

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,
Petitioner,

v.

EXTREMITY MEDICAL, LLC
Patent Owner.

Case IPR2023-00894
Patent 11,298,166

PETITIONER REPLY

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 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, <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
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1051	Declaration of Eli Jacobson
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I. Claim Construction

A. “Bore”

1. The Board’s construction is correct.

The Board preliminarily construed “bore” as “a hole or passage made by or as if by the turning or twisting movement of a tool such that its interior walls have cylindrical lateral cross-sections, and which do not exclude holes or passages having tapered or stepped longitudinal cross-sections.” Paper 15 (Institution Decision, “DI”), 13. The Board’s construction is underpinned by Patent Owner’s argument during prosecution of parent application serial no. 12/658,680 that the term “bore” is supported in the specification by tapered aperture 1130, which is not uniformly cylindrical. *Id.*; Paper 14 (Preliminary Reply, “Prelim. Reply”), 1–2.

2. The record contradicts Patent Owner’s proposed constructions.

Patent Owner first argues that “bore” should be limited to a uniformly cylindrical shape (Paper 22, Patent Owner Response (“POR”), sentence bridging 17–18), but Patent Owner’s prosecution argument clearly contradicts this. Patent Owner did not explain in the Response how its “regular cylinder” argument (as the Board refers to it, DI 13) comports with its identification of tapered aperture 1130 as the “bore” during the ’680 prosecution. By failing to address this issue, Patent Owner effectively concedes the “regular cylinder” construction.

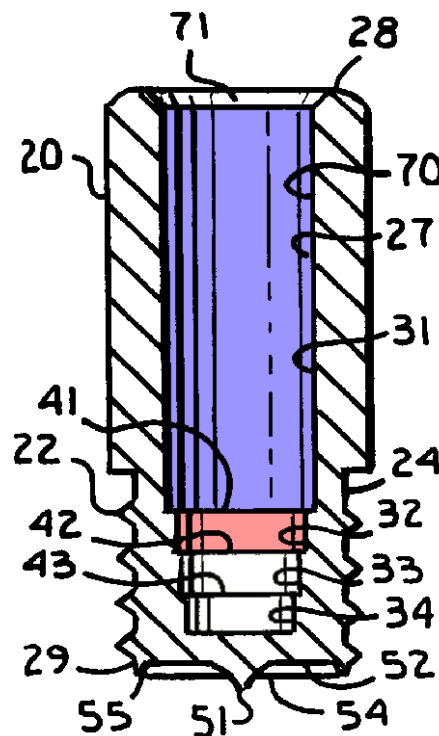
Patent Owner then proposes a construction requiring “a cylindrical hole” that can be “tapered” yet cannot have stepped longitudinal cross-sections. POR 18; *id.* at 15 (citing Ex. 2012 ¶ 41). Even setting aside the internal inconsistency in this construction— how can a cylindrical hole be tapered?— Patent Owner offers no evidence to support this argument beyond its expert’s say-so and post-dated documentary evidence.

Patent Owner cites its expert’s testimony that “a POSITA would understand that the term bore does not include two sections of a hole separated by a ledge or ‘stepped longitudinal cross-sections’” (POR 15, citing Ex. 2012 ¶ 41) but offers no evidence to support the expert’s opinion aside from one patent (US 10,357,299, Ex. 2017) that post-dates the ’166 patent. Patent Owner has not explained how a post-dated disclosure can serve as evidence of how a term was understood in the art as of the challenged patent’s filing date.¹ The testimony of Patent Owner’s expert hence is not supported by relevant underlying facts or data and therefore should be given little weight. *See* 37 C.F.R. § 42.65(a).

¹ And if post-dated evidence is relevant, other post-dated evidence contradicts Patent Owner. For example, Mishra describes a bone repair system with multiple bores that “may together be considered a single[] stepped cylindrical bore.” Ex. 1024 ¶ [0097].

3. *The art recognized “bore” to refer to stepped-diameter holes.*

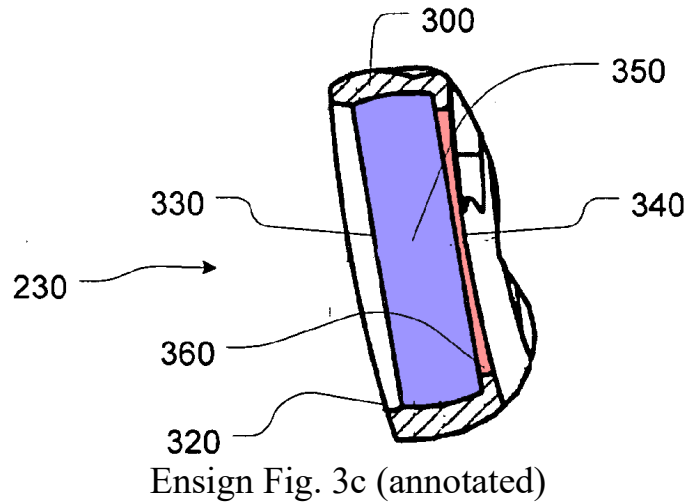
Ample prior-art evidence demonstrates that “bore” was routinely used in the orthopedic surgery field to include stepped-diameter holes. For example, as Mr. Dominguez explains (Ex. 1018 ¶¶ 4, 10), US6,056,753 (Jackson) describes a bone repair set screw in which “[t]he bore 27 comprises a first bore section 31, a second bore section 32,” etc. delineated by shoulders 41, 42, etc. (Ex. 1019, 5:24–43) as shown in annotated Fig. 3:



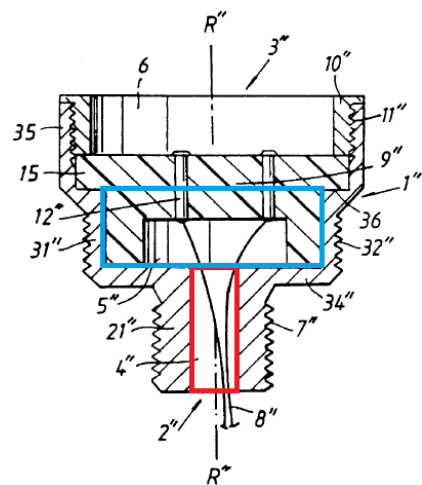
Jackson Fig. 3 (annotated)

And as Mr. Dominguez explains (Ex. 1018 ¶ 11), US2006/0200147 (Ensign) describes an orthopedic plate system having plate body 300 with “the thru-bore 230” that includes central cavity diameter 350 delineated from the smaller exit

diameter 340 by bore stop 360 (Ex. 1020, [0035]), as shown in annotated Fig. 3C:



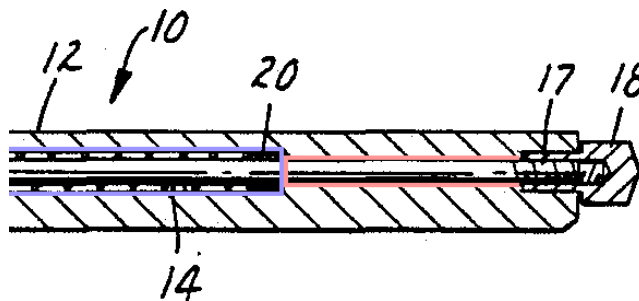
US5,562,670 (Brånemark) describes an osseous implantation device having body 1" with first and second holding portions 21", 31" and "an inner through bore with a first portion 4" in the first holding portion and a second portion 5" in the second holding portion." Ex. 1021, 4:44–46; Ex. 2018 ¶ 12. As shown in annotated Fig. 4, the through bore has stepped diameters in portions 4" and 5":



Each of these prior-art references uses the term “bore” to refer to a hole or tunnel having abutting cylindrical sections of different diameters. They constitute documentary evidence directly refuting Patent Owner’s new contention in its Response that a POSITA would have regarded the term “bore” to exclude them.

4. *The art referred to stepped bores as “cylindrical.”*

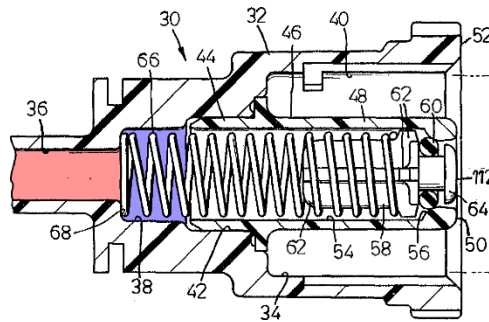
The art also referred to such stepped bores as “cylindrical.” For example, the surgical calipers described in Ray US4,726,121 (Ex. 1025, 2:10–11) include handle 12 having “stepped cylindrical bore 14.” Collar 20 of a shaft inserted in the bore “rests against a step of the bore 14” (*id.* at 2:14–15) as shown in detail from Fig. 1, with the segments of stepped cylindrical bore 14 annotated in blue and red (Ex. 2018 ¶ 13):



Ray Fig. 1 detail (annotated)

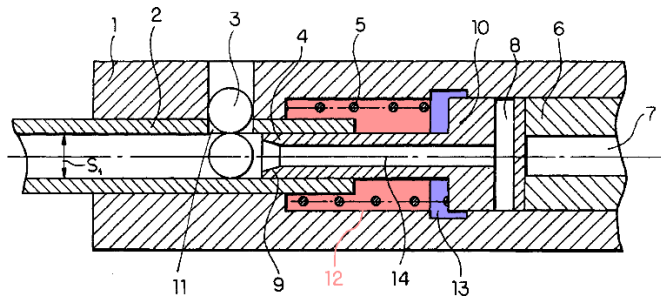
“Bore” is used similarly in other arts to describe stepped-diameter holes or tunnels. Brown US4,327,770 (Ex. 1026, 3:59–4:4) describes a fluid valve coupling member 30 in which “the stepped cylindrical bore 34 includes stepped fluid passage portions 36 and 38” (annotated in red and blue, respectively) with

further enlarged portions 42 and 40 (Ex. 2018 ¶ 14):



Brown Fig. 2 detail (annotated)

Staev US5,908,024 (Ex. 1027, 2:31–36) describes a housing for a pneumatic shooting device breech block in which “[t]he cylindrical bore in the housing 1” is “step-shaped” and has three portions 11, 12, 13 with different diameters (Ex. 1018 ¶ 15):



Staev Fig. 1 (annotated; lead line 12 added from Fig. 2)

Brumfield US4,827,917 (Ex. 1006, 6:41–47) describes “[a] hole” that is formed in bone using “a ‘step-drill’ or ‘step-reamer’ containing two diameters: a smaller diameter at its tip corresponding to the root diameter of the lag screw thread; and a larger diameter which is equal to the diameter of the smooth portion” of the lag screw. Brumfield thus uses the term “a hole” to identify a single void

having abutting cylindrical portions of different diameters, which refutes Patent Owner's contention. Ex. 1018 ¶ 16.

The '299 patent also refutes Patent Owner's position because it refers to the entire void reamed out as "[t]he hole," despite having multiple regions with different diameters. Ex. 2017, 15:28; Ex. 1018 ¶¶ 5–8.

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

Even Patent Owner's expert refers to a void having abutting cylindrical sections of different diameters in the singular as "a" tunnel, aperture, or hole. For example, in one journal article (published in 2006) Dr. Ledet illustrates an "axial fixation rod" having abutting cylindrical sections of different diameters:



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

Ex. 1023, 329; Ex. 1018 ¶ 24. Dr. Ledet then explains that the axial fixation rod is

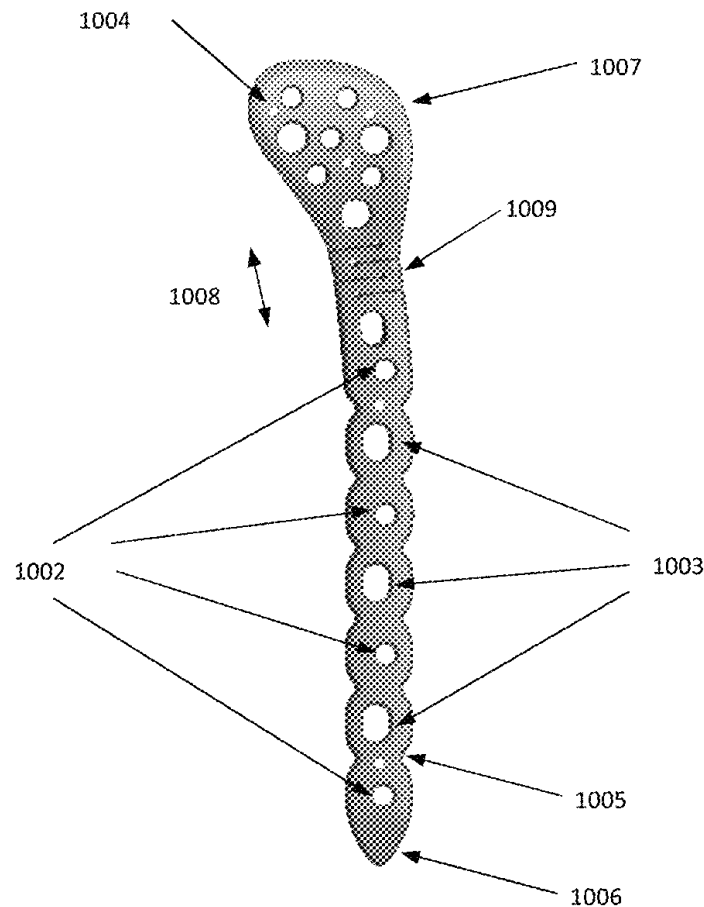
received in “[a] transosseous tunnel formed through the sacrum across the L₅–S₁ disc space”:



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

Ex. 1023, 330; Ex. 1018 ¶¶ 25–26. Figure 3 clearly shows that the transosseous tunnel has two sections with distinct diameters, corresponding to the distinct stepped diameters of Ledet’s axial fixation rod. Thus Dr. Ledet refers to a void having cylindrical sections of different diameters as a single “tunnel.”

And in his own US10,639,076, Dr. Ledet describes “holes 1002” (Ex. 1022, 28:66) as shown in Fig. 58 (Ex. 1018 ¶ 27):



Ledet (Ex. 1022), Fig. 58

Dr. Ledet then refers to the holes as “the apertures” and explains that the apertures may be “counterbored,” among other possibilities. *Id.* at 29:3–5.

Dr. Ledet does not refer to this void as “an aperture and a counterbore” but rather as an “aperture” that is “counterbored.” Thus, in his own patent Dr. Ledet regarded the counterbored section as merely a part of an aperture, not a separate void. Ex. 1018 ¶¶ 27–29.

Patent Owner’s position in the present proceeding thus contradicts numerous references in the art, as well as its expert’s own prior work. For these reasons, the

Board’s preliminary construction of “bore” as including holes having stepped longitudinal cross-sections is well-supported by evidence of record and should be maintained. Ex. 1018 ¶ 29.

B. “At a terminal end”

1. The Board’s interpretation is reasonable.

Although the Board declined to construe “at a terminal end,” it did find that the record at institution supports Petitioner’s position that the first aperture “need not align precisely with the terminal end.” DI 15. In reaching this determination, the Board gave particular weight to Patent Owner’s argument during the ’680 prosecution history that “the separation between first aperture 1130 and terminal end 1120 illustrated in Figure 11 nevertheless provides written description support for ‘a first aperture *at* a terminal end.’” *Id.* at 14 (emphasis in original). The Board noted that the record at institution provided “scant basis” on which to construe the maximum distance that would still be considered “at” a terminal end. *Id.* at 16. Ex. 1018 ¶ 31.

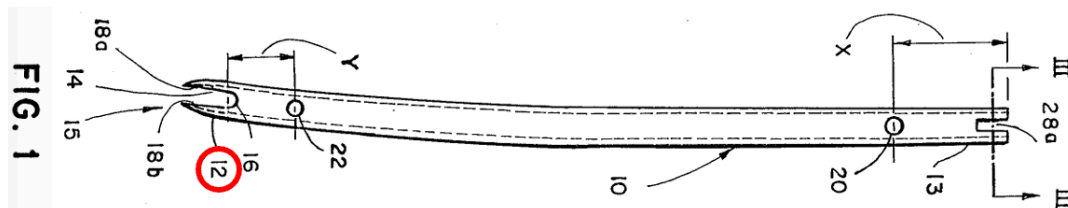
Patent Owner’s Response provides no basis to modify the Board’s construction, because Patent Owner presents no evidence addressing the “distance” issue.

2. Prior-art usage of “terminal end” supports the Board’s view.

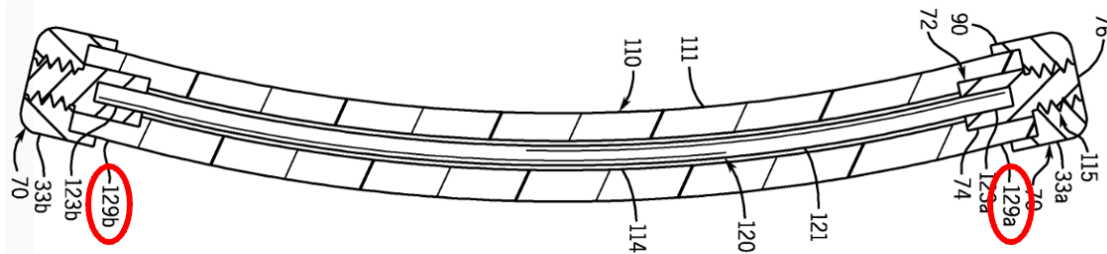
Ubiquitous references to “terminal end” in the prior art support the Board’s

position that the phrase does not require “precise alignment” with the end of an object but instead encompasses a region near the end of an elongated structure.

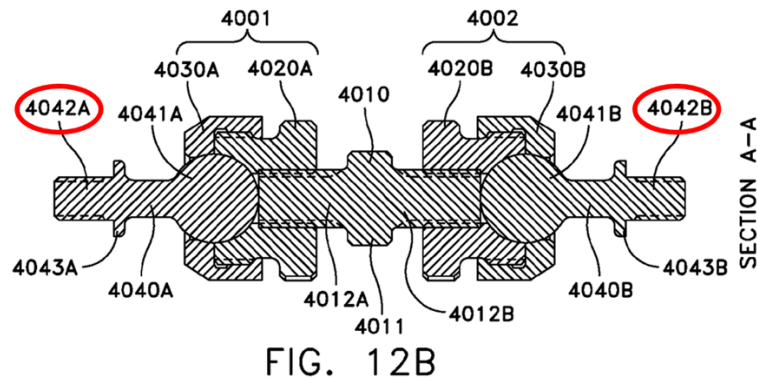
For example, US4,846,162 (Moehring) describes an orthopedic nail having “terminal end 12” (Ex. 1039, Fig. 1, 3:19; Ex. 2018 ¶ 36) which is not at the tip of the nail but includes the side:



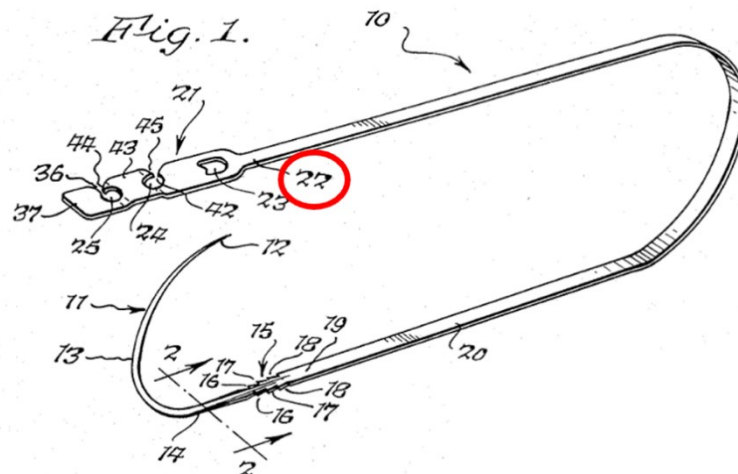
US2010/0160967 (Capozzoli) discloses a spine fixation rod having “terminal ends 129a-b” (Ex. 1040, Fig. 3A, ¶ [0035]; Ex. 2018 ¶ 37) which encompass the regions including the sidewalls:



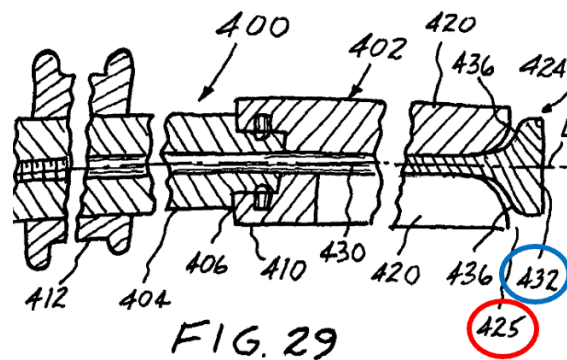
US2009/0118733 (Orsak) describes an orthopedic implant in which the ball joints have “terminal ends” 4042A-B encompassing portions of the shaft (Ex. 1041 ¶ [0118], Fig. 12B; Ex. 1018 ¶ 38):



U.S. Patent No. 4,535,764 to Ebert describes a surgical bone tie in which tie band 20 has “terminal end 22” (Ex. 1042, 4:8, Fig. 12; Ex. 1018 ¶ 39) that encompasses a considerable portion of the length of the device:



U.S. Patent No. 7,442,195 to Behrens describes a bone fracture reduction device in which working head 402 has “terminal end 425” which calls out a whole region of the device, whereas the end surface is separately called out as “front end 432” (Ex. 1043, 11:1–13, Fig. 29; Ex. 1018 ¶ 40):



And U.S. Patent No. 6,270,528 to McKay describes a bone spacer in which thread cutter 400 includes drive shaft 402 with “terminal end 406” referring to a region of the shaft, whereas the end is referred to separately as engager element 407 (Ex. 1044, 8:65–9:3, Fig. 6; Ex. 1018 ¶ 41): .

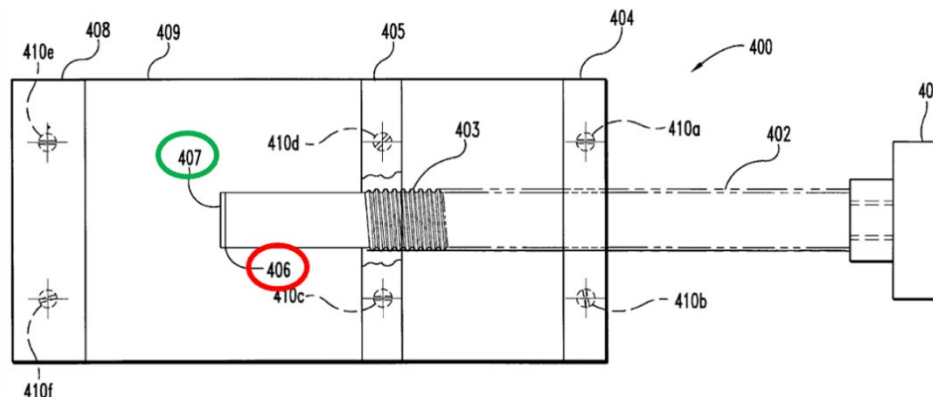


Fig. 6

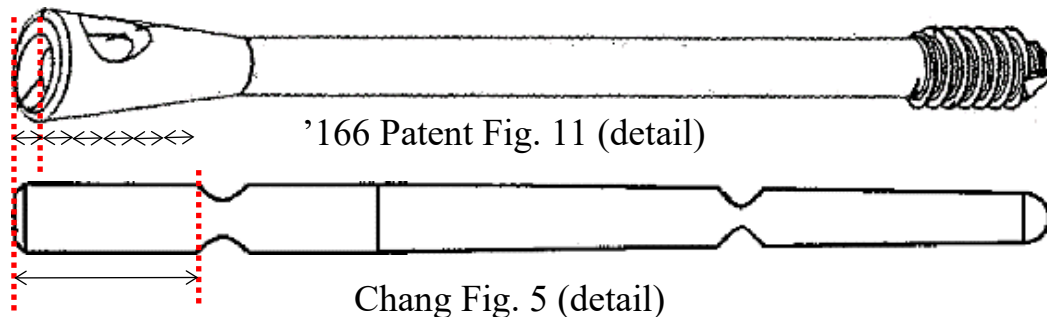
As this array of prior art demonstrates, “terminal end” is widely used to refer to an entire region of a part, not necessarily its very tip. Consequently, one of ordinary skill, presumed familiar with how “terminal end” is used in the art, would have understood that a description of being “at” a terminal end does not necessarily refer to the very tip but rather requires only that it be near the end. Thus the Board’s preliminary view is reasonable. Ex. 1018 ¶ 42.

3. Patent Owner exaggerates the scope of its supposed disclaimer.

Patent Owner instead argues that “at the terminal end” should be construed to require the aperture to “at least in part pass through the top surface of the third member” (POR 12) and to exclude apertures passing only through sidewalls, purportedly due to a disclaimer made during prosecution. POR 10–11. But Patent Owner exaggerates the scope, if any, of this supposed disclaimer, because Patent Owner made neither argument during prosecution, and neither argument was required to overcome the rejection at issue.

Patent Owner distinguished the Chang reference during the ’680 prosecution by arguing that Chang “only discloses through holes (101 and 102) that are merely provided *along* the shaft of the nail.” POR 11 (quoting Ex. 1015, 75–76) (emphasis added). Patent Owner did not draw a distinction between apertures in the sidewall and apertures through the top. Rather, Patent Owner merely argued that the holes were positioned further “along” the shaft.

The argument is more simply explained as Patent Owner having distinguished Chang for its apertures being much further “along” Chang’s nail shaft than are Patent Owner’s. When coupled with Patent Owner’s other prosecution argument—that aperture 1130 is “at” terminal end 1120 despite clearly illustrated as being distanced from it— Patent Owner’s Chang argument straightforwardly distinguishes Chang from the claim because Chang’s apertures are much further along the nail shaft than aperture 1130 is from terminal end 1120. When sized and oriented to be comparable, it is clear that the patent’s aperture is near the terminal end, about 3% of the total length of the nail, whereas Chang’s apertures are about six times further along the nail shaft:



A disclaimer made during prosecution must be “so clear as to show reasonable clarity and deliberateness,” and “so unmistakable as to be unambiguous evidence of disclaimer.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003); *accord Malvern Panalytical Inc. v. TA Instruments-Waters LLC*, 85 F.4th 1365, 1376 (Fed. Cir. 2023). The standard for finding disclaimer is “a

high one” that cannot be satisfied when the alleged disclaimer is “amenable to multiple reasonable interpretations.” *Avid Technology, Inc. v. Harmonic, Inc.*, 812 F. 3d 1040, 1045 (Fed. Cir. 2016).

Patent Owner has not shown clear evidence of unmistakable and unambiguous disclaimer of all sidewall apertures, because Patent Owner’s Chang argument can be read more simply as just distinguishing the claimed apertures “at” the terminal end because they are near the terminal end, whereas Chang’s are further away along the nail shaft.

Patent Owner’s disclaimer position, in essence, attempts to import a limitation from the specification into the claims. Patent Owner chose to draft its claims to recite “at” a terminal end, not “through” a terminal end. It is unnecessary to read “through a terminal end” into the claim in order to distinguish Chang. Consequently, Patent Owner’s Chang argument was not a clear and unmistakable disclaimer of sidewall apertures. The District Court handling the parallel litigation rejected Patent Owner’s similar disclaimer argument there. DI 15–16 (citing Ex. 2015, 13–15).²

Patent Owner has offered no new evidence or explanation to define how

² The Board referred to “Ex. 3002,” which appears not to be the District Court’s claim construction order. Ex. 2015 contains the order.

“near” to the end an aperture must be to be considered “at” it. But evidence of record is already sufficient to answer the patentability question. As will be discussed below, Simon’s aperture is located about the same relative distance from the nail end as is shown in the ’166 patent. Because claim terms are ordinarily not construed to exclude disclosed embodiments (*Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276 (Fed. Cir. 2008)), Simon meets this limitation, and further construction is not necessary. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir.1999) (claims construed “only to the extent necessary to resolve the controversy”). Ex. 1018 ¶ 32–33.

II. Cognet Challenges

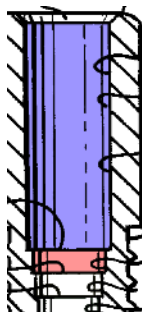
A. Anticipation

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

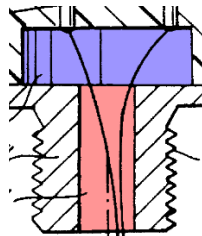
Patent Owner maintains its preliminary response argument that Cognet’s bore does not meet claim 1 because it has regions with different diameters between the first aperture and the second aperture. POR 20–26. This argument depends entirely, however, on a strained construction of “bore” the Board disfavors (DI 13) and that is belied by the evidence of record. Patent Owner’s argument amounts to verbal fencing over the particular words used to describe structures rather than a reasoned argument about whether the prior art discloses the structures as arranged

in the claims. The issue is whether a POSITA would have recognized as “a bore” the void indisputably extending in Cognet’s device from an aperture in its top surface to an aperture further down on the sidewall. The POSITA would have done so, for reasons discussed extensively above.

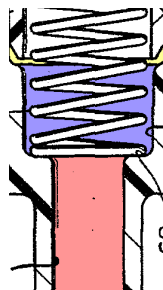
As shown in section I.A.3 (page 3), the art is replete with examples from orthopedic surgery and other fields in which artisans refer to a stepped-diameter void as “a bore,” just as Cognet refers to the same structure as “a tunnel” and Dr. Ledet refers to it as an “aperture”:



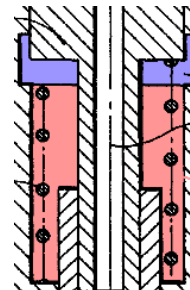
Jackson
Ex. 1019:
“the bore”



Brånemark
Ex. 1021:
“an inner
through bore”



Brown
Ex. 1026:
“the stepped
cylindrical bore”



Staev
Ex. 1027:
“the cylindrical
bore”



Cognet
Ex. 1004:
“the tunnel”

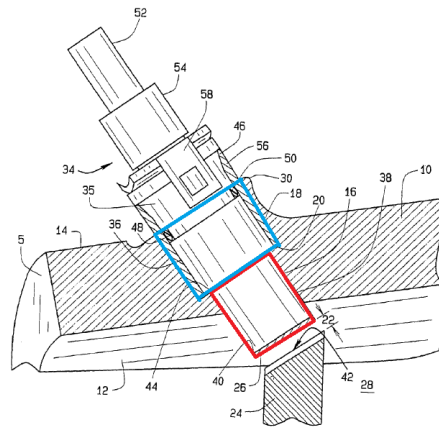
Brumfield and the '299 patent similarly describe a multi-diameter void drilled in bone as “a hole” (*supra* at 6), and Dr. Ledet describes it as “a tunnel” (*supra* at 7). For these reasons, a POSITA would have understood Cognet’s tunnel as meeting the recited bore.

Patent Owner argues that Cognet’s void is made of two distinct structures: a “bore” and a “counterbore,” such that neither extends all the way between the first

and second apertures. POR 22. But Patent Owner merely continues to manipulate terminology. As Dr. Ledet notes, a counterbore exists “in relationship to a bore.”

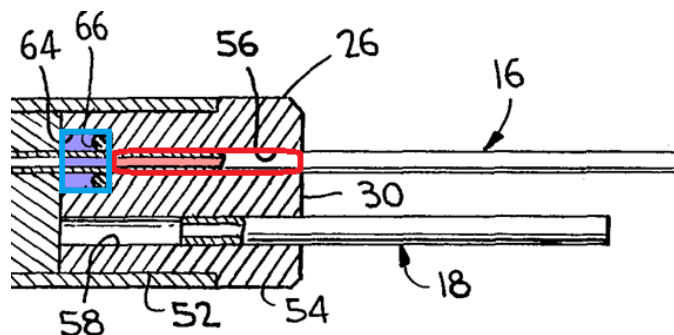
Ex. 1017, 29:25–30:2. That is, a counterbore does not exist in isolation; its presence implies the presence of an adjacent bore having a smaller stepped diameter.

Ex. 1018 ¶ 17. The art routinely refers to a counterbore as a part of its bore. For example, Laps US2008/0202235 discloses a sensor assembly with a housing in which “the bore 16 includes a counterbore 18” (Ex. 1028 ¶ [0033]; Ex. 1018 ¶ 18):



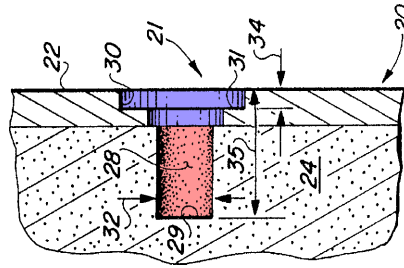
Laps Fig. 1 detail (annotated)

Martinez US4,753,234 describes a surgical cutting apparatus in which “[t]he bore 56 has a counterbore 64” (Ex. 1029, 3:61; Ex. 1018 ¶ 19):



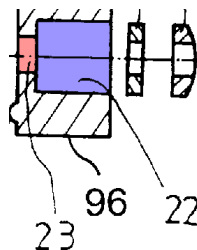
Martinez Fig. 1 detail (annotated)

Zang 5,522,843 discloses a bone anchor for which a “bore [that] includes a counterbore” is formed (Ex. 1030, 2:49); preferably bore 28 and counterbore 30 are drilled by a single tool (*id.* at 6:48–49; Ex. 1018 ¶ 20):



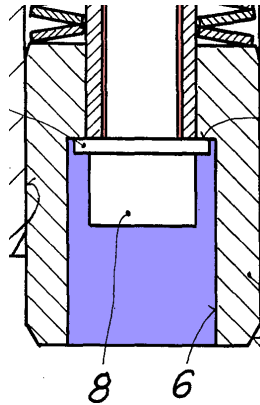
Zang Fig. 2B (annotated)

And Patent Owner’s expert Dr. Ledet, as discussed above (at page 9), describes apertures as “counterbored” and does not identify an aperture’s counterbore as a distinct structure. Ex. 1022, 29:3–5; Ex. 1018 ¶ 21. The prior art similarly describes this structure, for example as “a counterbored bore 23” in Seo (Ex. 1031, 3:46; Ex. 1018 ¶ 22):



Seo Fig. 4 detail (annotated)

and “counterbored axial bore 6” in Exner (Ex. 1032, 2:16; Ex. 1018 ¶ 23):



Exner Figure detail (annotated)

Thus, the evidence of record establishes that even when the art calls out a counterbore by a separate name, it still regards it as being part of the bore with which it is contiguous.

For all of these reasons, Cognet’s tunnel meets the recited bore. Because the Board found that Cognet discloses all other elements of claim 1 (DI 20), and Patent Owner argues no limitation of this claim other than “bore,” Cognet anticipates claim 1. Patent Owner similarly offers no other defense of claims 2, 5, 6, 12, or 13. Cognet anticipates each of these claims for the reasons given in the Petition.

2. Claims 3 and 7: Cognet’s screw head abuts the first aperture.

In defending claims 3 and 7, Patent Owner argues that Petitioner identified Cognet’s surface opening as the first aperture, a structure that Cognet’s screw head does not contact. POR 26–34.

The confusion Patent Owner seeks to capitalize upon concerning the precise

location of the first aperture is entirely the result of Patent Owner's identification of aperture 1130 as corresponding to the bore when arguing for written description support of the claims in the '680 prosecution. *See supra* at 1 (discussing prosecution history). Patent Owner thus equated two distinct terms to the same structure. By conflating these terms, Patent Owner created an indefiniteness in the claims. Patent Owner now seeks to use that indefiniteness as a shield from unpatentability by ignoring its own prosecution history and arguing that the recited structures are distinct. This Patent Owner may not do; it is constrained by the claim language and prosecution arguments it chose to make.

The '166 patent states that bulbous portion 1010 (which corresponds to the recited head portion) forms an interference fit with aperture 1130. Ex. 1001, 8:50–53, 9:66–10:2. That is the same interaction Petitioner shows between Cognet screw 4 and the shoulder in Cognet's tunnel (illustrated at POR 32). Patent Owner once again is dodging behind wording differences. Cognet discloses the screw abutting the shoulder, just as the '166 patent discloses the bulbous portion abutting aperture 1130. *Nothing in the claim requires that the first aperture be on an exterior surface of the device.*

Patent Owner's conduct during prosecution created this confusion. Petitioner has shown that Patent Owner defined its claim terms, however nonsensically, in a manner which still reads on the prior art. Ex. 1018 ¶¶ 44–45.

3. *Claim 4: Cognet's screw head must have a torque aperture.*

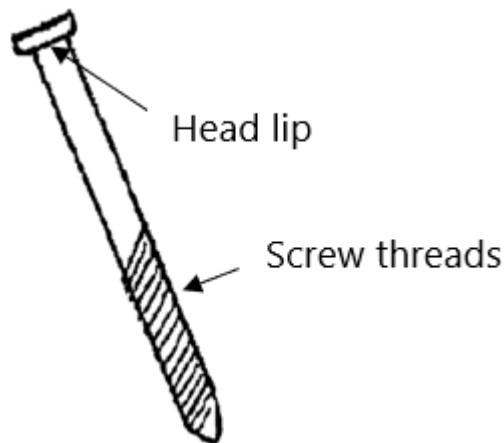
Petitioner's expert, Leonel Dominguez, testified that "the screw head has an internal drive feature located inside the head of the screw." Ex. 1002 ¶ 42(b). The internal drive feature is "used to transfer rotation torque (from a screwdriver) to drive the screw into bone." *Id.* A fastener that lacks an internal drive feature is "likely a 'bolt' and not a 'screw.'" *Id.* Patent Owner offers no reason to disregard this testimony. When considered in the context of this testimony, Petitioner's argument that "almost all screws comprise a torque transmitting aperture" (Pet. 25) means that any given screw inherently has a torque transmitting aperture unless the context dictates otherwise.

Mr. Dominguez further testified that a POSITA would "*assume*" that Cognet's screw has a torque transmitting aperture because that structure is so ubiquitous (Ex. 1002 ¶ 76, *emphasis added*), testimony which the Patent Owner similarly has given no reason to disregard.

Patent Owner displays an image of what it says is a "hex lag screw" (POR 35, Ex. 2012 ¶ 59), but Dr. Ledet admitted that it is not a medical device. Ex. 1017, 41:20–21. Patent Owner offers no evidence that this device has any recognized use in any medical application or that a POSITA would recognize it as a screw in the implantable medical device field. Ex. 1018 ¶ 49.

Even if a "hex lag screw" would be considered a type of screw and not a

“bolt,” this is the only example Patent Owner gives of a “screw” that lacks a torque-transmitting aperture. Patent Owner gives no reason to conclude that Cognet’s screw is of the “hex lag” type. Instead, Cognet shows that the screw head is round and therefore must have an internal drive feature in order to receive a screwdriver. Specifically, Fig. 1 shows external features of the screw (such as the threads and head lip) but does not show any external features along the perimeter of the screw head:



Cognet Fig. 1 detail (annotated)

If the screw head were hexagonal, the straight sides would have been identified by vertical lines delineating those sides. Ex. 1018 ¶ 48. Furthermore, Cognet discloses that the screw head has “a diameter.” Ex. 1004, 4:18–19. A POSITA would understand that “a diameter” is a property of a circular shape and not a polygon. Ex. 1018 ¶ 48. Patent Owner has not explained how torque could be applied to a circular structure unless there is an internal drive feature to push against. Thus Mr. Dominguez’s Petition testimony that a POSITA would “assume”

that Cognet’s screw must have a torque-transmitting aperture is reasonable.

4. Claim 9: Cognet discloses the axial intersection.

Patent Owner offers no evidence to refute Mr. Dominguez’s testimony that Cognet’s first and second bore axes intersect outside Cognet’s nail. Ex. 1002 ¶ 82; Ex. 2013, 164:16–169:21. Dr. Ledet does not challenge Mr. Dominguez’s testimony. Ex. 1018 ¶ 50. Instead, he offers an irrelevant hypothetical about twisting the second bore axis on the nail axis to destroy the intersection. Ex. 2012 ¶ 60.

B. Obviousness

1. Brumfield discloses conventional screw features.

Petitioner cites Brumfield simply as evidence that it was well known to secure intramedullary nails using bone screws with torque apertures (claim 4), tapered heads (claims 8, 14, 15), and self-tapping ends (claim 10). Patent Owner responds with a lengthy argument that Brumfield’s screws cannot be bodily incorporated into Cognet. POR 40–49. But this mischaracterizes Petitioner’s argument, and it is not the test for obviousness. *In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) (obviousness “does not require an actual, physical substitution of elements.”). The screws in Brumfield and Cognet function in the same way to achieve the same result: they are screwed in to secure items together. Borrowing design elements from Brumfield’s screws amounts to “the mere substitution of one element for another known in the field” to yield a predictable

result. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007). Similarly, “when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 417 (internal quotation omitted). Ex. 1018 ¶ 51.

Patent Owner offers no argument or evidence explaining why it would not have been obvious to employ screws with torque apertures (claim 4) or self-tapping ends (claim 10). With respect to claims 8, 14, and 15, Patent Owner argues, without explanation or evidence, that Brumfield’s bevels would cause “increased resistance to rotation of the screw.” POR 49. Even if this were the case (Patent Owner offers no supporting evidence beyond its expert’s verbatim say-so, Ex. 2012 ¶ 69), neither Patent Owner nor its expert state that the resulting device would fail to function in the manner required. At most, “increased resistance” is a trade-off for the benefits of a familiar beveled-head design. *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine”).

2. *Ferrante discloses all features added in claims 10 and 11.*

In challenging claim 11, Petitioner cited Ferrante merely as evidence that it was well known in the field to employ bone screws with self-tapping ends to

remove bone chips. Pet. 35–37; Ex. 1002 ¶ 110. Patent Owner’s only response is that this challenge does not address the limitations of claim 10 or explain why it would have been obvious to combine Cognet, Brumfield, and Ferrante. POR 50. Ex. 1018 ¶ 52.

But the limitation claim 11 adds— requiring the second member to have a self-tapping end— is the same limitation claim 10 imposes on the first member. The two claims do not impose any features of the self-tapping ends that distinguish the first from the second member. Therefore Ferrante’s disclosure of bone screws with self-tapping ends equally meets the limitations of both claims 10 and 11. The combination of Cognet’s bone fusion system with the evidence from Ferrante that it was well known to equip bone screws with self-tapping ends renders both claims obvious.

III. Simon Challenges

A. Anticipation

1. Simon discloses screws with head portions.

Patent Owner repeats its unsuccessful preliminary response argument that Petitioner has not shown how Simon discloses a first member (i.e., a screw) having a head portion. Patent Owner argues that (a) Simon contains no express disclosure of a screw with a head portion and (b) Mr. Dominguez’s testimony that “[s]ome

screws are ‘headless’” contradicts Petitioner’s position that locking screws 18, 19, 20 illustrated in Simon Fig. 1 contain head portions. POR 51–53 (citing Ex. 1002 ¶ 42a and Ex. 2013, 208:1–8). The Board already dismissed Patent Owner’s argument for taking Mr. Dominguez’s testimony out of context; as the Board observed, Mr. Dominguez limits his observation that “[s]ome screws are ‘headless’” to those screws that are “intended to be fully sunk into bone.” DI 23 (quoting Ex. 1002 ¶ 42a). “Headless” screws must have a torque transmitting aperture; otherwise they cannot be sunk fully. Ex. 1018 ¶ 53.

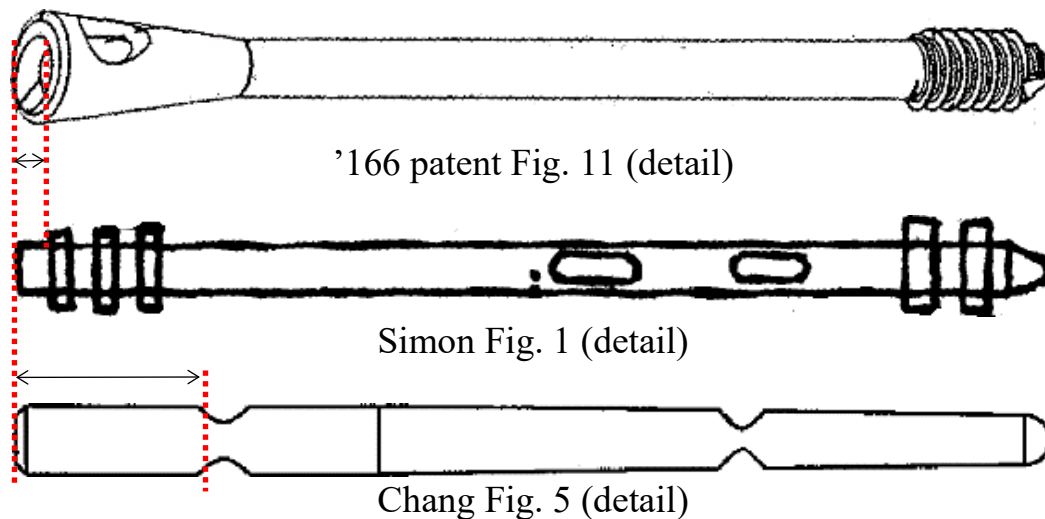
Patent Owner has not presented any additional evidence concerning how a POSITA would have interpreted Simon’s disclosure as to screw heads, aside from a single citation at the end of each argument paragraph to a near-identically worded argumentative paragraph in its expert’s declaration. *Compare* POR 51–52 with Ex. 2012 ¶¶ 71–75. Attorney argument does not become evidence simply by signing the expert’s name to it, and such conclusory evidence is given little weight. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 12 (PTAB Feb. 10, 2023) (Vidal, Dir.).

For these reasons, Patent Owner has not shown why the Board should revisit its determination that Simon discloses screws with head portions.

2. *Simon discloses an aperture “at” the terminal end.*

As discussed above (section I.B.2, *supra* at 14), a construction of “at a

terminal end” that reasonably accounts for Patent Owner’s conduct during prosecution encompasses apertures near the terminal end, regardless of whether they open to the end or only to the sidewall. In this regard, Simon’s aperture closely resembles aperture 1130 upon which Patent Owner based its written description for this claim limitation, because both are positioned at about the same distance away from the terminal end and well short of Chang’s:



Ex. 1018 ¶ 54. Because Simon resembles this embodiment of the '166 patent, and because claim terms are seldom construed to exclude a disclosed embodiment (*Oatey*, 514 F.3d at 1276), Simon meets this limitation. Yet again, Patent Owner merely recycles its unsuccessful preliminary response argument and does not supplement it with anything but verbatim “expertified” argument. *Compare* POR 55–63 with Ex. 2012 ¶¶ 78–83. The Board should maintain its finding that Simon meets this limitation, because Patent Owner has not developed the record with any

new meaningful evidence.

3. *Claim 4: Simon’s screw must have a torque aperture.*

Simon anticipates claim 4 for the same reason discussed above (section II.A.3, *supra* at 23): Mr. Dominguez’s testimony that “[s]ome screws are ‘headless’” was limited to those screws that are “intended to be fully sunk into bone.” DI 23 (quoting Ex. 1002 ¶ 42a).³ Ex. 1018 ¶ 55–56.

4. *Claims 10–11: Patent Owner ignores expert testimony.*

Although Patent Owner argues that Mr. Dominguez’s testimony that screws such as Simon’s “commonly have a self-tapping edge” is insufficient to show anticipation (POR 65, quoting Ex. 1002 ¶ 136), Patent Owner does not account for the rest of Mr. Dominguez’s testimony: that self-tapping edges are so common that the POSITA reading Simon would “immediately assume” that Simon’s screws have this structure for the purpose of bone removal. Ex. 1002 ¶ 136. Patent Owner offers no testimony of its expert to refute Mr. Dominguez’s opinion of how

³ Petitioner’s challenge to claim 4 for anticipation by Simon implicitly challenges claims 2 and 3. *See Garmin Int’l et al. v. Cuozzo Speed Techs LLC*, IPR2012-00001, Paper 15 at 18–19 (PTAB, Jan. 9, 2013) (challenge to parent claims “implicitly made” by challenge to dependent claim), *aff’d. sub nom. Cuozzo Speed Techs, LLC v. Lee*, 579 U.S. 261 (2016).

the POSITA would interpret Simon.

B. Obviousness

1. Obviousness: Simon/Ferrante and Simon/Cognet

The discussion above (section II.B.1, *supra* at 25) shows that *KSR* directly contradicts Patent Owner's response to both of these challenges that obviousness cannot be premised on a combination of references that perform the same function in the same way (POR 66, 68). Patent Owner's bodily incorporation argument (insisting that Petitioner should have "actually illustrated that it would have been obvious to combine" the references, *id.* at 67) is a mis-statement of the law.

In the Simon/Ferrante ground, Petitioner cited Ferrante as evidence that torque apertures (claim 4), tapered heads (claims 8, 14, 15), and self-tapping ends (claims 10, 11) were already so well known in the art for use with bone screws that a POSITA would have assumed that Simon would have employed them to obtain the recognized benefits. Pet. 58–61. Patent Owner offers no evidence in response that a POSITA would not have interpreted the cited art in this way. Ex. 1018 ¶ 57.

In the Simon/Cognet ground, Patent Owner does not otherwise challenge the facts or legal analysis underpinning Petitioner's argument.

2. Obviousness of claims 2, 3, 6, 7, and 13 over Simon and Leu.

Patent Owner criticizes this ground for not expressly laying out how the various parts of the prior art references would be combined, whether the

combination would undermine the intended function of the nail, or whether a POSITA would have a reasonable expectation of success. POR 69–70.

But these critiques are misplaced, because they are intrinsic to Simon’s express identification (Ex. 1008, [0015]) of Leu as an intramedullary nail susceptible to modification as laid out in Simon. *E.g.*, Simon [0057] (modifying a prior-art intramedullary nail to embody Simon’s invention). As Petitioner explained, Simon itself both suggests combination with the prior art and demonstrates success by presenting a successful implementation. Pet. 64. Ex. 1018 ¶ 58. The limitations added by independent claims 2, 3, 6, 7, and 13 concerning head portion geometry and location are conventional features regularly used with bone screws, as evidenced by Leu. Patent Owner offers no argument or evidence to refute this showing by Petitioner and Mr. Dominguez.

IV. CONCLUSION

Petitioner requests cancellation of all claims.

Dated: May 3, 2024

Respectfully submitted,
Fusion Orthopedics, LLC

By:
/Jennifer R. Brinkerhoff/
Jennifer R. Brinkerhoff, Reg. No. 78,696

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that this paper contains
5,550 words in the sections specified in § 42.24(c).

Dated: May 3, 2024

Respectfully submitted,
/Jennifer R. Brinkerhoff/
Jennifer R. Brinkerhoff

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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Dated: May 3, 2024

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