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Paper 10
Entered: April 8, 2014

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 IPR2014-00081
Patent 8,005,535

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

McKONE, *Administrative Patent Judge*.

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

# 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 (Ex. 1013, "the '535 patent"). *See* 35 U.S.C. § 311. NuVasive, Inc. ("Patent Owner") filed a Preliminary Response (Paper 9, "Prelim. Resp.").

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides as follows:

> THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the Petition and the Preliminary Response, we conclude that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to each of the challenged claims. Accordingly, we institute an *inter partes* review of claims 1-12 of the '535 patent.

## *B. Related Cases*

Petitioner has petitioned for an additional *inter partes* review of claims 1-12 of the '535 patent on other grounds, IPR2014-00087 (which is being entered concurrently with this decision). Pet. 1; Paper 8 at 2. Patent Owner has asserted the '535 patent against Petitioner in *Warsaw Orthopedic*

*Inc. v. NuVasive Inc.*, Case No. 3:12-cv-02738-CAB-MDD (S.D. Cal.).

Pet. 1; Paper 8 at 2.

*C. References Relied Upon*

Petitioner relies upon the following prior art references:

| | | | |
|---|---|---|---|
| Ex. 1001 | Obenchain | US 5,195,541 | Mar. 23, 1993 |
| Ex. 1002 | Drongelen | US 6,224,549 B1 | May 1, 2001 |
| Ex. 1003 | Mathews | US 5,171,279 | Dec. 15, 1992 |
| Ex. 1004 | Foley | US 5,902,231 | May 11, 1999 |
| Ex. 1005 | Marino | WO 00/38574 A1 | July 6, 2000 |
| Ex. 1006 | Kelleher | WO 01/37728 A1 | May 31, 2001 |
| Ex. 1007 | 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. 1008 | Rose | Robert D. Rose et al., *Persistently Electrified Pedicle Stimulation Instruments in Spinal Instrumentation, Technique and Protocol Development*, vol. 22, no. 3 SPINE 334-343 (Feb. 1, 1997) | |
| Ex. 1009 | NIM Guide | MEDTRONIC XOMED SURGICAL PRODUCTS, INC., NIM-RESPONSE, NERVE INTEGRITY MONITOR, INTRAOPERATIVE EMG MONITOR USER'S GUIDE (2000) | |
| Ex. 1010 | 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*

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 3-5):

| References | Basis | Claims challenged |
|---|---|---|
| Foley, Marino, Obenchain, and NIM Guide | § 103(a) | 1-12 |
| Foley, Marino, Obenchain, NIM Guide, and Rose | § 103(a) | 1-12 |
| Foley, Marino, Obenchain, NIM Guide, Rose, and Drongelen | § 103(a) | 1-12 |
| Foley, Marino, Obenchain, NIM Guide, Rose, Drongelen, and Mathews | § 103(a) | 4 |
| Foley, Marino, Obenchain, NIM Guide, Rose, Drongelen, and Moed | § 103(a) | 6 |
| Kelleher, Foley, and Obenchain | § 103(a) | 1-11 |
| Kelleher, Foley, Obenchain, and Isley | § 103(a) | 12 |
| Kelleher, Foley, Obenchain, and NIM Guide | § 103(a) | 1-12 |
| Kelleher, Foley, Obenchain, NIM Guide, and Moed | § 103(a) | 6 |
| Kelleher, Foley, Obenchain, NIM Guide, and Mathews | § 103(a) | 4 |

For the reasons described below, we institute an *inter partes* review of all challenged claims (1-12).

*E. The '535 Patent*

The '535 patent generally relates to techniques employing medical devices for spinal surgery. Ex. 1013, Abstract. Two aspects of the techniques described in the '535 patent include: (1) employing sequentially dilating cannulas (*e.g.*, Ex. 1013, 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 col. 10, ll. 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 col. 11, ll. 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 col. 11, ll. 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; col. 10, ll. 20-36. Upon detecting a nerve, the surgeon has the option of repositioning the K-wire or cannula to avoid the nerve. *Id.* at col. 11, ll. 35-38.

The cannulas bluntly dissect the tissue between the patient's skin and the surgical target site. *Id.* at col. 11, ll. 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.* at col. 11, ll. 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 col. 19, l. 60-col. 20, l. 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 col. 20, ll. 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 col. 20, ll. 12-23.

The surgeon inserts additional cannulas of increasing diameter sequentially over the first cannula until a desired working diameter is achieved. *Id.* at col. 20, ll. 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 col. 20, ll. 40-47. The surgeon can perform the nerve proximity testing as each of these devices is inserted into the patient. *Id.* at col. 11, ll. 9-18; col. 20, ll. 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 col. 22, l. 61-col. 23, l. 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*

As a step in our analysis for determining whether to institute a trial, we determine the meaning of the claims. The Board interprets claims using the broadest reasonable construction. *See* 37 C.F.R. § 100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). 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 path"*

Petitioner proposes construing "trans-psoas path" to mean "a path in which the instrument passes through the psoas muscle." Pet. 7 (citing Ex. 1013, col. 11, ll. 14-42). The portion of the specification cited by Petitioner describes establishing an operative corridor in a postero-lateral, trans-posas fashion without specifying a particular portion of the psoas muscle to traverse. Ex. 1013, col. 11, ll. 38-42. Patent Owner does not propose an explicit construction of "trans-psoas approach" in the Preliminary Response. Patent Owner, however, contends that "Obenchain's trans-psoas approach would have traversed the 'safer zone' of the psoas muscle (the anterior one-third, which contains few if any nerve roots), not a middle or posterior portion of the psoas muscle as depicted in the '535 patent," implying that the '535 patent limits "trans-psoas approach" to an approach through the middle or posterior portion of the psoas muscle. Prelim. Resp. 15-16. Patent Owner points to insufficient evidence

supporting this reading. Accordingly, for purposes of this decision, we adopt Petitioner's proposed construction, which is consistent with the description in the specification.

*2. "initial dilator cannula"*

Neither Petitioner nor Patent Owner provides an explicit construction for "initial dilator cannula," as recited in claim 1. Nevertheless, in arguing that Marino does not teach this limitation, Patent Owner contends 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)." Prelim. Resp. 22.

The '535 patent describes an "initial dilating cannula" as a tube that is advanced towards a target site with a K-wire disposed in its inner lumen. Ex. 1013, col. 19, ll. 64-67. Although the '535 patent describes an initial dilator cannula as inserted along a path in which other sequential dilator cannulas and a working corridor instrument are advanced subsequently (Ex. 1013, col. 20, ll. 31-35), Patent Owner does not explain persuasively why an initial dilator cannula is limited to this embodiment. We note that other elements of claim 1 specify the relationship among the initial dilator cannula, an elongate stimulation instrument, sequential dilator cannulas, and a working corridor instrument. Thus, any requirements of those elements should not be imported into the construction of the term "initial dilator cannula."

*3. Other terms*

All other terms in claims 1-12 are given their ordinary and customary meanings as would be understood by one with ordinary skill in the art and need not be construed expressly at this time.

*B. Effective Filing Date of the '535 Patent*

The '535 patent claims the benefit of U.S. Provisional Application No. 60/325,424 (Ex. 1014, "the '424 provisional"), filed September 25, 2001. Ex. 1013, col. 1, ll. 14-17. Petitioner contends that the '535 patent is not entitled to the benefit of the '424 provisional's filing date. Pet. 14.

When a petition identifies specific features and claims allegedly lacking written description and enablement support in earlier-filed applications, we consider whether the patent owner makes a sufficient showing of entitlement to an earlier filing date, in a manner commensurate in scope with the specific contentions made by the petitioner. *See Polaris Wireless, Inc. v. TruePosition, Inc.*, Case IPR2013-00323, Paper 9, at 29 (PTAB 2013).

Petitioner argues that the '424 provisional does not contain written description support for "establishing a trans-psoas operative corridor to an intervertebral disc of the spine using [a] working corridor instrument" or "delivering a spinal fusion implant through the trans-psoas operative corridor toward the spine," as recited in claim 1 of the '535 patent. Pet. 14. Specifically, Petitioner argues that the '424 provisional "does not make any mention of delivering a spinal fusion implant through an operative corridor formed by a working corridor instrument." *Id.*

Patent Owner responds that the ’424 provisional discloses a method of “extreme lateral lumbar *interbody fusion*,” which Patent Owner also characterizes as “eXtreme Lateral Interbody Fusion,” “XLIF,” or an “XLIF approach.” Prelim. Resp. 11 n. 1 (citing Ex. 1014 at 34, 41). Patent Owner cites to a one page summary of “XLIF” by Neill M. Wright, M.D., as demonstrating that the XLIF method necessarily includes “a large interbody graft” such as “an interbody spacer.” Prelim. Resp. 11 n. 1 (citing Ex. 2005 at 1). Patent Owner, however, does not explain persuasively how the Wright paper relates to the ’424 provisional or describes XLIF as necessarily including such features. On this record, Patent Owner has not shown that the ’424 provisional describes delivering a spinal fusion implant through a trans-psoas operative corridor toward the spine or establishing such an operative corridor using a working corridor instrument. Accordingly, we are not persuaded that the ’535 patent is entitled to the benefit of the ’424 provisional’s filing date.

*C. Asserted Grounds of Unpatentability*

*1. Obviousness Combinations Including Foley, Marino, Obenchain, and NIM Guide*

Petitioner raises several challenges to claims 1-12 of the ’535 patent based in whole or in part on the combination of Foley, Marino, Obenchain, and NIM Guide.

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. 1004, Abstract; col. 23, ll. 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 sequentially the tissue. *Id.* at col. 12, ll. 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 col. 12, ll. 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 col. 11, ll. 63-67, e.g., "posterolateral" and "anterior" approaches, *id.* at col. 12, ll. 6-8.

Marino describes various nerve surveillance systems for identifying and avoiding nerves during spinal surgery. Ex. 1005, p. 7, ll. 13-17. Figure 18, reproduced below, illustrates one example:

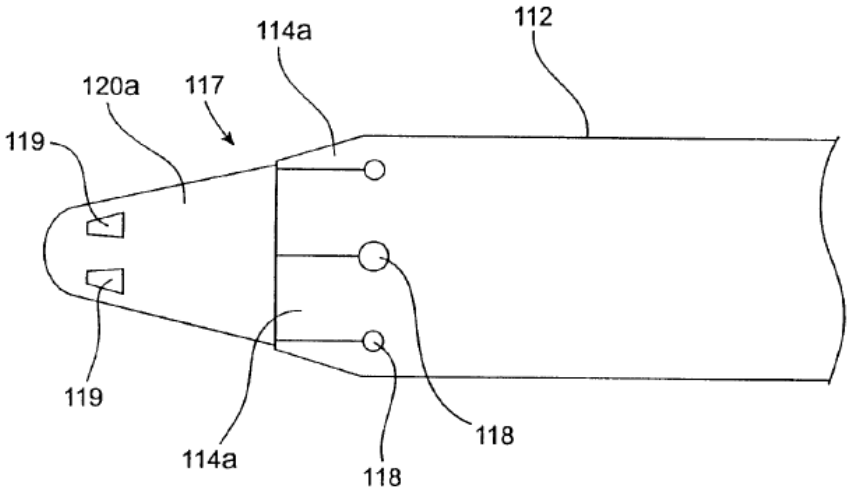


FIG. 18

Figure 18 shows an obturator 120a received within a cannula shaft 112 and protruding through an opening of the cannula shaft. Ex. 1005, p. 14, ll. 1-4. The obturator includes electrodes 119 radially spaced around the distal tip of the obturator. *Id.* at p. 14, ll. 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 p. 9, ll. 1-5; p. 14, ll. 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 p. 7, ll. 18-31; *see also id.* at p. 14, ll. 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.* at p. 9, ll. 5-7.

In another embodiment, Figure 28 shows cannula 300 with obturator 210 disposed therein and protruding through an opening. Ex. 1005, p. 16, ll. 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 p. 16, l. 29-p. 17, l. 12.

Obenchain describes a cannula (elongated cylinder) for spinal surgery (laparoscopic lumbar discectomy). Ex. 1001, Abstract; col. 1, ll. 32-33; col. 2, ll. 11-22. Several surgical components can be secured in the cannula, for example, an endoscope, a laser fiber, and irrigation conduits. *Id.* at col. 2, l. 39-col. 3, l. 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-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 col. 5, ll. 5-14.

As its title suggests, NIM Guide is a user's guide for an intraoperative EMG monitor. The EMG monitor described in NIM Guide outputs to a probe a stimulus signal, in the form of a monophasic square pulse, which a user can set to be between 0.0 and 3.0 mA. Ex. 1009 at 4, 12, 21, 37. The monitor receives EMG inputs from electrodes placed on the patient's body and displays EMG response information elicited by the stimulus signal. *Id.* at 6, 18. NIM Guide illustrates a touch screen that displays EMG waveforms and receives user input. *Id.* at 2, 6, 12, 21. According to NIM Guide, a user can program the EMG monitor with an EMG activity event threshold, in μV. *Id.* at 7. EMG activity that exceeds this threshold is displayed on the screen. *Id.* at 10. The monitor also can generate an audible tone when the EMG response amplitude exceeds the threshold. *Id.* at 29.

*a. Obviousness of Claims 1-12 over Foley, Marino, Obenchain, and NIM Guide*

Petitioner contends that claims 1-12 would have been obvious over Foley, Marino, Obenchain, and NIM Guide. 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, each with stimulation electrodes at its distal end, 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) NIM Guide teaches a control unit for providing a monophasic square wave signal to a probe and displaying corresponding EMG response information compared to a threshold.

Pet. 20-23, 25-34. Petitioner further notes that the teaching of each of these references is in the context of minimally invasive spine surgery using cannulated instruments. Pet. 23. According to Petitioner, a skilled artisan would have had reason to combine Foley, Marino, Obenchain, and NIM Guide because the nerve detection techniques of Marino and NIM Guide specifically are intended to make the surgical procedures of Foley and Obenchain safer. *Id.* Petitioner further argues that Marino teaches that the elongate stimulation instrument received within the cannula reduces the risk of nerve damage during spine surgery, and that such teaching would have been applicable to Foley's procedures. *Id.* at 23-24. On this record, we are persuaded that there is a reasonable likelihood that Petitioner will prevail with respect to claims 1-12.

Patent Owner makes several arguments, each based on features recited in claim 1. Patent Owner contends that the prior art teaches away from Petitioner's proposed combination. Prelim. Resp. 15. In particular, Patent Owner argues that nothing in Foley indicates that its cannulas would have traversed near nerve root structures or would have been adapted to have nerve monitoring capacity. *Id*. Instead, Patent Owner argues, Foley teaches a posterior approach that would not pass by important nerve root structures. Prelim. Resp. 19-20. "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." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) *accord In re Mouttet*, 686 F.3d 1322, 1333-34 (Fed. Cir. 2012). Patent Owner does not explain persuasively why Foley's teaching would have discouraged Petitioner's proposed combination, particularly when viewed in light of Marino's teaching, discussed above, of the desirability of nerve monitoring during spinal surgery, as well as Obenchain's teaching, also discussed above, that a psoas-traversing pathway was suitable in certain situations.

Patent Owner further contends that Obenchain does not teach an operative path through areas that would benefit from nerve monitoring. Prelim. Resp. 15-16, 21. Instead, Patent Owner argues, Obenchain teaches a trans-psoas approach that would traverse a "safer zone" of the psoas muscle. *Id.* In support of this argument, Patent Owner cites a continuation-in-part of Obenchain (Ex. 2006) as warning surgeons to avoid the psoas muscle. Prelim. Resp. 16. The continuation-in-part, however, also includes an embodiment in which "surgery may traverse through the psoas muscle."

Ex. 2006, col. 6, ll. 22-23. In any case, Patent Owner does not explain persuasively why its citation to the continuation-in-part should override the teaching of Obenchain, which describes a trans-psoas path as a path for spine surgery. Ex. 1001, col. 5, ll. 5-6. Patent Owner also cites to Figure 3 of Takatomo Moro et al., *An Anatomic Study of the Lumbar Plexus with Respect to Retroperitoneal Endoscopic Surgery*, 28 SPINE, at 423-28 (2002) (Ex. 2004), as showing that Obenchain's trans-psoas approach would have traversed a safer region of the psoas muscle. Prelim. Resp. 17. Patent Owner does not explain with sufficient detail how Obenchain teaches a "safer zone" than what allegedly is taught in the '535 patent, or why a distinction among various zones of the psoas is relevant to a claim that refers to a "trans-psoas" path without specifying a zone.

Patent Owner further argues that Obenchain teaches away from Foley's larger dilators and working cannula. Prelim. Resp. 14, 17-18. Patent Owner contends that Obenchain describes an outer cannula diameter of less than 10 mm as "important," Prelim. Resp. 17 (quoting Ex. 1001, col. 2, ll. 29-38), and that Foley's cannulas have diameters larger than 10 mm, Prelim. Resp. 18 (citing Ex. 1004, col. 12, ll. 40-46). Patent Owner also contends that Obenchain describes a procedure, using a single device, performed under gas insufflation, which Patent Owner argues would have been hindered by a larger working corridor. Prelim. Resp. 18-19. According to Obenchain:

> The cross-sectional outer diameter dimensions are also important, and must be large enough to accommodate the interior conduits, tubes, pipes, and other components, and yet be small enough to allow insertion into a relatively small incision, obviously preferable to minimize trauma. It has been

> found that a sleeve having a maximum exterior cross-sectional dimension of about 10 mm, and preferably between about 5 or about 9 mm is quite suitable for lumbar discectomy and many other procedures.

Ex. 1001, col. 2, ll. 29-38. Although Obenchain describes a preferred range of cannula diameters suitable for the procedures described therein, and notes that the diameter should be kept small to minimize trauma, we are not persuaded that it discourages the use of larger diameter cannulas for other procedures.

Moreover, "[i]t is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements." Mouttet, 686 F.3d at 1332. Although Obenchain's teachings are made in the context of a device smaller than that described in Foley, Petitioner merely cites Obenchain for surgery using instruments similar to Foley's in a different approach to the spine (lateral approach through the psoas muscle, avoiding the bowel, Ex. 1001, col. 5, ll. 10-14, instead of medial posterior, Ex. 1004, col. 12, ll. 5-6). While the diameter of Obenchain's preferred device is important for the particular procedures Obenchain describes, Patent Owner does not explain persuasively how Obenchain ties the importance of a small diameter more generally to procedures using a lateral, trans-psoas approach to the spine. Patent Owner also argues that Foley's medial posterior approach already avoids the bowels and, thus, a skilled artisan would not have had reason to use Obenchain's lateral trans-psoas approach to avoid the bowels. Prelim. Resp. 19-20. Patent Owner, however, does not explain persuasively how Foley discourages other approaches. Indeed, as Petitioner points out, Foley describes its cannulas as usable from "any approach," including

"posterolateral and anterior." Pet. 25; Ex. 1004, col. 12, ll. 6-8. Accordingly, we are not persuaded that Obenchain teaches away from Foley's system of dilating cannulas.

Patent Owner further contends that Marino does not teach an "initial dilator cannula," as recited in claim 1, because the cannula is the outermost instrument in Marino's system. Prelim. Resp. 14, 22-23. According to Patent Owner, "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 22. Patent Owner argues that Marino's cannula does not define a path for subsequent cannulas. *Id.* at 23-24. Petitioner, however, shows adequately that Foley teaches multiple cannulas and a working cannula inserted sequentially along the same path. Pet. 29-30. Regarding Foley, Patent Owner argues that Foley's initial dilator (Figure 10b, item 151) cannot have an elongate stimulation instrument disposed therein because it must remain vacant to receive the proximal end of a guide wire (Figure 10a, item 150). Prelim. Resp. 24-25. Petitioner shows adequately, however, that Marino teaches an initial dilator with an elongate stimulation instrument disposed therein. Pet. 26-27. In each of these instances, Patent Owner improperly 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 contends that secondary considerations, such as long-felt but unsolved need, praise by competitors, copying, and commercial

success, evidence non-obviousness. Prelim. Resp. 14, 25. "The obviousness assessment depends on what the prior art teaches and on what non-prior-art evidence of 'secondary considerations' (or objective indicia) may indicate about whether the invention would have been obvious at the relevant time." *Institut Pasteur & Univsite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1344 (Fed. Cir. 2013). "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); *accord Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Institut Pasteur*, 738 F.3d at 1346 ("To be afforded substantial weight, the objective indicia of non-obviousness must be tied to the novel elements of the claim at issue.").

To show commercial success, Patent Owner points to a presentation, purportedly by Petitioner, with a chart showing increasing sales for Patent Owner. Prelim. Resp. 26-27 (citing Ex. 2002 at 3). Patent Owner argues that this shows Petitioner's awareness of the commercial success of Patent Owner's XLIF method. Prelim. Resp. 26. Patent Owner asserts that its XLIF method is protected by the '535 patent. *Id.* at 1. Patent Owner, however, does not explain adequately how Exhibit 2002 shows commercial success, how that success is attributable to the XLIF method, or how the XLIF method relates to the claims of the '535 patent. On this record, Patent Owner has not persuaded us that commercial success evidences nonobviousness.

To show praise by competitors, Patent Owner points to a different page of the same presentation of Exhibit 2002, arguing that Petitioner (a competitor) praised Patent Owner's system. Prelim. Resp. 27 (citing

Ex. 2002 at 8). According to Patent Owner, the presentation shows impressive results of a study of the XLIF method and presents the results as reasons to perform a DLIF method. *Id.* Patent Owner further argues that another presentation purportedly by Petitioner evidences other competitors' attempts to occupy a minimally invasive lateral, trans-psoas market, further implying that those competitors copied the invention of the '535 patent. Prelim. Resp. 27-28 (citing Ex. 2001 at 9). Patent Owner, however, does not explain adequately how the DLIF method, the XLIF method, the purported praise of the XLIF method, or the purported activities of the competitors relate to the claims of the '535 patent. On this record, Patent Owner has not persuaded us that copying or praise by competitors evidences nonobviousness.

Regarding long-felt but unsolved need, Patent Owner argues that the teachings relied upon by Petitioner, as described by Petitioner's declarant, Dr. Schwartz, are all very old and that, although all of these teachings were in place long before the '535 patent's priority date, no one put them all together before the '535 patent. Prelim. Resp. 28-30. Patent Owner's evidence that each of the components of Petitioner's combination significantly pre-dated the '535 patent is not sufficient to evidence nonobviousness. *See Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Absent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness.") (citing *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977)). Rather, "long-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem." *Tex. Instruments v. U.S. Int'l Trade Comm'n*, 988 F.2d

1165, 1178 (Fed. Cir. 1993); *accord Leo Pharm. Prods., Ltd v. Rea*, 726 F.3d 1346, 1359 (Fed. Cir. 2013) (passage of 22 years between recognition in the art of a need for a single formulation of both vitamin D and corticosteroids in the treatment of psoriasis and fulfillment of that need was evidence of nonobviousness). "Evidence is particularly probative of obviousness when it demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1082 (Fed. Cir. 2012)). Merely stating what was known in the prior art is not evidence of an articulated, identified problem, or of unsuccessful efforts to solve that problem. On this record, we are not persuaded that the evidence shows a long-felt but unsolved need.

In sum, Petitioner has shown a reasonable likelihood that it will prevail with respect to claim 1. Moreover, upon consideration of Petitioner's arguments and evidence (Pet. 23-24, 30-34), we determine that Petitioner has shown a reasonable likelihood that it will prevail on claims 2-12 as obvious over Foley, Marino, Obenchain, and NIM Guide.

*b. Obviousness of Claim 6 over Foley, Marino, Obenchain, NIM Guide, 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 claim 6 would have been obvious over Foley, Marino, Obenchain, NIM Guide, Rose, Drongelen, and Moed. Pet. 36-37.

Moed describes performing nerve monitoring during spine surgery involving installing iliosacral implants (such as iliosacral screws). Ex. 1010 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. 37. Petitioner also argues that Moed establishes that a guide wire, such as shown in Foley, could have been used as a stimulation instrument. *Id.*

Upon consideration of the Petitioner's evidence and argument, we determine that Petitioner has demonstrated a reasonable likelihood that claim 6 would have been obvious over Foley, Marino, Obenchain, NIM Guide, and Moed.

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

Petitioner raises several challenges to claims 1-12 of the '535 patent based in whole or in part on the combination of Kelleher, Foley, and Obenchain.

Obenchain and Foley are discussed above. Kelleher describes a system and method for sensing the presence of a nerve during spine surgery. Ex. 1006, p. 1; p. 2, ll. 24-29. The system includes one or more probes with stimulation electrodes for stimulating nerves and EMG electrodes positioned on a patient's body for detecting corresponding EMG responses. *Id.* at p. 4,

ll. 1-9; p. 10, ll. 7-11. In one example, the probes can include an electrified cannula paired with a second probe within the cannula functioning as a "confirmation electrode." *Id.* at p. 8, ll. 3-9. In this case, the cannula acts as a probe as it is advanced into the patient. *Id.* at p. 8, ll. 9-12. When the cannula is in place, the confirmation electrode can be used to ensure that a nerve has not slipped into the operating space within the cannula. *Id.* at p. 8, ll. 15-20.

Kelleher's nerve detection system also includes a pulse generator that supplies a train of pulses to the stimulation electrodes. *Id.* at p. 23, ll. 10-20; Fig. 7. The system further receives inputs from the EMG electrodes, positioned on the legs of the patient, that detect EMG responses from the patient elicited by the stimulation electrodes. *Id.* at p. 11, ll. 21-30; p. 23, ll. 30-31. The EMG response data from the patient is displayed, for example, on a display using color LEDs. *Id.* at p. 15, ll. 12-30; Figs. 8a, 8b. The system can generate pulses of progressively higher stimulation current (e.g., a staircase), receive an EMG response, and generate a particular alarm level corresponding to the stimulation current level that elicits the response. *Id.* at p. 17, ll. 23-34. The alarm level indicates the probe's proximity to the nerve that generated the EMG response. *Id.*

*a. Obviousness of Claims 1-11 over Kelleher, Foley, and Obenchain*

Petitioner contends that claim 1 would have been obvious over Kelleher, Foley, and Obenchain. 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) Kelleher teaches an initial dilating cannula with a probe disposed therein, both with stimulation electrodes at their distal ends, and a control unit for providing stimulus pulses to the stimulation electrodes, receiving EMG response information from EMG electrodes placed on a patient's leg muscles, and displaying corresponding EMG response information compared to a threshold; and

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

Pet. 37-39, 42-49. Petitioner further notes that the teaching of each of these references is in the context of minimally invasive spine surgery using cannulated instruments. Pet. 40. According to Petitioner, a skilled artisan would have had reason to combine Kelleher, Foley, and Obenchain to enhance patient safety by avoiding nerve damage. *Id.* at 39-40. Petitioner argues that Kelleher's devices are intended for the same spinal procedures discussed in Foley and that Foley describes a typical spinal surgery procedure that would have used Kelleher's nerve monitoring system. *Id.* at 40. On this record, we are persuaded that there is a reasonable likelihood that Petitioner will prevail with respect to claims 1-11.

In response, Patent Owner makes arguments, all directed to claim 1, similar to those advanced against the combination of Foley, Marino, Obenchain, and NIM Guide. In particular, Patent Owner argues that Obenchain teaches away from Foley's large diameter dilating cannulas and working cannula. Prelim. Resp. 32-33. Patent Owner also argues that the

trans-psoas approach described in Obenchain would have traversed a safer zone of the psoas muscle with few or no nerve roots. Prelim. Resp. 33. For the reasons given in Section II.C.1.a, above, these arguments are not persuasive.

Patent Owner further argues that Kelleher does not teach an initial dilator cannula because its cannula is "the outermost instrument of Kelleher's entire access system." Prelim. Resp. 34. According to Patent Owner, Kelleher does not teach a cannula that includes an elongate stimulation instrument disposed therein and defines a path for subsequent dilator cannulas. *Id.* at 34-35. Similar to its approach to Marino (addressed in Section II.C.1.a, above) Patent Owner's arguments are unpersuasive because they address Kelleher individually without considering the combination proposed by Petitioner, including the features taught by Foley. *See Keller*, 642 F.2d at 426.

Patent Owner also contends that the guide wire taught by Foley cannot be an elongate stimulation instrument because it must be forced with a mallet into the spine before an initial dilator slides over its proximal end. Prelim. Resp. 35-36. Petitioner argues that, per Kelleher's teaching, any spine surgery instrument, including Foley's guide wire, could be implemented as a stimulation instrument. Pet. 39-40. According to Petitioner, a skilled artisan would have combined Kelleher's nerve monitoring features with Foley's guide wire to enhance patient safety and would have positioned it in a cannula to achieve a nerve-free path for the cannula to the spine. *Id.* at 40. Petitioner's declarant, Dr. Schwartz, explains that inserting the guide wire prior to or concurrently with the cannula would have been a matter of surgeon preference. Ex. 1011 ¶ 125.

We conclude that a finding that these limitations are taught in Kelleher and Foley is supported by the evidence.

Finally, for the reasons given in Section II.C.1.a, above, we are not persuaded by Patent Owner's arguments (Prelim. Resp. 36-38) that secondary considerations evidence non-obviousness.

In sum, Petitioner has shown a reasonable likelihood that it will prevail with respect to claim 1. Additionally, upon consideration of Petitioner's arguments and evidence (Pet. 40-42, 46-49), we determine that Petitioner has shown a reasonable likelihood that it will prevail on claims 2-11 as obvious over Kelleher, Foley, and Obenchain.

*b. Obviousness of Claim 12 over Kelleher, Foley, Obenchain, and Isley*

Claim 12 ultimately depends from claims 1, through claims 10 and 8, and adds "wherein the stimulation current pulses of the signal delivered by the elongate stimulation instrument comprises rectangular monophasic current pulses output from the elongate stimulation instrument when the initial dilator cannula and the elongate stimulation instrument are inserted into the trans-psoas path toward the spine." Petitioner cites to Isley as teaching a stimulation current in the form of rectangular monophasic current pulses output from an elongate stimulation instrument. Pet. 41, 49-50 (citing Ex. 1007 at 110 ("To date, the pedicle screw stimulation technique has been universally performed using monopolar stimulation with monophasic, square-wave, constant current or constant voltage, pulses.")). Petitioner argues that Isley provides more detail as to the type of current that would be used in Kelleher, which Petitioner asserts describes a system performing the

same surgeries as Isley's system. Pet. 41-42. On this record, Petitioner has shown a reasonable likelihood that it will prevail with respect to claim 12 as obvious over Kelleher, Foley, Obenchain, and Isley.

*c. Obviousness of Claim 6 over Kelleher, Foley, Obenchain, NIM Guide, and Moed*

Petitioner argues that claim 6 would have been obvious over Kelleher, Foley, Obenchain, NIM Guide, and Moed. Pet. 51-52. For reasons similar to those given in Section II.C.1.b, above, we determine that Petitioner has demonstrated a reasonable likelihood that claim 6 would have been obvious over Kelleher, Foley, Obenchain, NIM Guide, and Moed.

*3. Remaining Grounds of Unpatentability*

Petitioner asserts additional grounds of unpatentability as listed in Section I.D., *supra*. These additional grounds are redundant in light of the determination that there is a reasonable likelihood that the challenged claims are unpatentable based on the grounds of unpatentability on which we institute an *inter partes* review.

Accordingly, we decline to institute *inter partes* review on the following grounds:

(1) Claims 1-12 under 35 U.S.C. § 103(a) for obviousness over Foley, Marino, Obenchain, NIM Guide, and Rose;

(2) Claims 1-12 under 35 U.S.C. § 103(a) for obviousness over Foley, Marino, Obenchain, NIM Guide, Rose, and Drongelen;

(3) Claim 4 under 35 U.S.C. § 103(a) for obviousness over Foley, Marino, Obenchain, NIM Guide, Rose, Drongelen, and Mathews;

(4) Claim 6 under 35 U.S.C. § 103(a) for obviousness over Foley, Marino, Obenchain, NIM Guide, Rose, Drongelen, and Moed;

(5) Claims 1-12 under 35 U.S.C. § 103(a) for obviousness over Kelleher, Foley, Obenchain, and NIM Guide; and

(6) Claim 4 under 35 U.S.C. § 103(a) for obviousness over Kelleher, Foley, Obenchain, NIM Guide, and Mathews.

## III. CONCLUSION

We institute an *inter partes* review of claims 1-12 based on the following grounds:

(1) Claims 1-12 under 35 U.S.C. § 103(a) for obviousness over Foley, Marino, Obenchain, and NIM Guide;

(2) Claim 6 under 35 U.S.C. § 103(a) for obviousness over Foley, Marino, Obenchain, NIM Guide, and Moed;

(3) Claims 1-11 under 35 U.S.C. § 103(a) for obviousness over Kelleher, Foley, and Obenchain;

(4) Claim 12 under 35 U.S.C. § 103(a) for obviousness over Kelleher, Foley, Obenchain, and Isley; and

(5) Claim 6 under 35 U.S.C. § 103(a) for obviousness over Kelleher, Foley, Obenchain, NIM Guide, and Moed.

The Board has not yet made a final determination of the patentability of any claim.

## IV. ORDER

For the reasons given, it is

ORDERED that *inter parties* review is instituted as to claims 1-12 on the grounds listed in the Conclusion, above. No other ground is authorized;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '535 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for 2 PM Eastern Time on April 30, 2014. The parties are directed to the Office Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765-66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should be prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

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