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Paper 44
Entered: April 3, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case IPR2014-00087
Patent 8,005,535 B2

Before FRANCISCO C. PRATS, SCOTT E. KAMHOLZ, and DAVID C. McKONE, *Administrative Patent Judges.*

McKONE, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Medtronic, Inc. ("Petitioner") filed a Corrected Petition (Paper 5, "Pet.") to institute an *inter partes* review of claims 1–12 of U.S. Patent No. 8,005,535 B2 (Ex. 1015, "the '535 patent"). NuVasive, Inc. ("Patent Owner") filed a Preliminary Response (Paper 9, "Prelim. Resp."). Pursuant to 35 U.S.C. § 314, in our Decision to Institute (Paper 10, "Dec."), we instituted this proceeding as to all of the challenged claims of the '535 patent.

After the Decision to Institute, Patent Owner filed a Patent Owner Response (Paper 21, "PO Resp."), and Petitioner filed a Reply to the Patent Owner Response (Paper 26, "Reply").

B. Related Cases

Petitioner challenged the '535 patent, based on different art, in *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00081. Petitioner also challenged Patent Owner's U.S. Patent No. 8,000,782 B2 in *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00034; U.S. Patent No. 8,192,356 B2 in *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00073, and *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00074; and U.S. Patent No. 8,016,767 B2 in *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00075. A combined oral hearing (Paper 43, "Tr.") was held on December 4, 2014, to address the instant *inter partes* review and the related *inter partes* reviews.

C. References Relied Upon

Petitioner relies upon the following prior art references:

Ex. 1001	Obenchain	US 5,195,541	Mar. 23, 1993
Ex. 1005	Foley	US 5,902,231	May 11, 1999
Ex. 1006	Marino	WO 00/38574 A1	July 6, 2000
Ex. 1008	Epoch 2000	Axon Systems, Inc., Epoch 2000 Neurological Workstation, Food & Drug Admin. submission under 510(k) No. K971819	
Ex. 1011	Moed	Berton R. Moed, et al., *Evaluation of Intraoperative Nerve-Monitoring During Insertion of an Iliosacral Implant in an Animal Model*, vol. 81-A, No. 11 THE JOURNAL OF BONE AND JOINT SURGERY 1529–1537 (Nov. 1999)	

D. The Asserted Grounds

We instituted this proceeding based on the grounds of unpatentability set forth in the table below. Dec. 29.

References	Basis	Claims challenged
Marino, Foley, Obenchain, and Epoch 2000	§ 103(a)	1–12
Marino, Foley, Obenchain, Epoch 2000, and Moed	§ 103(a)	6

E. The '535 Patent

The '535 patent generally relates to techniques employing medical devices for spinal surgery. Ex. 1015, Abstract. Two aspects of the techniques described in the '535 patent include: (1) employing sequentially

dilating cannulas (*e.g.*, Ex. 1015, Fig. 18) to open a working corridor to a patient's spine; and (2) detecting the proximity and direction of nerves as the cannulas are inserted through the patient's tissue (*id.* at 10:53–58). Regarding the second aspect, a surgeon determines nerve proximity and direction using a stimulation electrode, placed on the distal tip of a cannula or a K-wire (guide wire), that depolarizes nerves that are in close proximity to the electrode. *Id.* at 11:25–30. The depolarized nerve produces a response in an innervated myotome at a different location in the patient's body that can be monitored with an electromyography ("EMG") harness positioned, for example, on the patient's legs. *Id.* at 11:30–35. The EMG harness and the stimulation electrode are coupled to a control unit with a display that provides visual feedback to the surgeon. *Id.* at Fig. 2, 10:20–36. Upon detecting a nerve, the surgeon has the option of repositioning the K-wire or cannula to avoid the nerve. *Id.* at 11:35–38.

The cannulas bluntly dissect the tissue between the patient's skin and the surgical target site. *Id.* at 11:9–14. The surgeon can use the cannulas to form an operative corridor between the skin and an intervertebral target site through the psoas muscle (a trans-psoas path). *Id.* 11:38–42. Figures 16–19 illustrate the sequential insertion of dilating cannulas of increasing diameters. A surgeon first inserts a thin cannula 48, with a K-wire 46 disposed inside, through a patient's body to a working site at a vertebra. *Id.* at 19:60–20:2, Fig. 16. The cannula and/or the K-wire includes a stimulation electrode 70 positioned at an angle relative to the longitudinal axis of the K-wire and cannula. *Id.* at 20:2–12. The response to the stimulation can be monitored using the EMG harness as the cannula is

rotated, allowing the surgeon to identify the proximity and direction of any nerves that come close to the cannula. *Id.* at 20:12–23.

The surgeon inserts additional cannulas of increasing diameter sequentially over the first cannula until a desired working diameter is achieved. *Id.* at 20:31–35, Fig. 17. The surgeon then inserts a working corridor over the widest cannula (Fig. 18) and removes the cannulas, leaving the working corridor in the patient's body (Fig. 19), establishing a corridor in which the surgeon can operate. *Id.* at 20:40–47. The surgeon can perform the nerve proximity testing as each of these devices is inserted into the patient. *Id.* at 11:9–18, 20:48–52. After establishing an operative corridor, the surgeon can perform surgical procedures on the patient's spine, such as installing a spinal fusion implant. *Id.* at 22:61–23:6.

Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A method of inserting a spinal implant through a trans-psoas operative corridor to an intervertebral disc, comprising:
>
> mounting a plurality of EMG electrodes proximate to selected leg muscles;
>
> activating a control unit operable to provide a stimulation signal and including a graphical user interface to receive user input and to display neuromuscular response information in response to signals from the EMG electrodes;
>
> inserting an initial dilator cannula in a trans-psoas path through bodily tissue toward a lateral aspect of a spine while an elongate stimulation instrument is disposed within an inner lumen of the initial dilator cannula;

activating the elongate stimulation instrument to deliver the stimulation signal proximate to a distal end of the initial dilator cannula when the initial dilator cannula is inserted into the trans-psoas path toward the spine;

monitoring the neuromuscular response information displayed by the control unit in response to delivery of the stimulation signal when the initial dilator cannula is inserted into the trans-psoas path toward the spine;

advancing two or more sequential dilator cannulas of increasing diameter in the trans-psoas path toward the spine;

advancing a working corridor instrument over the two or more sequential dilator cannulas in the trans-psoas path toward the spine;

establishing a trans-psoas operative corridor to an intervertebral disc of the spine using the working corridor instrument; and

delivering a spinal fusion implant through the trans-psoas operative corridor toward the spine.

II. ANALYSIS

A. Claim Construction

The Board interprets claims of an unexpired patent using the broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1279–81 (Fed. Cir. 2015). Claim terms generally 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. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In the Decision to Institute, we preliminarily construed "trans-psoas path" to mean "a path in which the instrument passes through the psoas muscle." Dec. 8–9. We specifically rejected Patent Owner's position that the '535 patent limits "trans-psoas approach" to an approach through the middle or posterior portion of the psoas muscle. *Id.*

We also preliminarily construed "initial dilator cannula" to carry its ordinary meaning. *Id.* at 9. We rejected Patent Owner's argument that the initial dilator cannula must be the particular structure that defines a path in such a manner that sequential dilator cannulas are advanced in that same path and a working corridor instrument is advanced over the sequential dilator cannulas. *Id.* at 9–10.

Petitioner and Patent Owner do not dispute these constructions in the PO Response or Reply. In view of this, and upon consideration of the complete record developed during this trial, we maintain these constructions.

Neither Petitioner nor Patent Owner identifies any additional terms requiring construction. No other terms require express construction for purposes of this Decision.

B. Effective Filing Date of the '535 Patent

The '535 patent claims the benefit of U.S. Provisional Application No. 60/325,424 (Ex. 1016, "the '424 provisional"), filed September 25, 2001. Ex. 1015, 1:14–17. In the Decision to Institute, we determined that the challenged claims of the '535 patent are not entitled to the benefit of the '424 provisional's filing date. Dec. 10–11. Patent Owner does not

challenge this determination in the PO Response. In view of this, and upon consideration of the complete record developed during this trial, we maintain this determination.

C. Petitioner's Motion to Exclude

Petitioner moves to exclude Exhibits 2013, 2014, and 2016–18 as irrelevant because Patent Owner does not cite to them in this trial. Mot. to Exclude (Paper 29) 1–2. Rather, these are exhibits that were used in the deposition of Dr. Robert G. Watkins, IV, a witness for Petitioner who did not testify in this trial. *Id.* Patent Owner argues that we should admit these exhibits because they are relevant to other related matters (IPR2014-00073, -00074, and -00075). Opp. to Mot. to Exclude (Paper 35) 2–4. Petitioner similarly seeks to exclude Exhibits 2070–73 as irrelevant because Patent Owner does not cite to them. Mot. to Exclude 3. Patent Owner confirms that it does not cite to these exhibits in this trial. Opp. to Mot. to Exclude 7. Because neither we nor the parties rely on Exhibits 2013, 2014, 2016–18, or 2070–73 in this trial, Petitioner's Motion is dismissed as moot as to these exhibits.

Petitioner moves to exclude Exhibits 2033–36, 2042, and 2051 as hearsay. Mot. to Exclude 2–3. Patent Owner argues that Exhibits 2033, 2035, and 2036 are offered to show the declarants' states of mind. Opp. to Mot. to Exclude 4–5 (citing FED. R. EVID. 803(3)). We agree that they are offered for non-hearsay purposes. Therefore, we deny the motion to exclude Exhibits 2033, 2035, and 2036. We do not rely on Exhibits 2034, 2042, and 2051. Therefore, Petitioner's motion to exclude them is dismissed as moot.

Petitioner moves to exclude Exhibits 2039, 2041, 2056, 2058, 2059, and 2066 as hearsay. Mot. to Exclude 4–5. Patent Owner introduces these exhibits as financial industry objective indicia of commercial success and praise. Patent Owner argues that these documents are introduced for non-hearsay purposes, such as showing industry praise and the states of mind of the declarants. Opp. to Mot. to Exclude 7–8. Petitioner contends that these exhibits are not reliable because the authors of those exhibits are not skilled artisans. Mot. to Exclude 4–5. We agree with Patent Owner (Opp. to Mot. to Exclude 9), however, that the credentials of the authors go to the weight of the evidence, not its admissibility. Accordingly, we deny Petitioner's motion to exclude Exhibits 2039, 2041, 2056, 2058, 2059, and 2066.

Petitioner moves to exclude Exhibit 2062 as being out of compliance with 37 C.F.R. § 42.53. Mot. to Exclude 5. We do not rely on Exhibit 2062. Therefore, Petitioner's motion to exclude it is dismissed as moot.

In sum, we deny-in-part and dismiss-in-part Petitioner's Motion to Exclude.

D. Asserted Grounds of Unpatentability

Petitioner raises several challenges to claims 1–12 of the '535 patent based in whole or in part on the combination of Marino, Foley, Obenchain, and Epoch 2000. Petitioner supports its contentions with the testimony of Daniel Schwartz, Ph.D. (Ex. 1012, "Schwartz Decl.").

1. Overview of Marino, Foley, Obenchain, and Epoch 2000

Foley is directed to a technique for providing a surgeon with a working channel for access to a location in a patient during surgery, for

example to install a fusion device during spinal surgery. Ex. 1005, Abstract, 23:10–14. Figures 10a–10i of Foley illustrate creating a working channel by inserting a guide wire (e.g., a K-wire), followed by a series of tissue dilators (dilating cannulas) of increasing diameter and decreasing length concentrically over each other to dilate the tissue sequentially. *Id.* at 12:1–39, Figs. 10b–10d. After inserting the dilators, the surgeon inserts a working channel cannula over the largest dilator (Fig. 10e) and removes the dilators, leaving the working channel cannula to establish a working corridor (Fig. 10f). *Id.* at 12:40–43. Although Foley describes a medial posterior approach, Foley explains that this technique can "be used from any approach and in other regions besides the spine," *id.* at 11:63–67, e.g., "posterolateral" and "anterior" approaches, *id.* at 12:6–8.

Marino describes various nerve surveillance systems for identifying and avoiding nerves during spinal surgery. Ex. 1006, 7:13–17. Figure 18, reproduced below, illustrates one example:

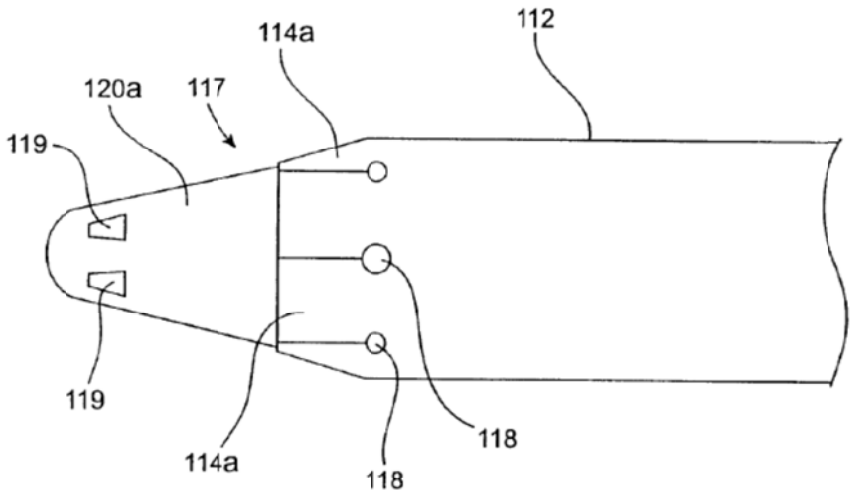

FIG. 18

Figure 18 shows an obturator 120a received within a cannula shaft 112 and protruding through an opening of the cannula shaft. Ex. 1006, 14:1–4. The obturator includes electrodes 119 radially spaced around the distal tip of the obturator. *Id.* at 14:4–7. As a surgeon inserts the cannula and obturator through patient tissue and close to a nerve, the electrode closest to the nerve depolarizes the nerve. *Id.* at 9:1–5, 14:8–13. "[S]tandard electromyographic techniques," including attaching needles or patches to muscles stimulated by the electrodes, are used to sense a response from the depolarized nerve. *Id.* at 7:18–31; *see also id.* at 14:8–13. Because the EMG information tells the surgeon which of the electrodes depolarized the nerve, the surgeon can identify the direction of the nerve. *Id.* 9:5–7.

In another embodiment, Figure 28 shows cannula 300 with obturator 210 disposed therein and protruding through an opening. Ex. 1005, 16:27–33. In this embodiment, nerve-stimulating electrodes are included on the

distal tips of both the cannula and the obturator (electrodes 316 and 320, respectively). *Id.* at 16:29–17:12.

Obenchain describes a cannula (elongated cylinder) for spinal surgery (laparoscopic lumbar discectomy). Ex. 1001, Abstract, 1:32–33; 2:11–22. Several surgical components can be secured in the cannula, for example, an endoscope, a laser fiber, and irrigation conduits. *Id.* 2:39–3:34. One of the approaches to the spine described in Obenchain is through the psoas muscle:

> If desired, the surgery may traverse through the psoas muscle. Where the surgery site is between LS and S-1, the dis[s]ection is preferably generally close to the midline between the iliac branches of the great vessels. Alternatively, for example, where the patent has extensive abdominal adhesions, it may be preferred to use a lateral puncture of the abdomen to avoid bowel perforation, and entry into the disc space is lateral, transversing the psoas muscle, or immediately in front of it.

Id. at 5:5–14.

Epoch 2000 is a redacted 510(k) FDA submission of Axon Systems, Inc., describing the Epoch 2000 Neurological Workstation. Ex. 1008, at 1–3. The system described in Epoch 2000 supplies a stimulation current, in the form of a monophasic square pulse, to a probe, and monitors EMG responses evoked by the stimulation current received through electrodes placed on the patient's body. *Id.* at 9–11, 33, 116, 118, 127, 170, 239. The EMG response information is displayed using a graphical user interface that includes a mouse or light pen for a user to input information. *Id.* at 88, 115, 130. Epoch 2000 also describes setting thresholds for EMG response waveforms such that EMG data is captured when EMG data, triggered by the stimulus signal, exceeds the threshold. *Id.* at 199, 228, 280.

2. The Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art would have knowledge of both neurophysiology and spine surgery. Ex. 1012 ¶ 23. Dr. Schwartz testifies that a skilled artisan, for example, could be a neurophysiologist (like himself) with knowledge of spine surgery or access to spine surgeons or a spine surgeon with experience in neurophysiology or access to neurophysiologists. *Id.* Petitioner argues that Patent Owner's declarants, although spine surgeons, lack expertise in neurophysiology. Reply 11–12.

Patent Owner, relying on the testimony of Frank Phillips, M.D. (Ex. 2020, "Phillips Decl.") ¶ 17, disagrees with Petitioner and contends that a skilled artisan would have been a surgeon who has specialized in spine surgery. Patent Owner argues that Petitioner's declarant, Dr. Schwartz, although having expertise in neuromonitoring, is not an expert in spine surgery. PO Resp. 38–39.

We agree with Petitioner that the claims of the '535 patent include aspects of both spine surgery and neurophysiology. We recognize that each declarant in this case has a particular expertise stronger in one aspect than the other. Nevertheless, we have considered the testimony of each of the declarants and have taken into account each's respective expertise in weighing his testimony.

Both parties argue that the other party's declarant was unfamiliar with the legal standards for obviousness. PO Resp. 36–38; Reply 11. We have taken the parties' arguments into account in weighing the testimony of the declarants. We recognize, however, that neither party's declarants are attorneys.

Patent Owner argues that Dr. Schwartz testified in deposition that his opinions were from the perspective of a skilled artisan at the time of his deposition, rather than from the time of the invention. PO Resp. 35–36. Dr. Schwartz testified in his Declaration that his opinions are from the perspective of a skilled artisan at the time of the invention. Ex. 1012 ¶ 22. Considering the context of the deposition question to which Patent Owner cites, we do not read Dr. Schwartz's testimony to mean that he was evaluating obviousness as of the time of the deposition. Ex. 2019, 188:1–190:25.

3. Obviousness of Claims 1–12 over Foley, Marino, Obenchain, and Epoch 2000

Petitioner contends that claims 1–12 would have been obvious over Foley, Marino, Obenchain, and Epoch 2000. Specifically, Petitioner argues that:

(1) Foley teaches spine surgery that includes insertion of a K-wire, sequential insertion of a plurality of dilating cannulas of increasing diameter and decreasing length to widen a corridor through patient tissue, insertion of a working corridor instrument, and delivery of an intervertebral implant;

(2) Marino teaches an initial dilating cannula with an elongate stimulation instrument disposed therein, both with stimulation electrodes at their distal ends, providing stimulus signals to the stimulation electrodes, and receiving EMG response information from EMG electrodes placed on a patient's leg muscles;

(3) Obenchain teaches spinal surgery using a trans-psoas approach; and

(4) Epoch 2000 teaches a control unit for providing stimulation current pulses in the form of a monophasic square wave signal to a probe and displaying corresponding EMG response information compared to a threshold.

Pet. 21–23, 25–35. Petitioner points out, in its claim charts, how the particular limitations of each of claims 1–12 are shown in the four references. *Id.*

The parties dispute whether a skilled artisan would have had reason to combine the teachings of Foley, Marino, Obenchain, and Epoch 2000. Essentially, Petitioner contends that a skilled artisan would have combined Marino's teaching of using an elongate stimulation instrument inside an initial dilating cannula along with Foley's teaching of a standard use of dilating cannulas to arrive at a method in which an elongate stimulation instrument is used inside Foley's first (initial) dilator cannula to create an approach for delivery of an implant. Pet. 24. Petitioner points to Obenchain as giving an example of spinal surgery performed through the psoas muscle using cannulated instruments. *Id.* at 23. Petitioner asserts that a skilled artisan would combine further Epoch 2000's teaching as an example of a standard EMG system that would be employed with the type of nerve monitoring described in Marino. *Id.* at 22.

Petitioner argues that the teachings of each of these references are in the context of minimally invasive spine surgery using cannulated instruments. Pet. 23. Petitioner argues that Foley, Marino, and Obenchain teach performing the same type of surgery using similar instruments. *Id.* at

24. According to Petitioner, Marino teaches that an elongate stimulation instrument received within a cannula reduces the risk of nerve damage during spine surgery, and such teaching would have been applicable to Foley's procedures. *Id.* Marino, for example, states that "[a]n advantage of determining the position of a para-spinal nerve with respect to the distal tip of the cannula in particular is that the para-spinal nerve can be avoided or gently moved out of the surgeon's way while inserting the cannula." Ex. 1006, 2:17–21.

Patent Owner does not challenge Petitioner's evidence of the disclosure of the particular limitations of claims 1–12. Rather, Patent Owner's arguments are directed to its contention that a skilled artisan, guided by conventional wisdom of the dangers of traversing the psoas muscle, would not have combined Foley, Marino, Obenchain, and Epoch 2000.

Patent Owner argues that Obenchain, which describes a procedure of passing a small endoscope through the anterior portion of the psoas muscle, does not teach passing instruments (including multiple dilators and working corridor instruments) safely through nerve-bearing portions of the psoas muscle. PO Resp. 41–42. Patent Owner contends that the "conventional wisdom" prior to its invention was to avoid the psoas muscle entirely as it was a "no man's land." *Id.* at 42–43. Patent Owner relies on the testimony of Theodore G. Obenchain, M.D., the named inventor on the Obenchain reference. *Id.* (citing Ex. 2025 ("Obenchain Decl.") ¶¶ 7, 9, 13–19). According to Patent Owner and Dr. Obenchain, the Obenchain reference only teaches traversing the psoas muscle incidentally, at its most anterior fibers where the risk of incurring nerve injury is low, in cases where

avoiding the psoas muscle is impossible. PO Resp. 42–45 (citing Ex. 2025 ¶¶ 7, 14, 21). The express disclosure of Obenchain is not so limited, however, as it states, without qualification, that "[i]f desired, the surgery may traverse through the psoas muscle." Ex. 1001, 5:5–6.

Patent Owner's argument also improperly assumes that the claims require a path through the nerve-rich portion of the psoas muscle. As explained in Section II.A above and as Patent Owner effectively conceded, a "trans-psoas path" is "a path in which the instrument passes through the psoas muscle" and is not limited to an approach through the middle or posterior portion of the psoas muscle. *See* Tr. 39:10–40:1; 113:5–114:3. Thus, even if we assume that Dr. Obenchain's testimony, offered over 20 years after his patent was filed, can be used to limit the otherwise general teaching of that patent to traversing only certain portions of the psoas muscle, Patent Owner's argument is unpersuasive because the claims of the '535 patent do not require traversing any particular portion of the psoas muscle.

Patent Owner also argues that Foley does not teach using its spinal access system in a trans-psoas approach and that its disclosure of using its system in "any approach" would not have suggested use through the psoas muscle. PO Resp. 44, 48. Similarly, Patent Owner argues that Marino does not teach a trans-psoas path. *Id.* at 48. Petitioner does not cite to Foley or Marino as teaching performing spinal surgery through a trans-psoas path. Rather, Obenchain is cited for that teaching. Pet. 26. Patent Owner argues that neither Foley nor Obenchain teaches nerve monitoring functionality. PO Resp. 48. Petitioner does not cite to Foley or Obenchain as teaching nerve monitoring. Rather, Marino is cited for that teaching. Pet. 26–27.

Patent Owner's arguments are unpersuasive because Patent Owner points out deficiencies of individual references without adequately addressing their combined teachings. *See In re Keller*, 642 F.2d 413, 426 (CCPA 1981) ("[O]ne cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references.").

In a similar argument, Patent Owner contends that there is "simply no prior art cited in the Petition that discloses or suggests performing a spinal fusion procedure through a trans-psoas approach to the spine." PO Resp. 51. This argument, again, does not address the combined teachings of, *inter alia*, Foley (which teaches a spinal fusion procedure) and Obenchain (which teaches spinal surgery through a trans-psoas approach).

Regarding Marino, Patent Owner argues that it describes avoiding para-spinal nerves, which are different from the nerve roots found in the psoas muscle. PO Resp. 49. Relying on Dr. Phillips, Patent Owner argues that the consequences of damaging the nerves in the psoas muscle are more severe and, thus, a teaching of avoiding the para-spinal nerves would not lead a skilled artisan to believe that traversing the psoas muscle would be safe. *Id.* at 49–50 (citing Ex. 2020 ¶¶ 19, 47, 70). We are not persuaded that Marino's teaching is limited to avoiding the para-spinal nerves. Rather, Marino itself notes the general applicability of its technique, explaining that it "can be used in all manner of minimally invasive surgery and is especially useful for approaching any target site having sensitive nerves adjacent thereto." Ex. 1006, 16:20–22. Moreover, as explained above, the "trans-psoas path" of the claims of the '535 patent is not limited to a path through the most nerve-rich and dangerous portions of the psoas muscle. We are persuaded, therefore, by Petitioner's evidence that a cannulated system, such

as Foley's, equipped with nerve monitoring technology, predictably would have had the benefits described in Marino, namely the ability to avoid nerves during spinal surgery.

Patent Owner argues that the "generalized" disclosure of Marino would not have provided a reason to traverse the non-nerve-rich portion of the psoas muscle, per the teaching of Obenchain. PO Resp. 41, 44–45. We do not, however, understand Patent Owner's evidence to suggest that spinal surgery performed through the anterior-most fibers of the psoas-muscle carries no risk of nerve damage; rather, this evidence suggests that it would have been less dangerous. Thus, we are persuaded that Marino's general teaching would have been applicable regardless of whether the surgery proceeded through the less-dangerous or more-dangerous portions of the psoas muscle.

In sum, Petitioner has presented sufficient evidence to conclude that every limitation of claims 1–12 of the '535 patent is taught in one or more of Foley, Marino, Obenchain, and Epoch 2000. Petitioner also has introduced persuasive evidence sufficient to show that a skilled artisan would have had reason to combine the features of these references, e.g., combining the features of these references would have been predictable.

4. Obviousness of Claim 6 over Foley, Marino, Obenchain, Epoch 2000, and Moed

Claim 6 depends from claim 1 and adds "wherein the elongate stimulation instrument comprises a K-wire instrument insertable into the initial dilator cannula." Petitioner argues that such a K-wire instrument is taught in Moed. Pet. 38–39.

Moed describes performing nerve monitoring during spine surgery involving installing iliosacral implants (such as iliosacral screws). Ex. 1011, at 1529. In particular, Moed describes using a 2.0 millimeter Kirschner wire (K-wire) as an electrode for delivering a monopolar, monophasic square wave stimulus signal. *Id.* at 1531, 1536. Petitioner argues that Moed specifically describes the use of an electrified K-wire to detect nerve proximity and that a person of ordinary skill in the art would have employed Moed's teachings to minimize the risk of neural injury during placement of implants during surgery. Pet. 38–39. Petitioner also argues that Moed establishes that a guide wire, such as shown in Foley, could have been used as a stimulation instrument. *Id.* at 38.

Patent Owner does not present separate arguments for this claim, instead referring to its argument for claim 1. PO Resp. 52.

Based on this evidence, Petitioner has persuaded us that every limitation of claim 6 is taught in one or more of Foley, Marino, Obenchain, Epoch 2000, and Moed. For the reasons given above, and in the Petition, Petitioner has introduced persuasive evidence sufficient to show that combining the features of these references would have been predictable.

5. Objective Indicia Do Not Evidence Non-Obviousness

Patent Owner contends that several objective indicia show non-obviousness. In evaluating whether an invention would have been obvious, "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Although

it is Patent Owner's burden to introduce evidence supporting such objective indicia, *see In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996), the ultimate burden of persuasion never shifts to Patent Owner, *see* 35 U.S.C. § 316(e). Rather, objective indicia should be considered along with all of the other evidence in making an obviousness determination. *See Eurand, Inc. v. Mylan Pharm. Inc. (In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litig.)*, 676 F.3d 1063, 1076–77 (Fed. Cir. 2012) ("It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.") (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983)).

In short, Patent Owner argues that the conventional wisdom among spine surgeons was that a lateral approach to the spine through the nerve-rich portion of the psoas muscle was dangerous and that surgeons were skeptical of procedures using that approach; nevertheless, there was a long-felt need for such an approach to avoid the disadvantages of other approaches; against this backdrop, Patent Owner developed a successful technique for traversing the psoas muscle; and, as a result, Patent Owner received extensive praise, created a new market, and ultimately achieved commercial success. PO Resp. 9–34. Patent Owner supports its argument with the Phillips Declaration (Ex. 2020) as well as the Obenchain Declaration (Ex. 2025) and the declaration testimony of Patrick Miles (Ex. 2024, "Miles Decl."), an executive for Patent Owner.

a. Nexus

"For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the

claimed invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). In particular, the objective indicia "must be tied to the novel elements of the claim at issue" and must "'be reasonably commensurate with the scope of the claims.'" *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013) (quoting *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013)).

Patent Owner's objective evidence of non-obviousness is centered on praise for, and success of, its "eXtreme Lateral Interbody Fusion" (XLIF) systems and methods. *See, e.g.*, PO Resp. 12–14. Patent Owner, however, does not establish adequately what XLIF is and whether it is encompassed by the claims of the '535 patent. Patent Owner repeatedly refers to features of this technique with a high degree of generality, for example stating that it is "the first minimally invasive lateral transpsoas approach to the lumbar spine using nerve monitoring," *id.* at 13, and quoting an article that describes features of XLIF used in conjunction with another Patent Owner product (EMG IOM, or NeuroVision®), *id*. We are unable to discern, from such general evidence, how Patent Owner is mapping the features of XLIF to the claims.

Patent Owner argues that Dr. Phillips, in his Declaration, compared XLIF to the independent claims of the '535 patent and concluded that "XLIF procedure and systems" embody those claims. PO Resp. 14 (citing Ex. 2020 ¶¶ 22–23, 27, Attachment E). Dr. Phillips, in turn, includes detailed claim charts and citations to literature that purportedly describes an "XLIF System." *See* Ex. 2020, Attachment E. Patent Owner makes no attempt, however, to explain in its Response how this evidence establishes a nexus. Instead, it is an improper incorporation by reference of arguments from the

Phillips Declaration into the PO Response. *See* 37 C.F.R. § 42.6(a)(3) ("Arguments must not be incorporated by reference from one document into another document.").

Additionally, it is unclear what product(s) Dr. Phillips is mapping to the claims. Dr. Phillips cites to Exhibit 2028, which he alternately contends describes the "XLIF surgical technique" and the "XLIF system." Ex. 2020 ¶ 22, Attachment E, p. 168. As its title suggests, however, Exhibit 2028 appears to describe a MaXcess II Access System, with XLIF being one surgical technique performable with this system. Ex. 2028, at 1. To the extent XLIF is a "system," it appears that such a system would not correspond to the claims of the '535 patent. For example, the XLIF instrument system includes several surgical devices, but does not include any cannulated devices with nerve monitoring capability. Ex. 2028, at 4. Rather, Dr. Phillips relies on disclosure of the MaXcess II Access system to show these features. Ex. 2020, Attachment E, p. 173–64, 178–79 (citing Ex. 2028, at 8). Another portion of the document details the catalog numbers of the components of the "XLIF System," none of which includes cannulated devices with nerve monitoring capability. Ex. 2028, at 24. In contrast, dilators are included in the "MaXcess II Access System," *id.* at 26, and nerve monitoring appears to be provided by a "NeuroVision JJB System" and disposable "NeuroVision JJB XLIF Module," *id.* at 27.

It appears, from this evidence, that XLIF is a marketing term that is sometimes used to identify a surgical technique and other times used to identify groups of products. Thus, when Patent Owner uses the shorthand term "XLIF" in its Response, without clarifying argument, we are unable to associate Patent Owner's objective evidence with particular products or

procedures. Rather, Patent Owner leaves it to us to figure out, on a case-by-case basis, what it references by the term "XLIF." That is the type of abuse that the rule against incorporation by reference is designed to prevent. *See* Rules of Practice for Trials Before The Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions; Final Rule, 77 Fed. Reg. 48,612, 48,617 (Aug. 14, 2012) ("In *DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (7th Cir. 1999), the court rejected 'adoption by reference' as a self-help increase in the length of the brief and noted that incorporation is a pointless imposition on the court's time as it requires the judges to play archeologist with the record. The same rationale applies to Board proceedings."). Accordingly, Patent Owner's general identification of XLIF as practicing the claims of the '535 patent is insufficient to show nexus.

Moreover, Patent Owner's objective indicia arguments all focus on the "key non-obvious inventive concept central to all of the claimed inventions of the NuVasive XLIF Patents[, namely,] the use of nerve monitoring techniques to safely traverse the psoas muscle during a spinal procedure and/or the specific devices (namely stimulated dilators) developed for such a procedure." Ex. 2020 (Phillips Decl.) ¶ 23. As Petitioner points out (Reply 8), Patent Owner's arguments assume that the claims require an "extreme" or "direct" lateral approach, as opposed to what Patent Owner argues is an incidental traversal of the psoas muscle in its characterization of Obenchain. As explained in Section II.A above, an extreme or direct lateral path through the psoas muscle is not a requirement of the claims. Even if we were to find a correspondence between XLIF and the claims, the "key non-

obvious inventive concept" on which Patent Owner primarily relies is not a requirement of the claims.

Accordingly, Patent Owner's evidence does not establish a nexus between its objective indicia and the novel elements of the claims, and such objective evidence is entitled to little weight.

b. Long-felt need

"Evidence that an invention satisfied a long-felt and unmet need that existed on the patent's filing date is a secondary consideration of nonobviousness." *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009). To show a long-felt need, Patent Owner must introduce evidence to show when such a need first arose and how long this need was felt, and must introduce evidence to show that this need was met by the patented invention. *Id.* "[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem." *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

Patent Owner contends that, prior to the '535 patent, surgeons preferred to perform lumbar spinal interbody fusion surgery by approaching the spine from anterior (from the front of the patient) and posterior (from the back of the patient) directions, rather than a lateral direction (from the side of the patient) through the psoas muscle. PO Resp. 3–4. According to Dr. Phillips, the psoas muscle includes nerve roots that control important bodily functions and, if injured, are unlikely to heal. *Id.* at 9–10 (citing Ex. 2020 ¶¶ 18–20). Patent Owner argues that the locations of these nerves are unpredictable. PO Resp. 10.

Other approaches, however, have severe drawbacks, Patent Owner argues. *Id.* at 10–11. According to Dr. Phillips, an anterior approach risks injuring the aorta and vena cava, among other issues, and a posterior approach requires removal of significant bone structure to access spinal disc space. *Id.* (citing Ex. 2020 ¶¶ 38–43). Patent Owner argues that, despite the drawbacks of anterior and posterior approaches, they were still preferred to lateral approaches, illustrating the severity of surgeons' concerns regarding a trans-psoas approach. PO Resp. 11. Patent Owner further argues that Petitioner had access to all of the technology it cites in this case, yet "it never occurred to Medtronic or anyone working with Medtronic, including Dr. Obenchain himself to combine nerve monitoring with instruments to safely and reproducibly create a lateral transpsoas approach to the lumbar spine." *Id.* at 12. Patent Owner also cites to what it characterizes as experimental attempts to lateral approaches that failed to gain widespread adoption. *Id.* at 12. According to Patent Owner, except for the incidental traversal of the psoas muscle described in Obenchain, these attempts either retracted the psoas muscle or did not mention it at all. *Id.*

Although Patent Owner has introduced evidence to show that each of the possible approaches has disadvantages and risks of patient injury, Patent Owner's evidence does not show that there was a long-felt need for a safe, reproducible lateral trans-psoas approach to the spine. Rather, at most, it shows that surgeons weighed the risks of each approach and opted for anterior and posterior approaches. Indeed, Petitioner introduces evidence that approaches other than lateral trans-psoas still comprise the majority of such spinal surgeries today. Reply 5.

Patent Owner's evidence is not sufficient to show a long-felt need. The existence of alternative approaches to the lumbar spine supports a finding that the need for a suitable approach to the lumbar spine had been solved. That those alternative approaches may have presented their own difficulties does not persuade us that there was a long-felt need for the lateral trans-psoas pathway, absent evidence that widespread efforts by ordinarily skilled artisans had failed in that trans-psoas approach. *See Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("[T]he mere passage of time without the claimed invention is not evidence of nonobviousness.") (citation omitted); *In re Allen*, 324 F.2d 993, 997 (CCPA 1963) (An allegation of a long-felt but unsolved problem in the art "is not evidence of unobviousness unless it is shown . . . that the widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem.").

Even assuming Patent Owner's evidence shows a long-felt need, Patent Owner has not shown that such a need was met by the invention of the '535 patent. To show that such a need was met, Patent Owner argues that its XLIF solution uses nerve monitoring to safely traverse the psoas muscle in an extreme lateral approach. PO Resp. 13. As explained in Section II.D.5.a above, Patent Owner's evidence does not establish a nexus between XLIF (or an extreme lateral approach) and the claims.

Accordingly, we are not persuaded by Patent Owner's evidence of long-felt need or its product's satisfaction of such a need.

c. Skepticism followed by Praise and Recognition

Skepticism that a patented device would work, followed by widespread acceptance and praise, can evidence non-obviousness of an invention. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1367–68 (Fed. Cir. 2012).

Patent Owner presents evidence that skilled artisans were initially skeptical of using XLIF in a trans-psoas approach, fearing it would be dangerous to the patient. PO Resp. 14–16. Much of this evidence consists of personal recollections of Dr. Phillips, including his recollections of conversations he had with surgeons (including those from Petitioner) in the 2003–2006 time frame as well as his review of deposition transcripts in related litigation. Ex. 2020 ¶¶ 28–33. Patent Owner also cites Dr. Obenchain as testifying that he would have been skeptical at that time. PO Resp. 16 (citing Ex. 2025 ¶¶ 15, 21).

As Petitioner points out (Reply 5–6), the objectivity of this evidence is questionable, as both Dr. Phillips and Dr. Obenchain are paid consultants to Patent Owner and are testifying long after the fact. *See* Ex. 2020 ¶¶ 1, 5; Tr. 143:6–23. *See also InTouch Techs., Inc. v. VGO Communications, Inc.*, 751 F.3d 1327, 1347, 1352 (Fed. Cir. 2014) ("[T]he district court must consider evidence showing objective indicia of nonobviousness, which constitutes *independent evidence* of nonobviousness" (internal quotation marks omitted, emphasis added) in order to "guard against . . . hindsight bias."); *Geo. M. Martin Co. v. Alliance Machine Sys. Int'l, LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010) (discounting "self-serving statements by Martin's president"). Even if fully credited, however, Patent Owner's

evidence is not persuasive to show a nexus between XLIF and the claims, as explained above.

As to eventual acceptance and praise, Patent Owner introduces evidence, mainly the recollection of Mr. Miles, an executive of Patent Owner, that one-by-one, surgeons stopped doubting XLIF and began to adopt it. PO Resp. 16–18 (citing Ex. 2024 ¶¶ 14–15). Additionally, Patent Owner introduces articles stating that XLIF and NeuroVision® are safe and reproducible and that nerve-sensing is an important part of that. PO Resp. 18–21. Much (but not all) of this evidence was funded by Patent Owner. *See*, *e.g.*, Ex. 2030, at 2; Ex. 2052, at 228; Ex. 2053, at 6. As the Federal Circuit has stated, "objective indicia of nonobviousness serve a particularly important role in a case, like this one, where there is a battle of scientific experts regarding the obviousness of the invention [because they] provide an *unbiased* indication regarding the credibility of that evidence." *Kinetic Concepts*, 688 F.3d at 1370–71 (emphasis added). Here, Patent Owner's evidence is less persuasive as an indication of the perceptions of independent, unbiased, surgeons because it was funded, at least in part, by Patent Owner.

Patent Owner also points to several examples of "improved patient outcomes," including testimonials from doctors and patients that XLIF resulted in decreased risks and complications. PO Resp. 21–26. This evidence discusses the benefits of XLIF generally. Other than one statement mentioning "strict adherence to surgical technique including neuromonitoring" (Ex. 2055, at 5), however, Patent Owner's testimonials do not discuss the use of nerve monitoring to traverse the psoas muscle or any other features of the claims.

In any case, as explained above, Patent Owner's evidence does not show a nexus between XLIF and the claims.

d. Commercial Success

Patent Owner argues that XLIF was introduced in 2003, that Patent Owner's revenues in 2004 were approximately $38 million, and that, by 2013, those revenues had grown to approximately $685 million. PO Resp. 26–27. According to Patent Owner, its commercial success has been "a direct result of its XLIF procedure and systems and the technology claimed by the '535 patent." *Id.* at 28. In support, Patent Owner relies on reports of market research from financial analysts crediting its success, at least in part, to XLIF. *Id.* at 28–30; Ex. 2041, at 289 ("The majority of NuVasive's revenue is directly related to the XLIF procedure and its related devices"); Ex. 2056, at 1, 3 (J.P. Morgan report attributing success to Maximum Access Surgery (MAS) platform, XLIF, NeuroVision®, and heavy salesforce investment); Ex. 2058, at 12 (Canaccord Genuity report attributing success to the "critical component" NeuroVision® and MaXcess retractor system); Ex. 2059, at 3–4 (Caris & Co. report stating that Patent Owner's core products are the MAS platform and XLIF).

Petitioner argues that Patent Owner owes its success to sales of unclaimed implants, sales of its MaXcess retractor system, and marketing to and training of surgeons, among other things. Reply 5, 7–8. "A prima facie case of nexus is made when the patentee shows both that there is commercial success, and that the product that is commercially successful is the invention disclosed and claimed in the patent." *Crocs, Inc. v. U.S. Int'l Trade Comm'n*, 598 F.3d 1294, 1310–11 (Fed. Cir. 2010). As explained in Section

II.D.5.a above, however, Patent Owner has not shown a correspondence between XLIF (or, for that matter, NeuroVision, MaXcess retractor system, and the MAS platform) and the claims.

Moreover, Patent Owner has not been consistent in its attribution of commercial success. In this matter, Patent Owner argues that "XLIF's commercial success (and by extension NuVasive's) is a direct result of the novel combination of the minimally invasive nerve monitoring enabled distractor(s)/dilator(s) with NuVasive's nerve monitoring system to safely and reproducibly perform a lateral transpsoas approach to the lumbar spine as claimed by the '535 patent." PO Resp. 30–31. In contrast, in IPR2014-00075, Patent Owner attributed its commercial success to a system that included both nerve monitoring and a retractor, stating that

> XLIF's commercial success (and by extension NuVasive's) is a direct result of the novel combination of the minimally invasive nerve monitoring enabled distractor(s)/dilator(s) and working corridor instrument (retractor) (also optionally nerve monitoring enabled) with NuVasive's nerve monitoring system to safely and reproducibly perform a lateral transpsoas approach to the lumbar spine as claimed by the '767 patent.

IPR2014-00075, Paper 26, at 30–31. As Petitioner points out (Reply 8–9), in yet another example, Patent Owner attributed its commercial success to its implants, stating that "the detailed testimony establishes a nexus between NuVasive's CoRoent XL implants and the invention of the '156 patent, and proves the commercial success of the product after NuVasive pioneered the market for lateral, trans-psoas interbody fusion surgeries with the CoRoent XL implant." Ex. 1026 (*Medtronic, Inc. v. NuVasive, Inc.*, IPR2013-00506, Paper 21 (PTAB May 21, 2014)) at 59. Patent Owner has made no argument that we should consider several or all of its patents in the

aggregate to show commercial success. *Cf. Apple Inc. v. Samsung Electronics Co., Ltd.*, 735 F.3d 1352, 1365 (Fed. Cir. 2013) ("[I]t may make sense to view patents in the aggregate where they all relate to the same technology or where they combine to make a product significantly more valuable.").

In addition, Petitioner directs us to evidence that the commercial success asserted by Patent Owner resulted, at least in part, from factors not associated with either the claims or the techniques or hardware of XLIF. Specifically, as Petitioner points out (Reply 1), a Form 10-K filed by Patent Owner with the United States Securities and Exchange Commission for the fiscal year ending December 31, 2013, states the following:

> To date, *the majority of our revenues have been derived from the sale of implants, biologics and disposables*, and we expect this trend to continue for the foreseeable future. We *generally loan our proprietary software-driven nerve monitoring systems and surgical instrument sets at no cost to surgeons* and hospitals that purchase disposables and implants for use in individual procedures. In addition, we place our proprietary software-driven nerve monitoring systems, MaXcess® and other MAS or cervical surgical instrument sets with hospitals for an extended period at no up-front cost to them.

Ex. 2038, at 69 (emphasis added). Thus, even if Patent Owner were able to show that XLIF embodies the claims of the '535 patent, Petitioner has shown persuasive evidence that products other than XLIF were the primary drivers of Patent Owner's commercial success.

Patent Owner also argues that XLIF created an entirely new market segment. PO Resp. 27–28. In support, Patent Owner points to documents from Petitioner referring to a "minimally invasive fusion market" (Ex. 2001,

at 8[1]), and "Lateral IB Market Share," (Ex. 2003, at 10[2]). It is unclear precisely what these particular markets include. For example, Exhibit 2001 shows Petitioner as having a larger share of the "minimally invasive fusion market" than Patent Owner from the year 2005 to 2008, while Exhibit 2003 shows Petitioner as having a smaller share of the "Lateral IB Market" than Patent Owner from the year 2005 to 2008. We doubt that these two exhibits are discussing the same market. Moreover, Petitioner argues that the market is the overall fusion market and that Patent Owner has less than 5% share of that market. Reply 5. The evidence Patent Owner presents is not sufficient to ascertain what is included in the markets to which Patent Owner refers.

In sum, Patent Owner's evidence is not sufficient to show its commercial success relative to the market or that any such commercial success is due to a product practicing the patent or, more precisely, due to the novel features of the '535 patent claims.

e. Copying

Patent Owner contends that Petitioner and other competitors copied its XLIF technology. PO Resp. 31–34. According to the Federal Circuit,

> copying requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented

[1] Consistent with the PO Response, we refer to the numbering at the bottom, right corner of the pages of Exhibit 2001.

[2] Consistent with the PO Response, we refer to the numbering at the bottom, left corner of the pages of Exhibit 2003.

> product combined with substantial similarity to the patented product.

Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Patent Owner relies on Petitioner's internal documents, one of which states that Patent Owner pioneered the lateral approach (Ex. 2001, at 8), and another that discusses XLIF (Ex. 2086, at 3), arguing that these documents show an internal recognition of XLIF. PO Resp. 31–33. Patent Owner then cites to a financial analyst report (from Caris Co.) stating that Petitioner introduced Direct Lateral Interbody Fusion (DLIF), its own version of XLIF. PO Resp. 33 (citing Ex. 2059, at 4). We are not persuaded of copying by Petitioner. Even assuming that XLIF practices the claims of the '535 patent (which Patent Owner's evidence does not show), Patent Owner has not introduced evidence sufficient to show the details of DLIF and, thus, Patent Owner's evidence does not show that DLIF practices the claims or was replicated from observations or studies of XLIF.

Patent Owner, citing a financial analyst report (from J.P. Morgan) further argues that other competitors introduced competing products and, thus, copied XLIF. PO Resp. 33 (citing Ex. 2066, at 1). This evidence similarly lacks sufficient detail to determine whether the competing products practice the claims or ascertain whether they were copied from XLIF.

In sum, Patent Owner's evidence does not show efforts by Petitioner, or others, to replicate XLIF. Accordingly, we are not persuaded that objective indicia of copying evidences non-obviousness.

6. Conclusion of Obviousness

As explained above, the prior art teaches each limitation of claims 1–12. Petitioner has introduced persuasive evidence that a skilled artisan would have had reasons to combine the prior art to arrive at these claims. We have weighed Petitioner's evidence against the objective evidence presented by Patent Owner. We consider that objective evidence to be entitled to little weight for the reasons given above. In sum, upon consideration of all the evidence, including the evidence in the Petition and Patent Owner's objective indicia of non-obviousness, we conclude that Petitioner has proved by a preponderance of the evidence that claims 1–12 would have been obvious over Marino, Foley, Obenchain, and Epoch 2000 and that claim 6 would have been obvious over Marino, Foley, Obenchain, Epoch 2000, and Moed.

III. CONCLUSION

Petitioner has demonstrated by a preponderance of the evidence that claims 1–12 are unpatentable based on the following grounds of unpatentability:

(1) Claims 1–12 under 35 U.S.C. § 103(a) as obvious over Marino, Foley, Obenchain, and Epoch 2000; and

(2) Claim 6 under 35 U.S.C. § 103(a) as obvious over Marino, Foley, Obenchain, Epoch 2000, and Moed.

IV. ORDER

For the reasons given, it is

ORDERED that, based on a preponderance of the evidence, claims 1–12 of U.S. Patent No. 8,005,535 B2 are held unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is denied-in-part and dismissed-in-part; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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