Paper 15 Date: November 17, 2023

### 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.

IPR2023-00894 Patent 11,298,166 B2

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Before JEFFREY N. FREDMAN, ROBERT A. POLLOCK, and JAMIE T. WISZ, *Administrative Patent Judges*.

POLLOCK, Administrative Patent Judge.

DECISION
Granting Institution of *Inter Partes* Review 35 U.S.C. § 314(a)

#### I. INTRODUCTION

### A. Background and Summary

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

We have authority under 35 U.S.C. § 314 and 37 C.F.R. § 42.4. After considering the Petition, the Preliminary Response, the Reply, the Sur-reply, and the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of claims 1–15 of the '166 patent, based on all of the grounds identified in the Petition. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); 37 C.F.R. § 42.108(a) ("When instituting post-grant review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.").

#### B. Real Parties-in-Interest

Petitioner identifies itself, Fusion Orthopedics, LLC, as the real party-in-interest. Pet. 1. Patent Owner identifies itself, Extremity Medical, LLC, as the real party-in-interest. Paper 5, 1.

### C. Related Matters

The '166 patent is at issue in *Extremity Medical, LLC. v. Fusion Orthopedics, LLC*, No. 2:22-cv-00723-PHX-GMS (D. Ariz.) ("the related litigation"). *See* Pet. 1; Paper 5, 1; Exs. 1010, 1011, 2002.

# D. Asserted Challenges to Patentability

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

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

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Mr. Leonel Dominguez. Ex. 1002. Considering his background and experience, Mr. Dominguez is amply qualified to testify as

<sup>&</sup>lt;sup>1</sup> Cognet, French Patent Appl. Publication No. FR 2,861,576 A1, pub. May 6, 2005. Exs. 1003, 1004 (Certified English Translation).

<sup>&</sup>lt;sup>2</sup> Brumfield, US 4,827,917, issued May 9, 1989. Ex. 1006.

<sup>&</sup>lt;sup>3</sup> Ferrante, US 2003/0187447 A1, pub. Oct. 2, 2003. Ex. 1007.

<sup>&</sup>lt;sup>4</sup> Simon, US 2006/0206044 A1, pub. Sept. 14, 2006. Ex. 1008.

<sup>&</sup>lt;sup>5</sup> Leu, US 6,270,499 B1, issued Aug. 7, 2001. Ex. 1009.

one of ordinary skill in the art as defined in section II.B, below. *See id.* ¶¶ 4–23, Attachment A.

# E. The '166 Patent and Relevant Background

The '166 patent, titled "Intraosseous Intramedullary Fixation Assembly and Method of Use," is directed to orthopedic implant devices for correcting deformities and the fusion of angled joints and bones. Ex. 1001, code (57), 1:25–28. Orthopedic implant devices, such as intramedullary nails, plates, rods and screws are often used to repair or reconstruct hand and foot bones. *Id.* at 1:28–33.

Figure 18 of the '166 patent is reproduced below.

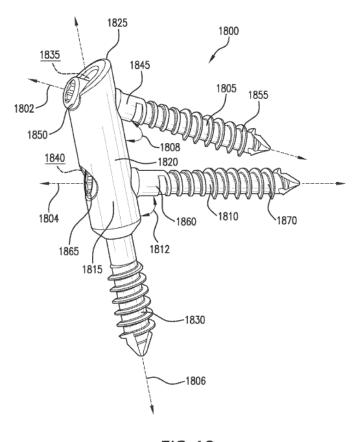


FIG. 18

Figure 18 shows a perspective view of an intramedullary fixation assembly 1800 having a plurality of lag screw members 1805, 1810. *Id.* at 4:11–14, 13:22–24. As assembled, "lag screw members **1805** and **1810** coupled to a tapered screw member **1815**... apply compression at multiple points on the bone fragment surface." *Id.* at 13:24–26.6 "Each of the lag screw members **1805** and **1810** forms an [sic, a] fixed acute angle with the tapered screw member **1815**, with these angles being predetermined by, for example, a surgeon to fix the bones in a human body." *Id.* at 13:31–34. In some embodiments,

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

*Id.* at 13:38–47.

### F. Challenged Claims

Petitioner challenges claims 1–15 of the '166 patent. Pet. 4.

Challenged claims 1 and 12 are independent, and the remaining challenged claims depend, directly or indirectly, either from independent claims 1 or 12.

Ex. 1001, 14:62–16:64. Claim 1, reproduced below, is illustrative of the subject matter challenged (paragraphing and labeling of limitations as added

<sup>&</sup>lt;sup>6</sup> With reference to challenged independent claims 1 and 2 (discussed below), we understand lag screw members 1805 and 1810 to map to claimed "first member" and "second member," respectively. Tapered screw member 1815 of Figure 18 maps to the claimed "third member."

in Petitioner's Specific Grounds; bolding added to indicate elements argued in the Patent Owner Preliminary Response).

1. An assembly for bone fusion, comprising:

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

1[a][ii]: wherein the first member comprises a shaft portion having an external surface and **a head portion** having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;

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

1[b][ii]: wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;

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

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

1[c][iii]: a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member

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

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

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

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

1[e]: wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture

1[f]: wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture

1[g]: wherein the first angle is in the range of about 0 degrees to about 90 degrees

1[h]: wherein the second angle is in the range of about 0 degrees to about 90 degrees

1[i]: wherein the second bore axis is substantially perpendicular to the third longitudinal axis.

Ex. 1001, 14:62–15:44; see Pet. 8–23. Independent claim 12 is substantially similar to claim 1 but omits element 1[h], "wherein the second angle is in the range of about 0 degrees to about 90 degrees." See Ex. 1001, 16:7–56.

#### II. ANALYSIS

## A. Legal Standards

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

*Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

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

Petitioner also contends that the challenged claims are unpatentable as obvious under § 103. Pet. 6. A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary

skill in the art to which the claimed invention pertains. See KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if any. Traham v. John Deere Co., 383 U.S. 1, 17–18 (1966).

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

<sup>&</sup>lt;sup>7</sup> Patent Owner does not rely on secondary considerations in its Preliminary Response.

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

### B. Person of Ordinary Skill in the Art

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

Petitioner proposes that a person of ordinary skill in the art would possess

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

Pet. 6–7 (citing Ex.  $1002 \, \P \, 29$ ). Patent Owner neither objects to the above definition nor offers a different definition of a person of ordinary skill in the art in its Preliminary Response. *See generally* Prelim. Resp. 1–37.

On the current record, and for the purposes of this decision, we accept Petitioner's proposed definition, as it appears consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '166 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may] reflect[] an appropriate level" as evidence of the

ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

#### C. Claim Construction

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

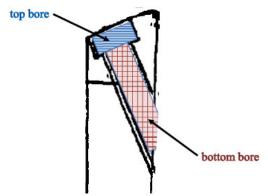
Petitioner bears the burden of stating "[h]ow the challenged claim is to be construed." 37 C.F.R. § 42.104(b)(3). But only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795,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

#### 1. "bore"

Claim 1, element 1[c][iii] and claim 12, element 12[c][iii] recite "a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member." Relying on the testimony of Mr. Dominguez, Petitioner proposes a construction of "bore" as "a usually cylindrical hole made by or as if by the turning or twisting

movement of a tool." Pet. 16 (citing Ex.  $1002 \, \P \, 58$ ). In this respect, Mr. Dominguez testifies that "[a] bore is a cylindrical hole made by the spinning rotation of a twist drill cutting tool. It is typically made by removing material from a solid or hollow object, similar to a tunnel or orifice." Ex.  $1002 \, \P \, 58$ .

Referencing Figure 1 of Cognet, Patent Owner argues that the claim term "bore" excludes a tunnel made by "two adjacent bores." *See* Prelim. Resp. 21–25; Sur-reply 1–4. Patent Owner's position is illustrated by the following figure from its Preliminary Response. *See* Prelim. Resp. 23.



The above figure represents Patent Owner's interpretation of a portion of Cognet's Figure 1, in which a passage having two distinct diameters is labeled as having a "top bore" and a "bottom bore." *Id.* Patent Owner bases this interpretation on Mr. Dominguez's testimony that "[a] bore is a cylindrical hole..." (Sur-reply 2 (citing Ex. 1002 ¶ 58)), and further notes that in connection with claims 2 and 3, Petitioner refers to this portion of Cognet as comprising a "first bore" and "a smaller diameter tunnel." (Prelim. Resp. 23 (citing Pet. 23–24)).

In response, Petitioner argues that nothing in the Petition or Mr. Dominguez's declaration admits that a uniformly cylindrical shape is the only possible configuration for the claimed bore. Reply 3–4. Consistent with

this position, Petitioner argues that during prosecution of related applications, Patent Owner itself identified in the specification a "bore" that tapers along its length, and acknowledged that combination of "recess 8" and "hole 10" of the Dierks reference constituted a single bore despite having two distinct diameters. Reply 1–3 (citations omitted).8

On the limited record before us, and insofar as nothing in the plain language of the claims appears to limit the interior shape of a bore to a regular cylinder, as Patent Owner appears to argue, we preliminarily construe 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. The parties are, nevertheless, invited to further address this construction at trial.

### 2. "At a terminal end"

Claim 1, element 1[c][ii] and claim 12, element 12[c][ii] recite "wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body." Relying on the testimony of

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<sup>&</sup>lt;sup>8</sup> Although not necessary to our determination, Patent Owner's position also appears inconsistent with the present claims. Dependent claims 8, 14, and 15 specify that "the head portion of the first member is tapered." See Ex. 1001, 15:61–62, 16:59–62. Given that "the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture," and/or "resides at least partially within the first bore [of the third member], we infer that the first bore of the third member may encompass a tapered or partially tapered interior aspect. See Ex. 1001, 15:48–50 (claim 3), 15:55–58 (claim 6). Admittedly, however, this reading of the dependent claims has not been addressed by experts for either party.

Mr. Dominguez, Petitioner argues that one of ordinary skill in the art would understand the claim phrase "at the terminal end" to indicate "a location nearer the terminal or proximal end, as opposed to merely along the shaft of the nail [(i.e., the third member)] at any location, or at the distal end." Pet. 15 (citing Ex. 1002 ¶ 55). Seeking to distinguish Simon (Ex. 1008), Patent Owner argues that Petitioner misconstrues "at a terminal end" to mean "near a terminal end." Prelim. Resp. 35; Sur-reply 4–5.

In support of its construction, Petitioner argues that, during prosecution of parent application serial No. 12/658,680, Patent Owner amended claim 1 to recite "a first aperture at a terminal end." Reply 4 (citing Ex. 1015, 21:10–11). According to Petitioner, "Patent Owner took the position during prosecution of the '680 patent that the separation between first aperture 1130 and terminal end 1120 illustrated in Figure 11 nevertheless provides written description support for 'the first aperture at a terminal end." Reply 5 (citing Ex. 1015, 78:12–13 (identifying "a first aperture [1130, Fig. 11,  $\P$  [0060] and/or 1630, Fig. 16,  $\P$  [0070]] at a terminal end [1120, Fig. 11, ¶[0060]] of the second end of the second elongated body"), 108:11 (referencing "[t]he bone fusion assembly 800 of the present invention, as claimed in independent claim 1 and as shown in Figure . . . 11"), 109:10–11 ("The second elongated body further comprises a first aperture 1130 at a terminal end 1120 of the second end of the second elongated body, and a bore extending along a third axis 1102 from the first aperture 1130 to a second aperture on an exterior surface 1135 of the second screw member 810.")). According to Petitioner, "Figure 11 shows that terminal end 1120 is at the surface of element 1110, while aperture 1130 is recessed well below that surface, i.e., 'at some distance' away from it." *Id*.

Considering this prosecution history, Petitioner argues that "Patent Owner may not now argue that a comparable separation between Simon's end and hole 20 fails to do so as well." *Id.* In response, Patent Owner contends that Petitioner's argument fails because Mr. Dominguez did not expressly consider the prosecution history relied on by Petitioner. Sur-reply 4–5.9 We do not, however, require Mr. Dominguez's guidance in reading the cited portions of the intrinsic record. In this respect, we note that claim construction is a legal determination and while expert testimony "can shed useful light on the relevant art'...it is 'less significant than the intrinsic record in determining 'the legally operative meaning of claim language'." *Phillips v. AWH Corp.*, 415 f.3d 1303, 1317 (Fed. Cir. 2005) (citations omitted); *see id.* at 1318 ("a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.").

Taken as a whole, the record before us would appear to support Petitioner's contention that the aperture of claim elements 1[c][ii] and 12[c][ii] need not align precisely with the terminal end as Patent Owner argues. Consistent with our views here, we note that the District Court similarly rejected Patent Owner's construction of "terminal end" as meaning

<sup>&</sup>lt;sup>9</sup> We also note Mr. Dominguez's somewhat opaque testimony seeming to suggest that, although in some circumstances the terms "nail head," "terminal end," and "nail termination" might be used synonymously, "[n]ail termination is more specific than that. It's really the very end of the nail before there's just air above it." *See* Ex. 2011.

"the very tip" of the third member, and declined to otherwise construe the term. See Ex. 3002, 13–15.

Further, and while we agree with Petitioner that the "at a terminal end" does not demand placement of the first aperture at the extreme proximal end of third member, the present record provides scant basis to determine the maximum distance the first aperture may be from the very tip of the third member and still fall within the scope of the asserted claims. Would the ordinarily skilled artisan understand the term to encompass a first aperture only within a few millimeters of the tip of the third member, the proximal 10% of the length of the third member, or some other value? Relatedly, we are unsure what basis one of ordinary skill would use to measure the distance between the tip of the third member and the first aperture—e.g., from the tip to the midline of the first aperture, or from the tip to the closest point of the first aperture. Accordingly, and absent a more robust discussion of the prosecution history and any other relevant evidence, we decline to further construe the meaning of this term as understood by one of ordinary skill in the art. But see, e.g., Micron Tech., Inc. v. Unification *Techs. LLC*, IPR2021-00343, Paper 42 at 45–46, 57 (PTAB July 8, 2022) (declining to reach a final decision on the merits where the panel could not ascertain claim scope with reasonable certainty). The panel may revisit this issue on a fuller record.

# D. Merits Analysis

Petitioner asserts seven grounds involving five references. Pet. 6. Patent Owner does not presently challenge the prior art status of any asserted reference. *See* Prelim. Resp. Grounds 1–3 are based on Cognet, either alone or with Brumfield or Ferrante. Grounds 4–7 are based on Simon, either

alone or with Ferrante, Cognet, or Leu. Patent Owner opposes Petitioner's reliance on Cognet and Simon in Grounds 1–3 and 4–7, respectively, for disclosing limitations recited in the independent claims. We focus below on Petitioner's anticipation grounds based on Cognet (Ground 1) and Simon (Ground 4).

# 1. Ground 1: Anticipation by Cognet

As Ground 1, Petitioner challenges independent claim 1 and its dependent claims 2–7 and 9 and independent claim 12 and its dependent claim 13 as anticipated by Cognet. Pet. 6, 8–32. Petitioner's challenge includes an element-by-element comparison of the claims to the cited art (*id.* at 9–32). Patent Owner opposes. Prelim. Resp. 20–25. We begin with an overview of the asserted reference and focus our analysis on the disputed elements of independent claim 1.

# a) Overview of Cognet (Exhibit 1004)

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

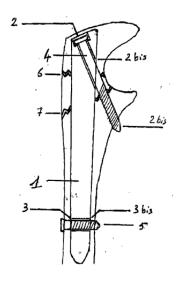
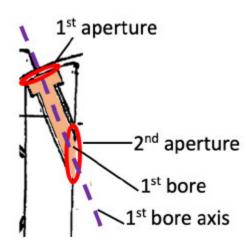


Figure 1 shows an exemplary device of Cognet in sagittal section. *Id.* at 3:21–23. According to Cognet, the device "consists of a nail (1) having a proximal orifice or tunnel (2) and at least two distal orifices facing one another or one distal tunnel (3) and into which screws are introduced, one in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

b) Whether Cognet discloses "a first bore extending along a first bore axis from the first aperture to a second aperture"

Relying on the testimony of Mr. Dominguez, Petitioner argues that Cognet discloses each limitation of independent claim 1. Pet. 8–23; Ex. 1002 ¶¶ 38–71. Patent Owner contends that Petitioner's argument fails because Cognet fails to disclose claim element 1[c][iii]: a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member. Petitioner illustrates its position with respect to element 1[c][iii] with reference to the following illustration.



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

Patent Owner, however, contends that the illustrated portion of 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." Prelim. Resp. 24. According to Patent Owner:

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".

*Id.* at 24–25. So construed, Patent Owner contends that the Petition "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." *Id.* at 25.

Contrary to Patent Owner's analysis, we preliminarily construe a "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 a cylindrical cross-section, and which do not exclude and may include holes or passages having tapered or stepped longitudinal cross-sections." *See supra* Section II.C.1. As such, and on the limited record before us, Cognet discloses a bore and further satisfies all elements of claim phrase 1[c][iii].

#### c) Conclusion as to Ground 1

In view of the above preliminary construction, Petitioner establishes sufficiently that Cognet discloses claim element 1[c][iii]. Patent Owner does not dispute any other element of Ground 1 in its Preliminary Response. Having considered the evidence of record, we determine that Petitioner has established sufficiently that these remaining elements are also disclosed in Cognet. According, and solely for the purpose of institution, Petitioner has demonstrated a reasonable likelihood that Cognet anticipates claim 1.

### 2. Ground 4: Anticipation by Simon

As Ground 4, Petitioner challenges independent claim 1 and its dependent claims 4, 5, 8, 10, and 11 and independent claim 12 and its dependent claims 14 and 15 as anticipated by Simon. Pet. 6, 37–58. Petitioner's challenge includes an element-by-element comparison of the claims to the cited art (*id.* at 38–58). Patent Owner opposes. Prelim. Resp. 25–35. As above, we begin with an overview of the asserted reference and focus our analysis on independent claim 1.

### a) Overview of Simon (Exhibit 1008)

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

Figure 1 of Simon is reproduced below.

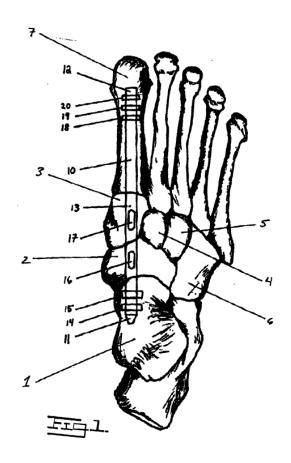


Figure 1 is a top-down view of a right human foot, depicting the bones and intramedullary nail 10 running through the mid-foot region. *Id.* ¶ 53. Simon discloses that "the proximal end 11 of the implant or intramedullary nail 10 is attached with at least one fastener []or locking screw, with two depicted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

b) Whether Simon discloses "a head portion"
Relying on the testimony of Mr. Dominguez, Petitioner argues that
Simon discloses each limitation of independent claim 1. Pet. 37–50;
Ex. 1002 ¶¶ 111–132. Patent Owner first contends that Petitioner's argument

fails because Simon fails to disclose the head portion of claim element 1[a][ii] ("wherein the first member comprises a shaft portion having an external surface and **a head portion** having an exterior surface"). Prelim. Resp. 26–27; Sur-reply 4 (noting that Petitioner does not address the alleged failure to identify a head portion in its Reply).

As an initial matter, Petitioner appears to identify one or more of elements 18–20 of Simon's Figure 1 as the claimed first member. *See* Pet. 40. But Figure 1 of Simon is a low-resolution drawing that does not clearly differentiate elements 18–20 as having distinct head and shaft portions. *See* Ex. 1008, Fig. 1. However, as noted in the Preliminary Response, when discussing support for element 1[a][ii] in Simon, Petitioner references its parallel discussion regarding Cognet. *See* Prelim. Resp. 26; Pet. 40 (citing "section V.A.1.b" of the Petition). In this parallel discussion, Petitioner asserts that the Cognet's "screw comprises a head portion which has an exterior surface." Pet. 11 (citing Ex. 1002 ¶ 42a).

In contrast to its assertion regarding Cognet, Petitioner does not expressly state that Simon's screws have a head but, more generally, that the entirely of element 1[a][ii] is satisfied because "Simon discloses elements 18, 19, and 20 as being locking screws [Ex. 1008, [0053]), interlocking cortical screws, or transfixation screws (Ex. 1008, [0039])." *Id.* at 40 (further citing Ex. 1002 ¶ 116). And in a related discussion pertaining to the claimed second member (which does not recite a head), Petitioner further states that

screws have an elongated body that extends from a first end (the tip of the screw) to a second end (the head of the screw) along a longitudinal axis. Ex.  $1002 \, \P \, 42$ . Figure 1 of Simon discloses a second screw (second member) (elements 14 or 15 of Figure 1) (Ex. 1008, [0053]). Simon further discloses that the second screw is also a locking screw (Ex. 1008, [0053]),

interlocking cortical screw, or transfixation screw (Ex. 1008, [0039]), and thus discloses this claim element. Ex.  $1002 \, \P \, 117$ . *Id.* at 40-41.

According to Patent Owner, the above statement fails to 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." Prelim. Resp. 26 (citing *Arbutus Biopharma Corp. v. Modernatx, Inc*, 65 F.4th 656, 662 (Fed. Cir. 2023)). Patent Owner further argues that any inherency argument is undercut by Mr. Dominguez's testimony that "[s]ome screws are 'headless'...." *Id*. (citing Ex. 1002 ¶ 42a).

Petitioner has a better argument at this stage of the proceeding. First, on the present record, we do not read paragraph 42a of Mr. Dominguez's declaration as undercutting Petitioner's position. Paragraph 42 of his declaration generally discusses the geometry of bone screws used in orthopedic surgery. See Ex. 1002 ¶ 42. Quoted in full, the sentence relied on by Patent Owner states that "[s]ome screws are 'headless' or have a 'threaded conical taper' shape with threads running all the way to include the head *intended to be fully sunk in bone*." *Id.* ¶ 42a (emphasis added). Absent evidence to the contrary, we understand Mr. Dominguez's testimony to indicate that while headless screws are known, at least those at issue in his statement are used to drive the screw entirely into the bone. The quoted passage, however, does not appear to apply to screw heads that instead make contact with a fixation assembly. In the present case, for example, we understand the head of the first member to be in contact with the third member, rather than with bone. See claim element 1[e] ("wherein the first member couples to the third member by inserting the first end of the first

member into the first aperture, through the first bore, and out of the second aperture"); see also Ex. 1001, Fig. 18 (proximal end 1850 of lag screw members 1805 coupled to a tapered screw member 1815).

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

c) Whether Simon discloses "a first aperture at a terminal end"

Patent Owner further argues that the Petition is defective for failing to show that Simon discloses element 1[c][ii], "wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body." Prelim. Resp. 32–36. For this element, Petitioner points to Simon Figure 2 and, in particular, fastener hole 20, which it contends "is at the terminal end [of the third elongated body] and not merely along the shaft." See Pet. 42–44 (citing Ex. 1008, Fig. 2, ¶54; Ex. 1002 ¶ 121). The parties' positions as to this element depend on their respective constructions of "at the terminal end." As discussed in section II.C.2, above, we do not agree with Patent Owner's position that "at a terminal end" demands placement of the first aperture at the extreme proximal end of third member, but note that the present record does not allow us to determine the maximum distance the first aperture may be from the very tip of the third member and still fall within the scope of the asserted claims. With this background, and solely for the purpose of institution, we credit Mr. Dominguez's presently

unopposed testimony that one of ordinary skill in the art would understand hole 20 in Simon's Figure 2 to be "at the terminal end of the third elongated body." Thus, and although Patent Owner's position might prove persuasive on a better developed record, we find that for the purpose of institution, Petitioner has sufficiently established that Simon discloses this element 1[c][ii].

#### d) Conclusion as to Ground 4

For the reasons set forth above, Petitioner establishes sufficiently that Simon discloses claim elements 1[a][ii] and 1[c][ii]. Patent Owner does not dispute any other elements of Ground 4 in its Preliminary Response. Having considered the evidence of record, we determine that Petitioner has established sufficiently that these remaining elements are also disclosed in Simon. According, and solely for the purpose of institution, Petitioner has established a reasonable likelihood that Simon anticipates claim 1.

#### 3. Other Claims and Grounds

Other than the claim terms discussed above (elements 1[c][iii] with respect to Cognet, and elements 1[a][ii] and 1[c][iii] with respect to Simon), Patent Owner does not presently dispute Petitioner's argument that each element is found within the four corners of the primary references. Nor, with respect to its obviousness grounds, does Petitioner argue that any of elements 1[c][iii], 1[a][ii] or 1[c][ii] are obvious in view of Cognet or Simon combined with any other reference. Accordingly, and having considered the evidence of record, Petitioner has shown sufficiently a reasonable likelihood that the challenged claims are unpatentable for the reasons set forth in Grounds 1–7.

# E. Discretionary Denial of Institution under 35 U.S.C. § 314(a)

Patent Owner contends that we should exercise our discretion to deny the Petition in favor of the related litigation taking place in the U.S District Court for the District of Arizona. Prelim. Resp. 5. Petitioner takes a contrary position, arguing that the Board should not deny institution. Pet. Reply 1–6. <sup>10</sup> We address the parties' arguments below.

#### 1. Legal standard

Under our precedential decision in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12–17 (PTAB May 13, 2020), the Board, in deciding "whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding," should consider a variety of factors, and, in evaluating these factors, "takes a holistic view of whether efficiency and integrity of the system are best served." *Fintiv*, Paper 11 at 5–6; *see also Samsung Elecs. Am., Inc. v. Uniloc 2017 LLC*, IPR2020-00117, Paper 11 at 7–11 (PTAB May 28, 2020) (same). According to Patent Owner, granting the Petition for *inter partes* review would be an inefficient use of Board resources and is contrary to Congress's intent in establishing IPR proceedings. Prelim. Resp. 17.

In *Fintiv*, the Board set forth six factors relating to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding:

<sup>&</sup>lt;sup>10</sup> The parties addressed discretionary denial in the Petition and Preliminary Response but did not request or provide further briefing on this issue. *See* Ex. 3001 (authorizing Petitioner's request for leave to file a Reply addressing Patent Owner's claim constructions); Reply; Sur-reply.

- 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.

Fintiv, Paper 11 at 6.

Particularly applicable to *Fintiv* factor 6, we are also guided by the USPTO's *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation*, June 21, 2022 (the "Guidance"). As stated by the Guidance, the Board will not rely on the *Fintiv* factors to discretionarily deny institution in view of parallel district court litigation when: (1) a petition presents compelling evidence of unpatentability; (2) a petitioner presents a stipulation (a "*Sotera* stipulation") not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised before the PTAB 12; and (3) if all other *Fintiv* factors weigh against exercising discretion to deny institution, or are

<sup>&</sup>lt;sup>11</sup> Available at https://www.uspto.gov/sites/default/files/documents/interim\_proc\_discretionary\_denials\_aia\_parallel\_district\_court\_litigation\_memo 20220621 .pdf (last visited September 24, 2023).

<sup>&</sup>lt;sup>12</sup> See Sotera Wireless, Inc. v. Masimo Corp., IPR2020-01019, Paper 12 (PTAB December 1, 2020) (precedential).

neutral, the proximity to trial should not alone outweigh all of those other factors. <sup>13</sup> Guidance 1–8.

### 2. Analysis

We consider the above interrelated factors and Guidance, as they apply to the facts of the Petition.

a) Fintiv Factor 1: whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted

Under the first *Fintiv* factor, we consider "whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted." *Fintiv*, Paper 11 at 6. On August 3, 2023, Petitioner Fusion Orthopedics filed a motion for stay of the district court litigation. *See* Ex. 3003. On August 17, Patent Owner Extremity Medical filed a response in opposition, to which Petitioner filed an August 24 reply. *Id.* The district court has not acted on that motion. *Id.* 

Patent Owner contends that "[i]t is not likely that a stay will be granted in the Parallel District Court Case." Prelim. Resp. 7. In support, Patent Owner cites the "timing and advanced stage of the Parallel District Court Case" (addressed in *Fintiv* Factor 3, *infra*) and the concluding paragraph of the court's case management order. *Id.* (citing Ex. 2003 ¶ 11). The referenced portion of the case management order states:

11. The Deadlines Are Real. 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

<sup>&</sup>lt;sup>13</sup> The Guidance notes that the *Fintiv* factors do not apply to parallel litigation before the U.S. International Trade Commission (ITC). Guidance 2–3, 5–7.

not extend the deadlines, absent good cause to do so. The pendency of settlement discussions or the desire to schedule mediation does not constitute good cause, unless discovery is substantially complete and the extension requested is minimal.

Ex. 2003 ¶ 11.

On the present record, we decline to speculate whether the pending motion to stay might be successful. Accordingly, *Fintiv* Factor 1 is neutral.

b) Fintiv Factor 2: proximity of the court's trial date to the Board's projected statutory deadline for a final written decision

Under the second *Fintiv* factor, we consider the "proximity of the court's trial date to the Board's projected statutory deadline for a final written decision." *Fintiv*, Paper 11 at 6. Petitioner argues that the Judge in the district court litigation has not yet set a trial date. Pet. 69. Patent Owner calculates a projected trial date of around August 28, 2024, more than two months before a Final Written Decision would be due if this case were instituted. Prelim. Resp. 9 (citing Ex. 2009).

Fintiv Factor 2 discusses consideration of a trial date. The Director's Guidance states that it may be useful to compare a trial date with evidence of a median time-to-trial. Guidance 8. The purpose is to ascertain the likelihood of the scheduled trial date actually occurring on or around that date. Id. at 8 ("Stakeholders correctly noted that scheduled trial dates are unreliable and often change[,]" and a "scheduled trial date . . . is not by itself a good indicator of [when] the district court trial will occur."). The Guidance does not state that median time-to-trial statistics are themselves a trial date, or otherwise replace consideration of a trial date under Fintiv Factor 2. In the

circumstances here, the usefulness of the median time-to-trial statistics is less clear and we will not speculate on when a trial may be scheduled.

We also note that, even if we were to consider the trial date statistics cited by Patent Owner, Exhibit 2009 does not support their argument. Although Patent Owner characterizes the "median time-to-trial" as 28 months, Exhibit 2009 actually shows 28 months as the "average time-to-trial," while the median time-to-trial is shown as being 34 months. Ex. 2009. The Director's Guidance states that, "when considering the proximity of the district court's trial date to the date when the PTAB final written decision will be due, the PTAB will consider the median time from filing to disposition of the civil trial for the district in which the parallel litigation resides." Guidance 3. Using the median time-to-trial statistics from Exhibit 2009 would project a trial date of around February 28, 2024, which is more than 3 months after our Final Written Decision date. <sup>14</sup>

Accordingly, *Fintiv* Factor 2 weighs against exercising discretion to deny institution.

c) Fintiv Factor 3: investment in the parallel proceeding by the court and the parties

Under the third *Fintiv* factor, we consider the "investment in the parallel proceeding by the court and the parties." *Fintiv*, Paper 11 at 6. Petitioner contends that this "case is in the early stages of discovery and a

<sup>&</sup>lt;sup>14</sup> Further, the Director's Guidance cites to a particular website for determining median time-to-trial statistics (https://www.uscourts.gov/statistics-reports/analysis-reports/federal-court-management-statistics). Guidance 3, fn.4. These statistics report a median time-to-trial of 37.3 months, which would push the projected trial date even further past our Final Written Decision date.

claim construction hearing for the '166 patent has not yet occurred." Pet. 69. But as Patent Owner makes clear, Petitioner's assertion is outdated and incorrect. *See* Prelim. Resp. 9–11. In particular, Patent Owner presents a timeline illustrating that, as of the August 23, 2023, filing of the Preliminary Response,

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.

*Id.* at 10–11 (including illustrated timeline); *see also id.* at 5 (further stating that "[a]ny Final Written Decision here (expected in November 2024), would come months after dispositive motions (due January 12, 2024) and also likely after trial)."

Petitioner has not contested Patent Owner's timeline, which appears generally consistent with our reading of the court's docket. *See generally* Ex. 3003. Considering the posture of the District Court proceeding and the investment by the court and parties, *Fintiv* Factor 3 weighs marginally in favor of exercising discretion to deny institution.

d) Fintiv Factor 4: overlap between issues raised in the petition and in the parallel proceeding

Under the fourth *Fintiv* factor, we consider the "overlap between issues raised in the petition and in the parallel proceeding." *Fintiv*, Paper 11 at 6. Upon filing the Petition, Petitioner asserted that "[a]t present, it is unclear how much overlap there will be between the two proceedings." Pet. 70. Petitioner has not, however, presented a *Sotera* stipulation, or any type of stipulation limiting the grounds it intends to pursue in the parallel

proceedings. See, e.g., Sand Revolution II, LLC v. Continental Intermodal Grp. – Trucking LLC, IPR2019-01393, Paper 24 at 12 (PTAB June 16, 2020) (informative). To the contrary, Patent Owner asserts that "at trial . . . Petitioner has reserved its ability to present the exact same unpatentability arguments it is advancing here." Prelim Resp. 5. Moreover, Patent Owner explains, all 15 claims of the '166 patent are challenged in both proceedings based on similar citations to substantially the same references—Cognet, Simon, Brumfield, and Ferrante. See id. at 12–13 (citing Ex. 2007, 2, 3, 8–63). Although Patent Owner admits that Petitioner does not assert Leu in the related district court litigation, this reference is only raised here with respect to Ground 7. See id. at 13.

Considering the present record, we agree with Patent Owner that "the Petition asserts the same claims and uses substantially the same evidence as in the Parallel District Court Case. This factor... weighs in favor of denying the Petition." *Id*.

e) Fintiv Factor 5: whether the petitioner and the defendant in the parallel proceeding are the same party

Under the fifth *Fintiv* factor, we consider "whether the petitioner and the defendant in the parallel proceeding are the same party." *Fintiv*, Paper 11 at 6. Petitioner here is the defendant in the related District Court Litigation. Pet. 70; Prelim. Resp. 2. Although this factor may, standing alone, be neutral, under these circumstances in which the trial date is not set and may occur after our Final Written Decision date (see discussion of *Fintiv* factor 2, above), we determine that the fifth *Fintiv* factor weighs against discretionary denial of institution.

f) Fintiv Factor 6: other circumstances that impact the Board's exercise of discretion, including the merits

Under the sixth *Fintiv* factor, we consider "other circumstances that impact the Board's exercise of discretion, including the merits." *Fintiv*, Paper 11 at 6. In this respect, the Director's Guidance addresses "the potential for inefficiency and gamesmanship in AIA proceedings." Guidance 1. Possibly implying that Petitioner is engaging in the latter conduct, Patent Owner several times points out that Petition was filed on the last possible day permitted under 35 U.S.C § 315(b). *See* Prelim. Resp. 1, 5. While Petitioner's timing undoubtedly contributed to the advanced stage of the parallel district court proceeding, filing a petition within the statutory limit set by congress, in and of itself, does not weigh in favor of denying institution. *See* 35 U.S.C § 315(b) (stating that a petition must be filed no more than one year after "the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent").

As to the merits, we determined and have discussed above that Petitioner establishes a reasonable likelihood of prevailing with respect to the challenged claims based on the asserted grounds. As discussed in detail above, the evidence and arguments presented by Petitioner meet our standard for instituting an *inter partes* review. Under these circumstances, we determine that the sixth *Fintiv* factor is neutral.

#### 3. Conclusion

Because *Fintiv* Factors 1–5, when weighed together, do not favor exercising our discretion to deny institution, there is no need to determine whether the Petition establishes compelling merits. *See* Guidance 4–5

(explaining that compelling merits can overcome what would otherwise warrant a discretionary denial under *Fintiv* analysis); *see also CommScope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 at 6 (PTAB Feb. 27, 2023) (precedential) ("[t]he Board should first assess *Fintiv* factors 1–5; if that analysis supports discretionary denial, the Board should engage the compelling merits question."). For the reasons stated above, the *Fintiv* factors do not support exercising our discretion to deny institution.

# F. Discretionary Denial of Institution under 35 U.S.C. § 325(d)

In their arguments for *Fintiv* Factor 6, Patent Owner also appears to argue that the Petition should be denied under 35 U.S.C. § 325(d) because Cogent was considered during prosecution of the '166 patent. Prelim. Resp. 14–15 (citing Exs. 1001, 2010). Under the first prong of the *Advanced Bionics* framework, we consider "whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8 (PTAB Feb. 13, 2020) (precedential).

We agree that Cogent appears to have been cited to the Office during prosecution in an Information Disclosure Statement ("IDS"), along with hundreds of other references. *See* Ex. 2010. Notably, however, Patent Owner does not argue that Simon was previously disclosed to the Office. Nor is Simon listed on the face of the challenged patent. *See* Ex. 1001, code (56). That Simon—the primary reference in four of Petitioner's seven Grounds—does not appear to have been previously presented to the Office, thus indicating that part 1 of the *Advanced Bionics* framework is not satisfied for

those grounds and 35 U.S.C. § 325(d) is not sufficiently implicated. Nevertheless, for completeness, we briefly address part 2 of the analysis.

Under the second part of the *Advanced Bionics* framework, we consider "whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims." *Advanced Bionics*, Paper 6, 8. As discussed in Section II.D.1., however, we find that Petitioner has established a reasonable likelihood that Cogent discloses all the limitations of claim 1. Therefore, we find that, on the current record, the Examiner erred by overlooking the relevant disclosure from Cogent discussed *supra*.

Accordingly, and for the reasons discussed above, we decline to exercise our discretion to deny institution under 35 U.S.C. § 325(d).

#### III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is instituted on claims 1–15 for all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review of the '166 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2023-00894 Patent 11,298,166 B2

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