

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner

v.

FLEXUSPINE, INC.,
Patent Owner

Case No.: IPR2015-_____
U.S. Patent No. 7,316,714
Issued: January 8, 2008
Application No: 10/660,155
Filed: September 11, 2003

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,316,714

TABLE OF CONTENTS

TABLE OF AUTHORITIES	iii
LIST OF EXHIBITS	v
I. INTRODUCTION	1
II. FORMALITIES	2
A. Mandatory Notices.....	2
1. Real Party in Interest (37 C.F.R. § 42.8(b)(1)).....	2
2. Designation of Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3)).....	2
3. Notice of Service (37 C.F.R. § 42.8(b)(4)).....	3
4. Related Matters (37 C.F.R. § 42.8(b)(2))	3
B. Grounds for Standing (37 C.F.R. § 42.104(a))	4
C. Procedural Statements.....	4
III. U.S. PATENT NO. 7,316,714 (“THE ‘714 PATENT”) (EX1001)	4
A. The ‘714 Patent Specification and Claims.....	5
B. The ‘74 Patent Prosecution History (EX1003).....	6
IV. THE PERSON HAVING ORDINARY SKILL IN THE ART AND THE STATE OF THE ART	8
V. CLAIM CONSTRUCTION	8
VI. THE PRIOR ART RELIED UPON IN THIS PETITION	9
A. U.S. Patent No. 5,782,832 to Larsen et al. (“the ‘832 patent” or “Larsen”) (EX1004).....	9
VII. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. §42.22(a))	9
VIII. IDENTIFICATION OF GROUNDS FOR UNPATENTABILITY (37C.F.R. § 42.104(b))	10
A. Ground 1: Claims 1 and 2 are unpatentable under 35 U.S.C. § 103 as obvious over Larsen in view of the knowledge of one of ordinary skill in the art (EX1004)	10

1. Claim 1.....	11
2. Claim 2.....	41
IX. CONCLUSION.....	45

TABLE OF AUTHORITIES

Cases

<i>In re Am Acad. Of Sci. Tech Ctr.</i> , 367 F.3d 1359 (Fed. Cir. 2004)	9
<i>In re Danly</i> , 263 F.2d 844, 120 U.S.P.Q. 528 (C.C.P.A. 1959)	21, 28, 31, 40
<i>In re Schreiber</i> , 128 F.3d 1473, 44 U.S.P.Q.2d 1429 (Fed. Cir. 1997)	21, 28, 31, 40
<i>In re Swinehart</i> , 439 F.2d 210, 169 U.S.P.Q. 226 (C.C.P.A. 1971)	21, 28, 31, 40
<i>KSR Int’l. Co. v. Teleflex, Inc.</i> , 550 U.S. 398 (2007).	10
<i>Pitney Bowes, Inc. v. Hewlett-Packard Co.</i> , 182 F.3d 1298, 51 U.S.P.Q.2d 1161 (Fed. Cir. 1999)	13

Statutes

35 U.S.C. § 102(b)	9
35 U.S.C. § 103	9, 10
35 U.S.C. § 311	1
35 U.S.C. § 312	1
35 U.S.C. § 313	1
35 U.S.C. § 314	1
35 U.S.C. § 314(a)	2
35 U.S.C. § 315	1
35 U.S.C. § 316	1
35 U.S.C. § 317	1
35 U.S.C. § 318	1
35 U.S.C. § 319	1

Other Authorities

M.P.E.P. § 2111	9
M.P.E.P. § 2111.02	13
M.P.E.P. § 2114	21, 28, 31, 40

Rules

37 C.F.R. § 42	1
37 C.F.R. § 42.10(b)	4
37 C.F.R. § 42.100(b)	8
37 C.F.R. § 42.104(a)	4

37 C.F.R. § 42.104(b)	10
37 C.F.R. § 42.106(a).....	4
37 C.F.R. § 42.63(e).....	4
37 C.F.R. § 42.8(b)(1).....	2
37 C.F.R. § 42.8(b)(2).....	3
37 C.F.R. § 42.8(b)(3).....	2
37 C.F.R. § 42.8(b)(4).....	3

LIST OF EXHIBITS

- EX1001 U.S. Patent No. 7,316,714
- 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. 7,316,714
- EX1004 U.S. Patent No. 5,782,832 to Larsen et al.
- EX1005 Declaration of Jorge A. Ochoa, P.E.
- EX1006 Curriculum Vitae of Jorge A. Ochoa, P.E.
- EX1007 U.S. Patent No. 5,665,122 to Kambin
- EX1008 U.S. Patent No. 6,045,579 to Hochshuler
- EX1009 U.S. Patent no. 6,936,071 B1 to Marnay
- EX1010 U.S. Patent no. 7,060,100 to Ferree
- EX1011 Blumenthal SL, Ohnmeiss DD. Intervertebral cages for degenerative spinal diseases. *Spine J.* Jul-Aug 2003;3(4):301-309
- EX1012 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
- EX1013 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
- EX1014 Foley KT, Holly LT, Schwender JD. Minimally invasive lumbar fusion. *Spine (Phila Pa 1976)*. Aug 1 2003;28(15 Suppl):S26-35
- EX1015 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.

- EX1016 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
- EX1017 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
- EX1018 Weiner BK, Fraser RD. Spine update lumbar interbody cages. Spine. 1998 Mar 1; 23(5):634-40
- EX1019 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
- EX1020 Claim chart – Claims 1 and 2 vs. U.S. Patent No. 5,782,832 to Larsen et al.

I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, the undersigned, on behalf of and representing Petitioner Globus Medical, Inc. (“Globus” or “Petitioner”) hereby petitions for *inter partes* review of claims 1 and 2 of U.S. Patent No. 7,316,714, titled “Artificial Functional Spinal Unit Assemblies” (“the ‘714 patent”), issued to Charles Gordon and Corey Harbold and assigned to Flexuspine, Inc. (“Flexuspine”). The ‘714 patent is attached as **EX1001**.

The invention of the ‘714 patent is not new. Rather, the claimed invention relates to expandable artificial intervertebral implants for use in the restoration and maintenance of disc space height. In this regard, the challenged claims of the ‘714 patent describe the invention having features that are well-known and/or inherent in the prior art orthopedic implant devices.

For the reasons set forth herein, Petitioner asserts that all of the challenged claims are unpatentable. The grounds for unpatentability presented in detail below, demonstrate how each of claims 1 and 2 of the ‘714 patent are obvious in view of the prior art. Evidentiary support for Petitioner’s conclusions is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. **EX1005**.¹ Dr. Ochoa is an expert with over 25 years of experience in the area of design and development of orthopedic medical devices, surgical instruments and techniques, as well as biomechanics, and

¹ Sometimes referred to herein as “Ochoa Decl.”

engineering biomaterials. Dr. Ochoa's declaration establishes that each of the challenged claims is rendered obvious in view of the prior art and confirms all of Petitioner's assertions of unpatentability.

Petitioner submits that this Petition demonstrates a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. 35 U.S.C. §314(a). Accordingly, Petitioner respectfully requests that this Petition be granted and that claims 1 and 2 of the '714 patent be reviewed and held unpatentable.

II. FORMALITIES

A. Mandatory Notices

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

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

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

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

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

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

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

Petitioner states that the ‘714 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 ‘714 patent. *See* **EX1002**.

Concurrently with this Petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 7,204,853 (“the ‘853 patent”). The ‘714 patent is related to the ‘853 patent through continuation practice. Also concurrently with this Petition, Petitioner is filing a Petition for *inter partes* review of U.S. Patent No. 7,909,869 (“the ‘869 patent”). The ‘869 patent is also related to the ‘853 patent, which is related to the ‘714 patent through continuation practice. Also concurrently with this Petition, Petitioner is filing a Petition for *inter partes* review of U.S. Patent No. 8,123,810 (“the ‘810 patent”). The ‘810 patent is also related to the ‘714 patent through continuation practice. Also concurrently with this Petition, Petitioner is filing a Petition for *inter partes* review of U.S. Patent No. 8,647,386

(“the ‘386 patent”). The ‘386 patent is also related to the ‘714 patent through continuation practice. Petitioner understands that the ‘714 patent, the ‘853 patent, the ‘869 patent, the ‘810 patent and the ‘386 patent are all commonly owned by Flexuspine.

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

Petitioner certifies that (1) the ‘714 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 ‘714 patent on the grounds identified in this Petition. It should be noted that, in this regard, service of the Summons and Complaint issued in the Pending Litigation was made on Petitioner on March 13, 2015. Consequently, Petitioner is not time barred by the Pending Litigation to bring this Petition.

C. Procedural Statements

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

III. U.S. PATENT NO. 7,316,714 (“THE ‘714 PATENT”) (EX1001)

The ‘714 patent issued on January 8, 2008, on a continuation-in-part

application filed on September 11, 2003. For purposes of this Petition only, the earliest priority date for the '714 patent is August 5, 2003. Petitioner, however, notes the subject matter of FIGS. 17a-c was added as new matter in the continuation-in-part application. That subject matter has a priority date of September 11, 2003.

A. The '714 Patent Specification and Claims

The '714 patent is generally directed to expandable intervertebral implants to restore and maintain disc space height. The '714 patent issued with 20 claims, of which only claims 1 and 2 are at issue in this Petition. Claim 1 is independent and Claim 2 is directly dependent from claim 1.

The written description and drawings of the '714 patent describe various embodiments of expandable intervertebral implants for restoration and maintenance of disk space height. More particularly, the challenged claims 1 and 2 are directed to FIGS. 17a, 17b, and 17c. These figures and accompanying specification describe a banana-shaped expandable intervertebral implant 800 having a round joint insert 810 as shown in FIG. 17a. **EX1001, Col. 12, lines 61-64.** The round joint insert

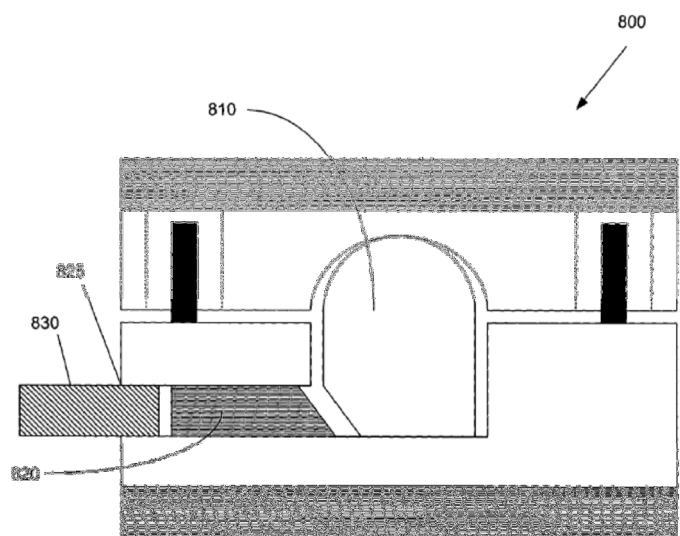
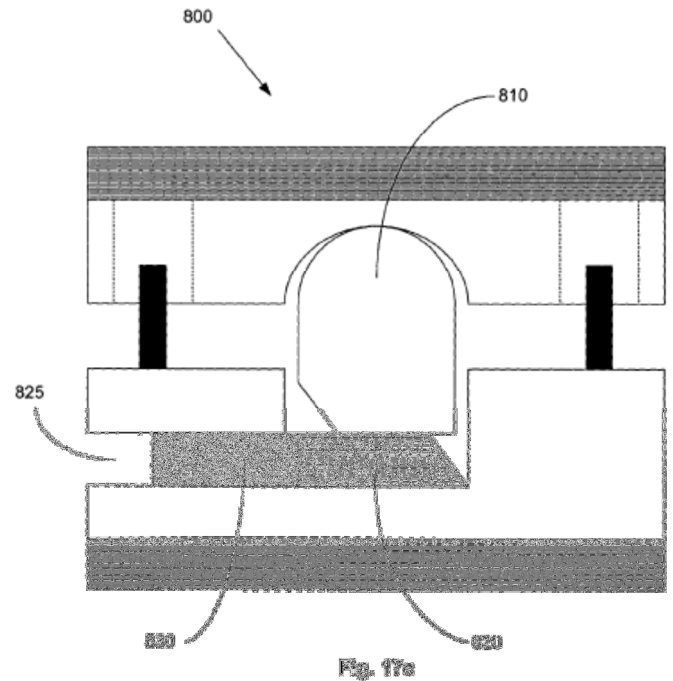


Fig. 17b

810 provides the closest approximation to natural biomechanical motion. *Id.* at Col. 12, lines 64-66. As described in FIGS. 17b and 17c, expansion plate 820 is inserted through expansion window 825. *Id.* at Col. 13, lines 1-3. Expansion window 825 is threaded, which allows a set screw 830 to move expansion plate 820 into position to engage joint insert 810. *Id.*, Col. 13,



lines 3-6. Set screw 830 prevents the dislocation of expansion plate 820 and allows the proper placement of expansion plate 820 with minimal impaction, which minimizes the stress on the surrounding area during the surgical procedure placing and expanding the device 800 in the intervertebral space. *Id.* at Col. 13, lines 6-11.

B. The ‘714 Patent Prosecution History (EX1003)

The continuation-in-part application leading to the ‘714 patent, Serial No. 10/660,155, was filed on September 11, 2003. This continuation-in-part application was based on Serial No. 10/634,950, filed on August 5, 2003, now U.S. Patent No. 7,204,853.

Prosecution before the U.S. Patent and Trademark Office (“PTO”) for the

application leading to the '714 patent, included a Preliminary Amendment filed on June 6, 2005, in which all pending claims were cancelled and new claims were submitted. **EX1003, at pages 74-80.** On September 19, 2005, the Examiner issued a Restriction Requirement. **EX1003, at pages 59-64.** On August 10, 2006, the PTO issued a Notice of Abandonment for Failure to Reply. **EX1003, at pages 41-42.** On August 22, 2006, the Applicant filed a Request for Withdrawal of Holding of Abandonment. **EX1003, at page 37-40.** On December 19, 2006, the Request for Withdrawal of Abandonment was granted. **EX1003, at page 35-36.** On January 29, 2007, the Restriction Requirement reissued. **EX1003, at page 29-34.**

On March 5, 2007, the Applicant filed a response to the Restriction Requirement in which the Applicant noted that the Restriction Requirement did not account for the Preliminary Amendment filed on June 6, 2005, on its face was deficient, and referenced terms with respect to species that did not appear in the pending claims. The Applicant concluded that as a result, an election could not be made and Applicant requested reconsideration. ***Id.* at pages 26-27.**

On August 8, 2007, a Notice of Allowance issued in which the reasons for allowance are noted as follows:

The prior art fails to disclose and/or fairly teach in combination an intervertebral implant an upper and lower bodies each defining inferior and superior surfaces; an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body prior to

insertion of the intervertebral implant; an expansion member configured to engage the insert; a set screw configured to be rotated to advance the expansion member to engage the insert such that the insert increases a separation distance between the upper body and the lower body after insertion of the intervertebral implant and the human spine; and wherein by increasing the separation distance between the upper body and the lower body allows increased articulation of the implant.

***Id.* at pages 15-20.**

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

As established in the Declaration of Dr. Ochoa, a person having ordinary skill in the art (PHOSITA) of the '714 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. **EX1005, at ¶ 18.**

V. CLAIM CONSTRUCTION

The claims of the '714 patent are to be given their broadest reasonable construction in light of the '714 patent's specification as understood by a person having ordinary skill in the art. 37 C.F.R. § 42.100(b).

The standard for claim construction in the United States Patent and Trademark Office is different than the standard used in litigation in the U.S. District Courts. *In re Am Acad. Of Sci. Tech Ctr.*, 367 F.3d 1359, 1364, 1369 (Fed. Cir. 2004); M.P.E.P. § 2111. Petitioner, therefore, expressly reserves the right to argue a different claim construction in a different forum for any term in the ‘714 patent, as appropriate in that proceeding.

VI. THE PRIOR ART RELIED UPON IN THIS PETITION

A. U.S. Patent No. 5,782,832 to Larsen et al. (“the ‘832 patent” or “Larsen”) (EX1004)

U.S. Patent No. 5,782,832 to Larsen et al., entitled “Spinal Fusion Implant and Method of Insertion Thereof,” issued on July 21, 1998. Larsen is prior art to the ‘714 patent under 35 U.S.C. § 102(b) because it is a printed publication more than one year prior to the date of the application for the ‘714 patent in the United States. Larsen was disclosed by the applicant during the prosecution of the application leading to the ‘714 patent, but was not referred to or relied on by the Examiner during the prosecution.

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

Petitioner seeks, by this Petition, a final, written decision that challenged claims 1 and 2 of the ‘714 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. Of the challenged claims, claim 1 is independent and claim 2 depends from

claim 1.

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

In summary, and as established by the declaration of Dr. Ochoa, Larsen renders claims 1 and 2 unpatentable as obvious under 35 U.S.C. § 103 (**EX1005 at ¶¶ 31-44**).

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

This petition presents the following Grounds of unpatentability:

- Ground 1: Claims 1 and 2 are unpatentable under 35 U.S.C. § 103 as obvious over Larsen in view of the knowledge of one of ordinary skill in the art (**EX1004**).²

A. Ground 1: Claims 1 and 2 are unpatentable under 35 U.S.C. § 103 as obvious over Larsen in view of the knowledge of one of ordinary skill in the art (EX1004)

Larsen discloses an intervertebral implant for insertion within an intervertebral space for supporting the vertebrae in a predetermined space relation during fusion procedures. (**EX1004, Col. 1, line 65-Col. 2, line 1; Col. 2, lines 59-63**) The disclosed implants include lower and upper plate members having contact surfaces for engaging end faces of adjacent vertebrae in a camming arrangement.

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

(*Id.* at Col. 2, lines 59-63) One disclosed embodiment includes an intervertebral implant for use in spinal fusion surgical procedures comprising an upper body (“upper support member” 402) and lower body (“lower support member” 404). Pyramid shaped projections (410) on the outer surfaces of the upper and lower bodies facilitate engagement with the adjacent vertebrae. (**EX1004, Col. 8, lines 8-15**) An insert, integral to the upper body, is positioned between the upper and lower bodies such that its inner surface (416) engages an inclined camming surface. (**EX1005, Ochoa Decl. at ¶ 32**) Rotation of a threaded element, e.g. screw 418, which traverses a bore 422 in the lower support member, advances the inclined camming block elevating the upper body while articulating about a pin (432). (*Id.* at Ochoa Decl. at ¶ 32)

A PHOSITA would have understood that the spinal implant taught in the Larsen patent renders claims 1 and 2 of the ‘714 patent obvious. The claim charts and accompanying analysis below, evidence this conclusion.

1. Claim 1

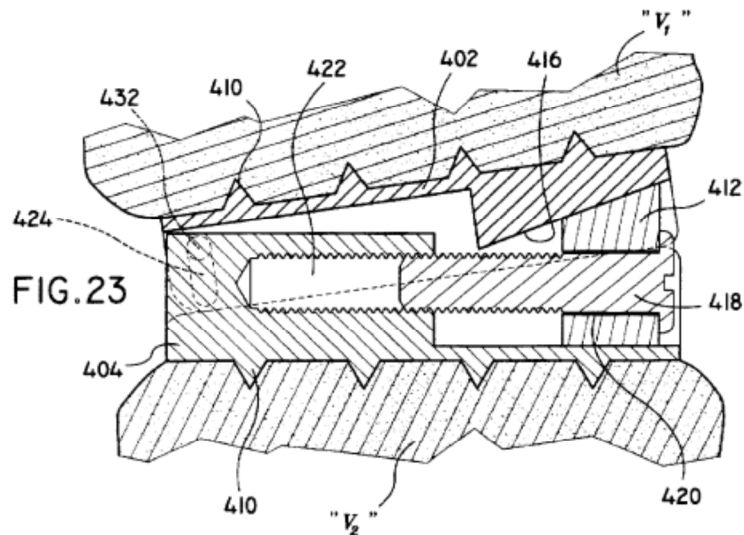
Claim 1 is directed to an implant device. Claim 1 is obvious in view of Larsen. This is demonstrated with reference to the chart below and the accompanying text.

‘714 patent Claim 1 vs. ‘832 patent	
<i>1. An intervertebral</i>	Larsen (the ‘832 patent) (EX1004) discloses: <ul style="list-style-type: none"> • An implant for insertion within an intervertebral space

implant for a human spine, comprising:

between adjacent vertebrae for supporting the vertebrae in predetermined space relation. **EX1004, Col. 1, line 65-Col. 2, line 1.**

- The implant further discloses at least the first and second support member having engaging surfaces for engaging vertebral implants of the vertebrae and a camming arrangement having at least one camming member operatively engaging with the first and second support members. **EX1004, Col. 2, line 59-63**
- The apparatus of the present disclosure is intended for fusing adjacent bone structures and has particular application in the spinal fusion of adjacent vertebrae subsequent to a discectomy procedure. The apparatus may be implanted using any conventional surgical approach, e.g., anterior and/or posterior approaches, or may be implanted utilizing minimally invasive or endoscopic surgical techniques currently being utilized to carry out discectomy and spinal implant procedures. **EX1004, Col. 4, lines 24-32**
- See e.g. **EX1004** at Fig. 23 below.



- Larsen discloses an intervertebral implant for a human spine. **EX1005, Ochoa Decl. at ¶ 33.**

The preamble of claim 1 merely states the intended use of the invention and

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

To the extent that the preamble limits the claim, a PHOSITA would have understood that the spinal implant of Larsen is for use in spinal fusion surgical procedures in association with vertebrae in a patient's spine. **EX1004, Col. 4, lines 24-32; FIG. 23; EX1005, Ochoa Decl. at ¶ 33.** A PHOSITA would have also understood that the spinal implant described in the Larsen reference is an interbody spacer for use in spinal fusion procedures. **EX1005, Ochoa Decl. at ¶ 33.** A PHOSITA would have recognized that the Larsen reference patent discloses an intervertebral implant for a human spine, as recited in the claims. **(EX1005, Ochoa Decl. at ¶ 33)**

Therefore, a PHOSITA would have understood that the Larsen reference discloses *an intervertebral implant for a human spine*, as recited in claim 1. ***Id.* at ¶33.**

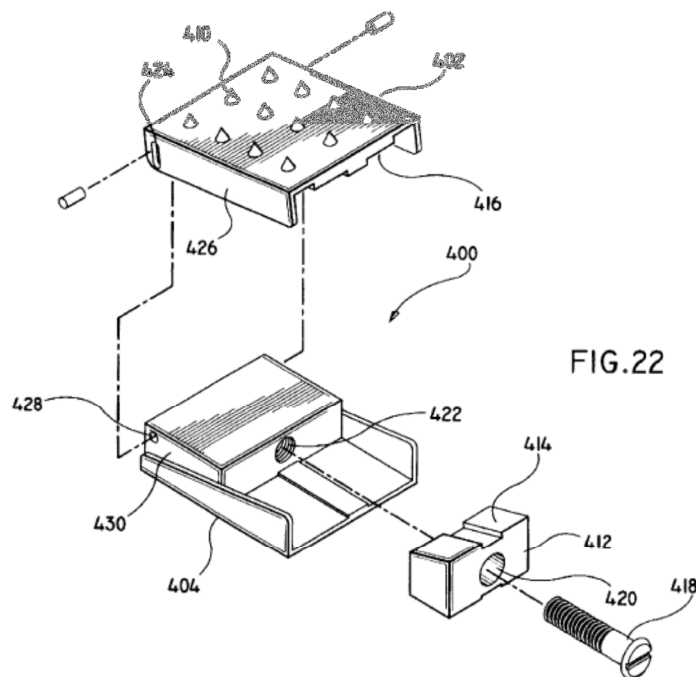
‘714 patent Claim 1 vs. ‘832 patent	
<i>an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the</i>	<p>Larsen (the ‘832 patent) (EX1004) discloses:</p> <ul style="list-style-type: none"> • Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-

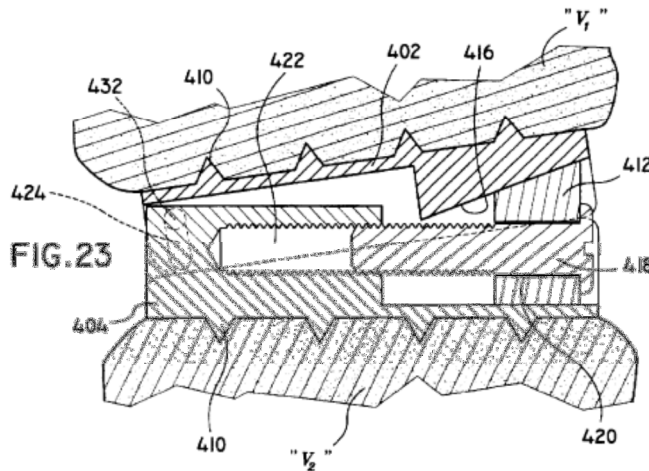
³ *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 U.S.P.Q.2d 1161, 1165 (Fed. Cir. 1999); M.P.E.P. § 2111.02.

upper body is configured to engage a first vertebra of the human spine;

shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V₁, V₂" upon insertion within the intervertebral space "i". Implant 400 further includes a camming arrangement for moving upper and lower support members 402, 404 between an open and a closed position. **EX1004, Col. 8, lines 8-19**

- FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402. **EX1004, Col. 8, lines 38-47**
- See e.g. **EX1004** at FIGS. 22 and 23 below.





- Larsen 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. **EX1005, Ochoa Decl. at ¶34.**

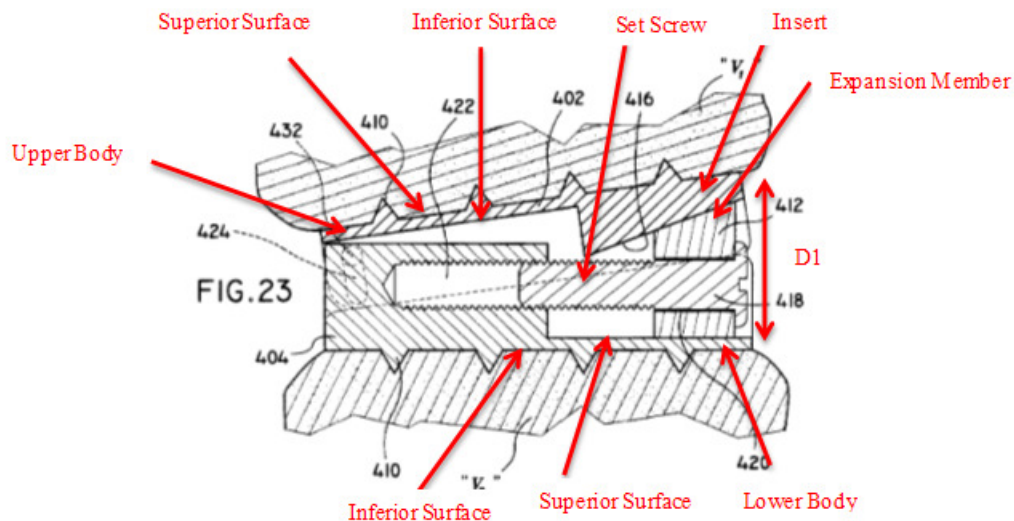
The phrase “*an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine,*” is a recitation of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and therefore is not material to patentability. As such, this language carries no patentable weight.⁴ Moreover, a PHOSITA would not understand the limitation, “*configured to engage,*” to disclose any intrinsic or structural limitation of the implant. **EX1005, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Larsen

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

reference discloses these limitations. A PHOSITA would have understood that the intervertebral implant (“implant” 400) described in Larsen comprises an upper body (“upper support member” 402) and a lower body (“lower support member” 404). **EX1004, Col. 8, lines 8-19; FIG. 22.** The upper and lower bodies comprise a plate-shaped form, each including upper and lower surfaces. ***Id.* at FIGS. 22 and 23.** Pyramid-shaped projections (410) on the superior surface (406) of the upper body and inferior surface (404) of the lower body facilitate engagement with the vertebral end plates of the adjacent vertebrae. ***Id.* at Col. 8, lines 8-19; FIG. 23; EX1005, Ochoa Decl. at ¶ 34.**

The following from FIG. 23 of Larsen identifies various claim elements tethered to the disclosure:



Therefore, a PHOSITA would have understood that the Larsen reference 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, as recited in claim 1. **EX1005, Ochoa Decl. at ¶34.**

‘714 patent Claim 1 vs. ‘832 patent	
<p><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;</i></p>	<p>Larsen (the ‘832 patent) (EX1004) discloses:</p> <ul style="list-style-type: none"> • Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V₁, V₂" upon insertion within the intervertebral space "i". Implant 400 further includes a camming arrangement for moving upper and lower support members 402, 404 between an open and a closed position. EX1004, Col. 8, lines 8-19 • FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402. EX1004, Col. 8, lines 38-47 • See e.g. EX1004 at FIGS. 22 and 23 below.

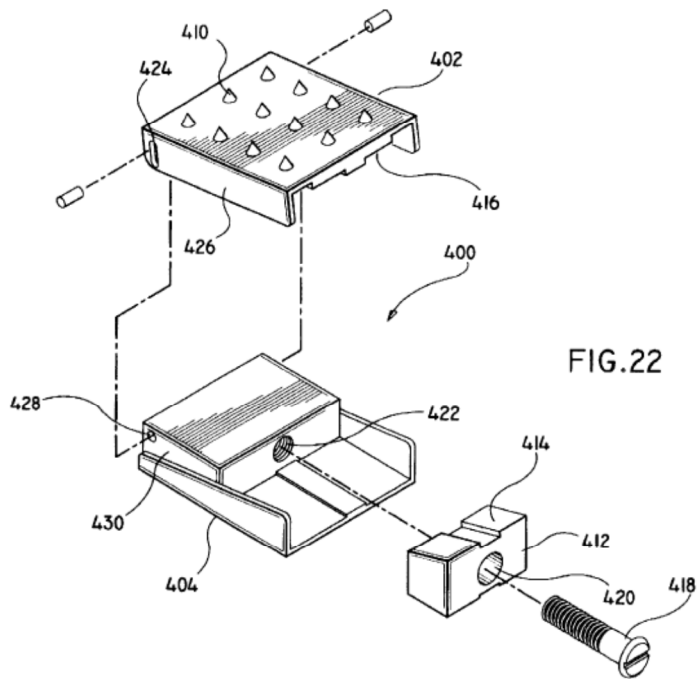


FIG. 22

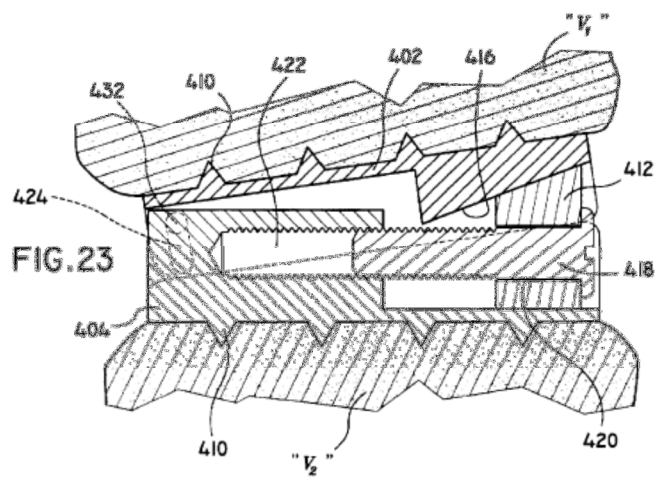


FIG. 23

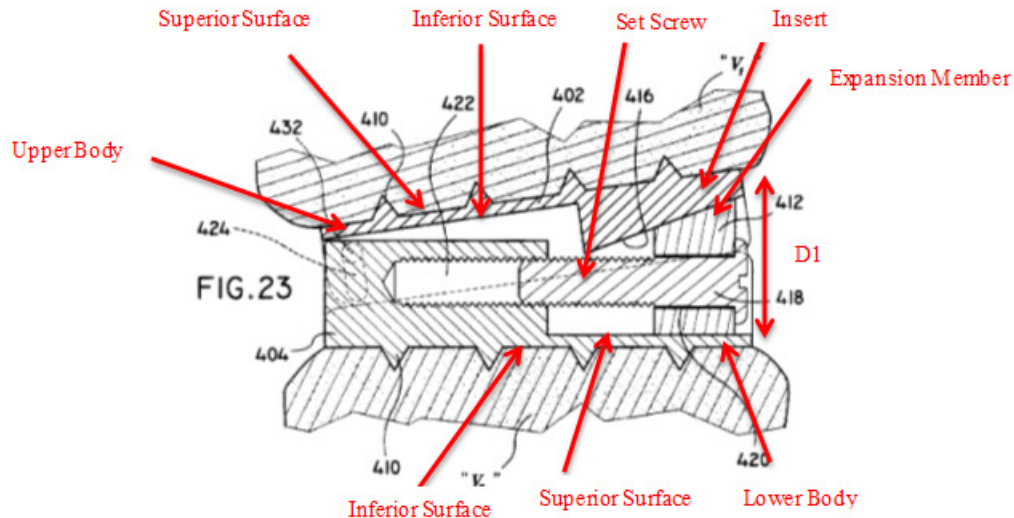
- Larsen discloses a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine. **EX1005, Ochoa Decl. at ¶ 34.**

The phrase “*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,*” is a recitation of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and therefore is not material to patentability. As such, this language carries no patentable weight.⁵ Moreover, a PHOSITA would not understand the limitation, “*configured to engage,*” to disclose any intrinsic or structural limitation of the implant. **EX1005, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Larsen reference discloses these limitations. A PHOSITA would have understood that the intervertebral implant (“implant” 400) described in Larsen comprises an upper body (“upper support member” 402) and a lower body (“lower support member” 404). **EX1004, Col. 8, lines 8-19; FIG. 22.** The upper and lower bodies comprise a plate-shaped form, each including upper and lower surfaces. ***Id.* at FIGS. 22 and 23.** Pyramid-shaped projections (410) on the superior surface (406) of the upper body and inferior surface (404) of the lower body facilitate engagement with the vertebral end plates of the adjacent vertebrae. ***Id.* at Col. 8, lines 8-19; FIG. 23; EX1005, Ochoa Decl. at ¶ 34.**

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.

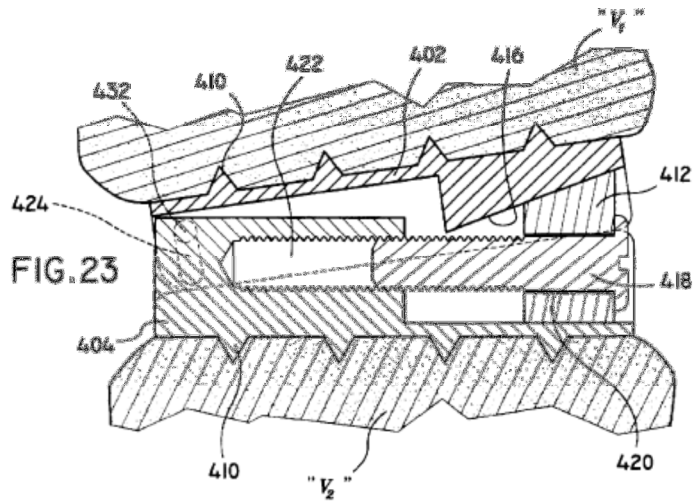
The following from FIG. 23 of Larsen identifies various claim elements tethered to the disclosure:



Therefore, a PHOSITA would have understood that the Larsen reference discloses *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 claim 1. **EX1005, Ochoa Decl. at ¶34.**

‘714 patent Claim 1 vs. ‘832 patent	
<i>an insert comprising a superior surface and an inferior surface, wherein the insert is configured to be positioned between the superior surface of the lower</i>	<p>Larsen (the ‘832 patent) (EX1004) discloses:</p> <ul style="list-style-type: none"> Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V₁, V₂" upon insertion within the intervertebral space "i". Implant 400 further includes a camming arrangement for moving

<p><i>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;</i></p>	<p>upper and lower support members 402, 404 between an open and a closed position. The preferred camming arrangement includes a camming block 412 which is adapted for traversing movement within the interior of implant 400. Camming block 412 defines an inclined camming surface 414 which engages a correspondingly dimensioned inner surface 416 of support member 402. The camming arrangement further includes a threaded element, e.g., screw 418, which traverses a bore 420 within camming block 412 and threadably engages an internal threaded bore 422 of lower support member 404.</p> <p>EX1004, Col. 8, lines 8-28</p> <ul style="list-style-type: none"> • Support members 402,404 are interconnected through a pin and slot arrangement. More particularly, support member 402 has a pair of transversely extending slots 424 formed in side plates 426. Support member 404 has a pair of correspondingly positioned apertures 428 formed in side plates 430. A pin 432 traverses each slot and opening arrangement to connect upper support member 402 and lower support member 404. EX1004, Col. 8, lines 29-37 • FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402. EX1004, Col. 8, lines 38-47 • See e.g. EX1004 at Fig. 23 below.
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- Larsen discloses an insert 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.
EX1005, Ochoa Decl. at ¶ 35.

The phrase “*an insert 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,*” is a recitation of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and therefore is not material to patentability. As such, this language carries no patentable weight.⁶ Moreover, a

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.

PHOSITA would not understand the limitation, “*configured to be positioned*,” to disclose any intrinsic or structural limitation of the implant. **EX1005, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Larsen reference discloses these limitations. A PHOSITA would understand that the upper body (“upper support member” 402) includes an insert, integral to the inferior surface, in the form of a block with an inclined surface (416). **EX1004, Fig. 23; EX1005, Ochoa Decl. at ¶ 35.** A PHOSITA would have understood that the upper and lower bodies (“upper support member” 402 and “lower support member” 404) are interconnected through a pin and slot arrangement, thus positioning the insert between superior surface of the lower body and inferior surface of the upper body when assembled. **EX1004, Col. 8, lines 29-37, Fig. 23.** Because Larsen does not discuss assembly of this device *in vivo*, a PHOSITA would have understood that assembly of the pin and slot arrangement would be performed before insertion of the implant. **EX1005, Ochoa Decl. at ¶ 35.**

Insofar as it may be contended that the insert disclosed in Figures 21-24 of the ‘832 patent does not comprise a superior and inferior surface, a PHOSITA would have recognized that the choice to combine the functionality of the plate element and wedge shaped insert element of the upper body in a single member would constitute one of many design choices. **EX1005, Ochoa Decl. at ¶ 36.** An

equally viable choice would have been to form the plate element and wedge-shaped insert using two separate members which could then be assembled using fasteners such as screws, a snap-fit, or other known assembly methods (see Figure 1 below). **EX1005, Ochoa Decl. at ¶ 36.** Addition of modularity would provide added benefit of allowing the surgeon to select inserts and camming blocks of varying sizes and/or angles at the time of surgery to allow varying independent degrees of elevation or angulation and reducing the need to hold inventory of various sizes. **EX1005, Ochoa Decl. at ¶ 36.** The concept of using modular components to allow for increased flexibility in sizing was well-known and widely used in the orthopedic industry and would have been recognized by a PHOSITA. **EX1013 Mayer, 2002, EX1015 Tropiano, 2003, EX1009 ‘071 Patent Figure 1; EX1005, Ochoa Decl. at ¶ 36.** A PHOSITA would have recognized that performing the simple substitution of a modular insert for the integrated insert disclosed in the ‘832 patent would have increased the functionality of the device in a predictable manner without any alteration in the way which the device functioned. **EX1005, Ochoa Decl. at ¶ 36.**

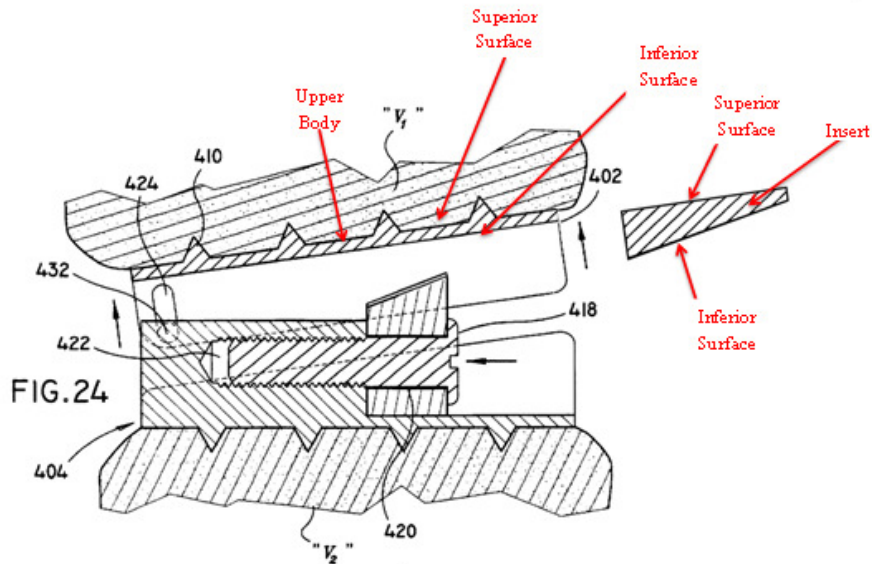
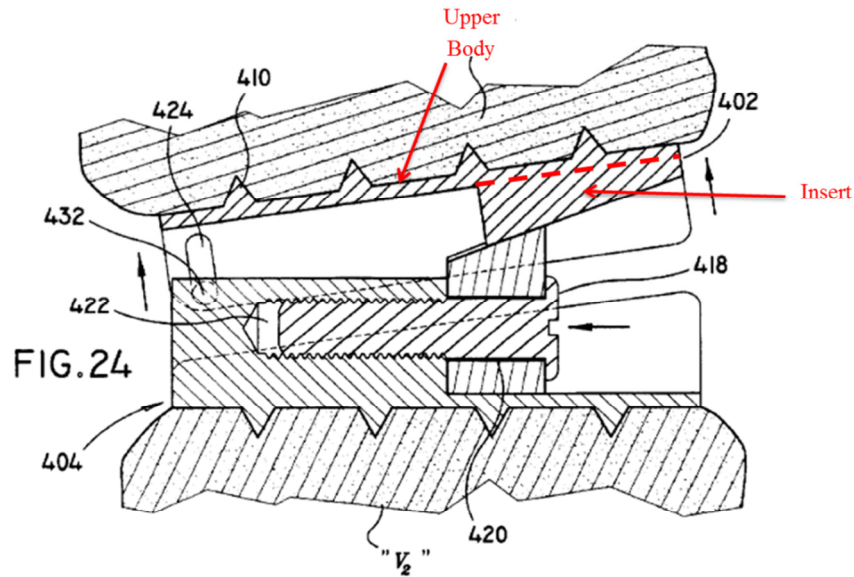


Figure 1. Excerpt from figure 24 of the '832 patent demonstrating the location of the interface between the upper body and insert as denoted by the dashed line (top) and after removing insert (bottom).

EX1005, Ochoa Decl. at ¶ 36.

A PHOSITA, therefore, would have been motivated in view of the benefits referenced above to combine the use of a modular insert with the device disclosed

in the '714 Patent to form a plate element and wedge-shaped insert using two separate members which could then be assembled using fasteners such as screws, a snap-fit, or other known assembly methods. **EX1005, Ochoa Decl. at ¶ 37.** A PHOSITA would have recognized that the resulting *insert 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*, would provide benefits resulting from the increased flexibility in sizing of the implant. **EX1005, Ochoa Decl. at ¶ 37.**

Therefore, a PHOSITA would have understood that the Larsen reference discloses *an insert 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*, as recited in claim 1. **Id. at ¶¶35-37.**

'714 patent Claim 1 vs. '832 patent	
<i>an expansion member configured to engage the insert;</i>	<p>Larsen (the '832 patent) (EX1004) discloses:</p> <ul style="list-style-type: none"> Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V₁, V₂" upon insertion within the intervertebral space "i". Implant

	<p>400 further includes a camming arrangement for moving upper and lower support members 402, 404 between an open and a closed position. The preferred camming arrangement includes a camming block 412 which is adapted for traversing movement within the interior of implant 400. Camming block 412 defines an inclined camming surface 414 which engages a correspondingly dimensioned inner surface 416 of support member 402. The camming arrangement further includes a threaded element, e.g., screw 418, which traverses a bore 420 within camming block 412 and threadably engages an internal threaded bore 422 of lower support member 404. EX1004, Col. 8, lines 8-28</p> <ul style="list-style-type: none"> • FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402. Col 8, line 37-47 • See e.g. EX1004 at FIGS. 22 and 23 below.
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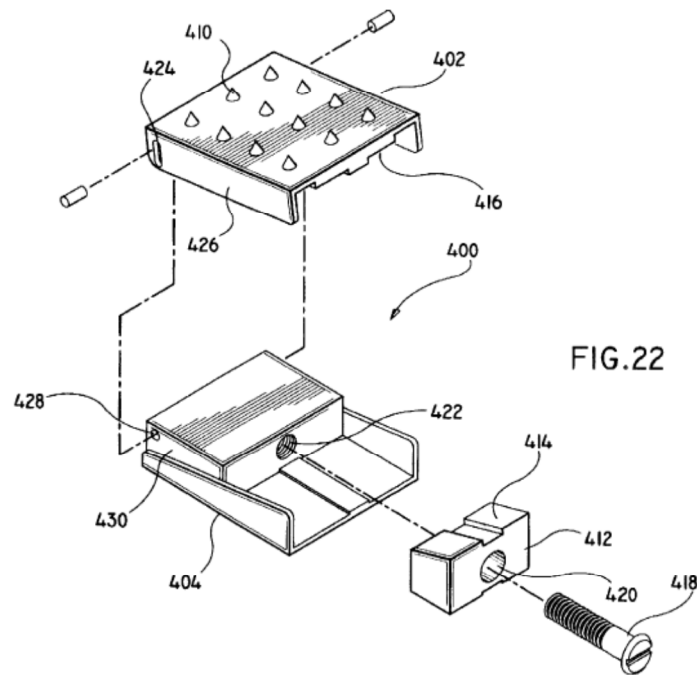


FIG.22

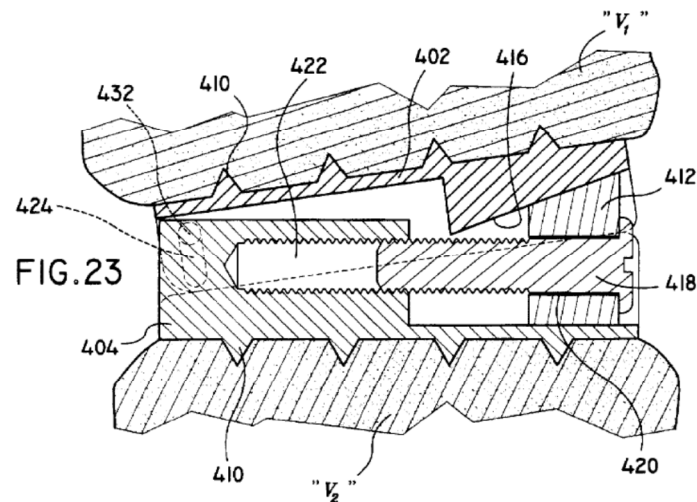


FIG.23

- Larsen discloses an expansion member configured to engage the insert. **EX1005, Ochoa Decl. at ¶ 38.**

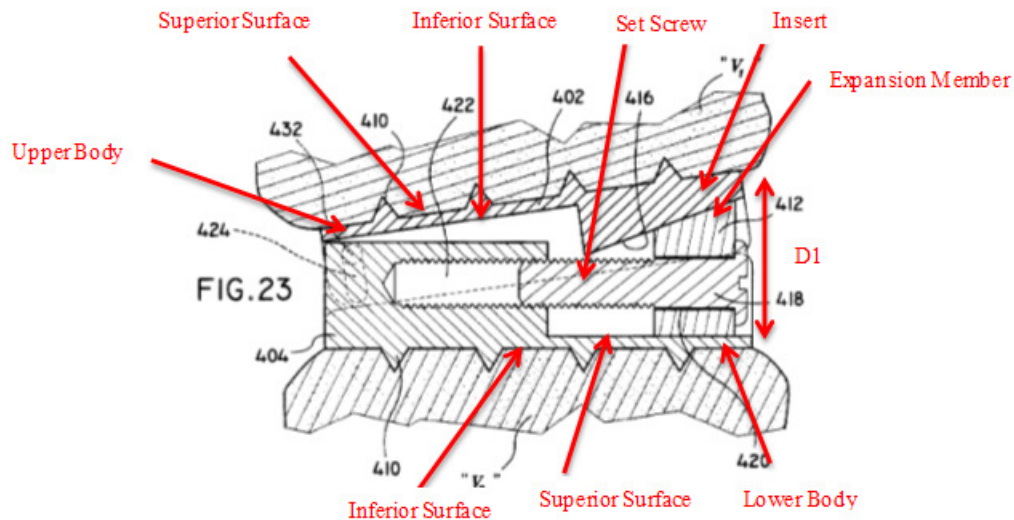
The phrase “*an expansion member configured to engage the insert,*” is a recitation of the intended use for the claimed apparatus; does not structurally

distinguish the claimed apparatus and therefore is not material to patentability. As such, this language carries no patentable weight.⁷ Moreover, a PHOSITA would not understand the limitation, “*configured to engage*,” to disclose any intrinsic or structural limitation of the implant. **EX1005, Ochoa Decl. at ¶ 22.**

However, to the extent that the language limits the claims, the Larsen reference discloses these limitations. A PHOSITA would have understood Larsen discloses an expansion member in the form of a camming block (412) which is adapted for traversing movement within the interior of the implant (400). **EX1004, Col. 8, lines 8-28; FIGS. 22 and 23.** A PHOSITA would have understood that the inclined superior surface (“inclined camming surface” 414) of the expansion member (“camming block” 412) engages the corresponding inclined surface (416) of the insert. **EX1005, Ochoa Decl. at ¶ 38.** Translation of the camming block is induced by rotation of a screw (418), advancing the camming block (412) and engaging the inclined inferior surface of the insert (416) such that the upper body (402) is displaced from the lower body (404). **EX1004, Col. 8, lines 8-29; Col. 8, lines 37-47; EX1005, Ochoa Decl. at ¶ 38.**

The following from FIG. 23 of Larsen identifies various claim elements tethered to the disclosure:

⁷ *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); and *In re Danly*, 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.



Therefore, a PHOSITA would have understood that the Larsen reference discloses *an expansion member configured to engage the insert*, as recited in claim

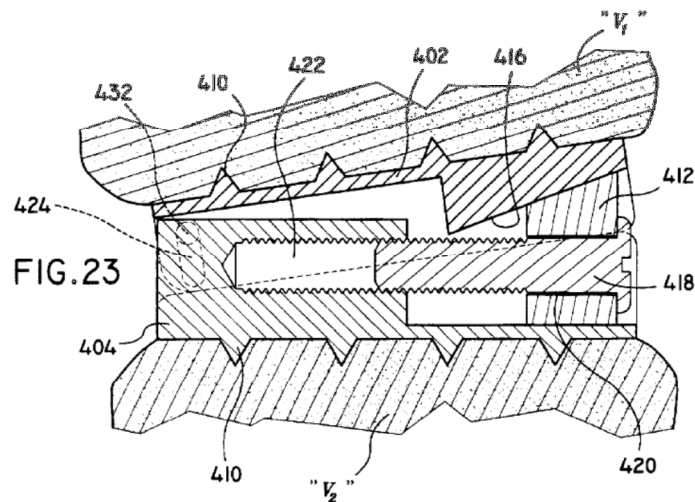
1. EX1005, Ochoa Decl. at ¶38.

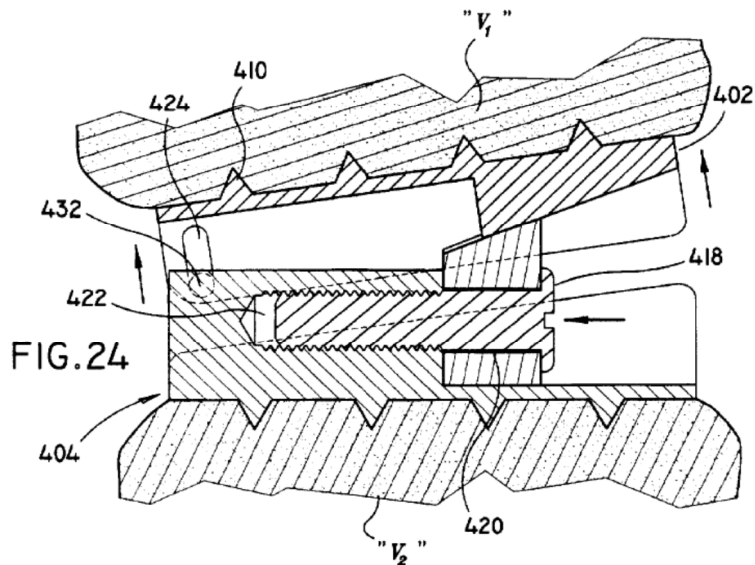
'714 patent Claim 1 vs. '832 patent	
<i>a set screw configured to be rotated to advance the expansion member to engage the insert such that the insert increases a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the</i>	<p>Larsen (the '832 patent) (EX1004) discloses:</p> <ul style="list-style-type: none"> • A spinal fusion implant includes lower and upper plate members dimensioned for at least partial insertion within the intervertebral space defined between adjacent vertebrae. The lower and upper plate members have contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae. A linkage mechanism including at least one link member operatively connects the lower and upper plate members. The linkage mechanism actuatable to cause relative movement of the lower and upper plate members, wherein upon actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members supporting the adjacent vertebrae in spaced relation during healing. EX1004, Abstract • Support members 402, 404 are interconnected through a pin and slot arrangement. More particularly, support

*human spine;
and*

member 402 has a pair of transversely extending slots 424 formed in side plates 426. Support member 404 has a pair of correspondingly positioned apertures 428 formed in side plates 430. A pin 432 traverses each slot and opening arrangement to connect upper support member 402 and lower support member 404. **EX1004, Col. 8, lines 29-36**

- FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402. **EX1004, Col. 8, lines 37-47**
- See e.g. **EX1004** at FIGS. 23 and 24 below.





- Larsen discloses a set screw configured to be rotated to advance the expansion member to engage the insert such that the insert increases a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine. **EX1005, Ochoa Decl. at ¶ 39.**

The phrase “a set screw configured to be rotated to advance the expansion member to engage the insert such that the insert increases a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine,” is a recitation of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and therefore is not material to patentability. As such, this language carries no patentable weight.⁸

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.

Moreover, a PHOSITA would not understand the limitation, “*configured to be rotated,*” to disclose any intrinsic or structural limitation of the implant. **EX1005, Ochoa Decl. at ¶ 22.**

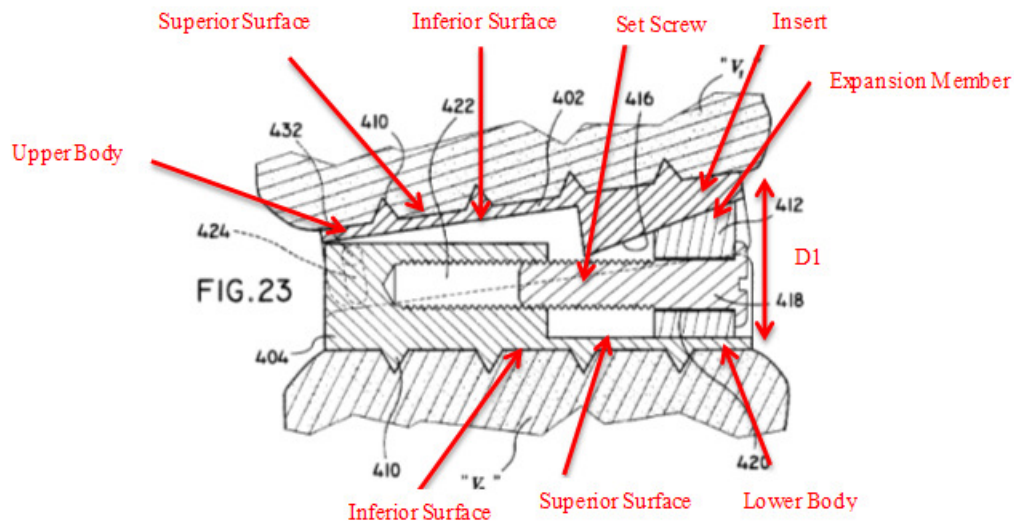
However, to the extent that this language limits the claims, the Larsen reference discloses these limitations. A PHOSITA would have understood that the separation distance between the upper (402) and lower (404) bodies of the implant (400) described in Larsen is increased when screw (418) is rotated in a clockwise direction, or generally progressing the screw into the implant. **EX1005, Ochoa Decl. at ¶ 39.** This causes the screw to advance within threaded bore (422) thereby advancing the expansion member (“camming block” 412) and in so doing displacing the insert and thus increasing the separation distance between the upper (402) and lower (404) bodies. **EX1004, Col. 8, lines 8-28; Col. 8, lines 37-47.** A PHOSITA would have understood that upon activation by rotation of the screw (418), the contacting surfaces of the lower and upper plate members would engage the vertebral faces and therefore the actuation would occur after insertion of the intervertebral implant in the spine. **EX1005, Ochoa Decl. ¶ 39.**

A PHOSITA would have recognized that a set screw can take many physical forms including headed and headless configurations, with multiple end configurations. A PHOSITA would have recognized that the ‘714 patent provides no guidance regarding specific form of the claimed set screw. To the extent that

the definition of a set screw is limited to a form which requires a screw to act against another body with a compressive force, the screw (418) of Larsen meets this limitation. More particularly, as the screw (418) is advanced into lower body (“lower support member” 404), screw (418) forces the camming block (412) to engage against a shoulder of lower body (“lower support member” 404) under a compressive load. The screw’s (418) threaded engagement with the lower body (“lower support member” 404) prohibits the camming block 412 from backing out of engagement with the shoulder of lower body (“lower support member” 404).

EX1005, Ochoa Decl. ¶ 40.

The following from Figure 2 identifies the various claim elements:



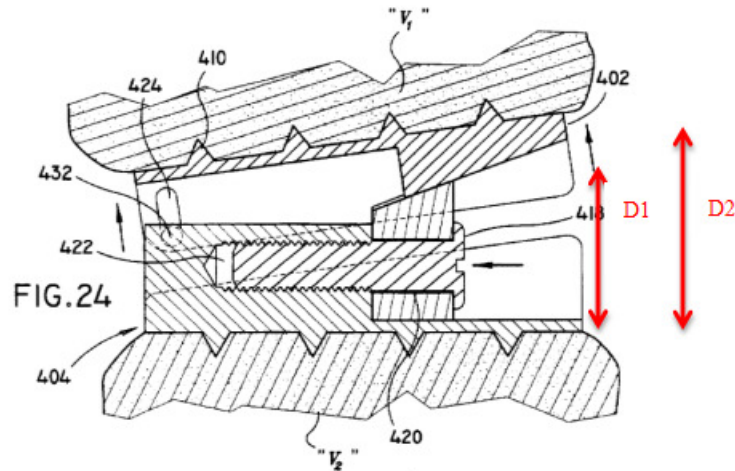


Figure 2. Excerpt from figure 24 of the '832 patent demonstrating the various claim elements including the difference between the initial separation distance (D1) and final separation distance (D2).

Therefore, a PHOSITA would have understood that the Larsen reference discloses *a set screw configured to be rotated to advance the expansion member to engage the insert such that the insert increases a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine*, as recited in claim 1. *Id.* at ¶¶39-40.

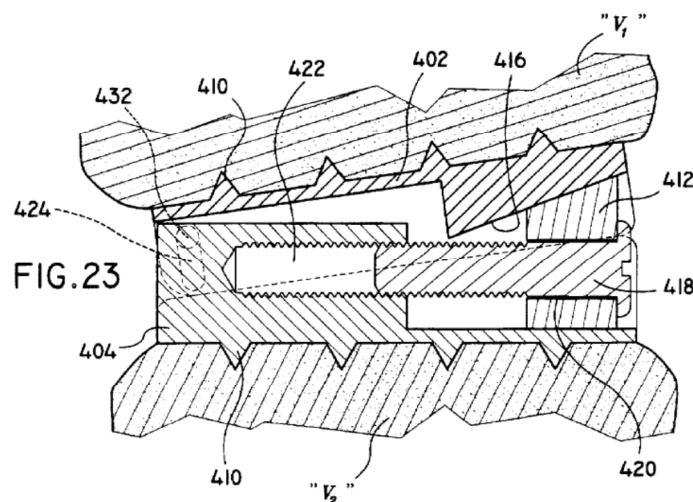
'714 patent Claim 1 vs. '832 patent	
wherein the intervertebral implant is configured such that increasing the separation distance between the upper body and the lower body allows articulation or increased	<p>Larsen (the '832 patent) (EX1004) discloses:</p> <ul style="list-style-type: none"> Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V₁, V₂" upon insertion within the intervertebral space "i". Implant 400 further includes a camming arrangement for moving upper and lower support members 402, 404 between an

*articulation of
the
intervertebral
implant.*

open and a closed position. The preferred camming arrangement includes a camming block 412 which is adapted for traversing movement within the interior of implant 400. Camming block 412 defines an inclined camming surface 414 which engages a correspondingly dimensioned inner surface 416 of support member 402. The camming arrangement further includes a threaded element, e.g., screw 418, which traverses a bore 420 within camming block 412 and threadably engages an internal threaded bore 422 of lower support member 404.

EX1004, Col. 8, lines 29-37

- See e.g. **EX1004** at Fig. 23 below.

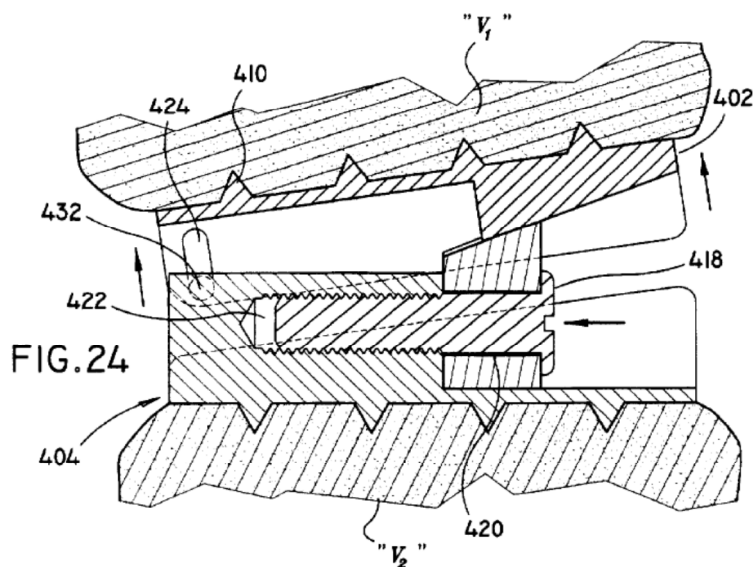


Larsen (the '832 patent) (**EX1004**) discloses:

- Support members 402, 404 are interconnected through a pin and slot arrangement. More particularly, support member 402 has a pair of transversely extending slots 424 formed in side plates 426. Support member 404 has a pair of correspondingly positioned apertures 428 formed in side plates 430. A pin 432 traverses each slot and opening arrangement to connect upper support member 402 and lower support member 404. **EX1004, Col. 8, lines 29-37**
- FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within

threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402. **EX1004, Col. 8, line 38-47**

- See e.g. **EX1004** at Fig. 24 below.



- Larsen discloses wherein the intervertebral implant is configured such that increasing the separation distance between the upper body and the lower body allows articulation or increased articulation of the intervertebral implant. **EX1005, Ochoa Decl. at ¶ 41-42.**

The phrase “*wherein the intervertebral implant is configured such that increasing the separation distance between the upper body and the lower body allows articulation or increased articulation of the intervertebral implant,*” is a recitation of the intended use for the claimed apparatus; does not structurally

distinguish the claimed apparatus and therefore is not material to patentability. As such, this language carries no patentable weight.⁹ Moreover, a PHOSITA would not understand the limitation, “*configured such that*,” to disclose any intrinsic or structural limitation of the implant. **EX1005, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Larsen reference discloses these limitations. A PHOSITA would have understood that the upper and lower bodies (“support members” 402 and 404) disclosed in Larsen are interconnected through a pin (432) and slot arrangement (424 and 428). **EX1004, Col. 8, lines 29-47, FIGS. 22 and 24.** As the camming block (412) is advanced, displacing the insert and increasing the separation distance between the upper (402) and lower (404) bodies, the upper body (402) articulates, pivoting about the axis of the pin (432) while translating along the slot. **EX1004, Col. 8, lines 29-47; FIGS. 22 and 24; EX1005, Ochoa Decl. at ¶ 41.**

A PHOSITA would have understood that after fully advancing the expansion member (“camming block” 412) the upper body (402) and insert would still have limited freedom to articulate on the expansion member (“camming block” 412). **EX1005, Ochoa Decl. at ¶ 42.** Due to the location of the slots (424) on the upper body (402) of the implant (400), the upper body (402) is not

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.

constrained to resist tangential motion of the pins (432) induced by a couple applied to the upper body (402) in a counter clockwise direction (see Figure 3 below). **EX1005, Ochoa Decl. at ¶ 42.**

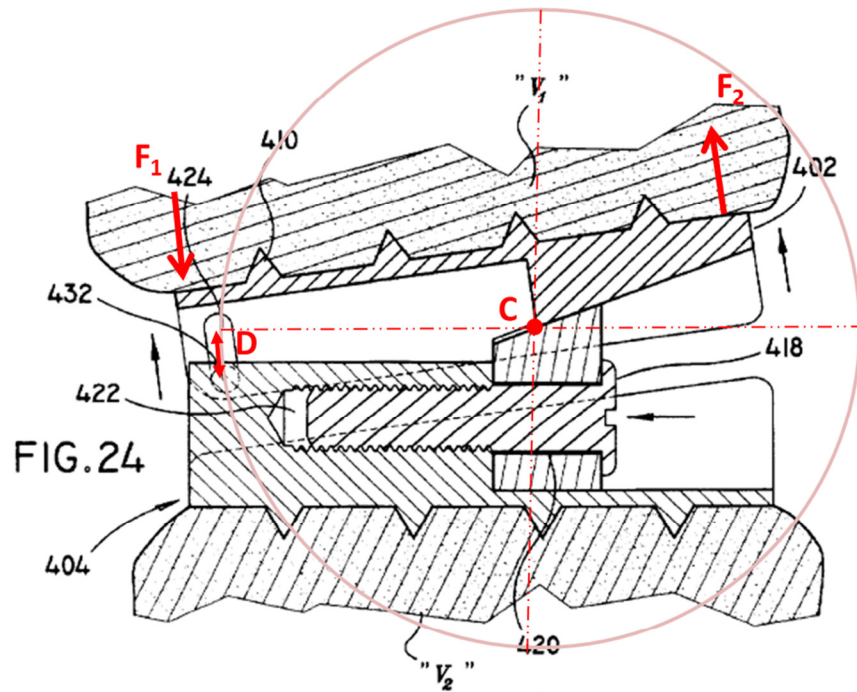


Figure 3. Excerpt from figure 24 of the '832 patent demonstrating the center of rotation (C) about which the upper body would articulate, and the distance (D) if a couple (F_1 , F_2) were applied to the upper body after full deployment of the device.

EX1005, Ochoa Decl. ¶ 42.

Therefore, a PHOSITA would have understood that the Larsen reference discloses *wherein the intervertebral implant is configured such that increasing the separation distance between the upper body and the lower body allows articulation or increased articulation of the intervertebral implant*, as recited in claim 1. ***Id.* at**

¶41-42.

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

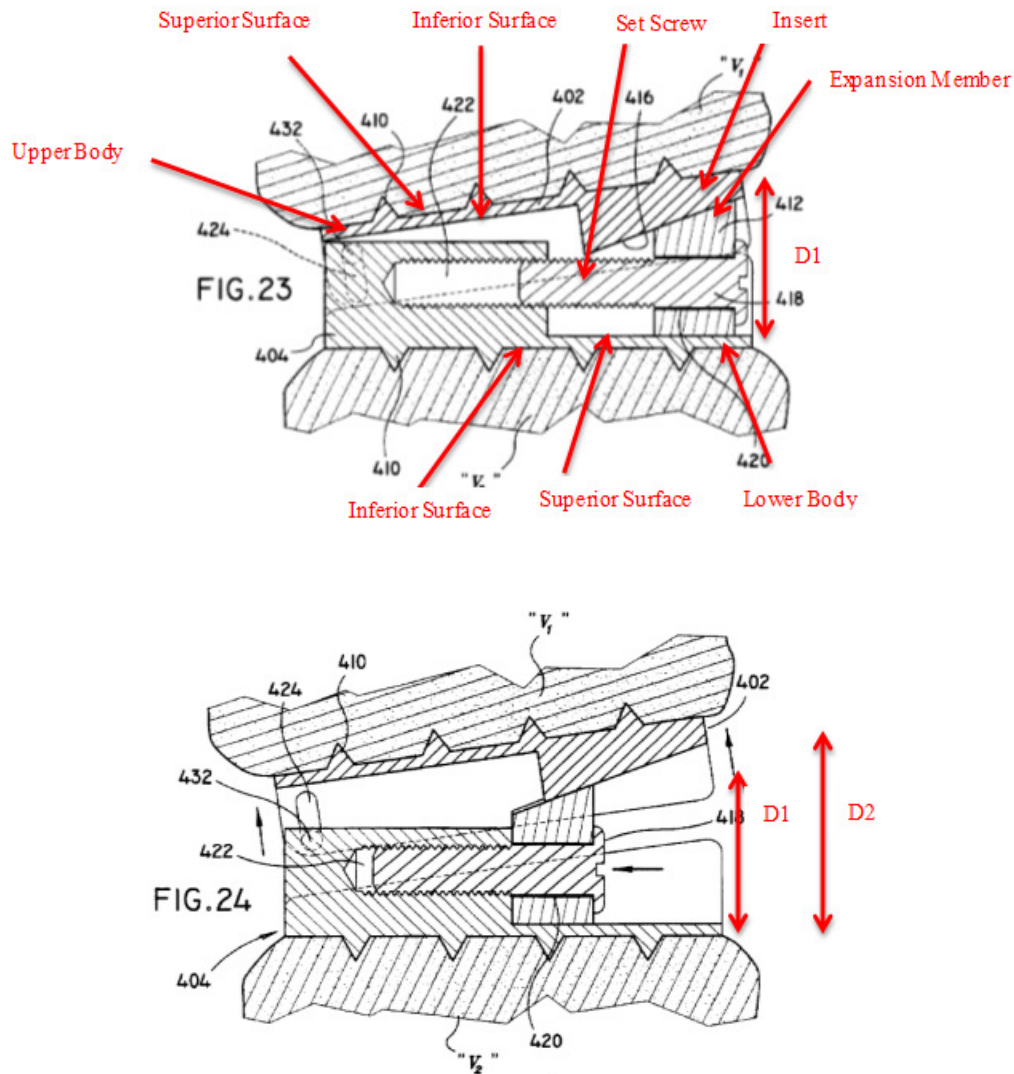


Figure 4. Excerpt from figures 23 and 24 of the '832 patent demonstrating the various claim elements including the difference between the initial separation distance (D1) and final separation distance (D2).

EX1005, Ochoa Decl. ¶ 42-43.

The claim charts attached as EX1020 provide additional details supporting the information that would have been conveyed by the ‘832 patent and understood by a PHOSITA at the time of the invention of the ‘714 patent. **EX1005, Ochoa Decl. ¶ 43.**

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

2. Claim 2

Claim 2 depends from claim 1 and is substantively identical. Claim 2 is directed to an intervertebral implant device for a human spine. Claim 2 is rendered obvious by Larsen. This is demonstrated with reference to the chart below.

A PHOSITA would have understood that *the intervertebral implant of claim 1, wherein the insert is configured to interact with at least a portion of the upper body or at least a portion of the lower body to increase the separation distance between the upper body and the lower body* taught in Larsen renders obvious claim 2 of the ‘714 patent. The claim charts and accompanying analysis below, evidence this conclusion.

‘714 patent Claim 2 vs. ‘832 patent	
2. <i>The intervertebral implant of claim 1, wherein the insert is configured to</i>	Larsen (the ‘832 patent) (EX1004) discloses: <ul style="list-style-type: none">• FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within

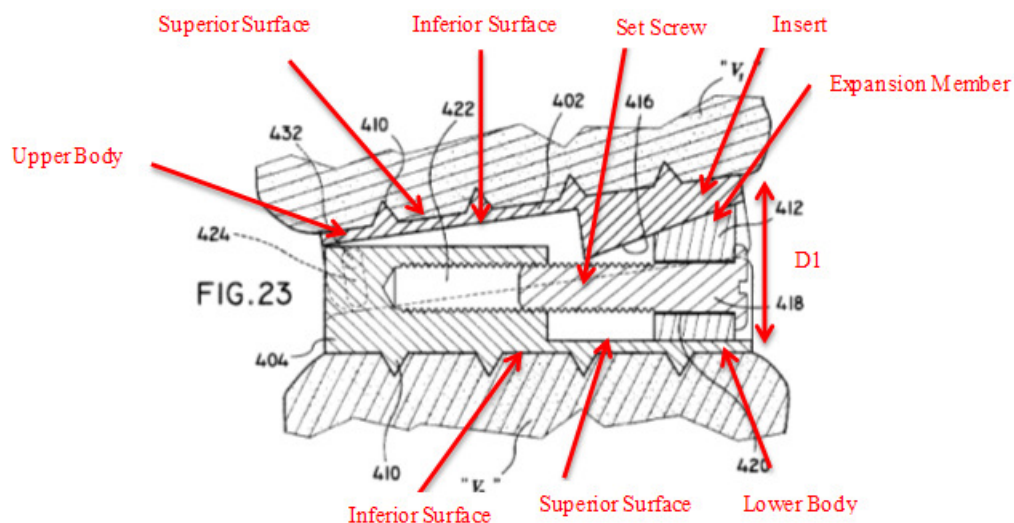
<p><i>interact with at least a portion of the upper body or at least a portion of the lower body to increase the separation distance between the upper body and the lower body.</i></p>	<p>threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402. EX1004, Col. 8, lines 39-47</p> <ul style="list-style-type: none"> • Larsen discloses the intervertebral implant of claim 1, wherein the insert is configured to interact with at least a portion of the upper body or at least a portion of the lower body to increase the separation distance between the upper body and the lower body. EX1005, Ochoa Decl. at ¶ 43.
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The phrase “*wherein the insert is configured to interact with at least a portion of the upper body or at least a portion of the lower body to increase the separation distance between the upper body and the lower body,*” is a recitation of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and therefore is not material to patentability. As such, this language carries no patentable weight.¹⁰ Moreover, a PHOSITA would not understand the limitation, *configured to interact,*” to disclose any intrinsic or structural limitation of the implant. **EX1005, Ochoa Decl. at ¶ 22.**

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

¹⁰ *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.

displacement induced between the camming block (412) and the inclined inferior surface of the insert (416) is transmitted to the upper body (“upper support member” 402) resulting in increased separation distance due to upwards displacement of the upper body (“upper support member “402”) from the lower body (“lower support member” 404). Because of the elongated shape of the slots (424) this displacement would occur at both the opening portion of the device and at the opposite, hinged portion (see Figure 5 below). **EX1005, Ochoa Decl. at ¶ 43.**



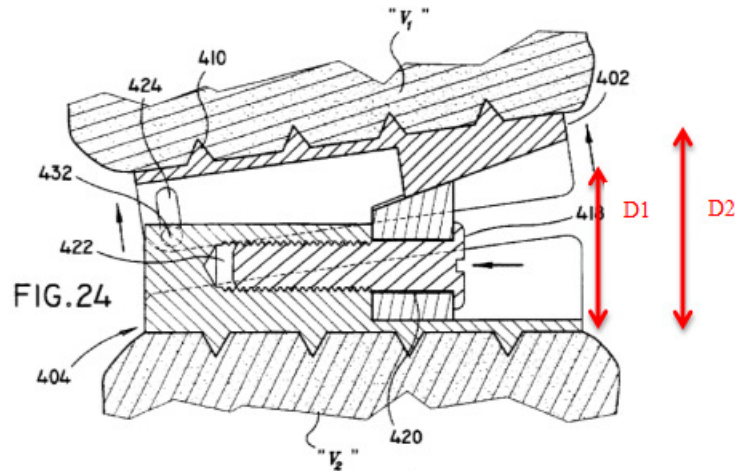


Figure 5. Excerpt from figure 24 of the '832 patent demonstrating the various claim elements including the difference between the initial separation distance (D1) and final separation distance (D2).

EX1005, Ochoa Decl. at ¶ 43.

Therefore, a PHOSITA would have understood that the Larsen reference discloses *wherein the insert is configured to interact with at least a portion of the upper body or at least a portion of the lower body to increase the separation distance between the upper body and the lower body*, as recited in claim 1.

EX1005, Ochoa Decl. at ¶ 43.

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

IX. CONCLUSION

Petitioner has demonstrated in this Petition that claims 1 and 2 of the '714 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '714 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. 7,316,714 to be served via FedEx, next day delivery, on lead and back-up counsel of record, on this 14th day of August, 2015:

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