

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIFE SPINE, INC.

Petitioner

v.

GLOBUS MEDICAL, INC.

Patent Owner

Patent No. 8,845,732

Issue Date: September 30, 2014

Title: EXPANDABLE FUSION DEVICE AND  
METHOD OF INSTALLATION THEREOF

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*Inter Partes* Review No. IPR2023-00041

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**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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### **EXHIBIT LIST**

<b>Ex. #</b>	<b>Exhibit</b>
1001	U.S. Patent No. 8,845,732
1002	Declaration of Prof. Troy D. Drewry
1003	Curriculum vitae of Prof. Troy D. Drewry
1004	Excerpts of Prosecution History for '732 Patent
1005	<i>Reserved</i>
1006	U.S. Patent Application Publication No. US 2008/0140207 A1 to Olmos et al. ("Olmos")
1007	U.S. Patent Application Publication No. US 2007/0270968 A1 to Baynham et al. ("Baynham")
1008	U.S. Patent No. 4,743,256 to Brantigan ("Brantigan")
1009	Excerpts of Leonard F. Peltier, <u>Orthopedics: A History and Iconography</u> (1993)
1010	<i>Reserved</i>
1011	U.S. Patent No. 8,308,804 to Krueger ("Krueger")
1012	<i>Reserved</i>
1013	<i>Engineering Mechanics: Wedges</i> , Mechanics Map: Open Textbook Project, <a href="http://mechanicsmap.psu.edu/websites/7_friction/7-3_wedges/wedges.html">mechanicsmap.psu.edu/websites/7_friction/7-3_wedges/wedges.html</a>
1014	U.S. Patent Application Publication No. US 2008/0114367 to Meyer ("Meyer")
1015	<i>Wedge</i> , Encyclopaedia Britannica (2008), <a href="https://www.britannica.com/technology/wedge">https://www.britannica.com/technology/wedge</a>
1016	U.S. Patent No. 8,906,095 to Christensen et al. ("Christensen")
1017	Video titled "Scissor Jack Animation SOLIDWORKS"
1018	<i>Reserved</i>
1019	<i>Reserved</i>
1020	Life Spine Stipulation



1021	Virk et al., <i>History of Spinal Fusion: Where We Came from and Where We Are Going</i> , 16 HSSJ 137 (2020)
1022	Tsuang et al., <i>Comparison of cage application modality in posterior lumbar interbody fusion with posterior instrumentation—A finite element study</i> , 31 Medical Engineering & Physics 565 (2009)
1023	Plaintiff Globus Medical, Inc.’s Preliminary Claim Construction Pleading
1024	Defendant Life Spine, Inc.’s Preliminary Claim Construction Pleading
1025	Declaration of Christopher McDonnell Regarding Claim Construction
1026	Kim, et al., <i>Posterior Lumbar Interbody Fusion using Unilateral Single Cage and Local Morselized Graft</i> , 1 Clinics in Orthopedic Surgery 214 (2009)
1027	Xiao, et al., <i>Unilateral Transforaminal Lumbar Interbody Fusion: a Review of the Technique, Indications, and Graft Materials</i> , 37 J. Int’l Med. Research 908 (2009)
1028	U.S. Patent Application Publication No. US 2003/0176926 to Boehm et al. (“Boehm”)
1029	U.S. Patent Application Publication No. US 2009/0062833 A1 to Song (“Song”)
1030	<i>Reserved</i>
1031	U.S. Patent No. 8,394,129 B2 to Morgenstern Lopez et al. (“Lopez”)
1032	U.S. Patent Application Publication No. US 2012/0185049 A1 to Varela et al. (“Varela-’049”)
1033	U.S. Provisional Patent Application No. 61/293,997 (“’997 provisional”)
1034	U.S. Provisional Patent Application No. 61/296,932 (“’932 provisional”)
1035	Kambin et al., <i>Arthroscopic Discectomy of the Lumbar Spine</i> , 337 Clinical Orthopaedics and Related Research 49 (1997).

1036	Excerpts of Webster’s II New College Dictionary (Houghton Mifflin Co., 2005) and The American Heritage College Dictionary (Houghton Mifflin Co., 2004)
1037	Comparison of the U.S. Patent Application No. 12/875,637 (“’637 Application”) and U.S. Patent Application No. 13/531,943 (“’943 Application”)
1038	Expanded Excerpt of U.S. Patent No. 8,845,731 (“’731 Patent”) File History
1039	Kim, <i>et al.</i> , “Clinical Applications of the Tubular Retractor on Spinal Disorders,” <i>J. Korean Neurosurg. Soc.</i> , 42:245-250 (2007)

## **I. INTRODUCTION**

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

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

### **A. Each Real Party-In-Interest**

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

### **B. Notice of Related Matters**

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

IPR2022-01603 ('739 Patent). In addition, Petitioner is concurrently filing a separate petition for *inter partes* review challenging the same claims of the '732 Patent in IPR2022-01599.

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

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

### **III. LEAD AND BACKUP COUNSEL**

**Lead Counsel:** Michael R. Houston (Reg. No. 58,486) **Tel:** 312-832-4378

**Backup Counsel:** George C. Beck (Reg. No. 38,072) **Tel:** 202-945-6014

**Backup Counsel:** Scott D. Anderson (Reg. No. 46,521) **Tel:** 414-297-5740

**Backup Counsel:** Jeffrey N. Costakos (Reg. No. 34,144) **Tel:** 414-297-5782

**Address:** Foley & Lardner LLP, 3000 K St NW, Suite 600, Washington, DC 20008

**Fax:** 312-832-4700

#### IV. SERVICE INFORMATION

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

Petitioner consents to electronic service at: LifeSpine-Globus-  
732IPR2@foley.com.

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

##### A. Grounds for Standing

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

##### B. Identification of Challenge

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

Ground	Claims	Basis	References
I	1, 7-13, 16	§102	Lopez
II	1, 7-13, 16	§103	Lopez with Baynham
III	1, 7-13, 16	§103	Varela-'049 with Lopez

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

An IPR petition must demonstrate “a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition.” 35 U.S.C. §314(a). The Petition meets this threshold. All elements of Claims 1, 7-13 and 16 of the ’732 patent are taught in the prior art as explained below. Also, for each ground under pre-AIA 35 U.S.C. §103, the reason to combine and the basis for a reasonable expectation of success are established.

## **VI. THE ’732 PATENT**

### **A. Overview of the ’732 Patent**

The ’732 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 claimed systems require a dilator, a cannula, and an implantable device that 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/systems having these features, and any additional claimed features, were well-known before the ’732 patent.

### **B. Priority Date**

The ’732 patent issued from Application No. 13/531,943 (“the ’943 Application”), which was filed June 25, 2012 as a continuation-in-part of

Application No. 12/875,637 (“the ’637 Application”), which issued as U.S. Patent No. 8,845,731. The ’943 Application added new matter beyond that of the ’637 Application, including disclosure of a dilator and cannula to be combined with an implantable device, which together comprise the claimed systems in all challenged claims of the ’732 Patent. Accordingly, the earliest date to which any challenged claim of the ’732 patent can claim priority is June 25, 2012.

To obtain the benefit of the priority date of an earlier application, a claim must meet the requirements of 35 U.S.C. §120. *See In re Huston*, 308 F.3d 1267, 1276 (Fed. Cir. 2002). Section 120 permits a patent application to rely on the filing date of an earlier application “only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. §112.” *PowerOasis, Inc. v. T-Mobile, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008). Claims that depend on “[s]ubject matter that arises for the first time in [a] CIP application do[] not receive the benefit of the filing date of the parent application.” *Id.* Thus, if “even a single feature” of a claimed invention was first disclosed in a CIP, and that feature is not inherent in the parent application, then the claim is only entitled to the filing date of the CIP. *Lockwood v. Am. Airlines, Inc.* 877 F. Supp. 500, 507 (S.D. Cal. 1994), *aff’d*, 107 F.3d 1565 (Fed. Cir. 1997). Once the party asserting invalidity presents invalidating prior art, the patentee has “the burden []

to come forward with evidence to show entitlement to an earlier filing date.”

*Research Corp. Techs, Inc. v. Microsoft Corp.*, 627 F.3d 859, 871 (Fed. Cir. 2010).

The ’637 Application does not describe or depict the dilator or cannula elements recited in independent claims 1, 13, and 16 of the ’732 Patent. For example, descriptions and figures illustrating a dilator and a cannula were newly added in the ’943 Application, as seen in Exhibit 1037, which is a redline comparison as between the ’943 Application and the earlier ’637 Application. *See, e.g.*, EX1037, 16-17, 74-76.

During prosecution of the ’943 Application, the Examiner also noted that the subject matter in the independent claims was not supported in the parent application, and thus that these claims have an effective filing date of June 25, 2012. EX1004, 000077.

Accordingly, June 25, 2012 is the ’732 patent’s earliest possible priority date.

### **C. Claim Construction**

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



## **VII. LEVEL OF SKILL IN THE ART**

The testimony evidence here confirms that a POSITA, as of September 3, 2010, would have had a bachelor's degree in mechanical engineering or biomedical engineering and two or more years of experience in biomechanical engineering, biomedical engineering, and/or spinal implant devices. A person could also have qualified as a POSITA with some combination of more formal education (*e.g.*, an M.D.) and less technical experience or less formal education and more technical or professional experience in the foregoing fields, and would have had further appreciation of various technical concepts in this field, as explained by Prof. Drewry. EX1002, ¶¶31. This level of skill in the art would not significantly change as between September 2010 and June 2012, but certain prior art falling within this period (*e.g.*, Lopez and Varela-'049) demonstrates further progress in the field, as further discussed herein. *Id.*, ¶32.

## **VIII. PRIOR ART**

### **A. Lopez**

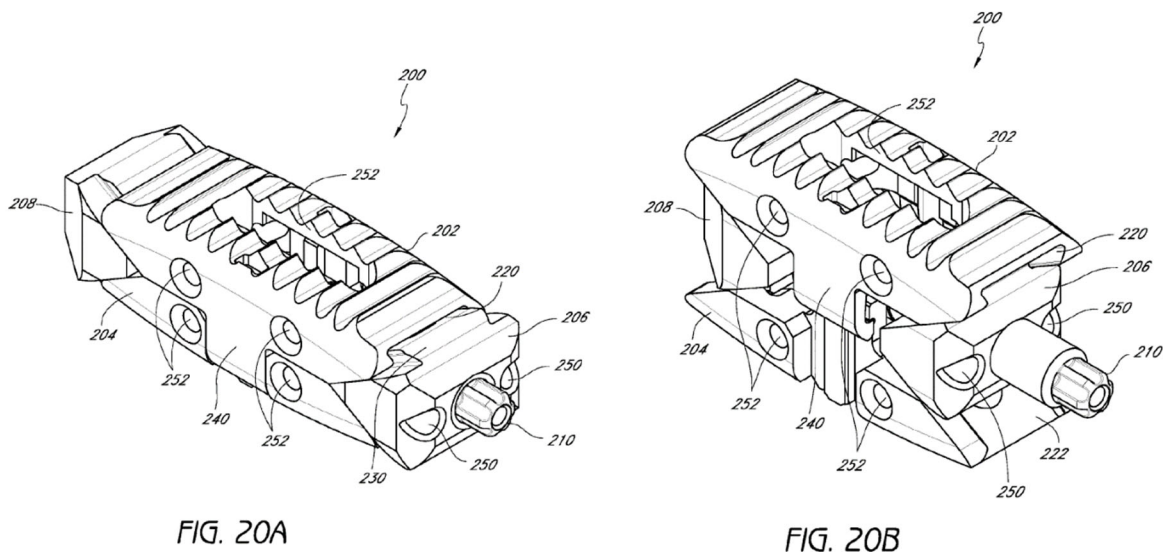
U.S. Patent No. 8,394,129 to Morgenstern Lopez et al. ("Lopez," EX1031) was filed on September 26, 2011, and is prior art under 35 U.S.C. §102(a). Lopez was not cited during prosecution of the application leading to the '732 patent.

Lopez is directed to "[a] dilation introducer for orthopedic surgery... for minimally invasive access for insertion of an intervertebral implant." EX1031 at

Abstract. Among other things, Lopez teaches that the disclosed system includes “a first dilator tube” and “[a]n access cannula,” and that “surgical instruments may pass through the access cannula to operate on an intervertebral disc and/or insert an intervertebral implant.” *Id.*

The intervertebral implant itself is also described in great detail, with Lopez teaching that “the implant 200 can be configured such that proximal and distal wedge members 206, 208 are interlinked with upper and lower body portions 202, 204,” and further teaching that an “actuator shaft 210 can facilitate expansion of the implant 200 through rotation....” EX1031 at 19:65-20:1, 20:38-39. Additional details regarding the structure and function of the implant are provided throughout Lopez’s specification.

Figures 20A and 20B show a “perspective view” of the “intervertebral implant” in its unexpanded and expanded states, respectively (*id.*, at 5:66-6:3):



*Id.* at Figs. 20A and 20B.

Figure 22 shows the side view of the intervertebral implant (*id.* at 6:6-7):

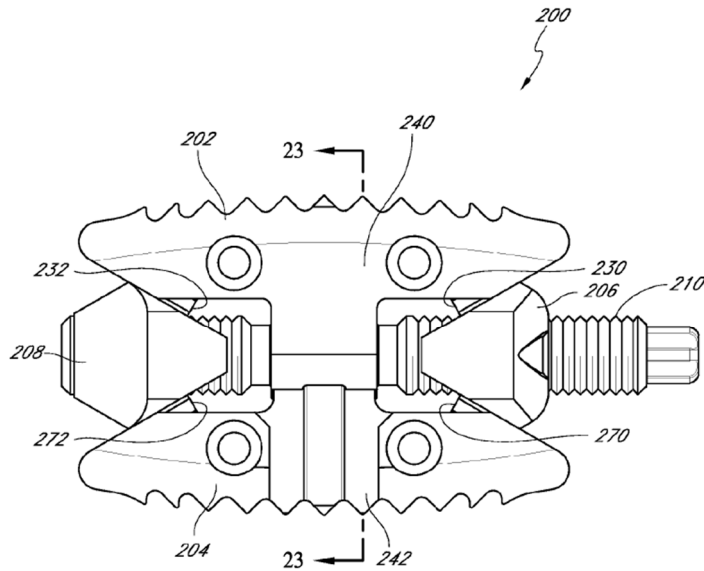


FIG. 22

*Id.* at Fig. 22.

Figure 7B shows an enlarged view of the distal tip of the dilator introducer, including the first dilator tube (element 40) and the access cannula (element 30) (*id.* at 4:62-67):

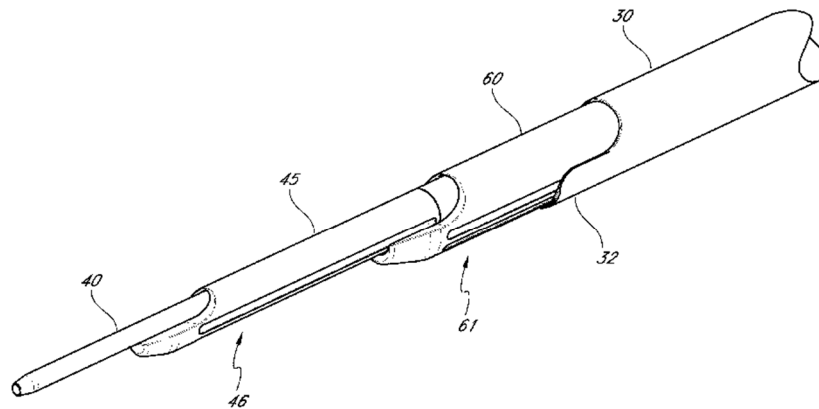


FIG. 7B

*Id.* at Fig. 7B

Figure 16A shows “a plan view of... an access cannula” (*id.*, 5:40-41):

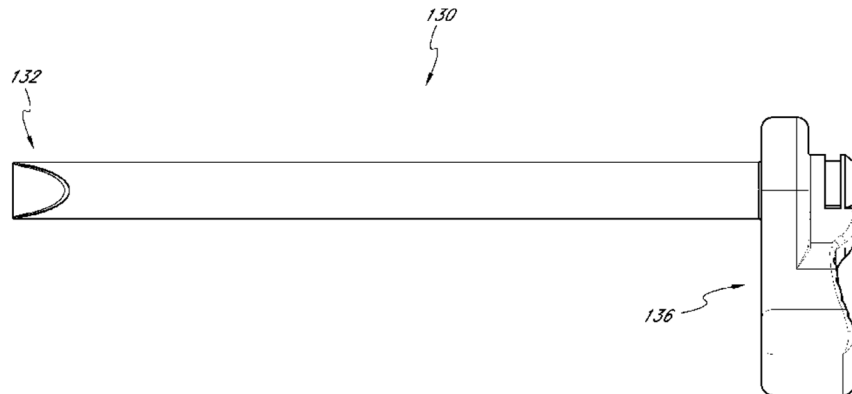


FIG. 16A

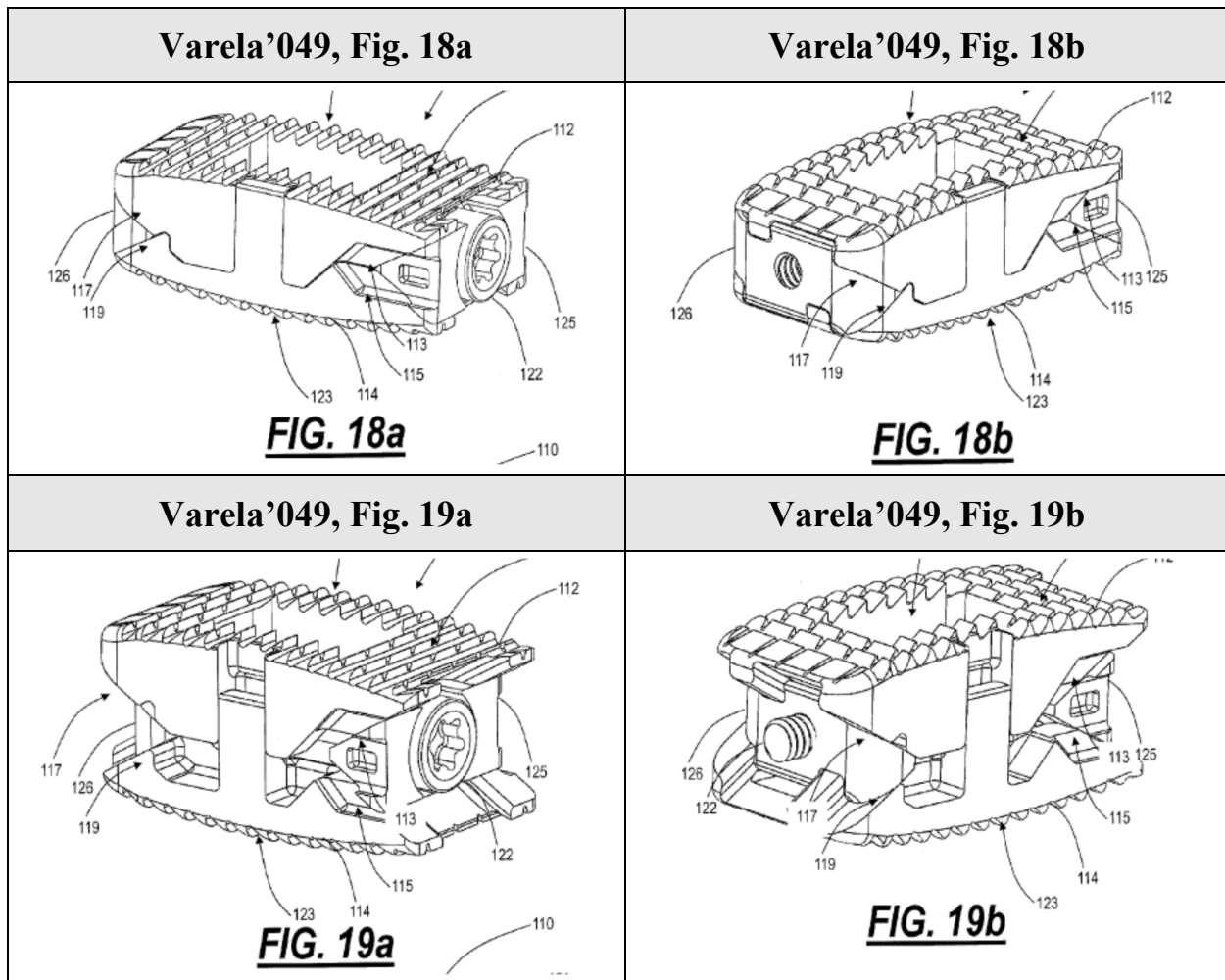
*Id.* at Fig. 16A.

### **B. Varela-’049**

U.S. Patent Application Publication No. US 2012/0185049 to Varela et al. (“Varela-’049,” EX1032) was filed on March 28, 2012, and is prior art under 35

U.S.C. §§102(a). Varela-'049 was not cited during prosecution of the application leading to the '732 patent.

Varela'049 discloses multiple “expandable intervertebral implant” embodiments having a “superior member 112” and “inferior member 114” that are designed to “nest” with one another when in the unexpanded or collapsed position. EX1032, ¶¶[0005], [0079]. Superior member 112 and inferior member 114, respectively, include “proximal ramp portions 113 and 115” as well as “distal ramp portions 114 and 116,” *Id.*, ¶[0079]. These ramp portions include “raised parallel rail structures 128” forming ramped surfaces. *See Id.* The “rail structures 128 are positioned and configured to engage corresponding recessed parallel slot structures 130 of the proximal and distal wedge structures 125 and 126.” *Id.* The rail structures 128 and slot structures 130 are positioned such that the ramped portions of the superior and inferior members and the proximal and distal wedge structures “are ‘nested’ when assembled, such that the form factor (i.e. both the vertical cross-section and the horizontal footprint) of the expandable intervertebral implant 110 is minimized when undeployed (i.e. unexpanded),” and “this makes the assembly as compact as possible, with the smallest possible undeployed vertical cross-section and the smallest/shortest possible undeployed horizontal footprint.” *Id.*



Moreover, to move the implant from an unexpanded to expanded state, Varela'049 discloses using an actuation bolt 122. *Id.*, ¶[0083]. Rotation of the actuation bolt 122 causes the wedge structures 125 and 126 to move either farther away or closer to one another which in turn causes the implant to either expand or collapse. *Id.*

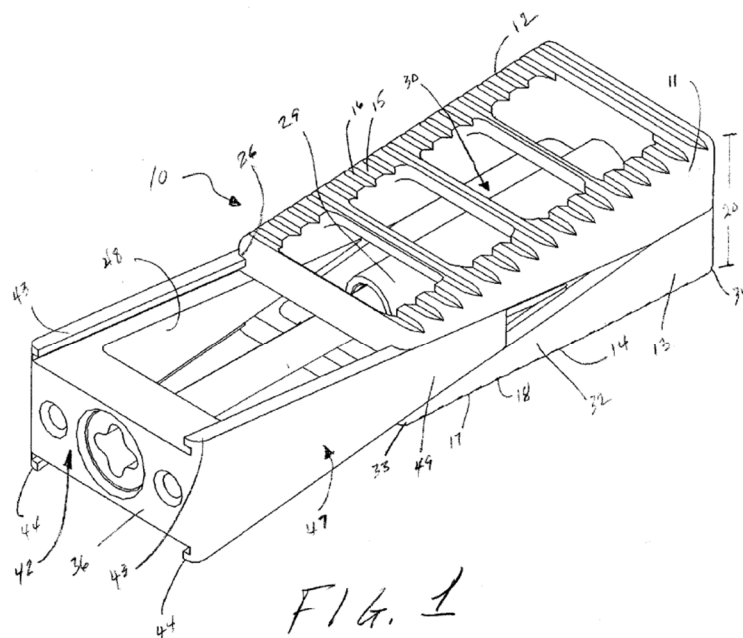
### C. Baynham

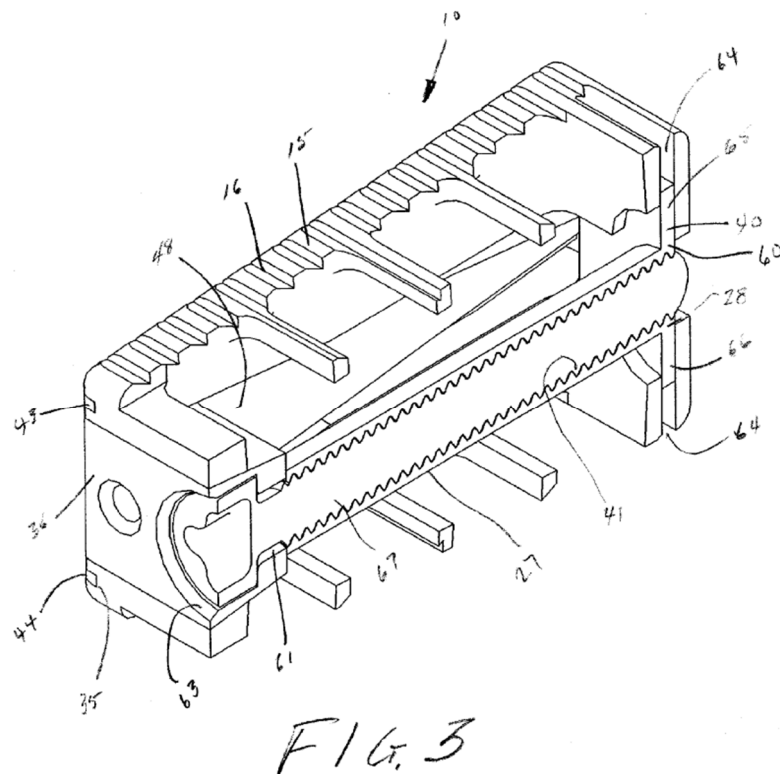
U.S. Patent Application Publication No. US 2007/0270968 to Baynham et al. (“Baynham,” EX1007) was first published on November 22, 2007 and is prior

art under 35 U.S.C. §§102(a)-(b). Baynham was listed in an Information Disclosure Statement submitted on June 19, 2014, but was not cited or discussed by the Examiner.

Baynham is directed to a “spinal fusion implant for implantation between adjacent vertebrae” with “an upper section and a lower section separate by a distractor” where the “sidewalls of the upper section and lower section terminate in inclined planes so that the sections move away from each other as the wedge shaped distractor increases the height of the device.” EX1007, Abstract.

The spinal fusion implant disclosed by Baynham is shown below in Figures 1 and 3:





*Id.*, Figs. 1, 3.

Baynham shows upper and lower sections having grooves 26, 35 which engage the flanges 43, 44 of distractor 42. EX1007, ¶¶[0025]-[0026]; Figs. 1, 3. Baynham further shows that distractor 42 also has an unthreaded bore 61 in its trailing edge for receiving a jack screw 67. *Id.*, Fig. 3. Additionally, a POSITA would have understood that Baynham discloses that the leading edge 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].

Baynham’s threaded tube (i.e., “extension”) extends toward the opposing ramp and engages the screw or actuation member, and as the actuation member 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.

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

### **A. Ground 1: Claims 1, 7-13 and 16 are anticipated by Lopez**

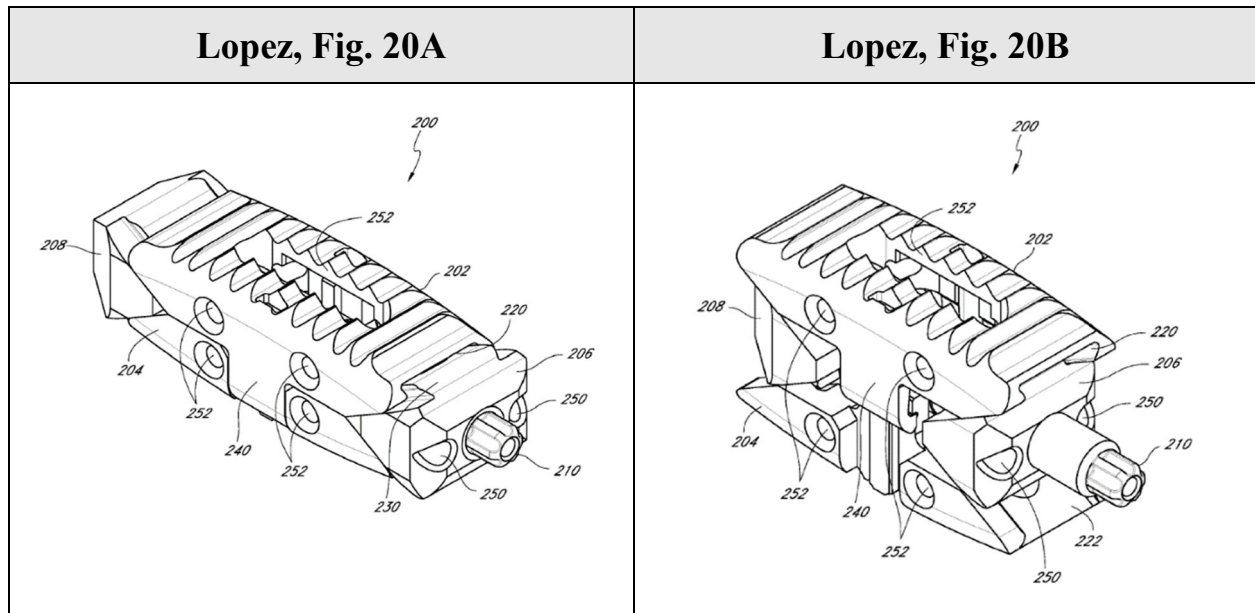
Claims 1, 7-13 and 16 are anticipated under 35 U.S.C. §102 by Lopez as detailed below and in Prof. Drewry’s declaration (*see* EX1002, ¶¶90-231).

#### **1. Claim 1**

##### **(a) Claim 1[a]**

Claim 1 is directed to a “**system for intervertebral fusion.**” Lopez discloses a system for intervertebral fusion through its disclosure of a device and method that “can be used for fusion, for example, by inserting an intervertebral implant to properly space adjacent vertebrae....” EX1031, 6:66-7:1; *see also id.*, 6:63-66 (“[C]ertain embodiments disclosed herein are discussed in the context of an intervertebral implant and spinal fusion because...the device and methods have

applicability and usefulness in such a field.”). The disclosed intervertebral implant is seen in Figs. 20A-B, below.

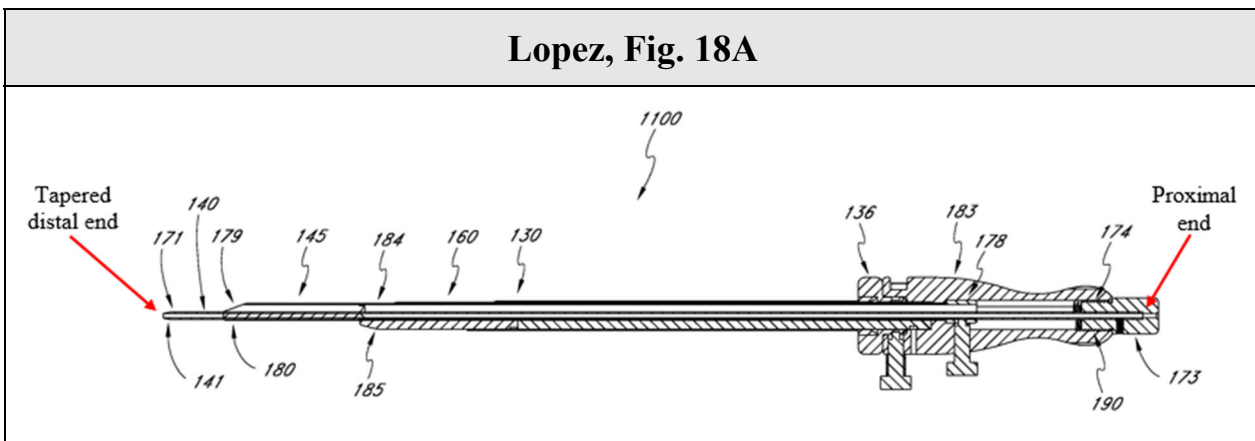


Lopez further discloses use of a dilation introducer for insertion of the intervertebral implant. *See* EX1031, Abstract, 2:41-56, 3:8-29. The dilation introducer includes a dilator tube and an access cannula. *Id.* The intervertebral implant, together with tools including a dilator and cannula, discloses a system for intervertebral fusion. EX1002, ¶90-92.

**(b) Claim 1[b]**

Claim 1 requires “**a dilator having a proximal end and a tapered distal end for penetrating soft tissue.**” Lopez discloses a dilation introducer including a first dilator tube 40/140. EX1031, Abstract, 2:38-40, 17:1-15, 14:53-65. Lopez further discloses that the first dilator tube has a proximal end and a tapered distal

Annotated Figs. 7B and 18A showing these features follow.

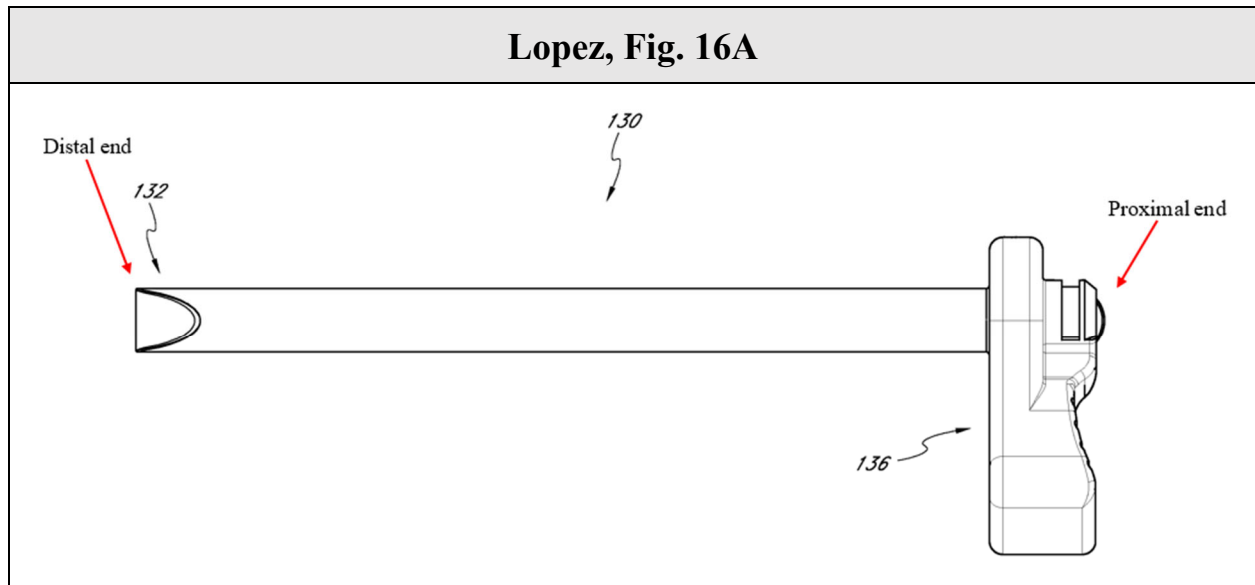


Accordingly, Lopez discloses this limitation. EX1002, ¶¶93-95.

**(c) Claim 1[c]**

Claim 1 recites “**a cannula having a proximal end and a distal end.**”

Lopez discloses an access cannula 30/130 having a proximal end and a distal end, (EX1031, Abstract, 3:19-29, 17:46-47 (“The access cannula 130 has a distal portion 161, a proximal portion 193, a proximal grip 136, and longitudinal lumen 164.”), Figs. 3, 6-7, 11-12, 16-18), as seen in Fig. 16A, below.

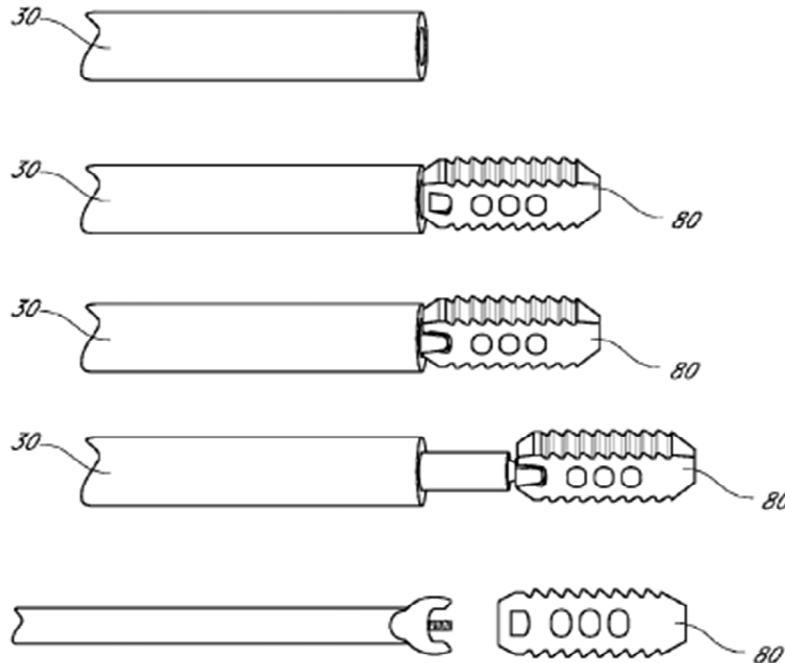


Accordingly, Lopez discloses this limitation. EX1002, ¶96-97.

**(d) Claim 1[d]**

Claim 1 recites “**an intervertebral implant sized for insertion into an intervertebral space through the cannula.**” Lopez discloses that “the intervertebral implant 80 may be introduced through the access cannula 30” (EX1031, 12:64-66; *see also id.*, 5:20-21) as seen in Figs. 12, below:

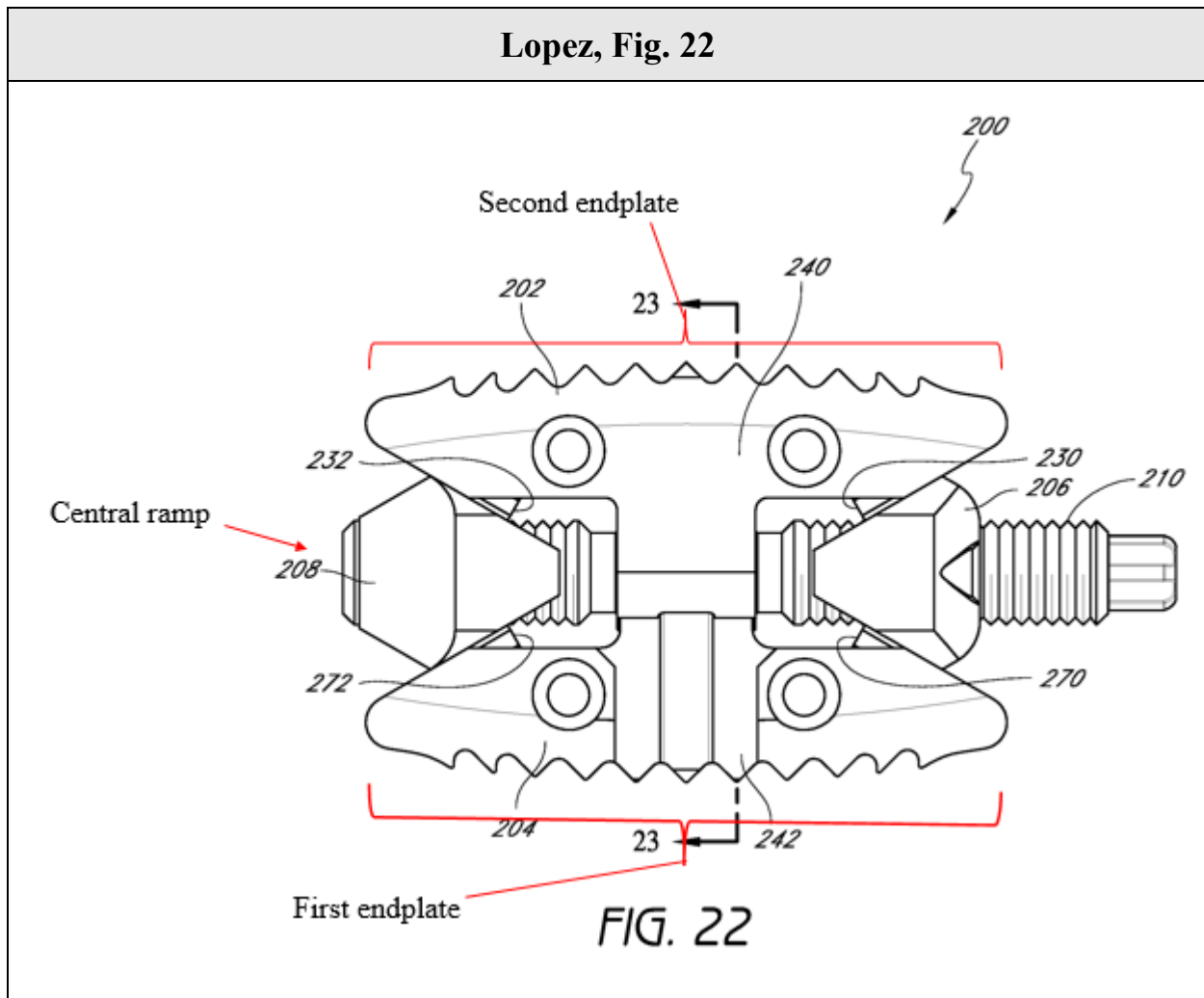
**Lopez, Fig. 12**



Accordingly, Lopez discloses this limitation. EX1002, ¶98-100.

**(e) Claim 1[e]**

Claim 1 recites that “**the intervertebral implant comprises a first endplate, a second endplate, and a central ramp disposed between the first endplate and the second endplate.**” Lopez discloses a first endplate (e.g., “lower body portion **204**”), a second endplate (e.g., “upper body portion **202**”), and a central ramp (e.g., “distal wedge member[.]... **208**”) disposed between the first endplate and the second endplate. EX1031, 19:63-20:15, 22:6-18, 22:40-51, Figs. 20A-B, 18. Figures 20A-B and 22 show this, with annotated Fig. 22 below.

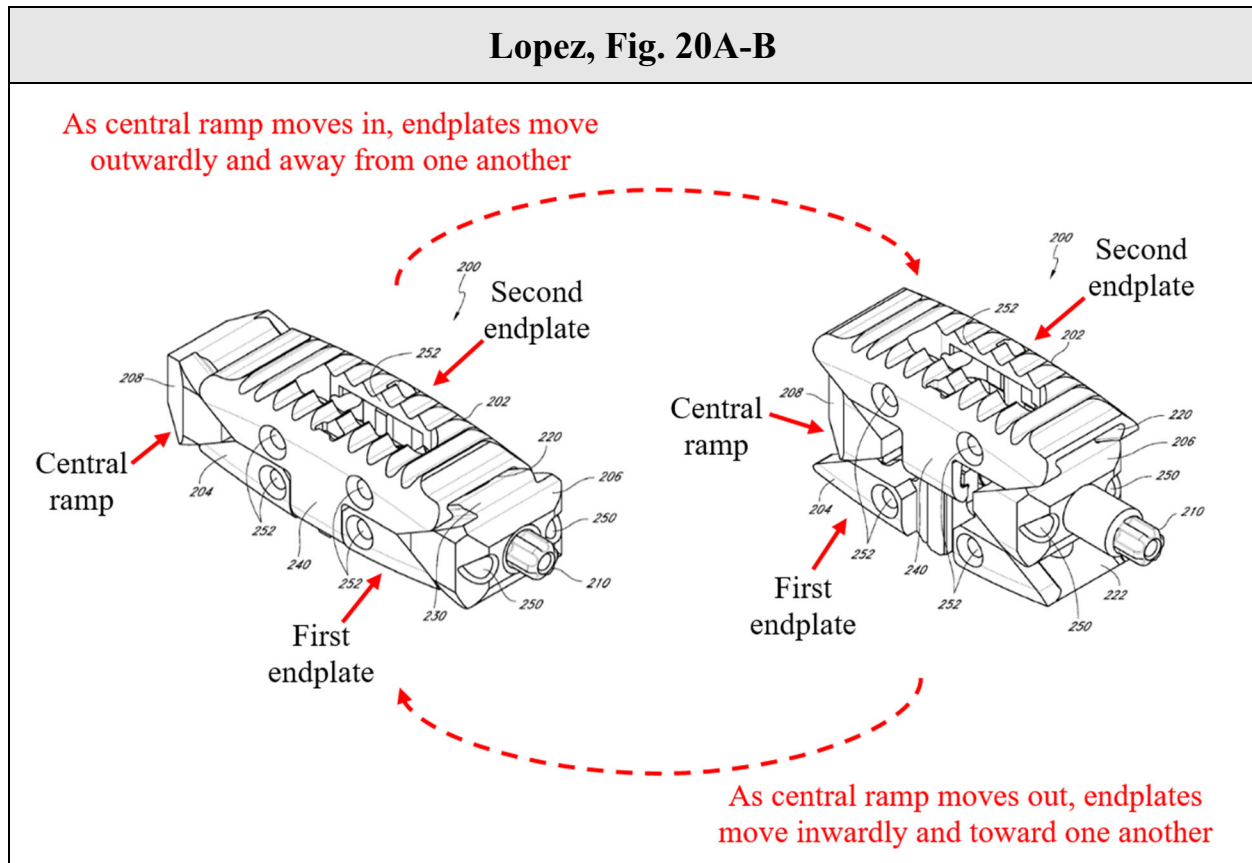


Accordingly, Lopez discloses this limitation. EX1002, ¶¶101-103.

**(f) Claim 1[f]**

Claim 1 recites that “**the central ramp is configured to move in a first direction and cause the first and second endplates to move outwardly and away from one another.**” Lopez discloses that, “upon rotation of the actuator shaft 210, the wedge members 206, 208 can be caused to move toward or away from each other to facilitate expansion or contraction of the implant 200.” EX1031,

23:23-37. Annotated Figs. 20A-B follow, showing a device according to Lopez satisfying these limitations.



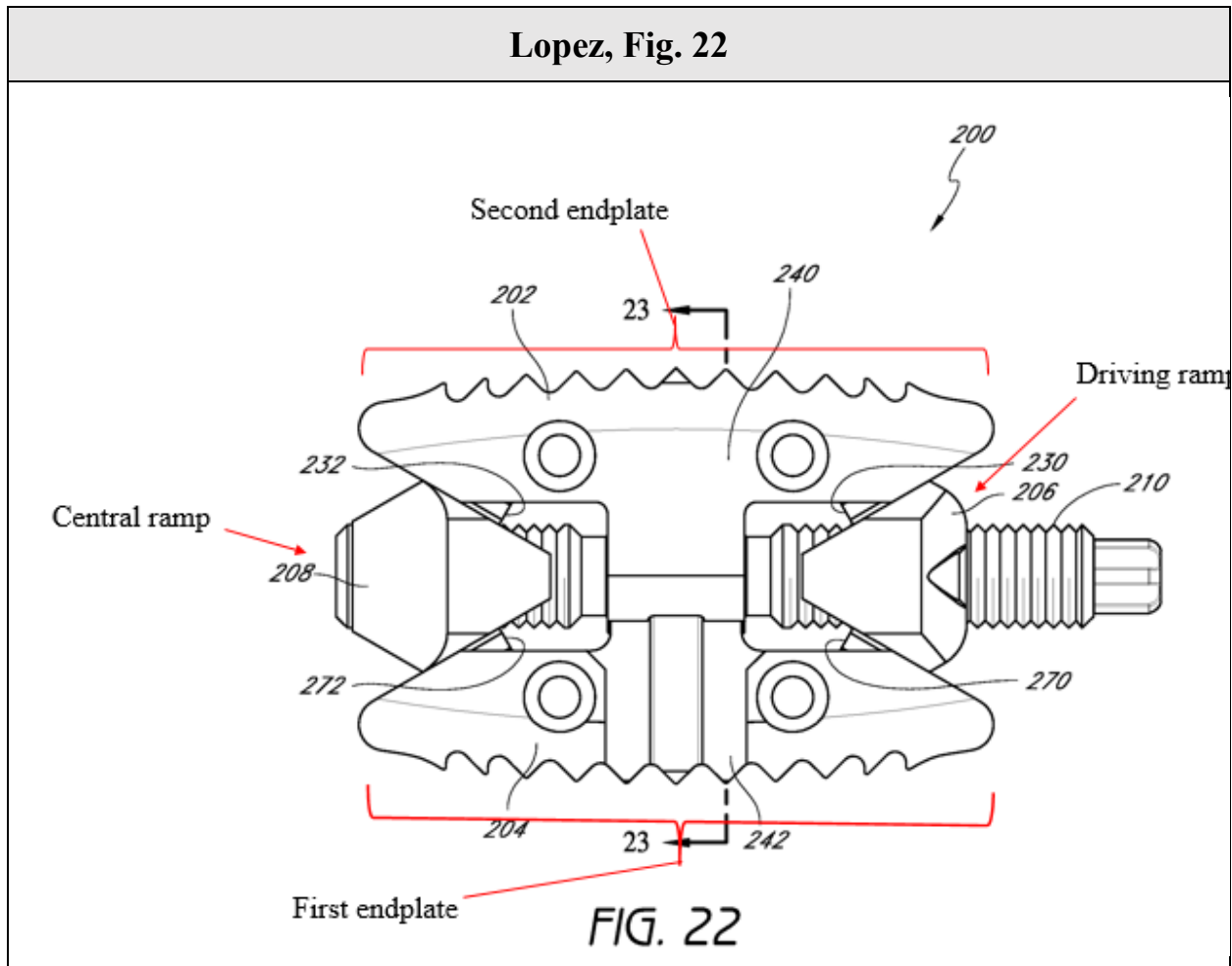
Accordingly, Lopez discloses this limitation. EX1002, ¶¶104-106.

**(g) Claim 1[g]**

Claim 1 recites “a driving ramp disposed between the first endplate and the second endplate at an opposite end of the intervertebral implant from the central ramp.” Lopez discloses a driving ramp (“proximal wedge member 206”) disposed between the first and the second endplates at an opposite end of the

endplates from the central ramp. EX1031, 20:5-14, 22:6-22, Figs. 20A-B, 18.

Annotated Fig. 22, below, shows this:



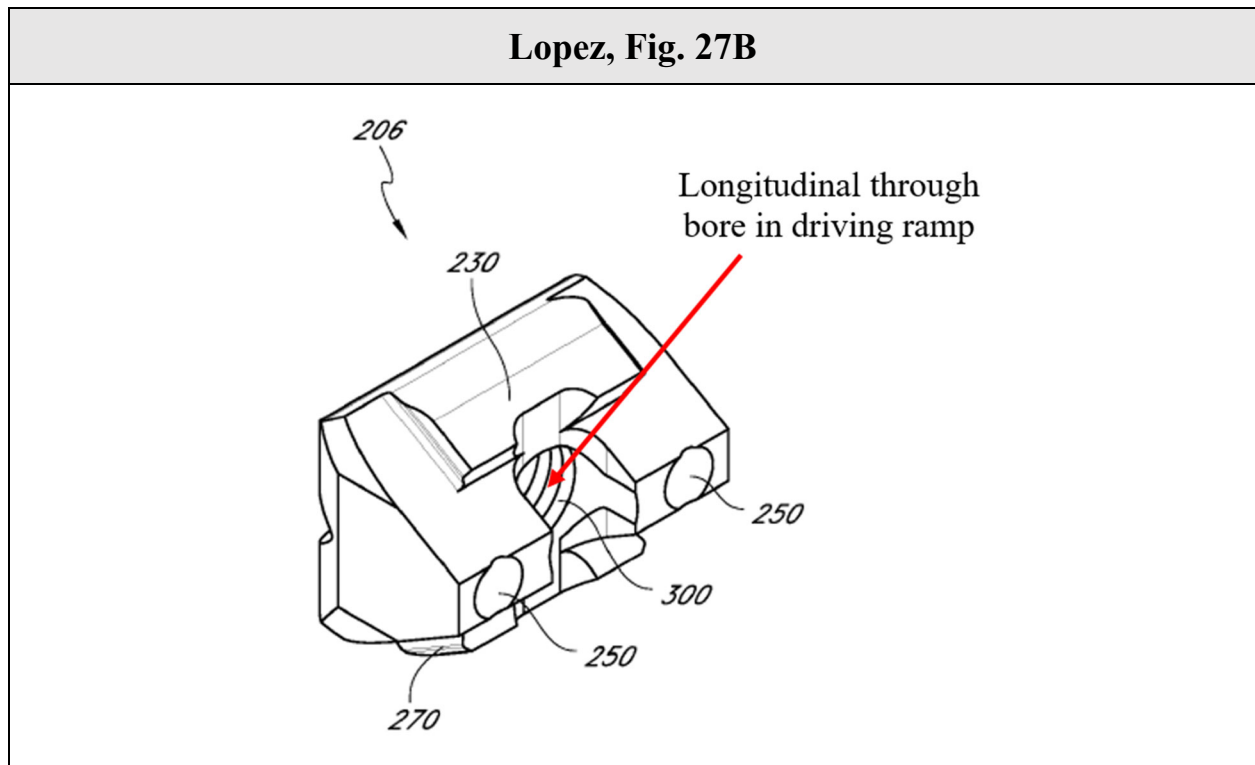
Accordingly, Lopez discloses this limitation. EX1002, ¶¶107-111.

**(h) Claim 1[h]**

Claim 1 recites that “**the driving ramp has a longitudinal through bore.**”

Lopez discloses that the driving ramp/proximal wedge member 206 has a longitudinal bore (“comprise[s] a central aperture **300**...”). EX1031, 23:58-60, Figs. 22, 27A-B. Annotated Fig. 27B follows.





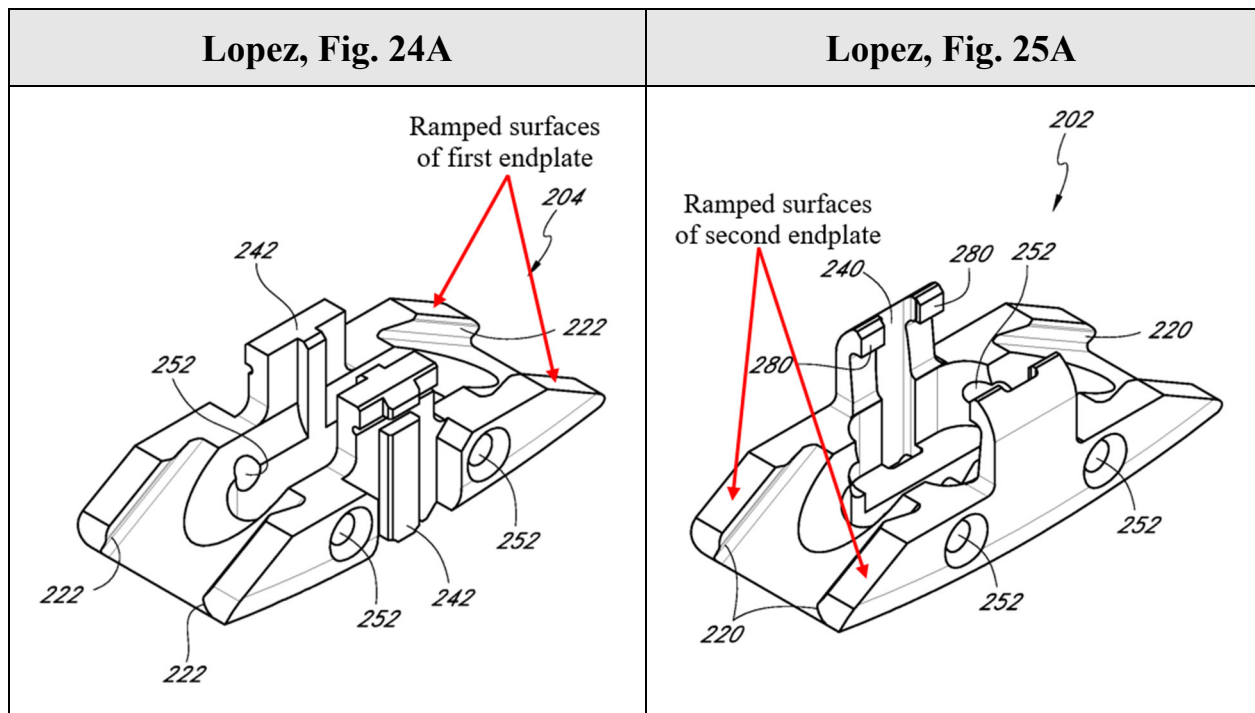
Accordingly, Lopez discloses this limitation. EX1002, ¶¶112-114.

**(i) Claim 1[i]**

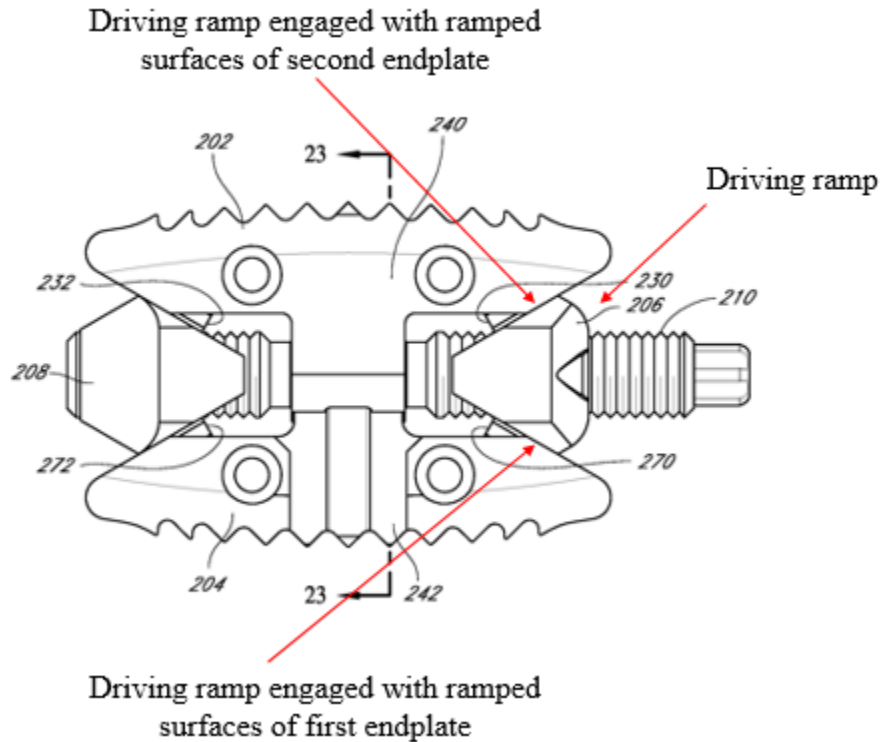
Claim 1 recites that “**wherein the driving ramp is configured to engage ramped surfaces of the first endplate and ramped surfaces of the second endplate.**” Lopez discloses that the driving ramp is configured to engage ramped surfaces of the first and second endplates. EX1031, Figs. 20A-B, 22, and 28A-B, 19:63-20:14, 22:6-28, 22:54-63 (“[T]he wedge members 206, 208 are engaged with upper and lower body portions 202, 204...”). As seen at least in Fig. 22, wedge members 206, 208 and upper and lower body portions, 202, 204 have an “angular relationship.” *Id.*, 22:19-22. At least based on these, a POSITA would

understand that the driving ramp engages ramped surface of the endplates.

Annotated Figs. 24A and 25A showing the ramped surfaces of the first and second endplate and Fig. 22 showing the driving ramp engaged with those ramped surfaces follow.



**Lopez, Fig. 22**



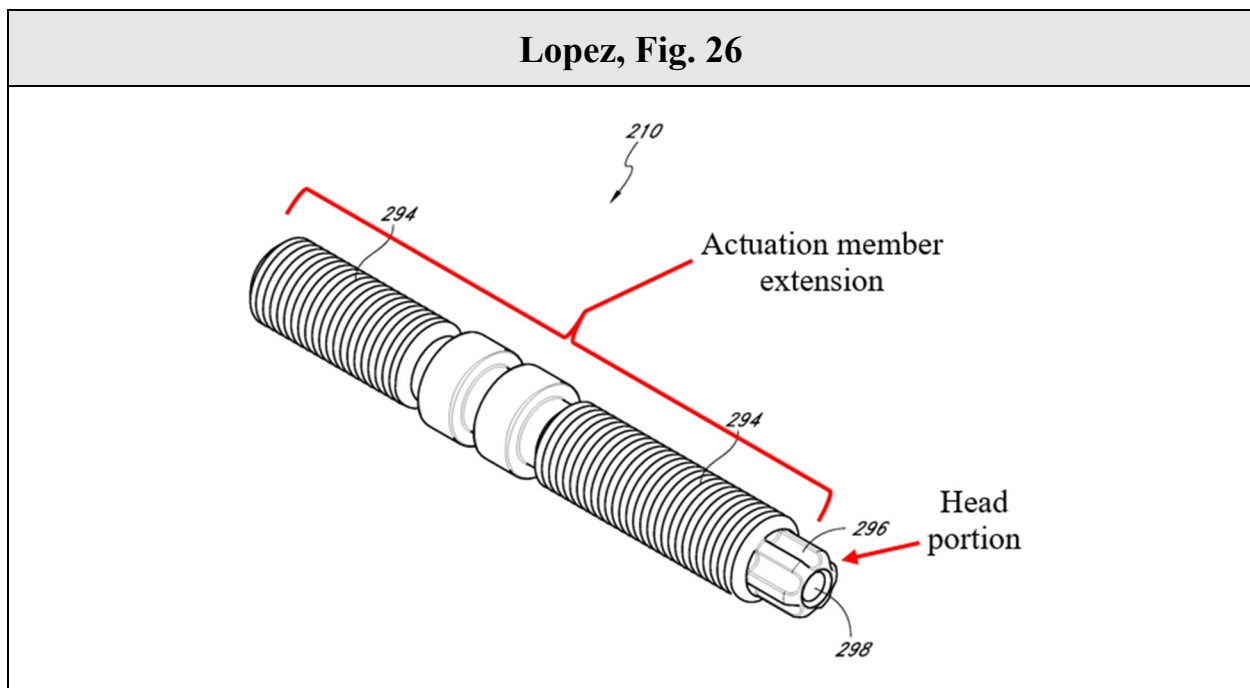
Accordingly, Lopez discloses these limitations. EX1002, ¶¶115-117.

**(j) Claim 1[j]**

Claim 1 recites that “**an actuation member comprising a head portion and an actuation member extension that extends through an unthreaded opening in a longitudinal through bore of the driving ramp to be received within an opening in the central ramp extension.**” Claim 1 does not recite “a central ramp extension,” thus rendering Claim 1 indefinite for lack of antecedent basis. However, assuming *arguendo* that this term refers to the same structure

referred to in Claim 12, this element is disclosed by Lopez. *See* §IX(A)(7)(a), *infra*.

Lopez discloses an actuation member comprising a head portion (“the actuator shaft **210** can also comprise a tool engagement section **296**”) and an actuation member extension (shaft portion). *See* EX1031, 23:38-47, Fig. 26. Annotated Fig. 36 showing these features follows:



Lopez further discloses that the driving ramp/proximal wedge member 206 has an unthreaded opening in a longitudinal through bore through which the actuation member extension extends (“central aperture **300** wherethrough an actuator shaft can be received,” in which “the actuator shaft can engage other [non-threaded] portions of the wedge member **206** for causing expansion or

contraction...”). EX1031, 23:60-64; *see also id.*, 20:40-42 (“The actuator shaft **210** can include threads that threadably engage at least one of the proximal and distal wedge members **206, 208.**” (underline added)). Lopez also discloses that the central ramp/distal wedge member 208 has a threaded opening in the extension into which the actuation member extension of the actuation member extends (“central aperture **302**...configured to receive an actuator shaft therethrough” which “can be threaded to correspond to the threads **294** of the actuator shaft **210**”). *Id.*, 24:3-9; *see also id.*, 20:47-53 (“[A]t least a portion of the actuator shaft can be axially fixed relative to one of the proximal and distal wedge members **206, 208** with the actuator shaft being operative to move the other one of the proximal and distal wedge members **206, 208** via rotational movement or longitudinal contraction of the pin.” (underline added)).

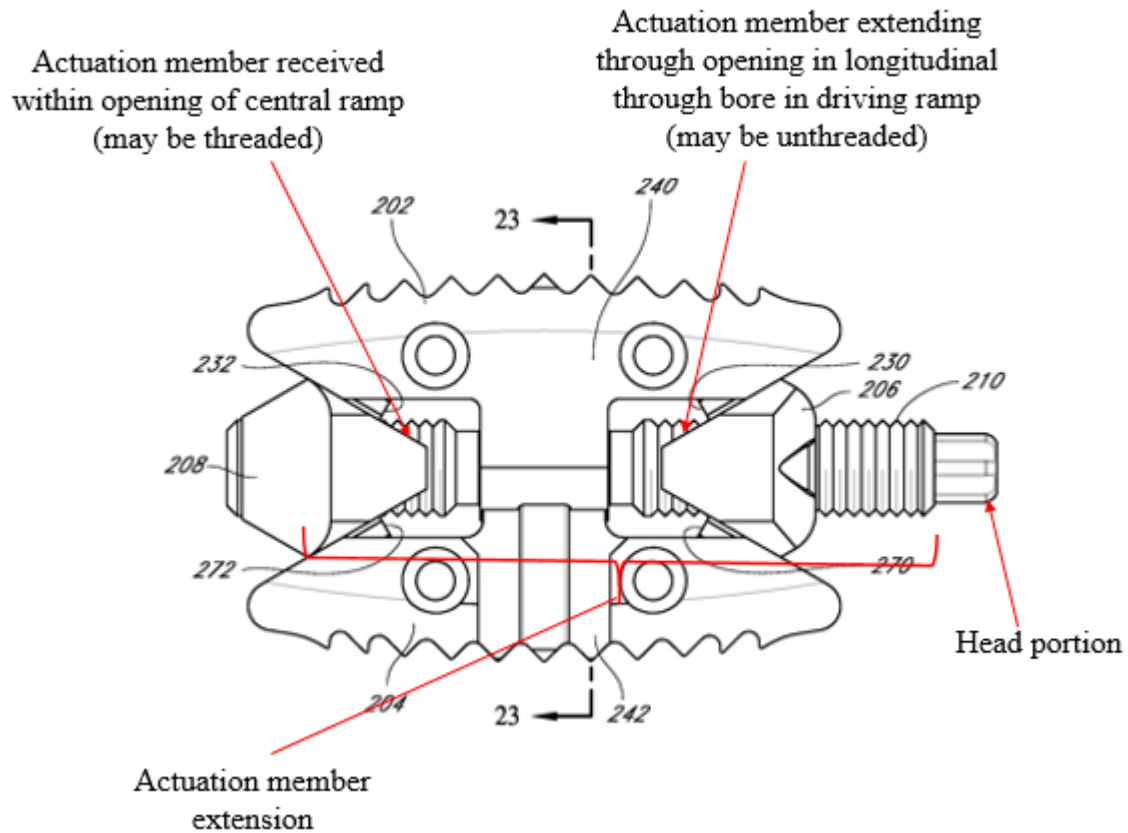
When an actuation has a left hand threads at one end and right hand threads at the opposite end, the actuation member would threadingly engage *both ramps* such that they move in opposing directions along the longitudinal axis of the actuator as it was rotated. *See, e.g.*, EX1031 at 23:23-37. In each of these cases, the actuation member would not be “axially fixed” with respect to either of the two ramps.

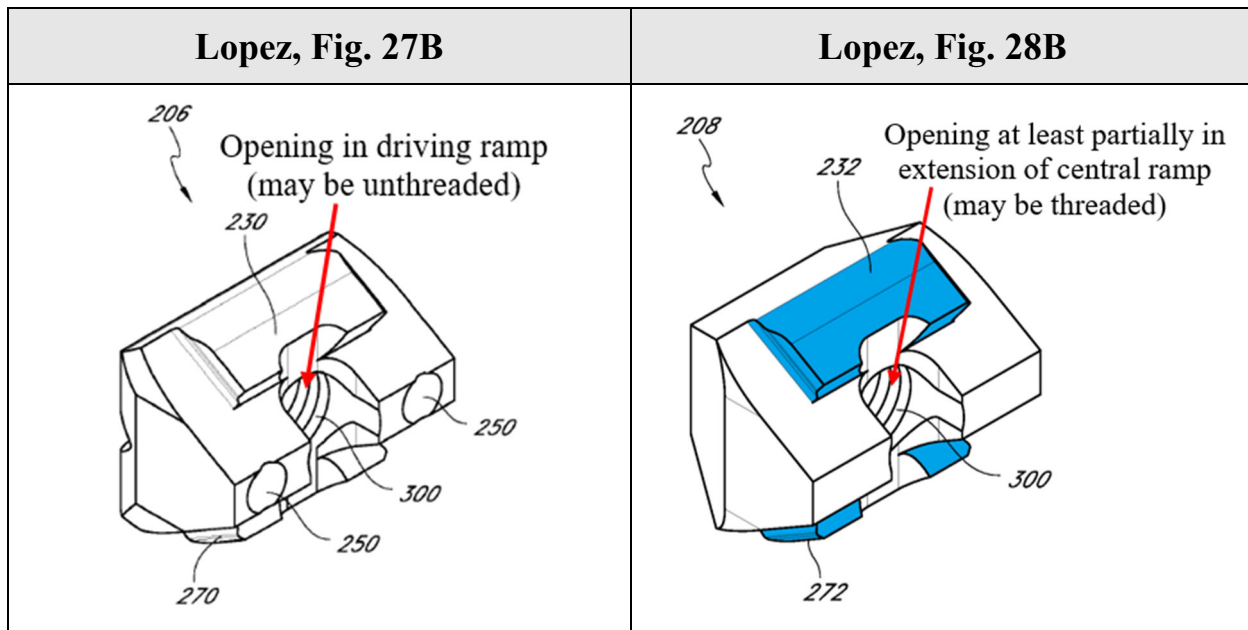
A POSITA would recognize from these disclosures that Lopez teaches an embodiment where the opening in the driving ramp is not threaded; specifically, if

the actuation member were theadingly engaged with the driving ramp opening, it could not be “axially fixed” relative to the driving ramp, while moving the central ramp when the actuator is rotated. EX1002, ¶¶125-128.

Figs. 22, 27A-B, and 28A-B also show that the actuation member extension of the actuation member extends through an opening in the driving ramp and into an opening in the extension of the central ramp. Annotated Figs. 22, 27B, and 28B follow for reference, with the extension in blue, appreciating that as noted above, Lopez alternatively teaches that the actuator’s extension can non-threadingly engage the driving ramp.

**Lopez, Fig. 22**



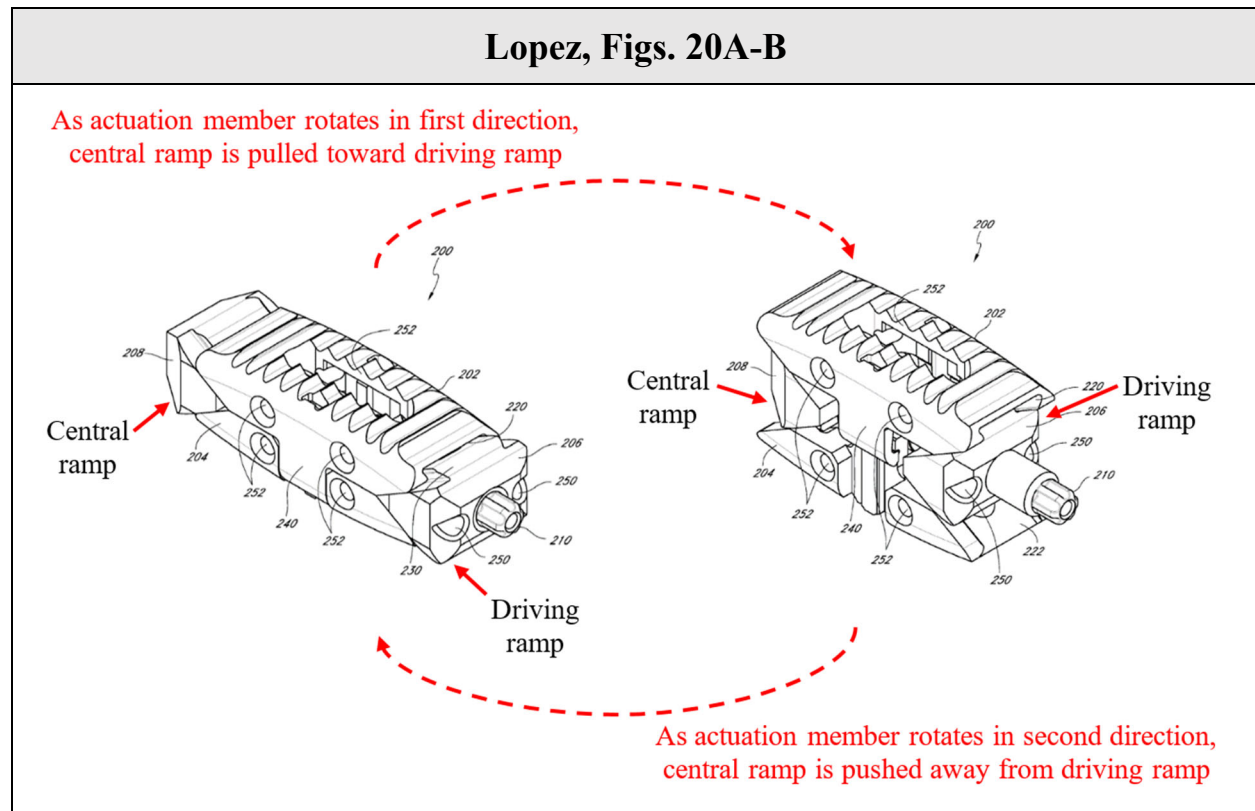


Accordingly, Lopez discloses these limitations. EX1002, ¶¶118-130.

**(k) Claim 1[k]**

Claim 1 recites that “**rotational movement of the actuation member in the first direction pulls the central ramp towards the driving ramp.**” Lopez discloses that the actuation member/actuator shaft 210 rotates in a first direction to move the central ramp towards the driving ramp, forcing the first and second endplates to move outwardly. EX1031, 20:38-53, 23:23-26. The relative movement of the ramps and endplates can also be observed at least by comparing Figs. 20A and B:





Accordingly, Lopez discloses these limitations. EX1002, ¶¶131-133.

**(I) Claim 1[I]**

Claim 1 recites that, “**when the actuation member is rotated, the driving ramp is fixed with respect to the actuation member and the central ramp is moved in either the first direction or a second direction.**” Lopez discloses both that rotating the actuator causes the wedges to move together and the endplates to move apart, and that the actuator shaft can be axially fixed relative to one wedge while moving the other wedge. EX1031, 20:38-53, 23:23-37, 23:66-24:9; EX1002, ¶¶134-135. In embodiments where the actuator shaft is “axially fixed relative to” proximal wedge member 206/driving ramp, distal wedge member 208/central ramp

will move in either a first or second direction when the actuation member is rotated. *See* §§IX(A)(1)(f), IX(A)(1)(k) (describing movement of central ramp in first direction and second direction), *supra*.

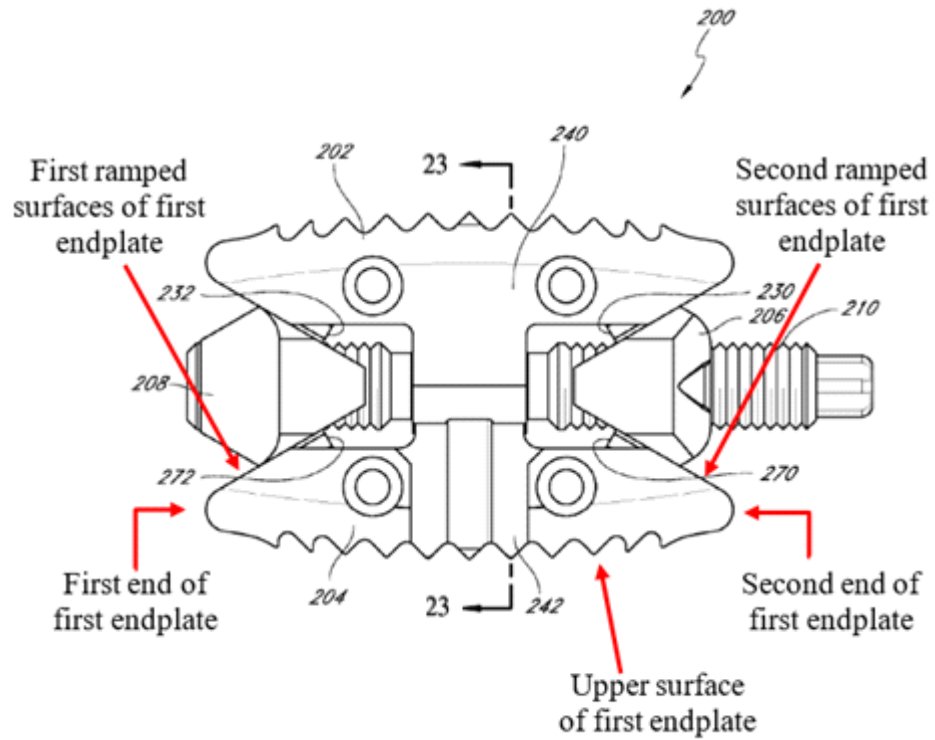
Accordingly, Lopez discloses these limitations. EX1002, ¶¶134-136.

## 2. Claim 7

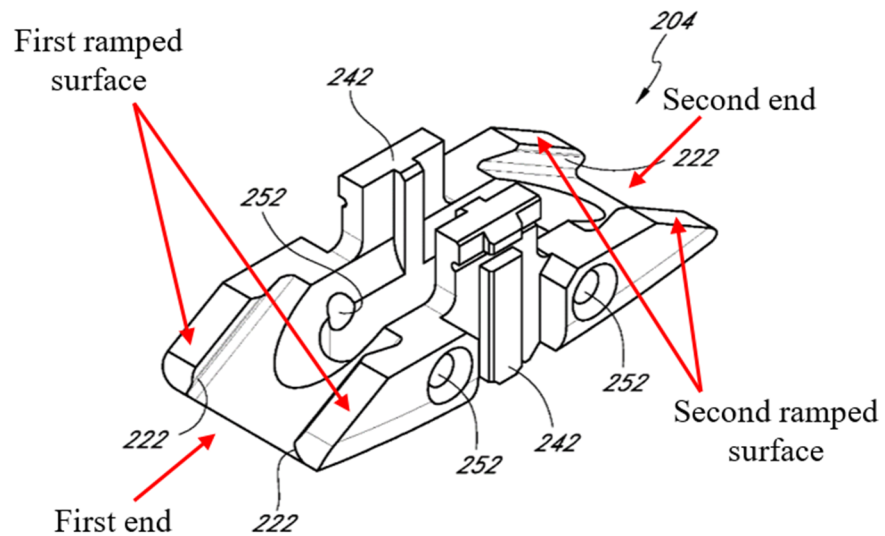
### (a) Claim 7[a]

Claim 7 recites that “**first endplate comprises a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the first endplate proximate the first end, second ramped surfaces on either side of the first endplate proximate the second end.**” Lopez’ first endplate has first and second ends, which are connected by an upper surface. *See* EX1031, 20:16-32, 21:62-22:5 (describing “proximal and distal ends” of upper and lower body portions 202, 204). Lopez further discloses that the proximal and distal ends have sloped surfaces. *Id.*, 22:40-51 (disclosing slots **222** having ramped surfaces). Figures 20-22 and 25A-B further show these structures, as well as the endplate’s respective upper and lower surfaces connecting the first end and the second end. Annotated Figs. 22 and 24A follow.

**Lopez, Fig. 22**



**Lopez, Fig. 24A**

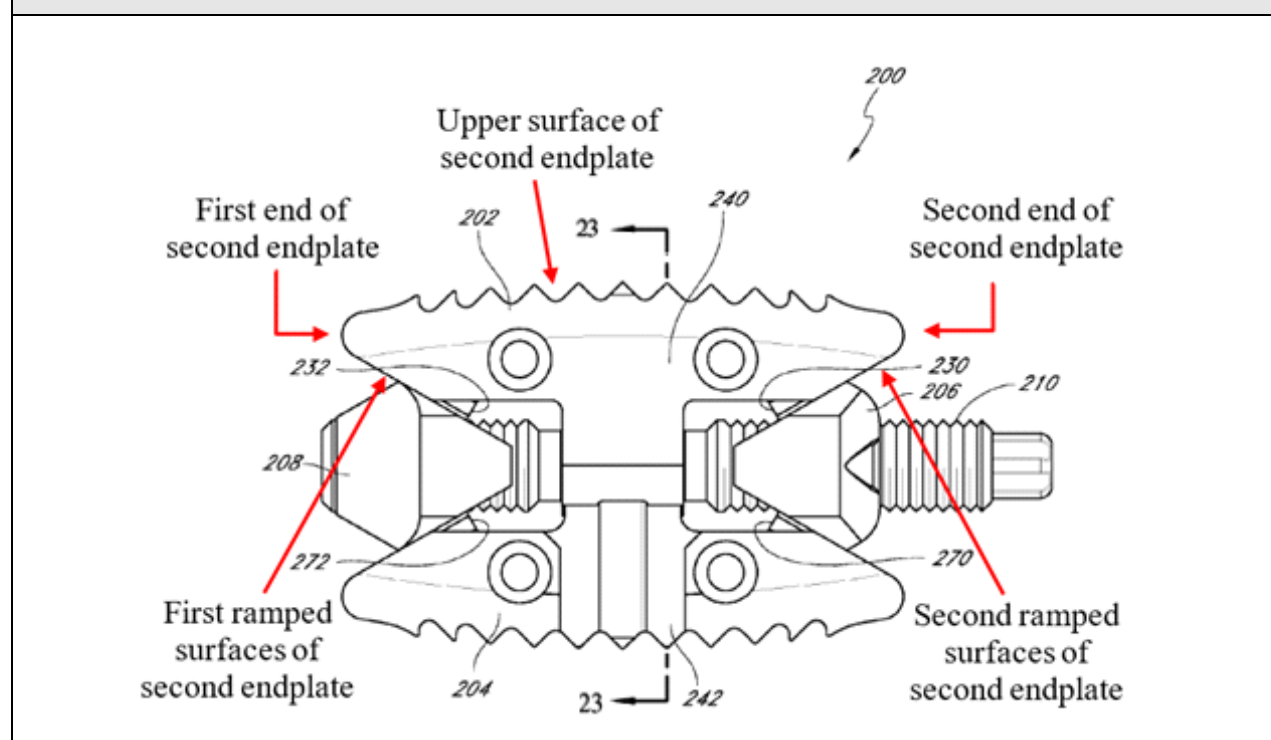


Accordingly, Lopez discloses these limitations. EX1002, ¶¶137-138.

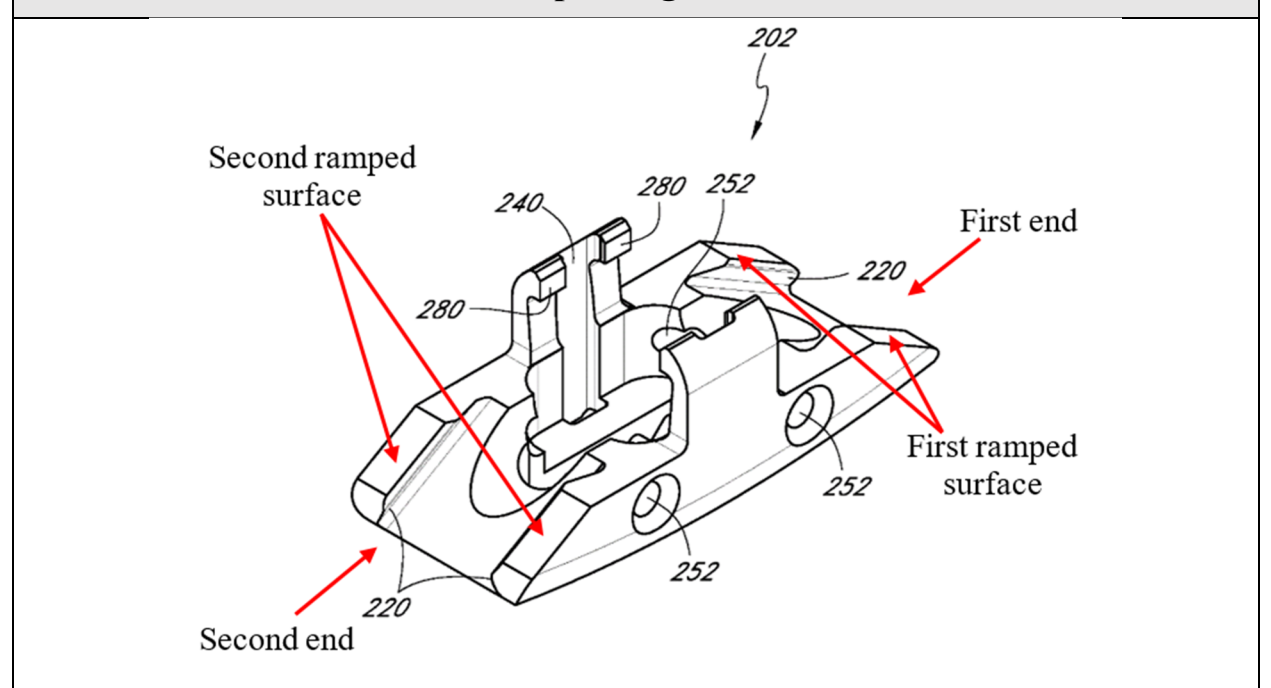
**(b) Claim 7[b]**

Claim 7 recites that “**second endplate comprises a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the second endplate proximate the first end, second ramped surfaces on either side of the second endplate proximate the second end.**” Lopez’s second endplate has first and second ends, which are connected by an upper surface. *See* EX1031, 20:16-32, 21:62-22:5 (describing “proximal and distal ends” of upper and lower body portions 202, 204). Lopez further discloses that the proximal and distal ends have sloped surfaces. *Id.*, 22:40-51 (disclosing slots **220** having ramped surfaces). Figures 20-22 and 25A-B further show these structures, as well as the endplate’s respective upper and lower surfaces connecting the first end and the second end. Annotated Figs. 22 and 25A follow.

**Lopez, Fig. 22**



**Lopez, Fig. 25A**

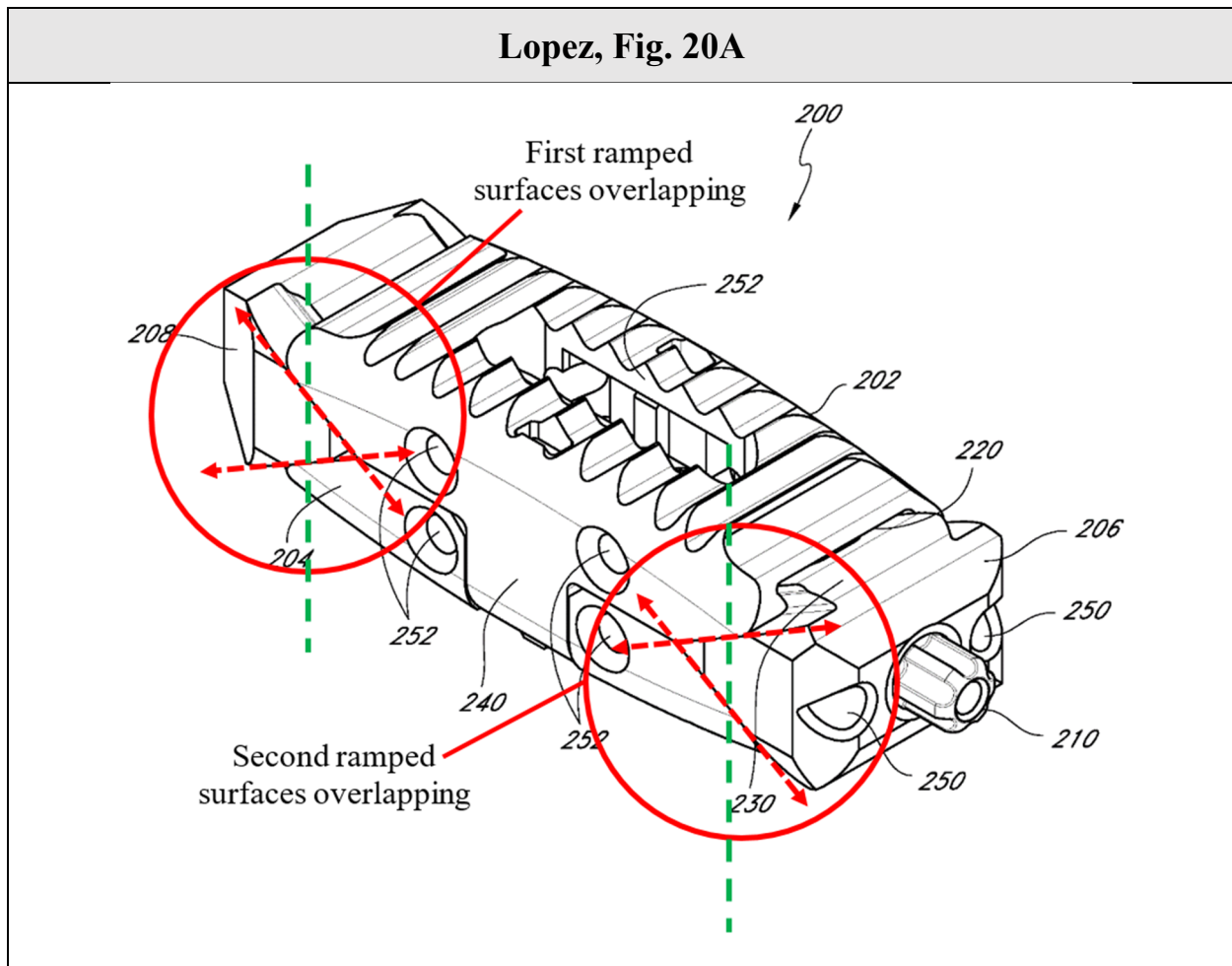


Accordingly, Lopez discloses these limitations. EX1002, ¶¶139-140.

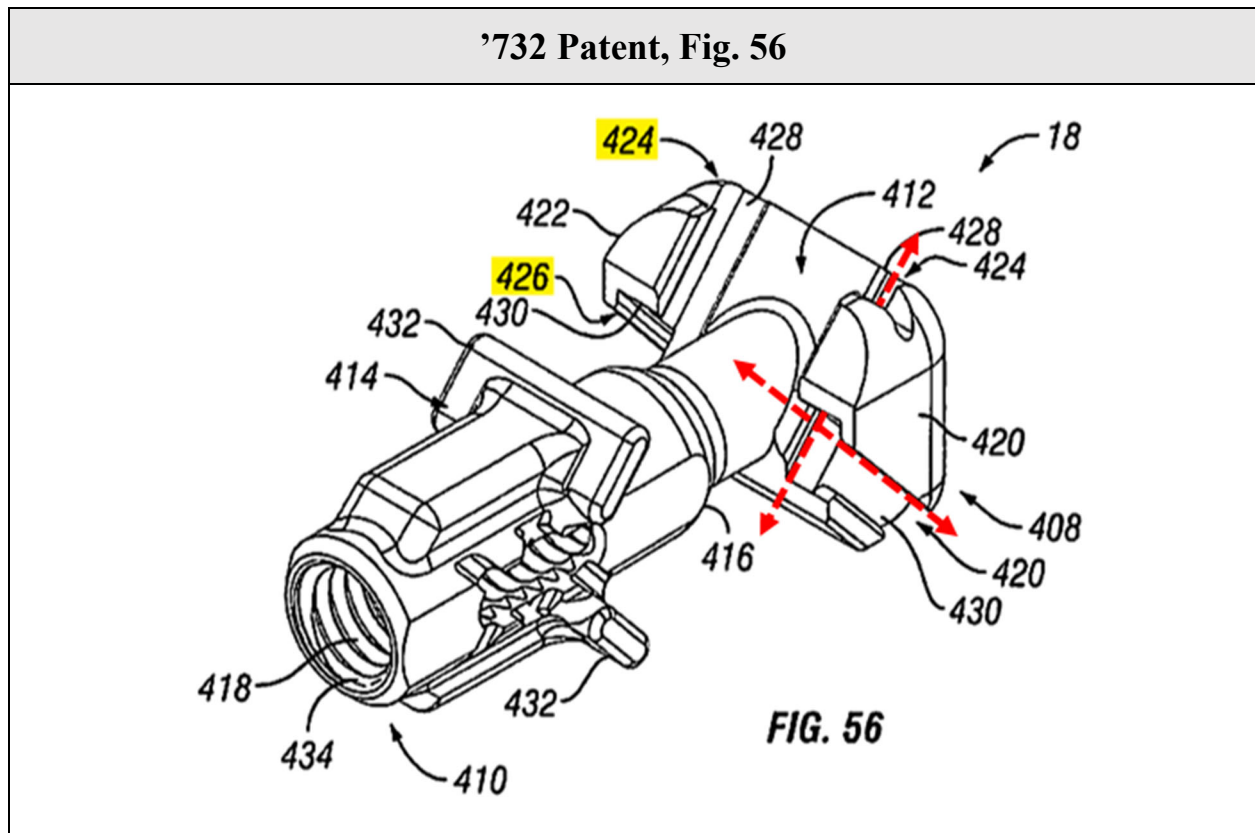
### 3. Claim 8

Claim 8, which depends from Claim 7, recites that “**when the intervertebral implant is in an unexpanded configuration, the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate overlap, and the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate overlap.**” As broadly claimed here, Lopez discloses that the first endplate’s first ramped surfaces overlap the second endplate’s first ramped surfaces and that the first endplate’s second ramped surfaces overlap the second endplate’s second ramped surfaces when Lopez’s device is in an unexpanded configuration. EX1031, Figs. 20A-B, 22.

The broadly claimed “overlap” between these ramped surfaces can be observed in at least two ways. First, the ramped surfaces overlap because the angles of the ramped surfaces intersect. Second, the ramped surfaces overlap because the ramped surfaces reside opposite each other (i.e., one over the other) within a given plane. Annotated Fig. 20A follows with the overlapping ramped surfaces denoted by red dashed arrows and the plane of overlap denoted by green dashed lines.



Moreover, the foregoing is consistent with the '732 patent disclosure of “overlapping” ramped components. For example, the '732 patent discloses that the central ramp has “a first ramped portion 424 that overlaps a second ramped portion 426.” EX1001, 19:9-14. As seen in annotated Fig. 56, below, ramped portions 424, 426 “overlap” in the same way as the ramped surfaces of Lopez’s endplates.



Accordingly, Lopez discloses this limitation. EX1002, ¶¶141-146.

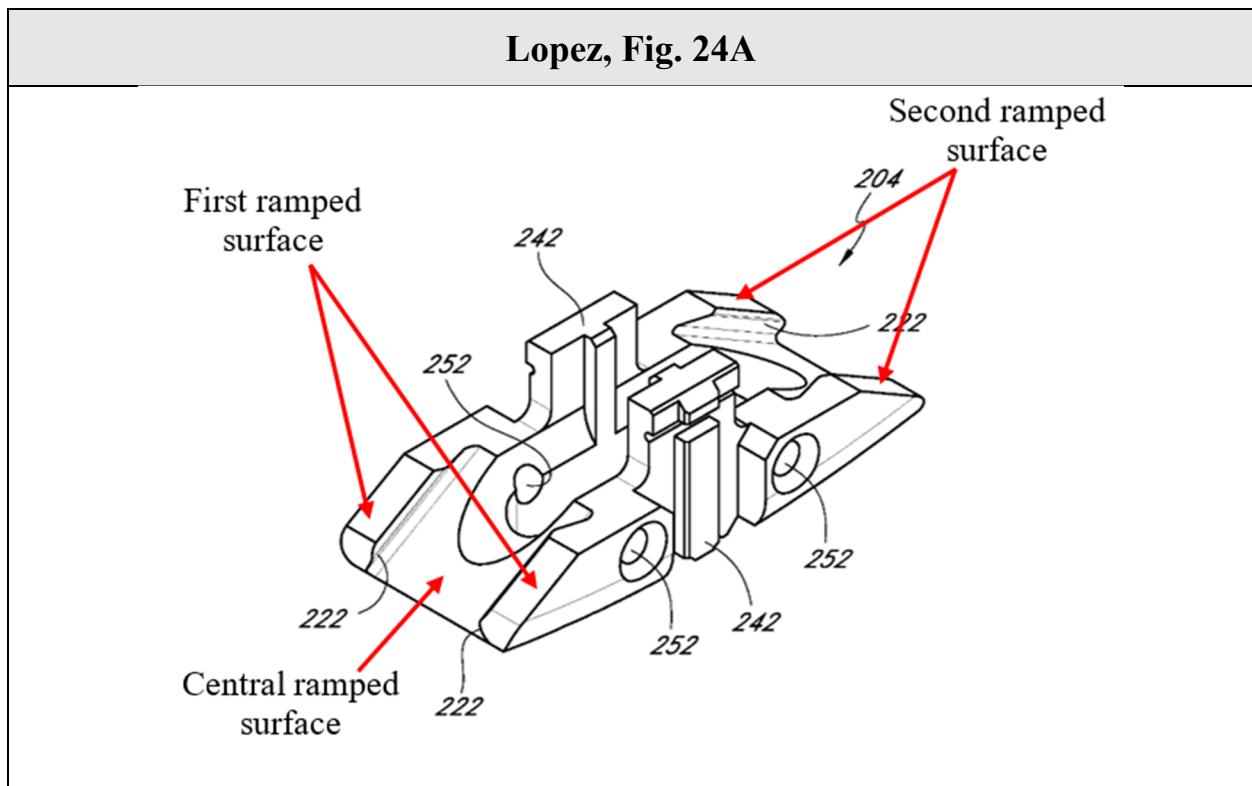
#### 4. Claim 9

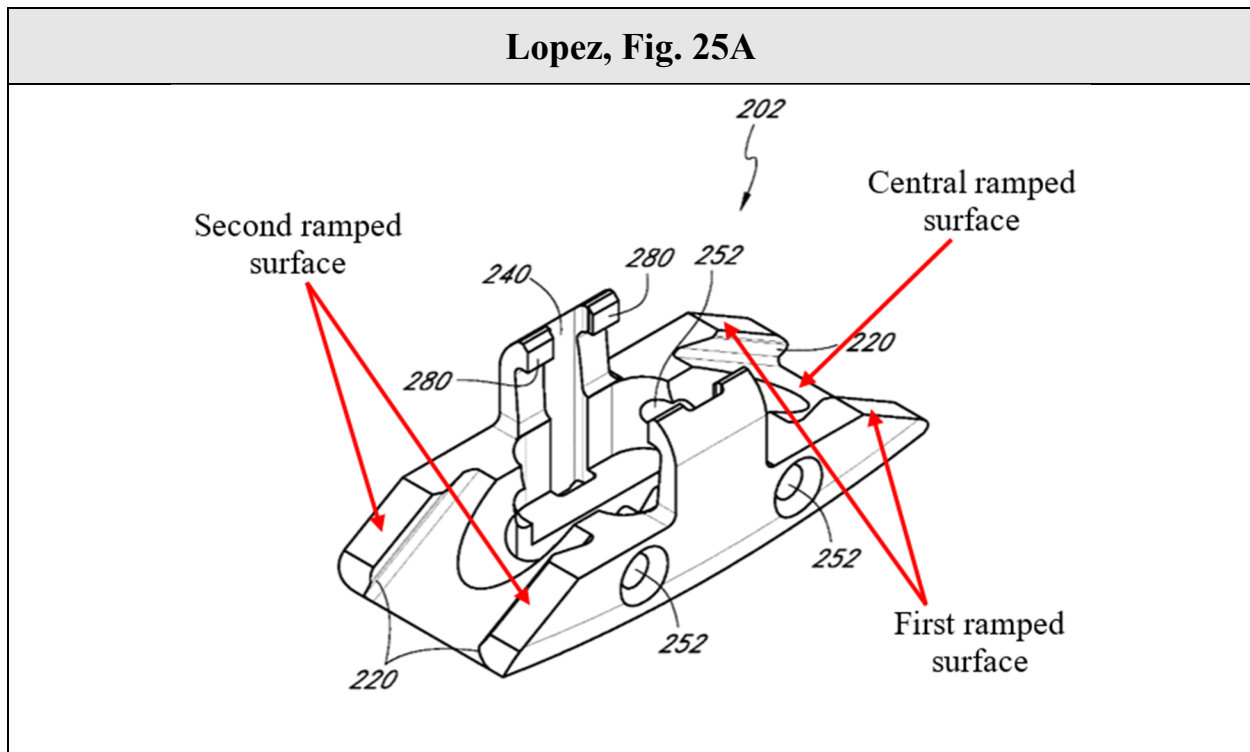
**(a) Claims 9[a] and 9[b]**

Claim 9 recites that “**the first endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the first endplate**” and that “**the second endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the second endplate.**” Lopez discloses that lower body portion 204 has a central ramped surface disposed between the first and second ramped surfaces in the form of the ramped, recessed surface of the dovetail-shaped groove formed between



slots 222 and central ramped surface disposed between the first and second ramped surfaces in the form of the ramped, recessed surface of the dovetail-shaped groove formed between slots 220. See EX1031, 22:6-39, Figs. 20B, 22, 24A-B and 25A-B. Annotated Figs. 24A and 25A showing these features follow:





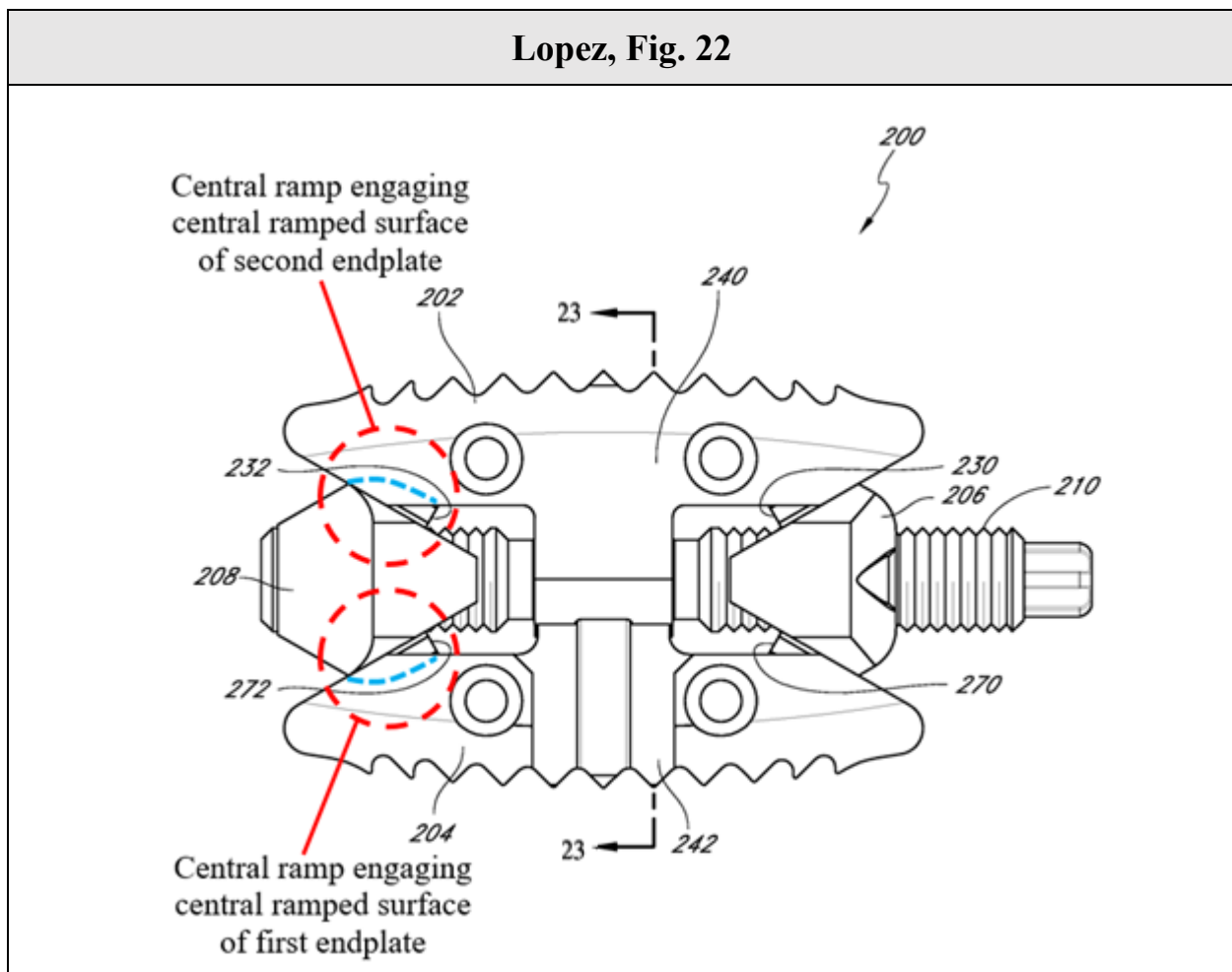
Accordingly, Lopez discloses this limitation. EX1002, ¶¶147-152.

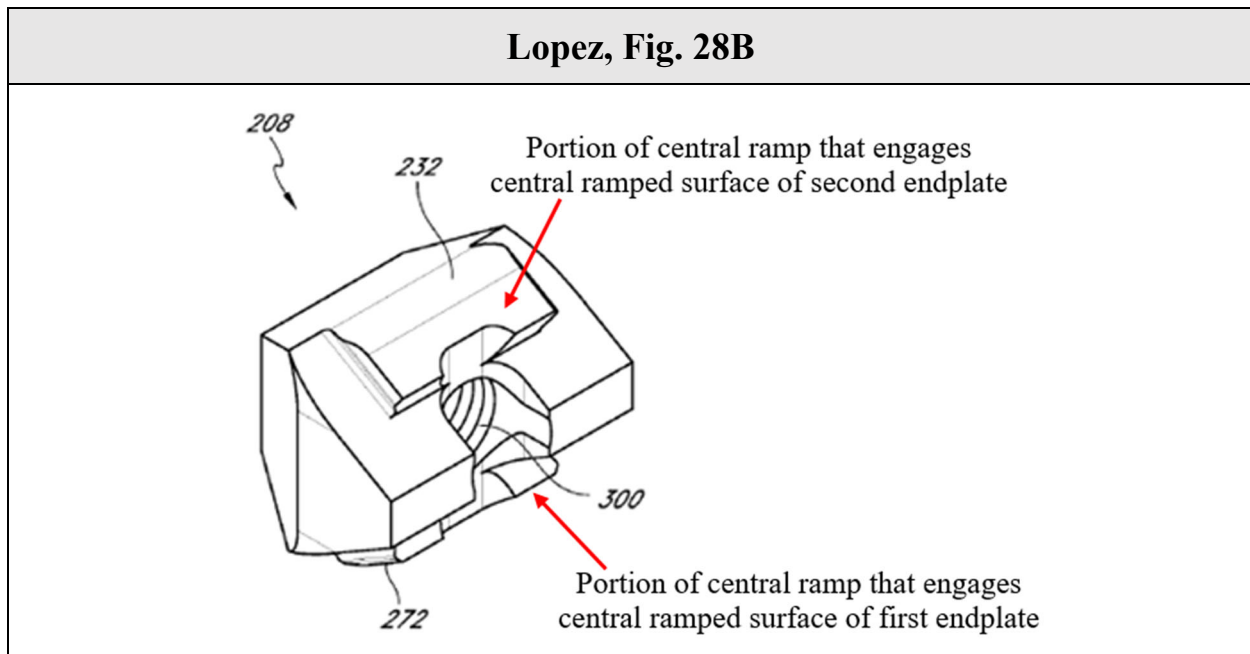
**(b) Claim 9[c]**

Claim 9 recites that “**the central ramped surface of the first endplate and...the central ramped surface of the second endplate are configured to engage the central ramp.**” Lopez discloses that the central ramped surfaces of the first and second endplates engage with the central ramp. Specifically, Lopez discloses that wedge member 208’s upper guide member 232 may be inserted into the upper body portion 202’s slots 220 and wedge member 208’s lower guide member 272 may be inserted into lower body portion 204’s slots 222. EX1031, 22:6-28 (“the dovetail shape of the slots and guide members ensures that for each

given slot and guide member, a given wedge member is generally interlocked with the give slot”), 22:40-51, 23:66-24:9, Figs. 20A-B, 22, 24A-B, 25A-B, 27A-B.

Thus, “the proximal and distal wedge members 206, 208 are securely engaged with the upper and lower body portions 202, 204,” with the aforementioned central ramped surfaces engaging upper and lower guide members 232, 272. *See id.*, 22:6-18. Annotated Lopez Figs. 22 and 28B follow, with the guide members’ surfaces that contact the central ramped surfaces approximated in blue in Fig. 22:





Accordingly, Lopez discloses these limitations. EX1002, ¶¶153-155.

**5. Claim 10**

Lopez discloses this limitation. *See* §IX(A)(3); EX1002, ¶¶156-158.

**6. Claim 11**

Lopez discloses this limitation. *See* §IX(A)(3); EX1002, ¶¶159-161.

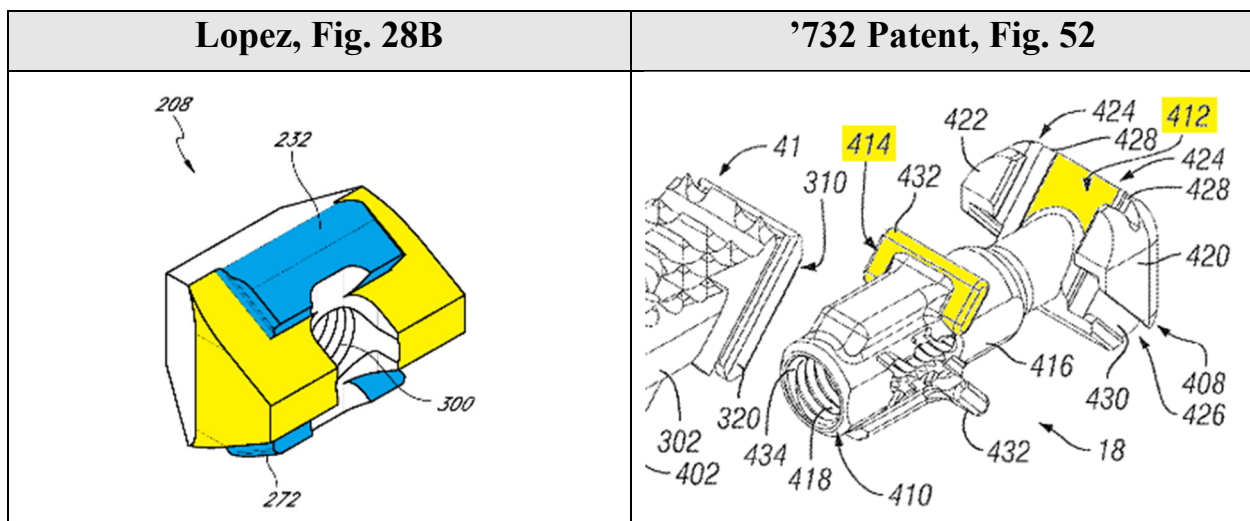
**7. Claim 12**

**(a) Claim 12[a]**

Claim 12 depends from Claim 7 and recites that “**the central ramp comprises a ramped expansion portion at one end of the intervertebral implant and a central ramp extension extending from the expansion portion.**”

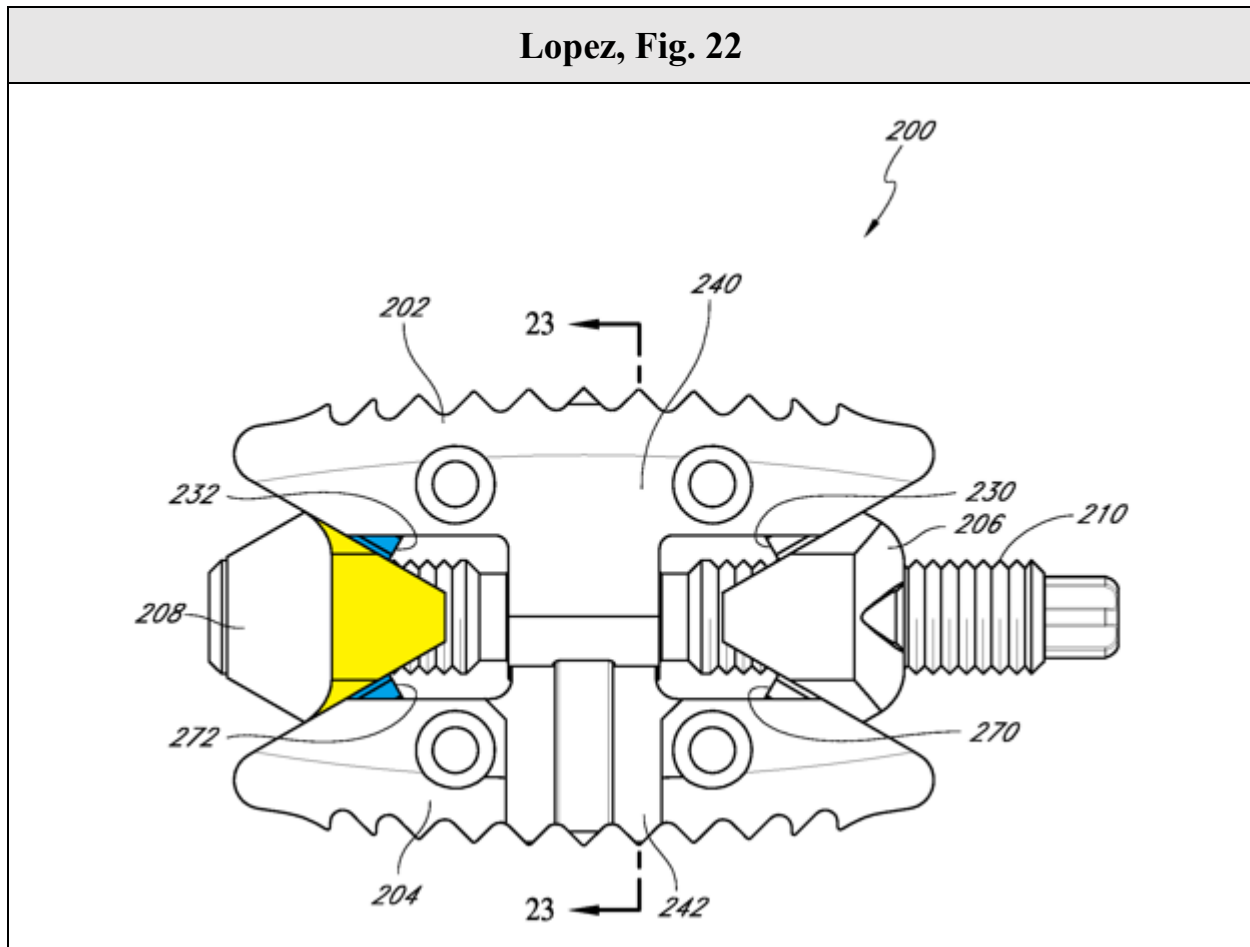
Lopez discloses that the central ramp/distal wedge member 208 has an expansion portion in the form of a broad ramped surface extending on each side of guide

members 232, 272 and the base of distal wedge member 208, which is comparable to the “first expansion portion 412” and/or the “second expansion portion 414” shown in ’732 Fig. 52. EX1031, 23:66-24:9, Fig. 20B, 22, 28B; EX1001, 19:1-6, Fig. 52; EX1002 ¶163. Annotated excerpts of Lopez Fig. 28B and ’732 Fig. 52 follow with their respective expansion portions in yellow:



Regarding the “extension,” Lopez discloses that the central ramp has an extension (“guide members **232**, **272**”) extending in a longitudinal axis from the expansion portion. EX1031, 19:63-20:14, 22:40-51. Lopez teaches that “guide member **232**...at least partially extends into a respective slot of the upper and lower body portions.” *Id.*, 19:63-20:14. This is observable in Figs. 20B, 22, and 28B, which also disclose guide member 272 as a second extending guide member on the opposite side of distal wedge member 208. The extending guide members

232, 272 of distal wedge member 208/central ramp are highlighted in blue in annotated Figs. 28B, *supra*, and 22, below.



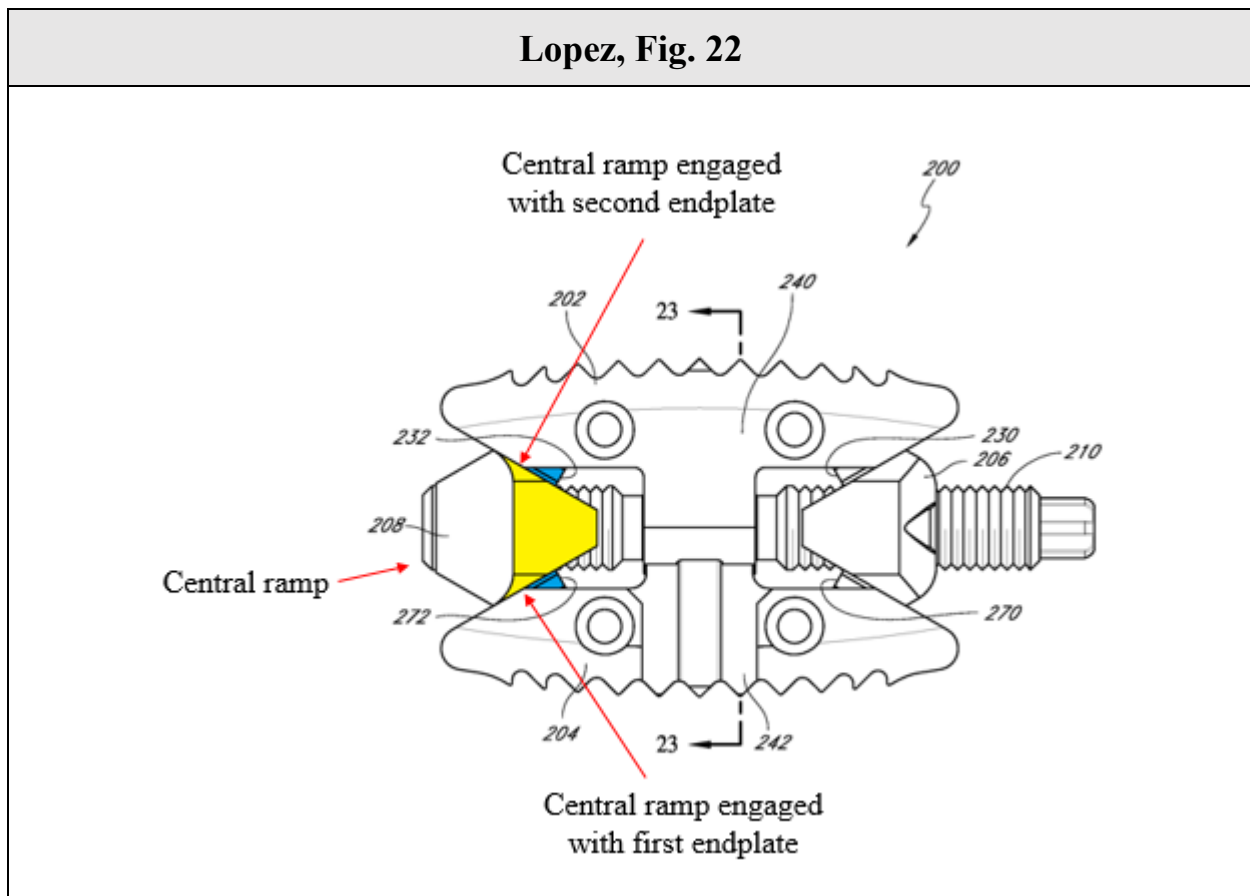
Accordingly, Lopez discloses these limitations. EX1002, ¶¶162-166.

**(b) Claim 12[b]**

Claim 12 recites that “**the central ramp is configured to engage the first endplate and the second endplate.**” Lopez’s central ramp is configured to engage the first and second endplates at least through guide members 232, 272 extending into the dovetail-shaped grooves formed by slots 220, 222 and engaging the

endplates' respective central ramped surfaces. See §IX(A)(4)(b), *supra*.

Additionally, Lopez discloses that other portions of the central ramp engage the first and second endplate. For example, Figs. 20A-B and 22 show the central ramp engaging the endplates' first ramped surfaces. Annotated Fig. 22 follows:



Accordingly, Lopez discloses this limitation. EX1002, ¶¶167-169.

## 8. Claim 13

### (a) Claim 13[a]

Lopez discloses this limitation. See §IX(A)(1)(a); EX1002, ¶170.

**(b) Claim 13[b]**

Lopez discloses this limitation. *See* §IX(A)(1)(b); EX1002, ¶¶171-172.

**(c) Claim 13[c]**

Lopez discloses this limitation. *See* §IX(A)(1)(c); EX1002, ¶¶173-174.

**(d) Claim 13[d]**

Lopez discloses this limitation. *See* §IX(A)(1)(d); EX1002, ¶¶175-176.

**(e) Claim 13[e]**

Lopez discloses this limitation. *See* §IX(A)(2)(a); EX1002, ¶¶177-178.

**(f) Claim 13[f]**

Lopez discloses this limitation. *See* §IX(A)(2)(b); EX1002, ¶¶179-180.

**(g) Claim 13[g]**

Lopez discloses this limitation. *See* §IX(A)(3); EX1002, ¶¶181-182.

**(h) Claim 13[h]**

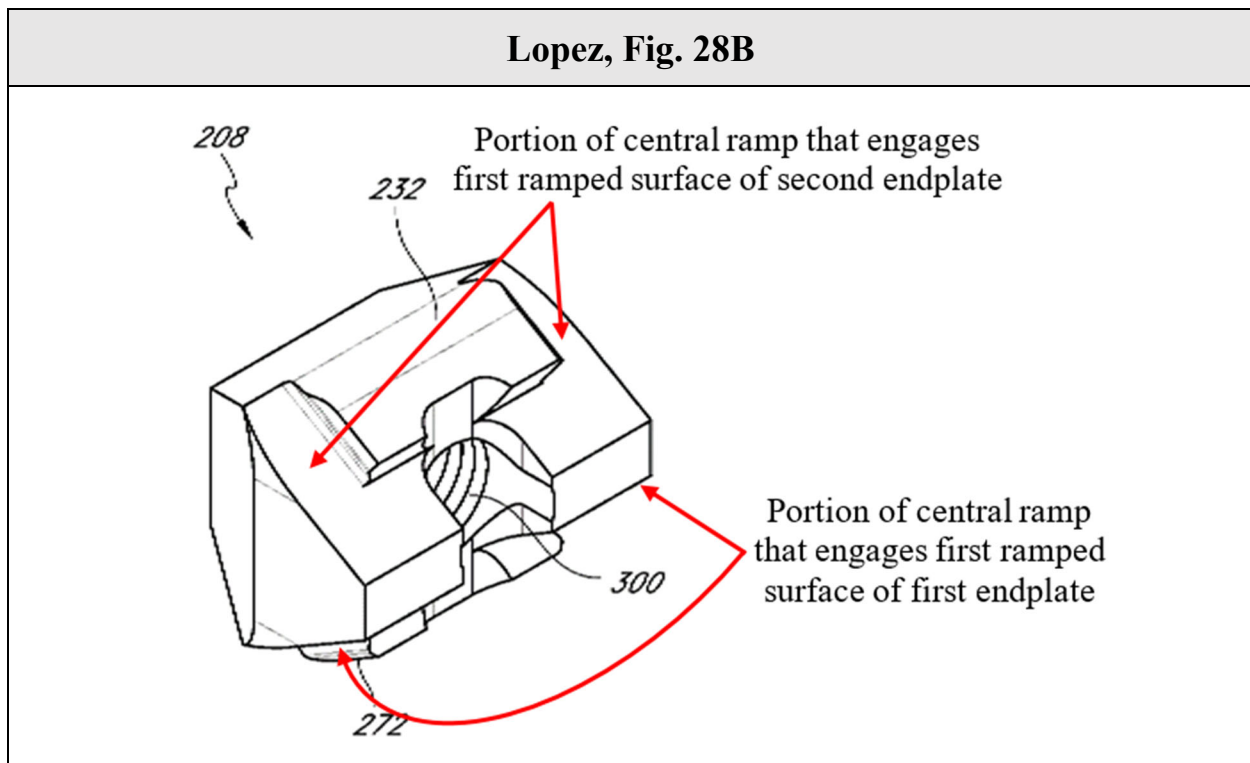
Lopez discloses this limitation. *See* §IX(A)(1)(e); EX1002, ¶¶183-184.

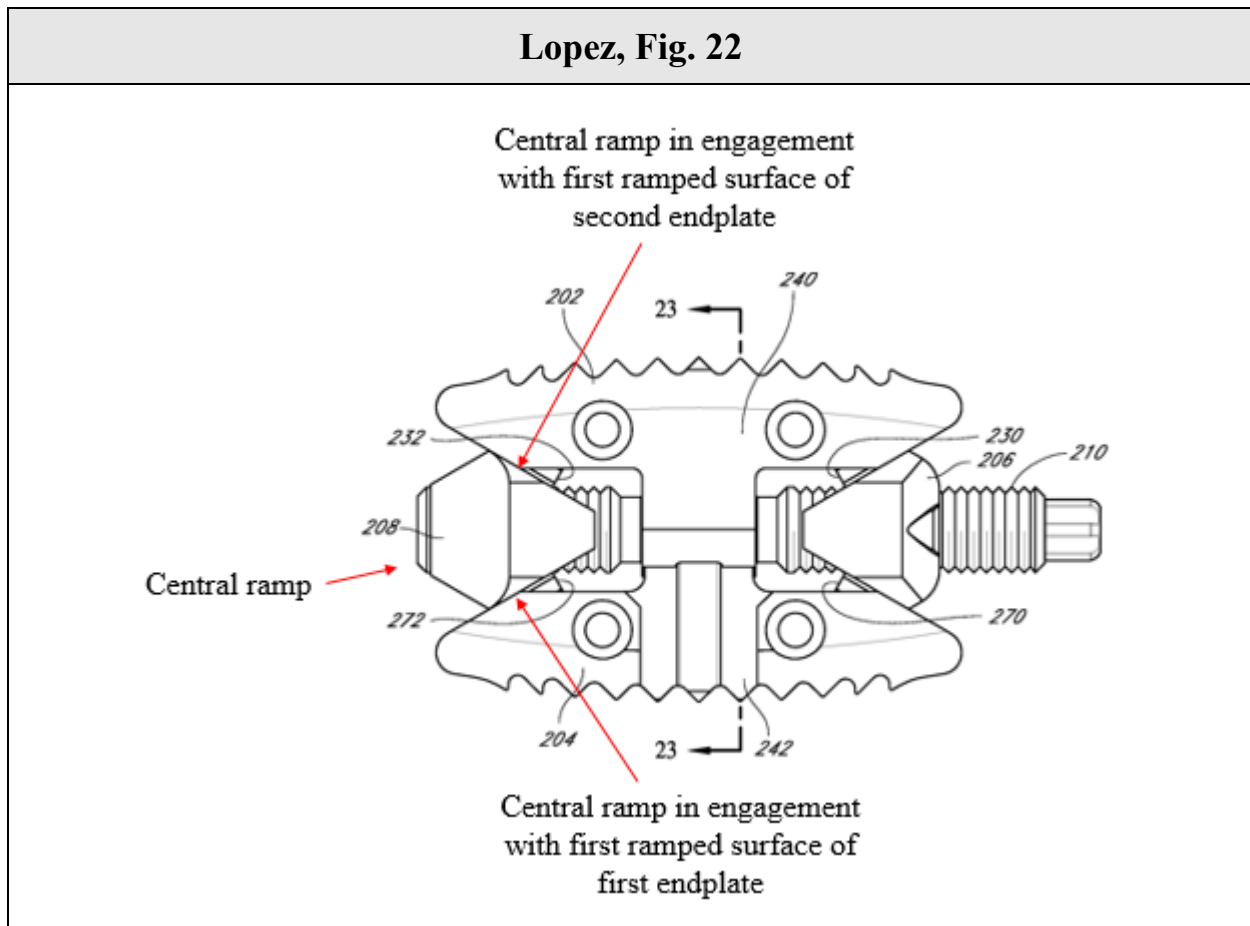
**(i) Claim 13[i]**

Claim 13 recites that “**the central ramp is configured to engage the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate.**” Lopez’s central ramp is configured to engage the first ramped surfaces of the first and second endplates. EX1031, Figs. 20A-B, 22, and 28A-B, 19:63-20:14, 22:6-28, 22:54-63 ([T]he wedge members 206, 208 are engaged with upper and lower body portions 202, 204...). As can be seen at least in Fig. 22,



wedge members 206, 208 and the upper and lower body portions, 202, 204 are at an angular relationship. *See id.*, 22:19-28. At least based on these, a POSITA would understand that the central ramp engages with ramped surface of the endplates. Annotated Figs. 28B and Fig. 22 follow for reference.





Accordingly, Lopez discloses this limitation. EX1002, ¶¶185-187.

**(j) Claim 13[j]**

Claim 13 does not recite “an expansion portion of the central ramp,” thus rendering Claim 13 indefinite for lack of antecedent basis. However, assuming *arguendo* that this refers to Claim 12’s “ramped expansion portion,” this element is disclosed by Lopez. See §§IX(A)(7)(a), IX(A)(1)(g); EX1002, ¶¶188-190.

**(k) Claim 13[k]**

Lopez discloses this limitation. See §§IX(A)(1)(h), IX(A)(1)(i); EX1002, ¶¶191-192.

**(l) Claim 13[l]**

Claim 13 does not recite “a central ramp extension,” thus rendering Claim 13 indefinite for lack of antecedent basis. However, assuming *arguendo* that this refers to Claim 12’s “central ramp extension,” this element is disclosed by Lopez. *See* §§IX(A)(7)(a), IX(A)(1)(j); EX1002, ¶¶193-195.

**(m) Claim 13[m]**

Lopez discloses this limitation. *See* §§IX(A)(1)(f), IX(A)(1)(k); EX1002, ¶¶196-197.

**(n) Claim 13[n]**

Lopez discloses this limitation. *See* §IX(A)(1)(l); EX1002, ¶¶198-199.

**9. Claim 16**

**(a) Claim 16[a]**

Lopez discloses this limitation. *See* §IX(A)(1)(a); EX1002, ¶200.

**(b) Claim 16[b]**

Lopez discloses this limitation. *See* §IX(A)(1)(b); EX1002, ¶¶201-202.

**(c) Claim 16[c]**

Lopez discloses this limitation. *See* §IX(A)(1)(c); EX1002, ¶¶203-204.

**(d) Claim 16[d]**

Lopez discloses this limitation. *See* §IX(A)(1)(d); EX1002, ¶¶205-206.

**(e) Claim 16[e]**

Lopez discloses this limitation. *See* §§IX(A)(2)(a), IX(A)(4)(a); EX1002, ¶¶207-208.

**(f) Claim 16[f]**

Lopez discloses this limitation. *See* §§IX(A)(2)(b), IX(A)(4)(a); EX1002, ¶¶209-210.

**(g) Claim 16[g]**

Lopez discloses this limitation. *See* §IX(A)(1)(e); EX1002, ¶¶211-212.

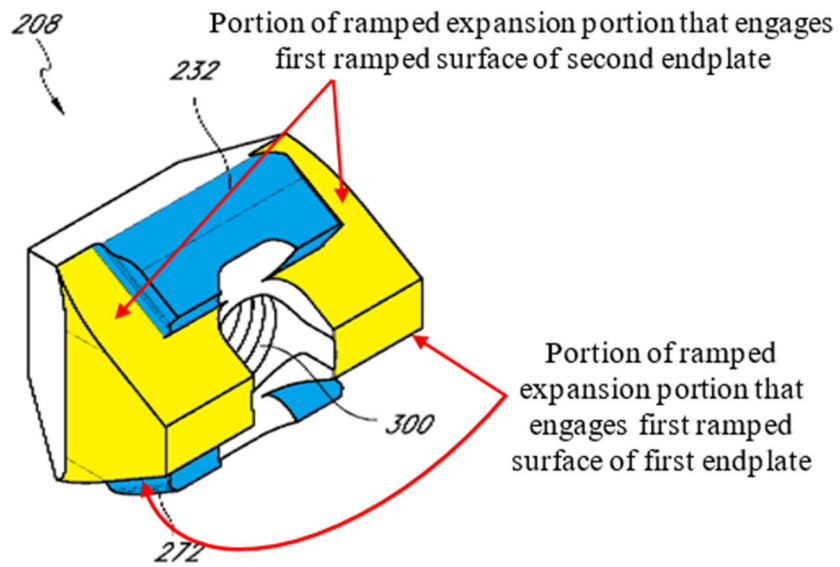
**(h) Claim 16[h]**

Lopez discloses this limitation. *See* §IX(A)(7)(a); EX1002, ¶¶213-214.

**(i) Claim 16[i]**

Claim 16 recites that “**the ramped expansion portion is configured to engage the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate.**” This limitation overlaps Claims 12 and 13. *See* §§IX(A)(7)(a), IX(A)(8)(i), *supra*. As explained by Petitioner’s expert, Lopez discloses this limitation, as can further be seen in at least Figs. 20A-B, 22, and 28A-B. Annotated Figs. 28B and 22 follow with the ramped expansion portion in yellow:

**Lopez, Fig. 28B**



### Lopez, Fig. 22

Ramped expansion portion in engagement with first ramped surface of second endplate

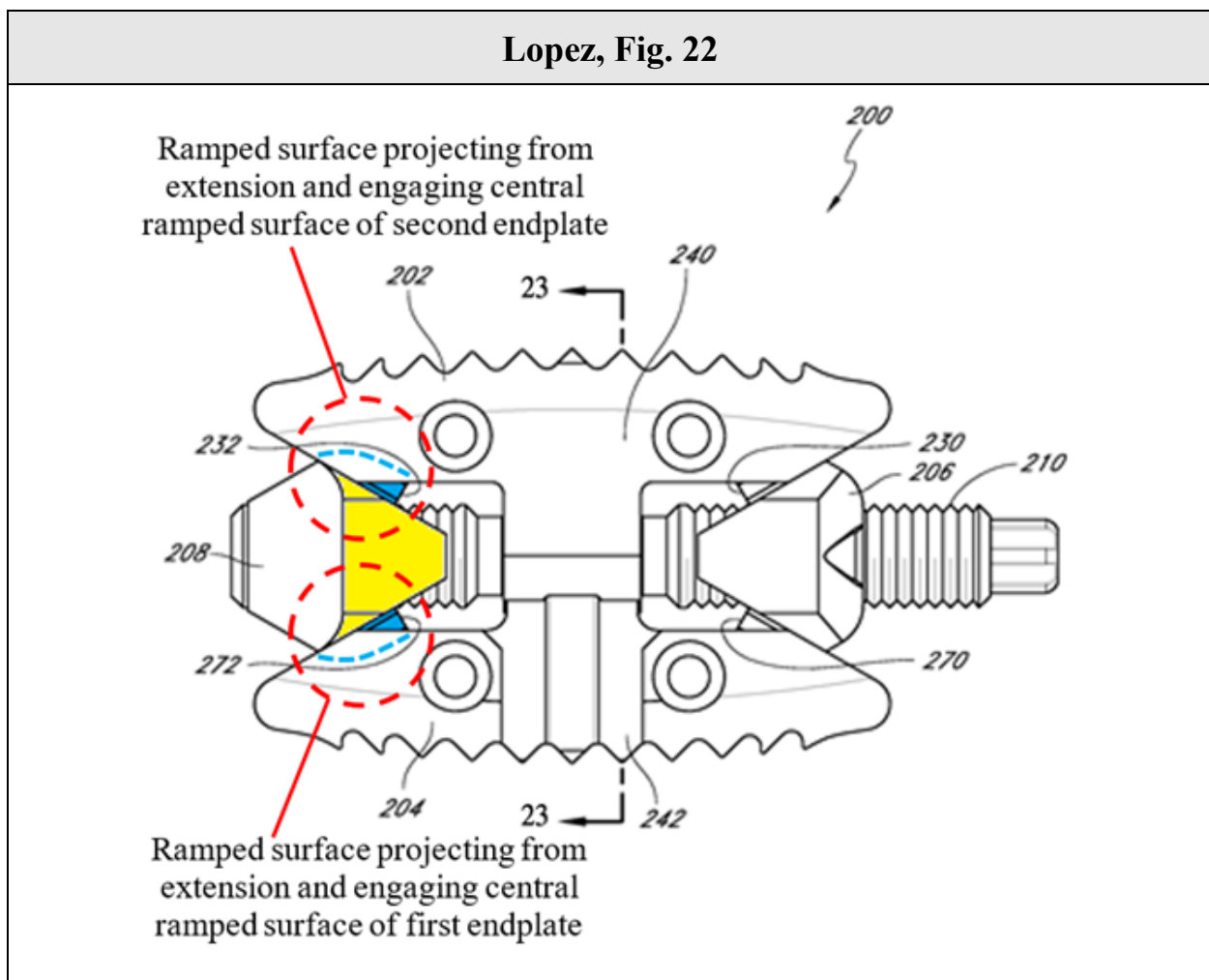
Central ramp

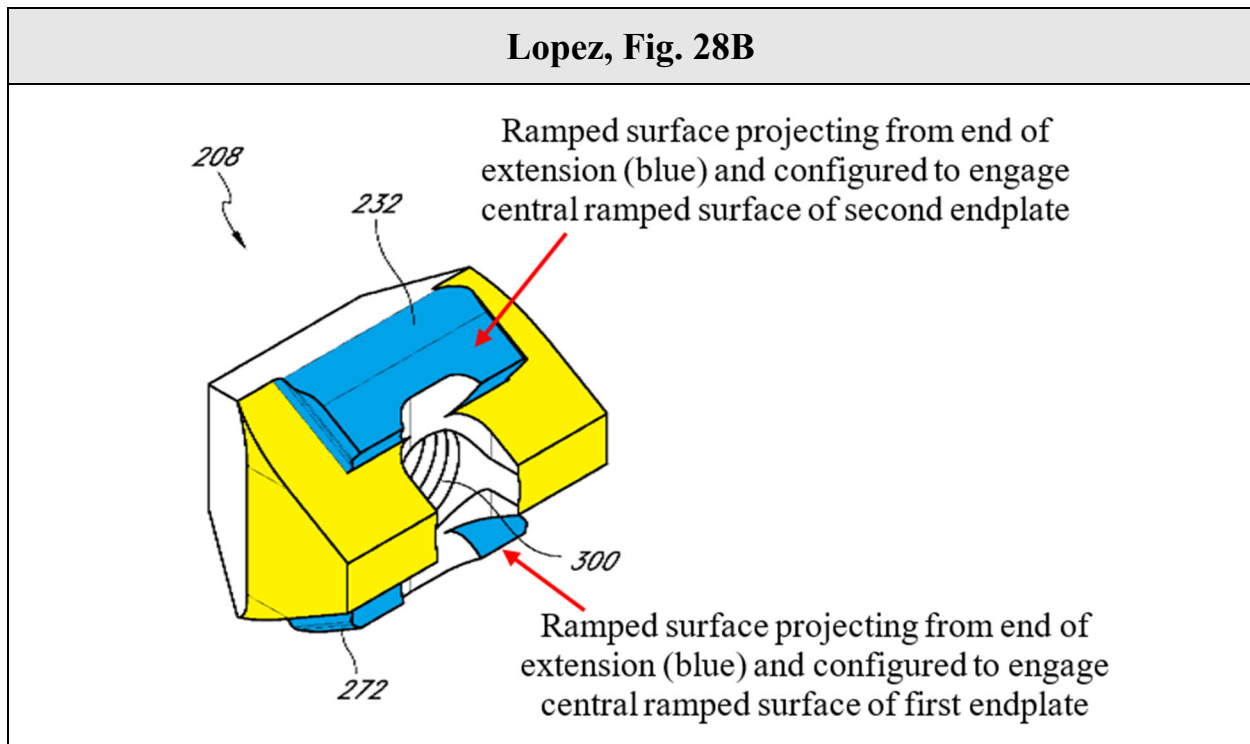
Ramped expansion portion in engagement with first ramped surface of first endplate

(j) **Claim 16[j]**

52

19:63-20:14, 22:19-28, Figs. 20A-B, 22, 28A-B. This can be seen in the following annotated Figs. 22 and 28B, with the extension in blue and (in Fig. 22) the ramped surfaces of the central ramp extension approximated in dashed blue lines. As seen therein, the ramped surfaces project back towards the wide end of the ramp from the actuator-receiving portion of the extension at the narrow end.





Accordingly, Lopez discloses this limitation. EX1002, ¶¶218-220.

**(k) Claim 16[k]**

Lopez discloses this limitation. See §IX(A)(1)(g), IX(A)(7)(a); EX1002, ¶¶221-222.

**(l) Claim 16[l]**

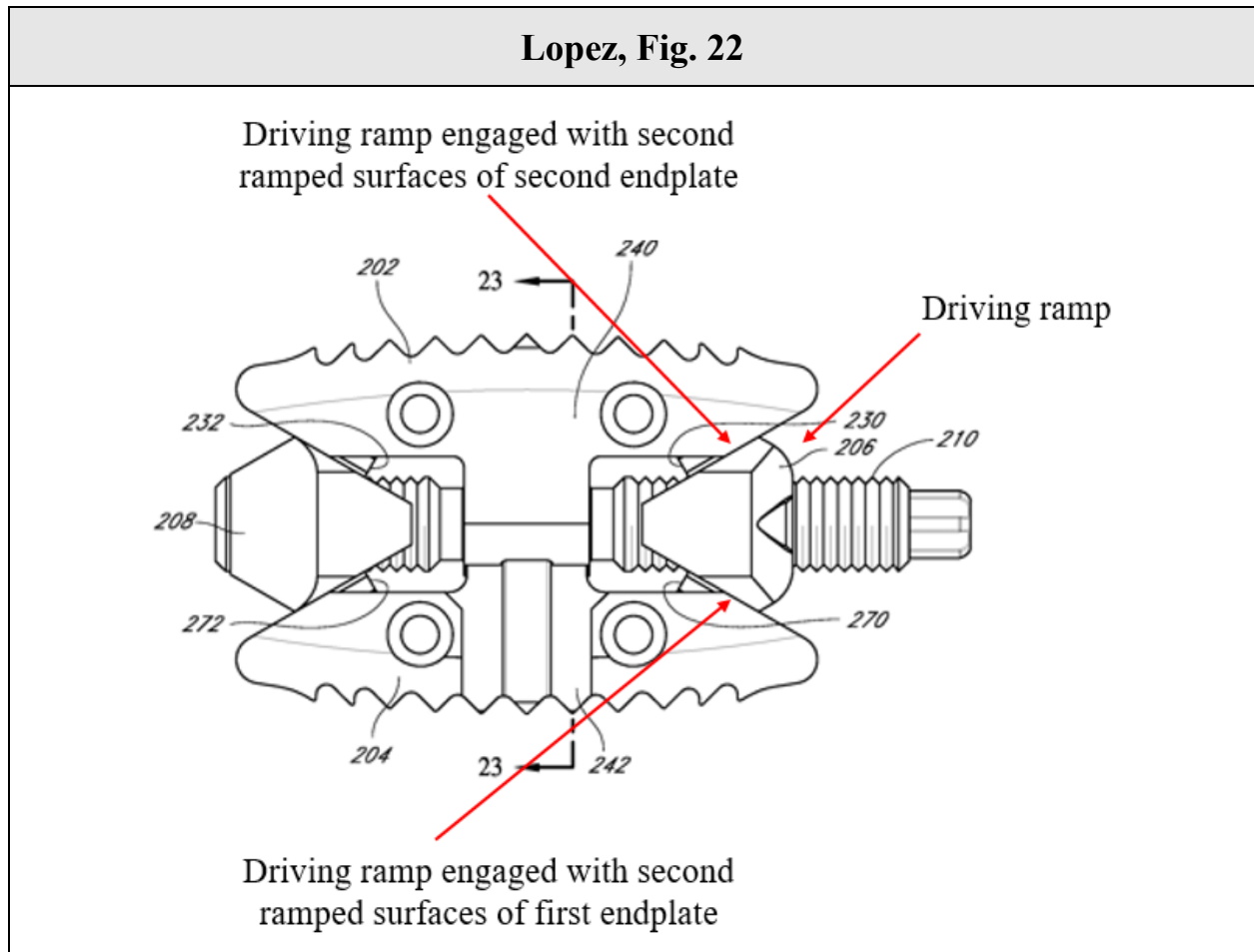
Lopez discloses this limitation. See §IX(A)(1)(h); EX1002, ¶¶223-224.

**(m) Claim 16[m]**

Claim 16 recites that “**the driving ramp is configured to engage the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate.**” Lopez’s driving ramp (*see* §IX(A)(8)(k)) engages the second ramped surfaces of the first and second endplates. EX1031, 22:19-28, Figs.



20A-B, 22. At least Figs. 20A-B and 22 further show this. Annotated Fig. 22 follows:



Accordingly, Lopez discloses this limitation. EX1002, ¶¶225-227; *see also* §§IX(A)(1)(i), IX(A)(2).

**(n) Claim 16[n]**

Lopez discloses this limitation. *See* §§IX(A)(1)(j), IX(A)(7)(a); EX1002, ¶¶228-229.

**(o) Claim 16[o]**

Lopez discloses this limitation. *See* §IX(A)(1)(k); EX1002, ¶¶230-231.

**B. Ground 2: Claims 1, 7-13, and 16 are obvious over Lopez in view of Baynham**

While Petitioner submits that Lopez discloses every element of Claims 1, 7-13, and 16, should Lopez be found to not disclose a “central ramp extension,” Claims 1, 7-13, and 16 are alternatively obvious under 35 U.S.C. §103 over Lopez in view of Baynham as detailed below and in Prof. Drewry’s declaration (*see* EX1002, ¶¶232-248).

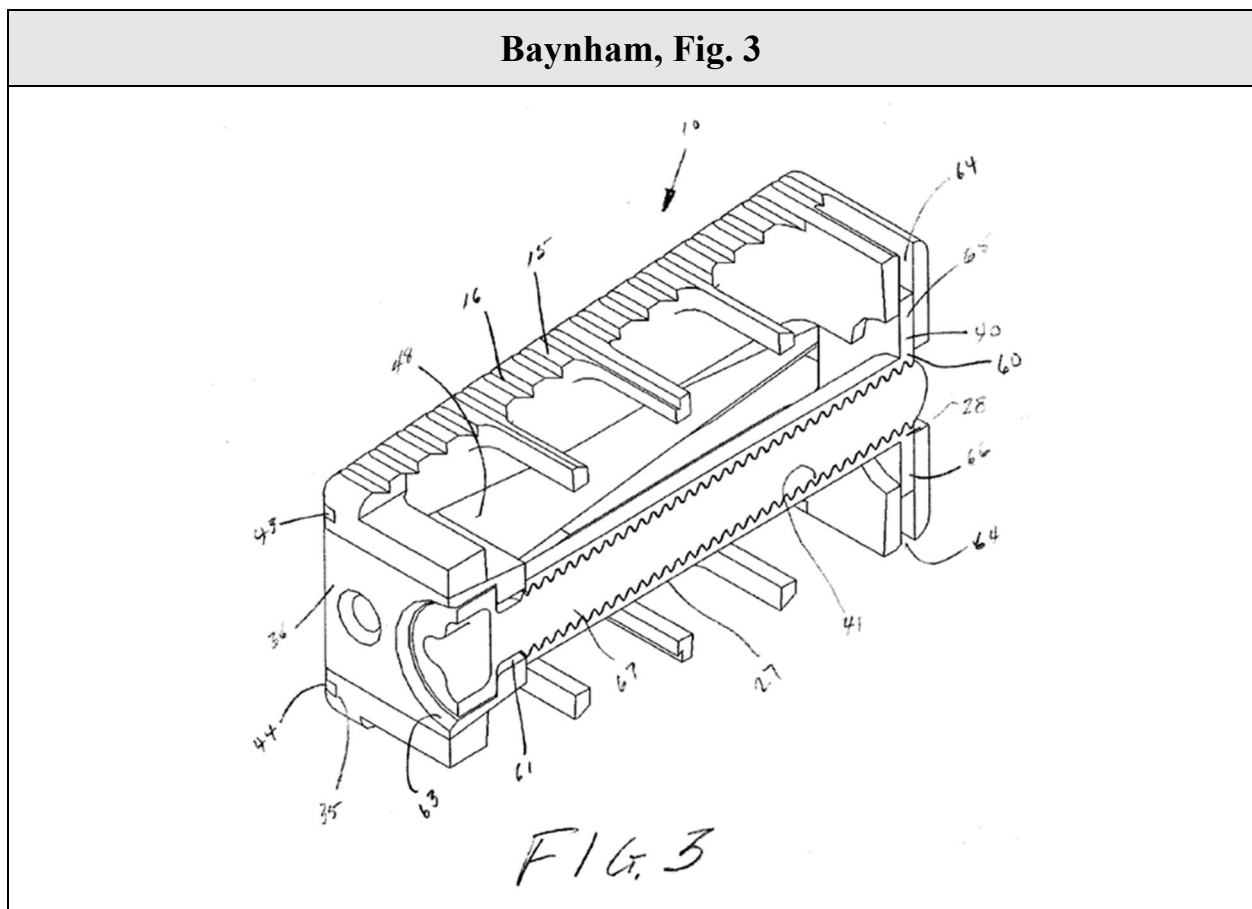
**1. Claims 1, 12, 13, and 16**

Lopez discloses the claimed central ramp extension as discussed above. §§IX(A)(1)(j), IX(A)(6)(a), IX(A)(7)(l), IX(A)(5)(j), *supra*. Alternatively, it would have been obvious to add a further extension to Lopez’s central ramp to engage the actuation member 40, as taught by Baynham, to satisfy the extension elements in Claims 1, 12, 13, and 16.

Baynham discloses a spinal fusion implant, shown below, composed of wedge-shaped upper section 11 and lower section 13, which interact with the opposing wedge shape of the ramp referred to as distractor 42. The upper and lower sections have grooves 26, 35 which engage the flanges 43, 44 of distractor

42. EX1007, ¶¶[0022], [0025]-[0029], Figs. 1, 3. Distractor 42 also has an unthreaded bore 61 in its trailing edge for receiving a jack screw 67. *Id.*

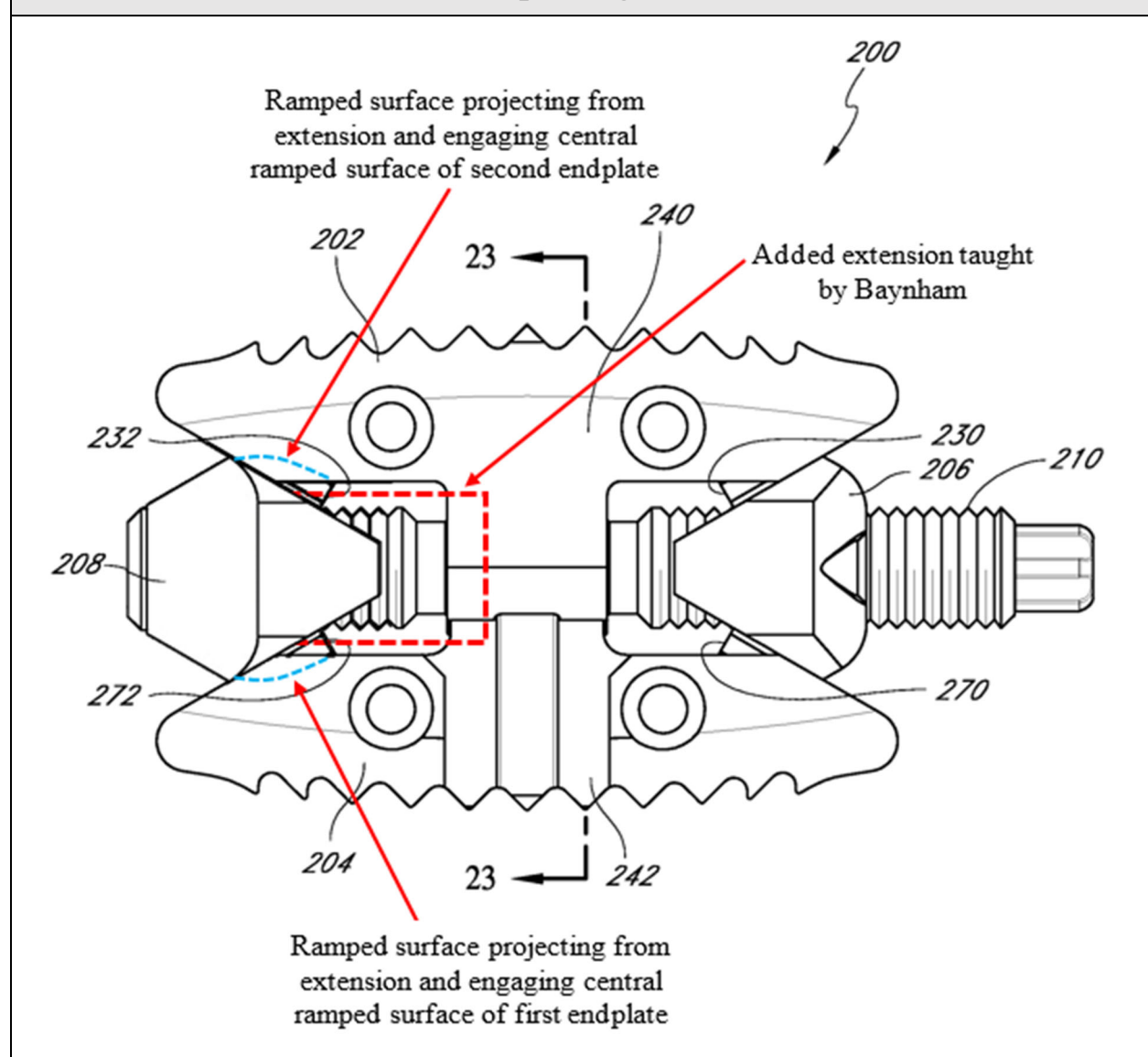
Furthermore, the Baynham implant's leading edge has a link 40 which fits between the upper and lower sections 11, 13 and includes flanges 65, 66, which are received in vertical slots 64 of the upper and lower sections. *Id.* Link 40 also includes a threaded tube 27 that “surrounds the bore 60 and extends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



Baynham's threaded tube (i.e., "extension") extends toward the opposing ramp and engages the screw/actuation member. As the actuation member rotates, the threaded tube causes the link and ramp to be drawn together. Simultaneously, the wedge shape of the ramp and the upper and lower sections cause the upper and lower sections to be forced apart. Accordingly, Baynham's tube 27 has the same structure and performs the same function as the extension recited in the '732 patent and central aperture 302 of Lopez – it "extend[s] from the expansion portion" and "an actuation member...[is] received within an opening in the central ramp extension." §§IX(A)(1)(j), IX(A)(7)(a), *supra*.

Applying Baynham's tube-shaped extension to Lopez's central ramp, a POSITA would understand that the ramped surfaces of the central ramp extension would still project from the modified rod-receiving extension, as required by Claim 16[j]. Combining Baynham's tube with Lopez simply involves elongating the area surrounding of Lopez's existing extension surrounding the rod-receiving opening as indicated by the red-dotted box below. Accordingly, the ramped surfaces would continue to extend from the elongated extension just as described in §IX(A)(9)(j), *supra*. EX1002, ¶239. The following annotated version of Fig. 22 shows this, with the ramped surfaces approximated in blue dashed lines:

Lopez, Fig. 22



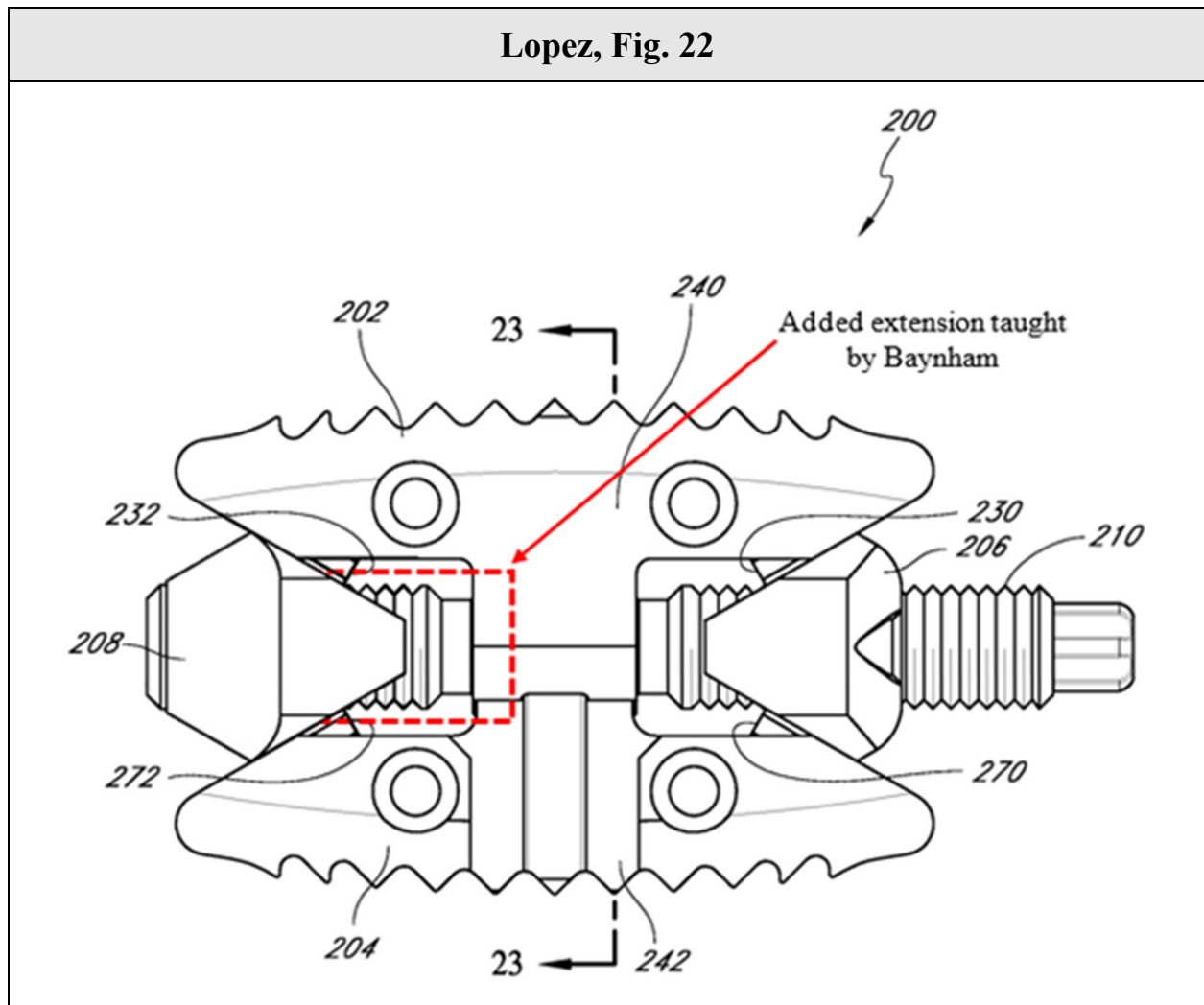
Accordingly, the extension elements of Claims 1, 12, 13, and 16 are disclosed by the combination of Lopez with Baynham which, together, render these claims obvious. EX1002, ¶¶232-240; *see infra*, §IX(B)(3) (detailing motivation to combine and reasonable expectation of success).

## **2. Claims 7-11**

Claims 7-11 depend either directly or indirectly from Claim 1. As discussed above, all elements added by these claims are expressly disclosed in Lopez. *See* §§IX(A)(2)-(6), *supra*. Accordingly, Claims 7-11 are likewise obvious for the reasons provided in Ground 1 and here. EX1002, ¶241.

## **3. Motivation to Combine**

A POSITA would have been motivated to modify the structure surrounding Lopez's central aperture 302 to further lengthen Lopez's extension longitudinally towards the driving ramp, as taught by Baynham's tube 27, and as indicated in annotated Fig. 22 below (EX1002, ¶¶242).



Extending the central aperture per Baynham's tube 27 would make the threaded bore longer and decrease the distance between the bores of Lopez's driving ramp and central ramp, which would provide clear advantages appreciated by a POSITA. First, incorporating Baynham's extension would allow the screw to engage the central ramp bore at a shorter distance and, once engaged, to engage a larger number of the central ramp's threads, which would have the benefit of improving the strength of the connection. EX1002, ¶243. Second, the modification

would allow use of a shorter screw, which will reduce or eliminate protrusion of the screw from the device when expanded, thereby reducing unwanted interference with adjacent anatomy. *Id.*, ¶244. Accordingly, a POSITA would have been motivated to incorporate the design of Baynham’s tube 27 with Lopez’s distal wedge member 208. *Id.*, ¶242-245.

Furthermore, Baynham’s “jack screw” functionality is directly analogous to the functionality disclosed in Lopez. *See* §§IX(A)(1)(l), IX(B)(1), *supra*. Accordingly, the combination amounts to nothing more than the simple substitution of known mechanical features with each performing their known and expected function. Because these are easily substituted and well-known mechanical features well within the level of skill in the art, a POSITA would have had a reasonable expectation of success in combining Baynham’s tube 27 with Lopez. EX1002, ¶¶246-248.

**C. Ground 3: Claims 1, 7-13 and 16 are Obvious over Varela-’049 in view of Lopez**

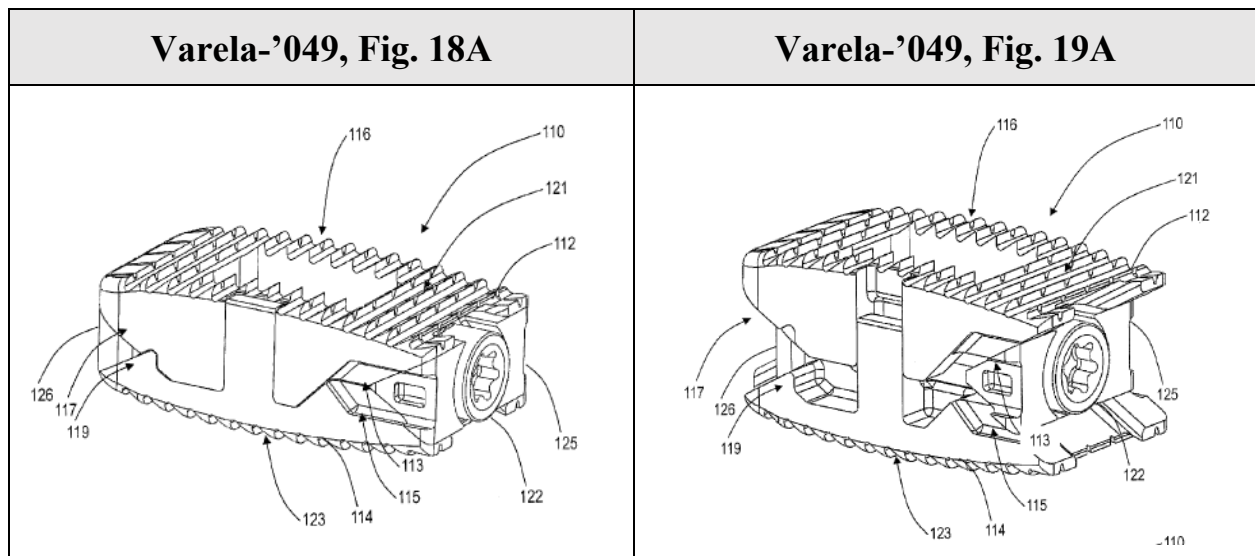
Claims 1, 7-13 and 16 are obvious under 35 U.S.C. §103 over Varela-’049 in view of Lopez as detailed below and in Prof. Drewry’s declaration (*see* EX1002, ¶¶249-397).



# 1. Claim 1

## (a) Claim 1[a]

Claim 1 is directed to a “**system for intervertebral fusion,**” which Varela-’049 discloses. Varela-’049 discloses “an intervertebral implant,” as seen in Figs. 18A and 19A, below, that is selectively disposed in the intervertebral space thereby “fusing a portion of the spine of a patient” (*see* EX1032, ¶¶[0002], [0005]).



Lopez discloses a dilator and cannula for insertion of an implant device. *See supra* §IX(A)(1)(a)-(c). Accordingly, Varela-’049 and Lopez together disclose a system for intervertebral fusion. EX1002, ¶249-251.

## (b) Claim 1[b]

Claim 1 requires “**a dilator having a proximal end and a tapered distal end for penetrating soft tissue.**” Lopez discloses the claimed dilator for penetrating soft tissue to implant an intervertebral fusion device. *Supra*

§IX(A)(1)(b). It would have been obvious to use Lopez’s dilator for penetrating soft tissue to create an access path to the intervertebral space for implantation of Varela-’049’s device. EX1002, ¶252, ¶¶387-397; *see also infra* §IX(C)(10).

Accordingly, Varela-’049 with Lopez discloses this limitation. EX1002, ¶252-253.

**(c) Claim 1[c]**

Claim 1 recites “**a cannula having a proximal end and a distal end.**” Lopez discloses the claimed cannula for implanting an intervertebral fusion device. *Supra* §IX(A)(1)(c). It would have been obvious to use Lopez’s cannula for implanting Varela-’049’s device given Lopez’s teaching of a cannula for this exact purpose, and the need to implant Varela-’049’s device. EX1002, ¶254, ¶¶387-397; *see also infra* §IX(C)(10).

Accordingly, Varela-’049 with Lopez discloses this limitation. EX1002, ¶254-255.

**(d) Claim 1[d]**

Claim 1 recites “**an intervertebral implant sized for insertion into an intervertebral space through the cannula.**” It would have been obvious to size Varela-’049’s implant for insertion into an intervertebral space through the cannula as taught by Lopez.

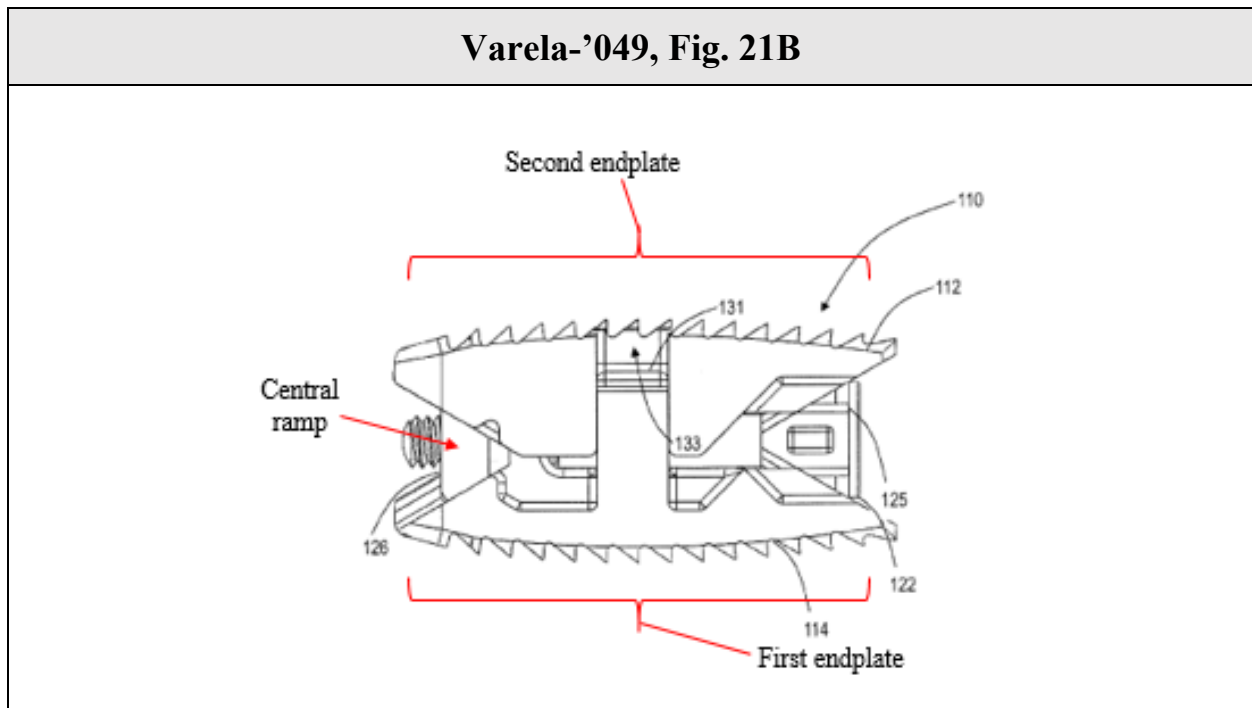
As discussed previously, Lopez teaches that “the intervertebral implant 80 may be introduced **through** the access cannula 30.” EX1032, 12:64-66; *see also id.*, 5:20-21, *supra* §IX(A)(1)(d). The dimension of Varela-’049’s intervertebral implant is similar to the implant disclosed by Lopez, which can be introduced through the cannula. EX1032, ¶[0062] (disclosing an implant “on the order of several millimeters to tens of millimeters” that can “provide a height expansion range of 7-18mm.”); EX1031, 27:7-15 (disclosing that “the implant can be expanded from approximately 9 mm to approximately 12.5 mm.”). At least based on similarity of the dimensions, a POSITA would have recognized that Varela-’049’s intervertebral implant is sized for insertion through the cannula. EX1002, ¶257. A POSITA would have appreciated the usefulness of combining/applying Lopez’s teachings with/to Varela-’049’s device, rendering this claim element obvious. EX1002, ¶¶387-397.; *see also infra* §IX(C)(10).

Accordingly, Varela-’049 with Lopez discloses this limitation. EX1002, ¶256-258.

**(e) Claim 1[e]**

Claim 1 recites that “**the intervertebral implant comprises a first endplate, a second endplate, and a central ramp disposed between the first endplate and the second endplate.**” Varela-’049 discloses a first endplate (e.g., “an inferior member 114”), a second endplate (e.g., “a superior member 112”), and

a central ramp (e.g., “distal wedge structure 126”) disposed between the first endplate and the second endplate. EX1032, ¶¶[0076]-[0078]. Figures 18A-B, 19A-B, and 21A-B show this, with annotated Fig. 21 below.



Accordingly, Varela-'049 discloses this limitation. EX1002, ¶¶259-261.

**(f) Claim 1[f]**

Claim 1 recites that “**the central ramp is configured to move in a first direction and cause the first and second endplates to move outwardly and away from one another.**” Varela-'049 discloses a device configured to move the central ramp/distal wedge structure 126 in a first direction and cause the superior member 112 and the inferior member 114 to move outwardly and away from one another. More specifically:

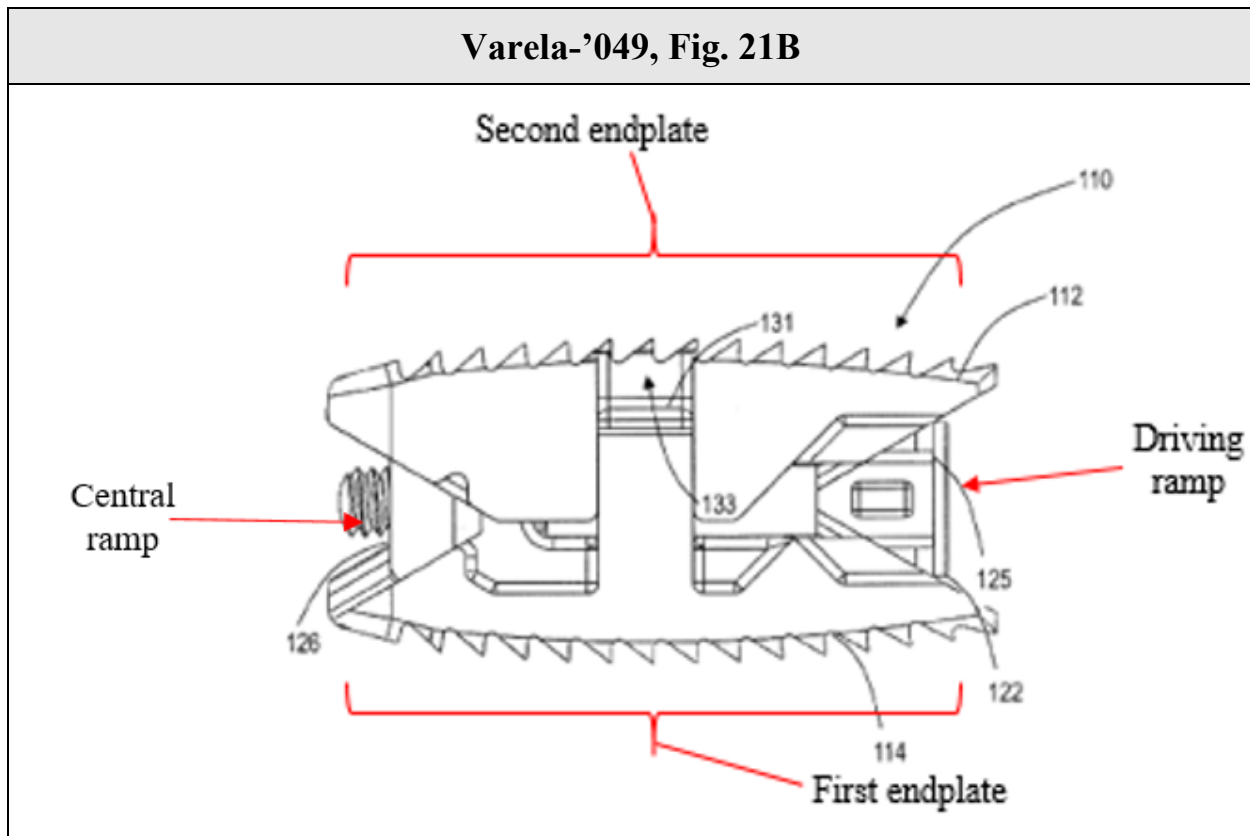
Annotated Figs. 18B and 19B follow, showing a device according to Varela-'049 satisfying these limitations.



Accordingly, Varela-'049 discloses this limitation. EX1002, ¶¶262-264.

**(g) Claim 1[g]**

Claim 1 recites “**a driving ramp disposed between the first endplate and the second endplate at an opposite end of the intervertebral implant from the central ramp.**” Varela-'049 discloses a driving ramp (“proximal wedge structure 125”) disposed between the first and the second endplates at an opposite end of the endplates from the central ramp. EX1032, ¶¶[0076]-[0078]. Annotated Fig. 21B follows for reference.

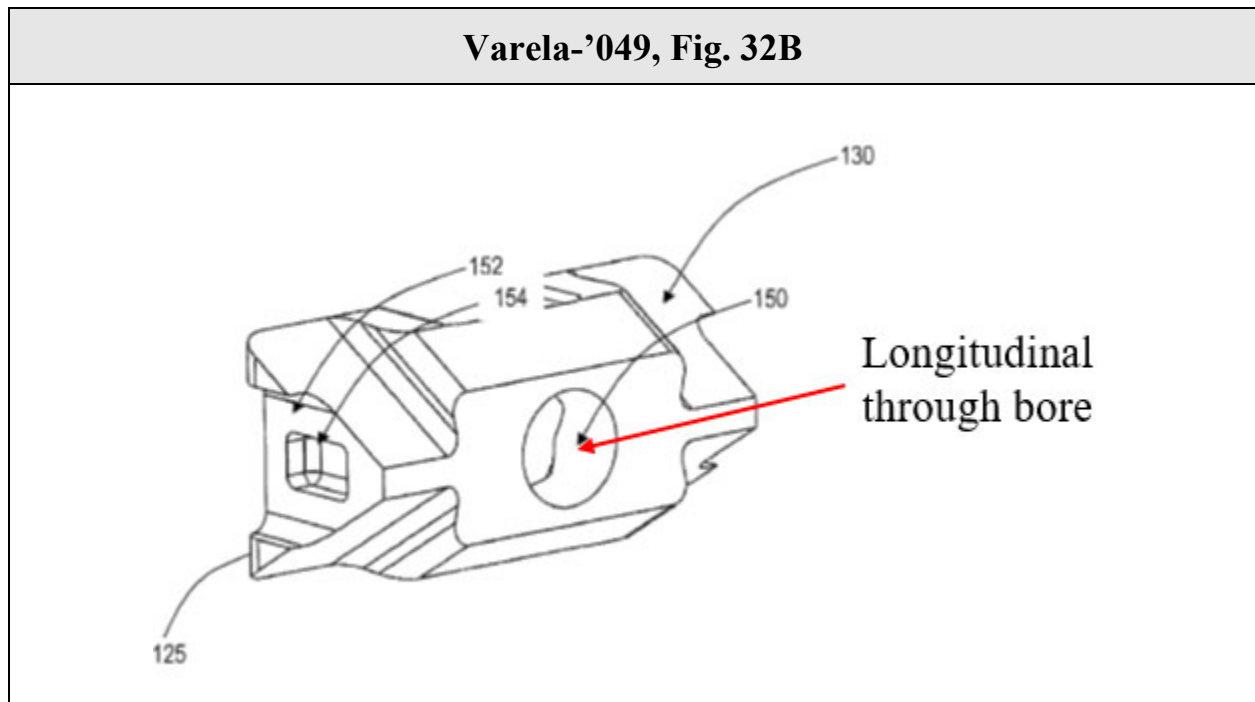


Accordingly, Varela-'049 discloses this limitation. EX1002, ¶¶265-268.

**(h) Claim 1[h]**

Claim 1 recites that “**the driving ramp has a longitudinal through bore.**”

Varela-’049 discloses that the driving ramp/proximal wedge structure 125 has a longitudinal bore (“includes...central bore 150...”). EX1032, ¶[0082], Figs. 31A-B, 32A-B.



Accordingly, Varela-’049 discloses this limitation. EX1002, ¶¶269-271.

**(i) Claim 1[i]**

Claim 1 recites that “**wherein the driving ramp is configured to engage ramped surfaces of the first endplate and ramped surfaces of the second endplate.**” Varela-’049 discloses that the driving ramp is configured to engage

ramped surfaces of the first and second endplates. EX1032, Figs. 27A-B, 28A-B,

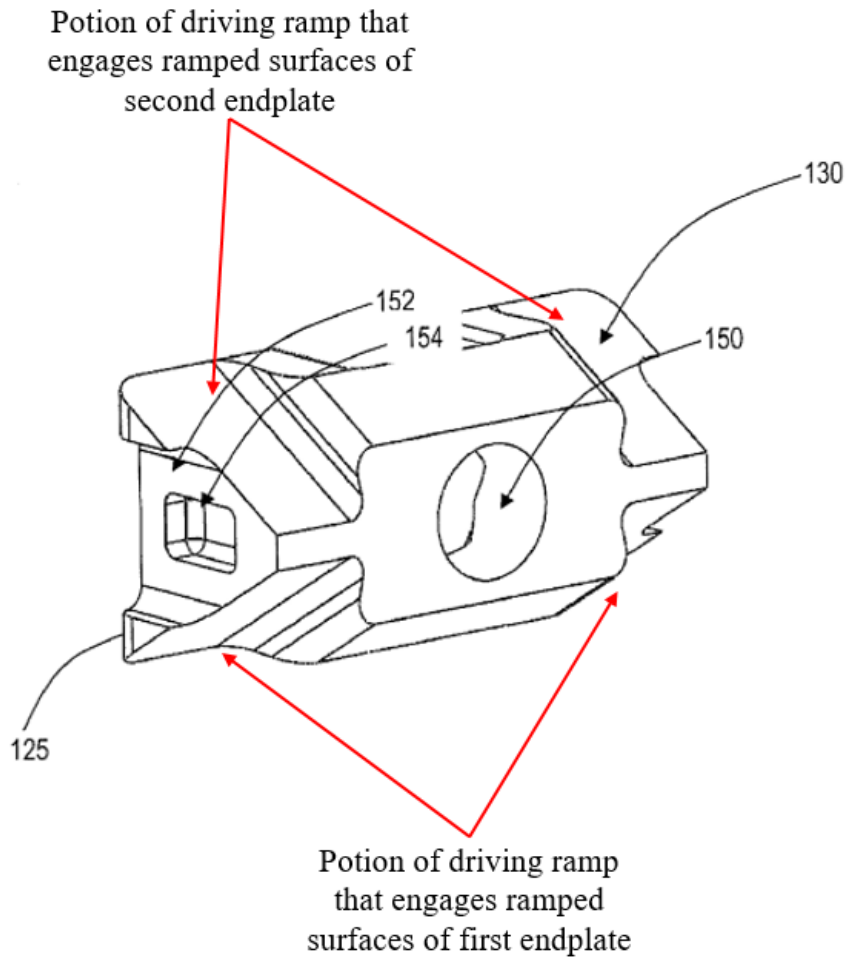
29A-B, 30A-B, 32A-B, ¶[0079]. Specifically, Varela-'049 discloses:

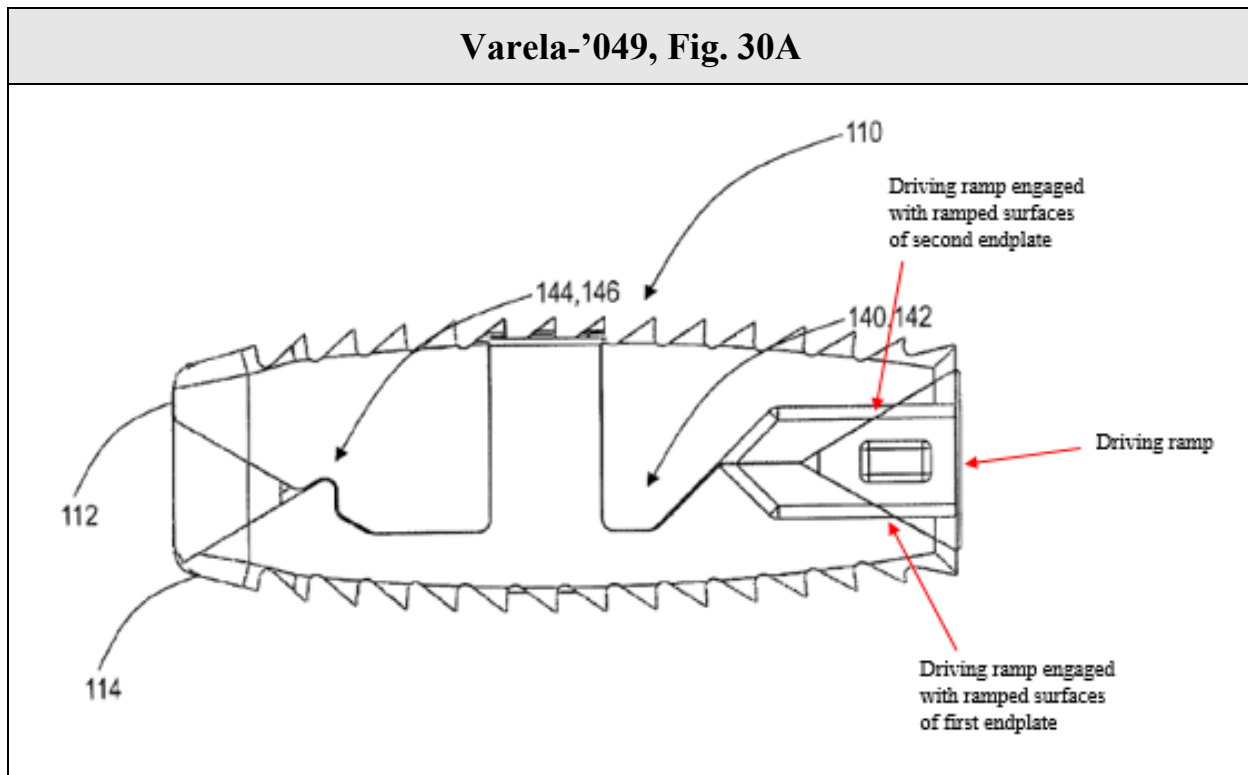
Each of the proximal ramp portions 113 and 115 and the distal ramp portions 117 and 119 of the superior member 112 and the inferior member 114, respectively, includes one or more raised parallel rail structures 128...These raised parallel rail structures 128 are positioned and configured to engage corresponding recessed parallel slot structure 130 of the proximal and distal wedge structures 125 and 126.

*Id.*, ¶[0079]. Annotated Figs. 32B and 30A follow.



**Varela-'049, Fig. 32B**



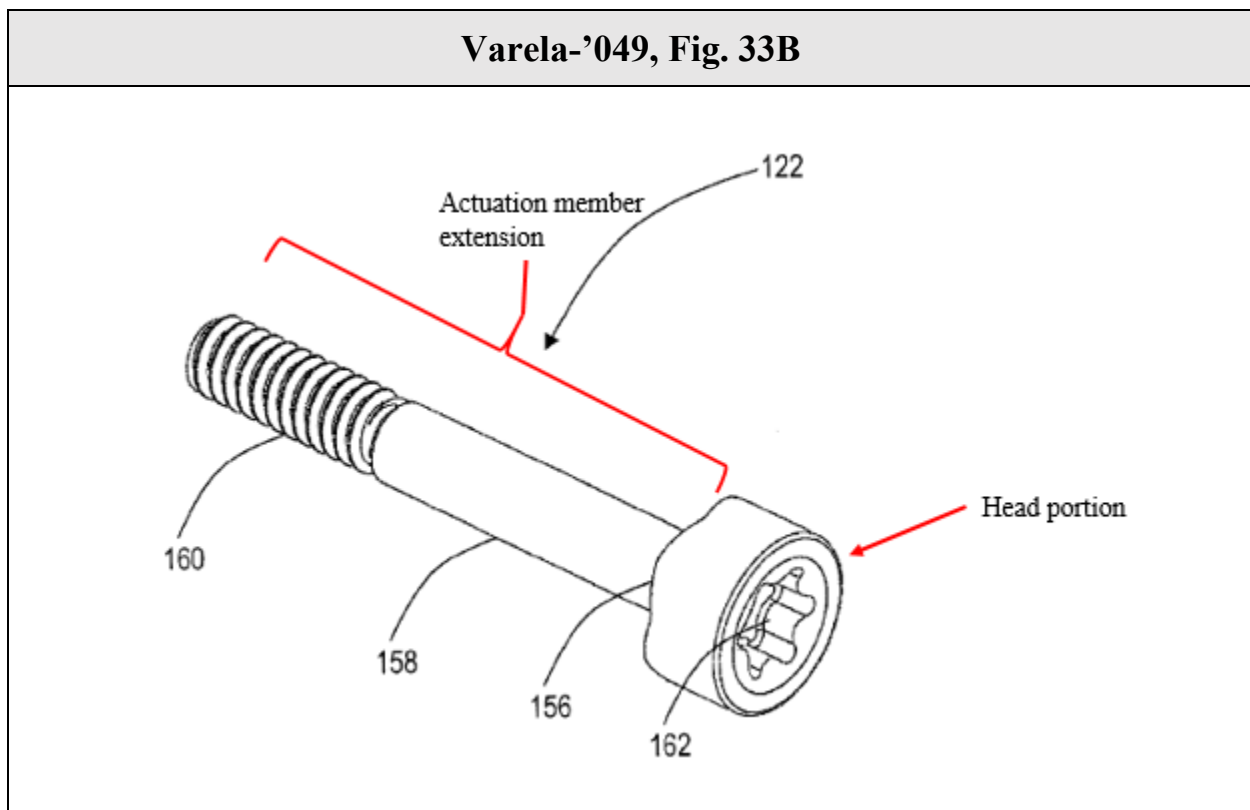


Accordingly, Varela-'049 discloses these limitations. EX1002, ¶¶272-275.

**(j) Claim 1[j]**

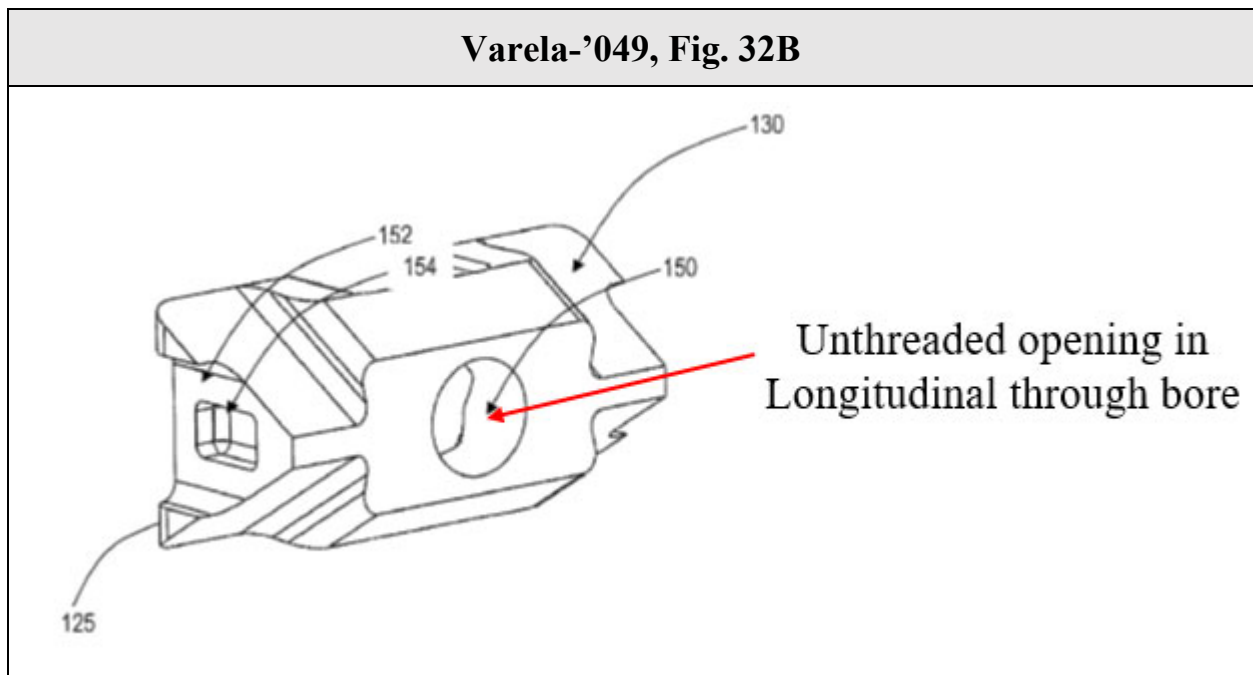
Claim 1 recites that “**an actuation member comprising a head portion and an actuation member extension that extends through an unthreaded opening in a longitudinal through bore of the driving ramp to be received within an opening in the central ramp extension.**” Claim 1 does not recite “a central ramp extension,” thus rendering Claim 1 indefinite for lack of antecedent basis. However, assuming *arguendo* that this term refers to the same structure referred to as “an extension” in Claim 12, this element is disclosed by Varela-'049. See §IX(C)(7), *infra*.

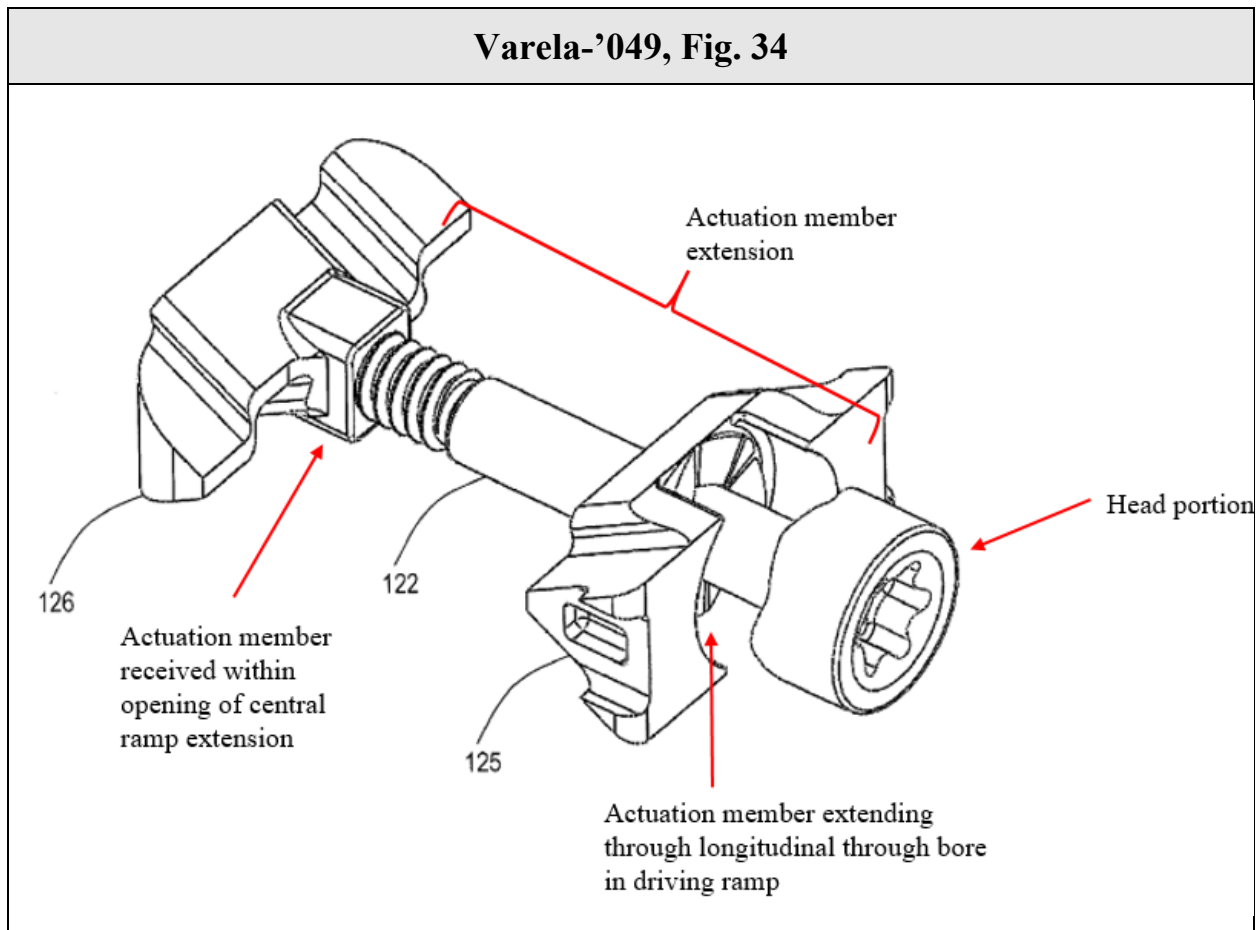
Varela-'049 discloses an actuation bolt comprising a head portion (“a complimentary radial spline 156 on the back side of the head portion”) and an actuation member extension that extends through an the driving ramp to be received within an opening in the central ramp extension (“a smooth shaft portion 158 for passing through the proximal wedge structure 125, and a threaded portion 160 for engaging the distal wedge structure 126.”). *See* EX1032, ¶[0083], Figs. 33A-B. Fig. 33B follows for reference.



Varela-'049 further discloses that the longitudinal through bore of the driving ramp/proximal wedge structure 125 is unthreaded. *See id.*, Figs. 32A-B, 33A-B, 34 ¶[0083] (“a smooth shaft portion 158 for passing through the proximal

wedge structure 125”). Annotated Figs. 32 and 34 show the unthreaded opening of the driving ramp and the assembly of an actuation member extending through the unthreaded opening and received within an opening in the central ramp extension, which follow for reference.





Accordingly, Varela-'049 discloses these limitations. EX1002, ¶¶276-282.

**(k) Claim 1[k]**

Claim 1 recites that “**rotational movement of the actuation member in the first direction pulls the central ramp towards the driving ramp.**” Varela-'049 discloses that the actuation member 122 rotates in a first direction to move the central ramp towards the driving ramp, forcing the first and second endplates to move outwardly. EX1032, ¶[0083] (“[T]he actuation bolt 122 is rotated to translate the proximal and/or distal wedge structure(s) 125 and 126”). The relative

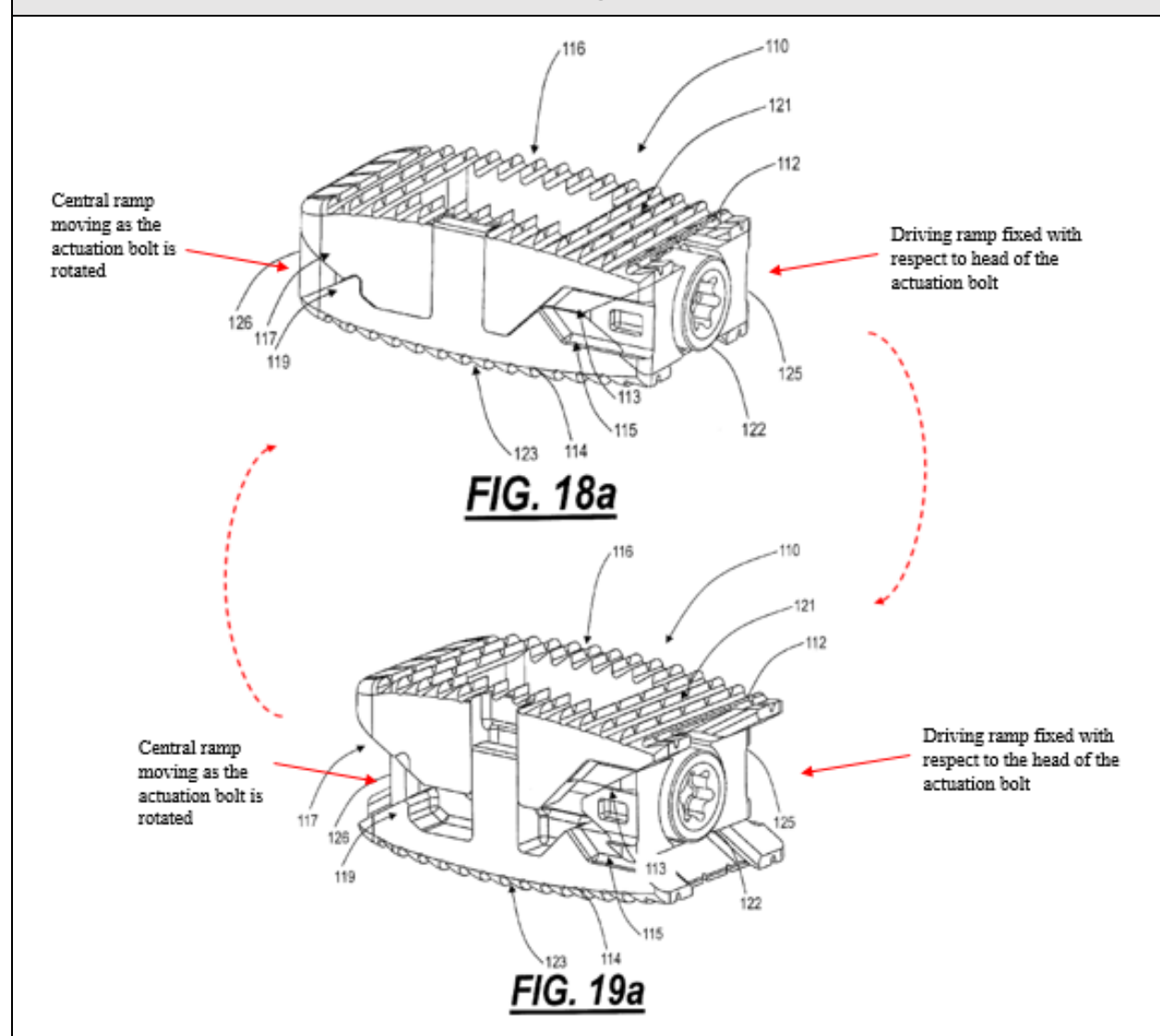
movement of the ramps and endplates can also be observed at least by comparing Figs. 18A-B and 19A-B. *See, e.g.*, §IX(C)(1)(f); EX1002, ¶283.

Accordingly, Varela-'049 discloses these limitations. EX1002, ¶¶283-284.

**(I) Claim 1[I]**

Claim 1 recites that, **“when the actuation member is rotated, the driving ramp is fixed with respect to the actuation member and the central ramp is moved in either the first direction or a second direction.”** Varela-'049 discloses the actuation bolt 112 including a radial spline 156 on the back of the head portion and a threaded portion 160 for engaging the central ramp/distal wedge structure 126. As the actuation bolt is rotated, the central ramp moves along the threaded portion of the bolt, and the distal ramp/proximal wedge structure 125 is fixed relative to the actuator, as it is abutted against the radial spline. *See* EX1032, Figs. 18A-B, 19A-B, ¶¶[0071], [0076], [0081]-[0082]. *See also* §§IX(C)(1)(f) (describing movement of central ramp in first direction and second direction), *supra*. Annotated Figs. 18A and 19B follow for reference.

**Varela-'049, Figs. 18A & 19A**



Accordingly, Varela-'049 discloses these limitations. EX1002, ¶¶285-287.

**2. Claim 7**

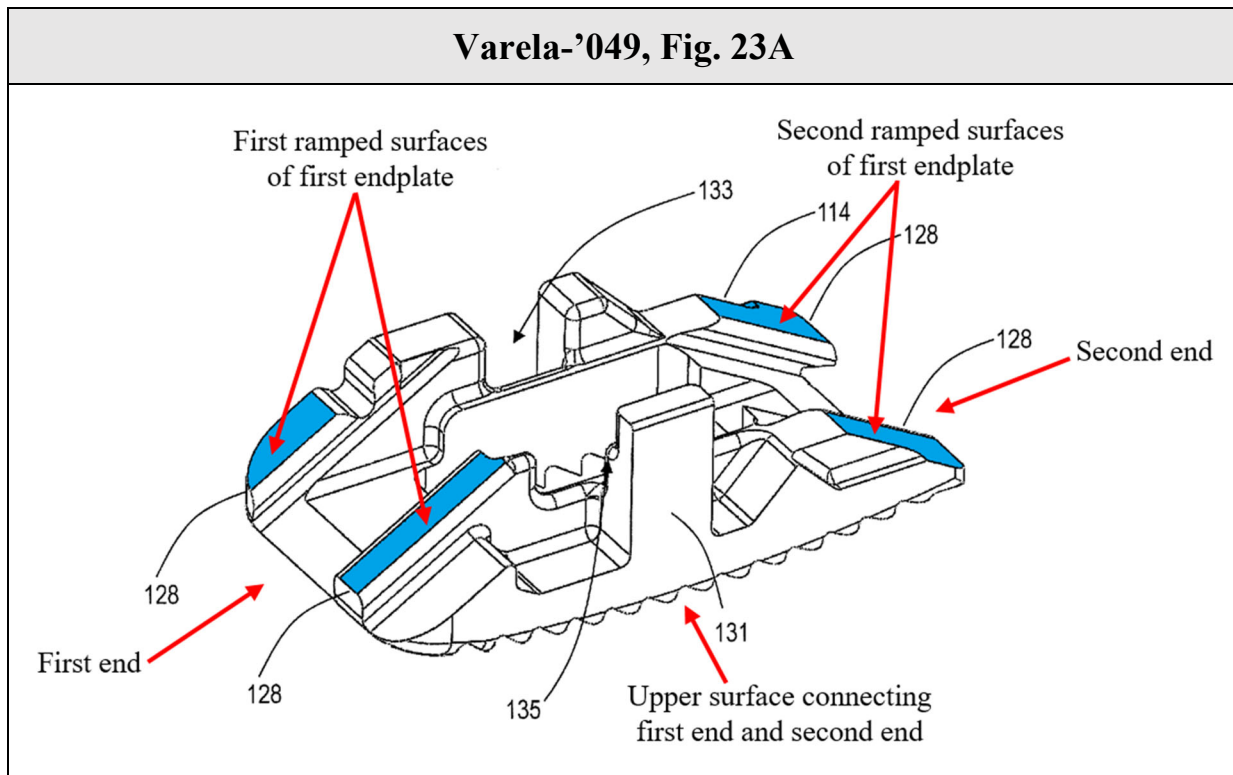
**(a) Claim 7[a]**

Claim 7 recites that “**first endplate comprises a first end, a second end, an upper surface connecting the first end and the second end, first ramped**

**surfaces on either side of the first endplate proximate the first end, second ramped surfaces on either side of the first endplate proximate the second**

**end.”** Varela-’049 discloses that the first and second endplates each have a first end and a second end, and first ramped surfaces on either side of the first endplate proximate the first end, second ramped surfaces on either side of the first endplate proximate the second end. *See* EX1032, ¶¶[0074] (describing “a proximal ramp portion 113 and 115” and “a distal ramp portion 117 and 119” of the superior member 112 and the inferior member 114), [0079] (“Each of the proximal ramp portions 113 and 115 and the distal ramp portions 117 and 119 of the superior member 112 and the inferior member 114, respectively, includes one or more raised parallel rail structures 128 that run from the central portion of the expandable intervertebral implant 110 to the respective end portion of the expandable implant 110.”). Figures 18A-B and 19A-B further show these structures, as well as the endplates’ respective upper and lower surfaces connecting the first end and the second end. Varela-’049 also discloses that the first endplate has a proximal and distal ramp surfaces formed by rail structures 128. *See* EX1032, ¶¶[0074], [0079], Annotated Fig. 23A, which shows a perspective view of the identical “superior and inferior members” (*id.*, ¶[0040]), follows for reference, with the first and second ramped surfaces in blue.





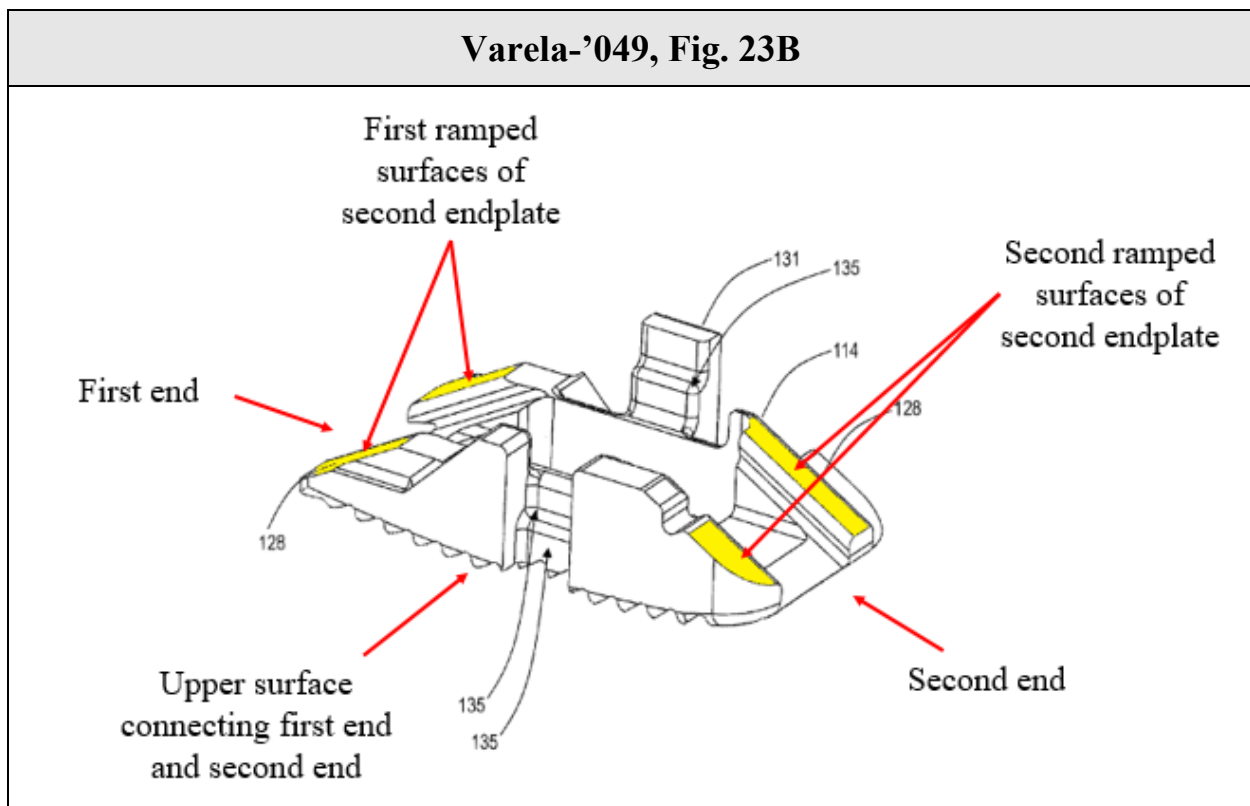
Accordingly, Varela-'049 discloses these limitations. EX1002, ¶¶288-291.

**(b) Claim 7[b]**

Claim 7 recites that “**second endplate comprises a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the second endplate proximate the first end, second ramped surfaces on either side of the second endplate proximate the second end.**” Varela-'049 discloses that the first and second endplates each have a first end and a second end, and first ramped surfaces on either side of the second endplate proximate the first end, second ramped surfaces on either side of the

second endplate proximate the second end. EX1032, ¶¶[0074], [0079]; *see also* §IX(C)(2)(a).

Varela-'049 also discloses that the second endplate has proximal and distal ramp surfaces formed by rail structures 128. *See* EX1032, ¶¶[0074], [0079], Figs. 18-19, 21A-B, 23-24. Annotated Fig. 23A, which shows a perspective view of the identical “superior and inferior members” (*id.*, ¶[0040]), follows for reference, with Fig. 23B showing the first and second ramped surfaces in yellow.



Accordingly, Varela-'049 discloses these limitations. EX1002, ¶¶292-294.

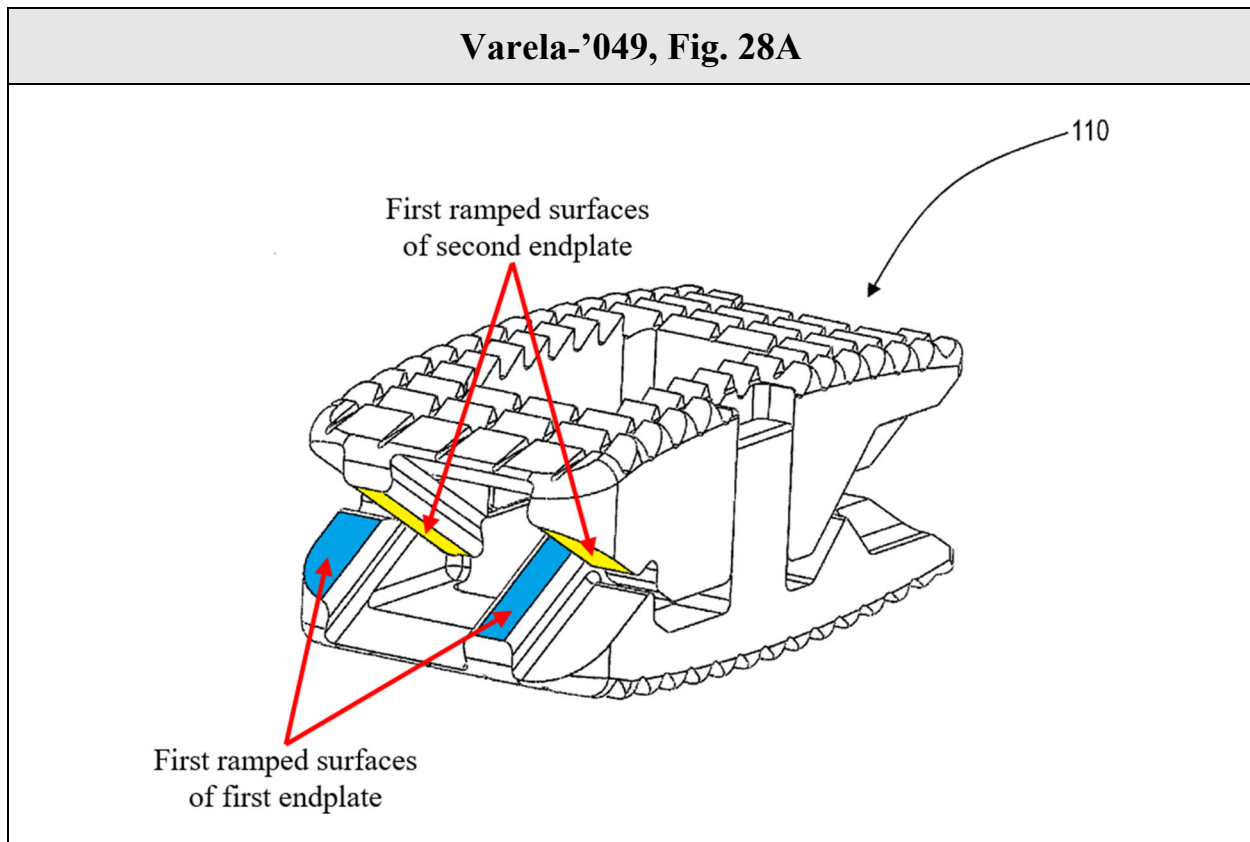
### 3. Claim 8

Claim 8, which depends from Claim 7, recites that “**when the intervertebral implant is in an unexpanded configuration, the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate overlap, and the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate overlap.**” As discussed in preceding section, Varela-’049 discloses ramped surfaces of the first and second endplates. *See* §§IX(C)(2)(a)-(b), *supra*. Varela-’049 further discloses that when in an unexpanded configuration, the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate overlap, and the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate overlap.

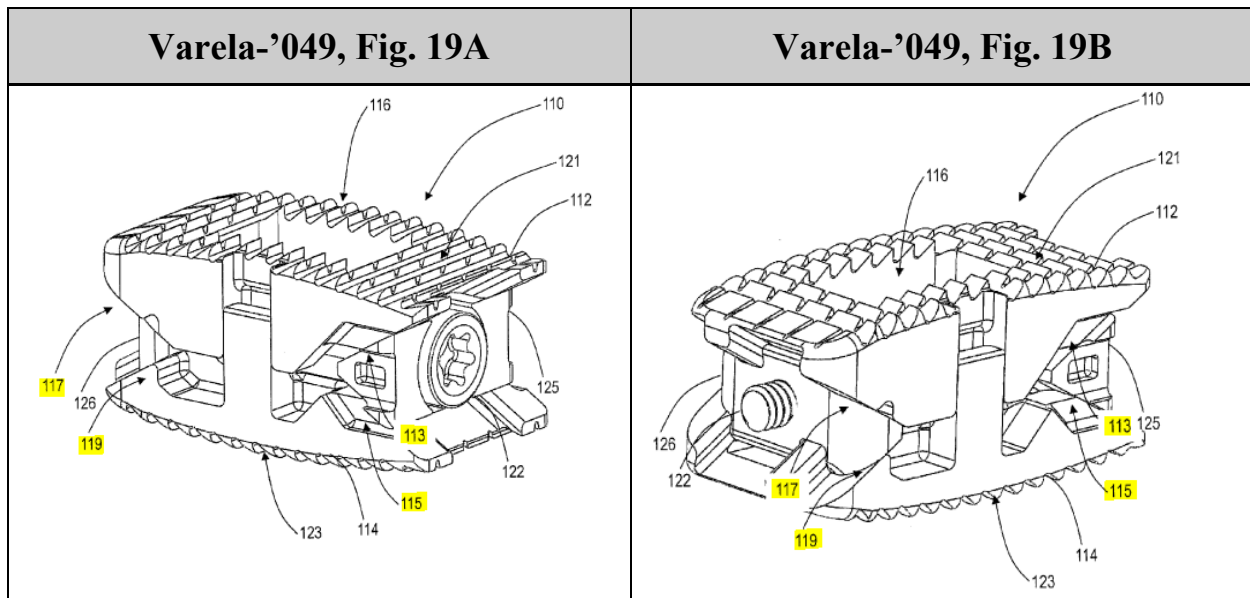
Specifically, Varela-’049 discloses that “[e]ach of the proximal ramp portions 113 and 115 and the distal ramp portions 117 and 119 of the superior member 112 and the inferior member 114, respectively, includes one or more raised parallel rail structures 128 that run from the central portion of the expandable intervertebral implant 110 to the respective end portion of the expandable implant 110.” EX1032, ¶[0079]. The surfaces of these rail structures constitute overlapping ramped portions because “[t]he rail structures 128...are staggered or offset such that the proximal ramp portions 113 and 115 and the distal

ramp portions 117 and 119 of the superior member 112...are ‘nested’ when assembled, such that the form factor (i.e. both the vertical cross-section and the horizontal footprint) of the expandable intervertebral implant 110 is minimized when undeployed (i.e. unexpanded).” *Id.*; *see also id.*, ¶[0075], Figs. 19(a)-(b).

Annotated Fig. 28A follows showing the first ramped surfaces of the first endplate (blue) (e.g., surfaces of ramped portion 119 as identified in Fig. 19) and the first ramped surfaces of the second endplate (yellow) (e.g., surfaces of ramped portion 117 as identified in Fig. 19) overlapping or “nesting” when the device is in a partially collapsed position. EX1002, ¶¶297-298. A POSITA would have appreciated that these surfaces will further overlap when the device is lowered to its fully collapsed state. *Id.* Annotated Fig. 28A shows the surfaces beginning to overlap as the endplates are collapsed towards each other:



In similar fashion, although not clearly visible in the figures of Varela-'049, a POSITA would have further appreciated that Varela-'049 discloses and describes that the second ramped surfaces at the distal/far end of the first endplate (e.g., surfaces of ramped portion 113 as identified in Fig. 19) likewise overlap or “nest” with the second ramped surfaces (e.g., surfaces of ramped portion 115 as identified in Fig. 19) at the distal/far end of the second endplate. EX1032, ¶[0079], Figs. 19(a)-(b). Annotated Figs. 19(a)-(b) follow, highlighting the identification of ramped portions 113, 115, 117, and 119 on each side of the device:

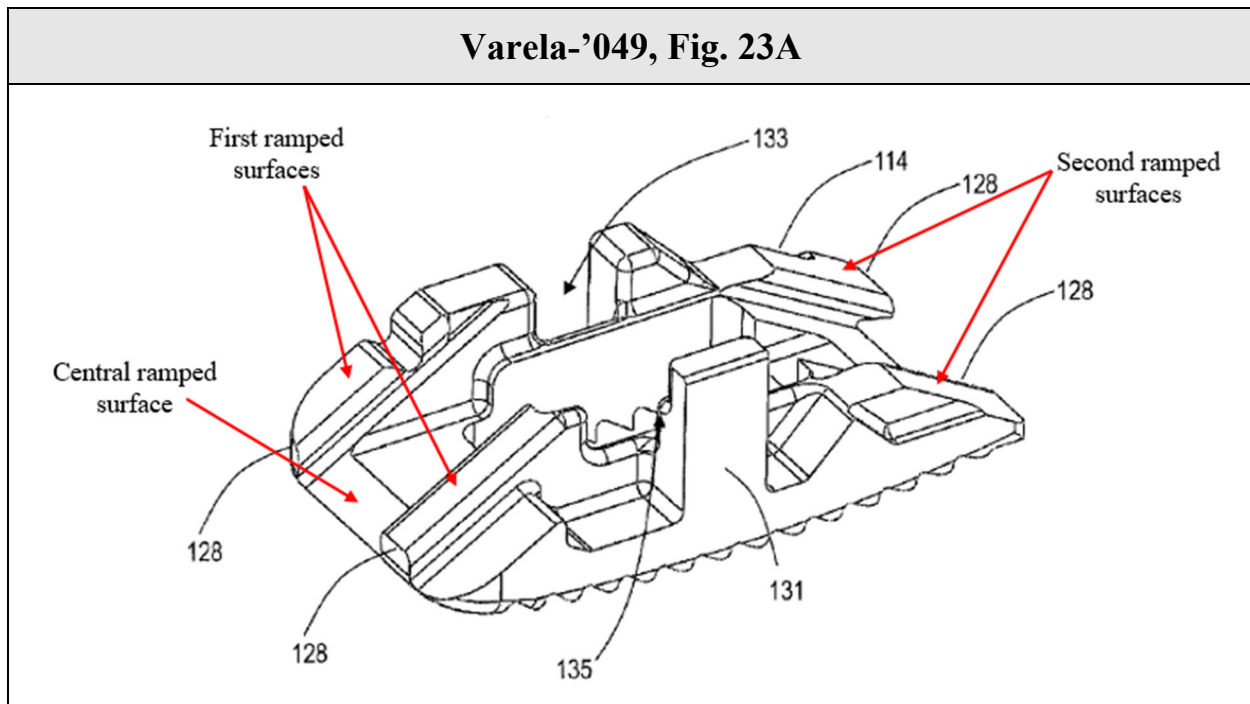


Accordingly, Varela-'049 discloses this limitation. EX1002, ¶¶295-301.

#### 4. Claim 9

##### (a) Claim 9[a]

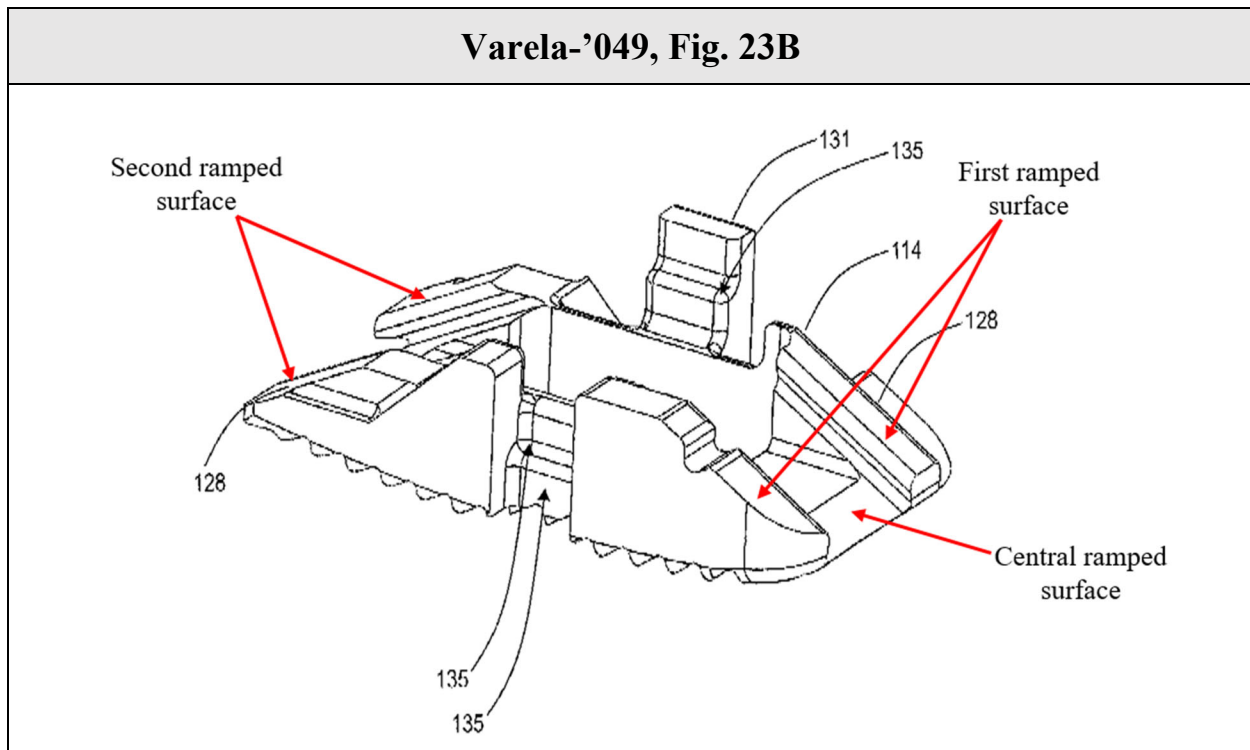
Claim 9 recites that “**the first endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the first endplate.**” Varela-'049 discloses that the first endplate has a proximal and distal ramp portions including ramped rail structures 128. *See* EX1032, ¶¶[0074], [0079], Figs. 18A-B, 19A-B, 21A-B, 23A-B, 24A-B. A central ramped surface exists between rail structures 128 on the first endplate. Annotated Fig. 23A, which shows a perspective view of the identical “superior and inferior members” (*id.*, ¶[0040]) follows for reference.



Accordingly, Varela-'049 discloses this limitation. EX1002, ¶¶302-304.

**(b) Claim 9[b]**

Claim 9 recites that “**the second endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the second endplate.**” Varela-'049 also discloses that the second endplate has a proximal and distal ramp portions including rail structures 128. *See* EX1032, ¶¶[0074], [0079], Figs. 18A-B, 19A-B, 21A-B, 23A-B, 24A-B. A central ramped surface exists between rail structures 128 on the first endplate. Annotated Fig. 23A, which shows a perspective view of the identical “superior and inferior members” (*id.*, ¶[0040]) follows for reference.



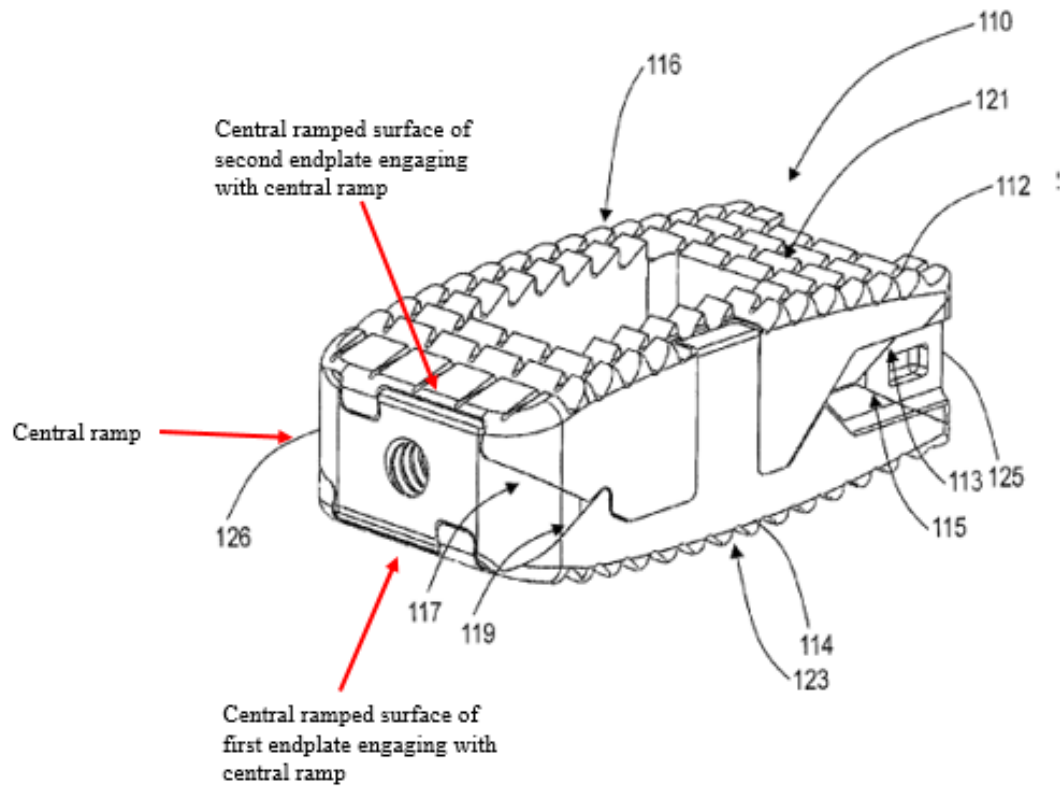
Accordingly, Varela-'049 discloses this limitation. EX1002, ¶¶305-307.

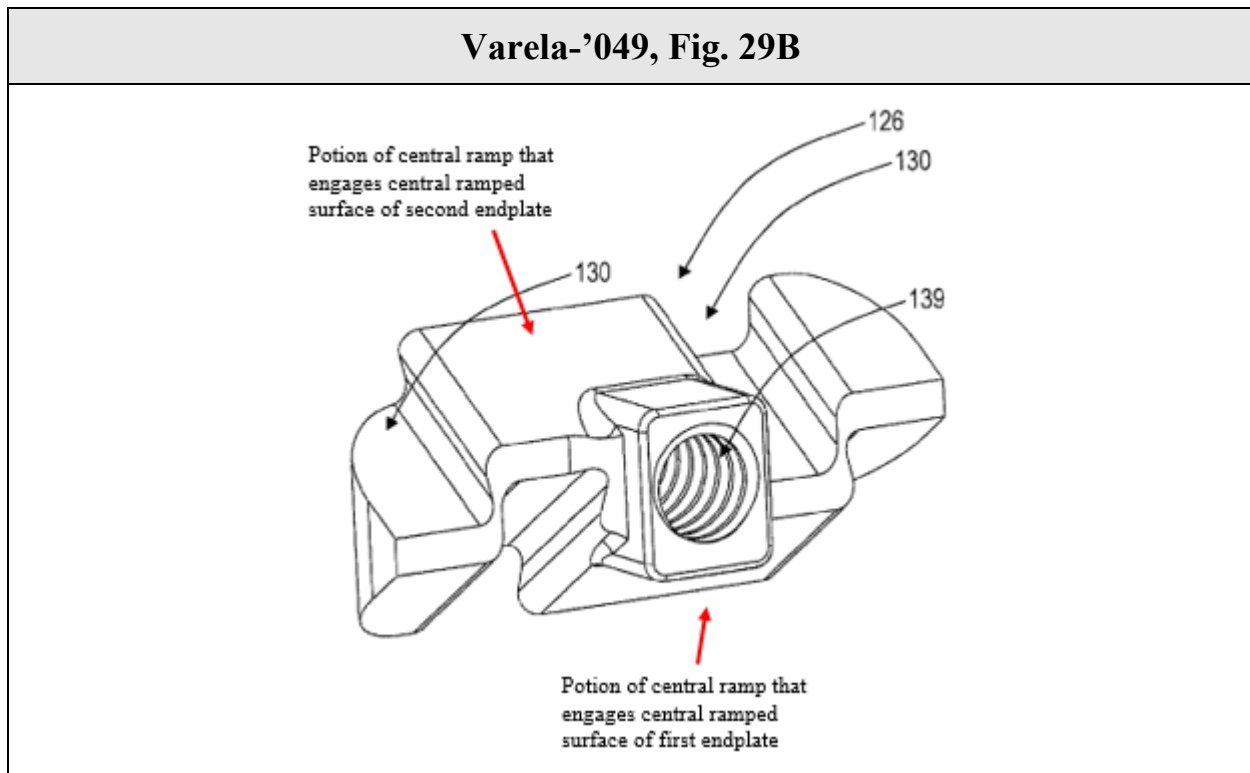
**(c) Claim 9[c]**

Claim 9 recites that “**the central ramped surface of the first endplate and...the central ramped surface of the second endplate are configured to engage the central ramp.**” Varela-'049 discloses that the central ramped surfaces of the first and second endplates engage with the central ramp. EX1032, Figs. 18A-B, 19A-B, 29A-B, 30A-B, ¶¶[0079], [0076] (the translation of proximal and distal wedge structures 125 and 126 “causes the proximal and distal wedge structures 125 and 126 to interact with the proximal and distal ramp portions 113, 115, 117, and 119”). Annotated Varela-'049 Figs. 18A and 29B follow.



**Varela-'049, Fig. 18A**





Accordingly, Varela-'049 discloses these limitations. EX1002, ¶¶308-310

#### **5. Claim 10**

Claim 10 is not materially distinguishable from Claim 8, and as previously discussed, Varela-'049 discloses these limitations. *See* §IX(C)(3); EX1002, ¶¶311-313.

#### **6. Claim 11**

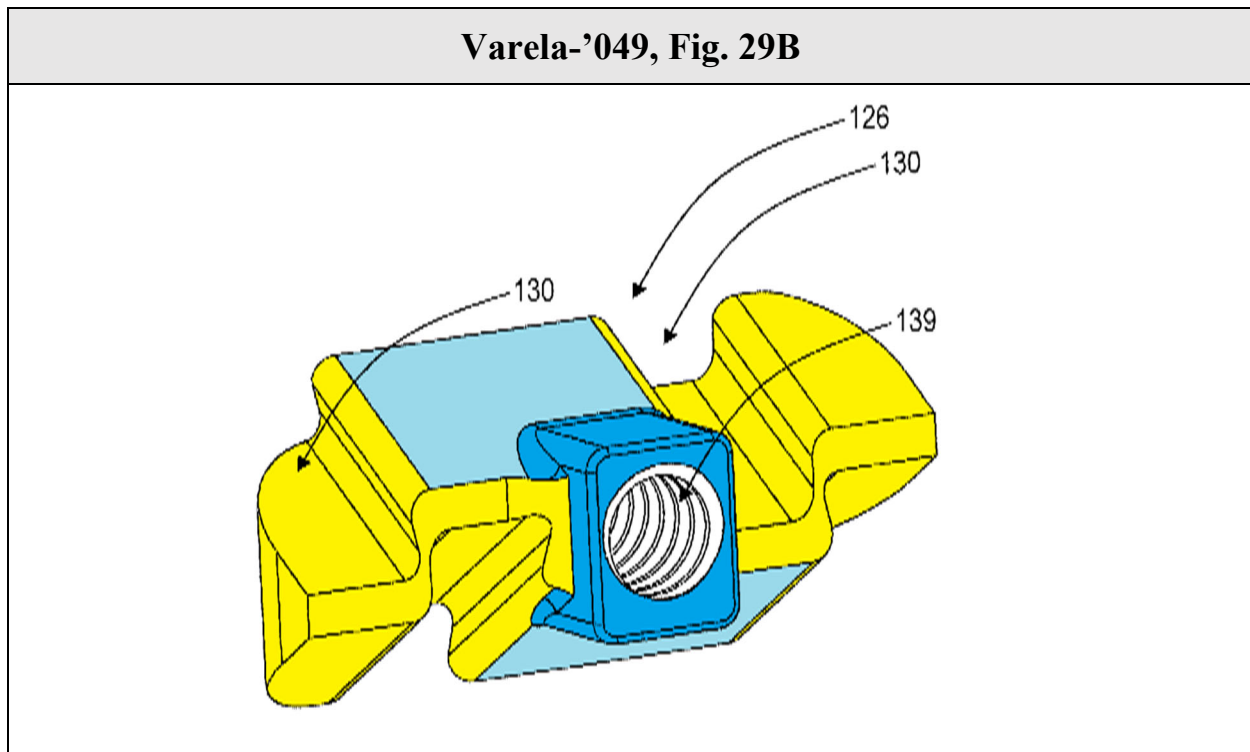
Claim 11 is not materially distinguishable from Claim 8, and as previously discussed, Varela-'049 discloses these limitations. *See* §IX(C)(3); EX1002, ¶¶314-316.

**7. Claim 12**

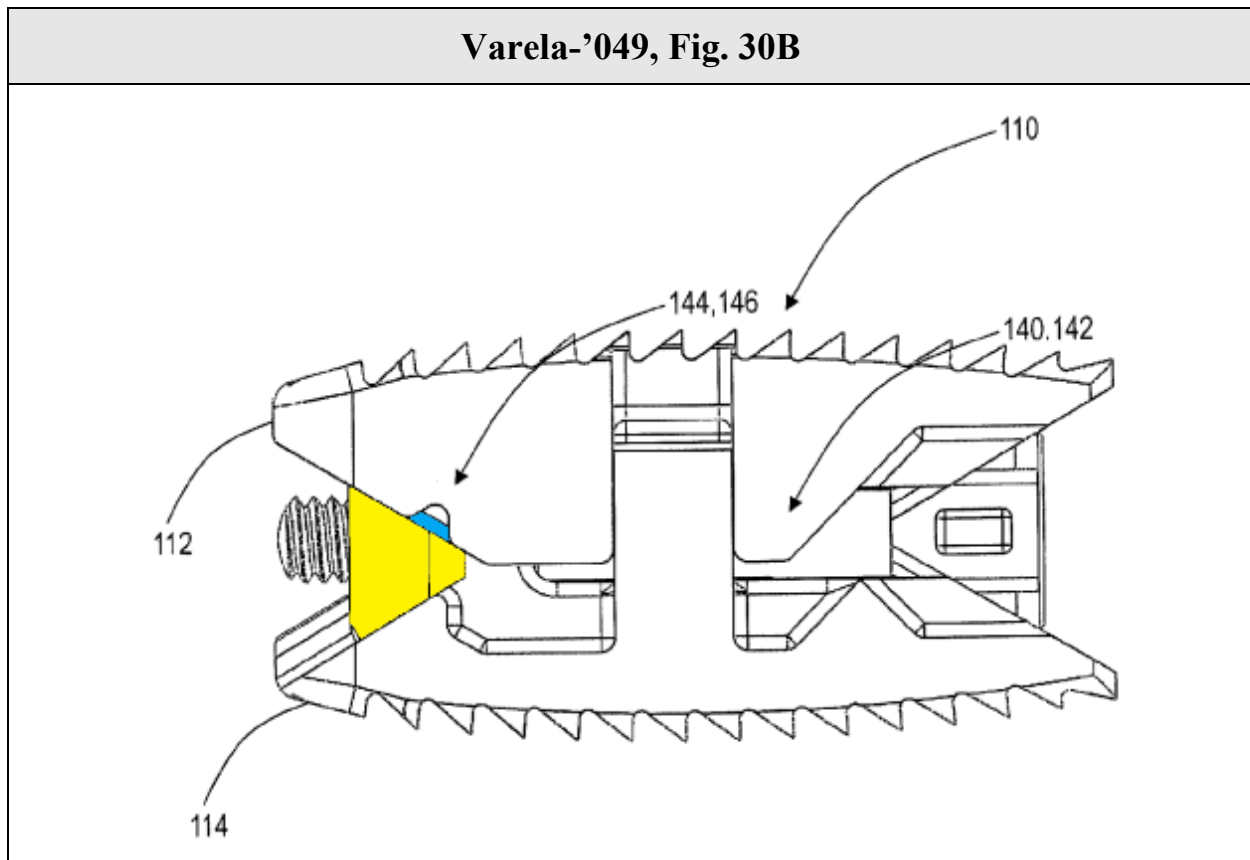
**(a) Claim 12[a]**

Claim 12 depends from Claim 7 and recites that **“the central ramp comprises a ramped expansion portion at one end of the intervertebral implant and a central ramp extension extending from the expansion portion.”**

Varela-’049 discloses that the central ramp/distal wedge structure 126 has an expansion portion in the form of a broad ramped surface to engage with distal ramp portions 117, 119. EX1032, ¶¶[0076], [0079], Figs. 21A-B, 28A-B, 29A-B, 30A-B. Varela-’049 further discloses a central ramp extension in the form of the protrusion surrounding the threaded bore 139, which further has ramped projections on the top and bottom of the ramp formed by the parallel recessed slot structures 130. *Id.*, Figs. 29A-B. These features can be seen in annotated Fig. 29B below, with the expansion portion in yellow, the central ramp extension in dark blue, and the extension’s projecting ramped surfaces in light blue.



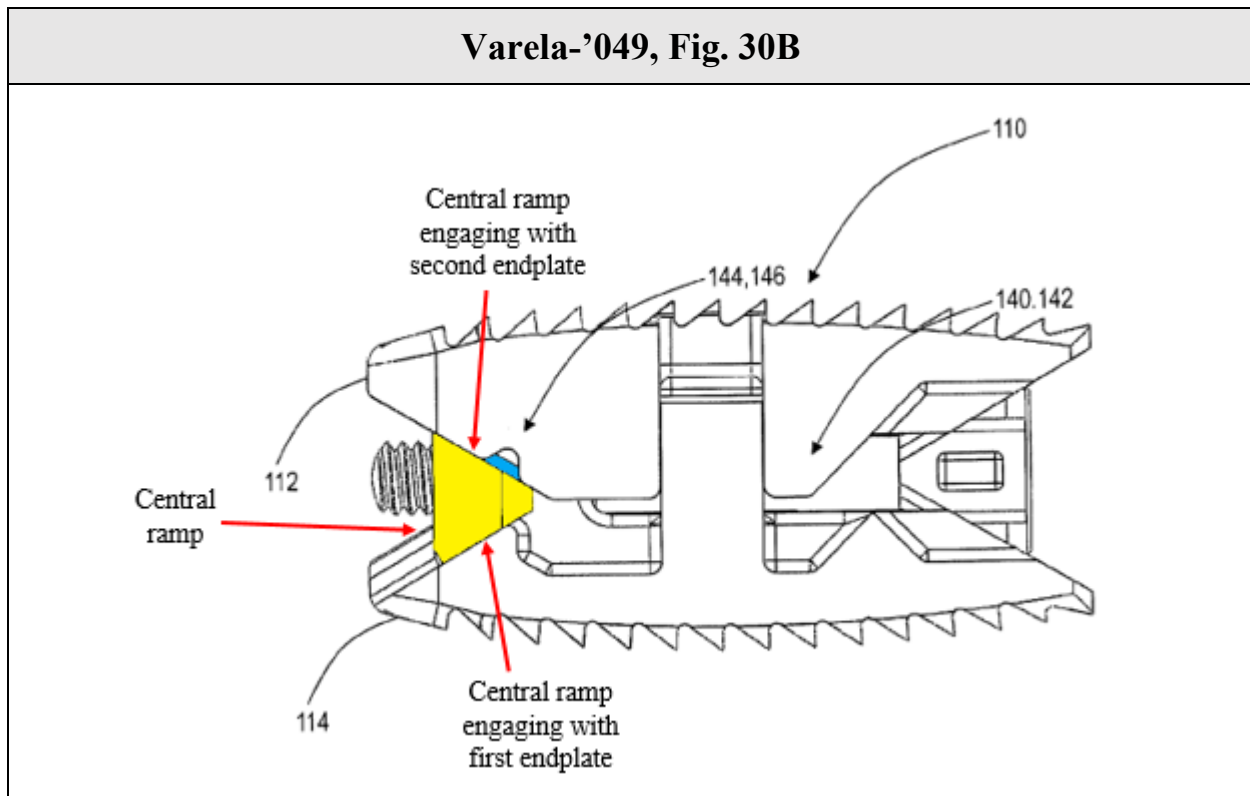
As seen in annotated Fig. 29B, above, and further seen in annotated Fig. 30B, below, the central ramp extension extends longitudinally from the expansion portion, with the structure surrounding threaded bore 139 extending toward the driving ramp and the central ramp extension's ramped projections formed by parallel recessed slot structures 130 extending outwardly to engage with first and second endplates (*see also id.*, ¶[0079]).



Accordingly, Varela-'049 discloses these limitations. EX1002, ¶¶317-320.

**(b) Claim 12[b]**

Claim 12 recites that “**the central ramp is configured to engage the first endplate and the second endplate.**” Varela-'049 discloses that the central ramp engages with the first and second endplate. EX1032, Figs. 18A-B, 19A-B, 29A-B, 30A-B, ¶¶[0079], [0076] (the translation of proximal and distal wedge structures 125 and 126 “causes the proximal and distal wedge structures 125 and 126 to interact with the proximal and distal ramp portions 113, 115, 117, and 119”). Annotated Fig. 30B follows for reference.



Accordingly, Varela-'049 discloses this limitation. EX1002, ¶¶321-323.

**8. Claim 13**

**(a) Claim 13[a]**

Varela-'049 with Lopez discloses this limitation. *See* §IX(C)(1)(a); EX1002, ¶324.

**(b) Claim 13[b]**

Varela-'049 with Lopez discloses this limitation. *See* §IX(C)(1)(b); EX1002, ¶¶325-326.

**(c) Claim 13[c]**

Varela-'049 with Lopez discloses this limitation. *See* §IX(C)(1)(c); EX1002, ¶¶327-328.

**(d) Claim 13[d]**

Varela-'049 with Lopez discloses this limitation. *See* §IX(C)(1)(d); EX1002, ¶¶329-330.

**(e) Claim 13[e]**

Varela-'049 discloses this limitation. *See* §IX(C)(2)(a); EX1002, ¶¶331-332.

**(f) Claim 13[f]**

Varela-'049 discloses this limitation. *See* §IX(C)(2)(b); EX1002, ¶¶333-334.

**(g) Claim 13[g]**

Varela-'049 discloses this limitation. *See* §IX(C)(3); EX1002, ¶¶335-336.

**(h) Claim 13[h]**

Varela-'049 discloses this limitation. *See* §IX(C)(1)(e); EX1002, ¶¶337-338.

**(i) Claim 13[i]**

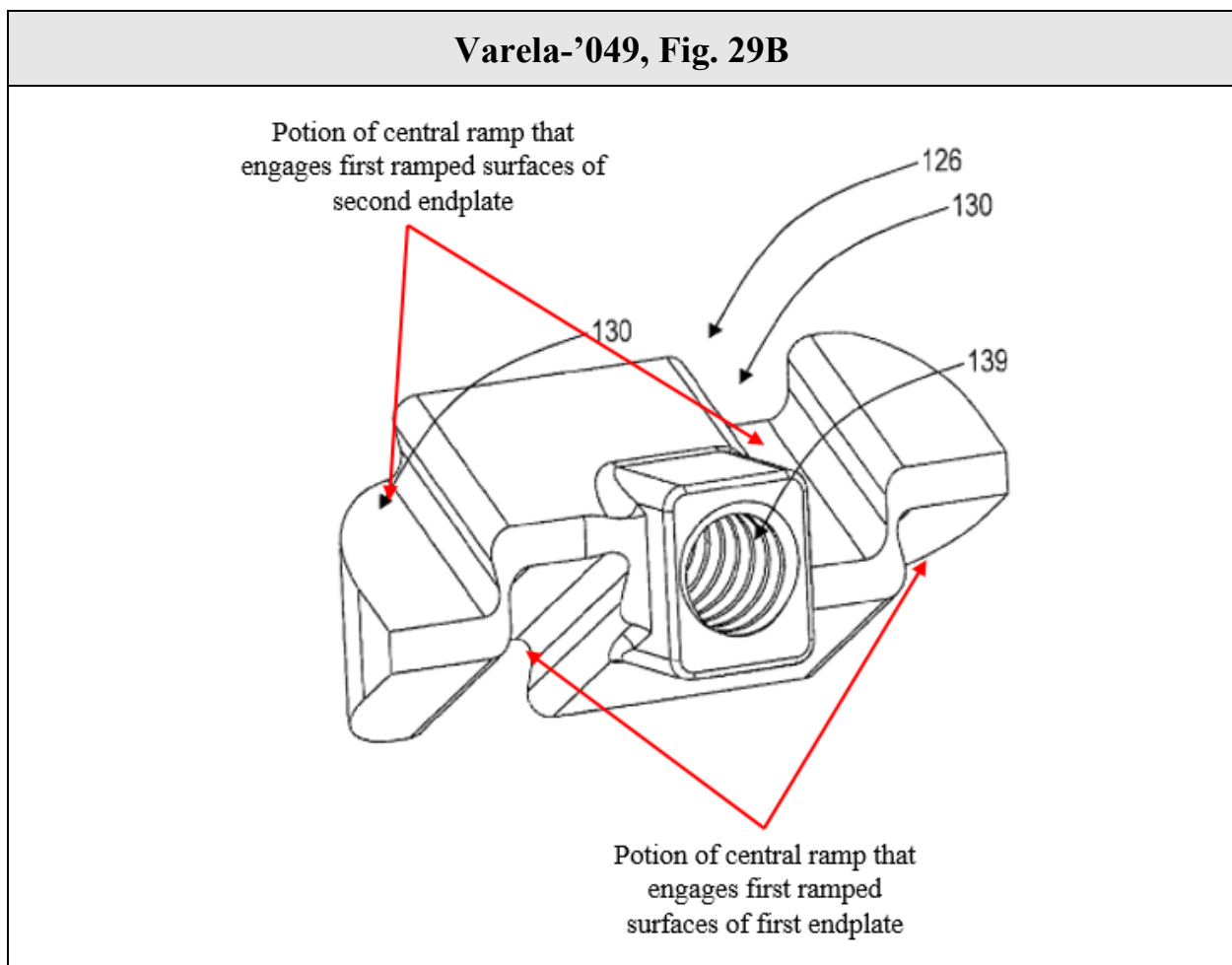
Claim 13 recites that **“the central ramp is configured to engage the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate.”** Varela-'049 discloses that the central ramp is configured to engage the first ramped surfaces of the first and second endplates. EX1032, Figs.

27A-B, 28A-B, 29A-B, 30A-B, 32A-B, ¶[0079]. Specifically, Varela-1012

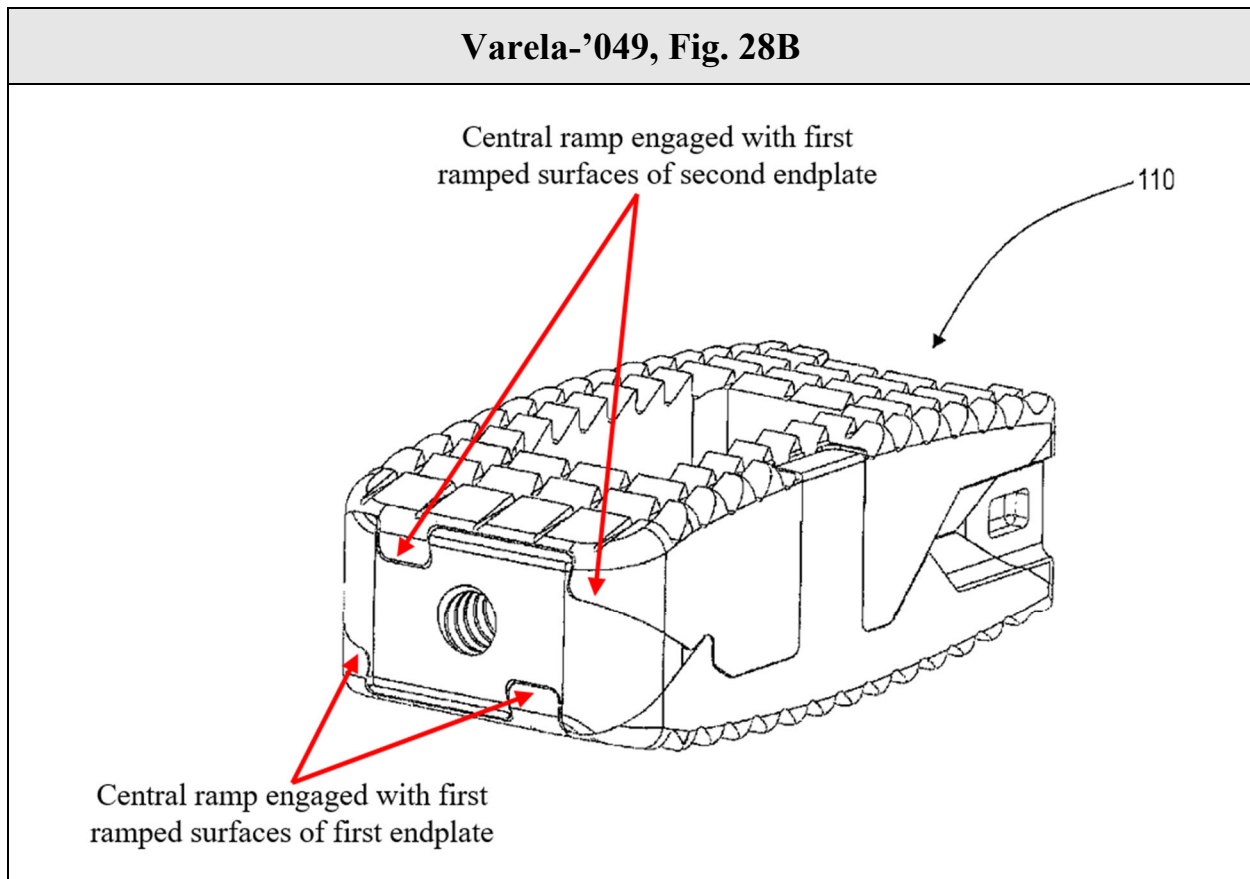
discloses:

Each of the proximal ramp portions 113 and 115 and the distal ramp portions 117 and 119 of the superior member 112 and the inferior member 114, respectively, includes one or more raised parallel rail structures 128...These raised parallel rail structures 128 are positioned and configured to engage corresponding recessed parallel slot structure 130 of the proximal and distal wedge structures 125 and 126.

*Id.*, ¶[0079]. Annotated Figs. 29B and 28B follow.







Accordingly, Varela-'049 discloses this limitation. EX1002, ¶¶339-341.

**(j) Claim 13[j]**

Claim 13 does not recite “an expansion portion of the central ramp,” thus rendering Claim 13 indefinite for lack of antecedent basis. However, assuming *arguendo* that this refers to Claim 12’s “ramped expansion portion,” this element is disclosed by Varela-'049. See §§IX(C)(1)(g), IX(C)(7)(a); EX1002, ¶¶342-344.

**(k) Claim 13[k]**

Varela-'049 discloses this limitation. See §§IX(C)(1)(h), IX(C)(1)(i); EX1002, ¶¶345-346.

**(l) Claim 13[l]**

Claim 13 does not recite “a central ramp extension,” thus rendering Claim 13 indefinite for lack of antecedent basis. However, assuming *arguendo* that this refers to Claim 12’s “central ramp extension,” this element is disclosed by Varela-’049. *See* §§IX(C)(1)(j), IX(C)(7)(a); EX1002, ¶¶347-349.

**(m) Claim 13[m]**

Varela-’049 discloses this limitation. *See* §§IX(C)(1)(f), IX(C)(1)(k), IX(C)(1)(l); EX1002, ¶¶350-351.

**(n) Claim 13[n]**

Varela-’049 discloses this limitation. *See* §IX(C)(1)(l); EX1002, ¶¶352-353.

**9. Claim 16**

**(a) Claim 16[a]**

Varela-’049 discloses this limitation. *See* §IX(C)(1)(a); EX1002, ¶354.

**(b) Claim 16[b]**

Varela-’049 with Lopez discloses this limitation. *See* §IX(C)(1)(b); EX1002, ¶¶355-356.

**(c) Claim 16[c]**

Varela-’049 with Lopez discloses this limitation, as discussed previously. *See* §IX(C)(1)(c); EX1002, ¶¶357-358.

**(d) Claim 16[d]**

Varela-'049 with Lopez discloses this limitation. *See* §IX(C)(1)(d); EX1002, ¶¶359-360.

**(e) Claim 16[e]**

Varela-'049 discloses this limitation. *See* §§IX(C)(2)(a), IX(C)(4)(a); EX1002, ¶¶361-362.

**(f) Claim 16[f]**

Varela-'049 discloses this limitation. *See* §§IX(C)(2)(b), IX(C)(4)(b); EX1002, ¶¶363-364.

**(g) Claim 16[g]**

Varela-'049 discloses this limitation, as discussed previously. *See* §IX(C)(1)(e); EX1002, ¶¶365-366.

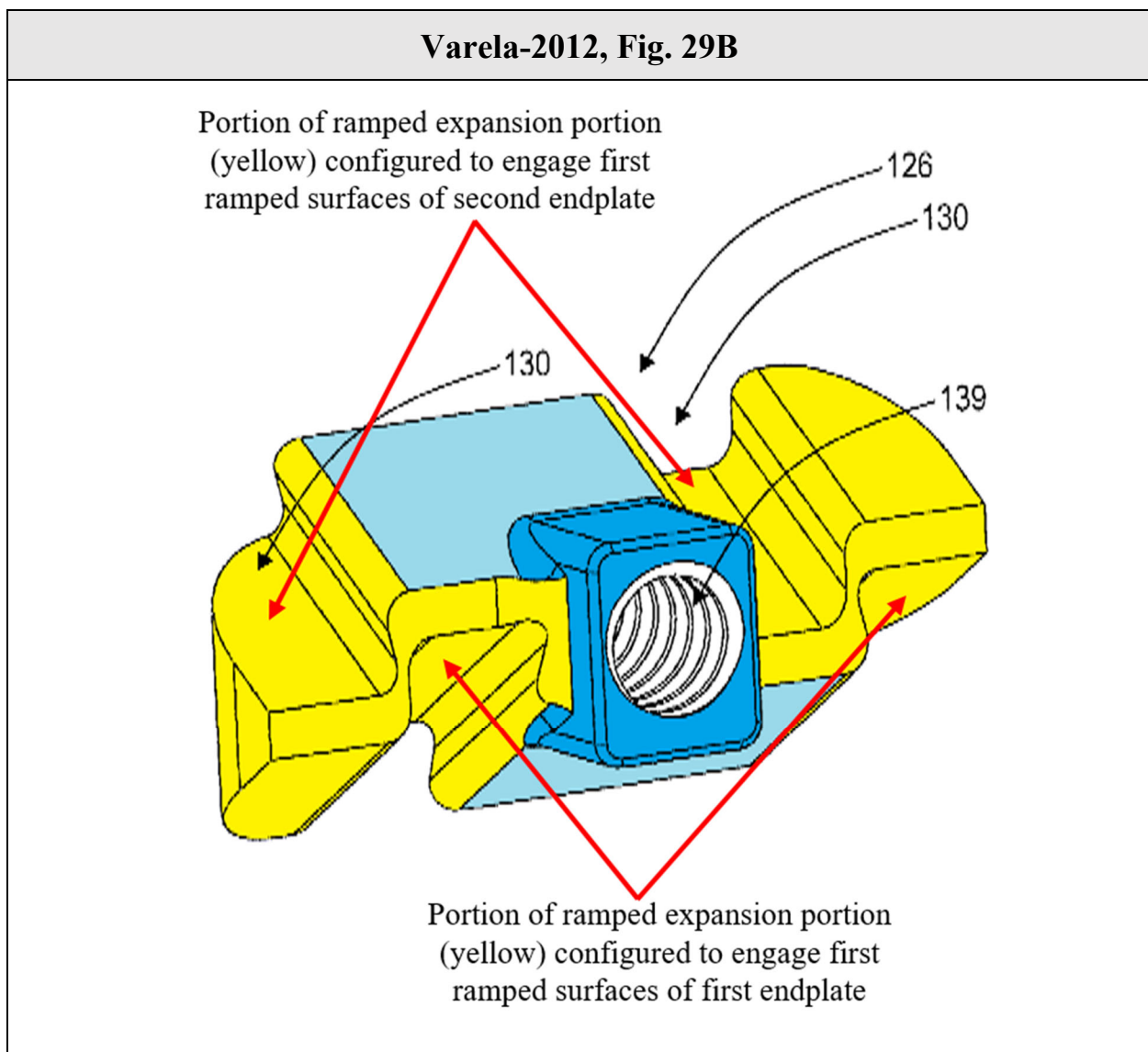
**(h) Claim 16[h]**

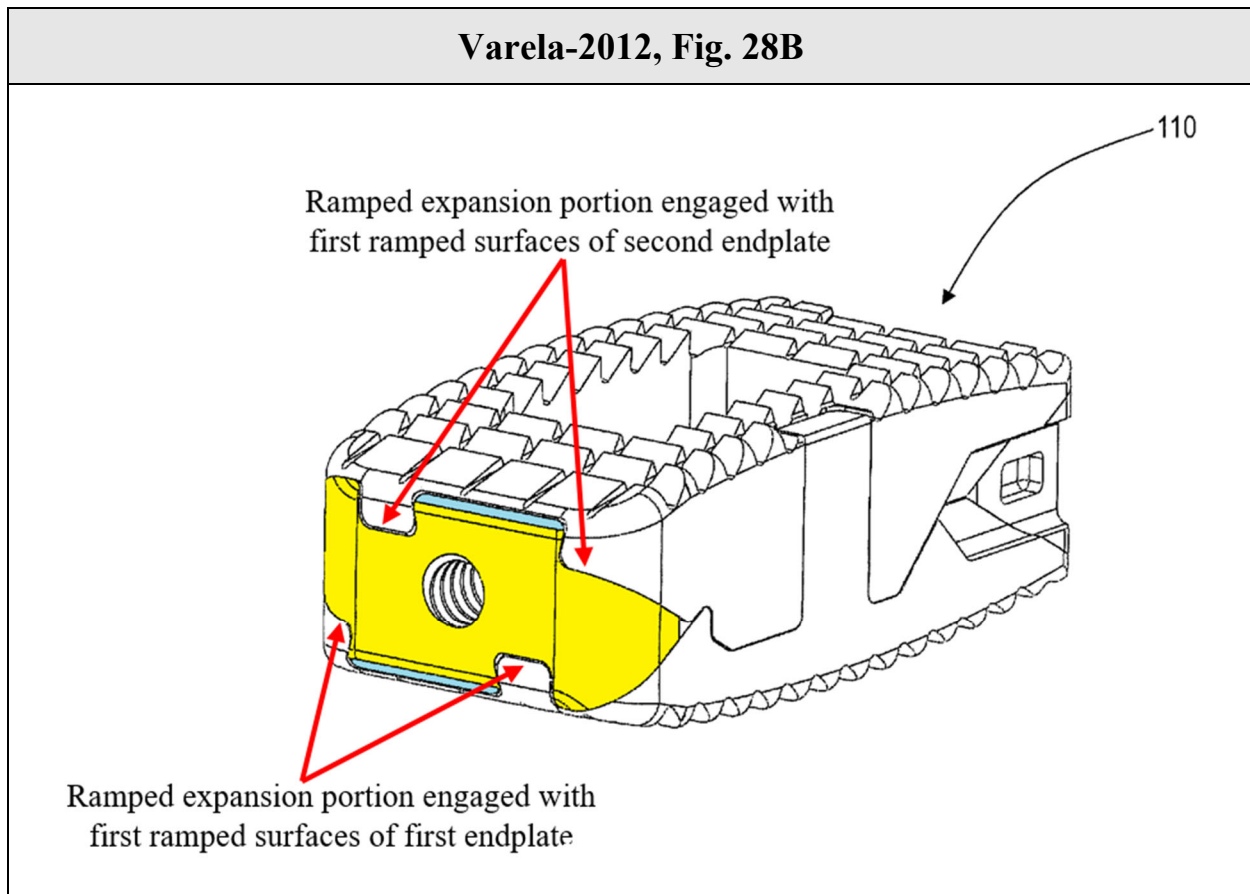
Varela-'049 discloses this limitation, as discussed previously. *See* §IX(C)(7)(a); EX1002, ¶¶367-368.

**(i) Claim 16[i]**

Claim 16 recites that “**the ramped expansion portion is configured to engage the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate.**” This limitation overlaps certain elements of Claims 12 and 13, which require the central ramp to be configured to engage the

ramped surfaces of the first and second endplates. *See* §§IX(C)(7)(a), IX(C)(8)(i), *supra*. As explained by Petitioner's expert, Varela-'049 discloses that the central ramp's ramped expansion portion is configured to engage the first ramped surfaces of the first and second endplates, as can further be seen in at least Figs. 18A-B, 19A-B, 29A-B, 30A-B. Annotated Figs. 29B and 30A follow for reference.



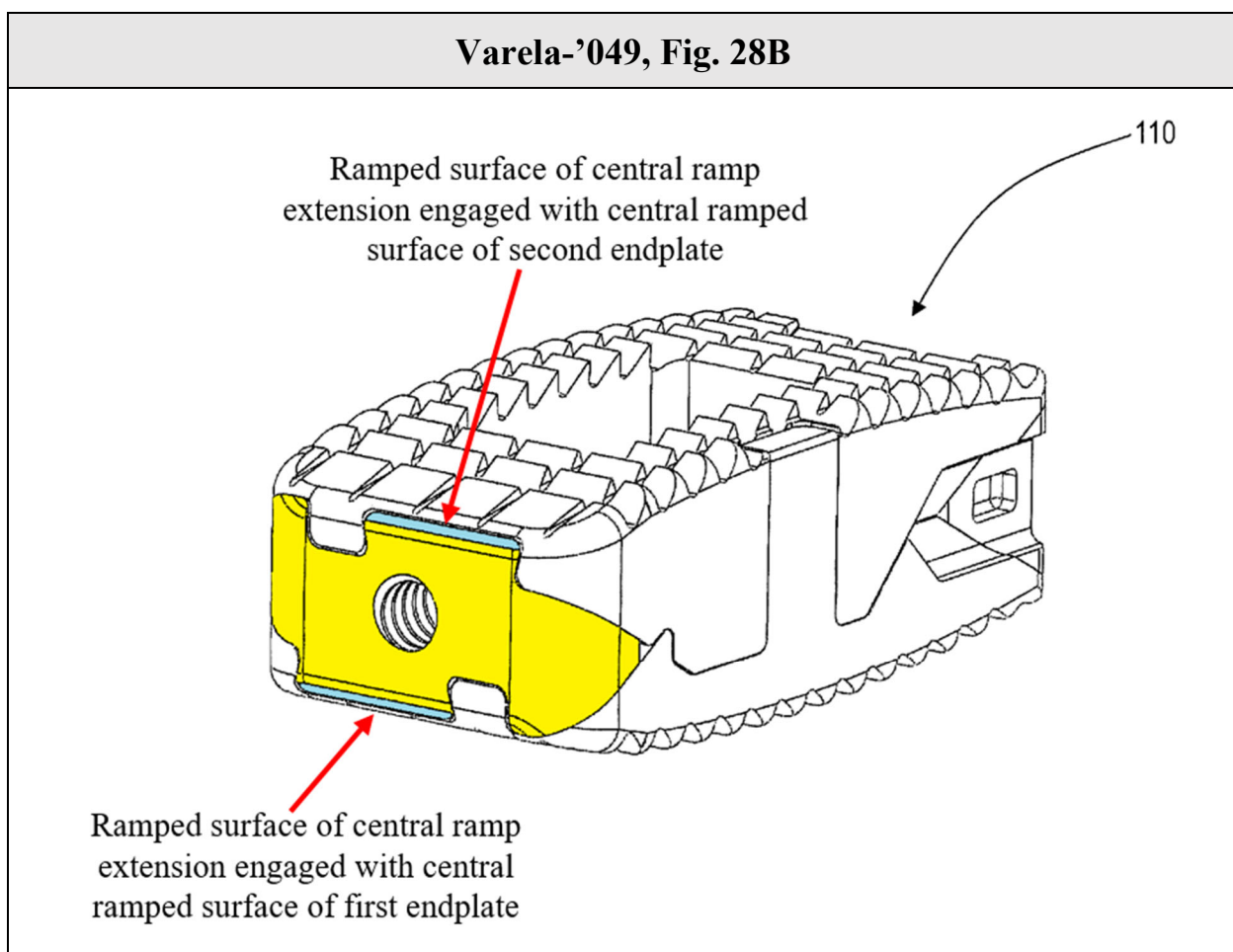


Accordingly, Lopez discloses this limitation. EX1002, ¶¶369-371.; *see also* §§IX(C)(7)(a), IX(C)(8)(i).

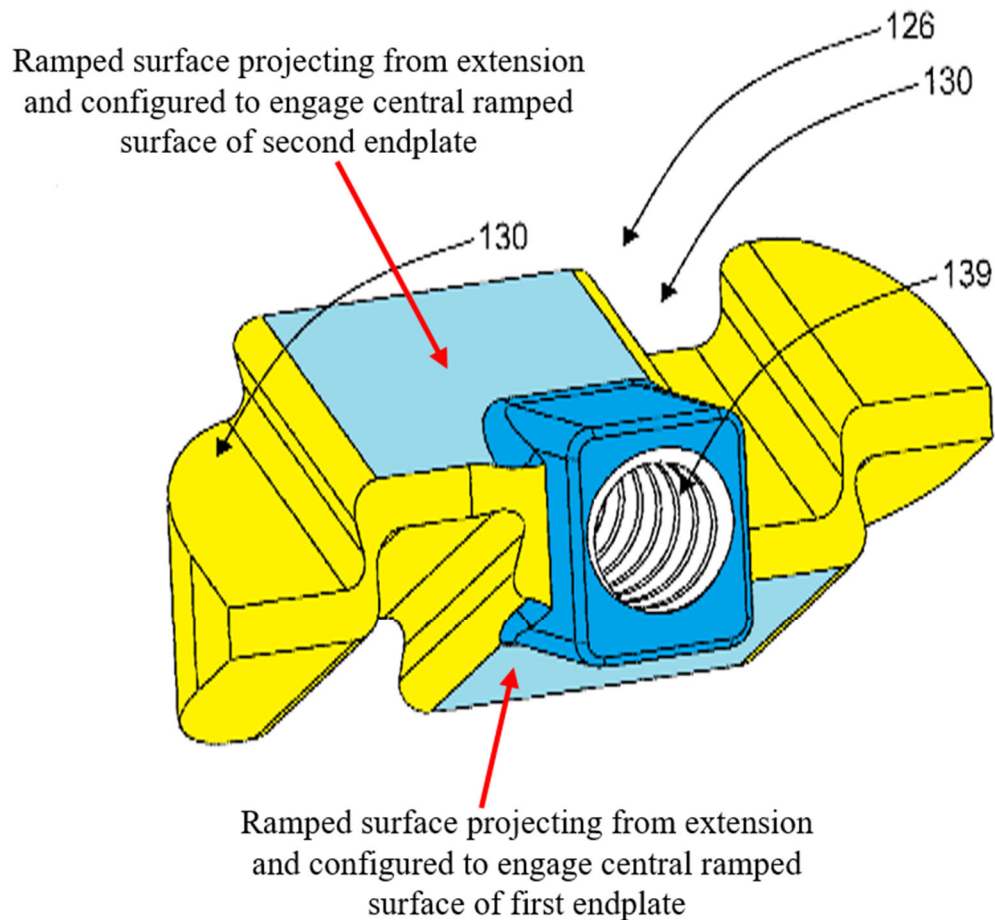
**(j) Claim 16[j]**

Claim 16 recites that “**the central ramp extension comprises ramped surfaces projecting from the central ramp extension and configured to engage the central ramped surface of the first endplate and the central ramped surface of the second endplate.**” Varela-’049 discloses a central ramp extension comprising ramped surfaces projecting from the central ramp extension and configured to engage the central ramped surfaces of the first and second endplates.

EX1032, Figs. 18A-B, 19A-B, 28A-B, 29A-B, 30A-B, ¶¶[0079], [0076]; *see also* §§IX(C)(7)(a)-(b). Specifically, the ramped surfaces formed by parallel recessed slot structures 130 project from the structure surrounding threaded bore 139 and are engaged with the central ramped surfaces of the first and second endplates. Annotated Figs. 28B and 29B showing this follow.



**Varela-'049, Fig. 29B**



Accordingly, Varela-'049 discloses this limitation. EX1002, ¶¶372-375.

**(k) Claim 16[k]**

Varela-'049 discloses this limitation. *See* §IX(C)(1)(g); EX1002, ¶¶376-377.

**(l) Claim 16[l]**

Varela-'049 discloses this limitation. *See* §IX(C)(1)(h); EX1002, ¶¶378-379.

**(m) Claim 16[m]**

Varela-'049 discloses this limitation. *See* §§IX(C)(8)(k), IX(C)(1)(i), IX(C)(2); EX1002, ¶¶380-382.

**(n) Claim 16[n]**

Varela-'049 discloses this limitation. *See* §§IX(C)(1)(j), IX(C)(7)(a); EX1002, ¶¶383-384.

**(o) Claim 16[o]**

Varela-'049 discloses this limitation. *See* §IX(C)(1)(k); EX1002, ¶¶385-386.

**10. Motivation to Combine**

A POSITA would have been motivated to combine Varela-'049 with the teachings of Lopez, specifically those related to the use of certain tools, such as dilators and cannulas, to create an access path to an intervertebral space and insert the intervertebral implant, with a reasonable expectation of success. A POSITA would have recognized that the device of Varela-'049 must be inserted into an intervertebral target site and that, as such, tools would be needed to create an access path to the site and to insert the device. EX1002, ¶390.

Notably, the use of dilators and cannulas to distract the vertebra to a desired height and guide the implant into the desired disc space was ubiquitous in the field of minimally invasive spinal surgery at the time of invention. For example, U.S. Patent Application Publication No. US 2009/0062833 A1 to Song (“Song”), which



is a prior art under 35 U.S.C. §§102(a)-(b), expressly discloses that numerous such methods and devices existed and described performing surgery “through a tube” or utilizing “tubes for percutaneous placement of interbody devices.” EX1032, ¶[0008]. Song further refers to U.S. Patent Application Publication No. US 2003/0176926 to Boehm et al. (“Boehm”), which Song describes as disclosing using “a sequence of serial dilators...to create a working channel.” *See id.* Song also notes that the tools are useful for “distracting the disc space, i.e. making the space between the discs wider.” *Id.*, ¶[0004].

A POSITA therefore would have been aware of the use of dilators and cannulas in the field and further would have been motivated to consider and follow the teachings of prior art references providing specific examples of such tools to implement the Varela-’049 system, including Lopez. EX1002, ¶¶388-389.

Furthermore, at least because use of the tools to create an access path to the intervertebral space was ubiquitous in the field of minimally invasive spinal surgery, a POSITA would have had a reasonable expectation of success in using such tools, including specifically dilators and cannulas, in Lopez’s system, including using a cannula to insert the Varela-’049 device into the intervertebral disc space through the cannula. EX1002, ¶¶388, 392-394.

Furthermore, a POSITA would have had a reasonable expectation of success in doing so given the similarities between the Varela-’049 device and the Lopez

devices. For example, like Varela-'049, Lopez discloses an intervertebral implant that is inserted into a disc space for purposes of intervertebral fusion. *E.g.*, EX1031, 1:60-2:16, 2:61-40, 19:54-62 (further describing the implant as expandable). A POSITA would have reasonably understood and expected that means for creating an access path into an intervertebral disc space for one such device (Lopez) would also work for another, similar device (Varela-'049). EX1002, ¶395.

Thus, it would have been obvious to a POSITA to combine the teachings of Lopez regarding the use of dilators and cannulas with Varela-'049. EX1002, ¶¶387-397.

## **X. DISCRETIONARY DENIAL IS NOT WARRANTED**

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

Regarding §325(d), the '732 patent has not previously been challenged at the PTAB. Lopez and Varela-'049 were not cited or considered during prosecution.

Baynham was submitted in an Information Disclosure Statement, (EX1004, 000018), but was not otherwise considered by the Examiner.

To the extent the disclosure of Lopez overlaps with that of Olmos, the Examiner rejected then-pending claims 1, 2, 7-15 and 17, among other bases, over Olmos in view of U.S. Patent Publication No. 2003/0176926 to Boehm.

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

Discretionary denial is not warranted here. Olmos discloses a driving ramp fixed to the actuator during rotation (wherein the central ramp is moved forwards or backwards depending on the direction of rotation), contrary to the Applicant's statements during prosecution. Applicant amendment and subsequent allowance show that this feature was the Examiner's basis for allowance. Yet, there is no evidence that the Examiner appreciated Olmos' disclosure of this feature (EX1006, ¶[0159]) when allowing the claims. Accordingly, *Becton Dickenson* factors (c)-(f)

disfavor denial under §325(d) given the facts noted above and the new light in which Olmos has been presented here. *Volkswagen Group of America, Inc. v. Michigan Motor Technologies LLC*, IPR2020-00452, Paper 12, 32-33 (finding §325(d) denial unwarranted where examiner “fail[ed] to fully consider” specific embodiment in cited reference).

Second, this Petition independently relies on Varela-’049 for an even more express teaching of this claim feature. *E.g., supra* §IX(C)(1)(l). Thus, to the extent Olmos is somehow determined to not expressly disclose this feature and Lopez’s disclosure overlaps with Olmos’ disclosure, Varela-’049 fills any remaining gap and is not cumulative to Olmos. Lopez and Varela-’049 also disclose other relevant features of the challenged claims, such as an unthreaded opening in the driving ramp, and various claimed features specific to the actuator screw not as clearly taught in Olmos. *E.g., supra* §§IX(A)(1)(j)-(l), IX(C)(1)(j)-(l). And both Lopez and Varela-’049 were **not** before the Examiner during prosecution.

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

## **XI. CONCLUSION**

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

Respectfully submitted,

Dated: October 14, 2022

By: s/Michael R. Houston/

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

## APPENDIX: CHALLENGED CLAIM LISTING

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

<b>Claim No.</b>	<b>Limitation</b>
7[a]	The system of claim 1, wherein first endplate comprises a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the first endplate proximate the first end, second ramped surfaces on either side of the first endplate proximate the second end, and
7[b]	wherein the second endplate comprises a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the second endplate proximate the first end, second ramped surfaces on either side of the second endplate proximate the second end.
8	The system of claim 7, wherein, when the intervertebral implant is in an unexpanded configuration, the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate overlap, and the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate overlap.
9[a]	The system of claim 7, wherein the first endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the first endplate,
9[b]	wherein the second endplate further comprises a central ramped surface disposed between the first and second ramped surfaces of the second endplate, and
9[c]	wherein the central ramped surface of the first endplate and wherein the central ramped surface of the second endplate are configured to engage the central ramp.
10	The system of claim 7, wherein, when the intervertebral implant is in an unexpanded configuration, the first ramped surfaces of the first endplate overlap the first ramped surfaces of the second endplate, and the second ramped surfaces of the second endplate overlap the second ramped surfaces of the first endplate.

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



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

<b>Claim No.</b>	<b>Limitation</b>
16[c]	a cannula having a proximal end and a distal end; and
16[d]	an intervertebral implant sized for insertion into an intervertebral space through the cannula
16[e]	wherein the intervertebral implant comprises: a first endplate comprising a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the first endplate proximate the first end, second ramped surfaces on either side of the first endplate proximate the second end, and a central ramped surface disposed between the first and second ramped surfaces;
16[f]	a second endplate comprising a first end, a second end, an upper surface connecting the first end and the second end, first ramped surfaces on either side of the second endplate proximate the first end, second ramped surfaces on either side of the second endplate proximate the second end, and a central ramped surface disposed between the first and second ramped surfaces;
16[g]	a central ramp disposed between the first endplate and the second endplate,
16[h]	wherein the central ramp comprises a ramped expansion portion at one end of the intervertebral implant and a central ramp extension extending from the expansion portion,
16[i]	wherein the ramped expansion portion is configured to engage the first ramped surfaces of the first endplate and the first ramped surfaces of the second endplate, and
16[j]	wherein the central ramp extension comprises ramped surfaces projecting from the central ramp extension and configured to engage the central ramped surface of the first endplate and the central ramped surface of the second endplate;
16[k]	a driving ramp disposed between the first endplate and the second endplate at an opposite end of the intervertebral implant from the expansion portion of the central ramp,
16[l]	wherein the driving ramp has a longitudinal through bore,

<b>Claim No.</b>	<b>Limitation</b>
16[m]	wherein the driving ramp is configured to engage the second ramped surfaces of the first endplate and the second ramped surfaces of the second endplate; and
16[n]	an actuation member comprising a head portion and an actuation member extension that extends through the longitudinal through bore of the driving ramp to be received within an opening in the central ramp extension,
16[o]	wherein rotational movement of the actuation member in the first direction pulls the central ramp and the driving ramp towards one another.

**CERTIFICATE OF WORD COUNT**

The undersigned certifies that the foregoing Petition complies with the requirements of 37 C.F.R. § 42.24. Excluding the portions exempted by 37 C.F.R. § 42.24(a) (a table of contents, a table of authorities, a listing of facts which are admitted, denied, or cannot be admitted or denied, a certificate of service or word count, or appendix of exhibits), the Petition contains 11,553 words as counted by the word processing system used to prepare it.

By: s/Michael R. Houston/

Michael R. Houston

Reg. No. 58,486

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 directed to the attorneys of record for the patent at the following address:

Globus Medical, Inc.  
Valley Forge Business Center  
2560 General Armistead Avenue  
Audubon, PA 19403

October 14, 2022

By: s/Michael R. Houston/

Michael R. Houston

Reg. No. 58,486

Counsel for Petitioner