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Paper 8
Date: August 12, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED, LLC,
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

IPR2022-00486
Patent 9,168,074 B2

Before HYUN J. JUNG, SUSAN L. C. MITCHELL, and MICHAEL A. VALEK, *Administrative Patent Judges.*

JUNG, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background and Summary

OsteoMed LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of an *inter partes* review of claims 1, 7, 8, 10, 13, and 15 of U.S. Patent No. 9,168,074 B2 (Ex. 1001, "the '074 patent"). Stryker

European Operations Holdings LLC ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition and for the reasons explained below, we determine that Petitioner has not shown a reasonable likelihood of prevailing with respect to at least one of the challenged claims.

Thus, we do not institute an *inter partes* review of claims 1, 7, 8, 10, 13, and 15 of the '074 patent.

B. Real Parties in Interest

Petitioner identifies OsteoMed LLC, Acumed LLC, and Colson Medical, LLC as real parties in interest. Pet. ix. Petitioner also lists Marmon Holdings, Inc. and Berkshire Hathaway Inc. as "additional parties that may be relevant" for "identifying potential conflicts and analysis under 35 U.S.C. § 315(b)" without conceding that they are real parties in interest. *Id.*

Patent Owner identifies itself as a real party in interest and states that it "is a wholly-owned subsidiary of Stryker Corporation." Paper 5, 2. Patent Owner also states that "Howmedica Osteonics Corp. is a wholly-owned subsidiary of Stryker Corporation and is an exclusive licensee of the challenged patent." *Id.*

C. Related Matters

Petitioner identifies *OsteoMed LLC v. Stryker Corp.*, 1:20-cv-06821 (N.D. Ill.), IPR2022-00487, and IPR2022-00488 as related matters. Pet. x. Patent Owner identifies the Northern District of Illinois litigation and

OsteoMed LLC v. Wright Medical Technology, Inc., 1:20-cv-01621 (D. Del.) as related matters. Paper 5, 2–3.

D. The '074 Patent (Ex. 1001)

The '074 patent issued on October 27, 2015, from an application filed on March 12, 2013, that is a continuation of an application filed on September 2, 2009, and claims priority to a foreign application filed on September 9, 2008. Ex. 1001, codes (22), (30), (45), (63).

The '074 patent "relates to an intramedullary implant for use between two bones or two bone fragments." Ex. 1001, code (57). Figures 1–3 of the '074 patent are reproduced below.

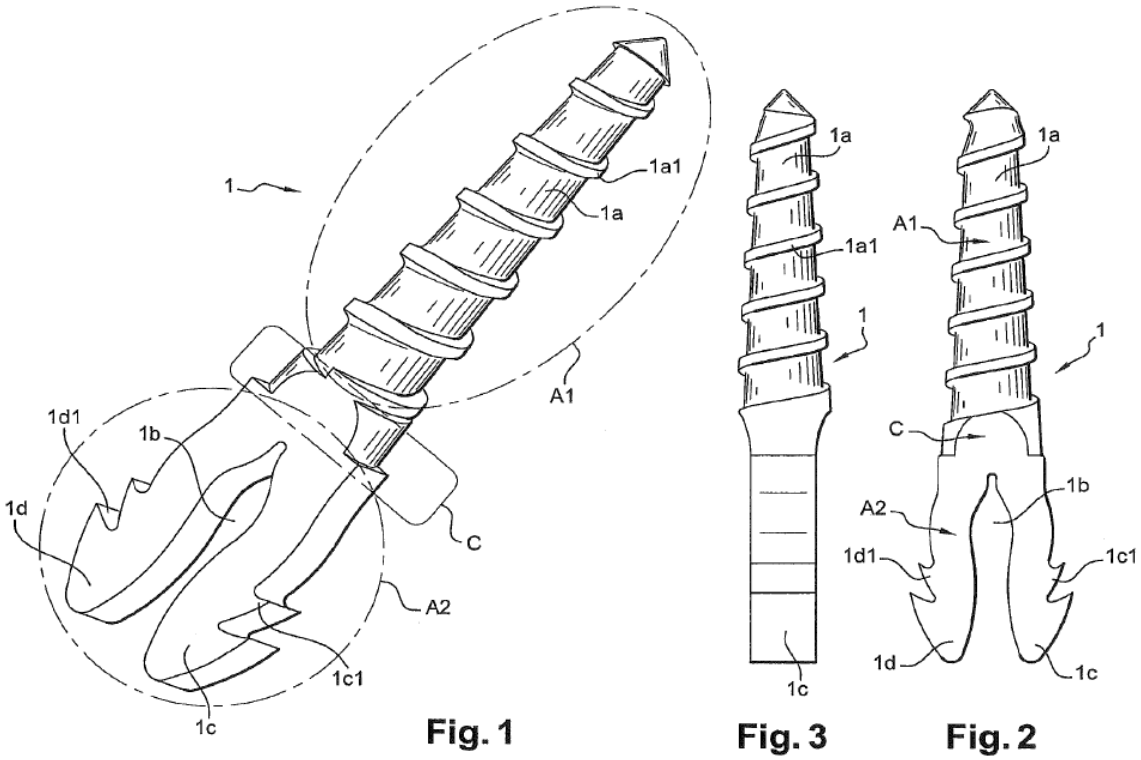


Fig. 1 Fig. 3 Fig. 2

Figures 1–3 are perspective, front, and side views, respectively, of the '074 patent's implant. *Id.* at 2:14–17.

The implant includes body 1 with first proximal zone A1 and second distal zone A2. Ex. 1001, 2:24–26. First proximal zone A1 has a cylindrical

section with generally cylindrical outer surface 1a having a helical rib forming screw thread 1a1. *Id.* at 2:35, 2:37–39. Second distal zone A2 is flat with opening 1b substantially at its center to define at least two anchor arms 1c, 1d each with at least one outwardly projecting tooth 1c1, 1d1. *Id.* at 2:36, 2:40–44. Zones A1, A2 can be offset by an angle adapted to a geometry of a bone site. *Id.* at 2:55–56.

E. Illustrative Claim

The '074 patent includes claims 1–18, of which Petitioner challenges claims 1, 7, 8, 10, 13, and 15. Of the challenged claims, claims 1 and 15 are independent, and reproduced below is claim 1.

> 1. An intramedullary implant for use between first and second bone parts, the implant comprising:
>
> a first threaded end for anchoring to the first bone part;
>
> a second end extending from the first end for anchoring to the second bone part, the second end having a longitudinal axis, a body portion, and a plurality of teeth projecting from the body portion, wherein at least a first tooth of the plurality of teeth is spaced from a second tooth of the plurality of teeth in a direction along the longitudinal axis of the second end, the first and second teeth extending from the body portion in a same direction, and at least the first tooth extending from the body portion in a different direction than a direction a third tooth of the plurality of teeth extends from the body portion.

Ex. 1001, 3:22–36.

Independent claim 15 recites substantially similar limitations. Ex. 1001, 4:26–38. Claim 15 additionally requires "the second end having an opening in a median portion thereof" but does not require "the second end having a longitudinal axis [and] a body portion" or "the first and second teeth extending from the body portion in a same direction." *Id.* at 4:29–38.

F. Asserted Prior Art and Proffered Testimonial Evidence

Petitioner identifies the following references as prior art in the asserted grounds of unpatentability:

Name	Reference	Exhibit
Carver	US 7,041,106 B1, issued May 9, 2006	1005
Coilard-Lavirotte	US 2008/0132894 A1, published June 5, 2008	1006
Jackson	GB 2 430 625 A, published Apr. 4, 2007	1004
Pietrzak	Pietrzak et al., *A Bioabsorbable Fixation Implant for Use in Proximal Interphalangeal Joint (Hammer Toe) Arthrodesis: Biomechanical Testing in a Synthetic Bone Substrate*, J. of Foot & Ankle Surgery, vol. 45, no. 5, September/October 2006	1007

Petitioner contends that Carver, Jackson, and Pietrzak are prior art under § 102(b) and that Coilard-Lavirotte is prior art under § 102(a) based on the foreign priority date and prior art under § 102(b) based on the filing date of the U.S. application.[1] Pet. 11–13. Petitioner also provides a Declaration of Michael Sherman. Ex. 1002.

[1] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the '074 patent claims priority to an application filed before that date, our citations to 35 U.S.C. §§ 102 and 103 in this Decision are to their pre-AIA versions. *See also* Pet. 3 (stating that "[a]ll references herein to 35 U.S.C. §§ 102-103 are to the pre-AIA versions thereof which apply to the Challenged Claims").

G. Asserted Grounds

Petitioner asserts that claims 1, 7, 8, 10, 13, and 15 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 10, 13	102	Jackson
7, 8, 13	103	Jackson
15	103	Jackson, Coilard-Lavirotte
1, 7, 8, 10, 13, 15	103	Carver, Coilard-Lavirotte
1, 7, 8, 10, 13, 15	103	Pietrzak, Coilard-Lavirotte

Pet. 8–9.

II. ANALYSIS

A. Legal Standards

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent [claim] it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden of persuasion 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 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).

Petitioner contends that the challenged claims of the '074 patent are unpatentable under §§ 102 and 103. Pet. 8–9. A claim is anticipated under § 102 "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

A claim is unpatentable under § 103 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 skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of elements produces a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

B. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art would have had "a Bachelor's Degree in mechanical engineering, biomedical engineering, biomechanics or similar discipline and had approximately three years of experience with orthopedic implant design." Pet. 4 (citing Ex. 1002 ¶¶ 58–60). Petitioner also asserts that the ordinary skilled artisan "would have had knowledge of design considerations known in the industry," "been familiar with then-existing products and solutions," and "been familiar with orthopedic implants, bone plates, and intramedullary implants." *Id.* (citing Ex. 1002 ¶¶ 1–20, 59, 60).

Patent Owner responds that

> the parties and the Board agreed that "a [person of ordinary skill in the art] at the time of the invention would be an individual having at least a bachelor's degree in engineering with at least two years of experience in the field, such as experience with the design of surgical implants, or a clinical practitioner with a medical degree and at least two years of experience as an orthopedic surgeon."

Prelim. Resp. 4. Patent Owner contends that "[f]or purposes of consistency, the same level of ordinary skill in the art at the time of the invention should be used here, given the similarities in the technology" and "disagrees with Petitioner's asserted level of ordinary skill in the art to the extent that it differs from the previously agreed-upon definition." *Id.*

We decline to adopt a specific formulation regarding the level of ordinary skill in the art, and instead find that the cited references are representative of the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the level of ordinary skill in the art may be evidenced by the cited references themselves). We need not provide a specific formulation because our analysis of the issues below would be the same regardless of whether we adopted Petitioner's or Patent Owner's proposed level of ordinary skill.

C. Claim Construction

In an *inter partes* review based on a petition filed on or after November 13, 2018, the claims are construed

> using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim 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) (2021); *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner proposes interpretations for "a body portion" and "a cross-section." Pet. 4–8. Patent Owner responds that "a body portion" does not need to be construed for determining whether to institute, and that Petitioner's proposed interpretation for "a cross-section" should be rejected. Prelim. Resp. 5, 6.

Because determining whether Petitioner shows a reasonable likelihood of prevailing does not depend on a particular interpretation for any claim term, we determine that no claim term requires express interpretation. *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.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

D. Asserted Anticipation by Jackson

Petitioner contends with citations to the record that Jackson discloses all the limitations of claims 1, 10, and 13. Pet. 14–23. Patent Owner responds that Petitioner fails to show that Jackson discloses all the elements of claim 1. Prelim. Resp. 18–24.

For the reasons explained below, Petitioner fails to show a reasonable likelihood of prevailing with respect to its anticipation challenge.

1. Jackson (Ex. 1004)

Jackson "relates to a peg for joining two or more bones together at a joint." Ex. 1004, 1:3. Figures 1–4 of Jackson are reproduced below.

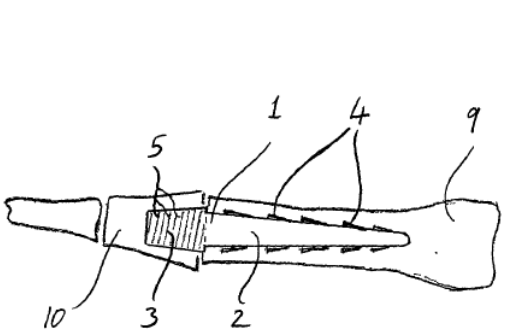


FIG. 1

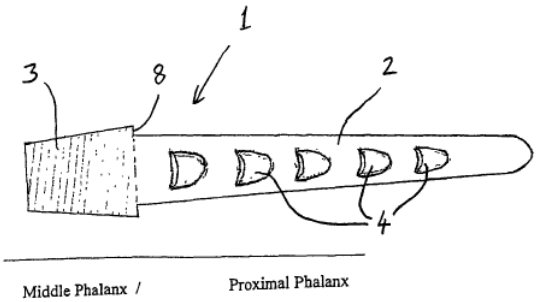


FIG. 2

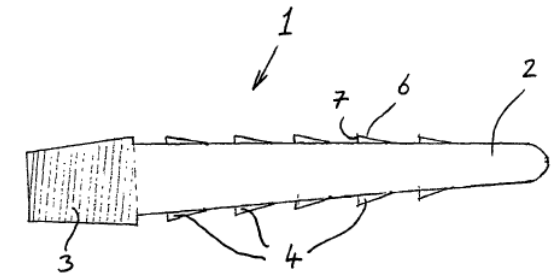


FIG. 3

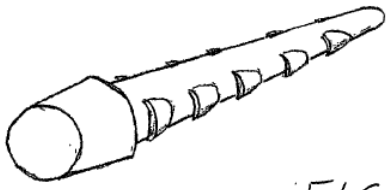


FIG. 4

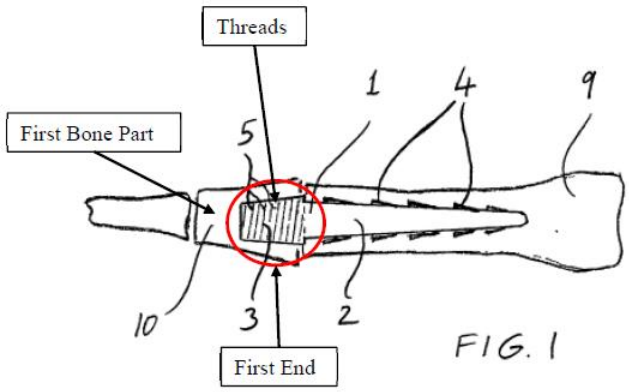
Figures 1–4 are sectional plan, side, top, and perspective views, respectively, of Jackson's peg. *Id.* at 5:28–6:3.

Peg 1 has a long thin conical shaped proximal limb 2 and a shorter wider conical shaped distal limb 3. Ex. 1004, 6:22–23. Proximal limb 2 includes flanges 4 on its sides so that flanges 4 can permit a press-fit of proximal limb 2. *Id.* at 6:23–25. Flanges 4 "are shaped to be similar to an intersecting cylinder with a shallow ramped surface 6" and can "excavate additional bone in order to create a channel within which the flanges will be securely located preventing rotation." *Id.* at 7:5–6, 7:9–10. "Resistance to removal . . . is generated by the edge between the shallow ramp surface 6 and the sharply projecting surface 7." *Id.* at 7:13–15. Sharply projecting surface 7 "has an effect similar to that of a barb." *Id.* at 7:13.

Distal conical limb 3 "is scored with oblique ridges 5 that lock the limb 3 in place" when fitted "by manually screwing and impacting it." Ex. 1004, 6:26–28. Oblique ridges 5 "are similar in structure to the ridges that would be found on a workshop file giving sufficient abrasiveness that it will be fitted securely." *Id.* at 6:29–30. "Other surface patterns and irregularities could be used." *Id.* at 6:31.

2. Independent Claim 1

Petitioner argues that Jackson discloses all the limitations of claim 1. Pet. 14–21. For "a first threaded end for anchoring to the first bone part," Petitioner provides an annotated Figure 1 from Jackson reproduced below. *Id.* at 15.



Petitioner's annotated Figure 1 is a sectional view of Jackson's peg with a circle around conical limb 3 and labels for "first end," "first bone part," and "threads." *Id.*; Ex. 1004, 5:28–29.

Petitioner argues that Jackson's joint fusion peg 1 has "conical limb 3 (first threaded end) with oblique ridges (threads), and is configured to lock into the middle phalanx (first bone) by manually screwing the conical limb into the cavity." Pet. 15 (citing Ex. 1004, 6:21–7:2, Fig. 1). Petitioner also argues that conical limb 3 "fuses to the middle phalanx bone with manual compression in a twisting motion 'to screw [the peg] home.'" *Id.* (citing

Ex. 1004, 8:6–7). Petitioner, thus, argues that Jackson discloses the recited first threaded end. *Id.* (citing Ex. 1002 ¶¶ 78, 79).

Patent Owner responds that Jackson's peg is not threaded. Prelim. Resp. 18. According to Patent Owner, "Jackson discloses a conical limb that has 'oblique ridges' that are 'scored' onto the surface of the conical limb where the 'oblique ridges' merely 'form a texture.'" *Id.* at 19 (citing Ex. 1004, 4:13–14, 6:27–31). Patent Owner also argues that Jackson's description of its oblique ridges confirms that Jackson does not disclose "a first threaded end." *Id.* at 19–21 (citing Ex. 1004, 6:24–26, 6:29–31, 7:26–27, Fig. 3).

The portion of Jackson cited in the Petition does not disclose that its conical shaped distal limb 3 has threads. *See* Ex. 1004, 6:21–7:2, 8:6–7. Jackson, instead, states expressly that "[t]he surface of the distal conical limb 3 of the device is scored with oblique ridges 5 that lock the limb 3 in place in the intermedullary cavity of a middle phalanx when it is fitted, by manually screwing and impacting it." *Id.* at 6:26–28. Jackson goes on to state that "[t]he oblique ridges are similar in structure to the ridges that would be found on a workshop file giving sufficient abrasiveness that it will be fitted securely within the middle phalanx." *Id.* at 6:29–31. None of the portions of Jackson that Petitioner relies upon discloses a "threaded end" as recited in the challenged claims. *See id.* at 6:21–7:2, 8:6–7.

To the extent that Petitioner is contending that Jackson's description of "manually screwing" discloses the presence of threads on limb 3, Jackson makes clear that limb 3 has oblique ridges 5, not threads. *See* Ex. 1004, 6:26–31. Petitioner's arguments do not address why one of ordinary skill in the art would understand Jackson to be disclosing threads when Jackson explicitly states that "[t]he oblique ridges are similar in structure to the

ridges that would be found on a workshop file." *See* Pet. 15; Ex. 1004, 6:29–31. Because this description is not even addressed and Petitioner's arguments clearly focus on what Jackson discloses, Petitioner has not sufficiently shown that a person of ordinary skill in the art would understand the oblique ridges on Jackson's limb 3 to be threads. *See* Pet. 15; Ex. 1002 ¶¶ 78, 79.

Petitioner's arguments for the "first threaded end for anchoring to the first bone part" also do not rely on inherency, i.e., Petitioner does not assert that, although Jackson lacks description regarding threads, threads must be necessarily present. Pet. 15. Because the arguments simply assert Jackson discloses "oblique ridges (threads)," Petitioner does not acknowledge that any descriptive material is missing. *Id.* Thus, Petitioner's arguments for this limitation cannot be read as relying on inherent anticipation. *See id.*

Because Petitioner relies on "oblique ridges" for disclosing "threads" (Pet. 15), Petitioner could be implicitly interpreting the term "threaded end" in claim 1 to include Jackson's limb 3 scored with oblique ridges 5. Petitioner, however, does not propose a construction for "threaded end." *See id.* at 4–8. Petitioner has not sufficiently shown that Jackson's oblique ridges would have "a *helical rib* forming a screw thread 1*a*1" (emphasis added), need a bone tap to form an inner screw on one side of a bone joint, and need a screwdriver on that same side. Ex. 1001, 2:38–39, 2:66–67, 3:5–12. Petitioner, thus, presents insufficient argument and evidence to demonstrate that "threaded end" could be construed to encompass Jackson's oblique ridges. *See Harmonic*, 815 F.3d at 1363 (stating that "petitioner has the burden from the onset to show with particularity why the patent [claim] it challenges is unpatentable"); *see also* 37 C.F.R. § 42.104(b)(3–4) (stating that the Petition must identify "[h]ow the challenged claim is to be

construed" and "[h]ow the construed claim is unpatentable" based on the asserted prior art).

The arguments in the Petition regarding "a first threaded end for anchoring to the first bone part" substantially repeat the cited declarant testimony. *Compare* Pet. 15, *with* Ex. 1002 ¶¶ 78, 79. The cited testimony relies on the same portions of Jackson discussed above and, thus, does not provide any additional evidence not already presented in the Petition and considered in our analysis. *See* Ex. 1002 ¶¶ 78, 79.

For the reasons above, Petitioner does not show a reasonable likelihood of prevailing in its challenge that Jackson anticipates claim 1.

3. Dependent Claims 10 and 13

Claim 10 depends from claim 1 and recites "wherein the first and third teeth are positioned at the same axial location along the longitudinal axis of the second end." Ex. 1001, 4:10–12. Claim 13 depends from claim 1 and recites "wherein a cross-section of the body portion is non-circular." *Id.* at 4:20–21.

With citations to the record, Petitioner argues that Jackson anticipates claims 10 and 13. Pet. 21–23. Patent Owner responds that Petitioner's analysis for claims 10 and 13 fails for the reasons argued for claim 1. Prelim. Resp. 24. Patent Owner additionally responds that Petitioner's arguments rely on a "nonsensical" interpretation of "a cross-section." *Id.*

For the reasons stated above for claim 1, because Petitioner does not sufficiently show that Jackson discloses all the elements, Petitioner does not show a reasonable likelihood of prevailing in its challenge that Jackson anticipates claims 10 and 13.

E. Asserted Obviousness Based on Jackson

1. Dependent Claims 7, 8, and 13

Claim 7 depends from claim 1 and recites "wherein a longitudinal axis through the first end is offset from the longitudinal axis of the second end by an angle less than 30 degrees." Ex. 1001, 4:1–3. Claim 8 depends from claim 7 and recites "wherein the offset is located at a position corresponding substantially to an arthrodesis line defined at the intersection of the first and second bone parts." *Id.* at 4:4–7. Claim 13 depends from claim 1 and requires a cross-section of the body portion be non-circular. *Id.* at 4:20–21.

With citations to the record, Petitioner argues that Jackson teaches the limitations of claims 7, 8, and 13. Pet. 24–29. Petitioner also asserts what one of ordinary skill in the art would have known about joints and would have understood about anatomic angles, an arthrodesis line, and cross-sections. *Id.* at 25, 26, 27, 28–29. Petitioner further argues that "[g]iven that Jackson discloses multiple embodiments, a [person of ordinary skill in the art] would have readily combined those embodiments to create an intramedullary implant as claimed by claims 7, 8, and 13 of the '074 Patent." *Id.* at 24 (citing Ex. 1002 ¶¶ 102–124).

Patent Owner responds that claims 7, 8, and 13 depend from claim 1, and that, because Petitioner's anticipation challenge to claim 1 is deficient, the obviousness challenge to claims 7, 8, and 13 also fails. Prelim. Resp. 24–25. Patent Owner also argues that the obviousness challenge does not cure the deficiencies of the anticipation challenge. *Id.* at 25.

For the reasons discussed above for claim 1, Petitioner does not show sufficiently that Jackson teaches or suggests "a first threaded end for anchoring to the first bone part," as recited by claim 1, from which claims 7, 8, and 13 depend. Petitioner's arguments for claims 7, 8, and 13 also do not

remedy the deficiencies of Jackson. Petitioner, thus, does not show a reasonable likelihood of prevailing in its challenge that Jackson would have rendered obvious claims 7, 8, and 13.

F. Asserted Obviousness Based on Jackson and Coilard-Lavirotte

Petitioner contends with citations to the record that Jackson in view of Coilard-Lavirotte would have rendered obvious independent claim 15. Pet. 29–37. Patent Owner responds that Petitioner fails to show that the proposed combination teaches all the limitations of claim 15 and that Petitioner provides an insufficient reason for combining the references. Prelim. Resp. 27–39.

For the following reasons, Petitioner fails to show a reasonable likelihood of prevailing with respect to its obviousness challenge to claim 15 based on Jackson and Coilard-Lavirotte.

1. Independent Claim 15

Claim 15 recites, in relevant part, "[a]n intramedullary implant for use between first and second bone parts, the implant comprising: a first threaded end for anchoring to the first bone part." Ex. 1001, 4:26–37.

Petitioner refers to the anticipation challenge based on Jackson to assert that Jackson discloses the first threaded end of claim 15. Pet. 33 (citing Ex. 1002 ¶¶ 78, 79, 138, 139; Ex. 1004, 6:21–7:2, Fig. 1). Petitioner also refers to previous arguments to contend that Jackson discloses all the other limitations of claim 15 except for "the second end having an opening in a median portion thereof" with additional citations to Jackson and declarant testimony. *Id.* at 33–35.

For the recited opening, Petitioner relies on Coilard-Lavirotte (discussed in more detail below) with citations to that reference and declarant testimony. Pet. 35–36. In particular, Petitioner argues that the

ordinary skilled artisan "looking for a way to improve the fixation and anchoring of Jackson's implant in the proximal interphalangeal joint of the toes would readily look to use the anchoring branches disclosed by Coilard-Lavirotte" and, thus, it would have been obvious to combine Coilard-Lavirotte's opening with Jackson's implant, thereby rendering obvious claim 15. *Id.* at 36–37 (citing Ex. 1002 ¶¶ 125–155).

Patent Owner responds that Petitioner relies on its anticipation argument for "a first threaded end for anchoring to the first bone part" which fails to show Jackson teaches or suggests the limitation. Prelim. Resp. 28–29 (citing Pet. 33).

For the same reasons discussed above regarding the "first threaded end for anchoring to the first bone part" recited by claim 1, Petitioner does not provide sufficient argument and evidence that Jackson teaches or suggests "a first threaded end for anchoring to the first bone part," as recited by claim 15. Pet. 33–35. Petitioner's proposed modification to Jackson also does not remedy the deficiencies of Jackson. Petitioner, thus, does not show a reasonable likelihood of prevailing in its obviousness challenge to claim 15 based on Jackson and Coilard-Lavirotte.

G. Asserted Obviousness Based on Carver and Coilard-Lavirotte

Petitioner contends with citations to the record that Carver in view of Coilard-Lavirotte would have rendered obvious claims 1, 7, 8, 10, 13, and 15. Pet. 37–59. Patent Owner responds that Petitioner fails to show that the proposed combination teaches all the limitations of these claims and that Petitioner provides an insufficient reason to combine the references. Prelim. Resp. 39–51.

For the reasons explained below, Petitioner fails to show a reasonable likelihood of prevailing with respect to its obviousness challenge based on Carver and Coilard-Lavirotte.

1. Carver (Ex. 1005)

Carver relates to "to bone pins, and more particularly, to a new and improved interphalangeal fusion pin which provides an anatomically correct angle between a first phalange and a second adjacent phalange." Ex. 1005, 1:5–8. Figure 3 of Carver is reproduced below.

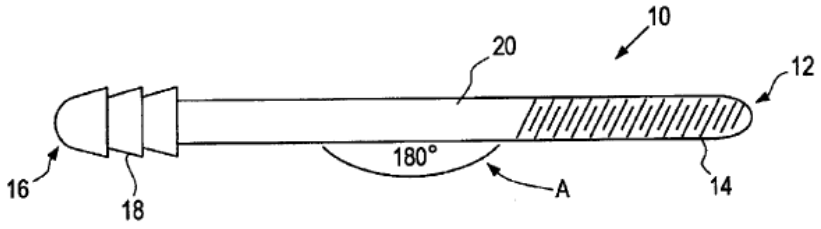


FIG. - 3

Figure 3 is a perspective view of a blank with threaded and shouldered surfaces. *Id.* at 3:12–14.

Carver describes blank 10 of reabsorbable material formed into device 100. Ex. 1005, 4:18–20. One end 12 of blank 10 has threaded surface 14 for insertion and retention in a proximal phalange. *Id.* at 4:23–26. Other end 16 has "shouldered, ribbed or helical surface 18" for insertion and retention in a distal phalange. *Id.* at 4:26–29. Blank 10 can be shaped to have an anatomically acceptable angle A, such as angle AA of 172.5°. *Id.* at 4:34–35, 4:41–42, 5:3–8, Fig. 4 (device 100 with angle AA of 172.5°).

2. Coilard-Lavirotte (Ex. 1006)

Coilard-Lavirotte particularly relates to "a medical implant intended to be interposed between a first bone and a second bone in order to support the bones . . . so as to obtain bone fusion." Ex. 1006 ¶ 2. Figures 1 and 3 of Coilard-Lavirotte are reproduced below.

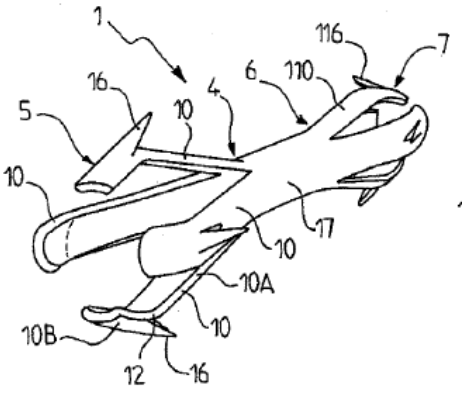


FIG.1

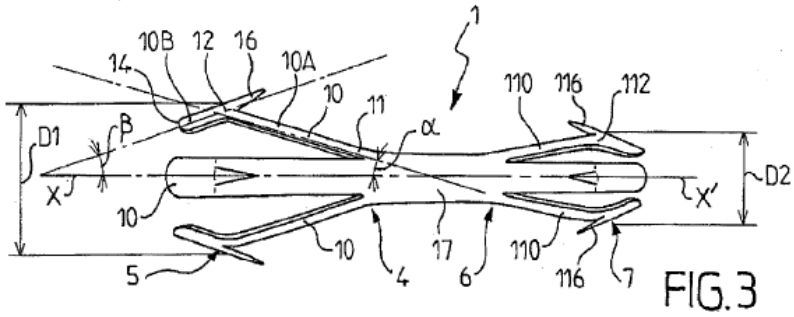


FIG.3

Figures 1 and 3 are isometric and sides views, respectively, of an implant. *Id.* ¶¶ 36, 38.

Implant 1 has first section 4 with first means 5 of fixing and second section 6 with second means 7 of fixing. Ex. 1006 ¶¶ 51, 52. First means 5 of fixing includes a plurality of anchoring branches 10 arranged in a non-coplanar layout. *Id.* ¶ 53. The term "non-coplanar layout" refers to anchoring branches 10 forming a network extending in three dimensions and preferably arranged as a corolla around first section 4. *Id.* ¶¶ 55, 62.

Anchoring branches 10 include divergent portion 10A that diverges from axis XX', convergent portion 10B that turns down to facilitate introducing implant 1, and bend 12 that marks a transition between divergent portion 10A and convergent portion 10B. Ex. 1006 ¶¶ 67, 79, 82, 83, 86. Divergent portion 10A extends between bend 12 and basic portion 11 that attaches anchoring branch 10 to first section 4. *Id.* ¶¶ 70, 85. Convergent

portion 10B extends between bend 12 and free end 14. *Id.* ¶¶ 85, 86. Bend 12 preferably has anti-return device 16, which can be a barb or lug. *Id.* ¶ 99.

Second means 7 of fixing can be similar to first means 5 of fixing. Ex. 1006 ¶ 102. Second means 7 of fixing can include a plurality of anchoring branches 110 in a non-coplanar layout around second section 6. *Id.* ¶¶ 104, 107.

3. Claim 1

Petitioner argues that Carver teaches almost all the limitations of claim 1. Pet. 40–46. Petitioner states that "Carver does not expressly teach or suggest a first and third tooth extending from opposite directions of the body portion of the second end." *Id.* at 47. Petitioner, however, argues that "Carver does disclose circular ribs that, effectively, form teeth projecting outward 360° around the longitudinal axis of the second end, and apply forces on the bone cavity of the second bone in different directions." *Id.* (citing Ex. 1002 ¶ 183; Ex. 1005, Fig. 7).

Petitioner also argues that Coilard-Lavirotte teaches "a plurality of anchoring branches with anti-return devices (teeth)" that "improve fixation of the implant." Pet. 47–48 (citing Ex. 1006 ¶ 99, Fig. 2). Petitioner contends that one of ordinary skill in the art "looking for a way to improve the fixation of Carver's implant in the proximal interphalangeal joint of the toes would readily look to use the anchoring branches with teeth disclosed by Coilard-Lavirotte" and would have "underst[oo]d that the plurality of anti-return devices (teeth) comprises a first and third tooth extending from the body portion on the anchoring branches such that the first tooth and third tooth extend from different directions of the body portion." *Id.* at 48 (citing Ex. 1002 ¶ 186).

In Petitioner's view, both references "disclose intramedullary implants for use between interphalangeal joints in the foot" and "describe anchor designs that are inserted into a bone cavity, secure to the interior bone wall, and prevent the implant from being removed." Pet. 37 (citing Ex. 1006 ¶¶ 50, 157–158; Ex. 1005, Fig. 7); *see also id.* at 38–39 (asserting what Carver and Coilard-Lavirotte teach) (citing Ex. 1002 ¶ 159; Ex. 1005, 4:26–30, Fig. 4; Ex. 1006 ¶ 99, Fig. 2). Petitioner also argues that one of ordinary skill in the art would have "recognize[d] that various anchoring structures can be used to accomplish the same anchoring functionality between an intramedullary implant and a bone." *Id.* at 37–38 (citing Ex. 1002 ¶ 158).

According to Petitioner, because "Carver and Coilard-Lavirotte both disclose anchoring devices that press into the bone cavity and anchor to the interior cavity wall at a plurality of anchor points with anti-return devices (teeth), barbs, or ribs," one of ordinary skill in the art "would have been motivated to combine Carver with Coilard-Lavirotte to improve the fixation of Carver's implant given the disclosure of the anchoring branches with anti-return devices (teeth) that can elastically deform to provide more secure fixation in Coilard-Lavirotte" and would have "recognize[d] that Carver discloses a known element (ribbed end) that could be combined with the anchoring branches with anti-return device (teeth) of Coilard-Lavirotte to obtain a predictable result (i.e., better anchoring)." Pet. 39–40 (citing Ex. 1002 ¶ 162).

Petitioner also contends that one of ordinary skill in the art would have known that "combining the teachings of Carver and Coilard-Lavirotte would result in a greater number of fixation points on anchoring branches that can elastically deform to provide a more secure anchor at each anchoring point" and would have been "motivated to combine the teachings

of Carver and Coilard-Lavirotte, to utilize a known technique for improving the implantation of an intramedullary implant (similar device), and obtain an improvement." Pet. 40 (citing Ex. 1002 ¶¶ 162–163).

Petitioner, thus, contends that Carver and Coilard-Lavirotte would have rendered obvious claim 1. Pet. 48 (citing Ex. 1002 ¶¶ 181–187).

a) Patent Owner's Preliminary Response

Patent Owner responds that Carver does not teach or suggest

> the second end having a longitudinal axis, a body portion, and a plurality of teeth projecting from the body portion, wherein at least a first tooth of the plurality of teeth is spaced from a second tooth of the plurality of teeth in a direction along the longitudinal axis of the second end, the first and second teeth extending from the body portion in a same direction, and at least the first tooth extending from the body portion in a different direction than a direction a third tooth of the plurality of teeth extends from the body portion.

Prelim. Resp. 39 (citing Pet. 43–46). Patent Owner notes that Petitioner relies only on Carver for teaching the above-quoted limitations, but that Petitioner does not acknowledge that the Office determined during prosecution that Carver did not teach these limitations. *Id.* at 39–41 (citing Ex. 1003, 506–509, 608, 612–618). Patent Owner also argues that Petitioner provides no explanation why the Office was wrong. *Id.* at 41 (citing Pet. 9).

Patent Owner also responds that one of ordinary skill in the art would not have understood Carver's ribbed, conical portion on the second end of its implant to teach the recited teeth. Prelim. Resp. 41–42 (citing Pet. 43, 44). Patent Owner contends that Carver's ribbed, conical portion are not analogous to the recited teeth and do not extend in any particular direction, as admitted by Petitioner, "because they extend in all directions around the implant." *Id.* at 42–43 (citing Pet. 47; Ex. 1001, Fig. 1; Ex. 1005, Fig. 3).

Patent Owner, thus, contends that Carver's ribbed, conical portion does not teach "at least the first tooth extending from the body in a different direction than a direction a third tooth . . . extends from the body portion." *Id.* at 43 (citing Ex. 1002 ¶¶ 173, 176). Patent Owner further responds that Petitioner admits that Carver fails to teach or suggest a first and third tooth extending from opposite directions. *Id.* (citing Pet. 47).

Regarding Petitioner's proposed modification, Patent Owner argues that "it is unclear whether Petitioner is proposing that the second end of Carver be entirely replaced by the second end of Coilard-Lavirotte, or whether the second of Carver be modified to include some portion of Coilard-Lavirotte." Prelim. Resp. 45. Patent Owner argues that, if Petitioner is proposing to replace Carver's second end with Coilard-Lavirotte's second end, "then Petitioner no longer has any basis for its assertion that Carver discloses several of the other elements of claim 1," such as the limitations quoted above for which Petitioner relies only on Carver. *Id.* at 45–46. Patent Owner also argues that, if Petitioner is proposing to add some portion of Coilard-Lavirotte's second end to Carver, "then Petitioner fails to provide any explanation regarding how a [person of ordinary skill in the art] would have allegedly created such a combination or whether a [person of ordinary skill in the art] would have a reasonable expectation of success in making such a combination." *Id.* at 46.

Patent Owner also responds that Petitioner's asserted motivation to combine merely describes similarities between Carver and Coilard-Lavirotte. Prelim. Resp. 50. In Patent Owner's view, "the mere fact that the references are both intramedullary implants does not explain why a [person of ordinary skill in the art] would have had reason to incorporate Coilard-

Lavirotte's anchoring branches with the implant of Carver" with support from case law. *Id.* at 50–51.

b) Petitioner Insufficiently Shows that Carver and Coilard-Lavirotte Teach All the Limitations of Claim 1

For the limitation "the second end having a longitudinal axis, a body portion, and a plurality of teeth projecting from the body portion," Petitioner argues that "Carver's implant comprises a second end 16 with a 'shouldered, ribbed or helical surface 18' (plurality of teeth)." Pet. 43–44 (citing Ex. 1005, 4:26–30, Fig. 7). Petitioner also argues that one of ordinary skill in the art "would understand that the second end of the intramedullary implant comprises a plurality of ribs, which are analogous to the teeth of the '074 Patent, along a longitudinal axis of the second end." *Id.* at 44 (citing Ex. 1002 ¶¶ 172–173). Petitioner, thus, argues that Carver discloses the limitation or the limitation would have been obvious in view of Carver's disclosure. *Id.* (citing Ex. 1002 ¶ 174).

The relied-upon portion of Carver teaches that "other end 16 of the blank 10 is provided with a shouldered, ribbed or helical surface 18 for facilitating insertion and retention into a distal (or intermediate) phalange." Ex. 1005, 4:26–30. The cited portion does not expressly teach teeth. *See id.* Petitioner seemingly acknowledges that Carver lacks an express teaching by asserting that Carver's ribs "are analogous to the teeth of the '074 Patent." *See* Pet. 44; *see also id.* at 47 (arguing that "Carver does disclose circular ribs that, effectively, form teeth").

For support, Petitioner refers to paragraphs 172 and 173 of its declarant testimony. Pet. 44. Those paragraphs are substantively the same as the arguments in the Petition and analogize teeth to ribs without further analysis or support. *Compare* Pet. 43–44, *with* Ex. 1002 ¶¶ 172–173.

Petitioner also does not provide a construction of "teeth" that would encompass Carver's ribs that are each "a shouldered, ribbed or helical surface." *See* Pet. 4–8 (proposing interpretations only for "a body portion" and "a cross-section"). Because Petitioner does not provide its understanding of the scope of the term "teeth" and does not explain why a one of ordinary skill in the art would understand Carver's ribs to be analogous to such, Petitioner does not provide a sufficient basis for determining what would have been taught or obvious in view of Carver's "shouldered, ribbed or helical surface." *See also* Ex. 1001, 2:42–44, Figs. 1–6 (describing and depicting only teeth 1c1, 1d1).

Petitioner also acknowledges that "Carver was considered" during prosecution of the '074 patent. Pet. 9. Thus, Petitioner should be aware that the Examiner expressly determined that Carver does not disclose the recited teeth. Ex. 1003, 506 (stating that "Carver et al. do not disclose that the second end includes a body portion, and a plurality of teeth projecting from the body portion"); *see also* Prelim. Resp. 39–40 (arguing that the Examiner found that Carver does not disclose limitations regarding teeth).

Thus, in view of the Examiner's determination that Carver does not disclose teeth, Petitioner should have foreseen that further evidence and analysis are necessary to show that Carver's ribs are "analogous to" or "effectively form" teeth. *See also* Prelim. Resp. 16–17 (arguing that Petitioner failed to argue that the Examiner erred during prosecution), 41 (arguing that Petitioner fails to address the Examiner's analysis of Carver and to explain why it is incorrect). The Petition, however, does not address the Examiner's findings regarding Carver, nor otherwise explain why one of ordinary skill in the art would understand Carver's ribs to effectively form or be analogous to the recited teeth. *See generally* Pet.

Turning to Petitioner's proposed modification of Carver with Coilard-Lavirotte's plurality of anchoring branches, the proposed modification does not address the deficiency regarding "a plurality of teeth." *See* Pet. 37–40, 46–48. Petitioner argues that "Carver does not expressly teach or suggest a first and third tooth extending from opposite directions of the body portion of the second end." *See id.* at 47. Petitioner, thus, proposes modifying Carver with Coilard-Lavirotte's plurality of anchoring branches because it would "improve the fixation of Carver's implant" and because one of ordinary skill in the art would have understood that "the plurality of anti-return devices (teeth) comprises a first and third tooth extending from the body portion on the anchoring branches such that the first tooth and third tooth extend from different directions of the body portion." *Id.* at 48; *see also id.* at 37–40 (arguing that Carver and Coilard-Lavirotte disclose similar implants and that one of ordinary skill in the art would have been motivated to combine them to improve Carver's fixation with predictable result).

We agree with Patent Owner (Prelim. Resp. 45) that Petitioner's proposed modification is not sufficiently clear. Because Petitioner argues that one of ordinary skill in the art would have understood that "the plurality of anti-return devices (teeth) comprises a first and third tooth extending from the body portion," Petitioner appears to be proposing to modify Carver so that it has Coilard-Lavirotte's anchoring branches instead of Carver's circular ribs. *See* Pet. 48. In such a modification, Petitioner does not sufficiently explain why the combination teaches the other limitations that Petitioner relies solely on Carver to teach. *See id.* at 41–46 (relying only on Carver for teaching the preceding limitations). In particular, Petitioner presents no arguments why Coilard-Lavirotte's anti-return devices or asserted teeth would be arranged so that "at least a first tooth of the plurality

of teeth is spaced from a second tooth of the plurality of teeth in a direction along the longitudinal axis of the second end," as required by claim 1. *See id.* at 37–48.

Further, we do not understand Petitioner's arguments to be modifying Carver so that Carver only has some portion of Coilard-Lavirotte's anchoring branches, such as its asserted tooth, because Petitioner's arguments are broader and specifically include the anchoring branches. *See, e.g.*, Pet. 39–40 (arguing that one of ordinary skill in the art "would recognize that Carver . . . could be combined with the anchoring branches with anti-return device (teeth) of Coilard-Lavirotte"), 47 (arguing that one of ordinary skill in the art "would readily look to use the anchoring branches and anti-return devices (teeth) disclosed by Coilard-Lavirotte"), 48 (arguing that one of ordinary skill in the art "would readily look to use the anchoring branches with teeth disclosed by Coilard-Lavirotte"). Petitioner's arguments cannot be understood to be contending that, for example, one of ordinary skill in the art would have added Coilard-Lavirotte's anti-return devices to Carver's rib. *See id.* at 37–48.

Finally, if Petitioner is proposing to combine Coilard-Lavirotte's anchoring branches with Carver's circular ribs, then, as explained above, Petitioner insufficiently shows that the proposed combination would have a first tooth spaced from a second tooth in a direction along a longitudinal axis because Petitioner does not propose modifying Carver's "shouldered, ribbed or helical surface," the asserted plurality of teeth. *See* Pet. 37–48. As discussed above, Petitioner insufficiently argues that Carver teaches or would have rendered obvious the recited plurality of teeth such that the proposed combination includes the plurality of teeth and, thus, a tooth spaced from another tooth. *See id.*

Therefore, for the reasons explained above, Petitioner does not show a reasonable likelihood of prevailing in its challenge that Carver and Coilard-Lavirotte would have rendered obvious claim 1.

4. Dependent Claims 7, 8, 10, and 13

For claims 7 and 8 that depend from claim 1, Petitioner argues that Carver teaches their limitations with citations to the record. Pet. 52–54. For claim 10 that depends from claim 1, Petitioner relies on Coilard-Lavirotte for teaching its limitations and argues that one of ordinary skill in the art "looking for a way to improve the fixation and anchoring of Carver's implant in the proximal interphalangeal joint of the toes would readily look to use the anchoring branches and anti-return devices (teeth) disclosed by Coilard-Lavirotte given that it is analogous art." Pet. 55–56 (citing Ex. 1002 ¶¶ 213, 214, 216; Ex. 1005, Fig. 7; Ex. 1006 ¶¶ 99, 134, 181, Fig. 3). Petitioner also argues that one of ordinary skill in the art "looking to improve the stability and resistance to displacement in any direction strength for the second end of the Carver implant would readily look to the disclosure of Coilard-Lavirotte describing a first and third tooth projecting from the body portion of the second end." *Id.* at 56–57 (citing Ex. 1002 ¶¶ 212–218). Petitioner, thus, contends that Carver and Coilard-Lavirotte would have rendered obvious dependent claim 10. *Id.* at 57 (citing Ex. 1002 ¶ 219).

For dependent claim 13, Petitioner argues with citations to the record that Carver teaches its limitations, and, to the extent that Carver does not, Coilard-Lavirotte teaches its limitations. Pet. 57–59. Petitioner also argues that one of ordinary skill in the art "looking to improve the stability and strength of the second end of the Carver implant would readily look to the disclosure of Coilard-Lavirotte describing a cross-section of the body

portion that is non-circular," and, thus, Carver and Coilard-Lavirotte would have rendered obvious claim 13. *Id.* at 59 (citing Ex. 1002 ¶¶ 220–228).

For dependent claims 7, 8, 10, and 13, Patent Owner responds that they depend from claim 1, and that, for the same reasons given for claim 1, Petitioner fails to show a reasonable likelihood of prevailing in showing that claims 7, 8, 10, and 13 are unpatentable. Prelim. Resp. 49. Patent Owner also responds that Petitioner's arguments for claim 13 rely on a "nonsensical" interpretation of "cross-section." *Id.* at 49–50.

For the reasons discussed above for claim 1, Petitioner does not show a reasonable likelihood of prevailing in its challenge that Carver and Coilard-Lavirotte would have rendered obvious dependent claims 7, 8, 10, and 13.

5. Independent Claim 15

For independent claim 15, Petitioner refers to its arguments for claim 1 to contend that Carver teaches almost all the limitations. Pet. 48–49 (citing also Ex. 1002 ¶¶ 138–139, 164–174, 176–177, 188–190, 193–196; Ex. 1005, 3:36–40, 4:18–34, 5:20–26, Figs. 4, 7). Petitioner also argues that Carver and Coilard-Lavirotte teach "at least the first tooth extending in a different direction than a third tooth of the plurality of teeth." *Id.* at 49 (citing Ex. 1002 ¶¶ 181–187, 197–198; Ex. 1005, 4:26–30, Fig. 4).

For "the second end having an opening in a median portion thereof," Petitioner states that "Carver does not expressly teach or suggest an opening median portion of the proximal limb (second end)" and argues that one of ordinary skill in the art "looking to improve the anchoring and stability of Carver's implant would look to analogous art such as Coilard-Lavirotte, which discloses the use of elastically deforming anti-return devices (teeth) and anchoring branches." Pet. 50 (citing Ex. 1002 ¶ 200). Petitioner also

argues that both references "describe anchor designs that are inserted into a bone cavity, secure to the interior bone wall, and prevent the implant from being removed." *Id.* (citing Ex. 1002 ¶ 201).

Petitioner asserts what Coilard-Lavirotte teaches and contends that one of ordinary skill in the art "looking for a way to improve the fixation and anchoring of Carver's implant in the proximal interphalangeal joint of the toes would readily look to use the teethed anchoring branches with an opening in the median portion disclosed by Coilard-Lavirotte given that it is analogous art." Pet. 50–51 (citing Ex. 1002 ¶ 203; Ex. 1006 ¶¶ 8, 13, 50, 99, 100, Fig. 2). Petitioner, thus, contends that Carver and Coilard-Lavirotte would have rendered obvious claim 15. *Id.* at 51–52 (citing Ex. 1002 ¶¶ 188–204).

For independent claim 15, Patent Owner responds that Carver does not teach

> a second end extending from the first end for anchoring to the second bone part and having a plurality of outwardly projecting teeth, at least a first tooth of the plurality of teeth spaced from a second tooth of the plurality of teeth in a direction along the longitudinal axis of the second end, and at least the first tooth extending in a different direction than a third tooth of the plurality of teeth

for the reasons asserted for similar limitations recited by claim 1. Prelim. Resp. 46–47 (citing Pet. 48–49). Patent Owner also respond that one of ordinary skill in the art would not have been motivated to combine Carver and Coilard-Lavirotte in the manner Petitioner proposes. *Id.* at 47 (citing Pet. 50; Ex. 1002 ¶ 162). Patent Owner further responds that Petitioner fails to explain what the proposed combination is or how it would have had a reasonable expectation of success. *Id.* at 48–49 (citing Pet. 51).

For the reasons stated above for claim 1 regarding its similar recitation of "a plurality of teeth" and Petitioner's proposed modification of Carver in view of Coilard-Lavirotte, Petitioner fails to show a reasonable likelihood of prevailing in its challenge to independent claim 15 based on those two references.

H. Asserted Obviousness Based on Pietrzak and Coilard-Lavirotte

Petitioner contends with citations to the record that Pietrzak in view of Coilard-Lavirotte would have rendered obvious claims 1, 7, 8, 10, 13, and 15. Pet. 59–82. Patent Owner responds that Petitioner fails to show that the proposed combination teaches all the limitations of these claims and that Petitioner provides an insufficient reason to combine the references. Prelim. Resp. 51–60.

For the reasons explained below, Petitioner fails to show a reasonable likelihood of prevailing with respect to its obviousness challenge based on Pietrzak and Coilard-Lavirotte.

1. Pietrzak (Ex. 1007)

Pietrzak is a journal article that describes a study comparing biomechanically a "threaded/barbed bioabsorbable fixation implant" with a Kirschner wire that is used in a common fixation method. Ex. 1007, 288, 289.[2] Figure 1 of Pietrzak is reproduced below.

[2] We, like Petitioner, cite to the article's page numbering, not the exhibit page numbering.

FIGURE 1 Photograph of bioabsorbable hammer toe fixation implant.

Figure 1 is a photograph of a "bioabsorbable hammer toe fixation implant." *Id.* at 289.

Pietrzak states that the implant has "a proximal portion consisting of 2-mm diameter, buttress-type threads (24 threads per inch) extending slightly over half the length of the implant." Ex. 1007, 289. "Opposite the threads was a distal portion containing 2 conically shaped barbs with a major diameter of 2 mm." *Id.* The implant was inserted into synthetic polyurethane bone. Figure 2 of Pietrzak is reproduced below.

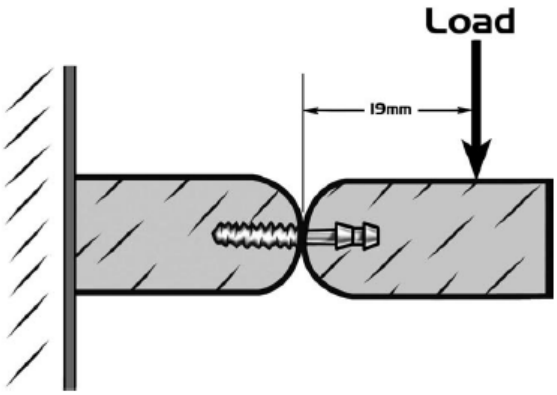


FIGURE 2 Schematic showing bioabsorbable implant providing fixation for the synthetic bone blocks. Note that schematic shows a saggital cross section.

Figure 2 is a schematic showing the bioabsorbable implant in the synthetic bone blocks with one block fixed and a load applied to the other block. *Id.* at 290.

"The threaded proximal end of the implant was torqued into the prepared hole." Ex. 1007, 290. "The barbed distal end was then inserted into a similar hole (untapped 1.57 mm diameter, 8 mm deep) in a second block." *Id.* "[T]he implant held both the proximal and distal blocks in linear alignment, simulating fixation." *Id.* "The proximal block was held fixed with a gripping device, while a load was applied to the distal block." *Id.* Pietrzak concludes that the biomechanical properties of the implant and the Kirschner wire were comparable. *Id.* at 293.

2. Claims 1, 7, 8, 10, 13, and 15

For claim 1, Petitioner argues that Pietrzak teaches almost all of its limitations with citations to the record. Pet. 63–69. Petitioner states that "Pietrzak does not expressly teach or suggest a first and third tooth extending from opposite directions of the body portion of the second end." *Id.* at 69. Petitioner, however, argues that "Pietrzak does disclose circular barbs that, effectively, form teeth projecting outward 360° around the longitudinal axis of the second end, and apply forces on the bone cavity of the second bone in different directions." *Id.* at 69–70 (citing Ex. 1002 ¶¶ 254–255; Ex. 1007, Figs. 1, 2).

Petitioner also argues that Coilard-Lavirotte teaches "a plurality of anchoring branches with anti-return devices (teeth)" that "improve fixation of the implant." Pet. 70 (citing Ex. 1006 ¶¶ 99, 100, Fig. 2). Petitioner contends that one of ordinary skill in the art "looking for a way to improve the fixation of Pietrzak's implant in the proximal interphalangeal joint of the toes would readily look to use the anchoring branches with teeth disclosed by Coilard-Lavirotte" and would have "underst[oo]d that the plurality of anti-return devices (teeth) comprises a first and third tooth extending from the body portion on the anchoring branches such that the first tooth and third

tooth extend from different directions of the body portion." *Id.* at 70–71 (citing Ex. 1002 ¶¶ 258, 259).

To support the proposed combination, Petitioner argues that both references "disclose intramedullary implants for use between interphalangeal joints in the foot" and "describe anchor designs that are inserted into a bone cavity, secure to the interior bone wall, and prevent the implant from being removed." Pet. 60 (citing Ex. 1006 ¶ 50; Ex. 1007, 288); *see also id.* at 60–61 (asserting what Pietrzak and Coilard-Lavirotte teach) (citing Ex. 1006 ¶¶ 50, 99; Ex. 1007, 289–290, Figs. 1, 2). Petitioner also argues that one of ordinary skill in the art would have "recognize[d] that various anchoring structures can be used to accomplish the same anchoring functionality between an intramedullary implant and a bone." *Id.* at 60 (citing Ex. 1002 ¶ 233).

According to Petitioner, because "Pietrzak and Coilard-Lavirotte both disclose anchoring devices that press into the bone cavity and anchor to the interior cavity wall at a plurality of anchor points with anti-return devices (teeth) or barbs," one of ordinary skill in the art "would have been motivated to combine Pietrzak with Coilard-Lavirotte to improve the fixation of Pietrzak's implant given the disclosure of the anchoring branches with anti-return devices (teeth) that can elastically deform to provide more secure fixation in Coilard-Lavirotte" and would have "recognize[d] that Pietrzak discloses a known element (a barbed distal end) that could be combined with the anchoring branches with anti-return device (teeth) of Coilard-Lavirotte to obtain a predictable result (i.e., better anchoring)." Pet. 61 (citing Ex. 1002 ¶¶ 233, 234; Ex. 1006 ¶ 148; Ex. 1007, 290).

Petitioner also contends that one of ordinary skill in the art would have known that "combining the teachings of Pietrzak and Coilard-Lavirotte

would result in a greater number of fixation points on anchoring branches that can elastically deform to provide a more secure anchor at each anchoring point" and would have been "motivated to combine the teachings of Pietrzak and Coilard-Lavirotte, to utilize a known technique for improving the implantation of an intramedullary implant (similar device), and obtain a similar improvement." Pet. 61–62 (citing Ex. 1002 ¶ 234).

Petitioner, thus, contends that Carver and Coilard-Lavirotte would have rendered obvious claim 1. Pet. 71 (citing Ex. 1002 ¶¶ 254–260).

a) Patent Owner's Preliminary Response

Patent Owner responds that Pietrzak does not teach the limitations related to the second end. Prelim. Resp. 51 (citing Pet. 65–66). Patent Owner also responds that one of ordinary skill in the art would not have understood Pietrzak's barbs on the second end of its implant to teach the recited teeth and are not analogous to the recited teeth. *Id.* (citing Pet. 66; Ex. 1002 ¶ 246). Patent Owner contends that Pietrzak's barbs do not extend in any particular direction, as admitted by Petitioner, "because they extend in all directions around the implant" and, thus, fail to teach first and second teeth extending in the same direction and "at least the first tooth extending from the body in a different direction than a direction a third tooth . . . extends from the body portion." *Id.* at 52 (citing Pet. 69; Ex. 1002 ¶¶ 252, 268; Ex. 1007, Fig. 2).

Regarding Petitioner's proposed modification, Patent Owner argues that "it is unclear whether Petitioner is proposing that the second end of Pietrzak be entirely replaced by the second end of Coilard-Lavirotte, or whether the second of Pietrzak be modified to include some portion of Coilard-Lavirotte." Prelim. Resp. 54. Patent Owner argues that, if Petitioner is proposing to replace Pietrzak's second end with Coilard-

Lavirotte's second end, "then Petitioner no longer has any basis" for contending that Pietrzak discloses the limitations related to the second end. *Id.* Patent Owner also argues that, if Petitioner is proposing to add some portion of Coilard-Lavirotte's second end to Pietrzak, "then Petitioner fails to provide any explanation regarding how a [person of ordinary skill in the art] would have allegedly created such a combination or whether a [person of ordinary skill in the art] would have a reasonable expectation of success in making such a combination." *Id.*

Patent Owner also responds that Petitioner's asserted reason to combine is conclusory and nearly identical to the conclusory assertions for combining Jackson or Carver with Coilard-Lavirotte. Prelim. Resp. 58 (citing Pet. 29–32, 37–40, 59–62; Ex. 2004). Patent Owner argues that the asserted motivation fails because it discusses similarities in the two references without explaining why the modification would have been made. *Id.* at 58–59. Patent Owner also argues that Petitioner does not explain why Pietrzak's fixation needs to be improved even though it apparently secures the implant sufficiently, as admitted by Petitioner. *Id.* at 59–60 (citing Pet. 66; Ex. 1007, 1, 4, 5, 6–7). Patent Owner further argues that Petitioner does not explain why the particular fixation of Coilard-Lavirotte would have been selected.

b) Petitioner Insufficiently Shows that Pietrzak and Coilard-Lavirotte Have All the Limitations of Claims 1, 7, 8, 10, 13, and 15

According to Petitioner, "Pietrzak does not expressly teach or suggest a first and third tooth extending from opposite directions of the body portion of the second end" but "does disclose circular barbs that, effectively, form teeth projecting outward 360°." Pet. 69–70 (citing Ex. 1002 ¶¶ 254–255;

Ex. 1007, Figs. 1, 2). Petitioner, thus, proposes modifying Pietrzak with Coilard-Lavirotte's plurality of anchoring branches because it would "improve the fixation of the implant" and because one of ordinary skill in the art would have understood that "the plurality of anti-return devices (teeth) comprises a first and third tooth extending from the body portion on the anchoring branches such that the first tooth and third tooth extend from different directions of the body portion." *Id.* at 70–71 (citing Ex. 1002 ¶¶ 258–259; Ex. 1006 ¶¶ 99–100); *see also id.* at 60–62 (arguing that Pietrzak and Coilard-Lavirotte disclose similar implants and that one of ordinary skill in the art would have been motivated to combine them to improve Pietrzak's fixation with predictable result).

As argued by Patent Owner (Prelim. Resp. 54), if Petitioner's proposed modification is to replace Pietrzak's asserted second end with Coilard-Lavirotte's second end, then Petitioner does not sufficiently argue why the combination teaches the other limitations that Petitioner relies solely on Pietrzak to teach. *See* Pet. 63–69 (relying only on Pietrzak for teaching the other limitations). In particular, Petitioner presents no arguments why Coilard-Lavirotte's anti-return devices or asserted teeth would be arranged so that "at least a first tooth of the plurality of teeth is spaced from a second tooth of the plurality of teeth in a direction along the longitudinal axis of the second end," as required by claim 1. *See id.* at 60–71.

Also, like the similarly argued challenge based on Carver and Coilard-Lavirotte, Petitioner does not apparently argue that one of ordinary skill in the art would have modified Pietrzak so that Pietrzak has some portion of Coilard-Lavirotte, such as its asserted tooth, because Petitioner's arguments are broader and specifically require the anchoring branches. *See, e.g.*,

Pet. 61 (arguing that "Pietrzak discloses a known element (a barbed distal end) that could be combined with the anchoring branches with anti-return devices (teeth) of Coilard-Lavirotte").

Finally, if Petitioner is proposing to combine Coilard-Lavirotte's anchoring branches with Pietrzak's barbs, Petitioner insufficiently shows that the proposed combination would have a plurality of teeth and a first tooth spaced from a second tooth in a direction along a longitudinal axis because Petitioner does not propose modifying Pietrzak's barbs, the asserted plurality of teeth. *See* Pet. 65–66.

In particular, for the limitation "the second end having . . . a plurality of teeth projecting from the body portion," Petitioner argues that "Pietrzak's implant comprises a barbed distal end (second end), further comprising two conically shaped barbs (plurality of teeth projection from the body portion)." Pet. 65–66 (citing Ex. 1007, 289–290, Fig. 2). Petitioner also argues that one of ordinary skill in the art would have "underst[oo]d that the barbs project from the second end of implant is configured to anchor the implant into a hole in the second bone" and that the "barbed end . . . act like teeth." *Id.* at 66 (citing Ex. 1002 ¶¶ 245–246); *see also id.* at 69 (arguing that "Pietrzak does disclose circular barbs that, effectively, form teeth"). Petitioner, thus, argues that Pietrzak discloses the limitation or the limitation would have been obvious in view of Pietrzak's disclosure. *Id.* (citing Ex. 1002 ¶¶ 245–247).

Petitioner's relied-upon portion of Pietrzak teaches "a distal portion containing 2 conically shaped barbs." Ex. 1007, 289. Pietrzak does not expressly teach teeth. *See id.* Pietrzak describes and shows "conically shaped barbs," a structure similar to the asserted teeth of Carver, "shouldered, ribbed or helical surface," which the Examiner previously

determined as failing to disclose the recited teeth. Ex. 1003, 506; Ex. 1005, 4:26–30; Ex. 1007, 289. For the same reasons discussed above regarding Carver and the recited teeth, Petitioner does not sufficiently argue that Pietrzak teaches or reasonably suggests teeth. *See* Pet. 65–66. Petitioner, thus, insufficiently argues that Pietrzak teaches or would have rendered obvious teeth such that the proposed combination would have a plurality of teeth and first and second teeth. *See id.*

Therefore, in view of the above, Petitioner does not show a reasonable likelihood of prevailing in its challenge that Pietrzak and Coilard-Lavirotte would have rendered obvious claim 1.

For dependent claims 7, 8, 10, and 13, Patent Owner responds that these claims depend from claim 1, and that Petitioner fails to show that they are unpatentable for the same responsive arguments presented for claim 1. Prelim. Resp. 57. Patent Owner also argues that Petitioner relies on a non-sensical interpretation of "a cross-section" for claim 13. *Id.* at 58.

For the reasons discussed above for claim 1, Petitioner does not show a reasonable likelihood of prevailing in its challenge that Pietrzak and Coilard-Lavirotte would have rendered obvious dependent claims 7, 8, 10, and 13.

For independent claim 15, Patent Owner responds that the combination of Pietrzak and Coilard-Lavirotte does not teach

> a second end extending from the first end for anchoring to the second bone part and having a plurality of outwardly projecting teeth, at least a first tooth of the plurality of teeth spaced from a second tooth of the plurality of teeth in a direction along the longitudinal axis of the second end, and at least the first tooth extending in a different direction than a third tooth of the plurality of teeth

for the reasons given regarding similar limitations recited by claim 1 because Petitioner cites back to its analysis for claim 1 to argue that Pietrzak alone or Pietrzak combined with Coilard-Lavirotte teaches these limitations. Prelim. Resp. 55 (citing Pet. 71–72). For "the second end having an opening in a median portion thereof," Patent Owner repeats its arguments that Petitioner's proposed combination of Pietrzak and Coilard-Lavirotte would not improve the fixation of Pietrzak's implant, and that one of ordinary skill in the art would not have been motivated to make the combination. *Id.* at 55–56 (citing Pet. 73–75; Ex. 1002 ¶ 233).

Patent Owner further responds that Petitioner fails to explain what the proposed combination is or how it would have had a reasonable expectation of success. Prelim. Resp. 56–57 (citing Pet. 74). Patent Owner repeats its argument that Petitioner fails to provide an explanation or analysis of how the proposed combination has a reasonable expectation of success. *Id.* at 56 (citing Pet. 74). Patent Owner also argues that Petitioner's combination lacks certain limitations if Petitioner is proposing to replace the second end of Pietrzak with Coilard-Lavirotte and lacks any explanation if Petitioner is proposing to add only a portion of Coilard-Lavirotte. *Id.* at 56–57.

For the reasons stated above for claim 1 regarding its similar recitation of "a plurality of teeth" and Petitioner's proposed modification of Pietrzak in view of Coilard-Lavirotte, Petitioner fails to show a reasonable likelihood of prevailing in its challenge to independent claim 15.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition and the cited evidence, Petitioner does not show that there is a

reasonable likelihood that it would prevail with respect to at least one of claims 1, 7, 8, 10, 13, and 15 of the ’074 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied, and no *inter partes* review is instituted.

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