

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Fusion Orthopedics, LLC,
Petitioner,

v.

Extremity Medical, LLC,
Patent Owner.

IPR2023-00894

Patent 11,298,166 B2

PETITION
for *Inter Partes* Review

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PETITIONER’S LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,298,166 B2 to Jeff Tyber, <i>et al.</i> , filed on May 18, 2021, issued on April 12, 2022. (“’166 patent”).
1002	Expert Declaration by Leonel Dominguez.
1003	French Patent Publication No. FR2,861,576 A1 to Cognet Jean Michel, filed on October 31, 2003, published on May 6, 2005. (“Cognet”)
1004	French Patent Publication No. FR2,861,576 A1 to Cognet Jean Michel, filed on October 31, 2003, published on May 6, 2005. Translated into English. (“Cognet”).
1005	Cognet Translation Affidavit.
1006	U.S. Patent No. 4,827,917 to David L. Brumfield, filed on December 30, 1986, issued on May 9, 1989. (“Brumfield”).
1007	U.S. Patent Publication No. 2003/0187447 to Joseph Ferrante, <i>et al.</i> , filed on April 7, 2003, published on October 2, 2003. (“Ferrante”).
1008	U.S. Patent Publication No. 2006/0206044 to William Simon, filed on August 1, 2003, published on September 14, 2006. (“Simon”).
1009	U.S. Patent No. 6,270,499 B1 to Dieter Leu, <i>et al.</i> , PCT filed on October 20, 1997; PCT published on April 29, 1999; issued on August 7, 2001. (“Leu”)
1010	Extremity Medical, LLC’s Response to Defendant Fusion Orthopedics, LLC’s First Set of Interrogatories (Nos. 1-6). No. CV-22-00723-PHX-GMS.
1011	Case Management Order, No. CV-22-00723-PHX-GMS, Document 49, Filed December 16, 2022.
1012	Memorandum: Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation, June 21, 2022

I. INTRODUCTION

Fusion Orthopedics, LLC (“Fusion”) petitions for *inter partes* review of claims 1–15 of U.S. Patent No. 11,298,166 (“’166 patent”) (Ex. 1001). For the reasons set forth in detail below, the claims are unpatentable as anticipated under 35 U.S.C. § 102 and/or as obvious under 35 U.S.C. § 103 in view of the references submitted by Petitioner.

II. MANDATORY NOTICES (37 C.F.R. § 42.8)

Pursuant to 37 C.F.R. §§ 42.8(a)(1) and 42.8(b), the following mandatory notices are provided as part of this Petition.

A. Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1))

Petitioner Fusion Orthopedics, LLC is the real party-in-interest.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

Petitioner identifies the following district court proceeding that is currently pending and involves the ’166 patent: *Extremity Medical, LLC. v. Fusion Orthopedics, LLC*, 2:22-cv-00723-PHX-GMS, in the United States District Court for the District of Arizona filed on April 28, 2022.

C. Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3))

Petitioner identifies its lead and backup counsel below. A Power of Attorney is filed concurrently herewith under 37 C.F.R. § 42.10(b).

Lead Counsel	Back-up Counsel
Jennifer Brinkerhoff Reg No. 78,696 Jen@FusionOrthopedics.com Phone: 480-324-6636 Fax: 800-403-6876 4135 S Power Rd STE 118 Mesa, Az 85212	Corby Vowell Vowell Law, PLLC corby@vowelllawfirm.com Phone: 817-313-9548 Fax: 800-403-6876 603 Walnut Hollow Drive Mansfield, TX 76063 <i>pro hac vice</i> application to be filed

D. Service Information (37 C.F.R. § 42.8(b)(4))

Fusion Orthopedics may be served through its counsel identified above. Electronic service of documents should be sent to the email addresses of the counsel identified above and to: sam@fusionorthopedics.com.

E. Payment of Fees

Petitioner authorizes the USPTO to charge Deposit Account No. 605043 for the fee set forth in 37 C.F.R §42.15(a) for this Petition.

III. GROUNDS FOR STANDING UNDER § 42.104(a)

Petitioner certifies that the '166 patent is available for IPR, and Petitioner is not barred or estopped from requesting IPR on the asserted grounds.

IV. SUMMARY AND CLAIM CONSTRUCTION

A. Summary of the '166 Patent

The '166 patent was filed on May 18, 2021. It is a continuation of application No. 17/002,005, filed on August 25, 2020, which is a

continuation of application No. 15/884,048, filed on Jan. 30, 2018, now Pat. No. 10,751,097, which is a continuation of application No. 15/181,435, filed on June 14, 2016, now Pat. No. 9,877,752, which is a continuation of application No. 14/599,671, filed on January 19, 2015, now Pat. No. 9,364,271, which is a division of application No. 12/658,680, filed on February 11, 2010, now Pat. No. 9,044,282, which is a continuation-in-part of application No. 12/456,808, filed on June 23, 2009, now Pat. No. 8,303,589, which claims priority to provisional application No. 61/132,932, filed on June 24, 2008. Extremity Medical, LLC (“Extremity”) has alleged that the earliest effective filing date to which the claims of the ’166 patent are entitled is February 11, 2010. Ex. 1010, pg. 8, ln. 16 – pg. 9, ln. 4. Extremity has alleged a conception date of Oct 13, 2009, with constructive reduction to practice on Feb 11, 2010. Ex. 1010, pg. 5 lns. 18-22.

The ’166 patent describes and claims an orthopedic implant for fusing bones in the human body. In general, the ’166 patent describes a fixation system used for internal fixation of angled joints, bones, and deformity correction. The fixation system disclosed comprises an intramedullary nail secured by two screws. Ex. 1002 ¶¶ 31.

The basic goal of using an intramedullary nail is bone repair (also known as osteosynthesis, or fusion). Osteosynthesis or fusion requires three primary conditions for the bones to regrow and repair themselves. First, fractured or surgically cut bones must be brought into proximity (reduced) using manual manipulation. Second, the broken bone ends should be what surgeons refer to as “bleeding bone” in order to have the body’s natural healing response surround the wound with the proper proteins inductive to create new bone formation. Third, the bones must be stably aligned and fixed in position for several weeks until fusion occurs. Often, an orthopedic medical device is used to create stable fixation across a bone fracture which should lead to bone fusion. Ex. 1002 ¶¶ 32.

For decades, the field of orthopedics has used intramedullary rods, plates, pins, wires and bone screws to join two or more bones fragments. These types of devices are widely used to heal bone in trauma fractures and deformity correction or where osteotomies are used. An intramedullary rod, also known as an intramedullary nail (IM nail), is a metal rod forced into the medullary cavity of a bone. IM nails have long been used to treat fractures of long bones of the body. Gerhard Küntscher is credited with the first modern use of this device in 1939, during World War II, for soldiers with fractures

of the femur. The concept of IM nail devices was miniaturized in practice to treat fractures of small bones of the foot, wrist, and hand and other small extremities. The basic principle of fixation and stabilization remains the same, using an elongated body (nail) with several through-bore holes positioned at various locations with varying degrees of angulation that direct bone screws to capture bone fragments to reduce the fracture. A distal bone screw is commonly positioned perpendicular to the nail's longitudinal axis which passes through a bore hole in the nail to lock the elongated nail to bone to help to prevent expulsion or rotation of the nail. Intramedullary nails commonly have traversing bone screws near the proximal-top of the nail and at the distal-end of the nail. Ex. 1002 ¶¶ 33.

Specific to foot and ankle fracture fusion surgery, there are numerous foot and ankle fusion nails used in the hindfoot, forefoot and midfoot for the treatment of small bone and extremity fractures that function similarly to and resemble the '166 patent. Specifically, the Cognet, Simon, Brumfield, Ferrante, and Leu references taught these devices. These designs have an elongated member (nail) having one or more bore holes that accepts the passage of screws at specific angles relative to the long axis of the elongated member that results in compression across bone fractures or osteotomies.

These references therefore anticipate or render obvious all claims of the '166 patent. Ex. 1002 ¶¶ 34.

B. Summary of Challenges

Petitioner asserts the following challenges, supported by the expert testimony of Leonel Dominguez (Ex. 1002, Background and Qualifications at ¶¶ 4-22). For purposes of this proceeding only, Petitioner assumes, without conceding, that the '166 patent is entitled to its earliest alleged effective filing date, February 11, 2010, and thus applies pre-AIA 35 U.S.C. § 102.

References	Basis	Claims Challenged
Cognet (Ex. 1004)	102(a), (b)	1-7,9,12, and 13
Cognet and Brumfield (Ex. 1006)	103	4,8,10, and 14-15
Cognet and Ferrante (Ex. 1007)	103	11
Simon (Ex. 1008)	102(a), (b)	1,4-5, 8, 10-12, and 14-15
Simon and Ferrante	103	4,8,10-11, and 14-15
Simon and Cognet	103	9
Simon and Leu (Ex. 1009)	103	2-3, 6-7, and 13

C. Person of Ordinary Skill in the Art

A person of ordinary skill in the art (POSA) pertaining to the '166 patent would have a bachelor's degree in biomedical and/or mechanical

engineering or similar training with at least five years of experience with the methods, processes, and implant devices used to stabilize fractures, correct deformities and fuse bone in small bone and/or long bone fractures using internal fixation, and preferably has experience in the operating room (OR) or cadaver labs to witness use and implementation. Ex. 1002 ¶ 29.

D. Claim Construction

All claim terms should be construed according to the *Phillips* standard. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005); 37 C.F.R. § 42.100(b). The terms in the claims of the '166 patent should be given their plain and ordinary meaning as understood by one of ordinary skill in the art. Ex.1002 ¶ 36. Here, because the claims of the '166 patent are anticipated and/or rendered obvious under any reasonable interpretation and because “claim terms need only be construed to the extent necessary to resolve the controversy,” no express constructions are required in this proceeding. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). Petitioner reserves the right to address any construction proposed by Patent Owner or the Board. Petitioner also reserves the right to pursue constructions in district court that are necessary to decide matters of infringement.

V. SPECIFIC GROUNDS FOR PETITION

A. Cognet Anticipates Claims 1-7, 9, 12, and 13.

Claims 1-7, 9, 12, and 13 are unpatentable under Pre-AIA 35 U.S.C. § 102(a) and (b) for anticipation by Cognet. Cognet discloses an orthopedic implant device for osteosynthesis, specifically for fixing fractures of the upper end of the ulna, and consists of an intramedullary nail, an upper fastening screw, and a lower attachment, or lower fastening screw. Ex. 1002 ¶¶ 39-40.

Cognet is a French Patent Application No. 0312825, Publication No. FR 2,861,576, which was filed on October 31, 2003, and published on May 6, 2005, and is included with this petition as Ex. 1003¹. Cognet is a prior-art printed publication because it was available to the public before the invention by the applicants for the '166 patent and more than one year prior to the earliest effective filing date to which the '166 patent is entitled of Feb 11, 2010, making the disclosures “described in a printed publication in this or a foreign country,” and publicly available.

The English translation for Cognet is included in this petition as Ex. 1004. The translation was provided by RWS Group Ltd., by a translator who

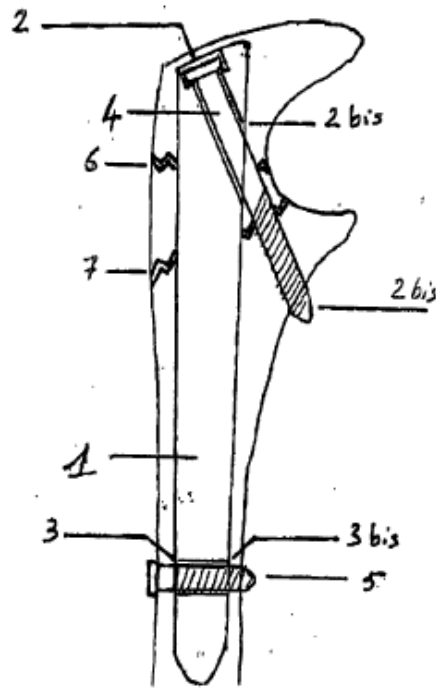
¹ Citations in the petition will refer to the English translation of the French Patent which is Ex. 1004.

is well acquainted with the French and English languages. Ex. 1005 ¶ 2.

1. Claim 1

Claim 1 of the '166 patent is directed to an assembly for bone fusion. Cognet describes an osteosynthesis device for fractures of the olecranon (ulna). Ex. 1004, pg. 1 ln. 54-59. Osteosynthesis is the bone healing from fracture or osteotomy and is synonymous with fusion. Ex. 1002 ¶¶ 31-34. The device in Cognet includes an intramedullary and two screws and is assembled by inserting two screws into the intramedullary nail. Thus, Cognet discloses an assembly for bone fusion and discloses the preamble of claim 1, to the extent it is given patentable weight. Ex. 1002 ¶¶ 39-40.

All of the figures provided in this section (V.A) of the petition are a cropped portion of Cognet Figure 1 unless otherwise indicated. These figures were provided by counsel and verified by expert Leonel Dominguez for accuracy in the labels. Ex. 1002 ¶ 35.

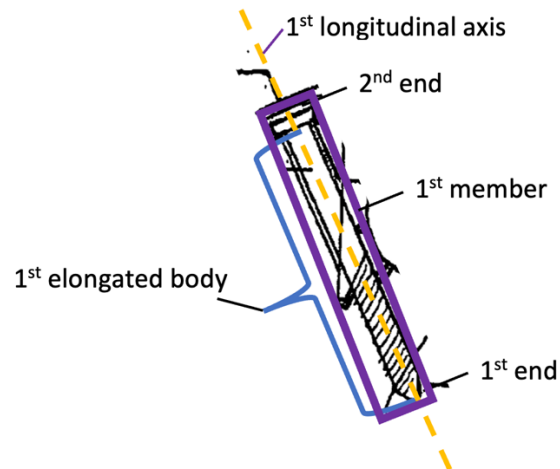


(Ex. 1003 and Ex. 1004, Figure 1)

a) 1[a][i]: “a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis”

Figure 1 of Cognet (above) discloses a first screw (element 2 of Figure 1) (first member). Ex. 1004, pg. 2 ln. 35. A screw has an elongated body that extends from a first end (the tip of the screw) to a second end (the head of the screw). Ex. 1002 ¶¶ 41-42, 44. A “longitudinal axis” is an axis along the lengthwise direction of a body, usually passing through its center of rotation. Ex. 1002 ¶¶ 45. The longitudinal axis for the screw is an axis that runs through the center of the screw from the tip of the screw to the head of the screw, as indicated below. Ex. 1002 ¶ 45. Thus, Cognet discloses

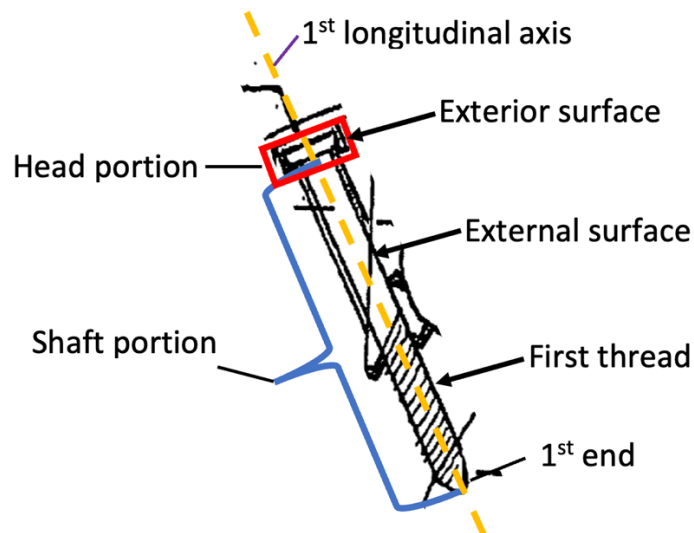
this claim element. Ex. 1002 ¶ 46.



b) 1[a][ii] “wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;”

The screw disclosed in Cognet comprises a shaft portion, which has an external surface. Ex. 1002 ¶ 42. The screw comprises a head portion which has an exterior surface. Ex. 1002 ¶ 42a. The screw comprises at least one thread which has a thread height. Ex. 1002 ¶ 42d. The thread height is the distance between the crest and the root of the thread, normal (or perpendicular) to the axis of the thread. *Id.* The threads on the screw extend radially outward from the external surface of the shaft portion of a screw. *Id.* By disclosing a screw (Ex. 1004, pg. 2 ln. 35) Cognet is disclosing a

member comprising a shaft having an external surface, a head having an exterior surface, and a thread with a height that extends radially outward from the external surface of the shaft. Ex. 1002 ¶¶ 47-48. Ex. 1004, pg. 4 lns. 14-15 (“The proximal screw (4) has a screw thread on the distal part thereof only”). Ex. 1004, pg. 4 lns. 18-19 (“The top of the screw has a head”).

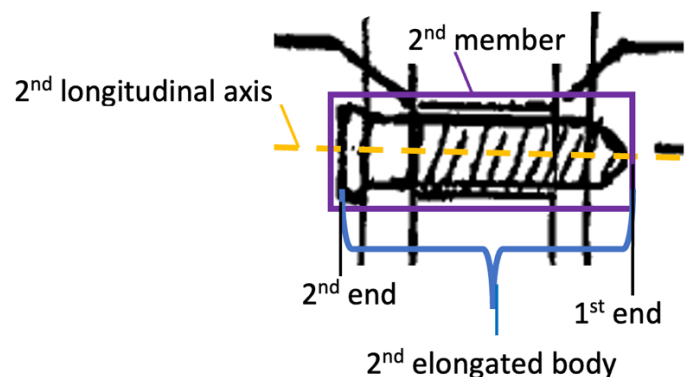


c) 1[b][i]: “a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis,”

Cognet discloses a second screw (second member) (Ex. 1004, pg. 3 ln. 2; Figure 1). As discussed above, the screw has an elongated body that extends from a first end (the tip of the screw) to a second end (the head of the screw) along a longitudinal axis. This is called the shaft and is shown

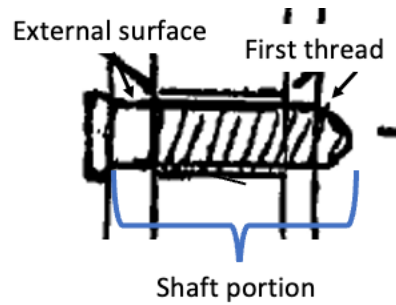
above in claim element 1[a][i] section (V.A.1.a). The longitudinal axis for the screw is an axis that runs through the center of the screw from the tip of the screw to the head of the screw. These features are also indicated below.

Thus, Cognet discloses this claim element. Ex. 1002 ¶¶ 45, 49.



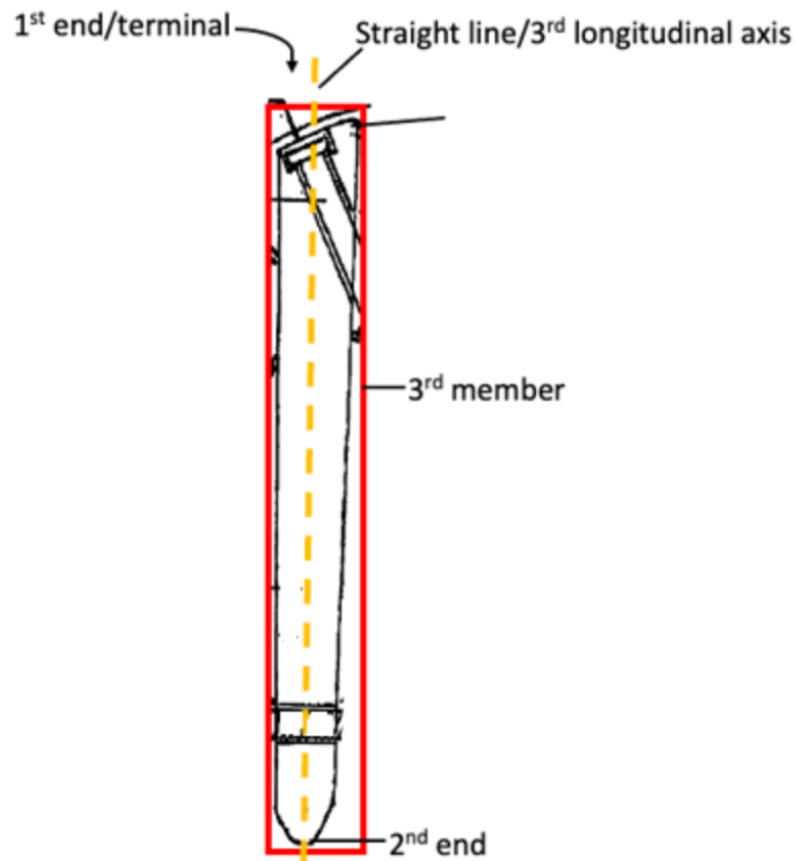
d) 1[b][ii]: “wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;”

As described above in section (V.A.1.b), screws are comprised of a shaft and at least one thread. The shaft has an external surface. The threads have a height, and they extend radially outward from the external surface of the shaft. Ex. 1002 ¶¶ 41, 42d, 50. Cognet discloses a screw as the second member, and thus discloses this claim element. Ex. 1004, pg. 4 lns. 25-26 (The distal screw or screws (5) has or have a continuous screw thread ...).



e) 1[c][i] “a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis,”

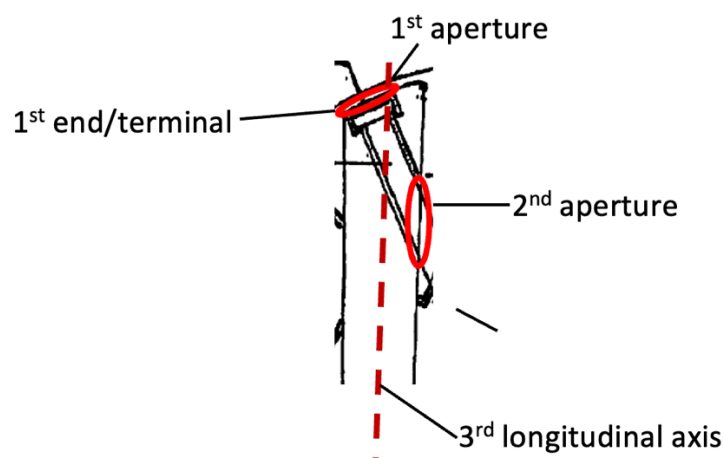
Cognet discloses a third member (a nail, element 1 in Ex. 1001, Fig. 1) comprising a body that extends along a straight line (the 3rd longitudinal axis) from a first end to a second end as indicated below. Ex. 1004, pg. 2 lns. 23-25. Ex. 1002 ¶¶ 51-52.



f) 1[c][ii] “wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body,”

“Terminal end” is undefined in the specification for the ’166 patent. A POSA would understand “terminal end” to refer to the end of the intramedullary nail that aligns closely with the top surface of the bone or slightly below the surface of bone into which the intramedullary nail is being inserted. Ex. 1002 ¶¶ 53-55. To a POSA, the phrase “at the terminal end” would refer to a location near the terminal or proximal end, as opposed to merely along the shaft of the nail at any location, or at the distal end.

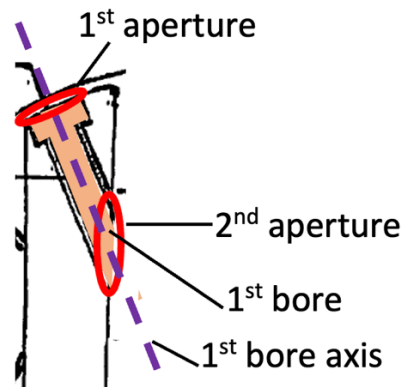
Ex. 1002 ¶ 55. Cognet discloses an end of the third member that aligns with the bone, or a terminal end. *Id.* Ex. 1004, pg. 2 lns. 28-31. Cognet further discloses a first aperture at the terminal end of the third elongated body as shown below. Ex. 1002 ¶ 57. Ex. 1004, pg. 2 lns. 32-34 (There is an orifice or tunnel at the top of the nail which follows an oblique downward path toward the coronoid process.). Ex. 1002 ¶¶ 56-57.



g) 1[c][iii] “a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member”

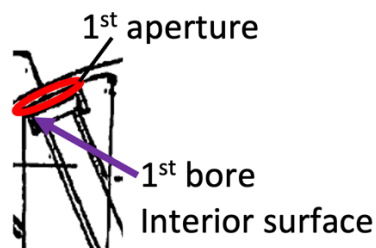
A bore is a usually cylindrical hole made by or as if by the turning or twisting movement of a tool. Ex. 1002 ¶ 58. Cognet discloses a tunnel at the top of the nail that descends. This tunnel is intended to receive a screw which allows the bone anchoring of the nail. (Ex. 1004, pg. 2 lns. 32-38).

Ex. 1002 ¶ 59. Cognet discloses a first bore extending along a first bore axis from the first aperture to a second aperture (see below). The second aperture is on an exterior surface of the third member. *Id.*



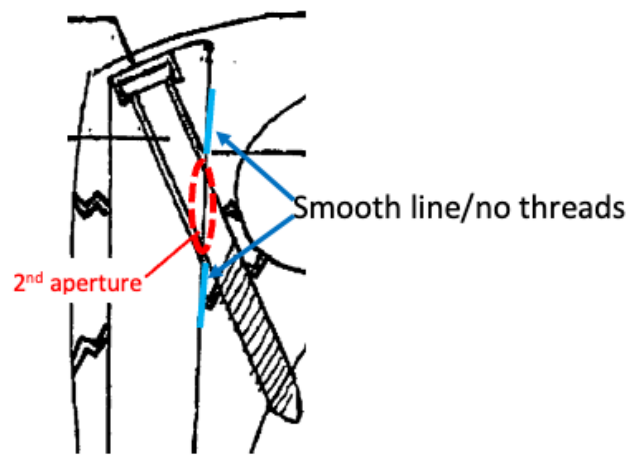
h) 1[c][iv] “wherein the first bore comprises an interior surface at the first aperture”

A bore is created by removing material from a solid, which results in an interior surface of the bore. As discussed above, Cognet discloses a bore at the first aperture. Since there is a bore at the first aperture, the bore will necessarily comprise an interior surface at the first aperture, thus disclosing this claim element. Ex. 1002 ¶ 60.



i) 1[c][v] “wherein there are no threads adjacent to the second aperture on the exterior surface of the third member”

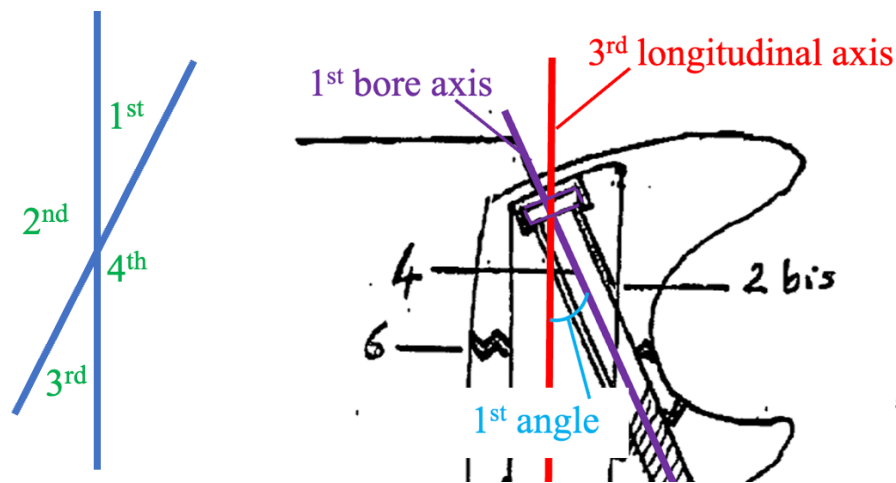
The smooth lines defining the exterior surface of the third member indicate that at least one embodiment comprises no threads. Ex. 1002 ¶ 61. Cognet discloses that there are no threads adjacent to the second aperture on the exterior surface of the third member and thus discloses this claim element. *Id.*



j) 1[c][vi] “wherein the third longitudinal axis and the first bore axis define a first angle”

The '166 patent requires the third longitudinal axis and the first bore axis define a first angle. This requires that the third longitudinal axis and the first bore axis intersect. Ex. 1002 ¶ 62. An axis is a straight line. Any two straight lines that intersect create 4 angles. Two of these angles will be less

than 90° and two of these angles will be greater than 90°, or all four angles will equal 90°. The '166 patent does not specify which of these angles is the first angle. *Id.* Cognet discloses a 3rd longitudinal axis and a first bore axis that intersect creating a first angle as indicated below. *Id.*



(exemplary axes)

(Cognet Fig. 1)

k) 1[d] “wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle”

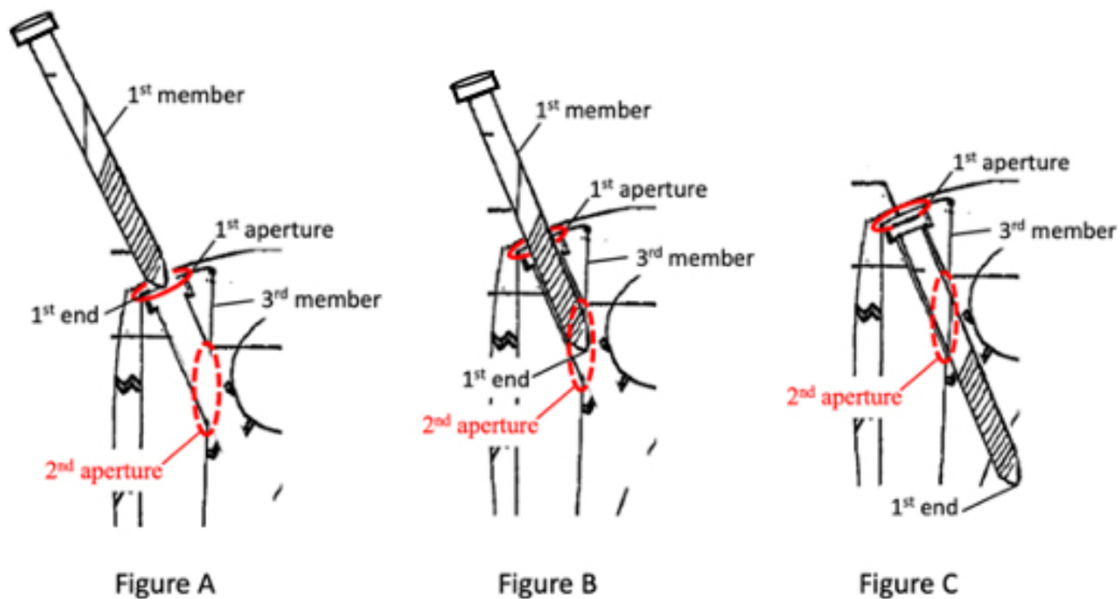
Cognet states that the nail (third member) has at least one orifice or tunnel at the distal part of the nail (Ex. 1004, pg. 2 lns. 38-39; pg. 3 lns. 1-5 “This nail also has at least one orifice or one tunnel situated at the distal part of the nail ...”). Cognet discloses a third and a fourth aperture on the exterior

surface of the third member with a second bore extending along a second bore axis between them. The second bore axis and the third longitudinal axis intersect and create a second angle, as shown below. Ex. 1002 ¶ 63.



l) 1[e] “wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture”

Cognet discloses the first bore is intended to receive a screw (first member). Ex. 1004, pg. 2 lns. 32-34. Ex. 1002 ¶¶ 64-65. Cognet discloses the first member coupling to the third member by inserting the first end of the first member into the first aperture (figure A below), through the first bore (figure B below), and out of the second aperture (figure C below) as can be determined by figure 1. Ex. 1004, pg. 3 ln.38; pg. 4 lns. 1-2 (“These tunnels are each intended to accept a screw ... that passes through the proximal tunnel ...”). Portions of Figure 1 of Cognet have been overlaid to show clearly how Cognet discloses these elements. Ex. 1002 ¶ 65.



m) 1[f] “wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture”

Cognet discloses the second member coupling to the third member by inserting the first end of the second member into the third aperture (Figure A below), through the second bore (Figure B below), and out the fourth aperture (Figure C below). Portions of Figure 1 of Cognet have been overlayed to show clearly how Cognet discloses these elements (see below). The second bore is “intended to receive a screw that allows the nail to be anchored into the bone” (Ex. 1004, pg. 3 lns. 1-3). Ex. 1002 ¶ 66.

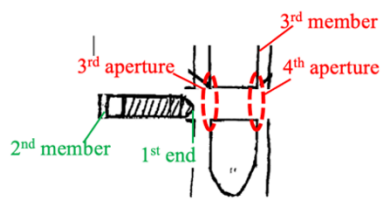


Figure A

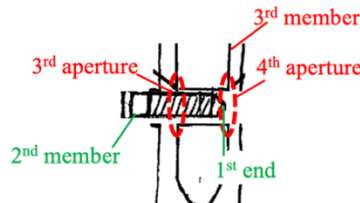


Figure B

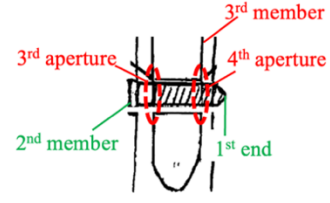
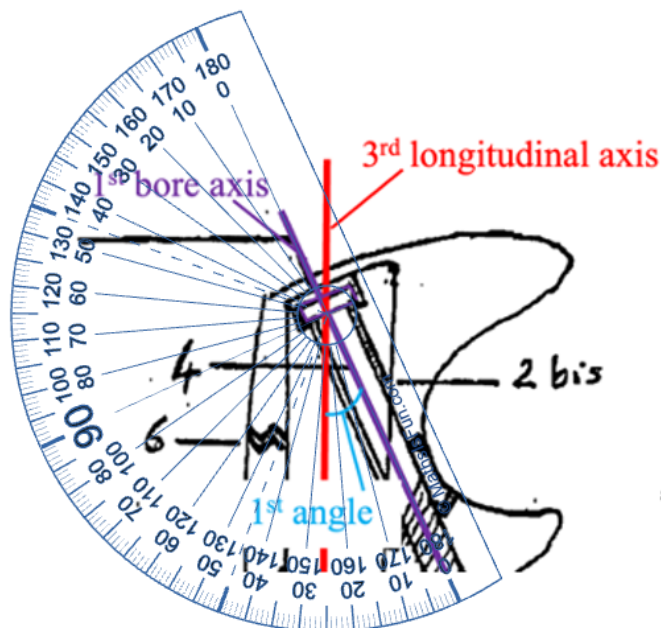


Figure C

n) 1[g] “wherein the first angle is in the range of about 0 degrees to about 90 degrees”

Cognet discloses a first angle defined by the third longitudinal axis and the first bore axis, as discussed in claim element 1[c][vi] (section (V.A.1.j) of this petition). It is easily discerned from the figures that the first angle is between 0° and 90°, and is about 25°. Ex. 1002 ¶¶ 67-68.



o) 1[h] “wherein the second angle is in the range of about 0 degrees to about 90 degrees”

Cognet discloses the second bore axis as being perpendicular to the third longitudinal axis (Ex. 1004, pg. 3 ln. 1). Perpendicular is 90° which is in the range of 0° to about 90°. Thus, Cognet discloses this claim element.

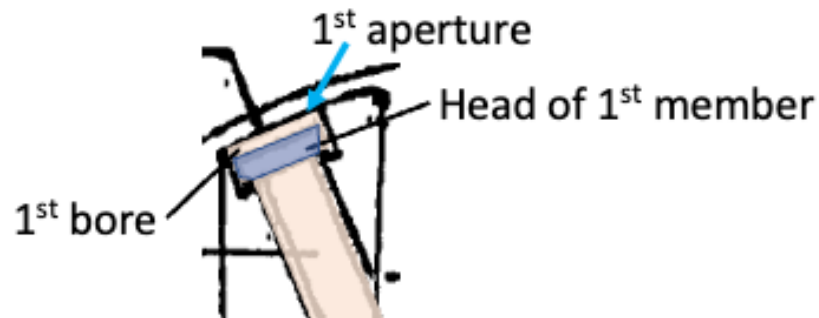
Ex. 1002 ¶¶ 69-70.

p) 1[i] “wherein the second bore axis is substantially perpendicular to the third longitudinal axis”

The '166 patent does not disclose what is meant by “substantially” perpendicular and there is no guidance provided in the '166 specification or figures for how to determine which range of degrees would fall within the scope of this claim term, other than something that is actually perpendicular. Cognet discloses the second bore axis as being perpendicular to the third longitudinal axis, and thus discloses this claim element (Ex. 1004, pg. 3 ln. 1). Ex. 1002 ¶ 71.

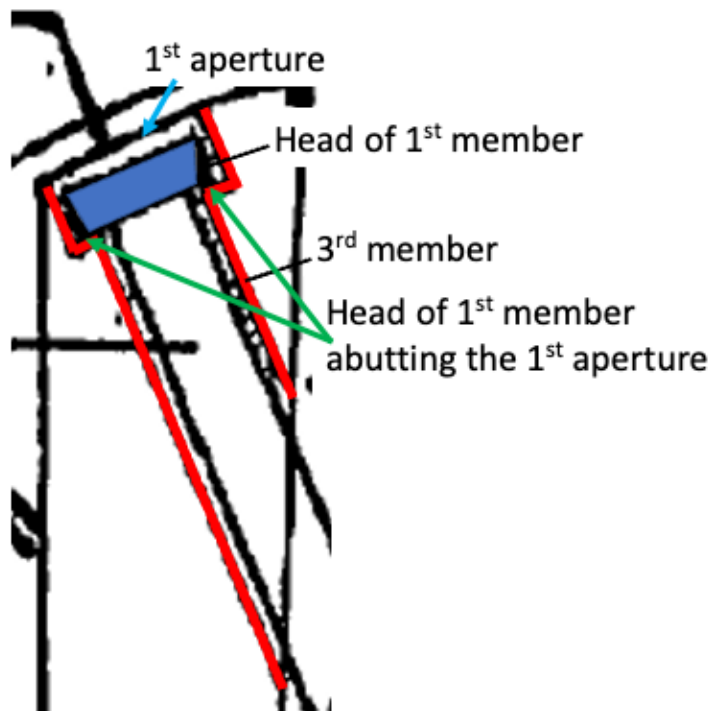
2. Claim 2

Claim 2 further limits claim 1 by requiring the head portion of the first member reside at least partially within the first bore. Figure 1 of Cognet shows the head portion of the first member (shaded blue) residing within the first bore (shaded orange). Ex. 1002 ¶¶ 72-73.



3. Claim 3

Claim 3 further limits claim 2 by requiring the exterior surface of the head portion of the first member abut the interior surface of the first bore at the first aperture. The use of the word abut refers to making contact along an edge. Ex. 1002 ¶ 74. Cognet discloses that the head of the screw (first member) has a larger diameter than the diameter than the tunnel (first bore) which makes it possible for the head to butt up against the smaller diameter tunnel to stop the progression of the screw and obtain a compression effect at the fracture site (Ex. 1004, 62-65). Ex. 1002, ¶ 75. Figure 1 of Cognet shows the exterior surface of the head portion of the first member abutting the interior surface of the first bore at the first aperture, thus disclosing this claim limitation. Ex. 1002 ¶ 75.

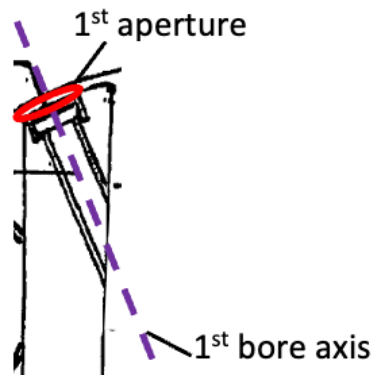


4. Claim 4

Claim 4 limits claim 3 by requiring the head portion of the first member comprise a torque transmitting aperture. Cognet discloses the first member as a screw. Since almost all screws comprise a torque transmitting aperture, this alone discloses that the first member comprises a torque transmitting apertures. Ex. 1002 ¶¶ 42b, 76.

5. Claim 5

Claim 5 further limits claim 1 to require the first aperture to be aligned on the first bore axis. The center of the first aperture is in line with the first bore axis, making them aligned. Ex. 1002 ¶¶ 77-78.



6. Claim 6

Claim 6 further limits claim 5 by requiring the head portion of the first member to at least partially reside within the first bore. This is the same limitation as claim 2. Cognet's disclosure of this requirement is discussed above in section (V.A.2) of this petition. Ex. 1002 ¶ 79.

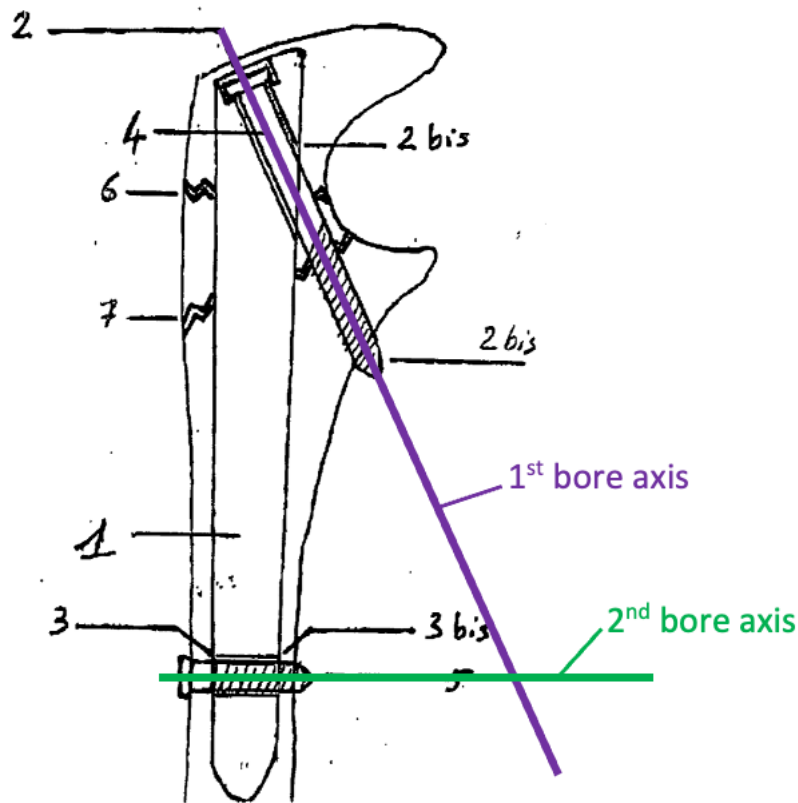
7. Claim 7

Claim 7 further limits claim 6 by requiring the head portion of the first member to abut the interior surface of first bore at the first aperture. This is the same limitation as claim 3. Cognet's disclosure of this requirement is discussed above in section (V.A.3) of this petition. Ex. 1002 ¶ 80.

8. Claim 9

Claim 9 further limits claim 1 by requiring the first bore axis and the second bore axis to intersect outside the third member. Cognet discloses these two axes intersecting outside the third member as shown below. Ex.

1002 ¶¶ 81-82.



9. Claim 12

The preamble for claim 12 has the same limitations as the preamble for claim 1 and is disclosed by Cognet as discussed in section (V.A.1) of this petition.

- a. 12[a][i]: “a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially**

outward from the external surface of said shaft portion;”

This claim element has the same limitations as claim element 1[a][i] and is disclosed by Cognet as discussed in section (V.A.1.a) of this petition.
Ex. 1002 ¶ 84.

- b. 12[a][ii] “wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;”**

This claim element has the same limitations as claim element 1[a][ii] and is disclosed by Cognet as discussed in section (V.A.1.b) of this petition.
Ex. 1002 ¶ 85.

- c. 12[b][i]: “a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis,”**

This claim element has the same limitations as claim element 1[b][i] and is disclosed by Cognet as discussed in section (V.A.1.c) of this petition.
Ex. 1002 ¶ 86.

- d. 12[b][ii]: “wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending**

radially outward from the external surface of said shaft;”

This claim element has the same limitations as claim element 1[b][ii] and is disclosed by Cognet as discussed in section (V.A.1.d) of this petition.

Ex. 1002 ¶ 87.

- e. 12[c][i] “a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis,”**

This claim element has the same limitations as claim element 1[c][i] and is disclosed by Cognet as discussed in section (V.A.1.e) of this petition.

Ex. 1002 ¶ 88.

- a) 12[c][ii] “wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body,”**

This claim element has the same limitations as claim element 1[c][ii] and is disclosed by Cognet as discussed in section (V.A.1.f) of this petition.

Ex. 1002 ¶ 89.

- b) 12[c][iii] “a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member”**

This claim element has the same limitations as claim element 1[c][iii] and is disclosed by Cognet as discussed in section (V.A.1.g) of this petition.

Ex. 1002 ¶ 90.

c) 12[c][iv] “wherein the first bore comprises an interior surface at the first aperture”

This claim element has the same limitations as claim element 1[c][iv] and is disclosed by Cognet as discussed in section (V.A.1.h) of this petition.

Ex. 1002 ¶ 91.

d) 12[c][v] “wherein there are no threads adjacent to the second aperture on the exterior surface of the third member”

This claim element has the same limitations as claim element 1[c][v] and is disclosed by Cognet as discussed in section (V.A.1.i) of this petition.

Ex. 1002 ¶ 92.

e) 12[c][vi] “wherein the third longitudinal axis and the first bore axis define a first angle”

This claim element has the same limitations as claim element 1[c][vi] and is disclosed by Cognet as discussed in section (V.A.1.j) of this petition.

Ex. 1002 ¶ 93.

f) 12[d] “wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein

the third longitudinal axis and the second bore axis define a second angle”

This claim element has the same limitations as claim element 1[d] and is disclosed by Cognet as discussed in section (V.A.1.k) of this petition. Ex. 1002 ¶ 94.

g) 12[e] “wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture”

This claim element has the same limitations as claim element 1[e] and is disclosed by Cognet as discussed in section (V.A.1.l) of this petition. Ex. 1002 ¶ 95.

h) 12[f] “wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture”

This claim element has the same limitations as claim element 1[f] and is disclosed by Cognet as discussed in section (V.A.1.m) of this petition. Ex. 1002 ¶ 96.

i) 12[g] “wherein the second angle is in the range of about 0 degrees to about 90 degrees”

This claim element has the same limitations as claim element 1[h] and is disclosed by Cognet as discussed in section (V.A.1.o) of this petition. Ex.

1002 ¶ 97.

j) 12[h] “wherein the second bore axis is substantially perpendicular to the third longitudinal axis”

This claim element has the same limitations as claim element 1[i] and is disclosed by Cognet as discussed in section (V.A.1.p) of this petition. Ex.

1002 ¶ 98.

10. Claim 13

This claim element has the same limitations as claim 2 and is disclosed by Cognet as discussed in section (V.A.2) of this petition. Ex.

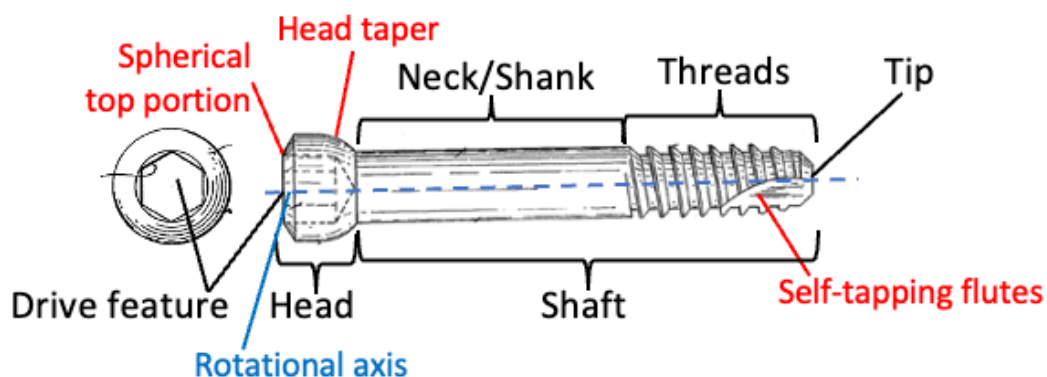
1002 ¶ 99.

B. Cognet and Brumfield make obvious claims 4, 8, 10, 14, and 15.

Claims 4, 8, 14-15 are unpatentable under 35 U.S.C. § 103 for obviousness over Cognet in view of Brumfield. Brumfield is U.S. Patent No. 4,827,917, which was issued on October 2, 2003, which is before the earliest effective filing date of the '166 patent. Brumfield is a prior art patent to the '166 patent under section 103 because the issue date of Brumfield is before the effective filing date of the '166 patent. Brumfield discloses a femoral fracture device. Ex. 1002 ¶ 100.

Brumfield is analogous art because it is an intramedullary nail secured

by multiple screws. It would have been obvious to a POSA to use the screws disclosed in Brumfield with the intramedullary nail disclosed in Cognet because the screw and nail in Brumfield are performing the same function in the same way as the screw and nail in Cognet. Namely, the proximal screw in Brumfield and Cognet is providing compression from the intramedullary nail to the fractured bone. Ex. 1002 ¶ 101.

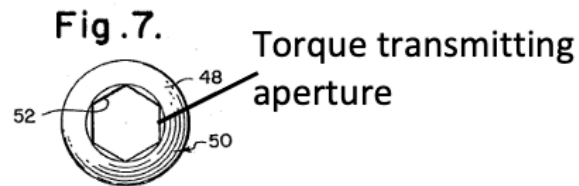


(Ex. 1006, Figures 6&7)

1. Claim 4

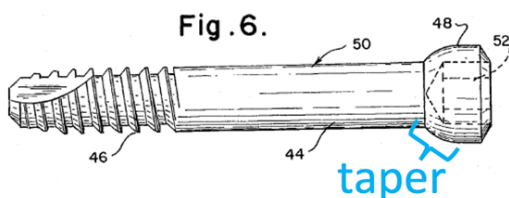
Claim 4 further limits claim 3 by requiring the head portion of the first member to comprise a torque transmitting aperture. Cognet discloses a screw. Ex. 1004, pg. 2 lns. 35-38. Although a POSA would assume that Cognet is disclosing an aperture in the head of the screw, it is not explicitly stated. Brumfield discloses a hexagonally shaped inset in the head portion of the screw that permits insertion of a suitable tool for compression of the screw. Ex. 1006, 5:22-24. This compression is accomplished by applying

torque to the screw. Ex. 1002 ¶ 102. The torque transmitting aperture is also shown in Figure 7, which is shown below.



2. Claim 8

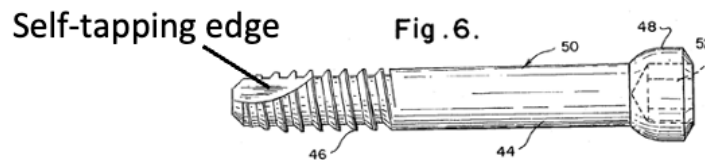
Claim 8 further limits claim 1 to require the head portion of the first member to be tapered. While it is a very common screw head shape and would be assumed by a POSA, Cognet does not explicitly state that the head of the first member is tapered. Brumfield discloses a screw with a “beveled head portion,” which is a tapered head portion as required by claim 8. Ex. 1006, 5:20-22. Ex. 1002 ¶ 103. This tapered head is shown as element 48 in Figure 6 shown below. *Id.*



3. Claim 10

Claim 10 further limits claim 1 by requiring that the first member includes a self-tapping edge for removing bone material. Cognet is not specific as to whether the first member includes a self-tapping edge or not.

Brumfield discloses a “self-tapping threaded end.” Ex. 1006, 5:20-22. The self-tapping threaded end, which is a self-tapping edge, and is shown as element 46 in Figure 6, included below. Ex. 1002 ¶ 104.



4. Claim 14

Claim 14 further limits claim 13 by requiring that the head portion of the first member is tapered. This claim has the same limitations as claim 8 and is disclosed by Brumfield as discussed in section (V.B.2) of this petition. Ex. 1002 ¶ 105.

5. Claim 15

Claim 15 further limits claim 12 by requiring that the head portion of the first member is tapered. This claim has the same limitations as claim 8 and is disclosed by Brumfield as discussed in section (V.B.2) of this petition. Ex. 1002 ¶ 106.

C. Cognet and Ferrante make obvious claim 11.

Claim 11 is unpatentable under 35 U.S.C. § 103 for obviousness over Cognet in view of Ferrante. Ferrante is U.S. Patent Publication No. 2003/0187447, which was published on October 2, 2003, (included with this

petition as Ex. 1007) which is before the earliest possible effective filing date of the '166 patent. This makes Ferrante prior art to the '166 patent under section 103. Ferrante discloses an orthopedic screw with a head, body, and shank with a thread extending radially outward from the shank.

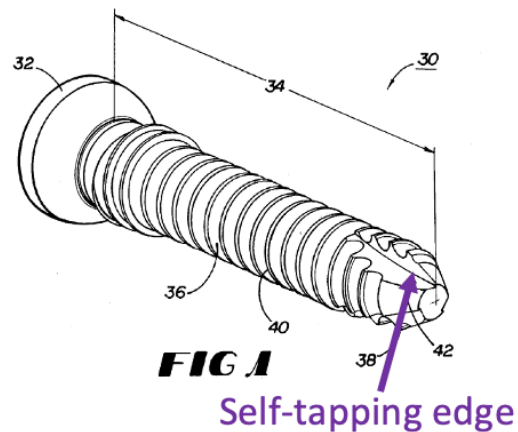
Ex. 1002 ¶¶ 42, 107.

Ferrante is analogous art because it discloses orthopedic screws being used in an intramedullary nail. Ex. 1007, Figs. 14-15; [0036]-[0037]. It would have been obvious to a POSA to use the screws disclosed in Ferrante with the intramedullary nail disclosed in Cognet because the screw and nail in Ferrante are performing the same function in the same way as the screw and nail in Cognet. Namely, the second member screw in Ferrante and Cognet are locking the nail in place. Ex. 1002 ¶ 108.

1. Claim 11

Claim 11 further limits claim 10 by requiring that the second member includes a self-tapping edge for removing bone material. While this is a very common characteristic of orthopedic screws, Cognet is not specific as to whether the second member includes a self-tapping edge or not. Ex. 1002 ¶ 109. Ferrante discloses a flute (42) for the removal of bone chips as screw (30) is implanted into bone (Ex. 1007, [0043]), which is a self-tapping edge

and is shown in figure 1, included below. Ex. 1002 ¶ 110.



D. Simon Anticipates Claims 1, 4-5, 8, 10-12, and 14-15.

Claims 1, 4-5, 8, 10-12, and 14-15 are unpatentable under Pre-AIA 35 U.S.C. § 102(a) and (b) for anticipation by Simon. Simon is U.S. Patent Publication No. 2006/0206044 (included as Ex. 1008 with this petition) which was filed on August 1, 2003, by William Simon and published on September 14, 2006, Simon is a prior-art printed publication because it was available to the public before the invention by the applicants for the ‘166 patent and more than one year prior to the earliest effective filing date to which the ‘166 patent is entitled of Feb 11, 2010, making the disclosures “described in a printed publication in this or a foreign country,” and publicly available.. Ex. 1002 ¶ 111.

Simon discloses a small intramedullary nail intended for insertion in a longer bone but used for bones in the mid-foot. All Figures in this section

(V.D) of this petition are from Simon Figure 1 unless otherwise noted.

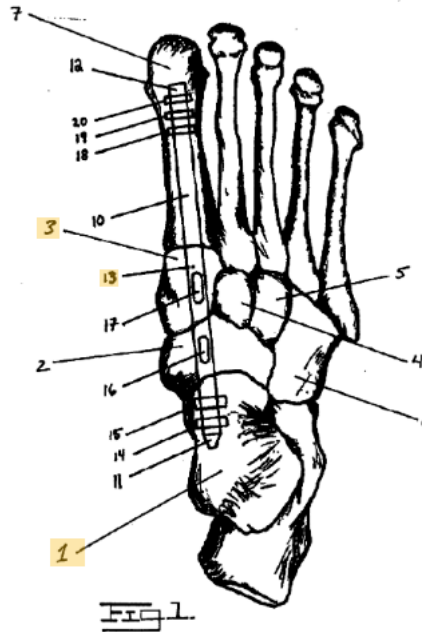
Ex. 1002 ¶ 112.

When first introducing the intramedullary nail (Ex. 1008, [0039]) Simon describes the “proximal head portion” as having “one or more transverse holes, ideally three” which is describing holes 18, 19, and 20. Simon later describes the “distal portion” as having “at least one fastener hole (ideally three)” to describe the same holes. Ex. 1008, [0046]. Similarly, Simon describes the tapered portion as the distal end (Ex. 1008, [0039] “distal tapered end portion”) and then later describes this same portion as the proximal end (Ex. 1008, [0046]). To avoid confusion, this petition will use the terms terminal end for the head portion (element 12 in Figure 1) and tapered end for the opposite end (element 11 in Figure 1). Ex. 1002 ¶ 113.

1. Claim 1

Claim 1 of the '166 patent is directed to an assembly for bone fusion. Simon is directed toward fusing the medial cuneiform and navicular bones (Simone [0045] “The present invention specifically relates to the fusion, and eventual rejuvenation of the bones in the midfoot region ...”). Additionally, Simon is assembled by inserting the screws into the intramedullary nail. Ex. 1008, [0045] (“... intramedullary nail ... and securing the nail with locking

screws”). Thus, Simon describes an assembly for bone fusion and discloses the preamble for claim 1, to the extent it is given patentable weight. Ex. 1002 ¶ 114.



(Simon, Fig. 1)

a) 1[a][i]: “a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis”

As discussed above in the Cognet anticipation arguments for claim element 1[a][i] (section (V.A.1.a) of this petition) a screw includes an elongated body extending from a first end (the tip) to a second end (the head) along a longitudinal axis. Simon discloses elements 18, 19, and 20 as being locking screws (Ex. 1008, [0053]), interlocking cortical screws, or

transfixation screws (Ex. 1008, [0039]), and thus discloses this claim element. Ex. 1002 ¶ 115.

b) 1[a][ii] “wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;”

As discussed in the Cognet anticipation arguments for this claim element (section V.A.1.b) of this petition), screws have a shaft portion with an external surface and a head portion with an exterior surface, and at least one thread, with a thread height, that extends radially outward from the external surface of the shaft portion. Simon discloses elements 18, 19, and 20 as being locking screws (Ex. 1008, [0053]), interlocking cortical screws, or transfixation screws (Ex. 1008, [0039]), and thus discloses this claim element. Ex. 1002 ¶ 116.

c) 1[b][i]: “a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis,”

As discussed above in the Cognet anticipation arguments for claim element 1[b][i] (section (V.A.1.c)), screws have an elongated body that extends from a first end (the tip of the screw) to a second end (the head of

the screw) along a longitudinal axis. Ex. 1002 ¶ 42. Figure 1 of Simon discloses a second screw (second member) (elements 14 or 15 of Figure 1) (Ex. 1008, [0053]). Simon further discloses that the second screw is also a locking screw (Ex. 1008, [0053]), interlocking cortical screw, or transfixation screw (Ex. 1008, [0039]), and thus discloses this claim element. Ex. 1002 ¶ 117.

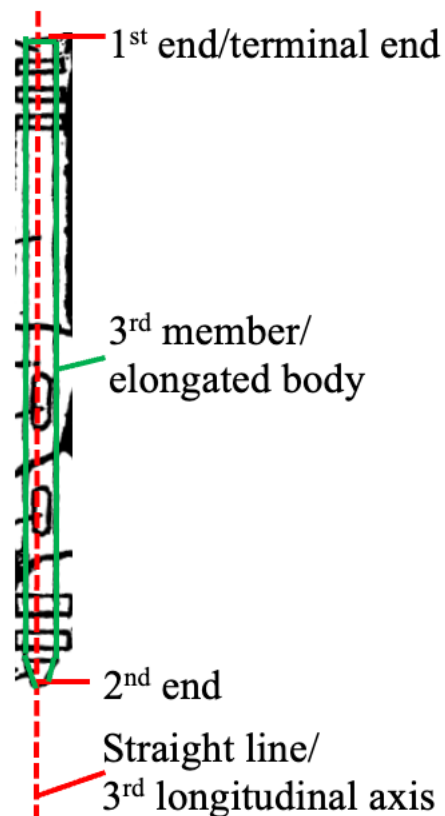
d) 1[b][ii]: “wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;”

As described above in the Cognet anticipation arguments for claim element 1[b][ii] (section V.A.1.d), screws are comprised of a shaft and at least one thread. Ex. 1002 ¶ 42. The shaft has an external surface. The threads have a height, and they extend radially outward from the external surface of the shaft. Ex. 1002 ¶ 42d. Simon discloses a screw as the second member, and thus discloses this claim element. Ex. 1008, [0053] (“...intramedullary nail 10 is attached with at least one fastener (or locking screw, with two depicted in FIG. 1, 14 & 15).”). Ex. 1002 ¶ 118.

e) 1[c][i] “a third member comprising a third elongated body extending along a

**straight line from a first end to a second end
along a third longitudinal axis,”**

Simon discloses a third member comprised of a body that extends along a straight line (the 3rd longitudinal axis) from a first end to a second end as indicated below. Ex. 1002 ¶ 119.



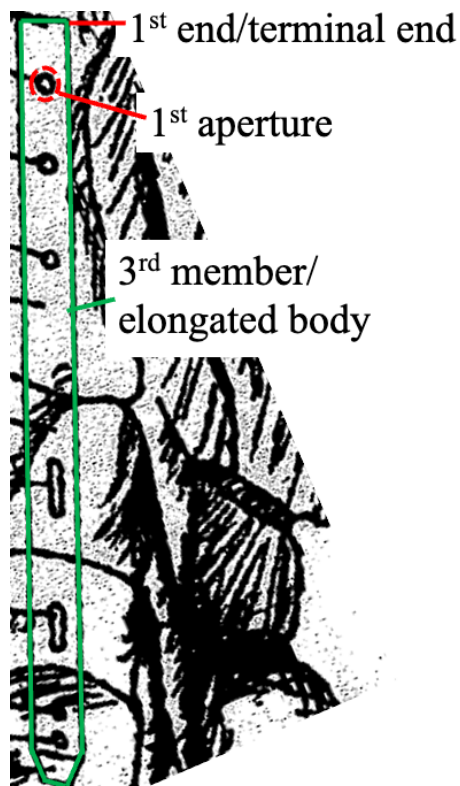
**f) 1[c][ii] “wherein the third member
comprises a first aperture at a terminal end of
the first end of the third elongated body,”**

As discussed above in the Cognet anticipation arguments for claim element 1[c][ii] (section (V.A.1.f)) a POSA would understand the phrase “at the terminal end” to refer to a location near the terminal end, as opposed to

merely along the shaft of the nail at any location, or at the tapered end.

Ex. 1002 ¶ 120.

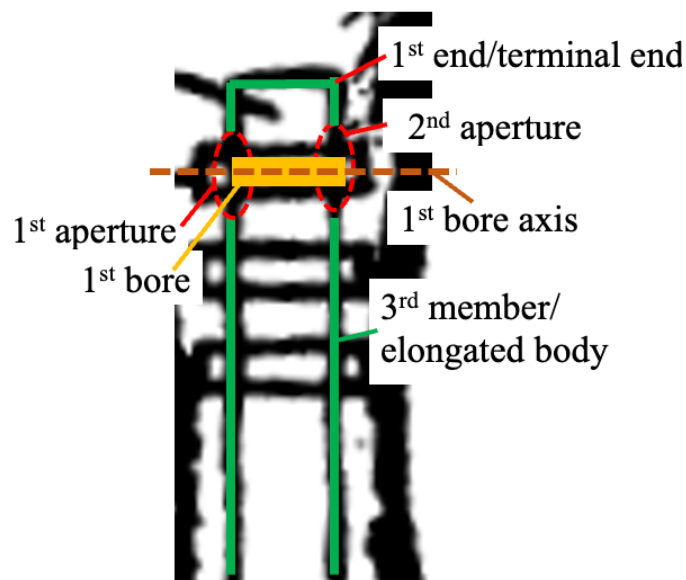
The first aperture (the first end of the first bore) was oriented on the exterior surface of the third member at the terminal end. Simon discloses “a number of proximal and distal fastener holes” (Ex. 1008, [0046]). Simon discloses a fastener hole (hole 20 in figure 2) at the terminal end of the third elongated body as shown below (Simon, Fig. 2 – cropped). Ex. 1008, [0054]. Ex. 1002 ¶ 121. Thus, fastener hole 20 is at the terminal end and not merely along the shaft (unlike the other fastener holes in the figure), and discloses this claim element.



Additionally, Simon discloses an intramedullary nail where the terminal end has “at least one bore which extends transversely to the central axis of the nail for receiving at a stable angle a bone fastener.” Ex. 1008, [0015]. Which teaches an aperture at the terminal end. Ex. 1002 ¶ 122.

g) 1[c][iii] “a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member”

Simon discloses a nail (third member) that would have “a number of proximal and distal fastener holes” (Ex. 1008, [0046]) and shows fasteners (at least element 20 of Figure 1) extending through the third body indicating that there is a hole extending through the third body, such as a tunnel or a bore. Ex. 1002 ¶ 123.

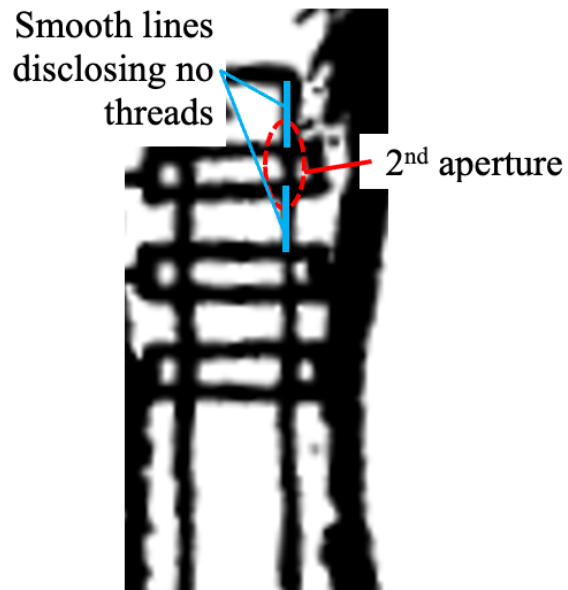


h) 1[c][iv] “wherein the first bore comprises an interior surface at the first aperture”

As discussed above in the Cognet anticipation arguments for claim element 1[c][iv] (section (V.A.1.h)) a bore has an interior surface. Simon discloses a bore at the first aperture (see above), thus disclosing this claim element. Ex. 1002 ¶ 124.

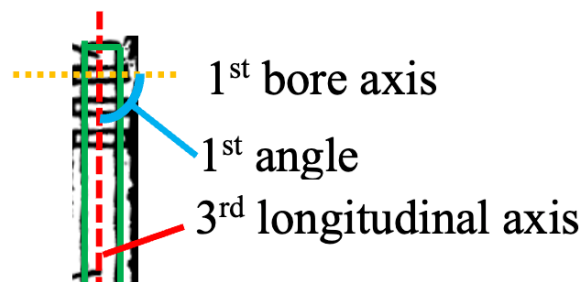
i) 1[c][v] “wherein there are no threads adjacent to the second aperture on the exterior surface of the third member”

Simon discloses a third member with no mention of threads adjacent to a second aperture. Simon’s silence on threads indicates to a POSA that the surfaces are smooth and unthreaded. Ex. 1002 ¶ 125. Additionally, the smooth lines on the figures disclose that in at least one embodiment there are no threads adjacent to the second aperture on the exterior surface of the third member. *Id.*



j) 1[c][vi] “wherein the third longitudinal axis and the first bore axis define a first angle”

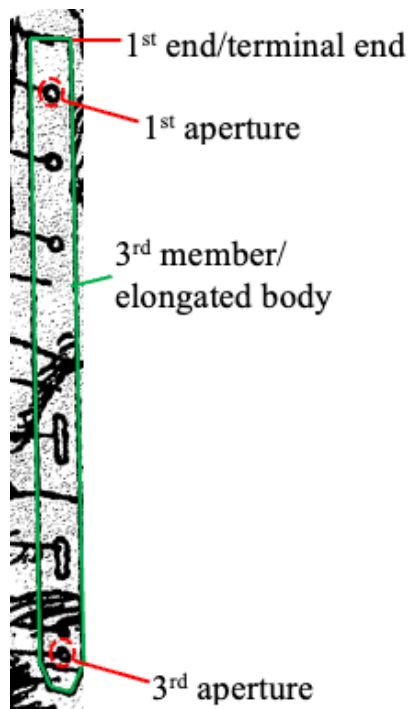
The '166 patent requires the third longitudinal axis and the first bore axis define a first angle. Simon discloses the third longitudinal axis and the first bore axis intersecting, creating a first angle as shown below. Ex. 1002 ¶ 126.



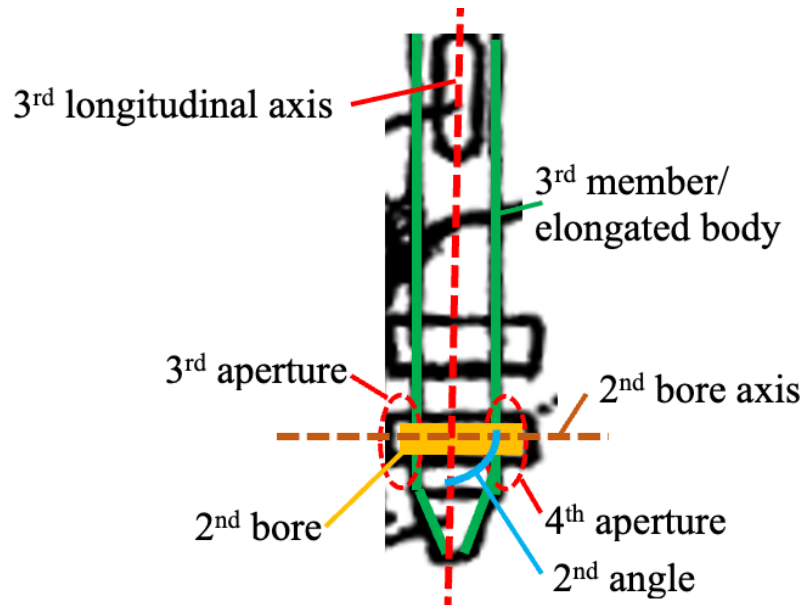
k) 1[d] “wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from

the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle”

Simon discloses fastener holes at the tapered end of the nail (3rd member) as 14 and 15 on Figure 2 (Ex. SIMON [0054]). Simon discloses a third and a fourth aperture on the exterior surface of the third member with a second bore extending along a second bore axis between them (see below). Ex. 1002 ¶ 127. Simon further discloses the third longitudinal axis intersecting the second bore axis to create a second angle (see below). *Id.*



(Simone, Fig. 2)



(Simon, Fig. 1)

l) 1[e] “wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture”

Simon discloses the fastener hole (first bore) is for the insertion of fasteners (first member) to fixate the nail (third member) to the talus. Ex. 1008, [0046]. A POSA would immediately understand that Simon is coupling the first member to the third member by inserting the first end (tip) of the first member (screw) into the first aperture, through the first bore, and out of the second aperture. Ex. 1002 ¶ 128.

m) 1[f] “wherein the second member couples to the third member by inserting the first end of the second member into the third aperture,

through the second bore, and out of the fourth aperture”

Simon discloses the fastener hole (second bore) is for the insertion of fasteners (second member) to fixate the nail (third member) to the first metatarsal. Ex. 1008, [0046]. A POSA would immediately understand that Simon is coupling the second member to the third member by inserting the first end (tip) of the second member (screw) into the third aperture, through the second bore, and out of the fourth aperture. Ex. 1002 ¶ 129.

n) 1[g] “wherein the first angle is in the range of about 0 degrees to about 90 degrees”

Simon discloses a first angle defined by the third longitudinal axis and the first bore axis. As discussed above in Cognet claim element 1[g] (section (V.A.1.n) of this petition), any two axes intersecting disclose this claim element. Simon discloses the third longitudinal axis intersecting with the first bore axis, and thus discloses this claim element. Ex. 1002 ¶ 130.

Additionally, A POSA would interpret Simon Figure 1 to disclose the first angle to be about 90°, which is in the claimed range of 0° to about 90°. *Id.*

o) 1[h] “wherein the second angle is in the range of about 0 degrees to about 90 degrees”

Simon discloses a second angle defined by the third longitudinal axis and the second bore axis. As discussed above in Cognet claim element 1[h]

(section (V.A.1.o) of this petition), any two axes intersecting disclose this claim element. Simon discloses the third longitudinal axis intersecting with the second bore axis, and thus discloses this claim element. Ex. 1002 ¶ 131. Additionally, A POSA would interpret Simon Figure 1 disclose the first angle to be about 90°, which is in the claimed range of 0° to about 90°. *Id.*

p) 1[i] “wherein the second bore axis is substantially perpendicular to the third longitudinal axis”

As discussed in Cognet claim element 1[i] (section (V.A.1.p)) the term “substantially perpendicular” is not explained in the ’166 patent, and there is no guidance provided in the specification or figures for how to determine which range of degrees would fall within the scope of this claim term, other than something that is perpendicular. Simon discloses the second angle to be about 90° as discussed above, which is “substantially perpendicular.” Ex. 1002 ¶ 132.

2. Claim 4

Claim 4 limits claim 3 by requiring the first member to comprise a torque transmitting aperture. A torque transmitting aperture is discussed in detail in the Cognet anticipation arguments for this claim (section (V.A.4) of this petition). Since almost all screws include a torque transmitting aperture,

by disclosing the first member to be a screw (Ex. 1008, [0039]) Simon is disclosing this claim's limitation. Ex. 1002 ¶¶ 42, 133.

3. Claim 5

Claim 5 further limits claim 1 to require the first aperture be aligned on the first bore axis. Being “aligned” is discussed in detail in the Cognet anticipation arguments for this claim (section (V.A.5) of this petition). Simon discloses the center of the first aperture aligned with the first bore axis, thus anticipating this claim. Ex. 1002 ¶ 134.

4. Claim 8

Claim 8 limits claim 1 by requiring the head portion of the first member be tapered. Simon discloses the first member can be screws or they can be interlocking or transfixion screws. (Ex. 1008, [0039]). Bone screws, interlocking screws or transfixion screws are all intended to traverse through the holes or slots in the nail and into bone to secure the nail in place. In order to maintain a low-profile stature, the heads of these screws would have a tapered shape. Simon describes using a locking screw of sufficient length to extend past through the nail hole and into the talus bone for proper fixation. Other fastener holes can be fitted with shorter interlocking screws that pass through the entry and exit holes of the nail. Ex. 1008, [0054]. A POSA

would immediately assume that the first member (interlocking screw) has a tapered head portion to permit low profile seating. Ex. 1002 ¶¶ 42, 135.

5. Claim 10

Claim 10 limits claim 1 by requiring the first member include a self-tapping edge for removing bone material. Simon discloses the first member to be an interlocking screw (Ex. 1008, [0039]). Interlocking screws commonly have a self-tapping edge. Ex. 1002 ¶¶ 42, 136. The purpose of a self-tapping edge is to bore through the material to make way for the body of the screw. Self-tapping edges remove some of the bone as it bores through the bone. *Id.* A POSA would immediately assume that the first member (interlocking screw) includes a self-tapping edge, and that the self-tapping edge is for removing bone material. *Id.*

6. Claim 11

Claim 11 limits claim 10 by requiring the first end of the second member include a self-tapping edge for removing bone material. Simon discloses the second member to be an interlocking screw (Ex. 1008, [0039]). As discussed in detail above (claim 10) A POSA would immediately assume the first end (tip) of the second member (interlocking screw) includes a self-tapping edge for removing bone material. Ex. 1002 ¶¶ 42, 137.

7. Claim 12

The preamble for claim 12 is the same as the preamble for claim 1 and is disclosed by Simon as discussed in section (V.D.1) of this petition.

Ex. 1002 ¶ 138.

- a. **12[a][i]: “a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;”**

This claim element has the same limitations as claim element 1[a][i] and is disclosed by Simon as discussed in section (V.D.1.a) of this petition.

Ex. 1002 ¶ 139.

- b. **12[a][ii] “wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;”**

This claim element has the same limitations as claim element 1[a][ii] and is disclosed by Simon as discussed in section (V.D.1.b) of this petition.

Ex. 1002 ¶ 140.

- c. **12[b][i]: “a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis,”**

This claim element has the same limitations as claim element 1[b][i] and is disclosed by Simon as discussed in section (V.D.1.c) of this petition.
Ex. 1002 ¶ 141.

- d. **12[b][ii]: “wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;”**

This claim element has the same limitations as claim element 1[b][ii] and is disclosed by Simon as discussed in section (V.D.1.d) of this petition.
Ex. 1002 ¶ 142.

- e. **12[c][i] “a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis,”**

This claim element has the same limitations as claim element 1[c][i] and is disclosed by Simon as discussed in section (V.D.1.e) of this petition.
Ex. 1002 ¶ 143.

a) 12[c][ii] “wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body,”

This claim element has the same limitations as claim element 1[c][ii] and is disclosed by Simon as discussed in section (V.D.1.f) of this petition.

Ex. 1002 ¶ 144.

b) 12[c][iii] “a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member”

This claim element has the same limitations as claim element 1[c][iii] and is disclosed by Simon as discussed in section (V.D.1.g) of this petition.

Ex. 1002 ¶ 145.

c) 12[c][iv] “wherein the first bore comprises an interior surface at the first aperture”

This claim element has the same limitations as claim element 1[c][iv] and is disclosed by Simon as discussed in section (V.D.1.h) of this petition.

Ex. 1002 ¶ 146.

d) 12[c][v] “wherein there are no threads adjacent to the second aperture on the exterior surface of the third member”

This claim element has the same limitations as claim element 1[c][v] and is disclosed by Simon as discussed in section (V.D.1.i) of this petition.

Ex. 1002 ¶ 147.

e) 12[c][vi] “wherein the third longitudinal axis and the first bore axis define a first angle”

This claim element has the same limitations as claim element 1[c][vi] and is disclosed by Simon as discussed in section (V.D.1.j) of this petition.

Ex. 1002 ¶ 148.

f) 12[d] “wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle”

This claim element has the same limitations as claim element 1[d] and is disclosed by Simon as discussed in section (V.D.1.k) of this petition.

Ex. 1002 ¶ 149.

g) 12[e] “wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture”

This claim element has the same limitations as claim element 1[e] and is disclosed by Simon as discussed in section (V.D.1.l) of this petition.

Ex. 1002 ¶ 150.

h) 12[f] “wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture”

This claim element has the same limitations as claim element 1[f] and is disclosed by Simon as discussed in section (V.D.1.m) of this petition.

Ex. 1002 ¶ 151.

i) 12[g] “wherein the second angle is in the range of about 0 degrees to about 90 degrees”

This claim element has the same limitations as claim element 1[h] and is disclosed by Simon as discussed in section (V.D.1.o) of this petition.

Ex. 1002 ¶ 152.

j) 12[h] “wherein the second bore axis is substantially perpendicular to the third longitudinal axis”

This claim element has the same limitations as claim element 1[i] and is disclosed by Simon as discussed in section (V.D.1.p) of this petition.

Ex. 1002 ¶ 153.

8. Claim 14

This claim has the same limitations as claim 8 and is disclosed by Simon as discussed in section (V.D.4) of this petition. Ex. 1002 ¶ 154.

9. Claim 15

This claim has the same limitations as claim 8 and is disclosed by Simon as discussed in section (V.D.4) of this petition. Ex. 1002 ¶ 155.

E. Simon in View of Ferrante Make Obvious Claims 4, 8, 10-11, and 14-15.

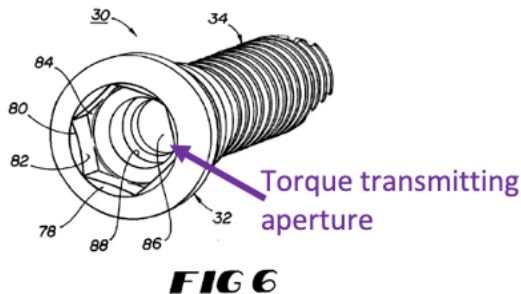
Ferrante discloses an orthopedic screw with a head, body, and shank with a thread extending radially outward from the shank. Ex. 1002 ¶ 156.

Ferrante is analogous art because it discloses orthopedic screws being used in an intramedullary nail. It would have been obvious to a POSA to use the screws disclosed in Ferrante with the intramedullary nail disclosed in Simon because the screw and nail in Ferrante (Ex. 1007, Fig. 14-15; ¶¶ 36-37) are performing the same function in the same way as the screw and nail in Simon. Ex. 1002 ¶ 157.

1. Claim 4

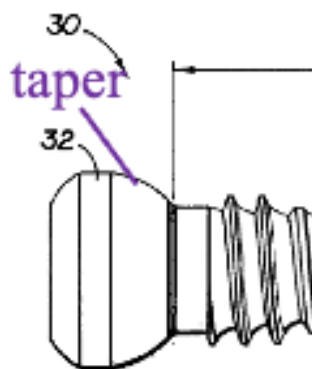
Claim 4 further limits claim 3 by requiring the head portion of the first member to comprise a torque transmitting aperture. Simon discloses a screw (first member). Ex. 1008, [0039] and [0053]. Ex. 1002 ¶¶ 42, 158. A POSA would assume that the screw head in Simon would have an aperture in the screw head to through which torque could be applied, but Simon does not explicitly state that the screw comprises such an aperture. Ferrante discloses

a screw with a hex socket (Ex. 1007, [0062]), which is a torque transmitting aperture. This aperture is clearly seen in Ferrante figure 6 below. Ex. 1002 ¶ 158.



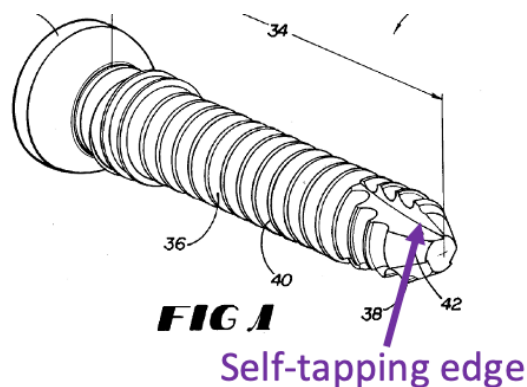
2. Claim 8

Claim 8 further limits claim 1 to require the head portion of the first member to be tapered. Simon discloses a locking screw (Ex. 1008, [0039] and [0053]). A POSA would assume this discloses a tapered head, but Simon does not explicitly state that the head is tapered. Ferrante discloses a screw with a tapered head at least in figure 2 shown below (cropped). Ex. 1002 ¶ 159.



3. Claim 10

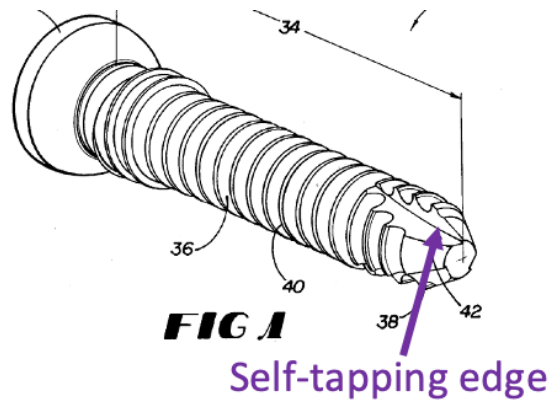
Claim 10 further limits claim 1 by requiring that the first member includes a self-tapping edge for removing bone material. While a POSA would assume that the first member includes a self-tapping edge, Simon does not explicitly state this feature. Ferrante discloses a flute (42) for the removal of bone chips as screw (30) is implanted into bone (Ex. 1007, [0043]), which is a self-tapping edge. Ex. 1002 ¶ 160. That Ferrante discloses a self-tapping edge is shown in figure 1, included below.



4. Claim 11

Claim 11 further limits claim 10 by requiring that the second member includes a self-tapping edge for removing bone material. While a POSA would assume that the second member includes a self-tapping edge, Simon does not explicitly state this feature. Ferrante discloses a flute (42) for the removal of bone chips as screw (30) is implanted into bone (Ex. 1007, [0043]). That Ferrante discloses a self-tapping edge is shown in figure 1,

included below. Ex. 1002 ¶ 161.

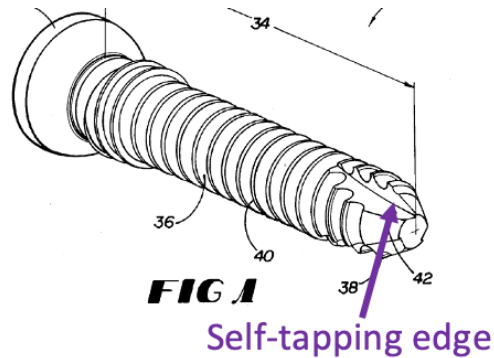


5. Claim 14

Claim 14 further limits claim 13 by requiring that the head portion of the first member is tapered. This claim has the same limitations as claim 8 and is disclosed by Ferrante as discussed in section (V.E.2) of this petition. Ex. 1002 ¶ 162.

6. Claim 15

Claim 15 further limits claim 12 by requiring that the head portion of the first member is tapered. This claim has the same limitations as claim 8 and is disclosed by Ferrante as discussed in section (V.E.2) of this petition. Ex. 1002 ¶ 163.



F. Simon in View of Cognet Make Obvious Claim 9.

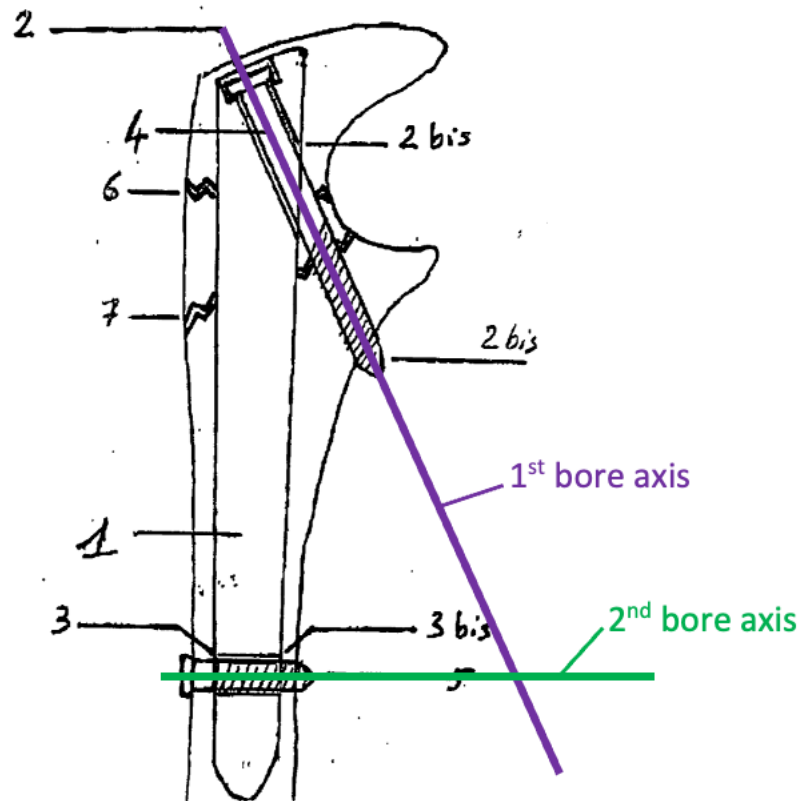
Claim 9 is unpatentable under 35 U.S.C. § 103 for obviousness over Simon in view of Cognet. Cognet is analogous art because it discloses an intramedullary nail for osteosynthesis. It would have been obvious to a POSA to use the features disclosed in Cognet with the intramedullary nail disclosed in Simon because the intramedullary nail in Cognet and the intramedullary nail in Simon are performing the same function in the same way. Additionally, Simon teaches the use of intramedullary nails intended for longer bone being used for bones in the mid-foot. Ex. 1008, [0057]. Ex. 1002 ¶ 164.

1. Simon and Cognet disclose all the Elements of Claim 9

Claim 9 limits claim 1 by requiring the first bore axis and the second bore axis intersect outside the third body. That Cognet discloses this and all the elements of this claim is discussed in detail in the Cognet arguments for

this claim (section V.A.8 of this declaration) and is also shown below.

Ex. 1002 ¶ 165.



(Cognet, Figure 1)

G. Simon in view of Leu Make Obvious Claims 2-3, 6-7, and 13.

Claims 2-3, 6-7, and 13 are unpatentable under 35 U.S.C. § 103 for obviousness over Simon in view of Leu. Leu is U.S. Patent No. 6,270,499 (“Leu”) (included in this petition as Ex. 1009) issued on August 7, 2001, and is the national stage of PCT No. PCT/CH97/00392, which was filed on October 20, 1997. The PCT was published on April 29, 1999, making it

available to the public. Leu is a prior art patent to the '166 patent under section 103 because the issue date of Leu is before the effective filing date of the '166 patent. Ex. 1002 ¶ 166.

Leu is analogous art because it is an intramedullary nail secured by multiple screws. It would have been obvious to a POSA to combine Leu with Simon because Simon gives an example embodiment that is an intramedullary nail intended for insertion in a longer bone (Ex. SIMON [0057]) and gives Leu as an example of an intramedullary nail intended for insertion in a longer bone (Ex. SIMON [0015]). Ex. 1002 ¶ 167.

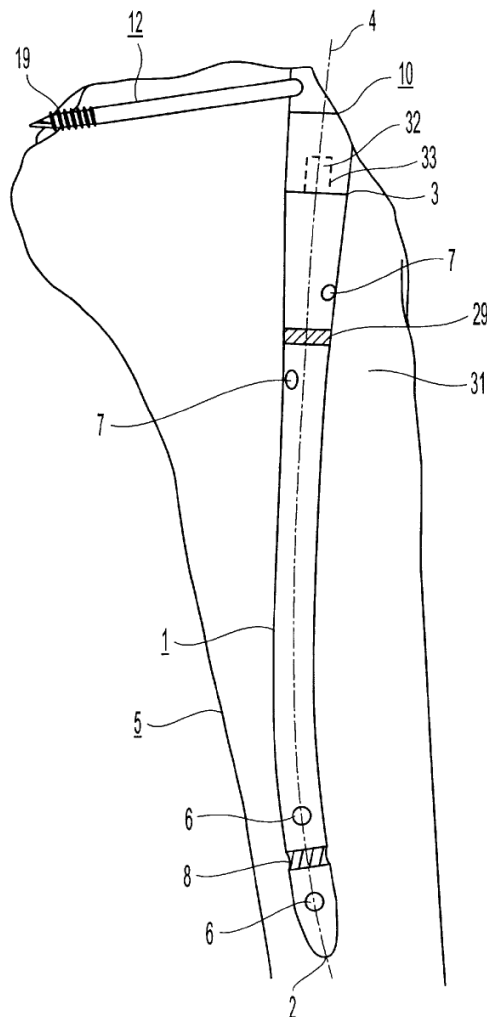


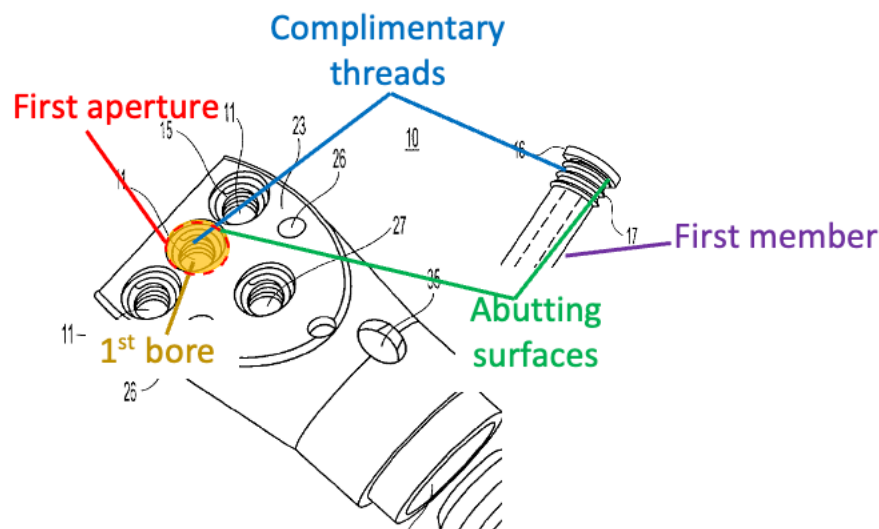
Fig. 1

(Ex. 1009, Figure 1)

1. Simon in view of Leu Discloses all the elements of Claim 2.

Claim 2 limits claim 1 by requiring the head portion of the first member to reside at least partially within the first bore. Leu discloses a screw (12) (first member) with threads (17) near the screw head. Ex. 1009,

4:5. These threads (17) have corresponding threads (15) within the bore (11) on the nail head (10), allowing for the screw head to lock into and sink within the first aperture (11). Ex. 1009, 4:63-67; 5:1-5. See cropped Figures 2 and 3 below. Ex. 1002 ¶ 168.



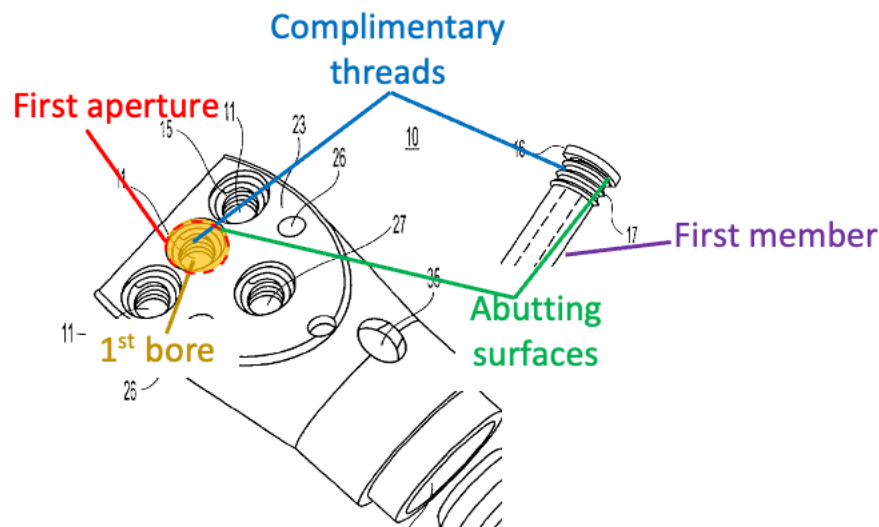
(Ex. 1009, Figures 2 and 3 – cropped)

2. Simon and Leu Discloses all the Elements of Claim 3

Claim 3 further limits claim 2 by requiring the exterior surface of the head portion of the first member abut the interior surface of the first bore at the first aperture. Leu discloses a countersink or shoulder cavity recess inside at the entrance to the first bore hole, which is a preferred manner to prevent a screw from entering past the preferred penetration depth of the screw. The internal shoulder serves to block further entry of the screw at the

moment when the screw head contacts the internal surface of the shoulder.

The underside (exterior surface) of the head of the screw (first member) will abut the interior surface of the first bore as shown below. Ex. 1002 ¶ 169.



(Ex. 1009, Figures 2 and 3 – cropped)

3. Simon and Leu Discloses all the Elements of Claim 6

Claim 6 further limits claim 5 by requiring the head portion of the first member to at least partially reside within the first bore, which is the same limitations as claim 2. The disclosure of this requirement by Simon and Leu is discussed above in section (V.G.1). Ex. 1002 ¶ 170.

4. Simon Discloses all the Elements of Claim 7

Claim 7 further limits claim 6 by requiring the head portion of the first member to abut the interior surface of first bore at the first aperture, which is

the same limitation as claim 3. The disclosure of this requirement by Simon and Leu is discussed above in section (V.G.2). Ex. 1002 ¶ 171.

5. Simon and Leu Disclose all the elements of Claim 13

This claim has the same limitations as claim 2 and is disclosed by Simon and Leu as discussed in section (V.G.1). Ex. 1002 ¶ 172.

VI. DISCRETIONARY DENIAL NOT WARRANTED

A. *Fintiv* Factors Favor Institution

An evaluation of the factors under *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020), weighs against discretion to deny institution. Moreover, this Petition presents compelling evidence of unpatentability and, per the PTO interim guidance dated June 21, 2022 (Ex. 1012) as clarified by *CommScope Technologies, LLC v. Dali Wireless Inc.*, IPR2022-01242, Paper 23 (PTAB Feb. 27, 2023), demonstrates that the PTAB should not discretionarily deny institution.

Factor 1 is whether the court granted a stay or whether evidence exists that one may be granted if IPR is instituted. No motion to stay has been filed, so the Board should not infer the outcome of such a motion. *Sand Revolution II LLC v. Continental Intermodal Group -- Trucking LLC*, IPR2019-01393, Paper 24 at 7 (PTAB June 16, 2020) ; see also *Dish*

Network L.L.C. v. Broadband iTV, Inc., IPR2020-01359, Paper 15 at 11 (PTAB Feb. 12, 2021) (“It would be improper to speculate, at this stage, what the Texas court might do regarding a motion to stay...”). Thus, this factor is neutral on discretionary denial.

Factor 2 is the proximity of the court’s trial date to the projected statutory deadline for the PTAB’s Final Written Decision (FWD). The Judge in the district court litigation involving the ’166 Patent has not yet set a trial date and the case is still in its early stages. Ex. 1011 at 2-3. Any trial in the litigation may not occur until well after a FWD issues in this IPR. Thus, this factor weighs strongly against discretionary denial.

Factor 3 is the investment in the parallel proceeding by the court and the parties. The case is in the early stages of discovery and a claim construction hearing for the ’166 patent has not yet occurred. The Parties in the litigation are currently in the briefing stage for claim construction and the hearing is set for June 22, 2023. Ex. 1011 at 2-3. In addition, no trial date has been set and all future deadlines after the claim construction hearing will be based on the date that the district court issues a claim construction ruling. *Id.* Thus, this factor weighs strongly against discretionary denial. See *HP Inc. v. Slingshot Printing LLC*, IPR2020-01084, Paper 13 at 10 (PTAB Jan.

14, 2021). There, the PTAB found that significant time and expense was still required by the district court by the institution deadline where the claim construction ruling had issued but fact discovery and expert discovery were still open as is the case here. *Id.* The PTAB also noted that, as Fusion Orthopedics did here, the petitioner filed the IPR within a few months after Preliminary Invalidity contentions were served. *Id.*

Factor 4 is the overlap between issues raised in the petition and in the parallel proceeding. Factor 4 weighs against discretionary denial. At present, it is unclear how much overlap there will be between the two proceedings. Given that no trial date has been assigned and the early stage of the district court litigation, “there is a reasonable likelihood that the Board will address the overlapping validity issues prior to the district court reaching them at trial..., thereby providing the possibility of simplifying issues for trial...” *Juniper Networks, Inc. v. Packet Intelligence LLC*, IPR2020-00339, Paper 21 at 18 (PTAB Sept. 10, 2020).

Factor 5 is whether petitioner and defendant in the parallel proceeding are the same party. Here, the Petitioner is the defendant in the co-pending district court litigation. That is true of most Petitioners in IPR proceedings, making this factor neutral. *HP Inc.*, IPR2020-01084, Paper 13 at 9 (PTAB

Jan. 14, 2021) (having the “same parties as parallel proceeding” makes factor 5 “neutral”).

Finally, factor 6 addresses other circumstances that impact the Board’s exercise of discretion, including the merits. Factor 6 weighs strongly against discretionary denial. Petitioner respectfully submits that the unpatentability challenge presented in this Petition is compelling. As discussed above, factors 1-5 already favor denial of institution, and this Petition presents a compelling case of anticipation by showing that every element of every challenged claim was disclosed in the Simon reference, in addition to the other grounds of unpatentability described herein.

Commscope, IPR2022-01242, Paper 23 at 5 (PTAB Feb. 27, 2023) (“In circumstances where, however, the Board’s analysis of *Fintiv* factors 1–5 favors denial of institution, the Board shall then assess compelling merits.”). As *Fintiv* noted, “if the merits of a ground raised in the petition seem particularly strong...institution of a trial may serve...overall system efficiency and integrity.” *Fintiv*, IPR2020-00019, Paper 11 at 14-15. Further, as discussed above, the ’166 Patent issued without the Examiner actually considering any of the art presented in this Petition. Institution is thus consistent with the significant public interest against “leaving bad patents

enforceable.” *Thryv, Inc. v. Click-To-Call Techs., LP*, 140 S. Ct. 1367, 1374 (2020). Based on a “holistic view of whether efficiency and integrity of the system are best served,” the facts here weigh against exercising discretionary denial. *Samsung Elecs. Co. Ltd. v. Dynamics Inc.*, IPR2020-00505, Paper 11 at 15 (PTAB Aug. 12, 2020).

B. No Support for Denial Under § 325(d)

Denial under § 325(d) is not warranted because the challenges presented in this petition are neither cumulative nor redundant to the prosecution of the '166 patent. The Examiner did not consider any of the references relied upon in this petition. Moreover, the challenges in this petition are non-cumulative because the art relied upon here teaches the claim elements that the Examiner deemed allowable. This is the first IPR Petition filed by Fusion Orthopedics, LLC to challenge the '166 Patent. To the extent Patent Owner makes any arguments regarding discretionary denial, Petitioner reserves the right to further address them at that time.

VII. CONCLUSION

For the foregoing reasons claims 1-15 are unpatentable and Petitioner requests their cancellation.

Respectfully submitted,

Dated: April 28, 2023

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24 (d), I certify that the present paper contains 11,817 words as counted by the word-processing program used to generate the Petition. The word count does not include a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.

Respectfully submitted,

Dated: April 28, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a) and (b), I certify that on the date listed below, a copy of this paper and every exhibit filed with this paper was served on the patent owner at the correspondence address of record and other addresses, as listed below:

Respectfully submitted,

Dated: April 28, 2023

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