

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOPEDIATRICS CORP.,
Petitioner,

v.

K2M, INC.,
Patent Owner.

Case IPR2018-00429
Patent 9,532,816 B2

Before LYNNE H. BROWNE, MICHAEL L. WOODS, and
ROBERT L. KINDER, *Administrative Patent Judges*.

BROWNE, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Orthopediatrics Corp. (“Petitioner”), on January 8, 2018, filed a Petition to institute *inter partes* review of claims 16, 18, 19, 21, and 22 of U.S. Patent No. 9,532,816 B2 (“the ’816 patent”). Paper 1 (“Pet.”). K2M, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition on April 18, 2018. Paper 6 (“Prelim. Resp.”).

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the Petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” For the reasons stated below, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim of the ’816 patent. Accordingly, we institute an *inter partes* review as to all claims and all grounds.

A. *Related Proceedings*

Petitioner indicates that the ’816 patent is the subject of *K2M, Inc. v. OrthoPediatrics Corp. & OrthoPediatrics US Distribution Corp.*, Case No. 1:17-cv-00061-GMS (D. Del.). Pet. 1.

Petitioner filed a second petition requesting *inter partes* review challenging claims 16, 18, 19, 21, and 22 of the ’816 patent. IPR2018-00521.

B. *The ’816 Patent*

The ’816 patent is directed to “to devices for stabilizing and fixing the bones and joints of the body. Particularly, the present invention relates to a manually operated device capable of reducing a rod into position in a rod receiving notch in the head of a bone screw with a controlled, measured

action.” Ex. 1001, 1:14–19. The device described in the ’816 patent achieves this objective by grasping “the head of a bone screw and reduc[ing] a rod into the rod receiving recess of the bone screw using a single manual control that can be activated in a controlled and measured manner.” *Id.* at 2:23–27.

Figure 4 reproduced below illustrates the device:

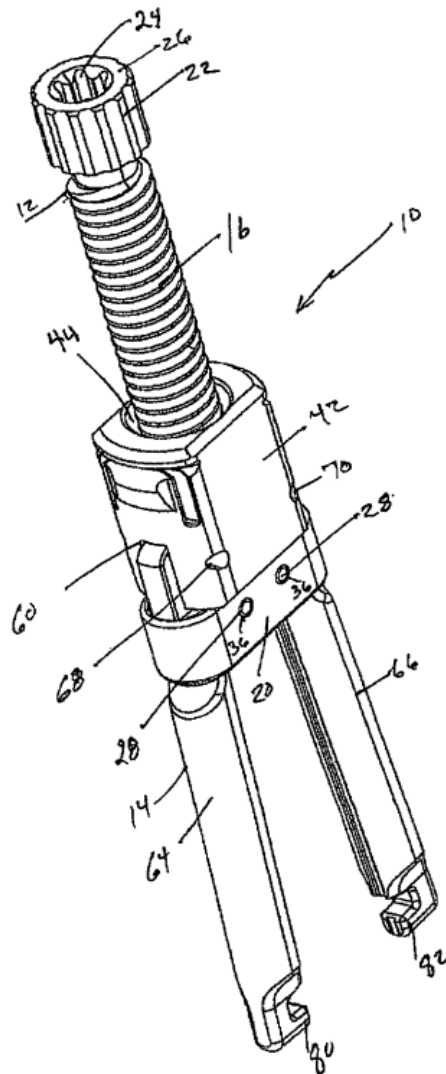


FIG 4

Figure 4 is an isometric view of the rod reducing device with the screw jack mechanism fully retracted and the two elongated grasping members in an open configuration. Ex. 1001, 3:27–30.

The '816 patent explains:

The device . . . is a rod **34** reduction device capable of reducing a rod into position in a rod receiving notch in the head of a bone screw with a controlled, measured action. The device is an elongated rod reduction device **10** that includes a screw jack mechanism **12** moveably engaged with an elongated grasping fork assembly **14**. The screw jack mechanism **12** includes an elongated threaded screw shaft **16** that terminates at its most proximal end with a controlling member **18** and terminates at its most distal end with a rod contact member **20**.

Id. at 3:63–4:5.

C. Illustrative Claim

Petitioner challenges claims 16, 18, 19, 21, and 22 of the '816 patent. Claim 16, reproduced below, is the challenged independent claim.

16. A rod reducing device comprising:
- a housing defining a longitudinal axis, the housing including first and second grasping members configured to grasp a portion of a bone anchor there between, the first and second grasping members defining a plane;
 - a rotatable member extending through the housing along the longitudinal axis; and
 - a rod contact member positioned at a distal end of the rotatable member, the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis, wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members.

Ex. 1001, 10:22–35.

D. References Relied Upon

The Petitioner relies in relevant part on the following references
(Pet. 3):

Name	Reference	Ex. No.
Iott	US 2006/0247630 A1, published Nov. 2, 2006	1002
Runco	US 2006/0079909 A1, published Apr. 13, 2006	1003
Trudeau	US 2006/0089651 A1, published Apr. 27, 2006	1004
Pond	US 2006/0036255 A1, published Feb. 16, 2006	1005

E. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the
following grounds:

Reference(s)	Basis	Claim(s) challenged
Iott	§ 102(e)	16, 18, 19, 21, and 22
Runco	§ 102(b)	16, 18, 19, 21, and 22
Trudeau	§ 102(b)	16, 18, 19, 21, and 22
Trudeau and Pond	§ 103(a)	16, 18, 19, 21, and 22

Pet. 3. Petitioner supports its challenge with the Declaration of Ottie
Pendleton, dated January 8, 2018 (“Pendleton Declaration”) (Ex. 1006).

II. ANALYSIS

A. *Discretion under 35 U.S.C. § 314*

The Board has discretion not to institute an *inter partes* review. *See*
35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under
particular circumstances, but not requiring institution under any

circumstances); *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining that under § 314(a), “the PTO is permitted, but never compelled, to institute an IPR proceeding”).

Patent Owner submits that we should exercise our discretion to deny institution of *inter partes* review because the Petition is redundant in light of the petition filed in IPR2018-00521. *See* Prelim. Resp. 20–23. In support of this submission, Patent Owner cites *General Plastic Industries Co., Ltd. v. Canon Kabushiki Kaisha*, No. IPR2016-01357 (PTAB Sept. 6, 2017) (precedential). However, as the Petition is the first petition filed, Patent Owner’s argument is unpersuasive because a first-filed petition cannot by its nature be redundant.

Accordingly, we decline to exercise our discretion under 35 U.S.C. § 314.

B. Claim Construction

Petitioner contends that no “specific claim terms of the Challenged Claims require construction for the purposes of this petition.” Pet. 4. Whereas, Patent Owner asserts that the terms “extending through the housing” and “grasping” require construction. *See* Prelim. Resp. at 11–20. For purposes of this decision we need only construe “extending through the housing.” *See, e.g., Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only those terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

1. ‘extending through the housing’

Noting that “the term ‘housing’ is not used explicitly in the Specification of the ’816 Patent except in reference to the bone screw,” Patent Owner contends that the claimed “housing” corresponds to the body

42 of the fork assembly 14. Prelim. Resp. 12. In support of this contention, Patent Owner explains that “the specification describes fork assembly body 42, which ‘defines a body through passage 44 that is sized and complimentary [sic] configured to permit passage of the elongated threaded screw shaft 16 of the screw jack mechanism 12.’” *Id.* at 12–13 (citing Ex. 1001, Fig. 4, 5:5–9). Acknowledging that “[c]laim 16 recites that ‘the housing includ[es] first and second grasping members,’” Patent Owner nevertheless contends that “[b]ased on the specification of the ’816 Patent, however, it is clear that the housing itself does not include the first and second grasping members; instead, the first and second grasping members are merely attached to the housing as separate features.” *Id.* at 13 (citations omitted).

With this construction of “housing” in mind, Patent Owner contends that “[e]xtending through the housing’ should be construed to mean ‘extending *entirely* through the housing’ consistent with Patent Owner’s proposed claim construction of ‘extending through the housing’ in the district court litigation.” *Id.* at 11 (citing Ex. 2004, 13–14; Ex. 2006, 19–20) (emphasis added). “Patent Owner proposes this construction as the only construction that is consistent with, and informed by, the claims, the specification, and the prosecution history of the ’816 Patent.” *Id.* at 11–12.

The Specification of the ’816 patent describes a rod reduction device 10 including “a screw jack mechanism 12 movably engaged with an elongated grasping fork assembly 14,” which includes “an elongated threaded screw shaft 16.” Ex. 1001, 3:67–4:3. In view of this description in the Specification, we understand the claimed “rotatable member” to correspond to the described screw shaft 16. As discussed *supra*, the

Specification states that the fork assembly includes a “fork assembly body 42 [that] defines a body *through* passage 44 that is sized and complimentary configured *to permit passage* of the elongated threaded screw shaft 16 of the screw jack mechanism 12.” *Id.* at 5:5–9 (original emphasis omitted, new emphasis added). In the concurrent District Court proceeding cited *supra*, the United States District Court for the District of Delaware construed the claim language at issue. Ex. 2100, 3–4. The District Court noted that as the screw shaft 16 moves through the fork assembly body through passage 44, both the fork assembly body 42 and the body through passage 44 do not move. *See id.* at 4. In view of this lack of movement and Patent Owner’s proffered definition of housing as a “rigid casing,” the District Court found “that ‘housing’ should be construed as ‘the fixed portion of the rod reducing device that defines the body through passage.’” *Id.* We agree with the District Court’s construction of the claim term “housing” and adopt it as our own at this stage of the proceeding.

The Specification further describes a “rod contact member 20, which is attached to the distal end of the elongated threaded screw shaft 16.” Ex. 1001, 6:27–29. The Specification explains that the rod contact member 20 is “forced downward along the length of the opposing first and second grasping members 64, 66 of the grasping fork assembly 14” such that “the rod contact member will be brought to bear against a rod positioned over the screw, which is firmly grasped by the grasping elements 80, 82 of the device.” *Id.* at 6:29–31, 41–44. Although the rod and bone screw are not illustrated in this figure, Figure 2 of the ’816 patent (reproduced below) illustrates the screw jack mechanism in its lowermost position where the rod

contact member 20 would bear against a rod positioned over the bone screw.
See id.

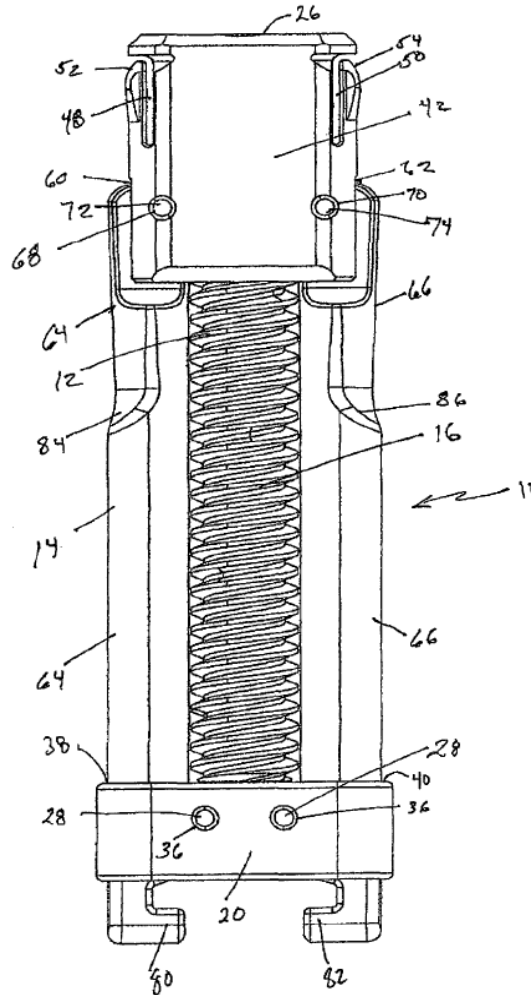


FIG 2

Figure 2 of the '816 patent is “a front view of the novel rod reducing device in an activated configuration.” Ex. 1001 3:23–24. As shown in Figure 2, screw shaft 16 *does not* extend past the distal end of the housing despite being in its lowermost position. *See id.* at 6:29–31, 41–44. As such, the rotatable member as shown and described in the '816 patent does not extend entirely through the housing. Rather, as noted by the District Court, “[t]he inclusion of the term ‘entirely’ or ‘entire’ would exclude the preferred

embodiments and would be read out portions of the specification.” Ex. 2100, 4. Accordingly, we also agree with the District Court’s construction of “the entire claim phrase to mean, ‘extending through the fixed portion of the rod reducing device that defines the body through passage.’” *Id.*¹

C. Principles of Law

To establish anticipation, each and every element in a claim, arranged as recited in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). “A reference anticipates a claim if it discloses the claimed invention such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention.” *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) (internal citation and emphasis omitted). Moreover, “it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826 (CCPA 1968).

¹ The parties are given notice that the United States Patent and Trademark Office published a proposed rules package that would change the standard for construing unexpired and proposed amended claims in trials under the America Invents Act. See 83 Fed. Reg. 21221 (May 9, 2018) (available at: <https://www.gpo.gov/fdsys/pkg/FR-2018-05-09/pdf/2018-09821.pdf>). We provide a preliminary claim construction for the sole purpose of determining whether to institute trial. We emphasize that any final claim construction shall be based on the full record developed during trial.

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and, when presented, (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

We analyze the asserted grounds of unpatentability in accordance with the above-stated principles.

D. Anticipation of Claims 16, 18, 19, 21 and 22 by Iott

Petitioner asserts that Iott discloses each and every limitation of claims 16, 18, 19, 21, and 22. Pet. 9–22.

1. Iott

Iott is directed “to a vertebral stabilization system, and more particularly, but not exclusively, to a percutaneous vertebral stabilization system.” Ex. 1002 ¶ 2. Figures 31 and 32, reproduced below, illustrate one embodiment of this system:

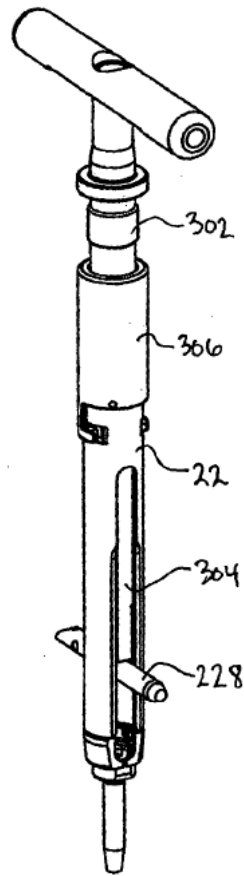


FIG. 31

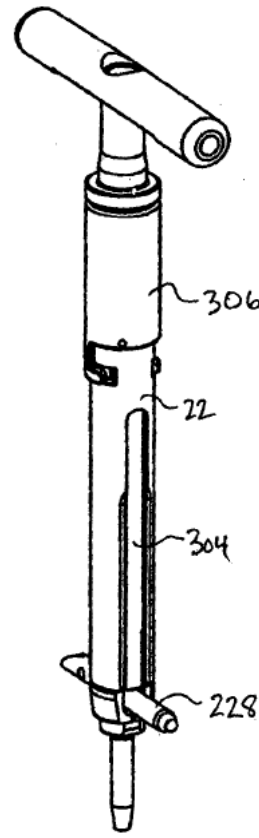


FIG. 32

Iott's Figure 31 is a perspective view of an assembly shown in operation in a first position, and Iott's Figure 32 is a perspective view of the assembly shown in operation in a second position. *Id.* ¶¶ 44, 45.

The assembly shown in Figures 31 and 32 includes “[r]od reducer instrument 300 [that] generally comprises a rotation shaft 302, a reducer shaft 304, and an attachment sleeve 306, configured to engage and attach to a proximal end of sleeves 22, 24.” Ex. 1002 ¶ 70. Iott explains that “[r]otation shaft 302 comprises a through-hole 310 adjacent a distal end of shaft 302 [that] is configured to receive a pin 312 therethrough to axially

connect rotation shaft 302 to reducer shaft 304.” *Id.* Iott further explains that “[p]in 312 is configured to engage a radial slot 314 of shaft 304 such that shaft 304 may rotate freely while remaining axially fixed to shaft 302” and “[r]otation shaft 302 comprises an externally threaded section 308 along a portion of the shaft configured to threadedly engage or mate with corresponding internal threads along the interior of attachment sleeve 306.” *Id.*

2. *Petitioner’s Challenge*

Petitioner maps elements from Iott to each limitation of claims 16, 18, 19, 21, and 22. Pet. 20–33. For example in challenging independent claim 16, Petitioner submits that:

- a. Iott’s rod reducer instrument 300 corresponds to the claimed rod reducing device. Pet. 10.
- b. Iott’ attachment sleeve 306 attached to sleeve 22, which includes inner sleeve member 52 and outer sleeve member 54, corresponds to the claimed housing. *Id.* at 11–12.
- c. Iott’s arms 72, 74 correspond to the claimed first and second grasping members. *Id.* at 12.
- d. Iott’s rotation shaft 302 corresponds to the claimed rotatable member. *Id.* at 14.
- e. Iott’s reducer shaft 304 corresponds to the claimed rod contact member. *Id.* at 15–16.
- f. Iott’s “rotation shaft 302 (i.e., the claimed rotatable member) extends through the attachment sleeve 306 (i.e., a portion of the claimed housing) along the longitudinal axis.” Pet. 15 (citing Ex. 1002, Figure 31).

Regarding the dependent claims, Petitioner submits that:

- a. In Iott, the distal ends of arms 72 and 74 each include a grasping feature (retainer portion 82 including finger members 84) engageable with a bone anchor as required by claim 18. Pet. 18–19.
- b. In Iott, movement of the rod contact member (reducer shaft 304) urges the rods towards the distal ends of the grasping members (arms 72, 74) as required by claim 19. *Id.* at 19–20.
- c. In Iott, the rod contact member (reducer shaft 304) is positioned between the grasping members (arms 72, 74) as required by claim 21. *Id.* at 20–21.
- d. In Iott, the rod contact member (reducer shaft 304) is attached to the distal end of the rotatable member (rotation shaft 302). *Id.* at 22.

In support of these submissions, Petitioner provides numerous annotated figures, including several versions of the same figure annotated to illustrate different elements of Iott. Pet. 10–21. For easy reference, some of these annotated figures are reproduced below with color added by Petitioner. Petitioner’s annotated Figure 31 is reproduced, below:

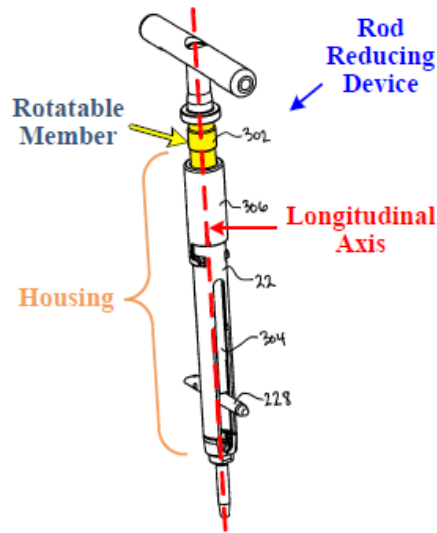
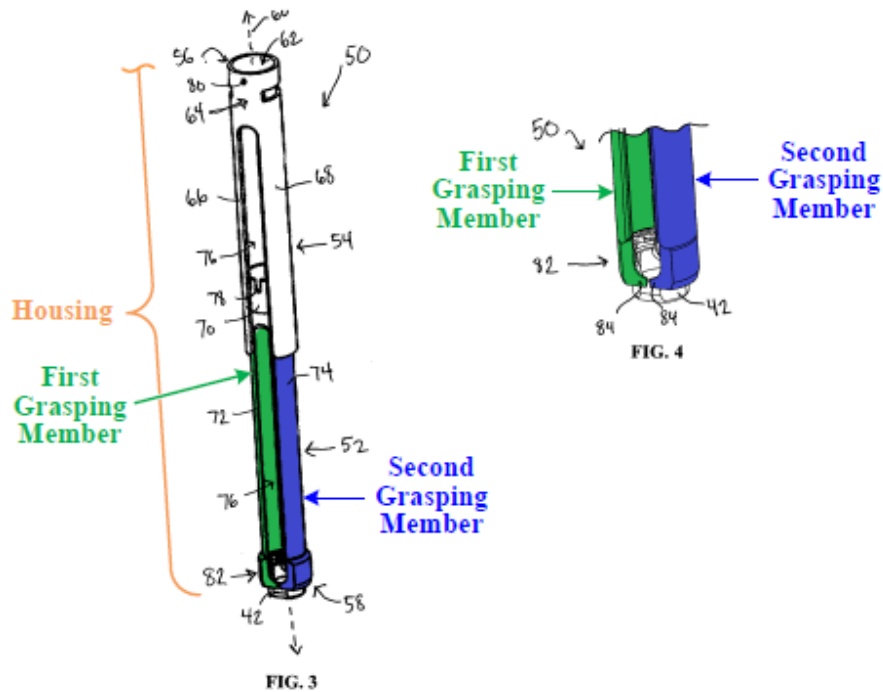


FIG. 31

Annotated Figure 31 is a perspective view of the assembly shown in operation in a first position annotated to indicate which elements correspond to the claimed housing, rotatable member, rod reducing device, and longitudinal axis. See Ex. 1002 ¶ 44.



Annotated Figure 3 is a perspective view of a sleeve shown in a first position, and annotated Figure 4 is an enlarged perspective view of this sleeve showing an anchor engaging portion. *See Ex. 1002 ¶¶ 18, 19.* These figures are annotated to indicate which elements correspond to the first and second grasping members.

Petitioner submits another annotated version of Figure 31, which we reproduce, below:

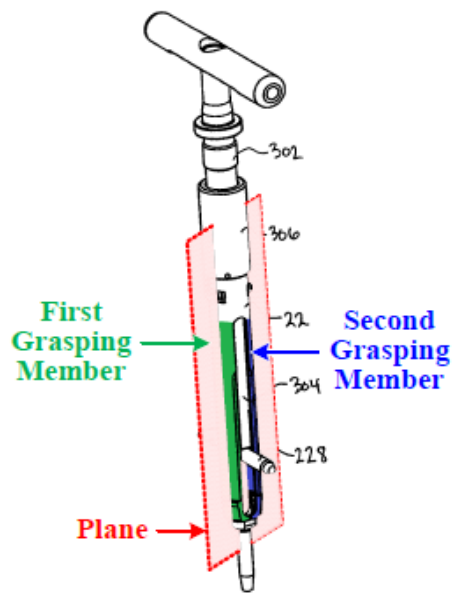
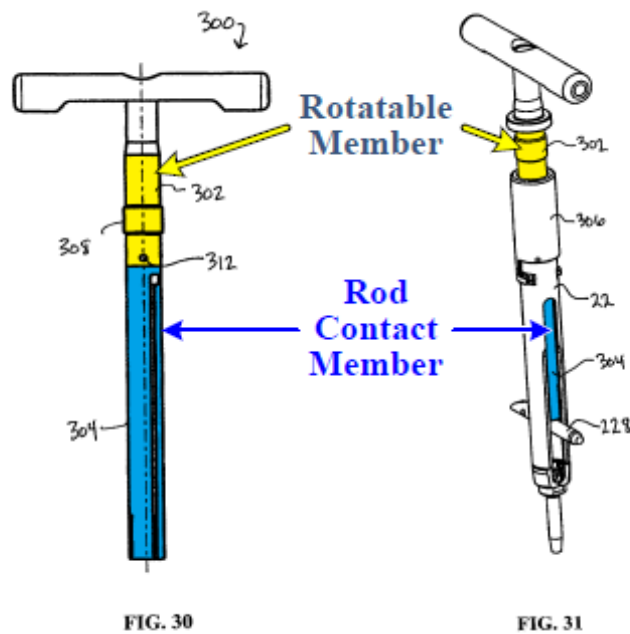


FIG. 31

This annotated version of Figure 31 illustrates the plane defined by the arms 72, 74 (i.e., the first and second grasping members). *See Pet. 13.*



Annotated Figure 30 and this third annotated version of Figure 31 indicate which portions of Iott's rod reducer assembly correspond to the claimed rotatable member and rod contact member. Ex. 1002 ¶ 43.

3. Patent Owner's Response

In response to Petitioner's challenge, Patent Owner presents the following three arguments:

- a. Iott fails to disclose a housing. Prelim. Resp. 28–30.
- b. Iott fails to disclose a rotatable member extending through the housing along the longitudinal axis. *Id.* at 30–36.
- c. Iott fails to disclose a rod contact member positioned at the distal end of the rotatable member. *Id.* at 36–38.

Patent Owner does not present arguments addressing the dependent claims. *See generally* Prelim. Resp. Rather, Patent Owner takes the position that none of the proposed grounds “invalidate any of the dependent claims in

the '816 Patent . . . [b]ecause the grounds fail to invalidate the independent claim[.]” *Id.* at 68.

4. Analysis

a. Alleged Failure to Disclose a Housing

At this stage in the proceeding, Petitioner establishes a reasonable likelihood that Iott discloses the claimed housing. As discussed *supra* the Specification of the '816 patent does not use this term except with respect to the bone anchor. Furthermore, although our definition of the term “housing”—for purposes of this proceeding—is broad, it is reasonable in light of the Specification, the plain meaning of that term, and consistent with the District Court’s interpretation. *See supra* Part II.B. Patent Owner does not explain why Iott’s sleeves do not constitute a housing. Rather, Patent Owner merely concludes that “[a] sleeve is not a housing.” Prelim. Resp. 29. Such conclusory statements are unconvincing at this phase of the proceeding.

b. Alleged Failure to Disclose Rotatable Member as Claimed

At this stage of the proceeding, Petitioner establishes a reasonable likelihood that Iott discloses the claimed rotatable member extending through the housing along the longitudinal axis. Patent Owner’s arguments are premised on the proposition that the claim requires a rotatable member that extends entirely through the housing, and even beyond the grasping members, which are claimed as part of the housing. *See* Prelim. Resp. 32–36. As discussed *supra*, at this stage of the proceeding our construction of this limitation does not require extension of the rotatable member entirely through the housing. Thus, Patent Owner’s argument is unconvincing.

c. Alleged Failure to Disclose a Rod Contact Member as Claimed

At this stage of the proceeding, Petitioner establishes a reasonable likelihood that Iott discloses the claimed rod contact member positioned at a distal end of the rotatable member. Although, Patent Owner is correct that Iott's rotation shaft 304 includes a cap at its distal end, as noted by Patent Owner, the cap is held in a channel formed in the distal end of the rotatable member. Prelim. Resp. 37. Iott states in relevant part:

As best seen in FIG. 33, reducer shaft 304 is a cannulated shaft including a central lumen 320 extending therethrough. Radial indentation or slot 314 is provided adjacent the proximal end to axially connect with rotation shaft 302. The proximal end of shaft 304 includes a rotation tool engaging feature to facilitate rotation of shaft 304 and *the distal end of shaft 304 is configured to hold a cap*. Referring to FIG. 34, in one embodiment, *the distal end comprises cap engaging or holding protrusions 322 extending inward to engage a cap*. Furthermore, *a pair of slits 324 may be provided to allow slight movement of the distal end of shaft 304 to releasably engage the fastener cap*. A key slot 326 may be provided to facilitate entry and alignment with sleeves 22, 24 and by extension anchors 12, 14 attached at the distal end thereof. *The cap held in the distal end has a channel or trough to engage the rod to push the rod downward toward the fastener*.

Ex. 1002 ¶ 71 (emphases added; numeral emphases omitted). One of ordinary skill in the art reading this paragraph would understand that Iott's cap is held within the distal end of shaft 304 such that both the cap and the distal end of the shaft would engage the rod at least before the cap is pushed down such that the channel in the cap engages the rod. Thus, Patent Owner's argument is unconvincing at this stage of the proceeding.

d. Conclusion Regarding Iott

For the foregoing reasons, we are persuaded at this stage of the proceeding by Petitioner's submission that Iott discloses each and every limitation of claim 16. Further, Patent Owner does not present arguments with respect to dependent claims 18, 19, 21, and 22, and we are also persuaded that Petitioner establishes a reasonable likelihood that Iott discloses each and every limitation of these claims as well.

E. Anticipation of Claims 16, 18, 19, 21, and 22 by Runco

Petitioner asserts that Runco discloses each and every limitation of claims 16, 18, 19, 21, and 22. Pet. 22–32.

1. Runco

Runco is directed to “[s]pinal fixation systems . . . used in orthopedic surgery to align and/or fix a desired relationship between adjacent vertebral bodies.” Ex. 1003 ¶ 2. Figures 27A–27C, reproduced below, illustrate one embodiment of these systems:

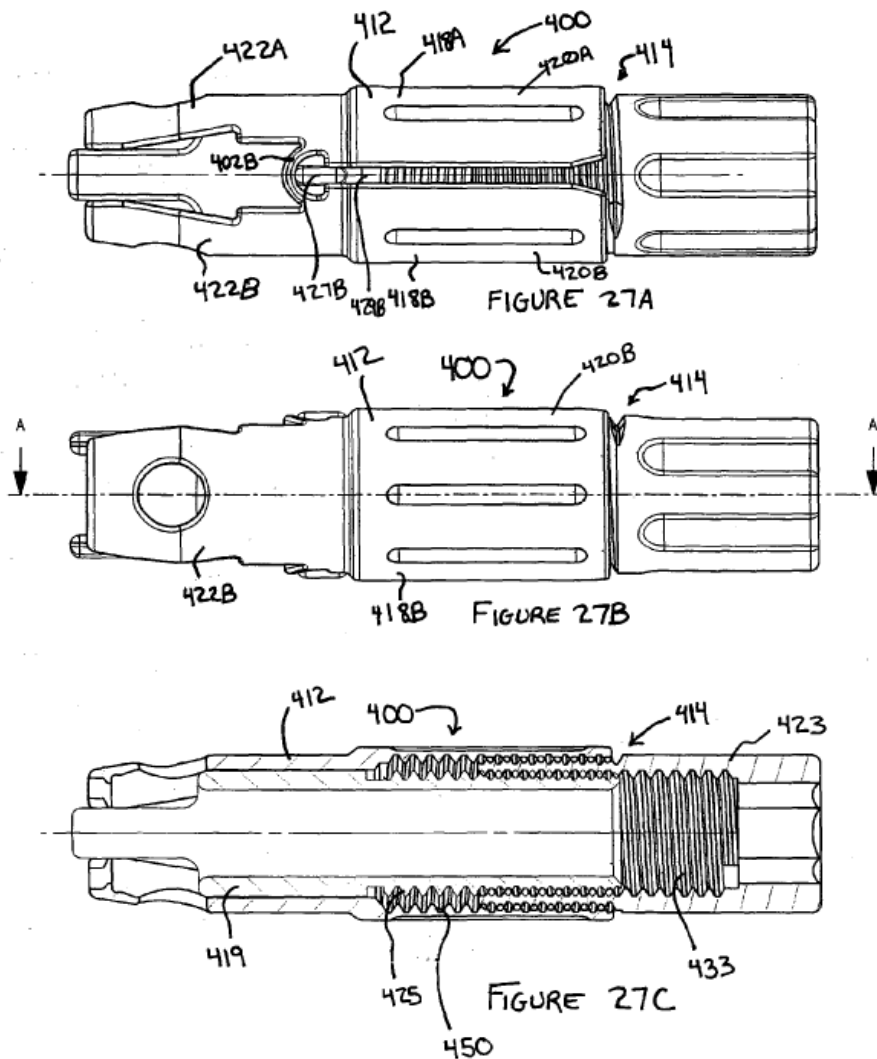


Figure 27A is a side view of an instrument for adjusting a spinal rod relative to a bone anchor, illustrating a rod adjusting tool positioned within a bone anchor engaging tool. Ex. 1003 ¶ 51. Figure 27B is a side view of the instrument shown in Figure 27A, and Figure 27C is a side view in cross section of this instrument. *Id.* ¶¶ 52, 53.

The instrument 400 shown in Figures 27A–27C “includes an implant (e.g., bone anchor) engaging tool 412 for engaging at least a portion of an implant such as a bone anchor” and “a rod adjustment tool 414 that is

connectable to the bone anchor engaging tool 412 [that] may be axially adjustable relative to the bone anchor engaging tool 412.” Ex. 1003 ¶ 100 (emphasis omitted). The bone anchor engaging tool includes “a first jaw member 418A and a second jaw member 418B which can cooperate to engage an implant such as a bone anchor” having “distal ends 422A, 42B to rotate from an approximately closed position in which the jaw members are proximate one another, as illustrated in FIG. 27D, to an open position in which the distal end 422A, 422B are displaced from one another. *Id.* ¶ 101 (emphases omitted).

The rod adjusting tool 414 also includes “a distal component 419 having a rod engaging surface 421 and a proximal component 423 connectable to and separable from the distal component 419.” *Id.* ¶ 104 (emphasis omitted). Runco explains that “[i]n operation, rotation of the proximal component 423 causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412.” *Id.*

2. *Petitioner’s Challenge*

Petitioner maps elements from Runco to each limitation of claims 16, 18, 19, 21, and 22. Pet. 22–32. For example in challenging independent claim 16, Petitioner submits that:

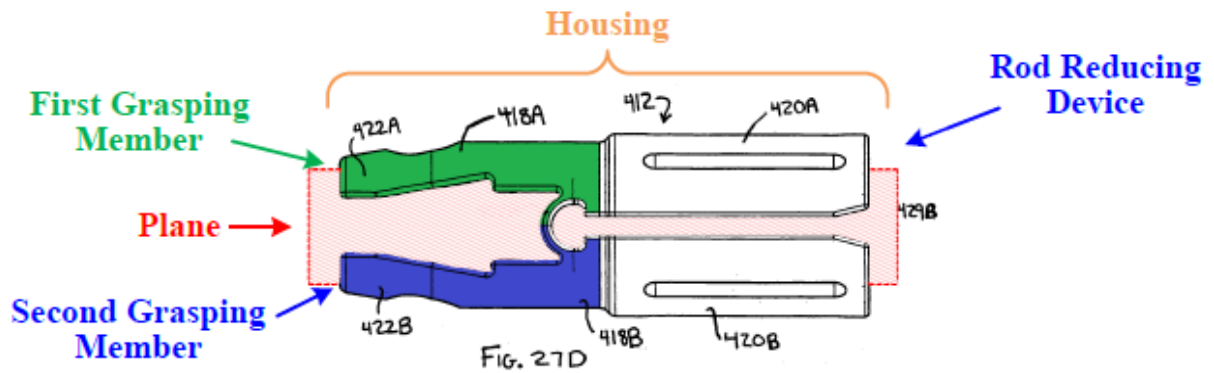
- a. Runco’s instrument 400 corresponds to the claimed rod reducing device. Pet. 23.
- b. Runco’s implant engaging tool 412 corresponds to the claimed housing. *Id.* at 23–24.
- c. Runco’s jaw members 418A, 418B correspond to the claimed first and second grasping members. *Id.* at 24.

- d. Runco's proximal component 423 corresponds to the claimed rotatable member. *Id.* at 26.
- e. Runco's distal component 419 corresponds to the claimed rod contact member. *Id.* at 27–28.

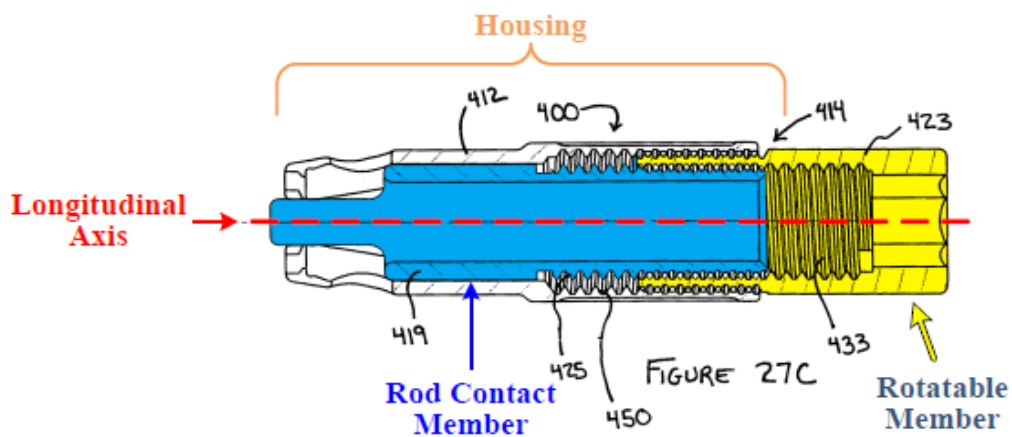
Regarding the dependent claims, Petitioner submits that:

- a. Runco indicates that bone anchor engaging tool 412 may be constructed in a manner analogous to the bone anchor engaging tool 12 which is described as including jaw members 18A, 18B. Pet. 29–30. Thus, Runco discloses grasping members (jaw members 418A, 418B) including at least one grasping feature engageable with a portion of a bone anchor. *Id.*
- b. In Runco, movement of the rod contact member (distal component 419) urges the rods towards the distal ends of the grasping members (jaw members 418A, 418B) as required by claim 19. *See id.* at 30–31.
- c. In Runco, the rod contact member (distal component 419) is positioned between the grasping members (jaw members 418A, 418B) as required by claim 21. *Id.* at 31–32.
- d. In Runco, the rod contact member (distal component 419) is attached to the distal end of the rotatable member (proximal component 423). *Id.* at 32–33.

In support of these submissions, Petitioner again provides numerous annotated figures, including several versions of the same figure annotated to illustrate different elements of Runco. Pet. 23–31. For easy reference, two of these annotated figures are reproduced below with color added by Petitioner:



Annotated Figure 27D is a side view of the instrument 400 annotated to indicate which elements correspond to the claimed housing, first and second grasping members, rod reducing device, and plane.



Annotated Figure 27C is a side view in partial cross section of the instrument 400 annotated to indicate which elements correspond to the claims housing, longitudinal axis, rod contact member, and rotatable member.

3. Patent Owner's Response

In response to Petitioner's challenge, Patent Owner presents the following two arguments:

- a. Runco fails to disclose a rotatable member extending through the housing along the longitudinal axis. Prelim. Resp. at 38–42.
- b. Runco fails to disclose a rod contact member and rotatable member translatable within the plane defined by the grasping members. *Id.* at 42–46. In support of this contention, Patent Owner asserts that the Petition improperly incorporates the declaration by reference. *See* Prelim. Resp. 43–44

Patent Owner does not present arguments addressing the dependent claims. *See generally* Prelim. Resp. Rather, Patent Owner takes the position that none of the proposed grounds “invalidate any of the dependent claims in the ’816 Patent . . . [b]ecause the grounds fail to invalidate the independent claim[.]” *Id.* at 68.

4. Analysis

a. Alleged Failure to Disclose a Rotatable Member as Claimed

At this stage of the proceeding, Petitioner establishes a reasonable likelihood that Runco discloses the claimed rotatable member extending through the housing along the longitudinal axis. Patent Owner’s arguments otherwise are premised on the proposition that the claim requires a rotatable member that extends entirely through the housing. *See* Prelim. Resp. 38–42. As discussed *supra*, this limitation does not require extension of the rotatable member entirely through the housing. Thus, at this stage of the proceeding, Patent Owner’s argument is unconvincing.

b. Alleged Failure to Disclose Claimed Translation Through a Plane

At this state of the proceeding, Petitioner establishes a reasonable likelihood that Runco discloses the claimed rod contact member and rotatable member that are translatable within a plane defined by the first and

second grasping members. Although Patent Owner contends that these elements are translatable within a plane that is perpendicular to the plane defined by the first and second grasping members (*see* Prelim. Resp. 42–43), Patent Owner, does not address the plane identified by Petitioner and illustrated in Annotated Figure 27D reproduced *supra*. Thus, Patent Owner’s argument is unconvincing. Further, as Annotated Figure 27D and Petitioner’s challenge pertaining thereto are included in the Petition, we are not persuaded by Patent Owner’s assertion the Petition improperly incorporates the Declaration of Ottie Pendleton. *Id.* at 43.

Patent Owner further contends that Petitioner misidentifies Runco’s rod contact member. Prelim. Resp. 44. In support of this contention, Patent Owner asserts that only rod engaging surfaces 421A, 421B at the distal ends of opposed distal legs 431A, 431B, which all are part of distal component 419, correspond to the claimed rod contact member. *See id.*

It is, however, unclear why Petitioner’s general reference to Runco’s distal component 419, as opposed to its subcomponents 421A, 421B prevents Petitioner showing that Runco discloses this limitation. Rather, Patent Owner’s argument illustrates why Petitioner’s reliance on Runco’s distal component 419 as corresponding to the claims rod contact member is reasonably supported by the record. *See* Runco Figure 27C; *see also* Pet. 27–28. Thus, Patent Owner’s argument is unconvincing at this stage of the proceeding.

c. Conclusion Regarding Runco

For the foregoing reasons, we are persuaded at this stage of the proceeding by Petitioner’s submission that Runco discloses each and every limitation of claim 16. Further, Patent Owner does not present arguments

with respect to dependent claims 18, 19, 21, and 22, and we are also persuaded that Runco discloses each and every limitation of these claims as well.

F. Anticipation of Claims 16, 18, 19, 21, and 22 by Trudeau

Petitioner asserts that Trudeau discloses each and every limitation of claims 16, 18, 19, 21, and 22. Pet. 33–45.

1. Trudeau

Trudeau is directed 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.” Ex. 1004 ¶ 1. Figure 7, reproduced below, illustrates one embodiment of this apparatus:

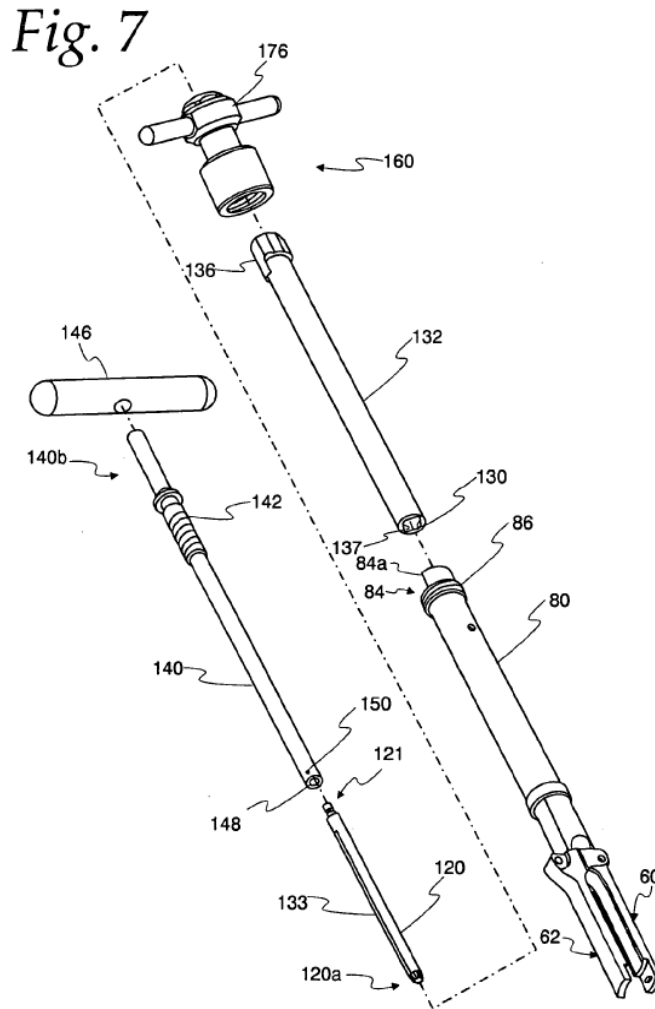


Figure 7 is “a partially exploded perspective view of the main body showing a sleeve coupling subassembly, a drive rod subassembly, a drive sleeve, and a tubular body portion of the surgical apparatus.” *Id.* ¶ 14.

The apparatus shown in Figure 7 includes a tool shaft 120 that translates linearly through a drive sleeve 132. *See id.* ¶ 78. The tool shaft 120 is connected to a drive rod 140 having a drive handle 146 at its upper end. *Id.* ¶¶ 79, 80. The tool shaft 120 advances a cap 30 to force the cap and a spinal rod 12 into the yoke 18 of a bone anchor. *See id.* ¶ 82. This apparatus further includes a stationary jaw 60 and movable jaw 62 joined

with a tubular body portion 80. *See id.* ¶¶ 50, 51. The jaws 60, 62 engage the yoke 18 during operation of the apparatus. *See id.* ¶ 49.

2. *Petitioner's Challenge*

Petitioner maps elements from Trudeau to each limitation of claims 16, 18, 19, 21, and 22. Pet. 33–45. For example in challenging independent claim 16, Petitioner submits that:

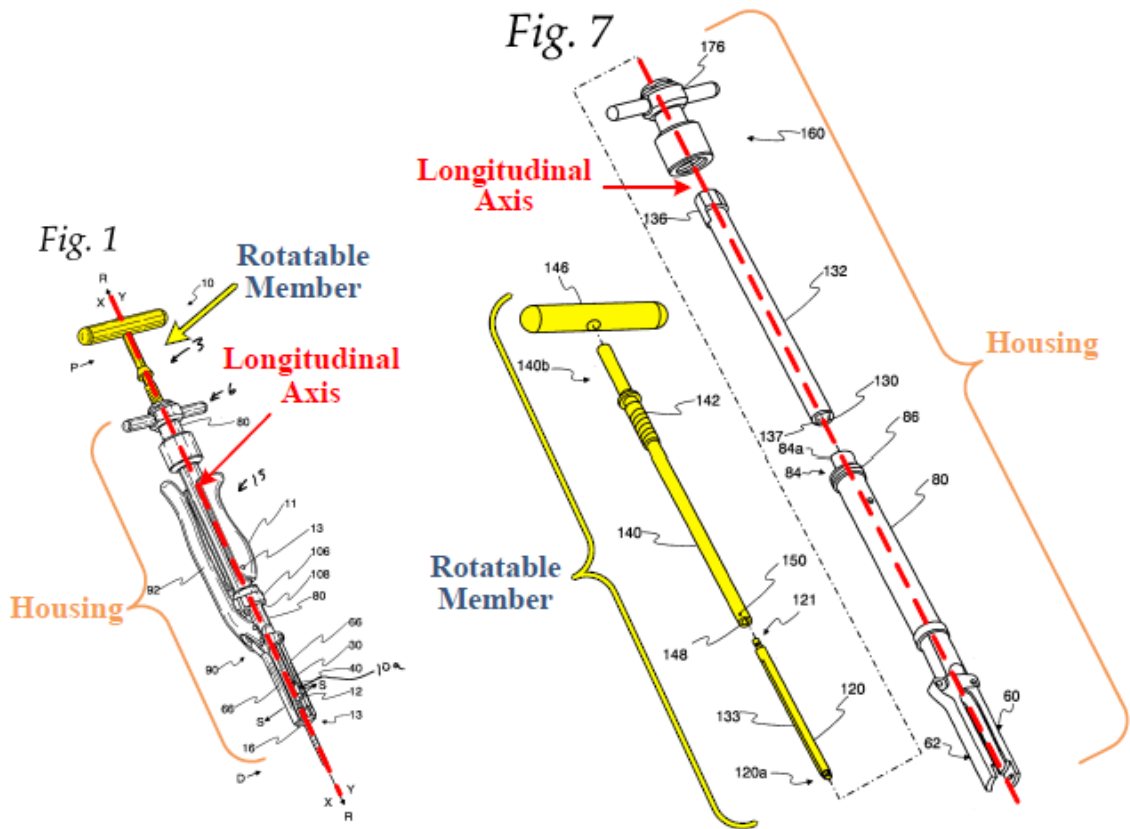
- a. Trudeau's rod persuader device 10 corresponds to the claimed rod reducing device. Pet. 33.
- b. Trudeau's clamping subassembly 90 including tubular body portion 80, rod drive sleeve 132, and sleeve coupling assembly 6 corresponds to the claimed housing. *Id.* at 34–35.
- c. Trudeau's jaws 60, 62 correspond to the claimed first and second grasping members. *Id.* at 35–36.
- d. Trudeau's drive rod subassembly 3 corresponds to the claimed rotatable member. *Id.* at 37.
- e. Trudeau's rod securing device 30 corresponds to the claimed rod contact member. *Id.* at 39.

Regarding the dependent claims, Petitioner submits that:

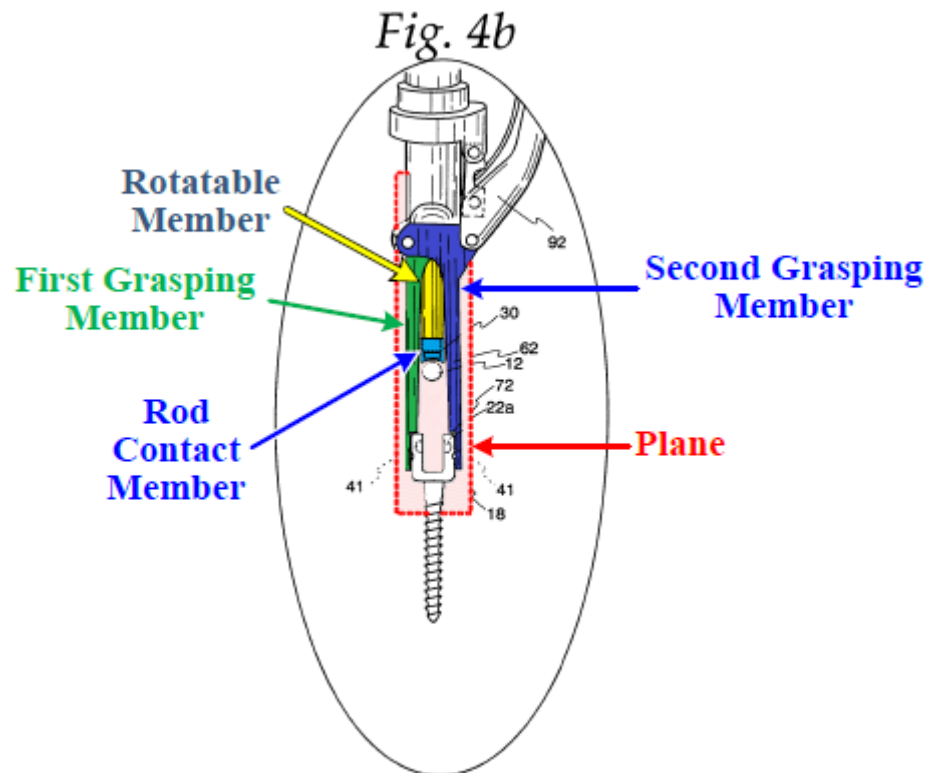
- a. Trudeau's teeth 38 correspond to the claimed at least one grasping feature. *See* Pet. 43.
- b. In Trudeau, movement of the rod contact member (rod securing device 30) urges the rod towards the distal ends of the grasping members (jaws 60, 62) as required by claim 19. *See id.* at 44.
- c. In Trudeau, the rod contact member (rod securing device 30) is positioned between the grasping members (jaws 60, 62) as required by claim 21. *Id.* at 44–45.

- d. In Trudeau, the rod contact member (rod securing device 30) is attached to the distal end of the rotatable member (rod subassembly 3). *Id.* at 45.

In support of these submissions, Petitioner again provides numerous annotated figures, including several versions of the same figures annotated to illustrate different elements of Trudeau. Pet. 33–44. For easy reference, several of these figures, including Figures 1 and 7, which immediately follow, are reproduced below with color added by Petitioner:



Annotated Figures 1 and 7 show the apparatus including a clamping mechanism having opposed jaw members. *See* Ex. 1004 ¶¶ 8, 14. These figures illustrate the elements which Petitioner considers to correspond to the claimed housing, rotatable member, and longitudinal axis.



Annotated Figure 4b is a perspective view showing the apparatus with the jaws in a closed position. *See* Ex. 1004 ¶ 11. This figure illustrates the elements which Petitioner considers to correspond to the claimed grasping members, rod contact member, rotatable member, and the plane defined by the grasping members.

3. Patent Owner's Response

In response to Petitioner's challenge, Patent Owner presents the following four arguments:

- a. Trudeau fails to disclose a housing as claimed. Prelim. Resp. 46–48.
- b. Trudeau fails to disclose a housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween. *Id.* at 48–50.

- c. Trudeau fails to disclose a rotatable member extending through the housing along the longitudinal axis. *Id.* at 51–53.
- d. Trudeau fails to disclose a rod contact member at a distal end of the rotatable member. *Id.* at 54–56.

Patent Owner does not present arguments addressing the dependent claims. *See generally* Prelim. Resp. Rather, Patent Owner takes the position that none of the proposed grounds “invalidate any of the dependent claims in the ’816 Patent . . . [b]ecause the grounds fail to invalidate the independent claim[.]” *Id.* at 68.

4. Analysis

a. Alleged Failure to Disclose a Housing

At this stage of the proceeding, Petitioner establishes that Trudeau discloses a housing as arranged in the claim. Patent Owner’s argument otherwise is conclusory and, and in the absence of any explanation, is unconvincing. *See* Prelim. Resp. 47, 48.

b. Alleged Failure to Disclose a Housing Including

First and Second Grasping Members

At this stage of the proceeding, Petitioner establishes that Trudeau discloses a housing including first and second grasping members as claimed. Patent Owner’s arguments otherwise are premised on the proposition that the claims require that both grasping members be movable. *See* Prelim. Resp. at 48–50. However, the plain language of claim 16 does not require two movable grasping members. *See* Ex. 1001. Thus, Patent Owner’s argument is unconvincing.

c. Alleged Failure to Disclose a Rotatable Member as Claimed

At this stage of the proceeding, Petitioner establishes that Trudeau discloses the claimed rotatable member extending through the housing along the longitudinal axis. Patent Owner's arguments otherwise are premised on the proposition that the claim requires a rotatable member that extends entirely through the housing. *See* Prelim. Resp. 51–53. As discussed *supra*, this limitation does not require extension of the rotatable member entirely through the housing. Thus, Petitioner's argument is unconvincing.

d. Alleged Failure to Disclose a Rod Contact Member as Claimed

At this stage of the proceeding, Petitioner establishes that Trudeau discloses the claimed rod contact member positioned at the end of the rotatable member. Patent Owner's argument otherwise directs our attention to the portion of Trudeau that explains that the cap 30a is not rotated until it is being secured. *See* Prelim. Resp. 54 (citing Ex. 1004 ¶ 76). However, this portion of Trudeau discusses when the cap 30a and the portion 120 of rod subassembly 3 is rotated, and is not responsive to Petitioner's challenge. *See* Ex. 1004 ¶ 76. Thus, Patent Owner's argument is unconvincing.

e. Conclusion Regarding Trudeau

For the foregoing reasons, we are persuaded at this stage of the proceeding by Petitioner's submission that Trudeau discloses each and every limitation of claim 16. Further, Patent Owner does not present arguments with respect to dependent claims 18, 19, 21, and 22, and we are also persuaded that Trudeau discloses each and every limitation of these claims.

G. Obviousness of Claims 16, 18, 19, 21, and 22

Based on Trudeau and Pond

Petitioner asserts that Trudeau and Pond disclose or suggest all of the limitations of claims 16, 18, 19, 21, and 22. Pet. 45–57. For the reasons discussed *supra*, we are persuaded at this stage of the proceeding that Trudeau anticipates claims 16, 18, 19, 21, and 22. As anticipation is the ultimate of obviousness, we are also persuaded that the combined teachings of Trudeau and Pond disclose or suggest all of the limitations of these claims. *In re Baxter Travenol Labs*, 952 F.2d 388, 391 (Fed. Cir. 1991).

III. CONCLUSION

For the foregoing reasons, upon review of Petitioner’s analysis and supporting evidence, we conclude that Petitioner has demonstrated a reasonable likelihood that it will prevail with regards to its challenges. Although, we exercise our discretion and institute review, we remind the parties that we have not yet made a final determination as to the patentability of any challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 16, 18, 19, 21, and 22 on all grounds raised in the Petition; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, the trial commencing on the entry date of this Decision.

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Patent 9,532,816 B2

PETITIONER:

Paul M. Ulrich
Christopher A. Singh
Ulmer & Berne LLP
pulrich@ulmer.com
csingh@ulmer.com

PATENT OWNER:

Christopher Douglas
Michael S. Connor
Lauren E. Burrow
Brian D. Hill
Alston & Bird LLP
christopher.douglas@alston.com
mike.connor@alston.com
lauren.burrow@alston.com
brian.hill@alston.com