

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. 8,123,810
Issued: February 28, 2012
Application No: 11/134,069
Filed: May 20, 2005

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,123,810

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LIST OF EXHIBITS

- EX1001 U.S. Patent No. 8,123,810
- EX1002 *Flexuspine, Inc. v. Globus Medical Inc.*, U.S. District Court for the Eastern District of Texas, Civil Action no. 15-cv-00201-JRG-KNM – Flexuspine, Inc.’s Claim Chart for P.R. 3-1 Infringement Contentions
- EX1003 Prosecution history of U.S. Patent No. 8,123,810
- EX1004 U.S. Patent No. 7,828,849 to Lim
- EX1005 U.S. Patent No. 6,595,998 to Johnson
- EX1006 Declaration of Jorge A. Ochoa, P.E.
- EX1007 Curriculum Vitae of Jorge A. Ochoa, P.E.
- EX1008 U.S. Patent No. 5,665,122 to Kambin
- EX1009 U.S. Patent No. 6,045,579 to Hochshuler
- EX1010 U.S. Patent no. 6,936,071 to Marnay
- EX1011 U.S. Patent no. 7,060,100 to Ferree
- EX1012 Blumenthal SL, Ohnmeiss DD. Intervertebral cages for degenerative spinal diseases. *Spine J.* Jul-Aug 2003;3(4):301-309
- EX1013 Dooris AP, Goel VK, Grosland NM, Gilbertson LG, Wilder DG. Load-sharing between anterior and posterior elements in a lumbar motion segment implanted with an artificial disc. *Spine (Phila Pa 1976)*. 2001;26(6):E122–129
- EX1014 Mayer HM, Wiechert K, Korge A, Qose I. Minimally invasive total disc replacement: surgical technique and preliminary clinical results. *Eur Spine J.* 2002 Oct;11 Suppl 2:S124-30.
- EX1015 Foley KT, Holly LT, Schwender JD. Minimally invasive lumbar fusion. *Spine (Phila Pa 1976)*. Aug 1 2003;28(15 Suppl):S26-35
- EX1016 Tropiano P, Huang RC, Girardi FP, Marnay T. Lumbar disc

replacement: preliminary results with ProDisc II after a minimum follow-up period of 1 year. J Spinal Disord Tech. 2003 Aug;16(4):362-8.

- EX1017 Folman Y, Lee S-H, Silvera JR, Gepstein R. Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer: a multicenter study. J Spinal Disord Tech.. 2003;16(5):455–460
- EX1018 Wagner PC, Bagby GW, Grant BD, Gallina A, Ratzlaff M, Sande R. Surgical stabilization of the equine cervical spine. Vet Surg 1979 8:7-12
- EX1019 Weiner BK, Fraser RD. Spine update lumbar interbody cages. Spine. 1998 Mar 1; 23(5):634-40
- EX1020 Zeegers WS, Bohnen LM, Laaper M, Verhaegen MJ. Artificial disc replacement with the modular type SB Charite III: 2-year results in 50 prospectively studied patients. Eur Spine J. 1999;8(3):210-217
- EX1021 Claim chart – Claim 17 vs. U.S. Patent No. 7,828,849
- EX1022 Claim chart – Claim 17 vs. U.S. Patent No. 6,595,998

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 claim 17 of U.S. Patent No. 8,123,810, titled “Expandable Intervertebral Implant With Wedged Expansion Member” (“the ‘810 patent”), issued to Charles Gordon, Corey T. Harbold and Heather S. Hanson and assigned to Flexuspine, Inc. (“Flexuspine”). The ‘853 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 claim 17 of the ‘810 patent is obvious in view of the prior art. Evidentiary support for Petitioner’s conclusions is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. **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 claim 17 of the ‘810 patent be reviewed and held unpatentable.

II. FORMALITIES

A. Mandatory Notices

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

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

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

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

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

Please direct all correspondence to lead counsel at the above address.

Petitioner consents to email service at the above-referenced email addresses.

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

Petitioner states that the ‘810 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 '810 patent. *See* **EX1002**.

Concurrently with this Petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 7,316,714 ("the '714 patent"), U.S. Patent No. 7,909,869 ("the '869 patent"), U.S. Patent No. 7,204,853 ("the '853 patent"), and U.S. Patent No. 8,647,386 ("the '386 patent"). The '386 patent, '714 patent, '869 patent, and '853 patent are related to the '810 patent through continuation practice. Petitioner understands that the '810 patent, the '714 patent, the '869 patent, the '853 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 '810 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 '810 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. 8,123,810 (“THE ‘810 PATENT”) (EX1001)

The continuation application leading to the ‘810 patent, Serial No. 11/134,069, was filed on May 20, 2005. This continuation was based on Serial No. 11/050,632, filed on February 3, 2005, which is a continuation-in-part of Serial No. 10/634,950 filed August 5, 2003, now U.S. Patent No. 7,204,853; Serial No. 10/660,155 filed on September 11, 2003 now U.S. Patent No. 7,316,714; Serial No. 10/777,411 filed on February 12, 2004; and PCT Application No. US2004/025090 filed August 4, 2004. PCT Application No. US2004/025090 claims the benefit of Serial No. 10/634,950; Serial No. 10/660,155; and Serial No. 10/777,411. Serial No. 10/777,411 is a continuation-in-part of Serial No. 10/634,950. Serial No. 10/660,155 is a continuation-in-part of Serial No. 10/634,950. Serial No. 10/634,950 was filed August 5, 2003.

For purposes of this Petition, the earliest priority for the ‘810 patent is February 3, 2005. Petitioner notes that the subject matter of Fig. 17 to which Claim 17 is directed was added in continuation-in-part Application No. 11/050,632, filed on February 3, 2005.

A. The '810 Patent Specification and Claims

The '810 patent is directed to an expandable intervertebral implant. The challenged claims are directed to a known implantable device for achieving the objective of restoration and maintenance of disk space height. The '810 patent issued with 19 claims of which only claim 17 is at issue in this Petition. Claim 17 is independent.

The written description and drawings of the '810 patent describe various embodiments of expandable intervertebral implants. A perspective view of the expandable implant elected

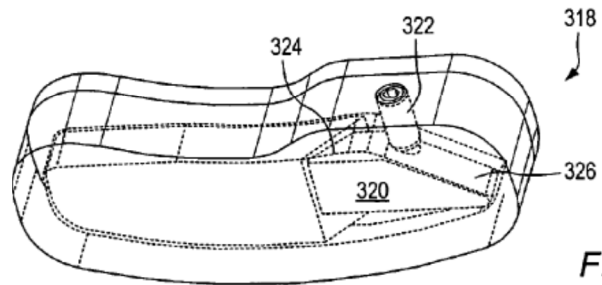


FIG. 17

by the Applicant pursuant to a restriction requirement (see Section B below) is at FIG. 17. **EX1001, Col. 6, lines 23-24; EX1003, at pages 1096.** Implant 318 includes expansion member 320. Expansion member 320 is advanced with advancing element 322. **EX1001, Col. 18, lines 7-9.** Advancing element 322 engages expansion member 320 from a side (e.g., anterior side, posterior side) of implant 318. **Id. at Col. 18, lines 9-14.** Expansion member 320 includes two angled portions. Angled portion 324 engages a portion of implant 318 (e.g., an insert or a portion of an upper body or a lower body). **Id. at Col. 18, lines 14-16.** Advancing element 322 engages angled portion 326, allowing a component of the

force from the advancing element to increase the height of implant 318. *Id.* at Col.18, lines 16-25.

B. The ‘810 Patent Prosecution History (EX1003)

The prosecution of the application before the U.S. Patent and Trademark Office leading to the ‘810 patent includes a Preliminary Amendment filed on August 17, 2005, in which all pending claims were cancelled and new claims were submitted. **EX1003, at page 1436.** On August 25, 2008, the Examiner issued a Restriction Requirement. **EX1003, at page 1104.** On October 22, 2008, the Applicant elected species 22, shown in Fig. 17. **EX1003, at page 1096.**

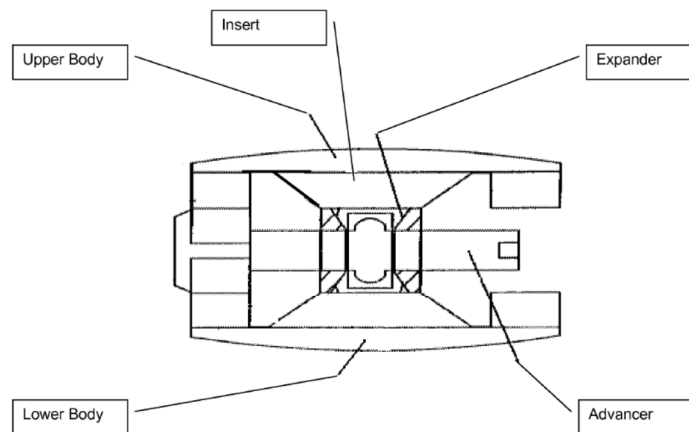
A Non-Final Office Action issued on December 24, 2008 in which all claims were rejected as anticipated by Dinsdale International Publication WO98/48739. **EX1003, at page 927.** On March 24, 2009, the Applicant responded to the Non-Final Office Action by adding claims 180 and 181 and by arguing the Dinsdale reference did not anticipate. **EX1003, at page 910.** On June 5, 2009, the Examiner issued an Office Action rejecting all claims as anticipated by Dinsdale, the Examiner noting that the arguments of the Applicant were not persuasive since they were based on mistake in the office action in which the insert component was mislabeled. **EX1003, at page 902.** The Examiner also noted the following:

Dinsdale discloses the same invention being an intervertebral implant (figures 27, and 31a-b) comprising upper body 203 having a superior surface that engages bone and an inferior surface that engages the insert 232a, lower body 204 an inferior surface that engages bone and a superior surface, an

expansion member 262a, and an advancer element 250 that drives the expansion member into the insert to increase the height of the implant. Both the insert and the expansion members comprise angled side surfaces that comprise wedges and flat upper and lower surfaces.

In regards to claims 163 and 173 the advancer element can be considered to advance into the device while the expansion member in the opposite direction.

In regards to claims 164 and 174 the advancer element can be considered to advance by rotating in an anterior to posterior direction while the expansion member is advanced in a perpendicular medial to lateral direction.



EX1003, at pages 904-905.

On September 8, 2009, the Applicant submitted its response to the Office Action in which it amended claim 169 as follows:

169. (currently amended): An intervertebral implant for a human spine, comprising:

an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine;

a lower body comprising a superior surface and an inferior surface, wherein the insert is configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine, and wherein the insert comprises an

angled portion;

an expansion member comprising a substantially flat inferior surface, a substantially flat superior surface, a first angled portion configured to engage the angled portion of the insert, and a second angled portion; and

an advancing element comprising an angled portion, wherein the advancing element is configured to be advanced linearly in a first direction such that~~wherein~~ the angled portion of the advancing element is ~~configured to engage~~ the second angled portion of the expansion member, thereby advancing the expansion member linearly in a second direction oblique to the first direction such that the first angled portion of the expansion member engages the angled portion of the insert, thereby increasing a separation distance between the upper body and the lower body of the intervertebral implant.

EX1003, at pages 888.

The Applicant amended claim 180 as follows:

180. (currently amended): An intervertebral implant for a human spine, comprising:

an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine;

a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine; and

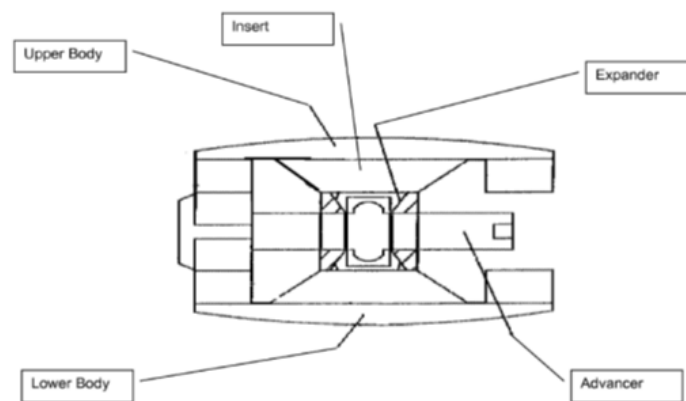
an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a face of a trailing end of the expansion member~~elongated body~~ opposite the insertion end of the ~~expansion member~~elongated body is configured to ~~cause advancement of~~ advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and substantially parallel to the inferior surface of the upper body and superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body.

EX1003, at pages 890.

On December 30, 2009, the Examiner issued a Final Rejection in which claims 169, 170, 172-174, 176, 178 and 179 were allowed, claims 158-160, 162, 165, 166, 168, 180 and 181 were rejected and claims 163 and 164 were objected to.

EX1003, at page 396. The Examiner noted the rejection as to claim 180 (which corresponds to issued claim 17) was based on 35 U.S.C. § 102(b) as anticipated by Dinsdale. **EX1003, at page 399.** The Examiner also noted as follows:

Dinsdale discloses the same invention being an intervertebral implant (figures 27, and 31a-b) comprising upper body 203 having a superior surface that engages bone and an inferior surface that engages the insert 232a, lower body 204 an inferior surface that engages bone and a superior surface, an expansion member 262a, and an advancer element 250 that drives the expansion member into the insert to increase the height of the implant. Both the insert and the expansion members comprise angled side surfaces that comprise wedges and flat upper and lower surfaces.



EX1003, at page 399.

On March 1, 2010, the Applicant responded to the Office Action, amending claims 180 and 181 as follows:

180. (currently amended): An intervertebral implant for a human spine, comprising:

an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine;

a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine; and

an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and ~~substantially parallel~~ at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body.

181. (currently amended): The intervertebral implant of claim 180, wherein applying a force to a face of the trailing end of the expansion member comprising advancing an advancing element into contact with a face of the trailing end of the elongated body of the expansion member, wherein the advancing element advances toward the expansion member in a direction at least partially oblique to the direction of advancement of the expansion member.

EX1003, at pages 385-386.

The Applicant's remarks concerning amended claim 180 are as follows:

Dinsdale discloses cam blocks (260,261), each having an internally threaded passage that is mated with a complementary external thread of a turnbuckle (250). (Dinsdale, p. 21, ll. 16-26). As disclosed by Dinsdale, the mated threads cause advancement of the cam blocks (260,261) upon rotation of the turnbuckle 250. The mated threads, however, also inhibit lateral movement

of the cam blocks (260,261) relative to the turnbuckle (250). That is, in Dinsdale application of a rotational torque to the turnbuckle (250) causes advancement of the cam blocks and, however, linear advancement via application of a force to a trailing end of the cam blocks (260,261) is actually inhibited by the mated threads.

Moreover, Applicant notes that the portions of the apparatus of Dinsdale that are advanced linearly (e.g., cam blocks 260,261) do not include an elongated body. The cam blocks are just that, blocks. In fact, the cam blocks (260, 261) appear to be of approximately equal length and height. Thus, Dinsdale does not disclose that applying a force to a trailing end of an elongated body of an expansion member that is configured to advance the expansion member in a substantially linear direction.

Further, Applicant notes that Dinsdale does not disclose advancing a first angled portion and substantially flat superior and inferior surfaces of an expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior and superior surfaces of the upper and lower bodies.

Accordingly, Applicant respectfully submit that Dinsdale does not teach or suggest at least the features of, “an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body, in combination with other features of the claim.

EX1003, at pages 389-390.

On April 19, 2010, the Examiner issued a Notice of Allowance. On June 16,

2010, the Applicant filed a Request for Continued Examination in which certain claims were amended and a new claim was added. **EX1003, at page 369.** On October 13, 2011, the Examiner issued a second Notice of Allowance. **EX1003, at page 26.**

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

As established in the Declaration of Dr. Ochoa (**EX1006 at ¶ 18**), a person having ordinary skill in the art (PHOSITA) of the '810 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience. The experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. Alternatively, a PHOSITA could have an advanced degree, in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

V. CLAIM CONSTRUCTION

The claims of the '810 patent are to be given their broadest reasonable construction in light of the '810 patent's specification as understood by a person

having ordinary skill in the art. 37 C.F.R. § 42.100(b).²

Claim 17, however, despite being given its broadest reasonable construction is not a model of clarity. More particularly, the following bolded claim limitation, reproduced in context, is not easily understood:

an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body **is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body** after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body.

EX1001, Col. 36, lines 13-29.

From the specification, Fig. 17 and the entirety of the written description concerning Fig. 17 are reproduced below:

FIG. 17 depicts a perspective view of an embodiment of a portion of an expandable implant. Implant 318 may include expansion member 320. Expansion member 320 may be advanced with advancing element 322. As depicted in FIG. 17, advancing element 322 may be a screw. In some embodiments, advancing element 322 may engage expansion member 320

² 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 '853 patent, as appropriate in that proceeding.

from a side (e.g., anterior side, posterior side) of implant 318. In some embodiments, expansion member 320 may include two angled portions. Angled portion 324 may engage a portion of implant 318 (e.g., an insert or a portion of an upper body or a lower body). Advancing element 322 may engage angled portion 326, thus allowing a component of the force from the advancing element to increase a height of implant 318. Accessing expansion member 320 from a longer side (e.g., posterior side) of implant 318 (PLIF approach) may advantageously require a smaller incision and/or cause less tissue damage during insertion of the implant than accessing the expansion member from shorter end of the implant (TLIF approach).

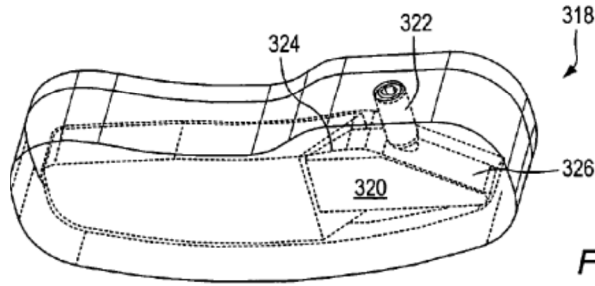
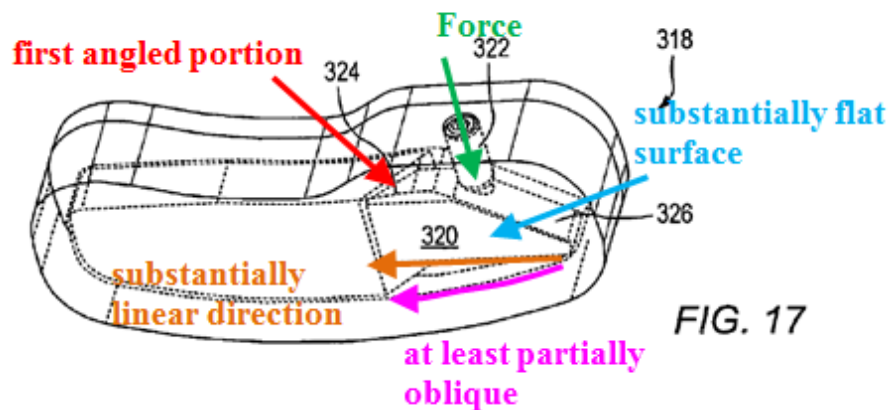
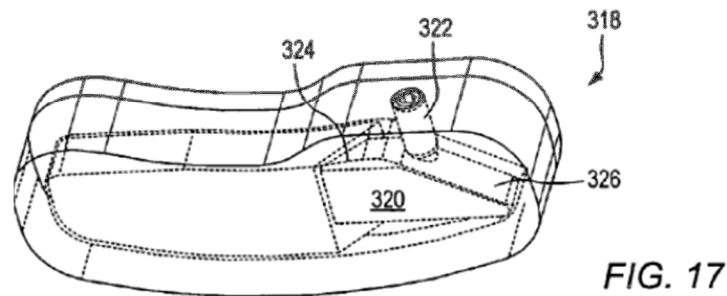


FIG. 17

EX1001, Col. 18, lines 6-25.

The written description standing alone provides insufficient guidance to understand the bolded claim limitation noted above concerning claim 17. Looking to the file history, however, as informed by the amendments and remarks of the Applicant to overcome WO 98/48739 to Dinsdale, the file history provides guidance on understanding claim 17. More particularly, during prosecution to distinguish over the Dinsdale reference the Applicant amended claim 180, which corresponds to issued claim 17, to add “at least partially oblique”. **EX1003 at pages 385-386.** The Applicant argued in its remarks in support of the amendment that the mated threads disclosed in Dinsdale inhibited lateral movement of cam blocks relative to a turnbuckle. *Id.* at **pages 389-390.** From the Applicant’s amendment and remarks, in conjunction with the written description and Fig. 17, it

appears clear that the curved shape of the upper and lower bodies of the implant at Fig 17 results in the expansion member (spacer) traveling in a substantially linear, generally tangential direction during deployment. Because of the curvature of the resulting path along the sidewall of the implant, the direction of travel would also be at least partially oblique (i.e. including a lateral/radial component) to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body. This is pictorially represented below, where Fig. 17 and Fig. 17 labelled, demonstrate the movement:



EX1006, Ochoa Decl. at ¶ 40.

With this understanding in place, Ground 1 below lays how Claim 17 is

unpatentable as obvious over the ‘849 patent (**EX1004**) in view of the knowledge of one of ordinary skill in the art. To the extent that the limitations of Claim 17 are read on their face, without consultation or reference to the specification or file history, Ground 2 below lays how Claim 17 is unpatentable as obvious over the ‘998 patent (**EX1005**) in view of the knowledge of one of ordinary skill in the art.

VI. THE PRIOR ART RELIED UPON IN THIS PETITION

A. U.S. Patent No. 7,828,849 to Lim (“the ‘849 patent” or “Lim”) (EX1004)

U.S. Patent No. 7,828,849 to Lim, entitled “Expanding Interbody Implant and Articulating Inserter and Method,” was filed on January 22, 2004. Lim is prior art to the ‘810 patent under 35 U.S.C. § 102(e) because it is a patent granted on an application for patent by another filed in the United States before the invention by the applicant of the ‘810 patent. Lim was neither disclosed by the patent applicant nor cited, referred to, or relied on by the Examiner during the prosecution of the application leading to the ‘810 patent.

B. U.S. Patent No. 6,595,998 to Johnson et al. (“the ‘998 patent” or “Johnson”) (EX1005)

U.S. Patent No. 6,595,998 to Johnson et al., entitled “Tissue Distraction Device,” published December 5, 2002. Johnson is prior art to the ‘810 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 ‘810 patent. Johnson was

disclosed by the applicant to the Patent Office during the prosecution of the application leading to the '810 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 claim 17 of the '810 patent is unpatentable as obvious to 35 U.S.C. § 103. As further discussed below, Petitioner submits that challenged independent claim 17 is obvious pursuant to 35 U.S.C. § 103.

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 claim 17 unpatentable as obvious under 35 U.S.C. § 103 (**EX1006 at ¶¶ 32-36**); and the '849 patent renders claim 17 unpatentable as obvious under 35 U.S.C. § 103³ (**EX1006 at ¶¶ 37-41**).

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

This petition presents the following Grounds of unpatentability:

- Ground 1: Claim 17 is unpatentable under 35 U.S.C. § 103 as obvious over

³ *KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

the '849 patent (**EX1004**) in view of the knowledge of one of ordinary skill in the art.

- Ground 2: Claim 17 is unpatentable under 35 U.S.C. § 103 as obvious over the '998 patent (**EX1005**) in view of the knowledge of one of ordinary skill in the art.

A. Ground 1: Claim 17 is unpatentable under 35 U.S.C. § 103 as obvious over the '849 patent (EX1004)

The '849 patent discloses an expandable intervertebral implant for use in spinal fusion surgical procedures. **EX1004, Col. 1, lines 32-39; Col. 10, lines 36-48; EX1006, Ochoa Decl. at ¶ 37.** The device ("spacer" 10) comprises three members, an upper body ("first member" 20) a lower body ("second member" 30) and an expansion member ("third member" 40). **EX1004, Col. 3, lines 47-53; FIG. 4; EX1006, Ochoa Decl. at ¶ 37.** Exterior, bone contacting surfaces ("contact surfaces" 21 and 31) are present on the superior surface of the upper body ("first member" 20) and the inferior surface of the lower body ("second member" 30). **EX1004, Col. 5, lines 25-32; Col. 10, lines 36-40; FIG. 4; EX1006, Ochoa**

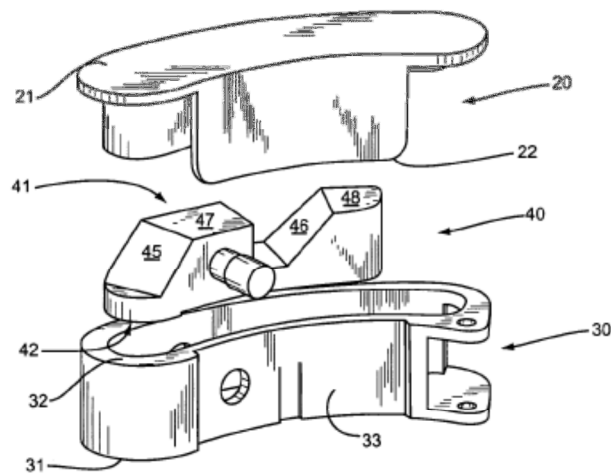


FIG. 4

Decl. at ¶ 37. Opposite the bone contacting surfaces, are interior surfaces, inner

section (39) on the lower body and support sections (27, 28) on the upper body.

EX1004, Col. 5, lines 7-14; Col. 5, lines 38-44; EX1006, Ochoa Decl. at ¶ 37.

During deployment, force is applied to the trailing end of the expansion member by a cam (84) on a delivery device (80), such that the expansion member (“third member” 40) advances relative to the upper and lower members (“first and second members” 20 and 30). **EX1004, Col. 7, lines 16-42; FIGS. 18 and 19; EX1006, Ochoa Decl. at ¶ 37.** Advancement of the expansion member causes sliding contact between angled sections 45 and 46 on the expansion member angled sections 25 and 26 on the upper body thus increasing the spacer height. **EX1004, Col. 5, lines 7-14; Col. 7, lines 25-42; FIG. 9; EX1006, Ochoa Decl. at ¶ 37.**

A PHOSITA would have understood that the implant of claim 17 is obvious as demonstrated with reference to the chart below.

1. Claim 17

Claim 17 is directed to an intervertebral implant device for a human spine. Claim 17 is obvious in view of Lim. The claim chart and accompanying analysis below evidence this conclusion.

‘810 patent Claim 17 vs. ‘849 patent	
<i>17. An intervertebral implant for a human spine, comprising:</i>	Lim (the ‘849 patent) (EX1004) discloses: <ul style="list-style-type: none">• The present invention is directed to a device for positioning between adjacent vertebral members. In one embodiment, the device generally includes a spacer, a delivery device, and a deployer. The spacer is positioned between adjacent vertebral members and is selectively

	<p>adjustable between a closed orientation, open orientation, and gradations therebetween. The delivery device positions the spacer within the patient, and the deployer moves the spacer to the selected orientation. EX1004, Col. 1, lines 32-39</p> <ul style="list-style-type: none"> • The spacer may be positioned within the disc space between adjacent vertebrae. Contact surfaces 21, 31 contact the end plates of the vertebra to space the vertebra as necessary. The spacer 10 may be inserted posteriorly, anteriorly, or laterally into the patient. EX1004, Col. 10, lines 36-41 • The contact surfaces 21, 31 may be porous to allow bone ingrowth into the spacer 10. One or both contact surfaces 21, 31 may include one or more apertures. Bone growth material is positioned within the apertures to accommodate bone growth through the entire implant. The bone growth material may include a sponge, matrix, and/or other carrier impregnated with a protein such as bone morphogenic protein (BMP), LIM mineralization protein (LMP), etc. EX1004, Col. 10, lines 42-48 • Lim discloses an intervertebral implant for a human spine. EX1006, Ochoa Decl. at ¶ 38.
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The preamble of claim 17 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.⁴

To the extent that the preamble limits the claim, a PHOSITA would have understood that the spinal implant described in the '849 patent is an interbody spacer for use in spinal fusion procedures. **EX1004, Col. 1, lines 32-39; Col. 10, lines 36-48.** The spinal implant is described as being deployed between adjacent

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.

vertebrae. **EX1004, Col. 1, lines 32-39; Col. 10, lines 36-41.**

A PHOSITA would have recognized that the '849 patent application discloses *an intervertebral implant for a human spine*, as recited in the claims.

EX1006, Ochoa Decl., ¶ 38.

'810 patent Claim 17 vs. '849 patent	
<i>an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine;</i> AND <i>a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine; and</i>	<p>The '849 patent (EX1004) discloses:</p> <ul style="list-style-type: none">• The present invention is directed to a device for positioning between adjacent vertebral members. FIG. 1 illustrates one embodiment, generally indicated as 9, which includes a spacer 10, delivery device 80, and a deployer 7. Spacer 10 is positioned between adjacent vertebral members and is selectively adjustable between a closed orientation, open orientation, and gradations therebetween. Delivery device 80 functions to position the spacer within the patient. Deployer 7 moves the spacer to the selected expanded orientations. EX1004, Col. 3, line 16-24• FIG. 4 illustrates one embodiment of the spacer 10 including a first member 20, a second member 30, and a third member 40. First member 20 includes contact surface 21 and second member 30 includes contact surface 31 each for contacting a vertebral member. Contact surfaces 21, 31 may be substantially smooth, or may have stabilization features such as ridges or knurls to contact the vertebral members. EX1004, Col. 3, line 47-53• See e.g. EX1004, at Fig. 4 below.

‘810 patent Claim 17 vs. ‘849 patent

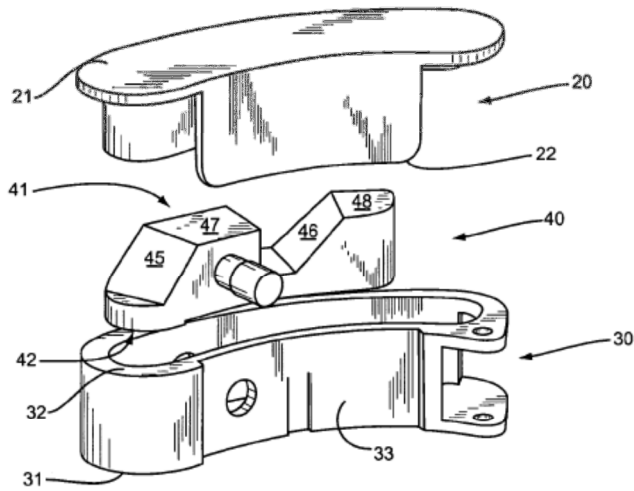


FIG. 4

- Lim discloses an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine **and** a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine and a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine. **EX1006, Ochoa Decl. at ¶ 39.**

The phrase “*an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine,*” **and** “*a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine,*” 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.⁵ Moreover, a PHOSITA would not understand the limitation, “*configured to engage*,” to disclose any intrinsic or specific structural limitation of the implant. **EX1006, Ochoa Decl. at ¶ 39.**

However, to the extent that this language limits the claims, the Lim reference discloses these limitations. A PHOSITA would have understood that during use of the implant as an interbody fusion device, the device described in the ‘849 patent, would be positioned between adjacent vertebrae and then expanded to contact the adjacent vertebrae, spacing them as necessary. **EX1004, Col. 3, lines 16-33; Col. 10, lines 36-40.** The intervertebral implant (“spacer” 10) comprises three members, an upper body (“first member” 20) a lower body (“second member” 30) and an expansion member (“third member” 40). **EX1004, Col. 3, lines 47-53; FIG. 4.** Exterior, bone contacting surfaces (“contact surfaces” 21 and 31) are present on the superior surface of the upper body (“first member” 20) and the inferior surface of the lower body (“second member” 30). **EX1004, Col. 5, lines 25-32; Col. 10, lines 36-40; FIG. 4.** The exterior, bone contacting surfaces (“contact surfaces” 21 and 31) may be porous to allow bone ingrowth into the spacer and may have stabilization features such as ridges or knurls. **EX1004, Col.**

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.

surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine, as recited in the claims. EX1006, Ochoa Decl., ¶ 39.

‘810 patent Claim 17 vs. ‘849 patent	
<i>an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first</i>	<p>Lim (the ‘849 patent) (EX1004) discloses:</p> <ul style="list-style-type: none"> • The present invention is directed to a device for positioning between adjacent vertebral members. FIG. 1 illustrates one embodiment, generally indicated as 9, which includes a spacer 10, delivery device 80, and a deployer 7. Spacer 10 is positioned between adjacent vertebral members and is selectively adjustable between a closed orientation, open orientation, and gradations therebetween. Delivery device 80 functions to position the spacer within the patient. Deployer 7 moves the spacer to the selected expanded orientations. EX1004, Col. 3, lines 16-24 • Spacer 10 has a variety of shapes and sizes depending upon the application, such as an elongated, curved shape. The spacer 10 is adjustable between a first position as illustrated in FIG. 2 having a reduced size to be minimally invasive when inserted into the patient between the vertebral members. FIG. 3 illustrates a second position with the spacer 10 expanded to contact the vertebral members. The spacer 10 may be expandable to a variety of different heights depending upon the desired application. EX1004, Col. 3, lines 25-33 • Third member 40 is positioned between the first member 20 and second member 30. Third member 40 includes a first side 41 having angled sections 45, 46 that mate with the first member 20, and a second side 42 to contact the second member 30. One embodiment of the first side 41 is illustrated in FIG. 4 and includes a first angled section 45 and adjacent support section 47, and a second angled section 46 and support section 48. Angled sections 45, 46 may have a variety of lengths, and may be positioned at a variety of angles relative to the second side 42. In one

angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body.

embodiment, the range of angles between sections 45, 46 and second side 41 is between about 20.degree. to about 40.degree.. Support sections 47, 48 are positioned at a different angle relative to the angled sections 45, 46. In one embodiment, support sections 47, 48 are substantially parallel with the second side 42. In one embodiment, second side 42 is flat which compliments a flat surface of the inner section 39. **EX1004, Col. 4, lines 29-45**

- See e.g. **EX1004** at Figs. 4 and 5 below.

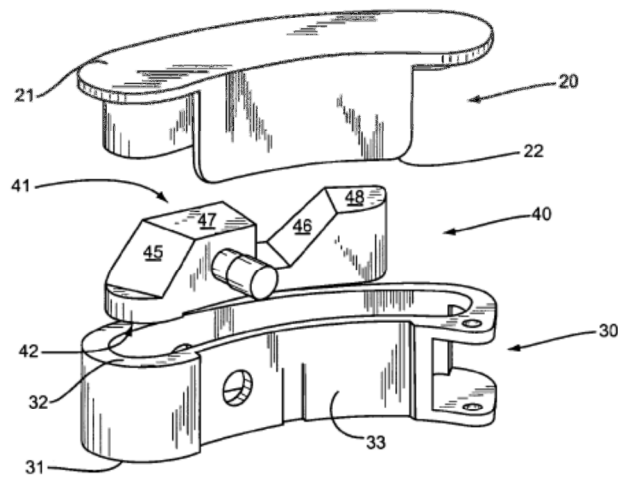


FIG. 4

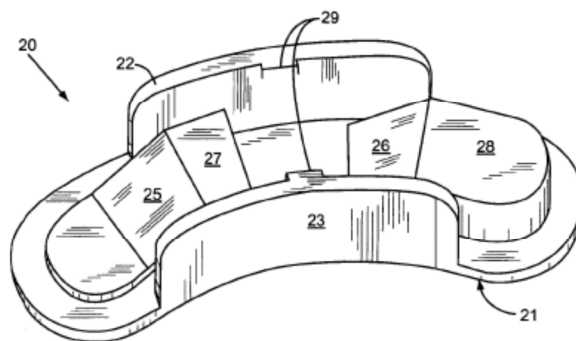


FIG. 5

- Third member 40 may have a width and length less than or equal to the boundary formed by the sidewalls 33 of the second member 30. The smaller size provides for sliding movement of the third member 40 relative to the second member 30. The relative positioning of the second and third members 30, 40 is illustrated in FIGS. 6 and 7. FIG. 6 illustrates a first position with the third member 40

positioned against a proximal edge of the second member 30. **EX1004, Col. 4, lines 46-53**

- FIG. 7 illustrates a second position with the third member 40 positioned against a distal edge of the second member 30. **EX1004, Col. 4, lines 54-55**
- Third member 40 moves relative to the first and second members 20, 30 to deploy the spacer 10 from the closed orientation to the open orientation. The spacer 10 may be positioned within the patient in the closed orientation that has a minimal size and shape to facilitate placement within the patient and between the vertebral members. The angled sections 25, 26, 45, 46 of the first and third members 20, 40 are disengaged in the closed orientation. **EX1004, Col. 4, lines 56-63**
- See e.g. **EX1004** at Figs. 6 and 7 below.

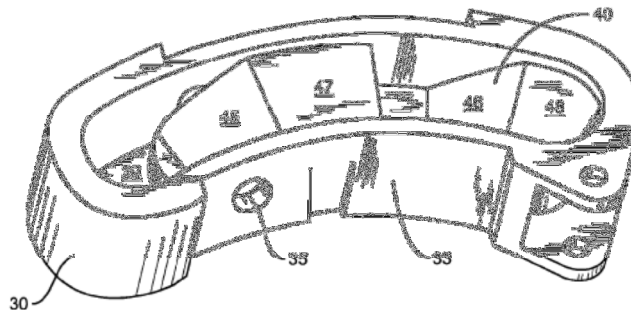


FIG. 6

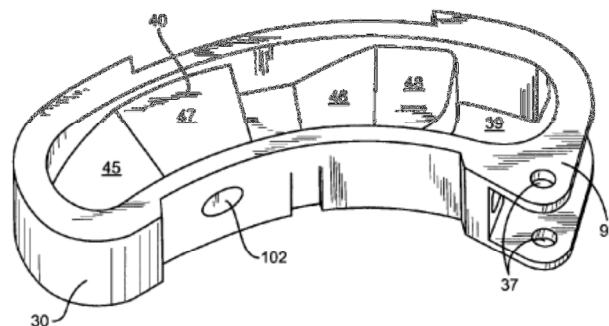


FIG. 7

- Deployment of the spacer 10 is caused by the third member 40 moving relative to the first member 20. Relative movement causes the angled sections 45, 46 of the third member 40 to contact the angled sections 25, 26

of the first member 20. This causes the first member 20 to move outward away from the centerline of the spacer 10. As the third member 40 is moved further, the angled sections continue to slide relative to one another and the first member 20 continues to move outward from the centerline increasing the overall height of the spacer 10.

EX1004, Col. 4, lines 64-Col. 5, line 6

- FIG. 9 illustrates one embodiment at the open position with full deployment. The sections 27, 28 on the first member 20 contact and rest on sections 47, 48 of the third member 40. In one embodiment, the sections 27, 28, 47, 48 are angled to a lesser amount than the angled sections 25, 26, 45, 46 to prevent the spacer 10 from moving towards the closed orientation. The angled sections 25, 26, 45, 46 may have the same angle. **EX1004, Col. 5, lines 7-14**
- See e.g. **EX1004** at Fig. 9 below.

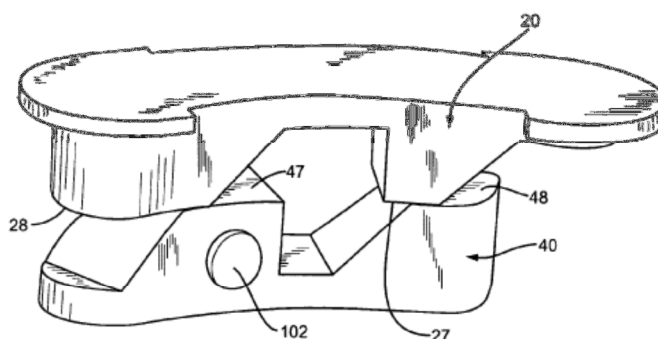


FIG. 9

- Once properly articulated and positioned between the vertebral members, spacer 10 is deployed from the closed orientation towards the open orientation. A deploying means is positioned within the delivery device 80 to deploy the spacer 10. In one embodiment, a cam 84 is positioned within delivery device and includes a distal end adjacent to the end of the delivery device 80, and a proximal end positioned at the deployer 7. In one embodiment, cam 84 is positioned within the second shaft 82 and is axially moved through the delivery device 80.

EX1004, Col. 7, lines 16-24

- Movement of the cam 84 is illustrated in FIGS. 18 and 19.

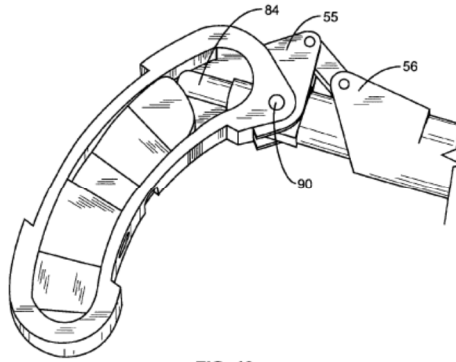


FIG. 19

- Lim discloses an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body. **EX1006, Ochoa Decl. at ¶ 40.**

The phrase “*an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first angled*

portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body,” 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.⁶ Moreover, a PHOSITA would not understand the limitation, “*configured to be positioned*” and “*configured to advance*” to disclose any intrinsic or specific structural limitation of the implant.

EX1006, Ochoa Decl. at ¶ 40.

However, to the extent that this language limits the claims, the Lim reference discloses these limitations. A PHOSITA would have understood that the expansion member (“third member” 40) disclosed in the ‘849 patent comprises a substantially flat inferior surface (“second side” 42) configured to contact the lower body (“second member” 30). **EX1004, Col. 4, lines 29-45; FIG. 4.** The superior surface of the expansion member comprises at least substantially flat

⁶ *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.

support sections (47 and 48) which are substantially parallel with the inferior surface (“second side” 42) and configured to contact the upper body (“first member” 20). **EX1004, Col. 4, lines 29-45; Col. 5, lines 7-14; FIG. 4.** A PHOSITA would have understood that the intervertebral implant (“spacer” 10) has an elongated shape and the shape of the expansion member (“third member” 40) has a similar elongated shape with a length greater than the width, each less than or equal to the boundary formed by the sidewalls (33) of the lower member (“second member” 30) (see Figure 4 below). **EX1004, Col. 3, lines 16-24; Col. 4, lines 46-53; FIG. 4.** A PHOSITA would have understood that the ‘849 patent discloses *an expansion member comprising an elongated body having a substantially flat inferior surface and a substantially flat superior surface.* Further, a PHOSITA would have understood that the expansion member (“third member” 40) disclosed in the ‘849 patent is *configured to be positioned between the upper body and the lower body*, the expansion member (“third member” 40) being positioned between the upper body (“first member” 20) and lower body (“second member” 30) as shown in Figure 4 below. **EX1004, Col. 4, line 29-30; EX1006, Ochoa Decl. at ¶ 40.**

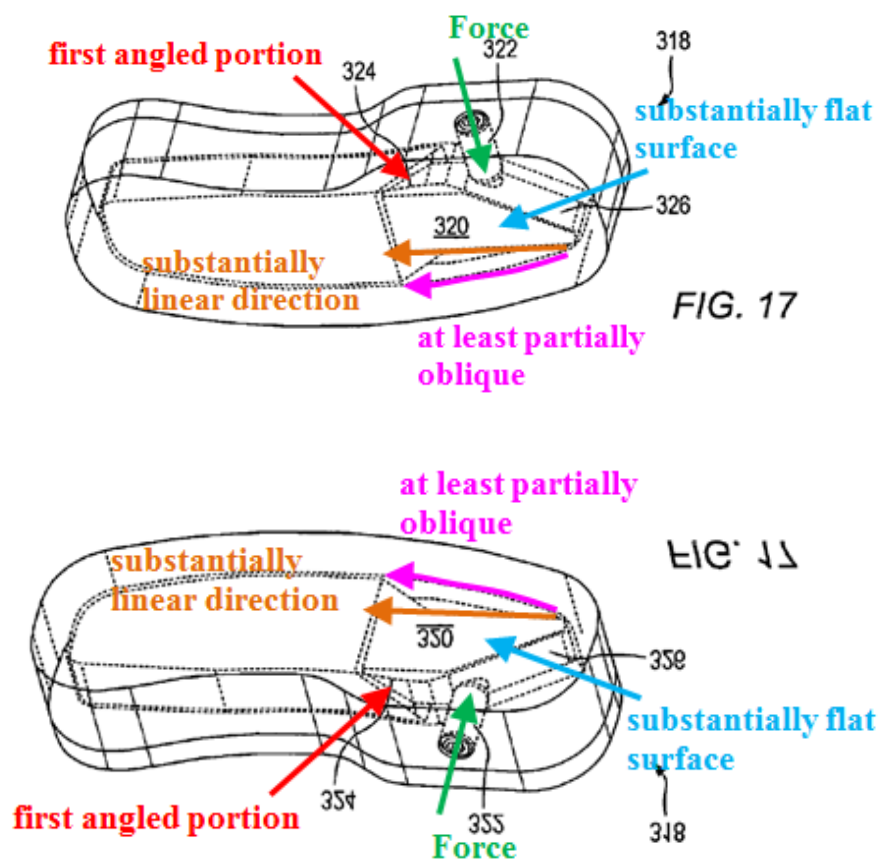
Therefore, a PHOSITA would understand that the '849 Patent discloses *that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member.* **EX1006, Ochoa Decl. at ¶ 40.**

A PHOSITA would have understood that axial movement of the cam (84) pushes the expansion member ("third member" 40) causing the angled sections (45, 46) of the expansion member ("third member" 40) to contact the angled sections (25, 26) of the upper body ("first member" 20) and slide relative to one another and increase moving the upper body ("first member" 20) away from the lower body ("second member" 30) increasing the spacer height. **EX1004, Col. 5, lines 7-14; Col. 7, lines 25-42; FIG. 9.** By deploying the device after placement, the need for an implant that may be effective to space the vertebral bodies in a minimally invasive manner is addressed. **EX1004, Col. 1, lines 13-28.** A PHOSITA would understand that the '849 Patent discloses an *increased separation distance between the superior surface of the upper body and the inferior surface of the lower body after insertion of the upper and lower body in the spine.* **EX1006, Ochoa Decl. at ¶ 40.**

A PHOSITA would have understood that the intervertebral implant ("spacer" 10) disclosed in the '849 patent has a variety of shapes and sizes

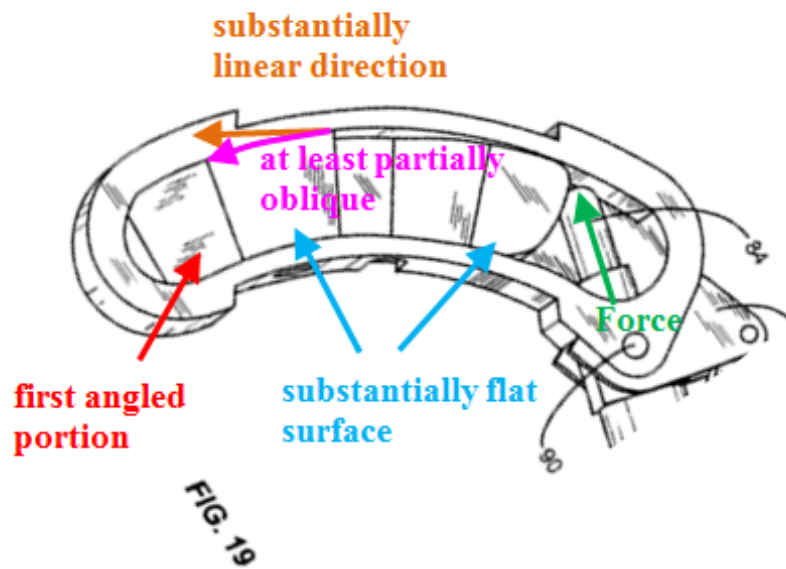
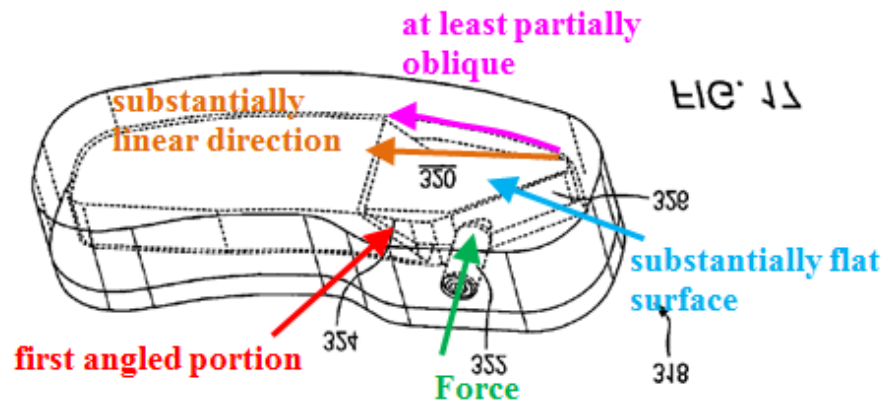
depending on the application, such as an elongated, curved shape. **EX1004, Col. 1, lines 13-28; Col. 3, lines 25-33.** During deployment axial movement of the cam (84) causes the expansion member (“third member” 40) to move relative to the lower body (“second member” 30), guided by the shape of the internal walls of the second member. **EX1004, Col. 4, lines 46-53; Col. 7, lines 25-42; FIGS. 18 and 19.** A PHOSITA would have understood the motion of the expansion member (“third member” 40) to be substantially linear and generally tangential to the modest curvature of the lower body (“second member” 30), with a lateral/radial component resulting in oblique motion. **EX1006, Ochoa Decl. at ¶ 40.** In view of the file history for the ‘810 patent, to overcome a rejection of claim 180, which later became claim 17, in view of WO 98/48739 by Dinsdale, the applicant argued that mated threads disclosed by Dinsdale inhibit lateral movement of cam blocks relative to a turnbuckle. ***Id.* at ¶ 40.** The applicant amended claim 180 to include the limitation “at least partially oblique to.” ***Id.* at ¶ 40.** A PHOSITA would have understood the lateral/radial movement of the insert disclosed in the Lim patent to be consistent with the arguments made during prosecution of the ‘810 patent. ***Id.* at ¶ 40.** As a result of the gently curved shape of the upper and lower bodies of the device, each point on the expansion member would travel in a substantially linear, generally tangential, direction during deployment. ***Id.* at ¶ 40.** Because of the curvature of the resulting path, the direction of travel would also be at least

partially oblique (i.e. including a lateral/radial component) to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body. *Id.* at ¶ 40. The figures below show this movement with the reference to labeled Figure 17 in two orientations, one from the '810 patent and the other as its mirror image.



EX1006, Ochoa Decl. at ¶ 40.

The mirror image above displays the direction of travel in the same orientation as the Lim reference. This mirror image is juxtaposed below to labelled Figure 19 of the Lim reference as follows:



EX1006, Ochoa Decl. at ¶ 40.

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

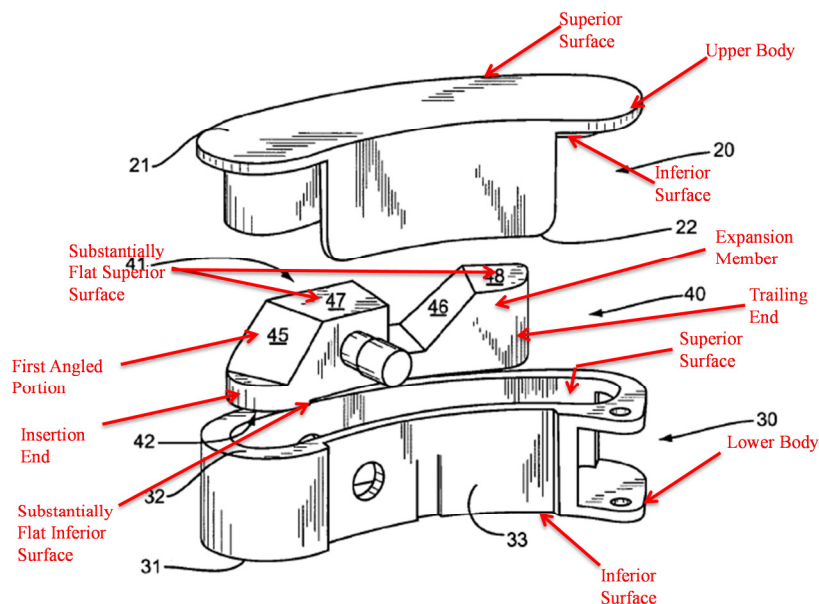


FIG. 4

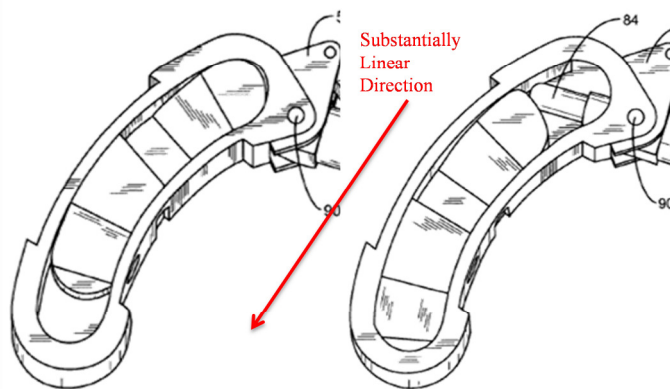


FIG. 18

FIG. 19

Figure 1. Excerpts from figure 4 of the '853 patent demonstrating the various claim elements.

EX1006, Ochoa Decl. at ¶ 40.

A PHOSITA would have, therefore, understood that the '849 patent discloses, *an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion*

member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body, as recited in the claims.

EX1006, Ochoa Decl. at ¶ 40.

The claim charts attached as **EX1021** provide additional details supporting my opinions as to the information that would have been conveyed by the ‘849 patent and understood by a PHOSITA at the time of the invention of the ‘810 patent. *Id.* at ¶ 41.

Consequently, and as supported by Dr. Ochoa, the ‘849 patent renders claim 17 unpatentable under 35 U.S.C. § 103.

B. Ground 2: Claim 17 is unpatentable under 35 U.S.C. § 103 as obvious over the ‘998 patent (EX1005) 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. **EX1005, Col. 4, line 64-Col. 5, line 6; EX1006, Ochoa Decl.**

at ¶ 32. In use, a plurality of wafers are inserted between an upper and lower vertebra to create a column which distract the disc space and provides support for the vertebral bodies. **EX1006, Ochoa Decl. at ¶ 32.** The resulting disclosed implant includes substantially flat wafers that engage the vertebrae and central wafers that consecutively act as inserts. **EX1006, Ochoa Decl. at ¶ 32.** By applying force to the trailing wafer end, each new wafer is added to the column and acts as an expansion member, separating the superior and inferior and surfaces, elevating the insert and increasing the height of the column, thereby distracting the surrounding tissues. **EX1005, Col. 4, line 64-Col. 5, line 6; Col. 5, lines 32-36; EX1006, Ochoa Decl. at ¶ 32.** Wafer designs include 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 increasing the separation distance between the upper and lower bodies as the expansion member advances. **EX1005, Col. 5, line 66-Col. 6, line 7; Col. 13, lines 8-24; EX1006, Ochoa Decl. at ¶ 32.**

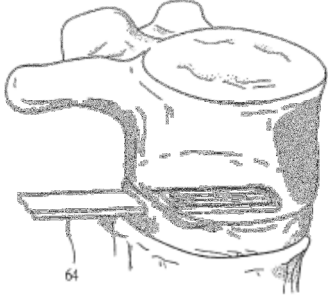
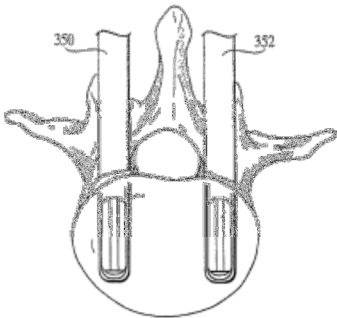
To the extent that the broadest reasonable construction, as informed by the written description and file history is not as noted in Section V. above, then based on the claim limitations of claim 17, a PHOSITA would have understood that the spinal implant taught in the '998 patent renders claim 17 of the '810 patent

obvious. The claim charts and accompanying analysis, below, evidence this conclusion.

1. Claim 17

Claim 17 is directed to an intervertebral implant device for a human spine.

Claim 17 is obvious in view of Johnson. The claim chart and accompanying analysis below evidence this conclusion.

‘810 patent Claim 17 vs. ‘998 patent	
17. An intervertebral implant for a human spine, comprising:	<p>Johnson (the ‘998 patent) (EX1005) discloses:</p> <ul style="list-style-type: none">• 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, calcaneus, distal tibial fractures, or distal radius (wrist) fractures. EX1005, 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. FIG. 61 illustrates a wafer inserter 64 in position in a vertebral disc. EX1005, Col. 25, lines 37-41.• See e.g. EX1005 at FIGS. 60 and 61 below. <div></div> <div><p>FIG. 60</p><p>FIG. 61</p></div>

	<ul style="list-style-type: none"> Johnson discloses an intervertebral implant for a human spine. EX1006, Ochoa Decl. at ¶ 33.
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The preamble of claim 17 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.⁷

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 interbody spacer for use in spinal fusion procedures. **EX1005, Col. 4, line 64-Col. 5, line 6; Col. 25, lines 37-41; FIGS. 60 and 61.** The implant disclosed in the Johnson reference is used to distract adjacent vertebrae. **EX1005, Col. 4, lines 37-41.**

A PHOSITA would have recognized that the '998 patent application discloses *an intervertebral implant for a human spine*, as recited in the claims. **EX1006, Ochoa Decl. at ¶ 32-33.**

'810 patent Claim 17 vs. '998 patent	
<i>an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first</i>	Johnson (the '998 patent) (EX1005) discloses: <ul style="list-style-type: none"> 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. EX1005, Abstract The top of a wafer or the top of the column is defined as

⁷ *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.

‘810 patent Claim 17 vs. ‘998 patent

vertebra of the human spine;

AND

a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine; and

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. **EX005, Col. 5, lines 51-59**

- See e.g. **EX1005** at Figs. 4, 8, 10, 12, 14, 16, 24 and 26 below.

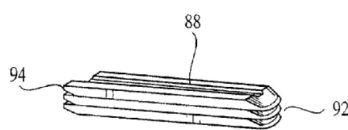


FIG. 8

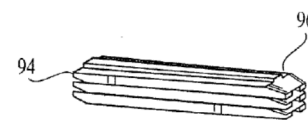


FIG. 10

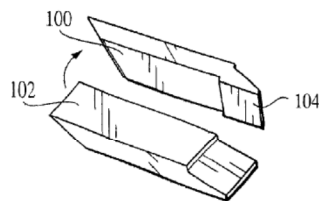


FIG. 12

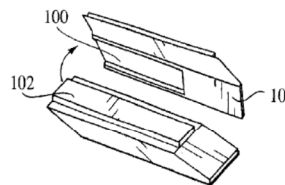


FIG. 14

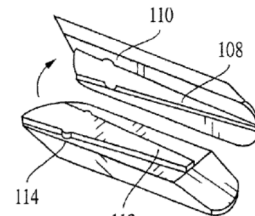


FIG. 16

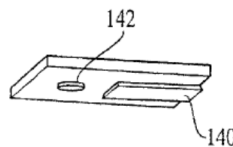


FIG. 24

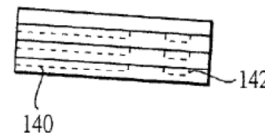


FIG. 26

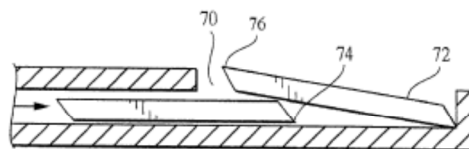


FIG. 4

'810 patent Claim 17 vs. '998 patent

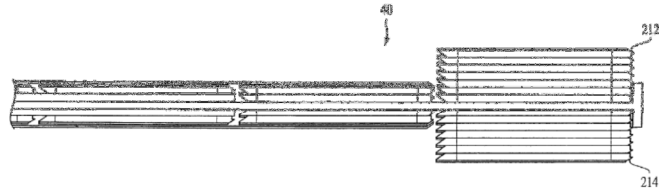


FIG. 29

- 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. **EX1005, Col. 5, lines 64-Col. 6, line 7**
- 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. **EX1005, Col. 10, lines 1-8.**
- 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. The wedge may increase in thickness from leading edge to trailing edge or vice versa, or may increase in thickness from side to side. The wedged wafers may be of various angles. For example, the physician reducing a compression fracture may observe that the column is not parallel to the end plate. As the end plate is returning to its anatomical position, an appropriately wedged wafer(s) may be inserted to gradually curve the column to provide a parallel interface with the end plate. Similarly, the wafers may be wedge shaped with the anterior aspect of the wafer

‘810 patent Claim 17 vs. ‘998 patent

thicker than the posterior aspect to reproduce the natural lordotic curvature of the spine for interbody fusion. In addition, wafers of different thickness may be inserted into the same column. **EX1005, Col. 10, line 61-Col. 11 line 10**

- See e.g. **EX1005** at Figs. 4 and 37 below.

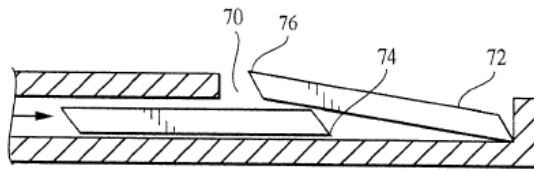


FIG. 4

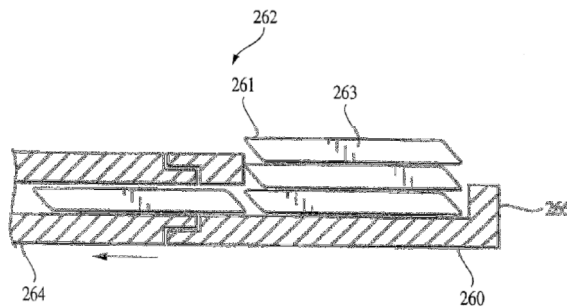


FIG. 37

- Bone spreaders/shavers are placed in the two openings and the vertebral bodies are distracted. The bone shaver or similar device is operated to remove the central portion of the annulus. A generally flat surface down to the bleeding bone of the superior and inferior endplates is prepared. The end plates are decorticated down to bleeding bone. **EX005, Col. 24, lines 43-48**
- The prepared surface supports the wafer columns. A wafer inserter is placed in each opening and used in the manner described above. It is preferred to insert wafers in an alternating fashion between the two inserters to uniformly distract the annulus. **EX1005, Col. 24, lines 49-53**
- Johnson discloses an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first

‘810 patent Claim 17 vs. ‘998 patent	
	vertebra of the human spine and a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine. EX1006, Ochoa Decl. at ¶ 34.

The phrase “*an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine,*” **and** “*a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine,*” are recitations of the intended use for the claimed apparatus; do not structurally distinguish the claimed apparatus and, therefore, are not material to patentability. As such, this language carries no patentable weight.⁸ Moreover, a PHOSITA would not understand the limitation, “*configured to engage,*” to disclose any intrinsic or specific 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 during use of the implant as an interbody fusion device, the wafer column and detachable tip described in the ‘998 patent would distract and provide support

⁸ *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.

between the bone surfaces of a decorticated superior and decorticated inferior endplate. **EX1005, Abstract; Col. 24, lines 43-53.** Each wafer in the column comprises a superior (upper) and inferior (lower) surface. **EX1005, Col. 5, lines 51-55.** The wafers may be flat or wedged with substantially planar surfaces. **EX1005, 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 use of appropriately wedged wafers would gradually curve the column to provide a parallel interface for improving engagement with the vertebral endplate. **EX1005, Col. 10, line 61-Col. 11, line 10.** As a result, the superior surface of the upper body (uppermost wafer in the wafer column) would engage the inferior surface of the superior endplate and the inferior surface of the lower body (lowest wafer in wafer column) would engage the superior surface of the inferior endplate. **EX1005, Col. 5, line 64-Col. 6, line 7; Col. 10, lines 1-8; FIGS. 29, 60 and 61.**

A summary illustrating the elements described above is included in Figure 3 below:

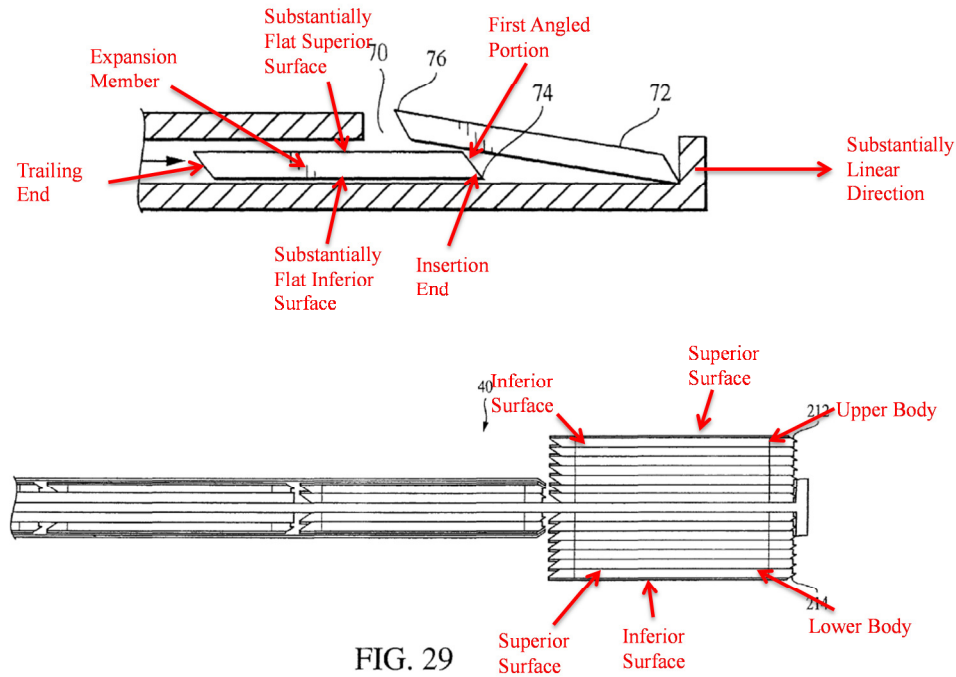


FIG. 29

Figure 1. Excerpted figures from the '998 patent demonstrating the various disclosed claim elements. Note that the inserter tip is shown in the unidirectional embodiment and would be symmetrical in the bidirectional embodiment.

A PHOSITA would have therefore understood that the '853 patent discloses, *an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine and a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine*, as recited in the claims. **EX1006, Ochoa Decl., ¶ 34.**

'810 patent Claim 17 vs. '998 patent	
<i>an expansion member</i>	Johnson (the '998 patent) (EX1005) discloses: <ul style="list-style-type: none"> • In use, the wafers are preferably stacked between two

comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at

tissue surfaces as they are implanted, thereby distracting and supporting the tissue surfaces simultaneously. In the 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. **EX1005, 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. Likewise, the bevel of the leading and trailing edges may be reversed enabling insertion of a trailing wafer above a leading wafer. 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

<p><i>least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body.</i></p>	<p>instrument. In all embodiments, by repeating the process with consecutive wafers, the column height increases to restore vertebral height. EX1005, Col. 5, line 66-Col. 6, line 17</p> <ul style="list-style-type: none"> • Specifically for vertebral compression fracture applications, exemplary wafer dimensions range as follows: <ul style="list-style-type: none"> Wafer length between 5 mm and 40 mm; Wafer width between 2 mm and 16 mm; Wafer thickness between 0.2 mm and 6 mm. <p>EX1005, Col. 10, lines 40-43</p> <ul style="list-style-type: none"> • In addition, the wafer thickness may be uniform or varies. Specifically, the wafers may be either flat or wedged, or alternatively include a combination of flat and wedged wafers. EX1005, Col. 10, lines 61-64 • 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. EX1005, Col. 13, lines 8-24 • See e.g. EX1005, at Figs. 4, 8, 10, 12, 14, 16, 24, 26, 29, 30 and 37 below.
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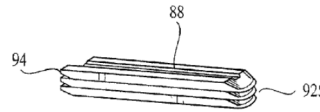


FIG. 8



FIG. 10

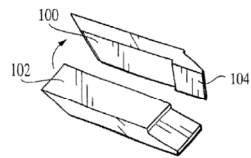


FIG. 12

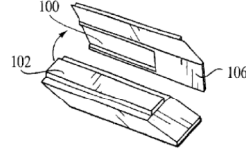


FIG. 14

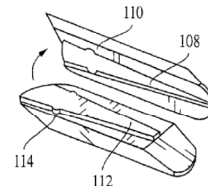


FIG. 16

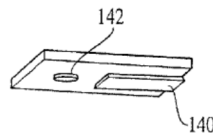


FIG. 24

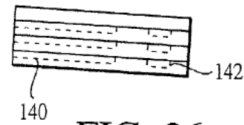


FIG. 26

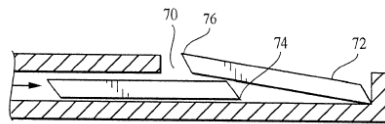


FIG. 4

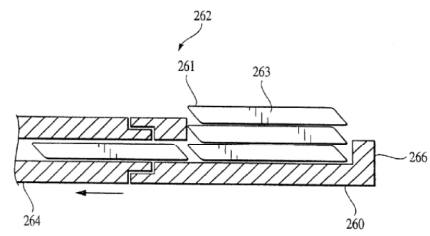


FIG. 37

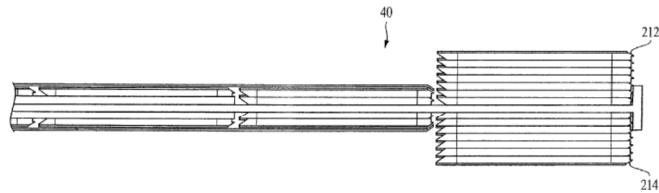


FIG. 29

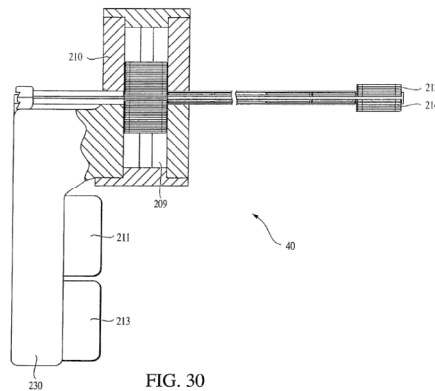


FIG. 30

- Johnson discloses an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body. **EX1006, Ochoa Decl. at ¶ 35.**

The phrase “*an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the*

insertion end of the elongated body is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body,” 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.⁹ Moreover, a PHOSITA would not understand the limitation, “*configured to be positioned*” and “*configured to advance*” to disclose any intrinsic or specific 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 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

⁹ *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.

wafer, thereby lifting the leading wafer. **EX1005, Col. 5, line 66-Col. 6, line 7; FIG. 4.** Therefore, a PHOSITA would have understood that following insertion of the upper body and lower body, each successive wafer would act as an expansion member. **EX1006, Ochoa Decl. at ¶ 35.** When *force is applied to the trailing end* of the expansion member (wafer), the *opposite* leading edge acts as a first angled portion at the leading, or *insertion end* (see Figure 4 below). **EX1005, Col. 5, line 66-Col. 6, line 7; FIG. 4.** Similarly, a PHOSITA would have understood that the ‘998 patent discloses that each wafer in the column comprises a substantially flat superior (upper) and inferior (lower) surface with sides that are longer than the leading and trailing edges (see Figure 4 below). **EX1005, Col. 5, lines 42-65; Col. 10, lines 61-64; FIGS. 4, 8, 10, 12, 14, 16, 24, 26, 29 and 30; EX1006, Ochoa Decl. at ¶ 35.** A PHOSITA would have understood that the wafer length and width dimensions vary, for example, wafer length between 5 mm and 40 mm; and wafer width vary between 2 mm and 16 mm. **EX1005, Col. 10, lines 40-43.** A PHOSITA would have understood that the wafers are elongated because their sides are longer than the leading/trailing edges, the length of the wafer being more than its width. **EX1005, Col. 10, lines 40-43.** A PHOSITA would have therefore understood that the ‘998 patent discloses, *an expansion member comprising an elongated body having a substantially flat inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated*

body (see Figure 4 below). **EX1006, Ochoa Decl. at ¶ 35.**

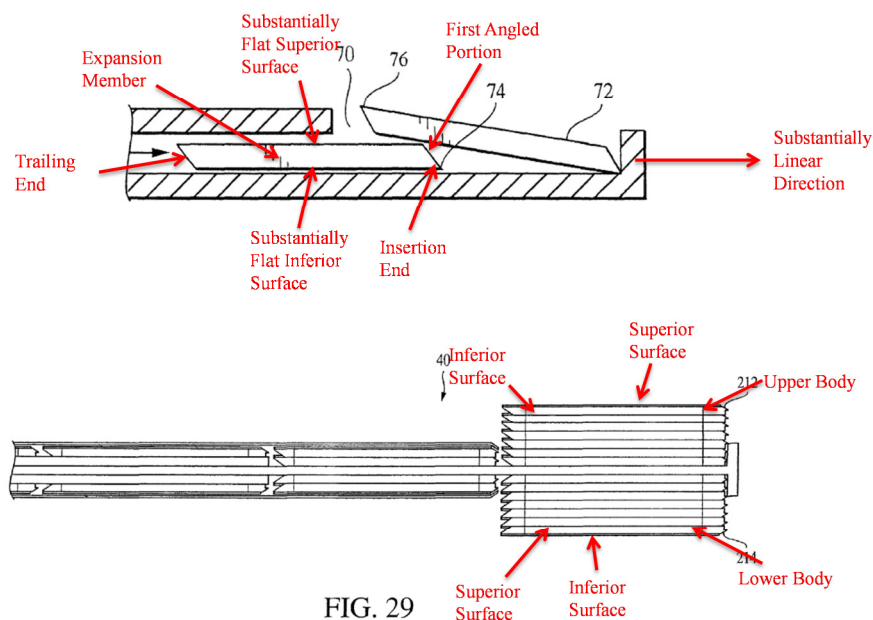


FIG. 29

Figure 4. Excerpted figures from the '998 patent demonstrating the various disclosed claim elements. Note that the inserter tip is shown in the unidirectional embodiment and would be symmetrical in the bidirectional embodiment. Further, note that the use of a chevron shaped wafer is not included in these figures.

EX1006, Ochoa Decl. at ¶ 35.

Further, a PHOSITA would have understood that as the column of wafers is being stacked, depending on the configuration of the wafers, each trailing wafer may be placed above, below, or between the leading wafers. **EX1005, Col. 5, line 66-Col. 6, line 17; EX1006, Ochoa Decl. at ¶ 35.** Therefore, a PHOSITA would have understood that the expansion member (wafer) is *configured to be positioned between the upper body and the lower body*. **EX1006, Ochoa Decl. at ¶ 35.** A PHOSITA would have understood that a straight *expansion member* (wafer) with a

chevron shaped insertion end (leading edge) could be deployed linearly between the inferior surface of the upper body and the superior surface of the lower body (see figure below which is an illustrative diagram based on a figure from the '998 patent demonstrating advancing a chevron shaped expansion member). **EX1005, Col. 5, line 66-Col. 6, line 17; Col. 13, lines 8-24; EX1006, Ochoa Decl. at ¶ 35.**

As the expansion member (wafer) slides between the trailing end of the upper and lower body the upper and lower bodies would be forced apart increasing the separation distance between the upper and lower bodies as the expansion member advances. **EX1006, Ochoa Decl. at ¶ 35.** During this motion, the first angled portion and superior and inferior surfaces of the expansion member would be positioned oblique to the inferior surface of the upper body and superior surface of the lower body (Figure 5 and Figure 6 below). **Id. at ¶ 35.** Similarly, the direction of advancement would also be oblique to the inferior surface of the upper body and superior surface of the lower body (Figure 6). **Id. at ¶ 35.** A PHOSITA

would have understood that this spreading apart, beginning at the trailing end of the upper and lower bodies and advancing towards the leading end, would be at least partially oblique to the interior surfaces of the upper and lower body. *Id.* at ¶ 35.

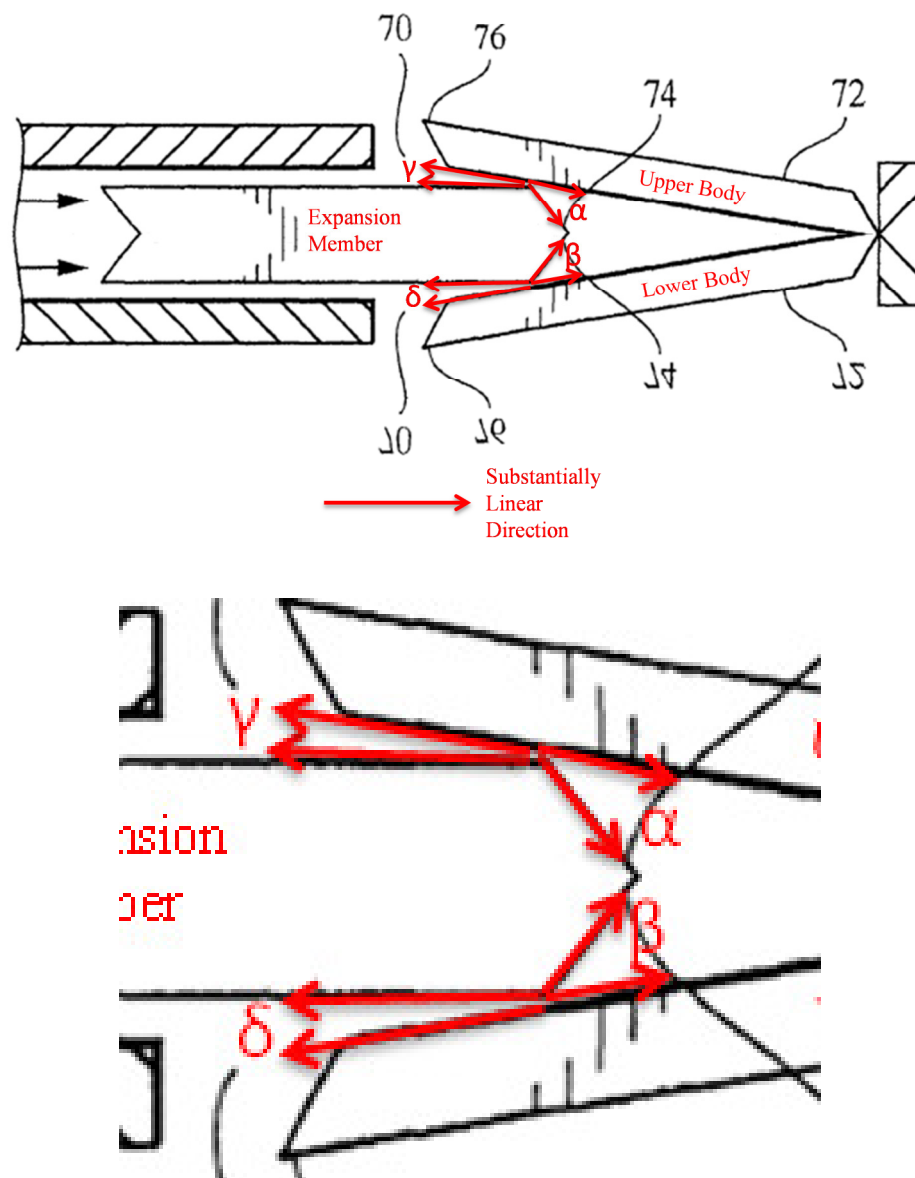


Figure 5. Illustrative diagrams based on figure from the '998 patent demonstrating oblique angles formed when advancing a chevron

shaped expansion member: α oblique angle between first angled portion and inferior surface of upper body, β oblique angle between first angled portion and superior surface of lower body, γ oblique angle between superior and inferior surfaces of the expansion member and the inferior surface of the upper body, δ oblique angle between superior and inferior surfaces of the expansion member and the superior surface of the lower body. Note that angle γ and δ are also illustrative of the oblique angle between the substantially linear direction of advancement and the lower surface of the upper body and the upper surface of the lower body respectively.

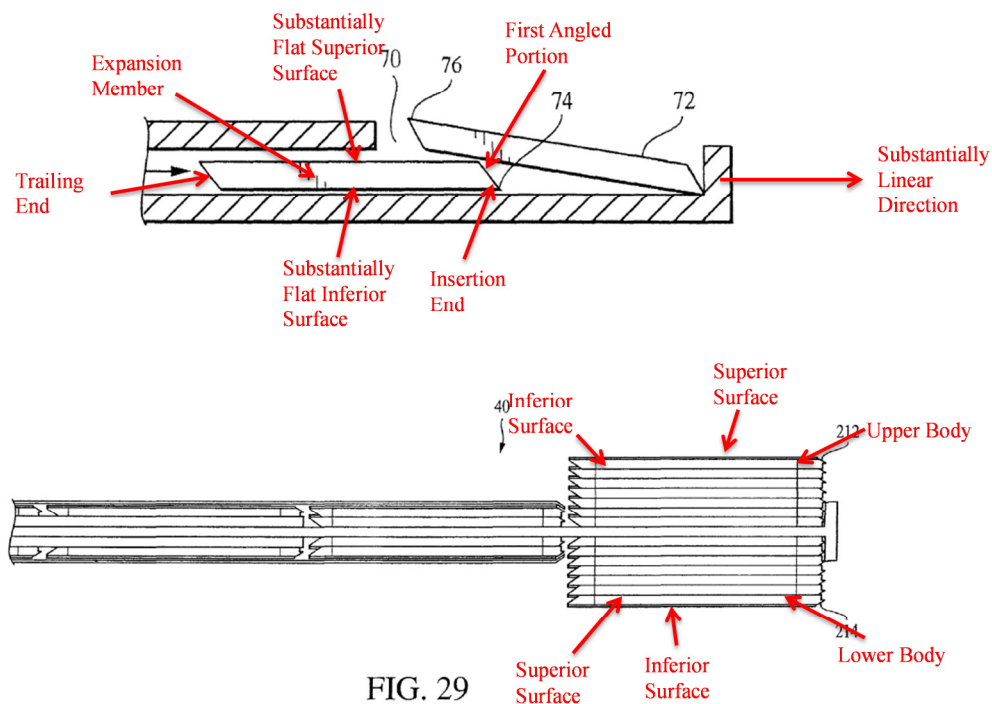


FIG. 29

Figure 6. Excerpted figures from the '998 patent demonstrating the various disclosed claim elements. Note that the inserter tip is shown in the unidirectional embodiment and would be symmetrical in the bidirectional embodiment. Further, note that the use of a chevron shaped wafer is not included in these figures.

EX1006, Ochoa Decl. at ¶ 35.

A PHOSITA would have therefore understood that the '998 patent discloses, *an expansion member comprising an elongated body having a substantially flat*

inferior surface, a substantially flat superior surface, and a first angled portion at an insertion end of the elongated body, wherein the expansion member is configured to be positioned between the upper body and the lower body such that applying a force to a trailing end of the elongated body opposite the insertion end of the elongated body is configured to advance the first angled portion and the substantially flat superior and inferior surfaces of the expansion member in a substantially linear direction between and at least partially oblique to at least a portion of the inferior surface of the upper body and at least a portion of the superior surface of the lower body after insertion of the upper and lower body in the spine to increase a separation distance between the superior surface of the upper body and the inferior surface of the lower body, as recited in the claims.

The claim charts attached as **EX1021** 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 '810 patent. **EX1006, Ochoa Decl. at ¶ 36.**

Consequently, and as supported by Dr. Ochoa, the Johnson reference renders claim 17 unpatentable as obvious under 35 U.S.C. § 103.

IX. CONCLUSION

Petitioner has demonstrated in this Petition that claim 17 of the '810 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '810 patent.

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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. 8,123,810 to be served via FedEx, next day delivery, on the below listed counsel, on this 27th day of August, 2015:

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