

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
Patent 11,298,166

**PETITIONER OPPOSITION
TO REVISED MOTION TO AMEND**

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PETITIONER’S UPDATED LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,298,166 B2 to Jeff Tyber, <i>et al.</i> , filed on May 18, 2021, issued on April 12, 2022. (“166 patent”).
1002	Expert Declaration by Leonel Dominguez
1003	French Patent Publication No. FR2,861,576 A1 to Cognet Jean Michel, filed on October 31, 2003, published on May 6, 2005. (“Cognet”)
1004	French Patent Publication No. FR2,861,576 A1 to Cognet Jean Michel, filed on October 31, 2003, published on May 6, 2005. Translated into English. (“Cognet”).
1005	Cognet Translation Affidavit
1006	U.S. Patent No. 4,827,917 to David L. Brumfield, filed on December 30, 1986, issued on May 9, 1989. (“Brumfield”).
1007	U.S. Patent Application Publication No. 2003/0187447 to Joseph Ferrante, <i>et al.</i> , filed on April 7, 2003, published on October 2, 2003. (“Ferrante”).
1008	U.S. Patent Application Publication No. 2006/0206044 to William Simon, filed on August 1, 2003, published on September 14, 2006. (“Simon”).
1009	U.S. Patent No. 6,270,499 B1 to Dieter Leu, <i>et al.</i> , PCT filed on October 20, 1997; PCT published on April 29, 1999; issued on August 7, 2001. (“Leu”)
1010	Extremity Medical, LLC’s Response to Defendant Fusion Orthopedics, LLC’s First Set of Interrogatories (Nos. 1-6). No. CV-22-00723-PHX-GMS.
1011	Case Management Order, No. CV-22-00723-PHX-GMS, Document 49, Filed December 16, 2022.
1012	Memorandum: Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation, June 21, 2022
1013	Declaration of Corby R. Vowell in Support of Pro Hac Vice Admission
1014	U.S. Patent No. 9,044,282 B2 to Jeff Tyber, <i>et al.</i> , filed on February 11, 2010, issued on June 2, 2015. (“282 patent”).
1015	U.S. Patent No. 9,044,282 file history selections (“680 application”)
1016	U.S. Patent Application Serial No. 12/906,454, filed on October 10, 2010, file history selections
1017	Transcript of Deposition of Eric H. Ledet, Ph.D., April 15, 2024
1018	Second Expert Declaration of Leonel Dominguez
1019	U.S. Patent No. 6,056,753 to Roger P. Jackson, filed on July 13, 1998, issued on May 2, 2000 (“Jackson”)

1020	U.S. Patent Application Publication No. 2006/0200147 A1 filed by Michael Ensign, <i>et al.</i> on February 17, 2006, published on September 7, 2006 (“Ensign”)
1021	U.S. Patent No. 5,562,670 to Per-Ingvar Brånemark, filed on April 26, 1994, issued on October 8, 1996 (“Brånemark”)
1022	U.S. Patent No. 10,639,076 to Eric H. Ledet, <i>et al.</i> , filed on March 12, 2018, issued on May 5, 2020
1023	Ledet et al., “Novel lumbrosacral axial fixation techniques.” <i>Expert Rev. Med. Devices</i> , 3(3), 327–334 (2006).
1024	U.S. Patent Application Publication No. 2017/0100174 A1 filed by Himanshu Mishra, <i>et al.</i> , on October 11, 2016, published on April 13, 2017 (“Mishra”)
1025	U.S. Patent No. 4,726,121 to Charles D. Ray, <i>et al.</i> , filed on March 9, 1987, issued on February 23, 1988 (“Ray”)
1026	U.S. Patent No. 4,327,770 to Peter W. Brown, <i>et al.</i> , filed on November 23, 1979, issued on May 4, 1982 (“Brown”)
1027	U.S. Patent No. 5,908,024 to Victor S. Staev, filed on November 21, 1997, issued on June 1, 1999 (“Staev”)
1028	U.S. Patent Application Publication No. 2008/0202235 A1 filed by Larry D. Laps, <i>et al.</i> , on July 20, 2006, published on August 28, 2008 (“Laps”)
1029	U.S. Patent No. 4,753,234 to Miguel Martinez, filed on November 3, 1986, issued on June 28, 1988 (“Martinez”)
1030	U.S. Patent No. 5,522,843 to Kerry Zang, filed on February 23, 1994, issued on June 4, 1996 (“Zang”)
1031	U.S. Patent No. 6,097,592 to Yeol-Gu Seo, et al., filed on October 16, 1997, published on August 1, 2000 (“Seo”)
1032	U.S. Patent No. 4,286,453 to Klaus Exner, filed on May 16, 1979, issued on September 1, 1981 (“Exner”)
1033	Spanish Patent No. ES 2,164,543 B1 to López-Oliva Munõz English translation and translation certification (“Lopez”)
1034	Computer file Fig-18.blend (paper placeholder filed)
1035	Computer file Fig-9.blend (paper placeholder filed)
1036	Still images from Fig-18.blend
1037	Still images from Fig-9.blend
1038	Still image from Fig-18.blend marked by Dr. Ledet
1039	U.S. Patent No. 4,846,162 to J. David Moehring, filed on September 14, 1987, issued on July 11, 1989 (“Moehring”)
1040	U.S. Patent Application Publication No. 2010/0160967 to Joseph Capozzoli, filed on December 22, 2009, published on June 24, 2010 (“Capozzoli”)
1041	U.S. Patent Application Publication No. 2009/0118733 to James Edward Orsak, <i>et al.</i> , filed on October 31, 2008, published on May 7, 2009 (“Orsak”)

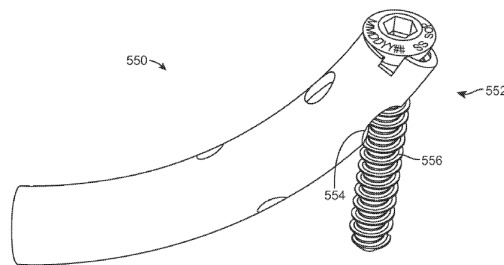
1042	U.S. Patent No. 4,535,764 to Edward A. Ebert, filed on April 15, 1983, issued on August 20, 1985 (“Ebert”)
1043	U.S. Patent No. 7,442,195 to Alfred F. Behrens, filed on September 12, 2005, issued on October 28, 2008 (“Behrens”)
1044	U.S. Patent No. 6270528 to William F. McKay, filed on August 6, 1999, issued on August 7, 2001 (“McKay”)
1045	Computer file Fig-18-final.blend (paper placeholder filed)
1046	Computer file Fig-9-final.blend (paper placeholder filed)
1047	Video Fig-18-final.mp4
1048	Video Fig-9-final.mp4
1049	Still images from Fig-18-final.blend
1050	Still images from Fig-9-final.blend
1051	Declaration of Eli Jacobson
1052	Declaration of Scott Kamholz
1053	Spanish Patent No. ES 2,164,543 B1 to López-Oliva Munõz, filed on July 19, 1999, published on February 16, 2002, issued on May 16, 2003
1054	Third Expert Declaration of Leonel Dominguez
1055	Transcript of Deposition of Eric H. Ledet, Ph.D., July 12, 2024
1056	U.S. Patent Application Publication No. 2011/0087227 A1 to Mazur <i>et al.</i> , filed December 18, 2009, published April 14, 2011 (“Mazur”)
1057	U.S. Provisional Patent Application Ser. No. 61/138,920, filed December 18, 2008 (“Mazur Provisional”)
1058	Chinese Utility Model No. CN2513533Y to Zhang <i>et al.</i> , published October 2, 2002, English translation and certification (“Zhang”)
1059	Chinese Utility Model No. CN2513533Y to Zhang <i>et al.</i> , published October 2, 2002
1060	U.S. Patent Application Publication No. 2011/0022173 A1 to Melkent <i>et al.</i> , filed July 24, 2009, published January 27, 2011 (“Melkent”)
1061	U.S. Patent No. 4,622,959, issued November 18, 1986 to Marcus (“Marcus”)
1062	U.S. Patent No. 6,579,293 B1 to Chandran, issued June 17, 2003 (“Chandran”)
1063	U.S. Patent Application Publication No. 2008/0221623 A1 to Gooch, published September 11, 2008 (“Gooch”).
1064	Additional still images from Fig-18-final.blend

I. THE PROPOSED NEW CLAIMS ARE UNPATENTABLE.

A. Mazur anticipates, or renders obvious, proposed claims 16–30.

Mazur US 2011/0087227 A1 was filed Dec. 18, 2009 and claims the benefit of provisional application Ser. No. 61/138,920 filed Dec. 18, 2008 containing near-identical specification and drawings. Mazur is effective prior art as of its provisional date because claim 1 of Mazur is fully supported by its provisional application, as shown below. Ex. 1054 ¶¶ 1–5.

Mazur discloses a bone fixation device having a hub 550 with a series of holes through which screws e.g. 556 pass to anchor the hub in bone. Figure 16A shows the hub and one screw that passes in through the end of the hub and out through hole 554, while another screw may pass through the more distal set of holes (Ex. 1054 ¶ 6):

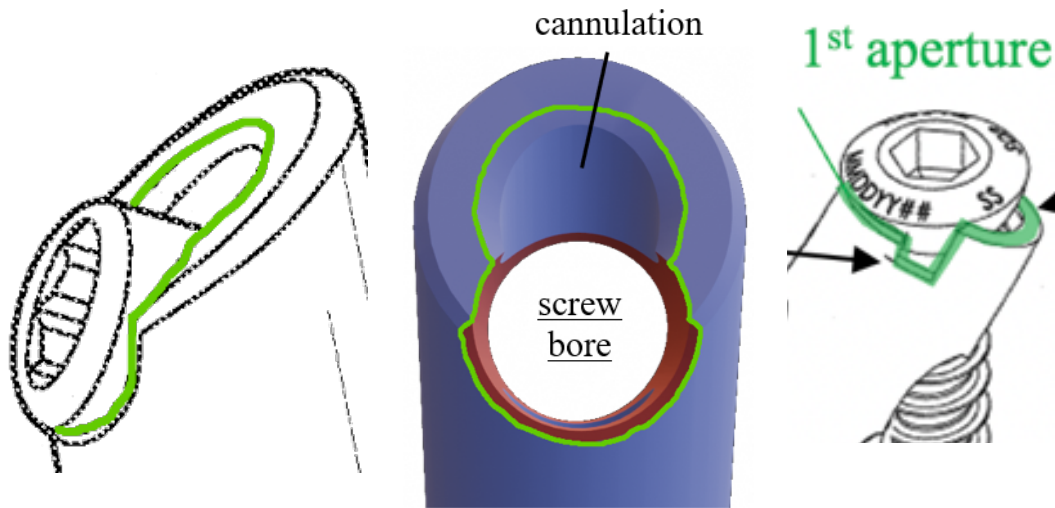


Mazur, Fig. 16A

Mazur discloses the newly-added 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” because the end of the hub Mazur’s screw passes through has a notch cut out of the hub sidewall. The end opening is on a top

exterior surface of the hub, and the notch, which is contiguous with the end opening, is on the side exterior surface. Ex. 1054 ¶ 7.

The opening Patent Owner identifies in Figure 18 as the recited “first aperture” similarly is composed from multiple contiguous voids resulting from the intersection of the nail hollowing (or “cannulation,” as described at Ex. 1001, 13:56–58), and the screw bore:



RMTA 7 (detail)

Ex. 1064, 3 (detail)

Mazur, Fig. 16A detail
(annotated)

The left view, above, is adapted from RMTA 7. The middle view is taken from additional stills Mr. Dominguez generated from the 3D model of Figure 18 (Ex. 1045) prepared for Petitioner’s Opposition to the first Motion to Amend. Ex. 1064, 3. In this view, the first member is removed, and the view is aligned along the first bore axis. As these views show, Patent Owner’s “first aperture” has several sharp corners where the contiguous voids intersect. In the right-most view

above, Mazur's aperture is traced in green. Because the Patent Owner relies on contiguous voids to trace out a "first aperture" in its figure, Mazur's open end on a top exterior surface and its contiguous sidewall notch on a side exterior surface together meet this limitation. Ex. 1054 ¶ 8.

Although Figure 16A shows a curved hub, Mazur discloses that the hub may instead be "straight." Ex. 1056 ¶ [0094]. Mr. Dominguez highlights numerous other places where Mazur emphasizes interchangeability of parts. Ex. 1054 ¶ 10 (citing Ex. 1056 Abstract and ¶¶ [0060], [0088]). An example of a straight hub is shown in Figure 7:

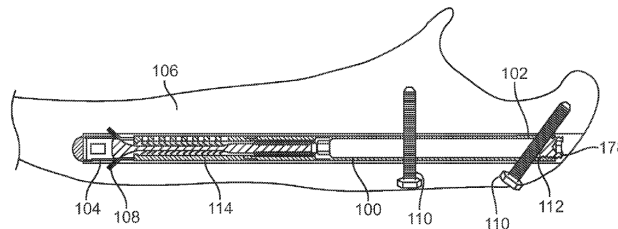
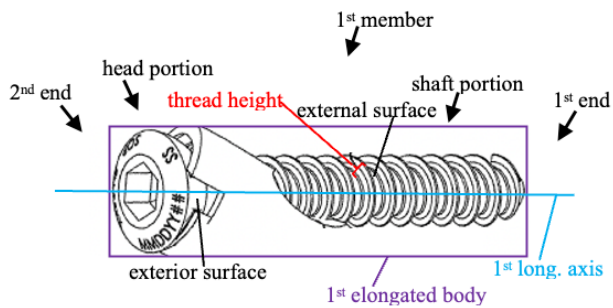
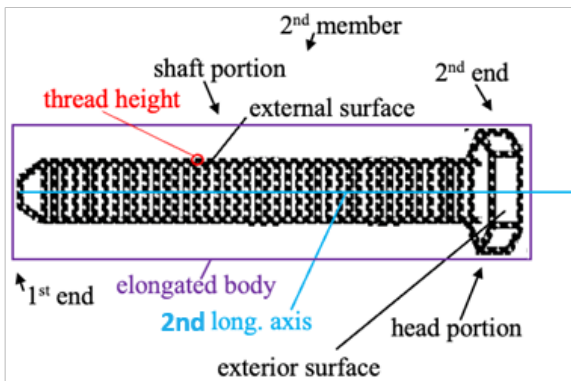


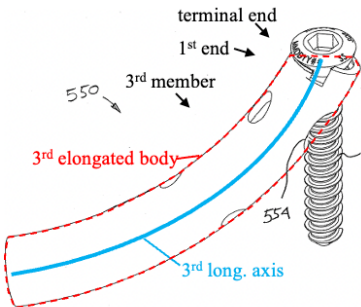
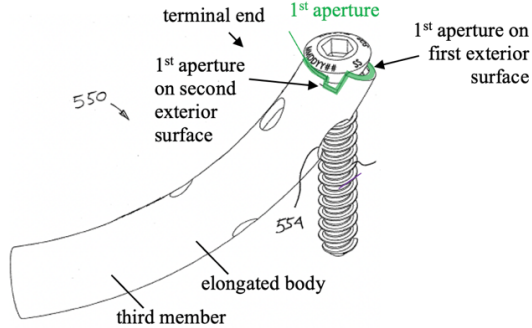
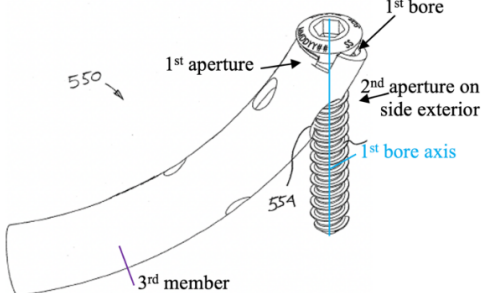
FIG. 7

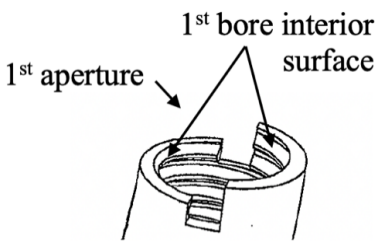
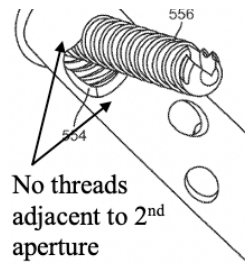
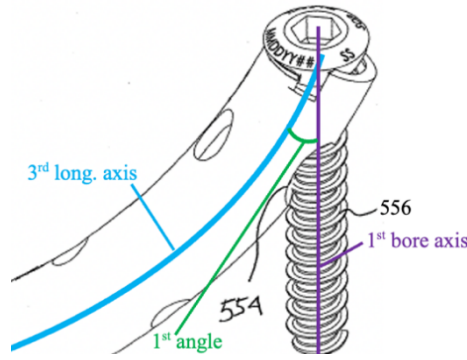
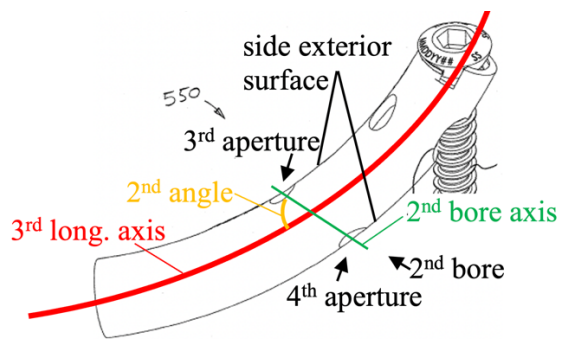
Ex. 1054 ¶ 9. In Mr. Dominguez's opinion, the resulting embodiment has a first screw passing through the notched open end of a straight hub, and a second screw passing through another pair of apertures at an angle substantially perpendicular to the straight hub, as shown for screw 110 in Figure 7. Ex. 1054 ¶ 11.

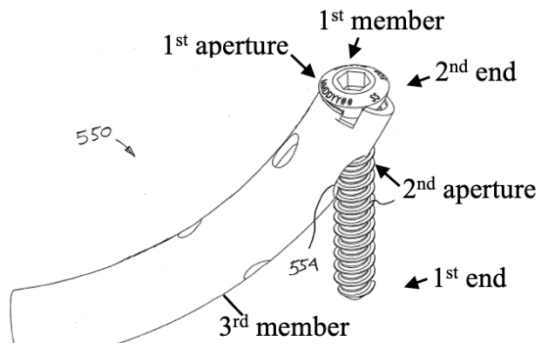
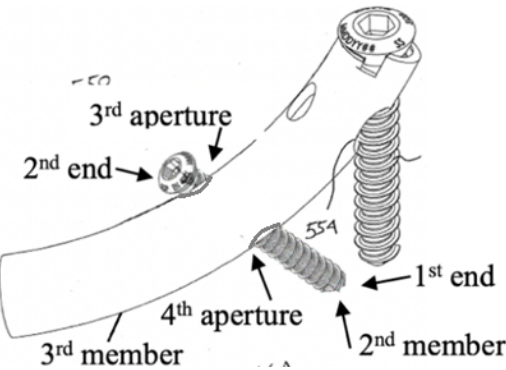
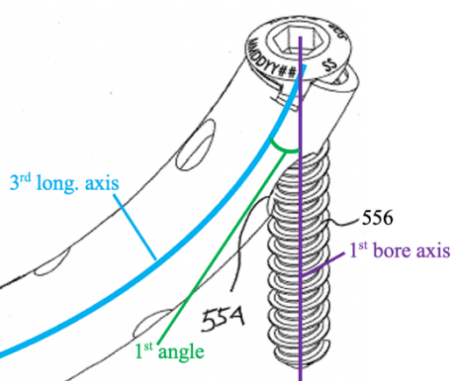
As shown in the following table and Mr. Dominguez's third declaration (Ex. 1054 ¶ 12), Mazur anticipates each of the proposed new claims either expressly as shown and described for Figure 16A or by disclosure elsewhere in the

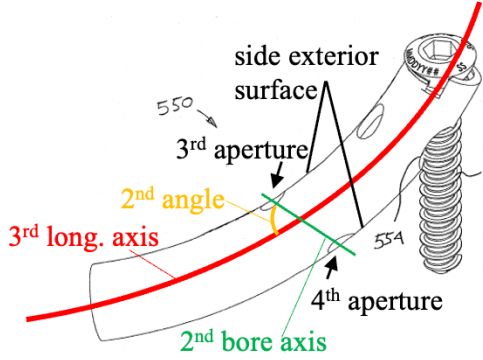
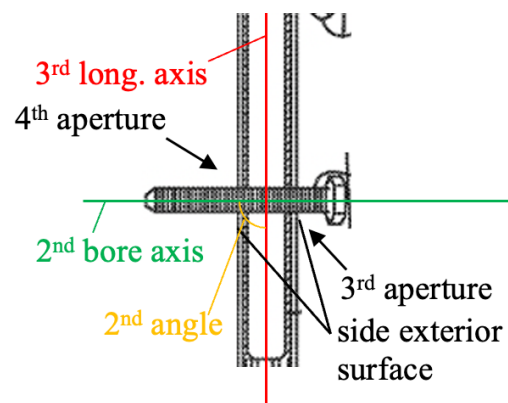
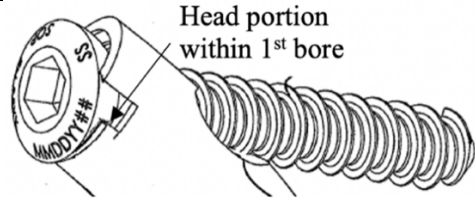
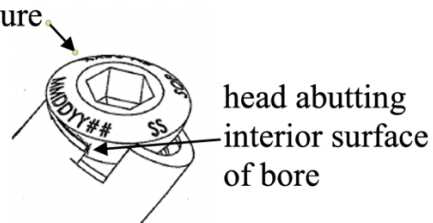
application that is applicable to the various hub embodiments.

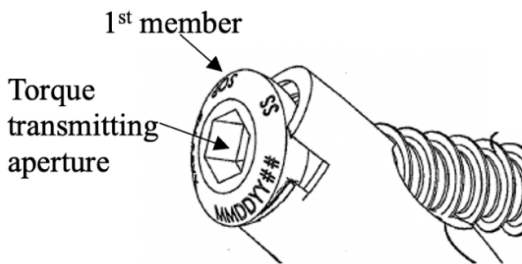
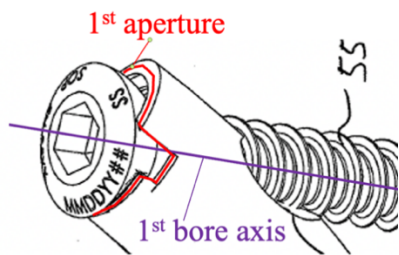
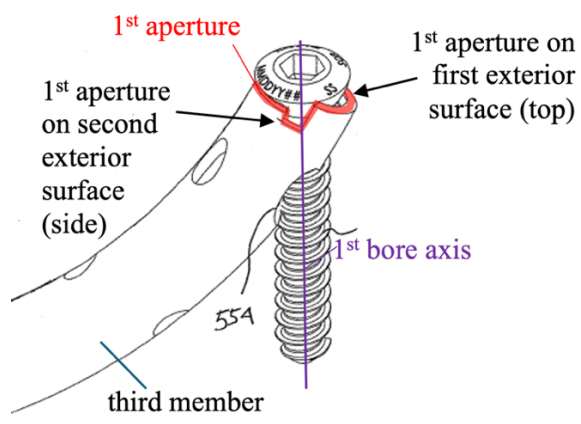
Claim	Limitation	Ex. 1056 Mazur; Ex. 1057 Mazur provisional (where different)
16a/ 27a	1. An assembly for bone fusion, comprising:	[0011] “bone fixation device”
16b/ 27b	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion 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;	 Fig. 16A detail (annotated)
16c/ 27c	a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;	 Fig. 7 detail (annotated)

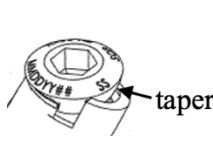
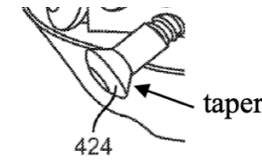
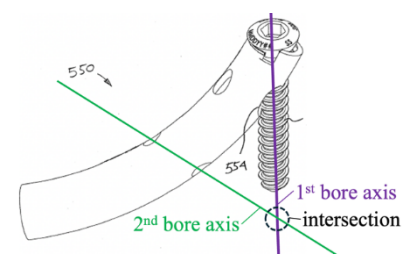
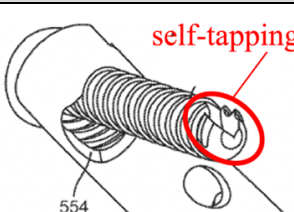
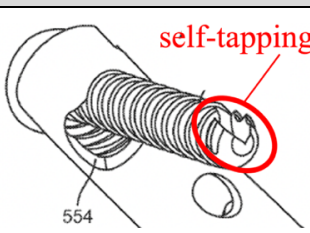
16d/ 27d	a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis,	 Fig. 16A (annotated) [0094] ([0093] <i>in prov.</i>) “Further, a straight, curved, flexible, rigid, or no hub at all may be used with the above combinations.”
16e/ 27e	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>	 Fig. 16A (annotated)
16f/ 27f	and a first bore extending along a first bore axis from the first aperture to a second aperture on a <u>side</u> exterior surface of the third member,	 Fig. 16A (annotated)

16g/ 27g	wherein the first bore comprises an interior surface at the first aperture,	 Fig. 13A detail (annotated)
16h/ 27h	wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and	 Fig. 16B detail (annotated)
16i/ 27i	wherein the third longitudinal axis and the first bore axis define a first angle ,	 Fig. 16A (annotated)
16j/ 27j	wherein the third member further 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 ,	 Fig. 16A (annotated)

16k/ 27k	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,	 Fig. 16A (annotated)
16l/ 27l	wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,	 Fig. 16A (annotated) – adapted to include a second member added to the figure as implied by the holes in the third member and described for other figures, such as Fig. 7.
16m	wherein the first angle is in the range of about 0 degrees to about 90 degrees,	 Fig. 16A (annotated)

16n/ 27m	wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	 Fig. 16A (annotated)
16o/ 27n	wherein the second bore axis is substantially perpendicular to the third longitudinal axis .	 Fig. 7 (annotated)
Claim 17, 21, & 28a		
17, 21, 28a	The assembly of claim 16/20/27, wherein the head of the first member resides at least partially within the first bore.	 Fig. 16A detail (annotated)
Claim 18 & 22		
18/ 22	The assembly of claim 17/21, wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the first aperture.	 Fig. 16A detail (annotated)
Claim 19		

19	The assembly of claim 18, wherein the head of the first member comprises a torque transmitting aperture.	 Fig. 16A detail (annotated)
	Claim 20 & 28b	
20a	The assembly of claim 16/27, wherein the first aperture of the third member is aligned on the first bore axis ,	 Fig. 16A detail (annotated)
20b/ 28b	<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>	 Fig. 16A (annotated)
	Claim 23, 29, & 30	

23, 29, 30	The assembly of claim 16/28/27, wherein the head portion of the first member is tapered .	  Fig. 16A detail (annotated) Fig. 12G detail (annotated) [0079] ([0081] in provisional) “The heads of screws 110 may be configured to be self-countersinking”
Claim 24		
24	The assembly of claim 16, wherein the first bore axis and the second bore axis intersect outside the third member.	 Fig. 16A (annotated)
Claim 25		
25	The assembly of claim 16, wherein the first end of the first member includes a self-tapping edge for removing bone material.	 Fig. 16B detail (annotated)
Claim 26		
26	The assembly of claim 25, wherein the first end of the second member includes a self-tapping edge for removing bone material.	 Fig. 16B detail (annotated) The second member is another instance of the first member and thus would include all of the properties of the first member. [0097] ([00096] in provisional) “holes 408 and 414 are aligned to receive a second bone screw”

Mazur's provisional supports Mazur claim 1 as follows (Ex. 1054 ¶ 13):

Ex. 1056, 11	Ex. 1057
1. An implantable bone fixation device comprising:	[0011] “a bone fixation device”
an elongate body having a flexible state and a rigid state;	[0069] “body portion 114 changes from being flexible to rigid”
a rigid hub connected to a proximal end of the elongated body,	[0012] “a hub located on a proximal end of the elongated body” [0093] “a straight, curved, flexible, rigid, or no hub at all may be used”
the hub having an array of pilot holes over a portion of an outer surface,	[0116] “Slots 702 permit in vivo screw hole formation by acting as long pilot holes for drill bits or bone screws.”
each of the pilot holes being configured to expand upon receipt of a fastener therethrough; and	[0116] “A bone screw tip may be inserted into one of the slots 702 without pre-drilling. Upon insertion, the slot and surrounding slots will deform to make way for the screw”
an actuator operably connected to the elongate body for changing the body from the flexible state to the rigid state.	[0069] “continued rotation of actuator 126 draws the proximal end 102 and the distal end 104 of device 100 closer together until cuts 116 are substantially closed. As this happens, body portion 114 changes from being flexible to rigid”

It is also Mr. Dominguez's opinion that Mazur renders each proposed claim obvious. The portions of Mazur disclosing that features of one embodiment apply to others, in particular the statement in Mazur paragraph [0094] (prov. [0093]) that “a straight, curved, flexible, rigid, or no hub at all may be used with the above combinations,” also suggest to the person having ordinary skill in the art (“POSA”) to modify the embodiment shown in Figure 16A to have a straight hub. Mazur's extensive description of straight-hubbed embodiments show how to

implement such an embodiment with a reasonable expectation of success. Mazur discloses all the remaining embodiments of the proposed claims in the manner discussed above. For these reasons, a POSA would have found it obvious from Mazur to reach the subject matter of every proposed claim. Ex. 1054 ¶ 14.

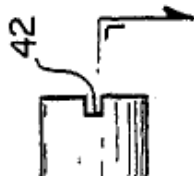
B. Cognet and Zhang render obvious claims 16–22, 24, and 27–28.

Patent Owner argues only that Cognet lacks the new limitation requiring that the first aperture be “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.” RMTA 19–20.

Cognet discloses an intramedullary nail assembly for promoting “osteosynthesis,” i.e., fixation of fractured bone. Ex. 1004, 4:31. Cognet explains that an “ancillary” is used to “facilitate the fitting” of the nail into the receiving bone. Ex. 1004, 4:31–33. As Mr. Dominguez explains, this “ancillary” is a tool that is attached temporarily to the top surface of the intramedullary nail in order to drive the nail into the receiving bone to the correct depth and rotation in order to align the screw bore with the fracture to be repaired. Ex. 1054 ¶¶ 15–16. The ancillary is keyed to the top of the nail in such a way that would allow force and torque applied to the tool to be transmitted to the nail. *Id.* As Mr. Dominguez explains, this was commonly done by means of a slot formed in the nail top, such as a slot for receiving a screwdriver. *Id.* The ancillary could simply be a screwdriver that fits into the slot in order to receive mallet strikes to drive the nail into

bone and to twist the nail to the correct angle. *Id.* The walls of the screwdriver slot provide a “stop” against which the screwdriver could be twisted in order to transmit torque and adjust the rotational position of the nail. *Id.* Or the ancillary could be a more sophisticated tool permitting other maneuvers, such as “perform[ing] the screw placement using automatic sighting.” Ex. 1004, 4:33–34; Ex. 1054 ¶ 17.

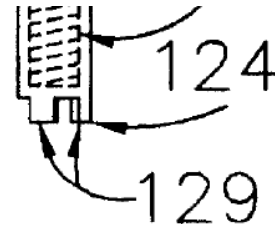
Numerous examples of such slots on nail ends exist in the art, including Brumfield’s slot 42, Marcus’s slot 62, and Chandran’s slots 129:



Brumfield (Ex. 1006),
Fig. 2 detail



Marcus (Ex. 1061),
Fig. 1 detail



Chandran (Ex. 1062),
Fig. 3 detail

Ex. 1006, 4:47–50 (describing slot 42 and its function); Ex. 1061, 6:5–12 (describing slot 62 and its function); Ex. 1062, 6:2–9 (describing slots 129 and their function). Ex. 1054 ¶ 17. (Patent Owner cited Marcus and Chandran during prosecution.)

By disclosing the use of an ancillary, Cognet suggested to the POSA that the top end of Cognet’s intramedullary nail 1 should be provided with some similar structure through which force and torque could be applied to the nail. Ex. 1054 ¶ 17.

Zhang, like Brumfield, Marcus, and Chandran, discloses intramedullary nail 1 with groove 4 formed in the head of the nail. Groove 4 is a slot for a screwdriver.

Ex. 1058, 4:30–34. The groove allows the user to insert a screwdriver into groove 4 and advance intramedullary nail 1 the last $\frac{1}{4}$ of the insertion depth while rotating it into the correct plane for inserting the locking nail at the appropriate angle to repair the bone fracture. Ex. 1058, 5:16–22; Ex. 1054 ¶ 18.

As Mr. Dominguez explains, a POSA would have found it obvious to implement Cognet’s instruction to use an ancillary by providing a groove in the top surface of Cognet’s intramedullary nail, as disclosed by Zhang. Ex. 1054 ¶ 19. The POSA would have done this in order to facilitate the process of inserting the nail and twisting it to the correct angle, to ensure that the tunnel for Cognet’s screw is properly aimed along a plane that intersects the fracture site. *Id.* Mr. Dominguez explains that the POSA would have oriented the screwdriver groove vertically and in the center of Cognet’s top surface, as Zhang does, in order to span the widest part of the nail and to ensure that the twisting action of the screwdriver would be aligned with the nail’s axis of rotation. *Id.*

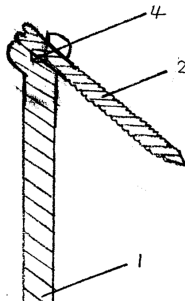
Mr. Dominguez explains that the simple and predictable nature of this modification would have given the POSA a reasonable expectation of success. Ex. 1054 ¶ 20. Mr. Dominguez explains that the modification is simple because it amounts merely to the addition of a commonplace structure (a screwdriver slot) to Cognet. *Id.* It is predictable because Cognet and Zhang share a similar geometry (a lag screw inserted through a top-facing bore of an intramedullary nail), and Zhang

clearly illustrates the result of combining the top-facing screw bore with a screwdriver slot. *Id.*

In particular, as Mr. Dominguez describes (Ex. 1054 ¶ 21), the head of Zhang’s intramedullary nail includes an “oblique hole” for receiving locking screw

2. Ex. 1058, 4:6–9. Zhang explains that the oblique hole is “provided in” groove

4. *Id.* Zhang’s figure similarly shows that the oblique hole is contiguous with groove 4 so that the aperture formed by the intersection of the oblique hole and groove 4 is on a portion of the top exterior surface of intramedullary nail 1 and also on a portion of the side exterior surface of intramedullary nail 1:

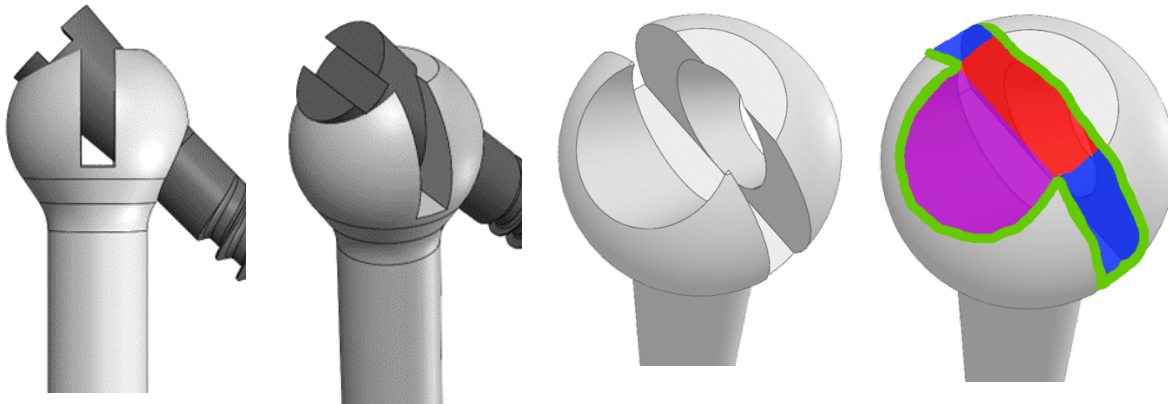


Zhang Ex. 1058 Figure (detail)



Zhang Ex. 1058 Figure (annotated)

The aperture formed on the top and side surfaces of Zhang’s intramedullary nail is best seen in the following views taken from a 3D model of Zhang’s assembly prepared by Mr. Dominguez:



Zhang 3D model,
front view

Zhang 3D model,
isometric view

Zhang 3D model,
isometric view with
screw removed

Zhang 3D model,
aperture (shaded)

Ex. 1054 ¶ 22. As can be readily appreciated in the isometric views with the screw removed, the first aperture (outlined in green) has a part on the top exterior surface shaded in red, parts on the side exterior surface shaded in blue, and a part on both the top and side exterior surfaces shaded in purple. These portions of Zhang’s first aperture are contiguous with one another as a result of the intersection of the oblique hole and the groove. *Id.*

As discussed above, Mr. Dominguez opines that the opening Patent Owner identifies in Figure 18 as the recited “first aperture” is the result of the intersection of the nail hollowing (or “cannulation,” as described at Ex. 1001, 13:56–58), and the screw bore, such that the opening from Figure 18 Patent Owner relies upon to meet the recited “first aperture” is composed from multiple voids that are contiguous with one another. Ex. 1054 ¶ 23. Patent Owner implicitly argues that its “first aperture” therefore can be formed from contiguous voids resulting from an inters-

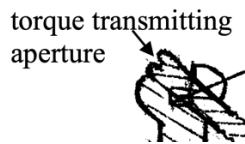
ection. Zhang's aperture is similarly formed from contiguous voids resulting from an intersection of the oblique hole and groove. For these reasons, it is Mr. Dominguez's opinion that Zhang's aperture meets the recited "first aperture." *Id.* ¶ 24.

The modification of Cognet described above would have resulted in a similar aperture on both top and side exterior surfaces of intramedullary nail 1. Ex. 1054 ¶ 25. This is because, as noted above, the POSA would position the screwdriver slot to span the middle of the nail top to maximize its width and to ensure that applied torque is centered on the nail's axis. *Id.* The void in the nail created by the screwdriver slot would intersect the void created by the screw bore, resulting in a single opening on several exterior surfaces of the nail. *Id.*

Thus, the modification Cognet suggests to its own intramedullary nail—accommodating an ancillary— would have resulted in a structure within the scope of proposed claim 16. For these reasons, proposed claims 16 and 27 would have been obvious over Cognet and Zhang. Claims 17–22, 24, and 28 (substitutes for claims 2–7, 9, and 13, respectively) would have been obvious over Cognet and Zhang because Cognet discloses the additional limitations of each of those claims, as detailed previously (Pet. 23–27, 32). Ex. 1054 ¶ 26.

With reference to claim 19 (replacing claim 4), the POSA would have assumed that Cognet discloses a torque transmitting aperture on the head portion of the first member given the ubiquity of this feature and the circular geometry of

Cognet’s screw head implying the presence of a screwdriver slot. Pet. 25; Reply 23–25; Ex. 1002 ¶¶ 42(b), 76; Ex. 1018 ¶¶ 48, 49. Zhang similarly shows a screwdriver slot (i.e., a “torque transmitting aperture”) on the top end of locking nail 2 (see figure below), thereby reinforcing the suggestion that such a feature is conventional, commonplace, and would have been obvious to include. Ex. 1054 ¶ 27.



Zhang Figure detail (annotated)

With reference to claim 20, the apertures for Cognet’s screw 4 and Zhang’s locking nail are on a top exterior surface of the intramedullary nail terminal end, and the aperture for Zhang’s screwdriver groove 4 is on the top exterior surface and also a portion of the side exterior surface of the intramedullary nail. These apertures are contiguous with one another and thereby constitute a single first aperture. Ex. 1054 ¶ 28.

C. Cognet, Zhang, and either Brumfield or Ferrante render obvious claims 19, 23, 25, 26, 29, and 30.

Claims 19, 23, 25, 26, 29, and 30 would have been obvious over Cognet, Zhang, and either Brumfield or Ferrante because Brumfield and Ferrante disclose the conventional screw features recited in each of the corresponding claims 4 (Pet. 22–34), 8 (*id.* at 34), 10 (*id.* at 34–35), 11 (*id.* at 35–36), 14 (*id.* at 35), and 15 (*id.*); Reply 25–27. Ex. 1054 ¶ 29.

With respect to claim 19 (replacing claim 4), the hexagonal inset in Brumfield's screw head, like Zhang's groove, would have been an obvious choice to include in Cognet's screw 4 as a well-known and ubiquitous design for a screwdriver to apply torque to a screw. Ex. 1006, 5:22–24; Ex. 1002 ¶ 12; Ex. 1054 ¶ 30.

With respect to claims 23, 29, and 30 (replacing claims 8, 14, and 15, respectively), a tapered head portion would have been obvious to a POSA because a tapered head portion, as evidenced by Brumfield's tapered head portion 48 (Ex. 1006, 5:20–22) is a very common screw head shape which facilitates countersinking the screw head. Ex. 1002 ¶ 103; Ex. 1054 ¶ 31.

With respect to claims 25 and 26 (replacing claims 10 and 11), the POSA would have found it obvious to employ bone screws with self-tapping ends because these are commonly used to facilitate removal of bone chips as screws are driven in bone. Pet. 35–37; Ex. 1002 ¶ 110; Reply 26–27; Ex. 1018 ¶ 52; Ex. 1054 ¶ 32.

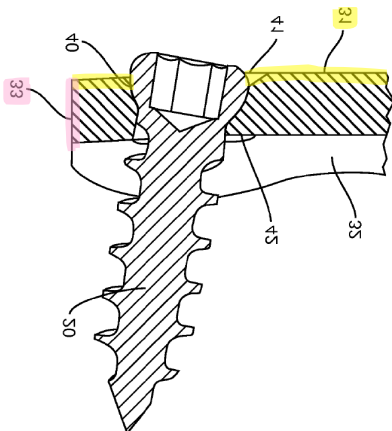
D. Cognet and Melkent or Gooch render obvious claims 16–22, 24, and 27–28.

Patent Owner argues only that Cognet lacks the new limitation requiring that the first aperture be “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.” RMTA 19–20.

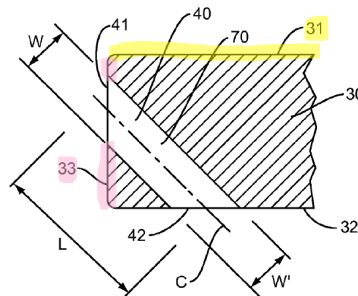
Cognet instructs the POSA to vary the angle of the proximal tunnel for screw 4 “[d]epending on the anatomical variations of the patients being operated on and

the particulars of embodiment.” Ex. 1004, 3:10–18; Ex. 1054 ¶¶ 33–34.

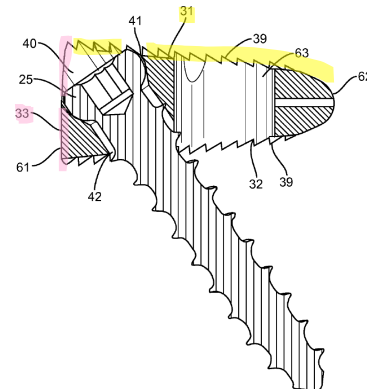
Melkent similarly discloses that screw passage angles may vary. Ex. 1060 ¶ [0040] (“The passage 40 may extend through the implant 30 at various orientations.”). In particular, Melkent explains that the aperture for its passage 40 (“first end 41”) may be positioned on the top exterior surface (“superior surface 31”) alone (Fig. 7), or on the side exterior surface (“sidewall 33”) alone (Fig. 9), or on both simultaneously (Fig. 3). These views are illustrated below, with the top surface highlighted in yellow and the side surface highlighted in pink:



Melkent Fig. 7 (rotated)



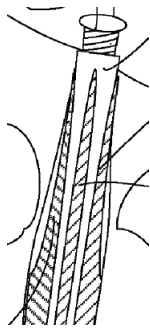
Melkent Fig. 9



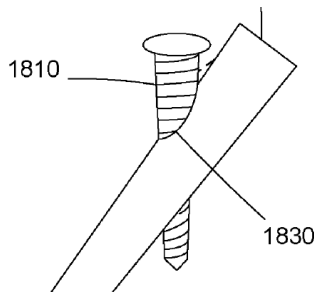
Melkent Fig. 3

Id.; Ex. 1054 ¶ 35. Melkent describes these as various “configurations” that one may select “depending upon the context of use.” Ex. 1060 ¶ [0040].

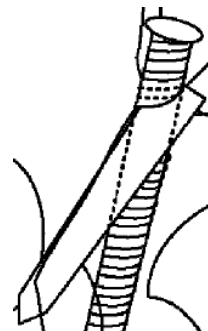
Gooch also discloses that the bore for a bone screw may be positioned on the top, side, or both top and side of a bone anchor:



Gooch Fig. 16B detail
(bore in top)



Gooch Fig. 18 detail
(bore in side)



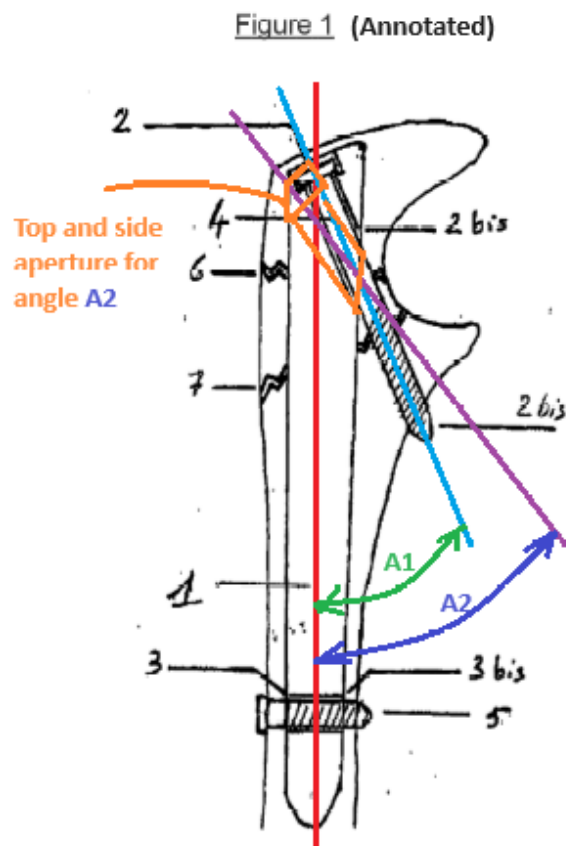
Gooch Fig. 20 detail
(bore in top and side)

Ex. 1063 ¶¶ [0094]–[0098] (describing these embodiments); Ex. 1054 ¶ 36.

(Patent Owner cited Gooch during prosecution.) Gooch explains that the screw can be inserted “directly,” “lateral[ly],” or “obliquely” as needed to achieve the required screw angle. Ex. 1063 ¶¶ [0095], [0097]; Ex. 1054 ¶ 36.

In Mr. Dominguez’s opinion, Cognet instructs the POSA to modify the screw tunnel angle as needed, and Melkent and Gooch each provide clear evidence that the POSA knew that the screw tunnel angle could be varied as required for a particular use case regardless of whether the chosen angle might cause the tunnel aperture to be positioned on a top surface, a side surface, or on both simultaneously. Ex. 1054 ¶ 37. Melkent and Gooch each show that it is an obvious matter of design choice depending upon context and that a screw tunnel that is isolated to the top exterior surface in one configuration may alternatively be positioned on both the top and side exterior surfaces as need dictates. Ex. 1060 ¶ [0040]; Ex. 1063 ¶ [0098]; Ex. 1054 ¶¶ 37- 39.

Mr. Dominguez explains that if, in response to Cognet's invitation to change the tunnel angle, the POSA wanted a slightly shallower tunnel angle to accommodate a slightly different anatomy or fracture site than shown in Cognet Figure 1, then an obvious choice would have been to tilt the tunnel so that the aperture spans the top and side exterior surfaces of Cognet:



Cognet Fig. 1 (annotated)

Ex. 1054 ¶ 40. In Mr. Dominguez's opinion, modifying Cognet to change the angle of the tunnel from angle "A1" (as annotated above in green) to "A2" (annotated in blue) would have been most readily achieved by repositioning the tunnel as shown in orange, because this modification represents a minimal change

to Cognet’s device. Ex. 1054 ¶¶ 40-41. As Mr. Dominguez explains, a POSA would have had a reasonable expectation of success because Cognet’s tunnel is already positioned at the top left corner of the intramedullary nail, and the modification would have been carried out in a manner that Melkent already taught to be a reasonable alternative. Ex. 1054 ¶¶ 40-41. Melkent’s and Gooch’s teachings about how to position apertures for screws that secure implants to vertebral bone are relevant and analogous to intramedullary nail systems such as Cognet, because such design considerations are “bone-agnostic.” Ex. 1054 ¶ 40; *see also* Ex. 1055, 10:16–11:16 (Dr. Ledet acknowledging that embodiments of his own patents that happen to be described in the context of vertebral applications are in fact “agnostic to the specific location in the body” (10:25) and “generic for bones” (11:8)).

For these reasons, proposed claims 16 and 27 would have been obvious over Cognet and Melkent Gooch. Claims 17–22, 24, and 28 (substitutes for claims 2–7, 9, and 13, respectively) would have been obvious over Cognet and Melkent or Gooch because Cognet discloses the additional limitations of each of those claims, as detailed previously (Pet. 23–27, 32). Ex. 1054 ¶ 42.

With reference to claim 19 (replacing claim 4), the POSA would have assumed that Cognet discloses a torque transmitting aperture on the head portion of the first member given the ubiquity of this feature and the circular geometry of

Cognet’s screw head implying the presence of a screwdriver slot. Pet. 25; Reply 23–25; Ex. 1002 ¶¶ 42(b), 76; Ex. 1018 ¶¶ 48, 49. Melkent similarly discloses receptacle 26 in head 25 of fastener 20 “to receive a tool for applying torque,” Ex. 1060 ¶ [0049], thereby reinforcing the suggestion that such a feature is ubiquitous and would have been obvious to include. Ex. 1054 ¶ 43.

With reference to claim 20, the aperture for Melkent’s fastener is on the top exterior surface 31 and also the side exterior surface 33. Ex. 1054 ¶ 44.

E. Cognet, Melkent or Gooch, and Brumfield or Ferrante render obvious claims 19, 23, 25, 26, 29, and 30.

Claims 19, 23, 25, 26, 29, and 30 would have been obvious over Cognet, Melkent or Gooch, and either Brumfield or Ferrante because Brumfield and Ferrante disclose the conventional screw features recited in each of the corresponding claims 4 (Pet. 22–34), 8 (*id.* at 34), 10 (*id.* at 34–35), 11 (*id.* at 35–36), 14 (*id.* at 35), and 15 (*id.*); Reply 25–27; Ex. 1054 ¶ 45.

With respect to claim 19 (replacing claim 4), the hexagonal inset in Brumfield’s screw head, like Melkent’s receptacle 26, would have been an obvious choice to include in Cognet’s screw 4 as a well-known and ubiquitous design for a screwdriver to apply torque to a screw. Ex. 1006, 5:22–24; Ex. 1002 ¶ 12; Ex. 1054 ¶ 46.

With respect to claims 23, 29, and 30 (replacing claims 8, 14, and 15,

respectively), a tapered head portion would have been obvious to a POSA because a tapered head portion, as evidenced by Brumfield's tapered head portion 48 (Ex. 1006, 5:20–22) is a very common screw head shape. Ex. 1002 ¶ 103; Ex. 1054 ¶ 47.

With respect to claims 25 and 26 (replacing claims 10 and 11), the POSA would have found it obvious to employ bone screws with self-tapping ends because these are commonly used to facilitate removal of bone chips as screws are driven in bone. Pet. 35–37; Ex. 1002 ¶ 10; Reply 26–27; Ex. 1018 ¶ 52; Ex. 1054 ¶ 48.

II. CONCLUSION

The Board should deny the revised motion to amend.

Respectfully submitted,
Fusion Orthopedics, LLC

By:

Dated: August 7, 2024

/Jennifer R. Brinkerhoff/
Jennifer R. Brinkerhoff
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6, I certify that on the date listed below, a copy of this paper and every exhibit filed with this paper was served on the following:

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