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. IPR2018-01548
Patent No. 9,655,664

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

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ORT-1216 Expert declaration of Ottie Pendleton

ORT-1217 U.S. App. Pub. No. 2006/0089651 ("Trudeau")

ORT-1218 U.S. Pat. Pub. No. 2007/0213714 ("Justis")

ORT-1219 U.S. Design Pat. No. D346,217 to Sparker et al. ("Sparker")

TABLE OF AUTHORITIES

Cases

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I. INTRODUCTION

OrthoPediatrics Corp. ("Petitioner") petitions for *inter partes* review ("IPR") of claims 1, 3, 5, 6, 8, 9, 10, 12, and 15-19 (the "Challenged Claims") of U.S. Patent No. 9,655,664 (ORT-1201), 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-1201 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.

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

Petitioner provides the following designation of counsel:

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

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

Please address all correspondence and service to the Lead Counsel and Back-up Counsel at the address provided above. Petitioner consents to electronic service by electronic mail.

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

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

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

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

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

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

Petitioner certifies that the '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-1216) 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(b) by Trudeau
Ground 2	9, 15, and 17-19	Obvious under 35 U.S.C. § 103(a) over Trudeau in view of Justis
Ground 3	1, 3, 5, and 6	Obvious under 35 U.S.C. § 103(a) over Sparker in view of Trudeau

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-1214; ORT-1215. In Patent Owner's preliminary responses to the two petitions for *inter partes* review, Patent Owner argued that two terms required construction: "grasping" and "extending through the housing." ORT-1212 at 9-19; ORT-1213 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-1214 at 10; ORT-1215 at 11. The Board did not construe "grasping," as its construction was not necessary to resolve the controversy. *See, e.g.*, ORT-1214 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 contain 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-1201 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.

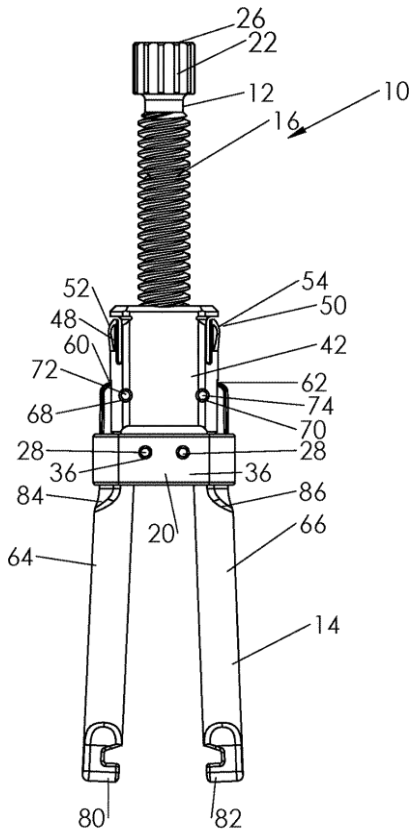


FIG 5

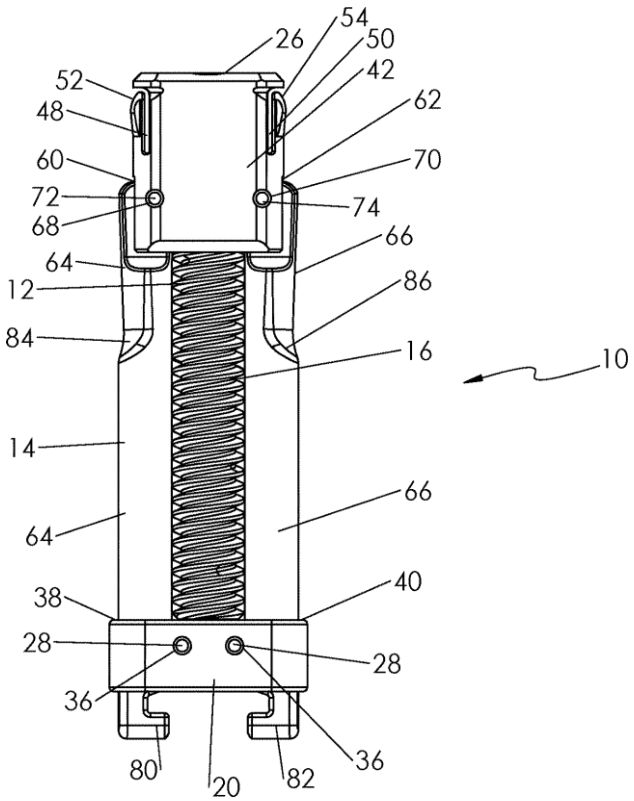


FIG 2

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 and 5, above). At the bottom (*i.e.*, distal end) of the screw shaft 16 is a "rod contact member" 20. *See id.* at 4:41-44.

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,
[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

Key	Listing of Claims
[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:
[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,

Key	Listing of Claims
[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;
[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.

Key	Listing of Claims
[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,
[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-1216 ¶ 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: All the Challenged Claims Are Anticipated by Trudeau

Trudeau also anticipates claims 1, 3, 5, 6, 8-10, 12, and 15-19 of the '664 Patent. Trudeau was filed on October 26, 2004, and was published on April 27, 2006. Therefore, Trudeau is prior art under at least 35 U.S.C. § 102(b). Trudeau was never cited nor considered by the Examiner during prosecution of the '664 Patent. ORT-1201 at 1-2.

Trudeau discloses surgical devices and methods for positioning and securing a spinal rod along a spine. ORT-1217 ¶¶ 1, 34. To that end, Trudeau discloses "a rod persuader device 10 for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16." *Id.* ¶ 34.

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

Listing of Elements	
'664 Claim Element	**Corresponding Feature(s) of Trudeau**
bone anchor	"pedicle screw fixture" (¶ 34)[1]
(connecting) rod	"spinal rod 12" (¶ 38)
rod reducing device / rod reduction device	"rod persuader device 10" (¶ 34)
housing / body	"clamping subassembly 90 including a tubular body portion 80," "a rod drive sleeve 132," and "sleeve coupling subassembly 6" (collectively) (¶ 35)
first (elongated) grasping member	"jaws 60, 62" (¶ 48)
second (elongated) grasping member	"jaws 60, 62" (¶ 48)
rotatable member	"drive rod subassembly 3" (¶ 35)
rod contact member	"rod securing device 30" (¶ 39)
grasping feature / screw grasping element	"teeth 38" (¶ 48)
additional orthopedic tool	

[1] All citations provided in the Listing of Elements refer to ORT-1217.

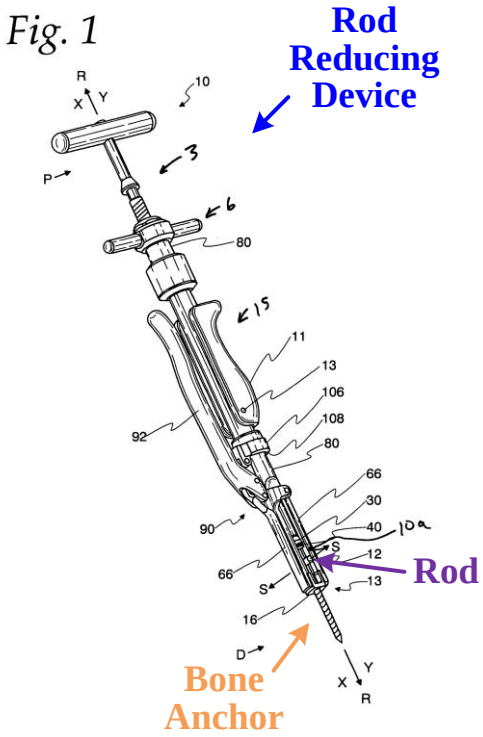
[bone anchor] bone engaging shaft	"pedicle bone screw 20" (¶ 38)
[bone anchor] rod-receiving housing	"yoke 18" (¶ 38)

1. Independent Claim 1:

a. Claim Limitation [1-PRE]

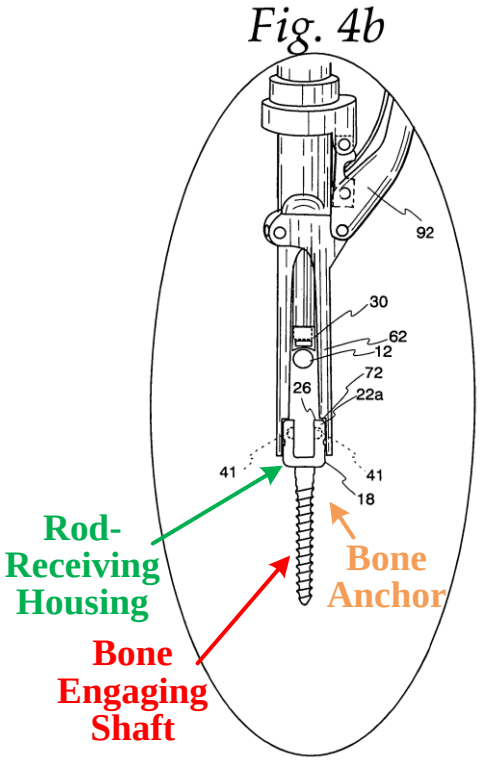
Trudeau discloses "a method of advancing a rod into a housing of a bone anchor" as recited in claim 1. For example, Trudeau recites "[t]he invention relates to an apparatus and ***method for securing a spinal rod along the spine*** and, more particularly, to an apparatus and ***method for securing the spinal rod to extend through a coupling device including an anchor member***." ORT-1217 ¶ 1 (emphasis added). *See also* ORT-1216 ¶¶ 42-43.

b. Claim Limitation [1-1]



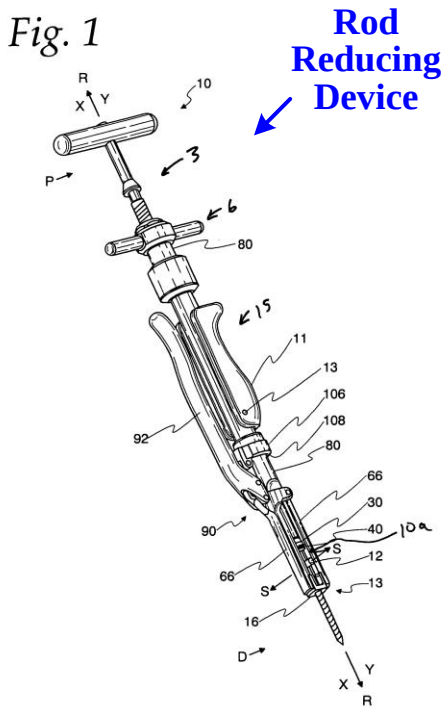
Trudeau discloses "coupling a rod reducing device to a bone anchor" as recited in claim 1. Specifically, Trudeau discloses a "***rod persuader device 10*** for advancing a spinal rod 12 towards a fixation device 14 in the form of a ***pedicle screw fixture 16***." ORT-1217 ¶ 34 (emphasis added). Trudeau recites that "[d]uring use, ***the persuader tool 10 is preferably secured to the pedicle screw fixture 16 via the clamping subassembly 90*** and, more specifically, opposed clamping jaw members 60, 62 thereof." *Id*. ¶ 41 (emphasis added). Trudeau adds that "[t]he pedicle screw fixture 16 and the tool 10 are provided with cooperating structure so that ***the tool 10 may be removably attached to the pedicle screw fixture 16 for operation***." *Id*. (emphasis added). *See also* ORT-1216 ¶¶ 44-45.

c. Claim Limitation [1-2]



Trudeau discloses "the bone anchor having a rod-receiving housing and a bone engaging shaft extending therefrom" as recited in claim 1. For example, Trudeau recites that a "fixation device 14 includes a screw fixture 16 secured to the pedicle portion of a vertebrae (not shown), such as with ***a pedicle bone screw 20 extending therefrom***. The pedicle screw fixture 16 includes ***a coupling device, such as a yoke 18 that may be formed unitary with the screw***." ORT-1217 ¶ 38 (emphasis added); FIG. 3*b* (annotated). *See also* ORT-1216 ¶¶ 46-47.

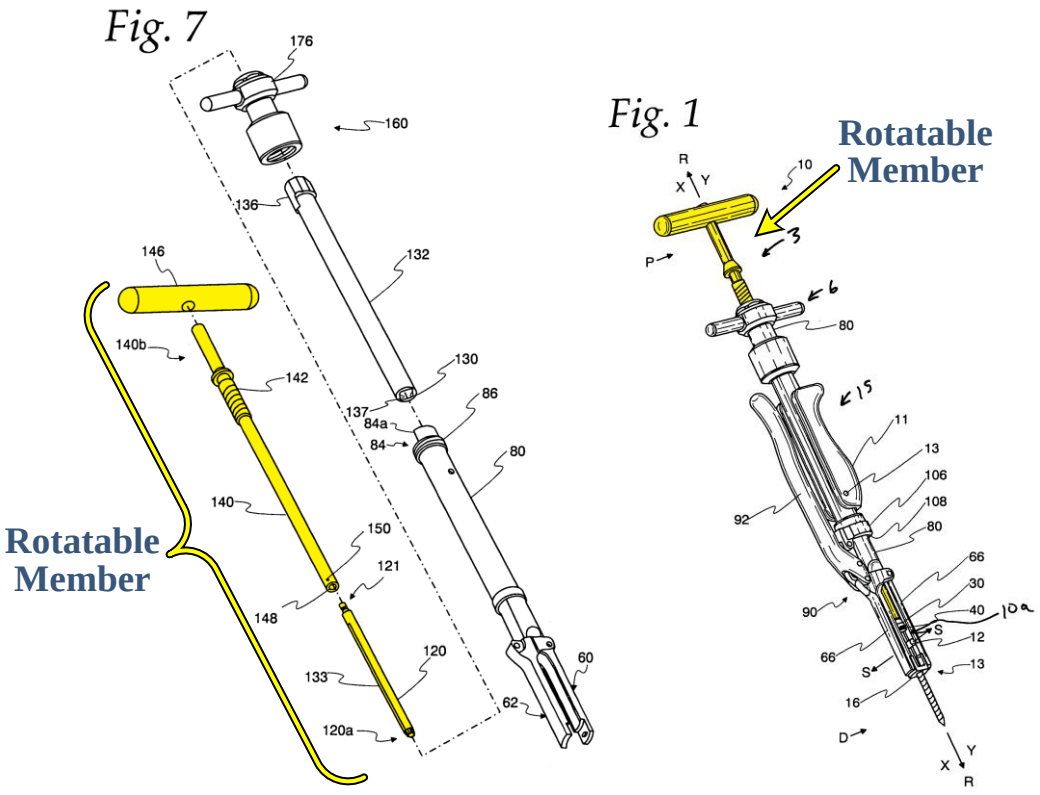
d. Claim Limitation [1-3]



Trudeau discloses the "rod reducing device" as recited in claim 1. As discussed, Trudeau recites "[r]eferring initially to FIG. 1, ***a rod persuader device 10*** for advancing a spinal rod 12 towards a fixation device 14 in the form of a

pedicle screw fixture 16 is depicted." ORT-1217 ¶ 34 (emphasis added); FIG. 1 (annotated). *See also* ORT-1216 ¶ 48.

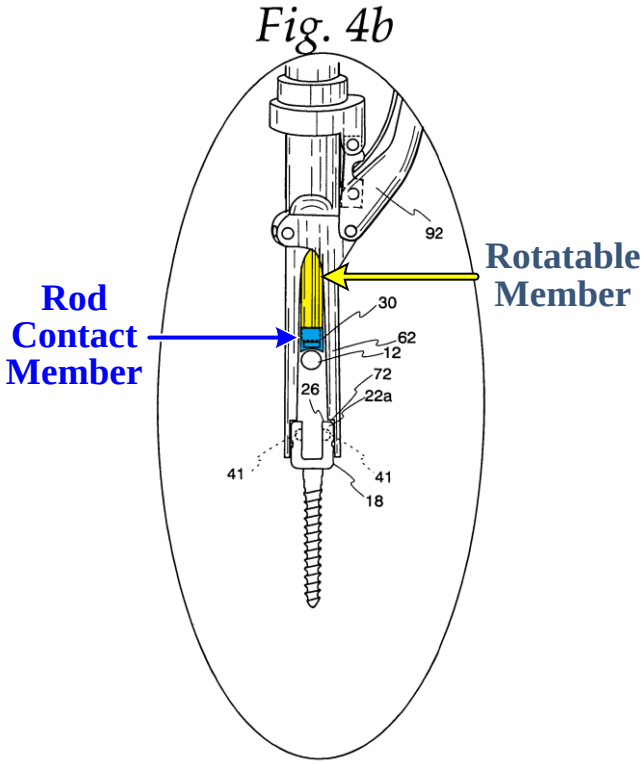
e. Claim Limitation [1-4]



Trudeau discloses the "rotatable member" as recited in claim 1. For example, Trudeau discloses "[a] tool 10 includes . . . ***a drive rod subassembly 3 including a drive rod 140***." ORT-1217 ¶ 35 (emphasis added); FIGS. 1, 7 (annotated). Trudeau discloses that the drive rod subassembly 3 further includes "a movable member," which "[i]n the preferred embodiment . . . is ***[the] tool shaft 120***." *Id.* ¶ 73 (emphasis added); FIG. 7 (annotated). Additionally, Trudeau states that "torque generated by a user in ***rotating the drive rod 140*** via the drive handle

146 advances the drive rod 140 along the threads." *Id.* ¶ 80 (emphasis added); FIGS. 1, 7 (annotated). *See also* ORT-1216 ¶ 49.

f. Claim Limitation [1-5]

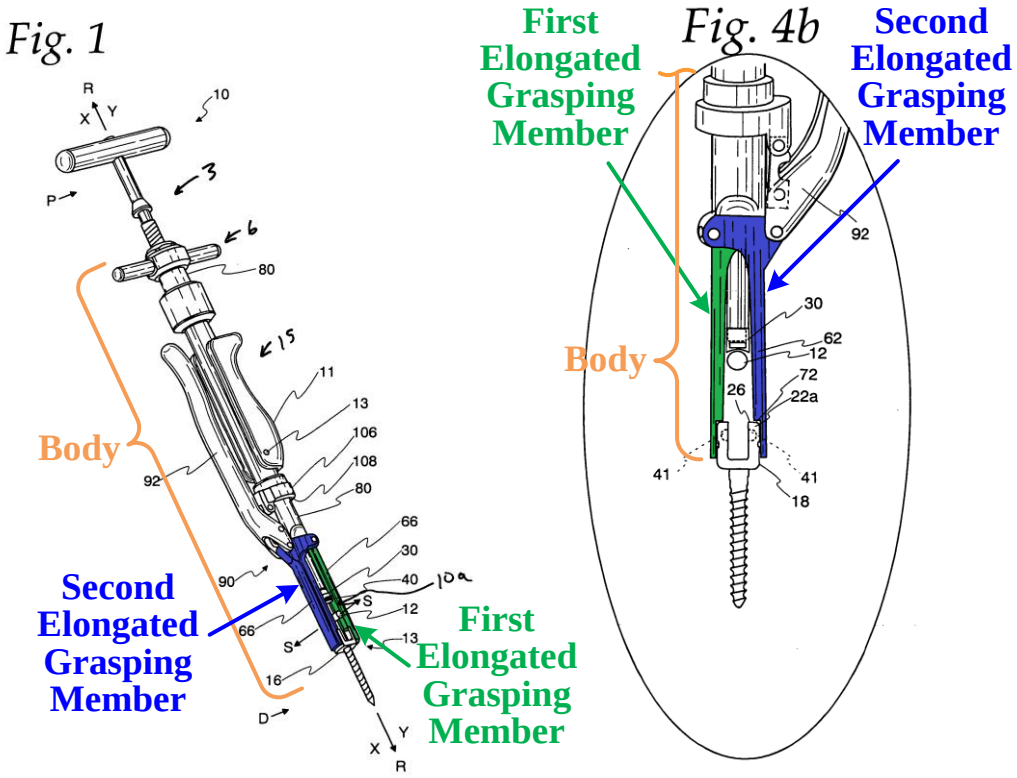


Trudeau discloses the "rod contact member positioned at a distal end of the rotatable member" as recited in claim 1. For example, Trudeau discloses "[a] rod securing device 30" including "[a] cap 30*a*" and "an intermediate clamping member 30*b*." ORT-1217 ¶ 39. Trudeau states that "***the cap 30a [of the rod securing device 30] is set on or removably attached to*** a gripping or torquing portion 120*a* [of the tool shaft 120] of ***the drive rod subassembly 3*** toward the distal end D of the tool 10." *Id*. (emphasis added); FIG. 4*b* (annotated).

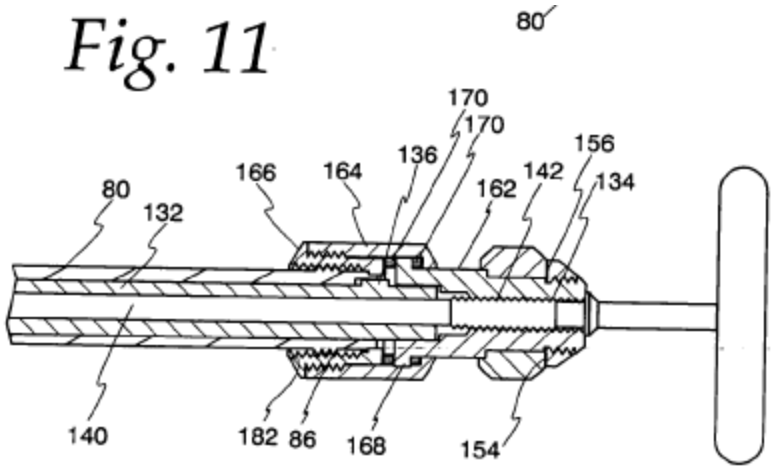
As discussed, Trudeau discloses that the drive rod subassembly 3 includes "a movable member," which "[i]n the preferred embodiment . . . is ***[the] tool shaft 120***." *Id.* ¶ 73 (emphasis added); FIG. 7 (annotated). Trudeau further discloses that "the tool shaft 120 engages and pushes against the cap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

Thus, Trudeau discloses the rod securing device 30 positioned at a distal end of the drive rod subassembly 3, as shown in Fig. 4*b*. *See also* ORT-1216 ¶¶ 50-54.

g. Claim Limitation [1-6]



Trudeau discloses the "body including first and second elongated grasping members extending therefrom" as recited in claim 1. With respect to a "body," Trudeau discloses "the tool 10 includes a clamping subassembly 90 including a tubular body portion 80, . . . a rod drive sleeve 132, and a sleeve coupling subassembly 6." ORT-1217 ¶ 35; FIG. 1 (annotated).



Alternatively, other features of Trudeau can reasonably be interpreted as being the claimed "body." For example, the ***handle sleeve 162***, as shown in FIG. 11, can separately be viewed as the claimed "body." *Id.* ¶ 95.

Further, Trudeau discloses "the tool 10 includes ***a pair of opposed jaws 60 and 62***" and that "the jaws 60, 62 may open and close relative to each other for attaching or releasing from the pedicle screw fixture 16." *Id*. ¶ 48 (emphasis added); FIG. *4b* (annotated). Trudeau adds that "[m]ore specifically, ***stationary jaw 60 is formed integral with or fixedly attached to the tubular body portion 80*** so as to form a generally unitary structure. ***Movable jaw 62 is pivotally secured with the clamping subassembly 90 including the movable jaw 62 to the tubular body portion 80*** and to the stationary jaw 60." *Id*. ¶ 50 (emphasis added). *See also* ORT-1216 ¶¶ 55-59.

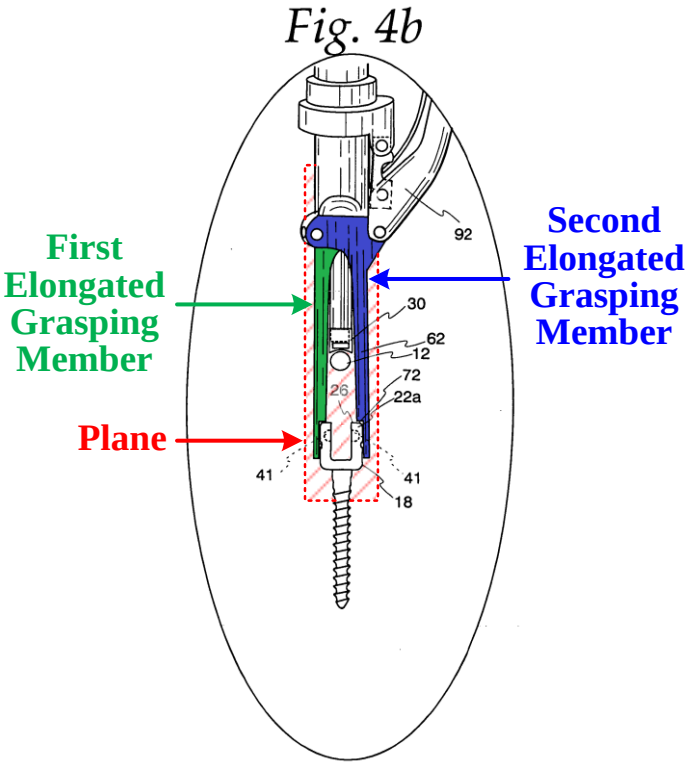
h. Claim Limitation [1-7]

Trudeau discloses "each of the first and second elongated grasping members having a screw grasping element" as recited in claim 1. In particular, Trudeau discloses "the tool 10 includes a pair of opposed jaws 60 and 62, and ***each jaw 60, 62 includes a tooth 38***." ORT-1217 ¶ 48 (emphasis added). Trudeau further discloses "[t]he terminal end 64 [of each jaw 60, 62] includes ***the tooth 38 and is clamped to the yoke 18*** during the spinal rod anchoring operation." *Id.* ¶ 49 (emphasis added). Specifically, Trudeau recites that "the teeth 38 on each jaw 60, 62 are received in one of the recesses 36 on the walls 22 of the yoke 18." *Id*. ¶ 48. *See also* ORT-1216 ¶¶ 60-61.

i. Claim Limitation [1-8]

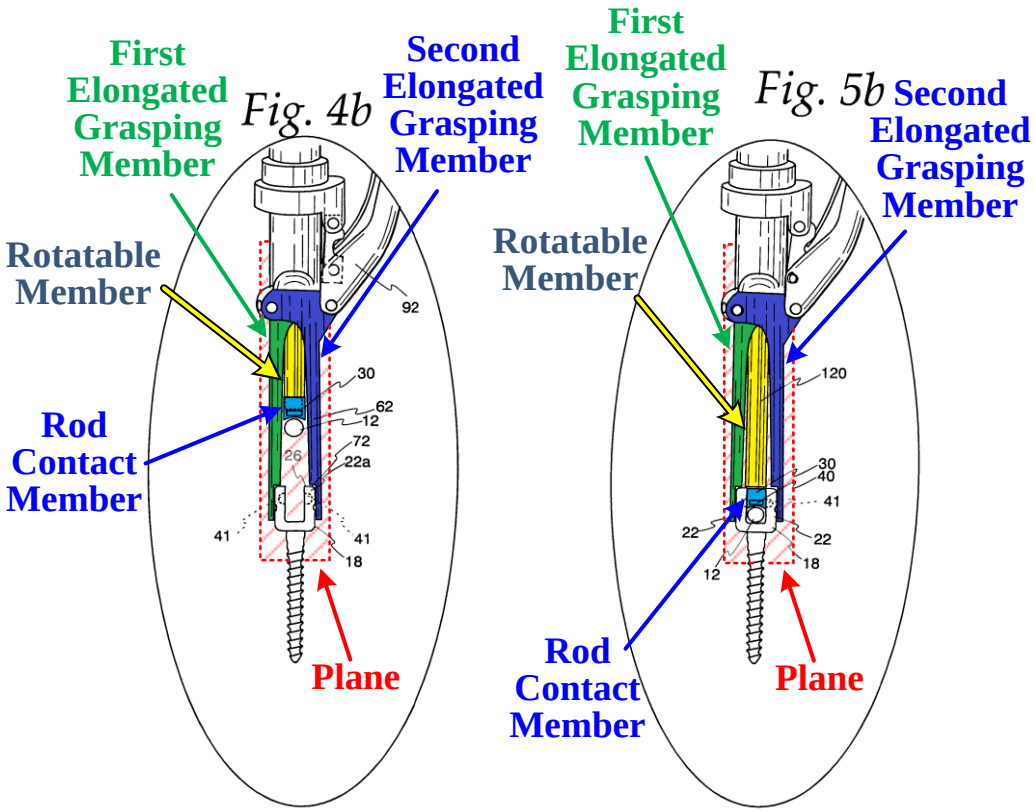
Trudeau discloses the "the rotatable member threadably coupled with the body" as recited in claim 1. For example, Trudeau recites that "[t]he drive rod 140 is threadably advanced or retracted in order to control its movement. More specifically, ***the drive rod 140 includes an externally threaded portion 142 that mates with an internally threaded portion 134 of the drive sleeve 132***. ORT-1217 ¶ 80 (emphasis added). *See also* ORT-1216 ¶¶ 62-63.

j. Claim Limitation [1-9]



Trudeau discloses "first and second elongated grasping members defining a plane" as recited in claim 1. As illustrated in annotated Fig. 4*b*, the opposed jaws 60, 62 implicitly define a plane. *See also* ORT-1216 ¶¶ 64-65.

k. Claim Limitation [1-10]



Trudeau discloses "the rotatable member and the rod contact member movable within the plane" as recited in claim 1. Trudeau discloses the following:

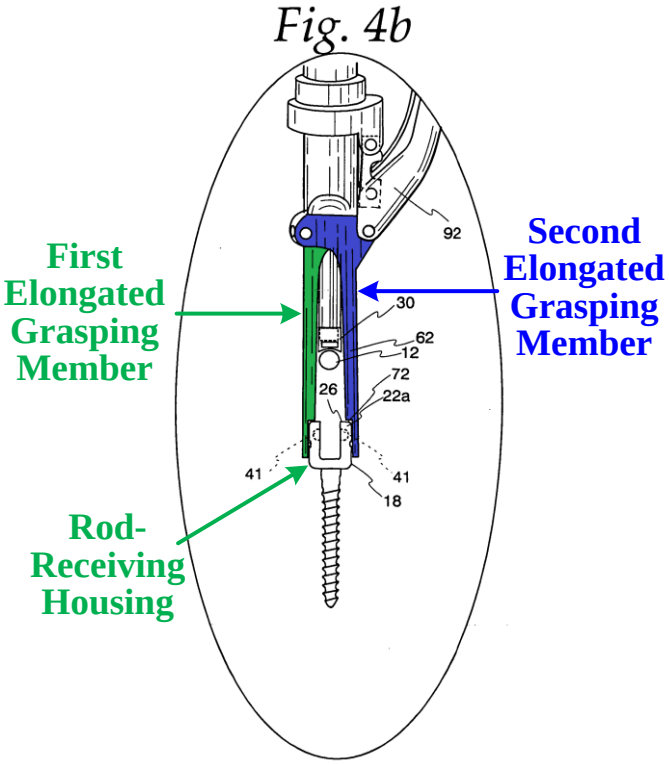
> the drive handle 146 is rotated such that the mating threads 134, 142 of the drive sleeve 132 and drive rod 140, respectively, ***effect linear movement of the drive rod 140*** along its longitudinal axis A . . . [w]hen this ***linear movement by the tool shaft 120*** [of the drive rod assembly 3] is towards the distal end D of the tool 10, ***the movement is transmitted to the cap 30 [of the rod securing device 30]*** and spinal rod 12 to force the cap 30 and spinal rod 12 into the yoke walls 22.

ORT-1217 ¶ 82 (emphasis added).

Such linear movement of the drive rod 140 and tool shaft 120, and thus, cap 30, clearly illustrates that both the drive rod subassembly 3 and the rod securing

device 30 are movable within the plane, as further shown in annotated FIG. 4*b*. *See also* ORT-1216 ¶¶ 66-68.

l. Claim Limitation [1-11]



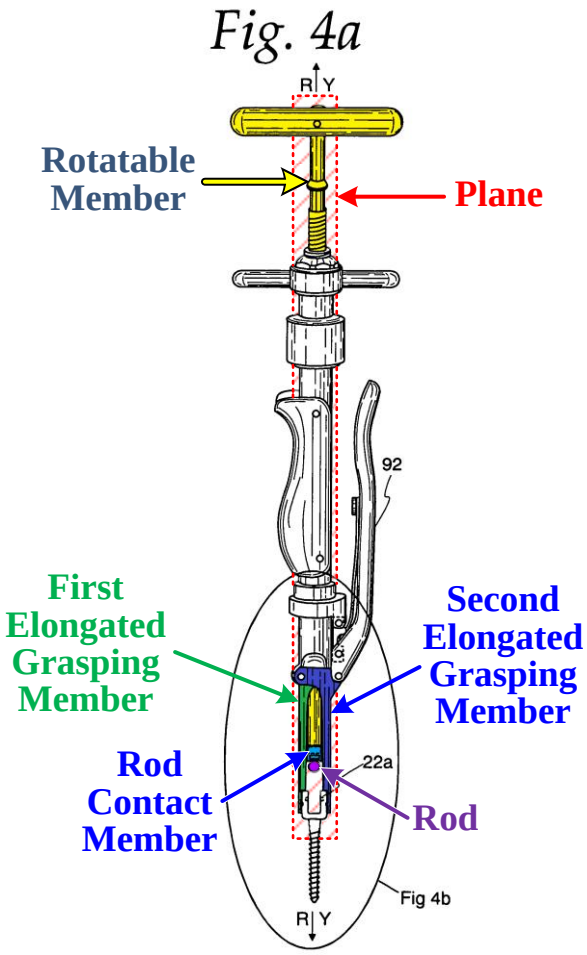
Trudeau discloses "securing the rod reducing device to the bone anchor by engaging the first and second elongated grasping members with the rod-receiving housing so that the rod-receiving housing is disposed between the first and second elongated grasping members" as recited in claim 1.

As discussed, Trudeau discloses a "***rod persuader device 10*** for advancing a spinal rod 12 towards a fixation device 14 in the form of a ***pedicle screw fixture 16***." ORT-1217 ¶ 34 (emphasis added). Trudeau recites that "[d]uring use, ***the persuader tool 10 is preferably secured to the pedicle screw fixture 16 via the***

clamping subassembly 90 and, more specifically, opposed clamping jaw members 60, 62 thereof." *Id*. ¶ 41 (emphasis added). Trudeau adds that "[t]he pedicle screw fixture 16 and the tool 10 are provided with cooperating structure so that ***the tool 10 may be removably attached to the pedicle screw fixture 16 for operation***." *Id*. (emphasis added). In particular, "[t]o attach the jaws 60, 62 and tool 10 to the yoke 18, the jaws 60, 62 are moved together, or closed, so that ***the teeth 38 on each jaw 60, 62 are received in one of the recesses 36 on the walls 22 of the yoke 18***." *Id*. ¶ 48 (emphasis added).

Further, and as shown in annotated FIG. 4*b*, it is clear that the yoke of the pedicle screw fixture is disposed between the jaws 60, 62. *See also* ORT-1216 ¶¶ 69-72.

m. Claim Limitation [1-12]



Trudeau discloses "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.

As discussed, Trudeau discloses the following:

> ***the drive handle 146 is rotated*** such that the mating threads 134, 142 of the drive sleeve 132 and drive rod 140, respectively, ***effect linear movement of the drive rod 140*** along its longitudinal axis A . . . [w]hen this ***linear movement by the tool shaft 120 [of the drive rod***

> ***assembly 3]*** is towards the distal end D of the tool 10, ***the movement is transmitted to the cap 30 [of the rod securing device 30] and spinal rod 12 to force the cap 30 and spinal rod 12 into the yoke walls 22***.

ORT-1217 ¶ 82 (emphasis added).

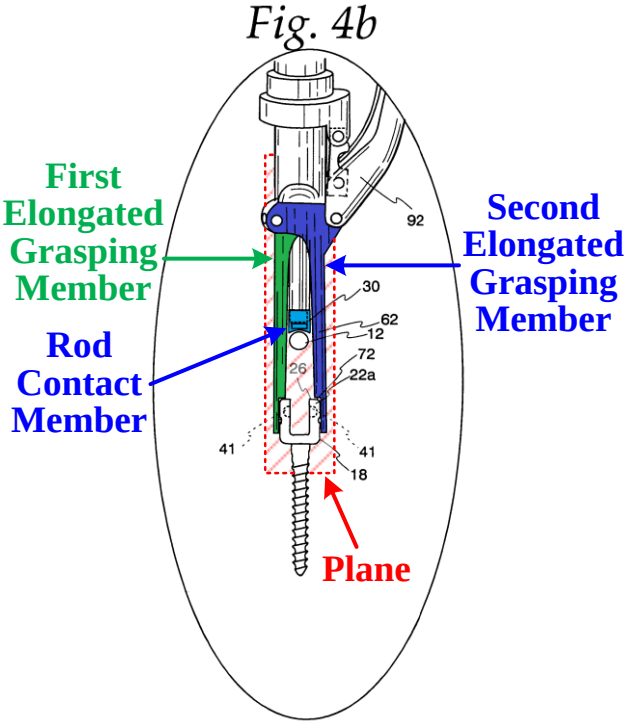
As Trudeau discloses that both the drive rod assembly 3 and the rod securing device 30, or portions thereof, are movable along the longitudinal axis A, the rod securing device 30 is likewise movable within the above-described plane to advance the spinal rod 12 disposed between the jaw members 60, 62 toward the yoke 18, as shown in annotated FIG. 4*b*. *See also* ORT-1216 ¶¶ 73-75.

2. Dependent Claim 3:

Trudeau discloses "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, Trudeau discloses "the tool 10 includes a pair of opposed jaws 60 and 62, and each jaw 60, 62 includes a tooth 38." ORT-1217 ¶ 48. Trudeau further discloses "***[t]he terminal end 64 [of each jaw 60, 62] includes the tooth 38 and is clamped to the yoke 18*** during the spinal rod anchoring operation." *Id*. ¶ 49 (emphasis added). Specifically, Trudeau recites that "the teeth 38 on each jaw 60, 62 are received in one of the recesses 36 on the walls 22 of the yoke 18." *Id*. ¶ 48. *See also* ORT-1216 ¶¶ 76-77.

3. Dependent Claim 5:



Trudeau discloses "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.

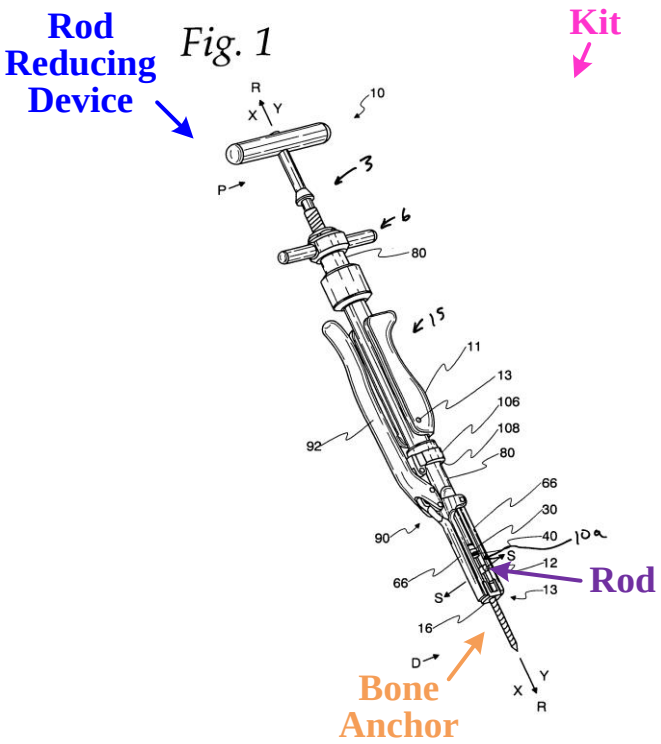
Trudeau discloses "the cap 30*a* [of the rod securing device 30] is utilized for capturing and/or securing the spinal rod 12 within the yoke, and ***the cap 30a is located or positioned between the jaws 60, 62***." ORT-1217 ¶ 72 (emphasis added); FIG. 4*b* (annotated). *See also* ORT-1216 ¶¶ 78-79.

4. Dependent Claim 6:

Trudeau discloses "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. Specifically, Trudeau discloses "***the cap 30*a** [of the rod securing device 30] ***is set on or removably attached to a gripping or torquing portion 120*a *[of the tools shaft 120] of the drive rod subassembly 3*** toward the distal end D of the tool 10." ORT-1217 ¶ 39 (emphasis added). *See also* ORT-1216 ¶¶ 80-81.

5. Independent Claim 8:

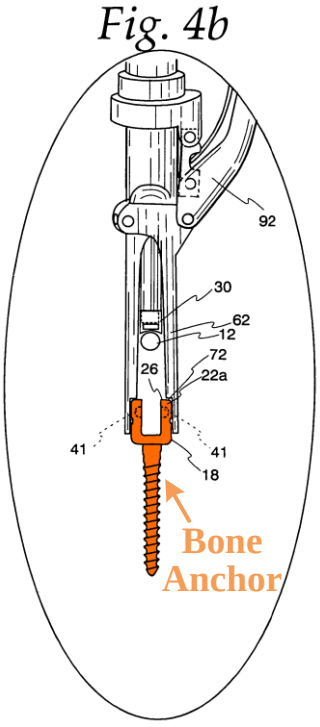
a. Claim Limitation [8-PRE]



Trudeau discloses the claimed "kit for reducing a rod." Trudeau recites "[r]eferring initially to FIG. 1, ***a rod persuader device 10 for advancing a spinal rod 12*** towards a fixation device 14 in the form of a pedicle screw fixture 16 is depicted." ORT-1217 ¶ 34 (emphasis added); FIG. 1 (annotated).

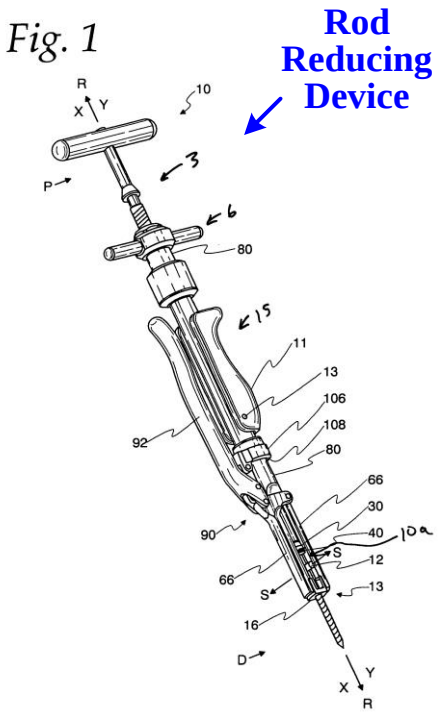
Further, Trudeau discloses that "[g]enerally, the rod persuader tool is used for seating the spinal rod 12 within one or more spinal rod anchoring or fixation devices 14," and that "[p]referably, the fixation device 14 includes a screw fixture 16 secured to the pedicle portion of a vertebrae (not shown), such as with a pedicle bone screw 20 extending therefrom," illustrating that a kit is disclosed. *Id.* ¶ 38. *See also* ORT-1216 ¶¶ 82-83.

b. Claim Limitation [8-1]



Trudeau discloses the "bone anchor" as recited in claim 8. As discussed, Trudeau recites that "[g]enerally, the rod persuader tool is used for seating the spinal rod 12 within one or more ***spinal rod anchoring or fixation devices 14***," and that "[p]referably, ***the fixation device 14 includes a screw fixture 16*** secured to the pedicle portion of a vertebrae (not shown), such as with a pedicle bone screw 20 extending therefrom." ORT-1217 ¶ 38 (emphasis added). *See also* ORT-1216 ¶¶ 84-85.

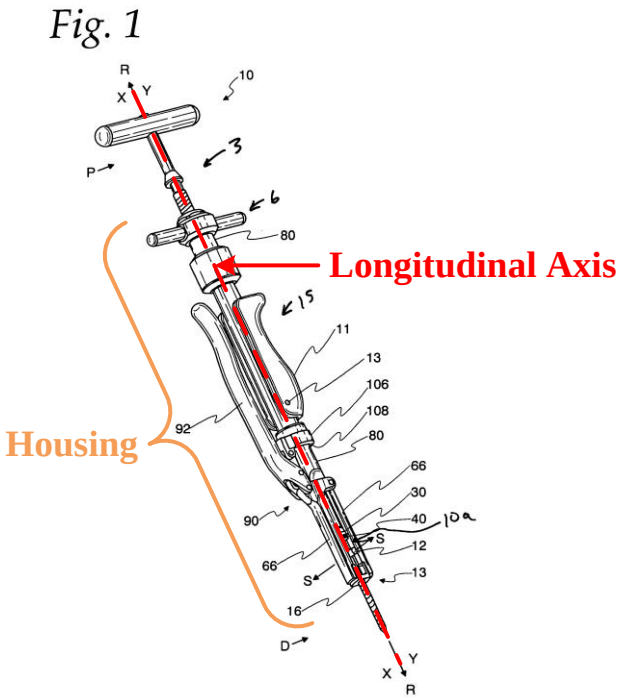
c. Claim Limitation [8-2]



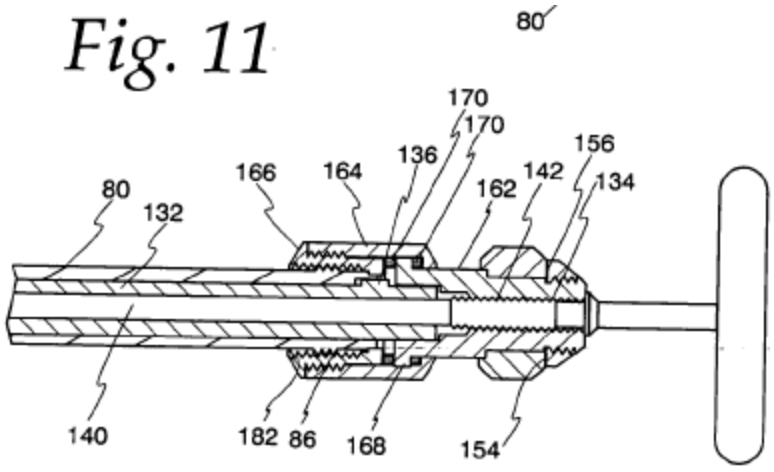
Trudeau discloses the "rod reducing device" as recited in claim 8. For example, Trudeau discloses "[r]eferring initially to FIG. 1, ***a rod persuader device 10*** for advancing a spinal rod 12 towards a fixation device 14 in the form of a

pedicle screw fixture 16 is depicted." ORT-1217 ¶ 34 (emphasis added); FIG. 1 (annotated). *See also* ORT-1216 ¶¶ 86-87.

d. Claim Limitation [8-3]

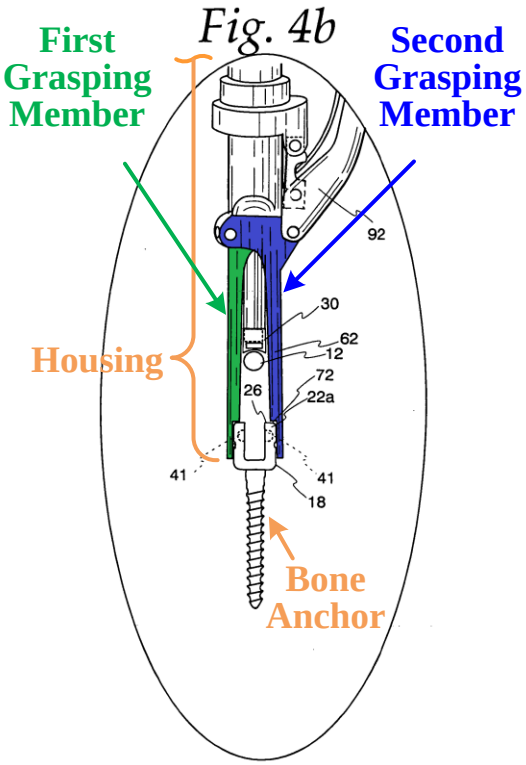


Trudeau discloses the "housing defining a longitudinal axis" as recited in claim 8. For example, Trudeau discloses "the tool 10 includes a clamping subassembly 90 including a tubular body portion 80, . . . a rod drive sleeve 132, and a sleeve coupling subassembly 6." *Id.* ¶ 35; FIG. 1 (annotated). Trudeau also discloses "[a] tool body longitudinal axis R." ORT-1217 ¶ 44; *see also* ORT-1216 ¶¶ 88-91.



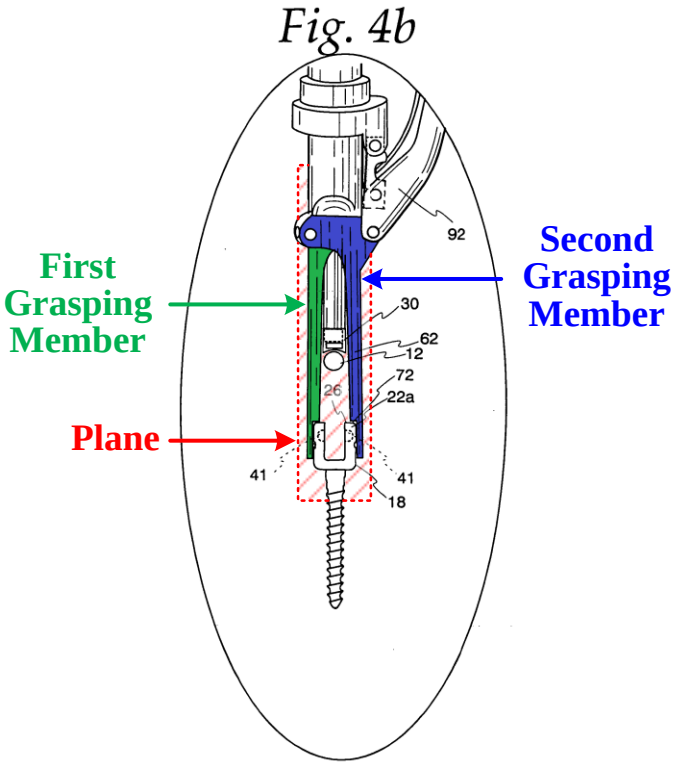
Alternatively, other features of Trudeau can reasonably be interpreted as being the claimed "housing." As discussed, the ***handle sleeve 162***, as shown in annotated FIG. 11, can separately be viewed as the claimed "housing." ORT-1217 ¶ 95.

e. Claim Limitation [8-4]



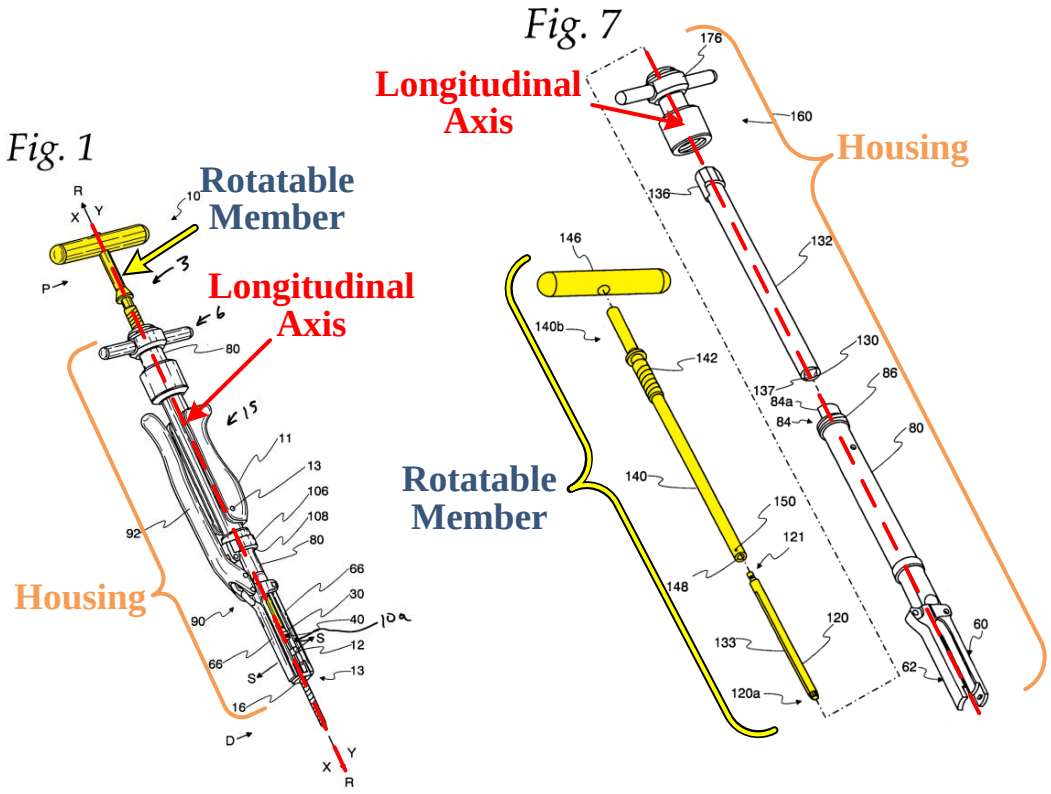
Trudeau discloses the "housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween" as recited in claim 8. In particular, Trudeau discloses "the tool 10 includes ***a pair of opposed jaws 60 and 62***" and "the jaws 60, 62 may open and close relative to each other for ***attaching or releasing from the pedicle screw fixture 16***." ORT-1217 ¶ 48 (emphasis added); FIG. 4*b* (annotated). *See also* ORT-1216 ¶¶ 92-95.

f. Claim Limitation [8-5]



Trudeau discloses the "first and second grasping members defining a plane" as recited in claim 8. As illustrated in annotated Fig. 4*b*, the opposed jaws 60, 62 implicitly define a plane. *See also* ORT-1216 ¶¶ 96-97.

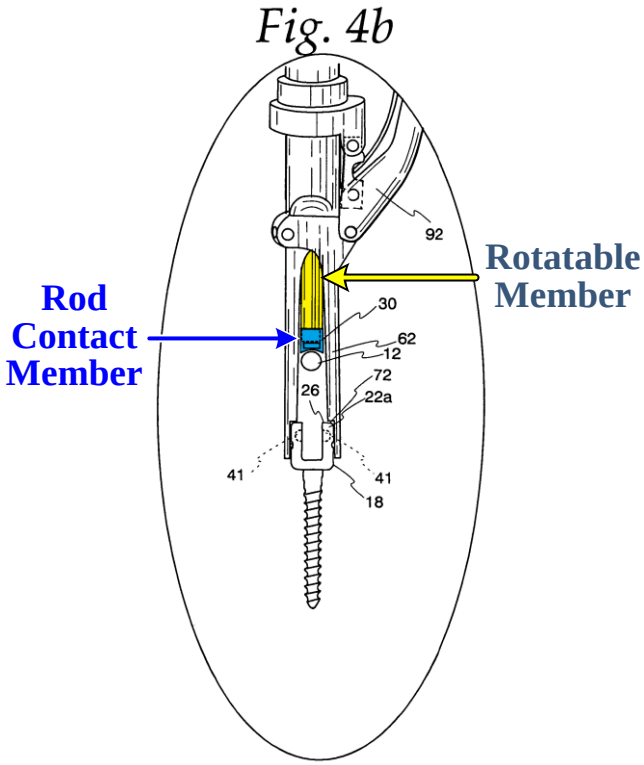
g. Claim Limitation [8-6]



Trudeau discloses the "rotatable member extending through the housing along the longitudinal axis" as recited in claim 8. For example, Trudeau discloses "[a] tool 10 includes . . . ***a drive rod subassembly 3 including a drive rod 140***." ORT-1217 ¶ 35 (emphasis added); FIGS. 1, 7 (annotated). Trudeau discloses that the drive rod subassembly 3 includes "a movable member," which "[i]n the preferred embodiment . . . is ***[the] tool shaft 120***." *Id.* ¶ 73 (emphasis added); FIG. 7 (annotated). Additionally, Trudeau states that "torque generated by a user in ***rotating the drive rod 140*** via the drive handle 146 advances the drive rod 140 along the threads." *Id.* ¶ 80 (emphasis added); FIGS. 1, 7 (annotated).

Trudeau also discloses that "the drive handle 146 is rotated [to] . . . effect linear movement of the drive rod 140 [of the drive rod subassembly 3] along its longitudinal axis A." *Id*. ¶ 82. *See also* ORT-1216 ¶¶ 98-99.

h. Claim Limitation [8-7]

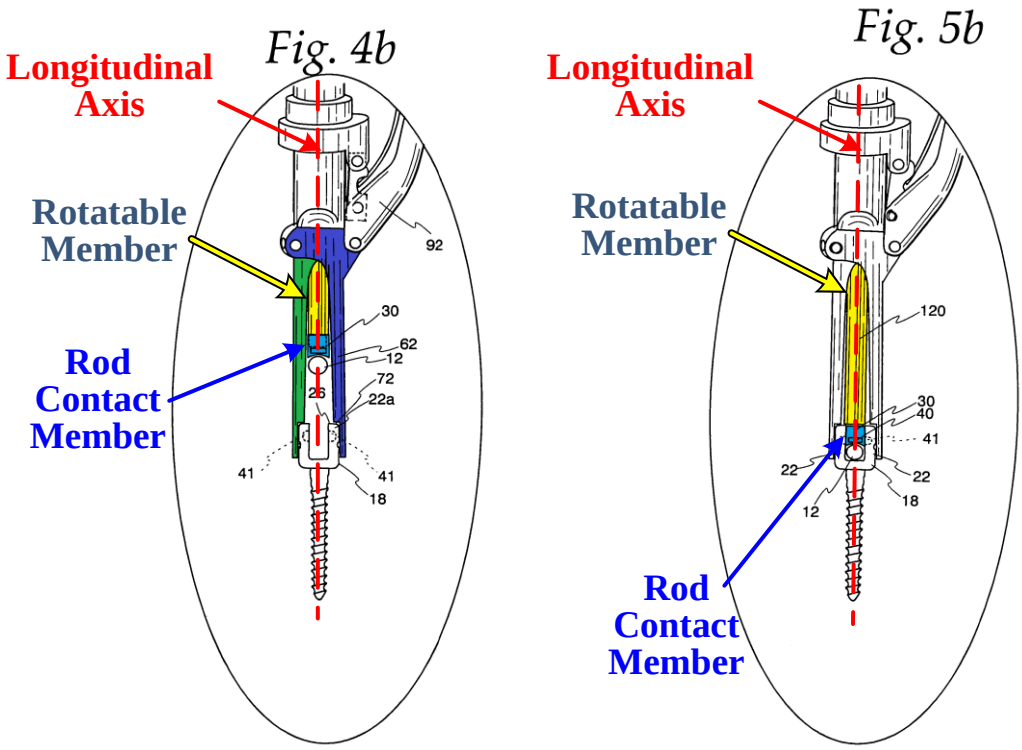


Trudeau discloses the "rod contact member positioned at a distal end of the rotatable member" as recited in claim 8. For example, Trudeau discloses "[a] rod securing device 30" including "[a] cap 30*a*" and "an intermediate clamping member 30*b*." ORT-1217 ¶ 39. Trudeau states that "***the cap 30a [of the rod securing device 30] is set on or removably attached to*** a gripping or torquing portion 120*a* [of the tool shaft 120] of ***the drive rod subassembly 3*** toward the distal end D of the tool 10." *Id*. (emphasis added); FIG. 4*b* (annotated).

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

Thus, Trudeau discloses the rod securing device 30 positioned at a distal end of the drive rod subassembly 3, as shown in Fig. 4*b*. *See also* ORT-1216 ¶¶ 100-104.

i. Claim Limitation [8-8]



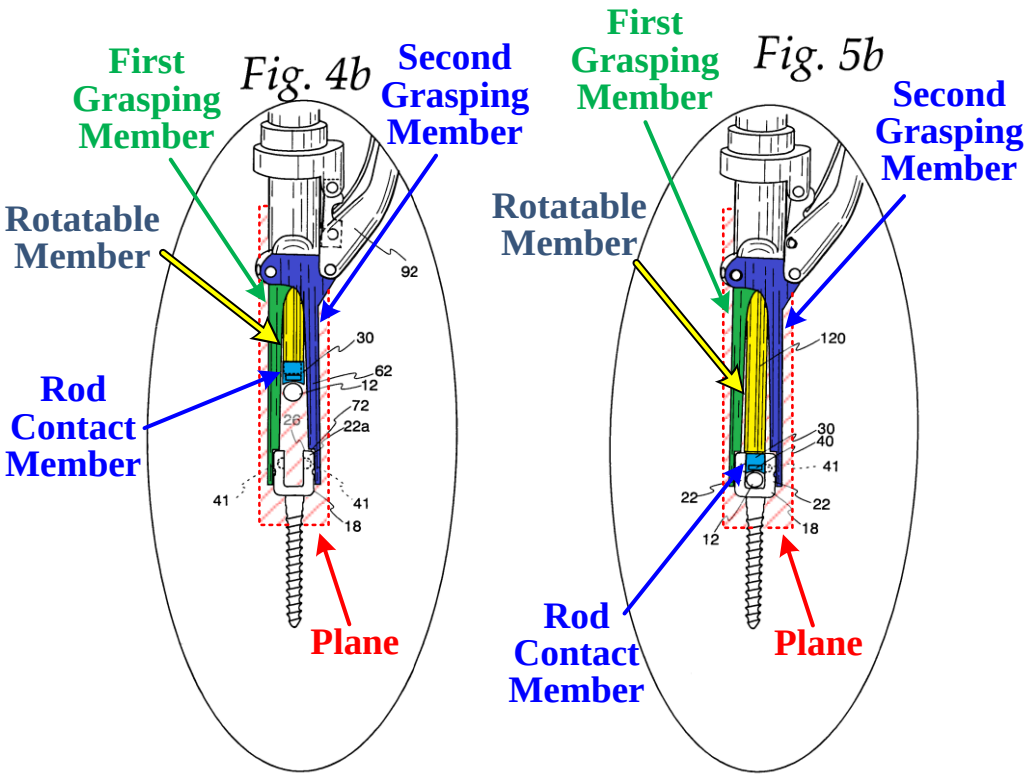
Trudeau discloses the "rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis" as recited in claim 8. As discussed, Trudeau discloses that "***rotating the drive rod 140*** [of the drive rod subassembly 3] via the drive handle 146 ***advances the drive rod 140***." ORT-1217 ¶ 80 (emphasis added).

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

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

As such, Trudeau discloses that the rod securing device 30 is translatable along the axis R in response to rotation of the drive rod subassembly 3 about the R axis. *See also* ORT-1216 ¶¶ 105-106.

j. Claim Limitation [8-9]



Trudeau discloses "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. Trudeau discloses the following:

> the drive handle 146 is rotated such that the mating threads 134, 142 of the drive sleeve 132 and drive rod 140, respectively, ***effect linear movement of the drive rod 140*** along its longitudinal axis A . . . [w]hen this ***linear movement by the tool shaft 120*** [of the drive rod assembly 3] is towards the distal end D of the tool 10, ***the movement is transmitted to the cap 30 [of the rod securing device 30]*** and spinal rod 12 to force the cap 30 and spinal rod 12 into the yoke walls 22.

ORT-1217 ¶ 82 (emphasis added).

Such linear movement of the drive rod 140 and tool shaft 120, and thus, cap 30, clearly illustrates that both the drive rod subassembly 3 and the rod securing device 30 are translatable within the plane defined by the opposed jaws 60, 62, as further shown in annotated FIG. 4*b*. *See also* ORT-1216 ¶¶ 107-109.

6. Dependent Claim 9:

Trudeau discloses a kit "further comprising a plurality of bone anchors and a plurality of rod reducing devices" as recited in claim 9. *See* ORT-1216 ¶¶ 110-115. First, Trudeau discloses "[r]eferring initially to FIG. 1, ***a rod persuader device 10*** for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16 is depicted." ORT-1217 ¶ 34 (emphasis added); FIG. 1 (annotated). Further, Trudeau recites that "[g]enerally, the rod persuader tool is used for seating the spinal rod 12 within ***one or more spinal rod anchoring or fixation devices 14***." ORT-1217 ¶ 38 (emphasis added).

While claim 9 calls for the duplication of the rod reducing device described, 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); *see also* ORT-1216 ¶¶ 114-115.

7. Dependent Claim 10:

Trudeau discloses 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. For example, Trudeau recites the following:

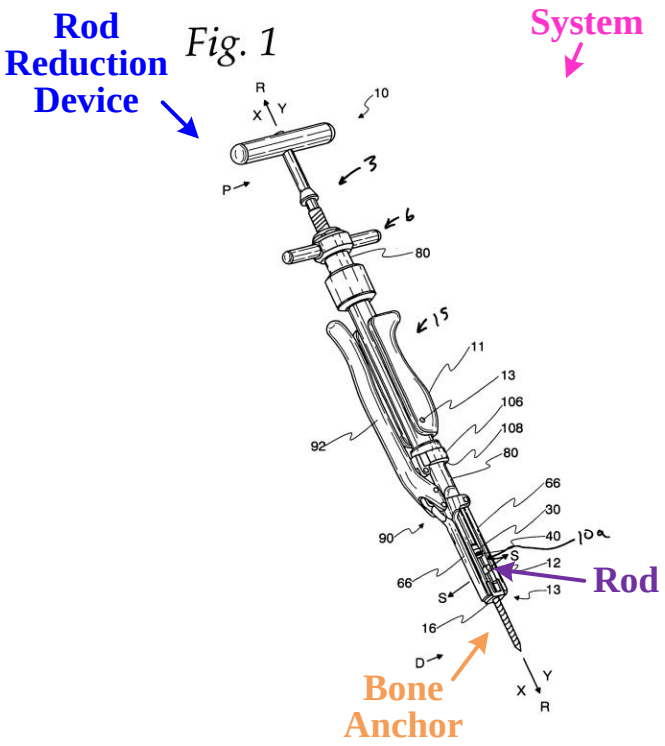
> [t]he cap 30 may be rotated to a final position to seat the cap 30 and spinal rod 12 within the yoke 18 such that the holding flanges 40 are fully located within the recesses 41 of the yoke 18, or may be rotated to a position sufficient to partially secure the cap 30 within the yoke 18 so that a surgeon may secure the spinal rod 12 to a plurality of yokes 18, ***and then secure the caps 30 with a separate instrument as a final locking step***.

ORT-1217 ¶ 104 (emphasis added).

Thus, the kit further comprises at least one additional orthopedic tool (*e.g.*, a locking device). *See also* ORT-1216 ¶¶ 116-118.

8. Independent Claim 12:

a. Claim Limitation [12-PRE]



Trudeau discloses the "system for reducing a connecting rod" as recited in claim 12. Trudeau recites "[r]eferring initially to FIG. 1, ***a rod persuader device 10 for advancing a spinal rod 12*** towards a fixation device 14 in the form of a pedicle screw fixture 16 is depicted." ORT-1217 ¶ 34 (emphasis added); FIG. 1 (annotated).

Further, Trudeau discloses that "[g]enerally, the rod persuader tool is used for seating the spinal rod 12 within one or more spinal rod anchoring or fixation devices 14," and that "[p]referably, the fixation device 14 includes a screw fixture 16 secured to the pedicle portion of a vertebrae (not shown), such as with a

pedicle bone screw 20 extending therefrom," illustrating that a system is disclosed. *Id*. ¶ 38. *See also* ORT-1216 ¶¶ 119-121.

b. Claim Limitation [12-1]

As discussed in Section VIII(A)(5)(b), Trudeau discloses "a bone anchor" and therefore likewise discloses the identical claim limitation in claim 12.

c. Claim Limitation [12-2]

Trudeau discloses the "connecting rod" as recited in claim 12. As discussed, Trudeau recites that "[g]enerally, the rod persuader tool is used for seating the ***spinal rod 12*** within one or more spinal rod anchoring or fixation devices 14. ORT-1217 ¶ 38 (emphasis added). *See also* ORT-1216 ¶¶ 122-123.

d. Claim Limitation [12-3]

As discussed in Section VIII(A)(5)(c), Trudeau 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-1201 at 3:21-47, 3:65-66, 4:1-2, 7:24-50.

e. Claim Limitation [12-4]

As discussed in Section VIII(A)(5)(d), Trudeau discloses "a housing defining a longitudinal axis" and therefore likewise discloses the identical claim limitation in claim 12.

f. Claim Limitation [12-5]

As discussed in Section VIII(A)(5)(e), Trudeau 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. Claim Limitation [12-6]

As discussed in Section VIII(A)(5)(f), Trudeau discloses "the first and second grasping members defining a plane" and therefore likewise discloses the identical claim limitation in claim 12.

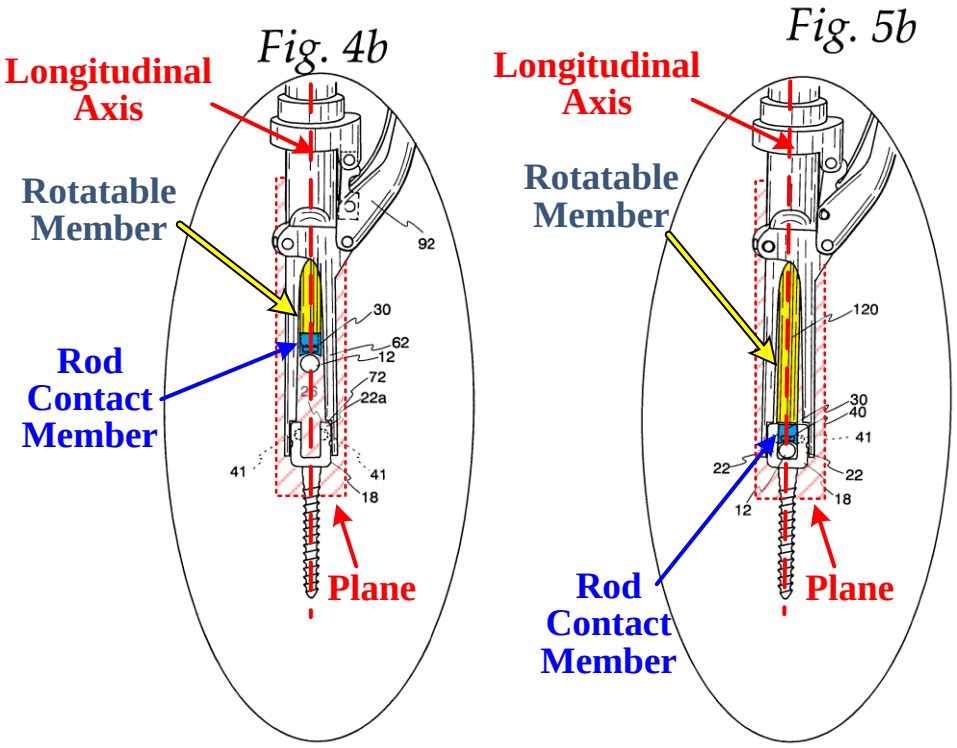
h. Claim Limitation [12-7]

As discussed in Section VIII(A)(5)(g), Trudeau discloses "a rotatable member extending through the housing along the longitudinal axis" and therefore likewise discloses the identical claim limitation in claim 12.

i. Claim Limitation [12-8]

As discussed in Section VIII(A)(5)(h), Trudeau 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. Claim Limitation [12-9]



Trudeau discloses the "rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis" as recited in claim 12. Trudeau discloses the following:

> ***the drive handle 146 is rotated*** such that the mating threads 134, 142 of the drive sleeve 132 and drive rod 140, respectively, ***effect linear movement of the drive rod 140*** along its longitudinal axis A . . . [w]hen this ***linear movement by the tool shaft 120*** [of the drive rod assembly 3] is towards the distal end D of the tool 10, ***the movement***

> ***is transmitted to the cap 30 [of the rod securing device 30]*** and spinal rod 12 to force the cap 30 and spinal rod 12 into the yoke walls 22.

ORT-1217 ¶ 82 (emphasis added).

Such linear movement of the drive rod 140 and tool shaft 120, and thus, cap 30, clearly illustrates that the rod securing device 30 is translatable within the above-described plane in response to rotation of the drive rod subassembly 3 about the R axis, as further shown in annotated FIG. 4*b*. *See also* ORT-1216 ¶¶ 145-148.

9. Dependent Claim 15:

Trudeau discloses 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. *See* ORT-1216 ¶¶ 149-157.

First, Trudeau discloses "[r]eferring initially to FIG. 1, ***a rod persuader device 10*** for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16 is depicted." ORT-1217 ¶ 34 (emphasis added); FIG. 1 (annotated). Further, Trudeau recites that "[g]enerally, the rod persuader tool is used for seating the spinal rod 12 within ***one or more spinal rod anchoring or fixation devices 14***." ORT-1217 ¶ 38 (emphasis added).

As discussed, Trudeau recites that "[d]uring use, ***the persuader tool 10 is preferably secured to the pedicle screw fixture 16 via the clamping subassembly 90*** and, more specifically, opposed clamping jaw

members 60, 62 thereof." ORT-1217 ¶ 41 (emphasis added). Trudeau adds that "[t]he pedicle screw fixture 16 and the tool 10 are provided with cooperating structure so that ***the tool 10 may be removably attached to the pedicle screw fixture 16 for operation***." *Id*. (emphasis added).

While claim 15 calls for the duplication of the rod reduction device described, 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); ORT-1216 ¶¶ 156-157.

10. Dependent Claim 16:

Trudeau discloses 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. For example, Trudeau recites the following:

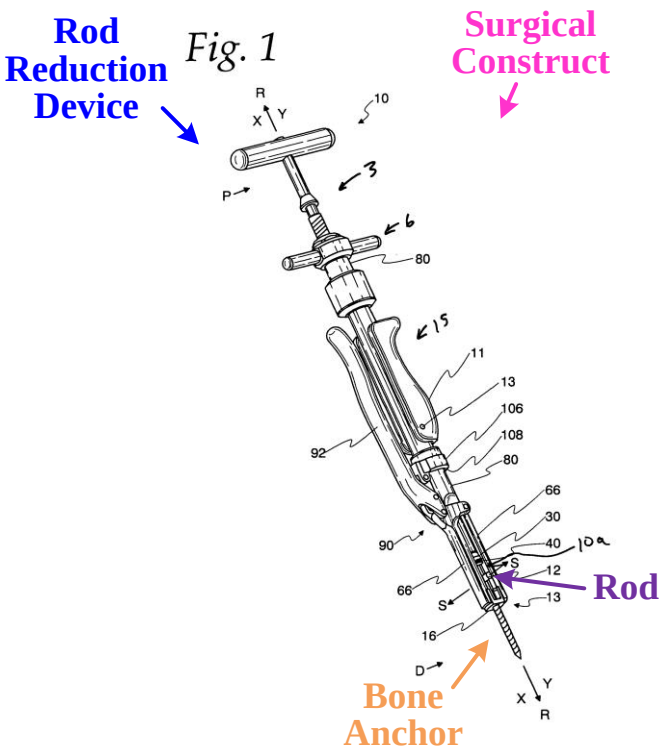
> [t]he cap 30 may be rotated to a final position to seat the cap 30 and spinal rod 12 within the yoke 18 such that the holding flanges 40 are fully located within the recesses 41 of the yoke 18, or may be rotated to a position sufficient to partially secure the cap 30 within the yoke 18 so that a surgeon may secure the spinal rod 12 to a plurality of yokes 18, ***and then secure the caps 30 with a separate instrument as a final locking step***.

ORT-1217 ¶ 104 (emphasis added).

Thus, the system further comprises an additional orthopedic tool or device (*e.g.*, a locking device). *See* ORT-1216 ¶¶ 158-160.

11. Independent Claim 17:

a. Claim Limitation [17-PRE]



Trudeau discloses the "surgical construct" as recited in claim 17. As discussed, Trudeau recites "[r]eferring initially to FIG. 1, a rod persuader device 10 for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16 is depicted." ORT-1217 ¶ 34; FIG. 1. Further, Trudeau recites that "FIG. 1 is a perspective view of a ***surgical apparatus*** in accordance with the present invention showing a clamping mechanism including opposed jaw members

clamped onto a coupling member of a spinal rod anchoring device." *Id*. ¶ 8 (emphasis added). Thus, a surgical construct is disclosed.

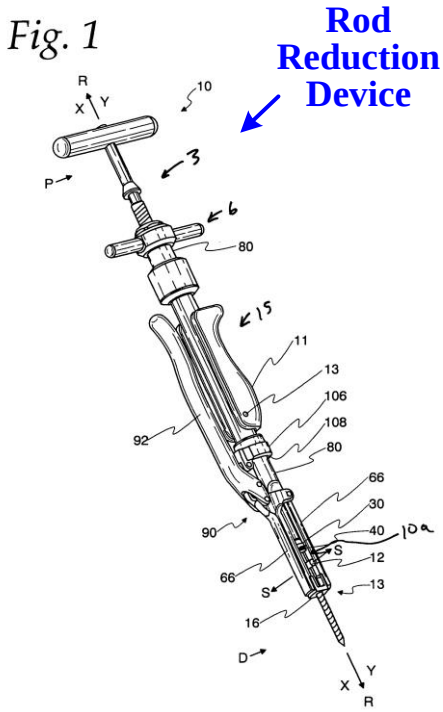
b. Claim Limitation [17-1]

Trudeau discloses the "plurality of bone anchors" as recited in claim 17. As discussed, Trudeau recites that "[g]enerally, the rod persuader tool is used for seating the spinal rod 12 within ***one or more spinal rod anchoring or fixation devices 14***." ORT-1217 ¶ 38 (emphasis added); *see* ORT-1216 ¶¶ 161-162.

c. Claim Limitation [17-2]

As discussed in Section VIII(A)(8)(c), Trudeau discloses "a connecting rod" and therefore likewise discloses the identical claim limitation in claim 17.

d. Claim Limitation [17-3]



Trudeau discloses the "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. *See* ORT-1216 ¶¶ 164-171. As discussed, Trudeau discloses "[r]eferring initially to FIG. 1, ***a rod persuader device 10*** for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16 is depicted." ORT-1217 ¶ 34 (emphasis added); FIG. 1 (annotated).

While claim 17 calls for the duplication of the rod reduction device[2] described, 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); ORT-1216 ¶¶ 170-171.

e. Claim Limitation [17-4]

As discussed in more detail below, Trudeau discloses rod reduction devices including all of the recited features of claim 17.

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

f. Claim Limitation [17-5]

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

g. Claim Limitation [17-6]

As discussed in Section VIII(A)(5)(e), Trudeau 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. Claim Limitation [17-7]

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

i. Claim Limitation [17-8]

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

j. Claim Limitation [17-9]

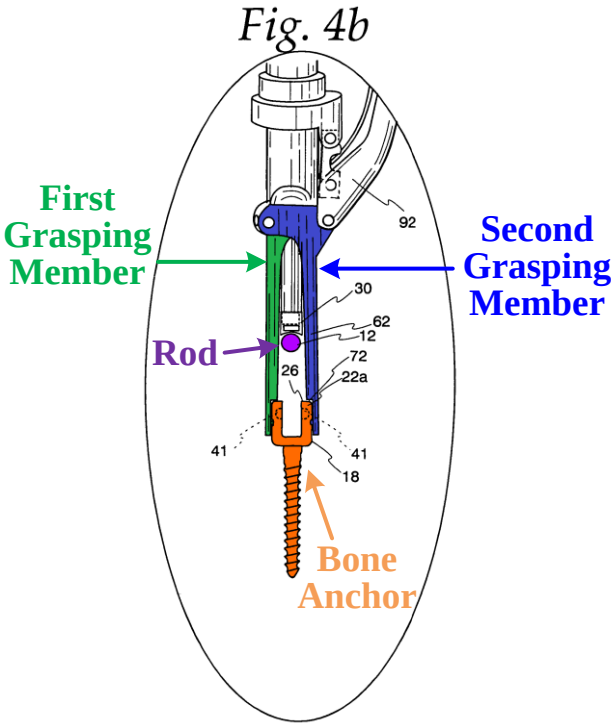
As discussed in Section VIII(A)(5)(h), Trudeau discloses "a rod contact member positioned at a distal end of the rotatable member" and therefore likewise discloses the identical claim limitation in claim 17.

k. Claim Limitation [17-10]

As discussed in Section VIII(A)(8)(j), Trudeau 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. Dependent Claim 18:

a. Claim Limitation [18-1]



Trudeau discloses "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. *See* ORT-1216 ¶¶ 195-202.

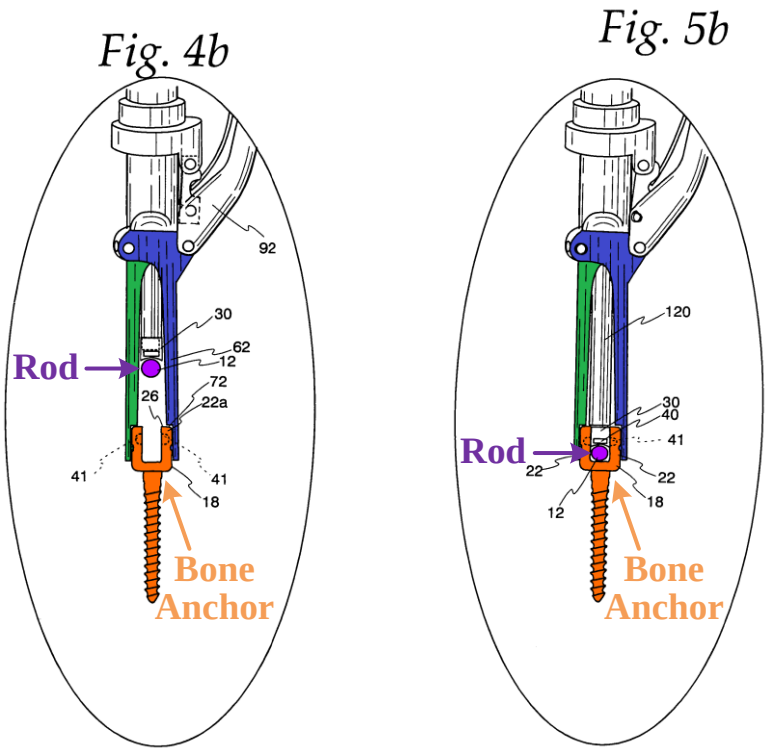
As discussed, Trudeau discloses "the cap 30*a* [of the rod securing device 30] is utilized for capturing and/or securing the spinal rod 12 within the yoke, and ***the cap 30a is located or positioned between the jaws 60, 62 prior to insertion of the spinal rod 12 between the jaws 60, 62*** so that a drive end 120*a* of the tool shaft 120 is received in a recess 122 in the cap 30*a*." ORT-1217 ¶ 72 (emphasis added); FIG. 4*b* (annotated).

As discussed, Trudeau discloses "[r]eferring initially to FIG. 1, ***a rod persuader device 10*** for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16 is depicted." ORT-1217 ¶ 34 (emphasis added); FIG. 1 (annotated).

While claim 18 refers to the duplication of the rod reduction device described, 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); *see* ORT-1216 ¶¶ 201-202.

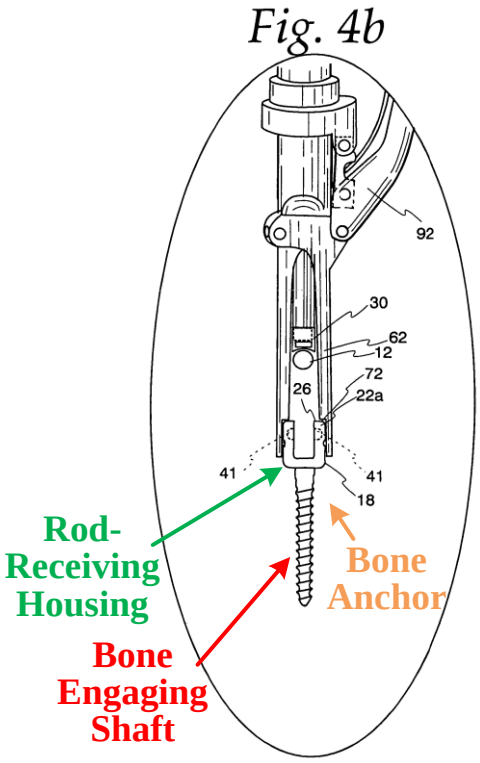
b. Claim Limitation [18-2]



Trudeau discloses "whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors" as recited in claim 18. *See* ORT-1216 ¶¶ 203-209. Specifically, Trudeau discloses "[t]he tool shaft 120 [of the drive rod subassembly 3] advances along the axis R of the persuader ***to push the cap 30a*** [of the rod securing device 30] ***and spinal rod 12 into the yoke 18***." *Id.* ¶ 74 (emphasis added); FIGS. 4*b*, 5*b* (annotated).

As discussed in Section VIII(A)(12), Trudeau discloses that such actuation can be performed for a plurality of rod reduction devices.

13. Dependent Claim 19:



Trudeau discloses "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. *See* ORT-1216 ¶¶ 210-214.

For example, Trudeau recites that a "fixation device 14 includes a screw fixture 16 secured to the pedicle portion of a vertebrae (not shown), such as with ***a pedicle bone screw 20 extending therefrom***. The pedicle screw fixture 16 includes ***a coupling device, such as a yoke 18 that may be formed unitary with the screw***." ORT-1217 ¶ 38 (emphasis added); FIG. 3*b*.

Further, and as discussed, Trudeau discloses "[t]he tool shaft 120 [of the drive rod subassembly 3] advances along the axis R of the persuader ***to push the cap 30a*** [of the rod securing device 30] ***and spinal rod 12 into the yoke 18***." *Id.* ¶ 74 (emphasis added); FIGS. 4*b*, 5*b* (annotated).

As discussed in Section VIII(A)(12), Trudeau discloses that such actuation can be performed for a plurality of rod reduction devices.

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

Claims 9, 15, and 17-19 of the '664 Patent are also rendered obvious by Trudeau in view of Justis. Justis was filed on February 7, 2006 and published on September 13, 2007. ORT-1218 at 1. Therefore, Justis is prior art under at least 35 U.S.C. § 102(e). Like Trudeau, Justis was never cited nor considered by the Examiner during prosecution of the '664 Patent. ORT-1201 at 1-2; ORT-1216 ¶ 215.

As discussed, Trudeau discloses surgical devices and methods for positioning and securing a spinal rod along a spine. ORT-1217 ¶¶ 1, 34. Similarly, Justis discloses systems and methods for positioning a connecting element adjacent the spinal column. ORT-1218 ¶ 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. Further, Justis also discloses a rod reducing device. For example, Justis recites that

once the connecting element is positioned in the respective space, "the one or more anchor extensions 100 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.

1. Dependent Claim 9:

The combination of Trudeau and Justis teaches a kit "further comprising a plurality of bone anchors and a plurality of rod reducing devices." ORT-1216 ¶ 216.

Claim 9 depends from claim 8, and as discussed in Section VIII(A)(5), Trudeau discloses each of the limitations of claim 8 (*i.e.*, claim limitations [8-PRE] through [8-9]). As discussed in Section VIII(A)(6), Trudeau discloses a "plurality of bone anchors" and, at least singularly, "a rod reducing device." *Id*. ¶¶ 217-218.

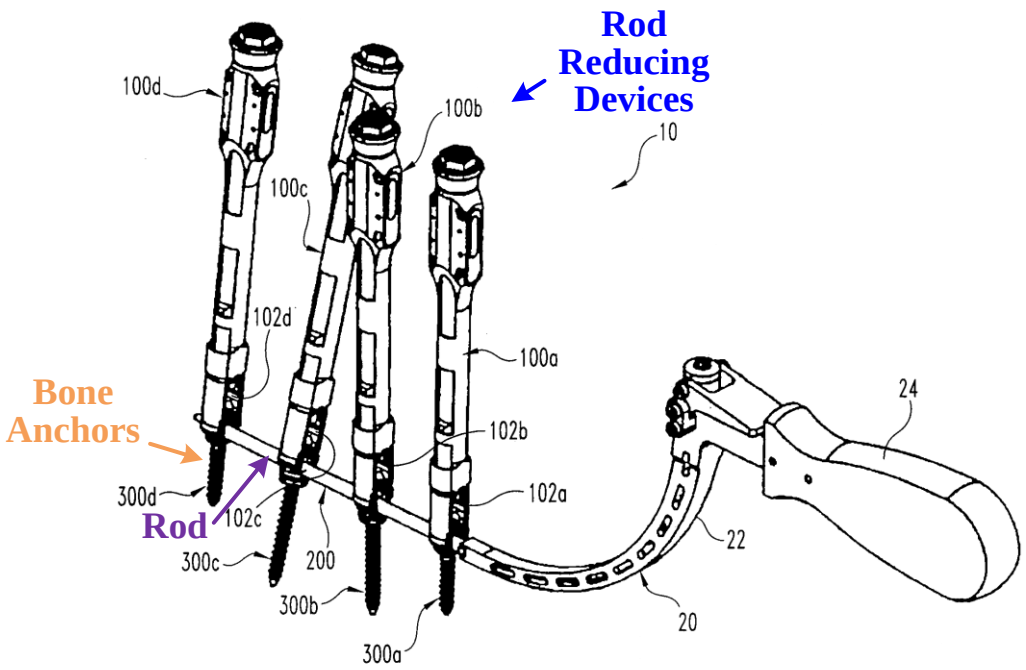


Fig. 3

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." ORT-1218 ¶ 65; FIG. 2 (annotated). ORT-1216 ¶ 220. As shown in annotated FIG. 2, 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. *Id*.

It would have been obvious to a POSITA to use a plurality of the rod reducing devices of Trudeau in a kit for reducing a rod, based on the teachings of Justis, with the plurality of bone anchors described in Trudeau. ORT-1216 ¶ 221. Support for such combination clearly lies in the fact that both Trudeau and Justis describe rod reducing devices and methods for positioning a connecting rod along a spine. *Id*. ¶ 221. Also, 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*. ¶ 227.

While this fact alone is sufficient, Trudeau further recites that "it is desirable to have an improved apparatus for use with such implant devices to direct or manipulate, for instance, a rod into a yoke and effect the securing of the rod therein." ORT-1217 ¶ 7. For example, Trudeau explains that a rod is typically "deformed or bent in a predetermined manner for the desired positioning of vertebrae," and that force is required to achieve proper seating of a spinal rod because "the deformation provided to the spinal rod prior to its securement with the yokes may not provide exact conformation with the position or alignment of the yokes." *Id*. ¶ 5. As Justis 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," it is clear that a POSITA would use a plurality of the rod reducing devices of

Trudeau in the manner described in Justis. ORT-1216 ¶ 223. 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. ORT-1216 ¶ 227.

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-1216 ¶ 219.

2. Dependent Claim 15:

The combination of Trudeau 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(A)(8), Trudeau discloses each of the limitations of claim 12 (*i.e.*, claim limitations [12-PRE] through [12-9]). As discussed in Section VIII(A)(9), Trudeau discloses a "plurality of bone anchors" and, at least singularly, "a rod reduction device," where the rod reduction device is "mountable to a bone anchor of the plurality of bone anchors." ORT-1216 ¶ 226.

Further, as discussed in Section VIII(B)(1), it would have been obvious to a POSITA to use a plurality of the rod reducing devices of Trudeau 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. ORT-1216 ¶¶ 227-228. For the same reasons described therein and above, Trudeau and Justis teach the claim limitations of claim 15. *Id.*

3. Independent Claim 17:

The combination of Trudeau and Justis teaches a surgical construct recited in independent claim 17. In particular, the combination of Trudeau and Justis teach 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 limitation [17-3].

As discussed in Section VIII(A)(11), Trudeau 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 Trudeau 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." ORT-1216 ¶ 230.

Further, as discussed in Section VIII(B)(1), it would have been obvious to a POSITA to use a plurality of the rod reducing devices of Trudeau 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 connectable to a bone anchor of the plurality of bone anchors. ORT-1216 ¶ 231. For the same reasons described therein, Trudeau and Justis teach the claim limitation [17-3], and thus, all the claim limitations of independent claim 17. ORT-1216 ¶¶ 229-231.

4. Dependent Claim 18:

The combination of Trudeau 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 whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors" as recited in claim limitations [18-1] and [18-2].

As discussed in Section VIII(A)(12), regarding claim 18, which depends from independent claim 17, Trudeau discloses "wherein the connecting rod is disposed between the first and second grasping members," at least with respect to a singular "a rod reduction device," where the rod reduction device is "mounted to [a] respective bone anchor[] of the plurality of bone anchors." ORT-1216 ¶ 233.

Further, as discussed in Section VIII(B)(1), it would have been obvious to a POSITA to use a plurality of the rod reducing devices of Trudeau 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 mounted to a bone anchor of the

plurality of bone anchors. ORT-1216 ¶¶ 234, 237. For the same reasons described therein, Trudeau and Justis teach the claim limitations [18-1] and [18-2]. ORT-1216 ¶¶ 232-234; 235-237.

5. Dependent Claim 19:

The combination of Trudeau 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(A)(13), regarding claim 19, which depends from independent claim 17, Trudeau discloses, at least singularly, "a rod reduction device," where the rod reduction device is "approximating [a] connecting rod toward the rod receiving housing of the bone anchor" of the plurality of bone anchors.

Further, as discussed in Section VIII(B)(1), it would have been obvious to a POSITA to use a plurality of the rod reducing devices of Trudeau in a kit for reducing a rod, based on the teachings of Justis, to approximate a connecting rod toward respective rod receiving housings of bone anchors of Trudeau. For the same reasons described therein, Trudeau and Justis teach the claim limitations of claim 19. ORT-1216 ¶¶ 238-240.

C. Ground 3: Claims 1, 3, 5, and 6 Are Rendered Obvious by Sparker in View of Trudeau

Claims 1, 3, 5, and 6 of the '664 Patent are also rendered obvious by Sparker in view of Trudeau. ORT-1216 ¶ 241. 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-1201 at 1-2.

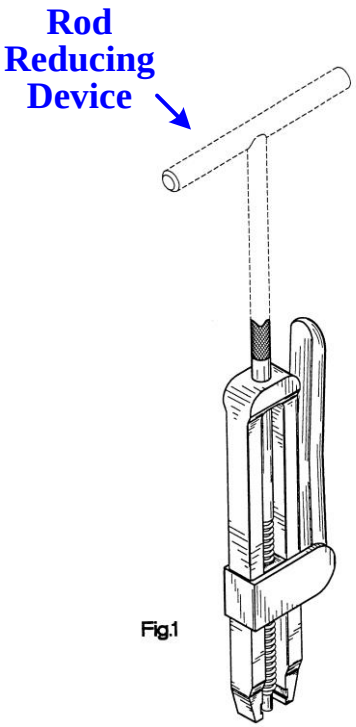
Sparker recites a "combined hook holder and rod mover for spinal surgery." ORT-1219 at Title, Claim. FIGS. 1-7 of Sparker show the construction of the same, and in association with the Title and Claim language, it would have been understood by a POSITA that the combined hook holder and rod mover for spinal surgery functions as a rod reducing device. ORT-1216 ¶ 245. 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*. ¶ 243.

Moreover, Trudeau discloses surgical devices and ***methods for positioning and securing a spinal rod along a spine***. ORT-1217 ¶¶ 1, 34; ORT-1216 ¶ 244. Like Sparker, Trudeau discloses a rod reducing device. ORT-1216 ¶ 245. Specifically, Trudeau discloses "a rod persuader device 10 for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16." *Id.* ¶ 34. Trudeau describes how its rod reducing device is used to perform a method

for securing a spinal rod. Since Sparker and Trudeau are in the same spinal surgery field for reducing rods, it would have been obvious to a POSITA to combine Sparker with Trudeau. ORT-1216 ¶ 245. As such, while Sparker is otherwise silent as to specifics of the functionality of its rod reducing device, it would have been obvious to a POSITA to operate Sparker's rod reducing device in the manner described for Trudeau's rod reducing device. *Id*. ¶ 245. Thus, to the extent any of the limitations of claim 1 are not disclosed by Sparker, it would have been obvious to a POSITA to modify Sparker in view of Trudeau. *Id*.

1. Claim 1:

a. Claim Limitation [1-PRE]



The combination of Sparker and Trudeau teaches "a method of advancing a rod into a housing of a bone anchor" as recited in claim 1. As discussed above, a POSITA would have understood that the "combined hook holder and rod mover" shown in annotated FIG. 1 is a rod reducing device that couples to a rod-receiving housing of a bone anchor and is used to advance a rod into such housing the bone anchor. ORT-1216 ¶ 243.

Nevertheless, Trudeau recites "[t]he invention relates to an apparatus and ***method for securing a spinal rod along the spine*** and, more particularly, to an apparatus and ***method for securing the spinal rod to extend through a coupling device including an anchor member***." ORT-1217 ¶ 1 (emphasis added). Further, and as shown in annotated FIG. 1, Trudeau discloses "a rod persuader device 10 [a rod reducing device] for advancing a spinal rod 12 towards a fixation device 14 in the form of a pedicle screw fixture 16." *Id.* ¶ 34; Section VIII(A)(1)(d).

As discussed, it would have been obvious to a POSITA that Sparker's rod reducing device would be used in the identical, or substantially identical, method as disclosed in Trudeau. *See* ORT-1216 ¶ 245. As such, it would have been obvious to a POSITA to employ and/or modify Sparker's rod reducing device to perform the method disclosed in Trudeau. ORT-1216 ¶ 245.

b. Claim Limitation [1-1]

The combination of Sparker and Trudeau teaches "coupling a rod reducing device to a bone anchor" as recited in claim 1.

As discussed in this Ground, a POSITA would have understood that in use Sparker's rod reducing device would couple to a bone anchor. Further, as discussed in Section VIII(A)(1)(b), Trudeau discloses "coupling a rod reducing device to a bone anchor."

Thus, in view of Trudeau's teachings, it would have been obvious to a POSITA that Sparker teaches first and second elongated grasping members for coupling to a bone anchor. ORT-1216 ¶¶ 246-248. Also, it would have been obvious to a POSITA to modify Sparker's rod reducing device to couple to a bone anchor, such as Trudeau's. *Id*.

c. Claim Limitation [1-2]

The combination of Sparker and Trudeau teaches the claimed "bone anchor having a rod-receiving housing and a bone engaging shaft extending therefrom."

Specifically, as discussed in Section VIII(A)(1)(c), Trudeau discloses "the bone anchor having a rod-receiving housing and a bone engaging shaft extending therefrom."

For the same reasons discussed in this Ground, it would have been obvious to a POSITA to use the rod reducing device of Sparker with a bone anchor such as the bone anchors of Trudeau. ORT-1216 ¶¶ 249-251.

d. Claim Limitation [1-3]

The combination of Sparker and Trudeau teaches "rod reducing device" as recited in claim 1.

Specifically, as discussed in Section VIII(C)(1)(a), each of Sparker and Trudeau teaches "a rod reducing device." ORT-1216 ¶¶ 252-253.

e. Claim Limitation [1-4]

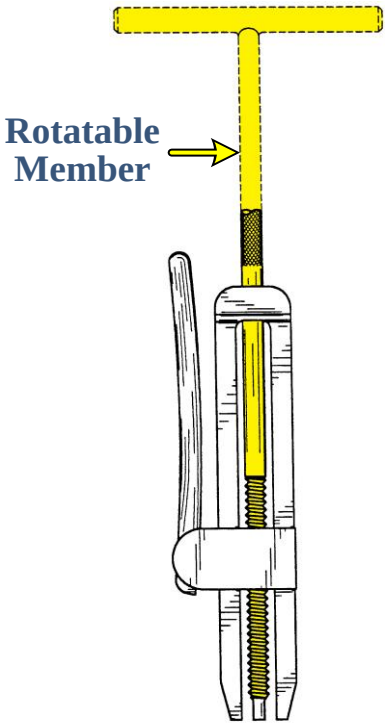


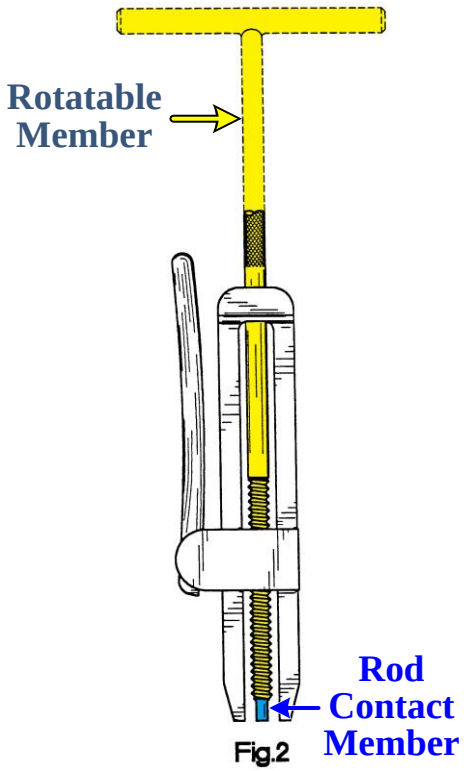
Fig.2

The combination of Sparker and Trudeau teaches the "rotatable member" as recited in claim 1. As shown in annotated FIG. 2, Sparker teaches the rod reducer

includes a threaded shaft with a handle at a proximal end, which discloses a rotatable member.

Moreover, in view of Trudeau's similar teaching (*see* Section VIII(A)(5)(g)), it would have been obvious that Sparker discloses a rotatable member. ORT-1216 ¶¶ 254-256.

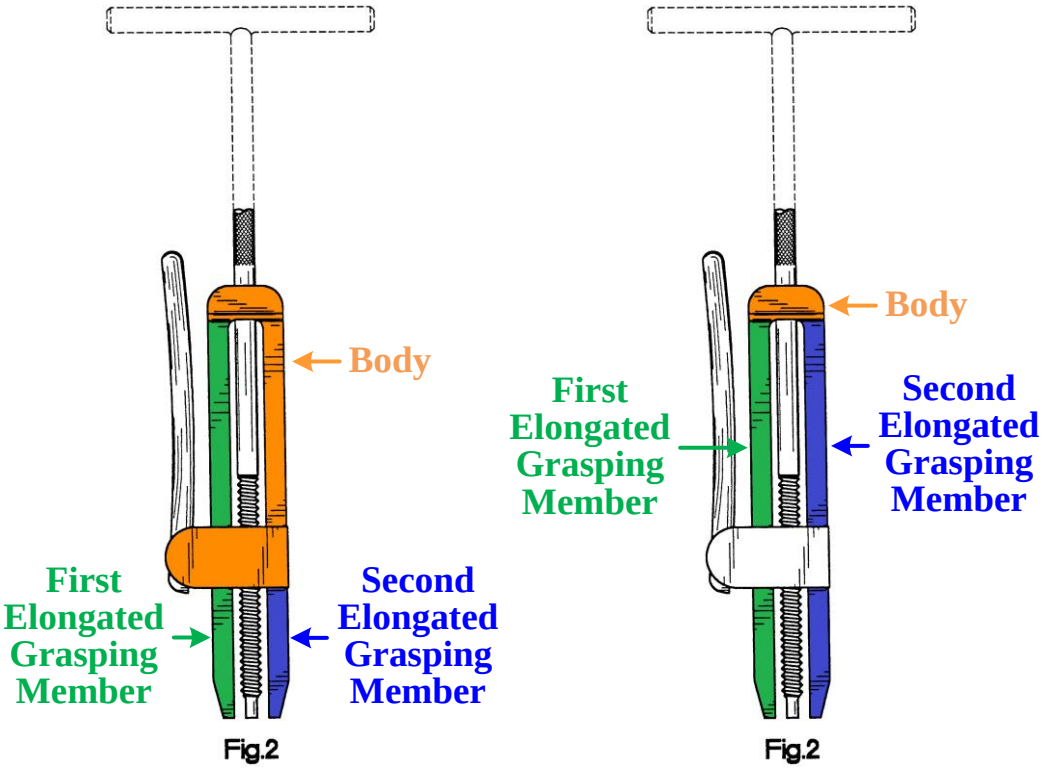
f. Claim Limitation [1-5]



The combination of Sparker and Trudeau teaches the "rod contact member positioned at a distal end of the rotatable member" as recited in claim 1. ORT-1216 ¶¶ 257-258. As illustrated in annotated FIG. 2, because Sparker discloses a rod reducing device, Sparker consequently discloses the distal end of the rotatable member of this rod reducing device would contact a rod.

Moreover, in view of Trudeau's similar teaching (*see* VIII(A)(1)(f)), it would have been obvious that Sparker discloses a rod contact member positioned at the distal end of a rotatable member. ORT-1216 ¶¶ 257-258.

g. Claim Limitation [1-6]



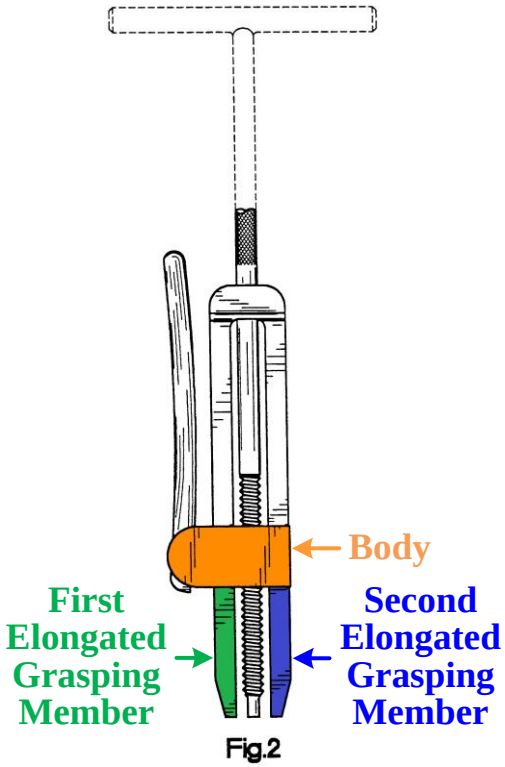
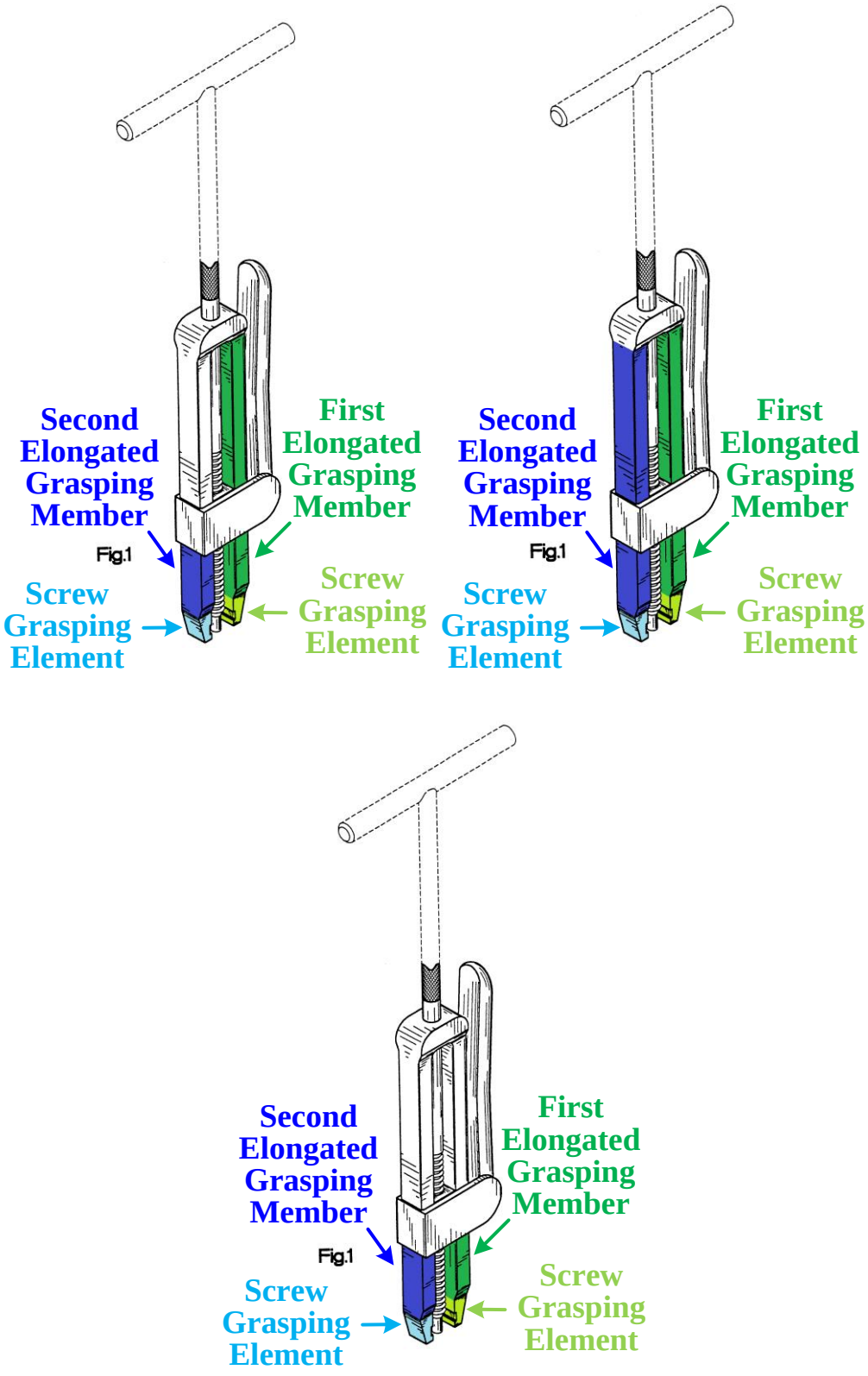


Fig.2

The combination of Sparker and Trudeau teaches the "body including first and second elongated grasping members extending therefrom" as recited in claim 1. *See* ORT-1216 ¶¶ 259-260. As shown in annotated FIG. 2, Sparker's rod reducing device includes a body and that body includes first and second elongated members extending therefrom constructed to grasp a bone anchor therebetween. As also shown, that body can take one of multiple forms. *Id.*

Moreover, in view of Trudeau's similar teaching (*see* VIII(A)(1)(g)), it would have been obvious that Sparker discloses a body including first and second elongated grasping members extending therefrom. ORT-1216 ¶¶ 259-260.

h. Claim Limitation [1-7]



The combination of Sparker and Trudeau teaches that "each of the first and second elongated grasping members having a screw grasping element" as recited in claim 1. ORT-1216 ¶¶ 261-262. As shown in annotated FIG. 1, Sparker discloses elements disposed at the distal ends of each of Sparker's first and second elongated grasping members which are constructed to grasp a screw. As also illustrated, each form of the body illustrated in Section VIII(C)(1)(h) includes respective first and second grasping members having a screw grasping element.

Moreover, in view of Trudeau's similar teaching (*see* § VIII(A)(1)(h)), it would have been obvious that Sparker discloses each of the first and second elongated grasping members having a screw grasping element. ORT-1216 ¶¶ 261-262.

i. Claim Limitation [1-8]

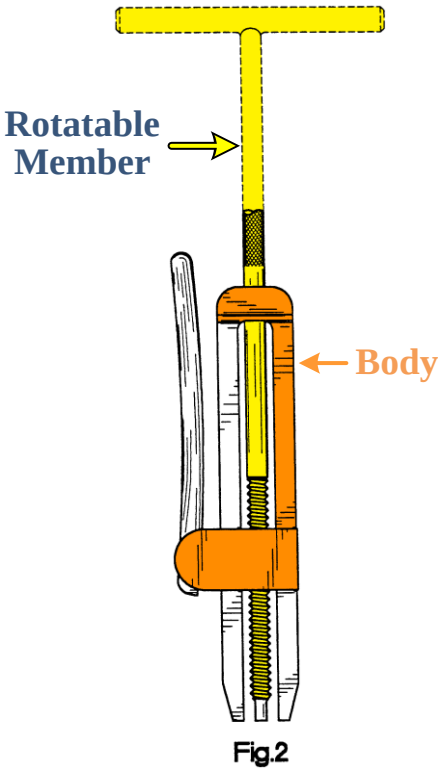


Fig.2

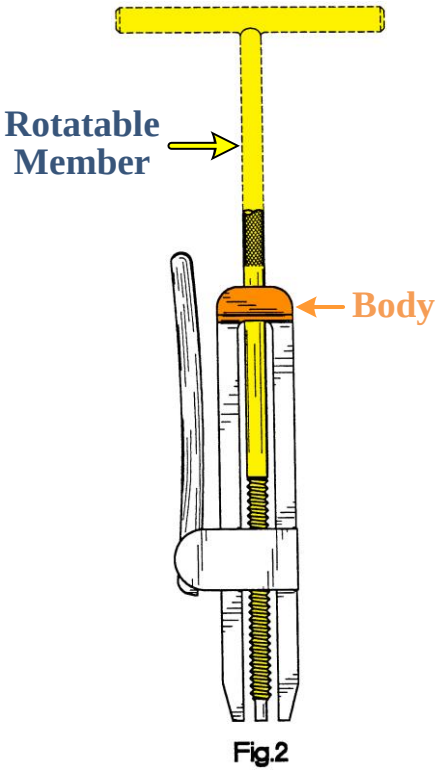


Fig.2

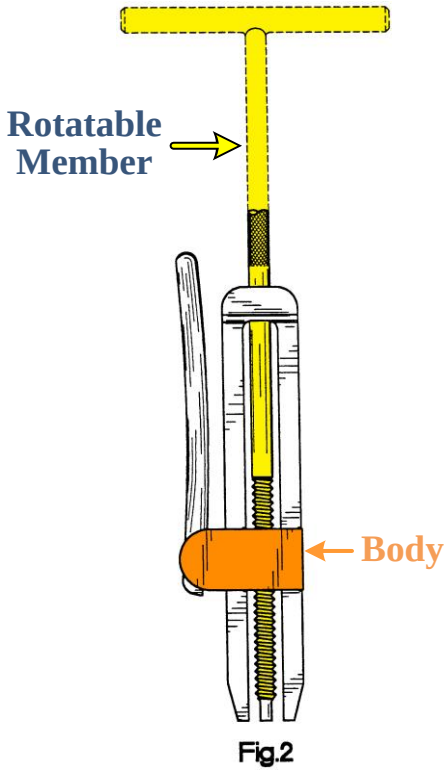
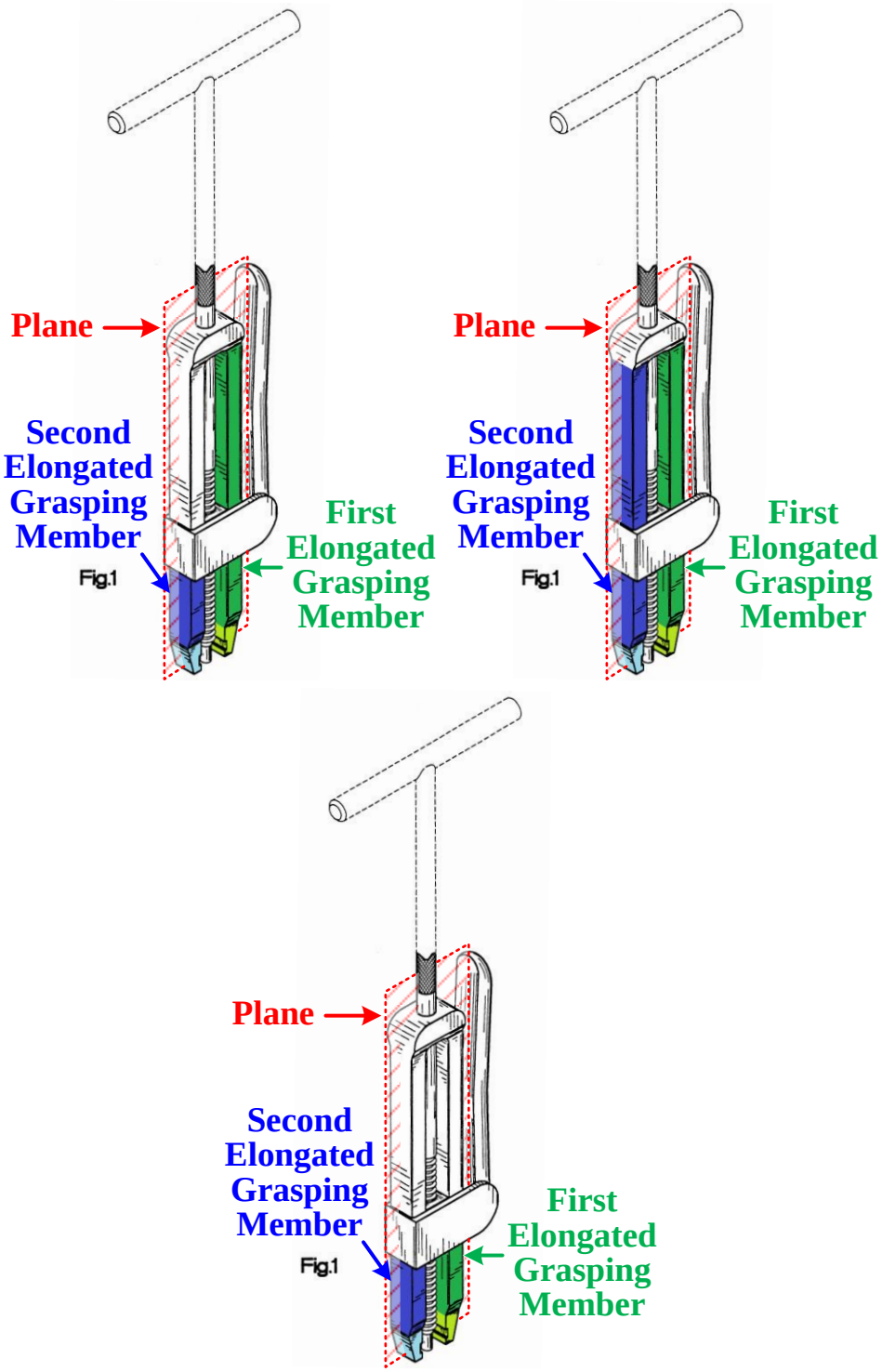


Fig.2

The combination of Sparker and Trudeau teaches the claimed "the rotatable member threadably coupled with the body." ORT-1216 ¶¶ 263-264. As shown in annotated FIG. 1, Sparker discloses that the rotatable member is threaded and extends into the body to threadly coupled thereto.

Moreover, Sparker, in view of Trudeau's similar teaching (*see* VIII(A)(1)(i)), discloses a threaded shaft that is threadably coupled with the body. ORT-1216 ¶¶ 263-264.

j. Claim Limitation [1-9]

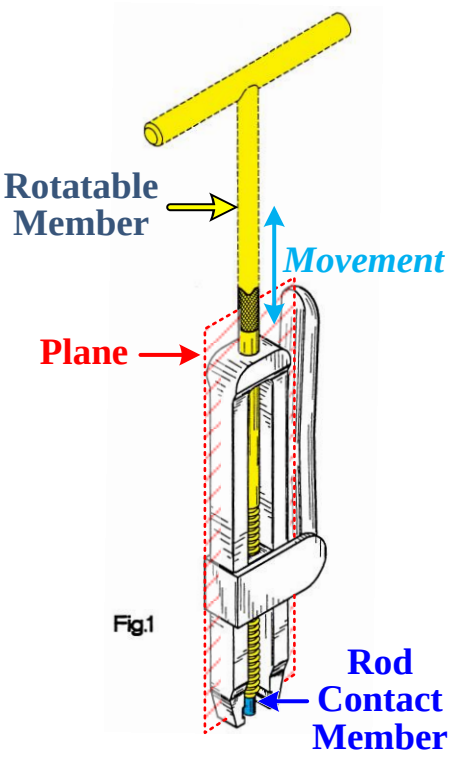


The combination of Sparker and Trudeau teaches "the first and second elongated grasping members defining a plane" as recited in claim 1. *See* ORT-

1216 ¶¶ 265-266. As shown in annotated FIG. 2, Sparker discloses that the first and second elongated grasping members define a plane.

Moreover, in view of Trudeau's similar teaching (*see* VIII(A)(1)(j)), it would have been obvious that Sparker's first and second grasping members define a plane. ORT-1216 ¶¶ 265-266.

k. Claim Limitation [1-10]



The combination of Sparker and Trudeau teaches "the rotatable member and the rod contact member movable within the plane" as recited in claim 1. *See* ORT-1216 ¶¶ 267-268. As discussed in this Ground, Sparker's rod reducing device includes a rotatable member and a rod contact member positioned at its distal end. Because Sparker's rotatable member is threadably coupled to the body and is

positioned between the grasping members, the rotatable member and rod contact member are movable within the plane defined by the grasping members.

Moreover, in view of Trudeau's similar teaching (*see* VIII(A)(1)(k)), it would have been obvious that Sparker's threaded shaft and associated rod contact member are movable within the plane. ORT-1216 ¶¶ 267-268.

l. Claim Limitation [1-11]

The combination of Sparker and Trudeau teaches "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 in this Ground, Sparker teaches a rod reducing device having a body including first and second elongated grasping members extending therefrom and that such first and second grasping member engage a rod-receiving housing of a bone anchor. A POSITA would also have understood Sparker's first and second grasping member are constructed to engage corresponding portions on the rod-receiving housing of a bone anchor and as such the rod-receiving housing is disposed between such grasping members, securing such rod reducing device to the bone anchor. In fact, a POSITA would have understood the lever could be

moved toward the Sparker's body to lock the first and second grasping members in position, further securing them from disengaging from the bone anchor.

Nevertheless, it would have been made obvious to a POSITA by Sparker, in view of Trudeau's similar teaching (*see* Section VIII(A)(1)(l)), to secure Sparker's rod reducing device to a bone anchor by engaging corresponding portions on the rod-receiving housing of the bone anchor with respective first and second grasping member of Sparker such that the rod-receiving housing is disposed between such grasping members. Moreover, Sparker also discloses the lever to further secure the grasping members to the bone anchor housing therebetween. *See* ORT-1216 ¶ 269-271.

m. Claim Limitation [1-12]

The combination of Sparker and Trudeau teaches "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. ORT-1216 ¶¶ 272-276.

As discussed in this Ground, Sparker teaches a rod reducing device having a body including first and second elongated grasping members extending therefrom, a rotatable member threadably coupled to the body, and a rod contact member positioned at a distal end thereof. Because the rod contact member is integral to

Sparker's threaded shaft *(i.e.*, rotatable member) and the rotatable member is threadably coupled to Sparker's body, a POSITA would have understood that Sparker teaches that upon rotation of the threaded shaft, the rotatable member would move relative to the body which, in turn, causes the rod contact member to move relative to the body within the plane advancing a rod disposed between the grasping members toward a rod-receiving housing of a bone anchor. ORT-1216 ¶ 274.

Moreover, in view of Trudeau's similar teaching (*see* VIII(A)(1)(m)), it would have been obvious that rotation of Sparker's threaded shaft would causes the rod contact member to move relative to the body within the plane and advance a rod disposed between the grasping members toward a rod-receiving housing of a bone anchor. ORT-1216 ¶¶ 272-276.

2. Dependent Claim 3:

The combination of Sparker and Trudeau teaches "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 in this Ground, Sparker teaches a rod reducing device having a body including first and second elongated grasping members extending therefrom, wherein each of the first and second elongated grasping members have a grasping

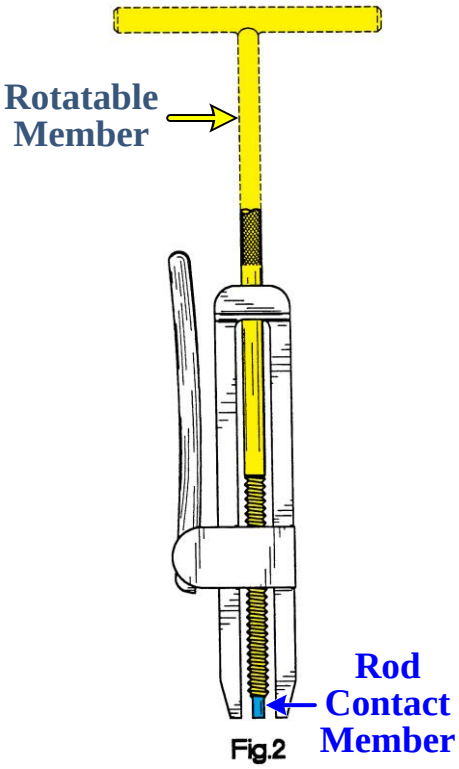
feature. A POSITA would have understood the features disposed at the distal ends of Sparker's grasping members are constructed to engage a rod-receiving housing of the bone anchor. ORT-1216 ¶ 278. If not anticipated by Sparker, in view of Trudeau (*see* Section VIII(A)(2)), it would have been obvious to a POSITA that securing the rod reducing device to the bone anchor would include coupling respective distal end features of Sparker's grasping members to engage a rod-receiving housing of a bone anchor, such as Trudeau's bone anchors. ORT-1216 ¶¶ 277-280.

3. Dependent Claim 5:

The combination of Sparker and Trudeau teaches "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. ORT-1216 ¶¶ 281-284.

As shown in the figures, Sparker discloses a portion of the rod contact member positioned between the grasping members. It would be understood by a POSITA, particularly in view of Trudeau (*see* Section VIII(A)(3)), that Sparker discloses or make obvious that coupling Sparker's rod reducing device to a bone anchor would include a portion of the rod contact member being positioned between the first and second elongated grasping members, as described in Trudeau. ORT-1216 ¶¶ 281-284.

4. Dependent Claim 6:



The combination of Sparker and Trudeau teaches "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. ORT-1216 ¶¶ 285-288.

As shown in the annotated FIG. 2, Sparker discloses a portion of the rod contact member positioned between the grasping members and is integral to the threaded shaft (*i.e.*, rotatable member). *See also* Sections VIII(A)(4); VIII(C).

Moreover, in view of Trudeau's similar teaching (*see* VIII(A)(4)), it would have been obvious that the distal and integral end of Sparker's threaded shaft contacts a spinal rod. ORT-1216 ¶¶ 285-288.

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,

/Paul M. Ulrich/

Paul M. Ulrich
Reg. No. 46,606
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202
Telephone: 513.698.5156
Facsimile: 513.698.5157

Attorney for Petitioner

CERTIFICATE OF COMPLIANCE

In accordance with 37 C.F.R. § 42.24(d), Petitioner certifies that the word count for this petition totals 12,527 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:

Carter DeLuca Farrell & Schmidt LLP
445 Broad Hollow Road, Suite 420
Melville, NY 11747

/Paul M. Ulrich/
Paul M. Ulrich
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202
Telephone: 513.698.5156
Facsimile: 513.698.5157