Trials@uspto.gov Tel: 571-272-7822

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC., Petitioner,

v.

FLEXUSPINE, INC., Patent Owner.

Case IPR2015-01721 Patent 7,316,714 B2

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

SAINDON, Administrative Patent Judge.

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

I. INTRODUCTION

Petitioner requests an *inter partes* review of claims 1 and 2 of U.S. Patent No. 7,316,714 B2 (Ex. 1001, "the '714 patent"). Paper 2 ("Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp.").

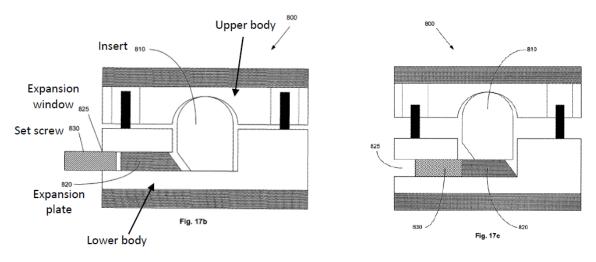
We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition, the exhibits cited therein, and Patent Owner's Preliminary Response, we do not institute an *inter partes* review on any challenged claims.

A. Related Matters

Petitioner represents that it has been accused of infringement of the '714 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.* at 3–4.

B. The '714 Patent

The '714 patent is directed to an expandable artificial intervertebral implant. Ex. 1001, Abstr. The particular embodiment recited in claims 1 and 2 is depicted in Figures 17a–c. Patent Owner included annotated versions of Figures 17b and 17c of Exhibit 1001, which are reproduced below:



Prelim. Resp. 4.

Figures 17b and 17c depict an expandable artificial intervertebral implant. Both figures depict an upper body and a lower body, with insert 810 in between. As shown in Figure 17b, set screw 830 can be advanced such as to press expansion plate 820 against insert 810. After advancing set screw 830 sufficiently, and as shown in Figure 17c, expansion plate 820 acts upon insert 810 to cause the insert to separate the upper and lower bodies. *See also* Ex. 1001, 12:61–13:14 (describing Figures 17b and 17c).

C. Illustrative Claim

Independent claim 1 is the sole independent claim challenged by Petitioner and is 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 comprising a superior surface and an inferior surface, wherein the insert is 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;

- a set screw configured to be rotated to advance the expansion member to engage the insert such that the insert increases a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine; and
- wherein the intervertebral implant is configured such that increasing the separation distance between the upper body and the lower body allows articulation or increased articulation of the intervertebral implant.

D. Prior Art and Asserted Grounds

Petitioner asserts that claims 1 and 2 of the '714 patent are unpatentable under 35 U.S.C. § 103 as obvious in view of Larsen (US Patent No. 5,782,832, issued July 21, 1998) (Ex. 1004), and the knowledge of one of ordinary skill in the art. Petitioner also relies on the testimony of Jorge A. Ochoa, Ph.D., P.E. (Ex. 1005).

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

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).

Petitioner does not offer a construction for any claim terms. Pet. 8–9. Patent Owner offers a construction of the term "insert," found in both challenged claims. Prelim. Resp. 8–9. For example, claim 1 recites "an insert comprising a superior surface and an inferior surface, wherein the insert is configured to be positioned between the . . . lower body and the . . . upper body." 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 9. 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.*

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. 22. On that matter, Petitioner argues that "configured to be positioned" does not "disclose any

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intrinsic or structural limitation of the implant." *Id.* at 23. 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 having various surfaces 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 also provides persuasive extrinsic 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").¹ The '714 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, 8:46–59, 9:22– 29, 9:50–55. 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."

¹ 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).

B. Petitioner's Ground

Claim 1 requires an implant having "an insert comprising a superior surface and an inferior surface, wherein the insert is configured to be positioned between the . . . lower body and the . . . upper body." Petitioner identifies the claimed insert as "integral to the inferior surface" of the upper body in Larsen. Pet. 23. Figure 23 of Larsen is reproduced below with Petitioner's identification of an insert highlighted in green:

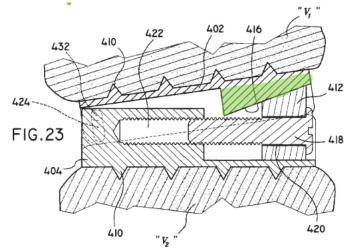


Figure 23 of Larsen depicts a spinal implant having upper support member 402 and lower support member 404 connected via a pin-and-slot arrangement (432, 424), with camming block 412 serving to push apart lower support member 404 and inner surface 416 of support member 402 when screw 418 is advanced. Ex. 1004, 8:8–28.

Petitioner identifies inner surface 416 of support member 402 as the claimed insert. Pet. 23. Patent Owner argues that inner surface 416 is not an insert because it is integral with the upper support member. Prelim. Resp. 12–13. 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. 23–26. Petitioner asserts that such a modification is "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 24. Petitioner offers evidence allegedly showing that such modularity was well known. *Id.* (citing Exs. 1005, 1009, 1013, 1015).

Exhibits 1009, 1013, and 1015 each describe similar artificial discs. As best shown in Figure 1 of Ex. 1009, reproduced below, these discs comprise upper part 2, lower part 3, and pivot insert 4:

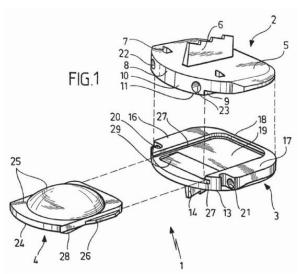


Figure 1 of Ex. 1009 depicts an artificial disc.

Exhibits 1013 and 1015 discuss similar discs, and also disclose that these three parts come in various sizes. Ex. 1013, S128; Ex. 1015, 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. 1005 ¶ 36.

Patent Owner argues that Petitioner's alternative ground is made without support. Prelim. Resp. 14–15. 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-andscrew design. *Id.* at 15. 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 a set screw used to engage 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 and set screws. Instead, the examples appear to allow users the ability to pick and choose various insert sizes, without the adjustment-type sizing implicated by the claimed insert and set screw 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. Consequently, Petitioner has not offered sufficient reasoning explaining why the subject matter of claim 1 would have been obvious in view of Larsen and the knowledge of a person of ordinary skill in the art.

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

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to be unpatentable. Petitioner's analysis for claim 2, which depends from claim 1, does not cure the underlying deficiency in the proposed ground for claim 1. *See* Pet. 41–44.

III. ORDER

In view of the foregoing, it is hereby ORDERED that the Petition is denied and no *inter partes* review is instituted.

PETITIONER:

George D. Moustakas David P. Utykanski HARNESS, DICKEY & PIERCE, P.L.C. gdmoustakas@hdp.com dutykanski@hdp.com

PATENT OWNER:

Brett M. Pinkus Jonathan T. Suder (pro hac vice motion pending) FRIEDMAN, SUDER & COOKE pinkus@fsclaw.com jts@fsclaw.com

Mark D. Strachan (pro hac vice motion pending) SAYLES | WERBNER, P.C. mstrachan@swtriallaw.com