UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner

v.

FLEXUSPINE, INC.,
Patent Owner

Case No.: IPR2015-_____
U.S. Patent No. 7,909,869
Issued: March 22, 2011
Application No: 10/777,411
Filed: February 12, 2004

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,909,869

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8:7-12

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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 23 and 37 of U.S. Patent No. 7,909,869, titled "Artificial Spinal Unit Assemblies" ("the '869 patent"), issued to Charles Gordon, Corey T. Harbold and Heather S. Hanson and assigned to Flexuspine, Inc. ("Flexuspine"). The '869 patent is attached as **EX1001**.

For the reasons set forth herein, Petitioner asserts that all of the challenged claims are unpatentable. The ground for unpatentability presented in detail below, demonstrate how claims 23 and 37 of the '869 patent are obvious in view of the prior art. Evidentiary support for Petitioner's conclusion is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. **EX1006.**[1] Dr. Ochoa is an expert with over 25 years of experience in the area of design and development of orthopedic medical devices, surgical instruments and techniques, as well as biomechanics, and engineering biomaterials. Dr. Ochoa's declaration establishes that each of the challenged claims is 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

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

it would prevail with respect to at least one of the claim challenged in the Petition. 35 U.S.C. §314(a). Accordingly, Petitioner respectfully requests that this Petition be granted and that claims 23 and 37 of the '869 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 '869 patent is asserted in *Flexuspine, Inc. v. Globus*

Medical Inc., U.S. District Court for the Eastern District of Texas, Civil Action no. 15-cv-00201-JRG-KNM ("the Pending Litigation"). Petitioner is a party to the Pending Litigation. Notably, in the Pending Litigation, Flexuspine has accused certain of Globus's spinal implant devices of infringing the challenged claim of the '869 patent. *See* **EX1002.**

Concurrently with this Petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 7,204,853 ("the '853 patent"). U.S. Patent No. 7,316,714 ("the '714 patent"), U.S. Patent No. 8,123,810 ("the '810 patent"), and U.S. Patent No. 8,647,386 ("the '386 patent"). The '853 patent, '714 patent, '386 patent and '810 patent are related to the '869 patent through continuation practice. Petitioner understands that the '869 patent, the 853 patent, the '714 patent, the '810 patent and the '386 patent are all commonly owned by Flexuspine.

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

Petitioner certifies that (1) the '869 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 '869 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 March 13, 2015. 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. 7,909,869 ("THE '869 PATENT") (EX1001)

The '869 patent issued on March 22, 2011, on an application filed on February 12, 2004. For purposes of this Petition only, the earliest priority date for the '869 patent is August 5, 2003. Petitioner notes, however, that the subject matter of FIG. 12i, for example, was added as new matter in the continuation-in-part application. This subject matter has a priority date of February 12, 2004.

A. The '869 Patent Specification and Claims

The '869 patent is generally directed to an expandable intervertebral implant. The challenged claim is directed to a known implantable device for achieving the objective of restoration and maintenance of disk space height. The '869 patent issued with 38 claims, of which only claims 23 and 37 are at issue in this Petition. Claims 23 and 37 are independent.

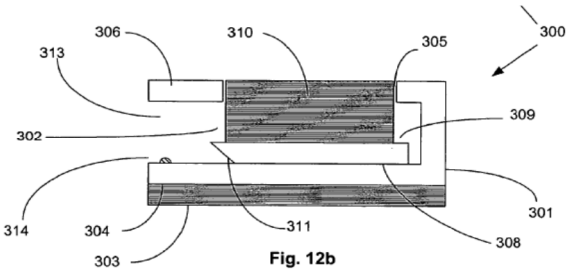


Fig. 12b

The written description and drawings of the '869 patent describe various embodiments of an intervertebral cage for restoration and maintenance of disc space height. As generally disclosed in FIG. 12a-c, the technique of expanding an artificial implant by inserting an expansion plate or similar device to expand a PLIF or TLIF cage is disclosed. **EX1001, Col. 11, line 64-Col. 12, line 18.**

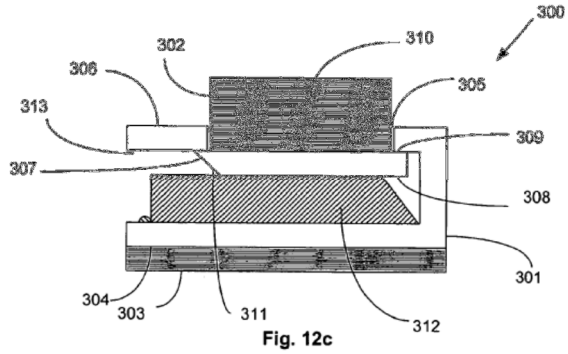


Fig. 12c

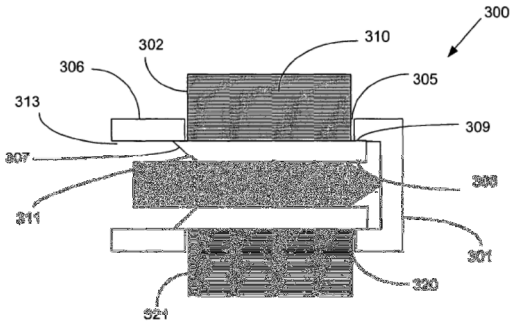


Fig. 12i

As disclosed in Fig. 12; the cage element 301 comprises an expansion window 320 through its inferior surface. ***Id.*** **at Col. 12, lines 30-36.** As expansion plate 312 is impacted into the device, both internal expandable elements 302, 321 are pushed through their respective expansion windows 305, 320. ***Id.*** **at Col. 12, lines 30-36.**

B. The '869 Patent Prosecution History (EX1003)

The prosecution of the application before the U.S. Patent and Trademark Office ("PTO") for the application leading to the '869 patent included multiple proceedings before the PTO. On September 13, 2010, the Examiner issued a Notice of Allowance. The reasons for allowance were noted as follows:

> Viccaro (U.S. Pat. No. 6,102,950) is an intervertebral implant that has inserts which may be raised up out of the cage element and into the surrounding

> vertebrae. The claims required that the insert component must be inserted into the cage element itself. Vicaro's inserts (50) are located within the upper surface of the cage element (20) and do not extend into the interior of the cage element.

***Id.* at page 107.**

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

As established in the Declaration of Dr. Ochoa, a person having ordinary skill in the art (PHOSITA) of the '869 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. **EX1006, Ochoa Decl. at ¶ 18.**

V. CLAIM CONSTRUCTION

The claims of the '869 patent are to be given their broadest reasonable construction in light of the '869 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 '869 patent, as appropriate in that proceeding.

VI. THE PRIOR ART RELIED UPON IN THIS PETITION

A. U.S. Patent No. 6,595,998 to Johnson et al. ("the '998 patent" or "Johnson") (EX1004)

U.S. Patent No. 6,595,998 to Johnson et al, entitled "Tissue Distraction Device," published July 22, 2003. Johnson is prior art to the '385 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 by the applicant of the '869 patent. Johnson patent was disclosed by the applicant to the Patent Office during the prosecution of the application leading to the '863 patent, but was not referred to or relied on by the Examiner during the prosecution.

B. U.S. Patent No. 6,176,882 to Biedermann et al. ("the '882 patent" or "Biedermann") (EX1005)

U.S. Patent No. 6,176,882 to Biedermann et al., entitled "Intervertebral Implant," published August 26, 1999. Biedermann is prior art to the '869 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 '869 patent in the United States. Biedermann was disclosed by the applicant to the Patent Office during the prosecution of the application leading to the '869 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 23 and 37 of the '869 patent is unpatentable as obvious pursuant to 35 U.S.C. § 103. The challenged claims are independent.

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 '998 patent and the '882 patent render claims 23 and 37 unpatentable as obvious under 35 U.S.C. § 103[2] (**EX1006, Ochoa Decl. at ¶ 18).**

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

This petition presents the following Grounds of unpatentability:

- Ground 1: Claim 23 is unpatentable under 35 U.S.C. § 103 as obvious over the '998 patent (**EX1004)** in view of the knowledge of one of ordinary skill in the

[2] *KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

art.

- Ground 2: Claim 37 is unpatentable under 35 U.S.C. § 103 as obvious over the '998 patent (**EX1004**) in view of the knowledge of one of ordinary skill in the art.

- Ground 3: Claim 37 is unpatentable under 35 U.S.C. § 103 as obvious over the '882 patent (**EX1005**) in view of the knowledge of one of ordinary skill in the art.

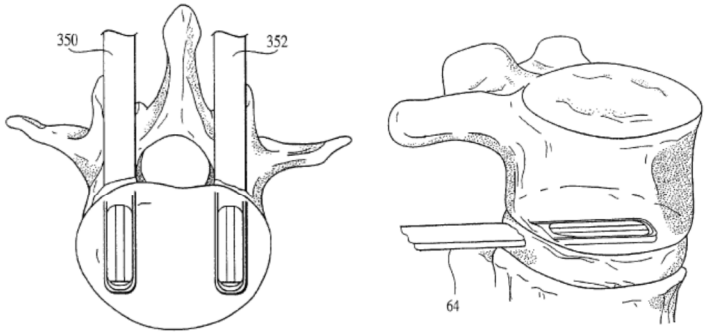
A. Ground 1: Claim 23 is unpatentable under 35 U.S.C. § 103 as obvious over the '998 patent (EX1004) in view of the knowledge of one of ordinary skill in the art

The'998 patent discloses an intervertebral implant for use in spinal fusion surgical procedures to distract and support two tissue interfaces. **EX1004, Col. 4, line 64-Col. 5, line 6.** In use, a plurality of wafers is inserted between an upper and lower vertebra to create a "wafer column" which distracts the disc space and provides support for the vertebral bodies. The resulting disclosed implant includes upper and lower wafers that engage the vertebrae and central wafers that consecutively act as inserts or expansion members. As each new wafer is added to the column, it acts as an expansion member, elevating the wafers above and below and increasing the height of the column, thereby distracting and supporting the surrounding tissues. **EX1004, Col. 5, lines 32-36; EX1006, Ochoa Decl. at ¶ 41.**

A PHOSITA would have understood that the spinal implant taught in the '998 patent renders claim 23 of the '869 patent obvious. The claim charts and accompanying text below evidence this conclusion.

1. Claim 23

Claim 23 is directed to an intervertebral implant device for a human spine. Claim 23 is obvious in view of Johnson. The claim chart and accompanying analysis below evidence this conclusion.

'869 patent Claim 23 vs. '998 patent	
23. An intervertebral implant for a human spine, comprising:	Johnson (the '998 patent) **(EX1004)** discloses: • The invention may be used to treat vertebral compression fractures, for replacement of vertebral discs, as an interbody fusion device, wedge opening high tibial osteotomy, tibial tuberosity elevation, as well as for treating other compression fractures including, but not limited to tibia plateau fractures, calcaneous, distal tibial fractures, or distal radius (wrist) fractures. **EX1004, Col. 4, line 64-Col. 5, line 6** • See **EX1004** at Figs. 60 and 61 below.  FIG. 60 FIG. 61 • Johnson discloses an intervertebral implant for a human spine. **EX1006, Ochoa Decl. at ¶ 42.**

The preamble of claim 23 states the intended use of the invention and does

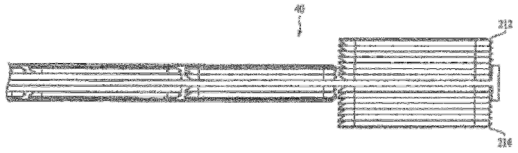
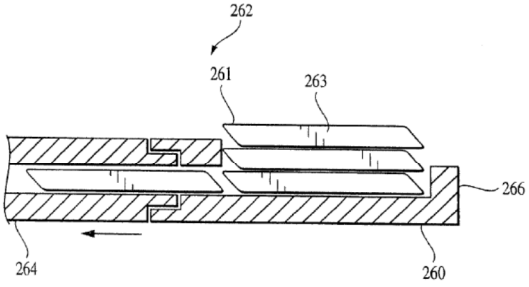
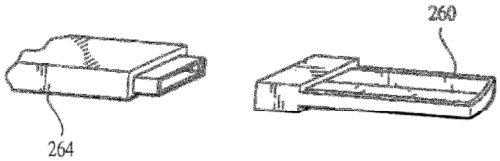
not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction.[3]

To the extent that the preamble limits the claims, a PHOSITA would have understood that the spinal implant described in the '998 patent is an intervertebral implant for use in the spine as an interbody fusion device. **EX1004, Col. 4, line 66-Col. 5, line 6, FIGS. 60 and 61.** A PHOSITA would have thus recognized that the '998 patent discloses *an intervertebral implant for a human spine*, as recited in the claims. **EX1006, Ochoa Decl. at ¶ 42.**

A PHOSITA would have thus recognized that the '998 patent discloses *an intervertebral implant for a human spine*, as recited in the claims**.** ***Id.*** **at ¶ 42.**

'869 patent Claim 23 vs. '998 patent	
a cage element with a superior surface and an inferior surface, wherein the inferior surface of the cage element comprises a first opening and the superior surface of the cage element comprises a second opening;	Johnson (the '998 patent) **(EX1004)** discloses: • The detachable tip wafer inserter embodiment, as seen in FIG. 37, includes a distal tip 260 of the wafer inserter 262 that is detachable from the main portion 264 of the inserter. One advantage provided by the detachable tip is that the height of the wafer column is not altered when the wafer inserter is removed. The tip 260 is preferably manufactured of the same material as the wafers. Thus, in a preferred embodiment, if the wafers are manufactured of PMMA, the distal tip 260 of the wafer inserter 262 is manufactured of PMMA. Alternately, the distal tip 260 may be manufactured of an implant grade metal or other medical grade implantable material. The distal tip 260 has a fixed distal shoulder 266 that holds the first wafer in place while the second wafer is inserted under the first.

[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 height of the distal shoulder 266 may provide a stop for one wafer, or it may provide a stop for two or more wafers. The considerations applicable to the height of the distal catch apply to the height of the distal shoulder as well. **EX1004, Col. 17, lines 47-64** • Both the fixed tip and detachable tip wafer inserters can be configured to deploy wafers in opposing columns. In such an embodiment, one column may be built in the positive Z-axis. Thus, if the supporting bone below the distal end of the track begins to yield, a second column in the negative Z-axis can be built by inserting wafers below the track. Once the negative Z-axis column has provided enough support for the wafer inserter, insertion of wafers into the positive Z-axis column can be resumed. The considerations applicable to distal stop or catch and material selection previously described also apply to the bidirectional wafer inserter. Reference is made to FIG. 30. **EX1004, Col. 18, lines 20-31** • See e.g. **EX1004** at Figs. 29, 37 and 38 below.  FIG. 29  FIG. 37  FIG. 38

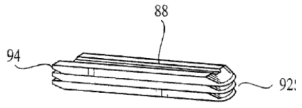
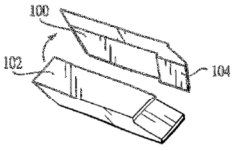
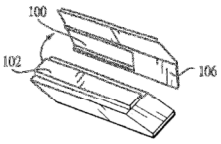
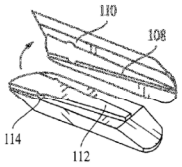
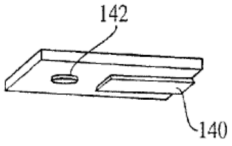
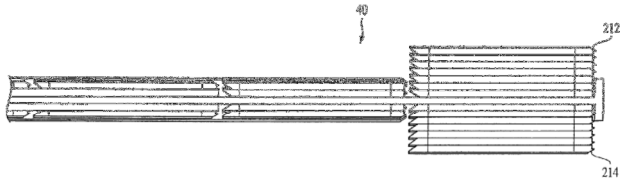
	• Johnson discloses a cage element with a superior surface and an inferior surface, wherein the inferior surface of the cage element comprises a first opening and the superior surface of the cage element comprises a second opening. **EX1006, Ochoa Decl. at ¶ 49.**

A PHOSITA would have understood that the intervertebral implant described in the '998 patent may be deployed using a wafer inserter capable of delivering wafers in opposite directions (superior and inferior). **EX1004, Col. 4, line 65-Col. 5, line 6; Col. 16, lines 52-65; FIGS. 29 and 30.** Further, a PHOSITA would have understood that use of a detachable wafer inserter tip (260) which becomes integral to the implant offers the advantage that the height of the wafer column is not altered when the wafer inserter is removed. **EX1004, Col. 17, lines 47-64; Col. 18, lines 20-31; FIGS. 37 and 38.** A PHOSITA would have understood that when using a bidirectional inserter with a detachable tip, that the tip would comprise a cage with a first opening in the superior surface and a second opening in the inferior surface through which the wafers are deployed. **EX1006, Ochoa Decl. at ¶ 49.** This is illustrated for a unidirectional wafer inserter tip in Figures 37 and 38 of the '998 patent. ***Id.* ¶ 49.**

A PHOSITA would have thus understood that the '998 patent discloses, *a cage element with a superior surface and an inferior surface, wherein the inferior surface of the cage element comprises a first opening and the superior surface of the cage element comprises a second opening*, as recited in the claims. ***Id.* ¶ 49.**

‘869 patent Claim 23 vs. ‘998 patent	
a first insert, wherein, during use, at least a portion of the first insert is inserted at least partially into the first opening, and wherein the first insert comprises a support surface that, during use, supports at least a portion of a first vertebra below and away from the inferior surface of the cage element and inhibits movement of the first vertebra towards a second vertebra; ***AND*** *a second insert, wherein, during use, at least a portion of the second insert is inserted at least partially into the second opening, and wherein the*	Johnson (the ‘998 patent) (EX1004) discloses: • An apparatus and method for distracting, in a given direction, and supporting two tissue surfaces. A plurality of wafers are consecutively inserted between the two tissue surfaces to create a column of wafers. The column of wafers is oriented between the tissue surfaces so as to expand in the given direction as the wafers are consecutively added to the column. **EX1004, Abstract** • The top of a wafer or the top of the column is defined as the face of the wafer or column in the direction of distraction. The bottom of a wafer or the bottom of the column is defined as the face opposite the top face. In similar fashion, above and below a wafer or column implies along the top and bottom of the wafer or column, respectively. Each wafer has a leading edge that enters the forming column first and a trailing edge opposite the leading edge. **EX1004, Col. 5, lines 51-59** • The axis of the column is defined as a line parallel to the direction of distraction. During implantation, the wafers are stacked to form a column to simultaneously distract and support the two tissue surfaces. The invention provides that trailing wafers can be positioned above or below the leading wafers to form a column. In one embodiment, the wafers are designed to be beveled at both their leading and trailing edges so that when lined up end-to-end, force on the trailing edge of the trailing wafer causes its leading edge to slide below the trailing edge of the leading wafer, thereby lifting up the leading wafer.**EX1004, Col. 5, line 63-Col. 6, line 7** • Alternately, the leading and trailing edges may be chevron shaped or curved when viewed from the side, enabling insertion of trailing wafers between any two leading wafers or on the top or bottom of the column. In another embodiment, the wafers may be configured with blunt edges wherein the wafers are stacked with the insertion instrument. **EX1004, Col. 6, lines 9-15** • A variation of wafer thicknesses may be used in

second insert comprises a support surface that, during use, supports at least a portion of a second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra; and	combination to form a column and multiple wafers may be inserted into the column simultaneously. **EX1004, Col. 6, lines 28-31** • In order to place the wafers between the tissue surfaces, a wafer inserter is positioned within the surgical site with access at its distal tip to the tissue surfaces to be distracted and supported. A wafer is placed on the track and a plunger is used to advance the wafer to the distal end of the track. This is repeated with consecutive wafers until a column of sufficient height is created per physician discretion. After the wafer(s) have been inserted, the insertion device is removed. The distal end of the insertion device may be manufactured from the same material as the wafers and/or be detachable. In this embodiment, the distal end of the insertion instrument would be detached after placing the wafer column, and the instrument removed. **EX1004, Col. 6, lines 36-48** • In addition, the wafer thickness may be uniform or varied. Specifically, the wafers may be either flat or wedged, or alternatively include a combination of flat and wedged wafers. **EX1004, Col. 10, lines 61-64** • It may be advantageous to form multiple wafer columns extending axially in opposite directions. This can be done by a variety of different methods. One method involves using multiple wafer inserters. For example, if two opposing wafer columns are to be formed, then one wafer inserter is deployed to form a wafer column directed superiorly, while a second wafer inserter is deployed to form a wafer column inferiorly, opposite the first column. The separate wafer inserters may have different access locations through the cortical wall of the vertebral body. The wafer inserters may be parallel to one another, or skewed to one another, or one may enter the vertebral body through the ipsilateral cortex relative to the first wafer inserter. In addition, the wafer inserters may be adjacent one another or may be separated by cancellous bone. Alternately, as seen in FIGS. 29 and 30, a single wafer inserter 40 might be used wherein the wafer inserter is able to deploy wafers in opposing directions, one column deployed superiorly 212 and the other deployed

	inferiorly 214. Deployment of wafers in each direction may be independent, in which case the physician, based on intraoperative assessment, may expand the wafer column proximally or distally as needed. Alternatively, wafer deployment may be simultaneous in each direction, in which case a wafer would be added to the wafer columns forming in opposing directions. **EX1004, Col. 14, line 47-Col. 15, line 4** • See e.g. **FIGS. 8, 10, 12, 14, 16, 24, 26, and 29.**  FIG. 8  FIG. 10  FIG. 12  FIG. 14  FIG. 16  FIG. 24  FIG. 26  FIG. 29 • Johnson discloses a first insert, wherein, during use, at least a portion of the first insert is inserted at least partially into the first opening, and wherein the first insert comprises a support surface that, during use, supports at least a portion of a first vertebra below and away from the inferior surface of the cage element and inhibits movement

	of the first vertebra towards a second vertebra **and** a second insert, wherein, during use, at least a portion of the second insert is inserted at least partially into the second opening, and wherein the second insert comprises a support surface that, during use, supports at least a portion of a second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra. **EX1006, Ochoa Decl. at ¶ 50.**

A PHOSITA would have understood that during use of the implant as an interbody fusion device, the wafer columns described in the '998 patent, would distract and provide support between the bone surfaces of a decorticated superior and decorticated inferior endplate. **EX1004, Abstract; Col. 24, lines 43-53.** A PHOSITA would have understood that by distracting and providing support to adjacent vertebrae, the interbody fusion device would occupy the intervertebral space thereby inhibiting movement of the vertebrae toward each other. **EX1006, Ochoa Decl. at ¶ 50.** The '998 patent discloses that each wafer in the column comprises a superior (upper) and inferior (lower) surface. **EX1004, Col. 5, lines 51-55.** The wafers may be flat or wedged with substantially planar surfaces. **EX1004, Col. 5, lines 51-59; Col. 10, lines 61-64; FIGS. 8, 10, 12, 14, 16, 24, 26, 29, 30.** A PHOSITA would have understood that the external, superior surface of the first insert, or uppermost wafer in the wafer column would contact and support the inferior surface of the superior endplate of a first vertebra while the internal,

lower surface of the uppermost wafer in the wafer column would engage the second highest wafer in the column. **EX1004, Col. 5, line 63-Col. 6, line 7; Col. 24, lines 43-48; FIGS. 29, 60 and 61; EX1006, Ochoa Decl. at ¶ 50.** Similarly, the external, inferior surface of the second insert, or lowest wafer in the wafer column would contact and support the superior surface of the inferior endplate of a second vertebra while the internal upper surface of the lowest wafer in the column would engage the second lowest wafer in the column. **EX1004, Col. 5, line 63-Col. 6, line 7; Col. 24, lines 43-48; FIGS. 29, 60 and 61; EX1005, Ochoa Decl. at ¶ 50.** Further, a PHOSITA would have understood that during use, the wafer inserter is positioned within the surgical site with access at its distal tip to the vertebral endplates. **EX1004, Col. 6, lines 36-48**. Wafer deployment may separate in each direction, in which case a wafer would be added to the wafer columns forming opposing directions, or alternatively a wafer with a chevron shaped leading end may be used to simultaneously distract the upper and lower bodies. **EX1004, Col. 14, line 47-Col. 15, line 4; Col; 6, lines 9-15; Col. 6, lines 28-31**. As this is repeated until a column of sufficient height is created, the first and second member followed by each subsequent wafer would traverse, or be inserted at least partially through the first and second opening in the cage ("detachable inserter tip" 260). **EX1004, Col. 6, lines 36-48; FIGS. 30 and 37.**

A PHOSITA would have thus understood that the '998 patent discloses, *a*

first insert, wherein, during use, at least a portion of the first insert is inserted at least partially into the first opening, and wherein the first insert comprises a support surface that, during use, supports at least a portion of a first vertebra below and away from the inferior surface of the cage element and inhibits movement of the first vertebra towards a second vertebra **and** *a second insert, wherein, during use, at least a portion of the second insert is inserted at least partially into the second opening, and wherein the second insert comprises a support surface that, during use, supports at least a portion of a second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra,* as recited in the claims. **EX1006, Ochoa Decl. ¶ 50.**

'869 patent Claim 23 vs. '998 patent	
an expansion member that, during use, is inserted in a third opening in the cage element to lower the support surface of the first insert below and away from the inferior surface of the cage element to support at least a portion of the first vertebra	Johnson (the '998 patent) **(EX1004)** discloses: • During implantation, the wafers are stacked to form a column to simultaneously distract and support the two tissue surfaces. The invention provides that trailing wafers can be positioned above or below the leading wafers to form a column. In one embodiment, the wafers are designed to be beveled at both their leading and trailing edges so that when lined up end-to-end, force on the trailing edge of the trailing wafer causes its leading edge to slide below the trailing edge of the leading wafer, thereby lifting up the leading wafer.**EX1004, Col. 5, line 66-Col. 6, line 7** • Alternately, the leading and trailing edges may be chevron shaped or curved when viewed from the side, enabling insertion of trailing wafers between any two leading wafers or on the top or bottom of the column. In another

below and away from the inferior surface of the cage element and inhibit movement of the first vertebra towards a second vertebra, ***AND*** *wherein the expansion member when inserted in the third opening raises the support surface of the second insert above and away from the superior surface of the cage element to support at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra.*	embodiment, the wafers may be configured with blunt edges wherein the wafers are stacked with the insertion instrument. **EX1004, Col. 6, lines 9-15** • A variation of wafer thicknesses may be used in combination to form a column and multiple wafers may be inserted into the column simultaneously. **EX1004, Col. 6, lines 28-31** • It may be advantageous to form multiple wafer columns extending axially in opposite directions. This can be done by a variety of different methods. One method involves using multiple wafer inserters. For example, if two opposing wafer columns are to be formed, then one wafer inserter is deployed to form a wafer column directed superiorly, while a second wafer inserter is deployed to form a wafer column inferiorly, opposite the first column. The separate wafer inserters may have different access locations through the cortical wall of the vertebral body. The wafer inserters may be parallel to one another, or skewed to one another, or one may enter the vertebral body through the ipsilateral cortex relative to the first wafer inserter. In addition, the wafer inserters may be adjacent one another or may be separated by cancellous bone. Alternately, as seen in FIGS. 29 and 30, a single wafer inserter 40 might be used wherein the wafer inserter is able to deploy wafers in opposing directions, one column deployed superiorly 212 and the other deployed inferiorly 214. Deployment of wafers in each direction may be independent, in which case the physician, based on intraoperative assessment, may expand the wafer column proximally or distally as needed. Alternatively, wafer deployment may be simultaneous in each direction, in which case a wafer would be added to the wafer columns forming in opposing directions. **EX1004, Col. 14, line 47-Col. 15, line 4** • See e.g. **EX1004 at FIGS. 29, 30 and 37**

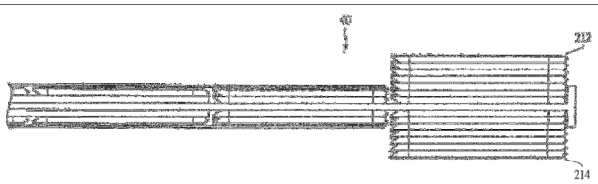


FIG. 29

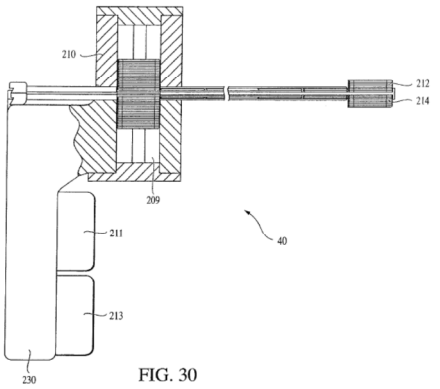


FIG. 30

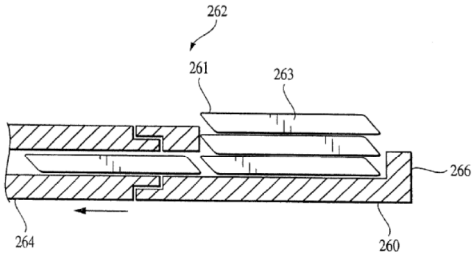


FIG. 37

- Johnson discloses an expansion member that, during use, is inserted in a third opening in the cage element to lower the support surface of the first insert below and away from the inferior surface of the cage element to support at least a portion of the first vertebra below and away from the inferior surface of the cage element and inhibit movement of the first vertebra towards a second vertebra,. **EX1006, Ochoa Decl. at ¶ 51.**

A PHOSITA would have understood the proximal opening in the detachable tip (260) disclosed in the ’998 Patent would form a third opening through which an expansion element in the form of a wafer (70) which is inserted during use. **EX1004, FIGS. 37 and 38.** A PHOSITA would have understood that during use,

the wafers are stacked to form a column to simultaneously distract and support the vertebral endplates. **EX1004, Col. 5, line 66-Col. 6, line 7.** The wafers, including the first member and second member, are designed to be beveled at both their leading and trailing ends. **EX1006, Ochoa Decl. at ¶ 51.** When lined up end to end, force on the trailing edge of the expansion element, (i.e. each wafer following the first and second members) cause its leading edge to slide below the first member, or alternatively above the second member thereby increasing the distance between the first and second member. **EX1004, Col. 5, line 66-Col. 6, line 7; FIGS. 29, 30 and 37.** The relative location of the beveling of sequential wafers determines the directionality of its deployment (inferior or superior). **EX1006, Ochoa Decl. at ¶ 51.** Wafer deployment may be simultaneous in each direction, in which case an expansion member in the form of a wafer would be added to the wafer columns forming opposing directions, or alternatively an expansion member (wafer) with a chevron shaped leading end may be used to simultaneously distract the upper and lower bodies. **EX1004, Col. 14, line 47-Col. 15, line 4; Col. 6, lines 9-15; Col. 6, lines 28-31; EX1006, Ochoa Decl. at ¶ 51.** A PHOSITA would have understood that by distracting both the upper and lower bodies simultaneously, the support surface of the first insert would be lowered below and away from the inferior surface of the cage element while the support surface of the second insert would be raised above and away from the superior surface of the cage element.

EX1006, Ochoa Decl. at ¶ 51. Further, a PHOSITA would have understood that during use of the implant as an interbody fusion device, the wafer columns described in the '998 patent, would distract and provide support between the bone surfaces of a decorticated superior and decorticated inferior endplate. **EX1004, Abstract; Col. 24, lines 43-53.** A PHOSITA would have understood that by distracting and providing support to adjacent vertebrae, the interbody fusion device would occupy the intervertebral space thereby inhibiting movement of the vertebrae toward each other. **EX1006, Ochoa Decl. at ¶ 51.**

A PHOSITA would have thus understood that the '998 patent discloses, *an expansion member that, during use, is inserted in a third opening in the cage element to lower the support surface of the first insert below and away from the inferior surface of the cage element to support at least a portion of the first vertebra below and away from the inferior surface of the cage element and inhibit movement of the first vertebra towards a second vertebra,* and *wherein the expansion member when inserted in the third opening raises the support surface of the second insert above and away from the superior surface of the cage element to support at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra,* as recited in the claims. **EX1006, Ochoa Decl. ¶ 51.**

A summary illustrating the elements is included in Figures 1 and 2 below.

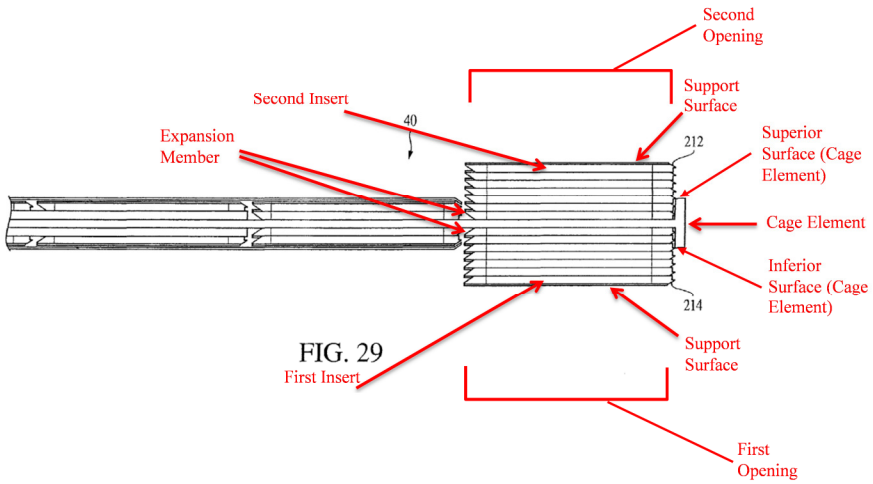


Figure 1. Excerpt from Figure 29 of the '998 patent demonstrating the various claim elements.

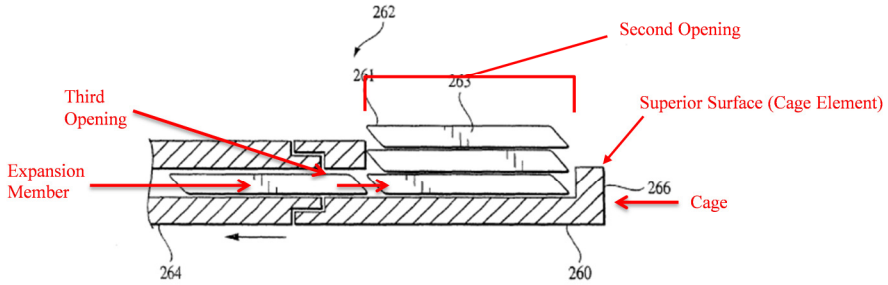


Figure 2. Excerpt from Figure 37 of the '998 patent demonstrating the detachable inserter tip. Note that the inserter tip is shown in the unidirectional embodiment and would be symmetrical in the bidirectional embodiment.

***Id.* at ¶ 51.**

The claim charts attached as **EX1018** provide additional details supporting the information that would have been conveyed by the '998 Patent and understood by a PHOSITA at the time of the invention of the '869 Patent.

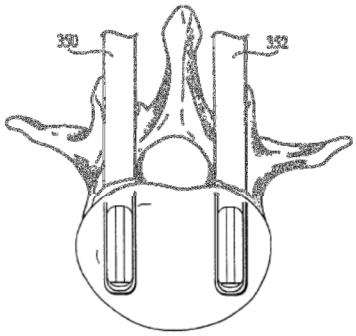
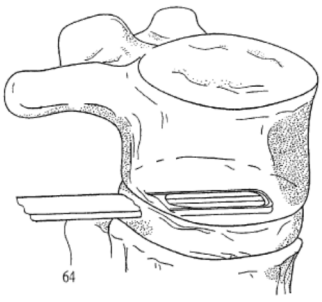
Consequently, and as supported by Dr. Ochoa, the '998 patent and renders claim 23 unpatentable under 35 U.S.C. § 103.

B. Ground 2: Claim 37 is unpatentable under 35 U.S.C. § 103 as obvious over the '998 patent (EX1004) in view of the knowledge of one of ordinary skill in the art

A PHOSITA would have understood that the spinal implant taught in the '998 patent renders claim 37 of the '869 patent obvious. The claim charts and accompanying text below evidence this conclusion.

1. Claim 37

Claim 37 is directed to an intervertebral implant device for a human spine. Claim 37 is obvious in view of Johnson. The claim chart and accompanying analysis below evidence this conclusion.

'869 patent Claim 37 vs. '998 patent	
37. An intervertebral implant for a human spine, comprising:	Johnson (the '998 patent) **(EX1004)** discloses: • The invention may be used to treat vertebral compression fractures, for replacement of vertebral discs, as an interbody fusion device, wedge opening high tibial osteotomy, tibial tuberosity elevation, as well as for treating other compression fractures including, but not limited to tibia plateau fractures, calcaneous, distal tibial fractures, or distal radius (wrist) fractures. **EX1004, Col. 4, line 64-Col. 5, line 6** • See **EX1004** at Figs. 60 and 61 below.  FIG. 60  FIG. 61

	• Johnson discloses an intervertebral implant for a human spine. **EX1006, Ochoa Decl. at ¶ 42.**

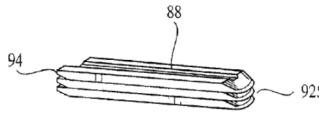
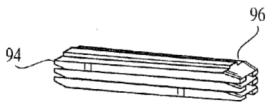
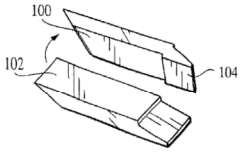
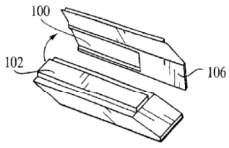
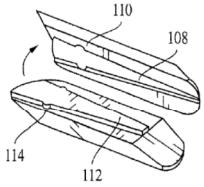
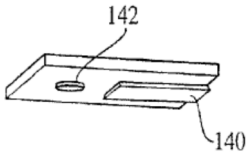
The preamble of claim 37 state the intended use of the invention and do not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction.[4]

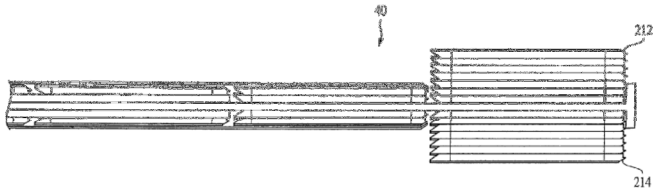
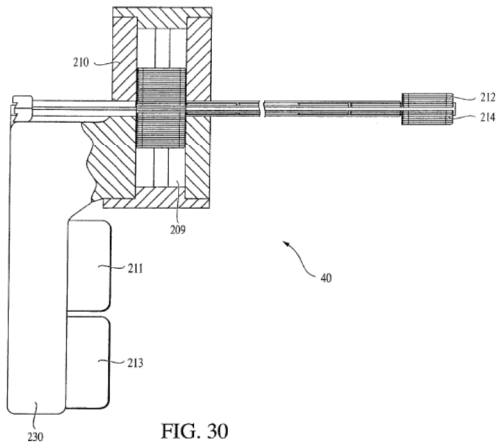
To the extent that the preamble limits the claim, a PHOSITA would have understood that the spinal implant of the '998 patent is for use in spinal fusion surgical procedures in association with vertebrae in a patient's spine. A PHOSITA would have understood that the spinal implant described in the '998 patent is an intervertebral implant for use in the spine as an interbody fusion device. **EX1004, Col. 4, Line 66-Col. 5, line 6, FIGS. 60 and 61; EX1006, Ochoa Decl. at ¶ 42.**

A PHOSITA would have thus recognized that the '998 patent discloses *an intervertebral implant for a human spine*, as recited in the claims**.** ***Id.*** **at ¶ 42.**

'869 patent Claim 37 vs. '998 patent	
a first member comprising a first inferior surface and a first superior surface, where the first superior surface comprises a substantially	Johnson (the '998 patent) **(EX1004)** discloses: • An apparatus and method for distracting, in a given direction, and supporting two tissue surfaces. A plurality of wafers are consecutively inserted between the two tissue surfaces to create a column of wafers. The column of wafers is oriented between the tissue surfaces so as to expand in the given direction as the wafers are consecutively added to the column. **EX1004, Abstract** • The top of a wafer or the top of the column is defined as

[4] *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.

planar surface configured to contact and support a first vertebra of a human spine; ***AND*** *a second member comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebra of a human spine;*	the face of the wafer or column in the direction of distraction. The bottom of a wafer or the bottom of the column is defined as the face opposite the top face. In similar fashion, above and below a wafer or column implies along the top and bottom of the wafer or column, respectively. Each wafer has a leading edge that enters the forming column first and a trailing edge opposite the leading edge. **EX1004, Col. 5, lines 51-59** • See e.g. **EX1004** at FIGS. 8, 10, 12, 14, 16, 24, and 26 below.  FIG. 8  FIG. 10  FIG. 12  FIG. 14  FIG. 16  FIG. 24  FIG. 26 • During implantation, the wafers are stacked to form a column to simultaneously distract and support the two tissue surfaces. The invention provides that trailing wafers can be positioned above or below the leading wafers to form a column. In one embodiment, the wafers are designed to be beveled at both their leading and trailing edges so that when lined up end-to-end, force on the trailing edge of the trailing wafer causes its leading edge to slide below the trailing edge of the leading wafer, thereby lifting up the leading wafer. **EX1004, Col. 5, lines 64-Col. 6, line 7**

	• See e.g. **EX__** at Fig. 29 below.  FIG. 29 • The invention provides that the wafer column is formed in vivo by using a wafer inserter. FIG. 3 illustrates a wafer inserter 64 placed within a vertebral body with a wafer 66 positioned distally on the wafer inserter 64. During implantation, the wafers are stacked to form a column to restore vertebral height. FIGS. 25 and 26 show a wafer column 192 supporting the proximal end plate of a vertebral body. **EX1004, Col. 10, lines 1-8** • In addition, the wafer thickness may be uniform or varied. Specifically, the wafters may be either flat or wedged, or alternatively include a combination of flat and wedged wafers. **EX1004, Col. 10, lines 61-64** • The prepared surface supports the wafer columns. A wafer inserter is placed in each opening. It is preferred to insert wafers in an alternating fashion between the two inserters to uniformly distract the annulus. **EX1004, Col. 24, lines 49-53** • See e.g. **EX1004** at Fig. 30 below.  FIG. 30 • Johnson discloses a first member comprising a first

	inferior surface and a first superior surface, where the first superior surface comprises a substantially planar surface configured to contact and support a first vertebra of a human spine and a second member comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebra of a human spine. **EX1004, Ochoa Decl. at ¶ 43.**

The phrase "*a first member comprising a first inferior surface and a first superior surface, where the first superior surface comprises a substantially planar surface configured to contact and support a first vertebra of a human spine,*" **and** "*a second member comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebra of a human spine,*" is a recitation 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.[5] Moreover, a PHOSITA would not understand the limitation, *configured to contact*," to disclose any intrinsic or structural limitation of the implant. **EX1006, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Johnson reference discloses these limitations. A PHOSITA would have understood that

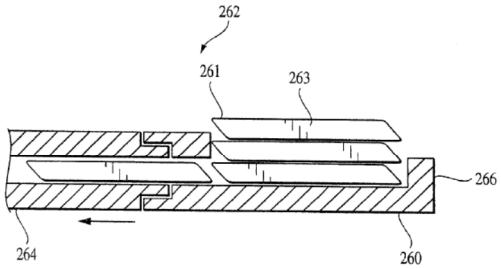
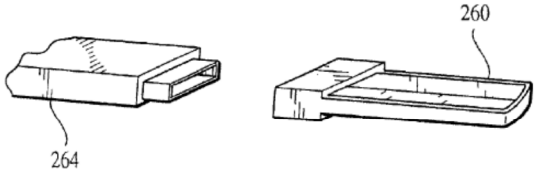
[5] *In re Schreiber,* 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart,* 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); *and In re Danly,* 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

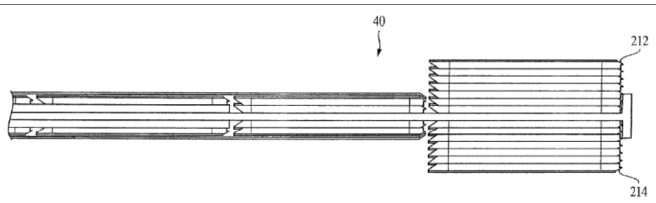
during use of the implant as an interbody fusion device, the wafer columns described in the '998 patent would distract and provide support between the bone surfaces of a decorticated superior and decorticated inferior endplate. ***Id.*** **at ¶ 43; EX1004, Abstract; Col. 24, lines 43-53.** Each wafer in the column comprises a superior (upper) and inferior (lower) surface. **EX1004, Col. 5, lines 51-55.** The wafers may be flat or wedged with substantially planar surfaces. ***Id.*** **at Col. 5, lines 51-59; Col. 10, lines 61-64; FIGS. 8, 10, 12, 14, 16, 24, 26, 29 and 30.** A PHOSITA would have understood that the external, superior surface of the first member, or uppermost wafer in the wafer column would contact and support the inferior surface of the superior endplate of a first vertebra while the internal, lower surface of the uppermost wafer in the wafer column would engage the second highest wafer in the column. ***Id.*** **at Col.5, lines 63-Col. 6, line 7; Col. 10, lines 1-8; Col. 24, lines 43-58; FIGS. 29, 60 and 61; EX1006, Ochoa Decl. at ¶ 43.** Similarly, the external, inferior surface of the second member, or lowest wafer in the wafer column would contact and support the superior surface of the inferior endplate of a second vertebra while the internal upper surface of the lowest wafer in the column would engage the second lowest wafer in the column. **EX1004, Col.5, lines 63-Col. 6, line 7; Col. 10, lines 1-8; Col. 24, lines 43-58; FIGS. 29, 60 and 61; EX1006, Ochoa Decl. at ¶ 43.** Further, a PHOSITA would have understood that the first and second members each comprise both inferior and

superior surfaces, whereby on each member ("wafer") an outward facing surface (first superior surface for first member, second inferior surface for second member) has a substantially planar rectangular contour facing toward each vertebral body. **EX1004, Col.5, lines 51-59; Col. 10, lines 61-64; FIGS. 8, 10, 12, 14, 16, 24, 26, 29, and 30; EX1006, Ochoa Decl. at ¶ 43.**

A PHOSITA would have thus understood that the '998 patent discloses, *a first member comprising a first inferior surface and a first superior surface, where the first superior surface comprises a substantially planar surface configured to contact and support a first vertebra of a human spine*, **and** *a second member comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebra of a human spine*, as recited in the claims. **EX1006, Ochoa Decl. ¶ 43.**

'869 patent Claim 37 vs. '998 patent	
a cage comprising a first opening in a superior surface of the cage and a second opening in an inferior surface of the cage, wherein, during use, the first member is inserted at least	The '998 patent (**EX1004**) discloses: • The detachable tip wafer inserter embodiment, as seen in FIG. 37, includes a distal tip 260 of the wafer inserter 262 that is detachable from the main portion 264 of the inserter. One advantage provided by the detachable tip is that the height of the wafer column is not altered when the wafer inserter is removed. The tip 260 is preferably manufactured of the same material as the wafers. Thus, in a preferred embodiment, if the wafers are manufactured of PMMA, the distal tip 260 of the wafer inserter 262 is manufactured of PMMA. Alternately, the distal tip 260 may be manufactured of an implant grade metal or other

partially into the first opening and the second member is inserted at least partially in the second opening; and	medical grade implantable material. The distal tip 260 has a fixed distal shoulder 266 that holds the first wafer in place while the second wafer is inserted under the first. The height of the distal shoulder 266 may provide a stop for one wafer, or it may provide a stop for two or more wafers. The considerations applicable to the height of the distal catch apply to the height of the distal shoulder as well. **Col. 17, lines 47-63** • See e.g. **EX1004** at Figs. 37 and 38 below.  FIG. 37  FIG. 38 • Both the fixed tip and detachable tip wafer inserters can be configured to deploy wafers in opposing columns. In such an embodiment, one column may be built in the positive Z-axis. Thus, if the supporting bone below the distal end of the track begins to yield, a second column in the negative Z-axis can be built by inserting wafers below the track. Once the negative Z-axis column has provided enough support for the wafer inserter, insertion of wafers into the positive Z-axis column can be resumed. The considerations applicable to distal stop or catch and material selection previously described also apply to the bidirectional wafer inserter. Reference is made to FIG. 30. **Col. 18, lines 20-31** • See e.g. **EX1004** at Fig. 29 below.

	 FIG. 29 • Johnson discloses a cage comprising a first opening in a superior surface of the cage and a second opening in an inferior surface of the cage, wherein, during use, the first member is inserted at least partially into the first opening and the second member is inserted at least partially in the second opening. **EX1006, Ochoa Decl. at ¶ 44.**

A PHOSITA would have understood that the intervertebral implant described in the '998 patent comprises a cage since a cage is a type of interbody implant that may be packed with bone graft and is used to mechanically stabilize the intervertebral region during fusion. **EX1004, Col. 9, lines 58-67; Col. 24, lines 49-53.** A PHOSITA would have understood that the device may be deployed using a wafer inserter capable of delivering wafers in opposite directions (superior and inferior). ***Id.*** **at Col. 16, Lines 52-65, FIGS. 29 and 30.** Further, a PHOSITA would have understood that use of a detachable wafer inserter tip (260) which becomes integral to the implant offers the advantage that the height of the wafer column is not altered when the wafer inserter is removed. ***Id.*** **at Col. 17, lines 47-64; Col. 18, lines 20-31; FIGS. 37 and 38; EX1006, Ochoa Decl. at ¶ 44.** A PHOSITA would have understood that when using a bidirectional inserter with a detachable tip, that the tip would comprise a cage with a first opening in the

superior surface and a second opening in the inferior surface. **EX1006, Ochoa Decl. at ¶ 44.** This is illustrated for a unidirectional wafer inserter tip in Figures 37 and 38 of the '998 patent. **EX1006, Ochoa Decl. at ¶ 44.** A PHOSITA would have understood that during use, wafer inserter is positioned within the surgical site with access at its distal tip to the vertebral endplates. **EX1004, Col. 6, lines 36-48.** A first and second member (first inferior and first superior wafer) are advanced to the distal end of the track. **EX1004, Col. 6, lines 36-48; FIG. 30.** As this is repeated until a column of sufficient height is created, the first and second member followed by each subsequent wafer would be inserted, at least partially through the first and second opening in the cage ("detachable inserter tip" 260). **EX1004, Col. 6, lines 36-48; FIGS. 30 and 37**; **EX1006, Ochoa Decl. at ¶ 44.**

A PHOSITA would have thus understood that the '998 patent discloses, *a cage comprising a first opening in a superior surface of the cage and a second opening in an inferior surface of the cage, wherein, during use, the first member is inserted at least partially into the first opening and the second member is inserted at least partially in the second opening,* as recited in the claims. **EX1006, Ochoa Decl. at ¶ 44.**

'869 patent Claim 37 vs. '998 patent	
an expansion element that, during use, is inserted between	The '998 patent (**EX1004**) discloses: • In use, the wafers are preferably stacked between two tissue surfaces as they are implanted, thereby distracting and supporting the tissue surfaces simultaneously. In the

the first inferior surface of the first member and the second superior surface of the second member, wherein insertion of the expansion member expands the first and second members relative to one another to increase a separation distance between the first superior surface of the first member and the second inferior surface of the second member, wherein the first superior surface is expanded above the superior surface of the cage and the second inferior surface is expanded below the inferior surface of the cage, such that the distance between the first superior surface	vertebral compression fracture application, it is preferable to distract along the Z-axis (along the axis of the spine) to restore vertebral height. However, in other applications, it may be preferable to provide distraction in a different direction. The features of a wafer and a column of wafers will be described relative to position and direction. The top of a wafer or the top of the column is defined as the face of the wafer or column in the direction of distraction. The bottom of a wafer or the bottom of the column is defined as the face opposite the top face. In similar fashion, above and below a wafer or column implies along the top and bottom of the wafer or column, respectively. Each wafer has a leading edge that enters the forming column first and a trailing edge opposite the leading edge. The sides of the wafer are adjacent the leading and trailing edges and the top and bottom faces of the wafer. In general, the sides are longer than the leading and trailing edges, however the sides may be shorter than the leading and trailing edges. The axis of the column is defined as a line parallel to the direction of distraction. **EX1004, Col. 5, lines 42-65** • During implantation, the wafers are stacked to form a column to simultaneously distract and support the two tissue surfaces. The invention provides that trailing wafers can be positioned above or below the leading wafers to form a column. In one embodiment, the wafers are designed to be beveled at both their leading and trailing edges so that when lined up end-to-end, force on the trailing edge of the trailing wafer causes its leading edge to slide below the trailing edge of the leading wafer, thereby lifting up the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7** • Alternately, the leading and trailing edges may be chevron shaped or curved when viewed from the side, enabling insertion of trailing wafers between any two leading wafers or on the top or bottom of the column. In another embodiment, the wafers may be configured with blunt edges wherein the wafers are stacked with the insertion instrument. **EX1004, Col. 6, lines 9-15** • The invention provides that the wafer column is formed in vivo by using a wafer inserter. FIG. 3 illustrates a wafer

and the second inferior surface is greater than the distance between the superior surface and the inferior surface of the cage, and wherein the first superior surface supports at least a portion of the first vertebra above the superior surface of the cage and the second inferior surface supports at least a portion of the second vertebra below the inferior surface of the cage.	inserter 64 placed within a vertebral body with a wafer 66 positioned distally on the wafer inserter 64. During implantation, the wafers are stacked to form a column to restore vertebral height. FIGS. 25 and 26 show a wafer column 192 supporting the proximal end plate of a vertebral body. **EX1004, Col. 10, lines 1-8** • It may be advantageous to form multiple wafer columns extending axially in opposite directions. This can be done by a variety of different methods. One method involves using multiple wafer inserters. For example, if two opposing wafer columns are to be formed, then one wafer inserter is deployed to form a wafer column directed superiorly, while a second wafer inserter is deployed to form a wafer column inferiorly, opposite the first column. The separate wafer inserters may have different access locations through the cortical wall of the vertebral body. The wafer inserters may be parallel to one another, or skewed to one another, or one may enter the vertebral body through the ipsilateral cortex relative to the first wafer inserter. In addition, the wafer inserters may be adjacent one another or may be separated by cancellous bone. Alternately, as seen in FIGS. 29 and 30, a single wafer inserter 40 might be used wherein the wafer inserter is able to deploy wafers in opposing directions, one column deployed superiorly 212 and the other deployed inferiorly 214. Deployment of wafers in each direction may be independent, in which case the physician, based on intraoperative assessment, may expand the wafer column proximally or distally as needed. Alternatively, wafer deployment may be simultaneous in each direction, in which case a wafer would be added to the wafer columns forming in opposing directions. **EX1004, Col. 14, line 47-Col. 15, line 4** • Alternatively, wafter deployment may be simultaneous in each direction, in which case a wafer would be added to the wafer columns forming in opposing directions. **EX1004, Col. 15, lines 1-4** • See e.g. **EX1004** at Figs. 29 and 30 below.

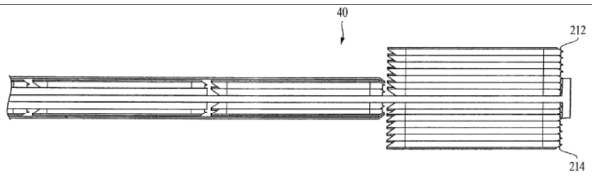


FIG. 29

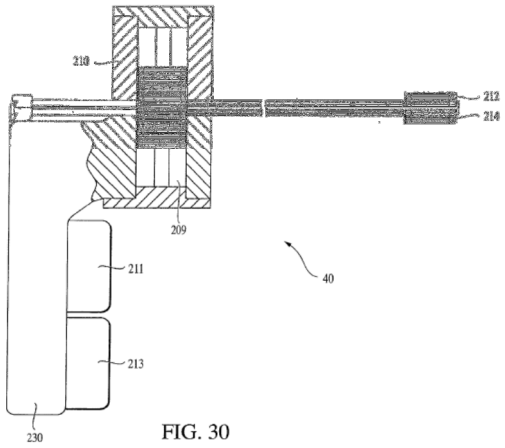


FIG. 30

- Johnson discloses an expansion element that, during use, is inserted between the first inferior surface of the first member and the second superior surface of the second member, wherein insertion of the expansion member expands the first and second members relative to one another to increase a separation distance between the first superior surface of the first member and the second inferior surface of the second member, wherein the first superior surface is expanded above the superior surface of the cage and the second inferior surface is expanded below the inferior surface of the cage, such that the distance between the first superior surface and the second inferior surface is greater than the distance between the superior surface and the inferior surface of the cage, and wherein the first superior surface supports at least a portion of the first vertebra above the superior surface of the cage and the second inferior surface supports at least a portion of the second vertebra below the inferior surface of the cage. **EX1006, Ochoa Decl. at ¶ 45-48.**

A PHOSITA would have understood the ’998 Patent discloses an expansion element in the form of a wafer (70) which is inserted under or above a preceding

wafer to form a wafer column (72) after insertion of the intervertebral implant in the spine. **EX1004, Col. 10, lines 8-24; Col. 5, lines 42-65; Col. 5, line 66-Col. 6, line 7; FIGS. 4 and 29.** A PHOSITA would have understood that during use, the wafers are stacked to form a column to simultaneously distract and support the vertebral endplates. **EX1004, Col. 5, line 66-Col. 6, line 7.** A wafer inserter is used to deploy wafers in opposite directions such that one wafer or wafer column is deployed superiorly (212), while the other wafer or wafer column is deployed inferiorly (214). **EX1004, Col. 14, line 61-Col. 15, line 4; FIGS. 29 and 30.** Therefore, a PHOSITA would have understood that the wafers, including the first member and second member, are designed to be beveled at both their leading and trailing ends. **EX1006, Ochoa Decl. at ¶ 45.** When lined up end to end, force on the trailing edge of the expansion element, (i.e. each wafer following the first and second members) cause its leading edge to slide below first member, or alternatively above the second member thereby increasing the distance between the first and second member. **EX1004, Col. 5, line 66-Col. 6, line 7; FIGS. 29, 30 and 37.** The relative location of the beveling of sequential wafers determines the directionality of its deployment (inferior or superior). **EX1006, Ochoa Decl. at ¶ 45.** Wafer deployment may be simultaneous in each direction, in which case a wafer would be added to the wafer columns forming opposite directions, or alternatively, a wafer with a chevron shaped leading end may be used to

simultaneously distract the upper and lower bodies. **EX1004, Col. 14, lines 47-Col. 15, line 4; Col. 6, lines 9-15; Col. 6, lines 28-31.**

A PHOSITA would have, therefore understood that the '998 patent discloses, *an expansion element that, during use, is inserted between the first inferior surface of the first member and the second superior surface of the second member, wherein insertion of the expansion member expands the first and second members relative to one another to increase a separation distance between the first superior surface of the first member and the second inferior surface of the second member,* as recited in the claims. **EX1006, Ochoa Decl. at ¶ 45.**

A PHOSITA would have understood that the '998 patent discloses that during use of the expansion element ("wafer" 70, 72) the first superior surface of the first member ("wafer", "wafers columns", "stackable wafers", 70, 72, 66, 192) is expanded above the edge of the implant, and similarly the second inferior surface of the second member ("wafer", "wafers columns", "stackable wafers", 70, 72, 66, 192) is expanded below the edge of the implant, or above and below the edges of the original wafer column or stack before it was expanded. **EX1006, Ochoa Decl. at ¶ 45.** In the '998 Patent, Figure 29 shows how a wafer inserter deploys wafers in opposing directions thus increasing the distance between the superior surface and inferior surface of the original wafer column. **EX1004, Col. 4, lines 61-65; FIGS. 29 and 30; EX1006, Ochoa Decl. at ¶ 46.**

A PHOSITA would have, therefore understood that the '998 patent discloses, *wherein the first superior surface is expanded above the superior surface of the cage and the second inferior surface is expanded below the inferior surface of the cage, such that the distance between the first superior surface and the second inferior surface is greater than the distance between the superior surface and the inferior surface of the cage*, as recited in the claims. **EX1006, Ochoa Decl. at ¶ 46.**

A PHOSITA would have understood that the '998 patent discloses that during use of the expansion element the first superior surface of the first member ("wafer" 70, 72) and second inferior surface of the second member ("wafer" 70, 72) are moved superiorly and inferiorly, respectively to distract and support two tissue surfaces. **EX1004, Col. 5, lines 42-45; Col. 5, line 66-Col. 6, line 7; Col. 14, lines 61-65; FIG. 29.** A PHOSITA would have understood that the using the wafer inserter to distract the annulus and stabilize and support adjacent vertebrae would require the first superior surface to be expanded beyond the superior surface of the cage ("detachable inserter tip" 260)and the second inferior surface to be expanded beyond the inferior surface of the cage ("detachable inserter tip" 260). **EX1004, Col. 24, lines 49-53; FIGS. 29 and 37; EX1006, Ochoa Decl. at ¶ 47.** Thereafter, the first superior surface of the first member ("wafer" 70, 72) supports at least a portion of the first vertebra above the superior surface of the cage, and the

second inferior surface of the second member ("wafer" 70, 72) supports at least a portion of the second vertebra below the inferior surface of the cage. **EX1004, Col. 5, lines 42-45; Col. 5, line 66-Col. 6, line 7; Col. 14, lines 61-65; FIG. 29; EX1006, Ochoa Decl. at ¶ 47.**

A PHOSITA would have, therefore understood that the '998 patent discloses, *wherein the first superior surface supports at least a portion of the first vertebra above the superior surface of the cage and the second inferior surface supports at least a portion of the second vertebra below the inferior surface of the cage*, as recited in the claims.

A summary image illustrating the elements discussed above is included in Figure 3 and Figure 4.

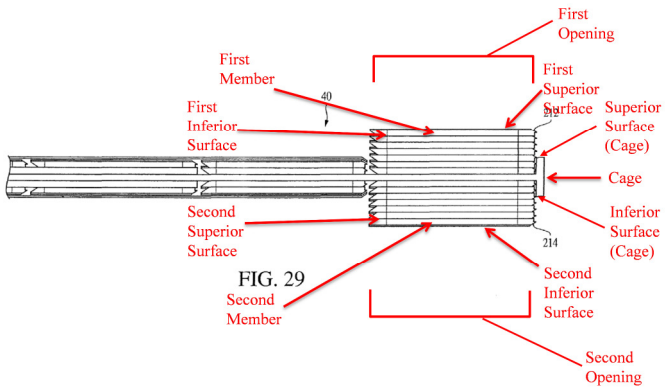


Figure 3. Excerpt from Figure 29 of the '998 patent demonstrating the various claim elements.

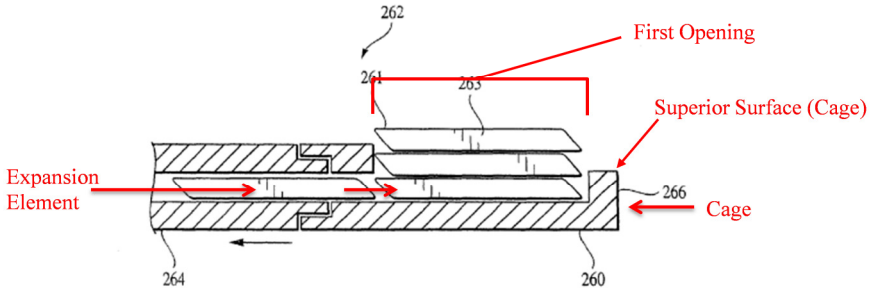


Figure 4. Excerpt from Figure 37 of the '998 patent demonstrating the detachable inserter tip. Note that the inserter tip is shown in the unidirectional embodiment and would be symmetrical in the bidirectional embodiment.

The claim charts attached as **EX1019** provide additional details supporting the information that would have been conveyed by the '998 Patent and understood by a PHOSITA at the time of the invention of the '869 Patent.

Consequently, and as supported by Dr. Ochoa, the '998 patent renders claim 37 unpatentable under 35 U.S.C. § 103.

C. Ground 3: Claim 37 is unpatentable under 35 U.S.C. § 103 as obvious over the '882 patent (EX1005) in view of one of ordinary skill in the art

The'882 patent discloses an intervertebral implant for use in spinal fusion surgical procedures. The disclosed intervertebral implant comprises a first member ("engagement member" 60) and second member ("engagement member" 61) each with interior facing surfaces and outward facing substantially planar surfaces to contact and support a first and second vertebra of the spine. The implant also comprises a cage with openings on the superior and inferior surfaces ("cavity" 5)

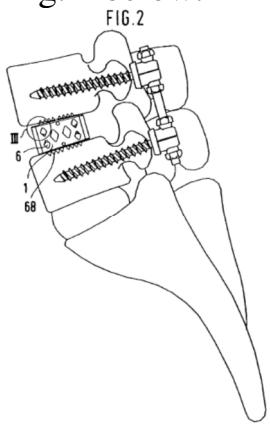
such that the first and second members ("engagement member" 60, 61) are positioned into openings. Additionally, the intervertebral implant also discloses an expansion element ("wedge members" 45, 46) inserted during use between the first and second members ("engagement members" 60, 61). Through rotation of a threaded spindle (15) the expansion element ("wedge members" 45, 46) moves the first and second members relative to one another to expand or increase the separation distance to support at least a portion of a first vertebra and second vertebra, above and below the cage, respectively. **EX1006, Ochoa Decl., ¶ 32.**

A PHOSITA would have understood that the spinal implant taught in the '882 patent renders claim 37 of the '869 patent obvious. The claim charts and accompanying text below evidence this conclusion.

1. Claim 37

Claim 37 is directed to an intervertebral implant device for a human spine. Claim 37 is obvious in view of Biedermann. The claim charts and accompanying analysis below evidence this conclusion.

'869 patent Claim 37 vs. '882 patent	
37. An intervertebral implant for a human spine, comprising:	The '882 patent (**EX1005**) discloses: • Such an implant is inserted after removal of an intervertebral disk for stabilizing the inverbertebral region until bone material which is filled in at the same time has grown to an osseous connection and strengthening. **EX1005, Col. 1, lines 9-12** • It is the object of the invention to provide an improved intervertebrael implant. **EX1005, Col. 1, lines 62-63**

	• See e.g. **EX1005** at Fig. 2 below.  • Biedermann discloses an intervertebral implant for a human spine. **EX1006, Ochoa Decl. at ¶ 33.**

The preamble of claim 37 state the intended use of the invention and do not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction.[6]

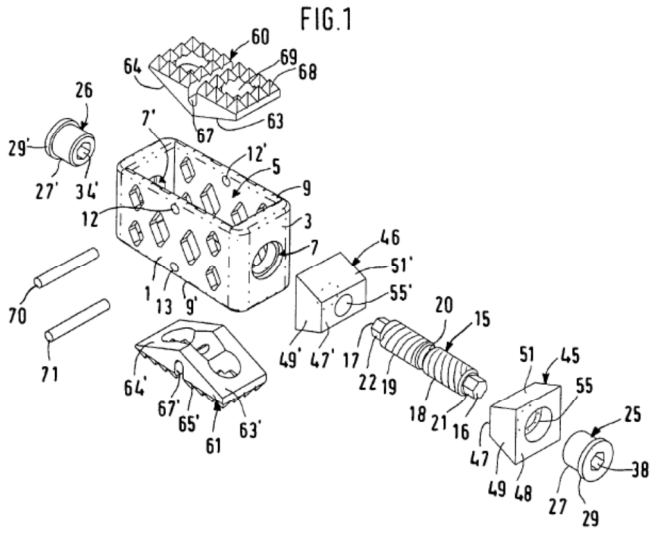
To the extent that the preamble limits the claim, a PHOSITA would have understood that the spinal implant of the '882 patent is for use in spinal fusion surgical procedures in association with vertebrae in a patient's spine. A PHOSITA would have understood that the spinal implant described in the '882 patent is an intervertebral implant for use in spinal fusion procedures to stabilize the intervertebral region after removal of an intervertebral disk. **EX1005, Col. 1, lines 9-12; Col. 1, lines 62-63; FIG. 2; EX1006, Ochoa Decl. at ¶ 33.**

A PHOSITA would have thus recognized that the '882 patent discloses *an*

[6] *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.

intervertebral implant for a human spine, as recited in the claims.

‘869 patent Claim 37 vs. ‘882 patent	
a first member comprising a first inferior surface and a first superior surface, where the first superior surface comprises a substantially planar surface configured to contact and support a first vertebra of a human spine; ***AND*** *a second member comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebra of a*	The ‘882 patent (**EX1005**) discloses: • A corresponding element 60, 61, respectively, is placed between the mutually inclined top faces 51, 51' and mutually inclined bottom faces 52, 52', respectively, which will be referred to as wedge faces, of the wedge members 45, 46, which element is formed at its lower side facing the wedge members in form of a roof gable with two mutually inclined sloping surfaces 63, 64 and 63', 64', respectively. The angle of inclination of the surfaces 63, 64, and 63', 64', respectively, corresponds to the wedge angle of the wedge members. Each engagement member 60, 61 comprises, on its side facing away from the threaded spindle 15, a surface with a rectangular contour. In longitudinal direction between the front wall and the back wall 3, 4, viewed in the center, each element comprises a U-shaped slit 67 extending parallel to the front wall and back wall 3, respectively, and perpendicular to the surface of the element, the bottom of which is directed to the lower side of the element. The surfaces comprise teeth 68 disposed on the contour of a square, respectively, as shown in particular in FIG. 1 and FIG. 4. A substantially circular depression 69 is disposed between the teeth such that the teeth arranged on the contour of a square form a ring of teeth. **EX1005, Col. 3, lines 57-Col. 4, line 11** • The dimensions of the wedge members 45, 46, the threaded portions 18, 19, the spindle 15 and the engagement members 60, 61, as well as the pitch of the threads is selected so as to allow the engagement members 60, 61 to be displaced from a first position shown in FIG. 7 in which the teeth are located beneath the edge 9, 9', and a second position, which is shown in FIG. 8, in which the teeth project over the respective edge 9, 9' of the implant. **EX1005, Col. 4, lines 27-34** • After having correctly positioned the implant between the vertebrae the two wedge members 45, 46 are moved towards each other by rotating the threaded spindle 15

human spine;	using a hexagon screw driver, whereby the wedged, mutually inclined surfaces exert a force onto the oblique surfaces 63, 64, and 63', 64' of the corresponding engagement members to raise the same until the teeth 68 project beyond the edge of the implant to thereby clutch the vertebrae, as particularly shown in FIG. 2 and FIG. 3. The lifting movement of the engagement members 60, 61 is limited by the stop formed by the rods 70, 71 to the lift shown in FIG. 8 whereby the teeth 68 of the corresponding engagement member project beyond the edge of the implant. **EX1005, Col. 4, lines 46-59** • See e.g. **EX1005** at Fig. 1 below.  • Biedermann discloses a first member comprising a first inferior surface and a first superior surface, where the first superior surface comprises a substantially planar surface configured to contact and support a first vertebra of a human spine **and** a second member comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebra of a human spine. **EX1006, Ochoa Decl. at ¶ 34.**

The phrase "*a first member comprising a first inferior surface and a first*

superior surface, where the first superior surface comprises a substantially planar surface configured to contact and support a first vertebra of a human spine," **and** "*a second member comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebra of a human spine,*" is a recitation 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.[7] Moreover, a PHOSITA would not understand the limitation, *configured to contact*," to disclose any intrinsic or structural limitation of the implant. **EX1006, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Biedermann reference discloses these limitations. A PHOSITA would have understood that the intervertebral implant described in the '882 patent comprises a first member ("engagement member" 60) and a second member ("engagement member" 61). **EX1005, Col. 3, line 57-Col. 4, line 11; Col. 4, lines 27-34; Col. 4, lines 46-59; FIG. 1.** The first and second members each comprise both inferior and superior surfaces, whereby on each member an outward facing surface (first superior surface for first member, second inferior surface for second member) has a

[7] *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.

substantially rectangular contour facing toward each vertebral body. ***Id.*** **at Col. 3, line 57-Col. 4, line 11; FIG. 1**. The outward facing surface on both members is configured with teeth (68) disposed on the surface creating the contour of a square able to contact and support the superior and inferior vertebra, respectively. (See Figure 5 below) ***Id.*** **at Col. 3, line 57-Col. 4, line 11; FIG. 1.** A PHOSITA would have understood that the surface formed on the contour of the rectangle is a substantially planar surface, including texture to enhance contact with the superior and inferior bone surfaces. **EX1006, Ochoa Decl. at ¶ 34.**

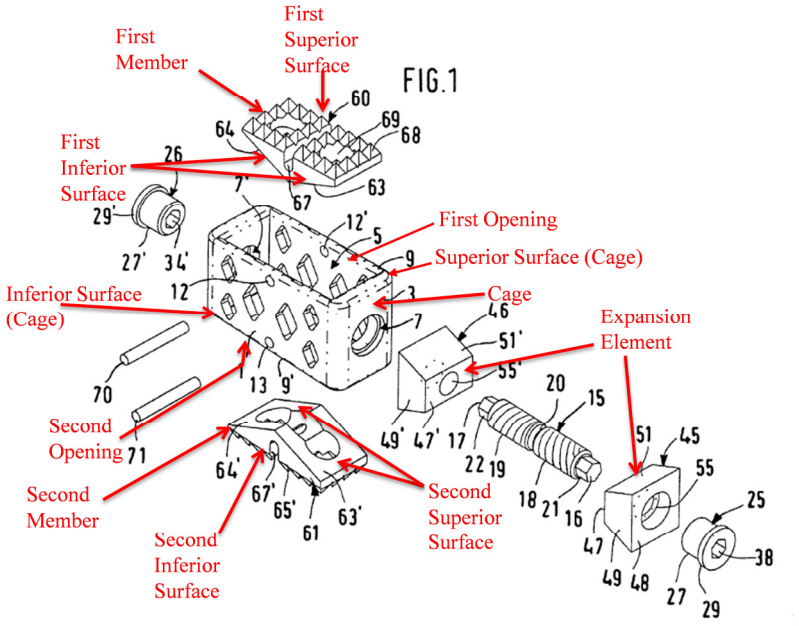


Figure 5. Excerpt from Figure 1 of the '882 patent demonstrating the various claim elements.

A PHOSITA would have thus understood that the '882 patent discloses, *a*

first member comprising a first inferior surface and a first superior surface, where the first superior surface comprises a substantially planar surface configured to contact and support a first vertebra of a human spine, **and** *a second member comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebra of a human spine*, as recited in the claims. **EX1006, Ochoa Decl., ¶ 34.**

'869 patent Claim 37 vs. '882 patent	
a cage comprising a first opening in a superior surface of the cage and a second opening in an inferior surface of the cage, wherein, during use, the first member is inserted at least partially into the first opening and the second member is inserted at least partially in the second opening; and	The '882 patent (**EX1005**) discloses: • In operation first the wedge members 45, 46 are brought into the position shown in FIG. 7, wherein the back faces 48 are in contact with the inner sides of the front and back wall 3, 4 of the implant facing the cavity 5, by rotating the threaded spindle 5 using a hexagon screw driver. This causes each engagement member 60, 61 to take up its lowermost position wherein the teeth 68 do not project beyond the edge of the implant. The implant can therefore easily be inserted into the area between the vertebrae and there is no risk of injuring the soft parts of the end plates of the vertebrae. After having correctly positioned the implant between the vertebrae the two wedge members 45, 46 are moved towards each other by rotating the threaded spindle 15 using a hexagon screw driver, whereby the wedged, mutually inclined surfaces exert a force onto the oblique surfaces 63, 64, and 63', 64' of the corresponding engagement members to raise the same until the teeth 68 project beyond the edge of the implant to thereby clutch the vertebrae, as particularly shown in FIG. 2 and FIG. 3. The lifting movement of the engagement members 60, 61 is limited by the stop formed by the rods 70, 71 to the lift shown in FIG. 8 whereby the teeth 68 of the corresponding engagement member project beyond the edge of the

implant. **EX1005, Col. 4, lines 37-59**

- See e.g. **EX1005** at Figs. 7 and 8 below.

FIG.7

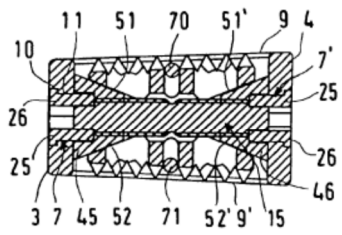
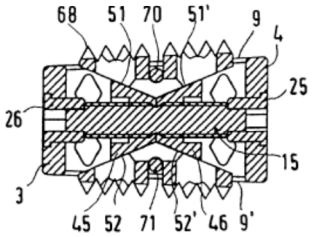
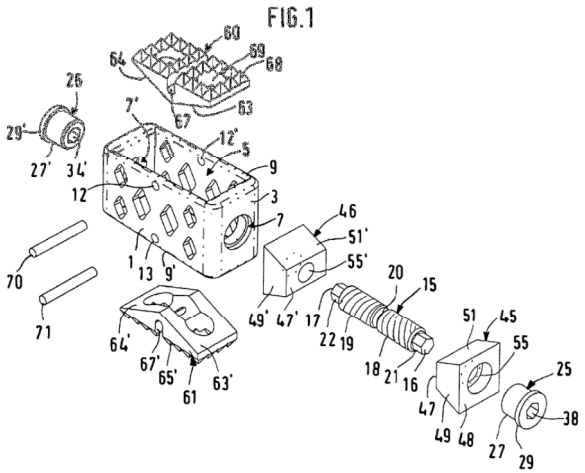


FIG.8



- As best shown in the FIGS. 1 and 4 to 6 the implant comprises a first side wall 1, a second side wall 2 spaced from the first side wall and a front wall 3 connecting the two side walls 1, 2 at their one end as well as a back wall 4 opposite to the front wall for connecting the two side walls at their opposite other ends. As best shown in FIG. 1 the bottom and top faces are open so that the four walls define a cavity 5 having an open bottom and an open top. As best seen in FIG. 5 the two side walls 1 and 2 have a plurality of apertures 6 which are preferably diamond-shaped and distributed over the side wall surfaces. **EX1005, Col. 2, line 27-37**
- See e.g. **EX1005** at Fig. 1 below.

FIG.1



- As best shown in the FIGS. 1 and 6 to 8 respective coaxial bores 7, 7' are provided in the front wall 3 and in the back wall 4 in the middle between the side walls. The center 8

	of the bores 7, 7' is equally spaced from the upper and lower edges 9, 9' of the implant and therefore at the center of the front and back wall, respectively. The bores 7, 7' have a first portion 10 with a first bore diameter adjacent to the outside of the front and back wall, respectively, and a following second portion 11 which opens into the cavity 5 and which has a second bore diameter which is slightly less than the first bore diameter. The second portion 11 thereby defines a shoulder. **EX1005, Col. 2, lines 38-49** • Biedermann discloses a cage comprising a first opening in a superior surface of the cage and a second opening in an inferior surface of the cage, wherein, during use, the first member is inserted at least partially into the first opening and the second member is inserted at least partially in the second opening. **EX1006, Ochoa Decl. at ¶ 35-36.**

A PHOSITA would have understood that the intervertebral implant described in the '882 patent comprises a cage since a cage is a type of interbody implant that may be typically packed with bone graft and is used to mechanically stabilize the intervertebral region during fusion. **EX1005, Col. 1, lines 9-12** A PHOSITA would have understood that the cage comprises four walls ("first side wall" 1, "second side wall" 2, "front wall" 3, and "back wall" 4) with upper and lower edges (9 and 9') forming a first opening in the superior surface and a second opening in the inferior surface, thus defining a cavity (5). **EX1005, Col. 2, lines 27-37; Col. 2, lines 38-49; FIG. 1; EX1006, Ochoa Decl. at ¶ 35.**

A PHOSITA would have understood that during use, the first member ("engagement member" 60) and second member ("engagement member" 61) are first taken to their lowermost position wherein the teeth (68) do not project beyond

the edge of the implant. After positioning the implant between the vertebrae, the first member and second member ("engagement members" 60 and 61) are raised until the superior surface of the first member is expanded beyond the superior extent or edge of the cage (9), while inferior surface of the second member is expanded below the inferior extent or edge of the cage (9'). Because the teeth (68) project beyond the edge of the implant, they thereby can clutch the vertebrae. **EX1005, Col. 4, lines 37-59; FIGS. 7 and 8; EX1006, Ochoa Decl. at ¶ 36.**

A PHOSITA would have thus understood that the '882 patent discloses, *a cage comprising a first opening in a superior surface of the cage and a second opening in an inferior surface of the cage, wherein, during use, the first member is inserted at least partially into the first opening and the second member is inserted at least partially in the second opening,* as recited in the claims. **EX1006, Ochoa Decl. at ¶ 36.**

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an expansion element that, during use, is inserted between the first inferior surface of the first member and the second superior surface of the second member, wherein	The '882 patent (**EX1005**) discloses: • A corresponding element 60, 61, respectively, is placed between the mutually inclined top faces 51, 51' and mutually inclined bottom faces 52, 52', respectively, which will be referred to as wedge faces, of the wedge members 45, 46, which element is formed at its lower side facing the wedge members in form of a roof gable with two mutually inclined sloping surfaces 63, 64 and 63', 64', respectively. The angle of inclination of the surfaces 63, 64, and 63', 64', respectively, corresponds to the wedge angle of the wedge members. **EX1005, Col. 3, lines 57-65** • In operation first the wedge members 45, 46 are brought

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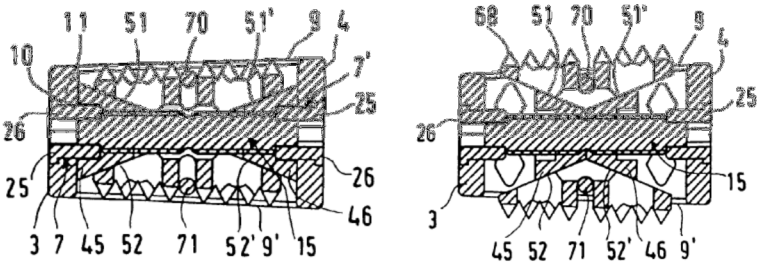
insertion of the expansion member expands the first and second members relative to one another to increase a separation distance between the first superior surface of the first member and the second inferior surface of the second member, wherein the first superior surface is expanded above the superior surface of the cage and the second inferior surface is expanded below the inferior surface of the cage, such that the distance between the first superior surface and the second inferior surface is greater than the distance between the superior surface	into the position shown in FIG. 7, wherein the back faces 48 are in contact with the inner sides of the front and back wall 3, 4 of the implant facing the cavity 5, by rotating the threaded spindle 5 using a hexagon screw driver. This causes each engagement member 60, 61 to take up its lowermost position wherein the teeth 68 do not project beyond the edge of the implant. The implant can therefore easily be inserted into the area between the vertebrae and there is no risk of injuring the soft parts of the end plates of the vertebrae. After having correctly positioned the implant between the vertebrae the two wedge members 45, 46 are moved towards each other by rotating the threaded spindle 15 using a hexagon screw driver, whereby the wedged, mutually inclined surfaces exert a force onto the oblique surfaces 63, 64, and 63', 64' of the corresponding engagement members to raise the same until the teeth 68 project beyond the edge of the implant to thereby clutch the vertebrae, as particularly shown in FIG. 2 and FIG. 3. The lifting movement of the engagement members 60, 61 is limited by the stop formed by the rods 70, 71 to the lift shown in FIG. 8 whereby the teeth 68 of the corresponding engagement member project beyond the edge of the implant. **EX1005, Col. 4, lines 37-59** • See e.g. **EX1005** at Figs. 7 and 8 below. FIG.7 FIG.8  • The transmission of the rotation of the tool through the threaded spindle and the wedge members allows for a precise adjustment of the lift of the engagement members

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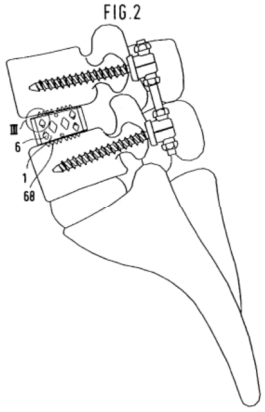
and the inferior surface of the cage, and wherein the first superior surface supports at least a portion of the first vertebra above the superior surface of the cage and the second inferior surface supports at least a portion of the second vertebra below the inferior surface of the cage.	and for an individual adaptation of the implant to the anatomic shape of the end plates of the vertebrae of the individual patient. **EX1005, Col. 4, lines 60-65**  FIG.2 • Biedermann discloses an expansion element that, during use, is inserted between the first inferior surface of the first member and the second superior surface of the second member, wherein insertion of the expansion member expands the first and second members relative to one another to increase a separation distance between the first superior surface of the first member and the second inferior surface of the second member, wherein the first superior surface is expanded above the superior surface of the cage and the second inferior surface is expanded below the inferior surface of the cage, such that the distance between the first superior surface and the second inferior surface is greater than the distance between the superior surface and the inferior surface of the cage, and wherein the first superior surface supports at least a portion of the first vertebra above the superior surface of the cage and the second inferior surface supports at least a portion of the second vertebra below the inferior surface of the cage. **EX1006, Ochoa Decl. at ¶ 37-40.**

A PHOSITA would have understood that the during use, an expansion element in the form of two wedge members (“wedge members” 45, 46) are moved

towards each other by rotating the threaded spindle (15) whereby the wedged, mutually inclined surfaces exert a force on the interior oblique surfaces (63, 64, 63' 64') of the engagement members (60, 61) to expand them until the they engage the neighboring vertebrae. **EX1005, Col. 4, lines 37-59; FIGS. 7 and 8.** A PHOSITA would have understood that during use, the expansion element ("wedge members" 45, 46) is inserted between the first inferior surface of the first member ("engagement member", 60) and the second superior surface of the second member ("engagement member" 61). **EX1005, Col. 4, lines 37-59; FIGS. 7 and 8; EX1006, Ochoa Decl. at ¶ 37.**

A PHOSITA would have, therefore understood that the '882 patent discloses, *an expansion element that, during use, is inserted between the first inferior surface of the first member and the second superior surface of the second member, wherein insertion of the expansion member expands the first and second members relative to one another to increase a separation distance between the first superior surface of the first member and the second inferior surface of the second member,* as recited in the claims. **EX1006, Ochoa Decl. at ¶ 37.**

A PHOSITA would have understood that the '882 patent discloses that during use of the expansion element ("wedge members" 45, 46) the first superior surface of the first member ("engagement member" 60) is expanded above the edge of the implant (9), or superior surface of the cage, and similarly the second

inferior surface of the second member ("engagement member" 61) is expanded below the edge of the implant (9'), or inferior surface of the cage. **EX1005, Col. 4, lines 37-59; FIGS. 7 and 8.** As shown in the transition from Figure 7 to Figure 8 in the '882 Patent, the movement of the first and second members ("engagement members" 60, 61) is such that the distance between the first superior surface (top of "engagement member" 60) and the second inferior surface (bottom of "engagement member" 61) is greater than the distance between the superior and the inferior edges of the implant, or surface of the cage. (See Figure 6 below). In this way, the prevailing shape of the vertebrae can be controlled through adjustment of the displacement of the first and second members ("engagement members" 60,61) all while the teeth clutch the bone. ***Id.*** **at Col. 2, lines 1-5.**

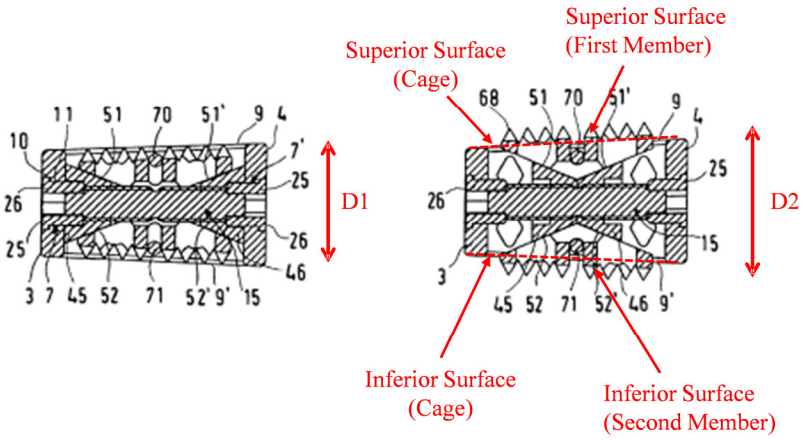


Figure 6. Excerpt from figure 7 and figure 8 of the '882 patent illustrating the spatial relation between the surface of the cage and the superior and inferior members before (left) and after (right) deployment. The separation distance between the first superior surface of the first member and the second inferior surface of the second member is noted by D1 and D2.

EX1006, Ochoa Decl. at ¶ 38.

A PHOSITA would have, therefore understood that the '882 patent discloses, *wherein the first superior surface is expanded above the superior surface of the cage and the second inferior surface is expanded below the inferior surface of the cage, such that the distance between the first superior surface and the second inferior surface is greater than the distance between the superior surface and the inferior surface of the cage*, as recited in the claims. **EX1006, Ochoa Decl. at ¶ 38.**

A PHOSITA would have understood that the '882 patent discloses that during use of the expansion element, the first superior surface of the first member ("engagement member" 60) and second inferior surface of the second member ("engagement member" 61) are moved above and below the superior and inferior surface of the cage until the teeth project beyond the edges of the implant ("upper and lower edges" 9 and 9') to thereby clutch the vertebrae. **EX1005, Col. 4, lines 46-65; FIGS. 2, 3 and 8; *Id.* at ¶ 39.** A PHOSITA would have understood that the implant is inserted after removal of an intervertebral disk and to mechanically stabilize the intervertebral region during fusion. **EX1006, Ochoa Decl. at ¶ 39.** Therefore, the first superior surface of the first member ("engagement member" 60) supports at least a portion of the first vertebra above the superior surface of the cage, and the second inferior surface of the second member ("engagement

member" 61) supports at least a portion of the second vertebra below the inferior surface of the cage. **EX1005, Col. 3, lines 60-65; Col. 4, lines 37-59; Col. 4, lines 60-65; FIGS. 2, 7 and 8; EX1006, Ochoa Decl. at ¶ 39.**

A PHOSITA would have understood that the '882 patent discloses, *wherein the first superior surface supports at least a portion of the first vertebra above the superior surface of the cage and the second inferior surface supports at least a portion of the second vertebra below the inferior surface of the cage*, as recited in the claims. **EX1006, Ochoa Decl. at ¶ 39.**

A summary image illustrating the elements discussed above is included in Figure 7 below.

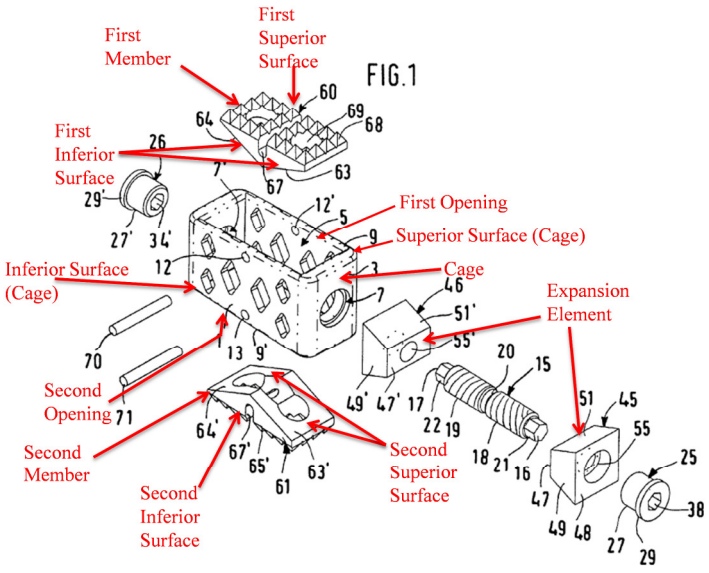


Figure 7. Excerpt from Figure 1 of the '882 patent demonstrating the various claim elements.

The claim charts attached as **EX1020** provide additional details supporting

the information that would have been conveyed by the '882 Patent and understood by a PHOSITA at the time of the invention of the '869 Patent.

Consequently, and as supported by Dr. Ochoa, the '882 patent renders claim 37 unpatentable under 35 U.S.C. § 103.

IX. CONCLUSION

Petitioner has demonstrated in this Petition that claims 23 and 37 of the '869 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '869 patent.

Dated: August 18, 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. 7,909,869 to be served via FedEx, next day delivery, on the below listed counsel, on this 18th day of August, 2015:

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