UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOPEDIATRICS CORP.,
Petitioner,

v.

K2M, INC.,
Patent Owner

Inter Partes Case No. IPR2018-00429
Patent No. 9,532,816

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,532,816

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LIST OF EXHIBITS

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ORT-1002	U.S. App. Pub. No. 2006/0247630 by Iott et al. ("Iott")
ORT-1003	U.S. App. Pub. No. 2006/0079909 by Runco et al. ("Runco")
ORT-1004	U.S. App. Pub. No. 2006/0089651 by Trudeau et al. ("Trudeau")
ORT-1005	U.S. App. Pub. No. 2006/0036255 by Pond, Jr. et al. ("Pond")
ORT-1006	Expert Declaration of Ottie Pendleton

TABLE OF AUTHORITIES

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I. INTRODUCTION

OrthoPediatrics Corp. ("Petitioner") petitions for *inter partes* review ("IPR") of claims 16, 18, 19, 21, and 22 (the "Challenged Claims") of U.S. Patent No. 9,532,816 (ORT-1001), which public records indicate is assigned to K2M, Inc. ("Patent Owner"). The Challenged Claims of U.S. Patent No. 9,532,816 ("the '816 Patent") relate to "a manually operated device capable of reducing a rod into position in a rod receiving notch in the head of a bone screw." ORT-1001 at 1:17-19. Each feature of the Challenged Claims is expressly or implicitly disclosed and/or rendered obvious by the prior art discussed below.

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

A. Real Parties-in-Interest under 37 C.F.R. § 42.8(b)(1)

The real parties-in-interest are Petitioner OrthoPediatrics Corp. and OrthoPediatrics US Distribution Corp., a wholly owned subsidiary of OrthoPediatrics Corp.

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

Patent Owner has asserted the '816 Patent against OrthoPediatrics Corp. and OrthoPediatrics US Distribution Corp. in a civil action, Case No. 1:17-cv-00061-GMS, filed on January 20, 2017, in the U.S. District Court for the District of Delaware.

C. Lead and Back-up Counsel under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel:

Lead Counsel	Back-up Counsel
Paul M. Ulrich (Reg. No. 46,404) ULMER & BERNE LLP 600 Vine Street, Suite 2800 Cincinnati, Ohio 45202 Telephone: (513) 698-5156 Fax: (513) 698-5157 E-mail: pulrich@ulmer.com	Christopher A. Singh (Reg. No. 61,236) ULMER & BERNE LLP 600 Vine Street, Suite 2800 Cincinnati, Ohio 45202 Telephone: (513) 698-5084 Fax: (513) 698-5085 E-mail: csingh@ulmer.com

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

Please address all correspondence and service to the lead counsel and back-up counsel at the address provided above. Petitioner consents to electronic service by electronic mail.

III. POWER OF ATTORNEY UNDER 37 C.F.R. § 42.10(b)

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this petition. The above-identified Lead and Back-up Counsel are registered practitioners associated with Customer No. 69,082 listed in that Power of Attorney.

IV. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

The fee set forth in 37 C.F.R. § 42.15(a) for requesting IPR of the Challenged Claims was paid at the time of filing this petition. Petitioner authorizes the United States Patent and Trademark Office ("the Office") to charge Deposit Account No. 501884 for any additional fees that may be due in connection with this petition.

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

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

Petitioner certifies that the '816 Patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR on the grounds identified herein.

B. Identification of Challenge under 37 C.F.R. § 42.104(b) and Relief Requested

Petitioner requests IPR of claims 16, 18, 19, 21, and 22 of the '816 Patent based on the prior art and grounds set forth below and requests that the Board find each of these claims to be unpatentable. In support of this petition, the declaration of Ottie Pendleton (ORT-1006) also has been submitted.

Ground	Claims	Basis for Unpatentability
Ground 1	16, 18, 19, 21, 22	Anticipated under 35 U.S.C. § 102(e)[1] by Iott
Ground 2	16, 18, 19, 21, 22	Anticipated under 35 U.S.C. § 102(b) by Runco
Ground 3	16, 18, 19, 21, 22	Anticipated under 35 U.S.C. § 102(b) by Trudeau
Ground 4	16, 18, 19, 21, 22	Obvious under 35 U.S.C. § 103(a) by Trudeau in view of Pond

[1] References to 35 U.S.C. §§ 102 and 103 throughout this petition are to the pre-AIA versions, which apply to the '816 Patent.

C. Claim Construction under 37 C.F.R. § 42.104(b)(3)

Petitioner does not believe any specific claim terms of the Challenged Claims require construction for the purposes of this petition.[2] Nevertheless, any terms that are construed should be given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b); *see also Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2144–45 (2016).

VI. SUMMARY OF THE PATENT

A. Background of the Art

The '816 Patent is generally directed to orthopedic surgery, and more specifically to devices for stabilizing and fixing bones, particularly vertebrae. ORT-1001 at 1:14-16. According to the '816 Patent, "a surgical procedure known as spinal fusion" is "a common solution" to various disorders, diseases, and types of injuries relating to the spinal column (*e.g.*, scoliosis). *Id.* at 1:37-39. Such a surgical procedure "involves fusing two or more vertebral bodies in order to eliminate motion at the intervertebral disc or joint." *Id.* at 1:39-41. The '816 Patent further explains that "it is common practice to ***place bone screws*** into the

[2] For reasons unrelated to the grounds set forth in this petition, Petitioner and Patent Owner dispute the construction of various claim terms of the Challenged Claims in the related district court proceeding, where a different claim construction standard applies.

vertebral bodies and ***then connect a metal rod*** between adjacent vertebral bodies" in order to immobilize the spinal column. *Id.* at 1:45-50 (emphasis added). That is, the surgeon uses a long spinal rod to connect multiple vertebrae by placing the rod into a "receiving slot" in each head of the bone screws that have already been attached to the vertebrae. *See id.*

"The process of properly inserting the spinal rod into the receiving slot of a bone screw and then securing that connecting rod in place often can require that the surgeon use a number of instruments." *See id.* at 1:54-58. According to the '816 Patent, "it is necessary that a device and method be provided by which the rod can be reduced into the head of each of the sequentially aligned bone screws and, as necessary, easily adjusted so as to facilitate the process for the surgeon with minimal effort and loss of time." *Id.* at 1:65–2:3. The '816 Patent further discloses that it is desired to provide a rod reduction instrument that "effectively reduces . . . a connecting rod into position in . . . a bone screw and holds that rod in position while other portions of the connecting rod are positioned and reduced into other bone screws allowing for position adjustment as necessary during the process." *See id.* at 2:4-11.

B. The Alleged Invention of the '816 Patent

The '816 Patent relates to a device that is used by a surgeon to lower—or ***reduce***—a spinal rod into the slot of a bone screw during an orthopedic surgery.

These types of devices—conventionally called "rod reducers" or "rod approximators"—have been around long before the named inventors of the '816 Patent filed their patent applications. According to the specification, the alleged invention allows the surgeon to accomplish two separate tasks: (1) grasp a bone screw and (2) reduce a spinal rod into the head of the bone screw. *See id.* at 2:22-26. In one embodiment of the '816 Patent, the rod reducer 10 uses a grasping fork assembly 14 with a "screw jack" mechanism 12, shown below in Figures 2 and 5 of the '816 Patent:

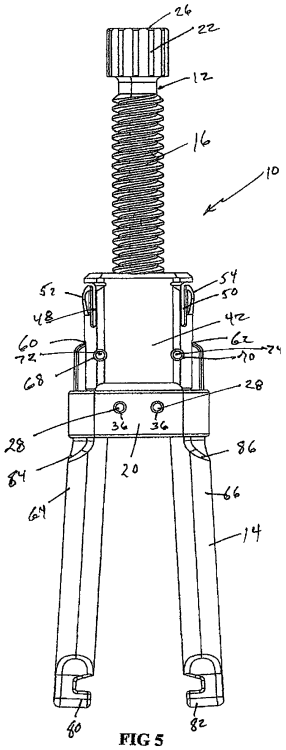


FIG 5

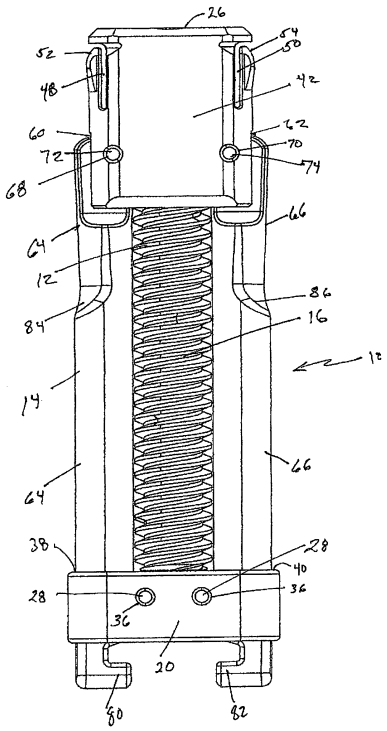


FIG 2

The rod reducer is a manually operated device capable of reducing a rod into a rod receiving slot of a bone screw head by the rotation of a screw shaft 16. *Id.* at

1:16-19. Figure 5 shows a front view of the device before rotation of the screw shaft 16, *i.e.*, "in a ready configuration." *Id.* at 3:31-32. The fork assembly includes two opposed, elongated "grasping members" 64 and 66. (*See id.* at 5:56-65; FIGS. 2 and 5, above. At the bottom (*i.e.*, distal end) of the screw shaft 16 is a "rod contact member" 20. *See id.* at 4:39-42. When a surgeon rotates the screw shaft 16, both it and the rod contact member 20 move downward. When a rod is positioned between the grasping members 64 and 66, rotation of the screw shaft 16 pushes the rod downward into the bone screw. *See, e.g., id.* at 6:9-55. Figure 2 thus shows the device "in an activated configuration." *Id.* at 3:23-24.

C. Claim Key

In discussing the limitations of the Challenged Claims, this petition refers to limitations according to the below "key":

Claim Limitations
[16-PRE] A rod reducing device comprising:
[16-1] a housing defining a longitudinal axis,
[16-2] the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween,
[16-3] the first and second grasping members defining a plane;
[16-4] a rotatable member extending through the housing along the longitudinal axis; and
[16-5] a rod contact member positioned at a distal end of the rotatable member,

Claim Limitations
[16-6] the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis,
[16-7] wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members.
[18-1] The rod reducing device of claim 16, wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable with a portion of a bone anchor.
[19-1] The rod reducing device of claim 16, wherein distal movement of the rod contact member urges a rod towards distal ends of the first and second grasping members.
[20-1] The rod reducing device of claim 16, wherein the rod contact member defines through passages configured for movement along the first and second grasping members.
[21-1] The rod reducing member of claim 16, wherein a portion of the rod contact member is positioned between the first and second grasping members.
[22-1] The rod reducing member of claim 16, wherein the rod contact member is attached to the distal end of the rotatable member.

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art at the time of the alleged invention would have at least a bachelor's degree in mechanical engineering or biomedical engineering combined with at least one year of post-graduate or industry work experience in orthopedic instruments or an equivalent. ORT-1006 ¶ 13.

VIII. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '816 PATENT IS UNPATENTABLE

As detailed below, each of claims 16, 18, 19, 21, and 22 of the '816 Patent is anticipated and/or rendered obvious by at least one or more references, singularly or in combination (the "Grounds"). Each of the Grounds independently shows a reasonable likelihood that one or more of the claims of the '816 Patent are unpatentable. The Grounds are not cumulative or redundant.

A. Ground 1: Claims 16, 18, 19, 21, and 22 Are Anticipated by Iott (ORT-1002)

Iott anticipates claims 16, 18, 19, 21, and 22 of the '816 Patent. Iott was filed on October 6, 2006, and was published on November 2, 2006. ORT-1002 at 1. Therefore, Iott is prior art under at least 35 U.S.C. § 102(e)[3] and 35 U.S.C. § 102(a). Iott was never cited nor considered by the Examiner during prosecution of the '816 Patent. ORT-1001 at 1-2.

Iott generally discloses a vertebral stabilization system. ORT-1002 ¶ 2. The system includes bone anchors and a connecting member extending therebetween for stabilizing vertebrae of a patient. *See id*. ¶ 51. A sleeve extends from each of the anchors to provide access to the anchors through the body of the patient. *See*

[3] The 35 U.S.C. § 102(e) critical reference date of Iott is at least as early as its filing date of October 6, 2005.

id. ¶ 55. Iott further discloses a rod reducer instrument attached to a proximal end of the sleeves. *See id.* ¶ 70.

1. Claim 16:

a. [16-PRE]: "A rod reducing device comprising"

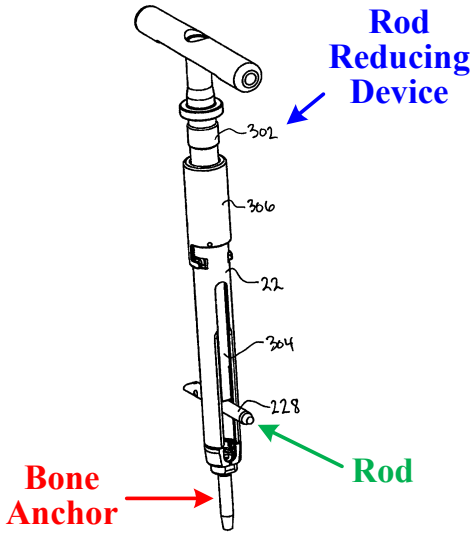


FIG. 31

Iott discloses the claimed "rod reducing device" as recited in claim 16. For example, Iott discloses "***one embodiment of a rod reducer instrument 300*** [the claimed *rod reducing device*][4] is shown that is configured and dimensioned to be utilized with the percutaneous systems described herein." *Id.* ¶ 70 (emphasis added); FIG. 31, above (annotated). Iott further states "in operation, . . . reducer

[4] To facilitate analysis of the Challenged Claims, many of the excerpts from the prior art in this petition include bracketed references to corresponding claim limitations of the '816 Patent.

shaft 304 is ***translated*** in the axial direction . . . providing a force in the axial direction that may be used . . . to force a spinal rod from a first position spaced from a fastener . . . to a second position proximate to a fastener." *Id.* ¶ 71 (emphasis added).

b. [16-1]: "a housing defining a longitudinal axis"

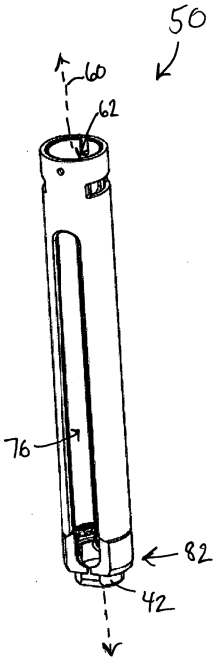


FIG. 5

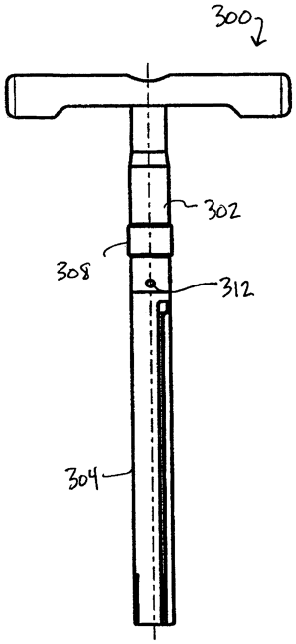


FIG. 30

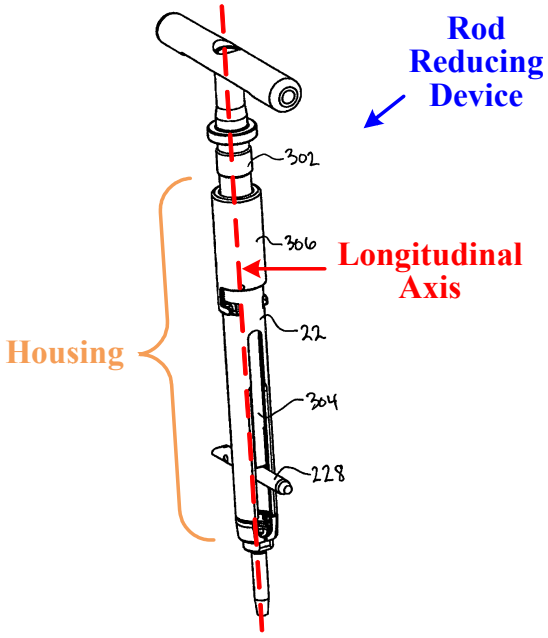


FIG. 31

Iott discloses the claimed "housing defining a longitudinal axis" as recited in claim 16. For example, Iott states that "[r]od reducer instrument 300 generally comprises . . . ***an attachment sleeve 306***, configured to engage and attach to a proximal end of ***sleeve[ ] 22*** [collectively, the claimed *housing*]." *Id.* (emphasis added); FIGS. 5, 30, 31 (annotated), above. Iott discloses one specific example of sleeve 22 as "one embodiment of a sleeve 50 [a portion of the claimed *housing*]

according to the invention is shown comprising an inner sleeve member 52 and an outer sleeve member 54 extending from a proximal end 56 to a distal end 58 along ***an axis 60*** [e.g., a *longitudinal axis*]." *Id.* ¶ 55 (emphasis added); FIG. 5, above.

c. [16-2]: "the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween"

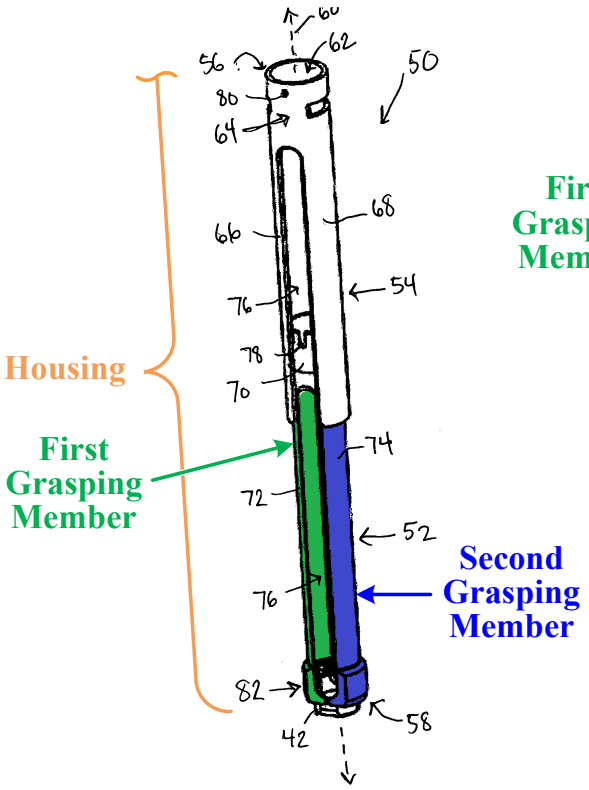


FIG. 3

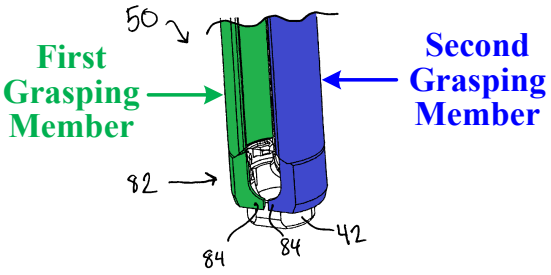


FIG. 4

Iott discloses the claimed "housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween" as recited in claim 16. In particular, Iott discloses "***arms 72, 74*** [the claimed *first and second grasping members*] ***of inner sleeve member 52 [that] may be compressed radially inward or expanded radially outward*** depending on the particular application." *Id.*

¶ 56 (emphasis added); FIGS. 3-4, above (annotated). Iott in FIG. 3 discloses that the sleeve 50 (*i.e.,* a portion of the claimed *housing*) includes inner sleeve 52.

Iott further states that "***when arms 72, 74*** [the claimed *first and second grasping members*] ***of inner sleeve member 52 are compressed radially inward, the coupling element 42 of screw 32*** [a *bone anchor*] is rotationally and axially ***fixed with respect to sleeve 50*** [a portion of the claimed *housing*] or radially contained within sleeve 50." *Id*. ¶ 57 (emphasis added).

d. [16-3]: "the first and second grasping members defining a plane"

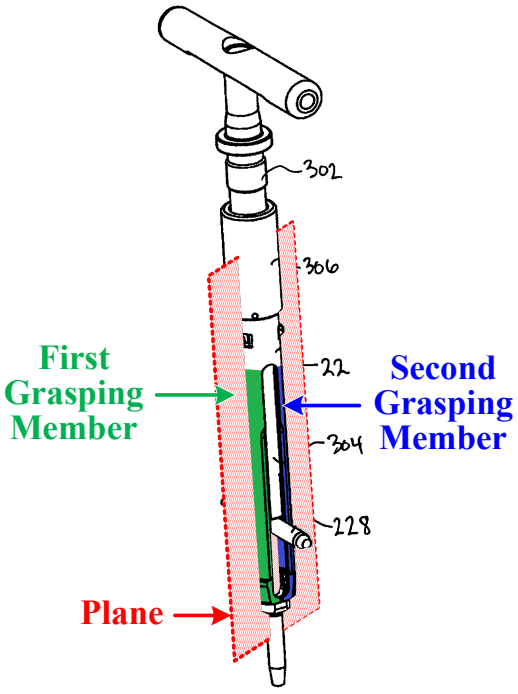


FIG. 31

Iott discloses the claimed "the first and second grasping members defining a plane." As shown in FIG. 31, the arms 72, 74 (*i.e.,* the claimed *first and second*

grasping members) of Iott implicitly define a plane. *Id.* at FIG. 31, above (annotated); *see also* ORT-1006 ¶¶ 52-53.

e. [16-4]: "a rotatable member extending through the housing along the longitudinal axis"

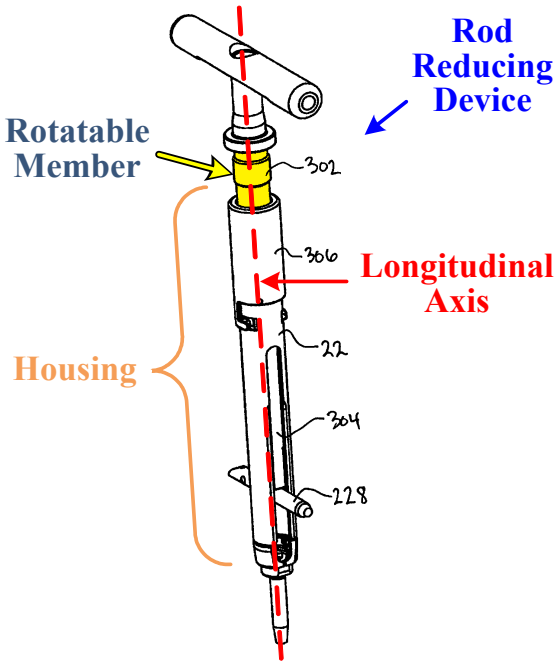


FIG. 31

Iott discloses the claimed "rotatable member extending through the housing along the longitudinal axis" as recited in claim 16. For example, Iott states that the "[r]od reducer instrument 300 [the claimed *rod reducing device*] generally comprises ***a rotation shaft 302*** [the claimed *rotatable member*], a reducer shaft 304, and an attachment sleeve 306, configured to engage and attach to a proximal end of sleeve[ ] 22 [collectively, the claimed *housing*]." ORT-1002 ¶ 70 (emphasis added); FIG. 31, above (annotated).

Iott further discloses "in operation, ***as shaft 302*** [the claimed *rotatable member*] ***is threadedly rotated*** with respect to attachment sleeve 306 [a portion of the claimed *housing*]." *Id.* ¶ 71 (emphasis added).

As such, the rotation shaft 302 (*i.e.,* the claimed *rotatable member*) extends through the attachment sleeve 306 (*i.e.,* a portion of the claimed *housing*) along the longitudinal axis, as shown above in FIG. 31.

f. [16-5]: "a rod contact member positioned at a distal end of the rotatable member"

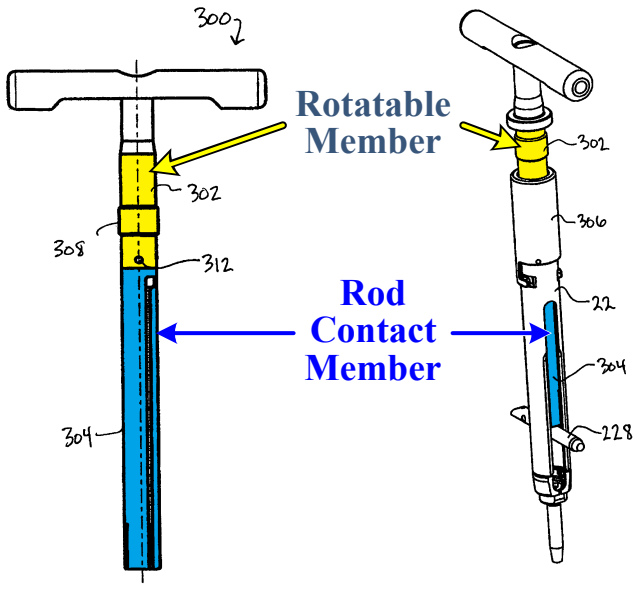


FIG. 30 FIG. 31

Iott discloses "a rod contact member positioned at a distal end of the rotatable member" as recited in claim 16. For example, Iott discloses "***[r]otation shaft 302*** [the claimed *rotatable member*] comprises a through-hole 310 adjacent a distal end of shaft 302 and is configured to receive a pin 312 therethrough ***to axially connect rotation shaft 302*** [the claimed *rotatable member*] ***to reducer***

shaft 304 [the claimed *rod contact member*]." *Id.* (emphasis added); FIG. 31, above (annotated). As shown in FIG. 31, the reducer shaft 304 (*i.e.,* the claimed *rod contact member*) contacts the stabilization member 228 (*i.e.,* a rod) and thus is a rod contact member.

Furthermore, FIG. 30 shows reducer shaft 304 (*i.e.,* the claimed *rod contact member*) positioned at the distal end of the rotation shaft 302 (*i.e.,* the claimed *rotatable member*) as recited in claim 16.

g. [16-6]: "the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis"

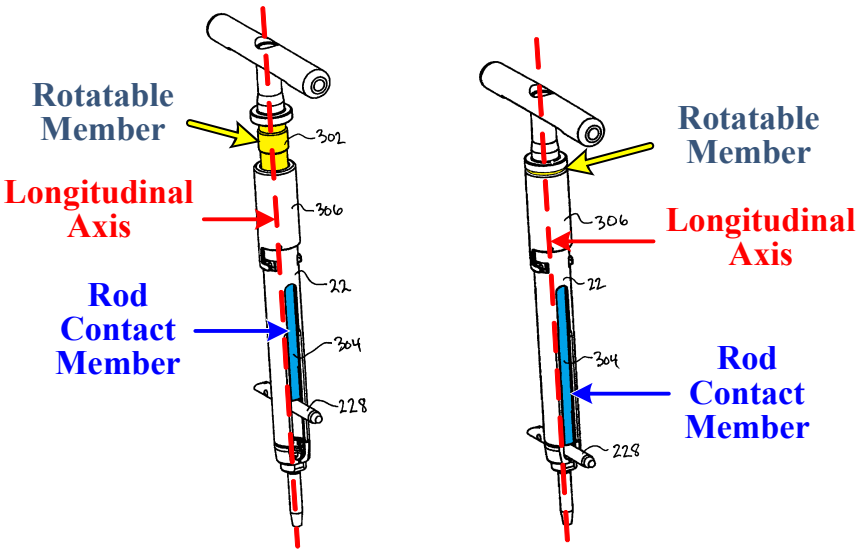


FIG. 31 FIG. 32

Iott discloses the claimed "rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis" as recited in claim 16. For example, Iott states "in operation, ***as shaft 302*** [the claimed *rotatable member*] ***is threadedly rotated*** with respect to

attachment sleeve 306 [a portion of the claimed *housing*], ***reducer shaft 304*** [the claimed *rod contact member*] ***is translated in the axial direction*** . . . providing a force in the axial direction ***that may be used . . . to force a spinal rod***." *Id.* ¶ 71 (emphasis added); FIGS. 31-32, above (annotated). Accordingly, the reducer shaft 304 (*i.e.,* the claimed *rod contact member*) translates in the axial direction (*i.e.,* the claimed *along the longitudinal axis*) in response to rotation of the rotation shaft 302 (*i.e.,* the claimed *rotatable member*).

h. [16-7]: "wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members"

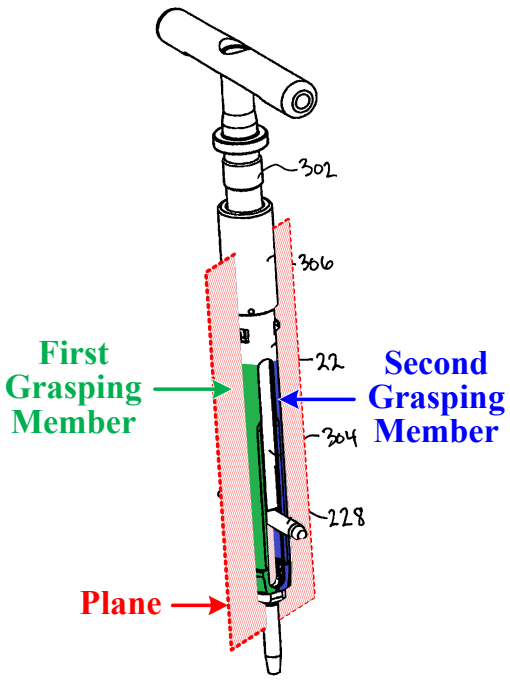


FIG. 31

Iott discloses the claimed "rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members" as

recited in claim 16. For example, as discussed above, Iott discloses that "in operation, as shaft 302 [the claimed *rotatable member*] is threadedly rotated with respect to attachment sleeve 306 [a portion of the claimed *housing*], reducer shaft 304 [the claimed *rod contact member*] is translated in the axial direction." *Id.* ¶ 71 (emphasis added); FIG. 31, above (annotated). As also discussed above, the arms 72 and 74 (*i.e.,* the claimed *first and second grasping members*) of Iott implicitly define a plane. *Id.* FIG. 31, above (annotated).

As illustrated, Iott discloses that both the reducer shaft 304 (*i.e.,* the claimed *rod contact member*) and rotation shaft 302 (*i.e.,* the claimed *rotatable member*) are translatable within the plane.

2. Claim 18: "The rod reducing device of claim 16, wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable with a portion of a bone anchor"

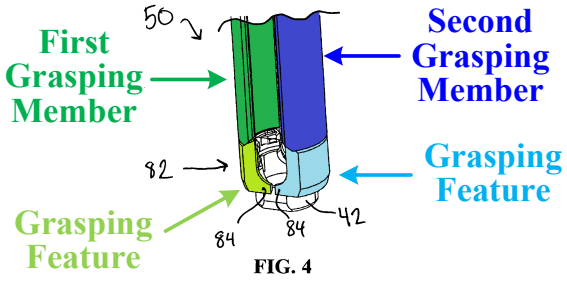


FIG. 4

Iott discloses the claimed "wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable with a portion of a bone anchor" as recited in claim 18. For example, Iott discloses that each of the arms 72 and 74 of the "[i]nner sleeve member 52 also includes ***a***

retainer portion 82 [the claimed *grasping feature*] ***at its distal end to attach an anchor*** [a *bone anchor*] to the distal end of sleeve 50 [a portion of the claimed *housing*]." *Id*. ¶ 56 (emphasis added); FIG. 4, above (annotated).

Iott further states "arms 72, 74 [the claimed *first and second grasping members*] may include ***finger members 84*** [alternatively, the claimed *grasping feature*] extending laterally inward from the distal end ***to provide additional retention capability***. *Id*. (emphasis added).

3. Claim 19: "The rod reducing device of claim 16, wherein distal movement of the rod contact member urges a rod towards distal ends of the first and second grasping members"

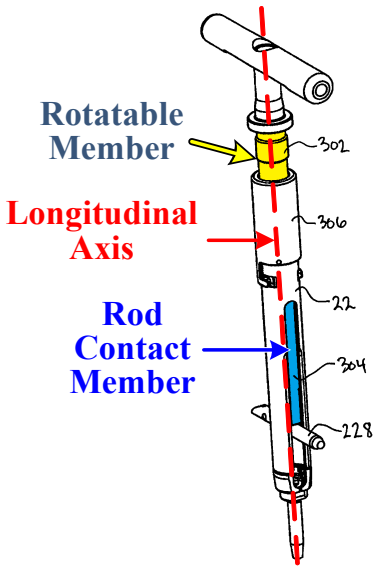


FIG. 31

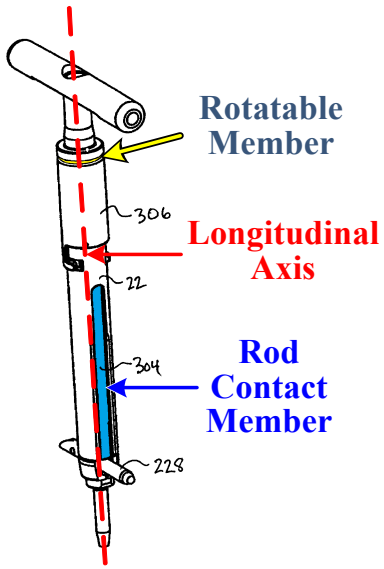


FIG. 32

Iott discloses the claimed "wherein distal movement of the rod contact member urges a rod towards distal ends of the first and second grasping members" as recited in claim 19. More specifically, Iott states "in operation, reducer shaft

304 [the claimed *rod contact member*] is ***translated in the axial direction*** . . . to force a spinal rod ***from a first position*** spaced from a fastener (FIG. 31) ***to a second position proximate to a fastener at the distal end of sleeve[ ] 22*** [a portion of the claimed *housing*] (FIG. 32)." *Id*. ¶ 71 (emphasis added); FIGS. 31-32, above (annotated). Clearly, Iott discloses distal movement of the reducer shaft 304 (*i.e.,* the claimed *rod contact member*) urging the stabilization member 228 (*i.e.,* a rod) toward the distal ends of arms 72 and 74 (*i.e.,* the claimed *first and second grasping members*) as recited in claim 19.

4. Claim 21: "The rod reducing member of claim 16, wherein a portion of the rod contact member is positioned between the first and second grasping members"

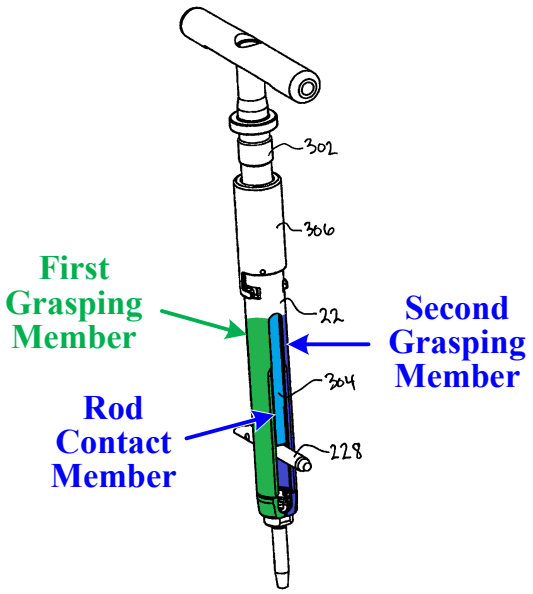


FIG. 31

Iott discloses the claimed "wherein a portion of the rod contact member is positioned between the first and second grasping members" as recited in claim 21.

As shown above in annotated FIG. 31, Iott discloses the reducer shaft 304 [the claimed *rod contact member*] positioned between the arms 72 and 74 [the claimed *first and second grasping members*].

Additionally, as discussed, Iott discloses that the "reducer shaft 304 [the claimed *rod contact member*] is ***translated in the axial direction*** . . . to force a spinal rod ***from a first position*** spaced from a fastener (FIG. 31) ***to a second position proximate to a fastener at the distal end of sleeve[ ] 22*** [a portion of the claimed *housing*] (FIG. 32)." *Id.* (emphasis added). Thus, Iott discloses reducer shaft 304 (*i.e.,* the claimed *rod contact member*) positioned between the arms 72 and 74 (*i.e.,* the claimed *first and second grasping members*).

5. Claim 22: "The rod reducing member of claim 16, wherein the rod contact member is attached to the distal end of the rotatable member"

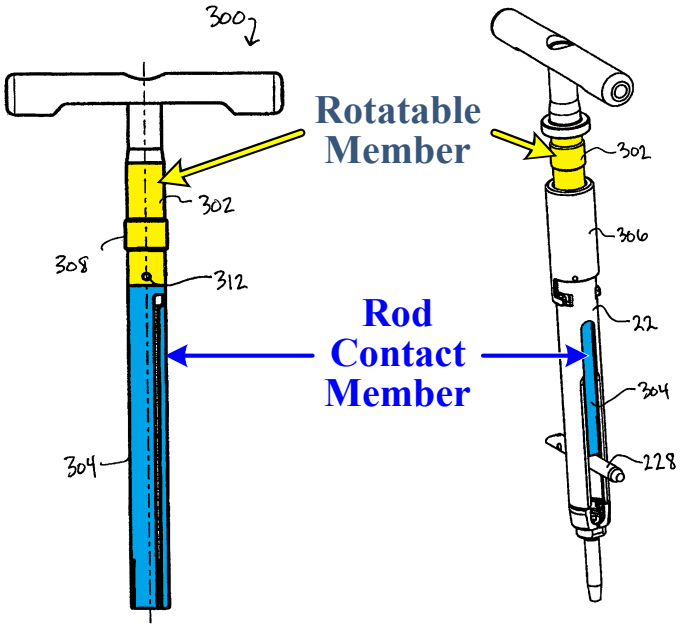


FIG. 30 FIG. 31

Iott discloses the claimed "wherein the rod contact member is attached to the distal end of the rotatable member" as recited in claim 22. For example, Iott discloses "[r]otation shaft 302 [the claimed *rotatable member*] comprises a through-hole 310 . . . configured to receive a pin 312 therethrough ***to axially connect rotation shaft 302 to reducer shaft 304*** [the claimed *rod contact member*]." *Id.* ¶ 70 (emphasis added); FIGS. 30 and 31, above (annotated).

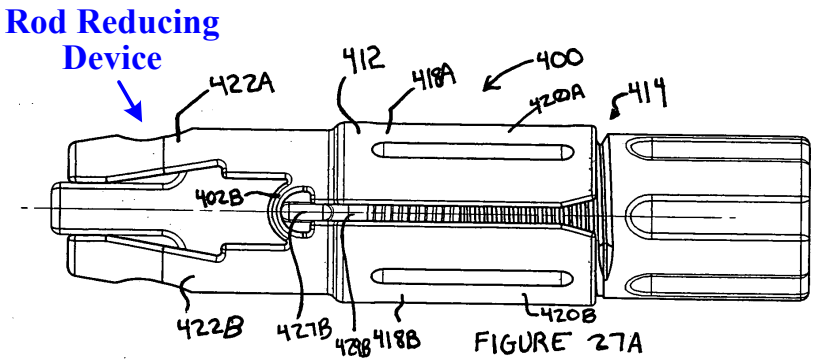
B. Ground 2: Claims 16, 18, 19, 21, and 22 are Anticipated by Runco (ORT-1003)

Runco likewise anticipates claims 16, 18, 19, 21, and 22 of the '816 Patent. Runco was filed on September 26, 2005 and was published on April 13, 2006, which is well more than one year prior to the '816 Patent's earliest filing date of July 13, 2007. ORT-1003 at 1. Therefore, Runco is prior art under at least 35 U.S.C. § 102(b). Runco was never cited nor considered by the Examiner during prosecution of the '816 Patent. ORT-1001 at 1-2.

Runco discloses rod reduction instruments configured to position a spinal rod within a rod-receiving portion of a bone anchor. *See, e.g.,* ORT-1003 ¶¶ 5-7. For example, Runco discloses "an instrument 400 for engaging an implant, such as a bone anchor, and positioning a fixation element, such as a spinal rod, relative to the bone anchor." *Id.* ¶ 100.

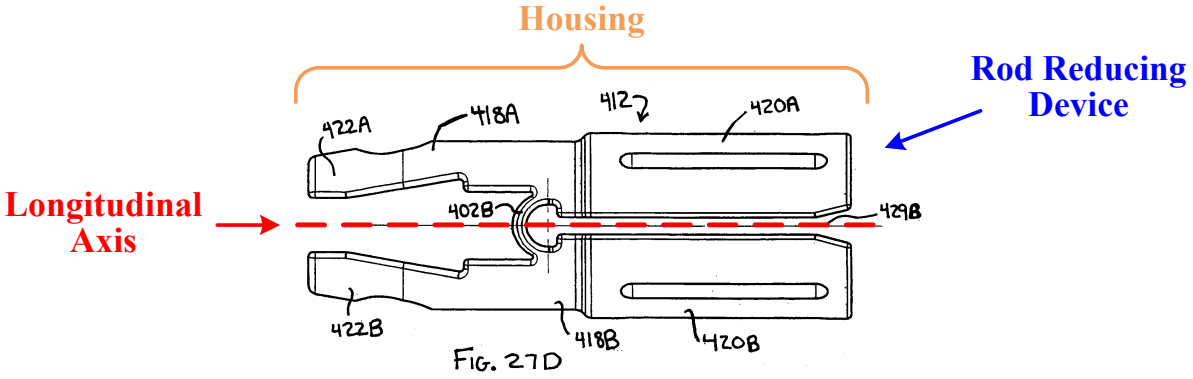
1. **Claim 16:**

a. **[16-PRE]: "A rod reducing device comprising"**



Runco discloses the claimed "rod reducing device." For example, Runco discloses "***an instrument 400*** [the claimed *rod reducing device*] for engaging an implant, such as a bone anchor, and ***positioning a fixation element, such as a spinal rod, relative to the bone anchor***." *Id.* ¶ 100 (emphasis added); FIG. 27A, above (annotated).

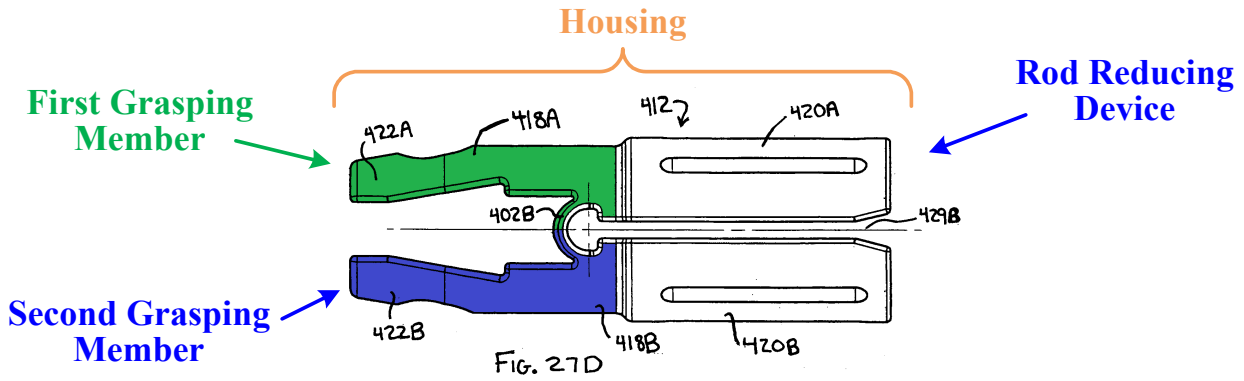
b. **[16-1]: "a housing defining a longitudinal axis"**



Runco discloses "a housing defining a longitudinal axis" as recited in claim 16. For example, Runco discloses "***an implant (e.g., bone anchor) engaging tool 412*** [the claimed *housing*] for engaging at least a portion of an implant." *Id.* ¶ 100

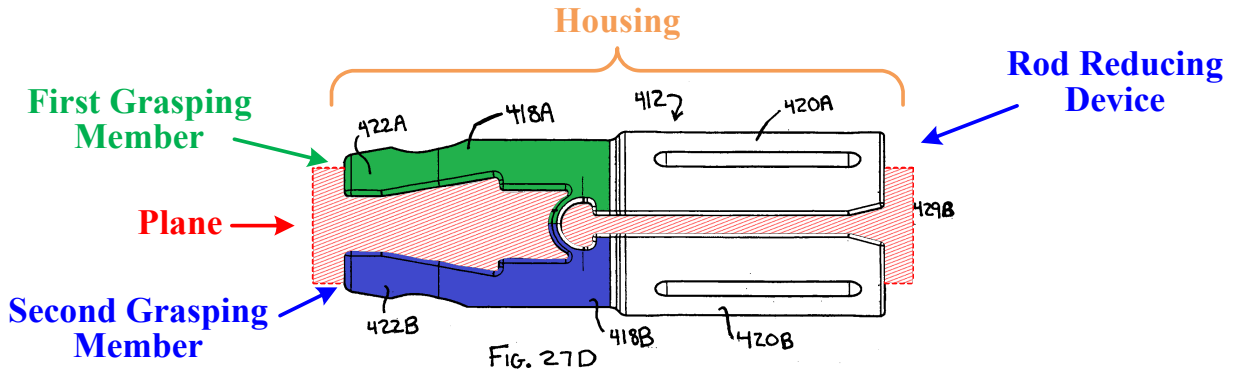
(emphasis added); FIG. 27A, above (annotated). Runco further discloses "***[t]he bone anchor engaging tool 412*** [the claimed *housing*] may include an adjustment mechanism that facilitates the adjustment of a second instrument . . . ***along the longitudinal axis of the tool 412***." *Id.* ¶ 101 (emphasis added); FIG. 27A, above (annotated).

c. [16-2]: "the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween"



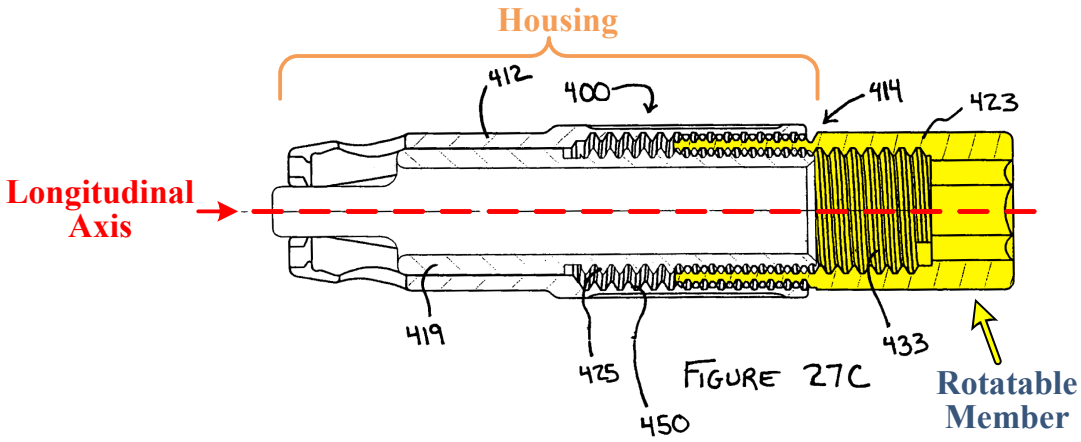
Runco discloses the claimed "housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween" as recited in claim 16. In particular, Runco discloses "***the bone anchor engaging tool 412*** [the claimed *housing*] may include ***a first jaw member 418A*** [the claimed *first grasping member*] ***and a second jaw member 418B*** [the claimed *second grasping member*] which can cooperate ***to engage an implant such as a bone anchor***." *Id.* ¶ 101 (emphasis added); FIG. 27D, above (annotated).

d. [16-3]: "the first and second grasping members defining a plane"



Runco discloses the claimed "first and second grasping members defining a plane" as recited in claim 16. In particular, the first and second jaw members 418A and 418B (*i.e.,* the claimed *first and second grasping members*) of Runco implicitly define a plane as demonstrated above in annotated FIG. 27D. *See also* ORT-1006 ¶¶ 81-82.

e. [16-4]: "a rotatable member extending through the housing along the longitudinal axis"



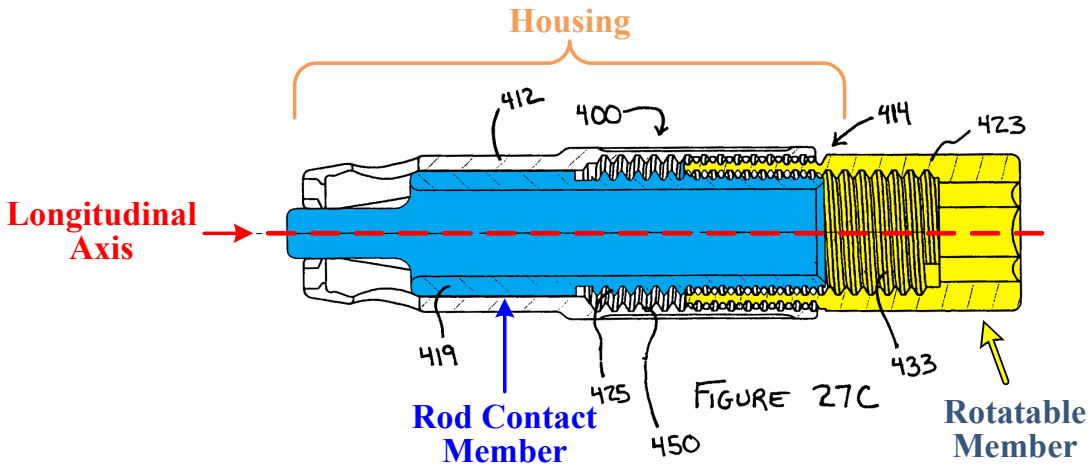
Runco discloses the claimed "rotatable member extending through the housing along the longitudinal axis" as recited in claim 16. For example, Runco

discloses "[t]he bone anchor engaging tool 412 [the claimed *housing*] may include ***an adjustment mechanism*** . . . such as, for example, ***the rod adjusting tool 414, along the longitudinal axis of the tool 412***." ORT-1003 ¶ 104 (emphasis added).

Runco further teaches that "***the rod adjusting tool 414 includes . . . a proximal component 423*** [the claimed *rotatable member*]" and "[i]n operation, ***rotation of the proximal component 423*** [the claimed *rotatable member*] causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412 [the claimed *housing*]." *Id.* (emphasis added); FIG. 27C, above (annotated).

Thus, Runco discloses the proximal component 423 (*i.e.,* the claimed *rotatable member*) extending through the bone anchor engaging tool 412 (*i.e.,* the claimed *housing*) along the longitudinal axis of the tool.

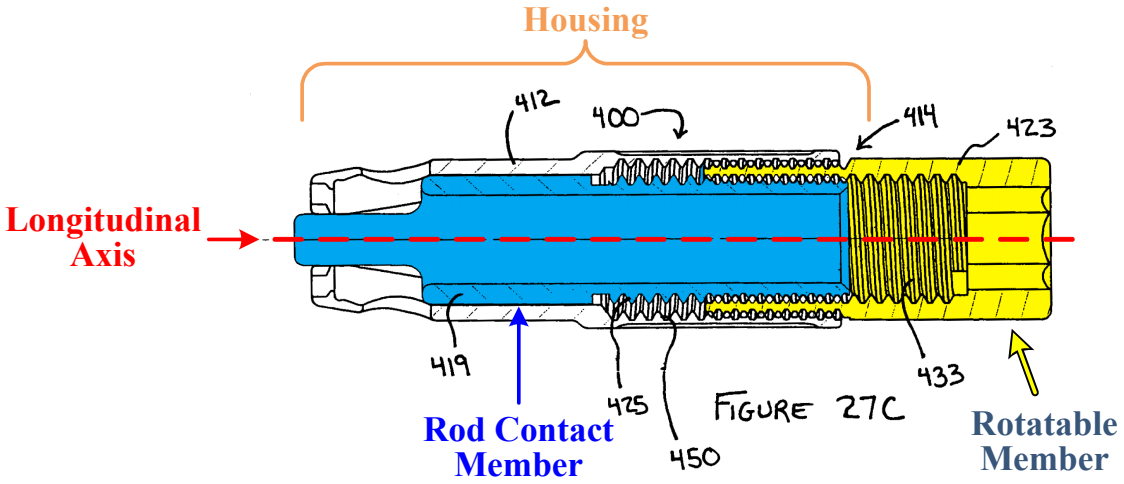
f. [16-5]: "a rod contact member positioned at a distal end of the rotatable member"



Runco discloses the claimed "rod contact member positioned at a distal end of the rotatable member" as recited in claim 16. For example, Runco discloses "the rod adjusting tool 414 includes ***a distal component 419*** [the claimed *rod contact member*] ***having a rod engaging surface 421***." *Id.* (emphasis added), FIG. 27C, above (annotated).

As shown, Runco discloses the proximal component 423 (*i.e.,* the claimed *rotatable member*) of the rod adjusting tool 414 having a rod engaging surface 421 of the distal component 419 (*i.e.,* the claimed *rod contact member*) positioned at the distal end of such proximal component 423.

g. [16-6]: "the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis"

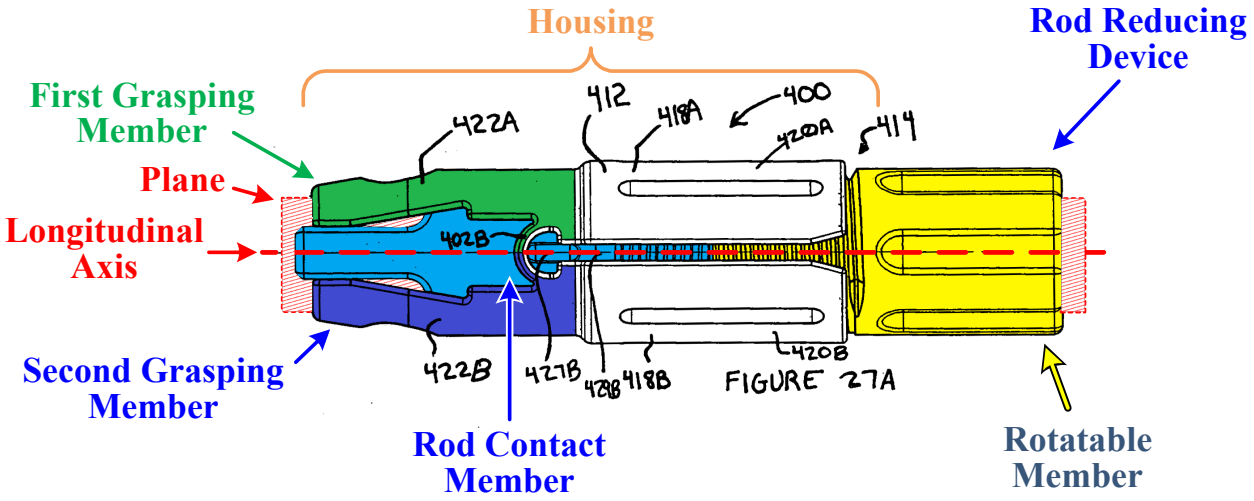


Runco discloses the claimed "rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis" as recited in claim 16. In particular, Runco discloses "[i]n

operation, rotation of the proximal component 423 [the claimed *rotatable member*] causes the distal component 419 [the claimed *rod contact member*] to advance axially relative to the bone anchor engaging tool 412 [the claimed *housing*]." *Id.*; FIG. 27C, above (annotated).

Accordingly, the distal component 419 (*i.e.,* the claimed *rod contact member*) is translatable along the longitudinal axis in response to rotation of the proximal component 423 (*i.e.,* the claimed *rotatable member*) about the longitudinal axis.

h. [16-7]: "wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members"



Runco discloses the claimed "rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members" as recited in claim 16. As discussed, Runco discloses that the rod adjustment tool 414 includes both the proximal component 423 (*i.e.,* the claimed *rotatable*

member) and the distal component 419 (*i.e.,* the claimed *rod contact member*) attached thereto. *Id.* ¶ 104. Runco also discloses "***[t]he exemplary rod adjustment tool 414*** may be ***advanced axially*** to position a spinal rod ***relative to a bone anchor engaged by the bone anchor engaging tool 412*** [the claimed *housing*]." *Id.* ¶ 100 (emphasis added); FIG. 27A, above (annotated). Runco further discloses "[i]n operation, rotation of the proximal component 423 [the claimed *rotatable member*] causes the distal component 419 [the claimed *rod contact member*] to advance axially relative to the bone anchor engaging tool 412." *Id*. ¶ 104.

Moreover, as shown in FIG. 27A above, the distal component 419 (*i.e.,* the claimed *rod contact member*) and the proximal component 423 (*i.e.,* the claimed *rotatable member*) are translatable within the plane defined by the first and second jaw members 418A and 418B (*i.e.,* the claimed *first and second grasping members*).

2. Claim 18: "The rod reducing device of claim 16, wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable with a portion of a bone anchor"

Runco discloses the claimed "wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable with a portion of a bone anchor" as recited in claim 18. For example, Runco discloses "[t]he exemplary bone anchor engaging tool 412 [the claimed *housing*] of the exemplary instrument 400 [the claimed *rod reducing device*] ***may be constructed***

in manner analogous to the bone anchor engaging tool 12." *Id*. ¶ 101 (emphasis added).

In reference to the bone anchor engaging tool 12, Runco discloses "[t]he distal end 22A,B on one or both of the jaw members 18A,B [the claimed *first and second grasping members*] may include ***an implant engagement mechanism*** [the claimed *grasping feature*] that provides a releasable connection between the distal end(s) and the implant [a *bone anchor*]." *Id*. ¶ 74 (emphasis added).

In a specific example of the implant engagement mechanism, Runco discloses that "each distal end 22A,B includes a cylindrical pin 54A,B [the claimed *grasping feature*] extending from an interior surface thereof" and "[t]he cylindrical pins 54A,B may be sized to engage swage holes provided in exterior surface of the rod receiving portion of a pedicle screw [a *bone anchor*], for example." *Id*.

3. Claim 19: "The rod reducing device of claim 16, wherein distal movement of the rod contact member urges a rod towards distal ends of the first and second grasping members"

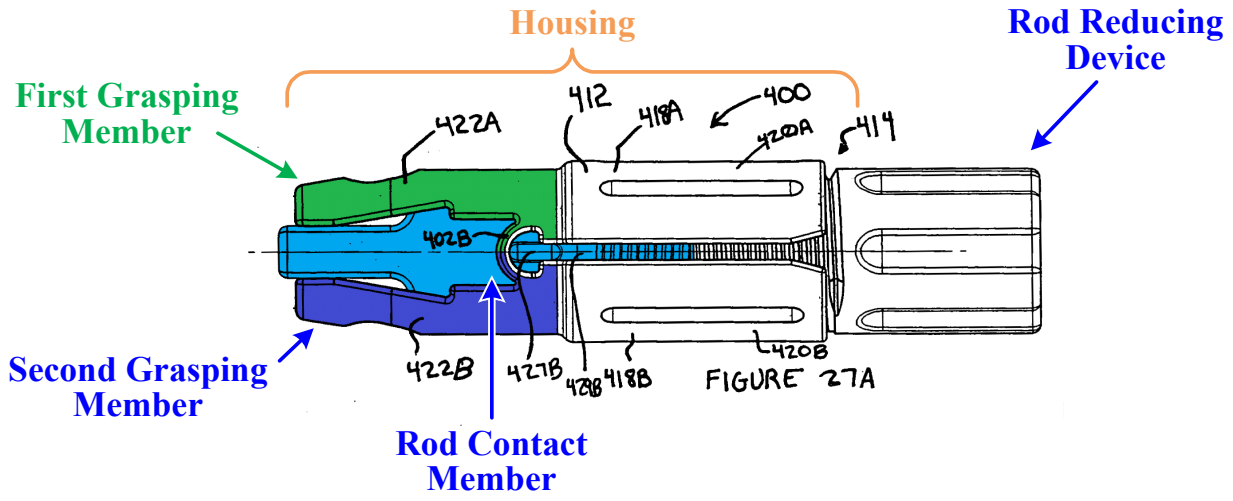
Runco discloses the claimed "wherein distal movement of the rod contact member urges a rod towards distal ends of the first and second grasping members" as recited in claim 19.

As discussed, Runco teaches that the rod adjustment tool 414 includes both the proximal component 423 (*i.e.,* the claimed *rotatable member*) and the distal component 419 (*i.e.,* the claimed *rod contact member*) attached thereto. *Id.* ¶ 104.

More specifically, Runco discloses "[t]he exemplary rod adjustment tool 414 may be ***advanced axially to position a spinal rod relative to a bone anchor engaged by the bone anchor engaging tool 412*** [the claimed *housing*]." *Id*. (emphasis added). Runco further discloses "[i]n operation, rotation of the proximal component 423 [the claimed *rotatable member*] ***causes the distal component 419*** [the claimed *rod contact member*] ***to advance axially relative to the bone anchor engaging tool 412*** [the claimed *urges a rod toward distal ends of the first and second grasping members*]." *Id*. (emphasis added).

As such, Runco discloses distal movement of the distal component 419 (*i.e.,* the claimed *rod contact member*) urging a rod towards distal ends of the first and second jaw members 418A and 418B (*i.e.,* the claimed *first and second grasping members*).

4. Claim 21: "The rod reducing member of claim 16, wherein a portion of the rod contact member is positioned between the first and second grasping members"



Runco discloses the claimed "wherein a portion of the rod contact member is positioned between the first and second grasping members" as recited in claim 21. More specifically, Runco discloses "[i]n operation, rotation of the proximal component 423 [the claimed *rotatable member*] causes the distal component 419 [the claimed *rod reducing device*] to advance axially relative to the bone anchor engaging tool 412 [the claimed *housing*]." *Id*. ¶ 104; FIG. 27A, above (annotated).

Moreover, as shown above in annotated FIG. 27A, the distal component 419 (*i.e.,* the claimed *rod contact member*) is positioned between the first and second jaw members 418A and 418B (*i.e.,* the claimed *first and second grasping members*).

5. Claim 22: "The rod reducing member of claim 16, wherein the rod contact member is attached to the distal end of the rotatable member"

Runco discloses the claimed "wherein the rod contact member is attached to the distal end of the rotatable member" as recited in claim 22. More specifically, Runco discloses "[i]n the exemplary embodiment, the rod adjusting tool 414 includes a distal component 419 [the claimed *rod contact member*] having a rod engaging surface 421 and ***a proximal component 423*** [the claimed *rotatable member*] ***connectable to*** and separable from ***the distal component 419***." *Id.* (emphasis added); *see also* FIG. 27C.

C. Ground 3: Claims 16, 18, 19, 21, and 22 Are Anticipated by Trudeau (ORT-1004)

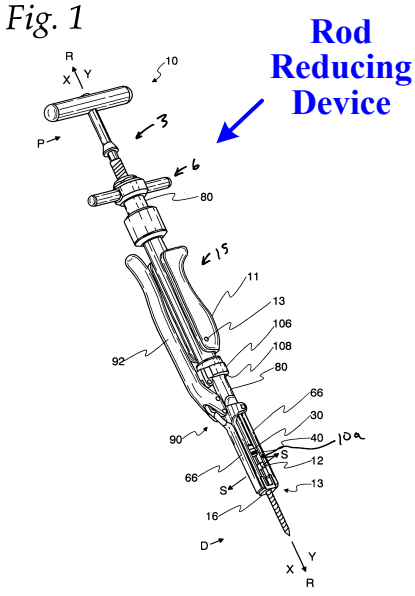
Trudeau also anticipates claims 16, 18, 19, 21, and 22 of the '816 Patent. Trudeau was filed on October 26, 2004, and was published on April 27, 2006, which is well more than one year prior to the '816 Patent's earliest filing date of July 13, 2007. ORT-1004 at 1. Therefore, Trudeau is prior art under at least 35 U.S.C. § 102(b). Trudeau was never cited nor considered by the Examiner during prosecution of the '816 Patent. ORT-1001 at 1-2.

Trudeau discloses surgical devices and methods for positioning and securing a spinal rod along a spine. *See, e.g.,* ORT-1004 ¶¶ 1, 34. To that end, Trudeau discloses "a rod persuader device 10 for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16." *Id.* ¶ 34.

1. Claim 16:

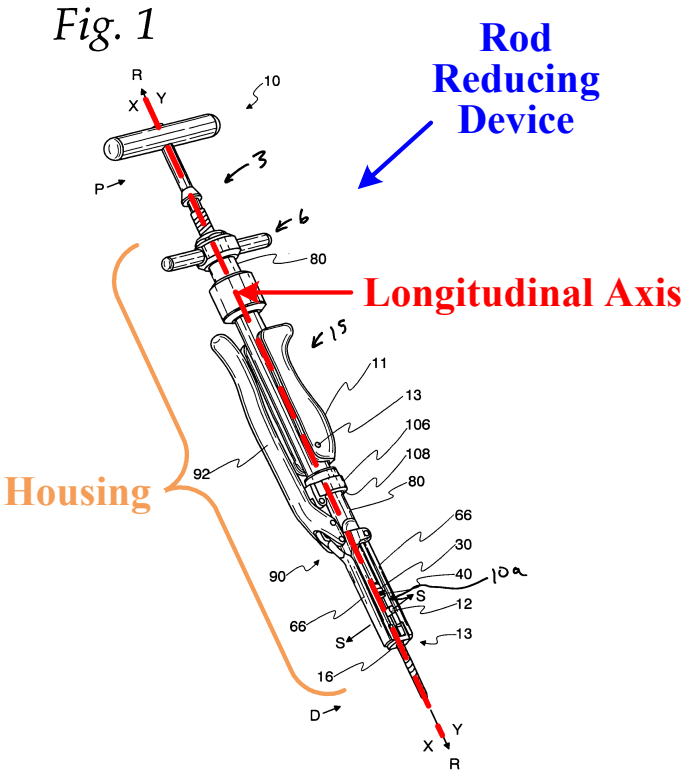
a. [16-PRE]: "A rod reducing device comprising"

Fig. 1



Trudeau discloses the claimed "rod reducing device." For example, Trudeau discloses "[r]eferring initially to FIG. 1, ***a rod persuader device 10*** [the claimed *rod reducing device*] for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16 is depicted." *Id.* ¶ 34 (emphasis added); FIG. 1, above (annotated).

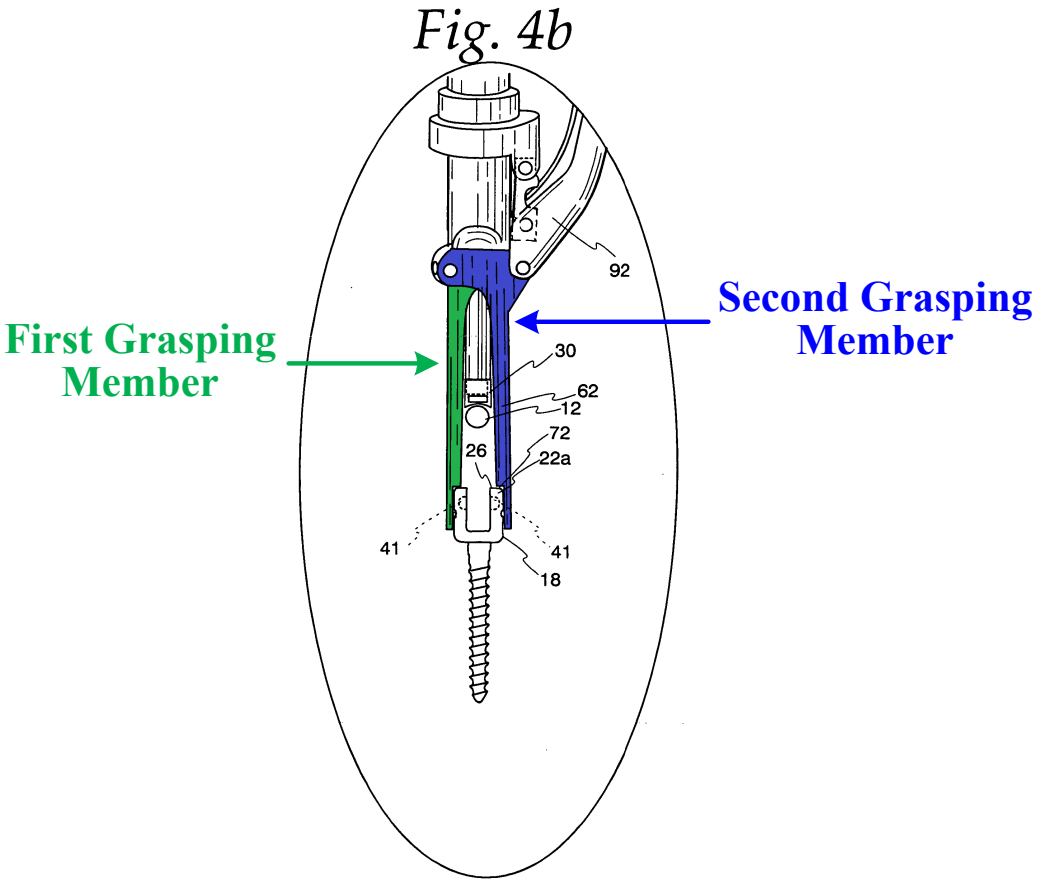
b. [16-1]: "a housing defining a longitudinal axis"



Trudeau discloses the claimed "housing defining a longitudinal axis" as recited in claim 16. For example, Trudeau discloses "the tool 10 [the claimed *rod reducing device*] includes a clamping subassembly 90 including a tubular body portion 80, . . . a rod drive sleeve 132, and a sleeve coupling subassembly 6

[collectively, the claimed *housing*]." *Id.* ¶ 35; FIG. 1, above (annotated). Trudeau also discloses "[a] tool body longitudinal axis R." *Id.* ¶ 44; *see also* ORT-1006 ¶ 122.

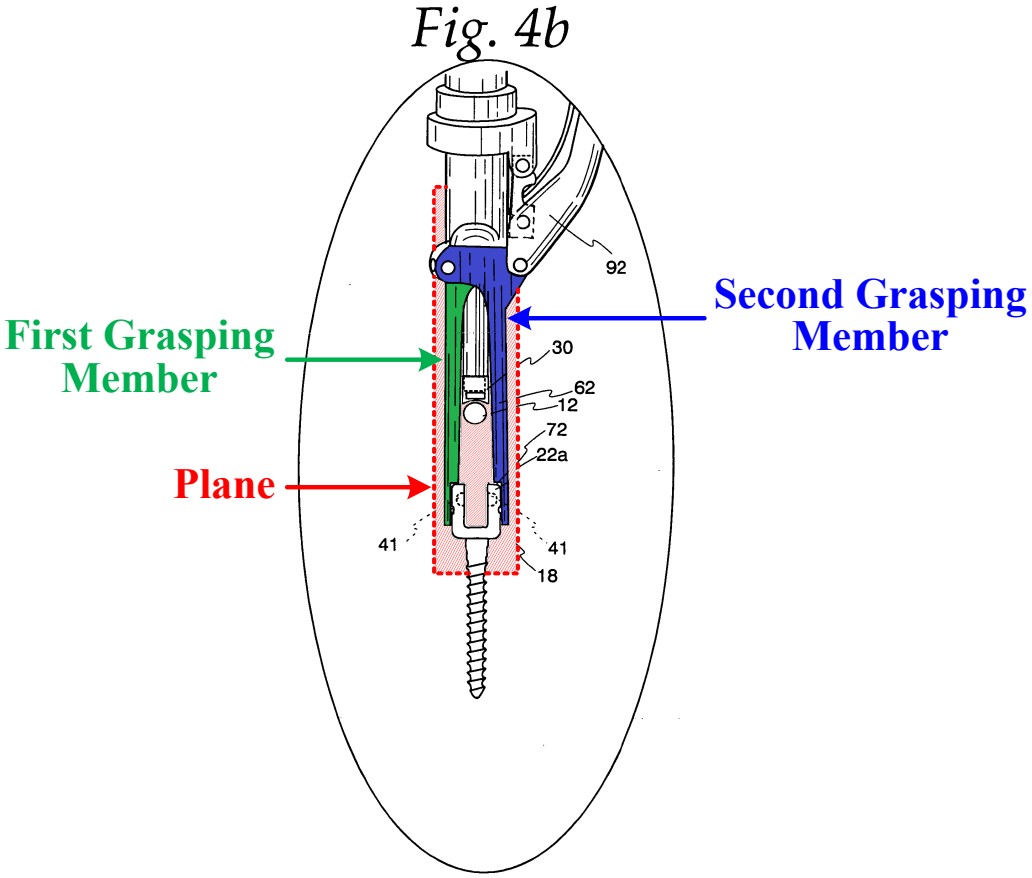
c. [16-2]: "the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween"



Trudeau discloses the claimed "housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween" as recited in claim 16. In particular, Trudeau discloses "the tool 10 [the claimed *rod reducing device*] includes ***a pair of opposed jaws 60 and 62*** [the claimed *first and*

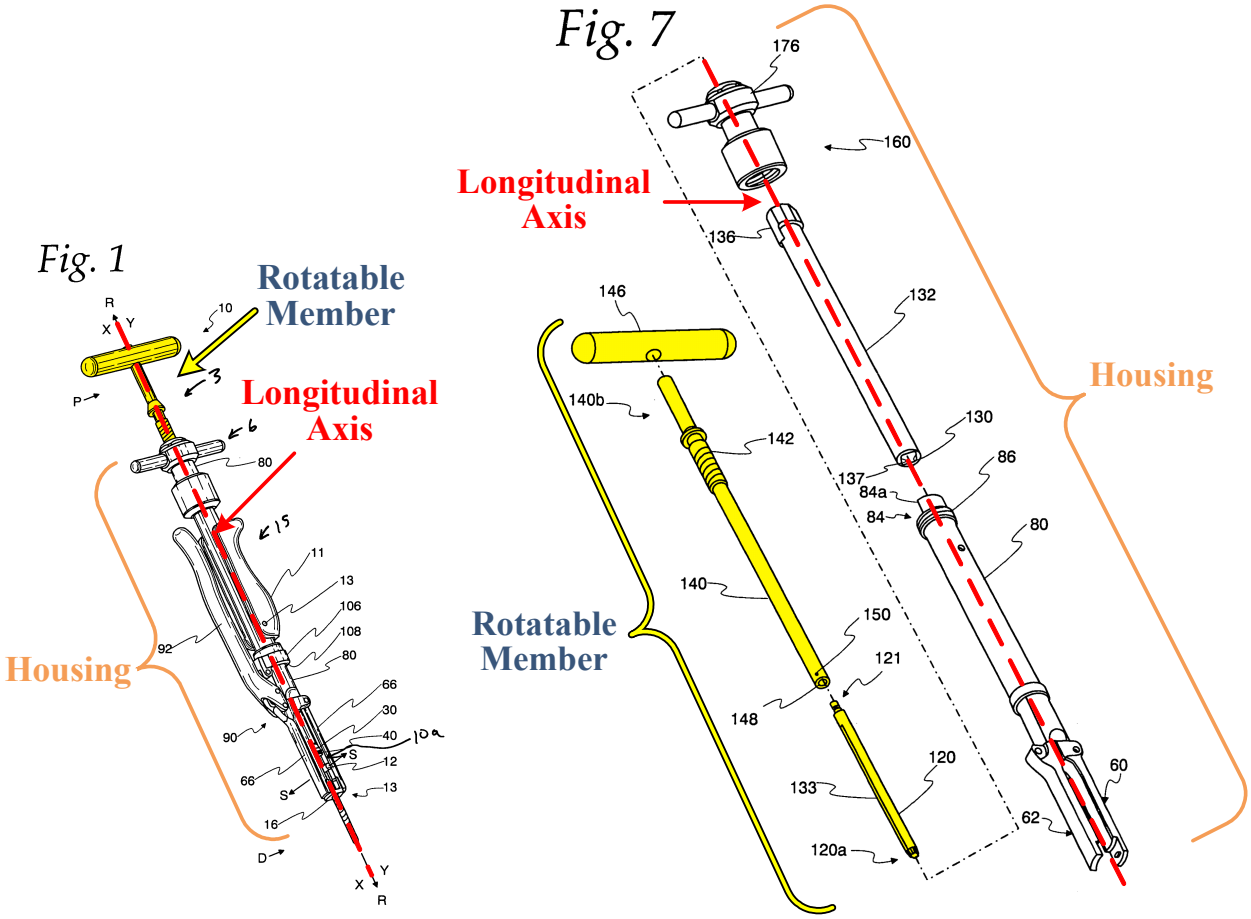
second grasping members]" and "the jaws 60, 62 may open and close relative to each other for ***attaching or releasing from the pedicle screw fixture 16*** [a *bone anchor*]." ORT-1004 ¶ 48 (emphasis added); FIG. 4b, above (annotated).

d. [16-3]: "the first and second grasping members defining a plane"



Trudeau discloses the claimed "first and second grasping members defining a plane." As illustrated in annotated Fig. 4b above, the opposed jaws 60, 62 (*i.e.,* the claimed *first and second grasping members*) of Trudeau implicitly define a plane. *See also* ORT-1006 ¶¶ 127-128.

e. [16-4]: "a rotatable member extending through the housing along the longitudinal axis; and"



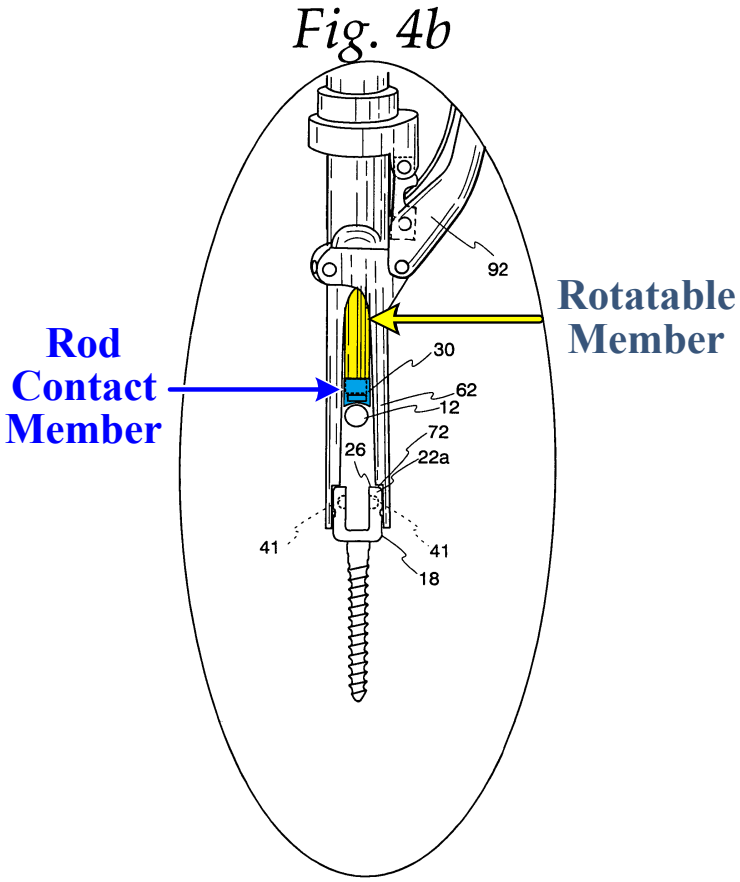
Trudeau discloses the claimed "rotatable member extending through the housing along the longitudinal axis" as recited in claim 16. For example, Trudeau discloses "[a] tool 10 [the claimed *rod reducing device*] includes . . . ***a drive rod subassembly 3*** [the claimed *rotatable member*] ***including a drive rod 140***." ORT-1004 ¶ 35 (emphasis added); FIGS. 1, 7, above (annotated).

Trudeau further discloses that the drive rod subassembly 3 includes "a movable member," which "[i]n the preferred embodiment . . . is ***[the] tool shaft 120***." *Id.* ¶ 73 (emphasis added); FIG. 7, above (annotated). Additionally, Trudeau

states that "torque generated by a user in ***rotating the drive rod 140*** via the drive handle 146 advances the drive rod 140 along the threads." *Id.* ¶ 80 (emphasis added); FIGS. 1, 7, above (annotated).

Trudeau also discloses that "the drive handle 146 is rotated [to] . . . effect linear movement of the drive rod 140 [of the drive rod subassembly 3, *i.e.*, the claimed *rotatable member*] along its longitudinal axis A." *Id.* ¶ 82.

f. [16-5]: "a rod contact member positioned at a distal end of the rotatable member"



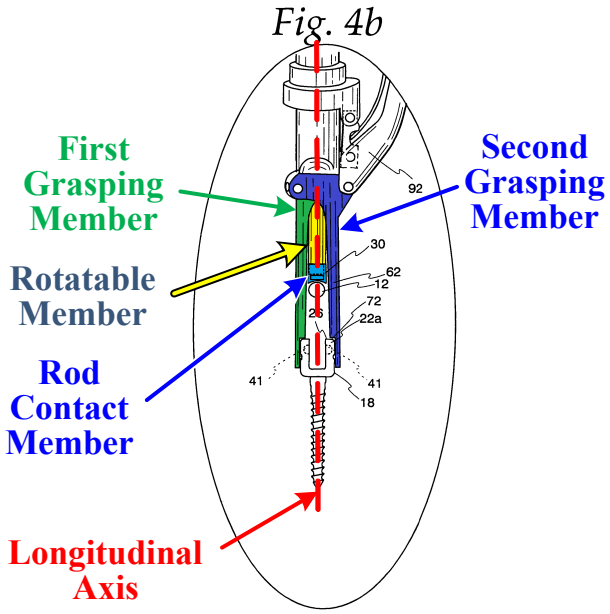
Trudeau discloses the claimed "rod contact member positioned at a distal end of the rotatable member" as recited in claim 16. For example, Trudeau

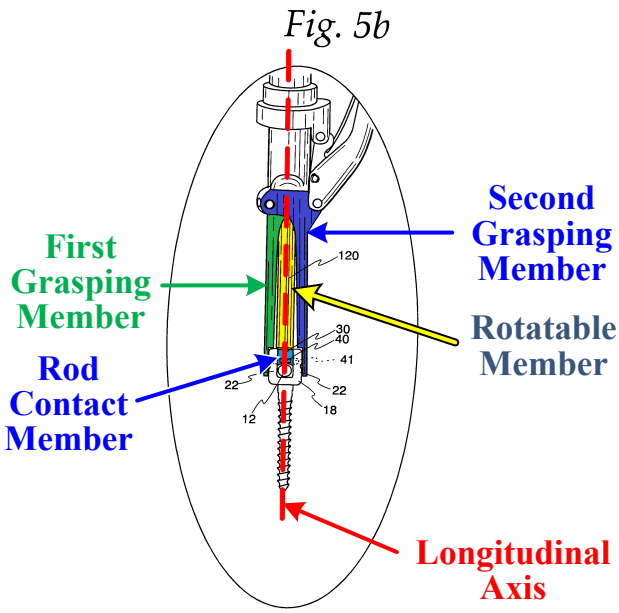
discloses "[a] rod securing device 30 [the claimed *rod contact member*]" including "[a] cap 30a" and "an intermediate clamping member 30b." *Id.* ¶ 39. Trudeau states that "***the cap 30a [of the rod securing device 30] is set on or removably attached to*** a gripping or torquing portion 120a [of the tool shaft 120] of ***the drive rod subassembly 3*** [the claimed *rotatable member*] toward the distal end D of the tool 10 [the claimed *rod reducing device*]." *Id*. (emphasis added); FIG. 4b, above (annotated).

As discussed, Trudeau discloses that the drive rod subassembly 3 includes "a movable member," which "[i]n the preferred embodiment . . . is ***[the] tool shaft 120***." *Id.* ¶ 73 (emphasis added); FIG. 7, above (annotated). Trudeau further discloses that "the tool shaft 120 engages and pushes against the cap 30a [of the rod securing device 30], which in turn ***causes the saddle 30b [of the rod securing device 30] to contact and advance against the spinal rod 12*** such that the rod securing device 30 [the claimed *rod contact member*] and spinal rod 12 are advanced into the yoke 18 [of the bone anchor]." *Id.* ¶ 74 (emphasis added).

Thus, Trudeau discloses the rod securing device 30 (*i.e.,* the claimed *rod contact member*) positioned at a distal end of the drive rod subassembly 3 (*i.e.,* the claimed *rotatable member*) as shown in Fig. 4b.

g. [16-6]: "the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis"





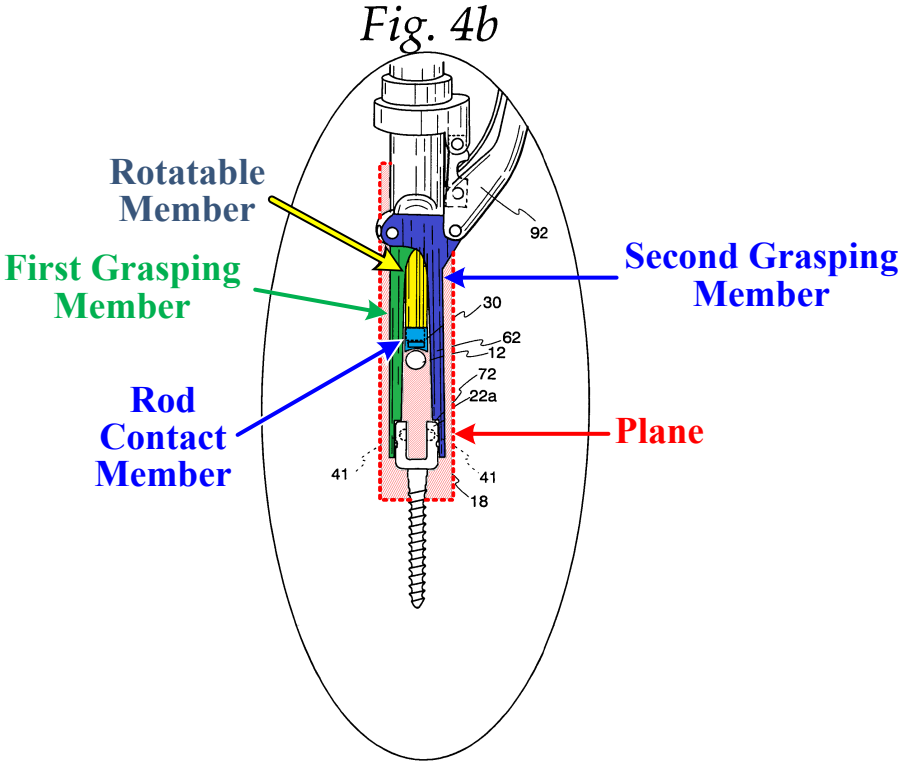
Trudeau discloses the claimed "rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis" as recited in claim 16. In particular, as discussed above, Trudeau discloses that "***rotating the drive rod 140*** [of the drive rod subassembly 3 (*i.e.,* the claimed *rotatable member*)] via the drive handle 146 ***advances the drive rod 140***." *Id.* ¶ 80 (emphasis added).

Trudeau also discloses that "***[t]he drive rod 140 and tool shaft 120*** [of the drive rod subassembly 3 (*i.e.,* the claimed *rotatable member*)] ***are cooperatively connected*** such that the tool shaft 120 and drive rod 140 move together along the axis A of the drive rod 140 in a generally linear manner." *Id.* ¶ 79 (emphasis added).

Trudeau further discloses that "***[t]he tool shaft 120 advances*** along the axis R of the persuader ***to push the cap 30a*** [of the rod securing device 30 (*i.e.,* the claimed *rod contact member*)] and spinal rod 12 into the yoke 18." *Id.* ¶ 74 (emphasis added); FIGS. 4b, 5b, above (annotated).

As such, Trudeau discloses the rod securing device 30 (*i.e.,* the claimed *rod contact member*) translatable along the axis R (*i.e.,* the claimed *longitudinal axis*) in response to rotation of the drive rod subassembly 3 (*i.e.,* the claimed *rotatable member*) about the R axis.

h. [16-7]: "wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members"



Trudeau discloses the claimed "rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members" as recited in claim 16. For example, as discussed above, Trudeau discloses that "***rotating the drive rod 140*** [of the drive rod subassembly 3 (*i.e.,* the claimed *rotatable member*)] via the drive handle 146 ***advances the drive rod 140***." *Id.* ¶ 80 (emphasis added).

Trudeau also discloses that "[t]he drive rod 140 and tool shaft 120 [of the drive rod subassembly 3 (*i.e.,* the claimed *rotatable member*)] are cooperatively connected ***such that the tool shaft 120 and drive rod 140 move together along the axis A of the drive rod 140 in a generally linear manner.***" *Id.* ¶ 79 (emphasis added).

Trudeau further discloses that "***[t]he tool shaft 120 advances*** along the axis R of the persuader ***to push the cap 30a*** [of the rod securing device 30 (*i.e.,* the claimed *rod contact member*)] and spinal rod 12 into the yoke 18 [of the anchor]." *Id.* ¶ 74 (emphasis added); FIG. 4b, above (annotated).

As illustrated above in annotated FIG. 4b, Trudeau discloses the rod securing device 30 (*i.e.,* the claimed *rod contact member*) and the drive rod subassembly 3 (*i.e.,* the claimed *rotatable member*) are translatable within the plane defined by the opposed jaws 60, 62 (*i.e.,* the claimed *first and second grasping members*).

2. Claim 18: "The rod reducing device of claim 16, wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable with a portion of a bone anchor"

Trudeau discloses the claimed "wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable with a portion of a bone anchor" as recited in claim 18. For example, Trudeau discloses "the tool 10 [the claimed *rod reducing device*] includes a pair of opposed jaws 60 and 62 [the claimed *first and second grasping members*], and ***each jaw 60, 62 includes a tooth 38*** [the claimed *grasping feature*]." *Id.* ¶ 48 (emphasis added). Trudeau further discloses "[t]he terminal end 64 [of each jaw 60, 62] includes ***the tooth 38 and is clamped to the yoke 18*** [the claimed *portion of a bone anchor*] during the spinal rod anchoring operation." *Id.* ¶ 49 (emphasis added).

3. Claim 19: "The rod reducing device of claim 16, wherein distal movement of the rod contact member urges a rod towards distal ends of the first and second grasping members"

Fig. 4b

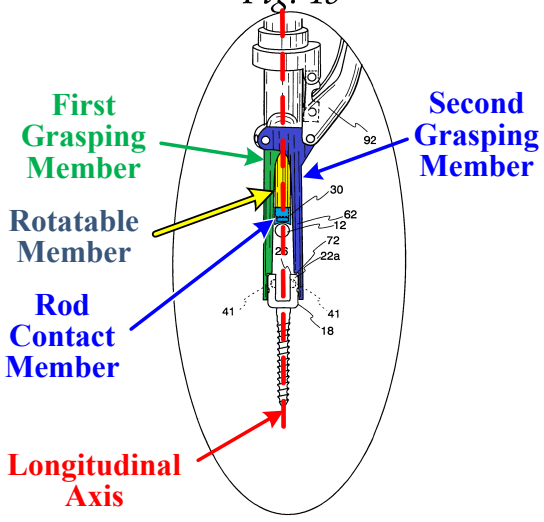
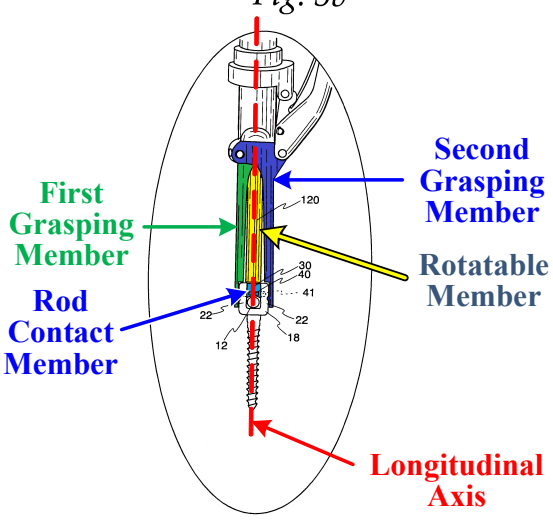


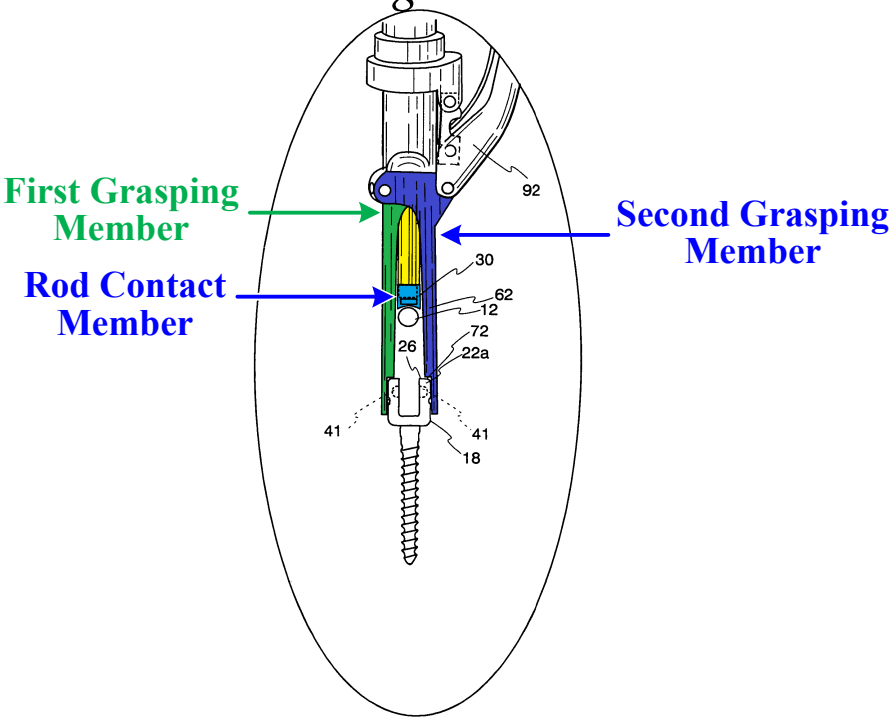
Fig. 5b



Trudeau discloses the claimed "wherein distal movement of the rod contact member urges a rod towards distal ends of the first and second grasping members" as recited in claim 19. More specifically, Trudeau discloses "***[t]he tool shaft 120*** [of the drive rod subassembly 3 (*i.e.,* the claimed *rotatable member*)] ***advances*** along the axis R of the persuader ***to push the cap 30a*** [of the rod securing device 30 (*i.e.,* the claimed *rod contact member*)] and spinal rod 12 into the yoke 18." *Id.* ¶ 74 (emphasis added); FIGS. 4b, 5b, above (annotated).

4. Claim 21: "The rod reducing member of claim 16, wherein a portion of the rod contact member is positioned between the first and second grasping members"

Fig. 4b



Trudeau discloses the claimed "wherein a portion of the rod contact member is positioned between the first and second grasping members" as recited in claim

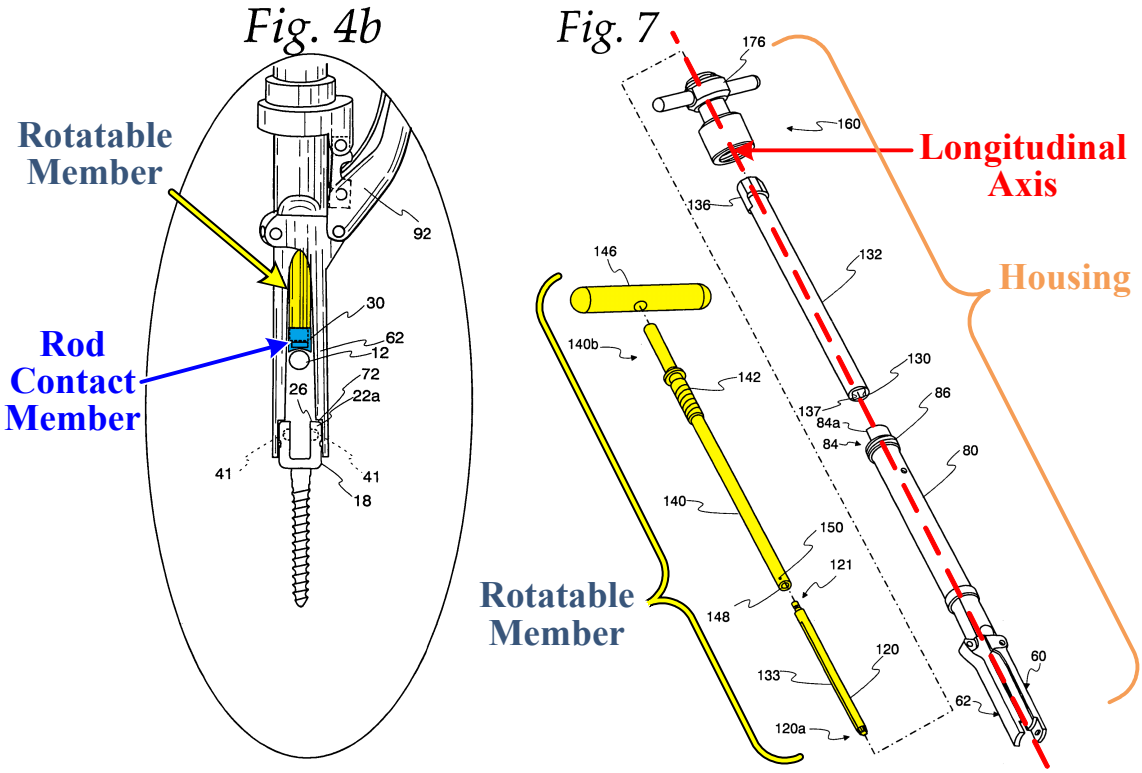
21. More specifically, Trudeau discloses "the cap 30a [of the rod securing device 30 (*i.e.,* the claimed *rod contact member*)] is utilized for capturing and/or securing the spinal rod 12 within the yoke, and ***the cap 30a is located or positioned between the jaws 60, 62*** [the claimed *first and second grasping members*]." *Id.* ¶ 72 ; FIG. 4b, above (annotated).

5. Claim 22: "The rod reducing member of claim 16, wherein the rod contact member is attached to the distal end of the rotatable member"

Trudeau discloses the claimed "wherein the rod contact member is attached to the distal end of the rotatable member" as recited in claim 22. More specifically, Trudeau discloses "***the cap 30a*** [of the rod securing device 30 (*i.e.,* the claimed *rod contact member*)] ***is set on or removably attached to a gripping or torquing portion 120a [of the tools shaft 120] of the drive rod subassembly 3*** [the claimed *rotatable member*] toward the distal end D of the tool 10 [the claimed *rod reducing device*]." *Id.* ¶ 39 (emphasis added).

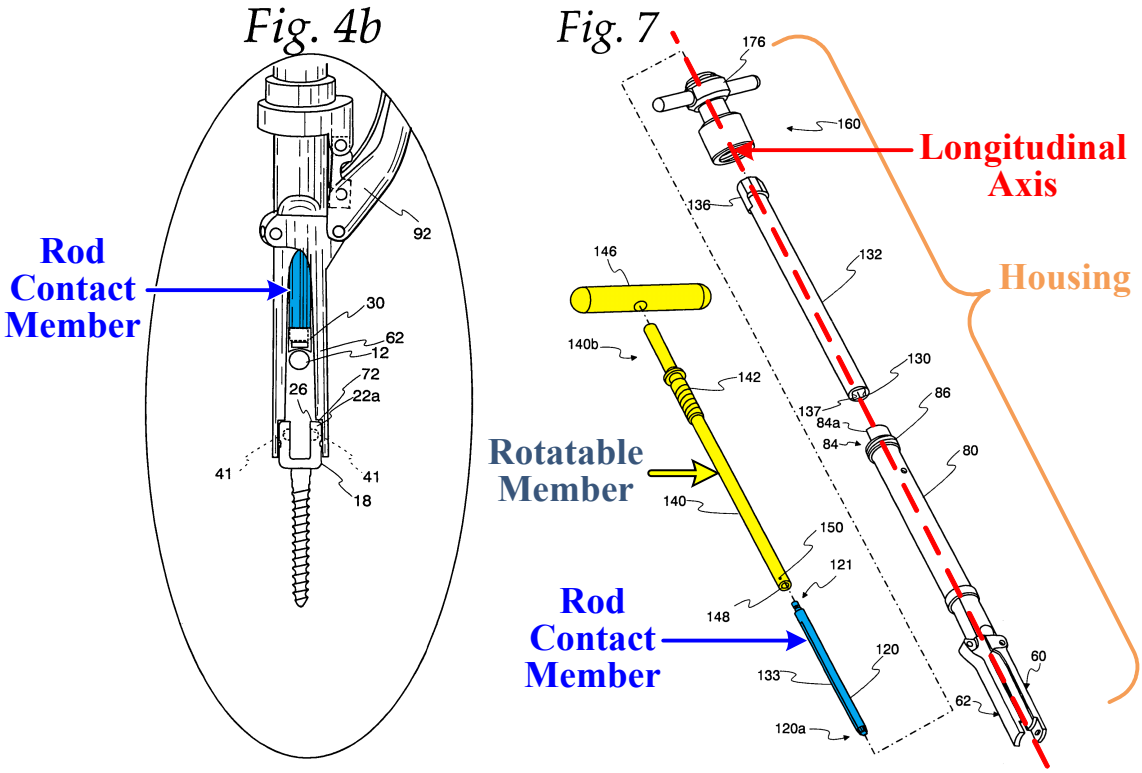
D. Ground 4: Claims 16, 18, 19, 21, and 22 Are Rendered Obvious by Trudeau (ORT-1004) in View of Pond (ORT-1005)

As discussed above, Trudeau anticipates each of the Challenged Claims. In that analysis, the "drive rod subassembly 3" of Trudeau discloses the claimed "rotatable member" of the '816 Patent. And the "rod securing device 30" of Trudeau discloses the claimed "rod contact member" of the '816 Patent. The below figures show both of these features of Trudeau:



A person of ordinary skill in the art, however, could view Trudeau differently. That is, in an alternative arrangement, the "rotatable member" of the '816 Patent can be seen not as the ***entire*** "drive rod subassembly 3," but rather only the ***top portion*** of the assembly, *i.e.*, "drive rod 140." Similarly, in this alternative arrangement, the "rod contact member" of the '816 Patent can be seen not as the "rod securing device 30" of Trudeau, but rather as the ***bottom portion*** of the "drive rod subassembly 3," *i.e.*, the "tool shaft 120" with the "rod securing device 30" ***removed***.

In contrast to the above images (reflecting the first arrangement, as discussed above in Section VIII(C), Ground 3), this alternative way of viewing Trudeau can be summarized by the below images:



As disclosed, the "rod securing device 30" of Trudeau includes "a cam lock member or cap." ORT-1004 ¶ 39. The functionality provided by cam lock members, set screws, or caps, however, is not necessary to reduce a rod. As such, it would have been obvious to a person of ordinary skill in the art to remove that component and simplify the device, such that the "tool shaft 120" would instead contact the rod. *See, e.g., Application of Kuhle*, 526 F.2d 553, 555 (C.C.P.A. 1975) ("We further agree with the board that deletion of the switch member (and other elements) found in Smith and Sherrard, thereby deleting their function, was an obvious expedient."); *Application of Larson*, 340 F.2d 965, 969 (C.C.P.A. 1965) ("The added structure shown in the [prior art reference] serves a particular purpose in that it increases the cargo carrying capacity. If this additional feature is not

desired, it would seem a matter of obvious choice to eliminate it and the function it serves.") Such a modification, moreover, would not change the rod persuader's principle of operation or make it inoperable for its intended purpose. *See, e.g.,* ORT-1006 ¶ 147.

Pond discloses such a rod reducer operating in this manner, that is, with a rod contact member that contacts a rod ***without*** a cap or set screw. ORT-1005 ¶ 65. As such, Trudeau—in this alternative arrangement—in view of Pond renders obvious claims 16, 18, 19, 21, and 22 of the '816 Patent.

Pond was filed on August 13, 2004 and was published on February 16, 2006—far more than one year prior to the '816 Patent's earliest filing date of July 13, 2007—and is therefore prior art with respect to the '816 Patent. ORT-1005 at 1. Pond was never cited nor considered by the Examiner during prosecution of the '816 Patent. ORT-1001 at 1-2

As discussed above, Trudeau generally discloses surgical devices and methods for positioning and securing a spinal rod along a spine. *See, e.g.,* ORT-1004 ¶¶ 1, 34. Pond generally discloses a system for positioning a connecting member (*e.g.*, a spinal rod) adjacent to a spinal column of a patient in a minimally invasive surgical procedure. *See, e.g.,* ORT-1005 ¶ 65. The system of Pond includes extenders mounted to bone anchors engaged to a patient's spinal column. *See, e.g., id.* ¶ 65. A reduction instrument is then placed over one or more of the

extenders to finally reduce the connecting member (*e.g.*, a spinal rod) into a position within the receiver members of the bone anchors. *See, e.g., id.* ¶ 124.

1. Claim 16:

As discussed above, Trudeau discloses each of the limitations of claim 16. In the alternative arrangement of Trudeau discussed in this Section, only the corresponding disclosures of limitations [16-4] through [16-7] are viewed differently, and they are therefore addressed below. The corresponding disclosures of the remaining limitations of claim 16, however, are viewed in the same manner as discussed above in Sections VIII(C)(1)(a)-(d).

a. [16-4] & [16-5]: "a rotatable member extending through the housing along the longitudinal axis" and "a rod contact member positioned at a distal end of the rotatable member"

Fig. 4b

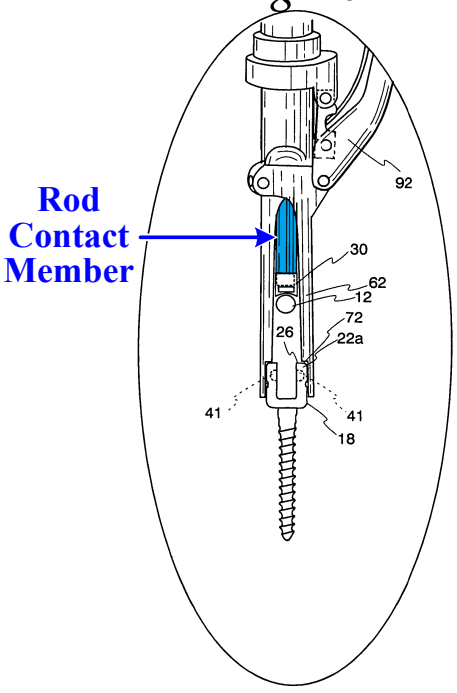
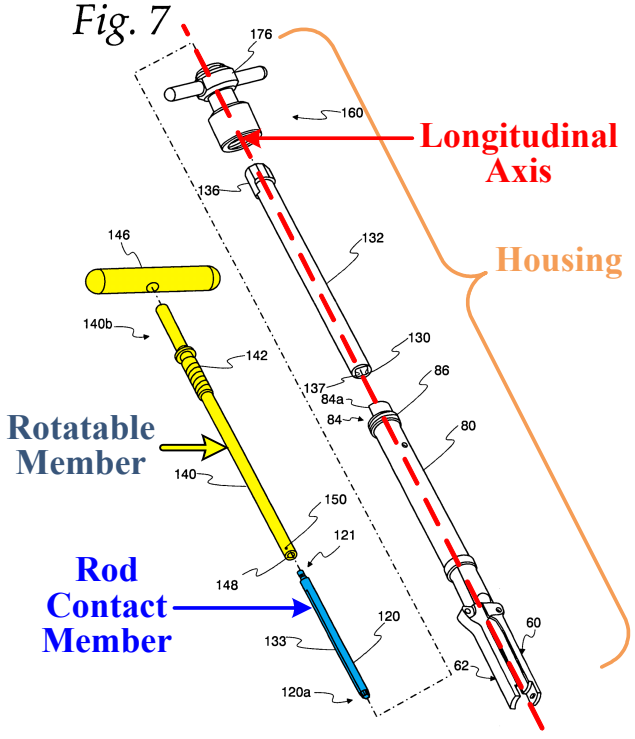


Fig. 7



Trudeau discloses the claimed "rotatable member extending through the housing along the longitudinal axis" as well as "a rod contact member positioned at a distal end of the rotatable member" as recited in claim 16. As discussed, a person of ordinary skill in the art would have recognized that ***the drive rod 140*** of the drive rod subassembly 3 could by itself be considered to be the "rotatable member" recited in claim 16 because, as disclosed by Trudeau, "torque generated by a user in ***rotating the drive rod 140*** via the drive handle 146 advances the drive rod 140 along the threads." *Id.* ¶ 80 (emphasis added); FIG. 7, above (annotated). In such a case, a person of ordinary skill in the art would also have recognized that the ***tool shaft 120*** of the drive rod subassembly 3 could have been used to "contact and advance against the spinal rod 12." *See, e.g., id.*; FIGS. 4b, 7, above (annotated).

More specifically, it would have been obvious to a person of ordinary skill in the art to use the ***tool shaft 120*** of Trudeau as the "rod contact member" instead of the rod securing device 30 (*e.g.*, a set screw) because such an arrangement would enable a surgeon to temporarily position a spinal rod into the receiving member(s) of one or more bone anchors and then finally secure the spinal rod after making any necessary adjustments. *See, e.g.,* ORT-1006 ¶ 153-154. Such a technique is taught by Pond, which discloses a reduction instrument configured to initially reduce and temporarily hold a spinal rod into the receiving members of a plurality of bone anchors and then secure the spinal rod within the receiving

members with set screws or plugs. More specifically, Pond discloses that a "[r]eduction instrument 400 can then be placed over none, one or both of the other extenders 50, 250 ***to finally reduce connecting member 100 into the receiver members of these anchors***" and the "[r]eduction instrument 400 can ***hold the connecting member 100 in the reduced position*** during engagement of the plug with the anchor." ORT-1005 ¶ 124 (emphasis added). Furthermore, as discussed above, the '816 Patent substantiates the advantages of initially reducing a spinal rod into a receiving portion of a bone anchor and temporarily holding the rod in place to allow the position of the rod to be adjusted, as necessary (*e.g.*, while positioning and reducing the rod into sequentially aligned bone anchors). *See, e.g.,* ORT-1001 at 1:65-2:11.

Fig. 4b

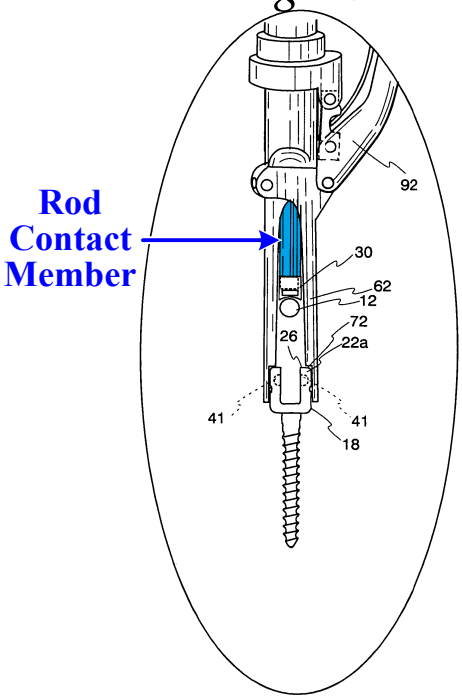
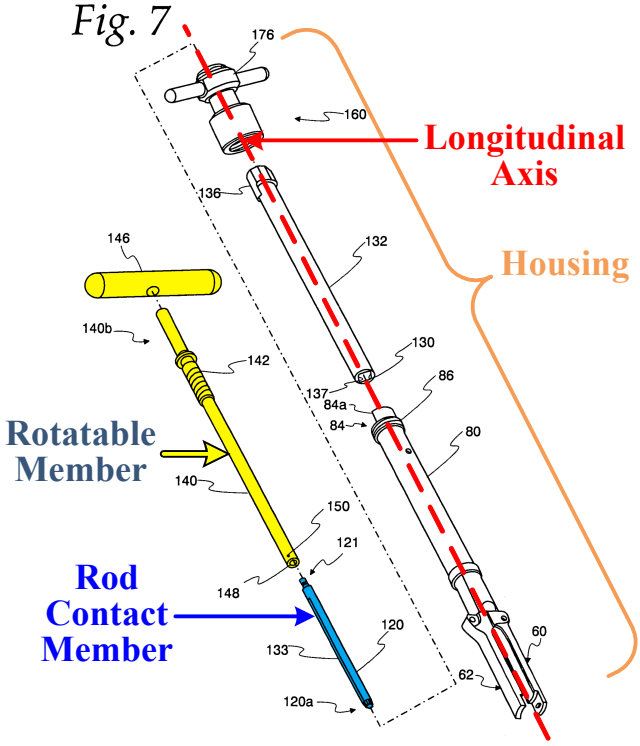
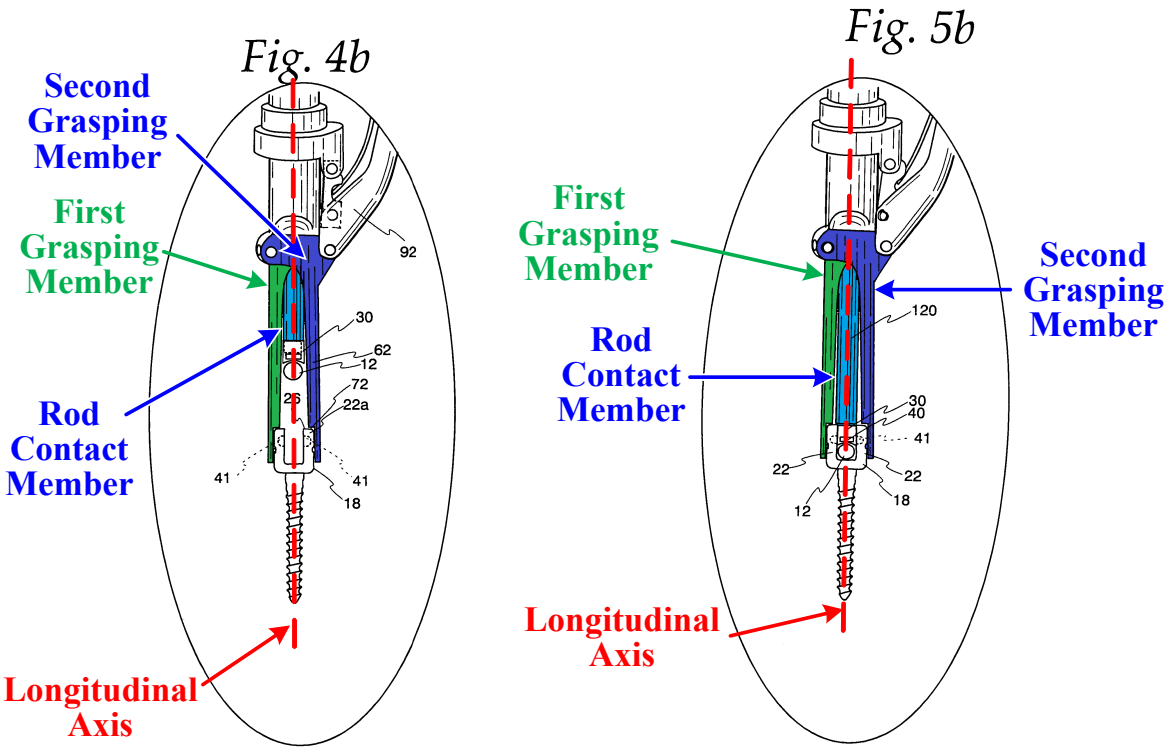


Fig. 7



b. [16-6]: "the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis"

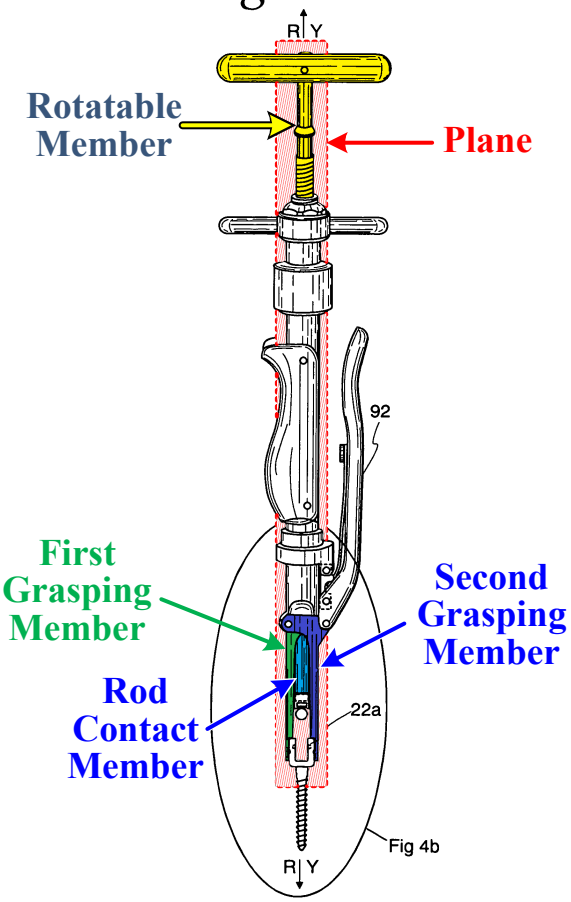


Trudeau discloses the claimed "rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis" as recited in claim 16. In particular, as discussed above, Trudeau discloses that "***rotating the drive rod 140*** [the claimed *rotatable member*] via the drive handle 146 ***advances the drive rod 140***." ORT-1004 ¶ 80 (emphasis added). Trudeau also discloses that "***[t]he drive rod 140*** [the claimed *rotatable member*] ***and tool shaft 120*** [the claimed *rod contact member*] ***are cooperatively connected*** such that the tool shaft 120 and drive rod 140 ***move together along the axis A*** of the drive rod 140 in a generally linear manner." *Id.* ¶ 79 (emphasis

added). Trudeau further discloses that "***[t]he tool shaft 120*** [the claimed *rod contact member*] ***advances*** along the axis R of the persuader." *Id.* ¶ 74 (emphasis added); FIGS. 4b, 5b, above (annotated).

c. [16-7]: "wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members"

Fig. 4a



Trudeau discloses the claimed "rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members" as recited in claim 16. For example, Trudeau discloses that "***the tool***

shaft 120 [the claimed *rod contact member*] ***and drive rod 140*** [the claimed *rotatable member*] ***move together along the axis A of the drive rod 140 in a generally linear manner.***" *Id*. ¶ 79 (emphasis added). Trudeau further discloses that "***[t]he tool shaft 120*** [the claimed *rod contact member*] ***advances*** along the axis R of the persuader." *Id.* ¶ 74 (emphasis added); FIG. 4a, above (annotated).

As illustrated above in annotated FIG. 4a, the tool shaft 120 (*i.e.,* the claimed *rod contact member*) and the drive rod 140 (*i.e.,* the claimed *rotatable member*) of Trudeau are translatable within the plane defined by the opposed jaws 60, 62 (*i.e.,* the claimed *first and second grasping members*).

2. Claim 18: "The rod reducing device of claim 16, wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable with a portion of a bone anchor"

As discussed above in Section VIII(C)(2), Trudeau discloses the claimed "wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable with a portion of a bone anchor," as recited in claim 18. More specifically, Trudeau discloses that the distal end of each jaw 60 and 62 includes a tooth 38 (i.e., the claimed *at least one grasping feature*) configured to be clamped to the yoke 18 (*i.e.,* the claimed *portion of a bone anchor*).

3. Claim 19: "The rod reducing device of claim 16, wherein distal movement of the rod contact member urges a rod towards distal ends of the first and second grasping members"

Fig. 4b

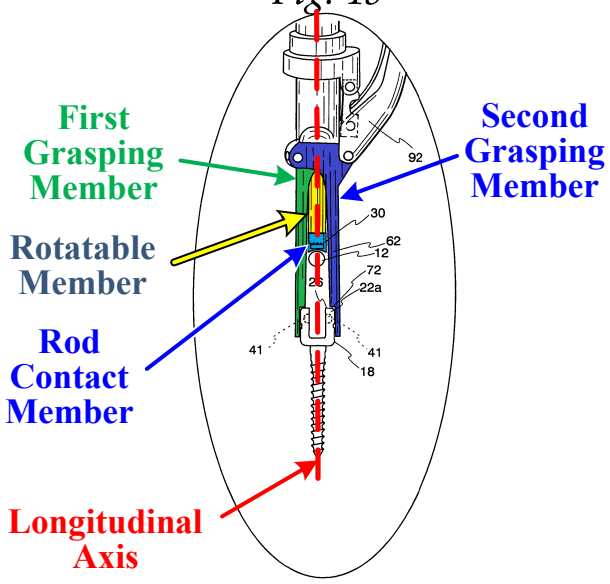
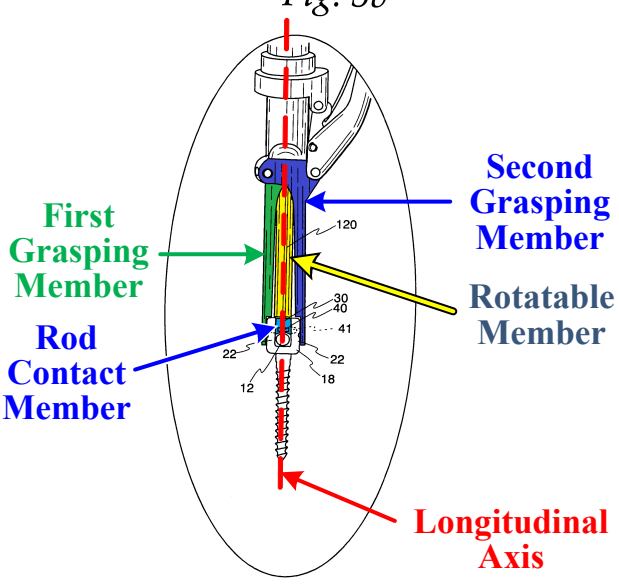
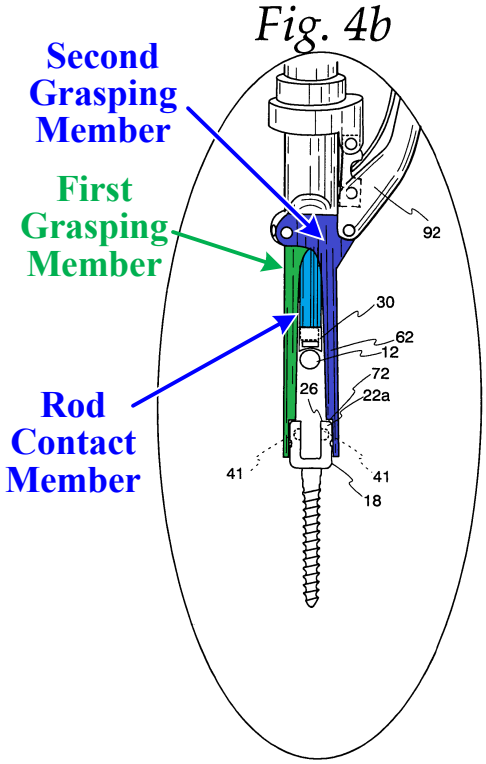


Fig. 5b



Trudeau discloses the claimed "wherein distal movement of the rod contact member urges a rod towards distal ends of the first and second grasping members" as recited in claim 19. More specifically, Trudeau discloses "***[t]he tool shaft 120*** [the claimed *rod contact member*] ***advances*** along the axis R of the persuader ***to push the . . . spinal rod 12*** into the yoke 18 [of the bone anchor]." *Id.* ¶ 74 (emphasis added); FIGS. 4b, 5b, above (annotated).

4. Claim 21: "The rod reducing member of claim 16, wherein a portion of the rod contact member is positioned between the first and second grasping members"



Trudeau discloses the claimed "wherein a portion of the rod contact member is positioned between the first and second grasping members" as recited in claim 21. More specifically, Trudeau discloses "[i]n the present form, the jaws 60, 62 [the claimed *first and second grasping members*] are connected to the tubular body portion 80 [of the housing] of the tool 10 [the claimed *rod reducing device*], and the tool shaft 120 [the claimed *rod contact member*] is retained by the tubular body portion 80 to permit translation of the tool shaft 120 relative to the tubular body portion 80." *Id.* ¶ 73.

Further, as shown above in annotated FIG. 4b, a portion of the tool shaft 120 [the claimed *rod contact member*] of Trudeau is positioned between the jaws 60, 62 [the claimed *first and second grasping members*].

5. Claim 22: "The rod reducing member of claim 16, wherein the rod contact member is attached to the distal end of the rotatable member"

Trudeau discloses the claimed "wherein the rod contact member is attached to the distal end of the rotatable member" as recited in claim 22. More specifically, Trudeau discloses "***[t]he drive rod 140*** [the claimed *rotatable member*] ***is connected to the tool shaft 120*** [the claimed *rod contact member*] so that it may threadably rotate independent of and advance without rotating the tool shaft 120 and the drive sleeve 132 [of the housing]." *Id*. ¶ 81 (emphasis added).

IX. CONCLUSION

As detailed above, each of claims 16, 18, 19, 21, and 22 of the '816 Patent is anticipated and rendered obvious by at least one or more prior art references. Petitioner has therefore established that there is a reasonable likelihood that one or more of the claims of the patent are unpatentable. Accordingly, Petitioner requests review of these claims.

Dated: January 8, 2018

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

In accordance with 37 C.F.R. § 42.24(d), Petitioner certifies that the word count for this petition totals 9,784 words, which is less than 14,000 allowed under 37 C.F.R. § 42.24(a)(i).

/Paul M. Ulrich/
Paul M. Ulrich

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on January 8, 2018, a complete and entire copy of this petition for *inter partes* review and all supporting exhibits were provided by Federal Express, cost prepaid, to the Patent Owner by serving the correspondence address of record as follows:

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