

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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FUSION ORTHOPEDICS, LLC,  
Petitioner,

v.

EXTREMITY MEDICAL, LLC,  
Patent Owner.

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

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**PATENT OWNER'S RESPONSE TO PETITION FOR  
*INTER PARTES* REVIEW OF U.S. PATENT NO. 11,298,166**

## TABLE OF CONTENTS

|      |                                                                                                                                                                                                                                                                                                    |    |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| I.   | Introduction.....                                                                                                                                                                                                                                                                                  | 1  |
| II.  | Background.....                                                                                                                                                                                                                                                                                    | 1  |
|      | A. Background of the Claimed Inventions.....                                                                                                                                                                                                                                                       | 1  |
| III. | Claim Construction.....                                                                                                                                                                                                                                                                            | 4  |
|      | A. Person of Ordinary Skill in the Art .....                                                                                                                                                                                                                                                       | 4  |
|      | B. Legal Standards .....                                                                                                                                                                                                                                                                           | 5  |
|      | 1. “First Aperture at a Terminal End”.....                                                                                                                                                                                                                                                         | 9  |
|      | 2. “Bore” .....                                                                                                                                                                                                                                                                                    | 14 |
| IV.  | Petitioner Has Not Met Its Burden To Show That The Claims Of The<br>’166 Patent Are Unpatentable.....                                                                                                                                                                                              | 18 |
|      | A. Petitioner Fails to Show that Any of the Challenged Claims are<br>Anticipated by Cognet or Obvious in View of Cognet and a<br>Secondary Reference.....                                                                                                                                          | 20 |
|      | 1. Invalidity Grounds 1-3 Fail Entirely Because Petitioner<br>Has Not Shown That Cognet Discloses a First Bore<br>Extending From the First Aperture to a Second Aperture<br>on the Exterior Surface of the Third Member, as Recited<br>in the Challenged Claims .....                              | 20 |
|      | 2. Petitioner Further Fails to Show Claims 3 and 7 are<br>Anticipated by Cognet (Invalidity Ground 1) Because<br>Petitioner Fails to Show Cognet Discloses the Exterior<br>Surface of a Head Portion of a First Member Abuts the<br>Interior Surface of the First Bore at the First Aperture ..... | 26 |
|      | 3. Petitioner Fails To Show Claim 4 is Anticipated by<br>Cognet (Invalidity Ground 1) Because Petitioner Fails to<br>Show Cognet Discloses That the Head Portion of the<br>First Member Comprises a Torque Transmitting Aperture .....                                                             | 34 |
|      | 4. Petitioner Fails To Show Claim 9 is Anticipated by<br>Cognet (Invalidity Ground 1) Because Petitioner Fails to<br>Show Cognet Discloses the First Bore Axis and the<br>Second Bore Axis Intersect Outside the Third Member.....                                                                 | 36 |

|    |                                                                                                                                                                                                                          |    |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| 5. | Petitioner Fails to Show Any Challenged Claims are Obvious In View of Cognet and Either Brumfield or Ferrante .....                                                                                                      | 39 |
| B. | Petitioner Fails to Show that Any of the Challenged Claims are Anticipated by Simon or Obvious in View of Simon and a Secondary Reference.....                                                                           | 51 |
| 1. | Invalidity Grounds 4-7 Fail Entirely Because Petitioner Has Not Shown That Simon Discloses a First Member Having a Head Portion as Recited in the Challenged Claims .....                                                | 51 |
| 2. | Invalidity Grounds 4-7 Fail Entirely Because Petitioner Has Not Shown That Simon Discloses a First Aperture at a Terminal End of the First End of the Third Elongated Body as Recited in the Challenged Claims.....      | 55 |
| 3. | Petitioner Fails To Show Claim 4 is Anticipated by Simon (Invalidity Ground 1) Because Petitioner Fails to Show Simon Discloses That the Head Portion of the First Member Comprises a Torque Transmitting Aperture ..... | 64 |
| 4. | Petitioner Fails To Show Claims 10 and 11 are Anticipated by Simon (Invalidity Ground 1) Because Petitioner Fails to Show Simon Discloses a Self-Tapping Edge.....                                                       | 65 |
| 5. | Petitioner Fails to Show Any Challenged Claims are Obvious In View of Simon and Either Ferrante, Cognet, or Leu .....                                                                                                    | 66 |
| V. | Conclusion .....                                                                                                                                                                                                         | 70 |

**TABLE OF AUTHORITIES**

|                                                                                                                                                     | <b>Page(s)</b> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <b>Cases</b>                                                                                                                                        |                |
| <i>ActiveVideo Networks, Inc. v. Verizon Communs., Inc.</i> ,<br>694 F.3d 1312 (Fed. Cir. 2012) .....                                               | 47             |
| <i>Ashland Oil, Inc. v. Delta Resins &amp; Refractories, Inc.</i> ,<br>776 F.2d 281 (Fed. Cir. 1985) .....                                          | 61             |
| <i>Best Med. Int'l, Inc. v. Elekta Inc.</i> ,<br>46 F.4th 1346 (Fed. Cir. 2022) .....                                                               | 5              |
| <i>Cioffi v. Google, Inc.</i> ,<br>632 F. App'x 1013 (Fed. Cir. 2015) .....                                                                         | 8              |
| <i>E.I. du Pont de Nemours &amp; Co. v. Unifrax I LLC</i> ,<br>921 F.3d 1060 (Fed. Cir. 2019) .....                                                 | 7              |
| <i>Ericsson, Inc. v. D-Link Sys., Inc.</i> ,<br>773 F.3d 1201 (Fed. Cir. 2014) .....                                                                | 6              |
| <i>Graham v. John Deere Co.</i> ,<br>383 U.S. 1 (1966) .....                                                                                        | 19             |
| <i>K-Fee Sys. GmbH v. Nespresso USA, Inc.</i> ,<br>89 F.4th 915 (Fed. Cir. 2023) .....                                                              | 8              |
| <i>KSR Int'l Co. v. Teleflex Inc.</i> ,<br>550 U.S. 398 (2007) .....                                                                                | 19             |
| <i>Nite Glow Indus. v. Cent. Garden &amp; Pet Co.</i> ,<br>Nos. 2020-1897, 2020-1983, 2021 U.S. App. LEXIS 20791 (Fed.<br>Cir. July 14, 2021) ..... | 9              |
| <i>P&amp;G v. Teva Pharm. USA, Inc.</i> ,<br>566 F.3d 989 (Fed. Cir. 2009) .....                                                                    | 20             |
| <i>Personal Web Techs., LLC v. Apple, Inc.</i> ,<br>848 F.3d 987 (Fed. Cir. 2017) .....                                                             | 20             |

|                                                                                                                                       |                |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <i>Phillips v. AWH Corp.</i> ,<br>415 F.3d 1303 (Fed. Cir. 2005) .....                                                                | 6, 7           |
| <i>SimpleAir, Inc. v. Sony Ericsson Mobile Communs. AB</i> ,<br>820 F.3d 419 (Fed. Cir. 2016) .....                                   | 56             |
| <i>Speedtrack, Inc. v. Amazon</i> ,<br>998 F.3d 1373 (Fed. Cir. 2021) .....                                                           | 9              |
| <i>Thorner v. Sony Comput. Entm't Am. LLC</i> ,<br>669 F.3d 1362 (Fed. Cir. 2012) .....                                               | 8              |
| <i>Tippmann Eng'g, LLC v. Innovative Refrigeration Sys.</i> ,<br>No. 2022-1318, 2023 U.S. App. LEXIS 5 (Fed. Cir. Jan. 3, 2023) ..... | 8              |
| <i>Trintec Indus., Inc. v. Top-U.S.A. Corp.</i> ,<br>295 F.3d 1292 (Fed. Cir. 2002) .....                                             | 19, 35, 64, 65 |
| <i>Verdegaal Bros. v. Union Oil Co. of California</i> ,<br>814 F.2d 628 (Fed. Cir. 1987) .....                                        | 19             |
| <i>Wang Labs., Inc. v. Am. Online, Inc.</i> ,<br>197 F.3d 1377 (Fed. Cir. 1999) .....                                                 | 7              |

## **Statutes**

|                            |   |
|----------------------------|---|
| 35 U.S.C. § 282(b) .....   | 6 |
| 35 U.S.C. § 316(a)(8)..... | 1 |

## **Other Authorities**

|                                                    |          |
|----------------------------------------------------|----------|
| 37 C.F.R. 42.100(b) .....                          | 4, 6, 13 |
| 37 C.F.R. § 1.75 .....                             | 25       |
| 37 C.F.R. § 42.6(e)(4), I.....                     | 72       |
| 37 C.F.R. §§ 42.24(a)(1)(i), (b)(1), and (d) ..... | 71       |
| 37 C.F.R. § 42.65(a).....                          | 61       |
| 37 C.F.R. § 42.120 .....                           | 1        |

**TABLE OF EXHIBITS**

| <b>Exhibit No.</b> | <b>Exhibit Description</b>                                                                                                                                 |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 <a href="http://www.docketnavigator.com">www.docketnavigator.com</a>                                                                         |
| 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                                                                                                                           |

| <b>Exhibit No.</b> | <b>Exhibit Description</b>                                                                                                                                 |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 Extremity Medical, LLC vs. Fusion Orthopedics, LLC, 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<br><a href="https://www.machinistguides.com/counterbores-all-about/">https://www.machinistguides.com/counterbores-all-about/</a> |
| 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                                                                                             |

## **I. INTRODUCTION**

Pursuant to 35 U.S.C. § 316(a)(8) and 37 C.F.R. § 42.120, Patent Owner Extremity Medical, LLC submits this Response to the Petition for *Inter Partes* Review (“IPR”) of U.S. Patent No. 11,298,166 (“the ’166 Patent”), which demonstrates, at least for the reasons set forth herein, that Petitioner has not met its evidentiary burden to show Claims 1-15 of the ’166 Patent (the “Challenged Claims”) are unpatentable. Accordingly, Patent Owner respectfully requests that the Board issue a final written decision finding Petitioner has not shown Claims 1-15 of the ’166 Patent to be unpatentable.

## **II. BACKGROUND**

### **A. BACKGROUND OF THE CLAIMED INVENTIONS**

28. The ’166 Patent, titled “Intraosseous Intramedullary Fixation Assembly and Method of Use,” issued on April 12, 2022. Ex. 1001, cover. The ’166 Patent discloses, *inter alia*, bone fixation systems comprising intramedullary fixation assemblies for treating and fixating deteriorated, damaged and/or fractured bones, such as bones in the human foot. “Intramedullary” assemblies are assemblies that may be implanted into the marrow space of a bone. Ex. 2012, ¶ 35.

The assemblies disclosed in the ’166 Patent may be used, for example, to fuse bones in a human hand or foot. The ’166 Patent specifically notes the utility of the disclosed inventions for those areas of the body. *See, e.g.*, Ex. 1001 at 1:25-

28, 10:61-63. Prior to the '166 Patent, devices used to correct bone fractures in the hand or foot commonly included a plate placed on the outer surface of the bones, and screws inserted through holes in the plate and into the bones to correct bone fractures in the hand or foot. The screws would hold the plate to the bones, and together with the plate, immobilize the bones while fractures healed. Because the plate remained on the outer surface of the bones, especially when used to correct fractures in the hands or feet, the plate could easily be felt through the skin, as there is very little soft tissue (e.g., muscle) between the bones and the skin. Ex. 2012, ¶ 36.

The '166 Patent provides a novel improvement over the prior practice for fixing fractures because the surgeon now has easy access to the fracture after the third member (1815) is implanted. Third member (1815) discloses an aperture (1835) at the terminal end of the top of the third member (1815). This disclosure results in a better fusion of joints without protrusion or with minimal protrusion of the assembly outside the bones. When the third member (1815) is implanted into the bone, the very top of the third member (1815) (i.e., the terminal end) is positioned at or below the surface of the bone, which allows the surgeon easy access to the terminal end of the third member (1815) to insert the first member (1805) through the aperture at the terminal end. Ex. 2012, ¶ 37.

As shown in Figure 18 of the '166 Patent, pasted below with specific reference numbers annotated in colored circles for emphasis, the '166 Patent discloses, *inter alia*, an intramedullary fixation assembly (1800) comprising a first member (1805), a second member (1810), and a third member (1815):

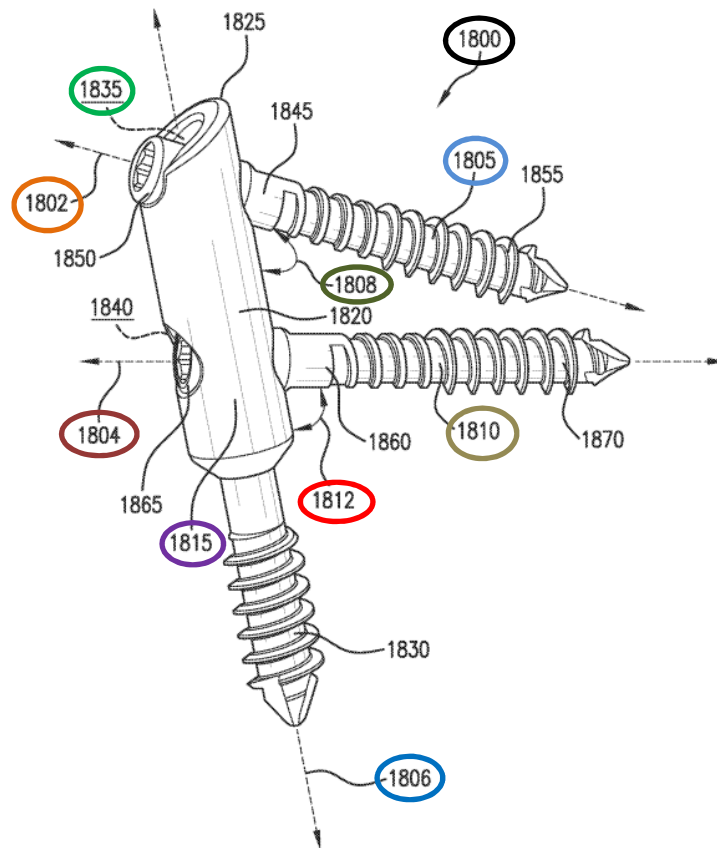


FIG. 18

Ex. 1001, FIG. 18. The third member (1815) extends along a straight line coinciding with axis (1806). An aperture (1835) at the terminal end of the top of the third member (1815) leads to a first bore extending along axis (1802), and a second bore extends through the third member (1815) along axis (1804). See Ex.

1001 at 13:22-14:17. The first member (1805) and the second member (1810) extend through the first and second bores at angles (1808) and (1812), respectively. Ex. 2012, ¶¶ 38-39.

### **III. CLAIM CONSTRUCTION**

In the Institution Decision, the Board identified two terms for construction: (1) “at a terminal end” and (2) “bore.” In light of the record discussed below, including a disclaimer made by Patent Owner during prosecution, the Board should construe the term “a first aperture at a terminal end” to exclude apertures that only pass through the sides of the shaft of the third elongated body.

For the term “bore,” the Board should adopt the construction proposed by Petitioner: “a cylindrical hole made by the spinning rotation of a twist drill cutting tool.” Alternatively, the Board should modify its preliminary construction to: “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.”

#### **A. PERSON OF ORDINARY SKILL IN THE ART**

Terms in a patent claim are construed in accordance with the ordinary and customary meaning of such claim as understood by a person of ordinary skill in the art (“POSITA”). *See, e.g.*, 37 C.F.R. 42.100(b). Factors pertinent to determining the characteristics of a hypothetical POSITA at the time of the claimed invention include the educational level of the inventor, the type of problems encountered in

the art, prior art solutions to those problems; the rapidity with which innovations are made, sophistication of the technology; and the educational level of active workers in the field. *See Best Med. Int'l, Inc. v. Elekta Inc.*, 46 F.4th 1346, 1353 (Fed. Cir. 2022).

Applying those factors here, a POSITA of the '166 Patent would hold a Bachelor's Degree in biomedical and/or mechanical engineering or similar training and would have at least three years of experience with implant devices used for internal fixation of bones. This hypothetical person would be capable of performing various design tasks and would understand the basic mechanical features and operation of orthopaedic implant devices. This hypothetical person would also have an appreciation for orthopaedic fusion techniques and the medical issues and concerns faced by a doctor/surgeon charged when performing operations to implant orthopaedic devices. Ex. 2012, ¶¶ 32-33. Petitioner posits a different standard, but the distinction between the parties' proposed definitions of a POSITA does not affect the arguments set forth herein. Ex. 2012, ¶ 34.

## **B. LEGAL STANDARDS**

A Patent Owner's Response to an IPR Petition may respond to any claim construction proposed by Petitioner and/or propose additional terms for construction. *See Consolidated Trial Practice Guide* (Nov. 2019) ("Consolidated

Practice Guide”)<sup>1</sup> at 44-45. In addition, “[i]f the Board raises a claim construction issue on its own, both parties will be afforded an opportunity to respond before a final written decision is issued.” *Id.*

Terms in a patent claim and terms in a substitute claim proposed in a motion to amend “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b). . . .” 37 C.F.R. 42.100(b). “This is the same claim construction standard used by Article III federal courts and the ITC, which follow *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc) and its progeny.” Consolidated Practice Guide at 46.

Claim construction “typically begins and ends with the intrinsic evidence” — the claims, the specification, and the prosecution history. *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1218 (Fed. Cir. 2014); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-17 (Fed. Cir. 2005) (en banc). The claim language provides substantial guidance as to the meaning of the terms, but the claims must be read in light of the specification, which usually is the single best guide to the meaning of a disputed term. *See Phillips*, 415 F.3d at 1315.

In addition to the language of the claims and the specification, the prosecution history—the complete record of the proceedings before the Patent

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<sup>1</sup> Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

Office—provides evidence of how the Patent Office and the inventor understood the patent. *See Phillips*, 415 F.3d at 1317. The record also includes statements made during prosecution of related parent applications. *See E.I. du Pont de Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1068-70 (Fed. Cir. 2019) (citations omitted); *Wang Labs., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1383-84 (Fed. Cir. 1999).

Extrinsic evidence, such as expert testimony and dictionaries, may also be considered. *See Phillips*, 415 F.3d at 1317. Expert testimony can provide background on the technology at issue, explain how an invention works, ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* at 1318. However, extrinsic evidence is viewed generally as less reliable than the intrinsic record and “unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19.

As a general rule, claim terms are given their plain-and-ordinary meaning as understood by a person of ordinary skill in the art. *See id.* at 1312-13. In some instances, the ordinary meaning to a person of skill in the art is clear, and claim construction may involve “little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314. But there are two

exceptions to the general rule: “1) when a patentee sets out a definition and acts as his own lexicographer,” or “2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

An applicant may act as their own lexicographer and rebut the presumption that claim terms are to be given their ordinary meaning. To act as its own lexicographer, “a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term.” *K-Fee Sys. GmbH v. Nespresso USA, Inc.*, 89 F.4th 915 (Fed. Cir. 2023) (internal quotations marks omitted).

Regarding disavowal, a disclaimer “attaches where an applicant, whether by amendment or by argument, unequivocally disavowed a certain meaning to obtain his patent.” *Cioffi v. Google, Inc.*, 632 F. App'x 1013, 1020 (Fed. Cir. 2015) (internal quotations and citation omitted). Although a disavowal must be clear, it need not be explicit, and “may be inferred from clear limiting descriptions of the invention in the specification or prosecution history.” *Tippmann Eng'g, LLC v. Innovative Refrigeration Sys.*, No. 2022-1318, 2023 U.S. App. LEXIS 5, at \*9 (Fed. Cir. Jan. 3, 2023) (citation omitted). Also, “[i]t is well established by Supreme Court cases that disclaimer can be determined from the applicant's amendment or cancellation of claims—not just from statements made by the

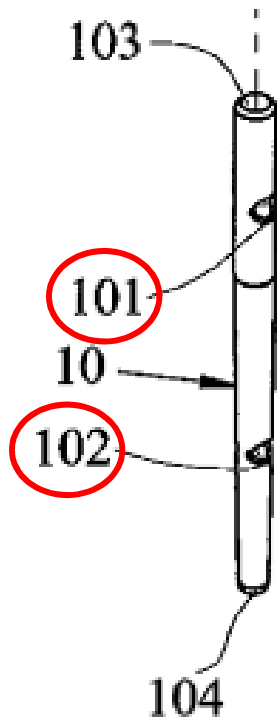
applicant.” *Nite Glow Indus. v. Cent. Garden & Pet Co.*, Nos. 2020-1897, 2020-1983, 2021 U.S. App. LEXIS 20791, at \*31 (Fed. Cir. July 14, 2021). “An applicant’s argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well.” *Speedtrack, Inc. v. Amazon*, 998 F.3d 1373, 1380 (Fed. Cir. 2021).

**1. “First Aperture at a Terminal End”**

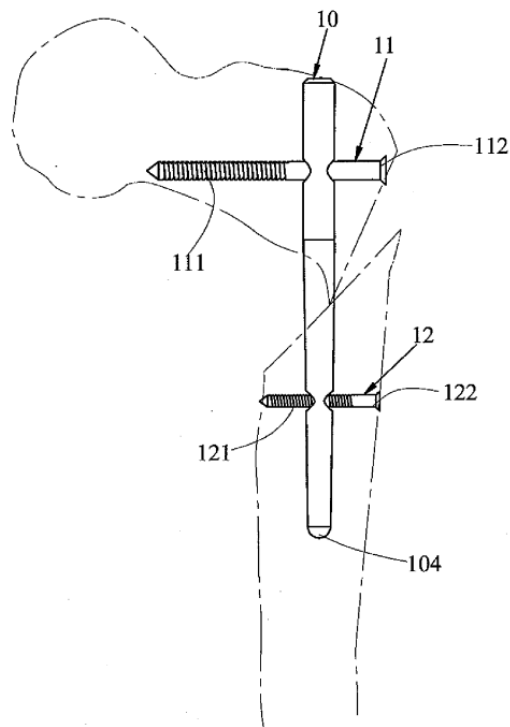
Claims 1 and 12 of the ’166 Patent recite a third elongated body extending from “a first end to a second end” and “a first aperture at a terminal end of the first end.” Ex. 1001 at 14:62, 15:11-15, 16:7, 16:24-29. The term “a first aperture at a terminal end” must be construed as excluding apertures that are merely along the shaft for based on three irrefutable pieces of evidence.

During prosecution of a related parent application to the ’166 Patent, Patent Owner made a disclaimer that excludes apertures that are merely along the shaft of the third member from the term “a first aperture at a terminal end.” Specifically, U.S. Patent Application No. 12/658,680 (the “’680 Application”), to which the ’166 Patent claims priority, included claims which recited an elongated body “having first and second ends,” and “a first aperture at a terminal end of the second end” of the elongated body. Ex. 1015 at 58 (Claim 1) and 10 (Claim 51). During prosecution of the ’680 Application, the Examiner cited U.S. Patent Publication

No. 2009/0240252 (“Chang”) as a prior art reference that disclosed the claimed inventions. *See* Ex. 1015 at 49-54 (citing Chang). A portion of Figure 2 and Figure 5 from Chang are pasted below—Figure 2 depicts a nail (10) having through holes (101) and (102), and Figure 5 depicts nail (10) as implanted in a bone, with screws in the through holes:



Chang FIG. 2



Chang FIG. 5

Ex. 2014, FIG. 5. To distinguish the claimed invention over Chang, Patent Owner disclaimed apertures (i.e., “through holes”) along the shaft of the nail as *not* apertures at the terminal end of a nail:

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 at 75-76 (emphasis added). Since Patent Owner distinguished the claims over Chang by arguing that Chang's apertures were not "at the terminal end" of the nail, a POSITA would understand that Patent Owner explicitly disclaimed apertures that are near—such as along the shaft—but not *at* the terminal end of the third member to be outside the scope of the '166 Patent's claims. Ex. 2012, ¶ 40. In other words, in the context of Chang's disclosure, a POSITA would understand Patent Owner disclaimed apertures that only pass through the sides of the shaft indicated with red lines below:

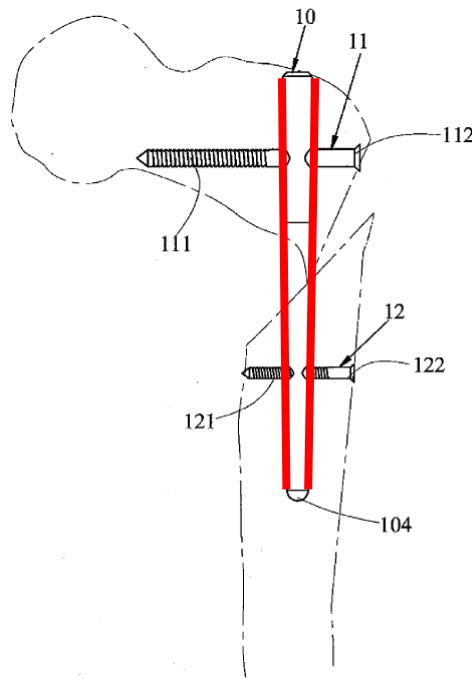


FIG. 5

Ex. 2014, FIG. 5 (annotations added). Since the apertures disclosed in Chang only pass through the shaft of the nail, they are not apertures at a terminal end. *See* Ex. 2012, ¶ 40.

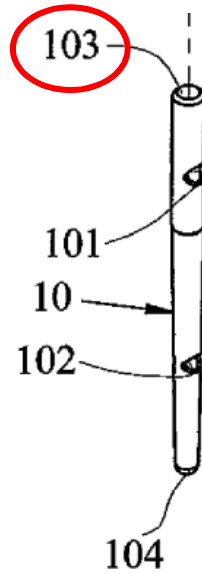
Accordingly, a POSITA would understand that the term “a first aperture at a terminal end” as recited in the claims of the '166 Patent means an aperture that would at least in part pass through the top surface of the third member. Ex. 2012, ¶ 40. And, in fact, the district court has already considered the disclaimer discussed above and decided this issue in Patent Owner's favor in the related litigation (*Extremity Medical, LLC vs. Fusion Orthopedics, LLC*, Case No. 2:22-cv-00723-PHX-GMS (D. Ariz.)), finding that “a POSITA would understand that

the '166 Patent's 'terminal end' is the open end of the third member's hollow base." Ex. 2015 at 15; *see also* 37 C.F.R. 42.100(b) ("Any prior claim construction determination concerning a term of the claim in a civil action . . . that is timely made of record in the inter partes review proceeding will be considered.")

The testimony of Petitioner's expert Mr. Dominguez supports Patent Owner's position twice. In his declaration for this proceeding, he states that "[a] POSA would understand 'terminal end' to refer to the end of the third elongated member that aligns closely with the top surface of the bone or slightly below the surface of bone." Ex. 1002, ¶ 53. Also, during claim construction in the related district court litigation, Mr. Dominguez confirmed that the "terminal end" is located at the very top of a nail when discussing Chang's Figure 2:

The way that I interpret Figure 2 in Chang is that *if you look at the bullet 103* . . . [t]hat'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 at 193:6-22; *see also id.* at 194:12-22.



Ex. 2014, FIG. 2 (annotated).

In view of Patent Owner's disclaimer during prosecution of the '680 Application, the District Court's Order in the related litigation, and the testimony of Petitioner's expert, the term "a first aperture at a terminal end" should be construed to exclude apertures that only pass through the sides of the shaft of the third elongated body. *See* Ex. 2012, ¶ 40.

## 2. "Bore"

Claims 1 and 12 each require "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 at 15:11-18, 16:24-31. Petitioner's expert unequivocally states that "[a] bore *is* a cylindrical hole made by the spinning rotation of a twist drill cutting tool." Exhibit 1002, ¶ 58 (emphasis added). At his deposition for this

proceeding, he confirmed the statement in his declaration, that “a bore *is* a cylindrical hole made by the spinning rotation of a twist drill cutting tool.” Ex. 2013 at 141:21-142:3. Under the construction of Petitioner's own expert, as discussed further below, the “tunnel” Petitioner identifies in Cognet as a “bore” in fact constitutes two bores, neither of which meets the requirement in the claims of a bore extending from a first aperture at the terminal end of the third member to an aperture on an exterior surface of the third member.

In the Institution Decision, the Board ignored the Petitioner's definition, “preliminarily constru[ing] the term ‘bore’ as a hole or passage made by or as if by the turning or twisting movement of a tool such that its interior walls have cylindrical lateral cross-sections, and which do not exclude holes or passages having tapered or stepped longitudinal cross-sections.” Paper 15 at 13. However, the Board's preliminary construction is unsupported by the record., First, it contradicts the construction proposed by Petitioner's expert, a construction that Patent Owner does not challenge.

Second, the Board's preliminary construction is inconsistent with the way the term “bore” is used in the field of the invention. A POSITA would understand that the term “bore,” whether tapered or not, does not include two sections of a hole separated by a ledge or “stepped longitudinal cross-sections,” as recited in the Board's preliminary construction. *See* Paper 15 at 13; Ex. 2012, ¶ 41. For

example, U.S. Patent No. 10,357,299, titled “Bone Joining Apparatus and Method” discloses that a “reamer prepares *a hole with a widened bore near the top* to accommodate the top 22 of the female component, e.g., as illustrated in FIG. 25C.” Ex. 2017 at 15:1-7. Figure 25C is depicted below with element 113—not the entire hole having stepped longitudinal cross-sections—identified as the “widened bore”:

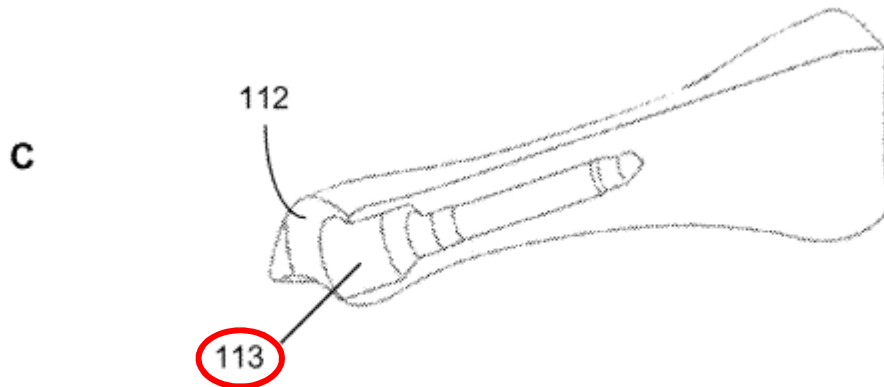


**FIG. 25**

*Id.*, FIG. 25C (annotation added); Ex. 2012, ¶ 41.

Petitioner cites to statements made during the prosecution history of U.S. Patent Application No. 12/906,454 (“the ’454 Application”) as evidence that a hole like the tunnel disclosed in Cognet constitutes a bore. But those statements are not controlling here because Petitioner ignores the important context in which those statement were made. That context shows that those statements have no evidentiary significance in this matter. Although both the ’166 Patent and the ’454 Application claim priority to an ultimate parent application, the ’166 Patent does

not claim priority to the '454 Application. *See* Ex. 1001 at 1. In addition, new matter was added to the '454 Application, a continuation-in-part application. The new matter included the following passage, *not found in the '166 Patent*, which defines the term “bore”:

Also, head portion 2205 has ***a central aperture or bore 2230*** that is aligned along axis 2235, with central aperture 2230 forming an acute angle 2265 with longitudinal axis 2215 (i.e., central aperture 2230 extends from a first surface 2275 (FIG. 22B) to opposed surface 2280 (FIG. 22B) along axis 2235). The ***central aperture 2230 is formed from a plurality of apertures*** formed on the internal surface of the head portion 2205. Particularly, ***internal surface 2240 has a spherical radius*** that defines a first aperture within the central aperture 2230 while ***internal surface 2245 has a second radius that defines a second aperture 2230 within central aperture 2230.***

Ex. 1016 at 30-31. As indicated above, the terms “central aperture or bore” were defined in the '454 Application as formed from a plurality of apertures. Such lexicography does not apply to the '166 Patent because it is not included in the '166 Patent specification. Therefore, Petitioner's citation to a discussion of a “bore” during prosecution of the '454 Application is not dispositive for construction of the term “bore” for the '166 Patent.

Instead, the Board should adopt a construction of the term “bore” as proposed by Petitioner and for which both parties agree: “a cylindrical hole made

by the spinning rotation of a twist drill cutting tool.” *See* Ex. 2012, ¶ 42.

Alternatively, the Board should modify its preliminary construction to, “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,” to account for the way the term “bore” has been used by POSITAs as indicated by the patents cited above.

#### **IV. PETITIONER HAS NOT MET ITS BURDEN TO SHOW THAT THE CLAIMS OF THE '166 PATENT ARE UNPATENTABLE**

Petitioner asserts seven grounds of invalidity—three based on Cognet, and four based on Simon:

| <b>References</b>                    | <b>Basis</b> | <b>Claims Challenged</b>    |
|--------------------------------------|--------------|-----------------------------|
| [1.] Cognet (Ex. 1004)               | 102(a), (b)  | 1-7, 9, 12, and 13          |
| [2.] Cognet and Brumfield (Ex. 1006) | 103          | 4, 8, 10, and 14-15         |
| [3.] Cognet and Ferrante (Ex. 1007)  | 103          | 11                          |
| [4.] Simon (Ex. 1008)                | 102(a), (b)  | 1, 4-5, 8, 10-12, and 14-15 |
| [5.] Simon and Ferrante              | 103          | 4, 8, 10-11, and 14-15      |
| [6.] Simon and Cognet                | 103          | 9                           |
| [7.] Simon and Leu (Ex. 1009)        | 103          | 2-3, 6-7, and 13            |

Paper 1 at 6.

In an IPR, “the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic*, 815 F.3d at

1363 (citing 35 U.S.C. § 312(a)(3) (requiring inter partes review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). First, to show that a claim is anticipated, the petitioner must show a single prior art reference “expressly or inherently describes each and every limitation set forth in the patent claim.” *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002); *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Second, to show a claim is invalid as obvious, the petitioner must show that “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (citing 35 U.S.C. § 103). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Also, a party seeking to invalidate a patent based on obviousness must demonstrate “that a skilled artisan would have been motivated to combine the

teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.”

*P&G v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009). A rationale to combine should “imply a motivation to pick out those two references and combine them to arrive at the claimed invention.” *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993–94 (Fed. Cir. 2017).

Because Petitioner fails to show that any of the cited references, alone or in combination, render the Challenged Claims unpatentable, the Board should find that Petitioner has not met its burden for any of its seven invalidity grounds.

**A. PETITIONER FAILS TO SHOW THAT ANY OF THE CHALLENGED CLAIMS ARE ANTICIPATED BY COGNET OR OBVIOUS IN VIEW OF COGNET AND A SECONDARY REFERENCE**

**1. Invalidity Grounds 1-3 Fail Entirely Because Petitioner Has Not Shown That Cognet Discloses a First Bore Extending From the First Aperture to a Second Aperture on the Exterior Surface of the Third Member, as Recited in the Challenged Claims**

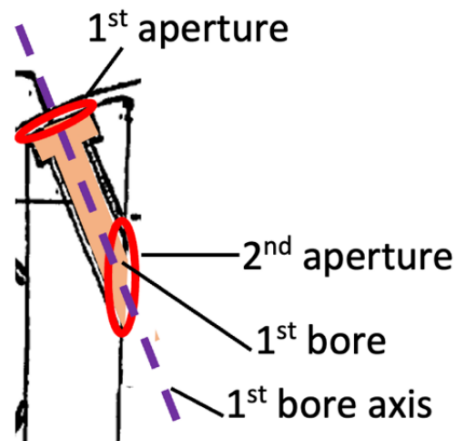
The two independent claims of the '166 Patent, Claims 1 and 12, as well as all of the dependent claims by virtue of their dependency from the independent claims, require a first bore that extends along a specific path and ends in a specific location. Both recite:

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. . . .

Ex. 1001 at 15:11-18, 16:24-31(emphasis added).

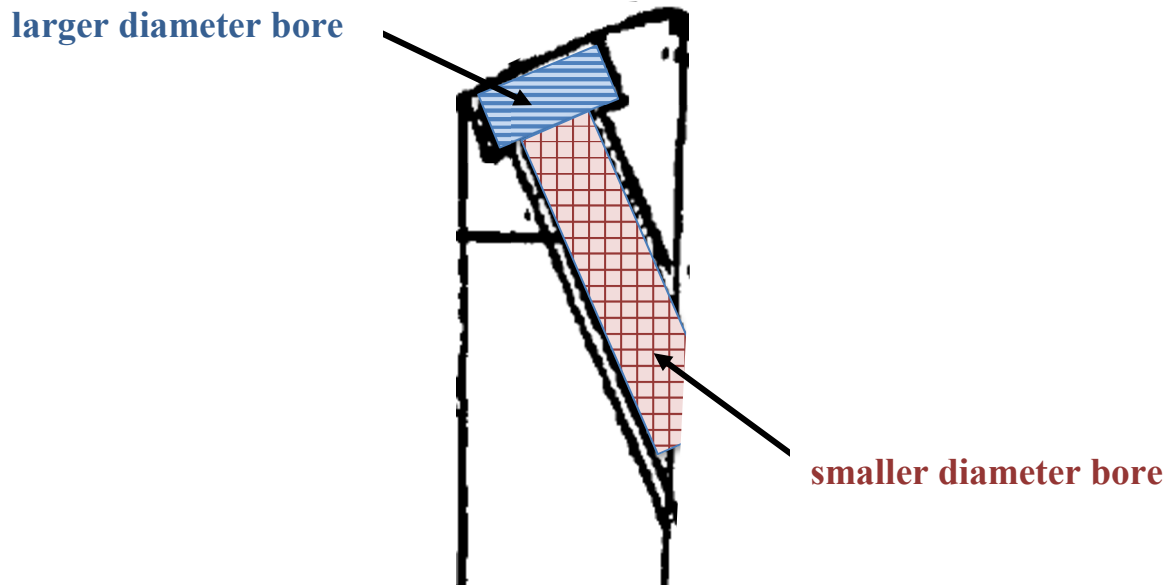
Such a bore cannot be found in Cognet. The tunnel Petitioner identifies as the “first bore” in Cognet is, in fact, created by *two* bores: a larger diameter bore intended to receive the head of a screw, and a smaller diameter bore intended to receive the shaft of the screw. *See* Ex. 2012, ¶ 45. Petitioner’s expert testified during his deposition that the tunnel identified by Petitioner is indicated by the orange-shaded region in this annotated Figure 1 from Cognet:



Ex. 2013 at 77:3-78:22; Paper 1 at 17; *see also* Paper 1 at 15-17, 29-30; Ex. 1002, ¶ 59. The figure above also denotes the “first aperture” and “second aperture” as identified by Petitioner, with the tunnel extending there between.

The orange-shaded region, however, does not show a single “first” bore; it shows two bores, i.e., a top cylindrical bore with a larger diameter (the top of the

“T”) (shown in blue in the figure below) and a second smaller diameter bore (the body of the “T”) (shown in pink grid in the figure below).

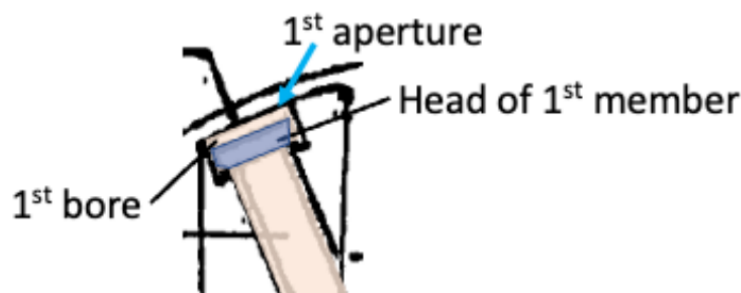


See Ex. 2012, ¶ 46. As discussed above (see Section III(B)(2)), a “bore” should be construed as “a cylindrical hole or passage made by or as if by the turning or twisting movement of a tool, not excluding holes or passages having tapered cross-sections.” See also Ex. 1002, ¶ 58 (“[a] bore is a cylindrical hole. . . .”); Ex. 2012, ¶ 47.

The top bore in Cognet may also be referred to as a “counterbore.” Ex. 2012, ¶ 48. A counterbore “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. 2018; see also *id.*

The two-bore construct of Cognet is significant here because all of the Challenged Claims require a single, “first” bore that extends *all the way along a first bore axis* from a very specific location to another specific location: (1) from the first aperture at a terminal end of the first end to (2) a second aperture on an exterior surface of the third member. Ex. 1001 at 15:11-18, 16:24-31. But in Cognet, to get from the first aperture at the top of the “T” to the aperture at the bottom of the “T” (the only other aperture at the exterior surface), you must pass through *two* bores – the larger diameter bore that represents the top portion of the “T” and the smaller diameter bore that represents the body portion of the “T”. See Ex. 2012, ¶ 49.

Even the Petition correctly acknowledges this two-bore construct in its discussion of Claims 2 and 3. See Paper 1 at 23-24. When discussing Claim 2, Petitioner alleges that “the head portion of the first member resides at least partially within *the first bore*,” and presents the following annotated figure showing the head portion of Cognet’s screw in the top, first bore:



Paper 1 at 24. Then, when discussing Claim 3, Petitioner states that the head of the screw (located in the top, first bore) has a larger diameter than *the bottom bore*, although Petitioner then incorrectly refers to the bottom bore as both the “first bore” which it is not, and the “smaller diameter tunnel,” which it is:

Cognet discloses that the head of the screw (first member) ***has a larger diameter than the diameter than [sic] the tunnel*** (first bore) which makes it possible for the head to butt up against ***the smaller diameter tunnel*** to stop the progression of the screw and obtain a compression effect at the fracture site (Ex. 1004, 62-65). Ex. 1002, ¶ 75. Figure 1 of Cognet shows the exterior surface of the head portion of the first member abutting the interior surface of the first bore at the first aperture, thus disclosing this claim limitation.

Paper 1 at 24 (citing Ex. 1002 ¶ 75) (emphasis added). Petitioner's identification of the “*smaller diameter tunnel*” logically implies the existence of a “*larger diameter tunnel*.” Thus, Petitioner's description of Cognet confirms that a POSITA would understand Cognet has two bores—the larger diameter tunnel and the smaller diameter tunnel. Accordingly, Cognet does not constitute invalidating prior art. *See* Ex. 2012, ¶ 51.

Patent Owner sought to cross-examine Mr. Dominguez about his opinions regarding the alleged “first bore” disclosed in Cognet, but he refused to provide straight answers. *See, e.g.*, Ex. 2013 at 81:3-83:10, 84:21-85:14. Mr. Dominguez

ultimately conceded, however, that Cognet discloses (1) a “smaller diameter bore,” and (2) a “larger diameter counterbore or countersink”:

I am saying that Cognet has a shoulder, he has a shoulder, that transitions from the smaller diameter bore into a larger diameter counterbore or countersink at the first aperture.

Ex. 2013 at 87:17-24 (emphasis added).<sup>2</sup>

Consistent with the construction of the term “bore” as “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”—or really any construction in view of Petitioner’s concession that Cognet’s tunnel consists of two bores (i.e., a smaller diameter bore and a larger diameter bore)—Petitioner fails to show Cognet discloses a “first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member,” which is a limitation recited in independent Claims 1 and 12, and in every dependent claim

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<sup>2</sup> Although Mr. Dominguez refers to both a “counterbore” and a “countersink,” a POSITA would understand a “counterbore” to be a cylindrical hole (i.e., a bore) and a “countersink” to be a tapered hole. *See* Ex. 2012, ¶ 51. Mr. Dominguez generally agrees. *See, e.g.,* Ex. 2013 at 87:4-8; 87:9-16; 90:5-6. When asked on cross-examination whether the identified “countersink or counterbore” portion of Cognet’s tunnel is tapered, Mr. Dominguez did not answer. *See id.* at 103:1-105:4.

by virtue of their dependency from the independent claims. *See* Ex. 2021, ¶ 52; 37 C.F.R. § 1.75.

For Invalidity Grounds 1 – 3, Petitioner relies solely on Cognet, asserting that all of the elements of Claims 1 and 12 are literally disclosed in Cognet. Petitioner does not allege that the elements of Claims 1 and 12 are disclosed in the secondary references (i.e., Brumfield, Ferrante, or Leu), or that those elements would have been obvious in view of Cognet. Because Cognet does not disclose *a first bore extending along a first bore axis* from (1) a first aperture to (2) a second aperture on an exterior surface of the third member, the Board should find that Petitioner has not met its burden to show by a preponderance of the evidence that any of the Challenged Claims are invalid in view of Cognet alone, or in view of Cognet and any other cited reference.

**2. Petitioner Further Fails to Show Claims 3 and 7 are Anticipated by Cognet (Invalidity Ground 1) Because Petitioner Fails to Show Cognet Discloses the Exterior Surface of a Head Portion of a First Member Abuts the Interior Surface of the First Bore at the First Aperture**

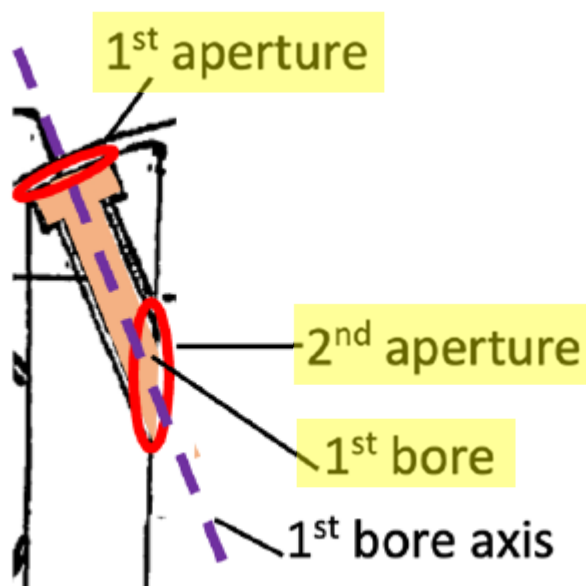
Claims 3 and 7 each recite, “wherein the exterior surface of the head portion of the first member *abuts the interior surface of the first bore at the first*

*aperture.*”<sup>3</sup> Ex. 1001 at 15:48-50, 15:58-60. (emphasis added). Petitioner alleges that this limitation is disclosed in Cognet. However, the exterior surface of the head portion in Cognet identified by Petitioner actually abuts *the shoulder* between the larger diameter bore and the smaller diameter bore; the head does not abut the interior surface of Cognet's tunnel—identified by Petitioner as the first bore—at the first aperture. See Ex. 2012, ¶ 53.

Petitioner identifies in the following annotated version of Cognet's Figure 1 where Cognet allegedly discloses (1) a first aperture, (2) a second aperture, and (3) a first bore:

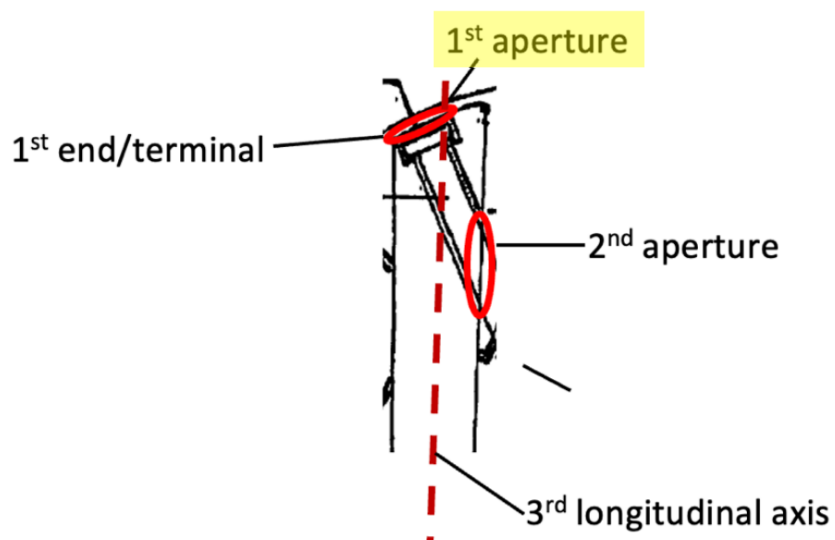
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<sup>3</sup> Claims 2 and 6, from which Claims 3 and 7 depend respectively, each recite, “the head portion of the first member resides at least partially within the first bore.” Ex. 1001 at 15:45-47, 15:55-57.

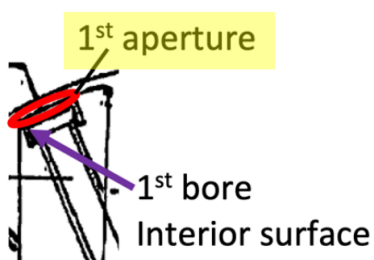


Paper 1 at 17 (citing Ex. 1002, ¶ 59) (highlighting added by Patent Owner).

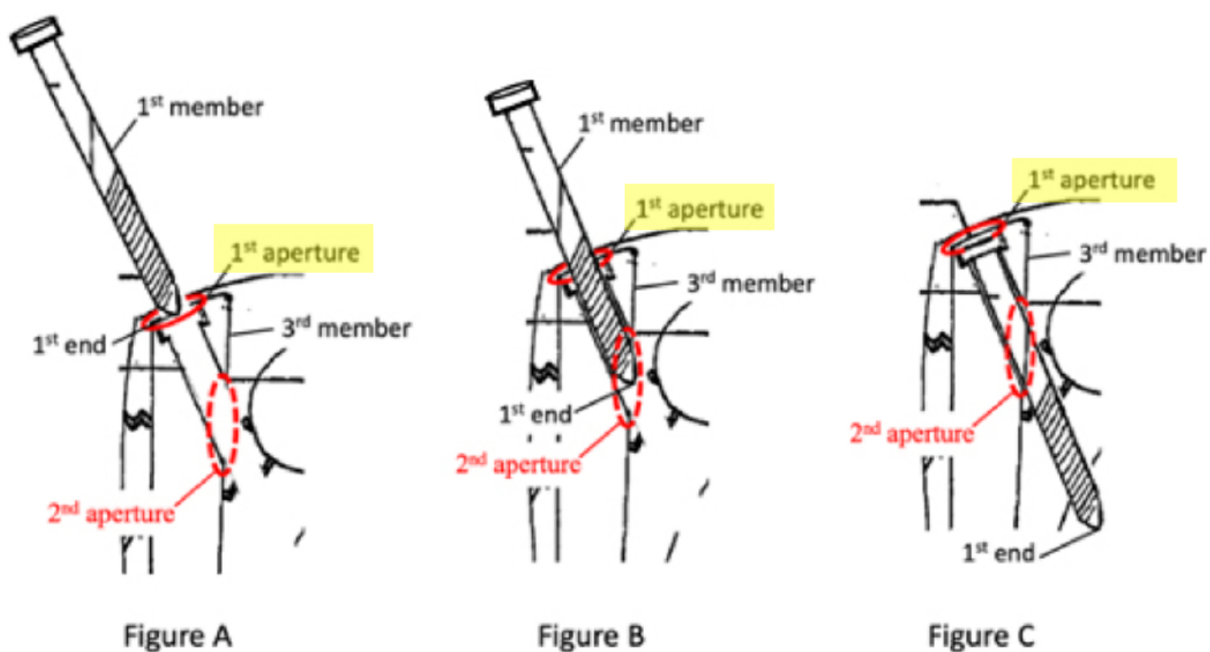
Consistent with the annotated figure above, Petitioner also repeatedly and consistently identifies the “first aperture” as the opening at the top of the larger diameter bore throughout the Petition:



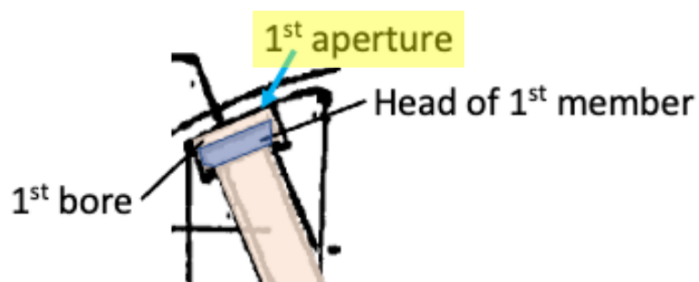
Paper 1 at 16 (citing Ex. 1002, ¶ 57) (highlighting added by Patent Owner);



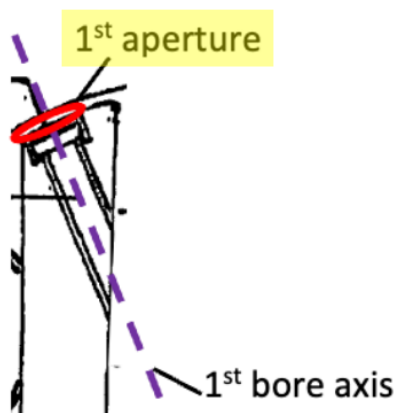
Paper 1 at 17 (citing Ex. 1002, ¶ 60) (highlighting added by Patent Owner);



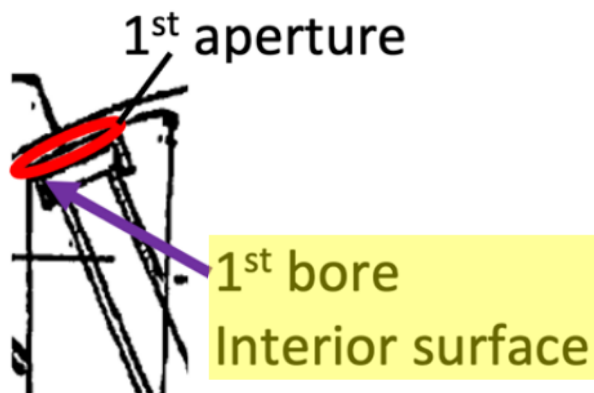
Paper 1 at 20-21 (citing Ex. 1002, ¶ 65) (highlighting added by Patent Owner);



Paper 1 at 24 (citing Ex. 1002 at ¶¶ 72-73) (highlighting added by Patent Owner);

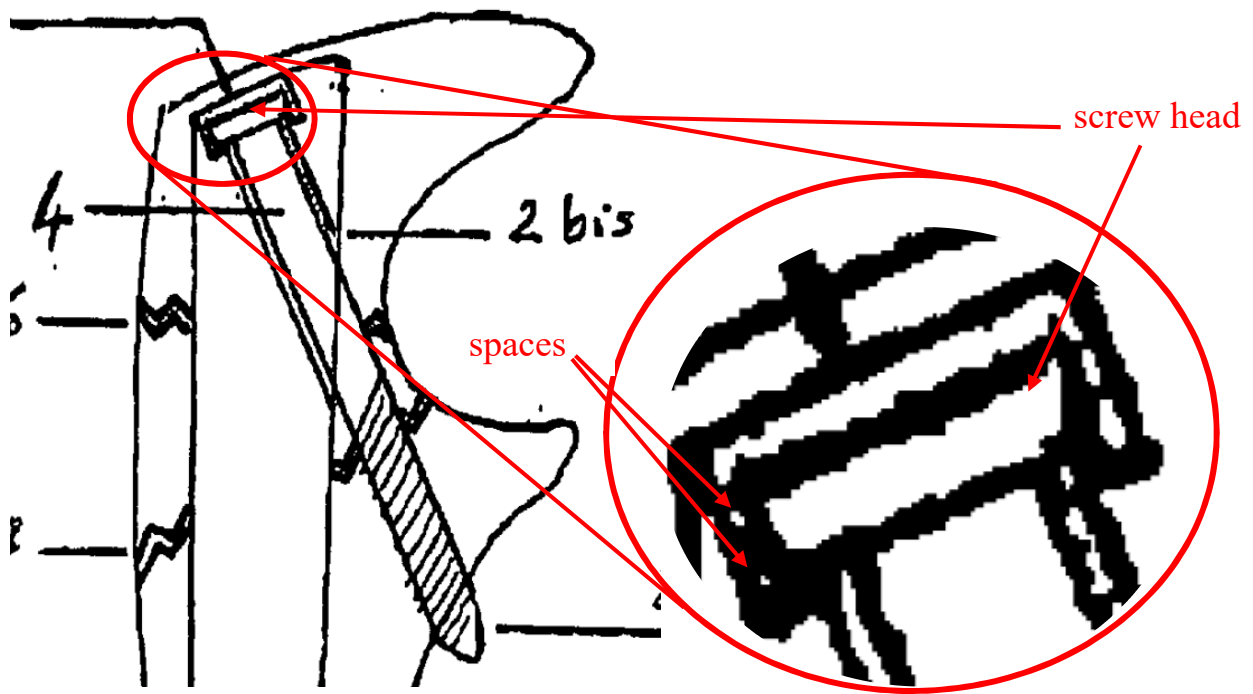


Paper 1 at 26 (citing Ex. 1002 at ¶¶ 77-78) (highlighting added by Patent Owner).  
Petitioner similarly identifies the location of the “interior surface at the first aperture” as adjacent to the opening to the T-shaped tunnel at the top of the third member:



Paper 1 at 17 (citing Ex. 1002 at ¶ 60) (highlighting added by Patent Owner). *See* Ex. 2012, ¶ 54.

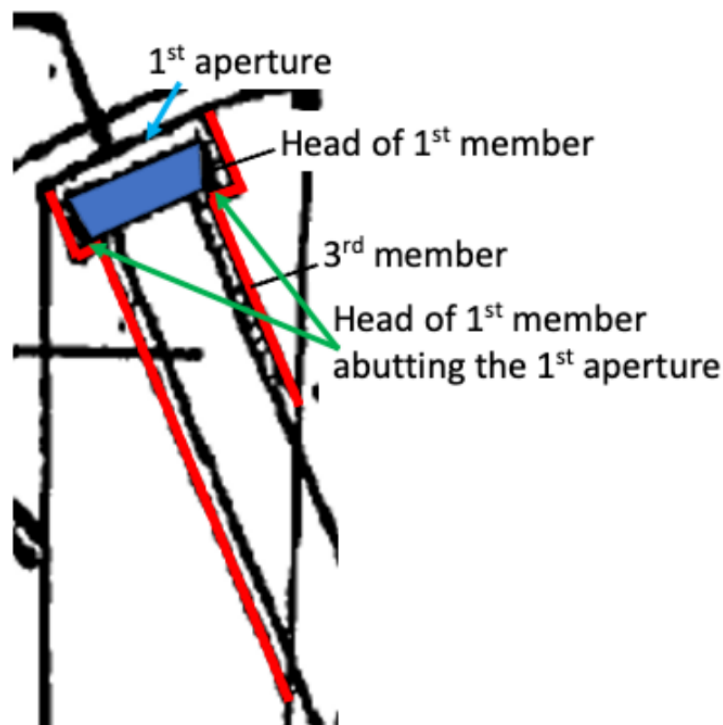
However, as shown by the white dots between the head of the screw and the wall of the large-diameter bore in Cognet's Figure 1, the head does not "abut the interior surface of the first bore at the first aperture":



Ex. 1003, Figure 1. The hand-drawn figures in Cognet are imprecise, but a POSITA would understand from Cognet's Figure 1 that the head of the screw does not abut the wall of the larger diameter bore, thereby allowing the head to rotate within the larger diameter bore without resistance from the wall. Accordingly, the head of the screw does not abut the interior surface of the first bore at the first aperture. *See* Ex. 2012, ¶ 55.

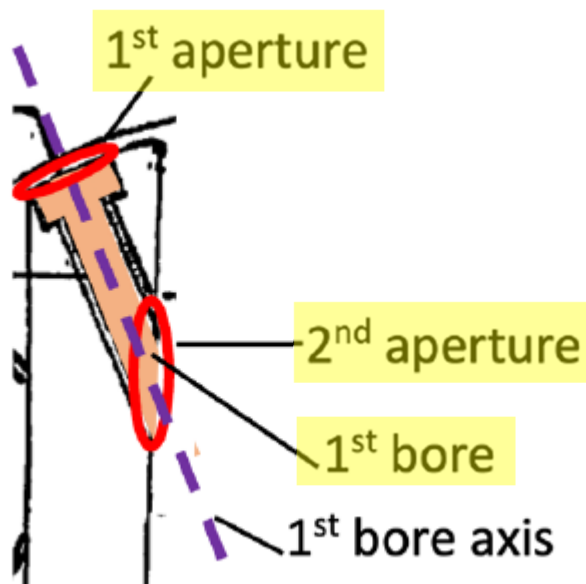
As a tacit admission that Cognet does not disclose "the head portion of the first member abut[ing] the interior surface of the first bore" at the location where

Petitioner has identified “the first aperture”, Petitioner changed its tune to try to make the disclosure in Cognet fit the limitations. As depicted in the figure below copied from the Petition, Petitioner identifies with green arrows the shoulder between the larger diameter bore and the smaller diameter bore as the location where the head of the first member abuts the first aperture:



Paper 1 at 25. At no other point does Petitioner identify the area designated by the green arrows as the “first aperture.” As discussed above, and as indicated in this figure, Petitioner identifies the first aperture as the opening at the top of the larger diameter bore. Petitioner’s identification of where the head of the screw abuts the first aperture is therefore inconsistent with Petitioner’s own position on the location of the first aperture. *See* Ex. 2012, ¶ 56.

Identifying the area designated by the green arrows as the first aperture is also inconsistent with Petitioner's arguments concerning the location of the "first bore." To support its argument that the first bore is Cognet's tunnel which, to meet Claims 1 and 12, must extend "from the first aperture to a second aperture," the first aperture and second aperture would need to be identified as indicated in the following figure annotated by Petitioner and highlighted by Patent Owner:



Paper 1 at 17 (citing Ex. 1002, ¶ 59) (highlighting added by Patent Owner).

Accordingly, the location in Cognet's tunnel identified by Petitioner as where "the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture," *i.e.*, where the larger diameter bore meets the smaller diameter bore, is not only a different location than where Petitioner has identified the "first aperture" (the opening at the top of the larger diameter bore),

but it also cannot be “at the first aperture” as required by Claims 3 and 7 if the bore is where Petitioner identifies it because the bore must extend from the first aperture to the second aperture. In contrast, the area identified by Petitioner is in the middle of the tunnel identified by Petitioner as the “first bore,” someplace between the “first aperture” and the “second aperture.” *See* Ex. 2012, ¶ 57.

Petitioner therefore has not met its burden to show by a preponderance of the evidence that Claims 3 and 7 are anticipated by Cognet. Nor does Petitioner allege that Claims 3 and 7 are obvious in view of Cognet or in view of Cognet in combination with any other reference. Accordingly, the Board should find that Petitioner has not met its burden to show by a preponderance of the evidence that Claims 3 and 7 are invalid. *See* Ex. 2012, ¶ 57.

**3. Petitioner Fails To Show Claim 4 is Anticipated by Cognet (Invalidity Ground 1) Because Petitioner Fails to Show Cognet Discloses That the Head Portion of the First Member Comprises a Torque Transmitting Aperture**

Claim 4 depends from Claim 3 and further recites, “the head portion of the first member comprises a torque transmitting aperture.” Petitioner does not allege that a torque transmitting aperture is disclosed in Cognet. Instead, Petitioner asserts, “*almost all screws* comprise a torque transmitting aperture. . . .” Paper 1 at 25 (citing Ex. 1002, ¶¶ 42b, 76) (emphasis added); Ex. 2012, ¶ 58. But “almost all” even if true, is not sufficient to find a torque transmitting aperture in Cognet.

There can be no credible dispute that a torque transmitting aperture is not expressly disclosed in Cognet.

For an element of the claimed invention to be inherently present in a prior art reference, the prior art reference must necessarily and always contain or produce that element; it is not sufficient if the element is possibly, or even probably, present in the prior art reference. *See, e.g., Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). If the teachings of the prior art may be practiced in a way that yields a product lacking the allegedly inherent property, the prior art in question does not inherently anticipate.

Here, there are alternative ways to transmit torque to a screw that do not involve a torque transmitting aperture, and in fact, Petitioner expressly acknowledges this by noting that not all screws comprise a torque transmitting aperture. For example, a hex lag screw does not include a torque transmitting aperture:

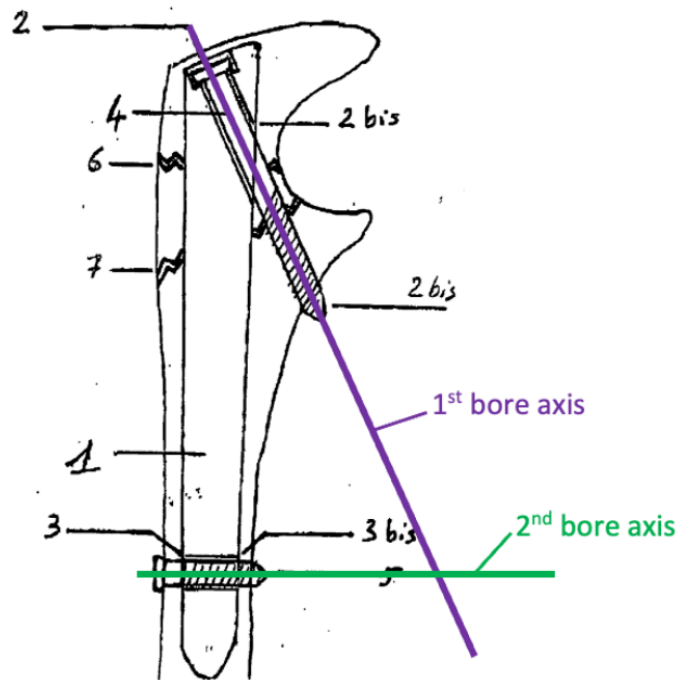


Ex. 2012, ¶ 59. Such a screw could be used as the “first member” identified by Petitioner in Cognet. The limitation of Claim 4, “the head portion of the first member compris[ing] a torque transmitting aperture” is therefore neither explicitly nor inherently disclosed by Cognet.

Petitioner has not met its burden to show by a preponderance of the evidence that Claim 4 is invalid in view of the disclosure in Cognet. Nor does Petitioner allege that Claim 4 is obvious in view of Cognet. Accordingly, the Board should find that Petitioner has not met its burden to show Claim 4 is invalid in view of Cognet. Petitioner also incorrectly alleges Claim 4 is obvious in view of Cognet and Brumfield, which is addressed below in Section IV(B)(5).

**4. Petitioner Fails To Show Claim 9 is Anticipated by Cognet (Invalidity Ground 1) Because Petitioner Fails to Show Cognet Discloses the First Bore Axis and the Second Bore Axis Intersect Outside the Third Member**

Claim 9 depends from Claim 1 and recites “the first bore axis and the second bore axis intersect outside the third member.” Petitioner cites the following annotated version of Cognet’s Figure 1 as evidence Cognet allegedly discloses that limitation:



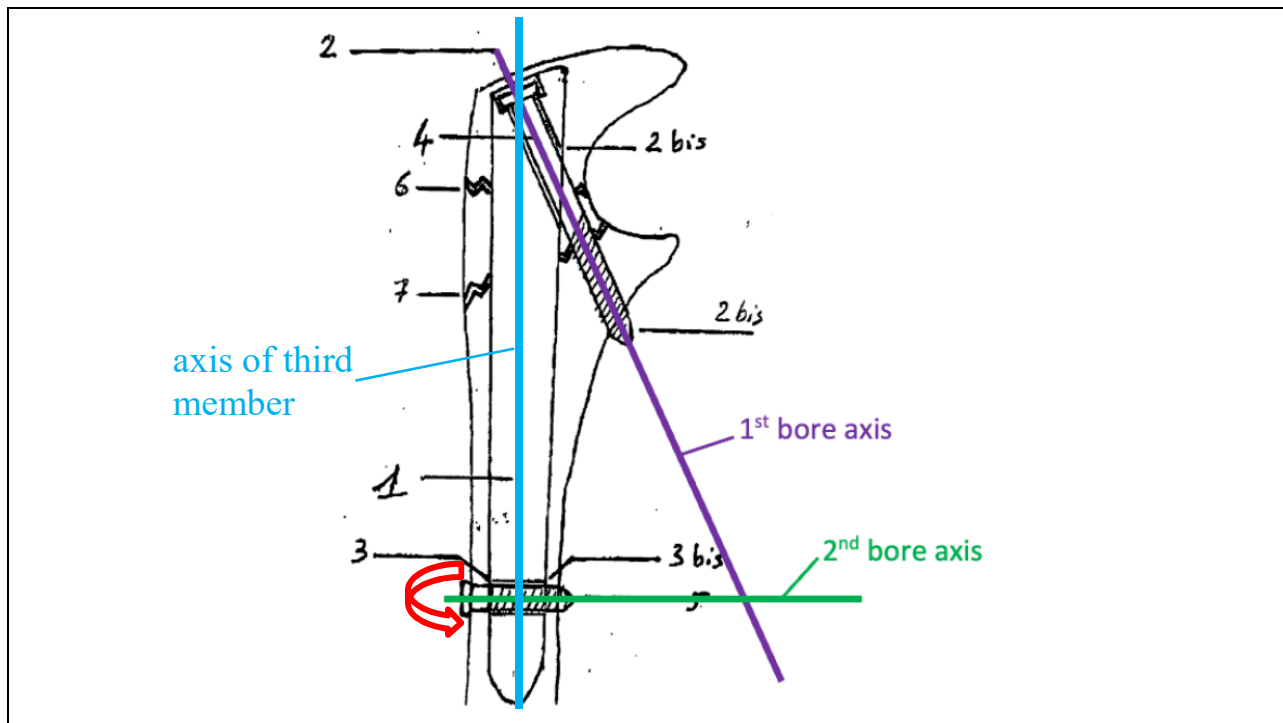
Paper 1 at 27 (citing Ex. 1002, ¶¶ 81-82). The portion of Mr. Dominguez's declaration cited by Petitioner concedes that two non-parallel lines will intersect only if they are in the same plane. *See* Ex. 1002, ¶ 81. Yet, Mr. Dominguez's declaration does not opine that the first and second bore axis identified by Petitioner in Cognet are, in fact, in the same plane. *See* Ex. 1002, ¶¶ 81-82. During cross-examination, Mr. Dominguez cited, for the first time, the following portion of Cognet that describes the alleged second bore (the bottom bore in the figure above) 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 at 165:8-24 (citing Ex. 1004 at 2-3 (emphasis added)). According to Mr. Dominguez, that disclosure means the "bore" axes labeled in annotated Figure 1 of

Cognet intersect because they are on the same plane. Ex. 2013 at 170:11-172:15.

But Mr. Dominguez's assumption that orienting the second axis (the green line above) perpendicular to the axis of the nail necessarily means it intersect the first axis (the purple line above) is wrong. See Ex. 2012, ¶ 60. Below is a further annotated version of Cognet's Figure 1, showing the axis of the third member (the light blue line), and how the second axis (the green line) could rotate around that axis (the blue line) as shown by the red arrow, but remain perpendicular to that axis (the blue line):



See Ex. 2012, ¶ 60. When asked if the second axis (the green line), instead of running side to side in the figure above could be pointed in any other direction on the horizontal plane (i.e., the plane formed by rotating the green line in the direction of the red arrow), would the second axis still be perpendicular to the axis

of the nail, Mr. Dominguez was unable or unwilling to answer the question. *See* Ex. 2013 at 172:16-175:17. But if the axes disclosed in Figure 1 are off by, for example, just one degree, they would be in different planes. *See* Ex. 2012, ¶ 60.

Petitioner therefore has not met its burden to show by a preponderance of the evidence that Claim 9 is anticipated by Cognet. *See* Ex. 2012, ¶ 61. Nor does Petitioner allege that Claim 9 is obvious in view of Cognet or in view of Cognet in combination with any other reference. Accordingly, the Board should find that Petitioner has not met its burden to show Claim 9 is invalid in view of Cognet alone, or in view of Cognet and any other reference.

**5. Petitioner Fails to Show Any Challenged Claims are Obvious In View of Cognet and Either Brumfield or Ferrante**

Petitioner alleges that Claims 4, 8, 10, and 14-15 are obvious in view of Cognet and Brumfield (Invalidity Ground 2), and Claim 11 is obvious in view of Cognet and Ferrante (Invalidity Ground 3). *See, e.g.*, Paper 1 at 6. As an initial matter, Petitioner does not allege that Brumfield or Ferrante disclose the elements missing from the disclosures in Cognet discussed in Section IV(A)(1)-(3) above. For that reason alone, the Board should find Petitioner has not met its evidentiary burden to show by a preponderance of the evidence that any of the Challenged Claims are invalid as obvious. In addition the Board should find that Petitioner failed to show the claims are obvious because Petitioner failed to show it would

have been obvious to a POSITA to combine Cognet and Brumfield (Invalidity Ground 2), and because Petitioner failed to show that Cognet and Ferrante disclose the invention recited in Claim 11 (Invalidity Ground 3).

**a. Petitioner Fails To Show Claims 4, 8, 10, 14, and 15 are Obvious in View of Cognet and Brumfield (Invalidity Ground 2) Because Petitioner Fails to Show it Would Have Been Obvious to a POSITA to Combine Those References**

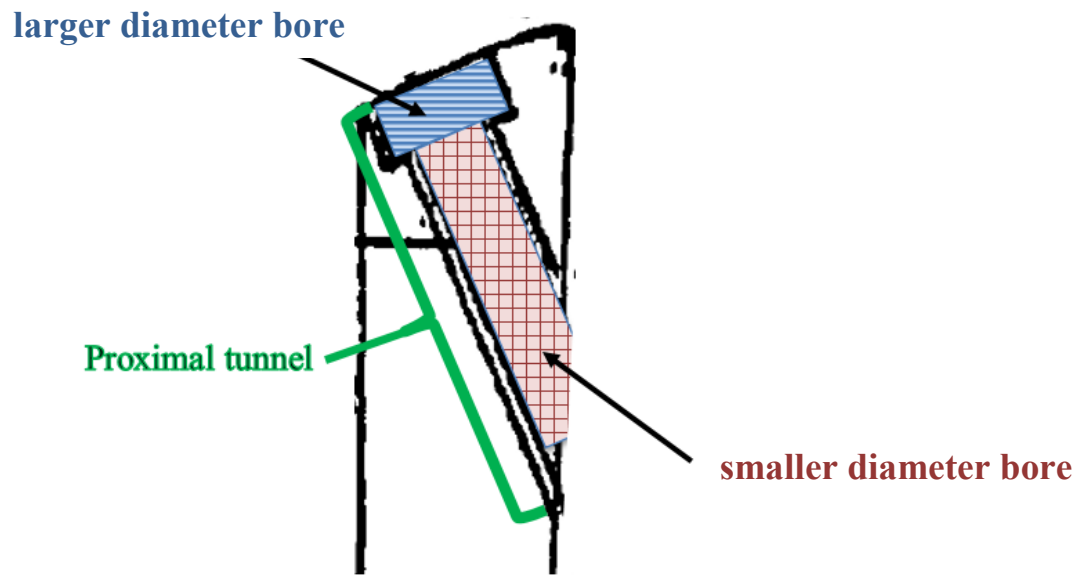
Regarding Cognet + Brumfeld, Petitioner alleges that it would have been obvious “to use the screws disclosed in Brumfield with the intramedullary nail disclosed in Cognet because the screw and nail in Brumfield are performing the same function in the same way as the screw and nail in Cognet.” Paper 1 at 33. However, Petitioner does not cite any legal authority relying on a common “function/way” to find that a POSITA would be motivated to combine these references and expect to successfully combine them. Nor is Petitioner correct that the references perform the same function in the same way.

Petitioner's sole bases for alleging a POSITA would be motivated to use the screws disclosed in Brumfield with the intramedullary nail disclosed in Cognet is an allegation that “the screw and nail in Brumfield are performing the same function in the same way as the screw and nail in Cognet.” Paper 1 at 33. However, Petitioner cites no support that such an argument, even if correct, meets the test for obviousness. And, in fact, the screw and nail in Brumfield do not

perform the same function in the same way as the screw and nail in Cognet. *See* Ex. 2012, ¶ 62.

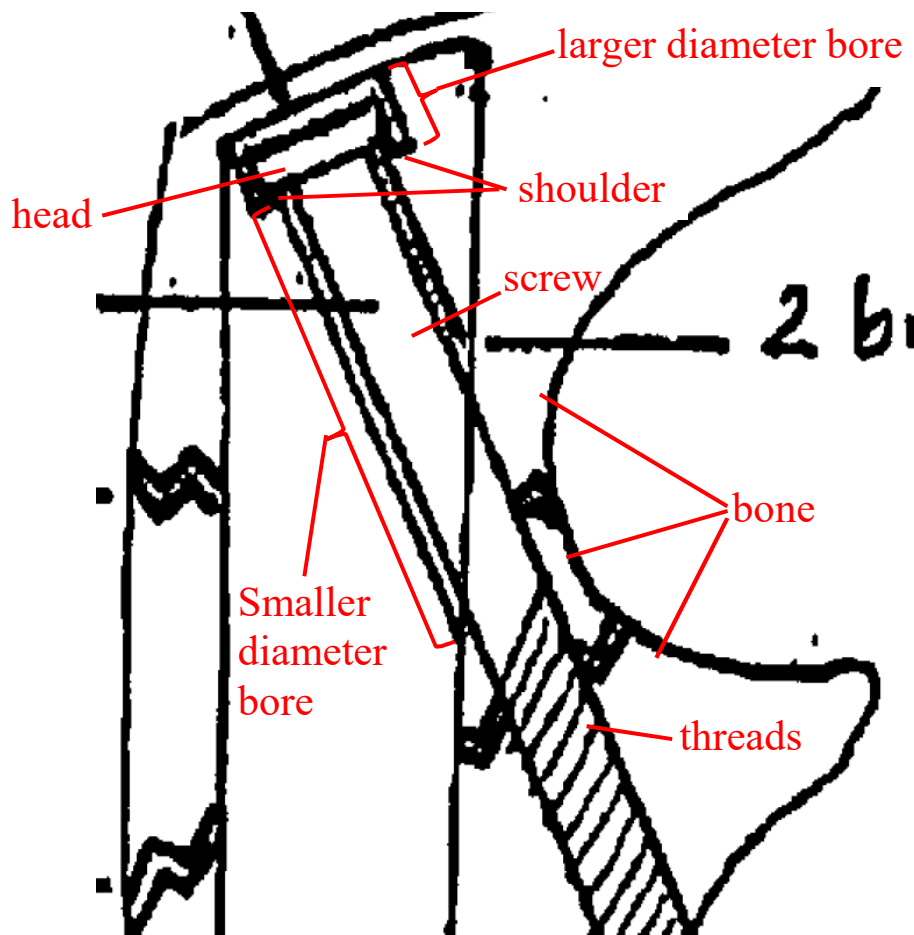
Cognet discloses a three-member device comprising “a nail through which there pass[es] at least two screws allowing this nail to be anchored into the bone.” Ex. 1004 at 2:22-25. The nail “comprises at least two tunnels; one tunnel starting from the top of the nail and leading in a direction that is oblique relative to the axis of the nail (2), and at least one tunnel situated in the distal part of the nail and perpendicular to the axis thereof (3).” Ex. 1004 at 3:31-37. Each of these tunnels is intended to accept a screw: the screw “that passes through the proximal tunnel (4) allows the fracture site (6 and 7) to be compressed,” and the screw that passes through the distal tunnel “block[s] rotation and prevent the nail from rising.” Ex. 1004 at 3:37-4:4. *See* Ex. 2012, ¶ 63.

As discussed above (see Section IV(A)(1)), the proximal tunnel in Cognet comprises two bores: a larger diameter bore and a smaller diameter bore:

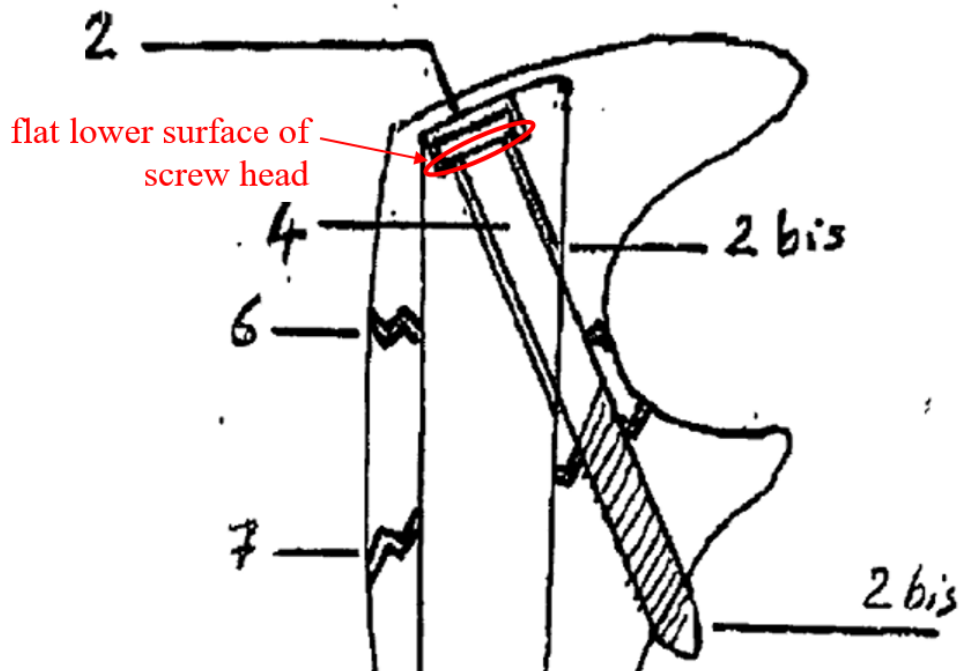


The screw intended to be inserted into the proximal tunnel is threaded at one end and has a head at the other end. *See* Ex. 1004, 4:14-23; FIG. 1; Ex. 2012, ¶ 65.

With reference to the annotated Figure 1 from Cognet below, the diameter of the head is wider than the diameter of the smaller diameter bore of the proximal tunnel “thereby making it possible to halt the progress of the screw in its tunnel and obtain a compression effect at the fracture site.” *Id.* The threaded end of the screw is inserted through the larger diameter bore, through the smaller diameter bore, and exits the tunnel at the bottom of the smaller diameter bore where it contacts bone. Ex. 2012, ¶ 65. Rotating the screw causes the threads to engage the bone, driving the screw into the bone. *Id.* As the screw is turned, it advances into the bone until the head of the screw contacts the shoulder where the larger diameter bore and smaller diameter bore meet:



Ex. 1004, FIG. 1 (annotations added). The shoulder is shown as a flat surface intended to mate with the flat underside surface of the screw head:



Ex. 1004, FIG. 1 (annotations added). The flat lower surface of the head of the screw disclosed in Cognet matches and is intended to contact the surface of the shoulder—shown as a flat surface between the top bore and the bottom bore—thereby facilitating the rotation of the screw in the tunnel. Ex. 2012, ¶ 65. As the screw is rotated, the flat lower surface of the head of the screw slides along the shoulder between the top bore and the bottom bore, and the threads of the screw advance into the bone or bone fragment into which it has been inserted. *Id.* As the threads advance, the bone or bone fragment is drawn in the direction of the head of the screw, compressing it with a bone or bone fragment in which the nail is implanted. *Id.*

In contrast to Cognet, Brumfield discloses “[a]n apparatus for treating fractures of the femur including a screw and an intramedullary rod.” Ex. 1006, Abstract; *see also* Ex. 1006 at 2:65-68 (“The present invention provides an apparatus for treating fractures of the femur. . . .”). Brumfield teaches inserting the intramedullary rod into the femur. *See, e.g.*, Ex. 1006 at 6:9-36. One or more lag screws are then inserted through holes in the rod. *See, e.g.*, Ex. 1006 at 6:49-56. As shown in the partial section of Brumfield’s Figure 1 below, unlike the screw head disclosed in Cognet which is intended to be inserted into Cognet’s tunnel, the head of the lag screws disclosed in Brumfield (circled in red) are not intended to enter the rod (shaded yellow):

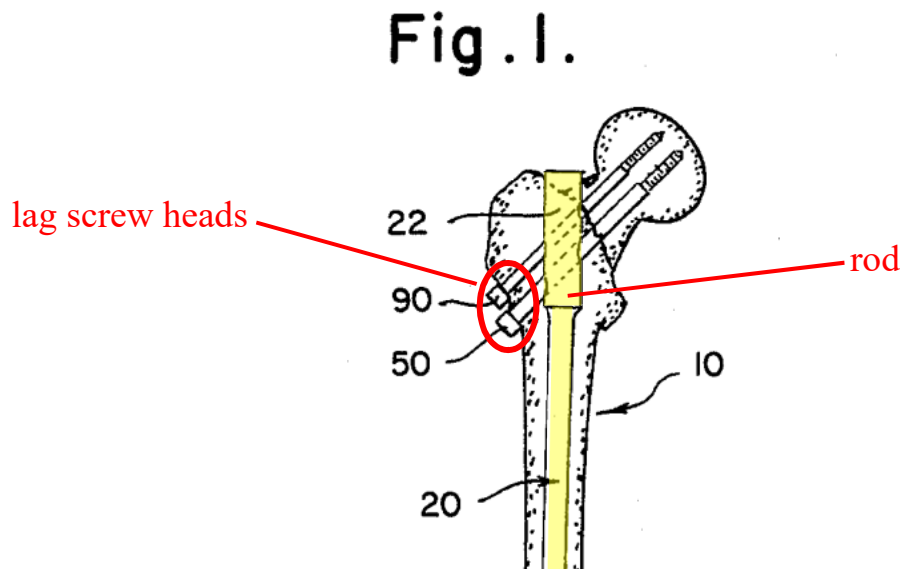


Exhibit 1006, FIG. 1 (annotations added); *See* Ex. 2012, ¶ 66.

It follows that the inventions in Cognet and Brumfield do not perform the same function in the same way. Cognet discloses a tunnel comprised of two bores, i.e., a larger diameter bore and a smaller diameter bore. At the intersection between the two bores there is a shoulder. The head of the screw is intended to abut the shoulder, thereby preventing the screw from advancing further into the bottom bore. Further rotation of the screw causes the threads to rotate in the bone and draw the bone toward the head of the screw, resulting in compression of the bone:

The top of the screw has a head, of a diameter wider than the diameter of the body 20 of the screw and than the tunnel (2) through which the screw passes, thereby making it possible to *halt the progress of the screw in its tunnel and obtain a compression effect at the fracture site.*

See Ex. 1004 at 4:18-23 (emphasis added). In contrast, the inventions disclosed in Brumfield do not perform the same way as Cognet. The head of the screws in Brumfield are not intended to abut a shoulder in, or any part of, Brumfield's rod. Instead, as shown in Brumfield's Figure 1, the head of the screws are intended to abut the exterior of the femur. See Ex. 2012, ¶ 67. Mr. Dominguez agrees:

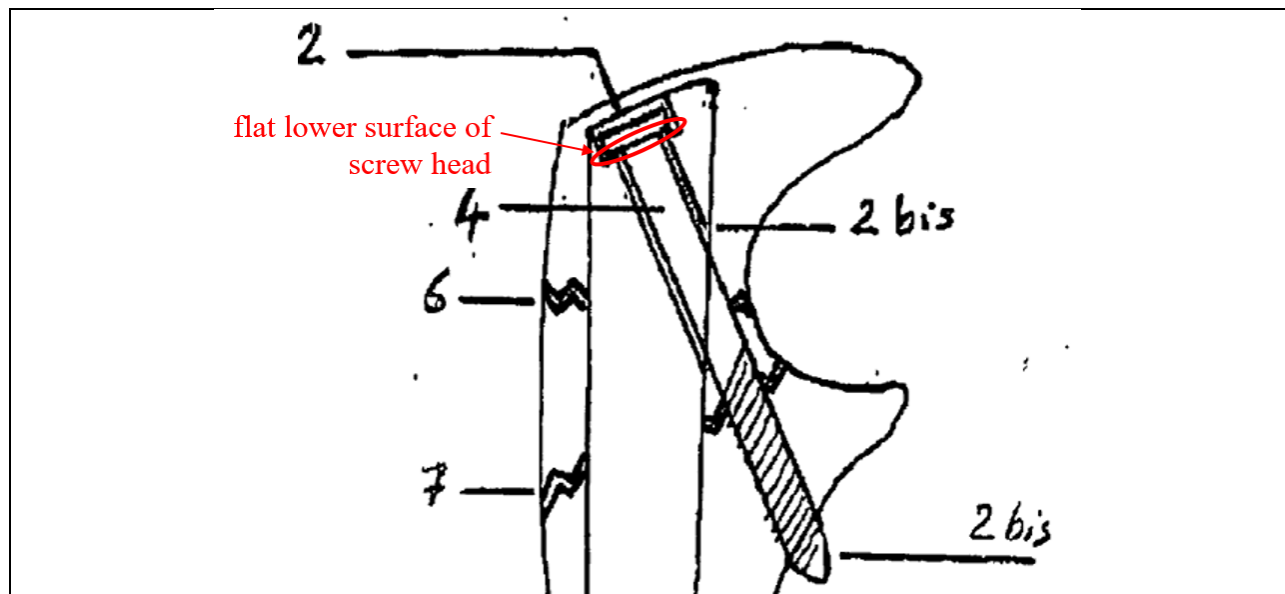
The screw in Brumfield is what we call exteriorized. It's outside on bone. So the head stops where it reaches bone.

Ex. 2013 at 184:13-15. Mr. Dominguez further testified that “if you didn’t have bone there, the head would stop as it reaches the nail.” *Id.* at 184:16-17. But inserting the Brumfield’s nail in the femur so it is surrounded by bone is the way Brumfield’s nail is intended to be used, and the only way it is disclosed as used in Brumfield. *See, e.g.,* Ex. 1006, Figure 1. Accordingly, the screw and nail in Brumfield do not perform the same way as the screw and nail in Cognet, as Petitioner alleges, and there is no support for Petitioner’s argument that it would have been obvious to combine the screws in Brumfield with the nail in Cognet.

Petitioner also does not address the extent to which the screws from Brumfield would be compatible with the nail disclosed in Cognet. For example, Mr. Dominguez conceded that he “didn’t go into addressing the exact mechanism of which there is contact there,” only “that there’s an abutment taking place.” Ex. 2013 at 197:20-198:8. Nor does Petitioner explain why a POSITA would be motivated to make the proposed combination, and why a POSITA might look to modify Cognet and/or Brumfield in the first place. *See ActiveVideo Networks, Inc. v. Verizon Communs., Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (requiring an explanation of why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does). For example, Petitioner does not identify any potential benefits that might be achieved, and which a POSITA might expect, from the proposed combination. Nor does

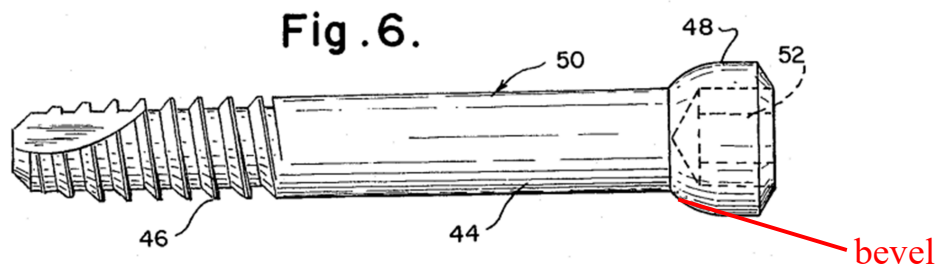
Petitioner address whether a POSITA would have had an expectation of success combining the references as Petitioner proposes, and the extent to which a POSITA might face any challenges or difficulties when trying to make the proposed combination, without using the Challenged Claims as hindsight. Nor does Petitioner identify any teachings in any of the references that would motivate a POSITA to combine the references as Petitioner proposes. *See* Ex. 2012, ¶ 68. It is Petitioner's burden to make these showings. If it has not done so, the Board must find that Cognet + Brumfeld is not an invalidating combination of references.

In fact, a POSITA would not consider combining Cognet and Brumfeld as Petitioner proposes. The head of the screw disclosed in Cognet is depicted as having a flat lower surface:



Ex. 1004, FIG 1 (annotations added). The flat lower surface of the head of the screw disclosed in Cognet matches and is intended to contact the surface of the

shoulder between the top bore and the bottom bore, thereby facilitating the rotation of the screw in the tunnel. Ex. 2012, ¶ 65. As the screw is rotated, the flat lower surface of the head of the screw slides along the shoulder between the top bore and the bottom bore, and the threads of the screw advance into the bone or bone fragment into which it has been inserted. A POSITA would not consider replacing the screw depicted in Cognet with a screw that has a beveled head portion as disclosed in Brumfield:



Ex. 1006, FIG. 6; *see* Ex. 2012, ¶ 69. The beveled head portion would not mate with the shoulder in the tunnel as described above for the screw disclosed in Cognet. Instead, the beveled head portion would only contact the edge of the aperture leading to the bottom bore, resulting in increased resistance to rotation of the screw. *See* Ex. 2012, ¶ 69.

Accordingly, the Board should find that Claims 4, 8, 10, 14, and 15 are not obvious in view of Cognet and Brumfield because it would not have been obvious to a POSITA to combine the disclosures in Cognet with the screw in Brumfield to practice the inventions recited in Claims 4, 8, 10, 14, and 15. *See* Ex. 2012, ¶ 70.

**b. Petitioner Fails to Show Claim 11 is Obvious in View of Cognet and Ferrante (Invalidity Ground 3) Because Petitioner Fails to Show the Limitation Recited in Intermediary Dependent Claim 10 is disclosed in those References**

Petitioner alleges Claim 11 is obvious in view of Cognet and Ferrante.

Claim 11 depends from Claim 10, which depends from Claim 1. See Ex. 1001 at 16:1-6. Accordingly, to show Claim 11 is invalid as obvious, Petitioner would need to show that the invention as a whole, including the limitations incorporated by reference from Claims 1 and 10 would have been obvious to a POSITA.

However Petitioner fails to allege that the limitation recited in Claim 10, would have been obvious to a POSITA in view of Cognet and Ferrante. Petitioner does not allege that either Cognet or Ferrante disclose the limitation of Claim 10 (“the first end of the first member includes a self-tapping edge for removing bone material”), or that the limitation of Claim 10 would have been obvious to a POSITA when practicing Claim 11. Nor does Petitioner allege that it would have been obvious to a POSITA to combine Brumfield—the reference cited for Claim 10—with both Cognet and Ferrante. This dooms this argument. Accordingly, the Board should find Claim 11 is not obvious in view of Cognet and Ferrante because Petitioner has not met its burden to show by a preponderance of the evidence that the invention recited in Claim 11—including the limitations of claims from which it depends—are disclosed or obvious in view of Cognet and Ferrante.

**B. PETITIONER FAILS TO SHOW THAT ANY OF THE CHALLENGED CLAIMS ARE ANTICIPATED BY SIMON OR OBVIOUS IN VIEW OF SIMON AND A SECONDARY REFERENCE**

**1. Invalidity Grounds 4-7 Fail Entirely Because Petitioner Has Not Shown That Simon Discloses a First Member Having a Head Portion as Recited in the Challenged Claims**

The independent claims of the '166 Patent, Claims 1 and 12, as well as all of the dependent claims by virtue of their dependency from the independent claims, require “a first member . . . wherein the first member comprises a shaft portion having an external surface and *a head portion* having an exterior surface. . . .” Ex. 1001 at 14:63-67 and 16:8-12 (emphasis added). Petitioner alleges Simon discloses that limitation, but Simon does not disclose a first member *comprising a head portion*. See Ex. 2012, ¶ 71.

Petitioner does not identify any express disclosure in Simon of a first member that comprises a head portion. See Paper 1 at 40 (Claim 1) and 53 (Claim 12). Instead, Petitioner merely argues that: (1) screws *generally* have a head portion; and (2) Simon discloses “elements 18, 19, and 20 as being locking screws (Ex. 1008, [0053]), interlocking cortical screws, or transfixation screws (Ex. 1008, [0039]). . . .” *Id.* Neither of those arguments, however, satisfy Petitioner's burden to show by a preponderance of the evidence that Simon discloses a first member having a head portion. See Ex. 2012, ¶ 72.

First, Petitioner generally argues that “screws have a shaft portion with an external surface and a head portion with an exterior surface. . . .” Petition at 40 (citing Section V.A.1.b of the Petition). As a threshold matter, the cited section of the Petition does not support that screws generally have a head portion. *See* Paper 1 at 11-12. Instead, that portion of the Petition asserts that a screw *in Cognet* comprises a head portion. For that reason alone, the Board should find that Petitioner has not shown that Claims 1 and 12 are anticipated by Simon. *See* Ex. 2012, ¶ 73.

The cited section of the Petition cites to a paragraph of Mr. Dominguez's declaration, but Mr. Dominguez does not opine that all screws have a head. On the contrary, Mr. Dominguez opines the opposite—that “[s]ome screws are ‘headless’ . . . .” Ex. 1002 at 20; Ex. 2013 at 208:1-8. Petitioner therefore cannot satisfy its burden to show by a preponderance of the evidence that a first member having a head portion is inherently disclosed by Simon. *See Arbutus*, 65 F.4th 656, 662 (“[a] claim is anticipated if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference.”). To the extent it was the start of an attempt to leave the door open for an inherency argument (an argument that Petitioner does not make) it has not even tried and could not meet the exacting standard for inherency. *See* Ex. 2012, ¶ 74.

Second, Petitioner asserts that “Simon discloses elements 18, 19, and 20 as being locking screws (Ex. 1008, [0053]), interlocking cortical screws, or transfixation screws (Ex. 1008, [0039]), and thus discloses [a first member having a head portion].” *See* Paper 1 at 40 (citing Ex. 1002 ¶ 116). However, that disclosure does not expressly disclose a head portion, and there is no evidence in the record to indicate that anyone of those screws would necessarily have a head portion. At no point did Petitioner argue that all locking screws, all interlocking cortical screws, and/or all transfixation screws include a head portion as recited in Claims 1 and 12. The listing of a few screw types does not show that Simon discloses either expressly or inherently, a first member having a head portion. *See* Ex. 2012, ¶ 75.

In the context of Claims 8, Petitioner further alleges that, to maintain a low-profile stature, the heads of bone screws, interlocking screws, or transfixation screws would have a tapered shape. Paper 1 at 51. However, Petitioner still does not allege that all of those types of screws would have a head portion, and does not cite to any portion of Simon that indicates that a low-profile stature was desired. Nor does Petitioner show that a tapered head is the only means to achieve a low-profile stature. Petitioner also asserts that POSITA would “immediately assume” an interlocking screw “has a tapered head portion to permit low profile seating.” Paper 1 at 51-52 (citing Ex. 1002 at ¶¶ 42 and 135). However, the expert opinions

cited in support of that argument are not supported by any actual evidence. *See* Ex. 2012, ¶ 76.

In the Institution Decision, the Board drew incorrect inferences from Mr. Dominguez's opinions to reach the incorrect conclusion that Simon discloses a screw with a head portion. Although the Board acknowledged Mr. Dominguez's concession that some screws are headless, the Board ruminated that "at least those [screw heads] at issue in his statement are used to drive the screw entirely into the bone." Paper 15 at 23. As noted above, however, Mr. Dominguez did not opine that any of the screws he identified always has a screw head. The Board also surmised that "the quoted passage [from Mr. Dominguez's declaration] . . . does not appear to apply to screw heads that instead make contact with a fixation assembly," whereas in the present case, the Board found that "the head of the first member to be in contact with the third member, rather than with bone. Paper 15 (citing '166 Patent claim element 1[e]). However, even if the Board's logic was supported by the evidence of record, which it is not, the Board's citation to claim element 1[e] of the "'166 Patent is misplaced—the question is not what the '166 Patent discloses, but what Simon discloses. And Simon does not disclose that any screw has a head, let alone whether any head makes contact with another part of the fixation assembly.

The Institution Decision also veers to Petitioner's discussion of the *second* member, in which Petitioner alleges screws extend to a second end having a head:

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.

Paper 15 at 40-41 (citing Ex. 1002, ¶ 42); *see also* Paper 15 at 22. But not only does that passage concern the *second* member, not the *first* member, the section of the Petition cited as support for the above passage (Section V.A.1.c) does not assert that screws generally have a head portion. *See* Paper 1 at 12-13.

In sum, Petitioner fails to show that the limitation of a first member having a head portion, as required by all of the Challenged Claims, is disclosed either expressly or inherently in Simon. The Board should therefore find that the Challenged Claims are not anticipated by Simon. *See* Ex. 2012, ¶ 77.

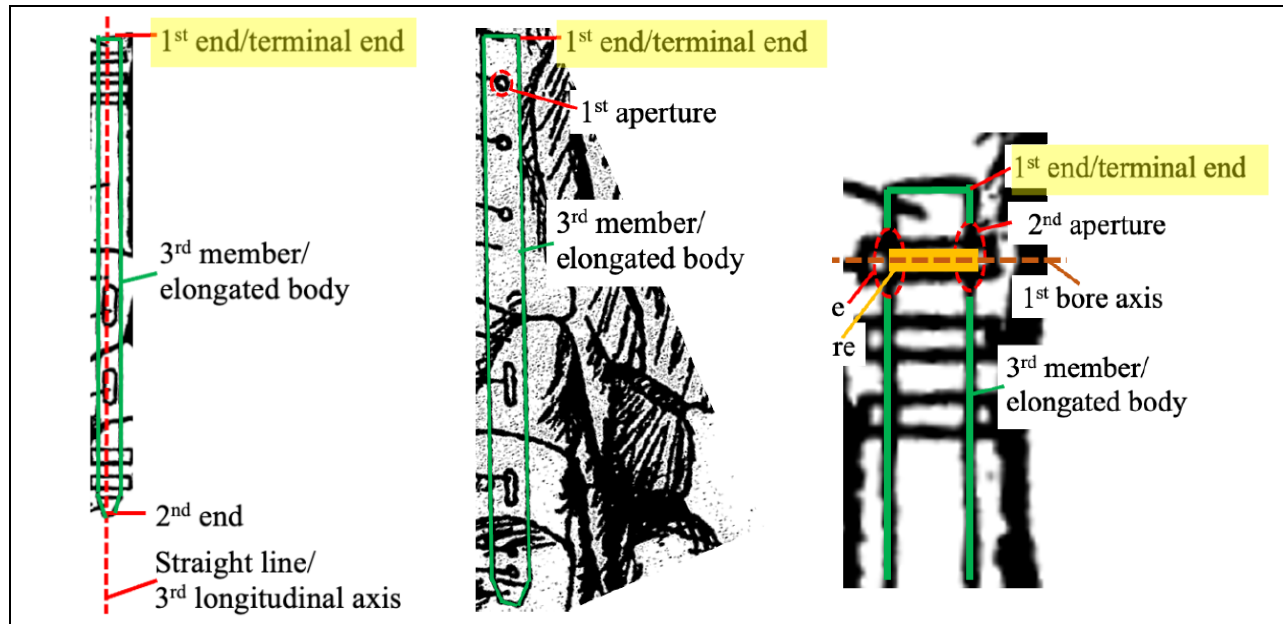
**2. Invalidity Grounds 4-7 Fail Entirely Because Petitioner Has Not Shown That Simon Discloses a First Aperture at a Terminal End of the First End of the Third Elongated Body as Recited in the Challenged Claims**

In addition to failing to show that Simon discloses a first member having a head portion (*see supra* at Section IV(B)(1)), Petitioner further fails to show Simon discloses an aperture at a “terminal end” of the first end of the third elongated

body, as required by independent Claims 1 and 12, as well as all of the dependent claims by virtue of their dependency from the independent claims:

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

Ex. 1001 at 15:11-18, 16:24-31 (emphasis added). *See* Ex. 2012, ¶ 78. As indicated above, the first aperture is not just at the “first end” of the third elongated body, but it is at the “terminal end of the first end” of the third elongated body. Yet, Petitioner and its expert repeatedly conflate the terms “first end” and “terminal end” to mean the same portion of the third member. *See SimpleAir, Inc. v. Sony Ericsson Mobile Communs. AB*, 820 F.3d 419, 429 (Fed. Cir. 2016) (“interpretations that render some portion of the claim language superfluous are disfavored.”) (citation and internal quotations omitted). For example, Petitioner's annotations to Simon's Figures identify the “first end” and the “terminal end” as the same element:

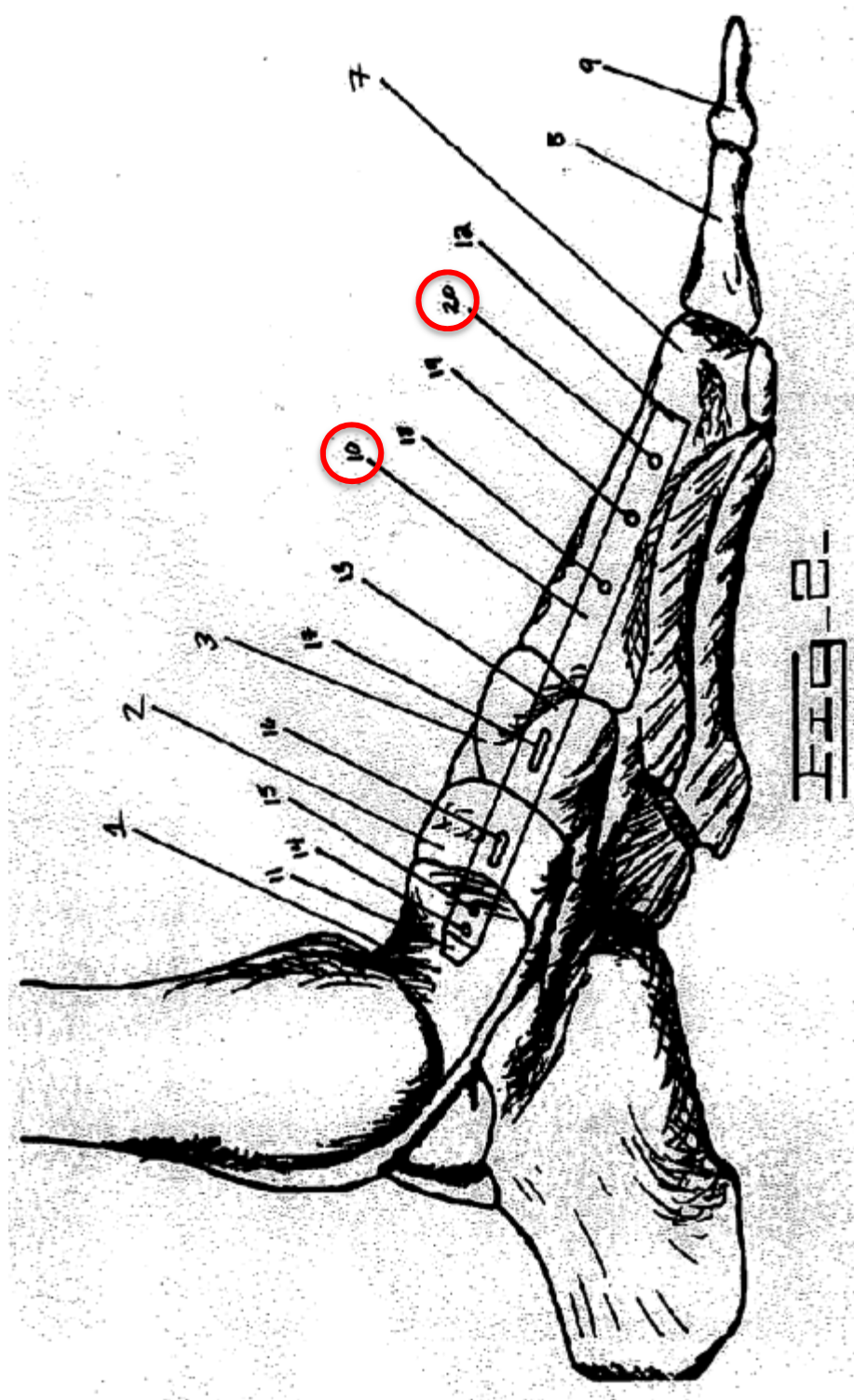


Paper 1 at 42-44. And Mr. Dominguez testified that he did not draw a distinction between the “first end” and “terminal end.” Ex. 2013 at 211:7-214:23.

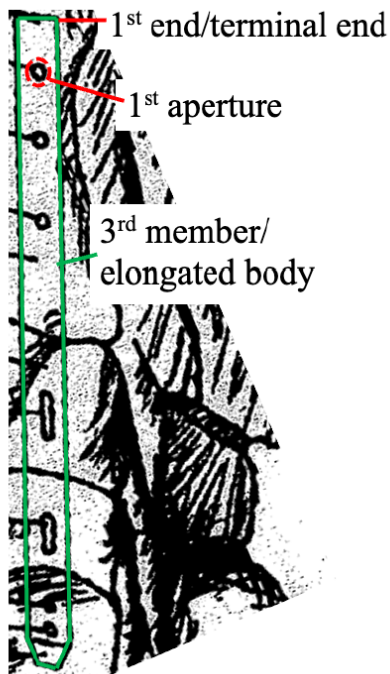
Petitioner’s failure to properly read the claims and distinguish between the first end and the terminal end undermines Petitioner’s arguments that Simon discloses a first aperture at the terminal end of the third elongated body.

As discussed above (see Section III(B)(1)), the term “a first aperture at a terminal end of the first end of the third elongated body” should be construed to exclude apertures that only pass through the sides of the shaft of the third elongated body. All of the apertures disclosed in Simon’s nail only pass through the sides of the shaft of the nail. *See, e.g.*, Ex. 1008, FIGS. 1, 2; Ex. 2012, ¶ 79. Therefore, Simon does not disclose any apertures at the terminal end of the first end of the third elongated body. *See* Ex. 2012, ¶ 79.

Petitioner alleges that hole (20) disclosed in Simon is a fastener hole at the terminal end of Simon's nail (10). Paper 1 at 43 (citing Ex. 1008, FIG. 2, [0054]). This annotated version of Simon's Figure 2 shows the location of hole (20) in relation to nail (10):



See Ex. 2012, ¶ 80. As shown in the following annotated figure presented by Petitioner, hole 20 (identified by Petitioner as “1st aperture”) is not at the terminal end, but some distance away from it:



Paper 1 at 43. To account for that discrepancy, Petitioner proposes reading the word “at” preceding the term “terminal end” to mean “near”:

To a POSA, the phrase “at the terminal end” would refer to a location near the terminal or proximal end, as opposed to merely along the shaft of the nail at any location, or at the distal end.

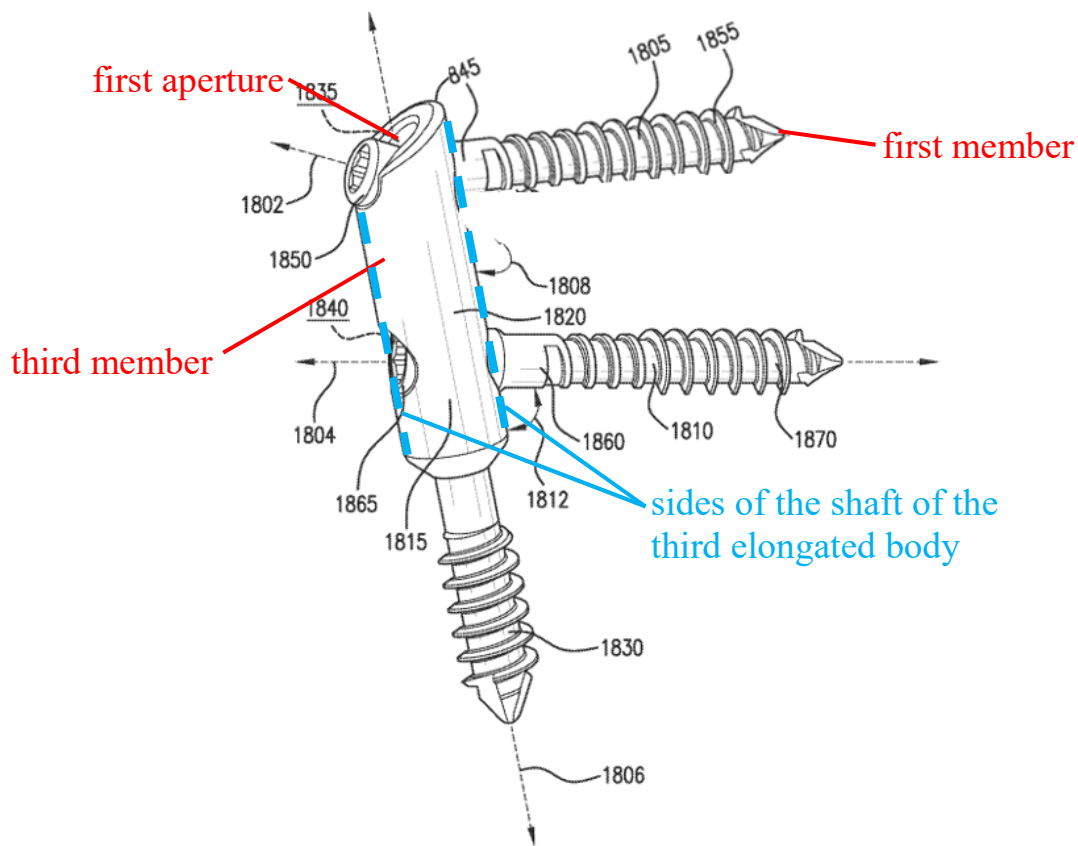
Petition at 15 (citing Ex. 1002 at ¶ 55). Petitioner only cites its expert's declaration as support for that construction, but the cited portion of the declaration does not itself cite any support for the construction or provide any reasoning for the proposed construction. It simply notes:

A POSA would understand “at the terminal end” to refer to a location near the nail termination, nail head or proximal end, as opposed to merely along the shaft at any location or at the distal end.

Ex. 1002, ¶ 55. Such *ipse dixit* statements are entitled to little or no weight. *See* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) (“Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination.”). The Board should not entertain Petitioner’s blatant attempt to rewrite the claim to buttress its invalidity arguments which do not find support in the cited reference. Instead, the Board should find that the Petition fails to show that any of the Challenged Claims are invalid in view of Simon, at least because Petitioner has not shown that Simon discloses a device with a first aperture at a terminal end. *See* Ex. 2012, ¶ 81.

Petitioner cites to Mr. Dominguez’s declaration as support for the assertion that “Simon discloses a fastener hole (hole 20 in figure 2) at the terminal end of the third elongated body. . . .” Paper 1 at 43 (citing Ex. 1002, ¶ 121; Ex. 1008, ¶ [0054]). Mr. Dominguez opines that because “Claim 1 allows for the first bore axis to be at 90° relative to the third longitudinal axis, . . . the first aperture (the

first end of the first bore) was oriented on the exterior surface of the third member at the terminal end.” Ex. 1002, ¶ 121; *see also* Ex. 2013 at 226:9-231:3. But an assembly with a first bore axis oriented at 90 degrees relative to the third longitudinal axis does not necessarily result in an aperture on the exterior surface of the third member. For example, if the first member in Figure 18 of the '166 Patent is oriented at 90 degrees relative to the third longitudinal axis, because of the chamfered (i.e., angled) surface at the top of the third member, the first aperture would not *only* pass through the sides of the shaft of the third elongated body—it is therefore still an aperture at the first terminal end of the third elongated body still also passes through the terminal end:



Petitioner also alleges that paragraph [0015] of Simon “teaches an aperture at the terminal end.” Paper 1 at 44 (citing Ex. 1002, ¶ 122). But paragraph [0015] of Simon merely identifies the Leu reference (U.S. Patent No. 6,270,499, Ex. 1009), and states that the patent “describes an intramedullary nail where the proximal end has at least one bore which extends transversely to the central axis of the nail for receiving at a stable angle a bone fastener.” Ex. 1008 at [0015]. Simon does not identify a terminal end of any nail in Leu, nor does it identify an aperture allegedly at a terminal end. *See* Ex. 2012, ¶ 82.

For the reasons set forth above, the Board should find that Petitioner fails to show that Claims 1 and 12 are anticipated by Simon. *See* Ex. 2012, ¶ 83.

**3. Petitioner Fails To Show Claim 4 is Anticipated by Simon (Invalidity Ground 1) Because Petitioner Fails to Show Simon Discloses That the Head Portion of the First Member Comprises a Torque Transmitting Aperture**

Claim 4 depends from Claim 3 and further recites, “the head portion of the first member comprises a torque transmitting aperture.” Petitioner does not allege that a torque transmitting aperture is disclosed in Simon. Instead, Petitioner cites to the section of the Petition that addresses Claim 4 for *Cognet* (Section V.A.4). But as explained above, that section does not show *Cognet* (or any reference) expressly or inherently discloses a first member comprising a torque transmitting aperture. *See* Paper 1 at 50. Petition also asserts, “[s]ince *almost all* screws include a torque transmitting aperture, by disclosing the first member to be a screw (Ex. 1008, [0039]) Simon is disclosing this claim’s limitation.” Paper 1 at 50-51 (citing Ex. 1002 ¶¶ 42, 133) (emphasis added). But “almost all” doesn’t meet Petitioner’s burden. For an element of the claimed invention to be inherently present in a prior art reference, the prior art reference must necessarily and always contain or produce that element; it is not sufficient if the element is possibly, or even probably, present in the prior art reference. *See, Trintec*, 295 F.3d 1292 at 1295. As noted for *Cognet* above, some screws do not include torque transmitting aperture, such as a hex lag screw. *See* Ex. 2012, ¶ 59. The limitation of Claim 4, “the head portion of the first member compris[ing] a torque transmitting aperture” is therefore neither explicitly nor inherently disclosed by Simon. Accordingly, the

Board should find that Petitioner has not met its burden to show by a preponderance of the evidence that Claim 4 is invalid in view of Simon.

**4. Petitioner Fails To Show Claims 10 and 11 are Anticipated by Simon (Invalidity Ground 1) Because Petitioner Fails to Show Simon Discloses a Self-Tapping Edge**

Claim 10 depends from Claim 1 and recites, “the first end of the first member includes a self-tapping edge for removing bone material.” Ex. 1001 at 16:1-3. Claim 11 depends from Claim 10 and recites, “the first end of the second member includes a self-tapping edge for removing bone material.” Ex. 1001 at 16:4-6. For both Claims 10 and 11, Petitioner alleges that Simon discloses that the first and second members may be interlocking screws and “[i]nterlocking screws *commonly* have a self-tapping edge.” Paper 1 at 52 (citing Ex. 1002 ¶¶ 42, 136). Once again, Petitioner attempts to make an inherency argument, but falls short of the standard for inherency. If an element is only “commonly” present, it does not necessarily and always contain that element, which it must in order to meet the standard for inherency. *See, Trintec*, 295 F.3d 1292 at 1295.

Accordingly, the Board should find that Petitioner fails to show that Claims 10 and 11 are anticipated by Simon.

**5. Petitioner Fails to Show Any Challenged Claims are Obvious In View of Simon and Either Ferrante, Cognet, or Leu**

Petitioner alleges Claims 4, 8, 10, 11, 14, and 15 are obvious in view of Simon and Ferrante (Invalidity Ground 5), Claim 9 is obvious in view of Simon and Cognet (Invalidity Ground 6), and Claims 2, 3, 6, 7, and 13 are obvious in view of Simon and Leu (Invalidity Ground 7). *See, e.g.*, Paper 1 at 6. As an initial matter, Petitioner does not allege that Ferrante, Cognet, or Leu disclose the elements missing from the disclosures in Simon discussed in Section IV(B)(1)-(4) above. For that reason alone, the Board should find Petitioner has not met its evidentiary burden to show by a preponderance of the evidence that any of the Challenged Claims are invalid as obvious. In addition, the Board should find that Petitioner failed to show the claims are obvious because Petitioner failed to show that a POSITA would have been motivated to combine Simon with the cited secondary references.

**a. Petitioner Fails to Show that Claims 4, 8, 10, 11, 14, and 15 are Obvious in View of Simon and Ferrante (Invalidity Ground 5) Because Petitioner Fails to Show a Motivation to Combine the References**

Petitioner alleges Claims 4, 8, 10, 11, 14, and 15 are obvious in view of Simon and Ferrante. Petitioner alleges it would have been obvious to combine Simon and Ferrante because the screw and nail in Ferrante “are performing the same function in the same way as the screw and nail in Simon.” Paper 1 at 58.

Petitioner does not cite to any legal authority that holds a Petitioner can meet its burden to show references are obvious to combine by showing they are performing the same function in the same way. Nor has Petitioner actually illustrated that it would be obvious to combine these references. Petitioner does not address the extent to which the screw and nail from Ferrante would be compatible with the screw and nail disclosed in Simon. Nor does Petitioner explain why a POSITA would be motivated to make the proposed combination, and why a POSITA might look to modify Simon and/or Ferrante in the first place. For example, Petitioner does not identify any potential benefits that might be achieved, and which a POSITA might expect, from the proposed combination. Petitioner also does not address whether a POSITA would have had an expectation of success combining the references as Petitioner proposes, or the extent to which a POSITA might face any challenges or difficulties when trying to make the proposed combination, without using the Challenged Claims as hindsight. Petitioner also does not identify any teachings in any of the references that would motivate a POSITA to combine the references as Petitioner proposes.

Furthermore, Claim 4 depends from Claim 3, which depends from Claim 2, which depends from Claim 1. *See* Ex. 1001 at 15:45-54. Petitioner alleges that the limitations of Claims 1 and 4 are disclosed by Simon or obvious in view of Simon and Ferrante. However, Petitioner does not allege that either Simon or Ferrante

disclose the limitations of Claims 2 and 3, which are also incorporated by reference into Claim 4. Petitioner therefore fails to allege that the all of the limitations of Claim 4 are disclosed in Simon or any reference in combination with Simon.

Accordingly, Petitioner fails to meet its burden to show by a preponderance of the evidence that Claims 4, 8, 10, 11, 14, and 15 are obvious in view of Simon and Ferrante.

**b. Petitioner Fails to Show that Claim 9 is Obvious in View of Simon and Cognet (Invalidity Ground 6) Because Petitioner Fails to Show a Motivation to Combine the References**

Claim 9 depends from Claim 1 and recites, “the first bore axis and the second bore axis intersect outside the third member.” Ex. 1001 at 15:63-64. Petitioner alleges Claim 9 is obvious in view of Simon and Cognet. *See, e.g.*, Paper 1 at 6. Petitioner does not identify a particular motivation that a POSITA might have had to combine Simon and Cognet. Instead, Petitioner alleges that it would have been obvious to combine the references because the intramedullary nail in Cognet and the intramedullary nail in Simon are performing the same function in the same way. Again, Petitioner does not cite to any legal authority that holds a Petitioner can meet its burden to show references are obvious to combine by showing they are performing the same function in the same way.

Also, as support for the allegation that Simon and Cognet together disclose the limitations recited in Claim 9, Petitioner cites to the portion of the Petition that alleges Claim 9 is anticipated by Cognet. For the reasons set forth above, however, Cognet does not disclose the limitations recited in Claim 9. Accordingly, Petitioner fails to meet its burden to show by a preponderance of the evidence that Claim 9 is obvious in view of Simon and Cognet.

**a. Petitioner Fails to Show Claims 2, 3, 6, 7, and 13 are Obvious In View of Simon and Leu (Invalidity Ground 7) Because Petitioner Fails to Show a Motivation to Combine the References**

According to Petitioner, Claims 2, 3, 6, 7, and 13 are obvious in view of Simon and Leu. *See, e.g.*, Paper 1 at 6. Petitioner alleges “[i]t would have been obvious to a POSA to combine Leu with Simon because Simon gives an example embodiment that is an intramedullary nail intended for insertion in a longer bone (Ex. SIMON [0057]) and gives Leu as an example of an intramedullary nail intended for insertion in a longer bone (Ex. SIMON [0015]).” Paper 1 at 64 (citing Ex. 1002, ¶ 167). Even if Simon discloses an intramedullary nail for insertion in long bones, and cites to Leu as an example of prior art that refers to nails used in large bones, such disclosures alone would not indicate that it would be obvious to a POSITA to combine Simon with Leu without any consideration of the structures and/or features of each nail, how they might be combined, whether such

combination would undermine the intended function of the nail, and whether a POSITA would have an expectation of combining the references, none of which Petitioner addresses. Accordingly, Petitioner fails to meet its burden to show by a preponderance of the evidence that Claims 2, 3, 6, 7, and 13 are obvious in view of Simon and Leu.

## V. CONCLUSION

For the reasons set forth above, the Board should find that Petitioner has not met its burden to show any of the Challenged Claims are invalid.

Respectfully submitted,

Dated: February 8, 2024

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**CERTIFICATION OF WORD COUNT**

Pursuant to 37 C.F.R. §§ 42.24(a)(1)(i), (b)(1), and (d), Patent Owner certifies that this Response includes 13,436 words, as measured by Microsoft Word, exclusive of the table of contents, table of authorities, appendix of exhibits, certificate of service, and certificate of word count.

Dated: February 8, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e)(4), I hereby certify that on February 8, 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 the Petitioner's Revised Mandatory Notices (Paper 18):

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