

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

SECOND DECLARATION OF DR. ERIC H. LEDET

Extremity Medical, LLC EXHIBIT 2023 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 second 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, for this second declaration, I have been asked to provide my opinions regarding whether there is written description support in the patent application that led to U.S. Patent No. 11,298,166 (“the ’166 Patent”) as well as in the patent application to which the ’166 Patent claims priority to, as filed, for substitute claims submitted by Patent Owner, and whether the substitute claims are patentable in view of the prior art.

2. This declaration sets forth the opinions that I have formed based on the information available to me as of the date of this declaration. The opinions and facts set forth in this declaration are based upon my analysis of the ’166 patent, 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 or of Petitioner Fusion Orthopedics, LLC (“Petitioner”). 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 declaration.

7. My qualifications for forming the opinions in this declaration are set forth in my original declaration (*see* Ex.2012, ¶¶ 6-19) as well as my curriculum

vitae (“CV”), attached thereto as Exhibit A, which are incorporated herein by reference.

III. MATERIALS AND OTHER INFORMATION CONSIDERED

8. 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, the prosecution history of U.S. App. Ser. No. 12/658,680, 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

9. Based on my experience and expertise, it is my opinion that: (1) the inventions recited in Substitute Claims 16-30 are supported by the written description of the patent application that led to the '166 Patent as well as the patent application that the '166 Patent claims priority to (U.S. App. Ser. No. 12/658,680); and (2) Substitute Claims 16-30 are patentable over the prior art I have reviewed, including the prior art cited in the Petition.

V. UNDERSTANDING OF PATENT LAW

10. I am not an attorney. For purposes of this declaration, I have an understanding about certain aspects of the law that are relevant to my opinions, as described in my original declaration (*see* Ex.2012, ¶¶ 22-29), which is incorporated herein by reference.

VI. PERSON OF ORDINARY SKILL IN THE ART

11. My opinion regarding the person of ordinary skill in the relevant art (“POSITA”) regarding the ’166 Patent is set forth in my original declaration (*see* Ex.2012, ¶¶ 30-34), which is incorporated herein by reference.

VII. PROPOSED SUBSTITUTE CLAIMS FOR THE ’166 PATENT

12. 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 (U.S. App. Ser. No. 12/658,680) 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

13. 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”¹), filed February 11, 2010.

14. 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

¹ Application 12/658,680 issued as U.S. Patent No. 9,044,282.

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.

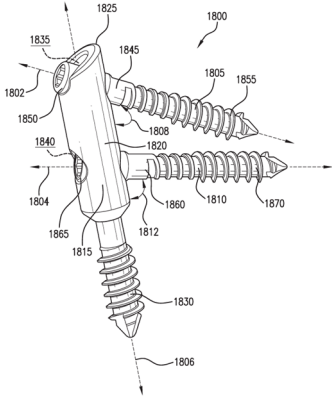
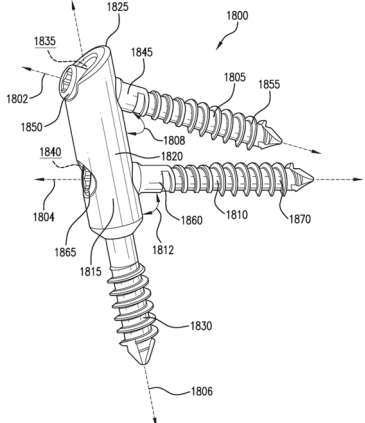
15. The support for each substitute Claim 16-30 is as follows:

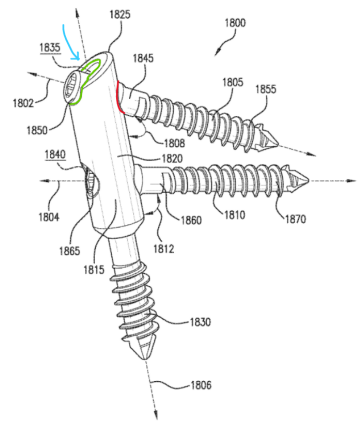
Cl. No.	Substitute Claim Text²	Support in Application 17/323,923³	Support in Application 12/658,680⁴
Substitute Claims 16 & 27			
16[a] & 27[a]	An assembly for bone fusion, comprising:	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
16[b] & 27[b]	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, where	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. The claimed “first member” and claimed components thereof are supported at least by the original disclosure showing and describing	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. The claimed “first member” and claimed components thereof are supported at least by the original disclosure showing and describing

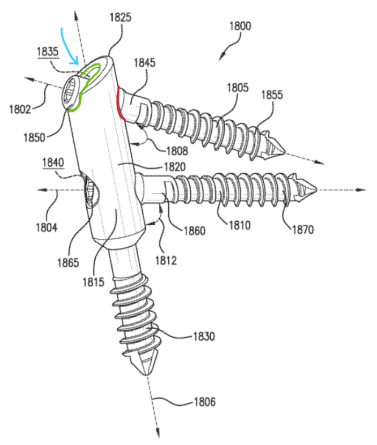
² Deletions from the original claims are shown by red brackets surrounding red text, and additions are shown in blue underlining with blue text.

³ The citations in this column are made to Corrected Exhibit 2020, which is the publicly available file history of Application 17/323,923. The citations are to the exhibit page numbers provided by Patent Owner.

⁴ The citations in this column are made to Corrected Exhibit 2021, which is the publicly available file history of Application 12/658,680. The citations are to the exhibit page numbers provided by Patent Owner.

Cl. No.	Substitute Claim Text ²	Support in Application 17/323,923 ³	Support in Application 12/658,680 ⁴
	in the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;	lag screw member 1805 shown in Figure 18 and described in the disclosure cited above. This claim limitation is also supported by originally filed Claim 1. Ex.2020, p. 17-18.  FIG. 18	lag screw member 1805 shown in Figure 18 and described in the disclosure cited above.  FIG. 18
16[c] & 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	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. The claimed “second member” and claimed components thereof are supported at least by the original disclosure showing and describing lag screw member 1810 shown in Figure 18 and described in the disclosure cited above. This claim limitation is also supported by originally filed Claim 1.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. The claimed “second member” and claimed components thereof are supported at least by the original disclosure showing and describing lag screw member 1810 shown in Figure 18 and described in the disclosure cited above.

Cl. No.	Substitute Claim Text ²	Support in Application 17/323,923 ³	Support in Application 12/658,680 ⁴
	thread having a first thread height extending radially outward from the external surface of said shaft;	Ex.2020, p. 17-18.	
16[d] & 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, wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, <u>wherein the first aperture is on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member</u> , and a first bore extending along a first bore axis from the first aperture to a second aperture on <u>[[an]] a side</u> exterior surface of the third member,	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. The claimed “third member” and claimed components thereof are supported at least by the original disclosure showing and describing tapered screw member 1815 shown in Figure 18 and described in the disclosure cited above. This claim limitation is also supported by originally filed Claim 1. Ex.2020, p. 17-18. Moreover, support for the newly added limitation is provided by at least by the aperture annotated in green on tapered screw member 1815 in Figure 18, set forth below.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. The claimed “third member” and claimed components thereof are supported at least by the original disclosure showing and describing tapered screw member 1815 shown in Figure 18 and described in the disclosure cited above. Moreover, support for the newly added limitation is provided by the aperture annotated in green on tapered screw member 1815 in Figure 18, set forth below.  FIG. 18

Cl. No.	Substitute Claim Text ²	Support in Application 17/323,923 ³	Support in Application 12/658,680 ⁴
	wherein the first bore comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the side exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,	 FIG. 18 See Ex.2030. Petitioner's expert confirmed this added limitation is supported by the aperture annotated in green in Figure 18. Ex.2022, 111:19-112:1 (Q. ... [I]s this aperture where my mouse is and where the green is on this Figure 18 [of the '166 Patent], is that an aperture that's on the top surface of member 1815 as well as on the side surface – side exterior surface of the same member? A. Yeah, I see the – I see the opening in green indicating part of it is on the top surface, part of it is on the side surface of the nail”).	See Ex.2030. Petitioner's expert, Mr. Dominguez, confirmed this added limitation is supported by the aperture annotated in green in Figure 18. Ex.2022, 111:19-112:1.
16[e] &	wherein the third member further	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11,	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11,

Cl. No.	Substitute Claim Text ²	Support in Application 17/323,923 ³	Support in Application 12/658,680 ⁴
27[e]	comprises a third aperture on the side 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 the side exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle,	18. The claimed “third member” and claimed components thereof are supported at least by the original disclosure showing and describing tapered screw member 1815 shown in Figure 18 and described in the disclosure cited above. This claim limitation is also supported by originally filed Claim 1. Ex.2020, p. 17-18.	18. The claimed “third member” and claimed components thereof are supported at least by the original disclosure showing and describing tapered screw member 1815 shown in Figure 18 and described in the disclosure cited above.
16[f] & 27[f]	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 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. The claimed coupling is supported at least by the original disclosure showing and describing the coupling of lag screw member 1805 to tapered screw member 1815 shown in Figure 18 and described in the disclosure cited above. This limitation is also supported by originally filed Claim 1. Ex.2020, p. 17-18.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. The claimed coupling is supported at least by the original disclosure showing and describing the coupling of lag screw member 1805 to tapered screw member 1815 shown in Figure 18 and described in the disclosure cited above.
16[g] & 27[g]	wherein the second member couples to the third member	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. The claimed	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. The claimed coupling

Cl. No.	Substitute Claim Text²	Support in Application 17/323,923³	Support in Application 12/658,680⁴
	by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,	coupling is supported at least by the original disclosure showing and describing the coupling of lag screw member 1810 to tapered screw member 1815 shown in Figure 18 and described in the disclosure cited above. This limitation is also supported by originally filed Claim 1. Ex.2020, p. 17-18.	is supported at least by the original disclosure showing and describing the coupling of lag screw member 1805 to tapered screw member 1815 shown in Figure 18 and described in the disclosure cited above.
16[h]	wherein the first angle is in the range of about 0 degrees to about 90 degrees,	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. The claimed “first angle” is supported at least by the original disclosure explaining that angle 1808 “may be any angle less than 90 degrees.” Ex.2020, 44:12-14. This limitation is also supported by originally filed Claim 1. Ex.2020, p. 17-18.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. The claimed “first angle” is supported at least by the original disclosure explaining that angle 1808 “may be any angle less than 90 degrees.” Ex.2021, 34:2-5. This limitation is also supported by originally filed Claim 53. Ex.2021, p. 50.
16[i] & 27[h]	wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. The claimed “second angle” is supported at least by the original disclosure explaining that angle 1812 “may be any angle less than 90 degrees.” Ex.2020, 44:12-14. This limitation is also supported by	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. The claimed “second angle” is supported at least by the original disclosure explaining that angle 1812 “may be any angle less than 90 degrees.” Ex.2021, 34:2-5. This limitation is also supported by originally

Cl. No.	Substitute Claim Text ²	Support in Application 17/323,923 ³	Support in Application 12/658,680 ⁴
		originally filed Claim 1. Ex.2020, p. 17-18.	filed Claim 53. Ex.2021, p. 50.
16[j] & 27[i]	wherein the second bore axis is substantially perpendicular to the third longitudinal axis.	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This claimed feature is supported at least by the original disclosure explaining that angle 1812 “may be any angle less than 90 degrees.” Ex.2020, 44:12-14. Meaning that the second bore may be 89.99 degrees to the third longitudinal axis. This limitation is also supported by originally filed Claim 1. Ex.2020, p. 17-18.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. This claimed feature is supported at least by the original disclosure explaining that angle 1812 “may be any angle less than 90 degrees.” Ex.2021, 34:2-5. Meaning that the second bore may be 89.99 degrees to the third longitudinal axis.
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 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 2. Ex.2020, p. 18.	Exhibit 2021, 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	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 3. Ex.2020, p. 18.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

Cl. No.	Substitute Claim Text ²	Support in Application 17/323,923 ³	Support in Application 12/658,680 ⁴
	bore at the first aperture.		
Substitute Claim 19			
	The assembly of claim [[3]] 18 , wherein the head portion of the first member comprises a torque transmitting aperture.	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 4. Ex.2020, p. 18.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 20			
	The assembly of claim [[1]] 16 , wherein the first aperture of the third member is aligned on the first bore axis, and further wherein the first exterior surface of the third member is a top exterior surface of the terminal end, and further wherein the second exterior surface of the third member is the side exterior surface of the third member.	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 5. Ex.2020, p. 18. <i>See also</i> written disclosure support identified for claim limitation 16[d].	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. <i>See also</i> written disclosure support identified for claim limitation 16[d].
Substitute Claim 21			
	The assembly of claim [[5]] 20 , wherein the head portion of the first	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

Cl. No.	Substitute Claim Text ²	Support in Application 17/323,923 ³	Support in Application 12/658,680 ⁴
	member resides at least partially within the first bore.	originally filed Claim 6. Ex.2020, p. 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 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 7. Ex.2020, p. 18.	Exhibit 2021, 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 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 8. Ex.2020, p. 19.	Exhibit 2021, 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 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 9. Ex.2020, p. 19.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
Substitute Claim 25			
	The assembly of claim [[1]] 16 , wherein the first end of the first member includes a	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

Cl. No.	Substitute Claim Text ²	Support in Application 17/323,923 ³	Support in Application 12/658,680 ⁴
	self-tapping edge for removing bone material.	originally filed Claim 10. Ex.2020, p. 19.	
Substitute Claim 26			
	The assembly of claim [[10]] 25 , wherein the first end of the second member includes a self-tapping edge for removing bone material.	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 11. Ex.2020, p. 19.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.
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, <u>and further wherein the first exterior surface of the third member is a top exterior surface of the terminal end, and further wherein the second exterior surface of the third member is the side exterior surface of the third member.</u>	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 13. Ex.2020, p. 20. <i>See also</i> written disclosure support identified for claim limitation 16[d].	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18. <i>See also</i> written disclosure support identified for claim limitation 16[d].
Substitute Claim 29			
	The assembly of claim [[13]] 28 , wherein the head	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

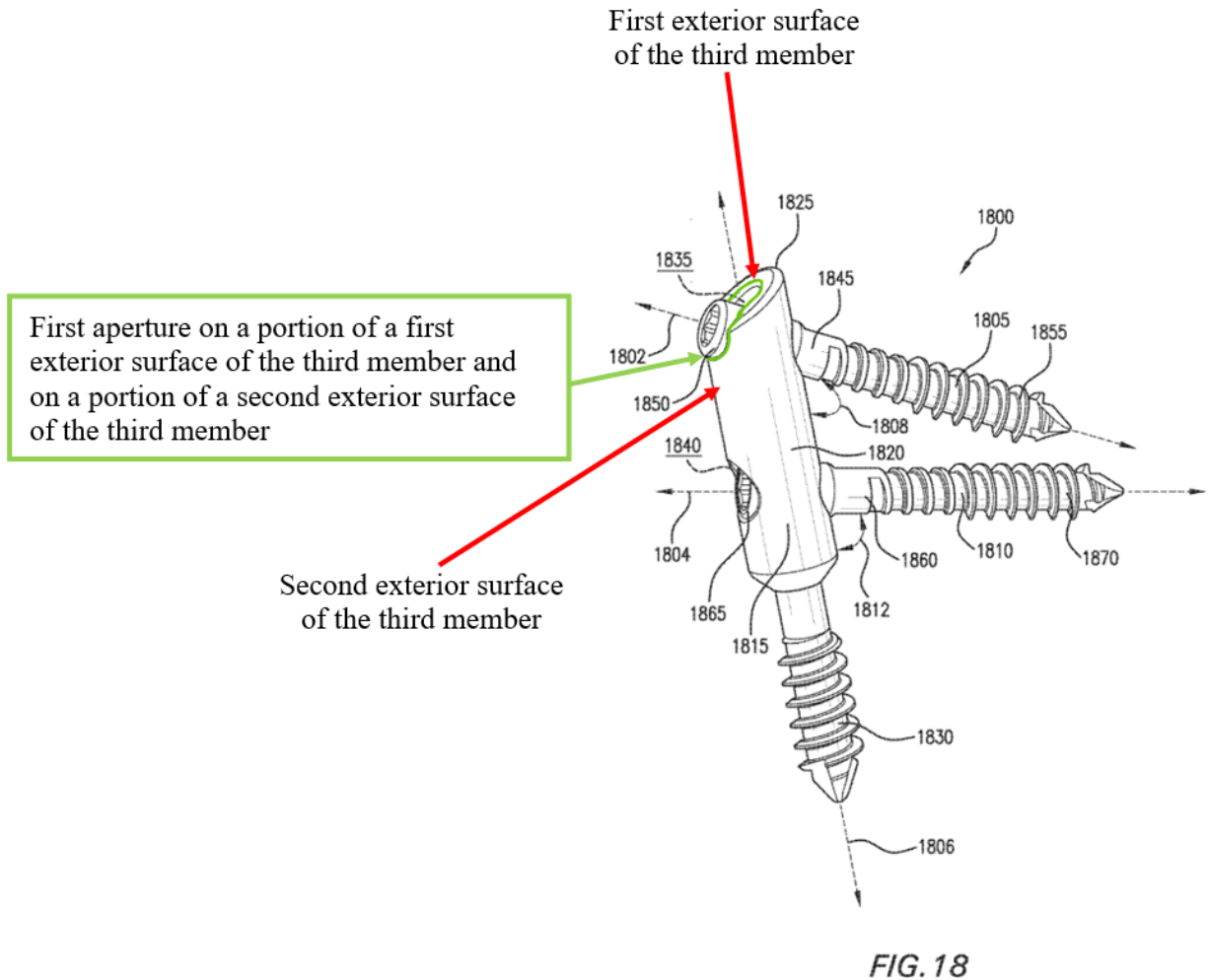
Cl. No.	Substitute Claim Text ²	Support in Application 17/323,923 ³	Support in Application 12/658,680 ⁴
	portion of the first member is tapered.	also supported by originally filed Claim 14. Ex.2020, p. 20.	
Substitute Claim 30			
	The assembly of claim ~~[[12]]~~ 27, wherein the head portion of the first member is tapered.	Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18. This limitation is also supported by originally filed Claim 15. Ex.2020, p. 20.	Exhibit 2021, p. 21-27, 35-37, 40-54; Figs. 9-11, 18.

16. 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.

17. As set forth above, the substitute independent claims add the following limitation to the existing scope of the original independent claims: “wherein the first aperture is on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member.”

18. It is my opinion that a POSITA would have understood at the time of the claimed invention that this limitation is supported in Application 17/323,923 and Application 12/658,680.

19. For example, Figure 18 of the '166 Patent, set forth below, shows an embodiment of this specific claimed configuration (annotations added to show the specifically claimed “first aperture”).



20. Specifically, as can be seen in the above annotated figure, Figure 18 clearly shows that the first aperture is on both a portion of a first exterior surface of the third member and a portion of a second exterior surface of the third member. I

understand that Petitioner's expert, Mr. Dominguez, confirmed that the first aperture shown in Figure 18 is on two exterior surfaces of the third member.

Ex.2022, 111:19-112:1 (**Q.** ... [I]s this aperture where my mouse is and where the green is on this Figure 18 [of the '166 Patent], is that an aperture that's on the top surface of member 1815 as well as on the side surface – side exterior surface of the same member? **A.** Yeah, ... I see the opening in green indicating part of it is on the top surface, part of it is on the side surface of the nail.”).

21. In light of the above, it is 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

22. It is my opinion that the meaning of the new limitation 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 a Third Member Having a First Aperture on a Portion of a First Exterior Surface of the Third Member and on a Portion of a Second Exterior Surface of the Third Member

23. The substitute independent claims, Claims 16 and 27, add the following limitation to the existing scope of the original independent claims:

“wherein the first aperture is on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member.”

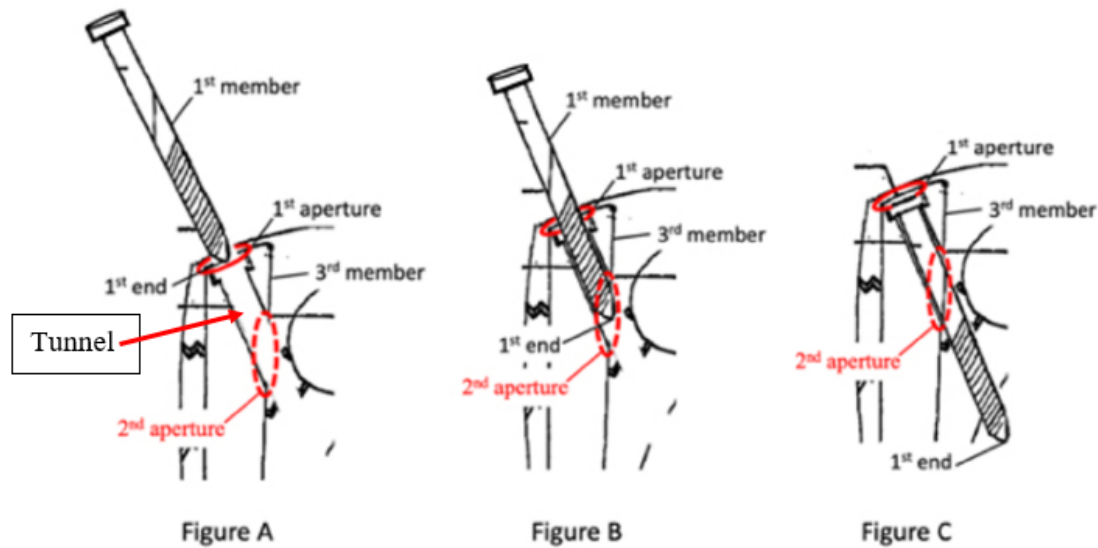
24. The Petition in this proceeding cites five prior art references for its alleged grounds of invalidity: French Patent Application Publication No. FR 2,861,576 (“Cognet”); U.S. Patent No. 4,827,917 (“Brumfield”); U.S. Patent Application Publication No. 2003/0187447 (“Ferrante”); U.S. Patent Application 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.

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

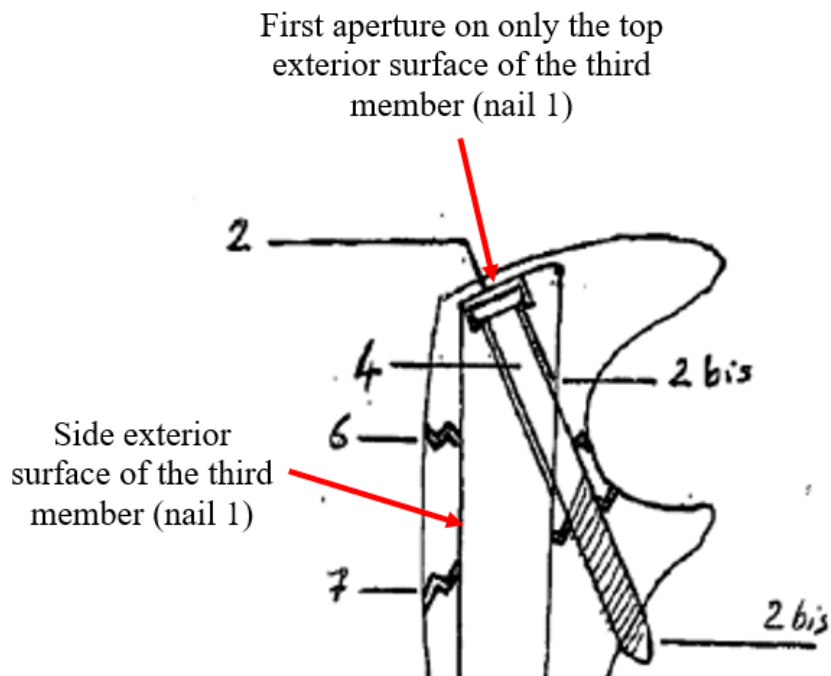
1. Cognet (Ex.1004) Does Not Disclose the New Limitation

26. 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 (shown in Figure A, below), through the tunnel running through the third member/nail (shown in Figure

B, below), and out of the second aperture (shown in Figure C, below), as shown by Figure 1 of Cognet. Paper 1 at 20-21.



27. As shown in the annotated image below of Cognet's Figure 1, however, the first aperture of the third member/nail is clearly only provided on one exterior surface of the third member (i.e., the top surface) and therefore Figure 1 of Cognet does not disclose a first aperture that is "on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member," as required by all the proposed substitute claims.



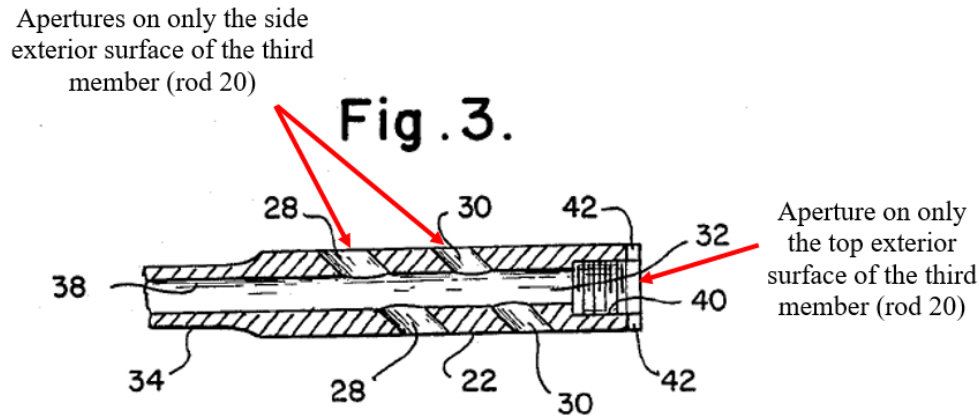
Ex.1004 at Figure 1. There is no other disclosure in Cognet that teaches this limitation.

28. As such, it is my opinion that Cognet does not teach or disclose an assembly for bone fusion “wherein the first aperture is on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member,” as required by all the proposed substitute claims.

2. Brumfield (Ex.1006) Does Not Disclose the New Limitation

29. Brumfield likewise does not disclose an aperture that is on two different exterior surfaces of the third member (Brumfield’s rod 20), as required by all the substitute claims. Rather, Brumfield discloses a rod (20) that has apertures either on just the top surface of the rod or on just the exterior side surface of the

rod (but not one aperture on both surfaces), as shown below in annotated Figure 3 of Brumfield:



Ex.1006 at Figure 3.

30. There is no other disclosure in Brumfield that teaches an assembly for bone fusion that includes a third member having a first aperture that is “on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member,” as required by all the proposed substitute claims.

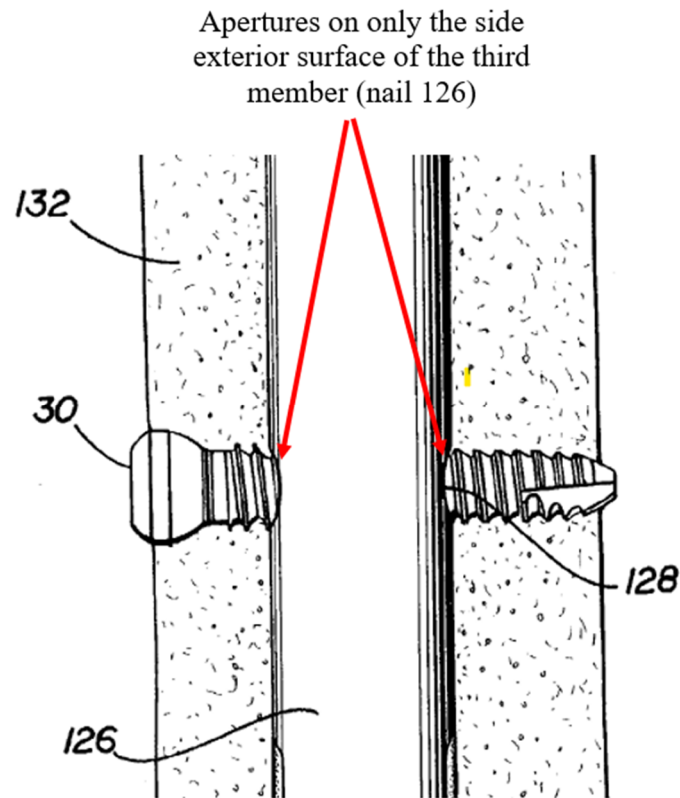
31. As such, it is my opinion that Brumfield does not teach or disclose an assembly for bone fusion “wherein the first aperture is on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member,” as required by all the proposed substitute claims.

3. Ferrante (Ex.1007) Does Not Disclose the New Limitation

32. Ferrante also does not disclose an aperture that is on two different exterior surfaces of the third member (Ferrante’s nail 126), as required by all the

substitute claims. Rather, Ferrante discloses a nail (126) that has apertures on only a side exterior surface of the nail, as shown below in annotated Figure 15 of

Ferrante:



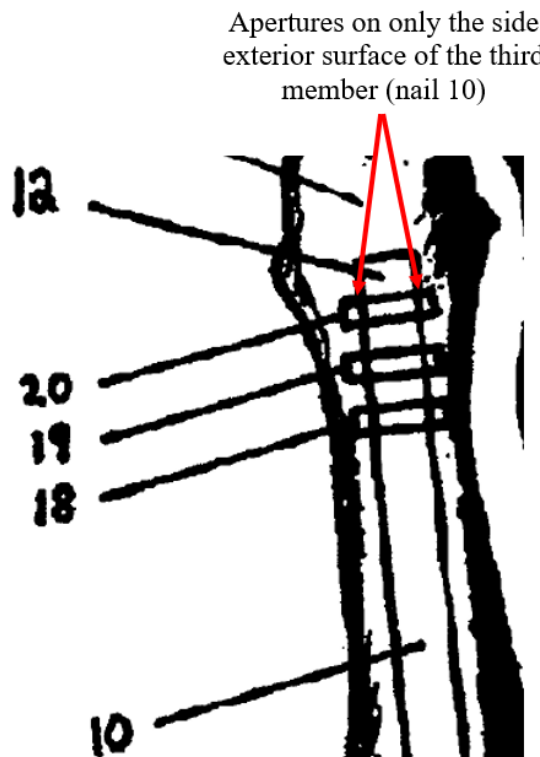
Ex.1007 at Figure 15.

33. There is no other disclosure in Ferrante that teaches an assembly for bone fusion that includes a third member having a first aperture that is “on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member,” as required by all the proposed substitute claims.

34. As such, it is my opinion that Ferrante does not teach or disclose an assembly for bone fusion “wherein the first aperture is on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member,” as required by all the proposed substitute claims.

4. Simon (Ex.1008) Does Not Disclose the New Limitation

35. Simon also does not disclose an aperture that is on two different exterior surfaces of the third member (Simon’s nail 10), as required by all the substitute claims. Rather, Simon discloses a nail (10) that has apertures on only a side exterior surface of the nail, as shown below in annotated Figure 1 of Simon:



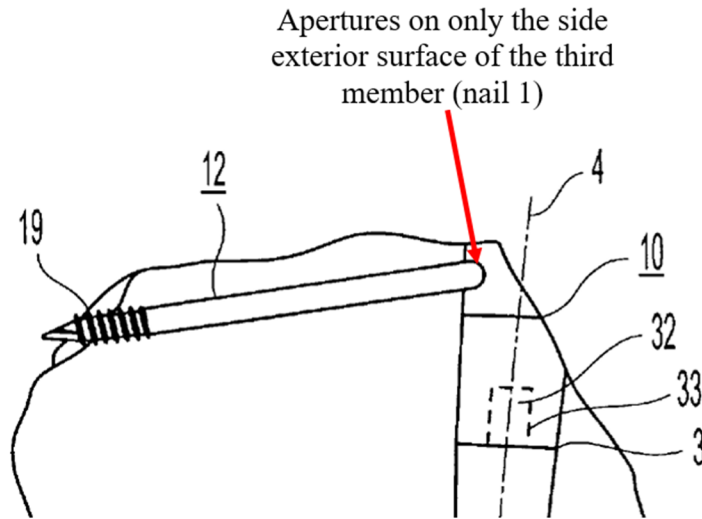
Ex.1008 at Figure 1.

36. There is no other disclosure in Simon that teaches an assembly for bone fusion that includes a third member having a first aperture that is “on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member,” as required by all the proposed substitute claims.

37. As such, it is my opinion that Simon does not teach or disclose an assembly for bone fusion “wherein the first aperture is on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member,” as required by all the proposed substitute claims.

5. Leu (Ex. 1009) Does Not Disclose the New Limitation

38. Leu does not disclose an aperture that is on two different exterior surfaces of the third member (Leu’s nail 1), as required by all the substitute claims. Rather, Leu discloses a nail (1) that has apertures on only a side exterior surface of the nail, as shown below in annotated Figure 1 of Leu:



Ex.1009 at Figure 1.

39. There is no other disclosure in Leu that teaches an assembly for bone fusion that includes a third member having a first aperture that is “on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member,” as required by all the proposed substitute claims.

40. As such, it is my opinion that Leu does not teach or disclose an assembly for bone fusion “wherein the first aperture is on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member,” as required by all the proposed substitute claims.

VIII. CONCLUSION

41. 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 first aperture is on a portion of a first exterior

surface of the third member and on a portion of a second exterior surface of the third member,” 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 June 20, 2024

By: _____

Eric H. Ledet