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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPINAL ELEMENTS, INC.,
Petitioner,

v.

SPECTRUM SPINE IP HOLDINGS, LLC
Patent Owner.

PGR2021-00050
Patent 10,709,575

PETITION FOR POST GRANT REVIEW OF U.S. PATENT 10,709,575

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 10,709,575 B2 to Robinson
1002	File History of U.S. Patent No. 10,709,575
1003	Expert Declaration of Brad Culbert
1004	U.S. Patent No. 8,382,842 B2 to Greenhalgh et al.
1005	U.S. Patent No. 8,852,279 B2 to Weiman
1006	U.S. Patent No. 8,062,375 B2 to Glerum et al.
1007	U.S. Patent No. 8,343,224 B2 to Lynn et al.
1008	U.S. Patent Publication 2007/0270968 A1 to Baynham
1009	U.S. Patent No. 8,216,316 B2 to Kirschman
1010	U.S. Patent Publication No. US2009/0222100 A1 to Cipoletti et al.
1011	U.S. Patent No. D566,276 S to Blain
1012	U.S. Patent Application 15/666,103 to Robinson
1013	U.S. Patent No. 8,398,713 B2 to Weiman
1014	Definition of “key” – Google’s English dictionary provided by Oxford Languages
1015	Definition of “keyed” – Google’s English dictionary provide by Oxford Languages
1016	File History of U.S. Patent Application No. 14/878,929 to Robinson
1017	Curriculum vitae of Brad Culbert
1018	Opticage® Expandable Interbody Fusion Device brochure

Exhibit No.	Description
1019	U.S. Patent No. 8,105,382 to Olmos et al.
1020	U.S. Patent No. 8,568,481 to Olmos et al.

Spinal Elements, Inc. ("Petitioner") requests post grant review ("PGR") of claims 1-9 ("Challenged Claims") of U.S. Patent 10,709,575 ("the '575 patent") (Ex. 1001) purportedly owned by Spectrum Spine IP Holdings, LLC ("Patent Owner").

I. INTRODUCTION

The human spine is comprised of vertebrae, which may become damaged and require surgical implants for supplemental support. The '575 patent describes expandable cage assemblies for supporting adjacent vertebrae. A surgeon inserts the unexpanded cage assembly (Figure 8A) between damaged vertebrae, and then expands the assembly (Figure 8B) to support the surrounding vertebrae.

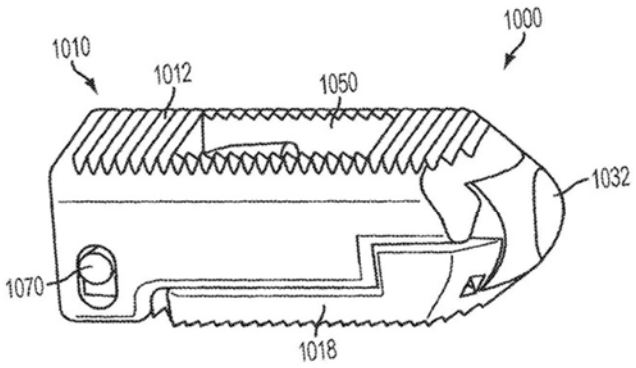


FIG. 8A

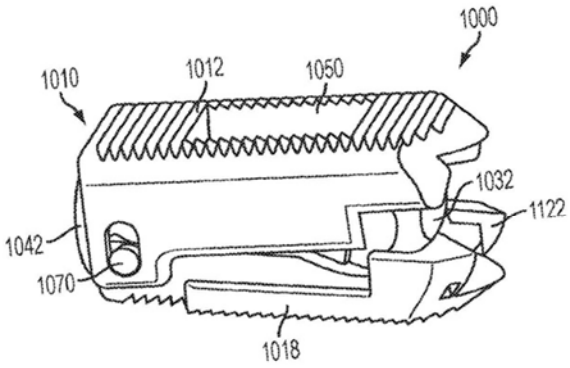


FIG. 8B

The cage assembly has a window extending vertically through the device, which the surgeon may pack with bone graft material to stimulate bone growth between the damaged vertebrae. Over time, the bone growth fuses the vertebrae together and creates long-term stability.

The '575 patent does not expressly identify the patent's alleged contribution to the art. The patent generically asserts that there "is a need for improved systems

and methods for lumbar interbody fusion." The patent alleges that some prior art repair devices inhibited normal movement of the spine. The patent also recognizes the benefits of using bone graft material to stimulate bone growth. However, expandable cages for repairing damaged vertebrae were well known before Patent Owner filed the '575 patent, as were expandable cages having windows for bone graft material.

Greenhalgh is a prior art patent that describes an expandable support device for repairing damaged vertebrae in a spine. The surgeon inserts Greenhalgh's unexpanded support device (Figure 2A) between the damaged vertebrae and then expands the device (Figure 3A) to support the vertebrae.

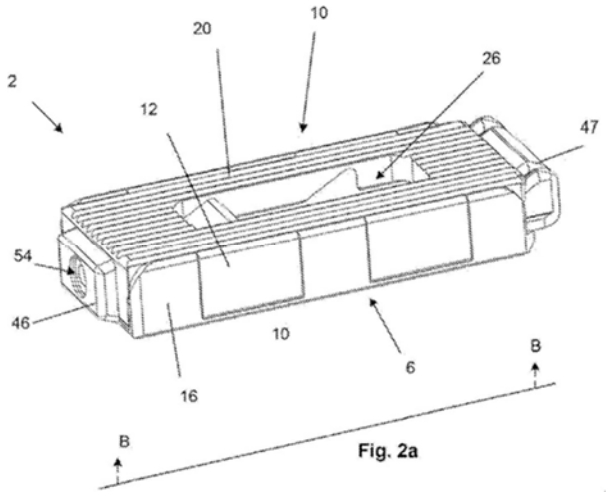


Fig. 2a

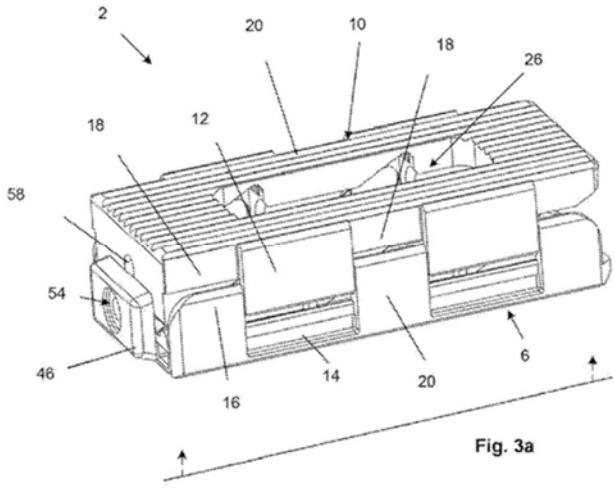


Fig. 3a

Greenhalgh's device includes a vertical window that the surgeon may pack with bone graft material to stimulate bone growth between the vertebrae.

Weiman is another prior art patent that describes an expandable fusion device for repairing damaged vertebrae in the spine. The surgeon inserts Weiman's

unexpanded support device (Figure 59) between the damaged vertebrae and then expands the device (Figure 60) to support the vertebrae.

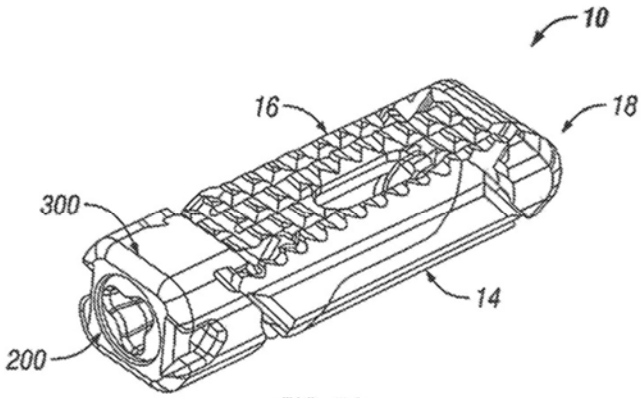


FIG. 59

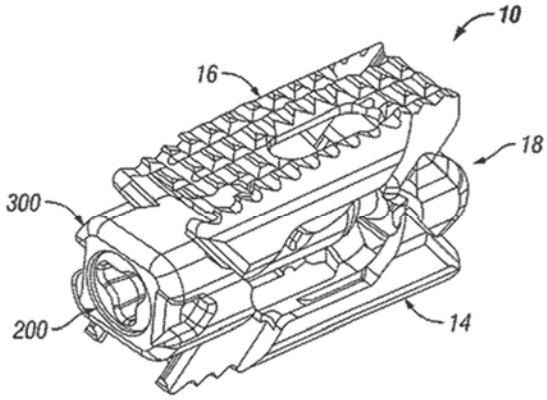


FIG. 60

Weiman's device includes a vertical window that the surgeon may pack with bone graft material to stimulate bone growth between the vertebrae.

Glerum is another prior art patent that discloses an expandable fusion device for repairing damaged vertebrae in the spine. As in Greenhalgh and Weiman, the surgeon inserts Glerum's unexpanded support device (Figure 5) between the damaged vertebrae and then expands the device (Figure 6) to support the vertebrae.

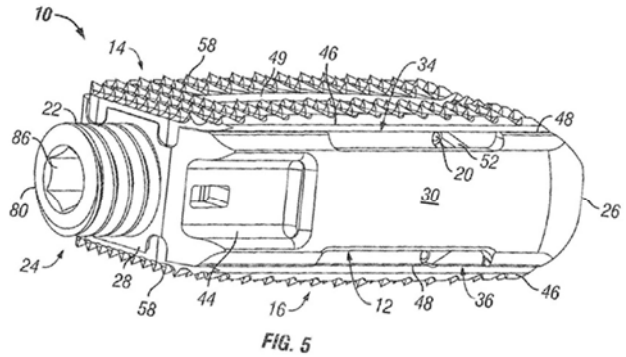


FIG. 5

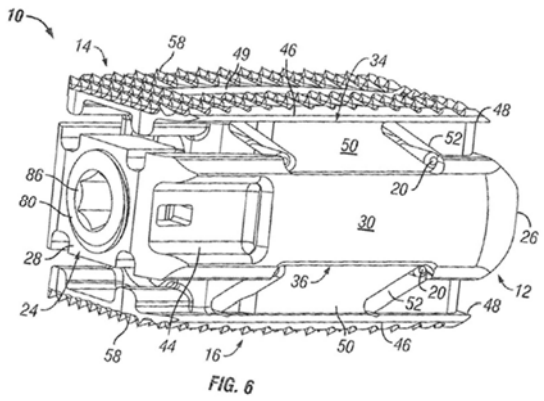


FIG. 6

Glerum's device also includes a vertical window that the surgeon may pack with bone graft to stimulate bone growth between the vertebrae.

Greenhalgh, Weiman, and Glerum disclose the limitations of the Challenged Claims, thereby rendering those claims unpatentable as anticipated or obvious. For the reasons below, the Board should institute this IPR to cancel the Challenged Claims.

II. ’575 PATENT

A. Overview

The ’575 patent describes expandable cage assemblies for supporting adjacent vertebrae of a spine. (Ex. 1001, 4:16-29.) The cage assemblies include a generally elongate cage body 1010 [red] and an expander 1032 [purple]. (*Id.*, 4:37-39.)[1]

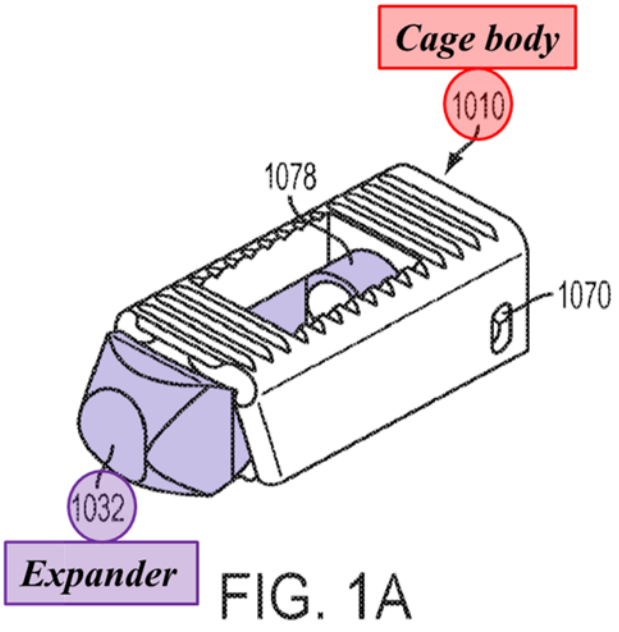


FIG. 1A

The cage body 1010 has an upper portion 1012 [blue] and a lower portion 1018 [green]. (*Id.*, 4:40-42.)

[1] Color and labels added to the figures in this petition unless otherwise noted.

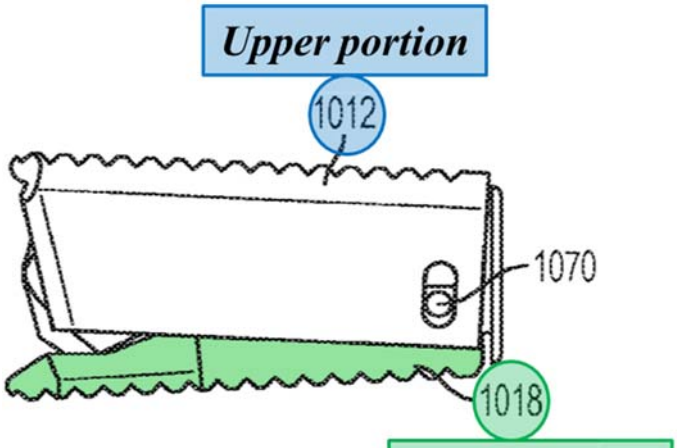


FIG. 2B

The space between the upper and lower portions forms an "internal cavity, space, or channel" that extends lengthwise through the cage body. (*Id.*, 4:46-48.) The expander 1032 [purple] fits within the internal cavity, space, or channel formed by the upper and lower portions of the cage body. (*Id.*, 4:56-65.) As illustrated in Figures 8A-8B, pulling the expander 1032 proximally into the internal cavity causes the expander to act upon the upper and lower portions to expand the cage body. (*Id.*, 5:23-26.)

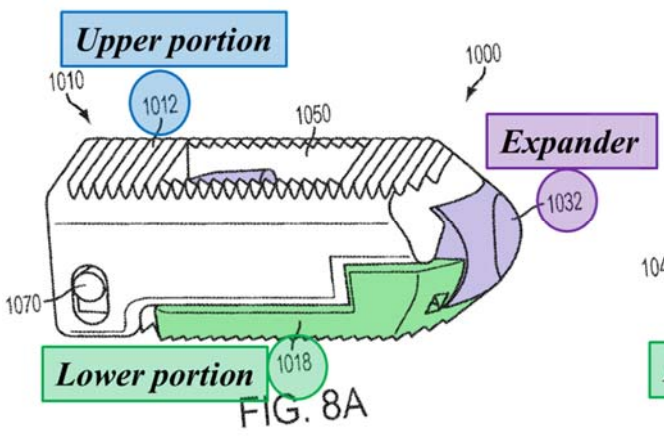


FIG. 8A

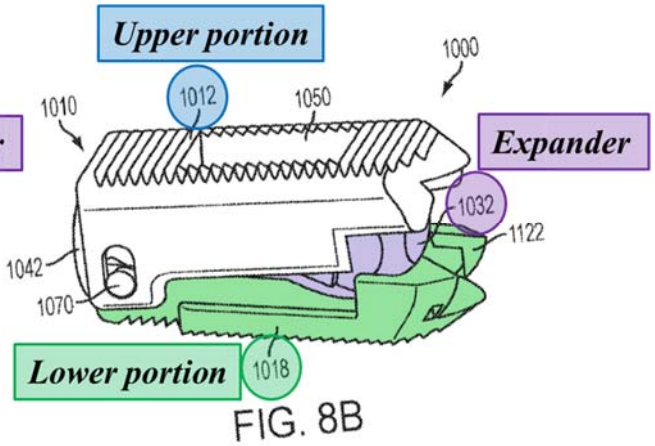


FIG. 8B

The proximal end 1078 of the expander 1032 [purple] includes a "socket or other feature" to receive the distal end of an insertion tool 1060 (not shown below). (*Id.*, 5:2-4.) The surgeon uses the insertion tool to pull the expander 1032 proximally (to the left in Figures 8A-8B above, to the right in Figures 15, 19 below) to expand the cage body. (*Id.*, 5:4-6.) Alternatively, the proximal (or trailing) end 1078 [purple] of the expander 1032 may receive an actuating screw 1090 [orange]. (*Id.*, 6:59-62.) Rotating the actuation screw pulls the elongate expander proximally to expand the cage body. (*Id.*, 6:64-67.)

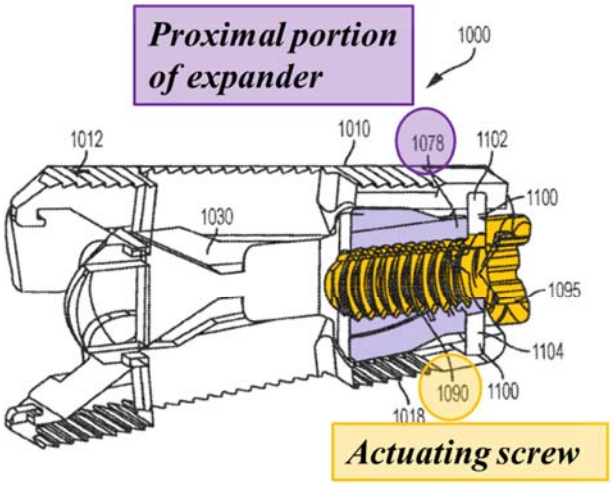


FIG. 15

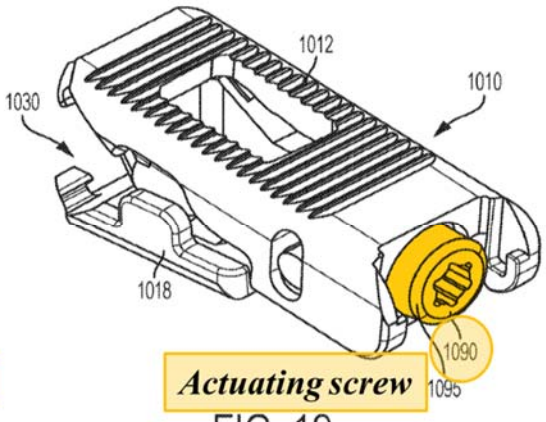


FIG. 19

The cage body also has windows 1050 [yellow] in the upper portion, lower portion, and elongate expander. (*Id.*, 4:48-50.) The windows align to form a cavity in the device. (*Id.*) The surgeon may pack the windows in the cage body with bone fusion material before the device is implanted. (*Id.*, 6:34-39, 7:50-56.) Alternatively,

the actuation screw may be cannulated and "bone fusion material may be inserted post expansion via the internal passageway of the actuating screw." (*Id.*, 7:53-56.)

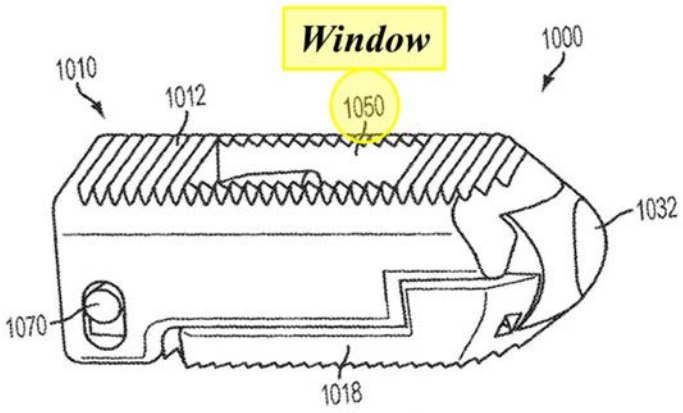


FIG. 8A

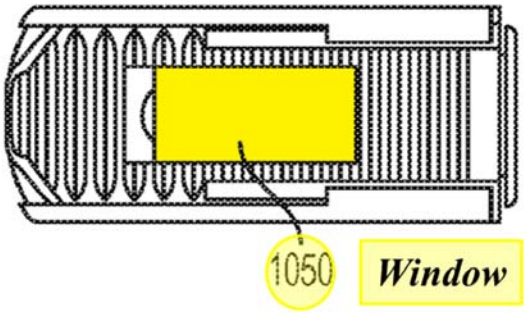


FIG. 5B

The "cage body 1010 … may also include a set screw 1042 [pink] for insertion into the proximal portion 1078 of the keyed shim." (*Id.*, 5:34-36.) "The set screw 1042 … may be sized and shaped to retain the expander 1032 firmly within its final position" and contain the fusion material within the cage assembly. (*Id.*, 5:39-45.)

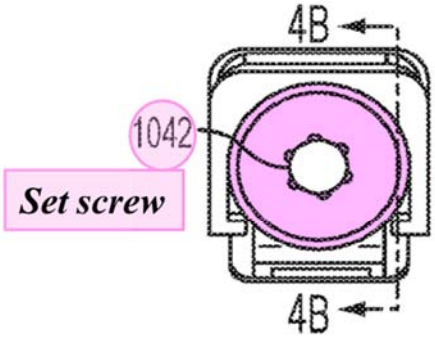


FIG. 3B

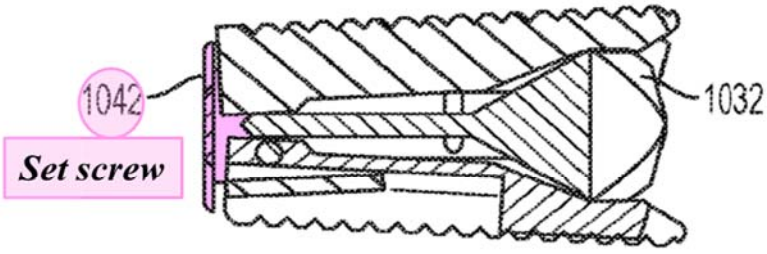


FIG. 4B

B. Prosecution History

Some of the Challenged Claims had different claim numbers during prosecution. The table below correlates the Challenged Claims to the Prosecution Claims.

Challenged Claims	Prosecution Claims
1-3	1-3
4	7
5	8
6	9
7	10
8	4
9	5

Prosecution Claims 1-6 of the ’575 patent were rejected as being anticipated by U.S. Patent Publication 2007/0270968 (“Baynham”). (Ex. 1002, 73-76; Ex. 1008.) The Examiner identified certain claim limitations in the Baynham device, as shown below.

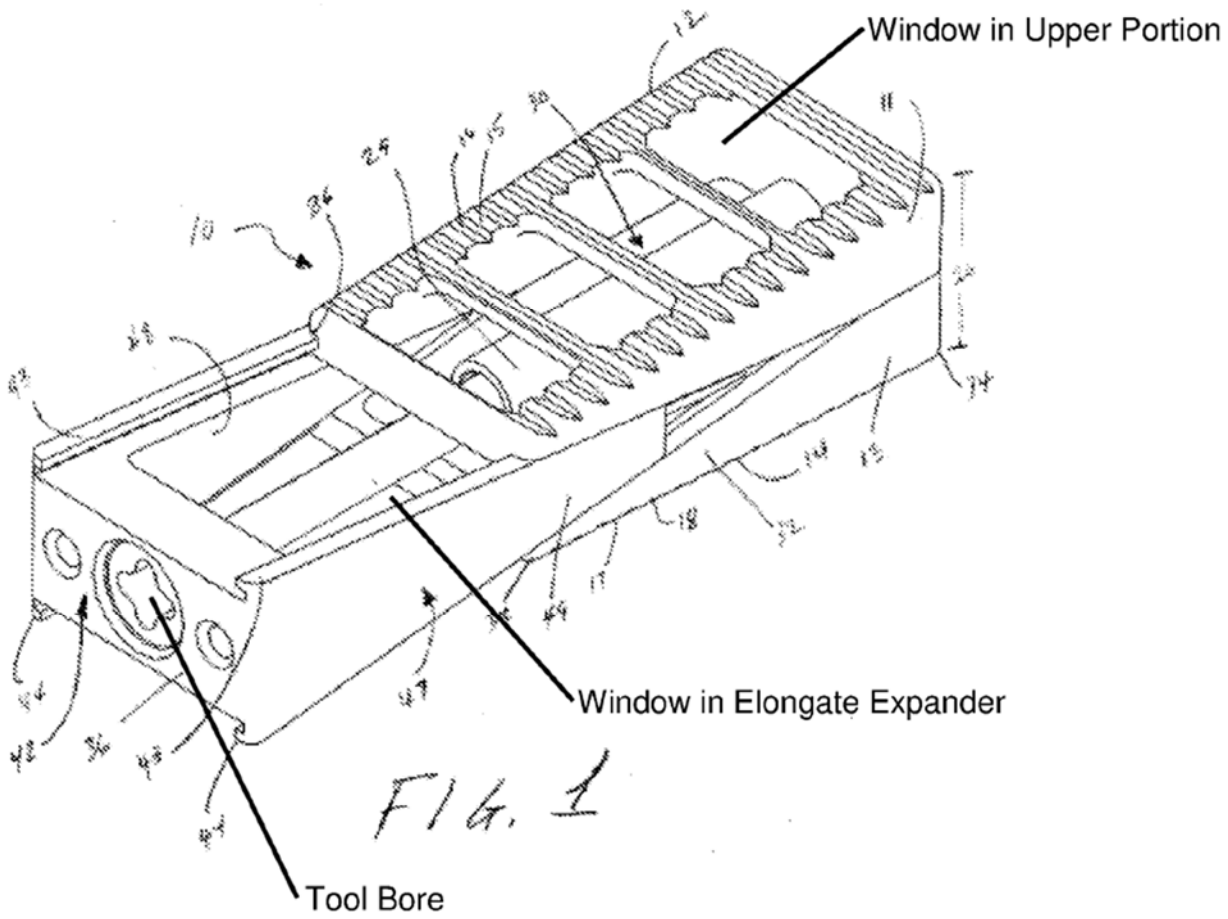


FIG. 1

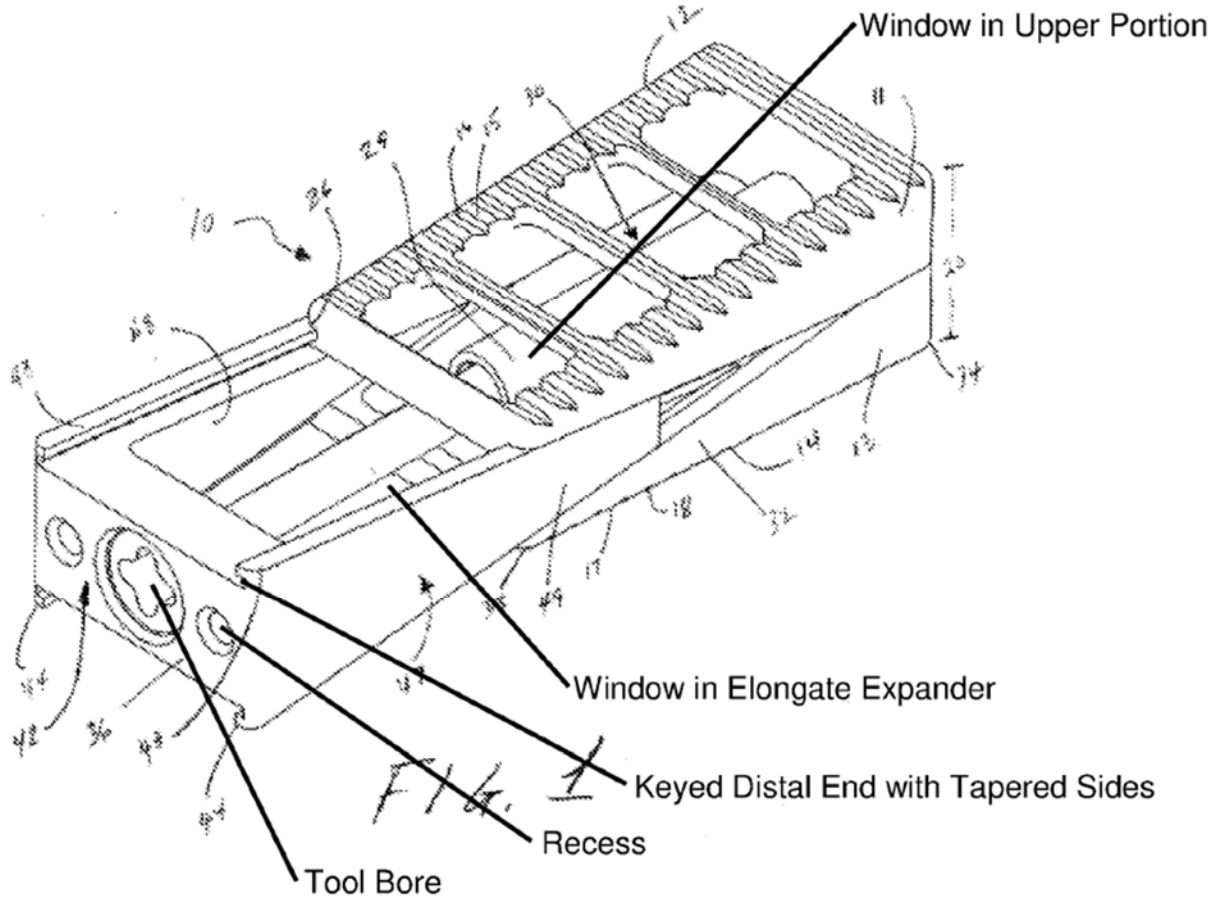
(Ex. 1002, 75.)

Patent Owner responded by amending Prosecution Claims 1-3 and adding new Prosecution Claims 7-20. (*Id.*, 57-61.) Patent Owner argued that (1) paragraph 0050[2] of the specification supported new Prosecution Claims 7-8, (2) paragraph

[2] Corresponds to ’575 patent at 4:66-5:12.

0055[3] supported new Prosecution Claim 9, and (3) paragraph 0051[4] supported new Prosecution Claim 10. (*Id.*, 61.)

In response, the Examiner finally rejected Prosecution Claims 1-10 as anticipated by Baynham, again identifying several claim limitations in Figure 1. (*Id.*, 40-45.)



(*Id.*, 43.)

[3] Corresponds to ’575 patent at 6:12-33.

[4] Corresponds to ’575 patent at 5:13-22.

Patent Owner responded by again amending Prosecution Claims 1, 2, and 4 and by rewriting claim 4 in independent form. (*Id.*, 22-29.) In Prosecution Claim 1, Patent Owner made the below amendments:

> an elongate expander positioned in a cavity or an internal space therebetween the upper portion lower surface and the lower portion upper surface, the elongate expander having a distal or leading end, a proximal or trailing end and a pair of side surfaces connecting the distal end and the proximal end having an unobstructed internal space or opening therebetween defining a window therethrough, wherein longitudinal translation of the elongate expander causes the expander to act upon portions of the upper portion and the lower portion to expand the cage body by separating at least a portion of the upper portion from at least a portion of the lower portion, wherein, in an expanded position, ~~at least a portion of~~ the windows in each of the upper portion, lower portion, and elongate expander are open and unobstructed with respect to one another when viewed from a top view.

(*Id.*, 22.)

Patent Owner argued that the amendments "made it clear that the windows 1050 of the lower portion, the upper portion and the expander are open and unobstructed with respect to one another when viewed from the top." (*Id.*, 29-30.) Patent Owner stated that "unobstructed" means "there are no features lying in the path and blocking the windows" and analogized to a window "not having any bars on a window or any other feature that blocks the window." (*Id*.) Patent Owner argued that the amendments distinguished Baynham, which allegedly "required an axle obstructing the window extending down the center which acts as a bar." (*Id*.)

The Examiner subsequently allowed the claims and the patent issued. (*Id.*, 9-13.)

C. The AIA Applies to the '575 Patent

The '575 patent issued from U.S. Application 16/140,500 ("'500 application"). The '500 application was a transitional application because it was filed after March 16, 2013 (the AIA effective date) but claimed the benefit of an application filed before March 16, 2013. *U.S. Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019, Paper 54, at 7-8 (PTAB Dec. 28, 2016).

The AIA applies to a transitional application if the application "contained ***at any time***…a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after" March 16, 2013. *Leahy-Smith America Invents Act*, Pub. L. No. 112-29, §3(n), 125 Stat. 293 (Sept. 16, 2011) (emphasis added) ("AIA §3(n)"); M.P.E.P. §2159.02. If the AIA applies to a transitional application, then the conditions for patentability in AIA 35 U.S.C. §§102-103 apply. M.P.E.P. §2159.02.

Original claim 2 of the '500 application recited:

> 2. The expandable cage of claim 1, wherein at least 50% of the windows in each of the upper portion, lower portion, and elongate expander are unobstructed with respect to one another when viewed from the top view.

(Ex. 1002, 143.) The Examiner concluded that the parent application (App. 15/666,103 – Ex. 1012) to the '500 application failed "to disclose that at least 50%

of the windows in the upper portion, the lower portion, and the elongate expander are unobstructed with respect to one another when viewed from the top view." (*Id.*, 71-72.) The Examiner stated that "'[a]t least 50%' provides a specific lower endpoint of a range from 50%-100%" and "the specification does not disclose such; nor do the figures illustrate such a specific value." (*Id.*) The Examiner concluded that Patent Owner should change the priority claim of the '500 application from continuation to continuation-in-part in light of the newly added subject matter. (*Id.*) Alternatively, the Examiner noted that Patent Owner could maintain the existing priority claim by cancelling the "non-supported subject matter from claim 2." (*Id.*)

Patent Owner acquiesced to the Examiner's rejection and amended the claim to remove the "at least 50%" limitation, as follows:

> 2. (Currently Amended) The expandable cage of claim 1, wherein a greater portion ~~at least 50%~~ of the windows in each of the upper portion, lower portion, and elongate expander are unobstructed with respect to one another when viewed from the top view in the expanded position compared to when viewed from the top view in the unexpanded position.

(*Id.*, 57.) Patent Owner admitted that "Claim 2 was amended as suggested in the Office Action" and that "[s]upport for the amendment to claim 2 is found in Figures 5A, 5B, and 7." (*Id.*, 61.)

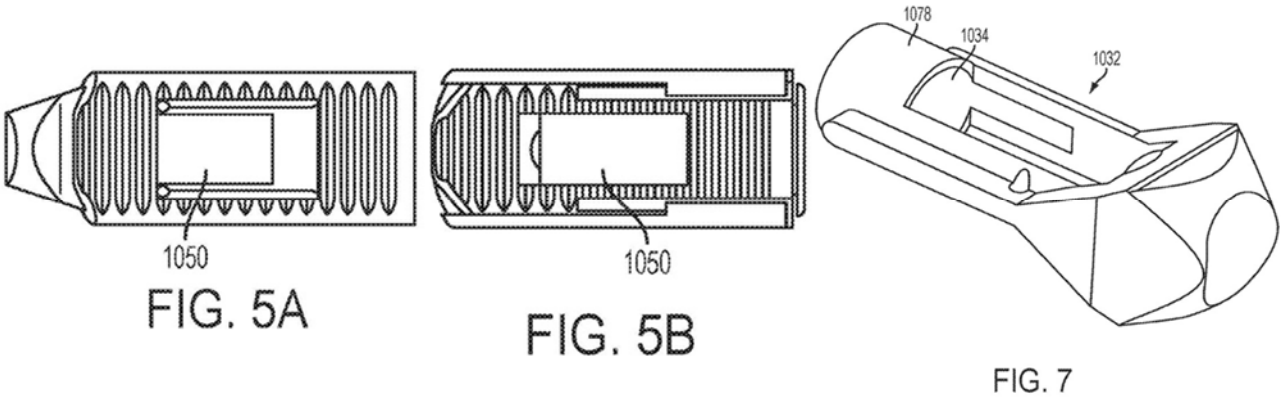


FIG. 5A FIG. 5B FIG. 7

(Ex. 1001, Figs. 5A-5B, 7.)

The Examiner correctly rejected original claim 2 because the parent application (Ex. 1012) to the ’575 patent does not provide adequate support or enablement for the claim. (Ex. 1003, ¶45.) The specification never discloses the specific lower endpoint of the range 50% to 100%. (*Id.*) “A description that merely renders the invention obvious does not satisfy the written description requirement.” *Indinex Pharms. LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1165 (Fed. Cir. 2019), *cert. denied*, __ S.Ct. __, 2021 WL 161021 (Jan. 19, 2021). Consequently, the effective filing date for original claim 2 was the filing date of the ’500 application, September 24, 2018. (Ex. 1001.)

Because the ’500 application included a claim that had an effective filing date on or after March 16, 2013, AIA 35 U.S.C. §§102-103 apply to the ’575 patent. Consequently, Patent Owner cannot remove any of the prior art references identified below by swearing behind them.

In addition, the AIA applies to a transitional application if the application "contained ***at any time***… a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim" that has an effective filing date on or after March 16, 2013. AIA §3(n) (emphasis added); M.P.E.P. §2159.02.

The '575 patent claims priority under section 120 to several applications including Application 14/878,929 ("'929 application"), ***filed on October 8, 2015***, which the Patent Owner identified as a ***continuation-in-part*** of U.S. Application 14/561,214 ("'214 application"), filed on December 4, 2014. (Ex. 1001, 1:6-23.) The '929 Application was filed with the following claims:

> 8. The expandable cage of claim 4, wherein the first shim and the cage body comprises a first material and the first and second shim comprise a second material, wherein the second material is harder than the first material.
> 9. The expandable cage of claim 8, wherein the first material is PEEK.
> 10. The expandable cage of claim 9, wherein the second material is Titanium.

(Ex. 1016, 191.) The Examiner of the '929 application found that the '214 application did not provide adequate support or enablement for claims 1-13. (*Id.*, 116.) Patent Owner acquiesced to Examiner's priority rejection. (*Id.*, 89-92.) Thus, the '929 application contained a claim that had an effective filing date after March 16, 2013 and provides another reason the AIA applies to the '575 patent. (Ex. 1003, ¶55.)

III. STATEMENT OF RELIEF REQUESTED

A. PGR Grounds

Petitioner asserts the below grounds of unpatentability.

1. Greenhalgh as Primary Reference

- **Ground 1a**: Claims 1-7 are anticipated by Greenhalgh under 35 U.S.C. §102(a);
- **Ground 1b**: Claims 8-9 are rendered obvious by Greenhalgh under 35 U.S.C. §103;
- **Ground 1c**: Claims 8-9 are rendered obvious by Greenhalgh in view of Lynn under 35 U.S.C. §103; and
- **Ground 1d**: Claims 8-9 are rendered obvious by Greenhalgh in view of Weiman under 35 U.S.C. §103.

2. Weiman as Primary Reference

- **Ground 2a**: Claims 1-9 are anticipated by Weiman under 35 U.S.C. §102(a); and
- **Ground 2b**: Claims 1-9 are rendered obvious by Weiman under 35 U.S.C. §103.

3. Glerum as Primary Reference

- **Ground 3a**: Claims 1, 4-6, and 8-9 are anticipated by Glerum under 35 U.S.C. §102(a); and

- **Ground 3b**: Claims 8-9 are rendered obvious by Glerum under 35 U.S.C. §103.

B. The Asserted References Are Prior Art

The earliest claimed priority date of the ’575 patent is August 8, 2012. (Ex. 1001.) However, as explained above, the ’575 patent is an AIA patent. (*Supra* II.C.) Thus, the prior art references relied on in this Petition qualify as prior art under AIA 35 U.S.C. §102(a) because they were either published or filed by another before the ‘575 patent’s earliest effective filing date in August 2012.

Greenhalgh (Ex. 1004) published on November 18, 2010 and is prior art to the ’575 patent under AIA 35 U.S.C. §102(a). Greenhalgh was not cited during prosecution of the ’575 patent. (Ex. 1001, pages 1-2.)

Weiman (Ex. 1005) was filed on June 25, 2012 and issued on October 7, 2014. Weiman is prior art to the ’575 patent under AIA 35 U.S.C. §102(a). Weiman was not cited during prosecution of the ’575 patent. (Ex. 1001, pages 1-2.) A parent application to Weiman (Ex. 1013), of which Weiman is a continuation-in-part, was cited, but not applied, during prosecution. (Ex. 1001, page 2.) Petitioner relies on the added subject matter in Weiman that was never before the Examiner.

Glerum (Ex. 1006) published on April 21, 2011 and is prior art to the ’575 patent under AIA 35 U.S.C. §102(a). Glerum was not cited during prosecution of the ’575 patent. (Ex. 1001, pages 1-2)

Lynn (Ex. 1007) was filed on March 16, 2011 and issued on January 1, 2013. Lynn is prior art to the ’575 patent under AIA 35 U.S.C. §102(a). Lynn was not cited during prosecution of the ’575 patent. (Ex. 1001, pages 1-2)

C. The Asserted References Are Analogous Art

The asserted references are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000-01 (Fed. Cir. 2016). Each reference is from the same field as the ’575 patent, e.g., implants for insertion between adjacent vertebrae to support the vertebrae. (Ex. 1003, ¶25.) The references are also pertinent to the problem the inventor was focused on, e.g., treating weakened or diseased intervertebral anatomy with an implant having windows to promote bone growth. (*Id*.) As analogous art, a person of ordinary skill in the art (“POSITA”) is presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

IV. LEVEL OF ORDINARY SKILL IN THE ART

A POSITA in August 2012 would have been (1) a mechanical or biomedical engineer with at least three years of experience in designing or developing medical devices in the orthopedics and/or spine implant field who would, where necessary or desired, work or consult with others, including an orthopedic surgeon or neurosurgeon, to develop such medical devices, or (2) an orthopedic surgeon or neurosurgeon with experience designing or developing medical devices in the

orthopedics and/or spine implant field who would, where necessary or desired, work or consult with others, including an engineer, to develop such medical devices. (Ex. 1003, ¶33.)

V. CLAIM CONSTRUCTION

The claim terms should receive their ordinary and customary meaning as understood by a POSITA at the time of filing and in accordance with the specification and the prosecution history. 37 C.F.R. §42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (establishing standard).

A. Proximal and Distal

The ’575 patent defines “proximal” and “distal,” stating “the words ‘proximal’ and ‘distal’ are used to describe items or portions of items that are situated closer to and away from, respectively, a user or operator such as a surgeon.” (Ex. 1001, 3:61-64.) The patent continues, “the tip or free end of a device may be referred to as the distal end, whereas the generally opposing end or handle may be referred to as the proximal end.” (*Id.*, 3:64-67.) Petitioner has applied these definitions. (Ex. 1003, ¶61.)

B. Open and Unobstructed

Claims 1 and 8 recite, “in an expanded position, the windows in each of the upper portion, lower portion, and elongate expander are ***open and unobstructed*** with respect to one another when viewed from a top view.” The Board should construe

"open" to mean "at least partially aligned." (*Id.*, ¶63.) The Board should construe "unobstructed" to mean "there are no features lying in the path and blocking the windows." (*Id.*, ¶71.)

Patent Owner added "open" to claim 1 during prosecution. (Ex. 1002, 22.) Patent Owner argued that the "amendment made it clear that the windows 1050 of the lower portion, the upper portion and the expander are open and unobstructed with respect to one another when viewed from the top." (*Id.*, 29.) Patent Owner did not otherwise explain the addition of the term "open" to the limitation "open and unobstructed."

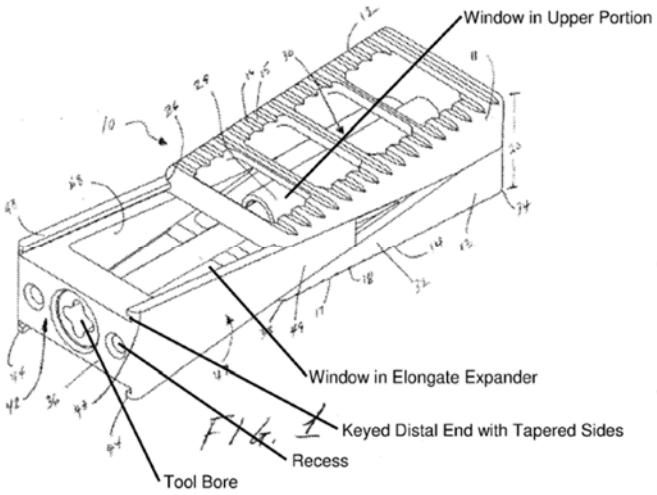
Simultaneously, Patent Owner amended dependent claim 2 to include the term "aligned":

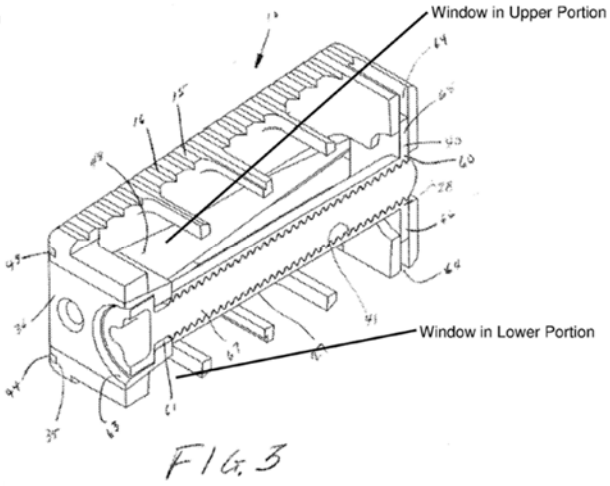
> 2. (currently amended) The expandable cage of claim 1, wherein a greater portion of the three windows in ~~each of~~ the upper portion, lower portion, and elongate expander are aligned and unobstructed with respect to one another when viewed from the top view in the expanded position compared to when viewed from the top view in the unexpanded position.

(*Id.*, 22.) In claim 2, "aligned" replaces "open" in the limitation "open and unobstructed," suggesting a relationship between the terms. (Ex. 1003, ¶63.) Claim 2 also states that a "greater portion of the three windows…are aligned and unobstructed…in the expanded position." Based on a comparison of claims 1 and 2, a POSITA would have understood that the windows are at least partially aligned in claim 1, and aligned to a greater extent in claim 2. (*Id.*)

Patent Owner did not define the term "open" in the specification, or use the term in connection with the windows in the three claimed parts (upper portion, lower portion, and elongate expander). (*Id*.) However, the plain meaning of an "open" window is well understood to be a state allowing passage through the window. (*Id.*) When the windows of the three claimed parts are at least partially aligned, a passage is formed through the windows, and the windows are open "with respect to one another," as claimed. (*Id.*) Consistently, Figures 5A-5B illustrate that in the preferred embodiment the windows are at least partially aligned in the unexpanded configuration, and further aligned in the expanded configuration, such that a passage is formed through the windows (*see* further explanation below). (*Id.*) The degree of alignment corresponds to how widely the windows are open. (*Id.*) Thus, based on the claim language and the specification, a POSITA would have understood "open" in claims 1 and 8 to mean "at least partially aligned." (*Id.*)

Patent Owner expressly defined "unobstructed" during prosecution. As explained above, the Examiner rejected Prosecution Claim 1 over Baynham. (*Supra* II.B.) The Examiner found that Baynham's Figures 1-3 disclosed that "at least a portion of the windows in the upper portion, lower portion, and elongate expander" were unobstructed in the expanded position. (Ex. 1002, 40-44.)

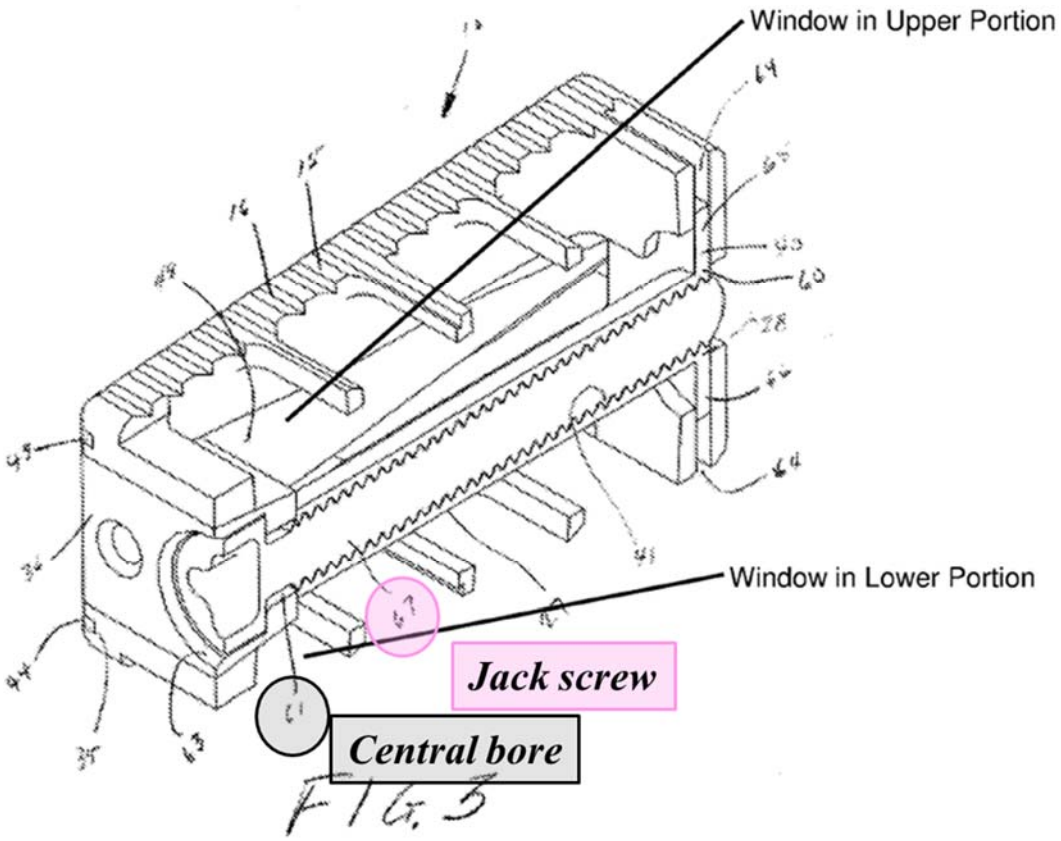




(*Id.*, 43-44 (labels by Examiner).)

Patent Owner amended Claim 1 to overcome the rejection. (*Supra* II.B.) In explaining the amendment, Patent Owner stated, "By unobstructed, applicants simply mean there are no features lying in the path and blocking the windows." (Ex. 1002, 29-30.) Patent Owner argued that Baynham's windows were obstructed because Baynham "required an axle obstructing the window extending down the center which acts as a bar." (*Id.*)

Baynham does not use the term "axle." (Ex. 1008.) However, Patent Owner presumably meant the jack screw 67 [pink] and/or central bore 61 [gray], which lie in the path of the windows, as illustrated in Baynham's Figure 3. (*Id.*, [0029].)



(Ex. 1002, 44.)

The claims and specification further inform the meaning of "unobstructed." Claim 2 requires that "a greater portion of the three windows in the upper portion, lower portion, and elongate expander are aligned and unobstructed with respect to one another when viewed from the top view in the expanded position compared to when viewed from the top view in the unexpanded position." Thus, claim 2 establishes that the three windows may be aligned and unobstructed to different degrees (i.e., a lesser or greater portion). (Ex. 1003, ¶¶67-70.)

The patent figures illustrate this concept. Patent Owner identified Figures 5A-5B as providing written description support for "a greater portion" in claim 2. Figure

5A (below left) is a top view of the expandable cage in the unexpanded position. (Ex. 1001, 2:37-38.) Figure 5B (below right) is a top view of the expandable cage in the expanded position. (*Id.*, 2:39-40.)

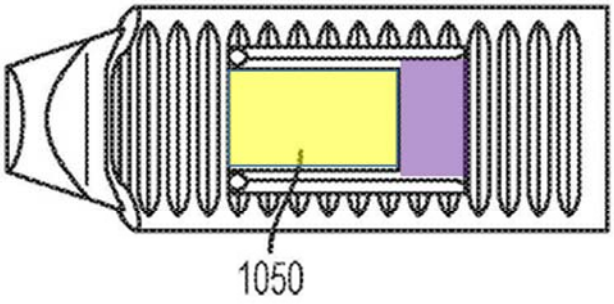


FIG. 5A

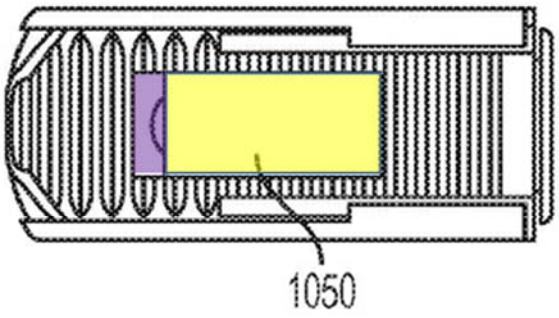


FIG. 5B

In the unexpanded position (Figure 5A), the three aligned windows [yellow] are open and unobstructed even though the elongate expander [purple] extends into, a partially blocks, the window 1050 in the upper portion. Despite the intrusion by the elongate expander, a POSITA would have understood that the three aligned windows [yellow] are open and unobstructed because there are no features lying in the path and blocking the windows. (Ex. 1003, ¶69.)

In the expanded position (Figure 5B), "a greater portion" of the three aligned windows [yellow] is open and unobstructed (i.e., the yellow box is larger) than in the unexpanded position. However, as shown, even in the expanded position, a portion of the elongate expander [purple] still extends into the window 1050 in the upper portion. Thus, while window 1050 is partially blocked by the elongate expander [purple], a POSITA would have understood that the portion of window

1050 that is aligned with the other two windows (lower portion and elongate expander) is still open and unobstructed because there are no features lying in the path and blocking the windows. (*Id.*, ¶70.)

For these reasons, the Board should construe "unobstructed" to mean "there are no features lying in the path and blocking the windows." (*Id.*, ¶71.)

C. <u>Keyed Distal End</u>

Claim 4 recites, "the elongate expander has a ***keyed distal end***." Claim 5 recites, "the ***keyed distal end*** has tapered sides." The Board should construe "keyed distal end" to mean "the distal end is sized and shaped to match the corresponding surfaces on the upper and lower portions." (Ex. 1003, ¶77.)

The '575 patent does not expressly define "keyed distal end." Referring to Figure 1A, the specification states, "the shim has 'key' on its distal portion." (Ex. 1001, 4:51-53.)

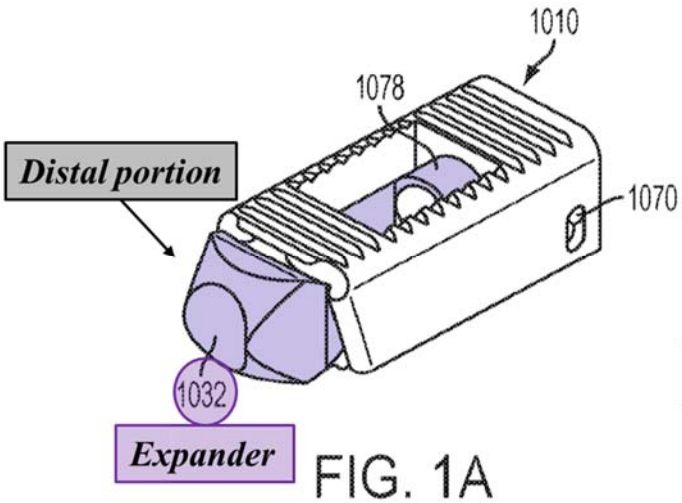


FIG. 1A

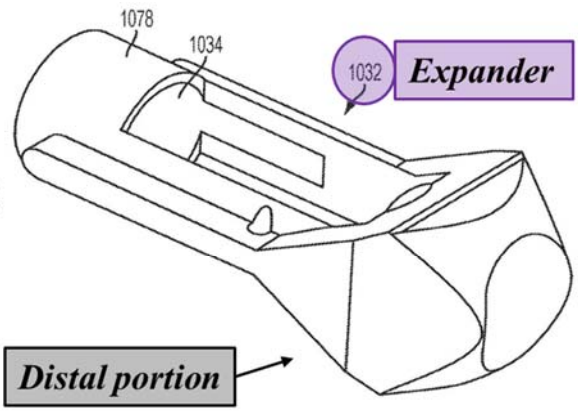


FIG. 7

The specification also states, "The key shape on the distal portion may be sized and shaped to fit within a distal cavity 1030." (*Id.*, 4:56-58.) "The size and shape of the key, together with its matching distal cavity 1030, may be used to create a cage body 1010 that opens to a desired height and angular orientation." (*Id.* at 4:62-65.) Figures 4A and 4B (below) illustrate that the distal end of the expander 1032 is sized and shaped to match the corresponding surfaces on the upper and lower portions. (*Id.*, 5:23-26.) The matching surfaces allow the expander to slide against the upper and lower portions to expand the cage and fit within the distal cavity 1030. (*Id.*)

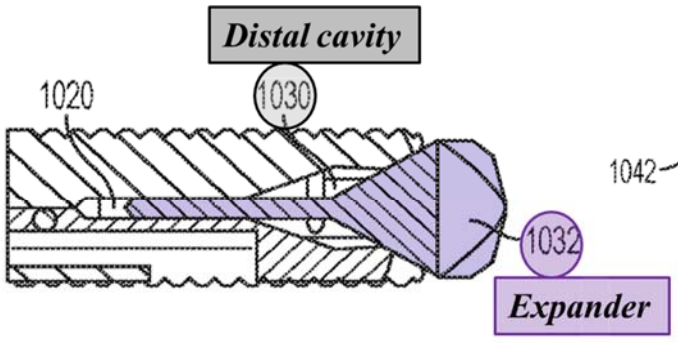


FIG. 4A

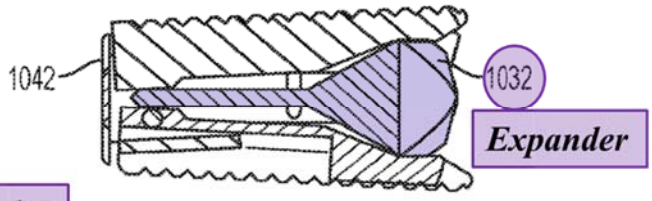


FIG. 4B

In a preferred embodiment, "the key is generally conical in cross section with a rectangular or square end, like the head of a bolt, and tapered on both sides." (*Id.*, 4:53-55.) While the preferred embodiment informs the meaning of "keyed distal end," the Board should not import limitations from the preferred embodiment, such as "rectangular or square end," into the claim. *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The dictionary definitions of "key" and "keyed" are not particularly helpful in construing "keyed distal end" because the standard definitions refer to locking two objects together. (*See e.g.*, Ex. 1014 ("key" definition); Ex. 1015 ("keyed" definition).) The '575 patent does not disclose that the keyed distal end ***locks*** any objects together. (Ex. 1003, ¶76.)

Thus, based on the intrinsic evidence, "keyed distal end" means "the distal end is sized and shaped to match the corresponding surfaces on the upper and lower portions." (*Id*., ¶77.)

D. Configured to Permit

Claim 8 recites, "wherein an ***aperture*** is defined in a proximal end of the elongate expander in communication with the cavity through the opening in the elongate expander and ***configured to permit*** packing the cavity through the open and unobstructed windows with bone growth material after expansion of the expandable cage." The Board should construe "configured to permit" to mean "does not prevent or unduly restrict." (Ex. 1003, ¶¶78-80.)

Claim 8 provides little information about the aperture. The claim states that the aperture is "in communication with the cavity," but provides no other information about how the aperture is "configured to permit" packing.

The specification provides no additional details about the aperture beyond the limitations in claim 8. The specification states, "the trailing end of the elongate

expander defines an aperture 1034 in communication with the internal space." (Ex. 1001, 6:51-53, Fig. 7.)

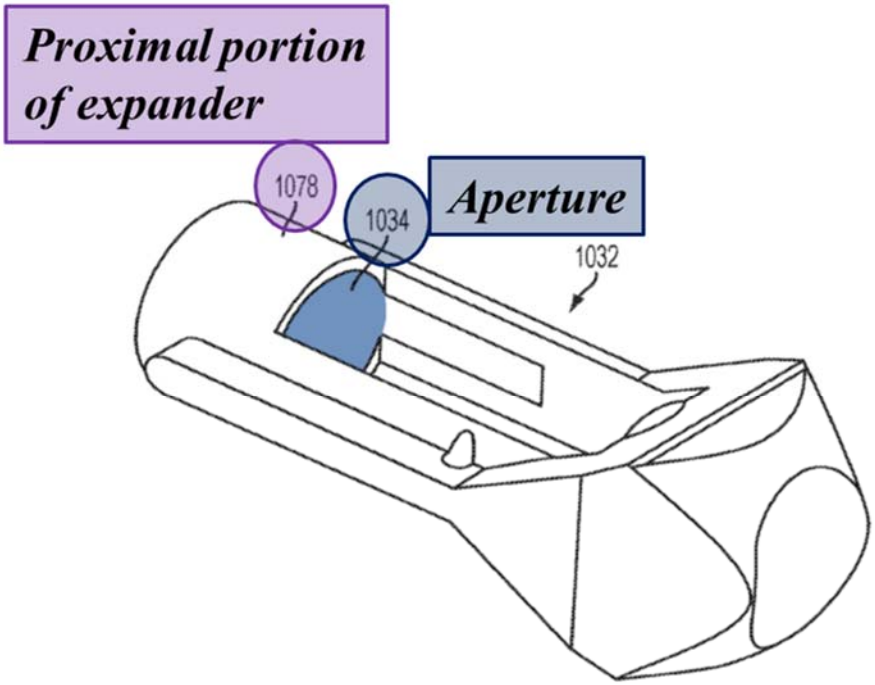


FIG. 7

The specification also states that in the embodiments having an actuating screw, "the actuating screw is positioned within the aperture 1034." (*Id.*, 7:24-25, Fig. 19.)

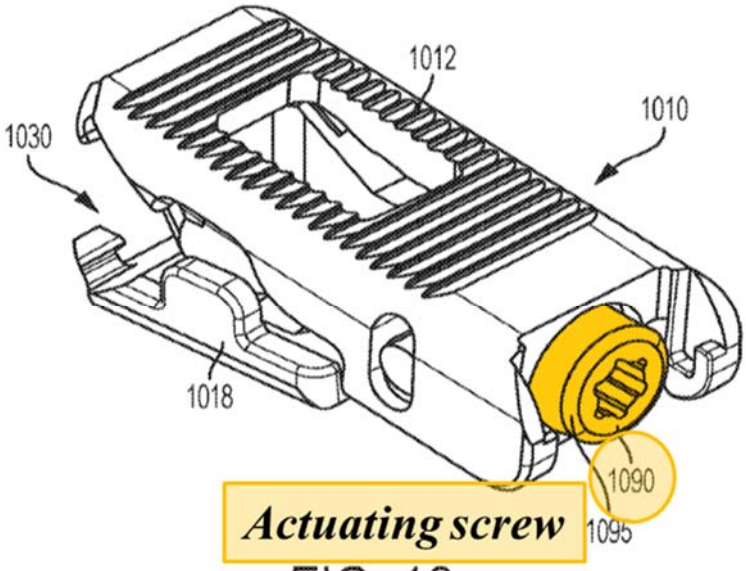


FIG. 19

The specification also states, "bone fusion material may be inserted…through the aperture in the proximal end 1079 of the expander, and thereby into the proximity of the surrounding bony structures, in order to promote fusion and to further secure the cage assembly 1000 in place." (*Id.*, 6:34-39.)

The '575 patent does not disclose an acceptable size, or range of sizes, for the aperture so that it is "configured to permit" packing. (Ex. 1003, ¶80.) Likewise, the patent does not disclose any other characteristics of the aperture that make it "configured to permit" packing of bone growth material. (*Id.*) Consequently, a POSITA would have broadly understood "configured to permit" packing with bone growth material to mean that the aperture "does not prevent or unduly restrict" the packing of bone growth material into the device. (*Id.*) A POSITA would understand that the bone growth material would be a viscous substance like a paste. (*Id.*) Under Petitioner's construction, the limitation "configured to permit" would exclude

devices having microscopically small apertures, such that the surgeon could not insert a tool to introduce the bone growth material. (*Id.*) Likewise, the construction would exclude configurations where a surgeon could insert a tool, but the resistance to flow of the paste-like bone growth material through the small opening would be impractically high. (*Id.*) The construction would also exclude tortuous apertures presenting undue resistance to flow, or apertures that do not fully extend into the central cavity. (*Id.*) However, absent these exclusions, almost any other opening in the proximal end of the elongate expander should satisfy the "configured to permit" limitation. (*Id.*)

Alternatively, if the Board construes "configured to permit" more narrowly, then the limitation does not have written description support in the specification and claims 8-9 are unpatentable pursuant to 35 U.S.C. §112.

Petitioner does not believe that any other claim terms require construction. Every other term should receive its ordinary and customary meaning.

VI. PROPOSED GROUNDS OF UNPATENTABILITY

A. Grounds 1a-1d: Greenhalgh Anticipates or Renders Obvious

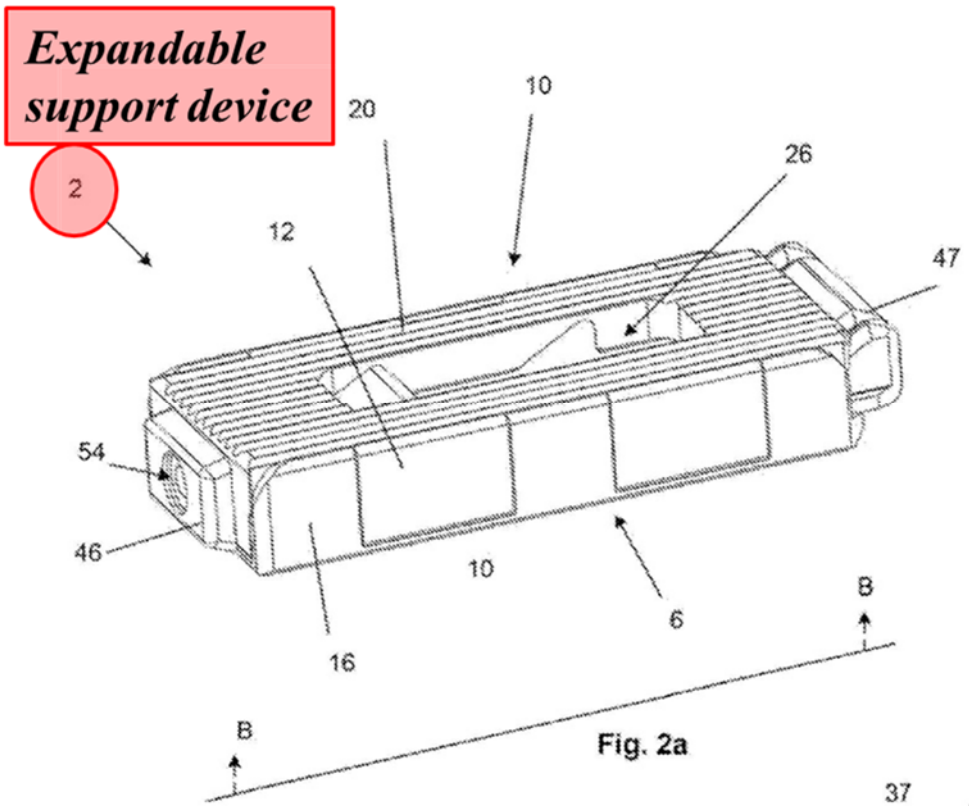
1. Claim 1

Greenhalgh anticipates claim 1. (Ex. 1003, ¶¶82-98.)

a. [1p] Preamble

Claim 1 recites: "An expandable cage for insertion into an intervertebral space, the expandable cage comprising." If the preamble is limiting, Greenhalgh discloses this limitation. (*Id.*, ¶¶83-84.)

Greenhalgh discloses an expandable support device 2 [red] for insertion into an intervertebral space. (Ex. 1004, 2:47-49, 4:46-55, Figs. 2a, 8-10.) The expandable support device is an expandable cage. (Ex. 1003, ¶84.)

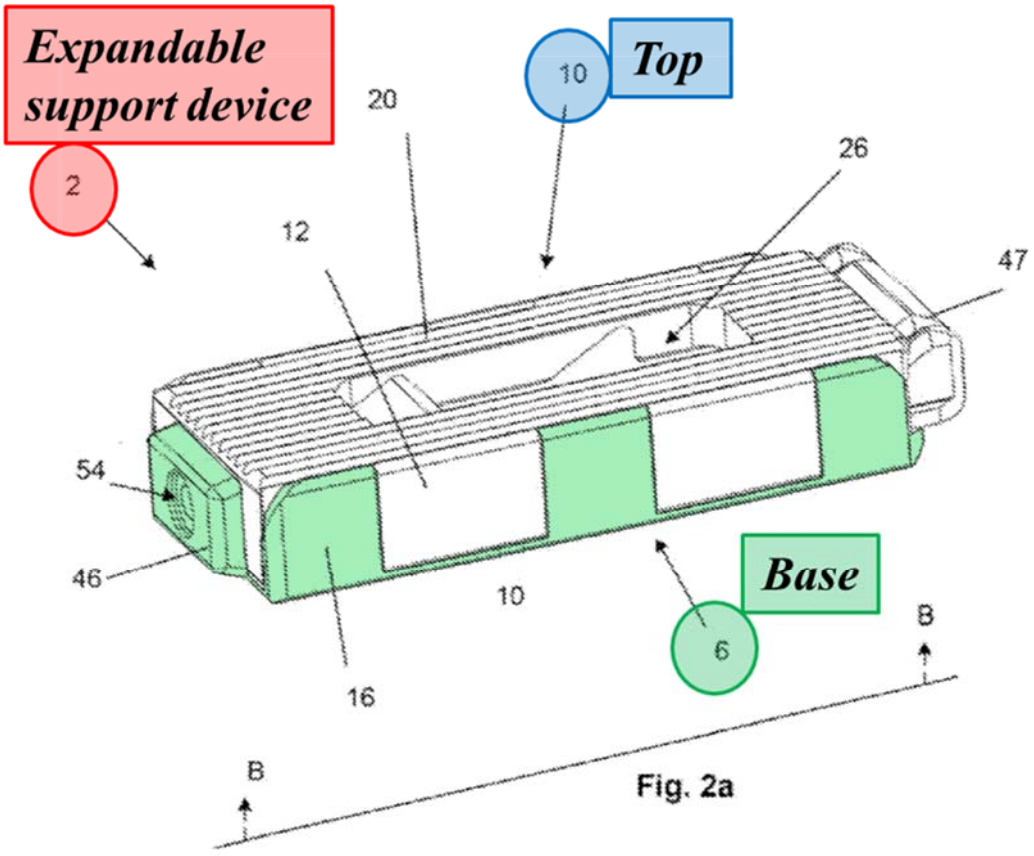


b. [1a] Cage

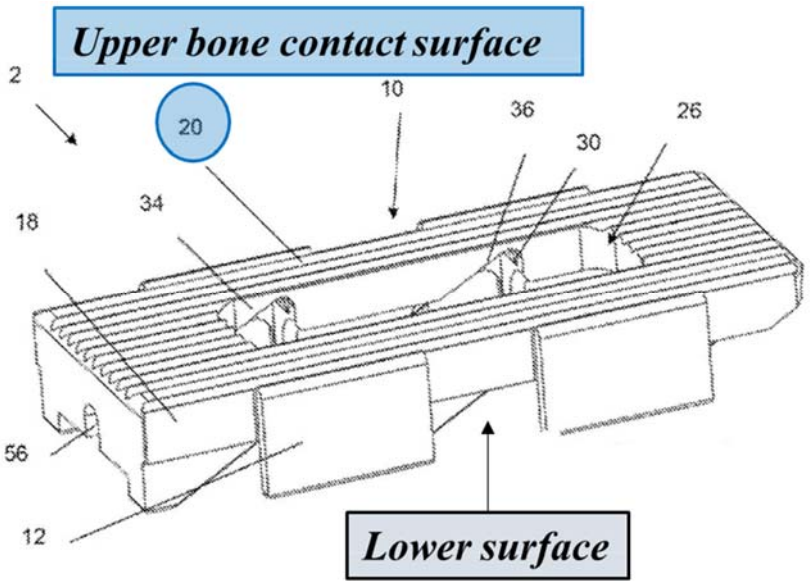
Claim 1 recites: "a cage having an upper portion and a lower portion, the upper portion having an upper bone contact surface and an upper portion lower surface, the lower portion having a lower bone contact surface and a lower portion upper

surface, wherein the upper portion and the lower portion each define a window configured to permit bone growth therethrough." Greenhalgh discloses this limitation. (Ex. 1003, ¶¶85-87.)

Greenhalgh's expandable support device 2 [red] has a base 6 [green] and a top 10 [blue]. (Ex. 1004, 4:56-58.)

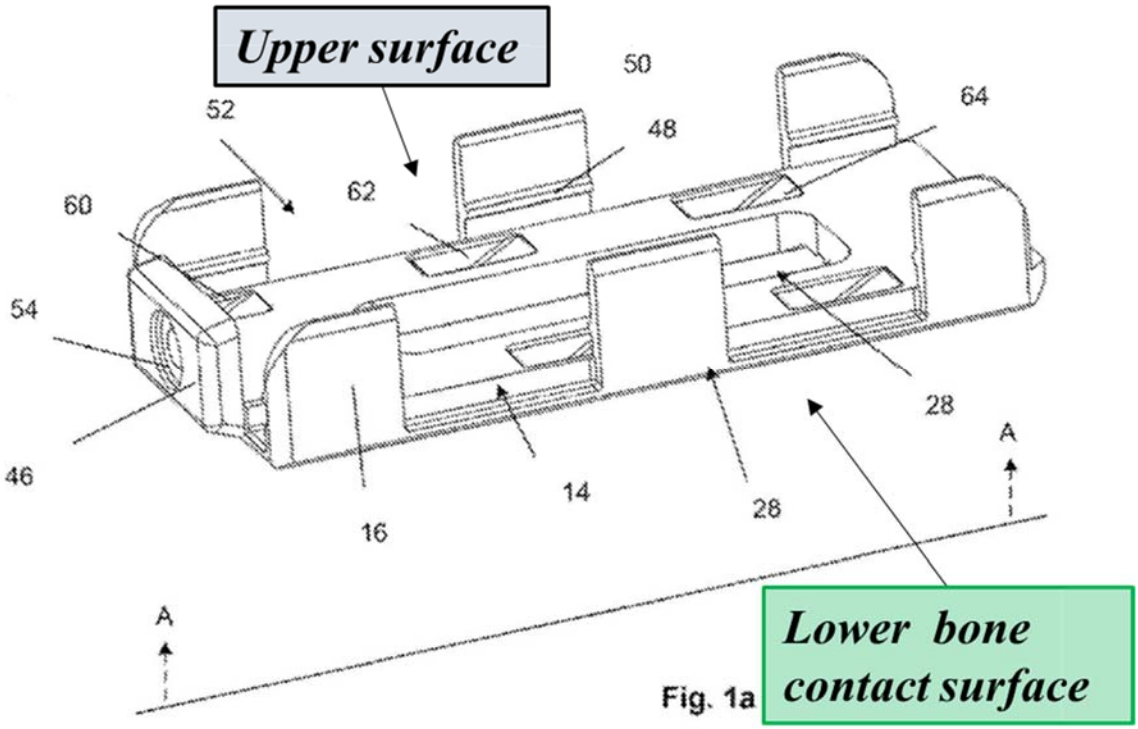


The top 10 has an upper bone contact surface [blue]. (*Id.*, 5:28-38.) The top 10 also has an upper portion lower surface [gray] facing away from the upper bone contact surface. (Ex. 1003, ¶86.)



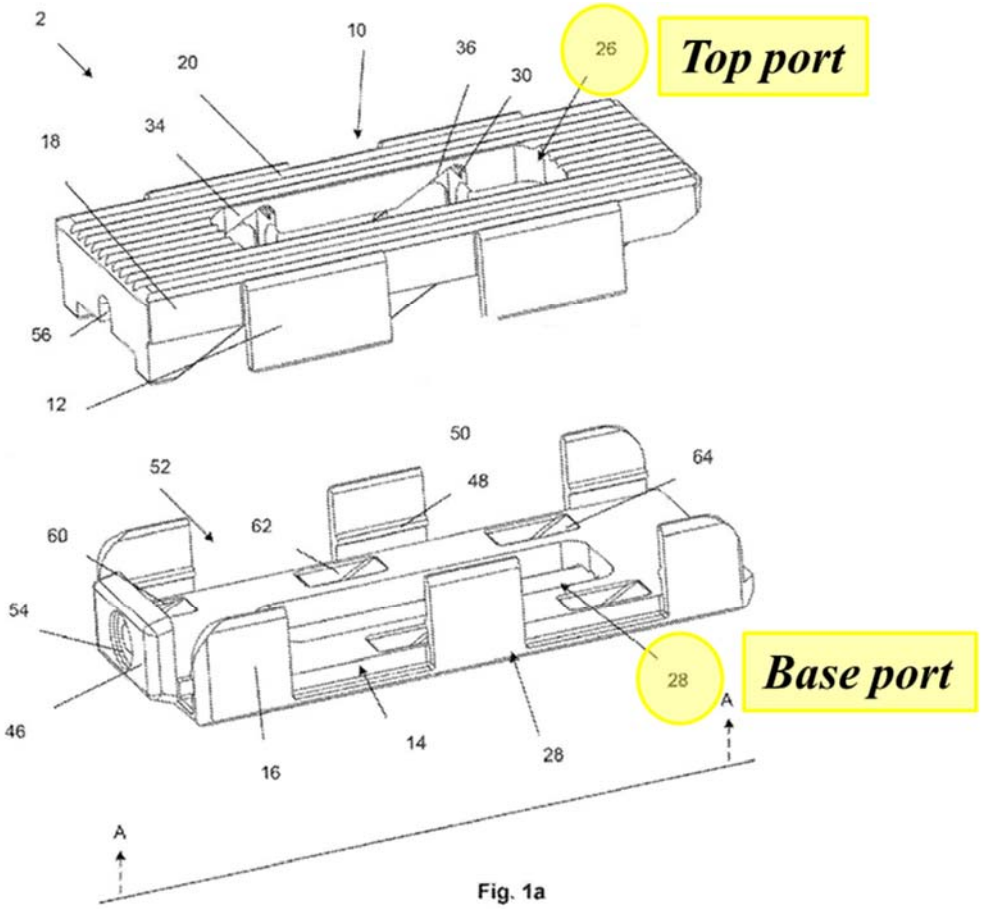
(Ex. 1004, Figure 1a (excerpted).)

The bottom 6 has a lower bone contact surface [green]. (Ex. 1004, 5:28-38.) The bottom 6 also has a lower portion upper surface [gray] facing away from the lower bone contact surface. (Ex. 1003, ¶86.)



(Ex. 1004, Figure 1a (excerpted).)

The top 10 includes a top port 26 [yellow] and the base includes a base port 28 [yellow]. (Ex. 1004, 5:39-43.) The top and base ports are windows. (Ex. 1003, ¶87.)



(*Id.*, Fig. 1a (excerpt).)

The ports are configured to permit bone growth therethrough. (Ex. 1004, 3:18-38, 7:1-4, 9:30-37, 10:16-41.) The purpose of the fusion device in Greenhalgh is to promote bone growth through the device to fuse the vertebrae together. (Ex. 1003, ¶87.) The device could not accomplish its purpose if the top and base ports were not

"configured to permit bone growth therethrough." (*Id.*) Persons of ordinary skill in the art trying to avoid bone growth would not have included windows because the windows decrease the overall strength of the device and increase the risk of stress and facture. (*Id.*)

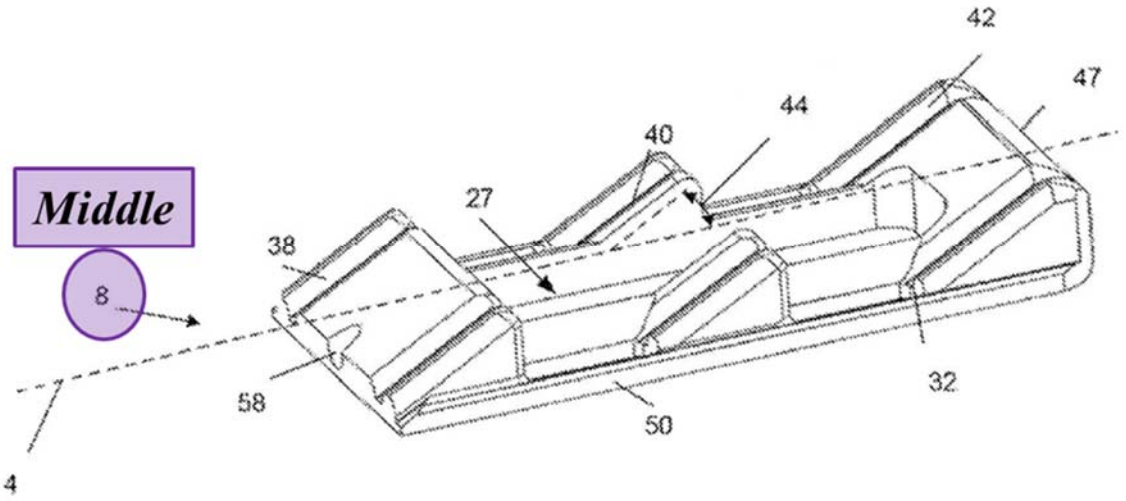
Further, the shape of the ports is similar to the windows in the embodiments disclosed in the '575 patent. (*See* Ex. 1001, Fig. 5B.) Therefore, if the windows in the '575 patent are "configured to permit bone growth therethrough," then so are the ports in Greenhalgh. (Ex. 1003, ¶87.) Conversely, if the windows in Greenhalgh are *not* "configured to permit bone growth therethrough," then the windows in the '575 patent are *not* "configured to permit bone growth therethrough" and the '575 patent lacks written description for this limitation. (*Id.*) A claim construction that renders a patent invalid for lack of written description would violate the canon favoring constructions that preserve claim validity and, therefore, would be unlikely to be the proper construction. *Ruckus Wireless, Inc. v. Innovative Wireless Solutions, LLC,* 824 F.3d 999, 1004 (Fed. Cir. 2016). As a result, a person of ordinary skill in the art would not understand "configured to permit bone growth therethrough" to be read so narrowly as to exclude the windows in the '575 patent or Greenhalgh. (*Id.*)

c. [1b] Elongate Expander

Claim 1 recites: "an elongate expander positioned in a cavity or an internal space therebetween the upper portion lower surface and the lower portion upper

surface, the elongate expander having a distal or leading end, a proximal or trailing end and a pair of side surfaces connecting the distal end and the proximal end having an unobstructed internal space or opening therebetween defining a window therethrough." Greenhalgh discloses this limitation. (Ex. 1003, ¶¶88-90.)

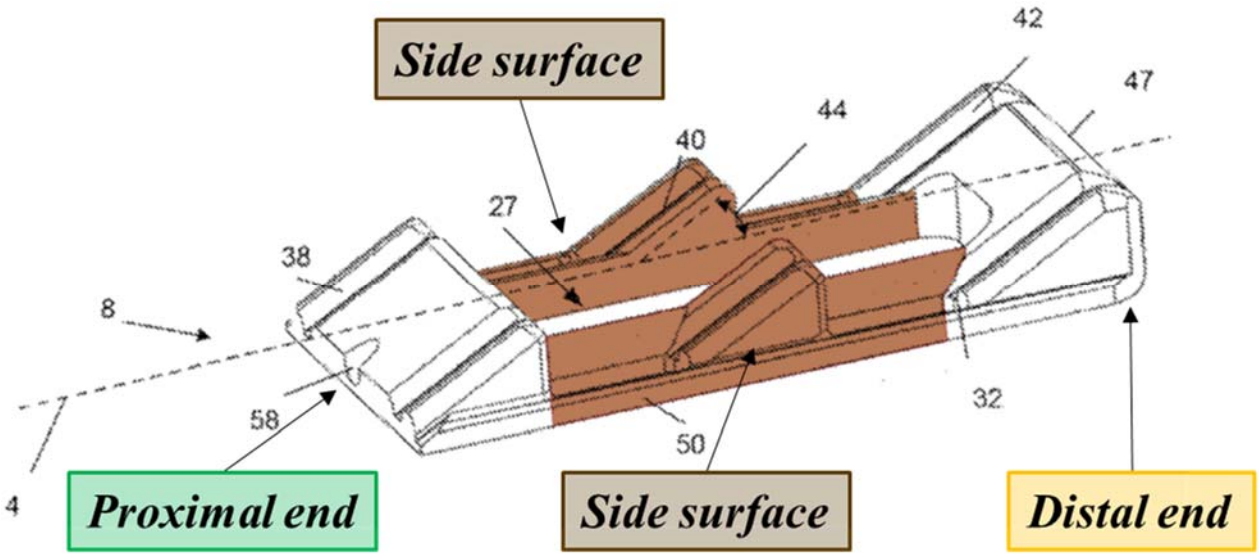
Greenhalgh's expandable support device 2 includes a middle 8 [purple]. (Ex. 1004, 4:56-67.) The middle 8 is an elongate expander because it is longer than it is wide, and it acts up on the top and bottom to expand the support device. (Ex. 1003, ¶89.)



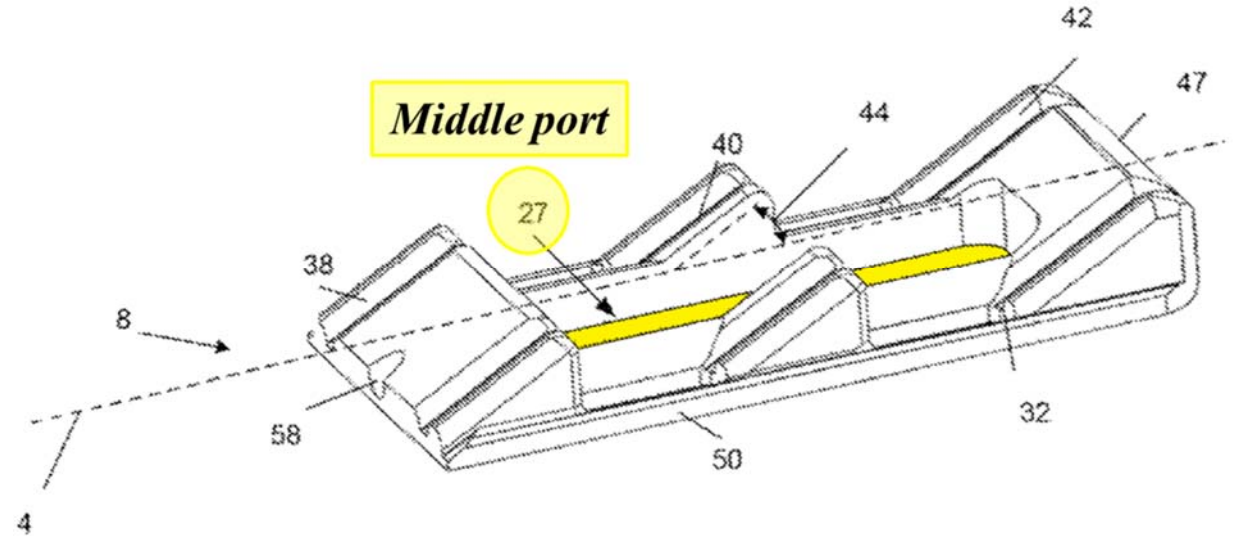
(*Id.*, Fig. 1a (excerpt).)

The middle 8 has a distal or leading end [orange], a proximal or trailing end [green], and a pair of side surfaces connecting the proximal and distal ends [brown].[5]

[5] Petitioner incorporates the analysis in claim 3 addressing the proximal and distal ends of the device. (*Infra* VI.A.3.)



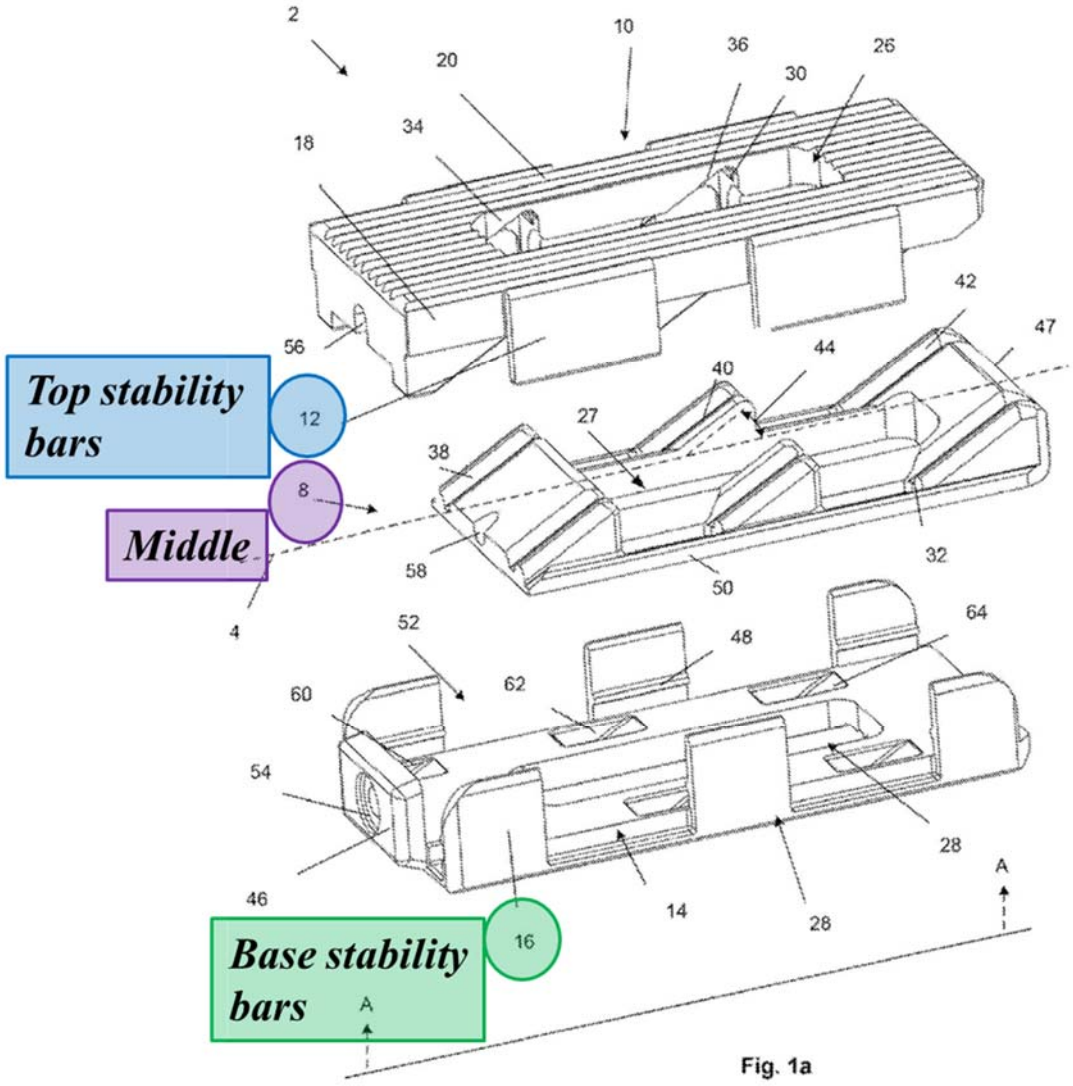
(*Id.*, Fig. 1a (excerpt).) The middle 8 also includes a middle port 27 [yellow], which is an unobstructed internal space or opening defining a window through the middle. (*Id.*, 6:66-7:9; Ex. 1003, ¶89.)



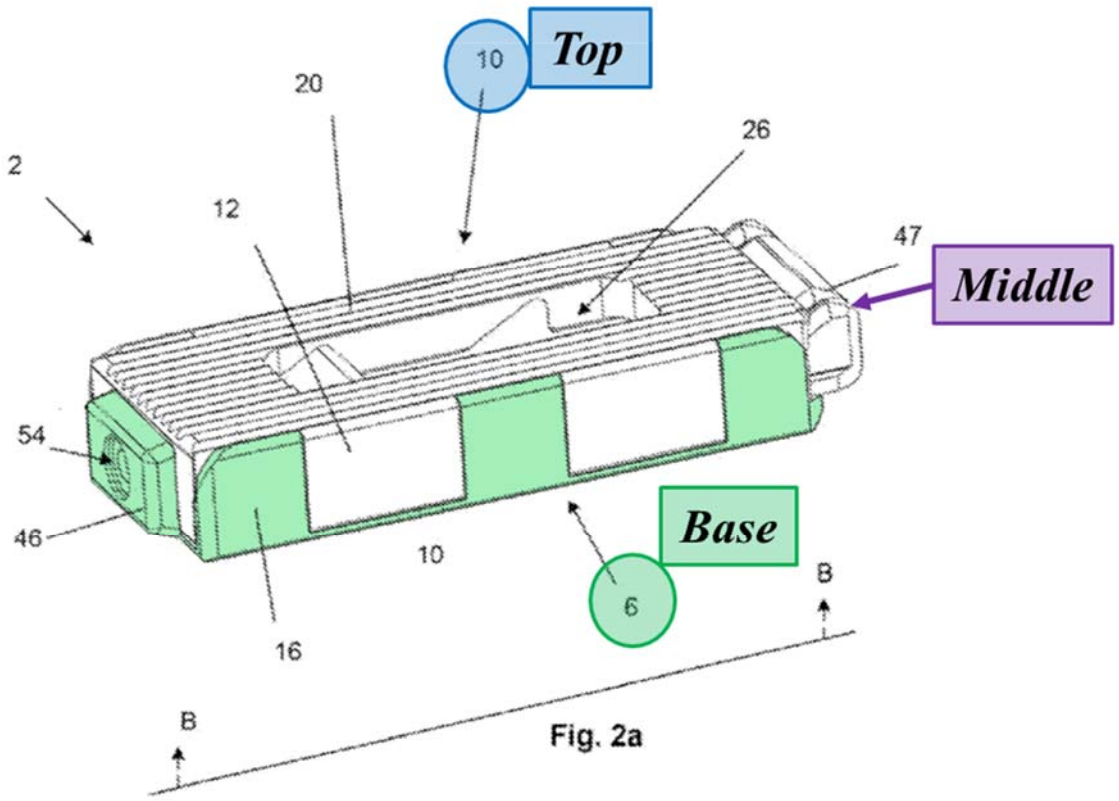
(Ex. 1004, Fig. 1a (excerpt).)

The top and base form a cavity or an internal space therebetween. The top 10 has top stability bars 12 [blue] that extend from the lateral sides of the top. (Ex. 1004, 5:1-11.) Likewise, the base 6 has base stability bars 16 [green] that extend from the

lateral sides of the base. (*Id.*, 5:12-24.) The stability bars (12, 16) in combination with the top and base create a cavity or internal space between the top's lower surface and the base's upper surface. (Ex. 1003, ¶90.)



The middle 8 [purple] is positioned within the cavity or internal space formed by the top and base. (Ex. 1004, 4:56-67, Figs. 2a-3b.)



d. [1c] Expander Expands the Cage

Claim 1 recites: "wherein longitudinal translation of the elongate expander causes the expander to act upon portions of the upper portion and the lower portion to expand the cage body by separating at least a portion of the upper portion from at least a portion of the lower portion." Greenhalgh discloses this limitation. (Ex. 1003, ¶¶91-96.)

Greenhalgh's "expandable support device 2 can have one, two, three or more sets of interacting wedges or ramps." (Ex. 1004, 5:47-48.) For example, the "top 10 and/or base 6 can have a series of unidirectional and/or bidirectional ramps." (*Id.*, 5:56-59.) Likewise, the "middle 8 can have a series of unidirectional and/or bidirectional ramps." (*Id.*, 5:60-63.) Sliding the middle 8 proximally causes the

middle ramps to act upon the top and/or base ramps to expand the cage body.[6] (*Id.*, 2:54-61, 6:44-46, 7:17-23, Figs. 5a-5c; Ex. 1003, ¶¶93-94.) Expanding the cage body separates the top from the base. (Ex. 1004, Figs. 3a-3b.)

In Figure 3b, top ramp 36 [blue] interacts with middle ramp 40 [purple]. (*Id.*, 5:64-6:3.) When the surgeon pulls the middle proximally, middle ramp 40 pushes on top ramp 36 to expand the device and separate the top from the base. (*Id.*, 6:44-46, 7:17-23.)

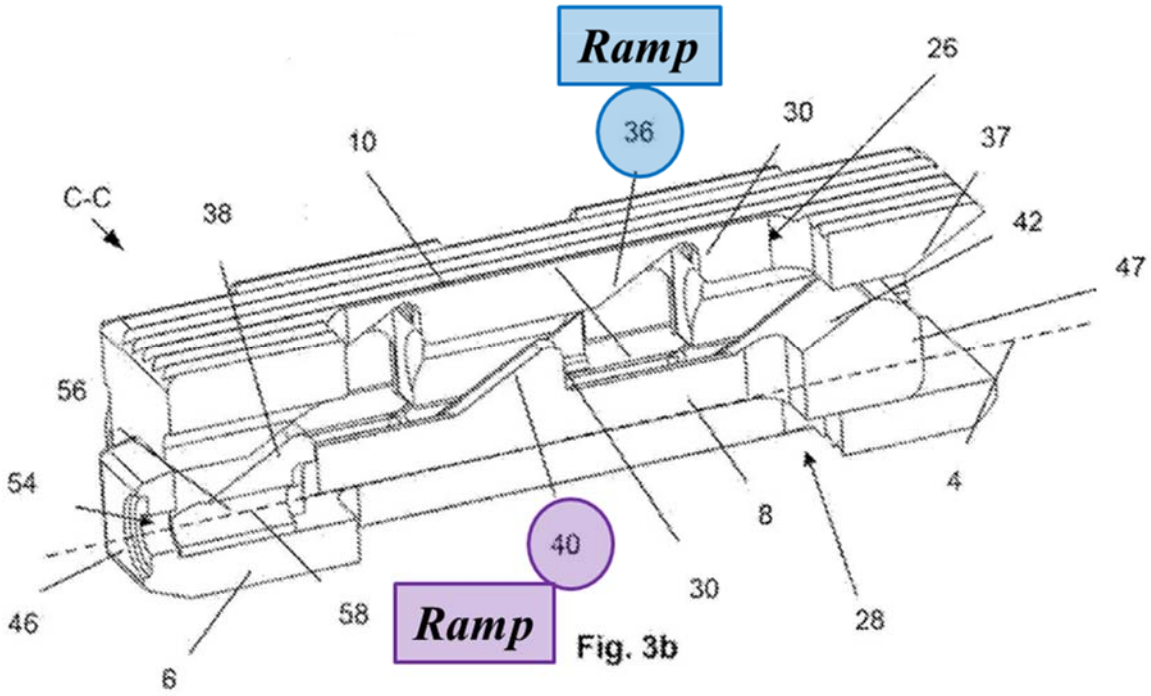


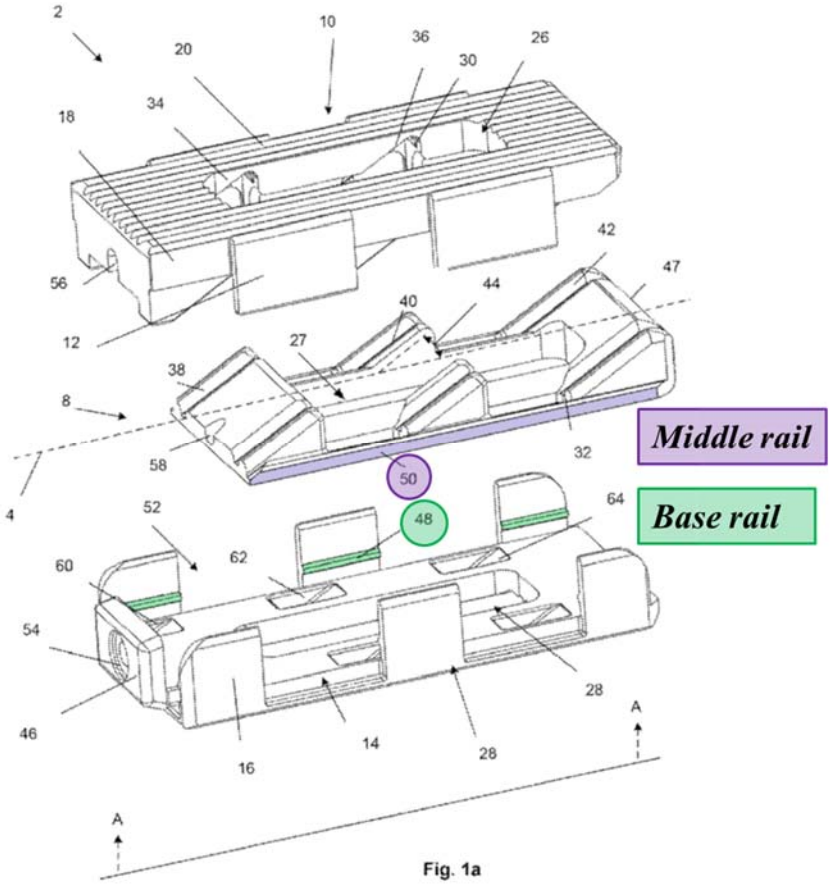
Fig. 3b

While Figure 3b illustrates ramps only on the top 10, Greenhalgh discloses that the top ***and*** base can have ramps. (*Id.*, 5:56-59, 7:43-46, 8:58-60.) In embodiments

[6] Petitioner incorporates the analysis in claim 3 addressing the proximal and distal ends of the device. (*Infra* VI.A.3.)

where the top and base have ramps, the middle acts upon the top and base to expand the cage. (Ex. 1003, ¶95.) Just as the middle ramps slide against and push upon the top ramps in Figure 3b above, ramps on the opposite side of the middle (i.e., the lower surface of the middle opposite ramp 40) would slide against and push upon the base ramps. (*Id.*, ¶95.)

Even in embodiments where the base 6 does not have ramps, the middle 8 still will "act upon" the base to expand the cage body, as claimed. (*Id.*, ¶96.) Greenhalgh discloses that the base has a base rail 48 [green]. (Ex. 1004, 6:14.) The middle has a corresponding middle rail 50 [purple] that "can be slidably fed onto or under the base rail 48." (*Id.*, 6:14-16.) The base rail 48 and middle rail 50 thereby "constrain relative motion between the middle 8 and the base 6 to the dimension of the longitudinal axis 4." (*Id.*, 6:16-18.)

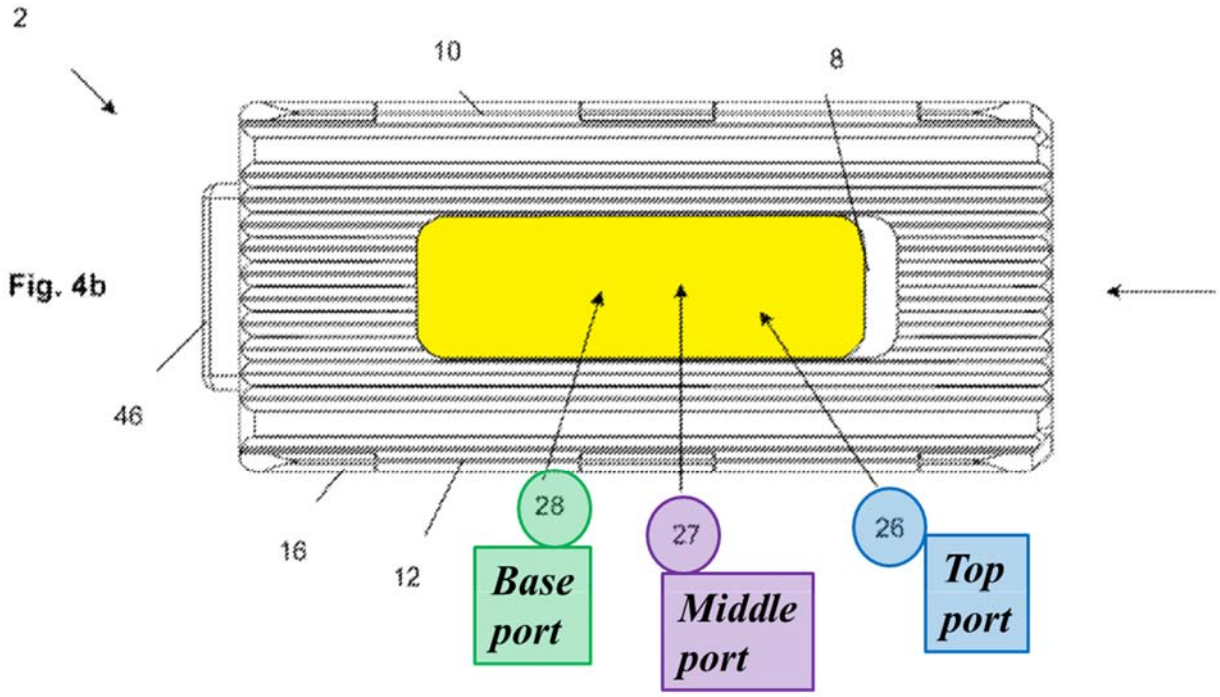


Thus, the middle rail 50 acts upon the base (i.e., holds the base) to prevent the base 6 from separating from the middle 8, while still permitting the base to translate longitudinally. (*Id.*, 6:16-18.) This sliding engagement allows the cage body to expand by separating the top from the base. (Ex. 1003, ¶96.)

e. [1d] Windows Are Unobstructed

Claim 1 recites: "wherein, in an expanded position, the windows in each of the upper portion, lower portion, and elongate expander are open and unobstructed with respect to one another when viewed from a top view." Greenhalgh discloses this limitation. (Ex. 1003, ¶¶97-98.)

When Greenhalgh's expandable support device 2 is in the expanded position, the windows in the top (upper portion), base (lower portion), and middle (elongate expander) are aligned so as to be open and unobstructed with respect to one another when viewed from a top view, as shown by the yellow window in Figure 4b below. (*Id.*, ¶98.) Greenhalgh states, "Figures 4*a* and 4*b* illustrate that the top port 26 [blue], middle port 27 [purple] and base port 28 [green] substantially align transverse with the longitudinal axis 4." (Ex. 1004, 6:66-7:1.) "The top/middle/base ports form a concurrent vertical port [yellow] through the device 2." (*Id.*, 7:1-2.) Greenhalgh discloses that the concurrent vertical port is "substantially unobstructed when the device 2 is in a height-expanded configuration, as shown in FIG. 4b." (*Id.*, 7:7-9.)



As shown above, the windows in the top, base, and middle are at least partially aligned and there are no features lying in the path and blocking the windows [yellow]. (Ex. 1003, ¶98.)

Greenhalgh's Figure 4b is similar to the '575 patent's Figure 5B. (*Id.*)

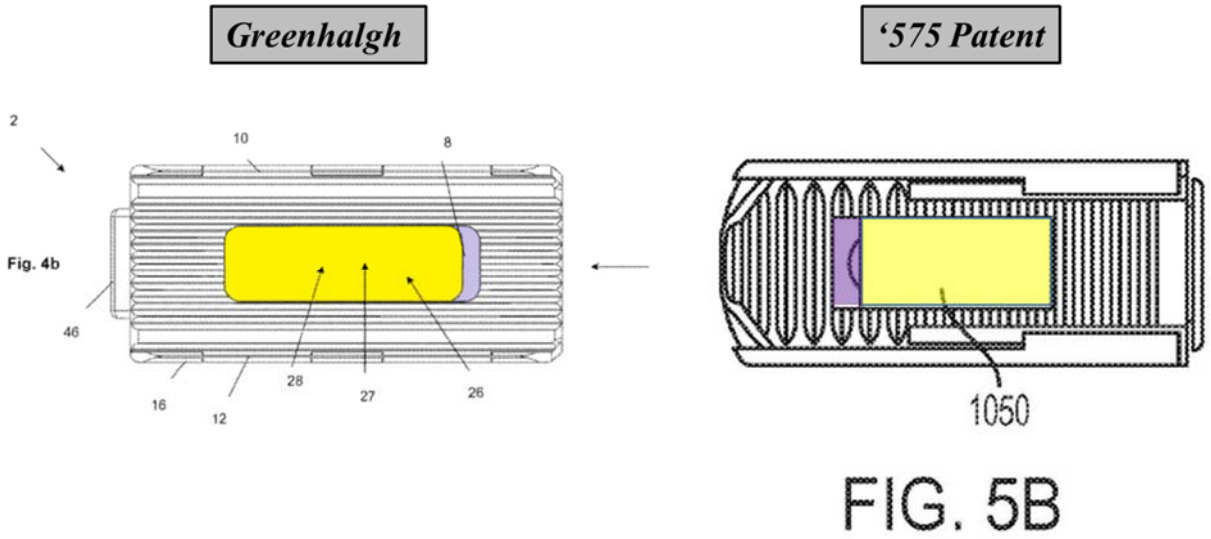


FIG. 5B

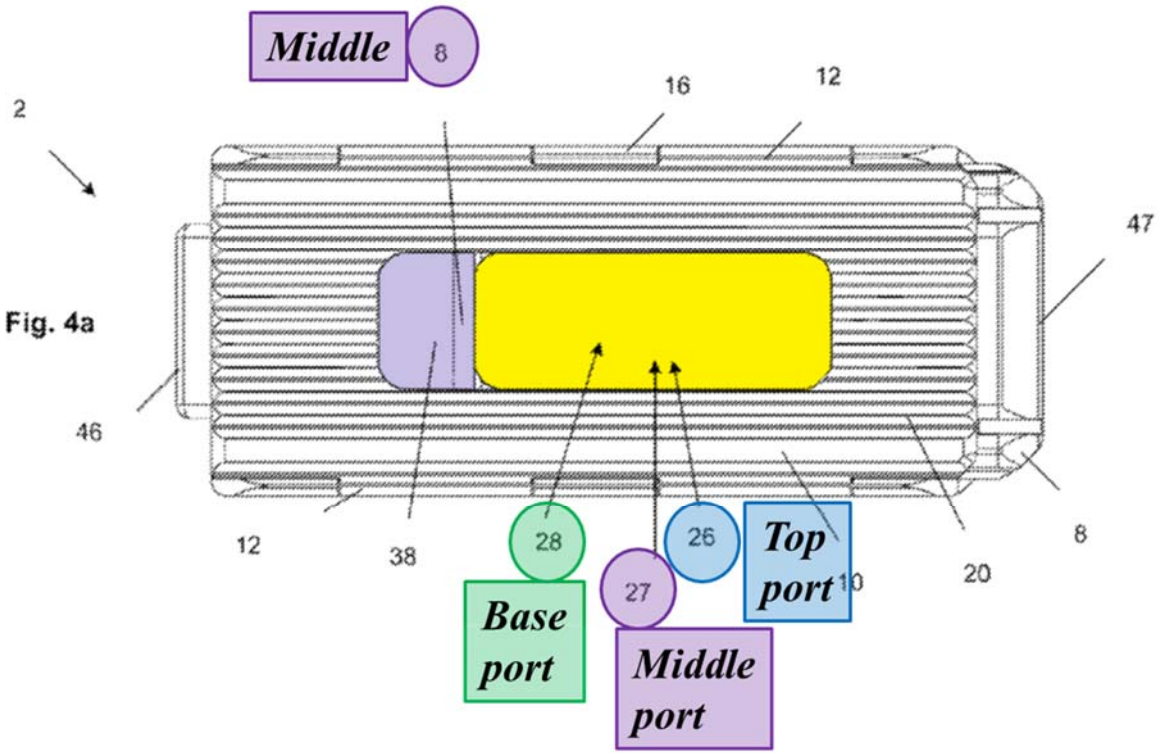
If the windows in Figure 5B are open and unobstructed, then the windows in Greenhalgh's Figure 4b are also open and unobstructed. (*Id.*) Conversely, if the windows in Greenhalgh's Figure 4b (above) are *not* "open and unobstructed," then the windows in Figure 5B of the '575 patent are *not* "open and unobstructed" and the '575 patent lacks written description for the limitation "open and unobstructed." (*Id.*) As a result, a person of ordinary skill in the art would not understand "open and unobstructed" to be read so narrowly as to exclude Figure 5B of the '575 patent or Greenhalgh's Figure 4B. (*Id.*); *see also Ruckus Wireless*, 824 F.3d at 1004 (rejecting a claim construction that would render the claims invalid for lack of written description).

For the above reasons, Greenhalgh anticipates claim 1. (Ex. 1003, ¶¶82-98.)

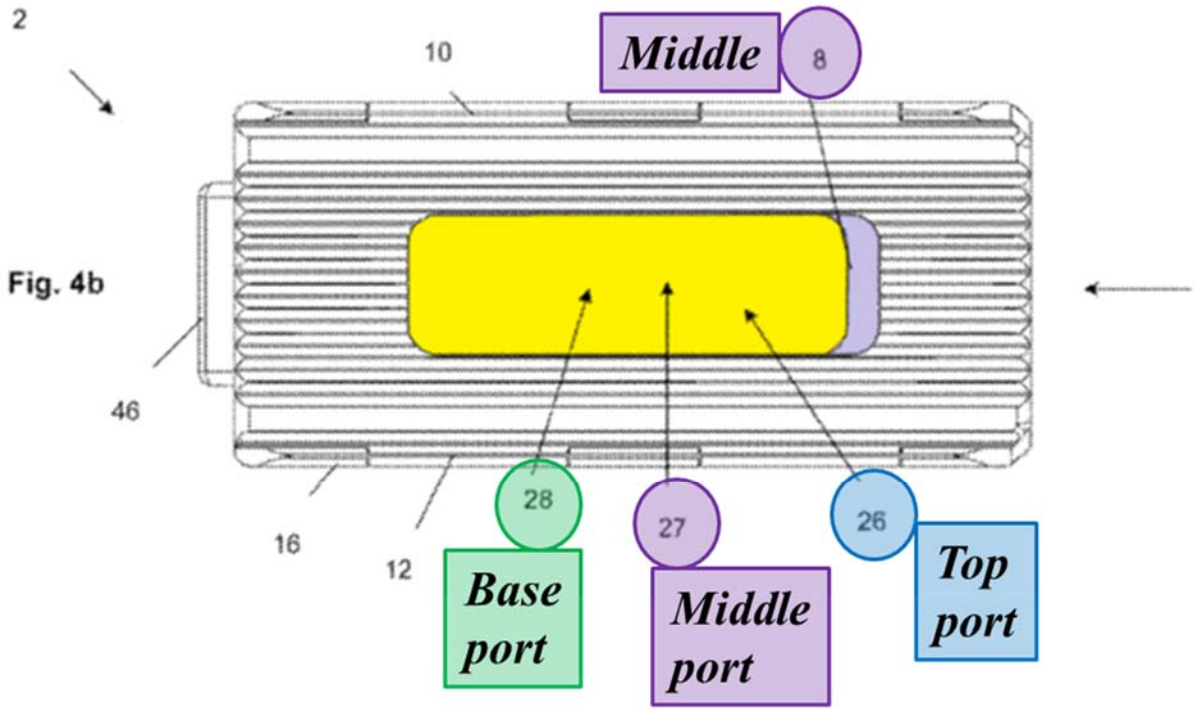
2. Claim 2

Claim 2 recites: "The expandable cage of claim 1, wherein a greater portion of the three windows in the upper portion, lower portion, and elongate expander are aligned and unobstructed with respect to one another when viewed from the top view in the expanded position compared to when viewed from the top view in the unexpanded position." Greenhalgh discloses this limitation. (Ex. 1003, ¶¶99-100.)

The top port, middle port, and base port of Greenhalgh's expandable support device "form a concurrent vertical port [yellow] through device 2." (Ex. 1004, 7:1-2.) Greenhalgh states, "The concurrent vertical port can be partially obstructed by the middle 8 [purple], including the middle first ramp 38, when the device is in a height-contracted configuration as shown in FIG. 4*a*." (*Id.*, 7:4-7.)



"The concurrent vertical port can be less obstructed, or substantially unobstructed when the device 2 is in a height-expanded configuration, as shown in FIG. 4*b*." (*Id.*, 7:7-9.)

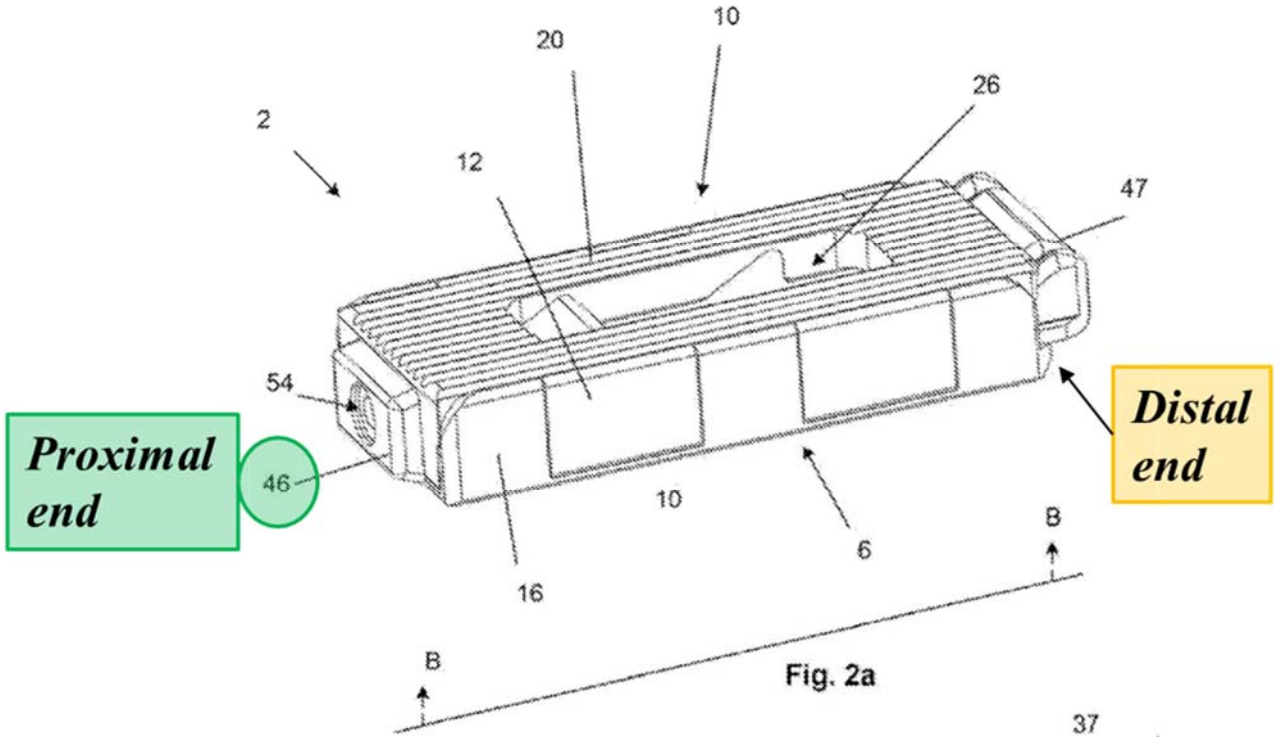


Consequently, a greater portion of the three windows in the top (upper portion), base (lower portion), and middle (elongate expander) are aligned and unobstructed with respect to one another when viewed from the top view in the expanded position compared to when viewed from the top view in the unexpanded position. (Ex. 1003, ¶100.) Thus, Greenhalgh anticipates claim 2. (*Id.*, ¶¶99-100.)

3. Claim 3

Claim 3 recites: "The expandable cage of claim 1, wherein the expandable cage comprises a proximal end and a distal end and the longitudinal translation of the elongate expander in the proximal direction of the expandable cage causes the elongate expander to act upon portions of the upper portion and the lower portion to expand the cage body." Greenhalgh discloses these limitations. (Ex. 1003, ¶¶101-104.)

Greenhalgh's expandable support device 2 has a first side plate 46 [green], which is the proximal end of the device. (Ex. 1004, 6:12-13.) The support device also has a distal end [orange]. (*Id.*, Fig. 2a.)



The first side plate 46 is the proximal end of the support device because it receives the deployment tool or rod. (Ex. 1003, ¶102.) Greenhalgh explains that a "first side outer port 54 can form a recess in the first side plate 46, for example to receive the head of a rod." (Ex. 1004, 6:28-30, 6:59-61, Figs. 2a-3b.) As shown in Figure 12 below, the deployment tool 84 [gray] attaches to the expandable support device 2 [red] at the end closer to the surgeon. (Ex. 1003, ¶102.) Thus, the first side plate 46 is at the proximal end of the device. (*Id.*)

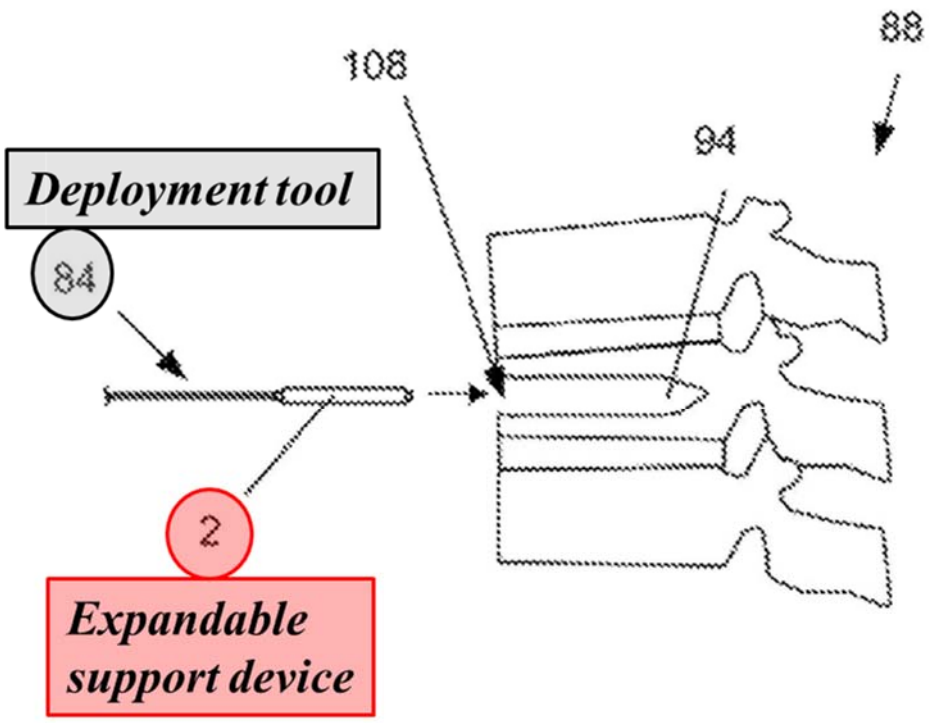
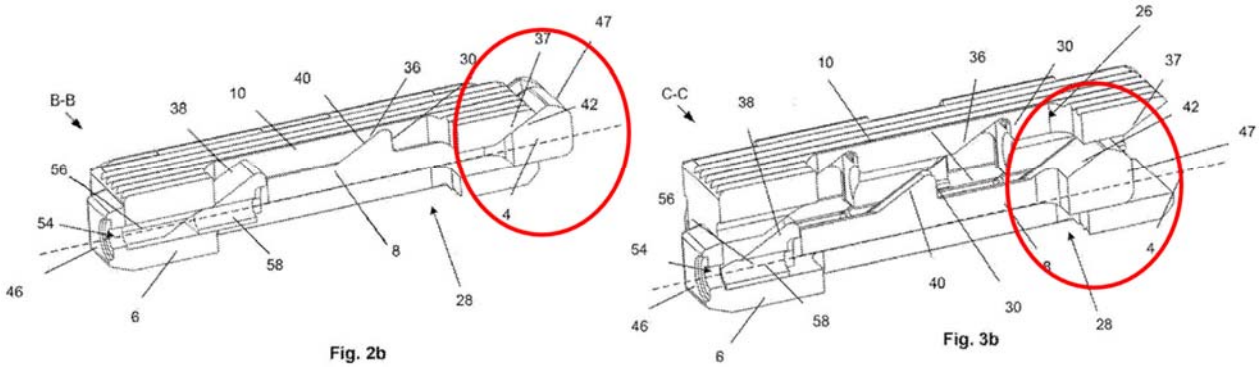
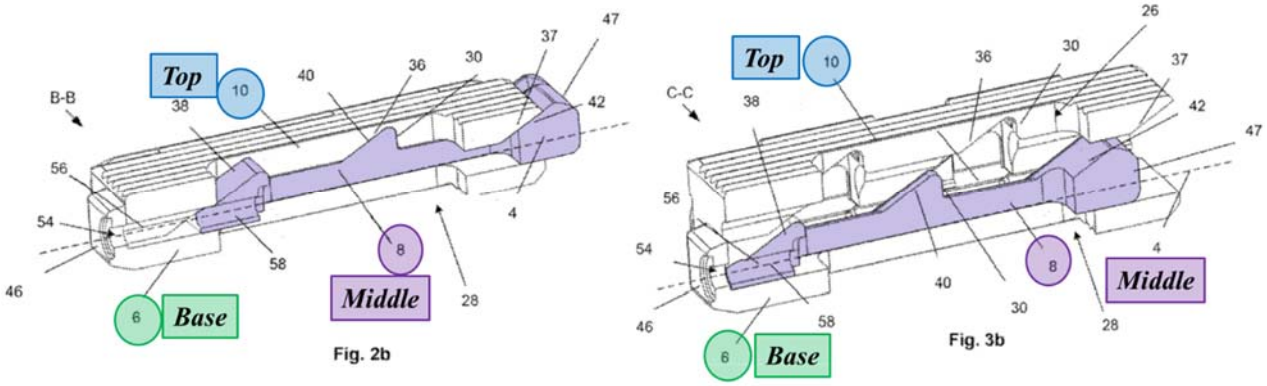


Fig. 12

In contrast, the free end of the device, or distal end, does not have an opening for the engagement of a deployment tool, as shown in figures 2a-2b below. (*Id.*, ¶103.) The free end, or distal end, of the device leads the device during insertion into the patient. (*Id.*) The distal end in figures 2b and 3b below has rounded or atraumatic edges to ease the insertion of the device into the tissue. (*See e.g.*, Ex. 1007, 9:1-16, Ex. 1010, [0005], [0039], [0050] (explaining need for rounded edges on leading edge.) The free end of the device is farther from the surgeon during insertion of the device into the patient, and, therefore, the free end of the device circled below is the distal end. (Ex. 1003, ¶103.)



The longitudinal translation of the middle 8 in the proximal direction of the expandable support device 2 causes the middle to act upon the top 10 and the base 8 to expand the cage body. (*Id.*, ¶104.) Figures 2b and 3b show cross-sections of the device in the unexpanded and expanded positions, respectively. (Ex. 1004, 3:55-60.) In Figure 3b, the middle 8 has been "slidably translated toward the first end." (*Id.*, 6:44-46.)



When the middle 8 slides proximally, it acts upon the top 10 and base 6 to expand the cage body. (*Supra* VI.A.1.d.) Thus, Greenhalgh anticipates claim 3. (Ex. 1003, ¶¶101-104.)

4. Claim 4

Claim 4 recites: "The expandable cage of claim 1, wherein the elongate expander has a keyed distal end." Greenhalgh discloses this limitation. (Ex. 1003, ¶¶105-106.)

The middle 8 (elongate expander) includes an angled ramp 42 at its distal end.[7] (Ex. 1004, 6:1-7, Fig. 1a.) The distal ramp is sized and shaped to match the corresponding surfaces on the top 10 (upper portion) and base 6 (lower portion). (*Id.*, 2:54-61, 6:1-13, 6:40-46, 7:17-23.) Consequently, the middle has a keyed distal end. (Ex. 1003, ¶106.)

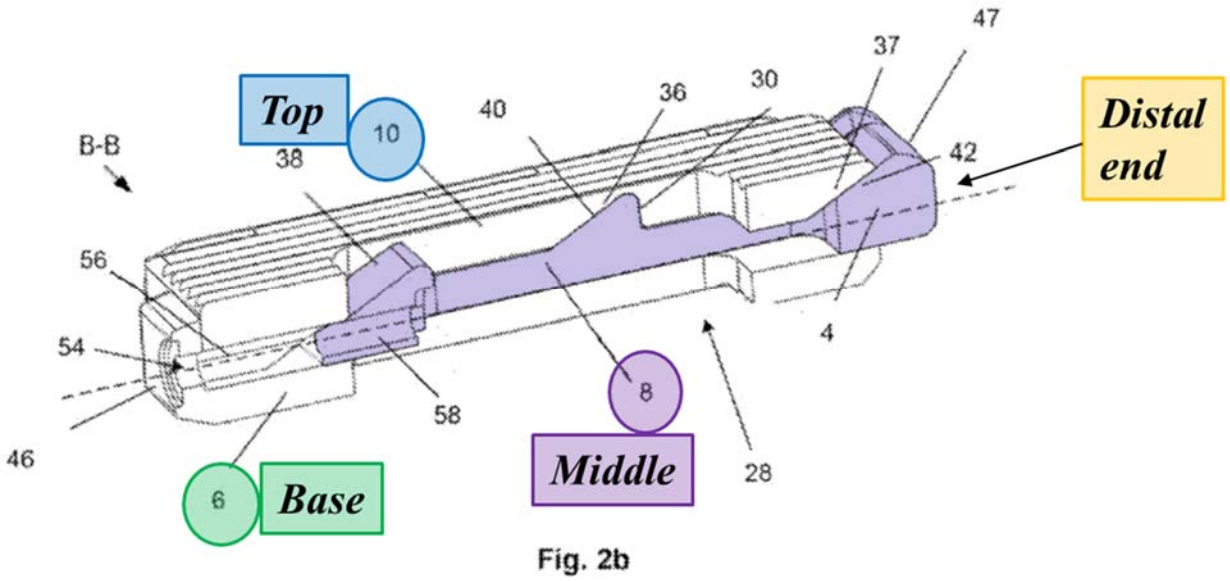


Fig. 2b

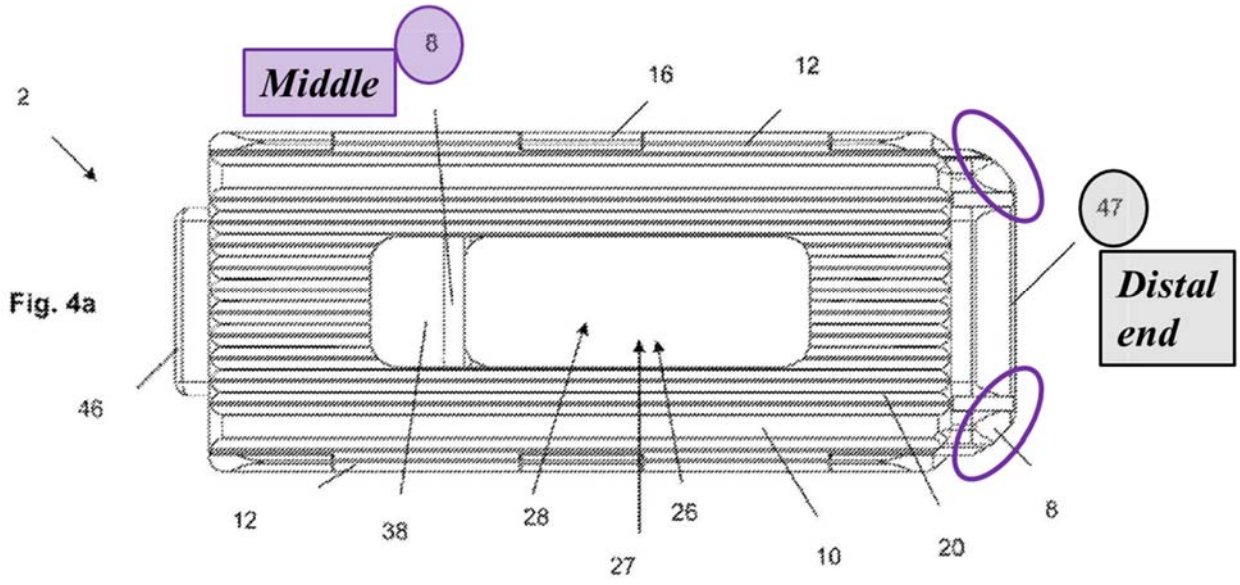
(Ex. 1004, Fig. 2b.) Thus, Greenhalgh anticipates claim 4. (Ex. 1003, ¶¶105-106.)

[7] Petitioner incorporates the analysis from claim 3 regarding the proximal and distal ends of the expander. (*Supra* VI.A.3.)

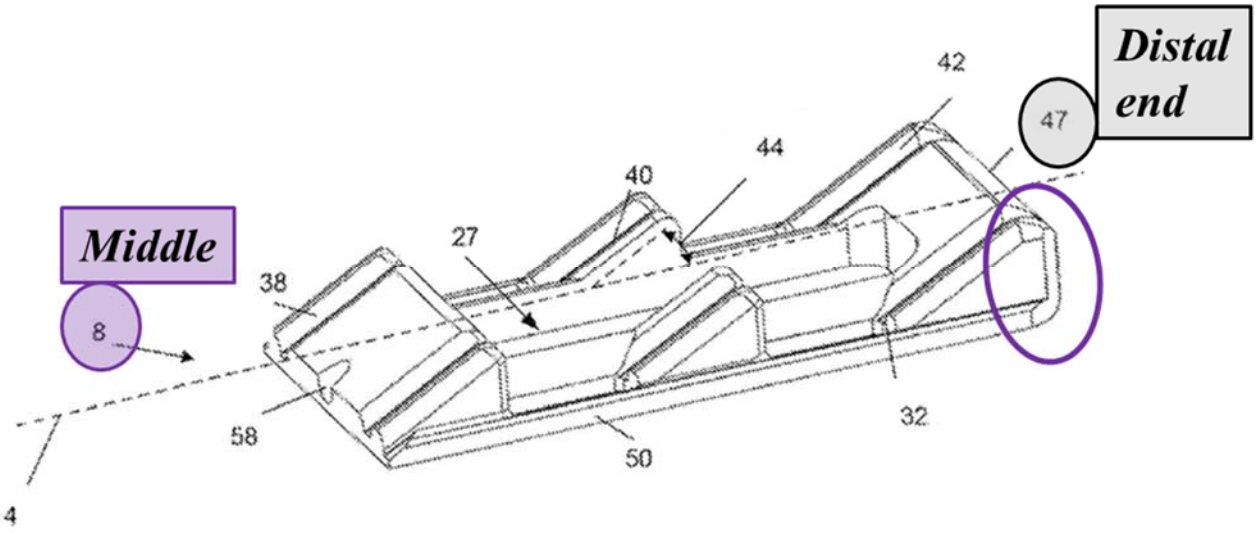
5. Claim 5

Claim 5 recites: "The expandable cage of claim 4, wherein the keyed distal end has tapered sides." Greenhalgh discloses this limitation. (Ex. 1003, ¶¶107-108.)

As shown by the purple circles below, the distal end of the middle 8 [purple] has tapered sides. (Ex. 1004, Fig. 4a; Ex. 1003, ¶108.)



The tapered sides are also visible in Figure 1a below, as identified by the purple circles. (Ex. 1003, ¶108.)

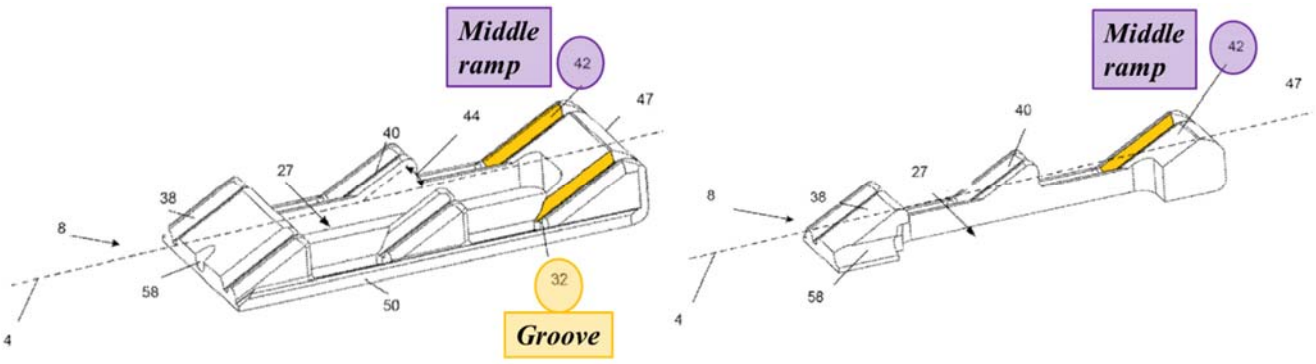


(Ex. 1004, Fig. 1a (excerpt).) Thus, Greenhalgh anticipates claim 5. (Ex. 1003, ¶¶107-108.)

6. Claim 6

Claim 6 recites: "The expandable cage of claim 1, wherein the elongate expander has a recess defined in the distal portion of the elongate expander." Greenhalgh discloses this limitation. (Ex. 1003, ¶¶109-110.)

Greenhalgh discloses that the "ramps can have ramp tongue and grooves 32." (Ex. 1004, 5:64.) "Ramp tongue and grooves 32 on corresponding ramps can be configured to slidably attach to the opposing tongues and grooves." (*Id.*, 5:64-66.) For example, the "middle ramps 38, 40, 42 can have middle tongues and grooves that can slidably engage the top tongues and grooves." (Ex. 1004, 6:1-3.) Each groove 32 [orange] within the distal middle ramp 42 is a recess defined in the distal portion of the elongate expander. (Ex. 1003, ¶110.)

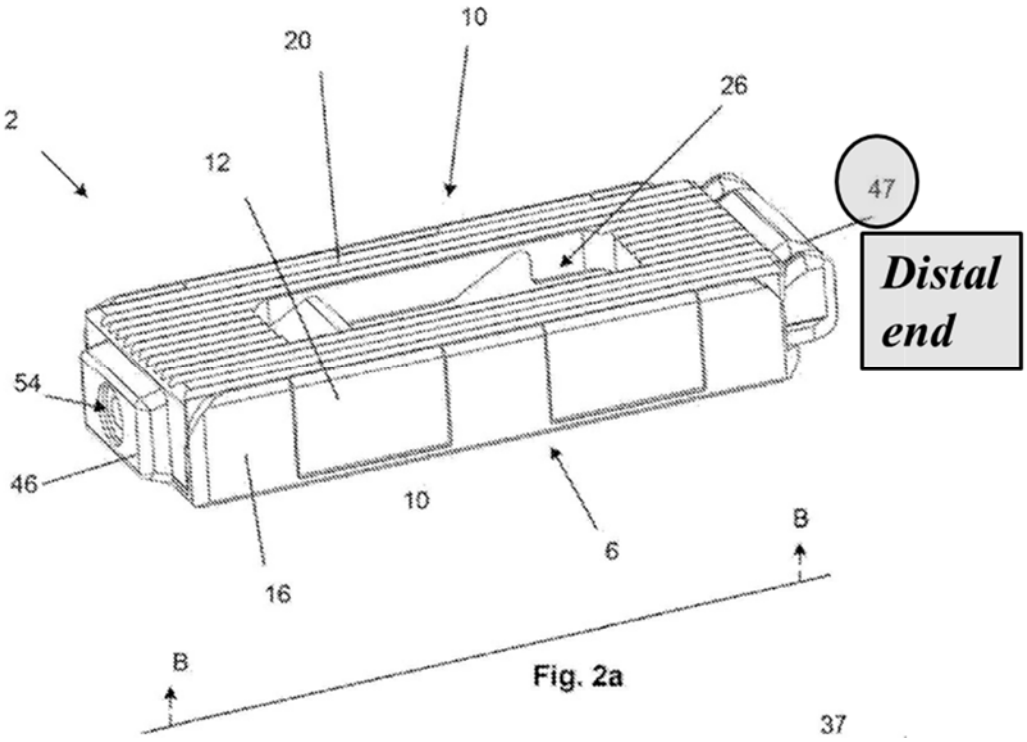


(Ex. 1004, Fig. 1 (excerpt).) Thus, Greenhalgh anticipates claim 6. (Ex. 1003, ¶¶109-110.)

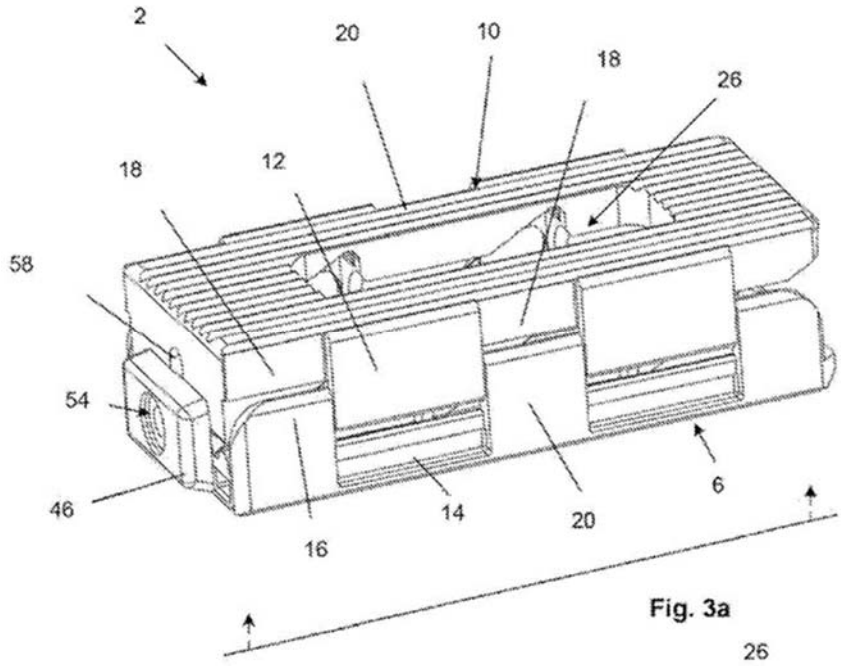
7. Claim 7

Claim 7 recites: "The expandable cage of claim 1, wherein the elongate expander moves from the first position to the second position by pulling the elongate expander proximally." Greenhalgh discloses this limitation. (Ex. 1003, ¶¶111-113.)

The middle 8 (elongate expander) is in a first position when the expandable support device 2 is in its "height-contracted configuration," as shown in Figure 2a below. (Ex. 1004, 3:55-56, Fig. 2a.) In this configuration, middle 8 protrudes outside of the footprint of the top and base at the distal end of the device. (*Id.*, 7:10-16.)



The middle 8 (elongate expander) is in a second position when the expandable support device 2 is in its "height-expanded configuration," as shown in Figure 3a below. (*Id.*, 3:58-59, Fig. 3a.)



The support device moves from the first to second position when the middle 8 is "slidably translated towards the first end." (*Id.*, 6:44-46.) The surgeon slidably translates the middle towards the first end by pulling the deployment rod attached to the proximal end of the middle towards the surgeon. (*Id.*, 7:30-33.) As explained previously, the "first end" is the proximal end. (*Supra* VI.A.3.) Thus, Greenhalgh anticipates claim 7. (Ex 1003, ¶111-113.)

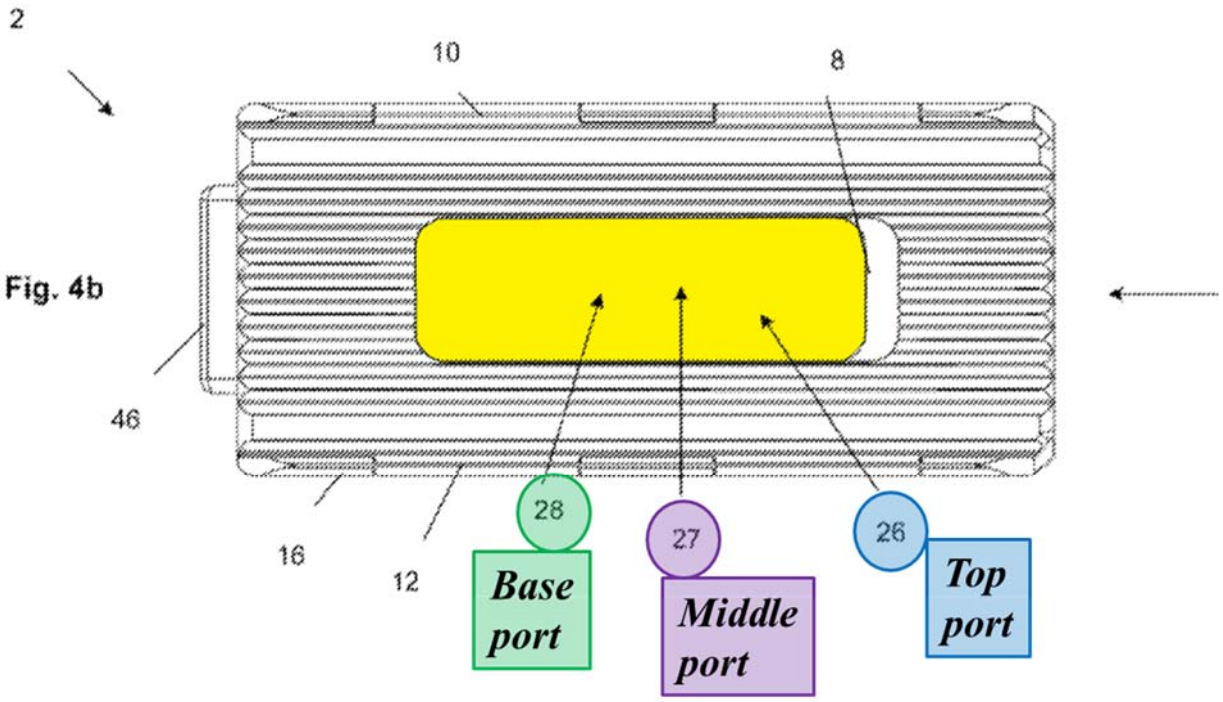
8. Claim 8

Claim 8 repeats the limitations of claim 1 and includes two additional limitations. Greenhalgh satisfies the limitations in claim 1 for the reasons previously presented. (*Supra* VI.A.1.) Greenhalgh alone or in combination with Lynn or Weiman renders the additional limitations obvious. (Ex. 1003, ¶¶114-142.)

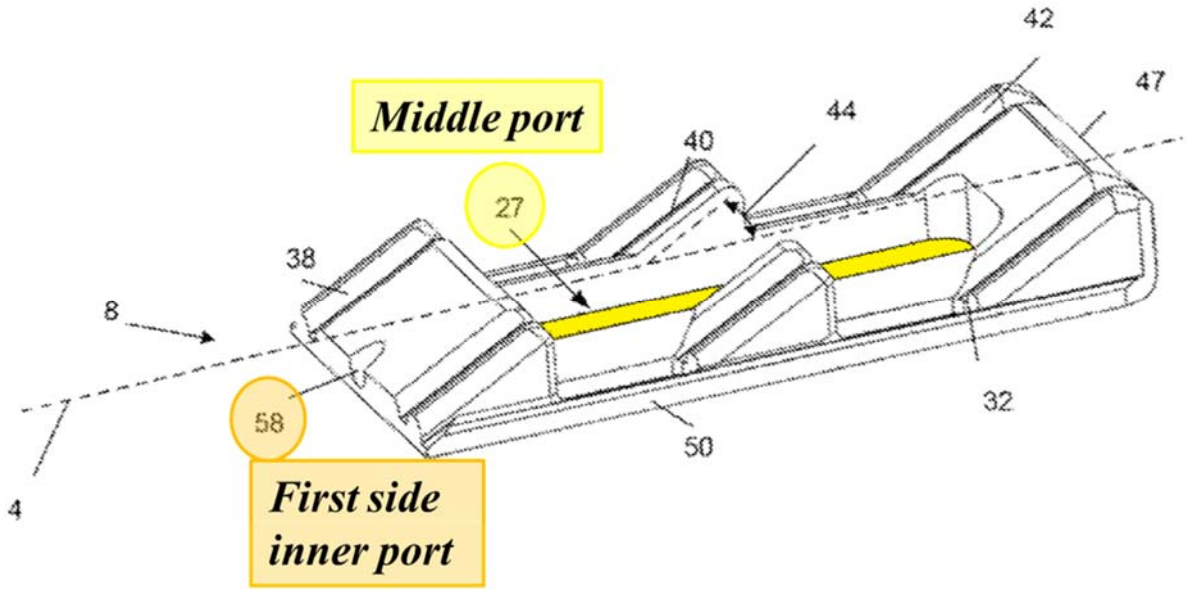
a. A Cavity and Aperture

Following the limitations in claim 1, claim 8 recites: "wherein the windows in each of the upper portion, lower portion, and elongate expander define the cavity, and wherein an aperture is defined in a proximal end of the elongate expander in communication with the cavity through the opening in the elongate expander and configured to permit packing of the cavity through the open and unobstructed windows with bone growth material after expansion of the expandable cage." Greenhalgh satisfies this limitation, or renders the limitation obvious. (Ex. 1003, ¶¶115-125.)

Greenhalgh discloses ports in the top, middle, and base, which "form a concurrent vertical port [yellow] through the device 2," as shown in Figure 4b below. (Ex. 1004, 6:66-7:2.) The vertical port is a cavity defined by the windows. (Ex. 1003, ¶116.)



The middle 8 (elongate expander) includes a first side inner port 58 [orange]. (Ex. 1004, 6:25-30, Figs. 1a-1b.) The first side inner port 58 is an aperture in the proximal end of the elongate expander. (Ex. 1003, ¶117.)



(Ex. 1004, Fig. 1a (excerpt).) As shown in Figures 1a above and 3b below, the first side inner port 58 is in communication with the middle port 27 [yellow], which forms part of the cavity. (*Id.*, Figs. 1a-1b, 2b, 3b; Ex. 1003, ¶117.)

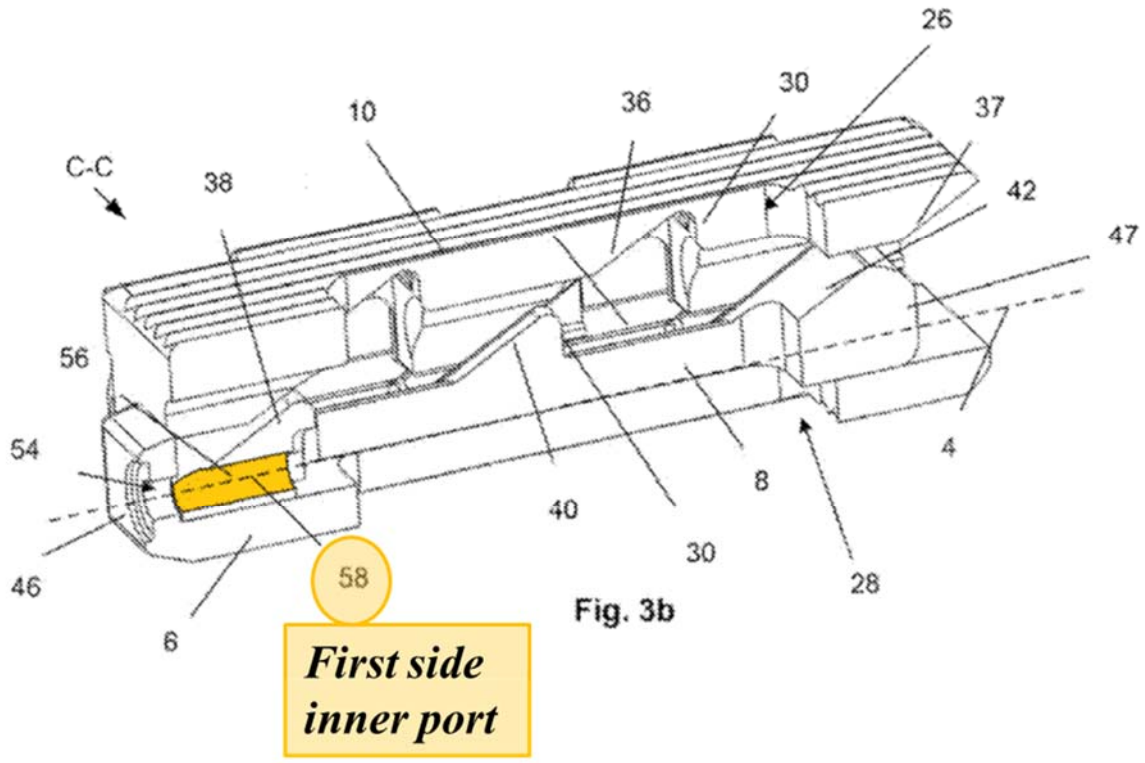


Fig. 3b

Greenhalgh states, "When the expandable support device 2 is in a deployed configuration in vivo, the expandable support device 2 can be partially or substantially filled with a liquid, gel, or solid (e.g., in small parts or granules) filler material, or combinations thereof, such as bone morphogenic powder or any other material disclosed herein or combinations thereof." (Ex. 1004, 9:30-35.) The "deployed configuration" is the expanded configuration. (*Id.*, 3:1-7.) Greenhalgh discloses a variety of bone growth materials for filling the vertical port (cavity). (*See e.g.*, *id.*, 3:17-38; 10:26-11:8 (listing materials).)

Greenhalgh does not expressly disclose how the surgeon fills the vertical port when the device is in the deployed configuration. However, the surgeon must fill the port through the first side inner port 58 [orange] if the expandable support device is "in a deployed configuration in vivo." (Ex. 1003, ¶119.)

In the deployed configuration, the top and base of the device 2 press against the vertebrae and surrounding tissue, as shown below. (Ex. 1004, 12:30-35, 13:35-38, Fig. 26.)

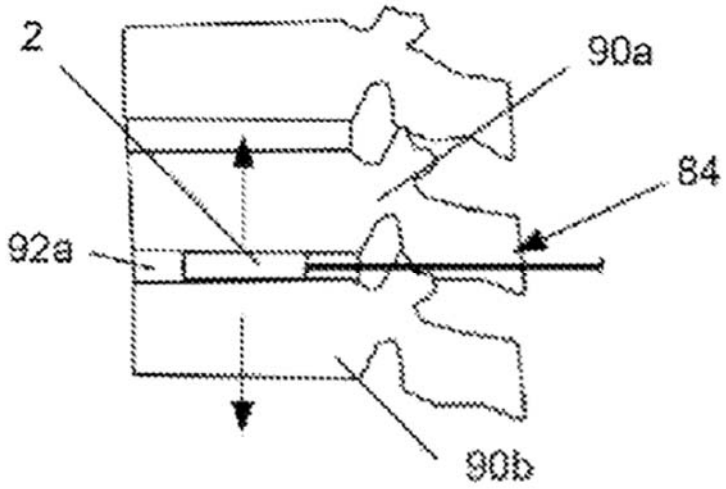


Fig. 26

Consequently, the surgeon cannot access the top or bottom ports to insert material. (Ex. 1003, ¶119.)

The surgeon would also have very limited access, if any, to the cavity through the sides of the device in the expanded position due to the top 12 [blue], base [green] and middle 8 [purple]. (*Id.*, ¶120) As shown in Figure 3a below, the top, bottom, and middle block access to the cavity from the sides. (*Id.*)

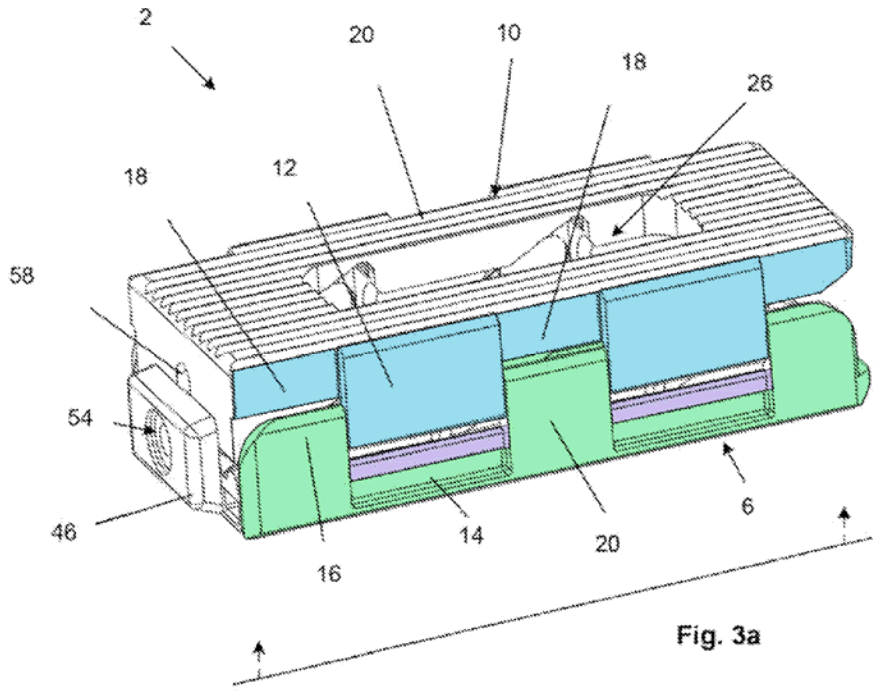


Fig. 3a

Because the top, bottom, and sides of the device are inaccessible, a POSITA would have understood that the only way to pack the internal cavity when the device is in the deployed configuration would be through the first side outer port 54 and first side inner port 58. (*Id.*)

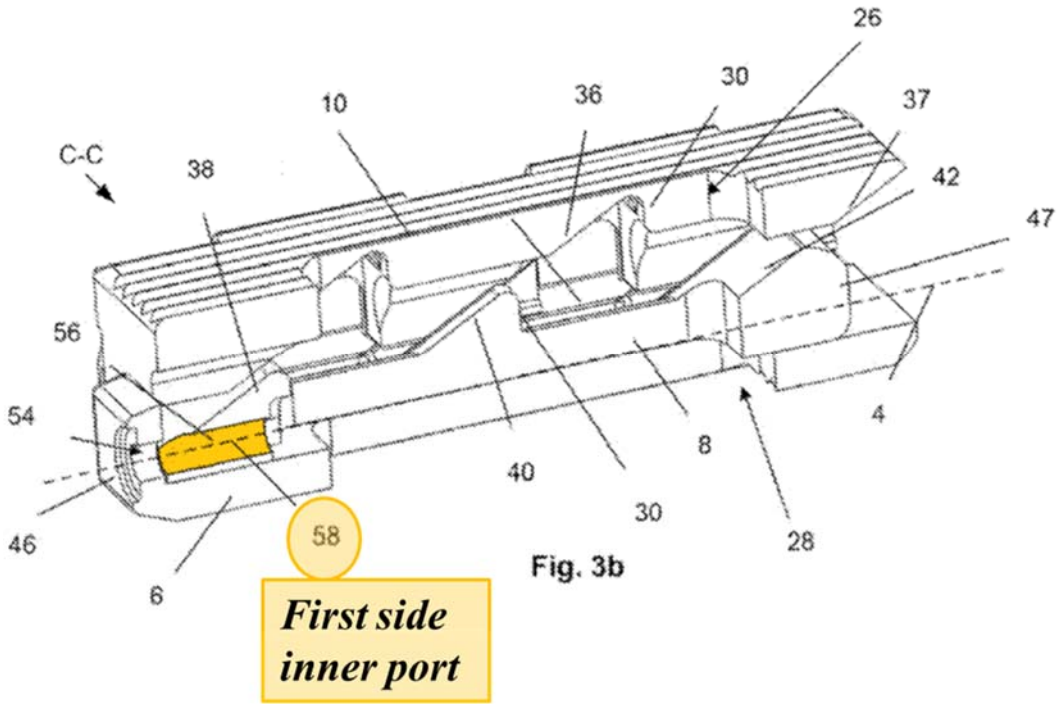


Fig. 3b

Thus, the first side inner port 58 is necessarily configured to permit packing of the cavity through the open and unobstructed windows with bone growth material after expansion of the expandable cage. (*Id.*, ¶121.) The first side inner port 58 would not prevent or unduly restrict the packing of the cavity. (*Id.*) Notably, the diameter of the first side ports (54, 58) in Greenhalgh's device is comparable to the diameter of the opening in the proximal end of the '575 patent's device (see green below). (*Id.*)

Greenhalgh ***'575 Patent***

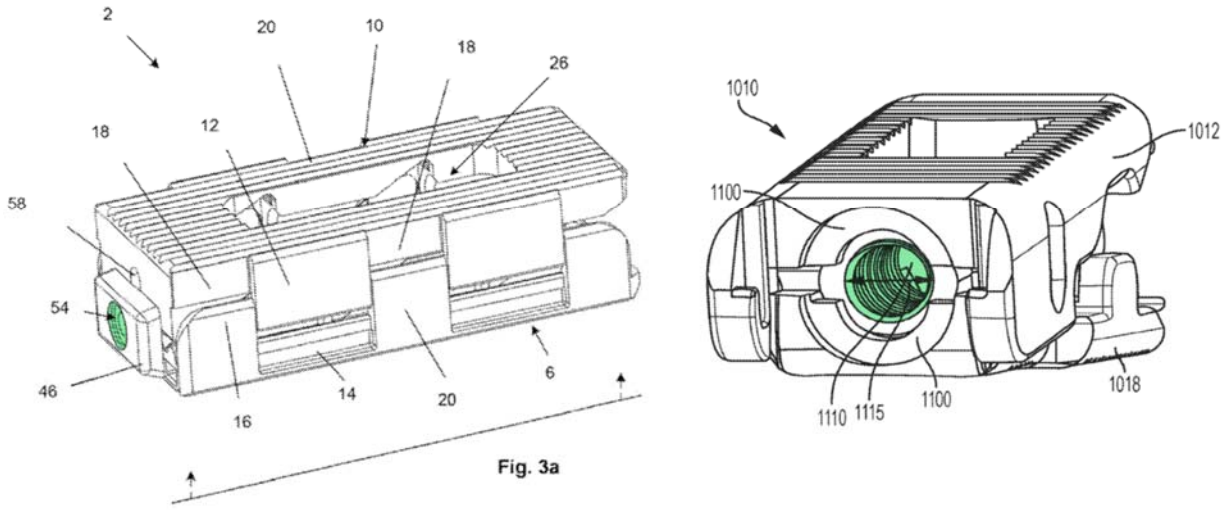


Fig. 3a

If the opening in the '575 patent is "configured to permit" packing of the cavity then so are Greenhalgh's ports. (*Id*.) Conversely, if the first side ports in Greenhalgh are *not* "configured to" permit packing of the cavity with bone growth material, then the opening in the '575 patent is *not* "configured to" permit packing of the cavity with bone growth material and the '575 patent lacks written description for this limitation. (*Id.*) As a result, a person of ordinary skill in the art would not understand "configured to permit" packing of the cavity with bone growth material to be read so narrowly as to exclude the opening in the '575 patent or Greenhalgh's first side ports. (*Id.*); *see also Ruckus Wireless*, 824 F.3d at 1004 (rejecting a claim construction that would render the claims invalid for lack of written description). For these reasons, Greenhalgh inherently discloses this limitation. (Ex. 1003, ¶121.)

Moreover, even if the surgeon could pack the vertical port through another opening, a POSITA would have found it obvious, and been motivated, to pack the

cavity through the first side inner port 58 when the device is in the deployed configuration. (Ex. 1003, ¶122.) The deployment rod attaches to the first side inner port 58 to deliver the device. (*See e.g.*, Ex. 1004, 6:19-30.) A POSITA would have been motivated to deliver bone growth material through the existing connection, rather than having to reposition the deployment tool, or insert another tool, to access a separate opening. (Ex. 1003, ¶122.)

A POSITA would have been familiar with prior art references, such as Lynn (Ex. 1007), which describe using a single deployment device for delivery of the implant, as well as bone growth material. (Ex. 1003, ¶122.) Lynn describes a cannulated insertion tool assembly 300´, which "can be used to both deliver the implant to its proper intervertebral position and to subsequently fill the interior chamber(s) of the implant 10 with one or more graft and/or other fill materials." (Ex. 1007, 24:39-45.) Lynn explains this configuration eliminates "the need to disengage the implant 10 from the distal end of the insertion tool assembly 300´ and engage a separate fill tool assembly." (*Id.*, 24:49-53.)

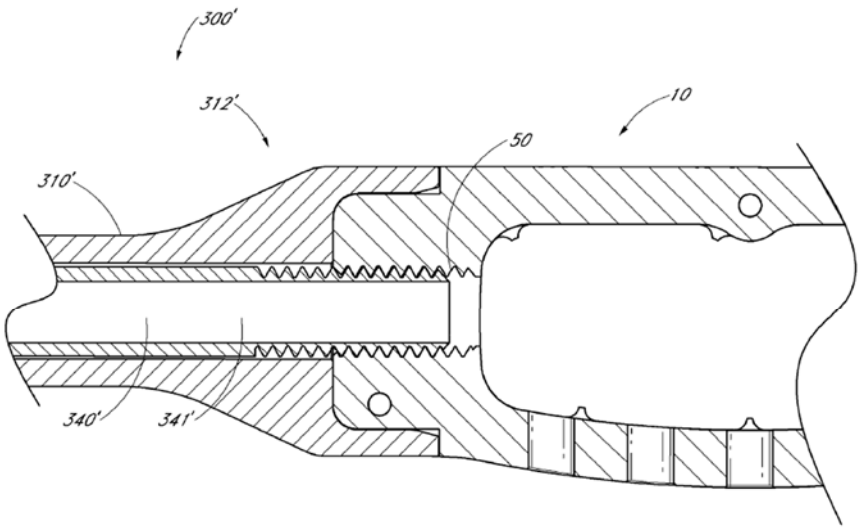


FIG. 18

(*Id.*, Fig. 18.)

A POSITA would have been motivated to use a single tool to deliver the implant and introduce bone growth material for many reasons, including reducing trauma to the patient, shortening the overall length of the surgical procedure, and minimizing opportunities for complications. (Ex. 1003, ¶124.) Further, because such tools existed in the prior art, as demonstrated by Lynn, a POSITA would have had an expectation of success in introducing bone growth material through the first side inner port 58 in Greenhalgh using such a tool. (*Id*.)

Thus, if Greenhalgh does not disclose this limitation, it renders the limitation obvious in light of the background of a POSITA. (*Id.*, ¶¶122-125.)

b. <u>Cap or Set Screw</u>

Claim 8 recites: "a cap or set screw, the cap or set screw being inserted into the aperture at the proximal end of the elongate expander to contain the bone growth

material." Greenhalgh alone, or in combination with Lynn or Weiman, renders this limitation obvious. (Ex. 1003, ¶¶126-142.)

i. Greenhalgh Alone

Greenhalgh discloses a first side plate 46 having a first side outer port 54 [green]. (Ex. 1004, 6:19-20.) The first side outer port 54 aligns with the first side central port 56 [blue] in the top 10 and the first side inner port 58 [orange] in the middle 8 to create an aperture [yellow] that extends from the proximal end of the device to the internal cavity. (*Id.*, 6:20-30, Figs. 1a, 2b.)

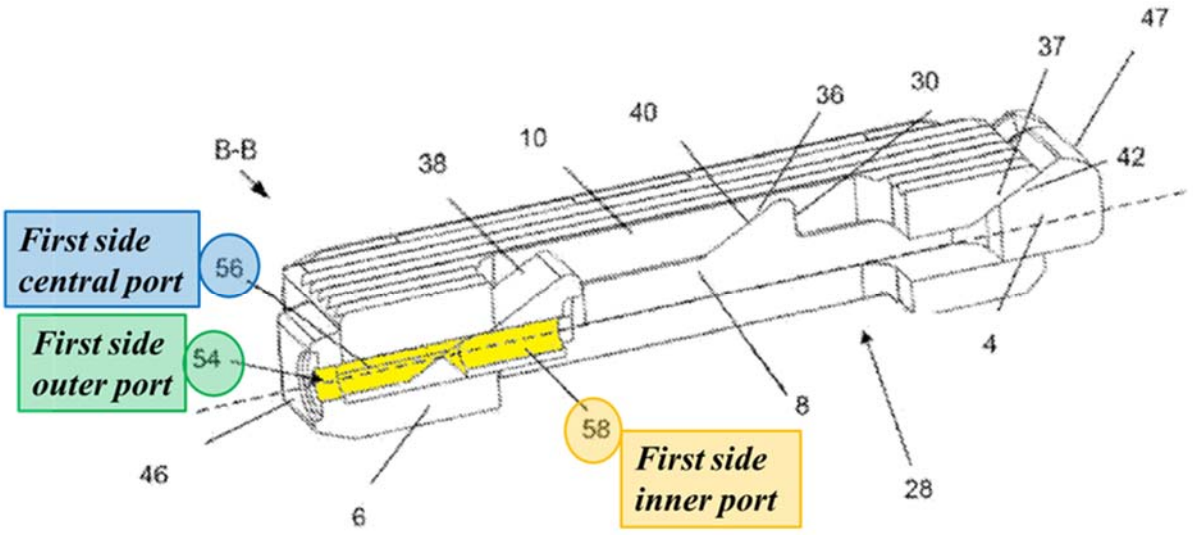
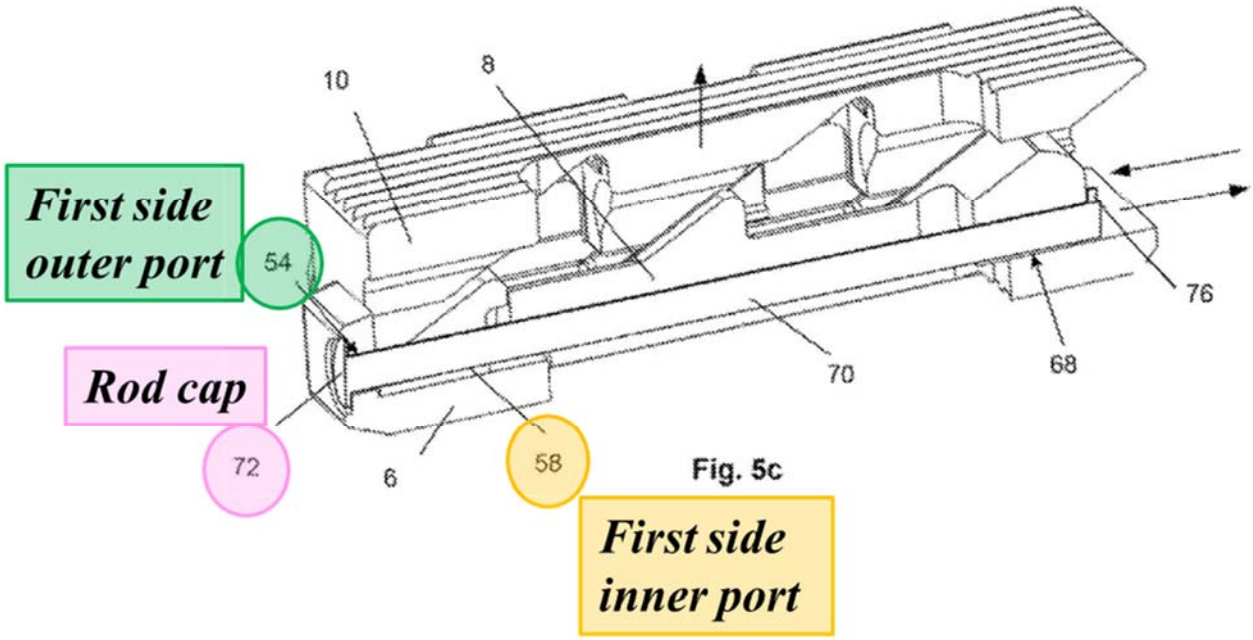


Fig. 2b

The first side outer port 54 forms a threaded recess in the first side plate 46 to receive devices. (*Id.*, 6:26-30.)

Greenhalgh also discloses a deployment rod or locking pin 70 having a "rod cap 72 or nut that can be outside the first port and interference fit with the wall surrounding the first port." (*Id.*, 7:25-29.) The cap or nut may include a "driver slot,"

as shown in Figure 5c[8] below, "configured to receive a screw driver or drill bit." (*Id.*, 7:34-39.)



Greenhalgh discloses that the rod cap 72 or nut is "attached or integral" with the deployment rod 70. (*Id.*, 7:25-29.) To the extent claim 8 requires the cap to be a separate feature, a POSITA would have recognized that the cap or nut could be

[8] Figure 5c depicts an embodiment where the deployment rod/pin 70 extends through the entire device. (Ex. 1003, ¶128.) However, Greenhalgh discloses several other embodiments where the rod does not span the device. In Figure 2b, for example, the distal end of the middle 8 does not include a second side port 68, which could accommodate a deployment rod. (*See e.g.*, Ex. 1004, 7:24-25 (explaining, "middle 8 can have a second side port 68").)

separate from the delivery device. (Ex. 1003, ¶129.) Caps are often separate from the devices they are sealing (e.g., bottle caps). (*Id.*) Thus, based on the disclosure in Greenhalgh, and the knowledge of a POSITA, a POSITA would have found it obvious to insert a separate cap (i.e., not attached to the deployment rod) into the first side outer port 54. (*Id.*)

Further, based on the specification, a POSITA would have found it obvious to select a cap that was long enough to extend from the first side outer port 54 [green] into the first side inner port 58 [orange]. (*Id.*, ¶130.) In the expanded configuration (below), the first side inner port 58 abuts the first side outer port 54. (Ex. 1004, Fig. 3b.)

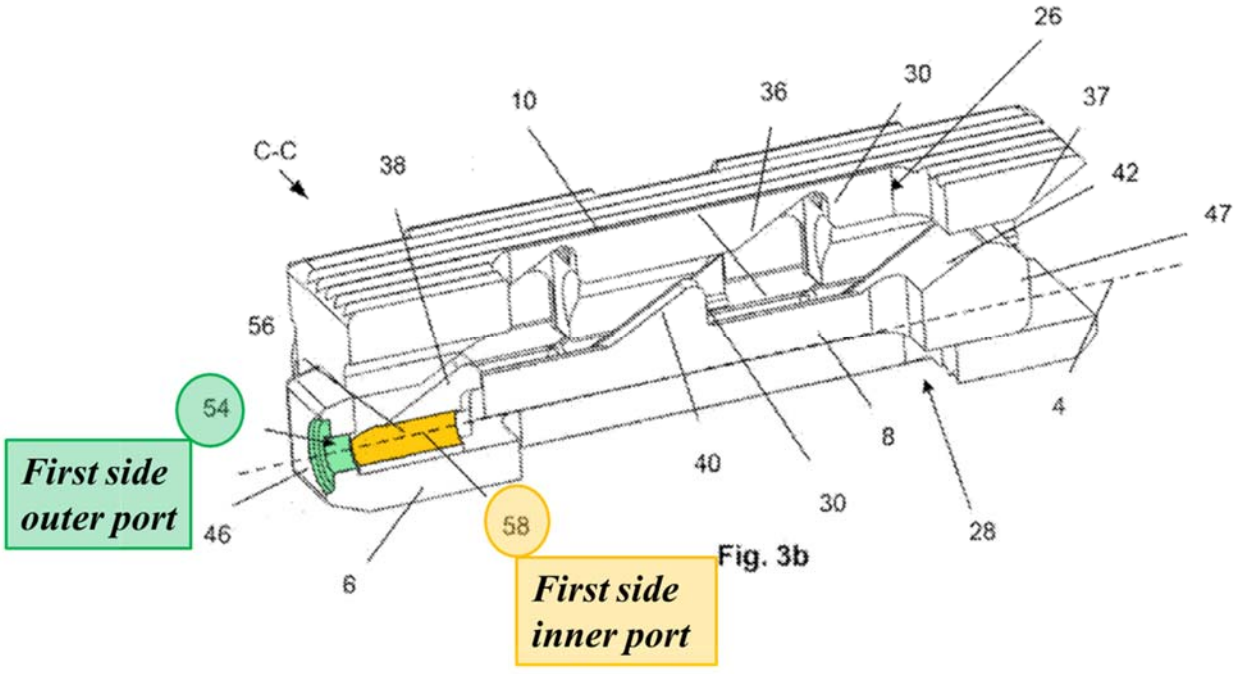


Fig. 3b

Thus, even a short cap would extend into the first side inner port 58. (Ex. 1003, ¶130.) Further, a POSITA would have been motivated to use a cap that extended into

the first side inner port 58 for two reasons. First, if the cap spanned from the first side outer port 54 to the first side inner port 58, the cap would help keep the base and middle aligned by preventing them from shifting vertically with respect to each other. (*Id.*) Second, the cap would prevent bone growth material from escaping into any gap between the first side outer port and first side inner port. (*Id.*) Thus, in light of Greenhalgh and the background knowledge of a POSITA, a POSITA would have found it obvious to use a cap inserted into the aperture (first side inner port) at the proximal end of the elongate expander (middle). (*Id.*)

Moreover, once inserted, the cap would contain the bone growth material within the device by blocking off the proximal ports. (*Id.*, ¶131.) A POSITA would have understood that a cap would prevent the bone growth material from escaping through the proximal ports. (*Id.*) Thus, Greenhalgh alone renders this limitation obvious. (*Id*.)

ii. Greenhalgh with Lynn

If Greenhalgh alone does not render this limitation obvious, a POSITA would have found it obvious to use the "cap or other sealing member" disclosed in Lynn with the support device in Greenhalgh. (Ex. 1003, ¶¶132-135.)

Lynn discloses "a spinal implant 10 configured for placement between adjacent vertebrae of a patient." (Ex. 1007, 6:66-7:1, Fig. 1.) The implant includes a port 1136 [orange] in its proximal end that receives a delivery tool and facilitates

"post-filling, at least partially an interior chamber or cavity of the implant with grafting agents and/or other filler materials." (*Id.*, 25:64-26:12.) A "cap or other sealing member 1138 [pink] can be secured to the port 1136." (*Id.*, 26:13-14, Fig. 20.)

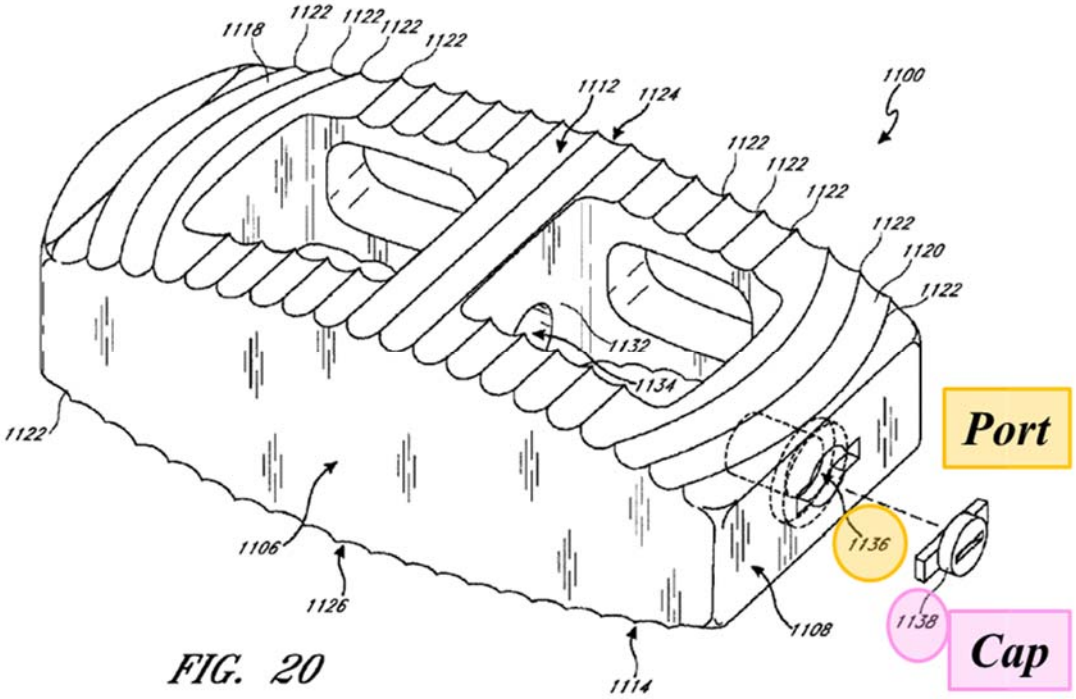


FIG. 20

Lynn discloses that the "cap 1138 can help ensure that grafting and/or filler materials delivered or otherwise positioned within the interior of the implant do not escape through the port 1136." (*Id.*, 26:14-17.)

A POSITA would have been motivated to use Lynn's cap with Greenhalgh's expandable support device to prevent bone growth material from escaping out of the proximal ports. (Ex. 1003, ¶134.) While the cap in Lynn extends a short distance into the device, a POSITA would have found it obvious to use a longer cap that

would span the distance between the first side outer port and first side inner port in Greenhalgh's device for the reasons discussed above. (*Id.*; *Supra* VI.A.8.b.i.)

For these reasons, Greenhalgh in combination with Lynn renders claim 8 obvious. (Ex. 1003, ¶¶132-135.)

iii. Greenhalgh with Weiman

A POSITA also would have found it obvious to use a set screw, like Weiman's actuator assembly 200, with the support device in Greenhalgh. (Ex. 1003, ¶¶136-142.) As explained more below (*infra* VI.B.1), Weiman discloses a fusion device that includes an actuator assembly 200. (Ex. 1005, 24:59-63.) The actuator assembly 200 is a set screw. (Ex. 1003, ¶136; *infra* VI.B.8.b.)

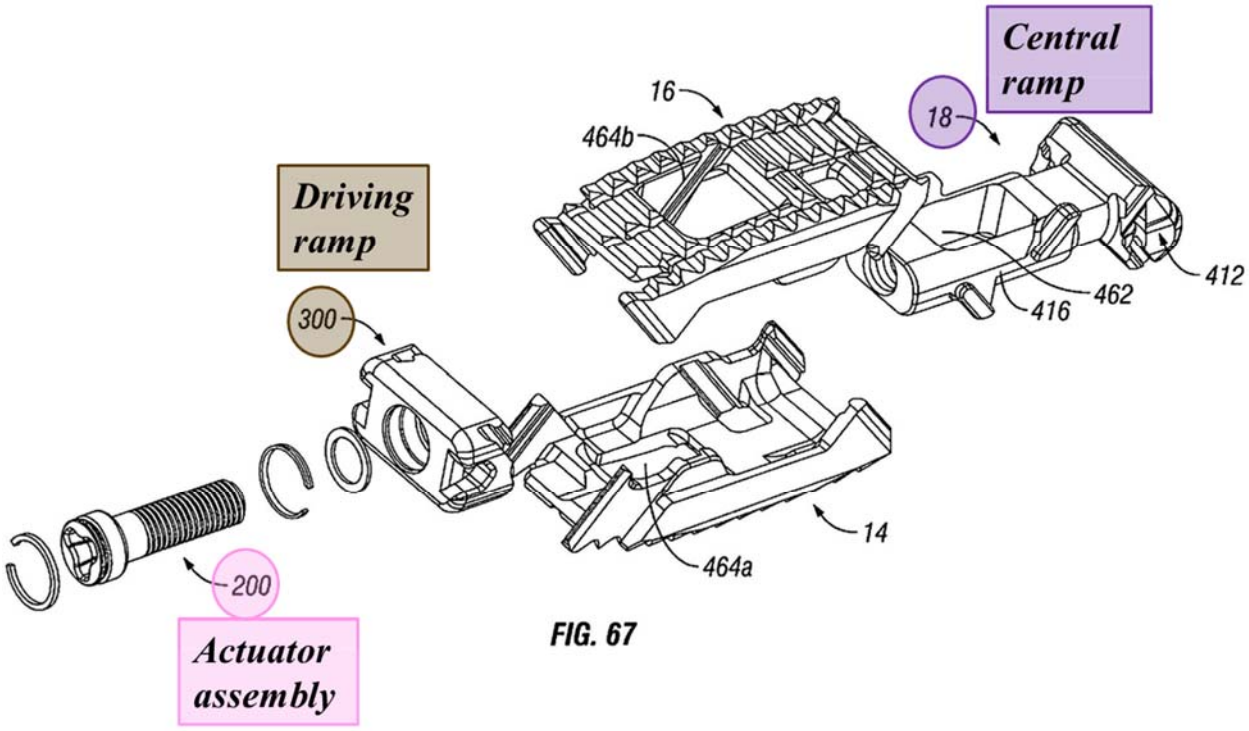


FIG. 67

The actuator assembly 200 engages the driving ramp 300 and the central ramp 18 of the support device. (Ex. 1005, 22:31-67.) Rotating the actuator assembly 200 pulls the ramp 18 towards the actuator assembly and expands the fusion device. (*Id.*, 23:49-51.)

A POSITA would have been motivated to consult Weiman when searching for ways to enhance the Greenhalgh device because the devices operate in a similar fashion. (Ex. 1003, ¶138.) The Greenhalgh and Weiman devices both expand by pulling a middle or central expander towards the proximal end of the device. (*Id.*) A POSITA would have been motivated to implement Weiman's actuator assembly (set screw) in Greenhalgh's device for at least two reasons. (*Id*.)

First, Greenhalgh requires the surgeon to pull a deployment rod proximally to expand the device. (Ex. 1004, 6:44-46, 7:30-33.) A POSITA would have recognized that this technique could lead to unpredictable deployment because it depends on how forcefully the surgeon pulls the rod. (Ex. 1003, ¶139.) If the surgeon pulls the rod too forcefully, the entire support device could shift or even dislodge from the proper position between the vertebrae. (*Id.*) A POSITA would have recognized that Weiman's rotatable actuator assembly 200 would expand the device more predictably because each turn, or partial turn, of the assembly results in specific increase in the device's overall height. (*Id.*) Further, rotating the assembly would

require less force than pulling the deployment rod and would reduce the risk of dislodging the device. (*Id.*)

Second, Greenhalgh implicitly recognizes the risk of dislodging the device and proposes to solve the problem by applying a resistive force to the support device to oppose the pulling force by the surgeon. (Ex. 1004, 7:30-33.) A POSITA would have recognized that Weiman would not require a similar resistive force because rotating the actuator assembly would not require a pulling force on the entire device. (Ex. 1003, ¶1405.) A POSITA would have found the Weiman actuator assembly preferable for this reason. (*Id*.)

Moreover, Greenhalgh's delivery device would require additional structure to apply the resistive force. (*Id*.) The added structure would increase the profile of the delivery device. (*Id.*) Yet, a POSITA would have been motivated to minimize the profile of delivery device to reduce potential trauma to the patient. (*Id.*) For this additional reason, a POSITA would have preferred a simpler and more compact system, such as Weiman's actuator assembly. (*Id.*)

A POSITA would have expected success in implementing Weiman's actuator assembly (set screw) in Greenhalgh's support device. (*Id.*, ¶141.) Greenhalgh discloses that the "first side outer 54, central 56, inner port 58 or a combination thereof can be internally threaded." (Ex. 1004, 6:26-28.) Thus, the Greenhalgh device is already equipped to accommodate Weiman's threaded actuator assembly.

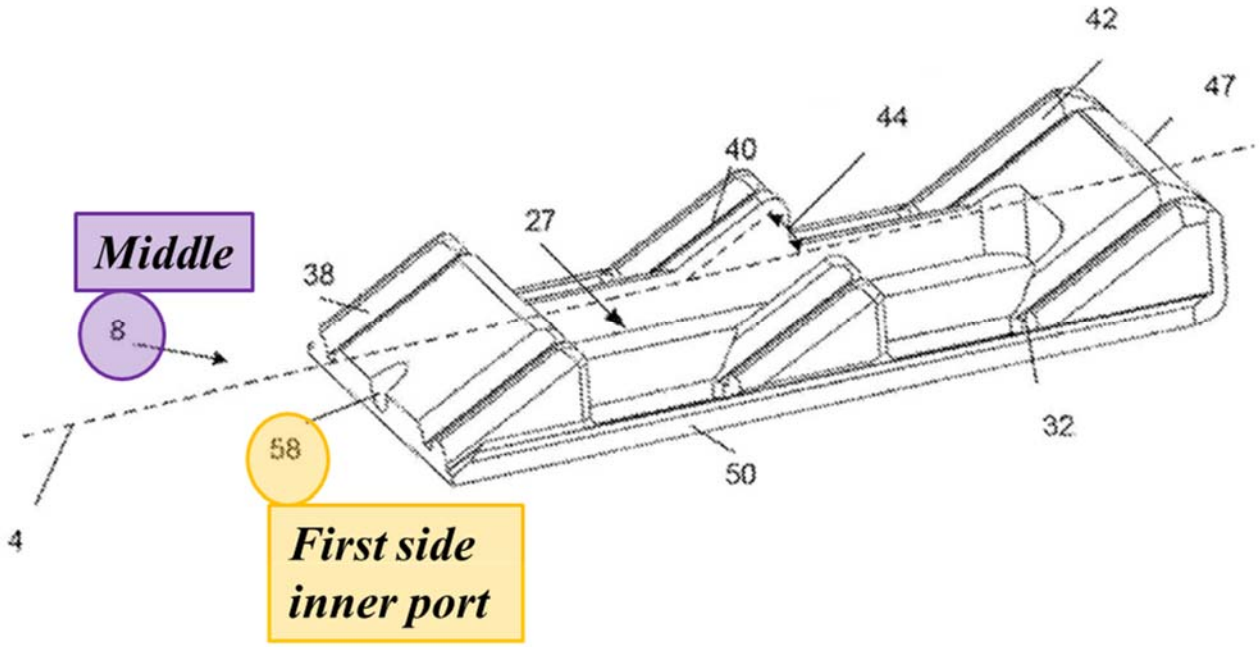
(Ex. 1003, ¶141.) Further, as discussed above, the user expands the Greenhalgh device by pulling a middle proximally. (Ex. 1004, 6:44-46, 7:30-33.) The actuator assembly in Greenhalgh causes the same result. (Ex. 1003, ¶141.)

For all of these reasons, Greenhalgh in combination with Weiman also renders claim 8 obvious. (Ex. 1003, ¶¶136-142.)

9. Claim 9

Claim 9 recites: "The expandable cage of claim 8, further comprising a tool bore, coaxial with the aperture, sized and shaped to accept an expansion tool." Greenhalgh satisfies this limitation. (Ex. 1003, ¶¶143-145.)

Greenhalgh's middle 8 [purple] has an aperture in its proximal end labeled "first side inner port 58" [orange]. (Ex. 1004, 6:25-30.)



Greenhalgh describes a tool bore [highlighted below] comprised of first side outer port 54 and first side central port 56 that is coaxial with the first side inner port 58 in the end of the middle (elongate expander). (Ex. 1004, 6:19-30, Fig. 2b.) The ports may be internally threaded. (*Id.*)

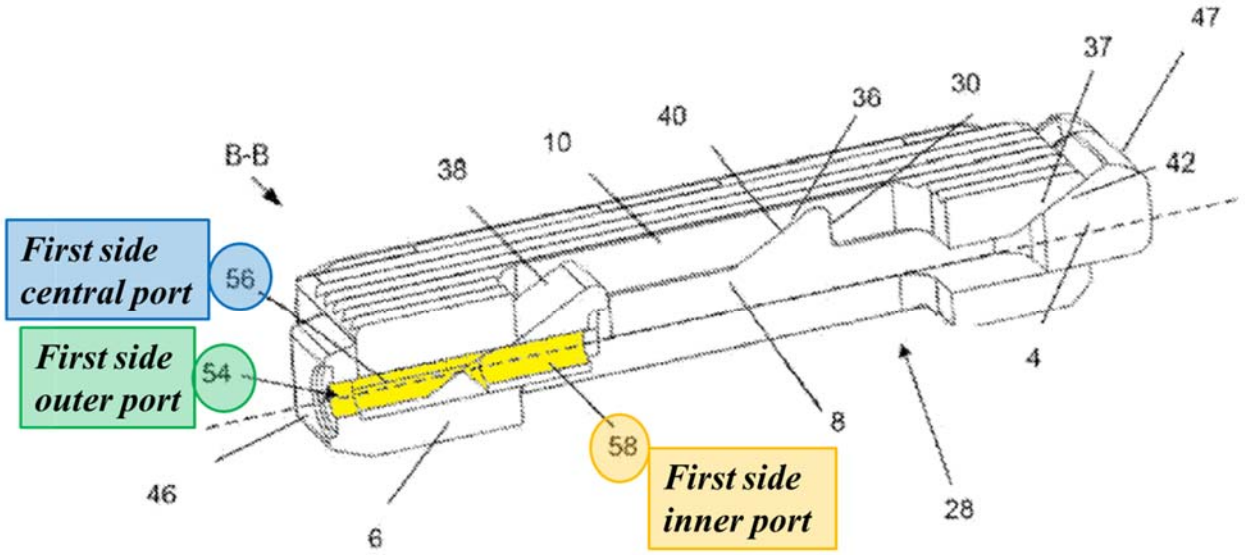


Fig. 2b

The first side ports (outer, central, and inner) are sized and shaped to accept the deployment rod. (Ex. 1004, 7:24-39, Fig. 5c.) The deployment rod is an expansion tool because the surgeon uses the rod to pull the middle proximally to expand the expandable support device 2. (*Id.*, 7:30-33; Ex. 1003, ¶145.) Thus, Greenhalgh renders claim 9 obvious because claim 9 depends from claim 8. (Ex. 1003, ¶¶143-145.)

B. Grounds 2a-2b: Weiman Anticipates or Renders Obvious

Petitioner focuses on the embodiments illustrated in Figure 50-67 of Weiman, with particular emphasis on Figure 67. The embodiments in Figures 50-67 reflect

similar embodiments having many identical features. (*See, e.g.,* Ex. 1005, 21:50-52; 22:31-33; 22:44-47; 23:11-14; 24:40-44, 24:63-67 (stating embodiments are similar). Weiman discloses combining features across the embodiments, making use of the disclosed features in the embodiments for anticipation or obviousness appropriate. (*Id.*; Ex. 1003, ¶146.) Moreover, a POSITA reading the reference as a whole would have been motivated to combine various features from the embodiments. (Ex. 1003, ¶146.)

1. Claim 1

Weiman anticipates claim 1 or renders the claim obvious. (*Id.*, ¶¶147-165.)

a. [1p] Preamble

If the preamble is limiting, Weiman discloses an expandable cage.[9] (*Id.*, ¶¶148-149.)

Weiman discloses an expandable fusion device capable of being inserted between adjacent vertebrae to facilitate the fusion process. (Ex. 1005, 1:15-19, 1:59-65, 24:59-67.) Figure 67 (below) is an exploded view of the expandable fusion device. (*Id.*, 5:22-24.) The expandable fusion device is an expandable cage. (Ex. 1003, ¶149.)

[9] Petitioner has not repeated the claim language for Grounds 2a-3b. The identifiers ([1p], [1a], etc.) refer back to the limitations identified in Grounds 1a-1d.

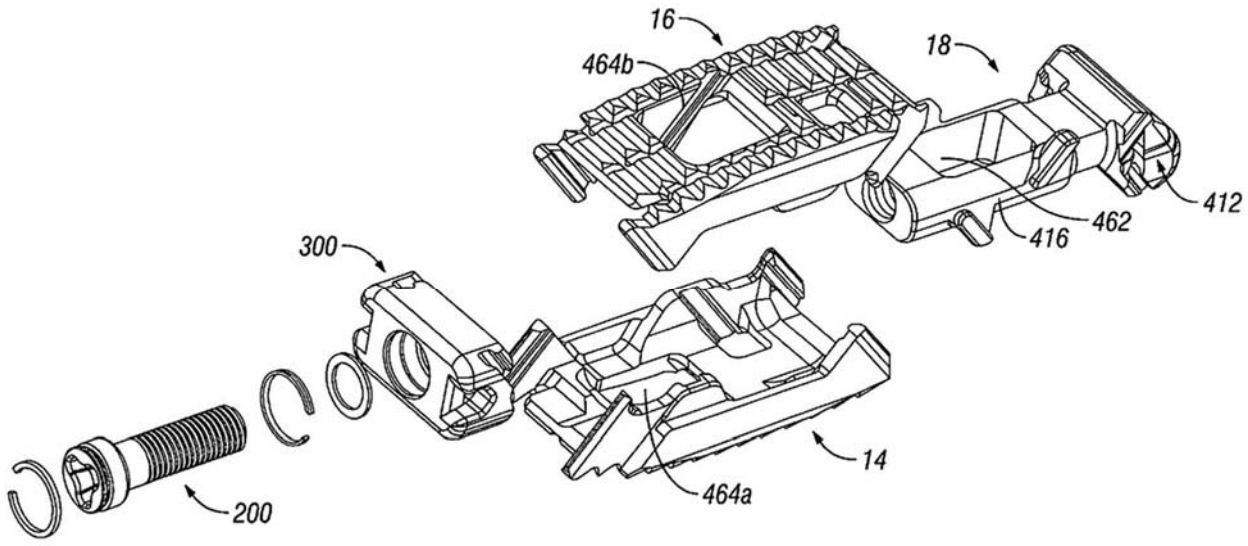


FIG. 67

b. [1a] Cage

Weiman discloses a cage having the features described in claim 1. (Ex. 1003, ¶¶150-153.)

Weiman's expandable fusion device (cage) includes a first endplate 14 [green] and a second endplate 16 [blue]. (Ex. 1005, 24:59-63.) The "second endplate 16 is substantially identical to the first endplate 14." (*Id.*, 17:33-37.) The first endplate 14 is a lower portion and the second endplate 16 is an upper portion, as illustrated below. (Ex. 1003, ¶151.)

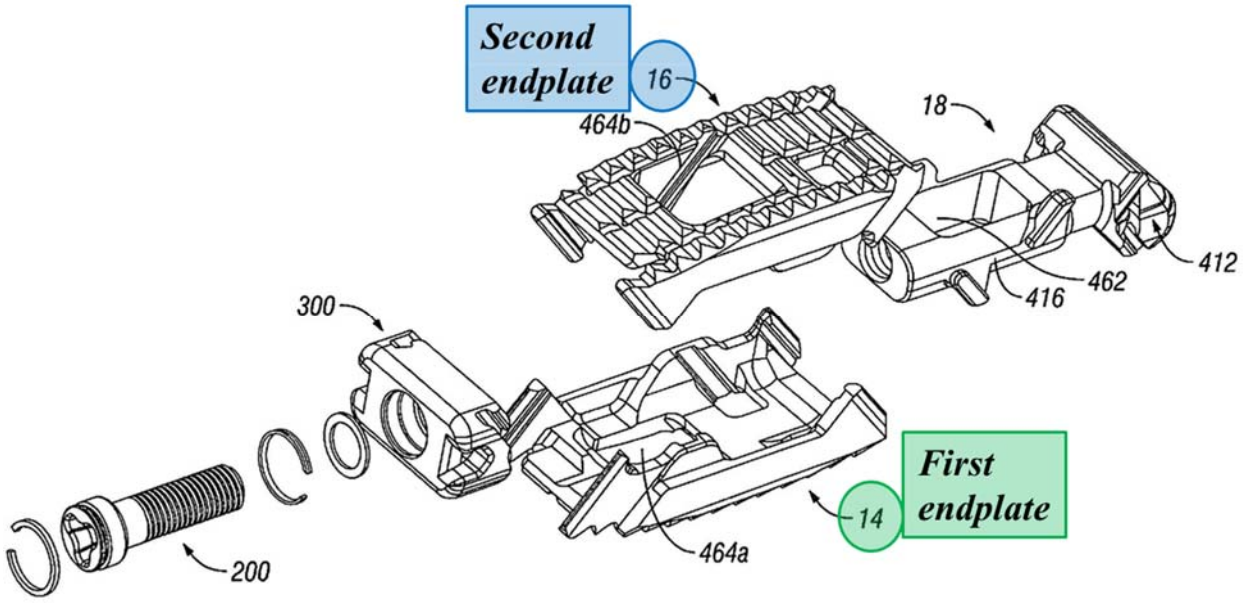


FIG. 67

The first and second endplates have upper and lower bone contact surfaces, which may include texturing to engage the adjacent vertebral bodies. (Ex. 1005, 17:42-45, 17:63-67, Fig. 67.) The first and second endplates also have a lower portion upper surface and upper portion lower surface, respectively. (*Id.*)

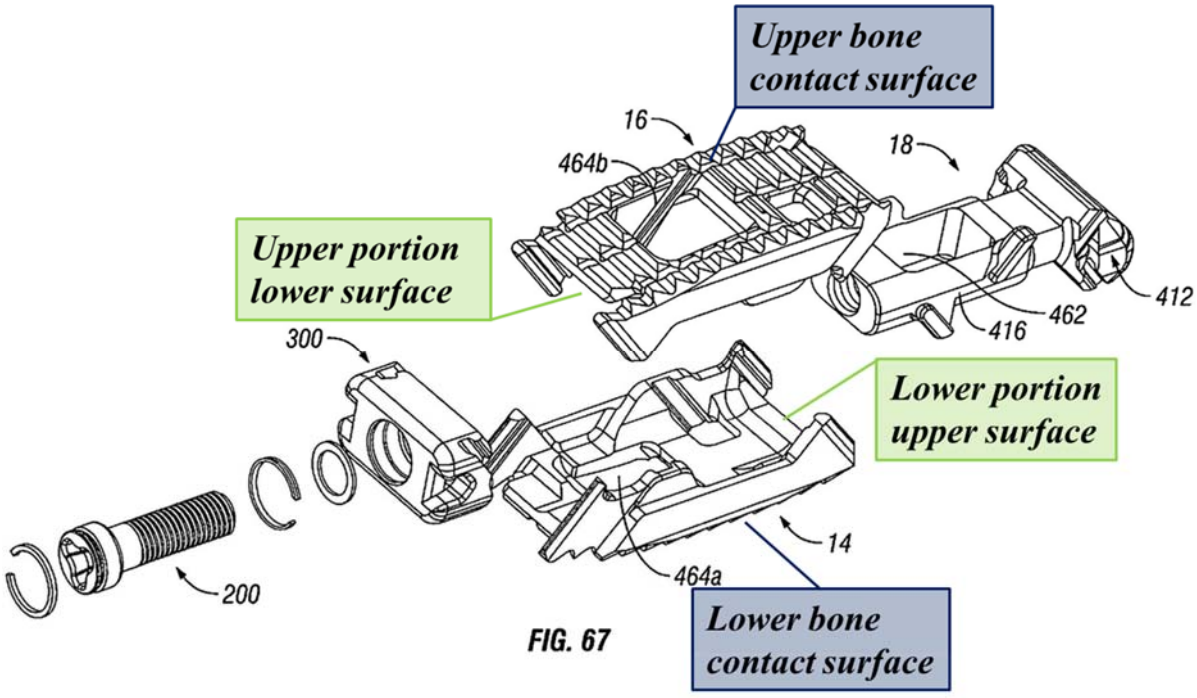


FIG. 67

The first and second endplates have openings 464a, 464b [yellow], which are sized to receive bone graft or similar bone growth inducing material. (*Id.*, 24:67-25:6; *see also* 17:48-52 (explaining the openings receive bone graft).)

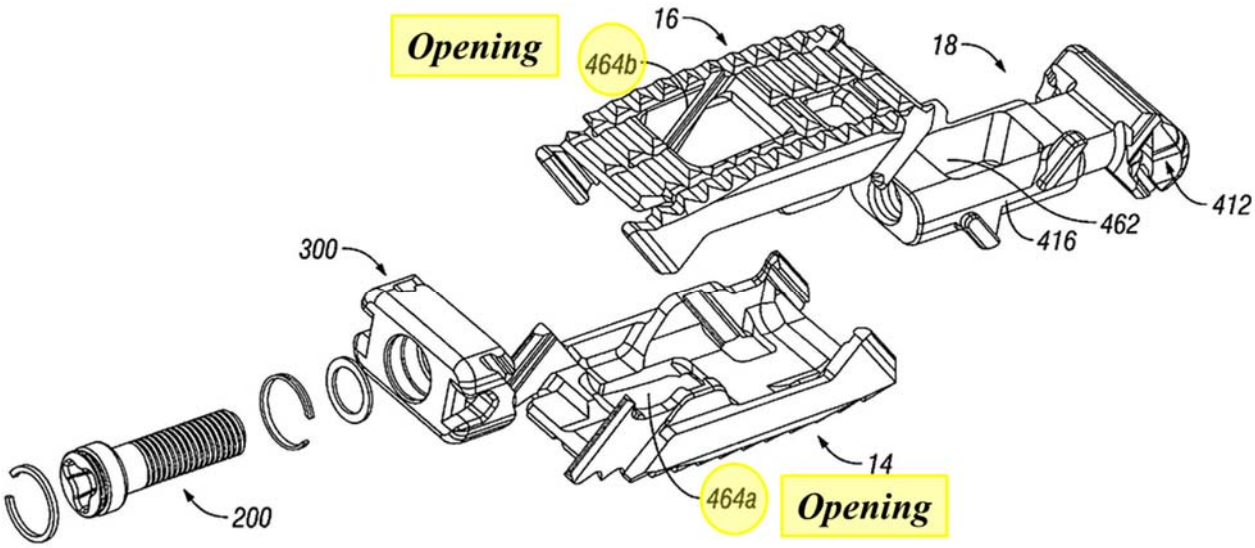


FIG. 67

The purpose of the openings in Weiman's fusion device is to promote bone growth through the device to fuse the vertebrae together. (Ex. 1003, ¶153.) The device could not accomplish its purpose if the openings were not "configured to permit bone growth therethrough." (*Id.*) Persons of ordinary skill in the art trying to avoid bone growth would not have included windows because the windows decrease the overall strength of the device and increase the risk of stress and facture. (*Id.*) The shape of the openings is similar to the windows in the embodiments disclosed in the '575 patent. (*See* Ex. 1001, Fig. 5B.) Therefore, if the windows in the '575 patent are "configured to permit bone growth therethrough," then so are the openings in Weiman. (*Id.*) Conversely, if the openings in Weiman are *not* "configured to permit

bone growth therethrough," then the windows in the '575 patent are *not* "configured to permit bone growth therethrough" and the '575 patent lacks written description for this limitation. (*Id.*); *see also Ruckus Wireless*, 824 F.3d at 1004 (rejecting a claim construction that would render the claims invalid for lack of written description). As a result, a person of ordinary skill in the art would not understand "configured to permit bone growth therethrough" to be read so narrowly as to exclude the windows in the '575 patent or Weiman. (Ex. 1003, ¶153.)

c. [1b] Elongate Expander

Weiman discloses an elongate expander have the features described in claim 1. (Ex. 1003, ¶¶154-156.)

Weiman discloses a central ramp 18. (Ex. 1005, 24:60-63.) The central ramp is an "elongate expander" because it is longer than it is wide and it acts upon the first and second endplates to expand the fusion device. (Ex. 1005, 20:50-21:3, 23:56-24-4; Ex. 1003, ¶155.)

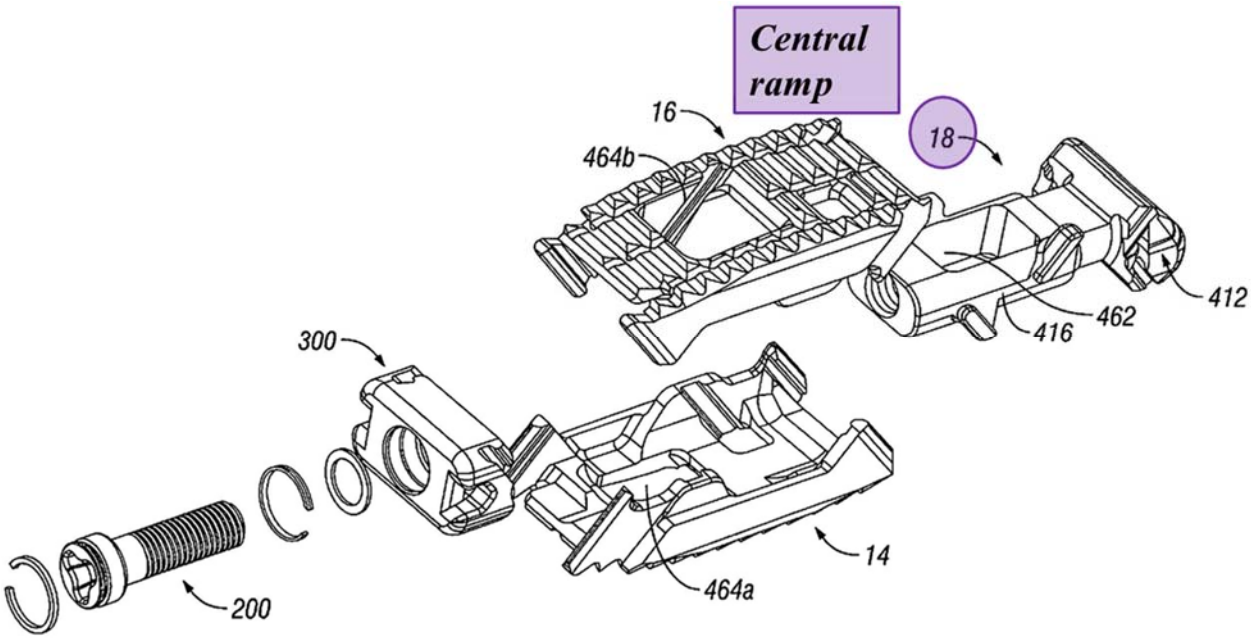


FIG. 67

The central ramp 18 has a distal or leading end and a proximal or trailing end [gray]. (Ex. 1005, 19:1-2; 21:56-62, 22:44-48, Fig. 67; Ex. 1003, ¶155.) The central ramp 18 also has a pair of side surfaces [red] connecting the distal and proximal ends. (*Id.*) The side surfaces of the central ramp surround "a radial through opening or window 462 [yellow]." (*Id.*, 24:63-67, Fig. 67.) The window is unobstructed, as shown in Figure 67. (*Id.*; Ex. 1003, ¶155.)

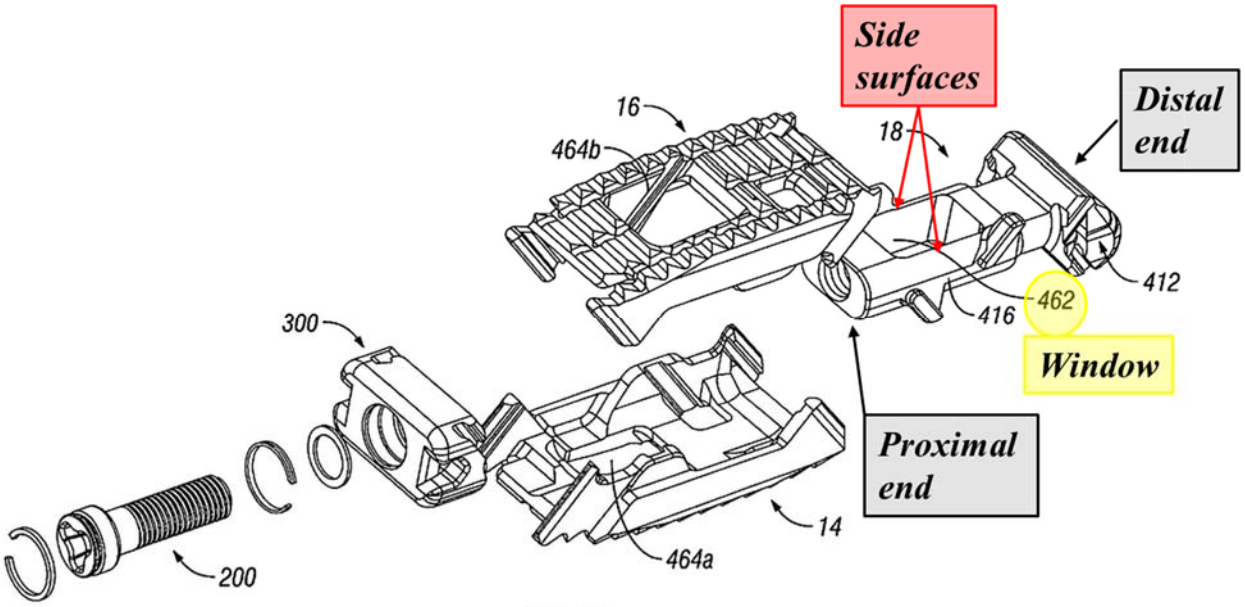


FIG. 67

The central ramp 18 is positioned in a cavity or an internal space between the first endplate's lower portion upper surface and the second endplate's upper portion lower surface, as shown below. (Ex. 1005, Figs. 50-51, 59-62, 65-67; Ex 1003, ¶156.)

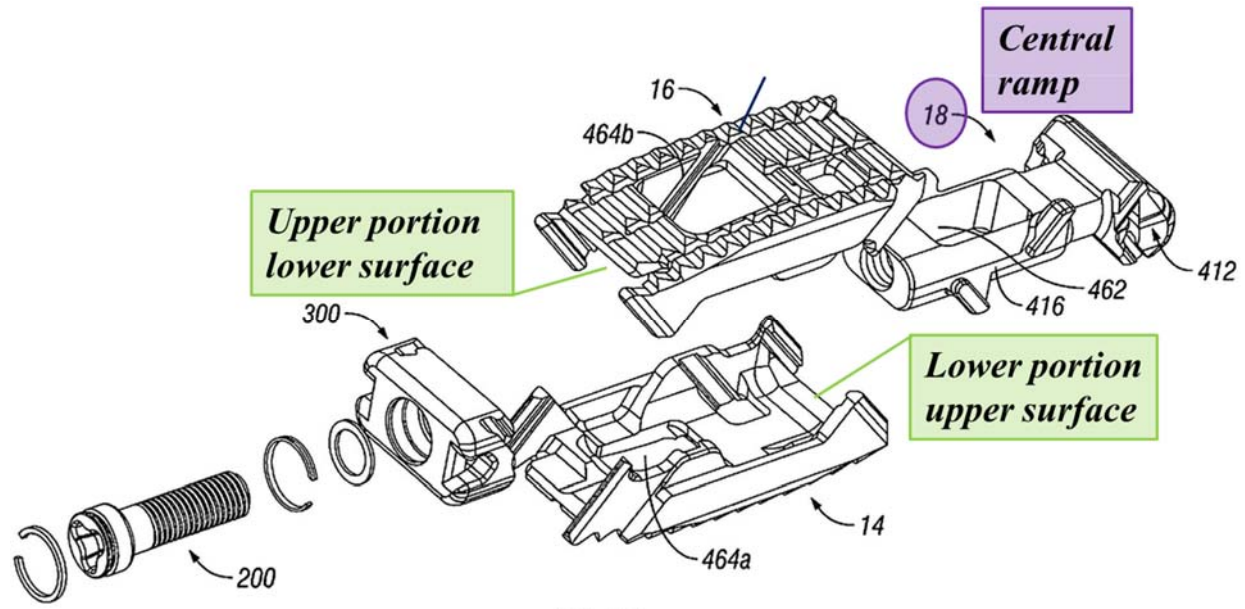


FIG. 67

d. [1c] Expander Expands the Cage

Weiman discloses an elongate expander that operates as described in claim 1. (Ex. 1003, ¶¶157-158.)

Weiman discloses that the central ramp 18 is pulled linearly (i.e., longitudinally) to expand the fusion device (cage). (Ex. 1005, 21:37-45; *see also* 20:41-49, 23:56-24:4.) Weiman states, "As the central ramp 18 is pulled towards the actuator assembly 200, the central ramp 18 acts to push endplates 14, 16 outwardly into the expanded position." (*Id.*, 23:56-24:4; *see also id.*, 21:50-22:6.) In the embodiment illustrated in Figure 67, the first [green] and second [blue] endplates separate during expansion. (*Id.*)

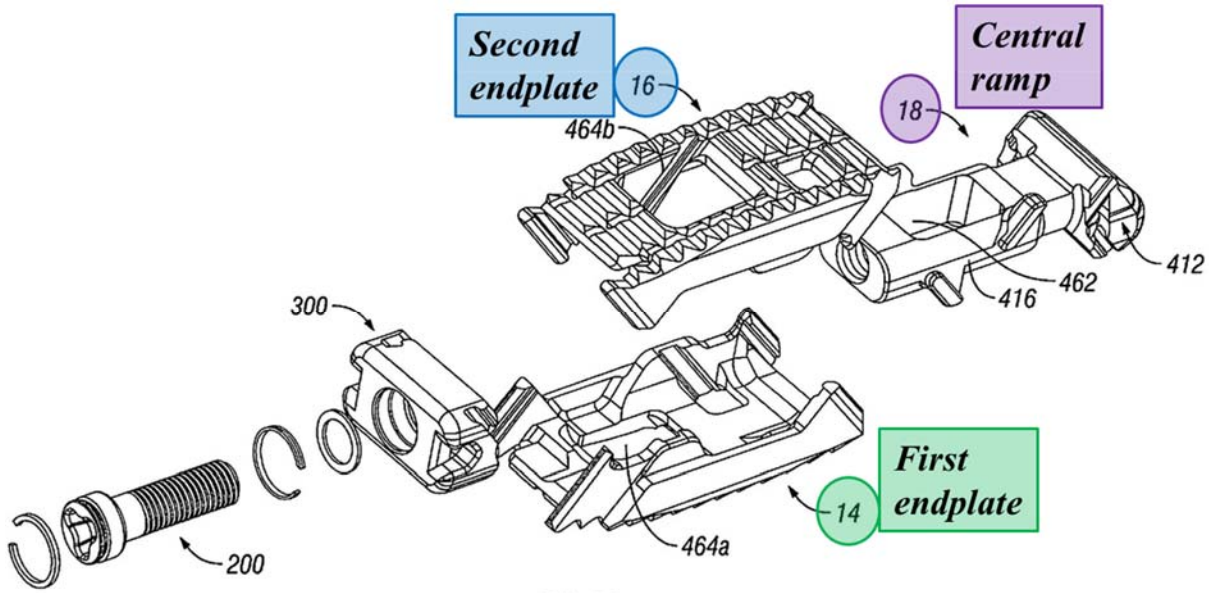


FIG. 67

e. [1d] Windows Are Unobstructed

Weiman discloses open and unobstructed windows, or renders the limitation obvious. (Ex. 1003, ¶¶159-165.)

Weiman discloses that the central ramp in Figure 67 includes a "radial through opening or window 462." (Ex. 1005, 24:63-67.) Figure 67 is an "alternative embodiment" to the embodiments in Figures 50-66 and Petitioner relies on this embodiment for the "open and unobstructed" limitation. The "window 462 may align with the through openings 464*a*, 464*b* in the first endplate 14 and second endplate 16, respectively." (*Id.*, 25:3-6.)

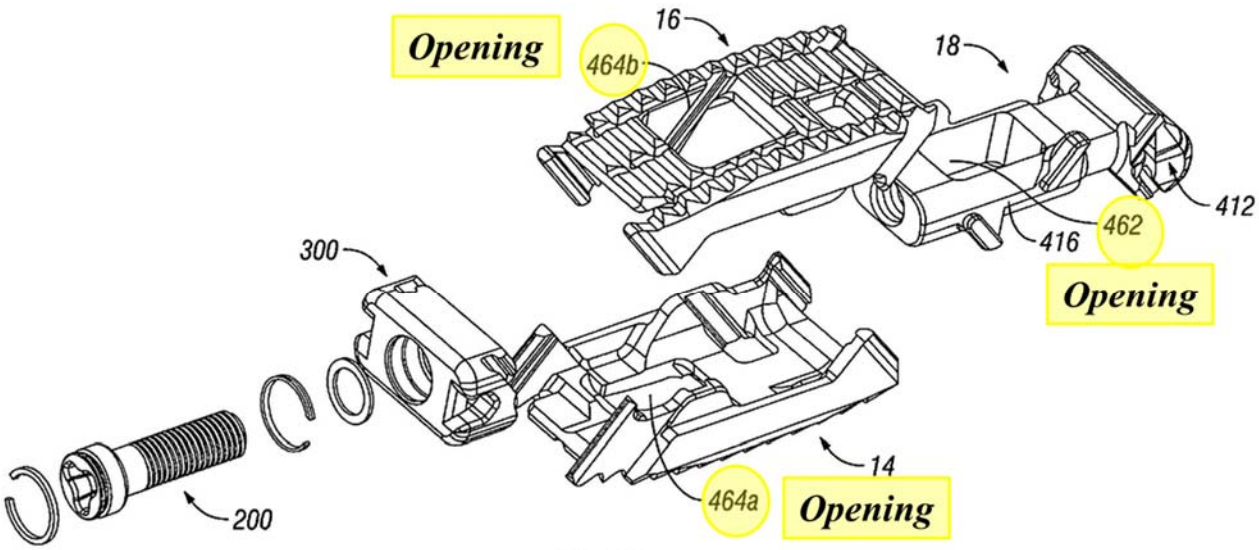


FIG. 67

Weiman does not include a top view of the embodiment in Figure 67. However, the windows would be open and unobstructed with respect to one another when viewed from the top. (Ex. 1003, ¶161.) As shown in Figure 67, the windows in the first and second endplates and the central ramp are not centered, but shifted slightly towards the proximal end of the endplates/ramp (i.e., the distance between the green lines is less than the distance between the red lines). (*Id.*)

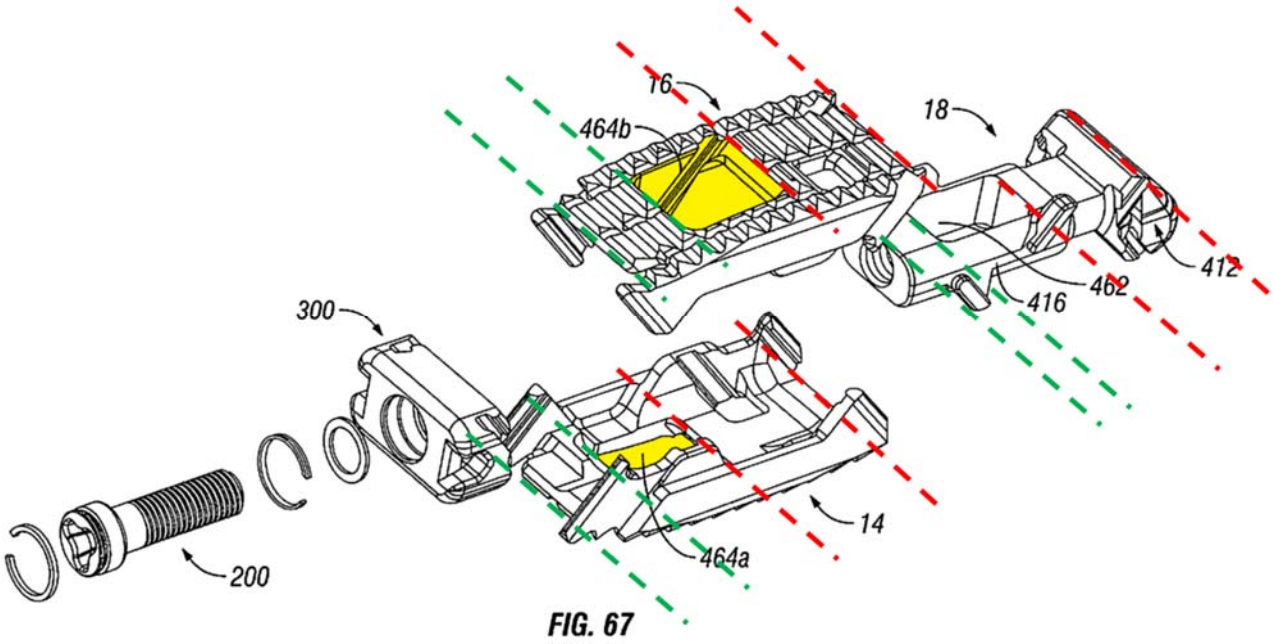


FIG. 67

While the windows in the first and second endplates always align, the same is not true for the window in the central ramp. (*Id.*) The central ramp is offset distally in the unexpanded position. (*See e.g.*, Ex. 1005, Fig. 65.) Thus, in the unexpanded positon, the windows would only partially align. (Ex. 1003, 161.) As the surgeon pulls the central ramp proximally and the device expands, the window in the central ramp would increasingly align with the windows in the first and second endplates. (*Id.*) The openings would fully align when the fusion device reaches its expanded position. (*Id.*)

Another issue is whether the actuator assembly 200 would lie in the path of the windows in the expanded configuration. Given the relative dimensions of the device, at most, only a small portion of the actuator assembly 200 would extend into the opening 462 in the central ramp in the expanded position, leaving the majority

of the window open and unobstructed. (*Id.*, ¶162.) Such a configuration would be similar to Figure 5B in the '575 patent where a portion of the elongate expander still extends into the openings in the top and bottom of the device. (*Id.*; *supra* V.B.)

The actuator assembly 200 engages the rod-receiving extension 416 in the central ramp. (Ex. 1005, 23:56-24:14, Figure 67.) By rotating the actuator assembly 200, the surgeon pulls the central ramp proximally to expand the fusion device. (*Id.*, 23:49-51.) However, before engaging the central ramp, the actuator assembly passes through the driving ramp 300. (*Id.*, 24:5-14.) As shown by the red highlighting below, the actuator assembly is roughly as long as the combined width of the driving ramp 300 and the proximal end of the rod-receiving extension 416. (Ex. 1003, ¶162.)

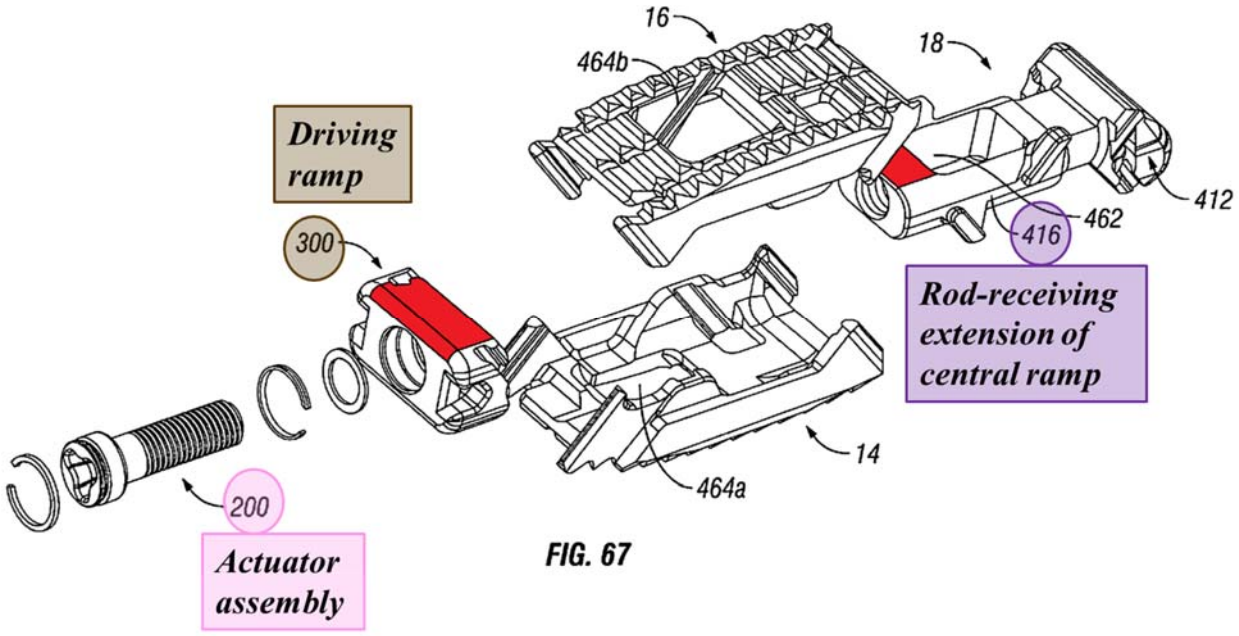


FIG. 67

Consequently, the actuator assembly would not extend into the opening 462 in the central ramp in the expanded position, or, at most, would extend only a very

short distance into the opening. (*Id.*) The actuator assembly is not long enough to lie in the path and block the opening 462 like a bar on a window. (*Id.*) Moreover, the ramps on the distal end of the central ramp are steep. (*Id.*) The central ramp needs to move only a short distance to expand the device, requiring only a few turns of the actuator assembly. (*Id.*) Consequently, the windows are open and unobstructed in the expanded configuration and Weiman discloses this limitation. (*Id.*)

If Weiman does not disclose this limitation, it renders the limitation obvious. The length of the actuator assembly 200 is a matter of design choice. (*Id.*, ¶163.) A POSITA could have selected shorter or longer assemblies depending on the desired result. (*Id.*) Here, Weiman discloses that the opening 462 in the central ramp may "receive bone graft or similar bone growth inducing material and allow bone graft or similar bone growth inducing material to be packed into the device 10." (Ex. 1005, 25:1-6.) A POSITA would have recognized that if the actuator assembly 200 extended too far into the opening 462 as the device expanded, it would displace the bone graft material and potentially inhibit or disrupt the desired bone growth. (Ex. 1003, ¶163.) Thus, a POSITA would have been motivated to select a shorter actuator assembly so that the assembly would not extend into the opening upon expansion. (*Id.*)

A POSITA would have also been motivated to ensure that the windows aligned in the expanded configuration. (*Id.*, ¶164.) The purpose of packing material

into the device is to facilitate bone growth and, eventually, fuse the vertebrae together. (*Id.*) Bone growth does not start until days or weeks after implanting the device. (*Id.*) Thus, a POSITA would have wanted to maximize the surface area of the bone growth material ***after*** expansion. (*Id.*)

Further, POSITAs designed expandable devices, such as the device in Weiman, based on the existing unexpandable cages. (*Id.*) Many of the prior art unexpandable cages, such as the cages shown below, included open and unobstructed cavities that the surgeon could pack with material to promote bone growth. (*Id.*)

Lynn (Ex. 1007)

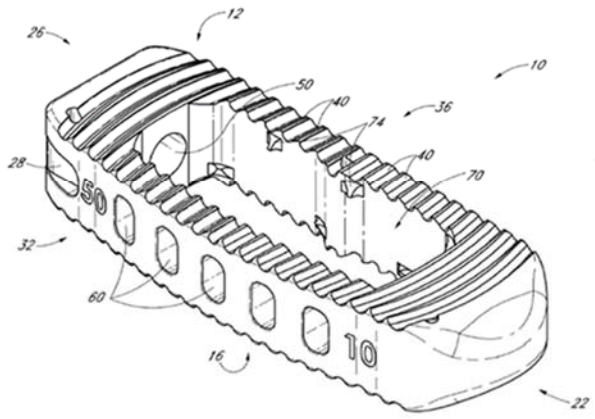
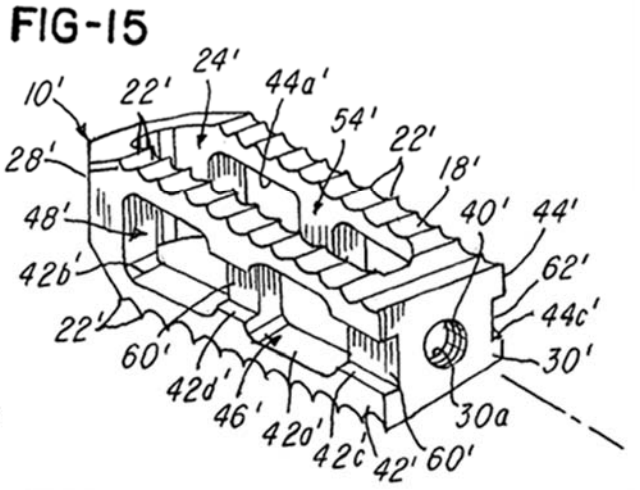


FIG. 1A

Ex. 1009



Petitioner has a design patent covering such a device, shown below. (Ex. 1011.)

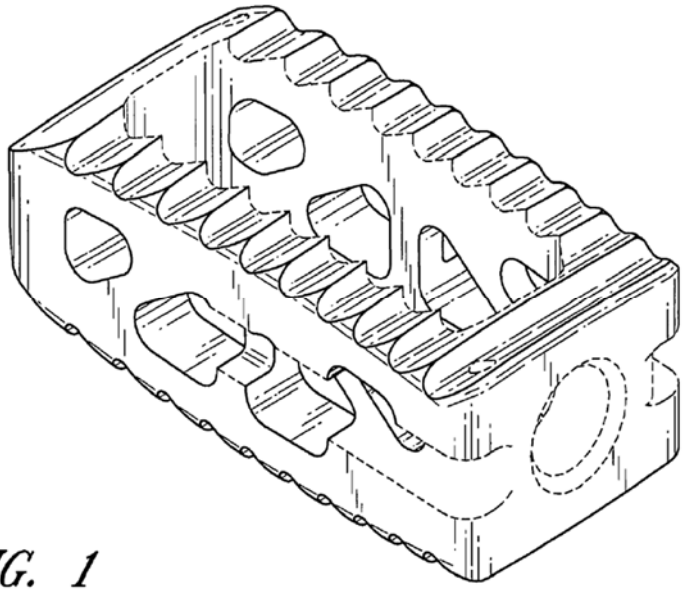


FIG. 1

In these prior art devices, the cavity was open and unobstructed when the device was implanted. (Ex. 1003, ¶164.) Based on the success of these early designs, a POSITA would have been motivated to design expandable cages, such as Weiman's device, to maximize the alignment of the windows upon implantation. (*Id.*)

Thus, if Weiman does not anticipate claim 1, it renders the claim obvious. (*Id.*, ¶¶147-165.)

2. <u>Claim 2</u>

Weiman discloses the limitations in claim 2 or renders them obvious. (Ex. 1003, ¶¶166-168.)

As explained above, the windows in the first and second endplates and the central ramp are not centered, but shifted slightly towards the proximal end of the endplates/ramp. (Ex. 1003, ¶167; *supra* VI.B.e.)

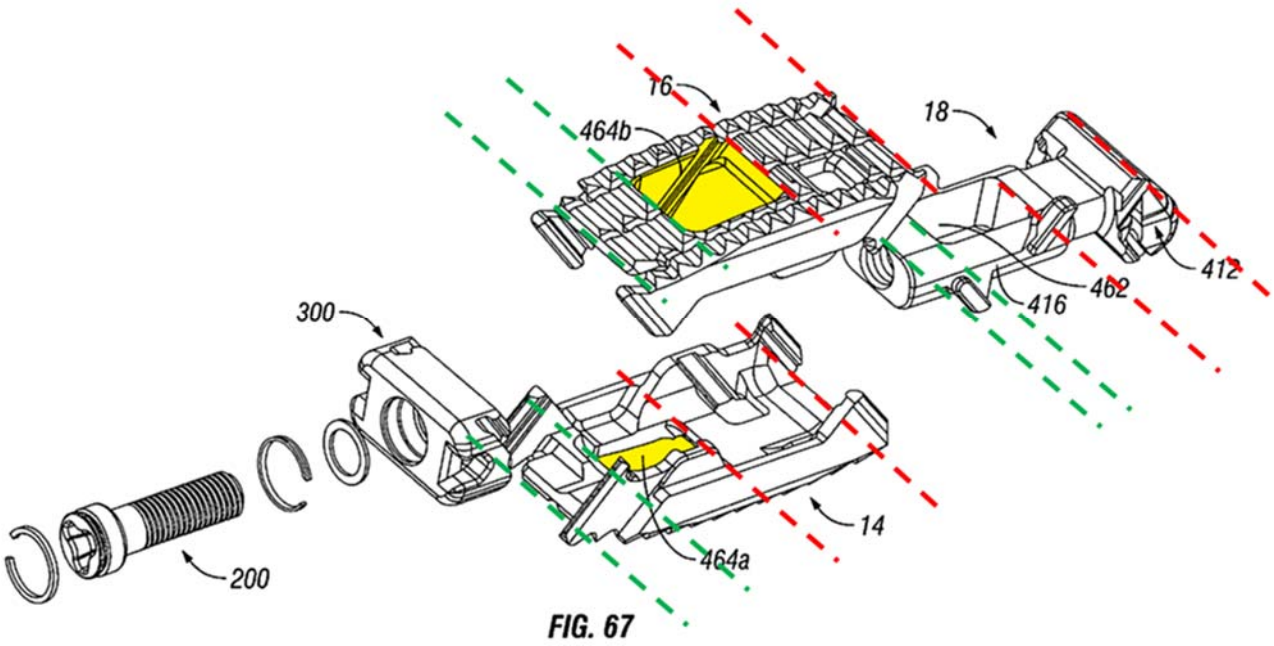


FIG. 67

In the unexpanded position, the central ramp 18 is distal of the first and second endplates, so the window in the central ramp does not fully align with the windows in the endplates. (*Id.*) However, as the central ramp moves proximally, the openings in the endplates and ramp increasingly align. (*Id.*) Weiman's disclosure that "the window 462 may align with through openings 464a, 464b in the first endplate 14 and second endplate 16, respectively" supports this understanding. (Ex. 1005, 25:3-6; Ex. 1003, ¶167.) Further, the windows are sized and shaped to contain bone graft material and promote bone growth therethrough. (Ex. 1005, 24:67-25:3.) In order to maximize the bone growth through the device, the windows must align in the expanded position when the bone growth occurs. (Ex. 1003, ¶167.) Thus, Weiman anticipates claim 2. (*Id.*)

However, if Weiman does not disclose the limitations in claim 2, it renders the limitations obvious. (*Id.*, ¶168.) Because the central ramp moves longitudinally with respect to the endplates during expansion, the openings in the endplates and central ramp cannot equally align in the unexpanded and expanded positions. (*Id.*) The openings must align more in the expanded position or the unexpanded position, but not both. (*Id.*) However, the purpose of the openings is to contain bone graft material and promote bone growth through the device. (Ex. 1005, 24:67-25:6.) The bone growth occurs after the surgeon implants the device in the expanded position. (Ex. 1003, ¶168.) As explained previously, a POSITA would have been motivated to maximize the alignment between the openings in the endplates and central ramp when the device was in the expanded position to maximize bone growth. (*Id.*; *supra* VI.B.1.e.) Thus, Weiman also renders claim 2 obvious. (Ex. 1003, ¶168.)

3. Claim 3

Weiman discloses the limitations in claim 3. (Ex. 1003, ¶¶169-171.)

Weiman's fusion device includes a first or front end 39 and a second or rear end 41. (Ex. 1005, 21:50-56, Fig. 58.) The front end 39 is the distal end because it is the free end of the device and resides farthest away from the surgeon during implantation. (*Id.*, 21:56-62; Ex. 1003, ¶170.)

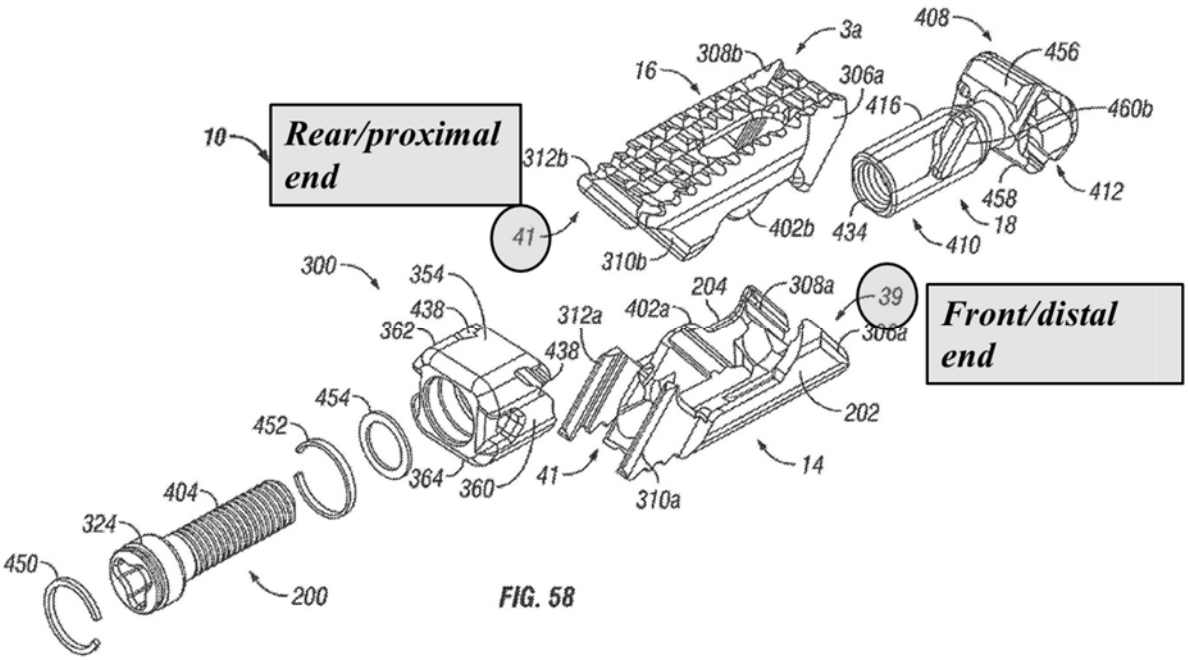


FIG. 58

The longitudinal translation of the central ramp 18 in the proximal direction of the fusion device causes the central ramp to act upon the first and second endplates to expand the device. (Ex. 1003, ¶170.) Weiman discloses that as "the central ramp 18 is pulled towards the actuator assembly 200, the central ramp 18 acts to push endplates 14, 16 outwardly into the expanded position." (Ex. 1005, 23:56-24:4; *see also id.*, 21:50-22:6, Figs. 65-66.) The actuator assembly is at the proximal end of the fusion device because it is nearest the surgeon. (*Id.*, 21:50-62, Fig. 58; Ex. 1003, ¶170.)

Thus, Weiman anticipates claim 3 or, depending on claim 1, renders claim 3 obvious. (Ex. 1003, ¶¶169-171.)

4. Claim 4

Weiman discloses the limitation in claim 4. (Ex. 1003, ¶¶172-174.)

The central ramp 18 [purple] has a first or distal end having an expansion portion 412 [red]. (Ex. 1005, 22:47-52.)

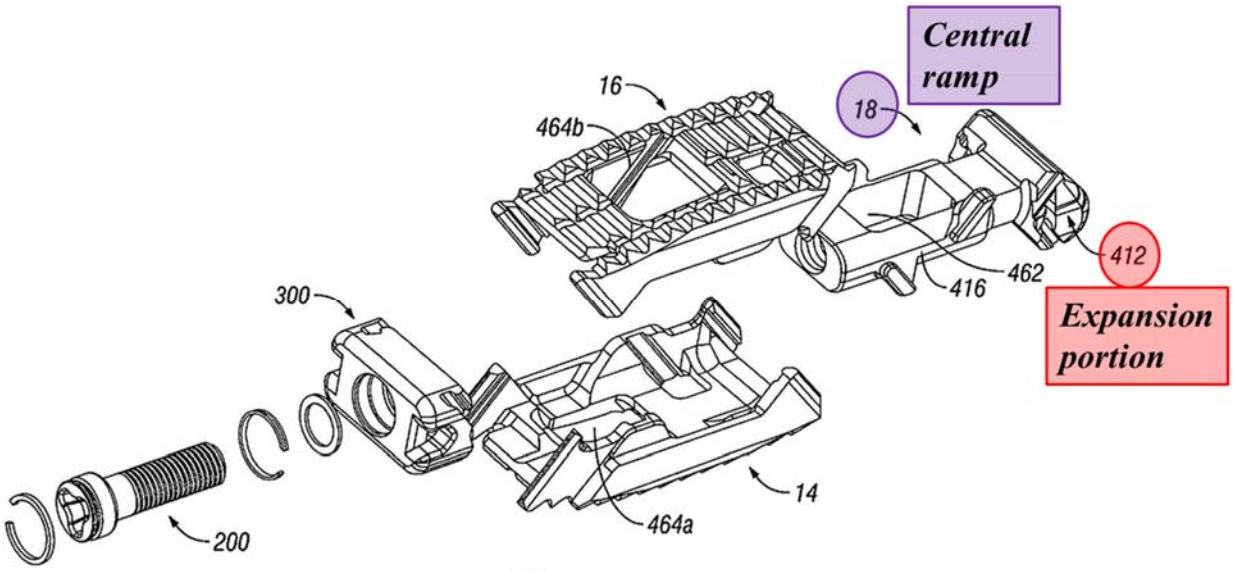


FIG. 67

The expansion portion 412 is a keyed distal end. (Ex. 1003, ¶173.) The expansion portion has first [red] and second [orange] ramped portions that "push against corresponding ramped portions in the first and second endplates 14, 16." (Ex. 1005, 23:56-61, Figs. 58, 61, 66-67.) The incline of the first and second ramped portions matches the incline of the corresponding ramped portions on the endplates. (*Id.*)

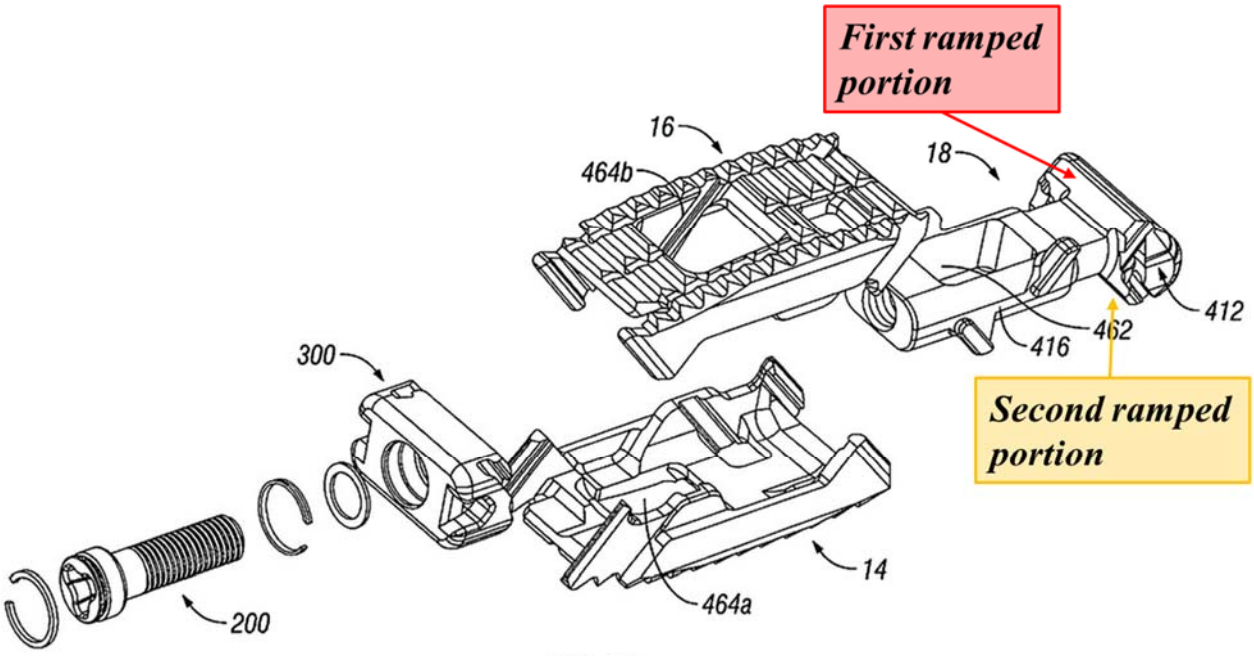


FIG. 67

Thus, Weiman anticipates claim 4 or, depending on claim 1, renders claim 4 obvious. (Ex. 1003, ¶¶172-174.)

5. Claim 5

Weiman discloses the limitation in claim 5. (Ex. 1003, ¶¶175-176.)

The distal end of the expansion portion 412 (keyed distal end) (i.e., the end opposite the ramped surfaces discussed above) has tapered sides. (Ex. 1003, ¶176.) The tapered sides are labeled below, but may also be seen in embodiments having similar distal ends, such as Figure 66. (*Id.*)

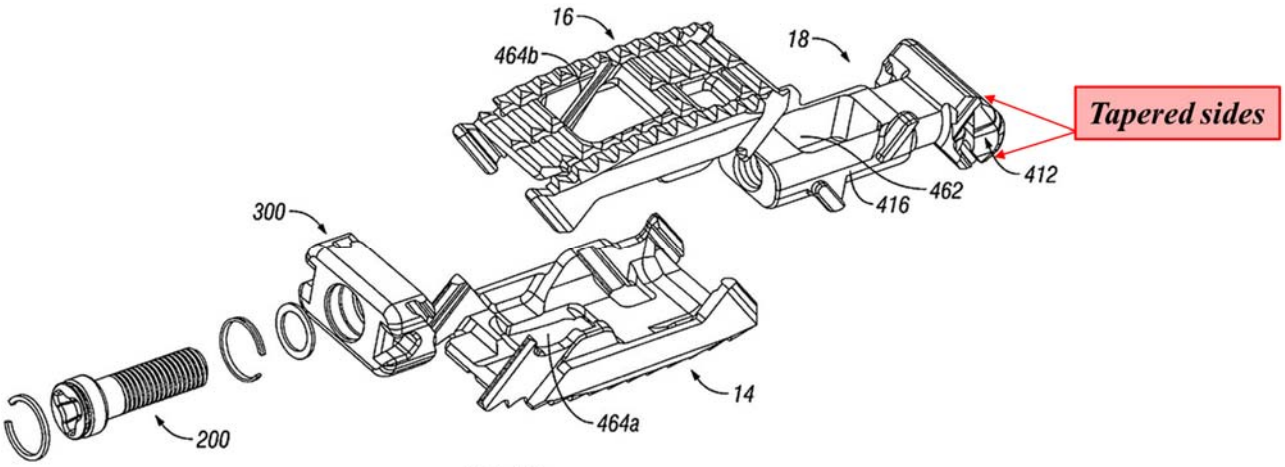


FIG. 67

Consequently, Weiman anticipates claim 5 or, depending on claim 1, renders claim 5 obvious. (Ex. 1003, ¶¶175-176.)

6. Claim 6

Weiman discloses the limitation in claim 6. (Ex. 1003, ¶¶177-179.)

Weiman discloses that the expansion portion 412 [purple] of the central ramp 18 may include angled grooves 428, 430 [orange]. (Ex. 1005, 19:12-19.) The grooves are sized to receive the corresponding tongues on the first and second endplates. (*Id.*, 19:19-24.) Each groove is a recess defined in the distal portion of the elongate expander. (Ex. 1003, ¶178.)

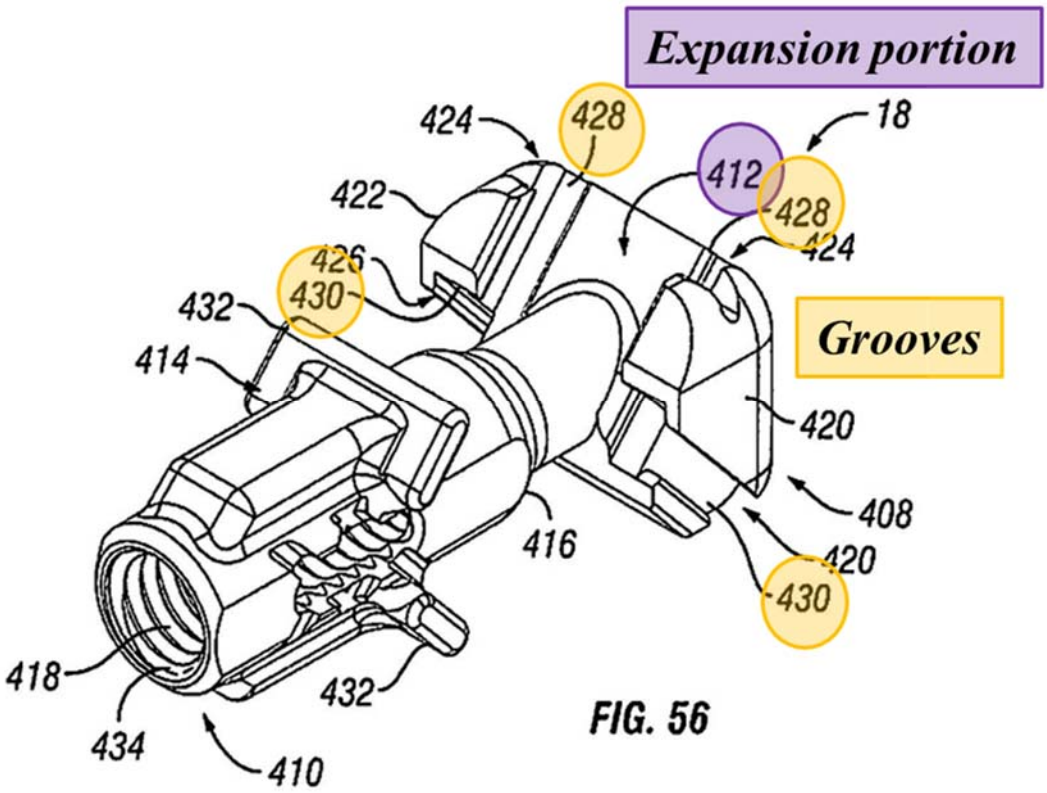


FIG. 56

Thus, Weiman anticipates claim 6 or, depending on claim 1, renders claim 6 obvious. (Ex. 1003, ¶¶177-179.)

7. Claim 7

Weiman discloses the limitations in claim 7. (Ex. 1003, ¶¶180-182.)

Weiman discloses that as "the central ramp 18 [purple] is pulled towards the actuator assembly 200 [pink], the central ramp 18 acts to push endplates 14, 16 [green, blue] outwardly into the expanded position." (Ex. 1005, 23:56-24:4; *see also id.*, 21:50-22:6.) The actuator assembly is at the proximal end of the fusion device. (*Id.*, 21:50-62, Fig. 58.)

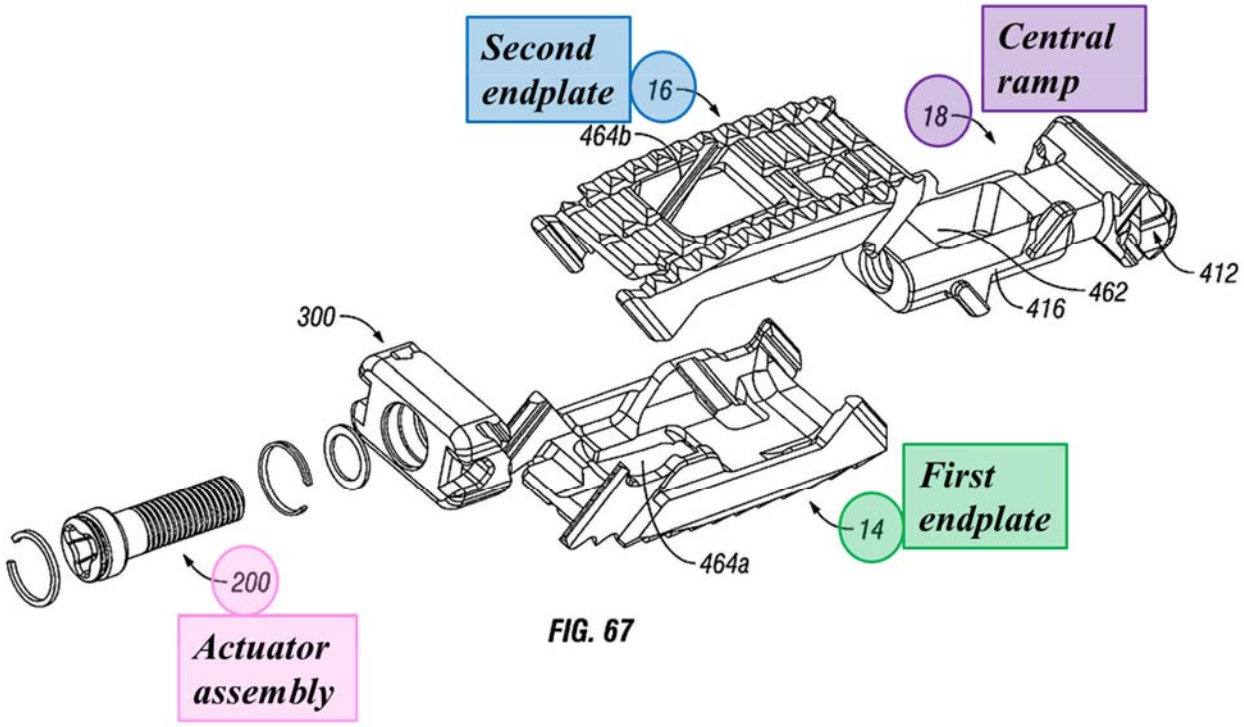


FIG. 67

Thus, Weiman anticipates claim 7 or, depending on claim 1, renders claim 7 obvious. (Ex. 1003, ¶¶180-182.)

8. Claim 8

Claim 8 repeats all of the limitations of claim 1 and then concludes with two additional limitations. Weiman satisfies the limitations in claim 1, or renders them obvious, for the reasons previously presented. (*Supra* VI.B.1.) Weiman discloses the additional limitations in claim 8, or renders them obvious, for the below reasons.

a. 8[a] A Cavity and Aperture

Weiman discloses the cavity and aperture required by claim 8, or renders the limitations obvious. (Ex. 1003, ¶¶184-189.)

Weiman discloses that the window 462 [yellow] in the central ramp "may align with through openings 464a, 464b [yellow] in the first endplate 14 and second endplate 16, respectively." (Ex. 1005, 25:3-6.) The through opening formed by the three aligned openings is a cavity in the expandable fusion device. (Ex. 1003, ¶185.)

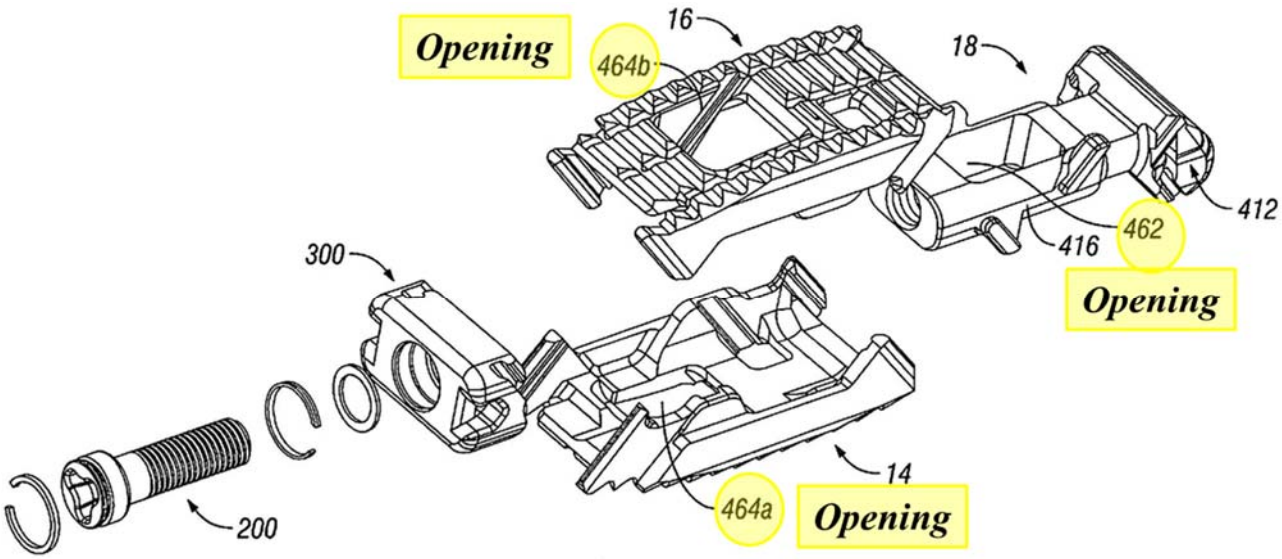


FIG. 67

The rod-receiving extension 416 [purple] of central ramp 18 has an opening [blue] at its proximal end. (Ex. 1005, 19:42-46, Fig. 67.) The opening is in communication with the cavity through opening 462 [yellow, above]. (*Id.; see also id.*, 19:1-6.)

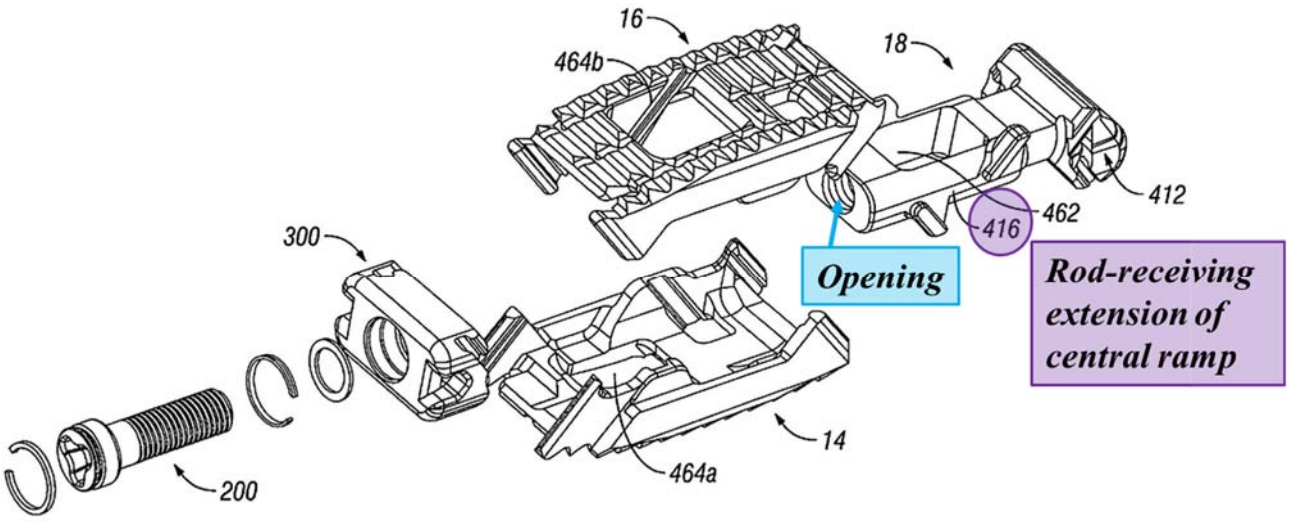


FIG. 67

The opening [blue] receives the actuator assembly 200. (*Id.*, 22:60-23:2.) Weiman discloses that the actuator assembly 200 [pink] may have a head portion 324 [red] and "a through bore 406 [brown] that extends longitudinally through the actuator assembly 200." (*Id.*, 18:54-57, Figs, 52, 54.)

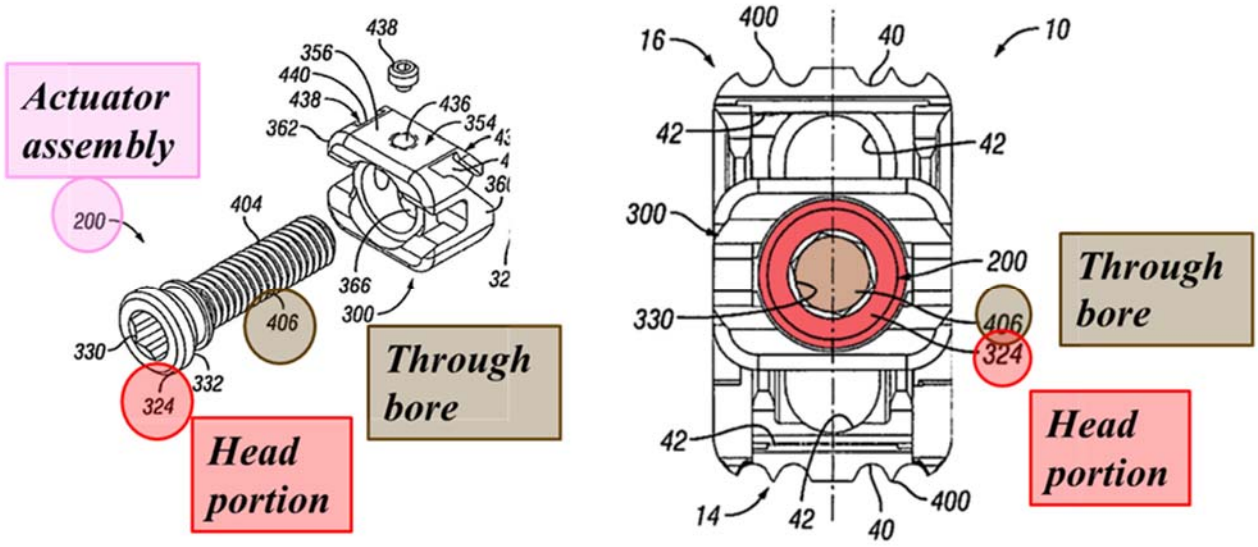


FIG. 54

If the actuator assembly in Figure 67 does not include a "through bore," a POSITA would have found it obvious to combine the through bore from Figures 52 and 54 with the embodiment in Figure 67. (Ex. 1003, ¶186.)

The opening in the proximal end of the central ramp is configured to permit packing of the cavity through the open and unobstructed windows with bone growth material after expansion of the expandable cage. (*Id.*, ¶¶187-189.) Weiman discloses that bone growth material may be packed between the first and second endplates "prior to, ***subsequent to***, or during implantation of the fusion device." (Ex. 1005, 6:15-18 (emphasis added).) Weiman also discloses that once the expandable fusion device is "expanded to the desired height," "[b]one graft or similar bone growth inducing material may then be introduced into the expandable fusion device 10 in the disc space." (*Id.*, 26:37-41.)

In the expanded configuration, the surgeon could introduce bone growth material only through the "through bore" in the actuator assembly because the openings in the first and second endplates are blocked by the vertebrae and surrounding tissue, and the sides of the device are blocked by the central ramp. (Ex. 1003, ¶188.) The opening in the central ramp is configured to permit packing of the cavity because it accepts the actuator assembly. (*Id.*) Any material packed through the actuator assembly necessarily passes through the opening in the central ramp. (*Id.*) Further, because the opening and the through bore extend into the cavity and

are not microscopically small or tortuous, the opening and through bore would not prevent or unduly restrict the packing of the cavity. (*Id.*)

Weiman's actuator assembly is similar to the cannulated screw in the '575 patent. The '575 patent describes inserting bone fusion material "post expansion" through a "cannulated actuation screw." (Ex. 1001, 7:53-56.) Based on the written description and figures, the '575 patent's cannulated actuation screw is almost identical to Weiman's actuator assembly. (Ex. 1003, ¶188.) The screw and assembly have the same function and the diameter of the through bores is comparable. (*Id.*) Thus, to the extent bone growth material can be inserted through the '575 patent's actuation screw, it can also be inserted through Weiman's actuator assembly. (*Id.*) Conversely, if the opening and through bore in Weiman are *not* "configured to permit" packing, then the opening and the cannulated actuation screw in the '575 patent are *not* "configured to permit" packing and the '575 patent lacks written description for this limitation. (*Id.*); *see also Ruckus Wireless*, 824 F.3d at 1004 (rejecting a claim construction that would render the claims invalid for lack of written description). As a result, a person of ordinary skill in the art would not understand "configured to permit" packing to be read so narrowly as to exclude the opening and cannulated actuation screw in the '575 patent or Weiman. (Ex. 1003, ¶188.) Consequently, Weiman discloses this limitation. (*Id.*)

Moreover, even if the surgeon could pack the device through another opening, a POSITA would have found it obvious to pack the device through the opening in the proximal end of the central ramp when the device is in the deployed configuration. (*Id.*, ¶189.) The fusion device is delivered through a cannula that abuts the proximal end of the fusion device. (Ex. 1005, 26:31-41.) Weiman discloses that the cannula may be equipped with adapters to facilitate the injection of materials into the fusion device. (*Id.*, 25:55-58.) A POSITA would have been motivated to use the existing cannula positioned at the proximal end of the fusion device to inject bone growth material, as opposed to inserting a separate tool, for the reasons explained in the Greenhalgh grounds. (*Supra* VI.A.8.a; Ex. 1003, ¶189.) Thus, if Weiman does not disclose this limitation, it renders the limitation obvious. (Ex. 1003, ¶¶183-189.)

b. 8[b] Cap or Set Screw

Weiman discloses the cap or set screw required by claim 8. (Ex. 1003, ¶¶190-192.)

Weiman's fusion device includes an actuator assembly 200. (Ex. 1005, 24:59-63.) The "actuator assembly 200 is threadingly engaged with the rod receiving extension 416 of the central ramp 18." (*Id.*, 23:47-49.) Rotating the actuator assembly 200 pulls the ramp 18 towards the actuator assembly and expands the

fusion device. (*Id.*, 23:49-51.) Thus, the actuator assembly 200 is a set screw inserted into the aperture at the proximal end of the elongate expander. (Ex. 1003, ¶191.)

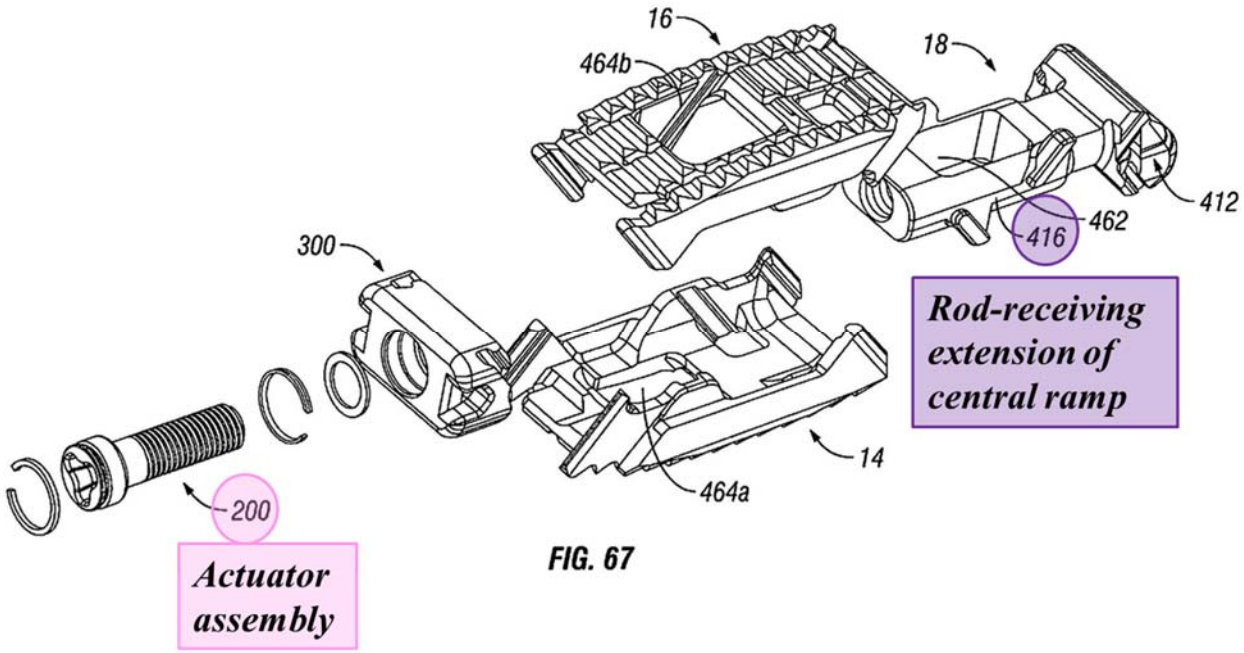


FIG. 67

The actuator assembly contains the bone growth material packed into the opening 462 in the central ramp 18. (*Id*.) The actuator assembly blocks the opening in the proximal end of the central ramp and prevents the bone growth material from escaping. (*Id.*) The actuator assembly 200 would be at least as effective at preventing bone growth material from escaping as the actuating screw or set screw described in the ’575 patent. (*Id.*)

For the reasons above, Weiman anticipates claim 8, or renders the claim obvious. (Ex. 1003, ¶¶183-192.)

9. Claim 9

Weiman discloses the limitations in claim 9. (Ex. 1003, ¶¶193-194.)

Weiman discloses that the actuator assembly 200 [pink] may have a head portion 324 [red] and "a through bore 406 [brown] that extends longitudinally through the actuator assembly 200." (Ex. 1005, 18:54-57.) The "through bore" is illustrated in the excerpt of Figure 52 below and Figure 54. (*Id.*)

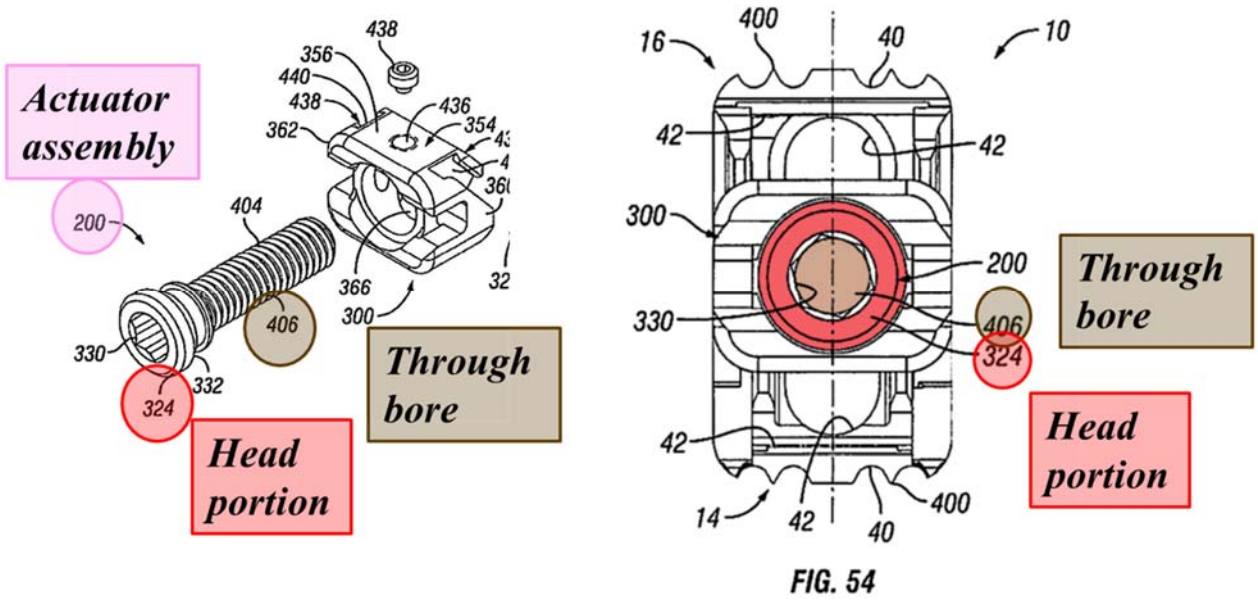
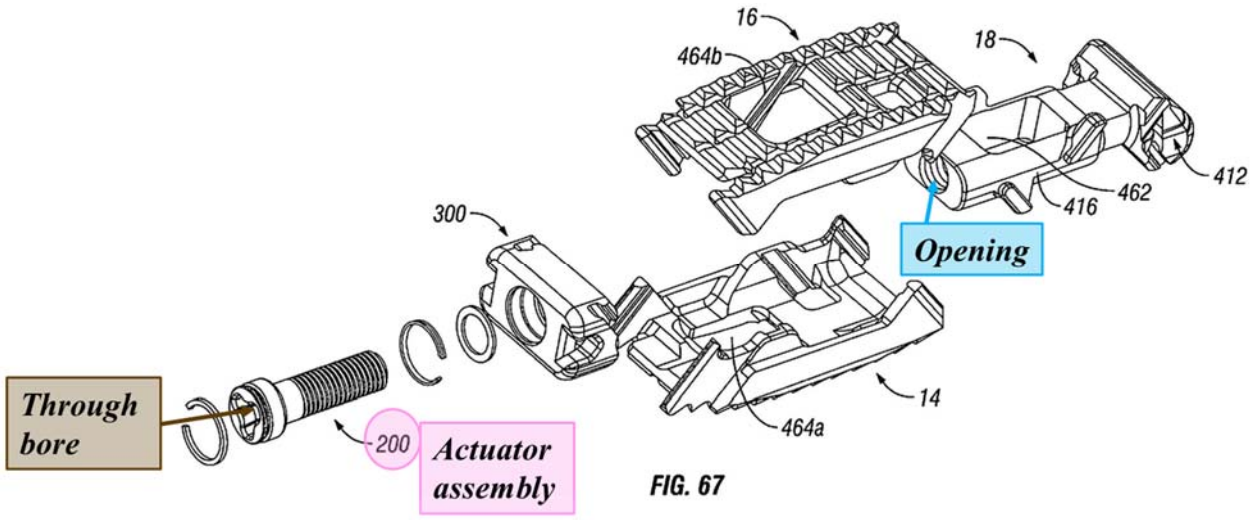


FIG. 54

The "through bore 406" is a tool bore. (Ex. 1003, ¶194.) Weiman explains that the head portion is sized and shaped to receive an instrument that can rotate the actuator assembly to expand the fusion device. (Ex. 1005, 23:42-51.) The disclosed instrument is an expansion tool because it expands the fusion device. (Ex. 1003, ¶194.) The through bore 406 is coaxial with the opening/aperture [blue] in the proximal end of the central ramp 18 because the actuator assembly is inserted into the aperture. (Ex. 1005, 23:47-51.)



Thus, Weiman anticipates claim 9, or depending on claim 8, renders the claim obvious. (Ex. 1003, ¶¶193-194.)

C. Grounds 3a-3b: Glerum Anticipates or Renders Obvious

1. Claim 1

Glerum anticipates claim 1. (Ex. 1003, ¶¶195-209.)

a. [1p] Preamble

If the preamble is limiting, Glerum discloses an expandable cage. (Ex. 1003, ¶¶196-197.)

Glerum discloses an expandable fusion device 10 [red] "capable of being installed inside an intervertebral disc space." (Ex. 1006, 1:52-56, Fig. 1 (below).) The expandable fusion device is an expandable cage. (Ex. 1003, ¶197.)

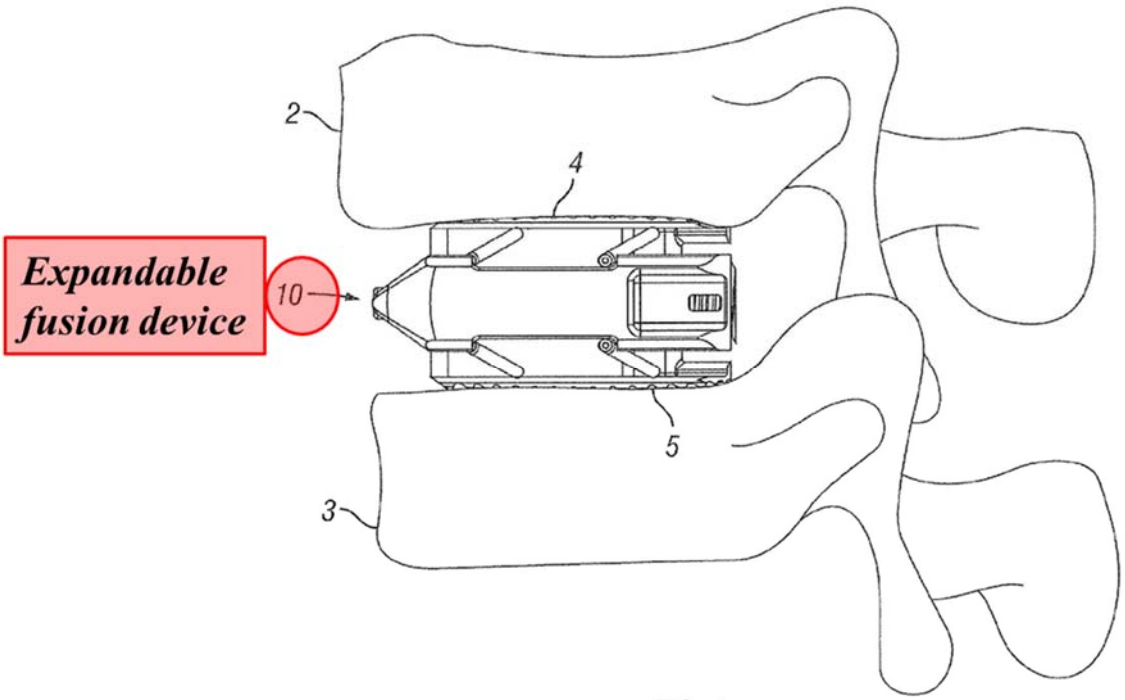
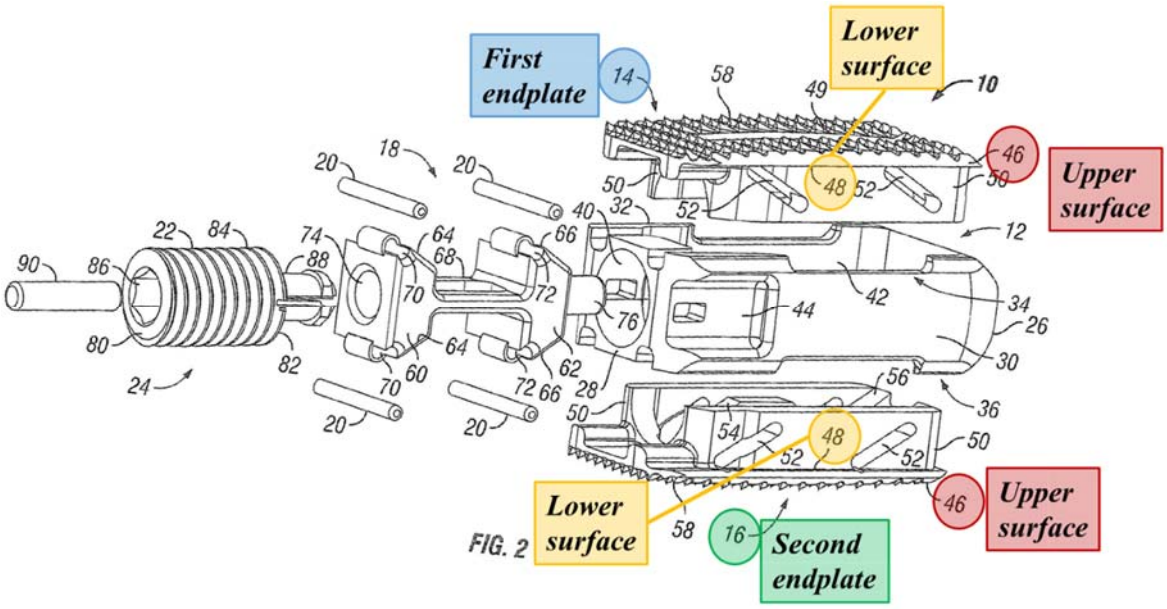


FIG. 1

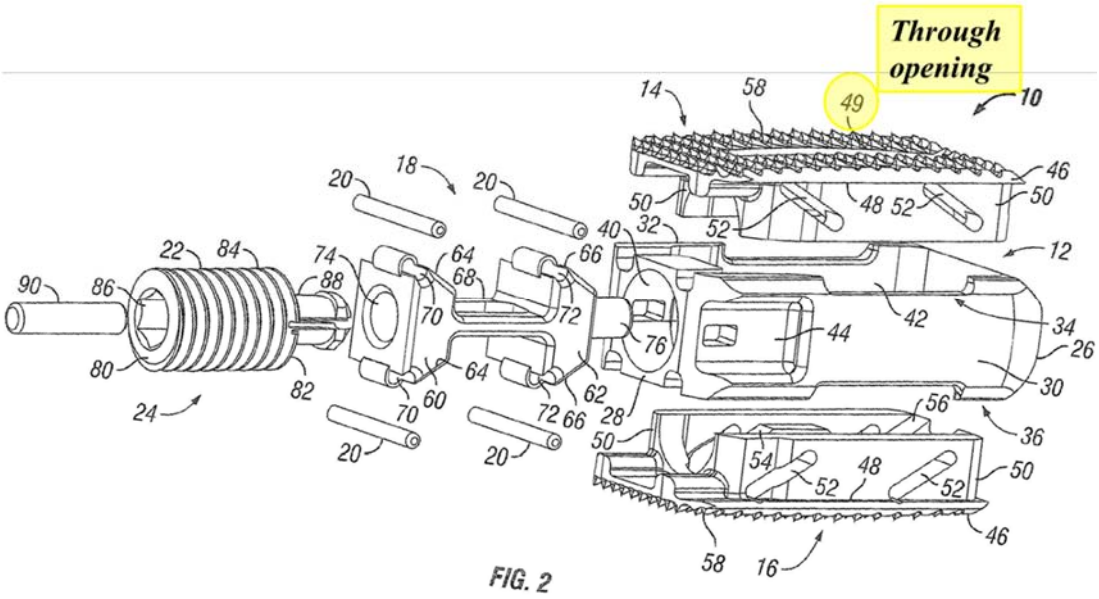
b. [1a] Cage

Glerum discloses a cage having the features described in claim 1. (Ex. 1003, ¶¶198-200.)

Glerum's fusion device includes a first endplate 14 (upper portion) [blue] and a second endplate 16 (lower portion) [green]. (Ex. 1006, 3:14-18.) The first and second endplates are "substantially identical." (*Id.*, 3:48-51.) The first endplate has an upper surface 46 (upper bone contact surface) [dark red] and a lower surface 48 (upper portion lower surface) [orange]. (*Id.*, 3:51-58.) Similarly, the second endplate has an upper surface 46 (lower bone contact surface) [dark red] and a lower surface (lower portion upper surface) [orange]. (*Id.*, 3:48-58, Fig. 2.)



The first and second endplates include through openings 49 (windows) [yellow], which are "sized to receive bone graft or similar bone growth inducing material." (*Id.*, 3:48-58.)



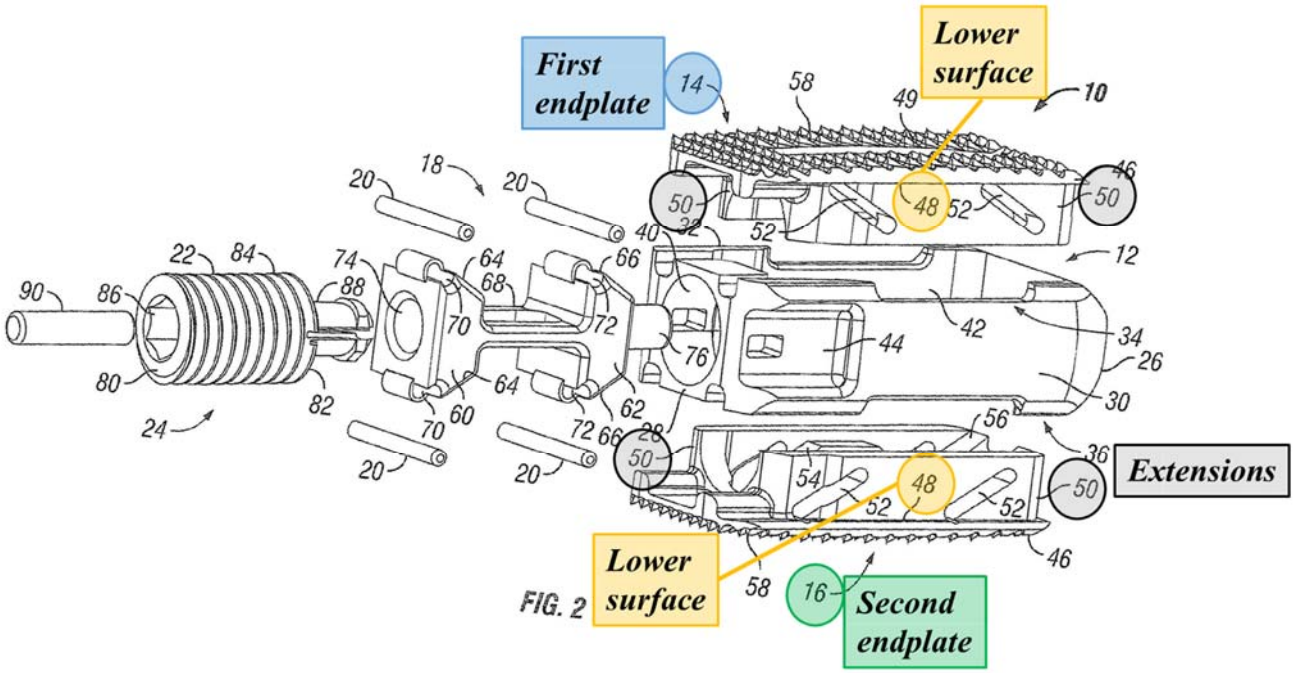
The openings 49 are configured to permit bone growth therethrough. (Ex. 1003, ¶200.) The purpose of the fusion device in Glerum is to promote bone growth

through the device to fuse the vertebrae together. (*Id.*) The device could not accomplish its purpose if the through openings were not "configured to permit bone growth therethrough." (*Id.*) Persons of ordinary skill in the art trying to avoid bone growth would not have included windows because the windows decrease the overall strength of the device and increase the risk of stress and facture. (*Id.*) The shape of the openings is similar to the windows in the embodiments disclosed in the '575 patent. (*See* Ex. 1001, Fig. 5B.) Therefore, if the windows in the '575 patent are "configured to permit bone growth therethrough," then so are the openings in Glerum. (Ex. 1003, ¶200.) Conversely, if the openings in Glerum are *not* "configured to permit bone growth therethrough," then the windows in the '575 patent are *not* "configured to permit bone growth therethrough" and the '575 patent lacks written description for this limitation. (*Id.*); *see also Ruckus Wireless*, 824 F.3d at 1004 (rejecting a claim construction that would render the claims invalid for lack of written description). As a result, a person of ordinary skill in the art would not understand "configured to permit bone growth therethrough" to be read so narrowly as to exclude the windows in the '575 patent or Glerum. (Ex. 1003, ¶200.)

c. [1b] Elongate Expander

Glerum discloses an elongate expander have the features described in claim 1. (Ex. 1003, ¶¶201-203.)

The first and second endplates include extensions 50 [gray], which extend from the lower surface 48 of each endplate. (Ex. 1006, 3:59-61.)



The extensions and first and second endplates (14, 16) form a cavity or an internal space between the first endplate's lower surface 48 (upper portion lower surface) [orange] and the second endplate's lower surface 48 (lower portion upper surface) [orange]. (*Id.*, Figs. 2, 4.)

Glerum also discloses a translation member 18 (elongate expander) [purple]. (*Id.*, 3:9-13.) The translation member has a distal end and a proximal end [gray]. (*Id.*, Fig. 2; *see also id.*, 5:29-32 (explaining first end 26 is leading or distal end of device); Ex. 1003, ¶203.)

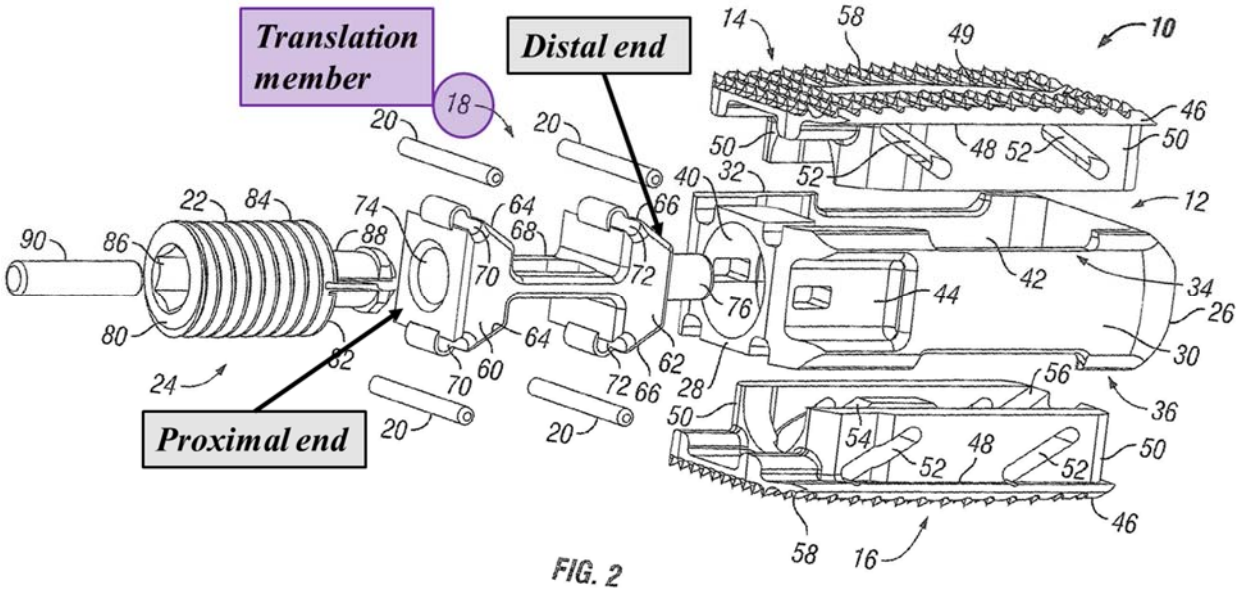


FIG. 2

The translation member 18 also includes bridge portions 68 (pair of side surfaces) [brown] that connect the proximal and distal ends of the translation member. (Ex. 1006, 4:34-38.) The bridge portions form an unobstructed internal space or opening [yellow] therebetween defining a window in the translation member. (*Id.*)

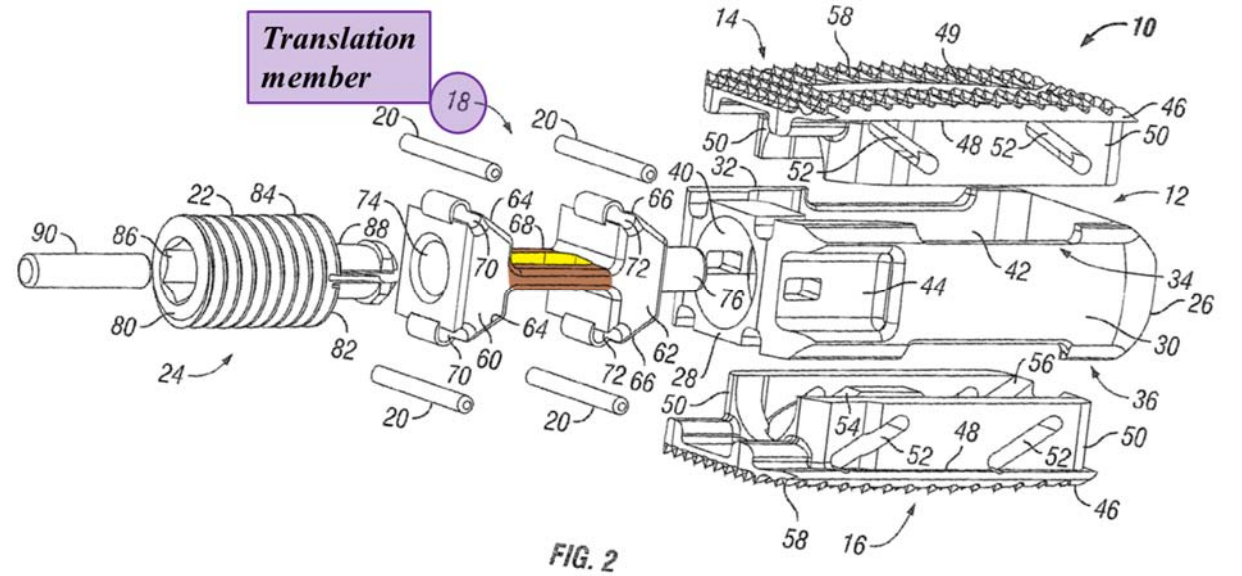


FIG. 2

The translation member 18 (elongate expander) is positioned in the cavity or an internal space between first endplate's lower surface 48 (upper portion lower surface) and the second endplate's lower surface 48 (lower portion upper surface). (*Id.*, Figs. 2-6.) The translation member 18 is an elongate expander because the member is longer than it is wide (*id.*, Fig. 2), and acts upon the first and second endplates to expand the fusion device (*id.*, 5:59-63, Figs. 10-11; Ex. 1003, ¶203.)

d. [1c] Expander Expands the Cage

Glerum discloses an elongate expander that operates as described in claim 1. (Ex. 1003, ¶¶204-205.)

Glerum discloses that the translation member 18 (elongate expander) is moved in a linear direction (longitudinal translation). (Ex. 1006, 5:49-59, Figs. 10-11; Ex. 1003, ¶205.) When the translation member 18 moves longitudinally, ramped surfaces on the translation member push against ramped surfaces on the endplates 14, 16, which force the endplates into the expanded position. (Ex. 1006, 5:59-63, Figs. 10-11.) Expansion of the fusion device separates at least a portion of the first endplate 14 (upper portion) from at least a portion of the second endplate 16 (lower portion). (*Id.*)

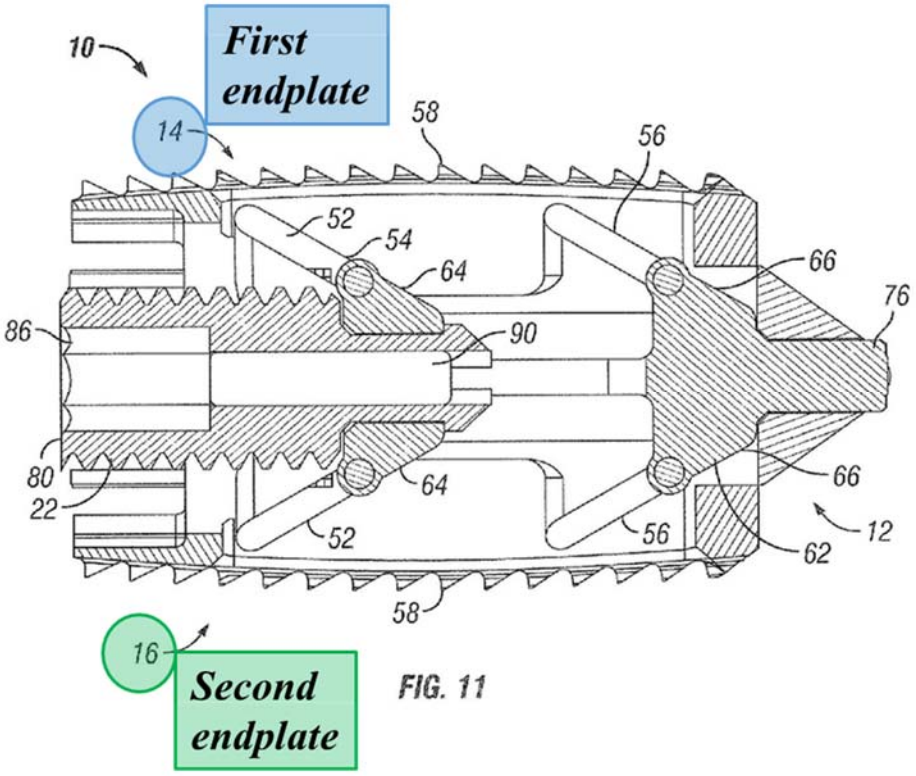


FIG. 11

e. [1d] Windows Are Unobstructed

Glerum discloses open and unobstructed windows as described in claim 1. (Ex. 1003, ¶¶206-209.)

Glerum's Figure 9 illustrates the top view of the unexpanded fusion device. (Ex. 1006, 2:28-29.) The device is unexpanded because the actuation member 22 extends beyond the proximal end of the device. (*Compare id.*, Figs. 5-6.) In the unexpanded position, the windows in the first and second endplates and the translation member are open and unobstructed when viewed from the top, as demonstrated by the yellow region below. (*Id.*, Fig. 9; Ex. 1003, ¶207.)

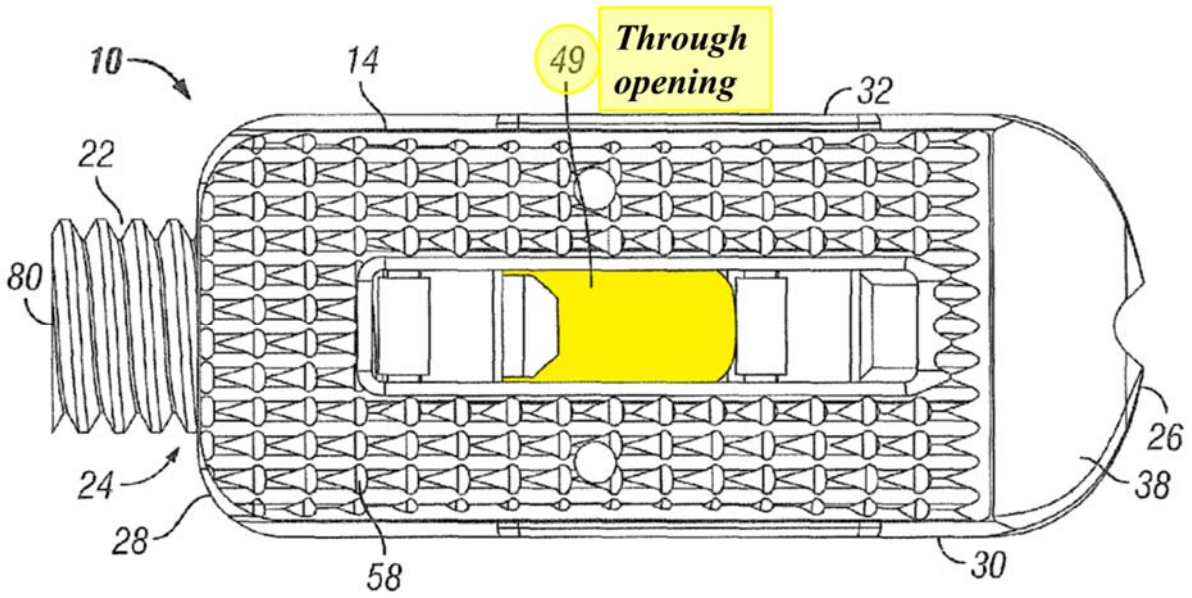


FIG. 9

Glerum does not include a figure showing the top view of the device in the expanded position. However, in the expanded position, the through opening in the first and second endplates and the translation member would still be open and unobstructed. (Ex. 1003, ¶208.) The location of the through opening would simply shift distally (in the direction of the red arrow below) as the translation member 18 is advanced. (*Id*.)

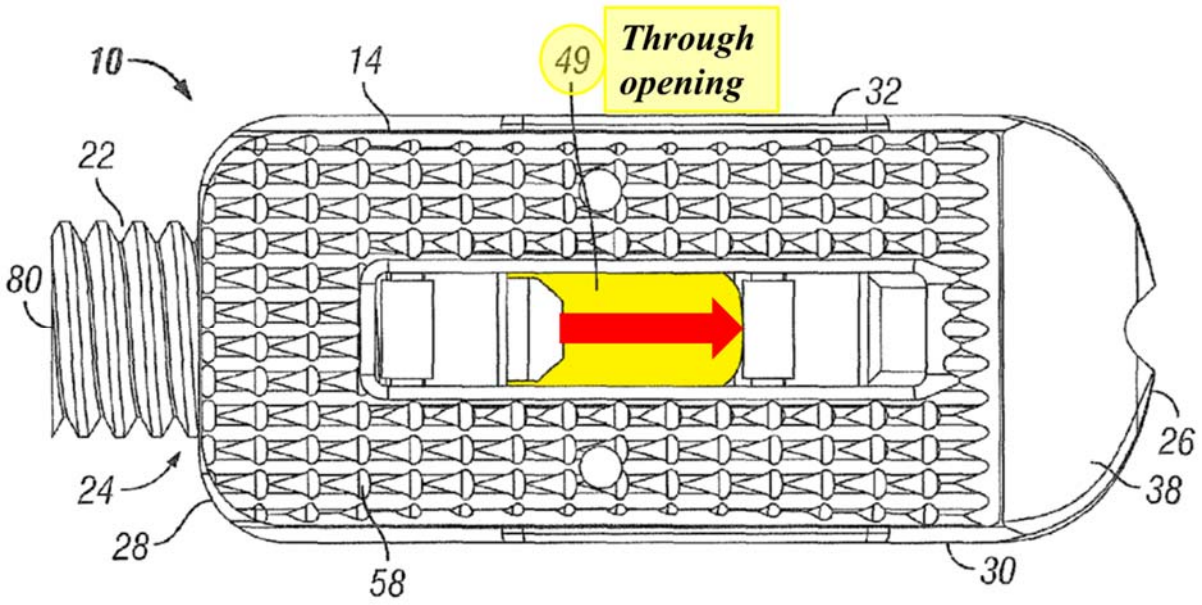


FIG. 9

Below is a comparison of the location of the through opening (between the red lines) in the unexpanded (Fig. 10) and expanded (Fig. 11) positions. (*Id.*)

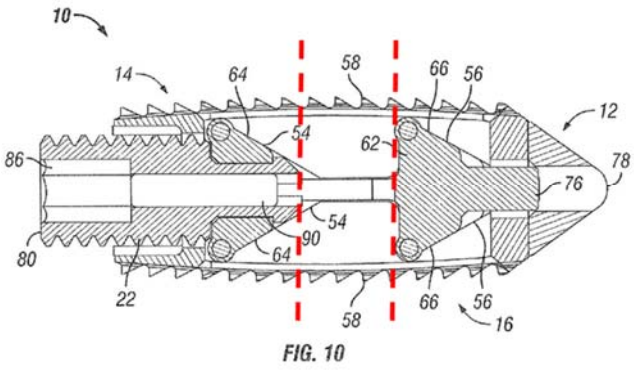


FIG. 10

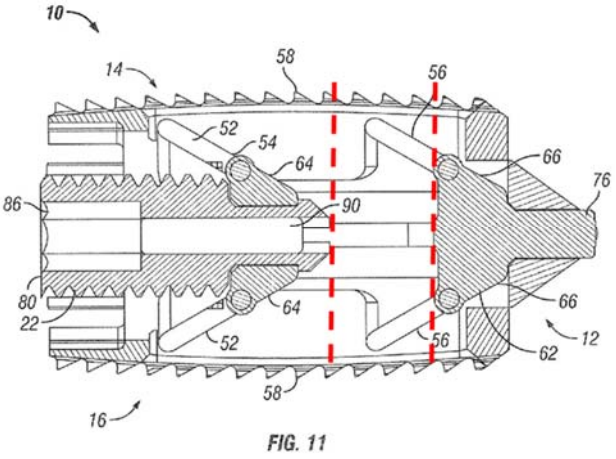


FIG. 11

As shown, the windows are at least partially aligned and the through opening is present in both positions, but the location of the opening is different. (*Id.*) As shown in Figure 9 above, there are no features lying in the path and blocking the aligned openings [yellow]. (*Id.*) Glerum's through opening 49 is similar to the '575 patent's

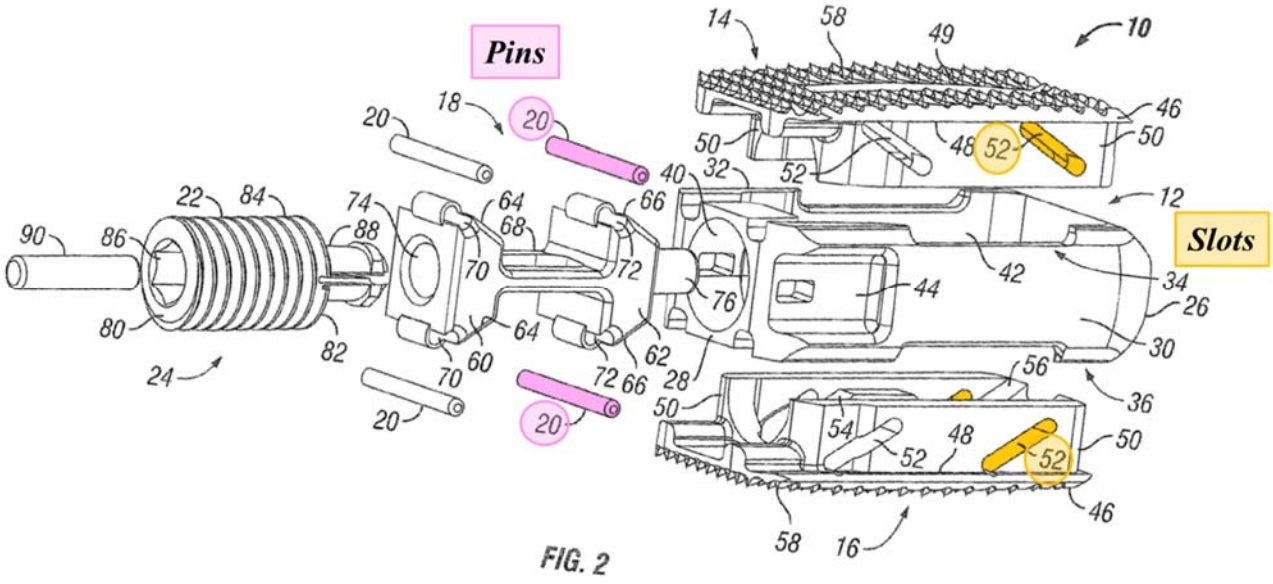
Figure 5B. (*Id.*) If the windows in Figure 5B of the ’575 patent are open and unobstructed, then the through opening 49 in Glerum is also open and unobstructed. (*Id.*) Conversely, if the through opening 49 in Glerum is *not* “open and unobstructed,” then the windows in Figure 5B of the ’575 patent are *not* “open and unobstructed” and the ’575 patent lacks written description for the limitation “open and unobstructed.” (*Id.*); *see also Ruckus Wireless*, 824 F.3d at 1004 (rejecting a claim construction that would render the claims invalid for lack of written description). As a result, a person of ordinary skill in the art would not understand “open and unobstructed” to be read so narrowly as to exclude Figure 5B of the ’575 patent or the through opening 49 in Glerum. (Ex. 1003, ¶208.)

For these reasons, Glerum anticipates claim 1. (*Id.*, ¶¶206-209.)

2. Claim 4

Glerum discloses the limitation in claim 4. (Ex. 1003, ¶¶210-211.)

The translation member 18 has a keyed distal end. (*Id.*) The distal end has a “plurality of pins 20” [pink] that are sized and shaped to match the corresponding surfaces of the slots 52 [orange] on the first and second endplates. (Ex. 1006, 3:65-4:4, Fig. 2; Ex. 1003, ¶211.) The pins fit within, and slide along, the matching slots to expand the device. (*Id.*)

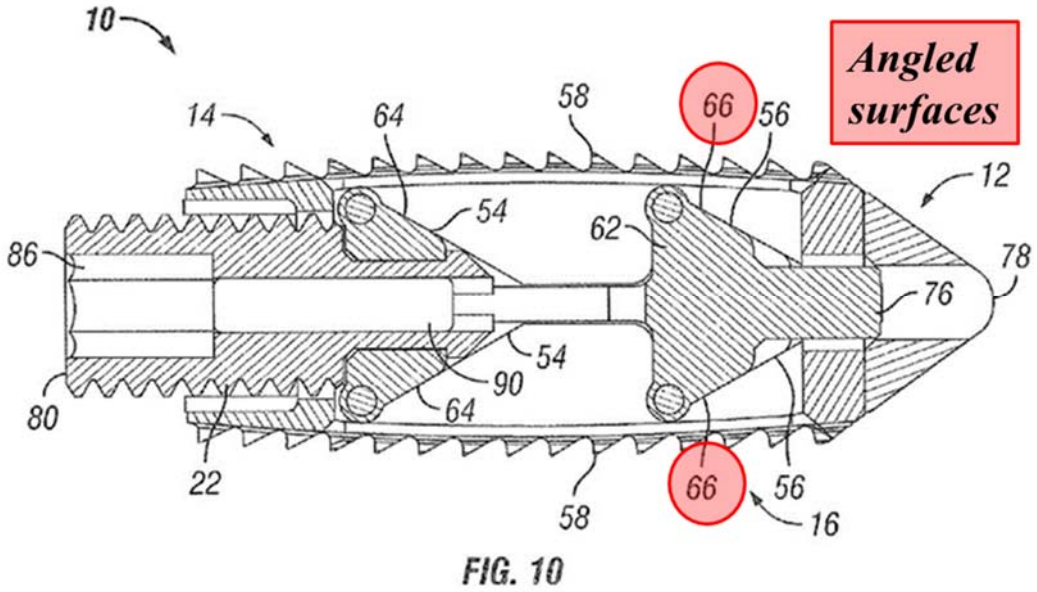


Thus, Glerum anticipates claim 4. (*Id.*)

3. Claim 5

Glerum discloses the limitation in claim 5. (Ex. 1003, ¶¶212-213.)

Glerum discloses that the distal end of the translation member 18 has "angled surfaces" 66 [red]. (Ex. 1006, 4:40-43, Figs. 2, 10-11.)

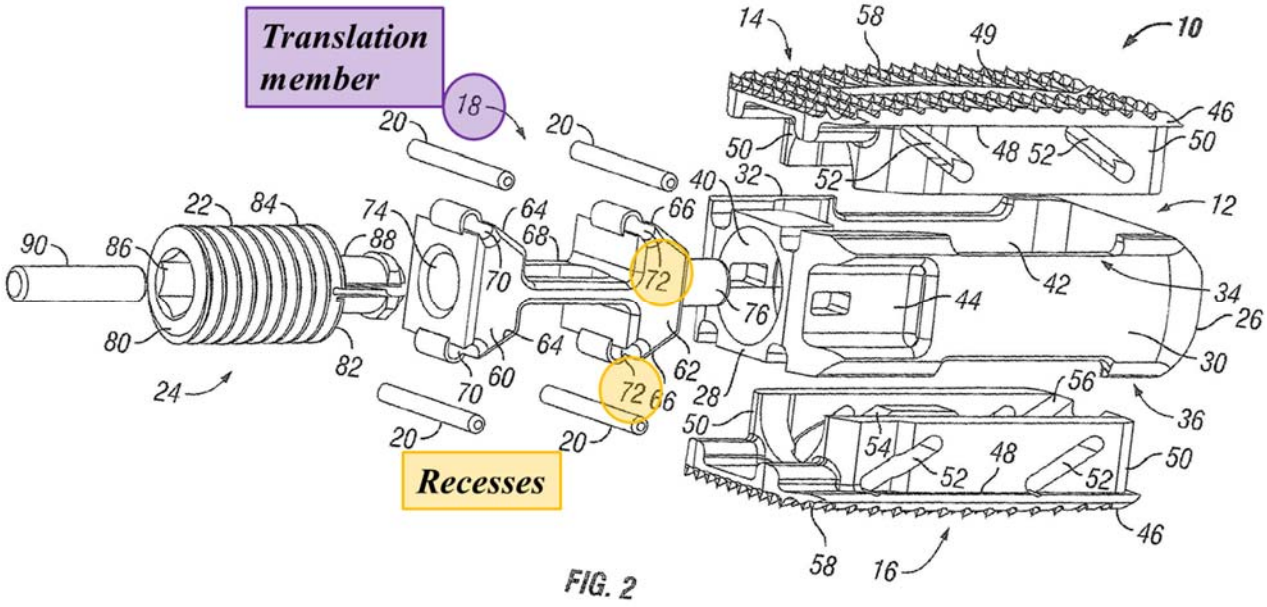


The angled surfaces are tapered sides. (Ex. 1003, ¶213.) Thus, Glerum anticipates claim 5. (*Id.*)

4. Claim 6

Glerum discloses the limitations in claim 6. (Ex. 1003, ¶¶214-215.)

Glerum discloses that the distal portion of the translation member 18 (elongate expander) includes "recesses" 72 [orange], which are sized to receive and retain pins 20. (Ex. 1006, 4:43-45.)



Thus, Glerum anticipates claim 6. (Ex. 1003, ¶¶214-215.)

5. Claim 8

Claim 8 repeats all of the limitations of claim 1 and then concludes with two additional limitations. Glerum discloses the limitations in claim 1 for the reasons previously presented. (*Supra* VI.C.1.) Glerum discloses the additional limitations in claim 8, or renders them obvious, for the below reasons.

a. [8a] A Cavity and Aperture

Glerum discloses the cavity and aperture required by claim 8, or renders them obvious. (Ex. 1003, ¶¶217-221.)

The openings (windows) in the first and second endplates and translation member define a cavity [yellow]. (Ex. 1006, Fig. 9; Ex. 1003, ¶218.)

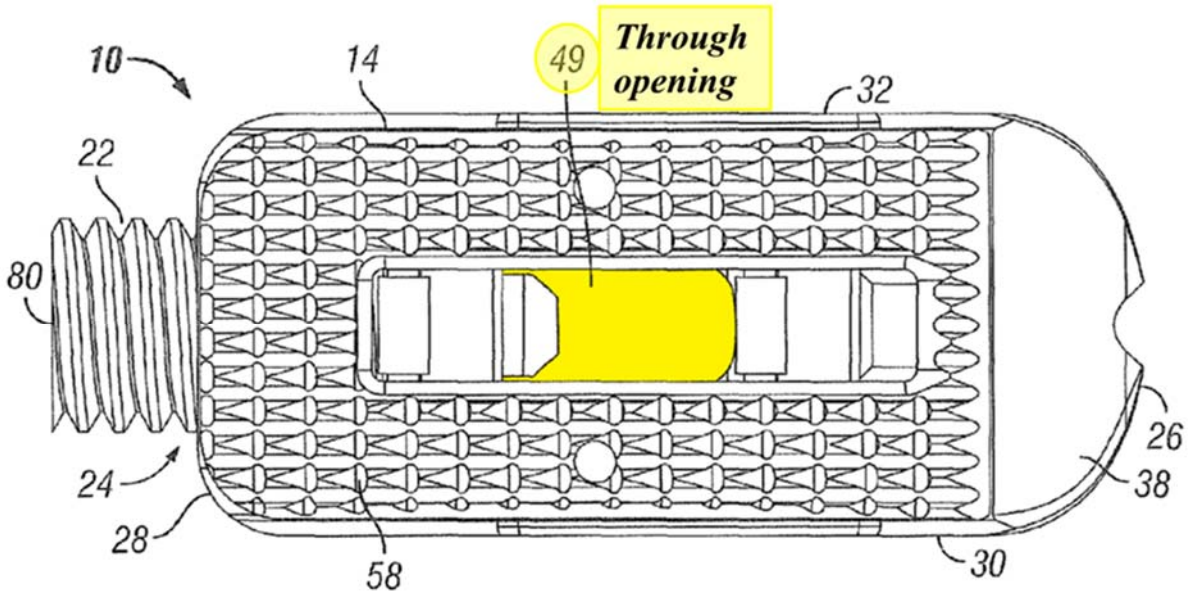


FIG. 9

The proximal end of the translation member 18 [purple] "includes an opening 74 [blue], which is sized to receive a portion of the actuation member 22." (Ex. 1006, 4:46-51.) The opening [blue] (aperture) is in communication with the cavity. (*Id.*, Figs. 2, 9-11.)

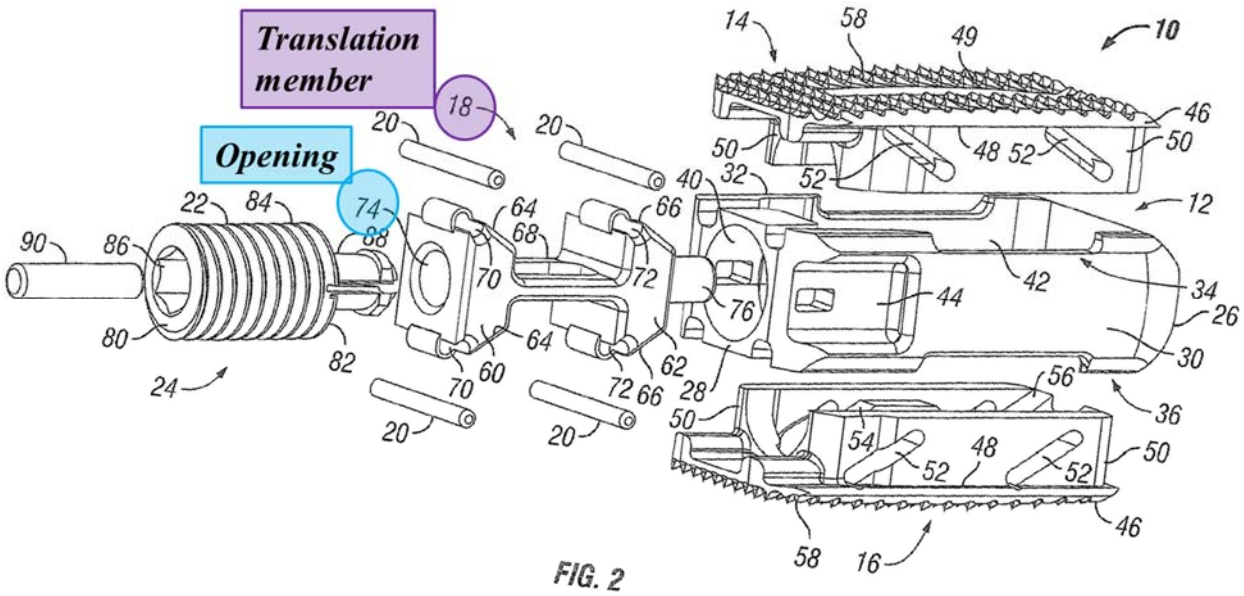


FIG. 2

Glerum discloses that the through opening 49 "is sized to receive bone graft or similar bone growth inducing material and further allow the bone graft or similar bone growth inducing material to be packed in the central opening 42 in the body portion 12." (Ex. 1006, 3:54-58.) Glerum also discloses that bone graft or similar bone growth inducing material "may be packed between the endplates of the adjacent vertebral bodies prior to, ***subsequent to***, or during implantation of the fusion device." (*Id.*, 3:4-7 (emphasis added).) However, in the expanded position, the openings in the endplates are pressed against the vertebrae and surrounding tissue and, therefore, inaccessible. (Ex. 1003, ¶220.) Likewise, the internal cavity is inaccessible from the sides of the device due to the body portion 12. (*Id.*) Therefore, the cavity must be packed through the opening 74. (*Id.*)

Moreover, the opening 74 in the translation member 18 is configured to permit packing of the cavity through the open and unobstructed windows with bone growth

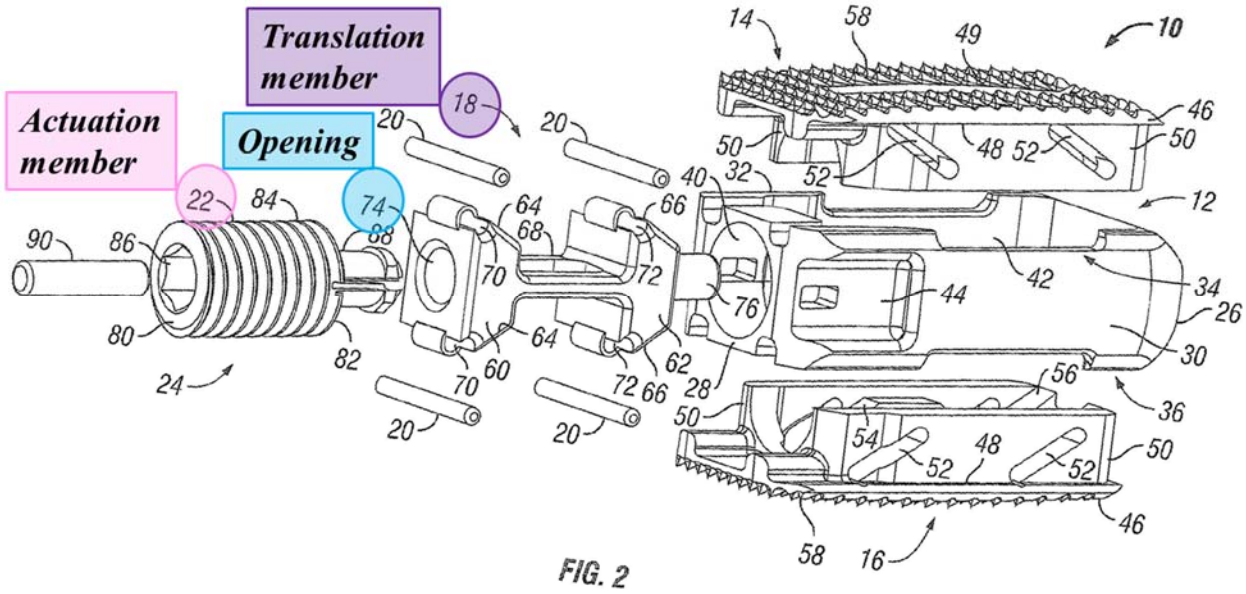
material after expansion of the expandable cage. (*Id.*) The opening 74 is sized to receive the actuation member 22, which includes its own recess 86. (Ex. 1006, 4:60-5:9, Figs. 2, 10-11.) The recess extends through the actuation member (*see e.g.,* Fig. 11) and provides a path to pack bone growth material into the cavity that is similar to the "cannulated actuation screw" described in the '575 patent. (Ex. 1001, 7:53-56.) The opening and recess would not prevent or unduly restrict the packing of the cavity. (Ex. 1003, ¶220.) If the cannulated actuation screw in the '575 patent is configured to permit packing of the cavity, then so is the recess in Glerum's actuation member 22. (*Id.*) Conversely, if the recess in Glerum is *not* "configured to" permit packing of the cavity with bone growth material, then the cannulated actuation screw in the '575 patent is *not* "configured to" permit packing of the cavity with bone growth material and the '575 patent lacks written description for this limitation. (*Id.*); *see also Ruckus Wireless,* 824 F.3d at 1004 (rejecting a claim construction that would render the claims invalid for lack of written description). As a result, a person of ordinary skill in the art would not understand "configured to" permit packing of the cavity with bone growth material to be read so narrowly as to exclude the cannulated actuation screw in the '575 patent or the recess in Glerum. (Ex. 1003, ¶220.) Thus, Glerum discloses this limitation either expressly or inherently. (*Id.*)

Moreover, even if the surgeon could pack the device through another opening, a POSITA would have found it obvious to pack the device through opening 74 when the device is in the expanded position. (Ex. 1003, ¶221.) The opening 74 receives actuation member 22, which has a recess 86 designed to receive the delivery instrument. (Ex. 1006, 4:60-63.) A POSITA would have been motivated to use the recess in the actuation member to pack the device, as opposed to inserting another tool, for the reasons explained in the Greenhalgh grounds. (*Id.*; *supra* VI.A.8.a.) Thus, if Glerum does not disclose this limitation, it renders the limitation obvious in light of the background of a POSITA. (Ex. 1003, ¶221.)

b. [8b] Cap or Set Screw

Glerum discloses the cap or set screw required by claim 8. (Ex. 1003, ¶¶222-224.)

Glerum discloses an actuation member 22 [pink]. (Ex. 1006, 4:52-55, Fig. 2.) The actuation member is a set screw. (Ex. 1003, ¶223.) By rotating the actuation member 22, the surgeon expands the fusion device. (Ex. 1006, 5:47-59.) The actuation member 22 is inserted into the opening 74 (aperture) [blue] at the proximal end of the translation element 18 (elongate expander) [purple]. (*Id.*, 4:46-51.)



The actuation member contains the bone growth material within the cavity by partially blocking the opening 74. (Ex. 1003, ¶223.) In addition, Glerum discloses that a pin member 90 can be inserted into the recess 86 in the actuation member 22, which would further block opening 74 and prevent any bone growth material from escaping. (*Id.*) Thus, Glerum discloses this limitation. (*Id.*)

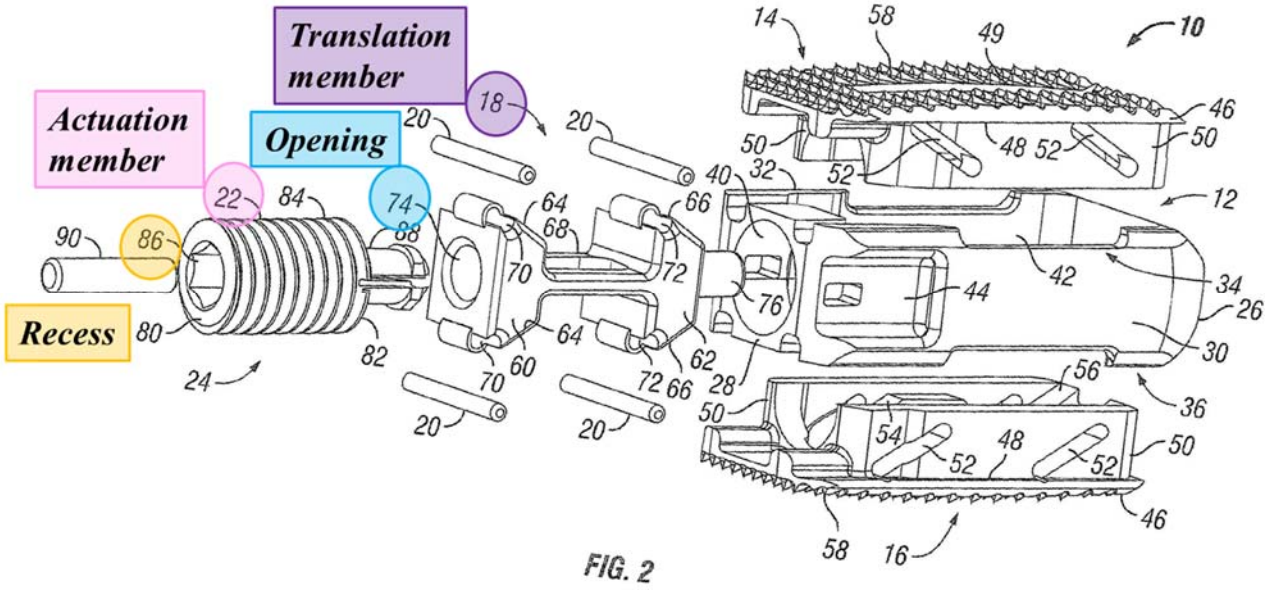
For the above reasons, Glerum anticipates claim 8 or renders the claim obvious. (Ex. 1003, ¶¶222-224.)

6. Claim 9

Glerum discloses the limitations in claim 9. (Ex. 1003, ¶¶225-227.)

The actuation member 22 [pink] includes a recess 86 [orange]. (Ex. 1006, 4:60-63, Fig. 2.) The recess 86 is "dimensioned to receive an instrument … that is capable of advancing the actuation member 22 with respect to the body portion 12

of the fusion device 10." (*Id*.)) Thus, the recess 86 is a tool bore shaped to accept an expansion tool. (Ex. 1003, ¶226.)



The recess 86 extends along the length of the actuation member because, for example, a pin member 90 [red] extend through the recess 86. (*Id.*, 6-9, Fig. 11.) Further, as shown below, the recess 86 is coaxial with the opening 74 (aperture) in the proximal end of the translation member. (Ex. 1006, Fig. 10-11.)

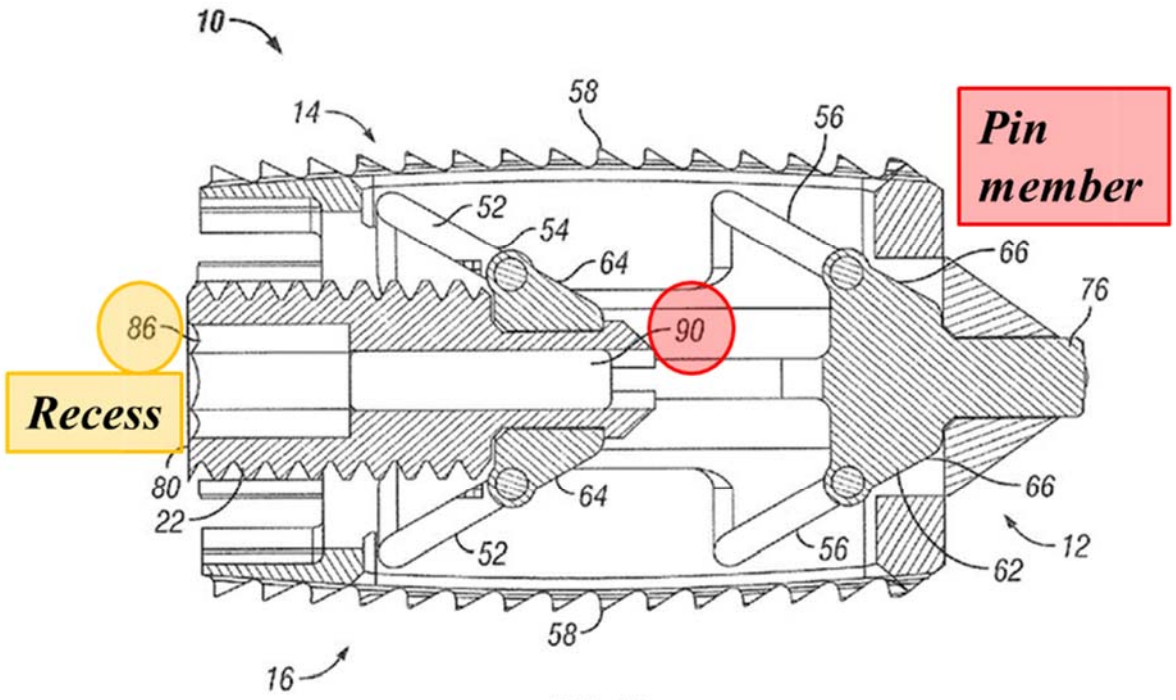


FIG. 11

For these reasons, Glerum anticipates claim 9 or, depending on claim 8, renders claim 9 obvious. (Ex. 1003, ¶¶225-227.)

VII. SECONDARY CONSIDERATIONS

Secondary considerations should be considered but do not control the obviousness conclusion. *See Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Petitioner understands that Patent Owner does not practice the ’575 patent or sell any products covered by the ’575 patent. Therefore, Petitioner is not aware of any evidence of secondary considerations, like commercial success. (Ex. 1003, ¶¶228-229.) If Patent Owner identifies any evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

VIII. MANDATORY NOTICES PURSUANT TO 37 C.F.R. §42.8(a)(1)

Pursuant to 37 C.F.R. §42.8(a)(1), the mandatory notices identified in 37 C.F.R. §42.8(b) are provided below as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. §42.8(b)(1))

Spinal Elements, Inc. is the real party-in-interest.

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

Petitioner is not aware of any judicial or administrative matter that would affect, or be affected by, a decision in this proceeding.

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

Spinal Elements provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Spinal Element's Power of Attorney.

Lead Counsel	Back-up Counsel
John B. Sganga, Jr., Reg. No. 31,302 Knobbe, Martens, Olson, & Bear, LLP 2JBS@knobbe.com Postal and Hand-Delivery Address: 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502	Joshua J. Stowell, Reg. No. 64,096 2JYS@knobbe.com Rabi N. Narula, Reg. No. 53,371 2RNN@knobbe.com Knobbe, Martens, Olson, & Bear, LLP Postal and Hand-Delivery Address: 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502

D. Service Information (37 C.F.R. §42.8(b)(4))

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxSpinalElements@knobbe.com.

IX. PAYMENT OF FEES

The undersigned authorize the Office to charge the §42.15(a) review fee to Deposit Account No. 11-1410. Review of 9 claims is requested. Payment for any additional fees due is authorized to be charged to the above-referenced Account.

X. ADDITIONAL REQUIREMENTS UNDER 37 C.F.R. §42.204

As explained above, the AIA applies to the '575 patent. (*Supra* II.C.) The '575 patent issued on July 14, 2020 and Petitioner has timely filed this Petition no later than ¶nine months after the date of the grant of the patent. 35 U.S.C. §321(c); 37 C.F.R. §42.202. Petitioner certifies that the '575 patent is available for PGR and that Petitioner is not barred or estopped from requesting PGR challenging the patent claims on the identified grounds.

XI. CONCLUSION

Claims 1-9 of the '575 patent are unpatentable and should be canceled.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 9, 2021

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Joshua J. Stowell, Reg. No. 64,096

Rabi N. Narula, Reg. No. 53,371
Customer No. 20,995
Attorneys for Petitioner
Spinal Elements, Inc.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that foregoing **PETITION FOR POST GRANT REVIEW OF U.S. PATENT 10,709,575**, exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 16,486 words and therefore complies with the type-volume limitations of 37 C.F.R. §42.24(a).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 9, 2021

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Attorneys for Petitioner
Spinal Elements, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR POST GRANT REVIEW OF U.S. PATENT 10,709,575** and **EXHIBITS 1001-1020** are being served on February 9, 2021, via Federal Express overnight delivery at the correspondence address of record for U.S. Patent 10,709,575 as identified in PAIR:

David L. King, Sr.
5131 N.E. County Road 340
High Springs, FL 32643

Dated: February 9, 2021

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