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. IPR2018-01546
Patent No. 9,655,664

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,655,664

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I. INTRODUCTION

OrthoPediatrics Corp. ("Petitioner") petitions for *inter partes* review ("IPR") of claims 1, 3, 5, 6, 8-10, 12, and 15-19 (the "Challenged Claims") of U.S. Patent No. 9,655,664 (ORT-1001), which public records indicate is assigned to K2M, Inc. ("Patent Owner"). The Challenged Claims of U.S. Patent No. 9,655,664 ("the '664 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 1:19-22. 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 '664 Patent and related U.S. Patent No. 9,532,816 ("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.

OrthoPediatrics Corp. has since petitioned for *inter partes* review of the '816 Patent in Case Nos. IPR2018-00429 and IPR2018-00521, both of which the Board instituted on June 28, 2018. ORT-1014; ORT-1015.

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

Petitioner provides the following designation of counsel:

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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 '664 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 the Challenged Claims 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-1016) also has been submitted.

Ground	Claims	Basis for Unpatentability
Ground 1	1, 3, 5, 6, 8-10, 12, and 15-19	Anticipated under 35 U.S.C. § 102(e)[1] by Iott
Ground 2	9, 15, and 17-19	Obvious under 35 U.S.C. § 103(a) over Iott in view of Justis
Ground 3	8, 10, 12, and 16	Obvious under 35 U.S.C. § 103(a) over Sparker in view of the DePuy Catalogs
Ground 4	9, 15, and 17-19	Obvious under 35 U.S.C. § 103(a) over Sparker in view of the DePuy Catalogs and Justis

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

Petitioner does not believe any specific claim term of the Challenged Claims requires construction for the purposes of this petition and that every claim term should be given its "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). Only those terms that are in controversy need to be construed—and only to the extent necessary to resolve the controversy. *See, e.g., Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

The Board instituted *inter partes* review of claims of related U.S. Patent No. 9,532,816 ("the '816 Patent"), also owned by Patent Owner. *See* ORT-1014; ORT-1015. In Patent Owner's preliminary responses to the two petitions for *inter partes*

[1] References to 35 U.S.C. §§ 102 and 103 throughout this petition are to the pre-AIA versions, which apply to the '664 Patent.

review, Patent Owner argued that two terms required construction: "grasping" and "extending through the housing." ORT-1012 at 9-19; ORT-1013 at 9-21. Patent Owner did not argue that any other claim term required construction.

In instituting *inter partes* review, the Board construed "extending through the housing" as "extending through the fixed portion of the rod reducing device that defines the body through passage." ORT-1014 at 10; ORT-1015 at 11. The Board did not construe "grasping," as its construction was not necessary to resolve the controversy. *See, e.g.*, ORT-1014 at 6 ("For purposes of this decision we need only construe 'extending through the housing.'") (citing *Vivid Techs.*, 200 F.3d at 803).

For purposes of this petition, Petitioner does not request that the Board construe "extending through the housing" differently than the Board construed the phrase in IPR2018-00429 or IPR2018-00521, which is consistent with Petitioner's understanding of the phrase's broadest reasonable interpretation.

The terms and phrases of the Challenged Claims are nearly identical to the terms and phrases of the claims challenged in IPR2018-00429 and IPR2018-00521. As no other terms or phrases are in dispute, the Board need not and should not construe any other terms or phrases. *See, e.g., Vivid Techs.*, 200 F.3d at 803. In essence, this petition is based on the claim constructions urged by Patent Owner in the related district court litigation.

Although Petitioner sought narrower claim constructions in the district court proceedings, the Federal Circuit has observed that the broadest reasonable interpretation of a claim term is often broader than the term's construction under the *Phillips* standard. *See, e.g., Facebook, Inc. v. Pragmatus AV, LLC*, 582 Fed. Appx. 864, 869 (Fed. Cir. 2014). Moreover, as the Board recognizes, "Our rules do not require positions consistent with related cases in different fora. Our rules require that the parties identify related matters. Various reasons may justify inconsistencies among fora, including differing legal or evidentiary standards, a change in litigation strategy, or a change in position." *Caterpillar Inc. v. Wirtgen America, Inc.*, IPR2017-02185, Paper 7, at 11 (PTAB May 3, 2018) (citing 37 C.F.R. § 42.8(b)(2)).

With respect to potential means-plus-function limitations, none of the Challenged Claims contains the word "means." As such, there is a presumption that none of the Challenged Claims invoke 35 U.S.C. § 112, ¶ 6. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015). Moreover, Patent Owner has not requested any construction under § 112, ¶ 6, and Petitioner has no reason to believe that Patent Owner will do so for purposes of this petition. The Board, therefore, need not and should not construe any terms or phrases under § 112, ¶ 6. *Vivid Techs.*, 200 F.3d at 803 ("only those terms need be construed that are in controversy"). Nevertheless, should Patent Owner request any construction

under § 112, ¶ 6, Patent Owner would have the burden of overcoming the presumption against § 112, ¶ 6 by a preponderance of the evidence. *See Apex Inc. v. Raritan Comp., Inc*., 325 F.3d 1364, 1372 (Fed. Cir. 2003).

VI. SUMMARY OF THE PATENT

A. Background of the Art

The '664 Patent is generally directed to orthopedic surgery, and more specifically, to devices for stabilizing and fixing bones, particularly vertebrae. ORT-1001 at 1:16-19. According to the '664 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 1:40-43. Such a surgical procedure "involves fusing two or more vertebral bodies in order to eliminate motion at the intervertebral disc or joint." *Id.* at 1:42-44.

The '664 Patent further explains that "it is ***common practice to place bone screws*** into the vertebral bodies and ***then connect a metal rod*** between adjacent vertebral bodies" to immobilize the spinal column. *Id.* at 1:48-53 (emphasis added). That is, the surgeon uses a metal rod to connect multiple vertebrae by placing the rod into a "receiving slot" in the head of each of the bone screws already attached to the vertebrae. *See id.*

B. The Alleged Invention of the '664 Patent

The '664 Patent relates to a device that is used by a surgeon to lower—or ***reduce***—such a metal rod into the receiving 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 '664 Patent filed their patent applications.

The rod reducer of the '664 Patent is a manually operated device that reduces a rod into a rod receiving slot of a bone screw head by the rotation of a screw shaft 16. *Id.* at 1:19-22.

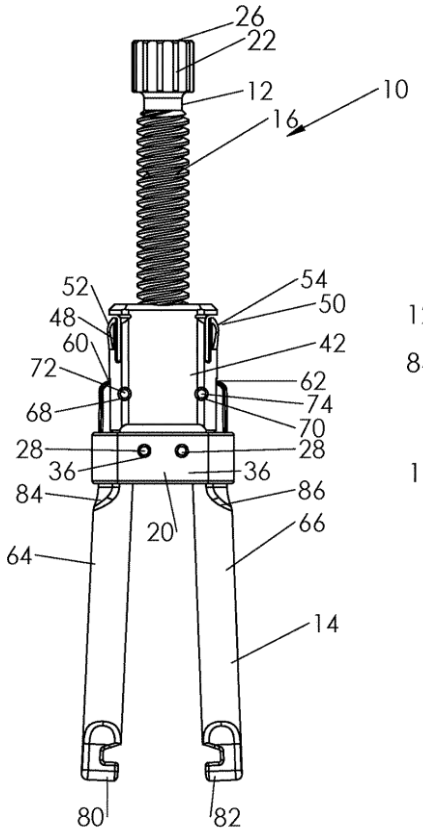


FIG 5

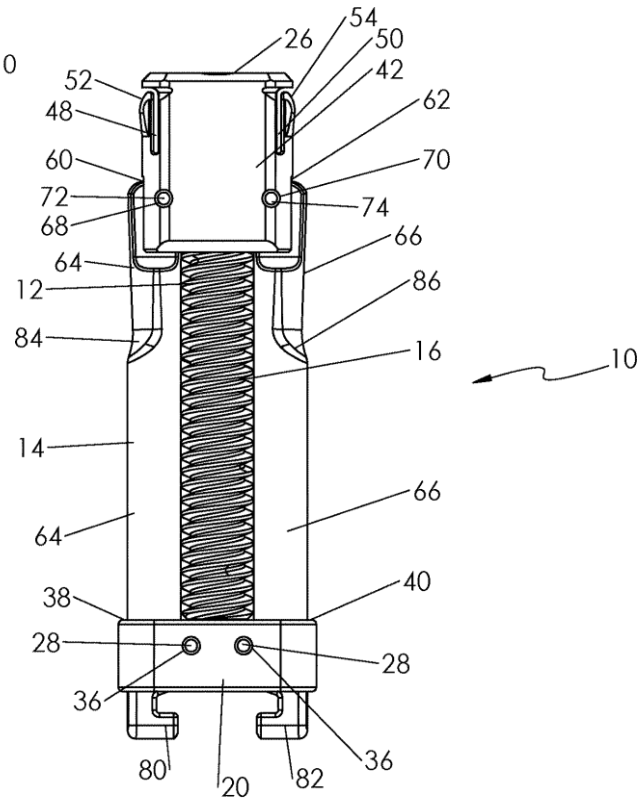


FIG 2

Figure 5 shows a front view of an embodiment of the device before rotation of the screw shaft 16. *Id.* at 3:33-34. The device includes two opposed, elongated "grasping members" 64 and 66. (*See id.* at 5:58-67; FIGS. 2, 5). At the bottom (*i.e.*, distal end) of the screw shaft 16 is a "rod contact member" 20. *See id.* at 4:41-44.

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 causes the rod contact member to push the rod downward into the receiving slot of the bone screw. *See, e.g., id.* at 6:27-57. Figure 2 thus shows the device after rotation of the screw shaft 16. *Id.* at 3:25-26.

C. Claim Key

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

Key	Listing of Claims
[1-PRE]	1. A method of advancing a rod into a housing of a bone anchor comprising:
[1-1]	coupling a rod reducing device to a bone anchor,
[1-2]	the bone anchor having a rod-receiving housing and a bone engaging shaft extending therefrom,
[1-3]	the rod reducing device including:
[1-4]	a rotatable member,

Key	Listing of Claims
[1-5]	a rod contact member positioned at a distal end of the rotatable member, and
[1-6]	a body including first and second elongated grasping members extending therefrom,
[1-7]	each of the first and second elongated grasping members having a screw grasping element,
[1-8]	the rotatable member threadably coupled with the body,
[1-9]	the first and second elongated grasping members defining a plane,
[1-10]	the rotatable member and the rod contact member movable within the plane;
[1-11]	securing the rod reducing device to the bone anchor by engaging the first and second elongated grasping members with the rod-receiving housing so that the rod-receiving housing is disposed between the first and second elongated grasping members; and
[1-12]	rotating the rotatable member thereby causing the rod contact member to move relative to the body within the plane to advance a rod disposed between the first and second elongated grasping members toward the rod-receiving housing.
[3-1]	3. The method of claim 1, wherein securing the rod reducing device to the bone anchor includes coupling respective distal ends of the first and second elongated grasping members having at least one grasping feature to engage the rod-receiving housing of the bone anchor.
[5-1]	5. The method of claim 1, wherein coupling the rod reducing device includes coupling the rod reducing device in which a portion of the rod contact member is positioned between the first and second elongated grasping members.
[6-1]	6. The method of claim 1, wherein coupling the rod reducing device includes coupling the rod reducing device in which the rod contact member is attached to the distal end of the rotatable member.
[8-PRE]	8. A kit for reducing a rod, the kit comprising:

Key	Listing of Claims
[8-1]	a bone anchor; and
[8-2]	a rod reducing device including:
[8-3]	a housing defining a longitudinal axis,
[8-4]	the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween,
[8-5]	the first and second grasping members defining a plane;
[8-6]	a rotatable member extending through the housing along the longitudinal axis; and
[8-7]	a rod contact member positioned at a distal end of the rotatable member,
[8-8]	the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis,
[8-9]	wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members.
[9-1]	9. The kit according to claim 8, further comprising a plurality of bone anchors and a plurality of rod reducing devices.
[10-1]	10. The kit of claim 8, further comprising at least one additional orthopedic tool selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device.
[12-PRE]	12. A system for reducing a connecting rod, the system comprising:
[12-1]	a bone anchor;
[12-2]	a connecting rod; and
[12-3]	a rod reduction device including:
[12-4]	a housing defining a longitudinal axis,
[12-5]	the housing including first and second grasping members configured to grasp a portion of the bone anchor therebetween,
[12-6]	the first and second grasping members defining a plane;

Key	Listing of Claims
[12-7]	a rotatable member extending through the housing along the longitudinal axis; and
[12-8]	a rod contact member positioned at a distal end of the rotatable member,
[12-9]	the rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis.
[15-1]	15. The system according to claim 12, further comprising a plurality of bone anchors and a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors.
[16-1]	16. The system of claim 12, further comprising an additional orthopedic tool or device selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device.
[17-PRE]	17. A surgical construct comprising:
[17-1]	a plurality of bone anchors;
[17-2]	a connecting rod; and
[17-3]	a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices connectable to a bone anchor of the plurality of bone anchors,
[17-4]	each rod reduction device of the plurality of rod reduction devices including:
[17-5]	a housing defining a longitudinal axis,
[17-6]	the housing including first and second grasping members configured to grasp a portion of the bone anchor therebetween,
[17-7]	the first and second grasping members defining a plane;
[17-8]	a rotatable member extending through the housing along the longitudinal axis; and
[17-9]	a rod contact member positioned at a distal end of the rotatable member,

Key	Listing of Claims
[17-10]	the rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis.
[18-1]	18. The construct of claim 17, wherein the connecting rod is disposed between the first and second grasping members of the plurality of the rod reduction devices with the plurality of rod reduction devices mounted to the respective bone anchors of the plurality of bone anchors,
[18-2]	whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors.
[19-1]	19. The construct of claim 17, wherein each bone anchor further comprises a rod receiving housing and a bone engaging shaft extending therefrom, each rod reduction device of the plurality of rod reduction devices approximating the connecting rod toward the rod receiving housing of the bone anchor.

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSITA") 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-1016 ¶ 13.

VIII. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '664 PATENT IS UNPATENTABLE

As detailed below, each of the Challenged Claims 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 '664 Patent are unpatentable. The Grounds are not cumulative or redundant.

A. Ground 1: Claims 1, 3, 5, 6, 8-10, 12, and 15-19 Are Anticipated by Iott

Iott anticipates claims 1, 3, 5, 6, 8-10, 12, and 15-19 of the '664 Patent. Iott was filed on October 6, 2005 and was published on November 2, 2006. ORT-1017 at 1. Therefore, Iott is prior art under at least 35 U.S.C. § 102(e)[2] and 35 U.S.C. § 102(a). Iott was never cited nor considered by the Examiner during prosecution of the '664 Patent.[3] ORT-1001 at 1-2; *see also* ORT-1002.

Iott generally discloses a vertebral stabilization system. ORT-1017 ¶ 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 id.* ¶ 55. Iott further discloses a rod reducer instrument attached to a proximal end of the sleeves. *See id.* ¶ 70.

[2] 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.

[3] Iott was also never cited nor considered by the Examiner during prosecution of the parent patents—the '816 and '523 Patents. *See, e.g.*, ORT-1004; ORT-1006.

To facilitate analysis of the Challenged Claims, the below table provides a textual mapping of various claim elements of the '664 Patent to disclosed features of Iott.

'664 Claim Element	Corresponding Feature(s) of Iott[4]
bone anchor	anchor(s) 12, 14
(connecting) rod	stabilization member 228
rod reducing device / rod reduction device	rod reducer instrument 300
housing / body	attachment sleeve 306 -or- attachment sleeve 306 and sleeve 22, 50
first (elongated) grasping member	arm(s) 72, 74
second (elongated) grasping member	arm(s) 72, 74
rotatable member	rotation shaft 302
rod contact member	reducer shaft 304
grasping feature / screw grasping element	retainer portion 82 -or- finger member(s) 84
[bone anchor] bone engaging shaft	shaft or shank 36
[bone anchor] rod-receiving housing	u-shaped body 44

[4] *See* ORT-1017, FIGS. 4-5, and 30-32.

1. Independent Claim 1:

a. Limitation-[1-PRE]:

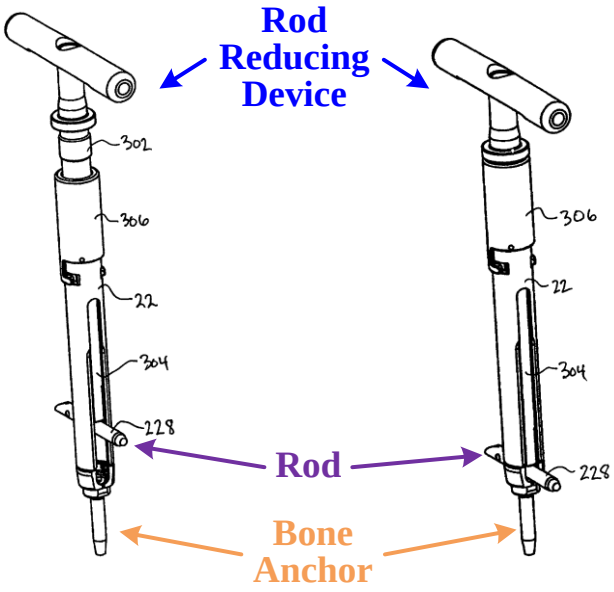


FIG. 31 FIG. 32

Iott discloses the "method of advancing a rod into a housing of a bone anchor" as recited in claim 1. *Id.* FIGS. 31-32 (annotated). For example, Iott discloses "***a method*** of percutaneously installing ***a vertebral stabilization system***" and "in operation, . . . reducer 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.* ¶¶ 14, 71. Iott further discloses "inserting a rod reducer instrument into the central channel of the access sleeve ***to force the stabilization member into a portion of the anchor***." *Id.* at Claim 21.

b. Limitation-[1-1]:

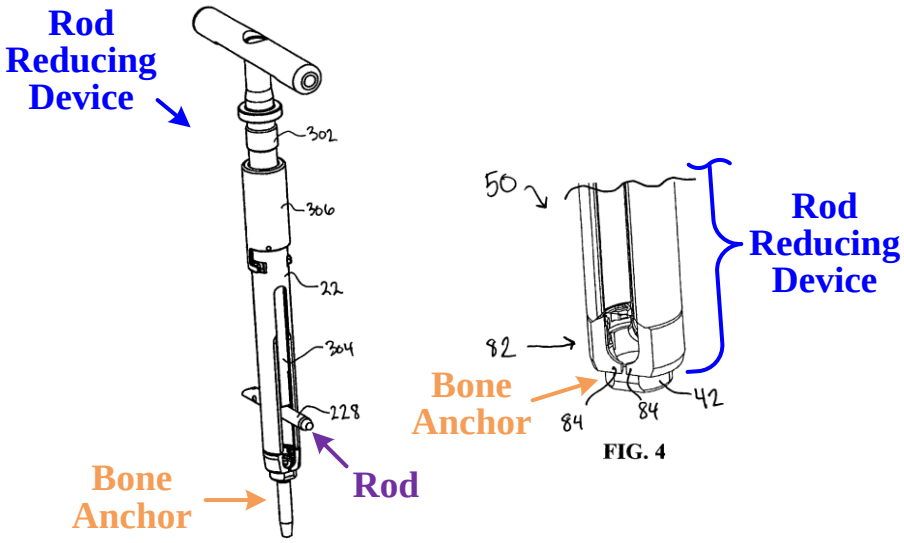


FIG. 31

FIG. 4

Iott discloses the claimed "rod reducing device" as recited in claim 1. For example, Iott discloses "***one embodiment of a rod reducer instrument 300*** 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 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).

Iott further discloses claimed "coupling" of the rod reducing device to "a bone anchor." *Id.* FIGS. 31, 4 (annotated). For example, Iott discloses "***[i]n operation***, arms 72, 74 of inner sleeve member 52 ***may be compressed radially***

inward" and "[i]nner sleeve member 52 also includes a retainer portion 82 at its distal end ***to attach an anchor to the distal end of sleeve 50***." *Id.* ¶ 56; FIG. 4 (annotated).

c. Limitation-[1-2]:

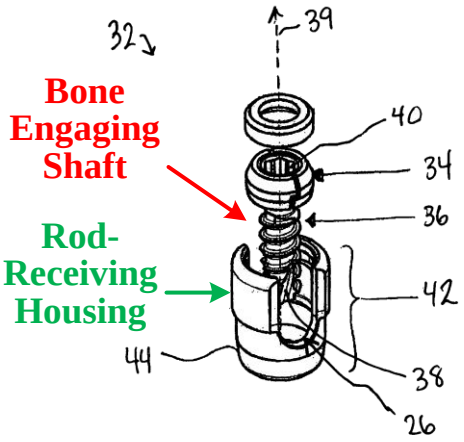


FIG. 2

Iott discloses the claimed "bone anchor having a rod-receiving housing and a bone engaging shaft extending therefrom" as recited in claim 1. In particular, Iott discloses that "[e]ach of the ***first and second anchors 12, 14*** generally comprises a bone fastener such as a bone screw 32 with a head 34 and ***a shaft or shank 36 having bone engaging threads***. " *Id.* ¶ 53 (emphasis added); FIG. 2 (annotated). Iott further discloses that in connection with the bone screw 32, "coupling element 42 includes a ***U-shaped body 44*** defining a channel 26 in which ***stabilization member 16*** may be locked or fixed in place." *Id.* ¶ 54; FIG. 2 (annotated).

d. Limitation-[1-3]:

As discussed in more detail below, Iott discloses a rod reducing device including all of the recited features of claim 1.

e. Limitation-[1-4]:

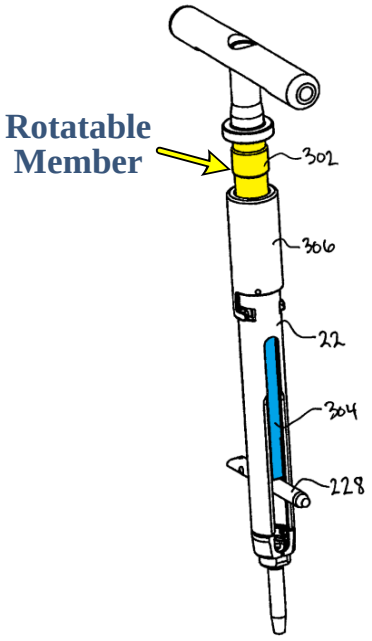


FIG. 31

Iott discloses the claimed "rotatable member" as recited in claim 1. For example, Iott states that the "[r]od reducer instrument 300 generally comprises ***a rotation shaft 302***, a reducer shaft 304, and an attachment sleeve 306, configured to engage and attach to a proximal end of sleeve[ ] 22." *Id.* ¶ 70 (emphasis added); FIG. 31, above (annotated).

Iott further discloses "in operation, . . . ***shaft 302 is threadedly rotated*** with respect to ***attachment sleeve 306***." *Id.* ¶ 71 (emphasis added).

f. Limitation-[1-5]:

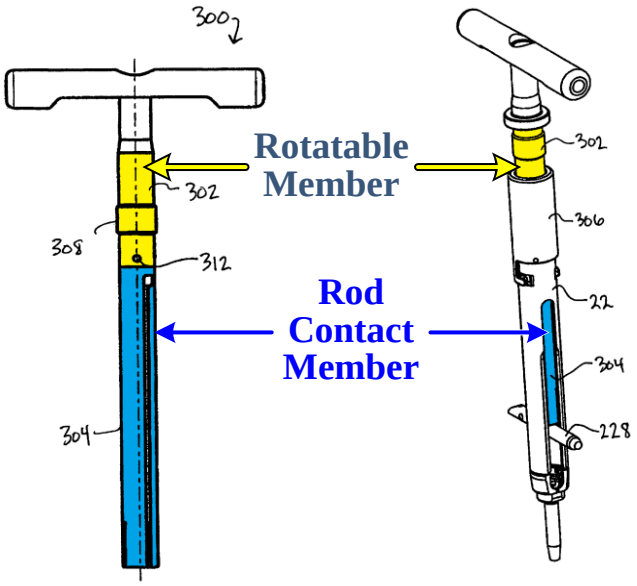


FIG. 30 FIG. 31

Iott discloses "a rod contact member positioned at a distal end of the rotatable member" as recited in claim 1. For example, Iott discloses "***[r]otation shaft 302*** 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 to reducer shaft 304***." *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 1.

g. Limitation-[1-6]:

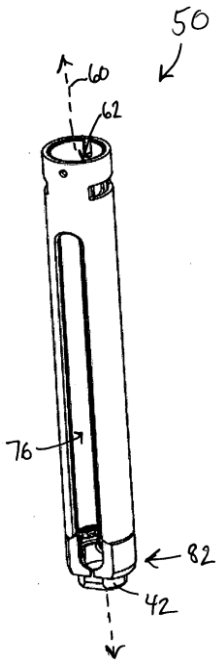


FIG. 5

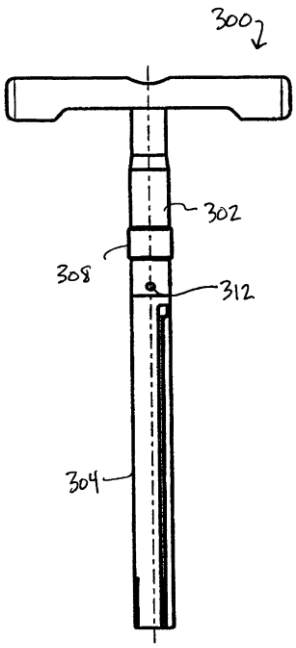


FIG. 30

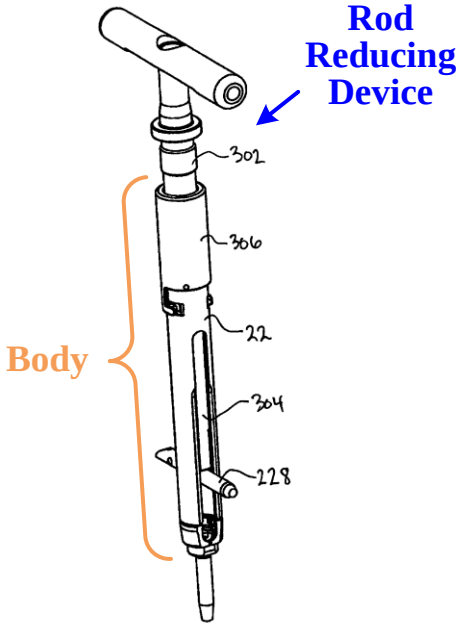


FIG. 31

Iott discloses the claimed "body" as recited in claim 1. 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***." *Id.* (emphasis added); FIGS. 5, 30, 31 (annotated). Iott also discloses that sleeve 50 is one specific example of sleeve 22. *Id.* ¶ 55; FIG. 5, above. When considered together, the attachment sleeve 306 and the sleeve 22, 50 of Iott can reasonably be interpreted as being the claimed "body."

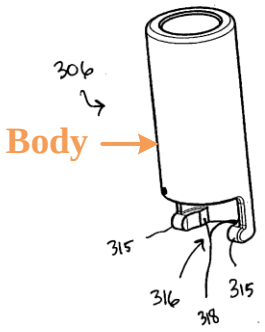


FIG. 35

Alternatively, other features of Iott can reasonably be interpreted as being the claimed "body." For example, the ***attachment sleeve 306*** can separately be viewed as the claimed "body." *Id.* at FIG. 35 (annotated); ORT-1016 ¶ 86.

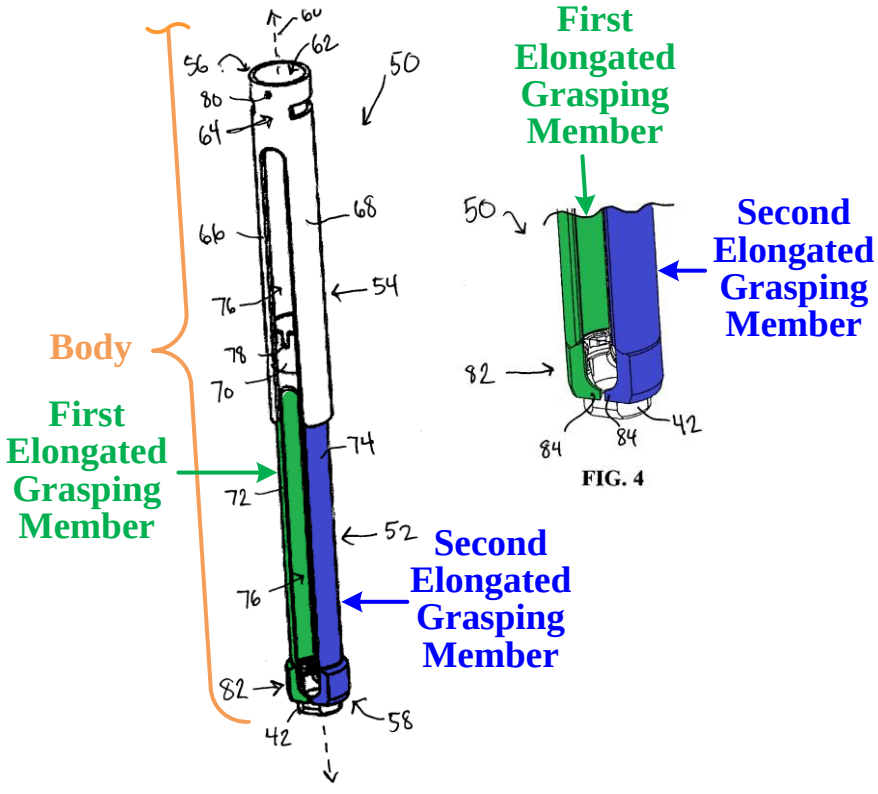


FIG. 3

FIG. 4

Iott also discloses that the claimed "body" includes "first and second elongated grasping members extending therefrom" as recited in claim 1. In

particular, Iott discloses that in connection with the sleeve 50 (*i.e.*, a portion of the claimed *body*), "***arms 72, 74*** of inner sleeve member 52 ***may be compressed radially inward or expanded radially outward*** depending on the particular application." ORT-1017 ¶ 56 (emphasis added); FIGS. 3-4, above (annotated).

Iott further states that "***when arms 72, 74*** of inner sleeve member 52 ***are compressed radially inward, the coupling element 42 of screw 32*** is rotationally and axially ***fixed with respect to sleeve 50*** or radially contained within sleeve 50." *Id*. ¶ 57 (emphasis added).

h. Limitation-[1-7]:

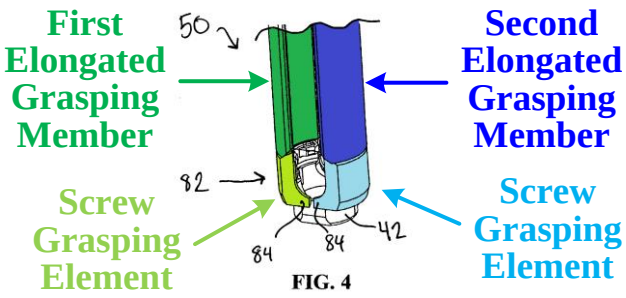


FIG. 4

Iott discloses the claimed "each of the first and second elongated grasping members having a screw grasping element" as recited in claim 1. 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*** at its distal end ***to attach an anchor*** to the distal end of sleeve 50." *Id*. ¶ 56 (emphasis added); FIG. 4, above (annotated).

Iott also that "arms 72, 74 may include ***finger members 84*** extending laterally inward from the distal end ***to provide additional retention capability***." *Id*.

(emphasis added). Such finger members 84 can also be considered the claimed "screw grasping element."

i. Limitation-[1-8]:

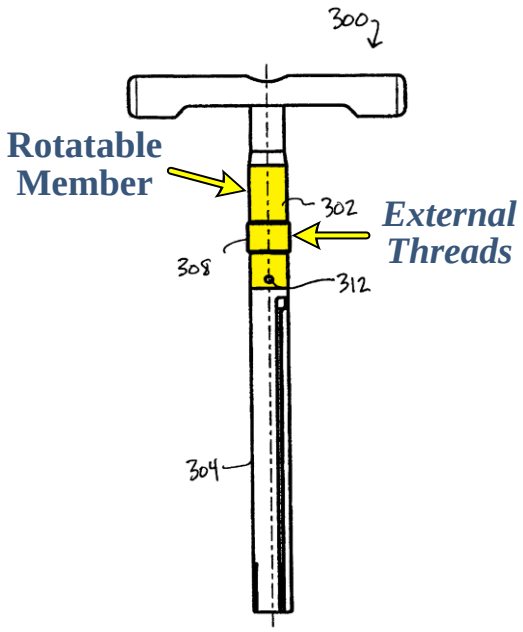


FIG. 30

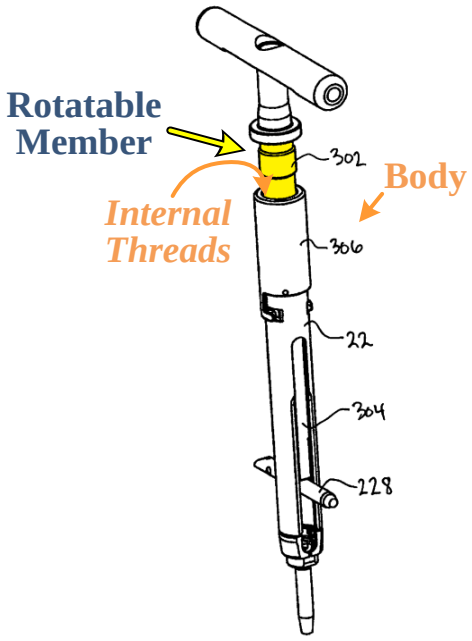


FIG. 31

Iott discloses the claimed " rotatable member threadably coupled with the body" as recited in claim 1. In particular, Iott states that "***[r]otation shaft 302*** comprises an ***externally threaded section 308*** along a portion of the shaft configured to ***threadedly engage or mate with corresponding internal threads*** along the interior of ***attachment sleeve 306***." *Id.* ¶ 70 (emphasis added); FIGS. 30-31 (annotated).

j. Limitation-[1-9]:

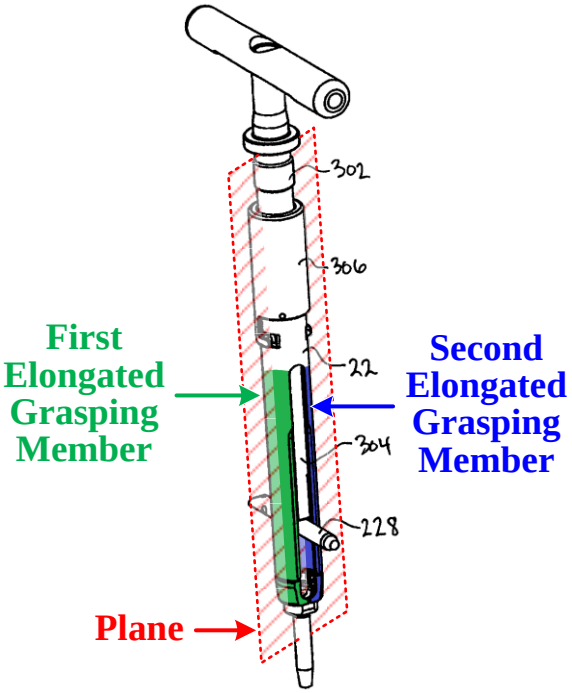


FIG. 31

Iott discloses the claimed "the first and second elongated grasping members defining a plane." As shown in FIG. 31, the arms 72, 74 (*i.e.*, the claimed *first and second elongated grasping members*) of Iott implicitly define a plane. *Id.* at FIG. 31, above (annotated); ORT-1016 ¶¶ 95-96.

k. Limitation-[1-10]:

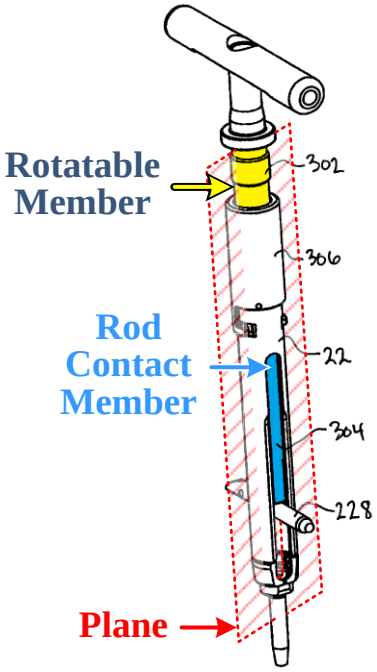


FIG. 31

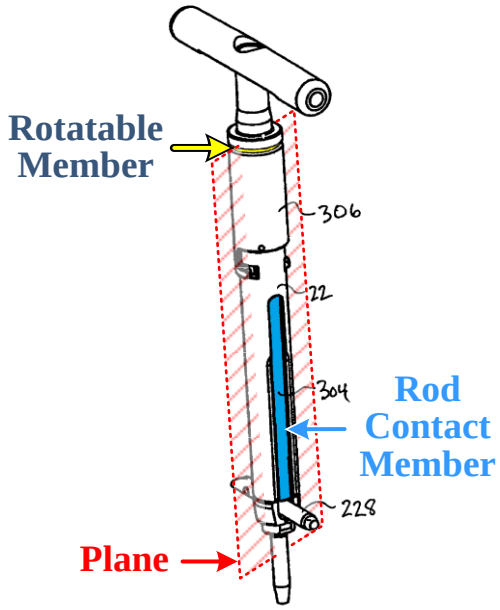


FIG. 32

Iott discloses the claimed "the rotatable member and the rod contact member movable within the plane" as recited in claim 1. For example, as discussed above, Iott discloses that "in operation, ***as shaft 302 is threadedly rotated*** with respect to attachment sleeve 306, ***reducer shaft 304 is translated in the axial direction***." ORT-1017 ¶ 71 (emphasis added); FIGS. 31, 32, 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 moveable within the plane. *Id.* FIGS. 31, 32, above (annotated).

l. Limitation-[1-11]:

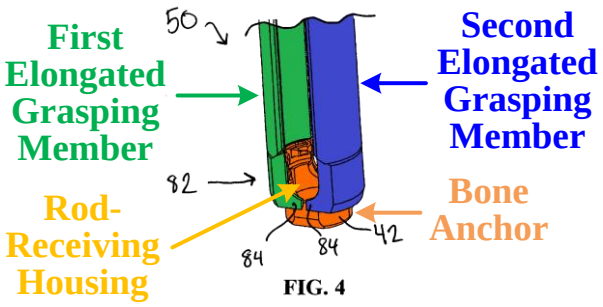


FIG. 4

Iott discloses the claimed "securing the rod reducing device to the bone anchor by engaging the first and second elongated grasping members with the rod-receiving housing so that the rod-receiving housing is disposed between the first and second elongated grasping members" as recited in claim 1. As discussed above, Iott discloses that "***[i]n operation***, arms 72, 74 of inner sleeve member 52 ***may be compressed radially inward***" and "[i]nner sleeve member 52 also includes a retainer portion 82 at its distal end ***to attach an anchor to the distal end of sleeve 50***." *Id.* ¶ 56; FIG. 4 (annotated).

m. Limitation-[1-12]:

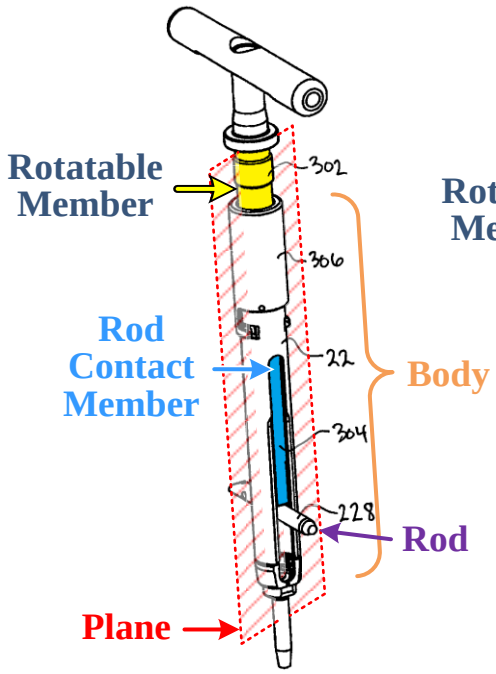


FIG. 31

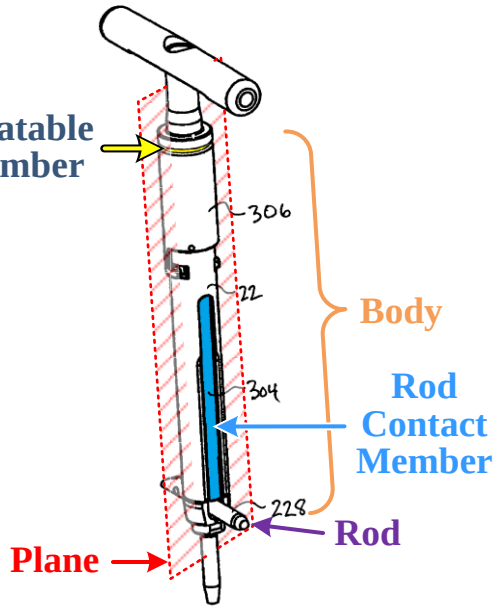
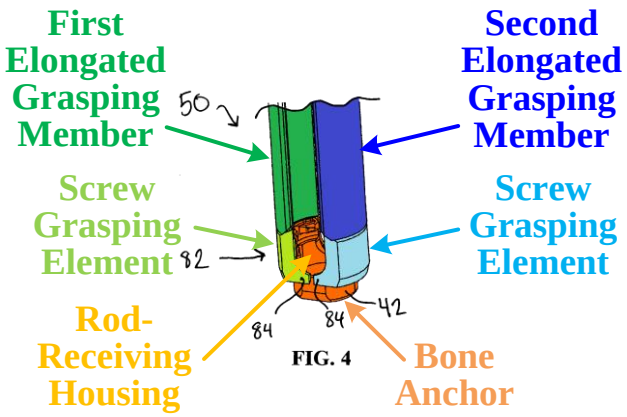


FIG. 32

Iott discloses the claimed "rotating the rotatable member thereby causing the rod contact member to move relative to the body within the plane to advance a rod disposed between the first and second elongated grasping members toward the rod-receiving housing" as recited in claim 1. In particular, as discussed above, Iott discloses that "***as shaft 302 is threadedly rotated*** . . ., ***reducer 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); FIGS. 31-32 (annotated).

2. Dependent Claim 3:



Iott discloses the claimed "wherein securing the rod reducing device to the bone anchor includes coupling respective distal ends of the first and second elongated grasping members having at least one grasping feature to engage the rod-receiving housing of the bone anchor" as recited in claim 3. As discussed above, Iott discloses that "***[i]n operation***, arms 72, 74 of inner sleeve member 52 ***may be compressed radially inward***" and "[i]nner sleeve member 52 also includes a retainer portion 82 at its distal end ***to attach an anchor to the distal end of sleeve 50***." *Id.* ¶ 56; FIG. 4 (annotated).

3. Dependent Claim 5:

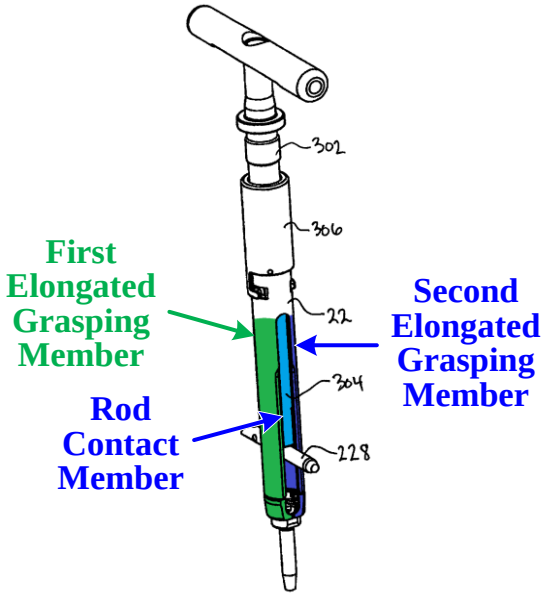


FIG. 31

Iott discloses the claimed "wherein coupling the rod reducing device includes coupling the rod reducing device in which a portion of the rod contact member is positioned between the first and second elongated grasping members" as recited in claim 5. As shown above in annotated FIG. 31, Iott discloses the ***reducer shaft 304*** positioned between the ***arms 72 and 74***.

Additionally, as discussed, Iott discloses that the "***reducer shaft 304*** is ***translated in the axial direction*** . . . to force a spinal rod ***from a first position*** spaced from a fastener . . . ***to a second position proximate to a fastener at the distal end of sleeve[ ] 22***." *Id.* ¶ 71 (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 elongated grasping members*).

4. Dependent Claim 6:

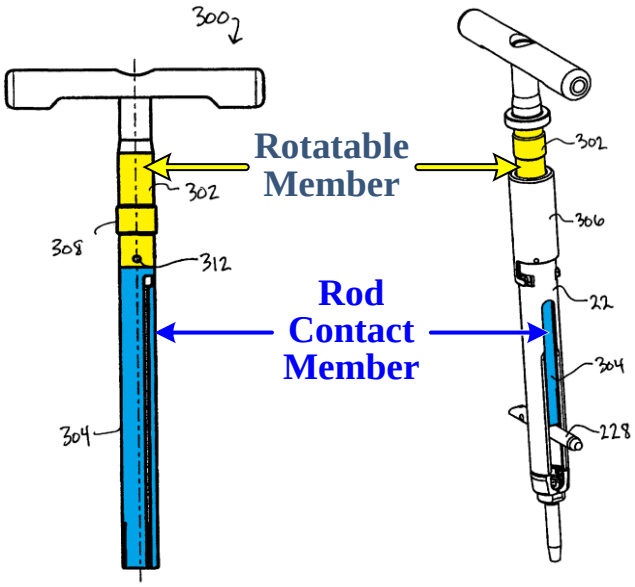


FIG. 30 FIG. 31

Iott discloses the claimed "wherein coupling the rod reducing device includes coupling the rod reducing device in which the rod contact member is attached to the distal end of the rotatable member" as recited in claim 6. For example, Iott discloses "***[r]otation shaft 302*** comprises a through-hole 310 . . . configured to receive a pin 312 therethrough ***to axially connect rotation shaft 302 to reducer shaft 304***." *Id.* ¶ 70 (emphasis added); FIGS. 30 and 31, above (annotated).

5. Independent Claim 8:

a. Limitation-[8-PRE]:

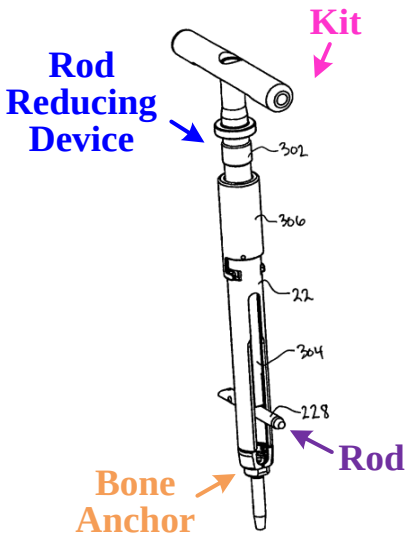


FIG. 31

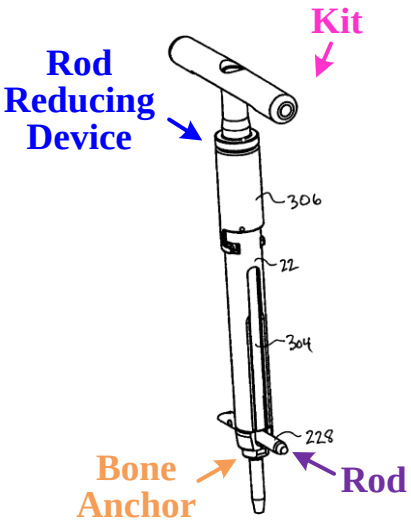
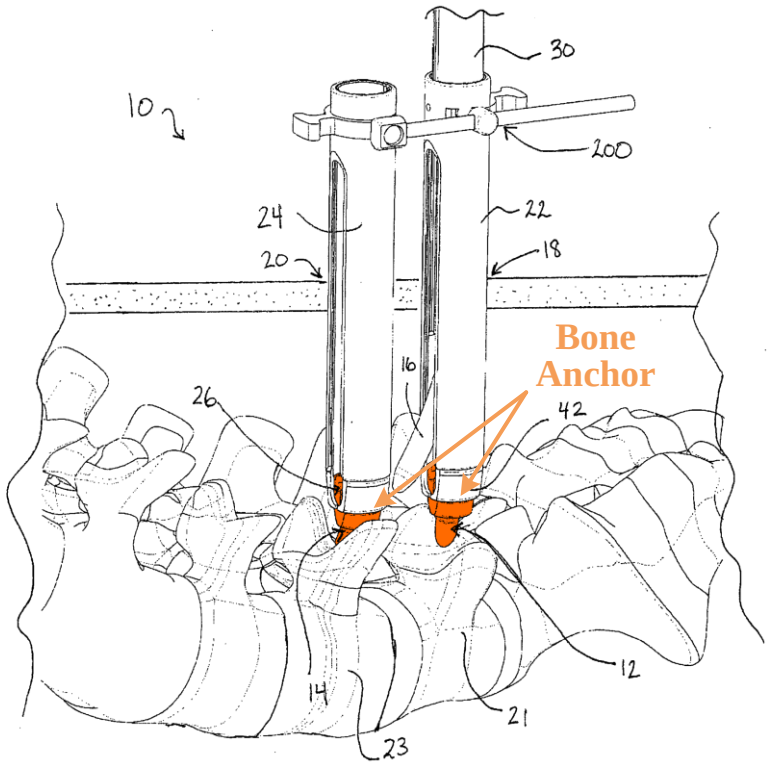


FIG. 32

Iott discloses the claimed "kit for reducing a rod" as recited in claim 8. In particular, Iott discloses percutaneous systems and "a rod reducer instrument 300 . . . configured and dimensioned to be utilized with the percutaneous systems," which include bone anchors. *Id.* ¶ 70; FIGS. 31-32, above (annotated). In doing so, Iott discloses all of the recited features of claim 8, each of which are discussed in more detail below.

b. Limitation-[8-1]:

FIG. 1



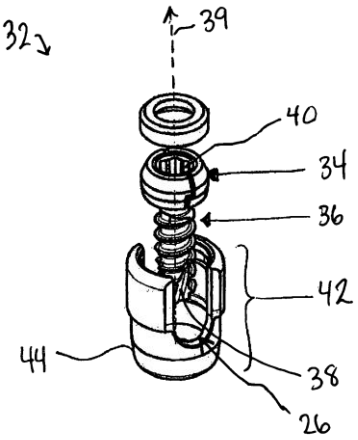


FIG. 2

Iott discloses the claimed "bone anchor." For example, Iott discloses that "[e]ach of the ***first and second anchors 12, 14*** generally comprises a bone fastener such as ***a bone screw 32*** with a head 34 and a shaft or shank 36 having bone engaging threads." *Id.* ¶ 53 (emphasis added); FIGS. 2, 31 (annotated).

c. Limitation-[8-2]:

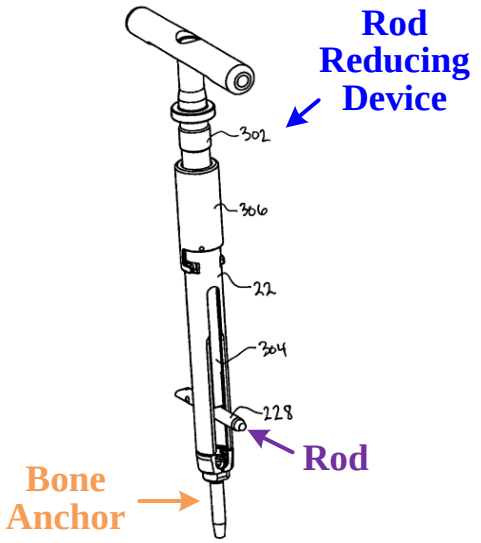


FIG. 31

Iott discloses the claimed "rod reducing device" as recited in claim 8. For example, Iott discloses "***one embodiment of a rod reducer instrument 300*** 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 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).

d. Limitation-[8-3]:

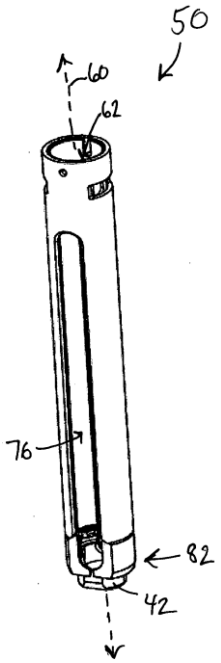


FIG. 5

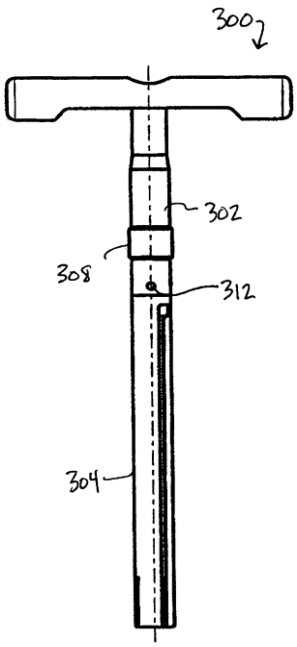


FIG. 30

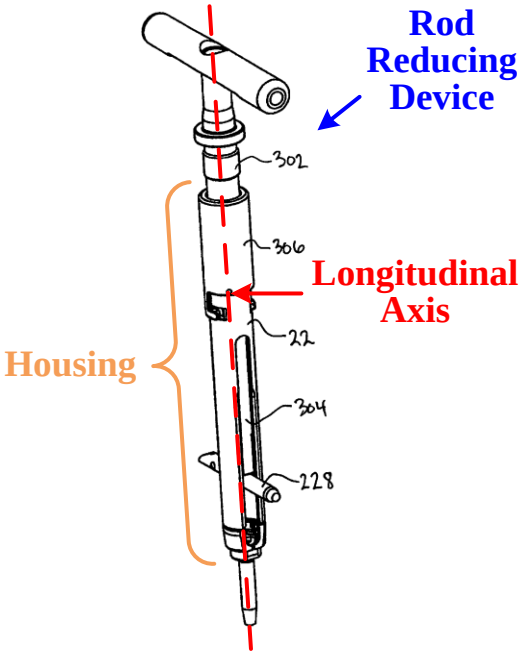


FIG. 31

Iott discloses the claimed "housing defining a longitudinal axis" as recited in claim 8. 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***." *Id.* (emphasis added); FIGS. 5, 30, 31 (annotated). Iott also discloses that sleeve 50 is one specific example of sleeve 22. *Id.* ¶ 55; FIG. 5, above. When considered together, the attachment sleeve 306 and the sleeve 22, 50 of Iott can reasonably be interpreted as being the claimed "housing."

In such arrangements, the "housing" of Iott defines the claimed "longitudinal axis." *Id.* FIG. 31 (annotated). For example, Iott discloses that the sleeve 22 comprises a ***longitudinal axis 208***. *Id.* ¶ 58; FIG. 18. Iott further discloses that the

sleeve 50 comprises "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***." *Id.* ¶ 55 (emphasis added); FIG. 5, above.

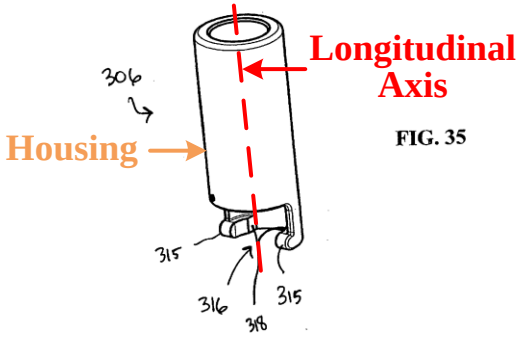


FIG. 35

Alternatively, other features of Iott can reasonably be interpreted as being the claimed "housing." For example, the ***attachment sleeve 306*** can separately be viewed as the claimed "housing" and, as shown above in annotated FIG. 35, the attachment sleeve 306 implicitly defines a longitudinal axis. ORT-1016 ¶ 120.

e. Limitation-[8-4]:

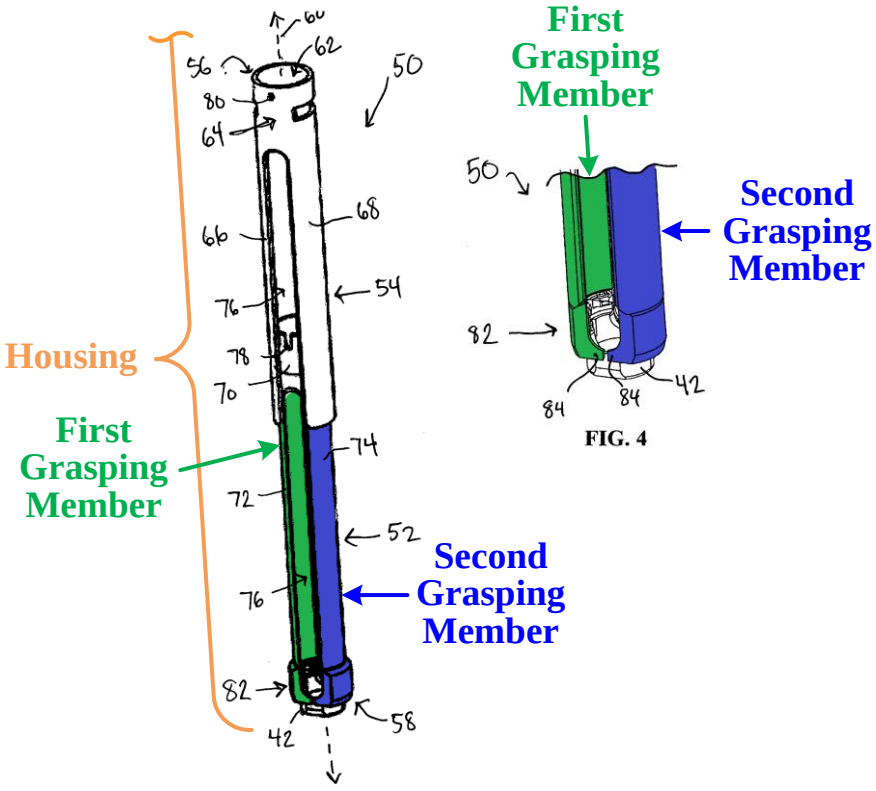


FIG. 4

FIG. 3

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 8. In particular, Iott discloses that in connection with the sleeve 50 (*i.e.*, a portion of the claimed *housing*), "***arms 72, 74*** of inner sleeve member 52 ***may be compressed radially inward or expanded radially outward*** depending on the particular application." ORT-1017 ¶ 56 (emphasis added); FIGS. 3-4, above (annotated).

Iott further states that "***when arms 72, 74*** of inner sleeve member 52 ***are compressed radially inward, the coupling element 42 of screw 32*** is rotationally

and axially ***fixed with respect to sleeve 50*** or radially contained within sleeve 50." *Id*. ¶ 57 (emphasis added).

f. Limitation-[8-5]:

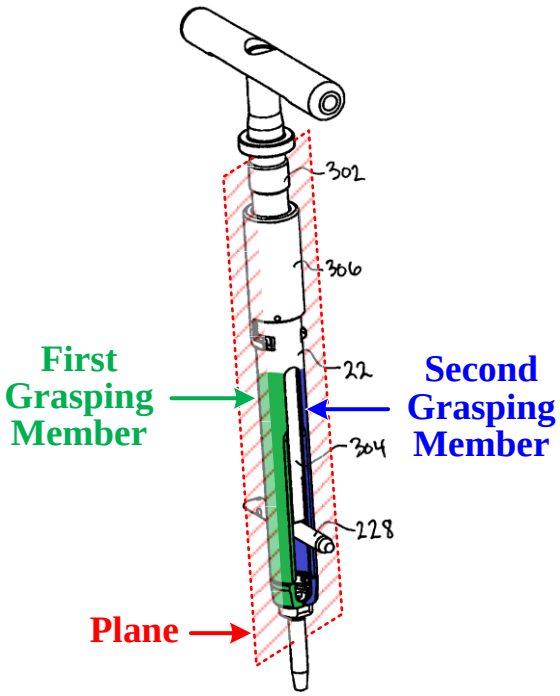


FIG. 31

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); ORT-1016 ¶¶ 124-125.

g. Limitation-[8-6]:

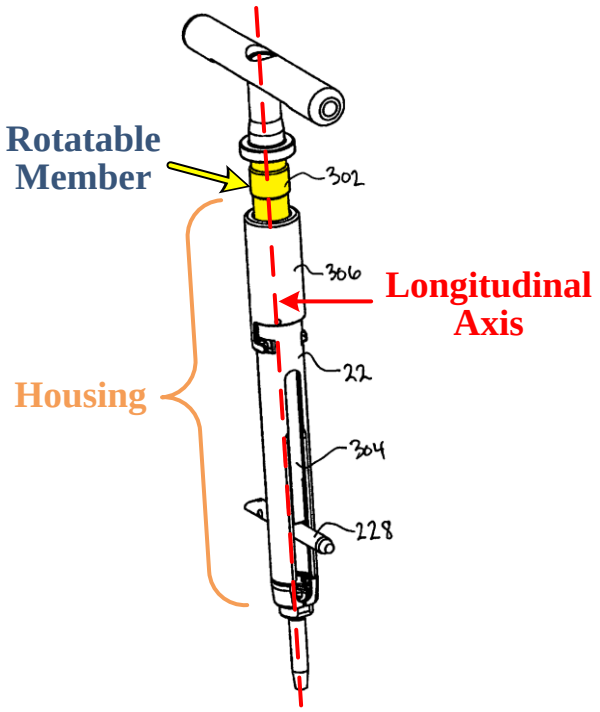


FIG. 31

Iott discloses the claimed "rotatable member extending through the housing along the longitudinal axis" as recited in claim 8. For example, Iott states that the "[r]od reducer instrument 300 generally comprises ***a rotation shaft 302***, a reducer shaft 304, and an attachment sleeve 306, configured to engage and attach to a proximal end of sleeve[ ] 22." ORT-1017 ¶ 70 (emphasis added); FIG. 31, above (annotated).

Iott further discloses "in operation, . . . ***shaft 302 is threadedly rotated*** with respect to ***attachment sleeve 306***." *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.

h. Limitation-[8-7]:

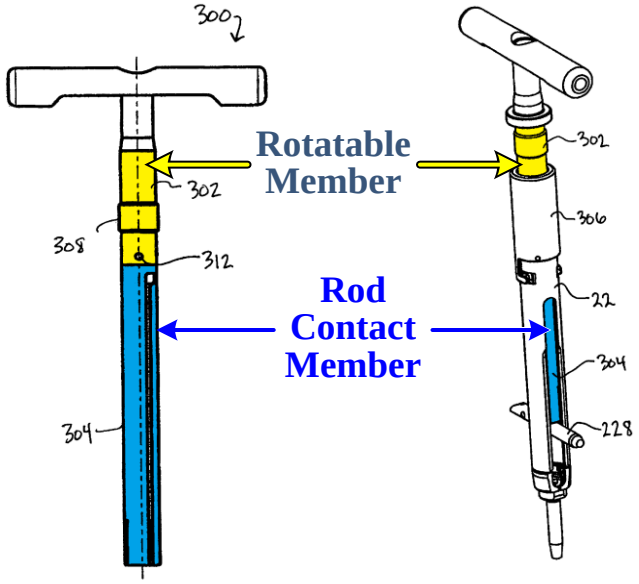


FIG. 30 FIG. 31

Iott discloses "a rod contact member positioned at a distal end of the rotatable member" as recited in claim 8. For example, Iott discloses "***[r]otation shaft 302*** 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 to reducer shaft 304***." *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 8.

i. Limitation-[8-8]:

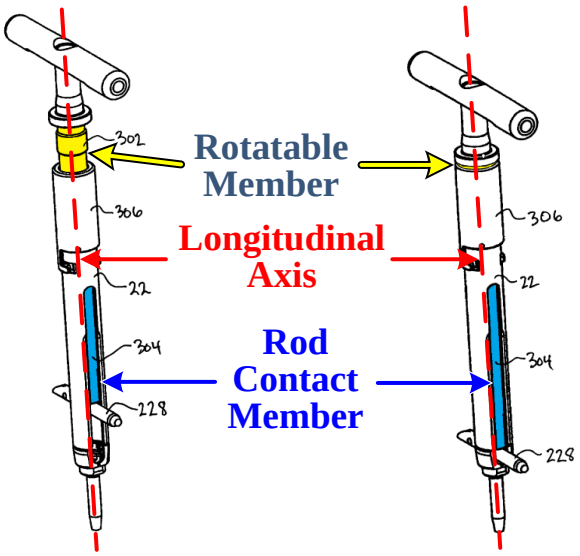


FIG. 31 FIG. 32

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 8. For example, Iott states "in operation, ***as shaft 302 is threadedly rotated*** with respect to attachment sleeve 306, ***reducer shaft 304 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 (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*).

j. Limitation-[8-9]:

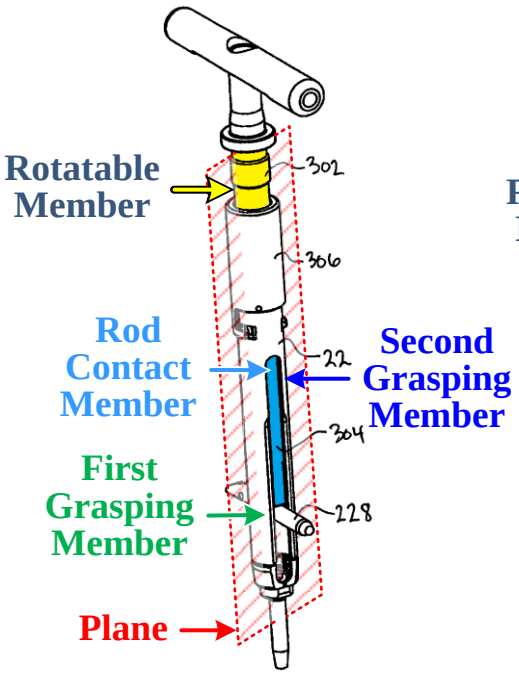


FIG. 31

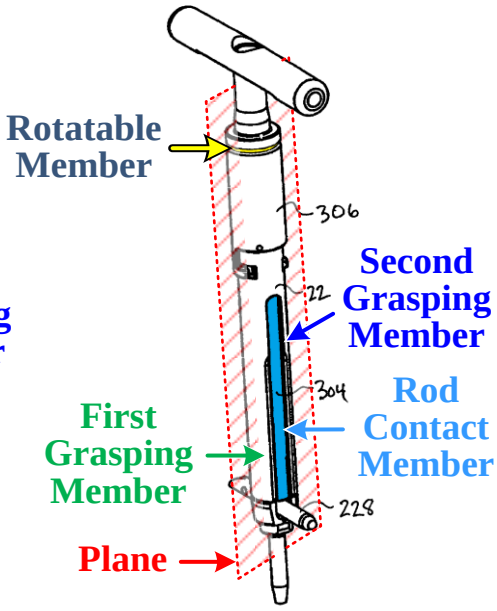


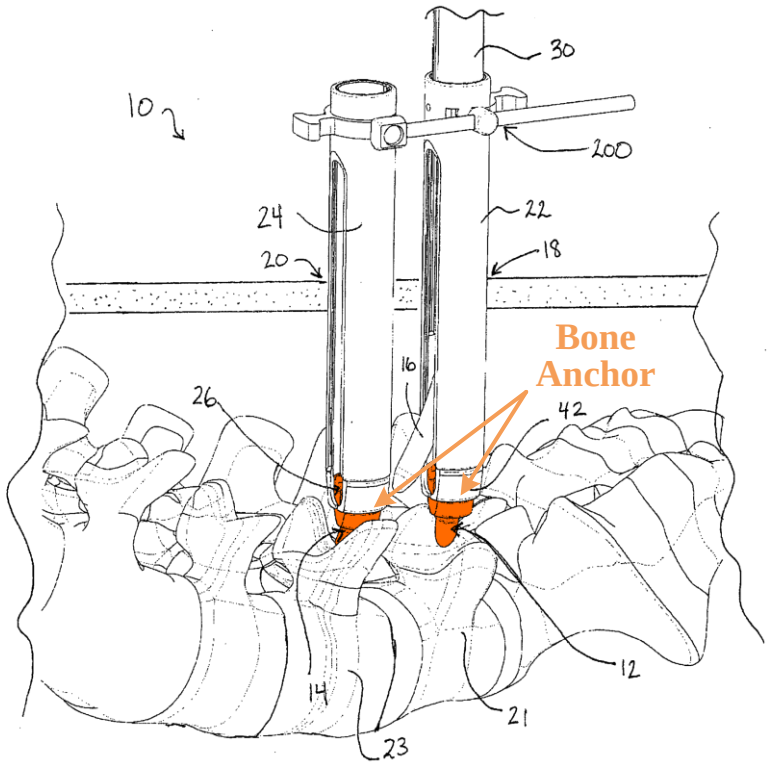
FIG. 32

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 8. For example, as discussed above, Iott discloses that "in operation, ***as shaft 302 is threadedly rotated*** with respect to attachment sleeve 306, ***reducer shaft 304 is translated in the axial direction***." *Id.* ¶ 71 (emphasis added); FIGS. 31, 32, 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.* FIGS. 31-32 (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. *Id.* FIGS. 31, 32, above (annotated).

6. Dependent Claim 9:

FIG. 1



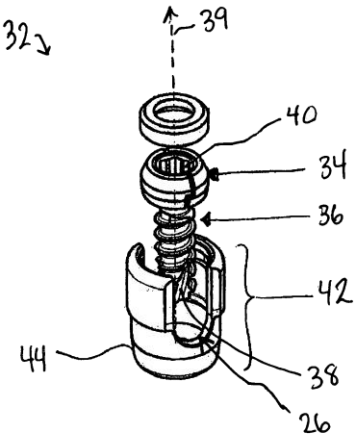


FIG. 2

Iott discloses the claimed "plurality of bone anchors," as recited in claim 9. For example, Iott discloses that "[e]ach of the ***first and second anchors 12, 14*** generally comprises a bone fastener such as a bone screw 32." *Id.* ¶ 53 (emphasis added); FIGS. 2, 31 (annotated).

Claim 9 further recites "a plurality of rod reducing devices." Claim 9 thus calls for the mere duplication of the rod reducing devices described in claim 8, but such a duplication does not have any patentable significance because it produces

no new or unexpected result. *See In re Harza*, 274 F.2d 669, 774 (CCPA 1960) ("It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced, and we are of the opinion that such is not the case here."); MPEP § 2144.04(VI)(B) (same).

7. Dependent Claim 10:

Iott discloses the claimed "at least one additional orthopedic tool selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device" as recited in claim 10. In particular, Iott discloses "***another driving tool*** may be inserted through rotation shaft 302 and lumen 320 of shaft 304 to rotationally engage a set screw and the set screw ***can then be tightened to secure the rod in place***." *Id.* ¶ 71 (emphasis added).

8. Independent Claim 12:

a. Limitation-[12-PRE]:

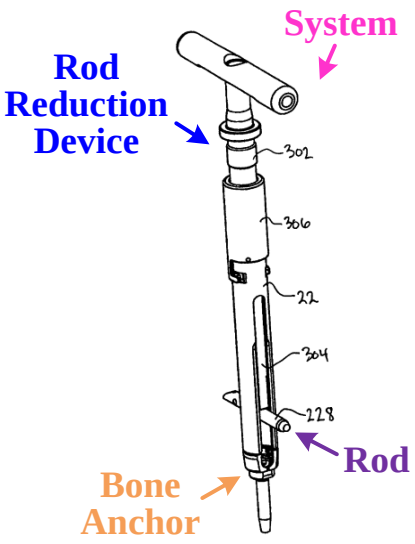


FIG. 31

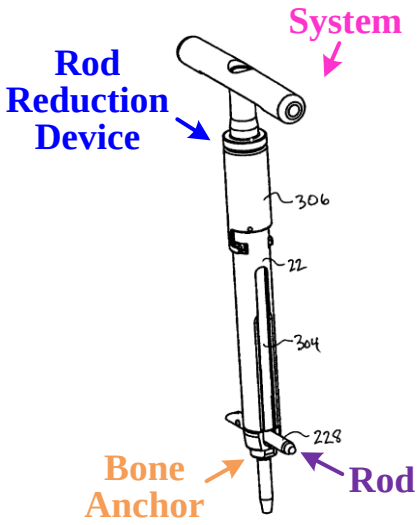


FIG. 32

Iott discloses the claimed "system for reducing a connecting rod" as recited in claim 12. In particular, Iott discloses percutaneous systems and "a rod reducer instrument 300 . . . configured and dimensioned to be utilized with the percutaneous systems," which include bone anchors. *Id.* ¶ 70; FIGS. 31-32, above (annotated). In doing so, Iott discloses all of the recited features of claim 12, each of which are discussed in more detail below.

b. Limitation-[12-1]:

As discussed in Section VIII(A)(5)(b) with respect to claim limitation [8-1], Iott discloses "a bone anchor" and therefore likewise discloses the identical claim limitation in claim 12.

c. Limitation-[12-2]:

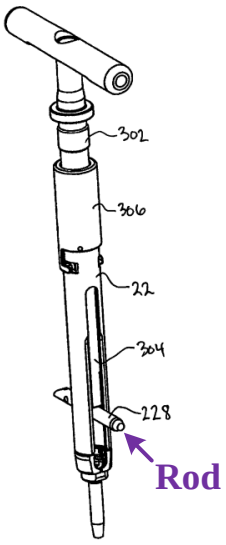


FIG. 31

Iott discloses the claimed "connecting rod" as recited in claim 12. In particular, Iott discloses ***a stabilization member 228***, which may be embodied as a rod. *Id.* ¶¶ 13, 64; FIG 31 (annotated).

d. Limitation-[12-3]:

As discussed in Section VIII(A)(5)(c) with respect to claim limitation [8-2] of claim 8, Iott discloses "a rod reducing device" and therefore likewise discloses claim limitation [12-3] of claim 12. Petitioner notes that claim limitation [8-2] recites "a rod ***reducing*** device" whereas claim limitation [12-3] recites "a rod ***reduction*** device." Petitioner submits that the specification of the '664 Patent uses "rod ***reducing*** device" and "rod ***reduction*** device" interchangeably to describe the *same* device. *See, e.g.*, ORT-1001 at 3:21-47, 3:65-66, 4:1-2, 7:24-50.

e. Limitation-[12-4]:

As discussed in Section VIII(A)(5)(d) with respect to claim limitation [8-3], Iott discloses "a housing defining a longitudinal axis" and therefore likewise discloses the identical claim limitation in claim 12.

f. Limitation-[12-5]:

As discussed in Section VIII(A)(5)(e) with respect to claim limitation [8-4], Iott discloses "the housing including first and second grasping members configured to grasp a portion of the bone anchor therebetween" and therefore likewise discloses the identical claim limitation in claim 12.

g. Limitation-[12-6]:

As discussed in Section VIII(A)(5)(f) with respect to claim limitation [8-5], Iott discloses "the first and second grasping members defining a plane" and therefore likewise discloses the identical claim limitation in claim 12.

h. Limitation-[12-7]:

As discussed in Section VIII(A)(5)(g) with respect to claim limitation [8-6], Iott discloses "a rotatable member extending through the housing along the longitudinal axis" and therefore likewise discloses the identical claim limitation in claim 12.

i. Limitation-[12-8]:

As discussed in Section VIII(A)(5)(h) with respect to claim limitation [8-7], Iott discloses "a rod contact member positioned at a distal end of the rotatable member" and therefore likewise discloses the identical claim limitation in claim 12.

j. Limitation-[12-9]:

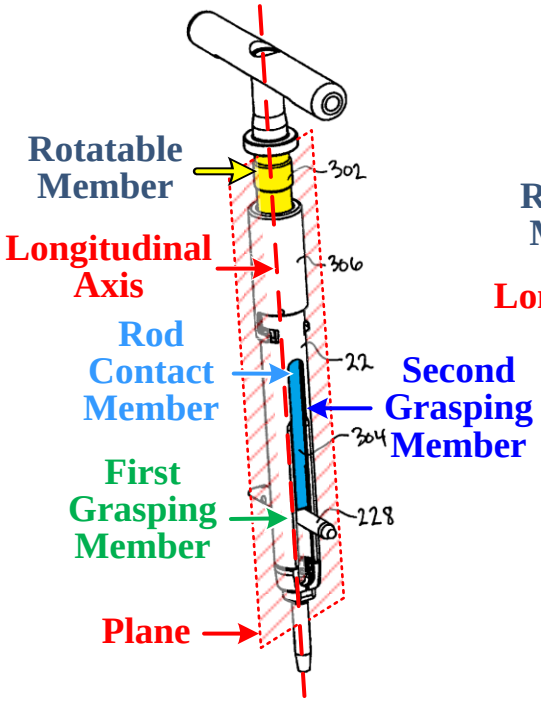


FIG. 31

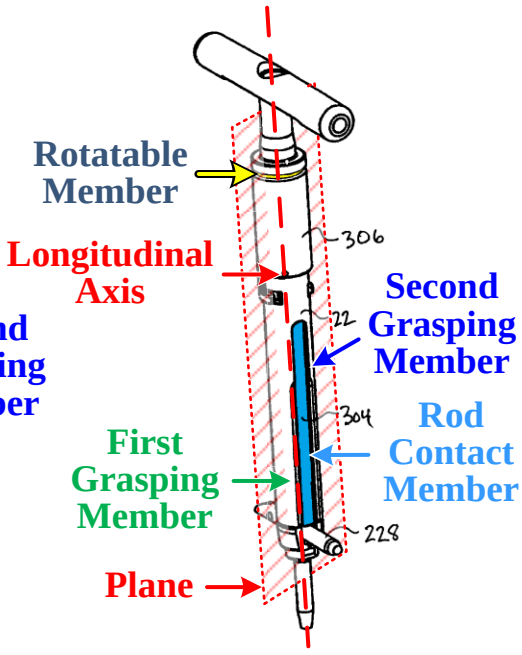


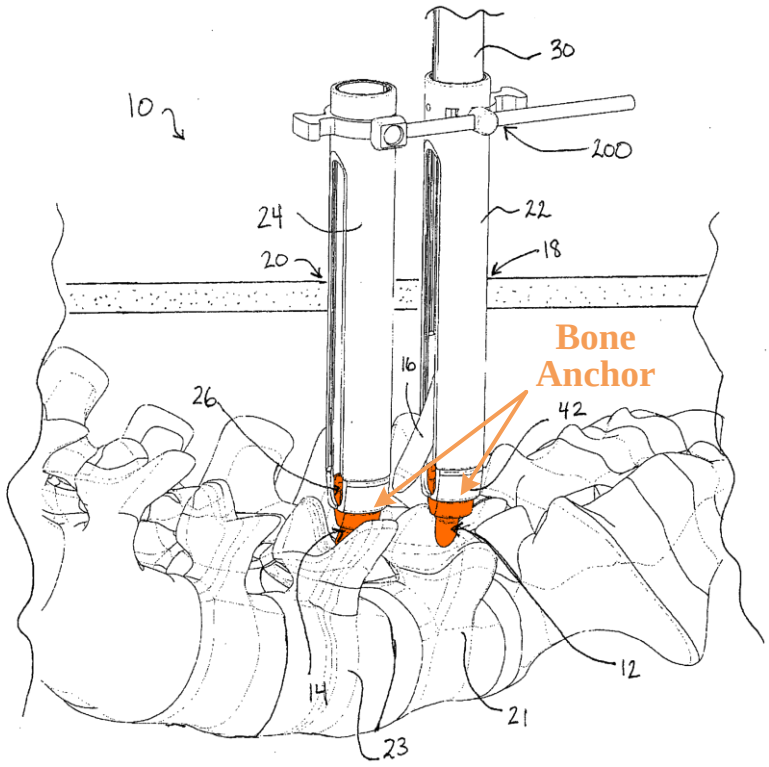
FIG. 32

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 12. For example, as discussed above, Iott discloses that "in operation, ***as shaft 302 is threadedly rotated*** with respect to attachment sleeve 306, ***reducer shaft 304 is translated in the axial direction***." ORT-1017 ¶ 71 (emphasis added); FIGS. 31, 32, 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.* FIGS. 31, 32, 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. *Id.* FIGS. 31, 32, above (annotated).

9. Dependent Claim 15:

FIG. 1



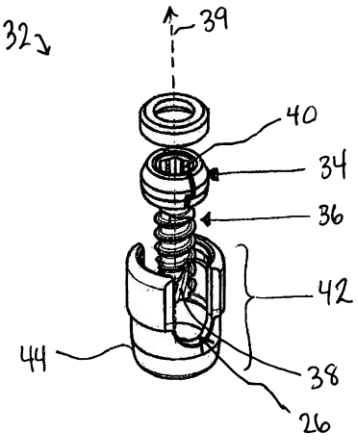


FIG. 2

Iott discloses the claimed "plurality of bone anchors," as recited in claim 15. For example, Iott discloses that "[e]ach of the ***first and second anchors 12, 14*** generally comprises a bone fastener such as a bone screw 32." *Id.* ¶ 53 (emphasis added); FIGS. 2, 31 (annotated).

Claim 15 further recites "a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors." Claim 15 thus calls for the mere

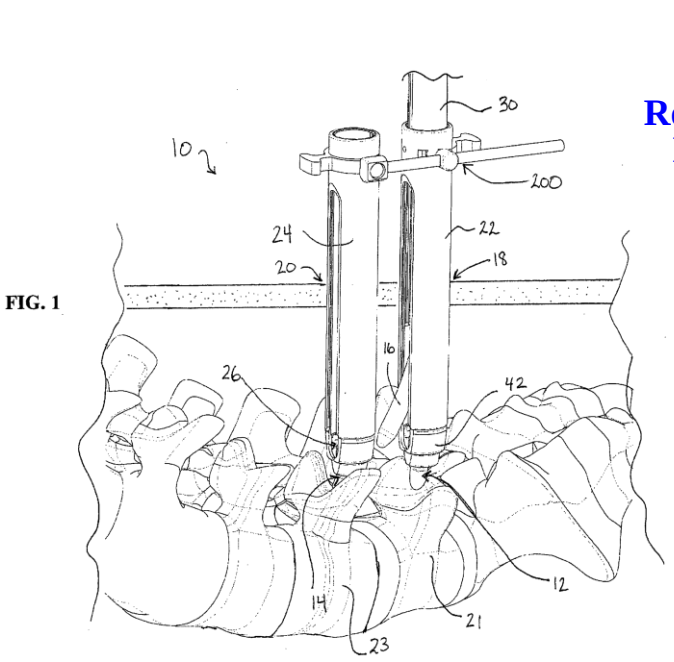
duplication of the rod reduction device described in claim 12, but such a duplication does not have any patentable significance because it produces no new or unexpected result. *See In re Harza*, 274 F.2d at 774 ("It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced, and we are of the opinion that such is not the case here."); MPEP § 2144.04(VI)(B) (same).

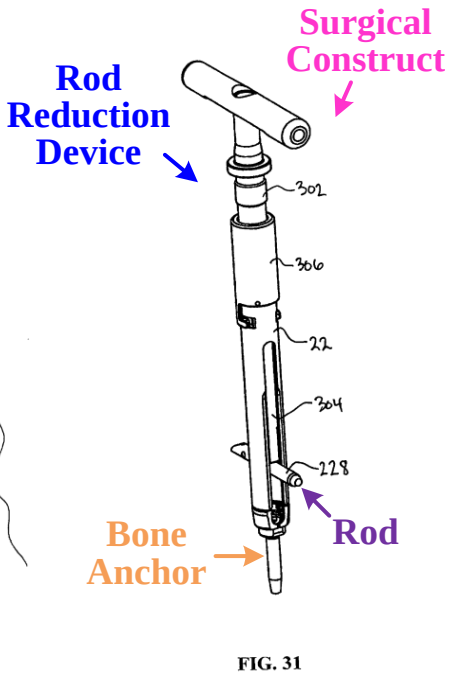
10. Dependent Claim 16:

Iott discloses the claimed "additional orthopedic tool or device selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device" as recited in claim 16. In particular, Iott discloses "***another driving tool*** may be inserted through rotation shaft 302 and lumen 320 of shaft 304 to rotationally engage a set screw and the set screw ***can then be tightened to secure the rod in place***." *Id.* ¶ 71 (emphasis added).

11. Independent Claim 17:

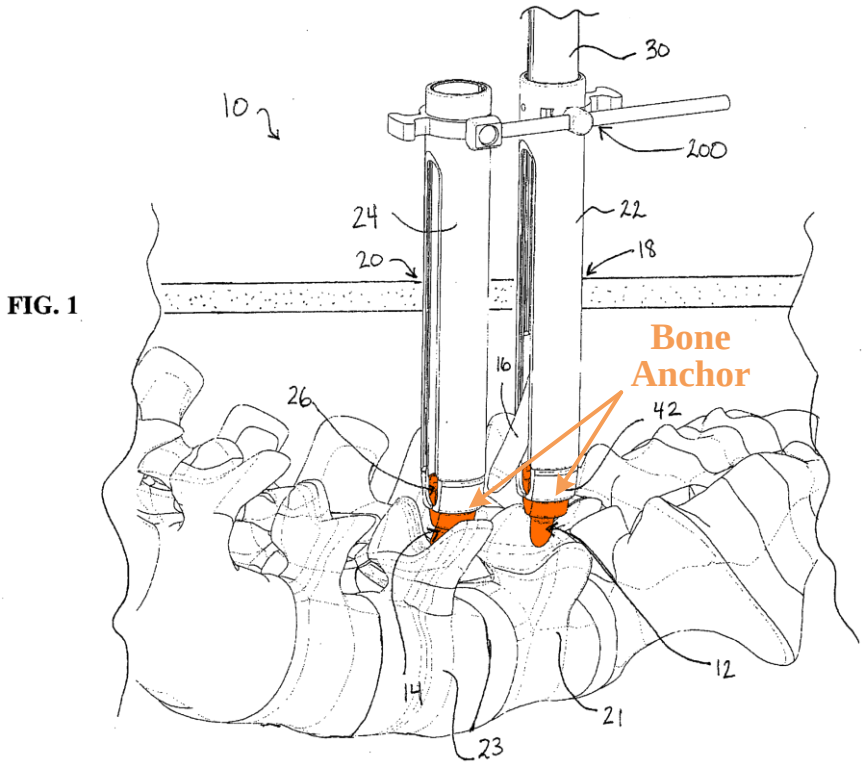
a. Limitation-[17-PRE]:





Iott discloses the claimed "a surgical construct" as recited in claim 17. In particular, Iott discloses percutaneous systems and "a rod reducer instrument 300 . . . configured and dimensioned to be utilized with the percutaneous systems," which include bone anchors. *Id.* ¶¶ 51, 70; FIGS. 1, 31 (annotated).

b. Limitation-[17-1]:



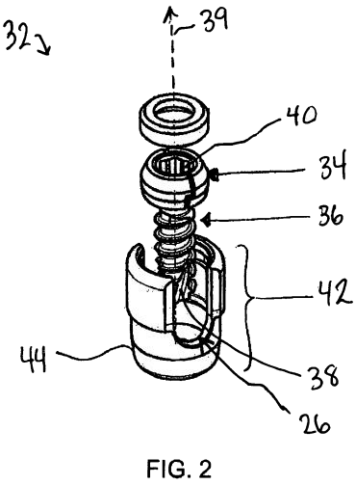


FIG. 2

Iott discloses the claimed "plurality of bone anchors." For example, Iott discloses that "[e]ach of the ***first and second anchors 12, 14*** generally comprises a bone fastener such as a bone screw 32." *Id.* ¶ 53 (emphasis added); FIGS. 2, 31 (annotated).

c. Limitation-[17-2]:

As discussed in Section VIII(A)(8)(c) with respect to claim limitation [12-2], Iott discloses "a connecting rod" and therefore likewise discloses the identical claim limitation in claim 17.

d. Limitation-[17-3]:

Claim 17 further recites "a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors." Claim 17 thus calls for the mere duplication of rod reducing devices, but such a duplication does not have any patentable significance because it produces no new or unexpected result. *See In re Harza*, 274 F.2d at 774 ("It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced, and we are of the opinion that such is not the case here."); MPEP § 2144.04(VI)(B) (same).

As discussed in Sections VIII(A)(5)(c) and VIII(A)(1)(b) with respect to claim limitations [8-2] and [1-1], respectively, Iott discloses "a rod reducing device"[5] and "coupling a rod reducing device to a bone anchor." Since the mere duplication of a rod reducing device lacks any patentable significance, Iott likewise discloses the claimed "plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors" as recited in claim 17.

[5] As discussed above, the specification of the '664 Patent uses "rod ***reducing*** device" and "rod ***reduction*** device" interchangeably to describe the *same* device.

e. Limitation-[17-4]:

As discussed in more detail below, Iott discloses rod reduction device(s)[6] including all of the recited features of claim 17.

f. Limitation-[17-5]:

As discussed in Section VIII(A)(5)(d), Iott discloses "a housing defining a longitudinal axis" and therefore likewise discloses the identical claim limitation in claim 17.

g. Limitation-[17-6]:

As discussed in Section VIII(A)(5)(e), Iott discloses "the housing including first and second grasping members configured to grasp a portion of the bone anchor therebetween" and therefore likewise discloses the identical claim limitation in claim 17.

h. Limitation-[17-7]:

As discussed in Section VIII(A)(5)(f), Iott discloses "the first and second grasping members defining a plane" and therefore likewise discloses the identical claim limitation in claim 17.

---

[6] As discussed, the mere duplication of rod reduction devices in claim 17 (*i.e.*, the claimed *plurality of rod reduction devices*) does not have any patentable significance because it produces no new or unexpected result. *See, e.g.*, *In re Harza*, 274 F.2d at 774; MPEP § 2144.04(VI)(B)

i. Limitation-[17-8]:

As discussed in Section VIII(A)(5)(g), Iott discloses "a rotatable member extending through the housing along the longitudinal axis" and therefore likewise discloses the identical claim limitation in claim 17.

j. Limitation-[17-9]:

As discussed in Section VIII(A)(5)(h), Iott discloses "a rod contact member positioned at a distal end of the rotatable member" and therefore likewise discloses the identical claim limitation in claim 17.

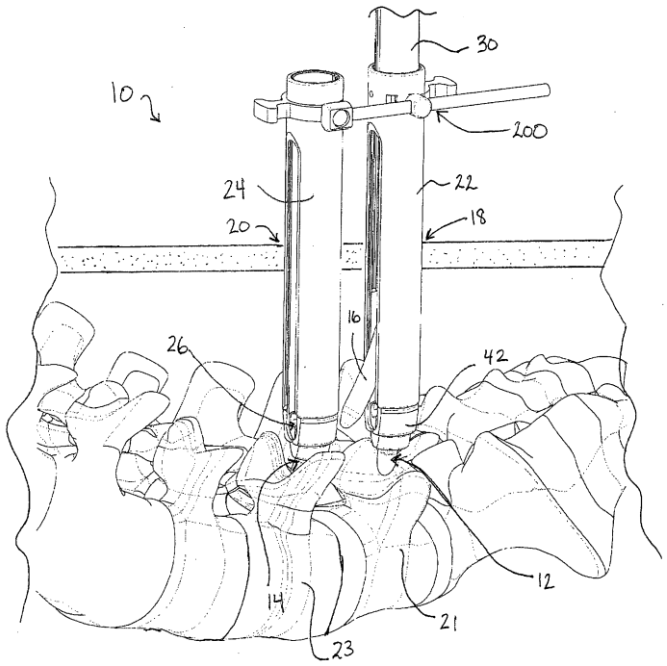
k. Limitation-[17-10]:

As discussed in Section VIII(A)(8)(j), Iott discloses "the rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis" and therefore likewise discloses the identical claim limitation in claim 17.

12. Depdendent Claim 18:

a. Limitation-[18-1]:

FIG. 1



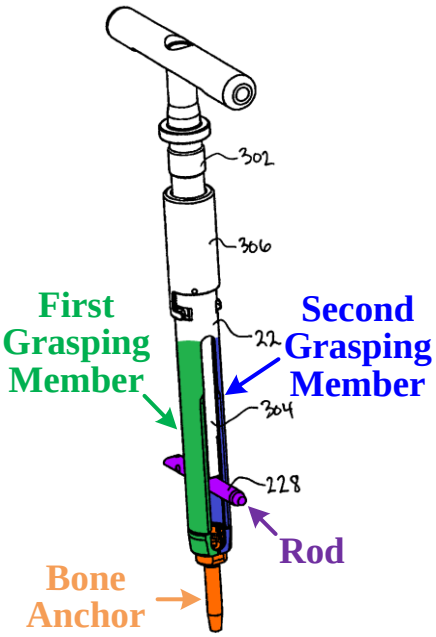


FIG. 31

Iott discloses the claimed "wherein the connecting rod is disposed between the first and second grasping members of the plurality of the rod reduction devices with the plurality of rod reduction devices mounted to the respective bone anchors of the plurality of bone anchors" as recited in claim 18. In particular, Iott discloses that "***as shaft 302 is threadedly rotated*** . . ., ***reducer shaft 304 is translated*** . . . providing a force . . . 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 at the distal end of sleeves 22, 24." *Id*. ¶ 71 (emphasis added); FIGS. 1, 31 (annotated). Furthermore, as shown above in annotated FIG. 31, Iott discloses the

stabilization member 228 positioned between the arms 72, 74 (*i.e.*, the claimed *first and second grasping members*) of the sleeve 22.

b. Limitation-[18-2]:

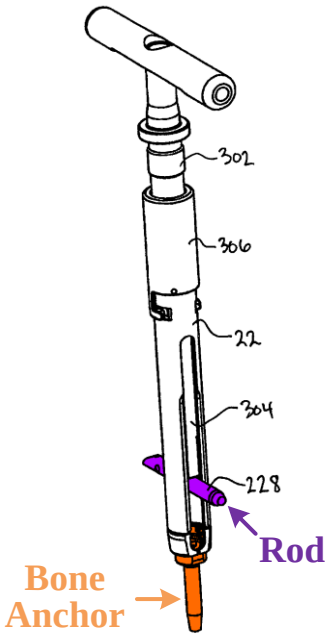


FIG. 31

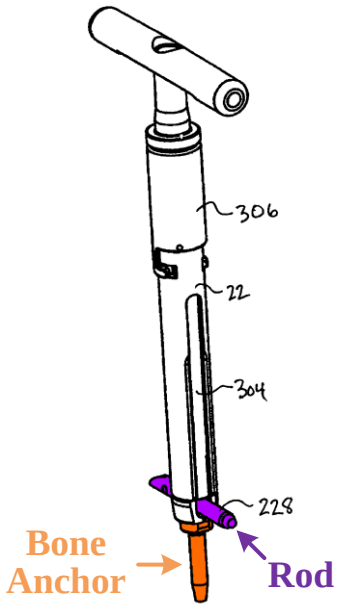


FIG. 32

Iott discloses the claimed "whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors" as recited in claim 18. In particular, Iott discloses that "***as shaft 302 is threadedly rotated*** . . ., ***reducer 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); FIGS. 31-32 (annotated).

13. Dependent Claim 19:

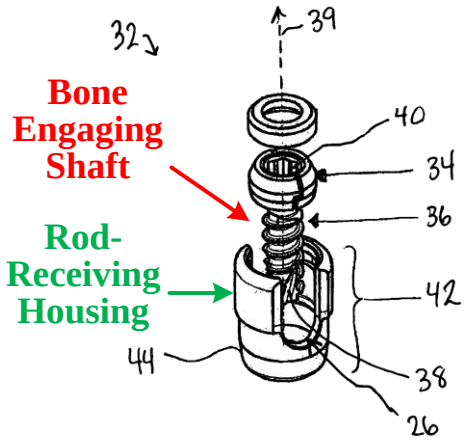


FIG. 2

Iott discloses the claimed "each bone anchor further comprises a rod receiving housing and a bone engaging shaft extending therefrom" as recited in claim 17. In particular, Iott discloses that "[e]ach of the ***first and second anchors 12, 14*** generally comprises a bone fastener such as a bone screw 32 with a head 34 and ***a shaft or shank 36 having bone engaging threads***. " *Id.* ¶ 53 (emphasis added); FIG. 2 (annotated). Iott further discloses that in connection with the bone screw 32, "coupling element 42 includes a ***U-shaped body 44*** defining a channel 26 in which ***stabilization member 16*** may be locked or fixed in place." *Id.* ¶ 54; FIG. 2 (annotated).

B. Ground 2: Claims 9, 15, and 17-19 Are Rendered Obvious by Iott in View of Justis

Claims 9, 15, and 17-19 of the '664 Patent are also rendered obvious by Iott in view of Justis. Justis was filed on February 7, 2006 and published on September 13, 2007. ORT-1018 at 1. Therefore, Justis is prior art under at least 35 U.S.C.

§ 102(e).[7] Like Iott, Justis was never cited nor considered by the Examiner during prosecution of the '664 Patent.[8] ORT-1001 at 1-2; *see also* ORT-1002.

As discussed, Iott discloses surgical systems and methods for stabilizing a portion of a patient's vertebrae. *See, e.g.,* ORT-1017 ¶¶ 2, 51. To do so, the surgical systems and methods disclosed by Iott include the use of a rod reducing instrument 300 configured to force a spinal rod downward into a housing of a bone anchor 12, 14 *See, e.g., id.* ¶¶ 53, 70-71; FIGS. 31-32.

[7] The 35 U.S.C. § 102(e) critical reference date of Justis is at least as early as its filing date of February 7, 2006.

[8] Justis was also never cited nor considered by the Examiner during prosecution of the parent patents—the '816 and '523 Patents. *See, e.g.,* ORT-1004; ORT-1006.

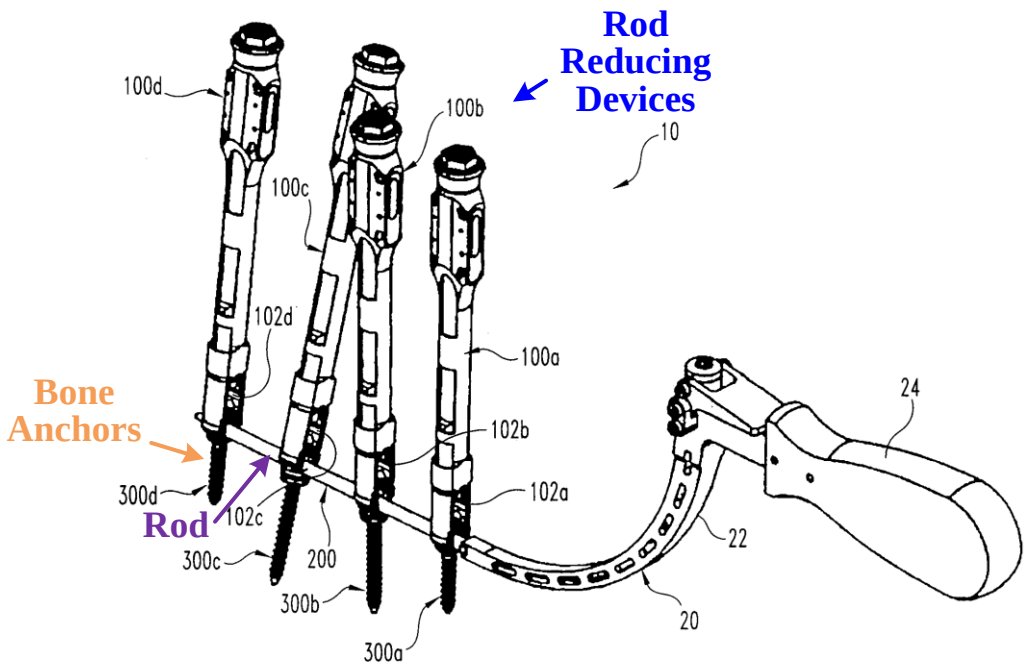


Fig. 3

Similar to Iott, Justis discloses minimally invasive systems and methods for positioning a connecting element adjacent the spinal column. ORT-1018 ¶ 5. For example, Justis discloses the use of a plurality of anchor extensions 100 with reduction capability (*e.g.*, rod reducing devices) configured to seat or otherwise position an elongated connecting element 200 (*e.g.*, a rod) into the receiving portions of releaseably mounted bone anchors 300. *See, e.g., id.* ¶¶ 31, 37-38; FIG. 3 (annotated).

Iott and Justis each disclose rod reducing devices and methods for advancing spinal rods into bone anchors along the spine. ORT-1016 ¶ 227. As such, it would have been obvious to a POSITA to use a plurality of the rod reducing devices of

Iott with the kit of Justis comprising a plurality of bone anchors. *Id*. Such an arrangement would enable a surgeon to separately adjust the position of the connecting rod relative to any one of the plurality of bone anchors. *Id*. ¶¶ 231-232.

1. Dependent Claim 9:

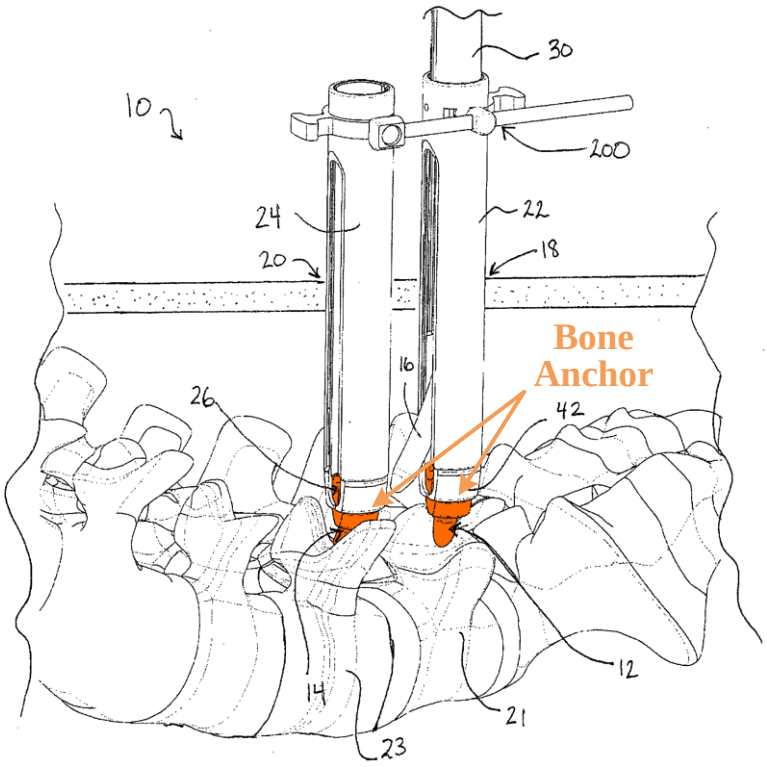


FIG. 1

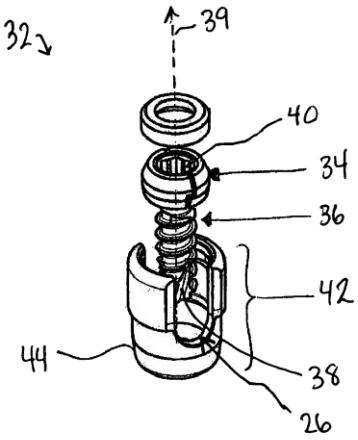


FIG. 2

Iott discloses the claimed "plurality of bone anchors," as recited in claim 9. For example, Iott discloses that "[e]ach of the ***first and second anchors 12, 14*** generally comprises a bone fastener such as a bone screw 32." ORT-1017 ¶ 53 (emphasis added); FIGS. 2, 31 (annotated).

Claim 9 further recites "a plurality of rod reducing devices." As discussed above in Section VIII(A)(5)(c) with respect to claim limitation [8-2], Iott discloses "a rod reducing device." Should it be determined that a *plurality* of rod reducing

devices is not explicitly or implicitly disclosed by Iott, and if the Board concludes that merely duplicating the rod reducing device of claim 8 provides patentable significance, Petitioner submits that, as discussed above in Section VIII(A)(6), such feature is disclosed by Justis. ORT-1016 ¶¶ 225-227.

2. Dependent Claim 15:

As discussed in Section VIII(B)(1), Iott in view of Justis discloses "a plurality of bone anchors" and "a plurality of rod reduction devices" and, therefore, likewise discloses the identical claim limitations in claim 15.

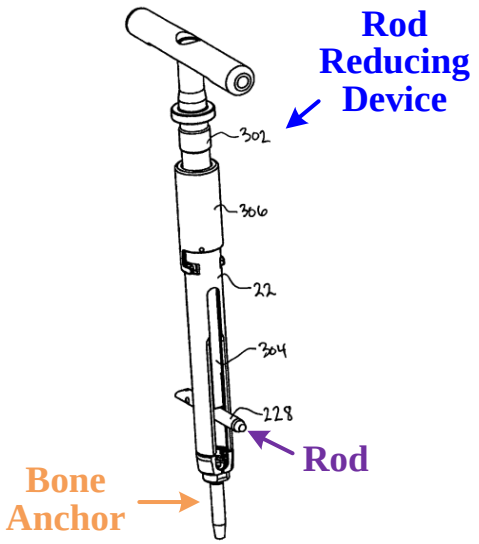


FIG. 31

Claim 15 also recites that "each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors." As discussed above in Section VIII(A)(5), and depicted above in annotated FIG. 31, Iott discloses a rod reducing device attached or mounted to a bone

anchor.[9] *See also* ORT-1017 ¶ 56; FIG. 4. It therefore follows that, similar to the rod reduction device disclosed by Iott, each of the plurality of rod reduction devices disclosed by Iott in view of Justis would likewise be mountable to a respective bone anchor. Therefore, Iott and Justis teach the all the claim limitations of claim 15.

3. Independent Claim 17:

As discussed in Section VIII(A)(11), Iott discloses each of the limitations of claim 17 (*i.e.*, claim limitations [17-PRE] through [17-10]). With respect to claim limitation [17-3], it was asserted that Iott discloses, at least singularly, "a rod reduction device," where the rod reduction device is "connectable to a bone anchor of the plurality of bone anchors." *See also* Sections VIII(A)(1)(b), VIII(A)(5)(c), above.

Further, for the same reasons discussed above in Section VIII(B)(1), it would have been obvious to a POSITA to use a plurality of the rod reducing devices of Iott, as taught by Justis, for reducing a rod. Therefore, Iott and Justis teach the claim limitation [17-3], and thus, all the claim limitations of independent claim 17.

[9] As discussed above, the specification of the '664 Patent uses "rod ***reducing*** device" and "rod ***reduction*** device" interchangeably to describe the *same* device.

4. Dependent Claim 18:

a. Limitation-[18-1]:

As discussed in Section VIII(A)(12)(a), Iott discloses the claimed "wherein the connecting rod is disposed between the first and second grasping members of the plurality of the rod reduction devices with the plurality of rod reduction devices mounted to the respective bone anchors of the plurality of bone anchors" as recited in claim 18.

b. Limitation-[18-2]:

As discussed in Section VIII(A)(12)(b), Iott discloses that "whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors" as recited in claim 18.

5. Dependent Claim 19:

As discussed in Section VIII(A)(13), Iott discloses that "each bone anchor further comprises a rod receiving housing and a bone engaging shaft extending therefrom, each rod reduction device of the plurality of rod reduction devices approximating the connecting rod toward the rod receiving housing of the bone anchor" as recited in claim 19.

C. Ground 3: Claims 8, 10, 12, and 16 Are Rendered Obvious by Sparker in View of the DePuy Catalogs

Claims 8, 10, 12, and 16 of the '664 Patent are also rendered obvious by Sparker in view of the DePuy 1998 Catalog, the DePuy 1999 Catalog, and the DePuy 2002 Catalog, or collectively, the "DePuy Catalogs."

As Sparker was filed on July 13, 1992 and published on April 19, 1994, Sparker is prior art under at least 35 U.S.C. § 102(b) and was never cited nor considered by the Examiner during prosecution of the '664 Patent. ORT-1001 at 1-2.

Sparker recites a "combined hook holder and rod mover for spinal surgery." ORT-1019 at Title, Claim. FIGS. 1-7 of Sparker show the construction of the same, and in association with the Title and Claim language, it would have been understood by a POSITA that the combined hook holder and rod mover for spinal surgery functions as a rod reducing device. ORT-1016 ¶ 30. As discussed, a POSITA would have understood Sparker's rod reducing device would connect to a head (housing) of a bone anchor along a spine and be used to advance a rod into this head. *Id*. ¶¶ 259-260.

The DePuy Catalogs are authentic, at a minimum, under Fed. R. Evid. 901(a) because Petitioner has produced "evidence sufficient to support a finding that the item is what the proponent claims it is"—*i.e.*, the catalogs were produced by DePuy in response to a subpoena requesting "prior art" for the '664 Patent,

including "operating manuals, service manuals, surgical techniques, [and] brochures." *See* ORT-1025 ¶¶ 2-5. Moreover, each catalog bears DePuy's name, trademark, address, phone number, and a copyright notice. As such, each catalog is also self-authenticating under Fed. R. Evid. 902(7) because they all bear "[a]n inscription, sign, tag, or label purporting to have been affixed in the course of business and indicating origin, ownership, or control."

For the same reasons, the catalogs are excluded by the rule against hearsay. Given the circumstances under which Petitioner obtained the catalogs, there are no legitimate issues of trustworthiness and there was no better way (than subpoena) to obtain the catalogs. *See* Fed. R. Evid. 807. Nevertheless, the catalogs are expressly excluded under Fed. R. Evid. 803(17) because they "are generally relied on by the public or by persons in particular occupations." *See* ORT-1016 ¶¶ 35, 41, 48; *United States v. Grossman*, 614 F.2d 295, 297 (1st Cir. 1980) ("under Rule 803(17) … the trial judge could properly have admitted the catalog as a commercial publication").

The DePuy 1998 Catalog was published in December 1998. ORT-1020 at DEPUY-0000026. The DePuy 1999 Catalog was published in September 1999. ORT-1021 at DEPUY-0000010. The DePuy 2002 Catalog was published in March 2002. ORT-1022 at DEPUY-0000060. Thus, each of the DePuy catalogs was published more than one year prior to the '664 Patent's earliest filing date of

July 13, 2007. Therefore, the DePuy Catalogs are prior art under at least 35 U.S.C. § 102(b). None of the DePuy Catalogs were cited or considered by the Examiner during prosecution of the '664 Patent. ORT-1001 at 1-2.

The DePuy Catalogs are product catalogs for spine systems of DePuy, such as "ISOLA®/VSP® Spine Systems," and the catalogs disclose kits and systems for spinal surgery. *See, e.g.*, ORT-1020 at DEPUY-0000011 – DEPUY-0000026; ORT-1021 at DEPUY-0000001 – DEPUY-0000010; and ORT-1022 at DEPUY-0000037 – DEPUY-0000060. Each of the catalogs discloses, among other items, rod reducing devices, spinal rods, spinal hooks, pedicle screws, and several instruments for use therewith. *See, e.g.*, ORT-1020 at DEPUY-0000013, DEPUY-0000014, and DEPUY-0000021; ORT-1021 at DEPUY-0000002, DEPUY-0000003, and DEPUY-0000006; and ORT-1022 at DEPUY-0000040, DEPUY-0000044, and DEPUY-0000050; ORT-1016 ¶¶ 248, 281.

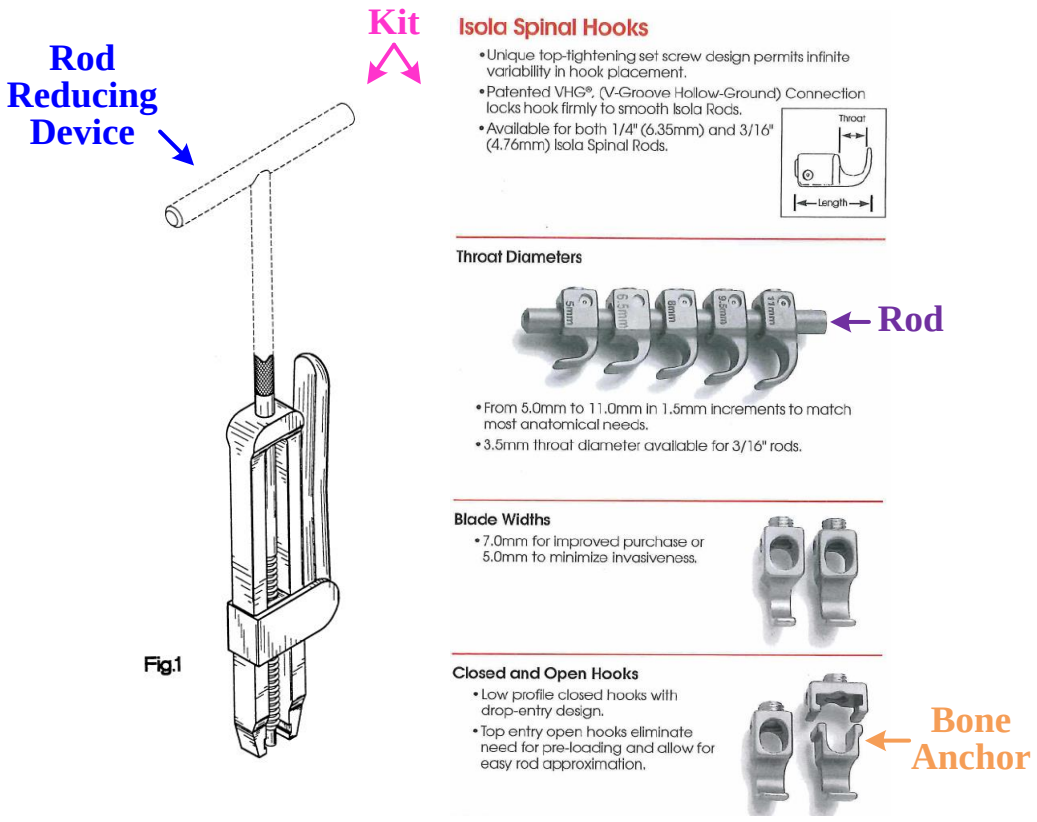
Not only are Sparker and the DePuy Catalogs directed to rod reducers used to advance spinal rods into bone anchors during spinal surgery, the DePuy 2002 Catalog lists "Des. 346,217" (*i.e.*, Sparker) among "patents [that] apply to ISOLA Instruments and Implants" and includes, among its "Hook Instruments," a rod reducing device labelled as "2050-63 CamLok Open Hook/Rod Approximator," which appears to be substantially similar, if not identical, to Sparker's rod reducing

device. ORT-1022 at DEPUY-0000050 and DEPUY-0000060. *See also* ORT-1020 at DEPUY-0000021; ORT-1021 at DEPUY-0000006; and ORT-1016 ¶ 249.

Accordingly, it would have been obvious to a POSITA to combine the DePuy Catalogs with Sparker.

1. Independent Claim 8:

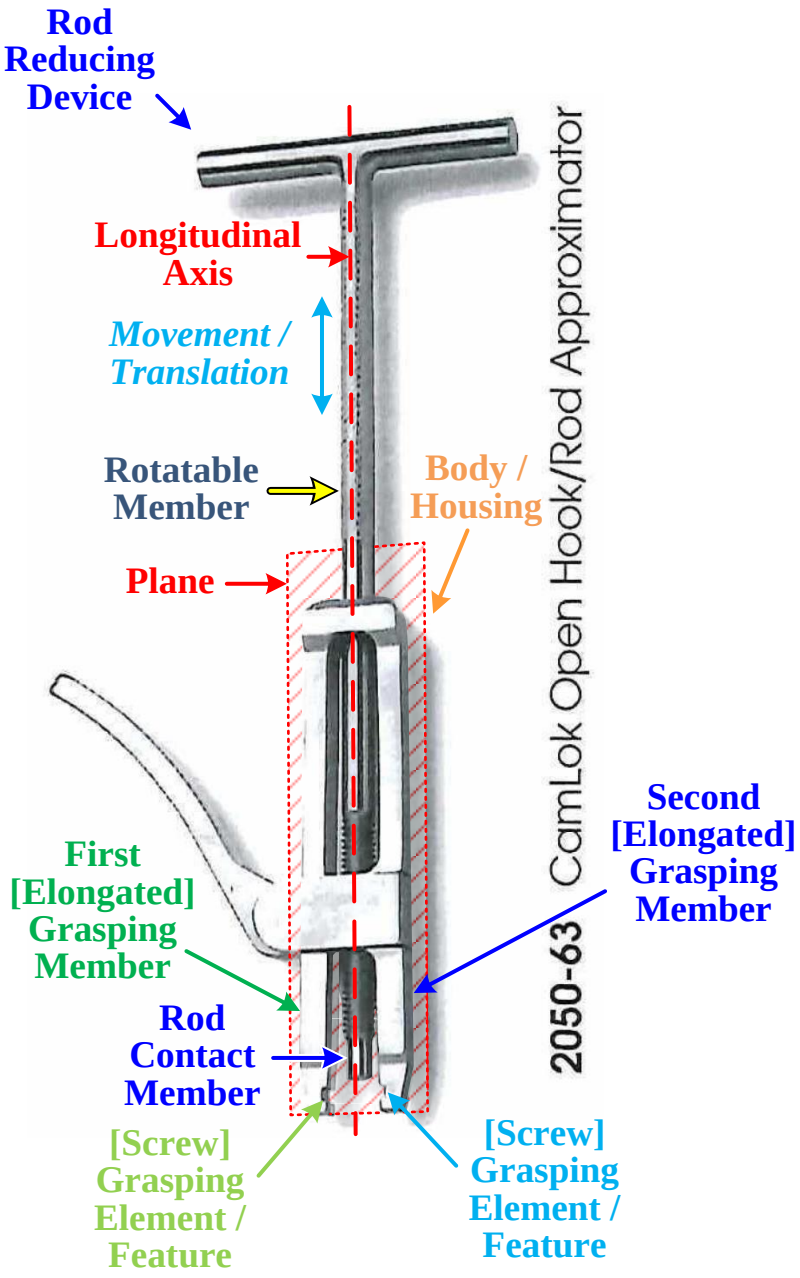
a. Limitation-[8-PRE]



The combination of Sparker and the DePuy Catalogs teaches "a kit for reducing a rod" as recited in claim 8. As shown in annotated FIG. 1, and as discussed in Section VIII(C), the "combined hook holder and rod mover for spinal surgery" of Sparker is a rod reducing device. *See also* ORT-1016 ¶¶ 246-247.

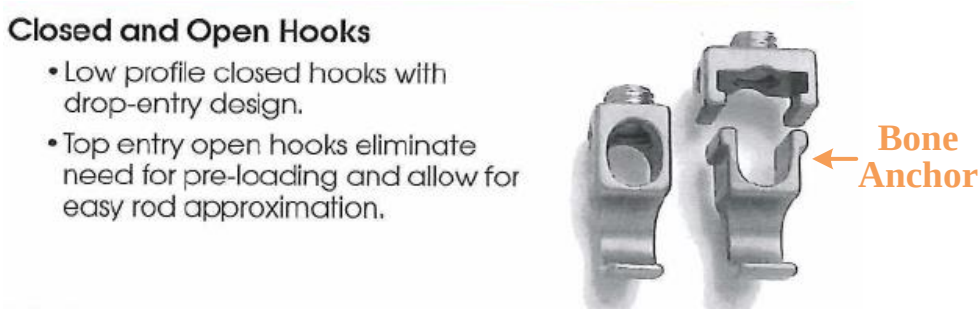
As discussed in this Ground, the DePuy Catalogs disclose kits and systems for spinal surgery, including "2050-63 CamLok Open Hook/Rod Approximator," which is a rod reducing device for advancing spinal rods (*e.g.*, Item No. 5000-1518) into receiving housings of bone anchors (*e.g.*, Item No. 5000-293). *See, e.g.*, ORT-1022 at DEPUY-0000037 – DEPUY-0000060; ORT-1016 ¶ 248.

As the annotated figure below illustrates, item no. "2050-63 CamLok Open Hook/Rod Approximator" of the DePuy Catalogs includes all the limitations of the claimed rod reducing device. *See, e.g.*, ORT-1020 at DEPUY-0000032; ORT-1021 at DEPUY-0000006; and ORT-1022 at DEPUY-0000050. *See also* ORT-1016 ¶ 249.



Accordingly, the DePuy Catalogs disclose a kit for reducing a rod. ORT-1016 ¶ 248.

b. Limitation-[8-1] "a bone anchor"

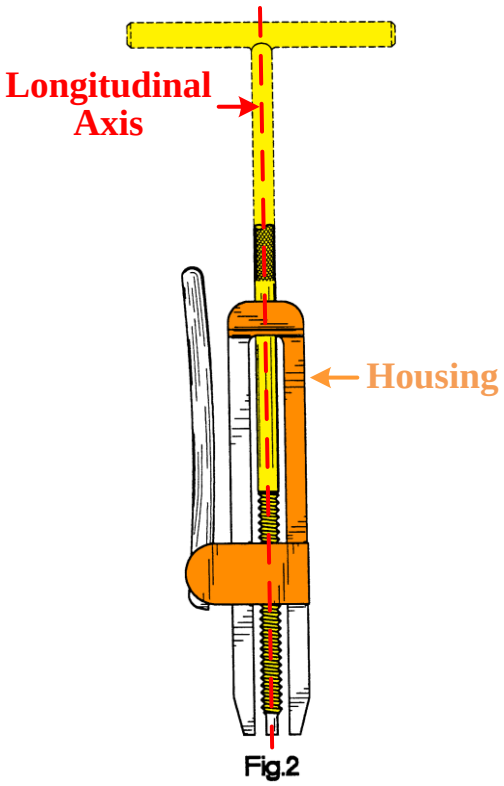


The combination of Sparker and the DePuy Catalogs teaches the "bone anchor" as recited in claim 8. As discussed, the DePuy Catalogs disclose a variety of spinal hooks, including open hooks (*e.g.*, Item No. 5000-293) and pedicle screws, such that the combination teaches a plurality of bone anchors. *See, e.g.*, ORT-1020 at DEPUY-0000013; ORT-1021 at DEPUY-0000003; and ORT-1022 at DEPUY-0000044; *see also* ORT-1016 ¶¶ 250-252.

c. Limitation-[8-2]:

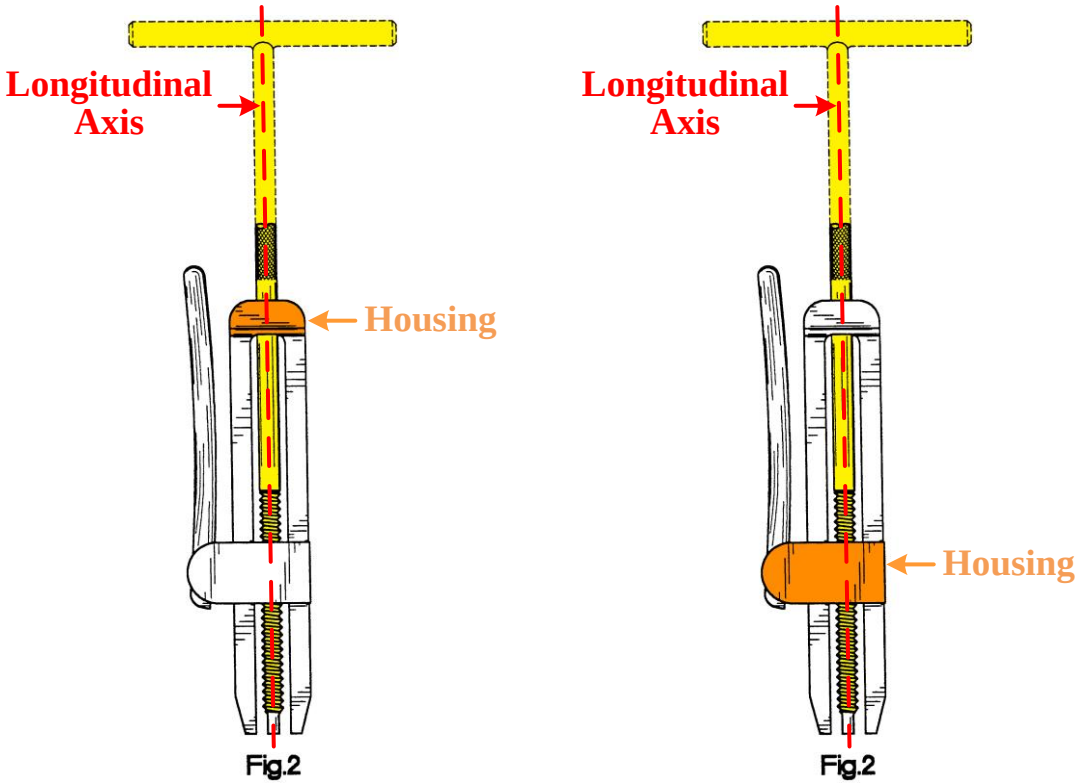
Each of Sparker and the DePuy Catalogs teaches the "rod reducing device" as recited in claim 8. As discussed in Section VIII(C)(1)(a), Sparker's "combined hook holder and rod mover for spinal surgery" and the DePuy Catalogs' "2050-63 CamLok Open Hook/Rod Approximator," respectively, are rod reducing devices.

d. Limitation-[8-3]:



Each of Sparker and the DePuy Catalogs teaches the "housing defining a longitudinal axis" as recited in claim 8. As shown in annotated FIG. 2, Sparker discloses the rod reducing device includes a housing defining a longitudinal axis. *See also* ORT-1016 ¶ 256.

Alternatively, the housing can be interpreted according to either annotated version of FIG. 2 shown below.



As shown in the annotated figure in Section VIII(C)(1)(a), the DePuy Catalogs' rod reducing device includes a housing defining a longitudinal axis. *See also id*. ¶ 256.

e. Limitation-[8-4]:

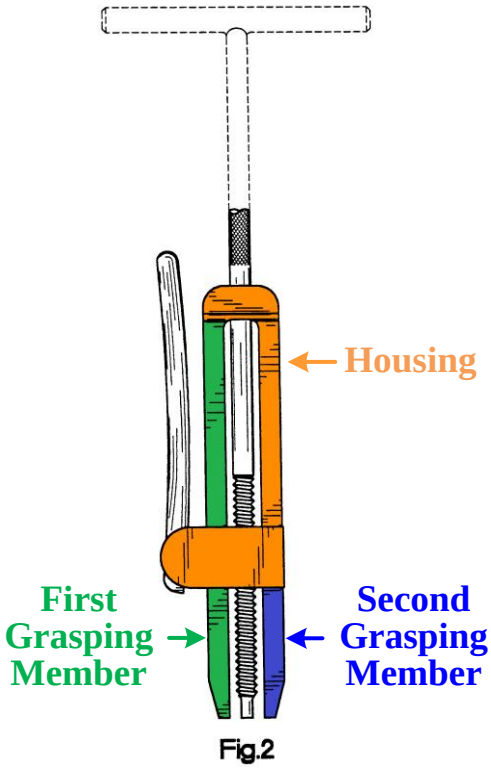
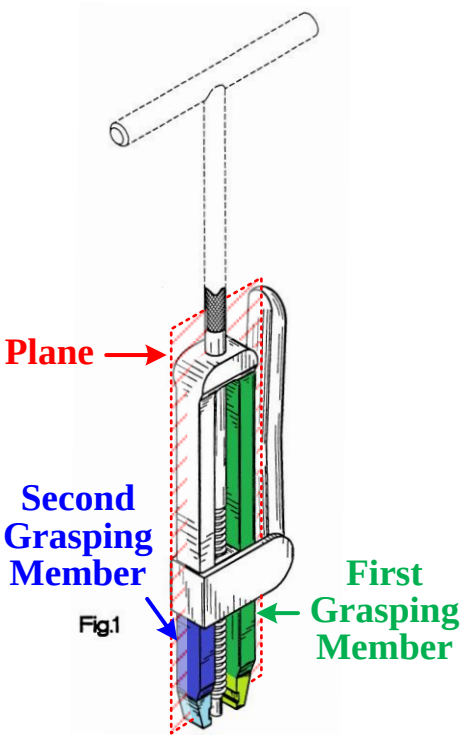


Fig.2

Each of Sparker and the DePuy Catalogs teaches the "housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween" as recited in claim 8. As shown in annotated FIG. 2, Sparker's housing includes first and second elongated members configured to grasp a portion of a bone anchor therebetween. *See also id* ¶ 260.

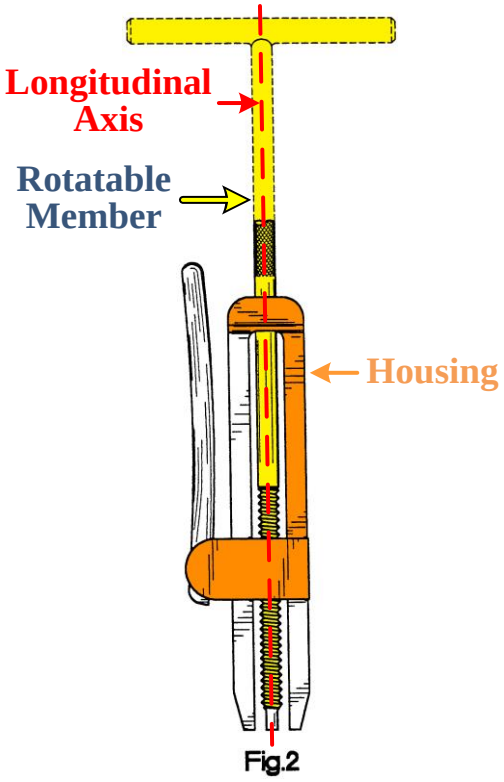
As shown in the annotated figure in Section VIII(C)(1)(a), the DePuy Catalogs' housing includes first and second grasping members configured to grasp a portion of a bone anchor therebetween.

f. Limitation-[8-5]:



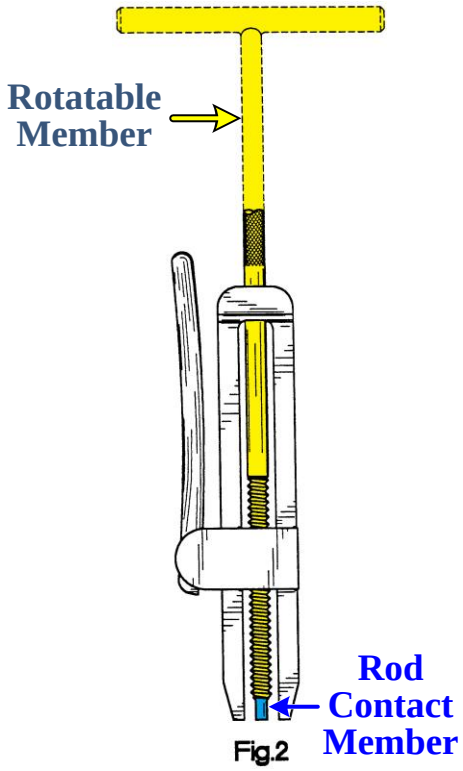
Each of Sparker and the DePuy Catalogs teaches the "the first and second grasping members defining a plane" as recited in claim 8. As shown in annotated FIG. 2 and the annotated figure in Section VIII(C)(1)(a), Sparker and the DePuy Catalogs, each respectively discloses grasping members that define a plane. *See also id.* ¶¶ 263-264.

g. Limitation-[8-6]:



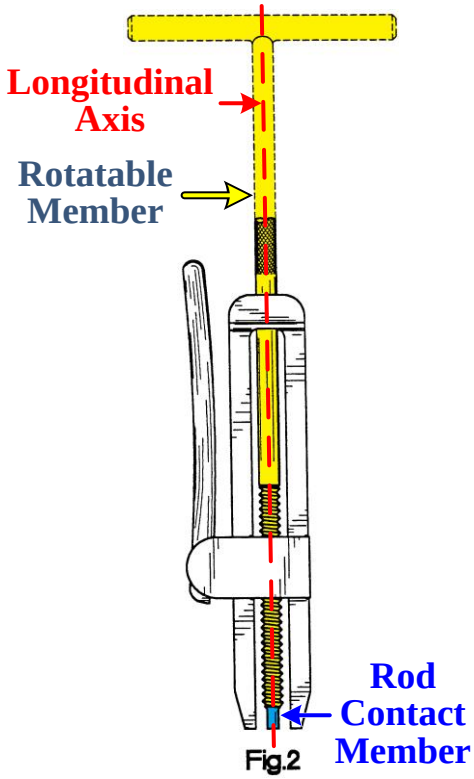
Each of Sparker and the DePuy Catalogs teaches the "rotatable member extending through the housing along the longitudinal axis" as recited in claim 8. As shown in annotated FIG. 2 and the annotated figure in Section VIII(C)(1)(a), the rod reducing devices of Sparker and the DePuy Catalogs each respectively includes a shaft (*i.e.*, rotatable member) threadably coupled to and extending through its housing along the longitudinal axis. *See also id.* ¶¶ 266-267.

h. Limitation-[8-7]:



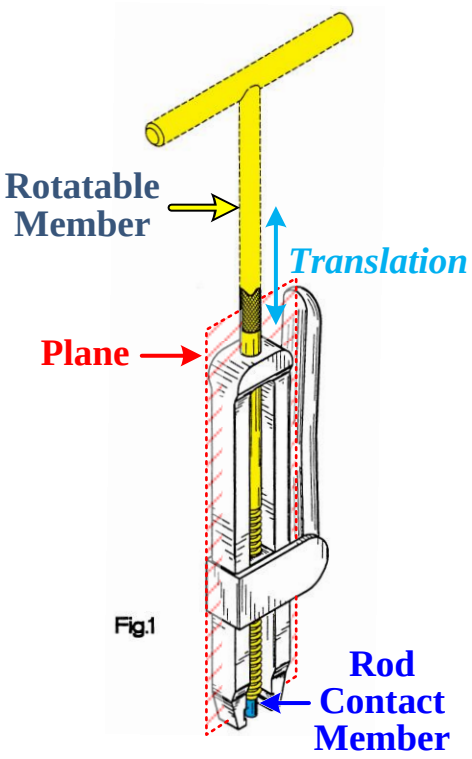
Each of Sparker and the DePuy Catalogs teaches the "rod contact member positioned at a distal end of the rotatable member" as recited in claim 8. As shown in annotated FIG. 2 and the annotated figure in Section VIII(C)(1)(a), Sparker and the DePuy Catalogs each respectively discloses a distal end of the rotatable member is constructed to contact a spinal rod and is positioned at a distal end of the rotatable member. *See also id.* ¶¶ 269-270.

i. Limitation-[8-8]:



Each of Sparker and the DePuy Catalogs teaches the "rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis" as recited in claim 8. As discussed, and as shown in annotated FIG. 2 and the annotated figure in Section VIII(C)(1)(a), the rotatable member of Sparker and the DePuy Catalogs each respectively is disposed along the longitudinal axis and includes a rod contact member integral to the rotatable member such that upon rotation of the rotatable member, the distal end translates along the longitudinal axis relative to the housing. *See also id.* ¶¶ 272-273.

j. Limitation-[8-9]:



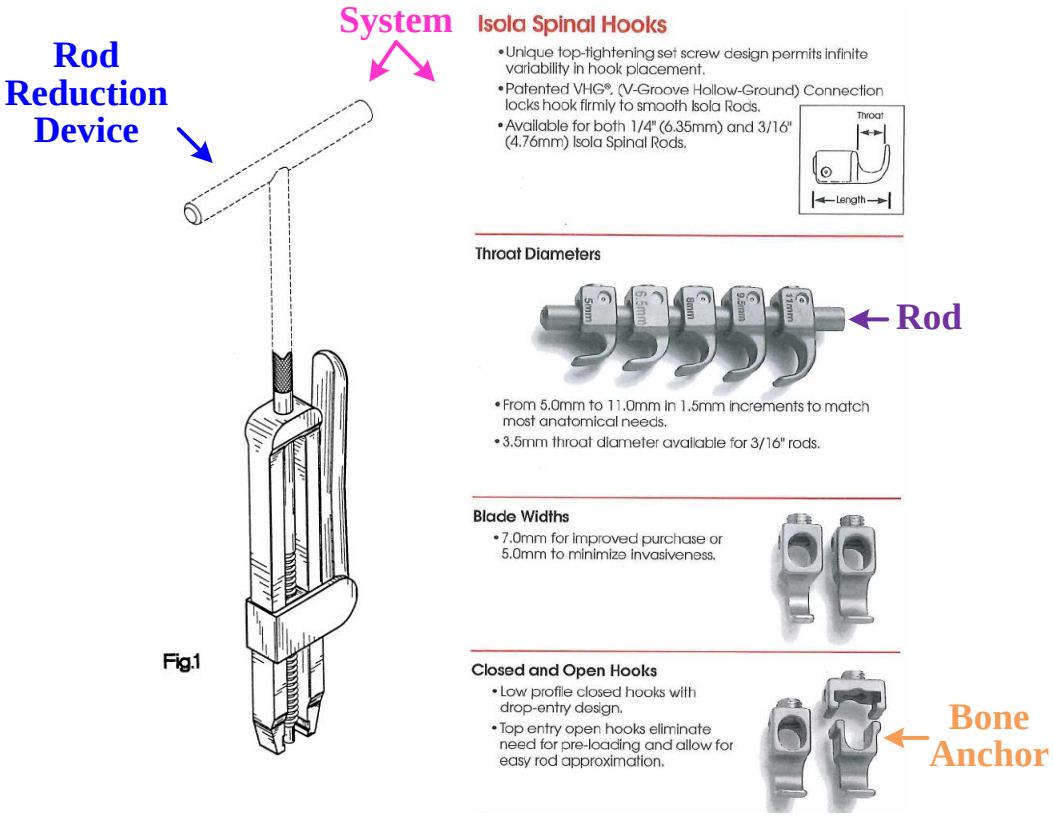
Each of Sparker and the DePuy Catalogs teaches "wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members" as recited in claim 8. As shown in annotated FIG. 2 and the annotated figure in Section VIII(C)(1)(a), Sparker and the DePuy Catalogs each discloses a rod contact member attached to a rotatable member. Since each of these rotatable members is threadably coupled to the respective housing, each is translatable along the longitudinal axis within the plane defined by respective grasping members in response to rotation of the rotatable member. *See also id.* ¶¶ 275-276.

2. Dependent Claim 10:

The combination of Sparker and the DePuy Catalogs teaches a kit "further comprising at least one additional orthopedic tool selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device" as recited in claim 10. In particular, the DePuy Catalogs disclose several additional orthopedic tools. For example, the DePuy 2002 Catalog lists Item No. 2025-46 "VSP Screw Alignment Rods" (*i.e.*, an alignment tube), Item No. 2025-4100 "VSP 45° Open End Wrench" (*i.e.*, tightening and/or loosening tool), Item No. 2050-36 "Open End Wrench, 5/16" (*i.e.*, tightening and/or loosening tool), and Item No. 2050-50 "Isola 1/8" Set Screw Wrench" (*i.e.*, tightening and/or loosening tool), among others. ORT-1022 at DEPUY-0000047. *See also* ORT-1020 at DEPUY-0000017 and DEPUY-0000018; ORT-1021 at DEPUY-0000007 and DEPUY-0000008; and ORT-1016 ¶ 278.

3. Independent Claim 12:

a. Limitation-[12-PRE]



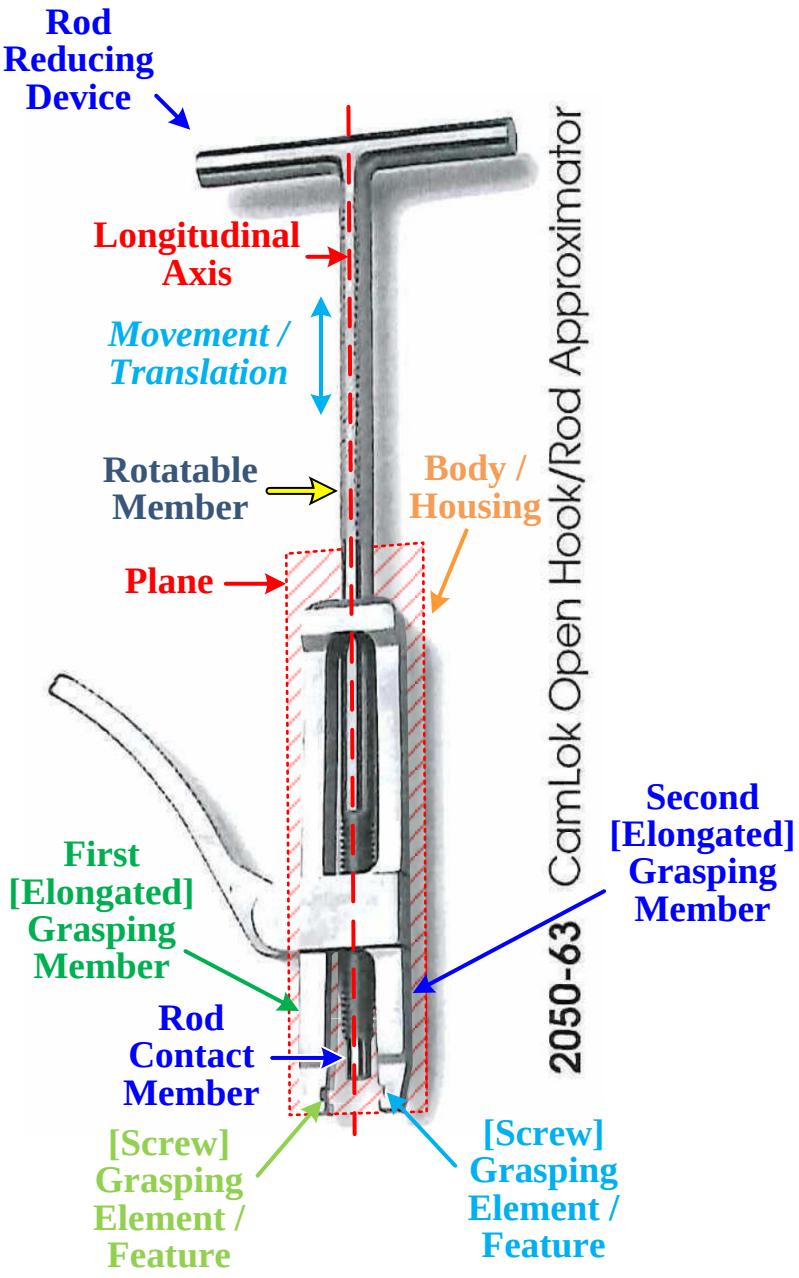
The combination of Sparker and the DePuy Catalogs teaches "a system for reducing a connecting rod" as recited in claim 12. As shown in annotated FIG. 1, and as discussed in Section VIII(C)(1)(a), Sparker's "combined hook holder and rod mover for spinal surgery" is a rod reducing device. *See also id.* ¶ 280.

The DePuy Catalogs are product catalogs for spine systems of DePuy, such as "ISOLA®/VSP® Spine Systems," and the catalogs disclose kits and systems for spinal surgery. *See, e.g.*, ORT-1020 at DEPUY-0000011 – DEPUY-0000026; ORT-1021 at DEPUY-0000001 – DEPUY-0000010; and ORT-1022 at DEPUY-

0000037 – DEPUY-0000060. Each of the catalogs discloses, among other items, rod reducing devices, spinal rods, spinal hooks, pedicle screws, and several instruments for use therewith. *See, e.g.*, ORT-1020 at DEPUY-0000013, DEPUY-0000014, and DEPUY-0000021; ORT-1021 at DEPUY-0000002, DEPUY-0000003, and DEPUY-0000006; and ORT-1022 at DEPUY-0000040, DEPUY-0000044, and DEPUY-0000050; ORT-1016 ¶ 281.

Further, for the same reasons discussed in Section VIII(C), it would be obvious to a person of ordinary skill in the art to use the rod reducing device of Sparker along with the various implants and instruments described in the DePuy Catalogs. *See also id.* ¶ 283.

As the annotated figure below illustrates, the DePuy Catalogs' "2050-63 CamLok Open Hook/Rod Approximator" includes all the limitations of the claimed rod reducing device. *See, e.g.*, ORT-1020 at DEPUY-0000032; ORT-1021 at DEPUY-0000006; and ORT-1022 at DEPUY-0000050. *See also* ORT-1016 ¶ 282.



b. Limitation-[12-1]

As discussed in Section VIII(C)(1)(b), the combination of Sparker and the DePuy Catalogs teaches "a bone anchor" and therefore likewise teaches the identical claim limitation in claim 12.

c. Limitation-[12-2]

Sparker and the DePuy Catalogs teach the "connecting rod" as recited in claim 12. As discussed, the DePuy Catalogs disclose a variety of spinal rods. *See, e.g.*, ORT-1020 at DEPUY-0000014; ORT-1021 at DEPUY-0000003; and ORT-1022 at DEPUY-0000040; ORT-1016 ¶ 287.

d. Limitation-[12-3]

As discussed in Section VIII(C)(1)(c), Sparker and the DePuy Catalogs each teaches "a rod reducing device"[10] and therefore likewise teaches the identical claim limitation in claim 12.

e. Limitation-[12-4]

As discussed in Section VIII(C)(1)(d), Sparker and the DePuy Catalogs each teaches "a housing defining a longitudinal axis " and therefore likewise teaches the identical claim limitation in claim 12.

f. Limitation-[12-5]

As discussed in Section VIII(C)(1)(e), Sparker and the DePuy Catalogs each teaches "the housing including first and second grasping members configured to grasp a portion of the bone anchor therebetween" and therefore likewise teaches the identical claim limitation in claim 12.

[10] As discussed, the specification of the '664 Patent uses "rod ***reducing*** device" and "rod ***reduction*** device" interchangeably to describe the *same* device.

g. Limitation-[12-6]

As discussed in Section VIII(C)(1)(f), Sparker and the DePuy Catalogs each teaches "the first and second grasping members defining a plane" and therefore likewise teaches the identical claim limitation in claim 12.

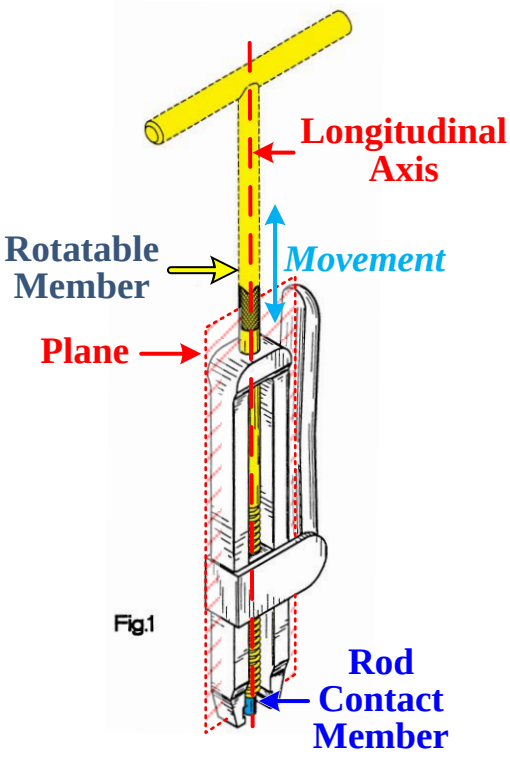
h. Limitation-[12-7]

As discussed in Section VIII(C)(1)(g), Sparker and the DePuy Catalogs each teaches "a rotatable member extending through the housing along the longitudinal axis" and therefore likewise teaches the identical claim limitation in claim 12.

i. Limitation-[12-8]

As discussed in Section VIII(C)(1)(h), Sparker and the DePuy Catalogs each teaches "a rod contact member positioned at a distal end of the rotatable member" and therefore likewise teaches the identical claim limitation in claim 12.

j. Limitation-[12-9]



Each of Sparker and the DePuy Catalogs teaches the "rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis" recited in claim 12. As discussed in Section VIII(C)(1)(i), Sparker and the DePuy Catalogs each discloses a rotatable member that is disposed along the longitudinal axis, and upon rotation of the rotatable member, the rod contact member at its distal end translates along the longitudinal axis within the plane defined by the grasping members. *See also id.* ¶¶ 296-298.

4. Dependent Claim 16:

The combination of Sparker and the DePuy Catalogs teaches a system "further comprising an additional orthopedic tool or device selected from the group

consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device," as recited in claim 16. In particular, the DePuy Catalogs disclose several additional orthopedic tools and devices. For example, the DePuy 2002 Catalog lists Item No. 2025-46 "VSP Screw Alignment Rods" (*i.e.*, an alignment tube), Item No. 2025-4100 "VSP 45° Open End Wrench" (*i.e.*, tightening and/or loosening tool), Item No. 2050-36 "Open End Wrench, 5/16" (*i.e.*, tightening and/or loosening tool), and Item No. 2050-50 "Isola 1/8" Set Screw Wrench" (*i.e.*, tightening and/or loosening tool), among others. ORT-1022 at DEPUY-0000047. *See also* ORT-1020 at DEPUY-0000017 and DEPUY-0000018; ORT-1021 at DEPUY-0000007 and DEPUY-0000008; and ORT-1016 ¶ 300.

D. Ground 4: Claims 9, 15, and 17-19 Are Rendered Obvious by Sparker in View of the DePuy Catalogs and Justis

Claims 9, 15, and 17-19 of the '664 Patent are also rendered obvious by Sparker in view of the DePuy Catalogs and Justis.

As discussed, Justis discloses systems and methods for positioning a connecting element adjacent the spinal column. ORT-1018 ¶ 5. Specifically, Justis discloses that the connecting element can be guided "to a location adjacent the nearest anchor 300 and anchor extension 100 and into the space 102 defined thereby." *Id.* ¶ 65. And as discussed in Section VIII(B), Justis also discloses a rod reducing device. Thus, since Justis is directed to the same field, *i.e.*, rod reducing

devices for spinal surgery, as Sparker and the DePuy Catalogs, it would have been obvious to a POSITA to combine Justis with Sparker and/or the DePuy Catalogs.

1. Dependent Claim 9:

The combination of Sparker, the DePuy Catalogs, and Justis teaches a kit "further comprising a plurality of bone anchors and a plurality of rod reducing devices" as recited in claim 9.

Claim 9 depends from claim 8, and as discussed in Section VIII(C)(1), the combination of Sparker and the DePuy Catalogs teaches each of the limitations of claim 8 (*i.e.*, claim limitations [8-PRE] through [8-9]). In particular, as discussed in Section VIII(C)(1)(b), the combination of Sparker and the DePuy Catalogs teaches a "plurality of bone anchors." Further, as discussed in Section VIII(C)(1)(c), Sparker teaches, at least singularly, "a rod reducing device."

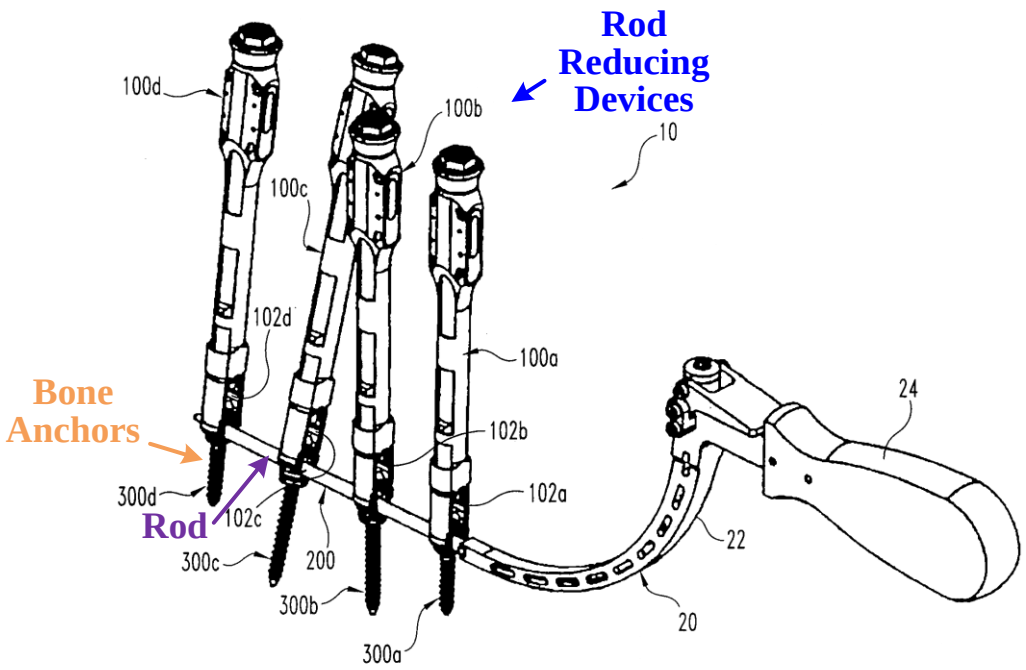


Fig. 3

Justis recites that "[t]he connecting element [200] is guided by the surgeon through the tissue to a location adjacent the nearest anchor 300 and anchor extension 100 [*i.e.*, rod reducing device] and into the space 102 defined thereby." *Id*. ¶ 65; FIG. 3 (annotated). As shown in annotated FIG. 3, Justis continues, reciting that "***[t]he connecting element can then be serially advanced through the other spaces 102 defined by the other anchors 300 and extensions 100***." *Id*. Not only is it clear that Justis discloses a plurality of bone anchors and a plurality of rod reducing devices, Justis discloses that each rod reducing device of the plurality of rod reducing devices is mountable to a bone anchor of the plurality of bone anchors. *See also* ORT-1016 ¶ 306.

It would have been obvious to a POSITA to use a plurality of the rod reducing devices of Sparker in a kit for reducing a rod, based on the teachings of Justis, with the plurality of bone anchors described in the DePuy Catalogs and/or Justis. Support for such combination clearly lies in the fact that both Sparker, the DePuy Catalogs, and Justis describe rod reducing devices. Justis further describes facilitating placement of a connecting rod and discloses that the rod reducing devices can be used to provide "distraction, compression or torsional forces . . . to provide a desired effect to the vertebrae." ORT-1018 ¶ 64. In view of the functionality described for rod reducing devices in Justis, it is clear that it would have been obvious to a POSITA to use a plurality of the rod reducing device of Sparker in the manner described in Justis. *See also* ORT-1016 ¶ 307.

2. Dependent Claim 15:

The combination of Sparker, the DePuy Catalogs, and Justis teaches a system "further comprising a plurality of bone anchors and a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors" as recited in claim 15.

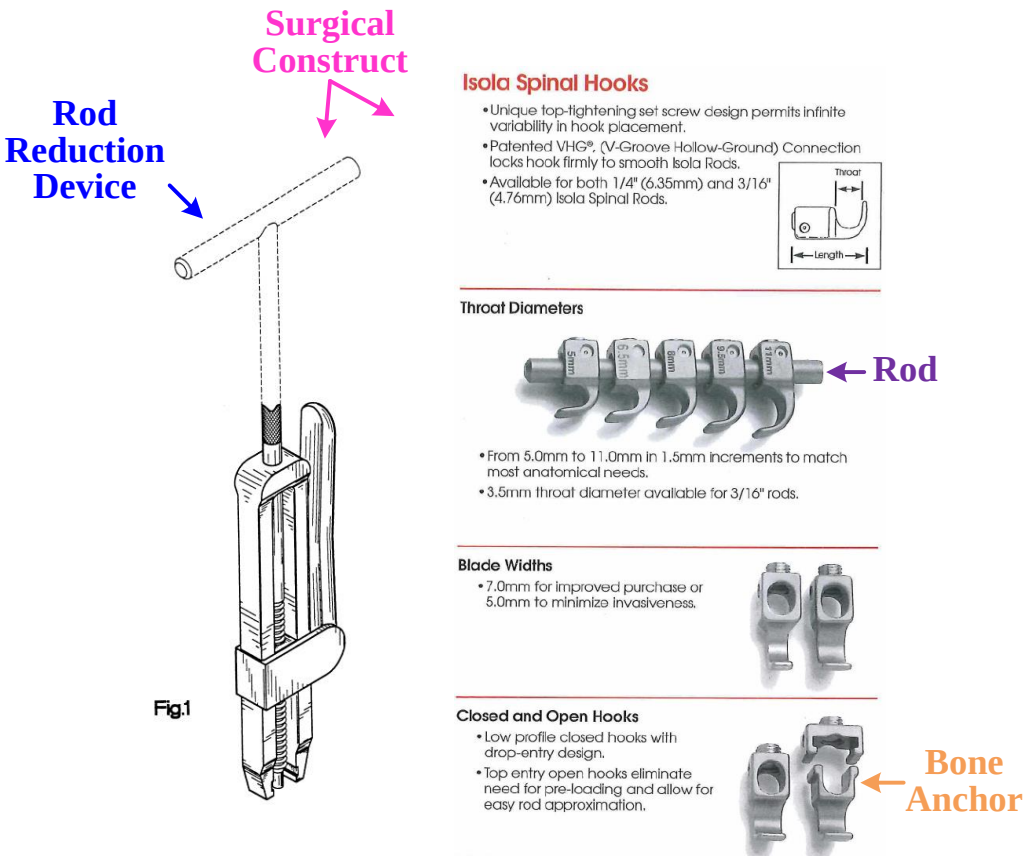
Claim 15 depends from claim 12, and as discussed in Section VIII(C)(3), the combination of Sparker and the DePuy Catalogs teaches each of the limitations of claim 12 (*i.e.*, claim limitations [12-PRE] through [12-9]). As discussed in Section

VIII(C)(1)(b), the combination of Sparker and the DePuy Catalogs teaches a "plurality of bone anchors," and Sparker and the DePuy Catalogs each teaches a rod reducing device (*see* Section VIII(C)(1)(c)).

For the same reasons discussed in Section VIII(D)(1), it would have been obvious to a POSITA to use a plurality of the rod reducing device of Sparker or the DePuy Catalogs in a kit for reducing a rod, based on the teachings of Justis, with each rod reducing device of the plurality of rod reducing devices being mountable to a bone anchor of the plurality of bone anchors.

3. Independent Claim 17:

a. Limitation-[17-PRE]



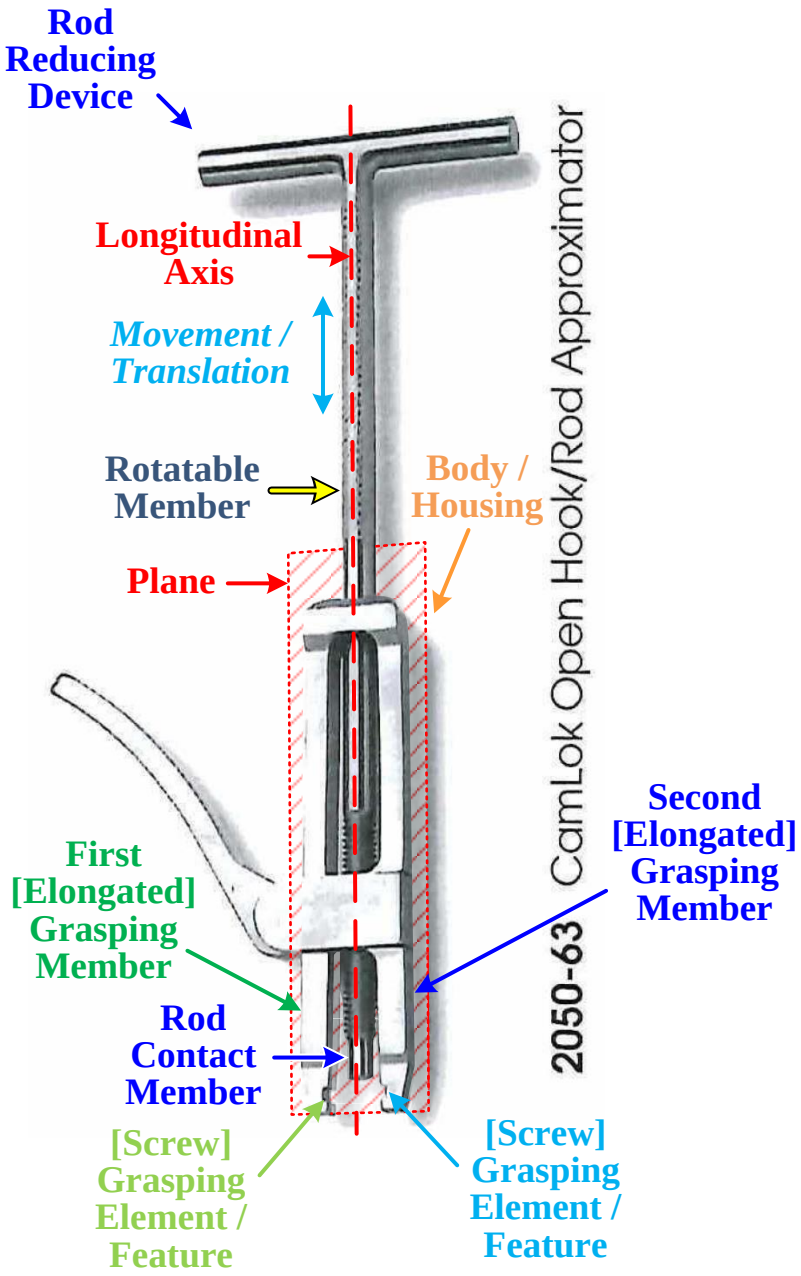
The combination of Sparker, the DePuy Catalogs, and Justis teaches "a surgical construct" as recited in claim 17. As shown in annotated FIG. 1, and as discussed in Section VIII(C)(1)(a), Sparker's "combined hook holder and rod mover ***for spinal surgery***" is a rod reducing device. *See also id.* ¶ 312.

As discussed, the DePuy Catalogs are product catalogs for spine systems of DePuy, such as "ISOLA®/VSP® Spine Systems," and the catalogs disclose kits and systems for spinal surgery. *See, e.g.,* ORT-1020 at DEPUY-0000011 – DEPUY-0000026; ORT-1021 at DEPUY-0000001 – DEPUY-0000010; and ORT-1022 at DEPUY-0000037 – DEPUY-0000060. Each of the catalogs discloses, among other items, rod reducing devices, spinal rods, spinal hooks, pedicle screws, and several instruments for use therewith. *See, e.g.*, ORT-1020 at DEPUY-0000013, DEPUY-0000014, and DEPUY-0000021; ORT-1021 at DEPUY-0000002, DEPUY-0000003, and DEPUY-0000006; and ORT-1022 at DEPUY-0000040, DEPUY-0000044, and DEPUY-0000050; ORT-1016 ¶ 313.

Further, for the same reasons discussed in Section VIII(C), it would be obvious to a person of ordinary skill in the art to use the rod reducing device of Sparker along with the various implants and instruments described in the DePuy Catalogs. *See also id.* ¶¶ 283, 317.

As the annotated figure below illustrates, the DePuy Catalogs' "2050-63 CamLok Open Hook/Rod Approximator" includes all the limitations of the

claimed rod reducing device. *See*, *e.g.*, ORT-1020 at DEPUY-0000032; ORT-1021 at DEPUY-0000006; and ORT-1022 at DEPUY-0000050. *See also* ORT-1016 ¶ 314.



b. Limitation-[17-1]

As discussed in Section VIII(C)(1)(b), the combination of Sparker and the DePuy Catalogs teaches "a plurality of bone anchors" and therefore likewise teaches the identical claim limitation in claim 17.

c. Limitation-[17-2]

As discussed in Section VIII(C)(3)(c), the combination of Sparker and the DePuy Catalogs teaches "a connecting rod" and therefore likewise teaches the identical claim limitation in claim 17.

d. Limitation-[17-3]

The combination of Sparker, the DePuy Catalogs, and Justis teaches a surgical construct having "a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices connectable to a bone anchor of the plurality of bone anchors," as recited in claim 17.

As discussed in Sections VIII(C)(1)(c) and VIII(C)(3)(d), Sparker and the DePuy Catalogs each respectively discloses a rod reducing device.[11]

For the same reasons discussed in Section VIII(D)(1), it would have been obvious to a POSITA to use a plurality of the rod reduction device of Sparker or the DePuy Catalogs in a surgical construct, based on the teachings of Justis, with

[11] As discussed above, the specification of the '664 Patent uses "rod ***reducing*** device" and "rod ***reduction*** device" interchangeably to describe the *same* device.

each rod reduction device of the plurality of rod reduction devices being connectable to a bone anchor of the plurality of bone anchors.

e. Limitation-[17-4]

As discussed in more detail below, Sparker and the DePuy Catalogs each respectively teaches rod reduction devices including all of the recited features of claim 17.

f. Limitation-[17-5]

As discussed in Section VIII(C)(1)(d), Sparker and the DePuy Catalogs each respectively teaches "a housing defining a longitudinal axis" and therefore likewise discloses the identical claim limitation in claim 17.

g. Limitation-[17-6]

As discussed in Section VIII(C)(1)(e), Sparker and the DePuy Catalogs each respectively teaches "the housing including first and second grasping members configured to grasp a portion of the bone anchor therebetween." and therefore likewise teaches the identical claim limitation in claim 17.

h. Limitation-[17-7]

As discussed in Section VIII(C)(1)(f), Sparker and the DePuy Catalogs each respectively teaches "the first and second grasping members defining a plane" and therefore likewise teaches the identical claim limitation in claim 17.

i. Limitation-[17-8]

As discussed in Section VIII(C)(1)(g), Sparker and the DePuy Catalogs each respectively teaches "a rotatable member extending through the housing along the longitudinal axis" and therefore likewise teaches the identical claim limitation in claim 17.

j. Limitation-[17-9]

As discussed in Section VIII(C)(1)(h), Sparker and the DePuy Catalogs each respectively teaches discloses "a rod contact member positioned at a distal end of the rotatable member" and therefore likewise teaches the identical claim limitation in claim 17.

k. Limitation-[17-10]

As discussed in Sections VIII(C)(1)(f), (i), and (j), Sparker and the DePuy Catalogs each respectively teaches "the rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis" and therefore likewise teaches the identical claim limitation in claim 17.

4. Dependent Claim 18:

a. Limitation-[18-1]

The combination of Sparker, the DePuy Catalogs, and Justis teaches a surgical construct "wherein the connecting rod is disposed between the first and second grasping members of the plurality of the rod reduction devices with the

plurality of rod reduction devices mounted to the respective bone anchors of the plurality of bone anchors," as recited in claim 18.

As discussed in Section VIII(C)(1)(c), Sparker and the DePuy Catalogs each respectively teaches "a rod reducing device," and in Section VIII(C)(1)(f), Sparker and the DePuy Catalogs each respectively teaches "first and second grasping members."

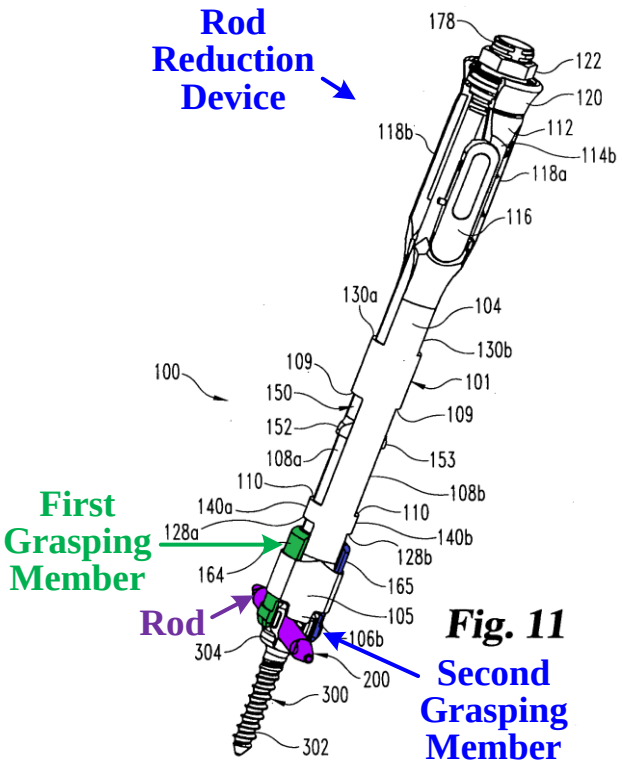


Fig. 11

As shown in annotated FIG. 11, Justis shows that the connecting element 200 (*i.e.*, connecting rod) is disposed between the flanged ends 164, 165 (*i.e.*, first and second grasping members) of the extension 100 (*i.e.*, a rod reduction device). *See also* ORT-1018 ¶ 58; ORT-1016 ¶ 331.

For the same reasons discussed in Section VIII(D)(1), it would have been obvious to a POSITA to dispose the connecting element of Justis and/or the spinal rod described in the DePuy Catalogs between the first and second grasping members of Sparker. Further, it would have been obvious to a POSITA to use a plurality of the rod reduction device of Sparker or the DePuy Catalogs in a surgical construct, based on the teachings of Justis, with the plurality of rod reduction devices being mounted to the respective bone anchors of the plurality of bone anchors.

b. Limitation-[18-2]

The combination of Sparker, the DePuy Catalogs, and Justis teaches a surgical construct "whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors" as recited in claim 18.

As discussed in Section VIII(C)(1)(c), Sparker and the DePuy Catalogs each respectively teaches "a rod reducing device."

Further, as discussed, Justis recites that once the connecting element is positioned in the respective space, "the one or more anchor extensions 100 [*i.e.*, rod reduction devices] with reduction capability can be manipulated so that the second member and the anchor 300 move relative to one another to seat the connecting element 200 relative to the anchor." ORT-1018 ¶ 37. *See also* ORT-1016 ¶ 335.

For the same reasons discussed in Section VIII(D)(1), it would have been obvious to a POSITA to actuate a plurality of the rod reduction device of Sparker or the DePuy Catalogs, based on the teachings of Justis, to approximate a connecting rod to a plurality of bone anchors.

5. Dependent Claim 19:

The combination of Sparker, the DePuy Catalogs, and Justis teaches a surgical construct "wherein each bone anchor further comprises a rod receiving housing and a bone engaging shaft extending therefrom, each rod reduction device of the plurality of rod reduction devices approximating the connecting rod toward the rod receiving housing of the bone anchor," as recited in claim 19.

As discussed in Section VIII(C)(1)(c), Sparker and the DePuy Catalogs each respectively teaches "a rod reducing device."

Justis recites that "[a]nchors 300 include a bone engaging portion 302 and a connecting element engaging portion 304." ORT-1018 ¶ 38. Justis continues, reciting that the "bone engaging portion 302 is a bone screw with a threaded shank to engage the bony structure of the underlying vertebra" and the "[c]onnecting element engaging portion 304 can be a receiver having a U-shape formed by a pair of opposing arms defining a longitudinal passage alignable along insertion axis I." *Id*. And as discussed, Justis recites that "the one or more anchor extensions 100 [*i.e.*, rod reduction devices] with reduction capability can be manipulated so that

the second member and the anchor 300 move relative to one another to seat the connecting element 200 relative to the anchor." *Id*. ¶ 37. *See also* ORT-1016 ¶ 340.

For the same reasons discussed in Section VIII(D)(1), it would have been obvious to a POSITA to use a plurality the rod reduction device of Sparker or the DePuy Catalogs with bone anchors described in Justis and/or the DePuy Catalogs. Further, it would have been obvious to a POSITA to actuate a plurality of the rod reduction device of Sparker or the DePuy Catalogs, based on the teachings of Justis, to approximate a connecting rod to a plurality of bone anchors.

IX. CONCLUSION

As detailed above, each of the Challenged Claims of the '664 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: August 21, 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 13,132 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 August 21, 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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