

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDSHAPE, INC.,
Petitioner,

v.

CAYENNE MEDICAL, INC.,
Patent Owner.

Case IPR2015-00848
Patent 8,435,294 B2

Before JAMES P. CALVE, MITCHELL G. WEATHERLY, and
JAMES A. TARTAL, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

DECISION

Institution of *Inter Partes* Review
37 C.F.R. § 42.108

Petitioner, Medshape, Inc., filed a Corrected Petition requesting an *inter partes* review of claims 6–11, 13, and 16–18 of U.S. Patent No. 8,435,294 B2 (“the ’294 patent”). Paper 4 (“Pet.”). Patent Owner, Cayenne Medical, Inc., filed a Preliminary Response. Paper 8 (“Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Upon consideration of the Petition and the Preliminary Response, we conclude the information presented shows there is a reasonable likelihood that Petitioner would prevail in showing the unpatentability of claims 16–18. Accordingly, we authorize an *inter partes* review to be instituted as to claims 16–18 of the ’294 patent. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner’s Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record, as fully developed during trial.

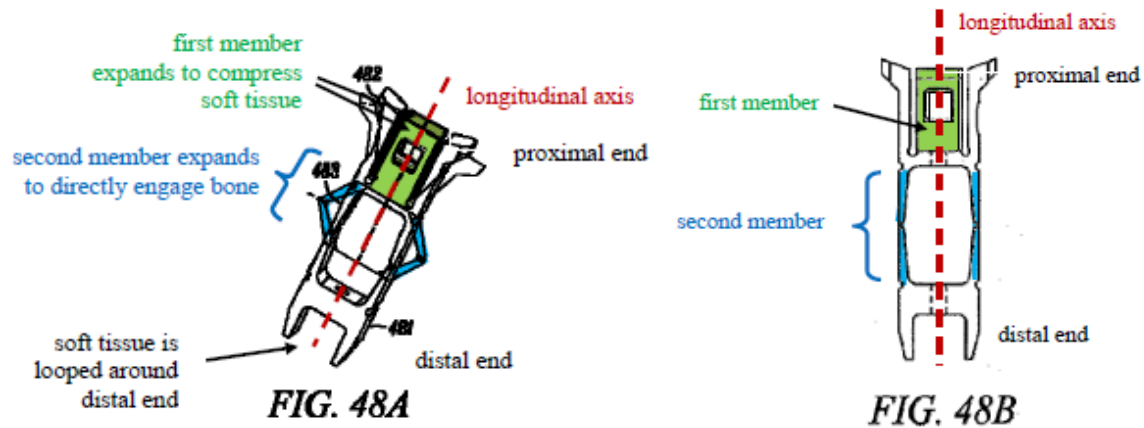
I. BACKGROUND

A. *The ’294 Patent (Ex. 1001)*

The ’294 patent, titled “Devices, Systems and Methods for Material Fixation,” issued May 7, 2013, from U.S. Application No. 12/634,581, filed December 9, 2009. Ex. 1001. The ’294 patent describes devices, systems and methods for fixation of soft material to hard material, including tendon to bone. Ex. 1001, Abstract; 2:66–3:5.

According to Patent Owner, Figure 48 of the '294 patent depicts a representative embodiment of the invention. Prelim. Resp. 5.

Figures 48A and 48B of the '294 patent are reproduced below, with annotations of additional coloring and labeling provided by Patent Owner. Prelim Resp. 5–6.¹



Figures 48A and 48B illustrate isometric and side views of a substantially non-cylindrical multiple component tendon anchor with two levels of expanding sections, as an embodiment of the '294 patent. Ex. 1001, 7:49–52. According to Patent Owner:

The embodiment includes a distal end where tissue is received, a proximal end comprised of four expanding arms, and an expanding mid-section. [Ex. 1001] (22:66–23:13). The four arms include a set of two “center arms,” the first member (labeled in green), that will be “in direct contact with a tendon” during use. *Id.* (23:2–3; 21:66–22:1; 21:34–36; 21:50–55). The other set of proximal arms, the “lateral arms,” will “directly contact the bone surface.” *Id.* (23:2–3; 21:66–22:1; 21:41–42). The mid-section, or second member (labeled in blue), will also directly contact the bone. *Id.* (23:6–13). As depicted, the first

¹ In addition to the coloring and labeling added by Patent Owner, Patent Owner has also altered Figure 48B by adding solid lines to create a box it identifies as the “first member.”

member and second member are axially spaced along the longitudinal axis of the implant and are of substantially different constructions. The inventors explain that “[t]he resulting implant structure 481 in this embodiment is intended to provide two levels of fixation in the bone hole.” *Id.* (23:11–13) . . . Figure 48A shows the operation of the implant during deployment. In use, soft tissue is looped around the distal end of the implant. *Id.* (23:2–3; 21:66–22:1; 21:35–47). The soft tissue is then guided along the body of the implant so that the strands of soft tissue cover the two arms of the first member. *Id.* During deployment, a wedge (not shown) is advanced to expand all of the arms at the proximal end of the implant, including the first member. The expansion of the first member will compress the soft tissue against the bone, thus indirectly engaging bone. *Id.* (21:35–37, 21:50–54; 21:66–22:1; 22:61–63). The advancement of the wedge will also cause the second member to “collapse and expand,” thus directly engaging adjacent bone. *Id.* at (23:6–9).

Prelim. Resp. 6–7.

B. Illustrative Claims

Claims 6 and 16 of the ’294 patent are independent. Claims 7–11 and 13 ultimately depend from claim 6, and claims 17 and 18 depend from claim 16. Claims 6 and 16 of the ’294 patent are illustrative of the claims at issue:

6. A material fixation system, comprising an implant which is placeable in a space defined by bone, said implant comprising:
 - a body having a longitudinal axis, a distal end, and a proximal end;
 - a first member on said body which is movably expandable outwardly;
 - a second member on said body which is disposed axially from said first member and is also movably expandable outwardly, said second member being of a substantially different construction than said first member;

- a distal end of said body comprising a space for receiving soft tissue therethrough, said space being defined by surfaces of said body which are oriented both generally parallel to said longitudinal axis and generally transverse to said longitudinal axis; and
- a deployment device which is movable in a generally axial direction to deploy at least one of said first and second members.

Ex. 1001, 25:31–49.

16. A method of anchoring soft tissue to bone, comprising:
 - placing the soft tissue on an implant having a longitudinal axis extending from a distal end of the implant to a proximal end of the implant, and disposing the implant within a space at a desired location within a portion of bone;
 - deploying a first member on said implant outwardly to engage adjacent bone; and
 - deploying a second member, disposed on said implant in axially spaced relationship from the first member, outwardly to engage adjacent bone;
- wherein the outward deployment of one of said first and second members compresses the soft tissue between said one of said first and second members and adjacent bone.

Id. at 26:34–48.

C. *Related Proceedings*

Petitioner states that the '294 patent is a subject of the following civil action: *Cayenne Medical, Inc. v. MedShape, Inc.*, Case No. 2:14-CV-00451 (HRH) (D. Ariz.). Pet. 2.

D. Asserted Grounds of Unpatentability

Petitioner contends that claims 6–11, 13, and 16–18 of the '294 patent are unpatentable based on the following grounds:

| Reference[s] | Basis | Challenged Claims |
|---------------------|----------|---------------------|
| Gerke ² | § 102(b) | 6–11, 13, and 16–18 |
| Justin ³ | § 102(b) | 6–11, 13, and 16–18 |
| Jacobs ⁴ | § 102(b) | 6–11, 13, and 16–18 |
| Jacobs and Gerke | § 103(a) | 6–11, 13, and 16–18 |
| Jacobs and Justin | § 103(a) | 6–11, 13, and 16–18 |

II. ANALYSIS

A. Claim Construction

The Board interprets claims of an unexpired patent using the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278 (Fed. Cir. 2015) (“We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA.”).

1. “substantially different construction”

Claim 6 recites “said second member being of a substantially different construction than said first member.” Petitioner contends that “substantially different construction” was added in an amendment during prosecution without support, and is not described or defined in the specification. Pet. 21.

² EP 1 066 805 A2, published January 10, 2001 (“Gerke,” Ex. 1005).

³ U.S. Patent No. 6,887, 271 B2, issued May 3, 2005 (“Justin,” Ex. 1006).

⁴ WO 02/32345 A3, April 25, 2002 (“Jacobs,” Ex. 1007)

Petitioner, nevertheless, contends without explanation or extrinsic support that “substantially different construction” means “more than a minor difference in shape or chemical composition.” Like “substantially different,” the phrase “more than a minor difference” is a term of degree that does not further inform a person of ordinary skill in the art of whether the recited limitation is disclosed in a prior art reference.

In its Preliminary Response, Patent Owner does not propose a construction for “substantially different construction,” but instead simply asserts that Petitioner hasn’t shown that either Gerke or Justin disclose a second member of substantially different construction because Petitioner’s arguments are “disingenuous.” Prelim. Resp. 29, 34. Patent Owner also contends certain features disclosed in Figure 48A of the ’294 patent are of “substantially different constructions,” but offers no explanation why that is the case. *See* Prelim. Resp. 6. While acknowledging that Patent Owner carries no burden at this stage of the proceeding, we note that Patent Owner’s argument sheds no light on why a first and a second member of any embodiment disclosed in the ’294 patent are of “substantially different construction,” while each of the pairs of members identified by Petitioner in various references are not.

A patent must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention.” 35 U.S.C. § 112, ¶ 2 (2006).⁵ “If a claim is

⁵ Paragraph 2 of 35 U.S.C. § 112 was replaced with newly designated § 112(b) when § 4(c) of the America Invents Act (“AIA”), Pub.L. No. 112–29, took effect on September 16, 2012. Because the applications resulting in the patents at issue in this case were filed before that date, we will refer to

amenable to two or more plausible claim constructions, the USPTO is justified in requiring the applicant to more precisely define the metes and bounds of the claimed invention by holding the claim unpatentable under 35 U.S.C. § 112, second paragraph, as indefinite.” *Ex Parte Miyazaki*, 89 USPQ2d 1207, 1211 (BPAI 2008) (precedential); *see also Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1369–70 (Fed. Cir. 2014) (quoting *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014)) (“A claim fails to satisfy this statutory requirement and is thus invalid for indefiniteness if its language, when read in light of the specification and the prosecution history, ‘fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.’”). A claim term that does not satisfy the definiteness requirement under *Nautilus* likewise fails to satisfy the definiteness requirement of *Miyazaki*.

Terms of degree, such as “substantially different,” are not inherently indefinite. *Interval Licensing*, 766 F.3d at 1370. For example, the claim phrase “not interfering substantially” was held not indefinite even though the construction “define[d] the term without reference to a precise numerical measurement,” where intrinsic evidence provided multiple examples that would allow a skilled artisan to determine whether a particular chemical bond linkage group would “interfer[e] substantially” with hybridization. *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1334–35 (Fed. Cir. 2010). Nevertheless, when a “word of degree” is used, the patent must provide “some standard for measuring that degree.” *Enzo Biochem*, 599 F.3d at 1332; *Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.*, 731 F.2d

818, 826 (Fed. Cir. 1984). “The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art.” *Interval Licensing*, 766 F.3d at 1371. When a claim term “depend[s] solely on the unrestrained, subjective opinion of a particular individual purportedly practicing the invention,” without sufficient guidance in the specification to provide objective direction to one of skill in the art, the term is indefinite. *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1260 (Fed. Cir. 2014) (quoting *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005)).

The phrase “substantially different” is highly subjective and, on its face, provides little guidance to one of skill in the art. Sufficient guidance is lacking in the written description of the ’294 patent as well. The specification of the ’294 patent does not contain the phrase “substantially different construction” outside of the claims, and neither party has directed us to any disclosure in the written description relevant to determining a standard for measuring the necessary degree of difference which is to be defined as “substantially different.” Likewise, neither party has directed us to any disclosure in the prosecution history that illuminates the relationship between the written description and the “substantially different construction” claim phrase. As noted above, the claim phrase was added in an amendment during prosecution, but the prosecution amendment at issue provides no disclosure to further illuminate the meaning of “substantially different construction.” *See* Ex. 1008, 334–346.

We determine that neither Petitioner nor Patent Owner has demonstrated that the recitation of “substantially different construction” in

the '294 patent, viewed in light of the specification and prosecution history, sufficiently informs those skilled in the art about the scope of the invention with reasonable certainty.

2. “*member*”

Petitioner contends “a first member on said body” should be construed to mean “a distinct portion of the body.” Pet. 20. In support of its proposed construction, with virtually no explanation, Petitioner relies on Figures 3A-3C as disclosing clover leaf extensions having a flared end to engage bone and a mid-section that is not flared. *Id.* Patent Owner asserts that the embodiment described in Figures 3A–3C “does not comprise members and is not covered by the claims.” Prelim. Resp. 22. Patent Owner instead contends that “member” is used in an ordinary manner in the '294 patent to connote “a distinct component part or piece.” *Id.* at 21. Patent Owner, however, also identifies Figure 48 B of the '294 patent as depicting a first member and a second member (as reproduced above), even though that embodiment appears to be a one-piece anchor with no “distinct” component parts or pieces.

At this stage of the proceeding, we do not adopt either party’s proposed interpretation of “member.” Petitioner’s interpretation of a “member” as a “portion” is too broad because it would encompass any two portions along the longitudinal axis of an anchor, no matter how small or close together, and regardless of whether the two portions differed in any discernable manner other than in their axial position. Patent Owner’s construction of “member” as being limited to “distinct” parts or pieces is too narrow in light of the specification, which depicts a one-piece anchor as

having multiple members. On the current record, a “member” encompasses discernably different portions of an anchor even if those portions are part of a one-piece anchor.

3. *Additional Claim Terms*

Petitioner proposes constructions for numerous additional claim terms, including “implant,” “having a longitudinal axis, a distal end, and a proximal end,” “moveably expandable outwardly,” and “to deploy.” Pet. 18–27. Patent Owner does not propose express construction for the terms addressed by Petitioner, but instead argues Petitioner’s proposed constructions are unnecessary and create more confusion than clarity. For purposes of this Decision we determine no additional express construction of any claim term is necessary.

B. *Challenges to Claims 6–11 and 13*

Petitioner contends that claims 6–11 and 13 are unpatentable in view of the asserted references. *See* section I.D., *supra*. Independent claim 6, however, recites the “said second member being of a substantially different construction than said first member.” As discussed above, Petitioner has not demonstrated that the recitation of “substantially different construction” in the ’294 patent, viewed in light of the specification and prosecution history, sufficiently informs those skilled in the art about the scope of the invention with reasonable certainty. *See* section I.D., *supra* II.A.1; 37 C.F.R. 42.104(b)(3). In the absence of any sufficient demonstration that claim 6 indicates the scope of the claimed invention, we do not attempt to apply claim 6 to the asserted prior art. *See United Carbon Co. v. Binney & Smith*

Co., 317 U.S. 228, 236–37 (1942) (holding that “the claims must be reasonably clearcut to enable courts to determine whether novelty and invention are genuine”); *In re Steele*, 305 F.2d 859, 862–63 (CCPA 1962) (holding that where a claim’s meaning is indefinite under 35 U.S.C. § 112, ¶ 2, any rejection based on prior art is improperly based on speculation); *Blackberry Corp. v. MobileMedia Ideas, LLC*, Case IPR2013-00036, slip op. at 20 (PTAB Mar. 7, 2014) (Paper 65). We reach the same conclusion with respect to dependent claims 7–11 and 13, which depend from claim 6. Accordingly, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to claims 6–11 and 13.

C. Anticipation of Claims 16–18 by Gerke

Petitioner contends that Gerke anticipates claims 16–18. Pet. 34–37. Gerke describes a bone anchor comprising a head region and supporting legs, and a method for soft tissue-bone grafting using such a bone anchor. Ex. 1005, Abstract. Petitioner provides Gerke Figure 1(c) with annotations, reproduced below, allegedly corresponding to features of claim 16 of the ’294 patent. Pet. 35.

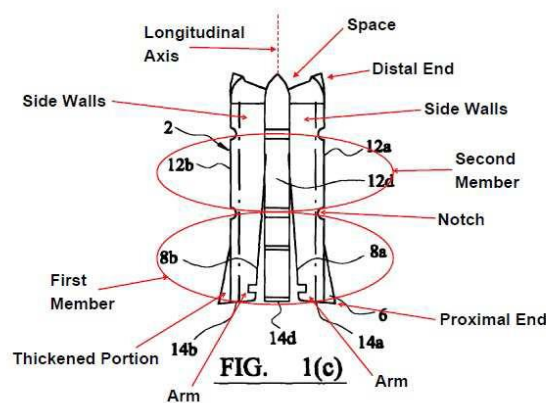


Figure 1(c) of Gerke is a front elevation of a bone anchor, and, as annotated by Petitioner, allegedly depicts a first member at a proximal end, separated by a medially disposed notch from a second member. *Id.* Petitioner contends the legs of the bone anchor are splayed outwardly into firm engagement against bone at a first axial location. *Id.* Petitioner further contends that the portion of the legs above a medial notch constitute a second member deployed outwardly when a peg is inserted. *Id.* at 36.

Patent Owner argues that “Gerke cannot reasonably be divided into multiple ‘portions’ that would allegedly represent axially spaced members.” Prelim. Resp. 25. Patent Owner also criticizes Petitioner’s reliance on the medially disposed notch in the bone anchor of Gerke as a boundary between the alleged first and second members as being unsupported by Gerke’s disclosure and unexplained by Dr. Higgs. *Id.* at 25–30.

Based on the current record, we are persuaded that the medially disposed notch in Gerke’s legs may be considered a discernable boundary between two portions of Gerke’s bone anchor which constitute a first and second member as claimed. Petitioner also persuades us that inserting the peg of Gerke constitutes moving a deployment device in a generally axial direction and likely causes both portions of the legs to expand outwardly and contact bone at different axial locations in the bone tunnel. Based on the record before us, Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that Gerke anticipates claims 16–18.

D. Anticipation of Claims 16–18 by Justin

Petitioner contends that Justin anticipates claims 16–18. Pet. 43–46. Justin describes a graft fixation system for fixing graft material in a bone

tunnel. Ex. 1006, Abstract. Petitioner provides Justin Figure 2 with annotations, reproduced below, allegedly corresponding to features of claim 16 of the '294 patent. Pet. 38, 45.

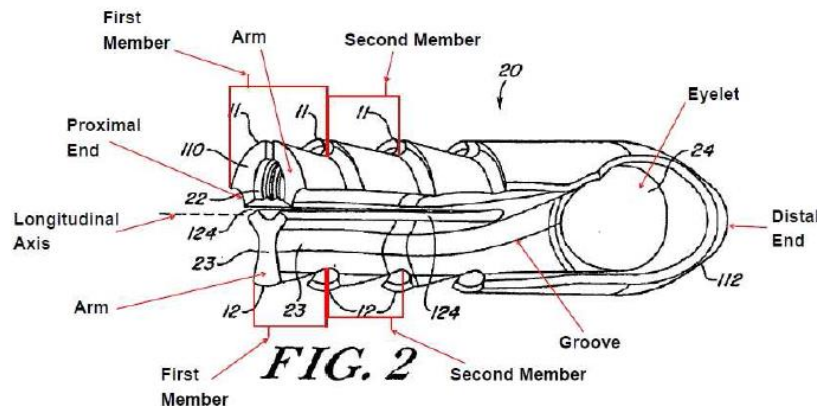


Figure 2 of Justin is perspective view of an expanding fixation member of a graft fixation system, and, as annotated by Petitioner, allegedly depicts two groups of bone engaging elements 11, 12 on fixation member 20 corresponding to the claimed first and second members. *Id.* at 45. Justin also describes threaded expansion plug 21 that, when screwed into the proximal end of member 20, causes engaging elements 11, 12 to expand outwardly and engage bone. *Id.* at 37 (citing Ex. 1006, 4:1–7, 4:60–5:8). *Id.*

Patent Owner contends that “Justin does not disclose members that are axially spaced on an implant.” Prelim. Resp. 30. Patent Owner reasons that “Justin routinely refers to the entire body containing bone engaging elements 11 and 12 as one ‘fixation member.’ There is no disclosure in Justin parsing these bone engaging elements into separate ‘portions;’ . . .” *Id.* at 31. Patent Owner further argues, without evidentiary support, that a skilled artisan might consider engaging elements 11 to be one member and

engaging elements 12 to be another member, but that these two parts of Justin's member 20 are not located at different axial locations as required in the claims. *Id.*

Justin's member 20 is divided into multiple axially distributed engaging elements 11, 12, which is sufficient, based on the current record, to describe the first and second members recited in the claims as construed for purposes of the Decision. Based on the record before us, we are persuaded that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that Justin anticipates claims 16–18.

E. Anticipation of Claims 16–18 by Jacobs

Petitioner contends that Jacobs anticipates claims 16–18. Pet. 50–52. Jacobs describes an intraosseous anchor for securing soft tissue, such as a tendon or ligament, to a cavity formed in a bone. Ex. 1007, 3. Petitioner provides Jacobs Figure 4A with annotations, reproduced below, allegedly corresponding to features of claim 16 of the '294 patent. Pet. 47, 50.

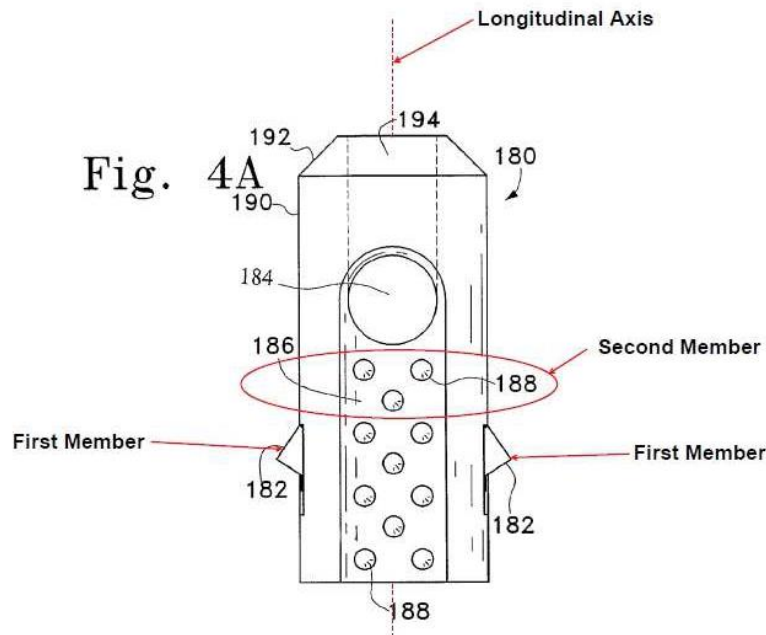


Figure 4A of Jacobs shows a side view of an anchor device in which barbs mechanically expand from the interior of the device into the bone. Ex. 1007, 6. Petitioner argues that rotating barbs 182 constitute a first member, and that a plurality of soft tissue barbs 188 constitutes a second member. Pet. 50–51. According to Petitioner, when pin 184 is inserted into anchor 180, “the two body portions would tend to expand outwardly in order to engage bone and to compress the soft tissue against the bone.” Pet. 51.

Patent Owner contends that Petitioner fails to cite evidence to establish that Jacobs describes the second member because the body of anchor 180 does not expand when pin 184 is inserted into the cavity. Prelim. Resp. 37. Patent Owner contends that Jacobs describes how anchor 180 of Figures 4A–D is manufactured in two body portions which, if expanded, would prevent the device from working properly. *Id.* at 35–36.

Figure 4D illustrates pin 184 as fitting within the opening in the proximal end of anchor 180 without any indication or description of the

body portions expanding due to pin 184. Jacobs's sole explanation of Figure 4D states: "The rotating barbs (182) are hinged so that as they rotate towards the exterior device upon the impetus of pin (184) as shown in Figure 4D, they dig into the interior of the crafted bone hole and secure device (180) in place." Ex. 1007, 11:25–12:3. Without evidence that the body portions of Jacob expand in response to pin 184, we similarly determine that Jacobs fails to describe the claimed step of "deploying a second member . . . outwardly to engage adjacent bone."

Based on our review of Jacobs and the parties' arguments, Petitioner has not sufficiently shown that Jacobs describes the expansion of the body portions that Petitioner identifies as the second member. Accordingly, we conclude that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that Jacobs anticipates claim 16 or its dependent claims 17 and 18.

F. Obviousness of Claims 16–18 Over Jacobs and Either Gerke or Justin

Petitioner contends claims 16–18 would have been obvious over Jacobs and either Gerke or Justin. Pet. 52–54. According to Petitioner, if pin 184 of Jacobs does not deploy the second member outwardly as recited in claim 16, Gerke and Justin "teach the use of a tapered member for deploying first and second members outwardly." Pet. 52–53. Petitioner contends that it would have been obvious to one skilled in the art to modify Jacobs to use a tapered member described by either Gerke or Justin "in order to force the hinged body portions apart to press the soft tissue against the bone to accelerate tissue growth and to engage the bone to fix the anchor in place." *Id.* at 54.

Based on our review of Jacobs, Gerke, and Justin, we are not persuaded by Petitioner's argument and supporting evidence. First, Petitioner cites portions of Jacobs that do not support its contention that the body portions of anchor 180 expand outwardly when anchor 180 is inserted into a bone cavity. Jacobs describes radial protuberances 182 to engage bone but not expansion of its body portions, Ex. 1007, 11:11–18, and Jacobs indicates that surgeons drill holes in the bone of a specific size to accept an anchor, *id.* at 9:16–18.

The only variation of Jacobs's device that "expands" to contact bone is the embodiment illustrated in Figure 2B which has two halves 134, 136 with "a certain amount of 'splay'" to provide "some definite amount of springiness which is used to secure the device (130) in the hole (148) when as shown in step 2." *Id.* at 10:14–17. Even this preset expansion of the proximal end of an anchor does not constitute an expansion of the distal portion of an anchor that Petitioner equates with the "second member." Accordingly, Jacobs does not teach or suggest the use of pin 184 to expand the portion of anchor 180 that Petitioner identifies as the "second member." Petitioner fails to sufficiently explain why an ordinarily skilled artisan would use the plugs taught by Gerke or Justin to expand Jacobs's anchor or why those plugs would cause the identified "second member" of Jacobs to expand and contact bone. We determine that Petitioner has not demonstrated a reasonable likelihood of showing that claims 16–18 are unpatentable as obvious over Jacobs and either Gerke or Justin.

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that *inter partes* review is *instituted* in IPR2015-00848 with respect to the following grounds of unpatentability:

- (1) claims 16–18 as anticipated by Gerke under 35 U.S.C. § 102(b);
- (2) claims 16–18 as anticipated by Justin under 35 U.S.C. § 102(b);

FURTHER ORDERED that no ground other than those specifically instituted above is authorized for the *inter partes* review;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '294 patent is hereby instituted in IPR2015-00848 commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

For PETITIONER

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For PATENT OWNER:

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