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Paper 44
Entered: April 3, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

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Case IPR2014-00034
Patent 8,000,782 B2

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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, 5, 7–9, 13–18, and 20 of U.S. Patent 8,000,782 B2 (Ex. 1017, "the '782 patent"). NuVasive, Inc. ("Patent Owner") filed a Preliminary Response (Paper 10, "Prelim. Resp."). Pursuant to 35 U.S.C. § 314, in our Decision to Institute (Paper 11, "Dec."), we instituted this proceeding as to all of the challenged claims of the '782 patent.

After the Decision to Institute, Patent Owner filed a Patent Owner Response (Paper 22, "PO Resp."), and Petitioner filed a Reply to the Patent Owner Response (Paper 27, "Reply").

## *B. Related Cases*

Petitioner challenged Patent Owner's U.S. Patent No. 8,192,356 B2 in *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00073, and *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00074; U.S. Patent No. 8,016,767 B2 in *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00075; and U.S. Patent No. 8,005,535 B2 in *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00081, and *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00087. 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.

Patent Owner has asserted the '782 patent against Petitioner in *Warsaw Orthopedic Inc. v. NuVasive Inc.*, Case No. 3:12-cv-02738-CAB-MDD (S.D. Cal.). Pet. 1; Paper 7 at 2.

*C. References Relied Upon*

Petitioner relies upon the following prior art references:

| | | | |
|---|---|---|---|
| Ex. 1001 | Smith | US 6,679,833 B2 | Jan. 20, 2004 (filed Mar. 23, 2001) |
| Ex. 1002 | Foley | US 5,792,044 | Aug. 11, 1998 |
| Ex. 1003 | Obenchain | US 5,195,541 | Mar. 23, 1993 |
| Ex. 1004 | Prass | US 6,292,701 B1 | Sept. 18, 2001 |
| Ex. 1005 | Simonson | US 6,159,179 | Dec. 12, 2000 |
| Ex. 1009 | Marino | WO 00/38574 A1 | July 6, 2000 |
| Ex. 1010 | Kelleher | WO 01/37728 A1 | May 31, 2001 |
| Ex. 1011 | Isley | Michael R. Isley et al., *Recent Advances in Intraoperative Neuromonitoring of Spinal Cord Function*: *Pedicle Screw Stimulation Techniques*, vol. 37, no. 2 AM. J. ELECTRONEURODIAGNOSTIC TECH., at 93–126 (June 1997) | |
| Ex. 1012 | Epoch 2000 | Axon Systems, Inc., Epoch 2000 Neurological Workstation, Food & Drug Admin. submission under 510(k) No. K971819 | |

*D. The Asserted Grounds*

We instituted this proceeding based on the grounds of unpatentability set forth in the table below. Dec. 33.

| References | Basis | Claims challenged |
|---|---|---|
| Smith, Marino, and Obenchain | § 103(a) | 1, 7 |
| Smith, Marino, Obenchain, and Prass | § 103(a) | 5 |
| Smith, Marino, Obenchain, and Simonson | § 103(a) | 8 |
| Smith, Marino, Obenchain, Prass, and Isley | § 103(a) | 9, 13–17 |
| Smith, Marino, Obenchain, Prass, Isley, and Epoch 2000 | § 103(a) | 18, 20 |
| Foley, Kelleher, Obenchain, and Prass | § 103(a) | 1, 5, 7 |
| Foley, Kelleher, Obenchain, Prass, and Simonson | § 103(a) | 8 |
| Foley, Kelleher, Obenchain, Prass, and Isley | § 103(a) | 9, 13–18, 20 |

*E. The '782 Patent*

The '782 patent generally relates to medical devices for spinal surgery. Ex. 1017, Abstract. Two aspects of the devices described in the '782 patent include sequentially dilating cannulas (e.g., Ex. 1017, Fig. 18) and structure for detecting the proximity and direction of nerves as the cannulas are inserted through tissue (*id.* at 10:49–54). Regarding the second aspect, a surgeon determines nerve proximity and direction using a stimulation electrode on the distal tip of a cannula that depolarizes nerves that are in close proximity to the electrode. *Id.* at 11:22–26. 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 11:26–32. 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, 10:16–29. Upon detecting a nerve, the surgeon has the option of repositioning the cannula to avoid the nerve. *Id.* at 11:32–35.

The cannulas are designed to dissect the tissue between a patient's skin and the surgical target site bluntly. *Id.* at 11:5–10. For example, the cannulas can form an operative corridor between the skin and an intervertebral target site through the psoas muscle (a trans-psoas path). *Id.* at 11:36–39. Figures 16–19 illustrate the sequential insertion of dilating cannulas of increasing diameters. A surgeon first inserts a thin cannula (48), along with a K-wire (46), through a patient's body to a working site at a vertebra. *Id.* at 19: 60–67, 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 19:67–20:10. 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 20:10–21. The cannula can have reference marks so that the surgeon knows which direction the electrode is facing. *Id.* at 20:18–24.

The surgeon inserts additional cannulas of increasing diameter sequentially over the first cannula until a desired working diameter is achieved. *Id.* at 20:29–33, 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 20:38–45. The surgeon performs the

nerve proximity testing as each of these devices is inserted into the patient. *Id.* at 11:5–14, 20:46–50.

*F. Illustrative Claim*

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

> 1. A surgical system for neural monitoring while forming an operative corridor in a trans-psoas approach to a spine, comprising:
>
> a sequential dilation access system comprising a plurality of dilating cannulas to form a trans-psoas corridor between a skin surface and a targeted spine site, the plurality of dilating cannulas comprising an outer dilating cannula fitting over another of the dilating cannulas when advanced in a trans-psoas path toward the targeted spine site,
>
> wherein a stimulation electrode is positioned on at least one of the dilating cannulas to deliver a stimulation signal for nerve monitoring proximate to a distal end of the dilating cannula when advanced in the trans-psoas path, the stimulation electrode being arranged in a fixed position relative to a longitudinal axis of the at least one dilating cannula such that the stimulation electrode rotates with the at least one dilating cannula when the at least one dilating cannula is rotated about the longitudinal axis;
>
> a working corridor instrument that is slidable over the outer dilating cannula to form a trans-psoas operative corridor to the targeted spine site.

## 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).

#### *1. "trans-psoas approach" / "when advanced in the trans-psoas path"*

In the Decision to Institute, we preliminarily determined that "trans-psoas approach" and "when advanced in the trans-psoas path," as recited in independent claims 1 and 9, are statements of intended use and are entitled to no patentable weight, beyond requiring an ability to follow a "trans-psoas path" or "trans-psoas approach." Dec. 8–9; *see also Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010) ("For apparatus claims . . . generally patentability 'depends on the claimed structure, not on the use or purpose of that structure.'") (quoting *Catalina Marketing Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002)); *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) ("It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.").

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

*2. Other terms*

In the Decision to Institute, we construed additional claim terms as reproduced in the table below.

| **Claim Phrase** | **Claim Construction in the Decision to Institute** |
|---|---|
| "fixed" (claim 1) | stationary |
| "only a radial portion of the distal end" (claims 9, 14) | around only a portion of the circumference of the insertion end |

Petitioner and Patent Owner do not dispute these constructions. We maintain these constructions based on the complete record developed during this trial. Neither Petitioner nor Patent Owner identifies any additional terms requiring construction. No other terms require express construction for purposes of this Decision.

*B. 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 30) 1. 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 36) 1–3. 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 3–4 (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 8), 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.

*C. Asserted Grounds of Unpatentability*

*1. Obviousness Combinations Including Smith, Marino, and Obenchain*

Petitioner raises several challenges to claims 1, 5, 7–9, 13–18, and 20 of the '782 patent based in whole or in part on the combination of Smith, Marino, and Obenchain. Petitioner supports its contentions with the testimony of Daniel Schwartz, Ph.D. (Ex. 1014, "Schwartz Decl.").

*a. Overview of Smith, Marino, and Obenchain*

Smith is directed to a technique for providing a surgeon with a working channel for access to a location in a patient's body during surgery, for example to view a working site in the patient's body with an endoscope during spinal surgery. Ex. 1001, Abstract, 6:43–47. Figures 10a–10i of Smith illustrate creating a working channel by inserting a series of tissue dilators (dilating cannulas) concentrically over one another to dilate the tissue sequentially. *Id.* at 12:27–36, 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 12:43–49. Although Smith focuses on a medial posterior approach, Smith explains that this technique can "be used from any approach and in other regions besides the spine," *id.* at 12:1–2, for example, "posterolateral" and "anterior" approaches, *id.* at 12:10–12.

Marino describes various nerve surveillance systems for identifying and avoiding nerves during spinal surgery. Ex. 1009, 7:13–17. Figure 6, one of the embodiments, is reproduced below:

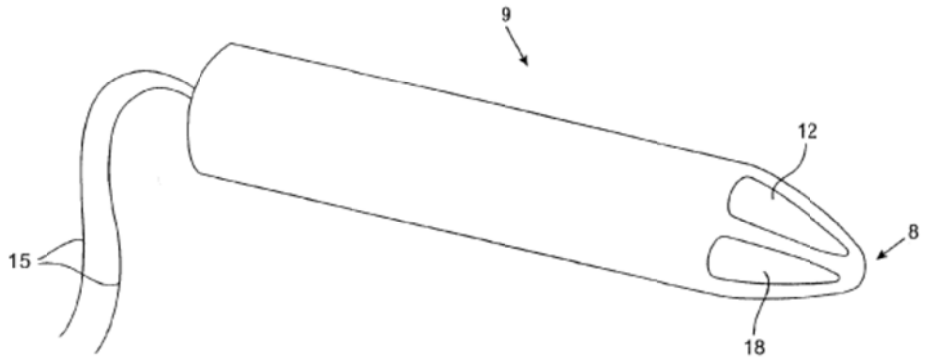


FIG. 6

Figure 6 shows nerve surveillance probe 9 with four electrodes (electrodes 12 and 18 are shown) disposed at radial locations on the distal end 8 of the probe. *Id.* 8:26–31. As the probe is inserted through patient tissue and nears a nerve, the electrode closest to the nerve depolarizes the nerve, the response to which can be detected using "standard" EMG techniques. *Id.* at 9:1–5, 7:18–31. Because the EMG signal tells the surgeon which of the electrodes depolarized the nerve, the surgeon can identify the direction of the nerve. *Id.* at 9:5–7.

In another embodiment, Figure 12 shows a cannula 112 with an expandable tip 113 comprising a plurality of petals 114, each of which includes an electrode 116a, 116b. *Id.* at 11:8–13, 11:29–31. In a manner similar to the probe of Figure 6, a surgeon can use the electrodes on the cannula to detect the presence and direction of nerves encountered as the cannula is inserted into a patient. *Id.* at 11:32–12:25. As shown in more detail in Figure 13, the petals 114 of expandable tip 113 are held together by seals 115 that break when a predictable amount of pressure is applied. *Id.* at 11:24–29. After the cannula is inserted into the patient and positioned, an

inner cannula can be inserted into cannula 112, breaking seals 115 and pushing out petals 114. *Id.* at 13:14–21. Marino describes an operative target site at a patient's intervertebral disc, but notes that "the present expandable tip cannula can be used in all manner of minimally invasive surgery and is especially useful for approaching any target site having sensitive nerves adjacent thereto . . . ." *Id.* at 16:16–22.

Obenchain describes a cannula (elongated cylinder) for spinal surgery (laparoscopic lumbar discectomy). Ex. 1003, 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.* at 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 L5 and S-l, 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.

*a. 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. 1014 ¶ 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 10.

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. 36.

We agree with Petitioner that the claims of the '782 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. 34–36; Reply 10. 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. 33. Dr. Schwartz testified in his Declaration that his opinions are from the perspective of a skilled artisan at the time of the invention. Ex. 1014 ¶ 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.

*b. Obviousness of Claims 1 and 7 over Smith, Marino, and Obenchain*

Petitioner argues that Smith teaches a sequential dilation access system with a plurality of cannulas and a working corridor instrument, that Marino teaches providing stimulation electrodes in fixed positions on cannulas for nerve monitoring when performing surgery in areas containing sensitive nerves, and that Obenchain teaches spinal surgery using a trans-psoas approach. Pet. 17–19, 25–27. Petitioner further notes that the teachings of each of these references are in the context of minimally invasive spine surgery using cannulated instruments. Pet. 19, 25. According to Petitioner, in light of Marino's teaching of the importance of monitoring for, and avoiding, nerves near a cannula as it is inserted to the intervertebral space, a skilled artisan, for safety, would have had reason to place electrodes on the cannula shafts of Smith, per Marino's teaching, when using a trans-psoas approach through nerve-rich areas, as recited in Obenchain. Pet. 18–19, 26. Based on this evidence, Petitioner has persuaded us that every limitation of claim 1 is taught in one or more of Smith, Marino, and Obenchain.

Patent Owner contends that Petitioner's proposed combination lacks factual underpinning because Obenchain does not teach traversing the nerve-rich portions of the psoas muscle. PO Resp. 40. Rather, Patent Owner argues, Obenchain teaches avoiding the psoas muscle entirely, using an

anterior or anterolateral approach, or, if that is not possible, incidentally traversing the psoas muscle at its most anterior fibers while avoiding its nerve-rich portions. *Id.* In support, Patent Owner cites a declaration (Ex. 2025, "Obenchain Decl.") it obtained from Theodore Obenchain, M.D., the named inventor of Obenchain. PO Resp. 40 (citing Ex. 2025 ¶¶ 7–9, 12, 14–17).

Patent Owner's argument is not persuasive. As explained in Section II.A.1, "trans-psoas approach" and "advanced in the trans-psoas path" are statements of intended use and do not limit the claims other than to require an ability to follow a "trans-psoas path" or "trans-psoas approach." As explained above, Smith teaches that its dilation system could be used in "any approach" to the spine. Ex. 1001, 12:1–2. Petitioner introduced evidence that one such approach includes a trans-psoas approach. Pet. 18 (citing Ex. 1014 (Schwartz Decl.) ¶¶ 74–80). We credit that evidence. Petitioner also cites Obenchain as an example of a cannulated instrument used in a trans-psoas path. Pet. 18. We find that Smith's cannulas, when equipped with nerve sensing technology, would have been capable of being used in a trans-psoas approach to the spine. Although Patent Owner argues that it was "conventional wisdom" to avoid the psoas muscle because of the critical nerve structures running through it, PO Resp. 40–41 (citing Ex. 2025 (Obenchain Decl.) ¶¶ 7, 9, 13–19), Patent Owner does not contend that Smith's cannulas, when equipped with nerve sensing technology, would have been incapable of such use.

Patent Owner's argument also assumes that the claims require a path through the nerve-rich portion of the psoas muscle. With that assumption, Patent Owner attempts to distinguish Obenchain, which Patent Owner and

Dr. Obenchain argue recommends avoiding that portion of the psoas muscle. PO Resp. 40 (citing Ex. 2025 (Obenchain Decl.) ¶¶ 7–9, 13–16). 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 in the Obenchain reference of traversing the psoas muscle, the claims of the '782 patent do not recite traversing any particular portion of the psoas muscle. Tr. 39:10–40:1; 113:5–114:3. Thus, Patent Owner's argument is unpersuasive.

Patent Owner further argues that the differences between Smith and Marino are such that a skilled artisan would not have combined them. Specifically, Patent Owner contends that Smith describes a system traditionally used in muscle tissue without important nerve structures where navigating nerves is not a factor, PO Resp. 42, 44–45, and that Smith itself does not teach incorporation of nerve monitoring functionality, *id.* at 45. In contrast, Patent Owner argues, Marino describes a very different system designed to be used where nerves are encountered, but that does not include sequential dilators. *Id.* at 42–44. These arguments are unpersuasive, because Patent Owner points out deficiencies of individual references without 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.").

Patent Owner also points to an embodiment of Marino, depicted in Figures 25 and 26, that uses the opening of petals to brush nerves aside, according to Patent Owner, without the use of nerve monitoring functionality. PO Resp. 43 (citing Ex. 1009, 15:32–16:26, Figs. 25, 26).

Although Marino describes the function of curved petals without reference to nerve monitoring, Ex. 1009, 15:32–16:7, we understand this description to be focusing on the distinctive function of curved petals (compared with the petal shape of Figures 12–14, for example), rather than a description of an embodiment without nerve monitoring. In any case, Petitioner does not rely on the curved petal feature of Marino. Thus, Patent Owner's argument is inapposite.

Patent Owner also argues that Petitioner has not explained adequately how a skilled artisan would have applied a circumferential electrode, shown in Figures 30–32 of Marino, to Smith's cannulas, in a fixed position relative to a longitudinal axis. PO Resp. 45–46. Petitioner does not rely on this feature; thus, Patent Owner's argument is inapposite.

Regarding the embodiments of Marino in which electrodes are placed on petals that can be expanded to displace nerves, Patent Owner argues that Petitioner has not explained adequately how these petals and electrodes would be incorporated into Smith's dilating cannulas. *Id.* at 45.

As a general matter, Patent Owner's arguments amount to a contention that Smith's cannulas cannot be physically combined with the various nerve sensing examples of Marino, or, at least, that Petitioner has not explained how these features would have been pieced together. This framework for analyzing obviousness is not persuasive. "It is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements." *In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012). Rather, "the test for obviousness is what the combined teachings of the references would have suggested to those having ordinary skill in the art." *Id.* at 1333.

In this case, Petitioner has presented evidence sufficient to conclude that Smith's cannulas were capable of being used in a trans-psoas path. Pet. 18. Petitioner also has introduced evidence that Marino, in general, teaches the benefits of using nerve-sensing technology when performing surgery (such as spinal surgery) using cannulated instruments in any area of the body where nerves are likely to be encountered. *Id.* at 18–19 (citing Ex. 1009, 2:17–28). Obenchain shows that it was known to perform spine surgery using a trans-psoas path, even if, as Patent Owner argues, such a path was not through the most dangerous part of that muscle. Ex. 1003, 5:5–14. Petitioner has introduced persuasive evidence sufficient to show that adding nerve sensing technology (such as that taught in Marino) to Smith's system of cannulas would have improved predictably Smith's system's ability to navigate nerve-rich areas, such as the psoas muscle, during surgery. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

Further, we have considered the argument and evidence Petitioner presents in the Petition (at 28) regarding claim 7. Patent Owner does not present separate arguments for this claim, instead referring to its argument for claim 1. PO Resp. 46. Based on this evidence, Petitioner has persuaded us that every limitation of claim 7 is taught in one or more of Smith, Marino, and Obenchain. 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.

*c. Obviousness of Claim 5 over Smith, Marino, Obenchain, and Prass*

Claim 5 depends from claim 1 and recites "wherein said at least one dilating cannula includes a reference mark proximate a proximal end of the at least one dilating cannula that is indicative of the radial position of the stimulation electrode on the at least one dilating cannula." Petitioner contends that Marino provides reference marks in the form of buttons (121 and 123 of Figure 6, reproduced above) that indicate the orientation of the electrodes relative to the cannula. Pet. 20. Petitioner further cites to Prass for a disclosure of such a reference mark. Pet. 20, 27–28.

Prass describes a hand-held bipolar electrical stimulus probe for performing nerve monitoring during surgery. Ex. 1004, 1:13–23. Figure 2, reproduced below, is illustrative:

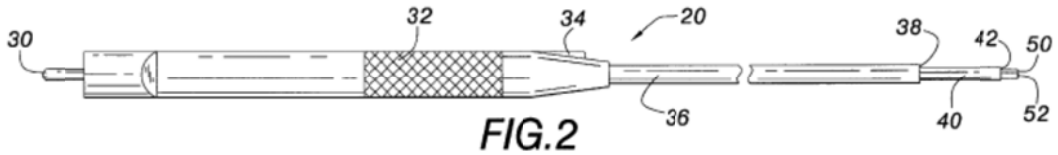

FIG.2

Figure 2 shows a cannula 36 that carries a flexible plastic molded jacket 40 with cathode and anode tips (50, 52). *Id.* at 6:28–34, 6:45–49. The probe of Figure 2 also includes a handle with grip area 32 and "transversely projecting salient tactile locator guide 34 aligned along the longitudinal axis of the handle." *Id.* at 6:10–22. As noted by Petitioner (Pet. 28), "[t]ransversely projecting locator guide 34 serves as a tactile salient feature aligned with the cathode conductor, thus allowing the surgeon to use a finger to orient the probe with the cathode conductor tip 50 in a desired angular direction." *Id.* at 7:31–34. Based on this evidence, Petitioner has persuaded

us that every limitation of claim 5 is taught in one or more of Smith, Marino, Obenchain, and Prass.

Petitioner contends that adding a reference mark, such as that shown in Prass, to the cannula of Marino and Smith would have been obvious because, absent such a reference mark, "a surgeon would have had difficulty determining the exact location (e.g., direction) of a nerve relative to the cannula, which is the very purpose of Marino." Pet. 20 (citing Ex. 1014 (Schwartz Decl.) ¶¶ 118–22).

Patent Owner contends that Marino's configuration of nerve-sensing electrodes would not have benefitted from reference marks and, instead, would have taught away from them. Specifically, Patent Owner argues that the '782 patent describes a reference mark in connection with determining the direction of a depolarized nerve when a cannula on which an electrode is positioned is rotated. PO Resp. 50–51. Patent Owner characterizes Petitioner's "motivation for the combination of a reference mark on the dilator structure [as] necessarily predicated on the ability to identify the location of the electrode when it is inside the patient and being rotated." *Id.* at 51–52. In contrast, Patent Owner argues, Marino describes a much more complex solution that includes four electrodes firing repeatedly in sequence. *Id.* at 50. In this case, Patent Owner contends, a reference mark is not necessary to determine a nerve's direction. *Id.* at 51. Indeed, Patent Owner argues, Marino's device would not work if rotated inside a patient. *Id.* at 50–52.

Patent Owner admits, however, that "the '782 claims do not require rotation as apparatus claims." *Id.* at 51. Moreover, Petitioner's declarant provided a sound reason why a reference mark would have been

advantageous (even necessary) in a multiple-electrode system such as Marino's:

> One of ordinary skill in the art would have known when using multiple electrode contacts for nerve location detection, as described in Marino, it would have been necessary to have some type of reference marking (whether on a handle portion or the body of the cannula itself) to denote which contact is serving as the active electrode (i.e., which cathode resulted in the low stimulation threshold).

Ex. 1014 ¶ 118. We find that such a use of a reference mark would not have rendered Marino inoperable and that Marino's teaching does not lead in a direction contrary to or divergent from a reference mark. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.").

Patent Owner argues that this passage of Dr. Schwartz's testimony misses the point; rather, "the question is whether it would have been obvious to have incorporated both the claimed distal stimulating electrode and the proximal reference mark into a dilating cannula such as those disclosed in Smith." PO Resp. 52. The evidence Petitioner introduces suggests that it would have. As explained above, Marino teaches that it is beneficial to equip surgical tools, such as Smith's cannulas, with nerve sensing technology for performing surgery in nerve sensitive areas. Even if Marino's multiple-electrode embodiment were bodily incorporated into one of Smith's cannulas (not a requirement of an obviousness analysis), a reference mark would have been beneficial for the reasons given by Dr. Schwartz.

Regarding Prass, Patent Owner argues that neither its stimulation electrode nor its reference mark is on its cannula. PO Resp. 53. Rather, the electrodes extend through a lumen of the cannula and the reference mark is on a separate handle. *Id.* According to Patent Owner, "the 'reference mark' must be part of the same instrument, namely, 'said at least one dilating cannula.'" *Id.* We are persuaded, however, by Dr. Schwartz's testimony that "[r]egardless of whether the reference mark appears on the body of the cannula, handle portion, or elsewhere, the only need was that the surgeon know where the stimulating cathode (or cathodes) is directed relative to that reference mark." Ex. 1014 ¶ 121. *See also Keller*, 642 F.2d at 426 ("[O]ne cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references.").

In sum, Petitioner has introduced persuasive evidence sufficient to show that a reference mark (such as described in Prass) would have served the same purpose when used with Smith's cannulas equipped with nerve sensing technology, namely, to orient the surgeon vis-à-vis the electrode(s), with the predictable result that the surgeon could identify the direction of a de-polarized nerve. *See KSR*, 550 U.S. at 417.

*d. Obviousness of Claim 9 over Smith, Marino, Obenchain, Prass, and Isley*

Petitioner cites to Smith's description of sequential dilators as teaching a "dilating cannula having longitudinal axis, a distal end, a proximal end, and a length such that said proximal end extends beyond a skin surface when said distal end is positioned adjacent to said spinal target site," as recited in claim 9. Pet. 21, 29. Petitioner cites to Marino's

description of electrodes placed on cannulas as teaching the recited "exposed stimulation electrode at said distal end [of the dilating cannula], said stimulation electrode being exposed along only a radial portion of said distal end." Pet. 21, 29–30. Petitioner cites to Obenchain as teaching a trans-psoas approach, and Prass's description of a guide as teaching claim 9's recited "reference mark viewable when said distal end of said dilating cannula is located between said skin surface and said spinal target site and indicative of the radial position of said exposed stimulation electrode." Pet. 21–22, 29–31.

Referring to its discussions of claims 1 and 5, Petitioner argues that a skilled artisan would have had reason to combine Smith, Marino, Obenchain, and Prass. Pet. 21–24.

Regarding the limitation "said dilator being insulated along the entire length with the exception of at least one exposed electrical contact at said proximal end and an exposed stimulation electrode at said distal end, said stimulation electrode being exposed along only a radial portion of said distal end," recited in claim 9, Petitioner cites Isley as describing an example of a stimulation instrument insulated along its length and argues that without insulation, Marino's device's entire surface would have conducted current, making it difficult to determine nerve proximity and direction. Pet. 22 (citing Ex. 1014 (Schwartz Decl.) ¶¶ 159–66).

Regarding claim 9's "stimulation clip," Petitioner cites Isley's teaching of an alligator clip connected to a pedicle probe as teaching this element, arguing that clips and cables were standard methods of providing electrical connections between a stimulator and cannulated instruments, and

would have been applicable to the cannulas of Marino and Smith. Pet. 24, 31 (citing Ex. 1011, Fig. 10, 112:3–6).

Patent Owner does not present separate arguments for claim 9, instead referring to its arguments for claims 1 and 5. PO Resp. 55. Those arguments are unpersuasive for the reasons given above.

Based on this evidence, Petitioner has persuaded us that every limitation of claim 9 is taught in one or more of Smith, Marino, Obenchain, Prass, and Isley. As explained above for claims 1 and 5, Petitioner has introduced persuasive evidence sufficient to show that a skilled artisan would have combined the features of Smith, Marino, Obenchain, and Prass. Petitioner also has introduced persuasive evidence that a skilled artisan would have incorporated the additional features of Isley.

Further, we have considered the argument and evidence Petitioner presents in the Petition (at 24–25, 31–33) regarding claims 13–17. Patent Owner does not present separate arguments for these claims, instead referring to its arguments for claims 1 and 5. PO Resp. 55. We are persuaded that Smith, Marino, Obenchain, Prass, and Isley teach each limitation of claims 13–17. For the reasons given above, and in the Petition, Petitioner has introduced persuasive evidence that combining the features of these references would have been predictable.

*e. Claims 8, 18, and 20*

We have considered the argument and evidence Petitioner presents in the Petition (at 20–21, 25, 31–33) regarding claims 8, 18, and 20. Patent Owner does not present separate arguments for these claims, instead referring to its arguments for claims 1 and 5. PO Resp. 55. Based on this evidence, Petitioner has persuaded us that every limitation of claim 8 is

taught in one or more of Smith, Marino, Obenchain, Prass, and Simonson. Petitioner also has persuaded us that every limitation of claims 18 and 20 is taught in one or more of Smith, Marino, Obenchain, Prass, Isley, and Epoch 2000. 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.

*f. 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). While 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. 9–32. 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.

*(1) 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. 12–13. Patent Owner, however, does not establish adequately what XLIF is and whether it is encompassed by the claims of the '782 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 12, and quoting an article that describes features of XLIF used in conjunction with another Patent Owner product (EMG IOM, or NeuroVision®), *id.* at 13. 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 '782 patent and concluded that "XLIF procedure and systems" embody those claims. PO Resp. 13 (citing Ex. 2020 ¶¶ 22–23, 27, Attachment B). Dr. Phillips, in turn, includes detailed claim charts and citations to literature that purportedly describes an "XLIF System." *See* Ex. 2020, Attachment B. 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 B, p. 129. 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 '782 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 B, p. 129–30 (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 features. 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 ’782 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.1 above, however, a trans-psoas approach (or an extreme lateral approach, for that matter) is not a requirement of the claims, other than the capability of the devices to traverse the psoas muscle. 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.

*(2) 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 '782 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 (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.* 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. 10. 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 11. Patent Owner also cites to what it characterizes as experimental attempts to lateral approaches that failed to gain widespread adoption. *Id.* 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.* at 11–12.

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 4–5.

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 '782 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.C.1.f(1) 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.

*(3) 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. 13–15. 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. 15 (citing Ex. 2025 ¶¶ 15, 21).

As Petitioner points out (Reply 5), 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. 16–17 (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. 17–20. 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. 21–25. 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.

*(4) 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. According to Patent Owner, its commercial success has been "a direct result of its XLIF procedure and systems and the technology claimed by the '782 patent." *Id.* at 27. In support, Patent Owner relies on reports of market research from financial analysts crediting its success, at least in part, to XLIF. *Id.* at 27–29; 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 4, 6–8. "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.C.1.f(1) above, however, Patent Owner has not shown a correspondence between XLIF (or, for that matter, NueroVision, 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 '782 patent." PO Resp. 29–30. 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 7), 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 '782 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. 26–27. 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.

[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.

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 '782 patent claims.

*(5) Copying*

Patent Owner contends that Petitioner and other competitors copied its XLIF technology. PO Resp. 30–32. 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 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. 30–31. 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. 31 (citing Ex. 2059, at 4). We are not persuaded of copying by Petitioner. Even assuming that XLIF practices the claims of the '782 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. 31 (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.

*g. Conclusion of Obviousness*

As explained above, the prior art teaches each limitation of claims 1, 7–9, 13–18, and 20. 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 and 7 would have been obvious over Smith, Marino, and Obenchain; claim 5 would have been obvious over Smith, Marino, Obenchain, and Prass; claim 8 would have been obvious over Smith, Marino, Obenchain, and Simonson; claims 9 and 13–17 would have been obvious over Smith, Marino, Obenchain, Prass, and Isley; and claims 18 and 20 would have been obvious over Smith, Marino, Obenchain, Prass, Isley, and Epoch 2000.

*2. Obviousness Combinations Including Foley, Kelleher, Obenchain, and Prass*

Petitioner raises several challenges to claims 1, 5, 7–9, 13–18, and 20 based in whole or in part on the combination of Foley, Kelleher, Obenchain, and Prass. Petitioner supports its contentions with the testimony of Dr. Schwartz (Ex. 1014).

*a. Overview of Foley, Kelleher, Obenchain, and Prass*

Obenchain and Prass are discussed above. Smith is a continuation-in-part of Foley. Ex. 1001, [63]. In general, Petitioner's citations to Smith (referenced above) are to material that overlaps with the disclosure of Foley. Thus, for purposes of this Decision, Foley's disclosure is substantially the same as Smith's.

Kelleher describes a nerve detection system for sensing the presence of a nerve during surgery. Ex. 1010, 1:9–10, 2:24–29. The system includes one or more probes with electrodes for stimulating the nerve and electrodes positioned on a patient's body for detecting a corresponding EMG response. *Id.* at 4:1–9, 10:7–11. For example, the probes can include an electrified cannula paired with a second probe within the cannula functioning as a "confirmation electrode." *Id.* at 8:3–9. In this case, the cannula acts as a probe as it is advanced into the patient. *Id.* at 8:9–12. The nerve detection system also includes a pulse generator that supplies a train of pulses to the stimulation electrodes. *Id.* at 23:12–20, Fig. 7. The system further receives inputs from the EMG electrodes that detect the EMG responses from the patient. *Id.* at 23:30–31. The EMG response data from the patient is

displayed, for example, on a display using color LEDs. *Id.* at 15:12–30, Figs. 8a, 8b.

*b. Obviousness of Claims 1, 5, and 7 over Foley, Kelleher, Obenchain, and Prass*

Petitioner contends that claim 1 would have been obvious over Foley, Kelleher, Obenchain, and Prass. Specifically, Petitioner argues that Foley teaches a sequential dilation access system with a plurality of cannulas and a working corridor instrument, that Kelleher and Prass each teach providing stimulation electrodes in fixed positions on cannulas for nerve monitoring when performing surgery in areas containing sensitive nerves, and that Obenchain teaches spinal surgery using a trans-psoas approach. Pet. 40–43, 48–49. Petitioner further notes that the teachings of each of these references are in the context of minimally invasive spinal surgery using cannulated instruments. Pet. 41, 43. As Petitioner argues (Pet. 41), Kelleher explains the importance of using nerve monitoring technology in surgery to avoid nerve damage. Ex. 1010, 1:32–2:2 ("It is especially important that such a system alerts an operator that a nerve is being approached as the surgical tool is advanced into the patient's body, and prior to contact with the nerve, such that a safety distance margin between the surgical tool and the nerve can be maintained."), 8:9–12 ("For example, as the operating (electrified) cannula is advanced into the patient, this operating cannula itself functions as a nerve detection probe. As such, the operating cannula can be advanced to the operating site without causing any nerve damage."). According to Petitioner, in light of Kelleher's teaching of the importance of nerve monitoring, a skilled artisan, for safety, would have had reason to combine

the nerve monitoring of Kelleher and Prass with Foley's cannulas when using a trans-psoas approach, as recited in Obenchain. Pet. 40–41. Based on this evidence, Petitioner has persuaded us that every limitation of claim 1 is taught in one or more of Foley, Kelleher, Obenchain, and Prass.

Regarding claim 5, as it did for the combination of Smith, Marino, and Obenchain, Petitioner cites to Prass for a description of the recited reference mark. Pet. 49–50. Based on this evidence, Petitioner has persuaded us that every limitation of claim 5 is taught in one or more of Foley, Kelleher, Obenchain, and Prass.

Patent Owner incorporates its arguments against the combination of Smith, Marino, and Obenchain in distinguishing the combination of Foley, Kelleher, Obenchain, and Prass from claims 1 and 5. PO Resp. 56. Similar to its arguments regarding Smith and Marino, Patent Owner argues that Foley and Kelleher are very different. Specifically, Patent Owner argues that Kelleher teaches an electrode positioned on the outermost cannula that serves as a working cannula rather than on a sequential dilating cannula over which a working cannula slides. *Id.* at 56–57. According to Patent Owner, Kelleher does not teach instrumentation designed to sequentially open up and go through nerve-rich musculature. *Id.* at 57. As to Foley, Patent Owner argues that it does not disclose nerve monitoring or use in a trans-psoas approach. *Id.* at 56. Patent Owner's arguments are unpersuasive, as they merely attack Foley and Kelleher individually, without meaningfully addressing the combination proposed by Petitioner. *See In re Keller*, 642 F.2d at 426.

Patent Owner further argues that Prass, which describes a bi-polar probe, is "markedly different" from the structure of the devices claimed in

the ’782 patent. PO Resp. 58. According to Patent Owner, Petitioner has not provided a sufficient reason to change Kelleher’s nerve monitoring per the teachings of Prass. *Id.* We disagree. Petitioner introduces evidence that Prass describes an angled electrode that rotates with a cannula and that such rotation assists a surgeon in determining the direction of a nerve relative to the cannula. Pet. 42–43 (citing Ex. 1004, 7:31–34, 7:43–45). According to Petitioner:

> One of ordinary skill in the art would have had reason to combine the directionality aspects of Prass with the electrode placement on a cannula of Kelleher (and hence Foley) because Kelleher states that the purpose of nerve detection in spine surgery is to redirect the path of the instrument to avoid the nerve.

Pet. 46 (citing Ex. 1010, 1:29–2:2). Thus, Petitioner has introduced persuasive evidence sufficient to show that Foley’s cannulas would have benefitted in a predictable way from the teachings of Kelleher and Prass.

Further, we have considered the argument and evidence Petitioner presents in the Petition (at 50) regarding claim 7. Patent Owner does not present separate arguments for this claim, instead referring to its argument for claim 1. PO Resp. 58. Based on this evidence, Petitioner has persuaded us that every limitation of claim 7 is taught in one or more of Foley, Kelleher, Obenchain, and Prass. For the reasons given above, and in the Petition, we determine that Petitioner has introduced persuasive evidence sufficient to show that combining the features of these references would have been predictable.

*c. Claim 8*

We have considered the argument and evidence Petitioner presents in the Petition (at 50) regarding claim 8. Patent Owner does not present separate arguments for this claim, instead referring to its arguments for claims 1 and 5. PO Resp. 58. Based on this evidence, Petitioner has persuaded us that every limitation of claim 8 is taught in one or more of Foley, Kelleher, Obenchain, Prass, and Simonson. For the reasons given above, and in the Petition, we determine that Petitioner has introduced persuasive evidence sufficient to show that combining the features of these references would have been predictable.

*d. Obviousness of Claims 9, 13–18, and 20 over Foley, Kelleher, Obenchain, Prass, and Isley*

For the reasons given for claims 1 and 5, we are persuaded that Foley, Kelleher, Obenchain, and Prass teach the recited dilating cannula, stimulation electrode, trans-psoas approach, and reference mark of claim 9. For the reasons given in Section II.C.1.d, above, we are persuaded that Isley teaches the stimulation clip recited in claim 9.

We also are persuaded that Prass teaches a stimulation electrode at the distal end of a probe exposed only along a radial portion of the distal end. Petitioner (Pet. 46) points to Figure 6 of Prass, reproduced below:

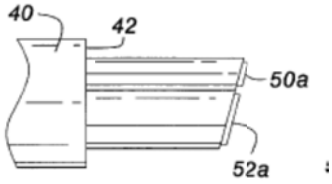

FIG.6

Figure 6 illustrates a close-up side view of a distal tip of a probe. Ex. 1004, 5, 57–59. In this example, stimulation electrode (cathode) 50a is exposed at a fifteen degree angle from normal with respect to the longitudinal axis of the probe, *id.* at 7:47–53, and, thus, is exposed around only a portion of the circumference of the insertion end. The rest of the electrode is encased in plastic wire insulation. *Id.* at 6:53–55. Petitioner argues that Prass's angled electrode provides directionality to the electrical stimulus and that it would have been obvious to incorporate this directionality into Kelleher's technique. Pet. 46.

Petitioner further contends that Kelleher describes an embodiment in which only the distal end of a cannula passes current and argues that this implies the use of insulation on the remainder of the cannula. Pet. 44. Petitioner also points to Isley as describing the use of insulated stimulation instruments to detect nerves. *Id.* at 45.

Based on this evidence, Petitioner has persuaded us that every limitation of claim 9 is taught in one or more of Foley, Kelleher, Obenchain, Prass, and Isley. As explained above for claims 1 and 5, Petitioner has introduced persuasive evidence that a skilled artisan would have combined the features of Foley, Kelleher, Obenchain, and Prass. Petitioner also has introduced persuasive evidence that a skilled artisan would have incorporated further the additional features of Isley. *See* Pet. 44–47; *see also* Section II.C.1.d above (discussion the parties' similar arguments and evidence for the combination of Smith, Marino, Obenchain, Prass, and Isley).

Further, we have considered the argument and evidence Petitioner presents in the Petition (at 53–55) regarding claims 13–18 and 20. Patent

Owner does not present separate arguments for these claims, instead referring to its arguments for claim 9. PO Resp. 58. Based on this evidence, Petitioner has persuaded us that every limitation of claims 13–18 and 20 is taught in one or more of Foley, Kelleher, Obenchain, Prass, and Isley. For the reasons given above, and in the Petition, we determine that Petitioner has introduced persuasive evidence sufficient to show that combining the features of these references would have been predictable.

*e. Objective Indicia Do Not Evidence Non-Obviousness*

Patent Owner's objective evidence of non-obviousness is unpersuasive for the reasons given in Section II.C.1.f above.

*f. Conclusion of Obviousness*

As explained above, the prior art teaches each limitation of claims 1, 7–9, 13–18, and 20. 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, 5, and 7 would have been obvious over Foley, Kelleher, Obenchain, and Prass; claim 8 would have been obvious over Foley, Kelleher, Obenchain, Prass, and Simonson; and claims 9, 13–18, and 20 would have been obvious over Foley, Kelleher, Obenchain, Prass, and Isley.

## III. CONCLUSION

Petitioner has demonstrated by a preponderance of the evidence that claims 1, 5, 7–9, 13–18, and 20 are unpatentable based on the following grounds of unpatentability:

(1) Claims 1 and 7 under 35 U.S.C. § 103(a) as obvious over Smith, Marino, and Obenchain;

(2) Claim 5 under 35 U.S.C. § 103(a) as obvious over Smith, Marino, Obenchain, and Prass;

(3) Claim 8 under 35 U.S.C. § 103(a) as obvious over Smith, Marino, Obenchain, and Simonson;

(4) Claims 9 and 13–17 under 35 U.S.C. § 103(a) as obvious over Smith, Marino, Obenchain, Prass, and Isley;

(5) Claims 18 and 20 under 35 U.S.C. § 103(a) as obvious over Smith, Marino, Obenchain, Prass, Isley, and Epoch 2000;

(6) Claims 1, 5, and 7 under 35 U.S.C. § 103(a) as obvious over Foley, Kelleher, Obenchain, and Prass;

(7) Claim 8 under 35 U.S.C. § 103(a) as obvious over Foley, Kelleher, Obenchain, Prass, and Simonson; and

(8) Claims 9, 13–18, and 20 under 35 U.S.C. § 103(a) as obvious over Foley, Kelleher, Obenchain, Prass, and Isley.

## IV. ORDER

For the reasons given, it is

ORDERED that, based on a preponderance of the evidence, claims 1, 5, 7–9, 13–18, and 20 of U.S. Patent No. 8,000,782 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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