***Id.*** **at 4:25-30**.
- The "cage" (body) of the device has a central opening that is configured to be filled with bone growth inducing material for promoting growth of bone through the central opening. **EX1009 Ochoa Decl. at ¶54.**

In claim 18, the phrase *"configured to be filled with bone growth inducing material for promoting growth of bone through the central opening"* is a recitation of the intended use for the claimed apparatus, does not structurally distinguish the claimed apparatus, and is not material to patentability. As such, this language carries no patentable weight.[5]

[5] *See* footnote 4, supra.

However, to the extent that this language limits the claims, the FR'034 application discloses these limitations. The FR'034 application discloses that the open internal body ("cage 1A") of the implant device is designed to receive graft materials such as spongy bone or bone substitute (*i.e.,* bone growth inducing materials). **EX1006 at 1:1-9, 2:7-8** and **2:26-32; EX1009 Ochoa Decl. at ¶54.** A PHOSITA would have understood that the open internal body would be configured to maximize the volume and exposed surface area available for graft materials to encourage fusion between the two vertebrae. **EX1009 Ochoa Decl. at ¶54.** This would create a large surface area of contact between the endplate and graft, thus providing an excellent milieu for arthrodesis. ***Id.*** A PHOSITA would have, therefore, understood that the FR'034 patent discloses that *the central opening is configured to be filled with bone growth inducing material for promoting growth of bone through the central opening*, as recited in the claims. ***Id.***

In summary, and as confirmed by Dr. Ochoa, the FR'034 application renders claim 18 obvious and unpatentable under 35 U.S.C. § 103.

B. Ground 2: Claims 9 and 10 are unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (EX1005) in view of Zdeblick ("the '909 patent") (EX1007).

Dependent claim 9 depends directly from claim 8 (discussed above) and dependent claim 10 depends directly from claim 9. Claims 9 and 10 further describe the geometry of the body of the apparatus of claim 8 as the upper and

lower surfaces defining an acute angle between one and twenty degrees (claim 9) and, further, between two and ten degrees (claim 10).

Claims 9 and 10 are obvious and unpatentable under 35 U.S.C. § 103(a) over the FR'034 application (**EX1005**) in view of Zdeblick (**EX1007**), as follows:

Although a specific acute angle between the top and bottom surfaces ("faces 8 and 9") of the implant device 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 acute angle 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). **EX1009 Ochoa Decl. at ¶43.**

As discussed above, the average angle of the intervertebral disc space had been documented and would have been known to a PHOSITA at the time of the invention to be between approximately 5 and 15 degrees in the lumbar spine. ***Id.*** Consequently, a PHOSITA would have been motivated to adapt the profile of the implant device to an acute angle within this range in order to restore a desired anatomical relationship between the vertebrae, e.g., in the lumbar region, and achieve the normal lordotic angle of the spine. ***Id.*** Further, a PHOSITA would have considered such a configuration to be an obvious design choice that would

have yielded a predictable effect in the resulting design[6] and would not have changed the principle of operation of the spinal implant FR'034 application.[7] ***Id.*** **at ¶44.** A PHOSITA would have understood that the acute angle within this range (between approximately 5 and 15 degrees) included acute angles both *between one degree and twenty degrees* as recited in claim 9 and *between two degrees and ten degrees*, as recited in claim 10. ***Id.*** **at ¶45.**

Zdeblick 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) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1009 Ochoa Decl. at ¶59.** The device is described as a tapered 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 the removal of damaged spinal disc material. ***Id.*** It would have been understood by a PHOSITA that the Zdeblick device was *used in association with bones in a patient's body*, as recited in the claims. **EX1009 Ochoa Decl. at ¶61.**

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[6] *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).

[7] *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).

An important feature of the Zdeblick device is that the outer diameter of the device is larger at its anterior end than at the posterior end. ***Id.*** **at ¶60.** As a result, the body wall tapers at an angle A about the centerline of the device. ***Id.*** The taper of the body wall is adapted to restore the normal relative angle between the adjacent vertebrae between which the device is implanted. In the lumbar region, the angle A is adapted to restore the normal lordotic angle of the spine in that region. ***Id.*** One specific example of the angle is 8.794°. ***Id.*** and **EX1007 7:11-21.**

A PHOSITA would have been motivated to look to the teachings of the FR'034 application, Zdeblick, 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. **EX1009 Ochoa Decl. at ¶63.**[8] Further, a PHOSITA would have been motivated to apply the teachings of Zdeblick to those of the FR'034 application because both the FR'034 application and Zdeblick 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

[8] *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).

intervertebral joint in a patient. ***Id.* at ¶64.**[9]

1. Claims 9 and 10

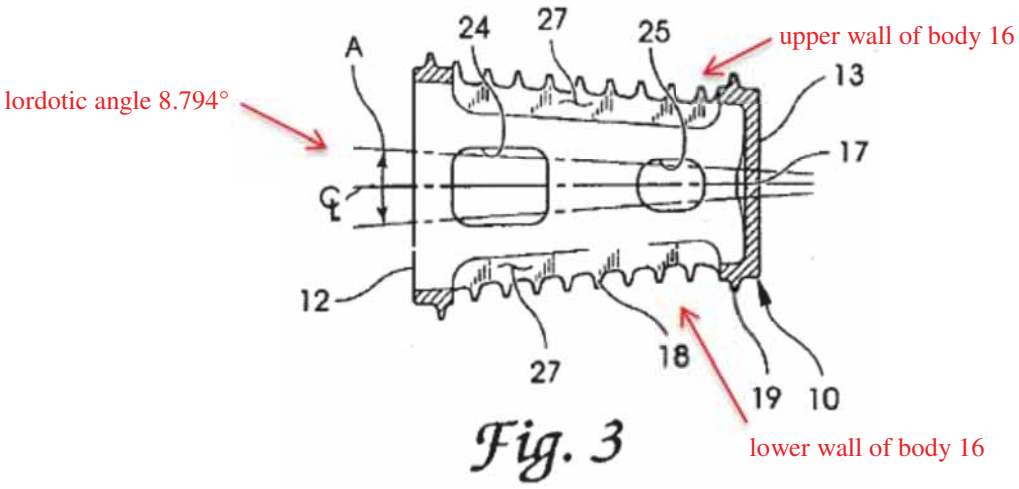
Claims 9 and 10 are obvious over the FR'034 application in view of Zdeblick, as follows:

'066 patent Claim 9 vs. the FR'034 Application and Zdeblick
The apparatus assembly of claim 8, wherein the acute angle is between one degree and twenty degrees.
'066 patent Claim 10 vs. the FR'034 Application and Zdeblick
The apparatus assembly of claim 9, wherein the acute angle is between two degrees and ten degrees.
The FR'034 application (**EX1005**) discloses: • *See* claim 8, 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. **EX1009 Ochoa Decl. at ¶31.** • The FR'034 application considered in its entirety is understood to disclose that the acute angle between the upper and lower surfaces of the body is between 1 and 20 degrees. **EX1009 Ochoa Decl. at ¶62.** Zdeblick (the '909 patent) (**EX1007**) 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) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. The device is placed into the intervertebral space left after the removal of a damaged spinal disk. **EX1007 at 1:9-14** and **EX1009 Ochoa Decl. at ¶59.** • Zdeblick discloses a device (the spinal implant) for use in association with bones (vertebrae) in a patient's body. **EX1009 Ochoa Decl. at ¶¶59-61.** • The interbody fusion device includes a tapered body defining a hollow

[9] *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).

interior for receiving bone graft or bone substitute material. **EX1007 at Abstract.**

- In one important feature of the interbody fusion device, the body 11 includes a tapered or conical form. In other words, the outer diameter of the device at its anterior end 12 is larger than the outer diameter at the posterior end 13. As depicted in FIG. 3, the body wall 16 tapers at an angle A about the centerline CL of the device 10. The taper of the body wall 16 is adapted to restore the normal relative angle between adjacent vertebrae. For example, in the lumbar region, the angle A is adapted to restore the normal lordotic angle and curvature of the spine in that region. In one specific example, the angle A is 8.794°. ***Id.* at 7:11-21.**
- *See*, *e.g.*, ***Id.* at FIG. 3**, as labeled below.



- The device has an acute angle between the upper and lower surfaces of the body of between one degree and twenty degrees. **EX1009 Ochoa Decl. at ¶62.**

A PHOSITA would have understood that Zdeblick discloses a spinal implant with a lordotic angle A of e.g. 8.794° of the body for use in the lumbar spine, which is an acute angle between one and twenty degrees and, further, between two and ten degrees. **EX1009 Ochoa Decl. at ¶62.**

It would have been recognized by a PHOSITA that the larger outer diameter at the anterior end 12 and smaller outer diameter at the posterior end 13 of the cage

in Zdeblick are analogous to the heights of the front face 5 and posterior face 3 of the cage of the FR'034 application. ***Id.*** **at ¶65.** The tapered body wall 16 of the Zdeblick interbody cage would interact with the vertebral endplates in a similar manner to the top and bottom faces of the device of the FR'034 application. ***Id.*** Therefore, the applicability and advantages of the specific lordotic angle of 8.794° for the taper of the device disclosed in Zdeblick to the device of the FR'034 application would have been readily apparent to a PHOSITA. ***Id.*** A PHOSITA would have understood that in order to restore a desired anatomical relationship between the vertebrae, e.g., in the lumbar region, and achieve the normal lordotic angle of the spine, it would be desirable that the shape and/or profile of the implant device be adapted to fit the intervertebral space between adjacent vertebrae in that region. ***Id.*** **at ¶66.**

Therefore, a PHOSITA would have been motivated in view of the combined teachings of the FR'034 application and Zdeblick to configure the interbody cage of the FR'034 application with an *acute angle between one and twenty degrees,* and further *between two and ten degrees,* between the upper and lower surfaces of the implant in order to fit within and conserve an appropriate intervertebral space. ***Id.*** **at ¶67.** Moreover, a PHOSITA would have considered such a modification an obvious design choice that would have yielded a predictable effect in the resulting design and would not have changed the principle of operation of the spinal implant

FR'034 application. ***Id.*** **at ¶68.**[10] Consequently, a PHOSITA would have understood that the product resulting from the combined teachings of the FR'034 application and Zdeblick would have produced a spinal implant wherein the upper and lower surfaces of the device define an acute angle of *between one degree and twenty degrees* and, more particularly, *between two degrees and ten degrees*, as recited in the claims. ***Id.*** **at ¶69.**

In summary, and as confirmed by Dr. Ochoa, claims 9 and 10 are unpatentable as obvious under 35 U.S.C. § 103(a) over the FR'034 application in view of Zdeblick.

C. Ground 3: Claims 16 and 17 are unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (EX1005) in view of Kozak ("the '364 patent") (EX1008).

Dependent claim 16 depends directly from claim 1 (discussed above) and dependent claim 17 depends directly from claim 16. Claims 16 and 17 further define features of the body of the apparatus of claim 1 as including a screw passage through a thick end surface (claim 16) and, further, that the screw passage is configured to receive a shank of a screw (claim 17). Claims 16 and 17 are rendered obvious over the FR'034 application (**EX1005**) in view of Kozak (**EX1008**).

Kozak discloses a spinal implant for use in a spinal fusion surgical procedure that changes the spatial relationship (*e.g.*, restores a desired anatomical

[10] *See* footnotes 6 and 7, supra.

relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1009 Ochoa Decl. at ¶71.** The spinal implant of Kozak is used as an anterior fixation device implanted in the intervertebral space left after the removal of damaged spinal disc material to assist in promoting interbody fusion. ***Id.*** and **EX1008 at 1:5-9, FIGs. 1** and **5.** It would have been understood by a PHOSITA that the Kozak device was *used in association with bones in a patient's body*, as recited in the claims. **EX1009 Ochoa Decl. at ¶72.**

The spinal implant described in Kozak can incorporate a fixed sagittal angle to maintain the patient's proper lordotic curvature once the device is implanted. **EX1008 at 10:16-24** and **FIG. 21**. As shown in FIG. 21, a device 21' can be provided in which the opposite end plate faces 30' diverge anteriorly at an angle A to approximate the sagittal angle, or lordosis, between two vertebrae. ***Id.*** The body 29 of each lateral spacer 21 further includes a screw bore 37 defined in the anterior face of the body 29. ***Id.*** **at 6:48-55.** This screw bore 37 terminates at its base in a threaded bore 38 which is adapted to engage one of the fixation screws 24 shown in FIG. 1. ***Id.*** The screw bore 37 also includes a head recess 39 which permits the head of the fixation screw to reside enshrouded within the body 20. ***Id.***

A PHOSITA would have been motivated to look to the teachings of the FR'034 application, Kozak, 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. **EX1009 Ochoa Decl. at ¶75.**[11] A PHOSITA would have been motivated to apply the teachings of Kozak to those of the FR'034 application because both the FR'034 application and Kozak 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.**[12]

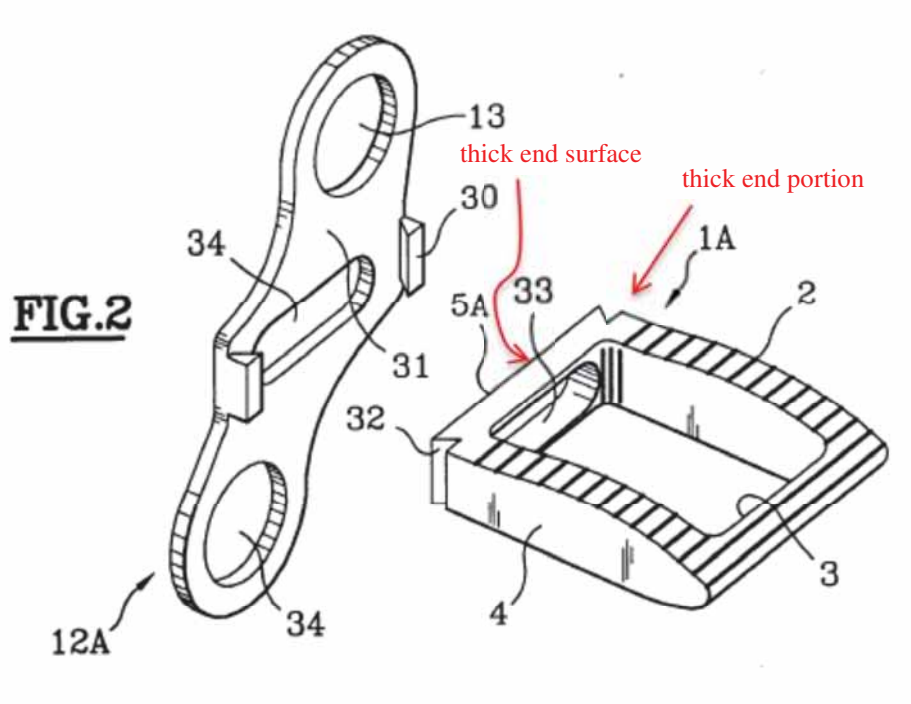
1. Claims 16 and 17

Dependent claims 16 and 17 are obvious over the FR'034 application in view of Kozak, as follows:

'066 patent Claim 16 vs. the FR'034 Application and Kozak
The apparatus assembly of claim 1, wherein the thick end portion defines a thick end surface, the thick end surface having a screw passage extending therethrough.
'066 patent Claim 17 vs. the FR'034 Application and Kozak
The apparatus assembly of claim 16, wherein the screw passage is configured to receive an elongated shank of a screw member.
The FR'034 application (**EX1005**) 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. **EX1009 Ochoa Decl. at ¶31.**

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

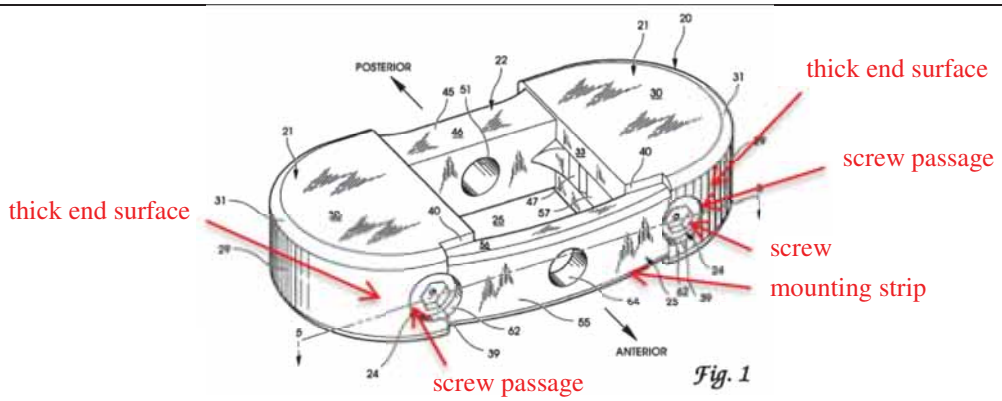
- *See*, *e.g.,* **EX1006 at FIG. 2,** as labeled below.



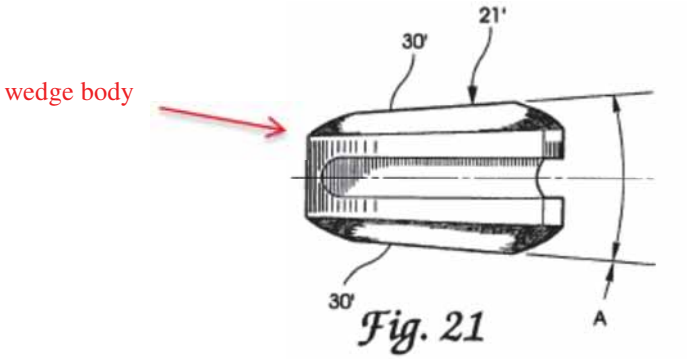
- The plate and cage can be made separately and are secured to each other by various assembly methods. ***Id.* at 3:21-24**.
- The "cage" (body) includes a thick end portion having a thick end surface. **EX1009 Ochoa Decl. at ¶37.**
- The mounting strip is attached to the thick end surface. **EX1009 Ochoa Decl. at ¶55.**

Kozak (the '364 patent) (**EX1008**) 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) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1009 Ochoa Decl. at ¶71.**
- Kozak discloses a device (the spinal implant) for use in association with bones (vertebrae) in a patient's body. **EX1009 Ochoa Decl. at ¶72.**
- A spinal implant for use as an anterior fixation device, and to an implant which is to be placed into the intervertebral space left after the removal of a damaged spinal disk to assist in promoting interbody fusion. **EX1008 at 1:5-9**; and *e.g.,* **FIG. 1**, as labeled below.



- The fusion device 20 is a four component device. The device 20 includes a pair of lateral spacers 21, a posterior central spacer 22 and an anterior central spacer 23, the central spacers of which are engaged to the lateral spacers to hold them apart. A pair of fixation screws 24 are provided for locking the entire assembly together to form the completed fusion device 20. The fully assembled device 20 defines a cavity 25 between the lateral and central spacers, which cavity is adapted 20 to receive bone graft material therein. ***Id.* at 5:10-21.**
- Moreover, the geometry of an appropriate fusion device can incorporate a fixed sagittal angle to maintain the patient's proper lordotic curvature once the device is implanted. As shown in FIG. 20, the device 21 has a fixed width W between end plate faces 30. Alternatively, a device 21' as shown in FIG. 21 can be provided in which the opposite end plate faces 30' diverge anteriorly at an angel A to approximate the sagittal angle, or lordosis, between two vertebrae. ***Id.* at 10:16-24** and **FIG. 21**, as labeled below.



- The body 29 of the lateral spacer 21 includes an inter-lock channel 24 defined in one side face 33 of the body, as shown most clearly in FIG. 6. The interlocking channel 34 has an end face 35 that is angled from the posterior to the anterior end of the device 20. The interlock channel 34 further includes opposite beveled walls 36 which are angled toward each other from the closed end to the open end of the channel, as readily seen in FIG. 7.

These walls 36 are oriented to include an angle A, which in one specific embodiment is 45°. ***Id.* at 6:38-47** and **FIG. 6**, as labeled below.

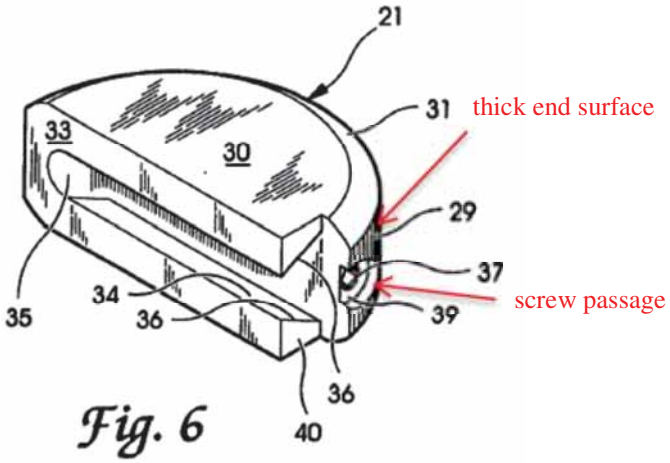


Fig. 6

- The body 29 of each lateral spacer 21 further includes a screw bore 37 defined in the anterior face of the body 29. This screw bore 37 terminates at its base in a threaded bore 38 which is adapted to engage one of the fixation screws 24 shown in FIG. 1. The screw bore 37 also includes a head recess 39 which permits the head of the fixation screw to reside enshrouded within the body 20. The anterior face of each of the lateral spacers 29 also includes a spacer notch 40 defined in the body at the end of the interlock channel 34 and immediately adjacent the screw bore 37, as shown most clearly in FIG. 6. ***Id.* at 6:48-59**.
- The particular features of each lateral spacer 21 are adapted for interlocking engagement with each of the centeral spacers 22, 23. ***Id.* at 6:60-62**.
- The anterior central spacer 23 includes a spacer body 55 having a pair of posteriorly directed arms 57 extending therefrom. Each of the arms 57 includes opposite angled faced 58 which, like the dovetail arms 47 of the posterior spacer, are configured to engage within the interlock channels 34 in the lateral spacers 21. Each of the posterior arms 57 includes an end face 59 which directly abuts the end of each of the anterior extensions 50 of the dovetail arms 47 for the posterior central spacer 22. Thus, when both anterior and posterior spacers are engaged within the lateral spacer interlock channels 34, the two central spacers are firmly pressed into contact with each other. ***Id.* at 7:31-45**.
- The anterior spacer body 55 also includes an inner posteriorly directed face 60 adjacent each of the arms 57. This face 60 contacts a portion of the spacer notches 40 in each of the lateral spacers 21, in order to maintain the anterior spacer in position. The anterior spacer body 55 further includes a pair of notches 62 defined in the sides of the body and oriented along the anterior

portion of the posterior directed arms 57. In the assembled configuration, these notches 62 align with the corresponding head recesses 39 in the lateral spacer bodies 29. The notches 62 in the anterior central spacer 23 combine with the head recesses 39 to form a generally circular recess to receive the head of a fixation screw 24 therein. Finally, the anterior spacer body 55 includes a central bore 64, which is aligned with the bore 51 in the posterior central spacer 22 when the device is being assembled. ***Id.* at 7:46-62**.

- In some instances, greater initial fixation of the interbody fusion device to the vertebrae may be desirable. Greater fixation of the device can be accomplished using a modified anterior central spacer 95 shown in FIGS. 22 and 23. The spacer 95 is identical in most respects to the anterior spacer 22 described above. Like the prior spacer 22, the anterior spacer 95 includes a bore 96 extending through the front face of the spacer, which bore is aligned for use with a guide rod 85 for insertion of the spacer. However, the alternative anterior spacer 95 includes an angled bore 97 that intersects the guide bore 96 at an angle. This angled bore is configured to receive an anchoring bone screw 98 there through, which screw is ultimately threaded into a vertebra. FIG. 24 illustrates such a construct with the bone screw 98 partially threaded into the L5 vertebra. The bone screw provides additional anchorage for the fusion device, which can speed the fusion process between the bone graft material G and the vertebrae. ***Id.* at 10:37-55** and **FIGs. 23-24**.

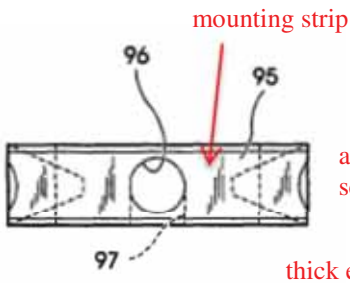


Fig. 23

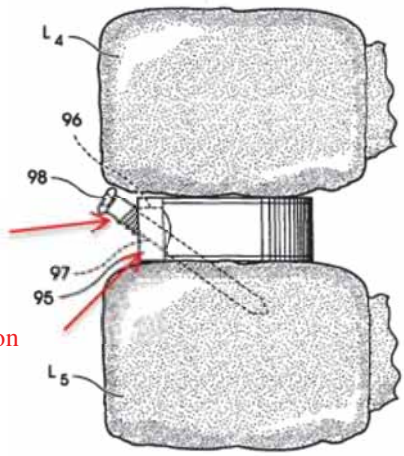
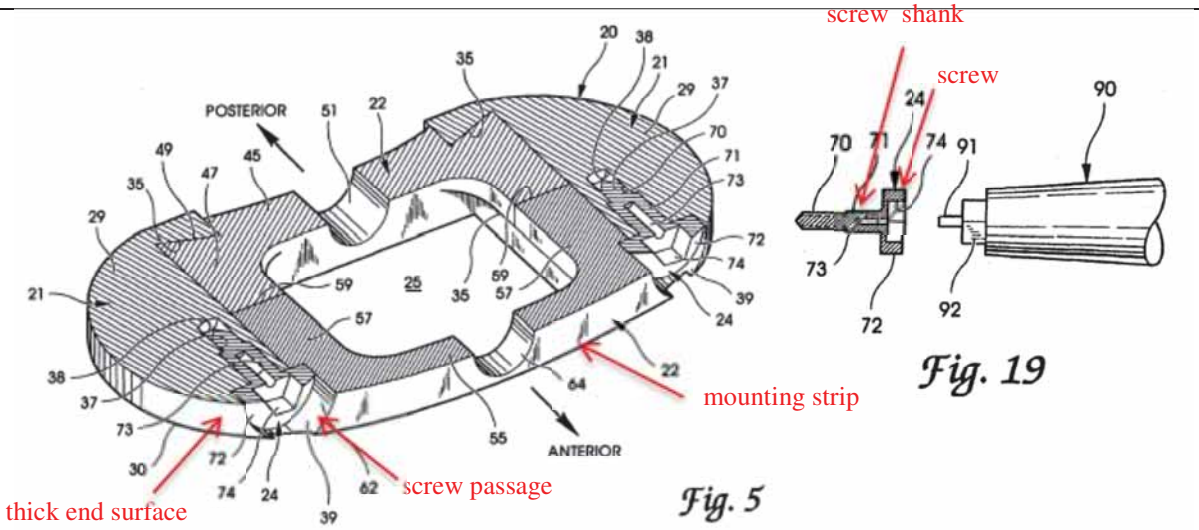


Fig. 24

- As shown in FIGs. 5 and 19, each of the fixation screws includes a screw threaded portion 70 adapted to engage the threaded bore 38 of each of the lateral spacers 21. These screws also include a guide portion 71 which guides the screw into the screw bores 37. The head 72 of each screw is sized to be received within the head recess 39 in the lateral spacers 21. ***Id.* at 9:24-31** and **FIGs. 5 and 19**, as labeled below.



- The "anterior spacer" (mounting strip) is secured to the "lateral spacer" (body) by a dovetail connection with the lateral spacer and by screws. **EX1009 Ochoa Decl. at ¶73.**
- A thick end portion of the body of the device defines a thick end surface having a screw passage extending therethrough**. EX1009 Ochoa Decl. at ¶¶73, 74, 77.**

A PHOSITA would have understood that Kozak describes a wedge shaped spinal implant for use during anterior interbody fusion and that the implant includes an internal cavity for insertion of bone graft material and an integrated anterior portion that is configured to receive anchoring bone screws to secure fixation of the cage to the adjacent vertebral bodies. **EX1009 Ochoa Decl. at ¶73.** The Kozak spinal implant is modular and includes a pair of lateral spacers, a posterior central spacer and an anterior central spacer that are assembled using dove tail joints. ***Id.*** In addition, fixation screws are used to clamp and hold the components of the device together. ***Id.*** The anterior central spacer of the device is configured to receive an anchoring bone screw to secure the device into an

adjacent vertebra and provide additional means to secure the device in the intervertebral space. ***Id.***

A PHOSITA would have understood that the implant of the FR'034 application is dimensioned to conserve an appropriate intervertebral space and that the body may have a profile and shape to enable it to fit perfectly in the intervertebral space and that to achieve the desired fit in the intervertebral space of the lumbar spine would require the body of the implant to have a thicker anterior or trailing portion and a thinner posterior or leading portion. ***Id.*** **at ¶74.** A PHOSITA would have understood that the implant comprises an assembly including a body ("cage 1A") and an external metallic strap or plate ("plate 12A") configured to include screw holes ("fixing holes 13 and 14") attached to the thick end surface of the body using various known assembly methods, including the use of a dovetail joint. ***Id.***

Like the described embodiment of the FR'034 application, the modular elements of Kozak are configured to interlock at dovetail elements. ***Id.*** **at ¶77.** In addition, clamping means, such as screws ("fixation screws 24"), are used to maintain the components in their assembled configuration. ***Id.*** In order to accommodate the screws, a screw passage, in the form of a bore passes through the anterior face of the body. ***Id.*** For a lordotic device (see e.g. Fig 21), the anterior face of the body would be at the thick end of the device. ***Id.*** Kozak further

discloses that the screw bore is threaded at its base with the remainder of the bore *configured to receive the shank portion of the screw*, as recited in claim 17. ***Id.*** The elongated shank portion of the screw interacts with the unthreaded portion of the bore to guide the screw into the threaded base of the screw bore. ***Id.*** A PHOSITA would have recognized the advantages taught by Kozak regarding the assembly of a modular interbody fusion device, including fixation of devices that utilize dovetail joints to the FR'034 application. ***Id.*** The use of screws, as disclosed in Kozak, would provide a known assembly method to secure the plate and internal cage to each other and prevent disassembly in vivo. ***Id.***

A PHOSITA would have recognized the advantages taught in the '364 patent regarding improvements to the methods for assembling modular interbody fusion devices that utilize dovetail connections to hold the components together and their applicability to the spinal implant device of the FR'034 application. ***Id.*** **at ¶78.** It would have been readily apparent to a PHOSITA that the spinal implant of the FR'034 application, where the plate is attached to the cage via a dovetail connection, would benefit from the addition of fixation screws to supplement the dovetail connections to more securely clamp the modular components together, thereby significantly reducing the possibility for the components to disassemble in vivo. ***Id.*** **at ¶79.** A PHOSITA would have considered such a modification an obvious design choice that would have yielded a predictable effect in the resulting

design and would not have changed the principle of operation of the spinal implant FR'034 application. ***Id.*** **at ¶80.**[13] Screws used in addition to the dovetail mechanism in the FR'034 application patent would provide improved clamping to substantially reduce the possibility of disassembly of the dovetail mechanism in vivo due to axial loading during lateral bending, flexion and extension by the patient. These improvements would have motivated a PHOSITA to modify the implant device of the FR'034 application in view of its teachings combined with the '364 patent. ***Id.*** **at ¶81.**

Consequently, a PHOSITA would have understood that the product resulting from such a combination would have comprised a spinal implant *wherein the thick end portion defines a thick end surface, the thick end surface having a screw passage extending therethrough,* as recited in claim 16. ***Id.*** **at ¶82.**

In claim 17, the phrase *"configured to receive an elongated shank of a screw member"* is a recitation of the intended use for the claimed apparatus, does not structurally distinguish the claimed apparatus, and is not material to patentability. As such, this language carries no patentable weight.[14] To the extent that this phrase, however, limits claim 17, as already discussed Kozak discloses that the screw bore is threaded at its base with the remainder of the bore unthreaded to guide the screw into the threaded base of the screw bore ***Id.*** **at ¶77.** The elongated

[13] *See* footnotes 6 and 7, supra.
[14] *See* footnote 4, supra.

shank portion of the screw interacts with the unthreaded portion of the bore. ***Id.*** Thus, Kozak discloses that *the screw passage is configured to receive the shank portion of the screw*, as recited in claim 17. ***Id.*** **at ¶82.**

In summary, as confirmed by Dr. Ochoa, the FR'034 application in view of Kozak renders claims 16 and 17 unpatentable as obvious under 35 U.S.C. § 103(a).

IX. CONCLUSION

Petitioner has demonstrated in this Petition that claims 1, 2, 3, 8, 9, 10, 13, 16, 17 and 18 of the '066 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '066 patent.

Dated: June 4, 2015

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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. 8,486,066 (and accompanying Exhibits **EX1001-EX1025**) 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:

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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, on this 4th day of June, 2015:

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