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Paper 65
Date: July 10, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,
Patent Owner.

Case IPR2013-00206
Patent 8,251,997 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

NuVasive, Inc. ("Petitioner") filed a petition (Paper 5) ("Pet.") seeking *inter partes* review of claims 9–30 of U.S. Patent No. 8,251,997 B2 (Ex. 1002, "the '997 patent") pursuant to 35 U.S.C. §§ 311–319.[1] On

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[1] We cite to Petitioner's Corrected Petition for *Inter Partes* Review of United States Patent No. 8,251,997 B2, filed April 3, 2013. Paper 5.

September 23, 2013, the Board instituted an *inter partes* review of all claims on six grounds of unpatentability (Paper 17) ("Dec. on Inst.").

Subsequent to institution, Warsaw Orthopedic, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 32) ("PO Resp."), and Petitioner filed a Reply (Paper 43) ("Pet. Reply"). Patent Owner also filed a Motion to Exclude Evidence. Paper 53. Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 59) ("Opp."), and Patent Owner filed a Reply (Paper 60) ("PO Reply"). An Oral Hearing was conducted on June 5, 2014, pursuant to a request for oral hearing filed by Petitioner (Paper 52) and Patent Owner (Paper 54).

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 17–23 of the '997 patent are unpatentable, but has not shown by a preponderance of the evidence that claims 9–16 and 24–30 of the '997 patent are unpatentable.

A. The '997 Patent (Ex. 1002)[2]

The '997 patent describes methods and instrumentation for performing surgery on the spine along its lateral aspect. Ex. 1002, 3:34–36; Figs. 1 and 2. Guide pin 30 is inserted from the lateral approach to the spine and functions as a guide post for distractor 100 that is placed over the guide pin and inserted into the disc space to distract the vertebrae. Ex. 1002, 8:52–53; 9:12–14; 10:10–12; Figs. 2–5. Extended outer sleeve 140 is placed over the distractor and inserted into the disc space. Ex. 1002, 10:22–25, Fig. 12.

[2] We refer to Ex. 1002 submitted by Petitioner and dated March 22, 2013.

A spinal implant I is introduced through the extended outer sleeve and installed across the disc space. Ex. 1002, 15:64–65; 16:24–26; Figs. 19, 22, 23, 30, and 30A.

B. Illustrative Claim

Claim 9 is illustrative of the claimed subject matter of the ’997 patent, and is reproduced as follows:

> 9. A method comprising:
>
> making an incision in skin of a patient’s body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;
>
> advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;
>
> advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space, said single elongated portion having a length, a thickness, and a width, the length of said single elongated portion being greater than the width and the thickness of said single elongated portion, the width of said single elongated portion being greater than the thickness of said single elongated portion, said single elongated portion being tapered to facilitate entry between the vertebral bodies of the two adjacent vertebrae;

inserting said single elongated portion into the disc space with the width of said single elongated portion being oriented along a height of the disc space; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

C. Cited Prior Art

The pending grounds of unpatentabililty in this *inter partes* review are based on the following prior art:

Jacobson	US 4,545,374	Oct. 8, 1985	(Ex. 1004)
Brantigan	US 5,192,327	Mar. 9, 1993	(Ex. 1006)
Frey	US 4,917,704	Apr. 17, 1990	(Ex. 1007)
Michelson ’247	US 5,015,247	May 14, 1991	(Ex. 1008)
McAfee	US 5,569,290	Oct. 29, 1996	(Ex. 1009)

Hansjörg F. Leu and Adam Schreiber; *Percutaneous Fusion of the Lumbar Spine: A Promising Technique*, 6(3) SPINE: STATE OF THE ART REVIEWS 593 (Sept. 1992) (Ex. 1005, “Leu”).

D. Pending Grounds of Unpatentability

This *inter partes* review involves the following asserted grounds of unpatentability:

Reference(s)	**Basis**	**Claims challenged**
Jacobson, Leu, McAfee, and Michelson ’247	§103	9 and 16
Jacobson, Leu, McAfee, Michelson ’247, and Frey	§103	10–15
Jacobson, Leu, and Brantigan	§103	17 and 23
Jacobson, Leu, Brantigan, and Frey	§103	18–22
Jacobson, Leu, and Michelson ’247	§ 103	24 and 30
Jacobson, Leu, Michelson ’247, and Frey	§ 103	25–29

E. Claim Interpretation

The parties appear to agree with the interpretation of various claim terms of the ’997 patent as described in the Decision on Institution with additions or modifications as set forth below. We incorporate our previous analysis for the non-disputed claim terms.

1. “a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes” (claim 9)

Patent Owner argues that an “axis lying in a coronal plane” should be construed as an axis that is lying in “a plane at right angles to a sagittal plane.” PO Resp. 11. Petitioner does not contest Patent Owner’s assertion that one of ordinary skill in the art would understand that a “coronal plane” would be oriented “at right angles to a sagittal plane.” Pet. Reply 1. Thus, no further construction of this term is necessary.

2. “elongated portion” (claim 9)

Patent Owner argues that the term “elongated portion” should be broadly, but reasonably, construed as a portion in which “its length is *substantially* greater than its width.” PO Resp. 12. Petitioner argues that “elongated” should be construed as a portion having a length greater than its width. Pet. Reply 1–2. As Petitioner points out, claim 9, for example, recites the “length of said single elongated portion being greater than the width . . . of said single elongated portion.” Patent Owner does not show persuasively that the claims recite a requirement that the length of the elongated portion is “substantially” greater than the width of the elongated portion or that the Specification discloses such a requirement. Patent Owner

also does not provide a persuasive rationale as to why one of ordinary skill in the art would have assumed that the length of the elongated portion is "substantially" greater than the width of the elongated portion in view of the absence of the disputed qualifier in the claims and Specification.

We construe the elongated portion as having a length that is greater than the width of the elongated portion.

II. ANALYSIS

A. Grounds Based at Least in Part on Jacobson, Leu, and Brantigan (Claims 17–23)

Claim 17 recites a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae. Patent Owner contends that a path having an axis lying in a coronal plane, as recited in claim 17, must be a path that is "a direct or true lateral path to the spine." PO Resp. 11. Petitioner concurs. Pet. Reply 1.

Jacobson – "lateral"

Jacobson discloses a procedure in which "a cannula is passed laterally through the body," a needle that "is inserted laterally through the patient's side" that "may act as a guide member . . . for instruments that create the percutaneous body channel," a speculum that "is laterally inserted through body tissue" and is "used to create the lateral cavity through body tissue into which the cannula will be inserted." Ex. 1004, 5:1–2, 5:27–28, 5:49–51, 5:40–42, 8:53–55. Jacobson also provides drawings of the approach to the intervertebral space. The drawings depict a lateral approach to the intervertebral space, consistent with the textual description. Ex. 1004, Figs. 1–6.

Patent Owner argues that while Jacobson discloses accessing a disc space from a "lateral" aspect, the term "lateral" "has any number of meanings, including anterolateral, posterolateral, direct lateral, and lateral to the midline of the vertebral bodies" and that, despite Jacobson's disclosure of a "lateral" approach, Jacobson actually "discloses a posterolateral – not a direct lateral – approach to the spine." PO Resp. 19 (citing Ex. 2039, 37:25 – 39:1).

Petitioner provides testimony of Dr. Robert E. Jacobson to demonstrate what one of ordinary skill in the art would have understood the term "lateral" to mean in the context of performing a spinal fusion procedure. Ex. 1030 ¶ 5. Dr. Jacobson testifies that one of ordinary skill in the art would not have used (or understood) the term "direct lateral" but, instead, would have used the term "lateral" as Patent Owner uses the term in the present proceedings.[3] We credit Dr. Jacobson's testimony that one of ordinary skill in the art would have understood the term "lateral" to mean what it says (i.e., to mean "lateral"), at least because it would have been reasonable for one of ordinary skill in the art to have construed a term (i.e., "lateral") with a common, accepted definition. Patent Owner's observation that a construction of the term "lateral" that was in use at the time of the invention included a "direct lateral" approach (as understood in this proceeding) further supports Dr. Jacobson's testimony that one of ordinary skill in the art would have understood the term "lateral" to mean "direct

[3] Dr. Jacobson testifies that "the phrase 'direct lateral' was not a phrase that I used in the technical parlance of my profession . . . at that time I had never heard the phrase 'direct lateral' to describe a 90 degree lateral approach to the spine. Instead, . . . I (and others) simply used the term 'lateral' when referring to a 90 degree lateral approach to the spine." Ex. 1030 ¶5.

lateral," as that term is presently construed in the instant proceedings. Also, we note that claim 17 does not recite the term "direct lateral," and Patent Owner does not assert that the '997 patent specification discloses the term "direct lateral." The absence of the term "direct lateral" in the '997 patent further supports that one of ordinary skill in the art at the time of the invention would not have used (or understood) the term "direct lateral."

In addition to Jacobson's explicit disclosure of, for example, "laterally inserting a cannula," Jacobson discloses figures that illustrate what Patent Owner now refers to as a "direct lateral" approach (i.e., lateral insertion along a path having an axis lying in a coronal plane). Ex. 1004, 2:26–27, Figs. 3–8. We note that in each of the figures of Jacobson, the outer side periphery of the instrument(s) inserted "laterally" into the intervertebral space, as illustrated, are depicted by parallel lines that are oriented at 90 degrees from a horizontal surface. Based on the depiction of the outer side contours of the instrument(s) as being oriented 90 degrees from a horizontal surface, one of ordinary skill in the art would have understood that the instrument(s) are perpendicular to an underlying horizontal surface in the superior-inferior perspective (with respect to the orientation of the patient). More importantly, as the outer side contours of the instruments are parallel in these perspectives, one of ordinary skill in the art would have understood the instruments, as illustrated by Jacobson, to be perpendicular to an underlying horizontal surface in the medial-lateral perspective (with respect to the orientation of the patient – i.e., that the orientation of the instrument(s) is "direct lateral," as Patent Owner uses that phrase, and not "posterolateral" or "anterolateral"). That is true because, assuming the instrument(s) illustrated in Jacobson are cylindrical, if the instrument(s) were angled away

from the viewer, the outer side contours of the instrument(s) at the point of insertion into the intervertebral space would appear farther away from each other as compared to the outer side contours of the instrument(s) at the point farthest from the point of insertion into the intervertebral space (i.e., the proximal end of the instrument(s), which would be located farther away from the viewer). Likewise, if the instrument(s) were angled toward the viewer, the outer side contours of the instrument(s) at the point of insertion into the intervertebral space would appear closer to each other as compared to the outer side contours of the instrument(s) at the point farthest from the point of insertion into the intervertebral space (i.e., the proximal end of the instrument(s), which is located closer to the viewer).

Moreover, as Petitioner's declarant (Dr. Paul McAfee) points out, an anterior cross sectional view of the instrument(s) in-situ (i.e., Ex. 1004, Fig. 6) shows an even and symmetrical view of the instruments throughout the length of the instrument(s). *See, e.g.*, Ex. 1029 ¶ 38. Dr. McAfee's testimony further supports that Jacobson discloses that the instruments are inserted along a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae, as recited in claim 17 (i.e., the "direct lateral" approach as presently understood in the instant proceedings).

Patent Owner argues that the figures as disclosed by Jacobson "appear to show a direct lateral path," but "do not clearly show the surgical approach" because the figures "are merely two-dimensional depictions [that depict the same orientation]" and that "these figures [of Jacobson] could just as likely disclose a posterolateral or anterolateral approach to the spine." PO Resp. 23–24 (citing Ex. 2038 ¶ 81). Patent Owner does not explain

adequately, however, how the anterior view of instrument(s) illustrated in Jacobson, with parallel outer side contours as described above or the anterior cross-sectional view of the instrument(s) throughout the length of the instrument(s) as also described above (i.e., instrument(s) that are normal to an underlying horizontal surface), "could just as likely" illustrate instrument(s) that are angled with respect to an underlying horizontal surface. While Patent Owner also argues that "surgeons are trained to orient an instrument in a patient's body by taking images of the instrument from multiple angles," Patent Owner does not demonstrate persuasively that, even if surgeons are trained to take images at multiple angles, that Jacobson illustrates that the instrument(s) are angled (i.e., a posterolateral or anterolateral approach). PO Resp. 24 (citing Ex. 2038 ¶ 81).

Patent Owner argues that Jacobson "discloses a method of performing percutaneous discectomy that implicates anatomical structures such as the spinal nerves and nerve root – structures that are encountered during a posterolateral (not direct lateral) approach to the spine" and a "stimulator [that] will cause motion in one of the patient's legs if it makes nerve contact [and that motor nerves are implicated only in a posterolateral approach.]" PO Resp. 19–20 (citing Ex. 2038 ¶¶ 76–77; Ex. 1004, 6:38–40). As Patent Owner indicates, Jacobson discloses "[t]o prevent nerve damage, a nerve stimulator . . . may be attached or passed down into the cannula or trocar to indicate if either instrument is hitting one of the spinal nerves or exiting nerve branches." Ex. 1004, 6:32–38. It is not disputed that Jacobson discloses a "lateral approach" that includes a "direct lateral" approach, as construed in the instant proceedings (see discussion above). Also, as described above, Jacobson discloses illustrations of a spinal fusion

procedure in which instruments are inserted into an intervertebral space (i.e., a "direct lateral" approach as presently understood) while oriented normal to an underlying horizontal surface (i.e., having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae). Patent Owner does not demonstrate sufficiently how Jacobson's further disclosure of the possible use of a "nerve stimulator" that indicates if an attached instrument contacts a nerve means that Jacobson does not disclose or suggest a lateral approach. For example, regardless of which approach Jacobson discloses, a "nerve stimulator" allegedly would be capable of detecting contact with a nerve because the functionality of a "nerve stimulator" would not be affected by whatever approach is disclosed by Jacobson.

Patent Owner argues that one of ordinary skill in the art would have understood that "the clearest path to a disc space is posterolaterally [and not direct lateral, as that term is used in these proceedings]." PO Resp. 21. Patent Owner further contends that Jacobson discloses "using a long spinal needle" to anesthetize the patient and that, based on this disclosure and the allegation that a posterolateral (and not "direct lateral") approach is the "clearest path" that avoids the bowel, one of ordinary skill in the art would have understood that Jacobson discloses a posterolateral approach and not a "direct lateral" approach. PO. Resp. 21–22. As previously described, however, Jacobson discloses a "lateral" approach, which includes a so-called "direct lateral" approach and illustrates such an approach. Patent Owner does not show persuasively that one of ordinary skill in the art, given these explicit teachings, would have understood that the apparent "direct lateral" approach of Jacobson is actually a "posterolateral" approach based on

Jacobson's disclosure of one choice of method of administering an anesthetic.

In any event, as Patent Owner indicates, Jacobson discloses a "go-no-go" indicator that determines if the needle can be used. If the needle of Jacobson cannot be used, "the procedure cannot be used on this particular patient." *Id*. at 21 (citing Ex. 1004, 5:23–36). In other words, Jacobson discloses that if the needle cannot be safely used on a particular patient, the procedure is not performed. Even assuming Patent Owner's contention to be correct that using a so-called "direct lateral" approach carries a risk of bowel perforation, Jacobson explicitly addresses any such potential complications of the procedure. Hence, we are not persuaded that the potential use (or non-use) of a needle in Jacobson would suggest to one of ordinary skill in the art of a particular route of entry of the needle in a patient.

Patent Owner argues that Jacobson discloses a procedure that "can 'be performed in approximately 15 minutes,'" and that one of ordinary skill in the art would have understood that performing the procedure using a "direct lateral" approach would have taken "significantly longer than" 15 minutes. *Id*. at 23 (citing Ex. 2038 ¶ 86). Based on this assumption, Patent Owner contends that Jacobson discloses a posterolateral approach. Jacobson discloses that "[i]nstruments constructed in accordance with the invention allow the procedure to be performed in approximately 15 minutes under only local anesthesia." Ex. 1004, 2:54–57.

Patent Owner's declarant (Dr. Barton L. Sachs) testifies that "[p]erforming such a procedure in 15 minutes is far more consistent with an approach that is [posterolateral] than one that is direct lateral" and that "[i]n my opinion, a direct lateral discectomy would take significantly longer than

15 minutes." Ex. 2038 ¶ 87. However, Dr. Sachs testifies that he is of the opinion that a 15 minute procedure is "consistent with" a posterolateral procedure, but does not assert or provide sufficient evidence to suggest that one of ordinary skill in the art would have understood that such a procedure taking 15 minutes or less would not have used the so-called "direct lateral" approach. In addition, even assuming Patent Owner's implication that performance of spinal fusion using the so-called "direct lateral" approach could never be completed within 15 minutes, we note that Dr. Sachs testifies that the so-called "direct lateral" approach takes longer than 15 minutes because such an approach "requires care to deal with anatomical structures such as the peritoneum, the bowel, vascular structures, and the psoas muscle." Ex. 2038 ¶ 87. Jacobson discloses that the procedure takes "approximately 15 minutes under only local anesthesia," suggesting that Jacobson's time estimate of 15 minutes would not include the time for administering anesthesia (or advancing a needle to administer the anesthetic). Hence, one of ordinary skill in the art would have understood that the alleged "rate-limiting" step (according to Dr. Sachs) of dealing with the bowel, for example, would not be included in Jacobson's time estimate of 15 minutes. Dr. Sachs (and Patent Owner) does not demonstrate that one of ordinary skill in the art would have understood that the so-called "direct lateral" approach must take longer than 15 minutes, even after the "anatomical structures" that Dr. Sachs cites are already "dealt with."

Patent Owner argues that Jacobson discloses "placement of a patient in a lateral decubitus position [that] does not necessarily mean his approach is directly lateral." PO Resp. 23. Patent Owner does not demonstrate sufficiently, however, that one of ordinary skill in the art would have

understood that placement of a patient in a lateral decubitus position would mean necessarily the approach is something other than the so-called "direct lateral" approach, particularly in view of the previously discussed disclosure of Jacobson suggesting to one of ordinary skill in the art that the approach disclosed is the so-called "direct lateral" approach.

Jacobson discloses that the surgical procedure is a "fusion" surgical procedure. Ex. 1004, 6:13. Petitioner states that "a 'fusion' procedure . . . necessarily includes the insertion of an implant into the disc space." Pet. 19. Hence, Petitioner argues that Jacobson discloses or suggests an implant. Patent Owner argues that a fusion surgical procedure "can be with or ***without*** an implant" and that an "[i]nherent disclosure by a prior art reference 'is appropriate only when the reference discloses prior art that must ***necessarily*** include the unstated limitation.'" PO Resp. 25 (citing Ex. 2039, 26:23 – 27:1). Hence, Patent Owner argues that a fusion surgical procedure does not necessarily include the insertion of an implant.

Based on the record, we agree with Patent Owner that a "fusion" surgical procedure does not require the insertion of an implant in every instance. Therefore, we agree with Patent Owner that a "fusion" surgical procedure does not "necessarily" include the insertion of an implant. We disagree, however, with Patent Owner's implication of a requirement of showing a claim limitation is inherently present in a prior art reference to support a prima facie showing of obviousness of the disputed claims over a combination of references. For example, a "single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005). In the present case, the ground of

unpatentability in dispute is not "by anticipation." Hence, whether the "fusion" surgical procedure of Jacobson "necessarily" includes insertion of an implant has not been shown to be relevant to the present proceedings.

Brantigan – "implant being sized to occupy substantially the full transverse widths of the vertebral bodies"[4]

Claim 17 recites the length of an implant being sized to occupy substantially the full transverse widths of the vertebral bodies of the two adjacent vertebrae. Petitioner argues that Brantigan discloses or suggests this feature. *See, e.g.*, Pet. 28. Patent Owner argues that Brantigan discloses implants that are "***shaped*** to conform with the general outline perimeter of the vertebrae," but fails to disclose or suggest that "the implant is ***sized*** to trace the outline perimeter of the [vertebrae]." PO Resp. 34. As Petitioner points out, however, Brantigan discloses, for example, a "plug . . . generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column." Ex. 1006, 4:6–8. Hence, Brantigan discloses an implant that is both shaped and sized with regard to the disc space.

Patent Owner argues that Brantigan discloses an implant "that is designed to sit within the apophyseal ring" and "designed to sit in the central region of adjacent vertebral bodies where bone tends to be more cancellous and vascular." PO Resp. 36–37 (citing Ex. 1006, 2:15–16, Fig. 1; Ex. 2041, 1520:2–16; Ex. 2039, 50:1–10; Ex. 2038 ¶ 110). Hence, Patent Owner argues that Brantigan fails to disclose an implant that includes (or overlaps)

[4] Patent Owner argues that "[c]ollateral estoppel precludes Petitioner from relitigating its rejected interpretation of the disclosures of Brantigan." PO Resp. 39. After careful consideration, we are not persuaded by Patent Owner's arguments for at least the reasons previously stated. *See, e.g.*, Dec. on Inst. 13.

the apophyseal ring of a vertebral body or extends beyond a central region of a vertebral body. As previously described, claim 17 recites an implant being sized to occupy substantially the full transverse width of the vertebral body. Patent Owner does not show that claim 17 also recites an implant being sized to extend onto the apophyseal ring of the vertebral body or an implant being sized to extend beyond a central region of a vertebral body. Nor does Patent Owner point to an explicit disclosure in the Specification regarding the length of the implant with respect to the alleged "apophyseal ring." We, therefore, are not persuaded by Patent Owner's contention.

Patent Owner argues that Brantigan discloses an implant "conforming in shape and size with opposing ***hard end plates*** of vertebrae'" that does not "include the outer periphery (or apophyseal ring) of a vertebral body" or "***the entire vertebral body***." PO Resp. 34 (citing Ex. 2038 ¶ 29). As an initial matter, claim 17 recites an implant being sized to occupy substantially the full transverse width of the vertebral body. Hence, claim 17 requires that the implant occupy "a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount." Dec. on Inst. 9. Patent Owner does not demonstrate that claim 17 requires that the implant includes "the entire vertebral body."

Also, as discussed above, Brantigan discloses that the implant is "sized to conform with the disc space between adjoining vertebrae." Ex. 1006, 4:6–7. We construe the term "disc space" recited in claim 17 broadly but reasonably and in light of the Specification to include a space between adjacent vertebral bodies. We agree with Petitioner that it would have been obvious to one of ordinary skill in the art that an implant that is "sized to conform with the disc space," as disclosed by Brantigan, would have

occupied at least a length that is less than the full transverse width of the vertebral bodies by an insubstantial amount (i.e., occupying "substantially" the full transverse width). Otherwise, an implant that does not occupy "substantially" the full transverse width would not have been sized to conform to the disc space, in contrast to Brantigan's disclosure that the implant is, in fact, sized to conform to the disc space.

Dr. Sachs testifies that the vertebral body contains a "vertebral endplate " that "is typically vascular," an "apophyseal ring" "anatomically distinct from the vertebral endplate" and "almost entirely avascular" located "[t]oward the vertebral periphery," and a "cortical rim" "distinct from the apophyseal ring" located "[a]t the very edge of the vertebral body." Ex. 2038 ¶ 29.

While Dr. Sachs provides testimony on the anatomy of the intervertebral space and disc, Dr. Sachs does not appear to provide testimony supporting Patent Owner's implied contention that one of ordinary skill in the art would have considered the term "occupying substantially the full transverse width of the vertebral body," as recited in claim 17, to mean "occupying no more than the width of the vertebral endplate" or "occupying (or not occupying) any portion of the apophyseal ring." Hence, even assuming that Dr. Sachs' characterization of the anatomy of the intervertebral disc space and vertebral bodies is correct, the testimony of Dr. Sachs provides insufficient evidence to refute the prima facie showing that it would have been obvious to one of ordinary skill in the art that an implant that is "sized to conform with the disc space," as disclosed by Brantigan, would occupy "substantially" the disc space (i.e., including a length that is less than the full transverse width of the vertebral bodies by an insubstantial

amount). In addition, even assuming claim 17 requires the length of the implant to overlap onto the "apophyseal ring" (claim 17 does not recite this requirement, however), the length of the implant of Brantigan would have included both the alleged "vertebral endplate" and the alleged "apophyseal ring" because both of these alleged structures overlie the space between adjacent vertebral bodies (i.e., the "disc space").

Patent Owner argues that Brantigan "expressly teaches an implant that is designed to sit within the apophyseal ring" as illustrated in Figure 10 of Brantigan, which, according to Patent Owner, "shows the implant 11 sitting well within the apophyseal ring." PO Resp. 36 (citing Ex. 1006 at Fig. 10). We note that Brantigan illustrates an implant within an intervertebral space in Figure 10; however, Patent Owner does not show persuasively that Brantigan "expressly teaches" that the implant illustrated in Figure 10 sits "within the apophyseal ring." For example, Brantigan does not appear to label any structure within Figure 10 as the "apophyseal ring." Nor does Patent Owner point to a disclosure in the textual portion of Brantigan indicating that the implant as illustrated in Figure 10 (or any other figure in Brantigan) sits "within the apophyseal ring." Indeed, as previously described, Brantigan appears to disclose the opposite (i.e., that the implant is "sized to conform with the disc space"). We, therefore, agree with Petitioner that one of ordinary skill in the art would not have understood that Brantigan discloses or suggests that the implant must not extend into the disc space encompassed by the apophyseal ring (not having been disclosed or suggested by Brantigan).

Patent Owner argues that "a figure in Brantigan . . . was admittedly drawn incorrectly." PO Resp. 36 (citing Ex. 2041, 1516:13–25, 1517:6–12;

Ex. 2039, 44:5–14). In particular, Patent Owner argues that Figure 11 of Brantigan allegedly contains discrepancies regarding the direction of insertion of the implant into the intervertebral space. *See, e.g.*, Ex. 2041, 1516:13–25. We are not persuaded by Patent Owner's argument at least because, even if Figure 11 discloses discrepancies regarding the direction of insertion of the implant, Patent Owner does not show persuasively that any such errors in Figure 11 sufficiently refute the prima facie case of obviousness that it would have been obvious to one of ordinary skill in the art to have provided an implant sized to occupy "substantially the full transverse widths of the vertebral bodies" given Brantigan's explicit disclosure that the implant is "sized to conform with the disc space."

Patent Owner argues that Brantigan discloses an implant that "can be rotated or reversed and still fit the vertebrae." PO Resp. 37 (citing Ex. 1006, 2:24–25; Ex. 2038 ¶ 113). Given that the implants of Brantigan are inserted "to support and fuse with adjacent vertebrae" (Ex. 1006, 1:65–66), we agree with Petitioner that one of ordinary skill in the art would have understood not to remove an implant once already inserted because doing so would not have permitted the implant to have provided the support desired or to have fused with adjacent vertebrae, as Brantigan discloses. Thus, we agree that one of ordinary skill in the art would have understood that Brantigan discloses that the implant of Brantigan may be selected to be inserted in any desired orientation (i.e., "rotated or reversed" prior to insertion so that the implant will "still fit the vertebrae").

In any event, regardless of which construction of "rotated or reversed and still fit the vertebrae" is used, as discussed previously, Brantigan discloses that the implant is "sized to conform with the disc space," which

one of ordinary skill in the art would have understood to mean sized to occupy substantially the full transverse widths of the vertebral bodies for reasons previously stated.

Patent Owner argues that Brantigan discloses "an anterior approach to the spine," as opposed to a lateral approach. PO Resp. 27. As previously discussed, Jacobson discloses or suggests this feature. We need not determine whether one of ordinary skill in the art would have understood Brantigan to also disclose this feature.

Leu – "interbody intraspinal implant"

Patent Owner argues that Leu discloses a "graft conglomerate" that, according to Patent Owner "is not a spinal fusion implant." PO Resp. 48 (citing Ex. 2038 ¶¶ 89, 97–99). Claim 17 recites an "interbody intraspinal implant." Patent Owner's declarant (Dr. Sachs) testifies that Leu discloses that the "graft conglomerate" contains "impacted bone" and "soft cancellous bone" that "is not a structural implant as claimed by the '997 [patent]." Ex. 2038 ¶ 97. Hence, Patent Owner appears to argue that one of ordinary skill in the art would have understood that an "interbody intraspinal implant," as recited in claim 17, must not contain "impacted bone" or "soft cancellous bone" such that the implant is not a "structural implant."

Patent Owner does not demonstrate that claim 17 recites that the "interbody intraspinal implant" must not contain "impacted bone" or "soft cancellous bone." Nor does Patent Owner indicate that the '997 patent specification discloses this explicit definition of the term. While Patent Owner's declarant (Dr. Sachs) testifies that "this graft conglomerate [of Leu] is not a structural implant as claimed by the '997 [patent]," Ex. 2038 ¶ 97,

Petitioner's declarant (Dr. McAfee) testifies that "nothing in Leu's suggestion for the 'porous apatite' graft . . . required an ordinary spinal surgeon . . . to limit his or her thoughts only to 'bits of porous apatites'" and that "spinal surgeons of ordinary skill understood that various non-bone elements were inserted into the disc space as part of conventional interbody fusion." Ex. 1029 ¶ 57. Hence, even if one of ordinary skill in the art would have understood that an "interbody interspinal implant," as recited in claim 17, must have provided structural support and that a "graft conglomerate" containing only "impacted bone" and "soft cancellous bone" would have provided insufficient structural support to be characterized as an "interbody intraspinal implant" (as Dr. Sachs testifies), we credit Dr. McAfee's testimony that one of ordinary skill in the art would have also understood that "non-bone elements were inserted into the disc space as part of conventional interbody fusion," to provide sufficient structural support to be classified as an "interbody interspinal implant."

In any event, Dr. McAfee also testifies that it would have been obvious to one of ordinary skill in the art to have "employ[ed] an implant structure *having a size/structure suggested by Brantigan* in the resulting surgical method of Jacobson in view of Leu." Ex. 1029 ¶ 57. Hence, Petitioner and Dr. McAfee argue that Brantigan also discloses an "interbody intraspinal implant," as recited in claim 17. Patent Owner does not appear to contest Petitioner's contention.

"Elongated portion"

Patent Owner argues that Jacobson fails to disclose or suggest an "elongated portion," as recited in claim 17 because, according to Patent

Owner, "[t]hese portions [as disclosed by Jacobson] are not 'positioned over' adjacent vertebrae." PO Resp. 50. Petitioner explains that Jacobson discloses "wires [that] are indeed positioned over the vertebrae." Pet. Reply 12, *see also* Pet. 26–27; Ex. 1029 ¶¶ 54–55. As Petitioner explains, Jacobson appears to disclose anchor wires (i.e., "elongated portions") that are positioned over adjacent vertebrae. Ex. 1030, Fig. 5. Patent Owner does not provide sufficient evidence of specific differences between the "elongated portion" being "positioned over" adjacent vertebrae, as recited in claim 17, and the "anchor wires" (that are "elongated portions") that are also "positioned over" adjacent vertebrae. We, therefore, are not persuaded by Patent Owner's argument.

Jacobson, Leu, Brantigan - combinability

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Jacobson, Leu, and Brantigan. PO Resp. 50–53. Jacobson discloses advancing instruments laterally into the disc space to perform a "fusion" procedure. Ex. 1004, 5:1–4, 6:11–13. Leu discloses fusion of the lumbar spine by introducing an "interbody graft" into the disc space. Ex. 1005, p. 603. Brantigan, like Leu, discloses "prosthetic implant devices" that are "suitable for . . . lateral placement in any area of the spine." Ex. 1006, 2:56–58. We agree with Petitioner that the combination of the known element of performing a spinal fusion procedure by laterally advancing instruments into the disc space (Jacobson) with the known element of using an "interbody graft" in a spinal fusion procedure (Leu and Brantigan) would have resulted in no more than the predictable and expected result of performing a spinal fusion procedure

(Jacobson) that includes inserting an implant into a disc space (Leu or Brantigan). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007).

Patent Owner argues that one of ordinary skill in the art would not have combined the teachings of Jacobson with Leu because "the sequential dilators [of Leu] would *widen the perforation* [caused by a needle puncture to the patient's intestines] without any warning to the surgeon." PO Resp. 51. We are not persuaded by Patent Owner's argument at least because none of Jacobson or Leu supports the contention made.

Patent Owner also argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Brantigan with any of Jacobson or Leu because, according to Patent Owner, Brantigan "teaches away from sizing an implant to rest on the apophyseal ring or be sized to occupy substantially the full transverse width of adjacent vertebral bodies." PO Resp. 51–52, 55–56. This issue was discussed previously above.

Patent Owner also argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of Brantigan with any of Jacobson or Leu because the "cannulae disclosed by Jacobson and Leu are too narrow to accommodate Brantigan's implant," that "a person of ordinary skill in the art would not be able to insert [Brantigan's] implant in Jacobson's [system]," and that "the shape of the Brantigan implant is not conducive to insertion through a cannula or similar surgical instrument [as disclosed by Jacobson or Leu]." PO Resp. 52–53. In other words, Patent Owner argues that the combination of Jacobson, Brantigan, and Leu would

not have been obvious to one of ordinary skill in the art because the prior art systems are not physically combinable (i.e., Brantigan's implant allegedly cannot be physically combined with the cannula of either Jacobson or Leu). "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference . . . . Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."). We are thus not persuaded by Patent Owner's argument.

Secondary considerations

We recognize that evidence of secondary considerations must always be considered en route to the determination of obviousness, but its existence alone does not control the conclusion of obviousness. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). The weight given to evidence of secondary considerations is dependent upon whether there is a nexus between the merits of the claimed invention and the evidence offered. *Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1539 (Fed. Cir. 1983).

Commercial Success

Patent Owner argues non-obviousness based on alleged commercial success of the claimed invention. PO Resp. 56–57. Patent Owner contends that Petitioner's product (i.e., the "XLIF procedure and CoRoent XL implants") and Patent Owner's product (i.e., the "DLIF procedure and

Clydesdale and Capstone L implants") have "enjoyed tremendous commercial success," based on "100,000 spinal levels" having been treated since 2003, sales of Petitioner's product of "$250M from May 2004 to June 2010," and sales of Patent Owner's product of over "$50M over approximately the same time period." PO Resp. 56–57 (citing Ex. 2038 ¶ 136; Ex. 2045, 47; Ex. 2046–2048).

Even assuming the sales figures quoted by Patent Owner for both Petitioner's product and Patent Owner's product are correct, and assuming that these sales figures represent "commercial success," Patent Owner has not demonstrated a sufficient nexus between the merits of the claimed invention and the evidence offered. Patent Owner contends that "in order to encourage surgeons to select its product, Petitioner touts the CoRoent XL implant as having the patent features of the '997 patent, such as a 'large foot print,' 'spans ring apophysis,' and 'maximizes fusion surface area.'" PO Resp. 57 (citing Ex. 2049, 21). We note that Patent Owner does not show that any of "large foot print," "spans ring apophysis," or "maximizes fusion surface area" is recited in the claims of the '997 patent. Not having identified any specific features in the claims of the '997 patent that form the basis for the commercial success of Petitioner's product, Patent Owner does not show persuasively a nexus between the claimed invention and the evidence proffered.

In addition, even assuming that these features are recited in the claims of the '997 patent, Patent Owner still does not demonstrate a sufficient nexus between these specific alleged features and the evidence relied upon to demonstrate commercial success (i.e., sales figures). Upon review of the marketing materials cited by Patent Owner, we observe that in addition to a

"large foot print," "spans ring apophysis," and "maximizes fusion surface area," the marketing materials also allege other benefits of the marketed product such as "minimal soft tissue/muscle damage," "reduced post-operative morbidity," "outpatient or 23 hr procedure," "adequate exposure," "safe and reproducible," and "meet or exceed traditional results." Ex. 2049, 17. Patent Owner provides insufficient evidence to show which of these alleged benefits of the marketed product (if any) would have resulted in (i.e., had a "nexus" to) the "commercial success" (i.e., sales revenue) alleged by Patent Owner.

Industry Praise

Patent Owner argues non-obviousness based on "industry praise" allegedly attributed to the claimed invention. PO Resp. 58–59. Industry praise must also be linked to the patented invention. *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010). Patent Owner cites to "Back.com," in which Dr. Richard Hynes states the benefits of the DLIF [Direct Lateral Interbody Fusion] procedure are that "you're approaching the disc from the side rather than from the front or back." Ex. 2050, p. 3. Petitioner has demonstrated that this feature (i.e., "direct lateral" approach), as discussed above, is disclosed by Jacobson. Hence, the feature that is allegedly praised was already present in the prior art. Under those circumstances, any evidence of secondary considerations stems from what was known in the prior art, so that there can be no nexus. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011) ("If [secondary considerations are] due to an element in the prior art, no nexus exists.").

Dr. Hynes alleges additional benefits of DLIF including "a very small, 1-2 cm incision," no "big incisions," no "cutting through muscles," "patients were in and out of the OR in less than an hour," and there was "major stabilization with no blood loss." Ex. 2050, p. 3. Patent Owner does not demonstrate sufficiently that any of these additional allegedly praiseworthy features are recited in the '997 patent claims. Hence, Patent Owner fails to demonstrate sufficiently a nexus between the alleged praise and the claimed invention.

Patent Owner also cites to Rose Mary Budge, "A New Solution," 2004–2009, available at http://www.spinaldoc.com/NuVasive_Spinal_Surgery.php. ("Budge," Ex. 2051). Budge discloses the procedure "involves side entry to the surgical [site] rather than from the back or the front." Ex. 2051 at 1. As previously described, this "praise," to the extent that this objective statement of the direction of entry to the surgical site can be considered "praise" at all, was known in the prior art (e.g., Jacobson), so that there can be no nexus. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011).

Budge further states other benefits of the procedure, including that the procedure is "less intimidating than the traditional methods," "can significantly lessen collateral damage," causes "less tissue trauma, less scarring, less blood loss and less post-operative discomfort." Ex. 2051 at 1. As previously described, Patent Owner does not show sufficiently a nexus between any of these additional allegedly praiseworthy features and the claimed invention because Patent Owner does not demonstrate that any of these features are recited in the claims of the '997 patent.

Patent Owner also cites to PR Newswire, "26 Technologies Receive 2009 Spine Technology Awards," 2009 ("PR Newswire," Ex. 2052) as demonstrating that "Petitioner's XLIF was selected as a 'Best New Technology for 2009' by Orthopedics This Week, an industry publication, and won an award in the "Minimally Invasive Care' category." PO Resp. 58. Even assuming that the "XLIF" won an award as Patent Owner asserts, Patent Owner does not show sufficiently that this award (or praise) had a nexus to a claim feature of the '997 patent (or which claim feature that might be).

Patent Owner further argues that Dr. Michelson testifies that Mr. Larry Boyd (presumably an officer at Sofamor Danek) had, for the first time, "seen a lateral retroperitoneal [approach]" at some point in time. PO Resp. 59 (citing Ex. 2041, 195:24 – 196:2). According to Patent Owner, officers at Sofamor Danek were "'very excited' about Dr. Michelson's technology and moved quickly to acquire it by signing a license agreement." PO Resp. 59 (citing Ex. 2041, 68:7–15). Patent Owner does not provide sufficient evidence explaining what features caused officers at Sofamor Danek to become "very excited" or why the officers allegedly "moved quickly" to sign a license agreement or how any alleged excitement or speed in the signing of license agreements pertains to specific features recited in claim 17. Hence, Patent Owner does not show a sufficient nexus between the claimed invention and the activities alleged to constitute "praise."

Copying

Patent Owner argues non-obviousness based on alleged copying of the claimed invention by competitors. PO Resp. 59–60. "[C]opying by a

competitor may be a relevant consideration in the secondary factor analysis." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (citing *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed.Cir.1984). "[A] nexus between the copying and the novel aspects of the claimed invention must exist for evidence of copying to be given significant weight in an obviousness analysis." *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (internal quotation omitted). Copying as objective evidence of nonobviousness requires evidence of effort to replicate a specific product. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Iron Grip*, 392 F.3d at 1325. Generally, evidence of alleged copying may be given little weight when the copy is not identical to the product embodying the claimed invention. *See Pentec, Inc. v. Graphic Controls, Corp.*, 776 F.2d 309, 317 (Fed. Cir. 1985).

Patent Owner asserts that Petitioner "worked on an early lateral access project called 'ELIF,' which stood for Extreme Lateral Interbody Fusion," trademarked the term "XLIF—for eXtreme Lateral Interbody Fusion" for the product, and eventually "evolved into a profitable company." PO Resp. 60 (citing Ex. 2041, 329:14–25, 434:2 – 435:14, 573:9 – 574:5, 979:19–24). Patent Owner also states that "prototypes created by Dr. Michelson included an implant with a 42 mm length, a distractor, outer sleeve, and other instruments." PO Resp. 60 (citing Ex. 2004). Patent Owner does not demonstrate sufficiently that the alleged copy (i.e., "ELIF" or "XLIF") is identical to the product embodying the claimed invention. Therefore, little weight is accorded to Patent Owner's allegations of copying. To the extent that Patent Owner argues that the "ELIF" or "XLIF" systems utilize implants

measuring 42 mm in length, a distractor, outer sleeve, and "other instruments," Patent Owner does not demonstrate that such a system embodies the claimed invention. For example, Patent Owner does not show that any of the claims of the '997 patent recite that the implant measures 42 mm in length and does not explain what the "other instruments" entail.

We have considered the evidence presented, but do not discern that it adequately establishes that the pertinent products are replications of a product that includes all the features of claim 17 of the '997 patent. In any event, even assuming that the noted "ELIF" or "XLIF" products do incorporate all the features of claim 17, it is not the case that "every competing product that arguably falls within the scope of a patent is evidence of copying." *IronGrip*, 392 F.3d at 1325. Rather, as noted above, copying requires the "replication" of a specific product. *Id*.

Patent Owner does not provide additional arguments or evidence with respect to claims 18–22. We are persuaded, by a preponderance of the evidence, that claims 17–23 are unpatentable over the combination of Jacobson, Leu, and Brantigan.

B. Grounds Based at least in part on Jacobson, Leu, and Michelson '247 (Claims 9–16 and 24–30)

Claim 9 recites the length of an implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae. Claim 24 recites the length of an implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae. Michelson '247 discloses "an artificial fusion implant to be placed into the intervertebral space left after the removal of a damaged spinal disc" in which a drill is used that is "such a length that it can not

penetrate more than **28** millimeters beyond the end of the drill sleeve" so that "the implant . . . is able to be inserted only 28 millimeters." Ex. 1008, 1:5–7; 9:40–42; 10:31–32. Michelson '247 also discloses that "the implant . . . is only 26 millimeters in length . . . [which] guarantees that the implant . . . will be recessed into the vertebral bodies more than 2 millimeters and can not protrude into the spinal canal." Ex. 1008, 10:32–36. While Michelson '247 discloses an implant that measures 26 millimeters in length and is inserted into a drilled opening that is 28 millimeters in length, Petitioner does not demonstrate sufficiently that Michelson '247 also discloses that the implant must occupy either substantially the full transverse width of the vertebral body (as recited in claim 9) or the full transverse width of the vertebral body (as recited in claim 24). For example, Michelson '247 merely discloses a specific length of 26 millimeters for the length of the implant (26 millimeters) and a specific length of a drilled opening (28 millimeters), but does not disclose the length of the implant (or opening) in relation to the size of the vertebral body.

Michelson '247 further discloses that the drill may be "varied and made smaller for enhanced safety," but does not appear to disclose elongating the drill to a length greater than 28 millimeters. Ex. 1008, 9:42–43. That further demonstrates that Michelson '247 fails to disclose or suggest sizing the implant to obtain the maximum sized implant with respect to the size of the vertebral body. Instead, Michelson '247 appears to suggest using only smaller sized implants "for enhanced safety."

Petitioner argues that Michelson '247 discloses "the length of the implant extend[s] longitudinally across nearly the full disc space along the direction of insertion." Pet. 10. Regarding claim 24, Petitioner does not

assert or demonstrate sufficiently that Michelson ’247 discloses or suggests an implant sized to occupy the *full* transverse width of the vertebral bodies. In any event, as Patent Owner points out, “there is ***nothing in the written disclosure*** of Michelson ’247 that teaches a surgeon to size an implant to span as much of the length as possible from an anterior to posterior direction.” PO Resp. 41 (citing Ex. 2039, 44:16–19; 45:6–16). Petitioner does not point out where specifically Michelson ’247 discloses or suggests this feature.

Petitioner argues that Patent Owner does not argue Michelson ’247 discloses an implant that would not rest on the apophyseal ring or that the implant is designed to rest only on a spongy center part of the vertebrae and that “the ’997 patent’s drill has the very same feature [as the drill disclosed by Michelson ’247].” Pet. Reply 11. Even assuming Petitioner’s allegations to be correct, Petitioner still does not demonstrate persuasively that Michelson ’247 discloses or suggests an “implant being sized to occupy the full” (or “substantially full”) dimension of the vertebral body, as recited in claim 9 or claim 24.

Claims 10–16 depend from claim 9 and claims 25–30 depend from claim 24. We are not persuaded that claims 9–16 and 24–30 would have been obvious over the combination of Jacobson, Leu, and Michelson ’247.

C. Motion to Exclude

In its Motion to Exclude, Patent Owner seeks to exclude the following documents:

1. Declaration of Dr. Paul McAfee (“McAfee Declaration,” Ex. 1001, 54–85);
2. Affidavit of Henry Vernon Crock (Ex. 1014–1021);

3. Second Declaration of Dr. Paul McAfee (Ex. 1029 ¶¶ 4, 7, 9, 10, 37–39, 43–45, 48, and 49);
4. Declaration of Dr. Robert E. Jacobson ("Jacobson Declaration," Ex. 1030 ¶¶ 4–6, 8, and 10);
5. Declaration of Patrick Miles ("Miles Declaration," Ex. 1032 ¶ 9);
6. William A Friedman, *Percutaneous Discectomy: An Alternative to Chemonucleolysis?*, NEUROSURGERY, Vol. 13, No. 5 (1983) ("Friedman Article," Ex. 1036);
7. Steven L. Kanter and William A. Friedman *Percutaneous Discectomy: An Anatomical Study*, NEUROSURGERY, Vol. 16, No. 2 (1985) ("Kanter Article," Ex. 1037);
8. Medtronic Corporate Structure (Ex. 1046);
9. Gregory M. Malham, et al., *Clinical Outcome and Fusion Rates after the First 30 Extreme Lateral Interbody Fusions*, THE SCIENTIFIC WORLD JOURNAL (2012) ("Malham Article," Ex. 1049);
10. Armen R. Deukmedjian, *Bowel and Vascular Injury Following 13,000 Lateral Interbody Fusions*, SMISS 2013 ANNUAL CONFERENCE ("Deukmedjian Article," Ex. 1050); and
11. Paul C. McAfee, et al., *Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine*, SPINE, Vol. 23, No. 13 (1998) ("McAfee Article," Ex. 1067).

For the reasons discussed below, the motion is dismissed.

Second Declaration of Dr. Paul McAfee – Ex. 1029 ¶ 38

Patent Owner alleges that the Second Declaration of Dr. Paul McAfee (Ex. 1029 ¶ 38) should be excluded because, according to Patent Owner,

"Dr. McAfee wrongly relies on Dr. Jacobson's declaration (Exhibit 1030) about the alleged surgeries he performed prior to 1995," that "Dr. McAfee wrongly relies on the Crock Affidavit (Exhibit 1014) in paragraphs 7 and 9 of his second declaration about the surgeries Dr. Crock allegedly performed prior to 1995," which, according to Patent Owner, "are not relevant to whether the challenged claims are unpatentable in light of the prior art patents and printed publications in the instituted claims." Paper 53 at 6.

The Second Declaration of Dr. Paul McAfee, however, is not relied upon for any alleged surgeries performed by Dr. Crock or Dr. Jacobson prior to 1995 (or at any other time). Rather, the Second Declaration of Dr. Paul McAfee is relied upon to support what one of ordinary skill in the art would have understood based on Figure 6 of the '997 patent at the time of the invention (see above). Ex. 1029 ¶ 38. Thus, we are not persuaded that the Second Declaration of Dr. Paul McAfee (at ¶ 38) should be excluded.

Jacobson Declaration – Ex. 1030 ¶ 5

Patent Owner moves to exclude the Jacobson Declaration (Ex. 1030 ¶ 5) based on various bases. Patent Owner alleges that the Jacobson Declaration (Ex. 1030 ¶ 5) "include[s] what Dr. Jacobson was allegedly ***doing*** prior [to] 1995, not what the Jacobson '374 reference discloses to a person of ordinary skill in the art." Paper 53, 9–10.

The Jacobson Declaration (Ex. 1030 ¶ 5) is relied upon to ascertain what one of ordinary skill in the art would have understood by the terms "lateral" and "direct lateral" at the time of the invention (see above) and is not relied upon for any procedures Dr. Jacobson may or may not have been

alleged to have performed prior to 1995. Thus, we are not persuaded that the Jacobson Declaration (at ¶ 5) should be excluded.

Other Evidence

As previously described, Patent Owner moves to exclude other evidence, none of which was relied upon by the Board. Therefore, Patent Owner's motion to exclude is moot with respect to the other evidence.

ORDER

Petitioner has demonstrated, by a preponderance of the evidence, that claims 17–23 are unpatentable over Jacobson, Leu, and Brantigan under 35 U.S.C. § 103(a). Petitioner has not demonstrated, by a preponderance of the evidence, that claims 9–16 are unpatentable over Jacobson, Leu, McAfee, and Michelson '247 under 35 U.S.C. § 103(a) or that claims 24–30 are unpatentable over Jacobson, Leu, and Michelson '247 under 35 U.S.C. § 103(a).

In consideration of the foregoing, it is hereby:

ORDERED that claims 17–23 of the '997 patent have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *dismissed*.

This is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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