

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

IPR2023-00894
Patent 11,298,166

PETITIONER OPPOSITION TO MOTION TO AMEND

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	CLAIM CONSTRUCTION	1
A.	“At a terminal end”	1
B.	“Angle is in the range of about 0 degrees to about 90 degrees”	1
C.	“Substantially perpendicular”	2
III.	THE PROPOSED CLAIMS INTRODUCE NEW MATTER.....	3
A.	A single blanket citation does not show support for each limitation.	3
B.	Patent Owner relies on drawings for features not visible in them.	4
C.	3D models consistent with Figures 9 and 18 demonstrate that there is not necessarily abutment.	11
IV.	THE PROPOSED NEW CLAIMS ARE UNPATENTABLE.....	15
A.	Lopez anticipates claims 16–23 and 25–29	16
B.	Lopez and Brumfield render obvious claims 16–30.	23
V.	CONCLUSION	25

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 Publication No. 2003/0187447 to Joseph Ferrante, <i>et al.</i> , filed on April 7, 2003, published on October 2, 2003. (“Ferrante”).
1008	U.S. Patent Publication No. 2006/0206044 to William Simon, filed on August 1, 2003, published on September 14, 2006. (“Simon”).
1009	U.S. Patent No. 6,270,499 B1 to Dieter Leu, <i>et al.</i> , PCT filed on October 20, 1997; PCT published on April 29, 1999; issued on August 7, 2001. (“Leu”)
1010	Extremity Medical, LLC’s Response to Defendant Fusion Orthopedics, LLC’s First Set of Interrogatories (Nos. 1-6). No. CV-22-00723-PHX-GMS.
1011	Case Management Order, No. CV-22-00723-PHX-GMS, Document 49, Filed December 16, 2022.
1012	Memorandum: Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation, June 21, 2022
1013	Declaration 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 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 <i>et al.</i> , “Novel lumbrosacral axial fixation techniques.” <i>Expert Rev. Med. Devices</i> , 3(3), 327–334 (2006).
1024	U.S. Patent Publication No. 2017/0100174 A1 filed by Himanshu Mishra, <i>et al.</i> , on October 11, 2016, published on April 13, 2017 (“Mishra”)
1025	U.S. Patent No. 4,726,121 to Charles D. Ray, <i>et al.</i> , filed on March 9, 1987, issued on February 23, 1988 (“Ray”)
1026	U.S. Patent No. 4,327,770 to Peter W. Brown, <i>et al.</i> , filed on November 23, 1979, issued on May 4, 1982 (“Brown”)
1027	U.S. Patent No. 5,908,024 to Victor S. Staev, filed on November 21, 1997, issued on June 1, 1999 (“Staev”)
1028	U.S. Patent Publication No. 2008/0202235 A1 filed by Larry D. Laps, <i>et al.</i> , on July 20, 2006, published on August 28, 2008 (“Laps”)
1029	U.S. Patent No. 4,753,234 to Miguel Martínez, filed on November 3, 1986, issued on June 28, 1988 (“Martínez”)
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, <i>et al.</i> , filed on October 16, 1997, published on August 1, 2000 (“Seo”)
1032	U.S. Patent No. 4,286,453 to Klaus Exner, filed on May 16, 1979, issued on September 1, 1981 (“Exner”)
1033	Spanish Patent No. ES 2,164,543 B1 to López-Oliva Munõz English translation and translation certification (“Lopez”)
1033a	Spanish Patent No. ES 2,164,543 B1 to López-Oliva Munõz, filed on July 19, 1999, published on February 16, 2002, issued on May 16, 2003
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 Publication No. 2010/0160967 to Joseph Capozzoli, filed on December 22, 2009, published on June 24, 2010 (“Capozzoli”)
1041	U.S. Patent Publication No. 2009/0118733 to James Edward Orsak, <i>et al.</i> , filed on October 31, 2008, published on May 7, 2009 (“Orsak”)
1042	U.S. Patent No. 4,535,764 to Edward A. Ebert, filed on April 15, 1983, issued on August 20, 1985 (“Ebert”)

1043	U.S. Patent No. 7,442,195 to Alfred F. Behrens, filed on September 12, 2005, issued on October 28, 2008 (“Behrens”)
1044	U.S. Patent No. 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

I. INTRODUCTION

Patent Owner's Corrected Motion to Amend ("MTA," Paper 23) should be denied because the proposed new claims introduce new matter and are unpatentable over prior art.

II. CLAIM CONSTRUCTION

A. "At a terminal end"

Despite extensive discussion in the Institution Decision (Paper 15, "DI") and an invitation from the Board to the parties to develop the record on the meaning of "at a terminal end" (DI 13–16), Patent Owner has offered little or no new evidence to address the construction of this term, so that its scope remains unclear. Ex. 2018 ¶ 59. Instead, Patent Owner proposes a strained prosecution disclaimer argument (POR 9–14) which Petitioner addresses in its Reply. Reply 14–17. Petitioner's argument that "at a terminal end" is properly construed to mean "near a terminal end" stands unrebutted.

B. "Angle is in the range of about 0 degrees to about 90 degrees"

Every proposed new claim requires "wherein the second angle is in the range of about 0 degrees to about 90 degrees" (MTA 8, 14) and proposed new claims 16–26 also require "wherein the first angle is in the range of about 0 degrees to about 90 degrees" (MTA 8). But the only discussion of the magnitude of these angles in the written description Patent Owner cites for

support is that these angles “may be any angles *less than* 90 degrees” (emphasis added). Ex. 2020, 37:15, 44:12–13. Patent Owner does not explain how an express disclosure that the angles are to be less than 90 degrees supports a claim that recites a range up to “about 90 degrees.” The care with which Patent Owner excluded 90-degree angles from the disclosure suggests the opposite: that the inventors specifically regarded 90-degree angles as outside the scope of their invention. Ex. 1018 ¶ 61.

C. “Substantially perpendicular”

Every proposed new claim requires that the second bore axis be “substantially perpendicular” to the third longitudinal axis. MTA 8, 14. The phrase “substantially perpendicular” does not occur anywhere in the specification common to the ’166 patent and the ’680 application. The specification’s only discussion of this angle indicates, if anything, that the angle *cannot* be perpendicular— as discussed above with reference to the “angle is in the range of about 0 degrees to about 90 degrees” limitation, the specification specifically limits this angle to “less than 90 degrees.” Patent Owner does not explain how a disclosure that excludes a 90-degree angle nevertheless supports a claim requiring a “substantially perpendicular” angle. Ex. 1018 ¶ 62.

Dr. Ledet testified that the second bore axis is “substantially

perpendicular” to the third longitudinal axis as shown in Figure 18 (Ex. 1017, 141:11–143:14) and confirmed that the angle illustrated in that Figure is “approximately 80 degrees” (*id.* at 144:13–19). Consequently, if the specification is found to provide support for the claim term “substantially perpendicular,” then this term is properly held to encompass angles of at least 80 degrees. Ex. 1018 ¶ 62.

III. THE PROPOSED CLAIMS INTRODUCE NEW MATTER

Patent Owner has not carried its burden to show that the claims are free of new matter, because it (*a*) makes a blanket, non-specific recitation of support rather than provide a description clearly stating where the specification and drawings support each limitation, and (*b*) relies on drawings that do not actually show the part of the claimed assembly to which the new limitation is directed. Petitioner also demonstrates that a reasonable interpretation of those drawings results in an assembly lacking the newly claimed feature.

Ex. 1018 ¶ 63.

A. A single blanket citation does not show support for each limitation.

Patent Owner has not carried its burden of production under 37 C.F.R. § 42.121(b) to show support for the added claims because it makes a single, identical, citation to 16 pages of specification and drawings (MTA 5–14:

“Exhibit 2020, p. 17-20, 34-38, 43-45; Figs. 9-11, 18”) for each limitation of every new claim rather than “describe how” each limitation in particular is supported. *See Consolidated Trial Practice Guide* (Nov. 2019), 69. An amendment should “clearly state” where the specification and drawings support all the limitations of the proposed claims. *Id.* at 71. Patent Owner’s repeated cookie-cutter statement provides no meaningful showing. It essentially leaves the Board to sift through every possibly relevant scrap of information to sort out whether and where support might be found. Patent Owner’s failure in this regard is, by itself, sufficient basis to deny the Motion to Amend. *Id.* (“If the Board is unable to determine how the specification and drawings support the proposed substitute claims, the motion to amend may be denied.”).

B. Patent Owner relies on drawings for features not visible in them.

The key limitation added in all the proposed new claims is “wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture.” MTA 8. This language does not appear anywhere in the ’166 patent or the ’680 application, nor is there any discussion anywhere in the specification of any contact between the head of the first member with the first bore *at the second aperture*. The Patent Owner instead relies on Figures 9 and 18 as providing disclosure of the head of the first

member abutting the interior surface of the first bore at the second aperture.

MTA 17–18. Relevant detail from Patent Owner’s annotated versions of these figures (*id.*) is reproduced below:

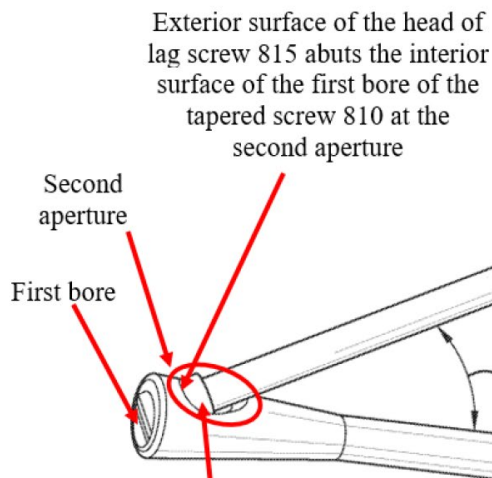


Fig. 9 detail, annotated

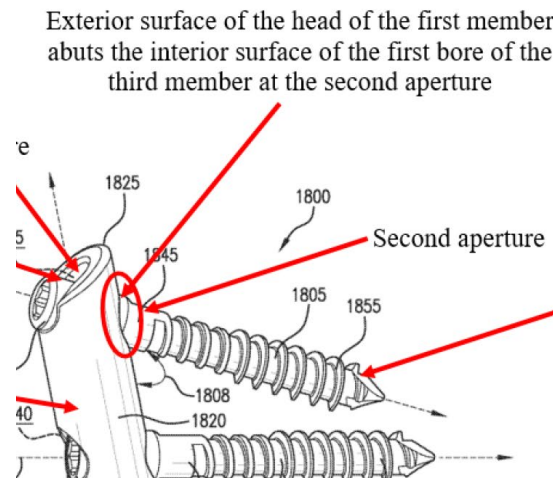


Fig. 18 detail, annotated

Patent Owner thus argues (and Dr. Ledet agrees, Ex. 1017, 72:11–73:15) that these figures show abutment between the head and the first bore at the second aperture because the lines delineating these structures intersect. As Dr. Ledet testified, this limitation requires abutment at the interface between the interior surface of the first bore and the exterior surface of the third member. Ex. 1017, 68:16–20, 70:20–71:3.

But these drawings do not actually show the screw head abutting the interior surface, because they do not show the area of contact between these surfaces. That is, the surfaces supposedly involved in the abutment are not illustrated in the drawings. Consequently, the drawings do not show the actual

abutment. This is appreciated most readily in Figure 18 (relevant portion shown above), where the first member extends toward its tip along an axis aimed away from the viewer (Ex. 1017, 104:12–105:2), so that the interior surface of the first bore is concealed by the external surface of the third member. Ex. 1018 ¶¶ 64-65.

Figure 9 also suffers from this shortcoming, because the first member again extends into the paper. But in the case of Figure 9, it is clear that the lower aspect of the first member head is not contacting the first bore *at the second aperture*, because a portion of the interior surface of the first bore at the second aperture is visible in the drawing and is clearly shown to be a countersink extending around the visible circumference of the second aperture (shaded in red below, shown more completely in Fig. 11). The head (shaded in blue) is constrained by the first bore and consequently clearly is not (and cannot be) abutting the countersunk area (Ex. 1018 ¶¶ 66-67):

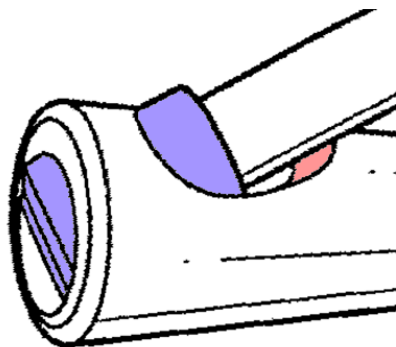


Fig. 9 detail, annotated

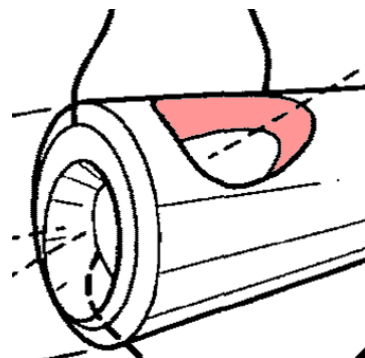


Fig. 11 detail, annotated

Thus, the head clearly is not contacting the interior surface of the bore at

the second aperture in the portions visible in Figure 9. It may be contacting the interior surface of the bore at deeper points, but certainly is not abutting at the surface, which is where the second aperture is located. Ex. 1018 ¶ 66.

This clear non-abutment in Figure 9 is also applicable to Figure 18, because the '166 patent explains that the lag screws and tapered screw of Figure 18 are “substantially similar” to the corresponding parts in Figure 9. Ex. 1001, 13:26–31; Ex. 2020, 23:23–24:2. Ex. 1018 ¶¶ 67-68.

Figures 9 and 18 consequently do not expressly show whether the portion of the head hidden behind the third member contacts the interior surface of the first bore at the second aperture, because the angle of view prevents the necessary visualization. The existence of a countersink between the second aperture and the first bore suggests that, in fact, there is not abutment at the second aperture. The figures simply fail to include enough information for the viewer to conclude that the head and the interior surface of the first bore abut at the second aperture. Ex. 1018 ¶¶ 64-68.

Nor does the specification provide further information to indicate whether there is such abutment. As discussed above, there is no express disclosure of it (Patent Owner surely would have cited it if there were). But the specification also fails to include any disclosure that indicates the unseen abutment is necessarily present. For example, the specification indicates that

the lag screw member 815/1805 in the Figure 9 and 18 embodiments has a tapered bulbous member that is received in the first bore with a “locked interference fit” so as to have a “fixed angle.” Ex. 2020, 34:18–19, 35:11–14 (Figs. 9–11), 44:8, 45:11–13 (Fig. 18). But nothing in the specification indicates that a locked interference fit exists at the *second* aperture. To the contrary, the specification clearly states that the locked interference fit results from contact at the *first* aperture 1130 (*id.* 35:12–14). And as Mr. Dominguez explains, the region of interference need not extend all the way to the second aperture; rather, the specification makes clear that the contact at the first aperture is sufficient to create the locked interference fit, which in turn creates the fixed angle. Ex. 1018 ¶¶ 69-70.

The specification and drawings, therefore, do not clearly disclose the new feature Patent Owner proposes to add to the claims. Ex. 1018 ¶¶ 70. Patent Owner therefore has not complied with the written description requirement, which requires that the claimed subject matter be “disclosed in a way that clearly allows a person of ordinary skill to recognize that the inventor invented what is claimed and possessed the claimed subject matter at the date of filing.” *Yeda Research & Dev. Co. v. Abbott GmbH & Co. KG*, 837 F.3d 1341, 1344 (Fed. Cir. 2016) (citing *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)).

It is not enough that a person of ordinary skill “might be able to construct the patentee’s device from the teachings of the disclosure.”

Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997) (internal citation and quotation omitted). Rather, the test for written description involves “whether the application necessarily discloses that particular device.” *Id.*

Nor is this standard relaxed when relying upon drawings; possession of the invention still must be “convey[ed] with reasonable clarity to those skilled in the art.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *id.* at 1566 (“Drawings constitute an adequate description if they describe what is claimed and convey to those of skill in the art that the patentee actually invented what is claimed.”).

And although a patent owner may rely on an inherent property not expressly disclosed in a specification, the circumstances under which this may be done are “narrow” and require a showing that the supposedly inherently feature is “necessarily” present. *Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Laboratories Inc.*, 923 F.3d 1368, 1382 (Fed. Cir. 2019) (citing *Yeda*).

As discussed above, nothing in the specification or drawings of the ’166 patent or its ’680 parent application discloses any contact between the head and the interior surface of the first bore at the second aperture. Ex. 1018 ¶¶ 69-70.

There is no description at all of any interaction between these parts, and the figures Patent Owner relies upon are presented at angles that obscure the view of those parts. If anything, the specification indicates that contact between the head and the first bore occurs by way of a “locking interference fit” at the first aperture, not the second. Consistent with this disclosure, Figure 9 clearly shows that there is at least some portion of the second aperture which is not contacted at all by the head. Ex. 1018 ¶¶ 64-68.

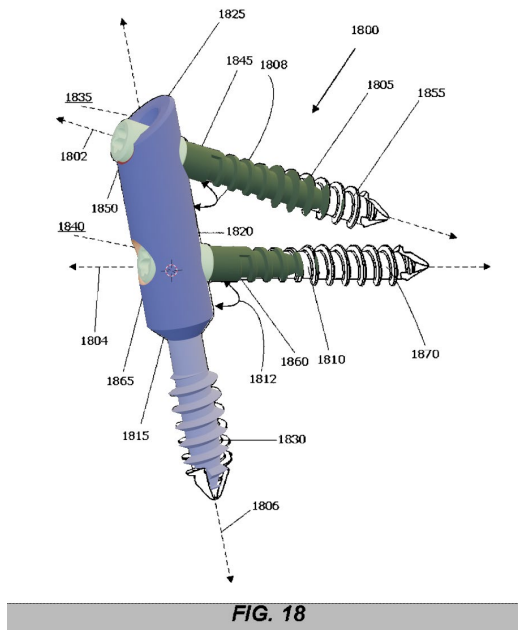
Patent Owner’s case for written description support comes down to the intersection of certain lines in Figures 9 and 18. But these figures are two-dimensional oblique views that necessarily cannot convey any information about features that are hidden by the chosen view. Ex. 1018 ¶ 65. And as Dr. Ledet testified, persons of ordinary skill “generally try not to use our imagination to interpret a mechanical drawing.” Ex. 1017, 105:9–23 (discussing Fig. 18).

Yet it is precisely an exercise in imagination on which Patent Owner relies in attempting to extract details from Figures 9 and 18 that are neither shown in the drawings nor implied by the descriptions of those drawings. Ex. 1018 ¶ 65. Patent Owner insists that the head and interior surface must contact at the second aperture because a line representing the head and a line representing the second aperture intersect in the drawings. But as will be

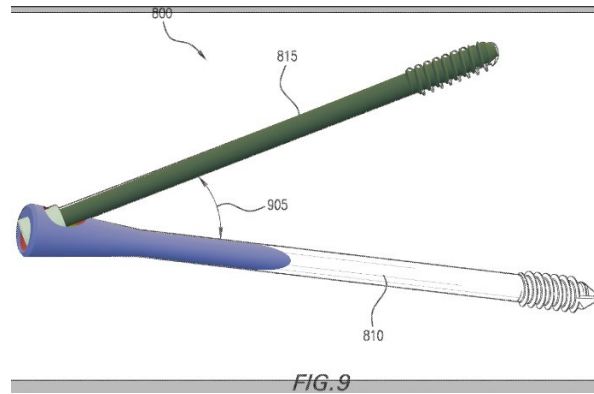
demonstrated, intersection of those lines results from the foreshortened views presented in Figures 9 and 18 and does not establish that the head and interior surface abut at the second aperture.

C. 3D models consistent with Figures 9 and 18 demonstrate that there is not necessarily abutment.

Petitioner created 3D models that match all relevant details in the figures Patent Owner relies upon. Ex. 1051 (declaration of model creator). In particular, Petitioner created a first model that matches Figure 18 (Ex. 1045) and a second model that matches Figures 9, 10, and 11 (Ex. 1046). By “matches,” Petitioner means that the lines representing the head of the first member, the first and second apertures, the contours of the third member, are all in agreement with the lines in the figures. Ex. 1051 ¶ 8; Ex. 1018 ¶¶ 71, 75. Videos providing animated views of the models are submitted as Exhibits 1047 and 1048, respectively. Ex. 1052 (declaration of video creator). Still images from the 3D models are provided in Exhibits 1049 and 1050, respectively. *Id.* The following images show the models superimposed on their respective figures:

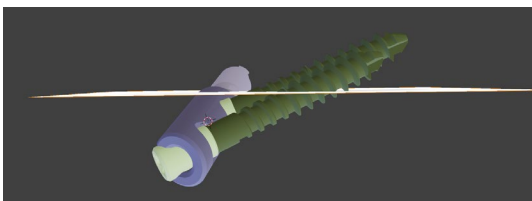


Ex. 1049, 2

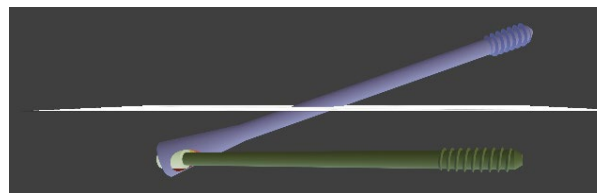


Ex. 1050, 2

The screw tips are invisible because they extend behind the plane of the page, as seen in overhead views, in which the white slivers represent the pages on which the patent figures are reproduced (Ex. 1017, 104:12–105:2; Ex. 1018 ¶¶ 72, 76):

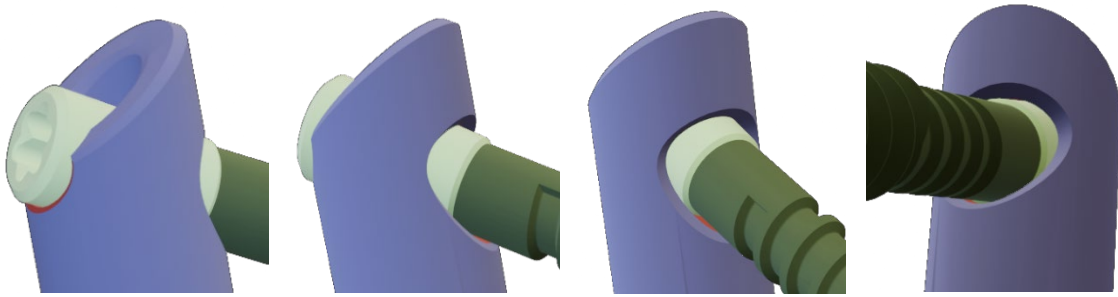


Ex. 1049, 3



Ex. 1050, 3

The following series of images shows the 3D model for Figure 18 (without the superimposed figure) being rotated from the view of Figure 18 toward the viewer (Ex. 1018 ¶ 77):



Ex. 1049: pages 4, 5, 6, 8 (detail)

These close-up images focus on the interaction of the first member and the third member. The first member is shaded green, with the head of the first member shaded in light green, and the third member is shaded in blue.

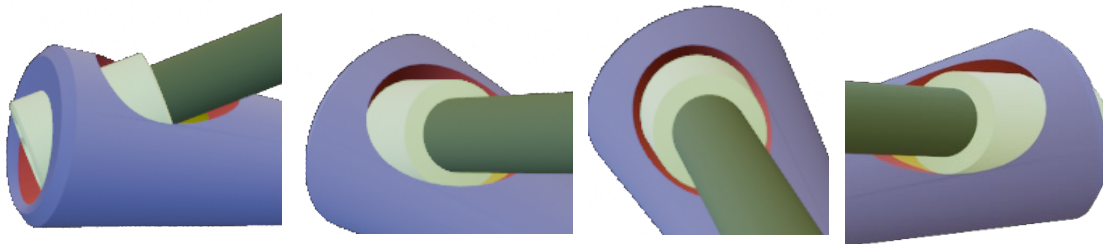
Ex. 1018 ¶¶ 77-78. The second member is not shown in these close-up images.

As this sequence of views shows, an assembly that is *fully in agreement* with Figure 18 nevertheless can lack any abutment between the head of the first member and the interior surface of the bore at the second aperture. The claim requires that the second aperture be at the exterior surface of the third member. These views show that Figure 18 allows for the possibility that the second aperture has a countersink such that the head does not abut the interior surface of the first bore at the second aperture on the exterior surface of the third member. Ex. 1018 ¶¶ 75-78.

Petitioner does not take the position that the Figure 18 embodiment necessarily must resemble what is shown in the 3D model. Rather, the model is presented as evidence that there is not enough information in Figure 18 to

rule out the possibility that there is no abutment between the head and the interior surface of the first bore at the second aperture. Figure 9 clearly shows the countersink at the second aperture, and the '166 patent specification expressly states that the corresponding parts in Figures 9 and 18 are “substantially similar.” Ex. 1001, 13:26–31; Ex. 2020, 23:23–24:2. Therefore, it is reasonable to interpret Figure 18 as not *necessarily* requiring the claimed abutment. Ex. 1018 ¶ 78. Because the claimed abutment is not necessarily present, the figures do not clearly convey to one of ordinary skill that Patent Owner had possession of an assembly with the recited abutment at the second aperture at the time the '166 patent was effectively filed.

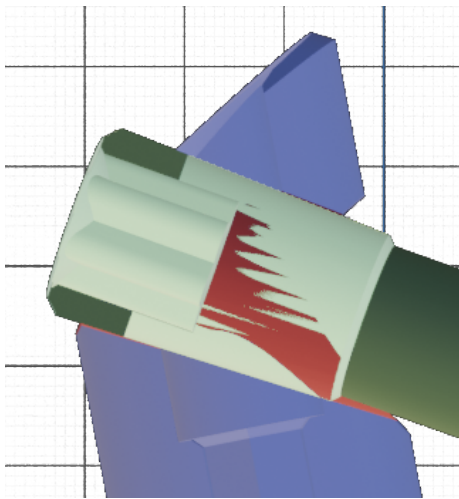
A similar sequence of views of the Figure 9 3D model shows that the Figure 9 assembly also does not necessarily disclose the recited abutment (Ex. 1018 ¶ 73):



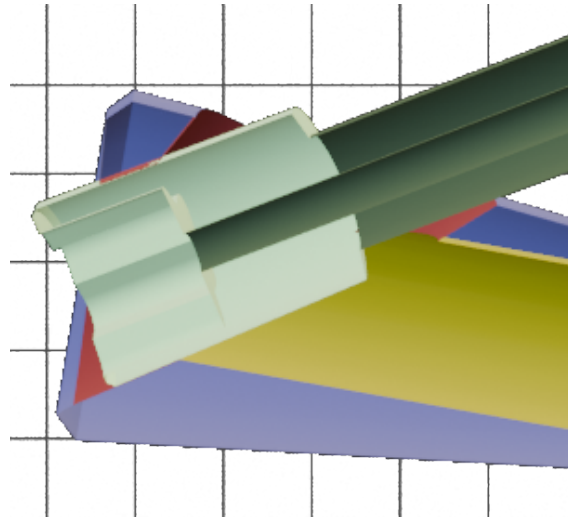
Ex. 1050: pages 4, 5, 6, 8 (detail)

Cross-sectional views of the Figure 18 and 9 models, taken with the models lying in a plane parallel to the paper (Ex. 1049, 8; Ex. 1050, 8) further

show that the models comport with all other disclosed features of the embodiments, most particularly tapered heads that engage the bore with a locking interference (indicated by scalloped red-green, areas of interference annotated at Ex. 1018 ¶¶ 74, 78) to form a fixed angle:



Ex. 1049, 10 (detail)



Ex. 1050, 10 (detail)

These models demonstrate that the specification and figures of the '166 patent do not clearly show abutment of the head with the interior surface of the first bore at the second aperture on the exterior surface of the third member. Ex. 1018 ¶¶ 74, 78. This feature is invisible in the figures filed with the '166 patent, nor is it implied by any other disclosure or necessarily present in embodiments that are fully consistent with the drawings. Ex. 1018 ¶ 79.

For these reasons, the proposed new claims introduce new matter.

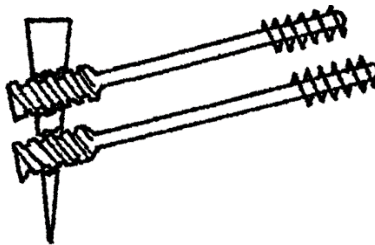
IV. THE PROPOSED NEW CLAIMS ARE UNPATENTABLE.

Even if the proposed claims were found to have support in the '680

application as filed, they are unpatentable for anticipation and/or obviousness over López-Oliva Muñoz ES 2,164,543 B1 (Ex. 1033a, English translation Ex. 1033) (“Lopez”). Lopez describes a bone repair implant having a nail secured by two screws, each screw having a head that contacts both apertures through which the screw penetrates the nail. Lopez thus discloses the new limitation added to the proposed claims as well as all other limitations of claims 16–26 and 27–30. Proposed new claim 24 adds a trivial limitation that would have been obvious over Lopez and Brumfield. Ex. 1018 ¶¶ 80, 106.

A. Lopez anticipates claims 16–23 and 25–29

Lopez discloses a system including a nail and two screws for bone fusion. Ex. 1033, 1:6–7, Fig. 12. The two screws correspond to the first member and second member, and the nail corresponds to the third member. *Id.* Lopez’s screws have heads that span the nail and abut both their incoming and outgoing apertures, as clearly seen in the following detail from Fig. 12:

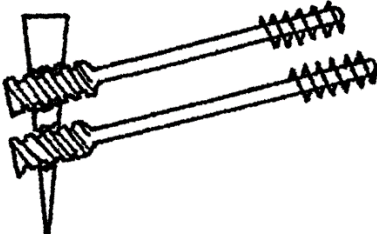
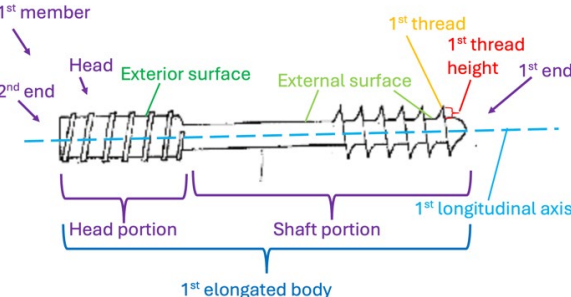


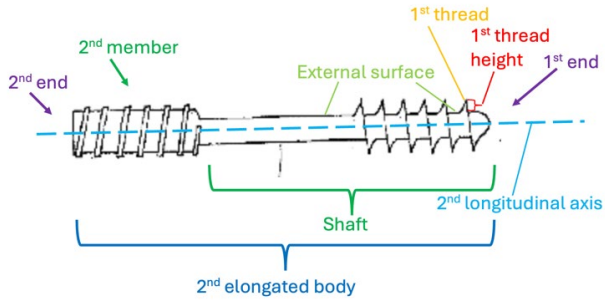
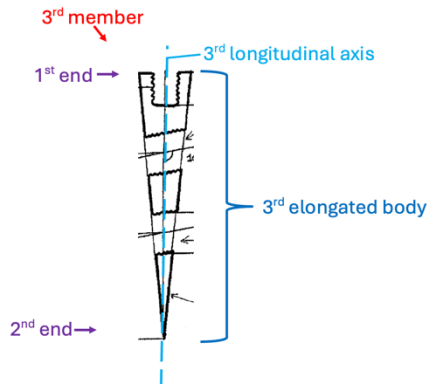
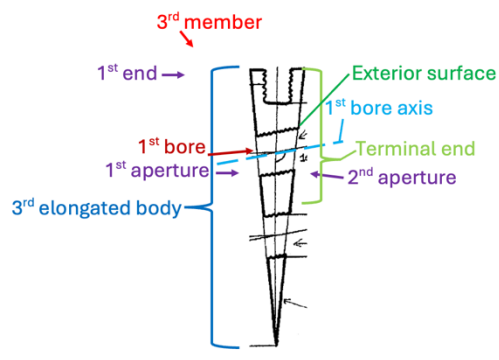
Lopez (Ex. 1033), Fig. 12 detail

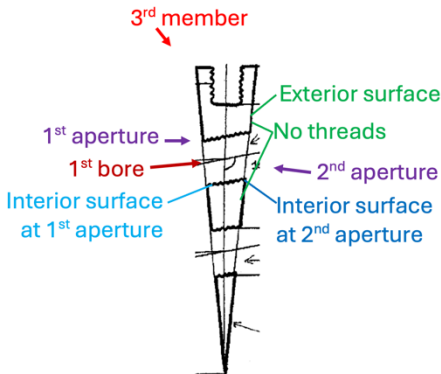
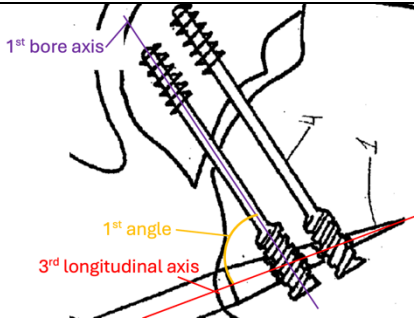
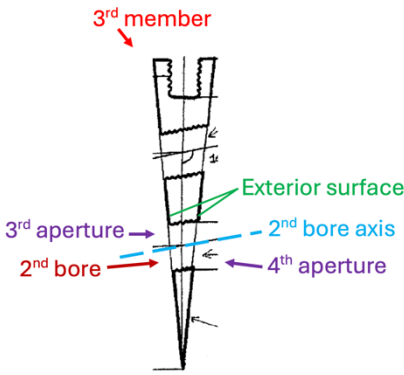
Lopez thus discloses the feature added in the proposed new claims, namely, that the head of the first member abuts the interior of the first bore at

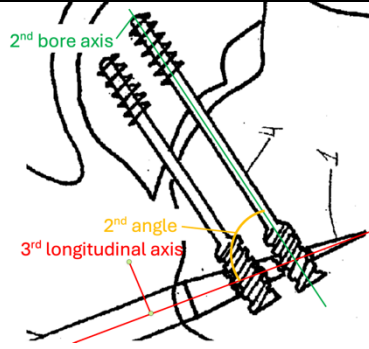
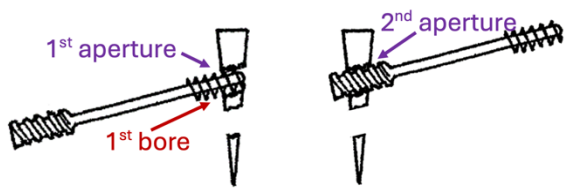
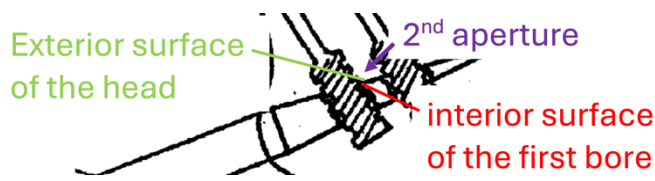
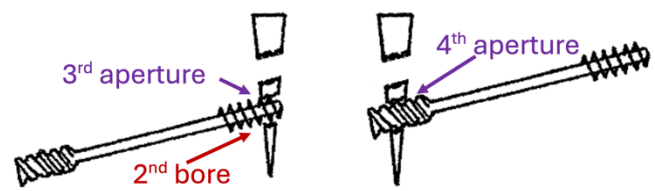
the second aperture on the exterior surface of the third member. Ex. 1018 ¶ 86.

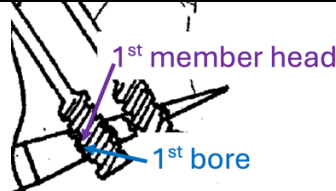
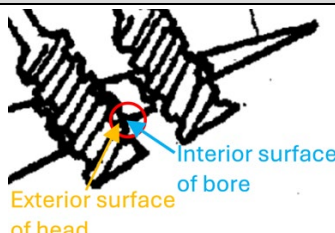
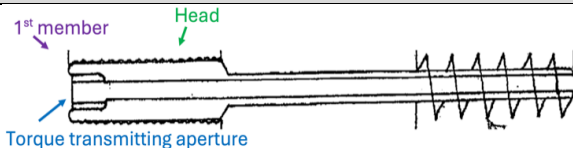
Lopez also discloses every element of proposed new claims 16-30, as detailed in Mr. Dominguez’s declaration (Ex. 1018 ¶¶ 80-104) and in the following chart (¶ 105).

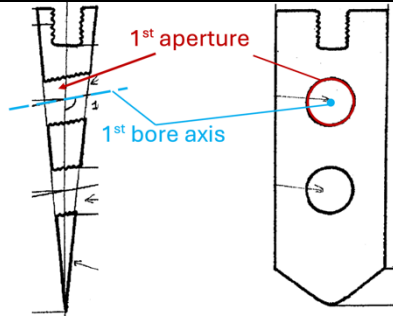
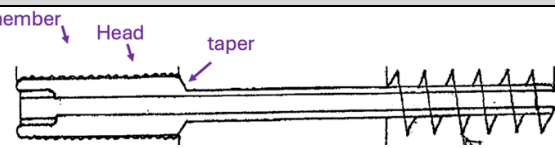
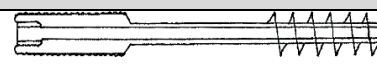
	Claim 16	Ex. 1033 López-Oliva
16a & 27a	1. An assembly for bone fusion, comprising:	Title: “arthrodesis” 1:6–7: “Locked nail system for arthrodesis reconstruction of fractures of the calcaneus.”  Fig. 12 detail
16b & 27b	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion comprising a head having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward	 Fig. 9 detail, annotated

	from the external surface of said shaft portion;	
16c & 27c	a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;	 Fig. 9 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. 1 detail, annotated
16e & 27e	wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the first aperture to a second aperture on an	

	exterior surface of the third member,	Fig. 1 detail, annotated
16f & 27f	wherein the first bore comprises an interior surface at the first aperture and an interior surface at the second aperture, wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and	 Fig. 1 detail, annotated
16g & 27g	wherein the third longitudinal axis and the first bore axis define a first angle,	 Fig. 12 detail, annotated
16h & 27h	wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member,	 Fig. 1 detail, annotated

16i & 27i	wherein the third longitudinal axis and the second bore axis define a second angle ,	 Fig. 12 detail, annotated
16j & 27j	wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture,	 Fig. 12 detail (adapted), annotated
16k & 27k	wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the second aperture	 Fig. 12 detail, 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. 12 detail (adapted), annotated
16m	wherein the first angle is in the range of about 0 degrees to about 90 degrees, wherein the second angle is in the range	4:29–30: “These holes have an inclination of 10 degrees to the horizontal.”

	of about 0 degrees to about 90 degrees, and	
27m	wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	4:29–30: “These holes have an inclination of 10 degrees to the horizontal.”
16n & 27n	wherein the second bore axis is substantially perpendicular to the third longitudinal axis.	4:29–30: “These holes have an inclination of 10 degrees to the horizontal.”
Claim 17		
17 & 28	The assembly of claim 16, wherein the head of the first member resides at least partially within the first bore .	 Fig. 12 detail, annotated
Claim 18		
18	The assembly of claim 17, wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the first aperture.	 Fig. 12 detail, annotated
Claim 19		
19	The assembly of claim 18, wherein the head of the first member comprises a torque transmitting aperture .	 Fig. 3 detail, annotated 6:4: “Cannulated screwdriver”
Claim 20		
20	The assembly of claim 16, wherein the first aperture of	

	the third member is aligned on the first bore axis.	 Figs. 1-2 detail, annotated
	Claim 21	
21	The assembly of claim 20, wherein the head of the first member resides at least partially within the first bore.	same as claim 17
	Claim 22	
22	The assembly of claim 21, wherein the exterior surface of the head of the first member abuts the interior surface of the first bore at the first aperture.	same as claim 18
	Claim 23	
23 & 29 & 30	The assembly of claim 16, wherein the head portion of the first member is tapered.	 Fig. 3 detail, 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. 3 detail 4:35–36: “This thread must be self-tapping at the two ends thereof.”
	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. 3 detail 4:35–36: “This thread must be self-tapping at the two ends thereof.”
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Lopez anticipates proposed new claims 27–30 for the same reasons as claims 16, 17, and 23, because those claims are identical except claims 27–30 do not require “wherein the first angle is in the range of about 0 degrees to about 90 degrees” in limitation 16m.

B. Lopez and Brumfield render obvious claims 16–30.

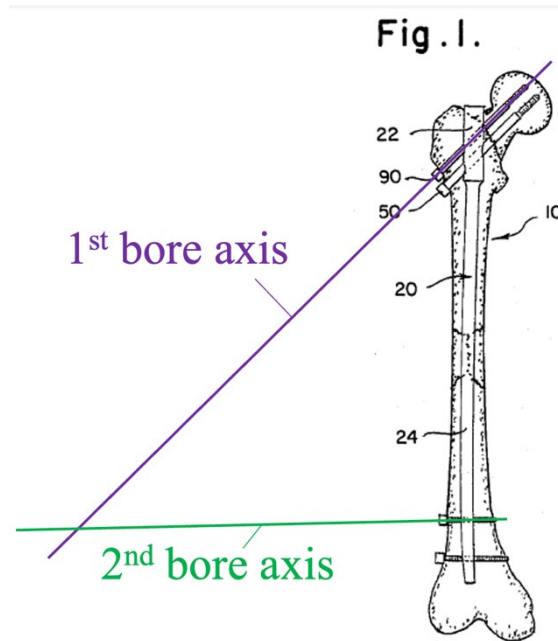
Even if the proposed claims were found not to be anticipated by Lopez because Lopez’s first aperture is not at a terminal end, the claims still would have been obvious over Lopez and Brumfield. Lopez teaches that its device is for the repair of calcaneal fractures, but the basic assembly – a nail spanned by two screws – is the basic geometry used to treat fractures in many other bones. For example, Brumfield discloses an assembly for repair of femoral fractures in which an intramedullary nail is spanned by lag screws and secured with locking screws. Given the conceptually similar geometries of the Lopez and Brumfield assemblies, it would have been obvious to adapt one to the other. For example, it would have been obvious to adapt Lopez’s nail, which is comparatively short in order to be suitable for the calcaneus, into a longer nail such as Brumfield

discloses, in order to make Lopez suitable for repair of long-bone fractures.

One of ordinary skill would have had a reasonable expectation of achieving an operable assembly from this combination because lengthening the nail of Lopez would not change any of its functional characteristics. Ex. 1018 ¶¶ 106–108.

In the assembly resulting from such a modification, the third member would be comparatively much longer, but the screws would still be positioned close to one end in order to have the correct geometry for fracture repair. As a result, the first aperture would be located at the terminal end of the third member, thereby satisfying all limitations of proposed new claims 16-23 and 25-29. Ex. 1018 ¶ 109.

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



Ex. 1018 ¶ 110.

V. CONCLUSION

The Board should deny the motion to amend.

Respectfully submitted,
Fusion Orthopedics, LLC

By:

Dated: May 3, 2024

/Jennifer R. Brinkerhoff/
Jennifer R. Brinkerhoff
Reg. No. 78,696
Counsel for Petitioner

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:

Vincent M. Ferraro (vferraro@kelleydrye.com)
Michael Zinna (MZinna@KelleyDrye.com)

Dated: May 3, 2024

/Jennifer R. Brinkerhoff/
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