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Paper 11
Entered: February 24, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

FLEXUSPINE, INC.,
Patent Owner.

Case IPR2015-01749
Patent 7,204,853 B2

Before WILLIAM V. SAINDON, HYUN J. JUNG, and TIMOTHY J. GOODSON, *Administrative Patent Judges*.

SAINDON, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner requests an *inter partes* review of claims 1 and 5 of U.S. Patent No. 7,204,853 B2 (Ex. 1001, "the '853 patent"). Paper 1 ("Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . 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, the exhibits cited therein, and Patent Owner's Preliminary Response, we institute an *inter partes* review on claim 5, but not claim 1, of the '853 patent.

Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial.

A. Related Matters

Petitioner represents that it has been accused of infringement of the '853 patent in *Flexuspine, Inc. v. Globus Medical, Inc.*, Case 15-cv-00201-JRG-KNM (E.D. Tex.). Pet. 3. Petitioner also represents that it has simultaneously requested *inter partes* reviews of several other patents owned by Patent Owner. *Id.*

B. The '853 Patent

The '853 patent is directed to an expandable artificial intervertebral implant. Ex. 1001, Abstr. The particular embodiment recited in claims 1 and 5 is depicted in Figures 6a–d. Figure 6c of the '835 patent is reproduced below with added annotation:

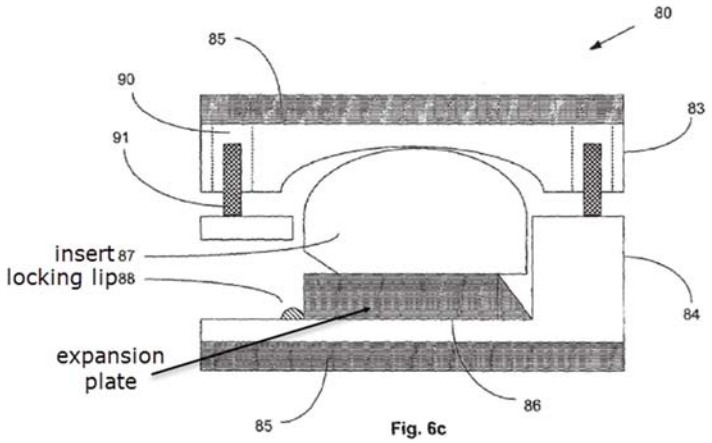


Fig. 6c

Figure 6c depicts implant 80 having upper body 83 and lower body 84. Insert 87 is lifted into place using expansion plate 86, after which locking lip 88 serves to prevent backout of expansion plate 86. In addition, extensions 91 project from the upper surface of lower body 84 and mate with recesses 90 in upper body 83, to inhibit dislocation.

C. Challenged Claims

Petitioner challenges independent claims 1 and 5, which are reproduced below.

> 1. An intervertebral implant for a human spine, comprising:
> an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine;

a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine;

an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine; and

an expansion member configured to elevate the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine,

and wherein a portion of the superior surface of the lower body is configured to inhibit backout of the expansion member from the intervertebral implant.

5. An intervertebral implant for a human spine, comprising:

a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a first vertebra of the human spine, and wherein the superior surface of the lower body comprises upwardly projecting extensions;

an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a second vertebra of the human spine, and wherein the upper body comprises recesses configured to accept the upwardly projecting extensions of the lower body;

an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine;

an expansion member configured to engage the insert to increase a separation distance between the upper

> body and the lower body after insertion of the intervertebral implant in the human spine; and
>
> wherein the upwardly projecting extensions of the lower body, when positioned in the recesses of the upper body, are configured to inhibit dislocation of the upper body from the lower body after insertion of the intervertebral implant in the human spine.

D. Prior Art and Asserted Grounds

Petitioner asserts that claims 1 and 5 of the '853 patent are unpatentable under 35 U.S.C. § 103 on the following grounds:

Reference(s)	**Claim Challenged**
Cohen[1]	1
Larsen[2] and Ferree[3]	1
Michelson[4]	5

Petitioner also relies on the testimony of Jorge A. Ochoa, Ph.D., P.E. (Ex. 1007).

II. ANALYSIS

A. Claim Construction

We interpret the claims of an unexpired patent using the broadest reasonable interpretation in light of the specification of the patent. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee, 84*

[1] U.S. Patent No. 6,454,806 B1, issued Sept. 24, 2002 (Ex. 1004).

[2] U.S. Patent No. 5,782,832, issued July 21, 1998 (Ex. 1005).

[3] U.S. Patent No. 6,491,724 B1, issued Dec. 10, 2002 (Ex. 1026)

[4] U.S. Patent No. 5,522,899, issued June 4, 1996 (Ex. 1006).

U.S.L.W. 3218 (U.S. Jan. 15, 2016) (No. 15-446). Under the broadest reasonable interpretation standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. "insert"

Petitioner does not offer a construction for any claim terms. Pet. 7. Patent Owner offers a construction of the term "insert," found in both challenged claims. Prelim. Resp. 14–15. For example, claim 1 recites "an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion." Patent Owner proposes that the ordinary and customary meaning of "insert," in the context of claim 1, is "a member separate from and disposed between the upper and lower bodies." *Id.* at 14. Patent Owner states that "[q]uite simply, something referred to as an insert must have been or is intended to be inserted into something; otherwise it would not be referred to as an insert." *Id.* at 15

Reading claim 1 in context, we agree with Patent Owner that the claimed insert must be a separate structure from the upper and lower bodies, in order to give due consideration to the term "insert" itself as well as to the relationship defined in the claims between the upper body, lower body, and the insert. To this end, we disagree with Petitioner's characterization of the "insert" limitation as "a recitation of the intended use for the claimed apparatus" and "not material to patentability." Pet. 31. Petitioner

specifically argues that "configured to be positioned" does not "disclose any intrinsic or structural limitation of the implant." *Id.* This argument is unpersuasive. The "insert . . . configured to be positioned between the . . . lower body and the . . . upper body" language sets forth structural features insofar as it requires (1) an insert and (2) the insert to be of a size and shape that allows it to be located between the upper and lower bodies in the manner claimed. Patent Owner provides persuasive evidence that an "insert" would be understood by a person of ordinary skill in the art as a structure capable of insertion (i.e., separate from that into which it is inserted). Prelim. Resp. 8–9 (citing Ex. 2003, dictionary definition of "insert").[5] The '853 patent's specification supports this understanding by consistently showing the insert to be a separate and discrete element from the upper and lower bodies. Ex. 1001, 8:33–45, 9:5–12, 9:33–35. Further, claim 1 specifies the place into which the insert is to be inserted: between the upper and lower bodies. Thus, the insert must be of a size and shape to accommodate insertion into such a location.

Accordingly, on this record, we are persuaded that the broadest reasonable interpretation of "insert" is "a member separate from, and disposed between, the upper and lower bodies."

[5] Although not controlling, we note that this term has been construed similarly in another proceeding. *See Miken Composites, L.L.C. v. Wilson Sporting Goods Co.*, 515 F.3d 1331, 1336–38 (Fed. Cir. 2008) (affirming construction of "insert" to mean "something inserted or intended for insertion" because the patent at issue "consistently use the term 'insert' in the sense of the ordinary meaning as 'something inserted or intended for insertion.'") (citations omitted).

2. "backout"

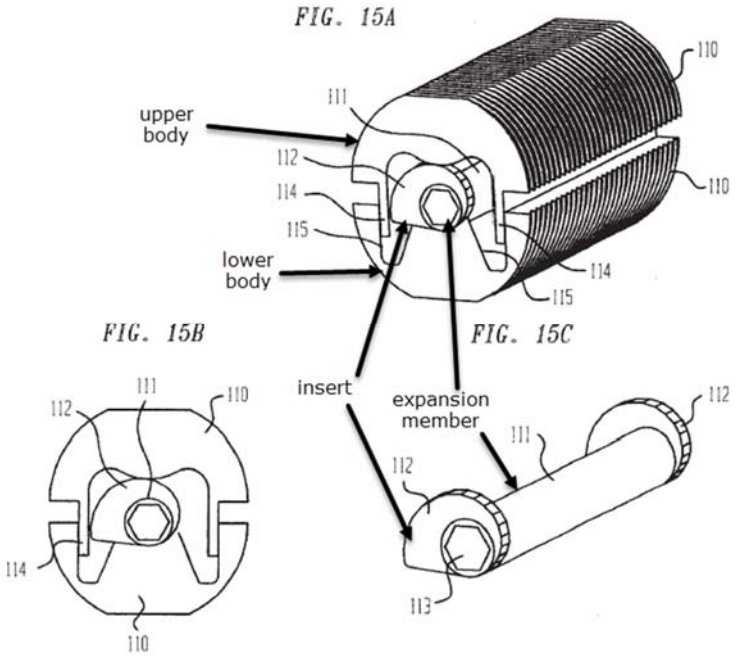
Claim 1 recites that a portion of the lower body "is configured to inhibit backout of the expansion member from the intervertebral implant." Patent Owner argues that the phrase means that "movement backward from an original position inside the implant toward the original direction from which it came so as to become dislocated." Prelim. Resp. 9–13. Petitioner offered no construction of the phrase and argues, in the alternative, that the phrase is "intended use" that "does not structurally distinguish the claimed apparatus." Pet. 20. We do not need to construe explicitly this limitation, or any further limitations, for the purposes of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only those terms or phrases that are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

B. Petitioner's Grounds

1. Claim 1: Cohen

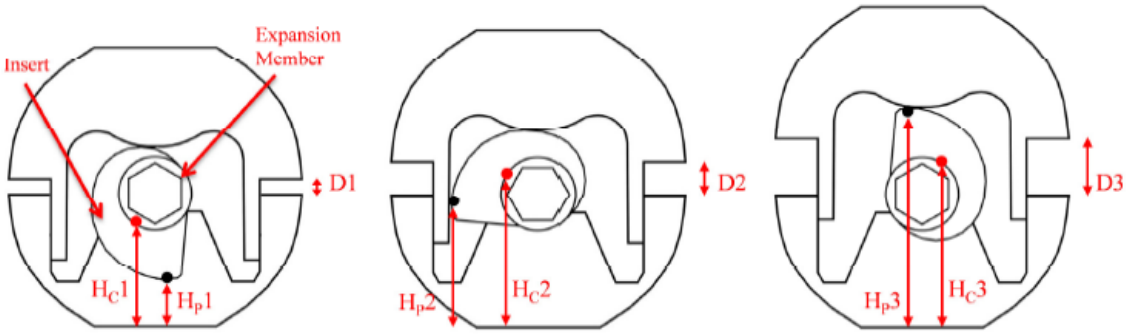
Claim 1 requires upper and lower bodies, an insert, and an expansion member. Claim 1 further requires the lower body be configured to "inhibit backout of the expansion member." Petitioner asserts that the subject matter of claim 1 would have been obvious in view of Cohen and the knowledge of one of ordinary skill in the art. Pet. 11–24. In particular, Petitioner asserts that Cohen has upper and lower bodies 110, insert 112, and expansion member 111. *Id.* These components are found on an embodiment shown in

Figures 15A–15C of Cohen, which are reproduced below with annotations explaining Petitioner's ground:



Figures 15A–15C of Cohen depict a cam-type expandable cage wherein rotation of rod 111 causes cams 112 to force apart upper and lower bearing surfaces 110. Ex. 1004, 10:42–55.

With respect to the "backout" limitation, Petitioner asserts that there is a "geometric interference between the inside surface of the cams and the upwards extensions of the lower body." Pet. 22. Petitioner asserts that this geometric interference prevents "backout of the expansion member ('rod' 111) from between the upper and lower bodies." *Id.* The figure reproduced below is taken from the Petition and is used by Petitioner to illustrate the alleged interference fit:



Pet. 21. The above figure is a modified version of Figure 15B of Cohen and illustrates Petitioner's understanding of how the device would look when rod 111 is rotated, such that the cam overhangs the upwardly extending portion of the lower body.

Petitioner's position implies that the type of backout prevented is of the cam/rod structure being pushed out an end of the hollow formed between the upper and lower bodies. The difficulty with Petitioner's position is that, even assuming Petitioner's reading of "backout" is correct, Cohen does not discuss how the device in Figures 15A–15C operates and it is not clear that Cohen prevents such a movement. *See* Ex. 1004, 10:42–55 (discussing Figures 15A-15C). Petitioner and its declarant both seem to assume that Cohen operates in the manner provided in the figure on page 21 of the Petition (reproduced immediately above), but we do not see a sufficient technical or factual basis supporting Petitioner's assumption. In effect, Petitioner is relying on the precision of drawings, but there is no evidence or reason before us to believe that the precision of Cohen's drawings may be relied on for such precision. *Cf. Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000) ("patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue").

Cohen's Figure 15A helps explain why these figures cannot be relied on for precision. Figure 15A is reproduced below with added annotations indicating several interfaces between separate components:

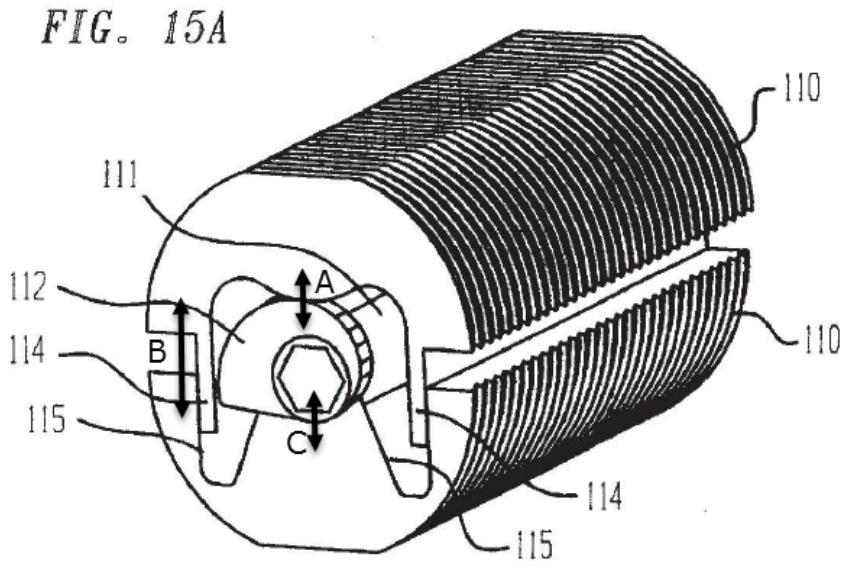


Figure 15A of Cohen depicts a perspective view of a cam-type expandable cage having upper body 110, lower body 110, and cam 112 between.

As marked in the drawing at "A," the outward-most face of upper body 110 and the outward-most face of cam 112 are shown as flush with each other. Similarly, the outward-most faces of upper body 110 and lower body 110 are shown as flush with each other, as marked in the drawing at "B." Accordingly, one would expect that the cam, upper body, and lower body faces to all be flush with each other. However, as marked at "C," and relied on by Petitioner in its ground, it appears that cam 112 is shown as overhanging lower body 110, by the depth of the cam. This relationship could be possible if the upwardly-projecting middle portion of lower body 110 were sloped inward, but there is no reason to believe that this is the case, as it is not shown in the drawings or described in the specification. Accordingly, the precise relationship between these elements cannot be

determined simply by looking at the drawings, and Petitioner and its declarant provide no convincing explanation as to why we should afford them the precision they allege, especially given what appears to be an inconsistency in the drawing. *See Hockerson-Halberstadt*, 222 F.3d at 956.

In view of the above, we determine that Petitioner has not shown a reasonable likelihood of demonstrating that claim 1 is unpatentable over Cohen.

2. Claim 1: Larsen and Ferree

Claim 1 recites "an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion." Petitioner's ground relies on Larsen for this feature. Pet. 31–35. Petitioner first asserts that Larsen discloses an insert "integral to the inferior surface [of upper support member 402]." *Id.* at 32. Figure 23 of Larsen is reproduced below with Petitioner's identification of an insert highlighted in green:

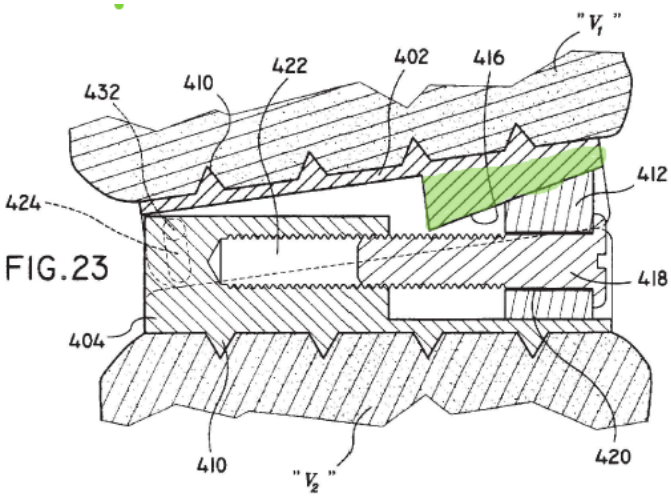


Figure 23 of Larsen depicts a spinal implant having upper support member 402 and lower support member 404 connected via a pin-and-slot arrangement (432, 424), with camming block 412 serving to push apart

lower support member 404 and inner surface 416 of support member 402 when screw 418 is advanced. Ex. 1004, 8:8–28.

Patent Owner argues that the integral surface identified by Petitioner is not an insert as claimed. Prelim. Resp. 23–24. Patent Owner's argument is persuasive because we have construed "insert," in the context of claim 1, as a structure separate from the upper and lower bodies.

Petitioner proposes an alternative ground, in which the wedge-shape of inner surface 416 is separated from upper support member 402 of Larsen. Pet. 32–35. Petitioner asserts that such a modification is "well-known" and would add "modularity" and the "benefit of allowing the surgeon to select inserts and camming blocks of varying sizes and/or angles." *Id.* at 33–34. Petitioner offers evidence allegedly showing that such modularity was well known. *Id.* (citing Exs. 1011, 1015, 1017).

Exhibits 1011, 1015, and 1017 each describe similar artificial discs. As best shown in Figure 1 of Ex. 1011, reproduced below, these discs comprise upper part 2, lower part 3, and pivot insert 4:

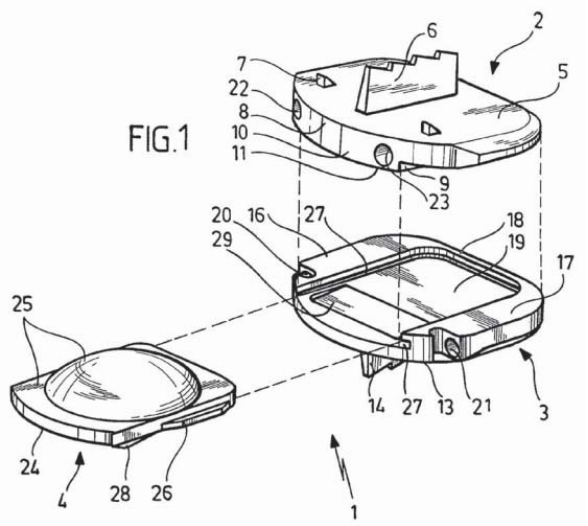


Figure 1 of Ex. 1011 depicts an artificial disc.

Exhibits 1015 and 1017 discuss similar discs, and also disclose that these three parts come in various sizes. Ex. 1015, S128; Ex. 1017, 363. Petitioner's declarant, Dr. Ochoa, reviews these Exhibits and concludes that making inner surface 416 of support member 401 of Larsen a separate component is a design choice. Ex. 1007 ¶ 45.

Patent Owner argues that Petitioner's alternative ground is made without support. Prelim. Resp. 23–25. Specifically, Patent Owner points out that Petitioner has not shown why the proposed additional modularity would be necessary or desirable because Larsen already allows for the change of elevation and angle of the implant using the existing wedge-and-screw design. *Id.* at 25. In other words, according to Patent Owner, the proposed modification adds no features to those already existing in Larsen.

Reviewing the record before us, we determine that Petitioner has not shown a reasonable likelihood of prevailing on this ground. In particular, claim 1 requires both an insert and an expansion member used to elevate the insert. Petitioner proposes to break up the upper portion of Larsen to create an insert, but Petitioner's reasons for doing so are unpersuasive. Although Petitioner shows that it was known to provide various sizes of implant components, the examples shown do not use an insert elevated by another structure. Instead, the examples appear to allow users the ability to simply pick and choose various insert sizes, without the adjustment-type sizing implicated by the claimed insert and expansion member arrangement; thus, they are different kinds of inserts. Accordingly, the "modularity" shown in those examples does not help explain why it would have been obvious to break up the upper portion of Larsen to create a separate insert. Petitioner has not offered any cogent reason for breaking up the upper portion of

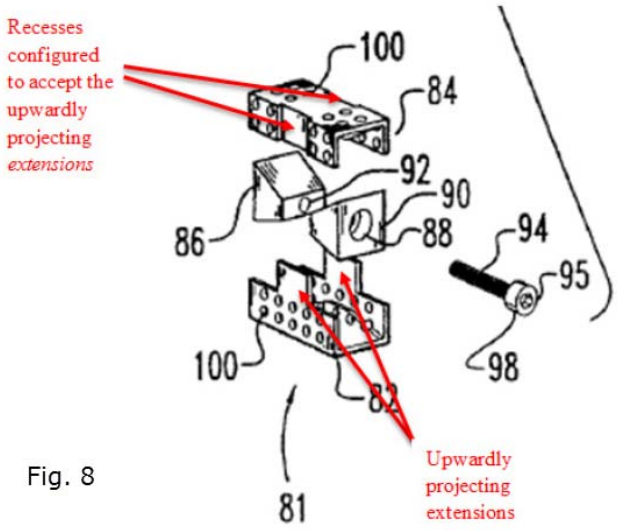
Larsen, nor has Petitioner offered evidence tending to show that this particular arrangement was known. Petitioner does not rely on any teachings of Ferree on this matter. In view of the above, we determine that Petitioner has not shown a reasonable likelihood of demonstrating that claim 1 is unpatentable over Larsen and Ferree.

3. Claim 5: Michelson

Independent claim 5 is similar to claim 1 in that it requires upper and lower bodies, an insert, and an expansion member. Claim 5 does not have a backout-inhibiting limitation, however, but rather requires that the "superior surface of the lower body comprises upwardly projecting extensions" and that the upper body includes recesses to accept those extensions. Claim 5 further recites that this arrangement "inhibit[s] dislocation of the upper body from the lower body." *See, e.g.*, Ex. 1001, Fig. 6c (depicting an embodiment having extensions 91 in recesses 90).

Petitioner asserts that Michelson, in view of the knowledge of one of ordinary skill in the art, renders obvious the subject matter of claim 5. Pet. 43–59. In particular, Petitioner asserts that Michelson depicts the claimed projections and recesses that inhibit dislocation. *Id.* at 49–50, 57–59.

Petitioner annotates a portion of Figure 8 of Michelson, reproduced below, to illustrate where the projections and recesses are located:



Pet. 49. Petitioner's annotated Figure 8 depicts an embodiment of the implant of Michelson showing alleged projections and recesses.

Petitioner asserts that these projections and recesses mate (*see* Ex. 1006, Fig. 9) and that the geometric interference between them would inhibit anterior-posterior dislocation of the upper body with respect to the lower body. *Id.* at 49–50, 57–59.

Patent Owner first argues that the projections in Michelson "are actually formed as part of the side wall of the lower body, not the superior surface of the lower body." Prelim. Resp. 30. This argument is not persuasive. First, the projections in Michelson extend from a superior surface of the lower body, insofar as they ultimately project from a space within the footprint of the lower body. Patent Owner does not offer a claim construction that would preclude such a reading. Second, the projections in the '853 patent appear to project from sidewalls in a similar manner. As shown in Figure 6c of the '853 patent, reproduced earlier in this Decision, the projection on the right side, for example, extends from a sidewall

extending from the base of the lower body. Accordingly, we do not consider this argument persuasive on this record.

Patent Owner next argues that Michelson does not provide any discussion in its written description regarding the projections and recesses, such as how they operate or how they would serve to prevent dislocation. Prelim. Resp. 31–32. Petitioner, however, offers a reasoned explanation as to why the interference fit between the tabs, shown plainly in Figures 8 and 9 of Michelson, would function to provide some measure of dislocation prevention by their very nature. Pet. 58–59 (citing Ex. 1007 ¶ 36); *see also In re Mraz*, 455 F.2d 1069, 1072 (CCPA 1972) (description via drawings and pictures can be relied upon alone as well as by words to anticipate claimed subject matter *if they clearly show the structure claimed*). At this stage of the proceeding and based on the record before us, this showing is sufficient to explain how Michelson's projections and recesses would serve to meet the functional language of the claim.

In view of the above, we determine that Petitioner has demonstrated a reasonable likelihood of showing claim 5 to be unpatentable.

C. Conclusion

In view of the above, we are persuaded that, on the record before us, Petitioner has not demonstrated a reasonable likelihood of showing claim 1 to be unpatentable but that Petitioner has demonstrated a reasonable likelihood of showing claim 5 to be unpatentable.

III. ORDER

In view of the foregoing, it is hereby:

ORDERED that *inter partes* review is instituted on the ground of whether claim 5 would have been obvious in view of Michelson and the knowledge of a person of ordinary skill in the art;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review of the '853 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial; and

FURTHER ORDERED that no ground other than that specifically provided above is authorized.

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