

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of U.S. Patent No. 11,298,166

Issued: April 12, 2022

Filed: May 18, 2021

Inventors: Jeff Tyber, *et al.*

Assignee: Extremity Medical LLC

Title: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND
METHOD OF USE

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**DECLARATION OF LEONEL DOMINGUEZ IN SUPPORT OF
PETITIONER, FUSION ORTHOPEDICS LLC'S PETITION FOR INTER
PARTES REVIEW OF CLAIMS 1-15 OF U.S. PATENT NO. 11,298,166**

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I, Leonel Dominguez, do hereby declare as follows:

[1] I have been retained to provide certain background and opinions concerning issues raised in Petitioner Fusion Orthopedics, LLC (“Fusion”) Petition for Inter Partes Review (“IPR”) of U.S. Patent No. 11,298,166 (“ ’166 patent”), which is being filed concurrently herewith. The ’166 patent which is filed as Exhibit 1001 to the IPR is directed to an intraosseous intramedullary fixation assembly.

[2] I am over the age of 18 and make this Declaration based upon personal knowledge, experience, and investigation that I have conducted. I will be available to provide oral testimony concerning my statements, opinions and conclusions set forth below and may amplify or add thereto through such testimony, demonstratives, or in further written declarations.

[3] A list of publications I have contributed to is included with my CV which is attached as Attachment A hereto.

I. BACKGROUND AND QUALIFICATIONS

[4] I have over 30 years of experience as a biomechanical engineer specializing in surgical implants and instrumentation. I received a Master of Science in Mechanical Engineering from Georgia Institute of Technology and a Bachelor

of Science in Mechanical Engineering from the University of Miami (Coral Gables).

[5] Senior Product Development Engineer at Smith & Nephew Richards, Inc. and was responsible for new product development from concept through manufacture of orthopaedic implants, external trauma fixation, bracing and manual instruments used in the treatment of bone fracture reduction, stabilization and deformity correction.

[6] I was the principal engineer for the Ilizarov® Circular-Ring External Fixation Device used in orthopaedic bone reconstruction and deformity correction. A premier platform system consisting of 200 unique components that are assembled to build stabilization frames for most bone fracture types.

[7] I developed a Trauma Circular Ring Fixator Platform utilizing multi-functional, connecting rods for quick assembly.

[8] I patented an x-ray opaque surgical instrument and drill guide which facilitates the placement of bone pins in the femur while utilizing anatomical landmarks to perform limb lengthening (distraction osteogenesis) while using an intramedullary rod implant.

[9] I worked to improve the radiolucency of the Calandruccio External Fixator device used in Tibiototalcalcaneal (TTC) Fusion surgery of the foot.

- [10] Director of Engineering at Medtronic-Xomed Surgical Products, Inc., I managed and directed the efforts of 20 engineers, designers and technical documentation personnel involved in the design and development of Ear, Nose, Throat (ENT) and Image-Guided Surgery medical devices from concept through commercialization to achieve the corporation's strategic goals for quality and responsive product introduction.
- [11] I conducted or approved technical design reviews for class I and II, electro-mechanical medical devices that include stress, tolerance analyses, product specifications, compliance to FDA, ISO, and Corporate Design Control requirements.
- [12] Managed and contributed to a design engineering group responsible for endoscopic, minimally-invasive powered devices, instruments and image-guided technologies that develops an average of 100 new products each year.
- [13] Led cross-functional team for a period of 2.5 years responsible for development of hand-held, powered surgical drills, shavers (micro-debrider) devices and capital equipment used to dissect, soft and bony tissue during ENT endo/microscopic surgery.
- [14] I was responsible for maintaining Design Control standards, training and reviews that achieve FDA, ISO and corporate quality systems regulations

streamline the product development process and reduce time-to-market for medical devices.

[15] While at Mekanika, Inc., a start-up spine orthopedics medical device company, I served as Vice-President of Research and Development, I designed, developed and produced intra-operative electro-medical diagnostic systems during a seven-month period to perform a real-time, diagnostic measure and recording of spinal instability during decompressive lumbar spinal surgery. Performed product installations, in-services and solicited surgeon feedback during surgery for next generation products.

[16] I was the Vice President Product Design and Development, for US Spine, LLC, a start-up spine orthopedics medical device company responsible for product development, manufacturing, quality systems, and intellectual property development of implantable surgical implants and instruments for the spine.

[17] Designed, developed and commercialized the company's first product, a polyaxial pedicle screw and instrument system during a 10 month period that was FDA 510(K) approved and commercially launched.

[18] Worked with surgeon thought leaders as part of several medical advisory teams established to design a patented minimally invasive facet fixation

screw, cervical plating system, a MIS retractor system and cervical allograft bone spacers.

[19] I was a Vice President of Research and Development for Scient'x USA, which is a fast growing, French-based spine orthopedic device company responsible for product development of lumbar, cervical, deformity, PEEK implants, non-fusion stabilization and motion preservation implantable device, supply-chain, quality management, and intellectual property development. I led a small and responsive hands-on technical group that interfaced with European colleagues and US surgeons to develop and improve products for the U.S. market through operating room observation and surgeon collaboration, including lumbar polyscrew and anterior cervical plating Systems.

[20] During the past 15 years, and currently I serve as President for Duraspine Medical Technologies LLC, (formerly known as Hyperjax Biomedical Consulting) which is a biomedical engineering firm that provides expertise in medical device design from concept through manufacture, quality systems, manufacturing and intellectual property development within Spine, Orthopaedics, ENT, Head and Neck and OB/GYN and other biomedical device markets.

- [21] I am an inventor on the following patents and patent applications:
- a. US7563275B2 Bone Fixation Implant System and Method
 - b. US8870957 Implant for Mammalian Bony Segment Stabilization
 - c. US8979910 Method, System, and Apparatus for Mammalian Bony Segment Stabilization
 - d. US20100121383 Method, System and Apparatus for Mammalian Bony Segment Stabilization
 - e. US20060089536 Expandable Surgical Retractor System for Minimal Access Surgery
 - f. USD616546 Intervertebral Implant
 - g. ZA200704321 (CN JP AU IL MX ZA) Bone Fixation Implant System and Method
 - h. US5403322 (WO) Drill Guide and Method for Avoiding Intramedullary Nails in the Placement of Bone Pins
 - i. US6770082 Surgical Headframe with Soft Contact Pads for Use with a Stereotactic System
 - j. US6893447 Surgical Reference Frame Fixation Device with Cannulated Post and Method of Use

k. AU6734194 (JP AU NZ) Drill Guide and Method for Avoiding
Intramedullary Nails in the Placement of Bone Pins

[22] As part of my independent analysis, I also analyzed the following
publications and materials, as well as the file history for the '166 patent and
the applications to which it claims priority:

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 No. FR2,861,576 A1 to Cognet Jean Michel, filed on October 31, 2003, published on May 6, 2005. (“Cognet”)
1004	French Patent 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

[23] I am not, and have never been, an employee of Patent Owner, Extremity Medical LLC (“Extremity”) nor Fusion Orthopedics LLC, and I am not a patent attorney or agent. Rather, I have been engaged to provide my independent analysis of the issues raised in the petition. I have not received compensation beyond normal hourly compensation, based on time actually spent studying this matter and I will not receive any compensation based on the substance of my opinions nor the outcome of this proceeding.

II. OVERVIEW OF CONCLUSIONS FORMED

[24] Conclusions set forth in this statement are formed based on my independent analysis, knowledge, personal experience and my review of the prior art patents and other materials listed above. Based upon that and in my opinion, the invention allegedly captured by claims 1-15 of the ‘166 patent are anticipated or made obvious by Cognet, Brumfield, Ferrante, Simon, and/or Leu.

III. PERSON OF ORDINARY SKILL IN THE ART

[25] For purposes of this Petition, the Relevant Field is orthopedic surgery methods, devices, and instruments.

[26] It is my understanding that the following may be considerations in determining what the level of ordinary skill in the art would be:

- a. The educational level of the inventor.
- b. The type of problems encountered in the art.
- c. Prior art solutions to those problems.
- d. The rapidity with which innovations are made.
- e. The sophistication of the technology.
- f. The education level of active workers in the field.

[27] In the following sections, I discuss problems raised in the ‘166 patent and known solutions to those problems. In short, I discuss the problems with bone fractures and/or deformities and how to correct them.

[28] The sophistication of the technology in the ‘166 patent is relatively common and is use-specific to certain types of small bone surgeries and types of fractures.

[29] In my opinion, a person of ordinary skill in the art (“POSA”) 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. I have the skills and experience above a

person of ordinary skill in the art, but my opinions expressed below are provided from the perspective of that skilled artisan.

IV. THE '166 PATENT

[30] I have been asked to review the '166 patent. Given my qualifications, experiences, and investigations, I had no trouble understanding the technology generally disclosed and claimed in the patent.

[31] The '166 patent describes a 3-member mechanical assembly that joins a bone fracture or osteotomy (surgical bone cut) in a stable condition to assist with bone fusion. This device has a primary elongated shaft body member (commonly referred to as a bone anchor or nail) having multiple through-holes. The first (top-proximal) through-hole allows a bone screw to enter and secure across a bone fracture. This first bone screw serves to reduce or join the bone across the fracture site while joined to the nail. The second (lower distal) through-hole in the nail allows a second bone screw to pass through and serves to lock the nail to uncompromised bone and serves to prevent unwanted axial and rotational movement of the nail. This distal screw is often referred to as a "Locking Screw" since it secures the nail to bone.

[32] First, a review of the basic goals that a user of said device is trying to accomplish, namely bone fracture repair. Bone Fracture Repair and Healing,

also known as 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.

[33] 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) or inter-locking nail or Küntscher nail (without proximal or distal fixation), 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. IM nails differ from IM rods in that IM nails have a distal hole(s) to accommodate distal locking bone screws where IM rods do not. 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, 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.

[34] 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 and resemble patent '166, specifically Cognet, Simon, Brumfield, Ferrante, and Leu have 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.

[35] All figures have been provided, annotated, etc., by counsel and they are annotated, etc., correctly.

V. THE '166 PATENT IS ANTICIPATED BY THE PRIOR ART

[36] I understand that a determination of invalidity requires a two-step process. First the claims must be properly construed to determine their meaning and scope. It is my opinion that 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. Second, the properly construed claims are compared to the teachings and disclosures of the prior art.

[37] I also understand that a patent claim can be held invalid under 35 U.S.C. § 102 if it is anticipated by the prior art. In order to anticipate a claim, a single prior art reference must disclose each and every element of the claimed invention in a manner sufficient to enable one skilled in the relevant art to reduce the invention to practice, thus placing the invention in the hands of the public.

A. Comparison of Cognet to the '166 Patent claims 1-7, 9, 12, and 13.

[38] In my opinion Cognet discloses each and every element of claims 1-7, 9, 12, and 13 of the '166 patent, and thereby anticipates each of these claims, in

a manner sufficient to enable one skilled in the relevant art to reduce the invention to practice, thus placing the invention in the hands of the public.

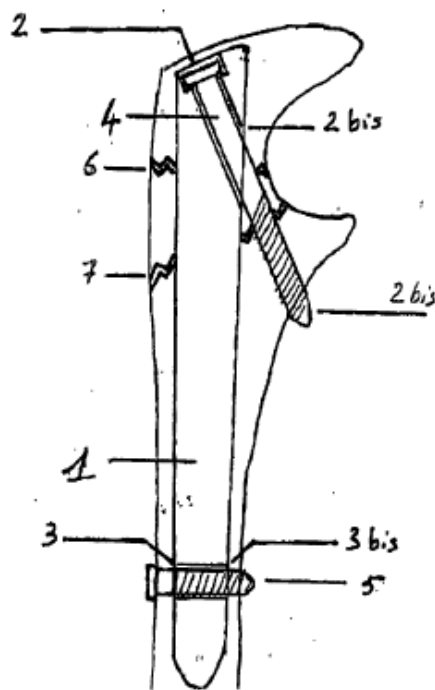
1. Cognet Discloses all the elements of Claim 1

a) Claim 1 Preamble: Cognet discloses “an assembly for bone fusion”

[39] As discussed above in paragraph [31] - [34] of this declaration, fusion and osteosynthesis are synonymous with the process of bone healing. By definition, osteosynthesis or “Bone Creation” describes the bone healing process that occurs when fractured bones (as a result of trauma or osteotomy) are rejoined and fixated stably for a period of time until healing (bone rejoining) occurs. The stable fixation is achieved by mechanical means often involving internal fixation devices such as bone screws, rods, pins, wires or plates or combinations thereof.

[40] Cognet discloses “an assembly for bone fusion.” For example, Cognet describes a device for the osteosynthesis of fractures (i.e. bone fusion), particularly of the olecranon. Ex. 1004, pg. 6 ln. 3 (claim 1) (“A device for the osteosynthesis of fractures”). The olecranon is the part of the ulna that cups the lower end of the humerus, creating a hinge for elbow movement. (The Olecranon is the tip of the elbow commonly referred to as the “funny bone”). The device includes “a nail through which there pass at least two

screws allowing this nail to be anchored into the bone.” Ex. 1004 pg. 2 ln. 23-25. Thus, the device is an “assembly” of a nail and at least two screws for the osteosynthesis of fractures, or “bone fusion.”



(Ex. 1004, Figure 1)

- b) **Claim element 1[a][i]: Cognet discloses “a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis”**

[41] Cognet (above) discloses a three-member assembly consisting of a nail 1 (third member) traversed by at least two screws (proximal screw 2 and distal screw 3) allowing the anchoring of the nail in the bone to create stability for bone fusion. Cognet describes the upper fixation screw (proximal screw) (first member) in element 4 of Figure 1 as having a thread on its distal part intended

to ensure grip in the bone. Ex. 1004, pg. 2 ln. 35. Cognet illustrates the proximal screw as having an elongated body that extends from a first end (the tip of the screw) to a second end (the head of the screw) comprised of a head, a shaft, and threads. A screw is a cylinder with raised helical spiral threads running on its outer surface. It converts torsional forces into compression. The primary functional objective in the design of a screw is to dissipate and distribute the mechanical load. Thread design should maximize initial contact, enhance surface area, dissipate and distribute stresses of the screw-bone interface and increase the pullout strength.

[42] In orthopedics “screw” refers to a bone screw. Bone screws are a common and essential member found in many fracture fixation assemblies. Bone screws serve as anchors in bone or to hold elements of the fixation assembly to bone or to join bone fractures to one another to facilitate bone fusion. Bone screws have specific features that include:

- a. **Head** – Most bone screws have a head that is tapered (an increase in volume from the shank to top of head). The taper can be a full straight taper or partially rounded taper at the top end. The taper is meant to be counter-sunk in the bone or on the implant to exhibit a low-profile stature which is less damaging to surrounding tissue and thus more

comfortable for a recipient. Some screws are “headless” or have a “threaded conical taper” shape with threads running all the way to include the head intended to be fully sunk in bone.

- b. **Drive Feature** – The screw head has an internal drive feature located inside the head of the screw. An internal hex, square, hexalobe (8-point star) are common geometries that can be used to transfer rotation torque (from a screwdriver) to drive the screw into bone. A “screw” that does not have an internal drive feature is likely a “bolt” and not a “screw.”
- c. **Neck or Shank** – Past the head is the neck or shank portion of the screw body. This section is threadless, usually straight, and has a diameter equal to the screw minor diameter. The screw shank can also taper increasingly from the thread to the screw head for added strength. Some screws are fully threaded from the top of the head to the tip and are intended to be fully sunk into bone.
- d. **Thread** - Threads are a feature created by the helical sweep of a spiral about a longitudinal shaft (central) axis of rotation. The thread is a helical-outward geometry that “bites” into bone to capture across both ends of a fracture to “pull and join” both bone ends together. This

compression across the fractured bones is one of the conditions needed for osteosynthesis or fusion. The shape of the thread is designed to have either “cortical” or “cancellous” type threads based on the type of bone intended to be secured. For example, cortical threads are better for purchase in hard density bone, such as the bone outer cortex (outer layer of bone) and have a fine (smaller) pitch. In a cortical thread pattern, the thread height is also smaller enabling easier insertion in hard bone. Cancellous threads are identified by a large thread pitch and height and are used to provide better purchase in soft-spongy bone (past the cortex) and can also be called “lag” screws due to their ability to compress across bone fractures better than cortical screws. The threads on a screw have a crest (tip) and a root (base). This distance between the crest and the root is the thread height. The threads have a decreasing taper from the base to the tip to form a “V-pattern”. A series of these V-patterns form the length of the screw threads and the distance between one V-pattern to the next is called the “pitch” of the screw. It is this helical tooth shape that cuts and advances as bone fills the tapered thread space (“V-pattern”) and creates compression and anchor in bone. A “screw” with no threads is

a “pin, rivet or nail” and is not actually a “screw” since it lacks a helical sweep.

- e. **Tip** - The starting tip of a bone screw can have different shapes depending on user preferences. Tips can be sharp or blunt. A sharp (tack point) tip has a “self-start” or “biting” feature when starting in bone without the need to predrill a bone hole. A blunt tip requires the bone to be initially drilled to get the screw started in bone to prevent slipping-off the bone. Usually, the tip of the bone screw has a conical taper geometry so as the screw tip is introduced into a small bone hole it starts small and expands as it travels deeper into bone. In a sense, it helps guide the bone screw into the bone hole along a guided path trajectory.
- f. **Self-Tapping Screws** – is a side-cutting edge (or flute) on the tip of the screw (or just past the tip) that cuts the bone as the screw advances. This creates a threaded path for the rest of the main screw threads to continue to cut and purchase into the bone. Self-tapping flutes serve to decrease the torque resistance to drive the screw into bone. Screws that do not have self-tapping threads will usually

require a bone predrill and tap to create the conditions to allow insertion of the bone screw.

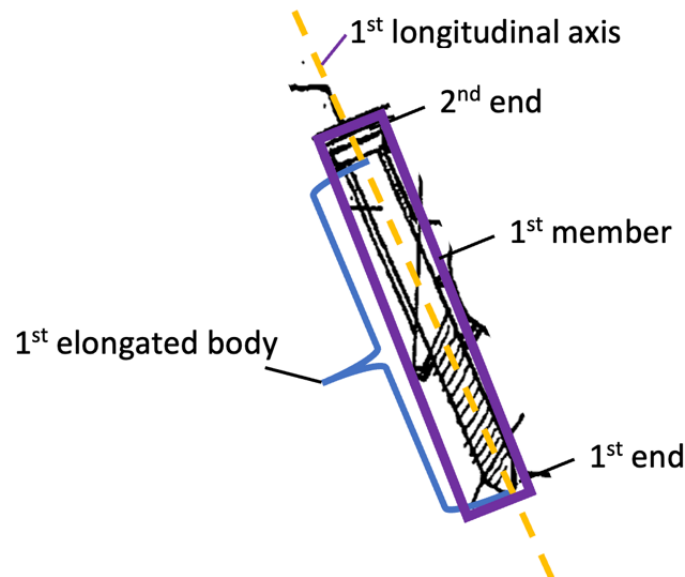
- g. **Self-Drilling Screws** – Eliminate the need to pre-drill a pilot hole and can self-tap threads as well. They have a sharp point and often are self-tapping. Screws that are not self-drilling will usually require a bone pre-drill to avoid the bone splitting or cracking.

[43] *(Intentionally left blank)*

[44] 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), it is called the shaft.

[45] A “longitudinal axis” is an axis along the lengthwise direction of a body, usually passing through its center of rotation. The longitudinal axis for a screw is the rotational axis which runs from the center of the tip, through the center of the shaft, to the center of the head.

[46] Cognet discloses these elements by disclosing a screw (first member) as shown below and depicted as item 4 in Cognet’s Figure 1.

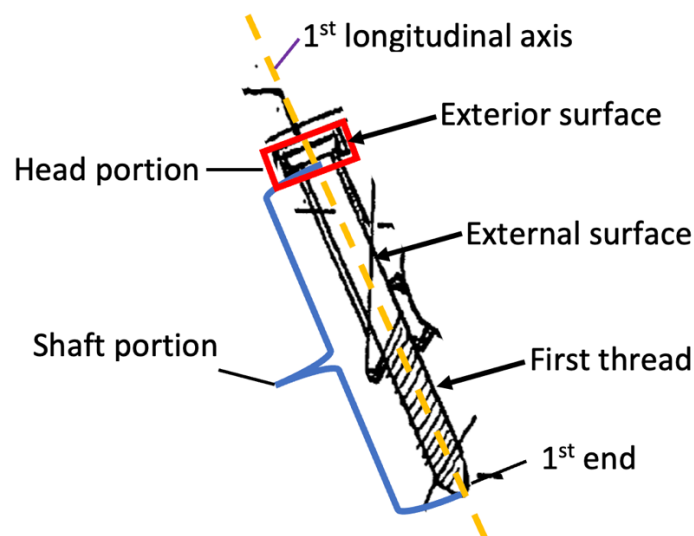


- c) **1[a][ii] – Cognet discloses “wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said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

[47] A screw comprises a shaft portion as discussed above in claim element 1[a][i] (section (V.A.1.b) of this declaration). The shaft has an external surface. A screw comprises a head portion as discussed above in claim element 1[a][i] (section (b) [42]a. of this declaration). The head has an exterior surface. A screw has at least one thread as discussed above in claim element 1[a][i] (section (V.A.1.b) [42]d. of this declaration) and all threads

have a thread height. The thread(s) on a screw extend radially outward from the external surface of the shaft portion of a screw.

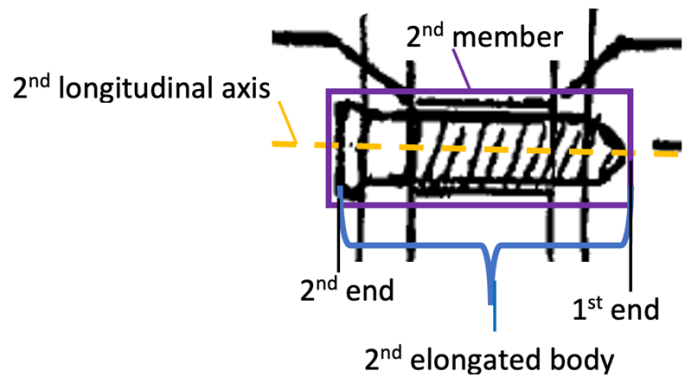
[48] By disclosing a screw as the first member, Cognet is disclosing these claim elements, as shown below. Ex. 1004, page 4, lns. 14-15 (“The proximal screw (4) has a screw thread on the distal part thereof only.)



d) **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,”**

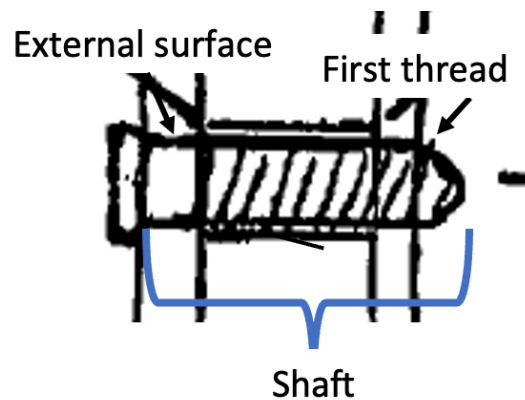
[49] Cognet discloses a second screw (second member) (Ex. 1004, pg. 3 ln. 2). A screw has an elongated body that extends from a first end (the tip of the screw) to a second end (the head of the screw), it is called the shaft and is shown above in claim element 1[a][i] (section (b) of this declaration). The

shaft runs along the longitudinal or rotational axis. These features are also indicated below.



- e) **1[b][ii]: Cognet discloses “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;”**

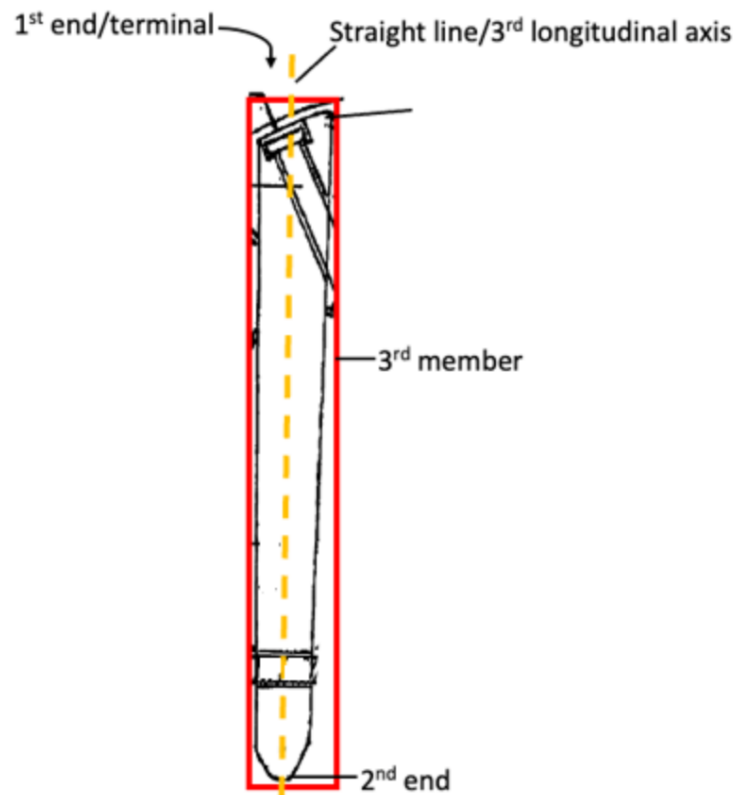
[50] As discussed above in claim element 1[a][i] (section (b) of this declaration), screws comprise a shaft. The shaft has an external surface. The threads have a thread height that extend radially outward from the external surface of the shaft. Cognet discloses these elements by disclosing a screw as the second member as shown below. Ex. 1004, pg. 4 lns. 25-30 “The distal screw(s) (5) comprise(s) a continuous thread so that the grip can be made on the two cortices of the (intramedullary) bone. It also has(have) a head with a diameter greater than the diameter of the body of the screw(s) and the tunnel (3) through which this/these screw(s) pass(s).”



- f) 1[c][i]: Cognet discloses “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,”

[51] Cognet discloses a third member (a nail, element 1 in Fig. 1) comprising a body that extends along a straight line (the 3rd longitudinal axis) from a first end to a second end as shown below. Ex. 1004, pg. 2 lns. 23-25 (“comprises a nail through which there pass at least two screws allowing this nail to be anchored into the bone.”).

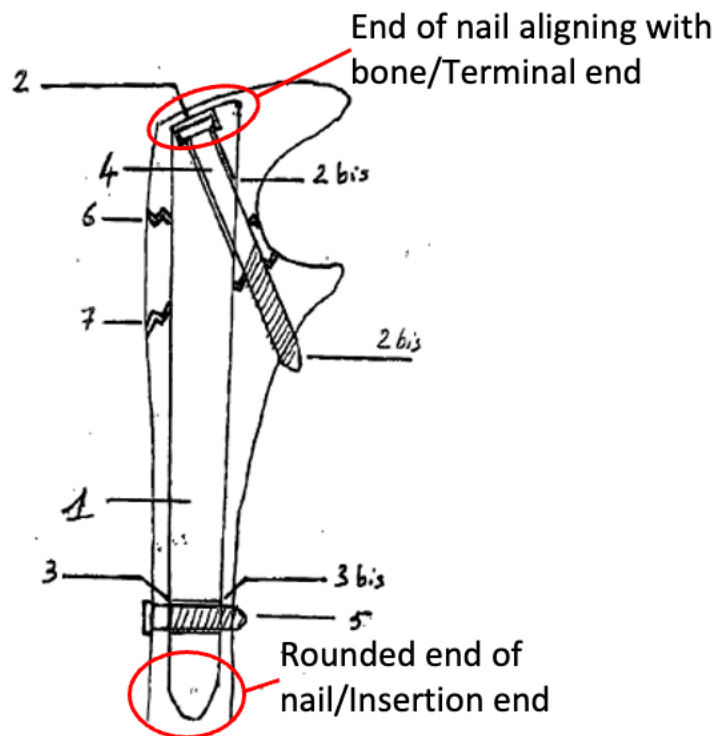
[52] Cognet discloses the third member (nail) in Fig 1 which is shown in the figure below.



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

[53] “Terminal end” is undefined in the specification for the ’166 patent. A POSA would understand “terminal end” to refer to the end of the third elongated member that aligns closely with the top surface of the bone or slightly below the surface of bone.

[54] The insertion end (distal end) is the end that leads the insertion of the nail into bone, and has a blunt-rounded end to facilitate insertion in bone

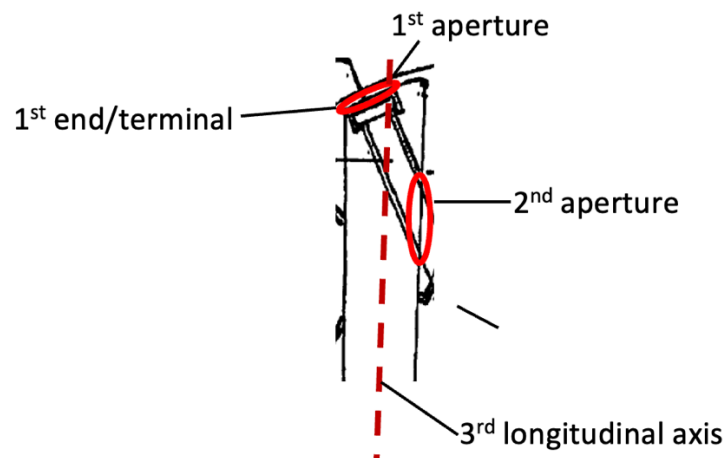


[55] Commonly intramedullary nails are inserted into bones with the smaller rounded end first into the intramedullary canal and the terminal end (or head) positioned near or flush with the outer surface of bone entry hole. The terms “proximal” refers to closest to the center of the body and “distal” refers to the distance farthest from the center of the body. A POSA would understand “at the terminal end” to refer to a location near the nail termination, nail head or proximal end, as opposed to merely along the shaft at any location or at the distal end.

[56] Cognet discloses an end of the third member that aligns with the bone, or a terminal end. Ex. 1004, pg. 2 lns. 28-31 (“The upper end of this nail is

chamfered and follows the natural curvature of the bone at this point of the anatomy, thus avoiding it becoming exteriorized.”).

[57] Cognet further discloses a first aperture at the terminal end of the third elongated body as shown below. 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.”).

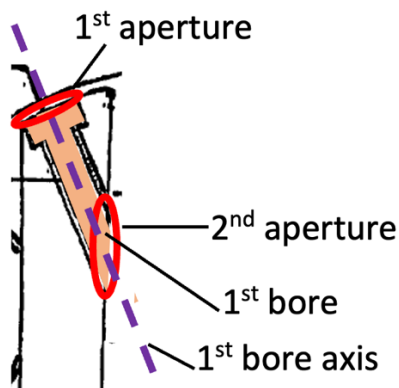


h) **1[c][iii]: Cognet discloses “a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member”**

[58] A bore is a cylindrical hole made by the spinning rotation of a twist drill cutting tool. It is typically made by removing material from a solid or hollow object, similar to a tunnel or orifice.

[59] 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 (“There is an orifice or tunnel at the top of the nail which follows an oblique downward path toward the coronoid process. This oblique downward path is intended to accept a screw passing from the proximal part toward the distal part to allow the nail to be anchored into the bone and compress the fracture site.”). Cognet discloses a first bore extending along a first bore axis from the first aperture to a second aperture (see figure below). The second aperture is on an exterior surface of the third member. Cognet acknowledges that the oblique angle of the proximal tunnel may vary based on anatomy of the fracture. Ex. 1004, pg. 3 ln. 17-19 (“The angle of the proximal tunnel relative to the axis of the nail may vary. The number and position of the distal tunnels may vary.”)

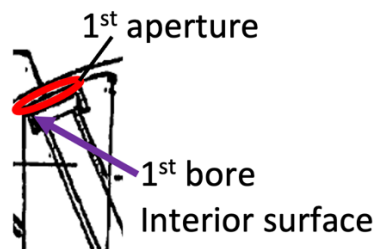


- i) **1[c][iv]: Cognet discloses “wherein the first bore comprises an interior surface at the first aperture”**

[60] Cognet describes proximal screw producing compression in bone.

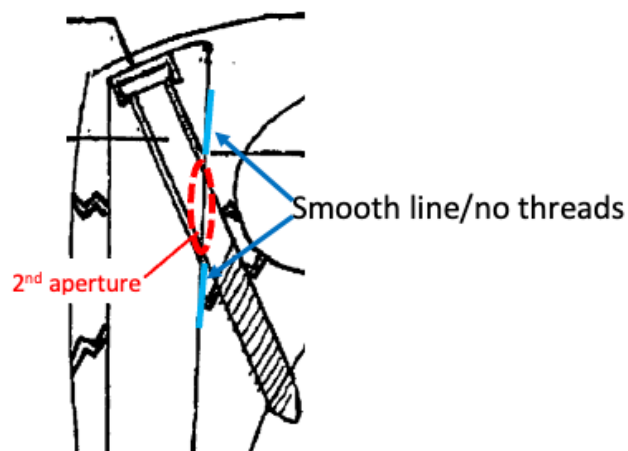
Ex. 1004, pg. 4 lns 18-23 (“The top of the screw has a head, with a diameter

larger than the diameter of the body of the screw and that the tunnel (2) through which the screw passes, which makes it possible to stop the progression of the screw in its tunnel and to obtain a compression effect at the level of the fracture site”). Cognet describes an interior surface at the opening of the nail member that disallows the head of the screw to continue any further in the nail recess to enable bone compression to take place. A bore hole is commonly created using a straight drill that is spinning along the drill’s axis of rotation. The rotational axis of the drill can be inclined at an angle relative to the surface being cut to establish a drill path angle or direction to the surface of the third member. The resulting internal size of the bore hole is of the same size as the drill used to create the hole. Because bore is created by removing material, a bore will have an interior surface. 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.



- j) **1[c][v]: Cognet discloses “wherein there are no threads adjacent to the second aperture on the exterior surface of the third member”**

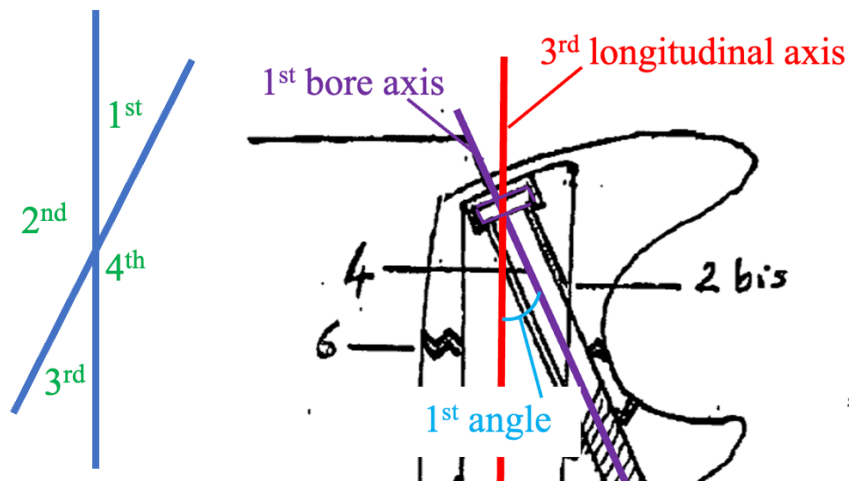
[61] The smooth lines defining the exterior surface of the third member indicate that at least one embodiment comprises no threads. Cognet discloses that there are no threads adjacent to the second aperture on the exterior surface of the third member and thus discloses this claim element.



- k) **1[c][vi]: Cognet discloses “wherein the third longitudinal axis and the first bore axis define a first angle”**

[62] Any two intersecting lines or axis create 4 angles as shown below (not Cognet figure 1). Two of these angles will be less than 90° and two of these angles will be greater than 90° , or (if the intersecting lines are perpendicular) all four angles will equal 90° . The '166 patent does not specify which of these angles is the first angle. The third longitudinal axis and the first bore axis are

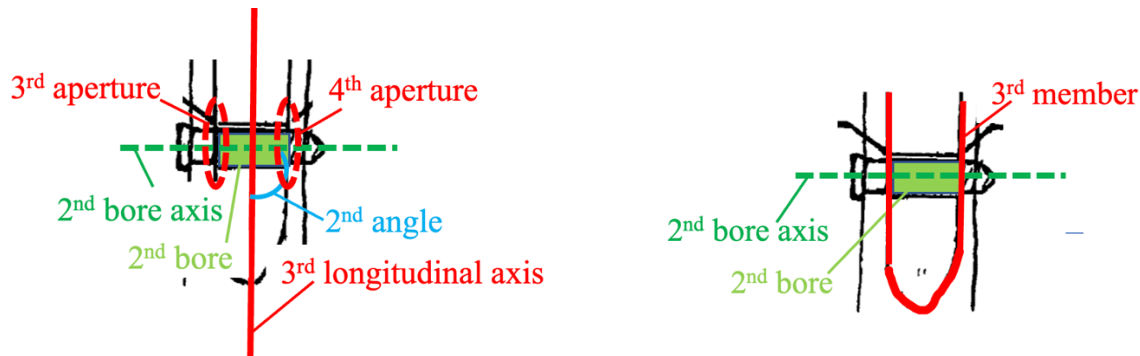
two straight lines that intersect in the third member creating a first angle as shown below. As stated in paragraph [60], Cognet describes that the oblique angle of the proximal tunnel may vary based on anatomy of the fracture. Ex. 1004, pg. 3 ln. 17-19 (“The angle of the proximal tunnel relative to the axis of the nail may vary. The number and position of the distal tunnels may vary.”)



- l) 1[d]: Cognet discloses “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”

[63] 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). 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.



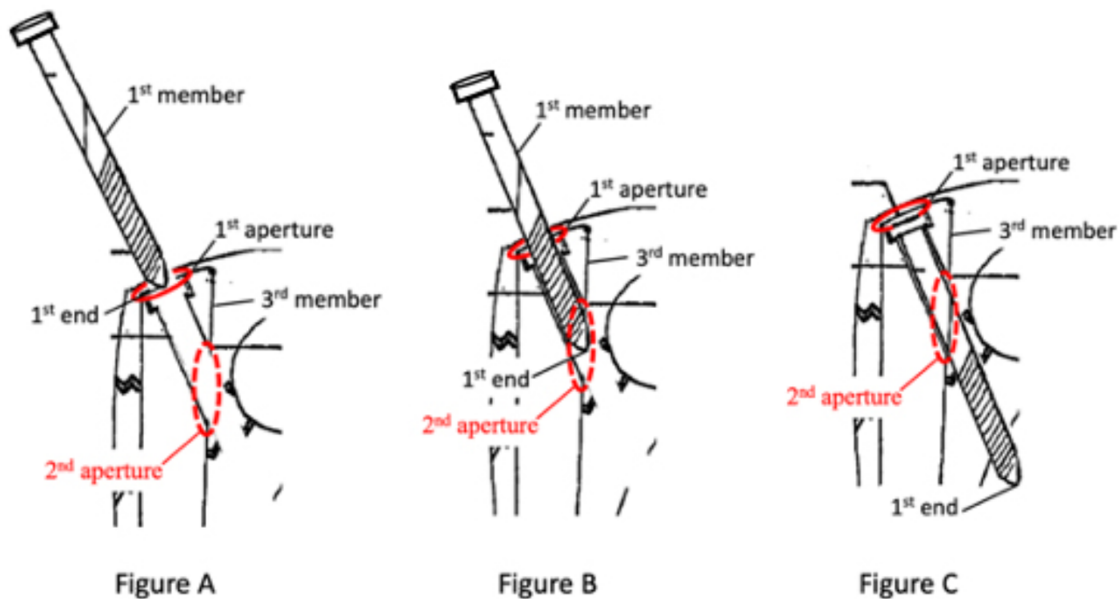
- m) 1[e]: Cognet discloses “wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture”

[64] In order for a screw to pass through a hole, the bored hole must be sized to permit passage of the screw body which normally includes screw tip, screw threads and screw shank. The bored through-hole would require being sized slightly larger than the external size of the screw to allow for ‘unobstructed clearance’ passage of the screw, but clearance no larger than the outer surface of the screw head in order to obstruct passage of the entire screw past the termination of the bore in the third member.

[65] Cognet discloses the first bore is intended to receive a screw (first member). Ex. 1004, pg. 2 lns. 32-34. 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.

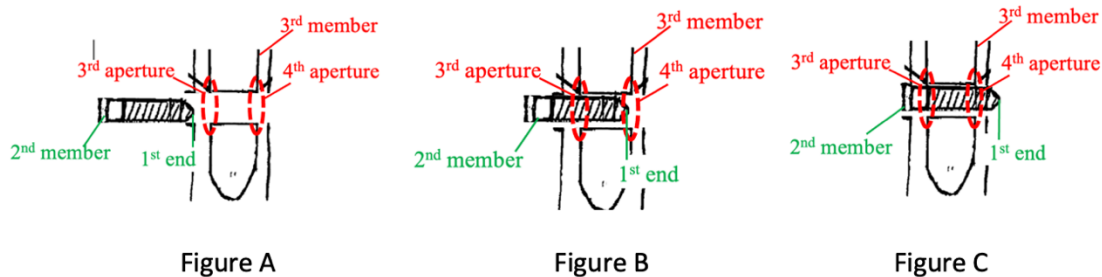
Ex. 1004, pg. 3 ln.38; pg. 4 lns. 1-2. Figure 1 of Cognet has been manipulated to show clearly how Cognet discloses these elements.



- n) 1[f]: Cognet discloses “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”

[66] 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) as can be seen by the following manipulation of Cognet

Figure 1 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). .

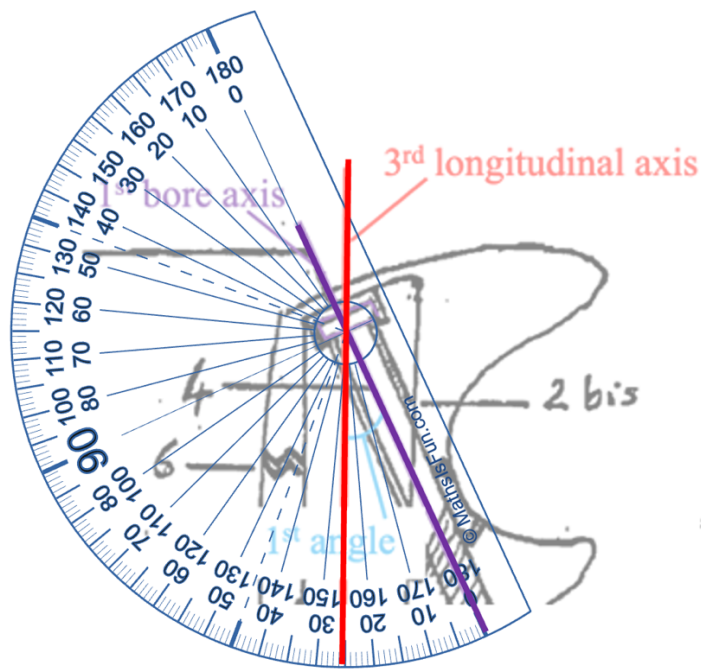


o) 1[g]: Cognet discloses “wherein the first angle is in the range of about 0 degrees to about 90 degrees”

[67] The first angle is the insertion angle of the first screw relative to the longitudinal axis of the third elongate member. For a person skilled in the art, the insertion angle value of near 0° does not have practical significance. A screw oriented at 0° as the first angle of insertion means the screw is directed on the same axis (coincident) as the third longitudinal axis. In practical terms, the bone screw is entering the first bore axis along the central axis of the third member having no ability to enter bone or create bone compression. In reality, granting the angulation range of 0 to 90 degree for the first member in this claim element is much too generous and would not serve the intended purpose.

[68] 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.k) of

this declaration). It is easily discerned from the Figures that the first angle is less than 90° and is about 25° . Cognet allows for the proximal screw insertion angle may vary dependent on anatomy and location of bone fracture.



p) **1[h]: Cognet discloses “wherein the second angle is in the range of about 0 degrees to about 90 degrees”**

[69] Similar to the above explanation for claim element 1[g], the second insertion angle for the second screw would not be practical at angles near 0° as this coincides with the longitudinal axis of the third member. A practical insertion angle would be in the approximate range of 45° to 90° .

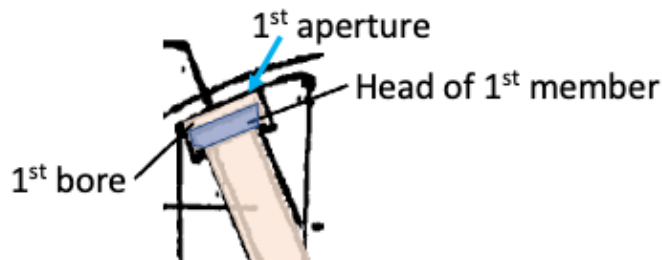
[70] Cognet discloses the second bore axis as being perpendicular, or 90° , to the third longitudinal axis (Ex. 1004, pg. 3 ln. 1).

q) **1[i]: Cognet discloses “wherein the second bore axis is substantially perpendicular to the third longitudinal axis”**

[71] 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. 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, running perpendicular to the axis thereof, and intended to accept a screw that allows the nail to be anchored into the bone, preventing it from mobilizing toward the proximal part of the olecranon and preventing the fracture site from twisting.”).

2. Cognet Discloses all the Elements of Claim 2

[72] 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).

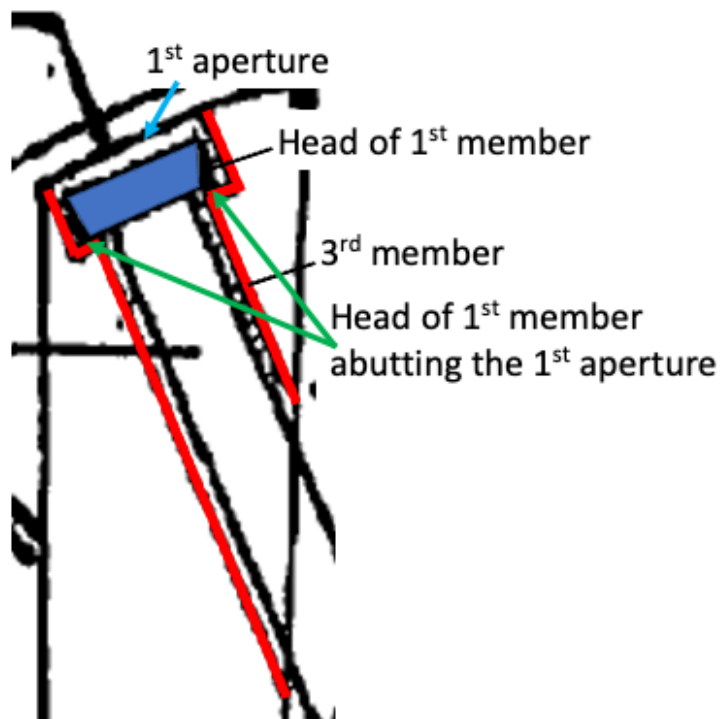


[73] A POSA knows to “seat” the terminal end of the screw flush or below the surface of bone to create a “low-profile” construct to prevent irritating surrounding tissues and avoid being felt in areas where there is minimal bone-to-skin thickness. In Cognet’s patent diagram above, a counter-sink recess is shown that captures the screw head to best sink the screw head prominence inside the terminal end of the third member.

3. Cognet Discloses all the Elements of Claim 3

[74] 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. Abut refers to touching (making contact) along an edge. Cognet creates a “countersink or shoulder” cavity recess inside at the entrance to a 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.

[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. Cogent further discloses that the head of the screw (first member) has a larger diameter than the diameter of 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, pg. 4 lns. 18-23 (“The top of the screw has a head, of a diameter wider than the diameter of the body of the screw ... than the tunnel (2) through which the screw passes, thereby making it possible to halt the progress of the screw in its tunnel and obtain a compression effect at the fracture site.”).

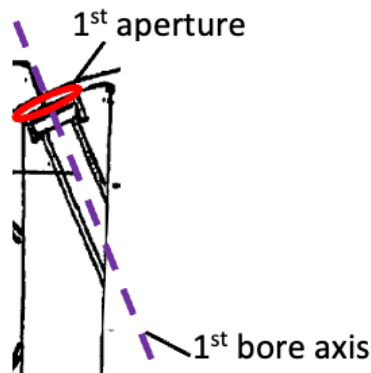


4. Cognet Discloses all the Elements of Claim 4

[76] 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, as discussed in section (V.A.1.b). Someone skilled in the art would have immediately understood that the screw head would require a torque driving geometry (often used with a screwdriver tool) to drive the bone screw into bone by rotating the screw. Almost all screws accomplish this with a torque transmitting aperture, so a POSA would assume Cognet is disclosing this claim limitation.

5. Cognet Discloses all the Elements of Claim 5

[77] 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.



[78] Since the screw head is intended to partially reside inside the aperture of the third member (claim 2) it is common in design to create the aperture cavity using a drill turned on this same axis (aligned) as the bored through-hole. The cavity aperture created on the first bore axis will ensure the screw head enters on the same path to the desired depth until screw abutment is reached as described in claim 3. A person skilled in the art would design the aperture in this manner which ensures that the first aperture is aligned on the first bore axis.

6. Cognet Discloses all the Elements of Claim 6

[79] 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 claim 2 (section (V.A.2) of this declaration).

7. Cognet Discloses all the Elements of Claim 7

[80] 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 claim 3 (section (V.A.3) of this declaration).

8. Cognet Discloses all the Elements of Claim 9

[81] Claim 9 further limits claim 1 requiring the first bore axis and the second bore axis intersect outside the third member. This is basic analytical geometry. Two non-parallel lines will intersect at a point in space provided they are the same plane. The nature of claim 9 prohibits the angle of first bore and second bore to be both perpendicular to the third member longitudinal axis as claimed in 1g and 1h as these lines would run parallel to one another and never intersect.

[82] Cognet discloses the first bore axis and the second bore axis intersecting outside the third member as shown below.



a) 12[a][i]: Cognet discloses “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;”

[84] 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.b) of this declaration.

b) **12[a][ii]: Cognet discloses “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;”**

[85] 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.c) of this declaration.

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

[86] 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.d) of this declaration.

d) **12[b][iii]: Cognet discloses “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;”**

[87] 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.e) of this declaration.

- e) **12[c][i]: Cognet discloses “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,”**

[88] 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.f) of this declaration.

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

[89] 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.g) of this declaration.

- g) **12[c][iii]: Cognet discloses “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”**

[90] 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.h) of this declaration.

- h) **12[c][iv]: Cognet discloses “wherein the first bore comprises an interior surface at the first aperture”**

[91] 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.i) of this declaration.

- i) **12[c][v]: Cognet discloses “wherein there are no threads adjacent to the second aperture on the exterior surface of the third member”**

[92] 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.j) of this declaration.

- j) **12[c][vi]: Cognet discloses “wherein the third longitudinal axis and the first bore axis define a first angle”**

[93] 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.k) of this declaration.

- k) **12[d]: Cognet discloses “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”**

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

- l) **12[e]: Cognet discloses “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”**

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

- m) **12[f]: Cognet discloses “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”**

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

- n) **12[g]: Cognet discloses “wherein the second angle is in the range of about 0 degrees to about 90 degrees”**

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

- o) **12[h]: Cognet discloses “wherein the second bore axis is substantially perpendicular to the third longitudinal axis”**

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

10. Cognet Discloses all the elements of Claim 13

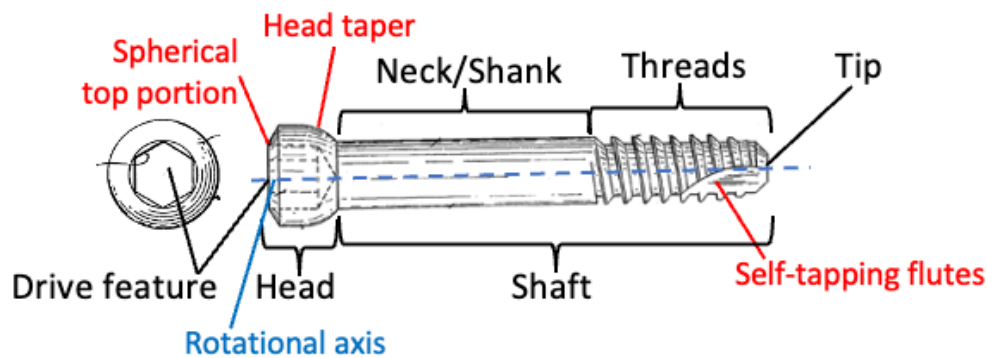
[99] This claim element has the same limitations as claim 2 and is disclosed by Cognet as discussed in section (V.A.2) of this declaration.

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

[100] Brumfield is U.S. Patent No. 4,827,917, which was issued on October 2, 2003, and discloses a femoral fracture device. 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.

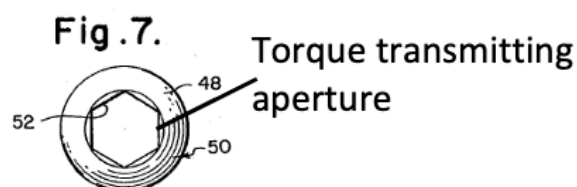
[101] Brumfield is analogous art because it is an intramedullary nail secured by multiple screws. It would have been obvious to a POSA to use the screws disclosed in Brumfield with the intramedullary nail disclosed in Cognet because the screw and nail in Brumfield are performing the same function in 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. 1006, 4:43-47. This first (proximal) screw has threads toward the end of the screw that enters, captures and helps reduce the bone fragment and applies compressive forces. *Id.* The portion of the bone screw within the nail or not in the fractured part of the bone is a smooth shank so that it spins smoothly about unfractured bone without imparting compression loading on it, since compression to reduce the fracture is preferred on the fractured bone side. *Id.*



(Ex. 1006, Figures 6&7)

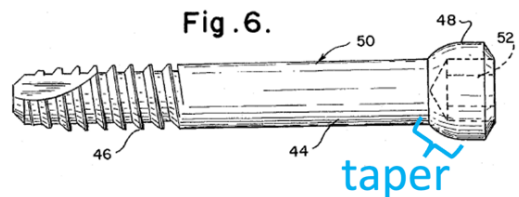
1. **Cognet in view of Brumfield Discloses all the elements of Claim 4**

[102] 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 that is driven by torque. 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. The torque transmitting aperture is also shown in Figure 7, which is shown below.



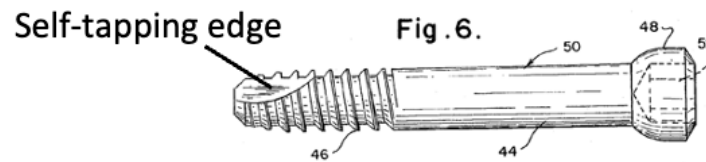
2. Cognet in View of Brumfield Discloses all the elements of Claim 8

[103] 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. This rounded tapered head is shown as element 48 in Figure 6 shown below.



3. Cognet in View of Brumfield Discloses all the elements of Claim 10

[104] 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.



4. Cognet in View of Brumfield Discloses all the elements of Claim 14

[105] 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 declaration.

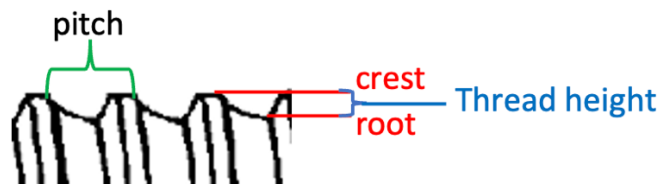
5. Cognet in View of Brumfield Discloses all the elements of Claim 15

[106] 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 declaration.

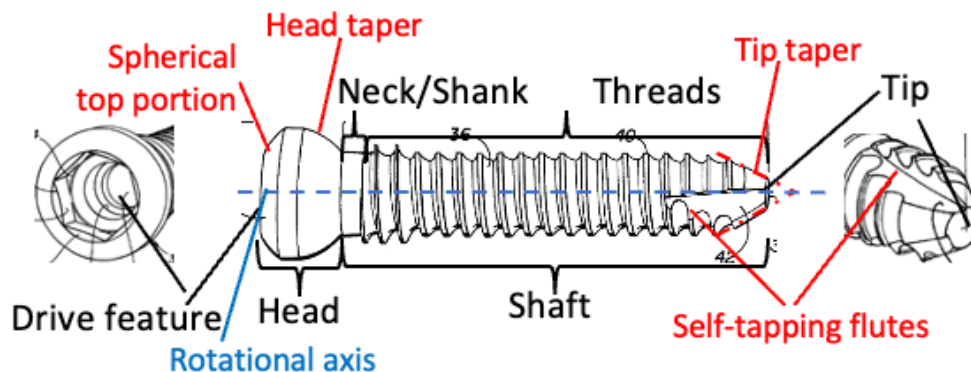
C. Cognet in View of Ferrante Make Obvious Claim 11.

[107] Ferrante is U.S. Patent Publication No. 2003/0187447, which was published on October 2, 2003, which is before the earliest effective filing date of the '166 patent. Ferrante is a prior art patent to the '166 patent under section 103 because the issue date of Ferrante is before the effective filing date of the '166 patent. Ferrante discloses an orthopedic screw with a head, body, having a short neck shank, and a shaft, with threads extending radially outward from the shaft.

[108] 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 Cognet 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 Cognet. Namely, the second member screw in Ferrante and Cognet are locking the nail in place and has screw threads that capture bone.



(Ex. 1007, Figure 1 - cropped)



(Ex. 1007, Figures 1, 3, & 6)

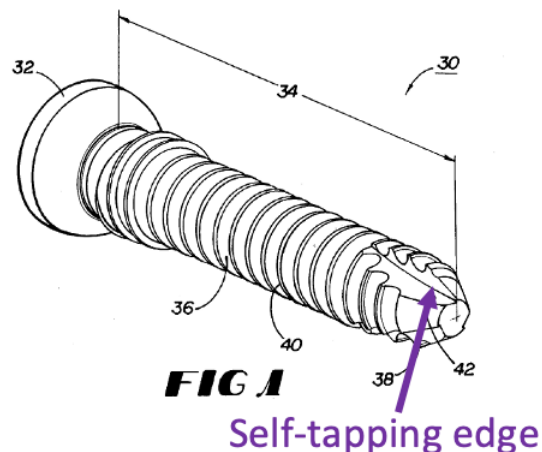
1. Cognet in View of Ferrante Discloses all elements of Claim 11

[109] 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. It is common practice for someone skilled in the art to use a blunt-tipped screw to secure across both cortices (bicortical) of a long bone and pass through the nail's core through hole (distal "locking" screw). The outer cortex of long bones are normally hard bone so, a cortical type screw is used. The end of the screw tip is blunt to avoid a sharp edge from irritating surrounding tissues as the screw tip exits the far cortex of bone. The length of this distal screw is precisely selected to not extend far past the outer wall of the nail member.

[110] Ferrante discloses a flute (42) for the removal of bone chips as screw (30) is implanted into bone (Ferrante [0043]), which is a self-tapping edge and is shown in figure 1, included below.



D. Comparison of Simon to the '166 Patent claims 1, 4-5, 8, 10-12, and 14-15.

[111] Claims 1, 4-5, 8, 10-12, and 14-15 are unpatentable under 35 U.S.C. § 102(a) for anticipation by Simon. Simon is U.S. Patent Publication No. 2006/0206044 which was filed on August 1, 2003 by William Simon and published on September 14, 2006, making it available to the public before the earliest effective filing date of the '166 patent.

[112] Simon discloses an intramedullary nail intended for insertion in a longer bone but is used for bones in the mid-foot. All Figures in this section (V.D) are from Simon Figure 1 unless otherwise noted.

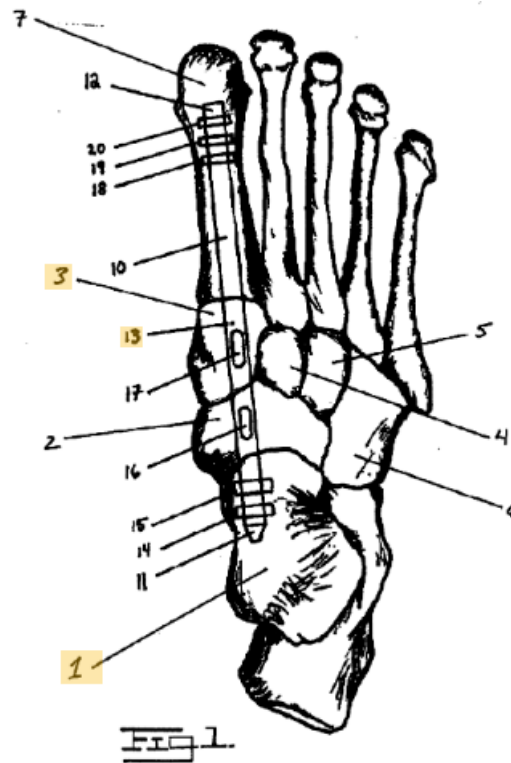
[113] When first introducing the intramedullary nail (Ex. 1008 [0039] and [0046]) Simon describes the “proximal” and “distal” ends of the nail in two ways. In [0046] the “proximal” portion of the nail has a tapered tip to aid insertion (element 11 in Simon Figure 1). He goes on to describe the “distal” portion to have three fastener holes, which is describing the terminal end (element 12) of the nail. In paragraph [0039] these descriptions are reversed. Proximal and distal are relative terms. The term “distal” refers to the farthest distance away from center of the body. The distal end of the foot is toward the first metatarsal. The proximal end of the of the foot is toward the ankle. Proximal and distal ends of the nail are referring to placement in the body and

can change as placement changes. To avoid confusion, this declaration 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).

1. Simon Discloses all the elements of Claim 1

[114] 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, the fixation device of 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.



(Simon, Fig. 1)

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

[115] As discussed above in claim 1[a][i] (section (V.A.1.b) of this declaration) 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.

- b) **1[a][ii]: Simon discloses “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;”**

[116] As discussed in the Cognet anticipation arguments for this claim element (section (V.A.1.c)), 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.

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

[117] Figure 1 of Simon discloses a second screw (second member) (elements 14 or 15 of Figure 1) (Ex. 1008 [0053]). As discussed above in Cognet claim element 1[b][i] (section (V.A.1.d)) 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. The second screw is also a locking screw

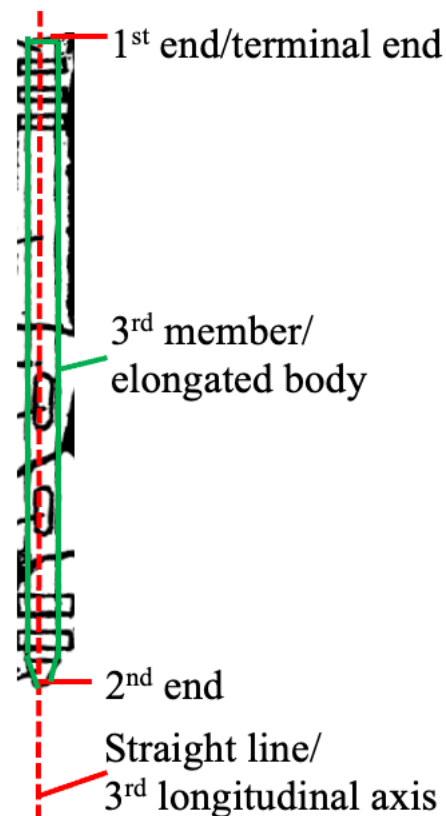
(Ex. 1008 [0053]), interlocking cortical screw, or transfixation screw (Ex. 1008 [0039]), and thus discloses this claim element.

- d) **1[b][ii]: Simon discloses “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;”**

[118] As described above in Cognet claim element 1[b][ii] (section (V.A.1.e)) 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. 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).”).

- e) **1[c][i]: Simon discloses “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,”**

[119] 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.



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

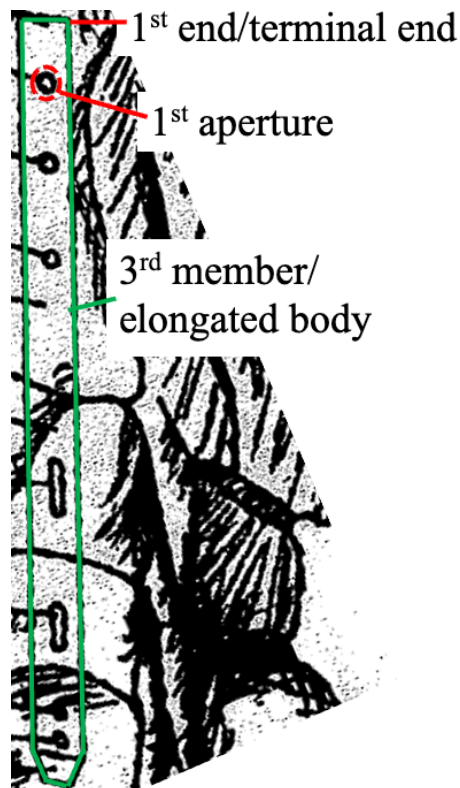
[120] As discussed above in Cognet claim element 1[c][ii] (section (V.A.1.g))

“terminal end” is understood by a POSA to refer to the end closest to the outer surface of bone as labeled above.

[121] Claim 1 allows for the first bore axis to be at 90° relative to the third longitudinal axis (i.e., the first angle can be 90°). Ex. 1001, 15:39-40. This would mean that 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]).

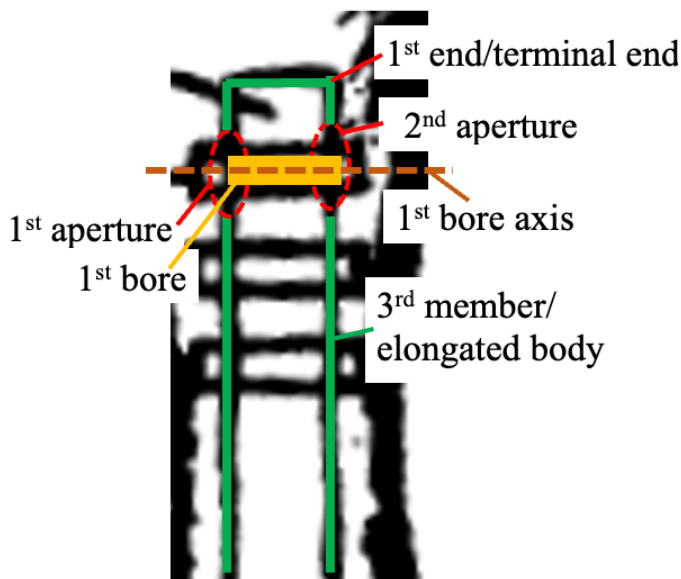
Simon discloses a fastener hole (hole 20 in figure 2) at the terminal end of the third elongated body as shown below (Simon, Fig. 2 – cropped). Ex. 1008 [0054].



[122] Simon also 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.

- g) **1[c][iii]: Simon discloses “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”**

[123] 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.

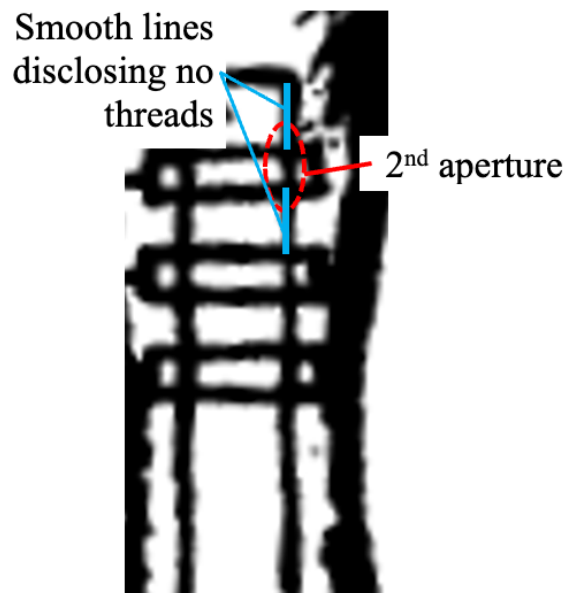


- h) **1[c][iv]: Simon discloses “wherein the first bore comprises an interior surface at the first aperture”**

[124] As discussed above in Cognet claim element 1[c][iv] (section (V.A.1.i) of this declaration) a bore has an interior surface. Simon discloses a bore at the first aperture (see above), and thus discloses this claim element.

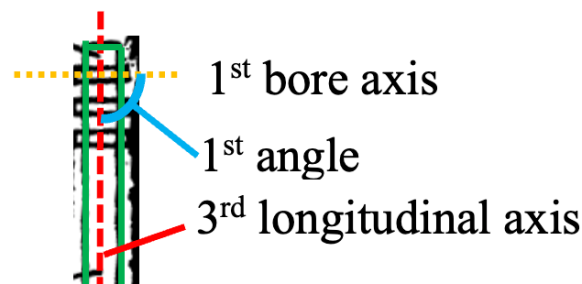
- i) **1[c][v]: Simon discloses “wherein there are no threads adjacent to the second aperture on the exterior surface of the third member”**

[125] 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. 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.



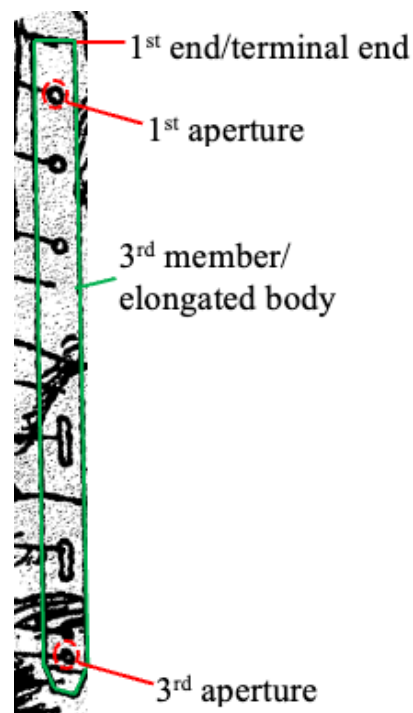
- j) **1[c][vi]: Simon discloses “wherein the third longitudinal axis and the first bore axis define a first angle”**

[126] 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.

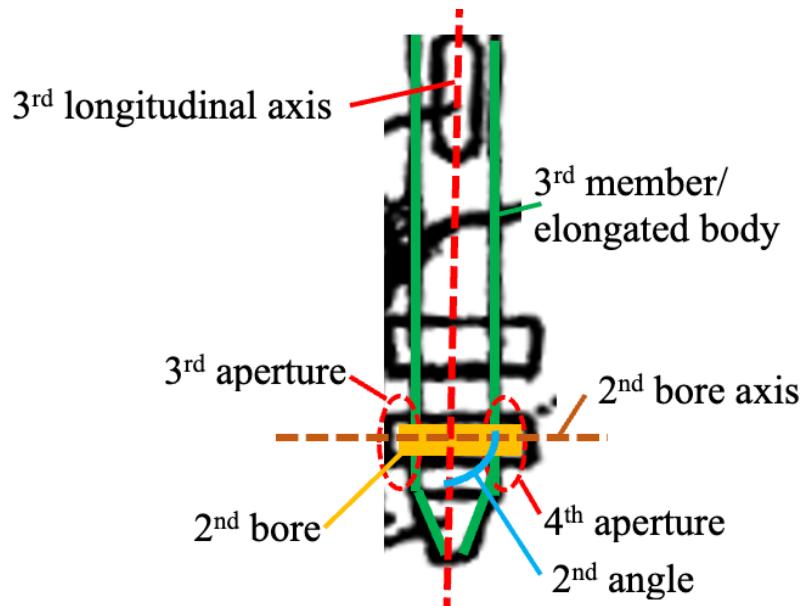


- k) **1[d]: Simon discloses “wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal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

[127] Simon discloses fastener holes at the tapered end of the nail (3rd member) as 14 and 15 on Figure 2 (Ex. 1008, [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). Simon further discloses the third longitudinal axis intersecting the second bore axis to create a second angle (see below).



(Simone, Fig. 2)



(Simon, Fig. 1)

- l) 1[e]: Simon discloses “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”

[128] 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.

m) 1[f]: Simon discloses “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”

[129] 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.

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

[130] 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.o) of this declaration), any two axes intersecting discloses this claim element. Simon discloses the third longitudinal axis intersecting with the first bore axis, and thus discloses this claim element. 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°.

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

[131] 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.p) of this declaration), any two axes intersecting discloses this claim element. Simon discloses the third longitudinal axis intersecting with the second bore axis, and thus discloses this claim element. Additionally, A POSA would interpret Simon Figure 1 as disclosing the first angle to be about 90°, which is in the claimed range of 0° to about 90°.

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

[132] Simon discloses the second angle to be about 90° as discussed above, which is “substantially perpendicular.”

2. Simon Discloses all the Elements of Claim 4

[133] 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 declaration). Because almost all screws include a torque transmitting aperture, by disclosing the first member to be a screw (Ex. 1008 [0039]) Simon is disclosing a torque transmitting aperture.

3. Simon Discloses all the Elements of Claim 5

[134] 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)). Simon discloses the center of the first aperture aligned with the center of the first bore axis, thus anticipating this claim.

4. Simon Discloses all the Elements of Claim 8

[135] 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. Ex. 1008, [0054] 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. A POSA would immediately assume that the first member (interlocking screw) has a tapered head portion to permit low profile seating.

5. Simon Discloses all the Elements of Claim 10

[136] 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. 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. 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.

6. Simon Discloses all the Elements of Claim 11

[137] 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 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 and facilitating insertion of the screw in bone.

7. Simon Discloses all the Elements of Claim 12

[138] 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 declaration.

- a) **12[a][i]: Simon discloses “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;”**

[139] 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 declaration.

- b) **12[a][ii]: Simon discloses “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;

[140] 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 declaration.

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

[141] 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 declaration.

- d) **12[b][ii]: Simon discloses “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;”**

[142] 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 declaration.

- e) **12[c][i]: Simon discloses “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,”**

[143] 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 declaration.

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

[144] 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 declaration.

- g) **12[c][iii]: Simon discloses “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”**

[145] 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 declaration.

- h) **12[c][iv]: Simon discloses “wherein the first bore comprises an interior surface at the first aperture”**

[146] 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 declaration.

- i) **12[c][v]: Simon discloses “wherein there are no threads adjacent to the second aperture on the exterior surface of the third member”**

[147] 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 declaration.

- j) **12[c][vi]: Simon discloses “wherein the third longitudinal axis and the first bore axis define a first angle”**

[148] 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 declaration.

- k) **12[d]: Simon discloses “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”**

[149] 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 declaration.

- l) **12[e]: Simon discloses “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”**

[150] 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 declaration.

- m) **12[f]: Simon discloses “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”

[151] 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 declaration.

n) **12[g]: Simon discloses “wherein the second angle is in the range of about 0 degrees to about 90 degrees”**

[152] 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 declaration.

o) **12[h]: Simon discloses “wherein the second bore axis is substantially perpendicular to the third longitudinal axis”**

[153] 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 declaration.

8. Simon Discloses all the elements of Claim 14

[154] This claim has the same limitations as claim 8 and is disclosed by Simon as discussed in section (V.D.4) of this declaration.

9. Simon Discloses all the elements of Claim 15

[155] This claim has the same limitations as claim 8 and is disclosed by Simon as discussed in section (V.D.4) of this declaration.

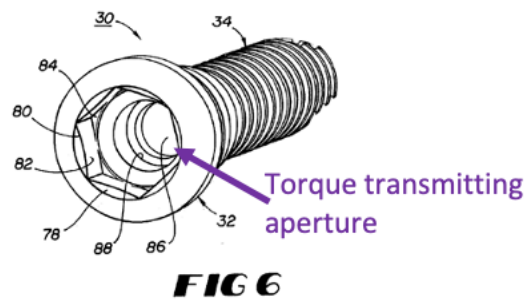
E. Simon in View of Ferrante Make Obvious Claims 4, 8, 10-11, and 14-15.

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

[157] 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.

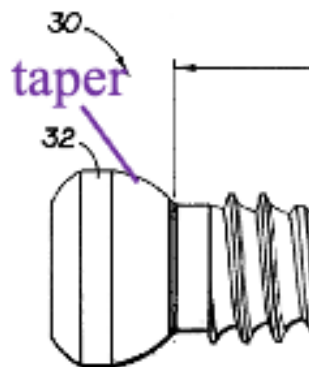
1. Simon and Ferrante Disclose all of the Elements of Claim 4

[158] 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) that is driven by torque but is not specific in the screw comprising an aperture. A POSA would assume that the screw head would have an aperture in the screw head to provide torque using a screwdriver that fills the aperture with similar shape, 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.



2. Simon and Ferrante Disclose all of the Elements of Claim 8

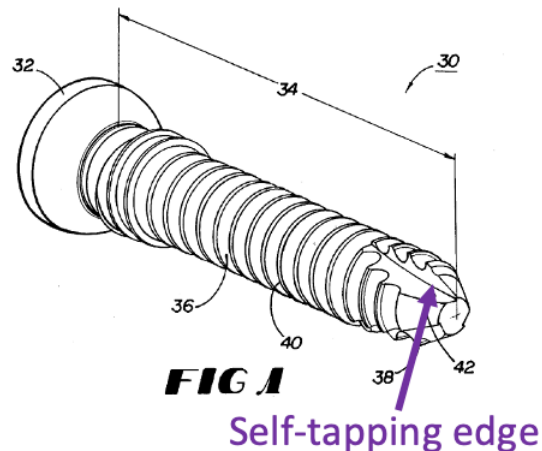
[159] Claim 8 further limits claim 1 to require the head portion of the first member to be tapered. Simon discloses a locking screw, which a POSA would assume discloses a tapered head. However, that the locking screw in Simon has a tapered head is not explicitly stated. Ferrante discloses a screw with a tapered head at least in figure 2 as shown below (cropped).



3. Simon and Ferrante Disclose all of the Elements of Claim 10

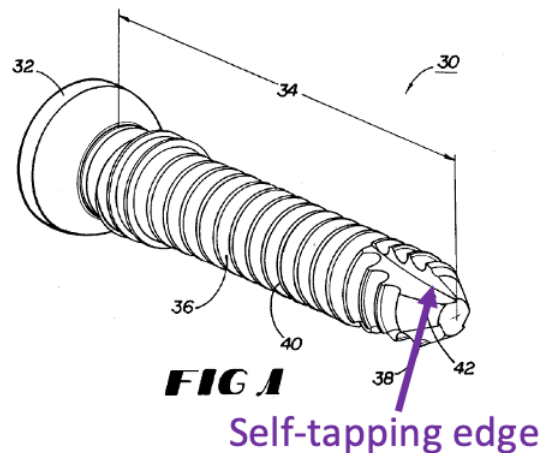
[160] Claim 10 further limits claim 1 by requiring that the first member includes a self-tapping edge for removing bone material. While a POSA would assume that the first member includes a self-tapping edge, Simon does

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. That Ferrante discloses a self-tapping edge is shown in figure 1, included below.



4. Simon and Ferrante Disclose all of the Elements of Claim 11

[161] 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 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]). That Ferrante discloses a self-tapping edge is shown in figure 1, included below.

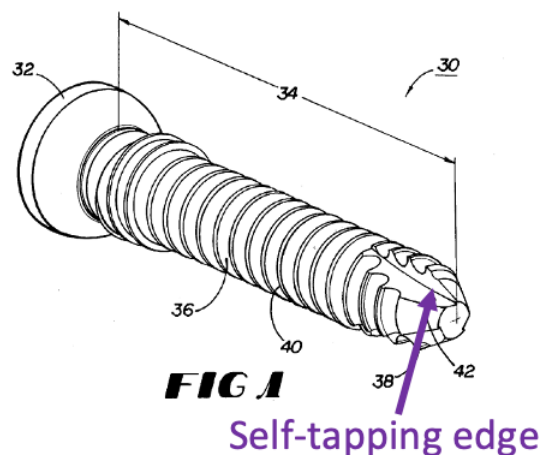


5. Simon and Ferrante Disclose all of the Elements of Claim 14

[162] 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 declaration.

6. Simon and Ferrante Disclose all of the Elements of Claim 15

[163] 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 declaration.

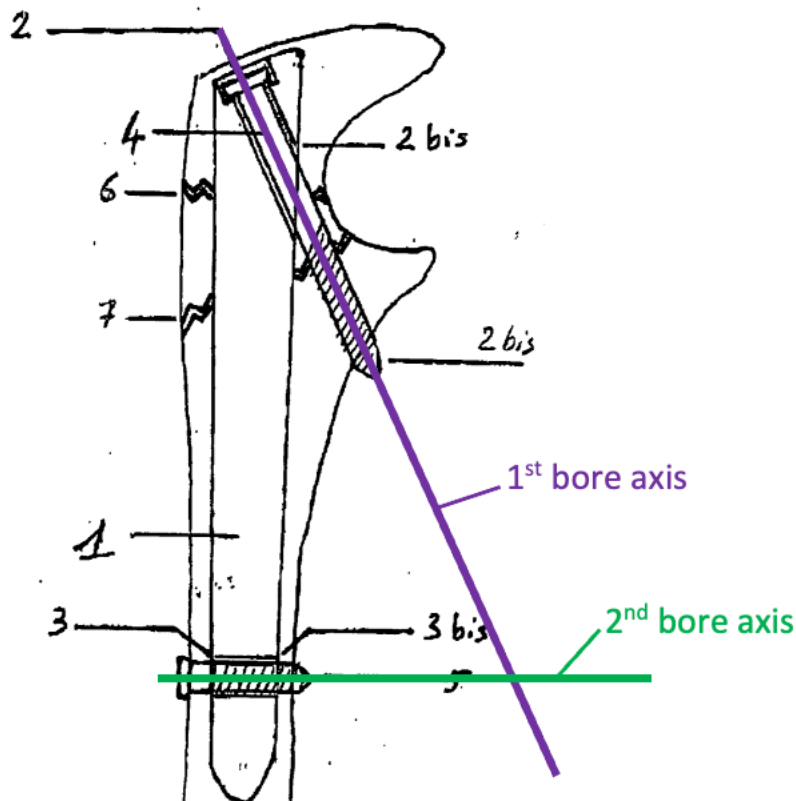


F. Simon in View of Cognet Make Obvious Claim 9.

[164] 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].

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

[165] 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.



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

[166] Leu is U.S. Patent No. 6,270,499 (“Leu”) which issued on August 7, 2001, and discloses a bone fixation device. 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.

[167] 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. 1008 [0057]) and cites to Leu

as an example of an intramedullary nail intended for insertion in a longer bone
(Ex. 1008 [0015]).

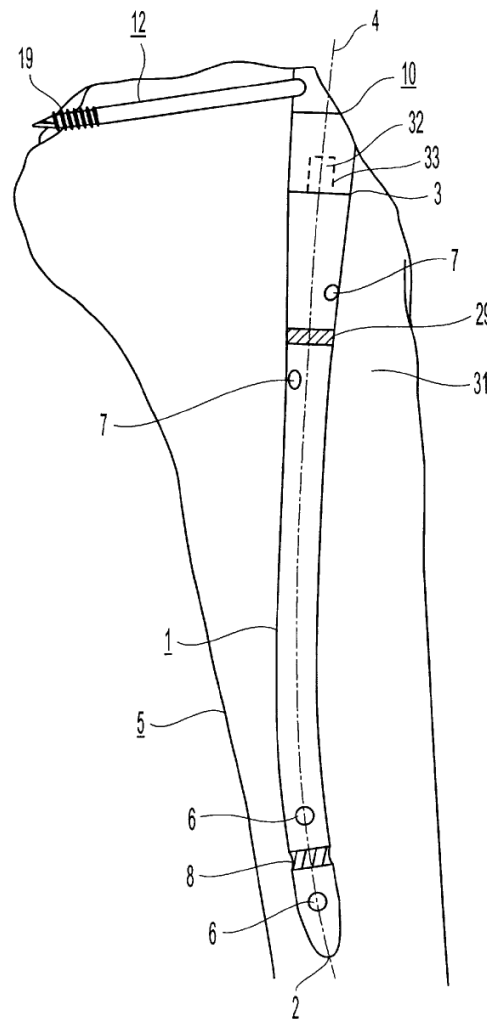
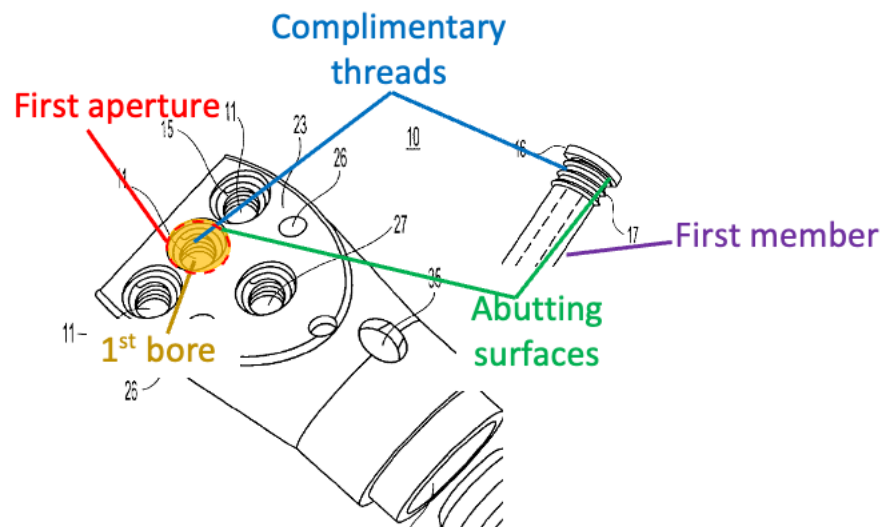


Fig. 1

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

[168] 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

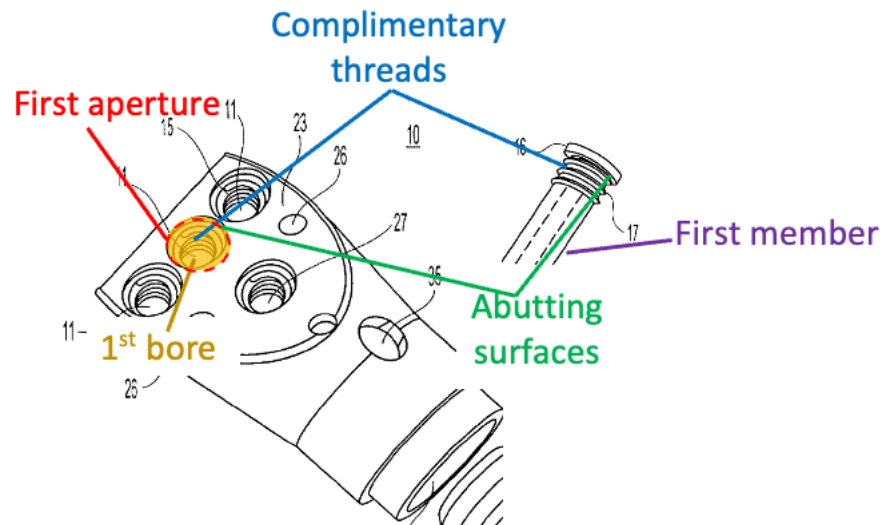
threads (17) have corresponding threads (15) within the bore (11) on the nail head (10), allowing for the screw head to lock into and sink within the first aperture (11). Ex. 1009, 4:63-67; 5:1-5. See cropped Figures 2 and 3 below.



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

[169] 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. 1009, 3:63-67; 4:1-21.



(Ex. 1009, Figures 2 and 3 – cropped)

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

[170] 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 (0).

4. Simon and Leu Disclose all the Elements of Claim 7

[171] 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).

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

[172] This claim has the same limitations as claim 2 and is disclosed by Simon and Leu as discussed in section (0) of this declaration.

VI. Conclusion

For the foregoing reasons claims 1-15 are unpatentable.

I hereby declare under penalty of perjury that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true. I understand that willfully false statements and the like are punishable by fine, imprisonment, or both under 18 U.S.C. §1001.

Executed on this the 28 day of April 2023.

Respectfully submitted,

/Leonel Dominguez/

Leonel Dominguez

ATTACHMENT A

Leonel Dominguez

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Palm Coast, FL 32137

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OBJECTIVE

To provide Technical Leadership in Product Development, Operations and Quality to growth-oriented, innovative, medical device companies seeking a professional with thirty years proven track record of rapid product commercialization with interest in serving customers' needs in a responsive manner.

PROFESSIONAL EXPERIENCE

Duraspine Medical Technologies LLC, Palm Coast FL *January 2007- Present*
(formerly known as Hyperjax Biomedical Consulting, Jacksonville, Florida)

President

A biomedical engineering firm that provides expertise in medical device design from concept through manufacture, quality systems, manufacturing and intellectual Property development within Spine, Orthopaedics, ENT, Head and Neck and OB/GYN and other biomedical device markets.

Medtech Momentum (Maitland, FL) *January 2020-Present*
Advisory Board member 2020- present

Provide business and technical advice to new and established growth-oriented companies in the medical industry.

Scient'x USA, Maitland, Florida *May 2005-January 2007*
Vice President, Research and Product Development

Technical leader of a fast growing, French-based spine orthopedic device company responsible for product development of lumbar, cervical, deformity, PEEK implants, non-fusion stabilization devices and motion preservation, outsource manufacturing, quality systems, and intellectual property development.

- Lead small, and responsive, hands-on technical group that interfaces with European colleagues and surgeons to develop and improve products for the US market. Averaging 50%+ growth during past 4 years.
- Implemented and monitor design controls and quality policies as the US company has evolved from distributor to manufacturer in the past 2.5 years. The US Company has been FDA audited in 2006 with no major observations.

US Spine, LLC, Boca Raton, Florida *August 2003-May 2005*
Vice President, Product Design and Development

Technical leader of a private, start-up spine orthopedic device company responsible for product development, manufacturing, quality systems, and intellectual property development. The company successfully raised \$5.0M in private financing during a one-year period.

- Designed, developed and commercialized a polyaxial pedicle screw and instrument system during a 10 month period that was 510(K) approved in 2004.
- Worked with surgeon thought leaders as part of several medical advisory teams established to design a minimally invasive facet fixation screw, a MIS retractor system and cervical allograft bone spacers.

- Submitted four provisional patent applications in the areas of MIS portal system, facet fixation system and cervical plate system.
- Established a custom manufacturing supply base and trained staff on Design Controls and GMP's.

Mekanika, Inc., Boca Raton, Florida

February 2002-August 2003

Vice President of R&D

Lead and direct the technical efforts, including fiscal responsibility of a private, start-up spine orthopedic device company involved in design, marketing and sales of electro-medical diagnostic equipment and composite surgical implants. The company successfully raised over \$14M in private equity financing during a two-year period.

- Established a four-person engineering team focused on product development, quality and manufacture of electro-medical hardware, software, disposable instruments and spinal implants.
- Established supply agreements with several ISO 9002 manufacturers to provide turnkey, manufactured products from specifications with initial orders valued at \$1M.
- Designed, developed and produced ten intra-operative medical diagnostic capital systems during a seven-month period to perform a real-time, diagnostic measure and record of spinal instability during decompressive lumbar spinal surgery. Performed product installations, in-services and solicited surgeon feedback during surgery for next generation products.
- Acquired EN60601 Electrical Safety and CE mark certification for the system which employs custom measurement software, touch-screen monitor, and integrated hand piece with a stepper motor and force transducer for the surgeon user.
- Continued the development, test and manufacture of a composite spinal plate system made of PEEK and carbon-fiber with a strategic manufacturing partner.
- Assumed full R&D management responsibility including design control, engineering records, intellectual property, budget, staff training, and presentations on company technology to the medical device investment community.

Medtronic-Xomed Surgical Products, Inc., Jacksonville, Florida 1998-February 2002

Director of R&D

Manage and direct the efforts of 20 engineers, designers and technical documentation personnel involved in the design and development of Ear, Nose, Throat (ENT) and Image-Guided Surgery devices from concept through commercialization to achieve the corporation's strategic goals for quality and responsive product introduction. Medtronic acquired Xomed for \$880M in late 1999.

- Responsible for chairing the executive group tasked to screen and approves new product ideas, business opportunities and their financial impact at a strategic level before development team resources are directed to execute plans. Efforts during the past several years amount to a strong product pipeline that accounts for 44% of annual sales revenue.
- Conduct or approve technical design reviews for class I and II, electro-mechanical medical devices that include stress and tolerance analyses, product specifications and compliance to FDA, ISO, and Corporate Design Control requirements.
- Extensive, hands-on approach to managing engineering development and problem solving while working with clinicians, marketing, regulatory, manufacturing and suppliers on new devices.
- Manager and technical contributor of a design engineering group responsible for endoscopic, minimally-invasive powered devices, instruments and image-guided technologies that develops an average of 100 new products each year.

Section Manager of R&D**1995-1998**

Served in roles as Business Team Leader, Project Manager and Product Development Engineering to work with clinicians, suppliers and cross-functional team members to rapidly develop product from concept through commercial introduction.

- Led cross-functional team for a period of 2.5 years responsible for development of hand-held, powered surgical drills, shavers (micro-debrider) devices and capital equipment used to dissect, soft and bony tissue during ENT endo/microscopic surgery. Platform product success has enabled capture of 55% market share in three years through a capital and disposable product line that accounts for 25% of total company sales. Both electro-mechanical systems were successfully developed in less than one year, was market introduced at an annual medical meeting and prominently highlighted in the company's Initial Public Offering (IPO) prospectus for investors in 1996.
- Investigated business-complimentary technology involving Image-Guided Surgery for ENT that led to a distribution agreement and development of surgical instruments the business has grown to \$15M in annual sales revenue during a two-year period with strong future growth potential.
- Responsible for maintaining Design Control standards, training and reviews that achieve FDA, ISO and corporate quality systems regulations streamline the product development process and reduce time-to-market for medical devices.

Smith & Nephew Richards, Inc., Memphis, Tennessee**Senior Product Development Engineer****1993-1995**

Lead project engineer responsible for new product development from concept through manufacture of orthopaedic implants, external trauma fixation, bracing and manual instruments used in the treatment of bone fracture reduction, stabilization and deformity correction. Utilized analytical, project management and communication skills to lead and direct project teams to develop medical devices within budget and schedule.

- Principal engineer for the Ilizarov® Circular-Ring External Fixation Device used in orthopaedic bone reconstruction and deformity correction. A premier platform system consisting of 200 unique components that are assembled to build stabilization frames for most bone fracture types.
- Developed Trauma Circular Ring Fixator Platform utilizing multi-functional, connecting rods for quick assembly. Development effort included market study and advertising campaign.
- Patented x-ray opaque surgical instrument and drill guide which facilitates the placement of bone pins utilizing anatomical landmarks to perform limb lengthening (distraction osteogenesis) while using an intramedullary rod implant.

United Technologies Optical Systems and Pratt & Whitney Aircraft, Palm Beach, FL**Associate Research Engineer****1988-1993**

- Conducted design, detailed structural analysis and mechanical testing of high precision mechanical/electro-optical systems for land, air and space involving lasers, optics, space shuttle main engine fuel pumps, jet engine turbine blades and nozzle components.

Motorola Inc., Paging Division, Boynton Beach, Florida**Product Development Engineer****1987-1988**

- Performed mechanical design and analysis of miniature electro-mechanical systems and components used in portable communications equipment subject to harsh environmental conditions.
- Acquired design experience with plastic injection molding, shock damping elastomers, structural adhesives, sheet metal forming and plating used in mass produced portable pagers.

EDUCATION

Master of Science in Mechanical Engineering, 1986
Georgia Institute of Technology, Atlanta, Georgia

Bachelor of Science in Mechanical Engineering, 1985 - Cum Laude
University of Miami, Coral Gables, Florida

PATENTS

Bone fixation implant system and method



WO US [US7563275B2](#) Leonel Dominguez U.S. Spinal Technologies, Llc

Priority 2002-10-10 • Filed 2004-10-26 • Granted 2009-07-21 • Published 2009-07-21

A system for performing bone arthrodesis includes an implant for bone arthrodesis and a bone fastening device. The implant includes a fastener with an elongated shaft having a head at one end and a bone-piercing point at the opposite end. A first washer has structure for engaging the head of the ...

Implant for mammalian bony segment stabilization

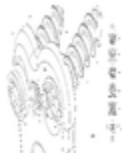


US [US8870957B2](#) Leonel Dominguez Amendia, Inc.

Priority 2009-03-04 • Filed 2009-03-04 • Granted 2014-10-28 • Published 2014-10-28

Embodiments of bony region stabilization implants including multiple fenestrations and bony ingrowth materials are described generally herein. Other embodiments may be described and claimed.

Method, system, and apparatus for mammalian bony segment stabilization

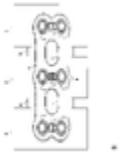


US [US8979910B2](#) Leonel Dominguez Verticor, Ltd.

Priority 2008-11-10 • Filed 2014-07-15 • Granted 2015-03-17 • Published 2015-03-17

Embodiments of bony region stabilization are described generally herein. Other embodiments may be described and claimed.

Method, system, and apparatus for mammalian bony segment stabilization



US US20100121383A1 Leonel Dominguez Todd Stanaford

Priority 2008-11-10 • Filed 2008-11-10 • Published 2010-05-13

Embodiments of bony region stabilization are described generally herein. Other embodiments may be described and claimed.

Expandable surgical retractor system for minimal access surgery



WO US20060089536A1 Leonel Dominguez U.S. Spinal Technologies, Llc

Priority 2004-10-26 • Filed 2004-10-26 • Published 2006-04-27

A retractor for surgery includes a retractor body and an elongated and expandable structure attached to the retractor body. The expandable structure, when expanded, has an elongated open interior for the insertion of a portion of a surgical instrument. Drive structure is provided for expanding the ...

Intervertebral implant



US USD616546S1 Leonel Dominguez Verticor, Ltd.

Priority 2009-03-04 • Filed 2009-03-04 • Granted 2010-05-25 • Published 2010-05-25

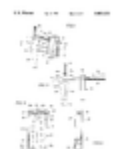
The ornamental design for an intervertebral implant, as shown and described.

Bone fixation implant system and method

~~EP~~ CN JP ~~KR~~ AU IL MX ZA ZA200704321B Dominguez Leonel U S Spinal Technologies Llc

Priority 2004-10-26 • Filed 2007-05-25 • Published 2008-10-29

Drill guide and method for avoiding intramedullary nails in the placement of ...



WO US AU US5403322A Leonel Dominguez Smith & Nephew Richards Inc.

Priority 1993-07-08 • Filed 1994-02-18 • Granted 1995-04-04 • Published 1995-04-04

A drill guide and method for guiding placement of external fixation pins in the bone of a human limb to avoid an implanted intramedullary nail with the drill guide having a plurality of guide holes adapted to guide and receive a bone drill bit and bone pins.

Surgical headframe with soft contact pads for use with a stereotactic system

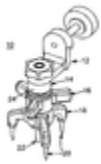


~~WO EP US AT DE~~ US6770082B2 **Leonel Dominguez** Medtronic, Inc.

Priority 2000-09-24 • Filed 2001-09-24 • Granted 2004-08-03 • Published 2004-08-03

A surgical headframe for maintaining a stereotactic system reference frame relative to a patient's head. The headframe includes a frame body, first and second arms, a plurality of contact pads, and a strap. The first and second arms extend from opposing sides of the frame body, respectively.

[Surgical reference frame fixation device with cannulated post and method of use](#)



~~WO EP US~~ US6893447B2 **Leonel Dominguez** Medtronic, Inc.

Priority 2000-09-24 • Filed 2001-09-24 • Granted 2005-05-17 • Published 2005-05-17

A surgical fixation device for mounting a stereotactic reference frame to a patient. The device includes a mounting bracket assembly, a cannulated post, a base, an anchor tube, a plurality of percutaneous pins, and a driving device.

[Drill guide and method for avoiding intramedullary nails in the placement of ...](#)

~~EP JP AU CA NZ AU~~ 6734194A **Leonel Dominguez** Smith & Nephew, Inc.

Priority 1993-07-08 • Filed 1994-07-07 • Published 1995-01-19