

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

Case IPR2023-00894
U.S. Patent No. 11,298,166

DECLARATION OF DR. ERIC H. LEDET

Extremity Medical, LLC EXHIBIT 2012 Fusion Orthopedics v. Extremity Medical Case IPR2023-00894

I, ERIC H. LEDET, declare as follows:

I. INTRODUCTION

1. I have been asked to submit this declaration on behalf of Extremity Medical, LLC (“Extremity Medical” or “Patent Owner”) in connection with Case IPR2023-00894 before the United States Patent and Trademark Office.

Specifically, I have been retained as an independent expert consultant by Patent Owner to provide my opinions regarding the technology of U.S. Patent No.

11,298,166 (“the ’166 Patent”), the statements in the Petition, opinions expressed in the Declaration of Leonel Dominguez (Exhibit 1002), the other exhibits submitted in support of the Petition, the knowledge that a person of ordinary skill in the art working in that field of technology would be expected to have, whether there is written description support in the patent application that led to the ’166 Patent, as filed, for substitute claims submitted by Patent Owner, and whether the substitute claims are patentable in view of the prior art.

2. This report sets forth the opinions that I have formed based on the information available to me as of the date below. The opinions and facts set forth in this report are based upon my analysis of the ’166 patent and the claims recited therein, the application that led to the ’166 Patent and related application, the provisional application to which that application claims priority, the prior art, the

state of the art at the time of the invention, as well as my knowledge and extensive experience in this field.

3. My analysis of the materials submitted in this proceeding is ongoing and I will continue to review any new material that is provided. This declaration is indicative of only those opinions that I have formed to date. I reserve the right to amend, revise, and/or supplement my opinions stated herein based on any new information that may become available to me or my continuing analysis of the materials already provided.

4. I am not currently and have not at any time in the past been an employee of Extremity Medical. I have no financial interest in Extremity Medical outside of assisting Extremity Medical as an expert in this and any related matters.

5. I am being compensated for my time in connection with this *Inter Partes* Review at my standard consulting rate, but no part of my compensation depends on the nature of my findings or the outcome of this proceeding, and I have no other interest in this proceeding.

II. QUALIFICATIONS

6. All of my opinions stated in this declaration are based on my own personal knowledge and professional judgment. In forming my opinions, I have relied on my knowledge and experience in designing, developing, researching, and teaching the technology referenced in this this declaration.

7. My qualifications for forming the opinions in this declaration are summarized herein and explained in more detail in my curriculum vitae (“CV”), attached hereto as Exhibit A.

8. The ’166 Patent is directed to “the field of orthopedic implant devices, and more particularly, to an intramedullary fixation assembly used for fusion of the angled joints, bones and deformity correction, such as the hand and foot bones.” ’166 Patent at 1:25-28.

9. As detailed in my CV, I have extensive experience in the design and development of orthopaedic implants for bone fusion, with a career spanning over 25 years in this field. I have conducted research on bone formation and fracture fixation, and I have taught courses on orthopaedic surgery, design of medical devices, and product development.

10. I am currently the Vice President of Research & Development and Director of the Health Innovation Incubator & Technology Center at the Center for Disability Services in Albany, NY. I am also Chief Operating Officer of ReVivo Medical, Inc., a company that develops implants for bone fusion.

11. From 2004 to 2021, I was a Professor of Biomedical Engineering at Rensselaer Polytechnic Institute (RPI), where I attained the rank of Full Professor. I currently hold the position of Adjunct Professor of Biomedical Engineering. I also hold an Adjunct Professorship of Orthopaedic Surgery at Albany Medical

College. I am also a Research Scientist (WOC) in the Rehabilitation R&D Service at the Stratton VA Medical Center.

12. For nine years I ran the research program in the Department of Orthopaedic Surgery at Albany Medical College.

13. Over the course of my career, I have spent hundreds of hours in the operating room observing orthopaedic surgeries.

14. I am named as an inventor on 17 issued U.S. patents and 4 issued foreign patents, including patents titled, "Bone Fixation Apparatus With Fastener Securement Mechanism and Method of Use" and "Dynamic Spinal Fixation System, Method of Use, and Spinal Fixation System Attachment Portions." I am also named as an inventor on a number of pending U.S. and foreign patent applications.

15. I received a Bachelor of Science in Mechanical Engineering from the University of Arizona, and a Master of Science and Ph.D in Biomedical Engineering from Rensselaer Polytechnic Institute.

16. In addition to designing and inventing new technologies, I have, throughout my career, mentored, trained, and supervised young engineers and can easily appreciate how a less experienced engineer would perceive the prior art and approach the technical problems disclosed in the prior art.

17. I have given 95 invited talks, most of which were related to orthopaedic surgery.

18. I am named as an author or co-author on 245 publications including journal articles, abstracts, conference presentations, and conference posters, most of which are related to orthopaedic surgery.

19. I have been a member of the Orthopaedic Research Society since 1998.

III. MATERIALS AND OTHER INFORMATION CONSIDERED

20. In preparation for this declaration, I have considered the materials discussed in this declaration, including, for example, the '166 Patent, the prosecution history of the '166 Patent, and the prior art references analyzed in this declaration. In addition, my opinions are also based on my education, training, experience, and knowledge in the relevant fields.

IV. SUMMARY OF OPINIONS

21. Based on my experience and expertise, it is my opinion that: (1) the claims of the '166 Patent are not unpatentable as anticipated or obvious in view of the prior art cited in the Petition; (2) the inventions recited in Substitute Claims 16-30 are supported by the written description of the patent application that led to the '166 Patent; and (3) Substitute Claims 16-30 are not unpatentable as anticipated or obvious in view of the prior art I have reviewed.

V. UNDERSTANDING OF PATENT LAW

22. I am not an attorney. For purposes of this report, I have an understanding about certain aspects of the law that are relevant to my opinions, as described below.

A. Claim Construction

23. I understand that a claim must be construed under the *Phillips* standard. Under that standard, words of a claim are given their plain and ordinary meaning as understood by person of ordinary skill in the art (“POSITA”) at the time of invention, in light of the specification and prosecution history, unless those sources show an intent to depart from such meaning, as well as pertinent evidence extrinsic to the patent. For purposes of this declaration, I applied the plain and ordinary meaning of each term as would have been understood by a person of ordinary skill in art at the time of the alleged invention unless explicitly stated otherwise.

24. I have also been informed and understand that claim construction is a matter of law and that the final claim constructions for this proceeding will be determined by the Patent Trial and Appeal Board.

B. Anticipation

25. I understand that a patent claim is invalid if it is anticipated by a single prior art reference. I understand that an anticipation analysis involves two steps. First, the patent claims are construed to ascertain their scope. Second, each

construed asserted claim is compared to the prior art reference on an element-by-element basis. If the prior art reference discloses each and every element of the claimed invention, either expressly or inherently, then it anticipates the claim. I understand that anticipation by inherent disclosure is appropriate only when a prior art reference necessarily includes or discloses unstated claim elements.

C. Obviousness

26. I understand that, even if all of the elements of a claim are not found in a single prior art reference, a patent claim may be found unpatentable if the differences between the subject matter in the prior art and the subject matter in the claim would have been obvious to a person of ordinary skill in the art at the time the application was filed.

27. I further understand that the ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of non-obviousness.

28. I also understand that a reference may be combined with the knowledge of a person of ordinary skill in the art, and that this knowledge may be used to combine multiple references. I further understand that a person of ordinary skill in the art is presumed to know the relevant prior art. I understand that the

obviousness analysis may take into account the inferences and creative steps that a person of ordinary skill in the art would employ.

29. In determining whether a combination based on either a single reference or multiple references would have been obvious, it is appropriate to consider at least the following factors:

1. whether the teachings of the prior art references disclose known concepts combined in familiar ways, which, when combined, would yield predictable results;
2. whether a person of ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
3. whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by a person of ordinary skill in the art;
4. whether a person of ordinary skill in the art would have recognized a reason to combine known elements in the manner described in the claim;
5. whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
6. whether the innovation applies a known technique that had been used to improve a similar device or method in a similar way.

VI. PERSON OF ORDINARY SKILL IN THE ART

30. I understand that there are various factors relevant to determining the level of ordinary skill in the pertinent art, including the educational level of active workers in the field at the time of the alleged invention, the sophistication of the

technology, the rapidity with which innovations are made, the type of problems encountered in the art, and the prior art solutions to those problems.

31. In determining the characteristics of a hypothetical person of ordinary skill in the art of the '166 patent at the time of the claimed invention, I considered several things, including the type of problems encountered in this field, and the rapidity with which innovations were made. I also considered the sophistication of the technology involved, and the educational background and experience of those actively working in the field, and the level of education that would be necessary to understand the '166 patent. Finally, I placed myself back in the relevant period of time and considered the state of the art and the level of skill of the persons working in this field at that time.

32. Based on the materials I have considered (including the prior art cited herein), my own knowledge and experience, and the level of skill required to design and build an orthopedic implant device, I have come to the conclusion that the characteristics of a person of ordinary skill in the art of the '166 patent would hold a Bachelor's Degree in biomedical and/or mechanical engineering or similar training and would have at least three years of experience with implant devices used for internal fixation of bones. This hypothetical person would be capable of performing various design tasks and would understand the basic mechanical features and operation of orthopaedic implant devices. This hypothetical person

would also have an appreciation for orthopaedic fusion techniques and the medical issues and concerns faced by a doctor/surgeon charged when performing operations to implant orthopaedic devices. I believe these understandings are demonstrated, for example, by the prior art I discuss herein.

33. My opinions concerning the '166 Patent and the prior art are from the perspective of a person of ordinary skill in the art ("POSITA"), as set forth above.

34. I also understand that Petitioner's expert has opined that a person of ordinary skill in the art 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. My opinions set forth herein, including my opinions concerning the '166 Patent and the prior art, would not change if viewed from the perspective of a POSITA as defined by Petitioner's expert.

VII. THE '166 PATENT

35. The '166 Patent discloses bone fixation systems comprising intramedullary fixation assemblies for treating and fixating deteriorated, damaged and/or fractured bones, such as bones in the human foot. "Intramedullary" assemblies are assemblies that may be implanted into the marrow space of a bone.

36. Prior to the '166 Patent, devices used to correct bone fractures in the hand or foot commonly included a plate placed on the outer surface of the bones, and screws inserted through holes in the plate and into the bones to correct bone fractures in the hand or foot. The screws would hold the plate to the bones, and together with the plate, immobilize the bones while fractures healed. Because the plate remained on the outer surface of the bones, especially when used to correct fractures in the hands or feet, the plate could easily be felt through the skin, as there is very little soft tissue (e.g., muscle) between the bones and the skin.

37. The '166 Patent provides a novel improvement over the prior practice for fixing fractures because the surgeon now has easy access to the fracture after the third member (1815) is implanted. Third member (1815) discloses an aperture (1835) at the terminal end of the top of the third member (1815). This disclosure results in a better fusion of joints without protrusion or with minimal protrusion of the assembly outside the bones. When the third member (1815) is implanted into the bone, the very top of the third member (1815) (i.e., the terminal end) is positioned at or below the surface of the bone, which allows the surgeon easy access to the terminal end of the third member (1815) to insert the first member (1805) through the aperture at the terminal end.

38. As shown in Figure 18 of the '166 Patent, pasted below with specific reference numbers annotated in colored circles for emphasis, the '166 Patent

discloses, *inter alia*, an intramedullary fixation assembly (1800) comprising a first member (1805), a second member (1810), and a third member (1815):

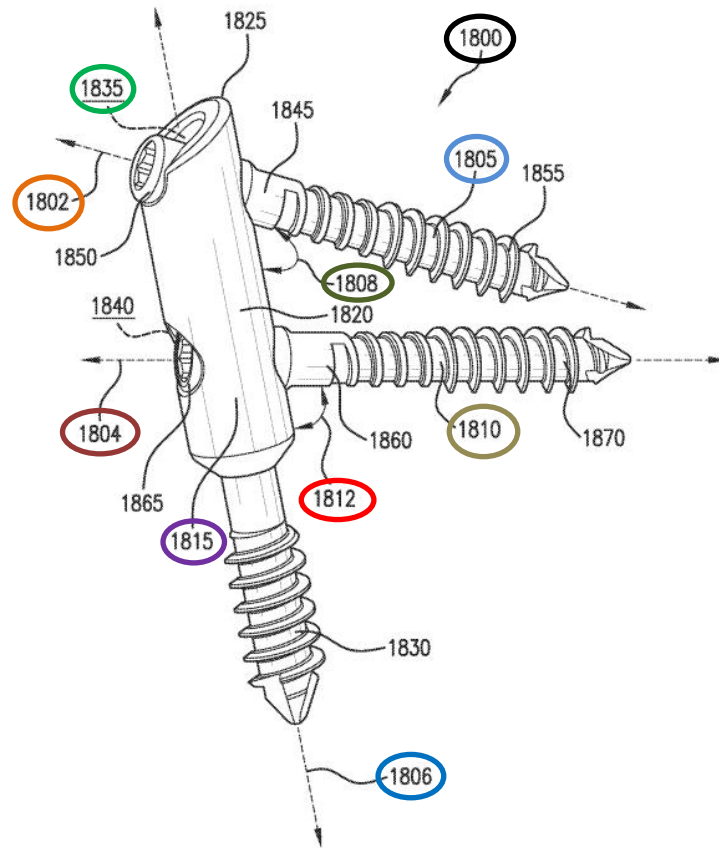


FIG. 18

39. The third member (1815) extends along a straight line coinciding with axis (1806). An aperture (1835) at the terminal end of the top of the third member (1815) leads to a first bore extending along axis (1802), and a second bore extends through the third member (1815) along axis (1804). See Ex. 1001 at 13:22-14:17.

The first member (1805) and the second member (1810) extend through the first and second bores at angles (1808) and (1812), respectively.

VIII. OPINIONS CONCERNING CLAIM CONSTRUCTION

A. “First Aperture at a Terminal End”

40. During prosecution of an application to which the ‘166 Patent claims priority, U.S. Patent Application No. 12/658,680 (the “’680 Application”), the Examiner cited U.S. Patent Publication No. 2009/0240252 (“Chang”) as a prior art reference that disclosed the claimed inventions. See Ex. 1015 at 49-54 (citing Chang). To distinguish the claimed invention over Chang, Extremity Medical disclaimed areas along the shaft of the nail as not the terminal end of a nail:

In fact, Chang specifically and only discloses ***through holes (101 and 102) that are merely provided along the shaft of the nail*** (See Chang, FIGS. 1-5, Abstract and paragraphs [0017] and [0024]). Notably, ***Chang does not discuss or disclose a structure having an aperture at a terminal end of the nail.***

Ex. 1015 at 75-76 (emphasis added). Since Patent Owner distinguished the claims over Chang by arguing that Chang’s apertures were not “at the terminal end” of the nail, a POSITA would understand that Patent Owner explicitly disclaimed apertures that are near—such as along the shaft—but not *at* the terminal end of the third member to be outside the scope of the ’166 Patent’s claims. In other words, in the context of Chang’s disclosure, a POSITA would understand Patent Owner disclaimed apertures that only pass through the sides of the shaft indicated with red lines below:

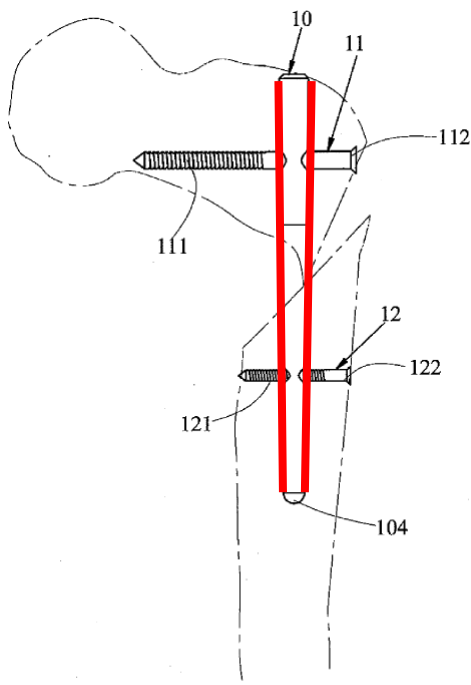


FIG. 5

Ex. 2014, FIG. 5 (annotations added). Since the apertures disclosed in Chang only pass through the shaft of the nail, they are not apertures at a terminal end.

Accordingly, a POSITA would understand that the term “a first aperture at a terminal end” as recited in the claims of the ’166 Patent means an aperture that would at least in part pass through the top surface of the third member, and would exclude apertures that only pass through the sides of the shaft of the third elongated body.

B. “Bore”

41. A POSITA would understand that the term bore does not include two sections of a hole separated by a ledge or “stepped longitudinal cross-sections.”

For example, U.S. Patent No. 10,357,299, titled “Bone Joining Apparatus and Method” discloses that a “reamer prepares a hole with a widened bore near the top to accommodate the top 22 of the female component, e.g., as illustrated in FIG. 25C.” Ex. 2017 at 15:1-7. Figure 25C is depicted below with only element 113—not the entire hole having stepped longitudinal cross-sections—identified as the “widened bore”:

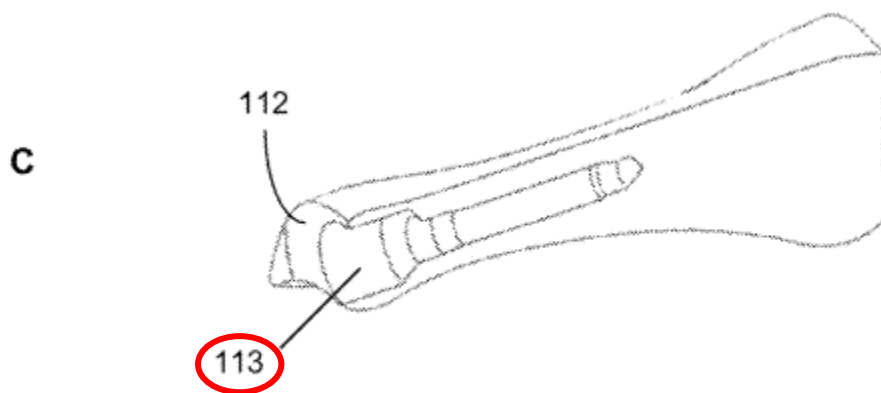


FIG. 25

Id. at Figure 25C (annotation added).

42. Claims 1 and 12 of the '166 Patent each require “a first bore extending along a first bore axis from a first aperture to a second aperture on an exterior surface of the third member.” Ex. 1001 at 15:11-18, 16:24-31. Mr. Dominguez states that “[a] bore is a cylindrical hole made by the spinning rotation of a twist drill cutting tool.” Exhibit 1002, ¶ 58 (emphasis added). At his deposition for this proceeding, he confirmed the statement in his declaration, that

“a bore is a cylindrical hole made by the spinning rotation of a twist drill cutting tool.” Ex. 2013 at 141:21-142:3. I agree with that construction.

43. Under the construction stated by Mr. Dominguez, the “tunnel” Petitioner identifies in Cognet as a “bore” in fact constitutes two bores, neither of which meets the requirement in the claims of a bore extending from a first aperture at the terminal end of the third member to an aperture on an exterior surface of the third member.

IX. PETITIONER’S INVALIDITY GROUNDS BASED ON COGNET ALONE OR IN COMBINATION WITH OTHER REFERENCES

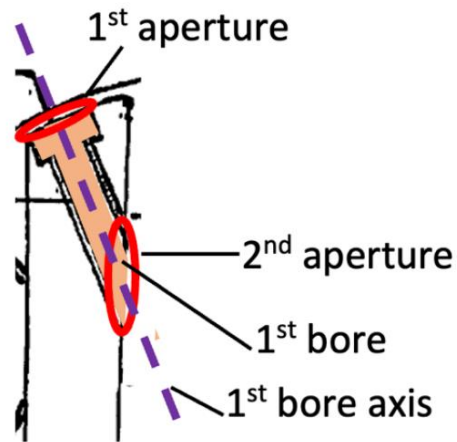
44. The two independent claims of the ’166 Patent, Claims 1 and 12, as well as all of the dependent claims by virtue of their dependency from the independent claims, require a first bore that extends along a specific path and ends in a specific location. Both recite:

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. 1001 at 15:11-18, 16:24-31(emphasis added).

45. Such a bore cannot be found in Cognet. The tunnel Petitioner identifies as the “first bore” in Cognet is, in fact, created by two bores: a larger diameter bore intended to receive the head of a screw, and a smaller diameter bore intended to receive the shaft of the screw. Petitioner’s expert testified during his

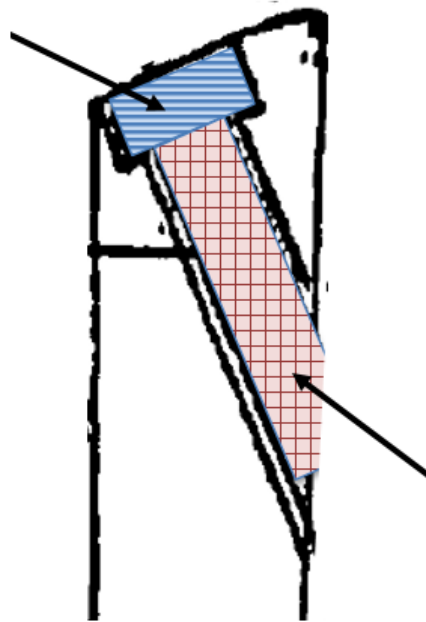
deposition that the tunnel identified by Petitioner is indicated by the orange-shaded region in this annotated Figure 1 from Cognet:



Ex. 2013 at 77:3-78:22; Paper 1 at 17; see also Paper 1 at 15-17, 29-30; Ex. 1002 at ¶ 59. The figure above also denotes the “first aperture” and “second aperture” as identified by Petitioner, with the tunnel extending there between.

46. The orange-shaded region, however, does not show a single “first” bore; it shows two bores, i.e., a top cylindrical bore with a larger diameter (the top of the “T”) (shown in blue in the figure below) and a second smaller diameter bore (the body of the “T”) (shown in pink grid in the figure below).

larger diameter bore



smaller diameter bore

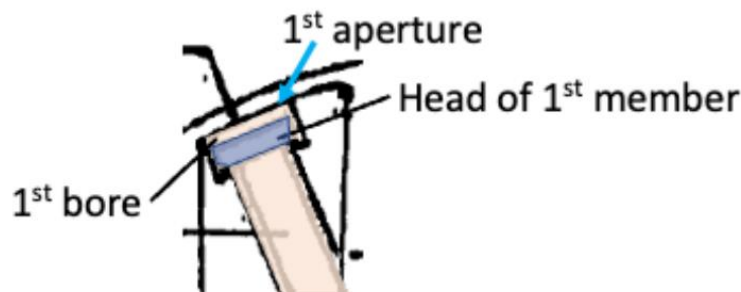
47. As discussed above, a “bore” should be construed as “a cylindrical hole or passage made by or as if by the turning or twisting movement of a tool, not excluding holes or passages having tapered cross-sections.” See also Ex. 1002, ¶ 58 (“[a] bore is a cylindrical hole. . .”).

48. The top bore in Cognet may also be referred to as a “counterbore.” A counterbore “is a circular hole with a flat bottom which coincides with another hole [and] . . . allows a bolt head or other fastener to be recessed.” See Ex. 2018 (<https://www.machinistguides.com/counterbores-all-about/>).

49. The two-bore construct of Cognet is significant here because all of the Challenged Claims require a single, “first” bore that extends all the way along a first bore axis from a very specific location to another specific location: (1) from the first aperture at a terminal end of the first end to (2) a second aperture on an

exterior surface of the third member. Ex. 1001 at 15:11-18, 16:24-31. But in Cognet, to get from the first aperture at the top of the “T” to the aperture at the bottom of the “T” (the only other aperture at the exterior surface), you must pass through two bores – the larger diameter bore that represents the top portion of the “T” and the smaller diameter bore that represents the body portion of the “T”.

50. Even the Petition correctly acknowledges this two-bore construct in its discussion of Claims 2 and 3. See Paper 1 at 23-24. When discussing Claim 2, Petitioner alleges that “the head portion of the first member resides at least partially within the first bore,” and presents the following annotated figure showing the head portion of Cognet’s screw in the top, first bore:



Paper 1 at 24. Then, when discussing Claim 3, Petitioner states that the head of the screw (located in the top, first bore) has a larger diameter than the bottom bore, although Petitioner then incorrectly refers to the bottom bore as both the “first bore” which it is not, and the “smaller diameter tunnel,” which it is:

Cognet discloses that the head of the screw (first member) **has a larger diameter than the diameter than [sic] the tunnel** (first bore) which makes it possible for the head to butt up against **the smaller**

diameter tunnel to stop the progression of the screw and obtain a compression effect at the fracture site (Ex. 1004, 62-65). Ex. 1002, ¶ 75. Figure 1 of Cognet shows the exterior surface of the head portion of the first member abutting the interior surface of the first bore at the first aperture, thus disclosing this claim limitation.

Paper 1 at 24 (citing Ex. 1002 ¶ 75) (emphasis added). Petitioner’s identification of the “smaller diameter tunnel” logically implies the existence of a “larger diameter tunnel.” Thus, Petitioner’s description of Cognet confirms that a POSITA would understand Cognet has two bores—the larger diameter tunnel and the smaller diameter tunnel. Accordingly, Cognet does not constitute invalidating prior art.

51. Although Mr. Dominguez refers to both a “counterbore” and a “countersink,” a POSITA would understand a “counterbore” to be a cylindrical hole (i.e., a bore) and a “countersink” to be a tapered hole.

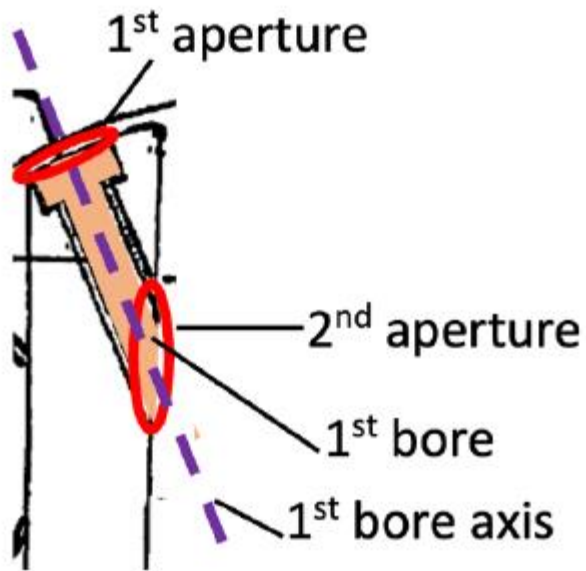
52. Consistent with the construction of the term “bore” as “a cylindrical hole or passage made by or as if by the turning or twisting movement of a tool, not excluding holes or passages having tapered cross-sections”—or really any construction in view of Petitioner’s concession that Cognet’s tunnel consists of two bores (i.e., a smaller diameter bore and a larger diameter bore)—Petitioner fails to show 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,” which is

a limitation recited in independent Claims 1 and 12 and in every dependent claim by virtue of their dependency from the independent claims.

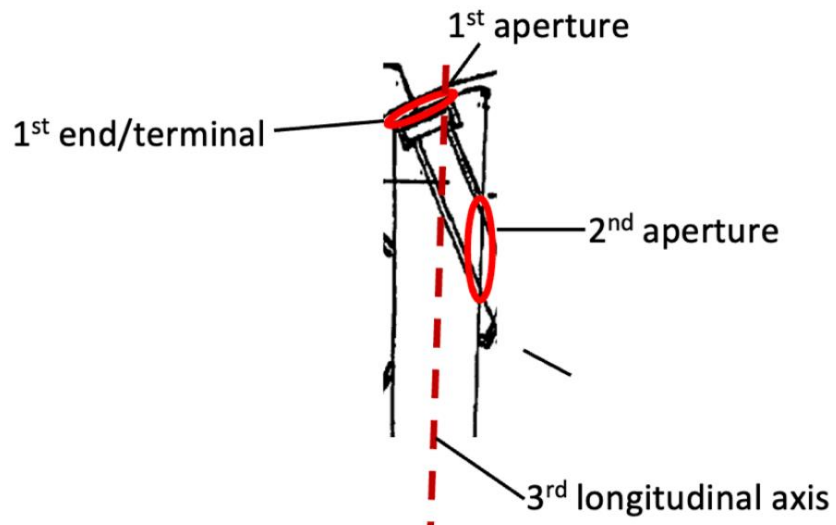
53. Claims 3 and 7 each recite, “wherein the exterior surface of the head portion of the first member *abuts the interior surface of the first bore at the first aperture.*”¹ Ex. 1001 at 15:48-50, 15:58-60. (emphasis added). Petitioner alleges that this limitation is disclosed in Cognet. However, the exterior surface of the head portion in Cognet identified by Petitioner actually abuts *the shoulder* between the larger diameter bore and the smaller diameter bore; the head does not abut the interior surface of Cognet’s tunnel—identified by Petitioner as the first bore—at the first aperture.

54. Petitioner identifies in the following annotated version of Cognet’s Figure 1 where Cognet allegedly discloses (1) a first aperture, (2) a second aperture, and (3) a first bore:

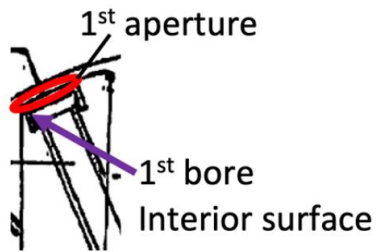
¹ Claims 2 and 6, from which Claims 3 and 7 depend respectively, each recite, “the head portion of the first member resides at least partially within the first bore.” Ex. 1001 at 15:45-47, 15:55-57.



Petition at 17 (citing Ex. 1002 at ¶ 59). Consistent with the annotated figure above, Petitioner also repeatedly and consistently identifies the “first aperture” as the opening at the top of the larger diameter bore throughout the Petition:



Paper 1 at 16 (citing Ex. 1002 at ¶ 57);



Paper 1 at 17 (citing Ex. 1002 at ¶ 60);

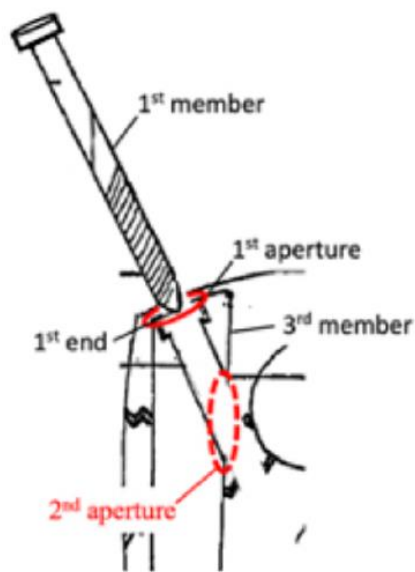


Figure A

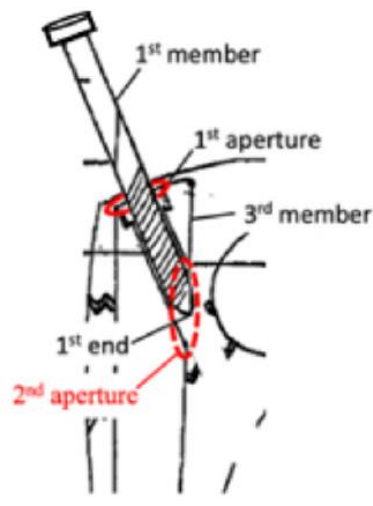


Figure B

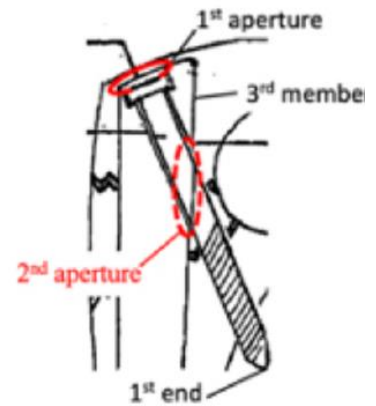
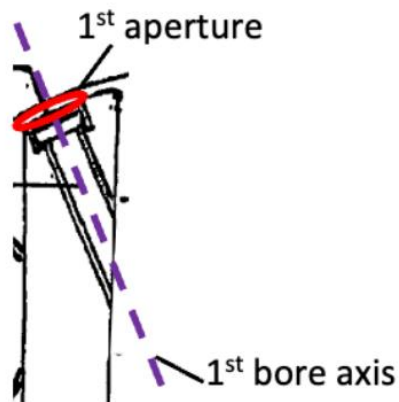
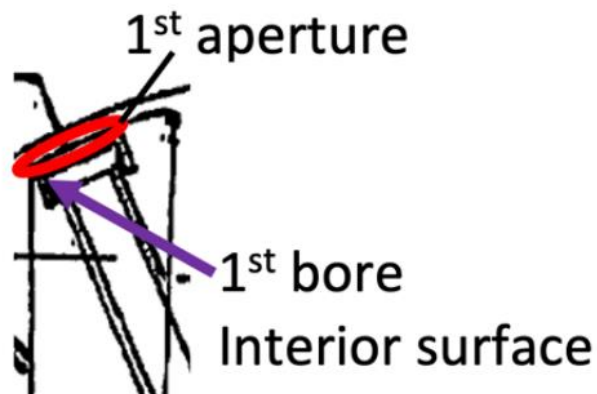


Figure C

Paper 1 at 21 (citing Ex. 1002 at ¶ 65);

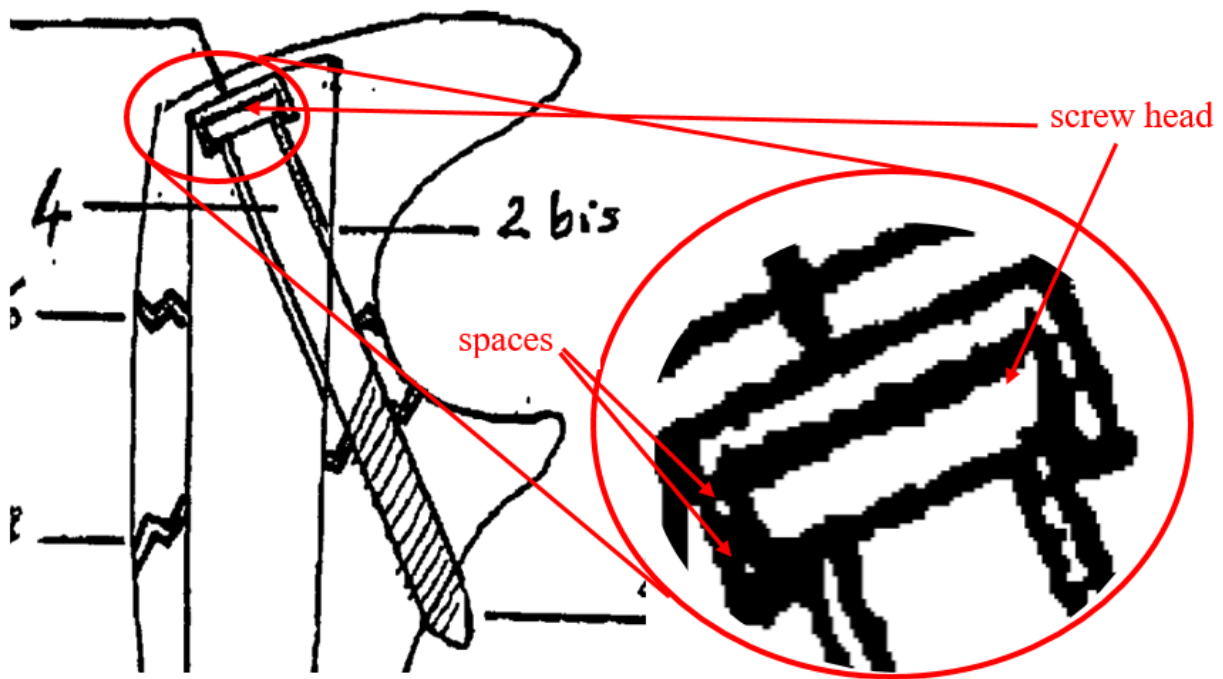


Paper 1 at 26 (citing Ex. 1002 at ¶¶ 77-78). Petitioner similarly identifies the location of the “interior surface at the first aperture” as adjacent to the opening to the T-shaped tunnel at the top of the third member:



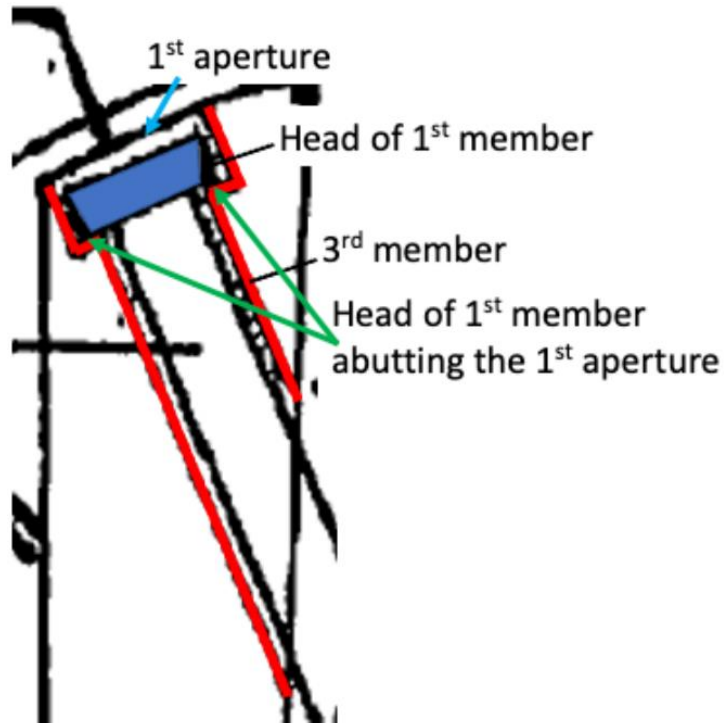
Paper 1 at 17 (citing Ex. 1002 at ¶ 60).

55. However, as shown by the white dots between the head of the screw and the wall of the large-diameter bore in Cognet’s Figure 1, the head does not “abut the interior surface of the first bore at the first aperture”:



Ex. 1003, Figure 1. The hand-drawn figures in Cognet are imprecise, but a POSITA would understand from Cognet's Figure 1 that the head of the screw does not abut the wall of the larger diameter bore, thereby allowing the head to rotate within the larger diameter bore without resistance from the wall.

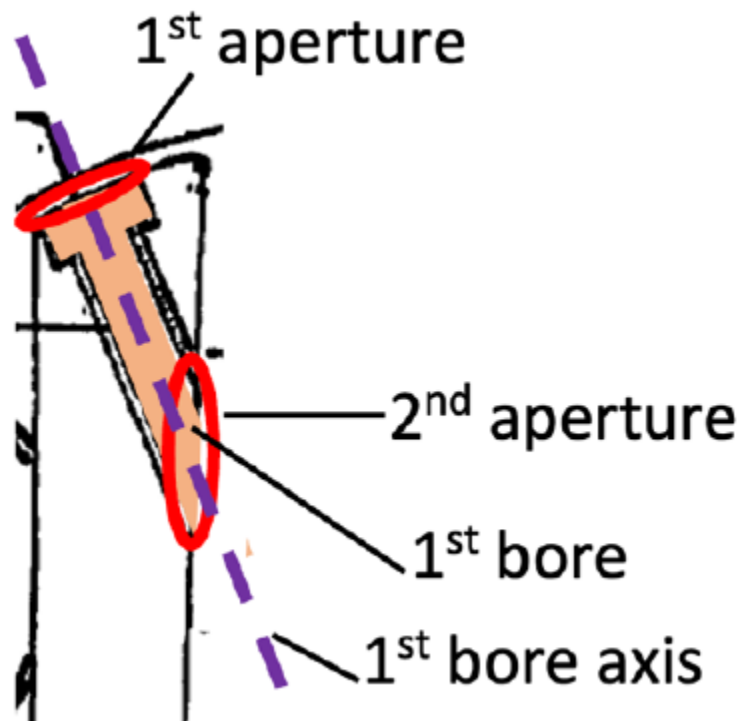
56. As depicted in the figure below copied from the Petition, Petitioner identifies with green arrows the shoulder between the larger diameter bore and the smaller diameter bore as the location where the head of the first member abuts the first aperture:



Paper 1 at 25. At no other point does Petitioner identify the area designated by the green arrows as the “first aperture.” As discussed above, and as indicated in this figure, Petitioner identifies the first aperture as the opening at the top of the larger diameter bore. Petitioner’s identification of where the head of the screw abuts the first aperture is therefore inconsistent with Petitioner’s own position on the location of the first aperture.

57. Identifying the area designated by the green arrows as the first aperture is also inconsistent with Petitioner’s arguments concerning the location of the “first bore.” To support its argument that the first bore is Cognet’s tunnel which, to meet Claims 1 and 12, must extend “from the first aperture to a second

aperture,” the first aperture and second aperture would need to be identified as indicated in the following figure annotated by Petitioner:



Paper 1 at 17 (citing Ex. 1002 at ¶ 59). Accordingly, the location in Cognet’s tunnel identified by Petitioner as where “the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture,” i.e., where the larger diameter bore meets the smaller diameter bore, is not only a different location than where Petitioner has identified the “first aperture” (the opening at the top of the larger diameter bore), but it also cannot be “at the first aperture” as required by Claims 3 and 7 if the bore is where Petitioner identifies it because the bore must extend from the first aperture to the second aperture. In contrast, the area identified by Petitioner is in the middle of the tunnel identified by

Petitioner as the “first bore,” someplace between the “first aperture” and the “second aperture.” It is therefore my opinion that Petitioner has not met its burden to show Claims 3 and 7 are anticipated by Cognet.

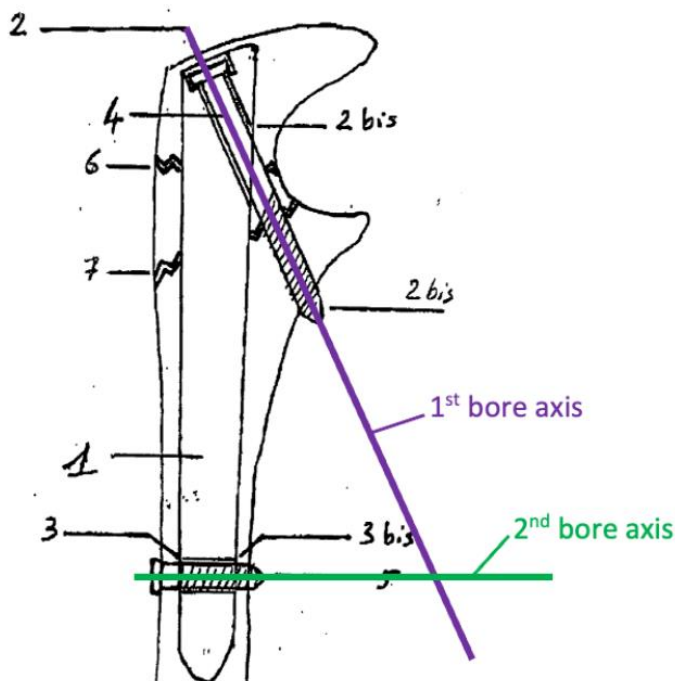
58. Claim 4 depends from Claim 3 and further recites, “the head portion of the first member comprises a torque transmitting aperture.” Petitioner does not allege that a torque transmitting aperture is disclosed in Cognet. Instead, Petitioner asserts, “***almost all screws*** comprise a torque transmitting aperture. . . .” Paper 1 at 25 (citing Ex. 1002, ¶¶ 42b, 76) (emphasis added).

59. Also, there are alternative ways to transmit torque to a screw that do not involve a torque transmitting aperture, and in fact, Petitioner expressly acknowledges this by noting that not all screws comprise a torque transmitting aperture. For example, a hex lag screw does not include a torque transmitting aperture:



Such a screw could be used as the “first member” identified by Petitioner in Cognet. It is therefore my opinion that Petitioner has not met its burden to show that Claim 4 is invalid in view of the disclosure in Cognet.

60. Claim 9 depends from Claim 1 and recites “the first bore axis and the second bore axis intersect outside the third member.” Petitioner cites the following annotated version of Cognet’s Figure 1 as evidence Cognet allegedly discloses that limitation:



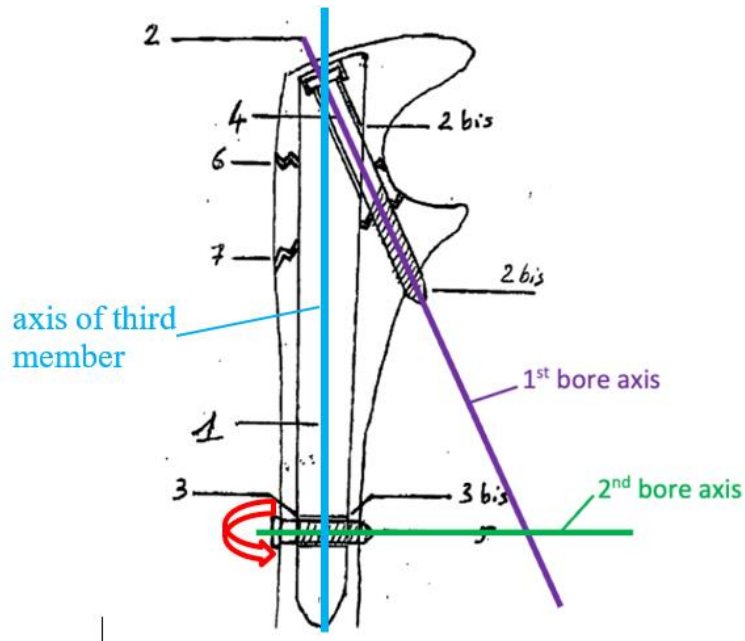
Paper 1 at 27 (citing Ex. 1002, ¶¶ 81-82). The portion of Mr. Dominguez’s declaration cited by Petitioner concedes that two non-parallel lines will intersect only if they are in the same plane. See Ex. 1002, ¶ 81. Yet, Mr. Dominguez’s declaration does not opine that the first and second bore axis identified by

Petitioner in Cognet are, in fact, in the same plane. See Ex. 1002, ¶¶ 81-82.

During cross-examination, Mr. Dominguez cited, for the first time, a portion of Cognet that describes the alleged second bore (the bottom bore in the figure above) as perpendicular to the axis of the nail (i.e., the third member):

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. . . .

Ex. 2013 at 164:8-24 (citing Ex. 1004 at 2-3). According to Mr. Dominguez, that disclosure means the “bore” axes labeled in annotated Figure 1 of Cognet intersect because they are on the same plane. Ex. 2013 at 170:11-172:15. But Mr. Dominguez’s assumption that orienting the second axis (the green line above) perpendicular to the axis of the nail necessarily means it intersect the first axis (the purple line above) is wrong. Below is a further annotated version of Cognet’s Figure 1, showing the axis of the third member (the light blue line), and how the second axis (the green line) could rotate around that axis (the blue line) as shown by the red arrow, but remain perpendicular to that axis (the blue line):



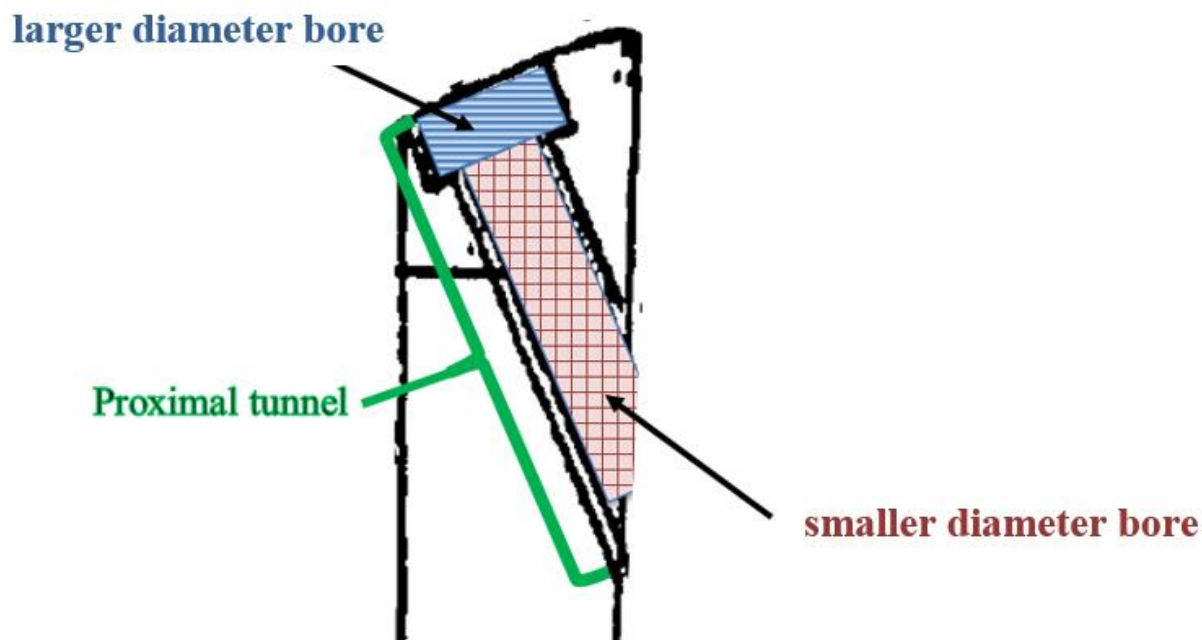
If the axes disclosed in Figure 1 are off by, for example, just one degree, they would be in different planes.

61. It is therefore my opinion that Petitioner has not met its burden to show Claim 9 is anticipated by Cognet.

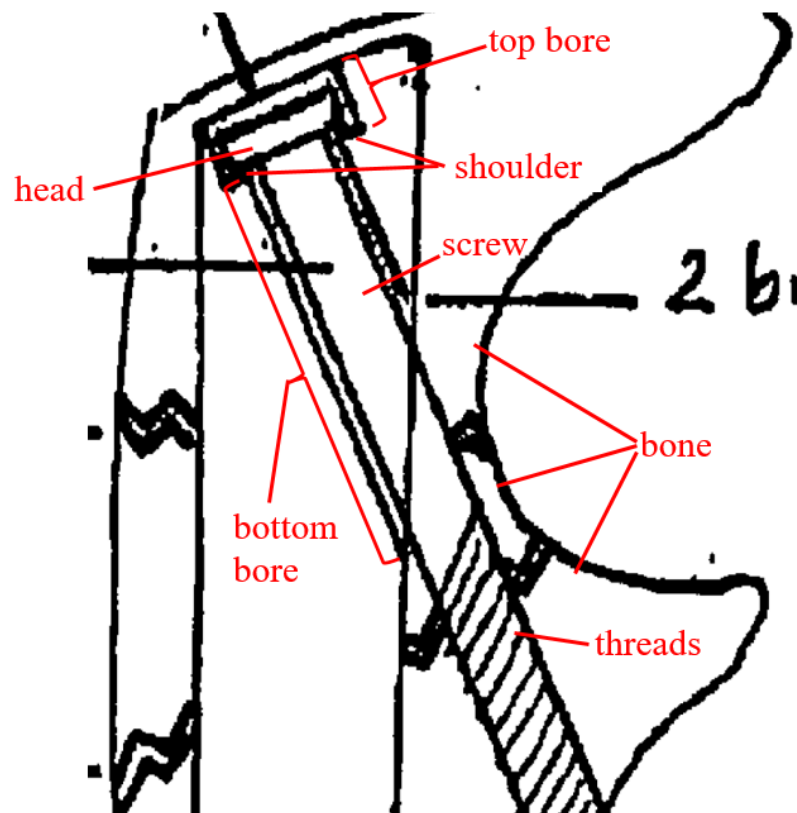
62. Petitioner alleges that Claims 4, 8, 10, and 14-15 are obvious in view of Cognet and Brumfield, and Claim 11 is obvious in view of Cognet and Ferrante. See, e.g., Paper 1 at 6. Petitioner's sole bases for alleging a POSITA would be motivated to use the screws disclosed in Brumfield with the intramedullary nail disclosed in Cognet is an allegation that "the screw and nail in Brumfield are performing the same function in the same way as the screw and nail in Cognet." Paper 1 at 33. However, the screw and nail in Brumfield do not perform the same function in the same way as the screw and nail in Cognet.

63. Cognet discloses a three-member device comprising “a nail through which there pass[es] at least two screws allowing this nail to be anchored into the bone.” Ex. 1004 at 2:22-25. The nail “comprises at least two tunnels; one tunnel starting from the top of the nail and leading in a direction that is oblique relative to the axis of the nail (2), and at least one tunnel situated in the distal part of the nail and perpendicular to the axis thereof (3).” Ex. 1004 at 3:31-37. Each of these tunnels is intended to accept a screw: the screw “that passes through the proximal tunnel (4) allows the fracture site (6 and 7) to be compressed,” and the screw that passes through the distal tunnel “block[s] rotation and prevent the nail from rising.” Ex. 1004 at 3:37-4:4.

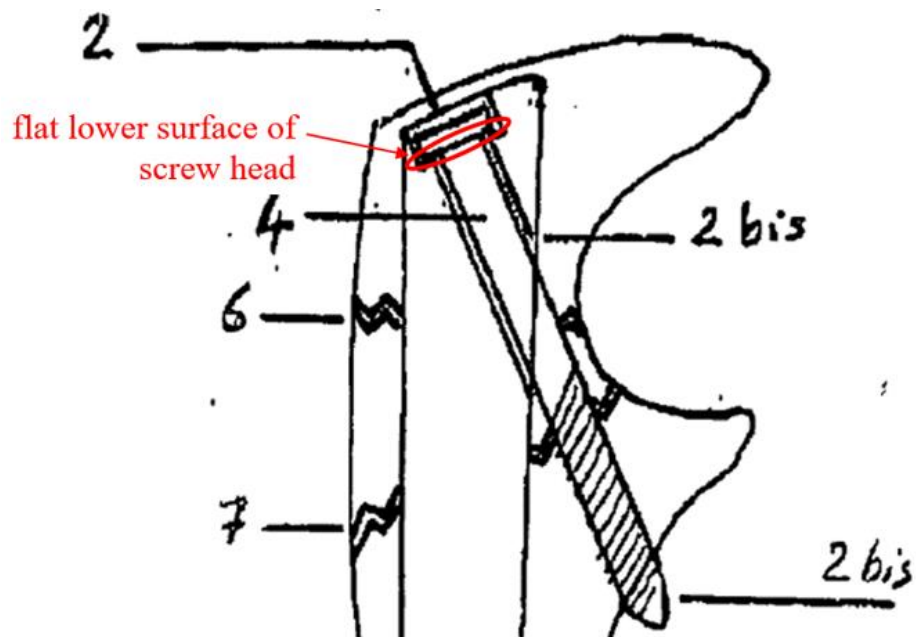
64. The proximal tunnel in Cognet comprises two bores: a larger diameter bore and a smaller diameter bore:



65. The screw intended to be inserted into the proximal tunnel is threaded at one end and has a head at the other end. See Ex. 1004, 4:14-23; FIG. 1. With reference to the annotated Figure 1 from Cognet below, the diameter of the head is wider than the diameter of the bottom bore of the proximal tunnel “thereby making it possible to halt the progress of the screw in its tunnel and obtain a compression effect at the fracture site.” *Id.* The threaded end of the screw is inserted through the larger diameter bore, through the smaller diameter bore, and exits the tunnel at the bottom of the smaller diameter bore where it contacts bone. Rotating the screw causes the threads to engage the bone, driving the screw into the bone. As the screw is turned, it advances into the bone until the head of the screw contacts the shoulder where the top, larger diameter bore, and bottom, smaller diameter bore meet:



Ex. 1004, FIG. 1 (annotations added). The shoulder is shown as a flat surface intended to mate with the flat underside surface of the screw head:



Ex. 1004, FIG. 1 (annotations added). The flat lower surface of the head of the screw disclosed in Cognet matches and is intended to contact the surface of the shoulder—shown as a flat surface between the top bore and the bottom bore—thereby facilitating the rotation of the screw in the tunnel. As the screw is rotated, the flat lower surface of the head of the screw slides along the shoulder between the top bore and the bottom bore, and the threads of the screw advance into the bone or bone fragment into which it has been inserted. As the threads advance, the bone or bone fragment is drawn in the direction of the head of the screw, compressing it with a bone or bone fragment in which the nail is implanted.

66. In contrast to Cognet, Brumfield discloses “[a]n apparatus for treating fractures of the femur including a screw and an intramedullary rod.” Ex. 1006, Abstract; see also Ex. 1006 at 2:65-68 (“The present invention provides an apparatus for treating fractures of the femur. . . .”). Brumfield teaches inserting the intramedullary rod into the femur. See, e.g., Ex. 1006 at 6:9-36. One or more lag screws are then inserted through holes in the rod. See, e.g., Ex. 1006 at 6:49-56. As shown in the partial section of Brumfield’s Figure 1 below, unlike the screw head disclosed in Cognet which is intended to be inserted into Cognet’s tunnel, the head of the lag screws disclosed in Brumfield (circled in red) are not intended to enter the rod (shaded yellow):

Fig .I.

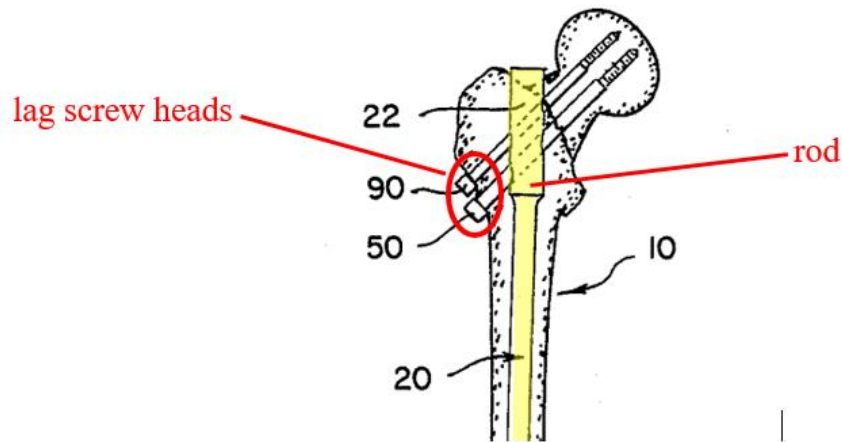


Exhibit 1006, FIG. 1 (annotations added).

67. It follows that the inventions in Cognet and Brumfield do not perform the same function in the same way. Cognet discloses a tunnel comprised of two bores, i.e., a larger diameter bore and a smaller diameter bore. At the intersection between the two bores there is a shoulder. The head of the screw is intended to abut the shoulder, thereby preventing the screw from advancing further into the bottom bore. Further rotation of the screw causes the threads to rotate in the bone and draw the bone toward the head of the screw, resulting in compression of the bone:

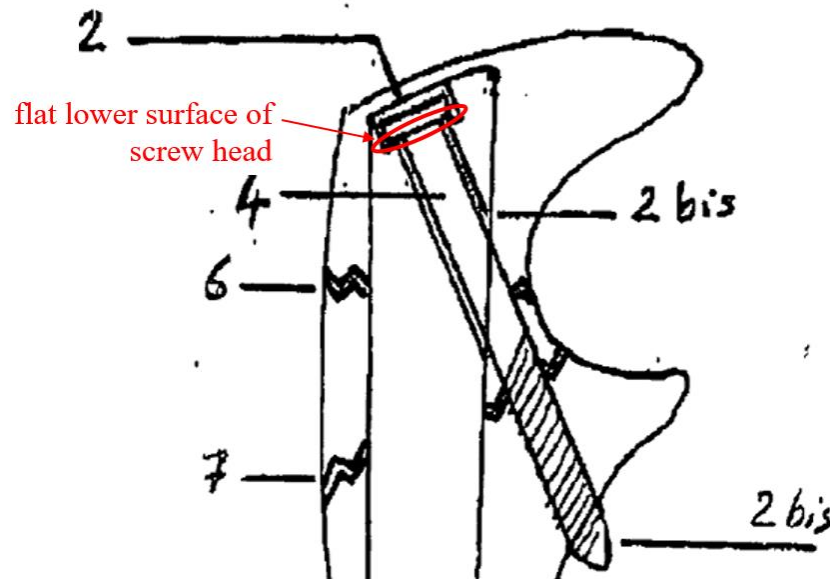
The top of the screw has a head, of a diameter wider than the diameter of the body 20 of the screw and than the tunnel (2) through which the screw passes, thereby making it possible to ***halt the progress of the screw in its tunnel and obtain a compression effect at the fracture site.***

See Ex. 1004 at 4:18-23 (emphasis added). In contrast, the inventions disclosed in Brumfield do not perform the same way as Cognet. The head of the screws in

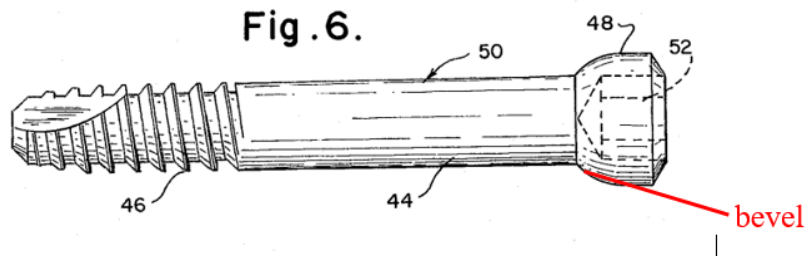
Brumfield are not intended to abut a shoulder in, or any part of, Brumfield's rod. Instead, as shown in Brumfield's Figure 1, the head of the screws are intended to abut the exterior of the femur. Accordingly, Cognet and Brumfield do not perform in the same way.

68. Petitioner also does not address the extent to which the screws from Brumfield would be compatible with the nail disclosed in Cognet. For example, Mr. Dominguez conceded that he "didn't go into addressing the exact mechanism of which there is contact there," only "that there's an abutment taking place." Ex. 2013 at 197:20-198:8. Nor does Petitioner explain why a POSITA would be motivated to make the proposed combination, and why a POSITA might look to modify Cognet and/or Brumfield in the first place. For example, Petitioner does not identify any potential benefits that might be achieved, and which a POSITA might expect, from the proposed combination. Nor does Petitioner address whether a POSITA would have had an expectation of success combining the references as Petitioner proposes, and the extent to which a POSITA might face any challenges or difficulties when trying to make the proposed combination, without using the Challenged Claims as hindsight. Nor does Petitioner identify any teachings in any of the references that would motivate a POSITA to combine the references as Petitioner proposes.

69. In fact, a POSITA would not consider combining Cognet and Brumfield as Petitioner proposes. The head of the screw disclosed in Cognet is depicted as having a flat lower surface:



Ex. 1004, FIG 1 (annotations added). The flat lower surface of the head of the screw disclosed in Cognet matches and is intended to contact the surface of the shoulder between the top bore and the bottom bore, thereby facilitating the rotation of the screw in the tunnel. As the screw is rotated, the flat lower surface of the head of the screw slides along the shoulder between the top bore and the bottom bore, and the threads of the screw advance into the bone or bone fragment into which it has been inserted. A POSITA would not consider replacing the screw depicted in Cognet with a screw that has a beveled head portion as disclosed in Brumfield:



Ex. 1006, FIG. 6. The beveled head portion would not mate with the shoulder in the tunnel as described above for the screw disclosed in Cognet. Instead, the beveled head portion would only contact the edge of the aperture leading to the bottom bore, resulting in increased resistance to rotation of the screw.

70. It is my opinion that it would not have been obvious to a POSITA to combine the disclosures in Cognet with the screw in Brumfield to practice the inventions recited in Claims 4, 8, 10, 14, and 15.

X. PETITIONER’S INVALIDITY GROUNDS BASED ON SIMON ALONE OR IN COMBINATION WITH OTHER REFERENCES

71. The independent claims of the ’166 Patent, Claims 1 and 12, as well as all of the dependent claims by virtue of their dependency from the independent claims, require “a first member . . . wherein the first member comprises a shaft portion having an external surface and **a head portion** having an exterior surface. . . .” Ex. 1001 at 14:63-67 and 16:8-12 (emphasis added). Petitioner alleges Simon discloses that limitation, but Simon does not disclose a first member *comprising a head portion*.

72. Petitioner does not identify any express disclosure in Simon of a first member that comprises a head portion. See Paper 1 at 40 (Claim 1) and 53 (Claim 12). Instead, Petitioner merely argues that: (1) screws generally have a head portion; and (2) Simon discloses “elements 18, 19, and 20 as being locking screws (Ex. 1008, [0053]), interlocking cortical screws, or transfixation screws (Ex. 1008, [0039]). . . .” *Id.*

73. First, Petitioner generally argues that “screws have a shaft portion with an external surface and a head portion with an exterior surface. . . .” Petition at 40 (citing Section V.A.1.b of the Petition). As a threshold matter, the cited section of the Petition does not support that screws generally have a head portion. See Paper 1 at 11-12. Instead, that portion of the Petition asserts that a screw in Cognet comprises a head portion.

74. The cited section of the Petition cites to a paragraph of Mr. Dominguez’s declaration, but Mr. Dominguez does not opine that all screws have a head. On the contrary, Mr. Dominguez opines the opposite—that “[s]ome screws are ‘headless’. . . .” Ex. 1002 at 20; Ex. 2013 at 208:1-8. It is my opinion that Petitioner has not shown a first member having a head portion is inherently disclosed by Simon.

75. Second, Petitioner asserts that “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 [a first member having a head portion].” See Paper 1 at 40 (citing Ex. 1002 ¶ 116). However, that disclosure does not expressly disclose a head portion, and there is no evidence in the record to indicate that anyone of those screws would necessarily have a head portion. At no point did Petitioner argue that all locking screws, all interlocking cortical screws, and/or all transfixation screws include a head portion as recited in Claims 1 and 12. The listing of a few screw types does not show that Simon discloses either expressly or inherently, a first member having a head portion.

76. In the context of Claims 8, Petitioner further alleges that, to maintain a low-profile stature, the heads of bone screws, interlocking screws, or transfixation screws would have a tapered shape. Paper 1 at 51. However, Petitioner still does not allege that all of those types of screws would have a head portion, and does not cite to any portion of Simon that indicates that a low-profile stature was desired. Nor does Petitioner show that a tapered head is the only means to achieve a low-profile stature. Petitioner also asserts that POSITA would “immediately assume” an interlocking screw “has a tapered head portion to permit low profile seating.” Paper 1 at 51-52 (citing Ex. 1002 at ¶¶ 42 and 135). However, the expert opinions cited in support of that argument are not supported by any actual evidence.

77. In sum, it is my opinion that Petitioner fails to show that the limitation of a first member having a head portion, as required by all of the Challenged Claims, is disclosed either expressly or inherently in Simon.

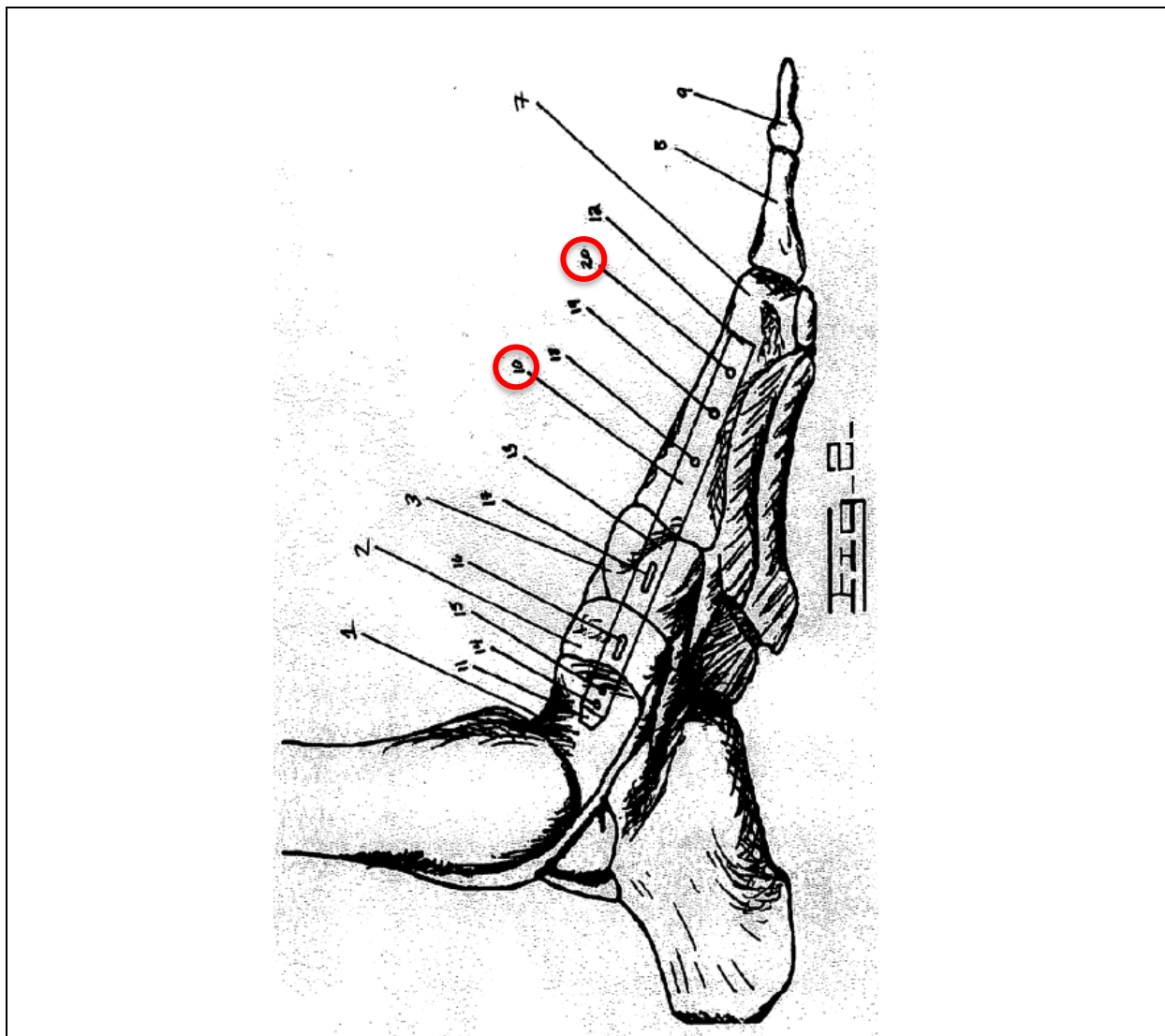
78. It is my opinion that Petitioner fails to show Simon discloses an “aperture at a terminal end” of the first end of the third elongated body, as required by independent Claims 1 and 12, as well as all of the dependent claims by virtue of their dependency from the independent claims:

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, wherein the third member comprises a first aperture ***at a terminal end of the first end*** of the third elongated body

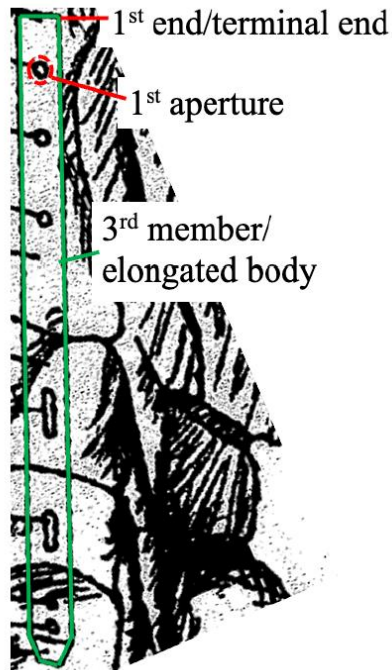
Ex. 1001 at 15:11-18, 16:24-31 (emphasis added).

79. As discussed above, the term, “a first aperture at a terminal end of the first end of the third elongated body” should be construed to exclude apertures that only pass through the sides of the shaft of the third elongated body. All of the apertures disclosed in Simon’s nail only pass through the sides of the shaft of the nail. See, e.g., Ex. 1008, FIGS. 1, 2. Therefore, Simon does not disclose any apertures at the terminal end of the first end of the third elongated body.

80. Petitioner alleges that hole (20) disclosed in Simon is a fastener hole at the terminal end of Simon’s nail (10). Paper 1 at 43 (citing Ex. 1008, FIG. 2, [0054]). This annotated version of Simon’s Figure 2 shows the location of hole (20) in relation to nail (10):

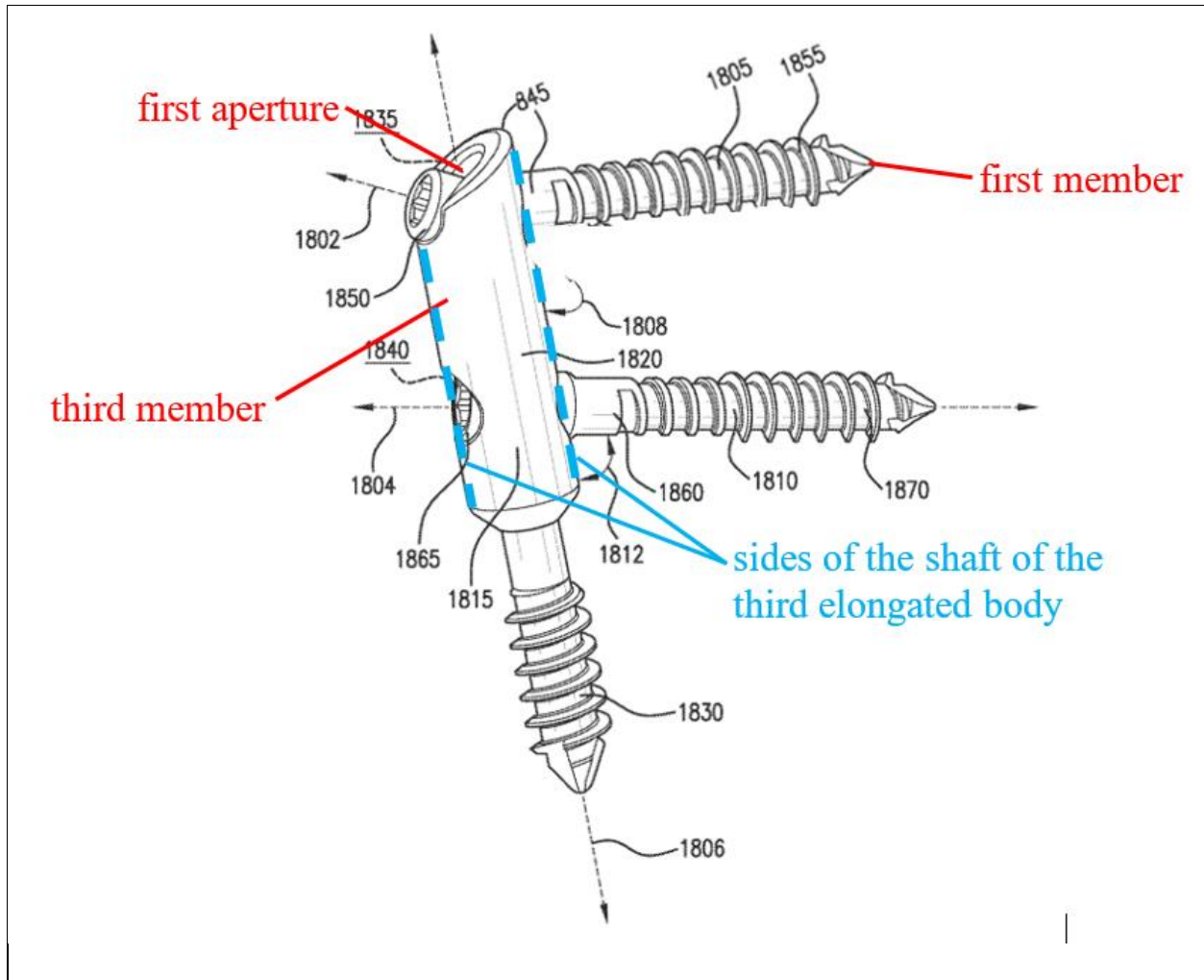


As shown in the following annotated figure presented by Petitioner, hole 20 (identified by Petitioner as “1st aperture”) is not at the terminal end because it only passes through the sides of the shaft of the third elongated body:



81. Petitioner cites to Mr. Dominguez’s declaration as support for the assertion that “Simon discloses a fastener hole (hole 20 in figure 2) at the terminal end of the third elongated body. . . .” Paper 1 at 43 (citing Ex. 1002, ¶ 121; Ex. 1008, ¶ [0054]). Mr. Dominguez opines that because “Claim 1 allows for the first bore axis to be at 90° relative to the third longitudinal axis, . . . the first aperture (the first end of the first bore) was oriented on the exterior surface of the third member at the terminal end.” Ex. 1002, ¶ 121; see also Ex. 2013 at 226:9-231:3. But an assembly with a first bore axis oriented at 90 degrees relative to the third longitudinal axis does not necessarily result in an aperture on the exterior surface of the third member . For example, if the first member in Figure 18 of the ’166 Patent is oriented at 90 degrees relative to the third longitudinal axis, because of

the chamfered (i.e., angled) surface at the top of the third member, the first aperture would not only pass through the sides of the shaft of the third elongated body—it is therefore still an aperture at the first terminal end of the third elongated body still also passes through the terminal end:



Ex. 1001, FIG. 18 (annotations added).

82. Petitioner also alleges that paragraph [0015] of Simon “teaches an aperture at the terminal end.” Paper 1 at 44 (citing Ex. 1002, ¶ 122). But paragraph [0015] of Simon merely identifies the Leu reference (U.S. Patent No. 6,270,499,

Ex. 1009), and states that the patent “describes an intramedullary nail where the proximal 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 at [0015]. Simon does not identify a terminal end of any nail in Leu, nor does it identify an aperture allegedly at a terminal end.

83. It is my opinion that Petitioner fails to show that Claims 1 and 12 are anticipated by Simon.

XI. PROPOSED SUBSTITUTE CLAIMS FOR THE '166 PATENT

84. I understand that Patent Owner is proposing substitute Claims 16-30 for the '166 Patent. Below I provide my analysis explaining that (1) the original application that led to the '166 Patent and its parent support the limitations added to proposed substitute Claims 16-30, and (2) none of the prior art asserted in this inter partes review teach or disclose the limitations added to proposed substitute Claims 16-30.

A. The Original Non-Provisional Application and its Parent Support the Limitations Added to Proposed Substitute Claims 16-30

85. The proposed substitute claims are supported by the original application of the '166 Patent, U.S. Patent Application No. 17/323,923

("Application 17/323,923"). Application 17/323,923 claims priority to U.S. Patent Application No. 12/658,680 ("Application 12/658,680"²), filed February 11, 2010.

86. The disclosures of Application 17/323,923 and Application 12/658,680 are included in the '166 Patent. Below I have inserted a table that shows the substitute claims with changes from the original claims, and also the location in each of Application 17/323,923 and Application 12/658,680 where the disclosure supports the substitute claim.

87. The support for each substitute Claim 16-30 is as follows:

² Application 12/658,680 issued as U.S. Patent No. 9,044,282.

Substitute Claim Text ³	Support in Application 17/323,923 ⁴	Support in Application 12/658,680 ⁵
thread having a first thread height extending radially outward from the external surface of said shaft portion;		
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;	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
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, wherein the third member comprises a first aperture at a terminal end of the first end of the third	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

Substitute Claim Text ³	Support in Application 17/323,923 ⁴	Support in Application 12/658,680 ⁵
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, wherein the first bore comprises an interior surface at the first aperture <u>and an interior surface at the second aperture</u>, wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture, wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,		
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	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

Substitute Claim Text ³	Support in Application 17/323,923 ⁴	Support in Application 12/658,680 ⁵
exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle,		
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,	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
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,	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
wherein the first angle is in the range of about 0 degrees to about 90 degrees,	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

Substitute Claim Text³	Support in Application 17/323,923⁴	Support in Application 12/658,680⁵
wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
wherein the second bore axis is substantially perpendicular to the third longitudinal axis.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 17		
The assembly of claim [[1]] 16 , wherein the head [[portion]] of the first member resides at least partially within the first bore.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 18		
The assembly of claim [[2]] 17 , wherein the exterior surface of the head [[portion]] of the first member abuts the interior surface of the first bore at the first aperture.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 19		
The assembly of claim [[3]] 18 , wherein the head [[portion]] of the first member comprises a torque transmitting aperture.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 20		

Substitute Claim Text³	Support in Application 17/323,923⁴	Support in Application 12/658,680⁵
The assembly of claim [[1]] 16 , wherein the first aperture of the third member is aligned on the first bore axis.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 21		
The assembly of claim [[5]] 20 , wherein the head [[portion]] of the first member resides at least partially within the first bore.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 22		
The assembly of claim [[6]] 21 , wherein the exterior surface of the head [[portion]] of the first member abuts the interior surface of the first bore at the first aperture.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 23		
The assembly of claim [[1]] 16 , wherein the head portion of the first member is tapered.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 24		
The assembly of claim [[1]] 16 , wherein the first bore axis and the second bore axis intersect outside the third member.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 25		

Substitute Claim Text³	Support in Application 17/323,923⁴	Support in Application 12/658,680⁵
thread having a first thread height extending radially outward from the external surface of said shaft portion;		
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;	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
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, wherein the third member comprises a first aperture at a terminal end of the first end of the third	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

Substitute Claim Text ³	Support in Application 17/323,923 ⁴	Support in Application 12/658,680 ⁵
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, wherein the first bore comprises an interior surface at the first aperture <u>and an interior surface at the second aperture</u>, wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,		
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	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

Substitute Claim Text³	Support in Application 17/323,923⁴	Support in Application 12/658,680⁵
bore axis define a second angle,		
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,	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
<u>wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,</u>	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
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,	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
wherein the second bore axis is substantially	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

Substitute Claim Text³	Support in Application 17/323,923⁴	Support in Application 12/658,680⁵
perpendicular to the third longitudinal axis.		
Substitute Claim 28		
The assembly of claim [[12]] 27 , wherein the head [[portion]] of the first member resides at least partially within the first bore.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 29		
The assembly of claim [[13]] 28 , wherein the head portion of the first member is tapered.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 30		
The assembly of claim [[12]] 27 , wherein the head portion of the first member is tapered.	Exhibit 2014, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2015, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

88. It is my opinion that, based on the above cited disclosures of Application 17/323,923 and Application 12/658,680, a POSITA would have understood that the inventors of the '166 Patent possessed the substitute claims' assembly for bone fusion at the time of each of those applications.

89. As set forth above, the substitute independent claims add the following limitations to the existing scope of the original independent claims: (1) the head portion of the first member comprising a head having an exterior surface;

(2) the first bore of the third member comprising an interior surface at the second aperture; and (3) wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture.

90. It is my opinion that a POSITA would have understood at the time of the claimed invention that each of these limitations are supported in Application 17/323,923 and Application 12/658,680.

91. First, as shown below, a head portion of the first member comprising a head having an exterior surface is disclosed in at least Figures 10 and 18 of Application 17/323,923 and Application 12/658,680 (annotated to identify the head portion comprising a head having an exterior surface):

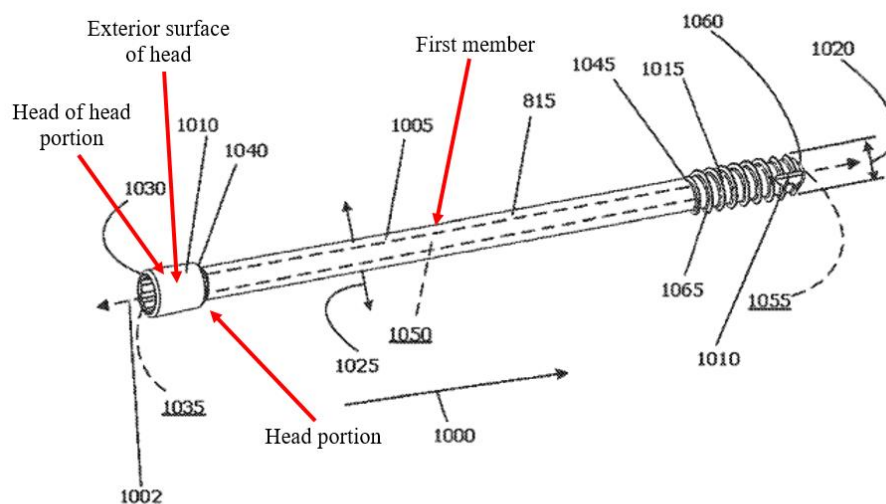


FIG. 10

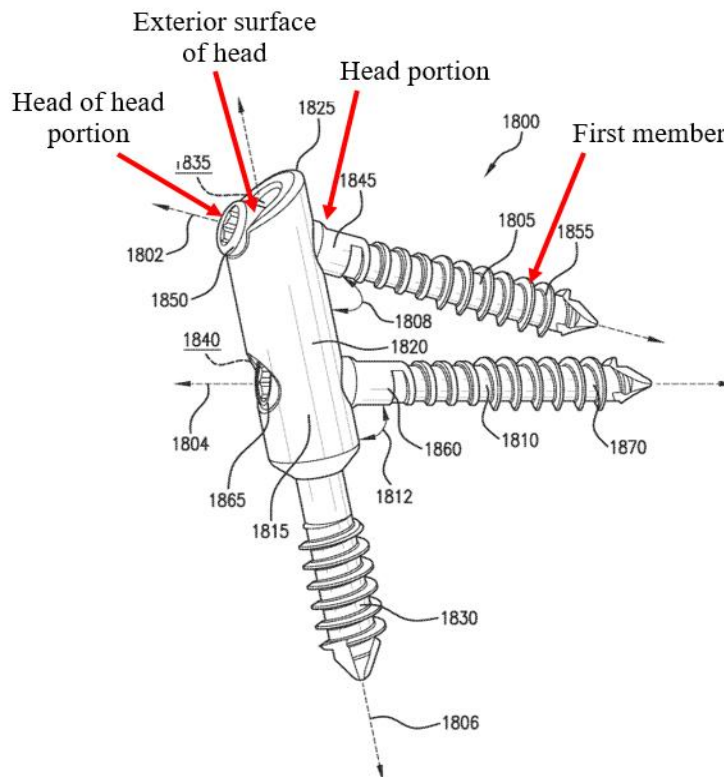


FIG. 18

92. In other words, a POSITA would understand that the head portion of the first member is the portion of the screw near the top of the screw, and the head of the head portion is the bulbous portion of the head portion. Further, all three figures clearly show that the head has an exterior surface.

93. Second, as shown below, the first bore of the third member (element 1815 in Figure 18) comprising an interior surface at the second aperture is shown and disclosed in at least Figures 18 and 11 of Application 17/323,923 and Application 12/658,680. Specifically, the first bore has an interior surface that runs the length of the first bore from the first aperture to the second aperture.

Thus, the first bore has an interior surface at both the first aperture and the second aperture. The claimed interior surface of the first bore at the second aperture is shown below in annotated Figure 18 of Application 17/323,923 and Application 12/658,680 (annotated to identify the interior surface of the first bore at the second aperture). The interior surface of the first bore at the second aperture is where the interior surface of the first bore meets the second aperture.

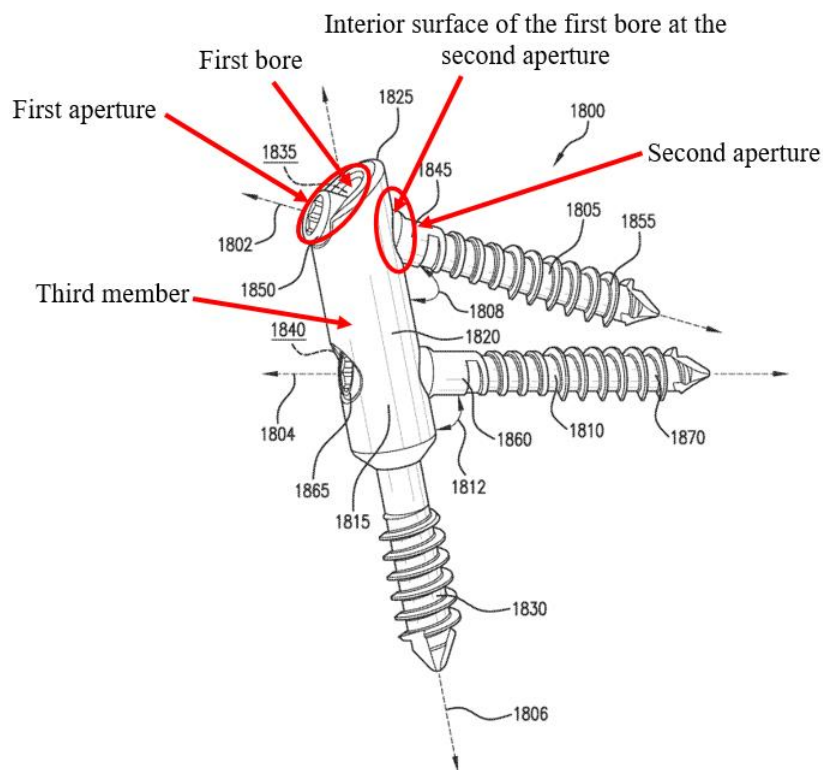


FIG. 18

94. As another example of Application 17/323,923 and Application 12/658,680 disclosing the interior surface of the first bore at the second aperture, below is Figure 11, which is annotated to illustrate the interior surface of the first bore at the second aperture. Again, the interior surface of the first bore at the

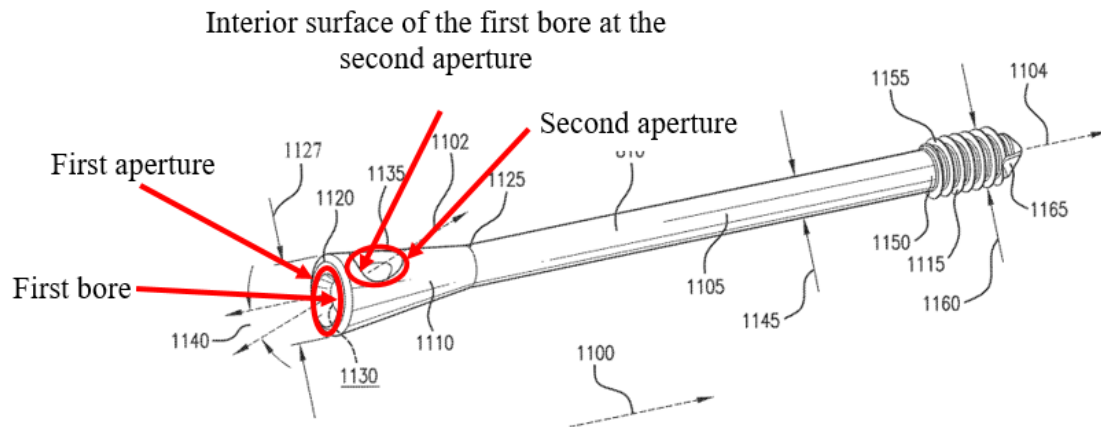


FIG. 11

95. Third, Application 17/323,923 and Application 12/658,680 disclose a first member that couples to the third member such that “the exterior surface of the head of the first member abuts the interior surface of the first bore [of the third member] at the second aperture.” A POSITA would know that this feature is shown and disclosed in at least Figures 18 and 9 of Application 17/323,923 and Application 12/658,680. Specifically, Figure 18 of Application 17/323,923 and Application 12/658,680 shows this specific claimed configuration (annotations added to show the exterior surface of the head of the first member abutting the interior surface of the first bore of the third member at the second aperture):

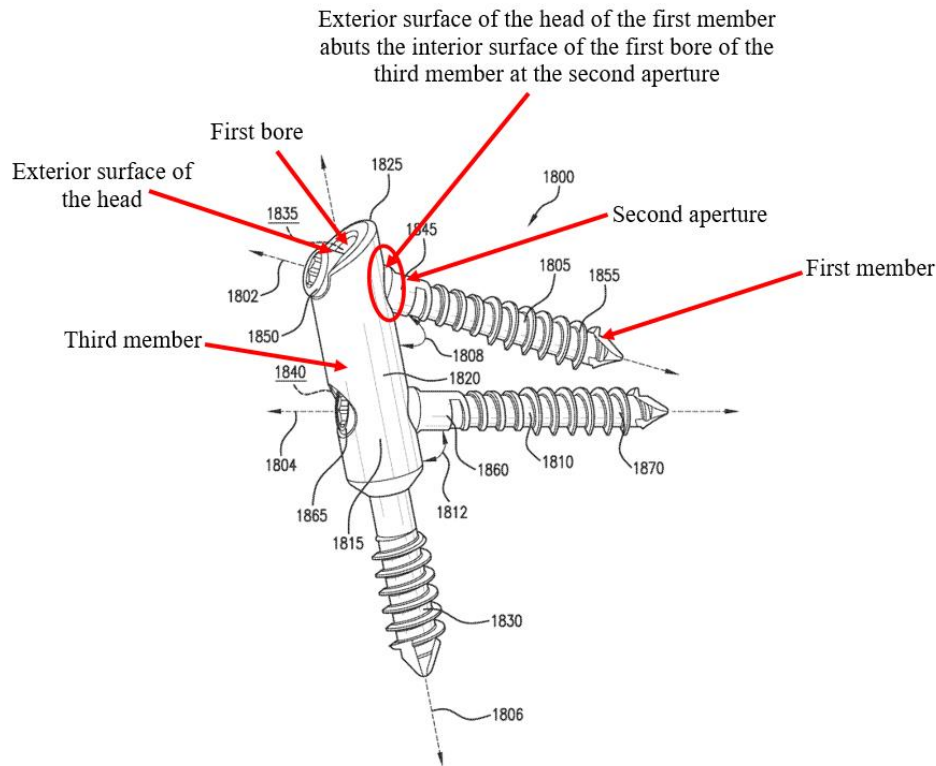


FIG. 18

96. Notably, Figure 18 shows that the bottom of the head of the first member protrudes out from the second aperture of the third member such that the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture. A POSITA would readily understand this to be the case based on the configuration shown in Figure 18. A POSITA would also understand this to be the case because, as disclosed in Application 17/323,923 and Application 12/658,680, the first member and third member are coupled to create a “locked interference fit” such that the exterior surface of the head of the first member abuts the interior surface of the first bore of the third member at the second aperture. *See, e.g.*, ’166 Patent at 13:50-53.

97. Figure 9 also shows a similar configuration where the bottom of the head of a lag screw 815 protrudes out from the second aperture of a tapered screw 810 such that the exterior surface of the head of the lag screw 815 abuts the interior surface of the bore at the second aperture. Figure 9 is provided below, annotated to show the exterior surface of the head of the lag screw 815 abutting the interior surface of the bore of the tapered screw 810 at the second aperture. Again, based on this configuration shown, a POSITA would know and understand that the bottom of the head of the lag screw 815 protrudes out from the second aperture of the tapered screw 810 such that the exterior surface of the head of the lag screw 815 abuts the interior surface of the first bore of the tapered screw 810 at the second aperture.

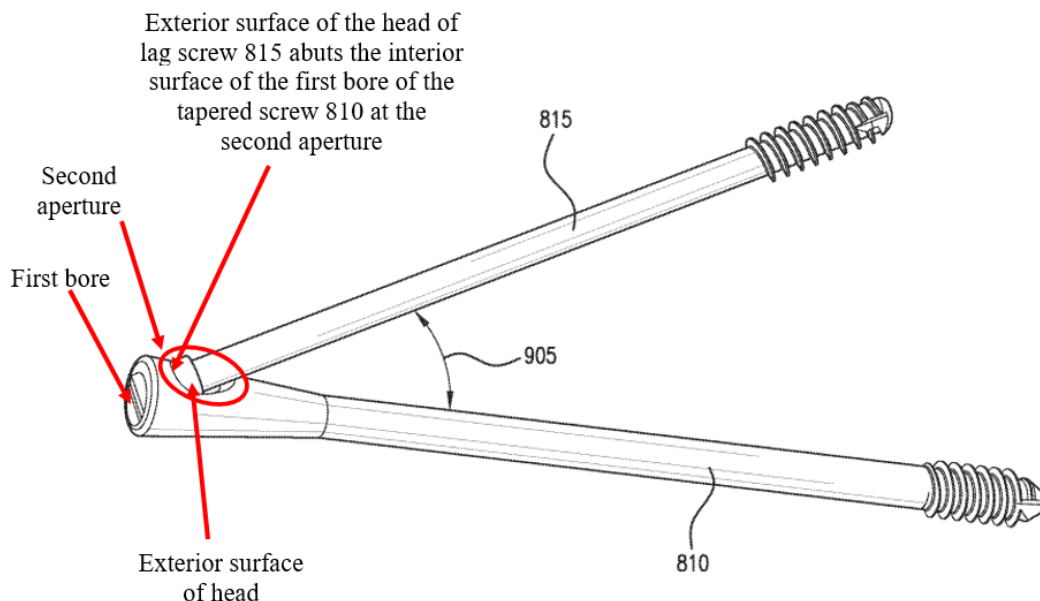


FIG. 9

98. It is therefore my opinion that Application 17/323,923 and Application 12/658,680 disclose all the limitations of proposed substitute Claims 16-30.

B. Claim Construction

99. It is my opinion that the meanings of the new limitations added to substitute independent Claims 16 and 27 are discernible from the context of Application 17/323,923, Application 17/002,005, Application 15/884,048, Application 15/181,435, Application 14/599,671, Application 12/658,680, Application 12/456,808, and Provisional 61/132,932, and would be readily understood by a POSITA at the time of the invention.

C. None of the References, Alone or in Combination, Teach Having the Exterior Surface of the Head of the First Member Abut the Interior Surface of the First Bore of the Third Member at the Second Aperture

100. The substitute independent claims, Claims 16 and 27, add the following limitations to the existing scope of the original independent claims: (1) the head portion of the first member comprising a head having an exterior surface; (2) the first bore of the third member comprising an interior surface at the second aperture; and (3) wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture.

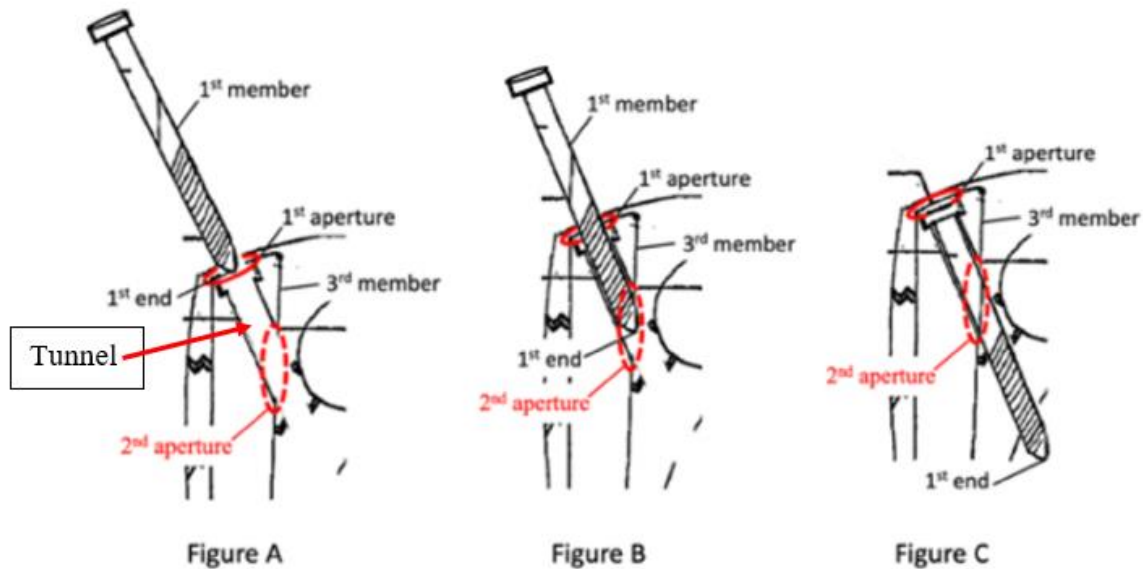
101. The Petition in this proceeding cites to five prior art references for its alleged grounds of invalidity: French Patent Application Publication No. FR

2,861,576 (“Cognet”); U.S. Patent No. 4,827,917 (“Brumfield”); U.S. Patent Application Publication No. 2003/0187447 (“Ferrante”); U.S. Patent Application Publication No. 2006/0206044 (“Simon”); and U.S. Patent No. 6,270,499 (“Leu”). Paper 1 (Petition) at 6; Paper 15 (Institution Decision) at 3.

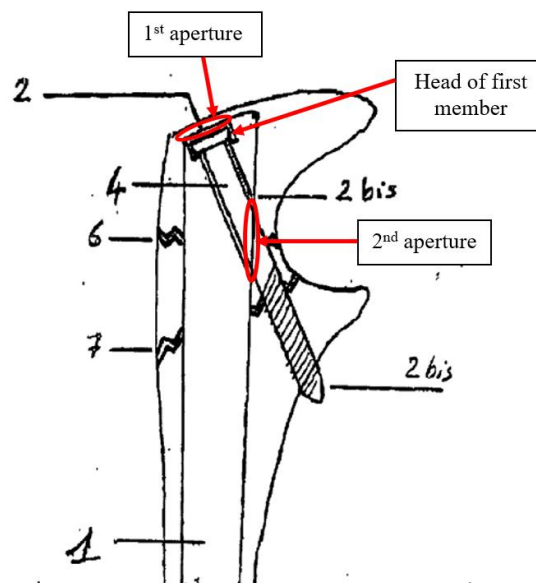
102. It is my opinion that none of Petitioner’s prior art references, alone or in combination, teach the above added limitations in combination with the other limitations recited in the proposed substitute claims.

1. Cognet (Ex. 1004) Does Not Disclose Having the Exterior Surface of the Head of the First Member Abut the Interior Surface of the First Bore of the Third Member at the Second Aperture

103. Petitioner asserts that Cognet discloses a first member (screw) that couples to a third member (nail) by inserting the first end of the first member/screw into the first aperture of the third member/nail (Figure A, below), through the tunnel running through the third member/nail (Figure B, below), and out of the second aperture (Figure C, below), as shown by Figure 1 of Cognet. Paper 1 at 20-21.



104. As shown in the annotated image below of Cognet's Figure 1, however, the head of first member (screw 4) clearly does not reach the second aperture and therefore does not disclose "wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture," as required by all the proposed substitute claims.

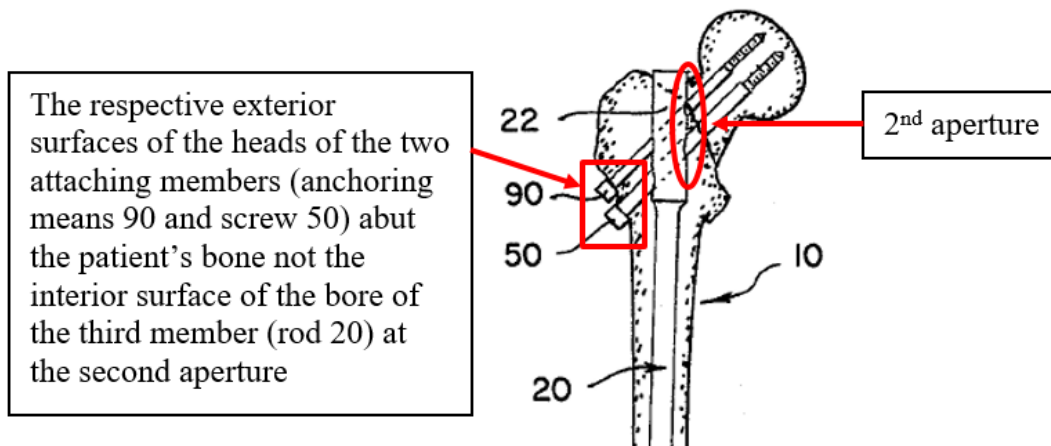


Ex. 1004 at Figure 1. There is no other disclosure in Cognet that teaches this limitation.

105. As such, it is my opinion that Cognet does not teach or disclose an assembly for bone fusion “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,” as required by all the proposed substitute claims.

2. Brumfield (Ex. 1006) Does Not Disclose Having the Exterior Surface of the Head of the First Member Abut the Interior Surface of the First Bore of the Third Member at the Second Aperture

106. Brumfield likewise does not disclose having the exterior surface of the head of any component that could be deemed the first member (i.e., either anchoring means 90 or screw 50) abut the interior surface of the first bore of the third member (rod 20) at the second aperture, as required by all the substitute claims. Rather, Brumfield discloses attaching members (anchoring means 90 and screw 50) that abut the patient’s bone, as shown below in annotated Figure 1 of Brumfield:



Ex. 1006 at Figure 1.

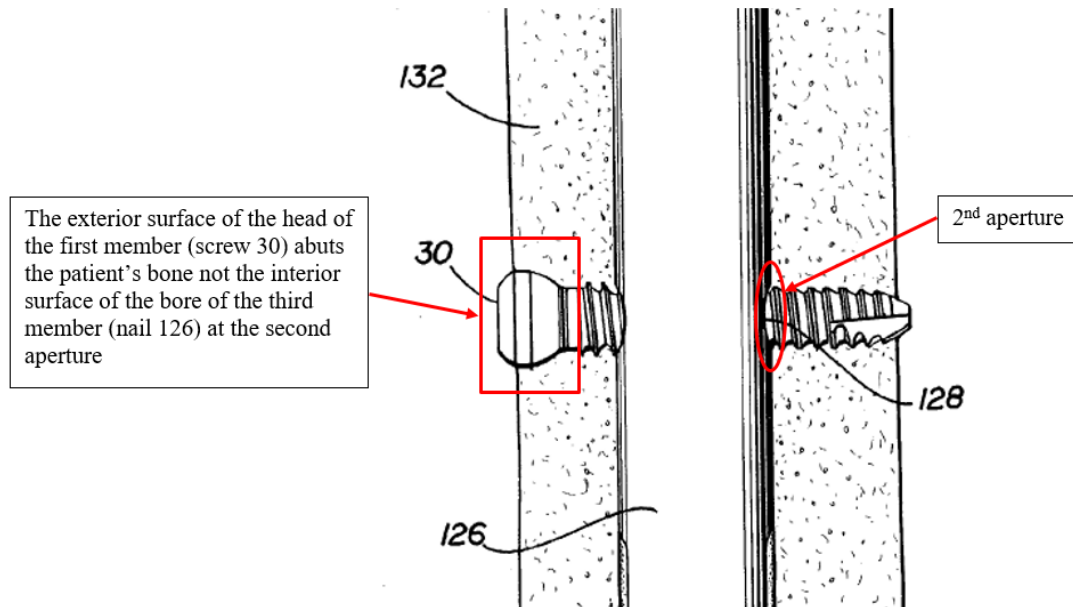
107. There is no other disclosure in Brumfield that teaches an assembly for bone fusion “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,” as required by all the proposed substitute claims.

108. As such, it is my opinion that Brumfield does not teach or disclose an assembly for bone fusion “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,” as required by all the proposed substitute claims.

3. **Ferrante (Ex. 1007) Does Not Disclose Having the Exterior Surface of the Head of the First Member Abut the Interior Surface of the First Bore of the Third Member at the Second Aperture**

109. Ferrante also does not disclose having the exterior surface of the head of the first member (screw 30) abut the interior surface of the first bore of the third member (nail 126) at the second aperture, as required by all the substitute claims.

Rather, similar to Brumfield, Ferrante discloses a screw (30) having a head that abuts the patient's bone (132), as shown below in annotated Figure 15 of Ferrante:



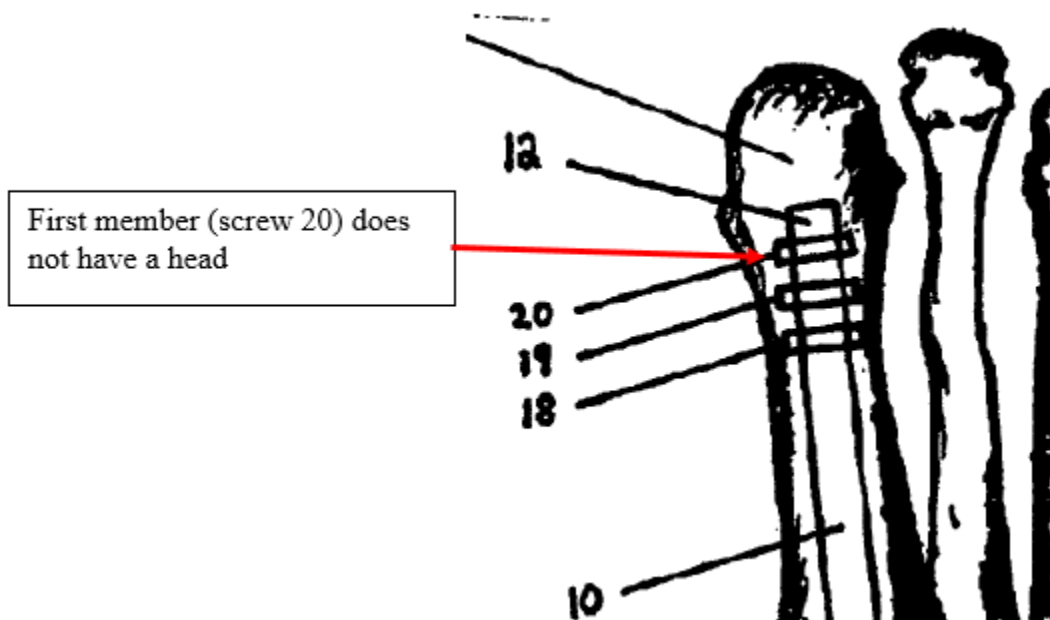
Ex. 1007 at Figure 1.

110. There is no other disclosure in Ferrante that teaches an assembly for bone fusion “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,” as required by all the proposed substitute claims.

111. As such, it is my opinion that Ferrante does not teach or disclose an assembly for bone fusion “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,” as required by all the proposed substitute claims.

4. Simon (Ex. 1008) Does Not Disclose a First Member Having a Head, and Therefore Does Not Disclose Having the Exterior Surface of a Head of a First Member Abut the Interior Surface of the First Bore of the Third Member at the Second Aperture

112. Simon does not disclose screws that have heads and therefore does teach having the exterior surface of a head of the first member (screw 20) abut the interior surface of the first bore of the third member (nail 10) at the second aperture, as required by all the substitute claims. For example, see annotated Figure 1 below:



Ex. 1008 at Figure 1.

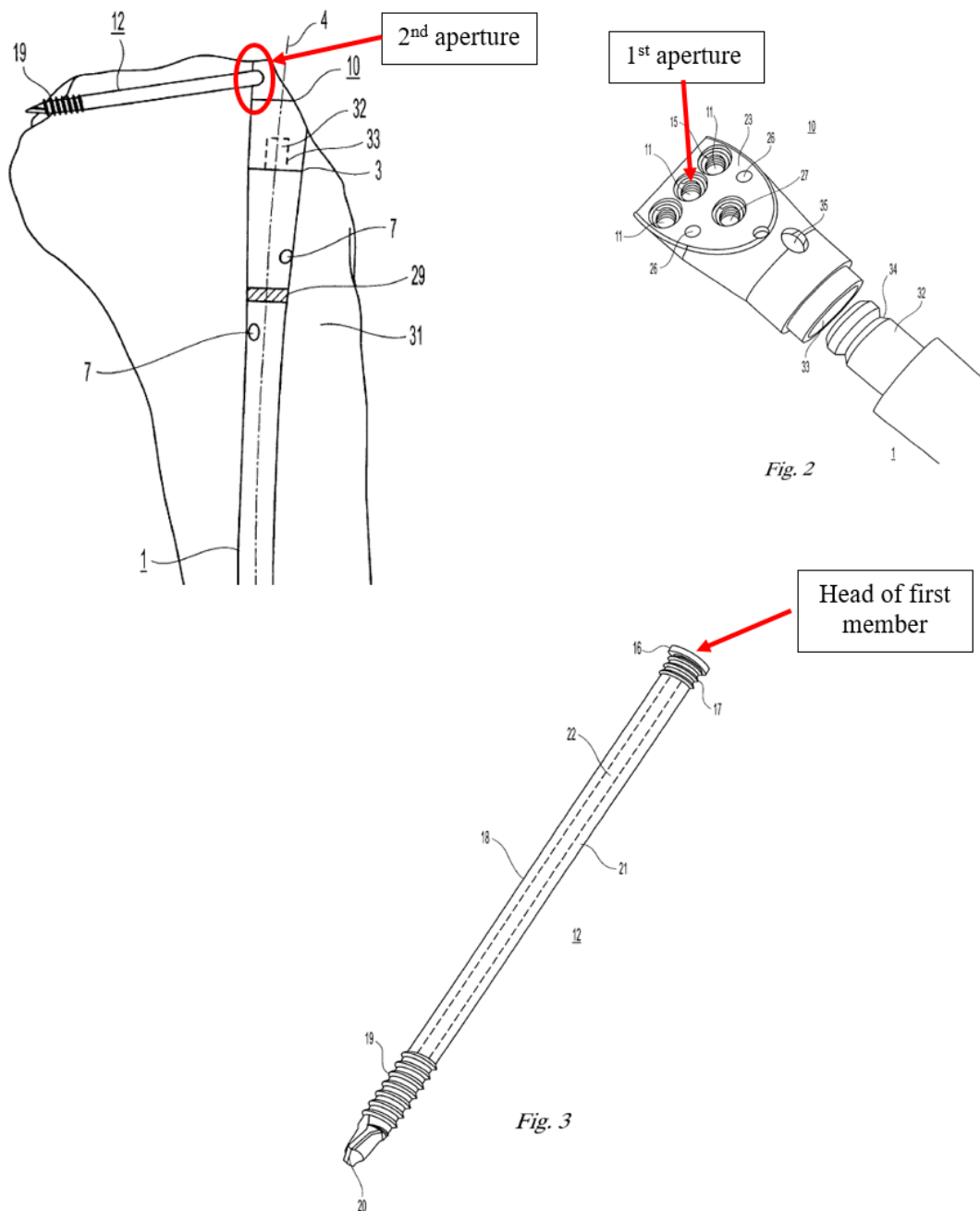
113. There is no other disclosure in Simon that teaches an assembly for bone fusion “wherein the exterior surface of the head of the first member abuts the

interior surface of the first bore at the second aperture,” as required by all the proposed substitute claims.

114. As such, it is my opinion that Simon does not teach or disclose an assembly for bone fusion “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,” as required by all the proposed substitute claims.

5. Leu (Ex. 1009) Does Not Disclose Having the Exterior Surface of the Head of the First Member Abut the Interior Surface of the First Bore of the Third Member at the Second Aperture

115. Leu does not disclose having the exterior surface of the head (16) of the first member (screw 12) abut the interior surface of the first bore of the third member (nail 1) at the second aperture, as required by all the substitute claims. Rather, as shown in the annotated images below of Leu’s Figures 1-3, the thin head (16) of first member (screw 12) rests completely on the lip just below the first aperture of the first bore and clearly does not reach the second aperture of the first bore. As such, the exterior surface of the head (16) of the first member (screw 12) does not abut the interior surface of the first bore of the third member (nail 1) at the second aperture, as required by all the proposed substitute claims.



Ex. 1009 at Figures 1-3.

116. There is no other disclosure in Leu that teaches an assembly for bone fusion “wherein the exterior surface of the head of the first member abuts the

interior surface of the first bore at the second aperture,” as required by all the proposed substitute claims.

117. As such, it is my opinion that Leu does not teach or disclose an assembly for bone fusion “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,” as required by all the proposed substitute claims.

118. It is my opinion that because, as explained above, none of Cognet, Brumfield, Ferrante, Simon, and Leu, alone or in combination, teach, disclose, or suggest the limitation, “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture,” substitute independent Claims 16 and 27, and the claims that depend directly or indirectly therefrom (Claims 17-26 and 28-30), are patentable over these asserted references.

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 February 8, 2024

By: 

Eric H. Ledet