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. 8,647,386
Issued: February 11, 2014
Application No: 12/841,792
Filed: July 22, 2010

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,647,386

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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 1, 2, 3 and 4 of U.S. Patent No. 8,647,386, titled "Expandable Intervertebral Implant System and Method" ("the '386 patent"), issued to Charles Gordon, Corey T. Harbold and Heather S. Hanson, and assigned to Flexuspine, Inc. ("Flexuspine"). The '386 patent is attached as **EX1001**.

For the reasons set forth herein, Petitioner asserts that all of the challenged claims are unpatentable. The grounds for unpatentability presented in detail below, demonstrate how each of claims 1, 2, 3 and 4 of the '386 patent are obvious in view of the prior art. Evidentiary support for Petitioner's conclusions is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. **EX1005.**[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 are 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 claims challenged in the Petition. 35 U.S.C. §314(a). Accordingly, Petitioner respectfully requests that this Petition be granted and that claims 1, 2, 3, and 4 of the '386 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 '386 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 claims of the '386 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. 7,909,869 ("the '869 patent"), and U.S. Patent No. 8,123,810 ("the '810 patent"). The '386 patent is related to the '853 patent, the '714 patent, the '869 patent and the '810 patent through continuation practice. Petitioner understands that the '386 patent, the 853 patent, the '714 patent, the '869 patent and the '810 patent are all commonly owned by Flexuspine.

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

Petitioner certifies that (1) the '386 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 '386 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. 8,647,386 ("THE '386 PATENT") (EX1001)

The continuation application leading to the '386 patent, Serial No. 12/841,792, was filed on July 22, 2010. This continuation was based on Serial No. 11/134,091, filed on May 20, 2005, which is a continuation of Serial No. 11/050,632, filed February 3, 2005, now U.S. Patent No. 7,753,958, which is a continuation-in-part of Serial No. 10/634,950, filed on August 5, 2003, now U.S. Patent No. 7,204,853, and a continuation-in-part of Serial No. 10/660,155, filed on September 11, 2003, now U.S. Patent No. 7,316,714, and a continuation-in-part of Serial No. 10/777,411, filed on February 12, 2004, now U.S. Patent No. 7,909,869, and a continuation-in-part of Serial No. PCT/US2004/025090, filed on August 4, 2004, said Serial No. 10/777,411 is a continuation-in-part of Serial No. 10/634,950, filed on August 5, 2003, now U.S. Patent No. 7,204,853, said Serial No. 10/660,155 is a continuation-in-part of Serial No. 10/634,950 filed on August

5, 2003, now U.S. Patent No. 7,204,853.

For purposes of this Petition only, the earliest priority date for the '386 patent is August 5, 2003. Petitioner, however, notes that the subject matter of FIGS. 9a-9f and 50a-50b, to which the issued claims are directed were added in the continuation-in-part application and therefore carry a later in time priority date.

A. The '386 Patent Specification and Claims

The '386 patent is generally directed to an expandable intervertebral implant. The challenged claims, however, are directed to known implantable devices for achieving the objective of restoration and maintenance of disk space height.

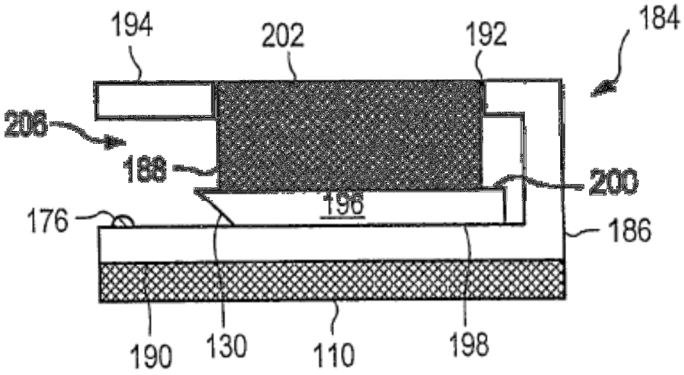


FIG. 9B

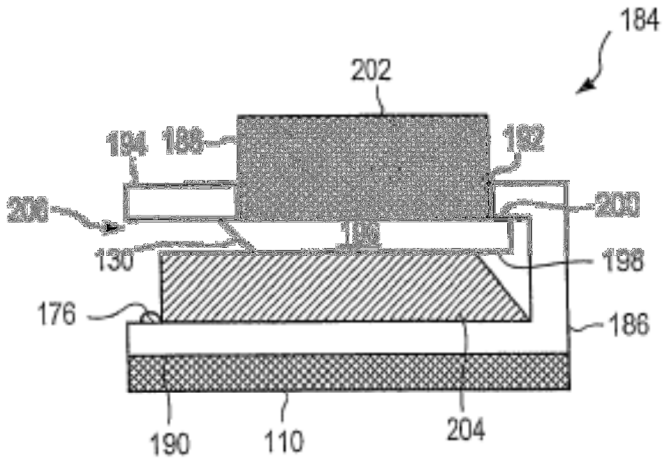


FIG. 9C

The '386 patent issued with 37 claims, of which only claims 1, 2, 3, and 4 are at issue in this Petition. Claim 1 is independent. Claims 2, 3, and 4 are directly or indirectly dependent from claim 1.

Claims 1, 2, 3, and 4, of the '386 patent are directed to FIGS. 9A-

9F and FIGS. 50A-50B. **EX1003 at 1506 and 1517.** FIGS. 9A-9C depict an expandable cage. **EX1001, Col. 14, lines 33-36.** FIG. 9B depicts a cross-sectional view of cage 184 before expansion. ***Id.*** **at Col. 14, lines 37-40.** Cage 184 includes cage element 186 and insert 188. ***Id.*** **at Col. 14, lines 37-40**.

Insert 188 includes member 196 having inferior surface 198 and superior surface 200. ***Id.*** **at Col. 14, lines 48-49.** Member 196 may be substantially planar (e.g., a plate). Member 196 includes angled portion 130. ***Id.*** **at Col. 14, lines 49-51.** Angled portion 130 facilitates expansion of cage 184 (e.g., elevation of insert 188) upon insertion of expansion member 204. **Id. at Col. 14, lines 53-55.** Expansion member 204 may be inserted into opening 206 of cage element 186 and advanced (e.g., impacted, driven) to engage angled portion 130 of member 196. ***Id.*** **at Col. 14, lines 53-55.** FIG. 9C depicts a cross-sectional view of expanded cage 184. ***Id.*** **at Col. 14, lines 58-59.**

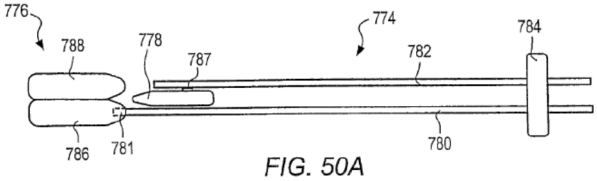


FIG. 50A

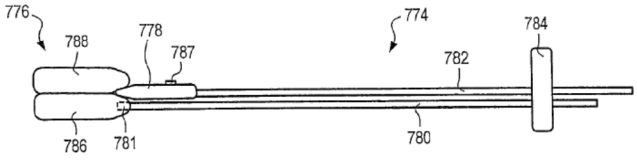


FIG. 50B

FIGS. 50A and 50B depict instrument 774 including a pair of rods for inserting implant 776 having spacer 778. ***Id.*** **at Col. 31, lines 24-25.** Bottom rod 780 and top rod 782 of instrument 774 may be commonly supported on base member 784. ***Id.*** **at Col. 14, lines 25-28.** Bottom rod 780 may include threaded

portion 781. ***Id.*** **at Col. 31, lines 27-28.** Threaded portion 781 may engage in a tapped hole in lower body 786 of implant 776. ***Id.*** **at Col. 31, lines 29-30.**

B. The '386 Patent Prosecution History (EX1002)

The prosecution of the application before the U.S. Patent and Trademark Office leading to the '386 patent includes on March 7, 2011, the USPTO issuing a Restriction Requirement. **EX1002 at page 1558.** On April 6, 2011, the Applicant responded to the Restriction Requirement noting that the Restriction Requirement was deficient. ***Id.*** **at page 1542.** On June 27, 2011, the Examiner withdrew the Restriction Requirement dated March 7, 2011 and issued a new Restriction Requirement. ***Id.*** **at page 1522.** On July 26, 2011, the Applicant responded to the new Restriction Requirement electing Group 10 (Figs. 9a-9f) of the "Intervertebral Implant" and Group 9 (Figs. 50a-50b) of the "Insertion Instrument." ***Id.*** **at page 1506.** The Applicant also noted that pending claims 158-168, 170, 172-183, 185-196, 198 and 200-202 read onto the elected species. ***Id.*** **at page 1517.**

On October 20, 2011, a Non-Final Rejection issued in which all claims were rejected. ***Id.*** **at page 1397.** The Examiner acknowledged that the Applicant elected with traverse, the implant species of Figs. 9a-9f and the instrument species of Figs. 50a-50b. ***Id.*** **at page 1400.** The Examiner also noted that the Applicant's arguments as to claims 200-202 were not persuasive, because these claims were drawn to a non-elected species. ***Id.*** **at page 1400.** The election was deemed final

and claims 200-202 were withdrawn. ***Id.*** **at page 1400.**

On January 19, 2012, the Applicant responded to the Non-Final Office Action by amending all independent claims. ***Id.*** **at page 382.** On March 23, 2012, the Examiner issued a Final Rejection on all pending claims. ***Id.*** **at page 303.**

On June 22, 2012, the Applicant filed a Response After Final in which the Applicant amended all independent claims and certain dependent claims. ***Id.*** **at page 276.** In the Applicant's remarks, the Applicant noted as to amended claim 158 as follows:

> wherein the elongated insertion instrument guides at least a portion of the linear advancement of the spacer after the first and second bodies have been disposed substantially between the first and second vertebrae from a position remote to the first and second bodies during use.

Id. **at page 286.**

In its remarks, the Applicant also noted as follows:

> Kambin, however, does not appear to disclose a spinal implant system wherein a spacer is positioned between an upper and lower body of the implant after the bodies have been positioned in an intervertebral space between the first and second vertebrae from a position remote to the first and second bodies during use, in combination with the features set forth in Applicant's claims. The Office Action states that this particular feature appears only in claim 158; however, Applicant respectfully submits that independent claims 172 and 186 refer to positioning an upper and lower body in an intervertebral space which between the first and second vertebrae, in combination with the features set forth in Applicant's claims. Kambin does not appear to disclose linearly advancing a spacer between two elongated insertion instruments from a substantially proximal end of the elongated insertion instrument to a substantially distal end of the elongated insertion instruments, in combination with the features set forth in Applicant's claims, but to the contrary teaches coupling a hexagonal wrench

to an end of a prepositioned expansion screw.

***Id.* at page 287.**

On July 19, 2012, the Examiner issued an Advisory Action. ***Id.* at page 272.** On August 22, 2012, the Applicant filed a Request for Continued Examination. ***Id.* at page 248.** On August 27, 2013, the Examiner issued a Notice of Allowance. ***Id.* at page 21.**

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

As established in the Declaration of Dr. Ochoa (**EX1005 at ¶ 18**), a person having ordinary skill in the art (PHOSITA) of the '386 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience. The experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. Alternatively, a PHOSITA could have an advanced degree, in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

V. CLAIM CONSTRUCTION

Unless stated otherwise in this section below, the claims of the '386 patent are to be given their broadest reasonable construction in light of the '386 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 '386 patent, as appropriate in that proceeding.

Concerning the limitation "move away from one another" in claim 1, **EX1001, Col. 34, lines 34-35**, the broadest reasonable construction in light of the '386 patent's specification as understood by a PHOSITA is "change in position relative to one another." More particularly, in reviewing the specification concerning FIGS. 9A-F, expansion member 204 in FIGS. 9A-E moves a single insert 196 (unidirectional) so that the first external surface 202 and second external surface 110 "move away from one another" -- "change in position relative to one another" to expand the height of the implant. **EX1001, Col. 14, lines 33-65.** In FIG. 9F, the expansion member 204 moves a pair of inserts 196 (bidirectional) so that the first external surface 202 and second external surface 110 "move away from one another" -- "change in position relative to one another" to expand the height of the implant. **EX1001, Col. 14, lines 33-65.** Whether unidirectional or

bidirectional the result is same, "*linear advancement of the spacer results in expansion of the intervertebral implant such that the first external surface and the second external surface move away from one another* [**change in position relative to one another**] *to expand a height of the implant."* **EX1001, Col. 34, lines 30-35**. **EX1005 Ochoa Decl. at ¶ 36.**

The broadest reasonable construction, "change in position relative to one another," is also confirmed by the file history. More particularly, in response to a restriction requirement the Applicant elected "Group 10 (Figs. 9A-F) of the "Intervertebral Implant" and Group 9 (Figs. 50A-50B) of the "Insertion Instrument." **EX1003 at page 1506.** The Applicant noted as part of the election that pending claims 158-168, 170, 172-183, 185-196, 198 and 200-202 read on to the elected species. ***Id.*** **at page 1517.** Post-election, as to the limitation at issue, the Applicant did <u>not</u> amend pending claim 158 (pending claim 158 corresponds to issued claim 1). Rather, pending claim 158 in its original form as found in the Preliminary Amendment of August 10, 2012, (***Id.*** **at page 1740)** and in its final from as found in issued claim 1 (**EX1001, Col. 34, lines 30-35**), is the same: "*wherein the linear advancement of the spacer results in expansion of the intervertebral implant such that the first external surface and the second external surface move away from one another to expand a height of the implant*."

Therefore, in view of the '386 patent's specification, Applicant's election of

FIGS. 9A-F, Applicant's remarks as to claim 158 reading on to the elected species of FIGS. 9A-F, and the fact that the claim at issue did not change during prosecution, the broadest reasonable construction of "move away from one another" is "change in position relative to one another." This construction reads on the unidirectional and bidirectional embodiments of FIGS. 9A-F and stays true to the specification and file history.

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 '386 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 '386 patent. Johnson was disclosed by the applicant to the Patent Office during the prosecution of the application leading to the '385 patent, but was not referred to or relied on by the Examiner during the prosecution.

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

Petitioner seeks, by this Petition, a final, written decision that challenged claims 1, 2, 3, and 4 of the '386 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. Of the challenged claims, claim 1 is independent and claims 2, 3,

and 4 depend from claim 1.

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

In summary, and as established by the declaration of Dr. Ochoa, the '998 patent renders claims 1, 2, 3, and 4 unpatentable as obvious under 35 U.S.C. § 103 (**EX1005 at ¶¶ 32-49**).

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

This petition presents the following Grounds of unpatentability:

- Ground 1: Claims 1, 2, 3, and 4 are unpatentable under 35 U.S.C. § 103 as obvious by the '998 patent (**EX1004**) in view of one of ordinary skill in the art.
- Ground 2: Claims 1, 2, 3, and 4 are unpatentable under 35 U.S.C. § 103 as obvious by the '998 patent (**EX1004**) in view of one of ordinary skill in the art.

A. Ground 1: Claims 1, 2, 3, and 4, are 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. **EX1004, Col. 4, line 6-Col. 5, line 6.** In use, a plurality of wafers and the detachable tip are inserted between an upper and lower vertebra to create a column which distracts the disc space and provide support for the vertebral bodies. **EX1005, Ochoa Decl. at ¶ 32.** The wafers and detachable tip are placed

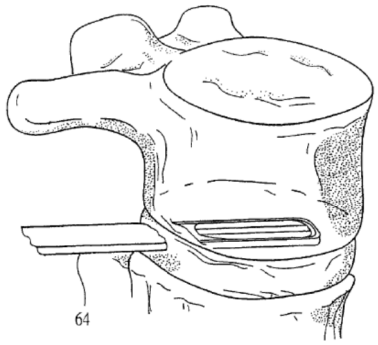
between the vertebrae via an inserter that engages the implant allowing for insertion. ***Id.*** **at Col. 31, lines 26-41.** The resulting implant includes upper and lower wafers that engage the vertebrae and central wafers that consecutively act as inserts. **EX1005, Ochoa Decl. at ¶ 32**. As each new wafer is added to the column, it acts as an expansion member, elevating the insert and increasing the height of the column, thereby distracting the surrounding tissues. **EX1004, Col. 4, line 6-Col. 5, line 6; Col. 5, lines 32-36.** Various methods could be applied to alter the interface between one wafer and a preceding or following wafer to provide various degrees of freedom or constraint between neighboring wafers, including alteration of the upper or lower surface of the wafer to inhibit backout. **EX1004, Col. 11, lines 11-20; FIGS. 6-26; EX1005, Ochoa Decl. ¶ 32.**

A PHOSITA would have understood that the spinal implant taught in the '998 patent renders claims 1, 2, 3, and 4 of the '386 patent obvious. The claim charts and accompanying analysis below, evidence this conclusion.

1. Claim 1

Claim 1 is directed to an implant device. Claim 1 is rendered obvious in view of Johnson. This is demonstrated with reference to the chart below and the accompanying text.

'386 patent Claim 1 vs. '998 patent	
1. An intervertebral	Johnson (the '998 patent) **(EX1004)** discloses: • The invention may be used to treat vertebral compression

implant system for a human spine, comprising:	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** • The prepared surface supports the wafer column. A wafer inserter is placed through the access channel and used in the manner described above to insert wafers and distract the adjacent vertebral bodies. **EX1004, Col. 25, lines 37-41** • See e.g. **EX1004** at Fig. 61 below.  FIG. 61 • Johnson discloses an intervertebral implant for a human spine. **EX1005, Ochoa Decl. at ¶ 33.**

The preamble of claim 1 merely states 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.[2]

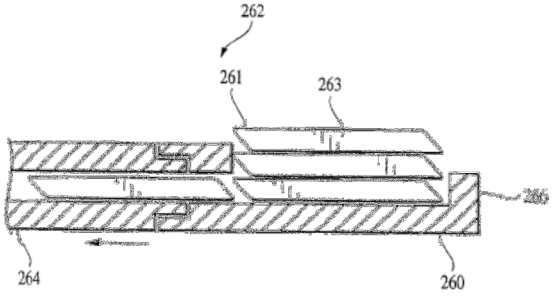
To the extent that the preamble limits the claim, a PHOSITA would have understood that the spinal implant of the Johnson patent is for use in spinal fusion surgical procedures in association with vertebrae in a patient's spine. **EX1004 at**

[2] *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.

1:1-9 and **EX1005 Ochoa Decl. at ¶ 33**. A PHOSITA would have understood that the spinal implant described in the Johnson patent is an implant used between vertebrae. **EX1004, Col. 4, line 64-Col. 5, line 6; Col. 25, lines 37-41; FIG. 61; EX1005 Ochoa Decl. at ¶ 33.**

Therefore, a PHOSITA would have recognized that the Johnson patent discloses *an intervertebral implant system for a human spine*, as recited in claim 1. ***Id.*** **at ¶ 33.**

'386 patent Claim 1 vs. '998 patent	
a first body comprising: a first external surface configured to be disposed adjacent a first vertebra during use, and a first internal surface opposite the first external surface; ***AND*** *a second body comprising: a second external surface configured to be disposed adjacent a second vertebra during use, and*	Johnson (the '998 patent) **(EX1004)** discloses: • The distraction device includes a plurality of stackable wafers designed for insertion between tissue surfaces to form a column. The wafer column is assembled in vivo to provide a distraction force as well as support and stabilization of the distracted tissue. **EX1004, Col. 5, lines 32-36** • 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. **EX1004, Col. 5, lines 51-55** • 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 63-Col. 6, line 7** • The invention provides that the wafer column is formed in

a second internal surface opposite the second external surface;	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** • 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. 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** • See e.g. **EX1004** at Fig. 37 below  FIG. 37 • In the detachable tip embodiment, wafers are inserted until the desired height or force is attained. As seen in FIG. 38, the distal tip 260 is then released from the main portion 264 of the wafer inserter and the main portion 264 of the

	inserter is removed. The distal tip may be pressfit onto the track or may be bonded with an appropriate adhesive. In either case, the interface is designed to support the forces generated while building a wafer column, but shear when the extraction plunger is used to remove the wafer inserter. Optionally, the distal tip 260 may be keyed to interlock with the main portion 264 of the wafer inserter. For example, the main portion of the inserter may interlock with the distal tip by spring-loaded hooks that are mechanically compressed when the tip is to be released. Alternately, the hooks may be spring-loaded in the release position and mechanically expanded to engage the distal tip. In another embodiment, the detachable tip may be pressfit onto the wafer inserter or bonded with a weak adhesive. When the wafer inserter is to be removed, a force may be applied using a longer plunger or equivalent mechanism as in the fixed tip wafer inserter to dislodge the removable tip. The track of the wafer inserter may be then removed. **EX1004, Col. 17, line 65-Col. 18, line 19** • Johnson discloses a first body comprising: a first external surface configured to be disposed adjacent a first vertebra during use, and a first internal surface opposite the first external surface and a second body comprising: a second external surface configured to be disposed adjacent a second vertebra during use, and a second internal surface opposite the second external surface. **EX1005, Ochoa Decl. at ¶ 34.**

The phrase in claim 1 that "*a first body comprising a first external surface is configured to be disposed adjacent a first vertebra during use, and a first internal surface opposite the first external surface,*" **and "***a second body comprising: a second external surface configured to be disposed adjacent a second vertebra during use, and a second internal surface opposite the second external surface*" are recitations of the intended use for the claimed apparatus; does not structurally

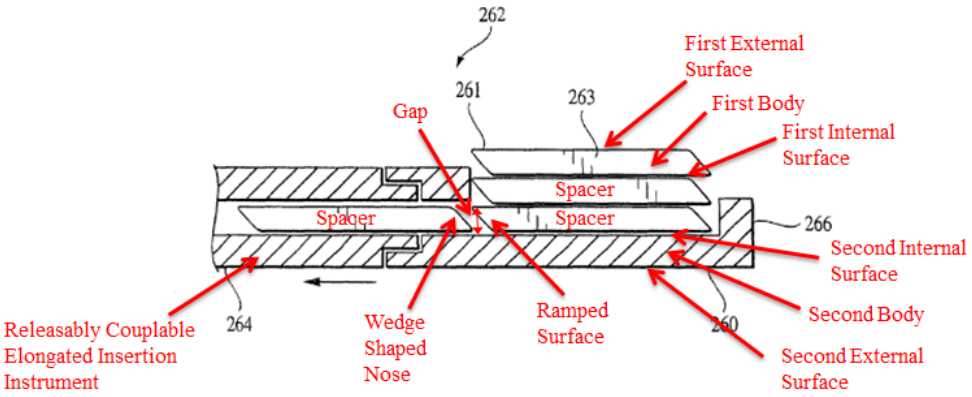
distinguish the claimed apparatus and, therefore, is not material to patentability. As such, this language carries no patentable weight.[3] Moreover, a PHOSITA would not understand the limitation, "*configured to be disposed*", to disclose any intrinsic or specific structural limitation of the implant. **EX1005 Ochoa Decl. at ¶22.**

However, to the extent that this language limits the claims, the Johnson patent discloses these limitations. A PHOSITA would have understood that during use as an interbody fusion device, the wafer columns described in the '998 patent would be supported between the bone surfaces of a decorticated superior and decorticated inferior endplate. **EX1004, Col. 24, lines 43-53.** Each wafer in the column comprises a superior (upper) and inferior (lower) surface. **EX1004, Col. 5, lines 51-55.** As a result, the external, upper surface of the uppermost wafer in the wafer column would engage the inferior surface of the superior endplate and the internal, lower surface of the uppermost wafer in the wafer column would engage the superior surface of the second highest wafer in the column. **EX1005 Ochoa Decl. at ¶ 34.** Similarly, the external, lower surface of the lowest wafer in the column, would engage the superior surface of the inferior endplate and the internal upper surface of the lowest wafer in the column would engage the inferior surface of the second lowest wafer in the column. **EX1004, Col. 5, line 63-Col. 6, line 7;**

[3] *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.

Col. 10, lines 1-8; FIGS. 29, 60 and 61. Alternatively, a PHOSITA would have understood that a detachable tip wafer inserter could be used in place of the lowermost wafer. **EX1004, Col. 17, lines 47-64; FIG. 37.** The distal tip (260) of the inserter is detachable from the main portion (264) of the inserter. After inserting wafers until the desired height or force is attained, the distal tip is released from the main portion, leaving the distal tip in place acting as a wafer within the wafer stack. **EX1004, Col. 17, line 65-Col. 18, line 19; FIG. 37.** This provides the advantage that the height of the wafer column is not altered when the inserter is removed. **EX1004, Col. 17, lines 47-53; EX1005 Ochoa Decl. at ¶ 34.**

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



Therefore, a PHOSITA would have understood that the '998 patent discloses *a first body comprising: a first external surface is configured to be disposed adjacent a first vertebra during use, and a first internal surface opposite the first*

external surface, **and** *a second body comprising: a second external surface configured to be disposed adjacent a second vertebra during use, and a second internal surface opposite the second external surface,* as recited in claim 1. **EX1005 Ochoa Decl. at ¶ 34.**

'386 patent Claim 1 vs. '998 patent	
an elongated insertion instrument releasably couplable to the first or second body during use; and	The '386 patent (**EX1004**) discloses: • A wafer inserter is provided as part of the invention to deliver the wafers to the surgical site and to form a column of wafers. In one embodiment, the wafer inserter applies a force along the X-axis (the axis of insertion) to a wafer that is to be added to the column. As previously described, the wafers may be configured with beveled ends to facilitate lengthening along the Z-axis of the column as the additional wafer is inserted. In an alternate wafer embodiment also previously described, the edges of the wafers are squared and the wafer inserter raises the leading wafer to place the trailing wafer thereunder. **EX1004, Col. 15, lines 55-65** • A wafer inserter configured for deployed wafer columns in opposite directions is depicted in FIG. 30. Two triggers, 211 and 213 are included in the handle 230 and are operatively coupled to upper and lower magazines of wafers 210 and 209, respectively. The upper trigger 211 inserts a wafer at the bottom of the top wafer column 212 and advances that column superiorly (in the positive Z-axis). The bottom trigger 213 inserts a wafer at the top of the lower wafer column and advances that column inferiorly (in the negative Z-axis). Alternatively, the wafer inserter could be designed so that one trigger could control both columns independently. Other configurations for deploying opposing wafer columns with a single wafer inserter may be used as would be obvious to a person skilled in the art. **EX1004, Col. 16, lines 52-65** • See e.g. **EX1004** at Fig. 34 below.

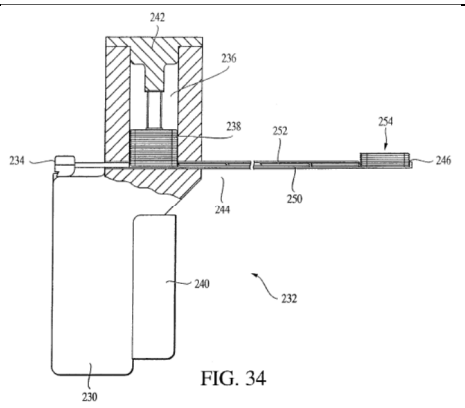


FIG. 34

- 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. 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, line 47-64**
- See e.g. **EX1004** at Fig. 37 below.

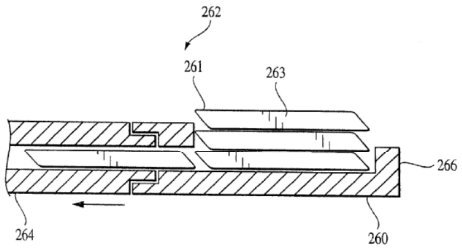


FIG. 37

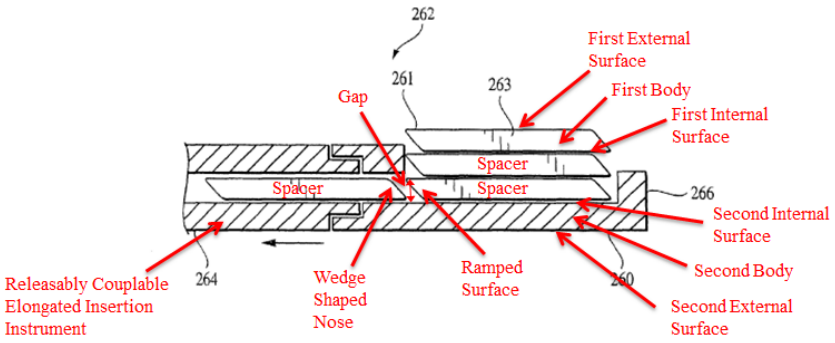
- In the detachable tip embodiment, wafers are inserted until

	the desired height or force is attained. As seen in FIG. 38, the distal tip 260 is then released from the main portion 264 of the wafer inserter and the main portion 264 of the inserter is removed. The distal tip may be pressfit onto the track or may be bonded with an appropriate adhesive. In either case, the interface is designed to support the forces generated while building a wafer column, but shear when the extraction plunger is used to remove the wafer inserter. Optionally, the distal tip 260 may be keyed to interlock with the main portion 264 of the wafer inserter. For example, the main portion of the inserter may interlock with the distal tip by spring-loaded hooks that are mechanically compressed when the tip is to be released. Alternately, the hooks may be spring-loaded in the release position and mechanically expanded to engage the distal tip. In another embodiment, the detachable tip may be pressfit onto the wafer inserter or bonded with a weak adhesive. When the wafer inserter is to be removed, a force may be applied using a longer plunger or equivalent mechanism as in the fixed tip wafer inserter to dislodge the removable tip. The track of the wafer inserter may be then removed. **Col. 17, line 65-Col. 18, line 19** • Johnson discloses an elongated insertion instrument releasably couplable to the first or second body during use. **EX1005, Ochoa Decl. at ¶ 35.**

A PHOSITA would have understood that '998 patent discloses an elongated insertion instrument, or wafer inserter. **EX1004, Col. 15, lines 55-65; FIG. 34.** A PHOSITA would have understood that the use of elongated instruments was common in spinal surgery where the portions of the neck, back, thorax, or abdomen may be traversed in order to reach a relatively small access field for insertion of the interbody device. **EX1005 Ochoa Decl. at ¶ 35.** Further, a PHOSITA would have understood the need for such elongated insertion instrument

to be coupled to the devices being deployed during surgery, but decoupled once the implantation was complete. **EX1005 Ochoa Decl. at ¶ 35.** A PHOSITA would have also understood that the modular design of the implant and insertion instrument, including the detachable distal tip of the elongated wafer inserter, could be used in place of the lowermost wafer, thus replacing the second body. **EX1004, Col. 17, lines 47-64; FIG. 37; EX1005 Ochoa Decl. at ¶ 35.** After inserting wafers until the desired height or force is attained, the distal tip is released from the main portion of the inserter, leaving the distal tip in place. **EX1004Col. 17, line 65-Col. 18, line 19; FIG. 37** This provides the advantage that the height of the wafer column is not altered when the inserter is removed. **EX1004Col. 17, lines 47-53; EX1005 Ochoa Decl. at ¶ 35.** With the distal tip serving as the second body, and the insertion instrument decoupling from the distal tip once the procedure is complete, the insertion instrument releasably couples to the second body. **EX1005, Ochoa Decl. at ¶ 35.**

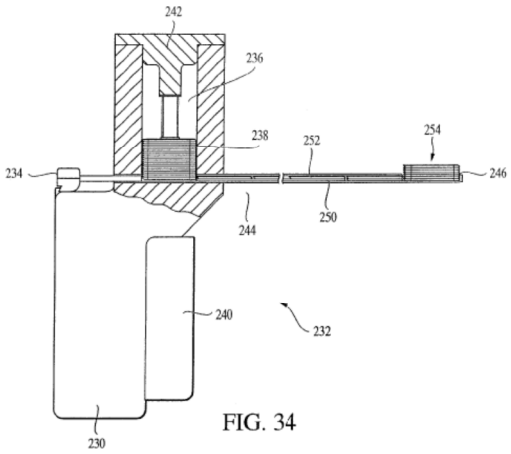
A summary image illustrating the elements discussed above is included in the Figure below.

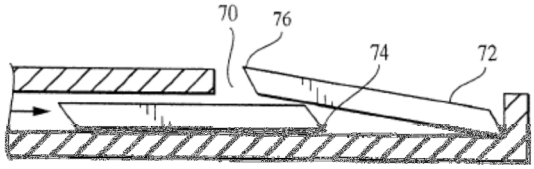
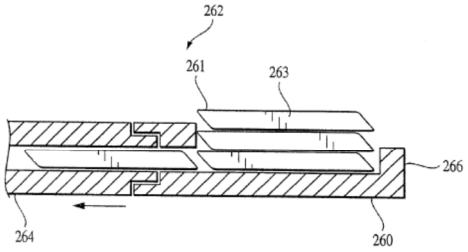


Therefore, a PHOSITA would have understood that the Johnson reference discloses *an elongated insertion instrument releasably couplable to the first or second body during use*, as recited in claim 1. **EX1005 Ochoa Decl. at ¶ 35.**

'386 patent Claim 1 vs. '998 patent	
a spacer linearly advanced between the first internal surface of the first body and the second internal surface of the second body during use, wherein the elongated insertion instrument guides at least a portion of the linear advancement of the spacer after the first and second bodies have been disposed substantially between the first and second vertebrae from a position remote to the first and second bodies during use, and	The '998 patent (**EX004**) 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** • 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. **EX1004, Col. 6, lines 36-43** • A further wafer option is to alter the shape of the wafers. The wafers may be straight or may be curved along a constant radius extending from an axis parallel to the axis of the desired wafer column. In the case of straight wafers, stacking is longitudinal and the insertion instrument deploys the wafers linearly. In the case of curved wafers, stacking is along the arch of the curve and the insertion instrument deploys the wafers along an arch. Reference is made to FIG. 46. Alternatively, the curved wafers may have a ridge on the top surface of slightly different configuration than that of the mating groove on the under

	surface thereby creating a frictional lock when one wafer is inserted under another. In all wafer embodiments containing mating ridges and grooves, the ridges are described as being on the top surface of the wafer and the groove on the bottom surface. The wafers would function equivalently if the groove were on the top surface and the ridge on the bottom surface. **EX1004, Col. 13, lines 8-24;** • Numerous variations of the wafer inserter are possible, the embodiments generally including, but not limited to, a track, a plunger, and a cartridge. The wafer inserter is comprised of a track, which is a long narrow channel through which wafers pass when placed into the wafer column. A plunger generally advances wafers down the track. Multiple wafers are housed in a cartridge of the wafer inserter for advancement down the track. Preferably included is a mechanism for feeding subsequent wafers into the track in front of the plunger. **EX1004, Col. 15, line 66-Col. 16, line 8;** • One embodiment of the wafer inserter is illustrated in FIG. 34. The handle 230 may be gripped to position the wafer inserter 232. The wafer inserter 232 has, at its proximal end 234, a magazine 236 containing wafers 238. The wafers 238 may be stacked in the magazine 236 with a top surface of one wafer supporting the bottom surface of an adjacent wafer. The handle 230 is equipped with a trigger 240 for forcing wafers out of the magazine 236. Optionally, the magazine 236 is equipped with a spring 242 to load wafers 238 along the track 244 of the inserter 232. The track 244 of the inserter 232 extends from the magazine 236 to the surgical site at its distal end 246. As they enter the wafer track 244, the wafers 238 are aligned with the leading edge of one wafer adjacent the trailing edge of a preceding wafer. The track 244 in the embodiment shown in FIG. 34 includes a lower cavity 250 and an upper cavity 252. The plunger extends through the lower cavity 250 while the wafers 238 are aligned along the upper surface of the plunger. An opening is provided along the top surface of the lower cavity 250 at the distal end 246 of the track 244 to accommodate a wafer. Thus, as the plunger is retracted past the trailing edge of the furthest

	distal wafer, the wafer drops into the lower cavity. The plunger pushes the wafer distally to form a column of wafers 254. FIG. 35 provides a close up of the wafer inserter magazine 236, track 244, and distal end 246. FIG. 36 shows an extreme close up of the distal end 246 of the wafer inserter 232 along the track 244. **EX004, Col. 16, lines 25-51** • See e.g. **EX1004** at Fig. 34 below.  FIG. 34 • A wafer inserter configured for deployed wafer columns in opposite directions is depicted in FIG. 30. Two triggers, 211 and 213 are included in the handle 230 and are operatively coupled to upper and lower magazines of wafers 210 and 209, respectively. The upper trigger 211 inserts a wafer at the bottom of the top wafer column 212 and advances that column superiorly (in the positive Z-axis). The bottom trigger 213 inserts a wafer at the top of the lower wafer column and advances that column inferiorly (in the negative Z-axis). Alternatively, the wafer inserter could be designed so that one trigger could control both columns independently. Other configurations for deploying opposing wafer columns with a single wafer inserter may be used as would be obvious to a person skilled in the art. **EX1004, Col. 16, lines 52-65** • 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. 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 47-63** • See e.g. **EX1004** at Figs. 4 and 37 below.  FIG. 4  FIG. 37 • Johnson discloses a spacer linearly advanced between the first internal surface of the first body and the second internal surface of the second body during use, wherein the elongated insertion instrument guides at least a portion of the linear advancement of the spacer after the first and second bodies have been disposed substantially between the first and second vertebrae from a position remote to the first and second bodies during use. **EX1005, Ochoa Decl. at ¶ 36.**

A PHOSITA would have understood that '998 patent discloses the use of a wafer inserter to place wafers between tissue surfaces. As described in the patent, *"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."* **EX1004, Col. 6, lines 36-43.** A PHOSITA would have understood that the plunger is used to move the wafer linearly as it is guided from a magazine at the proximal end of the inserter through a long narrow track to the surgical site. **EX1004, Col. 13, lines 8-24; Col. 15, line 66-Col. 16, line 8; Col. 16, lines 25-65; FIGS. 4, 34, 37, 60 and 61.** A PHOSITA would have also understood that the wafers are designed with beveled leading and trailing edges so that when lined up end-to-end, force on the trailing edge of the wafer causes its leading edge to slide below the trailing edge of the leading wafer, thereby lifting the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7; FIG. 4.** Therefore, after insertion of the first wafer, each subsequent wafer would be linearly advanced between the bottom surface of the first body (uppermost wafer) and the top surface of the second body (distal tip "260"). **EX1005 Ochoa Decl. at ¶ 36.**

A PHOSITA would have therefore understood that the '998 patent discloses, *a spacer linearly advanced between the first internal surface of the first body and*

the second internal surface of the second body during use, wherein the elongated insertion instrument guides at least a portion of the linear advancement of the spacer after the first and second bodies have been disposed substantially between the first and second vertebrae from a position remote to the first and second bodies during use, as recited in the claims. **EX1005, Ochoa Decl. ¶ 36.**

A summary image illustrating the elements discussed above is included in Figure 1.

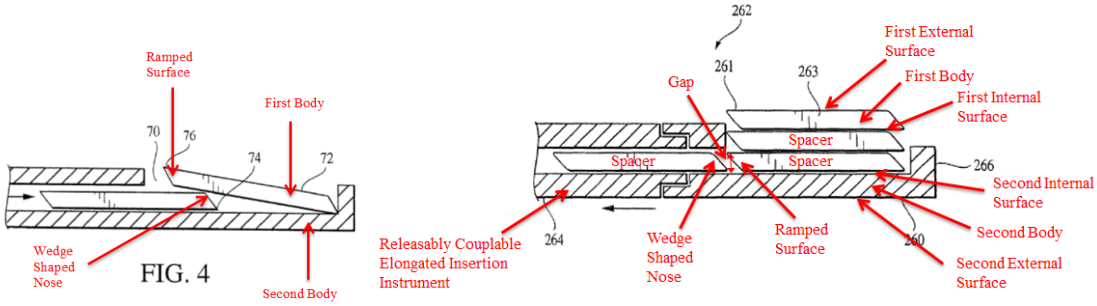


Figure 1. Excerpt from the '899 patent illustrating various claim elements.

'386 patent Claim 1 vs. '998 patent	
wherein the linear advancement of the spacer results in expansion of the intervertebral implant such that the first external surface and the second external surface	The '998 patent (**EX004**) discloses: • See chart above for citations to the specification that are incorporated herein by reference. • Johnson discloses wherein the linear advancement of the spacer results in expansion of the intervertebral implant such that the first external surface and the second external surface move away from one another to expand a height of the implant. **EX1005, Ochoa Decl. at ¶ 36.**

move away from one another to expand a height of the implant.	

A PHOSITA would have understood that '998 patent discloses the use of a wafer inserter to place wafers between tissue surfaces. As described in the patent, *"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."* **EX1004, Col. 6, lines 36-43.** A PHOSITA would have understood that the plunger is used to move the wafer linearly as it is guided from a magazine at the proximal end of the inserter through a long narrow track to the surgical site. **EX1004, Col. 13, lines 8-24; Col. 15, line 66-Col. 16, line 8; Col. 16, lines 25-65; FIGS. 4, 34, 37, 60 and 61.** A PHOSITA would have also understood that the wafers are designed with beveled leading and trailing edges so that when lined up end-to-end, force on the trailing edge of the wafer causes its leading edge to slide below the trailing edge of the leading wafer, thereby lifting the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7; FIG. 4.** Therefore, after insertion of the first wafer, each subsequent wafer would be linearly advanced between the bottom

surface of the first body (uppermost wafer) and the top surface of the second body (distal tip "260"). **EX1005 Ochoa Decl. at ¶ 36.** The linear advancement of the spacer results in the expansion of the intervertebral implant such that the first and second external surfaces "move away from one another" – "change in position relative to one another" to expand the height of the implant. **EX1005 Ochoa Decl. at ¶ 36.**

A summary image illustrating the elements discussed above is included in Figure 2 below.

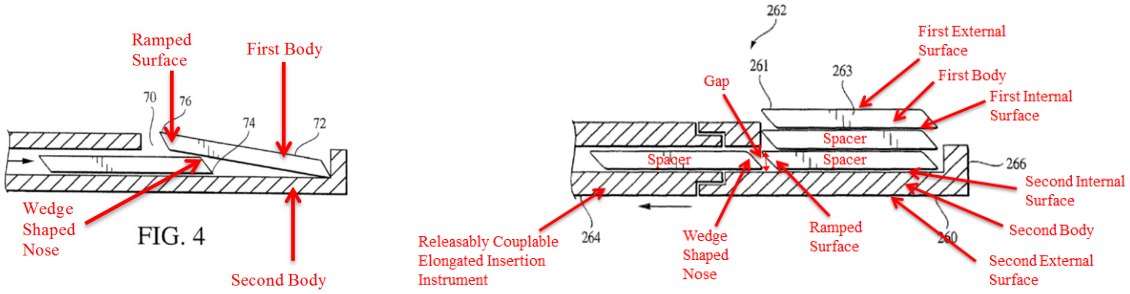


Figure 2. Excerpt from the '899 patent illustrating various claim elements and illustrating the external surfaces change in position relative to one another.

A PHOSITA would have therefore understood that the '998 patent discloses, *wherein the linear advancement of the spacer results in expansion of the intervertebral implant such that the first external surface and the second external surface move away from one another* [change in position relative to one another] *to expand a height of the implant*, as recited in the claims. **EX1005, Ochoa Decl. ¶ 36.**

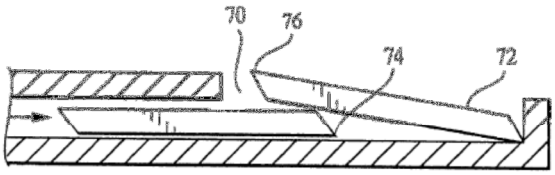
The claim charts attached as **EX1017** provide additional details supporting the information that would have been conveyed by the '899 patent and understood by a PHOSITA at the time of the invention of the '386 patent. **EX1005, Ochoa Decl. at ¶ 36.**

Consequently, and as supported by Dr. Ochoa, the Johnson reference renders claim 1 obvious and unpatentable under 35 U.S.C. § 103.

2. Claim 2

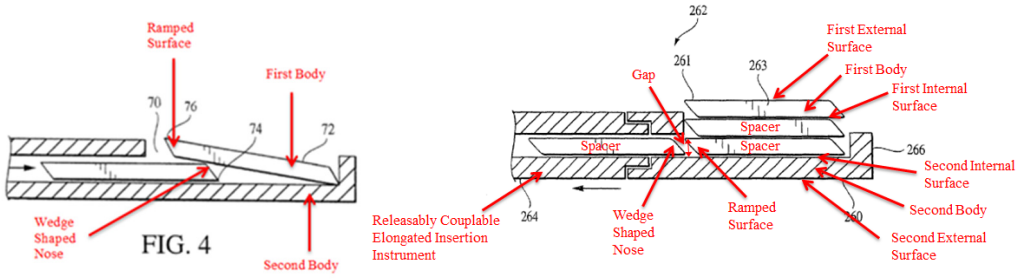
Claim 2 depends from claim 1. Claim 2 further describes device as including *wherein the spacer is disposed in a gap between the first and second internal surfaces of the first and second bodies during use*. Claim 2 is obvious in view of Johnson. This is demonstrated with reference to the chart below and accompanying text.

'386 patent Claim 2 vs. '998 patent	
2. The system of claim 1, wherein the spacer is disposed in a gap between the first and second internal surfaces of the first and second bodies during use.	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** • See e.g. **EX1004** at Fig. 4 below.

	 FIG. 4 • Johnson discloses the spacer is disposed in a gap between the first and second internal surfaces of the first and second bodies during use. **EX1005, Ochoa Decl. at ¶ 37.**

A PHOSITA would have understood that the wafers disclosed in the'998 patent are designed with beveled leading and trailing edges so that when lined up end-to-end, force on the trailing edge of the wafer causes its leading edge to slide into a gap below the trailing edge of the leading wafer, thereby lifting the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7; FIG. 4.** Therefore, after insertion of the first wafer, each subsequent wafer would be linearly advanced between the bottom surface of the first body (uppermost wafer) and the top surface of the second body (distal tip "260"). **EX1005, Ochoa Decl. at ¶ 37.**

The summary image illustrating the elements above is included in the Figure below.



A PHOSITA would have therefore understood that the '998 patent discloses, *wherein the spacer is disposed in a gap between the first and second internal surfaces of the first and second bodies during use*, as recited in the claims. **EX1005, Ochoa Decl. at ¶ 37.**

Consequently, and as supported by Dr. Ochoa, the Johnson reference renders claim 2 obvious and unpatentable under 35 U.S.C. § 103.

3. Claim 3

Claim 3 depends from claim 1. Claim 3 further describes the *wherein a leading end of the spacer comprises a wedge shaped nose.* Claim 3 is obvious in view of the Johnson patent. This is demonstrated with reference to the chart below and accompanying text.

'386 patent Claim 3 vs. '998 patent	
3. The system of claim 1, wherein a leading end of the spacer comprises a wedge shaped nose.	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, lines 64-Col. 6, line 7** • See e.g. **EX1004** at Figs. 4, 8, 10, 12, 14, and 16 below.

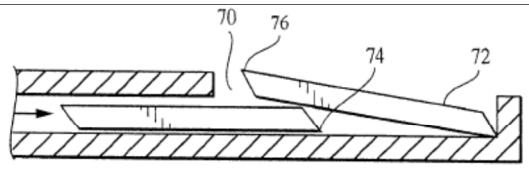


FIG. 4

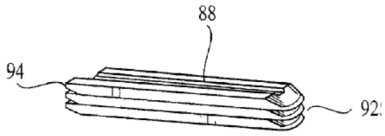


FIG. 8

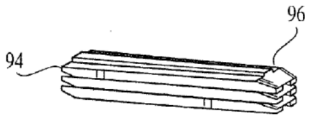


FIG. 10

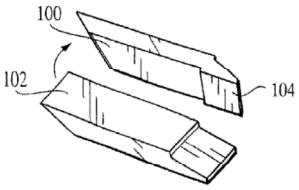


FIG. 12

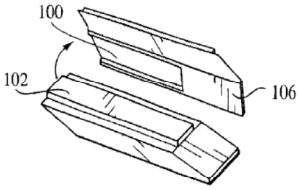


FIG. 14

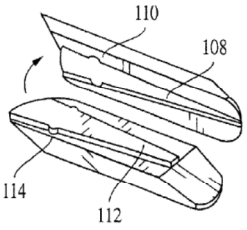


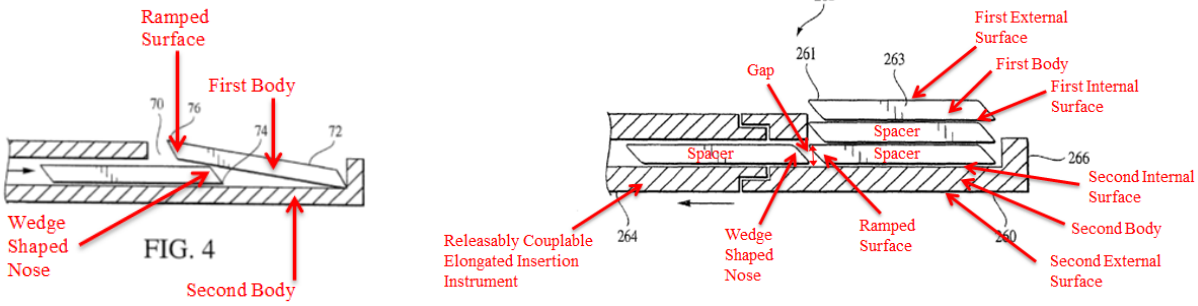
FIG. 16

- Johnson discloses a leading end of the spacer comprises a wedge shaped nose. **EX1005, Ochoa Decl. at ¶ 38.**

A PHOSITA would have understood that the wafers disclosed in the‘998 patent are designed with wedge shaped noses (beveled leading) and trailing edges so that when lined up end-to-end, force on the trailing edge of the wafer causes its leading edge to slide into a gap below the trailing edge of the leading wafer, thereby lifting the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7; FIGS. 4, 8, 10, 12, 14, 16, 34.** Therefore, after insertion of the first wafer, each subsequent wafer would be linearly advanced between the bottom surface of the first body (uppermost wafer) and the top surface of the second body (distal tip “260”).

EX1005, Ochoa Decl. at ¶ 38.

The summary image illustrating the elements above is included in the Figure below.



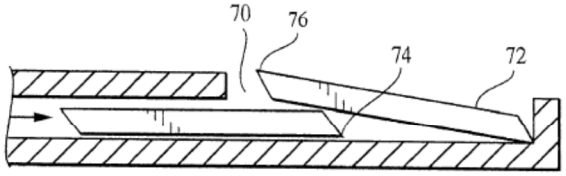
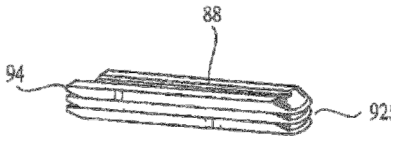
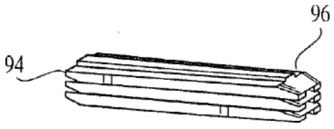
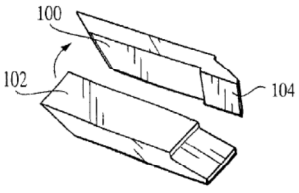
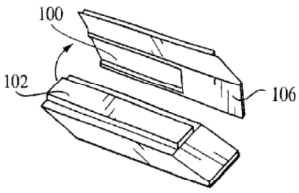
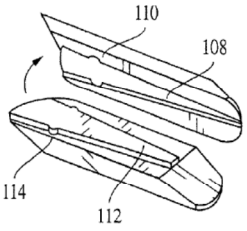
A PHOSITA would have therefore understood that the '998 patent discloses, *the system of claim 1, wherein a leading end of the spacer comprises a wedge shaped nose, as recited in the claims.* **EX1005, Ochoa Decl. at ¶ 38.**

Consequently, and as supported by Dr. Ochoa, the Johnson reference renders claim 3 obvious and unpatentable under 35 U.S.C. § 103.

4. Claim 4

Claim 4 depends from claim 1 and further describes *wherein at least one of the first or second bodies comprise a ramped surface engaged by the wedge shaped nose as the spacer is linearly advanced during use.* Claim 4 is obvious in view of the Johnson patent. This is demonstrated with reference to the chart below and accompanying text.

'386 patent Claim 4 vs. '998 patent	
4. The system of claim 3, wherein	Johnson (the '998 patent) **(EX1004)** discloses: • During implantation, the wafers are stacked to form a

at least one of the first or second bodies comprise a ramped surface engaged by the wedge shaped nose as the spacer is linearly advanced during use.	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. **EX1004** at Figs. 4, 8, 10, 12, 14, and 16 below.  FIG. 4  FIG. 8  FIG. 10  FIG. 12  FIG. 14  FIG. 16 • Johnson discloses at least one of the first or second bodies comprise a ramped surface engaged by the wedge shaped nose as the spacer is linearly advanced during use. **EX1005 Ochoa Decl. at ¶ 39.**

A PHOSITA would have understood that the wafers disclosed in the‘998 patent are designed with wedge shaped noses (beveled leading) and trailing edges so that when lined up end-to-end, force on the trailing edge of the wafer causes its leading edge to slide into a gap below the trailing edge of the leading wafer, thereby lifting the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7; FIGS. 4, 8, 10, 12, 14, 16 and 34.** Therefore, after insertion of the first wafer, each subsequent wafer would be linearly advanced between the bottom surface of the first body (uppermost wafer) and the top surface of the second body (distal tip “260”). **EX1005, Ochoa Decl. at ¶ 39.**

A PHOSITA would have therefore understood that the ‘998 patent discloses, *the system of claim 3, wherein at least one of the first or second bodies comprise a ramped surface engaged by the wedge shaped nose as the spacer is linearly advanced during use*, as recited in the claims. **EX1005, Ochoa Decl. at ¶ 39.**

Consequently, and as supported by Dr. Ochoa, the Johnson reference renders claim 4 obvious and unpatentable under 35 U.S.C. § 103.

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

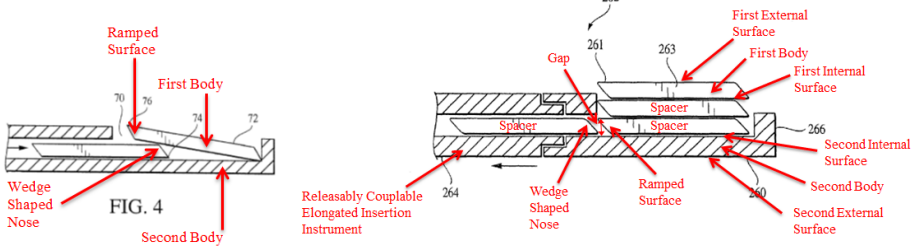


FIG. 4

The claim charts attached as **EX1017** provide additional details supporting the information that would have been conveyed by the '899 patent and understood by a PHOSITA at the time of the invention of the '386 patent.

Consequently, and as supported by Dr. Ochoa, the Johnson reference renders claims 1-4 obvious and unpatentable under 35 U.S.C. § 103.

B. Ground 2: Claims 1, 2, 3, and 4, are 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

To the extent that "move away from one another" is narrowly interpreted as requiring the first and second external surfaces to each move (bidirectional), the Johnson reference discloses a bidirectional implant that renders claims 1-4 obvious under 35 U.S.C. § 103 as noted below:

1. Claim 1

The excerpts from the specification and the corresponding support and statements noted in Ground 1 support all claim limitations in claim 1, with the exception of what is reflected below, and are incorporated herein by reference from Ground 1.

As to the claim language concerning, "*a first body comprising:…"* and "*a second body comprising:…"* a PHOSITA would have understood that during use as an interbody fusion device the wafer columns described in the '998 patent would be supported between the bone surfaces of a decorticated superior and

decorticated inferior endplate. **EX1004, Col. 24, line 43-53.** Each wafer in the column comprises a superior (upper) and inferior (lower) surface. **EX1004, Col. 5, line 51-55.** As a result, the external, upper surface of the uppermost wafer in the wafer column would engage the inferior surface of the superior endplate and the internal, lower surface of the uppermost wafer in the wafer column would engage the superior surface of the second highest wafer in the column. **EX1005, Ochoa Decl. at ¶ 43.** Similarly, the external, lower surface of the lowest wafer in the column, would engage the superior surface of the inferior endplate and the internal upper surface of the lowest wafer in the column would engage the inferior surface of the second lowest wafer in the column. **EX1004, Col. 5, line 63-Col. 6, line 7; Col. 10, line 1-8, Figure 29, Figure 60, Figure 61; EX1005, Ochoa Decl. at ¶ 43.**

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

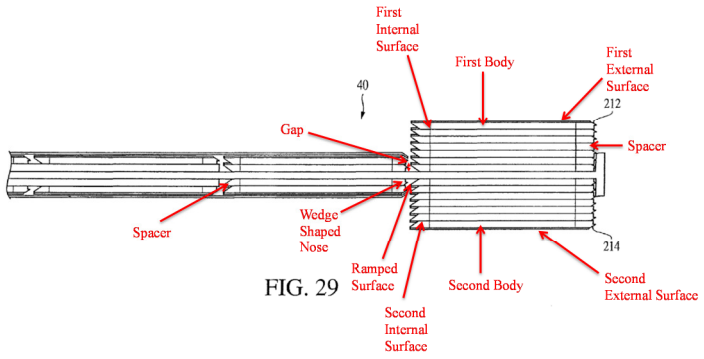


FIG. 29

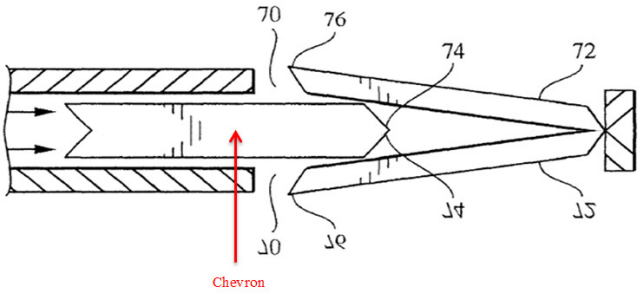
As to the claim limitation "*an elongated insertion instrument releasably*

couplable to the first or second body during use," a PHOSITA would have understood that '998 patent discloses an elongated insertion instrument, or wafer inserter. **EX1004, Col. 15, lines 55-65; FIG. 30.** A PHOSITA would have understood that the use of elongated instruments was common in spinal surgery where the portions of the neck, back, thorax, or abdomen may be traversed in order to reach a relatively small access field for insertion of the interbody device. **EX1004, Col. 15, line 55-65, Figure 30.** A PHOSITA would have understood that is was common for elongated insertion instruments to be coupled to the implantable devices being deployed during surgery but decoupled once the implantation was complete. **EX1005, Ochoa Decl. at ¶ 44.** After inserting wafers until the desired height or force is attained, the distal tip is released from the main portion of the inserter, leaving the distal tip in place. **EX1004, Col. 17, line 65-Col. 18, line 19, Figure 37.** This provides the advantage that the height of the wafer column is not altered when the inserter is removed. **EX1004, Col. 17, line 47-53.** A PHOSITA would have understood that in certain applications, it may be beneficial for the wafers to be secured to one another after insertion. **EX1004, Col. 13, line 25-34.** When used for intervertebral fusion securing the wafer stack would prevent instability due to shearing between neighboring wafers. **EX1004, Col. 13, line 25-34; Col. 6, line 49-58.** Securing the wafer stack is achieved either by modifying the wafer interfaces by means of an adhesive bond, a chemical bond

and/or a mechanical interlock. **EX1004, Col. 11, line 11-20; Col. 12, line 50-58; Col. 13, line 1-8; Col. 13, line 25-56; Col. 6, line 49-58.** A PHOSITA would have understood that application of any of these means would result in coupling of the detachable distal tip of the inserter to the wafer column and in turn to the first and/or second bodies. **EX1005, Ochoa Decl. at ¶ 44.**

As to the claim language concerning, *a spacer linearly advanced between the first internal surface of the first body and the second internal surface of the second body during use, wherein the elongated insertion instrument guides at least a portion of the linear advancement of the spacer after the first and second bodies have been disposed substantially between the first and second vertebrae from a position remote to the first and second bodies during use and wherein the linear advancement of the spacer results in expansion of the intervertebral implant such that the first external surface and the second external surface move away from one another to expand a height of the implant*, a PHOSITA would have understood that as described in the patent, "*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.*" **EX1004, Col. 6, line 36-42.** A PHOSITA

would have understood that the plunger is used to move the wafer linearly as it is guided from a magazine at the proximal end of the inserter through a long narrow track to the surgical site. **EX1004, Col. 15, line 66-Col. 16, line 8; Col. 16 lines 25- 65, Figures 4, 34, 37, 60, 61.** A PHOSITA would have also understood that the wafers are designed with beveled leading and trailing edges so that when lined up end-to-end, force on the trailing edge of the wafer causes its leading edge to slide below the trailing edge of the leading wafer, thereby lifting the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7, Figure 4.** Therefore, after insertion of the first wafer, each subsequent wafer would be linearly advanced between the bottom surface of the first body (uppermost wafer) and the top surface of the second body (lowermost wafer). **EX1005, Ochoa Decl. at ¶ 45.** A PHOSITA would have understood that a single wafer insert could be used wherein the wafer inserter is able to deploy wafers in opposing directions, one column deployed superiorly and the other deployed inferiorly. **EX1004, Col. 14, line 61-65.** Wafer deployment may be simultaneous 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 nose (leading edge) as noted in the figure below 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.**



A PHOSITA would have, thus understood that the upper and lower body would move away from each other during distraction. **EX1005, Ochoa Decl. at ¶ 45.**

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

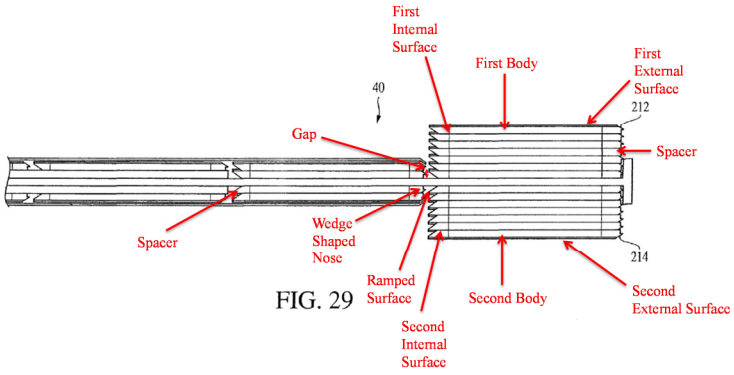


FIG. 29

Consequently, and as supported by Dr. Ochoa, under a narrower interpretation the Johnson reference renders claims 1 obvious and unpatentable under 35 U.S.C. § 103.

2. Claim 2

A PHOSITA would have understood that the wafers disclosed in the '998 patent are designed with beveled leading and trailing edges so that when lined up

end-to-end, force on the trailing edge of the wafer causes its leading edge to slide into a gap below the trailing edge of the leading wafer, thereby lifting the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7; FIG. 4.** Therefore, after insertion of the first wafer, each subsequent wafer would be linearly advanced between the bottom surface of the first body (uppermost wafer) and the top surface of the second body (lowermost wafer). A PHOSITA would have therefore understood that the '998 patent discloses, *the system of claim 1, wherein the spacer is disposed in a gap between the first and second internal surfaces of the first and second bodies during use*, as recited in the claims. **EX1005, Ochoa Decl. at ¶ 46.**

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

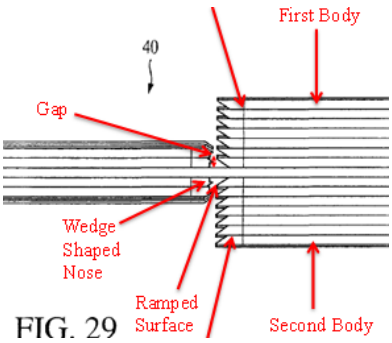
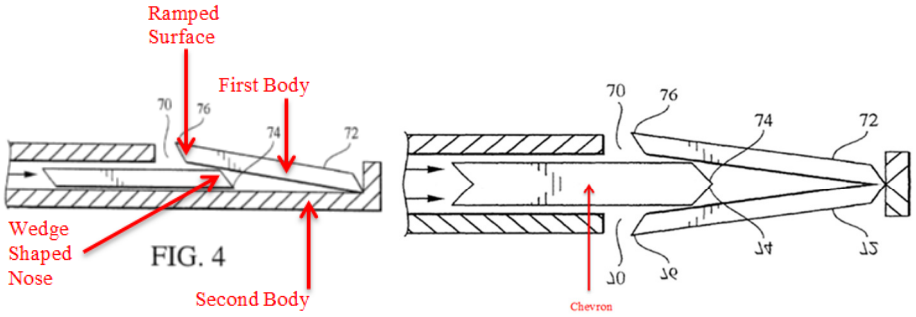


FIG. 29

3. Claim 3

A PHOSITA would have understood that the wafers disclosed in the'998 patent are designed with wedge shaped noses (beveled leading) and trailing edges so that when lined up end-to-end, force on the trailing edge of the wafer causes its leading edge to slide into a gap below the trailing edge of the leading wafer,

thereby lifting the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7; FIGS. 4, 8, 10, 12, 14, 16, and 34.** Therefore, after insertion of the first wafer, each subsequent wafer would be linearly advanced between the bottom surface of the first body (uppermost wafer) and the top surface of the second body (lowermost wafer) (as noted by way of illustration in the unidirectional figure below and by way of the illustration for a chevron).

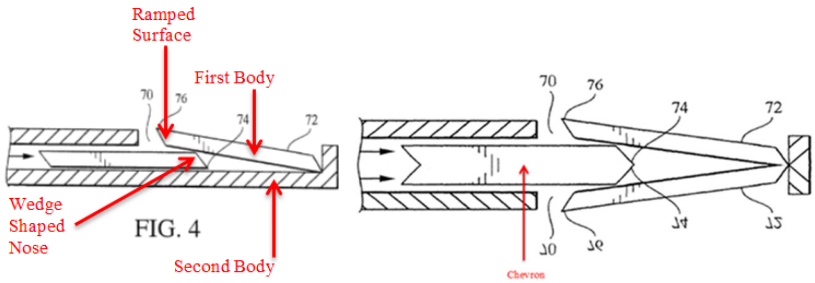


A PHOSITA would have therefore understood that the '998 patent discloses, *the system of claim 1, wherein a leading end of the spacer comprises a wedge shaped nose*, as recited in the claims. **EX1005, Ochoa Decl. at ¶ 47.**

4. Claim 4

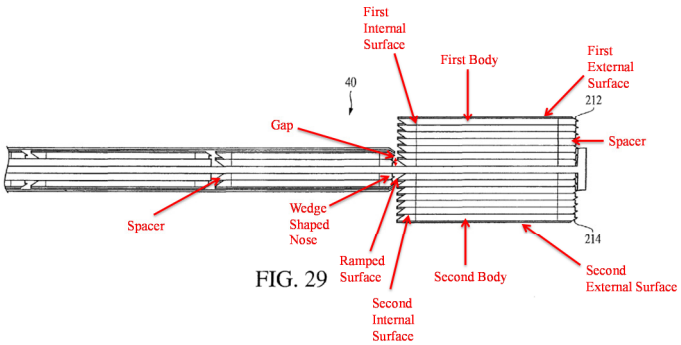
A PHOSITA would have understood that the wafers disclosed in the'998 patent are designed with wedge shaped noses (beveled leading) and trailing edges so that when lined up end-to-end, force on the trailing edge of the wafer causes its leading edge to slide into a gap below the trailing edge of the leading wafer, thereby lifting the leading wafer. **EX1004, Col. 5, line 66-Col. 6, line 7, FIGS. 4, 8, 10, 12, 14, 16 and 34.** Therefore, after insertion of the first wafer, each

subsequent wafer would be linearly advanced between the bottom surface of the first body (uppermost wafer) and the top surface of the second body (lowermost wafer) (as noted by way of illustration in the unidirectional figure below and by way of the illustration for a chevron).



A PHOSITA would have therefore understood that the '998 patent discloses, t*he system of claim 3, wherein at least one of the first or second bodies comprise a ramped surface engaged by the wedge shaped nose as the spacer is linearly advanced during use*, as recited in the claims. **EX1005, Ochoa Decl. at ¶ 48.**

Consequently, and as supported by Dr. Ochoa, under a narrower interpretation the Johnson reference (bidirectional) renders claims 1-4 obvious and unpatentable under 35 U.S.C. § 103. A summary image illustrating the elements is included in the Figure below.



The claim charts attached as **EX1018** provide additional details supporting the information that would have been conveyed by the '899 patent and understood by a PHOSITA at the time of the invention of the '386 patent.

IX. CONCLUSION

Petitioner has demonstrated in this Petition that claims 1, 2, 3, and 4 of the '386 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '386 patent.

Dated: August 24, 2015 By: / George D. Moustakas /

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CERTIFICATION OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, this is to certify that I caused a true and correct copy of the PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,647,386 to be served via FedEx, next day delivery, on the below listed counsel, on this 24th day of August, 2015:

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