

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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GLOBUS MEDICAL, INC.,  
Petitioner,

v.

FLEXUSPINE, INC.,  
Patent Owner.

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Case IPR2015-01795  
Patent 8,647,386 B2

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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 1–4 of U.S. Patent No. 8,647,386 B2 (Ex. 1001, “the ’386 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 of all challenged claims.

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 ’386 patent in *Flexuspine, Inc. v. Globus Medical, Inc.*, Case 15-cv-00201-JRG-KNM (E.D. Tex.). Pet. 2–3; Paper 4, 2. Petitioner also represents that it has simultaneously requested *inter partes* reviews of several other patents owned by Patent Owner. Pet. 3.

### B. Illustrative Claim

Independent claim 1 is the sole independent claim challenged by Petitioner and is reproduced below.

1. An intervertebral implant system for a human spine, comprising:
  - a first body comprising:
    - a first external surface configured to be disposed adjacent a first vertebra during use; and
    - a first internal surface opposite the first external surface;
  - a second body comprising:
    - a second external surface configured to be disposed adjacent a second vertebra during use, and
    - a second internal surface opposite the second external surface;
  - an elongated insertion instrument releasably couplable to the first or second body during use; and
  - a spacer linearly advanced between the first internal surface of the first body and the second internal surface of the second body during use, wherein the elongated insertion instrument guides at least a portion of the linear advancement of the spacer after the first and second bodies have been disposed substantially between the first and second vertebrae from a position remote to the first and second bodies during use, and wherein the linear advancement of the spacer results in expansion of the intervertebral implant such that the first external surface and the second external surface move away from one another to expand a height of the implant.

### *C. Prior Art and Asserted Grounds*

Petitioner challenges claims 1–4 under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 6,595,998 B2 to Johnson, issued July 22, 2003 (Ex. 1004, “Johnson”) and the knowledge of one of ordinary skill in

the art. Pet. 13–49. 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).

#### 1. “first body”

Petitioner first argues that the “first body” limitation is a “recitation[] of the intended use for the claimed apparatus” and “is not material to patentability.” Pet. 18–19. We disagree because the claim is directed to a structure—a body—and that body is claimed to have certain features by being “configured to be disposed adjacent a first vertebra during use.” Although broad, the “configured to” limitation precludes those structures not capable of being disposed adjacent a vertebra. *See K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1999) (“the functional language tells us

something about the structural requirements of the attachment between the bootie and the base [of an inline skate] . . .”).

Petitioner’s alternative argument as to why Johnson teaches this limitation, in the event it is given weight, sheds light on Petitioner’s interpretation of this limitation. Petitioner argues that a person of ordinary skill in the art “would have understood that . . . the wafer columns . . . would be supported between the bone surfaces.” Pet. 19. In other words, Petitioner is reading the claimed “first body” on the uppermost wafer in the stack of wafers depicted in Figure 37 of Johnson. The following annotated version of Figure 37 of Johnson illustrates Petitioner’s position:

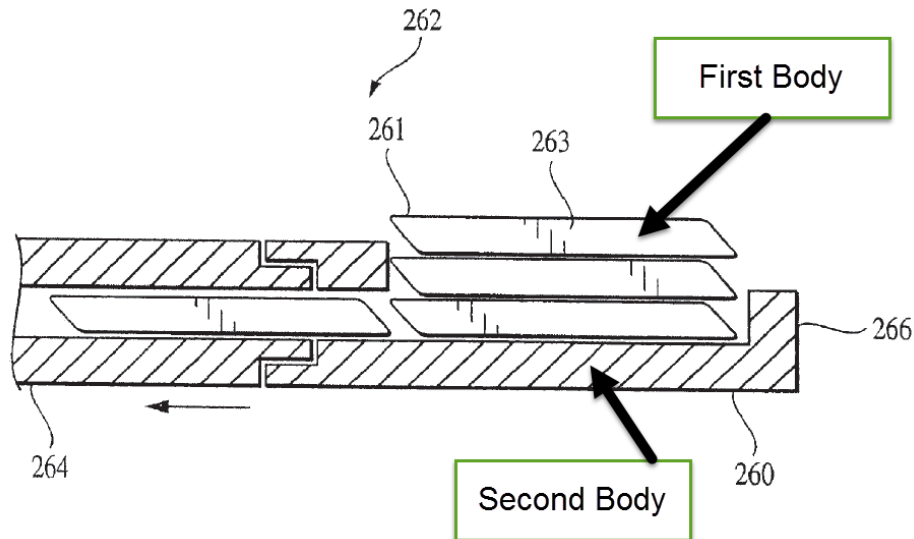


FIG. 37

Figure 37 of Johnson depicts detachable tip wafer inserter 260, wherein wafers 263 are inserted to distract and support tissue, such as vertebrae. Ex. 1004, 4:54–65, 17:47–50, 21:26–33. Petitioner has identified detachable tip 260 as the claimed second body and wafer 263 as the claimed first body. *See, e.g.*, Pet. 20 (noting identifications on annotated figure).

Accordingly, we understand Petitioner's position to be that the first body of claim 1 is the structure of the implant that is disposed against a vertebra.

Patent Owner argues that "Johnson is simply a different structural arrangement" and that, before the wafers are inserted, "there would be no first body having a superior surface arranged adjacent the upper vertebra." Prelim. Resp. 16. Patent Owner also argues that "Petitioner is improperly and unreasonably interpreting the claim language by changing the identity of the claimed 'spacer' each time an additional wafer is inserted." *Id.* at 17. Accordingly, Patent Owner's argument appears to be that claim 1 requires that the first body not be the same type of structure as the claimed spacer.

The claims do not describe the structural features of the first body and the spacer in detail. The first body is described as having external and internal surfaces, with the external surface configured to be disposed adjacent a vertebra. The '386 patent's specification describes many different embodiments having many different configurations. Figures 1–8, for example, show structures identified as upper and lower bodies. *See, e.g.*, Ex. 1001, 13:63–14:8 (describing upper and lower bodies configured in particular ways to accommodate an insert). The bodies are described generally as interfacing with bone (as is required by claim 1). *See, e.g., id.* at 10:40–51 (describing bodies having surfaces to "reduc[e] the possibility of subluxation and/or dislocation"). Figures 9A–9F depict a cage embodiment where an insert is pushed out past the cage. *Id.* at 14:35–58. The cage has one or two apertures that permit an insert to move out from the cage into contact with the vertebra. *Id.* The '386 patent does not describe any feature in this embodiment as a "body." *See generally id.* at 14:33–15:18. Figures 18 and 24A–24E depict a device having two bodies and a

spacer, wherein the spacer acts as a shim to expand the implant. *Id.* at 18:27–63. The spacers are described generally as having a fixed size to provide a fixed separation distance between upper and lower bodies. *See, e.g., id.* at 18:52–63. The spacers “may have substantially the same shape and/or profile as upper body” and may be made “of the same material as an implant into which the spacer is to be inserted.” *Id.* at 18:39–41, 58–61.

Reviewing the specification, we find little guidance as to what structural features are required by a body, aside from the fact that it is a portion of the implant designed to interface with bone, but that already is recited in claim 1. The bodies in the specification are described generally as having features on the interior side conforming to the shape of various inserts, e.g., Figures 1–8, but claim 1 does not include an insert and is not directed to these embodiments. In embodiments showing a spacer, e.g., Figure 24, the discussion focuses on the spacer, not the body. *See generally id.* at 22:30–23:3. Accordingly, the specification by itself does not appear to shed much light on the structural features of a body. In addition, just because one series of embodiments has both bodies and a spacer and the claim has bodies and a spacer does not mean that we import limitations from those embodiments into the claims. *Superguide Corp. v. DirecTV Enter., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment). Here, claim 1 is broader than those embodiments, as it generically recites features of the body and spacer, without the level of detail of any particular embodiment.

We next look to evidence of how a person of ordinary skill in the art would understand the term “body” in view of the specification. The record

before us includes testimony of Dr. Ochoa, who testifies that the “first body” limitation reads on the topmost wafer in Johnson, in his opinion. Ex. 1005 ¶ 34.<sup>1</sup> Thus, Dr. Ochoa’s testimony provides evidence that a person of ordinary skill in the art would understand the term as proposed by Petitioner.

Lastly, we turn to the prosecution history that Petitioner has brought to our attention. Pet. 11. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (“In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.”) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005)); *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (instructing the PTO to consider prosecution history in *inter partes* review). As we mentioned above, the embodiments in Figures 9A–9F are among the few that are not described as having a body. Notwithstanding, according to the prosecution history, this is the embodiment the applicant selected in response to a restriction requirement. Ex. 1003, 1515–1517 (applicant electing “Group 10 (Figs. 9A–9F),” which included corresponding claim 158); *id.* at 16, 1507, 1740 (showing allowed claim 158 is claim 1 of the ’386 patent).

In view of the above and on the present record, we understand the term “first body” to be a structural element having the claimed features of an external surface configured to be adjacent a first vertebra and an internal surface opposite the first surface.

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<sup>1</sup> Dr. Ochoa, however, does not provide an explicit analysis of how a person of ordinary skill in the art would understand the terms “body” or “spacer” in view of the specification.



2. “move away from one another”

Claim 1 recites that “linear advancement of the spacer results in expansion of the intervertebral implant such that the [first and second bodies] move away from one another.” Petitioner asserts that this term reads on both (1) one body moving away from another, unmoving body and (2) both bodies moving away from a central reference location. Pet. 10–12. As support for both interpretations, Petitioner points to the embodiments in Figure 9 of the ’386 patent, which include one body moving up (Figs. 9B–9E) and two bodies moving away from a central location (Fig. 9F). *Id.*

Patent Owner does not offer a construction of this term.

We agree with Petitioner, based on embodiments shown in Figures 9B–9F, that a person of ordinary skill in the art would understand that “move away from one another” includes both types of movement suggested by Petitioner. Accordingly, the broadest reasonable interpretation of the term in light of the specification only requires one body to move for the bodies to be moving away from one another as claimed.

*B. Analysis of Petitioner’s Grounds*

Petitioner asserts that the subject matter of claims 1–4 is unpatentable in view of Johnson and the level of ordinary skill in the art. Pet. 13–40. In particular, Petitioner reads the first body on the topmost wafer of Johnson (which is adjacent a vertebra) and the second body on distal tip 260 of wafer inserter 262. *Id.* at 16–21. Petitioner reads the elongated insertion instrument on the wafer inserter of Johnson (*id.* at 21–25) and the spacer on the wafer(s) inserted after the first wafer (*id.* at 25–30). Petitioner’s Figure 1, reproduced below, illustrates Petitioner’s position:

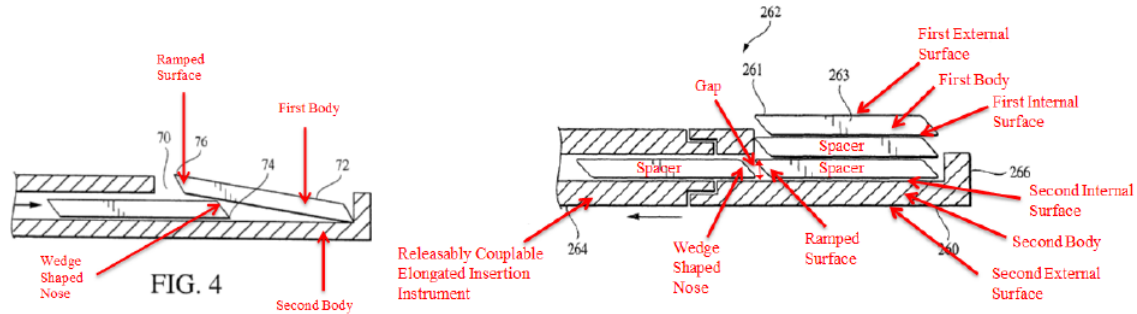


Figure 1. Excerpt from the '899 patent illustrating various claim elements.

Figure 1 depicts annotated copies of Figures 4 and 37 of Johnson showing how Petitioner reads the claim limitations onto Johnson's implant.

Patent Owner argues that "Petitioner makes no attempt to identify the missing elements and then explain why they would be obvious to the skilled artisan." Prelim. Resp. 15; *see also id.* at 18 (making a similar argument). Patent Owner also argues that "Johnson is simply a different structural arrangement" from claim 1, an argument we understand to be that Johnson does not disclose a first body and spacers. *Id.* at 15–16. Patent Owner next argues that the claim provides for only a single spacer, whereas Johnson has multiple spacers. *Id.* Patent Owner argues that, in Johnson, "before the first wafer is inserted, there would also be no first body." *Id.* at 16–17. Patent Owner does not argue the dependent claims at this time. *Id.* at 19, n.5.

As to Patent Owner's argument that the claim precludes multiple spacers, we note no such limiting language is found in the claims. The claim is in open-ended "comprising" form and claims "a spacer"; the transition "comprising" coupled with "a" or "an" is a form understood to permit a plurality of elements. *Baldwin Graphic Systems, Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2005) ("[t]his court has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of

‘one or more’ in open-ended claims containing the transitional phrase ‘comprising’”) (internal quotation and citations omitted). Patent Owner points to no passage in the claims, specification, or any other evidence in support of its position that “a spacer” means one and only one spacer. *Cf. id.* at 1343 (“An exception to the general rule that ‘a’ or ‘an’ means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule”). Reviewing the record before us, we are not persuaded that the structure recited in claim 1 would preclude multiple spacers.

Patent Owner’s argument that Johnson is a different structural arrangement is also not persuasive. The claimed first body is described as having external and internal surfaces, with the external surface configured to be disposed adjacent a vertebra. Under our construction of the term “first body,” the topmost wafer in Johnson satisfies that limitation. The topmost wafer 263 has the claimed surfaces and is intended to be disposed adjacent a vertebra. *See, e.g.*, Ex. 1004, 13:45–47 (contemplating wafer-to-bone bonding), Figs. 27–28 (depicting wafers 198 adjacent a vertebra).<sup>2</sup> As claimed, a spacer is described as configured such that its linear advancement results in expansion of the implant, i.e., movement of the bodies away from each other. Wafers 263 also are configured such that linear advancement results in a force being applied to the bone, by way of their sloped edges. *See, e.g., id.* at 17:65–66 (“wafers are inserted until the desired height or force is attained”). Although Petitioner is reading two limitations on the

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<sup>2</sup> We further note that the embodiment shown in Figure 28 of Johnson has a specialized wafer as the first wafer, i.e., the wafer adjacent the vertebra. Ex. 1004, 14:31–39, Fig. 28.

same type of structure (a wafer), we are not persuaded that this is impermissible because Petitioner is pointing to two distinct wafers, not the same wafer, as meeting both structural elements. The physical characteristics of the wafers in Johnson appear to satisfy the limitations of both the first body and the spacer of claim 1. Accordingly, we are not persuaded, under our preliminary construction and in view of the record before us at this time, that Johnson discloses a different structural arrangement from what is claimed.

Patent Owner next argues that, under Petitioner's reading of the claims on Johnson, that "before the first wafer is inserted, there would also be no first body." Prelim. Resp. 16–17. According to Petitioner's ground, the claimed spacer is the second wafer (and/or subsequent wafers) of Johnson. *See, e.g.*, Pet. 30 (depicting Petitioner's Figure 1, also reproduced above). Claim 1 requires that a spacer is something that is guided into location using a guide after the bodies have been disposed between the vertebrae. In this regard, the first inserted wafer in Johnson may not meet this limitation, but the second and any subsequent wafers would. At the time when the second wafer is to be inserted, the first wafer would have been in place between the vertebrae. As such, Patent Owner's argument is not persuasive.

Patent Owner's argument that Petitioner has failed to address explicitly which limitations, if any, were missing in Johnson is well taken but not persuasive that Petitioner has failed to show a reasonable likelihood of success. Because Petitioner has addressed where Johnson discloses each claim element, we determine that Petitioner has shown a reasonable likelihood of success on its obviousness ground. *See Cohesive Techs. Inc. v.*

*Waters Corp.*, 543 F.3d 1351, 1363–66 (Fed. Cir. 2008) (discussing the “anticipation is the epitome of obviousness” maxim and the distinctions between anticipation and obviousness).

Accordingly, based on the record before us, we determine that Petitioner has shown a reasonable likelihood that the subject matter of claim 1 would have been obvious in view of Johnson. Having shown “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition,” we institute review on claims 1–4 of the ’386 patent.

Petitioner offers a second ground of obviousness of Johnson, Pet. 40–49, in the event we construed the phrase in claim 1—“move away from one another”—in a manner to require both bodies to move. *Id.* at 40. We do not read the claim so narrowly and, thus, do not reach this alternative ground.

### III. ORDER

In view of the foregoing, it is hereby:

ORDERED that *inter partes* review is instituted on the ground of whether claims 1–4 would have been obvious in view of Johnson 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 ’386 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.

Case IPR2015-01795

Patent 8,647,386 B2

PETITIONER:

George Moustakas

David Utykanski

[gdmoustakas@hdp.com](mailto:gdmoustakas@hdp.com)

[dutykanski@hdp.com](mailto:dutykanski@hdp.com)

PATENT OWNER:

Brett M. Pinkus

FRIEDMAN, SUDER & COOKE

[pinkus@fsclaw.com](mailto:pinkus@fsclaw.com)

Jonathan T. Suder

(pro hac vice motion pending)

FRIEDMAN, SUDER & COOKE

[jts@fsclaw.com](mailto:jts@fsclaw.com)

Mark D. Strachan

(pro hac vice motion pending)

SAYLES | WERBNER, P.C.

[mstrachan@swtriallaw.com](mailto:mstrachan@swtriallaw.com)

[hermesch@fsclaw.com](mailto:hermesch@fsclaw.com)

[dunn@fsclaw.com](mailto:dunn@fsclaw.com)