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.

FINAL WRITTEN DECISION 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Orthopediatrics Corp. ("Petitioner"), on January 8, 2018, filed a Petition requesting *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."). We issued a Decision to Institute an *inter partes* review (Paper 8, "Dec.") of all challenged claims (16, 18, 19, 21, and 22) under all grounds, namely Grounds 1–4 discussed below.

After institution of trial, K2M, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 24, "PO Resp."), to which Petitioner replied (Paper 30, "Pet. Reply"), and a Sur-Reply (Paper 35, "PO Sur-Reply).

Oral argument was concurrently conducted on February 21, 2019, for this and related proceeding IPR2018-00521, and the transcript of the hearing has been entered as Paper 41.

We have jurisdiction under 35 U.S.C. § 318(a). After considering the evidence and arguments of both parties, and for the reasons set forth below, we determine that Petitioner has not met its burden of showing, by a preponderance of the evidence, that any of claims 16, 18, 19, 21, and 22 are unpatentable.

II. BACKGROUND

A. Related Proceedings

Petitioner is a defendant in a lawsuit involving the '816 patent. Pet. 1 (referencing *K2M*, *Inc. v. OrthoPediatrics Corp. & OrthoPediatrics US Distribution Corp.*, Case No. 1:17-cv-00061-GMS (D. Del.)).

On the same day that the Petition in the instant proceeding was filed, Petitioner filed a second petition requesting *inter partes* review also challenging claims 16, 18, 19, 21, and 22 of the '816 patent. IPR2018-

00521. Subsequently, Petitioner filed three petitions challenging claims 1, 3, 5, 6, 8–10, 12, and 15–19 of U.S. Patent No. 9,655,664 B2, which is a divisional of the '816 patent. IPR2018-01546, 1547, 1548.

B. The '816 Patent

The '816 patent is directed "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:

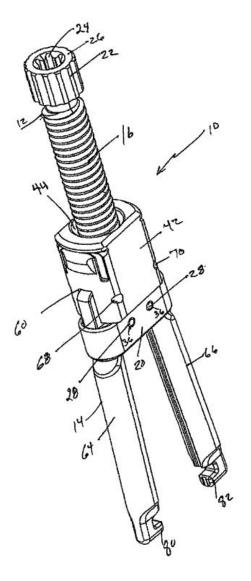


FIG 4

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 states that

The device . . . is a rod 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 only challenged independent claim and illustrative of the claims at issue.

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 therebetween, 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—claims 16, 18, 19, 21, and 22—are unpatentable on the following grounds:

Reference(s)	Basis	Claims 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 (Ex. 1006). Patent Owner supports its opposition to these challenges with the Declaration of Troy Drewry, dated September 14, 2018 (Ex. 2021).

III. ANALYSIS

A petition must show how the construed claims are unpatentable under the statutory ground it identifies. 37 C.F.R. § 42.104(b)(4). Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish the facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A. Claim Construction

In our Decision to Institute *inter partes* review in this proceeding, we construed the terms "extending through the housing" and declined to construe, as unnecessary to our decision, the term "grasping." Dec. 6–10. As the construction of neither of these terms is necessary to our final decision, we maintain our construction of "extending through the housing" and again decline to construe "grasping." In our Decision to Institute *inter partes review*, we also adopted the definition of "housing" advanced by the United States District Court for the District of Delaware. In accordance with that definition, we understand the claim term "housing" to be "the fixed portion of the rod reducing device that defines the body through passage." Dec. 8. For purposes of this final decision, we likewise adopt this definition of "housing."

Central to our decision below is our construction of the claim term "rod contact member." Accordingly, an issue before us is the proper construction of this term. Specifically, at issue is whether we construe "rod contact member" to require direct contact of the rod by the member.

Neither Patent Owner nor Petitioner proposes an explicit claim construction for this term. *See* PO Resp. 8–23; Pet. 4, PO Sur-Reply 2–18; Pet. Reply 1–10. Both Patent Owner and Petitioner, however, allude to their construction of this term in their arguments. For example, in the Patent Owner's Response, Patent Owner states, "[t]he rod contact member, as is

explicitly recited in the claim, is the element of the claims that is in direct contact with the rod." PO Resp. 30. Further, in contesting the challenge based on Iott, Patent Owner asserts that "Petitioner overlooks the requirement that the 'rod contact member' contact the rod and, instead, opts to identify a component, reducer shaft 304, which never makes contacts with the rod." *Id.* at 37. Thus, we understand Patent Owner to construe the claim term "rod contact member" to require actual contact of the rod by that member. Similarly, Petitioner's construction is apparent from their arguments. For example, in arguing that "claim 16 . . . does not recite a rod," Petitioner construes this term to encompass elements that do not directly contact the rod. Pet. Reply 16–17 (emphasis omitted).

1. Principles of Claim Construction

In this proceeding, we determine the meaning of a claim using the "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b) (2017); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation approach).¹

In addition to the specification, the prosecution history plays an important role in claim construction. *Tempo Lighting, Inc. v. Tivoli, LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014) ("In claim construction, this court gives

¹ On October 11, 2018, the USPTO revised its rules to harmonize the Board's claim construction standard with that used in federal district court. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018). This rule change, however, applies to petitions filed after November 13, 2018, and does not apply to this proceeding. *Id*.

primacy to the language of the claims, followed by the specification. Additionally, the prosecution history, while not literally within the patent document, serves as intrinsic evidence for purposes of claim construction. This remains true in construing patent claims before the PTO." (citing *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997)). Indeed, the U.S. Court of Appeals for the Federal Circuit has indicated, in the context of an *inter partes* review, that "[t]he PTO should . . . consult the patent's prosecution history in proceedings in which the patent has been brought back to the agency for a second review." *Microsoft Corp. v Proxyconn, Inc.*, 789 F.3d 1292 (2015) (citing *Tempo Lighting*, 742 F.3d at 798).

2. Express Claim Language

In accordance with the broadest reasonable interpretation, the plain meaning of "rod contact member" is a member that contacts a rod. Any other interpretation reads the word "contact" out of the term. Thus, the express claim language reasonably supports Patent Owner's construction of "rod contact member" as requiring a member that directly contacts the rod.

3. Specification

The specification describes rod contact member 20 as being "brought to bear against a rod positioned over [a] screw." Ex. 1001, 6: 41–42. Further, as shown in Figure 3B of the '816 Patent, reproduced below, rod

contact member 20 is designed to come into direct contact with the head of a screw placed in the opening between grasping members 80 and 82.

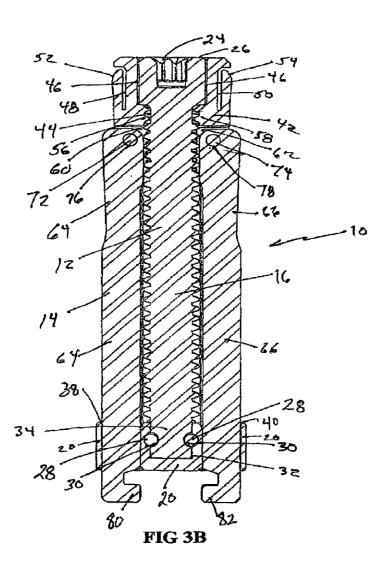


Figure 3B is a cross-sectional view of the rod reducing device with the screw jack mechanism fully extended. Thus, the Specification also supports Patent Owner's interpretation of "rod contact member."

4. Prosecution History

During prosecution, the Examiner also construed "rod contacting member" to require a member that directly contacts the rod. For example, in

the Final Action mailed August 19, 2016, the Examiner relied upon this interpretation in rejecting claim 17 as anticipated by Jackson (US 5,720,751).² Specifically, the Examiner identified Jackson's pusher bar or rod engaging member 15 as corresponding to the claimed "rod contact member." Ex. 2001, 73. Jackson describes its pusher bar or rod engaging member 15 as including abutment member 20 that is "sized and shaped to conform to the shape of a portion of the outer surface of a spinal rod 7." Jackson, 6:40–41. Describing the operation of its device, Jackson states, "The surgeon (not shown) then rotates the stem 16 to advance the pusher bar 15 toward the bone screw 11 positioned within the cradle 67 of the implant engaging portion 52 until the abutment member 20 of the pusher bar 15 engages the spinal rod 7." *Id.* at 8:11–15. Thus, the Examiner construed "rod contact member" to require a member that directly contacts the rod. Accordingly, the prosecution history supports Patent Owner's construction of "rod contact member.

5. Summary

Upon reviewing the explicit claim language, the specification, and the prosecution history, we conclude that "rod contact member" requires a member that directly contacts the rod.

B. 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.

² Then pending claim 17 is renumbered as claim 16 in the '816 patent.

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).

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.³ *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.

³ In its Response, Patent Owner presents objective evidence of nonobviousness. PO Resp. 70–74. As consideration of objective evidence of nonobviousness is not necessary to our decision, we do not address this evidence in our analysis below.

C. Anticipation of Claims 16, 18, 19, 21 and 22 by lott

Petitioner contends that claims 16, 18, 19, 21, and 22 are anticipated by lott in accordance with 35 U.S.C. § 102(e). Pet. 9–22. Having now considered the evidence in the complete record established during trial, we are not persuaded that Petitioner has demonstrated by a preponderance of the evidence that these claims would have been anticipated by lott. We begin our analysis with a brief overview of lott. Next, we address the parties' contentions and then we discuss our reasoning. Our analysis focuses on independent claim 16, from which all other challenged claims depend.

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:

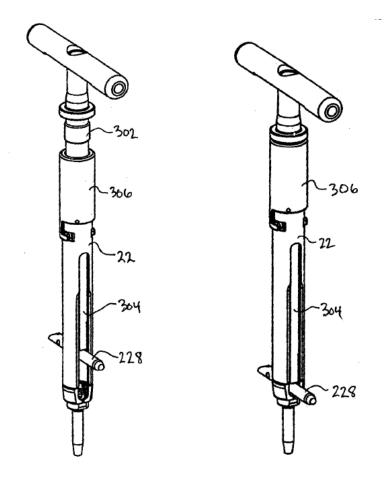


FIG. 31

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's 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.

Specifically, with respect to the claimed rod contact member, Petitioner contends that "Iott discloses 'a rod contact member positioned at a distal end of the rotatable member' as recited in claim 16." Pet. 15. In support of this contention, Petitioner explains that "Iott discloses '*[r]otation* *shaft 302* [the claimed *rotatable member*] comprises a through-hole 310 adjacent a distal end of shaft 302 and is configured to receive a pin 312 therethrough *to axially connect rotation shaft 302* [the claimed *rotatable member*] *to reducer shaft 304* [the claimed *rod contact member*]." *Id.* at 15–16 (citing Ex. 1001 ¶ 71; Fig. 31) (emphasis omitted). Iott's Figures 30 and 31, as annotated by Petitioner, are reproduced below:

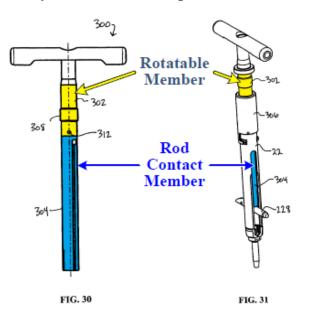


Figure 30 (left) is an annotated side view of a rod reducer assembly and Figure 31 (right) is an annotated perspective view of assembly. Ex. 1001 ¶ 44–45. According to Petitioner, "[a]s shown in FIG. 31, the reducer shaft 304 (*i.e.*, the claimed *rod contact member*) contacts the stabilization member 228 (*i.e.*, a rod) and thus is a rod contact member." Pet. 16.

In its Reply, Petitioner provides alternative theories for how lott meets the rod contact member limitation. Reply 16–18. Petitioner contends that claim 16 does not require direct contact between the rod contact member and the rod. *Id.* at 16–17. In support of this contention, Petitioner asserts that "K2M's expert concedes, [that] claim 16 (unlike claim 19) does *not* recite a 'rod.'" *Id.* (citing Ex. 1006, 59:6–60:12). Petitioner further alleges that"claim 16 does *not recite* that anything must *directly contact* a rod." *Id.* at 17 (emphasis omitted).

Alternatively, Petitioner contends that Iott's reducer shaft 304 directly contacts the rod. *Id.* at 17–18. Noting that "K2M's expert admits, [that] cap 30—which, according to K2M, prevents direct contact—is *not* depicted in FIG. 32," Petitioner asserts that "a 'cap' is not necessarily required in *all* embodiments of Iott." *Id.* at 17 (citing Ex. 2021, 86). In support of this assertion, Petitioner notes that "Iott discloses that '*in one embodiment,* the distal end [of reducer shaft 304] comprises cap engaging or holding protrusions 322 extending inward to engage a cap." *Id.* (citing Ex. 1003 ¶ 70). Petitioner further argues that "the Board correctly recognized that *both* the cap *and* the distal end of the reducer shaft 304 *together* contact the rod, satisfying the limitation." *Id.* at 18 (citing PO Resp. 41; Dec. 19.)

3. Patent Owner's Response

Among other contentions, Patent Owner contends that Iott fails to disclose "a rod *contact* member positioned at the distal end of the rotatable member" as required by claim 16. PO Resp. 40 (emphasis added). Patent Owner's contention is premised on the proposition that the rod contact must directly contact the rod. *See id.* In support of this contention, Patent Owner argues that "Iott's rod reduction device does not contact the rod. Instead Iott discloses the rod is contacted by an implant—a cap—specifically designed to contact the rod." *Id.*

Patent Owner disagrees with Petitioner's contention that direct contact by the rod contacting member with the rod is not required by claim 16. *See* PO Resp. 40–41. According to Patent Owner, "[t]he intrinsic record only

supports direct contact of the rod contact member against the rod. As is clear from the claim, a "rod contact member" is the claim element that contacts the rod." *Id.* at 40. Noting that "[t]he specification states that the rod contact member is 'brought to bear against a rod positioned over the screw' (Ex. 1001, 6:40–44) so that the 'rod can be forced downward into a receiving recess of a bone screw head," Patent Owner argues that "[t]here is no support in the specification that the 'rod contact member' is anything other than what makes direct contact with the rod." *Id.* at 40–41. Patent Owner further notes that "Petitioner's declarant does not cite to anything [in support of his contention]." *Id.* at 41 (citing Ex. 1006 ¶ 57).

Responding to Petitioner's arguments in Petitioner's Reply that claim 16 does not recite anything that directly contacts a rod (Pet. Reply 16–17), Patent Owner asserts that Petitioner "reads out Claim 16's limitation of a *rod contact* member." Sur-Reply 21.

Turning to Petitioner's alternative theory that lott discloses direct contact between its reducer shaft 304 and the rod, Patent Owner asserts that Petitioner disregards the plain language of claim 16. PO Resp. 41 (citing Ex. 2021 ¶¶ 179–180). Patent Owner notes that lott "explicitly discloses that a cap located at the distal end of the reducer shaft 304 contacts the rod, not the reducer shaft 304." *Id.* (citing Ex. 1002 ¶ 71). Based on this description in Iott, Patent Owner asserts that "[t]his cap may not be omitted as it is necessary to secure the rod within the fastener (Ex. 2021[] ¶¶ 180–181). Thus[,] Iott discloses that the cap that contacts the rod, not the reducer shaft 304 alleged by Petitioner." *Id.* (citing Ex. 2021 ¶ 182).

Responding to Petitioner's argument in the Reply, Patent Owner asserts that "Petitioner's reliance on Iott's figures for arguing reducer shaft

304 'makes *direct contact* with rod 228' not only conflicts with Petitioner's prior acknowledgement that the figures are imprecise but also with Iott's clear disclosure that the rod would be affixed into a bone anchor." Sur-Reply 22 (citing Reply 14, 17). Patent Owner alleges that "Petitioner's reliance on paragraph 70 of Iott to allege that only one embodiment requires cap 30 fails to acknowledge what was well-known by a POSITA: a rod is affixed, such as by a cap, so the rod would not come free." *Id.* (citing Ex. 2021 ¶ 181) (footnote omitted). Rather, according to Patent Owner, "Iott disclosed removing the rod reducer only once a cap secured the rod in place." *Id.* (citing Ex. 1002 ¶¶ 71, 80). Patent Owner further asserts that "Petitioner's argument that reducer shaft 304 and cap together contact the rod mixes the roles of instruments and implants." *Id.*

4. Analysis

Having considered Patent Owner's arguments and the full record developed during trial and if view our construction of the claim term "rod contact member" as requiring direct contact between the member and a rod, we determine Petitioner has not shown the challenged claims to be unpatentable.

As noted above, Petitioner's challenge identifies Iott's reducer shaft 304 as corresponding to the claimed rod contact member. Pet. 15–16. Petitioner does not identify Iott's cap as corresponding to the claimed rod contact member. *See id.* Further, Iott does not describe its cap as a part of reducer shaft 304. Rather, as quoted below, Iott states that reducer shaft 304 engages the cap in a releasable manner. Ex. 1002 ¶ 71.

In paragraph 71, reproduced below, Iott describes its reducer shaft 304 (identified by Petitioner as corresponding to the claims rod contact member) as follows:

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 releaseably 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).

Nothing in this paragraph supports Petitioner's position that Iott's reducer shaft 304 contacts the rod as required by claim 16. Rather, this paragraph explicitly states that the cap engages the rod. *See id.* Moreover, we do not understand Iott's paragraph 70 to limit the use of a cap to only one embodiment of Iott's device. We recognize that while it is possible that Iott's cap could be held in such a way that both the cap and the rod reducer shaft contact the rod, there is no evidence in support of such a determination. This ambiguity weighs against a final determination that Petitioner has established by a preponderance of the evidence that Iott discloses the claimed limitation. *See* 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the

grounds for the challenge to each claim")); 37 C.F.R. § 42.104(b) (requiring a petition for *inter partes* review to identify how the challenged claim is to be construed and where each element of the claim is found in the prior art patents or printed publications relied on); *see Harmonic Inc. V. Avid Tech, Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) ("In an [inter partes review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.

5. Conclusion Regarding Iott

For the foregoing reasons, we conclude that Petitioner fails to establish by a preponderance of evidence that Iott anticipates claim 16 in accordance with 35 U.S.C. § 102(e). For the same reasons, we conclude that Petitioner fails to establish that Iott anticipates claims 18, 19, 21, and 22, which depend from claim 16, in accordance with § 102(e).

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

Petitioner asserts that Runco anticipates claims 16, 18, 19, 21, and 22 in accordance with 35 U.S.C. § 102(b). Pet. 22–32. Having now considered the evidence in the complete record established during trial, we are not persuaded that Petitioner has demonstrated by a preponderance of the evidence that these claims would have been anticipated by Runco. We begin our analysis with a brief overview of Runco. Next, we address the parties' contentions and then we discuss our reasoning. Our analysis focuses on independent claim 16, from which all other challenged claims depend.

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:

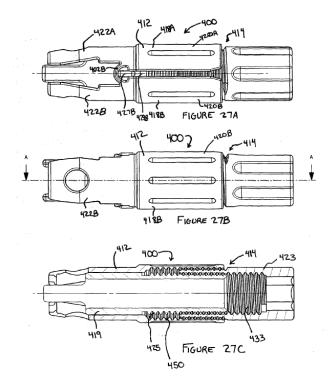


Figure 27A is a side view of an instrument for adjusting a spinal rod relative to a bone anchor, illustrating a rod adjusting tool positioned within a bone anchor engaging too. Ex. 1003 ¶ 51. Figure 27B is a side view of the instrument shown in Figure 27A, and Figure 27C is a side view in cross section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

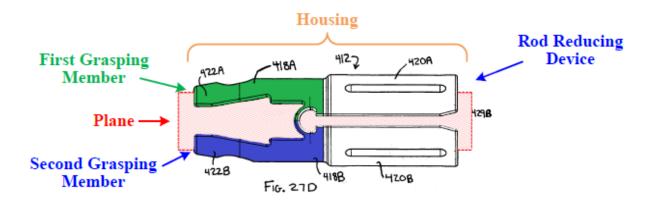
Rod adjusting tool 414 also includes "a distal component 419 having a rod engaging surface 421 and a proximal component 423 connectable to and separable from the distal component 419." *Id.* ¶ 104 (emphasis omitted). Runco explains that "[i]n operation, rotation of the proximal component 423 causes the 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

- 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.

As noted above, Petitioner identifies Runco's engaging tool 412 as corresponding the claimed housing. Petitioner's position is illustrated in annotated Figure 27D, reproduced below:



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.

3. Patent Owner's Response

As discussed above in Part IIIA, we adopted the claim construction advanced by the United States District Court for the District of Delaware for the claim term "housing." This definition defines the claim term "housing" to be "the fixed portion of the rod reducing device that defines the body through passage." Dec. 8.

Among other contentions, Patent Owner contends that Runco fails to disclose a housing. PO Resp. 44. In support of this contention, Patent Owner argues that "[a] POSITA would understand that no part of Runco is fixed and therefore Runco does not have a housing." *Id.* Patent Owner explains that in Runco "both the proximal ends 420A, 420B and distal ends 422A, 422B are not fixed because both must move: proximal ends 420A, 420B move inwardly to allow for compression which, in turn, causes the

distal ends to open so the device may be placed onto a bone anchor." *Id.* (citing Ex. 2021 ¶¶ 197–199, 206; Ex. 1003, [0105]).

4. Analysis

As discussed above, for this proceeding, the claim term "housing" has been defined as "the fixed portion of the rod reducing device that defines the body through passage." *Supra* Part III.A. Petitioner does not contest this definition. Rather, in asserting that we correctly construed "extending through the housing" as "extending through the fixed portion of the rod reducing device that defines the body through passage," Petitioner implicitly adopts this definition of housing. Pet. Reply 5.

We agree with Patent Owner that one skilled in the art would not have considered Runco's engaging tool 412 to be fixed, because its components are "analogous to a clothespin in that a user compresses one side to open the other." PO Resp. 44 (citing Ex. 2030, 154:24–155:22, 171:3–9; Ex. 2021 ¶ 198). Accordingly, Runco's engaging tool 412 is not a housing in accordance with our construction of that claim term.

5. Conclusion Regarding Runco

For the foregoing reason, we conclude that Petitioner fails to establish by a preponderance of evidence that Runco anticipates claim 16 in accordance with 35 U.S.C. § 102(b). For the same reason, we conclude that Petitioner fails to establish that Runco anticipates claims 18, 19, 21, and 22, which depend from claim 16, in accordance with § 102(b).

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

Petitioner asserts that Trudeau discloses anticipates claims 16, 18, 19, 21, and 22in accordance with 35 U.S.C. § 102(b). Pet. 33–45. Having now considered the evidence in the complete record established during trial, we

are not persuaded that Petitioner has demonstrated by a preponderance of the evidence that these claims would have been anticipated by Trudeau. We begin our analysis with a brief overview of Trudeau. Next, we address the parties' contentions and then we discuss our reasoning. Our analysis focuses on independent claim 16, from which all other challenged claims depend.

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:

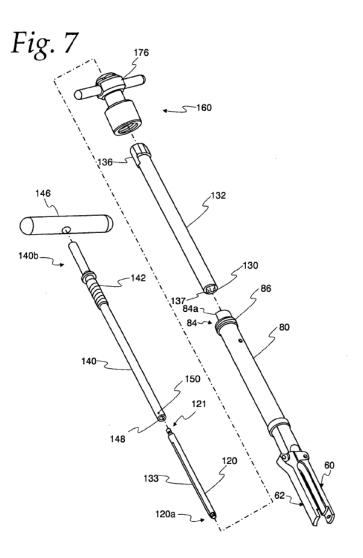


Figure 7 is "a partially exploded perspective view of the main body showing a sleeve coupling subassembly, a drive rod subassembly, a drive sleeve, and a tubular body portion of the surgical apparatus." *Id.* ¶ 14.

The apparatus shown in Figure 7 includes a tool shaft 120 that translates linearly through a drive sleeve 132. *See id.* ¶ 78. Tool shaft 120 is connected to a drive rod 140 having a drive handle 146 at its upper end. *Id.* ¶¶ 79, 80. 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

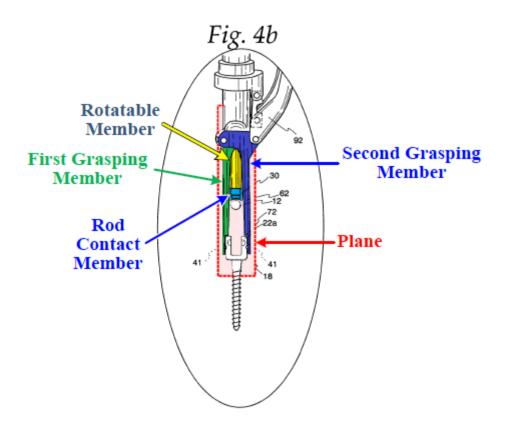
portion 80. *See id.* ¶¶ 50, 51. Jaws 60, 62 engage yoke 18 during operation of the apparatus. *See id.* ¶ 49.

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.

As noted above, with respect to the rod contact member, Petitioner identifies Trudeau's rod securing device 30 as corresponding to the claimed rod contact member. Pet. 39. Trudeau's rod securing device is shown in annotated Figure 4b reproduced below:



Annotated Figure 4b is a perspective view showing the apparatus with the jaws in a closed position. See Ex. 1004 ¶ 11.

3. Patent Owner's Response

Among other contentions, Patent Owner contends that Trudeau fails to disclose a rod contact member at a distal end of the rotatable member. PO Resp. 61. Patent Owner asserts that "the alleged 'rod contact member' is not part of a rod reduction device and is, instead, an implant that is designed to be left in a patient." *Id.* Patent Owner notes that "cap 30 is explicitly disclosed to be an implant that is secured to the head of a bone anchor and implanted into a patient." *Id.* at 62 (citing Ex. 1004 ¶ [0097] (describing the securing of the cap to the bone anchor)). Patent Owner concludes that "because cap 30a is an implant, Petitioner's asserted ground does not

disclose the claimed 'rod contact member' and, thus, Trudeau fails to anticipate Claim 16." *Id*.

4. Analysis

Describing the operation of rod the rod persuader tool 10, Trudeau states:

The preferred and illustrated rod persuader tool 10 herein is especially well-adapted for use with the spine rod anchoring system ... Generally, the rod persuader tool is used for seating the spinal rod 12 within one or more spinal rod anchoring or fixation devices 14. Preferably, 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. The pedicle screw fixture 16 includes a coupling device, such as a yoke 18 that may be formed unitary with the screw, but preferably the voke and screw are distinct components for polyaxial anchoring of the screws relative to the coupling member . . . The spinal rod 12 is captured by a turning of rod securing device 30 including a cam lock member or cap 30a. The preferred securing device 30 includes an intermediate clamping member 30b rotatably secured to the cap 30a by a connector member in the form of a distinct spring clip.

The yoke 18 has a pair of upstanding and opposed walls 22 for receiving the rod therebetween. The spinal rod 12 is captured by a turning of rod securing device 30 including a cam lock member or cap 30a. The preferred securing device 30 includes an intermediate clamping member 30b rotatably secured to the cap 30a by a connector member in the form of a distinct spring clip. To simplify assembly and operation, it is preferred that the tool 10 pushes the spinal rod 12 into the yoke 18 and secures the cap 30a to the yoke 18 to lock at least partially and secure the spinal rod 12 therein. *In the preferred embodiment, the cap 30a is set on or removably attached to a gripping or torqueing portion 120a of the drive rod subassembly 3 toward the distal end D of the tool 10*, the spinal rod 12 may then be set in or otherwise located in a cooperating fashion with a retaining portion 10a of the clamping subassembly 90 toward the distal

end D of the tool 10, and the cap 30a and spinal rod 12 are shifted between the walls 22 of the yoke 18.

Once the spinal rod 12 has been urged into and seated in the yoke 18 between its walls 22 so that holding flanges 40 of the cap 30a are aligned with recesses 41 in the yoke walls 22, *the cap 30a may then be turned by the drive rod 140 so that the cap 30a is at least partially secured to the yoke 18 with the spinal rod 12 captured therein*. To achieve this, the user operates a handle 160 of the sleeve coupling subassembly 6 toward the proximate end P of the tool 10 so that the gripping portion 120a of the drive rod subassembly 3 toward the tool distal end D turns the cap assembly 30 within the yoke 18 for partially locking the spinal rod 12 therein.

Trudeau ¶¶ 38–40 (emphasis added). In other words, Trudeau describes a system wherein Trudeau's rod securing device 30 is attached to yoke 18 of pedicle screw fixture 16, such that rod securing device 30 (and its cap 30a) is part of the implant, not part of rod persuader tool 10. This description is consistent with the description in paragraph 97 cited by Patent Owner in support of its position that Trudeau's cap 30a is an implant and not a rod contacting member as claimed. PO Resp. 62. Accordingly, we agree with Patent Owner that Trudeau fails to disclose a rod contact device as claimed.

5. Conclusion Regarding Trudeau

For this reason, we conclude that Petitioner fails to establish by a preponderance of evidence that Trudeau anticipates claim 16 in accordance with 35 U.S.C. § 102(b). For the same reason, we conclude that Petitioner fails to establish that Trudeau anticipates claims 18, 19, 21, and 22, which depend from claim 16, in accordance with § 102(b).

F. Obviousness of Claims 16, 18, 19, 21, and 22 Based on Trudeau and Pond

Petitioner asserts that claims 16, 18, 19, 21, and 22 are unpatentable under 35 U.S.C. § 103(a) based on Trudeau and Pond. Having now considered the evidence in the complete record established during trial, we are not persuaded that Petitioner has demonstrated by a preponderance of the evidence that these claims would have been unpatentable over Trudeau and Pond. As an overview of Trudeau is provided above, we begin our analysis with a brief overview of Pond. Next, we address the parties' contentions and then we discuss our reasoning. Our analysis focuses on independent claim 16, from which all other challenged claims depend.

1. Pond

Pond is directed to "a system 40 for positioning a connecting member adjacent the spinal column in a minimally invasive surgical procedure." Ex. $1005 \P 65$. Pond's system 40 provides at least a pair of extenders mountable to anchors engaged to the spinal column." *Id.* In system 40, "[t]he extenders extend proximally from the anchors, and guide the placement of a connecting member from a position remote from the spinal column to a position adjacent the spinal column." *Id.* Pond states that "[t]he extenders are configured so that when the connecting member is adjacent the spinal column, the connecting member extends between the at least a pair of anchors." *Id.*

Petitioner's challenge is based on the embodiment of system 40 shown in Pond's Figure 40 reproduced below:

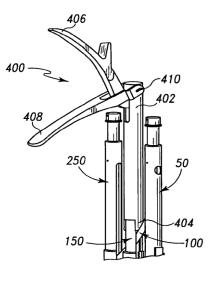


Fig. 40

Figure 40 shows a connecting member 100 positioned through extenders 150 and a reduction instrument 400 positioned over the second extender. Ex. 1005 \P 43. Pond describes this embodiment in paragraphs 123–128. Of particular interest to this proceeding is Pond's statements that

When final reduction has been obtained, a set screw or plug can be delivered through extender 150 to engage connecting member 100 to anchor 160. Reduction instrument 400 can then be placed over none, one or both of the other extenders 50, 250 to finally reduce connecting member 100 into the receiver members of these anchors.

Id. ¶ 124.

2. *Petitioner's Challenge*

Petitioner asserts that Trudeau and Pond discloses or suggest all of the limitations of claims 16, 18, 19, 21, and 22. Pet. 45–57. For this challenge, Petitioner maps Trudeau to the claims as outlined above in Section E, except Petitioner admits that "[a] person of ordinary skill in the art, however, could view Trudeau differently" than in the previous challenge. Pet. 46.

According to Petitioner, "in an alternative arrangement, the 'rotatable member' of the '816 Patent can be seen not as the entire 'drive rod subassembly 3,' but rather only the top portion of the assembly, i.e., 'drive rod 140.'" *Id.* (emphasis omitted). In this instance, Petitioner asserts that "the 'rod contact member' of the '816 Patent can be seen not as the 'rod securing device 30' of Trudeau, but rather as the bottom portion of the 'drive rod subassembly 3,' i.e., the 'tool shaft 120' with the 'rod securing device 30' of Trudeau includes 'a cam lock member or cap.'" *Id.* at 47 (citing Ex. 1004). Then, Petitioner reasons that "[t]he functionality provided by cam lock members, set screws, or caps, however, is not necessary to reduce a rod. As such, it would have been obvious to a person of ordinary skill in the art to remove that component and simplify the device, such that the 'tool shaft 120' would instead contact the rod." *Id.* (citations omitted).

In addition, Petitioner alleges that "Pond discloses such a rod reducer operating in this manner, that is, with a rod contact member that contacts a rod without a cap or set screw." *Id.* at 48 (citing Ex. 1005). Specifically, Petitioner asserts that Pond "discloses a reduction instrument configured to initially reduce and temporarily hold a spinal rod into the receiving members of a plurality of bone anchors and then secure the spinal rod within the receiving members with set screws or plugs." *Id.* at 49–51. Based on this assertion, Petitioner concludes that "Trudeau—in this alternative arrangement—in view of Pond renders obvious claims 16, 18, 19, 21, and 22 of the '816 Patent." *Id.* at 48.

3. Patent Owner's Response

Patent Owner contends that "Petitioner's theory whereby a POSITA would not rely on cap 30a of Trudeau . . . overlooks Trudeau's requirement of a cap 30a to secure the rod and that removing the cap renders the resultant combination inoperable." PO Resp. 64–65. According to Patent Owner, Trudeau's "rod securing device 30 is essential to the operation of the instrument and for securing the rod." *Id.* at 66. Patent Owner explains that "[n]ot only does rod securing device 30 secure the rod into the yoke of the bone anchor, Trudeau explains that the cap is necessary to prevent rotation, which will 'minimize friction and damage' to the rod being reduced." *Id.* (citing Ex. 1004 ¶¶ 74, 75, 77; Ex. 2021 ¶ 286). Thus, Patent Owner asserts, "[a] POSITA would understand both the importance of these [rotation prevention and minimization of friction and damage] functions and that they are required for Trudeau to operate." *Id.* at 67.

Patent Owner further asserts that "[t]he sole rational[e] that Petitioner[]s asserted to modify Trudeau disregards that Trudeau already allowed a surgeon to first temporarily secure a rod before fully securing the rod so that the surgeon could making any desired adjustments." *Id.* at 65 (citing Ex. 2021 ¶ 283). According to Patent Owner, "Trudeau disclosed temporarily positioning a spinal rod into a bone anchor and making any necessary adjustments before securing the cap 30." *Id.* (citing Ex. 1004 ¶¶ 39, 40, 49, 76, 77, 83, 85, 89, 101, 104; Ex. 2021 ¶¶ 283–284). As an example, Patent Owner alleges that "Trudeau teaches that a surgeon is to partially secure the cap after rod reduction, which allows for any necessary adjustments" and that "Trudeau also discloses to later fully secure the spinal rod after making any necessary adjustments." *Id.* (citing Ex. 1004 ¶ 104).

Turning to Pond, Patent Owner asserts that Pond's teachings cannot be applied to Trudeau's instrument. *See* PO Resp. 67–70. Patent Owner explains that "Pond's reduction instrument 400 includes a reduction member 402 having an inner passage sized to go over one of the extenders." *Id.* at 68 (citing Ex. 1005 ¶ 120). Patent Owner further explains that "[f]or Pond to function, the reduction instrument must travel externally to the extenders so the central passage remains open so that a screw may be inserted to secure the rod to the anchor after the rod has been reduced." *Id.* (citing Ex. 1005 ¶ 124). Patent Owner notes that "Petitioner never provides an explanation as to how an instrument can travel on the outside of Trudeau." *Id.* at 69.

In view of this difference between Trudeau's device and Pond's device, Patent Owner asserts that Petitioner's proposed modification of Trudeau would not work because Trudeau's "tool shaft 120 cannot hold the rod in place and, simultaneously, allow installation of a set screw. If the tool shaft 120 was removed after 'initially reduc[ing] and temporarily hold[ing]' rod in place (Petition, 50), the rod would not stay in place and would later need to be reduced." PO Resp. 69. According to Patent Owner, operating Trudeau's device "without its rod securing device results in Trudeau no longer functioning to secure a rod in a bone anchor. Petitioner's rationale for combining Trudeau and Pond renders the combination inoperable and, thus, a POSITA would not be motivated to modify Trudeau based on Pond." *Id.* at 70.

Patent Owner also offers evidence of in support of non-obviousness. See PO Resp. 70–74. Our determination, discussed below, does not rely on this evidence. Accordingly, this evidence is unnecessary to our decision and we do not address it.

4. Analysis

As discussed above, Petitioner's challenge is premised on the proposition that it would have been obvious to remove Trudeau's cap 30. *See, e.g.*, Pet. 47; Pet. Reply 27. In support of this proposition, Petitioner cites *In re Kuhle*, 526 F. 2d 553, 555 (CCPA 1975) and *Application of Larson*, 340 F.2d 965, 969 (CCPA 1965). Pet. 47; Pet. Reply 29. These cases stand for the general principle that if a feature or device is not desired or required, it would be obvious to eliminate that feature or device. *Kuhle*, 526 F.2d at 555; *Larson*, 340 F.2d at 969.

Trudeau's cap 30 performs several functions, most notably, the functions of securing and capturing rod 12 in yoke 18. *See, e.g.*, Ex. 1004 ¶¶ 39, 40, and 83. Petitioner's proposed modification of eliminating cap 30 would thus result in the elimination of its securing and rod capturing functions. Petitioner, however, has not adequately explained why one skilled in the art would have desired to remove these functions. Rather, Petitioner has merely alleged that other rod reducers operate without a cap. *See*, Pet. 48. In support of this allegation, Petitioner asserts that Pond discloses such a device. *Id.* Petitioner's assertion mischaracterizes Pond's device.

As discussed above, Pond discloses "a set screw or plug . . . delivered through extender 150 to engage connecting member 100 to anchor 160." Ex. 1005 ¶ 124. Although, Pond's set screw or plug (i.e. cap) is delivered in a different manner than Trudeau's cap, Pond does not suggest elimination of such devices. Thus, Pond does not support Petitioner's position. Lacking supporting evidence or adequate explanation of why one skilled in the art

would have wanted to eliminate Trudeau's cap and its functions of securing and capturing the rod, Petitioner's reasoning lacks rational underpinning.

Moreover, to the extent that this challenge relies upon modification of Trudeau's system in view of Pond's teaching of reduction of a rod into bone anchors before employing a set screw,⁴ we agree with Patent Owner that Petitioner has not adequately explained why one skilled in the art would make such a modification. Rather, Petitioner merely concludes that such a device would be "simpler" without adequately explaining in what way the device would be simpler and why that would be desirable. *See* Pet. Reply 29.

For these reasons, we conclude that Petitioner fails to establish by a preponderance of evidence that Trudeau and Pond render claim 16 unpatentable in accordance with 35 U.S.C. § 103(a). For the same reasons, we conclude that Petitioner fails to establish that Trudeau and Pond render claims 18, 19, 21, and 22, which depend from claim 16, as unpatentable in accordance with § 103(a).

6. MOTION TO EXPUNGE

Patent Owner filed a Motion to Expunge their originally filed Patent Owner's Sur-Reply (Paper No. 33) and replace it with the later filed

⁴ We note that in Petitioner's Reply, Petitioner explicitly states that "Petitioner does not propose physically combining elements of Pond with Trudeau." Pet. Reply. 28. Petitioner's arguments, however, rely on such combination. *See* Pet. Reply 29–30.

corrected copy (Paper No. 35) because it did not include the correct versions of the images. Paper 36, 1. Petitioner does not oppose this motion.

7. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not shown by a preponderance of the evidence that any of claims 16, 18, 19, 21, and 22 of the '429 patent are unpatentable. Specifically, Petitioner has not shown that (1) claims 16, 18, 19, 21, and 22 of the '816 are anticipated by Iott, (2) claims 16, 18, 19, 21, and 22 are anticipated by Runco, (3) claims 16, 18, 19, 21, and 22 are anticipated by Trudeau, and (4) claims 16, 18, 19, 21, and 22 are unpatentable over Trudeau and Pond.

In addition, we grant Patent Owner's motion to expunge their originally filed Patent Owner's Sur-Reply and to replace it with the later filed version.

8. ORDER

In consideration of the foregoing, it is hereby

ORDERED that on the record before us, Petitioner has not shown by a preponderance of the evidence that claims 16, 18, 19, 21, and 22 of the ''429 patent are unpatentable.

FURTHER ORDERED that this is a Final Written Decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. §90.2

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