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Paper 64
Date: November 4, 2024

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 B2

Before ROBERT A. POLLOCK, TIMOTHY G. MAJORS, and JAMIE T. WISZ, *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
Denying Patent Owner's Contingent Motion to Amend With Respect to Claims 16–25 and 27–30, but Not Reaching Claim 26
Denying-in-part and Dismissing-in-part Patent Owner's Motion to Exclude
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Procedural Background

Fusion Orthopedics, LLC ("Fusion Orthopedics," "Petitioner") filed a Petition for an *inter partes* review of claims 1–15 of U.S. Patent No. 11,298,166 B2 ("the '166 patent," Ex. 1001). Paper 1 ("Pet."). Extremity Medical, LLC ("Extremity Medical," "Patent Owner") timely filed a Preliminary Response. Paper 12 ("Prelim. Resp."). With our authorization (*see* Ex. 3001), Petitioner filed a Reply to the Preliminary Response (Paper 13, "Prelim. Reply") and Patent Owner filed a corresponding Sur-reply (Paper 14).

In view of the then-available record, we concluded that Petitioner satisfied the burden, under 35 U.S.C. § 314(a), to show that there was a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, on behalf of the Director (37 C.F.R. § 42.4(a) (2018)), and in accordance with *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018) and the Office's Guidance on the Impact of *SAS* on AIA Trial Proceedings (Apr. 26, 2018) ("Guidance"),[1] we instituted an *inter partes* review of claims 1–15 on all the asserted grounds. Paper 15 ("Inst. Dec." or "DI"), 35.

After institution, Patent Owner filed a Patent Owner Response to the Petition. Paper 22 ("POR"). Petitioner filed a Reply to Patent Owner's Response (Paper 28, "Reply") and Patent Owner filed a Sur-reply (Paper 43, "Sur-reply"). With our authorization, Petitioner filed a Sur-sur-reply to

[1] https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

address allegedly new arguments and evidence in the Sur-reply. Paper 46, 6; Paper 50 ("Sur-sur-reply").

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). Here, Patent Owner filed a first (corrected) Contingent Motion to Amend, which proposed substituting challenged claims 1–15 with a first set of new claims 16–30. Paper 26, 1. Petitioner opposed the motion. Paper 29. Patent Owner requested non-binding Preliminary Guidance on its motion, as permitted under the MTA Pilot Program. MTA, 1; *see Notice Regarding a New Pilot Program Concerning Motion to Amend*, 84 Fed. Reg. 9497 (March 15, 2019). In summarizing that Preliminary Guidance, we stated that "Patent Owner ha[d] not shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend." Paper 32, 3.

Patent Owner then filed a Revised Contingent Motion to Amend, which proposed substituting challenged claims 1–15 with a second set of new claims 16–30, which we address in Section II.F, below. Paper 44 ("RMTA"), 1. Petitioner opposed the revised motion (Paper 49, "Opp. RMTA"); Patent Owner filed a Reply in support (Paper 53, ("Reply RMTA")). Patent Owner also filed a motion to exclude (Paper 56, "Mot."), which Petitioner opposed (Paper 57, "Opp. Mot.").

On September 13, 2024, the parties presented arguments at an oral hearing, the transcript of which is of record. Paper 63 ("Tr.").

We have authority under 35 U.S.C. § 6. We issue this Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine Petitioner has shown by a preponderance of the

evidence that original claims 1–10 and 12–15 would have been unpatentable for the reasons set forth in the Petition.[2] We also address proposed substitute claims 16–25 and 27–30, and find that these claims are unpatentable over the prior art. Accordingly, we deny Patent Owner's Revised Motion to Amend with respect to claims 16–25 and 27–30. We do not reach proposed substitute claim 26 as it corresponds to original claim 11.

B. Real Parties-in-Interest

Petitioner identifies itself, Fusion Orthopedics, LLC, as the real party-in-interest. Paper 18, 1. Patent Owner identifies itself, Extremity Medical, LLC, as the real party-in-interest. Paper 54, 1.

C. Related Matters

The '166 patent is at issue in *Extremity Medical, LLC. v. Fusion Orthopedics, LLC*, No. 2:22-cv-00723-PHX-GMS (D. Ariz.). *See* Paper 18, 1; Paper 54, 1; Exs. 1010, 1011, 2002.

D. Asserted Challenges to Patentability

Petitioner challenges the patentability of claims 1–15 on the following seven Grounds (Pet. 6).

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[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '166 Patent are presumed to have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103 in this Decision. *See* Pet. 6. The outcome of this proceeding does not, however, depend on which version of the statute applies.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–7, 9, 12, 13	102(a), 102(b)	Cognet[3]
2	4, 8, 10, 14, 15	103	Cognet, Brumfield[4]
3	11	103	Cognet, Ferrante[5]
4	1, 4, 5, 8, 10–12, 14, 15	102(a), 102(b)	Simon[6]
5	4, 8, 10, 11, 14, 15	103	Simon, Ferrante
6	9	103	Simon, Cognet
7	2, 3, 6, 7, 13	103	Simon, Leu[7]

In support of its patentability challenge, Petitioner relies on, *inter alia*, the First, Second, and Third Declarations of Mr. Leonel Dominguez. Exs. 1002, 1018, and 1054, respectively. Patent Owner relies on, *inter alia*, the First, Second, and Third Declarations of Dr. Eric H. Ledet. Exs. 2012,[8] 2023, and 2037, respectively.

E. The '166 Patent and Relevant Background

The '166 patent, titled "Intraosseous Intramedullary Fixation Assembly and Method of Use," is directed to orthopedic implant devices for correcting deformities and the fusion of angled joints and bones. Ex. 1001, code (57), 1:25–28. Orthopedic implant devices, such as intramedullary

[3] Cognet, French Patent Appl. Publication No. FR 2,861,576 A1, pub. May 6, 2005. Exs. 1003, 1004 (Certified English Translation).

[4] Brumfield, US 4,827,917, issued May 9, 1989. Ex. 1006.

[5] Ferrante, US 2003/0187447 A1, pub. Oct. 2, 2003. Ex. 1007.

[6] Simon, US 2006/0206044 A1, pub. Sept. 14, 2006. Ex. 1008.

[7] Leu, US 6,270,499 B1, issued Aug. 7, 2001. Ex. 1009.

[8] We refer herein to the two-part, corrected version of Exhibit 2012.

nails, plates, rods and screws are often used to repair or reconstruct hand and foot bones. *Id.* at 1:28–33. "Intramedullary" refers to implantation into the marrow space of a bone. *See* Ex. 2012 ¶ 35.

Figure 18 of the '166 patent is reproduced below.

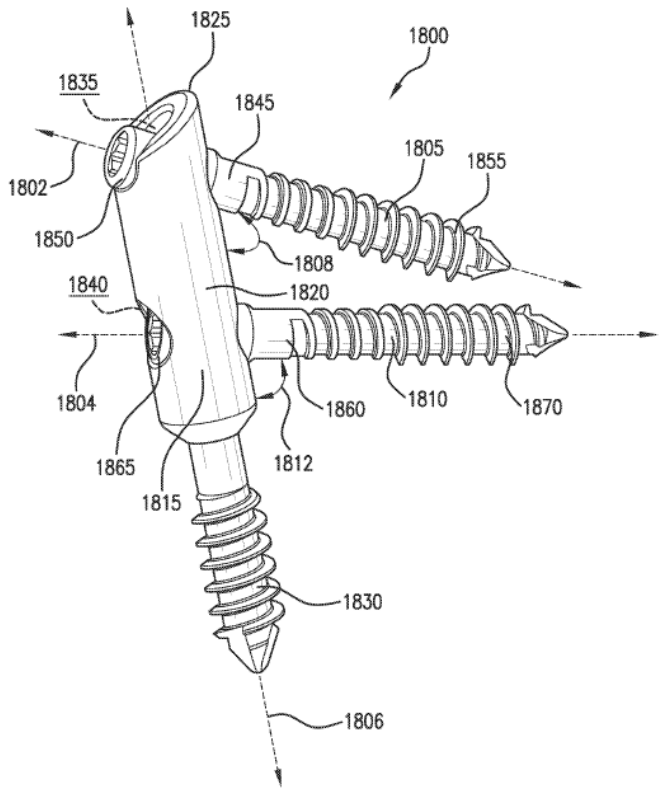


FIG. 18

Figure 18 shows a perspective view of intramedullary fixation assembly 1800 having a plurality of lag screw members 1805, 1810. Ex. 1001, 4:11–14, 13:22–24. In this assembly, "lag screw members **1805** and **1810** coupled to a tapered screw member **1815** . . . apply compression at multiple points on the bone fragment surface." *Id.* at 13:24–26.

With reference to the first, second and third members recited in the independent claims 1 and 12 (discussed below), lag screw members 1805 and 1810 of Figure 18 map to the claimed "first member" and "second

member," respectively, whereas the larger, substantially vertical, tapered screw member 1815 maps to the claimed "third member." *See, e.g.,* Ex. 2012 ¶ 38.

Addressing interactions of first member 1805 and second member 1810 with third member 1815, the Specification discloses that "[e]ach of the lag screw members 1805 and 1810 forms a[] fixed acute angle with the tapered screw member 1815, with these angles being predetermined by, for example, a surgeon to fix the bones in a human body." Ex. 1001, 13:31–34. In some embodiments,

> end 1825 has a tapered aperture 1835, which is aligned on axis 1802 and forms a fixed angle 1808 with axis 1806. Fixed angle 1808 determines the angle for fixation of tapered screw member 1810 with respect to lag screw member 1805. Also, tapered screw member 1815 has a second tapered aperture 1840, aligned along axis 1804 and forms a fixed angle 1812 with axis 1804. The fixed angle 1812 determines the angle for fixation of lag screw member 1810 with tapered screw member 1815.

Id. at 13:38–47.

F. Challenged Claims

Petitioner challenges claims 1–15 of the '166 patent. Pet. 1. Of these, only claims 1 and 12 are independent. Ex. 1001, 14:62–16:64. Claim 1, reproduced below, is illustrative of the subject matter challenged (paragraphing and labeling of limitations as added in Petitioner's Specific Grounds).

> 1. An assembly for bone fusion, comprising:
>
> 1[a][i]: a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis

1[a][ii]: 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;

1[b][i]: a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis,

1[b][ii]: 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;

1[c][i]: 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,

1[c][ii]: wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body,

1[c][iii]: 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

1[c][iv]: wherein the first bore comprises an interior surface at the first aperture

1[c][v]: wherein there are no threads adjacent to the second aperture on the exterior surface of the third member

1[c][vi]: wherein the third longitudinal axis and the first bore axis define a first angle

1[d]: wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle

> 1[e]: 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
>
> 1[f]: 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
>
> 1[g]: wherein the first angle is in the range of about 0 degrees to about 90 degrees
>
> 1[h]: wherein the second angle is in the range of about 0 degrees to about 90 degrees
>
> 1[i]: wherein the second bore axis is substantially perpendicular to the third longitudinal axis.

Ex. 1001, 14:62–15:44; *see* Pet. 8–23.

Independent claim 12 is substantially similar to claim 1 but without language corresponding to element 1[g], "wherein the second angle is in the range of about 0 degrees to about 90 degrees." *See* Ex. 1001, 16:7–56.

II. ANALYSIS

A. Legal Standards

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (2012) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

Petitioner contends that the challenged claims are anticipated by the prior art. Pet. 6. To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). In evaluating anticipation, it is permissible to take into account not only the literal teachings of the prior art reference, but also the inferences the skilled artisan would draw from them. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. At Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017) (holding that the "dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from a prior art reference that every claim element is disclosed in that reference"). As such, "a reference can anticipate a claim even if it does not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (internal quotation and alteration marks omitted).

Petitioner also contends that the challenged claims would have been obvious under § 103. Pet. 6. A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the claimed invention pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of

underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if any.[9] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotation marks omitted).

We address Petitioner's challenges with these standards in mind, and in view of the definition of the skilled artisan and the claim constructions discussed below.

[9] Patent Owner does not rely on secondary considerations.

G. Person of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

In our Institution Decision, we adopted Petitioner's proposed definition of a person of ordinary skill in the art as having

> a bachelor's degree in biomedical and/or mechanical engineering or similar training with at least five years of experience with the methods, processes, and implant devices used to stabilize fractures, correct deformities and fuse bone in small bone and/or long bone fractures using internal fixation, and preferably has experience in the operating room (OR) or cadaver labs to witness use and implementation.

DI 10–11 (citing Pet. 6–7; Ex. 1002 ¶ 29).

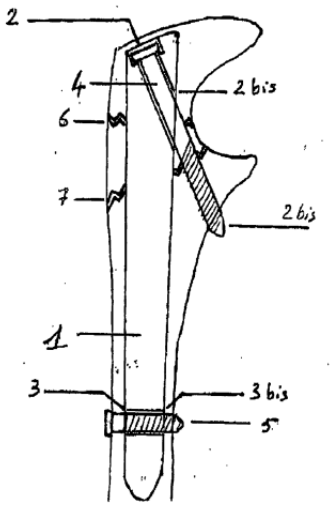
Patent Owner subsequently proposed an alternative definition, as a person having "[a] Bachelor's Degree in biomedical and/or mechanical engineering or similar training and . . . at least three years of experience with implant devices used for internal fixation of bones." POR 5 (citing Ex. 2012 ¶¶ 32–33). According to Patent Owner, "[t]his hypothetical person would be capable of performing various design tasks and would understand the basic mechanical features and operation of orthopaedic implant devices [and] have an appreciation for orthopaedic fusion techniques and the medical issues and concerns faced by a doctor/surgeon charged when performing operations to implant orthopaedic devices." *Id.*

Despite some differences in wording, Patent Owner asserts (and Petitioner does not contest) that any "distinction between the parties' proposed definitions of a POSITA does not affect the arguments set forth herein." *Id.* (citing Ex. 2012 ¶ 34). Consistent with this view, we find the parties' constructions equally applicable in light of the prior art of record and the disclosure of the '166 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may] reflect[] an appropriate level" as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)). We adopt, for convenience, Petitioner's definition, but our analysis does not change depending on which of the two articulations are applied here.

H. Overview of the Asserted References

1. Overview of Cognet (Exhibit 1004)

Cognet discloses a device for the osteosynthesis of fractures. *See, e.g.*, Ex. 1004, code (57). Figure 1 of Cognet is reproduced below.

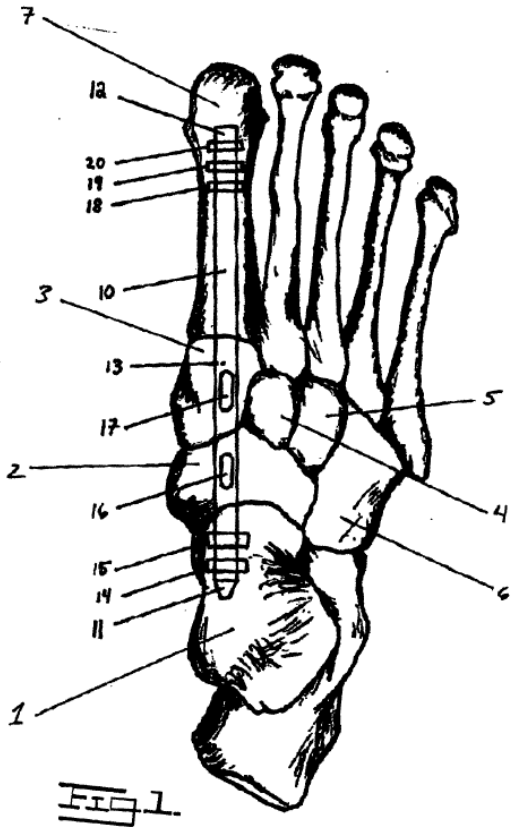


Id. at Fig. 1. Figure 1 shows an exemplary device of Cognet in sagittal section. *Id.* at 3:21–23. According to Cognet, the device "consists of a nail (1) having a proximal orifice or tunnel (2) and at least two distal orifices facing one another or one distal tunnel (3) and into which screws are introduced, one in a proximal situation (4) and the other or others (5) in a distal situation." *Id.* at code (57).

2. Overview of Simon (Exhibit 1008)

Simon discloses a "device, method, and system for treatment or fixation of a fractured, damaged, or deteriorating bone or bones in a mid-foot region." Ex. 1008, code (57). According to Simon, the device is "an implant with both proximal and distal fastener holes, along with fastener slots in a central elongated body, for securing the implant to the appropriate osseous cortical structures of the foot." *Id.*

Figure 1 of Simon is reproduced below.

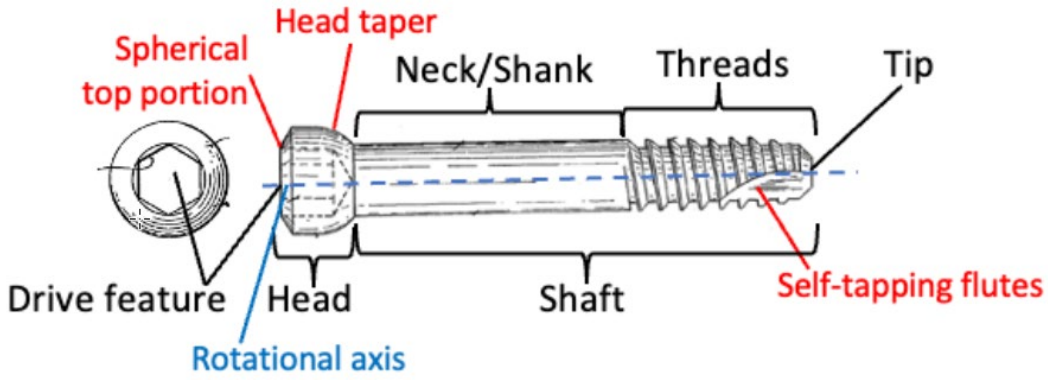


Id. at Fig. 1. Figure 1 is a top-down view of a right human foot, depicting the bones and intramedullary nail 10 running through the mid-foot region. *Id.* ¶ 53. Simon discloses that "the proximal end 11 of the implant or intramedullary nail 10 is attached with at least one fastener []or locking screw, with two depicted in FIG. 1, 14 & 15[]." *Id.* Intramedullary nail 10 includes fastener holes 16, 17, which transverse axial central axis 13 of nail 10. *Id.* "[D]istal end 12 of the intramedullary nail 10 is attached by way of at least one fastener (or locking screw, with three depicted in FIG. 1, 20, 19, & 18)." *Id.*

3. Overview of Brumfield (Exhibit 1006)

Brumfield discloses "[a]n apparatus for treating fractures of the femur including a screw and an intramedullary rod." Ex. 1006, Abstr. According to

Brumfield, the "invention provides an apparatus for treating fractures of the femur which marries the fixation attributes of an intramedullary nail with the proven benefits of the sliding compression screw." *Id.* at 2:65–68. Relevant features of Brumfield's compression screw are shown in the following composite of Brumfield's Figures 6 and 7, annotated by Dr. Dominguez.

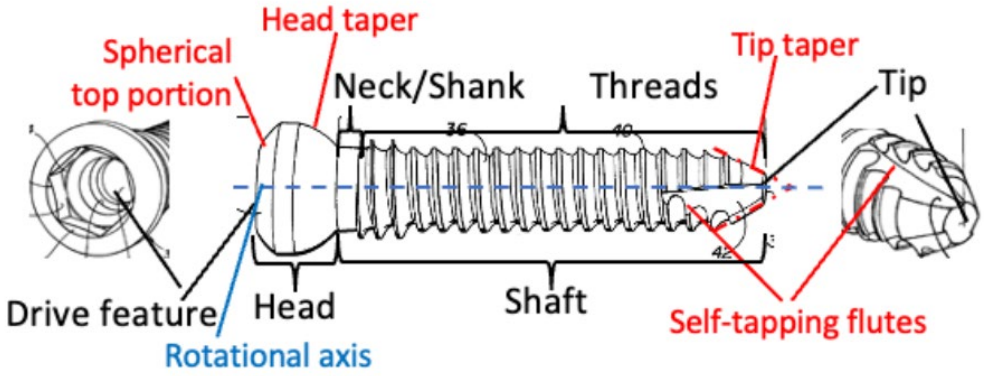


(Ex. 1006, Figures 6&7)

Ex. 1002 ¶ 101; Ex. 1006, 3:67–4:1, Figs. 6, 7. The above figure illustrates the head, shaft, threads, and drive feature of Brumfield's compression screw.

4. Overview of Ferrante (Exhibit 1007)

Ferrante discloses "[a]n orthopedic screw with a screw head, a screw body with distal tip, a shank with an enlarged diameter at the trailing end and a thread extending radially outward from the shank, and an internal capture surface." Ex. 1007, Abstr. Relevant features of Ferrante's orthopedic screw are shown in the following composite of Ferante's Figures 1, 3, and 6, annotated by Dr. Dominguez.



(Ex. 1007, Figures 1, 3, & 6)

Ex. 1002 ¶ 108; Ex. 1007 ¶¶ 23, 25, 28, Figs. 1, 3, 6. The above figure illustrates the head, shaft, threads, and drive feature of Ferrante's orthopedic screw.

5. Overview of Leu (Exhibit 1009)

Leu disloses "[a] bone fracture fixation device . . . includ[ing] an intramedullary nail and an intramedullary nail head." Ex. 1009, Abstr. Leu discloses a screw with threads 17 near the screw head that can engage corresponding threads 15 in a bore of the intramedullary nail. *See* Ex. 1009, 3:1–14, 3:66–4:9, 4:14–22, Figs. 2, 3.

I. Claim Construction

We construe claims "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100 (2021). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the

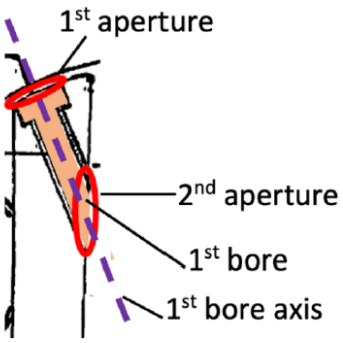
invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id*.

Petitioner bears the burden of stating "[h]ow the challenged claim is to be construed." 37 C.F.R. § 42.104(b)(3). But only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs*. in the context of an AIA trial proceeding). For the purpose of this Decision, we need formally address only the term "bore."

1. "*bore*"

Claim 1, element 1[c][iii] and claim 12, element 12[c][iii] recite "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." The construction of "bore" is pertinent to whether Cognet's Figure 1 discloses this claim element ("the first bore limitation"). *See, e.g.*, POR 20–26.

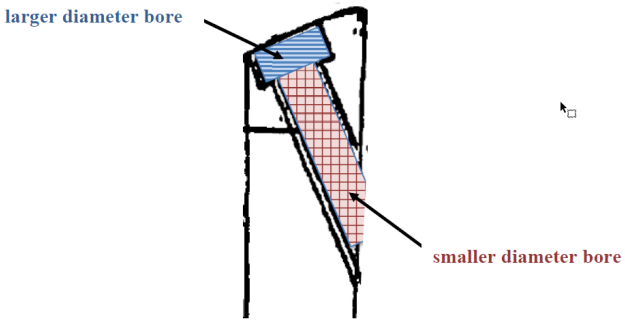
Petitioner's interpretation of Cognet's Figure 1 is illustrated below:



The above figure shows Cognet's Figure 1 as annotated by Petitioner to illustrate "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." Pet. 17 (citing Ex. 1002 ¶ 59).

Patent Owner's competing interpretation of Cognet's Figure 1 is illustrated below:



The above figure shows Cognet's Figure 1 as annotated by Patent Owner to illustrate a passage comprising a "larger diameter bore" or counterbore, contiguous with a "smaller diameter bore." POR 22 (citing Ex. 2012 ¶ 46). *Id.* According to Patent Owner, Cognet's Figure 1 does not satisfy the first bore limitation because it comprises two distinct bores, neither of which, taken alone, extends along an "axis from the first aperture to a second aperture on an exterior surface of the third member." *Id.* at 23 (citing Ex. 2012 ¶ 49).

In light of the above, we revisit our earlier determination of whether one of ordinary skill in the art would understand that "bore," as used in the context of claims 1 and 12, encompasses a multi-diameter passage, and in particular, one having stepped longitudinal cross sections such as that shown in Cognet's Figure 1. *See generally* DI 11–13. For the reasons that follow, we conclude that one of ordinary skill in the art would have understood "bore" as such.

Relying on the testimony of Mr. Dominguez, Petitioner initially proposed a construction of "bore" as "a usually cylindrical hole made by or

as if by the turning or twisting movement of a tool." Pet. 16 (citing Ex. 1002 ¶ 58). Petitioner's proposal relied on Mr. Dominguez's testimony that "[a] bore is a cylindrical hole made by the spinning rotation of a twist drill cutting tool. It is typically made by removing material from a solid or hollow object, similar to a tunnel or orifice." Ex. 1002 ¶ 58.

Pointing to its annotation of Cognet's Figure 1, above, Patent Owner argued that that the term "bore" excludes a tunnel made by "two adjacent bores." *See* Prelim. Resp. 21–25. In view of the then-available evidence, we provisionally 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. DI 13.

Post-institution, Petitioner agrees with our refinement of its original construction as set forth in the Institution Decision. Reply 1. Patent Owner, however, contends that we should either apply Petitioner's original construction ("a usually cylindrical hole made by or as if by the turning or twisting movement of a tool"),[10] or modify our preliminary construction to exclude stepped—but not tapered—cross sections ("a cylindrical hole or passage made by or as if by the turning or twisting movement of a tool, not excluding holes or passages having tapered cross-sections"). POR 17–18.

[10] We note that Petitioner's original construction does not appear to distinguish Cognet insofar as a stepped bore could be constructed merely by repositioning a rotary tool, changing the cutting head, or by employing a contoured cutting head of the nature of the bone reamer disclosed in Weiner, US 10, 357,299 B2, issued July 23, 2019. *See* Ex. 2017, Fig. 25 (discussed at Ex. 1018 ¶¶ 5–8).

Although the Specification does not recite, let alone define, the term "bore," the prosecution history of the related '680 application (Application No. 12/658,680) is informative.[11] During prosecution of the '680 application, Patent Owner amended claim 1 to recite "a bore extending along a third axis from the first aperture to a second aperture on an exterior surface of the second screw member." Ex. 1015, 21. In discussing support for claim 1, Patent Owner points to Figure 11, reproduced below.

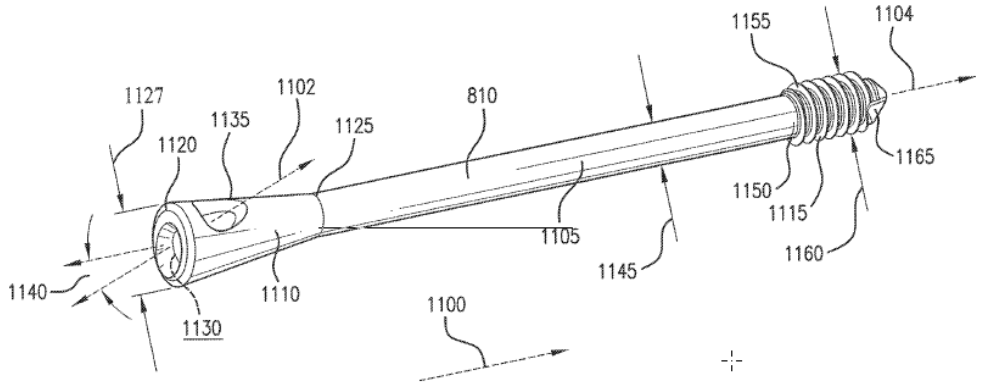


FIG. 11

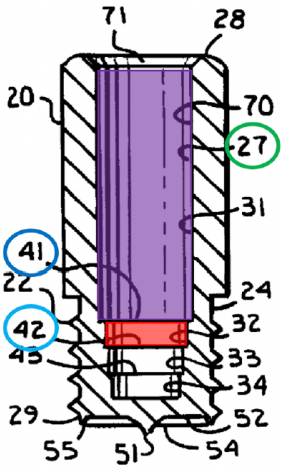
Id. at 107–109.

Figure 11 is "a perspective view of a the tapered screw member used in the intramedullary fixation assembly shown in FIGS. 8-9 according [an] embodiment of the invention." Ex. 1001, 3:54–57. According to Patent Owner, the element shown in Figure 11 comprises a first aperture 1130 at a terminal end of 1120 . . . and a bore extending along a third axis 1102 from the first aperture 1130 to a second aperture on an exterior surface at the first

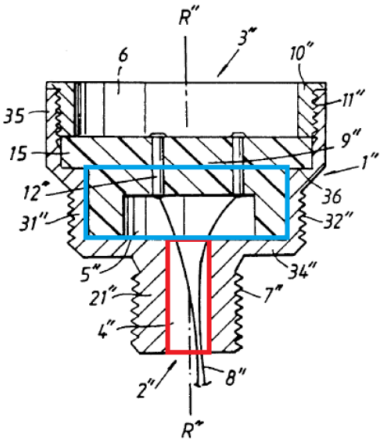
[11] The '166 patent issued from a divisional application of the '680 application via a series of continuation applications such that the two applications share essentially the same specification. *See* Ex. 1001, code (60).

aperture 1130," wherein "the bore comprises an interior surface at the first aperture 1130." Ex. 1015, 109. As noted by Petitioner, "[t]he specification describes structure 1130 as a 'tapered aperture 1130' that 'traverses' the device along 'axis 1102' to 'emanate from surface 1135." Prelim. Reply 2 (citing Ex. 1001, 9:46–49; Ex. 1014, 9:23–26). As such, we understand Patent Owner to have described the bore of its preferred embodiment as including a larger diameter counterbore (the conical interior surface of first aperture 1130), contiguous with a smaller diameter passage. With respect to the scope of the term bore, we find it of little moment that transition between the two sections in Figure 11 is at an angle less than the 90° transition of Cognet. We similarly find probative Petitioner's observation that "Patent Owner's argument does nothing to explain why the term "bore" should exclude stepped diameters." *See* Sur-sur-reply 3.

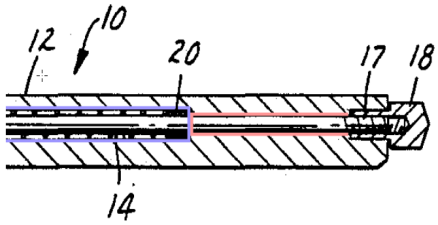
We also find persuasive Mr. Dominguez's explanation that one of ordinary skill in the art would have understood "bore" as including stepped diameter holes, sometimes described as a bore having a counterbore. *See generally* Ex. 1018 ¶¶ 4–29; Reply 3–10. Three of Mr. Dominguez's illustrative examples are reproduced in the annotated figures below.



(Ex. 1019, Fig. 3 – annotated)



(Ex. 1021, Fig. 4 - annotated)



(Ex. 1025, Fig. 1 detail - annotated)

The above figures show Mr. Dominguez's annotated illustrations from the Jackson (Ex. 1019, Fig. 3), Brånemark (Ex. 1021, Fig. 4), and Ray (Ex. 1025, Fig. 1) references as discussed at paragraphs 10, 12, and 13, respectively, of Mr. Dominguez's Second Declaration. With reference to the above figures, Mr. Dominguez testifies that "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)" (Ex. 1018 ¶ 10); "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" (*id.* ¶ 12); and Ray discloses surgical calipers including "handle 12 having 'stepped cylindrical bore 14,'" wherein "[c]ollar 20 of a shaft inserted in the bore 'rests against a step of the bore 14' (2:14–15)" (*id.* ¶ 13).

Patent Owner responds that Mr. Dominguez's examples "that allegedly show a single bore encompassing two or more stepped-diameter holes or a counterbore . . . . are specific to these references and divorced

from the disclosures of the '166 patent." Sur-Reply 7. Insofar as the '166 patent makes no mention of the term "bore" outside the claims, and Mr. Dominguez's examples are all taken from the field of orthopedic surgery, we do not find this argument persuasive. Patent Owner further appears to contend that exemplary references to a "cylindrical *stepped down* bore" or a "*stepped* cylindrical bore" are too specific to be within the scope of the term "bore." Sur-Reply 7–8. As these terms merely describe species within a larger genus, and Patent Owner presents no cogent reason to exclude them, we do not find this argument availing.

Relatedly, we are also not persuaded by Patent Owner's argument that "the prior art treats a 'bore' as an element that is distinct from a 'counterbore.'" *Id.* at 8. Rather, we credit Mr. Dominguez's testimony that "[a] counterbore is not a structure unto itself, a counterbore is part of a larger structure" as exemplified by numerous examples including Laps (Ex. 1028 ¶ 33 (sensor assembly wherein "bore 16 includes a counterbore 18")); Martinez (Ex. 1029, 3:61 (surgical cutting instrument wherein "bore 56 has a counterbore 64")); Zang (Ex. 1030, 2:49 (bone anchor having a "bore [that] includes a counterbore")); Ledet (Ex. 1022, 29:3–5 (vertebral fixation plate having "through holes . . . . countersunk, or counterbored to accommodate the head of a bone screw")); Seo (Ex. 1031, 3:45 (chair leg employing "counterbored bore 23")); and Exner (Ex. 1032, 2:16 (extrusion press including "counterbored axial bore 6")). Ex. 1018 ¶¶ 17–23. That a reference may refer to a figure as showing "bore 103" with "counterbore 105 . . . formed on one end" does not indicate that they are distinct structures as Patent Owner contends, but merely that the focus of each term is directed to the entire bore or to a particular aspect of the bore, i.e., its counterbore. *See*

Sur-Reply 8 (citing, e.g., Ex. 2024 5:44–50); *see also id.* at 1–2 (explaining how Small[12] (Ex. 2025) "uses the term 'bore' to refer to a void with multiple stepped-diameter portions including counterbore 128").

We are similarly unpersuaded by Patent Owner's contention that Weiner's[13] reference to the use of a reamer to "prepare[] a hole with a widened bore near the top," is inconsistent with how one of ordinary skill in the art would have understood the term "bore" in the context of the '166 patent. *See* POR 15–16 (citing Ex. 2017, 15:1–7, Fig. 25C; Ex. 2012 ¶ 41). As an initial matter, Patent Owner has not established that Weiner is prior art, or that it otherwise informs the understanding of one of ordinary skill in the art at the time of the invention. *See* Reply 7. Moreover, contrary to Patent Owner's argument, we read Weiner's teaching to "prepare[] a hole with a widened bore near the top," as using the word "hole" as synonymous with "bore," and merely drawing our attention to the widened portion of the bore. *See* Ex. 2017, 15:1–7; Reply 7 (arguing that Weiner "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. 1018 ¶¶ 5–8 (Mr. Dominguez's testimony that Weiner shows "that a counterbore is considered to be part of a larger structure or hole"). Regardless of Weiner's alleged support for Patent Owner's narrow interpretation of "bore," we conclude that it does not override the other intrinsic and extrinsic evidence as to the broader meaning of "bore" discussed above.

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[12] Small et al., US 5,139,499, issued Aug. 18, 1992.

[13] Weiner et al., US 10,357,299 B2, issued July 23, 2019.

In light of the above, and all of the argument and evidence adduced at trial, we maintain our initial construction of "bore" as meaning 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. *See* Inst. Dec. 13.

J. Grounds 1–7

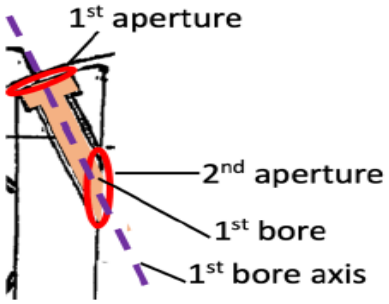
For the reasons discussed below, Petitioner has demonstrated that claims 1–10 and 12–15 are unpatentable under the Grounds set forth in the Petition.

1. Ground 1: Anticipation by Cognet

As Ground 1, Petitioner challenges independent claim 1 and its dependent claims 2–7 and 9 and independent claim 12 and its dependent claim 13 as anticipated by Cognet. Pet. 6, 8–32; Reply 17–25. Petitioner's challenge includes an element-by-element comparison of the claims to the cited art. *See* Pet. 9–32. Patent Owner opposes. POR 20–49; Sur-reply 8–17. We address with particularity only those elements addressed by Patent Owner, finding the remaining elements supported by Petitioner's unrebutted arguments and evidence.

a) "*a first bore extending along a first bore axis from the first aperture to a second aperture*"

Petitioner contends that Cognet discloses "a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member," as required by independent claims 1 and 12. Petitioner illustrates its position with respect to element 1[c][iii] with reference to the following illustration.



Pet. 16–17 (citing Ex. 1002 ¶ 59). According to the Petition, the above figure shows a terminal portion of the nail member from Cognet's Figure 1 annotated to show a first bore having a first bore axis and first and second apertures. *See id.*

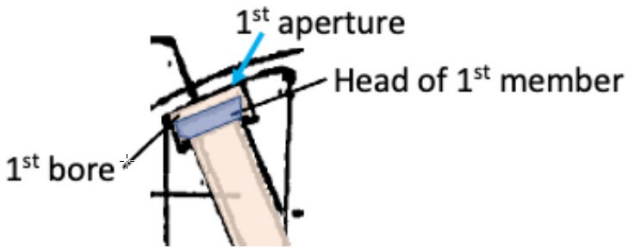
Patent Owner, however, contends that Cognet fails to disclose the recited claim element because "[t]he tunnel Petitioner identifies as the 'first bore' in Cognet is, in fact, created by *two* bores: a larger diameter bore intended to receive the head of a screw, and a smaller diameter bore intended to receive the shaft of the screw." POR 21 (citing Ex. 2012 ¶ 45).

Patent Owner's position requires us to construe "bore" as excluding a passage having a stepped cross-section such as that shown in Cognet's Figure 1. As discussed in detail in section II.D.1, however, we construe the term to mean 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*. Because our construction encompasses the "1st bore" passage of Petitioner's annotated version of Cognet's Figure 1, we find that Cognet discloses "a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member." Considering that Patent Owner argues no other limitation of

claims 2, 5, 6, 12, and 13, we find these claims anticipated for the reasons set forth in the Petition, as supported by the persuasive testimony of Mr. Dominguez. *See* Ex. 1002 ¶¶ 38–99.

b) "*wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture*"

Claims 2 and 6 require that "the head portion of the first member resides at least partially within the first bore." To illustrate this limitation, Petitioner provides the following annotated version of Cognet's Figure 1.

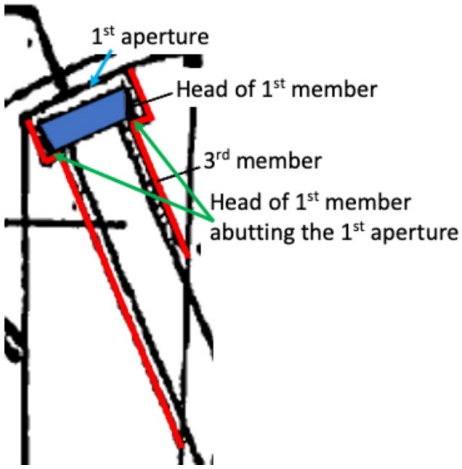


According to Petitioner, the above figure "shows the head portion of the first member (shaded blue) residing within the first bore (shaded orange). Pet 23–24 (citing Ex. 1003 ¶¶ 72–73).

Depending from claims 2 and 6, respectively, claims 3 and 7 further require that "the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture." With respect to this limitation, Patent Owner argues that Cognet's head portion does not abut the interior surface of the first bore "at the first aperture" but, instead, at "*the shoulder* between the larger diameter bore and the smaller diameter bore." POR 27 (citing Ex. 2012 ¶ 53). In short, Patent Owner contends that Petitioner identifies the first aperture as limited solely to a two-dimensional plane defining the outer edge of Cognet's tunnel, whereas the head of

Cognet's screw is recessed below, rather than abutting the edge of that plane. *See generally id.* at 26–34; Sur-reply 9–14.

As an initial matter, nothing in the Specification or claims requires that the first aperture be limited to a two-dimensional plane at the very end of the bore, nor do we read the Petition so narrowly. To illustrate the limitation of claims 3 and 7, the Petition included the following annotated version of Cognet's Figure 1.



According to the Petition, the above figure "shows the exterior surface of the head portion of the first member abutting the interior surface of the first bore at the first aperture." Pet. 24–25 (citing Ex. 1002 ¶ 75). Although Petitioner's blue arow points generally to the tunnel's upper opening as the "1st aperture," the green arrows pointing to the intersection of the head and bottom of the countersunk portion of Cognet's bore—defining where the head abuts the first aperture—clearly indicate Petitioner's position that the "first aperture" is not a planar element, but extends at least to the end of the countersunk portion of the bore.

Petitioner's view that the first aperture has such depth is supported by the prosecution history of the '680 application in which Patent Owner described Figure 11, reproduced below, as having "a first aperture 1130 at a

terminal end 1120 of the second end of the second elongated body, and a bore extending along a third axis 1102 from the first aperture 1130 to a second aperture on an exterior surface 1135 of the second screw member 810." Ex. 1015, 108–109.

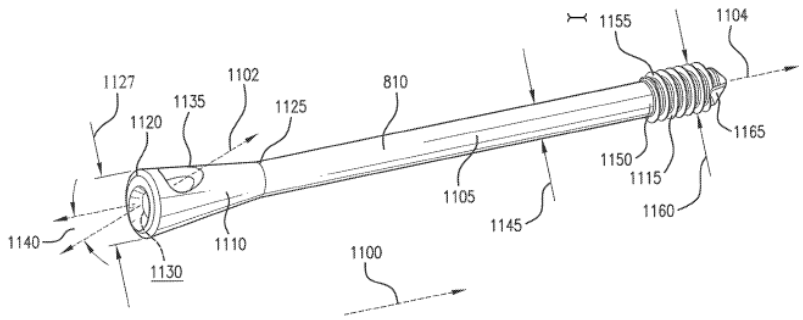


FIG. 11

As shown in Figure 11, the arrow pointing to "first aperture 1130" enters the counterbored portion of the bore, which we read as indicating that the first aperture is not limited to a 2-dimensional plane marking the entrance to the bore, but has some depth. With further reference to the same structure, the Specification similarly states that "first end 1120 has a tapered aperture 1130, which traverses tapered portion 1110 along axis 1102, which causes tapered portion aperture 1130 to emanate from surface 1135"—again suggesting that aperture 1130 is not limited to a planar structure. *See* Ex. 1001, 9:46–49.

Accordingly, we understand first aperture/tapered aperture 1130 to have at least the depth of the countersunk portion of the bore. Moreover, as noted by Petitioner, the Specification further "states that bulbous portion 1010 (which corresponds to the recited head portion) forms an interference fit with aperture 1130." Reply 22 (citing Ex. 1001, 8:50–53, 9:66–10:2). As

such, we agree with Petitioner that this "is the same interaction Petitioner shows between Cognet screw 4 and the shoulder in Cognet's tunnel." *Id.*

Considering the record as a whole, we find that Cognet discloses "the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture," as recited in claims 3 and 7.

c) "*a torque transmitting aperture*"

Claim 4 requires that "the head portion of the first member comprises a torque transmitting aperture." Petitioner contends that Cognet discloses the first member as a screw and, "almost all screws comprise a torque transmitting aperture." Pet. 25 (citing Ex. 1002 ¶¶ 42b, 76). Mr. Dominguez further explains that the head of an orthopedic bone screw

> has an internal drive feature located inside the head of the screw. An internal hex, square, hexalobe (8-point star) are common geometries that can be used to transfer rotation torque (from a screwdriver) to drive the screw into bone. A "screw" that does not have an internal drive feature is likely a "bolt" and not a "screw."

Ex. 1002 ¶ 42b; *see also* Reply 23 (arguing that "any given screw inherently has a torque transmitting aperture unless the context dictates otherwise"). With respect to claim 4, Mr. Dominguez testifies that one of ordinary skill in the art "would have immediately understood that [Cognet's] screw head would require a torque driving geometry (often used with a screwdriver tool) to drive the bone screw into bone by rotating the screw." *Id.* ¶ 76.

Patent Owner contends that Petitioner has not shown that Cognet anticipates claim 4 because the assertion that "***almost all screws*** comprise a torque transmitting aperture . . . . is not sufficient to find a torque transmitting aperture in Cognet." POR 34. By way of illustration, Patent

Owner contends that a "hex lag screw," reproduced below, "does not include a torque transmitting aperture."

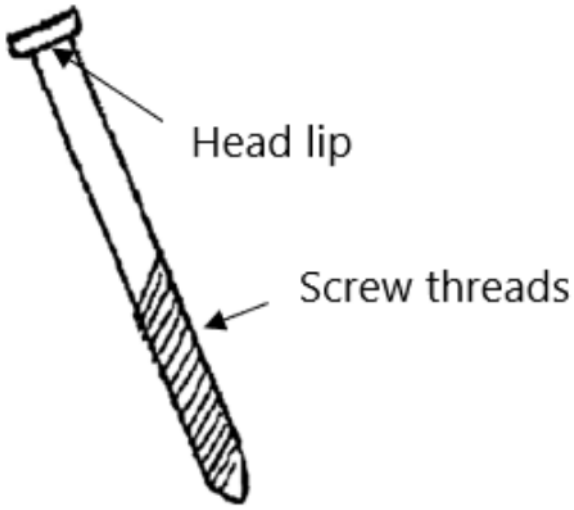
POR 35–36 (citing Ex. 2012 ¶ 59). Patent Owner's position is undercut by its admission that the above example "is not to be taken as exactly a screw that would be placed into a human body." Tr. 30:4–22. We are also not persuaded by Dr. Ledet's somewhat vague testimony that "[s]uch a screw *could* be used as the 'first member' identified by Petitioner in Cognet," which is unsupported by any example of a "hex lag screw" used, or intended for use, in orthopedic surgery. Ex. 2012 ¶ 59 (emphasis added). Rather, we credit Mr. Dominguez's testimony that:

> The hex cap lag screw example supplied by the Patent Owner (POR 35, Ex. 2012 ¶ 59) is typically used to affix heavy lumber under intense loads, is not a bone screw that would be used in orthopedic surgery, and was taken from a non-medical website according to Patent Owner's expert, Dr. Ledet. (Ex. 1017, 40:19). Because the object is not a medical device, it is my opinion than one of ordinary skill in the art would not have recognized it as a screw as that term is used in implantable medical device design.

Ex. 1018 ¶ 49; *see also* Ex. 1017, 40:15–41:21 (Dr. Ledet's testimony that he copied the above photo from a non-medical website); Reply 23.

We are also persuaded that nothing in Cognet suggests a hex-headed screw, or any head configuration other than round. *See*, *e.g.*, Reply 24;

Ex. 1018 ¶ 48; Tr. 16:1–14, 53:7–18. We credit, in particular, Mr. Dominguez's testimony with respect to Cognet and the portion of Cognet's Figure 1, reproduced below.



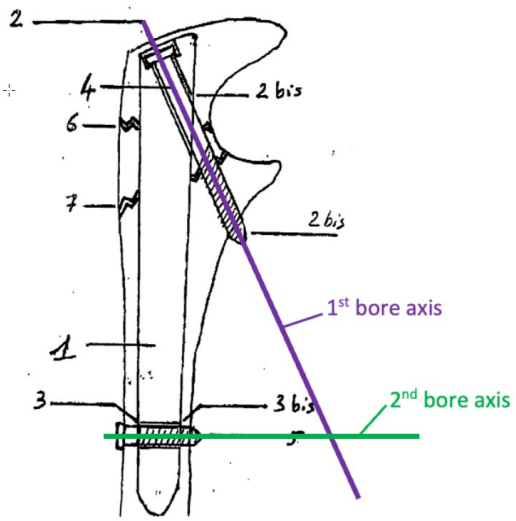
Ex. 1018 ¶ 48. The above figure, annotated by Mr. Dominguez, is a detail side view of the screw 4 from Cognet's Figure 1. Mr. Dominguez testifies that the head of Cognet's screw 4 is round, based in part on "the lack of lines on the head." *Id.* "[I]f it were not circular and instead had straight sides,the sides would have been delineated with lines. For example, if the head were a hex head, Cognet would have included one or two such lines to show two or three sides of the hex head." *Id.* According to Mr. Dominguez, "Cognet gives no indication that the screw head is anything other than circular." *Id.* To the contrary, "Cognet discloses that the head has a diameter. . . . [which] is a property of a circular shape because the diameter is the same wherever it is measured on a circle." *Id.* (citing Ex. 1004, 3:14). Accepting that Cognet's discloses a round screwhead, we credit Mr. Dominguez's testimony that "one of ordinary skill would assume that Cognet's screw had a torque aperture because it is the only reasonable, cost effective and space efficient

way that a circular screw could be driven into bone (through the use of a screw driver, or similar tool)." Ex. 1018 ¶ 49.

Considering the record as a whole, we find that the skilled artisan would understand Cognet to disclose that "the head portion of the first member comprises a torque transmitting aperture," as recited in claim 4.

d) *"the first bore axis and the second bore axis intersect outside the third member"*

Claim 9 requires that "the first bore axis and the second bore axis intersect outside the third member." In asserting that this element is disclosed, Petitioner relies on the testimony of Mr. Dominguez and the annotated version of Cognet's Figure 1, reproduced below.



Pet. 26–27; Ex. 1002 ¶¶ 81–82. Mr. Dominguez presents the above version of Cognet's Figure 1 to illustrate the intersection of the first and second bore axes as understood by one of ordinary skill in the art. *See* Ex. 1002 ¶ 82; Ex. 2013, 163:13–169:24. In connection with this figure, Mr. Dominguez testifies that "[t]wo non-parallel lines will intersect at a point in space provided they are the same plane." Ex. 1002 ¶ 81. Dr. Ledet, however,

argues that the two axes would not be in the same plane—and, thus, not intersect—if the second bore axis was rotated out of the plane of the first. *See* Ex. 2012 ¶ 60; POR 38–39.

Despite this hypothetical proposal regarding how Cognet's second bore axis might be manipulated, Dr. Ledet does not dispute Mr. Dominguez's testimony that "Cognet discloses the first bore axis and the second bore axis *intersecting* outside the third member," as required by claim 9. *See* Ex. 1018 ¶ 50 (citing Ex. 1002 ¶¶ 81–82); Reply 25. Also, we credit Mr. Dominguez's interpretation of Cognet's Figure 1 and related disclosure over the unsubstantiated hypothetical manipulation of Figure 1 urged by Patent Owner's declarant. And on the record before us, we agree with Petitioner that Cognet discloses all elements of claim 9.

e) Conclusion as to Ground 1, Claims 1–7, 9, 12, 13

Considering the record before us, and in light of our construction of "bore," we find that Petitioner has shown persuasively that claims 1–7, 9, 12, 13 are unpatentable over Cognet.

2. Ground 2: Obviousness in view of Cognet and Brumfield

As Ground 2, Petitioner challenges claims 4, 8, 10, 14, 15 as obvious over Cognet in combination with Brumfield. Pet. 6, 32–35; Reply 25–26. Patent Owner opposes. POR 39–40; Sur-sur-reply 17–18. We address with particularity only those elements raised by Patent Owner, finding the remaining elements supported by Petitioner's unrebutted arguments and evidence.

Patent Owner contends that Petitioner has not identified why one of ordinary skill in the art would have combined Cognet and Brumfield with a reasonable expectation of success in achieving the inventions described in

claims 4, 8, 10, 14, 15. POR 40–49; Sur-Reply 17. We do not find Patent Owner's arguments persuasive for the reasons set forth at pages 25–26 of the Reply, which we adopt.

a) Reason to Combine

Petitioner points to Brumfield's compression screw as disclosing or rendering obvious certain claim limitations relating to the first member. Pet. 31–35; *see also* Reply 25–26 ("Petitioner cites Brumfield simply as evidence that it was well known to secure intramedullary nails using bone screw with torque apertures (claim 4), tapered heads (claims 8, 14, 15), and self-tapping ends (claim 10)."). Patent Owner contends that Petitioner has not pointed to evidence that one of ordinary skill in the art would have been motivated to combine the teachings of Cognet and Brumfield. POR 40–49; Ex. 2012 ¶¶ 62–70 . We disagree with Patent Owner. Indeed, we credit Mr. Dominguez's testimony:

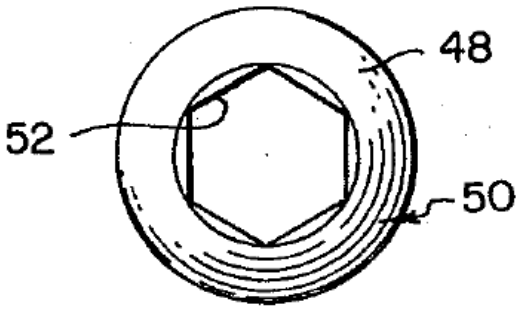
> It would have been obvious to a POSA to use the screws disclosed in Brumfield with the intramedullary nail disclosed in Cognet because the screw and nail in Brumfield are performing the same function in the same way as the screw and nail in Cognet. Namely, the proximal screw in Brumfield and Cognet is providing compression from the intramedullary nail to the fractured bone.

Ex. 1002 ¶ 101 (citing Ex. 1006, 4:43–47); Ex. 1018 ¶ 51 (similar). We do not find persuasive Dr. Ledet's testimony to the contrary, i.e., that Cognet and Brumfield are directed to different applications. *See* Ex. 2012 ¶¶ 62–70. Although Cognet and Brumfield disclose orthopedic assemblies for different applications, both rely on screw mechanisms to apply compression to bone.

b) "*a torque transmitting aperture*"

With respect to the individual elements, Petitioner points to the hex-shaped inset forming the drive feature of Brumfield's screw as the "a torque

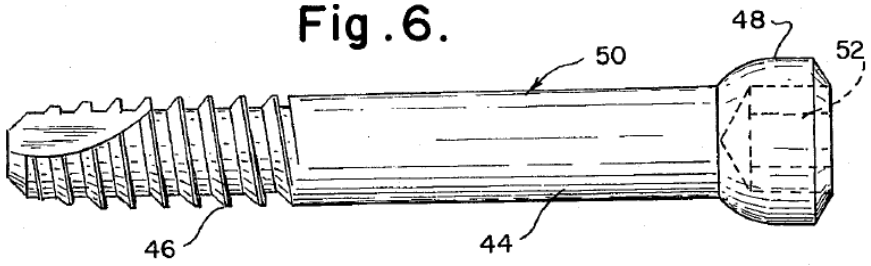
transmitting aperture," of claim 4. Pet. 33–34; Ex. 1002 ¶ 101–102. Brumfield's Figure 7 is reproduced below.



Ex. 1006, Fig. 7. Figure 7 is a top end view of Brumfield's screw showing that "[a] hexagonally shaped inset 52 in the head portion 48 permits insertion of a suitable tool for compression of lag screw 50." *Id.* at 3:67-4:1, 5:22–24. Although we agree with Petitioner that one of ordinary skill in the art would be motivated to use the hexagonally shaped internal drive feature such as that disclosed in Brumfield with Cognet's device, we also find that Cognet alone discloses such a "torque transmitting aperture." *See* Section II.E.1.c, above.

c) "*wherein the head portion of the first member is tapered*"

Claims 8, 14, and 15 recite "wherein the head portion of the first member is tapered." Petitioner relies on Brumfield's "beveled head portion" 48 for this limitation. Pet. 34–35. Figure 6 of Brumfield is reproduced below.



Ex. 1006, Fig. 6. As shown in Figure 6, Brumfield's "lag screw 50 includes a smooth portion 44, a self-tapping threaded end 46 and a beveled head portion 48." *Id.* at 5:20–22.

Relying on the testimony of Dr. Ledet, Patent Owner contends that the use of Brumfield's bevel-headed "screw [with] the flat shoulder of Cognet's nail renders the combination inoperable." *See* Sur-reply 18 (citing Ex. 2012 ¶¶ 68–69). In particular, Dr. Ledet states that whereas Cognet's beveled screw head is designed to contact an intramedullary nail, Brumfield's screw head is designed to contact bone, and using Brumfield's screw head in Cognet's device would cause "increased resistance to rotation of the screw." Ex. 2012 ¶¶ 68–69. Dr. Ledet, however, provides no context as to *how much* increased resistance might be expected from such a substitution, nor any explanation of why such an increase might be disfavored, let alone render the combination inoperable. As such, we find Patent Owner's position speculative and accord it little weight. We also disagree with Patent Owner's arguments because they presume the bodily incorporation of Brumfield's screw into Cognet's device, which ignores, for example, the ordinarily skilled artisan's ability to modify the countersunk portion of Cognet's device to better accommodate a beveled screw head. *See* Reply 25 (citing *In re Mouttet*, 686 F.3d 1322, 1332 (Fed Cir. 2012)).

Considering the record as a whole, Petitioner has established by a preponderance of the evidence that one of ordinary skill in the art would have found it obvious to combine Brumfield's beveled screw with Cognet's fixation device.

d) *"wherein the first end of the first member includes a self-tapping edge for removing bone material"*

Claim 10 recites, "wherein the first end of the first member includes a self-tapping edge for removing bone material." For this limitation, Petitioner points to Brumfield's disclosure of a "self-tapping threaded end." Pet. 34–35 (citing Ex. 1006, 5:20–22, Fig. 6; Ex. 1002 ¶ 104); *see also* element 46 in Brumfield's Fig. 6, reproduced above.

According to Mr. Dominguez, self-tapping screws have

> a side-cutting edge (or flute) . . . that cuts the bone as the screw advances. This creates a threaded path for the rest of the main screw threads to continue to cut and purchase into the bone. Self-tapping flutes serve to decrease the torque resistance to drive the screw into bone. Screws that do not have self-tapping threads will usually require a bone predrill and tap to create the conditions to allow insertion of the bone screw.

Ex. 1002 ¶ 42f; *see also* Ex. 2013, 208:4–15 (Mr. Dominguez's testimony that "one end of the bone screw needs to have . . . a tip with a self-cutting flute so that the screw could be advanced into the bone"). Mr. Dominguez further explains that, although not expressly recited in Cognet, a self-tapping edge as in Brumfield "is a very common characteristic of orthopedic screws," that aids in "the removal of bone chips." Ex. 1002 ¶¶ 109–110; 136–137, 160–161; Ex. 1018 ¶¶ 52 (Mr. Dominguez's testimony that "[t]he self-tapping design feature is very desirable because it removes the pre-drilling step, which shortens time spent during the operation"), 57.

Considering the record as a whole, we agree with Petitioner that it would have been obvious to use Brumfield's self-tapping screw in Cognet's device.

Having considered the evidence of record, we determine that Petitioner has shown persuasively that claims 4, 8, 10, 14, and 15 would have been obvious for the reasons set forth in the Petition.

3. Grounds 3: Obviousness over Cognet and Ferrante

As Ground 3, Petitioner challenges claim 11 as obvious over Cognet in combination with Ferrante. Pet. 6, 35–37; Reply 26–27. Claim 11 is directed to "the assembly of claim 10, wherein the first end of the ***second member*** *includes a self-tapping edge* for removing bone material" (emphasis added). Claim 10, in turn, is directed to the assembly of claim 1, wherein the first end of the ***first member*** *includes a self-tapping edge* for removing bone material" (emphasis added).

In Section II.E.1, above, we determined that Cognet alone discloses all elements of claim 1. In opposing Ground 3, Patent Owner contends that because claim 11 depends from claim 10, Petitioner would have had to assert in the Petition that the limitations of claim 10 would have been obvious in view of Cognet and Ferrante, or that claim 11 was obvious in view of Cognet in combination with Ferrante and Brumfield. *See generally* POR 39–40; Sur-sur-reply 17–20; Tr. 33:23–26. Consistent with Patent Owner's position, we find neither argument in the Petition. Petitioner's failure to timely set forth its argument with respect to the limitations of claim 10 is, thus, a fatal flaw in its challenge to its dependent claim, claim 11. *See Microsoft Corp. v. IPA Techs. Inc.*, No. 2021-1412, 2022 WL 989403, at *6 (Fed. Cir. Apr. 1, 2022) (affirming the Board's determination that Petitioner insufficiently pleaded the unpatentability of claims 29–47 where the petition only addressed the limitations of dependent claims 30–47 without analyzing those of claim 29 from which the others depend).

"It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify 'with particularity' the 'evidence that supports the grounds for the challenge to each claim.'" *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (quoting 35 U.S.C. § 312(a)(3)). Here, however, not until its Reply does Petitioner belatedly suggest that Ferrante's disclosure of bone screws with self-tapping ends equally meets the limitation of claim 10 (with respect to the first member) as with claim 11 (with respect to the second member), and that both claims are obvious in light of "evidence" from Ferrante "that it was well known to equip bone screws with self-tapping ends." Reply 26–27. We do not discern these arguments in the Petition, and consider them waived. *See Netflix, Inc. v. DivX, LLC*, 84 F.4th 1371,1377 (Fed. Cir. 2023) ("While the Board should not take an overly mechanistic view of a petition and decline to address an argument because the petitioner did not present it with ideal vigor and clarity, the Board should also not have to decode a petition to locate additional arguments beyond the ones clearly made.").

In sum, Petitioner's error in failing to first address limitations of claim 10 in the Petition specific to the Cognet/Ferrante combination indicates

> a failure to meet the particularity requirements for what must be in the petition and cannot be left to be filled in on reply. *See* 35 U.S.C. § 312(a)(3); 37 C.F.R. §§ 42.22(a)(2) (requiring, among other things, "a detailed explanation of the significance of the evidence"), 42.104(b)(4)–(5) (requiring that petition "specify where each element of the claim is found in the prior art patents or printed publication relied upon" and, regarding submitted evidence, state "the relevance of the evidence to the challenge raised, including identifying specific portions of the evidence that support the challenge").

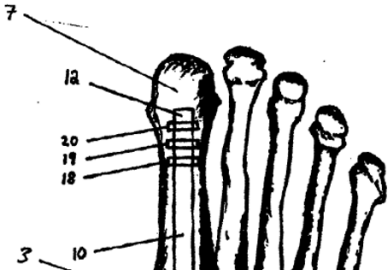
Microsoft, 2022 WL 989403, at *6. Accordingly, Petitioner has not shown persuasively that claim 11 would have been obvious in light of Cognet and Ferrante for the reasons set forth in the Petition.

Because Petitioner has demonstrated sufficiently that all claims of the '166 patent but for claim 11 are unpatentable under Grounds 1–3 (based on Cognet),[14] we need only address Grounds 4–7 (based on Simon), to the extent they bear on claim 11.

4. Ground 4: Anticipation by Simon

As Ground 4, Petitioner challenges independent claim 1 and its dependent claims 4, 5, 8, 10, and 11, as well as independent claim 12 and its dependent claims 14 and 15 as anticipated by Simon. Pet. 6, 37–58; Reply 27–32. Patent Owner opposes. POR 55–65; Sur-reply 20–27.

Independent claims 1 and 12 recite that "the first member comprises a shaft portion having an external surface and a head portion having an exterior surface." In our Institution Decision, we noted that the Petition "appears to identify one or more of elements 18–20 of Simon's Figure 1 as the claimed first member," and that "Figure 1 of Simon is a low-resolution drawing that does not clearly differentiate elements 18–20 as having distinct head and shaft portions. DI 22 (citing Pet. 40, Ex. 1008, Fig. 1). By way of illustration, we reproduce below an excerpt of Simon's Figure 1.



[14] Claim 11 is addressed in Ground 3, but not in Grounds 1 and 2.

With respect to this portion of Figure 1, Simon explains that, "the first metatarsal 7 is the bone that makes up the big toe in the human foot, where the distal end 12 of the intramedullary nail 10 is attached by way of at least one fastener (or locking screw, with three depicted in FIG. 1, 20, 19, & 18)." Ex. 1009 ¶ 53.

We also noted that the Petition "does not expressly state that Simon's screws have a head but, more generally, that the entirety of element 1[a][ii] is satisfied because "Simon discloses elements 18, 19, and 20 as being locking screws [Ex. 1008, [0053]), interlocking cortical screws, or transfixation screws (Ex. 1008, [0039])." [Pet.] 40 (further citing Ex. 1002 ¶ 116)." DI 22. We also addressed Mr. Dominguez's testimony that "[s]ome screws are 'headless' or have a 'threaded conical taper' shape with threads running all the way to include the head *intended to be fully sunk in bone*." Ex. 1002 ¶ 42a (emphasis added), which we understood to convey that, "while headless screws are known, at least those at issue in his statement are used to drive the screw entirely into the bone." *Id.* at 23.

Patent Owner contends that Simon fails to disclose screws with a head portion. POR 51–55; Sur-reply 20–23; Ex. 2012 ¶¶ 71–77. We note, in particular, that closer inspection of Simon's Figure 1, upon which Petitioner relies, makes clear that screws 18, 19, and 20 are "fully sunk in the first metatarsal bone 7 of a foot." *See* Sur-reply 20–21. Patent Owner further supports its position by noting that "Simon does not expressly disclose that its screws have a head portion." Finally, Patent Owner points to Mr. Dominguez's testimony "a screw with a 'non-bulbous portion'—one where 'there's nothing there that is larger than the rest of the screw,'" would be considered "a headless screw." Sur-reply 21–22 (citing Ex. 2022, 120).

As noted by Patent Owner, "[t]his is precisely how Simon depicts screws 18, 19, and 20." *Id.* at 22 (citing Ex. 1008, Fig. 1). Considering the record before us, we understand Simon to disclose the use of only headless screws.

Considering the record before us, Petitioner has not established sufficiently that Simon discloses a screw having a head portion, as required by the independent claims. As such, Petitioner has failed to establish that claims 1, 4, 5, 8, 10–12, 14, 15 are anticipated under Ground 4.

5. Ground 5: Obviousness in view of Simon and Ferrante

As Ground 5, Petitioner challenges claims 1, 4, 5, 8, 10–12, 14, 15 as obvious over Simon in combination with Ferrante. Pet. 6, 58–61; Reply 31. Patent Owner opposes. *See generally* POR 51–68; Sur-reply 27.

Patent Owner contends that Ground 5 fails because Petitioner has not shown that one of ordinary skill in the art would have been motivated to combine Simon with Ferrante. POR 66–67; Sur-reply 27. We agree with Patent Owner.

The sole explanation underpinning Petitioner's reason to combine in the Petition states:

> Ferrante is analogous art because it discloses orthopedic screws being used in an intramedullary nail. It would have been obvious to a POSA to use the screws disclosed in Ferrante with the intramedullary nail disclosed in Simon because the screw and nail in Ferrante (Ex. 1007, Fig. 14-15; ¶¶ 36-37) are performing the same function in the same way as the screw and nail in Simon.

Pet. 58 (citing Ex. 1002 ¶ 157). Mr. Dominguez's referenced testimony at paragraph 157 of Exhibit 1002 repeats exactly the same statement without providing any additional detail.

In Section II.E.2, above, we credited Mr. Dominguez's testimony that one of ordinary skill in the art would have had reason to combine Brumfield and Cognet because the proximal screw in both references provides compression from the intermedullary nail to the fractured bone. *See, e.g.*, Ex. 1002 ¶ 101. Petitioner presents no such explanation with respect to Simon and Ferrante.[15] Nor does Petitioner adequately address Patent Owner's numerous criticisms regarding Petitioner's reasoning as to why one of ordinary skill in the art would have been motivated to modify or combine the teachings of Simon or Ferrante with a reasonable expectation of success. *See* POR 66–67.

At best, Petitioner argues in its Reply that the Petition "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." Reply 31 (citing Pet. 58–61). With respect to claim 10, for example, the Petition states: "While a POSA would assume that the first member includes a self-tapping edge, Simon does not explicitly state this feature. Ferrante discloses

[15] We note that the screw heads in Brumfield contact the surface of the affected bone (Ex. 1006, Fig. 1), and those in Cognet contact the intermedullary nail (Ex. 1004, Fig. 1). The screws in Simon and Ferrante, however, display a different relationship. Whereas Ferrante discloses a beveled screw head partially sunk into the surface of the bone (Ex. 1007, Fig. 15), Figure 1 of Simon shows headless screws sunk entirely within a bone (*see* Section II.4, above). As such, it is not clear that the similarity between Brumfield and Cognet, if properly asserted, would even apply to Simon and Ferrante because Simon's screw lacks a head anchoring it to a solid object.

a flute (42) for the removal of bone chips as screw (30) is implanted into bone (Ex. 1007,[0043]).” Pet. 60.

We do not find Petitioner’s argument persuasive. Despite Petitioner’s contention that one of ordinary skill in the art would have “assumed” that Simon included a self-tapping edge, the Petition’s mere identification of the missing feature in Ferrante does not, on this record, equate to a persuasive reason to combine. Accordingly, we agree with Patent Owner that Petitioner fails to meet its burden with respect to Ground 5. *See* Sur-reply 27.

For the reasons discussed above, Petitioner has not shown persuasively that claims 4, 8, 10, 11, 14, 15 would have been obvious over Simon in combination with Ferrante for the reasons set forth in the Petition.

6. Grounds 6 and 7

Petitioner further challenges claim 9 under Ground 6, and claims 2, 3, 6, 7, and 13 under Ground 7. Because Petitioner has shown that claims 1–10 and 12–15 are unpatentable under Grounds 1–3, but has failed to show that claim 11 is unpatentable under Grounds 4 or 5, we need not address Grounds 6 and 7 as they do not address claim 11.

K. Patent Owner’s Revised Motion to Amend

Patent Owner filed a Revised Motion to Amend (Paper 44, “RMTA”) original challenged claims 1–15 contingent on a finding of unpatentability of any of those claims and relied on its Second Declaration of Dr. Eric H. Ledet (Ex. 2023). Petitioner filed an Opposition to the Revised Motion to Amend (Paper 49, “Opp. RMTA”) and relied on its Third Expert Declaration of Leonel Dominquez (Ex. 1054). In response to the Opposition, Patent Owner filed a Reply (Paper 53, “Reply RMTA”) and relied on its Third Declaration

of Dr. Eric H. Ledet (Ex. 2037). Thereafter, Petitioner filed a Sur-reply (Paper 58, "Sur-reply RMTA").

1. Statutory and Regulatory Requirements

a) Proposal of a reasonable number of substitute claims

Patent Owner proposes a reasonable number of substitute claims. Patent Owner proposes a one-to-one substitution of proposed claims 16–30 for original claims 1–15. RMTA 1–2, 3–4, Claims App. Petitioner does not argue otherwise. *See generally* Opp. RMTA; Sur-reply RMTA.

b) Amendments responsive to a ground of unpatentability

The amendments respond to the grounds of unpatentability involved in this proceeding. *See* RMTA § VII. Petitioner does not argue otherwise. *See generally* Opp. RMTA; Sur-reply RMTA.

c) No enlargement of the scope of the claims

The amendments do not enlarge the scope of the claims but include narrowing limitations to the original claims. *See* RMTA Claims App. Petitioner does not argue otherwise. *See generally* Opp. RMTA; Sur-reply RMTA.

d) No introduction of new matter

The amendments do not add new matter. *See* RMTA Claims App. Petitioner does not argue otherwise. *See generally* Opp. RMTA; Sur-reply RMTA.

2. Patentability

In submitting its Revised Motion to Amend, Patent Owner requests that we "maintain any original claims found to be patentable." RMTA 1. Petitioner has not shown that claim 11 is unpatentable for the reasons set forth in the Petition and as we discussed above. Because proposed claim 26

corresponds to claim 11 (*see* RMTA Claims App'x), our analysis applies to the patentability of proposed claims 16–25 and 27–30.[16]

The Board must assess the patentability of proposed substitute claims "without placing the burden of persuasion on the patent owner." *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc); *see also Lectrosonics, Inc. v. Zaxcom, Inc*., IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019) (precedential). The petitioner must prove that the proposed substitute claims are unpatentable by a preponderance of the evidence. *Bosch Auto. Serv. Sols., LLC v. Matal*, 878 F.3d 1027, 1040 (Fed. Cir. 2017); *Lectrosonics*, Paper 15 at 3–4.

As explained further below, having considered the arguments and evidence presented by the parties at trial, we determine Petitioner has shown by a preponderance of the evidence that proposed substitute claims 16–25 and 27–30 would have been unpatentable over the prior art.

Petitioner challenges the substitute claims as anticipated by, or obvious in view of, Mazur,[17] and obvious in view of Cognet in combination with Zhang,[18] Brumfield, Ferrante, Melkent[19] and/or Gooch.[20] *See generally* Opp. RMTA 1–25. For the purpose of this proceeding, it is sufficient that we address the challenges based on Mazur. In this respect, Petitioner asserts that

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[16] We note, however, that Patent Owner raises no independent argument with respect to proposed claim 26.

[17] Mazur, US 2011/0087227 A1, pub. Apr. 14, 2011. Ex. 1056.

[18] Zhang, Chinese Utility Model No. CN 2513533Y, issued Oct. 2, 2002. Exs. 1058 (Certified English Translation), 1059.

[19] Melkent, US 2011/0022173 A1, pub. Jan. 27, 2011. Ex. 1060.

[20] Gooch, US 2008/0221623 A1, pub. Sept. 11, 2008. Ex. 1063.

the substitute claims are unpatentable under 35 U.S.C. § 102 as anticipated by Mazur. Opp. RMTA 1–12. Petitioner provides a chart mapping every limitation of the proposed substitute claims to the disclosures of Mazur and Mazur's provisional application (Ex. 1057). *Id.* at 4–11.

In response, Patent Owner presents three reasons we should find that Petitioner has not shown Mazur anticipates the proposed claims. *See* Reply RMTA 1–4. These arguments pertain to whether Mazur discloses the claimed 1) first aperture, (2) straight hub[21] and (3) intersecting bore axes specified in dependent claim 24. We address these elements below, finding the remaining elements supported by Petitioner's unrebutted arguments and evidence.

Mazur discloses a bone fixation device with an elongate body having a longitudinal axis. *See*, *e.g.*, Ex. 1056, code (57). Figure 16A of Mazur is reproduced below.

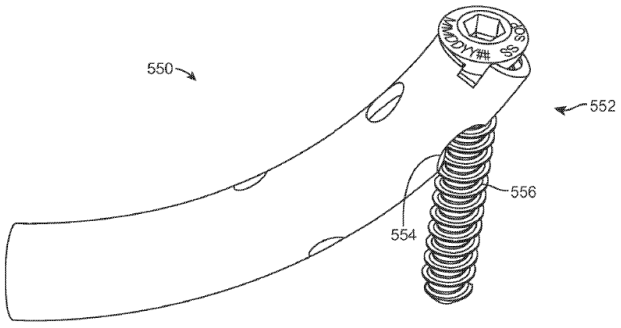


FIG. 16A

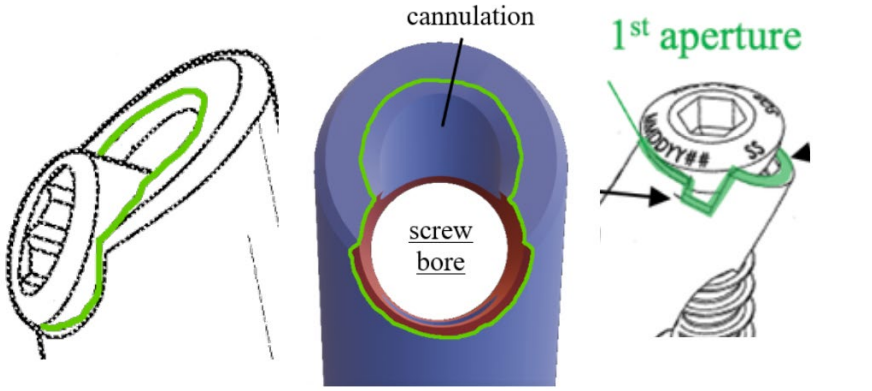
[21] Petitioner argues that Mazur also renders obvious the substitute claims because "portions of Mazur disclos[e] that features of one embodiment apply to others" and that there would have been a reasonable expectation of success in implementing "Mazur's extensive description of straight-hubbed embodiments." *Id.* at 11–12 (citing Ex. 1056 ¶ 94; 1054 ¶ 14).

Figure 16A shows an exemplary bone fixation device hub 550. *Id.* ¶¶ 55, 110. Bone fixation device hub 550 includes proximal end 552 with transversely elongated hole 554 that allows screw 556 "to be located along the central axis, or off-axis in either direction as may be desired for engaging harder bone or securing additional bone fragment(s)." *Id.* ¶ 110.

> a) "*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*"

Petitioner asserts that 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 Mazur's bone fixation device hub 550 which screw 556 "passes through has a notch cut out of the hub sidewall." Opp. RMTA 1 (reproducing Ex. 1056, Fig. 16A). Petitioner argues that the first aperture depicted in the '166 patent's Figure 18 "similarly is composed from multiple contiguous voids resulting from the intersection of the nail hollowing" (or "cannulation") as that of Mazur's aperture. *Id.* at 2.

Petitioner provides the following three-panel composite to illustrate the relationship between tapered first aperture region of Figure 18 of the '166 patent and the hub portion of Mazur's Figure 16A.



RMTA 7 (detail) Ex. 1064, 3 (detail) Mazur, Fig. 16A detail (annotated)

Id. The above panels show (a) a partial view of the '166 patent's Figure 18 from the Revised Motion to Amend (RMTA 7), (b) a partial view of a still generated from a 3D model of that Figure 18 (Ex. 1064, 3), and (c) a partial reproduction of Mazur's Figure 16A, all annotated with a green line to trace around the perimeter of the apertures. *Id.* at 2–3. According to Petitioner, "[b]ecause 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." *Id.* at 3 (citing Ex. 1054 ¶ 8).

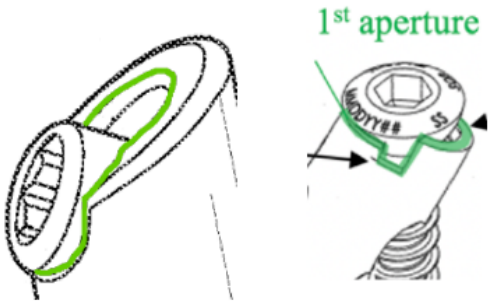
Patent Owner responds that Petitioner has not shown that Mazur discloses the new limitations of claims 16–30, because although Mazur discloses an aperture on the top of its hub, the aperture is not also on the side of the hub. Reply RMTA 3 (citing Ex. 2023 ¶¶ 20–24). According to Patent Owner, Mazur's "sidewall notch" is not part of that aperture. *Id.* Patent Owner further argues that the '166 patent's corresponding aperture has a purpose and geometry that are "tied to" a bore, which is to provide an opening for a screw to enter and a surface for the screw to abut and rest on. *Id.* (citing Ex. 1001, Figs. 9, 11, 17, 18, claim 3; Ex. 2037 ¶ 21). Patent Owner argues that Mazur's screw does not engage the notch and "serves an

entirely different purpose: to allow the hub to engage with an insertion tool." *Id.* at 3–4 (citing Ex. 1056 ¶¶ 72–73, Figs. 4, 6; Ex. 1054 ¶¶ 16–18; Ex. 2038, 34:23–35:16; Ex. 2037 ¶ 22).

We disagree with Patent Owner's arguments. Reply RMTA 3. We first note that Patent Owner concedes that Mazur's aperture has the same purpose as that of the aperture at issue in the '166 patent, i.e., for allowing a screw to enter and rest on the nail because Patent Owner states, "Mazur's figures show that the 'open end' on the top surface of Mazur's hub serves this purpose." *Id.* Then, although Patent Owner argues that the '166 patent's aperture has a purpose and geometry that are "tied to" a bore (*id.*), we find no such feature in any proposed claim. *See* Tr. 40:18–43:20. Consequently, we fail to see why the purpose and geometry of Mazur's aperture is not the same as those of the '166 patent—allowing a screw to enter and rest on the nail.

Although Patent Owner contends that Mazur's notch serves a different (additional) purpose of allowing a hub to engage with an insertion tool, we agree with Petitioner that the claims do not preclude this purpose. *See* Opp. RMTA 2–3. And to the extent that Patent Owner is arguing Mazur's aperture does not include the notch, such argument is unavailing because the notch is part of the perimeter of the aperture of Mazur's nail. If we were to characterize Mazur's notch as *not* being a part of the aperture, then we would *also* characterize the '166 patent's side exterior surface as *not* forming a part of the first aperture recited in the substitute claims.

Further addressing Patent Owner's "purpose" arguments, we reproduce below a side-to-side comparison of excerpts from Figure 18 of the '166 patent and Figure 16A of Mazur as annotated by Petitioner.



RMTA 7 (detail)

Mazur, Fig. 16A detail (annotated)

Sur-reply RMTA 4. The above comparison of aperture regions from Figure 18 of the '166 patent and Figure 16A of Mazur shows that, to the extent Patent Owner is arguing that the '166 patent's first member must fit through the aperture and bore, so does Mazur's corresponding first member, and that both figures show that the head of the first member (screw) does not occupy the entire aperture. RMTA 3–4.

Considering the record before us, we agree with Petitioner that Mazur discloses "wherein the first aperture is on a portion of a first exterior surface of the third member and on a portion of a second exterior surface of the third member," as required by the proposed independent claims.

> b) "*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*"

As with original independent claims 1 and 12, proposed independent claims 16 and 27 require "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." With respect to this element, Petitioner asserts that although Mazur's Figure 16A shows a curved hub 550, Mazur additionally discloses that the hub may be straight as shown in its Figure 7. Opp. RMTA 3 (citing Ex. 1056, Abstr., ¶¶ 94, 60, 88, Fig. 7; Ex. 1054 ¶¶ 9–11).

Patent Owner argues that, in pointing to the embodiments illustrated in Mazur's Figures 16A–16E and Figure 7, Petitioner has not shown that Mazur "is sufficiently clear in disclosing the combinability of those elements such that a skilled artisan would at once envisage the claimed combination." Reply RMTA 1–2 (citing *The Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1350 (Fed. Cir. 2019) (internal quotations omitted)). Patent Owner contends that to combine these embodiments, Petitioner relies on the disclosure in Mazur's paragraph 94 that "[f]urther, a straight, curved, flexible, rigid, or no hub at all may be used with the above combinations" but, according to Patent Owner, "the above combinations" refers only to combinations of components discussed earlier in the same paragraph, i.e., arguing "'[d]evice 300,' which is the embodiment in Figures 11A–11D and is different from that in Figures 16A–16E." *Id.* at 2 (citing Opp. RMTA 5; Ex. 1056 ¶¶ 46, 55; Ex. 2037 ¶¶ 15–16). Patent Owner contends that the embodiment of Figures 16A–16E is not introduced until later in the Specification, and "when asked whether 'device 300' is the embodiment in Figures 11A–11D and what 'above combinations' refers to, Petitioner's expert was unable or unwilling to answer." *Id.* (citing Ex. 1056 ¶ 110; Ex. 2037 ¶ 16; Ex. 2038, 29:7–11, 29:21–30:1, 31:7–32:24).

We agree with Petitioner that one of ordinary skill in the art would have understood Mazur to disclose a straight hub. *See* Opp. RMTA 1–3; Ex. 1054 ¶¶ 9–12. With reference to Figures 16A–16E in paragraph 94, Mazur teaches that "a straight, curved, flexible, rigid, or no hub at all may be used with the above combinations." Ex. 1056 ¶ 94. Although at the beginning of paragraph 94 Mazur states "[d]evice 300 is an example of an embodiment utilizing mixed gripper types," Mazur does not refer to "the

above *embodiments*," but rather, to "the above *combinations*." *Id.* (emphasis added). Within paragraph 94, Mazur mentions different types of grippers, such as a scissor-arm tripod gripper and a bendable arm gripper, and "various *combinations* of gripper(s) and/or flexible-to-rigid body portion(s)." *Id.* (emphasis added). Mazur then discloses that "[i]t is envisioned that virtually any *combination* of zero, one, two, or more grippers may be used in *combination* with zero, one, two or more flexible-to-rigid body portions to form a device adapted to a particular bone anatomy, fracture, disease state or fixation purpose" and that "the components may also be designed to be *interchangeable* and/or produced in various sizes so that surgical kits may be provided." *Id.* (emphasis added). Mazur explains that "[s]uch kits would allow surgical teams to select from a variety of components to build devices themselves, each suited to a particular patient's unique situation." *Id.* Taking paragraph 94 as a whole, we do not view "the above combinations" as limited to prior described embodiments as Patent Owner argues, but rather merely as referring to the different combinations of grippers and body portions that are "interchangeable."

With respect to obviousness, Petitioner contends that Mazur also renders obvious the substitute claims because "portions of Mazur disclos[e] that features of one embodiment apply to others" and that there would have been a reasonable expectation of success in implementing "Mazur's extensive description of straight-hubbed embodiments." *Id.* at 11–12 (citing Ex. 1056 ¶ 94; Ex. 1054 ¶ 14). Patent Owner, however, argues that Petitioner has failed to show that a person of ordinary skill in the art "would have been motivated to modify Mazur with a reasonable expectation of success, to arrive at the inventions of claims 16–30." Reply RMTA 5 (citing

Ex. 2037 ¶¶ 31–37). In other words, Patent Owner challenges Petitioner's position that it would have been obvious to modify Mazur's curved hub as depicted in its Figure 16A to be a straight hub. *See* Opp. RMTA 11–12 (Petitioner arguing that Mazur also renders obvious the substitute claims because "portions of Mazur disclos[e] that features of one embodiment apply to others" and arguing that there would have been a reasonable expectation of success in implementing "Mazur's extensive description of straight-hubbed embodiment"). According to Patent Owner, Petitioner "says nothing" about the differences between Mazur's straight hub embodiments in its Figures 1–9 and Mazur's curved hub embodiments in its Figures 16A–16E, which Patent Owner contends, "have very different designs and different applications." *Id.* (citing Ex. 2037 ¶¶ 32–34). Patent Owner contends that Petitioner should have provided the comparison of the designs and applications of those two embodiments and a comparison of reasons for using a straight hub and using a curved hub. *Id.* Patent Owner contends Petitioner's statement that Mazur "suggest[s] to [a person of ordinary skill in the art] to modify the embodiment in Figure 16A to have a straight hub" is a conclusory statement. *Id.* at 5–6 (citing Opp. RMTA 11; Ex. 2037 ¶¶ 29–30).

Patent Owner also argues that "Mazur discloses only that a straight hub 'may be used' for the embodiment in Figures 11A–11D" rather than for the embodiment in Figures 16A–16D. *Id.* at 6 (citing Ex. 2037 ¶ 31).[22] Patent Owner contends that such disclosure "suggests a mere possibility of

[22] Patent Owner appears to rely on Mazur's paragraph 94's disclosure of device 300, which is described in preceding paragraph 93 relative to Figures 11C and 11D, as an example. *See* Ex. 2037 ¶ 31.

making a modification to the embodiment of Figures 11A–11D without providing a reason for a [person of ordinary skill in the art] to make it." *Id.* Patent Owner argues that Petitioner fails to show a reasonable expectation of success because "the straight hub in Figures 1–9 is dimensioned and configured for the proximal ulna, while the curved hub in Figures 16A–16E is dimensioned and configured for the distal radius." *Id.* (citing Ex. 2037 ¶¶ 32–34). According to Patent Owner, "[w]hen asked whether the embodiment in Figure 7 could be used in a radial bone and about the purpose of the curvature in embodiment in Figures 16A–16E, Petitioner's expert was unable or unwilling to answer." *Id.* (citing Ex. 2038, 22:6–24:6, 25:3–26:18).[23]

We find unpersuasive Patent Owner's argument that it would not have been obvious to modify Mazur's curved hub in Figure 16A to be a straight hub. *See* Reply RMTA 5. We do not find pursuasive Patent Owner's contention that Mazur's curved hub embodiments in its Figures 16A–16E "have very different designs and different applications" compared to its other embodiments. *Id.* (citing Ex. 2037 ¶¶ 32–24). Rather, all of Mazur's embodiments have designs for the same application of repairing bone fractures. While a particular feature of one embodiment, such as the length of the hub, might be particular to a first type of bone, there is no evidence presented by Patent Owner that given the knowledge of a person of ordinary

[23] We note that throughout this cited testimony Mr. Dominguez emphasized Mazur's teaching of the interchangeability of parts and the ability to adapt the devices for use in any of the bones in the body. *See, e.g.*, Ex. 2038, 26:9–18.

skill in the art, one embodiment could not be modified for repairing a different bone having a different length.

The Supreme Court has emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418. As noted by the Court in *KSR,* "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416. Nothing in the record here suggests that Petitioner's proposed combination of known prior art elements according to their known functions would involve more than routine engineering efforts.

Accordingly, we find unavailing Patent Owner's argument that Petitioner fails to show a reasonable expectation of success because "the straight hub in Figures 1–9 is dimensioned and configured for the proximal ulna, while the curved hub in Figures 16A–16E is dimensioned and configured for the distal radius." Reply RMTA 6. Notably, Petitioner directs our attention to the many disclosures of a straight hub in Mazur, and provides reasons to have a straight hub. Opp. RMTA 3 (citing Ex. 1056 Abstr., ¶¶ 94, 60, 88, Fig. 7; Ex. 1054 ¶ 9–11). For instance, Mazur discloses that "[t]he devices of this invention can be adapted for use in any of the bones of the body as will be appreciated by those skilled in the art." Mazur ¶ 60. Thus, a straight versus curved hub is an obvious design choice that the skilled artisan may select according to the particular need. *See, e.g.*, Ex. 2038, 26:9–18 (Mr. Dominguez's testimony that one of ordinary skill in

the art would appreciate that Mazur's devices "can be adapted for use in any of the bones of the body"). Even if some unpredictability remained because the exact condition of one bone is different from that of another bone, that would not mean the claims are nonobvious. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) ("[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability in the art . . . , the expectation of success need only be reasonable, not absolute.").

Our analysis is consistent with Petitioner's arguments in its RMTA Sur-reply, which we reiterate below and adopt. First, Petitioner argues that "the above combinations" referred to in Mazur's paragraph 94 would include Figures 16A–16E, because those figures are mentioned in paragraph 55. Sur-reply RMTA 2. Although paragraph 55 is in the Brief Description of the Drawings section of Mazur, it is notable that Mazur's paragraph 95 describes Figures 12A–20B as "further examples of the hubs discussed above," where "the hubs discussed above" include those of Figures 11A–11D. *Id.* This disclosure would lead a skilled artisan to regard the embodiment of Figure 16A, which has a curved hub, as similar to the embodiment of Figures 11A–11D, which also has a curved hub and discussed in paragraphs 92–93 for example (e.g., disclosing that a "[c]urved hub 302 may be configured with the same geometry of the curved opening in the bone"), which is also similar to the curved hub referred to in paragraph 94 (disclosing that "a straight, curved, flexible, rigid, or no hub at all may be used with the above combinations").

Petitioner further points out that the testimony of Patent Owner's declarant, Dr. Ledet, concerning "the curved hub in Figures 16A–16E and *in situ* Figures 12G–12I" acknowledges that Figures 16A–16E show the same

embodiment as that of Figures 12G–12I which is consistent with Mazur's disclosure that Figures 12G–12I "show details of a curved hub 400 similar to hub 302 illustrated in FIGS. 11A–11D." *Id.* (citing Ex. 2037 ¶ 34; Ex. 1056 ¶ 96). Petitioner reproduces, as shown below, portions of Figures 11A, 12A, and 16A of Mazur for a side-to-side comparison to demonstrate that the hubs in those figures are "identical or similar." *Id.*

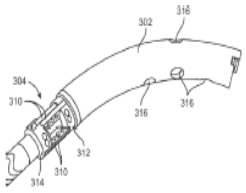


Fig. 11A (detail)

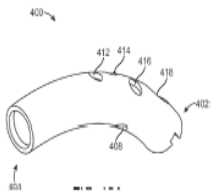


Fig. 12A (detail)

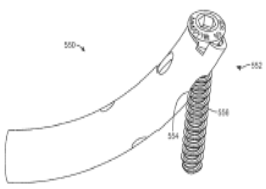
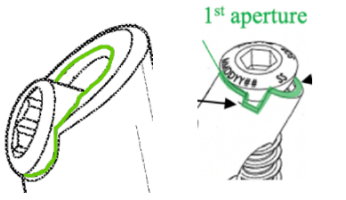


Fig. 16A (detail)

Id.

Petitioner argues that by Patent Owner stating that "[b]ut 'above combinations' refers to combinations of components discussed earlier in paragraph [0094] with respect [to] '[d]evice 300,' which is the embodiment in Figures 11A–11D," Patent Owners acknowledges that Mazur's disclosure of a straight hub as disclosed in Mazur's paragraph 94 can be applied to the embodiment in Figures 11A–11D (which has a curved hub). *Id.* at 2 (citing Reply RMTA 2). Consequently, Petitioner argues that Patent Owner's characterization of Figures 16–16E as a "different embodiment" is inconsistent with Mazur's disclosure and Patent Owner's earlier characterization of Mazur. *Id.* Petitioner argues that in contrast to the interchangeability of Mazur's hubs, Mazur discloses that only a few items are not interchangeable, such as screw 422 and screw 424. *Id.* (citing Ex. 1056 ¶ 99).



RMTA 7 (detail) Mazur, Fig. 16A detail (annotated)

Id.

Finally, in response to Patent Owner's argument that Mazur lacks motivation to combine the embodiment of Figure 7, which shows a straight hub, with the embodiment of Figures 16A–16E, which shows a curved hub, because of the "differences" between the two, Petitioner asserts that the test for obviousness is not bodily incorporation. *Id.* at 5 (citing *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (quoting *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981); *In re Mouttet*, 686 F.3d at 1332).

Petitioner also contends that its argument does not rely on a conclusory statement, but instead explains "how and where Mazur describes the interchangeability of parts and invites the [person of ordinary skill in the art] to modify the embodiments as the context requires." *Id.* at 6 (citing Opp. RMTA 3). In response to Patent Owner's argument that Mazur's Figures 1–9 are specific to the proximal ulna bone and Mazur's Figures 16A–16E are specific to the distal radius bone, Petitioner points out that Mazur discloses the embodiment of Figures 1–9 can also be used for the distal radius. *Id.* (citing Reply RMTA 6; Ex. 1056 ¶ 88). Petitioner argues that in contrast, Patent Owner's declarant, Dr. Ledet, provides no underlying facts to support his opinion that a straight hub could not be used in the distal radius, and that despite Dr. Ledet's assertion that Mazur's Figures 1–9 include grippers, whereas Mazur's Figures 16A–16E do not, Mazur discloses that the

embodiment of Figures 1–9 does not necessarily require grippers. *Id.* at 6–7 (citing Ex. 1056 ¶ 81).

In sum, and considering the record before us, we agree with Petitioner that Mazur discloses—and renders obvious—"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," as recited in the proposed independent claims.

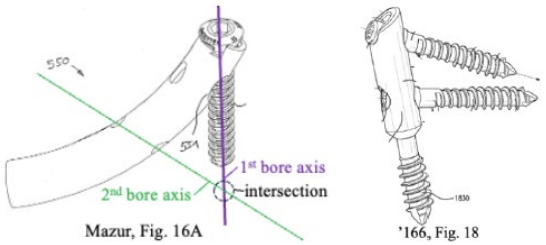
> a) "*wherein the first bore axis and the second bore axis intersect outside the third member*"

For this element, Petitioner relies on the testimony of Mr. Dominguez indicating that one of ordinary skill in the art would understand that Mazur's Figure 16A shows intersecting first and second bore axes. *See* Opp. RMTA 10; Ex. 1054 ¶ 12; *see also* Ex. 2038 59:22–60:11 (Mr. Dominguez deposition testimony regarding the axes of Mazur Figure 16A).

Patent Owner contends that Mazur does not disclose a first bore axis intersecting a second bore axis outside the third member (i.e., outside the body of its nail or hub) as required for proposed dependent claim 24. Reply RMTA 4. Patent Owner argues Mazur's Figure 16A does not disclose this limitation because the axes of its bores "may lie on any of an infinite number of planes, and may never intersect." *Id.* (citing Ex. 2037 ¶¶ 25–28). Patent Owner contends that "[w]hen Petitioner's expert was asked about this issue in his deposition, he was unable or unwilling to answer any of the questions." *Id.* (citing Ex. 2038, 57:16–60:16).[24]

[24] We note that at his deposition, Mr. Dominguez repeatedly testified that the two bore axes of Mazur Figure 16A did intersect but that he did not recall addressing what plane they were on in his declaration, nor what their

Insofar as Patent Owner is relying on Figure 18 of the '166 patent to show the co-planarity of the first and second bore axis for their intersection, we find that Mazur's Figure 16A shows the same, as illustrated in Petitioner's side-by-side comparison of the figures, which is reproduced below.



Sur-reply RMTA 4. The above figures compare Figure 18 of the '166 patent with Mazur Figure 16A, as annotated by Petitioner.

Considering the evidence of record, we credit Mr. Dominguez's testimony that one of ordinary skill in the art would have understood Mazur to disclose all elements of proposed dependent claim 24.

In view of the above, we deny Patent Owner's Revised Motion to Amend with respect to proposed claims 16–25 and 27–30; we do not reach a determination with respect to proposed claim 26 because Petitioner did not establish that corresponding original claim, claim 11, is unpatentable for reasons set forth in the Petition.

L. Patent Owner's Motion to Exclude

In Paper 56, Patent Owner moves to exclude Exhibits 1034–1038 and 1045–1050, paragraphs 71–79 of Exhibit 1018, and paragraphs 2 and 22–24 of Exhibit 1054. Mot. 1–9. Petitioner opposes. Paper 57, Opp. Mot. 1–4.

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relationship would be if the orientation of the apertures was changed. Ex. 2038, 58:2–60:16.

As noted by Patent Owner, the referenced portions of Exhibit 1018 as well as Exhibits 1049 and 1050 are "responsive only to Patent Owner's *original* Motion to Amend." Mot. 9. Petitioner further points out that *each* of Exhibits 1034–1038 and 1046–1050 pertain to the original motion to amend, and are not pertinent to our discussion of the original claims or those of Patent Owner's Revised Motion to Amend. Opp. Mot. 2. As we do not here address the original motion to amend, nor otherwise rely on these exhibits in the instant Decision, we dismiss this portion of Patent Owner's motion as moot.

Petitioner asserts Zhang in opposing Patent Owner's Revised Motion to Amend. Opp. RMTA 12–18. Exhibit 1045 and the referenced portion of Exhibit 1054 relate to Mr. Dominguez's testimony regarding how one of ordinary skill in the art would understand the Zhang reference cited in opposition to the Revised Motion to Amend. *See, e.g.*, Opp. Mot. 1 (Petitioner's assertion that "[t]he Zhang model illustrated in Exhibit 1054, and the '166 patent models illustrated in Figures 1034–1038, 1045–1050, and 1064 were presented as interpretive aids to show how a POSA would have understood them"). Because we do not reach Petitioner's arguments regarding Zhang, we dismiss this portion of Patent Owner's motion as moot.

Exhibit 1064 is an interpretive model prepared by Mr. Dominguez to explain, in paragraphs 8, 23, and 24 of Exhibit 1054, how one of ordinary skill in the art would understand Figure 18 of the '166 patent. Patent Owner contends this exhibit and the related testimony is speculative and irrelevant under Federal Rules of Evidence 401 and 402, and should be excluded under Federal Rule of Evidence 403 because "[its] value is substantially

outweighed by a danger of unfair prejudice to Patent Owner and confusing the issues." Mot. 7–9. In response, Petitioner argues that Exhibit 1064

> was presented expressly for the purpose of showing the shape of Patent Owner's purported first aperture more clearly and not for any other reason. Patent Owner does not dispute that the exhibit accurately depicts the purported first aperture. To the extent this exhibit aids the Board in its interpretation of the Revised Motion to Amend, it is relevant to the proceeding and can be accorded the appropriate weight.

Opp. Mot. 4. Petitioner further notes that "the Board is perfectly capable of assigning appropriate weight to the objected-to evidence without the need to protect a jury or other factfinder lacking administrative expertise from prejudice." *Id.* at 3. We agree with, and adopt, Petitioner's argument. As such, Patent Owner's motion is denied with respect to Exhibit 1064, and paragraphs 8, 23, and 24 of Exhibit 1054.

III. CONCLUSION

A. Original Claims

For the foregoing reasons, original claims 1–10 and 12–15 have been shown to be unpatentable, but original claim 11 has not been shown to be unpatentable. Our conclusions are summarized in the following table.

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–7, 9, 12, 13	102	Cognet	1–7, 9, 12, 13	
4, 8, 10, 14, 15	103	Cognet, Brumfield	4, 8, 10, 14, 15	
11	103	Cognet, Ferrante		11
4, 5, 8, 10, 11	102	Simon		4, 5, 8, 10, 11

4, 8, 10, 11, 14, 15	103	Simon, Ferrante[25]		11
9	103	Simon, Cognet[26]		
2, 3, 6, 7, 13	103	Simon, Leu		
Overall Outcome			1–10, 12–15	11

Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

B. Proposed Replacement Claims

For the foregoing reasons, we deny Patent Owner's Revised Contingent Motion to Amend with respect to proposed claims 16–25 and 27–30. We do not address proposed claim 26, as it maps to original claim 11, which was not shown to be unpatentable. Our conclusions are

[25] Because claims 4, 8, 10, 14, 15 are determined to be unpatentable in view of Cognet and Brumfield, we only address whether claim 11 is shown to be obvious based on Simon and Ferrante.

[26] We do not address Petitioner's arguments with respect to grounds based on Simon and Cognet, or Simon and Leu, because claims 1–10 and 12–15 are determined to be unpatentable based on other grounds and the Simon with Cognet/Leu grounds do not relate to claim 11.

summarized in the following table.

Motion to Amend Outcome	Claim(s)
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	16–30
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	16–25, 27–30
Substitute Claims: Not Reached	26

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 1–10 and 12–15 of the '166 patent are unpatentable;

FURTHER ORDERED that Petitioner has not shown by a preponderance of the evidence that claim 11 of the '166 patent is unpatentable;

FURTHER ORDERED that Patent Owner's Revised Contingent Motion to Amend is denied with respect to proposed substitute claims 16–25 and 27–30;

FURTHER ORDERED that Patent Owner's Revised Contingent Motion to Amend is not reached with respect to proposed substitute claim 26;

FURTHER ORDERED that Patent Owner's motion to exclude Exhibits 1034–1038, 1045–1050, and paragraphs 71–79 of Exhibit 1018 is denied as moot;

FURTHER ORDERED that Patent Owner's motion to exclude Exhibit 1064 and paragraphs 2 and 22–24 of Exhibit 1054 is denied on the merits;

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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