

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EXACTECH, INC.,
Petitioner,

v.

ZIMMER, INC.,
Patent Owner.

IPR2022-00840
Patent 7,029,477 B2

Before BARBARA A. PARVIS, SCOTT C. MOORE, and
SEAN P. O'HANLON, *Administrative Patent Judges*.

O'HANLON, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Exactech, Inc. (“Petitioner”) filed a Petition for *inter partes* review of claims 18–21 (“the challenged claims”) of U.S. Patent No. 7,029,477 B2 (Ex. 1001, “the ’477 patent”). Paper 2 (“Pet.”), 1. Zimmer Inc. (“Patent Owner”)¹ filed a Preliminary Response. Paper 6 (“Prelim. Resp.”).

Institution of an *inter partes* review is authorized by statute only when “the information presented in the petition . . . and any response . . . 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.” 35 U.S.C. § 314(a) (2018). We have authority, acting on the designation of the Director, to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). For the reasons set forth below, upon considering the Petition, Preliminary Response, and evidence of record, we conclude that the information presented in the Petition fails to establish a reasonable likelihood that Petitioner would prevail in showing the unpatentability of any of the challenged claims. Accordingly, we decline to institute *inter partes* review.

B. Real Parties in Interest

Petitioner identifies itself, Osteon Intermediate Holdings II, Inc., and Blue Ortho SAS as real parties in interest. Pet. 3.

¹ Patent Owner explains that, “[f]or clarity, Zimmer Technology, Inc. (the assignee of record for U.S. Patent No. 7,029,477), was merged into Zimmer, Inc. on November 27, 2012, with Zimmer, Inc. being the surviving corporation.” Paper 4, 1.

Patent Owner identifies itself as the sole real party in interest.

Paper 4, 1. Patent Owner states that it is a subsidiary of Zimmer Biomet Holdings, Inc. *Id.* Patent Owner further states that “Zimmer US, Inc. and ORTHOsoft ULC d/b/a Zimmer CAS are parties to [litigation involving the ’477 patent identified in § I.C below] and have an interest in the outcome of this proceeding.” *Id.*

C. Related Matters

The parties indicate that the ’477 patent is the subject of the following district court proceeding:

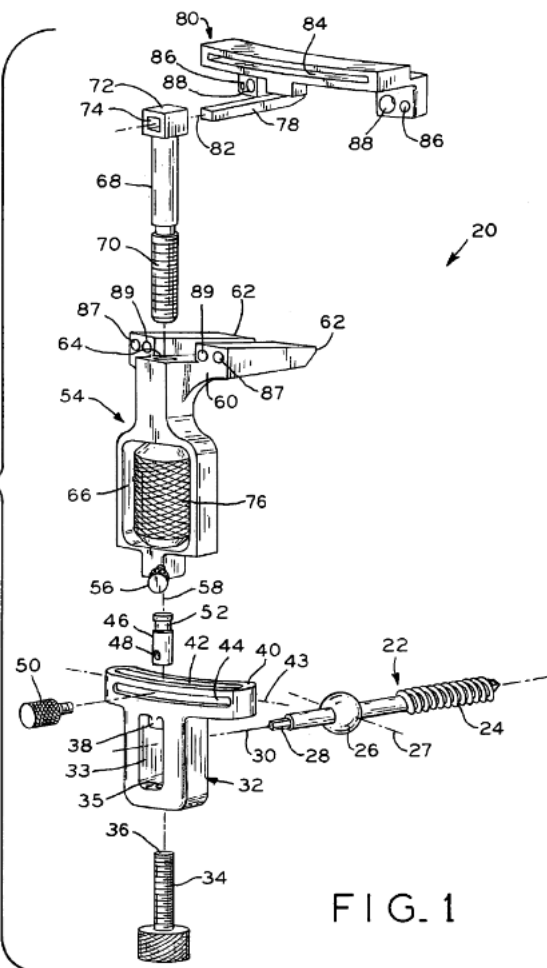
Zimmer, Inc. v. Exactech, Inc., Case No. 8:21-cv-995 (M.D. Fla. filed April 27, 2021).

Pet. 3; Paper 4, 2.

D. The Challenged Patent

The ’477 patent discloses a surgical guide and method for properly positioning a surgical instrument with respect to an anatomical structure. Ex. 1001, 1:7–10. Figure 1 shows an exploded view of the surgical instrument and is reproduced below. *Id.* at 5:33–34. Surgical instrument 20 includes anchoring member 22, first carriage body 32, second carriage body 54, support shaft 68, and implement portion 80. *Id.* at 5:52–7:4. Anchoring member 22 secures the surgical instrument to the patient’s tibia.

Id. at 5:53–56. First carriage body 32 adjustably engages anchoring member spherical portion 26 and is secured thereto via set screw 34. *Id.* at 5:59–6:7. Second carriage body 54 is coupled to the first carriage body via slide pin 46 and set screws 50, 56. *Id.* at 6:8–26. Slide shaft 68 is coupled to second carriage member adjustment knob 76 via its threaded section 70. *Id.* at 6:34–39. Implement portion 80 is disposed within slide shaft throughway 74 via its mounting member 78. *Id.* at 6:46–55.



In use, the surgical instrument is secured to the patient's tibia by securing anchoring member 22 to the patient's tibia via threaded shaft 24. Ex. 1001, 5:53–56, 10:5–6. Implement portion 80 is properly positioned with respect to the anchoring member about rotational axis 30, and the rotational position is secured by tightening set screw 34 against spherical portion 26 of anchoring member 22. *Id.* at 10:29–33. Implement portion 80 is positioned in the correct translational position with respect to the anchoring member by moving slide pin 46 within first carriage body slot 42, and the translational position is secured by tightening set screw 50. *Id.* at 10:33–43. Implement portion 80 is properly positioned about axis 58 by

rotating second carriage body 54 about slide pin 46, and the rotational position is secured by tightening set screw 56. *Id.* at 10:44–49. Implement portion 80 is set to the correct height by rotating knob 76, causing support shaft 68 to translate along axis 58. *Id.* at 10:49–52. The anterior/posterior slope of resection is set by loosening set screw 34, rotating the surgical tool about rotational axis 27, and retightening set screw 34. *Id.* at 10:52–58. In this position, distal ends 62 of second carriage body support structure 60 contact the patient's tibia. *Id.* at 6:27–31. Implement portion 80 is translated along axis 82 until it contacts the patient's tibia. *Id.* at 10:62–66. The implement portion is secured to the patient's tibia by placing pins through openings 86 into the patient's tibia or by securing screws to the tibia through openings 88. *Id.* at 10:66–11:1. The resection guide formed by slot 84 is then used to guide a cutting blade in the resection of the patient's tibia. *Id.* at 11:2–4.

Surgical instrument 20 can be used in a computer-implemented image guidance system, in which case reference member 90 (*see* Figures 4, 5) is used to register the surgical instrument with the system. Ex. 1001, 7:5–26. The reference member is inserted into slot 84, positioning reference elements 96 in known positions and orientations relative to implement portion 80. *Id.* at 7:16–21. Alternatively, the reference members can be attached directly to the implement portion. *Id.* at 7:27–29. The system includes a light source, and a localizing portion of the system detects the light reflected from the reference elements and computes the location of the elements (and the surgical tool) in a known manner. *Id.* at 9:40–44.

E. The Challenged Claims

Petitioner challenges claims 18–21 of the '477 patent. Pet. 1.
Claim 18 is the sole independent claim challenged and is reproduced below.

18. A surgical instrument for resecting a tibia, said instrument comprising:
- a fastener selectively secured to the tibia;
 - a resection guide, said resection guide being selectively translatable relative to said fastener and selectively rotatable relative to said fastener; and
 - at least one reference element registerable in a computer implemented image guidance system, said at least one reference element mounted in a predetermined orientation relative to said resection guide.

Ex. 1001, 13:3–12.

F. Asserted Grounds of Unpatentability

The Petition relies on the following prior art references:

Name	Reference	Exhibit
DeOrio	US 5,681,316, issued October 28, 1997	1004
Stulberg	S. David Stulberg et al., <i>Computer-Assisted Total Knee Replacement Arthroplasty</i> , 10 Operative Techs. Orthopaedics 25, 25–39 (2000)	1005

Petitioner asserts the following ground of unpatentability:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
18–21	103(a) ²	DeOrio, Stulberg

² The application resulting in the '477 patent was filed prior to the date when the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125

Pet. 6. Petitioner submits a declaration of Troy D. Drewry (Ex. 1003, “Drewry Declaration”) in support of its contentions.

II. PATENTABILITY ANALYSIS

A. Principles of Law

1. *Inter Partes* Review

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 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”)). Petitioner bears the burden of persuasion to prove unpatentability of each challenged claim by a preponderance of the evidence. 35 U.S.C. § 316(e). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). The Board may authorize an *inter partes* review if we determine that the information presented in the Petition and Patent Owner’s Preliminary Response shows that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a).

2. *Obviousness*

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

Stat. 284 (2011), took effect. Thus, we refer to the pre-AIA version of section 103.

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 the 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 skill in the art, and (4) when in evidence, any objective evidence of nonobviousness.³ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art is “a prism or lens” through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). The person of ordinary skill in the art is a hypothetical person presumed to have known the relevant art at the time of the invention. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, we may consider certain factors, including: “(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Best Med. Int’l, Inc. v. Elekta Inc.*, 46 F.4th 1346, 1353 (Fed. Cir. 2022) (citations omitted). “The patent’s purpose can also be informative.” *Id.* (citation omitted).

³ At this stage of the proceeding, the parties have not directed us to any such objective evidence.

Petitioner contends that a person having ordinary skill in the art at the time of the invention would have “a Bachelor’s degree in Mechanical Engineering, Biomedical Engineering, or a related field, and approximately 2-3 years of experience in orthopedic product engineering.” Pet. 17. Petitioner further contends that “[a]dditional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education.” *Id.*

Patent Owner does not contest Petitioner’s definition of the ordinary level of skill or offer its own definition. *See generally* Prelim. Resp.

We find Petitioner’s description to be consistent with the problems and solutions disclosed in the patent and prior art of record, and adopt it as our own for purposes of this Decision. *See, e.g., In re GPAC Inc.*, 57 F.3d at 1579 (approving the determination of the level of ordinary skill in the art by appeal to the references of record).

C. Claim Construction

In an *inter partes* review, claims are construed using the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b), including construing the claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b). “[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention” and “after reading the entire patent.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 1321 (Fed. Cir. 2005) (en banc). In addition to the

specification and prosecution history, we also consider use of the terms in other claims and extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Id.* at 1312–17. Usually, the specification is dispositive, and it is the single best guide to the meaning of a disputed term. *Id.* at 1315.

Neither party proposes definitions for any claim terms. *See* Pet. 17–18; Prelim. Resp. 3.

For purposes of this Decision, and based on the record before us, we determine that no construction of any term is necessary. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’” (alteration in original) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

D. Overview of the Asserted Prior Art

1. DeOrio

DeOrio discloses a tibial resection guide. Ex. 1004, 1:4–6. Figure 1 shows a perspective view of the resection guide and is reproduced below. *Id.* at 2:38–40. Tibial resection guide 10 includes mounting sleeve 12, mounting block 16, horizontal mounting assembly 20, vertical mounting assembly 22, and cutting guide block 26. *Id.* at 2:63–3:11. Mounting block 16 is adjustably connected to mounting sleeve horizontal mounting

rod 14. *Id.* at 3:1–4. Horizontal mounting assembly 20 is pivotally mounted on a lower portion of the mounting block. *Id.* at 3:4–6. Vertical mounting assembly 22 engages and slides along a top portion of the mounting block. *Id.* at 3:6–8. Cutting block 26 is mounted on a bottom portion of the vertical mounting assembly. *Id.* at 3:8–11.

In use, a bore is drilled into the intramedullary canal of the patient's tibia. Ex. 1004, 6:30–31. The resection guide is mounted on intramedullary rod 28 by inserting the rod through mounting sleeve 12, and the rod is positioned within the bore.

Id. at 6:31–33, Fig. 4. The resection guide is secured to the intermedullary rod by tightening thumbscrew 34, thereby setting an initial vertical position of the resection guide. *Id.* at 3:20–23, 6:33–36. Fine vertical positioning of cutting guide block 36 is achieved by moving mounting assembly 22 along horizontal mounting assembly 20. *Id.* at 4:39–46, 6:36–41. A pawl and detent arrangement may be used to control such fine movement. *Id.* at 4:46–65, Figs. 5, 6. Horizontal positioning in the anteroposterior plane is achieved by sliding mounting block 16 along mounting rod 14 and locking the mounting block in place via thumbscrew 38. *Id.* at 6:42–49. The

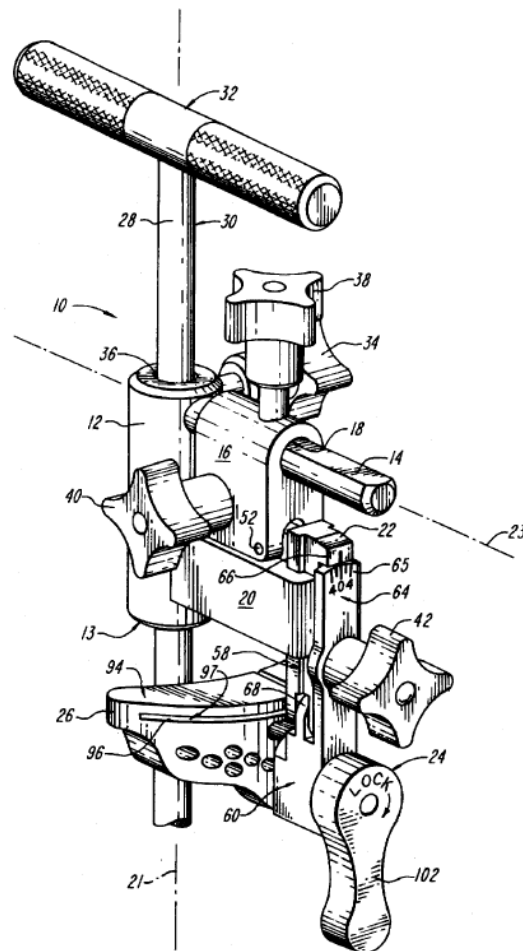


FIG. 1

anteroposterior slope of the resection guide (and, hence, its cutting surface 97) is adjustable by rotating horizontal mounting assembly 20 with respect to mounting member 16, and can be locked in place via thumbscrew 40. *Id.* at 3:44–4:3, 6:50–67, Fig. 4. The mediolateral slope of the resection guide (and, hence, its cutting service 97) is adjustable by rotating vertical mounting assembly lower segment 60 relative to vertical mounting assembly upper segment 58, and can be locked in place via thumbscrew 42. *Id.* at 4:14–20, 7:1–12, Fig. 3. When the resection guide is correctly positioned, it is fixed to the anterior surface of the patient’s tibia by inserting pins through guide block bores 98 and into the tibia. *Id.* at 7:13–17, Fig. 3. The remaining components of guide 10 and intramedullary rod 28 are then removed, and tibial resection is performed by inserting a saw through transverse slot 96. *Id.* at 7:17–22.

2. *Stulberg*

Stulberg is a journal article discussing computer-assisted total knee replacement arthroplasty. Ex. 1005, 25.⁴ The equipment used to guide the positioning of cutting blocks used during such surgery include an optical localizer, rigid bodies containing diodes, a computer, a monitor, and a foot control. *Id.* at 27. The rigid bodies are securely affixed to the patient’s bones using screws, and the optical localizer has cameras that detect infrared radiation emitted by the diodes contained in the rigid bodies. *Id.* A surgeon activates the foot control to show the position of bones on the computer screen. *Id.* Rigid bodies are also attached to the cutting block, which can

⁴ Like Petitioner (*see, e.g.*, Pet. 39), we cite to the article pagination rather than the exhibit pagination.

also be depicted on the monitor. *Id.* at 29. A surgeon uses a probe to palpate the patient's tibia plateau, and uses the acquired information to determine the level of tibial resection. *Id.* The surgeon uses the computer system to correctly position the cutting block on the patient's tibia for resection. *Id.*

E. Petitioner's Challenge

Petitioner argues that claims 18–21 would have been obvious in view of DeOrio and Stulberg. Pet. 18–57. In support of its showing, Petitioner relies upon the Drewry Declaration. *Id.* (citing Ex. 1003). We have reviewed Petitioner's assertions and supporting evidence. For the reasons discussed below, and based on the record before us, we determine that Petitioner does not demonstrate a reasonable likelihood of prevailing in showing that at least one challenged claim would have been obvious in view of the combination of DeOrio and Stulberg.

Independent claim 18 recites, in relevant part, a surgical instrument for resecting a tibia comprising “a fastener selectively secured to the tibia.” Ex. 1001, 13:3–5. Petitioner argues that “DeOrio discloses an intramedullary rod 28 that is secured to the tibia by being press-fit or screwed into a bore drilled into the intramedullary canal of the tibia.”⁵ Pet. 33 (citing Ex. 1004, 6:28–33, Fig. 4; Ex. 1003 ¶¶ 50, 73).

Patent Owner argues that DeOrio does not disclose a fastener selectively secured to a patient's tibia as recited in claim 18 for a number

⁵ Throughout the Petition, Petitioner presents the names of the asserted references in boldface font. When quoting the Petition herein, we omit such boldface formatting.

reasons. Prelim. Resp. 19–27. First, Patent Owner argues that DeOrio’s intramedullary rod is an anchor, not a fastener. *Id.* at 20. According to Patent Owner, “A fastener is a device that connects or secures elements.” *Id.* Patent Owner argues that DeOrio’s intramedullary rod does not meet this definition because it “is temporarily inserted into a pre-drilled bore in the intramedullary canal to anchor the cutting guide so it can be aligned,” but is “removed for resection and thus does not connect or secure elements.” *Id.* (citing Ex. 1004, 3:12–19, 7:17–20). Patent Owner argues that “DeOrio’s intramedullary rod merely contacts the inside of the intramedullary canal to anchor a surgical instrument and is not a fastener.” *Id.* at 21–22. Patent Owner argues that Mr. Drewry’s opinion that DeOrio discloses its intermedullary rod being press-fit or screwed into the tibia (*see* Ex. 1003 ¶ 73) is unsupported and entitled to little weight. *Id.* at 22–24.

Petitioner relies on DeOrio to *disclose* that its intermedullary rod is press-fit or screwed to the tibia. Pet. 33. Petitioner and its declarant, Mr. Drewry, rely on column six, lines 28–33 and Figure 4 to support the contention that “DeOrio *discloses* an intramedullary rod 28 that is secured to the tibia by being press-fit or screwed into a bore drilled into the intramedullary canal of the tibia.” *Id.* (emphasis added) (citing Ex. 1004, 6:28–33, Fig. 4; Ex. 1003 ¶¶ 50, 73); Ex. 1003 ¶ 73 (citing Ex. 1004, 6:28–33, Fig. 4). However, DeOrio makes no such disclosure of a press-fit or screwed connection between the intermedullary rod and the tibia. The relevant portion of column six discloses only that “a bore is drilled into the intramedullary canal of a patient’s tibia.” Ex. 1004, 6:30–31. Figure 4 illustrates shaft 30 of intermedullary rod 28 extending into the tibia, presumably in the bore drilled therein. DeOrio does not provide details

regarding how the intermedullary rod is positioned within the bore, and certainly makes no disclosure of a press-fit or screwed connection as asserted by Petitioner. Thus, DeOrio does not support Petitioner's contentions.

Next, Patent Owner argues that DeOrio's "intramedullary rod is not selectively secured to the tibia." Prelim. Resp. 24–26. Patent Owner argues that "DeOrio's intramedullary rod is positioned within the tibial canal, not secured *to* the tibia." *Id.* at 25. Patent Owner argues that "[t]he term 'selectively' means that the fastener is securable to the tibia in multiple positions." *Id.* Patent Owner argues that DeOrio's intramedullary rod does not meet this definition because it "can only be placed in the drilled bore of the patient's intramedullary canal." *Id.* (citing Ex. 1004, 6:30–34).

Neither Petitioner nor Mr. Drewry addresses the recitation that the fastener be *selectively* secured to the tibia. *See* Pet. 33–35; Ex. 1003 ¶¶ 72–80. Instead, Petitioner merely asserts that DeOrio's intermedullary rod "is secured to the tibia." Pet. 33. By failing to address all of the claim recitations, Petitioner has failed to explain with requisite particularity how the asserted references disclose or suggest all aspects of the challenged claims. *See* 35 U.S.C. § 312(a)(3); 37 C.F.R. § 42.104(b).

Finally, Patent Owner argues that DeOrio's intermedullary rod is not part of its surgical instrument because the intermedullary rod is removed prior to resection. Prelim. Resp. 26. Patent Owner notes that the intermedullary rod must be removed before resection because it is in the cutting path. *Id.* at 26–27 (reproducing Petitioner's annotated version of DeOrio's Figure 4 (*see* Pet. 33)). Thus, Patent Owner defines DeOrio's

surgical instrument for resecting a tibia as just cutting guide block 26.

Prelim. Resp. 27.

DeOrio supports Patent Owner's arguments. DeOrio states that, after the cutting guide block is correctly positioned and affixed to the patient's tibia, "[t]he remaining components of the guide 10, together with intramedullary rod 28, are removed, leaving only the cutting guide block 26 in place." Ex. 1004, 7:17–20. By mentioning both "[t]he remaining components of the guide 10" and "intramedullary rod 28," DeOrio indicates that the intramedullary rod is not a component of the resection guide. Moreover, DeOrio supports Patent Owner's contention that the intramedullary rod is removed prior to resection. *Id.* Accordingly, we agree with Patent Owner that DeOrio's intramedullary rod 28 is not part of a surgical instrument as recited in claim 18. For this additional reason, Petitioner has failed to explain with requisite particularity how the asserted references disclose or suggest all aspects of the challenged claims.

For at least the foregoing reasons, Petitioner has not shown sufficiently that DeOrio discloses or teaches a fastener as recited in claim 18. Petitioner's reliance on Stulberg to teach a computer-assisted tracking system does not correct this deficiency. *See* Pet. 38–41. Therefore, Petitioner does not demonstrate a reasonable likelihood of prevailing in showing that claim 18 or its dependent claims 19–21 would have been obvious in view of DeOrio and Stulberg.

III. DISCRETIONARY DENIAL

Patent Owner argues that we should discretionarily deny institution of *inter partes* review under 35 U.S.C. § 325(d) because substantially the same

prior art advanced by Petitioner were presented during prosecution of the application resulting in the '477 patent. Prelim. Resp. 9–18. Because we determine that the Petition fails to set forth a reasonable likelihood that Petitioner would prevail with respect to its challenge to the '477 patent, we do not reach Patent Owner's argument that we should exercise discretion under § 325(d) to deny institution.

IV. CONCLUSION

For the foregoing reasons, we are not persuaded that the Petition establishes a reasonable likelihood that Petitioner would prevail in its challenge to claims 18–21 of the '477 patent.

V. ORDER

In consideration of the foregoing, it is hereby ordered that the Petition is *denied*, and no trial is instituted.

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