

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,
Petitioner,

v.

EXTREMITY MEDICAL, LLC
Patent Owner.

Case IPR2023-00894
Patent 11,298,166

**SECOND DECLARATION OF LEONEL DOMINGUEZ
IN SUPPORT OF PETITIONER**

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I. Materials Considered

[001] As part of my independent analysis, I also analyzed the following publications and materials:

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.
1014	U.S. Patent No. 9,044,282 B2 to Jeff Tyber, <i>et al.</i> , filed on February 11, 2010, issued on June 2, 2015. (“282 patent”).

1015	U.S. Patent No. 9,044,282 file history selections (“’680 application”)
1016	U.S. Patent Application Serial No. 12/906,454, filed on October 10, 2010, file history selections
1017	Transcript of Deposition of Eric H. Ledet, Ph.D., April 15, 2024
1019	U.S. Patent No. 6,056,753 to Roger P. Jackson, filed on July 13, 1998, issued on May 2, 2000 (“Jackson”)
1020	U.S. Patent Publication No. 2006/0200147 A1 filed by Michael Ensign, <i>et al.</i> on February 17, 2006, published on September 7, 2006 (“Ensign”)
1021	U.S. Patent No. 5,562,670 to Per-Ingvar Brånemark, filed on April 26, 1994, issued on October 8, 1996 (“Brånemark”)
1022	U.S. Patent No. 10,639,076 to Eric H. Ledet, <i>et al.</i> , filed on March 12, 2018, issued on May 5, 2020
1023	Ledet et al., “Novel lumbrosacral axial fixation techniques.” <i>Expert Rev. Med. Devices</i> , 3(3), 327–334 (2006).
1024	U.S. Patent Publication No. 2017/0100174 A1 filed by Himanshu Mishra, <i>et al.</i> , on October 11, 2016, published on April 13, 2017 (“Mishra”)
1025	U.S. Patent No. 4,726,121 to Charles D. Ray, <i>et al.</i> , filed on March 9, 1987, issued on February 23, 1988 (“Ray”)
1026	U.S. Patent No. 4,327,770 to Peter W. Brown, <i>et al.</i> , filed on November 23, 1979, issued on May 4, 1982 (“Brown”)
1027	U.S. Patent No. 5,908,024 to Victor S. Staev, filed on November 21, 1997, issued on June 1, 1999 (“Staev”)
1028	U.S. Patent Publication No. 2008/0202235 A1 filed by Larry D. Laps, <i>et al.</i> , on July 20, 2006, published on August 28, 2008 (“Laps”)
1029	U.S. Patent No. 4,753,234 to Miguel Martinez, filed on November 3, 1986, issued on June 28, 1988 (“Martinez”)
1030	U.S. Patent No. 5,522,843 to Kerry Zang, filed on February 23, 1994, issued on June 4, 1996 (“Zang”)

1031	U.S. Patent No. 6,097,592 to Yeol-Gu Seo, et al., filed on October 16, 1997, published on August 1, 2000 (“Seo”)
1032	U.S. Patent No. 4,286,453 to Klaus Exner, filed on May 16, 1979, issued on September 1, 1981 (“Exner”)
1033	Spanish Patent No. ES 2,164,543 B1 to López-Oliva Munõz English translation and translation certification (“Lopez”)
1033a	Spanish Patent No. ES 2,164,543 B1 to López-Oliva Munõz, filed on July 19, 1999, published on February 16, 2002, issued on May 16, 2003
1039	U.S. Patent No. 4,846,162 to J. David Moehring, filed on September 14, 1987, issued on July 11, 1989 (“Moehring”)
1040	U.S. Patent Publication No. 2010/0160967 to Joseph Capozzoli, filed December 22, 2009, published Jun 24, 2010 (“Capozzoli”)
1041	U.S. Patent Publication No. 2009/0118733 to James Edward Orsak, <i>et al.</i> , filed on October 31, 2008, published on May 7, 2009 (“Orsak”)
1042	U.S. Patent No. 4,535,764 to Edward A. Ebert, filed on April 15, 1983, issued on August 20, 1985 (“Ebert”)
1043	U.S. Patent No. 7,442,195 to Alfred F. Behrens, filed on September 12, 2005, issued on October 28, 2008 (“Behrens”)
1044	U.S. Patent No. 6,270,528 to William F. McKay, filed on August 6, 1999, issued on August 7, 2001 (“McKay”)
1045	Computer file Fig-18-final.blend (paper placeholder filed)
1046	Computer file Fig-9-final.blend (paper placeholder filed)
1049	Still images from Fig-18-final.blend
1050	Still images from Fig-9-final.blend
1051	Declaration of Eli Jacobson
1052	Declaration of Scott Kamholz
2012	Declaration of Eric Ledet
2017	U.S. Patent No. 10,357,299 to Weiner
	Patent Owner Preliminary Response, Paper 12 (“POPR”)
	Patent Owner Response to Petition, Paper 22 (“POR”)
	Institution Decision, Paper 15 (“DI”)

	Petitioner Reply to Preliminary Response, Paper 13 (“PPR”)
	Corrected Motion to Amend, Paper 26 (“MTA”)

II. Background and Qualifications

[002] My background and qualifications are set forth in my original declaration (Ex. 1002, [4]-[22]).

[003] 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.

A. Bore

1. The Board’s construction is correct.

[004] The Board’s preliminary construction of “bore” as a hole or passage made by or as if by the turning or twisting movement of a tool such that its interior walls have cylindrical lateral cross-sections, and which do not exclude holes or passages having tapered or stepped longitudinal cross-sections is correct, based on how that term is used by individuals having ordinary skill in the art, as I will discuss below.

2. *Support cited contradicts Patent Owner's proposed construction*

[005] Patent Owner and Dr. Ledet opine that a POSITA would understand that the term bore does not include two sections of a hole separated by a ledge or “stepped longitudinal cross-section;” (POR 15, citing Ex. 2012 ¶41), citing US Patent No. 10,357,299 to Weiner, *et al.*, (“Weiner”) to support this opinion. However, it is my opinion that Weiner describes a single hole with varying geometries, including a stepped longitudinal cross-section.

[006] Weiner refers to “[t]he hole cut by proximal reamer 100” (Ex. 2017, 15:28, emphasis added). The Fig. 25C hole has a stepped longitudinal cross-section (referred to as the widened bore 113) which is “cut by shoulder 107” (Ex. 2017, 15:41) of proximal reamer 100 depicted in Fig. 25A.

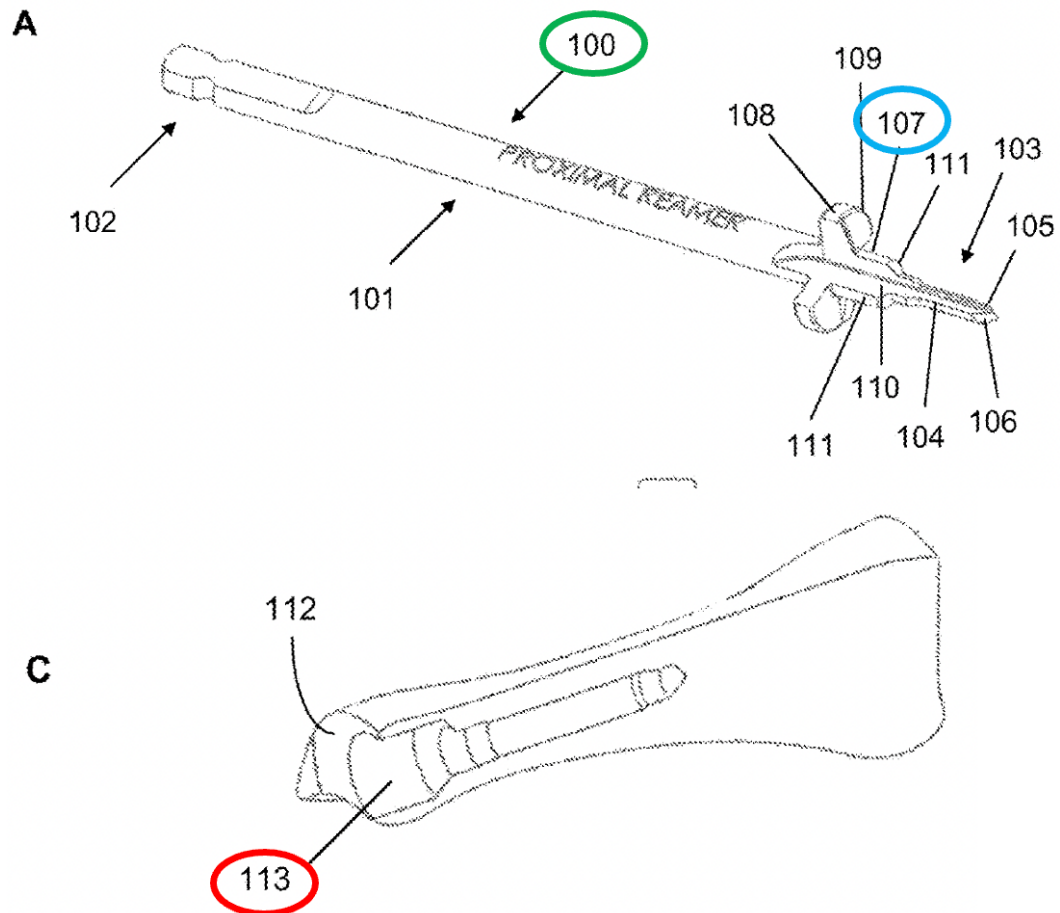
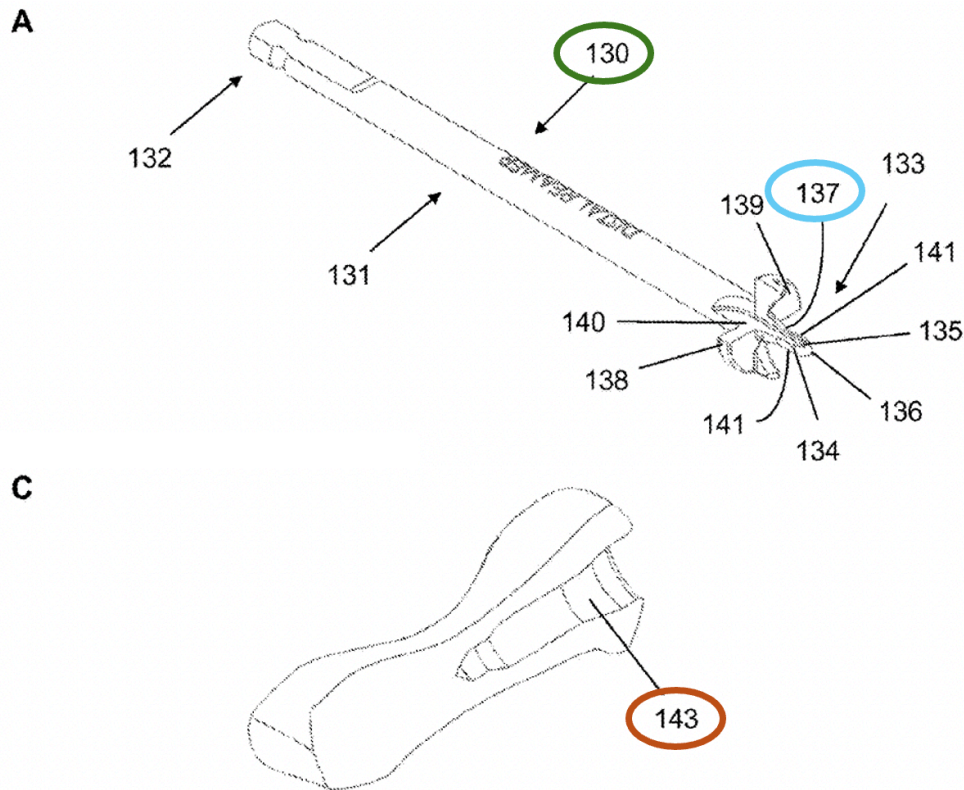


FIG. 25

(Weiner, Figs. 25A & 25C)

[007] Further, a second hole (the distal hole 143) depicted in Fig. 27C is very similar in shape to the proximal hole in that it includes a stepped longitudinal cross-section created by the shoulder 137 of the distal reamer 130, but the entire structure is referred to a single structure, or hole 143. (Ex. 2017, 16:18-67)



[008] Thus, Patent Owner and Dr. Ledet have not shown that bore does not include two sections of a hole separated by a ledge or stepped longitudinal cross-section, but have certainly shown that a counterbore is considered to be part of a larger structure or hole.

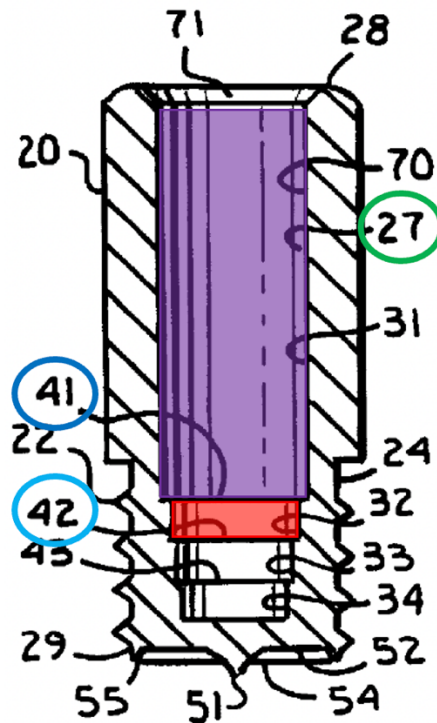
3. *“Bore” refers to stepped longitudinal cross-sections in the art*

[009] The Patent Owner’s new contention that a POSA would have regarded the term “bore” to exclude bores with a stepped longitudinal cross-

section is unfounded. Each of the following prior-art references uses the term “bore” to refer to a hole or tunnel having abutting cylindrical sections of different diameters (stepped longitudinal cross-sections).

a) Jackson depicts a single bore with at least one stepped longitudinal cross-sections

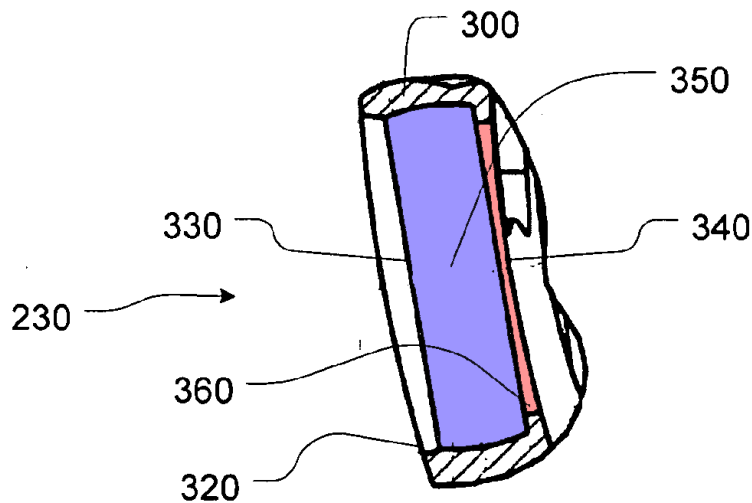
[010] U.S. Patent No. 6,056,753 to Jackson describes a bone repair set screw in which “[t]he bore 27 comprises a first bore section 31, a second bore section 32,” etc. delineated by shoulders 41, 42, etc. (Ex. 1019, 5:24–43) as shown in annotated Fig. 3:



(Ex. 1019, Fig. 3 – annotated)

b) Ensign depicts a single bore with a stepped longitudinal cross-section

[011] U.S. Patent Publication No. 2006/0200147 to Ensign describes an orthopedic plate system having plate body 300 with “the thru-bore 230” that includes central cavity diameter 350 delineated from the smaller exit diameter 340 by bore stop 360 (Ex. 1020, [0035]), as shown in annotated Fig. 3C:

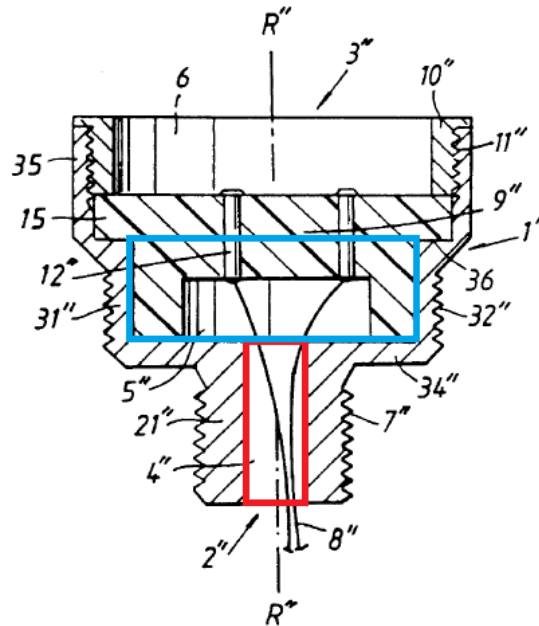


(Ex. 1020, Fig. 3c - annotated)

c) Brånemark depicts a single bore with a stepped longitudinal cross-section

[012] U.S. Patent No. 5,562,670 to Brånemark describes an osseous implantation device having body 1" with first and second holding portions 21", 31" and “an inner through bore with a first portion 4" in the first holding portion and a second portion 5" in the second holding portion.” Ex. 1021,

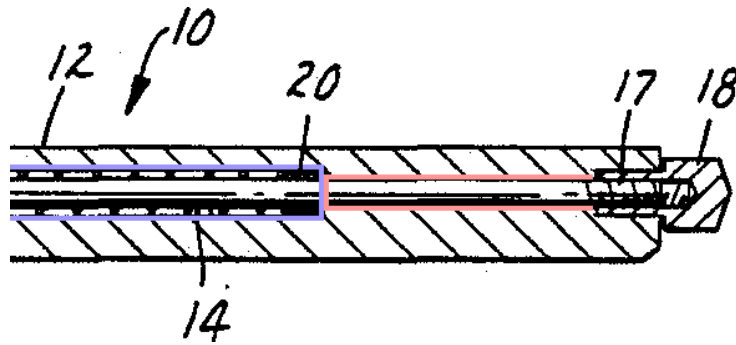
4:44–46. As shown in annotated Fig. 4, the through bore has stepped diameters in portions 4" and 5":



(Ex. 1021, Fig. 4 - annotated)

d) Ray depicts a single bore with a cylindrical stepped longitudinal cross-section

[013] U.S. Patent No. 4,726,121 to Ray, *et al.*, (“Ray”) titled “Surgical Caliper”, was filed March 9, 1987, and issued on February 23, 1988. The surgical calipers described in Ray (Ex. 1025, 2:10–11) include handle 12 having “stepped cylindrical bore 14.” Collar 20 of a shaft inserted in the bore “rests against a step of the bore 14” (2:14–15) as shown in detail from Fig. 1, with the segments of stepped cylindrical bore 14 annotated in blue and red:

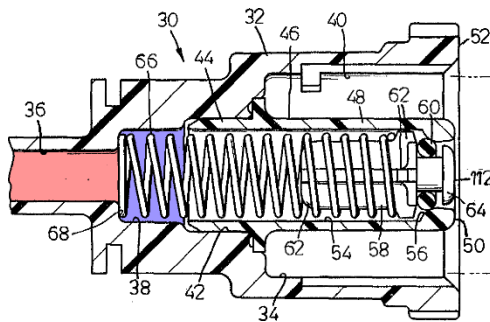


(Ex. 1025, Fig. 1 detail - annotated)

e) Brown depicts a single bore with a stepped longitudinal cross-section

[014] U.S. Patent No. 4,327,770 to Brown (Ex. 1026, 3:59–4:4)

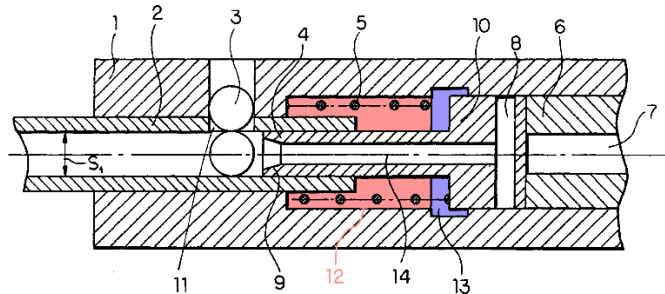
described a fluid valve coupling member 30 in which “the stepped cylindrical bore 34 includes stepped fluid passage portions 36 and 38” (annotated in red and blue, respectively) with further enlarged portions 42 and 40:



(Ex. 1026, Fig. 2 detail - annotated)

f) Staev depicts a single bore with a stepped longitudinal cross-section

[015] U.S. Patent No. 5,908,024 to Staev described a housing for a pneumatic shooting device breech block in which “[t]he cylindrical bore in the housing 1” is “step-shaped” and has three portions 11, 12, 13 with different diameters (Ex. 1027, 2:31–36):



(Ex. 1027, Fig. 1 annotated; lead line 12 added from Fig. 2)

g) Brumfield depicts a single bore with a stepped longitudinal cross-section

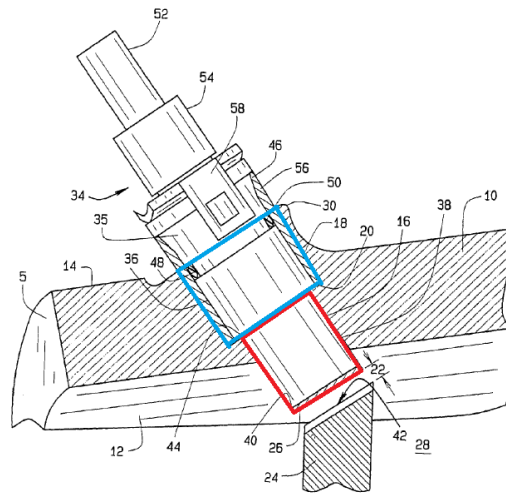
[016] U.S. Patent No. 4,827,917 to Brumfield describes “[a] hole” that is formed in bone using “a ‘step-drill’ or ‘step-reamer’ containing two diameters: a smaller diameter at its tip corresponding to the root diameter of the lag screw thread; and a larger diameter which is equal to the diameter of the smooth portion” of the lag screw. Ex. 1006, 6:41–47. Brumfield thus describes a single void having abutting cylindrical portions of different diameters as “a hole,” which refutes Patent Owner’s contention.

4. *A counterbore is a part of its bore.*

[017] Ledet says “I know what a counterbore is in relationship to a bore” (Ex. 1017, 29:25-30:2) which is how an expert would understand it. A counterbore is not a structure unto itself, a counterbore is part of a larger structure. This is exemplified in the art by the following:

a) Laps depicts a bore and a counterbore as a single structure

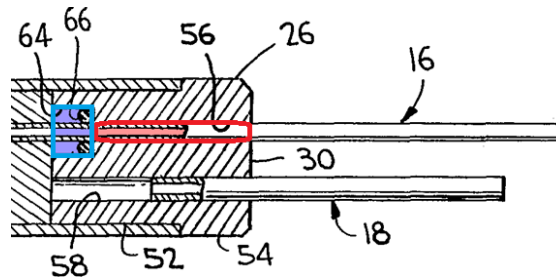
[018] U.S. Patent Publication No. 2008/0202235 to Laps discloses a sensor assembly with a housing in which “the bore 16 includes a counterbore 18” (Ex. 1028, [0033]):



(Ex. 1028, Fig. 1 detail - annotated)

b) Martinez depicts a bore and a counterbore as a single structure

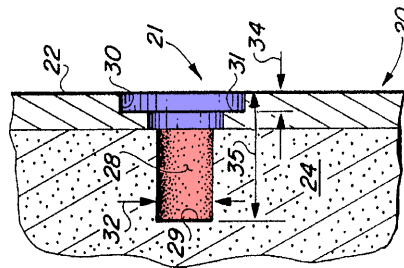
[019] U.S. Patent No. 4,753,234 to Martinez describes a surgical cutting apparatus in which “[t]he bore 56 has a counterbore 64” (Ex. 1029, 3:61):



(Ex. 1029, Fig. 1 detail - annotated)

c) Zang depicts a bore and a counterbore as a single structure

[020] U.S. Patent No. 5,522,843 to Zang discloses a bone anchor for which a “bore [that] includes a counterbore” is formed (Ex. 1030, 2:49); preferably bore 28 and counterbore 30 are drilled by a single tool (6:48–49):



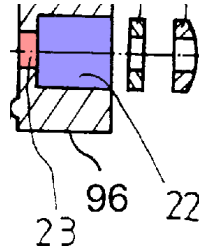
Zang Fig. 2B (annotated)

d) Ledet depicts an aperture and a counterbore as a single structure

[021] U.S. Patent No. 10,639,076 to Ledet describes apertures as “counterbored” and does not identify an aperture’s counterbore as a distinct structure. Ex. 1022, 29:3–5.

e) Seo depicts a bore and a counterbore as a single structure

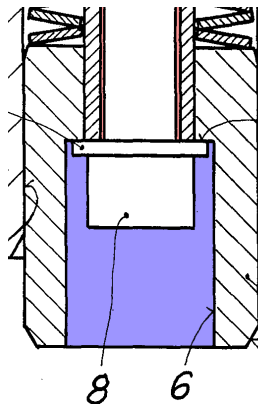
[022] U.S. Patent No. 6,097,592 to Seo describes a bore with stepped-diameter geometry as “a counterbored bore 23” (Ex. 1032, 3:45):



Ex. 1032 Fig. 4 detail (annotated)

f) Exner depicts a bore and a counterbore as a single structure

[023] U.S. Patent No. 4,286,453 to Exner describes a bore with a stepped-diameter geometry as “counterbored axial bore 6” in (Ex. 1033, 2:16):



Ex. 1033 Figure detail (annotated)

5. Dr. Ledet’s prior work matches Petitioner’s construction

[024] Patent Owner’s expert refers to a void having abutting cylindrical sections of different diameters in the singular as “a” tunnel, aperture, or

hole. For example, in a 2006 research paper “Novel lumbrosacral axial fixation techniques” Dr. Ledet illustrates an “axial fixation rod” having abutting cylindrical sections of different diameters:



Figure 2. The TranS1, Inc. Axial Fixation Rod is shown in three different lengths.

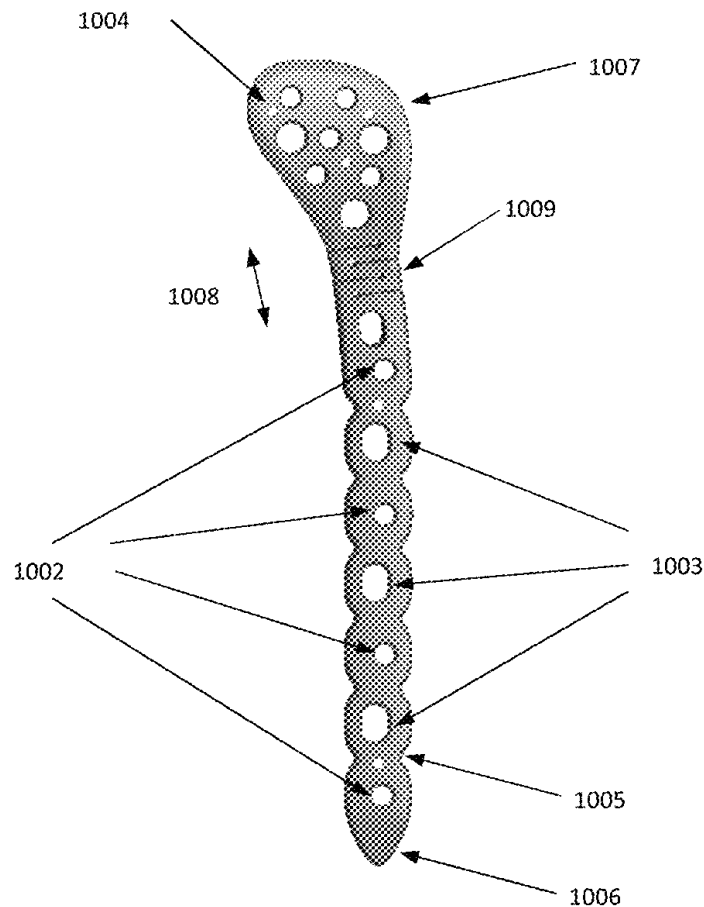
[025] Ex. 1023, 329. Dr. Ledet then discloses that the axial fixation rod is received in “[a] transosseous tunnel formed through the sacrum across the L₅–S₁ disc space” (page 330).



Figure 3. A transosseous tunnel is formed through the sacrum across the L₅-S₁ disc space and the Axial Fixation Rod is inserted.

[026] Thus Dr. Ledet refers to a void having cylindrical sections of different diameters as a single “tunnel.”

[027] And in US 10,639,076, Dr. Ledet describes “holes 1002” (Ex. 1022, 28:66) as shown in Fig. 58:



Ledet (Ex. 1106), Fig. 58

[028] Dr. Ledet then refers to the holes as “the apertures” and explains that the apertures may be “counterbored,” among other possibilities. Col. 29:3–5. Patent Owner acknowledges that a counterbored hole has abutting cylindrical sections of different diameters (POR 22; Ex. 2018).

[029] Thus, in his own publication and patent, Dr. Ledet describes a void having two abutting cylindrical sections as a unitary “tunnel,” “aperture,” or “hole.” Dr. Ledet’s prior disclosures are therefore inconsistent with the position Patent Owner now takes.

[030] (reserved)

B. at the terminal end

1. The Board's interpretation is reasonable

[031] In the Institution Decision (“DI”, Paper 15) the Board viewed “at the terminal end” to not require “placement of the first aperture at the extreme proximal end of the third member” (DI 16). I agree with the Board’s interpretation, because it is consistent with how persons of ordinary skill in the art use the term.

2. Patent Owner's proposed construction is unsupported

[032] Patent Owner has mischaracterized my testimony. Patent Owner quotes my deposition testimony (POR pg. 13 – emphasis removed): “The way that I interpret Figure 2 in Chang is that if you look at the bullet 103 ... [t]hat’s referring to the very top of terminal end. That would be what I would represent as the terminal end of the nail.” However, identifying 103 as the “very top of the terminal end” does not limit the terminal end to the top surface of the nail.

3. “at the terminal end” has no intrinsic meaning in art

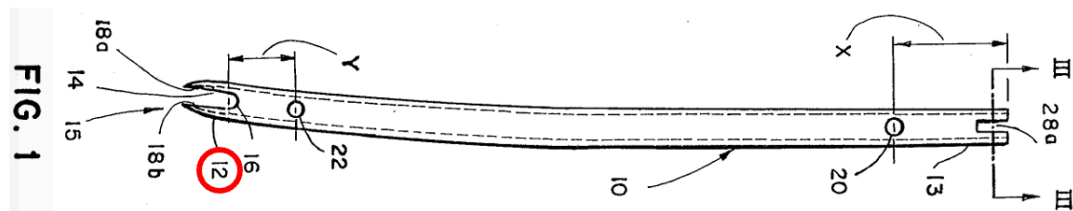
[033] “Terminal end” does not have an intrinsic meaning to a POSA, specifically there is no general understanding in the field that “terminal end” means the very top surface.

[034] (reserved)

[035] (reserved)

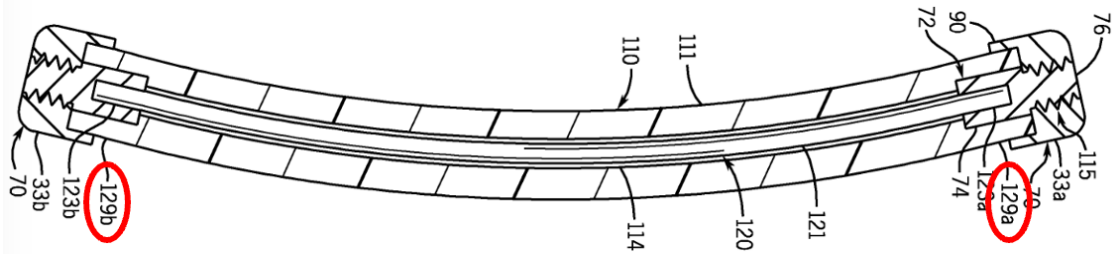
a) Moehring discloses terminal end to include the side of the nail shaft

[036] U.S. Patent No. 4,846,162 to Moehring titled “Orthopedic nail and method of bone fracture fixation” (published July 11, 1989) discloses a terminal end 12 (Ex. 1039, 3:19) which is not the top (nor bottom) surface of a nail but is the side of the nail.



b) Capozzoli discloses terminal end to include the side of the rod

[037] U.S. Patent Publication No. 2010/0160967 to Capozzoli (“Capozzoli”) titled, “Variable tension spine fixation rod,” (application published June 24, 2010) discloses terminal ends 129a-b (Ex. 1040, [0035]) which do not limit the terminal to the top surface, but include the side of the rod, as shown below in figure 3A.



(Ex. 1040, Fig. 3A)

c) Orsak discloses terminal end to include a portion of the shaft

[038] U.S. Patent Publication No. 2009/0118733 to Orsak (“Orsak”) titled “Orthopedic device” describes an orthopedic implant in which the ball joints have “terminal ends” 4042A and 4042B that include a portion of the shaft (Ex. 1041 [0118]) as shown below in figures 12B and 12C.

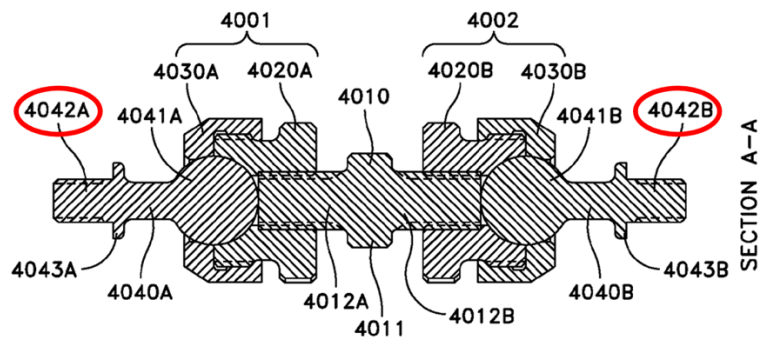


FIG. 12B

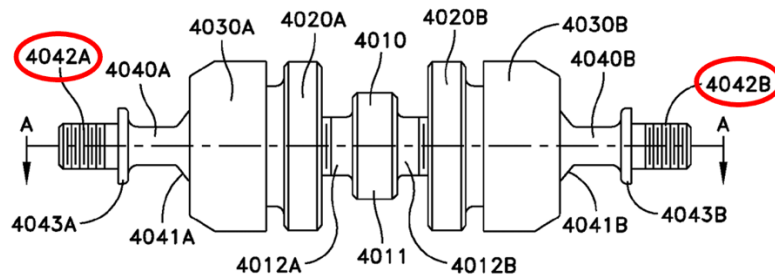
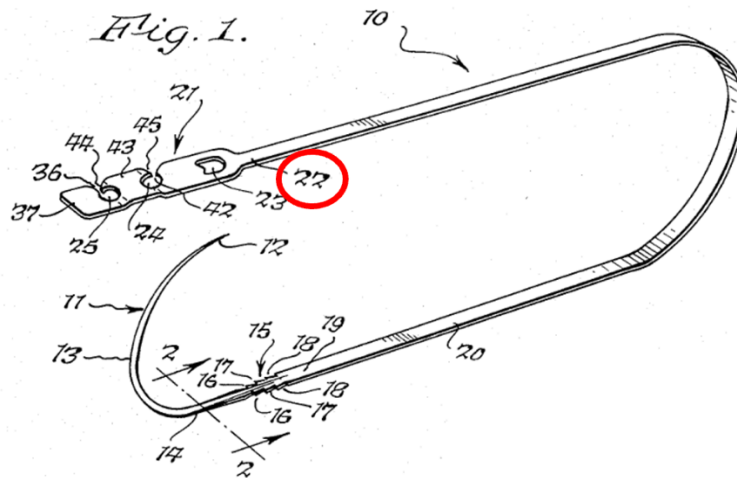


FIG. 12C

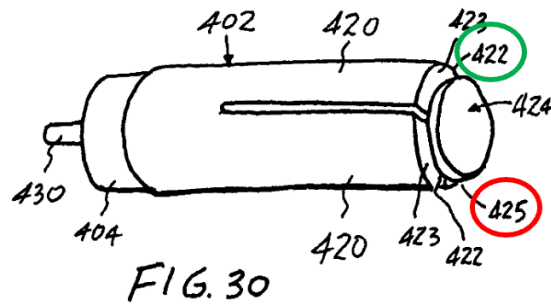
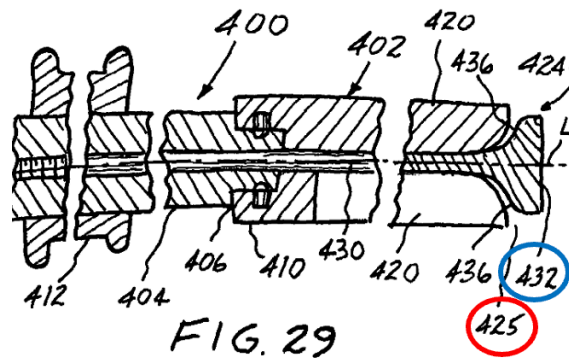
d) Ebert shows terminal end is not limited to the top surface

[039] U.S. Patent No. 4,535,764 to Ebert (“Ebert”) (published August 20, 1985) describes a surgical bone tie in which tie band 20 has terminal end 22 (Ex. 1042, 4:8) that’s not even located at the tip as shown below in figure 1.



e) Behrens

[040] U.S. Patent No. 7,442,195 to Behrens describes a bone fracture reduction device in which the instrument has working head 402 with terminal end 425 (and 422). Of note is that terminal end 425 refers to a whole region of the device, whereas the end surface is separately called out as a distinct structure (front end 432) as shown below in figures 29 and 30 (Ex. 1043, 11:1-13).



f) McKay

[041] U.S. Patent No. 6,270,528 to McKay (“McKay”) describes an intervertebral bone spacer in which thread cutter 400 includes drive shaft 402 with terminal end 406 (Ex. 1044, 8:65-9:3). Terminal end 406 refers to a whole region of the drive shaft, whereas the end is referred to separately by element 407 as shown below in figure 6.

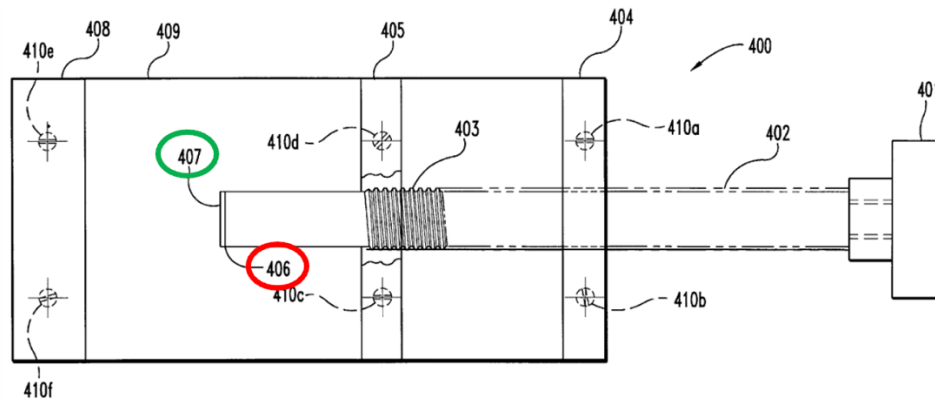


Fig. 6

[042] It is clear from the prior art that “terminal end” can include the sides of the shaft and is not limited to just the tip. In my opinion, therefore, references in the art to something being “at” the terminal end may mean that it can be near the end, since “terminal end” refers to an entire region of a part.

III. Cognet Challenges

A. Anticipation

1. *Claims 1, 2, 5, 6, 12, and 13 hinge on the construction of “bore”*

[043] Claims 1, 2, 5, 6, 12, and 13 anticipate if the Board’s construction of “bore” is correct. It is correct as discussed previously in the claim construction of bore (section II.A). Cognet discloses the structures as arranged in the claims. A POSA would have recognized “a bore” to be the

void extending from an aperture through the top surface to an aperture further down on the sidewall of Cognet's device.

2. *Claims 3 and 7: Cognet's screw head abuts at the first aperture*

a) The shoulder is at the first aperture

[044] Patent Owner is trying to narrow the claim by construing "at the first aperture" to mean interference fit on the first aperture, or some similar variation. As discussed previously in the Petitioner Reply to Preliminary Response (Paper 13 "PPR") "at the terminal end" means near the terminal end (PPR 4). The shoulder in Cognet is near the first aperture. It is reasonable to say that the contact between the shoulder and the screw is at the first aperture.

[045] Patent Owner has identified 1130 as the bore (PPR 1-2) and as the first aperture (PPR 4). Since bore and first aperture (distinguished as separate from the bore and the second aperture) are not used in the specification, it difficult to follow exactly how these member interact with each other. The '166 patent states that bulbous portion 1010 (head portion) forms an interference fit with aperture 1130 (which is not required to be on the exterior surface of the third member). Ex. 1001, 8:50–53, 9:66–10:2.

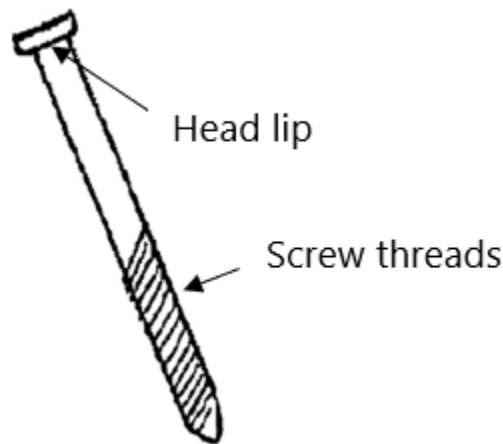
That is the same interaction disclosed between Cognet screw 4 and the shoulder in Cognet's tunnel.

[046] (reserved)

[047] (reserved)

3. *Claim 4: Cognet discloses a torque transmitting aperture*

[048] Cognet discloses a screw with a round (i.e, circular) head. Cognet illustrates the screw 4 as a solid object, which is made clear by the inclusion of surface features of the screw, such as threads and the line delineating the head from the shank. It apparent from the lack of lines on the head that the head is circular, because if it were not circular and instead had straight sides, the sides would have been delineated with lines. For example, if the head were a hex head, Cognet would have included one or two such lines to show two or three sides of the hex head. In addition, Cognet discloses that the head has a diameter (Ex. 1004, 3:14). As shown below, Cognet gives no indication that the screw head is anything other than circular. There are no lines that would delineate a hex geometry. Hex head shapes have flats and are not circular heads. A diameter is a property of a circular shape because the diameter is the same wherever it is measured on a circle. It is not a property of a polygonal shape because the span distance varies depending on whether it is drawn across sides or vertices.



Cognet Fig. 1 detail

[049] The hex cap lag screw example supplied by the Patent Owner (POR 35, Ex. 2012 ¶ 59) is typically used to affix heavy lumber under intense loads, is not a bone screw that would be used in orthopedic surgery, and was taken from a non-medical website according to Patent Owner's expert, Dr. Ledet. (Ex. 1017, 40:19). Because the object is not a medical device, it is my opinion that one of ordinary skill in the art would not have recognized it as a screw as that term is used in implantable medical device design. I stated in paragraph 76 of my earlier declaration that one of ordinary skill would assume that Cognet's screw had a torque aperture because it is the only reasonable, cost effective and space efficient way that a circular screw could be driven into bone (through the use of a screw driver, or similar tool). The only reasonable interpretation from the description and

drawings is that Cognet discloses a circular screw head with a torque transmitting aperture.

4. *Claim 9: intersection*

[050] In paragraph 82 in my declaration, I state “Cognet discloses the first bore axis and the second bore axis *intersecting* outside the third member.” (Ex. 1002 [81]-[82] - emphasis added) I do not find evidence that Dr. Ledet is disagreeing that the first bore axis and the second bore axis intersect outside the third member.

B. Obviousness

1. *Brumfield discloses conventional screw features.*

[051] Brumfield is evidence that it was well known to secure intramedullary nails using bone screws with torque apertures, tapered heads, and self-tapping ends. The screws in Brumfield and Cognet function in the same way to achieve the same result, specifically they are screwed in to secure items together and provide compression across a fracture site when assembled with a nail.

2. *Ferrante discloses conventional screw features*

[052] Ferrante’s discloses bone screws with self-tapping ends meets the limitations of both claims 10 (first member comprising a self-tapping end) and 11 (second member comprising a self-tapping end). The self-tapping

design feature is very desirable because it removes the pre-drilling step, which shortens time spent during the operation. The claimed screw features can generally be used in an orthopedic bone screw. The combination of Cognet's bone fusion system with the evidence from Ferrante that it was well known to equip bone screws with self-tapping ends renders both claims obvious.

IV. Simon Challenges

A. Anticipation

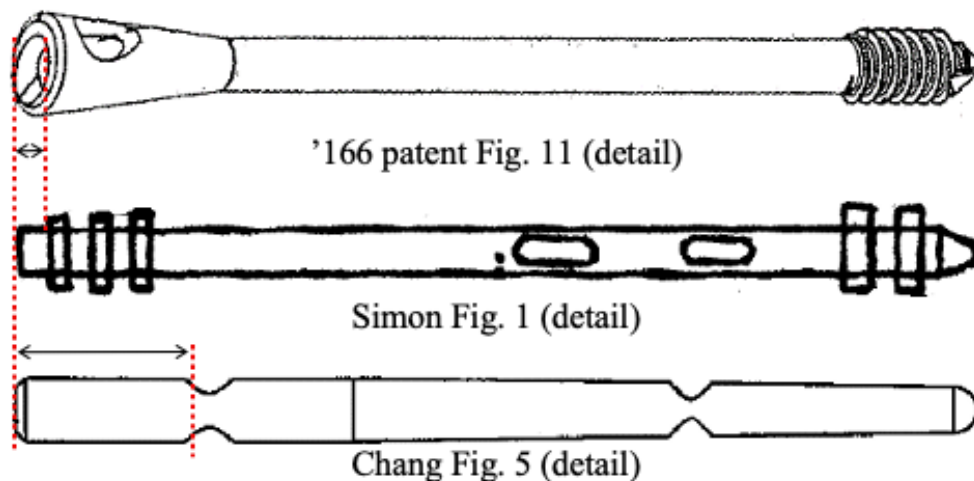
1. Simon discloses a screw with a head portion

[053] Simon discloses a screw that can be a locking screws (Ex. 1008, [0053]), interlocking cortical screws, or transfixation screws (Ex. 1008, [0039]) (Petition, pg. 39-40). Patent Owner has not defined what "head portion" is. Therefore, it can be a bulbous portion, a portion that is partially bulbous, or a non-bulbous portion. It can be the portion of the screw that accepts torque forces from driving tools. Simon Fig. 1 illustrates screws, and they have a head portion even though a bulbous portion is not indicated. As previously mentioned, the '166 patent does not require that the head portion be bulbous. "Headless" screws must have a torque transmitting aperture because they are intended to be sunk fully into the receiving material, so that the only mechanism by which to impose torque on a headless screw is by

way of an aperture on the head, and the portion of the “headless” screw that contains the aperture would be considered the “head portion.”

2. *First aperture “at a terminal end”*

[054] As previously discussed in claim construction (section II.B.3 of this declaration) “at a terminal end” can mean near the terminal end. Simon discloses a fastener hole (20 – Fig. 2) approximately as near to the terminal end of the third elongated body as Patent Owner’s first aperture (1130) is to the terminal end (1120), and they both are some distance closer to the terminal end than Chang, as shown below.



3. *Claim 4 torque transmitting aperture*

[055] A POSA would understand that Simon is referring to a typical surgical screw with a head containing a torque transmitting aperture unless the specification indicates otherwise because that screw design is so

prevalent. Simon gives no indication that a typical surgical screw with a head portion containing a torque transmitting aperture is not what is being referred to by the terms locking screws, interlocking cortical screws, or transfixation screws.

[056] The hex lag screw presented presented by Patent Owner was found by Dr. Ledet on a non-medical website (Ex. 1017, 41:20-21). This screw would not be used with an intramedullary nail, nor even in any surgical application, so a POSA would not consider this screw as an option for Simon.

B. Obviousness

1. Simon/Ferrante

[057] Ferrante is an example of a typical screw used with intramedullary nails. Ferrante shows very clearly the torque transmitting aperture, tapered head, and self-tapping end (Petition 35-37, 58-60) that were well known in the art and prevalently used. As I explained in my first declaration, these types of screws are common because they help remove bone chips and therefore save time in the operating room by eliminating the step of pre-drilling before installation of bone screws. Simon would have recognized the benefits of using the screws disclosed in Ferrante.

2. Simon/Leu

[058] Simon says that an intramedullary nail for the mid-foot region could have any or all of the similar properties, features, and characteristics of the prior art intramedullary nails, which largely refers to nails used in much larger bones (Simon [0011]). Simon gives Leu as an example of prior art (Simon [0015]) and as such, Leu would have similar properties, features, and characteristics to Simon. Simon presents an intramedullary nail that has been used in a surgery and is expected to be successful (Simon [0056]). Surgical implants that are not expected to be successful are not used on patients as Simon's implant was (Simon [0056]).

V. Substitute Claims are unpatentable

A. Claims 16 and 27 are indefinite and/or lack written description

1. "at the terminal end" is unclear

[059] In the Institution Decision (DI 16) the Board notes that a POSA cannot determine an acceptable distance from the end of the nail, nor would they know how to measure (to the uppermost edge of the first aperture?). I share the Board's confusion on this matter and find this claim unclear.

[060] (reserved)

2. About 0 to about 90 degrees

[061] Patent Owner uses the range “about 0 degrees to about 90 degrees” (MTA 8, 14) to claim the range of the first angle and the second angle.

“About 90 degrees” would be understood by a POSA to include 90 degrees and some number of degrees above 90 degrees and some number of degrees below 90 degrees. The description of these angles in the section cited for support is “may be angles less than 90 degrees.” Ex. 2020, 37:15, 44:12-13. This angle range seems to intentionally exclude 90 degrees and angles above 90 degrees and therefore would not support a range that includes 90 degrees.

3. *Substantially perpendicular*

[062] Patent Owner also describes the second angle as “substantially perpendicular,” which does not appear in the written description. A POSA would typically understand “substantially perpendicular” to be close to perpendicular with a range of angles above and below perpendicular that is reasonable for the application, typically accounting for manufacturing tolerances. Dr. Ledet testified that the second bore axis is substantially perpendicular to the third longitudinal axis in Figure 18 (Ex. 1017, 142:12-16) and measured that angle to be 80 degrees (Ex. 2017, 144:15-19). In fact, the view in Figure 18 slightly exaggerates the size of this angle due to the oblique perspective, and the actual angle is closer to 78 degrees. (Ex. 2017, 146:20–25). I would not generally consider 80 degrees to be substantially

perpendicular and thus the figure does not disclose this claim limitation.

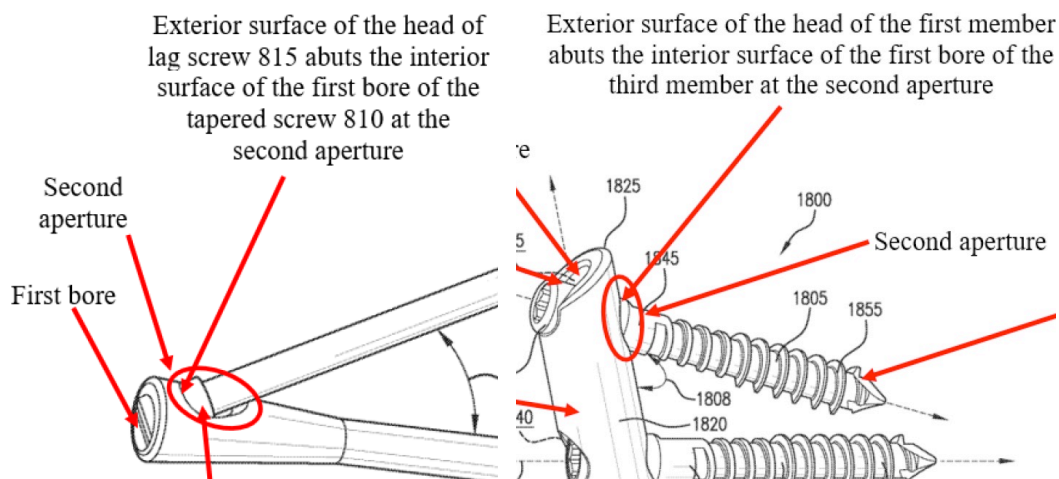
However, if it is found that “substantially perpendicular” is supported in the specification, it would have to include 80 degrees at least.

B. Proposed amended claims contain new matter

[063] Neither the cited paragraphs nor the cited figures in the proposed amended claim chart (MTA 5-14) disclose the exterior surface of the head of the first member (or any part of the first member) abutting the interior surface of the first bore at the second aperture, nor has Patent Owner shown that they do, making this claim new matter.

1. Cited figures do not disclose the proposed claim limitation

[064] Patent Owner has indicated portions of Figure 9 and Figure 18 that allegedly disclose abutment of the head of the first member with the interior surface of the first bore (MTA 17-18).



[065] However, the angle of the device in both of these figures obscures the pertinent part of the device. The '166 patent Figure 18 does not have a view of the second aperture at all and Figure 9 does not show an appropriate angle to see abutment, or lack thereof. Dr. Ledet says that small differences in dimensions could have a huge functional change (Ex. 1017 155:9-12) in reference to a 3D reproduction of Figures 9 and 18, yet a POSA is meant to extrapolate information given in Figures 9 and 18 in such a way as to make a functional conclusion.

[066] Figures 9 and 11 show that the bore exit is countersunk (shown in red). The head (shaded in blue) is locked at the first aperture with an interference fit, but the lower portion of the head is clearly not contacting the interior surface of the bore at the second aperture because the countersink creates a barrier of sorts between the head and the second aperture. The countersink appears to extend along the circumference of the second aperture, thus suggesting that there is no abutment at all between the lag screw head and the interior surface of the bore at the second aperture.

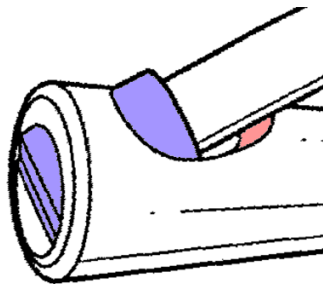


Fig. 9 detail, annotated

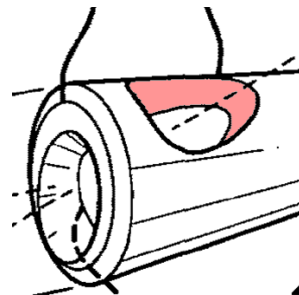


Fig. 11 detail, annotated

[067] Since the Figure 18 screws are substantially similar to the respective screws in Figure 9, the non-abutment between the head of the lag screw and the interior surface of the bore at the second aperture of Figure 9 also apply to the screws in Figure 18 (Ex. 1001, 13:26-31).

[068] Thus, none of the figures 9-11, nor 18 show support for this proposed claim limitation.

2. *The specification does not disclose abutment at the second aperture*

[069] The specification describes that the device of Figure 9 would translate compression applied to bone fragments by the tapered screw and lag screw. The bulbous portion of the lag screw has a taper, with a width that decreases from the second end in the direction of the first end (tip) and is generally cylindrical. The first bore is tapered and provides for a locked interference fit with lag screw (Ex. 1001, 8:24-10:24).

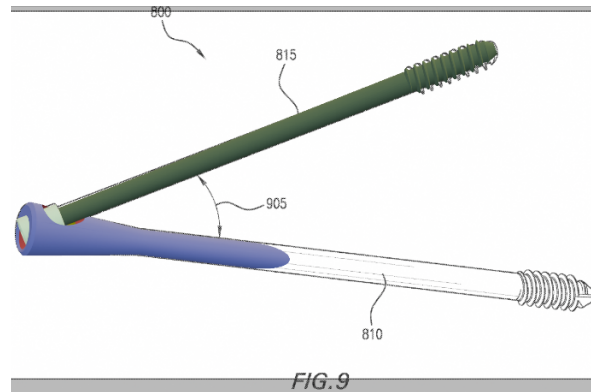
[070] A locked interference fit does not require the head abut the bore around the entire circumference of the screw bulbous portion. It just needs to abut enough to stop the progression of the screw. A fixed angle would require that the locked interference fit be over an area of the circumference and the length of the bore, but not the entirety of either. The locked interference fit is located at the first aperture 1130 (Ex. 1001, 8:50-53),

which create the fixed angle. In other words, the region of interference need not extend all the way to the second aperture; rather, the specification makes clear that the contact at the first aperture is sufficient to create the locked interference fit, which in turn creates the fixed angle. Thus, the specification does not specify anything about the interaction between the screw and the second aperture and certainly does not show that the head of the screw must abut the interior surface of the bore at the second aperture.

3. Models of Figures 9 and 18 show that abutment not necessarily present

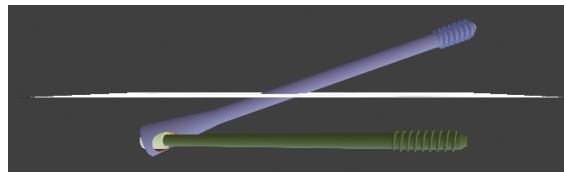
[071] The described elements of Fig. 9 are disclosed in the model provided to me and shown below. The model matches all the relevant details in the figures upon which Patent Owner relies. The lines representing the head of the first member, the first and second apertures, and the contours of the third member, are all in agreement with the lines in the figure. The assembled model would translate compression applied to bone fragments by the tapered screw and lag screw into uniform compression through multi-point fixation. The bulbous portion of the lag screw has a taper, with a width that decreases from the second end in the direction of the first end (tip) and is generally cylindrical. The first bore is tapered and provides for a locked

interference fit with lag screw. Below is an image of the 3D model superimposed on the patent figure.



(Ex. 1050, 2)

[072] The orientation of Figure 9 requires the screw tips extend through the page, making the tapered screw head not viewable from the figure view, but can be seen in an overhead view, shown below (the white sliver is the page containing the patent figure viewed top-edge on).

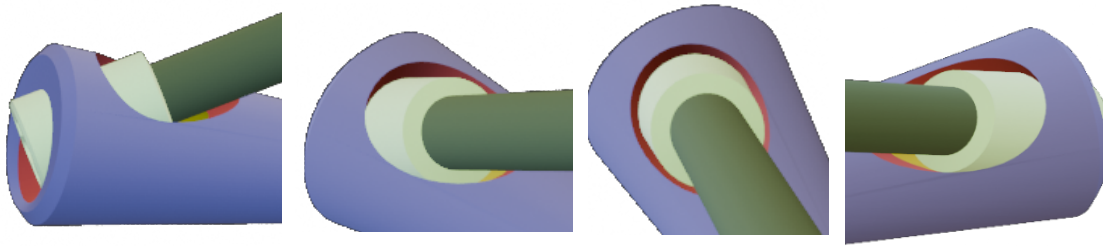


(Ex. 1050, 3)

[073] The 3D model was made accounting for the description of unviewable elements from the patent specification. Again, there is nothing in the specification that describes the interaction of the screw with the bore at the second aperture, but the figures show a countersink positioning the

second aperture away from the head of the lag screw (shaded light green).

The images from the 3D model clearly show that it is possible to have a device as described in the specification and shown in the figures that has no contact between the screw and the interior of the bore at the second aperture.



Ex. 1050: pages 4, 5, 6, 8 (detail)

[074] The cross-section view of the Figure 11 model shows this more clearly, see below.

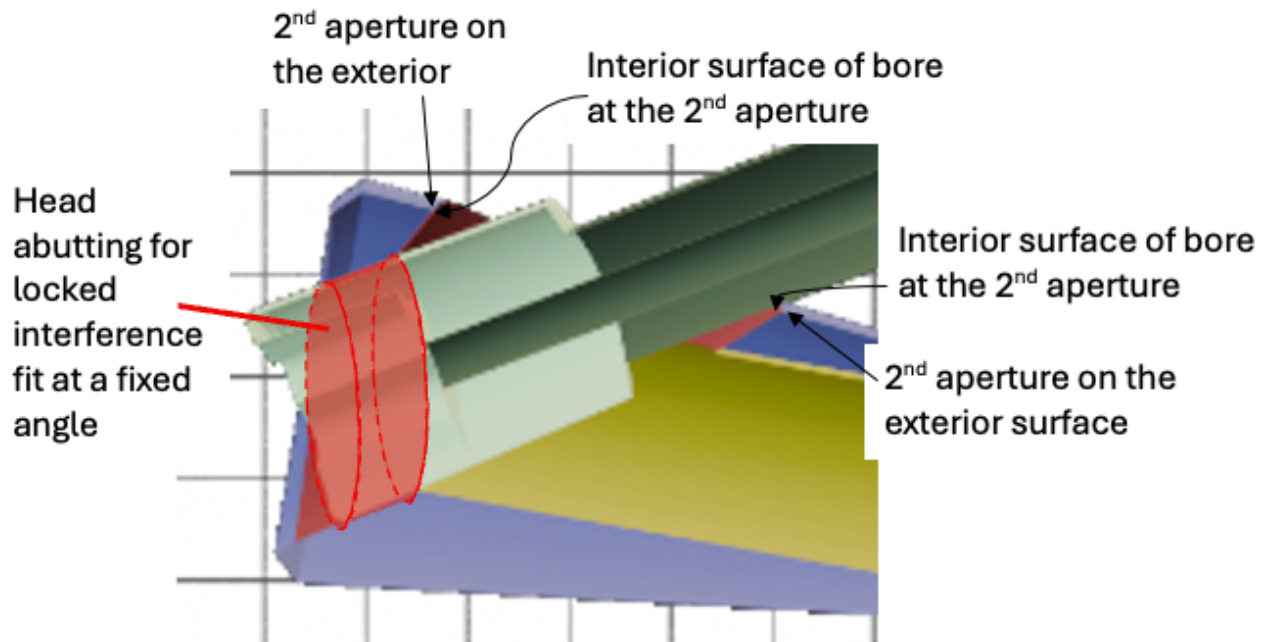
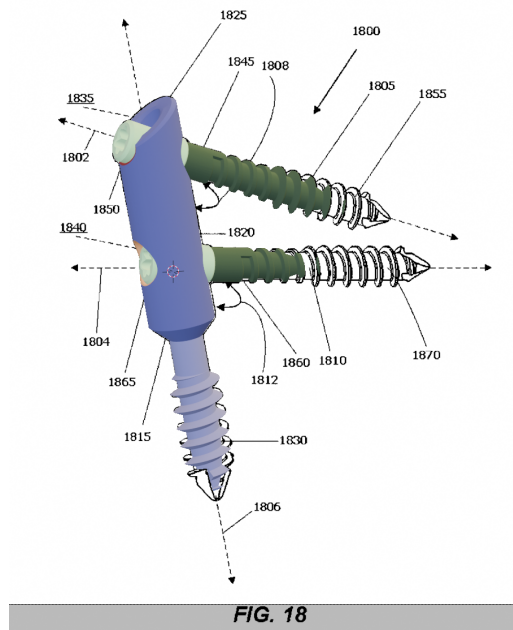


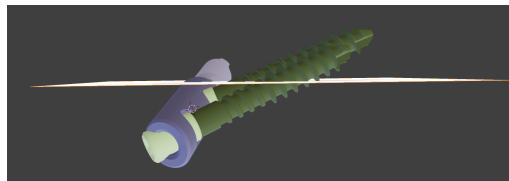
Fig. 1050, 10 (annotated)

[075] The disclosed elements for Fig. 18 are shown in the model provided to me and shown below. The model matches all the relevant details in the figures upon which Patent Owner relies. The lines representing the head of the first member, the first and second apertures, and the contours of the third member, are all in agreement with the lines in the figure. The model shows an assembly for bone fusion that would provide compression on the bone fragment surface. The lag screw (first and second members) is substantially similar to the Fig. 9 lag screw (first member) in that it is tapered and forms a predetermined fixed acute angle with tapered screw (third member). The tapered screw (third member) is substantially similar to the tapered screw of Fig. 9. The first bore is tapered and aligned on the first bore axis at a fixed acute angle with the third longitudinal axis. The second bore is tapered and aligned on the second bore axis and forms a fixed acute angle with the third longitudinal axis. It may be canulated or solid, but the threaded portion of the third member is solid. (Ex. 1001, 13:22-14:17). Shown below is the 3D model of Figure 18 superimposed on the patent figure.



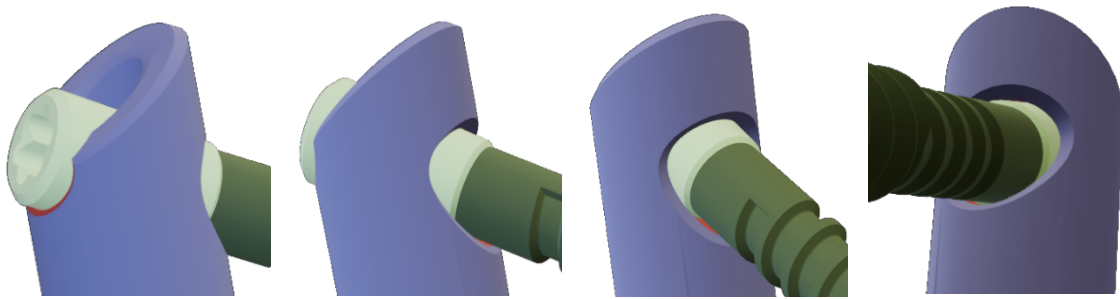
(Ex. 1049, 2)

[076] The orientation of Figure 18 requires the screw tips extend through the page, obscuring them from view, but can be seen in an overhead view, shown below (the white streak is the page containing the patent figure).



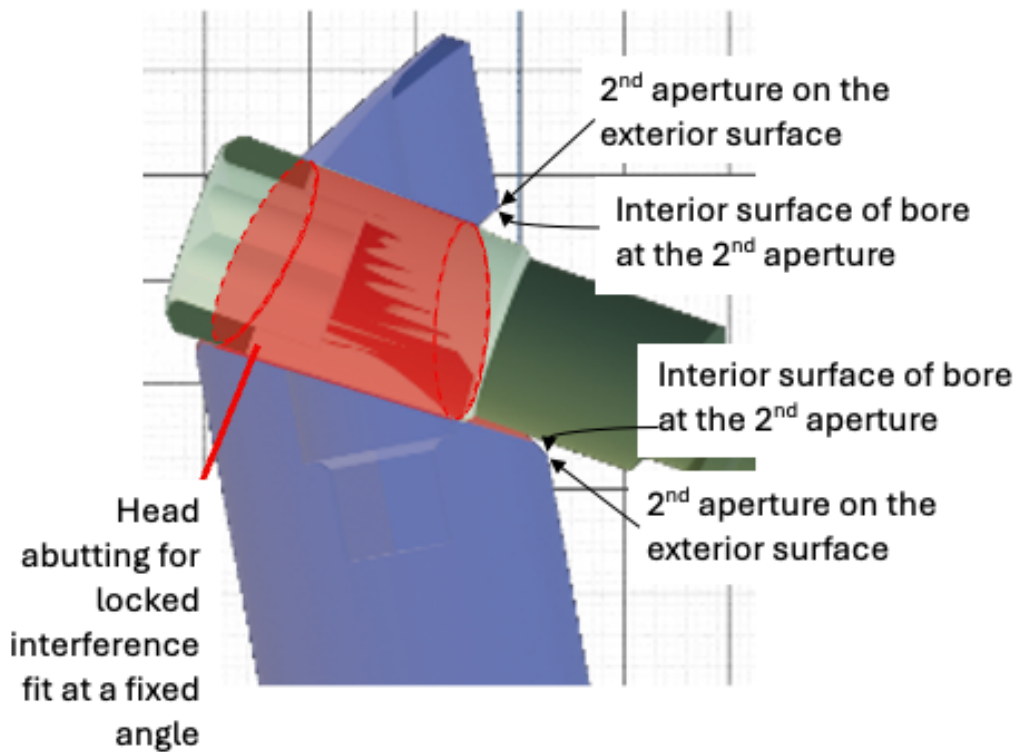
(Ex. 1049, 3)

[077] As with Figure 9, there is no description in the patent about the interaction of the screw and the bore at the second aperture. These detail images of rotating Figure 18 show how the lag screw, shaded green, (first member) exits the tapered screw, shaded blue (third member).



(Ex. 1049, 4, 5, 6, 8 – detail)

[078] These figures show that an assembly that has all the features described for Figure 18 and still avoids abutment between the head of the first member and the interior surface of the first bore at the second aperture. Similar to Figure 9, the bore exit has a countersink positioning the second aperture away from the first member head. The cross-section view of the Figure 11 model shows this more clearly, see below.



Ex. 1049, 10 (detail) - annotated

[079] The specification and the figures do not include enough detail to conclude that the head of the first member (shaded in light green) must abut the interior surface of the bore at the second aperture, and the countersinks would indicate that they do not.

C. Lopez anticipates the proposed amended claims

[080] Spanish Patent No. ES 2,164,543 B1 to López-Oliva Muñoz describes a three-member assembly for bone fusion, specifically for arthrodesis reconstruction of the calcaneus. The assembly has a nail with two bores and two screws for insertion into the two bores. Each of the

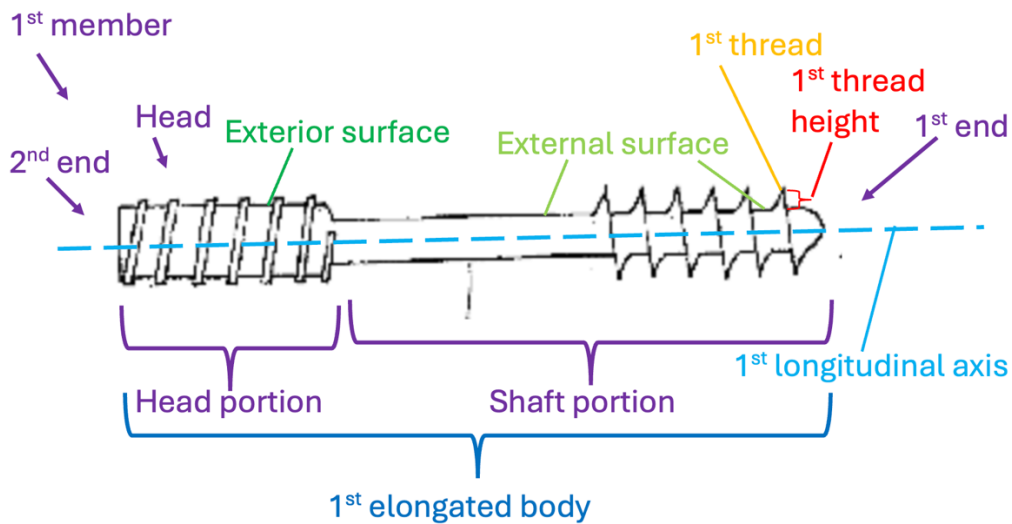
screws has a head that contacts both apertures of the bore through which they are inserted.

a) Lopez discloses claim element 16[a] and 27[a]- An assembly for bone fusion, comprising:

[081] Lopez discloses a "...[l]ocked nail system for arthrodesis reconstruction of fractures ..." (Ex. 1033, 1:6-7) and an assembly comprising a "nail being locked by two screws (4)." (Ex. 1033, claim 1). Arthrodesis is synonymous with bone fusion. Thus, Lopez discloses an assembly for bone fusion.

b) Lopez discloses claim element 16[b] and 27[b]- 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 comprising a head 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;

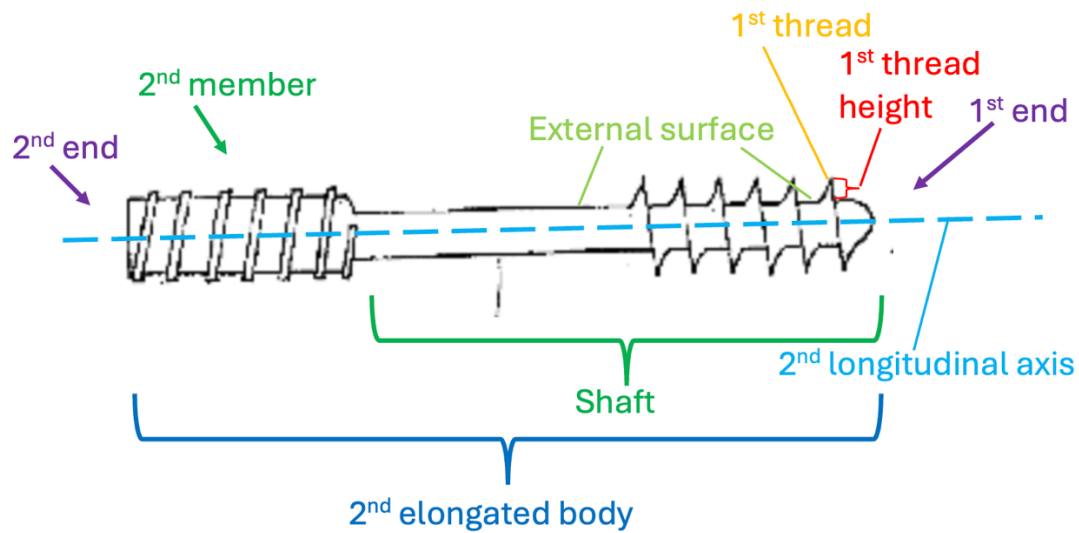
[082] The limitations of claim element 16[b] and 27[b] are disclosed at least in Figure 9 of Lopez as shown below.



Ex. 1033, Fig. 9 (annotated)

c) Lopez discloses claim element 16[c] and 27[c]- **a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, 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;**

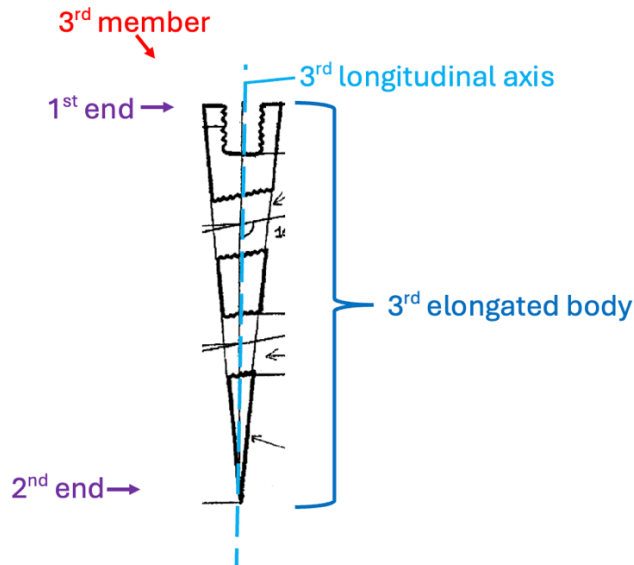
[083] Lopez discloses “nail being locked by two screws (4).” (Ex. 1033, claim 1). Thus, Lopez discloses a first member screw and a second member screw. Each limitation of claim element 16[c] and 27[c] is disclosed in at least figure 9 of Lopez as shown below.



(Ex. 1033, Fig. 9, annotated)

d) Lopez discloses claim element 16[d] and 27[d] - **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,**

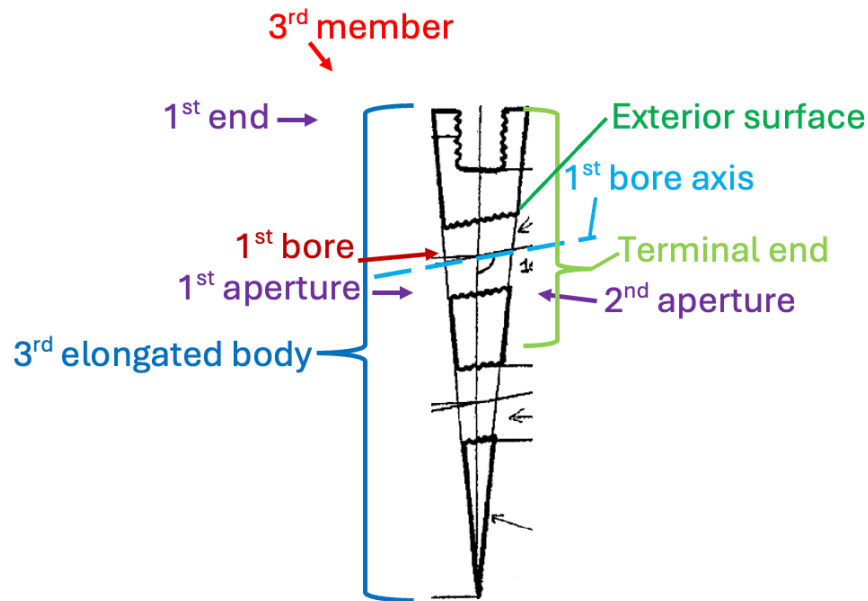
[084] Each limitation of claim element 16[d] and 27[d] is disclosed in at least figure 1 of Lopez as shown below.



(Ex. 1033, Fig. 1, annotated)

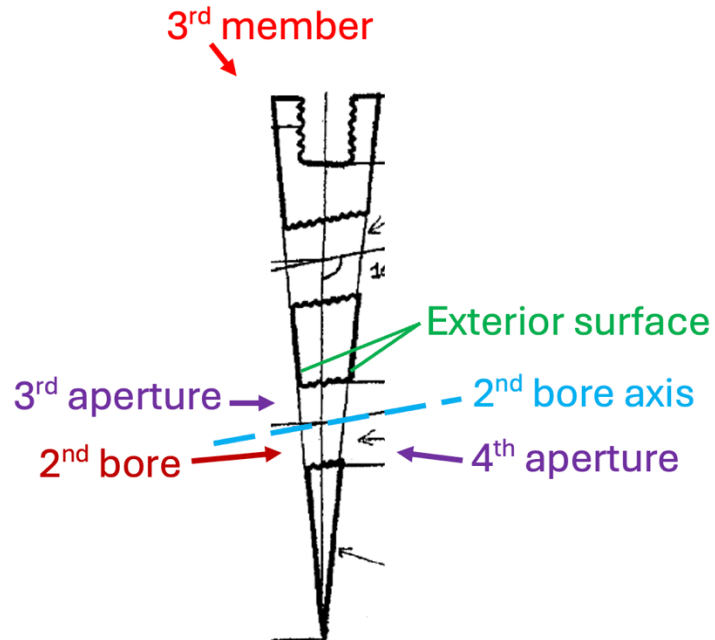
e) Lopez discloses claim element 16[e] and 27[e]-
**wherein the third member comprises a first aperture
at a terminal end of the first end of the third
elongated body, and a first bore extending along a
first bore axis from the first aperture to a second
aperture on an exterior surface of the third member,**

[085] Each limitation of claim element 16[e] and 27[e] is disclosed in at
least figure 1 of Lopez as shown below.



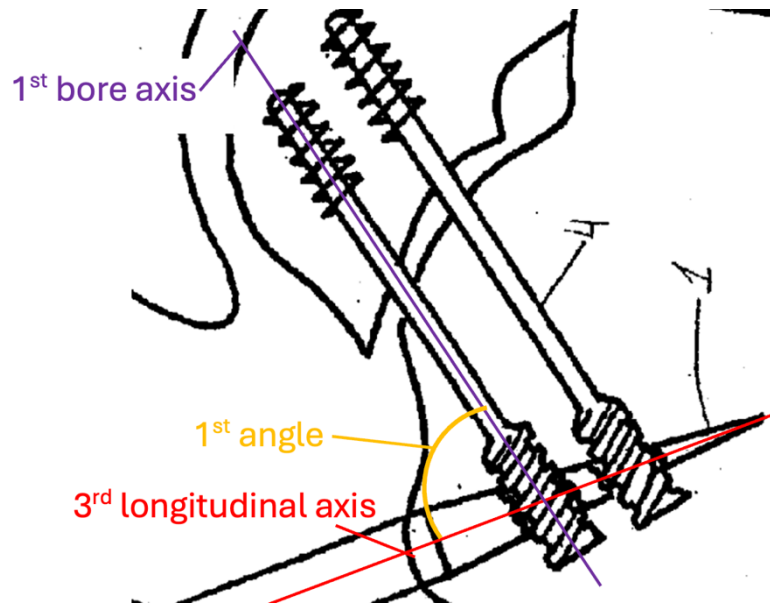
f) Lopez discloses claim element 16[f] and 27[f] -
**wherein the first bore comprises an interior surface at
the first aperture and an interior surface at the
second aperture, wherein there are no threads
adjacent to the second aperture on the exterior
surface of the third member, and**

[086] Each limitation of claim element 16[f] and 27[f] is disclosed at least in figure 1 of Lopez as shown below.



g) Lopez discloses claim element 16[g] and 27[g] - **wherein the third longitudinal axis and the first bore axis define a first angle,**

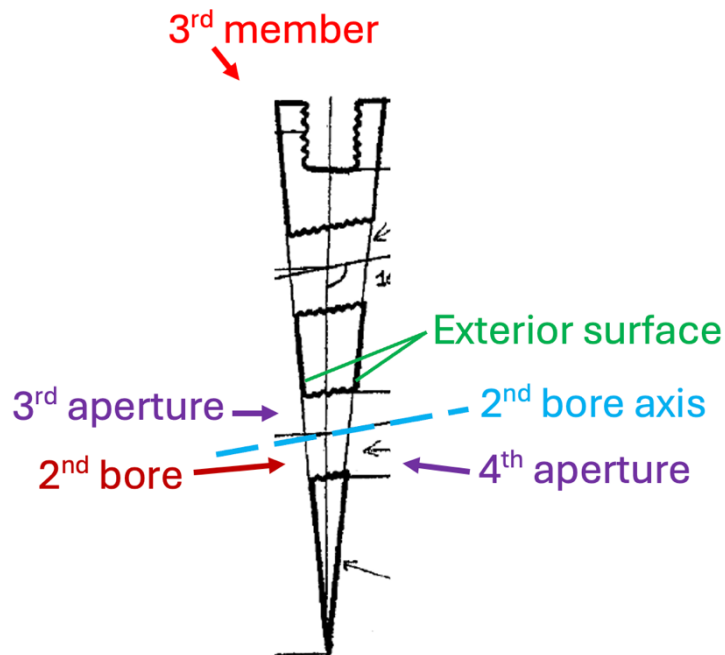
[087] Each limitation of claim element 16[g] and 27[g] is disclosed at least in figure 12 of Lopez as shown below.



(Ex. 1033, Fig. 12)

h) Lopez discloses claim element 16[h] and 27[h] - 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,

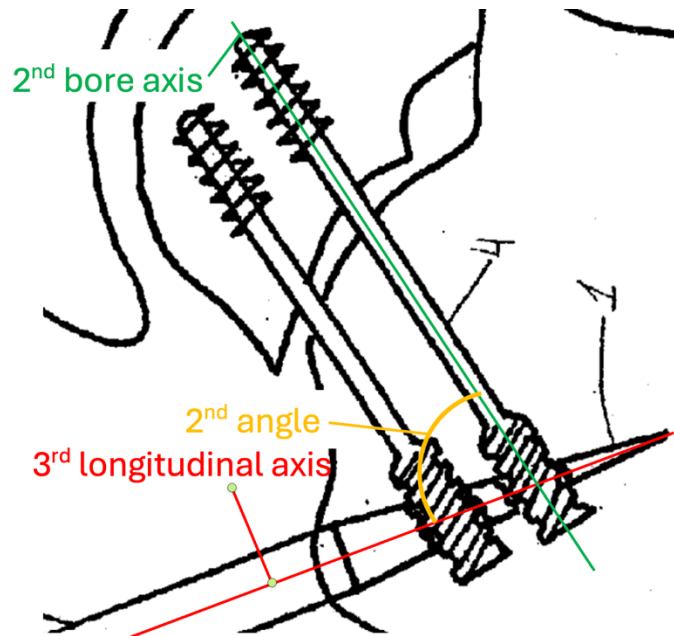
[088] Each claim limitation of claim element 16[h] and 27[h] is disclosed at least in figure 1 of Lopez as shown below.



(Ex. 1033, Fig. 1, annotated)

i) Lopez discloses claim element 16[i] and 27[i]-
**wherein the third longitudinal axis and the second
bore axis define a second angle,**

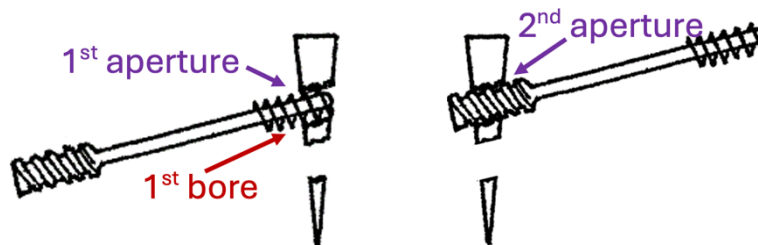
[089] Each limitation of claim element 16[i] and 27[i] is disclosed at
least in figure 12 of Lopez as shown below.



(Ex. 1033, Fig. 12, annotated)

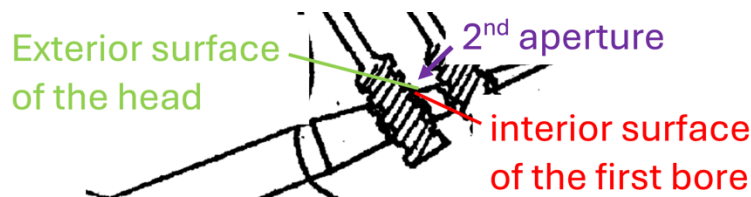
j) Lopez discloses claim element 16[j] and 27[j] -
wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture,

[090] Lopez discloses a first member (screw) that couples to the third member (nail) by inserting the first end of the screw into the first aperture, through the first bore, and out of the second aperture as depicted below in figures adapted from figure 12 of Lopez.



k) Lopez discloses claim element 16[k] and 27[k] - wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture

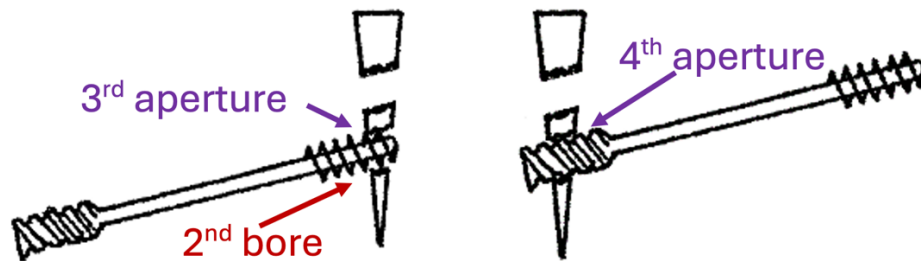
[091] Lopez discloses a threaded first bore (Ex. 1033, 4:25-28) and a first member with a threaded head (Ex. 1033, 4:36-38). The head threads are part of the exterior surface of the head. The bore threads are part of the interior surface of the first bore. The head threads and the bore threads will at least contact each other, which discloses the exterior surface of the head of the first member abutting the interior surface of the first bore at the second aperture. Each limitation of claim element 16[k] and 27[k] is also disclosed in at least figure 12 of Lopez as shown below.



l) Lopez discloses claim element 16[l] and 27[l] - 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,

[092] Lopez discloses a second member (screw) that couples to the third member (nail) by inserting the first end of the screw into the third aperture,

through the second bore, and out of the fourth aperture as depicted below in a figure adapted from figure 12 of Lopez.



m) Lopez discloses claim element 16[m] and 27[m] - **wherein the first angle is in the range of about 0 degrees to about 90 degrees, wherein the second angle is in the range of about 0 degrees to about 90 degrees, and**

and Lopez discloses claim element 27[m] - **wherein the second angle is in the range of about 0 degrees to about 90 degrees, and**

[093] Lopez discloses the first bore and the second bore can have an angle that is “10 degrees to the horizontal” (Ex. 1033, 4:29-30). This discloses a possible first angle of 80 degrees and possible second angle of 80 degrees. This also discloses a possible first angle of 100 degrees and a possible second angle of 100 degrees. As I discussed above, I do not consider 80 degrees to be “substantially perpendicular,” but if it is so held to be, then discloses a substantially perpendicular relationship. Although the

angle on the underside of Fig. 18 in the '166 patent is the one indicated in its specification, there is no limitation in the claim about where the angle is measured. Lopez's nail and screw intersect with an angle 10 degrees "to the horizontal," which means that one side of the angle measures 100 degrees, and the other side measures 80 degrees. I consider these angles to be equivalent for purposes of evaluating the claim for the reasons given above. Thus, Lopez discloses a first angle and a second angle in the range of about 0 degrees to about 90 degrees.

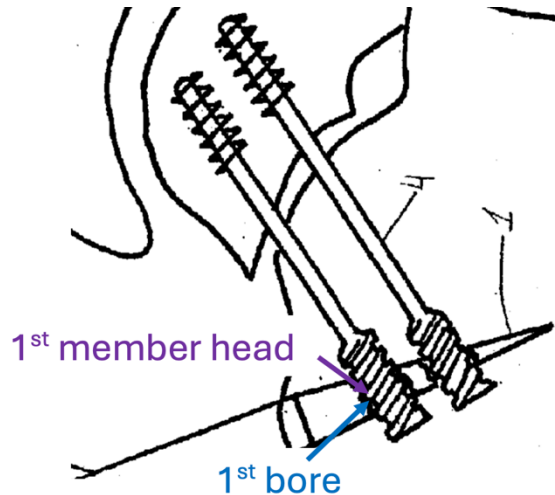
n) Lopez discloses claim element 16[n] and 27[n] - wherein the second bore axis is substantially perpendicular to the third longitudinal axis.

[094] "Substantially perpendicular" is not defined in the specification, but it is shown to include 79 degrees in figure 18 of the '166 patent. In other words, "substantially perpendicular" is shown as 90 degrees +/- at least 11 degrees. Lopez discloses a second bore axis that can be 80 degrees with respect to the longitudinal axis of the nail (third member) and a second bore axis that can be 100 degrees with respect to the longitudinal axis (Ex. 1033, 4:29-30). Thus, Lopez discloses this claim element.

2. Claim 17 and Claim 28

[095] Claim 17 and 28 further limits claim 16 and 27 respectively to require the head of the first member reside at least partially within the first

bore. As described in claim element 16[k] and 27[k] (section V.C.k) the first member head threads interact with the first bore threads, thus the head of the first member resides at least partially within the first bore. This can also be seen in figure 12 of Lopez

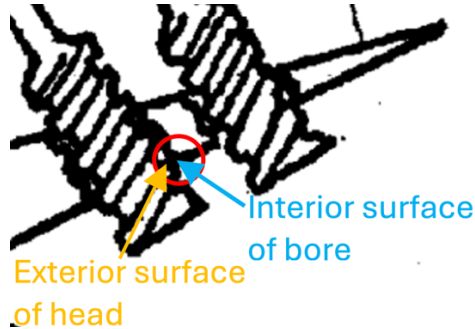


(Ex. 1033, Fig. 12, annotated)

3. *Claim 18*

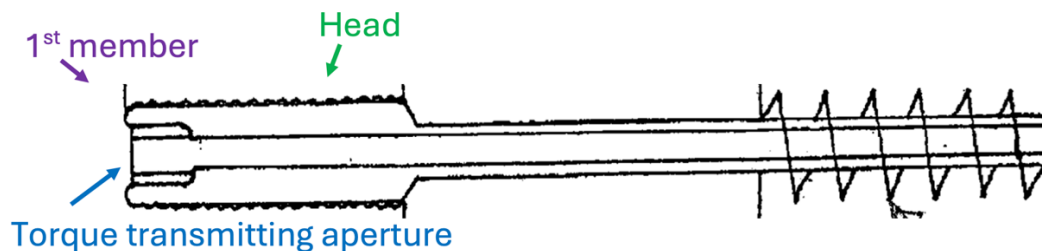
[096] Claim 18 further limits claim 17 to require the exterior surface of the head of the first member abut the interior surface of the first bore at the first aperture. Lopez discloses a threaded first bore (Ex. 1033, 4:25-28) and a first member with a threaded head (Ex. 1033 4:36-38). At least the bore threads portion of the interior surface of the first bore at the first aperture will abut the first member head threads portion of the exterior surface of the

head of the first member, thus disclosing this claim element. This limitation can also be seen in figure 12 of Lopez, shown below.



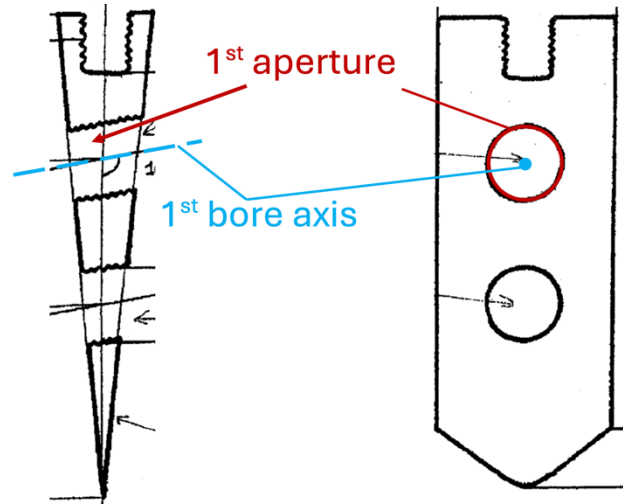
4. *Claim 19*

[097] Claim 19 further limits claim 18 to require the head of the first member comprise a torque transmitting aperture. Lopez discloses a cannulated screwdriver (Ex. 1033, 6:4) which indicates the screws comprise a torque transmitting aperture to mate with the end of the screwdriver. Additionally, a screw head comprising a torque transmitting aperture is disclosed in figure 3 as shown below.



5. *Claim 20*

[098] Claim 20 further limits claim 16 to require that the first aperture of the third member is aligned on the first bore axis. Lopez discloses this claim limitation in at least figures 1 and 2 as shown below.



6. *Claim 21*

[099] Claim 21 further limits claim 20 to require the head of the first member reside at least partially within the first bore. This is the same limitation as claim 17. Lopez discloses this claim limitation as discussed in the claim 17 discussion (section V.C.2) of this declaration.

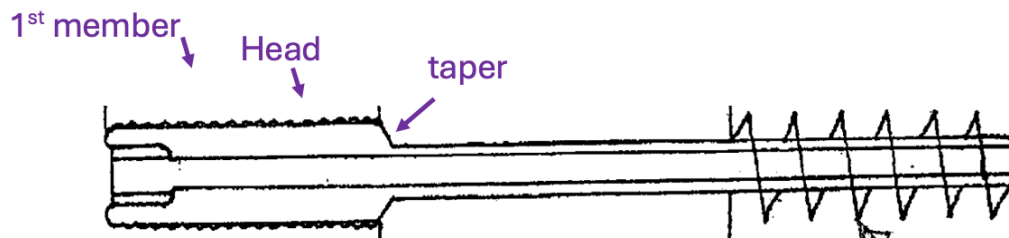
7. *Claim 22*

[100] Claim 22 further limits claim 21 to require the exterior surface of the head of the first member abuts the interior surface of the first bore at the first aperture. This is the same limitation as claim 18. Lopez discloses this

claim limitation as shown in the claim 1 discussion (section V.C.3) of this declaration.

8. *Claims 23, 29, and 30*

[101] Claims 23, 29, and 30 further limits claim 16, 28, and 27 respectively to require the head portion of the first member is tapered. Lopez discloses a screw with a tapered head at least in figure 3, shown below.



9. *Claim 24*

[102] Claim 24 further limits claim 16 to require the first bore axis and the second bore axis intersect outside the third member. It was well known in the art that angles of 90 degrees provide the best pull out strength because an orthogonal relationship orients the pull-out force most fully against the interacting surfaces. It would have been obvious to modify the second bore to be 90 degrees to take advantage of this known feature and expect predictable success.

10. *Claim 25*

[103] Claim 25 further limits claim 16 to require the first end of the first member include a self-tapping edge for removing bone material. Lopez

discloses a screw with threads at the first end that “must be self-tapping”

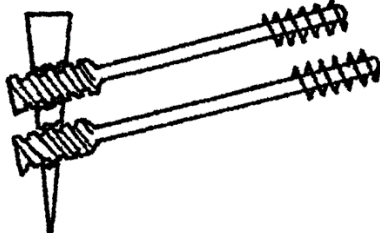
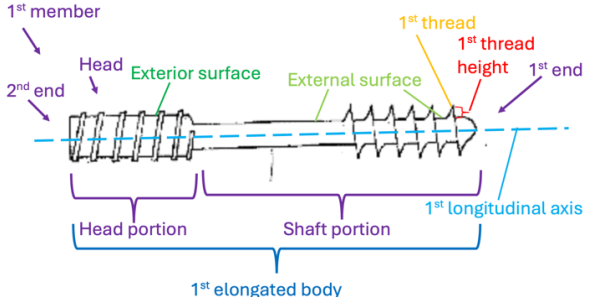
(Ex. 1033, 4:35-36), and thus discloses this claim

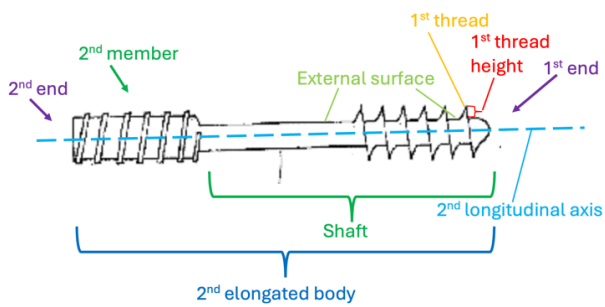
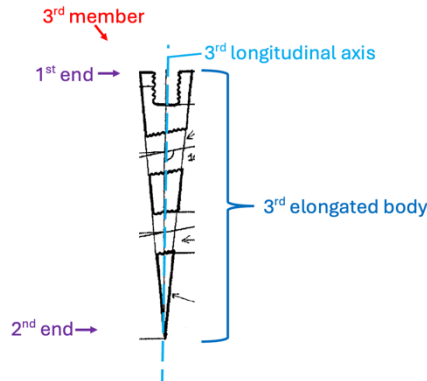
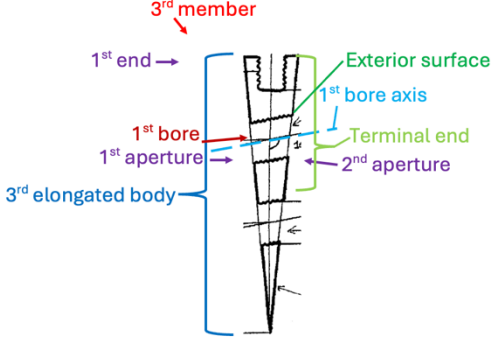
11. Claim 26

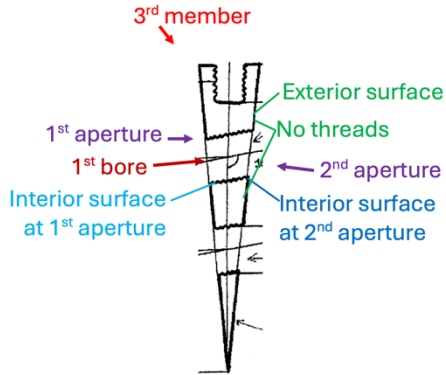
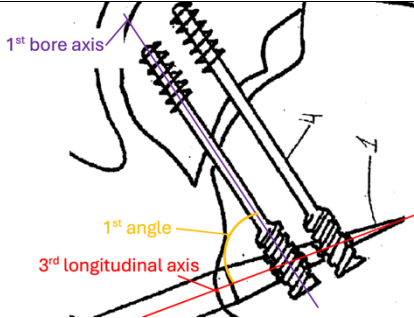
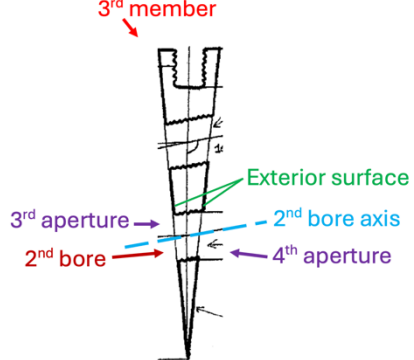
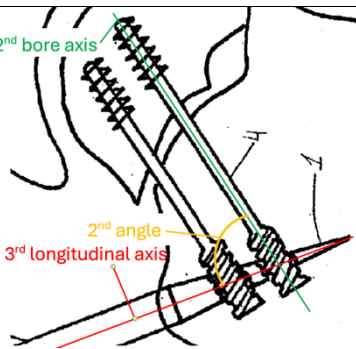
[104] Claim 26 further limits claim 25 to require the first end of the second member include a self-tapping edge for removing bone material.

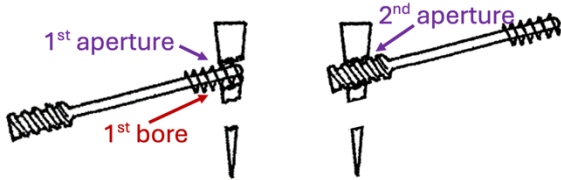
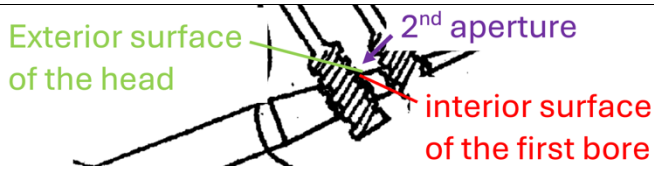
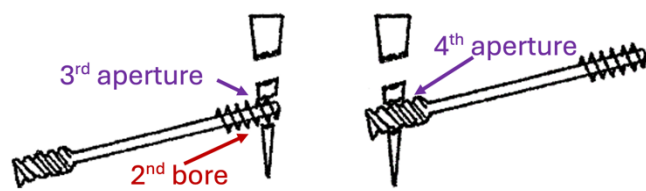
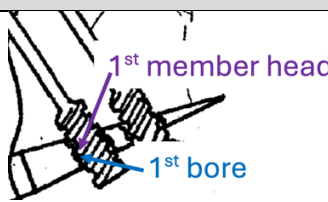
Lopez discloses a screw with threads at the first end whose threads “must be self-tapping” (Ex. 1033, 4:35-36), and thus discloses this claim.

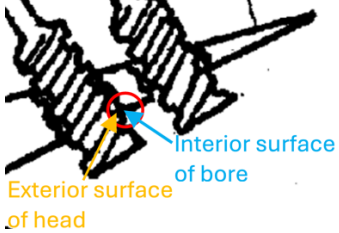
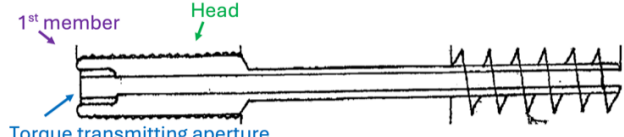
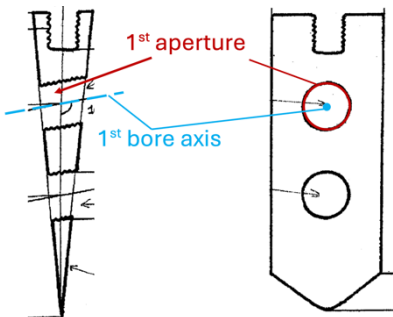
[105]

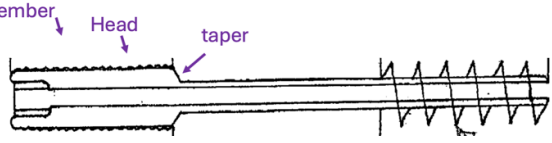
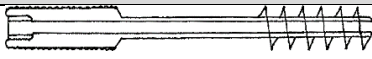
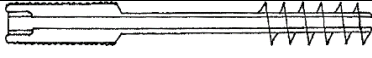
	Claim 16	Ex. 1033 López-Oliva
16a & 27a	1. An assembly for bone fusion, comprising:	Title: “arthrodesis” Locked nail system for arthrodesis reconstruction of fractures of the calcaneus. (Ex. 1033, Abstract, 1:6-7) Detail from Fig. 12: 
16b & 27b	a first member comprising a first elongated body extending 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 comprising a head having an	 (Ex. 1033, Fig. 9)

	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;	
16c & 27c	a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, 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;	 (Ex. 1033, Fig. 9)
16d & 27d	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,	 (Ex. 1033, Fig. 1)
16e & 27e	wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, and 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,	 (Ex. 1033, Fig. 1)

16f & 27f	wherein the first bore comprises an interior surface at the first aperture and an interior surface at the second aperture , wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and	 (Ex. 1033, Fig. 1)
16g & 27g	wherein the third longitudinal axis and the first bore axis define a first angle ,	 (Ex. 1033, Fig. 12)
16h & 27h	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 ,	 (Ex. 1033, Fig. 1)
16i & 27i	wherein the third longitudinal axis and the second bore axis define a second angle ,	 (Ex. 1033, Fig. 12)

16j & 27j	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,	 (Ex. 1033, Fig. 1 - adapted)
16k & 27k	wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture	 (Ex. 1033, Fig. 12)
16l & 27l	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,	 (Ex. 1033, Fig. 12 - adapted)
16m	wherein the first angle is in the range of about 0 degrees to about 90 degrees, wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	These holes have an inclination of 10 degrees to the horizontal (Ex. 1033, 4:29-30)
27m	wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	These holes have an inclination of 10 degrees to the horizontal (Ex. 1033, 4:29-30)
16n & 27n	wherein the second bore axis is substantially perpendicular to the third longitudinal axis.	These holes have an inclination of 10 degrees to the horizontal (Ex. 1033, 4:29-30)
Claim 17		
17 & 28	The assembly of claim 16, wherein the head of the first member resides at least partially within the first bore.	 (Ex. 1033, Fig. 12)
Claim 18		

18	The assembly of claim 17, wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the first aperture.	 Exterior surface of head Interior surface of bore (Ex. 1033, Fig. 12 - cropped)
	Claim 19	
19	The assembly of claim 18, wherein the head of the first member comprises a torque transmitting aperture.	 1st member Head Torque transmitting aperture (Ex. 1033, Fig. 3) Cannulated screwdriver (Ex. 1033, 6:4)
	Claim 20	
20	The assembly of claim 16, wherein the first aperture of the third member is aligned on the first bore axis.	 1st aperture 1st bore axis (Ex. 1033, Fig. 1)
	Claim 21	
21	The assembly of claim 20, wherein the head of the first member resides at least partially within the first bore.	same as claim 17
	Claim 22	
22	The assembly of claim 21, wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the first aperture.	same as claim 18
	Claim 23	

23 & 29 & 30	The assembly of claim 16, wherein the head portion of the first member is tapered.	 (Ex. 1033, Fig. 3)
	Claim 24	
24	The assembly of claim 16, wherein the first bore axis and the second bore axis intersect outside the third member.	Obvious over López-Oliva and Brumfield
	Claim 25	
25	The assembly of claim 16, wherein the first end of the first member includes a self-tapping edge for removing bone material.	 (Ex. 1033, Fig. 3) This thread must be self-tapping at the two ends thereof. (Ex. 1033, 4:35-36)
	Claim 26	
26	The assembly of claim 25, wherein the first end of the second member includes a self- tapping edge for removing bone material.	 (Ex. 1033, Fig. 3) This thread must be self-tapping at the two ends thereof. (Ex. 1033, 4:35-36)

D. López and Brumfield make obvious the proposed amended claims

[106] Terminal end has been shown previously in the document to be open to interpretation (see above at paragraph 33). It is my opinion that López anticipates a first aperture at a terminal end. However, that opinion may be dependent upon the construction of “at a terminal end.” If López is found to not be anticipatory, then López and Brumfield make the “a first aperture at a terminal end” claim limitation (16e and 27e) obvious.

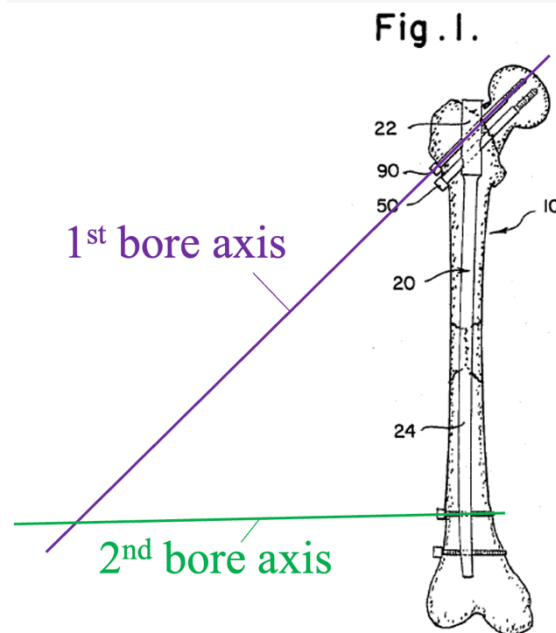
[107] U.S. Patent No. 4,827,917 to Brumfield (“Brumfield”) was described in the petition (Petition pg. 32-33).

[108] Lopez teaches that its device is for the repair of calcaneal fractures, but the basic assembly – a nail spanned by two screws – is the basic geometry used to treat fractures in many other bones. For example, Brumfield discloses an assembly for repair of femoral fractures in which an intramedullary nail is spanned by lag screws and secured with locking screws. Given the conceptually similar geometries of the Lopez and Brumfield assemblies, it would have been obvious to adapt one to the other. For example, it would have been obvious to adapt Lopez’s nail, which is comparatively short in order to be suitable for the calcaneus, into a longer nail such as Brumfield discloses, in order to make Lopez suitable for repair of long-bone fractures. One of ordinary skill would have had a reasonable expectation of achieving an operable assembly from this combination because lengthening the nail of Lopez would not change any of its functional characteristics.

[109] In the assembly resulting from such a modification, the third member would be comparatively much longer, but the screws would still be positioned close to one end in order to have the correct geometry for fracture repair. As a result, the first aperture would be located at the terminal end of

the third member, thereby satisfying all limitations of proposed new claims 16-23 and 25-29.

[110] Claim 24 further limits claim 1 to require the first bore axis and the second bore axis intersect outside the third member. Brumfield discloses this claim limitation as shown below. It would be obvious to a POSA to use Lopez in a long bone repair with proximal and distal screws arranged as disclosed in Brumfield; a proximal screw (at a terminal end), and a distal screw at a 90 degree angle.



VI. CONCLUSION

[111] I declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both under Section 1001 of the Title 18 of the United Stated Code.

Dated: May 3, 2024

By: / Leonel Dominguez /
Leonel Dominguez