

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

Case IPR2023-00894
U.S. Patent No. 11,298,166

PATENT OWNER'S SUR-REPLY

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PATENT OWNER'S UPDATED TABLE OF EXHIBITS

Exhibit No.	Exhibit Description
2001	Declaration of Michael J. Zinna in Support of Patent Owner's Motion For Pro Hac Vice Admission Pursuant To 37 C.F.R. § 42.10(c)
2002	Complaint from Parallel District Court Case: <i>Extremity Medical, LLC vs. Fusion Orthopedics, LLC</i> , Case No. 2:22-cv-00723-PHX-GMS (D. Ariz.) (ECF 1)
2003	Case Management Order from Parallel District Court Case (ECF 49)
2004	July 10, 2023 Scheduling Order from Parallel District Court Case (ECF 74)
2005	July 28, 2023 Scheduling Order from Parallel District Court Case (ECF 76)
2006	Patent Owner's infringement contentions served in the Parallel District Court Case
2007	Petitioner's invalidity contentions served in the Parallel District Court Case and Exhibits A2 and A6 thereto
2008	<i>Markman</i> Order issued by the Court in the Parallel District Court Case (ECF 73)
2009	Printout from www.docketnavigator.com
2010	July 15, 2021 "List of References cited by applicant and considered by examiner" for U.S. Patent Application No. 17/323,923
2011	Selected Pages of the Transcript from the June 7, 2023 Deposition of Leonel Dominguez
2012	Declaration of Dr. Eric H. Ledet

Exhibit No.	Exhibit Description
2013	Transcript from the January 18, 2024 Deposition of Leonel Dominguez
2014	U.S. Patent Publication No. 2009/0240252 ("Chang")
2015	Claim Construction Order issued in <i>Extremity Medical, LLC vs. Fusion Orthopedics, LLC</i> , Case No. 2:22-cv-00723-PHX-GMS (D. Ariz.)
2016	Transcript from the June 7, 2023 Deposition of Leonel Dominguez
2017	U.S. Patent No. 10,357,299
2018	Printout from the website https://www.machinistguides.com/counterbores-all-about/
2019	Reserved
2020	Prosecution History for U.S. Patent Application No. 17/323,923
2021	Prosecution History for U.S. Patent Application No. 12/658,680
2022	Transcript from the June 6, 2024 Deposition of Leonel Dominguez
2023	Second Declaration of Dr. Eric H. Ledet
2024	U.S. Patent No. 5,057,103
2025	U.S. Patent No. 5,139,499
2026	U.S. Patent No. 7,967,851
2027	U.S. Patent No. 8,221,478
2028	Enlarged image from paragraph 75 of Mr. Dominguez's Declaration (Ex. 1002)
2029	Enlarged image from paragraph 57 of Mr. Dominguez's

Exhibit No.	Exhibit Description
	Declaration (Ex. 1002)
2030	Marked up image of Figure 18 of U.S. Patent No. 11,298,166
2031	Image of Figure 25C from U.S. Patent No. 10,357,299 marked by Mr. Dominguez
2032	U.S. Patent No. 7,901,459
2033	U.S. Patent No. 8,105,327
2034	U.S. Patent No. 9,521,999
2035	U.S. Patent Application Publication No. 2004/0106950
2036	U.S. Patent Application Publication No. 2009/0192546

I. INTRODUCTION

In its Response, Patent Owner ("PO") demonstrated that Claims 1-15 of the '166 Patent are patentable over the instituted grounds. Petitioner has not met its evidentiary burden to show otherwise. Nothing in Petitioner's Reply changes this.

While the entire Petition and Reply are deficient, Petitioner's arguments regarding Claims 3, 4, and 7 are particularly weak because of its expert's admissions. Based on these admissions, there can be no credible dispute that at least Claims 3, 4, and 7 are patentable over all of the instituted grounds.

For the reasons explained in the Response and herein, PO respectfully requests the Board to issue a final written decision finding Claims 1-15 of the '166 Patent to be patentable over Petitioner's challenges.

II. CLAIM CONSTRUCTION

A. First Aperture "at a Terminal End"

Claims 1 and 12 of the '166 Patent recite a third member that comprises "a first aperture at a terminal end of the first end of the third elongated body." As discussed in Patent Owner's Response ("POR," Paper 22), this term should be construed to mean an aperture that, at least in part, passes through the top surface of the third member and excludes apertures that pass through only the side of the shaft of the third member. POR, 9-14. Petitioner makes two flawed arguments to

support its contention that this claim term should encompass “a region near the end of an elongated structure.” Reply, 10-17.

First, Petitioner argues that PO exaggerates the scope of its disclaimer when it distinguished the claimed invention over Chang in connection with the related '680 Application. Reply, 14-17. Not so. To the contrary, it is Petitioner that attempts to rewrite the clear words of the disclaimer and explain the words away to render the disclaimer narrower than it is. Specifically, Petitioner argues:

Patent Owner did not draw a distinction between apertures in the sidewall and apertures through the top. Rather, Patent Owner merely argued that **the holes were positioned further “along” the shaft**. The argument is more simply explained as Patent Owner having distinguished Chang for **its apertures being much further “along” Chang’s nail shaft** than are Patent Owner’s.

Reply, 14-15 (emphasis added). This is wrong. What PO actually argued to the Patent Office is:

In fact, Chang specifically and **only** discloses **through holes** (101 and 102) **that are merely *provided* along the shaft of the nail . . .**

Notably, Chang does **not discuss or disclose** a structure having **an aperture at a terminal end of the nail**.

Ex.1015, 75-76 (emphasis added). Critically, PO made no comparison between Chang and the claimed invention regarding the distance between an aperture and a “terminal end,” and certainly never used the words “further along” in this context,

as Petitioner wrongly asserts. Petitioner manufactures this argument out of thin air to support its improper construction. PO clearly distinguished its claimed invention from Chang by arguing that through holes provided on the shaft of a nail, regardless of where the holes are in relation to the tip, are not at the terminal end of the nail (*i.e.*, the tip of the nail). PO's "clear and unmistakable" disclaimer that an "aperture at a terminal end" cannot be on only the shaft of the nail requires the Board to reject Petitioner's manufactured argument and adopt PO's proposed construction. *See, e.g., Genuine Enabling Tech. LLC v. Nintendo Co.*, 29 F.4th 1365, 1375 (Fed. Cir. 2022) (finding disclaimer based on arguments patent owner made during prosecution to overcome prior art).^{1,2}

¹ Petitioner argues that another of PO's prosecution statements supports its "further along" argument: that tapered aperture 1130 is described as "at" the terminal end 1120 of screw 810 despite allegedly being illustrated as distanced from it. Reply, 15. This argument is misplaced. Figure 11 actually depicts tapered aperture 1130 passing through, at least in part, the top surface of screw 810. Ex.1015, 109:10-11.

² Petitioner's assertion that the District Court rejected PO's disclaimer is wrong. Reply, 16. The District Court merely held that the scope of PO's disclaimer does not support construing the terminal end as the "very tip." Ex.2015, 14. But the District Court did not hold that there was no disclaimer to support excluding

Accordingly, the comparison that Petitioner makes between the screw depicted in Figure 11 of the '166 Patent and the nail depicted in Figure 5 of Chang with respect to the “distance” of each aperture to the terminal end (Reply, 15) is irrelevant.

Second, Petitioner also relies on the alleged use of “terminal end” in the art. Reply, 10-14. But Petitioner's reliance on extrinsic evidence is a red herring because such evidence cannot overcome PO's clear disclaimer during the prosecution of the '680 Application (discussed in the POR at 9-13 and above). *See, e.g., Genuine Enabling Tech.*, 29 F.4th at 1373-75 (extrinsic evidence cannot overcome inventor's disclaimer). In any event, Petitioner's cherry-picked references are irrelevant because they do not provide general definitions of “terminal end” or even purport to do so. Nor do they bear any connection to how “terminal end” is used in the intrinsic record of the '166 Patent. Accordingly, the Board should disregard these references.

Further, as explained in the POR, Petitioner's own expert Mr. Dominguez has unequivocally admitted—both in this proceeding and in the District Court

apertures that pass only through the side of the shaft of the third member. As explained in the POR, the District Court ruled that the “terminal end” is “the open end of the third member's hollow base.” Ex.2015, 15.

action—that the “terminal end” is located at the “very top” of a nail. POR, 13-14 (citing Ex.1002, ¶53; Ex.2016, 193:6-22, 194:12-22). These admissions are so clear that Petitioner does not even attempt to explain them away.

In sum, Petitioner misrepresents the language of PO's disclaimer, relies on extrinsic evidence that cannot overcome this clear disclaimer, and fails to address its own expert's fatal admissions that contradict Petitioner's proposed construction. As such, the Board should reject Petitioner's proposed construction.

For all the reasons in PO's Response and above, the term a first aperture “at a terminal end” should be construed to exclude apertures that pass only through the side of the shaft of the third member. POR, 9-14.

B. “Bore”

Claims 1 and 12 each require a very specific bore: “a first bore extending along a first bore axis from a first aperture to a second aperture on an exterior surface of the third member.” Ex.1001, 16:24-31 (emphasis added). That is, the first bore must be a singular bore that extends continuously from a first aperture to a second aperture. As explained in the POR, “bore” should be construed as: “cylindrical hole made by the spinning rotation of a twist drill cutting tool,” a construction that both Petitioner's expert and PO agree is appropriate. POR, 14-15. Alternatively, the Board should modify its preliminary construction to be “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, 14-15, 17-18.³ These proposed constructions are supported by Petitioner's expert's testimony and other record evidence. *Id.*

Petitioner argues that “bore” can include “holes having stepped longitudinal cross-sections,” and contends that such a construction is supported by PO's expert's previous work and additional extrinsic evidence. Petitioner is wrong on both points.

Petitioner first argues that PO's expert, Dr. Ledet, has referred to “a void having abutting cylindrical sections of different diameters in the singular as ‘a’ tunnel, aperture, or hole.” Reply, 7-9 (citing Ex.1023, 329-330; Ex.1022, 28:66, 29:3-5, Fig. 58). Not so. The cited journal article (Ex.1023) neither states nor depicts that the tunnel (which is formed in the vertebrae of a human) has a stepped diameter. That is, Figure 3 of the journal article does not “clearly show[]” what Petitioner asserts it does. Reply, 8. In any event, even if Figure 3 shows what

³ Petitioner attempts to discredit the alternative construction because, in its view, it is not clear how a cylindrical hole can be tapered. Reply, 2. This argument highlights Petitioner's ignorance given that the prior art is replete with disclosures of cylindrical holes that are tapered. *See*, Ex.2032, 15:41-52; Ex.2033, 10:28-31; Ex.2034, 4:1-3; Ex.2035, ¶[0023]; Ex.2026, ¶[0049].

Petitioner asserts, “a transosseous tunnel” formed in the vertebrae of a human cannot be equated with a “bore” contained within a component of a bone fixation assembly. Ex.1023, 329-330. As for Dr. Ledet’s patent (Ex.1022), the cited portion at 29:3-5 does not indicate that a bore can have cylindrical sections of different diameters. In fact, the passage does not use the word “bore” at all, which Petitioner’s own expert concedes. Ex.2022, 60:5-7.

Petitioner also relies on a number of references that allegedly show a single bore encompassing two or more stepped-diameter holes or a counterbore. Reply, 3-7. But Petitioner’s citations to portions of these self-serving references—the teachings of which are specific to these references and divorced from the disclosures of the ’166 Patent—are irrelevant because they do not define “bore.”

For example, the cited Jackson patent introduces its “bore” as a specific “cylindrical *stepped down* bore **27**,” not merely “a bore.” Ex.1019, 5:21 (emphasis added). Similarly, the cited Brown patent introduces its “bore” as another specific “*stepped* cylindrical bore **34**.” Ex.1026, 3:60 (emphasis added). The remaining patent references—including Ensign (Ex.1020), Brånemark (Ex.1021), Ray (Ex.1025), Staev (Ex.1027), and Brumfield (Ex.1006)—each describes a bore designed to achieve a specific objective in accordance with the respective invention, and Mr. Dominguez concedes this point for every reference. Ex.2022,

27:19-25, 29:1-11, 31:8-22, 34:11-35:2, 38:18-39:21, 48:5-18, 50:7-51:5, 54:2-13, 55:14-23, 57:22-58:3, 63:9-21, 76:23-77:21. The references do not define “bore.”

Further, and to the contrary, the prior art treats a “bore” as an element that is distinct from a “counterbore.” *See, e.g.*, Ex.2024, 5:44-50 (describing “bore 103” and “counterbore 105” as two separate structures); Ex.2025, 3:16-50 (same), Ex.2026, 4:31-43 (same), Ex.2027, 3:54-4:2 (same).

III. PETITIONER HAS NOT MET ITS BURDEN FOR GROUNDS 1-3

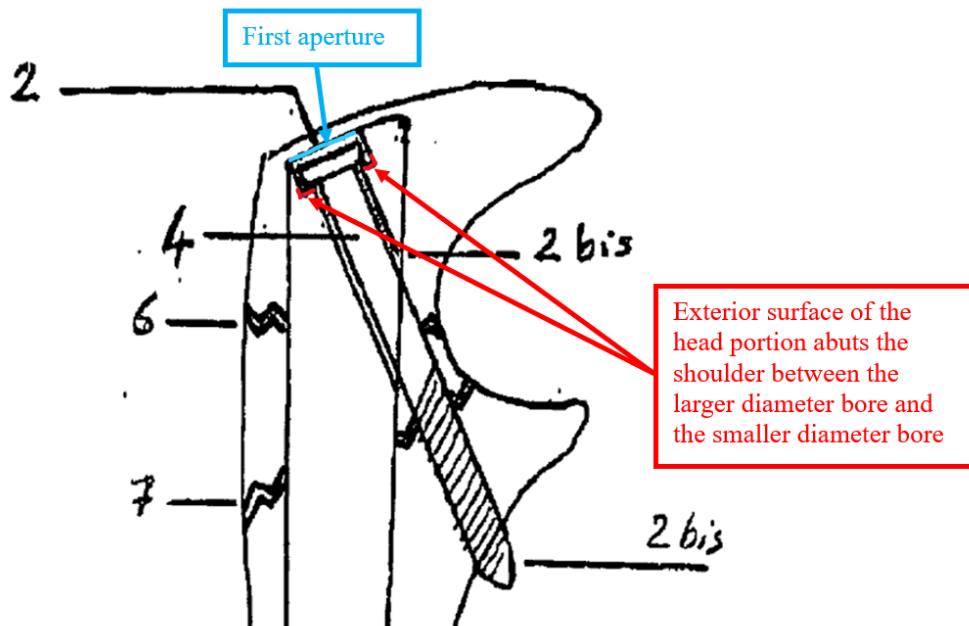
A. Petitioner Fails to Show that Cognet Discloses the Recited “First Bore,” Therefore Grounds 1-3 Fail and Claims 1-15 are Patentable

Petitioner's Reply argument regarding Cognet's anticipation of Claim 1 largely repeats its argument regarding the construction of “bore.” When “bore” is properly construed, *supra* Section II.B. (POR, 14-18), Cognet does not disclose “a first bore extending along a first bore axis from the first aperture to a second aperture on the exterior surface of the third member,” as recited in Claims 1 and 12. POR, 20-26. Petitioner does not assert that any other secondary reference discloses this claim limitation. Therefore, Petitioner has not carried its burden to show that any of Claims 1-15 are unpatentable over Cognet alone, or in combination with any other cited reference.

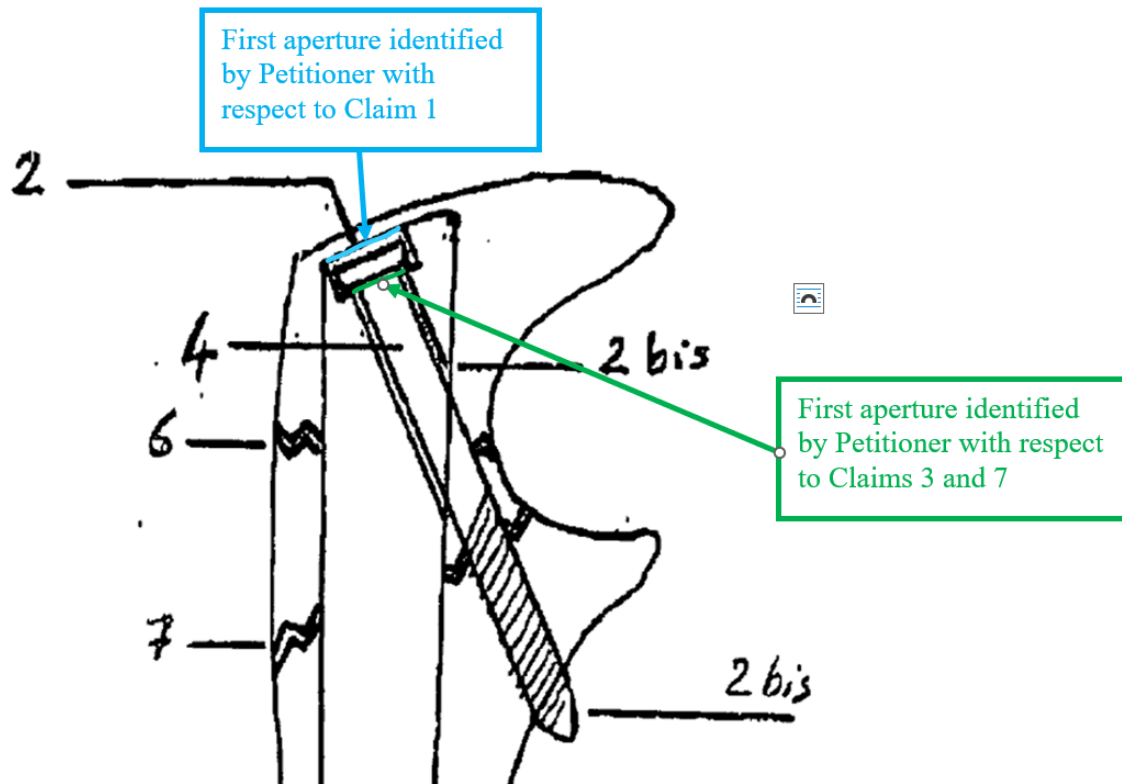
B. Cognet's Screw Head does not Abut the Interior Surface of the First Bore at the First Aperture, Therefore Claims 3 and 7 are Patentable and Ground 1 with Respect to These Claims Fails

In addition to Petitioner's failure to show that Cognet anticipates independent Claim 1, *supra* Section III.A., there are three additional, independent reasons to reject Petitioner's challenge as to dependent Claims 3 and 7: (1) waiver of an alternative theory; (2) failure to address independent Claim 1 under such alternative theory; and (3) on the merits, a lack of disclosure in Cognet of the limitations recited in Claims 3 and 7.

Claims 3 and 7 each recites: "wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture." As explained in the POR, and as depicted below, the exterior surface of the head portion in Cognet does not abut the interior surface of Cognet's tunnel at the *first aperture initially identified* by Petitioner with respect to Claim 1; instead, the exterior surface of the head portion abuts the *shoulder* between the larger diameter bore and the smaller diameter bore *subsequently identified* by Petitioner with respect to Claims 3 and 7. POR, 26-34.



Ex.1003, Fig. 1 (annotated by PO). As also explained in the POR, Petitioner has taken inconsistent positions regarding the location of the claimed “first aperture” within Figure 1 of Cognet. POR, 26-34. Specifically, for Claim 1, Petitioner identifies the opening at the top of the larger diameter bore as the claimed “first aperture.” *Id.* But the exterior surface of the head portion does not abut the interior surface of Cognet’s tunnel at this location. Apparently realizing this problem for Claims 3 and 7, which ultimately depend from Claim 1, Petitioner changes course and identifies the shoulder between the larger diameter bore and the smaller diameter bore as the claimed “first aperture.” *Id.* This inconsistency is depicted in the below annotated Figure 1 of Cognet.



Now, after PO identified this inconsistency in its POR, Petitioner all but admits that it has taken inconsistent positions,⁴ and concocts a convoluted argument as to how Cognet still anticipates Claims 3 and 7. Reply, 21-22. There are three independent reasons that Petitioner's and Mr. Dominguez's admissions that they have taken inconsistent positions are fatal to Petitioner's challenge.

⁴ On cross-examination, Mr. Dominguez admitted that he (and Petitioner) have taken inconsistent positions. Ex.2022, 109:6-23 (regarding Claim 1, Mr. Dominguez confirming that he identified the "aperture at the top of the bore" as the "first aperture"); 108:3-21 (regarding Claims 3 and 7, Mr. Dominguez confirming that the he identified the "shoulder" of Cognet as the "first aperture").

First, if it were Petitioner's intention to present one theory of unpatentability for Claim 1 and an alternative theory for Claims 3 and 7 (as to the location of the claimed "first aperture" in Cognet's nail), Petitioner was required to expressly state that it was advancing an alternative theory. Because Petitioner did not do so, the alternative theory is waived. *See, e.g., Netflix, Inc. v. DivX, LLC*, 84 F.4th 1371, 1380 (Fed. Cir. 2023) (Holding unstated alternative argument waived, explaining: "we emphasize that it is the petitioner's burden to make clear when alternative arguments are being presented and to sufficiently expound on each one. The Board should not have to work as hard as [Petitioner] wants to identify all arguments fairly presented in a petition.").

Second, Petitioner cannot succeed on Claims 3 and 7 without also addressing how its alternative theory impacts the patentability of Claim 1. *See Microsoft Corp. v. IPA Techs. Inc.*, No. 2021-1412, 2022 U.S. App. LEXIS 8711, at *16-17 (Fed. Cir. Apr. 1, 2022) (affirming patentability determination of dependent claims where Petitioner only addressed the dependent claims, not the independent claim). Petitioner addresses the patentability of only Claims 3 and 7 under its alternative theory that the shoulder between the larger diameter bore and the smaller diameter bore is the claimed "first aperture," and does not address the patentability of Claim 1 under this theory. Thus, under *Microsoft*, Petitioner fails to meet its burden that Cognet renders Claims 3 and 7 unpatentable.

Third, even if the Board were to reach the merits on Petitioner's alternative theory, Petitioner's challenge fails. Petitioner's attempt to shift the blame for its "confusion" to PO (Reply, 22) is misplaced. PO never "equated two distinct terms to the same structure" or "conflated" them. *Id.* Rather, PO argued:

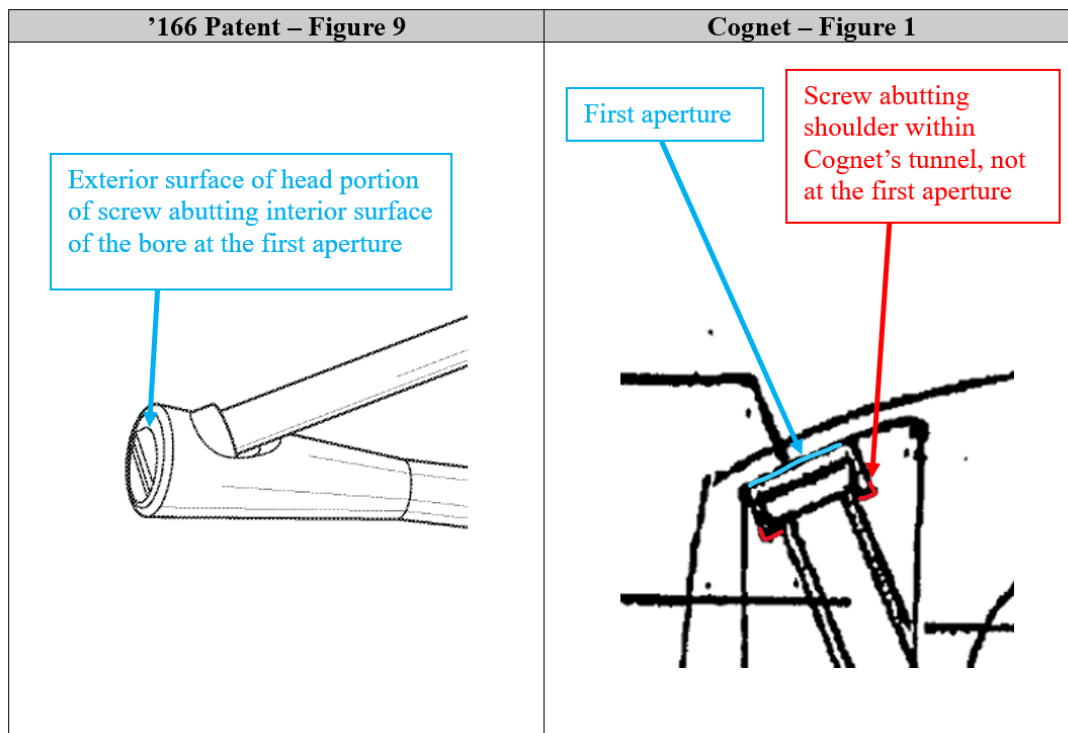
The second elongated body further comprises **a first aperture 1130** at a terminal end 1120 of the second end of the second elongated body, and **a bore extending** along a third axis 1102 **from the first aperture 1130** to a second aperture on an exterior surface 1135 of the second screw member 810. As shown in Figure 11, **the bore comprises an interior surface at the first aperture 1130.**

Ex.1015, 109. In this passage, PO clearly discussed two separate and distinct features, and did not conflate "aperture" with "bore" (both clearly visible in Figure 11) or create any "confusion."

Petitioner further argues that Cognet discloses the screw abutting the shoulder just as the '166 Patent discloses the bulbous portion abutting tapered aperture 1130. Reply, 22. This a red herring. The salient point here is that Petitioner is now presenting an alternative theory of anticipation by pointing to the shoulder as the first aperture instead of the aperture at the top surface of Cognet's nail.

Putting aside that this argument is both waived and incomplete, Petitioner is wrong on the facts. Petitioner ignores an important distinction between the two

configurations. In Figure 11 of the '166 Patent, there is a first aperture on the top surface of the screw 810 and a tapered aperture 1130 just below the first aperture that extends through tapered portion 1110 to a second aperture on side exterior surface 1135. Ex.1001, 9:46-49. And, as shown in the Figures of the '166 Patent and as required by Claims 3 and 7, the exterior surface of the head portion of screw 815 (Figure 9) abuts the interior surface of the first bore at the first aperture located on the top surface of screw 810. In contrast, the exterior surface of the head of screw 4 in Cognet abuts the interior surface of Cognet's tunnel not at the first aperture, but instead, at the shoulder within Cognet's tunnel. The side-by-side comparison of the below annotated figures highlights this important distinction.



**C. Cognet does not Disclose “a Torque Transmitting Aperture,”
Therefore Claim 4 is Patentable and Ground 1 with Respect to
Claim 4 Fails**

Claim 4, which depends from Claim 3, recites “the head portion of the first member comprises a torque transmitting aperture.” In addition to Petitioner's failure to show that Cognet anticipates Claims 1 and 3, *supra* Sections III.A. and III.B., Petitioner additionally fails to show that Cognet anticipates Claim 4.

Petitioner does not assert that Cognet expressly discloses a torque transmitting aperture. Instead, Petitioner baldly concludes that “Cognet's screw head must have a torque aperture.” Reply, 25. This is thinly supported by Petitioner's expert's conclusory, single-paragraph opinion that a POSA would “assume” or “immediately underst[an]d” that Cognet's screw has a torque transmitting aperture. Reply, 23-24 (citing Ex.1002, ¶76). This sounds like an inherency argument, although Petitioner never calls it that. Assuming Petitioner intends to argue inherency, Petitioner does not satisfy the exacting standard:

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. . . . Inherency, however, may not be established by *probabilities or possibilities*. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added) (internal quotations and citations omitted); *see also Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1297 (“Inherency does not embrace probabilities or possibilities.”). Cognet’s screw is, at best, *possibly* a screw with a torque transmitting aperture. But it is not *necessarily* so. Thus, Petitioner fails to show that Cognet anticipates Claim 4.

Petitioner also makes the observation that the head of Cognet’s screw has a diameter and thus, must be circular. Reply, 24. As an initial matter, the Board should disregard this new argument as waived because the argument does not appear in the Petition. *Netflix*, 84 F.4th at 1382. In any event, on the merits, Petitioner’s attempt to shift the burden to PO to explain how torque could be applied to a screw with a circular head if not via a torque transmitting aperture is legally flawed. It is not PO’s burden to explain how a prior art reference works or why the claims of the challenged patent are not anticipated. Rather, it remains at all times Petitioner’s burden to show how the prior art anticipates the challenged claims. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (“[T]he burden of persuasion is on the petitioner to prove ‘unpatentability by a preponderance of the evidence,’ 35 U.S.C. § 316(e), and that burden never shifts to the patentee.”). Because, as explained above, Petitioner has

not shown that Cognet discloses, expressly or inherently, the limitation of Claim 4, Petitioner's challenge fails. *Id.* at 1378-79.

D. Petitioner Fails to Meet its Burden of Showing that Cognet and Brumfield Render Obvious Claims 4, 8, 10, 14, and 15 and Therefore Ground 2 Fails

Petitioner asserts that Claims 4, 8, 10, 14, and 15 are obvious in view of Cognet and Brumfield. As explained in the POR, Petitioner fails to meet its burden that it would have been obvious to a POSA to combine the teachings of Cognet and Brumfield because, for example, Petitioner does not: (1) identify a motivation for a POSA to make the proposed combination; (2) identify any potential benefits that might be achieved from the proposed combination; (3) address whether a POSA would have had an expectation of success in making the proposed combination; or (4) address the extent to which a POSA might face any challenges or difficulties in making the proposed combination. POR, 47-48. This is fatal to Petitioner's obviousness challenge, and alone is sufficient for the Board to find that Petitioner has not met its burden with respect to Ground 2.

Further, regarding why a POSA would not combine the references, an example PO identifies is that the beveled head of Brumfield's screw would not mate with the flat shoulder in the tunnel of the Cognet nail. POR, 48-49. Instead, the beveled head would wedge into the aperture leading to the bottom bore of Cognet, resulting in increased resistance to the rotation of the screw. POR, 49.

Petitioner now contends that “[a]t most, ‘increased resistance’ is a trade-off for the benefits of a familiar beveled-head design.” Reply, 26. As an initial matter, Petitioner never analyzes any such trade-offs, much less explains a single benefit or drawback of a beveled-head design. The Board should disregard this new argument as waived. *Netflix*, 84 F.4th at 1382. In any event, the mismatch between the beveled-head design of Brumfield’s screw and the flat shoulder of Cognet’s nail renders the combination inoperable. Ex.2012, ¶¶68-69. “In cases involving mechanical device or apparatus claims, ... if references taken in combination would produce a seemingly inoperative device, ... such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness.” *In re Urbanski*, 809 F.3d 1237, 1243 (Fed. Cir. 2016). Petitioner does not address the operability of the combination, and thus, fails to make a prima facie case of obviousness.

E. Petitioner Fails to Meet its Burden of Showing that Cognet and Ferrante Render Obvious Claim 11 and Therefore Ground 3 Fails

Claim 11 depends from Claim 10. Petitioner asserts that Claim 11 is obvious in view of Cognet and Ferrante. But as explained in the POR, Petitioner fails to address Claim 10 in its discussion of the obviousness of Claim 11 in view of Cognet and Ferrante. POR, 50. This dooms Petitioner’s obviousness challenge because, under *Microsoft*, Petitioner was required to show how Cognet and

Ferrante render obvious Claim 10. 2022 U.S. App. LEXIS 8711, at *16-17. But Petitioner addresses Claim 10 with respect to only Cognet and Brumfield in an entirely separate ground (Ground 2).

Faced with this fatal flaw, Petitioner contends now for the first time⁵ that it cited Ferrante “merely as evidence” that the limitation recited in Claim 11 was well-known in the field. Reply, 26-27. This new argument is disingenuous. The Petition states unequivocally that “[i]t would have been obvious to a POSA to use the screws disclosed in Ferrante with the intramedullary nail disclosed in Cognet.” Petition, 36. This evinces an intention to combine Cognet and Ferrante, not to “merely” provide evidence of the knowledge of a POSA. Notably, the Petitioner presents the Cognet and Ferrante combination using the same language used for several other combinations. *Compare* Petition, 36 (Cognet and Ferrante) *with id.*, 33 (Cognet and Brumfield), 58 (Simon and Ferrante), 62 (Simon and Cognet). Accordingly, Petitioner’s downplaying of its express combination in attempt to overcome a fatal flaw in its Petition fails (and, in fact, is a concession that the Petition’s obviousness argument is incomplete). Petitioner also now argues, for the first time, that Cognet and Ferrante render obvious not only claim 11, but also

⁵ This new argument as waived. *Netflix*, 84 F.4th at 1382.

claim 10. Reply, 27. The Board should disregard this new argument too as waived. *Netflix*, 84 F.4th at 1382.

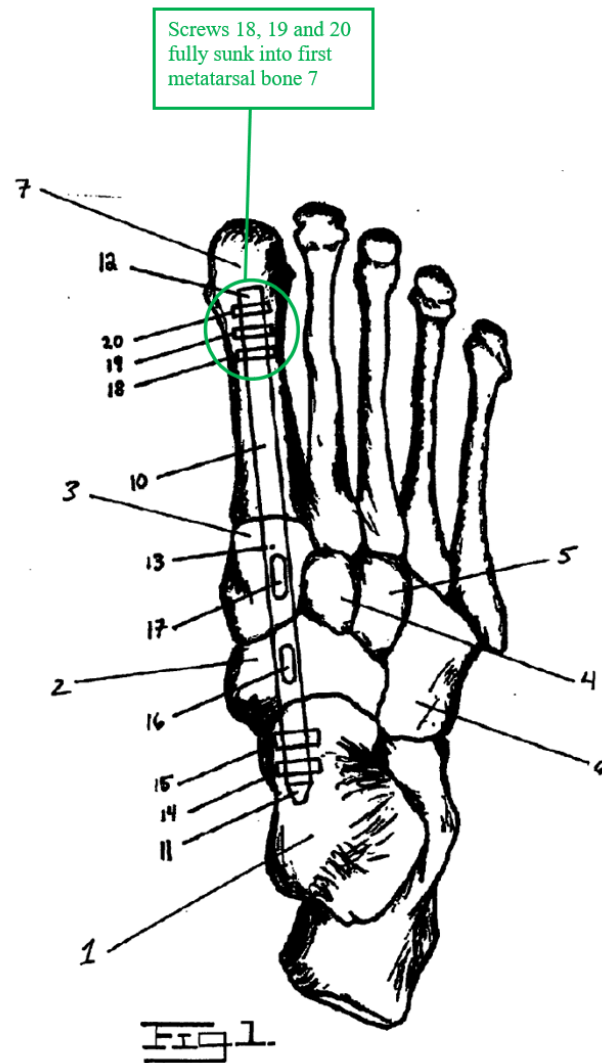
IV. PETITIONER HAS NOT MET ITS BURDEN FOR GROUNDS 4-7

A. Petitioner Fails to Show that Simon Discloses a Screw with “a Head Portion,” Therefore Grounds 4-7 Fail and Claims 1-15 are Patentable

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.” As explained in the POR, Petitioner does not and cannot assert that Simon expressly discloses a “first member” having “a head portion.” POR, 51-55. Instead, Petitioner appears to assert that Simon inherently discloses screws having a head portion, without stating it is arguing inherency. Petitioner, however, does not establish that Simon’s screws *necessarily* have a head. *Robertson*, 169 F.3d 743 at 745; *Trintec*, 295 F.3d at 1297. And, Petitioner’s own expert, Mr. Dominguez, has now made two admissions that doom Petitioner’s challenge.

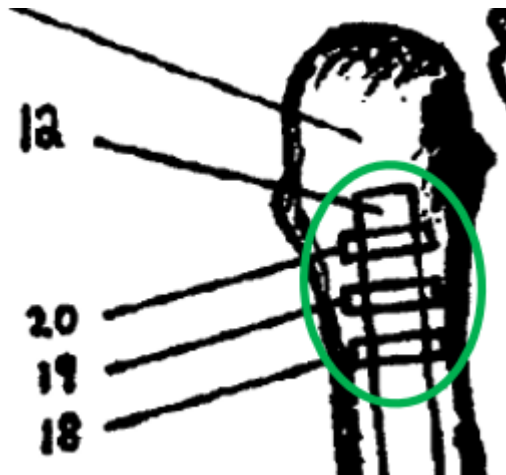
First, Mr. Dominguez admitted that some screws are “headless.” Ex.1002, ¶42.a. To avoid this admission, Petitioner rests on the Board’s finding in its Institution Decision that that opinion is limited to “those screws that are ‘intended to be fully sunk into bone.’” Reply, 30. In short, Mr. Dominguez’s opinion is that only screws that are intended to be fully sunk into bone can be headless. This all but proves that Simon does not disclose screws with head portions because

Simon's screws are, in fact, intended to be fully sunk into a human foot. Critically, Figure 1 of Simon depicts screws 18, 19 and 20 fully sunk into the first metatarsal bone 7 of a foot.



Ex.1008 (Fig. 1; annotated); *see also id.* at ¶49. And, Simon does not expressly disclose that its screws have a head portion. Thus, contrary to Petitioner's assertion, Simon's screws 18, 19 and 20 are headless.

Second, in his most recent deposition, Mr. Dominguez admitted that he considers a screw with a “non-bulbous portion” – one where “there’s nothing there that is larger than the rest of the screw” – to be “a headless screw.” Ex.2022, 120, 20-23. This is precisely how Simon depicts screws 18, 19 and 20 – they do not have a bulbous portion, and instead they are all the same diameter from one end to the other:



Ex.1008, Fig. 1 (annotated).

Accordingly, Simon not only fails to expressly disclose screws having a head portion, but it actually depicts its screws in a manner that even Petitioner's own expert admitted he would consider “headless.” Moreover, the fact that Simon's screws are “fully sunk into bone” further leads to the conclusion that they are “headless.”

In light of the above, Petitioner has not and cannot establish that Simon expressly or inherently discloses a screw having a head portion, as required by all of the Challenged Claims. Claims 1-15 are therefore patentable over Simon.

B. Simon Does Not Disclose “a First Aperture at a Terminal End of the First End of the Third Elongated Body,” Therefore Grounds 4-7 Fail and Claims 1-15 are Patentable

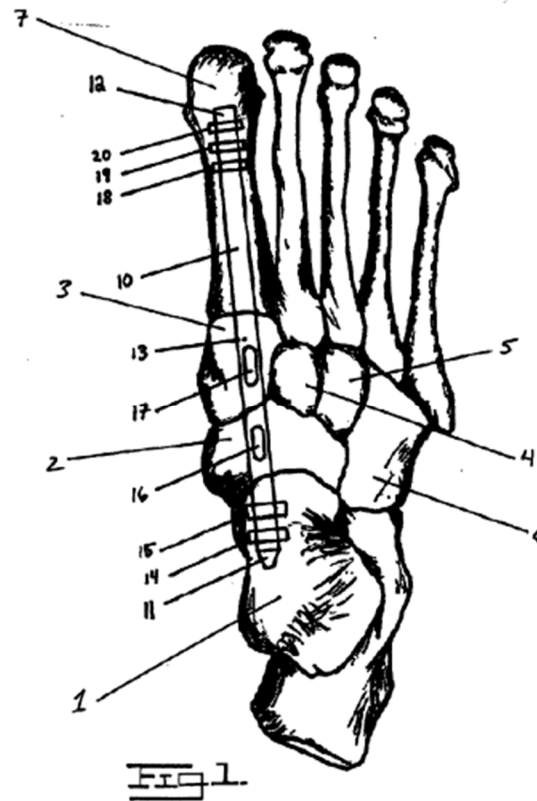
Claims 1 and 12 recite “a first aperture at a terminal end of the first end of the third elongated body.” As discussed in the POR, when first aperture “at a terminal end” is properly construed, *supra* Section II.A., Simon does not disclose this claim limitation. As an extension of its argument for the construction of a first aperture “at a terminal end,” Petitioner again draws a comparison between the screw in Figure 11 of the '166 Patent and the nail in Figure 5 of Chang, and also compares the nail in Figure 1 of Simon. Reply, 29. For the reason discussed above in connection with the construction of “at a terminal end,” Petitioner’s comparison among these components regarding “distance” is irrelevant. Section II.A.

C. Simon Does Not Disclose “a Torque Transmitting Aperture,” Therefore Claim 4 is Patentable and Ground 4 with Respect to Claim 4 Fails

Claim 4, which depends from Claim 3, recites “the head portion of the first member comprises a torque transmitting aperture.” In addition to Petitioner’s failure to show that Simon anticipates Claims 1 and 3 (*supra* Sections IV.A.,

IV.B.), Petitioner also fails to show that Simon anticipates Claim 4. Petitioner refers back to its argument as to how Cognet anticipates Claim 4. Reply, 30. For the same reasons that Cognet does not anticipate Claim 4, *supra* Section III.C., Simon too does not anticipate Claim 4.

Petitioner also appears to argue that Simon discloses a screw with a head portion in its attempt to challenge Claim 1 (Reply, 27-28) while at the same time asserting that “[h]eadless screws must have a torque transmitting aperture; otherwise they cannot be sunk fully” (Reply, 28 (citing Ex.1018, ¶53)) in its attempt to set up an unpatentability argument for Claim 4 based on Simon. But as seen in Figure 1 of Simon, Simon discloses screws (18, 19, 20) that are all of a single type: either they all have a head portion or they all are headless.



Ex.1008, Fig. 1. Accordingly, Petitioner's position that "headless screws" necessarily have a torque transmitting aperture must be irrelevant in any discussion about Simon, because it runs counter to Petitioner's anticipation argument for Claim 1, wherein Petitioner argues that *Simon's screw has a head portion*. Put another way, if Simon's screw is found to be headless as Petitioner argues in its attempt to challenge Claim 4, Simon does not anticipate Claim 1.

On the other hand, Petitioner does not argue that a screw with a head portion will necessarily have a torque transmitting aperture, and Simon does not expressly disclose a torque transmitting aperture. Accordingly, if Simon's screw is deemed

to have a head portion, Petitioner fails to meet its burden to show that Simon does, in fact, have a torque transmitting aperture.

D. Simon Does Not Disclose “a self-tapping edge for removing bone material,” Therefore Claims 10 and 11 are Patentable and Ground 4 with Respect to These Claims Fails

Claim 10 recites “the first end of the first member includes a self-tapping edge for removing bone material.” Similarly, Claim 11 recites “the first end of the second member includes a self-tapping edge for removing bone material.” In addition to Petitioner’s failure to show that Simon anticipates Claim 1, *supra* Sections IV.A. and IV.B., Petitioner additionally fails to show that Simon anticipates Claims 10 and 11. Petitioner relies on Mr. Dominguez’s opinion that “[a] POSA would immediately assume that the first member (interlocking screw) includes a self-tapping edge.” Reply, 30 (quoting Ex.1002, ¶136). Petitioner, at best, shows that Simon’s screws *possibly* have a “self-tapping edge,” not that Simon’s screws *necessarily* have one. Accordingly, Petitioner fails to satisfy the exacting standard for inherency. *Robertson*, 169 F.3d 743 at 745; *Trintec*, 295 F.3d at 1297.

E. Petitioner Fails to Meet its Burden of Showing that Simon and Ferrante Render Obvious Claim 4, Therefore Claim 4 is Patentable and Ground 5 with Respect to Claim 4 Fails

Claim 4 depends from Claim 3, which, in turn, depends from Claim 2. In addition to Petitioner’s failure to show that Simon anticipates Claim 1, *see supra*

Sections IV.A. and IV.B., Petitioner additionally fails to show that Simon and Ferrante render obvious Claim 4. As explained in the POR, Petitioner fails to allege that either Simon or Ferrante discloses the limitations of Claims 2 and 3. POR, 67-68. And, Petitioner concedes as much with its silence on this point. This dooms Petitioner's challenge to Claim 4. *Microsoft*, 2022 U.S. App. LEXIS 8711, at *16-17.

F. Petitioner's Obviousness Combinations are Flawed Therefore Grounds 5-7 Fail

In the POR, PO explains why all of Petitioner's obviousness combinations regarding Simon fail: Petitioner fails to show a motivation to combine the references. POR, 66-70. In its Reply, Petitioner now asserts that it relies on these secondary references merely to show that the relevant claim limitations "were already so well known in the art" (Reply, 31), or merely "conventional features" (Reply, 32). With this new argument, Petitioner essentially concedes that the Petition is fatally flawed, and for that reason alone, Petitioner fails to meet its burden with respect to Grounds 5-7. Further, as explained above, *supra* Section III.E., the Board should disregard this new argument as waived. *Netflix*, 84 F.4th at 1382.

V. CONCLUSION

For the reasons explained in the POR and herein, Claims 1-15 should be found patentable over Petitioner's challenges.

Respectfully submitted,

Dated: June 20, 2024

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CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), Patent Owner certifies that this Sur-Reply contains 5,511 words exclusive of the Table of Contents, Table of Exhibits, Certification of Word Count, and Certificate of Service, and as measured by Microsoft Word.

Respectfully submitted,

Dated: June 20, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), I hereby certify that on June 20, 2024, I caused a copy of the foregoing document and the accompanying exhibits to be served via electronic mail to the following addresses for counsel for Petitioner as indicated in Petitioner's Revised Mandatory Notices (Paper 18):

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