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Paper 11
Entered: April 8, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

NUVASIVE, INC.
Patent Owner

Case IPR2014-00034
Patent 8,000,782

Before DEBORAH KATZ, 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, 5, 7-9, 13-18, and 20 of U.S. Patent 8,000,782 (Ex. 1017, "the '782 patent"). *See* 35 U.S.C. § 311. NuVasive, Inc. ("Patent Owner") filed a Preliminary Response (Paper 10, "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 established 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, 5, 7-9, 13-18, and 20 of the '782 patent.

B. Related Cases

Petitioner has petitioned for an additional *inter partes* review of claims 1, 5, 7-9, 13-18, and 20 of the '782 patent on other grounds, IPR2014-00035 (which is being entered concurrently with this decision).

Pet. 1; Paper 7 at 2. 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. 1006	Shmulewitz	US 6,095,987	Aug. 1, 2000
Ex. 1007	Drongelen	US 6,224,549 B1	May 1, 2001
Ex. 1008	Mathews	US 5,171,279	Dec. 15, 1992
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	
Ex. 1013	NIM Guide	MEDTRONIC XOMED SURGICAL PRODUCTS, INC., NIM-RESPONSE,	

NERVE INTEGRITY MONITOR, INTRAOPERATIVE EMG MONITOR USER'S GUIDE (2000)

D. The Asserted Grounds

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 2-4):

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
Smith, Marino, Obenchain, Prass, Isley, and NIM Guide	§ 103(a)	17
Smith, Marino, Obenchain, Prass, Isley, NIM Guide, and Drongelen	§ 103(a)	18, 20
Smith, Marino, Obenchain, and Mathews	§ 103(a)	7
Smith, Marino, Obenchain, Prass, and Shmulewitz	§ 103(a)	5
Smith, Marino, Obenchain, Prass, Isley, Epoch 2000, and Shmulewitz	§ 103(a)	9, 13-18, 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

Foley, Kelleher, Obenchain, Prass, Isley, and Marino	§ 103(a)	9, 13-18, 20
Foley, Kelleher, Obenchain, Prass, Isley, Marino, and NIM Guide	§ 103(a)	18, 20
Foley, Kelleher, Obenchain, Prass, and Mathews	§ 103(a)	7
Foley, Kelleher, Obenchain, Prass, and Shmulewitz	§ 103(a)	5
Foley, Kelleher, Obenchain, Prass, Isley, Marino, NIM Guide, and Shmulewitz	§ 103(a)	9, 13-18, 20

For the reasons described below, we institute an *inter partes* review of all challenged claims (1, 5, 7-9, 13-18, and 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 col. 10, ll. 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 col. 11, ll. 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 col. 11, ll. 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; col. 10, ll. 16-29.

Upon detecting a nerve, the surgeon has the option of repositioning the cannula to avoid the nerve. *Id.* at col. 11, ll. 32-35.

The cannulas are designed to dissect bluntly the tissue between a patient's skin and the surgical target site. *Id.* at col. 11, ll. 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 col. 11, ll. 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 col. 19, ll. 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 col. 19, l. 67-col. 20, l. 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 col. 20, ll. 10-21. The cannula can have reference marks so that the surgeon knows which direction the electrode is facing. *Id.* at col. 20, ll. 18-24.

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. 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. Ex. 1017, col. 20, ll. 38-45. The surgeon performs the nerve proximity testing as each of these devices is inserted into the patient. *Id.* at col. 11, ll. 5-14; col. 20, ll. 46-50.

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

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. § 42.100(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 approach" / "when advanced in the trans-psoas path"

Petitioner argues that "when advanced in the trans-psoas path" and "trans-psoas approach" are phrases that recite an intended use of an apparatus, rather than structure, and therefore, should not be given patentable weight. Pet. 6.

We agree that these terms are statements of intended use. "For apparatus claims . . . generally patentability 'depends on the claimed structure, not on the use or purpose of that structure.'" *Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010) (quoting *Catalina Marketing Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002)); *accord In re Gardiner*, 171 F.2d 313, 315-16 (CCPA 1948) ("It is trite to state that the patentability of apparatus claims must be shown in the structure claimed and not merely upon a use, function, or result thereof."); *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.").

Claims 1 and 9 are both system claims. Claim 1 is directed to a "surgical *system* for neural monitoring while forming an operative corridor in a *trans-psoas approach* to a spine" (emphasis added), and includes a plurality of dilating cannulas "to form a trans-psoas corridor," the cannulas fitting one over another "when advanced in a trans-psoas path," and featuring a stimulation electrode on at least one of the cannulas proximate to the distal end of the cannula "when advanced in the trans-psoas path." Similarly, claim 9 is directed to a "*system* for forming a path to a spinal target site via a *trans-psoas approach*" (emphasis added), and includes a dilating cannula whose proximal end extends outside of a patient's skin "when said distal end is positioned adjacent to said spinal target site via a *trans-psoas approach* to said spinal target site" (emphasis added). In both claims 1 and 9, the recitations of "trans-psoas path" and "trans-psoas approach" describe how structural elements, such as cannulas and electrodes, are positioned or moved in a patient. However, these recitations do not describe the structure of the elements of the claimed system, beyond the ability to follow such a path or approach. As such, the recitations of "trans-psoas path" and "trans-psoas approach" are statements of intended use and are entitled to no patentable weight, beyond an ability to follow a "trans-psoas path" or "trans-psoas approach." *See Schreiber*, 128 F.3d at 1477.

2. "fixed"

Petitioner argues that the term "fixed" is not used in the specification of the '782 patent, except in the claims, and contends that it should be given little patentable weight. Pet. 6. If the term "fixed" is to be given weight, Petitioner proposes construing "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," as recited in claim 1, to mean "the electrode is on the cannula such that it rotates with the cannula." *Id.* (citing Ex. 1017, col. 11, ll. 5-14). The ordinary meaning of "fixed" is "[f]irmly in position; stationary." THE AMERICAN HERITAGE COLLEGE DICTIONARY 525 (4th ed. 2004) (Ex. 3001). Petitioner's proposed construction, which simply states that the electrode is on the cannula such that it rotates with the cannula, would read "fixed" out of claim 1. Petitioner does not explain adequately how the passage it cites from the specification justifies a departure from the ordinary meaning. Accordingly, for purposes of this decision, "fixed" means "stationary."

3. "only a radial portion of the distal end"

Petitioner argues that the specification of the '782 patent lacks support for "only a radial portion of the distal end," as recited in claims 9 and 14 and contends that this term should be given little weight. Pet. 7. Petitioner further argues that Patent Owner, in litigation, proposed construing "only a radial portion of the distal end" to mean "around only a portion of the circumference of the insertion end," and Petitioner states that it has applied that construction in its obviousness analysis here. Pet. 7. Patent Owner does

not provide an explicit construction for this term in the Preliminary Response.

Claim 9 recites a dilating cannula, with proximal and distal ends, that is insulated along its entire length, except for an exposed electrical contact at the proximal end (outside the patient, to which a stimulation clip attaches) and an exposed stimulation electrode at the distal end (inside the patient). Consistent with this claim language, the '782 patent explains:

> In an important aspect, each surgical access component 46-50 is insulated along its entire length, with the exception of the electrode(s) at their distal end (and, in the case of the dilating cannula 48 and working cannula 50, the electrical contacts at their proximal ends for engagement with the clamp 57).

Ex. 1017, col. 19, ll. 20-25. Claim 9 further recites "said stimulation electrode *being exposed along only a radial portion of said distal end*" (emphasis added).

The '782 patent describes an insulated cannula and shows a stimulation electrode as an exposed window in the insulation occurring near the distal tip of the cannula and at an angle relative to the longitudinal axis of the cannula. According to description in the '782 patent, "each electrode 70 is positioned at an angle relative to the longitudinal axis of the K-wire 46 and dilator 48 (and working cannula 50). In one embodiment, this angle may range from 5 to 85 degrees from the longitudinal axis of these surgical access components 46-50." Ex. 1017, col. 20, ll. 5-10. Figure 16 provides an illustration:

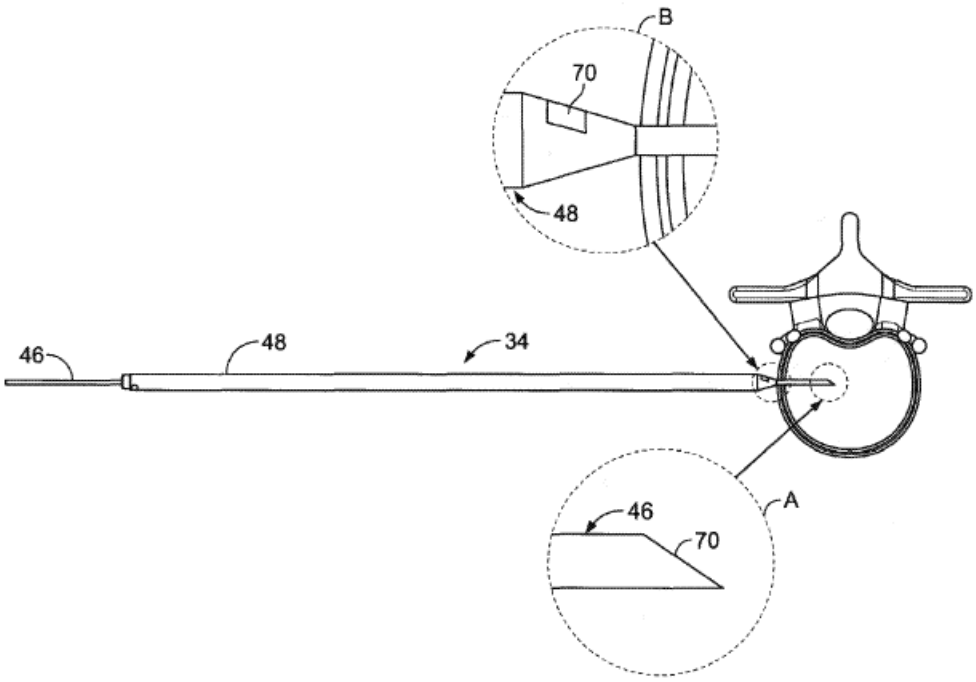

FIG. 16

Figure 16 shows a cannula 48 with a stimulation electrode 70, shown in inset B as an exposed patch on an angled portion of the circumference of cannula 48. The example shown in Figure 16, inset B, is consistent with the construction Petitioner alleges Patent Owner proposed in litigation. Accordingly, for purposes of this decision, we construe "only a radial portion of the distal end" to mean "around only a portion of the circumference of the insertion end."

4. Other terms

All other terms in claims 1, 5, 7-9, 13-18, and 20 are given their ordinary and customary meaning as would be understood by one with ordinary skill in the art and need not be construed expressly at this time.

B. 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.

Smith 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 view a working site in a patient with an endoscope during spinal surgery. Ex. 1001, Abstract; col. 6, ll. 43-47. Figures 10a-10i of Smith illustrate creating a working channel by inserting a series of tissue dilators (dilating cannulas) concentrically over each other to dilate sequentially the tissue. *Id.* at col. 12, ll. 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 col. 12, ll. 43-49. Although Smith describes a medial posterior approach, Smith explains that this technique can "be used from any approach and in other regions besides the spine," *id.* at col. 12, ll. 1-2, for example, "posterolateral" and "anterior" approaches, *id.* at col. 12, ll. 10-12.

Marino describes various nerve surveillance systems for identifying and avoiding nerves during spinal surgery. Ex. 1009, p. 7, ll. 13-17. Petitioner refers in particular to the embodiments shown in Figures 6 and 12. Pet. 26-27. Figure 6 is reproduced below:

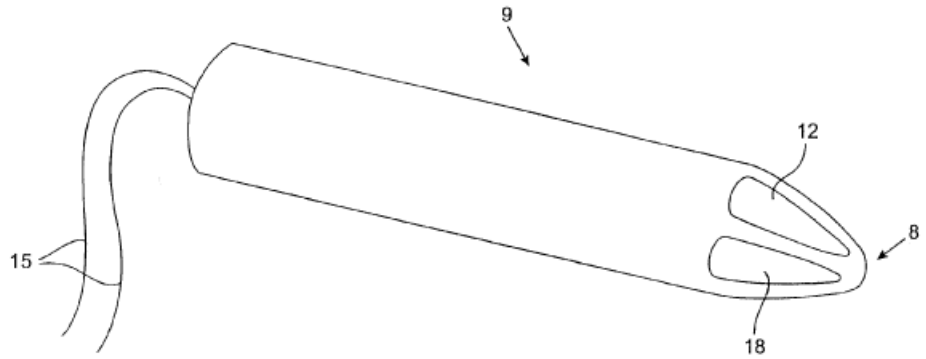

FIG. 6

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.* at p. 8, ll. 26-31. As the probe is inserted through patient tissue and close to a nerve, the electrode closest to the nerve depolarizes the nerve, the response to which can be detected using "standard" EMG techniques. *Id.* at p. 9, ll. 1-5; *see also id.* at p. 7, ll. 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 p. 9, ll. 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 p. 11, ll. 8-13, 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 p. 11, l. 32-p. 12, l. 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 p. 11, ll. 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 p. 13, ll. 14-21. Marino describes an operative target site at a patient's intervertebral disk, 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 p. 16, ll. 16-22.

Obenchain describes a cannula (elongated cylinder) for spinal surgery (laparoscopic lumbar discectomy). Ex. 1003, 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 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 col. 5, ll. 5-14.

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

Petitioner contends that claim 1 would have been obvious over Smith, Marino, and Obenchain. Specifically, 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 teaching of each of these references is 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. On this record, we are persuaded that there is a reasonable likelihood that Petitioner will prevail with respect to claim 1.

Patent Owner responds that Marino describes electrodes positioned on petals that can be displaced radially outwards from the longitudinal axis of a cannula. Prelim. Resp. 17-20. Patent Owner characterizes this as "the exact opposite" of fixed positions. *Id.* at 20. We are not persuaded. First, as explained above, Petitioner (Pet. 26-27) cites to two embodiments of Marino, only one of which includes electrodes on petals that can be displaced radially. *Compare* Ex. 1009, Fig. 6 *with id.*, Fig. 12. Second, even in the second embodiment cited by Petitioner (Pet. 27), which includes petals, the petals are secured in place with breakable seals while the cannula is inserted into the patient. Ex. 1009, p. 11, l. 24-p. 12, l. 25. Patent Owner does not adequately explain why the electrodes are not fixed relative to the longitudinal axis of the cannula when the breakable seals are intact.

Patent Owner also argues that the cited art does not teach incorporating a nerve monitoring capability into an access system that includes both a sequential dilation access system with a cannula and a working corridor instrument that is slidable over an outer dilating cannula. Prelim. Resp. 17-18, 20-24. Specifically, Patent Owner argues that Marino does not teach a working corridor instrument inserted over a cannula shaft. *Id.* at 21. Petitioner shows adequately, however, that this feature is taught in Smith. Pet. 27. Patent Owner also argues that Marino does not teach an instrument designed to open up sequentially and go through musculature with important nerve root structures. Prelim. Resp. 21-22. Petitioner shows adequately, however, that this feature is taught in Smith. *See* Pet. 25-26. Patent Owner further contends that Smith does not teach traversing near nerve root structures. Prelim. Resp. 22. Petitioner shows adequately, however, that this feature is taught in both Marino and Obenchain. *See* Pet. 25-27. 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.").

Regarding Obenchain, Patent Owner argues that the trans-psoas approach described therein would have traversed a "safer zone" of the psoas muscle with few or no nerve roots. Prelim. Resp. 22-24. According to Patent Owner, Obenchain does not teach traversing the psoas muscle in the middle or posterior portion, where there is a danger of encountering nerves. *Id.* at 24 (citing Takatomo Moro et al., *An Anatomic Study of the Lumbar*

Plexus with Respect to Retroperitoneal Endoscopic Surgery, 28 SPINE, at 423-28 (2003) (Ex. 2005, "Moro"), at 425, Fig. 3).

As construed above, the claim terms including "trans-psoas" do not carry patentable weight beyond the ability of the cannulas to follow a "trans-psoas path" or "trans-psoas approach" to form a trans-psoas operative corridor. Thus, we are not persuaded that a specific trans-psoas trajectory distinguishes Obenchain from the claimed system. Furthermore, even if the term carried patentable weight, Patent Owner has not explained with sufficient detail how Obenchain teaches a "safer zone" than what allegedly is taught in the '782 patent, or why a distinction among various zones of the psoas is relevant to a claim that refers to a "trans-psoas" path or approach without specifying a zone.

Patent Owner further argues that Obenchain teaches away from Smith's larger dilators and working cannula. Prelim. Resp. 18, 24-27. Patent Owner contends that Obenchain describes an outer cannula diameter of less than 10 mm as "important," Prelim. Resp. 24 (quoting Ex. 1003, col. 2, ll. 29-38), and that Smith's cannulas have diameters larger than 10 mm, Prelim. Resp. 25 (citing Ex. 1001, col. 12, ll. 46-51). Patent Owner also contends that Obenchain describes a procedure performed under gas insufflation, which Patent Owner argues would have been hindered by a larger working corridor. Prelim. Resp. 25.

"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). 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. 1003, 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. Accordingly, we are not persuaded that Obenchain teaches away from Smith's system of dilating cannulas.

Patent Owner also contends that secondary considerations, such as long-felt but unsolved need and commercial success, evidence non-obviousness. Prelim. Resp. 18, 27-29. Specifically, 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 '782 patent's priority date, no one put them all together before the '782 patent. Prelim. Resp. 27-28. Patent Owner's evidence that each of the components of Petitioner's combination significantly pre-dated the '782 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 Inc. 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 demand for the patented invention or failed attempts to satisfy that demand.

Regarding commercial success (Prelim. Resp. 28-29), Patent Owner does not cite to evidence. Patent Owner's assertion that Petitioner "knows very well the commercial success that [Patent Owner] has achieved" (*id.* at 28) is not evidence. Thus, on this record, we are not persuaded that commercial success weighs against obviousness. 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. 28), we determine that Petitioner has shown a reasonable likelihood

that it will prevail as to claim 7 as obvious over Smith, Marino, and Obenchain.

b. 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, col. 1, ll. 13-23. Figure 2 is illustrative:

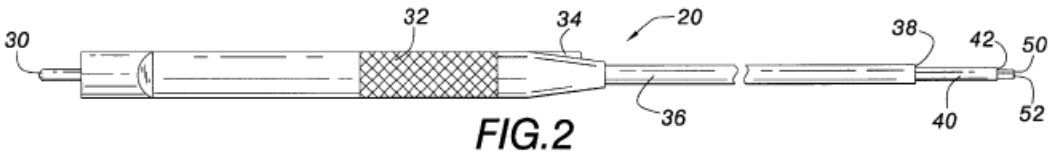

FIG.2

Figure 2 shows a cannula 36 that carries a flexible plastic molded jacket 40 with cathode and anode tips (50, 52). Ex. 1004, col. 6, ll. 28-34, 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 col. 6, ll. 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 col. 7, ll. 31-34.

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. Patent Owner responds that the claimed dilators are meant to be rotated by hand while inside the patient and, thus, benefit from the reference marks. Prelim. Resp. 31. In contrast, Patent Owner argues, Marino's cannula does not need to be rotated and, thus, Marino teaches away from reference marks. *Id.* Patent owner, however, does not explain persuasively why the lack of a need for a reference mark on the Marino cannula would have discouraged including one. *See Mouttet*, 686 F.3d at 1333-34. In any case, because Marino's cannula has several electrodes positioned on the cannula, a reference mark would have allowed a surgeon to determine the direction, relative to the mark, of the electrode that stimulated a nerve. Pet. 20; Ex. 1014 ¶¶ 118, 121.

Patent Owner further argues that neither Marino nor Prass describes a reference mark and a stimulation electrode on the same cannula. Prelim. Resp. 31-33. According to Petitioner's declarant, however,

> 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 credit Dr. Schwartz's testimony on this point. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Whether the reference mark is on the cannula itself or on a handle designed to aid in inserting the cannula, the reference mark serves the same purpose, i.e., to indicate how the electrode(s) are oriented in the patient relative to the reference mark. As Dr. Schwartz explains, "[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.

In sum, Petitioner has shown a reasonable likelihood that it will prevail as to claim 5 as obvious over Smith, Marino, Obenchain, and Prass.

c. 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.

In response, Patent Owner, referring to its discussions of claims 1 and 5, argues that the prior art does not teach a dilating cannula having both a distal stimulation electrode and a proximal reference mark on the same cannula, that Obenchain teaches away from Smith's larger dilators, and that secondary considerations evidence nonobviousness. Prelim. Resp. 36-37, 40-42. For the reasons given for claims 1 and 5, we are persuaded that the evidence supports a finding that Smith, Marino, Obenchain, and Prass teach the recited dilating cannula, simulation electrode, trans-psoas approach, and reference mark.

Claim 9 also recites:

> a stimulation clip having a first end attachable to said proximal end of said dilating cannula and a cable for establishing electrical communication between said stimulation clip and an electrical stimulator, said first end establishing electrical communication between said at least one electrical contact of said dilating cannula and said stimulation clip when said stimulation clip is attached to said dilating cannula,

Petitioner recites Isley's teaching of an alligator clip connected to a pedicle probe as teaching this element. Pet. 31 (citing Ex. 1011, Fig. 10, p. 112, ll. 3-6). Figure 10 of Isley shows an alligator clip attached to a pedicle probe

used in spinal surgery. Ex. 1011 at 110. The alligator clip is connected to a stimulator for supplying an electrical signal for eliciting an EMG response. *Id.* Petitioner argues that Isley shows 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. We agree that the evidence supports a finding that this claim limitation is taught in Isley.

Claim 9 further recites "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." Petitioner contends that Marino and Isley teach this element. Pet. 22-23, 29-30. According to Petitioner, relying on its declarant, Dr. Schwartz, although Marino does not describe explicitly an insulated cannula, if the cannula were uninsulated, the entire surface would have conducted current, making it difficult to determine nerve proximity and direction. Pet. 22 (citing Ex. 1014 ¶¶ 159-66). Petitioner then cites Isley as describing an example of a stimulation instrument insulated along its length. *Id.*

Patent Owner argues that Petitioner is reading Isley incorrectly, and that Isley does not describe a stimulator with insulation between an exposed electrode at a distal end and an exposed electrical contact at a proximal end. Prelim. Resp. 37-38. Instead, Patent Owner argues, Isley's probe is insulated only along the distal end, which the surgeon holds, while the portion from alligator clip to the proximal tip is uninsulated. *Id.* at 38-40.

We are persuaded, on the present record, that a person of ordinary skill in the art would have understood that a lack of insulation on Marino's

probe would have made it difficult to detect proximity and direction of nerves relative to Marino's electrodes. Ex. 1014 ¶ 161. As explained by Dr. Schwartz, Marino describes emitting a stimulus current directionally relative to the cannula, and that, as a matter of "conventional wisdom," without insulation the stimulus current would have been emitted from the entire surface of the cannula, rather than a single stimulus electrode. *Id.* Thus, on this record, we are persuaded that a person of ordinary skill in art would have known to insulate Marino's cannula along its entire length with the exception of an exposed electrical contact at the proximal end (to attach a clip to supply a signal) and an exposed stimulation electrode at the distal end (to emit the signal directionally). *Id.* ¶ 163; *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009) (An obviousness analysis "also may include recourse to logic, judgment, and common sense available to the person of ordinary skill.").

In sum, Petitioner has shown a reasonable likelihood that it will prevail as to claim 9 as obvious over Smith, Marino, Obenchain, Prass, and Isley.

Moreover, upon consideration of Petitioner's arguments and evidence (Pet. 24-25, 31-33), we determine that Petitioner has shown a reasonable likelihood that it will prevail as to claims 13-17 as obvious over Smith, Marino, Obenchain, Prass, and Isley.

d. Claims 8, 18, and 20

Upon consideration of Petitioner's arguments and evidence (Pet. 20-21, 25, 33-34), we determine that Petitioner has shown a reasonable likelihood that it will prevail on claim 8 as obvious over Smith, Marino,

Obenchain, Prass, and Simonson; and claims 18 and 20 as 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 of the '782 patent based in whole or in part on the combination of Foley, Kelleher, Obenchain, and Prass.

Obenchain and Prass are discussed above. Smith is a continuation-in-part of Foley. Ex. 1001 at 1. 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, p. 1, ll. 9-10; p. 2, ll. 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 p. 4, ll. 1-9; p. 10, ll. 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 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. The nerve detection system also includes a pulse generator that supplies a train of pulses to the stimulation electrodes. *Id.* at p. 23, ll. 12-20; Fig. 7. The system further receives inputs from the EMG electrodes that detect the EMG responses from the patient. *Id.* at 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.

a. 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 teaching of each of these references is in the context of minimally invasive spinal surgery using cannulated instruments. Pet. 41, 43. 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. On this record, we are persuaded that there is a reasonable likelihood that Petitioner will prevail with respect to claim 1.

In response, Patent Owner argues that Kelleher teaches a stimulation electrode on the outermost working cannula rather than on a sequential dilating cannula of a system that includes a working corridor instrument. Prelim. Resp. 43-44. Patent Owner further argues that no single reference teaches using sequential dilator cannulas and a working corridor instrument to open up nerve-laden muscle tissue such as the psoas muscle. Prelim.

Resp. 44-45. As with the combination of Smith, Marino, and Obenchain (Section II.B.1.a., above), Patent Owner's arguments are unpersuasive because they address the references individually without considering the combined teachings of those references. *See Keller*, 642 F.2d at 426.

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. 45-46. For the reasons given in Section II.B.1.a., above, this argument is unpersuasive. Patent Owner further argues that Obenchain teaches away from Foley's large diameter dilating cannulas and working cannula. Prelim. Resp. 43, 46-48. This argument, too, is unpersuasive for the reasons given in Section II.B.1.a., above. Moreover, for the reasons given in Section II.B.1.a., above, we are not persuaded by Patent Owner's argument (Prelim. Resp. 49-51) that secondary considerations evidence non-obviousness.

Regarding claim 5, Petitioner cites to Prass for a description of the recited reference mark. Pet. 49-50. Patent Owner responds that the electrode and reference mark described in Prass are not on Prass's cannula. Prelim. Resp. 51-52. For the reasons given in Section II.B.1.b., above, Patent Owner's argument is not persuasive. On this record, Petitioner has shown a reasonable likelihood that it will prevail as to claim 5 as obvious over Foley, Kelleher, Obenchain, and Prass.

Moreover, upon consideration of Petitioner's arguments and evidence (Pet. 50), we determine that Petitioner has shown a reasonable likelihood that it will prevail as to claim 7 as obvious over Foley, Kelleher, Obenchain, and Prass.

b. Claim 8

Upon consideration of Petitioner's arguments and evidence (Pet. 50), we determine that Petitioner has shown a reasonable likelihood that it will prevail on claim 8 as obvious over Foley, Kelleher, Obenchain, Prass, and Simonson.

c. 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 the evidence supports a finding 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.B.1.c., 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:

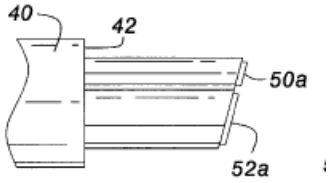

FIG.6

Figure 6 illustrates a close-up side view of a distal tip of a probe. Ex. 1004, col. 5, ll. 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 col. 7, ll. 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 col. 6, ll. 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. In response, Patent Owner argues that Isley does not teach the insulation feature of claim 9. Prelim. Resp. 54-55. For the reasons given in Section II.B.1.c., however, we are persuaded that a skilled artisan would have understood that a lack of insulation on a probe would have made it difficult to detect proximity and direction of nerves relative to an electrode on the probe. *See also* Pet. 45; Ex. 1014 ¶¶ 180-86. Accordingly, there is a reasonable likelihood that Petitioner will prevail in showing that it would have been predictable to combine the angled electrode of Prass with Kelleher's electrified cannula, resulting in a cannula insulated along its length except for an exposed angled electrode at the distal end and an exposed contact at the proximal end.

In sum, Petitioner has shown a reasonable likelihood that it will prevail as to claim 9 as obvious over Foley, Kelleher, Obenchain, Prass, and Isley. Upon consideration of Petitioner's arguments and evidence (Pet. 53-55), we further determine that Petitioner has shown a reasonable likelihood that it will prevail as to claims 13-18 and 20 as obvious over Foley, Kelleher, Obenchain, Prass, and Isley.

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) Claim 17 under 35 U.S.C. § 103(a) for obviousness over Smith, Marino, Obenchain, Prass, Isley, and NIM Guide;

(2) Claims 18 and 20 under 35 U.S.C. § 103(a) for obviousness over Smith, Marino, Obenchain, Prass, Isley, NIM Guide, and Drongelen;

(3) Claim 7 under 35 U.S.C. § 103(a) for obviousness over Smith, Marino, Obenchain, and Mathews;

(4) Claim 5 under 35 U.S.C. § 103(a) for obviousness over Smith, Marino, Obenchain, Prass, and Shmulewitz;

(5) Claims 9, 13-18, and 20 under 35 U.S.C. § 103(a) for obviousness over Smith, Marino, Obenchain, Prass, Isley, Epoch 2000, and Shmulewitz;

(6) Claim 7 under 35 U.S.C. § 103(a) for obviousness over Foley, Kelleher, Obenchain, Prass, and Mathews;

(7) Claim 5 under 35 U.S.C. § 103(a) for obviousness over Foley, Kelleher, Obenchain, Prass, and Shmulewitz;

(8) Claims 9, 13-18, and 20 under 35 U.S.C. § 103(a) for obviousness over Foley, Kelleher, Obenchain, Prass, Isley, and Marino;

(9) Claims 18 and 20 under 35 U.S.C. § 103(a) for obviousness over Foley, Kelleher, Obenchain, Prass, Isley, Marino, and NIM Guide; and

(10) Claims 9, 13-18, and 20 under 35 U.S.C. § 103(a) for obviousness over Foley, Kelleher, Obenchain, Prass, Isley, Marino, NIM Guide, and Shmulewitz.

III. CONCLUSION

We institute an *inter partes* review of claims 1, 5, 7-9, 13-18, and 20 based on the following grounds:

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

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

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

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

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

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

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

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

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, 5, 7-9, 13-18, and 20 on the grounds listed in the Conclusion. No other ground is authorized;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '782 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 Patent 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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