

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

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

PATENT OWNER'S PRELIMINARY RESPONSE

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TABLE OF EXHIBITS

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

I. INTRODUCTION

Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 42.107, Patent Owner Extremity Medical, LLC hereby submits the following Preliminary Response to the Petition for *Inter Partes* Review (“IPR”) of U.S. Patent No. 11,298,166 (“the ’166 Patent”).

The Board should deny institution for at least one of two independent reasons: (i) in the interest of efficiency and fairness because the Petition was filed far too late and there is a corresponding district court case that is speeding ahead, and (ii) because the cited references do not disclose the claimed inventions, so there is not a reasonable likelihood that Petitioner will prevail with respect to any of the challenged claims.

First, the Board should discretionarily deny institution in view of *Extremity Medical, LLC vs. Fusion Orthopedics, LLC*, Case No. 2:22-cv-00723-PHX-GMS (D. Ariz.) (the “Parallel District Court Case”) which is at an advanced stage now, and for which trial could conclude before the issuance of a Final Written Decision in this proceeding. The district court has already issued its claim construction ruling and fact discovery will be completed in a few weeks. Having waited until the last possible day to file its IPR Petition, Petitioner all but ensured that *Fintiv* would apply. All six *Fintiv* factors support discretionary denial.

Second, the Petition fails to sufficiently demonstrate how the limitations of the challenged claims are disclosed in Petitioner's proffered references. For example, for independent Claims 1 and 12, which the Petition alleges are anticipated by either Cognet or Simon, the Petition fails to show Cognet discloses a third member comprising "a first bore extending along a first bore axis from the first aperture to a second aperture," or that Simon discloses a first member comprising a "head portion." Both of those limitations are recited in each independent claim, so they are also incorporated into every dependent claim. The Petition also fails to show that the dependent claims are anticipated by Cognet or Simon, or obvious in view of Simon or Cognet and one of the secondary references (Brumfield, Ferrante, and Leu). Petitioner therefore cannot show a reasonable likelihood that any of the challenged claims are unpatentable.

Institution should be denied.

II. BACKGROUND OF THE PARALLEL DISTRICT COURT CASE AND THE '166 PATENT

A. PROCEDURAL HISTORY OF THE PARALLEL DISTRICT COURT CASE

On April 28, 2022, Patent Owner filed the Parallel District Court Case in the District of Arizona, alleging that Petitioner infringes the '166 Patent. *See* Ex. 2002. On December 16, 2022, the Court entered a Case Management Order in the Parallel District Court Case, setting dates for, *inter alia*, infringement contentions,

invalidity contentions, claim construction briefing and a *Markman* Hearing. *See* Ex. 2003. The Order explicitly stated that the Court intends to stick to its schedule:

The parties are advised that the Court intends to enforce the deadlines set forth in this Order and should plan their litigation activities accordingly. Even if all parties stipulate to an extension, the Court will not extend the deadlines, absent good cause to do so.

Id. at 8. On July 10, 2023 and July 28, 2023, the Court further set deadlines for expert reports, completion of expert discovery, and filing dispositive motions. *See* Exs. 2004 and 2005.

Pursuant to the Court's Orders, Patent Owner served its infringement contentions on January 6, 2023, and Petitioner served its invalidity contentions on February 17, 2023. *See* Exs. 2006, 2007. On April 7, 2023, Patent Owner filed its Opening Claim Construction Brief. *See* Ex. 2003. On May 12, 2023, Petitioner filed its Responsive Claim Construction Brief. *Id.* On June 13, 2023, Patent Owner filed its Reply Brief. *Id.* The Court held a *Markman* Hearing on June 22, 2023, and issued a 23-page *Markman* Order on July 7, 2023. *See* Ex. 2008.

On August 3, 2023 — despite having filed its IPR Petition three months earlier — Petitioner filed a motion to stay the Parallel District Court Case. Patent Owner filed an opposition to the motion to stay on August 17, 2023, explaining why a stay is not warranted. As of the date of this filing, the Court has not ruled on Petitioner's motion. Absent a stay, the parties are scheduled to complete written

discovery by August 25, 2023, complete fact depositions by September 22, 2023, serve expert reports by November 17, 2023, and complete expert discovery, including expert depositions, by December 15, 2023. *See* Ex. 2005. Dispositive motions are due January 12, 2024. *See* Ex. 2004.

B. OVERVIEW OF THE '166 PATENT

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. For example, assemblies disclosed in the '166 Patent may be used to restore the arch in a human foot by coupling the assembly to the medullary canals of the first metatarsal, medial cuneiform, navicular and/or talus bones in the foot. An exemplary figure from the '166 Patent is provided below:

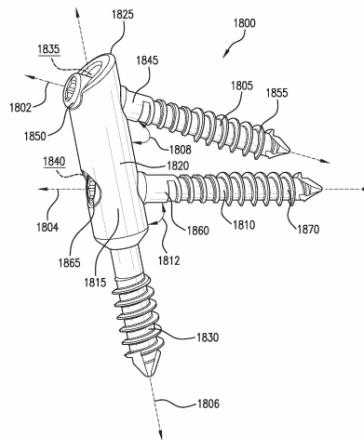


FIG. 18

Ex. 1001, FIG. 18.

III. THE BOARD SHOULD DISCRETIONARILY DENY INSTITUTION BECAUSE THE PETITION WAS FILED AT THE LAST MINUTE AND THE PARALLEL DISTRICT COURT CASE IS FAR ALONG

Under 35 U.S.C. § 314(a), the Director has discretion to deny institution of an *inter partes* review. *See Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”); *Harmonic v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.”).

Here, Petitioner waited 365 days to file its IPR Petition on the last day it could so, and at this point, the Parallel District Court Case is at an advanced stage. Claim construction is already complete and the district court issued a *Markman* order on July 7, 2023. *See* Ex. 2008. By the time the Board issues an institution decision (expected around November 23, 2023), fact discovery will be closed (as of September 23, 2023), and the parties will have exchanged opening and rebuttal expert reports (by November 17 2023).

Any Final Written Decision here (expected in November 2024), would come months after dispositive motions (due January 12, 2024) and also likely after trial — a trial at which Petitioner has reserved its ability to present the exact same unpatentability arguments it is advancing here. The Board should deny institution because continuing this proceeding will unnecessarily waste the Board’s resources.

See Cisco Sys., Inc. v. Ramot at Tel Aviv Univ. Ltd., IPR2020-00123, Paper 14 at 10 (PTAB May 15, 2020) (denying institution because “the parallel proceedings would duplicate effort. This is an inefficient use of Board, party, and judicial resources and raises the possibility of conflicting decisions.”).

In *Apple Inc. v. Fintiv, Inc.*, the Board identified the following six non-exclusive factors “that balance considerations of system efficiency, fairness, and patent quality when a patent owner raises an argument for discretionary denial due to the advanced state of a parallel proceeding”:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 15 at 7-8 (PTAB May 13, 2020).

Each of the six *Fintiv* factors favors denying institution here.

A. FACTOR 1 FAVORS DISCRETIONARY DENIAL BECAUSE A STAY IS NOT LIKELY TO BE GRANTED IN THE PARALLEL DISTRICT COURT CASE

It is not likely that a stay will be granted in the Parallel District Court Case, despite the fact that Petitioner has moved for a stay.

First, as a threshold matter, the district court has made it very clear that it intends to stick to the schedule it set for the Parallel District Court Case, even if the parties stipulate to extensions, absent good cause to do so:

The parties are advised that the Court intends to enforce the deadlines set forth in this Order and should plan their litigation activities accordingly. Even if all parties stipulate to an extension, the Court will not extend the deadlines, absent good cause to do so.

Ex. 2003 at 8.

Even if the district court had not expressly made its proclivity to keep the case moving very clear, the timing and advanced stage of the Parallel District Court Case demonstrate that a stay of the case is unlikely. Again, as noted above, the district court has already issued its claim-construction opinion and order. *See* Ex. 2008. By the time an institution decision is expected (by November 23, 2023), fact discovery will have been closed (as of September 22, 2023), and the parties will have exchanged expert reports (by November 17, 2023). *See* Exs. 2004, 2005. Expert depositions are scheduled to be completed by December 15, 2023, and dispositive motions are due shortly thereafter on January 12, 2024, only about six

weeks after the institution decision is expected. *See id.* On these facts it is not likely that a stay will be granted because the Court and the parties have expended too much time and effort in the Parallel District Court Case, as argued in Patent Owner's opposition to the stay. The motion is presently pending.

Because the district court is unlikely to grant a stay, Factor 1 favors denial of institution. *See, e.g., Intel Corporation v. Koninklijke Philips N.V.*, IPR2021-00328 Paper 9 at 8-9 (PTAB July 16, 2021). However, given that there is a motion to stay pending and there is an outside possibility that it will be granted, the Board could choose to consider this factor neutral.

B. FACTOR 2 FAVORS DISCRETIONARY DENIAL BECAUSE THE TIME TO TRIAL WILL LIKELY FALL BEFORE THE DEADLINE FOR A FINAL WRITTEN DECISION

The Board has routinely found this factor weighs in favor of denying institution when the anticipated trial date precedes the Final Written Decision. *See e.g., Satco Products, Inc. v. The Regents of the University of California*, IPR2021-00794, Paper 14 at 19 (PTAB Nov. 10, 2021); *Stanley Black & Decker, Inc., et al. v. Zircon Corp.*, IPR2020-01572, Paper 10 at 12 (PTAB April 19, 2021); *Next Caller, Inc. v. TrustID, Inc.*, IPR2019-00961, Paper 10 at 14-15 (PTAB Oct. 16, 2019); *E-One, Inc. v. Oshkosh Corp.*, IPR2019-00161, Paper 16 at 6 (PTAB May 15, 2019).

In the District of Arizona, since 2008, for “small” cases (defined as cases with less than five accusations), the median time-to-trial has been 28 months. *See* Ex. 2009. The Parallel District Court Case here is a “small case” with just one accusation—one patent asserted against one defendant. At a median time-to-trial of 28 months from the April 28, 2022 filing date of that case, the projected trial date will be around August 28, 2024, months before a Final Written Decision is expected here. Thus, Factor 2 also favors denying institution.

C. FACTOR 3 FAVORS DISCRETIONARY DENIAL BECAUSE THE PARTIES HAVE INVESTED A SIGNIFICANT AMOUNT OF TIME AND MONEY IN THE PARALLEL DISTRICT COURT CASE

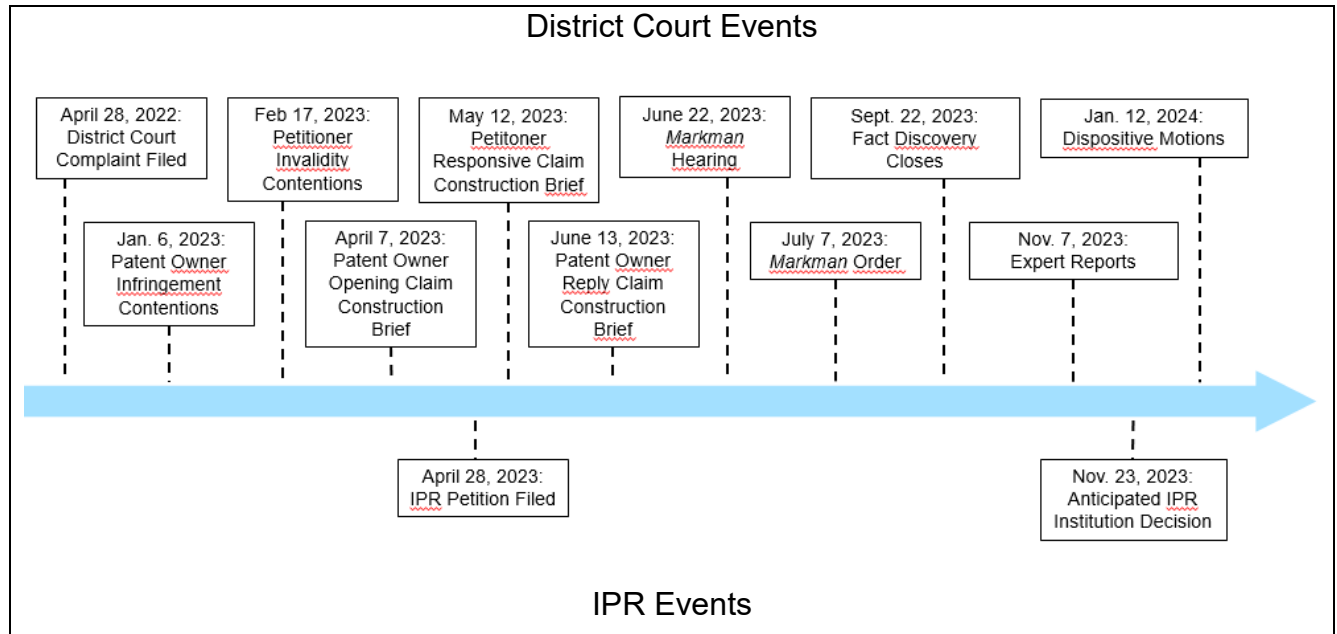
The Board finds this factor to weigh against institution and regularly exercises its discretion to deny institution where there is evidence of significant investment in the parallel proceeding. *See, e.g., E-One*, IPR2019-00161, Paper 16 at 6; *Vector Flow, Inc. v. Hid Glob. Corp.*, No. IPR2023-00353, 2023 WL 5167491, at *5 (PTAB July 17, 2023).

Here, Petitioner's assertions that “[t]he case is in the early stages of discovery and a claim construction hearing for the '166 patent has not yet occurred” are outdated and incorrect. Paper 1 at 69. On the contrary, like in *Vector Flow*, several key events have already happened in the Parallel District Court Case, including the exchange of infringement and invalidity contentions, filing of claim construction briefs, issuance of a Claim Construction Order, and

substantial completion of fact discovery. Fact discovery will have closed and the parties will exchange expert reports before the expected date of the Institution Decision. *See Vector Flow*, IPR2023-00353, Paper 8 at 21 (July 17, 2023). Patent Owner served its infringement contentions on January 6, 2023, and Petitioner served its invalidity contentions on February 17, 2023. Exs. 2006, 2007. Also, between December 2022 and February 2023, the parties exchanged interrogatories and document requests. Between April 7, 2023 to June 9, 2023, the parties fully briefed claim construction. The district court held a *Markman* Hearing on June 22, 2023, and issued a 23-page *Markman* Order on July 7, 2023. *See* Exhibit 2008.

Fact Discovery is also largely complete. Again, the parties are scheduled to complete written discovery in just few days, by August 25, 2023, complete fact depositions by September 22, 2023, serve expert reports by November 7, 2023, and complete expert depositions by December 15, 2023. *See* Ex. 2005. Dispositive motions are due January 12, 2024. *See* Ex. 2004.

In short, as shown in the case timeline below, the Parallel District Court Case has been pending for almost 16 months, claim construction is over, document discovery is on the verge of completion, fact depositions are scheduled to be completed in just over a month, and expert reports (along with potentially some expert depositions) will be completed by the time the Board is expected to issue its Institution Decision:



The parties and the district court have already made a significant investment in the Parallel District Court Case. This alone warrants weighing this factor in favor of exercising discretion to deny institution. But beyond that, Petitioner seems to have little regard for the implications of its delay, moving slowly at every turn. Petitioner not only waited a whole year to file its IPR Petition on the deadline to do so, it then waited three months before filing a motion to stay the Parallel District Court Case. *See Samsung Electronics Co., Ltd. et al v. Ancora Tech. Inc.*, IPR2020-01184, Paper 11 at 17 (PTAB Jan. 5, 2021) (exercising its discretion to deny institution where “the record does not show that Petitioner acted expeditiously in filing this Petition.”) (quotation omitted). Moreover, the Board is likely to waste its resources considering arguments that could be addressed in the

district court at summary judgment in early 2024 or at trial, before any Final Written Decision. Factor 3 favors denial.

D. FACTOR 4 FAVORS DISCRETIONARY DENIAL BECAUSE THE PETITION CHALLENGES THE SAME CLAIMS USING SUBSTANTIALLY THE SAME PRIOR ART THAT PETITIONER ASSERTS IN THE PARALLEL DISTRICT COURT CASE

“[I]f the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, th[at] fact has favored denial.” *Fintiv*, IPR2020-00019, Paper 11 at 12-13 (“The parties should indicate whether all or some of the claims challenged in the petition are also at issue in district court.”). The ’166 Patent recites 15 claims, including two independent claims, Claims 1 and 12. The Petition challenges all 15 claims. *See* Paper 1 at 6. The Parallel District Court Case also involves all 15 claims. *See* Ex. 2007.

Regarding the prior art cited in the Petition, the two primary references, Cognet and Simon, are asserted by Petitioner in the Parallel District Court Case too. *See* Ex. 2007 at 2-3. Aside from using the exact same references, Petitioner identified similar disclosures within those references in both the Petition here and its Invalidity Contentions in the Parallel District Court Case. *Compare, e.g.*, Paper 1 at 8-63 with Ex. 2007 at Exs. A2, A6.

Two of the three secondary references cited in the Petition (Brumfield and Ferrante) are also used by Petitioner in the Parallel District Court Case. *See id.* The third secondary reference, Leu, is not used in the Parallel District Court Case but is cited for only one of the seven grounds of invalidity asserted in the Petition. *See* Paper 1 at 6.

Thus, the Petition asserts the same claims and uses substantially the same evidence as in the Parallel District Court Case. This factor therefore weighs in favor of denying the Petition.

E. FACTOR 5 FAVORS DISCRETIONARY DENIAL BECAUSE THE PARTIES IN THIS CASE AND THE PARALLEL DISTRICT COURT CASE ARE THE SAME

Factor 5 favors denial of institution because “the petitioner [here] and the defendant in the parallel proceeding are the same party.” *See Fintiv*, IPR2020-00019, Paper 15 at 15. Petitioner incorrectly cites to *HP, Inc. v. Slingshot Printing LLC* for the proposition that having the same parties as in a parallel proceeding makes this factor neutral. Paper 1 at 70-71 (citing *HP, Inc. v. Slingshot Printing LLC*, IPR2020-01084, Paper 13 at 9 (PTAB Jan. 14, 2021)). On the contrary, in *HP*, the Board opined on factors 1, 2 and 5 together, and found that taken as a whole, they were neutral. *HP*, IPR2020-01084, Paper 13 at 9.

Factor 5 favors discretionary denial.

**F. FACTOR 6 FAVORS DISCRETIONARY DENIAL BECAUSE
THE PETITION IS WEAK ON THE MERITS**

A “balanced assessment of factors [related to discretionary denial] may include consideration of the merits.” *Fintiv*, Paper 15 at 15. However, “[a] full merits analysis is not necessary as part of deciding whether to exercise discretion not to institute, but rather the parties may point out, as part of the factor-based analysis, particular ‘strengths or weaknesses’ to aid the Board in deciding whether the merits tip the balance one way or another.” *Id.* Here, like in *Fintiv*, “some of Petitioner’s challenges contain certain weaknesses and, taken as a whole, the strengths of the merits do not outweigh other factors [that are] in favor of discretionary denial.” *Id.* at 16; *see also id.* at 17 (granting discretionary denial and noting that “[i]t is sufficient that Patent Owner has pointed out that Petitioner’s case, at least as to two of three independent claims, is a close call.”).

As noted above and in more detail in Section IV *infra*, for the limitations of independent Claims 1 and 12, which are also incorporated by reference in all of the challenged dependent claims (Claims 2-11 and 13-15), Petitioner cites only Cognet and Simon as disclosing those limitations. Petitioner does not allege that the limitations are disclosed in any of the other cited references, or that the limitations would have been obvious to a person of ordinary skill in the art in view of Cognet, Simon, the other cited references, or otherwise. Notably, Cognet was disclosed to

the Patent Office during prosecution of the application that led to the '166 Patent, and the '166 Patent issued anyway. Under 35 U.S.C. § 325(d), “[i]n determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31 [“Inter Partes Review”], the Director may take into account whether, and reject the petition or request because, *the same* or substantially the same *prior art* or arguments *previously were presented to the Office.*” 35 U.S.C. § 325(d) (emphasis added).

During prosecution of the application that led to the '166 Patent, the Examiner indicated that Cogent was in fact considered during prosecution. *See* Ex. 2010. Cogent is also cited on the face of the '166 Patent. *See* Ex. 1001. At least in the interest of efficiency, the Board should not consider instituting a proceeding that would require the Patent Office to consider the same reference again. *See Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (reflecting a “commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.”).

Regarding the Simon reference, as discussed further in Section IV *infra*, Petitioner fails to identify where in Simon all of the challenged independent claims' limitations can be found, as it must do to meet its burden to show that Simon anticipates the independent claims. Petitioner also does not allege that the

limitations of the independent claims—which are incorporated into each dependent claim—are disclosed in Simon or any of the cited secondary references, or would have been obvious to a person of ordinary skill in the art in view of those references, as it must do to meet its burden to show that the dependent claims are invalid as anticipated or obvious. For example, the first limitation of independent Claims 1 and 12 of the '166 Patent recites, “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). Instead of actually identifying in Simon a member that comprises a head portion as Petitioner should have, Petitioner merely argues that screws generally have a head portion. *See* Petition at 40 (“screws have a shaft portion with an external surface and a head portion with an exterior surface. . . .”). This reads a bit like the start of an inherency argument (although Petitioner did not argue inherency). Even if Petitioner had tried to meet the exacting standard for inherency, it would be unable to do so here, because *Petitioner’s own expert admits that not all screws include a head portion. See* Ex. 1002 at 20 (“Some screws are ‘headless’. . . .”). Accordingly, the Petition fails to identify any disclosure in Simon that meets at least the first limitation of each independent claim of the '166 Patent. That limitation is also included in each dependent claim by virtue of the fact that all limitations of the independent claims are incorporated

into the corresponding dependent claims. *See* 37 C.F.R. § 1.75 (“Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.”). For the dependent claims, Petitioner does not identify any portion of Simon or the cited secondary references as disclosing that limitation. Nor does Petitioner argue that the limitation would have been obvious in view of Simon or the secondary references.

In sum, as discussed above and further below, all of the elements of the independent claims are not met by either Cognet or Simon. And it follows that all of the elements of the dependent claims also are not met. (*See* 37 C.F.R. § 1.75).

For at least the reasons discussed above, this factor, at a minimum, tips the balance in favor of discretionary denial.

IV. THE BOARD SHOULD DENY INSTITUTION BECAUSE THERE IS NO REASONABLE LIKELIHOOD THAT PETITIONER WOULD PREVAIL WITH RESPECT TO ANY CHALLENGED CLAIMS

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”)). To show a claim is anticipated, the petitioner must show “each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference.” *Arbutus Biopharma Corp. v.*

Modernatx, Inc., 65 F.4th 656, 662 (Fed. Cir. 2023); *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

To show a claim is invalid as obvious under 35 U.S.C. § 103(a), 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). 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).

Petitioner asserts seven grounds of invalidity, the first three grounds cite Cognet as the primary reference, and the last four grounds cite Simon as the primary reference:

References	Basis	Claims Challenged
[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. As discussed above, the limitations recited in independent claims 1 and 12, are also incorporated by reference into each of the corresponding dependent claims. *See* 37 C.F.R. § 1.75 (“Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.”). Specifically, the limitations of Claim 1 are incorporated by reference into dependent Claims 2-11, and the limitations of Claim 12 are incorporated by reference into dependent Claims 13-15. *See, id*; Ex. 1001 at 15:45-16:6, 16:56-63. For each element of independent Claims 1 and 12, for every

ground of invalidity, Petitioner only alleges that the elements are disclosed in the primary references, Simon (for grounds 1-3) or Cognet (for grounds 4-7).

Petitioner does not allege that those elements are disclosed in the secondary references (i.e., Brumfield, Ferrante, or Leu), or that those elements would have been obvious in view of any of the references.

Accordingly, for all seven grounds of invalidity, the Board should find that Petitioner has not shown a reasonably likelihood that it will prevail with respect to any claim because Petitioner cannot show that each element of the independent claims is disclosed entirely in Cognet or entirely in Simon. In other words, based on the way it has chosen to construct its arguments, Petitioner's entire petition falls apart if it cannot meet its burden to show that each and every element set forth in Claim 1 or Claim 12 is found, either expressly or inherently, in Cognet or Simon. Petitioner has not done this. As explained in more detail below, the Board should therefore deny institution because it is not reasonably likely that Petitioner will prevail on any of its grounds.

A. THE PETITION FAILS TO SHOW ANY CHALLENGED CLAIM IS INVALID IN VIEW OF COGNET ALONE OR IN COMBINATION WITH ANY OTHER REFERENCE

Claims 1 and 12 each require a first bore extending along a first boar axis from a first aperture to a second aperture. Both claims 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. . . .

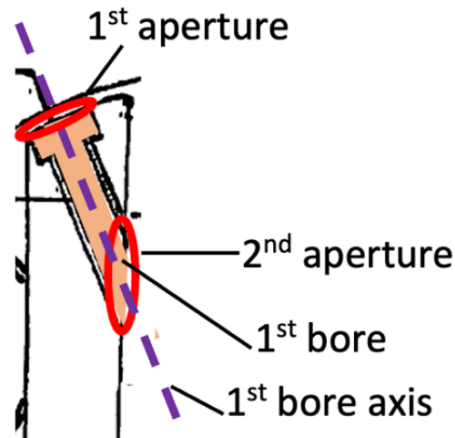
Ex. 1001 at 15:11-18, 16:24-31(emphasis added).

Cognet does not disclose a “first bore that extends along a first bore axis from a first aperture to a second aperture” as recited in Claims 1 and 12 and the Petition does not provide a compelling argument to the contrary. For Claim 1, Petitioner discusses the first bore in Sections V(A)(1)(f) and (g) of the Petition. *See* Paper 1 at 15-17. For Claim 12, the Petition merely refers back to Sections V(A)(1)(f) and (g). *See* Paper 1 at 29-30.

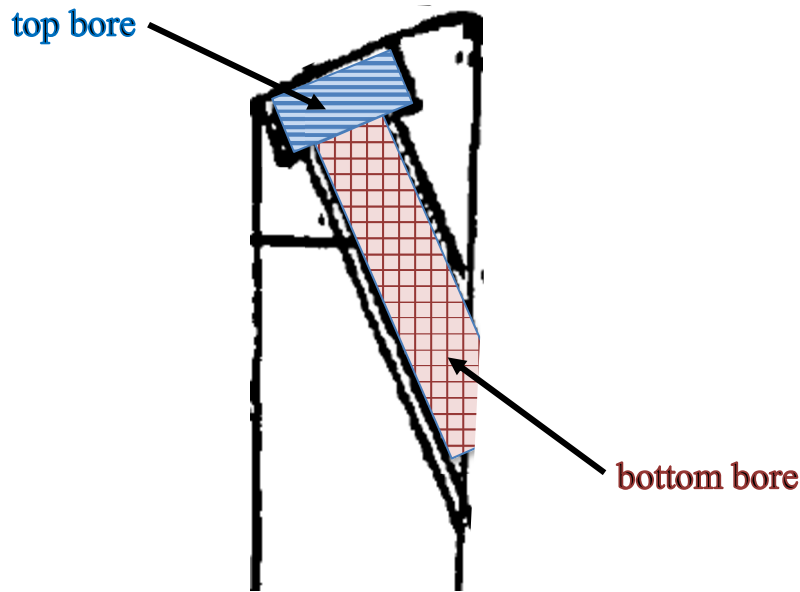
In Section V(A)(1)(g), the Petition states that “[a] bore is a usually cylindrical hole made by or as if by the turning or twisting movement of a tool.” Paper 1 at 16 (citing Ex. 1002, ¶ 58). Petitioner’s expert is more unequivocal, stating that “[a] bore *is* a cylindrical hole made by the spinning rotation of a twist drill cutting tool.” Exhibit 1002, ¶ 58 (emphasis added).

When discussing where the “first bore” that extends “along a first bore axis from a first aperture to a second aperture” can allegedly be found in Cognet, Petitioner refers to a “tunnel” disclosed in Cognet. It is unclear exactly where this tunnel is, but it is presumably shown in orange in the following annotated figure

from the Petition, which also provides Petitioner's assessment of allegedly where the relevant first aperture, second aperture and first bore axis are located:

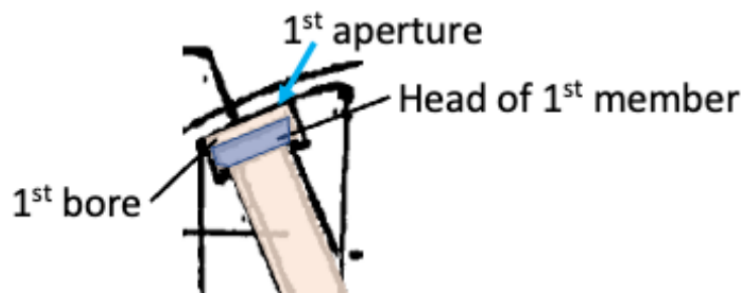


Paper 1 at 17. Petitioner alleges that the orange highlighted portion extends from a “first aperture” to a “second aperture,” both shown in red in its annotated drawing. What this argument overlooks, however, is that the orange highlighted portion, does not show a single “first” bore; it shows two bores, 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 narrower bore (the body of the “T”) (shown in pink grid in the figure below). In short, Cognet discloses a top bore (shown in blue) comprising a larger diameter cylindrical hole at the upper end, and a bottom bore (shown filled with a pink grid) comprising a smaller diameter cylindrical hole at the lower end:



Ex. 1003, FIG. 1.

The Petition correctly acknowledges this two-bore construct in its discussion of Claims 2 and 3. *See* Paper 1 at 23-24. First, 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 the first member 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,*

(but incorrectly and sloppily refers to the bottom bore as both the “first bore” and the “smaller diameter tunnel”):

Cogent discloses that the head of the screw (first member) ***has a larger diameter than the diameter than 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. Ex. 1002 ¶ 75.

Paper 1 at 24 (emphasis added). Petitioner's confusing nomenclature aside, it is clear that Cognet discloses two bores—a top bore (the top of the “T”) with a larger diameter that may receive the head of the screw, and a smaller diameter bottom bore (the body of the “T”) through which the head of the screw cannot pass.

The two-bore construct of Cognet is significant here because Claims 1 and 12 require a single bore, i.e., a “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, in order 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 bore that represents the top portion of the “T” and the narrower bore that represents the body portion of the “T”.

For at least this reason, Petitioner does not show that Cognet discloses a “first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member.” Nor does Petitioner allege that this limitation would have been obvious to a person of ordinary skill in the art by combining Cognet with any other reference. Accordingly, the Board should reject Petitioner's first three invalidity grounds because they are all premised on Cognet disclosing all of the limitations of Claims 1 and 12.

B. THE PETITION FAILS TO SHOW ANY CHALLENGED CLAIM IS INVALID IN VIEW OF SIMON ALONE OR IN COMBINATION WITH ANY OTHER REFERENCE

As discussed above, Petitioner also fails to show at least that Simon discloses a “head portion” of a first member, as required by independent Claims 1 and 12, and Petitioner therefore cannot meet its burden to show there is a reasonable likelihood that it will prevail with respect to any of its invalidity grounds premised on Simon. In addition, Petitioner's invalidity grounds improperly rely on a misreading of the “terminal end” limitation of Claims 1 and 12, further dooming its invalidity arguments related to Simon. For each of these independent reasons, the Board should find that Petitioner fails to show that its invalidity grounds premised on Simon are reasonably likely to prevail.

1. PETITIONER FAILS TO IDENTIFY A FIRST MEMBER HAVING A HEAD PORTION IN SIMON

The first limitation of independent Claims 1 and 12 of the '166 Patent, recites, “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). Simon, however, does not disclose a first member comprising a head portion, as recited in Claims 1 and 12.

For Claim 1, Petitioner discusses the head portion limitation in Section V(D)(1)(b) of the Petition. *See* Paper 1 at 40. For Claim 12, the Petition merely refers back to Section V(D)(1)(b). *See* Paper 1 at 53. Yet inexplicably, Section V(D)(1)(b) of the Petition does not identify any actual disclosure in Simon of a first member that comprises a head portion. Instead, Petitioner merely argues that screws generally have a head portion. *See* Petition at 40 (“screws have a shaft portion with an external surface and a head portion with an exterior surface. . . .”). This unsupported statement does not satisfy Petitioner's burden to show “each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference.” *Arbutus*, 65 F.4th 656, 662. 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 could never meet the exacting standard for inherency. Perhaps most importantly, the argument is even less compelling

because it *contradicts Petitioner's own expert*, who opined that not all screws include a head portion. *See* Ex. 1002 at 20 (“Some screws are ‘headless’. . .”).

2. PETITIONER DOES NOT ALLEGE THAT THE “HEAD PORTION” RECITED IN THE DEPENDENT CLAIMS IS OBVIOUS IN VIEW OF SIMON AND ANY OF THE SECONDARY REFERENCES

Dependent Claims 5 and 9-11 do not reference the “head portion” limitation recited in Claims 1 and 12, discussed above, but that limitation is incorporated by reference into those claims. *See* 37 C.F.R. § 1.75. When discussing those claims in particular, the Petition does not address that limitation by reference to Simon or any other reference. *See* Paper 1 at 25, 60-61, 62. And as noted above, Petitioner failed to show that Simon discloses that limitation. Accordingly, Petitioner fails to show that the inventions recited in Dependent Claims 5 and 9-11—including the first member comprising a head portion—are invalid or obvious in view of the cited references.

Dependent Claims 2-4, 6-8, and 13-15 further limit the “head portion” limitation recited in Claims 1 and 12. Petitioner's grounds allege those claims are obvious in view of Simon and one of the secondary references. However, the cited disclosures do not show that the inventions recited in those claims—including a first member comprising a head portion—would have been obvious to a person of ordinary skill in the art. In addition, Petitioner fails to argue that a person of ordinary skill in the art would have been motivated to combine the cited

disclosures to practice the claimed inventions. For at least those reasons, the Board should find that Petitioner is not reasonably likely to show that the dependent claims are invalid.

Claims 2, 6, and 13 recite “the head portion of the first member resides at least partially within the first bore.” For Claim 2, Petitioner discusses a disclosure from the secondary reference Leu, but does not allege that the claimed invention would have been obvious in view of Simon and that disclosure:

Claim 2 limits claim 1 by requiring the head portion of the first member to reside at least partially within the first bore. Leu discloses a screw (12) (first member) with threads (17) near the screw head. Ex. 1009, 4:5. These threads (17) have corresponding threads (15) within the bore (11) on the nail head (10), allowing for the screw head to lock into and sink within the first aperture (11). Ex. 1009, 4:63-67; 5:1-5. See cropped Figures 2 and 3 below. Ex. 1002 ¶ 168.

Paper 1 at 65-66. For Claims 6 and 13, Petitioner only refers to the quoted paragraph above. *See id.* at 67 (discussing Claim 6), 68 (discussing Claim 13).

That paragraph merely discusses a disclosure from Leu, not whether the claimed inventions would have been obvious to a person of ordinary skill in the art in view of Simon and that disclosure. Accordingly, Petitioner fails to allege that the inventions recited in Claims 2, 6, and 13 are obvious in view of Simon and Leu.

Claims 3 and 7 recite, “the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture.” For Claim 3, Petitioner cites to another portion of Leu, but again does not allege that the claimed invention would have been obvious in view of Simon and Leu:

Claim 3 further limits claim 2 by requiring the exterior surface of the head portion of the first member abut the interior surface of the first bore at the first aperture. Leu discloses a countersink or shoulder cavity recess inside at the entrance to the first bore hole, which is a preferred manner to prevent a screw from entering past the preferred penetration depth of the screw. The internal shoulder serves to block further entry of the screw at the moment when the screw head contacts the internal surface of the shoulder. The underside (exterior surface) of the head of the screw (first member) will abut the interior surface of the first bore as shown below. Ex. 1002 ¶ 169.

Paper at 66-67. For Claim 7, Petitioner only refers to the quoted paragraph above. *See id.* at 67-68. Again, that paragraph merely discusses a disclosure from Leu, not whether the claimed inventions would have been obvious to a person of ordinary skill in the art in view of Simon and that disclosure. Accordingly, Petitioner fails to allege that the inventions recited in Claims 2, 6, and 13 are obvious in view of Simon and Leu.

Claim 4 recites “the head portion of the first member comprises a torque transmitting aperture.” For that claim, Petitioner maintains its misplaced reliance

on Simon for disclosing the head portion, and cites to secondary reference Ferrante merely for the disclosure of a torque transmitting aperture:

Simon discloses a screw (first member). Ex. 1008, [0039] and [0053]. Ex. 1002 ¶¶ 42, 158. A POSA would assume that the screw head in Simon would have an aperture in the screw head to through [*sic*] which torque could be applied, but Simon does not explicitly state that the screw comprises such an aperture. Ferrante discloses a screw with a hex socket (Ex. 1007, [0062]), which is a torque transmitting aperture. This aperture is clearly seen in Ferrante figure 6 below. Ex. 1002 ¶ 158.

Paper 1 at 58-59. Although that paragraph alleges Ferrante discloses a torque transmitting aperture, it does not allege that it would have been obvious to combine that torque transmitting aperture with the screw disclosed in Simon. Accordingly, Petitioner fails to allege that the invention recited in Claim 4 is obvious in view of Simon and Ferrante.

Finally, Claims 8, 14, and 15 recite, “the head portion of the first member is tapered.” For Claim 8, Petitioner again maintains its misplaced reliance on Simon for disclosing the head portion, and cites to secondary reference Ferrante merely for the disclosure of a taper:

Claim 8 further limits claim 1 to require the head portion of the first member to be tapered. Simon discloses a locking screw (Ex. 1008, [0039] and [0053]). A POSA would assume this discloses a tapered

head, but Simon does not explicitly state that the head is tapered.

Ferrante discloses a screw with a tapered head at least in figure 2 shown below (cropped). Ex. 1002 ¶ 159.

Paper 1 at 59. For Claims 14 and 15, Petitioner merely refers to the quoted paragraph above. *See id.* at 61. Although that paragraph alleges Ferrante discloses a screw with a tapered head, it does not allege that it would have been obvious to combine that tapered head with the screw disclosed in Simon. Accordingly, Petitioner fails to allege that the invention recited in Claims 8, 14, and 15 are obvious in view of Simon and Ferrante.

In addition to failing to show how the cited disclosures from the secondary references could combine with the disclosure in Simon to meet the limitations recited in Claims 2-4, 6-8, and 13-15, Petitioner does not identify any motivation that a person of ordinary skill in the art would have had to combine the secondary references with Simon. Instead, Petitioner merely asserts that the references disclose intramedullary nails, an argument that might concern whether the secondary references are analogous art, but which does not address motivation to combine the references. For Leu, Petitioner merely argues:

Leu is analogous art because it is an intramedullary nail secured by multiple screws. It 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]). Ex. 1002 ¶ 167.

Paper 1 at 63-64. Likewise, for Ferrante, Petitioner merely argues:

Ferrante is analogous art because it discloses orthopedic screws being used in an intramedullary nail. It would have been obvious to a POSA to use the screws disclosed in Ferrante with the intramedullary nail disclosed in Simon because the screw and nail in Ferrante (Ex. 1007, Fig. 14-15; ¶¶ 36- 37) are performing the same function in the same way as the screw and nail in Simon. Ex. 1002 ¶ 157.

Paper 1 at 58.

Accordingly, the Board should find that the Petition fails to establish a reasonable likelihood that Petitioner would prevail in showing unpatentability of any of the Challenged Claims in view of Simon and the secondary references.

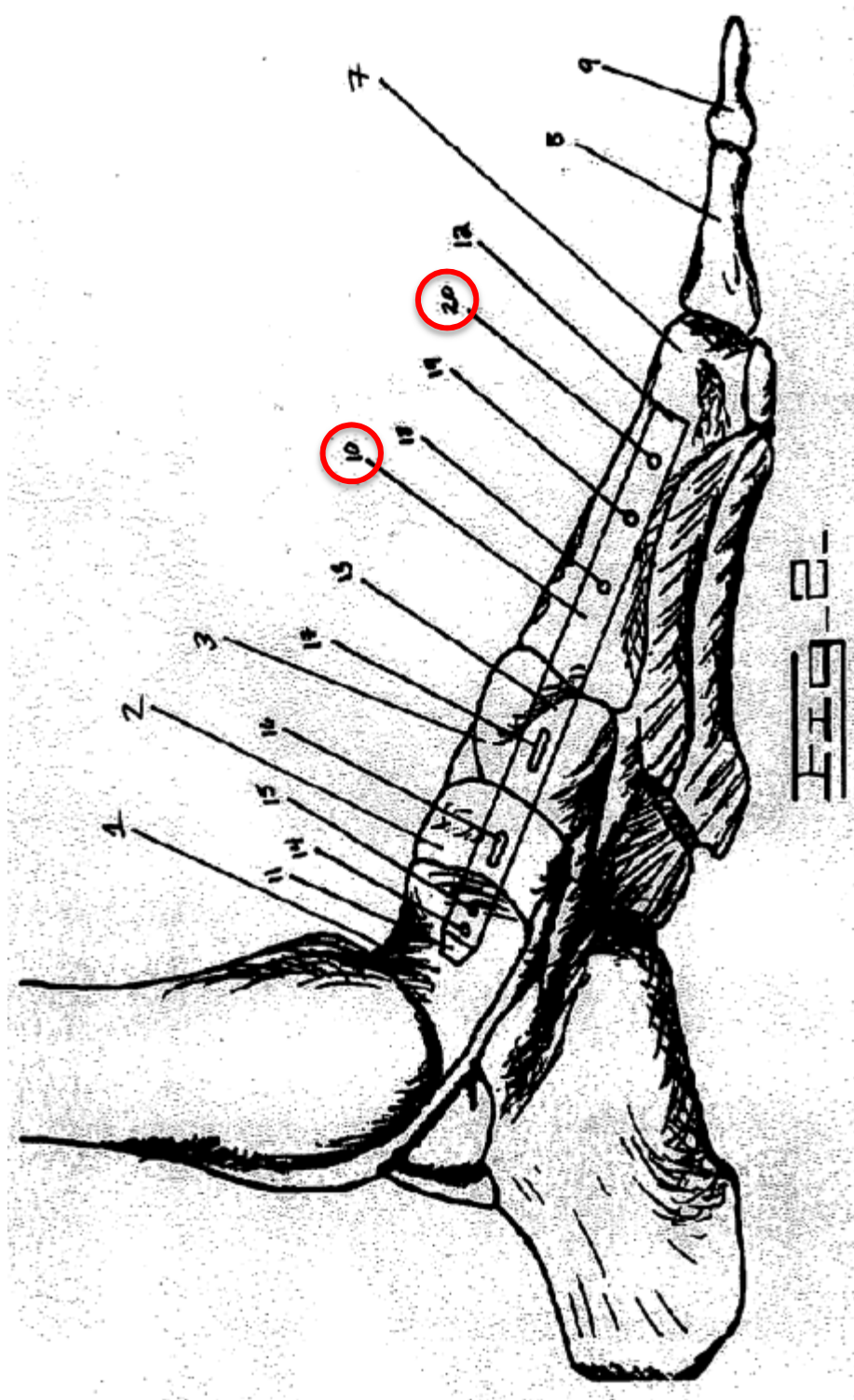
3. THE BOARD SHOULD NOT ACCEPT PETITIONER'S REVISION OF THE CLAIMS TO SUPPORT ITS ARGUMENT THAT SIMON DISCLOSES A FIRST APERTURE AT A "TERMINAL END" OF THE FIRST END OF THE THIRD ELONGATED BODY

Each ground based on Simon should be denied because Simon's first member does not have a head portion (*see supra*), but Simon is also missing an aperture at a "terminal end" of the first end of the third elongated body, as required by Claims 1 and 12:

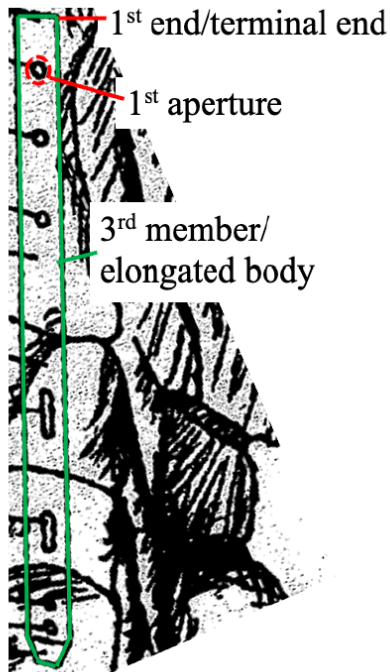
a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis, wherein the third member comprises a first aperture ***at a terminal end of the first end*** of the third elongated body

Ex. 1001 at 15:11-18, 16:24-31 (emphasis added). 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. As Petitioner’s expert testified in the Parallel District Court Case, the terminal end is “the very end of the nail before there’s just air above it.” Ex. 2011 at 188:21-25.

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]). An annotated version of Simon’s Figure 2, copied below, shows the location of hole (20) in relation to nail (10).



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 establish a reasonable likelihood that Petitioner would prevail in showing unpatentability of any of the Challenged Claims in view of Simon, at least because Petitioner has not shown that Simon discloses a device with a first aperture at a terminal end. All grounds premised in whole or in part on Simon should not be instituted.

V. CONCLUSION

Discretionary denial is warranted here based on duplicating efforts while the Parallel District Court Case moved ahead, and denial of institution is also warranted because of the substantive deficiencies in Petitioner’s invalidity

arguments. For either (or both) of these independent reasons, Patent Owner respectfully requests that the Board decline to institute *inter partes* review of the '166 Patent.

Respectfully submitted,

Dated: August 23, 2023

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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 8,024 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: August 23, 2023

Respectfully submitted,

/David G. Lindenbaum/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), I hereby certify that on August 23, 2023, 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 Petition:

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