**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**PATENT TRIAL AND APPEAL BOARD**

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OsteoMed LLC
Petitioner

v.

Stryker European Operations Holdings LLC
Patent Owner

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CASE: IPR2022-00486
U.S. PATENT NO. 9,168,074

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# PETITION FOR *INTER PARTES* REVIEW

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
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Alexandria, VA 22313-1450

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| Exhibit No. | Description |
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| 1001 | U.S. Pat. No. 9,168,074 to Prandi et al. ("'074 Patent") |
| 1002 | Declaration of Michael Sherman |
| 1003 | File History of U.S. Patent Application No. 13/795,946 |
| 1004 | G.B. Pat. Pub. No. 2,430,625 to Jackson et al. ("Jackson") |
| 1005 | U.S. Patent No. 7,041,106 to Carver et al. ("Carver") |
| 1006 | U.S. Pat. Publication No. 2008/0132894 A1 to Coilard-Lavirotte et al. ("Coilard-Lavirotte") |
| 1007 | "*A Bioabsorbable Fixation Implant for Use in Proximal Interphalangeal Joint (Hammer Toe) Arthrodesis: Biomechanical Testing in a Synthetic Bone Substrate*," by William S. Pietrzak, PhD, Timothy P. Lessek, MS, MBA, and Stephen V. Perns, DPM ("Pietrzak") |
| 1008 | The American Heritage College Dictionary, Fourth Edition (2007) |
| 1009 | Cross section, https://byjus.com/maths/cross-section/ (last visited January, 26 2022) |
| 1010 | Reserved |
| 1011 | CV of Michael Sherman |
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## MANDATORY NOTICES (37 C.F.R. § 42.8(B))

### A. Real Parties-In-Interest

The following are real parties-in-interest pursuant to 37 C.F.R. §42.8(b)(1):

- OsteoMed LLC
- Acumed LLC
- Colson Medical, LLC

Without conceding that the following would be determined to be real parties-in-interest under the governing legal standard, but for the purposes of identifying potential conflicts and analysis under 35 U.S.C. §315(b)[1] [2], Petitioner identifies the following additional parties that may be relevant to the determinations:

- Marmon Holdings, Inc.
- Berkshire Hathaway Inc.

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[1] *See Proppant Express Investments, LLC v. Oren Techs., LLC*, Case IPR2017-01917, Paper 86 at 14-15 (Feb. 13, 2019) (precedential).

[2] None of these identified parties are subject to any time bar for the filing of an *inter partes* review petition, such that a determination as to their actual status as a real party-in-interest is not necessary. Nevertheless Petitioner has listed them out of an abundance of caution.

### B. Related Matters

Patent Owner, Stryker European Operations Holdings LLC, along with its exclusive licensee, Howmedica Osteonics Corp., and parent corporation, Stryker Corp., asserted the '074 Patent in the following litigation.

- *OsteoMed LLC v. Stryker Corp. et al.*, Case No. 1:20-cv-06821 (N.D. Illinois) ("NDIL Action").

The following patents are also being asserted by Patent Owner in the NDIL Action:

- U.S. Patent No. 9,078,713; and
- U.S. Patent No. 10,993,751.

Petitions for *Inter Partes* Review have been filed for the above-referenced patents in the following matters (collectively with this proceeding, the "OsteoMed IPRs"):

- IPR2022-00487; and
- IPR2022-00488.

### C. Lead and Backup Counsel and Service (37 C.F.R. § 42.8(b)(3)-(4))

| Lead Counsel | Backup Counsel |
|---|---|
| **Jason A. Engel**<br>Reg. No. 51,654<br>K&L Gates LLP<br>70 W. Madison Street, Suite 3100<br>Chicago, IL 60602<br>Jason.Engel.PTAB@klgates.com<br>T: (312) 807-4236<br>F: (312) 827-8145 | **Katherine L. Allor**<br>Reg. No. 72,691<br>K&L GATES LLP<br>70 W. Madison Street, Suite 3100<br>Chicago, IL 60602<br>Katy.Allor@klgates.com<br>T: (312) 807-4325<br>F: (312) 345-9987 |

Petitioner consents to electronic service by email.

## I. INTRODUCTION

Petitioner requests institution of *Inter Partes* Review ("IPR") of claims 1, 7, 8, 10, 13, and 15 ("Challenged Claims") of the '074 Patent (Ex. 1001) and cancellation of the Challenged Claims in view of the Grounds described below. This Petition is supported by the declaration of Michael Sherman, an expert in the field of the '074 Patent and the prior art. (Ex. 1002).

## II. '074 PATENT OVERVIEW

The '074 Patent was filed on March 12, 2013 and issued on October 27, 2015. (Ex. 1001, Cover). The '074 Patent describes and claims "an intramedullary implant for use between two bones or two bone fragments." (Ex. 1001, Abstract; Ex. 1002, ¶¶42-60). Specifically, the '074 Patent claims "[a]n intramedullary implant" that has "a first threaded end" and "a second end extending from the first end" that has "a body portion, and a plurality of teeth projecting from the body portion." (Ex. 1001, cl. 1). Figure 1 shows an exemplary application of the intramedullary implant:

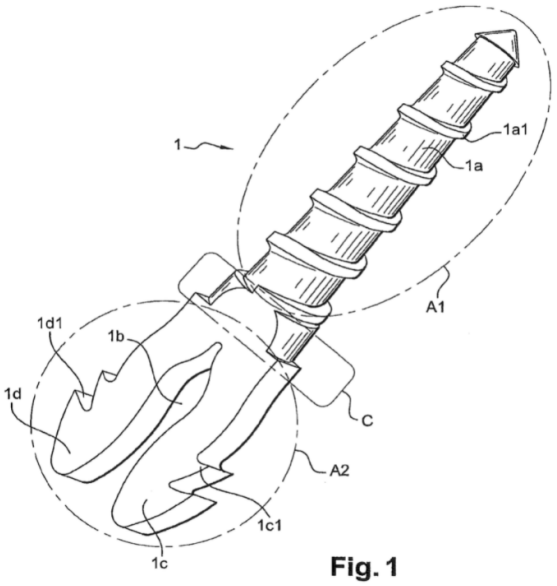


Fig. 1

(Ex. 1001, FIG. 1).

As set forth in this Petition, the '074 Patent fails to add anything to the then-existing state of the art, and merely describes known techniques for fusing two bones between a fracture or a joint. (Ex. 1002, ¶¶74, 94-101, 103, 125, 186-187, 203-228).

### A. Prosecution History of the '074 Patent

During the prosecution of the '074 Patent, the Examiner issued a Non-Final Office Action rejecting the claims for nonstatutory double patenting over U.S. Patent No. 8,414,583, and under §103 in view of U.S. Patent No. 7,041,106 to Carver et al. (Ex. 1005) and WO 2008/129214 A1. (Ex. 1003, 504-07). Applicant proposed amended claims in response to the Office Action (*Id.*, 600-606), filed a terminal disclaimer to overcome the double patent rejection (*Id.*, 607), and further argued that WO 2008/129214 A1 was not prior art (*Id.*, 608-09). The claims as amended were then allowed. (*Id.*, 612-18).

### B. ’074 Patent Priority

The ’074 Patent claims priority to foreign application FR0856035A filed September 9, 2008, through intervening Application No. 12/918,105. (Ex. 1001, Cover). Application No. 12/918,105 was filed as National Stage application PCT/FR2009/051658 on September 2, 2009, and issued as U.S. Patent No. 8,414,583. (*Id.*). For the purposes of this Petition, no determination as to intervening priority need be made; all of the prior art relied upon herein is prior art under 35 U.S.C. § 102(b) to the earliest possible priority date in 2008, unless otherwise specified herein. All references herein to 35 U.S.C. §§ 102-103 are to the pre-AIA versions thereof which apply to the Challenged Claims.

## III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))

Petitioner certifies that (1) the ’074 Patent is available for IPR; (2) Petitioner is not barred or estopped from requesting an IPR on the Grounds identified herein; and (3) Petitioner has not filed a complaint relating to the ’074 Patent.

## IV. PAYMENT OF FEES (37 C.F.R. §§ 42.15 and 42.103)

Petitioner authorizes the USPTO to charge any required fees to Deposit Account 02-1818.

## V. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) is a hypothetical person who is presumed to know the relevant prior art and has ordinary creativity when

interpreting and combining prior art. *In re Coutts*, 726 F. App'x 791, 796 (Fed. Cir. 2018); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007).

With respect to the '074 Patent, a POSITA as of September 2009, had, among other attributes, a Bachelor's Degree in mechanical engineering, biomedical engineering, biomechanics or similar discipline and had approximately three years of experience with orthopedic implant design. (Ex. 1002, ¶¶58-60). Such a POSITA would have had knowledge of design considerations known in the industry and would have been familiar with then-existing products and solutions. (Ex. 1002, ¶59). A POSITA would have been familiar with orthopedic implants, bone plates, and intramedullary implants. (Ex. 1002, ¶¶1-20, ¶60).

## VI. CLAIM CONSTRUCTION

The *Phillips* claim construction standard is applicable for this proceeding. 37 C.F.R. § 42.100(b); 83 Fed. Reg. 51340, 51340-41 (Oct. 11, 2018) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)). Claims are to be construed under the same standard as in federal court, in view of the specification and intrinsic record. *Id.*

Petitioner sets forth constructions of two terms in claims 1 and 13 that need to be resolved by the Board in this matter—"a cross section" and "a body portion." (Ex. 1002, ¶¶22-41).

**A. "a body portion"**

Petitioner sets forth a proposed construction for "a body portion" to clarify the portion of the second end that the '074 Patent purports to include in "a cross-section." Petitioner further notes that the construction of "a body portion" is for clarification purposes and does not impact the construction of "a cross-section."

Claim 1 recites "the second end having a longitudinal axis, ***a body portion***, and a plurality of teeth projecting from the body portion," and claim 13 recites "a cross-section of the body portion is non-circular."[3] (Ex. 1001, cl. 1, cl. 13). The written description does not recite "a body portion" and thus, Petitioner looks to elements recited in claim 1 to determine what is and is not included in "a body portion." The specification describes how "[t]he implant according to the invention has a one-piece body 1 of elongated shape and having a first proximal zone A1 and a second distal zone A2." (Ex. 1001, 2:24-26). The specification further describes how "[t]he zone A2 is flat and has, substantially in its center, an opening 1*b* adapted to enable elastic deformation of the zone A2. More particularly, the opening 1*b* defines at least two anchor arms 1*c* and 1*d*, each having at least one outwardly projecting tooth 1*c*1, 1*d*1." (Ex. 1001, 2:40-44). These elements are shown below with respect to Figure 1:

[3] All emphasis added unless otherwise indicated.

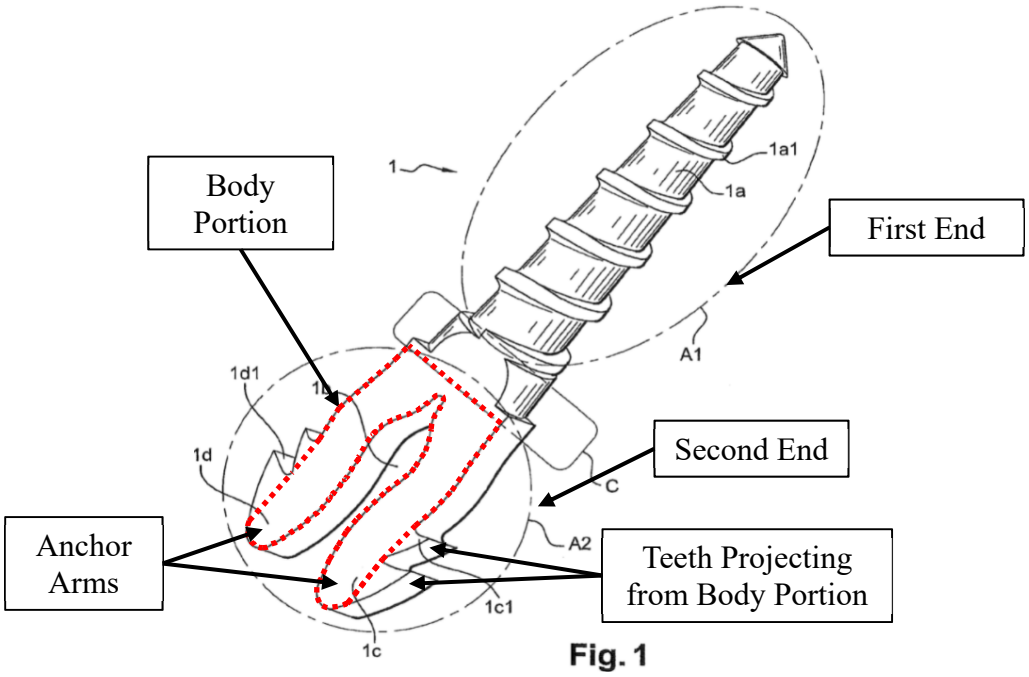



Fig. 1

(Ex. 1001, FIG. 1 (annotated); *see also id.*, 2:24-44). Given that the "plurality of teeth" are "projecting from the body portion," the body portion must exclude the teeth.

Thus, Petitioner asks the Board to construe "a body portion" as "a portion of the second end that excludes a plurality of teeth." However, a construction of "a body portion" that includes the plurality of teeth would not impact the construction of "a cross-section."

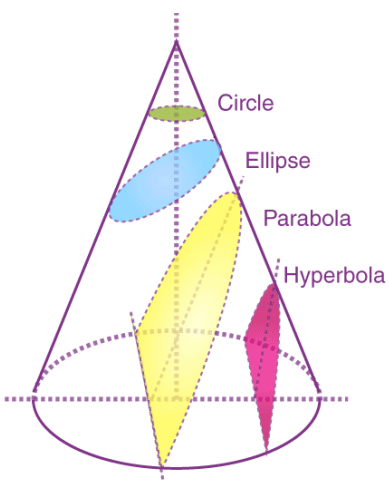
**B. "a cross-section"**

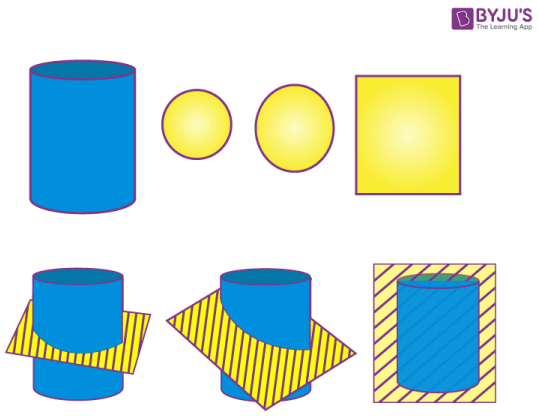
Claim 13 recites "a cross-section of the body portion is non-circular." (Ex. 1001, cl. 13). While the written description does not recite "a cross-section," the term is well-known in the art as "a section formed by a plane cutting through an

object, usually at right angles to an axis." (Ex. 1008, 340; Ex. 1002, ¶¶21-30). While this dictionary definition includes "usually at right angles to an axis," a POSITA would understand that "usually" does not mean "always," and that a reference axis can be drawn in any direction when dealing with a 3-dimensional object. (Ex. 1002, ¶27). Given that an axis is not specified in claim 13, Petitioner looks to the other claims for guidance.

Only one other claim, claim 17, refers to "a cross-section." Specifically, claim 17 recites "wherein the second end has ***a cross-section*** with opposing flat first and second surfaces ***when viewed in a direction perpendicular to a longitudinal axis thereof***." (Ex. 1001, cl. 17). Thus, a longitudinal axis is one contemplated axis that can be used as a reference axis from which to cut the plane for the cross-section claimed by claim 13. Based on the principles of claim differentiation, the scope of claim 13 encompasses "a cross section of the body portion" taken at ***any*** viewing angle relative to ***any*** reference axis. Thus, relative to the more narrow scope of claim 17, claim 13 is afforded a boarder scope.

The figures below illustrate the range of cross-sections that may be taken from a 3-dimensional geometric object:




(Ex. 1009, 3). The figures illustrate that "a cross-section", may, but does not require, that the cross-section be taken from a right angle to an axis.

Thus, Petitioner asks the Board to construe "a cross-section" as "a section formed by a plane cutting through an object."

## VII. STATEMENT OF PRECISE RELIEF REQUEST AND REASONS THEREFORE

Petitioner requests the institution of IPR and the cancellation of the Challenged Claims on the following Grounds:

| Ground | Basis | Relied-On References | Claim(s) |
|---|---|---|---|
| 1 | § 102 | Jackson (Ex. 1004) | 1, 10, 13 |
| 2 | § 103 | Jackson | 7, 8, 13 |
| 3 | § 103 | Jackson in view of Coilard-Lavirotte (Ex. 1006) | 15 |
| 4 | § 103 | Carver (Ex. 1005) in view of Coilard-Lavirotte | 1, 7, 8, 10, 13, 15 |

| Ground | Basis | Relied-On References | Claim(s) |
|---|---|---|---|
| 5 | § 103 | Pietrza (Ex. 1007) in view of Coilard-Lavirotte | 1, 7, 8, 10, 13, 15 |

### A. The Petition Should Not Be Discretionarily Denied

#### 1. *Becton, Dickinson*

The claims of the '074 Patent have not been considered in view of Jackson, Coilard-Lavirotte, or Pietrzak. While Carver was considered, the Examiner did not consider it in combination with Coilard-Lavirotte as is presented in this Petition. Accordingly, the present Petition should not be discretionarily denied under 35 U.S.C. § 325(d). *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential).

#### 2. *Fintiv*

The Board should not deny this Petition in view of 35 U.S.C. § 314(a). *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020), sets forth six factors to consider in a discretionary denial under 35 U.S.C. § 314(a). When assessed holistically, these six factors do not warrant discretionary denial.

First, Petitioner is going to file a motion to stay the NDIL Action in view of and as it relates to the OsteoMed IPRs. The motion to stay will be filed before the deadline set forth in Northern District of Illinois Local Patent Rule 3.5(b). And the Northern District of Illinois has granted, at least in part, approximately seventy-three

percent of motions to stay in view of *inter partes* AIA proceedings. (Ex. 1012, 1-2). Thus, factor 1 favors not exercising discretionary denial.

Second, there is no trial date presently set for any litigation involving the '751 Patent. Thus, factor 2 favors not exercising discretionary denial.

Third, the parties have made some investment in the district court litigation, but discovery is still open and the claim construction hearing is not yet scheduled and likely will not occur until after an institution decision comes out. Thus, factor 3 weighs in favor of institution.

Fourth, the merits of the arguments presented to the Board here strongly warrant consideration, thus weighing factor 6 in favor of institution.

The remaining factors (4 - overlap of issues, and 5 - same parties) are seemingly neutral and do not outweigh the benefits of instituting.

Balancing these factors holistically, the Board should not exercise its discretion to deny this Petition.

### B. Overview of Prior Art

The Challenged Claims merely represent a collection of known components modified or combined according to known methods to yield predictable results, and are therefore obvious under 35 U.S.C. § 103. (*See, e.g.*, Ex. 1002, ¶¶61-72).

**1. Jackson (Ex. 1004)**

Jackson was filed September 30, 2005 and published April 4, 2007. (Ex. 1004, Cover). Jackson qualifies as prior art under §102(b).

Jackson discloses a joint fusion peg configured to fuses the joint between the middle and proximal phalanges of the toe:

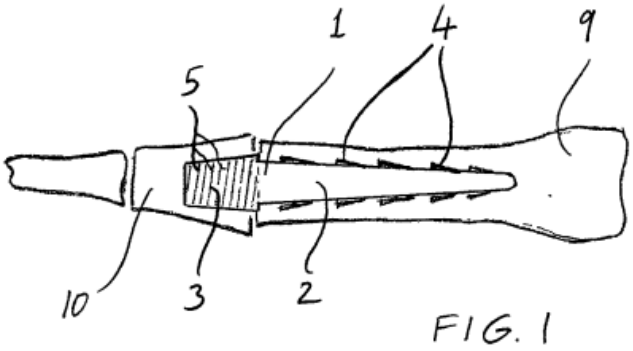


FIG. 1

(Ex. 1004, FIG. 1).

**2. Carver (Ex. 1005)**

Carver was filed June 15, 2001 and issued May 9, 2006. (Ex. 1005, Cover). Carver qualifies as prior art under §102(b).

Carver discloses an arthrodesis implant configured for joint fusion and the treatment of deformities of the fingers and toes:

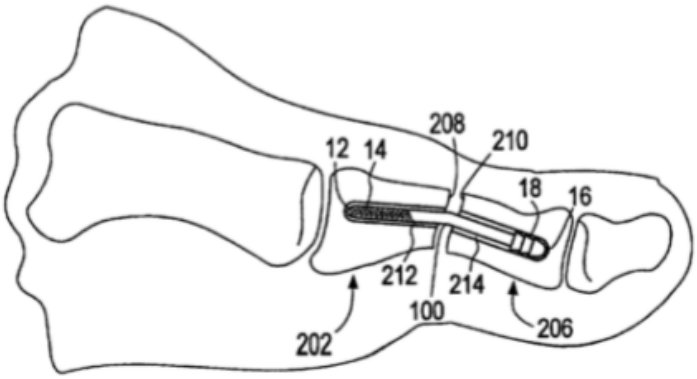



FIG. - 7

(Ex. 1005, FIG. 7, *see also id.*, 3:36-40, 4:18-34). The implant comprises a first end and second end that anchors into a respective cavity of a first bone and second bone, and creates an anatomically correct angle between the first bone and second bone. (*Id.*).

### 3. Coilard-Lavirotte (Ex. 1006)

Coilard-Lavirotte was filed November 15, 2007 and published June 5, 2008. (Ex. 1006, Cover). Coilard-Lavirotte qualifies as prior art under §102(a) to the '074 Patent's September 9, 2008 French priority date, but, more importantly, is prior art under §102(b) because it published more than one year prior to the date of the application for patent in the United States (i.e., September 2, 2009).

Coilard-Lavirotte discloses an intramedullary implant for use between the inter-phalangeal joints in the foot:

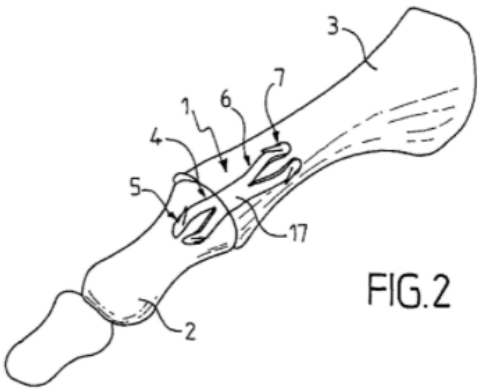


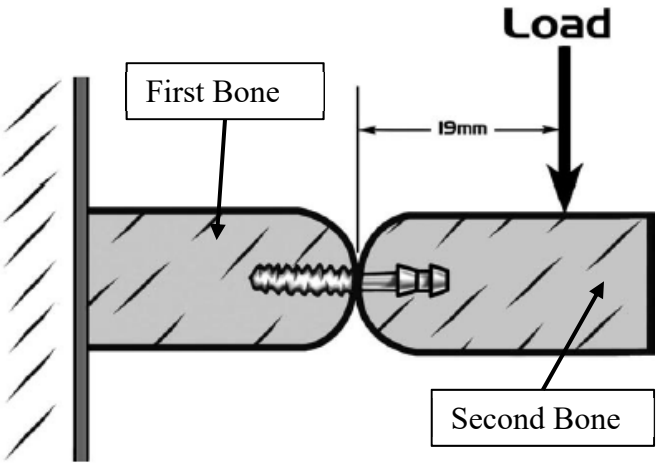

FIG.2

(Ex. 1006, FIG. 2, ¶50).

#### 4. Pietrzak (Ex. 1007)

Pietrzak published in October of 2006 and qualifies as prior art under §102(b). (Ex. 1007).

Pietrzak discloses a fixation implant configured for proximal interphalangeal (PIP) joint arthrodesis between a first and second phalangeal bone in the foot:



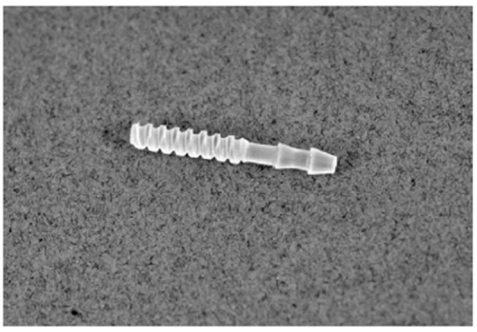



**FIGURE 1** Photograph of bioabsorbable hammer toe fixation implant.

(Ex. 1007, FIGS. 1, 2 (annotated); *see also id.*, 289-90). Pietrzak's fixation implant comprises a proximal threaded end and a distal barbed end, wherein each end is configured to anchor into a prepared hole in a respective bone. (*Id.*).

### C. Ground 1: Claims 1, 10, and 13 are Unpatentable Under 35 U.S.C. § 102 as Anticipated by Jackson

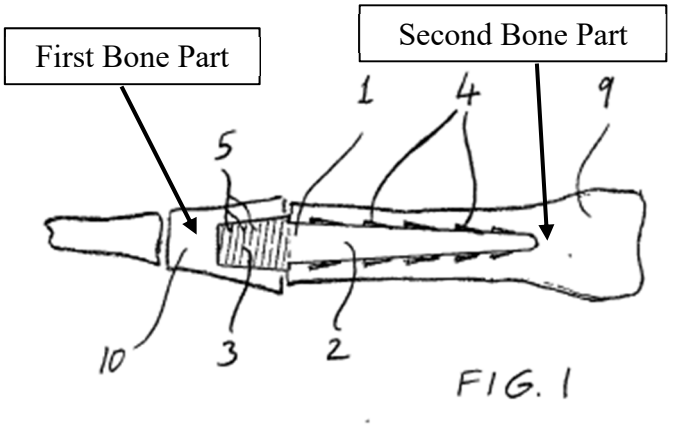
As explained below, independent claim 1 and dependent claims 10 and 13 are anticipated by Jackson. (Ex. 1002, ¶¶73-101).

#### 1. Claims 1, 10, and 13 are Anticipated by Jackson

##### *a. Independent Claim 1*

###### i. [1Pre] An intramedullary implant for use between first and second bone parts, the implant comprising:

Jackson's intramedullary implant is configured to fuse a joint between two bone parts:

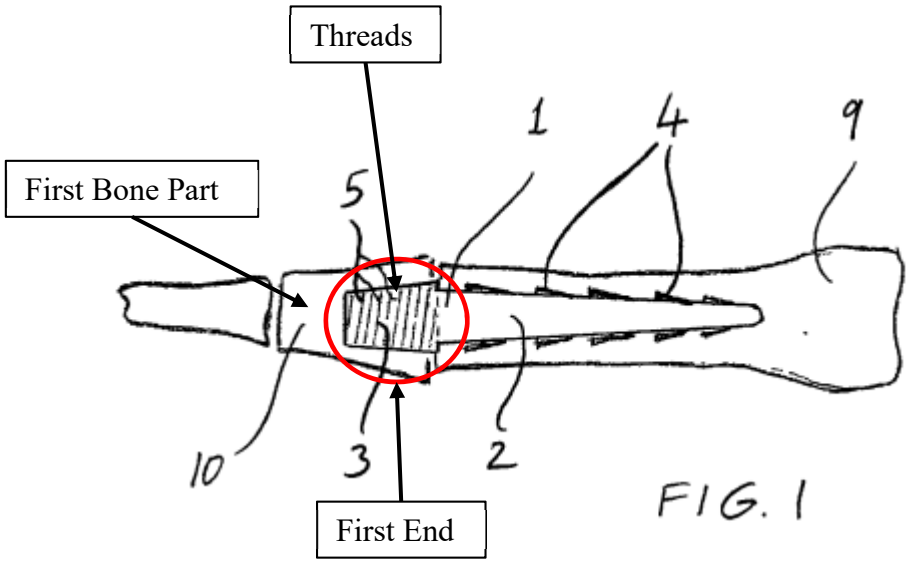



(Ex. 1004, FIG. 1 (annotated); *see also id.*, 6:21-7:2).

Thus, Jackson discloses this element. (Ex. 1002, ¶¶75-77).

ii. [1a] a first threaded end for anchoring to the first bone part;

Jackson's joint fusion peg 1 comprises a 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:

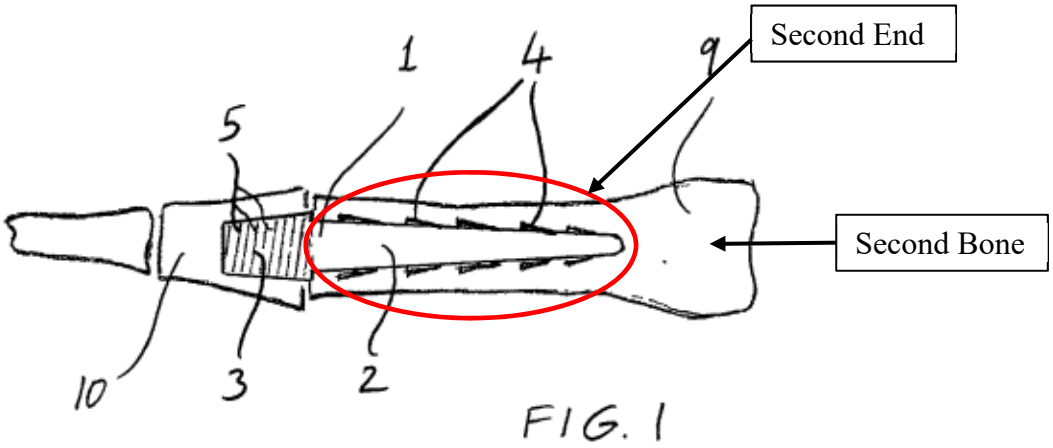



(Ex. 1004, FIG. 1 (annotated); *see also id.*, 6:21-7:2). The peg comprises a "distal conical limb 3" that fuses to the middle phalanx bone with manual compression in a twisting motion "to screw it [the peg] home." (Ex. 1004, 8:6-7).

Thus, Jackson discloses this element. (Ex. 1002, ¶¶78-79).

iii. [1b] a second end extending from the first end for anchoring to the second bone part,

Jackson's joint fusion peg 1 comprises a second end, a "proximal limb 2," that is connected to the conical proximal limb and positioned into the intramedullary cavity of a proximal phalanx, preventing rotation:

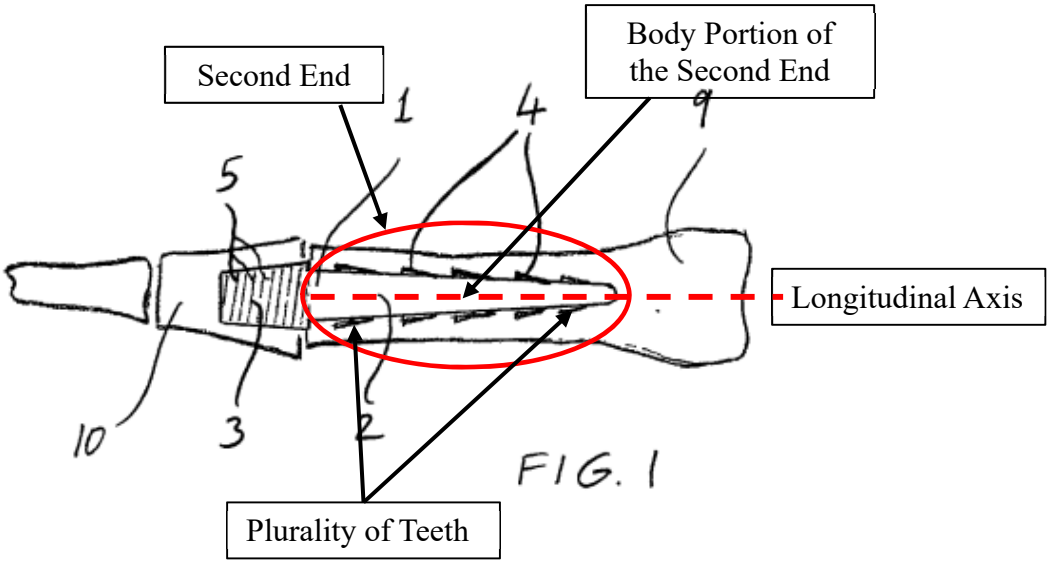



(Ex. 1004, FIG. 1 (annotated); *see also id.*, 7:21-8:2). In addition, "as the proximal limb 2 is pushed into the proximal phalanx, it will excavate additional bone in order to create a channel within which the flanges will be securely located preventing rotation of the limb within the proximal phalanx," and "[t]he flanges 4 permit a press-fit of the proximal limb 2 to lock it into position," thereby anchoring the second end in the second bone part. (Ex. 1004, 7:8-10, 6:24-25).

Thus, Jackson discloses this element. (Ex. 1002, ¶¶80-82).

iv. [1c] the second end having a longitudinal axis, a body portion, and a plurality of teeth projecting from the body portion,

Jackson's joint fusion peg 1 comprises a proximal limb 2 (body portion of second end) with a plurality of flanges 4 (teeth), as shown in Figure 1:

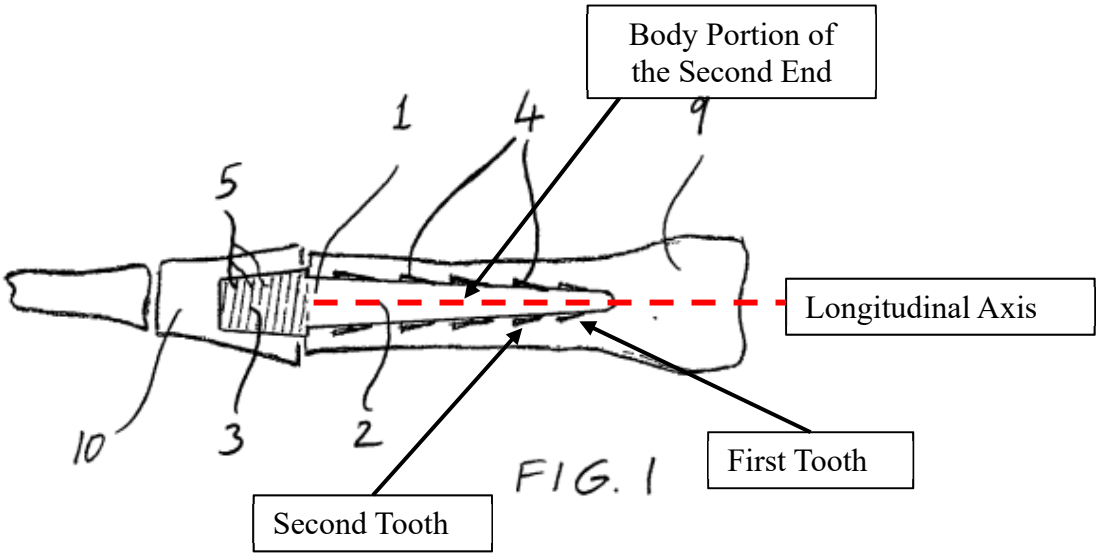



(Ex. 1004, FIG. 1 (annotated); *see also id.*, 7:21-8:2). The flanges 4 (teeth) enable the proximal limb 2 to lock into the intramedullary cavity of the proximal phalanx. (*Id.*). Jackson further discloses that the plurality of flanges 4 are preferably arranged along the surface of the proximal limb 2 in two longitudinal lines, projecting from the body portion, as shown above in Figure 1. (*See* Ex. 1004, FIG. 1; *see also id.*, 4:9-11 ("It is also preferred that there are a plurality of flanges on a limb, the flanges being angularly aligned along the surface of the limb, and it is further preferred that the flanges are angularly aligned along the surface in two longitudinal lines.")).

Thus, Jackson discloses this element. (Ex. 1002, ¶¶83-85).

v. [1d] 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,

Jackson's intramedullary implant comprises a plurality of flanges 4 (teeth) spaced apart and angularly aligned along the longitudinal axis of the proximal limb 2 (second end):

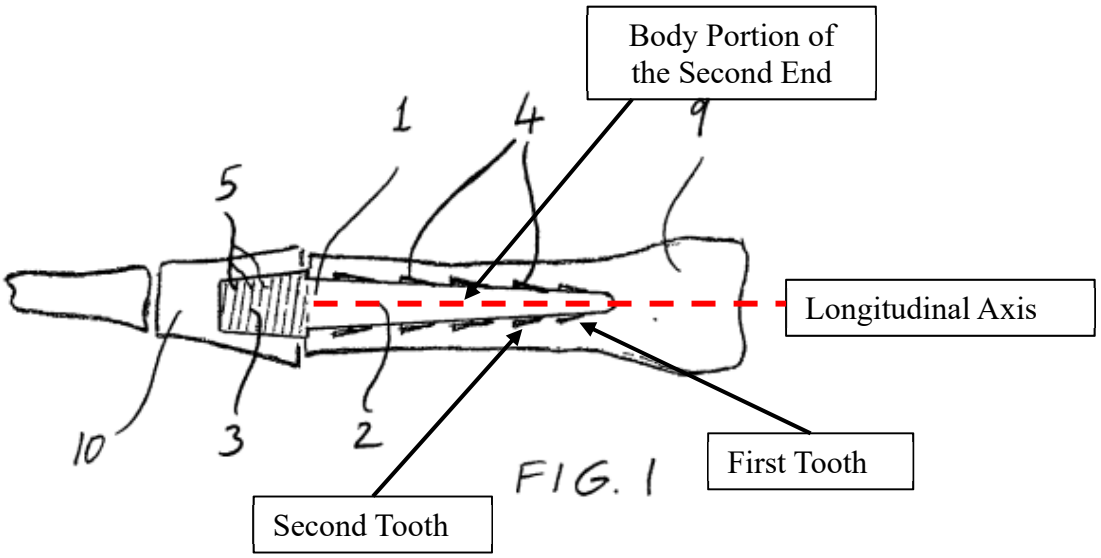



(Ex. 1004, FIG. 1 (annotated); *see also id.*, 4:9-11, 6:23-26). Each flange comprises a ramped surface or "cutting cone" that prevents the removal of the proximal limb 2 from the bone. (Ex. 1004, 4:1-7).

Thus, Jackson discloses this element. (Ex. 1002, ¶¶86-87).

vi. [1e] the first and second teeth extending from the body portion in a same direction, and

Jackson's intramedullary implant comprises a plurality of flanges 4 (teeth) angularly aligned along two longitudinal lines of proximal limb 2 (second end) that extend in the same direction from the body portion:

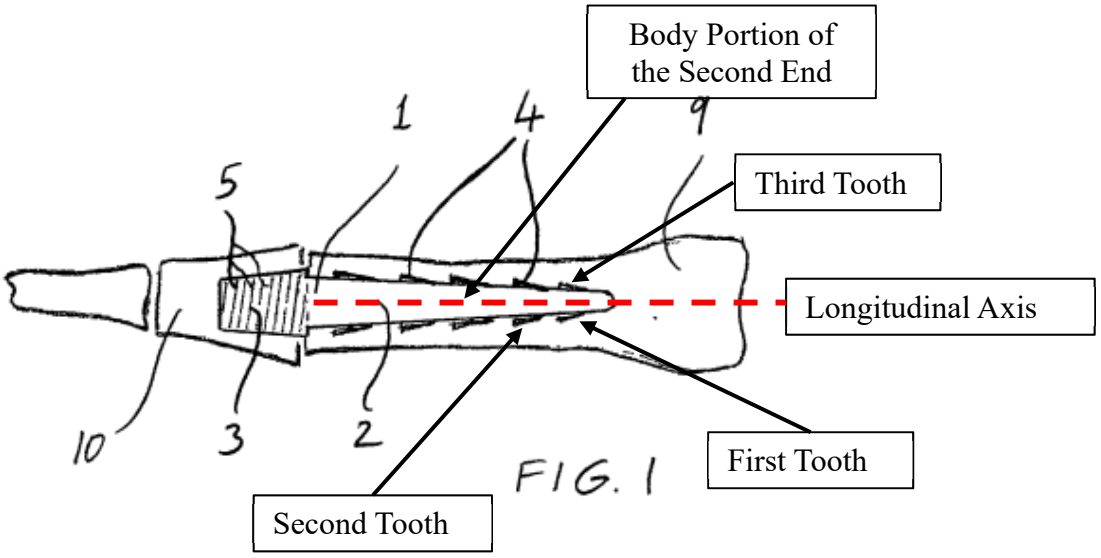



(Ex. 1004, FIG. 1 (annotated); *see also id.*, 4:9-11, 6:23-26). Each flange is a sharply projecting surface like a barb that prevents the removal of the proximal limb 2 from the excavated cavity of the bone. (Ex. 1004, 4:1-7).

Thus, Jackson discloses this element. (Ex. 1002, ¶¶88-89).

vii. [1f] 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.

Jackson's intramedullary implant comprises a proximal limb 2 (second end) with two lines of flanges 4 (teeth) angularly aligned along the body portion of the second end, where the third tooth extends in a different direction from the first tooth:




(Ex. 1004, FIG. 1 (annotated); *see also id.*, 3:26-32 ("Preferably ***the surface texture of at least one of the limbs includes one or more flanges*** whereby positive engagement between the surface of the bone and limb is achieved by a press-fit. Advantageously the limb would be easy to insert into a bone cavity. Advantageously the surface of the limb need only have a flange on one or two regions of the limb. Preferably ***these regions are on opposing sides of the limb***; more preferably along the full length of the limb."); *id.*, 4:9-11 ("It is also preferred that there are a plurality

of flanges on a limb, the flanges being angularly aligned along the surface of the limb, and it is further preferred that the flanges are angularly aligned along the surface in two longitudinal lines."); Ex. 1002, ¶¶90).

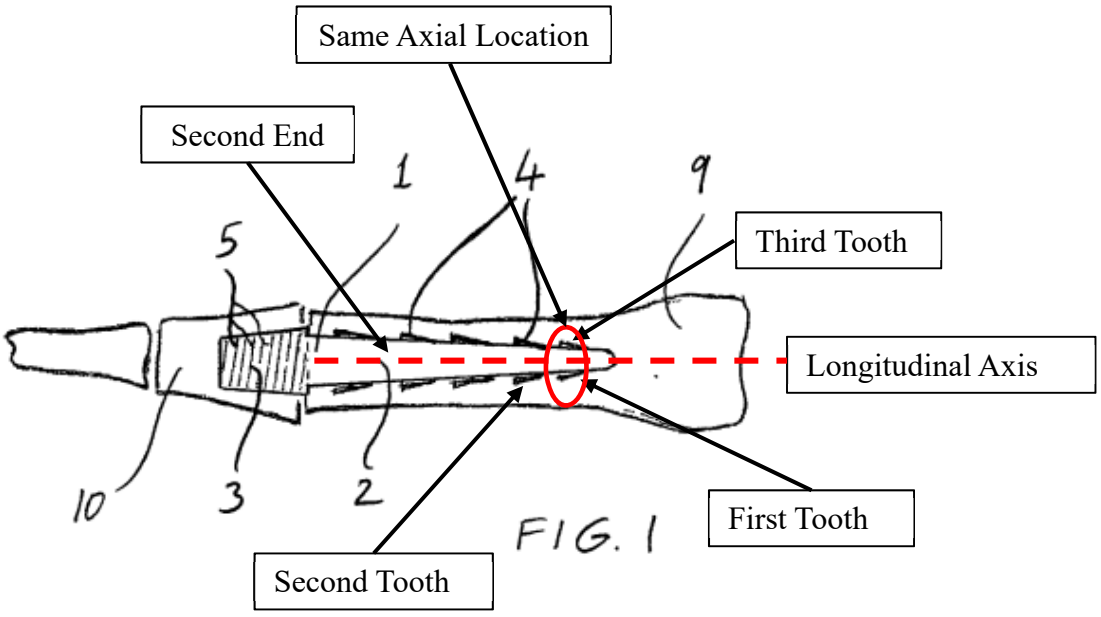
Thus, Jackson discloses this element. (Ex. 1002, ¶¶90-93).

As detailed above, Figure 1 of Jackson discloses each and every element of claim 1 of the '074 Patent. (Ex. 1002, ¶¶94). Thus, claim 1 is anticipated by Jackson.

*b. Dependent Claims 10 and 13*

i. Claim 10: The intramedullary implant of claim 1, wherein the first and third teeth are positioned at the same axial location along the longitudinal axis of the second end.

Jackson's intramedullary implant comprises a proximal limb 2 (second end) with two lines of flanges 4 (teeth) angularly aligned along the longitudinal axis of the second end:



(Ex. 1004, FIG. 1 (annotated); *see also id.*, 4:9-11, 6:23-26). Each flange is a sharply projecting surface like a barb that prevents the removal of the proximal limb 2 (second end) from the excavated cavity of the bone. (Ex. 1004, 4:1-7). As shown in Figure 1, the first tooth and the third tooth are located at the same axial location along the longitudinal axis of the proximal limb 2 (second end). (Ex. 1002, ¶¶95-96).

Thus, claim 10 is anticipated by Jackson. (Ex. 1002, ¶97).

ii. Claim 13: The intramedullary implant of claim 1, wherein a cross-section of the body portion is non-circular.

Jackson's intramedullary implant comprises a proximal limb 2 (second end) with a plurality of flanges 4 (teeth) angularly aligned along the longitudinal axis of the second end, wherein the proximal limb 2 (second end) is conically shaped:

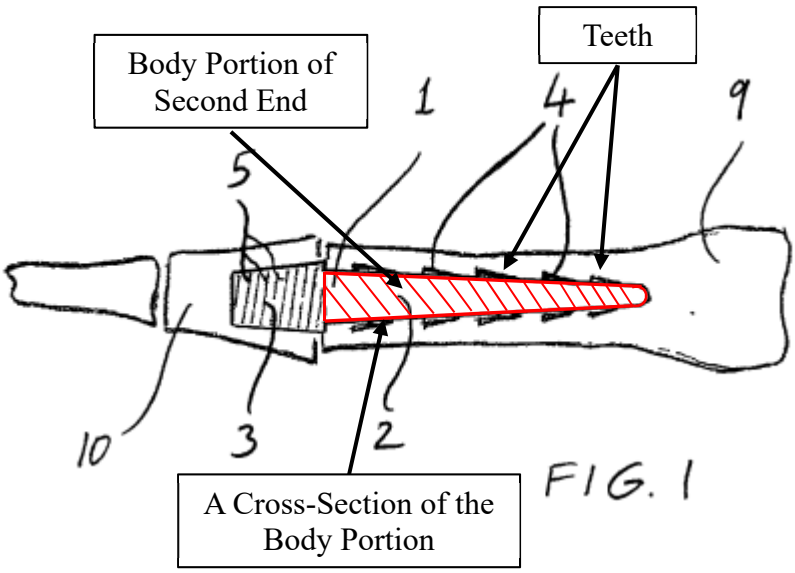



FIG. 1

(Ex. 1004, FIG. 1 (annotated); *see also id.*, 4:9-11, 6:23-26). As shown in Figure 1, one of the many cross-sections that may be taken of the proximal limb (body portion of the second end) includes a generally triangular cross section, and thus a cross section of the proximal limb (body portion of the second end) is non-circular. (Ex. 1002, ¶¶98-100).

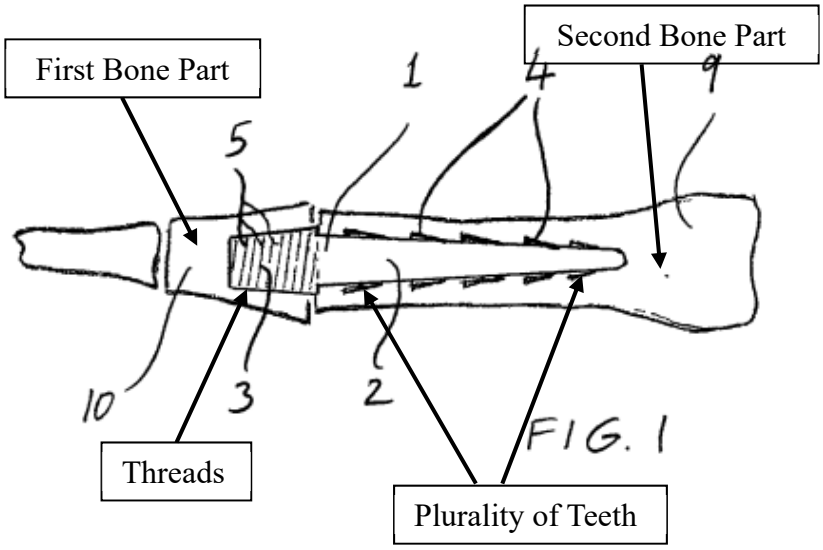
Thus, claim 13 is anticipated by Jackson. (Ex. 1002, ¶101).

### D. Ground 2: Claims 7, 8, and 13 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious over Jackson

#### 1. Basis for Obviousness in view of Jackson

The scope and content of the prior art includes Jackson and the technical expertise of a POSITA, which collectively discloses all of the elements of claims 7, 8, and 13. There are no differences between the subject matter of these claims and the combination of Jackson and the technical expertise of a POSITA.

Figure 1 of Jackson discloses an intramedullary implant for use between two bone parts, that has threads at one end, and teeth at the other end for anchoring the implant to the bone:




(Ex. 1004, FIG. 1 (annotated)). Given that Jackson discloses multiple embodiments, a POSITA would have readily combined those embodiments to create an intramedullary implant as claimed by claims 7, 8, and 13 of the '074 Patent. (Ex. 1002, ¶¶102-124).

**2. Claims 7, 8, and 13 are Obvious over Jackson**

*a. Dependent Claims 7, 8, and 13*

i. Claim 7: The intramedullary implant of claim 1, 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.

The main embodiment, as shown in Figure 1 below, shows the implant being used in the proximal interphalangeal joint, with a conical limb 3 (first end) and proximal limb 2 (second end), where the first end is offset from the longitudinal axis of the second end by zero degrees:

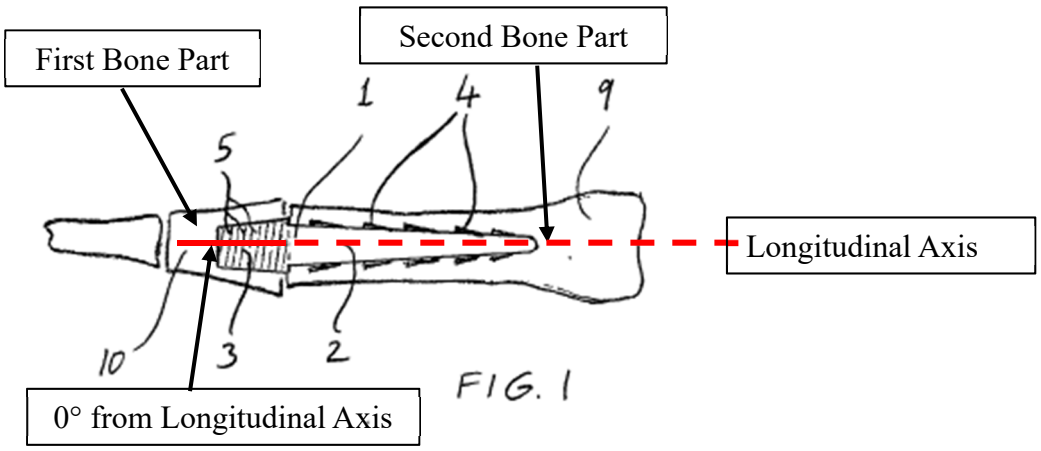



FIG. 1

(Ex. 1004, FIG. 1 (annotated)). Jackson discloses that a straight peg "enable[es] the joint being fused such as a proximal interphalangeal joint, to be fused in a straight position." (Ex. 1004, 4:26-27). A POSITA would know that the proximal interphalangeal joint is found in both the hands and the feet, between the distal head of the proximal phalange and the proximal base of the middle phalange. (Ex. 1002, ¶109). A POSITA would know that there is an associated and similar joint, the distal interphalangeal joint, found between the distal head of the middle phalange and proximal base of the distal phalange. (Ex. 1002, ¶110).

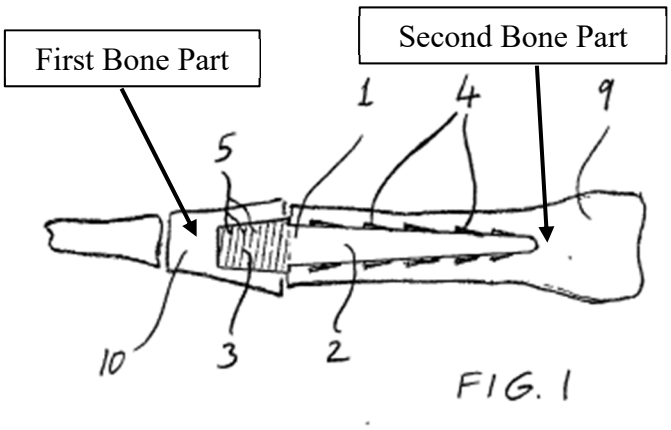
Moreover, a POSITA would know that the interphalangeal joints of the foot are classified as uniaxial hinge joints, which are a type of synovial joint that permit movement along one axis, in this case flexion (plantarflexion) and extension (dorsiflexion) of the middle and distal phalanges. (Ex. 1002, ¶111). Jackson recognizes that sometimes these joints in the foot may need to be fused in an angle: "[t]he limbs of the peg may be angled relative to each other such that on fixation

fusion is encouraged to occur with the bones located relative to each other in an optimised position." (Ex. 1004, 4:24-26). A POSITA would further recognize that matching the anatomic angle of the joint is likely to result in most comfortable application for patient. (Ex. 1002, ¶113). Thus, a POSITA would understand that an angle greater than 30 degrees would result in an unnatural angle and likely result in patient discomfort. (Ex. 1002, ¶114). Therefore, it would be obvious to a POSITA that the angle of offset of the first end from the longitudinal axis of the second end would be less than 30 degrees to anatomically conform to the natural angle of the joint between the bones. (Ex. 1002, ¶115).

Thus, Jackson discloses this claim, or at least a POSITA would find this claim obvious in view of the disclosure by Jackson. (Ex. 1002, ¶¶102-115).

ii. Claim 8: The intramedullary implant of claim 7, 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.

As shown in Figure 1, Jackson's intramedullary implant comprises a conical limb 3 (first end) and a proximal limb 2 (second end), where each limb is configured to fit into the intramedullary cavity of each bone:



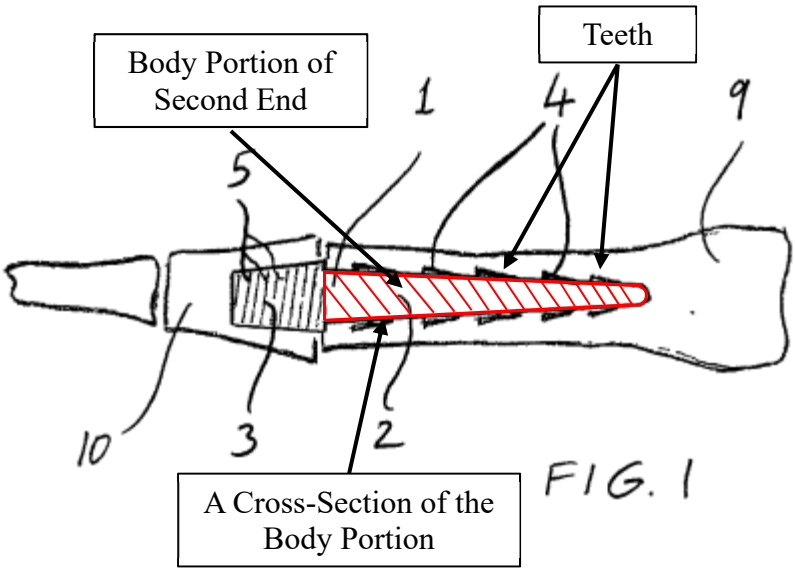

(Ex. 1004, FIG. 1). Additionally, Figure 1 shows that the first end of the implant is located in the first bone and that the second end is located in the second bone, with the joint space located where the two ends meet. (Ex. 1002, ¶116). A POSITA would understand that an arthrodesis line is at the joint that is fused when the implant is placed. (Ex. 1002, ¶117). A POSITA would further understand that if the implant had an angle of offset of less than 30 degrees of the first end from the longitudinal axis of the second end to anatomically conform with the natural angle of the joint between the bones, that offset would occur where the arthrodesis line is located, at the joint. (Ex. 1002, ¶118).

Thus, this claim is disclosed by Jackson, or at least this claim would have been obvious to a POSITA in view of the disclosure of Jackson. (Ex. 1002, ¶116-119).

iii. Claim 13: The intramedullary implant of claim 1, wherein a cross-section of the body portion is non-circular.

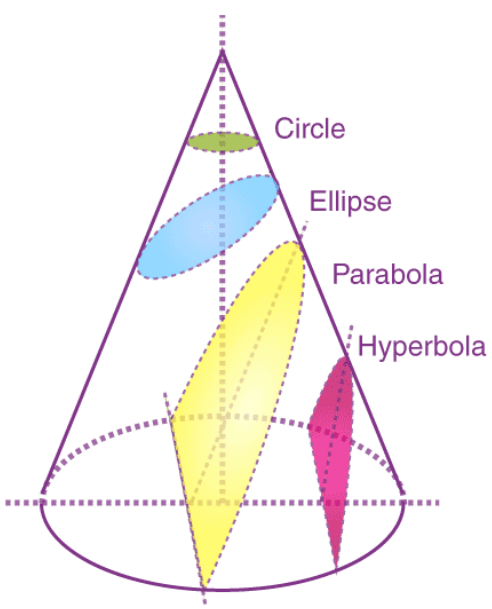
Patent Owner may argue that Jackson does not explicitly disclose that its body portions include a non-circular cross-section. For the reasons discussed above in Section VII.C.b.ii, Petitioner submits that Jackson does explicitly, if not inherently, disclose this element. Regardless, a POSITA would understand that this element is clearly taught or suggested by Jackson. (Ex. 1002, ¶120).

Jackson's intramedullary implant comprises a proximal limb 2 (second end) with a plurality of flanges 4 (teeth) angularly aligned along the longitudinal axis of the second end, wherein the proximal limb 2 (second end) is conically shaped:




(Ex. 1004, FIG. 1 (annotated); *see also id.*, 4:9-11, 6:23-26). While the shape of the implant in Jackson is generally conical, a POSITA would understand that a cross-section of the proximal limb (body portion of the second end), viewed at any relative

angle to the longitudinal axis, would include a variety of non-circular shapes such as triangles, ellipses, parabolas, and hyperbolas, as shown in the image below




(Ex. 1009, 3; Ex. 1002, ¶¶122-124).

Thus, this claim is disclosed by Jackson, or at least this claim would have been obvious to a POSITA in view of the disclosure of Jackson. (Ex. 1002, ¶¶120-124).

### E. Ground 3: Claim 15 is Unpatentable Under 35 U.S.C. § 103(a) as Obvious over Jackson and Coilard-Lavirotte

Independent claim 15 would have been obvious in view of the combination of Jackson and Coilard-Lavirotte. (Ex. 1002, ¶¶125-155).

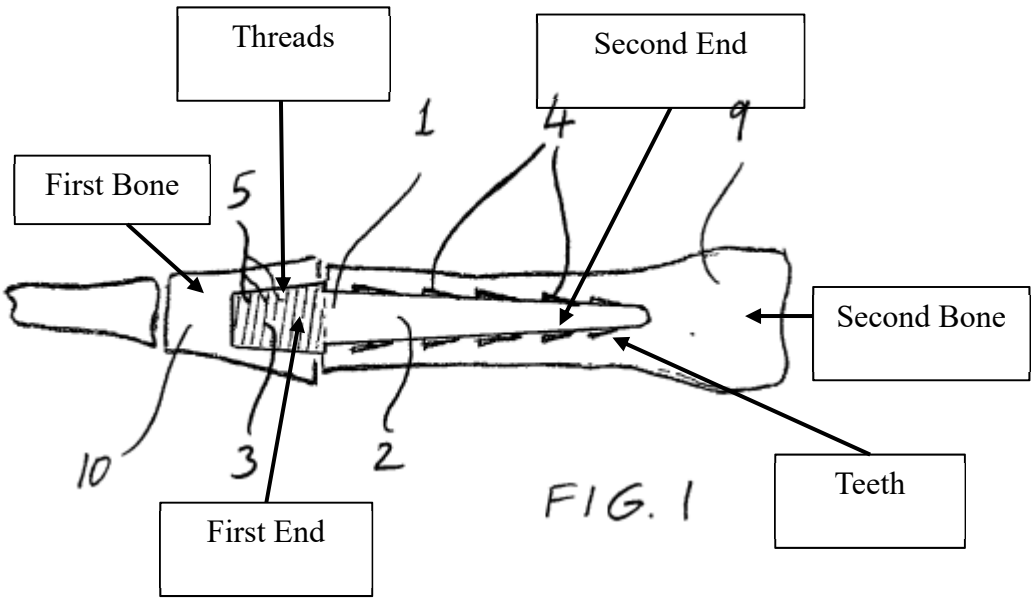
#### 1. Basis for the Combination of Jackson and Coilard-Lavirotte

The scope and content of the prior art includes Jackson and Coilard-Lavirotte, which collectively disclose all of the elements of claim 15. There are no differences

between the subject matter of these claims and the combination of Jackson and Coilard-Lavirotte.

Both Jackson and Coilard-Lavirotte disclose intramedullary implants for use between interphalangeal joints in the foot. (Ex. 1004, 4:26-27; Ex. 1006, FIG. 2, ¶50). Both Jackson and Coilard-Lavirotte describe anchor designs that are inserted into a bone cavity, secure to the interior bone wall, and prevent the implant from being removed. (Ex. 1002, ¶127). A POSITA would recognize that various anchoring structures can be used to accomplish the same anchoring functionality between an intramedullary implant and a bone. (Ex. 1002, ¶128).

Jackson's joint fusion peg comprises a conical limb 3 with oblique ridges or threads, and a proximal limb 2 with flanges or teeth, and each limb of the joint fusion peg is configured to secure to an excavated channel in a respective bone, and thus securely fuse the first and second bone, as shown in Figure 1:




(Ex. 1004, FIG. 1 (annotated); *see also id.*, 7:21-8:7). Jackson describes how the conical limb 3 fuses to the middle phalanx bone with manual compression in a twisting motion "to screw it [the peg] home," whereas "the proximal limb 2 is pushed into the proximal phalanx, it will excavate additional bone in order to create a channel within which the flanges will be securely located preventing rotation of the limb within the proximal phalanx," thereby anchoring the second end in the second bone part. (Ex. 1004, 7:8-10, 8:6-7).

Coilard-Lavirotte discloses an arthrodesis implant configure to fuse a first and second bone at a joint. (Ex. 1006, ¶30, ¶99). Coilard-Lavirotte's arthrodesis implant comprises a plurality of anchoring branches 10 with anti-return devices (teeth), configured to anchor the implant to bony tissue of the second bone. (*Id.*).

Jackson 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 flanges. (Ex. 1004, 3:26-32; Ex. 1006, ¶148; Ex. 1002, ¶132). A POSITA would have been motivated to combine Jackson with Coilard-Lavirotte to improve the fixation of Jackson'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. (Ex. 1002, ¶133). A POSITA would recognize that Jackson discloses a known element (conical shaped body with teeth on opposite sides and along longitudinal axis) 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). (Ex. 1002, ¶¶129-130). A POSITA would know that combining the teachings 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. Thus, a POSITA would be motivated to combine the teachings of Jackson and Coilard-Lavirotte, to utilize a known technique for improving the implantation of an intramedullary implant (similar device), and obtain a similar improvement. (Ex. 1002, ¶¶134).

### 2. Claim 15 is Obvious in view of the Combination of Jackson and Coilard-Lavirotte

*a. Independent Claim 15*

i. [15Pre] An intramedullary implant for use between first and second bone parts, the implant comprising:

For at least the reasons set forth in Section VII.C.1.a.i, Jackson discloses this element. (*See* Ex. 1004, FIG. 1, 6:21-7:2; Ex. 1002, ¶¶75-77, 135-137).

ii. [15a] a first threaded end for anchoring to the first bone part;

For at least the reasons set forth in Section VII.C.1.a.ii, Jackson discloses this element. (*See* Ex. 1004, FIG. 1, 6:21-7:2; Ex. 1002, ¶¶78-79, 138-139).

iii. [15b] a second end extending from the first end for anchoring to the second bone part and having a plurality of outwardly projecting teeth,

For at least the reasons set forth in Sections VII.C.1.a.iii and VII.C.2.a.iv, Jackson discloses this element. (*See* Ex. 1004, FIG. 1, 7:21-8:2, 7:8-10, 6:24-25, 4:9-11; Ex. 1002, ¶¶80-85, 140-141).

iv. [15c] 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

For at least the reasons set forth in Section VII.C.1.a.v, Jackson discloses this element. (*See* Ex. 1004, FIG. 1, 4:9-11, 6:23-26, 4:1-7; Ex. 1002, ¶¶86-87, 142-143).

v. [15d] at least the first tooth extending in a different direction than a third tooth of the plurality of teeth,

For at least the reasons set forth in Section VII.C.1.a.vii, Jackson discloses this element. (Ex. 1002, ¶¶90-94, 144-145).

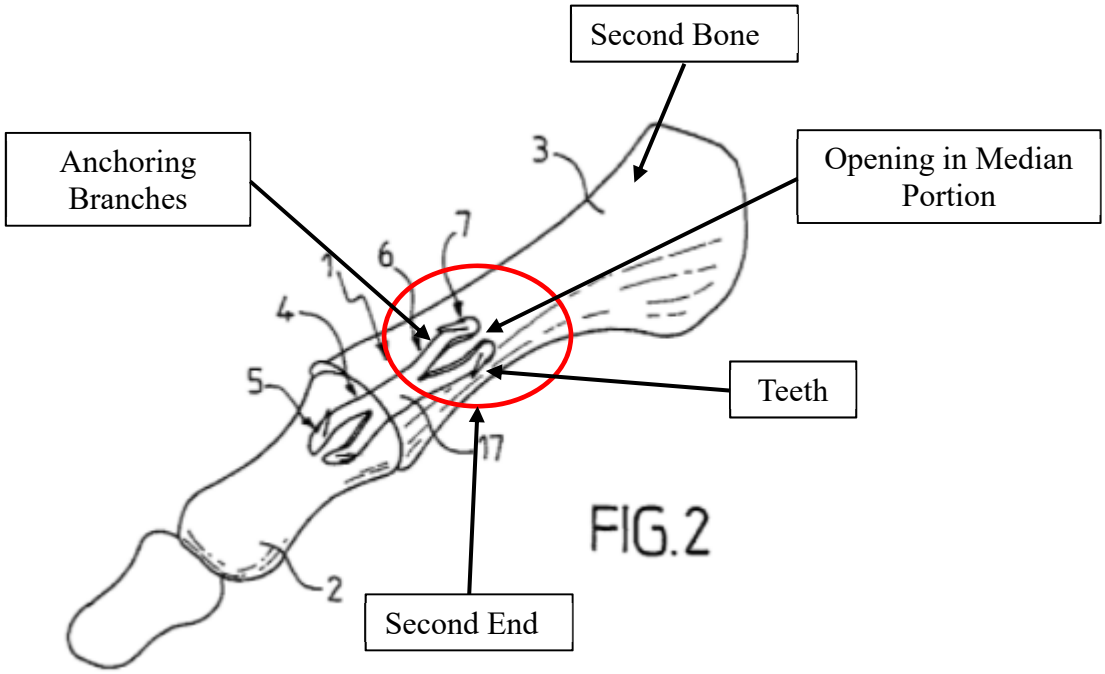
vi. [15e] the second end having an opening in a median portion thereof.

The purpose of the opening median portion of the second end is to allow a portion of the second end to elastically deform upon entry into a bone cavity and to enhance anchoring and stability of the implant. (*See* Ex. 1001, 1:58-63 ("To solve the given problem of enabling a deformation by elasticity, thus causing an expansion adapted to the geometry of the site and to the properties of the material, the flat cross-section zone has, substantially in its median portion, an opening adapted to enable elastic deformation of the zone. The opening defines at least two anchor arms."); *id.*, 2:40-44 ("The zone A2 is flat and has, substantially in its center, an opening 1*b* adapted to enable elastic deformation of the zone A2. More particularly, the opening 1*b* defines at least two anchor arms 1*c* and 1*d*, each having at least one outwardly projecting tooth 1*c*1, 1*d*1."); *id.*, 3:14-20 ("The advantages are readily apparent from the description; in particular, it is to be emphasized and understood that the combination of the two anchor zones A1 and A2 of cylindrical and flat shape, respectively, significantly enhances anchoring and stability of the implant adapted

to the geometry of the bone site and the material properties, namely, a resorptive material.").

Jackson does not expressly teach or suggest an opening median portion of the proximal limb (second end). However, a POSITA looking to improve the anchoring and stability of Jackson'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. (Ex. 1002, ¶149). Both Jackson and Coilard-Lavirotte describe anchor designs that are inserted into a bone cavity, secure to the interior bone wall, and prevent the implant from being removed. (Ex. 1002, ¶150).

Coilard-Lavirotte specifically discloses an arthrodesis implant comprising a first section 4 (first end) and a second section 6 (second end), the second section further comprising a plurality of anchoring branches 10 with anti-return devices (teeth):




(Ex. 1006, FIG. 2 (annotated); *see also id.*, ¶99). Coilard-Lavirotte further discloses that the anchoring branches with the teeth help to improve fixation of the implant. (Ex. 1006, ¶¶99-100). Coilard-Lavirotte discloses how implants used between the first and second bones of interphalangeal joints must have secure fixation to prevent unwanted relative movements that prevent proper healing. (Ex. 1006, ¶8, ¶13, ¶50). Thus, a POSITA 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 given that it is analogous art. (Ex. 1002, ¶¶152-154). Therefore, it would be obvious to combine the opening in the second end of the Coilard-Lavirotte's implant with Jackson's implant. (Ex. 1002, ¶155).

Thus, a POSITA would find this element obvious in view of Jackson and Coilard-Lavirotte. (Ex. 1002, ¶155).

As detailed above, Jackson in view of Coilard-Lavirotte discloses each and every element of claim 15 of the '074 Patent. (Ex. 1002, ¶¶125-155). Thus, claim 15 is obvious in view of Jackson and Coilard-Lavirotte.

### F. Ground 4: Claims 1, 7, 8, 10, 13, 15 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious over Carver and Coilard-Lavirotte

Independent claims 1 and 15, and dependent claims 7, 8, 10, 13, would have been obvious in view of the combination of Carver and Coilard-Lavirotte. (Ex. 1002, ¶¶156-228).

#### 1. Basis for the Combination of Carver and Coilard-Lavirotte

The scope and content of the prior art includes Carver and Coilard-Lavirotte, which collectively disclose all of the elements of claims 1, 7, 8, 10, 13, 15. There are no differences between the subject matter of these claims and the combination of Carver and Coilard-Lavirotte.

Both Carver and Coilard-Lavirotte disclose intramedullary implants for use between interphalangeal joints in the foot. (Ex. 1005, FIG. 7; Ex. 1006, ¶50). Both Carver and Coilard-Lavirotte describe anchor designs that are inserted into a bone cavity, secure to the interior bone wall, and prevent the implant from being removed. (Ex. 1002, ¶¶157-158). A POSITA would recognize that various anchoring

structures can be used to accomplish the same anchoring functionality between an intramedullary implant and a bone. (Ex. 1002, ¶158). Carver's implant comprises an end with a "shouldered, ribbed or helical surface 18" configured for the insertion and retention into a distal or intermediate phalange:

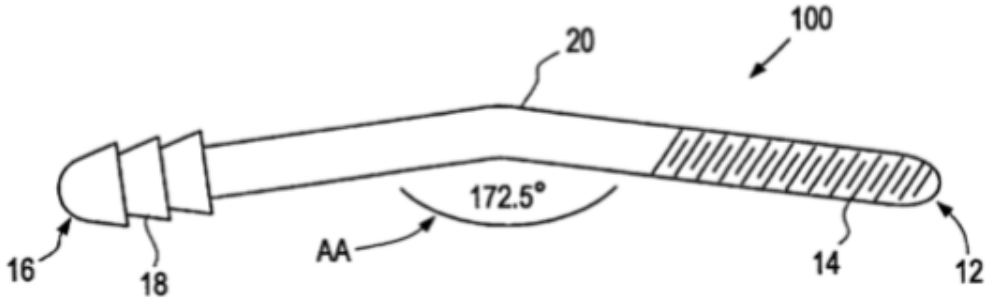



FIG. - 4

(Ex. 1005, FIG. 4; *see also id.*, 4:26-30). These ribbed surfaces are used to prevent the implant from being removed once inserted. (Ex. 1002, ¶159). Coilard-Lavirotte discloses an arthrodesis implant configured to fuse a first and second bone at a joint:

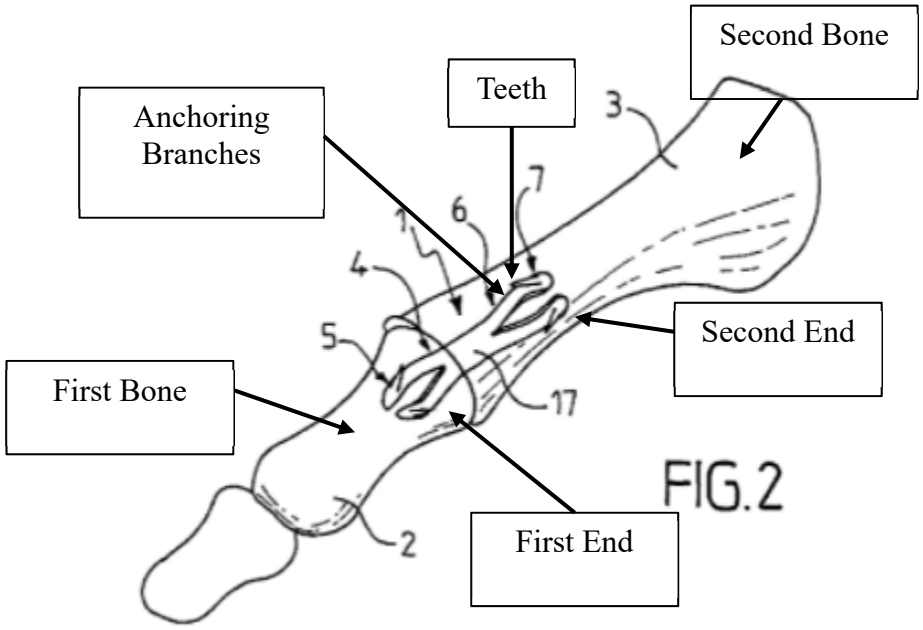



FIG.2

(Ex. 1006, FIG. 2 (annotated), *id.*, ¶99). Coilard-Lavirotte's arthrodesis implant comprises a plurality of anchoring branches 10 with anti-return devices (teeth), configured to anchor the implant to bony tissue of the second bone. (*Id.*).

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. (Ex. 1005, 4:18-34; Ex. 1006, ¶148). A POSITA 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. (Ex. 1002, ¶163). A POSITA would recognize 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). (Ex. 1002, ¶162). A POSITA would know 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. (Ex. 1002, ¶162-163). Thus, a POSITA would be 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. (Ex. 1002, ¶163).

**2. Claims 1, 7, 8, 10, 13, 15 are Obvious over Carver and Coilard-Lavirotte**

*a. Independent Claim 1*

i. [1Pre] An intramedullary implant for use between first and second bone parts, the implant comprising:

Carver discloses an intramedullary implant configured to fuse a joint between two discrete bones such as a proximal phalange (first bone part) and intermediate phalange (second bone part):

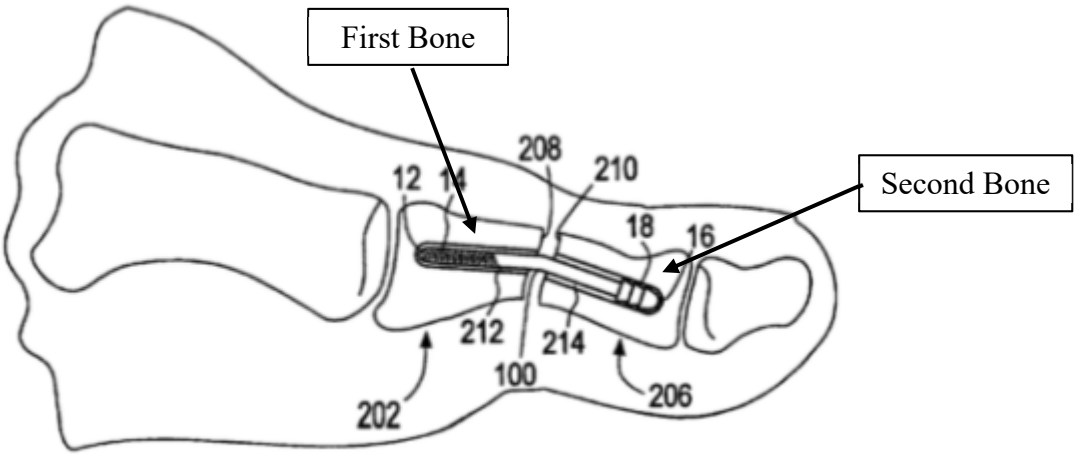



FIG. - 7

(Ex. 1005, FIG. 7 (annotated); *see also id.*, 3:36-40, 4:18-34).

Thus, Carver discloses this element. (Ex. 1002, ¶¶164-166).

ii. [1a] a first threaded end for anchoring to the first bone part;

Carver's intramedullary implant comprises a first end 14 (first threaded end) configured to anchor to bored distal surface within the proximal phalange (first bone) with a threaded surface:

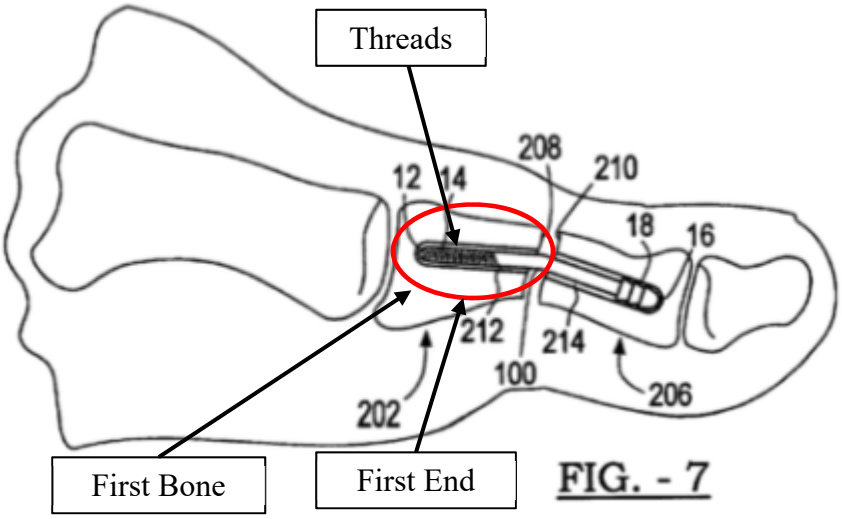



FIG. - 7

(Ex. 1005, FIG.7 (annotated); *see also id.*, 5:20-26).

Thus, Carver discloses this element. (Ex. 1002, ¶¶167-168).

iii. [1b] a second end extending from the first end for anchoring to the second bone part,

Carver's implant comprises a second end 16 configured for the insertion and retention (anchoring) into a distal or intermediate phalange (second bone):

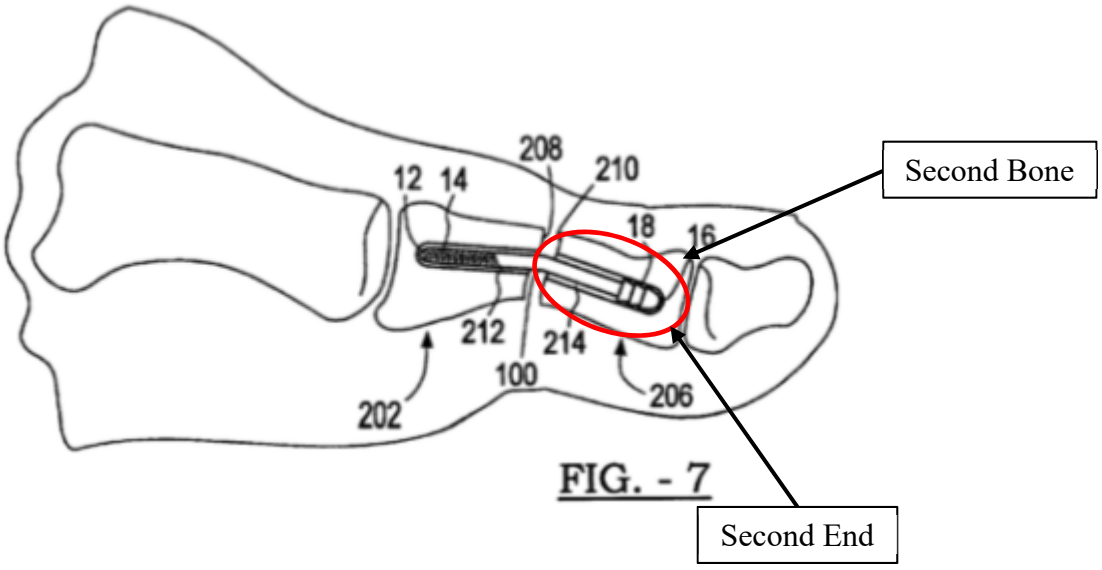



FIG. - 7

(Ex. 1005, FIG. 7 (annotated); *id.*, 4:26-30). A POSITA would understand that the barbed or ribbed surface of the second end anchors in a press-fit motion to a cavity of the second bone at a sufficient depth for a secure fixation, thereby anchoring the implant in the second bone part. (Ex. 1002, ¶¶169-170).

Thus, Carver discloses this element. (Ex. 1002, ¶171).

iv. [1c] the second end having a longitudinal axis, a body portion, and a plurality of teeth projecting from the body portion,

Carver's implant comprises a second end 16 with a "shouldered, ribbed or helical surface 18" (plurality of teeth) configured for the insertion and retention into a distal or intermediate phalange (second bone):

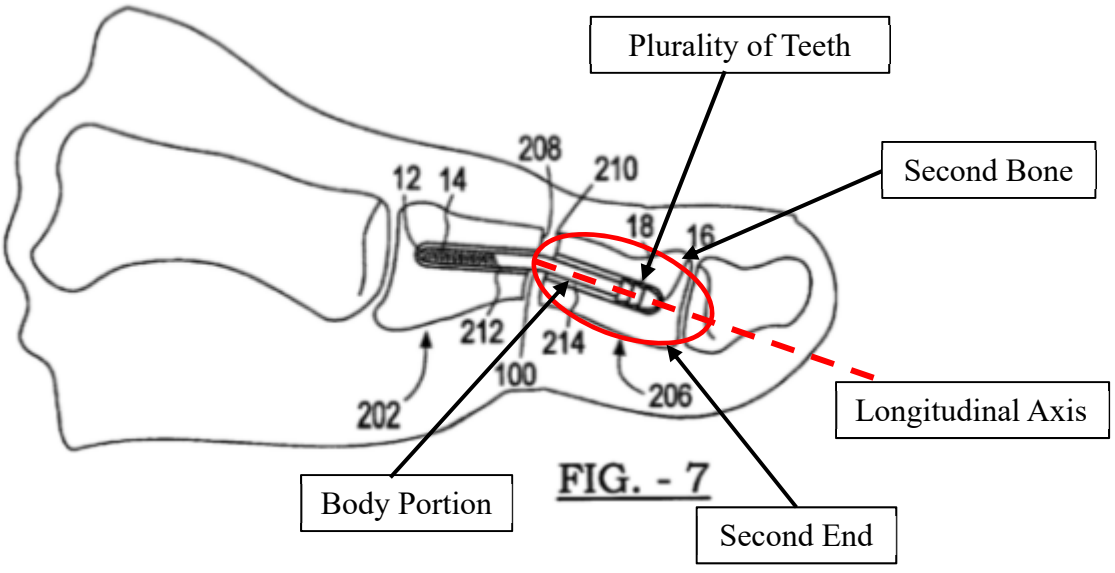



FIG. - 7

(Ex. 1005, FIG. 7 (annotated); *id.*, 4:26-30). A POSITA looking at Carver 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. (Ex. 1002, ¶¶172-173).

Thus, Carver discloses this element, or at least a POSITA would find this element obvious in view of the disclosure of Carver. (Ex. 1002, ¶¶174).

v. [1d] 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,

Carver's implant comprises a second end 16 with a "shouldered, ribbed or helical surface 18" (plurality of teeth) configured for the insertion and retention into a distal or intermediate phalange (second bone):

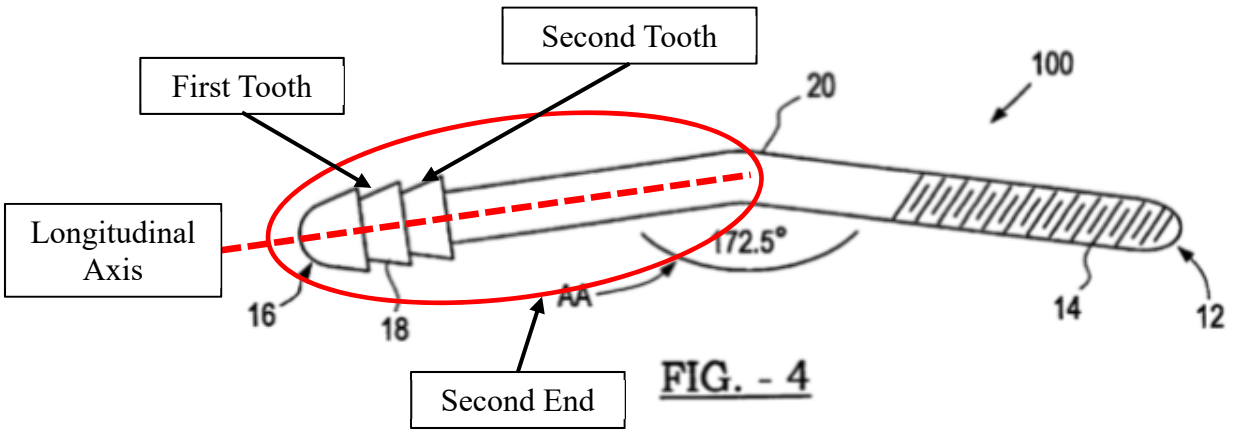



FIG. - 4

(Ex. 1005, FIG. 4 (annotated); *id.*, 4:26-30). A POSITA looking at Carver would understand the spacing along a longitudinal axis of a first tooth and a second tooth that are aligned in a direction along the longitudinal axis. (Ex. 1002, ¶¶175-176).

Thus, Carver discloses this element, or at least a POSITA would find this element obvious in view of the disclosure of Carver. (Ex. 1002, ¶177).

vi. [1e] the first and second teeth extending from the body portion in a same direction, and

Figure 4 of Carver illustrates a "shouldered, ribbed or helical surface 18" along a longitudinal axis of the second end 16:

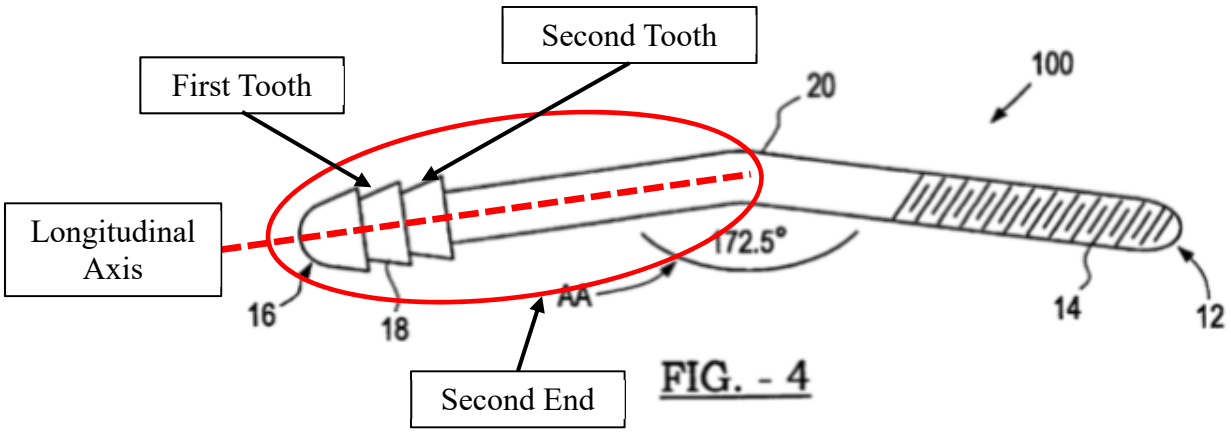



FIG. - 4

(Ex. 1005, FIG. 4 (annotated); *id.*, 4:26-30). A POSITA looking at Carver would understand that a first and second tooth face the same direction, as shown in Figure 4. (Ex. 1002, ¶179). Additionally, the first tooth and second tooth are configured for a press-fit application that allow the second end to be inserted into the bone cavity but prevent the second end from being removed. (Ex. 1002, ¶178-178). A POSITA

looking at Carver would understand that the first tooth and second tooth face the same direction, such that they oppose a force to remove the implant from the bone cavity. (Ex. 1002, ¶180).

Thus, Carver discloses this element, or at least a POSITA would find this element obvious in view of the disclosure of Carver. (Ex. 1002, ¶¶178-180).

vii. [1f] 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.

The purpose of the first and third tooth of the second end is to apply forces in different directions within the bone cavity of the second bone. (*See* Ex. 1001, 2:40-44 ("The zone A2 is flat and has, substantially in its center, an opening 1*b* adapted to enable elastic deformation of the zone A2. More particularly, the opening 1*b* defines at least two anchor arms 1*c* and 1*d*, each having at least one outwardly projecting tooth 1*c*1, 1*d*1."); *id.*, 3:14-20 ("The advantages are readily apparent from the description; in particular, it is to be emphasized and understood that the combination of the two anchor zones A1 and A2 of cylindrical and flat shape, respectively, significantly enhances anchoring and stability of the implant adapted to the geometry of the bone site and the material properties, namely, a resorptive material.").

Although Carver does not expressly teach or suggest a first and third tooth extending from opposite directions of the body portion of the second end, 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. (*See* Ex. 1005, FIG. 7; Ex. 1002, ¶183). A POSITA would readily look to use the anchoring branches and anti-return devices (teeth) disclosed by Coilard-Lavirotte given that it is analogous art when looking for a way to improve the fixation and anchoring of Carver's implant in the proximal interphalangeal joint of the toes. (Ex. 1002, ¶184).

Coilard-Lavirotte discloses an arthrodesis implant comprising a first section 4 (first end) and a second section 6 (second end), the second section further comprising a plurality of anchoring branches 10 with anti-return devices (teeth):

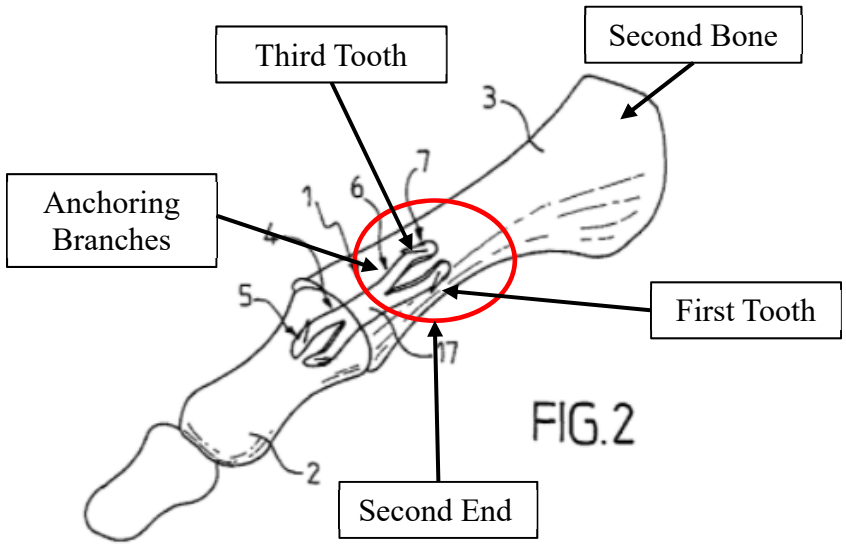



FIG.2

(Ex. 1006, FIG. 2 (annotated); *see also id.*, ¶99). Coilard-Lavirotte further discloses that the anchoring branches with the teeth help to improve fixation of the implant. (Ex. 1006, ¶¶99-100). A POSITA 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. (Ex. 1002, ¶186). In addition, a POSITA would understand 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.*).

Thus, a POSITA would find this element obvious in view of Carver and Coilard-Lavirotte. (Ex. 1002, ¶187).

As detailed above, Carver in view of Coilard-Lavirotte discloses each and every element of claim 1 of the '074 Patent. (Ex. 1002, ¶¶181-187). Thus, claim 1 is obvious in view of Carver and Coilard-Lavirotte.

*b. Independent Claim 15*

i. [15Pre] An intramedullary implant for use between first and second bone parts, the implant comprising:

For at least the reasons set forth in Section VII.F.2.a.i, Carver discloses this element. (*See* Ex. 1005, FIG. 7, 3:36-40, 4:18-34; Ex. 1002, ¶¶164-166, 188-190).

ii. [15a] a first threaded end for anchoring to the first bone part;

For at least the reasons set forth in Section VII.F.2.a.ii, Carver discloses this element. (*See* Ex. 1005, FIG.7, 5:20-26; Ex. 1002, ¶¶167-168, 138-139).

iii. [15b] a second end extending from the first end for anchoring to the second bone part and having a plurality of outwardly projecting teeth,

For at least the reasons set forth in Sections VII.F.2.a.iii and VII.F.2.a.iv, Carver discloses this element, or at least a POSITA would find this element obvious in view of the disclosure of Carver. (*See* Ex. 1005, FIG. 7; 4:26-30; Ex. 1002, ¶¶169-174, 193-194).

iv. [15c] 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

For at least the reasons set forth in Section VII.F.2.a.v, Carver discloses this element, or at least a POSITA would find this element obvious in view of the disclosure of Carver. (*See* Ex. 1005, FIG. 4, 4:26-30; Ex. 1002, ¶¶176-177, 195-196).

v. [15d] at least the first tooth extending in a different direction than a third tooth of the plurality of teeth,

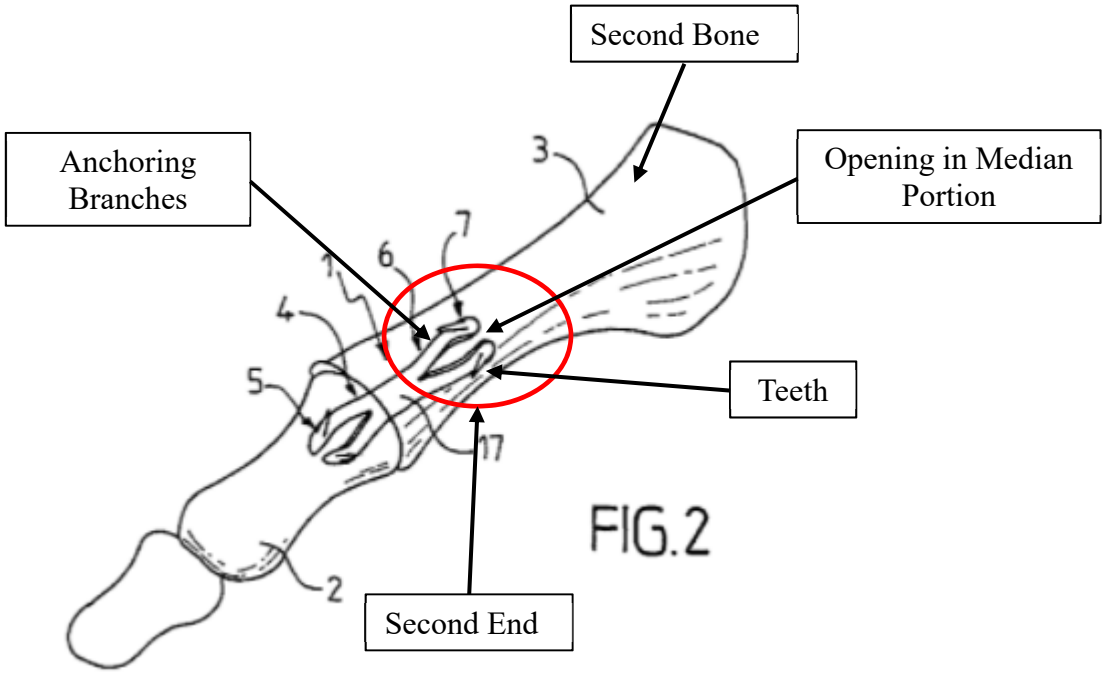
For at least the reasons set forth in Section VII.F.2.a.vii, a POSITA would find this element obvious in view of Carver and Coilard-Lavirotte. (*See* Ex. 1005, FIG. 4, 4:26-30; Ex. 1002, ¶¶181-187, 197-198).

vi. [15e] the second end having an opening in a median portion thereof.

As discussed above, the purpose of the opening median portion of the second end is to allow a portion of the second end to elastically deform upon entry into a bone cavity and to enhance anchoring and stability of the implant. (*See* Section VII.E.2.a.vi (citing Ex. 1001, 1:58-63, 2:40-44, 3:14-20).

Carver does not expressly teach or suggest an opening median portion of the proximal limb (second end). However, a POSITA 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. (Ex. 1002, ¶200). Both Carver and Coilard-Lavirotte describe anchor designs that are inserted into a bone cavity, secure to the interior bone wall, and prevent the implant from being removed. (Ex. 1002, ¶201).

Coilard-Lavirotte specifically discloses an arthrodesis implant comprising a first section 4 (first end) and a second section 6 (second end), the second section further comprising a plurality of anchoring branches 10 with anti-return devices (teeth):




(Ex. 1006, FIG. 2 (annotated); *see also id.*, ¶99). Coilard-Lavirotte further discloses that the anchoring branches with the teeth help to improve fixation of the implant. (Ex. 1006, ¶¶99-100). Coilard-Lavirotte discloses how implants used between the first and second bones of interphalangeal joints must have secure fixation to prevent unwanted relative movements that prevent proper healing. (Ex. 1006, ¶8, ¶13, ¶50). Thus, a POSITA 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. (Ex. 1002, ¶203). Therefore, it would be obvious to combine the opening in the second end of the Coilard-Lavirotte's implant with Carver's implant. (Ex. 1002, ¶204).

Thus, a POSITA would find this element obvious in view of Carver and Coilard-Lavirotte. (Ex. 1002, ¶¶199-204).

As detailed above, Carver in view of Coilard-Lavirotte discloses each and every element of claim 15 of the '074 Patent. (Ex. 1002, ¶¶188-204). Thus, claim 15 is obvious in view of Carver and Coilard-Lavirotte.

*c. Dependent Claims 7, 8, 10, 13*

i. Claim 7: The intramedullary implant of claim 1, 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.

Carver discloses an intramedullary implant comprising a first end 14 and a second 16, wherein the first end and second end are offset at an angle of approximately 172.5 degrees, at the central potion 20, to anatomically conform to the joint angle.

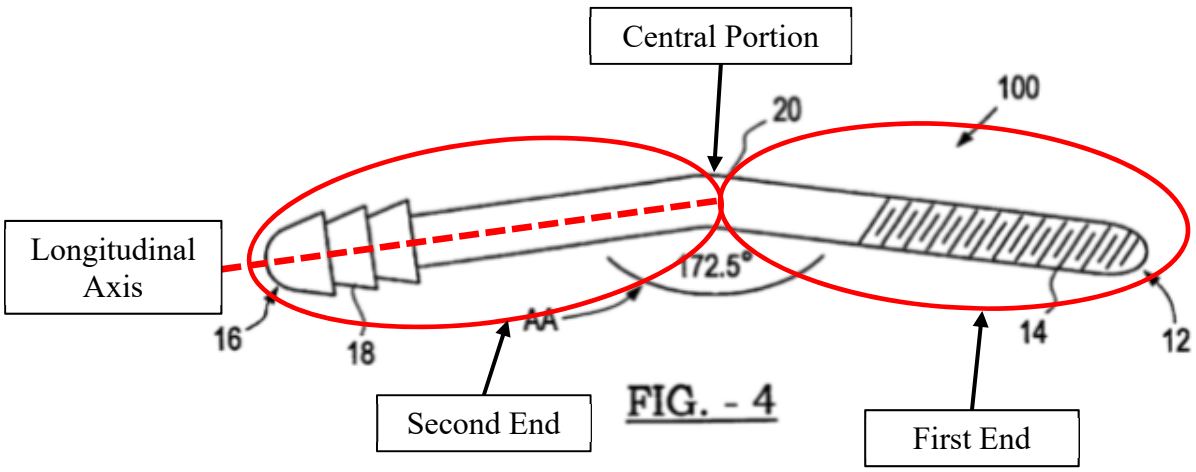



FIG. - 4

(Ex. 1005, FIG. 4 (annotated); *id.*, 4:35-59). A POSITA would recognize that the offset angle of 7.5 degrees is the supplementary angle of the 172.5° angle in FIG 4 (any angle + its supplementary angle = 180°) and the 7.5° is less than 30 degrees. (Ex. 1002, ¶¶205-206).

Thus, this claim is disclosed by Carver, or at least this claim would have been obvious to a POSITA in view of the disclosure of Carver. (Ex. 1002, ¶207).

ii. Claim 8: The intramedullary implant of claim 7, 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.

Carver's intramedullary implant comprises a central portion 20 between the first end 14 and the second end 16 creating an angle between respective ends. The angle is configured to match an anatomic angle of the joint and properly align the proximal phalange (first bone) and intermediate phalange (second bone):

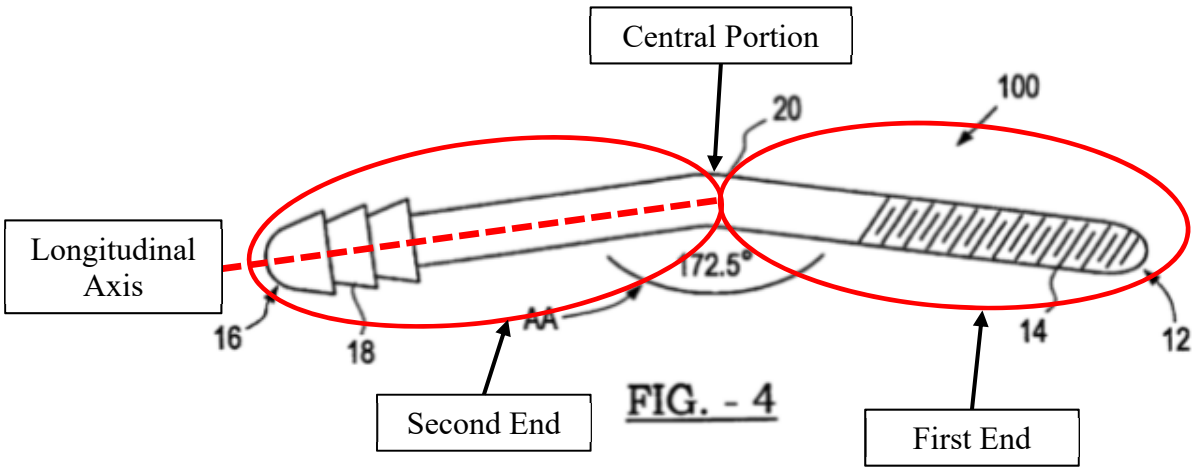



FIG. - 4

(Ex. 1005, FIG. 4 (annotated); *id.*, 4:35-59).

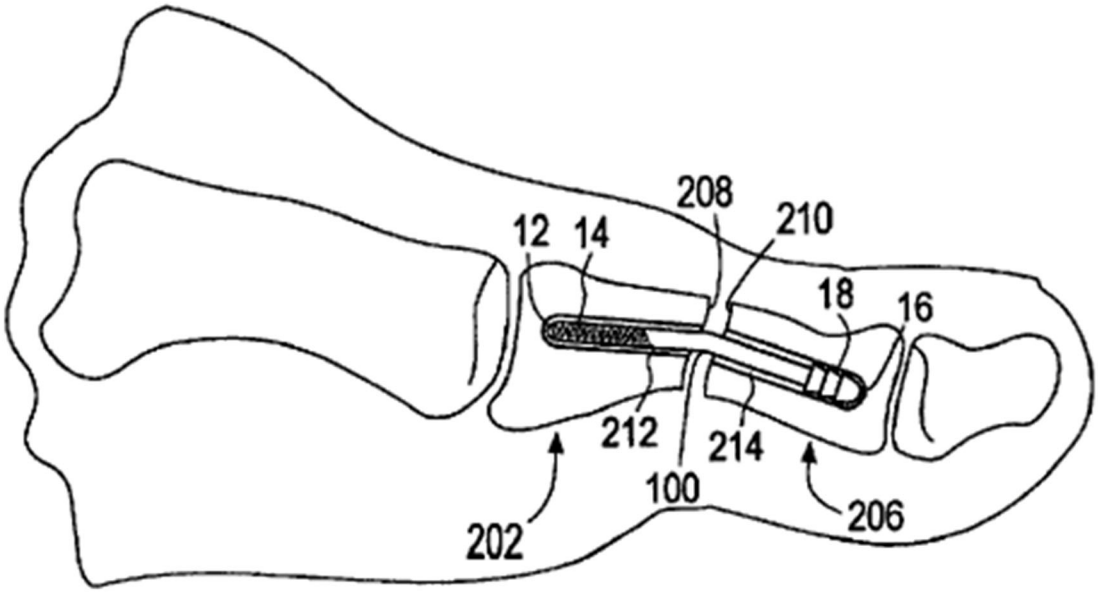



FIG. - 7

In reference for FIGS. 5-7, Carver describes how "the threaded portion 14 of the device 100 is screwed into the bore 212 of the distal surface 208 of the proximal phalange 202 to a sufficient depth with the remaining portion of the device 100 being oriented in an anatomically correct position with respect to the intermediate phalange 206." (Ex. 1005, 5:21-26). As can be seen in Figure 7 above, implant 100 is positioned so that the offset is located at the joint line. (Ex. 1005, FIG. 7). A POSITA would understand that the offset angle at the central potion is at the arthrodesis line between the first bone and the second bone. (Ex. 1002, ¶¶208-210).

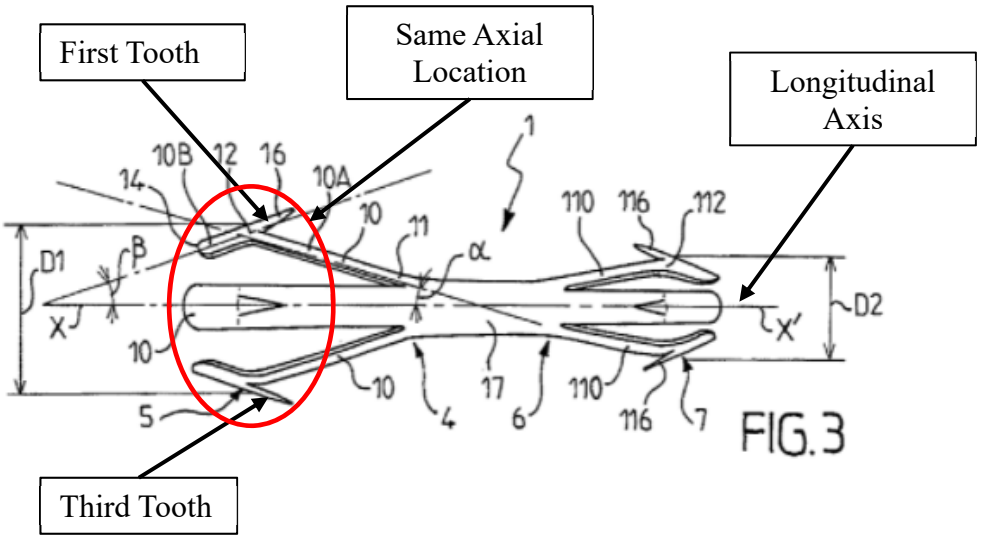
Thus, this claim is disclosed by Carver, or at least this claim would have been obvious to a POSITA, in view of the disclosure of Carver. (Ex. 1002, ¶211).

iii. Claim 10: The intramedullary implant of claim 1, wherein the first and third teeth are positioned at the same axial location along the longitudinal axis of the second end.

As discussed above, the purpose of the first and third tooth of the second end is to apply forces in different directions within the bone cavity of the second bone. (*See* Section VII.F.2.a.vii (citing Ex. 1001, 2:40-44, 3:14-20).

Although Carver does not expressly teach or suggest a first and third tooth extending from opposite directions of the body portion of the second end, 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. (*See* Ex. 1005, FIG. 7; Ex. 1002, ¶213). A POSITA 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. (Ex. 1002, ¶214).

Coilard-Lavirotte's intramedullary implant comprises a plurality of anti-return devices 16 (teeth) equidistantly spaced on the anchoring branches 10:




(Ex. 1006, FIG. 3 (annotated); *see also id.*, ¶99, ¶134). A POSITA would understand that a first tooth and a third tooth are equidistantly spaced relative to a longitudinal axis and thus, in the same axial location along the longitudinal axis, as depicted in Figure. 3. (Ex. 1002, ¶216). Coilard-Lavirotte further discloses the advantages of multiple anchoring points in different directions:

> [T]he implant … has an excellent seating in the bones, which is due not only to the multiplicity of anchoring points but also to the geometry of its means of fixing, which confer on the built-in links thus produced a firm and rigid resistance, whatever the direction of the mechanical stress on the link.

(Ex. 1006, ¶181). Thus, a POSITA 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. (Ex. 1002, ¶¶212-218).

Thus, a POSITA would find this claim obvious in view of Carver and Coilard-Lavirotte. (Ex. 1002, ¶219).

iv. Claim 13: The intramedullary implant of claim 1, wherein a cross-section of the body portion is non-circular.

Carver's implant comprises a second end 16 with a "shouldered, ribbed or helical surface 18" (plurality of teeth) configured for the insertion and retention into a distal or intermediate phalange (second bone):

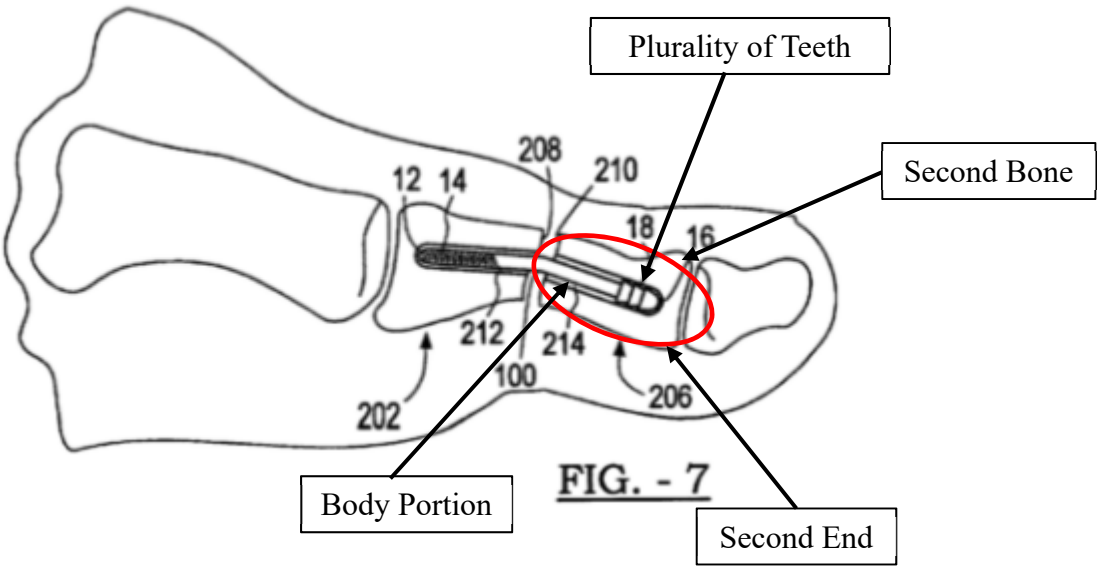
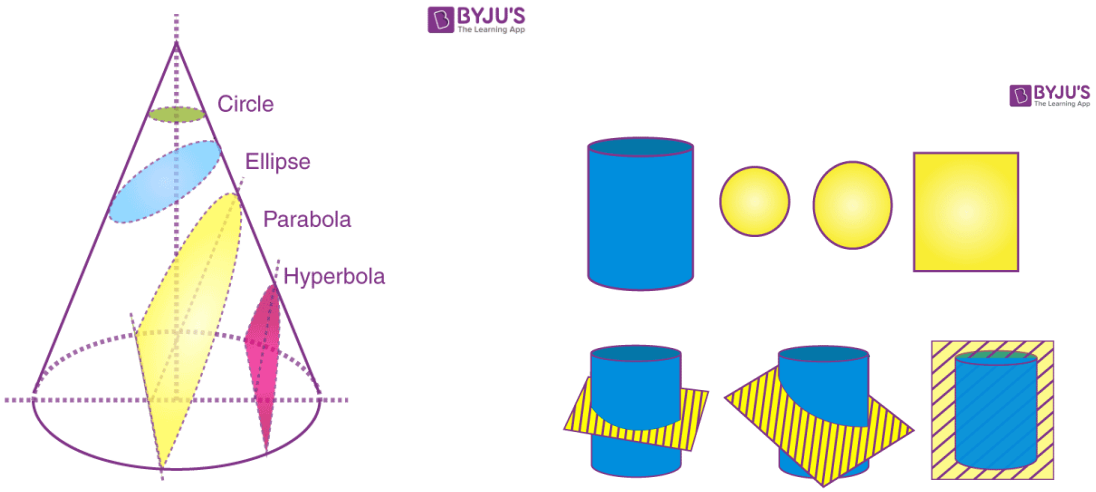



FIG. - 7

(Ex. 1005, FIG. 7 (annotated); *see also id.*, 4:26-30). While the shape of the implant in Carver is generally cylindrical, a POSITA would understand that a cross-section

of the proximal limb (body portion of the second end), viewed at any relative angle to the longitudinal axis, would include a variety of non-circular shapes such as ellipses, parabolas, hyperbolas, or squares, as shown in the image below:




(Ex. 1009, 3; Ex. 1002, ¶222).

Thus, this claim is disclosed by Carver, or at least this claim would have been obvious to a POSITA in view of the disclosure of Carver. (Ex. 1005, FIG. 2; Ex. 1002, ¶224).

To the extent that Carver does not disclose this element, Coilard-Lavirotte discloses an arthrodesis implant 1 that is formed by a tubular element, where "the tubular element is formed by any sectional profile, optionally open (U-, T, L-shaped, square, circular, and the like)." (Ex. 1006, ¶124). Coilard-Lavirotte further describes how there are instances where non-circular implants may be advantageous:

> [T]he cross-sections 2T, 3T (represented by dotted lines in FIG. 8) of two successive phalanges generally have one or more favoured

> directions of extension and not a constant radius under all azimuths, i.e., the cross-sections 2T, 3T are not generally circular but rather ovoid or polylobed. The implant can advantageously reproduce the existing natural offset in alignment between the favoured directions of extension unique to each cross-section and thus share in each phalange the Zones most provided with bony matter in order to improve the fixing, both in extent, thus in stability, and in strength.

(Ex. 1006, ¶119). Thus, a POSITA 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. (Ex. 1002, ¶¶227).

Thus, a POSITA would find this claim obvious in view of Carver and Coilard-Lavirotte. (Ex. 1002, ¶¶220-228).

### G. Ground 5: Claims 1, 7, 8, 10, 13, 15 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious over Pietrzak in view of Coilard-Lavirotte

Independent claims 1 and 15, and dependent claims 7, 8, 10, 13, would have been obvious in view of the combination of Pietrzak and Coilard-Lavirotte. (Ex. 1002, ¶¶229-302).

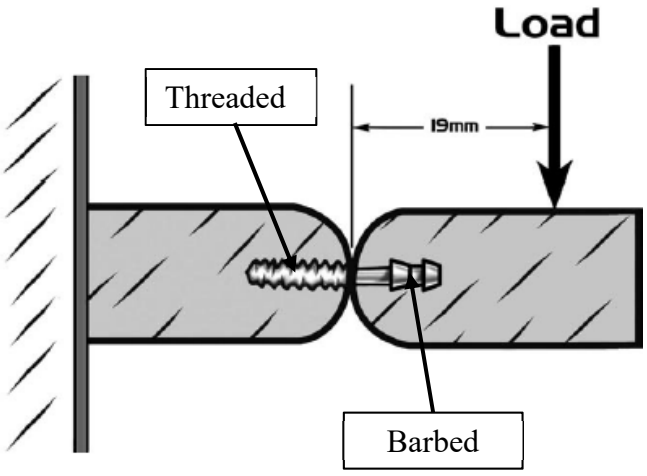
#### 1. Basis for the Combination of Pietrzak and Coilard-Lavirotte

The scope and content of the prior art includes Pietrzak and Coilard-Lavirotte, which collectively disclose all of the elements of claims 1, 7, 8, 10, 13, 15. There are

no differences between the subject matter of these claims and the combination of Pietrzak and Coilard-Lavirotte.

Both Pietrzak and Coilard-Lavirotte disclose intramedullary implants for use between interphalangeal joints in the foot. (Ex. 1007, 288; Ex. 1006, ¶50). Both Pietrzak and Coilard-Lavirotte describe anchor designs that are inserted into a bone cavity, secure to the interior bone wall, and prevent the implant from being removed. (Ex. 1002, ¶230-233). A POSITA would recognize that various anchoring structures can be used to accomplish the same anchoring functionality between an intramedullary implant and a bone. (Ex. 1002, ¶233).

Pietrzak discloses a fixation implant that comprises a threaded end and a barbed distal end configured to anchor the distal end into a prepared cavity of the intermediate phalange:



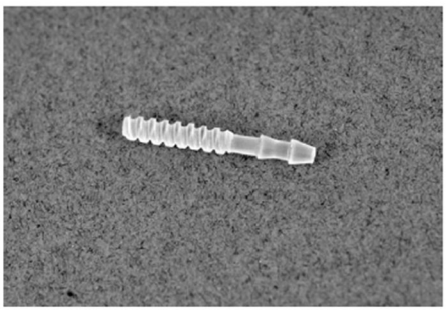



FIGURE 1 Photograph of bioabsorbable hammer toe fixation implant.

(Ex. 1007, FIGS. 1, 2 (annotated); *see also id.*, 289-90). The barbed distal end further comprises two conically shaped barbs that anchor the fixation implant to the bone. (*Id.*).

Coilard-Lavirotte discloses an arthrodesis implant configure to fuse a first and second bone at a joint. (Ex. 1006, ¶50, ¶99). Coilard-Lavirotte's arthrodesis implant comprises a plurality of anchoring branches 10 with anti-return devices (teeth), configured to anchor the implant to bony tissue of the second bone. (*Id.*).

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. (Ex. 1007, 290; Ex. 1006, ¶148). A POSITA 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. (Ex. 1002, ¶¶233-234). A POSITA would recognize 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 to obtain a predictable result (i.e., better anchoring). (Ex. 1002, ¶233). A POSITA would know 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. (Ex.

1002, ¶234). Thus, a POSITA would be 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.

Additionally, Pietrzak's fixation implant is configured to simulate the natural fixation of the proximal interphalangeal joint. (Ex. 1007, 290). This disclosure guides a POSITA to angle the respective ends between the first bone and the second bone the contour the fixation implant to the natural angle of the joint. (Ex. 1002, ¶¶230-233). Similarly, Coilard-Lavirotte discloses a relative angle between 10° and 20°, between a first end and second end of an arthrodesis implant. (Ex. 1006, ¶115). Coilard-Lavirotte further discloses that the relative angle "can actually reproduce ideally the natural angling of the proximal phalange relative to the distal phalange and, more precisely, the angle formed by the medullary axes of the phalanges." (*Id.*).

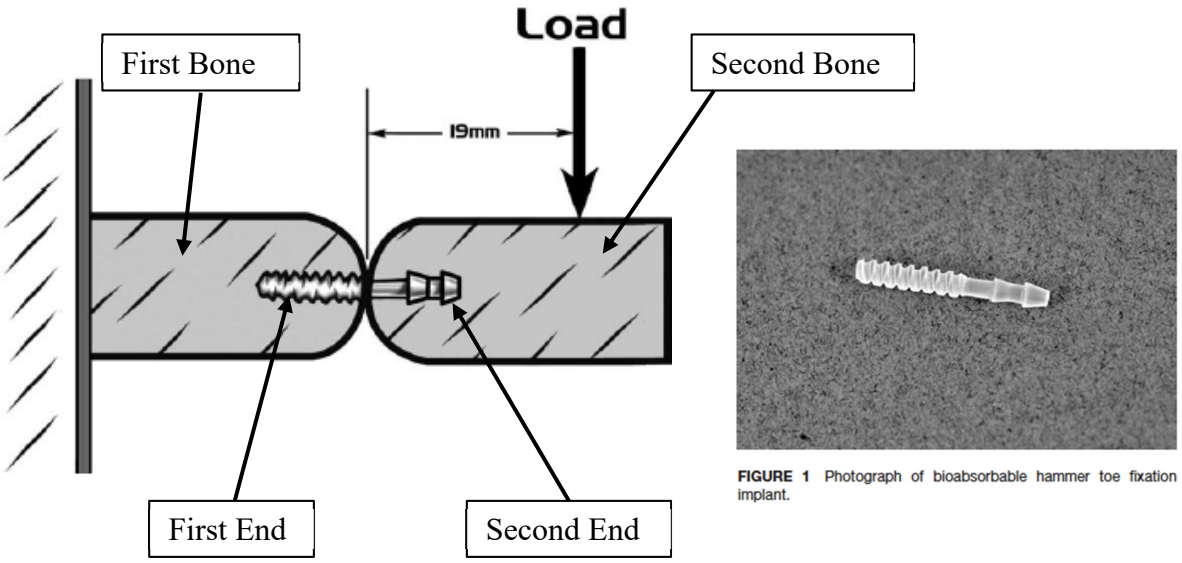
Thus, a POSITA would be motivated to combine Pietrzak and Coilard-Lavirotte and modify Pietrzak's fixation implant to conform to the anatomically accurate angle of the fixation joint. (Ex. 1002, ¶¶229-233).

**2. Claims 1, 7, 8, 10, 13 and 15 are Obvious over Pietrzak in view of Coilard-Lavirotte**

*a. Independent Claim 1*

i. [1Pre] An intramedullary implant for use between first and second bone parts, the implant comprising:

Pietrzak discloses a fixation implant for the proximal interphalangeal joint arthrodesis between a first (first bone) and second phalangeal bone (second bone) in the foot:

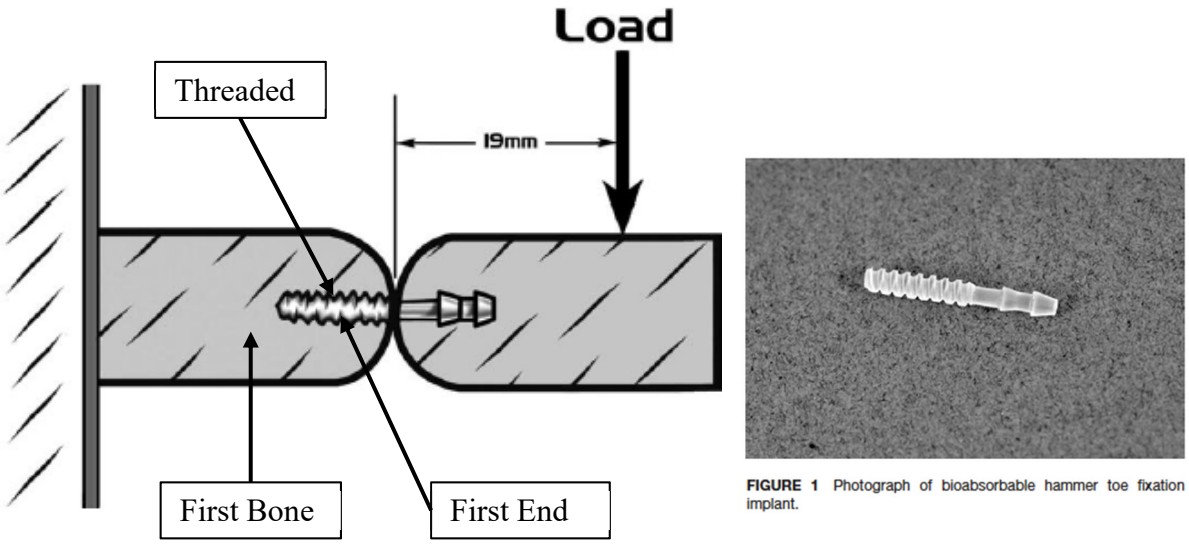



(Ex. 1007, FIGS. 1, 2 (annotated); *see also id.*, 288 ("A Bioabsorbable Fixation Implant for Use in Proximal Interphalangeal Joint (Hammer Toe) Arthrodesis: Biomechanical Testing in a Synthetic Bone Substrate")).

Thus, this element is disclosed by Pietrzak. (Ex. 1002, ¶¶235-238).

ii. [1a] a first threaded end for anchoring to the first bone part;

Pietrzak's fixation implant comprises a threaded proximal end (first threaded end) configured to be torqued into a prepared hole in a first bone with the threaded surface:

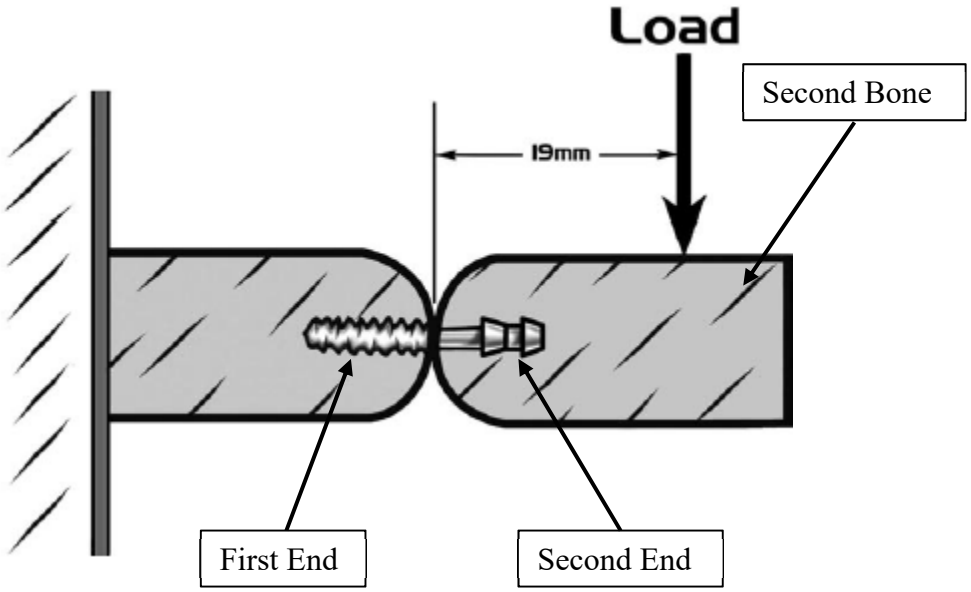



(Ex. 1007, FIGS. 1, 2 (annotated); *see also id.*, 288 ("This study biomechanically compared a threaded/barbed bioabsorbable fixation implant made of a copolymer of 82% poly-L-lactic acid and 18% polyglycolic acid with a 1.57-mm Kirschner wire using the devices to fix 2 synthetic bone blocks together. Constructs were evaluated by applying a cantilever load, which simulated a plantar force on the middle phalanx.")).

Thus, this element is disclosed by Pietrzak. (Ex. 1002, ¶¶239-241).

iii. [1b] a second end extending from the first end for anchoring to the second bone part,

Pietrzak's fixation implant comprises a barbed distal end configured to anchor the distal end into a prepared cavity of the intermediate phalange (second bone):



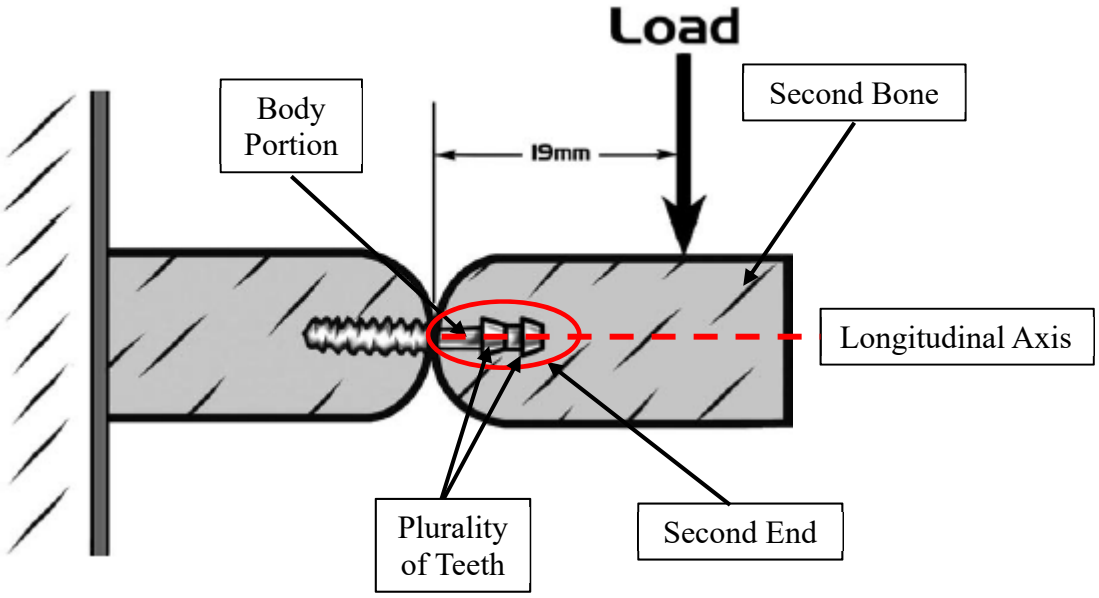

(Ex. 1007, FIG. 2 (annotated); *see also id.*, 290 ("The barbed distal end was then inserted into a similar hole (untapped 1.57 mm diameter, 8 mm deep) in a second block.")).

Thus, this element is disclosed by Pietrzak. (Ex. 1002, ¶¶242-244).

iv. [1c] the second end having a longitudinal axis, a body portion, and a plurality of teeth projecting from the body portion,

Pietrzak's fixation implant comprises a barbed distal end (second end), further comprising two conically shaped barbs (plurality of teeth projection from the body

portion) configured to anchor the distal end into a prepared cavity of the intermediate phalange (second bone):

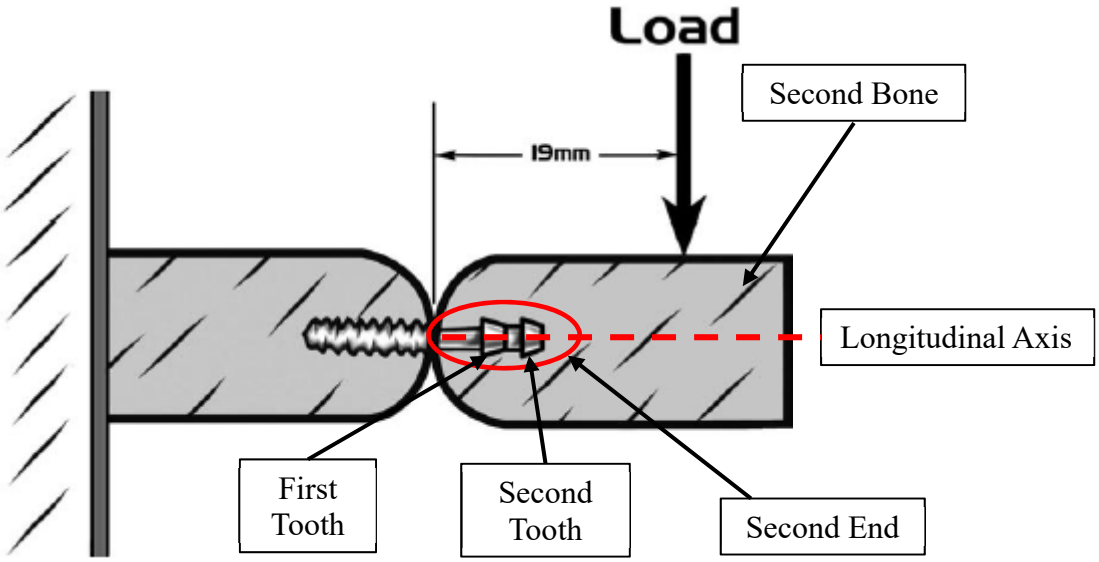



(Ex. 1007, FIG. 2 (annotated); *see also id.*, 289-90). A POSITA would understand that the barbs project from the second end of implant is configured to anchor the implant into a hole in the second bone of the proximal interphalangeal joint. (Ex. 1002, ¶245-246). The barbed end is configured to be inserted into the hole such that the implant may be inserted into the hole but cannot be removed and act like teeth. (Ex. 1002, ¶¶246).

Thus, this element is disclosed by Pietrzak, or at least a POSITA would find this element obvious in view of the disclosure of Pietrzak. (Ex. 1002, ¶¶245-247).

v. [1d] 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,

Pietrzak's fixation implant comprises a barbed distal end (second end), further comprising two conically shaped barbs (first tooth spaced from a second tooth) configured to anchor the distal end into a prepared cavity of the intermediate phalange (second bone):



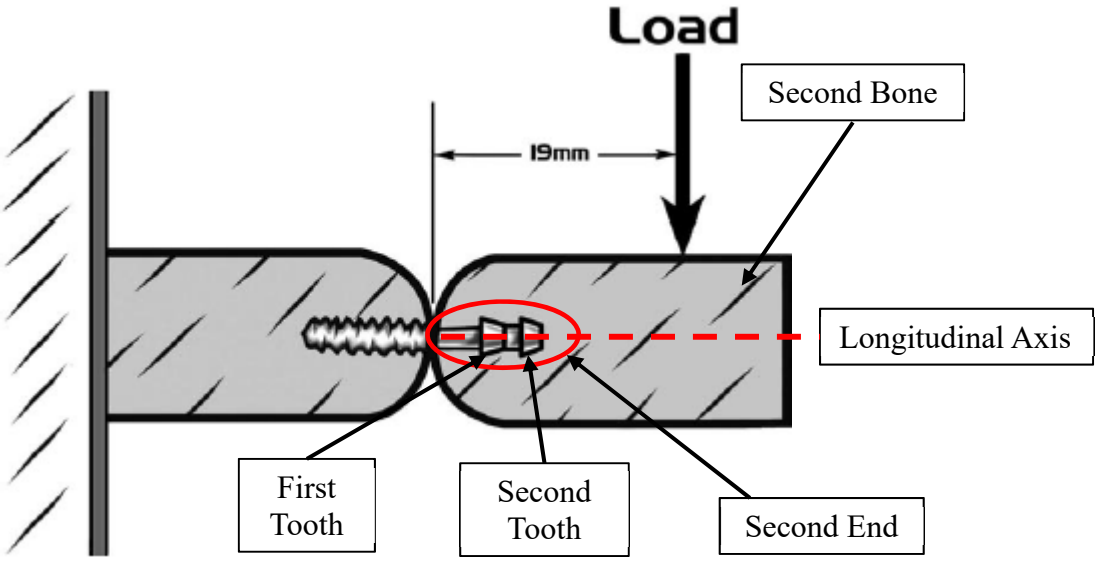

(Ex. 1007, FIG. 2 (annotated); *see also id.*, 289-90). A POSITA would understand that Pietrzak discloses two barbs (a first and second tooth) configured to anchor the implant to the second bone of the proximal interphalangeal joint. (Ex. 1002, ¶248). Additionally, the first tooth and second tooth are to be inserted into the hole such that the implant may be inserted into the hole but cannot be removed. (Ex. 1002, ¶248-249). A POSITA would understand that the first tooth and second tooth are

spaced apart and face the same direction, such that they oppose a force to remove the implant from the bone cavity. (Ex. 1002, ¶249).

Thus, this element is disclosed by Pietrzak, or at least a POSITA would find this element obvious in view of the disclosure of Pietrzak. (Ex. 1002, ¶¶248-250).

vi. [1e] the first and second teeth extending from the body portion in a same direction,

Pietrzak's fixation implant comprises a barbed distal end (second end), further comprising two conically shaped barbs (first tooth spaced from a second tooth) configured to anchor the distal end into a prepared cavity of the intermediate phalange (second bone):




(Ex. 1007, FIG. 2 (annotated); *see also id.*, 289-90). A POSITA would understand that the first and second tooth face the same direction, as shown in Figure 2. (Ex. 1002, ¶¶251). A POSITA would further understand that Pietrzak discloses two barbs

(a first and second tooth) configured to anchor the implant to the second bone of the proximal interphalangeal joint. (Ex. 1002, ¶251-252). Additionally, a POSITA would understand that the first tooth and second tooth are to be inserted into the hole such that the implant may be inserted into the hole but cannot be removed. (Ex. 1002, ¶252). A POSITA would also understand that the first tooth and second tooth are spaced apart and face the same direction, such that they oppose a force to remove the implant from the bone cavity. (*Id.*).

Thus, this element is disclosed by Pietrzak, or at least this element would have been obvious to a POSITA in view of the disclosure of Pietrzak. (Ex. 1002, ¶¶251-253).

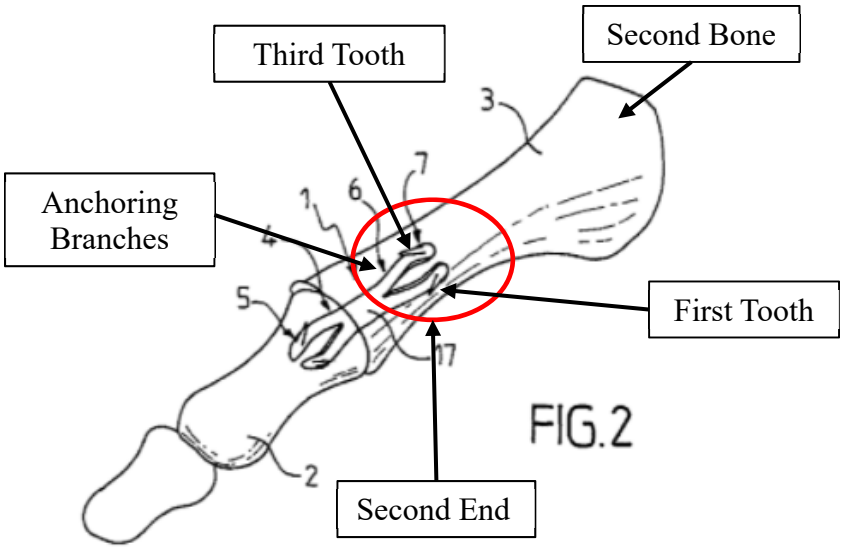
vii. [1f] and at least the first tooth extending from the body portion in a different direction than a direction a third tooth of the plurality of teeth extends from the body portion.

As discussed above, the purpose of the first and third tooth of the second end is to apply forces in different directions within the bone cavity of the second bone. (*See* Section VII.F.2.a.vii (*citing* Ex. 1001, 2:40-44, 3:14-20).

Although Pietrzak does not expressly teach or suggest a first and third tooth extending from opposite directions of the body portion of the second end, 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. (*See* Ex. 1007, FIGS. 1, 2; Ex. 1002, ¶¶254-255). A POSITA looking for a way to improve the fixation and anchoring of Pietrzak'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. (Ex. 1002, ¶257).

Coilard-Lavirotte discloses an arthrodesis implant comprising a first section 4 (first end) and a second section 6 (second end), the second section further comprising a plurality of anchoring branches 10 with anti-return devices (teeth):




(Ex. 1006, FIG. 2 (annotated); *see also id.*, ¶99). Coilard-Lavirotte further discloses that the anchoring branches with the teeth help to improve fixation of the implant. (Ex. 1006, ¶¶99-100). A POSITA 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. (Ex. 1002, ¶258-259). In addition, a POSITA would understand 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. (Ex. 1002, ¶259).

Thus, a POSITA would find this element obvious in view of Pietrzak and Coilard-Lavirotte. (Ex. 1002, ¶260).

As detailed above, Pietrzak in view of Coilard-Lavirotte discloses each and every element of claim 1 of the '074 Patent. (Ex. 1002, ¶¶254-260). Thus, claim 1 is obvious in view of Pietrzak and Coilard-Lavirotte.

*b. Independent Claim 15*

i. [15Pre] An intramedullary implant for use between first and second bone parts, the implant comprising:

For at least the reasons set forth in Section VII.G.2.a.i, Pietrzak discloses this element. (*See* Ex. 1007, FIGS. 1, 2, 288; Ex. 1002, ¶¶235-238, 261-263).

ii. [15a] a first threaded end for anchoring to the first bone part;

For at least the reasons set forth in Section VII.G.2.a.ii, Pietrzak discloses this element. (*See* Ex. 1007, FIGS. 1, 2, 288; Ex. 1002, ¶¶239-241, 264-265).

iii. [15b] a second end extending from the first end for anchoring to the second bone part and having a plurality of outwardly projecting teeth,

For at least the reasons set forth in Sections VII.G.2.a.iii and VII.G.2.a.iv, Pietrzak discloses this element or at least a POSITA would find this element obvious in view of the disclosure of Pietrzak. (*See* Ex. 1007, FIG. 2, 289-90; Ex. 1002, ¶¶242-244-247, 266-267).

iv. [15c] 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,

For at least the reasons set forth in Section VII.G.2.a.v, Pietrzak discloses this element, or at least a POSITA would find this element obvious in view of the disclosure of Pietrzak. (*See* Ex. 1007, FIG. 2, 289-90; Ex. 1002, ¶¶248-250, 268-269).

v. [15d] and at least the first tooth extending in a different direction than a third tooth of the plurality of teeth,

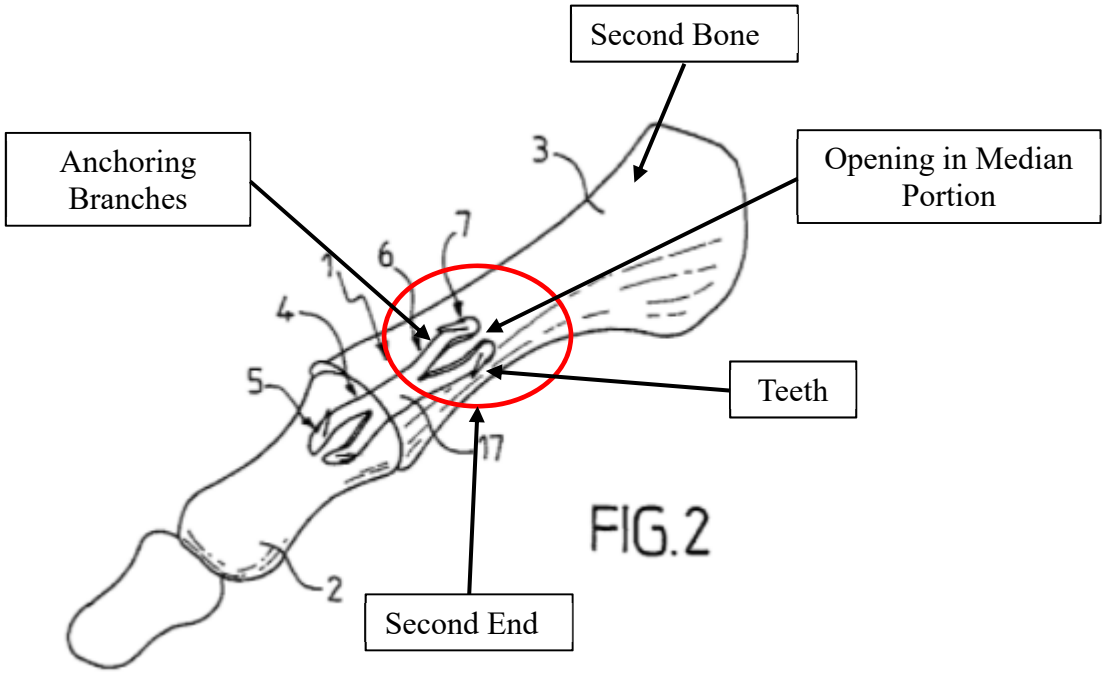
For at least the reasons set forth in Section VII.G.2.a.vii, a POSITA would find this element obvious in view of Pietrzak and Coilard-Lavirotte. (*See* Ex. 1007, FIGS. 1, 2; Ex. 1006, FIG. 2, ¶¶99-100; Ex. 1002, ¶¶254-260, 270-271).

vi. [15e] the second end having an opening in a median portion thereof.

As discussed above, the purpose of the opening median portion of the second end is to allow a portion of the second end to elastically deform upon entry into a bone cavity and to enhance anchoring and stability of the implant. (*See* Section VII.E.2.a.vi (citing Ex. 1001, 1:58-63, 2:40-44, 3:14-20).

Pietrzak does not expressly teach or suggest an opening median portion of the proximal limb (second end). However, a POSITA looking to improve the anchoring and stability of Pietrzak'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. (Ex. 1002, ¶273). Both Pietrzak and Coilard-Lavirotte describe anchor designs that are inserted into a bone cavity, secure to the interior bone wall, and prevent the implant from being removed. (Ex. 1002, ¶¶274-275).

Coilard-Lavirotte specifically discloses an arthrodesis implant comprising a first section 4 (first end) and a second section 6 (second end), the second section further comprising a plurality of anchoring branches 10 with anti-return devices (teeth):




(Ex. 1006, FIG. 2 (annotated); *see also id.* ¶99). Coilard-Lavirotte further discloses that the anchoring branches with the teeth help to improve fixation of the implant. (Ex. 1006, ¶¶99-100). Coilard-Lavirotte discloses how implants used between the first and second bones of interphalangeal joints must have secure fixation to prevent unwanted relative movements that prevent proper healing. (Ex. 1006, ¶8, ¶13, ¶50). Thus, a POSITA looking for a way to improve the fixation and anchoring of Pietrzak'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. (Ex. 1002, ¶276). Therefore, it would be obvious to combine the opening in the second end of the Coilard-Lavirotte's implant with Pietrzak's implant. (Ex. 1002, ¶¶276-277).

Thus, a POSITA would find this element obvious in view of Pietrzak and Coilard-Lavirotte. (Ex. 1002, ¶277).

As detailed above, Pietrzak in view of Coilard-Lavirotte discloses each and every element of claim 15 of the ’074 Patent. (Ex. 1002, ¶¶272-277). Thus, claim 15 is obvious in view of Pietrzak and Coilard-Lavirotte.

*c. Dependent Claims 7, 8, 10, 13*

i. Claim 7: The intramedullary implant of claim 1, 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.

Pietrzak discloses a fixation implant configured to simulate the fixation between the proximal interphalangeal joint. (Ex. 1007, 290). This disclosure guides a POSITA to configure the fixation implant at a slight angle to simulate the anatomic angle created by the joint. (Ex. 1002, ¶279).

Coilard-Lavirotte further discloses an arthrodesis implant comprising a first end extending along a first axis XX’ (longitudinal axis through the first end) and a second end extending along a second axis YY’ (longitudinal axis through the second end), where intersection of the first and second axis is between 10° and 20°:

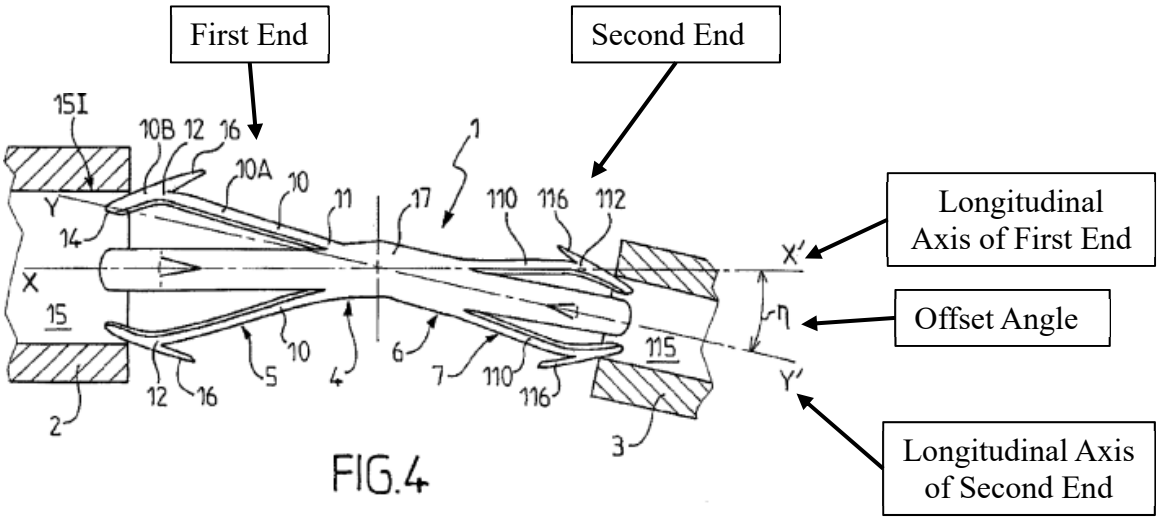


FIG.4

(Ex. 1006, FIG. 4 (annotated); *see also id.*, ¶115).

Thus, a POSITA would find this claim obvious in view of Pietrzak and Coilard-Lavirotte. (Ex. 1002, ¶¶278-281).

ii. Claim 8: The intramedullary implant of claim 7, 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.

Pietrzak discloses a fixation implant configured to simulate the fixation between the proximal interphalangeal joint. (Ex. 1007, 290). This disclosure guides a POSITA to configure the fixation implant at a slight angle to simulate the anatomic angle created by the joint. (Ex. 1002, ¶283).

Coilard-Lavirotte further discloses an arthrodesis implant comprising a first end extending along a first axis XX' and a second end extending along a second axis

YY', such that the intersection line creates a natural alignment angle between a proximal phalange (first bone) and a distal phalange (second bone):

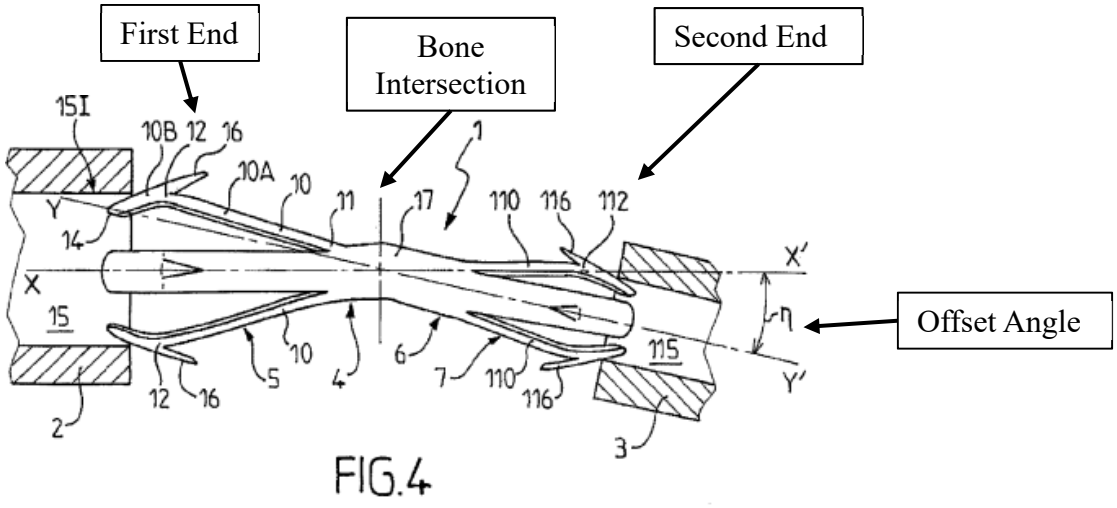



FIG.4

(Ex. 1006, FIG. 4 (annotated); *see also id.*, ¶115).

Thus, a POSITA would find this claim obvious in view of Pietrzak and Coilard-Lavirotte. (Ex. 1002, ¶¶282-285).

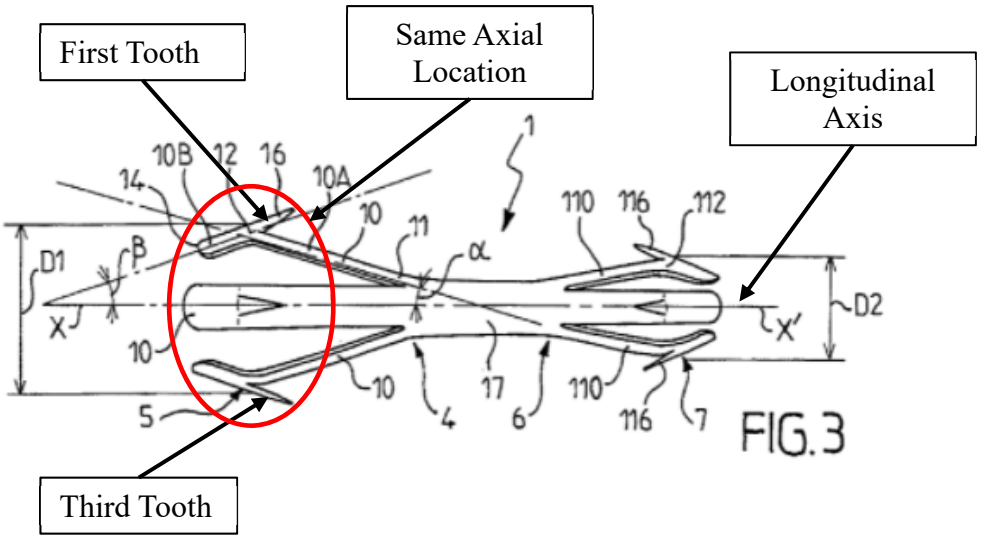
iii. Claim 10: The intramedullary implant of claim 1, wherein the first and third teeth are positioned at the same axial location along the longitudinal axis of the second end.

As discussed above, the purpose of the first and third tooth of the second end is to apply forces in different directions within the bone cavity of the second bone. (*See* Section VII.F.2.a.vii (citing Ex. 1001, 2:40-44, 3:14-20).

Although Pietrzak does not expressly teach or suggest a first and third tooth extending from opposite directions of the body portion of the second end, 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. (*See* Ex. 1007, FIGS. 1, 2; Ex. 1002, ¶287). A POSITA looking for a way to improve the fixation and anchoring of Pietrzak'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. (Ex. 1002, ¶288).

Coilard-Lavirotte's intramedullary comprises a plurality of anti-return devices 16 (teeth) equidistantly spaced on the anchoring branches 10:




(Ex. 1006, FIG. 3 (annotated); *see also id.*, ¶99, ¶134). A POSITA would understand that a first tooth and a third tooth are aligned and equidistantly spaced relative to a longitudinal axis and thus, in the same axial location along the longitudinal axis, as

depicted in Figure. 3. (Ex. 1002, ¶290). Coilard-Lavirotte further discloses the advantages of multiple anchoring points in different directions:

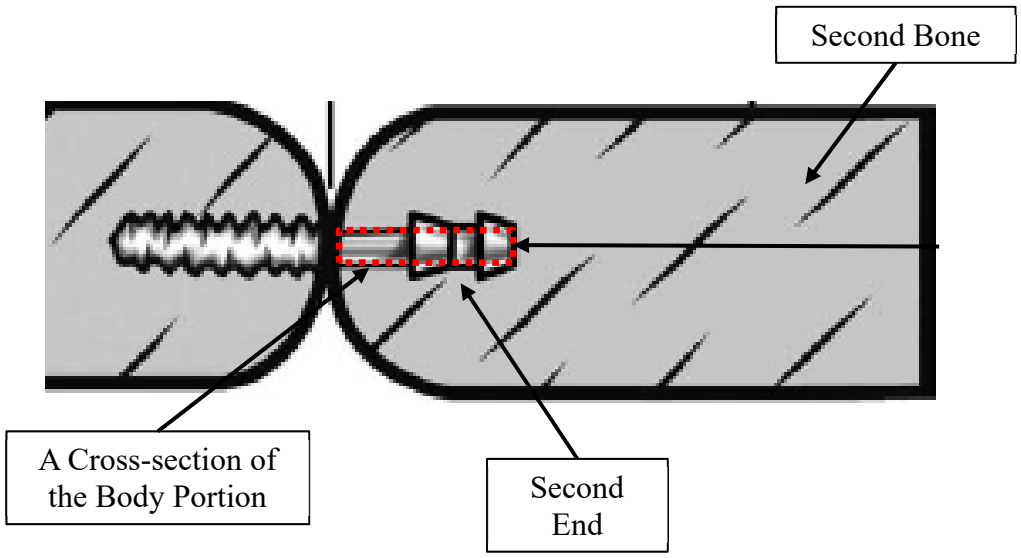
> [T]he implant … has an excellent seating in the bones, which is due not only to the multiplicity of anchoring points but also to the geometry of its means of fixing, which confer on the built-in links thus produced a firm and rigid resistance, whatever the direction of the mechanical stress on the link.

(Ex. 1006, ¶181). Thus, a POSITA looking to improve the stability and resistance to stresses in any direction strength for the second end of the Pietrzak 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. (Ex. 1002, ¶291-292).

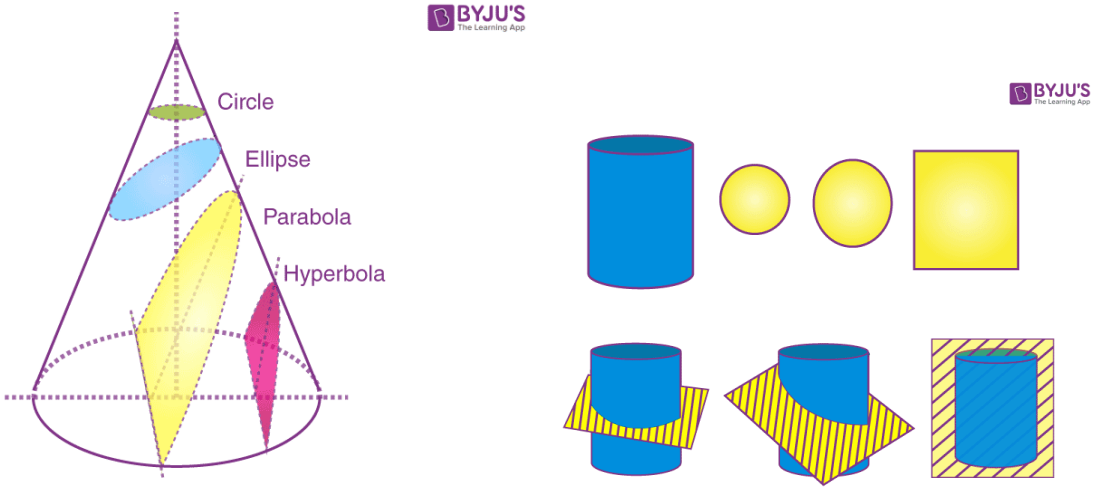
Thus, a POSITA would find this claim obvious in view of Pietrzak and Coilard-Lavirotte. (Ex. 1002, ¶¶286-293).

iv. Claim 13: The intramedullary implant of claim 1, wherein a cross-section of the body portion is non-circular.

Pietrzak's fixation implant comprises a barbed distal end (second end), further comprising two conically shaped barbs (plurality of teeth projection from the body portion) configured to anchor the distal end into a prepared cavity of the intermediate phalange (second bone):




(Ex. 1007, FIG. 2 (annotated); *see also id.*, 289-90). While the shape of the implant in Pietrzak is generally cylindrical, a POSITA would understand that a cross-section of the proximal limb (body portion of the second end), viewed at any relative angle to the longitudinal axis, would include a variety of non-circular shapes such as ellipses, parabolas, hyperbolas, or squares, as shown in the image below:




(Ex. 1009, 3; Ex. 1002, ¶¶296-).

Thus, this claim is disclosed by Pietrzak, or at least this claim would have been obvious to a POSITA in view of the disclosure of Pietrzak. (Ex. 1002, ¶¶298-299).

To the extent that Pietrzak does not disclose this element, Coilard-Lavirotte discloses an arthrodesis implant 1 that is formed by a tubular element, where "the tubular element is formed by any sectional profile, optionally open (U-, T, L-shaped, square, circular, and the like)." (Ex. 1006, ¶124). Coilard-Lavirotte further describes how there are instances where non-circular implants may be advantageous:

> [T]he cross-sections 2T, 3T (represented by dotted lines in FIG. 8) of two successive phalanges generally have one or more favoured directions of extension and not a constant radius under all azimuths, i.e., the cross-sections 2T, 3T are not generally circular but rather ovoid or polylobed. The implant can advantageously reproduce the existing natural offset in alignment between the favoured directions of extension unique to each cross-section and thus share in each phalange the Zones most provided with bony matter in order to improve the fixing, both in extent, thus in stability, and in strength.

(Ex. 1006, ¶119). Thus, a POSITA looking to improve the stability and strength of the second end of the Pietrzak implant would readily look to the disclosure of Coilard-Lavirotte describing a cross-section of the body portion that is non-circular. (Ex. 1002, ¶¶300-301).

Thus, a POSITA would find this claim obvious in view of Pietrzak and Coilard-Lavirotte. (Ex. 1002, ¶¶294-302).

## VIII. CONCLUSION

This Petition demonstrates a reasonable likelihood that at least one claim of the '074 Patent is unpatentable under 37 C.F.R. § 42.108(c). Accordingly, all grounds in this Petition should be instituted. *SAS Institute Inc. v. Iancu*, 138 S.Ct. 1348, 1359–60 (2018); Trial Practice Guide Update, 31 (July 2019).

Respectfully submitted by

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## IX. CLAIM APPENDIX OF THE CHALLENGED CLAIMS

[1pre] An intramedullary implant for use between first and second bone parts, the implant comprising:

[1a] a first threaded end for anchoring to the first bone part;

[1b] a second end extending from the first end for anchoring to the second bone part,

[1c] the second end having a longitudinal axis, a body portion, and a plurality of teeth projecting from the body portion,

[1d] 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,

[1e] the first and second teeth extending from the body portion in a same direction,

[1f] 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.

[7] The intramedullary implant of claim 1, 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.

[8] The intramedullary implant of claim 7, 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.

[10] The intramedullary implant of claim 1, wherein the first and third teeth are positioned at the same axial location along the longitudinal axis of the second end.

[13] The intramedullary implant of claim 1, wherein a cross-section of the body portion is non-circular.

[15Pre] An intramedullary implant for use between first and second bone parts, the implant comprising:

[15a] a first threaded end for anchoring to the first bone part;

[15b] a second end extending from the first end for anchoring to the second bone part and having a plurality of outwardly projecting teeth,

[15c] 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,

[15d] and at least the first tooth extending in a different direction than a third tooth of the plurality of teeth,

[15e] the second end having an opening in a median portion thereof.

**Certification of Service Under 37 C.F.R. § 42.6(e)(4)**

A copy of this Petition for *Inter Partes* Review and supporting materials has been served at the following correspondence address of record for the subject patent via Federal Express Priority Overnight® on this 28th day of January, 2022:

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**Certification of Word Count Under 37 C.F.R. § 42.24(d)**

The undersigned hereby certifies that the foregoing Petition for *Inter Partes* Review contains 13,197 words, not including a table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, appendix of exhibits or appendix of claim listing as specified by 37 C.F.R. §42.24, according to the word count feature of the word-processing software used to prepare the Petition.

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