

Patent Owner's Demonstratives

FUSION ORTHOPEDICS, LLC
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

U.S. Patent No. 11,298,166
Case IPR2023-00894
Oral Hearing: September 13, 2024

Topics

Claim Construction of “[first aperture] at a terminal end” and “bore”

Petitioner Has Not Established Any Ground of Unpatentability of Original Claims 1-15

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

Patent Owner’s Motion to Exclude Irrelevant and Prejudicial Evidence

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The Invention Claimed in the '166 Patent

(12) **United States Patent**
Tyber et al.

(10) **Patent No.:** US 11,298,166 B2
(45) **Date of Patent:** *Apr. 12, 2022

(54) **INTRAOSEOUS INTRAMEDULLARY
FIXATION ASSEMBLY AND METHOD OF
USE**

(12) **United States Patent**
Tyber et al.

(10) **Patent No.:** US 8,303,589 B2
(45) **Date of Patent:** Nov. 6, 2012

(54) **FIXATION SYSTEM, AN INTRAMEDULLARY
FIXATION ASSEMBLY AND METHOD OF
USE**

(75) **Inventors:** Jeff Tyber, Dordrecht, PA (US); Jimmy
Gannon, West Milford, NJ (US); Chris
Dignovanni, Barrington, RI (US)

(73) **Assignee:** Extremity Medical LLC, Parsippany,
NJ (US)

(*) **Notice:** Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 266 days.

(21) **Appl. No.:** 12/456,808

(22) **Filed:** Jun. 23, 2009

(65) **Prior Publication Data**
US 2010/0121324 A1 May 13, 2010

Related U.S. Application Data
(60) Provisional application No. 61/132,932, filed on Jun.
24, 2009.

(51) **Int. Cl.** (2006.01)
A61B 17/56

(52) **U.S. Cl.** 606/82; 606/54; 606/86 R; 606/96;
606/501

(58) **Field of Classification Search** 606/54;
606/82; 80, 96
See application file for complete search history.

(56) **References Cited**

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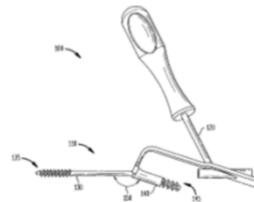
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Primary Examiner — Eduardo C Robert
Assistant Examiner — Stuart S Bray
(74) **Attorney, Agent, or Firm** — Ward & Zima, LLC

(57) **ABSTRACT**

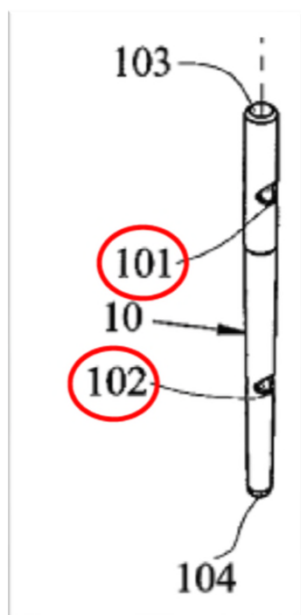
A fixation system, including an intramedullary fixation
assembly and an instrument for coupling the intramedullary
fixation assembly to bones. The intramedullary fixation
assembly includes a proximal screw member positioned at a
proximal end of the intramedullary fixation assembly, a distal
member positioned at a distal end of the intramedullary fixation
assembly, wherein the proximal screw member is slidably
coupled to the distal member and makes a fixed angle with the
distal member.

60 Claims, 8 Drawing Sheets



Construction of “[first aperture] at a terminal end”

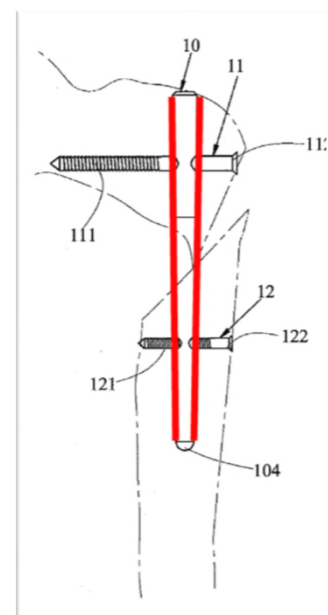
- Patent Owner disclaimed apertures *along the shaft* (e.g., Chang’s through holes **101** and **102**), distinguishing them from an aperture “at the terminal end.”



Patent Owner’s Response,
p. 10

In fact, Chang specifically and only discloses through holes (101 and 102) that are merely provided along the shaft of the nail. (See Chang, FIGS. 1-5, Abstract and paragraphs [0017] and [0024]). Notably, Chang does not discuss or disclose a structure having an aperture at a terminal end of the nail.

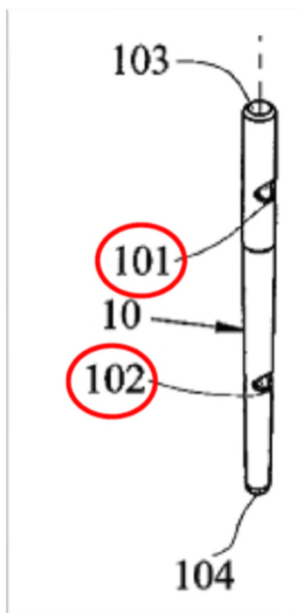
Ex. 1015, pp. 75-76



Patent Owner’s Response,
p. 12

Construction of “[first aperture] at a terminal end”

- Petitioner’s expert admitted that in Chang, it is through hole **103** that is at the “terminal end.”
- Thus, “[first aperture] at a terminal end” should be construed to exclude apertures that pass through only the side of the shaft of the third member.



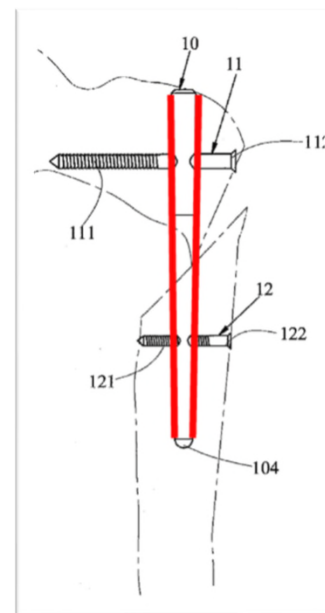
Patent Owner’s Response,
p. 10

A. The way that I interpret Figure 2 in Chang is that if you look at the bullet 103.

Q. Yes.

A. That's referring to the very top of terminal end. That would be what I would represent as the terminal end of the nail.

Ex. 2016, 193:6-22; see also *id.* at 194:12-22



Patent Owner’s Response,
p. 12

Construction of “bore”

- The evidentiary record does not support the preliminary construction adopted by the Board in the Institution Decision.
- Patent Owner’s expert opined that a “POSITA would understand that the term bore does not include two sections of a hole separated by a ledge or ‘stepped longitudinal cross-sections.’” Ex. 2012, ¶ 41.
- Petitioner’s expert opined that a “bore” is “a cylindrical hole made by the spinning rotation of a twist drill cutting tool,” Ex. 1002, ¶ 58, and repeated this opinion verbatim in his deposition, Ex. 2013, 141:21-142:3.
- Thus, “bore” should be construed as “a cylindrical hole made by the spinning rotation of a twist drill cutting tool,” because that would be consistent with both experts’ opinions.
- Alternatively, the preliminary construction should be modified as follows: “a cylindrical 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~~ ing holes or passages having tapered or stepped longitudinal cross-sections.”
- Petitioner’s cited references (*e.g.*, Jackson, Brånemark, Brown, Staev, and Cognet) disclose particularized uses of the term “bore”—they do not establish that “bore” is used in those ways ordinarily and customarily or in the ’166 Patent.

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Petitioner Has Not Established Any Ground of Unpatentability

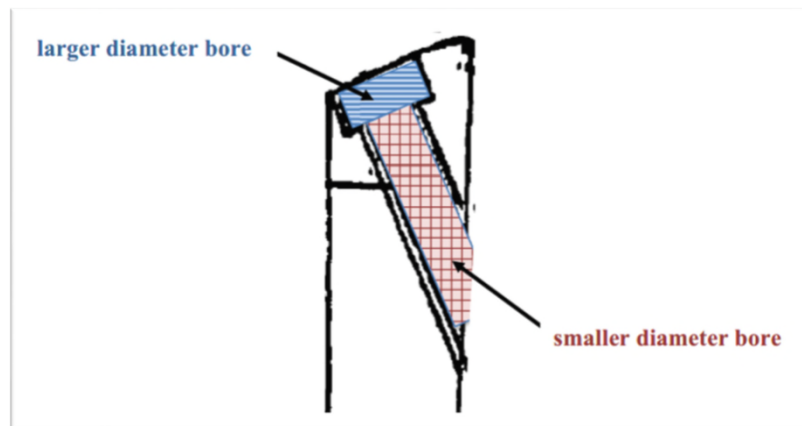
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Ground 3	Petitioner Fails to Show Obviousness Over Cognet and Ferrante for Claim 11
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Ground 5	Petitioner Fails to Show Obviousness Over Simon and Ferrante for Claims 4, 8, 10, 11, 14, and 15
Ground 6	Petitioner Fails to Show Obviousness Over Simon and Cognet for Claim 9
Ground 7	Petitioner Fails to Show Obviousness Over Simon and Leu for Claims 2, 3, 6, 7, and 13

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Claims 1 and 12: Cognet Does Not Disclose “a first bore extending . . . from the first aperture to a second aperture”

- Under a proper construction of “bore,” Cognet does not disclose or suggest a *single* bore that extends from the first aperture to a second aperture, as required by claims 1 and 12 of the '166 Patent.
- Instead, Cognet discloses a nail having *two* bores.

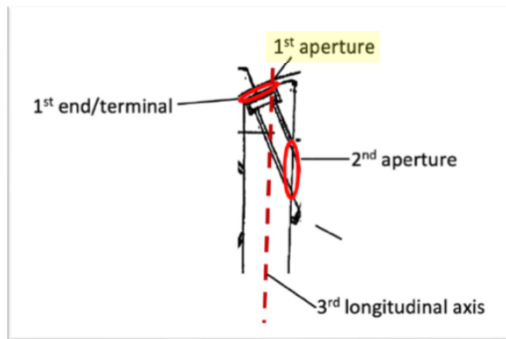


Ex. 2012, ¶ 46

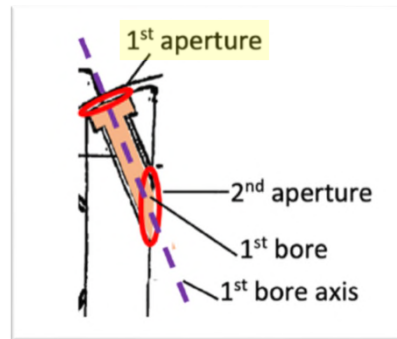
- In the figure, the top (larger diameter) bore is a “counterbore,” which is a “circular hole with a flat bottom which coincides with *another hole* [and] . . . allows a bolt head or other fastener to be recessed.” Ex. 2012, ¶ 48.

Claims 3 and 7: Cognet Does Not Disclose “the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture”

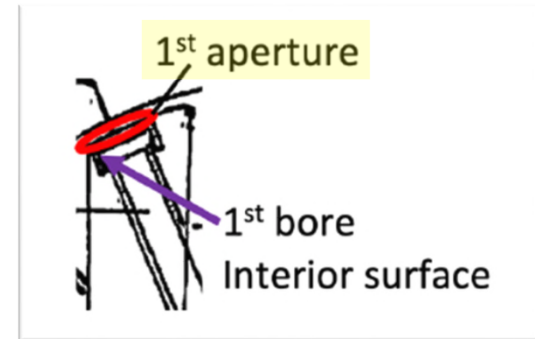
- Throughout its anticipation analysis for claim 1, Petitioner repeatedly points to one particular location for where the “first aperture” in Cognet’s nail lies.



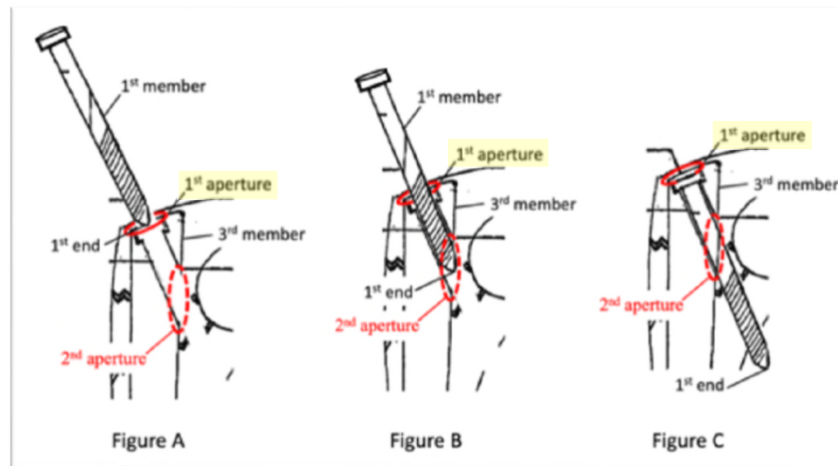
Petition, p. 16



Petition, p. 17



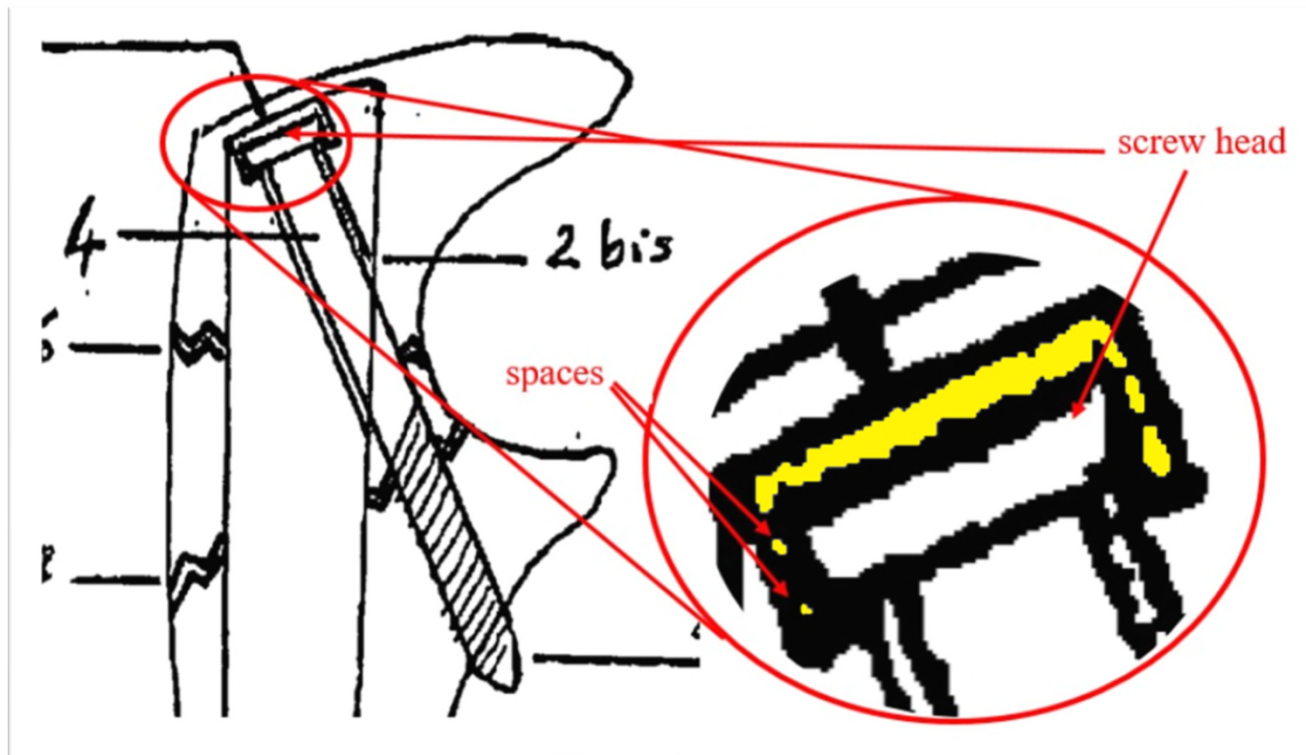
Petition, p. 17



Petition, p. 21

Claims 3 and 7: Cognet Does Not Disclose “the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture”

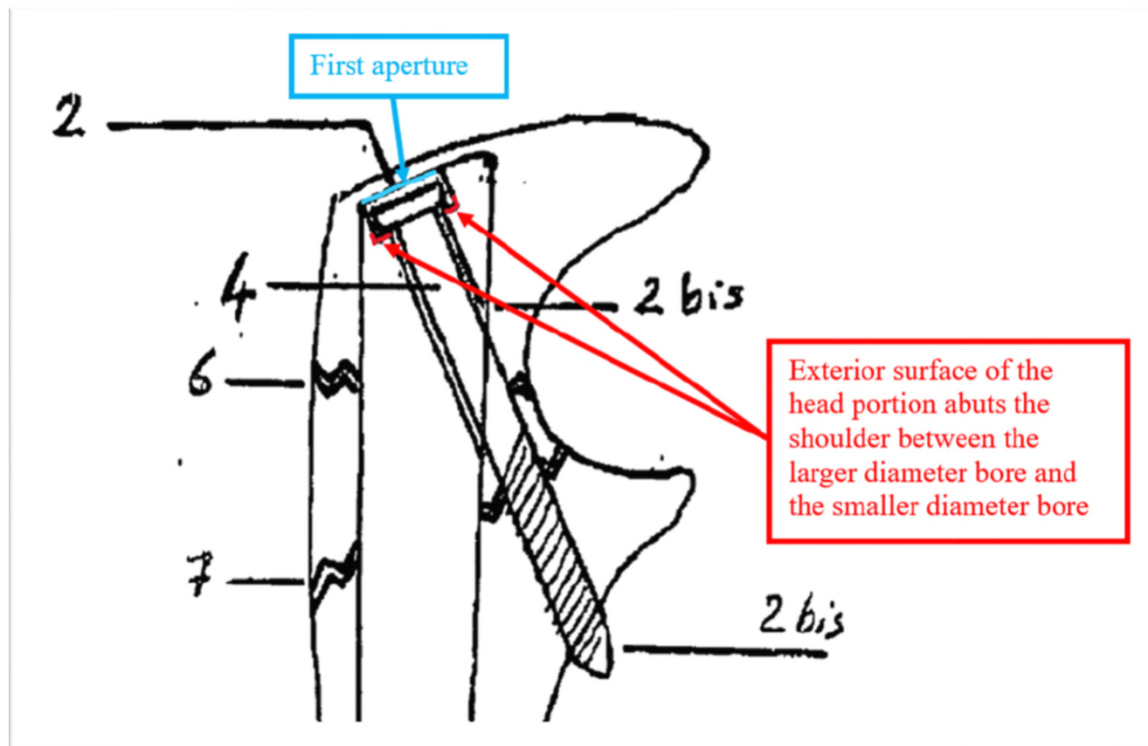
- But Petitioner cannot show that *at that particular location* of the “first aperture,” the head portion of Cognet’s screw abuts the interior surface of the bore. Ex. 2012, ¶ 55.



Ex. 2012, ¶ 55

Claims 3 and 7: Cognet Does Not Disclose “the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture”

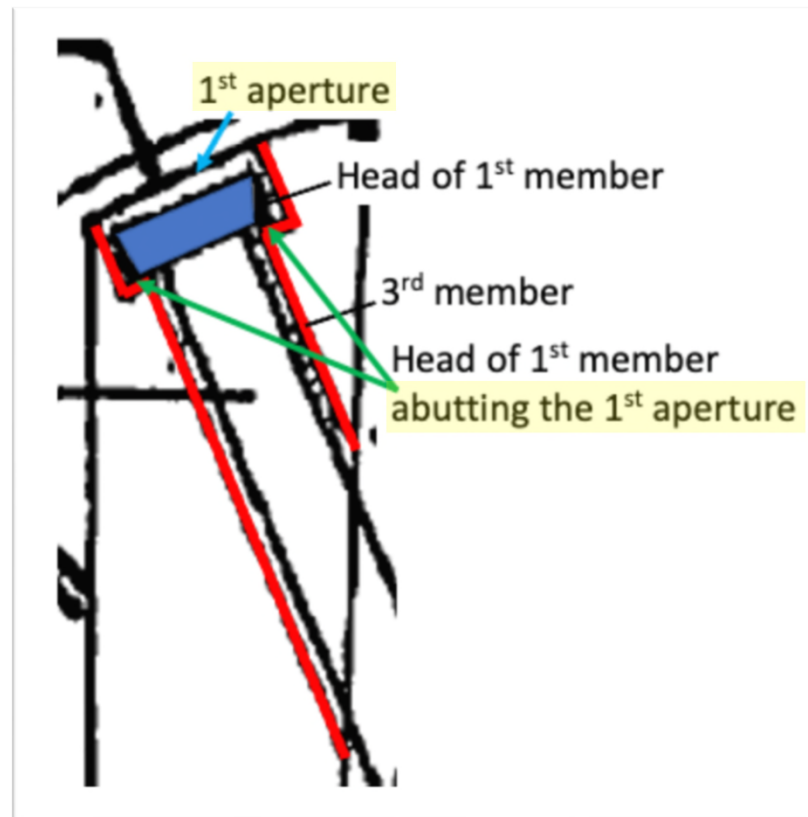
- The head portion of Cognet’s screw actually abuts the interior surface of the first bore at the *shoulder* between the first (*i.e.*, larger diameter) and second (*i.e.*, smaller diameter) bores. Ex. 2012, ¶ 55.



Ex. 2012, ¶ 55

Claims 3 and 7: Cognet Does Not Disclose “the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture”

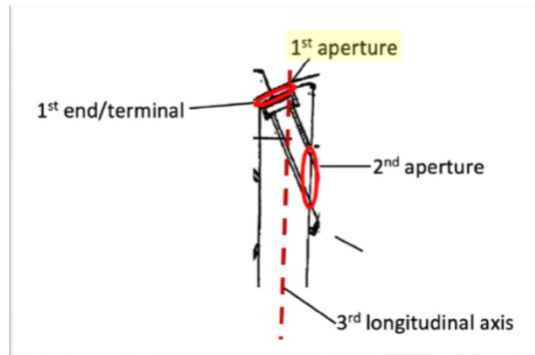
- Petitioner has taken inconsistent positions as to the location of the “first aperture” for its anticipation analyses for claim 1, on the one hand, and claims 3 and 7, on the other.



Petition, p. 24

Claims 3 and 7: Cognet Does Not Disclose “the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture”

- Petitioner’s expert’s testimony confirms the inconsistency.



Ex. 1002, ¶ 57

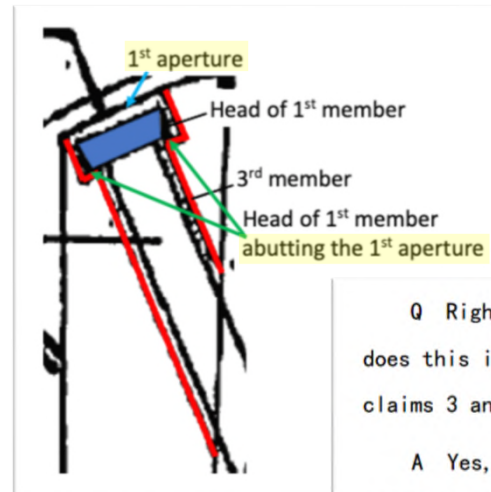
Q So is it fair to say that in your opinion, this image shows that Cognet has a first aperture at a terminal end as recited in claim 1 of the '166 patent?

A That is my understanding, yes.

Q And that in this image, you're referring to the first aperture at the top of the bore?

A Yeah, the first aperture is indicating the end of the bore — the end of the — is the opening — or the aperture is the first opening into the bore at the first — at the first terminal end.

Ex. 2022, 109:11-23



Ex. 1002, ¶ 75

Q Right. So in other words, in your opinion, does this image show that Cognet anticipates claims 3 and 7? Is that your position?

A Yes, Cognet's screw head abuts the first aperture and it is reflective of claims 3 and 7.

Q Right. Understood. But the point is the point of contact is where the arrows are; that's where you're saying the abutting is happening, correct?

A Yeah, in my opinion that's where it's occurring, yes.

Ex. 2022, 107:23-108:2, 108:16-21

Claims 3 and 7: Cognet Does Not Disclose “the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture”

- Petitioner taking inconsistent positions as to where the “first aperture” lies and attempting to shift the blame for the “confusion” as to where it lies to Patent Owner (Reply, pp. 21-22) fails for at least three independent reasons:
 1. If it were Petitioner’s intention to present one theory of unpatentability for claim 1 and an alternative theory for claim 3 and 7, 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).
 2. Petitioner cannot succeed on its challenge to claims 3 and 7 without also addressing how its alternative theory impacts the patentability of claim 1, which it has not done.

See, e.g., Microsoft Corp. v. IPA Techs. Inc., No. 2021-1412, 2022 U.S. App. LEXIS 8711, at *16-17 (Fed. Cir. Apr. 1, 2022).
 3. Petitioner’s blame-shifting argument is both waived under *Netflix* and wrong. Patent owner never “equated two distinct terms to the same structure” or “conflated” them. Rather, Patent Owner merely 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, p. 109.

Claim 4: Cognet Does Not Disclose “the head portion of the first member comprises a torque transmitting aperture”

- Petitioner can point to no express disclosure in Cognet of a “torque transmitting aperture.”
- Petitioner appears to argue that Cognet inherently discloses a screw having a torque transmitting aperture, without stating that it is arguing inherency. But Petitioner has not met the exacting standard to establish inherency, which requires Petitioner to show that the screw *necessarily* has a torque transmitting aperture; it is not sufficient that the screw *possibly*, or even *probably*, has such an aperture.
 - *See, e.g., Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002).
- Some screws do not have such an aperture—for example, a hex lag screw, which a POSA would understand could be used in Cognet’s assembly. Ex. 2012, ¶ 59.
- Therefore, Petitioner can assert only that “[a]lmost all screws” have a torque transmitting aperture. Ex. 1002, ¶ 76 (emphasis added). Legally, this argument, even if assumed to be correct, clearly fails to meet the standard.



Ex. 2012, ¶ 59

Claim 4: Cognet Does Not Disclose “the head portion of the first member comprises a torque transmitting aperture”

- Petitioner’s new argument that Cognet discloses that the screw head has “a diameter” (Reply, p. 24) fails for two independent reasons:

1. Petitioner could have and should have made the argument in its Petition, but did not make it until its Reply. Thus, Petitioner waived the argument and the Board should disregard it.

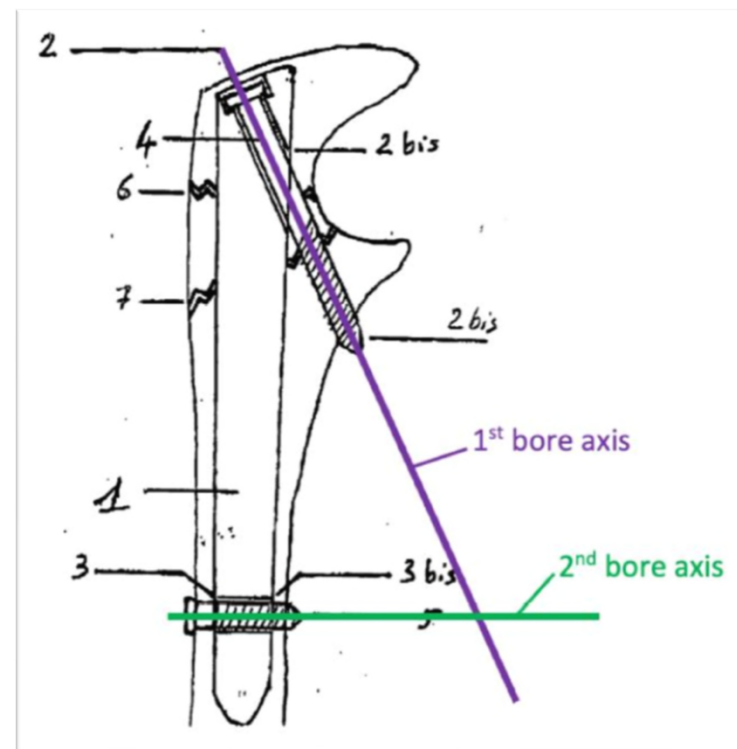
See, e.g., Netflix, 84 F.4th at 1380.

2. Petitioner’s attempt to shift the burden to Patent Owner to show how torque could be applied to a screw with a circular head if not via a torque transmitting aperture is improper. It is Petitioner’s burden to show how the prior art anticipates the challenged claims.

See, e.g., Dynamic Drinkware, LLC v. Nat’l Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015).

Claim 9: Cognet Does Not Disclose “the first bore axis and the second bore axis intersect outside the third member”

- Petitioner’s expert admits that as a matter of “basic analytical geometry,” “[t]wo non-parallel lines will intersect at a point in space provided they are the [sic] same plane.” Ex. 1002, ¶ 81.
- Yet Petitioner merely relies on the below annotated figure without expressly arguing that the two axes *necessarily* lie on the same plane, much less providing any support for assumption so (there is none). Ex. 2012, ¶ 60.
- Thus, Petitioner has not met its burden to show that the two axes actually intersect.



Ex. 2012, ¶ 60

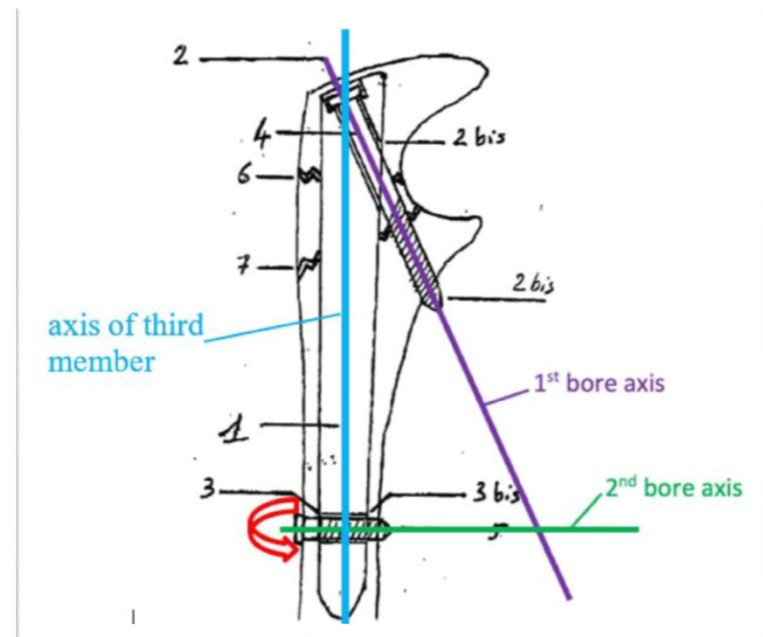
Claim 9: Cognet Does Not Disclose “the first bore axis and the second bore axis intersect outside the third member”

- During cross-examination, Petitioner’s expert cited, for the first time, a portion of Cognet that describes the alleged second bore (*i.e.*, bottom bore) as perpendicular to the axis of the nail (*i.e.*, the third member):

“This nail also has at least one orifice or one tunnel situated at the distal part of the nail, running perpendicular to the axis thereof. . . .”

Ex. 2013, 164:8-24 (citing Ex. 1004, pp. 2-3).

- As an initial matter, the argument is waived because it was not made in the Petition, and thus, should be disregarded.
 - See, e.g., Netflix*, 84 F.4th at 1380.
- In any event, even on the merits, this argument too is wrong. Ex. 2012, ¶ 60.



Ex. 2012, ¶ 60

Petitioner Has Not Established Any Ground of Unpatentability

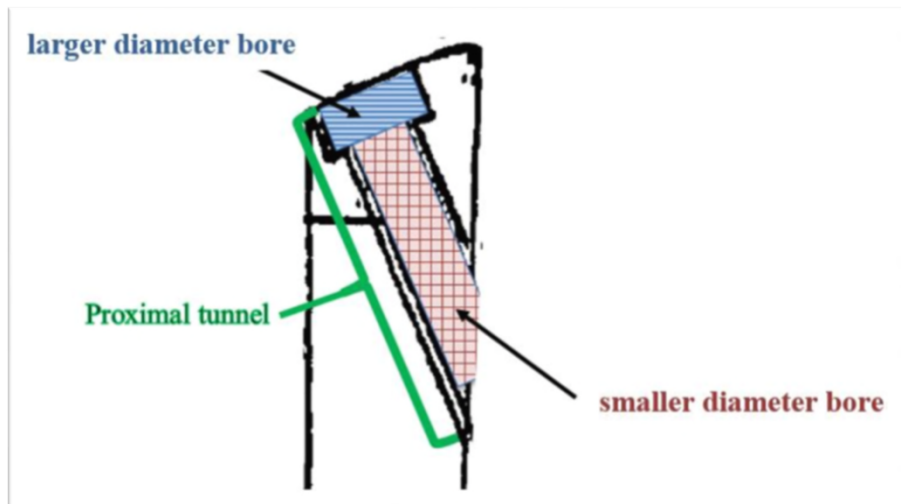
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Petitioner Fails to Show Obviousness Over Cognet and Brumfield for Claims 4, 8, 10, and 14-15

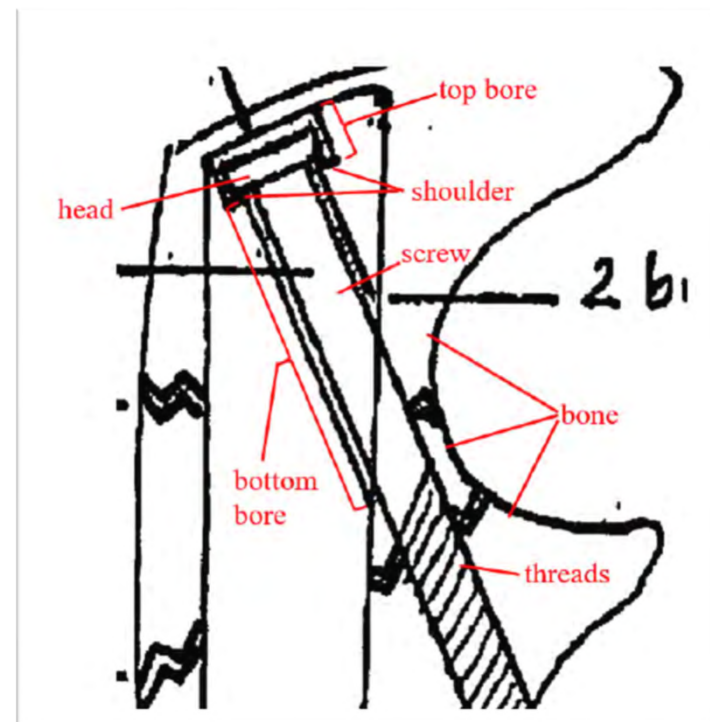
- Regarding the combination of Cognet and Brumfield, Petitioner fails to address whether a POSA would:
 - have any motivation to make the proposed combination (*e.g.*, any potential benefits that might be achieved from the proposed combination);
 - have had an expectation of success in making the proposed combination; or
 - face any challenges or difficulties in making the proposed combination.
- Petitioner argues merely that “the screw and nail in Brumfield are performing the same function in the same way as the screw and nail in Cognet.” Petition, p. 33. Even this is wrong. Ex. 2012, ¶¶ 62-67.

Petitioner Fails to Show Obviousness Over Cognet and Brumfield for Claims 4, 8, 10, and 14-15

Cognet



Ex. 2012, ¶ 64

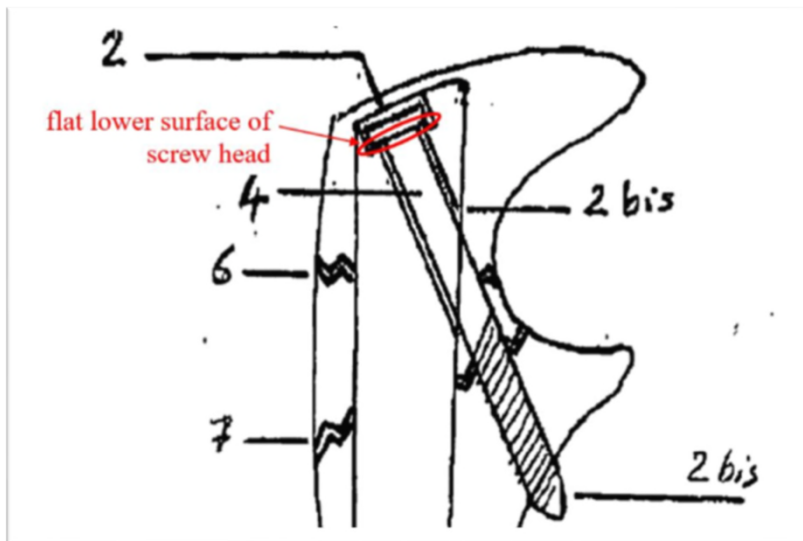


Ex. 2012, ¶ 65

Petitioner Fails to Show Obviousness Over Cognet and Brumfield for Claims 4, 8, 10, and 14-15

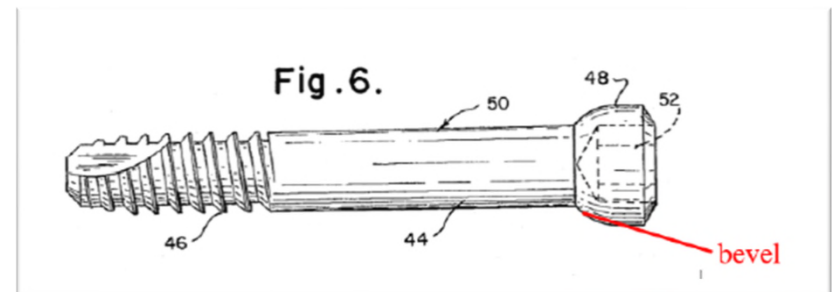
- A POSA would not consider replacing Cognet's screw with a screw having a beveled head portion as disclosed in Brumfield. Ex. 2012, ¶¶ 69-70.

Cognet



Ex. 2012, ¶ 69

Brumfield



Ex. 2012, ¶ 69

Petitioner Fails to Show Obviousness Over Cognet and Brumfield for Claims 4, 8, 10, and 14-15

- Petitioner’s new argument that “[a]t most, ‘increased resistance’ is a trade-off for the benefits of a familiar beveled-head design” (Reply, p. 26) fails for three independent reasons:
 1. Petitioner could have and should have made the argument in its Petition, but did not make it until its Reply. Thus, Petitioner waived the argument and the Board should disregard it.

See, e.g., Netflix, 84 F.4th at 1380.
 2. The argument is based entirely on conclusory attorney say-so (*i.e.*, no supporting expert opinion).
 3. Patent Owner’s expert opined that the “beveled head portion [of Brumfield’s screw] would not mate with the shoulder in the tunnel” of Cognet’s nail. Ex. 2012, ¶¶ 69-70. Petitioner did not address operability, and thus, fails to meet its burden of proof on a preponderance of the evidence.

“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).

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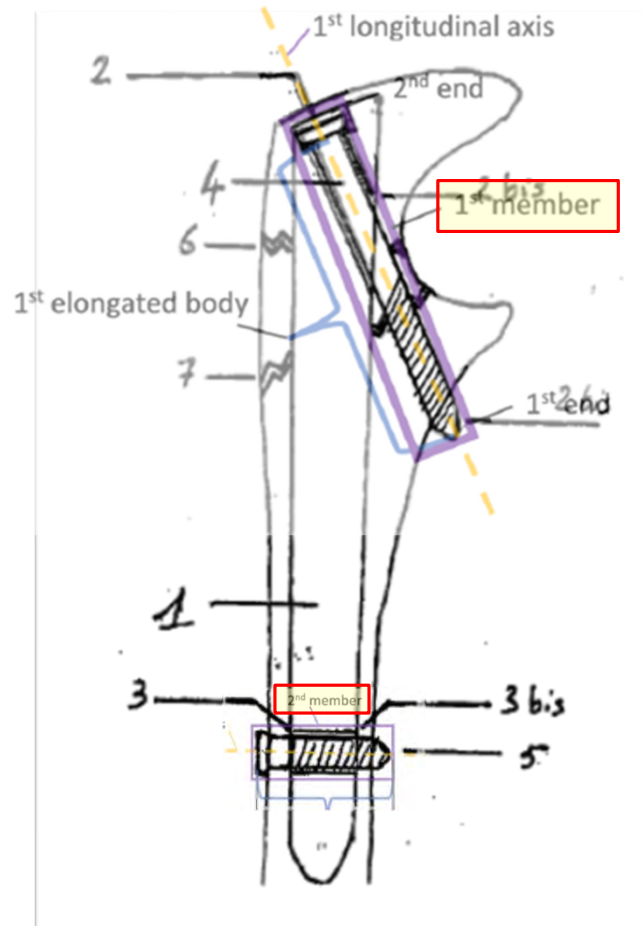
Petitioner Fails to Show Obviousness Over Cognet and Ferrante For Claim 11

10. The assembly of claim **1**, wherein the first end of the first member includes a self-tapping edge for removing bone material.

11. The assembly of claim 10, wherein the first end of the second member includes a self-tapping edge for removing bone material.

Ex. 1001, claims 10 and 11

Petitioner Fails to Show Obviousness Over Cognet and Ferrante For Claim 11



Petition, pp. 11, 13

Petitioner Fails to Show Obviousness Over Cognet and Ferrante For Claim 11

- Petitioner concedes that Cognet does not disclose or suggest the limitations of claims 10 and 11.

3. Claim 10

Claim 10 further limits claim 1 by requiring that the first member includes a self-tapping edge for removing bone material. Cognet is not specific as to whether the first member includes a self-tapping edge or not.

Petition, p. 34

1. Claim 11

Claim 11 further limits claim 10 by requiring that the second member includes a self-tapping edge for removing bone material. While this is a very common characteristic of orthopedic screws, Cognet is not specific as to whether the second member includes a self-tapping edge or not. Ex. 1002

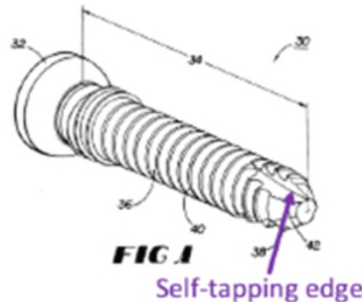
Petition, p. 36

Petitioner Fails to Show Obviousness Over Cognet and Ferrante For Claim 11

- Petitioner argues that *Ferrante* teaches a self-tapping edge as to claim 11, but fails to address claim 10.

1. Claim 11

Claim 11 further limits claim 10 by requiring that the second member includes a self-tapping edge for removing bone material. While this is a very common characteristic of orthopedic screws, Cognet is not specific as to whether the second member includes a self-tapping edge or not. Ex. 1002 ¶ 109. Ferrante discloses a flute (42) for the removal of bone chips as screw (30) is implanted into bone (Ex. 1007, [0043]), which is a self-tapping edge and is shown in figure 1, included below. Ex. 1002 ¶ 110.



Petition, pp. 36-37

Petitioner Fails to Show Obviousness Over Cognet and Ferrante For Claim 11

- In sum, Petitioner concedes that Cognet does not disclose or suggest the limitation of claim 10, yet fails to argue anywhere that Ferrante discloses or suggests it. *See* Petition, pp. 35-36. This is a fatal flaw as to claim 11 due to its dependency on claim 10.

See, e.g., Microsoft Corp. v. IPA Techs. Inc., No. 2021-1412, 2022 U.S. App. LEXIS 8711, at *16-17 (Fed. Cir. Apr. 1, 2022).

- Petitioner’s new argument that it cites Ferrante “merely as evidence” (Reply, pp. 26-27) that the limitation recited in claim 11 was well-known in the field fails for two independent reasons:

1. Petitioner could have and should have made the argument in its Petition, but did not make it until its Reply. Thus, Petitioner waived the argument and the Board should disregard it.

See, e.g., Netflix, 84 F.4th at 1380.

2. The argument is disingenuous. *Compare* Petition, p. 36 (Cognet and Ferrante) *with id.* at p. 33 (Cognet and Brumfield), p. 58 (Simon and Ferrante), and p. 62 (Cognet and Ferrante).

- Petitioner’s new argument that claim 10 is also obvious (Reply, p. 27) should have been, but was not, included in its Petition. Thus, Petitioner waived the argument and the Board should disregard it.

See, e.g., Netflix, 84 F.4th at 1380.

Petitioner Has Not Established Any Ground of Unpatentability

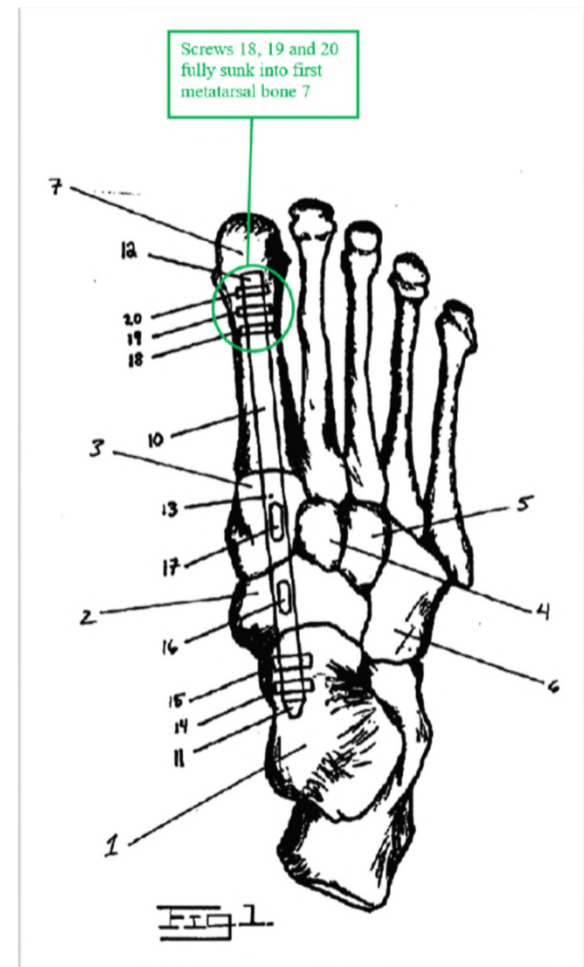
Ground 1	Petitioner Fails to Show Anticipation By Cognet for Claims 1-7, 9, 12, and 13
Ground 2	Petitioner Fails to Show Obviousness Over Cognet and Brumfield for Claims 4, 8, 10, 14, and 15
Ground 3	Petitioner Fails to Show Obviousness Over Cognet and Ferrante for Claim 11
Ground 4	Petitioner Fails to Show Anticipation By Simon for Claims 1, 4, 5, 8, 10-12, 14, and 15
Ground 5	Petitioner Fails to Show Obviousness Over Simon and Ferrante for Claims 4, 8, 10, 11, 14, and 15
Ground 6	Petitioner Fails to Show Obviousness Over Simon and Cognet for Claim 9
Ground 7	Petitioner Fails to Show Obviousness Over Simon and Leu for Claims 2, 3, 6, 7, and 13

Claims 1 and 12: Simon Does Not Disclose “the first member comprises . . . a head portion”

- Petitioner can point to no express disclosure in Simon of a “first member . . . wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface . . . ,” as required by claims 1 and 12.
- Petitioner appears to argue that Simon inherently discloses a screw having a head portion, without stating that it is arguing inherency. But Petitioner has not met the exacting standard to establish inherency, which requires Petitioner to show that the screw necessarily has a head portion; it is not sufficient that the screw *possibly*, or even *probably*, has a head portion.
 - *See, e.g., Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002).

Claims 1 and 12: Simon Does Not Disclose “the first member comprises . . . a head portion”

- The Board acknowledged that “the Petition is not a model of clarity as to support for [a head portion] in Simon.” See Institution Decision, p. 24.
- While the Board found Petitioner’s evidence sufficient to identify a screw head for the purposes of institution, the evidence is not sufficient now to meet Petitioner’s burden of proof.
- *First*, Petitioner’s expert admitted (as he must) that while “[m]ost screws have a head,” some screws are “headless.” Ex. 1002, ¶ 42.a.
- The Board limited this opinion as referring to screws that are “intended to be fully sunk in bone,” and concluded that it does not apply to Simon. See Institution Decision, p. 23. But the opinion does apply to Simon’s screws because they are intended to be fully sunk into the metatarsal bone.



Sur-Reply, p. 21

Claims 1 and 12: Simon Does Not Disclose “the first member comprises . . . a head portion”

- *Second*, none of the other statements the Board cited establish that Simon’s screws necessarily have a head portion.

c) 1[b][ii]: “a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis,”

As discussed above in the Cognet anticipation arguments for claim element 1[b][i] (section (V.A.1.c)), screws have an elongated body that extends from a first end (the tip of the screw) to a second end (the head of the screw) along a longitudinal axis. Ex. 1002 ¶ 42. Figure 1 of Simon discloses a second screw (second member) (elements 14 or 15 of Figure 1) (Ex. 1008, [0053]). Simon further discloses that the second screw is also a locking screw (Ex. 1008, [0053]), interlocking cortical screw, or transfixation screw (Ex. 1008, [0039]), and thus discloses this claim element. Ex. 1002 ¶ 117.

Petition, pp. 40-41

Second, while the Petition is not a model of clarity as to support for element 1[a][ii] in Simon, we find Petitioner’s reference to Simon’s Figure 1 and its disclosure of a second screw comprising “a locking screw (Ex. 1008, [0053]), interlocking cortical screw, or transfixation screw (Ex. 1008, [0039]),” coupled with the testimony of Mr. Dominguez, sufficient—at least for the purpose of institution—to identify the screw head of claim element 1[a][ii]. See Pet. 40; Ex. 1002 ¶ 117.

Institution Decision, p. 24

c) 1[b][ii]: Simon discloses “a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis,”

[117] Figure 1 of Simon discloses a second screw (second member) (elements 14 or 15 of Figure 1) (Ex. 1008 [0053]). As discussed above in Cognet claim element 1[b][i] (section (V.A.1.d)) screws have an elongated body that extends from a first end (the tip of the screw) to a second end (the head of the screw) along a longitudinal axis. The second screw is also a locking screw (Ex. 1008 [0053]), interlocking cortical screw, or transfixation screw (Ex. 1008 [0039]), and thus discloses this claim element.

Ex. 1002, ¶ 117

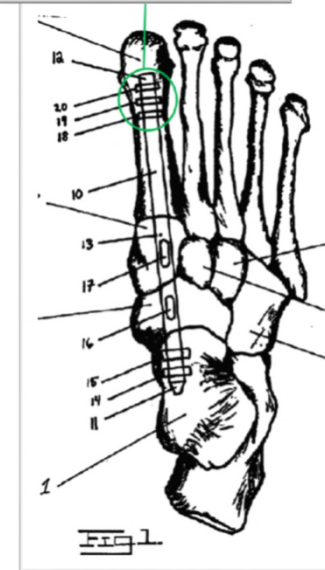
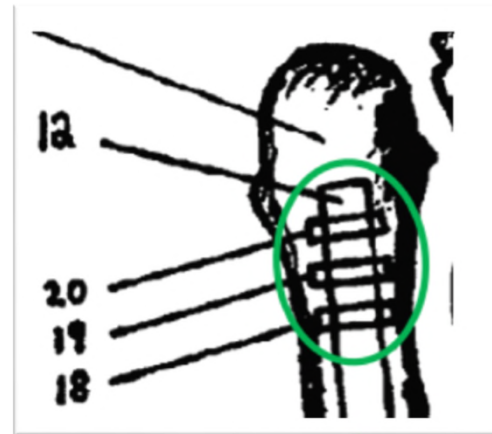
Claims 1 and 12: Simon Does Not Disclose “the first member comprises . . . a head portion”

- Third, Petitioner’s expert’s testimony as to what he considers to be a “headless screw” matches the screws that Simon shows in its Figure 1.

Q So then what would you say a headless screw is? What’s the distinction between a headless screw and a screw with a head portion that you’re making here?

A Well, what I’m saying here is that the screw head — the screw head could have a bulbous portion, it could be partially bulbous, or it may have a non-bulbous portion. So if it’s a non-bulbous portion, there’s nothing there that is larger than the rest of the screw, then that’s what I would consider to be a headless screw. So whether it’s a

Ex. 2022, 120:13-25



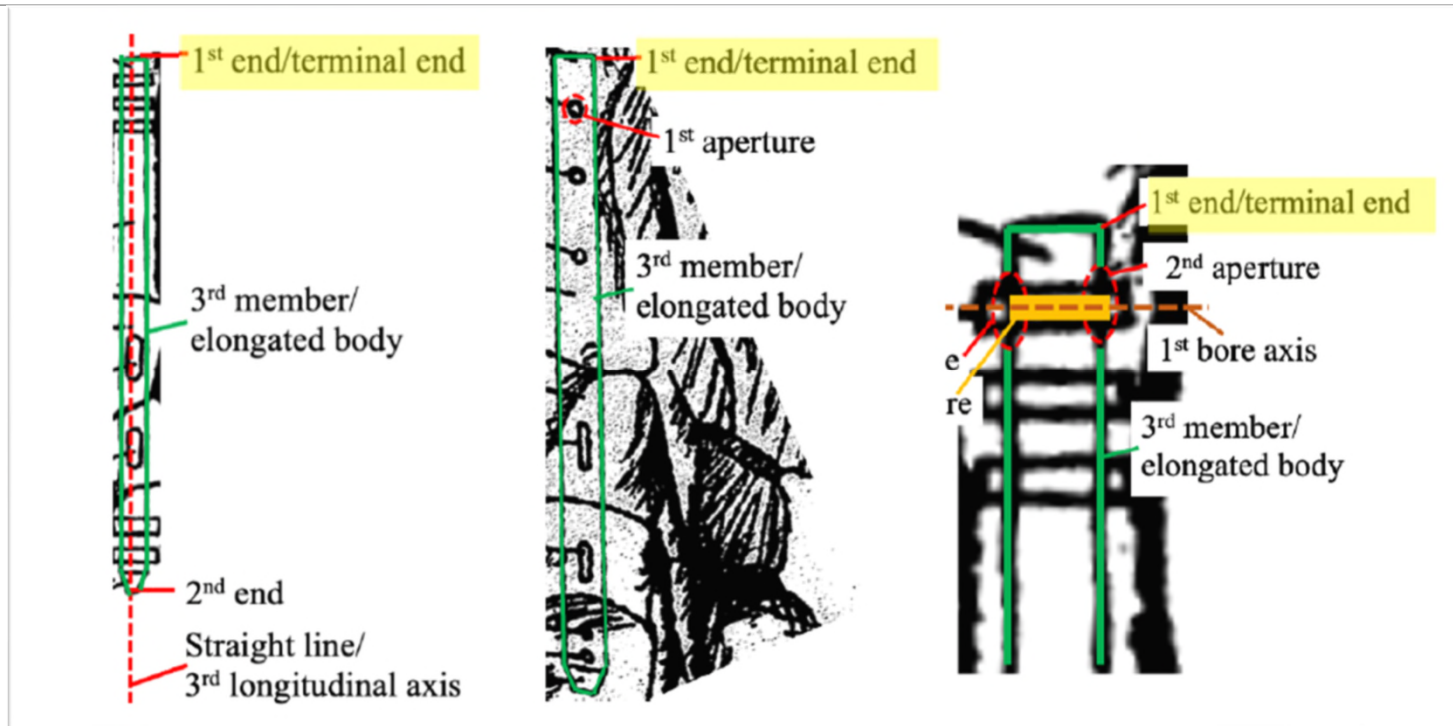
Sur-Reply, pp. 21-22

Claims 1 and 12: Simon Does Not Disclose “a first aperture at a terminal end of the first end”

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, wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member, wherein the first bore comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,

Ex. 1001, claims 1 and 12

Claims 1 and 12: Simon Does Not Disclose “a first aperture at a terminal end of the first end”



Petition, pp. 42-44

Q. But you're treating the term "first end" and "terminal end" as synonymous?

A. In this figure, yes.

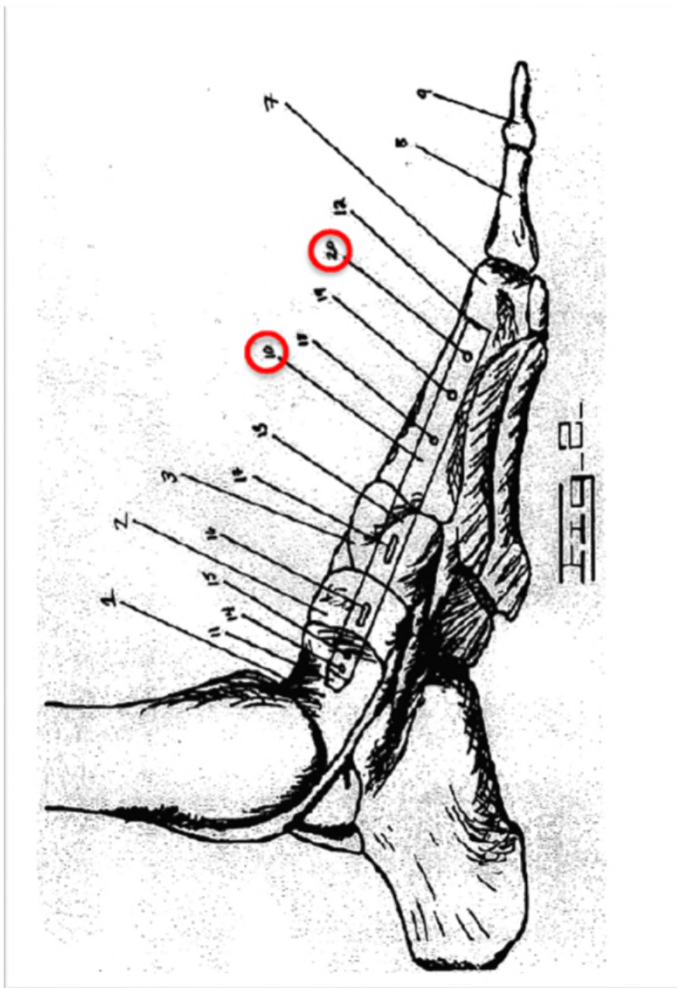
Ex. 2013, 213:12-14

Q. Okay. And so, here again, you are treating the term "first end" and "terminal end" as synonymous, correct?

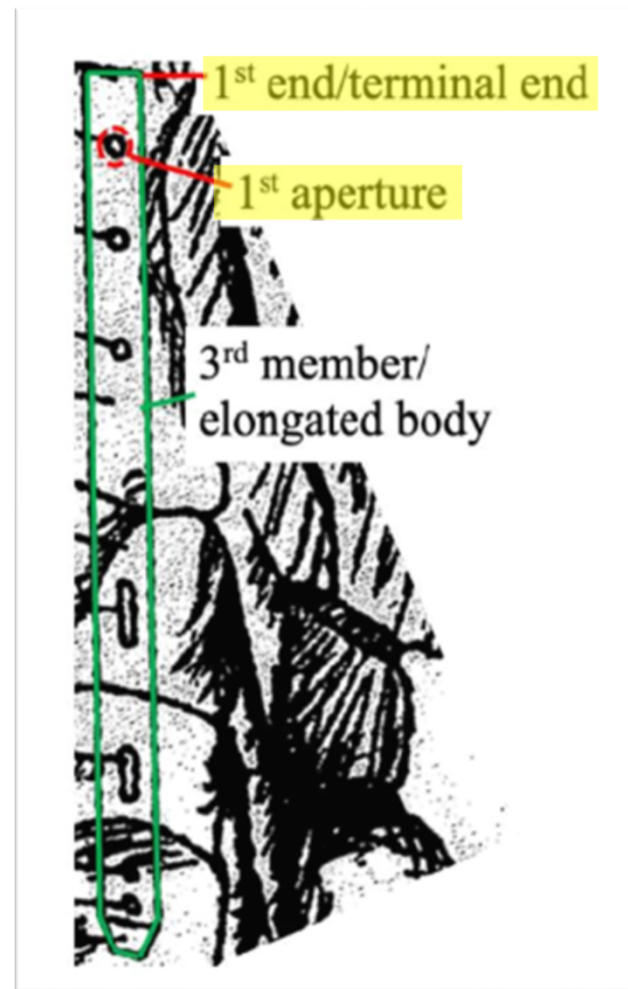
A. Correct.

Ex. 2013, 214:20-23

Claims 1 and 12: Simon Does Not Disclose “a first aperture at a terminal end of the first end”



Ex. 2012, ¶ 80



Ex. 2012, ¶ 80

Claim 4: Simon Does Not Disclose “the head portion of the first member comprises a torque transmitting aperture”

- Just as for Cognet, Petitioner can point to no express disclosure in Simon of a “torque transmitting aperture.”
- Petitioner appears to argue that Simon inherently discloses a screw having a torque transmitting aperture, without stating that it is arguing inherency. But Petitioner has not met the exacting standard to establish inherency, which requires Petitioner to show that the screw *necessarily* has a torque transmitting aperture; it is not sufficient that the screw *possibly*, or even *probably*, has such an aperture.
 - *See, e.g., Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002).
- Some screws do not have a torque transmitting aperture (*e.g.*, a hex lag screw). Ex. 2012, ¶ 59.
- Therefore, Petitioner can assert only that “[a]lmost all screws” have a torque transmitting aperture. Ex. 1002, ¶ 76 (emphasis added). Legally, this argument, even if assumed to be correct, clearly fails to meet the standard.



Ex. 2012, ¶ 59

Claims 10 and 11: Simon Does Not Disclose the First End of the First or Second Member Including a Self-Tapping Edge

- Petitioner can point to no express disclosure in Simon of either “the first end of the first member includes a self-tapping edge for removing bone material” (claim 10) or “the first end of the second member includes a self-tapping edge for removing bone material” (claim 11).
- Petitioner appears to argue that Simon inherently discloses screws having a self-tapping edge, without stating that it is arguing inherency. But Petitioner has not met the exacting standard to establish inherency, which requires Petitioner to show that Simon’s screws *necessarily* have a self-tapping edge; it is not sufficient that the screws *possibly*, or even *probably*, have a self-tapping edge.
 - *See, e.g., Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002).
- Petitioner can assert only that “[a] POSA would immediately assume that the first member (interlocking screw) includes a self-tapping edge,” because “[i]nterlocking screws **commonly** have a self-tapping edge.” Ex. 1002, ¶ 136 (emphasis added). Legally, this argument, even if assumed to be correct, clearly fails to meet the standard.

Petitioner Has Not Established Any Ground of Unpatentability

Ground 1	Petitioner Fails to Show Anticipation By Cognet for Claims 1-7, 9, 12, and 13
Ground 2	Petitioner Fails to Show Obviousness Over Cognet and Brumfield for Claims 4, 8, 10, 14, and 15
Ground 3	Petitioner Fails to Show Obviousness Over Cognet and Ferrante for Claim 11
Ground 4	Petitioner Fails to Show Anticipation By Simon for Claims 1, 4, 5, 8, 10-12, 14, and 15
Ground 5	Petitioner Fails to Show Obviousness Over Simon and Ferrante for Claims 4, 8, 10, 11, 14, and 15
Ground 6	Petitioner Fails to Show Obviousness Over Simon and Cognet for Claim 9
Ground 7	Petitioner Fails to Show Obviousness Over Simon and Leu for Claims 2, 3, 6, 7, and 13

Petitioner Fails to Show Obviousness Over Simon and Ferrante for Claim 4

2. The assembly of claim 1, wherein the head portion of the first member resides at least partially within the first bore.

3. The assembly of **claim 2**, wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture.

4. The assembly of **claim 3**, wherein the head portion of the first member comprises a torque transmitting aperture.

Ex. 1001, claims 2-4

- Petitioner fails to assert anywhere in the Petition that Simon or Ferrante discloses the limitations of claims 2 and 3. This is a fatal flaw as to claim 4 due to its dependency on claims 2 and 3.

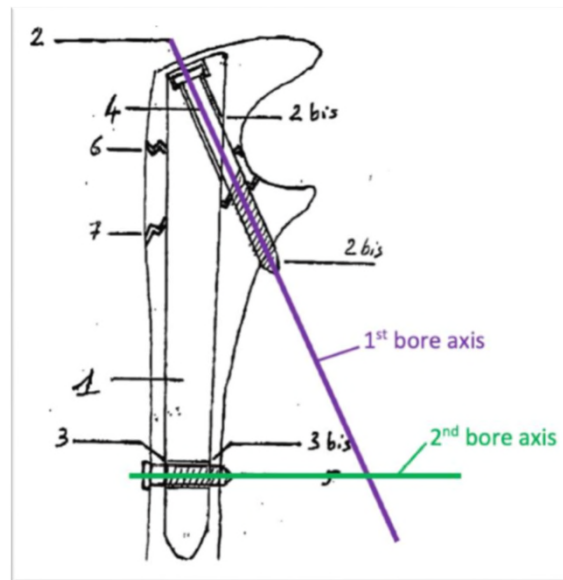
See, e.g., Microsoft Corp. v. IPA Techs. Inc., No. 2021-1412, 2022 U.S. App. LEXIS 8711, at *16-17 (Fed. Cir. Apr. 1, 2022).

Petitioner Has Not Established Any Ground of Unpatentability

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Ground 6	Petitioner Fails to Show Obviousness Over Simon and Cognet for Claim 9
Ground 7	Petitioner Fails to Show Obviousness Over Simon and Leu for Claims 2, 3, 6, 7, and 13

Neither Simon Nor Cognet Discloses “the first bore axis and the second bore axis intersect outside the third member” (Claim 9)

- Petitioner relies entirely on its argument that Cognet discloses the limitation of claim 9, *i.e.*, it does not argue that Simon discloses it.
- As discussed earlier with respect to Ground 1 and Cognet, Petitioner does not expressly argue that the two axes it drew *necessarily* lie on the same plane, much less provide any support for such assumption (there is none). Ex. 2012, ¶ 60.



Ex. 2012, ¶ 60

Petitioner Has Not Established Any Ground of Unpatentability

Ground 1	Petitioner Fails to Show Anticipation By Cognet for Claims 1-7, 9, 12, and 13
Ground 2	Petitioner Fails to Show Obviousness Over Cognet and Brumfield for Claims 4, 8, 10, 14, and 15
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Ground 7	Petitioner Fails to Show Obviousness Over Simon and Leu for Claims 2, 3, 6, 7, and 13

Petitioner Fails to Show That It Would Have Been Obvious to Combine Simon and Ferrante, Cognet, or Leu (Claims 2-4, 6-11, and 13-15)

- Regarding the combination of Simon and one of Ferrante, Cognet, and Leu, Petitioner fails to address whether a POSA would:
 - have any motivation to make the proposed combinations (*e.g.*, any potential benefits that might be achieved from the proposed combination);
 - have had an expectation of success in making the proposed combinations; or
 - face any challenges or difficulties in making the proposed combinations.
- Petitioner’s new argument that it cites Ferrante merely “as evidence” (Reply, pp. 31-32) that the limitations recited in the claims at issue were “already so well known in the art” should have been, but was not, included in its Petition. Thus, Petitioner waived the argument and the Board should disregard it.

See, e.g., Netflix, 84 F.4th at 1380.

Topics

Claim Construction of “[first aperture] at a terminal end” and “bore”

Petitioner Has Not Established Any Ground of Unpatentability of Original Claims 1-15

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

Patent Owner’s Motion to Exclude Irrelevant and Prejudicial Evidence

Proposed Substitute Claim 16

Claim 16. [Proposed substitute for Claim 1] An assembly for bone fusion, comprising:

- a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis . . . ;
- a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis . . . ;
- 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, wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, 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, and a first bore extending along a first bore axis from the first aperture to a second aperture on [[an]] a side exterior surface of the third member, wherein the first bore comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the side exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,

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

wherein the first member couples to the third member . . . ,

wherein the second member couples to the third member . . . ,

wherein the first angle is in the range of about 0 degrees to about 90 degrees,

wherein the second angle is in the range of about 0 degrees to about 90 degrees, and

wherein the second bore axis is substantially perpendicular to the third longitudinal axis.

Proposed Substitute Claim 20

Claim 20. [Proposed substitute for Claim 5] The assembly of claim [[1]] 16, wherein the first aperture of the third member is aligned on the first bore axis, and further wherein the first exterior surface of the third member is a top exterior surface of the terminal end, and further wherein the second exterior surface of the third member is the side exterior surface of the third member.

Proposed Substitute Claim 27

Claim 27. [Proposed substitute for Claim 12] An assembly for bone fusion, comprising:

- a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis . . . ;
- a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis . . . ;
- 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, wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, 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, and a first bore extending along a first bore axis from the first aperture to a second aperture on [[an]] a side exterior surface of the third member, wherein the first bore comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the side exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,

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

wherein the first member couples to the third member . . . ,

wherein the second member couples to the third member . . . ,

wherein the second angle is in the range of about 0 degrees to about 90 degrees, and

wherein the second bore axis is substantially perpendicular to the third longitudinal axis.

Proposed Substitute Claim 28

Claim 28. [Proposed substitute for Claim 13] The assembly of claim [[12]] 27, wherein the head portion of the first member resides at least partially within the first bore, and further wherein the first exterior surface of the third member is a top exterior surface of the terminal end, and further wherein the second exterior surface of the third member is the side exterior surface of the third member.

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

Petitioner Fails to Show That the Original Prior Art Discloses or Suggests the Original Limitations of Claims 16-30

Petitioner Fails to Show Obviousness Over Cognet and Zhang for Claims 16-30

Petitioner Fails to Show That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch's Disclosures for Claims 16-30

Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

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Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

Petitioner Fails to Show That the Original Prior Art Discloses or Suggests the Original Limitations of Claims 16-30

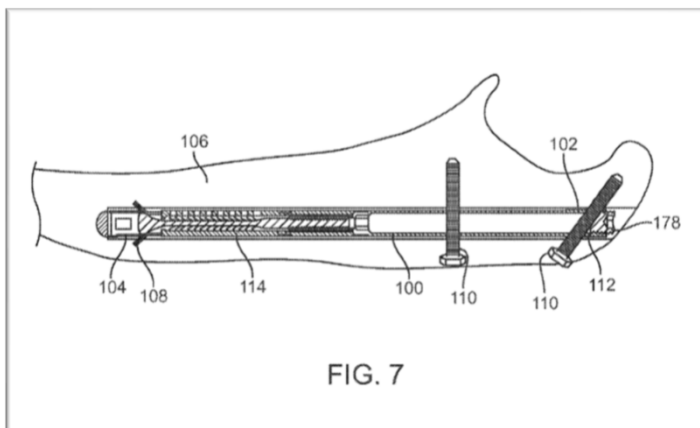
Petitioner Fails to Show Obviousness Over Cognet and Zhang for Claims 16-30

Petitioner Fails to Show That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch's Disclosures for Claims 16-30

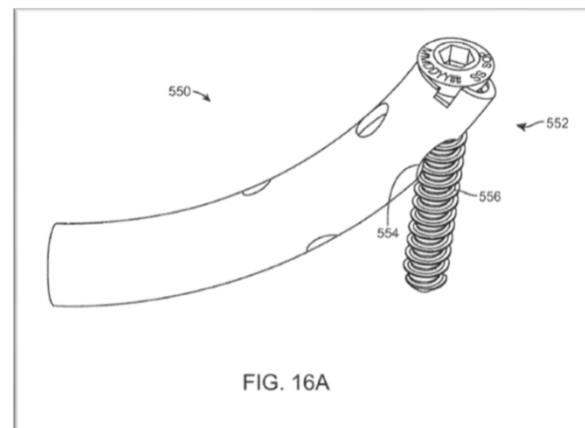
Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

- Petitioner relies primarily on the embodiment in Mazur's Figures 16A-16E to show anticipation, but seemingly asks the Board to envision modifications to that embodiment based on a different embodiment in Figure 7.

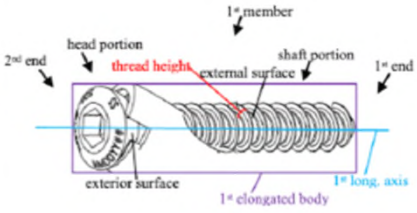
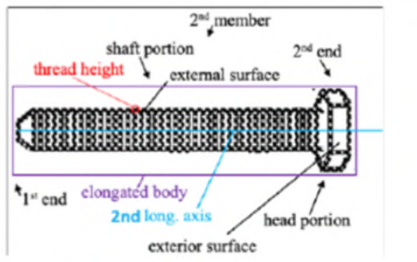


Ex. 1056, FIG. 7

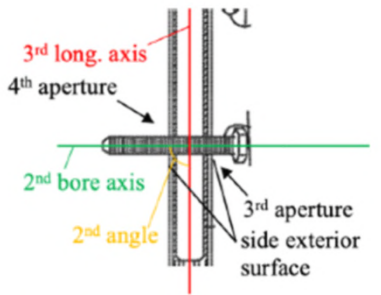


Ex. 1056, FIG. 16A

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

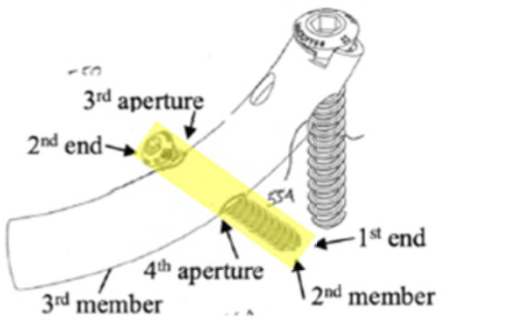
16b & 27b	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;	 Fig. 16A detail (annotated)
16c & 27c	a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;	 Fig. 7 detail (annotated)

Ex. 1054, p. 6

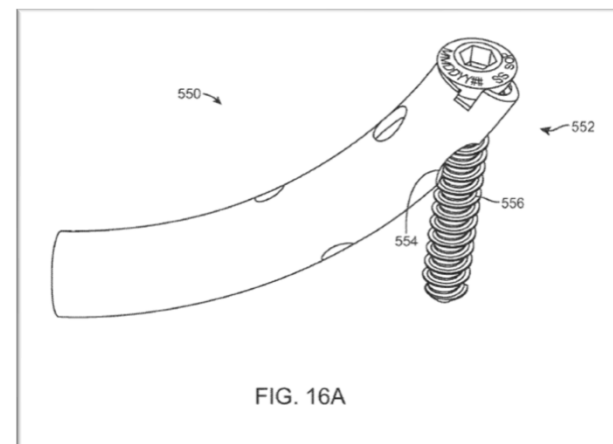
16o & 27n	wherein the second bore axis is substantially perpendicular to the third longitudinal axis.	 Fig. 7 (annotated)
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Ex. 1054, p. 10

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

161 & 271	wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,	 Fig. 16A (annotated) – adapted to include a second member added to the figure as implied by the holes in the third member and described for other figures, such as Fig. 7.
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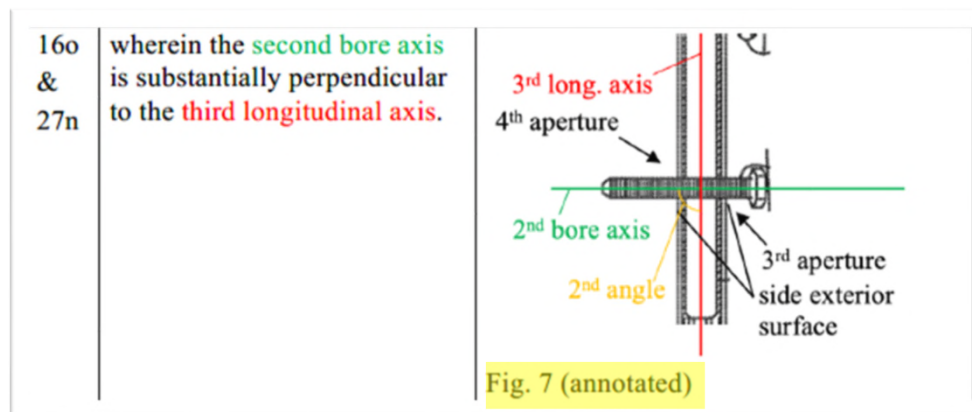
Ex. 1054, p. 10



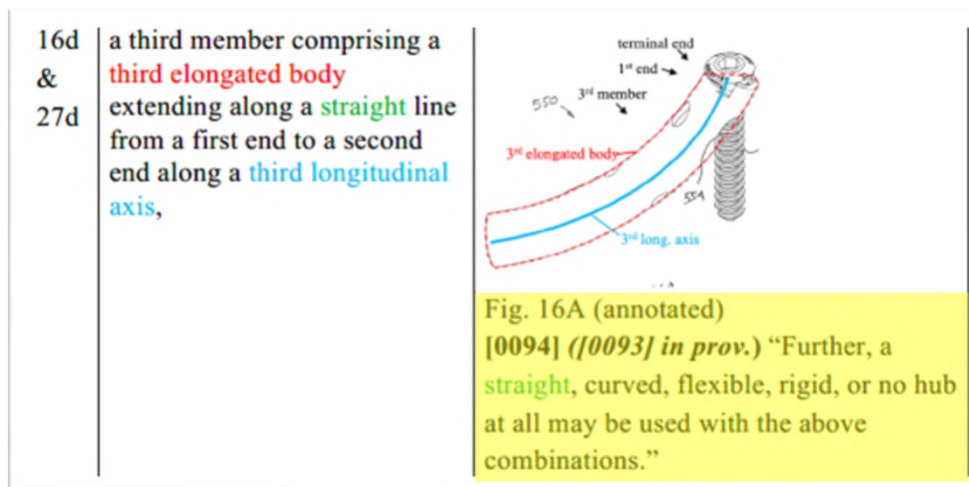
Ex. 1056, FIG. 16A

- The argument fails because Petitioner has not argued (or provided any evidence) in its Opposition that Mazur “is sufficiently clear in disclosing the combinability of those elements such that a skilled artisan would at once envisage the claimed combination.”
- *The Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1350 (Fed. Cir. 2019)

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30



Ex. 1054, p. 10



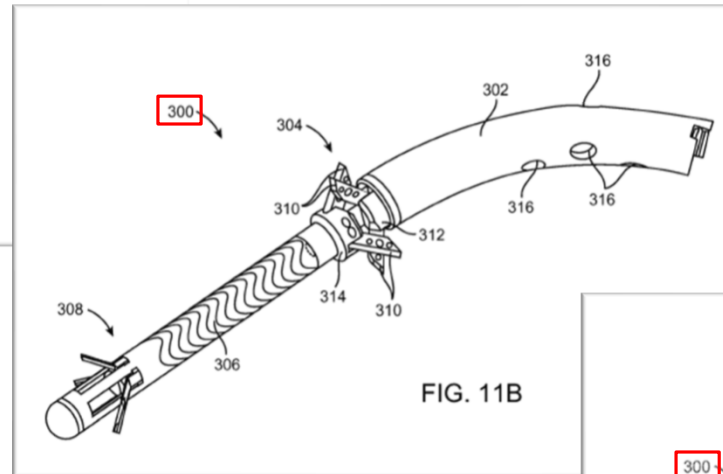
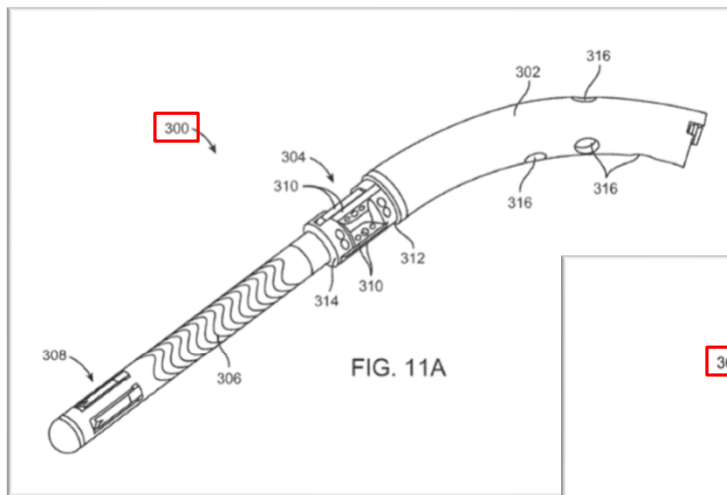
Ex. 1054, p. 7

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

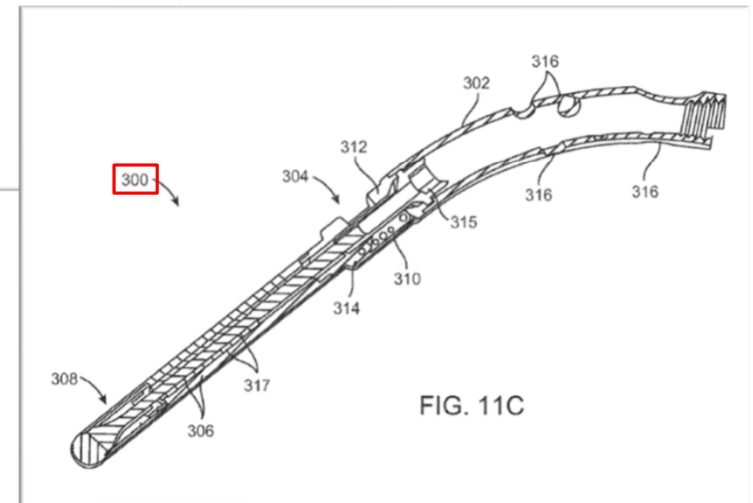
[0094] Device 300 is an example of an embodiment utilizing mixed gripper types. In other words, this device uses one scissors-arm tripod gripper 304 and one bendable-arm gripper 308. Other embodiments of the invention (not shown) use various combinations of gripper(s) and/or flexible-to-rigid body portion(s). Further exemplary gripper embodiments are described in detail in co-pending U.S. application Ser. No. 61/100,652 filed Sep. 26, 2008 and entitled Fracture Fixation Device, Tools and Methods. It 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. The grippers and/or flexible-to-rigid body portions may each be of identical or different construction, and may be placed together or at other locations along the device. Further, a straight, curved, flexible, rigid, or no hub at all may be used with the above combinations. Additionally, screws, K-wires, sutures or no additional fixation may be used with these various devices. The devices may be specially designed and constructed for a particular purpose or range of purposes. According to aspects of the invention, the components may also be designed to be interchangeable and/or produced in various sizes so that surgical kits may be provided. Such 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.

Ex. 1056, ¶ [0094]

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30



Ex. 1056, FIGS. 11A-11C



Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

[0046] FIG. 11A is perspective view of another embodiment of a bone fixation device shown in a retracted or undeployed state.

[0047] FIG. 11B is perspective view of the device shown in FIG. 11A shown in a deployed state.

[0048] FIG. 11C is a cross-sectional view of the device shown in FIG. 11A shown in a retracted or undeployed state.

[0049] FIG. 11D is a cross-sectional view of the device shown in FIG. 11A shown in a deployed state.

Ex. 1056, ¶¶ [0046]-[0049]

[0055] FIGS. 16A-16E show various views of another exemplary embodiment of a bone fixation device hub.

Ex. 1056, ¶ [0055]

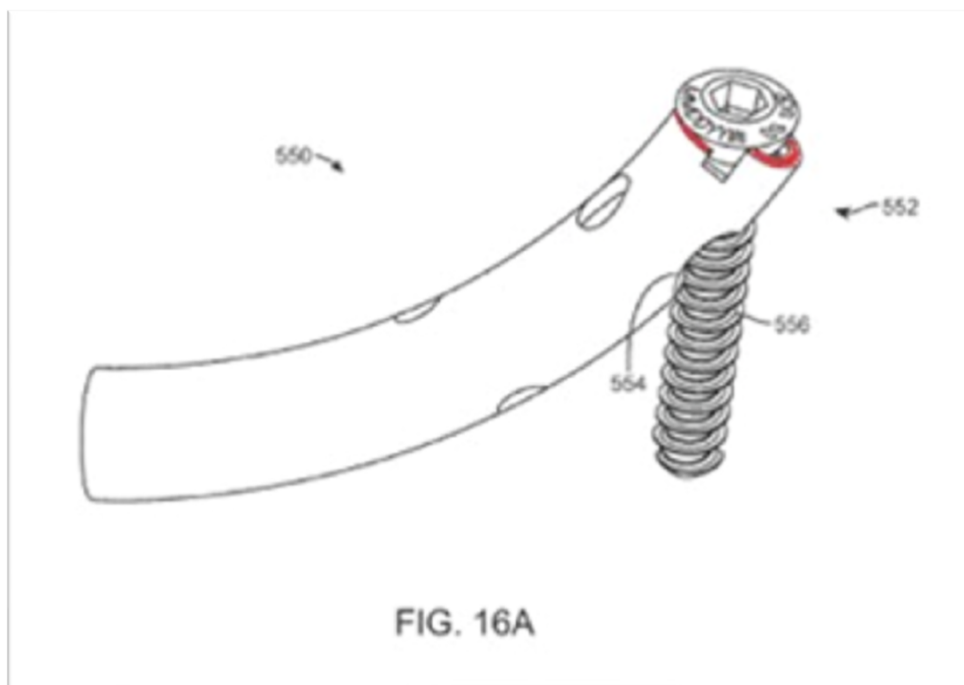
Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

[0110] FIGS. 16A-16E show another exemplary embodiment of a bone fixation device hub 550. As best seen in FIG. 16D, hub 550 includes at its proximal end 552 a transversely elongated hole 554. Hole 554 allows a 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). This of arrangement of hole 554 may be configured to hold screw 556 tightly at all angles. This may be accomplished, for example, by using a hole 554 slot width that is equal to or smaller than the minor diameter of screw 556. The wall thickness of hub 550 may fit into the screw threads, providing additional locking of screw 556. In other embodiments, the angle of elongated hole 554 may be oriented differently as desired.

Ex. 1056, ¶ [0110]

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

- Mazur, at best, discloses an aperture that is on a first exterior surface (*e.g.*, top), but does not disclose an aperture that is on both a first exterior surface *and* a second exterior surface, as required by the new claim limitations of substitute claims 16-30. Ex. 2037, ¶¶ 20-24.



Ex. 2037, ¶ 20

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

- The dual purposes of the claimed “first aperture” are to provide:
 - an opening for a first member (*e.g.*, a screw) to enter the third member (*e.g.*, a nail); and
 - abutment of the head of the first member on a surface of the bore.

Ex. 2037, ¶ 21.

3. The assembly of claim 2, wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture.

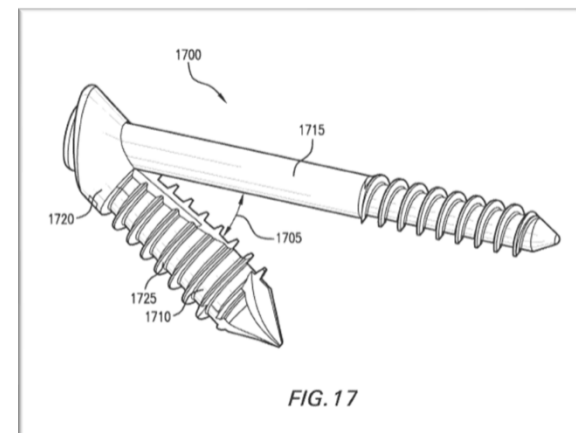
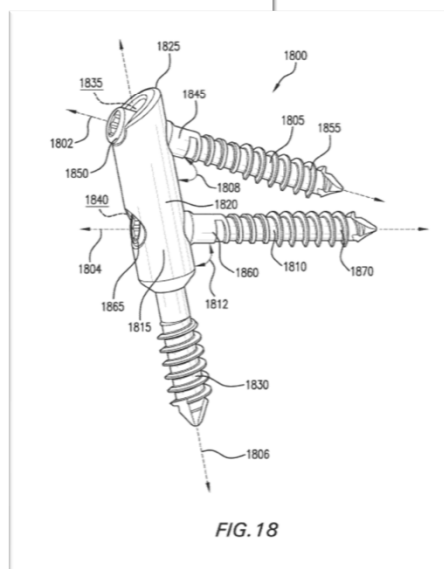
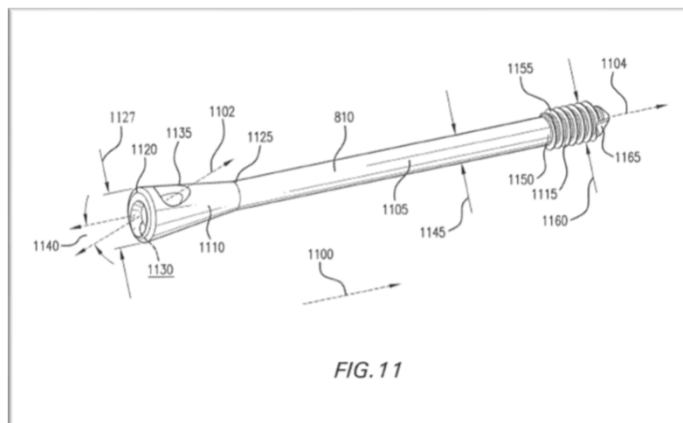
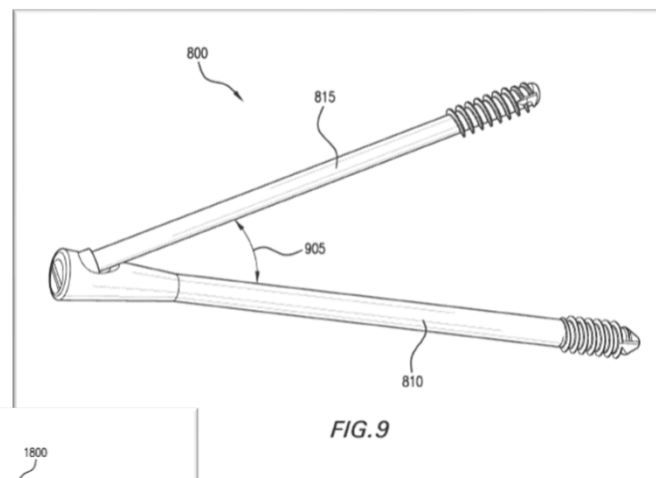
Ex. 1001, claim 3

38. It is also my opinion that the screw tunnel angle is an obvious matter of design choice from practical considerations that arise when making such devices. A POSA understands that during the drilling process used to create a first bore containing a first aperture in the nail, the drill cylindrical size, entry location and drill angle affects the appearance of the surfaces being modified by the drilling process. For example, if the drill is in proximity to the nail terminal end or an edge, it is not unusual for the aperture to breach the multiple surfaces at the terminal end of the nail provided the aperture serves the intended purpose to provide abutment for the screw head and a recess in which to hide all or part of the screw head. The importance of the aperture's function to enable abutment is common practice when seating the bone screws head into the nail implant. Whether or not the aperture passes through “first and second exterior surfaces” of the nail is of no importance for the function of the aperture taught in Pat. '166.

Ex. 1054, ¶ 38

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

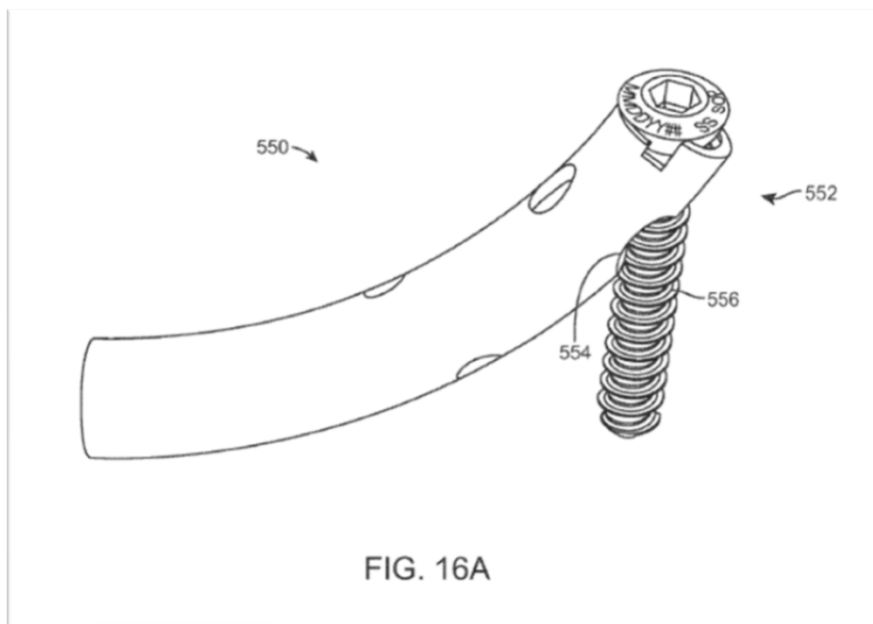
- Further, because the first member must fit through the aperture if it to fit through the bore as intended, the geometry of the aperture is dependent on that of the bore. Ex. 2037, ¶ 21.
- For example, the aperture must be at least as wide as the widest part of the bore. Ex. 2037, ¶ 21.



Ex. 1001, FIGS. 9, 11, 17, 18

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

- Mazur's Figures 16A and 16C show that it is the open end on the top surface of Mazur's hub, not the notch on the side surface, that serves the purposes of the claimed "first aperture." Ex. 2037, ¶ 22.



Ex. 1056, FIGS. 16A, 16C

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

- Contrarily, the notch in Mazur's hub serves a very different purpose than the aperture: to allow the hub to engage/mate with an insertion tool. Ex. 2037, ¶ 22.

[0072] FIG. 4 illustrates a combination tool 138 useful for inserting device 100, actuating gripper 108, compressing flexible-to-rigid body portion 114, approximating the fracture in bone 106, aligning anchor screw(s) 110, and removing device 100, if desired. In this exemplary embodiment, tool 138 includes an L-shaped body 140 that mounts the other components of the tool and also serves as a handle. The main components of tool 138 are a device attachment portion 142, a rotary driver 132, an approximating driver 144, and a screw alignment portion 146.

[0073] FIG. 5 shows a cross-section of the tool 138 and device 100 illustrated in FIG. 4. As shown, device attachment portion 142 includes a knob 148 rigidly coupled to a tube 150 which is rotatably mounted within sleeve 152. Sleeve 152 in turn is fixedly mounted to tool body 140. The distal end of tube 150 is provided with external threads for engaging the internal threads on the proximal end of device 100. As best seen in FIG. 4, both the distal end of sleeve 152 and the proximal end of device 100 may be provided with semicircular steps that inter-engage to prevent device 100 from rotating with respect to sleeve 152. With this arrangement, device 100 can be prevented from rotating when it is secured to tool 138 by tube 150 of device attachment portion 142. The mating semicircular steps also serve to position device 100 in a particular axial and angular orientation with respect to tool 138 for aligning screws with screw holes, as will be later described.

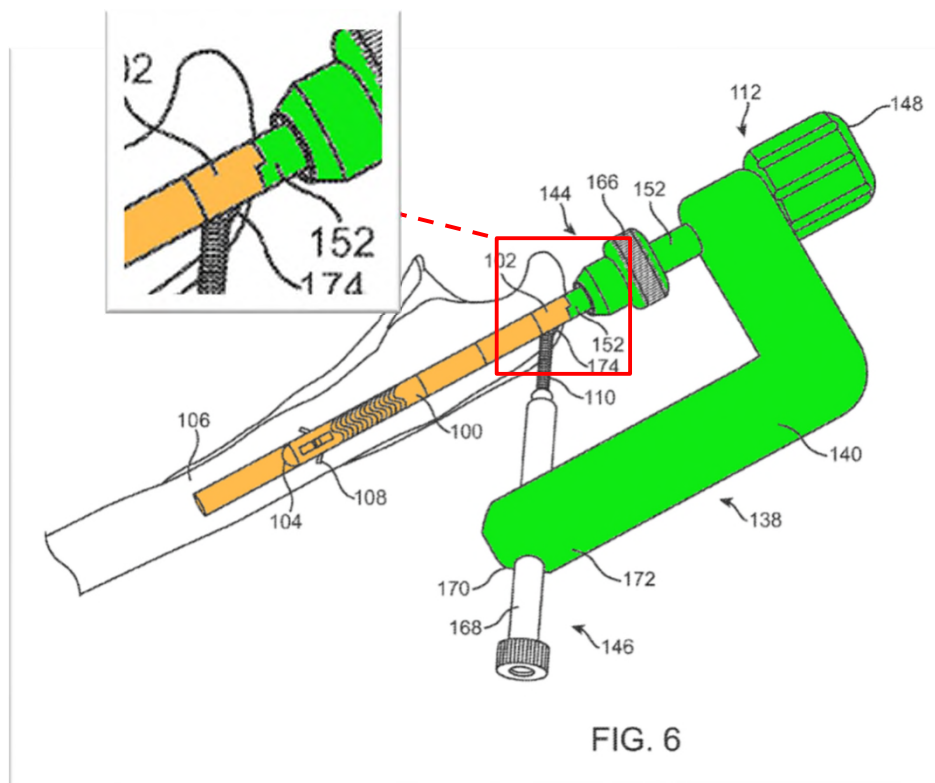


FIG. 6

Ex. 1056, FIG. 6

Ex. 1056, ¶¶ [0072], [0073]

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

Q. What's the purpose of the so-called notch cut-out feature?

A. Notch cut-out features, such as shown in Mazur, and other POSAs show notch cut-out features on their nails, such as Brumfield, Marcus, Chandran, all show notch features on the end of the nail.

Q. What's the purpose of all these notch features?

A. These notch features are used with ancillary devices for the purpose of insertion and rotation of the nail to position it properly in the bone.

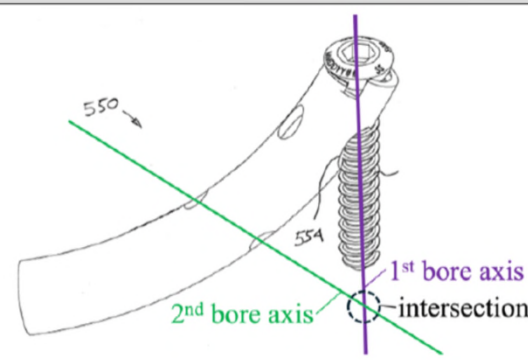
Ex. 2038, 35:4-16

23. As to the geometry of Mazur's notch, it is completely unrelated to the bore in Mazur's hub. The notch can be sized independently of the hub because the notch is designed to engage with an insertion tool, not to receive a screw through it. Therefore, in my opinion, a POSITA would not consider the notch in Mazur's hub to be part of the "aperture."

Ex. 2037, ¶ 23

Petitioner Fails to Show Anticipation By Mazur for Claim 24

- Just like it does as to Cognet, Petitioner mistakenly assumes that the two axes formed by the two pairs of apertures in Mazur's Fig. 16A necessarily lie on the same plane. Ex. 2037, ¶¶ 25-28; *supra* slides 20, 21.

Claim 24		
24	The assembly of claim 16, wherein the first bore axis and the second bore axis intersect outside the third member.	 The diagram shows a perspective view of a mechanical assembly. A vertical purple line is labeled '1st bore axis'. A green line, labeled '2nd bore axis', passes through the assembly at an angle. The two lines intersect at a point labeled 'intersection'. The intersection point is located outside a cylindrical component labeled '554'. A curved line labeled '550' is also shown. The diagram is labeled 'Fig. 16A (annotated)' at the bottom.

Ex. 1054, p. 12

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

Petitioner Fails to Show That the Original Prior Art Discloses or Suggests the Original Limitations of Claims 16-30

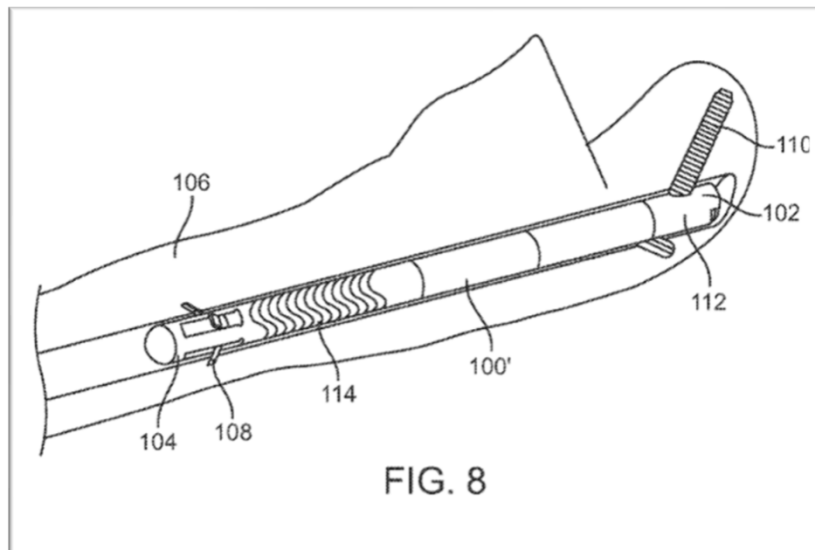
Petitioner Fails to Show Obviousness Over Cognet and Zhang for Claims 16-30

Petitioner Fails to Show That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch's Disclosures for Claims 16-30

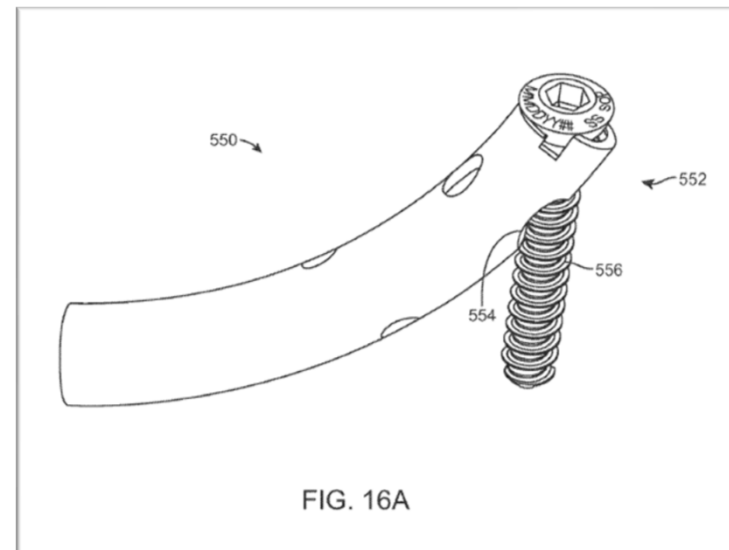
Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

- Petitioner has not established a motivation to modify Mazur with a reasonable expectation of success. Ex. 2037, ¶¶ 29-37.
- In particular, Petitioner says nothing about the differences between the straight hub embodiment (in Figures 1-9) and the curved hub embodiment (in Figures 16A-16E). The two embodiments have different designs and applications. Ex. 2037, ¶¶ 32-34.



Ex. 1056, FIG. 8



Ex. 1056, FIG. 16A

Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

- As to a motivation to modify, Petitioner makes a conclusory statement that Mazur “suggest[s] to [a POSA] to modify the embodiment in Figure 16A to have a straight hub.” Opp., p. 11. This is not enough. Ex. 2037, ¶¶ 29-30.
- Mazur discloses only that a straight hub “may be used” for the embodiment in Figures 11A-11D. See *supra* slides 61-62.
- This does not provide the requisite motivation because it says nothing about the embodiment in Figures 16A-16E, and also suggests a mere possibility of making a medication without providing a reason to make it. Ex. 2037, ¶ 31.

Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

- As to a reasonable expectation of success, Petitioner has not considered that 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, thereby failing to show that a POSA would consider one a substitute for the other. Ex. 2037, ¶¶ 32-33.
- A straight hub could not be used in the distal radius because it would have to be inserted through the articular surface of the distal radius, thereby completely disrupting the wrist. Ex. 2037, ¶ 34.
- Even if a straight hub could somehow be used in the distal radius, it would require additional modifications. For example, the screw could no longer be oriented obliquely as shown in Figures 16A-16E, and would instead have to be oriented orthogonally (or substantially orthogonally) through the side of the hub. Thus, the modified embodiment could not possibly meet the new limitations of claims 16-30 of the '166 Patent that require the aperture to be both on a first (*e.g.*, top) exterior surface and a second (*e.g.*, side) exterior surface of the third member. Ex. 2037, ¶ 35.

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

Petitioner Fails to Show That the Original Prior Art Discloses or Suggests the Original Limitations of Claims 16-30

Petitioner Fails to Show Obviousness Over Cognet and Zhang for Claims 16-30

Petitioner Fails to Show That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch's Disclosures for Claims 16-30

Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

Petitioner Fails to Show That the Original Prior Art Discloses or Suggests the Original Limitations of Substitute Claims 16-30

- Petitioner generally relies on references cited in the Petition (Cognet, Brumfield, and Ferrante) (the “Original Prior Art”) for disclosure of the claim limitations carried over from original claims 1-15 (the “original limitations”).
- But in its Opposition, Petitioner either is silent as to where and how the Original Prior Art discloses or suggests these limitations or merely cites its Petition and Reply papers in asserting that the Original Prior Art discloses or suggests the limitations “as detailed previously.” Opp., pp. 17-19, 23-25.
- While Petitioner does not expressly state that it intends to incorporate its prior arguments into its Opposition to the Motion to Amend, that is what Petitioner *de facto* has done.
- Incorporation by reference is improper.
 - 37 C.F.R. § 42.6(a)(3): “**Incorporation by reference; combined documents.** Arguments must not be incorporated by reference from one document into another document. Combined motions, oppositions, replies, or other combined documents are not permitted.”

Petitioner Fails to Show That the Original Prior Art Discloses or Suggests the Original Limitations of Substitute Claims 16-30

- There is good cause for the Board to disregard the improperly incorporated arguments, and doing so would serve the interests of justice. Petitioner's violation is highly prejudicial to Patent Owner.
- The Federal Circuit has repeatedly blessed the Board's disregarding arguments that violate 37 C.F.R. § 42.6(a)(3) as a proper exercise of the Board's discretion. *See, e.g.:*
 - *Parus Holdings, Inc. v. Google LLC*, 70 F.4th 1365, 1370-738 (Fed. Cir. 2023);
 - *3M Co. v. Evergreen Adhesives Inc.*, 860 Fed. Appx. 724, 728 (Fed. Cir. 2021);
 - *Gen. Access Sols., Ltd. v. Sprint Spectrum LP*, 811 Fed. Appx. 654, 657-59 (Fed. Cir. 2020);
 - *Bos. Sci. Neuromodulation Corp. v. Nevro Corp.*, 813 Fed. Appx. 572, 582-83 (Fed. Cir. 2020).
- If the Board disregards the improperly incorporated arguments, then all of Petitioner's grounds of unpatentability as to substitute claims 16-30 that involve combining references fail because Petitioner has not addressed how certain limitations are disclosed in, or suggested by, the Original Prior Art, or provided any motivation to combine the Original Prior Art references with one another.

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

Petitioner Fails to Show That the Original Prior Art Discloses or Suggests the Original Limitations of Claims 16-30

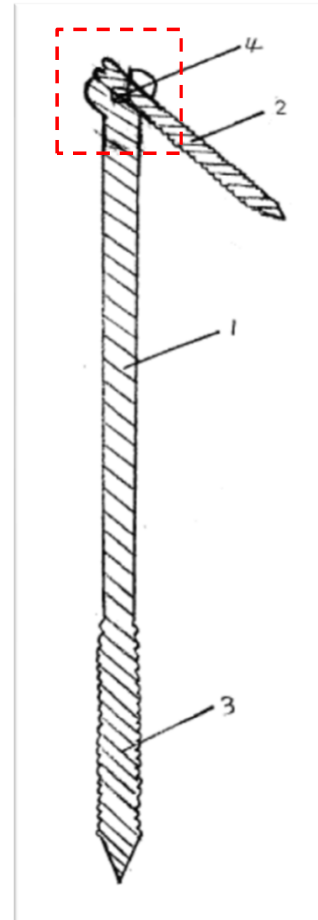
Petitioner Fails to Show Obviousness Over Cognet and Zhang for Claims 16-30

Petitioner Fails to Show That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch's Disclosures for Claims 16-30

Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

Petitioner Fails to Show Obviousness Over Cognet and Zhang for Claims 16-30

- Zhang's singular figure has very limited detail, and does not clearly show whether and where exactly on an exterior surface of the intramedullary nail 1 an aperture is formed.
- Assuming *arguendo* that Zhang's figure is considered to disclose an aperture, Petitioner still fails to meet its burden to show that Zhang discloses the new limitations of claims 16-30 requiring the aperture to be on a first *and* a second exterior surface.
- The aperture would be formed entirely on the "nail tail region," which is bulbous and potentially spherical, and accordingly, has a *single* surface. Ex. 2037, ¶ 42; Ex. 1038, 4:32-36.



Ex. 1058, Figure

Petitioner Fails to Show Obviousness Over Cognet and Zhang for Claims 16-30

- Even if, however, Zhang’s “nail tail region” is considered to have multiple surfaces, Petitioner still fails to meet its burden to the extent it relies on the “groove 4” to show that the aperture is on not only a first (e.g., top) exterior surface, but also a second (e.g., side) exterior surface.
- Zhang’s “groove 4” is not a part of the aperture for the same reasons discussed earlier with respect to Mazur’s notch. Ex. 2037, ¶ 43.

intramedullary nail 1 in a region near a nail tip. A nail tail region is hemispherical, and is provided with a groove 4 enabling the intramedullary nail to be turned with a screwdriver, and an oblique hole is provided in a region of the groove. The lock nail 2 is an ordinary

Ex. 1058, 4:32-36

18. Zhang, like Brumfield, Marcus, and Chandran, discloses intramedullary nail 1 with groove 4 formed in the head of the nail. Groove 4 is a slot for a screwdriver. Ex. 1058, 4:30-35. The groove allows the user to insert a screwdriver into groove 4 and advance intramedullary nail 1 the last ¼ of the insertion depth while rotating it into the correct plane for inserting the locking nail at the appropriate angle to repair the bone fracture. Ex. 1058, 5:16-22.

Ex. 1054, ¶ 18

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

Petitioner Fails to Show That the Original Prior Art Discloses or Suggests the Original Limitations of Claims 16-30

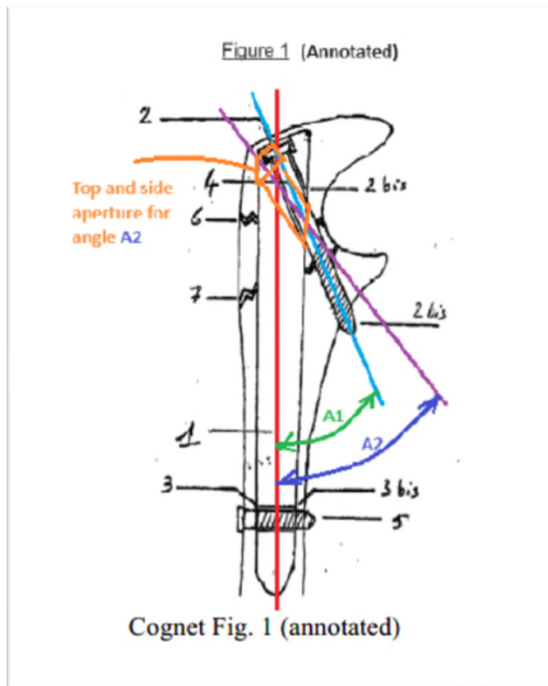
Petitioner Fails to Show Obviousness Over Cognet and Zhang for Claims 16-30

Petitioner Fails to Show That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch's Disclosures for Claims 16-30

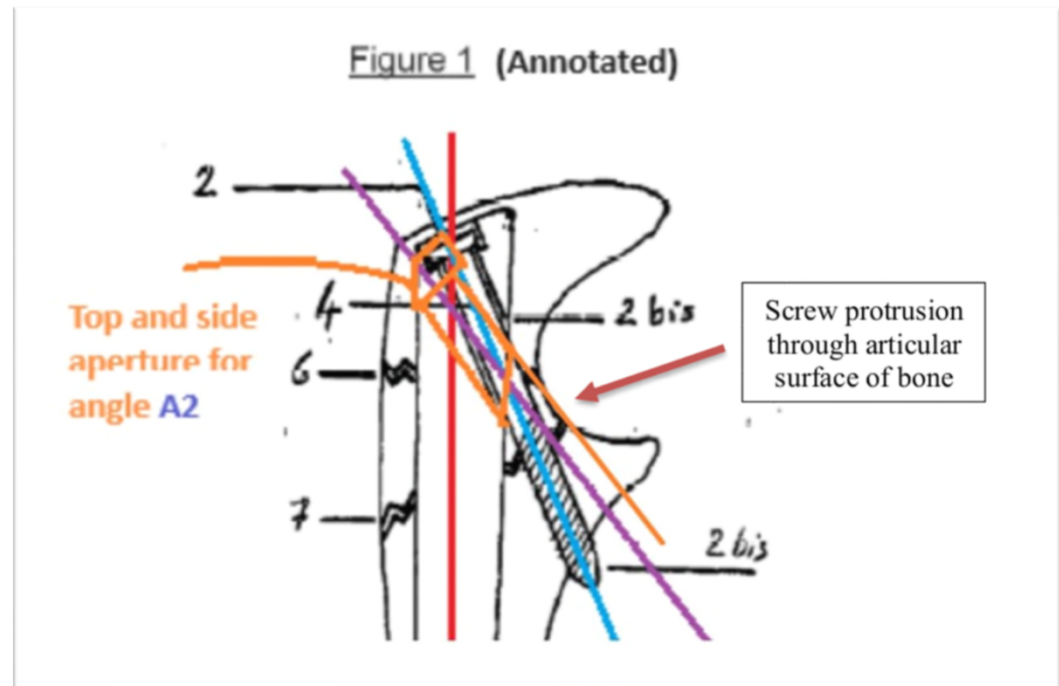
Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

Petitioner Fails to Show That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch's Disclosures for Claims 16-30

- There is a strong motivation not to modify Cognet's nail by changing the screw tunnel angle from "A1" to "A2" as Petitioner contends: a risk of irreparable joint pathology if the screw were inadvertently drilled through the articular surface of the bone, which would cause great harm to the patient – a risk that no competent surgeon would want to take without good reason. Ex. 2037, ¶¶ 49-50.



Ex. 1054, ¶ 40



Ex. 2037, ¶ 48

Petitioner Fails to Show That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch's Disclosures for Claims 16-30

- Petitioner fails to even acknowledge the risk of harm to the patient, much less provide a reason for a surgeon to take this risk. This completely undercuts a reasonable expectation of success. Ex. 2037, ¶ 50.

Q. Well, did you ever consider in your analysis whether a surgeon would want to avoid driving Cognet's screw too close to the articular surface of the bone, as shown in Cognet's Figure 1?

A. Not being a doctor, I don't recall addressing in my declaration of whether it's close to the joint or not. So it's not something that I considered.

Ex. 2038, 85:22-86:5

Q. Well, wouldn't you say that it would be a risk for the screw to be too close to the joint -- close to the articular surface of the bone shown in Cognet's Figure 1?

A. Again, I don't recall addressing that specific instance in my declaration.

Ex. 2038, 86:6-11

Q. Does your analysis here with respect to obviousness over Cognet and/or other references consider at all risks to the patient in making this modification of changing the angle of the screw?

A. I do not recall addressing that in my declaration.

Ex. 2038, 87:8-14

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

Petitioner Fails to Show Anticipation By Mazur for Claims 16-30

Petitioner Fails to Show Obviousness Over Mazur for Claims 16-30

Petitioner Fails to Show That the Original Prior Art Discloses or Suggests the Original Limitations of Claims 16-30

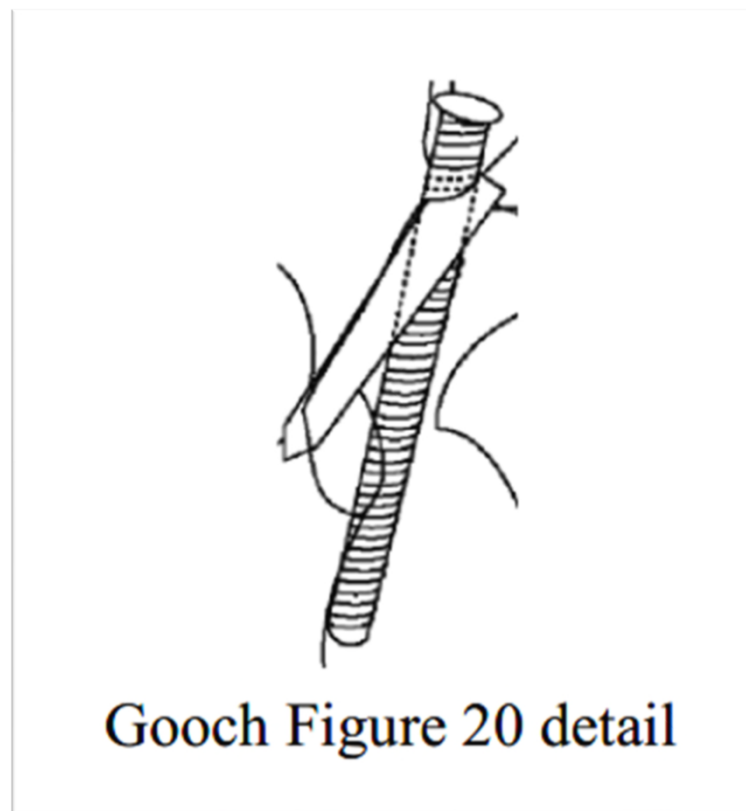
Petitioner Fails to Show Obviousness Over Cognet and Zhang for Claims 16-30

Petitioner Fails to Show That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch's Disclosures for Claims 16-30

Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

- Gooch's Figure 20 is drawn in such a way that a POSA would have no certainty as to whether the figure shows that the aperture is on *both the top and side* exterior surfaces, *or* whether it shows that the aperture is on *only the side* exterior surface, of the bone anchor. Ex. 2037, ¶¶ 54-55.
- Figure 20 may reflect a perspective of the assembly such that the screw is inserted into the anchor through an aperture that lies entirely on a side surface, and the screw partially *obscures* the top surface, rather than being *inserted into* the top surface, of the anchor. Ex. 2037, ¶¶ 54-55.



Ex. 2037, ¶ 55

Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30



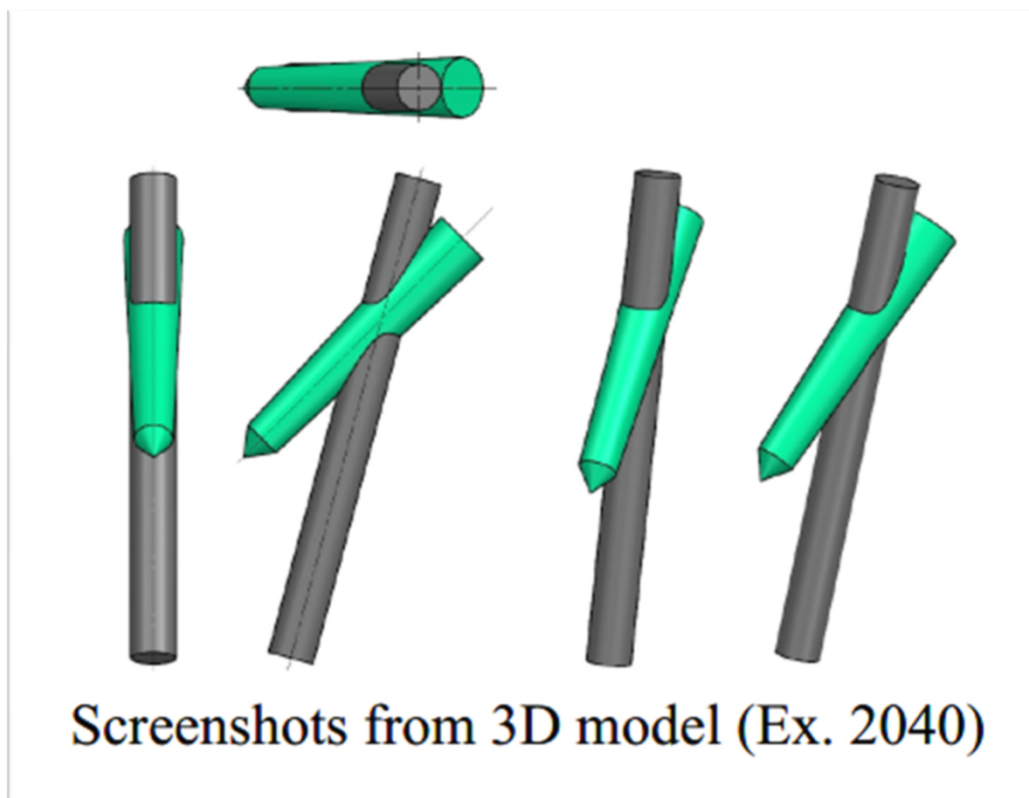
Gooch Figure 20 detail



Screenshot from 3D model (Ex. 2040)

Ex. 2037, ¶ 55

Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30



Ex. 2037, ¶ 55

Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

- Petitioner's expert does not dispute that Gooch's Figure 20 might show something other than what he has opined it shows.

Q. And you'd agree that in Figure 20 of Gooch, the screw is drawn such that at least part of the aperture lies behind the screw?

A. I don't recall addressing that in my declaration.

Ex. 2038, 100:16-20

Q. And in this two-dimensional view, you don't -- you don't know for sure whether the screw in Gooch's Figure 20 is obstructing the view of part of the aperture in the nail, correct?

A. I don't recall addressing that in my declaration.

Ex. 2038, 102:3-9

Q. Do you have an opinion on whether the screw obscures part of the view of the aperture in Figure 20?

A. No. I don't recall addressing that in my declaration.

Ex. 2038, 102:10-14

Petitioner Fails to Show Obviousness Over Cognet and Gooch for Claims 16-30

- Because the parties and their expert's competing interpretations of Figure 20 are arguably "equally plausible," Petitioner fails to show by a preponderance of the evidence that Gooch discloses or suggests the new limitations requiring an aperture to be on a first (*e.g.*, top) exterior surface and a second (*e.g.*, side) exterior surface of the third member.
- *See, e.g., Samsung Elecs. Co., Ltd. v. Neonode Smartphone LLC*, No. 2023-1464, 2024 WL 3451828 (Fed. Cir. 2024)

Topics

Claim Construction of “[first aperture] at a terminal end” and “bore”

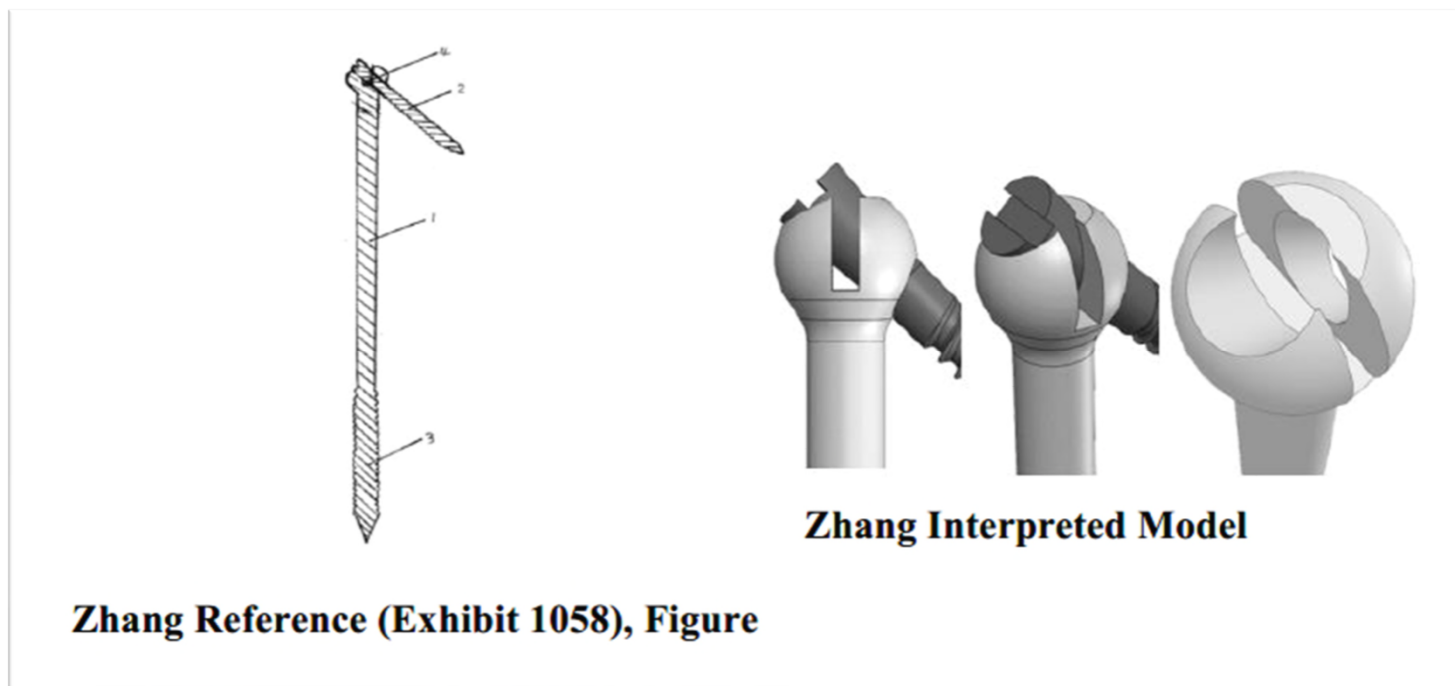
Petitioner Has Not Established Any Ground of Unpatentability of Original Claims 1-15

Petitioner Has Not Established That Any of Substitute Claims 16-30 Are Unpatentable

Patent Owner’s Motion to Exclude Irrelevant and Prejudicial Evidence

The Zhang Interpretation Model Is Irrelevant

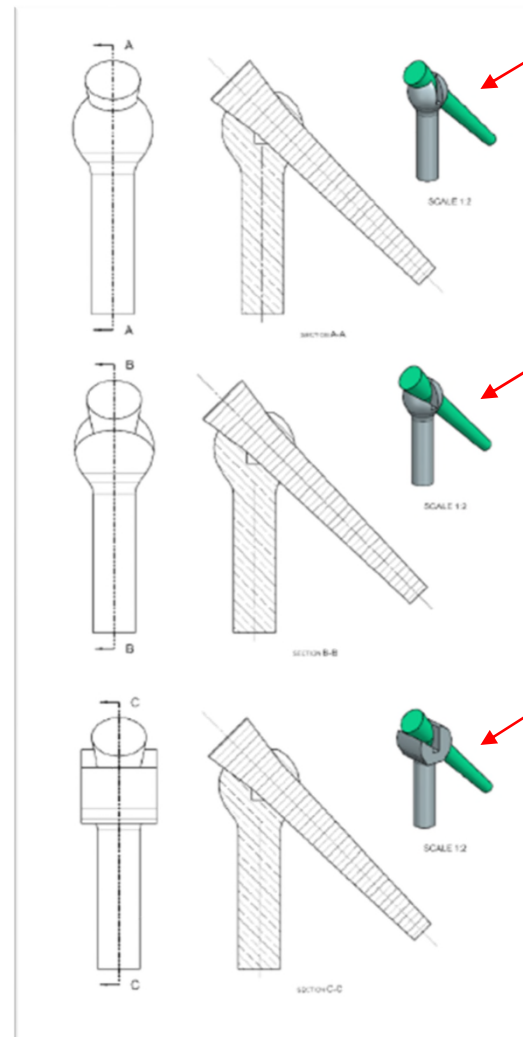
- Under Federal Rules of Evidence 401/402, the Zhang Interpretation Model is irrelevant to the issues in this case because it adds a significant amount of speculative detail not provided in the Zhang reference itself.



Motion to Exclude, p. 2

The Zhang Interpretation Model Is Prejudicial

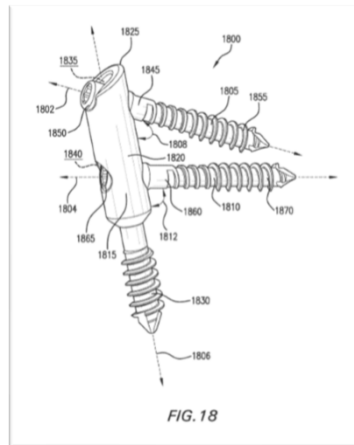
- Under Federal Rule of Evidence 403, any possible probative value of the Zhang Interpretation Model is substantially outweighed by a danger of unfair prejudice to Patent owner and a danger of confusing the issues.
- Petitioner misleadingly wants the Board to believe that the Zhang Interpretation Model is the factually correct model of Zhang's assembly. Not so. That is very unlikely.
- There are, in fact, many possible interpretations of Zhang's figure, and no one 3D model can claim to be the correct one.



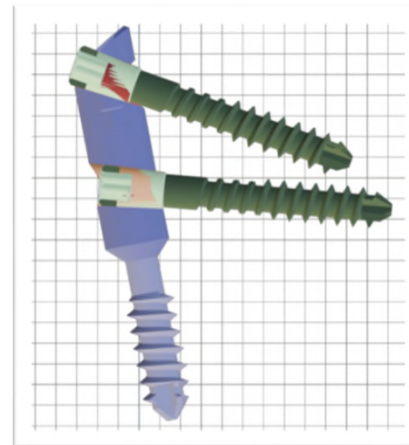
Ex. 2037, ¶ 44

The '166 Patent Interpretation Models Are Irrelevant and Prejudicial

- Under Federal Rules of Evidence 401/402, the '166 Patent Interpretation Models are irrelevant to the issues in this case because they add a significant amount of speculative detail not provided in the '166 Patent itself.
- Under Federal Rule of Evidence 403, any alleged probative value of the '166 Patent Interpretation Models is substantially outweighed by a danger of unfair prejudice to Patent Owner and a danger of confusing the issues. The risk is that the models will be considered substitutes for the '166 Patent's figure—which they are indisputably not – or in conjunction with the '166 Patent's figures, which is not appropriate because they are not part of the '166 Patent.



Ex. 1001, FIG. 18



Ex. 1049, p. 10