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. 10,137,001

Issue Date: November 27, 2018

Title: EXPANDABLE FUSION DEVICE AND METHOD OF INSTALLATION THEREOF

Inter Partes Review No. IPR2022-01435

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

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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)

I. INTRODUCTION

Petitioner Life Spine, Inc. ("Petitioner") respectfully requests *inter partes* review of Claims 1-11 of U.S. Patent No. 10,137,001 ("the '001 patent," EX1001), which according to PTO records is 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 1-11 recite nothing more than methods using devices that were widely known the industry prior to the effective filing date of the '001 patent.

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 '001 patent is related to several pending matters. Patent Owner is asserting, *inter alia*, the '001 patent and related U.S. Patent Nos. 8,845,731 ("the '731 patent") and 8,845,732 ("the '732 patent") against Petitioner in *Globus Medical, Inc. v. Life Spine, Inc.*, 21-cv-1445 (D. Del.). Petitioner has filed a petition for *inter partes* review challenging claims 1-15 of the '731 patent in IPR2022-01434.

In addition, the following related U.S. patent applications, which claim priority to the same parent application as the '001 patent, are currently pending:

- 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 the Petitioner is not barred or estopped from requesting

an *inter partes* review challenging the patent claims on the grounds identified in the Petition.

B. Identification of Challenge

Petitioners request review and cancellation of Claims 1-11 of the '001 patent[1] for the reasons explained in this petition, which are summarized as follows:

Ground	Claims	Basis	References
I	1, 3, 4, 10	§102/§103	Chung
II	2, 5-9, 11	§103	Chung with the knowledge of a POSITA or Olmos
III	1-10	§103	Chung with Baynham or Baynham and Olmos
IV	1-11	§102/§103	Olmos
V	1-9, 11	§103	Olmos with Chung

This Petition includes 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 '001 patent.

A petition for *inter partes* review 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.

[1] A listing of challenged claims is provided as an appendix.

Each of the elements of Claims 1-11 of the ’001 patent is taught in the prior art as explained below in the proposed grounds of unpatentability.

VI. THE ′001 PATENT

A. Overview of the ′001 Patent

The ’001 patent, titled “Expandable Fusion Device and Method Installation Thereof,” issued from Application No. 14/466,468, filed August 22, 2014. The ’001 patent claims priority to Application No. 12/875,637, filed on September 3, 2010, which issued as the ’731 patent.

The ’001 patent 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 device generally includes “a central ramp, a first end plate, and a second endplate, the central ramp capable of being moved in a first direction to move the first and second endplates outwardly and into an expanded configuration.” *Id.* However, as detailed below, devices having the claimed features and methods of using the same were well-known before the ’001 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. EX1021-EX1023.

VII. LEVEL OF SKILL IN THE ART

As established by testimonial evidence, a POSITA, as 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 and basic surgical techniques in this field, as explained by Prof. Drewry. EX1002, ¶31, 43-64.

VIII. PRIOR ART

A. Chung

Korean Reg. Utility Model No. KR20-0290059 to Chung ("Chung," EX1005[2]) was published on September 26, 2002 and is prior art under 35 U.S.C.

[2] Exhibit 1005 includes a certified translation of Chung, per 37 C.F.R. § 42.63(b).

§102(a)-(b). Chung was not cited in any rejection during prosecution of the application leading to the '001 patent.

B. Olmos

U.S. Patent Application Publication No. US 2008/0140207 A1 to Olmos et al. ("Olmos," EX1006) was first published on June 12, 2008 and is prior art under 35 U.S.C. §§102(a)-(b). Olmos was submitted and discussed during prosecution leading to the '001 patent. *See* §X, *infra*.

C. Baynham

U.S. Patent Application Publication No. US 2007/0270968 A1 to Baynham et al. ("Baynham," EX1007) was first published on November 22, 2007 and is prior art under 35 U.S.C. §§102(a)-(b). Baynham was listed among dozens of other references in certain Information Disclosure Statements filed during prosecution (*e.g.,* EX1004, 0000323), but was not discussed in the substantive grounds for rejection.

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

A. Ground 1: Claims 1, 3, 4, and 10 are anticipated by and/or obvious over Chung

Anticipation under 35 U.S.C. §102 requires that every element of the claimed invention be disclosed expressly or inherently in a single prior art reference. *In re Paulson*, 30 F.3d 1475, 1478–79 (Fed. Cir. 1994).

Chung anticipates Claims 1, 3, 4, and 10 of the '001 patent under 35 U.S.C. §102(a)-(b) or alternatively renders these claims obvious under 35 U.S.C. §103 as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶81-207).

1. Claim 1

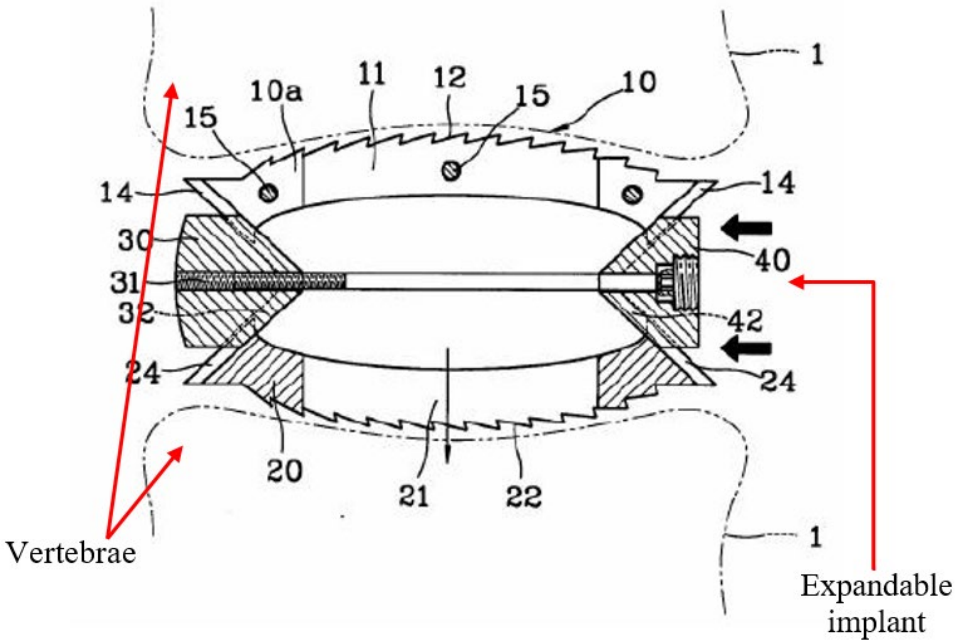
(a) Claim 1[pre]

Claim 1 is directed to a "**surgical method**," which Chung discloses. Chung describes a lumbar holder inserted between the lumbar back bones to maintain the appropriate space according to the patient's state, further disclosing treating a patient with same. EX1005, 3; *see also id.*, 7. A POSITA would understand this to disclose a surgical method. EX1002, ¶¶81-82.

(b) Claim 1[a]

Claim 1 recites "**creating an access path to an intervertebral disc space**" and "**inserting an expandable implant into the disc space**." Chung's device "is inserted between the back bones consisting of the lumbar," which a POSITA would understand to involve creating an access path needed to place the device in an intervertebral disc space. EX1005, 3, 7; EX1002, ¶85. The intervertebral disc space is illustrated, for example, in Figs. 4 and 5, showing Chung's device inserted between two vertebra, which necessarily followed an access path to arrive at that location. Annotated Fig. 4 follows.

Chung, Fig. 4

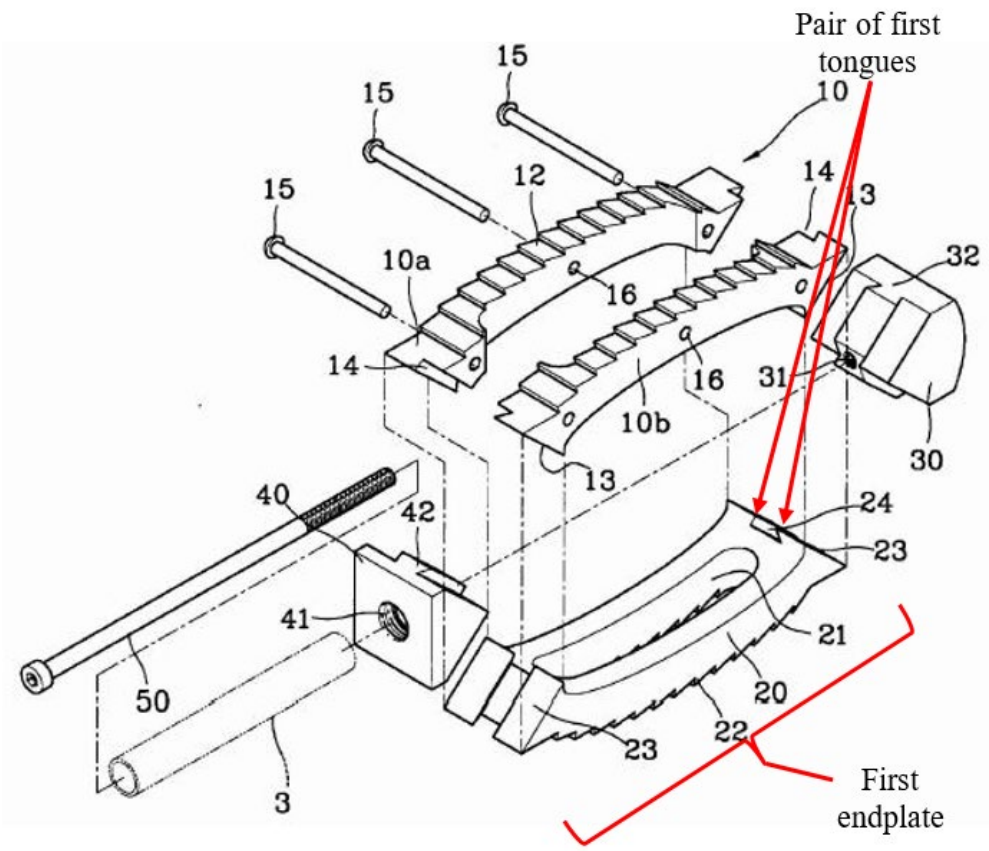


Chung further discloses that its device is expandable, noting that a surgeon can "adjust the distance between" upper and lower endplates ("holder bodies (10) (20)") after insertion. EX1005, 3-4. Accordingly, Chung discloses these limitations. EX1002, ¶¶83-86.

(c) Claim 1[b]

Claim 1 recites a "**first endplate having a pair of first tongues**." Chung discloses a first endplate ("holder body (20)") having a pair of first tongues (the edges formed by "dovetail groove[]…(24)…formed along…guiding surfaces…(23)"). EX1005, 5; EX1002, ¶¶62, 87. This is further seen in at least Figs. 1-2, with annotated Fig. 2 below.

Chung, Fig. 2



This interpretation is consistent with the ’001 patent. Specifically, describing Fig. 45, the specification discloses that the endplates include “tongue portions 316, 318” and “tongue portions 320, 322” at their respective ends. EX1001, 14:35-39. The specification further discloses that the central ramp’s “angled grooves 348, 350 are sized to receive the corresponding tongues 316, 318, 320, 322 in the first and second endplates.” *Id.*, 15:23-28; *see also id.*, 19:23-29 (describing, *inter alia*, Fig. 52 having similar “tongues 316, 318, 320, 322,” which slot into “angled grooves 428, 430” of the central ramp). Thus, multiple embodiments of the ’001

patent disclose tongues with generally the same structure and function as the pair of first tongues in Chung.[3] Annotated Figs. 45 and 52 below highlight the various disclosed tongues:

'001 Patent, Fig. 45

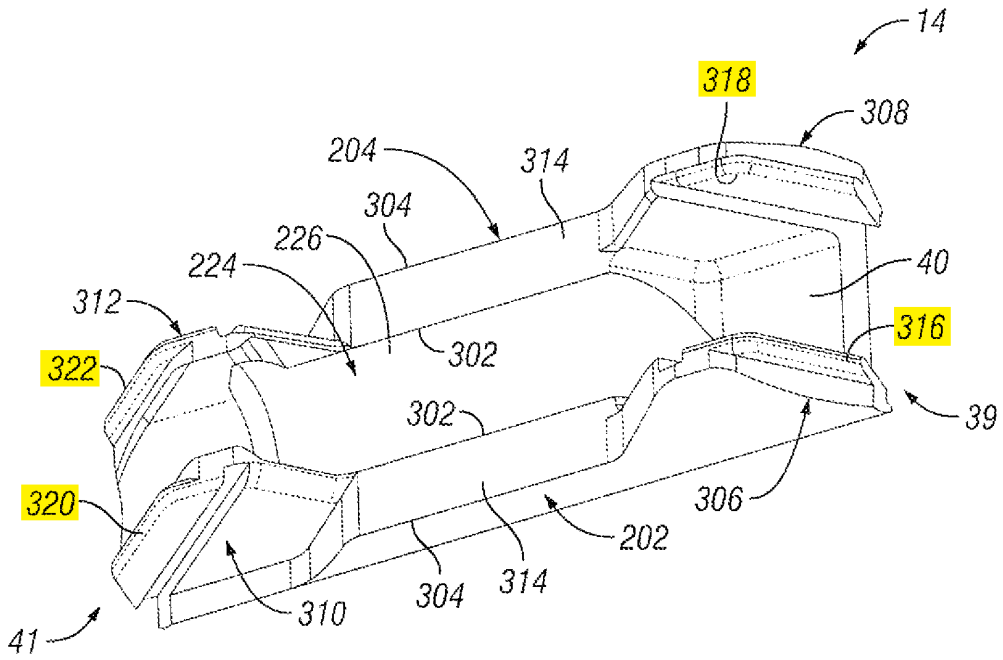


FIG. 45

[3] Notably, the '001 patent further contemplates the endplates engaging the central ramp in what "may be described as a dovetail connection." *Id.*, 11:34-38.

'001 Patent, Fig. 52

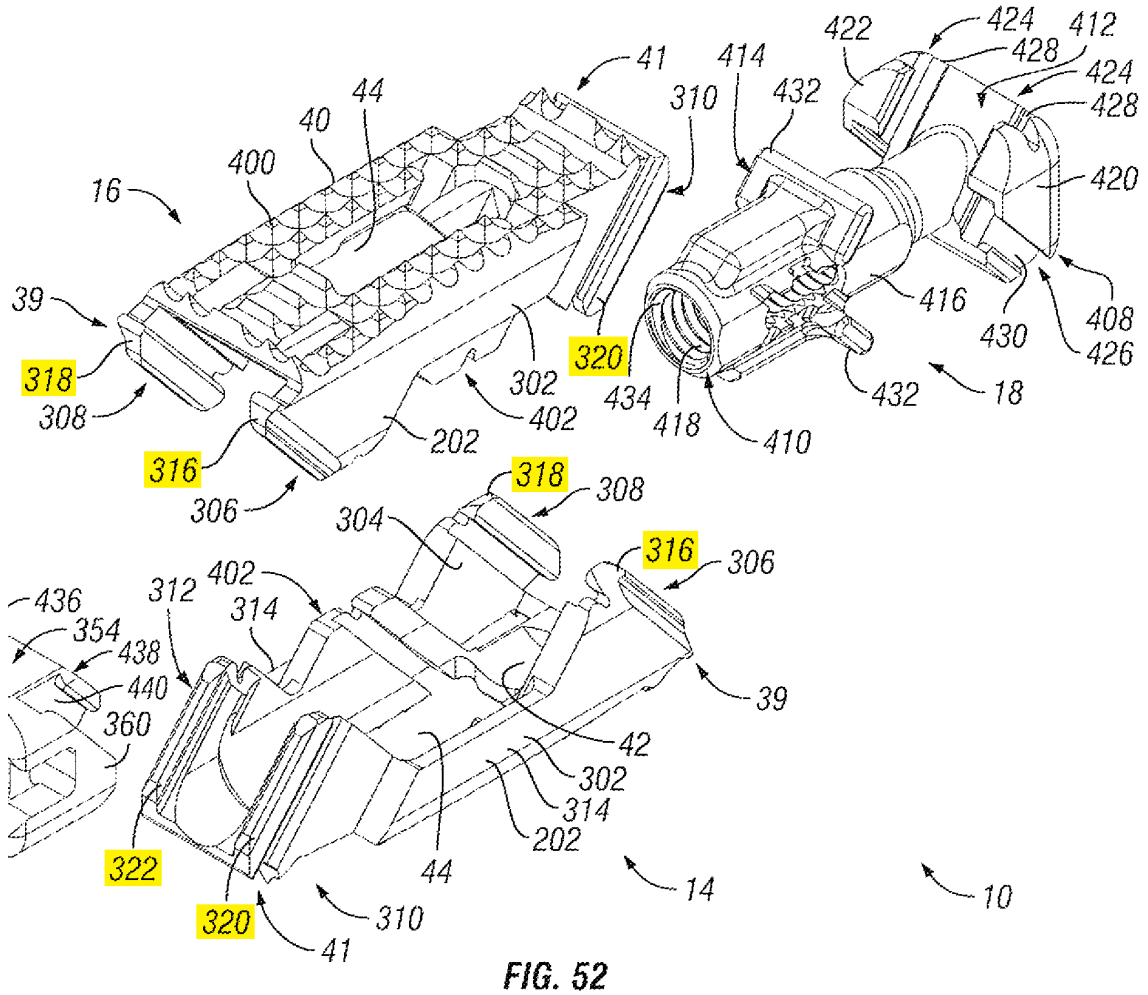


FIG. 52

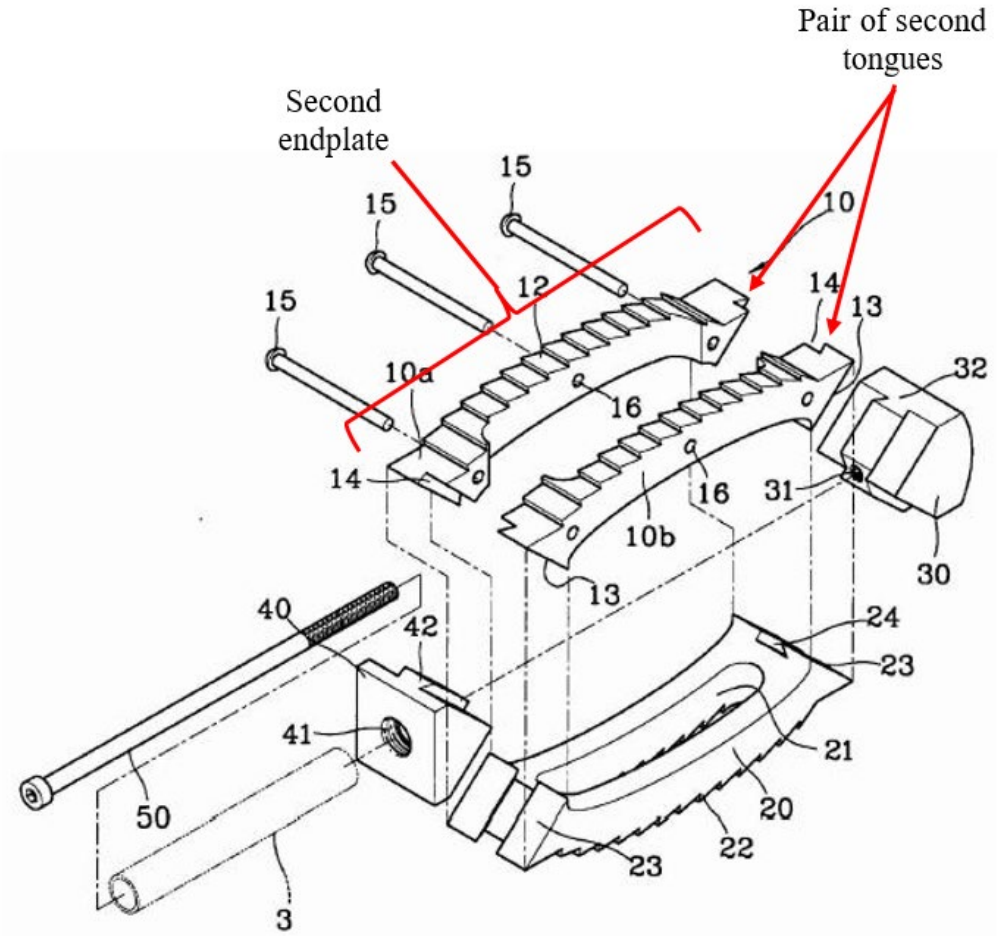
Accordingly, Chung discloses this limitation. EX1002, ¶¶87-91.

(d) Claim 1[c]

Claim 1 recites "**a second endplate opposed to the first endplate, the second endplate having a pair of second tongues**." Chung discloses a second endplate ("holder body (10)") having a pair of second tongues (the edges formed by "dovetail groove[] (14)…formed along…guiding surface[] (13)…"). EX1005,

5; EX1002, ¶92. The second endplate/holder body (10) 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.*; Fig. 2. Chung further discloses that the endplates are opposed ("main holder bodies (10) (20)…[are] positioned facing each other symmetrically"). *Id.* Figures 1-4 further show these structures, with annotated Fig. 2 below.

Chung, Fig. 2



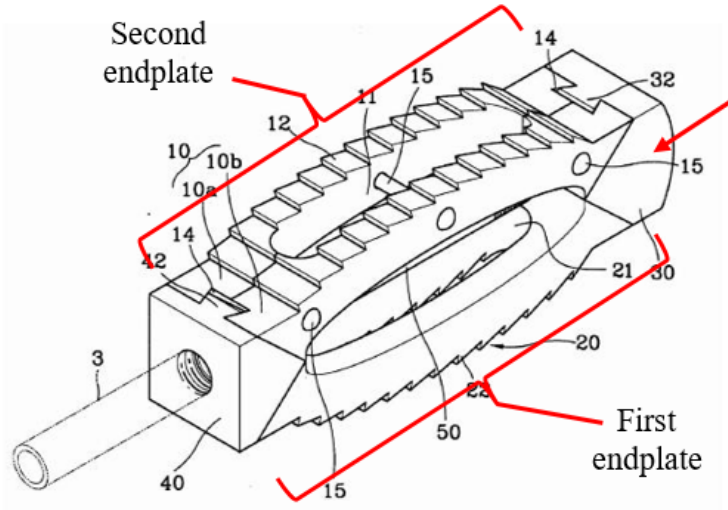
This interpretation is consistent with the '001 patent as set forth in §IX(A)(1)(c), *supra*, which explains how multiple embodiments of the '001 patent disclose pairs of tongues with the same structure and function as the pair of second tongues in Chung.

Accordingly, Chung discloses this limitation. EX1002, ¶¶92-96.

(e) Claim 1[d]

Claim 1 recites "**a central ramp positioned between the first endplate and the second endplate**." Chung's "lead wedge (30)" is a central ramp positioned between the endplates. *See* EX1005, 4. Chung describes "lead wedge (30)" as a "separation device[] in order to adjust the space between the aforementioned main holder bodies (10) (20)" that is "slid between [the] ends of the aforementioned main holder bodies (10) (20)." *Id.*, 5. This is also seen in Figs. 1-4, with annotated Fig. 1 below.

Chung, Fig. 1

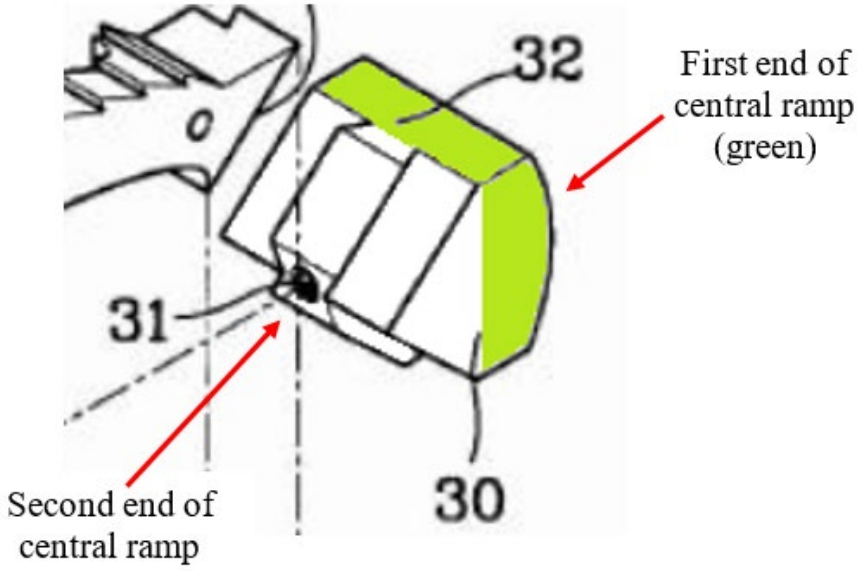


Accordingly, Chung discloses this limitation. EX1002, ¶¶97-99.

(f) Claim 1[e]

Claim 1 recites that "**the central ramp comprises a first end and a second end**." Chung Figs. 1-4 show a central ramp having a first end (wider end of lead wedge (30)) and a second end (narrow end of lead wedge (30)). EX1005, Figs. 1-4. Annotated Fig. 2 follows.

Chung, Fig. 2

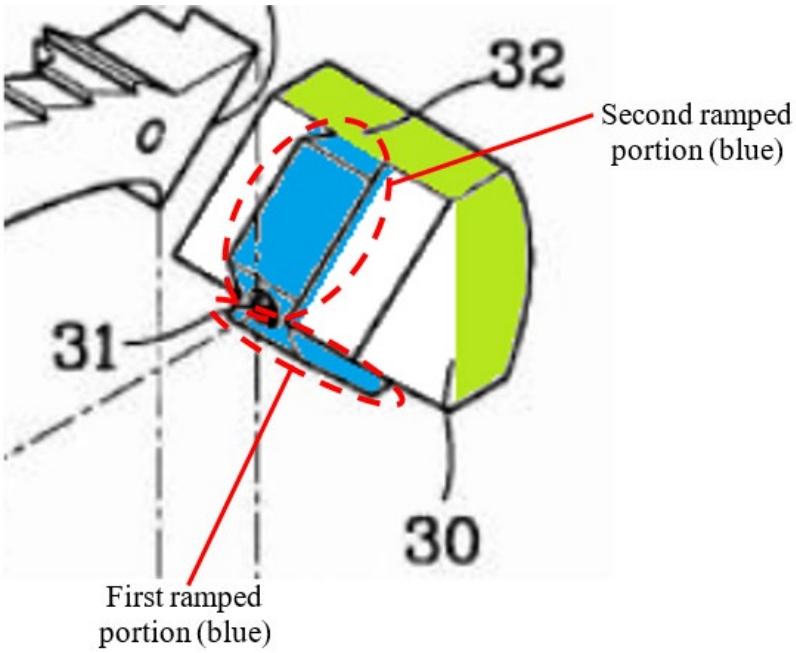


Accordingly, Chung discloses this limitation. EX1002, ¶¶100-101.

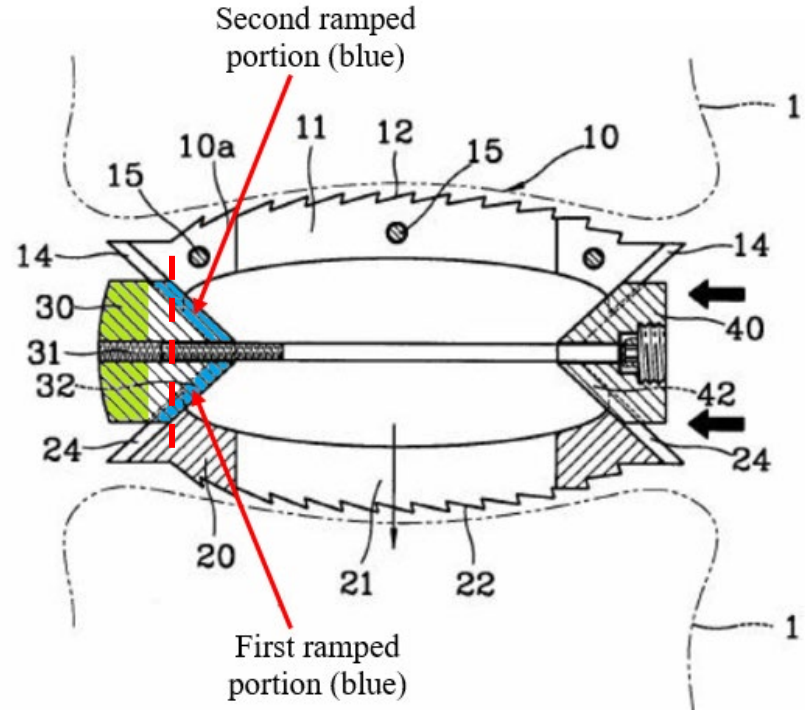
(g) Claim 1[f]

Claim 1 recites that "**the second end includes a first ramped portion configured to engage a portion of the first endplate and a second ramped portion configured to engage a portion of the second endplate**." The second end of Chung's central ramp has a first ramped portion (lower "dovetail[] (32)" and the adjacent surface below its overhanging edges) and a second ramped portion (upper "dovetail[] (32)" and the adjacent surface below its overhanging edges). EX1005, 5. These can further be observed in at least Figs. 2-4, with annotated Figs. 2 and 4 below.

Chung, Fig. 2

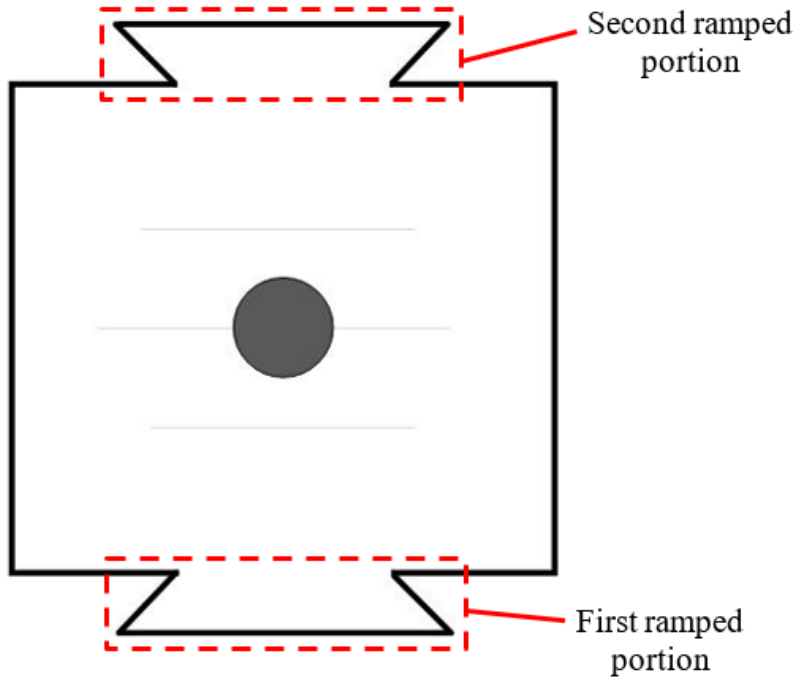


Chung, Fig. 4



The following depiction of a vertical cross-section of Chung's central ramp (taken approximately at the red dashed line in Fig. 4, *supra*) further shows the first and second ramped portions:

Petitioner-Generated Figure



The first and second ramped portions are respectively configured to engage portions of the first and second endplates through their mating dovetail configurations. *Id.*, 5; *see also id.*, 4. Figure 1 shows this engagement.

Moreover, this identification in Chung is consistent with the identification of these same structures in the '001 patent. Specifically, describing the embodiment in Figs. 25-27, the specification discloses that "[t]he second end 236 of the central ramp 18…includes opposing angled surfaces 246," which are "configured and

dimensioned to engage the ramped surface 228…in each of the first and second endplates 14, 16."[4] EX1001, 11:26-34. Thus, the "end" of ramp 18 is described as including angled surface 246. As seen in annotated Figs. 24-25, below, this is the same as Chung in all meaningful respects:

[4] The '001 patent appears to use the terms "angled" and "ramped" interchangeably. *E.g., compare* EX1001, 7:21-29 (referring to "angled surface 33") *with* 7:34-46 (referring to "ramped surfaces 33").

'001 Patent, Figs. 24-25

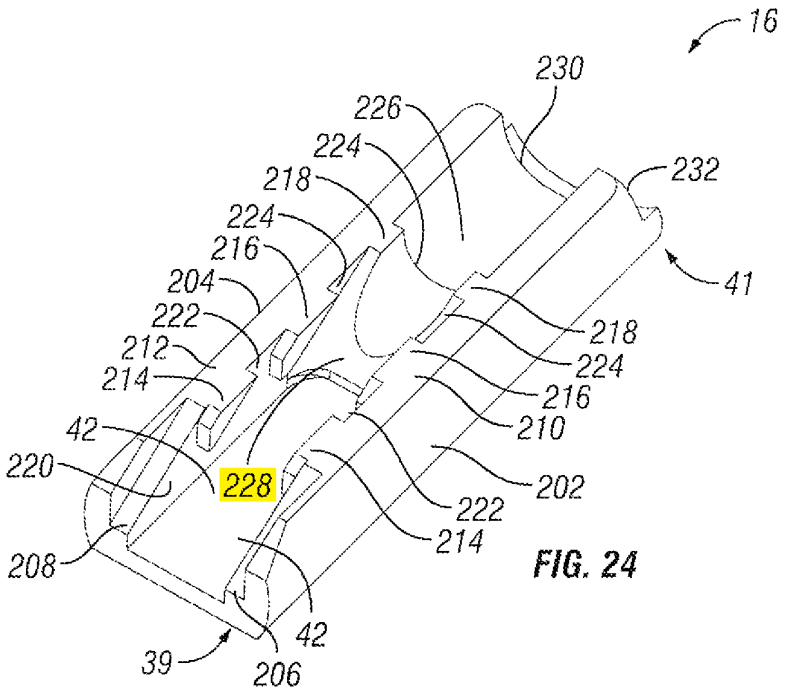


FIG. 24

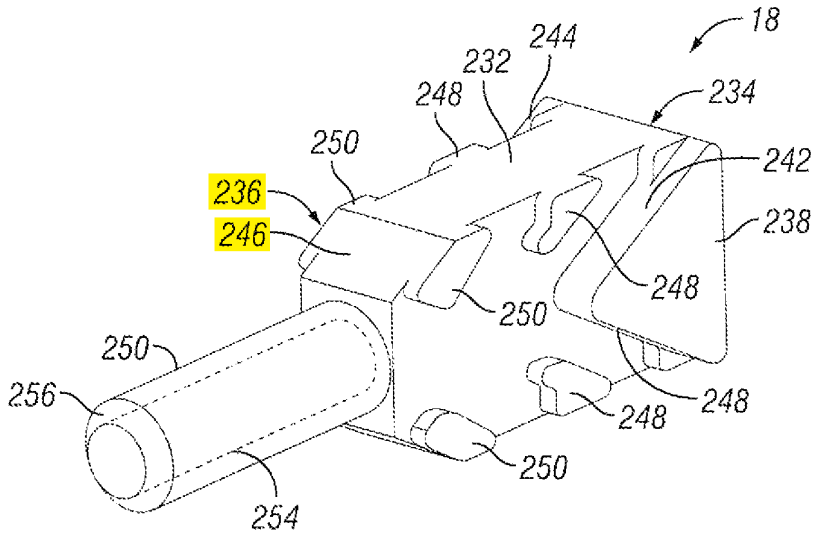


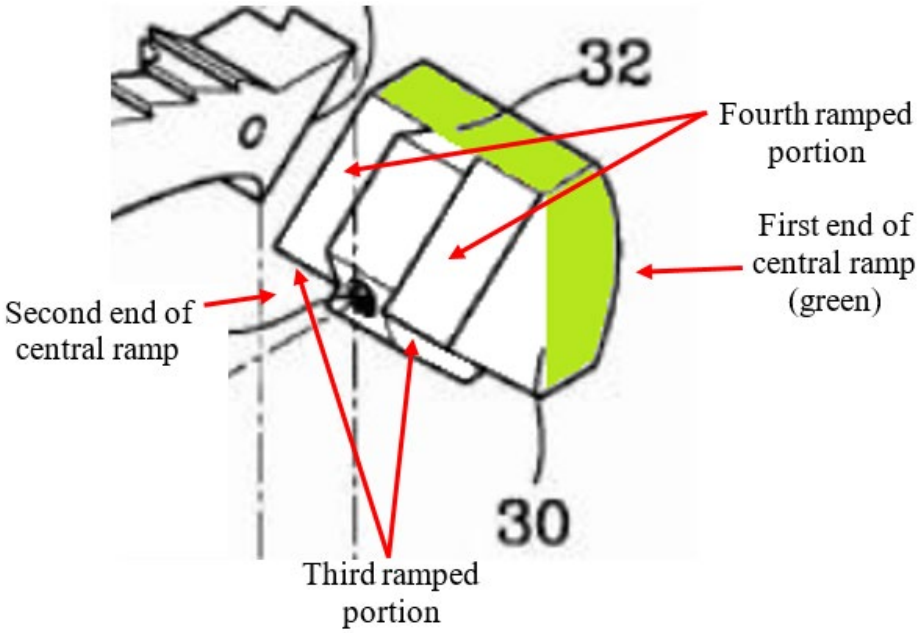
FIG. 25

Accordingly, Chung discloses this limitation. EX1002, ¶¶102-106.

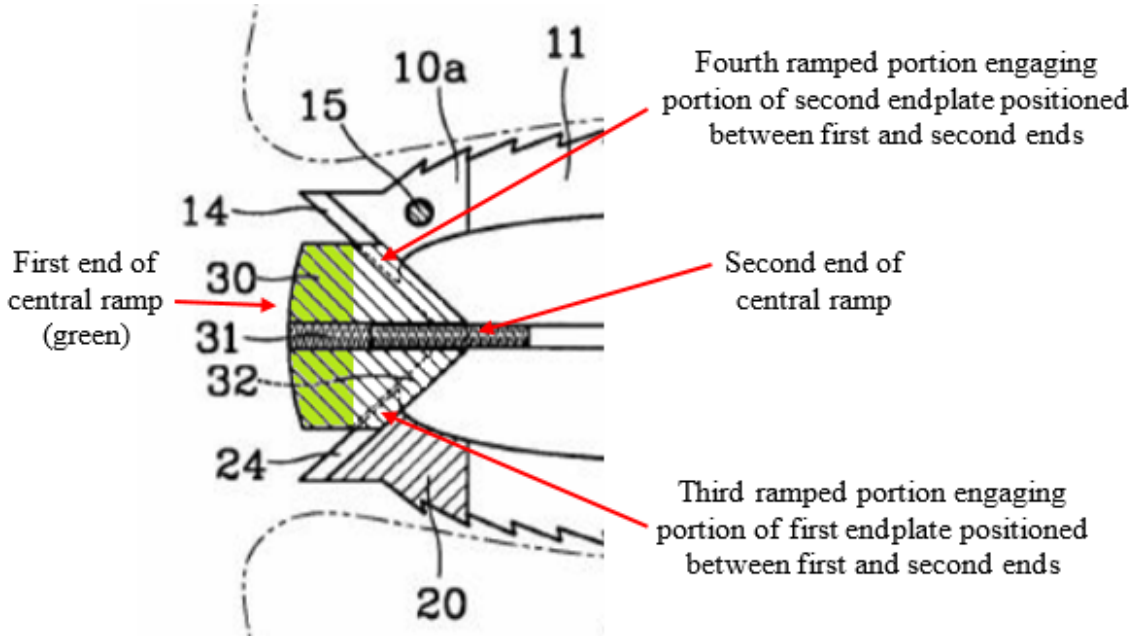
(h) Claim 1[g]

Claim 1 further recites "**a third ramped portion configured to engage a portion of the first endplate and a fourth ramped portion configured to engage a portion of the second endplate positioned between the first and second ends**." Chung's central ramp has third and fourth ramped portions (either of the flat surfaces adjacent to dovetails (32)), which are configured to fit and engage with a portion the first and second endplates, respectively. *Id.*, 4 (disclosing "a lead wedge whose both sides are positioned close to the guiding surfaces of the front ends of the aforementioned both main holder bodies, that have dovetails that dovetail with the dovetail grooves of the aforementioned main holder bodies along the lengthwise direction of each of the contact surfaces"); 5 (disclosing that central ramp's "contacting surfaces are fitted to the dovetail grooves (14) (24) of the aforementioned main holder bodies (10) (20)"); Figs. 1-4. Annotated excerpts of Figs. 2 and 4 follow.

Chung, Fig. 2



Chung, Fig. 4



Moreover, this interpretation is consistent with the ’001 patent. Describing the embodiment in Figs. 25-27, the specification discloses that the central ramp also has “angled surfaces 242, 244 configured and dimensioned to engage the ramped surfaces 206, 208 of the first and second endplates 14, 16 and force apart the first and second endplates 14, 16.” EX1001, 11:16-21. As seen in annotated Fig. 25, below, this captures Chung’s configuration in all meaningful respects:

'001 Patent, Figs. 24-25

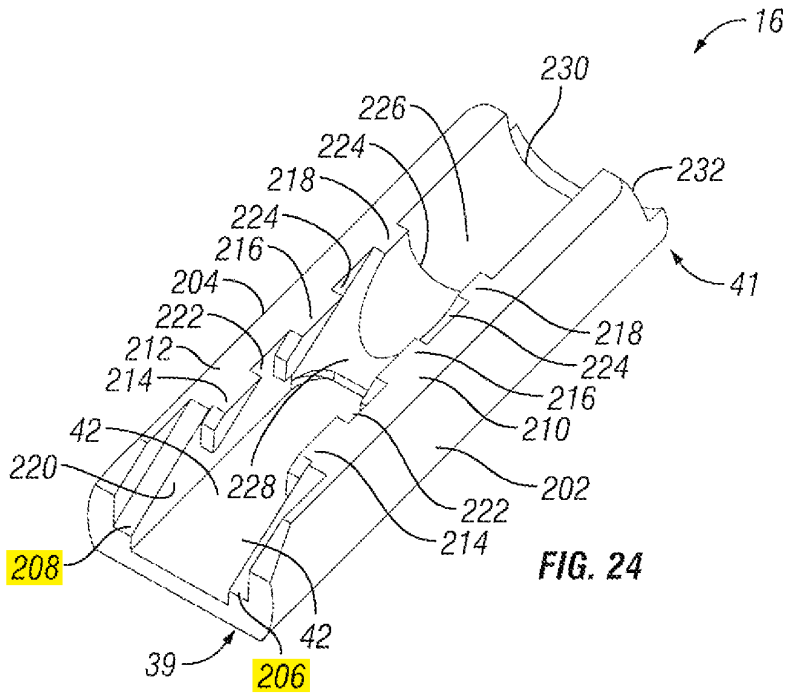


FIG. 24

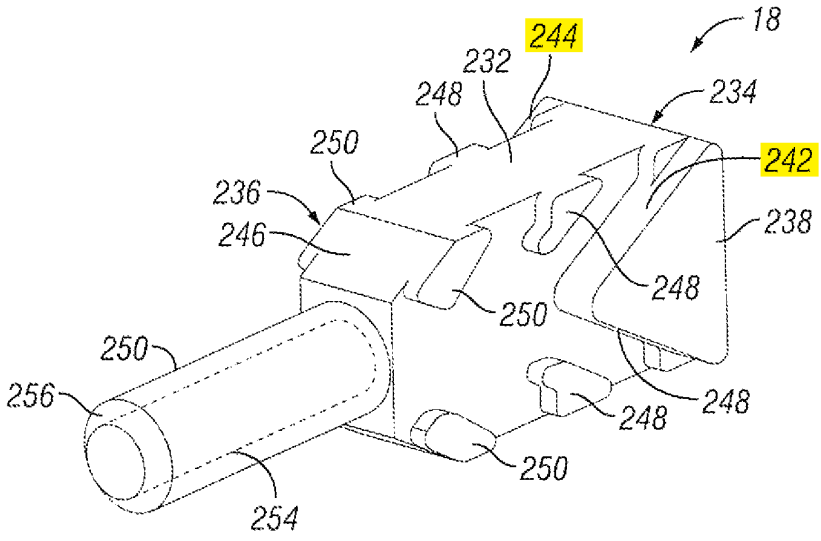


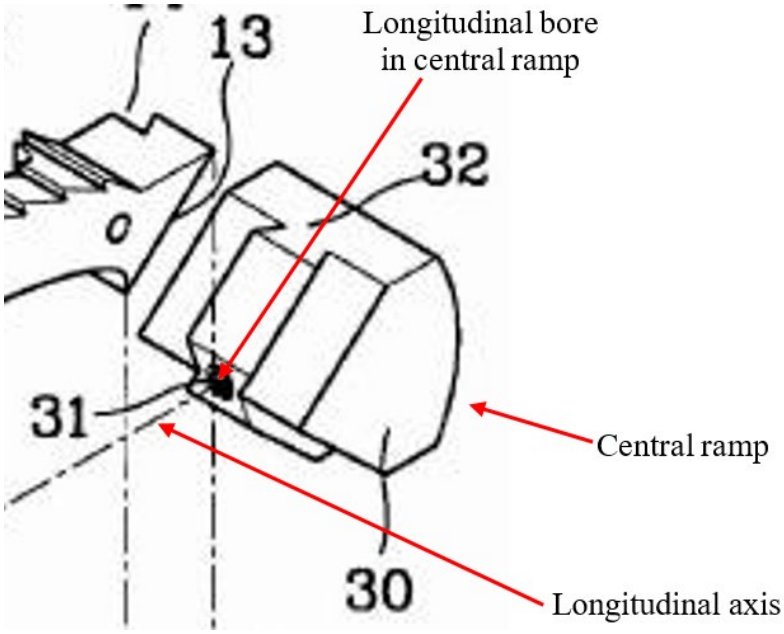
FIG. 25

Accordingly, Chung discloses this limitation. EX1002, ¶¶107-110.

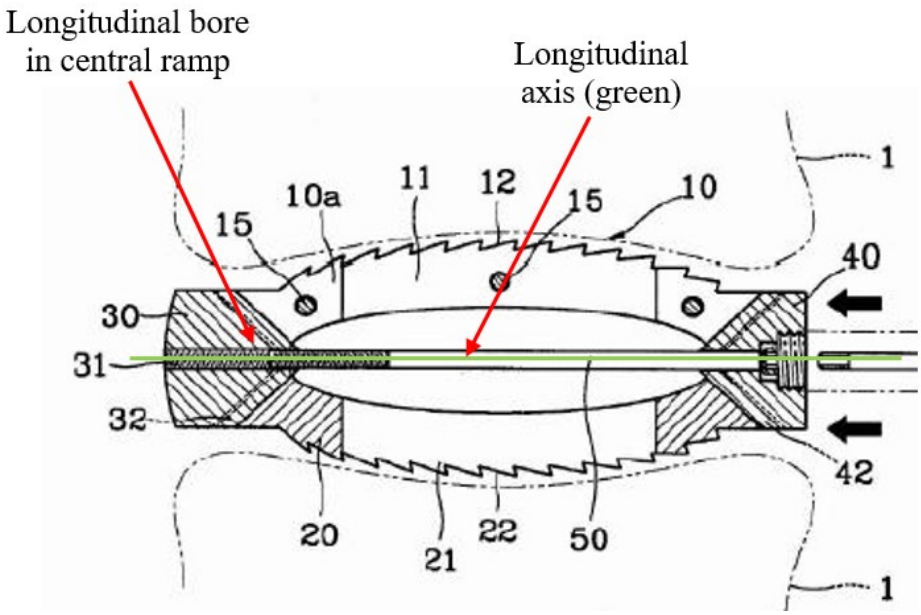
(i) Claim 1[h]

Claim 1 recites that "**the central ramp has a longitudinal bore**." Chung's central ramp has a longitudinal bore ("screw hole (31)"). EX1005, 5-6. Figures 2-4 further show this limitation, with annotated excerpts of Figs. 2 and 3 below.

Chung, Fig. 2



Chung, Fig. 3

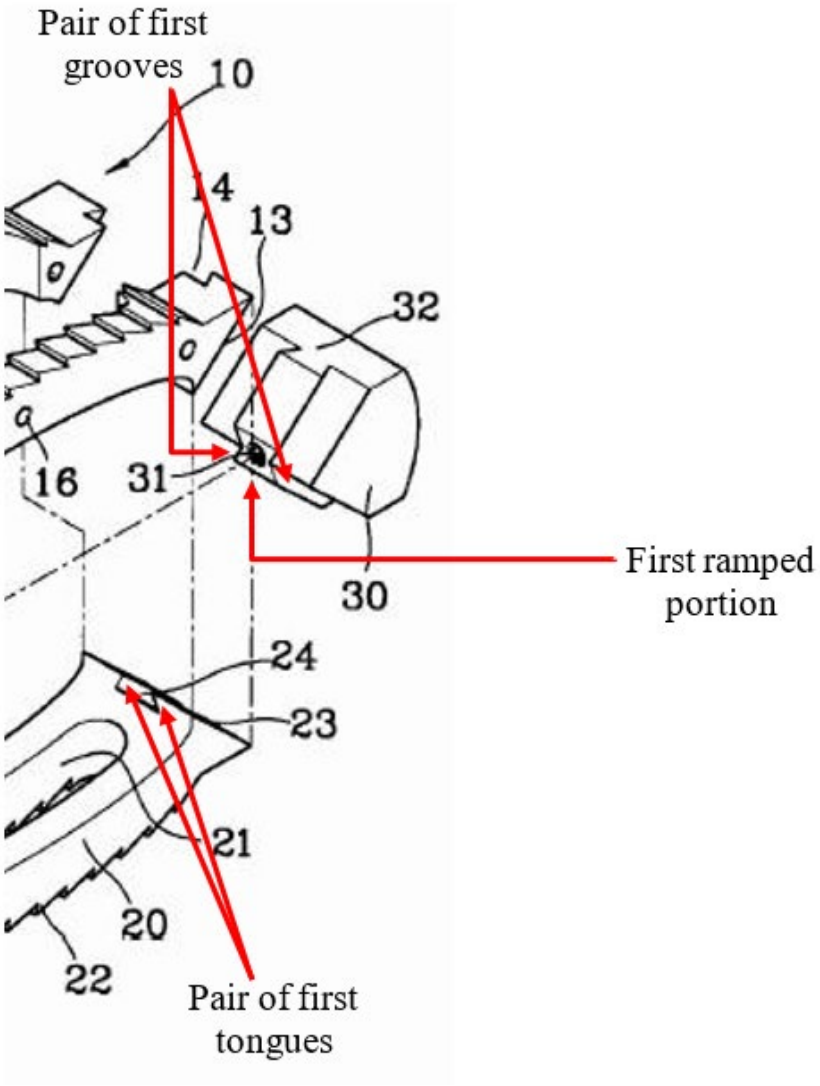


Accordingly, Chung discloses this limitation. EX1002, ¶¶111-113.

(j) Claim 1[i]

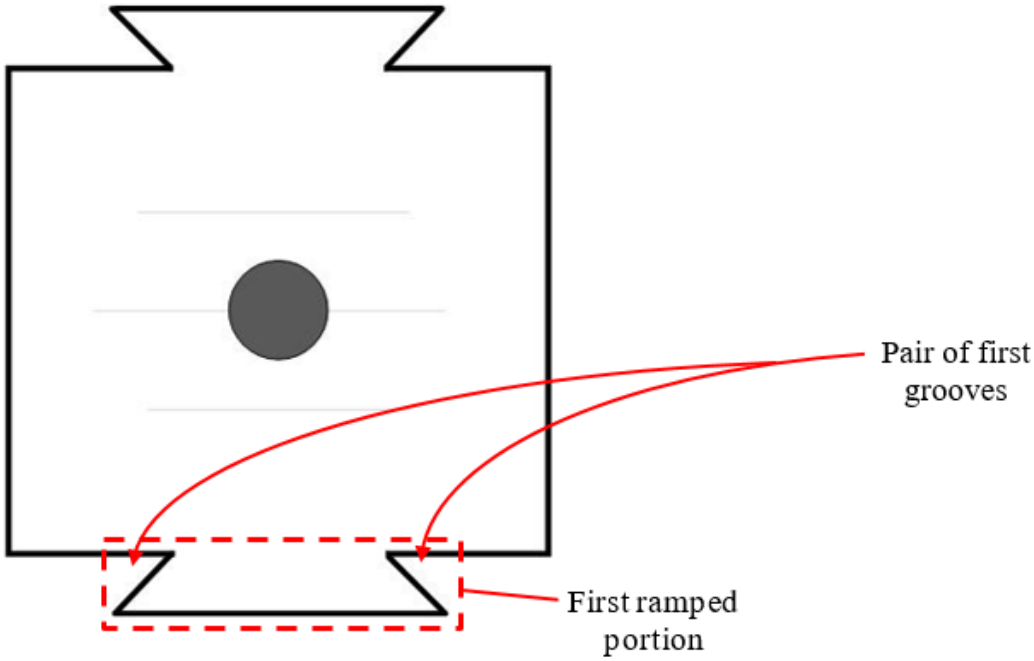
Claim 1 recites that "**the first ramped portion has a pair of first grooves, each of the first grooves sized to receive one of the first tongues**." Chung's first ramped portion has a pair of first grooves (created by the overhanging edges on either side of lower dovetail (32)), each sized to receive one of the first tongues from the corresponding endplate dovetail structure. EX1005, 4; *see also id.*, 5. This is observable in Fig. 2, below.

Chung, Fig. 2



Furthermore, the following depiction of a vertical cross-section of Chung's central ramp (*see* §IX(A)(1)(g), *supra*) further illustrates the pair of first grooves:

Petitioner-Generated Figure



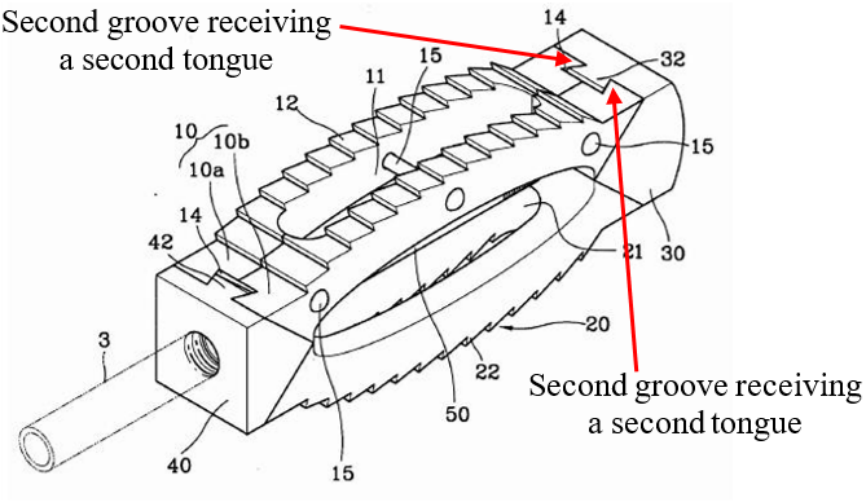
Accordingly, Chung discloses this limitation. EX1002, ¶¶114-117; *see also* EX1004, 000066-67 (finding Olmos's guide members 232, 272, which are comparable to Chung's dovetails (32), disclose Claims 1[i]-[j]); §§IX(A)(1)(b), (f), *supra*.

(k) Claim 1[j]

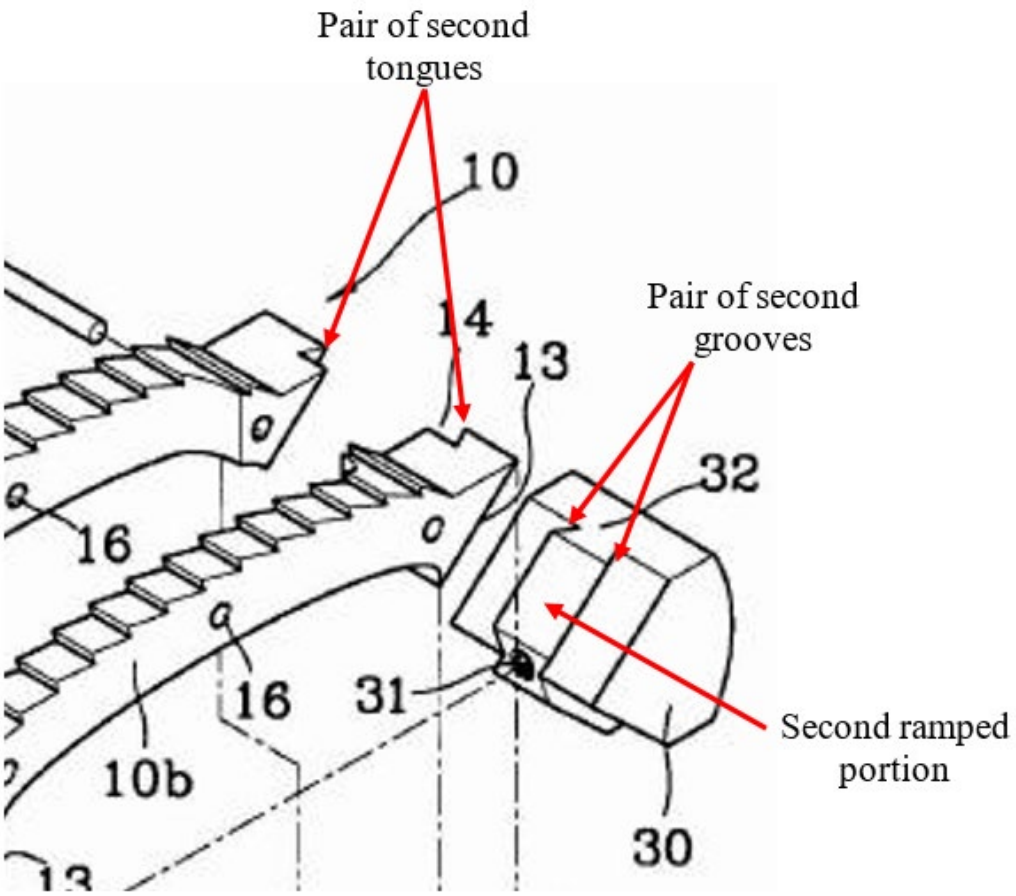
Claim 1 recites that "**the second ramped portion has a pair of second grooves, each…sized to receive one of the second tongues**." Chung's second ramped portion has a pair of second grooves (created by the two overhanging edges on either side of upper dovetail (32)), each sized to receive one of the second

tongues from the corresponding endplate dovetail structure. EX1005, 4; *see also id.*, 5. Annotated Figs. 1-2, below, show these structures.

Chung, Fig. 1

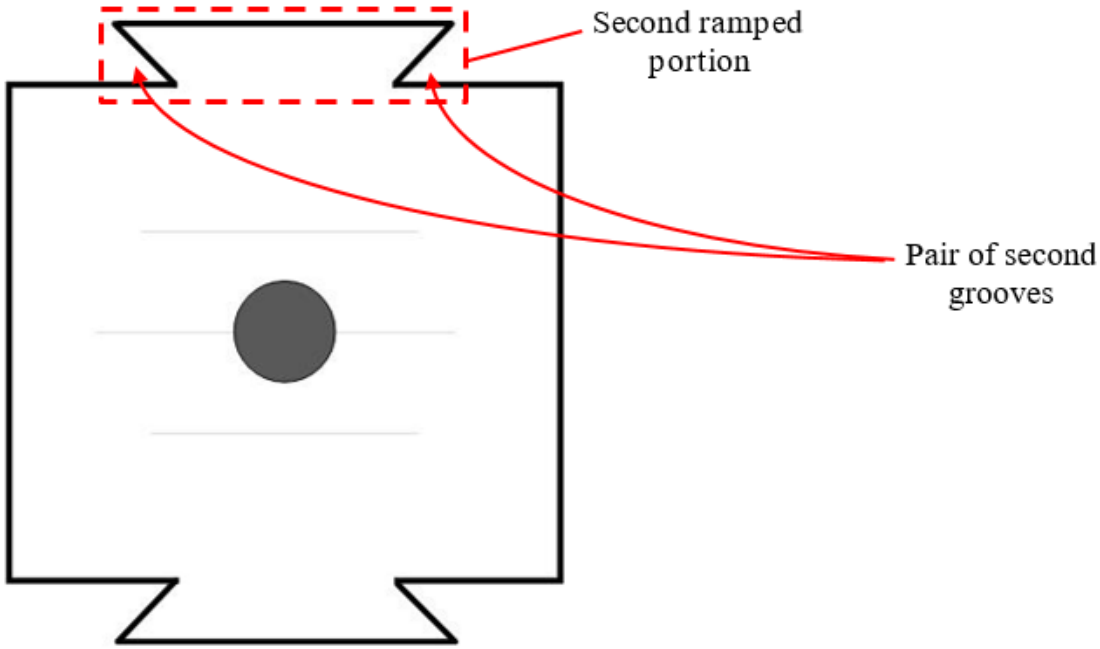


Chung, Fig. 2



Furthermore, the following depiction of the aforementioned vertical cross-section of Chung's central ramp (*see* §IX(A)(1)(g), *supra*) further illustrates the pair of second grooves:

Petitioner-Generated Figure



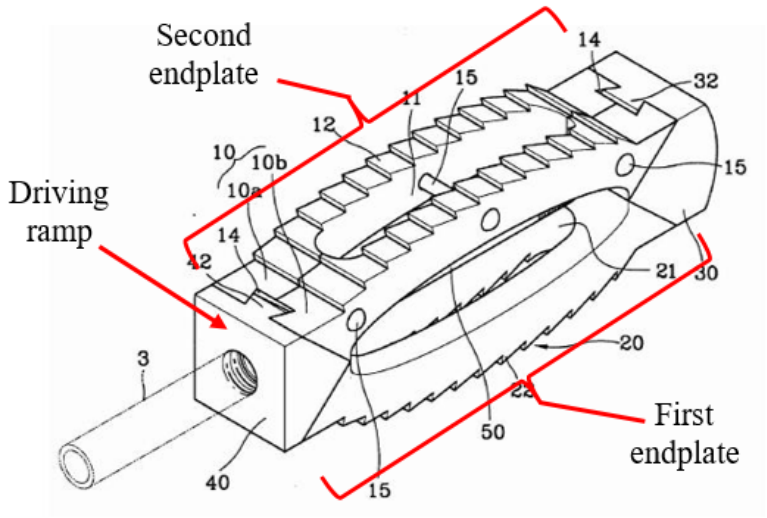
Accordingly, Chung discloses this limitation. EX1002, ¶¶118-121; *see also* EX1004, 000066-67 (finding Olmos's guide members 232, 272, which are comparable to Chung's dovetails (32), disclose Claims 1[i]-[j]); §§IX(A)(1)(c), (f), *supra*.

(l) Claim 1[k]

Claim 1 recites "**a driving ramp positioned between the first endplate and the second endplate**." Chung's "opposing wedge (40)" is a driving ramp positioned between the first endplate and the second endplate. EX1005, 4. Chung's opposing wedge (40) is a "separation device[] in order to adjust the space between the aforementioned main holder bodies (10) (20)…" that is "slid between [the]

ends of the aforementioned main holder bodies (10) (20)." *Id.*, 5. This is also visible in Figs. 1-4, with annotated Fig. 1 below.

Chung, Fig. 1

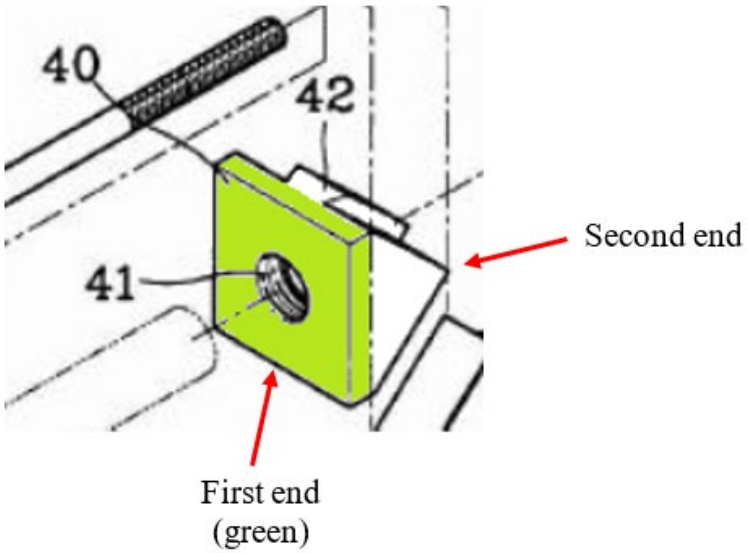


Accordingly, Chung discloses this limitation. EX1002, ¶¶122-126.

(m) Claim 1[l]

Claim 1 recites that "**the driving ramp comprises a first end and a second end**." Chung's driving ramp has a first (wider) end and a second (narrowed) end. EX1005, Figs. 1-4. An annotated excerpt of Fig. 2 follows.

Chung, Fig. 2

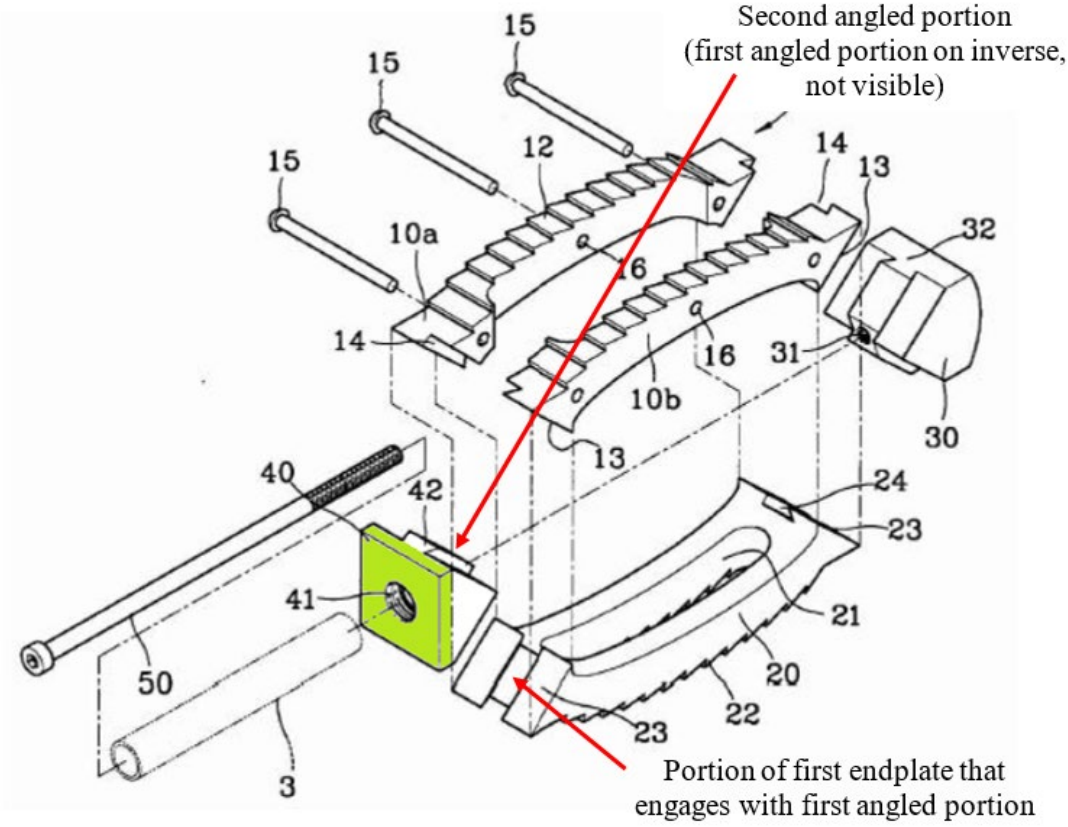


Accordingly, Chung discloses this limitation. EX1002, ¶¶127-129.

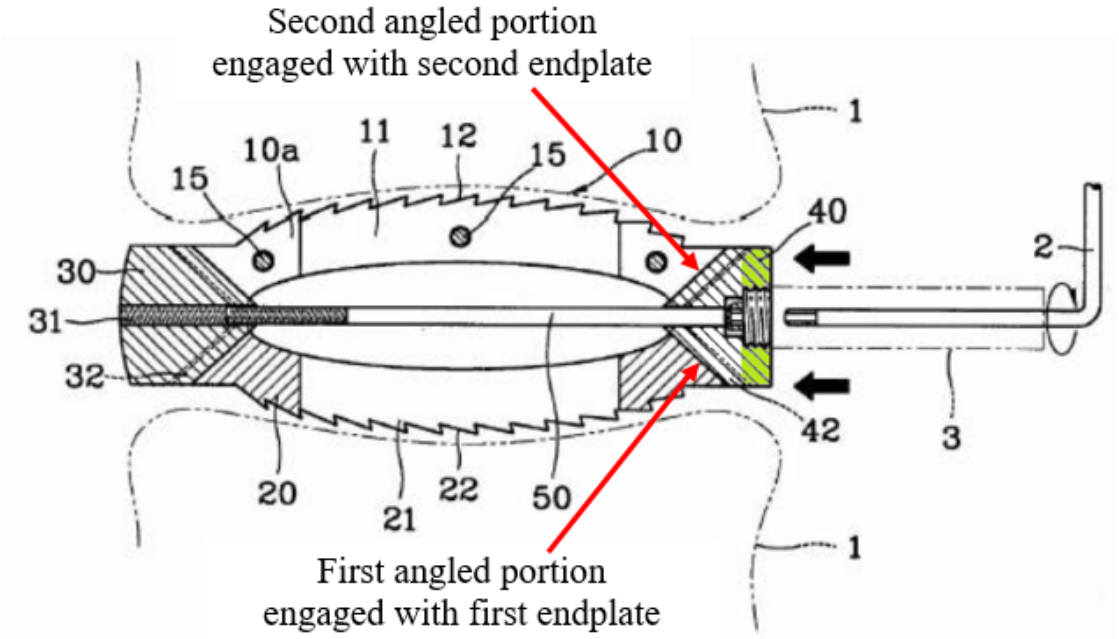
(n) Claim 1[m]

Claim 1 recites that "**the second end includes a first angled portion configured to engage a portion of the first endplate and a second angled portion configured to engage a portion of the second endplate**." The second end of Chung's driving ramp has first and second angled portions comprising the flat surfaces of lower and upper dovetail (42). EX1005, 5. These portions are seen in Figs. 2-4, with annotated Figs. 2-3 provided below.

Chung, Fig. 2


Second angled portion
(first angled portion on inverse,
not visible)
15
15
15
12
14
13
32
10a
16
14
16
31
10b
30
13
40
42
24
23
41
21
50
20
22
23
3
Portion of first endplate that
engages with first angled portion

Chung, Fig. 3



The first and second angled portions are respectively configured to engage portions of the first and second endplates through their mating dovetail structures. *Id.*, 5; *see also id.*, 4. Figure 1 shows this engagement.

Moreover, Chung is consistent with the '001 patent. Although the '001 specification never uses the term "angled portion" and never describes the driving ramp as having a "first end" or a "second end," in describing the Figs. 25-27 embodiment, the '001 patent discloses that "[t]he second end 236 of the central ramp 18…includes opposing angled surfaces 246," which are "configured and dimensioned to engage the ramped surface 228…in each of the first and second endplates 14, 16." EX1001, 11:26-34. Since a POSITA would reasonably assume

that this description likewise applies to the relevant features in the driving ramp, this described configuration is the same as Chung's driving ramp in all meaningful respects. This is further observable in annotated Figs. 24-25, below:

'001 Patent, Figs. 24-25

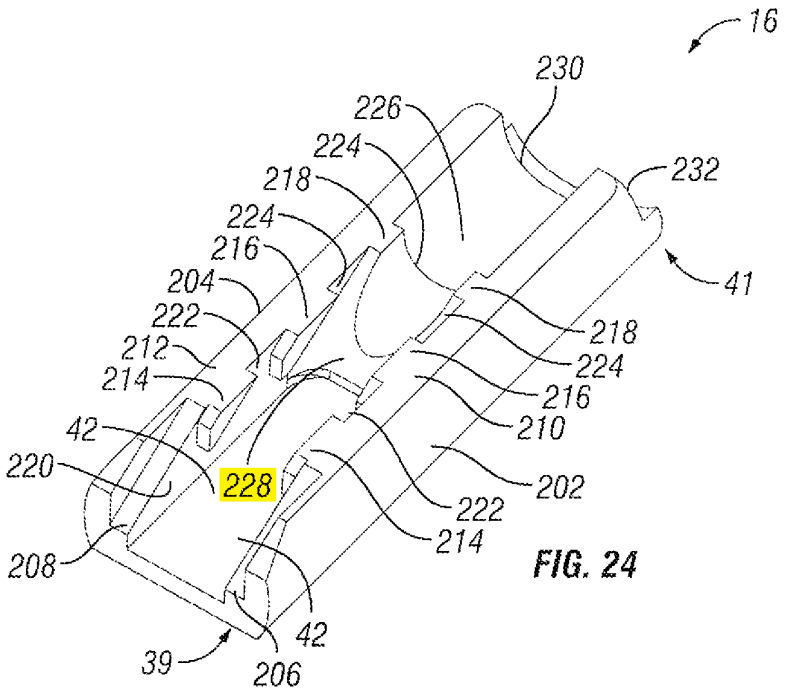


FIG. 24

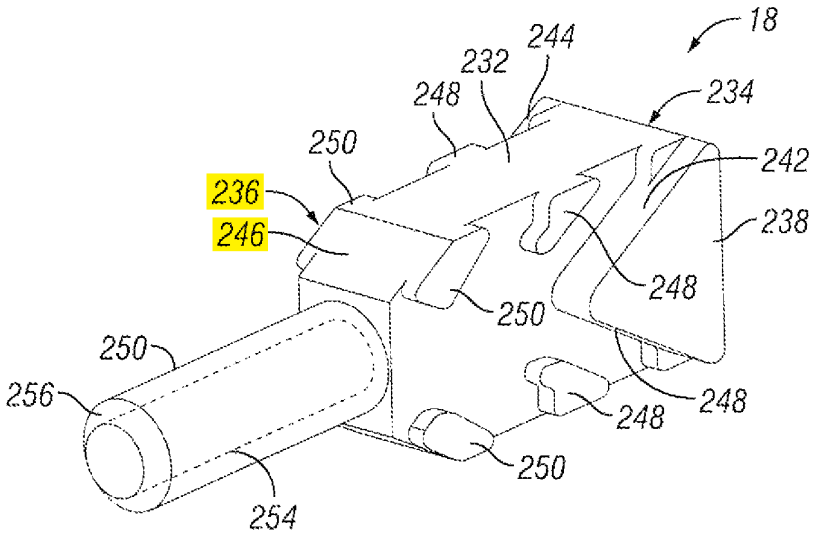


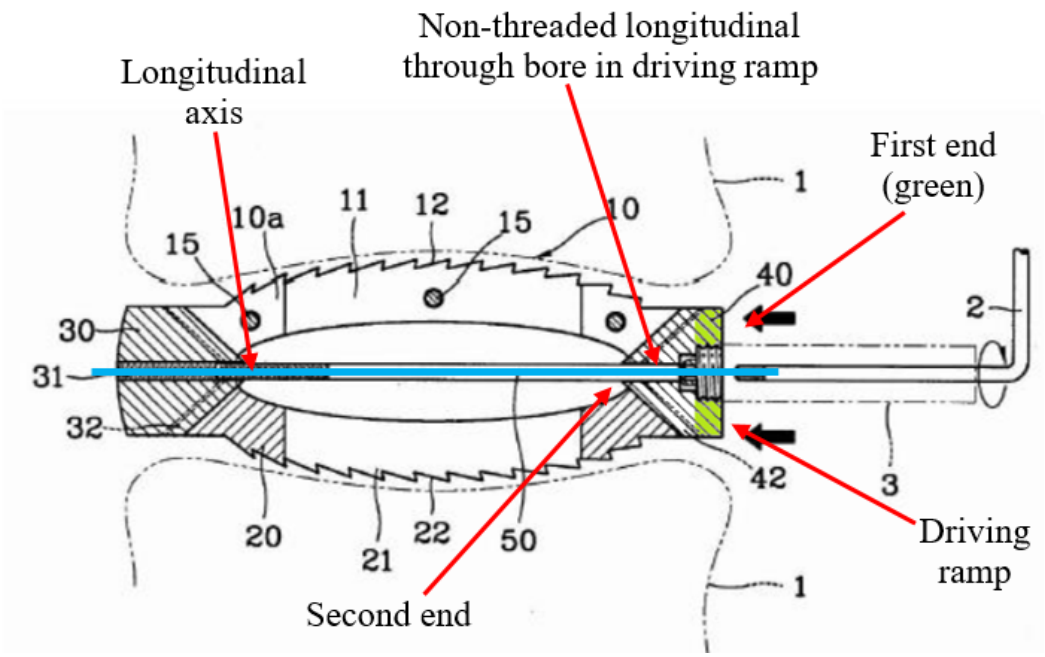
FIG. 25

Accordingly, Chung discloses this limitation. EX1002, ¶¶130-132; *see also* §IX(A)(1)(k), *supra*.

(o) Claim 1[n]

Claim 1 recites that "**the driving ramp has a non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp**." Chung's driving ramp has a non-threaded longitudinal through bore ("penetrating hole (41)") extending from the first end to the second end. EX1005, 6. This limitation is visible in at least Chung Figs. 2-4, with an annotated excerpt of Fig. 3 provided below.

Chung, Fig. 3



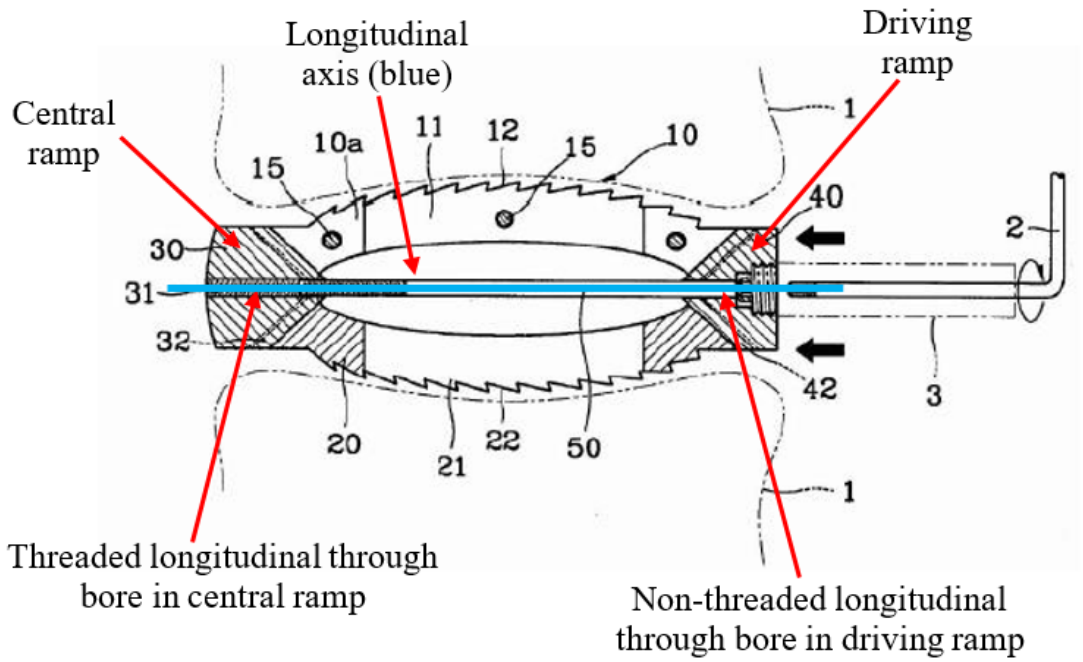
In addition, while bore hole's outermost portion has a wider diameter and shows some threads within the first end of the driving ramp (shown in green), these threads are situated within the first end itself, and are not related to the operation of the groove fastening screw; instead, these threads facilitate attachment of a structure Chung identifies as a "wrapper (3)," which the surgeon uses to maintain control and positioning of the device. EX1005, 6. A POSITA would have been well aware of other methods and configurations for maintain control and positioning of the device, which would have made such threads in the outer portion of Chung's bore hole superfluous. EX1002, ¶139. Accordingly, it would have been an obvious modification to simply omit these particular threads from the outer portion of Chung's bore hole, thereby providing an entirely unthreaded bore hole. *Id*.

Accordingly, Chung discloses this limitation and/or renders it obvious. EX1002, ¶¶133-140.

(p) Claim 1[o]

Claim 1 recites that "**the longitudinal bore of the of the [*sic*] central ramp and the non-threaded longitudinal through bore of the driving ramp are coaxially aligned**." Chung Figs. 2-4 show that the central ramp bore ("screw hole (31)") and non-threaded driving ramp bore ("penetrating hole (41)") are coaxially aligned along a longitudinal axis. Excerpted Fig. 3 shows this configuration:

Chung, Fig. 3

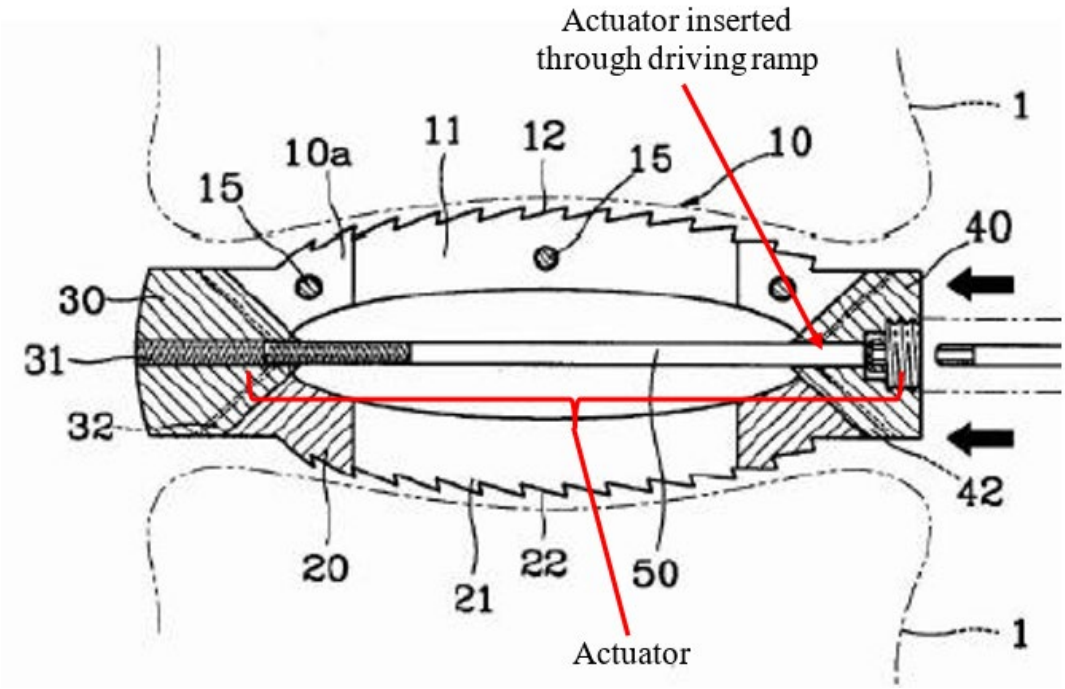


Accordingly, Chung discloses this limitation. EX1002, ¶¶141-142.

(q) Claim 1[p]

Claim 1 recites "**an actuator insertable through the driving ramp**." Chung's actuator ("groove fastening screw (50)") is insertable through the driving ramp. EX1005, 6. This is observable in at least Figs. 3-4, with an annotated excerpt of Fig. 3 below.

Chung, Fig. 3

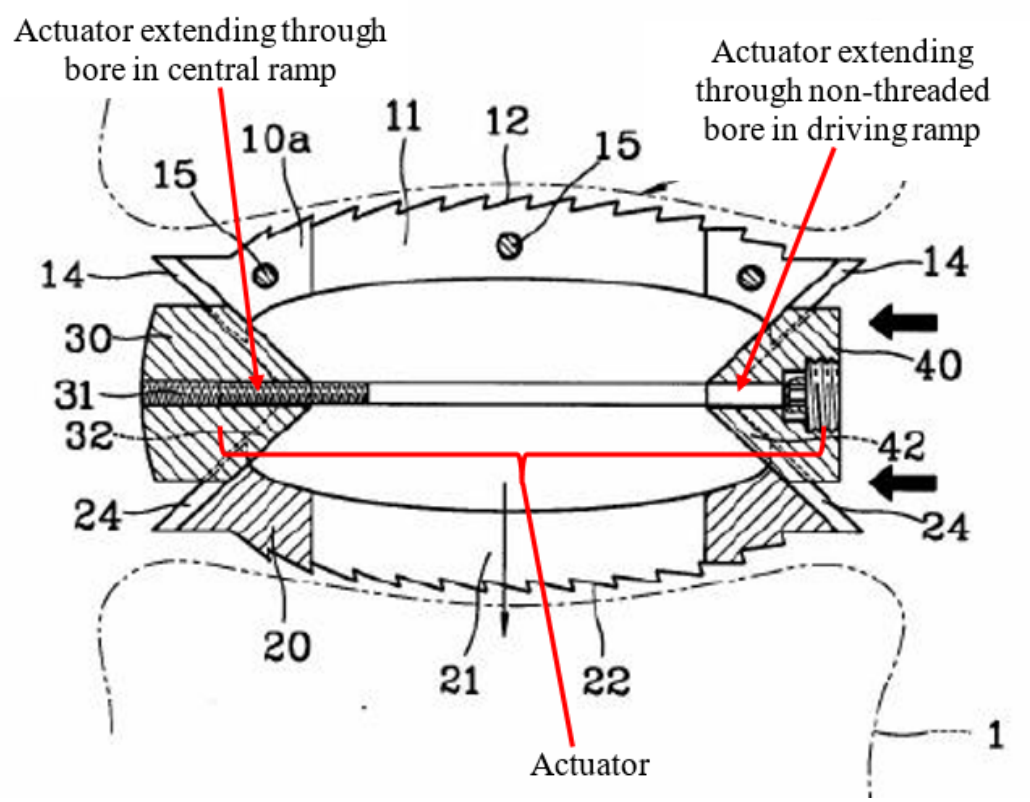


Accordingly, Chung discloses this limitation. EX1002, ¶¶143-145.

(r) Claim 1[q]

Claim 1 recites that "**a portion of the actuator extends through the non-threaded longitudinal through bore of the driving ramp and the longitudinal bore of the central ramp**." A portion of Chung's actuator ("groove fastening screw (50)") extends through the non-threaded driving ramp bore and the central ramp bore. EX1005, 6; *see also id.*, 1 (describing screw hole (31), penetrating hole (41), and "a groove fastening screw that is fastened between the aforementioned opposing wedge and the aforementioned lead wedge"). This is further observable in at least Figs. 3-4, with annotated Fig. 4 below.

Chung, Fig. 4



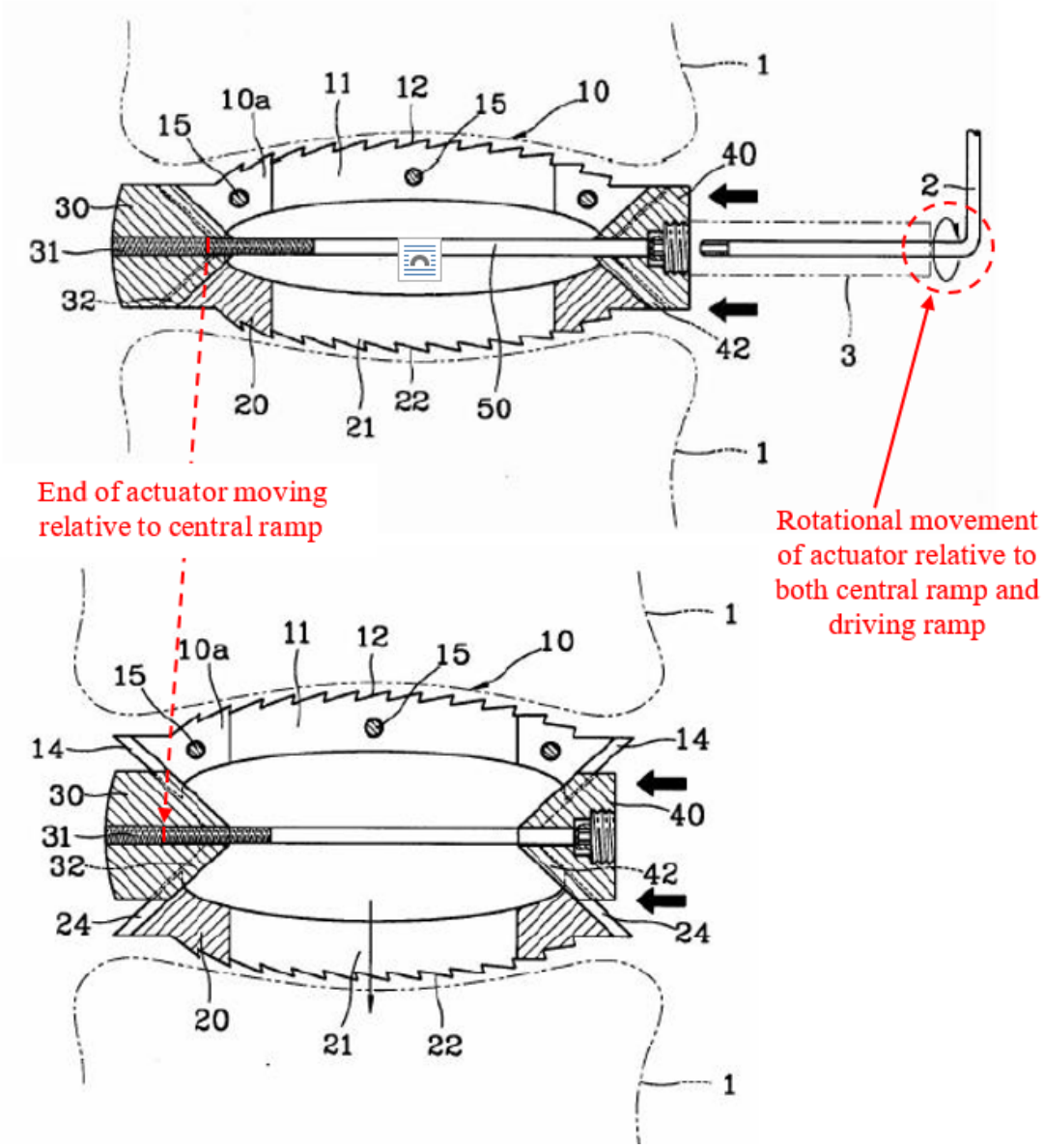
Accordingly, Chung discloses this limitation. EX1002, ¶¶146-148.

(s) Claim 1[r]

Claim 1 recites that "**the actuator is disposed and remains within the non-threaded longitudinal bore, and the actuator is movable with respect to the central ramp and the driving ramp**." Chung's actuator is disposed and remains within driving ramp's non-threaded bore ("opposing wedge (40) has a penetrating hole (41) with a raised spot in order for the aforementioned groove fastening screw (50)'s head to be held") and is movable with respect to the central and driving ramps (noting that both wedges slide along the main holder body guiding surfaces

as groove fastening screw (50) is tightened). EX1005, 6; *see also id.*, 1. This is further observable in annotated Figs. 3-4, which indicate the actuator's rotational movement relative to both ramps (note the circular arrow in Fig. 3) and the actuator's translational movement relative to the central ramp:

Chung, Figs. 3-4

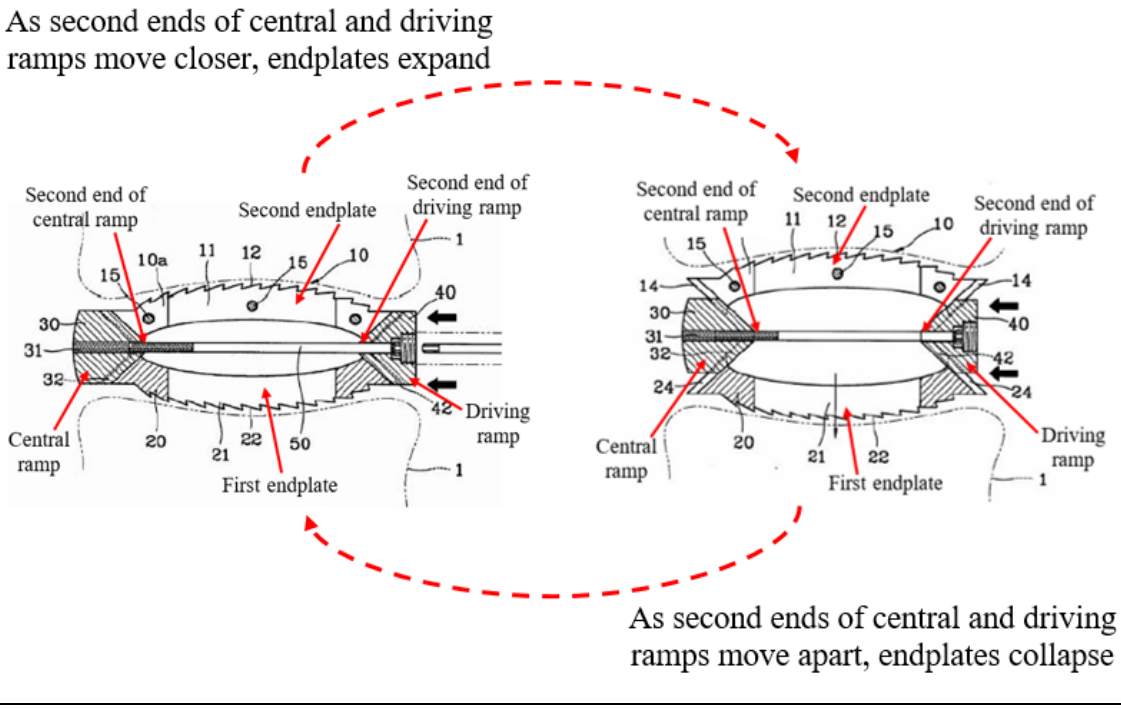


Accordingly, Chung discloses this limitation. EX1002, ¶¶149-152.

(t) Claim 1[s]

Claim 1 recites that "**the actuator is configured to translate the driving ramp such that the second end of the driving ramp is moved closer to the second end of the central ramp to thereby cause expansion of the first endplate and the second endplate**." Chung's fastening screw is configured to move the ramps closer together, thereby causing expansion of the endplates ("push[ing] the aforementioned main holder bodies (10) (20) outward"). EX1005, 6. This is observable by comparing Figs. 3 and 4:

Chung, Figs. 3-4

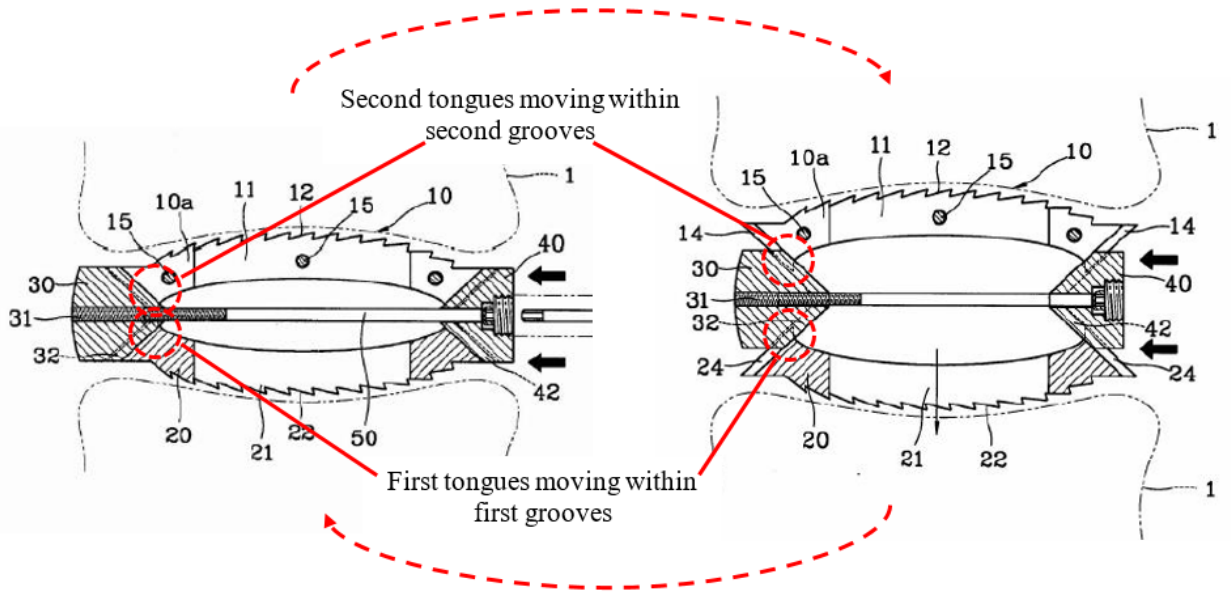


Accordingly, Chung discloses this limitation. EX1002, ¶¶153-155.

(u) Claim 1[t]

Claim 1 recites that "**the first tongues and the second tongues are configured to move within corresponding first grooves and second grooves to expand and compress the expandable implant**." Chung's first and second tongues (of the first and second endplates/holder bodies (10) (20)) move within the corresponding first and second ramp grooves to expand and compress the expandable implant as the ramps move away from or towards each other. EX1005, 5-6; *see also* §§IX(A)(1)(c)-(d), (j)-(k), *supra*. This is seen in annotated Figs. 3-4:

Chung, Figs. 3-4



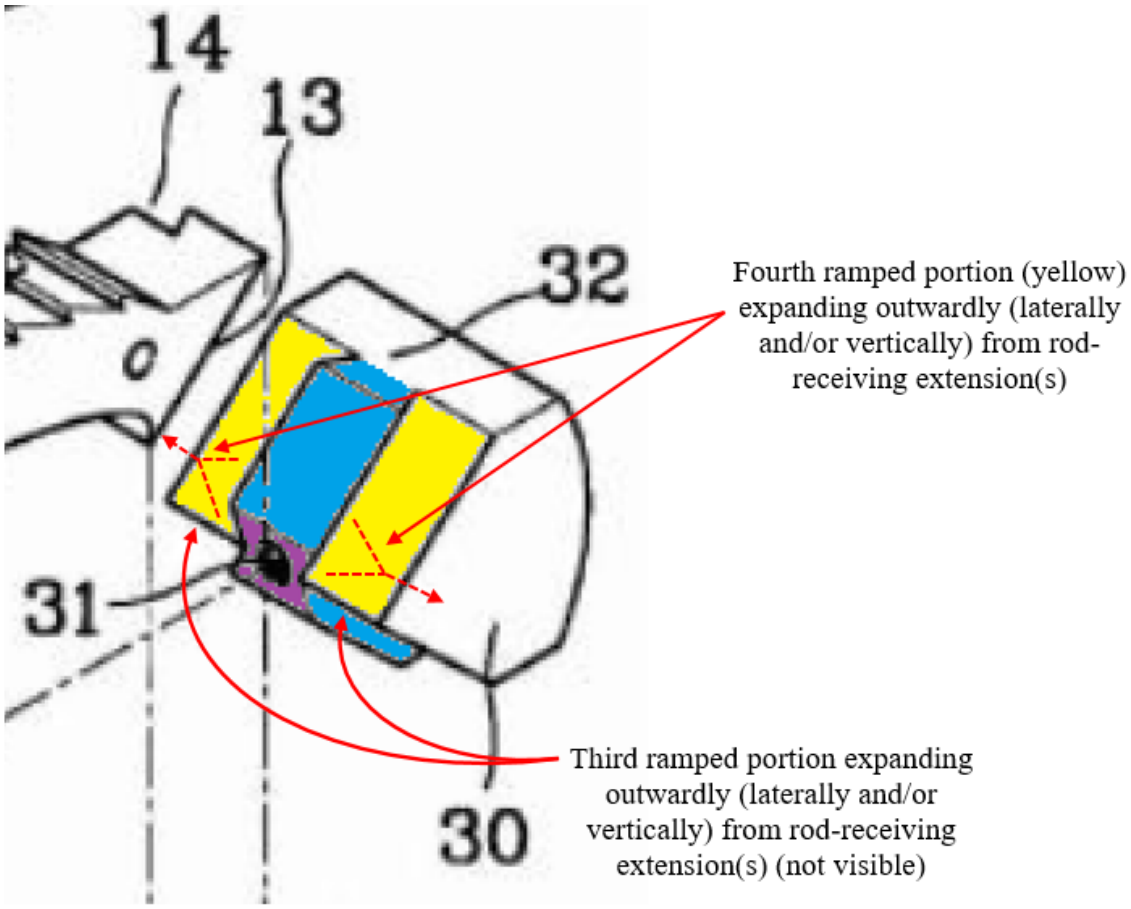
Accordingly, Chung discloses this limitation. EX1002, ¶¶156-158.

(v) Claim 1[u]

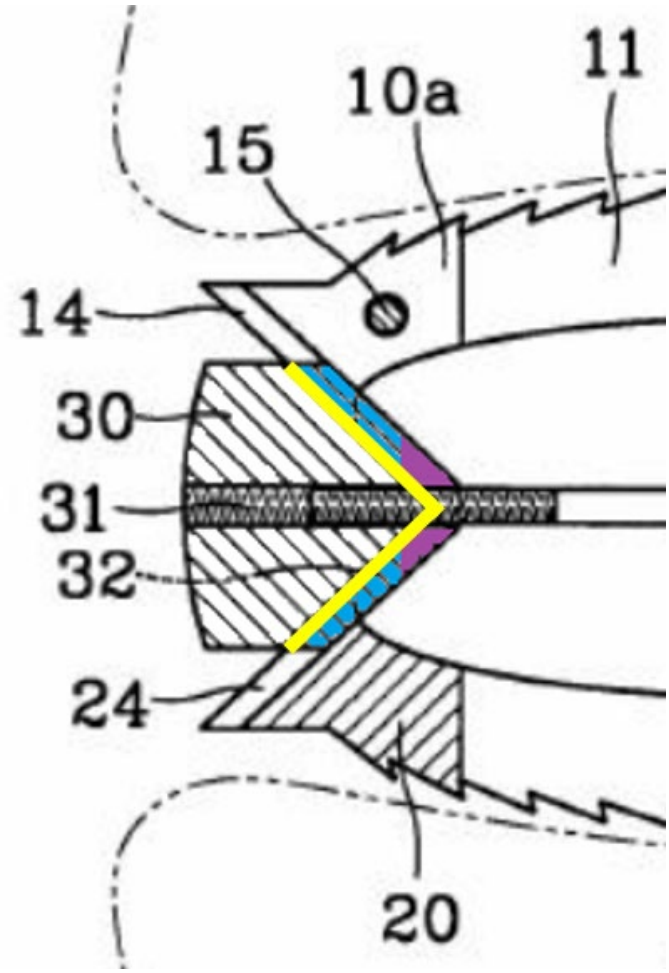
Claim 1 recites that "**the third ramped portion and the fourth ramped portions extend outwardly from a rod receiving extension of the central ramp**." Chung discloses this limitation in at least two ways. First, Chung's dovetail 32 "extends" from the surface of lead wedge (30) and houses bore hole 31 for receiving the rod-shaped groove fastening screw (50), thus serving as one embodiment of a "rod receiving extension," as highlighted in blue in the annotated Fig. 4 excerpt below. Second, part of dovetail 32 further extends longitudinally from lead wedge (30) toward opposing wedge (40), having bore hole 31 for receiving the rod-shaped groove fastening screw, which thereby represents a second embodiment of the claimed "rod receiving extension," as highlighted in purple in the figure annotations below. *See* EX1005, 6, Figs. 3-5.

The third and fourth ramp portions (shown in yellow) extend outwardly (i.e., laterally to either side and/or vertically above and below) from the extensions identified in blue and purple, as indicated below:

Chung, Fig. 2


14
13
32
31
30
Fourth ramped portion (yellow) expanding outwardly (laterally and/or vertically) from rod-receiving extension(s)
Third ramped portion expanding outwardly (laterally and/or vertically) from rod-receiving extension(s) (not visible)

Chung, Fig. 4



Accordingly, Chung discloses this limitation. EX1002, ¶¶159-166.

(w) Claim 1[v]

Claim 1 recites "**introducing bone graft material adjacent the expandable implant**." Chung discloses that "opening part (101) is installed in order to allow nutrition to flow into the body, and through the aforementioned opening part (101) the back bone implant that facilitates bonding of body parts is being filled." Chung's device further has "long penetrating holes formed at the

center in order for the back bone implant material to pass through due to their combination." EX1005, 3-4. A POSITA would have understood introducing a "back bone implant material" adjacent to the expandable implant to refer to the introduction of "bone graft material" adjacent to the expandable implant because bone grafting is the desired outcome in such procedures. EX1002, ¶¶167-169. Accordingly, Chung discloses this limitation. *Id*.

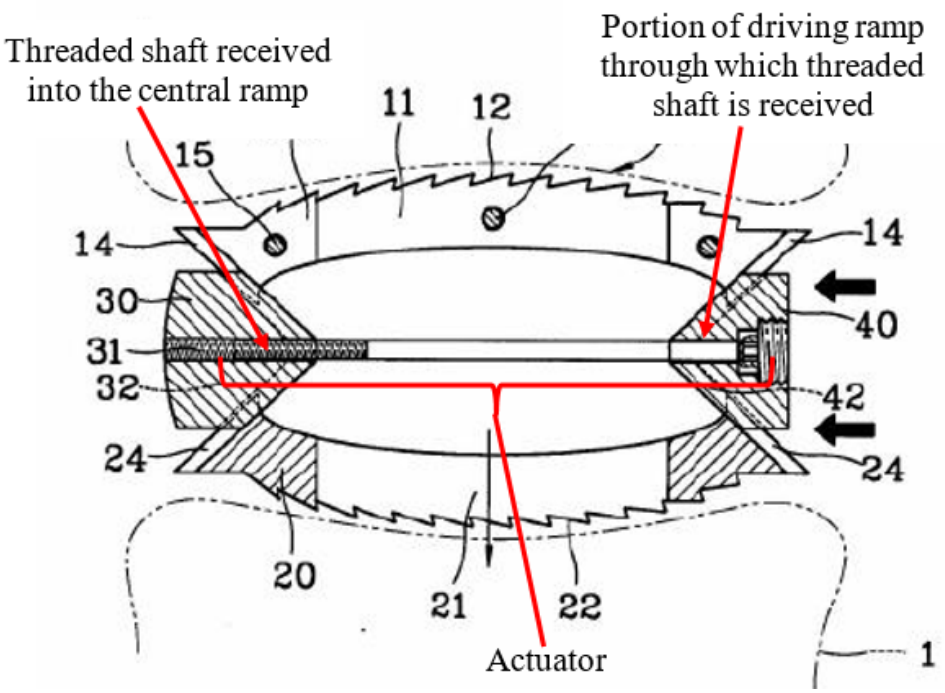
Alternatively, to the extent Patent Owner argues that Chung does not expressly disclose that "back bone implant material" is bone graft material, it would have been obvious to a POSITA to introduce bone graft material adjacent to the Chung implant given that this treatment was well-known in the art at the time, and was considered to be the "gold standard" approach. EX1002, ¶¶46, 168-169. Thus, Claim 2 would also be obvious over Chung in view of the knowledge of a POSITA. *Id*.

2. Claim 3

Claim 3 recites that "**the actuator comprises a threaded shaft that is received through the driving ramp and into the central ramp**." Chung's actuator comprises a threaded shaft ("the screw component of the aforementioned groove fastening screw (50)") that is received through the driving ramp's penetrating hole (41) and into the central ramp's screw hole (31). EX1005, 6; *see also id.*, 5 (describing "the groove fastening screw (50) that is fastened between the

aforementioned lead wedge (30) and the opposing wedge (40)"). Figures 3-4 show these features, with annotated Fig. 4 provided below.

Chung, Fig. 4



Accordingly, Chung discloses this limitation. EX1002, ¶¶170-173.

3. Claim 4

Claim 4 recites that "**the actuator is rotatable**." Chung's groove fastening screw (50) can be "loosened or tightened," which a POSITA would have understood to mean the actuator is rotatable. EX1005, 6; *see also* Fig. 3 (showing circular arrow to indicate rotation of screw/actuator). Accordingly, Chung discloses this limitation. EX1002, ¶¶174-176.

4. Claim 10

Claim 10 consists solely of limitations already addressed previously, as detailed below.

(a) Claim 10[pre]

Chung discloses a surgical method. *See* §IX(A)(1)(a)*;* EX1002, ¶177.

(b) Claim 10[a]

Claim 10 recites "**creating an access path to an intervertebral disc space**" and "**inserting an expandable implant into the disc space**." Chung discloses these limitations. *See* §IX(A)(1)(b); EX1002, ¶¶178-179.

(c) Claim 10[b]

Claim 10 recites a "**first endplate having a pair of first tongues**." Chung discloses this limitation. *See* §IX(A)(1)(c); EX1002, ¶¶180-181.

(d) Claim 10[c]

Claim 10 recites a "**second endplate opposed to the first endplate, the second endplate having a pair of second tongues**." Chung discloses this limitation. *See* §IX(A)(1)(d); EX1002, ¶¶182-183.

(e) Claim 10[d]

Claim 10 recites a "**central ramp positioned between the first endplate and the second endplate**." Chung discloses this limitation. *See* §IX(A)(1)(e); EX1002, ¶¶184-185.

(f) Claim 10[e]

Claim 10 recites that "**the central ramp comprises a first end and a second end**." Chung discloses this limitation. *See* §IX(A)(1)(f); EX1002, ¶¶186-187.

(g) Claim 10[f]

Claim 10 recites that:

> **the second end includes a first ramped portion configured to engage a portion of the first endplate and a second ramped portion configured to engage a portion of the second endplate, and a third ramped portion configured to engage a portion of the first endplate and a fourth ramped portion configured to engage a portion of the second endplate positioned between the first and second ends**.

Chung discloses this limitation. *See* §IX(A)(1)(g)-(h); EX1002, ¶¶188-189.

(h) Claim 10[g]

Claim 10 recites that "**the central ramp has a longitudinal bore**," and that "**the first ramped portion has a pair of first grooves, each of the first grooves sized to receive one of the first tongues**." Chung discloses these limitations. *See* §IX(A)(1)(i)-(j); EX1002, ¶¶190-191.

(i) Claim 10[h]

Claim 10 recites that "**the second ramped portion has a pair of second grooves, each of the second grooves sized to receive one of the second tongues**." Chung discloses this limitation. *See* §IX(A)(1)(k); EX1002, ¶¶192-193.

(j) Claim 10[i]

Claim 10 recites a "**driving ramp positioned between the first endplate and the second endplate**." Chung discloses this limitation. *See* §IX(A)(1)(l); EX1002, ¶¶194-195.

(k) Claim 10[j]

Claim 10 recites that "**the driving ramp comprises a first end and a second end**" and that "**the second end includes a first angled portion configured to engage a portion of the first endplate and a second angled portion configured to engage a portion of the second endplate**." Chung discloses this limitation. *See* §IX(A)(1)(m)-(n); EX1002, ¶¶196-197.

(l) Claim 10[k]

Claim 10 recites an "**actuator insertable through the driving ramp**." Chung discloses this limitation. *See* §IX(A)(1)(q); EX1002, ¶¶198-199.

(m) Claim 10[l]

Claim 10 recites that:

> **a portion of the actuator extends through the driving ramp and the central ramp, the actuator is disposed and remains within the bore of the driving ramp and the actuator is movable with respect to the central ramp and the driving ramp**.

Chung discloses this limitation. *See* §IX(A)(1)(r)-(s); EX1002, ¶¶200-201.

(n) Claim 10[m]

Claim 10 recites that:

> **the actuator is configured to translate the driving ramp such that the second end of the driving ramp is moved closer to the second end of the central ramp to thereby cause expansion of the first endplate and the second endplate**.

Chung discloses this limitation. *See* §IX(A)(1)(t); EX1002, ¶¶202-203.

(o) Claim 10[n]

Claim 10 recites that "**the first tongues and the second tongues are configured to move within corresponding first grooves and second grooves to expand and compress the expandable implant**." Chung discloses this limitation. *See* §IX(A)(1)(u); EX1002, ¶¶204-205.

(p) Claim 10[o]

Claim 10 recites that "**the third ramped portion and the fourth ramped portions extend outwardly from a rod receiving extension of the central ramp**." Chung discloses this limitation. *See* §IX(A)(1)(v); EX1002, ¶¶206-207.

Accordingly, Chung anticipates or renders obvious claims 1, 3-4, and 10 of the '001 patent.

B. Ground 2: Claims 2, 5-9, and 11 are obvious over Chung in view of the knowledge of a POSITA or Olmos

Claims 2, 5-9, and 11 of the '001 patent are obvious under 35 U.S.C. §103 over Chung in view of the knowledge of a POSITA and/or Olmos, as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶208-253).

1. Claim 2

Claim 2 recites that "**the access path is created via a posterolateral approach**." It would have been obvious to a POSITA use a posterolateral approach to implant the Chung device in view of the knowledge of a POSITA and/or Olmos.

The posterolateral approach is one of several approaches that were well-known and conventional in the field of spinal surgery at the time of invention. EX1002, ¶213. Moreover, Olmos teaches that an intervertebral implant may be introduced into a disc space using any of a number of different approaches, including "***posterior[ly] in an posterior lumbar interbody fusion (PILF) or posterial lateral interbody fusion***." EX1006, ¶[0071] (emphasis added). Accordingly, Chung with the knowledge of a POSITA and/or Olmos discloses creating an access path via a posterolateral (i.e., posterial lateral) approach. *Id.*, ¶¶208-214.

2. Claim 5

Claim 5 recites "**introducing a second expandable implant into the disc space**." It would have been obvious to introduce a second Chung device into the disc space in view of Olmos. Specifically, Olmos discloses that "the number of implants used in the spinal fusion procedure can also be varied to include one or more" and that "a plurality of intervertebral implants…can be disposed in an intervertebral space of the spine…." EX1006, ¶¶[0143]-[0144]; *see also* EX1022, 565 ("Numerous cage designs have been commercialized, all suggesting bilateral cages insertion…."); EX1026, 219 (describing "implantation of two cages" as "common"); §IX(D)(5), *infra*.

Accordingly, Chung with Olmos discloses this limitation. *Id.*, ¶¶215-220.

3. Claim 6

Claim 6 recites that "**the second expandable implant also includes a central ramp, a driving ramp, and an actuator**." This claim merely repeats elements found in Claim 1, applying them to the second device of Claim 5. For the reasons set forth in Ground 1 (*see* §§IX(A)(1)(f), IX(A)(1)(m), IX(A)(1)(r)) and as to Claim 5 above, it would have been obvious to use the same device for both implants called for in Claim 5. EX1002, ¶¶221-224. Accordingly, Chung with Olmos discloses this limitation. *Id*.

4. Claim 7

Claim 7 recites that "**the second expandable implant is introduced via the same access path as the expandable implant**." When introducing a second device as taught by Olmos (*see* claim 5 above), it would have been obvious to use the same access path when the intended locations of the two devices are close enough together that a single access path can be used, based on at least the knowledge of a POSITA.

When discussing introduction of a plurality of devices, Olmos discloses that various "configurations, orientations, and operational parameters are contemplated in order to aid the clinician in ensuring that the adjacent vertebrae are properly supported, and that such procedure is performed in a minimally invasive manner." *Id.* Depending on the patient's needs, the devices may be introduced using either a unilateral/single access path technique, or a bilateral/multiple access path technique. EX1002, ¶¶227-228; *see* EX1026 at 219 (teaching unilateral and bilateral procedures as the two options when introducing multiple devices).

A POSITA would have understood that, depending on where the two expandable implants needed to be oriented or positioned to provide optimal support, the implant locations may both be accessible using a single access path (e.g., if the implants are to be positioned on the same side of the spinal cord in a unilateral fusion), or may be accessible only using two different access paths (e.g.,

if the implants must be positioned on different sides of the spinal cord in a bilateral fusion). EX1002, ¶¶227-228. In the former situation, a POSITA would have understood that the second expandable implant could be introduced via the same access path as the first expandable implant, which will be more practical and time-efficient and would also meet Olmos's stated goal of "aid[ing] the clinician in ensuring…that such procedure is performed in a minimally invasive manner." EX1002, ¶228; EX1006, ¶[0144]. In other words, when feasible, one incision is better than two. *Id*.

Accordingly, Chung with Olmos and the knowledge of a POSITA renders this claim obvious. *Id.*, ¶¶225-233.

5. Claim 8

Claim 8 recites that "**the second expandable implant is introduced via a different access path as the expandable implant**." When introducing a second device as taught by Olmos (*see* claim 5 above), it would have been obvious (required, even) to use different access paths when the intended locations of the two devices are far enough apart that a single access path could not be used.

Olmos recognizes that implants may be introduced in a variety of angular orientations and positions, depending on how the adjacent vertebrae need to be supported. EX1006, ¶[0144]; §IX(D)(7), *infra*. A POSITA would have understood that, depending on where the two expandable implants needed to be oriented or

positioned to provide optimal support, the implant locations may be accessible only using two different access paths (e.g., if the implants must be positioned on different sides of the spinal cord in a bilateral fusion), which has actually been the more traditional approach. EX1026, 219 (disclosing bilateral (i.e., multi-access path) procedure for multiple implants); EX1002, ¶¶227-228. A POSITA thus would have understood that the second expandable implant is sometimes introduced via a different access path than the first expandable implant, which is the more traditional approach even while more recent techniques seek to use a single access path whenever possible to minimize intrusiveness. EX1002, ¶237; *cf.* EX1026, 219-220; EX1027 at 910-13.

Accordingly, Chung with Olmos and the knowledge of a POSITA renders this claim obvious. *Id.*, ¶¶234-239.

6. Claim 9

Claim 9 recites that "**at least one of the access path and the different access path are formed via posterolateral approaches**." Olmos discloses this limitation, as discussed previously. *See* §IX(B)(1); *see also* §§IX(D)(2), *infra*. Moreover, a POSITA would recognize that, in a bilateral procedure, which was traditionally more common than a unilateral procedure, using a posterolateral approach for both access paths (and thus for "at least one of the access path and the different access path") would be beneficial as it allows a surgeon to create two

access paths, one on each side of the spinal cord, without having to move the patient. EX1002, ¶243. Accordingly, Claim 9 is rendered obvious by Chung with Olmos, and/or with the knowledge of a POSITA. EX1002, ¶¶240-244.

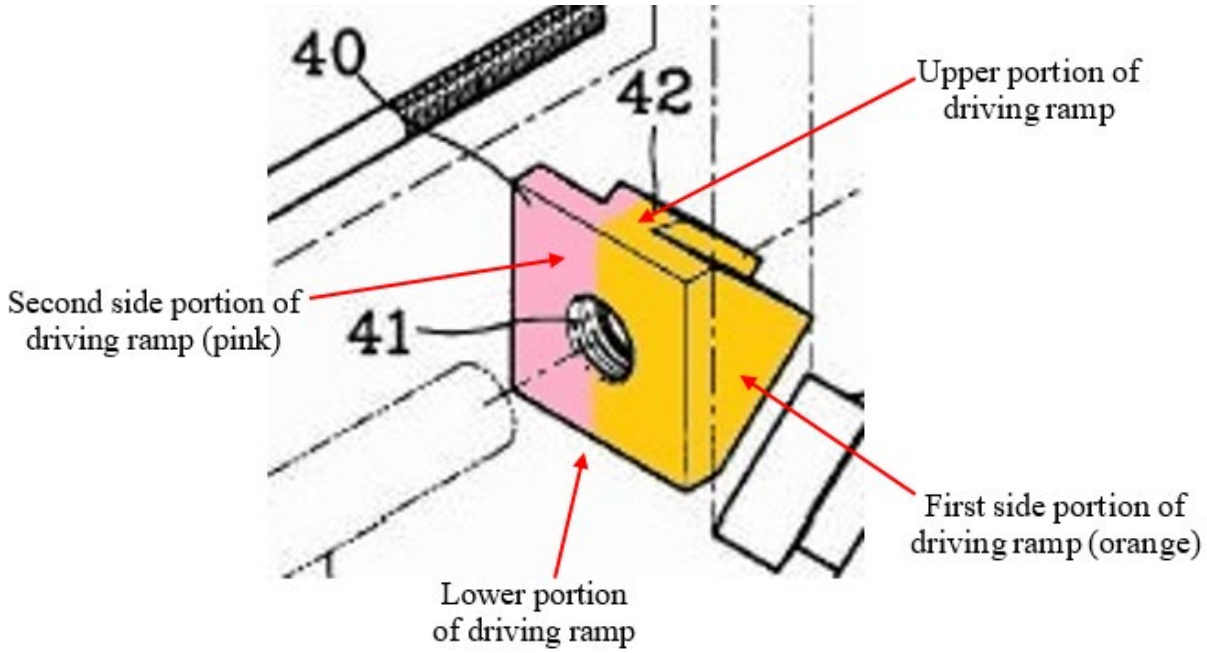
7. Claim 11

Claim 11 depends from Claim 1.

(a) Claim 11[a]

Claim 11 recites that "**the driving ramp includes a first side portion and an opposite second side portion extending from an upper portion to a lower portion of the driving ramp**." Chung's driving ramp has a first side portion and an opposite second side portion (the lateral portions each extending from one lateral sidewall towards the middle of the wedge) extending from an upper portion to a lower portion, as can be seen in at least Fig. 2, below.

Chung, Fig. 2



Accordingly, Chung discloses this limitation. EX1002, ¶¶245-246.

(b) Claim 11[b]

Claim 11 further recites that "**the first side portion and the second side portion include a pair of third grooves extending into the first and second side portions, respectively**." Olmos expressly discloses these elements. *See* §IX(D)(11)(b), *infra*. It would have been obvious to a POSITA to add a pair of third grooves extending into the first and second side portions to Chung's driving ramp in view of Olmos, which expressly discloses a pair of third grooves in the form of "anti-torque structures 250." *See* §IX(D)(11)(b), *infra*.

Accordingly, Chung with Olmos discloses this limitation. EX1002, ¶¶247-253.

8. Motivation to Combine

A POSITA would have been motivated to combine Chung's device with the teachings of Olmos for each of the foregoing claims.

Regarding Claims 2 and 9, a POSITA would have been motivated to use a posterolateral approach, and would have had a reasonable expectation of success in doing do, because this approach was ubiquitous in the field at the time of invention and was commonly used to implant a wide variety of intervertebral devices. Indeed, as Prof. Drewry explains, this approach has been used since at least 1944 and is now a "widely used interbody surger[y]" technique. EX1002, ¶¶213, 243 (quoting EX1021, 137-38).

Regarding Claims 5 and 6, a POSITA would have been motivated to implant a second, identical expandable implant in view of Olmos' express teachings that more than one implant is needed and used in some circumstances. EX1006, ¶¶[0143]-[0144]; *see also* EX1026, 219-220 (teaching multiple implant devices). A POSITA would have appreciated that introducing a second expandable implant in appropriate cases would provide greater and more balanced support for the adjacent discs than would be provided by a single implant device. EX1002, ¶¶219, 222.

A POSITA would have had a reasonable expectation of success in combining Chung with the teachings of Olmos because the use of multiple implant devices (such as Chung's) in such operations was already well-known in this field. EX1002, ¶¶220, 232. In addition, both Olmos and Chung disclose an expandable implant that is surgically inserted between two vertebrae to provide structural support, where the Chung and Olmos devices are structurally and functionally comparable, such that, in view of Olmos's teaching that at least two identical devices can be implanted in a single operation, a POSITA would have considered using two identical devices of either style when implanting multiple devices in a single spinal fusion operation. EX1002, ¶222. Accordingly, a POSITA would have had a reasonable expectation of success in applying Olmos's disclosure of introducing a second expandable implant into the disc space while utilizing Chung's devices. EX1002, ¶¶220, 222.

Regarding Claims 7 and 8, a POSITA would have understood that, depending on where the multiple implants needed to be positioned/oriented to provide optimal support in a given procedure, the second implant could be implanted either via the same access path (e.g., if the implants are to be positioned in the same relative location in adjacent intervertebral spaces or in parallel between a single pair of vertebrae) or via a different access path (e.g., if the implants must be positioned at different angles between adjacent vertebrae or in nonadjacent

intervertebral spaces, on either side of the spinal cord, etc.). EX1002, ¶¶228, 229-232, 236-238. In the former scenario, a POSITA would have understood that the same access path could be used to insert the second expandable implant, which is consistent with Olmos's preference for minimally invasive surgical procedures (*see* EX1006, ¶¶[0013], [0067], [0144]). *Id.* However, where it is not possible to use a single access path, as in the latter scenario, a POSITA would have understood that a different access path would be needed to insert the second expandable implant. *Id.* Thus, a POSITA would have been motivated to use either of these approaches depending on the needs of the specific patient and would have had a reasonable expectation of success in doing so given that there are only two possibilities when inserting two implants – using the same access path for both implants or using two different access paths. EX1006, ¶[0071]; EX1002, ¶¶228, 231, 237; *see also* EX1026, 219.

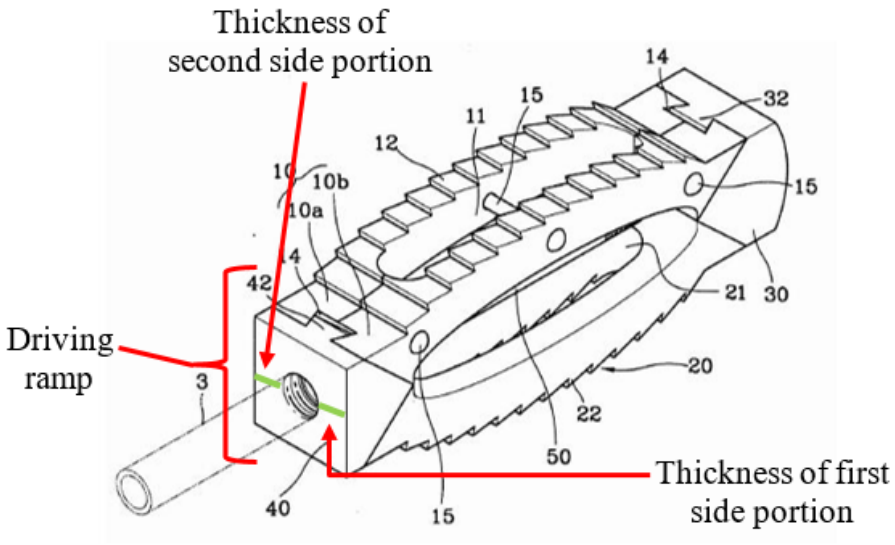
Regarding Claim 11, a POSITA further would have been motivated to add a pair of third grooves, as taught by Olmos, to the first and second side portions of Chung's driving ramp because doing so would improve the ability to keep the device in a stable orientation when it is deployed. Specifically, Olmos teaches that its anti-torque structures 250 (i.e., the "third pair" of grooves (*see* §IX(D)(11)(b), *infra*)) are advantageous because, when the clinician inserts and expands the implant using a deployment tool, "the anti-torque structures 250 can be engaged by

a non-rotating structure of the deployment tool to maintain the rotational orientation of the implant 200 while the actuator shaft 210 is rotated." EX1005, ¶[0161]. Thus, the third pair of grooves in Olmos help prevent the implant from undesirably rotating and falling out of alignment with the adjacent vertebrae, especially as the axial screw is turned. *Id.*

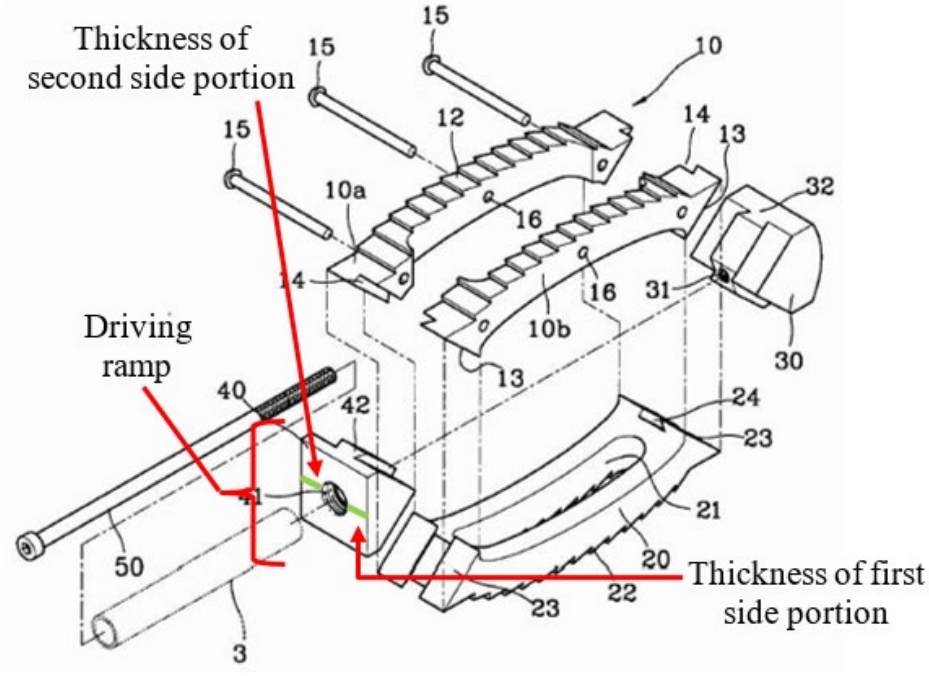
A POSITA would have understood that Chung's device likewise needs to be held in a particular position/orientation during implantation and expansion, and that a physical means or structure to accomplish this would be very advantageous. Accordingly, a POSITA would have been motivated to consider one of the many other solutions in the prior art, such as Olmos' anti-torque structures 250 described above, for this purpose. EX1006, ¶¶[0161], [0177]. A POSITA therefore would have been motivated to combine Olmos' anti-torque structures 250 with Chung's device to arrive at a device meeting Claim 11's limitation. EX1002, ¶¶250-251.

A POSITA further would have had a reasonable expectation of success in such a combination. As can be seen at least Chung Figs. 1-2, the side portions of the driving ramp are sufficiently thick that adding a pair of third grooves in the form of Olmos' anti-torque structures 250 would not affect the structural integrity or function of the driving ramp or any other component of the structure. EX1002, ¶252. Annotated Figs. 1-2 follow.

Chung, Fig. 1



Chung, Fig. 2



For the foregoing reasons, a POSITA would have been motivated to combine the teachings of Olmos with those of Chung, and would have had a reasonable expectation of success in doing so, thereby rendering the challenged claims obvious.

C. Ground 3: Claims 1-11 are obvious over Chung in view of Baynham or Baynham and Olmos

While Petitioner submits that Chung discloses or renders obvious every element of Claims 1, 3, 4, and 10, should Patent Owner argue that Chung fails to disclose the required access path, rod-receiving extension, and bone graft material elements, these claims are alternatively obvious under 35 U.S.C. §103 over Chung in view of Baynham as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶254-285). Likewise, while Petitioner submits that Chung with Olmos discloses every limitation of Claims 2, 5-9, and 11, these claims are alternatively obvious under 35 U.S.C. §103 over Chung in view of Olmos and Baynham.

1. Claims 1 and 10

Chung discloses all elements of Claims 1 and 10 as discussed above. §§IX(A)(1), IX(A)(10). However, should Patent Owner argue Chung does not disclose the "creating an access path" or "rod-receiving extension" elements of Claims 1 and 10 or the "introducing bone graft material" element of Claim 1,

Claims 1 and 10, and their dependent claims, are further obvious over Chung in view of Baynham.

(a) Claims 1[a] and 10[a]

Chung discloses this limitation as discussed above. *See* §§IX(A)(1)(b), IX(A)(10)(b). In addition, it would have been obvious to create an access path to an intervertebral disc space as taught by Baynham.

Baynham explicitly states it is necessary and conventional to create an access path to the spine when conducting surgical methods related to vertebrae (such as that in Chung). EX1007, ¶¶[0006], [0011]. Accordingly, Chung in combination with Baynham teaches claim element 1[a]/10[a]. EX1002, ¶¶255-261.

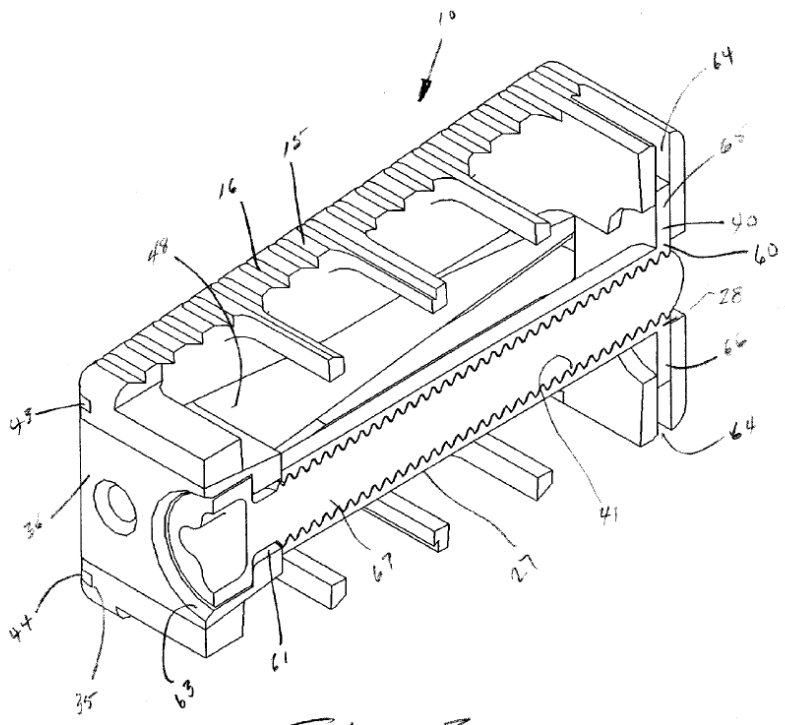
(b) Claims 1[u] and 10[o]

Chung discloses a "rod-receiving extension" as discussed above. *See* §§IX(A)(1)(v), IX(A)(10)(p). In addition, it would have been obvious to add a further rod-receiving extension to Chung's central ramp to further engage the actuation member 40, as taught by Baynham.

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 flanges 43, 44 of distractor 42. EX1007, Figs. 1, 3. Distractor 42 also has an unthreaded bore 61 in its trailing edge

for receiving a jack screw 67. *Id.*, Fig. 3. Furthermore, the leading edge of the Baynham implant 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 bore 60 and extends toward bore 61." *Id.*, ¶[0029]. Figure 3 follows for reference:

Baynham, Fig. 3

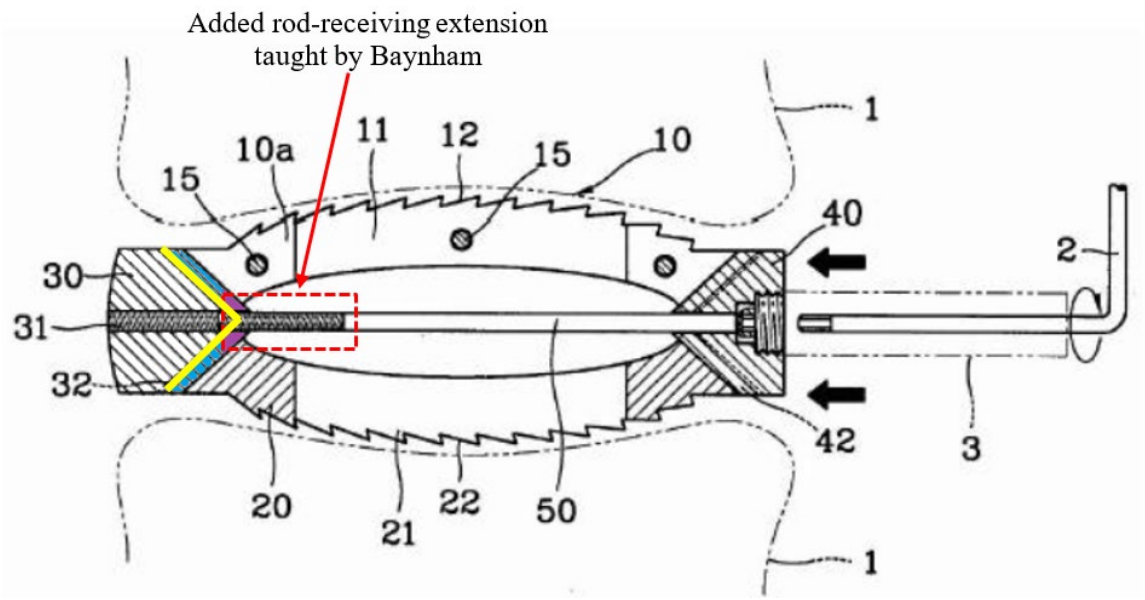


Baynham's threaded tube (i.e., "rod-receiving extension") extends toward the opposing ramp and engages the screw/actuation member; as the screw is

rotated, the threaded tube causes the link and ramp to be drawn together. At the same time, 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 '001 patent and screw hole (31) of Chung – i.e., it is "a rod receiving extension." §IX(A)(1)(w).

When adding Baynham's tube-shaped extension to the Chung central ramp, a POSITA would understand that the third and fourth ramped portions would extend outwardly (both laterally to the sides, and vertically above and below) from the modified rod-receiving extension. Combining Baynham's tube with Chung simply involves elongating Chung's existing rod-receiving extension (shown purple-colored in §IX(A)(1)(v), *supra*) as indicated by the red-dotted box below. Accordingly, the third and fourth ramped portions would continue to extend from the elongated extension just as described in §IX(A)(1)(v), *supra*. EX1002, ¶269. Annotated Fig. 3, below, shows this, with the third and fourth ramped portions in yellow:

Chung, Fig. 3



Accordingly, this limitation is disclosed by Chung with Baynham. EX1002, ¶¶262-275.

(c) Claim 1[v]

Chung discloses introducing bone graft material as discussed above. *See* §IX(A)(1)(w). In addition, it would have been obvious to do so, as taught by Baynham.

Baynham explicitly states bone graft material is introduced adjacent to an implant during spinal stabilization procedures. *E.g.,* EX1007, ¶[0005], [0014]. Accordingly, Chung in combination with Baynham discloses this limitation. EX1002, ¶¶276-283.

2. Claims 3 and 4

Claims 3 and 4 depend either directly or indirectly from Claim 1. As discussed above, Chung discloses all elements added by these claims. *See* §§IX(A)(2)-(3), *supra*. Accordingly, Claims 3 and 4 are likewise obvious for the reasons provided for these claims in Ground 1 and here. EX1002, ¶284.

3. Claims 2, 5-9, and 11

Claims 2, 5-9, and 11 also depend either directly or indirectly from Claim 1. As discussed above, all elements added by these claims are disclosed by a combination of Chung and Olmos (and/or the knowledge of a POSITA). *See* §IX(B), *supra*. Accordingly, Claims 2, 5-9, and 11 are likewise obvious for the reasons provided for these claims in Ground 2 and here. EX1002, ¶285.

4. Motivation to Combine

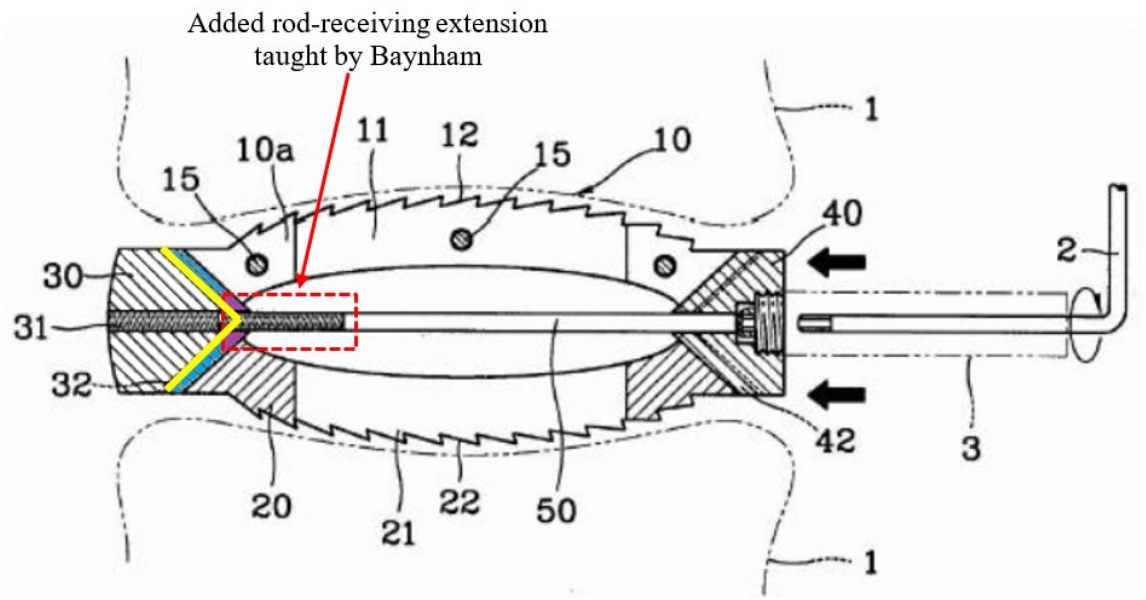
Regarding Claims 1[a]/10[a], a POSITA would have been motivated to combine Chung with the teachings of Baynham with a reasonable expectation of success. A POSITA would have understood that the device of Chung must be inserted into an intervertebral target site and that some access path must be created to do so. EX1002, ¶258. Baynham expressly discloses that posterior access paths are conventionally used to avoid interfering with internal organs and tissue, and teaches uses such an access path, e.g., a posterior approach, for the disclosed implant. EX1007, ¶¶[0006], [0011]). A POSITA would been motivated to follow

Baynham's teachings to efficiently and safely implant Chung's devices as intended. EX1002, ¶¶258-259.

Furthermore, a POSITA would have had a reasonable expectation of success in doing so given the similarities between the Chung and Baynham devices. For example, like Chung, Baynham discloses an intervertebral implant that is inserted into a disc space and expanded through the interaction of various ramped portions and wedges or distractors and through the use of an actuator. *E.g.,* EX1007, Abstract, ¶¶[0022]-[0023], [0030]. A POSITA would have reasonably understood and expected that means for creating an access path into an intervertebral disc space for one such device (Baynham) would also work for another, similar device (Chung). EX1002, ¶260.

Regarding Claims 1[u]/10[o], a POSITA would have been motivated to modify the structure surrounding Chung's screw hole (31), as shown for example in Fig. 3, below, to lengthen it longitudinally toward the bore in Chung's driving ramp, as exemplified by Baynham's tube 27.

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 more of the central ramp's threads, which would have the benefit of improving the strength of the connection. EX1002, ¶270. Second, the modification would allow use of a shorter screw, which would reduce or eliminate protrusion of the screw from the expanded device, thereby reducing unwanted interference with adjacent anatomy. *Id*., ¶271. Accordingly, a POSITA would have been motivated to incorporate the design of Baynham's tube 27 with Chung's wedge (30).

EX1002, ¶¶270-272.

Furthermore, Baynham's functionality is directly analogous to the "jack screw" functionality disclosed in Chung. EX1007, ¶[0029]; §IX(A)(1)(t), *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, ¶¶273-274.

Regarding Claim 1[v], a POSITA likewise would have been motivated to combine Chung with the teachings of Baynham and would have had a reasonable expectation of success in doing so. Baynham teaches that, "[n]ormally, the vertebral disk material which separates the vertebrae is removed and bone graft material is inserted in the space for interbody fusion" during a spinal fusion procedure and that such bone graft material may be inserted "[i]n addition to" a spinal implant like that disclosed in Baynham and Chung. *See* EX1007, ¶[0005]. When using Chung's device in any surgical method, a POSITA would have been motivated to consider and adopt "[c]onventional" techniques like those disclosed in Baynham as a matter of best practices and patient safety. EX1002, ¶¶279-280. A POSITA was also well aware that bone graft material is generally useful in spinal

fusion procedures, as it has been used in such procedures for over a century and, as taught by Baynham, remains "conventional" today. *Id*.; EX1007, ¶[0005]. Accordingly, a POSITA would have been motivated to combine Baynham's teachings with Chung to achieve these known benefits when implanting Chung's device. EX1002, ¶¶279-280. Furthermore, a POSITA would have had a reasonable expectation of success in such a combination for at least the reasons set forth previously in this section , especially in view of Chung's teaching to introduce "back bone implant material." EX1005, 3-4; EX1002, ¶¶281-282.

D. Ground 4: Claims 1-11 are anticipated by and/or obvious over Olmos

Claims 1-11 of the '731 patent are anticipated by Olmos under 35 U.S.C. §§102(a)-(b) or, alternatively, are obvious under 35 U.S.C. §103 over Olmos, as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶286-437).

1. Claim 1

(a) Claim 1[pre]

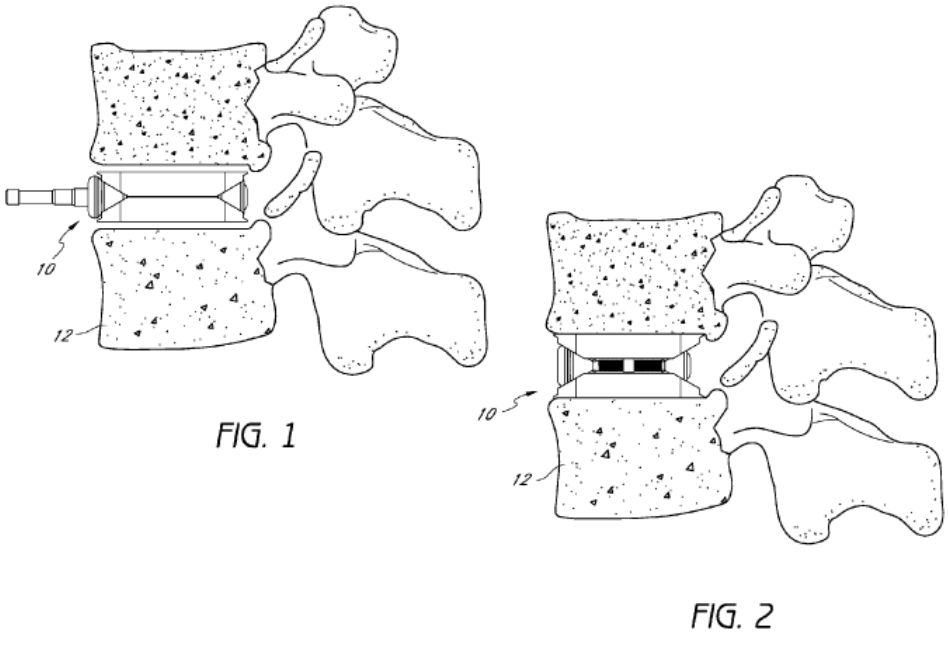
Olmos discloses a "**surgical method**." In addition to generally describing "spinal fusion" procedures that are "known in the art," Olmos expressly provides a specific "method of implanting a[n] implant." EX1006, ¶¶[0017]-[0018], [0074] [0124]; *see also id.*, ¶[0075] (disclosing specific steps of surgical operation).

Accordingly, Olmos discloses a surgical method. EX1002, ¶¶286-287; EX1004, 000063 ("Olmos discloses a surgical method…").

(b) Claim 1[a]

Olmos describes creating a "percutaneous[]" access path to "insert, place, and deploy the intervertebral implant." EX1006, ¶[0084]; *see also id.*, ¶¶[0017]-[0018], [0075], [0128], Figs. 1-2. Olmos further discloses "implanting or installing the spinal fusion implant 10" by "positioning the intervertebral implant **10** between two vertebral bodies and…caus[ing] the intervertebral implant **10** to expand intermediate the vertebral bodies." EX1006, ¶[0124]; *see also id.*, ¶¶[0017]-[0018], [0074]-[0075]. Figures 1-2 show an expandable implant inserted into the disc space:

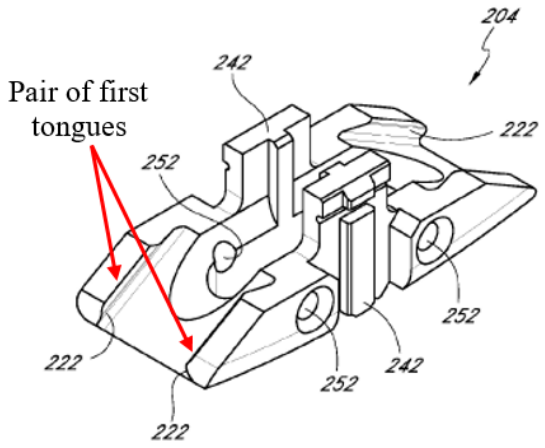
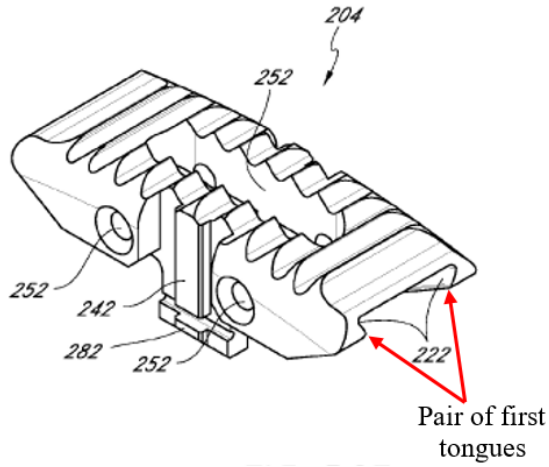
Olmos, Figs. 1-2



Accordingly, Olmos discloses these limitations. EX1002, ¶¶288-290; EX1004, 000063-64 (finding Olmos discloses Claim 1[a] without traverse).

(c) Claim 1[b]

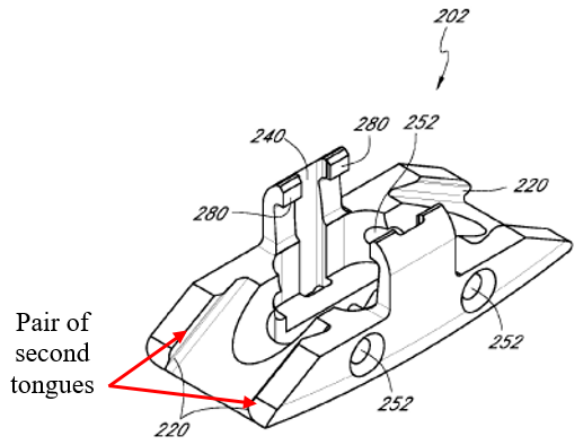
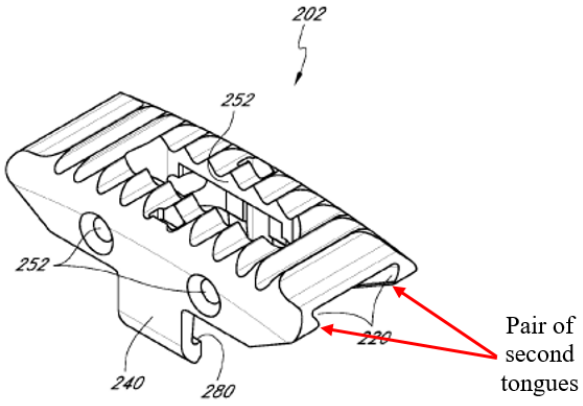
Olmos discloses a first endplate ("lower body portion **204**") having a pair of first tongues (edges of "slots **222**"). EX1006, ¶¶[0167]-[0168], [0170], [0173], [0178]. Figures 20A-B further show these structures:

Olmos, Fig. 20A	Olmos, Fig. 20B
	

Olmos' disclosure of a pair of first tongues is consistent with that of the '001 patent. *See* §IX(A)(1)(c), *supra*. Accordingly, Olmos discloses this limitation. EX1002, ¶¶291-294; EX1004, 000066 (Examiner finding Olmos discloses Claim 1[b] without traverse).

(d) Claim 1[c]

Olmos discloses a first endplate ("upper body portion **202**") having a pair of second tongues (edges of "slots **220**"). EX1006, ¶¶[0167]-[0168], [0170], [0173], [0178]. Figures 16B and 21A-B show these structures:

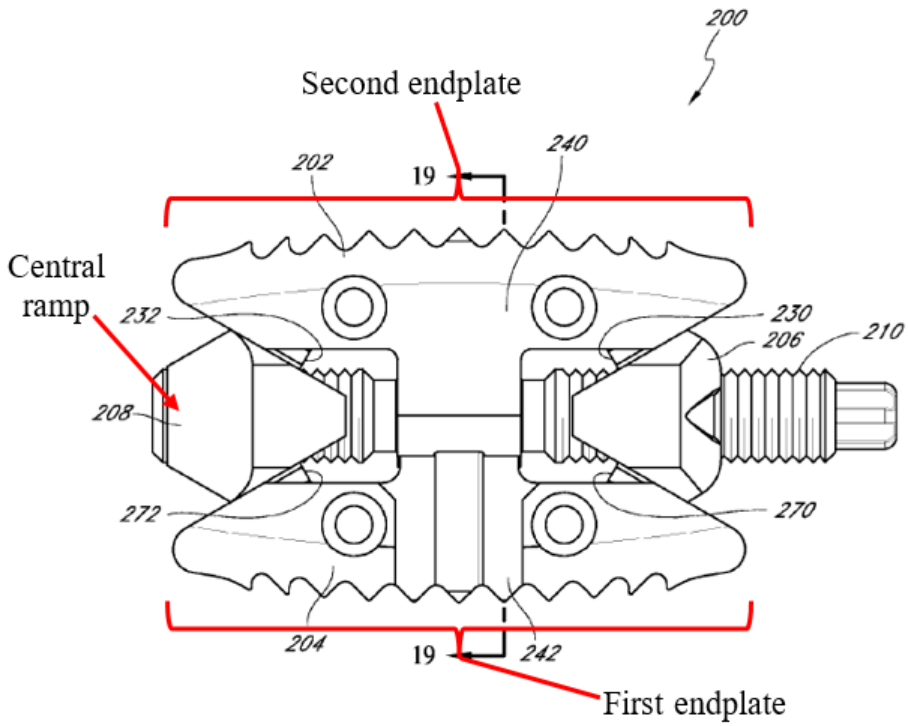
Olmos, Fig. 21A	Olmos, Fig. 21B
	

Olmos' disclosure is consistent with that of the '001 patent. *See* §IX(A)(1)(d), *supra*. Accordingly, Olmos discloses this limitation. EX1002, ¶¶295-298; EX1004, 000066 (Examiner finding Olmos discloses Claim 1[c] without traverse).

(e) Claim 1[d]

Olmos discloses a central ramp ("distal wedge member[]…**208**") between the first and second endplates ("disposed at the distal ends…of the upper and lower body portions…with at least a portion of the distal wedge member contacting the distal surfaces of the upper and lower body portions"). EX1006, ¶¶[0021], [0152]. Figures 16A-B and 18 show these structures, with annotated Fig. 18 below.

Olmos, Fig. 18

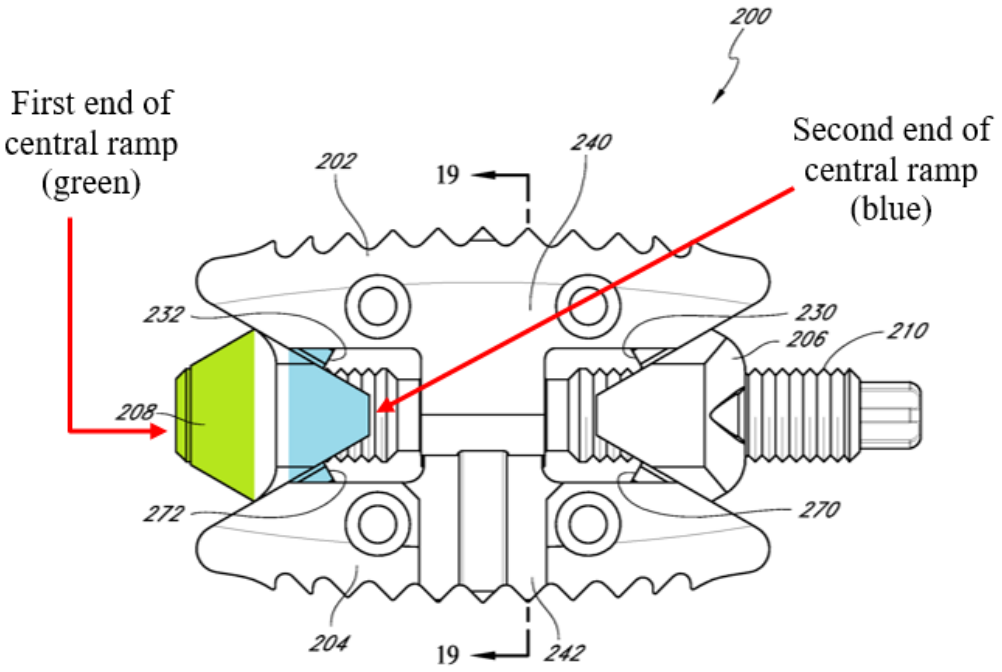


Accordingly, Olmos discloses this limitation. EX1002, ¶¶299-301; EX1004, 000064 (Examiner finding Olmos discloses a central ramp positioned between the endplates, without traverse).

(f) Claim 1[e]

Olmos Figs. 16A-B, 18, and 24A-B show a central ramp (distal wedge member 208) having a first (wider) end and a second (narrower) end. EX1006, Figs. 16A-B, 18, and 24A-B. Annotated Figs. 18 and 24B follow.

Olmos, Fig. 18



Olmos, Fig. 24B

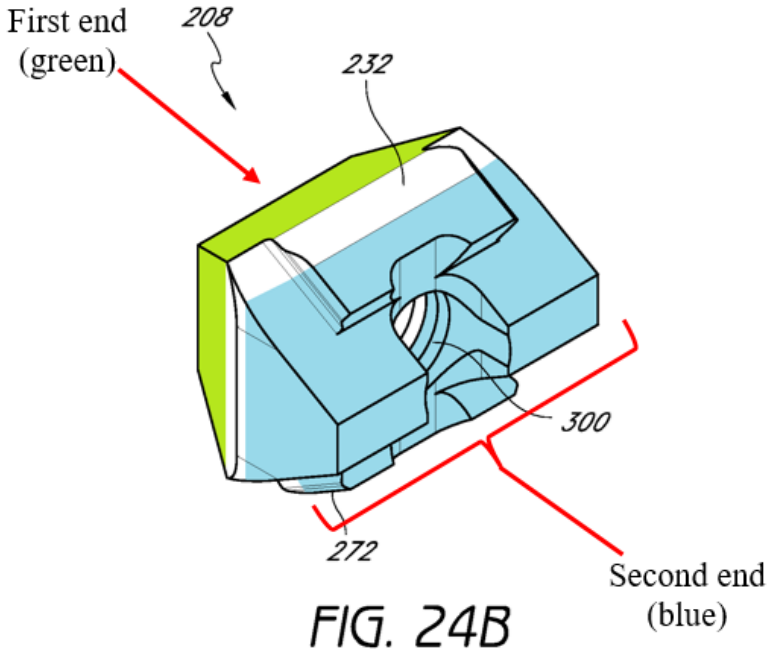


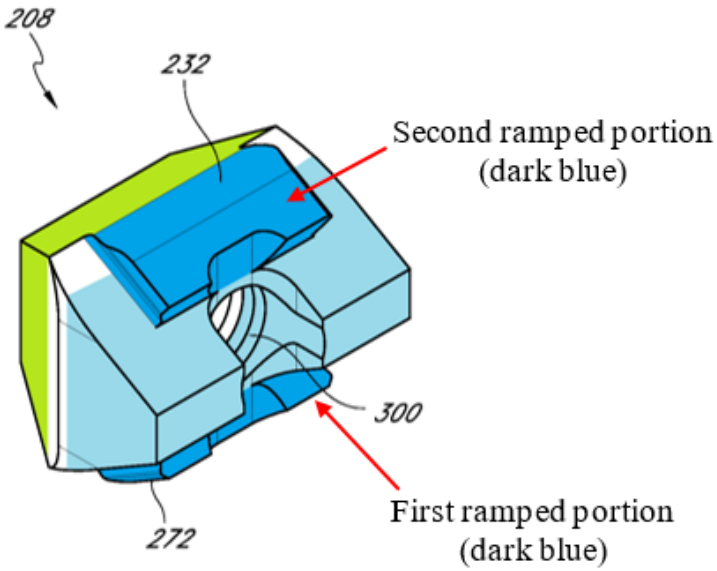
FIG. 24B

Accordingly, Olmos discloses this limitation. EX1002, ¶¶302-303; EX1004, 000064 (Examiner finding Olmos discloses Claim 1[e] without traverse).

(g) Claim 1[f]

Olmos discloses a central ramp having first and second ramped portions ("guide members **232**, **272**" and the adjacent surfaces below their overhanging edges), the first and second ramped portions engaging the first and second endplates, respectively. EX1006, Figs. 16A-B, 18, 24A-B; ¶¶[0167]-[0168], [0170], [0178], [0111]-[0112]. Annotated Figs. 24B and 18 follow.

Olmos, Fig. 24B



Olmos, Fig. 18

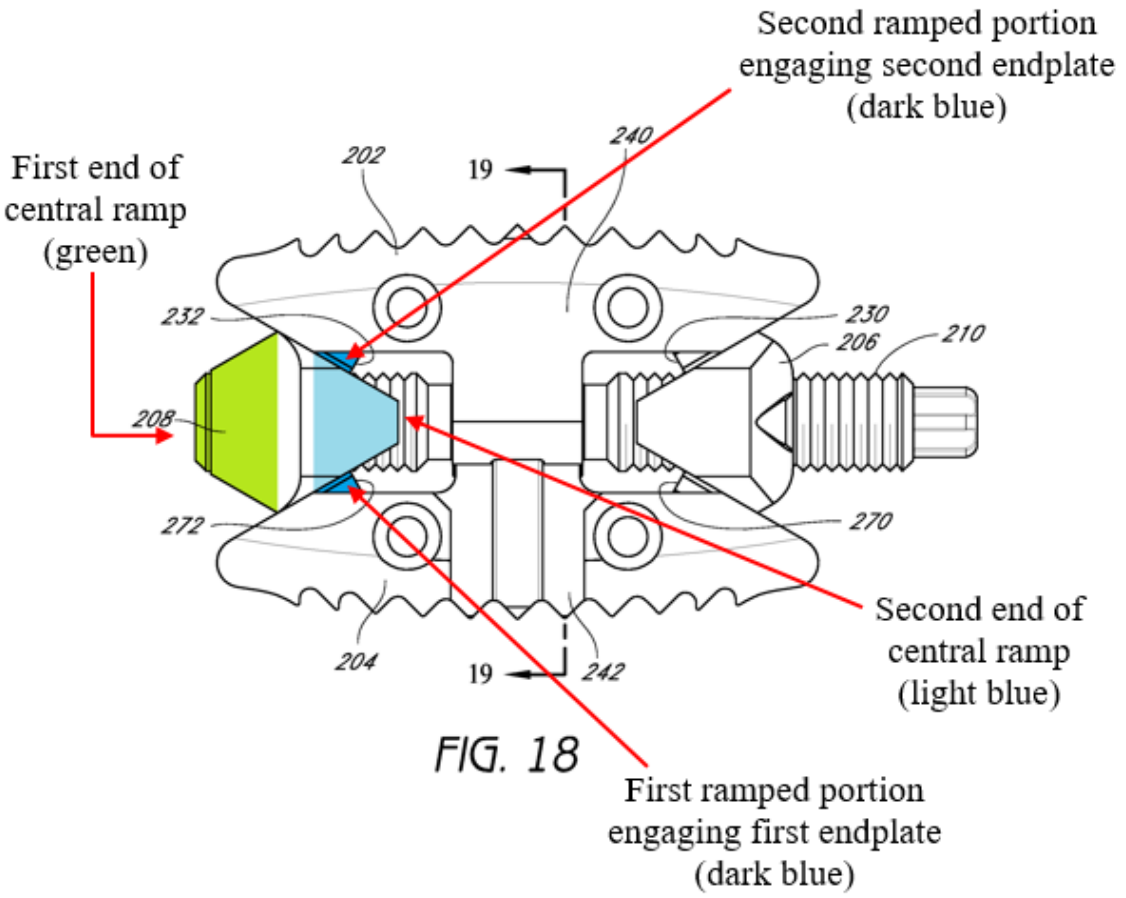


FIG. 18

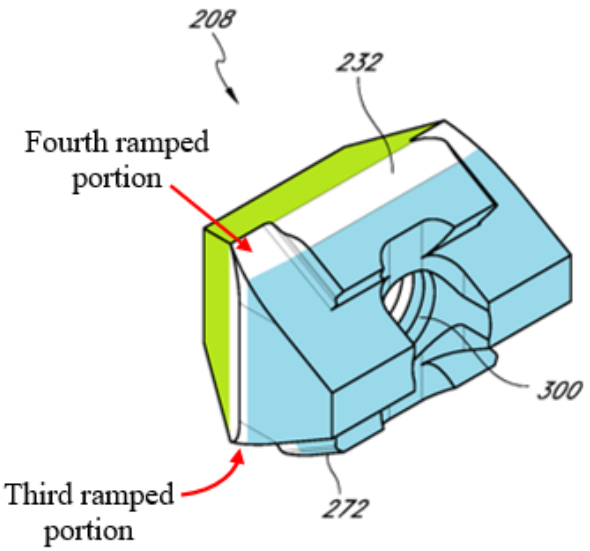
Olmos' disclosure in this regard is consistent with that of the '001 patent. *See* §IX(A)(1)(g), *supra*. Accordingly, Olmos discloses this limitation. EX1002, ¶¶304-308.

(h) Claim 1[g]

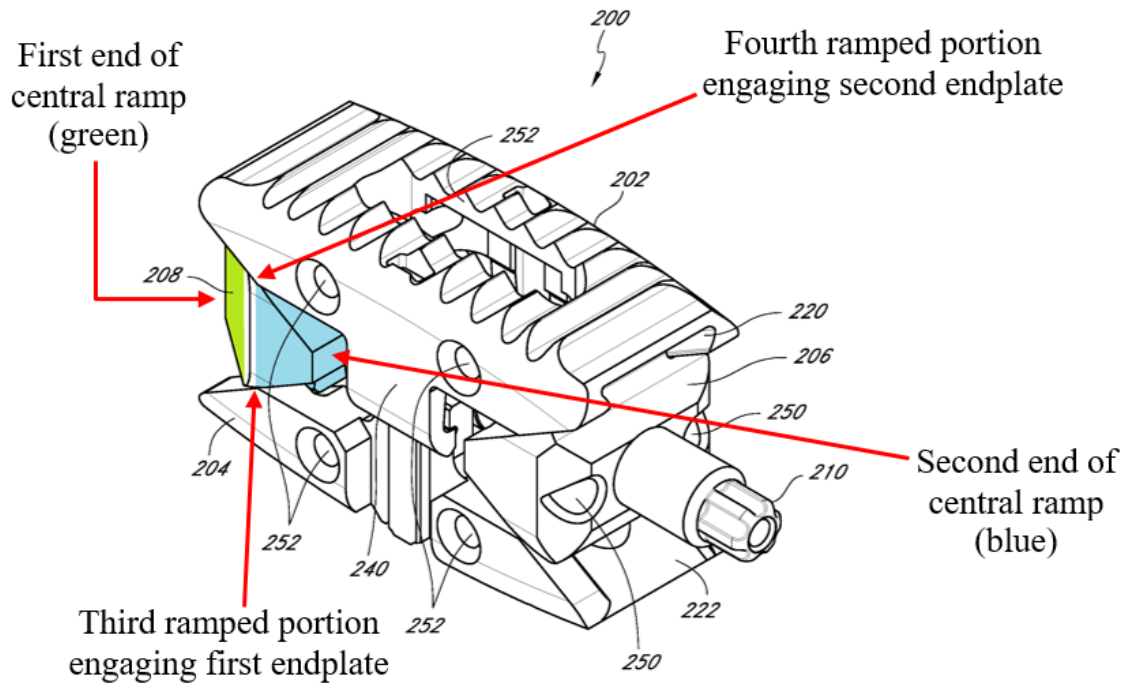
Olmos discloses a central ramp ("distal wedge member **208**") having third and fourth ramped portions (the flat surface(s) adjacent "guide members **232**, **272**"), the third and fourth ramped portions engaging the first and second

endplates, respectively. EX1006, Figs. 16A-B, 18, 24A-B; ¶¶[0111]-[0112], [0167]-[0168], [0170], [0178]. Figures 16A-B, 18, and 24B show these structures, with annotated Figs. 24B and 16B below.

Olmos, Fig. 24B



Olmos, Fig. 16B



Should Patent Owner attempt to argue that the Examiner rejected the proposition that Olmos discloses third and fourth ramped portions during prosecution, this is incorrect. The Examiner allowed the claims after Patent Owner amended the claims to include this limitation and argued that no embodiment of Olmos discloses "a third ramped portion configured to engage a portion of the first endplate and a fourth ramped portion configured to engage a portion of the second endplate positioned between the first and second ends." EX1004 at 000053-54. But this is directly contradicted by the aforementioned sections and figures of Olmos and, specifically, Olmos' disclosure of at least four ramped portions on the central ramp – guide members 232, 272 (*see* §XII(A)(g), *supra*) and the two flat surfaces

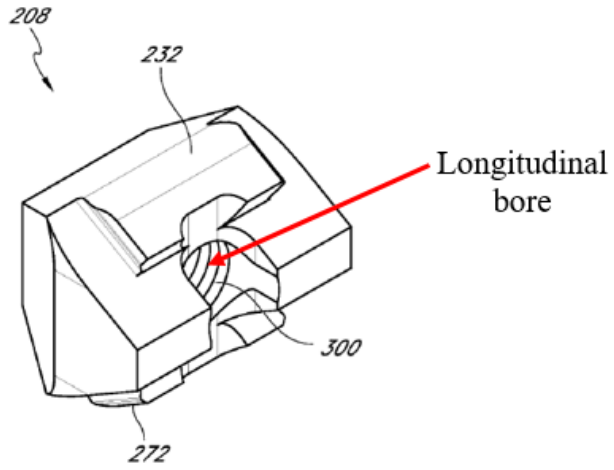
adjacent to guide members 232, 272 discussed herein. There is no evidence that the Examiner was made aware of these express teachings or ever considered this embodiment of Olmos and, therefore, it would be incorrect to suggest that the Examiner already considered/rejected the argument raised herein as to this embodiment of Olmos. *See also* §X, *infra*.

As noted previously, Olmos' disclosure is consistent with that of the '001 patent. *See* §IX(A)(1)(g), *supra*. Accordingly, Olmos discloses this limitation. EX1002, ¶¶309-314.

(i) Claim 1[h]

Olmos discloses that the central ramp ("distal wedge member **208**") has a longitudinal bore (a "central aperture **302**…configured to receive an actuator shaft therethrough"). EX1006, ¶[0178]. Figures 24A-B further show this structure. Annotated Fig. 24B follows.

Olmos, Fig. 24B

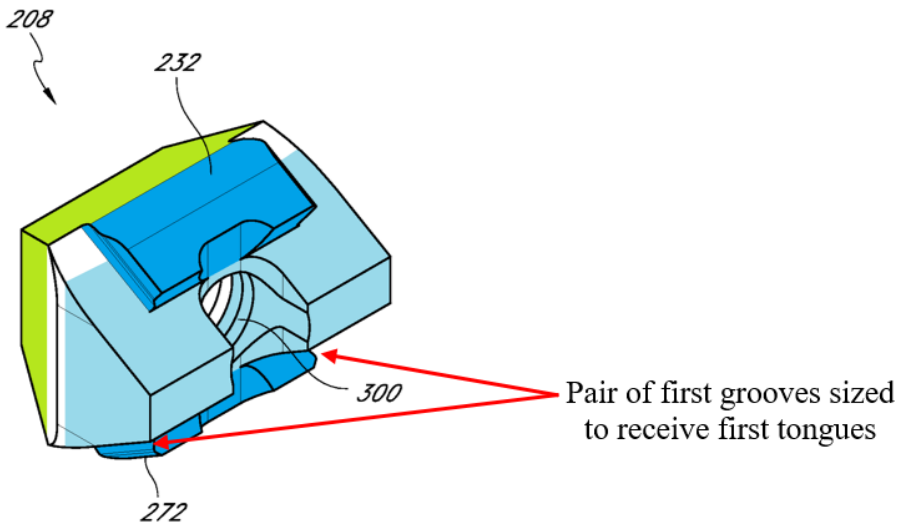


Accordingly, Olmos discloses this limitation. EX1002, ¶¶315-317; EX1004, 000064 (finding Olmos discloses Claim 1[h] without traverse).

(j) Claim 1[i]

Olmos discloses that the first ramped portion has a pair of first grooves (the two overhanging edges on either side of "generally dovetail shape[d]…guide member[]…**272**"), each sized to receive one of the first tongues (guide member 272 is "insert[ed]…into the slots **222** of the lower body portion **204**" with "the dovetail shape of the slots and guide members ensur[ing] that for each given slot and guide member, a given wedge member is generally interlocked with the give[n] slot…"). EX1006, ¶¶[0167]-[0168]; *see also id.*, ¶¶[0111]-[0112], [0178]. Figures 16A-B, 18, and 24B further show these structures. Annotated Fig. 24B follows.

Olmos, Fig. 24B

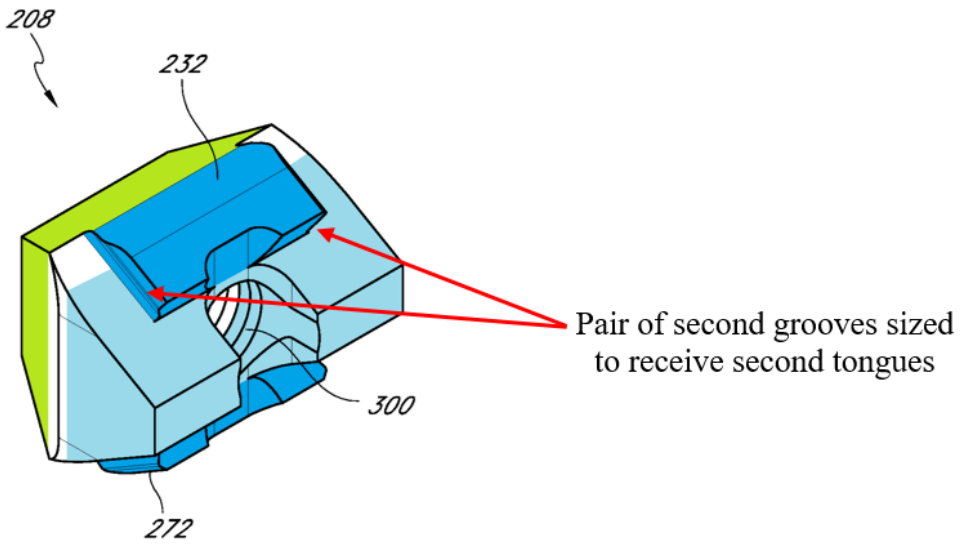


Accordingly, Olmos discloses this limitation. EX1002, ¶¶318-320; EX1004, 000066-67 (finding Olmos discloses Claim 1[i] without traverse).

(k) Claim 1[j]

Olmos discloses a second ramped portion having a pair of second grooves (the two overhanging edges on either side of "generally dovetail shape[d]…guide member[] **232**"), each sized to receive one of the second tongues, just as described above for the first ramped portion and its dovetail-fit with the corresponding body portion. EX1006, ¶¶[0167]-[0168]; *see also id.*, ¶¶[0111]-[0112], [0178]. Figures 16A-B, 18, and 24B further show these structures. Annotated Fig. 24B follows.

Olmos, Fig. 24B

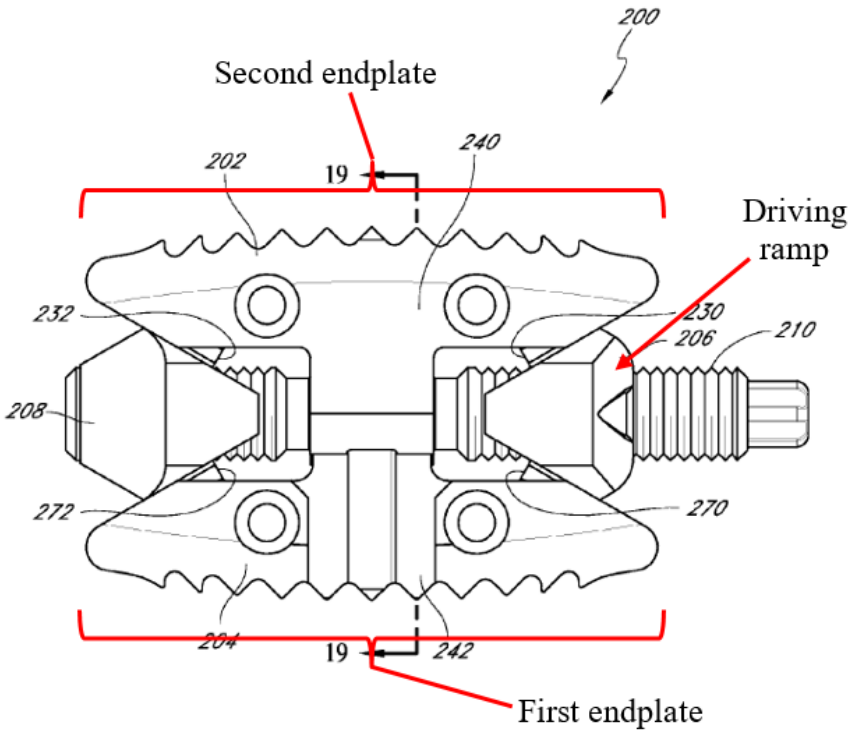


Accordingly, Olmos discloses this limitation. EX1002, ¶¶321-323; EX1004, 000066-67 (finding Olmos discloses Claim 1[j] without traverse).

(l) Claim 1[k]

Olmos discloses a driving ramp ("proximal wedge member **206**") between the first and second endplates ("disposed at the proximal ends of the respective ones of the upper and lower body portions…with at least a portion of the proximal wedge member contacting the proximal surfaces of the upper and lower body portions"). EX1006, ¶¶[0021], [0152], [0156]. Olmos further discloses that the driving ramp causes separation of the endplates. *Id.*, ¶[0155]. Figures 16A-B and 18 further show these features, with annotated Fig. 18 below.

Olmos, Fig. 18

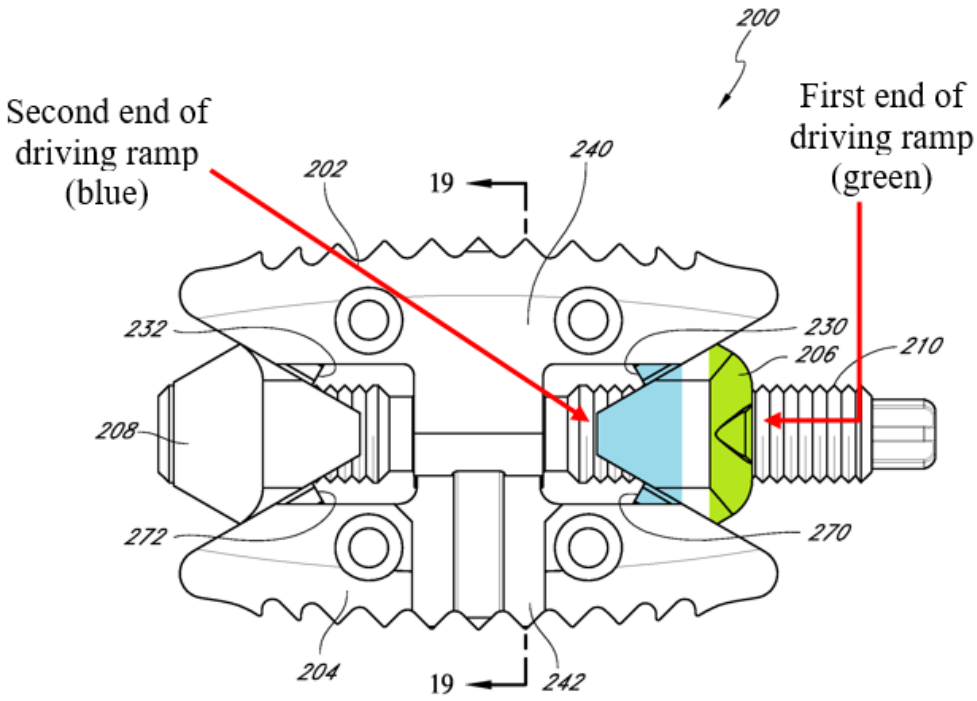


Accordingly, Olmos discloses this limitation. EX1002, ¶¶324-327; EX1004, 000064 (finding Olmos discloses Claim 1[k] without traverse).

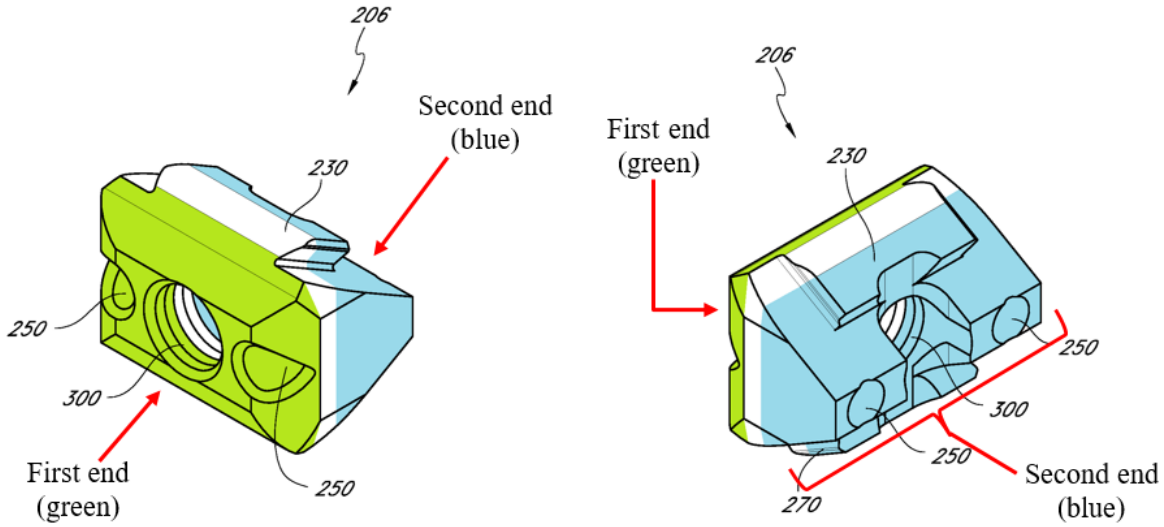
(m) Claim 1[l]

Olmos Figs. 16A-B, 18, and 23A-B show a driving ramp (proximal wedge member 206) having a first (wider) end and a second (narrower) end. EX1006, Figs. 16A-B, 18, and 23A-B. Annotated Figs. 18 and 23A-B follow.

Olmos, Fig. 18



Olmos, Fig. 23A-B

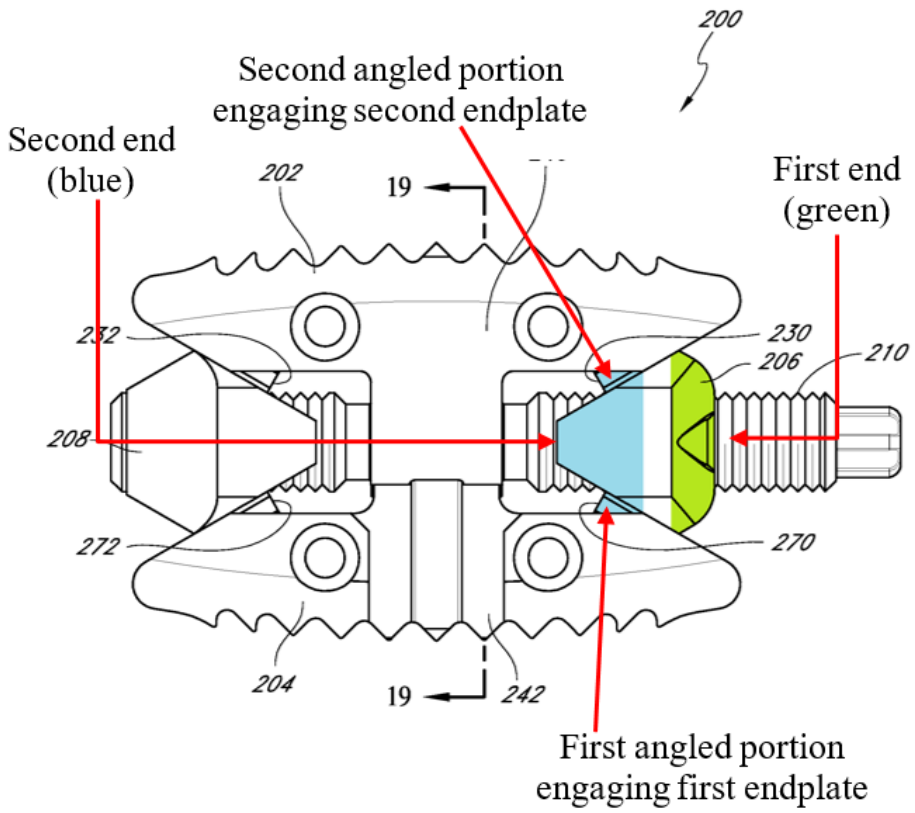


Accordingly, Olmos discloses this limitation. EX1002, ¶¶328-330; EX1004, 000064 (Examiner finding Olmos discloses Claim 1[l] without traverse).

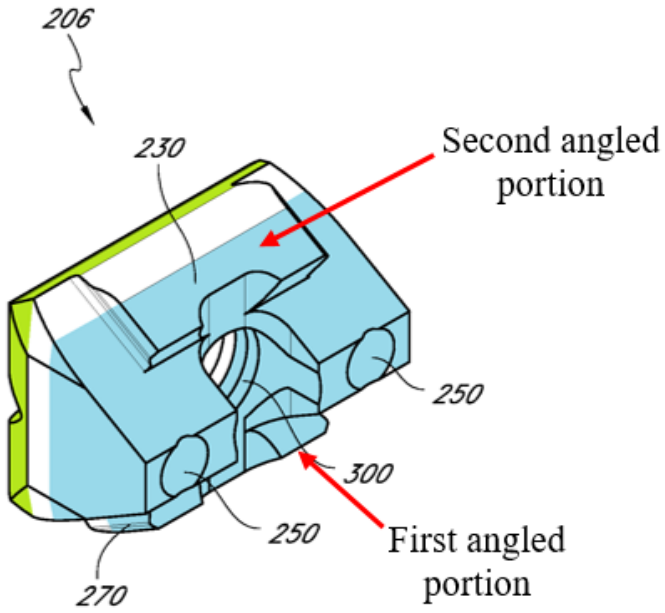
(n) Claim 1[m]

Olmos discloses the driving ramp having first and second angled portions (the top surfaces of "guide members **230**, **270**"), the first and second angled portions engaging the first and second endplates, respectively. EX1006, Figs. 16A-B, 18, 23A-B; ¶¶[0167]-[0168], [0170], [0178], [0111]-[0112]. Annotated Figs. 23B and 18 follow.

Olmos, Fig. 18



Olmos, Fig. 23B



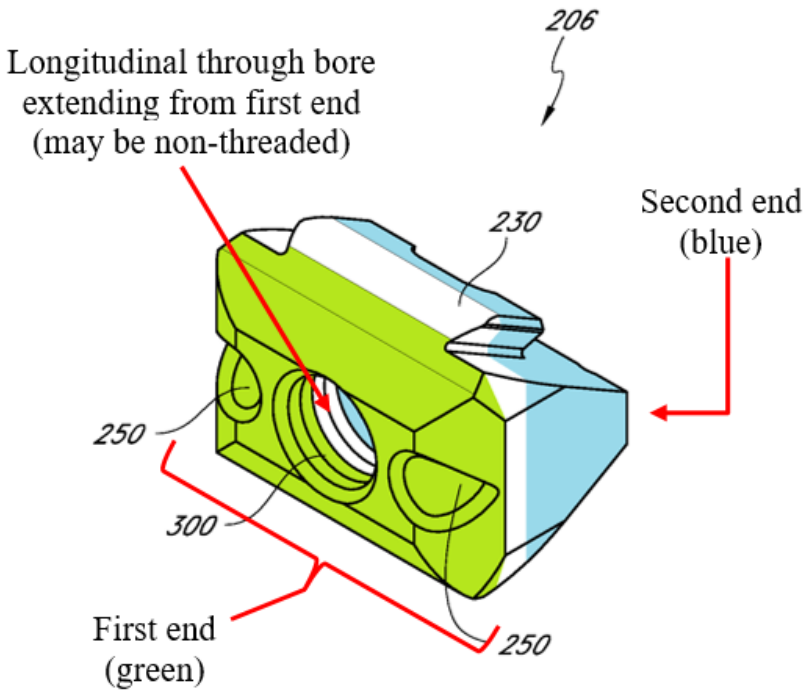
Olmos' disclosure is consistent with that of the '001 patent. *See* §IX(A)(1)(n), *supra*. Accordingly, Olmos discloses this limitation. EX1002, ¶¶331-334; EX1004, 000064 (Examiner finding Olmos discloses Claim 1[m] without traverse).

(o) Claim 1[n]

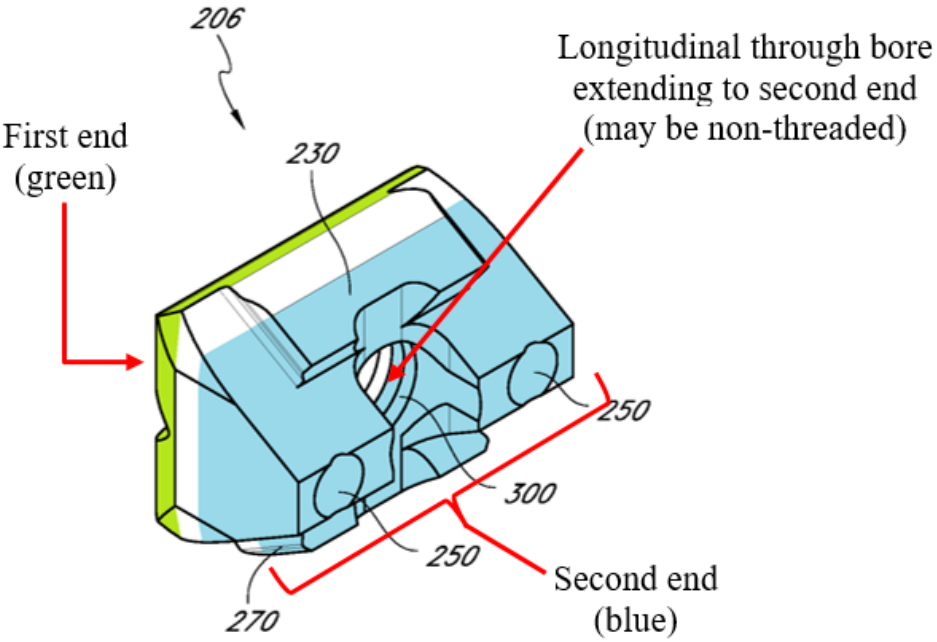
Olmos discloses that the driving ramp ("proximal wedge member **206**") has a longitudinal through-bore extending from the first end to the second end ("comprise[s] a central aperture **300** wherethrough an actuator shaft can be received"). EX1006, ¶[0177] (further stating: "the actuator shaft can engage other portions of the wedge member **206** [besides threads] for causing expansion"); Figs.

18, 23A-B. Olmos notes that aperture 300 **can** be threaded (EX1006, ¶[0177]), which a POSITA would understand to disclose that the aperture can alternatively be non-threaded. EX1002, ¶336. Such an understanding of Olmos is consistent with a POSITA's understanding of scissor jacks generally, which include well-known configurations where one side of the scissor jack is threaded and the other side either is or is not threaded depending on whether reverse threads or an unthreaded screw with a head portion is used to hold that side of the screw jack. *Id.* Annotated Figs. 23A-B follow showing aperture 300; while these figures contain indications of threads, as noted above Olmos discloses that the aperture can also be non-threaded.

Olmos, Fig. 23A



Olmos, Fig. 23B

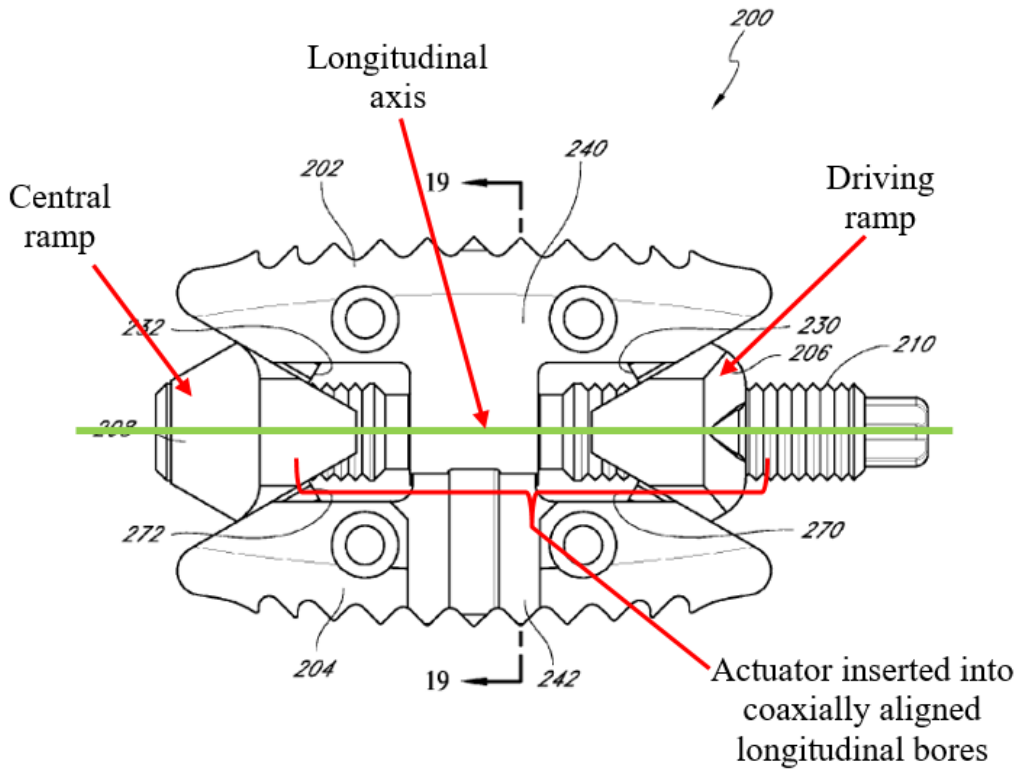


Accordingly, Olmos discloses this limitation. EX1002, ¶¶335-338; EX1004, 000064 (finding Olmos discloses Claim 1[n] without traverse).

(p) Claim 1[o]

Olmos's actuator passes through both bores in the driving and central ramps, and shows that these bores are coaxially aligned. EX1006, ¶¶[0170], [0177]-[0178], Fig. 18; *see also id.*, ¶¶[0159], [0174]. Figures 18, 23A-B, and 24A-B further show this, as seen in annotated Fig. 18:

Olmos, Fig. 18

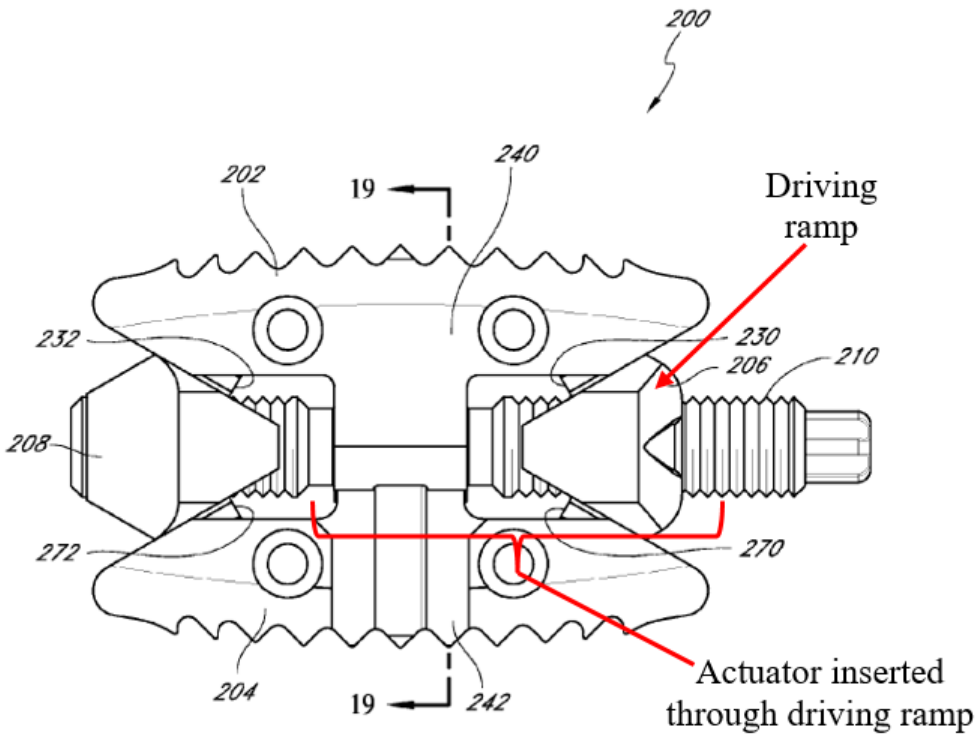


Accordingly, Olmos discloses this limitation. EX1002, ¶¶339-341; EX1004, 000064 (Examiner finding Olmos discloses Claim 1[o] without traverse).

(q) Claim 1[p]

As noted in §IX(B)(1)(q), *supra*, Olmos discloses an actuator ("actuator shaft **210**") insertable through the driving ramp's central aperture **300**. Figures 16A-B and 18 further show these elements, with annotated Fig. 18 below.

Olmos, Fig. 18

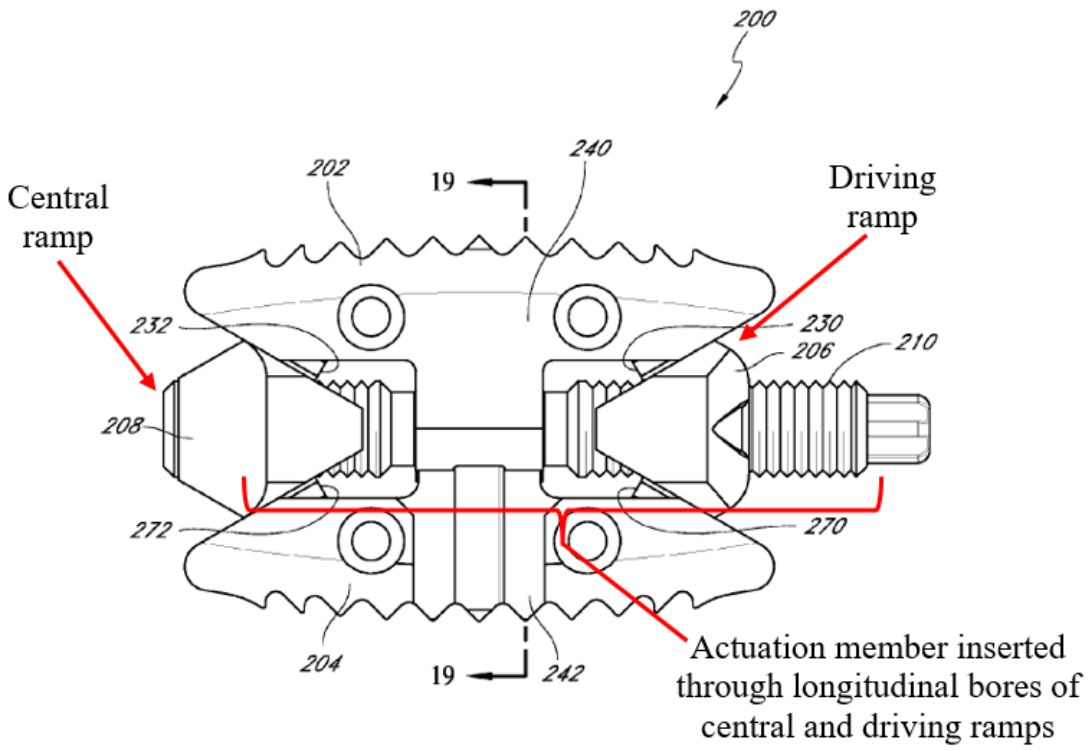


Accordingly, Olmos discloses this limitation. EX1002, ¶¶342-344; EX1004, 000065 (Examiner finding Olmos discloses Claim 1[p] without traverse).

(r) Claim 1[q]

As noted in §IX(D)(1)(q), *supra*, Olmos discloses that actuator shaft 210 extends through the driving and central ramps' bores. EX1006, ¶¶[0177]-[0178], Fig. 18; *see also id.*, ¶¶[0155], [0159], [0174]. Annotated Fig. 18 follows, appreciating that as noted above, Olmos alternatively teaches that aperture 300 can be non-threaded (*supra* §IX(D)(1)(o)).

Olmos, Fig. 18



Accordingly, Olmos discloses this limitation. EX1002, ¶¶345-347; EX1004, 000065 (finding Olmos discloses Claim 1[q] without traverse).

(s) Claim 1[r]

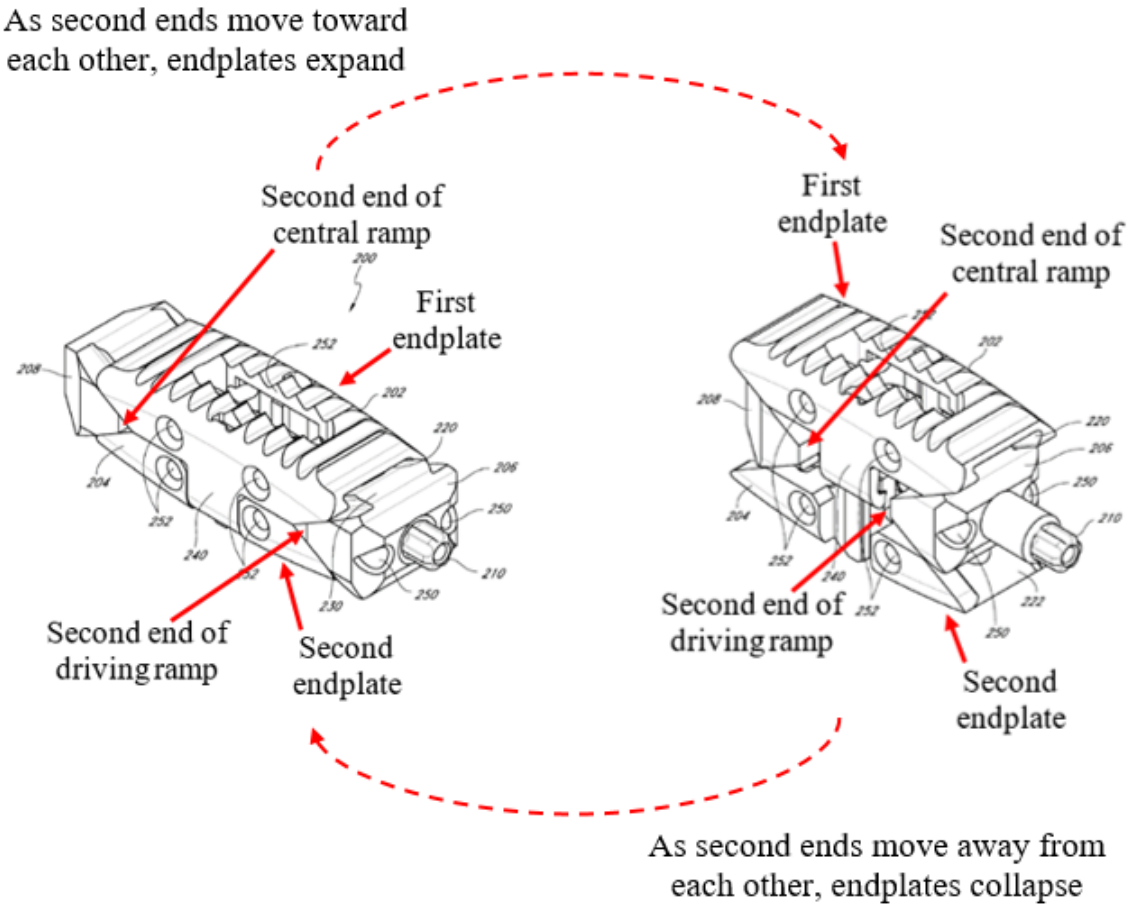
Olmos' actuator is disposed and remains within the non-threaded longitudinal bore and is movable (e.g., via rotation) with respect to the central ramp and the driving ramp ("actuator shaft **210** can be rotated to cause the proximal and distal wedge members to move toward each other"). EX1006, ¶¶[0155], [0177]; *see also id.*, ¶¶[0145]-[0147], [0159]. When a non-threaded bore is used (*see* §IX(D)(1)(o), *supra*), the actuator will remain axially fixed within the non-threaded bore of the driving ramp when the actuator is rotated to move the ramps together or apart. EX1002, ¶¶336, 348-350.

Accordingly, Olmos discloses this limitation. *Id.*; EX1004, 000065 (finding Olmos discloses Claim 1[r] without traverse).

(t) Claim 1[s]

Olmos' actuator "can be rotated to cause the proximal and distal wedge members to move toward each other, thus causing the upper and lower body portions **202**, **204** to be separated." EX1006, ¶[0155]; *see also id.*, ¶¶[0145]-[0147], [0159]. Figs. 16A-B show the relative movement of the ramps and endplates:

Olmos, Fig. 16A-B



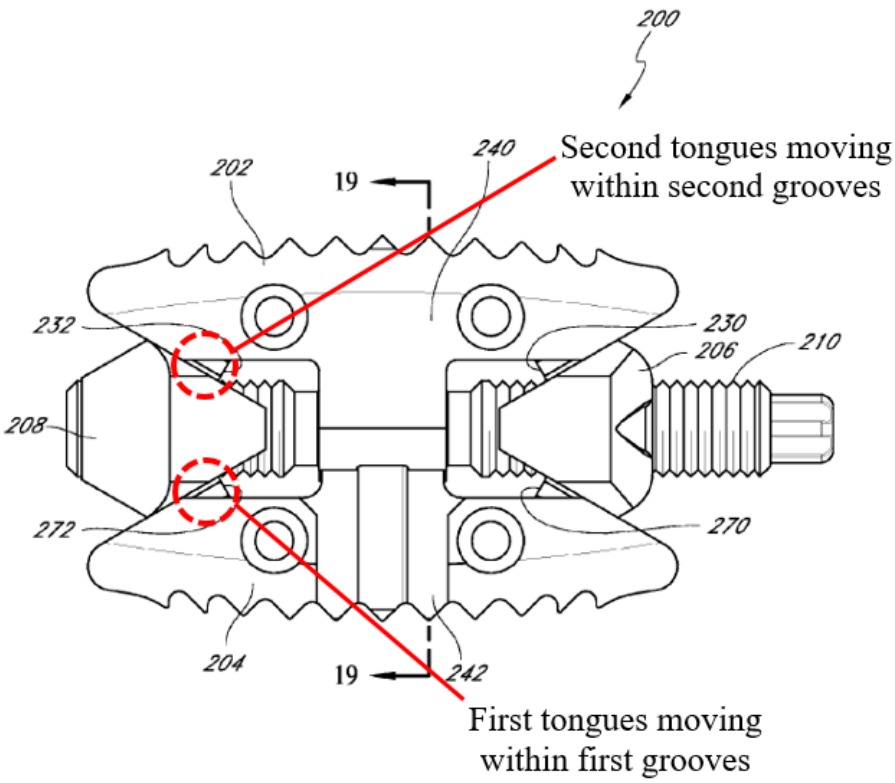
Accordingly, Olmos discloses this limitation. EX1002, ¶¶351-353; EX1004, 000065 (finding Olmos discloses Claim 1[s] without traverse).

(u) Claim 1[t]

Olmos discloses this claimed tongue-and-groove movement in relation to the mating dovetail structures on the wedges and endplates. EX1006, ¶¶[0167]-[0170]; *see also* §IX(D)(1)(j), *supra*. Figures 16A-B and 18 show the tongues within the

grooves when the implant is in the process of expanding or collapsing. Annotated Fig. 18 follows.

Olmos, Fig. 18



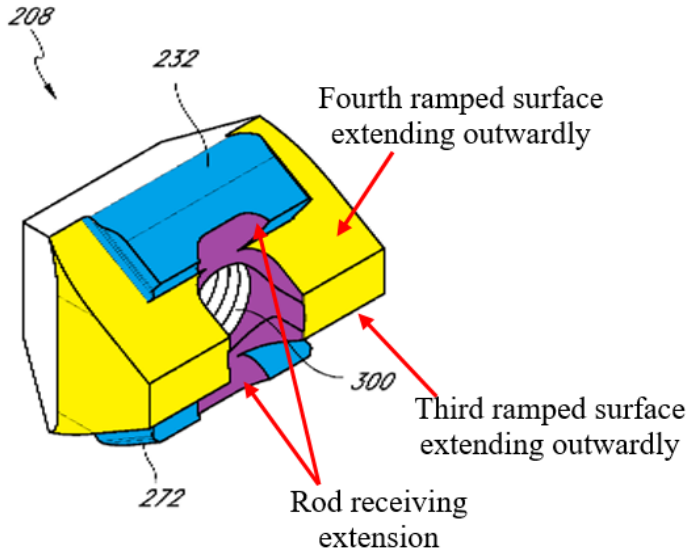
Accordingly, Olmos discloses this limitation. EX1002, ¶¶354-356; EX1004, 000066-67 (finding Olmos discloses Claim 1[t] without traverse).

(v) Claim 1[u]

As seen in Olmos Fig. 24B, upper guide member 232 and lower guide member 272 extend outwardly (laterally to the sides, and vertically above and below) from the surface of distal wedge member 208 and at least partially along a

longitudinal axis. Furthermore, at least a portion of members 232 and 272 are configured to receive a rod (actuator shaft 210), and third and fourth ramped portions extend outwardly from this portion. Annotated Fig. 24B shows the central ramp's extending guide members in blue, the rod-receiving portion in purple, and the third and fourth ramped portions in yellow.

Olmos, Fig. 24B

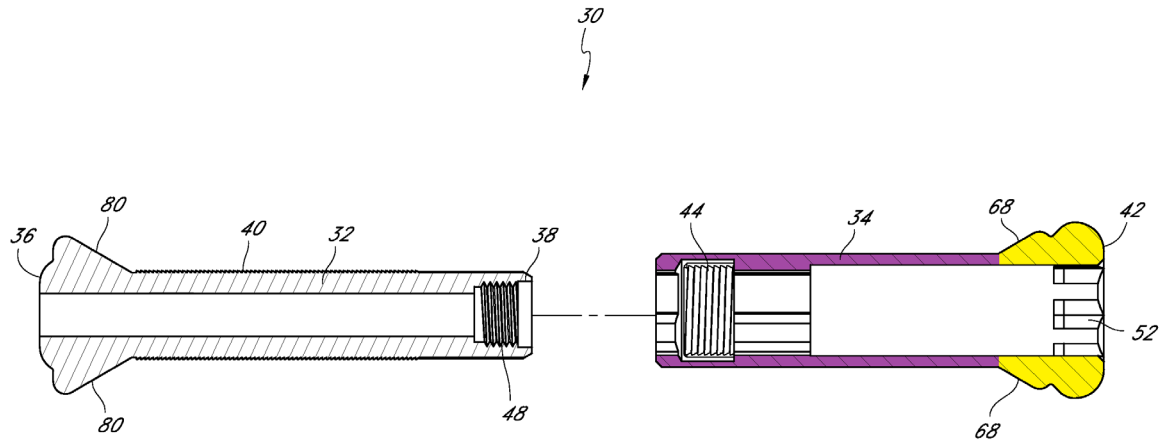


Accordingly, Olmos discloses this limitation. EX1002, ¶¶357-360.

Alternatively, it would have been obvious to add the further extension disclosed in Olmos Fig. 8 to the central ramp of Fig. 24B. In this embodiment, Olmos discloses that "proximal wedge member **68** 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. EX1006, ¶¶[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 expansion portion in yellow, follows.

Olmos, Fig. 8



A POSITA would further understand that adding Fig. 8's extension to the Fig. 16-24 embodiment's central ramp would still result in the third and fourth ramped portions extending outwardly (i.e., laterally to either side, and vertically above and below) from the modified rod-receiving extension. Combining Fig. 8's extension with the Fig. 16-24 embodiment simply involves elongating the existing

rod-receiving portion marked in purple in annotated Fig. 24B above. Accordingly, the third and fourth ramped portions would extend from the elongated extension just as described above and in connection with Chung in §§IX(A)(1)(v) and IX(C)(1)(b), *supra*. EX1002, ¶363; *see also* EX1010, 38 (alleging infringement of indistinguishable structure).

A POSITA would have been motivated to combine these two Olmos embodiments by applying Fig. 8's rod-receiving extension to the distal wedge/central ramp of the embodiment(s) of Figs. 16-24 for several reasons. EX1002, ¶¶364-367. Specifically, a POSITA would have understood that combining Fig. 8's extension with the embodiment(s) of Figs. 16-24 would allow the rod-shaped actuator to engage the distal wedge member/central ramp more quickly and over a greater distance and/or allow use of a shorter actuator. This would make the device more robust and serve Olmos's stated purpose of maintaining minimally invasive surgical procedures, while also maintaining the interconnecting structural components of the primary embodiments. EX1002, ¶¶364-366. These components, including the guide members of the ramps and the slots of the endplates, are structurally advantageous because "[t]he arrangement of the slots and the guide members can enhance the structural stability and alignment of the implant **200**." EX1006, ¶[0156]. Additionally, as Olmos expressly teaches as to Fig. 8, the use of an integrally-formed extension "can be advantageous in that

fewer parts are required, which can facilitate manufacturing and use of the intervertebral implant." *Id.*, ¶[0107].

A POSITA would have been motivated to make this combination even though the Fig. 8 embodiment effectively reverses the threaded engagement from that described in the '001 patent claims (e.g., the internally threaded extension in Fig. 8 is located on the proximal wedge/driving ramp rather than on the distal wedge/central ramp). Adding a threaded rod-receiving extension to the distal wedge/central ramp would have been most logical for a POSITA considering the advantages of embodiment(s) of Figs. 16-24, because the actuator in those figures is inserted through the proximal wedge/driving ramp. There would be no need for an extension on the proximal wedge/driving ramp in such an embodiment because the purpose of the extension is to improve engagement of the actuator threads with the ramp threads over a greater distance. Where, as here, the actuator is inserted through an unthreaded opening in the proximal wedge/driving ramp and into a threaded opening in the distal wedge/central ramp, a POSITA would have recognized that adding an extension instead to the distal wedge/central ramp would result in the aforementioned advantages. Accordingly, the teachings of Fig. 8 as a whole would motivate a POSITA to add a rod-receiving extension with a threaded opening to the central ramp from which the third ramped portion and the fourth ramped portions would extend outwardly. EX1002, ¶367.

Moreover, because this combination amounts to nothing more than the simple substitution of known mechanical features with each performing their known and expected function, a POSITA would have had a reasonable expectation of success in combining Baynham's tube 27 with Chung. EX1002, ¶368.

To the extent Patent Owner argues that the Examiner rejected the idea that Olmos discloses such an extension by allowing the claims after the Applicant amended Claim 11 to recite "a rod receiving extension of the central ramp," (*see* EX1004 at 000022, 000038), this argument should be disregarded. There is no indication in the prosecution history that the Examiner ever considered or even appreciated the foregoing disclosures. Moreover, the Examiner certainly was not presented with evidence establishing that a POSITA would have had clear motivations to combine the extension of Fig. 8 with the embodiments of Figs. 16-24 with a reasonable expectation of success.

Accordingly, Claim 1 is also obvious over Olmos. EX1002, ¶¶361-370.

(w) Claim 1[v]

Olmos teaches that, "[o]nce the implant is inserted into the intervertebral space, osteogenic substances, such as autogenous bone graft or bone allograft, can be strategically implanted adjacent the implant to prompt bone ingrowth in the intervertebral space." EX1006, ¶[0009]; *see also id.*, ¶[0075]. Accordingly, Olmos

discloses this limitation. EX1002, ¶¶371-372; EX1004, 000065 (finding Olmos discloses Claim 1[v] without traverse).

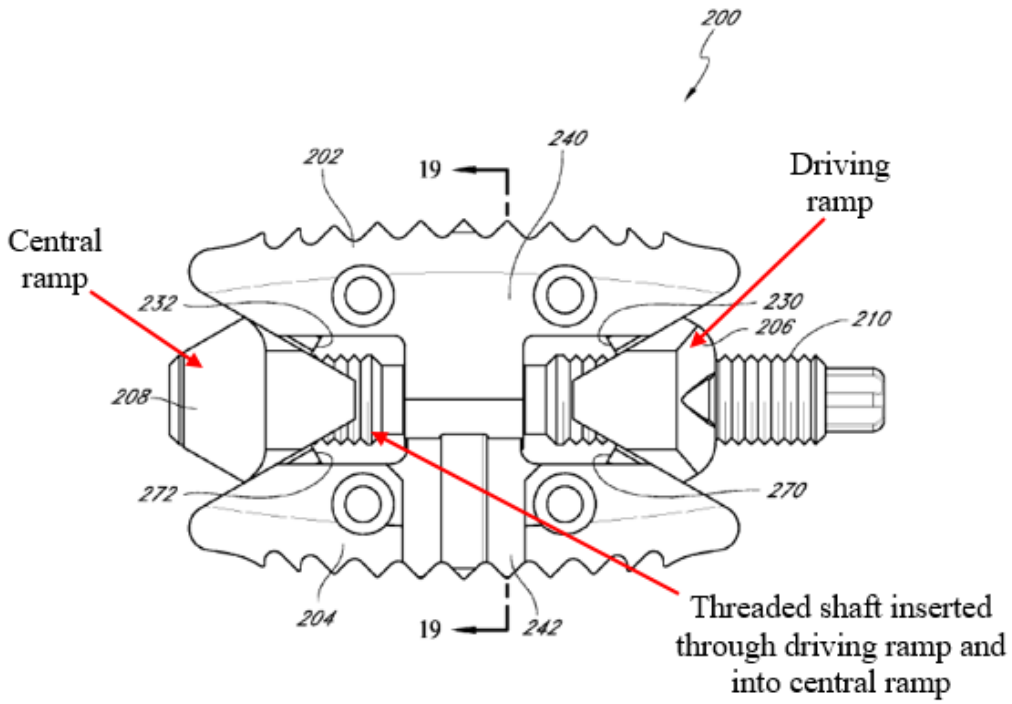
2. Claim 2

Olmos discloses that "the implant can also be introduced into the disc space…posterior[ly] in a[]…posterial lateral interbody fusion…." EX1006, ¶[0071]. Accordingly, Olmos discloses this limitation. EX1002, ¶¶373-375; EX1004, 000065 (finding Olmos discloses all elements of Claim 2 without traverse).

3. Claim 3

Olmos discloses that the actuator has a threaded shaft that is received through the driving ramp and into the central ramp ("actuator shaft **210** can be a single, continuous component having threads **294** disposed thereon for engaging the proximal and distal wedge members **206**, **208**"). EX1006, ¶[0174]; *see also id.*, ¶¶[0146], [0159], [0177]-[0178]. Annotated Fig. 18 showing these structures follows.

Olmos, Fig. 18



Accordingly, Olmos discloses this limitation. EX1002, ¶¶376-379; EX1004, 000065 (Examiner finding Olmos discloses all elements of Claim 3 without traverse).

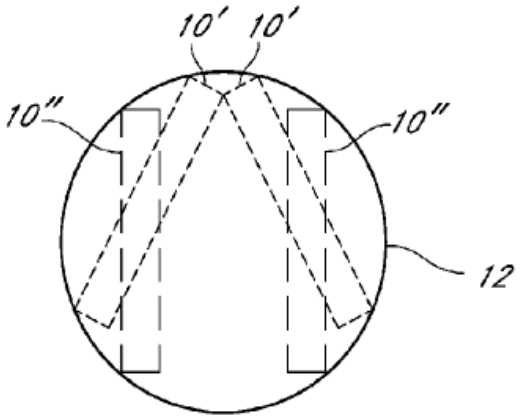
4. Claim 4

Olmos discloses that "the actuator shaft 210 can be rotated…." EX1006, ¶[0155]; *see also id.*, ¶¶[0145], [0159]. Accordingly, Olmos discloses this limitation. EX1002, ¶¶380-382; EX1004, 000065 (Examiner finding Olmos discloses all elements of Claim 4 without traverse).

5. Claim 5

Olmos discloses that "a plurality of intervertebral implants **10'** and **10"**…can be disposed in an intervertebral space…." EX1006, ¶¶[0143]-[0144] ("at least two implants…can be implanted"). That is, Olmos discloses introducing two or more implants 10' or two or more implants 10". This is seen in Fig. 14D, below.

Olmos, Fig. 14D



Accordingly, Olmos discloses this limitation. EX1002, ¶¶383-386; EX1004, 000065 (Examiner finding Olmos discloses all elements of Claim 5 without traverse).

6. Claim 6

Olmos discloses that where multiple implants are inserted into the disc space, the first and second implant are the same (*e.g.*, both are "implant 10' " or "implant 10" "). EX1006, ¶¶[0143]-[0144]. It also would have been obvious to a

POSITA to use identical devices when using more than one implant as using two identical devices with identical footprints and specifications makes it easier to maintain consistent and symmetrical expansion. EX1002, ¶222. Because Olmos's "expandable implant" includes "a central ramp, a driving ramp, and an actuator" (*see* §§IX(D)(1)(f), IX(D)(1)(m), IX(D)(1)(r)), a "second expandable implant" would also include those components.

Accordingly, Olmos discloses these limitations. EX1002, ¶¶387-390; EX1004, 000066 (Examiner finding Olmos discloses all elements of Claim 6 without traverse).

7. Claim 7

As previously discussed, the limitations of this claim are disclosed by Olmos in view of the knowledge a POSITA. *See* §IX(B)(4). Indeed, a POSITA would have known that there were only two options when implanting two devices – using one access path for both devices or using two access paths, one for each device – and would have found it obvious to try either based on the patient's specific needs. Moreover, as explained by Petitioner's expert, both of these techniques were well-known in the art. EX1002, ¶¶392-393.

Accordingly, this claim is obvious over Olmos in view of the knowledge of a POSITA. EX1002, ¶¶391-394.

8. Claim 8

As previously discussed, the limitations of this claim are disclosed by Olmos in view of the knowledge a POSITA. *See* §IX(B)(5). Indeed, as discussed in §IX(D)(8), *supra*, a POSITA would have found it obvious to use either one access path or two access paths to implant two devices based on the specific patient's needs, as both techniques were well-known in the art. EX1002, ¶396.

Accordingly, this claim is obvious over Olmos in view of the knowledge of a POSITA. EX1002, ¶¶395-397.

9. Claim 9

Olmos discloses the limitation of Claim 9, as discussed previously with respect to Claim 2. *See* §IX(D)(2). Moreover, a POSITA would recognize that, in bilateral procedures, which were traditionally more common than unilateral procedures, using a posterolateral approach for both access paths (and thus for "at least one of the access path and the different access path") would be beneficial as it allows a surgeon to create two access paths, one on each side of the spinal cord, without having to move the patient. EX1002, ¶¶398-401.

10. Claim 10

(a) Claim 10[pre]

Olmos discloses a surgical method. *See* §IX(D)(1)(a); EX1002, ¶402.

(b) Claim 10[a]

Olmos discloses these limitations. *See* §IX(D)(1)(b); EX1002, ¶¶403-404.

(c) Claim 10[b]

Olmos discloses this limitation. *See* §IX(D)(1)(c); EX1002, ¶¶405-406.

(d) Claim 10[c]

Olmos discloses this limitation. *See* §IX(D)(1)(d); EX1002, ¶¶407-408.

(e) Claim 10[d]

Olmos discloses this limitation. *See* §IX(D)(1)(e); EX1002, ¶¶409-410.

(f) Claim 10[e]

Olmos discloses this limitation. *See* §IX(D)(1)(f); EX1002, ¶¶411-412.

(g) Claim 10[f]

Olmos discloses this limitation. *See* §§IX(D)(1)(g)-(h); EX1002, ¶¶413-414.

(h) Claim 10[g]

Olmos discloses this limitation. *See* §§IX(D)(1)(i)-(j); EX1002, ¶¶415-416.

(i) Claim 10[h]

Olmos discloses this limitation. *See* §IX(D)(1)(k); EX1002, ¶¶417-418.

(j) Claim 10[i]

Olmos discloses this limitation. *See* §IX(D)(1)(l); EX1002, ¶¶419-420.

(k) Claim 10[j]

Olmos discloses this limitation. *See* §§IX(D)(1)(m)-(n); EX1002, ¶¶421-422.

(l) Claim 10[k]

Olmos discloses this limitation. *See* §IX(D)(1)(q); EX1002, ¶¶423-424.

(m) Claim 10[l]

Olmos discloses this limitation. *See* §§IX(D)(1)(r)-(t); EX1002, ¶¶425-426.

(n) Claim 10[m]

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

(o) Claim 10[n]

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

(p) Claim 10[o]

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

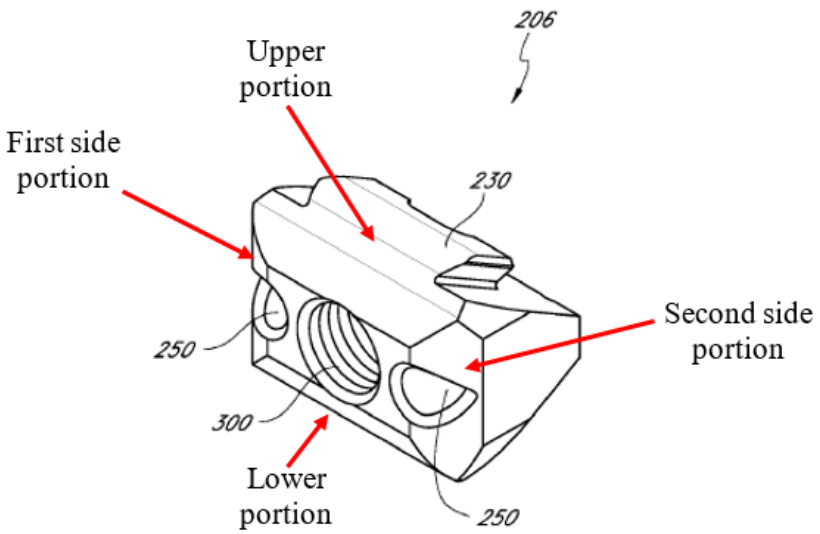
11. Claim 11

Claim 11 depends from Claim 1.

(a) Claim 11[a]

Olmos discloses a driving ramp/proximal wedge member 206 having a first side portion and an opposite second side portion extending from an upper portion to a lower portion, as can be seen in at least Figs. 16A-B and 23A-B. Annotated Fig. 23A follows.

Olmos, Fig. 23A

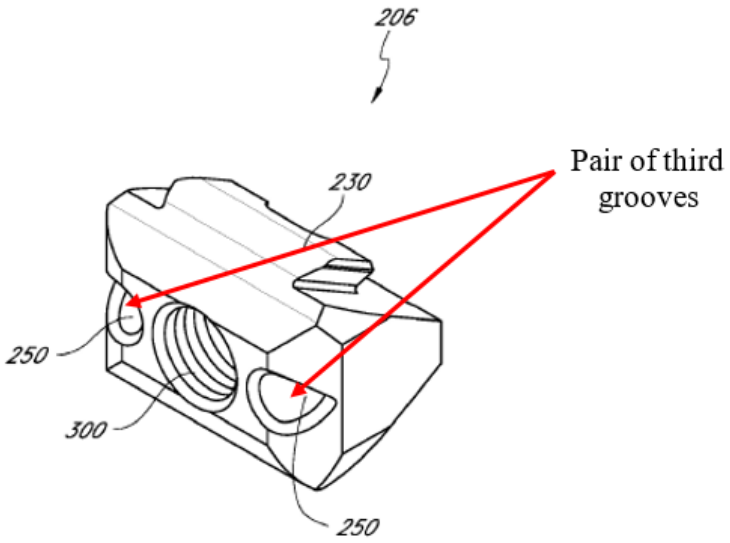


Accordingly, Olmos discloses this limitation. EX1002, ¶¶433-434.

(b) Claim 11[b]

Olmos discloses that the driving ramp has a pair of third grooves extending onto the first and second side portions (the "inwardly extending holes or indentations" designated as "anti-torque structures 250"). EX1006, ¶¶[0161], [0177]. These structures can be observed in at least Fig. 23A, below.

Olmos, Fig. 23A



Accordingly, Olmos discloses this limitation. EX1002, ¶¶435-437.

E. Ground 5: Claims 1-9 and 11 are Obvious over Olmos in View of Chung

While Petitioner submits that Olmos discloses every element of the '001 patent claims, should Patent Owner argue that Olmos does not teach a non-threaded driving ramp through-bore (along with the corresponding portion of the actuator), Claims 1-9 and 11 are further obvious under 35 U.S.C. §103 over Olmos in view of Chung, as detailed below and in Prof. Drewry's declaration (*see* EX1002, ¶¶438-444).

1. Claim 1

(a) Claim 1[n]

As noted in §IX(A)(1)(k), *supra*, Chung expressly discloses using a non-threaded bore in the driving ramp. EX1002, ¶439.

(b) Claims 1[o], 1[q], and 1[r]

Claim elements 1[o], 1[q], and 1[r] simply describe further characteristics of the driving ramp's non-threaded through-bore unrelated to its lack of threads. All such characteristics are disclosed by both Chung and Olmos. *See* §§IX(A)(1)(p), IX(A)(1)(s)-(t), IX(D)(1)(p), IX(D)(1)(s)-(t), *supra*. Accordingly, these limitations are disclosed by Olmos alone, and/or by Olmos as modified by Chung. EX1002, ¶¶442-443.

2. Claims 2-9 and 11

Claims 2-9 and 11 depend either directly or indirectly from Claim 1, and all elements added by these claims are expressly disclosed in Olmos. *See* §§IX(D)(2)-(9), IX(D)(11), *supra*. Accordingly, Claims 2-9 and 11 are likewise obvious for the reasons provided in Ground 4 and here. EX1002, ¶444.

3. Motivation to Combine

A POSITA would have been motivated to combine Olmos with Chung with a reasonable expectation of success. EX1002, ¶¶440-441.

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, ¶440. Chung expressly discloses an actuation member that non-threadingly engages portions of the driving ramp. *See* §IX(A)(1)(o), *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 expressly shown in Chung, a threaded actuator-receiving opening would be superfluous. Actuating the driving ramp using an unthreaded bore and actuator head as taught by Chung is a simple mechanical design choice, with no unexpected or surprising results. A POSITA therefore would have been motivated to simplify the Olmos design by omitting such threads to improve the manufacturing and operation of the device, consistent with Chung. EX1002, ¶¶440-441; *see also id*., ¶336.

A POSITA would have had a reasonable expectation of success in doing so given the similarity between Olmos and Chung. 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' 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, ¶¶336, 440.

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 '001 patent has not previously been challenged at the PTAB. Chung was not cited or considered during prosecution. Baynham was listed among dozens of other references in certain IDS filings (*e.g.,* EX1004, 000323), but was not otherwise discussed by the Examiner.

The Examiner rejected pending claims over Olmos in seven office actions. *See, e.g., id.,* 000060-79. In an April 9, 2018 amendment, however, Applicant cancelled several previously rejected claims and amended the sole remaining independent claims to recite a third ramped portion and a fourth ramped portion and further asserted that this feature distinguished from Olmos because, in Olmos, "there is not a third ramped portion configured to engage a portion of the first endplate and a fourth ramped portion configured to engage a portion of the second

endplate positioned between the first and second ends." *Id.*, 000053-54. An Examiner-Initiated Interview followed on July 10, 2018, wherein the Examiner indicated, without any further analysis, that adding further recitations to both independent claims would "put [the] claims in condition for allowance." *Id.*, 000038. The Applicant agreed (*id.*), and the claims were then allowed without any further substantive comment from the Examiner. *Id.*, 000030-37.

While Olmos was discussed and relied upon in numerous rejections during prosecution, Petitioner submits that the Examiner erred in concluding that Olmos did not teach the allegedly distinguishing feature of the central ramp comprising third and fourth ramped portions that extend outwardly from a rod-receiving extension of the central ramp. As discussed *supra* §IX(D)(1)(u), at least Olmos Fig. 24B, either alone or as modified by Olmos Fig. 8, discloses such an embodiment. This disclosure from Olmos may have been overlooked given Applicant's statements that Olmos did not teach or suggest these features (EX1004, 000053-54). These statements are also irreconcilable with Applicant's infringement contentions, which allege these same features exist in structures indistinguishable from Olmos' combined disclosure. *See* EX1010, 23, 38; *supra* §IX(D)(1)(v)(discussing combination of Olmos Figs. 16-24 with Fig. 8 embodiment).

Discretionary denial is not warranted under these circumstances. First, Olmos discloses a third ramped portion and a fourth ramped portion that extend outwardly from a rod-receiving extension of the central ramp—contrary to the Applicant's suggestions during prosecution, but consistent with Applicant's infringement contentions. The interview summary, amendments submitted by the Applicant and Examiner, and subsequent allowance show that this limitation was the Examiner's basis for allowance. Yet, there is no evidence that the Examiner appreciated Olmos' disclosure of this feature when allowing the claims, or Applicant's reading of these claims in its infringement contentions. Accordingly, *Becton Dickenson* factors (c)-(f) disfavor denial under §325(d) in view of 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, the other grounds in this Petition independently rely on Chung for an even more express teaching of these features. *E.g.*, §§IX(A)(1)(u), IX(A)(10)(o), *supra*. Thus, to the extent that Olmos is somehow determined to not meet this limitation, Chung does and is not cumulative to Olmos. Chung was also **not** before the Examiner during prosecution. Accordingly, *Becton Dickenson* factors (a)-(c) and (f) likewise disfavor denial under §325(d) in view of the

Petition's presentation of Chung. Discretionary denial under §325(d) is unwarranted for these additional reasons. *Oticon Medical AB v. Cochlear Ltd*., IPR2019-00975, Paper 15, 19-20 (PTAB Oct. 16, 2019) (precedential as to §§II(B)-(C); refusing to deny institution given new, noncumulative prior art asserted in the Petition).

XI. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that Trial be instituted and that Claims 1-11 be canceled.

Respectfully submitted,

Dated: September 26, 2022 By: s/*Michael R. Houston*/

Michael R. Houston
Reg. No. 58,486
Counsel for Petitioner

APPENDIX: CHALLENGED CLAIM LISTING

Claim No.	Limitation
1[pre]	A surgical method comprising:
1[a]	creating an access path to an intervertebral disc space; inserting an expandable implant into the disc space,
1[b]	wherein the expandable implant comprises: a first endplate having a pair of first tongues;
1[c]	a second endplate opposed to the first endplate, the second endplate having a pair of second tongues;
1[d]	a central ramp positioned between the first endplate and the second endplate,
1[e]	wherein the central ramp comprises a first end and a second end,
1[f]	wherein the second end includes a first ramped portion configured to engage a portion of the first endplate and a second ramped portion configured to engage a portion of the second endplate, and
1[g]	a third ramped portion configured to engage a portion of the first endplate and a fourth ramped portion configured to engage a portion of the second endplate positioned between the first and second ends,
1[h]	wherein the central ramp has a longitudinal bore, and
1[i]	wherein the first ramped portion has a pair of first grooves, each of the first grooves sized to receive one of the first tongues, and
1[j]	wherein the second ramped portion has a pair of second grooves, each of the second grooves sized to receive one of the second tongues;
1[k]	a driving ramp positioned between the first endplate and the second endplate,
1[l]	wherein the driving ramp comprises a first end and a second end,
1[m]	wherein the second end includes a first angled portion configured to engage a portion of the first endplate and a second angled portion configured to engage a portion of the second endplate,

Claim No.	Limitation
1[n]	wherein the driving ramp has a non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp,
1[o]	the longitudinal bore of the of the central ramp and the non-threaded longitudinal through bore of the driving ramp are coaxially aligned;
1[p]	an actuator insertable through the driving ramp,
1[q]	wherein a portion of the actuator extends through the non-threaded longitudinal through bore of the driving ramp and the longitudinal bore of the central ramp,
1[r]	the actuator is disposed and remains within the non-threaded longitudinal bore, and the actuator is movable with respect to the central ramp and the driving ramp, and
1[s]	wherein the actuator is configured to translate the driving ramp such that the second end of the driving ramp is moved closer to the second end of the central ramp to thereby cause expansion of the first endplate and the second endplate;
1[t]	wherein the first tongues and the second tongues are configured to move within corresponding first grooves and second grooves to expand and compress the expandable implant;
1[u]	wherein the third ramped portion and the fourth ramped portions extend outwardly from a rod receiving extension of the central ramp; and
1[v]	introducing bone graft material adjacent the expandable implant.
2	The method of claim 1, wherein the access path is created via a posterolateral approach.
3	The method of claim 1, wherein the actuator comprises a threaded shaft that is received through the driving ramp and into the central ramp.

Claim No.	Limitation
4	The method of claim 3, wherein the actuator is rotatable.
5	The method of claim 1, further comprising introducing a second expandable implant into the disc space.
6	The method of claim 5, wherein the second expandable implant also includes a central ramp, a driving ramp, and an actuator.
7	The method of claim 6, wherein the second expandable implant is introduced via the same access path as the expandable implant.
8	The method of claim 6, wherein the second expandable implant is introduced via a different access path as the expandable implant.
9	The method of claim 8, wherein at least one of the access path and the different access path are formed via posterolateral approaches.
10[pre]	A surgical method comprising:
10[a]	creating an access path to an intervertebral disc space; inserting an expandable implant into the disc space,
10[b]	wherein the expandable implant comprises: a first endplate having a pair of first tongues;
10[c]	a second endplate opposed to the first endplate, the second endplate having a pair of second tongues;
10[d]	a central ramp positioned between the first endplate and the second endplate,
10[e]	wherein the central ramp comprises a first end and a second end,

Claim No.	Limitation
10[f]	wherein the second end includes a first ramped portion configured to engage a portion of the first endplate and a second ramped portion configured to engage a portion of the second endplate, and a third ramped portion configured to engage a portion of the first endplate and a fourth ramped portion configured to engage a portion of the second endplate positioned between the first and second ends,
10[g]	wherein the central ramp has a longitudinal bore, and wherein the first ramped portion has a pair of first grooves, each of the first grooves sized to receive one of the first tongues, and
10[h]	wherein the second ramped portion has a pair of second grooves, each of the second grooves sized to receive one of the second tongues;
10[i]	a driving ramp positioned between the first endplate and the second endplate,
10[j]	wherein the driving ramp comprises a first end and a second end, wherein the second end includes a first angled portion configured to engage a portion of the first endplate and a second angled portion configured to engage a portion of the second endplate; and
10[k]	an actuator insertable through the driving ramp,
10[l]	wherein a portion of the actuator extends through the driving ramp and the central ramp, the actuator is disposed and remains within the bore of the driving ramp and the actuator is movable with respect to the central ramp and the driving ramp, and
10[m]	wherein the actuator is configured to translate the driving ramp such that the second end of the driving ramp is moved closer to the second end of the central ramp to thereby cause expansion of the first endplate and the second endplate;
10[n]	wherein the first tongues and the second tongues are configured to move within corresponding first grooves and second grooves to expand and compress the expandable implant; and

Claim No.	Limitation
10[o]	wherein the third ramped portion and the fourth ramped portions extend outwardly from a rod receiving extension of the central ramp.
11[a]	The method of claim 1, wherein the driving ramp includes a first side portion and an opposite second side portion extending from an upper portion to a lower portion of the driving ramp,
11[b]	wherein the first side portion and the second side portion include a pair of third grooves extending into the first and second side portions, respectively.

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, mandatory notices under 37 C.F.R. § 42.8, a certificate of service or word count, or appendix of exhibits), the Petition contains 13,788 words as counted by the word processing system used to prepare it.

By: s/*Michael R. Houston*/

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Counsel for Petitioner

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 or an equivalent next-day delivery service, directed to the attorneys of record for the patent at the following address:

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Audubon, PA 19403

September 26, 2022

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