UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFE SPINE, INC.

Petitioner

v.

GLOBUS MEDICAL, INC.

Patent Owner

Patent No. 8,845,732

Issue Date: September 30, 2014

Title: EXPANDABLE FUSION DEVICE AND METHOD OF INSTALLATION THEREOF

Inter Partes Review No. IPR2022-01599

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§311-319 AND 37 C.F.R. §42.100 *ET SEQ*.

TABLE OF CONTENTS

EXHIBIT LIST

Ex. #	Exhibit
1001	U.S. Patent No. 8,845,732 ("'732 patent")
1002	Declaration of Prof. Troy D. Drewry
1003	Curriculum vitae of Prof. Troy D. Drewry
1004	Excerpts of Prosecution History for '732 Patent
1005	Certified Translation of Korean Reg. Utility Model No. KR20-0290058 ("Chung")
1006	U.S. Patent Application Publication No. US 2008/0140207 A1 to Olmos et al. ("Olmos")
1007	U.S. Patent Application Publication No. US 2007/0270968 A1 to Baynham et al. ("Baynham")
1008	U.S. Patent No. 4,743,256 to Brantigan ("Brantigan")
1009	Excerpts of Leonard F. Peltier, Orthopedics: A History and Iconography (1993)
1010	*Reserved*
1011	U.S. Patent No. 8,308,804 to Krueger ("Krueger")
1012	*Reserved*
1013	*Engineering Mechanics: Wedges*, Mechanics Map: Open Textbook Project, mechanicsmap.psu.edu/websites/7_friction/7-3_wedges/wedges.html
1014	U.S. Patent Application Publication No. US 2008/0114367 to Meyer ("Meyer")
1015	*Wedge*, Encyclopaedia Britannica (2008), https://www.britannica.com/technology/wedge
1016	U.S. Patent No. 8,906,095 to Christensen et al. ("Christensen")
1017	Video titled "Scissor Jack Animation SOLIDWORKS"
1018	*Reserved*
1019	*Reserved*

1020	Life Spine Stipulation
1021	Virk et al., *History of Spinal Fusion: Where We Came from and Where We Are Going*, 16 HSSJ 137 (2020)
1022	Tsuang et al., *Comparison of cage application modality in posterior lumbar interbody fusion with posterior instrumentation—A finite element study*, 31 Medical Engineering & Physics 565 (2009)
1023	Plaintiff Globus Medical, Inc.'s Preliminary Claim Construction Pleading
1024	Defendant Life Spine, Inc.'s Preliminary Claim Construction Pleading
1025	Declaration of Christopher McDonnell Regarding Claim Construction
1026	Kim, et al., *Posterior Lumbar Interbody Fusion using Unilateral Single Cage and Local Morselized Graft*, 1 Clinics in Orthopedic Surgery 214 (2009)
1027	Xiao, et al., *Unilateral Transforaminal Lumbar Interbody Fusion: a Review of the Technique, Indications, and Graft Materials*, 37 J. Int'l Med. Research 908 (2009)
1028	U.S. Patent Application Publication No. US 2003/0176926 to Boehm et al. ("Boehm")
1029	U.S. Patent Application Publication No. US 2009/0062833 A1 to Song ("Song")
1030	U.S. Patent Application Publication No. US 2011/0172774 A1 to Varela ("Varela-'774")
1031	*Reserved*
1032	*Reserved*
1033	U.S. Provisional Patent Application No. 61/293,997 ("'997 provisional")
1034	U.S. Provisional Patent Application No. 61/296,932 ("'932 provisional")
1035	Kambin et al., *Arthroscopic Discectomy of the Lumbar Spine*, 337 Clinical Orthopaedics and Related Research 49 (1997).

1036	Excerpts of Webster's II New College Dictionary (Houghton Mifflin Co., 2005) and The American Heritage College Dictionary (Houghton Mifflin Co., 2004)
1037	Excerpts of Prosecution History for U.S. Patent No. 8,845,731
1038	U.S. Patent Application Publication No. US 2002/0143343 A1 to Castro
1039	Kim, *et al*., "Clinical Applications of the Tubular Retractor on Spinal Disorders," *J. Korean Neurosurg. Soc*., 42:245-250 (2007)

I. INTRODUCTION

Petitioner Life Spine, Inc. ("Petitioner") respectfully requests *inter partes* review of Claims 1, 7-13, and 16 of U.S. Patent No. 8,845,732 ("the '732 patent," EX1001), assigned to Globus Medical, Inc. ("Patent Owner"), in accordance with 35 U.S.C. §§311-319 and 37 C.F.R. §42.100 *et seq.* Claims 1, 7-13, and 16 recite only devices and methods that were widely known the industry prior to the '732 patent's effective filing date.

II. MANDATORY NOTICES UNDER 37 C.F.R. §42.8

A. Each Real Party-In-Interest

The real party-in-interest is Petitioner Life Spine, Inc., located at 13951 South Quality Drive, Huntley, IL 60142.

B. Notice of Related Matters

The '732 patent is related to several pending matters. Patent Owner is asserting the '732 patent and, *inter alia*, related U.S. Patent Nos. 8,845,731 ("the '731 patent"), 10,137,001 ("the '001 patent"), 10,925,752 ("the '752 patent"), and 10,973,649 ("'649 patent") against Petitioner in *Globus Medical, Inc. v. Life Spine, Inc*., 21-cv-1445 (D. Del.). Petitioner has filed or is concurrently filing petitions for *inter partes* review challenging each of the patents asserted in the litigation. *See* IPR2022-1434 ('731 Patent); IPR2022-01435 ('001 Patent); IPR2022-01600 ('649 Patent); IPR2022-01601 ('752 Patent); IPR2022-01602 ('087 Patent); and

IPR2022-01603 (’739 Patent). In addition, Petitioner has filed or is concurrently filing a separate petition for *inter partes* review challenging the same claims of the ’732 Patent in IPR2023-00041.

In addition, Petitioner is aware of the following related U.S. patent applications believed to have a common or overlapping claim of priority as the ’732 patent:

- 17/192,231;
- 17/409,079;
- 17/410,335; and
- 17/589,029.

III. LEAD AND BACKUP COUNSEL

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IV. SERVICE INFORMATION

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V. REQUIREMENTS FOR IPR UNDER 37 C.F.R. §42.104

A. Grounds for Standing

Petitioner certifies that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review of the challenged patent claims.

B. Identification of Challenge

Petitioner requests review and cancellation of Claims 1, 7-13, and 16 of the '732 patent for the reasons explained in this petition, summarized as follows:

Ground	Claims	Basis	References
I	1, 7-13, 16	§103	Chung with Boehm and/or Song
II	1, 7-13, 16	§103	Chung with Boehm and/or Song, and further with Baynham
III	8, 10-11, 13	§103	Chung with Boehm and/or Song, and further with Varela-'774 or with Varela-'774 and Baynham
IV	1, 7-13	§103	Olmos with Boehm and/or Song
V	1, 7-13	§103	Olmos with Boehm and/or Song, and further with Chung

VI	8, 10-11, 13	§103	Olmos with Boehm and/or Song, and further with Varela-'774 or with Varela-'774 and Chung

This Petition is supported by the Declaration of Prof. Troy Drewry (EX1002), explaining what the art would have conveyed to a person of ordinary skill in the art ("POSITA") as of the priority date of the '732 patent.

An IPR petition must demonstrate "a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition." (35 U.S.C. §314(a).) The Petition meets this threshold. All elements of Claims 1, 7-13 and 16 of the '732 patent are taught in the prior art as explained below.

VI. THE '732 PATENT

A. Overview of the '732 Patent

The '732 patent, titled "Expandable Fusion Device and Method Installation Thereof," claims priority to another application filed September 3, 2010, and is directed to "an expandable fusion device capable of being installed inside an intervertebral disc space to maintain normal disc spacing and restore spinal stability, thereby facilitating an intervertebral fusion." EX1001, Abstract. The claimed systems require a dilator, a cannula, and an implantable device that generally includes first and second endplates that move apart or together as two

ramps move together or apart, respectively. *Id*. However, as detailed below, devices/systems having the claimed features were well-known before the '732 patent.

B. Claim Construction

Petitioner does not believe any terms require constructions differing from their plain and ordinary meaning in this IPR. The parties' litigation claim construction disclosures to date are attached. EX1023-EX1025.

VII. LEVEL OF SKILL IN THE ART

The testimony evidence here confirms that a POSITA, as of the earliest possible filing date of September 3, 2010, would have had a bachelor's degree in mechanical engineering or biomedical engineering and two or more years of experience in biomechanical engineering, biomedical engineering, and/or spinal implant devices. A person could also have qualified as a POSITA with some combination of more formal education (*e.g.*, an M.D.) and less technical experience or less formal education and more technical or professional experience in the foregoing fields, and would have had further appreciation of various technical concepts in this field, as explained by Prof. Drewry. EX1002, ¶¶31-32.

VIII. PRIOR ART

A. Chung

Korean Reg. Utility Model No. KR20-0290058 to Chung ("Chung," EX1005[1]) was published on September 26, 2002 and is prior art under at least 35 U.S.C. §§102(a)-(b). Chung was not cited during prosecution leading to the '732 patent.

B. Olmos

U.S. Patent Application Publication No. US 2008/0140207 to Olmos *et al.* ("Olmos," EX1006) was first published on June 12, 2008 and is prior art under at least 35 U.S.C. §§102(a)-(b). While Olmos was discussed during prosecution, the grounds presented herein depend on key disclosures in Olmos that were not raised or appreciated by the Examiner.

Specifically, Olmos clearly discloses an embodiment wherein the actuator remains axially fixed in regards to the driving ramp. EX1006, ¶¶[0159]; *see infra*, §IX(D)(1)(j), (l). However, during prosecution, Applicant amended the claims to recite that "the driving ramp is fixed with respect to the actuation member," and argued that Olmos did not "teach or suggest this feature." EX1004, 000063-64.

[1]A certified translation of Chung has been provided per 37 C.F.R. §42.63(b).

Misdirected by Applicant's errant remarks, the Examiner overlooked Olmos' full teachings. *See infra*, §§IX(D)(1)(j)-(l); §X.

C. Boehm

U.S. Patent Application Publication No. US 2003/0176926 to Boehm et al. ("Boehm," EX1028) was first published on September 18, 2003 and is prior art under at least 35 U.S.C. §§102(a)-(b). Boehm was cited during prosecution as disclosing a system for intervertebral fusion comprising a dilator, a cannula, and an intervertebral implant sized for insertion through the cannula. EX1004, 000107-109. Applicant did not traverse the Examiner's reliance on Boehm for these teachings or its combination with Olmos.

D. Song

U.S. Patent Application Publication No. US 2009/0062833 to Song ("Song," EX1029) was first published on March 5, 2009 and is prior art under at least 35 U.S.C. §§102(a)-(b). Song was not cited during prosecution of the application leading to the '732 patent.

E. Varela-'774

U.S. Patent Application Publication No. US 2011/0172774 to Varela ("Varela-'774," EX1030) was first published on July 14, 2011. Varela-'774 claims priority to Provisional Application Nos. 61/293,997 (EX1033) and 61/296,932 (EX1034), filed January 11, 2010, and January 21, 2010, respectively, and is prior

art under at least 35 U.S.C. §§102(e). Varela-'774 was not cited during prosecution of the application leading to the '732 patent.

A patent reference is "entitled to claim the benefit of the filing date of its provisional application if the disclosure of the provisional application provides support for the claims…in compliance with 35 U.S.C. §112, ¶1." *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1381 (Fed. Cir. 2015). Here, all of the relevant disclosures are set out in the provisional applications and the disclosure of the provisional provides support for the claims pending when Varela-'774 was published.

For example, the following table demonstrates support in Provisional Application No. 61/296,932 ("the '932 provisional," EX1034) for Claim 1 of Varela-'774:

Varela-'774	**'932 Provisional**
1. An expandable intervertebral implant, comprising:	EX1034, Figs. 1-14. "[T]he present invention relates to an expandable, in-situ, intervertebral body fixation orthosis and/or fusion assembly." *Id.*, Abstract.
a superior member configured to engage a superior intervertebral body;	*Id.*, Fig. 1-14. "In an exemplary embodiment of the present invention, an expandable intervertebral body stabilization

Varela-'774	'932 Provisional
	assembly includes superior and inferior members with convex surfaces." *Id.*, 2.
an inferior member configured to engage an inferior intervertebral body; and	*Id.*
an expansion mechanism disposed between the superior member and the inferior member configured to selectively adjust a separation of the superior member and the inferior member.	*Id.*, Figs. 8, 11-13. "The present invention also includes a wedge shaped member (13) which can be disposed at the distal end of an expansion bolt. The wedge shaped member can be sized and configured to contact the plurality of angled, nested and staggered distal surfaces of both the superior and inferior members." *Id.*, 3. "As the bolt is turned the wedge shaped member is pulled proximally, thereby raising and lowering the superior and inferior members, respectively, of the assembly, and causing an overall increase in height; in other words, creating a vertical expansion of the device." *Id.*

Further, as relevant here, the '932 provisional application describes expandable intervertebral body stabilization devices having a small profile due to the superior and inferior members or endplates being "nested together" through the use of staggered, overlapping ramped portions. See EX1034, 2, Figs. 3-5. Thus, Varela-'774 qualifies as prior art under 35 U.S.C. §102(e).

F. Baynham

U.S. Patent Application Publication No. US 2007/0270968 to Baynham et al. ("Baynham," EX1007) was first published on November 22, 2007 and is prior art under at least 35 U.S.C. §§102(a)-(b). Baynham was listed in an Information Disclosure Statement submitted on June 19, 2014, but was not cited or discussed by the Examiner.

IX. CLAIM-BY-CLAIM EXPLANATION OF GROUNDS FOR UNPATENTABILITY

A. Ground 1: Claims 1, 7-13, and 16 are obvious over Chung in view of Boehm and/or Song

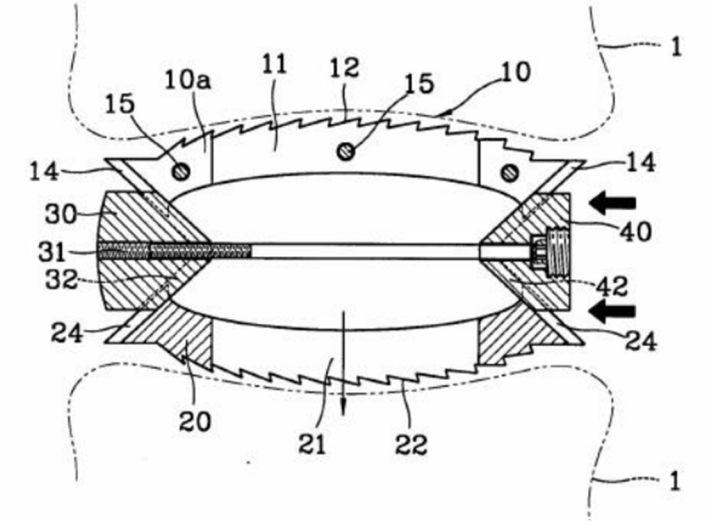
Claims 1, 7-13, and 16 are obvious under 35 U.S.C. §103 over Chung in view of Boehm and/or Song as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶99-274).

1. Claim 1

(a) Claim 1[a] "system for intervertebral fusion"

Chung discloses "a medical device for correcting the back" in the form of "a lumbar holder that is inserted between the back bones in order to fix the back bones robustly" (EX1005, 3-4), as depicted in Fig. 4:

Chung, Fig. 4



Chung further discloses using additional tools, e.g., a "wrapper (3)" and a "wrench (2)," to insert and configure the device during the bone fixation (i.e., "fusion") procedure. *Id.*, 6-7; *see also id*. at 3 (noting that Chung's device "facilitates bonding of body parts").

Accordingly, Chung discloses a system for intervertebral fusion. EX1002, ¶¶99-101.

(b) Claim 1[b] "a dilator having a proximal end and a tapered distal end for penetrating soft tissue"

Chung does not expressly mention a dilator, but it would have been obvious to use a dilator to create an access path to the intervertebral space for insertion of Chung's device, as taught by Boehm and/or Song.

Boehm discloses a device and method for performing percutaneous interbody spinal fusion. EX1028, Abstract, ¶[0002]. Specifically, Boehm teaches a "dilator system 60," comprised of an initial dilator in the form of "guide needle 68" over which "a series of dilators 70 are inserted…to enlarge the disc space." *Id.*, ¶¶[0032]; *see also id.*, ¶[0036], Fig. 5. As seen below, the initial dilator/guide needle 68 has a proximal end and a rounded (i.e., "tapered") distal end for penetrating soft tissue:

Boehm, Fig. 5

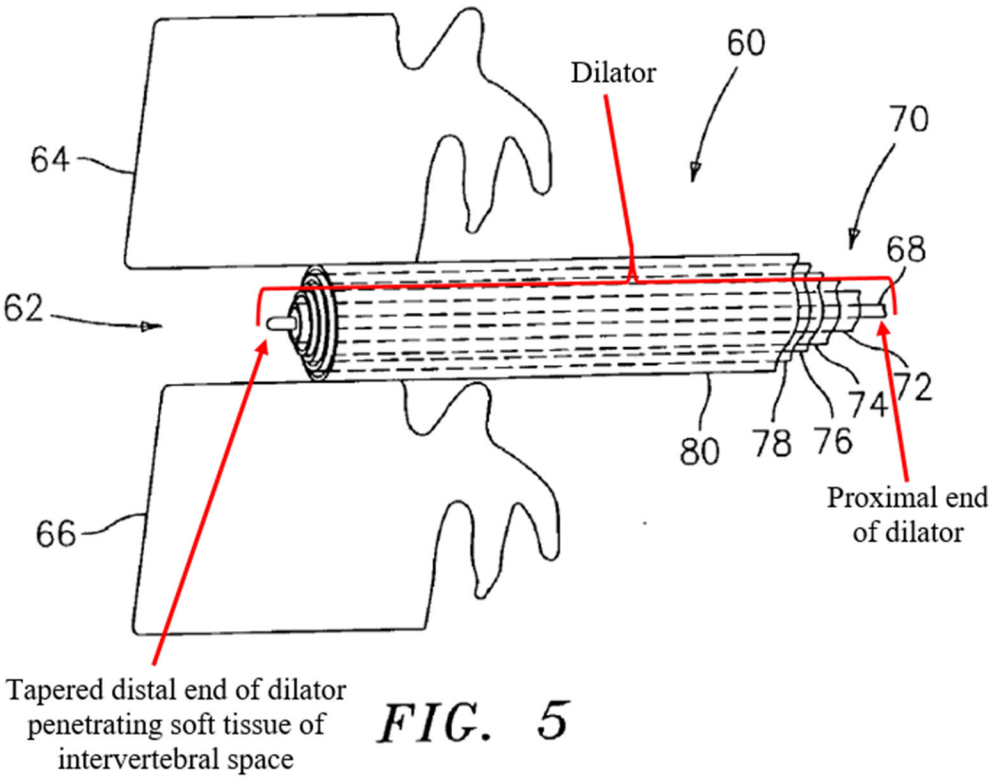


FIG. 5

Accordingly, this limitation is disclosed by Boehm, which the Examiner likewise found. EX1002, ¶¶102-107; EX1004, 000082-83 (finding "Boehm discloses…a dilator (#68) having a proximal end and a tapered distal end for penetrating soft tissue (see Fig below where the distal end is tapered to a rounded end)" without traverse). The series of dilator tubes of increasing diameter also create a tapered end. EX1002, ¶108.

This element is alternatively disclosed by Song, which teaches a method of placing an interbody device percutaneously into the space between vertebrae. EX1029, Abstract, ¶[0009]. Specifically, Song discloses "an initial dilator, which is tapered at the leading edge to facilitate entry into the disc space and to push delicate nerves aside." *Id.*, ¶¶[0021], [0050] ("The initial dilator has a tapered tip (201) to ease passage into the disc space and other soft tissue."). This is seen in Song Figs. 2A-C, with annotated Fig. 2C below.

Song, Fig. 2C

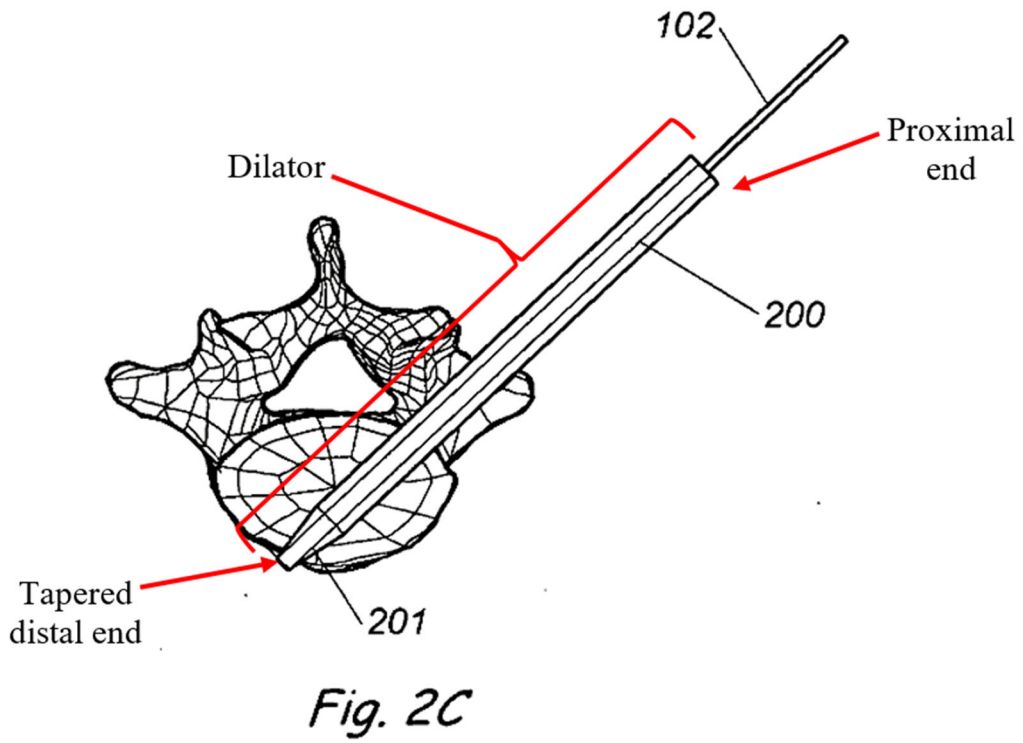


Fig. 2C

Accordingly, this limitation is also disclosed by Song. EX1002, ¶¶102-103, 109-112.

(c) Claim 1[c] "a cannula having a proximal end and a distal end"

Chung does not expressly mention a cannula, but it would have been obvious to incorporate a cannula with Chung, as taught by Boehm and/or Song.

Boehm discloses a cannula ("outermost dilator 80") through which an expandable implant may be inserted into the disc space. EX1028, ¶¶[0033], [0036], Figs. 5, 8. As seen below, the cannula has a proximal end and a distal end:

Boehm, Fig. 5

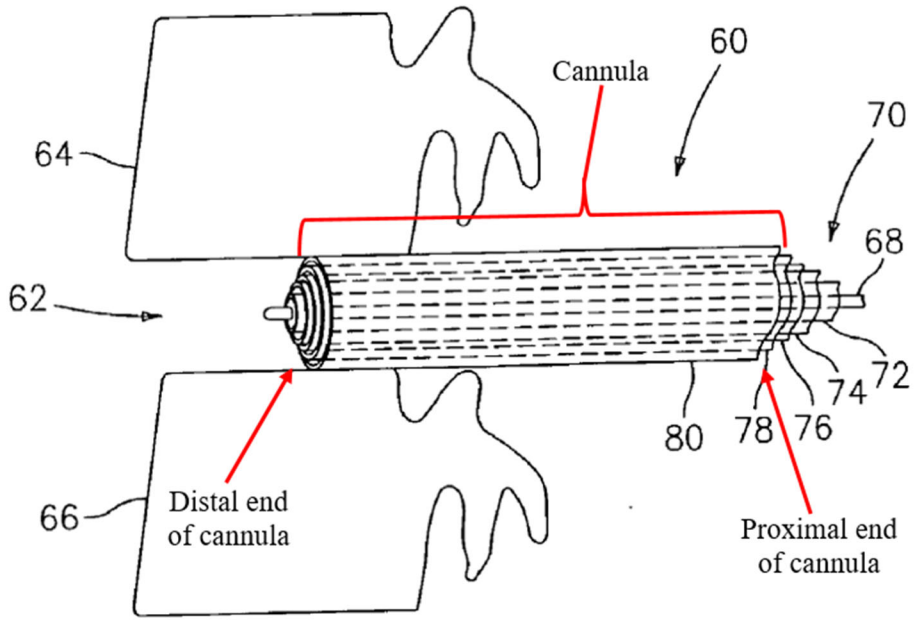


FIG. 5

Boehm, Fig. 8

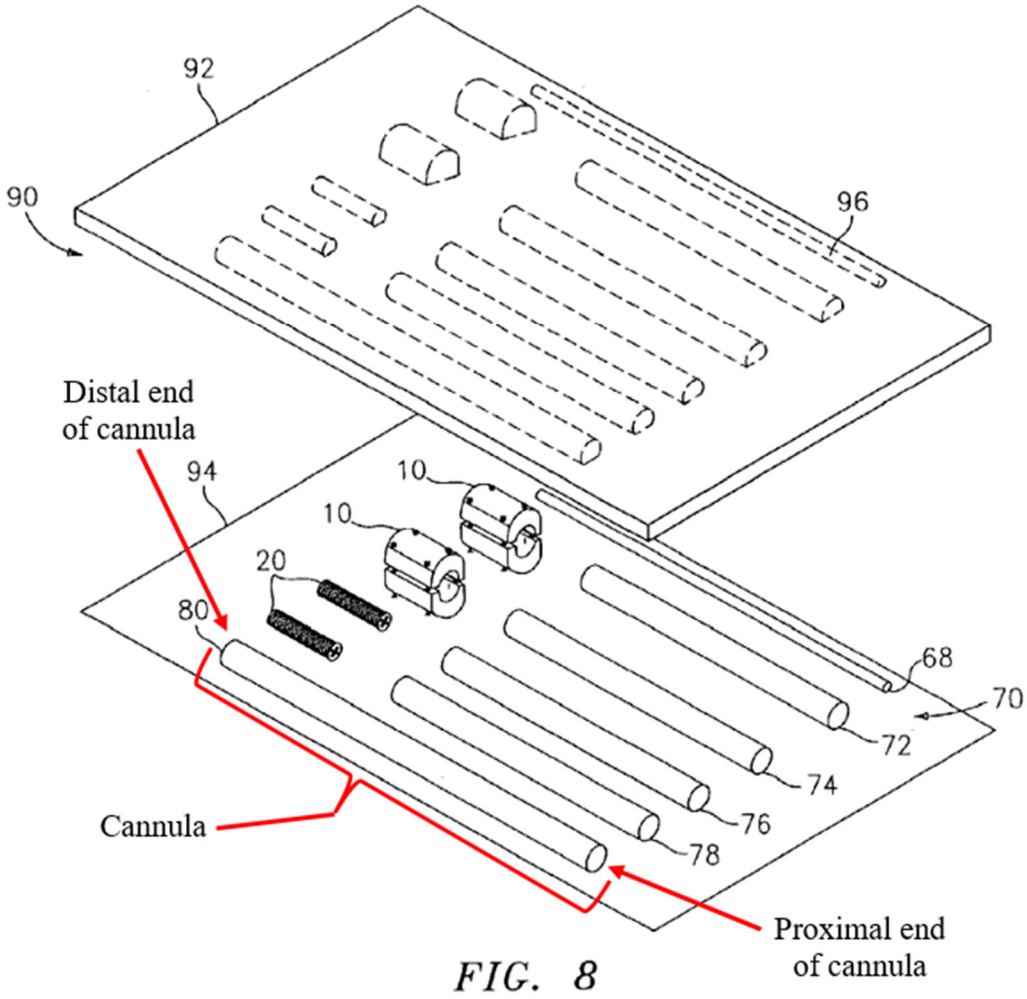
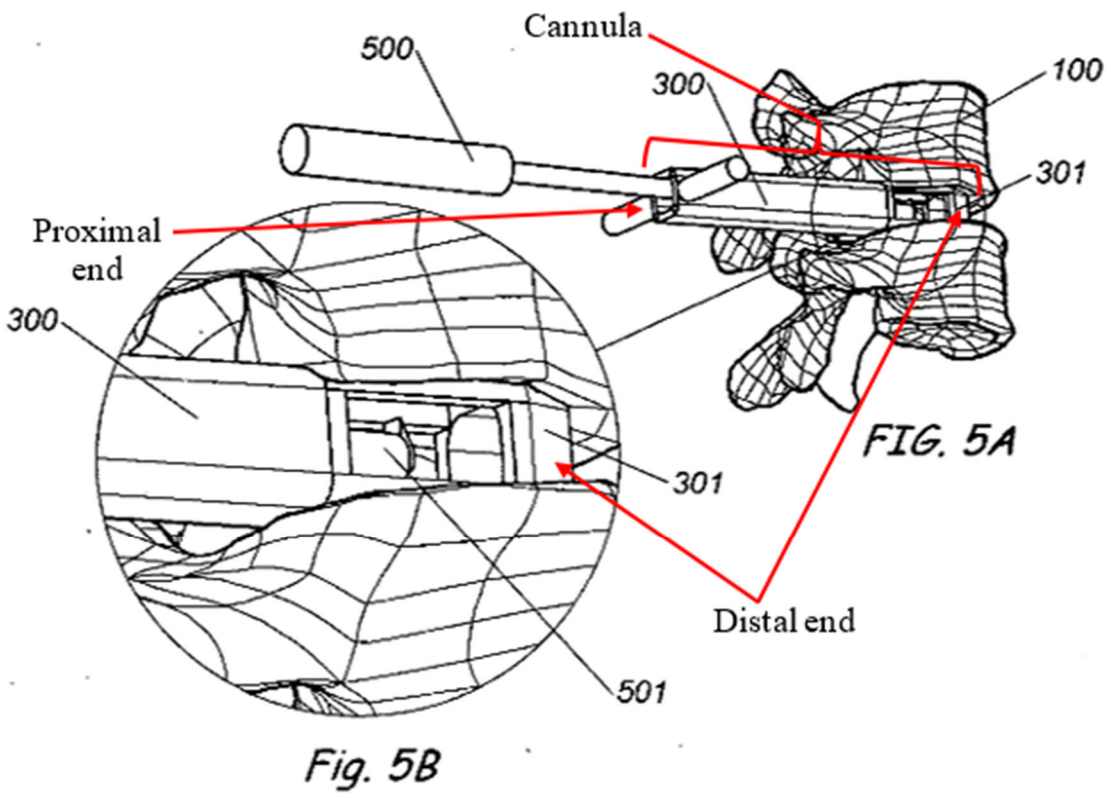


FIG. 8

Accordingly, this limitation is disclosed by Boehm. EX1002, ¶¶113-118; *see also* EX1004, 000082-83 (finding Boehm discloses Claim 1[c] without traverse).

This feature is also disclosed by Song, which discloses a cannula ("working tube"). EX1029, ¶¶[0022]-[0025]; *see also id.,* Figs. 5A-D. As seen below, the working tube has proximal and distal ends.

Song, Fig. 5B



Accordingly, this limitation is disclosed by Chung with Song. EX1002, ¶¶113-114, 119-121.

(d) Claim 1[d] "an intervertebral implant sized for insertion into an intervertebral space through the cannula"

It would have been obvious to size Chung's implant for insertion into an intervertebral space through the cannulas as taught by Boehm and/or Song.

Boehm discloses an expandable intervertebral implant ("spacer 10") sized for insertion into an intervertebral pace through the cannula ("outermost dilator

80") through which an expandable implant may be inserted into the disc space. EX1028, ¶¶[0033], [0036]. This is shown below:

Boehm, Fig. 6

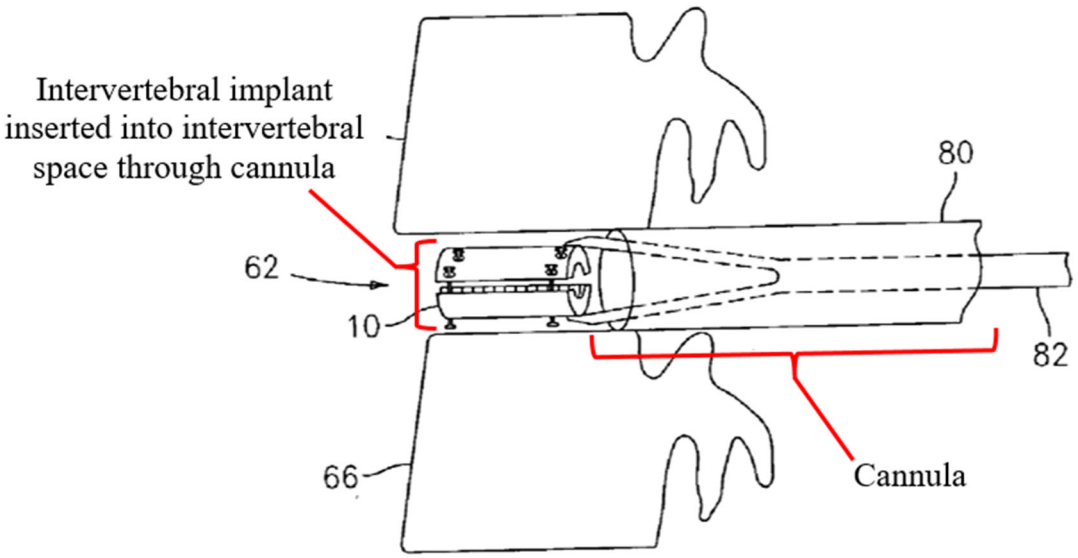


FIG. 6

Accordingly, this limitation is disclosed by the combination of Chung and Boehm. EX1002, ¶¶122-127; *see also* EX1004, 000082-83 (finding Boehm discloses Claim 1[d] without traverse).

This feature is also disclosed by Song, which teaches that "a fixed-size implant can be placed through the working tube and into the disc space." EX1029, ¶¶[0022]-[0025]. Song Figs. 6A-B show an embodiment in which "the final implant (600) is a separate device which is placed through the working tube."

Song, Fig. 6A

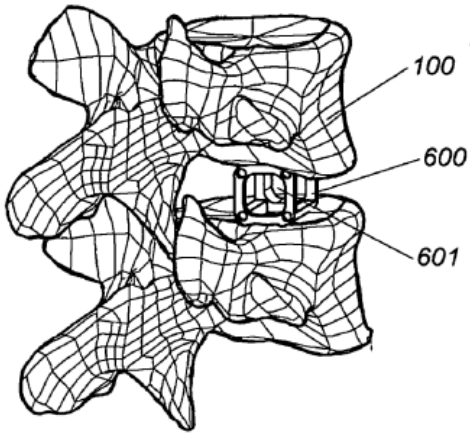


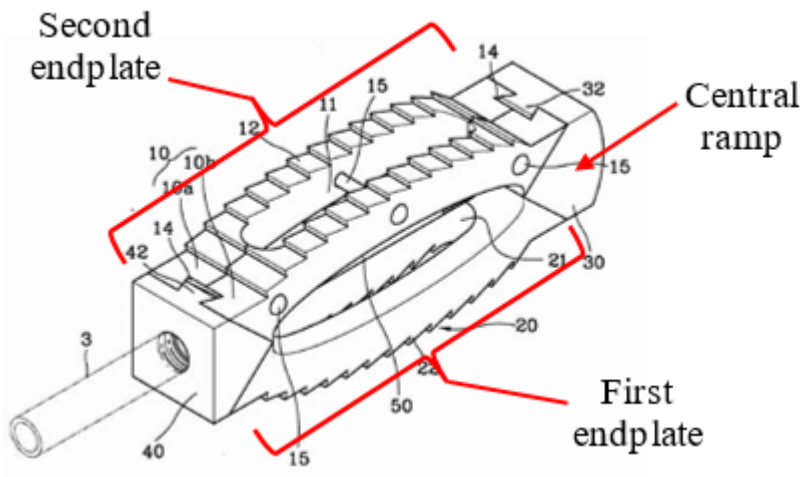
Fig. 6A

Accordingly, this limitation is disclosed by the combination of Chung and Song. EX1002, ¶¶122-123, 128-130.

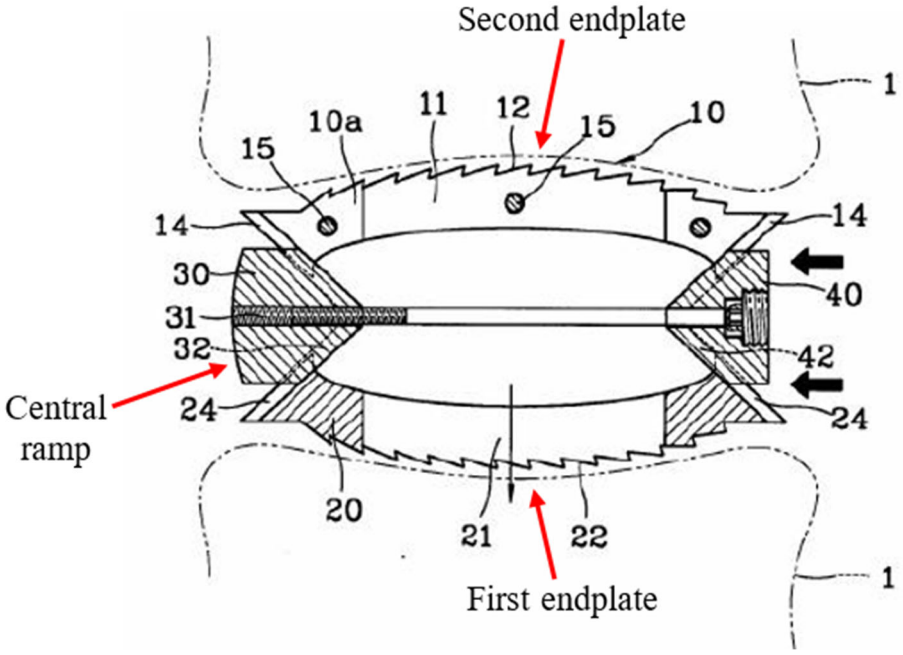
(e) Claim 1[e] "the intervertebral implant comprises a first endplate, a second endplate, and a central ramp disposed between the first endplate and the second endplate"

Chung discloses first and second endplates (holder bodies (20) and (10)), and a central ramp ("lead wedge (30)") disposed between the endplates. Chung teaches that "the lead wedge (30) and the opposing wedge (40)…are slid between both ends of the…holder bodies (10)(20)." EX1005, 4-5. These features are seen below:

Chung, Fig. 1



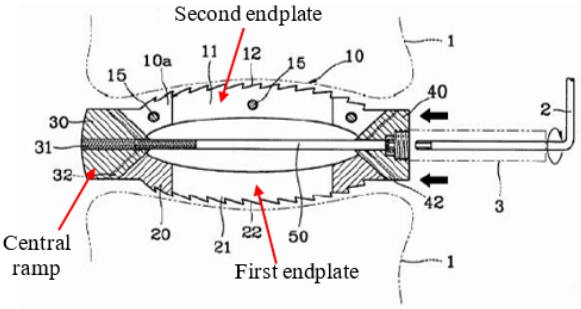
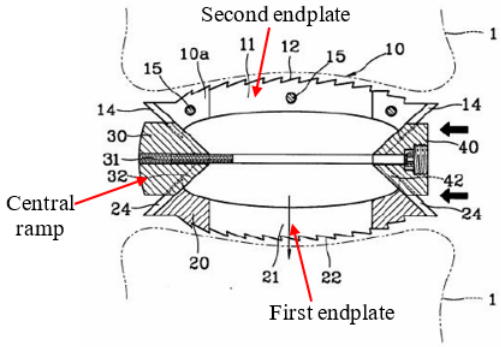
Chung, Fig. 4



Accordingly, Chung discloses this limitation. EX1002, ¶¶131-134.

(f) Claim 1[f] "the central ramp is configured to move in a first direction and cause the first and second endplates to move outwardly and away from one another"

Chung discloses that the central ramp/lead wedge (30) moves toward opposing wedge (40) to cause the first and second endplates/holder bodies (10) and (20) to move away from one another. EX1005, 4 (describing Chung's device as configured to "adjust the distance between the aforementioned opposing wedge and the lead wedge in order to adjust the distance between the aforementioned holder bodies"). Figure 4 shows that as the wedges slide towards each other along the endplates' guiding surfaces, they push the endplates apart. *Id.*, 6. Annotated Figs. 3-4 illustrate this:

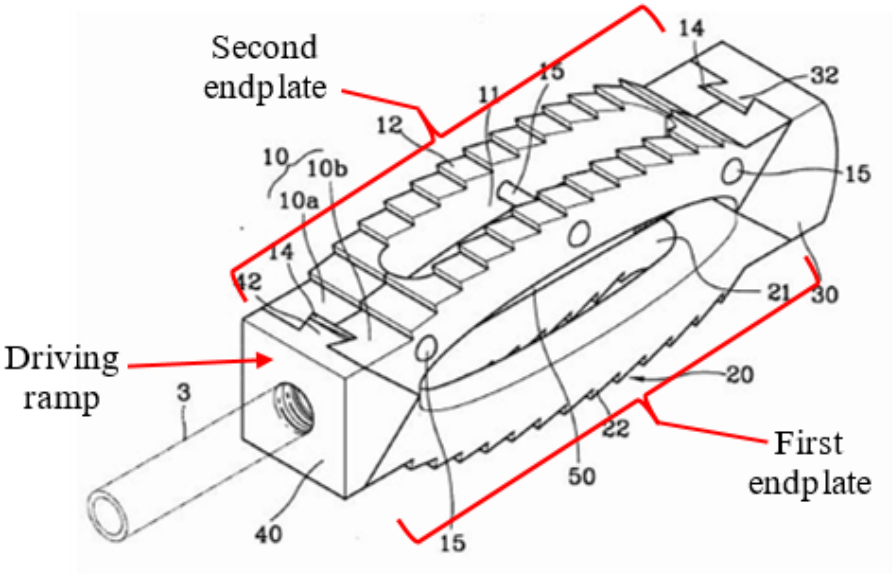
Chung, Fig. 3	Chung, Fig. 4
	

Accordingly, Chung discloses this limitation. EX1002, ¶¶135-137.

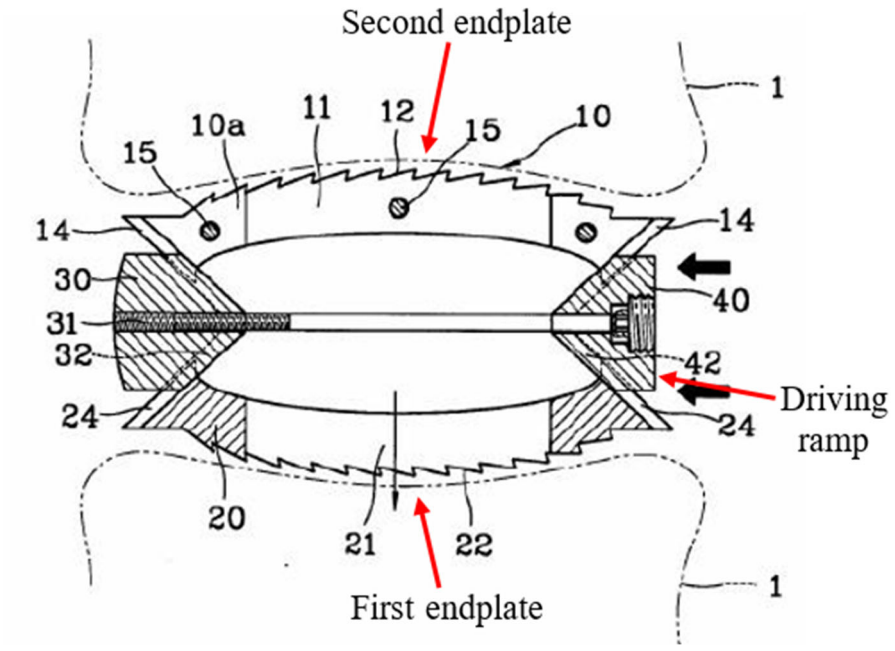
(g) Claim 1[g] "a driving ramp disposed between the first endplate and the second endplate at an opposite end of the intervertebral implant from the central ramp"

Chung discloses a driving ramp as "opposing wedge [(40)]." EX1005, 4. In cooperation with the central ramp, Chung's "opposing wedge (40)" slides between and separates main holder bodies (10) (20). *Id.*, 5. Annotated Figs. 1 and 4 follow.

Chung, Fig. 1



Chung, Fig. 4

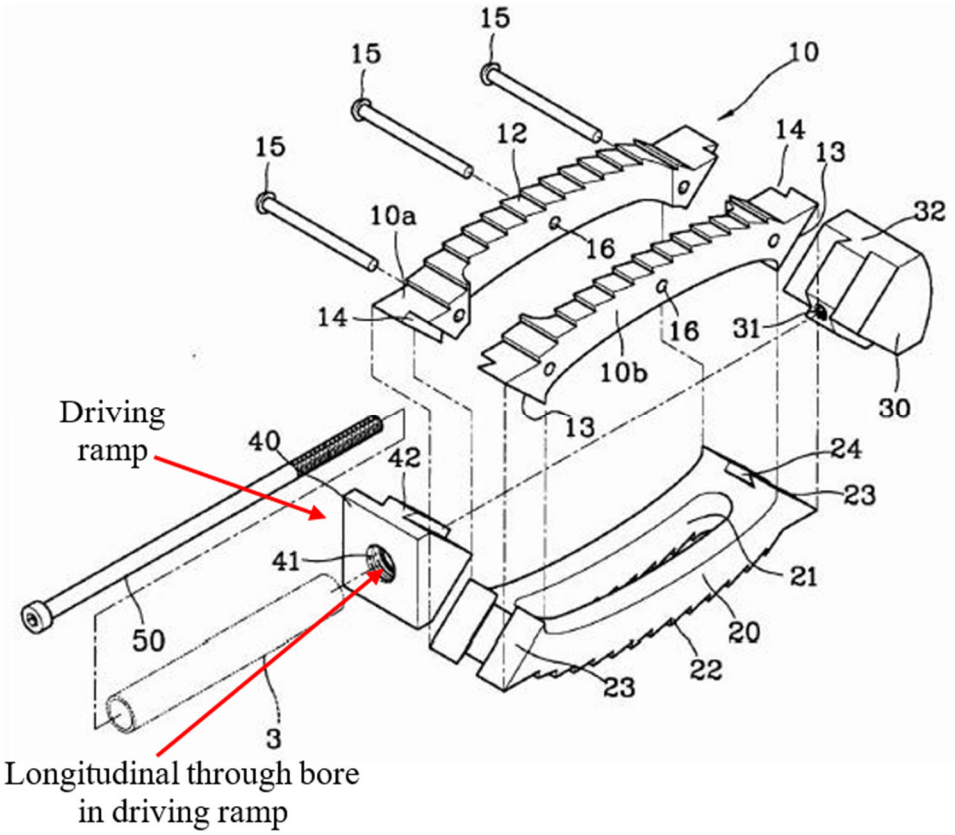


Accordingly, Chung discloses this limitation. EX1002, ¶¶138-142.

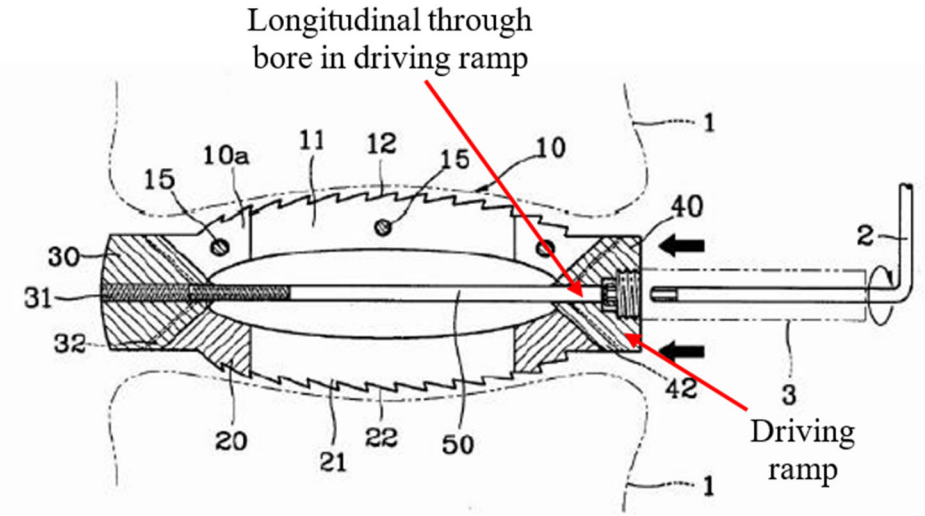
(h) Claim 1[h] "the driving ramp has a longitudinal through bore"

Chung's driving ramp has penetrating hole (41) that receives the actuation member's connecting portion (EX1005, 6, Figs. 1-4), as seen below:

Chung, Fig. 2



Chung, Fig. 3

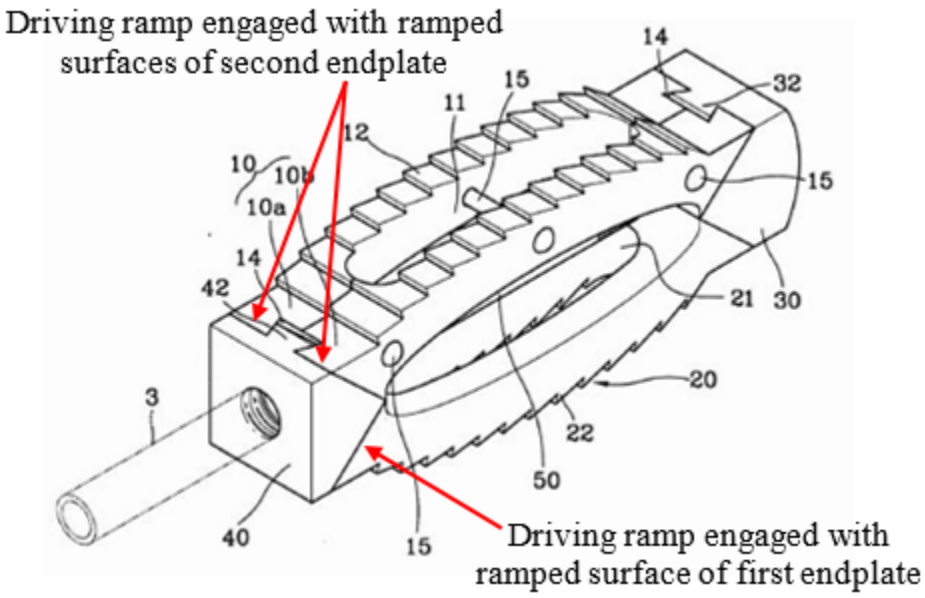


Accordingly, Chung discloses this limitation. EX1002, ¶¶143-144.

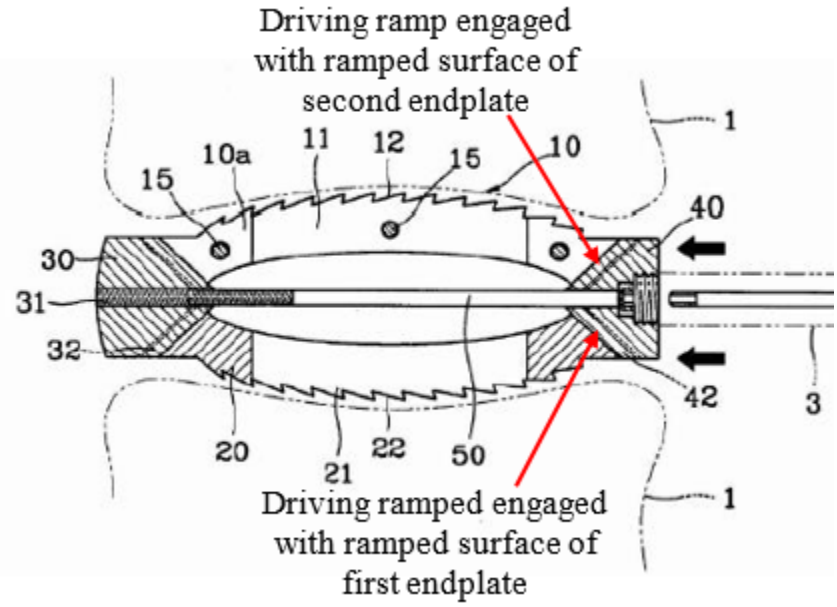
(i) Claim 1[i] "wherein the driving ramp is configured to engage ramped surfaces of the first endplate and ramped surfaces of the second endplate"

Chung's driving ramp is configured to engage with ramped surfaces of the first and second endplates through its "dovetails…(42)" and the adjacent surfaces of the driving ramp, which are held in contact with the ramped surfaces of the endplates. EX1005, 5, Figs. 1-4. Annotated Figs. 1 and 3 show this:

Chung, Fig. 1



Chung, Fig. 3



Accordingly, Chung discloses these limitations. EX1002, ¶¶145-146.

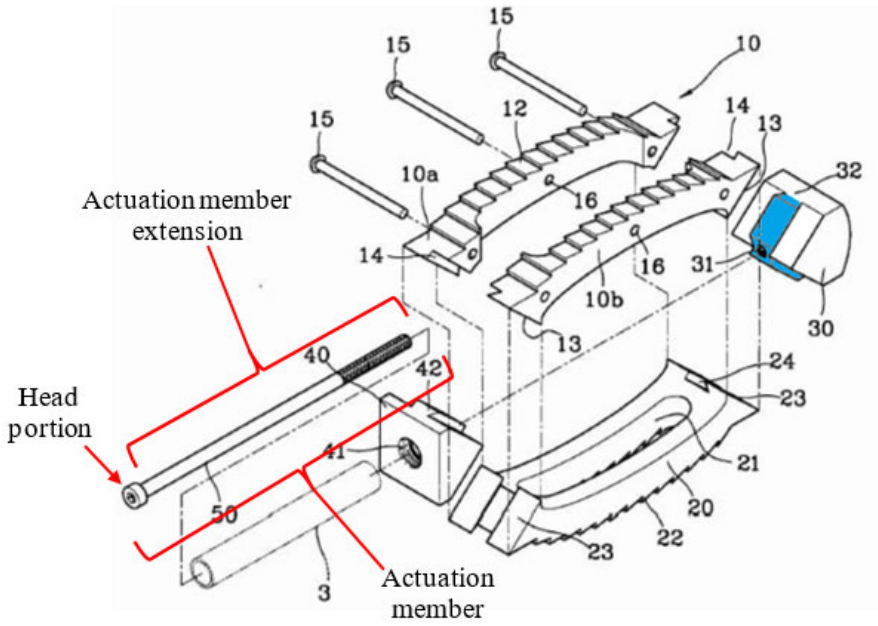
(j) Claim 1[j] "an actuation member comprising a head portion and an actuation member extension that extends through an unthreaded opening in a longitudinal through bore of the driving ramp to be received within an opening in the central ramp extension"

Claim 1 does not recite "a central ramp extension," thus rendering Claim 1 indefinite for lack of antecedent basis. However, assuming *arguendo* that this term refers to Claim 12's "central ramp extension," this element is disclosed by Chung. *See* §IX(A)(4)(a), *infra*; EX1002, ¶147.

Chung discloses an actuation member ("groove fastening screw (50)") comprising a head portion and an actuation member extension. *See* EX1005, 6,

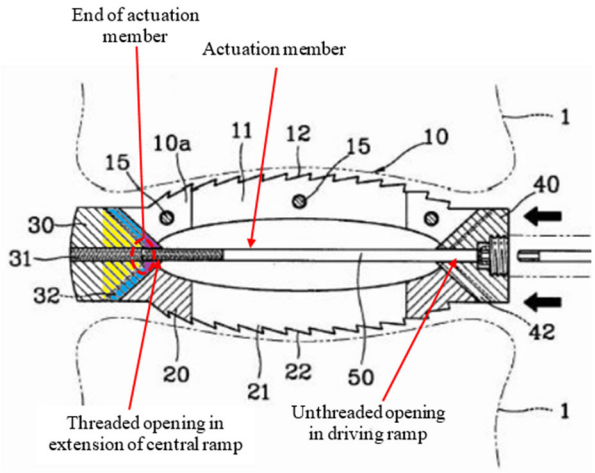
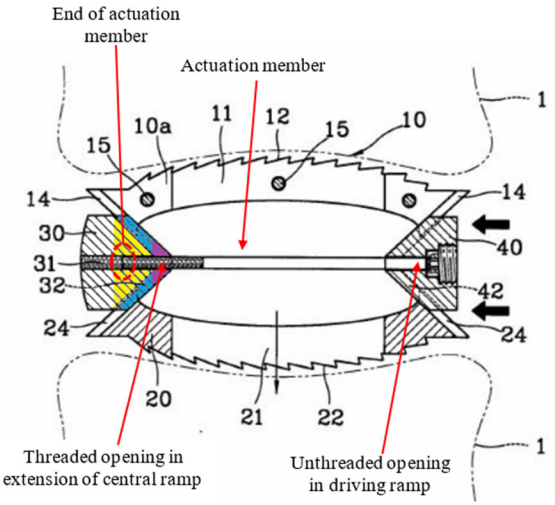
Fig. 2. Chung's central ramp has a screw hole (31) for accepting the fastening screw, while Chung's driving ramp has an unthreaded penetrating hole (41) for the fastening screw. EX1005, 6. Fastening screw (50) extends through the driving ramp's unthreaded opening (via penetrating hole (41)) and engages the threads in the central ramp's screw hole (31).

Chung, Fig. 2



As Prof. Drewry explains (EX1002, ¶148), Figures 3-4 show that central ramp opening (31) is threaded while driving ramp opening (41) is unthreaded. Figure 4 shows the actuation member rotating to engage the threads in the central ramp's opening, as evidenced by the actuation member's further extension into the opening as compared to its position in Fig. 3. Yet the actuation member's position

remains unchanged relative to the driving ramp, indicating the driving ramp's opening (41) is unthreaded. Furthermore, the shading of central ramp's opening (31) adjacent to the actuation member indicates threading, which is absent in the driving ramp's opening (41).

Chung, Fig. 3	**Chung, Fig. 4**
	

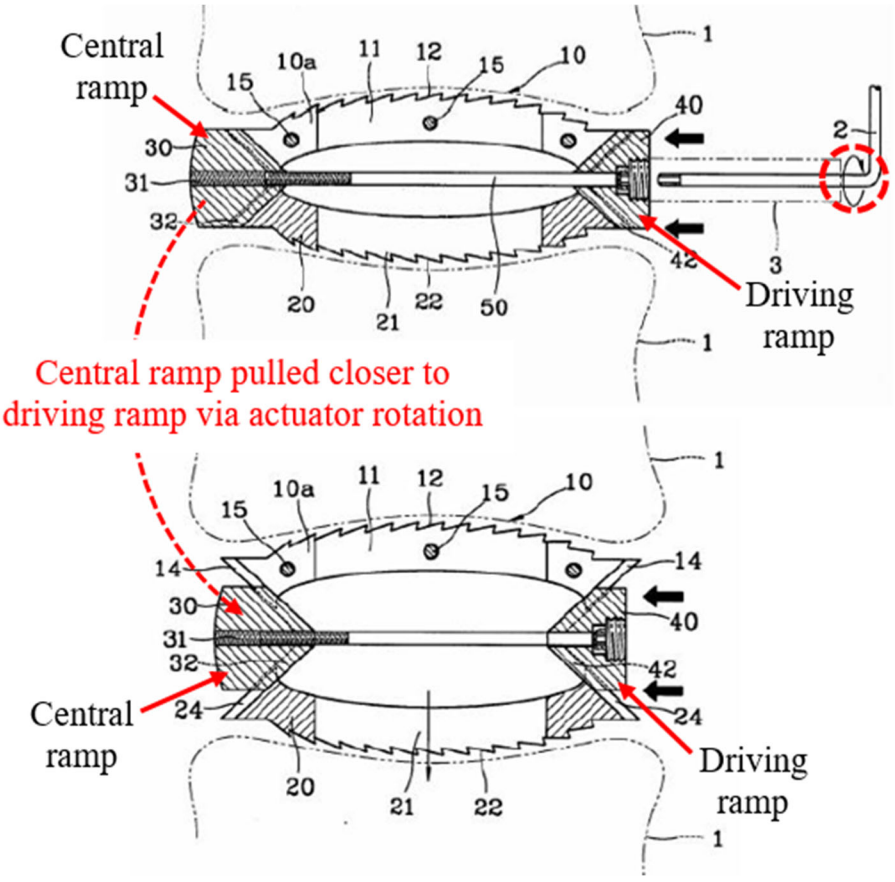
Accordingly, Chung discloses these limitations. EX1002, ¶¶147-157.

(k) Claim 1[k] "rotational movement of the actuation member in the first direction pulls the central ramp towards the driving ramp"

Chung's device is configured to pull the central ramp towards the driving ramp in response to rotating the actuation member. EX1005, 4 (disclosing the device is configured to "adjust the distance between the aforementioned opposing wedge and the lead wedge in order to adjust the distance between the aforementioned holder bodies"). Figures 3-4 illustrate that, in response to rotating

the fastening screw (indicated by the circular arrow circled in red below), the central ramp is pulled toward the driving ramp. *Id*., 6, Figs. 3-4.

Chung, Figs. 3-4



Accordingly, Chung discloses this limitation. EX1002, ¶¶158-160.

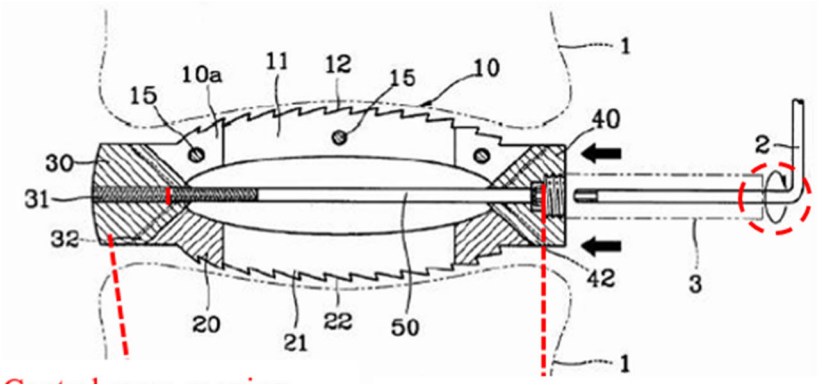
(l) Claim 1[l] "when the actuation member is rotated, the driving ramp is fixed with respect to the actuation member and the central ramp is moved in either the first direction or a second direction"

As Chung's screw is rotated, the two wedges/ramps move either together or apart (thereby adjusting the endplates' separation). EX1005, 6. The circular arrow

in Fig. 3 shows that threaded "groove fastening screw (50)" was designed to be rotated. EX1002, ¶161.

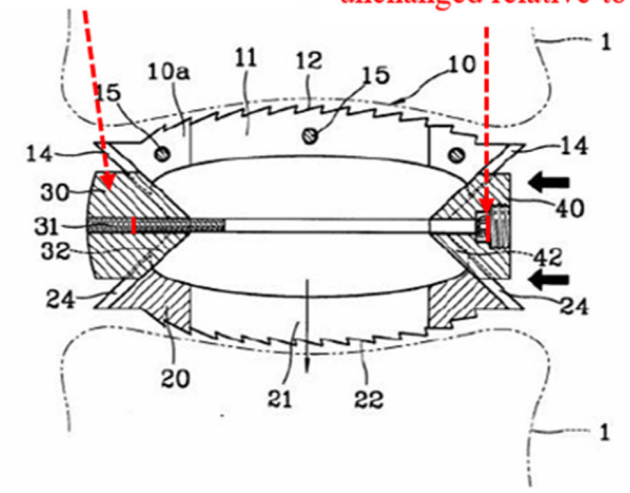
As seen below, the driving ramp is fixed relative to the fastening screw, while the central ramp moves backward or forward (i.e., a first or second direction) relative to the actuation member depending on the direction of rotation. *Id*.

Chung, Fig. 3-4



Central ramp moving relative to actuation member

Actuation member location unchanged relative to driving ramp



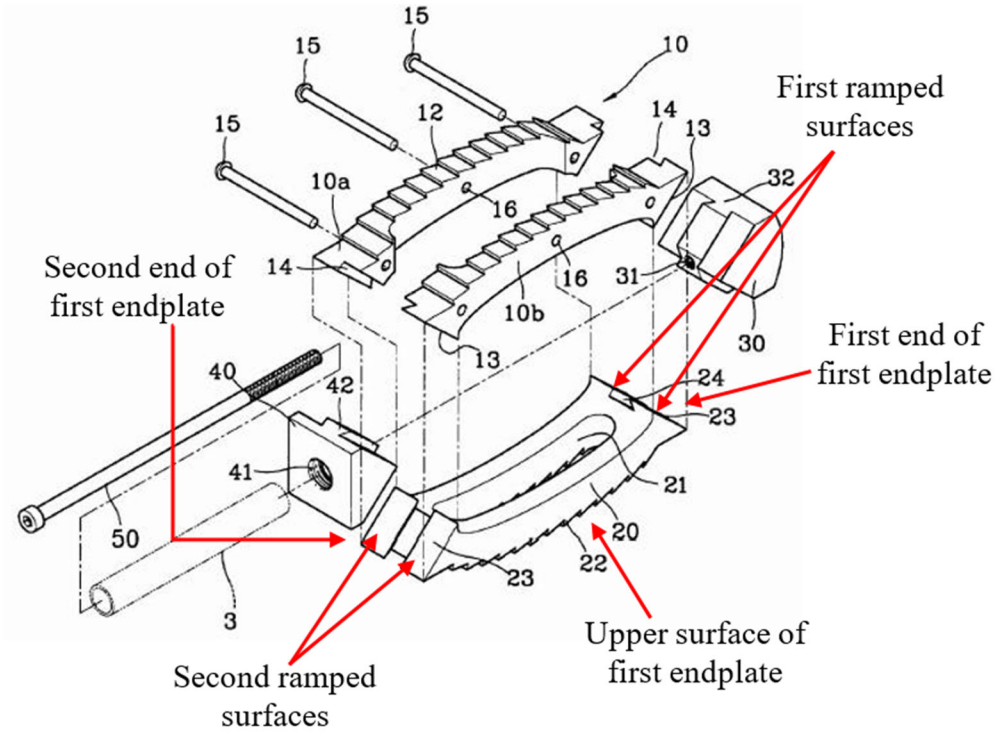
Accordingly, Chung discloses this limitation. EX1002, ¶¶161-164.

2. Claim 7

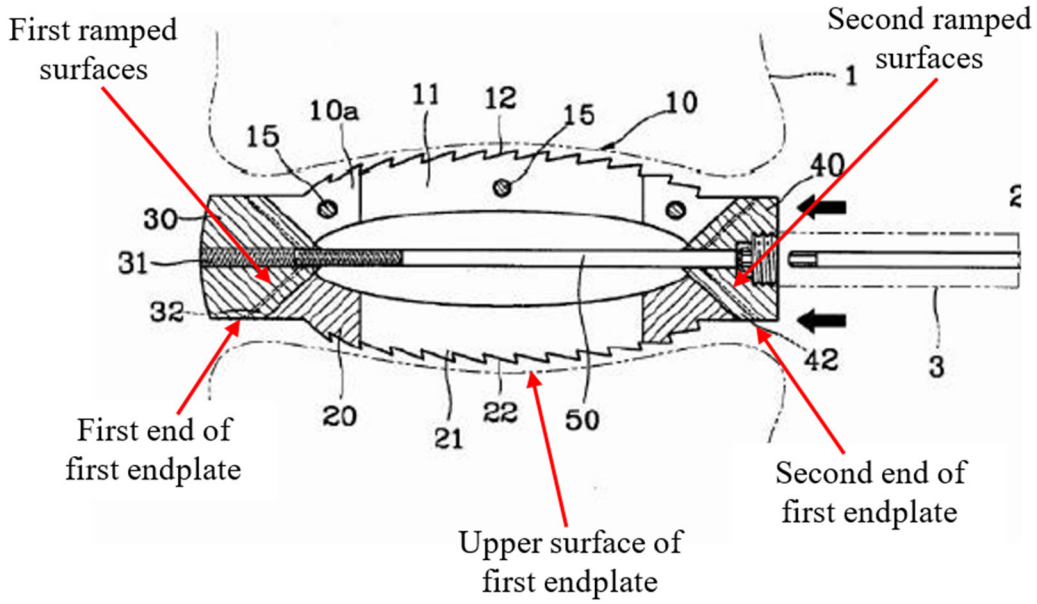
(a) Claim 7[a] "first endplate comprises a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the first endplate proximate the first end, second ramped surfaces on either side of the first endplate proximate the second end"

Chung discloses a first endplate having a first end and second end. *See* EX1005, 5 (referring to "both ends" of main holder body (20)). Chung further discloses an upper surface connecting the first and second ends, with first ramped surfaces on either side of the first endplate proximate the first end, and second ramped surfaces on either side of the first endplate proximate the second end ("sloped guiding surfaces[]…(23)"). EX1005, 5, Figs 2-3. Annotated Figs. 2-3 follow for reference:

Chung, Fig. 2

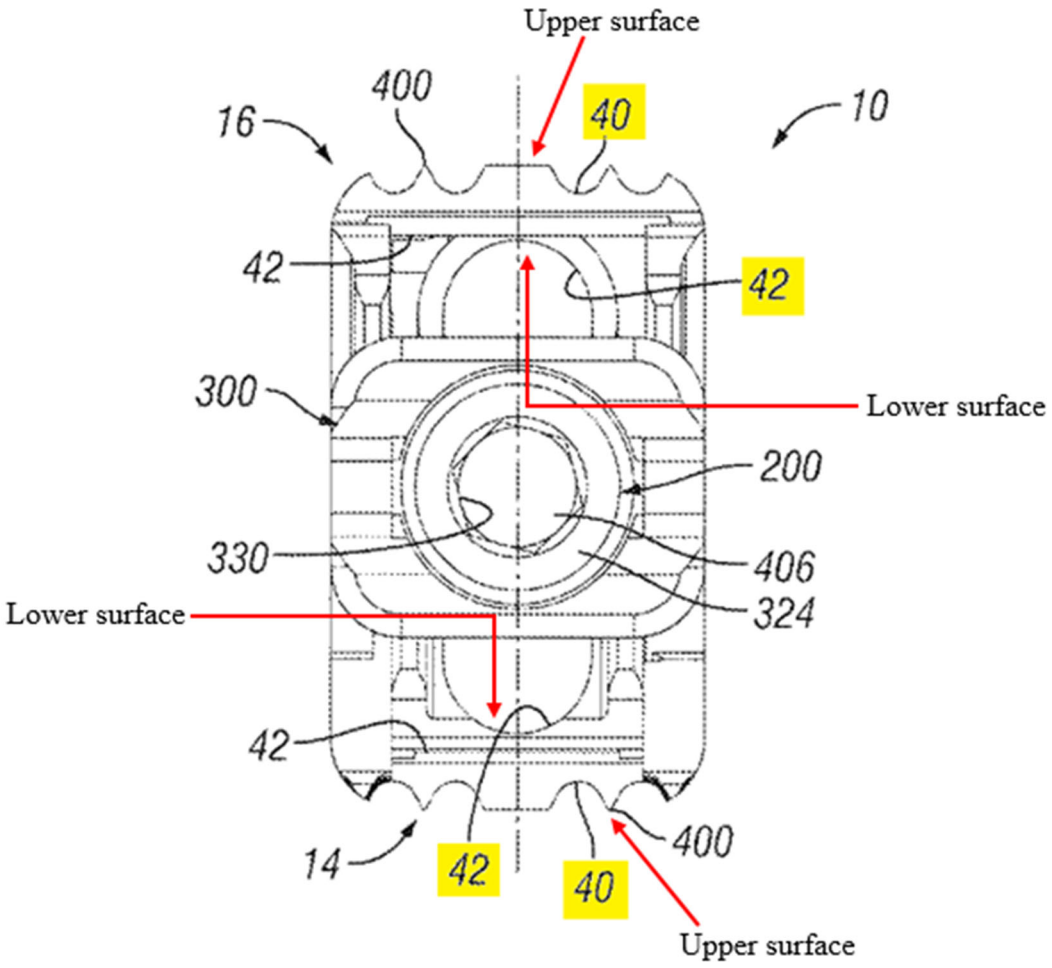


Chung, Fig. 3



This interpretation of Chung is consistent with the '732 Patent's disclosure of the "upper" surface in both endplates as element 40, while the "lower" surface is element 42. EX1001, 17:33-48. As seen in '732 patent Fig. 54, these structures are mirrored between the two endplates such that the "upper surface" of one endplate is downward-facing, with the "lower surface" upward-facing.

'732 Patent, Fig. 54

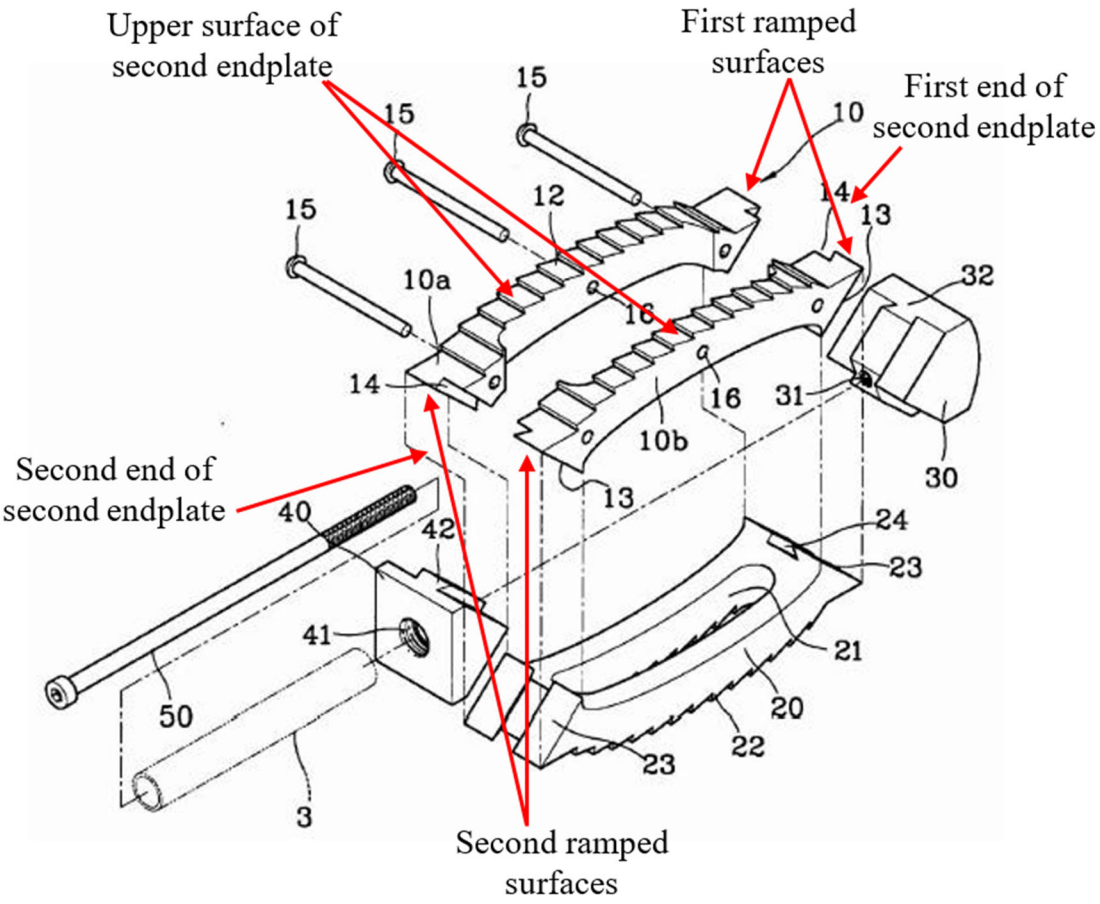


Accordingly, Chung discloses this limitation. EX1002, ¶¶165-169.

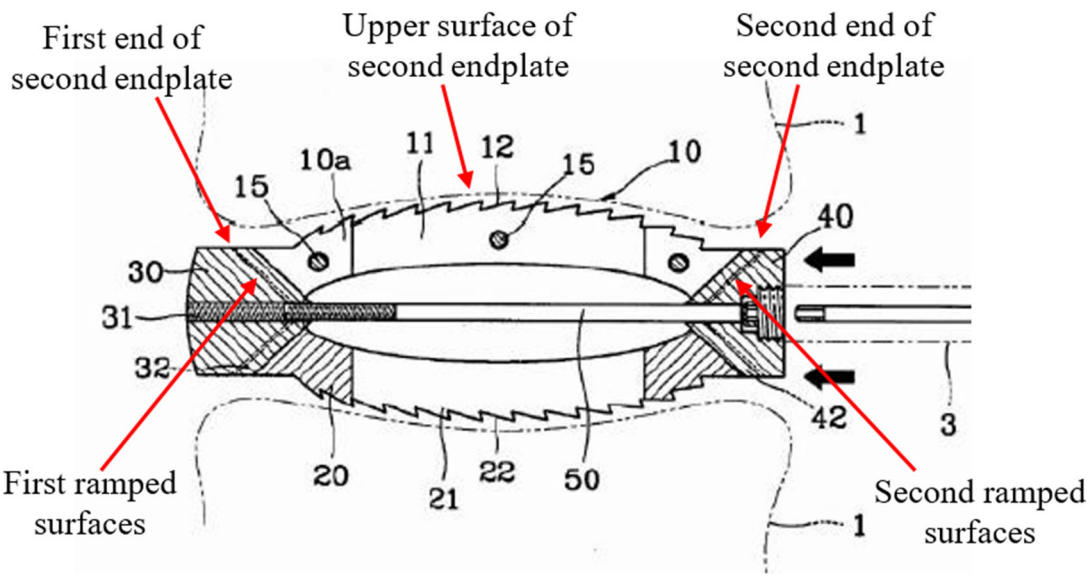
(b) Claim 7[b] "second endplate comprises a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the second endplate proximate the first end, second ramped surfaces on either side of the second endplate proximate the second end"

Chung discloses a second endplate having first and second ends. *See* EX1005, 5 (referring to "both ends" of main holder body (10)). The second endplate is formed by combining a pair of divided main holder bodies (10a) (10b) by inserting fasteners (15) through fastening holes (16) in each divided main holder body, thus constructing the second endplate from two separate halves. *Id.*, 5, Fig. 2; EX1002, ¶170. Chung further discloses first ramped surfaces on either side of the second endplate proximate the first end, second ramped surfaces on either side of the second endplate proximate the second ("sloped guiding surfaces (13)"). EX1005, 5, Figs 2-3. Annotated Figs. 2-3 follow for reference:

Chung, Fig. 2


Upper surface of second endplate
First ramped surfaces
First end of second endplate
Second end of second endplate
Second ramped surfaces
15
10
12
14
13
32
10a
16
31
30
10b
40
42
24
23
41
21
50
20
22
3

Chung, Fig. 3



Accordingly, Chung discloses these limitations. EX1002, ¶¶170-172.

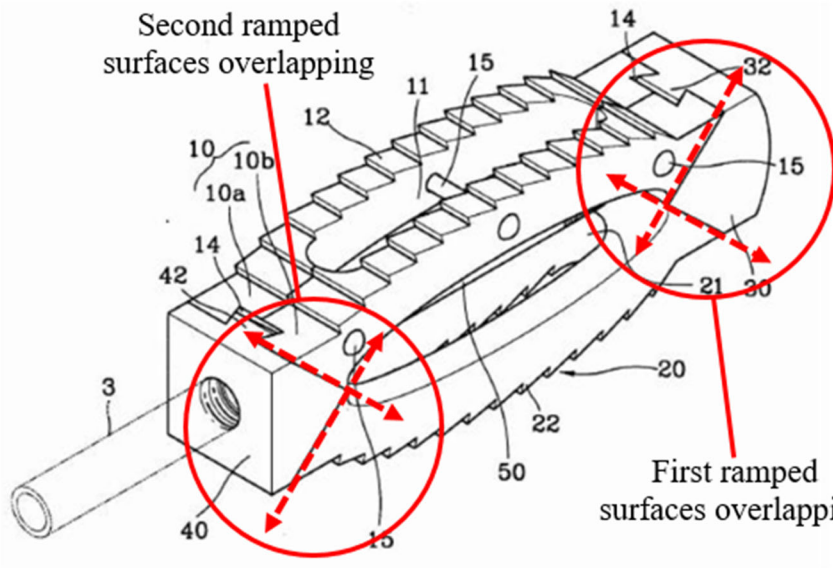
3. Claim 8 "when the intervertebral implant is in an unexpanded configuration, the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate overlap, and the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate overlap"

As broadly claimed here, Chung discloses that, when Chung's device is in an unexpanded configuration, the first endplate's first ramped surfaces overlap the second endplate's first ramped surfaces, and that the first endplate's second ramped surfaces overlap the second endplate's second ramped surfaces. EX1005, Figs. 1, 3.

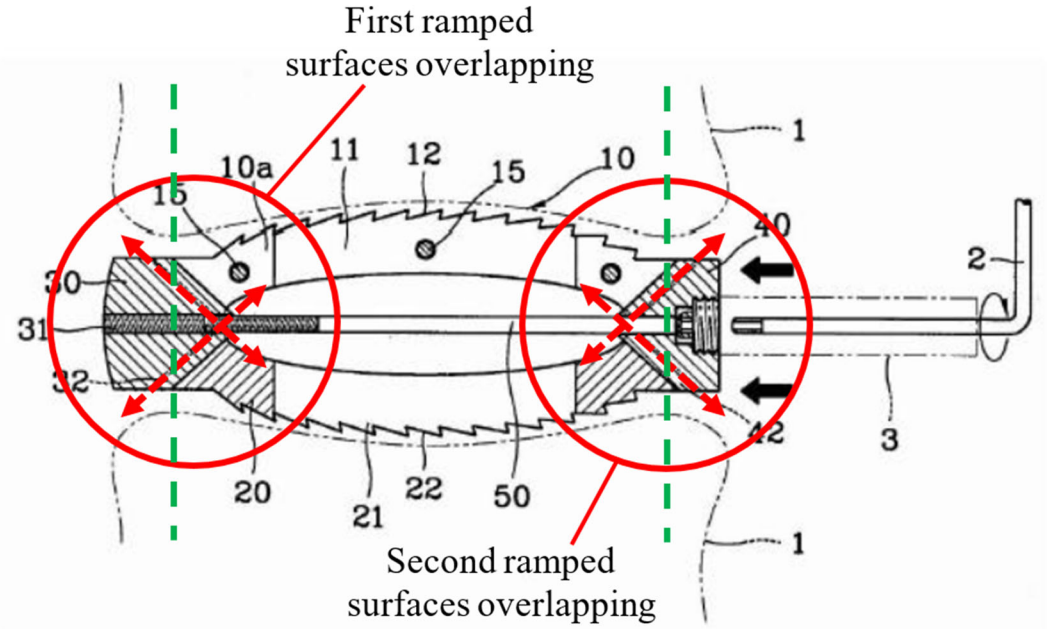
The overlap between these ramped surfaces can be observed in at least two ways. First, the ramped surfaces overlap because the angles of the ramped surfaces

intersect. Second, the ramped surfaces overlap because the ramped surfaces reside vertically opposite each other (i.e., one over the other). Annotated Figs. 1 and 3 show the overlapping ramped surfaces denoted by red dashed arrows and (as to Fig. 3) the vertical overlap denoted by green dashed lines.

Chung, Fig. 1

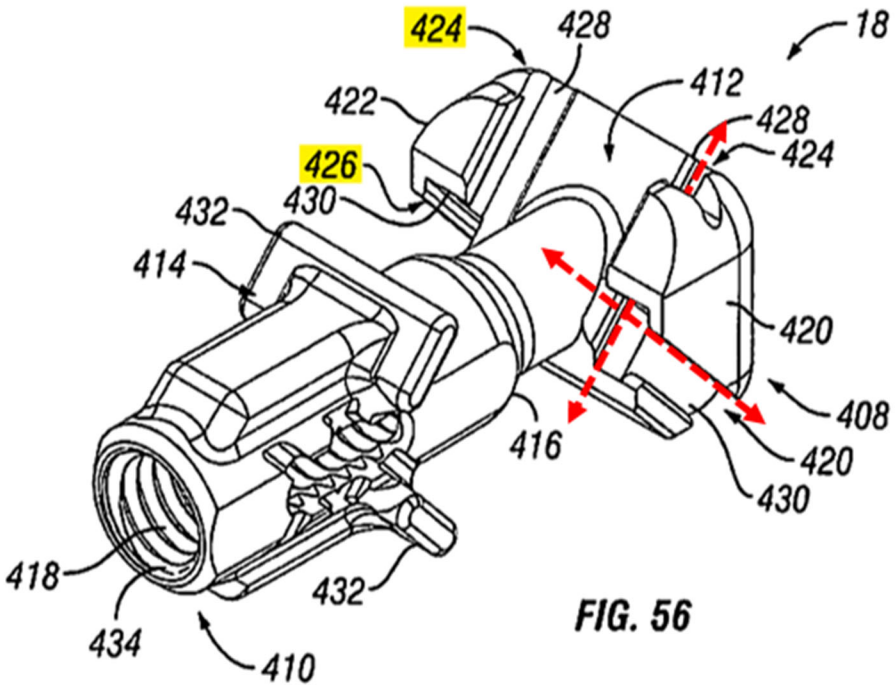


Chung, Fig. 3



The foregoing is consistent with the '732 Patent specification. For example, the specification discloses that the central ramp has "a first ramped portion 424 that overlaps a second ramped portion 426." EX1001, 19:9-14. As seen in annotated Fig. 56, below, ramped portions 424, 426 "overlap" in the same way as do the ramped surfaces of Chung's endplates.

'732 Patent, Fig. 56



Accordingly, Chung discloses these limitations. EX1002, ¶¶173-179.

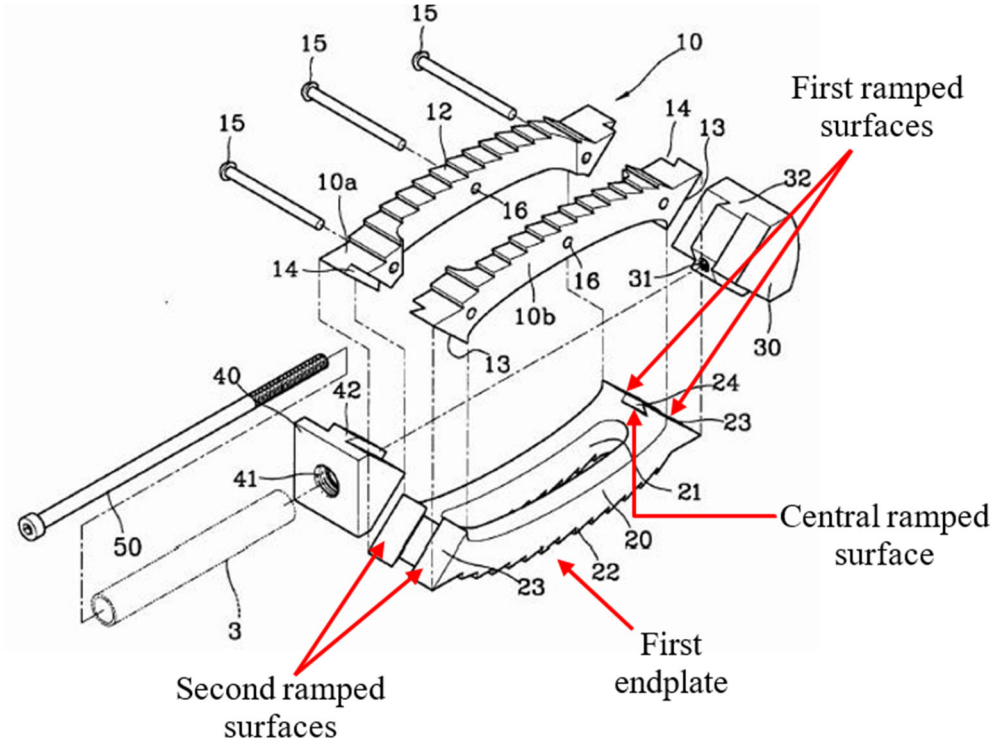
4. Claim 9

(a) Claims 9[a] and 9[b] "the first endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the first endplate" and **"the second endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the second endplate"**

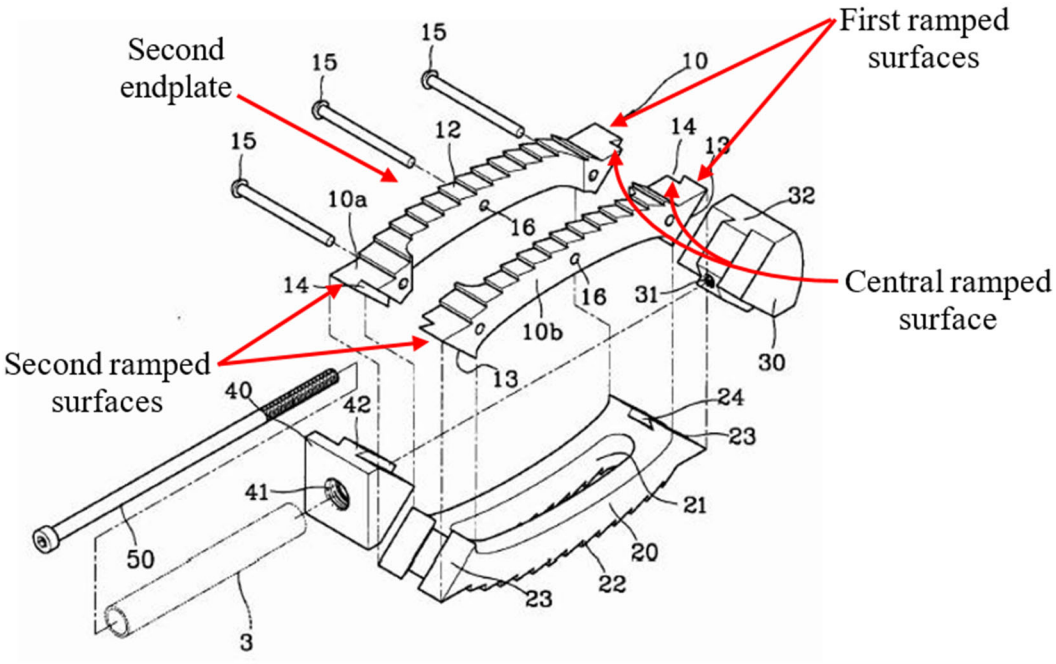
Chung discloses a central ramped surface ("dovetail groove (24)") disposed between the first end plate's first and second ramped surfaces, and a central ramped surface ("dovetail groove (14)") disposed between the second endplate's first and second ramped surfaces. *See* EX1005, 4 (disclosing "a lead wedge whose

both sides…have dovetails that dovetail with the dovetail grooves of the aforementioned main holder bodies along the lengthwise direction of each of the contact surfaces…"), Fig. 2. Annotated Figs. 2 and 4 follow.

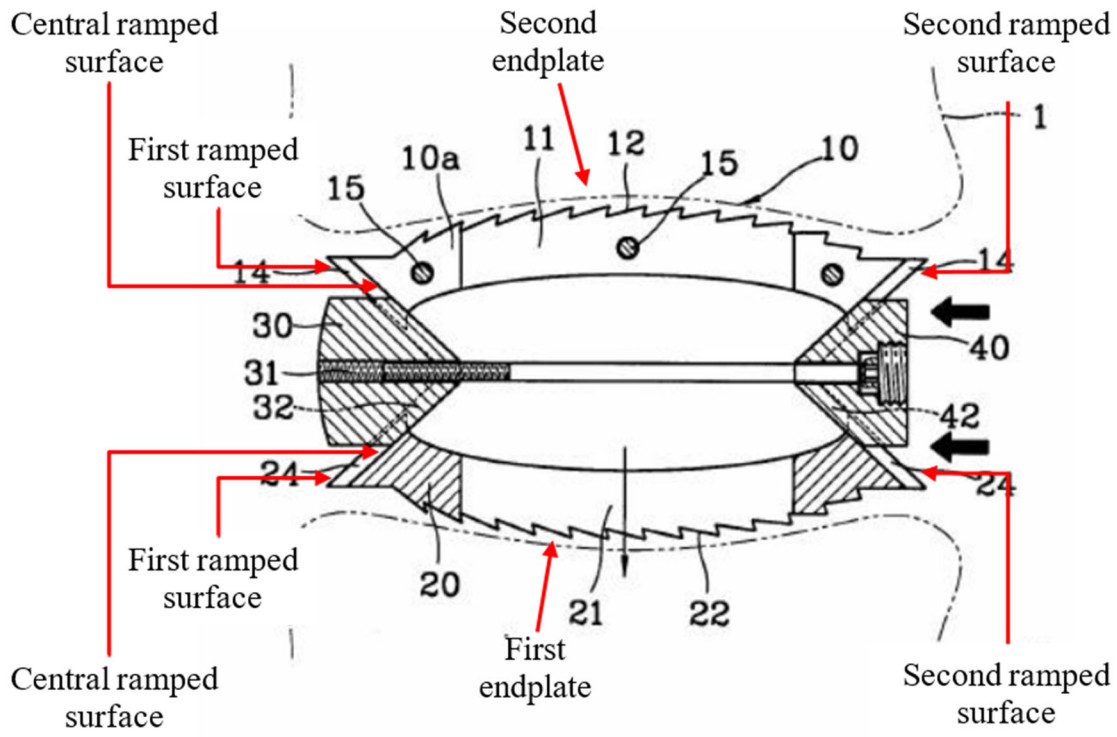
Chung, Fig. 2



Chung, Fig. 2


Second endplate
First ramped surfaces
Second ramped surfaces
Central ramped surface
15
10
12
14
13
32
10a
16
31
10b
30
40
42
24
23
41
21
50
20
22
3

Chung, Fig. 4

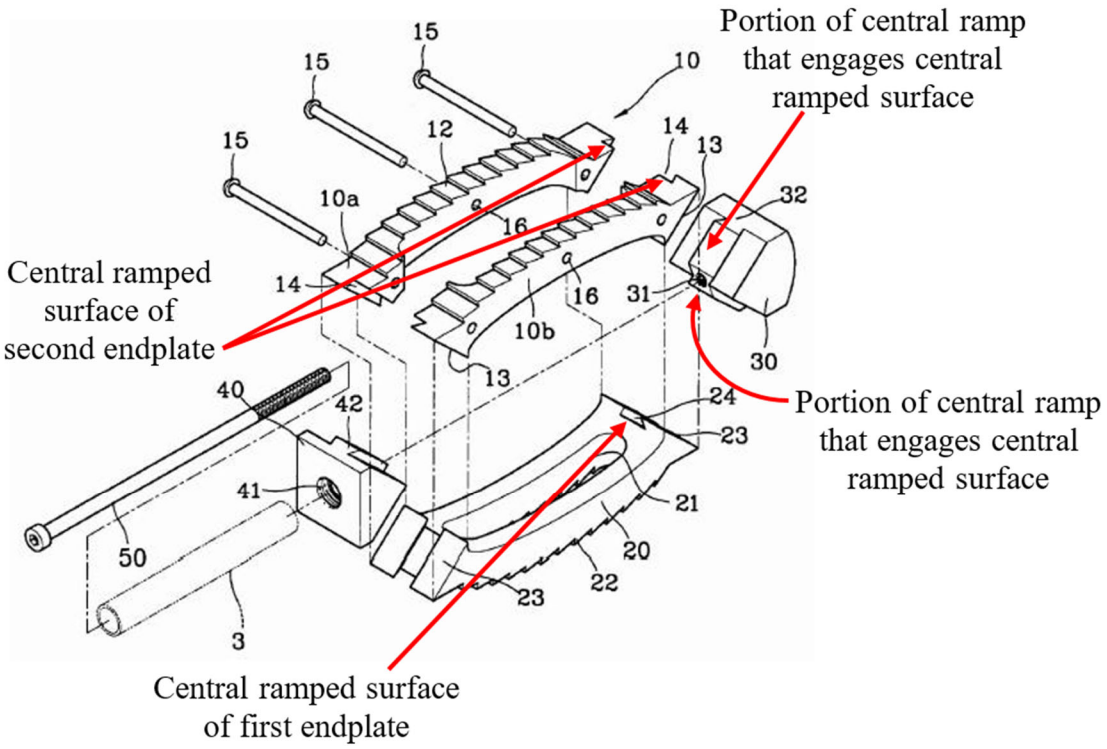


Accordingly, Chung discloses these limitations. EX1002, ¶¶180-185.

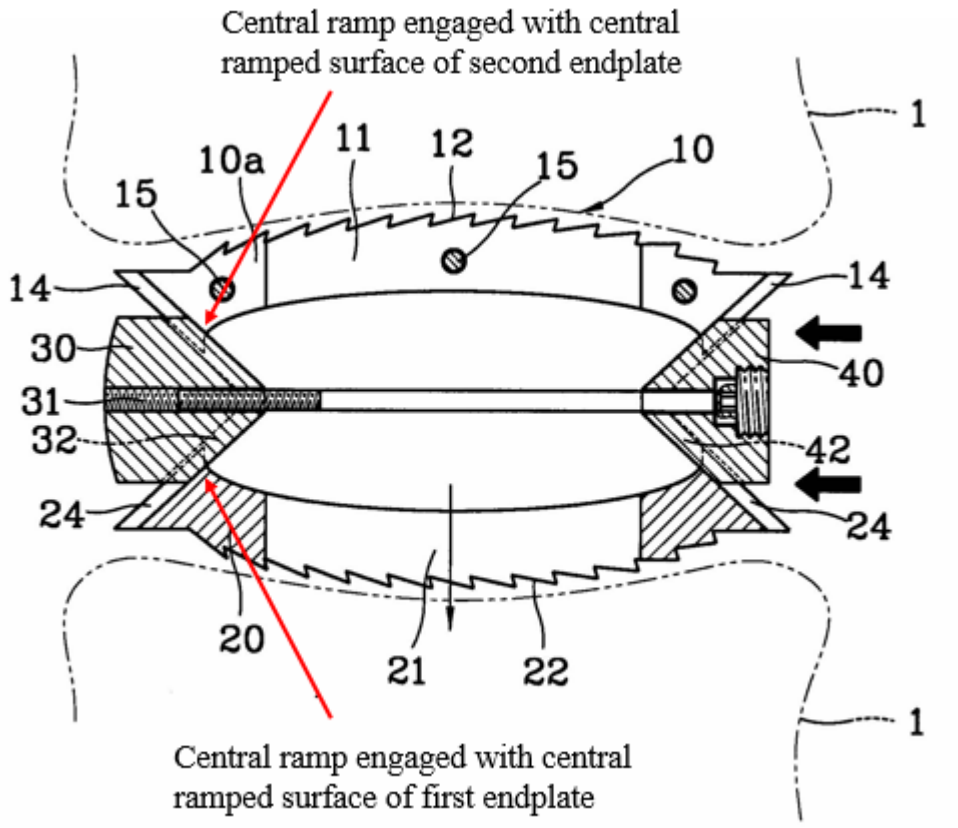
(b) Claim 9[c] "the central ramped surface of the first endplate and…the central ramped surface of the second endplate are configured to engage the central ramp"

Chung discloses that the central ramped surfaces (the recessed ramped surfaces of "dovetail grooves (14) (24)") of the first and second endplates are configured to engage the central ramp/lead wedge (30). *See* EX1005, 5 (disclosing that the central ramp's dovetails (32) "are fitted to the dovetail grooves (14) (24)); *see also id.* at 4. This can be seen in Figs. 2-4, with annotations below:

Chung, Fig. 2


Portion of central ramp that engages central ramped surface
Central ramped surface of second endplate
Portion of central ramp that engages central ramped surface
Central ramped surface of first endplate
15
15
15
10
12
14
13
32
10a
16
14
16
31
10b
30
13
40
42
24
23
41
21
50
20
22
23
3

Chung, Fig. 4



Accordingly, Chung discloses these limitations. EX1002, ¶¶186-188.

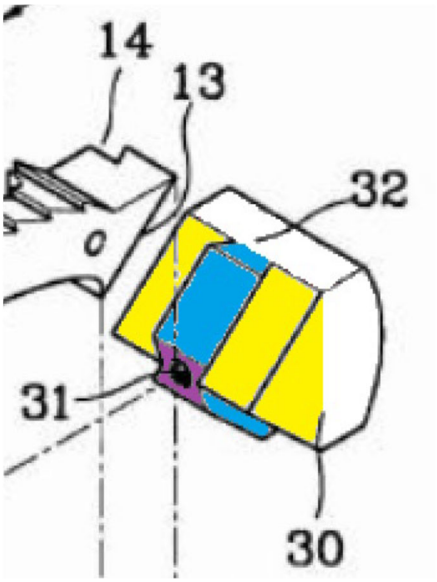
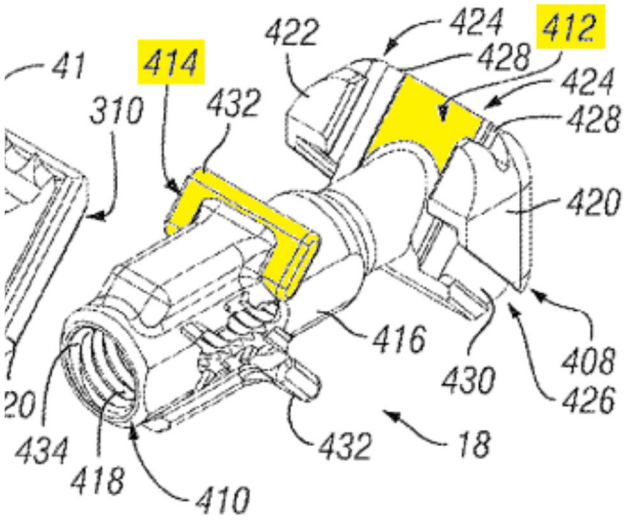
5. Claims 10 and 11

Petitioner is unable to discern any substantive difference between any of Claims 8, 10, and 11. Claims 10 and 11 are therefore obvious for the same reasons discussed for Claim 8. *See* §IX(A)(3); EX1002, ¶¶189-193.

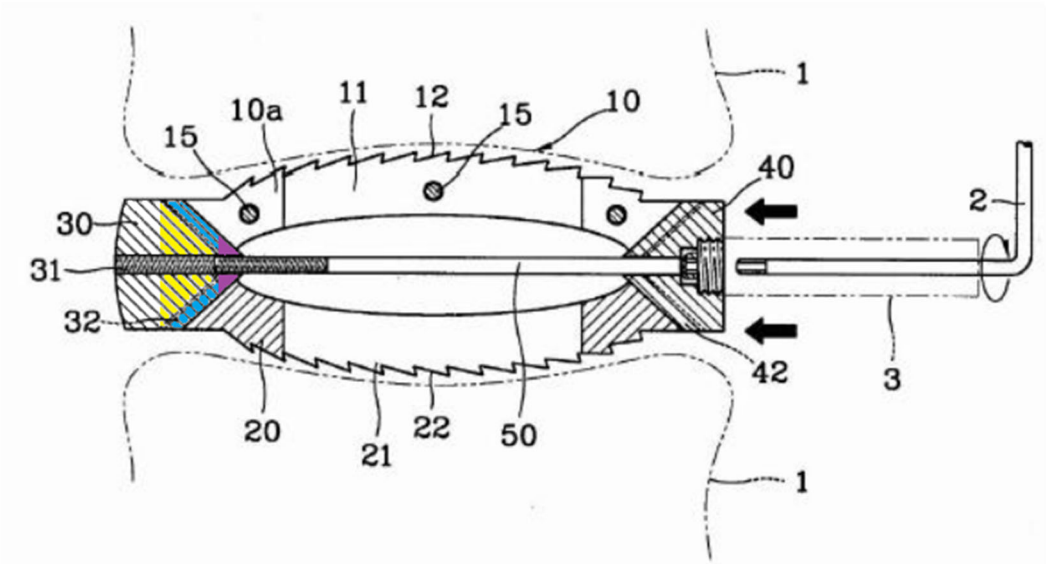
6. Claim 12

(a) Claim 12[a] "the central ramp comprises a ramped expansion portion at one end of the intervertebral implant and a central ramp extension extending from the expansion portion"

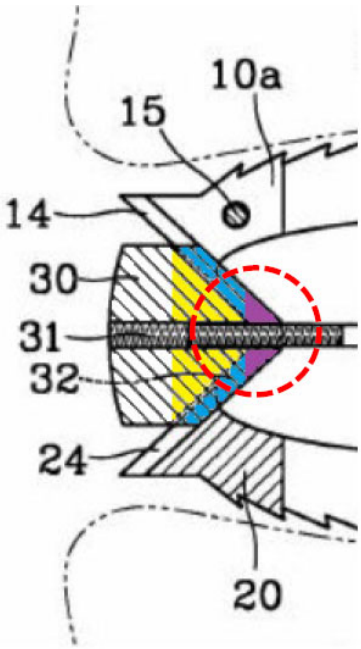
Chung discloses a central ramp having an expansion portion (the broad ramped surface extending on each side of the dovetail structure and at the base of "lead wedge (30)") at one end of the implant. EX1005, 5, Figs. 2-4. This identification is comparable to the "first expansion portion 412" and/or the "second expansion portion 414" shown in '732 Patent Fig. 52. EX1001, 19:1-6, Fig. 52. Excerpts of Chung Figs. 2-3 and '732 Patent Fig. 52 follow with expansion portions in yellow:

Chung, Fig. 2	'732 Patent, Fig. 52
	

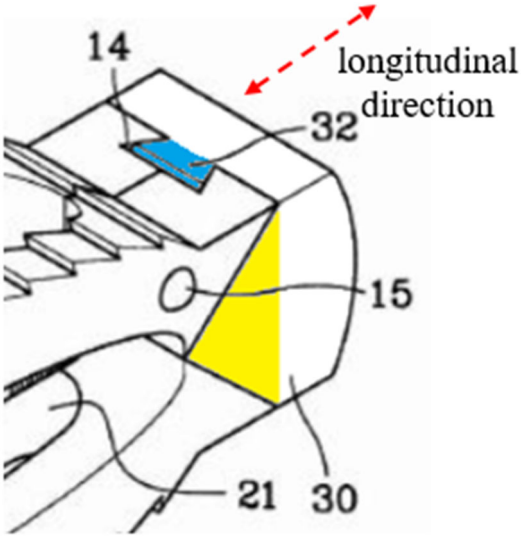
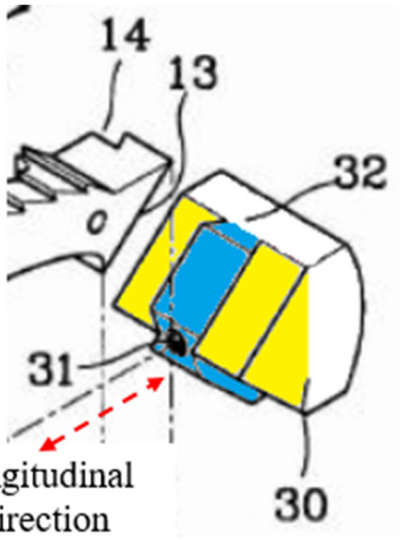
Chung, Fig. 3



Chung's "lead wedge (30)" also has an extension ("dovetail[] (32)"), that extends from the expansion portion. As seen in Figs. 2 and 4, a portion of dovetail (32) extends from "lead wedge (30)" and receives the actuation member. The dovetail's rod-receiving extension portion is highlighted in purple and circled below:

Chung, Fig. 4


In addition, the entirety of dovetail (32) also constitutes an "extension," extending from the central ramp. *See id.*, 5, Figs. 1-2. Specifically, dovetail (32) extends from the surface of lead wedge (30), as highlighted in blue below:

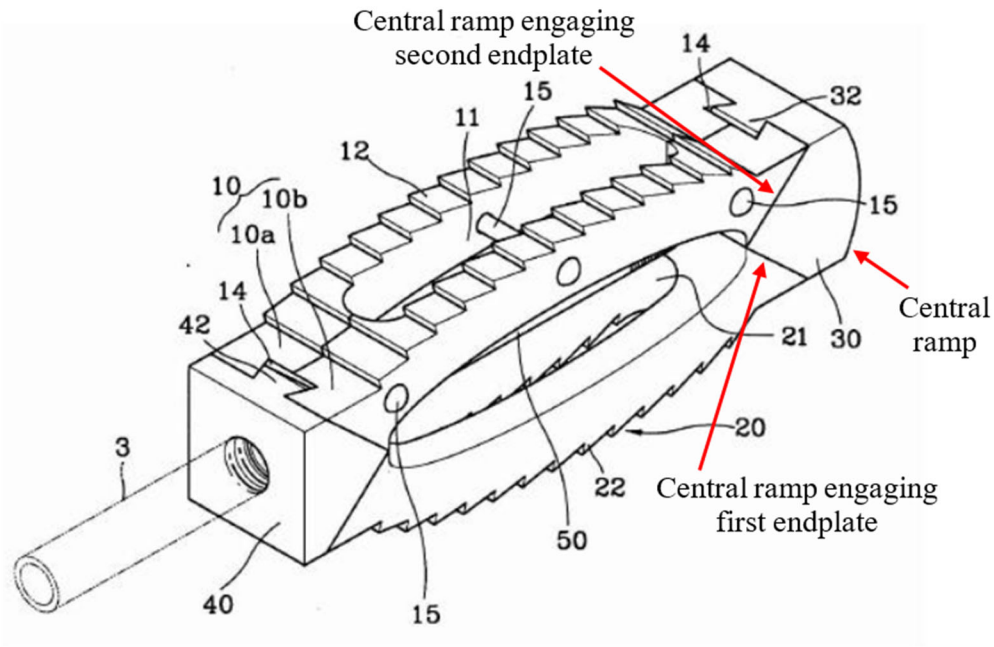
Chung, Fig. 1	Chung, Fig. 2
	

Accordingly, Chung discloses this limitation. EX1002, ¶¶194-202.

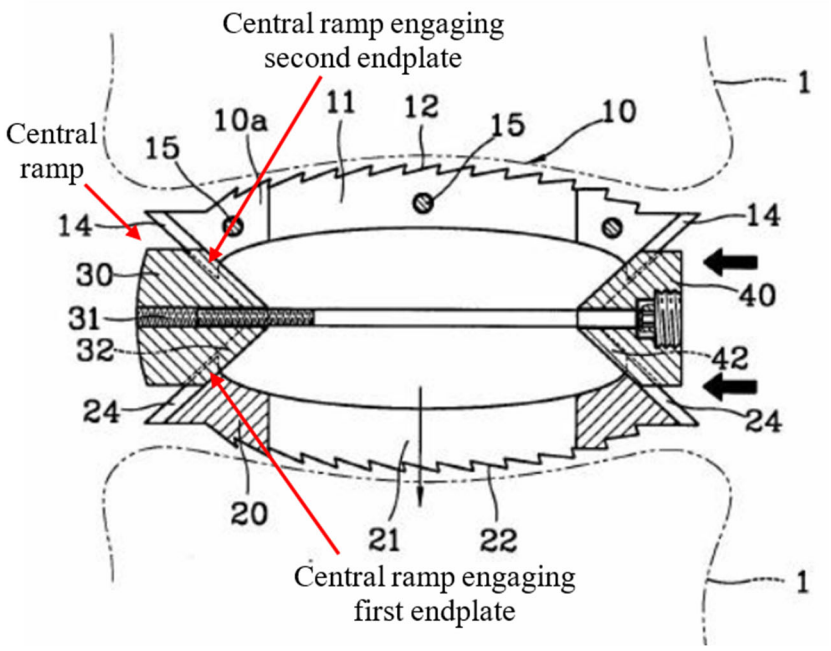
(b) Claim 12[b] "the central ramp is configured to engage the first endplate and the second endplate"

Chung's central ramp is configured to engage the first and second endplates. *See* EX1005, 4 (disclosing that lead wedge (30) has "dovetails that dovetail with the dovetail grooves of the aforementioned main holder bodies…"); Figs. 1-4. Annotated Figs. 1 and 4 showing this follow.

Chung, Fig. 1



Chung, Fig. 4



Accordingly, Chung discloses this limitation. EX1002, ¶¶203-205.

7. Claim 13

(a) Claim 13[a]

Chung with Boehm and/or Song discloses a system for intervertebral fusion. *See* §IX(A)(1)(a); EX1002, ¶206.

(b) Claim 13[b]

Chung with Boehm and/or Song disclose this limitation. *See* §IX(A)(1)(b); EX1002, ¶¶207-208.

(c) Claim 13[c]

Chung with Boehm and/or Song disclose this limitation. *See* §IX(A)(1)(c); EX1002, ¶¶209-210.

(d) Claim 13[d]

Chung with Boehm and/or Song disclose this limitation. *See* §IX(A)(1)(d); EX1002, ¶¶211-212.

(e) Claim 13[e]

Chung discloses this limitation. *See* §IX(A)(2)(a); EX1002, ¶¶213-214.

(f) Claim 13[f]

Chung discloses this limitation. *See* §IX(A)(2)(b); EX1002, ¶¶215-216.

(g) Claim 13[g]

Chung discloses this limitation. *See* §IX(A)(3); EX1002, ¶¶217-218.

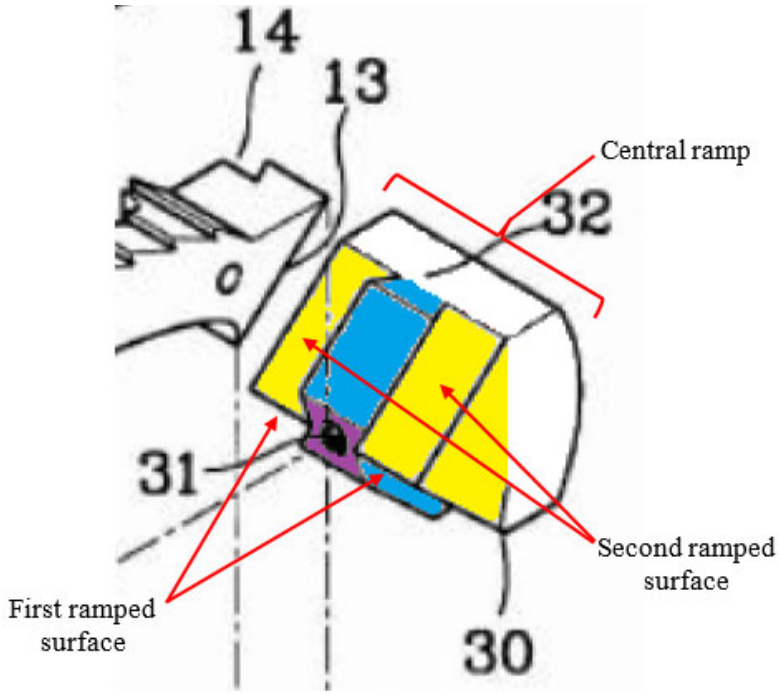
(h) Claim 13[h]

Chung discloses this limitation. *See* §IX(A)(1)(e); EX1002, ¶¶219-220.

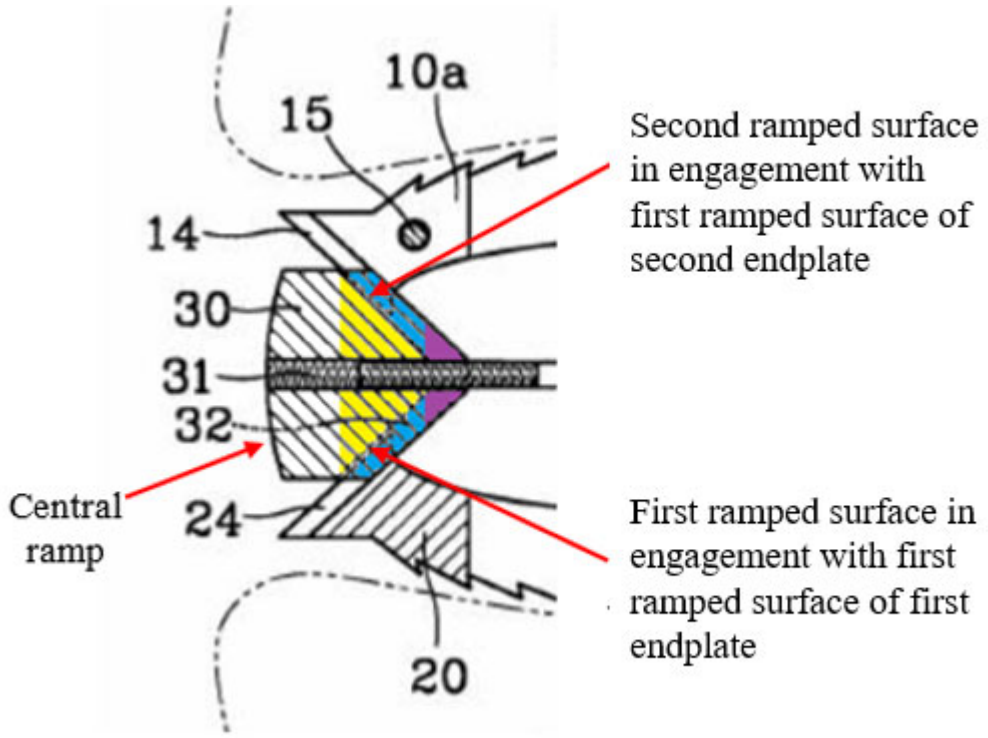
(i) Claim 13[i] "the central ramp is configured to engage the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate"

Chung's central ramp expansion portion (*see* §IX(A)(6)(a)) has first and second ramped surfaces (the flat surfaces adjacent to dovetails (32)), the first and second ramped surfaces engaging the endplates' ramped surfaces. EX1005, 4-5; Figs. 1-4. Annotated excerpts of Figs. 2 and 4 follow:

Chung, Fig. 2



Chung, Fig. 4



Accordingly, Chung discloses this limitation. EX1002, ¶¶221-222.

(j) Claim 13[j]

Claim 13 does not recite "an expansion portion of the central ramp," thus rendering Claim 13 indefinite for lack of antecedent basis. However, assuming *arguendo* that this refers to Claim 12's "ramped expansion portion," this element is disclosed by Chung. *See* §IX(A)(6)(b), §IX(A)(1)(g); EX1002, ¶¶223-225.

(k) Claim 13[k]

Chung discloses this limitation. *See* §§IX(A)(1)(h), IX(A)(1)(i). EX1002, ¶¶226-227.

(l) Claim 13[l]

Claim 13 patent does not recite "a central ramp extension," thus rendering Claim 13 indefinite for lack of antecedent basis. However, assuming *arguendo* that this refers to Claim 12's "central ramp extension", this element is disclosed by Chung. *See* §§IX(A)(6)(a), IX(A)(1)(j); EX1002, ¶¶228-230.

(m) Claim 13[m]

Chung discloses this limitation. *See* §§IX(A)(1)(f), IX(A)(1)(k); EX1002, ¶¶231-232.

(n) Claim 13[n]

Chung discloses this limitation. *See* §IX(A)(1)(l); EX1002, ¶¶233-234.

8. Claim 16

(a) Claim 16[a]

Chung with Boehm and/or Song discloses a system for intervertebral fusion. *See* §IX(A)(1)(a); EX1002, ¶235.

(b) Claim 16[b]

Chung with Boehm and/or Song discloses this limitation. *See* §IX(A)(1)(b); EX1002, ¶¶236-237.

(c) Claim 16[c]

Chung with Boehm and/or Song discloses this limitation. *See* §IX(A)(1)(c); EX1002, ¶¶238-239.

(d) Claim 16[d]

Chung with Boehm and/or Song discloses this limitation. *See* §IX(A)(1)(d); EX1002, ¶¶240-241.

(e) Claim 16[e]

Chung discloses this limitation. *See* §§IX(A)(2)(a), IX(A)(4)(a); EX1002, ¶¶242-243.

(f) Claim 16[f]

Chung discloses this limitation. *See* §§IX(A)(2)(b), IX(A)(4)(a); EX1002, ¶¶244-245.

(g) Claim 16[g]

Chung discloses this limitation. *See* §§IX(A)(1)(e); EX1002, ¶¶246-247.

(h) Claim 16[h]

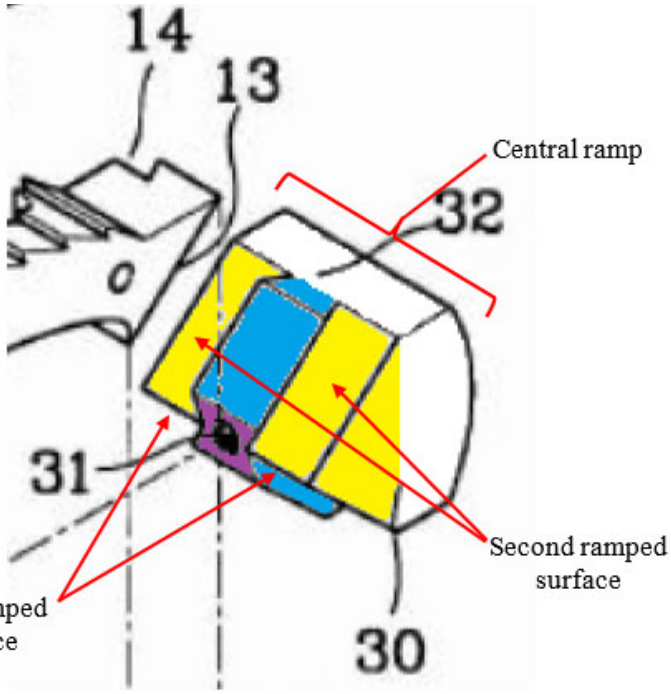
Chung discloses this limitation. *See* §§IX(A)(6)(a); EX1002, ¶¶248-249.

(i) Claim 16[i] "the ramped expansion portion is configured to engage the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate"

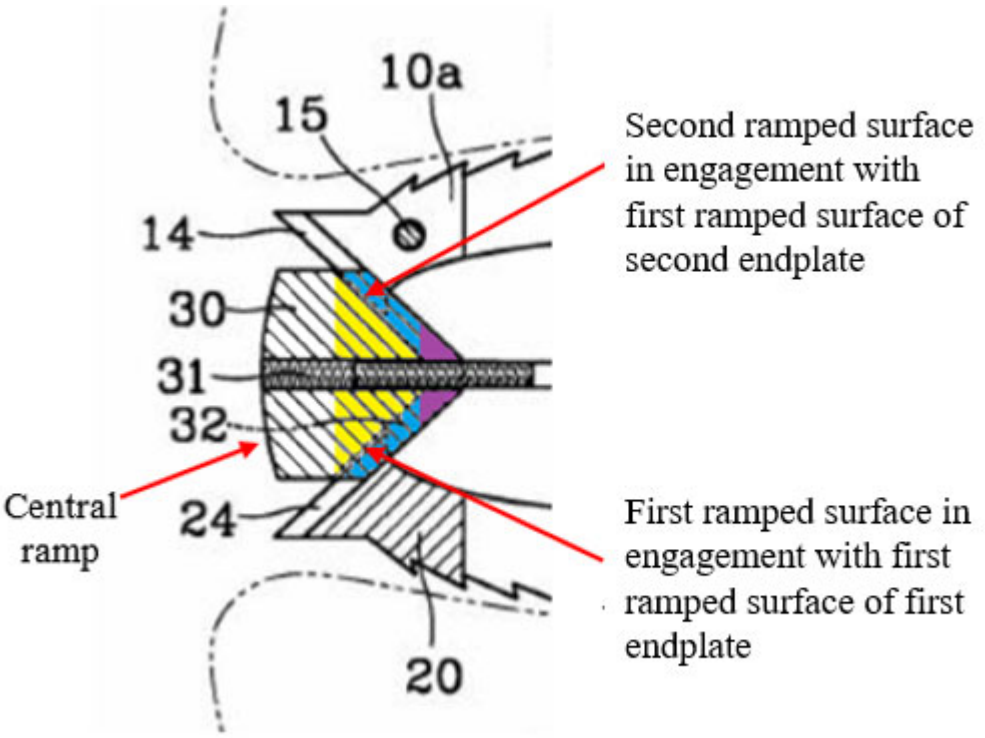
Chung's central ramp expansion portion (*see* §IX(A)(6)(a)) has first and second ramped surfaces (the flat surfaces adjacent to dovetails (32)), the first and

second ramped surfaces engaging the endplates' ramped surfaces. EX1005, 4-5; Figs. 1-4. Annotated excerpts of Figs. 2 and 4 follow:

Chung, Fig. 2



Chung, Fig. 4



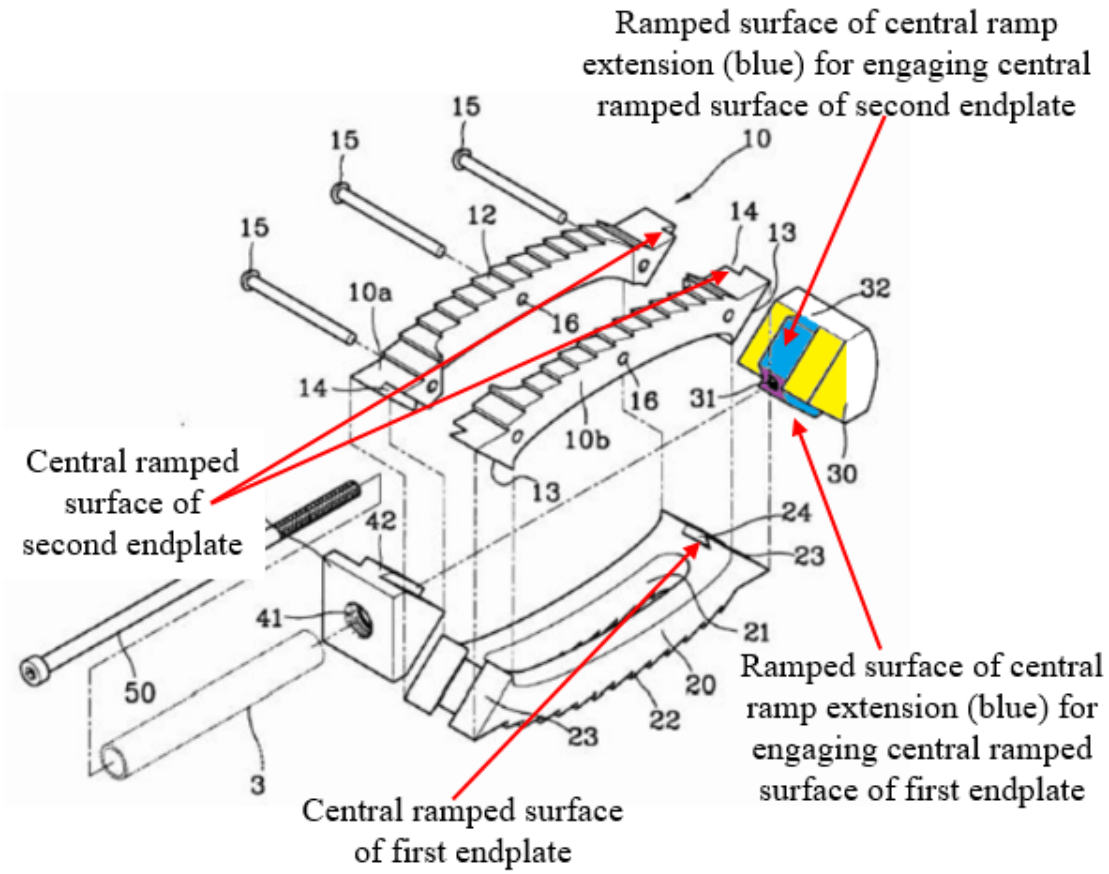
Accordingly, Chung discloses this limitation. EX1002, ¶¶250-251.

(j) Claim 16[j] "the central ramp extension comprises ramped surfaces projecting from the central ramp extension and configured to engage the central ramped surface of the first endplate and the central ramped surface of the second endplate"

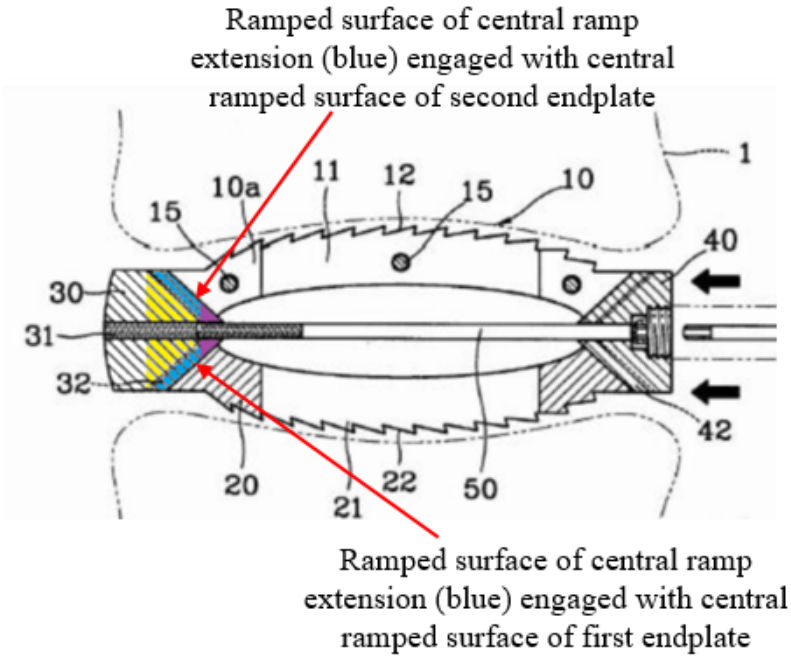
As previously discussed, Chung discloses a central ramp extension in the form of dovetail (32), which extends from the surface of lead wedge (30) and mates with the dovetail grooves (14) (24) of main holder bodies (10) (20), the recessed ramped surfaces of "dovetail grooves (14) (24)" comprising the central ramped surfaces of the second and first endplates, respectively. *See* §§IX(A)(2),

IX(A)(4), *supra*. As shown in the following annotated Figs. 2-3, the central ramp extension of dovetail (32) (alternatively highlighted in blue and purple) has ramped surfaces projecting therefrom that engage the central ramped surfaces of the first and second endplates:

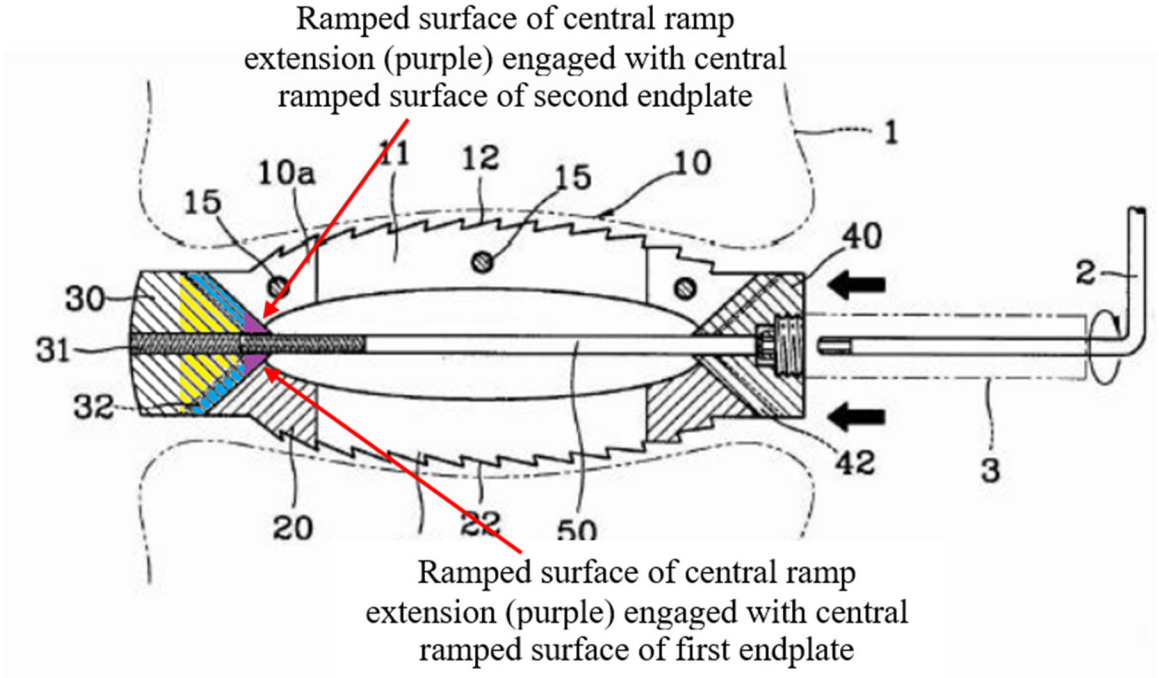
Chung, Fig. 2



Chung, Fig. 3



Chung, Fig. 3



Accordingly, Chung discloses this limitation. EX1002, ¶¶252-254.

(k) Claim 16[k]

Chung discloses this limitation. *See* §IX(A)(1)(g); EX1002, ¶¶255-256.

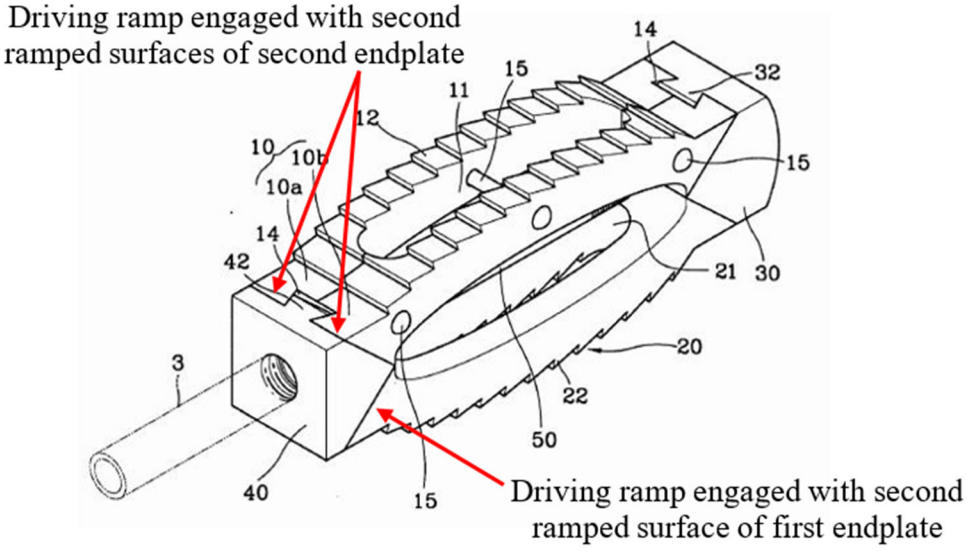
(l) Claim 16[l]

Chung discloses this limitation. *See* §IX(A)(1)(h); EX1002, ¶¶257-258.

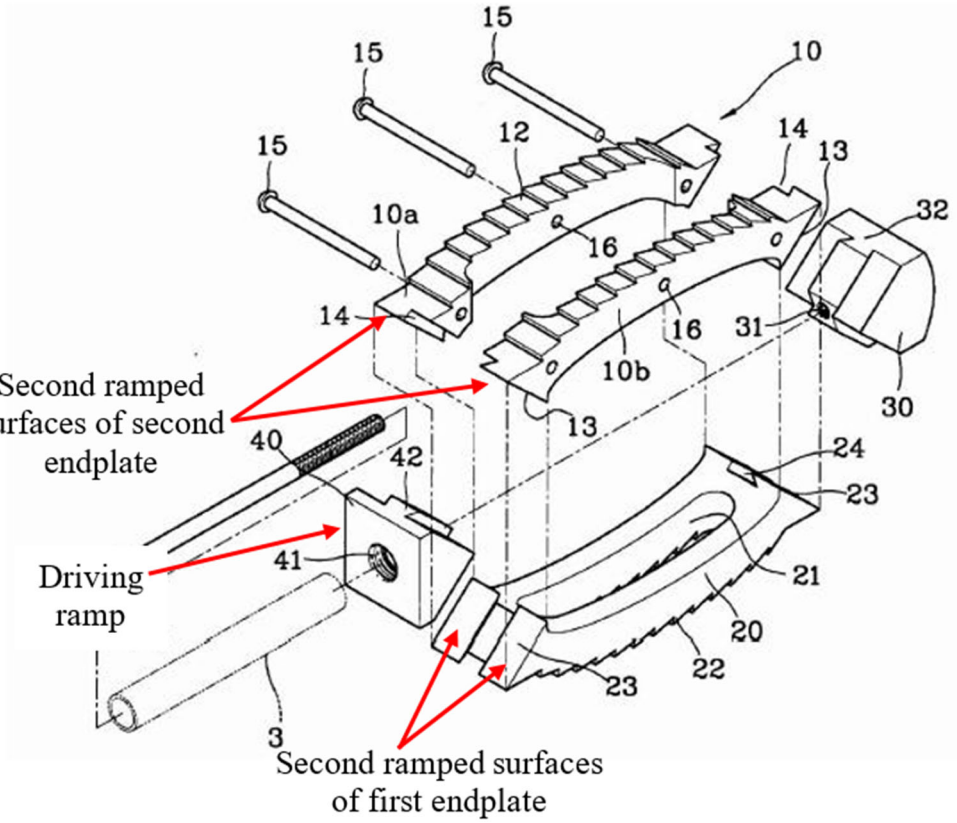
(m) Claim 16[m] "the driving ramp is configured to engage the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate"

Chung's driving ramp (*see* §IX(A)(8)(k)) engages the second ramped surfaces of the first and second endplates. EX1005, 4-5; Figs. 1-4. Annotated Figs. 1-2 follow:

Chung, Fig. 1



Chung, Fig. 2



Accordingly, Chung discloses this limitation. EX1002, ¶¶259-261; *see also* §§IX(A)(1)(i), IX(A)(2)(a)-(b).

(n) Claim 16[n]

Chung discloses this limitation. *See* §§IX(A)(1)(j), IX(A)(6)(a); EX1002, ¶¶262-263.

(o) Claim 16[o]

Chung discloses this limitation. *See* §IX(A)(1)(k); EX1002, ¶¶264-265.

9. Motivation to Combine

A POSITA would have been motivated to combine Chung with the teachings of Boehm and/or Song—specifically those related to the use of certain tools such as dilators and cannulas—to create an access path to an intervertebral space and insert the intervertebral implant, with a reasonable expectation of success. A POSITA would have recognized that the device of Chung must be inserted into an intervertebral target site and that various tools would have facilitated creating an access path to the site and inserting the device. EX1002, ¶266. The Examiner found obvious the combination of Boehm with Olmos (EX1004, 000119), which was not traversed by Applicant, and the same rationale identified by the Examiner likewise applies to Chung with Boehm and/or Song, as further detailed below.

Notably, the use of dilators and cannulas to distract the vertebra to a desired height and guide the implant into the desired disc space was ubiquitous in the field of minimally invasive spinal surgery at the time of invention. *See* EX1002, ¶¶267-268. For example, Song expressly discloses that numerous such methods and devices existed and described performing surgery "through a tube" or utilizing "tubes for percutaneous placement of interbody devices," including Boehm, which Song describes as disclosing using "a sequence of serial dilators…to create a working channel." *See* EX1029, ¶[0008]. Song also notes that the tools are useful

for "distracting the disc space, i.e. making the space between the discs wider." *Id*., ¶[0004].

A POSITA was thus aware of the use of dilators and cannulas in the field, and further would have been motivated to consider and follow prior art teachings providing specific examples of tools useful for implanting the Chung device, such as those disclosed by Boehm and Song. EX1002, ¶¶269-271. Specifically, the use of a dilator with a tapered end, for example, helps minimize trauma to surrounding tissue as it is being inserted, and also helps separate the discs to create the necessary space/height between them for subsequent insertion of the implant via the cannula (wherein the cannula helps guide the implant to the desired location, while again minimizing trauma to surrounding tissues and avoiding the spinal cord). *Id*.

Furthermore, at least because use of the tools to create an access path to the intervertebral space was ubiquitous in the field of minimally invasive spinal surgery, a POSITA would have had a reasonable expectation of success in using Boehm's and Song's dilators and cannulas to create the desired pathway to the appropriate intervertebral disc space and insert Chung's device where desired through the cannula. EX1002, ¶272. A POSITA would have had a reasonable expectation of success in doing so given the similarities between Chung's device and the Boehm/Song devices. For example, like Chung, Boehm and Song each

disclose an intervertebral implant that is inserted into a disc space for purposes of intervertebral fusion. *E.g.,* EX1029, ¶¶[0009], [0015], [0054]; EX1028, ¶¶[0017], [0032]-[0033] (further describing the implant as expandable). A POSITA would have reasonably understood and expected that means for creating an access path and inserting a device into an intervertebral disc space for one such device (Boehm or Song) would also work for another, similar device (Chung). EX1002, ¶272.

Thus, it would have been obvious to a POSITA to combine the teachings of Boehm and/or Song regarding the use of dilators and cannulas with Chung. EX1002, ¶¶266-274.

B. Ground 2: Claims 1, 7-13, and 16 are obvious over Chung in view of Boehm and/or Song, and further in view of Baynham

Should Chung be found to not disclose a "central ramp extension," Claims 1, 7-13, and 16 are alternatively obvious under 35 U.S.C. §103 further in view of Baynham as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶275-290).

1. Claims 1, 12, 13, and 16

Chung discloses the claimed central ramp extension as discussed above. §§IX(A)(1)(j), IX(A)(6)(a), IX(A)(7)(l), IX(A)(8)(j), *supra*. Alternatively, it also would have been obvious to add a further extension to Chung's central ramp to

engage the actuation member 40, as taught by Baynham, satisfying the extension element.

Baynham discloses a spinal fusion implant, shown below, composed of wedge-shaped upper section 11 and lower section 13, which interact with the opposing wedge shape of the ramp referred to as distractor 42. The upper and lower sections have grooves 26, 35 which engage the flanges 43, 44 of distractor 42. EX1007, ¶¶[0022], [0025]-[0029], Figs. 1, 3. Distractor 42 also has an unthreaded bore 61 in its trailing edge for receiving a jack screw 67. *Id.*

Furthermore, the Baynham implant's leading edge has a link 40 which fits between the upper and lower sections 11, 13 and includes flanges 65, 66, which are received in vertical slots 64 of the upper and lower sections. *Id.* Link 40 also includes a threaded tube 27 that "surrounds the bore 60 and extends toward the bore 61." *Id.*, ¶[0029]. Figure 3 provides reference:

Baynham, Fig. 3

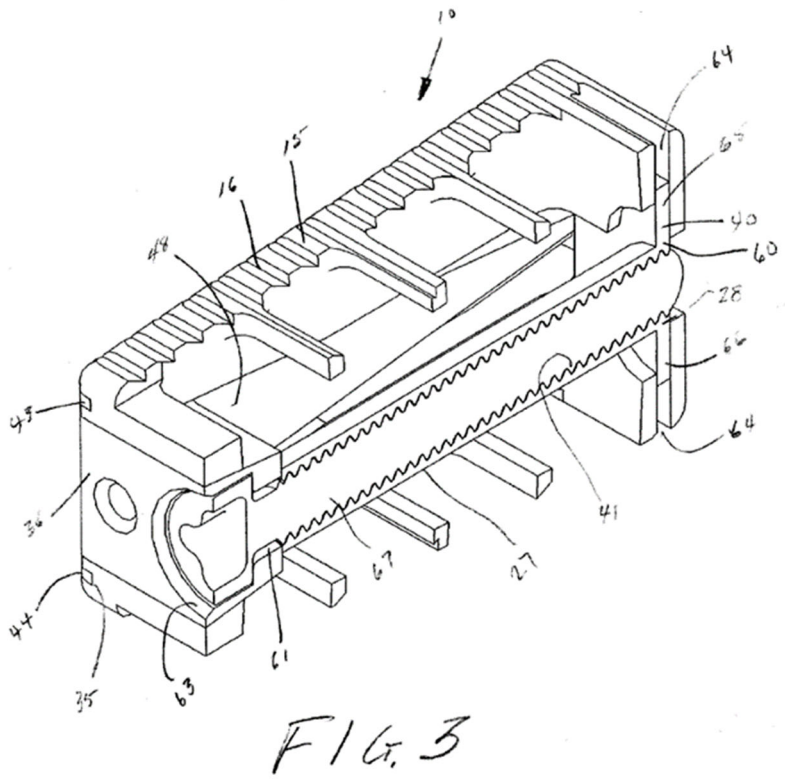


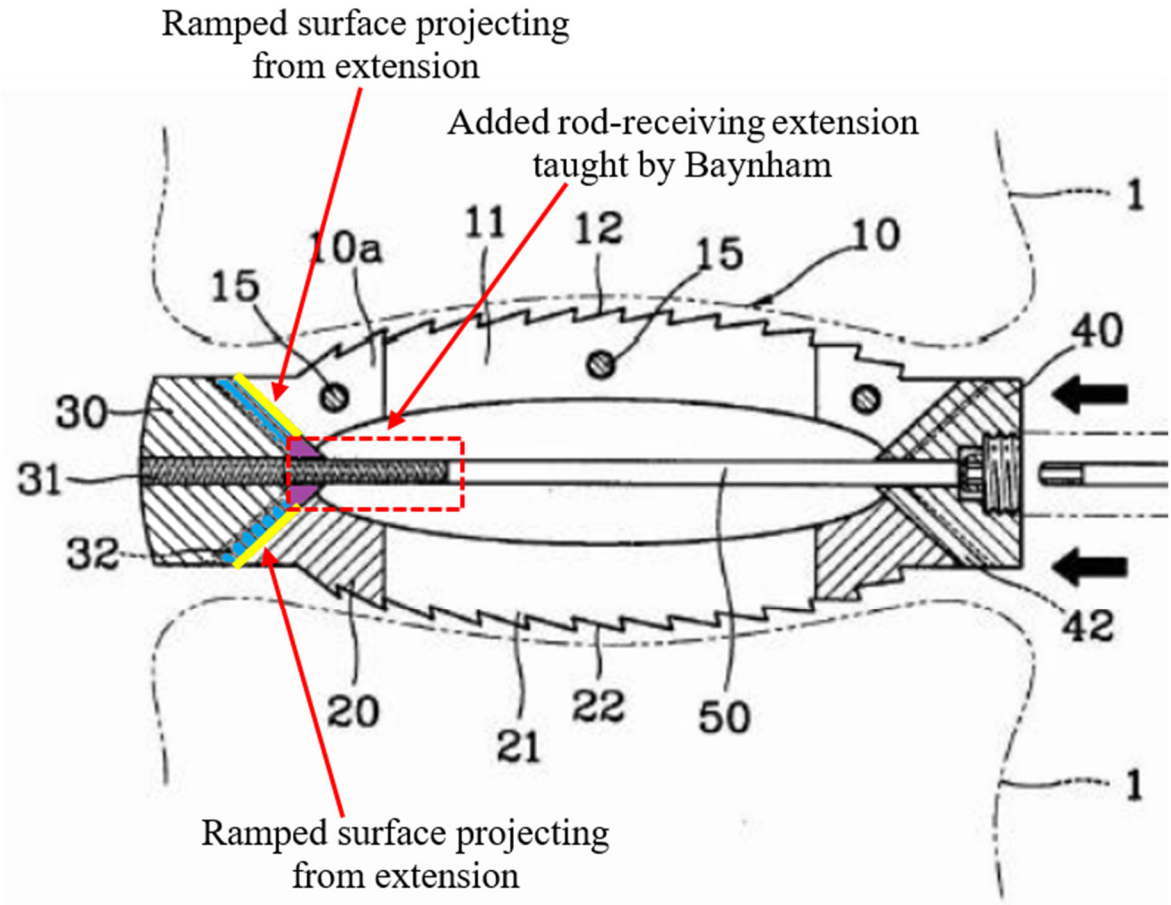
FIG. 3

Baynham's threaded tube (i.e., "extension") extends toward the opposing ramp and engages the screw/actuation member. As the actuation member rotates, the threaded tube causes the link and ramp to be drawn together. Simultaneously, the wedge shape of the ramp and the upper and lower sections cause the upper and lower sections to be forced apart. Accordingly, Baynham's tube 27 has the same structure and performs the same function as the extension recited in the '732 patent and screw hole (31) of Chung – i.e., it "extend[s] from the expansion portion" and

"an actuation member…[is] received within an opening in the central ramp extension." §§IX(A)(1)(j), IX(6)(a), *supra*.

Applying Baynham's tube-shaped extension to Chung's central ramp, a POSITA would understand that the ramped surfaces of the central ramp extension would still project from the modified rod-receiving extension as required by Claim 16[j]. Combining Baynham's tube with Chung simply involves elongating Chung's existing rod-receiving extension as indicated by the red-dotted box below. Accordingly, the ramped surfaces would continue to extend from the elongated extension just as described in §IX(A)(8)(j), *supra*. EX1002, ¶282. The following annotated excerpt of Fig. 3 shows this, with the ramped surfaces in yellow:

Chung, Fig. 3



Accordingly, the extension elements of Claims 1, 12, 13, and 16 are disclosed by Chung with Boehm and/or Song, and further with Baynham. EX1002, ¶¶275-283.

2. Claims 7-11

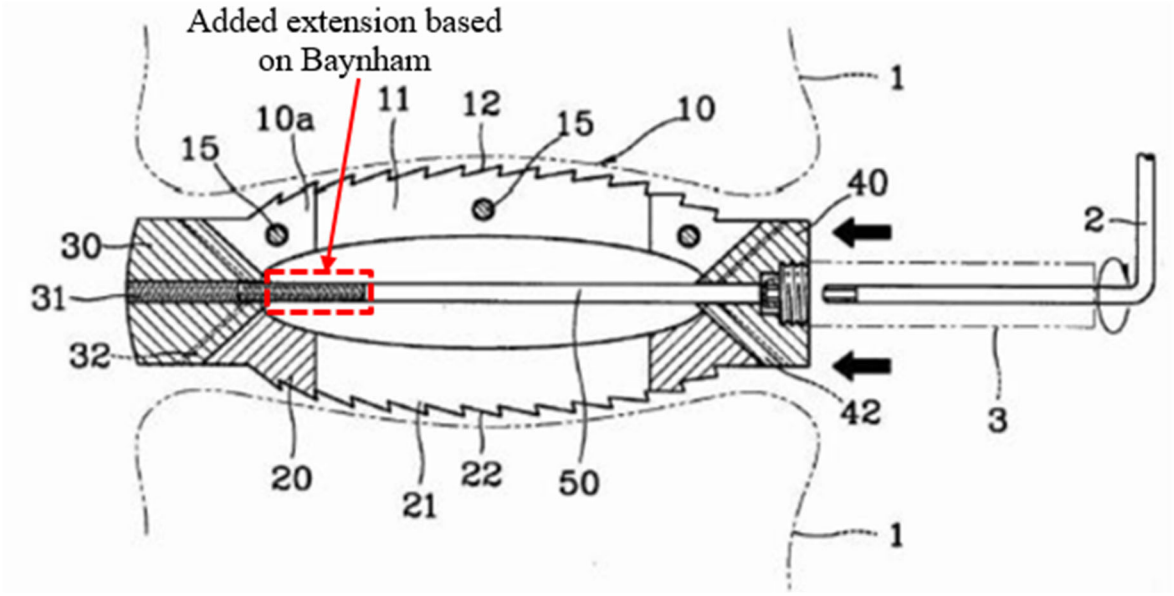
Claims 7-11 depend either directly or indirectly from Claim 1. As discussed above, all elements added by these claims are expressly disclosed in Chung. *See*

§§IX(A)(2)-(5), *supra*. Accordingly, Claims 7-11 are likewise obvious for the reasons provided in Ground 1 and here. EX1002, ¶284.

3. Motivation to Combine

A POSITA would have been motivated to combine Chung with Boehm and/or Song as discussed previously. *See* §IX(A)(9). A POSITA would have been motivated to modify the structure surrounding Chung's screw hole (31) to further lengthen Chung's extension longitudinally towards the driving ramp, as taught by Baynham's tube 27, and as indicated in annotated Fig. 3 below (EX1002, ¶¶285-288).

Chung, Fig. 3



Extending the screw hole per Baynham's tube 27 would make the threaded bore longer and decrease the distance between the bores of Chung's driving ramp

and central ramp, which would provide clear advantages appreciated by a POSITA. First, incorporating Baynham's extension would allow the screw to engage the central ramp bore at a shorter distance and, once engaged, to engage a larger number of the central ramp's threads, which would have the benefit of improving the strength of the connection. EX1002, ¶285. Second, the modification would allow use of a shorter screw, which will reduce or eliminate protrusion of the screw from the device when expanded, thereby reducing unwanted interference with adjacent anatomy. *Id*., ¶286. Accordingly, a POSITA would have been motivated to incorporate the design of Baynham's tube 27 with Chung's wedge (30).

Furthermore, Baynham's "jack screw" functionality is directly analogous to the functionality disclosed in Chung. *See* §§IX(A)(1)(l), IX(B)(1), *supra*. Accordingly, the combination amounts to nothing more than the simple substitution of known mechanical features with each performing their known and expected function. Because these are easily substituted and well-known mechanical features well within the level of skill in the art, a POSITA would have had a reasonable expectation of success in combining Baynham's tube 27 with Chung. EX1002, ¶¶289-890.

C. Ground 3: Claims 8, 10-11 and 13 are obvious over Chung in view of Boehm and/or Song (with or without Baynham), and further in view of Varela-'774

Claims 8, 10-11 and 13 are further obvious under 35 U.S.C. §103 over Chung in view of Boehm and/or Song (as detailed in Ground 1 above), and further in view of Varela-'774 or Varela-'774 and Baynham as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶291-336).

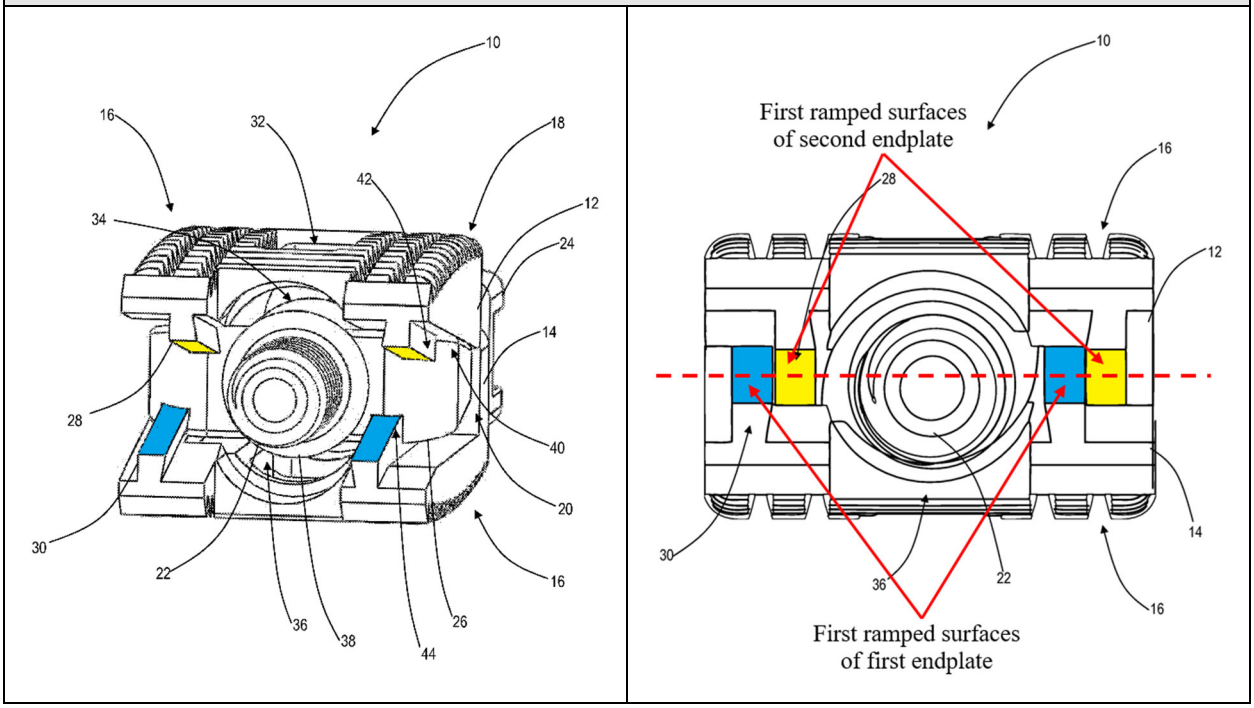
1. Claim 8

Claim 8, which depends from Claim 7, recites that "**when the intervertebral implant is in an unexpanded configuration, the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate overlap, and the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate overlap**." To the extent not already present (*see* §IX(A)(3), *supra*), it would have been obvious to a POSITA to modify Chung to include such a feature in view of the teachings of Varela.

Varela-'774 discloses an expandable intervertebral implant that "has a very small undeployed cross-section or footprint due to the use of superior and inferior members that nest against one another…." EX1030, ¶[0002]. More specifically, Varela-'774 discloses that the first and second endplates (disclosed as inferior and superior members) have ramped "track structures 28 and 30" that "are offset from one another relative to the central axis of the expandable intervertebral implant 10

such that they sit side-by-side when the expandable intervertebral implant 10 is un-depolyed [*sic*], thereby making the assembly as compact as possible." *Id.*, ¶[0039]. That is, the ramped track structures include ramped surfaces that overlap when the device is in the collapsed position. This can further be observed in Figs. 3 and 5, annotated below, which show the device in an expanded state (Fig. 3) and in a collapsed state (Fig. 5), with the ramped surfaces of the first endplate in blue and the ramped surfaces of the second endplate in yellow and (in Fig. 5) the plane of overlap denoted with a red dashed line.

Varela-'774, Figs. 3, 5



Accordingly, Varela-'774 alternatively discloses this limitation. EX1002, ¶¶291-295. Moreover, for the reasons described herein and in §IX(C)(4), *infra*, it

would have been obvious to a POSITA to modify Chung according to the teachings of Varela-'774 such that, in an unexpanded configuration, Chung's first ramped surfaces of the first and second endplates overlap, and the second ramped surfaces of the first and second endplates overlap.

2. Claims 10 and 11

Like Claim 8, Claims 10 and 11 depend from Claim 7, but Petitioner is unable to discern any substantive difference between any of Claims 8, 10, and 11. Claims 10 and 11 are therefore obvious for the same reasons as discussed above for Claim 8. *See* §IX(C)(1); EX1002, ¶¶296-301.

3. Claim 13

(a) Claims 13[a]-[f], 13[h]-[n]

Chung, either alone or with Boehm and/or Song, disclose these limitations. *See* §IX(A)(7); EX1002, ¶¶302-312, ¶¶315-330.

(b) Claim 13[g]

Chung with Boehm and/or Song and further with Varela-'774 disclose this limitation. *See* §IX(C)(1); EX1002, ¶¶313-314.

4. Motivation to Combine

In addition to being motivated to combine Chung with Boehm and/or Song as discussed previously (§IX(A)(9), *supra*), a POSITA further would have been

motivated to combine Chung with Varela-'774 for at least the reasons expressly set forth in Varela-'774 itself.

Specifically, Varela-'774 teaches the desirability of overlapping an intervertebral implant's endplates so that they "nest" with one another when the device is in an unexpanded state allows and thereby achieve "the smallest possible form factor for insertion through the skin and musculature of the patient and into the intervertebral space." EX1030, ¶[0034]; *see also id.*, ¶[0039]. Varela-'774 describes this as an advantage particularly when used in "preferably, minimally-invasive surgical procedure[s]." *Id*., ¶[0002]. These teachings would have motivated a POSITA to reconfigure the endplates in Chung to have overlapping ramped surfaces when in an unexpanded position, thus enabling the implant to maintain a lower profile and be more easily inserted as part of a minimally invasive surgical procedure. EX1002, ¶¶332-333.

A POSITA would have had a reasonable expectation of success in making the aforementioned modifications to Chung because these are straight-forward mechanical features/designs that, as the prior art shows, a POSITA was well capable of incorporating. Moreover, the devices of Chung and Varela-'774 are structurally and functionally comparable, with both Varela-'774 and Chung disclosing an expandable implant for surgical insertion between two vertebra to provide structural support and expansion by moving at least one wedge through the

rotation of an actuator. EX1002, ¶¶334. As such, a POSITA would have a reasonable expectation of success in applying Varela-'774's overlapping track structures with offset ramped surfaces to the device of Chung in order to maintain a compact configuration when the device is in a collapsed position. *Id.* .

As evidenced by U.S. Patent Application Publication No. US 2012/0185049 ("Varela-'049," EX1032), which discloses the overlapping ramped surfaces applied to a device having two wedges when in an unexpanded position, A POSITA would have been further motivated to apply Varela-'774's teaching of the overlapping ramped surfaces when in an unexpanded position to Chung's device with two wedge structures. . EX1002, ¶¶335.

Accordingly, Claims 8, 10-11, and 13 are obvious over Chung in view of Boehm and/or Song (or Boehm and/or Song and Baynham) and further in view of Varela-'774. EX1002, ¶¶331-336.

D. Ground 4: Claims 1 and 7-13 are obvious over Olmos in view of Boehm and/or Song

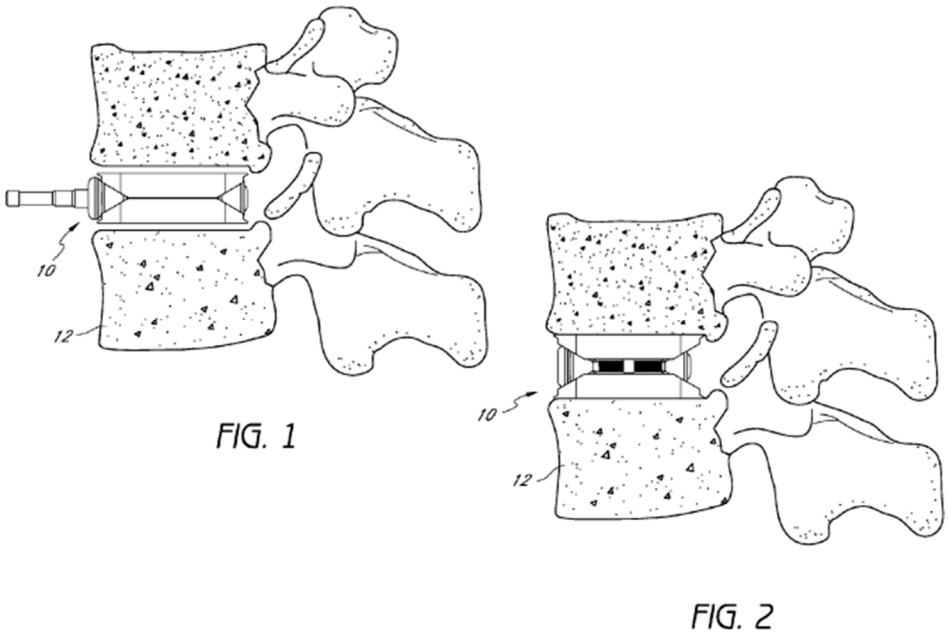
Claims 1 and 7-13 are obvious under 35 U.S.C. §103 over Olmos in view of Boehm and/or Song as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶337-466).

1. Claim 1

(a) Claim 1[a]

Olmos discloses a system for intervertebral fusion through its disclosure of "an adjustable spinal fusion intervertebral implant," which may be used to carry out a variety of known fusion procedures. EX1006, ¶¶[0019], [0071]; *see also id.*, Abstract. Moreover, Figs. 1-2 show the Olmos fusion implant inserted into the intervertebral space:

Olmos, Figs. 1-2



Accordingly, Olmos discloses a system for intervertebral fusion. EX1002, ¶337-339; *see also, e.g.,* EX1004, 000113 ("Olmos discloses a system for intervertebral fusion…").

(b) Claim 1[b]

Although Olmos does not expressly disclose a dilator having a proximal end and a tapered distal end for penetrating soft tissue, it would have been obvious to use a dilator to help insert Olmos' device in view of Boehm and/or Song. Boehm and Song each disclose this limitation, as discussed previously. *See* §IX(A)(1)(b); EX1002, ¶¶340-341.

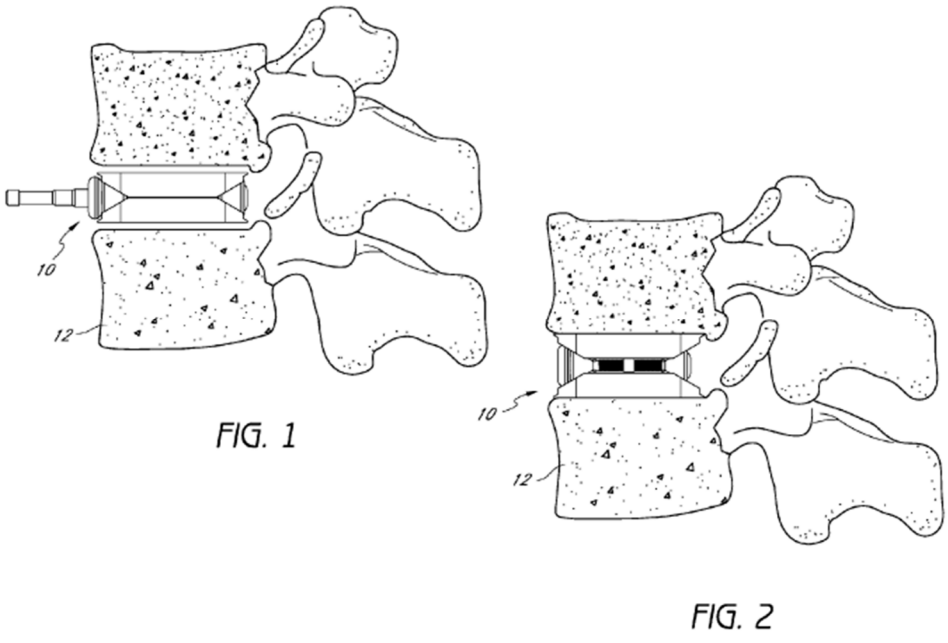
(c) Claim 1[c]

Although Olmos does not expressly disclose a cannula having a proximal end and a distal end, it would have been obvious to use a cannula to help insert Olmos' device in view of Boehm and/or Song. Boehm and Song each disclose this limitation, as discussed previously. *See* §IX(A)(1)(c); EX1002, ¶¶342-343.

(d) Claim 1[d]

Olmos discloses inserting the implant into an intervertebral space. Specifically, Olmos discloses "positioning the intervertebral implant **10** between two vertebral bodies." EX1006, ¶[0124]; *see also id.*, ¶¶[0017]-[0018], [0074]-[0075]. Figures 1-2 show Olmos's implant inserted into an intervertebral space:

Olmos, Figs. 1-2



Olmos further discloses that the implant is of sufficiently small size to be inserted into an intervertebral space through a cannula. Specifically, Olmos discloses an implant of about 7-15mm in height and 7-11mm in width (EX1006, ¶[0153]), which a POSITA would have recognized as of a sufficiently small size to be inserted through known cannulas. EX1002, ¶345.

Accordingly, Olmos discloses an intervertebral implant sized for insertion into an intervertebral space through a cannula. EX1002, ¶¶344-346; *see also* EX1004, 000113 ("Olmos discloses a system for intervertebral fusion comprising: an intervertebral implant sized for insertion into an intervertebral space through the cannula" without traverse).

Alternatively, to the extent Olmos does not expressly disclose inserting an implant into an intervertebral space through the cannula, it would have been obvious to do so as taught by Boehm and/or Song. Boehm and Song each disclose this limitation, as discussed previously. *See* §IX(A)(1)(d); EX1002, ¶¶347-348.

(e) Claim 1[e]

Olmos discloses a first endplate (e.g., "lower body portion **204**"), a second endplate (e.g., "upper body portion 202"), and a central ramp (e.g., "distal wedge member[]… **208**") disposed between the first endplate and the second endplate. EX1006, ¶¶[0021], [0152]. Figures 16A-B and 18 show this, with annotated Fig. 18 below.

Olmos, Fig. 18

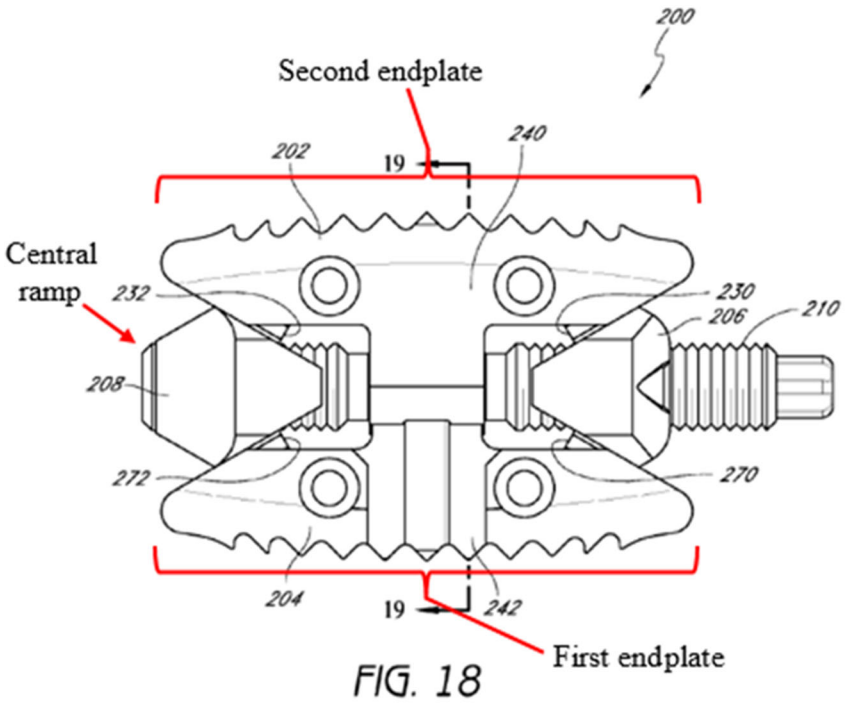


FIG. 18

Accordingly, Olmos discloses this limitation. EX1002, ¶¶349-352.

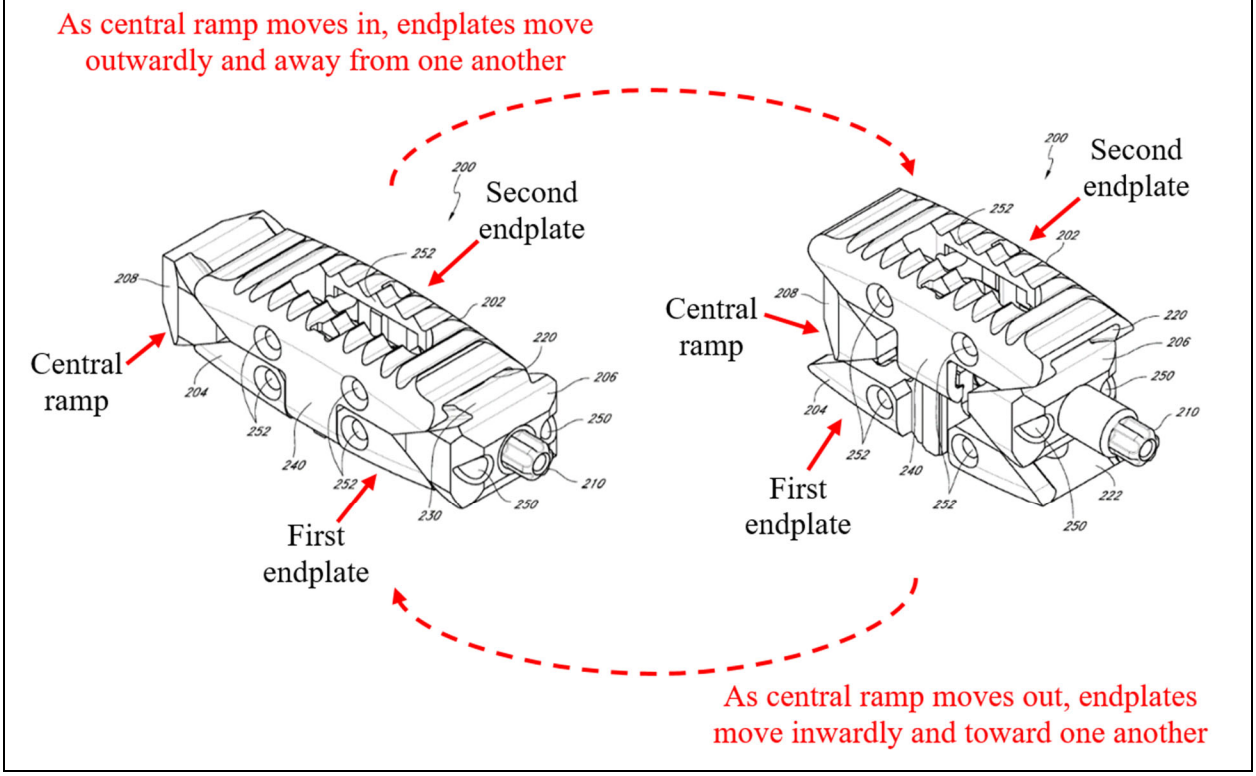
(f) Claim 1[f]

Olmos discloses a device configured "to draw the proximal and distal wedged members 68, 80 together to cause the implant to move to an expanded state." EX1006, ¶[0145]. More specifically:

> [U]pon rotation of the screw mechanism **150**, the proximal and distal wedged members **68**, **80** can be axially drawn closer together. As a result of this axial translation, the proximal and distal wedged members **68**, **80** can contact the respective ones of the proximal and distal surfaces **18**, **20** and **70**, **72** in order to facilitate separation of the upper and lower body portions **14**, **16.**

Id., ¶[0147]; *see also id.*, ¶¶[0145]-[0146], [0155] ("proximal and distal wedge members…move toward each other, thus causing the upper and lower body portions 202, 204 to be separated"). Annotated Figs. 16A-B follow, showing a device according to Olmos satisfying these limitations.

Olmos, Fig. 16A-B



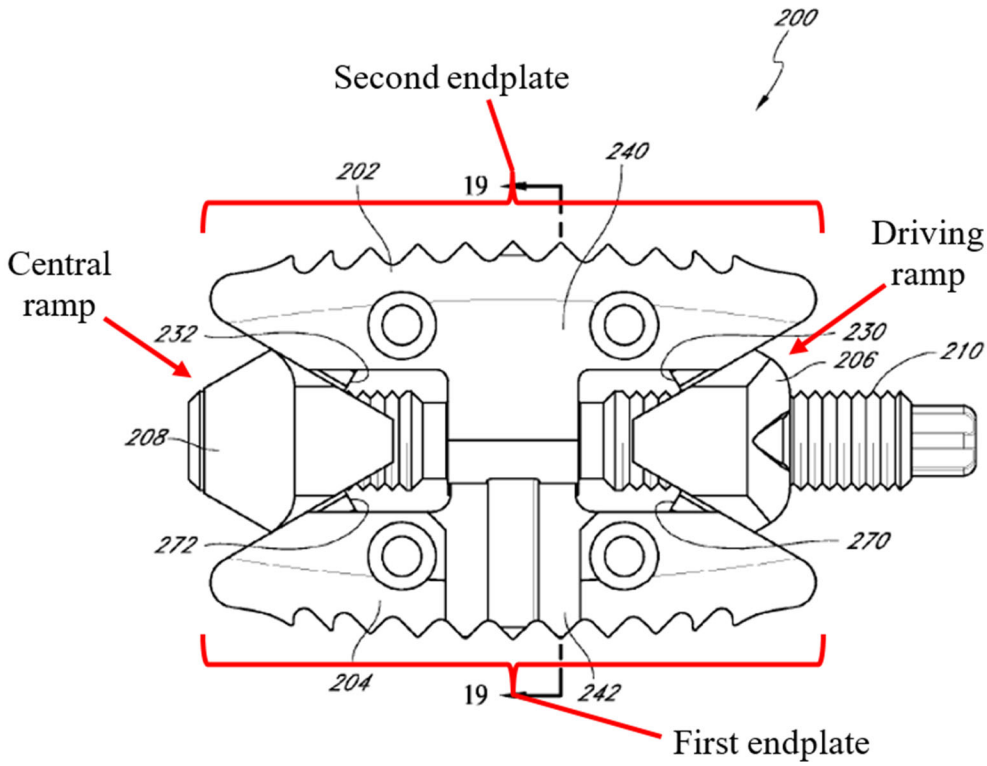
Accordingly, Olmos discloses this limitation. EX1002, ¶¶353-355.

(g) Claim 1[g]

Olmos discloses a driving ramp ("proximal wedge member **206**") disposed between the first and the second endplates at an opposite end of the endplates from

the central ramp. EX1006, ¶¶[0021], [0152], [0156]; Figs. 16A-B, 18. Annotated Fig. 18, below, shows this:

Olmos, Fig. 18

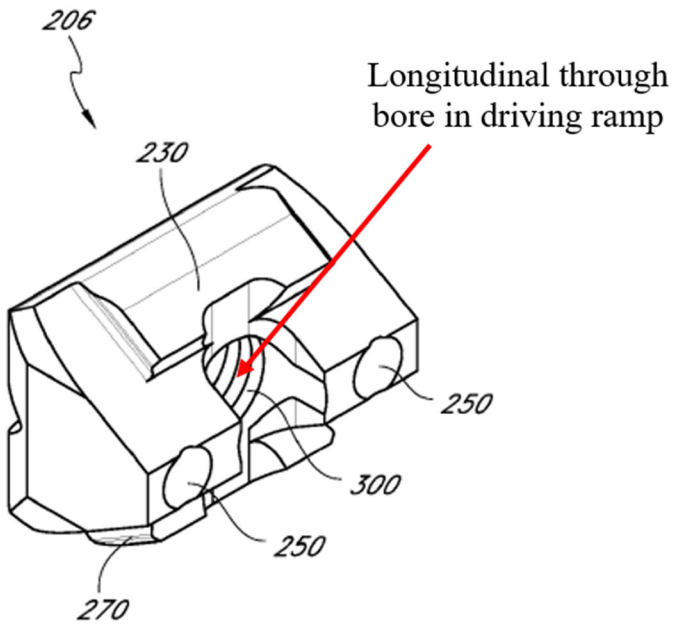


Accordingly, Olmos discloses this limitation. EX1002, ¶¶356-360.

(h) Claim 1[h]

Olmos discloses that the driving ramp/proximal wedge member 206 has a longitudinal bore ("comprise[s] a central aperture **300**…"). EX1006, ¶[0177]; *see also id.*, ¶¶[0159], [0174], Figs. 18, 23A-B. Annotated Fig. 23B follows.

Olmos, Fig. 23B

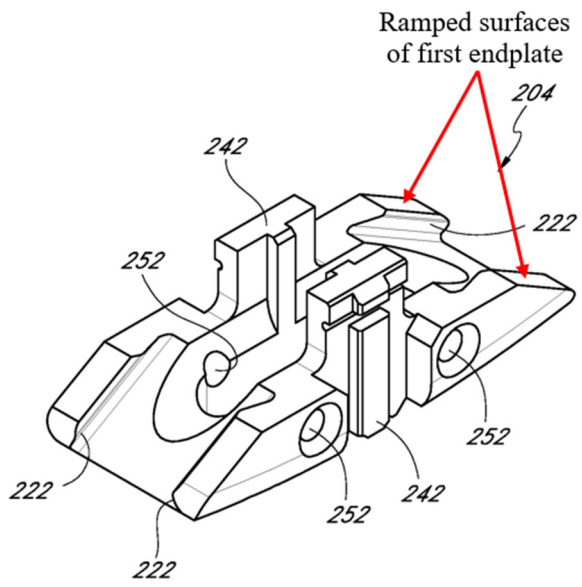
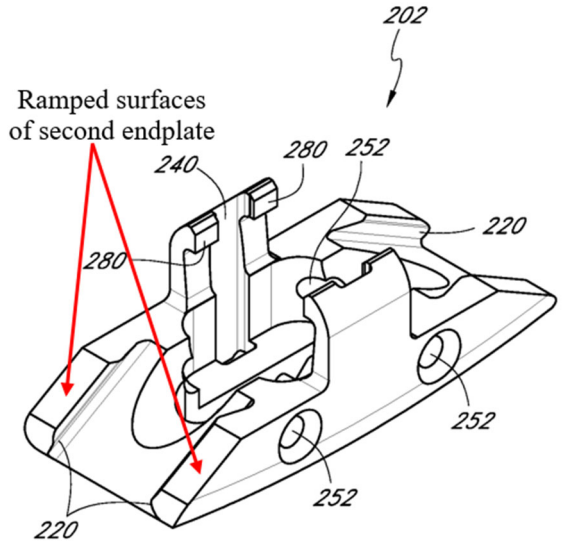


Accordingly, Olmos discloses this limitation. EX1002, ¶¶361-363.

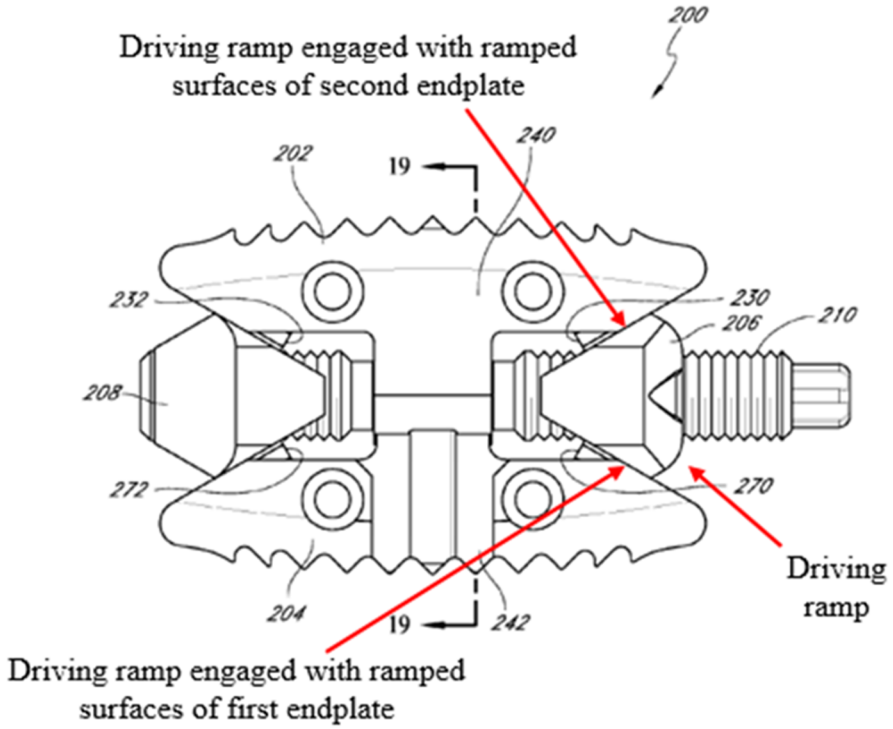
(i) Claim 1[i]

Olmos discloses that the driving ramp is configured to engage ramped surfaces of the first and second endplates. EX1006, Figs. 16A-B, 18, and 24A-B, ¶¶[0024] ("The implant can be configured wherein the proximal and distal surfaces of the upper and lower body portions are sloped."), [0111]-[0112] (distal and proximal wedge members "can be sized and configured to contact the distal [or proximal] surfaces…of the respective ones of the upper and lower body portions"), [0168] (describing "the angular relationship of the proximal and distal wedge members **206**, **208** and the upper and lower body portions **202**, **204**"). Annotated

Figs. 20A and 21A showing the ramped surfaces of the first and second endplate, and Fig. 18 showing the driving ramp engaged with those ramped surfaces, follow.

Olmos, Fig. 20A	**Olmos, Fig. 21A**
	

Olmos, Fig. 18



Accordingly, Olmos discloses these limitations. EX1002, ¶¶364-366.

(j) Claim 1[j]

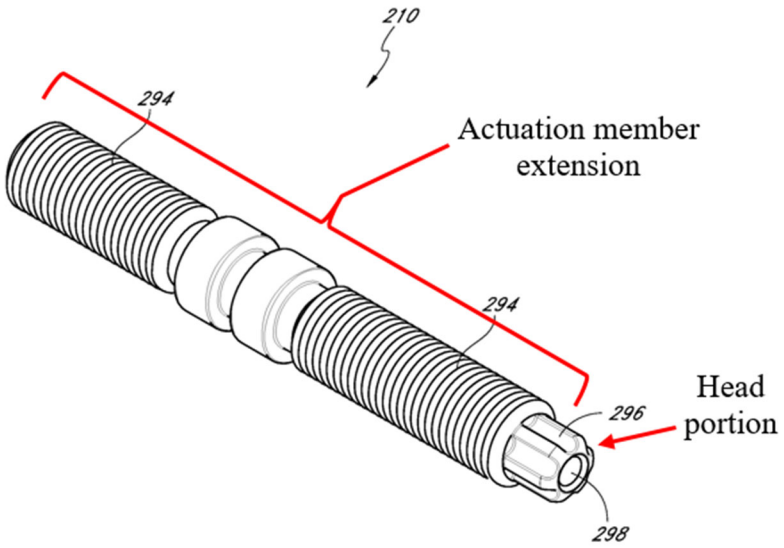
Claim 1 does not recite "a central ramp extension," which renders Claim 1 indefinite for lack of antecedent basis. However, assuming *arguendo* that this term refers Claim 12's "central ramp extension," this element is disclosed by Olmos. *See* §IX(D)(7)(a), *infra*.

Olmos discloses an actuation member comprising a head portion ("the actuator shaft **210** can also comprise a tool engagement section **296**") and an

actuation member extension (shaft portion). *See* EX1006, ¶[0175], Figs. 18, 22.

Annotated Fig. 22 showing these features follows:

Olmos, Fig. 22



Olmos further discloses that the driving ramp/proximal wedge member 206 has an unthreaded opening in a longitudinal through bore through which the actuation member extension of the actuation member extends ("central aperture **300** wherethrough an actuator shaft can be received," in which "the actuator shaft can engage other [non-threaded] portions of the wedge member **206** for causing expansion or contraction…"). EX1006, ¶[0177]; *see also id.*, ¶[0159] ("The actuator shaft **210** can include threads that threadably engage at least one of the proximal and distal wedge members **206**, **208**." (underline added)). Olmos also discloses that the central ramp/distal wedge member 208 has a threaded opening in

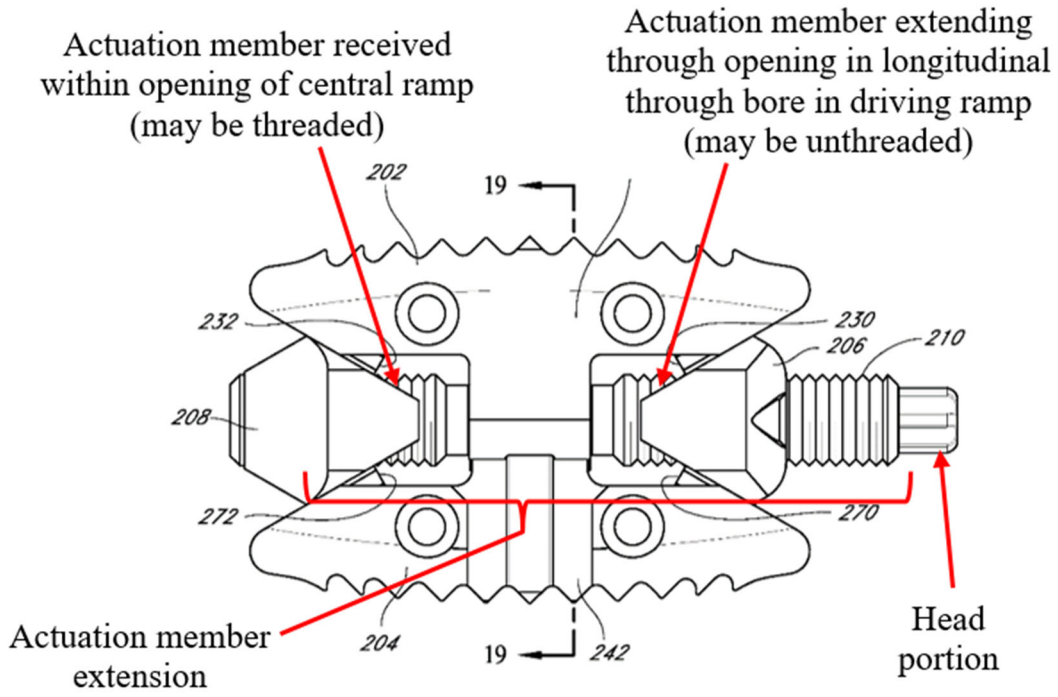
the extension into which the actuation member extension of the actuation member extends ("central aperture **302**…configured to receive an actuator shaft therethrough" which "can be threaded to correspond to the threads **294** of the actuator shaft **210**"). *Id*., ¶[0178]; *see also id*., ¶[0159] ("[A]t least a portion of the actuator shaft can be axially fixed relative to one of the proximal and distal wedge members **206**, **208** with the actuator shaft being operative to move the other one of the proximal and distal wedge members **206**, **208** via rotational movement or longitudinal contraction of the pin." (underline added)).

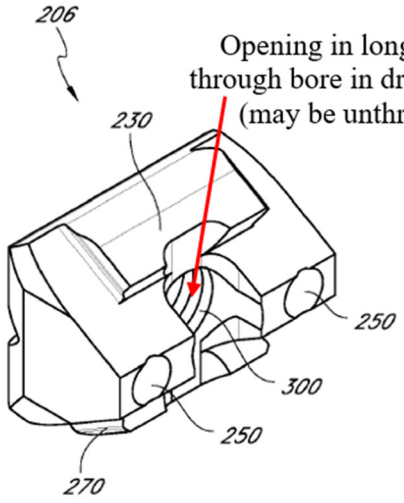
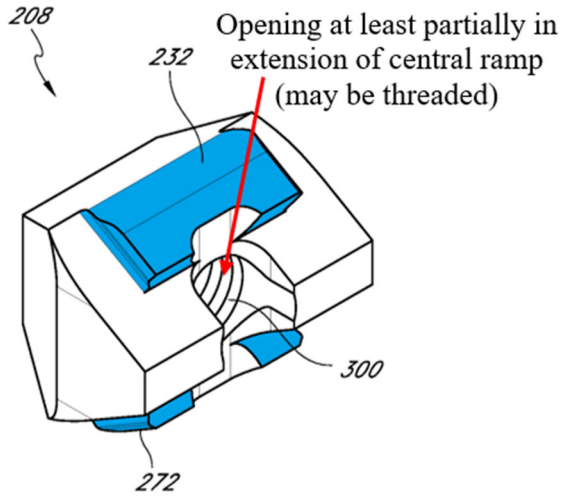
A POSITA would recognize from these disclosures (that the actuator can threadingly engage "at least one of" the wedges (i.e., need not be both), and that the actuator can be axially fixed relative to one of the wedges) that Olmos teaches an embodiment where the opening in the driving ramp is not threaded; specifically, if the actuation member were theadingly engaged with the driving ramp opening, it could not be "axially fixed" relative to the driving ramp, while moving the central ramp when the actuator is rotated. EX1002, ¶¶375-3789.

Figs. 18, 23A-B, and 24A-B also show that the actuation member extension of the actuation member extends through an opening in the driving ramp and into an opening in the extension of the central ramp. Annotated Figs. 18, 23B, and 24B follow showing the central ramp's extension in blue, appreciating that as noted

above, Olmos alternatively teaches that the actuator's extension can non-threadingly engage the driving ramp.

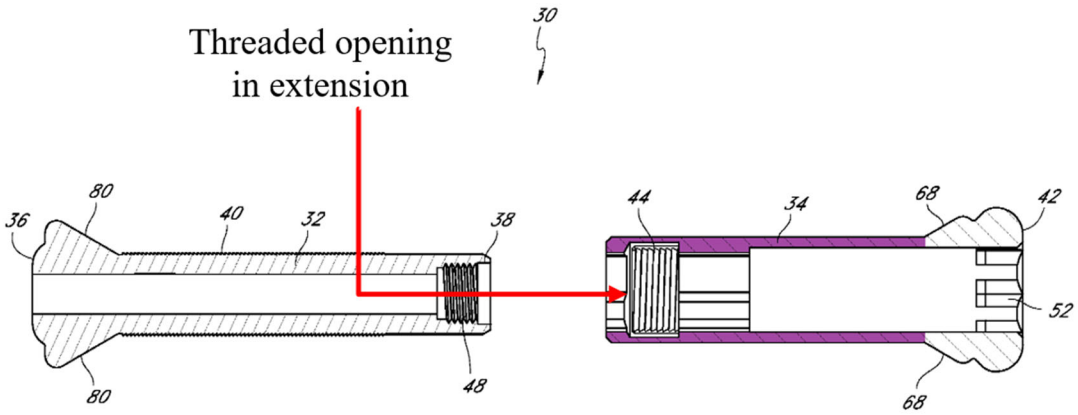
Olmos, Fig. 18



Olmos, Fig. 23B	**Olmos, Fig. 24B**
	

Likewise, where the extension of the Fig. 8 embodiment is combined with the Fig. 16-26 embodiment (*see* §IX(D)(7)(a), *infra*), the extension has a threaded opening, as seen in annotated Fig. 8, with the extension in purple:

Olmos, Fig. 8

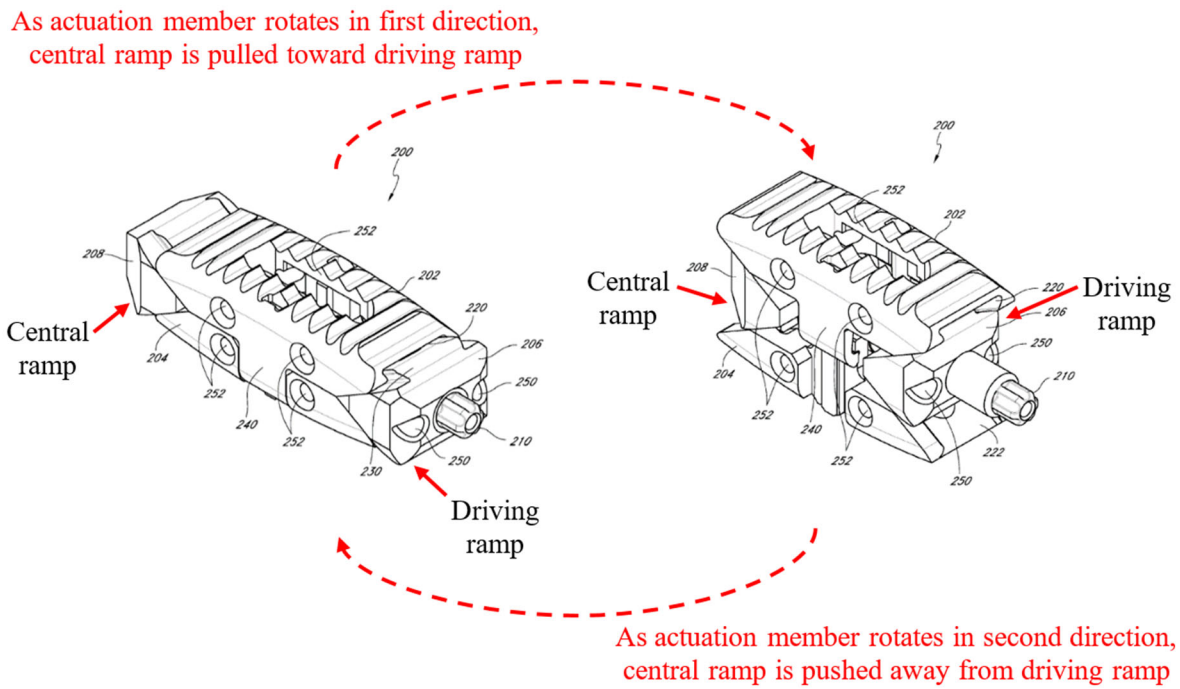


Accordingly, Olmos discloses these limitations. EX1002, ¶¶367-383.

(k) Claim 1[k]

Olmos discloses that the actuation member/actuator shaft 210 rotates in a first direction to move the central ramp towards the driving ramp, forcing the first and second endplates to move outwardly. EX1006, ¶¶[0155], [0159]. The relative movement of the ramps and endplates can also be observed at least by comparing Figs. 16A and B:

Olmos, Figs. 16A-B



Accordingly, Olmos discloses these limitations. EX1002, ¶384-386.

(l) Claim 1[l]

Olmos discloses both that rotating the actuator causes the wedges to move together and the endplates to move apart, and that the actuator shaft can be axially fixed relative to one wedge while moving the other wedge. EX1006, ¶¶[0155], [0159]; *see also id.*, ¶¶[0145]-[0146]; EX1002, ¶¶387-388. In embodiments where the actuator shaft is "axially fixed relative to" proximal wedge member 206/driving ramp, distal wedge member 208/central ramp will move in either a first or second direction when the actuation member is rotated. *See* §§IX(D)(1)(f), IX(D)(1)(k)

(describing movement of central ramp in first direction and second direction), *supra*.

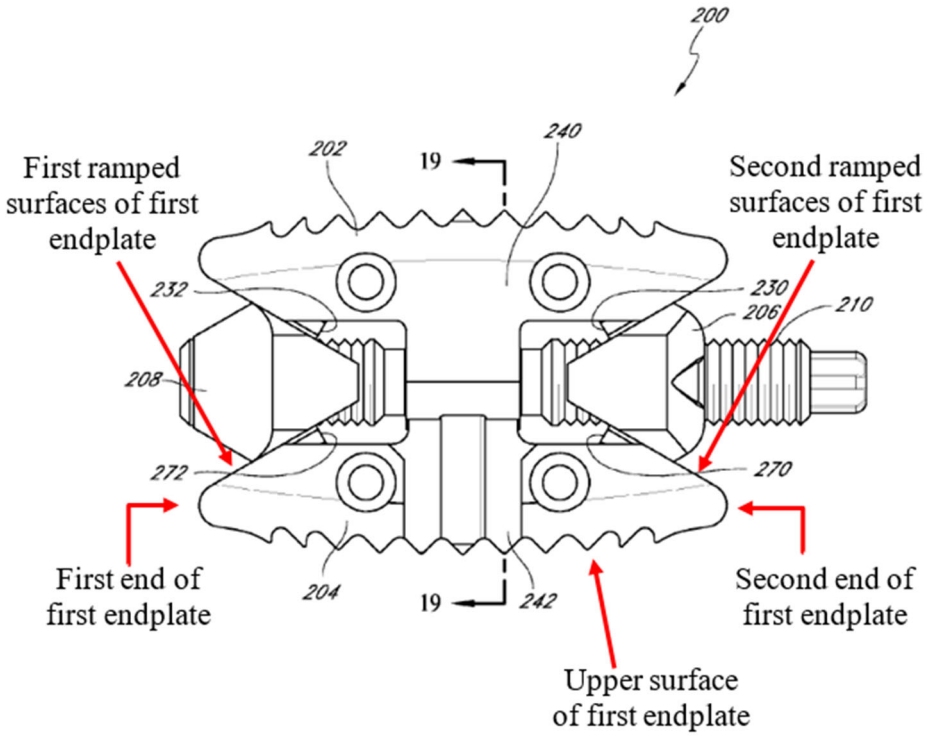
Accordingly, Olmos discloses these limitations. EX1002, ¶¶387-390.

2. Claim 7

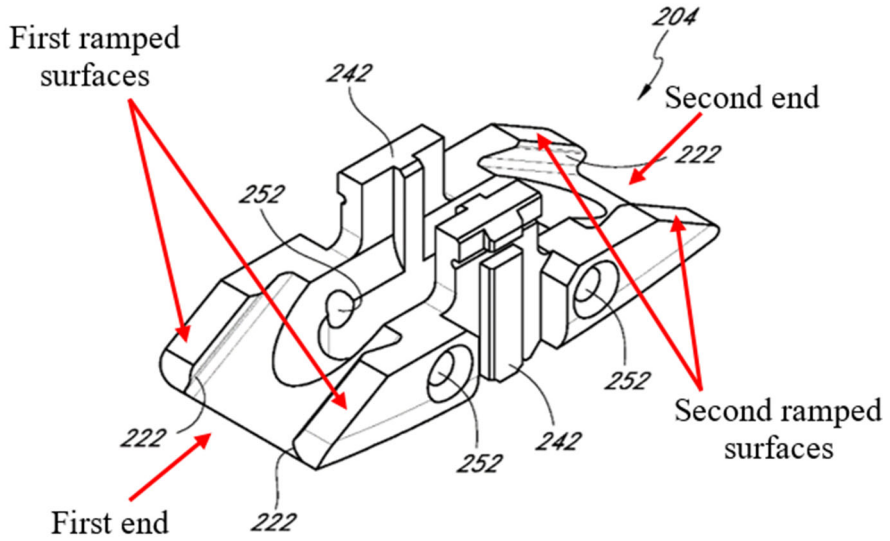
(a) Claim 7[a]

Olmos' first endplate has a first end and a second end, which are connected by an upper surface. *See* EX1006, ¶¶[0152], [0020] (describing "proximal and distal ends" of upper and lower body portions 202, 204). Olmos further discloses that the "proximal and distal surfaces of the upper and lower body portions are sloped," thus teaching first ramped surfaces on either side of the first endplate proximate the first end and second ramped surfaces on either side of the first endplate proximate the second end. *Id.*, ¶[0024], Figs. 20A-B. Figures 16-18 and 20A-B further show these structures, as well as the endplate's upper surface connecting the first end and the second end. Annotated Figs. 18 and 20A follow.

Olmos, Fig. 18



Olmos, Fig. 20A

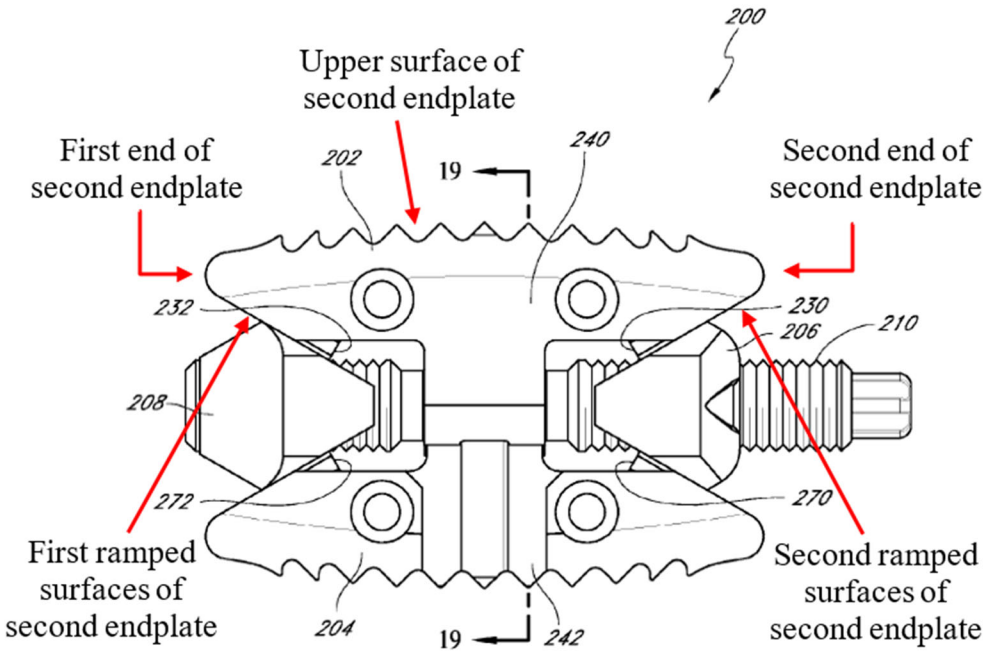


Accordingly, Olmos discloses these limitations. EX1002, ¶¶391-393.

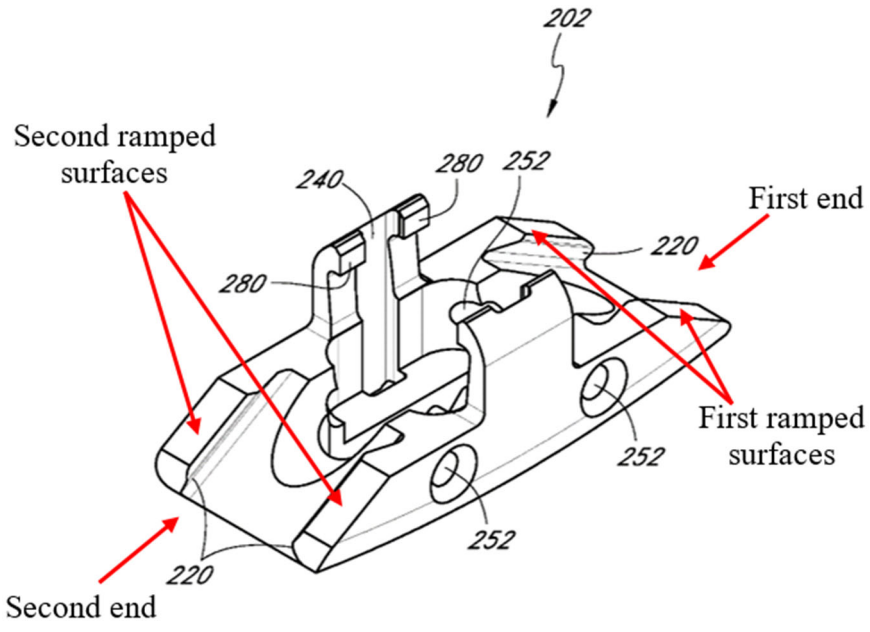
(b) Claim 7[b]

Olmos' second endplate has first and second ends. *See* EX1006, ¶¶[0152], [0020] (describing "proximal and distal ends" of upper and lower body portions 202, 204). Olmos further discloses first ramped surfaces on either side of the second endplate proximate the first end, and second ramped surfaces on either side of the second endplate proximate the second end. *Id.*, ¶[0024], Figs. 21A-B. Figures 16-18 and 21A-B further show these structures, as well as the endplates' respective upper and lower surfaces connecting the first end and the second end. Annotated Figs. 18 and 21A follow.

Olmos, Fig. 18



Olmos, Fig. 21A



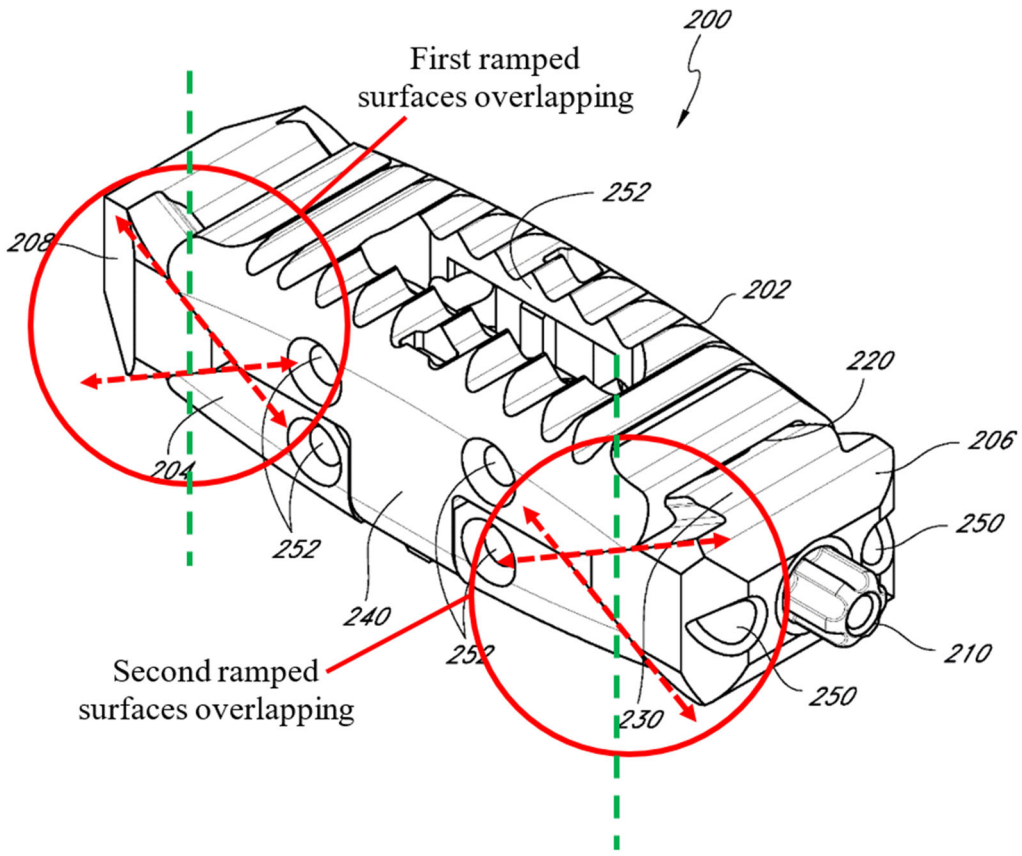
Accordingly, Olmos discloses these limitations. EX1002, ¶¶394-395.

3. Claim 8

As broadly claimed here, Olmos discloses that the first endplate's first ramped surfaces overlap the second endplate's first ramped surfaces and that the first endplate's second ramped surfaces overlap the second endplate's second ramped surfaces when Olmos's device is in an unexpanded configuration. EX1006, Figs. 16A-B, 18.

The broadly claimed "overlap" between these ramped surfaces can be observed in at least two ways. First, the ramped surfaces overlap because the angles of the ramped surfaces intersect. Second, the ramped surfaces overlap because the ramped surfaces reside opposite each other (i.e., one over the other) within a given plane. Annotated Fig. 16A follows with the overlapping ramped surfaces denoted by red dashed arrows and the plane of overlap denoted by green dashed lines.

Olmos, Fig. 16A



Moreover, the foregoing is consistent with the '732 patent disclosure of "overlapping" ramped components. *See* §IX(A)(3), *supra*.

Accordingly, Olmos discloses this limitation. EX1002, ¶¶396-399.

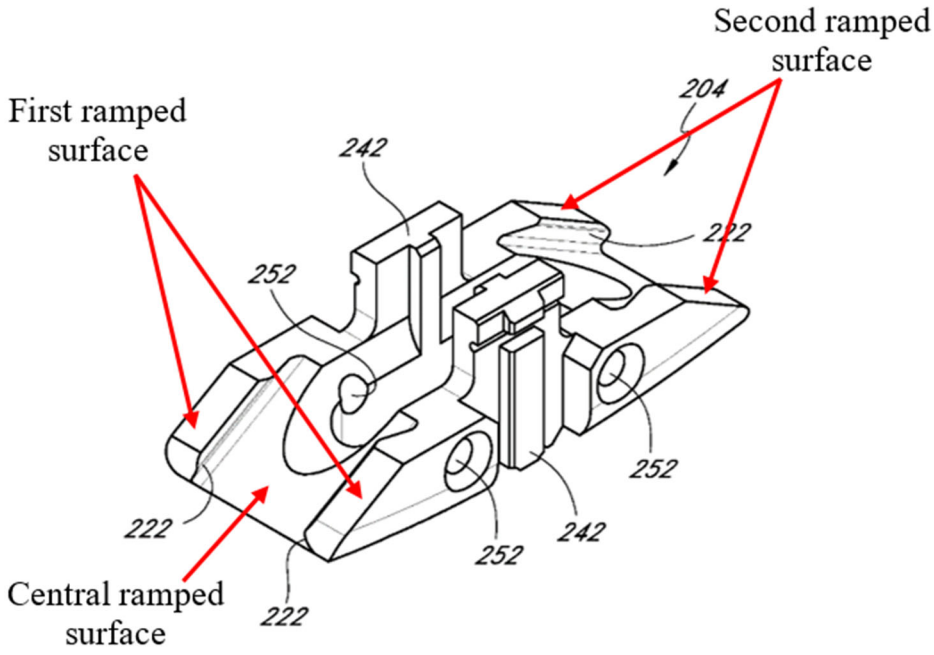
4. Claim 9

(a) Claims 9[a] and 9[b]

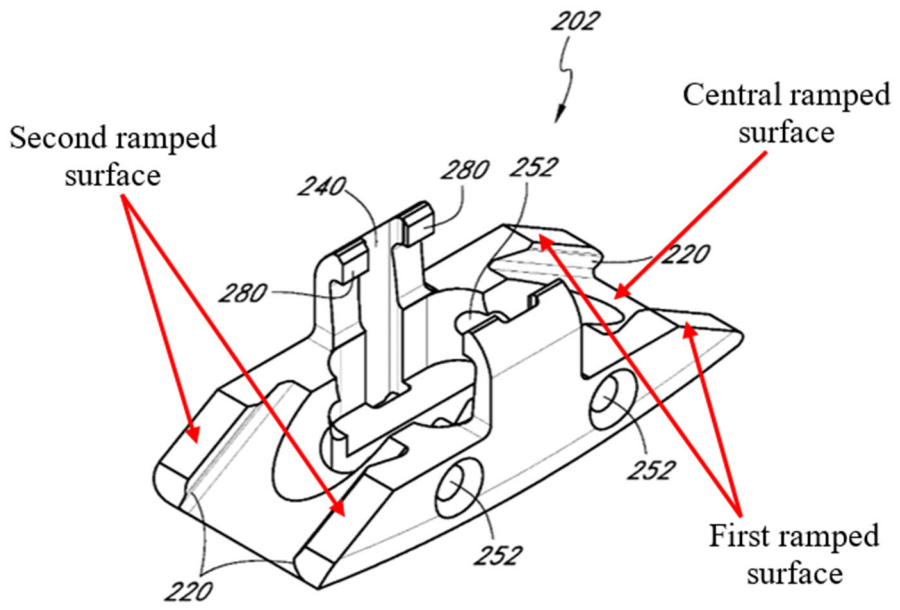
Olmos discloses that lower body portion 204 has a central ramped surface disposed between the first and second ramped surfaces in the form of the ramped, recessed surface of the dovetail-shaped groove formed between slots 222 and

central ramped surface disposed between the first and second ramped surfaces in the form of the ramped, recessed surface of the dovetail-shaped groove formed between slots 220. *See* EX1006, ¶¶[0167]-[0168], [0170]; Figs. 16B, 18, 20A-B, 21A-B. Annotated Figs. 20A and 21A showing these features follow:

Olmos, Fig. 20A



Olmos, Fig. 21A



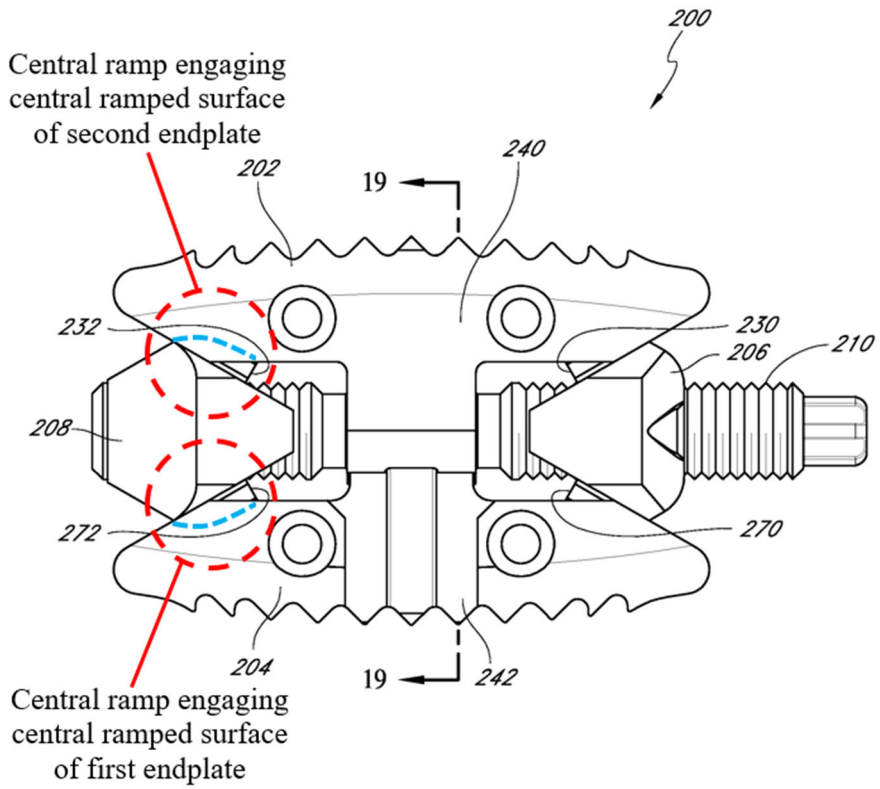
Accordingly, Olmos discloses these limitations. EX1002, ¶¶400-405.

(b) Claim 9[c]

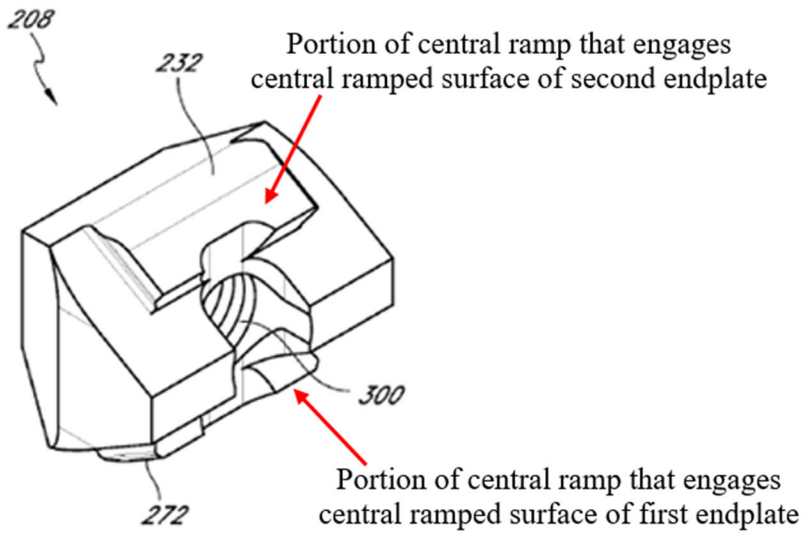
Olmos discloses that the central ramped surfaces of the first and second endplates engage with the central ramp. Specifically, Olmos discloses that wedge member 208's upper guide member 232 may be inserted into the upper body portion 202's slots 220 and wedge member 208's lower guide member 272 may be inserted into lower body portion 204's slots 222. EX1006, ¶¶[0167]-[0168] ("the dovetail shape of the slots and guide members ensures that for each given slot and guide member, a given wedge member is generally interlocked with the give slot"), [0170], [0173], Figs. 16A-B, 18, 20A-B, 21A-B, 23A-B. Thus, "the proximal and

distal wedge members 206, 208 are securely engaged with the upper and lower body portions 202, 204," with the aforementioned central ramped surfaces engaging upper and lower guide members 232, 272. *See id.*, ¶[0167]. Annotated Olmos Figs. 18 and 24B follow, with the guide members' surfaces that contact the central ramped surfaces approximated in blue in Fig. 18:

Olmos, Fig. 18



Olmos, Fig. 24B



Accordingly, Olmos discloses these limitations. EX1002, ¶¶406-408

5. Claim 10

Olmos discloses this limitation. *See* §IX(D)(3); EX1002, ¶¶409-411.

6. Claim 11

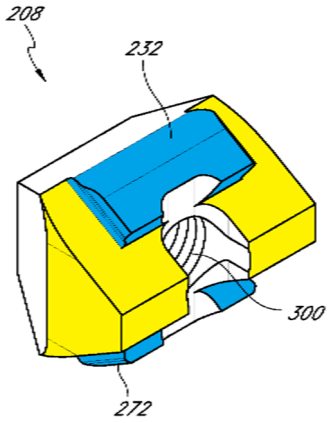
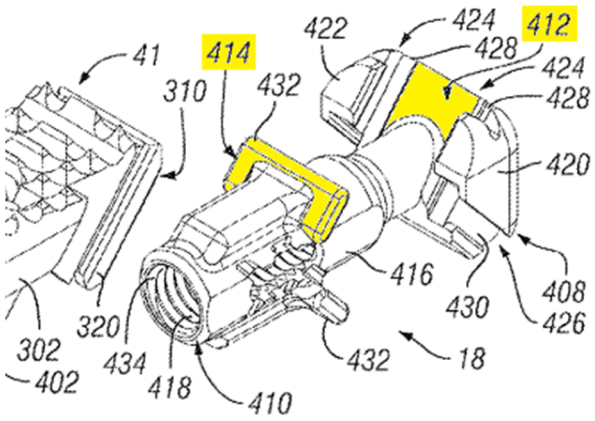
Olmos discloses this limitation. *See* §IX(D)(3); EX1002, ¶¶412-414.

7. Claim 12

(a) Claim 12[a]

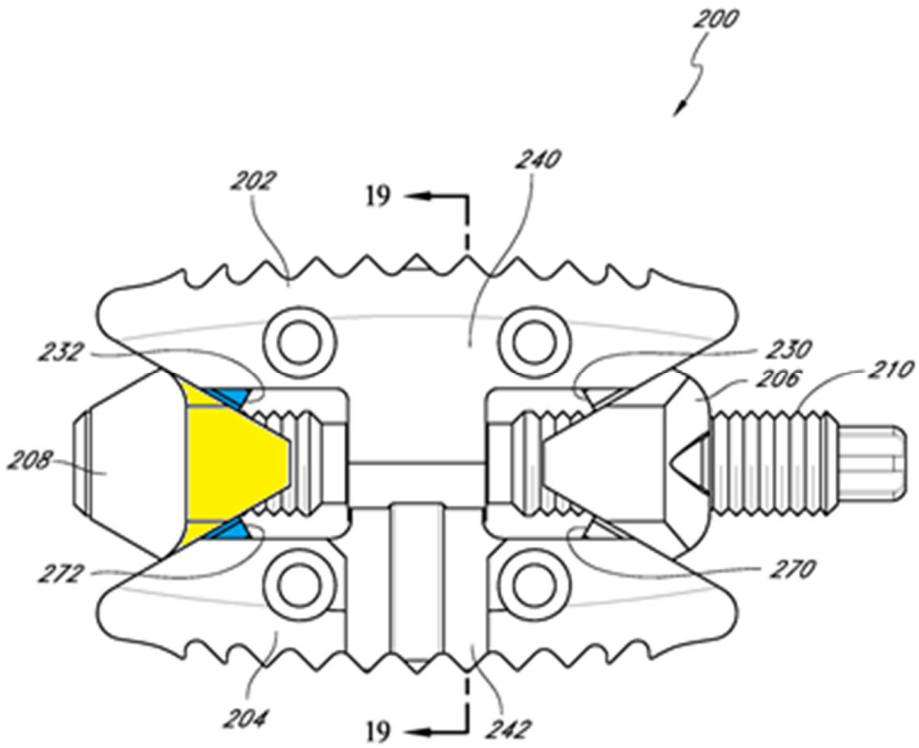
Olmos discloses that the central ramp/distal wedge member 208 has an expansion portion in the form of a broad ramped surface extending on each side of guide members 232, 272 and towards the base of distal wedge member 208, which is comparable to the "first expansion portion 412" and/or the "second expansion portion 414" shown in '732 Fig. 52. EX1006, ¶[0178], Fig. 16B, 18, 24B; EX1001,

19:1-6, Fig. 52; EX1002, ¶416. Annotated excerpts of Olmos Fig. 24B and '732 Fig. 52 follow with their respective expansion portions in yellow:

Olmos, Fig. 24B	**'732 Patent, Fig. 52**
	

Regarding the "extension," Olmos discloses that the central ramp has an extension ("guide members **232**, **272**") extending in a longitudinal axis from the expansion portion. EX1006, ¶¶[0156], [0178]. Olmos teaches that "guide member **232**" "at least partially extends into a respective slot of the upper and lower body portions." *Id*., ¶[0156]. Figures 16B, 18, and 24B, which also disclose guide member 272 as a second extending guide member on the opposite side of distal wedge member 208, illustrate this. Distal wedge member 208/central ramp's extending guide members 232, 272 are highlighted in blue in annotated Figs. 24B, *supra*, and 18, below.

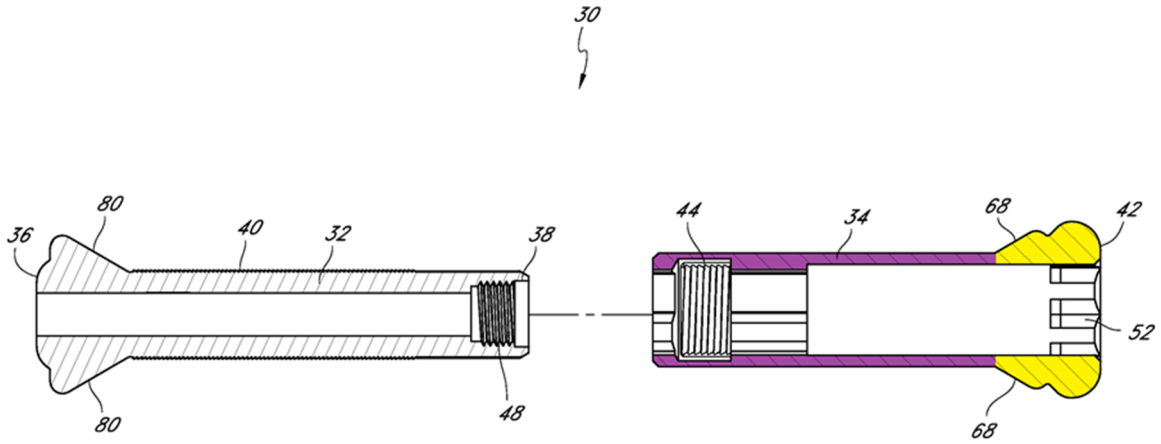
Olmos, Fig. 18



Alternatively, it would have been obvious to add a further extension to the central ramp as shown in Olmos Fig. 8's alternative embodiment. In this embodiment, Olmos discloses that "proximal wedge member **68** [i.e., driving ramp] can also be integrally formed with and/or permanently coupled to [an] outer sleeve member **34**," which extends longitudinally from an expansion portion of the driving ramp/proximal wedge and receives the actuator shaft 30. *See also id*., ¶¶[0106]-[0107]. As seen in Fig. 8, outer sleeve member 34 further has an internally threaded "retention structure[]…**44**" for engaging the threaded "retention structure[] **40**" of the distal wedge/central ramp's inner member 32 and aiding in

expansion and contraction of the device, similar to how the actuation member is used in other embodiments. *Id*., ¶[0090]. Annotated Fig. 8, showing the outer sleeve member 34 in purple and the proximal wedge/driving ramp expansion portion in yellow, follows.

Olmos, Fig. 8



Accordingly, Olmos discloses these limitations. EX1002, ¶¶415-422.

(b) Claim 12[b]

Olmos' central ramp is configured to engage the first and second endplates at least through guide members 232, 272 extending into the dovetail-shaped grooves formed by slots 220, 222 and engaging the endplates' respective central ramped surfaces. *See* §IX(D)(4)(b), *supra*. Additionally, Olmos discloses that other portions of the central ramp engage the first and second endplate. For example,

Figs. 16A-B and 18 show the central ramp engaging the endplates' first ramped surfaces. Annotated Fig. 18 follows:

Olmos, Fig. 18

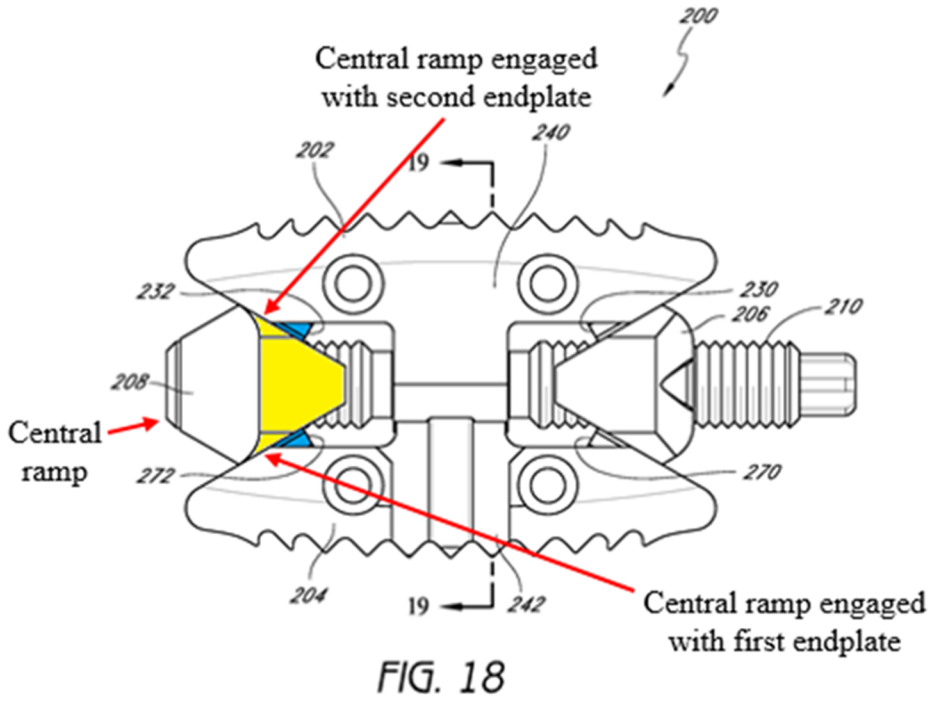


FIG. 18

Accordingly, Olmos discloses this limitation. EX1002, ¶¶423-425; *see also* §IX(D)(4)(b), *supra*.

8. Claim 13

(a) Claim 13[a]

Olmos discloses this limitation. *See* §IX(D)(1)(a); EX1002, ¶426.

(b) Claim 13[b]

Olmos discloses this limitation. *See* §IX(D)(1)(b); EX1002, ¶¶427-428.

(c) Claim 13[c]

Olmos discloses this limitation. *See* §IX(D)(1)(c); EX1002, ¶¶429-430.

(d) Claim 13[d]

Olmos discloses this limitation. *See* §IX(D)(1)(d); EX1002, ¶¶431-432

(e) Claim 13[e]

Olmos discloses this limitation. *See* §IX(D)(2)(a); EX1002, ¶¶433-434.

(f) Claim 13[f]

Olmos discloses this limitation. *See* §IX(D)(2)(b); EX1002, ¶¶435-436.

(g) Claim 13[g]

Olmos discloses this limitation. *See* §IX(D)(3); EX1002, ¶¶437-438.

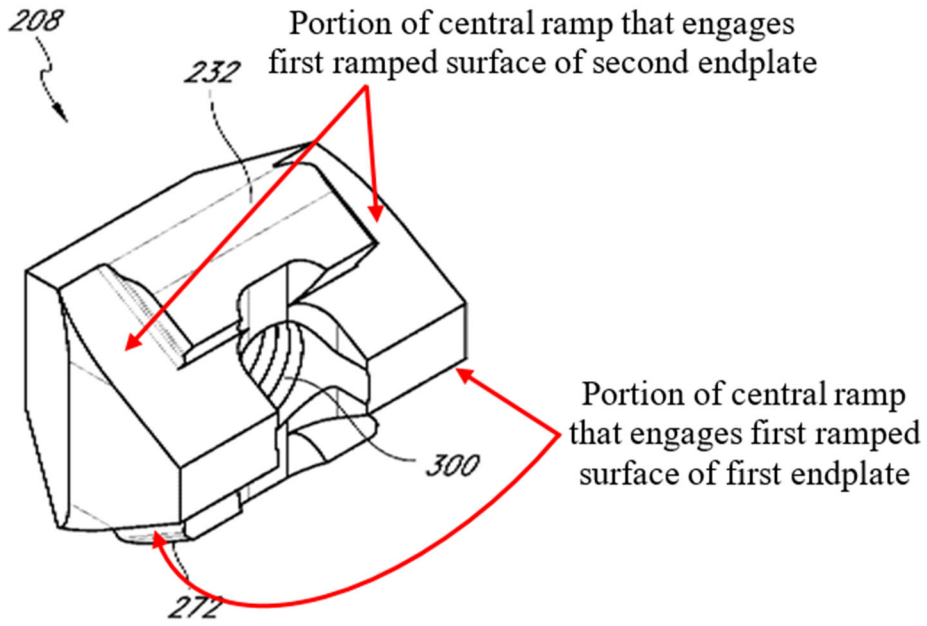
(h) Claim 13[h]

Olmos discloses this limitation. *See* §IX(D)(1)(e); EX1002, ¶¶439-440.

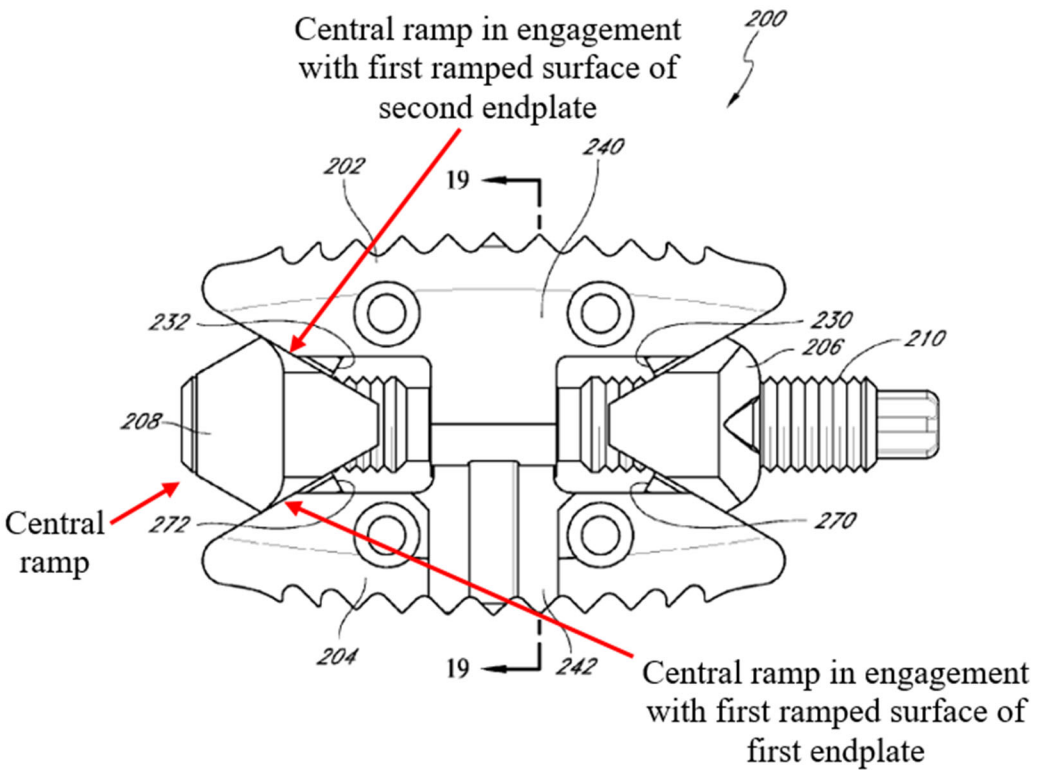
(i) Claim 13[i]

Olmos's central ramp is configured to engage the first ramped surfaces of the first and second endplates. EX1006, ¶¶[0024], [0111]-[0112] ("distal wedge member 80 can be…configured to contact the distal surfaces 70, 72 of the respective ones of the upper and lower body portions 14, 16"), Figs. 16A-B, 18, and 24A-B; *see also id.*, ¶¶[0168], [0178]. Annotated Figs. 24B and Fig. 18, below, show this.

Olmos, Fig. 24B



Olmos, Fig. 18



Accordingly, Olmos discloses this limitation. EX1002, ¶¶441-443.

(j) Claim 13[j]

Claim 13 does not recite "an expansion portion of the central ramp," thus rendering Claim 13 indefinite for lack of antecedent basis. However, assuming *arguendo* that this refers to Claim 12's "ramped expansion portion," this element is disclosed by Olmos. *See* §§IX(D)(7)(a), IX(D)(1)(g); EX1002, ¶¶444-446.

(k) Claim 13[k]

Olmos discloses this limitation. *See* §§IX(D)(1)(h), IX(D)(1)(i); EX1002, ¶¶447-448.

(l) Claim 13[l]

Claim 13 does not recite "a central ramp extension," thus rendering Claim 13 indefinite for lack of antecedent basis. However, assuming *arguendo* that this refers to Claim 12's "central ramp extension," this element is disclosed by Olmos. *See* §§IX(D)(7)(a), IX(D)(1)(j); EX1002, ¶¶449-451.

(m) Claim 13[m]

Olmos discloses this limitation. *See* §§IX(D)(1)(f), IX(D)(1)(k), IX(D)(1)(l); EX1002, ¶¶452-453.

(n) Claim 13[n]

Olmos discloses this limitation. *See* §IX(D)(1)(l); EX1002, ¶¶454-455.

9. Motivation to Combine

(a) Combination of Olmos with Boehm and/or Song

As with Chung, a POSITA would have been motivated to combine Olmos with Boehm and/or Song, specifically regarding the use of dilators and cannulas to create an access path to an intervertebral space and insert the intervertebral implant, with a reasonable expectation of success. A POSITA would have recognized that the device of Olmos must be inserted into an intervertebral target site and that, as such, tools would be needed to create an access path to the site and guide/insert the device where desired. EX1002, ¶458. Indeed, the Examiner found

obvious the combination of Boehm with Olmos (EX1004, 000119), which was not traversed by Applicant.

Moreover, as discussed previously, it was well-known in the art to use dilators and cannulas at the time of invention, as Song and Boehm themselves explain. *See* §IX(A)(6), *supra*. A POSITA thus would have been aware of the use of dilators and cannulas in the field and would have been motivated to consider and follow the teachings of prior art providing examples of such tools, including Boehm and/or Song, to implant the Olmos device. EX1002, ¶457.

Given that it was well-known to use tools to create an access path to the intervertebral space in the field of spinal surgery, a POSITA would have had a reasonable expectation of success in using common tools, such as the dilators and cannulas of Boehm and Song, in combination with Olmos's device, including using a dilator to distract the disc space and a cannula to insert/guide the Olmos device into the intervertebral disc space. EX1002, ¶¶457-459. Furthermore, as noted above, Olmos expressly discloses the small size of its device, and a POSITA would have recognized that a device of that size could be inserted through common-sized cannulas. *See* §IX(D)(1)(d), *supra*.

Furthermore, a POSITA would have had a reasonable expectation of success in doing so given the similarities between Olmos's device and the Boehm/Song devices. For example, like Olmos, Boehm and Song each disclose an intervertebral

implant that is inserted into a disc space for purposes of intervertebral fusion. *E.g.,* EX1029, ¶¶[0009], [0015], [0054]; EX1028, ¶¶[0017], [0032]-[0033] (further describing the implant as expandable). A POSITA would have reasonably understood and expected that means for creating an access path into an intervertebral disc space for one such device (Boehm or Song) would also work for another, similar device (Olmos). EX1002, ¶460.

Thus, it would have been obvious to a POSITA to combine the teachings of Boehm and/or Song regarding the use of dilators and cannulas with Olmos. EX1002, ¶¶456-460.

(b) Combination of Olmos Embodiments

A POSITA would have been motivated to combine Fig. 8's teaching of an extension to the distal wedge/central ramp with the embodiment(s) of Figs. 16-26 for several reasons. EX1002, ¶¶461-466. First, a POSITA would have understood that Fig. 8's extension allows the actuator to engage with the distal wedge member/central ramp more quickly and over a greater distance, while allowing use of a shorter actuator/screw. *Id.*, ¶¶462-463. This would make the connection between the wedges stronger, while serving Olmos' stated purpose of maintaining minimally invasive surgical procedures since the actuator will not need to stick out the far end of the central ramp when the device is expanded. *Id*. Second, adding Fig. 8's extension to Fig. 16-24's embodiment would preserve the structurally

advantageous, interconnecting components of the primary embodiments, including the ramp's guide members and the endplate's slots. *Id*.; EX1006, ¶[0156] ("The arrangement of the slots and the guide members can enhance the structural stability and alignment of the implant 200."). Third, an integrally-formed extension advantageously requires fewer parts, which facilitates both manufacturing and use, as recognized by Olmos. EX1006, ¶[0107]; EX1002, ¶464.

The motivations to combine these emodiments are not negated by Olmos's Fig. 8 illustrating a reversed threaded engagement from that described in the '732 patent claims (e.g., the internally threaded extension in Fig. 8 stemming from the proximal wedge/driving ramp, rather than from the distal wedge/central ramp). These configurations are simple mirror images of each other, with no difference in their functionality or purpose. EX1002, ¶465. Adding a threaded extension to the distal wedge/central ramp would have been most logical for a POSITA considering the advantages of embodiment(s) of Figs. 16-26, simply because the actuator in those figures is inserted through the proximal wedge/driving ramp, and the advantages associated with the disclosed extension would have been realized because the purpose of the extension is to improve engagement of the actuator threads with the ramp threads over a greater distance. A POSITA would have recognized that adding an extension in accordance with Olmos' Fig. 8 to the distal wedge/central ramp would result in the aforementioned advantages. Accordingly,

the teachings regarding Fig. 8 would have motivated a POSITA to add an extension with a threaded opening to the central ramp. EX1002, ¶¶465.

A POSITA further would have been motivated and had a reasonable expectation of success in doing so, since it merely involves the combination of known mechanical elements that do not interact in any surprising or unexpected way, rendering ithe modification a simple, obvious substitution. *KSR Int'l Co. v. Teleflex*, 550 U.S. 398, 417 (2007). Indeed, Olmos expressly teaches that "all features discussed in connection with any one embodiment herein can be readily adapted for use in other embodiments herein to form various combinations and sub-combinations," and that integrally formed extensions like that in Fig. 8 are common and relatively simple to manufacture. *Id.*, ¶¶[0107], [0188]; EX1002, ¶466.

Moreover, during prosecution of the '637 Application, of which the '732 patent is a continuation-in-part, the Examiner combined the embodiment of Figs. 16-26 with similar Olmos embodiments (e.g., Fig. 5), noting that it "would have been obvious to one having ordinary skill in the art at the time the invention was made having the teachings of Olmos in front of him/her to modify the implant of Olmos (as shown in Figs 16a-26) to substitute the [features] as taught in another embodiment of Olmos." *See, e.g.,* EX1037, 000063-64, 000072-73, 000132-33,

000137-38. Notably, this "other embodiment" was frequently that depicted in Figs. 1-6, which is very similar to Fig. 8. *Id.*

E. Ground 5: Claims 1 and 7-13 are obvious over Olmos in view of Boehm and/or Song, and further in view of Chung

Claims 1 and 7-13 are obvious under 35 U.S.C. §103 over Chung in view of Boehm and/or Song as detailed above, and further in view of Chung as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶467-484).

1. Claims 1 and 13

Olmos with Boehm and/or Song disclose every limitation of Claims 1 and 13, as discussed previously. *See* §§IX(D)(1), IX(D)(8).

Alternatively, should Olmos be found to not teach an unthreaded driving ramp through bore, it would have been obvious to modify Olmos' driving ramp/proximal wedge to have an unthreaded opening as required by Claim 1[j] in view of Chung. *See infra* §IX(E)(3). As noted in §IX(A)(1)(j), *supra*, Chung expressly discloses this limitation. EX1002, ¶¶467, 469-470.

Likewise, should Olmos' tool engagement section 296 of actuator shaft 210 be found to not comprise a "head portion" as recited in Claims 1[j] and 13[l], it would have been obvious to use the actuator disclosed in Chung having a head portion. *See* §IX(A)(1)(j), *supra*.; EX1002, ¶467-468, 470.

2. Claims 7-12

Claims 7-12 depend either directly or indirectly from Claim 1. As discussed above, all elements added by these claims are expressly disclosed in Olmos. *See* §§IX(D)(2)-(7), *supra*. Accordingly, as with Claim 1, Olmos with Boehm and/or Song and further with Chung discloses the limitations of Claims 7-12. EX1002, ¶471.

3. Motivation to Combine

A POSITA would have been motivated to combine Olmos with Boehm and/or Song, as discussed previously. *See* §IX(D)(9), *supra*. A POSITA would have been motivated to further combine Olmos with Chung with a reasonable expectation of success. EX1002, ¶¶472-484.

To begin with, Olmos teaches that "the actuator shaft can engage other portions of the wedge member **206** for causing expansion or contraction thereof," through means other than threads. EX1006, ¶[0177]; EX1002, ¶480. Chung expressly discloses an actuator that non-threadingly engages portions of the driving ramp. *See, e.g.*, §IX(A)(1)(j), *supra*. Because Chung also teaches that the actuator-receiving opening in the driving ramp lacks threads (*id.*), a POSITA would have understood that, where the actuator engages unthreaded portions of the driving ramp as in both Olmos and Chung, a threaded actuator-receiving opening would be superfluous. A POSITA therefore would have been motivated to simplify the

Olmos design by omitting any such threads to improve the manufacturing and operation of the device. EX1002, ¶¶480-482.

Another motivation to replace Olmos' actuator with Chung's is that, the tool engagement section 296 of Olmos' actuator extends beyond the end of the driving ramp regardless of whether the device is expanded (*see* EX1006, Figs. 16B, 18) or unexpanded (*see id.*, Fig. 16A). In contrast, the head of Chung's actuator is recessed within the driving ramp in both the expanded and unexpanded positions (*see* EX1005, Figs. 1, 3-4). As a result, the head portion of Chung's actuator does not protrude from the device, which a POSITA would have considered advantageous so that the recessed head portion does not interfere with adjacent anatomy and potentially injure the patient after the device is implanted. EX1002, ¶477.

A POSITA would have had a reasonable expectation of success in combining Chung's actuator and unthreaded bore with Olmos's device given the similarity between Olmos and Chung. These configurations of Chung and Olmos represent similar mechanical scissor-jack-type designs performing the same general function (i.e., causing the ramps to move closer to each other when the actuator is rotated). *Id*., ¶478. Chung's design could thus have been readily incorporated into Olmos' device with each component continuing to perform its

known function, with no surprising or unexpected results. *KSR Int'l Co. v. Teleflex*, 550 U.S. 398, 417 (2007).

Moreover, actuators having head portions like Chung's groove fastening screw (50), are ubiquitous in the art, and have similar structures and functionality as the Olmos actuator. EX1002, ¶¶473-474, 477-478. In addition, the embodiment depicted in Olmos' Figs. 5-6 shows a wedge 68 having a non-threaded bore for receiving the outer sleeve member 34 of actuator shaft 30, which would equally apply to Olmos's Fig. 8 embodiment, and is very similar to Chung's teachings of a non-threaded driving ramp and corresponding portion of the actuator screw, further illustrating that such design configurations were well within the POSITA's level of skill in this art. EX1006, ¶[0106], Figs. 5-6; EX1002, ¶¶473-474, 476.

Accordingly, a POSITA would have understood that Chung's groove fastening screw (50) can serve as Olmos' actuator to provide a screw for implementing Olmos' disclosed embodiment calling for an actuator that remains axially-fixed to the driving ramp (EX1006, ¶[0159]), and that any threads in Olmos' driving ramp would then be omitted as superfluous, especially given Olmos' teaching that a component of the actuator other than threads can be used to "engage other portions of the wedge member **206**." *See* EX1006, ¶[0177]; EX1002, ¶¶483.

F. Ground 6: Claims 8, 10-11, and 13 are obvious over Olmos in view of Boehm and/or Song (with or without Chung), and further in view of Varela-'774

Olmos discloses the first ramped surfaces of the first and second endplates overlapping when Olmos's device is in an unexpanded position as discussed above. §§IX(D)(3), IX(D)(5)-(6), IX(D)(8)(g), *supra*. Alternatively, should Olmos be found to not disclose overlapping ramped surfaces, Claims 8, 10-11, and 13 are obvious under 35 U.S.C. §103 over Olmos in view of Boehm and/or Song (or in view of Boehm and/or Song with Chung) as detailed above, and further in view of Varela-'774 as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶485-496).

1. Claims 8, 10, and 11

As previously discussed, Claims 8, 10, and 11 all contain essentially the same elements, as does Claim Element 13[g]. *See* §§IX(D)(3), IX(D)(5)-(6), IX(D)(8)(g), *supra*; *see also* EX1002, ¶485.

Should Olmos be determined to not expressly disclose a device that meets the limitations of Claims 8/10/11, it would have been obvious to modify Olmos to include such a feature in view of the teachings of Varela-'774. As discussed in §IX(C)(1)-(3), *supra*, Varela-'774 expressly discloses the elements of Claims 8/10/11, specifically through a track and rail system that causes the ramped

portions of a first endplate to overlap the ramped portions of a second endplate when the disclosed device is in an unexpanded position.

Accordingly, Olmos with Boehm and/or Song and further with Varela-'774 (or alternatively, Olmos with Boehm and/or Song, further with Chung, and further with Varela-'774) discloses the limitations of Claims 8, 10, and 11. EX1002, ¶¶485-487.

2. Claim 13

Although Claim 13 does not depend from Claims 8, 10, and 11, as previously noted, Claim 13[g] contains essentially the same elements as Claim 8. *See* §IX(D)(8)(g), *supra*. Thus, should Patent Owner argue that Olmos does not disclose these elements, it again would have been obvious to modify Olmos to include such a feature in view of the teachings of Varela-'774. *See* §IX(F)(1), *supra*.

All other limitations of Claim 13 are disclosed by Olmos with Boehm and/or Song (or with Boehm and/or Song and further with Chung). *See* §§IX(D)(8), IX(E)(1), *supra*. Accordingly, as with Claims 8, 10, and 11, Olmos with Boehm and/or Song and further with Varela-'774 (or alternatively, Olmos with Boehm and/or Song, further with Chung, and further with Varela-'774) discloses the limitations of Claims 13. EX1002, ¶488-490.

3. Motivation to Combine

In addition to being motivated to combine Olmos with Boehm and/or Song as discussed previously (§IX(D)(9), *supra*), a POSITA further would have been motivated to combine Olmos with Varela-'774 for at least the reasons expressly set forth in Varela-'774 itself.

Specifically, as previously noted, Varela-'774 teaches that configuring an intervertebral implant's endplates such that they overlap or "nest" with one another when the device is in an unexpanded state, thus advantageously allowing for "the smallest possible form factor for insertion through the skin and musculature of the patient and into the intervertebral space." *See* §IX(C)(5), *supra*. Such teachings would have motivated a POSITA to reconfigure the Olmos endplates such that their ramped surfaces would overlap when the implant was in an unexpanded position, thus enabling the implant to maintain a lower profile and be more easily inserted as part of a minimally invasive surgical procedure. EX1002, ¶¶492-493.

A POSITA further would have had a reasonable expectation of success in combining Olmos and Varela-'774 because the devices of Olmos and Varela-'774 are structurally and functionally comparable. For example, both Varela-'774 and Olmos disclose an expandable implant that is surgically inserted between two vertebra to provide structural support and is expanded by moving at least one wedge through the rotation of an actuator. EX1002, ¶¶494. Thus, a POSITA would

have a reasonable expectation of success in taking Varela-'774's disclosure of using offset, overlapping track structures to maintain a compact configuration when the device is in a collapsed position and applying it to the device of Olmos. *Id.*

As evidenced by Varela-'049, which discloses the overlapping ramped surfaces applied to a device having two wedges when in an unexpanded position, a POSITA would have been further motivated to apply Varela-'774's teaching of the overlapping ramped surfaces when in an unexpanded position to Olmos's device with two wedge structures. *Id.*, ¶495.

Accordingly, Claims 8, 10-11, and 13 are obvious over Olmos in view of Boehm and/or Song (or Boehm and/or Song and Chung) and further in view of Varela-'774. EX1002, ¶¶491-496.

X. DISCRETIONARY DENIAL IS NOT WARRANTED

The Board has discretion to deny institution under §314(a) and/or §325(d). However, Petitioner has provided a *Sotera*-type stipulation in the parallel litigation (EX1020) which, in addition to the strong merits presented herein, precludes discretionary-denial under §314(a). *See* Director Vidal Memorandum, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation, at 3-5, 7-8 (June 21, 2022).

Regarding §325(d), the ’732 patent has not previously been challenged at the PTAB. Chung, Song, and Varela-’774 were not cited or considered during prosecution. Baynham was submitted in an Information Disclosure Statement, (EX1004, 000018, but was not otherwise considered by the Examiner.

The Examiner rejected pending claims 1, 2, 7-15 and 17, among other bases, over Olmos in view of U.S. Patent Publication No. 2003/0176926 to Boehm.

Petitioner submits that the Examiner erred in concluding that Olmos did not teach the allegedly distinguishing feature of a driving ramp fixed to the actuator during actuation/rotation. As discussed *supra* §IX(D)(1)(l), at least Olmos ¶[0159] expressly discloses such an embodiment. This disclosure in Olmos may have been overlooked given the Examiner’s primary focus on Olmos’ figures with no office action citing Olmos ¶[0159], and given Applicant’s representations that “Olmos does not teach or suggest either of the wedge members 206 and 208 are fixed with respect to the threaded actuation member.” EX1004, 000113-000126, 000064.

Discretionary denial is not warranted here. First, Olmos discloses a driving ramp fixed to the actuator during rotation (wherein the central ramp is moved forwards or backwards depending on the direction of rotation), contrary to the Applicant’s statements during prosecution. Applicant amendment and subsequent allowance show that this feature was the Examiner’s basis for allowance. Yet, there is no evidence that the Examiner appreciated Olmos’ disclosure of this

feature (EX1006, ¶[0159]) when allowing the claims. Accordingly, *Becton Dickenson* factors (c)-(f) disfavor denial under §325(d) given the facts noted above and the new light in which Olmos has been presented here. *Volkswagen Group of America, Inc. v. Michigan Motor Technologies LLC*, IPR2020-00452, Paper 12, 32-33 (finding §325(d) denial unwarranted where examiner "fail[ed] to fully consider" specific embodiment in cited reference).

Second, some ground in this Petition independently relies on Chung for an even more express teaching of this claim feature. *E.g.*, *supra* §IX(A)(1)(l). Thus, to the extent that Olmos is somehow determined to not expressly disclose this feature, Chung fills any remaining gap and is not cumulative to Olmos. Chung also discloses other relevant features of the challenged claims, such as an unthreaded opening in the driving ramp, and various claimed features specific to the actuator screw not as clearly taught in Olmos. *E.g.*, *supra* §§IX(E)(1), IX(A)(1)(j)-(l). And Chung was **not** before the Examiner during prosecution.

Accordingly, *Becton Dickenson* factors (c)-(f) disfavor denial under §325(d) in view of the facts noted above, and discretionary denial under §325(d) is unwarranted for these additional reasons. *Oticon Medical AB v. Cochlear Ltd.*, IPR2019-00975, Paper 15 at 19-20 (PTAB Oct. 16, 2019)(precedential as to §§II(B)-(C))(refusing to deny institution given new, noncumulative prior art asserted in Petition).

XI. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that Trial be instituted and that Claims 1, 7-13, and 16 be canceled.

Respectfully submitted,

Dated: October 14, 2022

By: *s/Michael R. Houston/*
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APPENDIX: CHALLENGED CLAIM LISTING

Claim No.	Limitation
1[a]	A system for intervertebral fusion comprising:
1[b]	a dilator having a proximal end and a tapered distal end for penetrating soft tissue;
1[c]	a cannula having a proximal end and a distal end; and
1[d]	an intervertebral implant sized for insertion into an intervertebral space through the cannula,
1[e]	wherein the intervertebral implant comprises a first endplate, a second endplate, and a central ramp disposed between the first endplate and the second endplate,
1[f]	wherein the central ramp is configured to move in a first direction and cause the first and second endplates to move outwardly and away from one another,
1[g]	a driving ramp disposed between the first endplate and the second endplate at an opposite end of the intervertebral implant from the central ramp,
1[h]	wherein the driving ramp has a longitudinal through bore,
1[i]	wherein the driving ramp is configured to engage ramped surfaces of the first endplate and ramped surfaces of the second endplate; and
1[j]	an actuation member comprising a head portion and an actuation member extension that extends through an unthreaded opening in a longitudinal through bore of the driving ramp to be received within an opening in the central ramp extension,
1[k]	wherein rotational movement of the actuation member in the first direction pulls the central ramp towards the driving ramp;
1[l]	wherein when the actuation member is rotated, the driving ramp is fixed with respect to the actuation member and the central ramp is moved in either the first direction or a second direction.
7[a]	The system of claim 1, wherein first endplate comprises a first end, a second end, an upper surface connecting the first end and the

Claim No.	Limitation
	second end, first ramped surfaces on either side of the first endplate proximate the first end, second ramped surfaces on either side of the first endplate proximate the second end, and
7[b]	wherein the second endplate comprises a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the second endplate proximate the first end, second ramped surfaces on either side of the second endplate proximate the second end.
8	The system of claim 7, wherein, when the intervertebral implant is in an unexpanded configuration, the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate overlap, and the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate overlap.
9[a]	The system of claim 7, wherein the first endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the first endplate,
9[b]	wherein the second endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the second endplate, and
9[c]	wherein the central ramped surface of the first endplate and wherein the central ramped surface of the second endplate are configured to engage the central ramp.
10	The system of claim 7, wherein, when the intervertebral implant is in an unexpanded configuration, the first ramped surfaces of the first endplate overlap the first ramped surfaces of the second endplate, and the second ramped surfaces of the second endplate overlap the second ramped surfaces of the first endplate.
11	The system of claim 7, wherein, when the intervertebral implant is in an unexpanded configuration, one of the first ramped surfaces of

Claim No.	Limitation
	the first endplate overlaps one of the first ramped surfaces of the second endplate, and another one of the first ramped surfaces of the second endplate overlaps another one of the first ramped surfaces of the second endplate.
12[a]	The system of claim 7, wherein the central ramp comprises a ramped expansion portion at one end of the intervertebral implant and a central ramp extension extending from the expansion portion,
12[b]	wherein the central ramp is configured to engage the first endplate and the second endplate.
13[a]	A system for intervertebral fusion comprising:
13[b]	a dilator having a proximal end and a tapered distal end for penetrating soft tissue;
13[c]	a cannula having a proximal end and a distal end; and
13[d]	an intervertebral implant sized for insertion into an intervertebral space through the cannula,
13[e]	wherein the intervertebral implant comprises: a first endplate comprising a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the first endplate proximate the first end, second ramped surfaces on either side of the first endplate proximate the second end;
13[f]	a second endplate comprising a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the second endplate proximate the first end, second upper surfaces on either side of the second endplate proximate the second end,
13[g]	wherein, when the intervertebral implant is in an unexpanded configuration, the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate overlap, and the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate overlap;

Claim No.	Limitation
13[h]	a central ramp disposed between the first endplate and the second endplate,
13[i]	wherein the central ramp is configured to engage the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate;
13[j]	a driving ramp disposed between the first endplate and the second endplate at an opposite end of the intervertebral implant from the expansion portion of the central ramp,
13[k]	wherein the driving ramp has a longitudinal through bore, wherein the driving ramp is configured to engage the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate; and
13[l]	an actuation member comprising a head portion and an actuation member extension that extends through the longitudinal through bore of the driving ramp to be received within an opening in the central ramp extension,
13[m]	wherein rotational movement of the actuation member in the first direction pulls the central ramp and the driving ramp towards one another, thereby moving the first and second endplates outwardly and away from one another
13[n]	wherein when the actuation member is rotated, the driving ramp is fixed with respect to the actuation member.
16[a]	A system for intervertebral fusion comprising:
16[b]	a dilator having a proximal end and a tapered distal end for penetrating soft tissue;
16[c]	a cannula having a proximal end and a distal end; and
16[d]	an intervertebral implant sized for insertion into an intervertebral space through the cannula
16[e]	wherein the intervertebral implant comprises: a first endplate comprising a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side

Claim No.	Limitation
	of the first endplate proximate the first end, second ramped surfaces on either side of the first endplate proximate the second end, and a central ramped surface disposed between the first and second ramped surfaces;
16[f]	a second endplate comprising a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the second endplate proximate the first end, second ramped surfaces on either side of the second endplate proximate the second end, and a central ramped surface disposed between the first and second ramped surfaces;
16[g]	a central ramp disposed between the first endplate and the second endplate,
16[h]	wherein the central ramp comprises a ramped expansion portion at one end of the intervertebral implant and a central ramp extension extending from the expansion portion,
16[i]	wherein the ramped expansion portion is configured to engage the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate, and
16[j]	wherein the central ramp extension comprises ramped surfaces projecting from the central ramp extension and configured to engage the central ramped surface of the first endplate and the central ramped surface of the second endplate;
16[k]	a driving ramp disposed between the first endplate and the second endplate at an opposite end of the intervertebral implant from the expansion portion of the central ramp,
16[l]	wherein the driving ramp has a longitudinal through bore,
16[m]	wherein the driving ramp is configured to engage the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate; and
16[n]	an actuation member comprising a head portion and an actuation member extension that extends through the longitudinal through bore of the driving ramp to be received within an opening in the central ramp extension,

Claim No.	Limitation
16[o]	wherein rotational movement of the actuation member in the first direction pulls the central ramp and the driving ramp towards one another.

CERTIFICATE OF WORD COUNT

The undersigned certifies that the foregoing Petition complies with the requirements of 37 C.F.R. § 42.24. Excluding the portions exempted by 37 C.F.R. § 42.24(a) (a table of contents, a table of authorities, a listing of facts which are admitted, denied, or cannot be admitted or denied, a certificate of service or word count, or appendix of exhibits), the Petition contains 13,458 words as counted by the word processing system used to prepare it.

By: */Michael R. Houston/*
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition for *Inter Partes* Review together with all exhibits and other papers filed therewith was served on Patent Owner, by USPS Express Mail directed to the attorneys of record for the patent at the following address:

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October 14, 2022

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