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PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Requester and Appellant

v.

NUVASIVE, INC.
Patent Owner and Respondent

Appeal 2012-009491
Reexamination Control 95/001,247
Patent 7,582,058¹
Technology Center 3900

Before JEFFREY B. ROBERTSON, DANIEL S. SONG, and
JOSIAH C. COCKS, *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ The patent involved in this *inter partes* reexamination proceeding (the “’058 Patent”) issued to Miles et al. on September 1, 2009.

A. STATEMENT OF THE CASE

I. Summary

Third Party Requester Medtronic, Inc. (“Medtronic”) appeals under 35 U.S.C. §§ 134(c) and 315(b) the Examiner’s decisions favorable to the patentability of claims 1, 2, 4-8, 10-55, and 57-64² Patent Owner NuVasive, Inc. (“NuVasive”)³ urges that the Examiner’s decisions must be affirmed.⁴ We have jurisdiction under 35 U.S.C. §§ 134 and 315.

Oral argument was heard on September 21, 2012.

II. The Invention

The ’058 Patent summarizes its disclosed invention as follows (’058 Patent, 2:60-3:4):

The present invention [provides] a novel access system and related methods which involve: (1) distracting the tissue between the patient’s skin and the surgical target site to create an area of distraction (otherwise referred to herein as a

² See Medtronic’s “Brief on Appeal” filed September 6, 2011 (“App. Br.”) and “Rebuttal Brief” filed February 27, 2012 (“Reb. Br.”). We observe that although Medtronic states that the Examiner’s indication of the patentability of each of claims 56 and 65 is also appealed (App. Br., 1), review of the record reveals that Medtronic has proposed no rejection for those claims in this *inter partes* reexamination proceeding.

³ See Patent Assignment Abstract of Title, Reel 016585 Frame 0978 which was entered into the record of this proceeding as “Title Report” on October 16, 2009.

⁴ See NuVasive’s “Corrected Respondent Brief” filed December 8, 2011 (“Resp. Br.”).

‘distraction corridor’); (2) retracting the distraction corridor to establish and maintain an operative corridor; and/or (3) detecting the existence of (an optionally the distance and/or direction to) neural structures before, during and after the establishment of the operative corridor through (or near) any of a variety of tissues having such neural structures which[,] if contacted or impinged, may otherwise result in neural impairment for the patient.

Claims 1, 4, 6, 10, and 30 are independent claims and are each directed to a method of accessing a surgical target cite. Claim 1, which is illustrative of the appealed subject matter, reads as follows (App. Br. Claims App’x., i):

1. A method of accessing a surgical target site, comprising the steps of:

creating an initial distraction corridor through tissue extending between an incision point and a surgical target site via an initial distraction assembly including a K-wire and at least one dilator capable of being slideably passed over said K-wire;

distracting said tissue from said initial distraction corridor to a secondary distraction corridor with an instrument capable of being guided to said surgical target site along said at least one dilator of said initial distraction assembly;

introducing a plurality of retractor blades for retracting said tissue from said secondary distraction corridor to create an operative corridor to said surgical target site; and

introducing a plurality of retractor blades for retracting said tissue from said secondary distraction corridor to create an operative corridor to said surgical target site; and

providing a control unit capable of electrically stimulating at least one stimulation electrode provided on said initial distraction assembly, sensing a response of a nerve depolarized by said stimulation, determining at least one of nerve proximity and nerve direction from said initial distraction assembly to the nerve based on [sic] the sensed response, and communicating to a user at least one of visual indicia and audio communications representing at least one of said determined nerve proximity and said determined nerve direction.

III. The Prior Art

Medtronic relies on the following prior art in urging that NuVasive's claims should be rejected:

U.S. Patents

Mathews ("Mathews '279")	5,171,279	Dec. 15, 1992
Neubardt	5,474,558	Dec. 12, 1995
Michelson	5,772,661	Jun. 30, 1998
Finneran et al. ("Finneran")	6,004,312	Dec. 21, 1999
Koros et al. ("Koros")	6,139,493	Oct. 31, 2000
Foley et al. ("Foley '871")	6,152,871	Nov. 28, 2000
Mathews et al. ("Mathews '826")	6,206,826	Mar. 27, 2001
Mamo et al. ("Mamo")	6,847,849	Jan. 25, 2005
Smith et al. ("Smith")	7,261,688	Aug. 28, 2007

International Patent Applications

Marino et al. ("Marino")	WO 00/38574	Jul. 6, 2000
Kelleher et al. ("Kelleher")	WO 01/37728	May 31, 2001

Non-Patent Documents

Mathews et al., Laparoscopic Discectomy With Anterior Lumbar Interbody Fusion, Spine, Vol. 20, No. 16, pp. 1797-1802 (1995) ("**Mathews Article**")

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Rose et al., Persistently Electrified Pedicle Stimulation Instruments in Spinal Instrumentation: Technique and Protocol Development, Spine, Vol. 22(3), pp. 334-343 (February 1, 1997) (“**Rose**”)

A document characterized as “Epoch 2000 Neurological Workstation 510(k), FDA No. K971819 (published December 30, 2997 [sic])” (“**Epoch 2000**”)⁵

Foley et al., Microendoscopic Discectomy, Techniques in Neurosurgery, Vol. 3, No. 4, pp. 301-307 (December 1997) (“**Foley Article**”)

Medtronic Xomed Surgical Products, Inc., NIM-Response Nerve Integrity Monitor Intraoperative EMG Monitor User’s Guide, Revision B (March 2000) (“**NIM Guide**”)

Schick et al., Microendoscopic Lumbar Discectomy Versus Open Surgery: an Intraoperative EMG Study, European Spine Journal, Vol. 11, pp. 20-26 (published online July 31, 2001) (“**Schick**”)

IV. Other Evidence

Medtronic’s “Declaration of Hallett Mathews, M.D. Under 37 C.F.R. § 1.132” dated March 18, 2010 (“**Mathews Decl.**”)

Medtronic’s “Declaration of David Hacker Under 37 C.F.R. § 1.132” dated March 19, 2010 (“**Hacker Decl.**”)

NuVasive’s “Declaration of Dr. Steven Garfin Under 37 C.F.R. § 1.132” dated February 13, 2010 (“**Garfin Decl.**”)

V. The Involved Rejections

Medtronic characterizes this *inter partes* reexamination appeal proceeding as directed to the following rejections proposed by Medtronic but which have not been adopted or maintained by the Examiner:⁶

⁵ App. Br., Evidence App’x, xv.

Proposed Prior Art Rejections

“[C]laims 1 and 4, and the claims that depend therefrom” as unpatentable under 35 U.S.C. § 103(a) over:⁷

- (1) Foley Article and Kelleher;
- (2) Foley ’871 and Marino;
- (3) Smith and Rose;
- (4) Foley Article and Epoch 2000; and
- (5) Mathews ’279 and Neubardt.

“[C]laim 4, and the claims that depend therefrom” as unpatentable under 35 U.S.C. § 103(a) over:⁸

- (6) Mathews Article and Kelleher;
- (7) Mamo and Foley ’871; and
- (8) Mathews ’826 and Kelleher.

Claim 6, and the claims that depend therefrom,⁹ as unpatentable under 35 U.S.C. § 103(a) over:

- (9) Foley Article, Kelleher, and Schick;
- (10) Foley ’871, Marino, and Michelson;
- (11) Mathews Article, Kelleher, and Michelson;
- (12) Smith, Rose, and Schick;
- (13) Foley Article, Epoch 2000, and Schick;
- (14) Mathews ’279, Neubardt, and Michelson; and
- (15) Mathews ’826 and Kelleher.

⁶ App. Br., 2-3.

⁷ *Id.* at 2-3.

⁸ *Id.* at 3.

⁹ Although page 3 of Medtronic’s Appeal Brief does not expressly indicate that the rejection of claims that depend from claim 6 are appealed, it is apparent from the record, including the Notice of Appeal filed July 6, 2011, that rejections of those dependent claims are also before us in this appeal.

“[C]laim 10, and the claims that depend therefrom” as unpatentable under 35 U.S.C. § 103(a) over:¹⁰

- (16) Mathews '826, Michelson, Kelleher, and Finneran;
- (17) Koros, Michelson, Foley '871, Kelleher, and NIM Guide;
- and
- (18) Smith, Michelson, Koros, Marino, and NIM Guide.

“[C]laim 30, and the claims that depend therefrom” as unpatentable under 35 U.S.C. § 103(a) over:¹¹

- (19) Mathews '826, Michelson, and Kelleher;
- (20) Koros, Foley '871, Michelson, and Kelleher; and
- (21) Smith, Michelson, Marino, and NIM Guide.

Other Proposed Rejections

- (22) A proposed rejection of claims 10-50 under 35 U.S.C. § 314 for improper broadening.
- (23) Proposed rejections of claims 10-50 and 57 under 35 U.S.C §112, first paragraph.

B. ISSUES

1. Was the Examiner correct in not rejecting claims 10-50 as being impermissibly enlarged in scope under 35 U.S.C. § 314?
2. Was the Examiner correct in not rejecting any of claims 10-50 and 57 as lacking adequate written description in the specification of the '058 patent for any recited claim features?
3. Does the record show that a person of ordinary skill in the art would have regarded a tubular type working cannula as a retractor blade or a plurality of retractor blades?

¹⁰ *Id.*

¹¹ *Id.*

4. Does the record show that a person of ordinary skill in the art would have understood from the prior art that a surgical target site in a patient's spine may be reached via a "lateral trans-psoas" approach or path?

5. Has Medtronic adequately shown that the Examiner was not correct in concluding that none of NuVasive's claims would have been obvious in light of the teachings of prior art?

C. ANALYSIS

This *inter partes* reexamination appeal proceeding involves proposed grounds of rejection based on the prior art as well as rejections proposed under 35 U.S.C. §§ 314 and 112, first paragraph.

I. The Rejection Under 35 U.S.C. § 314

Title 35 U.S.C. § 314(a) provides that in connection with an *inter partes* reexamination proceeding:

[T]he patent owner shall be permitted to propose any amendment to the patent and a new claim or claims, except that no proposed amended or new claim enlarging the scope of the claims of the patent shall be permitted.

Medtronic submits that NuVasive's claims 10-50, which were added via amendment during the course of this reexamination proceeding, improperly enlarge the scope of the claims of the '058 Patent and should thus be rejected as violating 35 U.S.C. § 314(a). Medtronic argues that independent claims 10 and 30¹² are each based on original claim 4 but are

¹² Claims 11-29 ultimately depend on claim 10 and claims 31-50 ultimately depend on claim 30. The dependent claims include all the limitations of the independent claim on which they ultimately depend.

broader in scope than claim 4. (App. Br., 44-45.) In particular, Medtronic makes the following contentions with respect to each of claims 10 and 30 (*id.*) (emphasis in original):

Independent claim 30 is based on original claim 4, which recites “a secondary instrument advanceable to said surgical target site *along said at least one dilator* of said initial assembly” (emphasis added). New claim 30 broadens the scope of this feature by reciting “a secondary instrument advanceable to said surgical target site *along the lateral, trans-psoas path after insertion of said at least one dilator* of said initial assembly” (emphasis added). This new recitation does not require that the secondary instrument be advanced along a path after insertion of the dilator. Thus, with the new recitation, the dilator could be removed prior to advancing the secondary instrument as long as the secondary instrument later followed a similar path, a scenario not covered by original claim 4. Thus claim 30 broadens the scope of the invention claimed in the patent.

Independent claim 10 is also based on original claim 4. Original claim 4 recites a step of “sensing a *response of a nerve* depolarized by said stimulation” (emphasis added). New claim 10 broadens this feature by reciting “sensing an electromyographic (EMG) *response of a muscle* coupled to a nerve depolarized by said stimulation” (emphasis added). Because claim 10 changes the sensing step to focus on muscles instead of nerves, the Patent Owner has impermissibly changed the scope of the claims.

NuVasive challenges the above-noted contentions and urges that claims 10 and 30 are instead narrower in scope than claim 4. (Resp. Br., 24-25.) Thus, NuVasive contends that the Examiner was correct in “refusing to adopt” the proposed rejections. (*Id.* at 24.)

In a reexamination proceeding, “[a]n amended claim has been enlarged if it includes within its scope any subject matter that would not

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have infringed the original patent.” *Quantum Corp. v. Rodime PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995) (citing *In re Freeman*, 30 F.3d 1459, 1464 (Fed. Cir. 1994)). As noted above in connection claim 30, Medtronic offers a plausible scenario in which the process laid out in claim 30 may be performed in a manner not required by claim 4. That is, the process of claim 30 would seemingly not have infringed the process of claim 4, because in claim 30, the dilator could be removed prior to advancing the secondary instrument and the secondary instrument could later follow a similar path. As a result, claim 30 is broader than claim 4. Although NuVasive generally urges that claim 30 is narrower in all respects as compared to claim 4, NuVasive does not address the scenario raised by Medtronic or explain why it is incorrect.

With respect to claim 10, we also agree with Medtronic that sensing the response of a nerve, as in claim 4, is not the same act as sensing the response of a muscle, as in claim 10. The record suitably demonstrates that a nerve and a muscle are not the same. NuVasive offers only the following statement in connection with its position (Resp. Br., 25):

There are many options of how to sense a response of a nerve (thus providing a boarder scope in claim 4), and sensing the EMW response of the muscle coupled to the nerve is merely one of those options (thus providing the narrower scope in claim 10).

That statement is, however, merely argument of counsel. Such argument cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997). Notably, NuVasive does not accompany its statement with citation to any portion of

the record which provides underlying support for its position that sensing the response of a muscle is simply a “narrower” form of how to “sense a response of a nerve.” (*Id.*)

In light of the record before us, and after due consideration of each party’s position, we agree that claims 10-50 are enlarged in scope as compared with the original claims of the ‘058 Patent. We, therefore, are of the opinion that the Examiner erred in not adopting the proposed rejections of those claims as violating 35 U.S.C. § 314. That the rejections were not applied is effectively a decision by the Examiner favorable to the patentability of those claims. We reverse that decision.

Accordingly, we conclude that the Examiner should have entered a rejection of claims 10-50 under 35 U.S.C. § 314(a). **By operation of 37 C.F.R. § 41.77 (b), our above-noted reversal of the Examiner’s decision is designated a new ground of rejection.**

II. The Rejection Under 35 U.S.C. § 112

Medtronic proposed rejections to claims 10-50 and 57 under 35 U.S.C. § 112, first paragraph. Medtronic argues the claims in five separate groupings: (a) claims 10-29 and 57; (b) claims 30-50; (c) claims 10-29; (d) claims 28, 29, and 44; and (e) claims 17 and 37.

a. Claims 10-29 and 57

Medtronic submits that claims 10-29 and 57 lack adequate written description support in the specification of the ‘058 Patent. To satisfy the written description requirement of 35 U.S.C. § 112, an applicant, or as here a patentee, must convey with reasonable clarity to those skilled in the art that he or she was in possession of the claimed invention. *See Vas-Cath Inc. v.*

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Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). One shows “possession” of the invention by describing the invention using such descriptive means as words, structures, and figures that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). It is, however, not necessary that the exact terms that appear in the claim must also appear in the description. *Id.*

The dispute here centers on a feature that, but for minor differences in terminology, is common to each of claims 10 and 57. The pertinent feature as it appears in claim 10 is reproduced below (App. Br. Claims App’x, iii) (*emphasis added*):

creating an operative corridor through tissue extending between an incision point and a surgical spinal target site in a lumbar spine via a distraction assembly that creates a tissue distraction corridor along a lateral, trans-psoas path to the spinal target site in the lumbar spine and a retraction assembly comprising a pair of directly opposed retractor blades that are advanced along the lateral, trans-psoas path to the spinal target site in the lumbar spine *only after* the distraction assembly creates said tissue distraction corridor[.]

According to Medtronic, although the specification of the ’058 Patent describes an embodiment of its disclosed invention in which retractor blades are advanced to a target site “after” the creation of a distraction corridor the temporal restriction arising from the term “only” allegedly runs afoul of the written description requirement. (App. Br., 45; Reb. Br., 19.) However, as is pointed out by NuVasive (Resp. Br., 25), the ’058 Patent includes a lexicographic definition for the term “retraction” and “retracting” which establishes that an operative corridor is formed “by increasing the cross-sectional area of” a distraction corridor that has already been formed. (’058

Patent, 3:9-12.) It is the “operative corridor” through which surgical instruments, such as retractor blades, are ultimately advanced. (*Id.* at 3:13-15.) Thus, although the term “only” does not appear in that context, the ’058 Patent clearly provides that the formation of the operative corridor necessarily occurs only after the formation of the distraction corridor.

Therefore, we find that the ’058 Patent suitably conveys that the inventors of the ’058 Patent were in possession of the above-discussed feature. We therefore affirm the Examiner’s decision not to adopt the proposed rejection.

b. Claims 30-50

Independent claim 30 introduces “an elongate inner element” as a part of a distraction assembly and requires the step of electrically stimulating “at least one stimulation electrode during insertion of said elongate element through psoas muscle tissue....” (App. Br. Claim App’x, vii.) In reciting “at least one stimulation electrode” associated with an elongate inner element, the claim contemplates multiple such electrodes. According to Medtronic, however, the ’058 Patent lacks suitable written description support for more than one electrode in connection with each elongate inner element. (App. Br., 46; Reb. Br., 20.) NuVasive contends otherwise. (Resp. Br., 26.) We agree with NuVasive.

The ’058 Patent explains that (’058 Patent, 12:56-60):

The initial distraction assembly 12 (FIGS. 2-4) may be provided with one or more electrodes for use in providing the neural monitoring capabilities of the present invention. By way of example only, the K-wire 44 may be equipped with a distal electrode 200.

The '058 Patent also describes that “one or more stimulation electrodes are provided on the various components of the distraction assemblies and/or retraction assemblies[.]” (*Id.* at 4:7-9.) Furthermore, throughout the specification of the '058 Patent, reference is made to “electrode(s)” in the context of one or more of such components. (*E.g., id.* at 10:51-52.)

Although it is clear that the '058 Patent contemplated benefits to more than one electrode associated generally with its various assemblies, such as its distraction assemblies, Medtronic is of the view that the patent conveys only that the inventors possessed that a single electrode is associated with any given component that makes up those assemblies. The apparent basis for that view is that as noted above in connection with column 12, the '058 Patent sets forth an “example” in which a particular component, *i.e.*, “K-wire **44**” is expressed as being equipped with “a” distal electrode. Evidently, Medtronic extrapolates from the use of “a” in that context to justify its position that only a single given electrode was envisioned as being implemented on any given component.

In light of our review of the record, we view Medtronic’s tenuous reliance on a single “example,” which discusses only one single electrode, as an overly limited assessment of what the '058 Patent discloses with respect to electrode configurations. Given the multiple disclosures in the '058 Patent involving more than one electrode associated with various surgical assemblies, we are unpersuaded that the '058 Patent demonstrates that the involved inventors were not in possession of the “at least one stimulation electrode” feature of claim 30.

Accordingly, because we find that the “at least one stimulation electrode” feature of claim 30 has adequate written description support in the ‘058 Patent, we affirm the Examiner’s decision not to adopt the proposed rejection.

c. Claims 10-29

In challenging the adequacy of the written description of claims 10-29, Medtronic takes the position that the ’058 Patent does not support the requirement of those claims that retractor blades are “directly opposed.” (App. Br., 46; Reb. Br., 20.) NuVasive challenges Medtronic’s position, urging that Figures 1, 8, and 32 illustrate retractor blades 90 and 92 as directly opposed from one another. (Resp. Br., 26.) We agree with NuVasive.

Medtronic does not address NuVasive’s reliance on the above-noted figures as depicting a directly opposed configuration of the retractor blades. In our view, the figures clearly illustrate retractor blades that are directly opposed with respect to, or are across from, one another. The illustrated content of a patent’s figures can provide appropriate descriptive means for aspects of a claimed invention. *Lockwood*, 107 F.3d at 1572.

We discern no error in the Examiner’s decision not to adopt the rejection proposed with respect to claims 10-29. We, therefore, affirm the decision.

d. Claims 28, 29, and 44

Claims 28, 29, and 44 each require that an initial assembly and secondary instrument of a distraction assembly be removed “while” the retraction assembly maintains an operative corridor. (App. Br. Claims

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App'x, vii, x.) Medtronic submits that the pertinent feature of the claims is not supported in the '058 Patent. Pointing to column 15, line 12 through column 16, line 16, Medtronic contends that the '058 Patent sets forth only that the initial assembly and secondary instrument are removed "before" the retractor assembly is operated to maintain an operative corridor, not "while." (App. Br. 46, Reb. Br., 20.) Relying on the very same content at columns 15 and 16, NuVasive generally contends otherwise without further elaboration. (Resp. Br., 26.)

In our review of the noted portions at columns 15 and 16 of the '058 Patent, we conclude that Medtronic has the better assessment of what is disclosed therein. The initial assembly of the distraction assembly constitutes, by our understanding, the inner dilator 46, the outer dilator 48, and the K-wire 44. (*See* '058 Patent, 6:49-54.) Column 15, line 12 through column 16, line 16 express that the initial assembly, including the dilators 46 and 48, are removed prior to the introduction of any retractor blades for maintaining an operative corridor. We do not discern how removal of the initial assembly before the introduction of the retractor assembly, provides the requisite support for the claimed recitation that at least the initial assembly is removed "while" the retractor assembly maintains an operative corridor.

Accordingly, we conclude that the above-noted written description rejection under 35 U.S.C. § 112, first paragraph, as proposed by Medtronic, should have been adopted by the Examiner. Accordingly, we reverse the Examiner's decision not to adopt that rejection. **Our reversal constitutes a**

new ground of rejection pursuant to 37 C.F.R. § 41.77(b) as to claims 28, 29, and 44 and is hereby designated as such.

e. Claims 17 and 37

Each of claims 17 and 37 requires a step directed to “releasably” connecting a cable of a nerve monitoring system to a component of the distraction assembly. (App. Br. Claims App’x, v, ix.) Medtronic contends that such a feature has no adequate underlying written description support. NuVasive provides the following statement in challenge to Medtronic’s contention: “The ‘058 patent also provides a clear teaching for the embodiments dependent claims 17 and 37. (’058 Patent at 10:41-45; FIG. 12.)” (Resp. Br., 26.) Accordingly, we look to column 10, lines 41-45 and Figure 12 as guided by NuVasive.

Column 10, lines 39-45 is reproduced below and constitutes a single sentence:

The connectors **156a**, **156b**, **156c** are suitable to establish electrical communication between the hand-held stimulation controller **152** and (by way of example only) the stimulation electrodes on the K-wire **44**, the dilators **46**, **46**, the speculum blades, **20**, **22**, the retractor blades **90**, **92**, and/or the guard members **114** (collectively “surgical access instruments”).

The above-quoted portion conveys that the connectors operate to “establish electrical communication” but provides no elucidation as to a releasable nature of the connection. Neither do we discern what, if anything, is conveyed in Figure 12 concerning “releasably” connecting cables. Although a step of releasing a cables connection may well be obvious, a disclosure that merely renders the later-claimed invention obvious is

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insufficient to meet the written description requirement. *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998).

Accordingly, because NuVasive has not suitably demonstrated adequate written description support in the '058 Patent for features added by claims 17 and 37, and because we also cannot find suitable underlying support, we reverse the Examiner's decision not to enter the pertinent rejections concerning the limitation of the claims drawn to "releasably" connecting a cable of a nerve monitoring system to a component of the distraction assembly.

We enter a new ground of rejection to claims 17 and 37 as violating the written description requirement of 35 U.S.C. § 112, first paragraph. Because claim 18 is dependent on claim 17 and thus also includes the inadequately supported feature, **we also enter a ground of rejection of claim 18 on the same basis.**

III. The Prior Art Rejections

By our count, Medtronic has proposed twenty-one grounds of rejection based on prior art which were not adopted by the Examiner and which are involved in the present appeal. All of the rejections proposed are based on obviousness. In urging that the Examiner erred in declining to adopt any of the involved prior art rejections, Medtronic focuses its arguments on the content of the independent claims 1, 4, 6, 10, and 30 and in the following groupings: (a) claims 1 and 4; (b) claim 4; (c) claim 6; (d) claim 10; and (e) claim 30.

a. Claims 1 and 4

In dispute in connection with claims 1 and 4 are five grounds of rejection numbered (1)-(5) in this opinion.

i. Rejection (1) over the Foley Article and Kelleher

With respect to this rejection, there appears to be several bases of dispute between the parties. In particular, one basis centers on the requirements in each of claims 1 and 4 pertaining to the use of a “retractor blade” or “blades.” Although we observe that claim 4 refers only to a “retraction assembly,” NuVasive argues that the presence of at least one retractor blade is an intrinsic requirement of claim 4 when the term “retraction assembly” is considered in light of the ’058 Patent. (Resp. Br., 11.) Another basis emerges in connection with the use of the retraction components of the claims which create an “operative corridor” to a surgical target site in the manner required by claims 1 and 4. Yet another basis hinges on whether there is adequate motivation to combine the teachings of the Foley Article and Kelleher. We proceed to evaluate the points of dispute.

“Retractor Blades” or
“At Least One Retractor Blade”

At the outset, we agree with NuVasive that its claim 4 requires at least one retractor blade. A patentee may act as his own lexicographer by clearly setting forth an explicit definition in the patent for a claim term. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990, 50 USPQ2d 1607, 1610 (Fed.Cir.1999). That is the case here. The ’058 Patent states the following (’058 Patent, 3:9-15) (emphasis added):

‘[R]etraction’ or ‘retracting’ is defined as the act of creating an operative corridor by increasing the cross-sectional area of the distraction corridor (and/or modifying its shape) *with at least one retractor blade* and thereafter maintaining that increased cross-sectional area and/or modified shape such that surgical instruments can be passed through operative corridor to the surgical target site.

Thus, in connection with the ’058 Patent, the term “retraction” in connection with a “retraction assembly” as in claim 4 requires the presence of at least one retractor blade. With that in mind, we turn to the content of the Foley Article with respect to the “plurality of retractor blades” as required by claim 1 or “at least one retractor blade” as required by claim 4.

The Foley Article describes “a new percutaneous procedure for lumbar disc disease, microendoscopic discectomy (MED)” (Foley Article, Abstract) which incorporates insertion of a “tubular retractor” (*id.* at 303). At issue is whether a “tubular retractor” is understood as constituting one or more retractor blades. Although that is a position taken by Medtronic (*e.g.*, Reb. Br., 2), the record reveals a different understanding to those of ordinary skill in the art.

In particular, NuVasive’s expert witness, Dr. Garfin, testifies that “a working cannula or tubular retractor is different from a retractor blade of a retraction assembly.” (Garfin Decl., ¶ 5.) The ’058 Patent itself also expresses disparagement of “the generally cylindrical nature of the so-called ‘working cannula[.]’ as being limited or restrictive in allowing a surgeon to access the surgical target site. (’058 Patent, 1:67-2:5.) That the patent then proceeds to describe the invention as operating with retractor blades undermines any implication that a working cannula of a general cylindrical

nature, *i.e.*, a tubular retractor, is itself a retractor blade or blades. In light of the record, we reject Medtronic's argument to the contrary.

We observe that Medtronic also takes a different approach in accounting for the retractor blade requirement of claims 1 and 4 in the context of the Foley Article and Kelleher combination. That approach amounts simply to an allegation that the use of claimed retractor blades is "obvious." (App. Br., 19; Reb. Br., 2.) The only basis urged for that allegation is paragraph 7 of Mathews' declaration testimony. (*Id.*) To that end, Dr. Mathews testifies that "Tubular retractors and retractors formed of separate blades are obvious variations of each other." (Mathews Decl., ¶ 7.) Obviousness is a question of law based on underlying findings of fact. *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009).

Here, the factual basis underpinning Mathews' testimony is unclear. It is not apparent that either the Foley Article or Kelleher provides an adequate underlying factual showing of the claimed retractor blades. Indeed, Medtronic relies on Kelleher for disclosure of a nerve response monitoring or sensing components and not for any teachings with respect to retractor blades. Evidently, Mathews' testimony is itself offered as the factual basis to support Mathews' subsequent conclusion of obviousness. Yet, the involved proposed ground of rejection which was not adopted by the Examiner was not premised on Mathews' testimony as itself forming part of the ground. Moreover, the opinion of expert witness as to the legal conclusion of obviousness is of limited value, particularly, where, as here, it rests on an inadequately established factual assertion.

Accordingly, on the record before us, we are unpersuaded that the recitation of “retractor blades” in claim 1 or the “at least one retractor blade” as required by claim 4 are accounted for by the teachings of the Foley Article or Kelleher.

“Operative corridor”

Each of claims 1 and 4 also requires the creation of an “operative corridor” to a targeted surgical site. In claim 1, the operative corridor is created by a plurality of retractor blades which are for “retracting” tissue. In claim 4, the corridor is formed by operation of a “retraction” assembly. As discussed above, the terms “retracting” and “retraction” have been given special meaning in the context of the ’058 Patent and require the formation of an operative corridor via at least one retractor blade by increasing the cross-sectional area, or modifying the shape, of a distraction corridor. (*See* ’058 Patent, 3:9-15.)

Medtronic argues that NuVasive’s definition of “retracting” and “retraction” in the claims is “improper” because it imports an “overly restrictive definition” from the specification. (App. Br., 19-20.) Medtronic’s position appears not to consider that, in this case, the ’058 Patent has defined “retracting” and “retraction” so as to impart a special meaning to these claim terms. Furthermore, although Medtronic proceeds to assert that the Foley Article still “meets” the noted definition of retracting or retraction, the apparent premise for that assertion is that “nothing in that definition precludes a tubular retractor from being considered a retractor blade.” (*Id.* at 20.) As discussed above, however, that is a position not supported by record and with which we do not agree.

After due consideration of the record, and for the foregoing reasons, we conclude that the rejection predicted on the combination of the Foley Article and Kelleher is inadequate to account for all the limitations recited in claims 1 and 4. Accordingly, we are not persuaded that the Examiner erred in declining to adopt the proposed rejection.

We affirm the Examiner's decision in that regard. We also affirm the Examiner's decision not to so adopt a rejection of the claims 2, 51, and 52 which depend from claim 1 and claims 5, 7, 8, and 53-56 which ultimately depend from claim 4 based on the Foley Article and Kelleher.

ii. Rejections (2) and (4)

Medtronic proposed rejections of claims 1 and 4 based on Foley '871 and Marino (rejection (2) in this opinion), and Foley Article and Epoch 2000 (rejection (4)). Foley '871 is similar in its disclosure to the Foley Article and is directed to a device for performing percutaneous surgery that is characterized as a "cannula" which is illustrated as having a tubular configuration. (Foley '871, Abstract.) Medtronic characterizes the cannula as constituting a "tubular retractor" (App. Br., 21.) Each of Marino and Epoch 2000 are relied upon to account for nerve monitoring features of the claims and not for teachings of retractor blades. (*Id.*)

Rejections (2) and (4) demonstrate deficiencies which are essentially the same those discussed above with respect to rejection involving the Foley Article and Kelleher. Correspondingly, we are persuaded that the Examiner was correct in not adopting proposed rejection (2) based on Foley '871 and Marino, or rejection (4) based on the Foley Article and Epoch 2000.

We affirm the Examiner's decision in that regard with respect to claims 1 and 4 and those claimed which depend therefrom.

iii. Rejection (3) Smith and Rose

Smith is directed to a method and device for performing percutaneous surgery in a patient. (Smith, Abstract.) As a part of its disclosed invention, Smith describes the use of a “retractor” 20 including a first portion 22 and a second portion 42. (*Id.* at 5:18-31.) Medtronic contends that the portions 22 and 42 constitute “retractor blades” of retractor 20. (App. Br., 25.) NuVasive does not challenge that contention. Medtronic urges that all the features required by claims 1 and 4 are disclosed in Smith with the exception of those features characterized by Medtronic as being directed to “nerve monitoring.” (*Id.*)

Rose is a journal article that sets forth its “[o]bjectives” as (Rose, 334):

To describe in sufficient detail the technique of persistently electrified pedicle stimulation instruments, so that this technique will be available generally to all clinical neurophysiologists and spine surgeons; and to demonstrate the use, typical results, interpretation, and protocol of the technique.

As a part of its disclosed technique, Rose describes components operable to provide “appropriate neurophysiologic monitoring[.]” (*Id.* at 334, second column.) Medtronic argues that Rose's disclosure accounts for the “nerve monitoring functions” required by each of claims 1 and 4. (App. Br., 25.)

NuVasive offers two reasons why the proposed combination of Smith and Rose is inadequate to account for claims 1 and 4. In particular, NuVasive summarizes its reasons as follows (Resp. Br., 7; *see also* 13-14)

First, neither Smith nor Rose, alone or combined, discloses or suggests a method in which nerve monitoring is utilized in initial distraction, and it is pure hindsight to say this would have been obvious. Second, the Rose Article, which is relied upon as disclosing the claimed “control unit,” does not disclose or suggest a control unit capable of performing the claimed functions of “sensing,” “determining” and “communicating.”

We are not persuaded by NuVasive’s arguments. With respect to the first argument, although NuVasive is of the view that it is “pure hindsight” to conclude that a skilled artisan would have applied Rose’s teachings of nerve monitoring to Smith, NuVasive’s position in this regard is premised on its belief that the spinal surgical procedure disclosed in Rose is something different than the spinal surgery disclosed in Smith. Even assuming that is true, however, Rose does not limit its disclosure of nerve monitoring to any one particular surgical procedure to the exclusion of any and all others. Thus, one of ordinary skill in the art would have had a reason to apply Rose’s teachings of nerve monitoring to Smith.

We are cognizant of NuVasive’s reliance on the testimony of Dr. Garfin at paragraph 6 of his declaration as supporting its view of the non-obviousness of its claims involving the teachings of Smith and Rose. (*See* Resp. Br., 7.) That paragraph, however, is limited to discussion of the Foley article and the Foley ’871 patent and provides little, if any, insight as to the Smith and Rose combination.

In any event, even were we to attempt to draw significance from the testimony in connection with the Smith and Rose combination, NuVasive's non-obviousness position in that regard is unavailing. Dr. Garfin testifies that a certain spinal surgical technique, termed a "posterior approach" occurs at a location "in which exiting nerve roots are not present." (Garfin Decl., ¶ 6.) On that basis, Dr. Garfin states that employing nerve monitoring would thus be "considered unnecessary and an inefficient use of a surgeon's time[.]" (*Id.*)

However, we observe that Smith does not limit its teachings to any one particular type of spinal surgery and instead describes a wide variety of types of surgeries to which Smith's invention may be applied. To that end Smith discloses (Smith, 2:37-42; 51-54):

The present invention provides instruments and methods for performing percutaneous surgery, including spinal surgeries that include one or more techniques such as laminotomy, laminectomy, foramenotomy, facetectomy, discectomy, interbody fusion, spinal nucleus or disc replacement, and implant insertion, for example.

The retractor can be used with any surgical approach to the spine, including anterior, posterior, posterior mid-line, lateral, postero-lateral, and/or anterolateral approaches, and in other regions besides the spine.

NuVasive does not address the above-noted teachings of Smith with respect to the multiple surgical procedures other than the "posterior" approach. Neither does NuVasive explain why the various other disclosed procedures would not have benefited from nerve monitoring, including nerve monitoring during initial distraction when proceeding with other of the

surgical approaches noted above, such as a “lateral” approach. In our view, it would have been obvious to a skilled artisan to combine Rose’s teachings involving nerve monitoring with the invention of Smith and, as a result, perform nerve monitoring during initial distraction.

We are also not persuaded by NuVasive’s second argument. That is, we share Medtronic’s view (App. Br., 26-27) that Rose discloses an electronic component which operates to perform each of the “stimulating,” “sensing,” “determining,” and “communicating” functions of the control unit of claims 1 and 4. NuVasive’s challenge is essentially that, while Rose discloses determining nerve proximity, the determination is not performed by a “control unit.” (Resp. Br., 8.) However, Rose describes a monitoring component which records and displays electromyographic (EMG) activity reflective of nerve responses to stimulation, including the determination of “[n]erve thresholds” and “ascertain[ing] nerve location.” (Rose, 336-337.) NuVasive does not adequately explain why that description in Rose is not understood reasonably as disclosure of a control unit which determines nerve proximity as required by claims 1 and 4.

After due consideration of the record, we conclude that the Examiner erred in declining to adopt or maintain the rejection of claims 1 and 4 over the combined teachings of Smith and Rose as proposed by Medtronic. Those rejections are set forth in a claim chart titled “Claim Chart D” which was filed with Medtronic’s request for *inter partes* reexamination on October 14, 2009. Claims 2, 51, and 52 depend from claim 1 and claims 5, 7, 8, and 53-55 depend from claim 4. Medtronic’s proposed rejections of

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claims 1, 2, 4, 5, 7, 8, and 51-55¹³ are laid out in “Claim Chart D” and the “Claim Chart D – Continued” filed March 19, 2010.

Pursuant to 37 C.F.R. § 41.77(b), our conclusion that the Examiner erred in declining to adopt the above-noted rejections, and our entry of the rejections herein as proposed by Medtronic, constitutes a new ground of rejection of claims 1, 2, 4, 5, 7, 8, and 51-55.

iv. Rejection (5) Mathews ’279 and Neubardt

In conjunction with the proposed rejection involving Mathews ’279 and Neubardt, NuVasive offers three reasons why the Examiner was correct in declining to adopt the rejection. In particular, according to NuVasive; (1) the two involved references “teach away from one another” (Resp. Br. 9; *see also* 14); (2) the combined teachings of the references do not suggest a stimulation electrode associated with an “initial distraction assembly” (*Id.* at 10; *see also* 14); and (3) “Neubardt does not disclose the claimed ‘control unit’ capable of performing the ‘sensing,’ ‘determining’ and ‘communicating’ functions recited in the” claims. (*Id.*) Medtronic takes an opposing view with respect to the above-noted claim features. (App. Br., 30-32.)

After careful review of the parties conflicting positions, we agree with Medtronic’s assessment of what the combined teachings of Mathews ’279 and Neubardt would have conveyed to one of ordinary skill in the art. NuVasive’s teaching away argument is premised on a comparison of the

¹³ As noted *supra* Medtronic has proposed no prior art rejection of claim 56 which depends from claim 4. Claim 56 requires that the “secondary instrument” introduced in claim 4 is a “speculum assembly.” (App. Br., Claims App’x, xi.)

discussion in Mathews '279 of known detriments to a known prior art spine surgery technique taken alongside Neubardt's Figure 2. Yet, Neubardt's Figure 2 is itself characterized as "prior art" and, evidently, depicts a surgical practice with recognized disadvantages, which Neubardt's invention seeks to overcome. (Neubardt, 2:66-3:2.) NuVasive does not explain why the recognition in each reference as to deficiencies in known prior art surgical techniques establishes that they "teach away" from one another.

NuVasive's second argument narrowly focuses on the content of Neubardt and does not adequately account for what the combined teachings of Mathews '279 and Neubardt would have suggest to one of ordinary skill in the art. *See In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991) ("The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art.") As observed by Medtronic (App. Br., 31), each of the references discloses a similar guide wire associated with a spinal surgery tool. In Mathews '279, the guide wire forms part of an initial distraction assembly. (*E.g.*, Mathews '279, col. 5, ll. 17-39.) In Neubardt, the guide wire incorporates an electrical stimulation device to stimulate nerves. (*E.g.*, Neubardt, col. 9, l. 58-col. 10, l. 28.) In our view, a person of ordinary skill in the art, who is also one of ordinary creativity, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007), would have appreciated readily from the combined teachings of the references that an electrical stimulation component may be associated with an initial distraction assembly.

NuVasive's third argument is also unavailing. It is clear from Neubardt's disclosure that an electrical stimulating component is presented

which functions to stimulate nerves. Neubardt also provides that a “electromyography (EMG) unit” may be included which “will provide either visual or audible signals as an indication of nerve twitching.” (Neubardt, 7:11-17.) Given those teachings, we are unpersuaded that Neubardt does not convey a control unit which performs the operations set forth in claims 1 and 4.

For the foregoing reasons, we are persuaded by Medtronic that the Examiner was incorrect in declining to adopt rejections of NuVasive claims based on the combined teachings of Mathews ’279 and Neubardt. Thus, the Examiner erred in not adopting the rejections which are set forth in Medtronic’s “Claim Chart F” filed October 14, 2009 directed to claims 1, 2, 4, 5, 7, and 8. Accordingly, we reverse the Examiner’s decision not to enter the above-noted rejections. **Our decision in that regard, and our entry of the rejections herein as proposed by Medtronic, constitutes a new ground of rejection pursuant to 37 C.F.R. § 41.77(b).**

b. Claim 4

Medtronic contends that additional prior art rejections to “claim 4, and the claims that depend therefrom” should have been adopted. Those rejections are numbered in this opinion as: (6) Mathews Article and Kelleher; (7) Mamo and Foley ’871; and (8) Mathews ’826 and Kelleher. (App. Br., 3.)

In reviewing Medtronic’s Appeal Brief, we observe that Medtronic is of the view that NuVasive’s claim 4 does not require a retractor “blade.” As discussed above, we do not agree with that view given the explicit definition of “retraction” and “retracting” set forth in the ’058 Patent. It is evident that

with respect to rejections (6) and (7), Medtronic applies tubular cannula assemblies of the Mathews Article and Foley'871 as constituting the retraction assembly set forth in claim 4. (*E.g.*, App. Br., 32-34.) Because we do not agree that a tubular cannula assembly constitutes a retractor "blade" we are not persuaded that the Examiner was incorrect in declining to adopt rejections (6) and (7).

With respect to rejection (8), it is clear that Mathews '826 discloses at least one retractor blade (components 10 of Mathews '826). In urging that the rejection should not be adopted, NuVasive submits that Mathews '826 is deficient as it allegedly fails to account of a "secondary instrument" that is "advanceable to said surgical target site" as is set forth in claim 4. (Resp. Br., 15-16.) Medtronic likens the "sleeve 118" in Mathews '826 to the required secondary instrument and urges that it, in use, is indeed advanced to a surgical target site and thus satisfies the above-noted requirement of claim 4. (App. Br., 36-37.)

In reviewing Mathews '826, we agree with Medtronic. We think it clear from the content of Mathews '826, such as Figure 21, that sleeve 118 is readily understood as being positioned at the surgical target site and is thus "advanceable to said surgical target site" as required by claim 4. We, thus, reject NuVasive's argument to the contrary.

Accordingly, after full consideration of Medtronic's and NuVasive's arguments, and for the above-noted reasons, we are not persuaded that the Examiner was incorrect in declining to adopt rejection (6) and (7). The Examiner's decision in that regard is affirmed.

However, we are persuaded that rejection (8) should have been adopted. Accordingly, the Examiner's decision with respect to that rejection is reversed. Medtronic's "Claim Chart I" filed October 14, 2009 lays out Medtronic's proposed rejection of claim 4 and dependent claims 5, 7, and 8 and, in our view, should have been adopted. **Pursuant to 37 C.F.R. § 41.77(b), our reversal of the Examiner's decision not to adopt the rejections of claims 4-8 of Medtronic's Claim Chart I, and our entry of those rejections, constitutes a new ground of rejection.**

c. Claim 6

At issue with respect to claim 6 and claims that depend therefrom are seven grounds of rejection that were proposed by Medtronic but were not adopted by the Examiner. Those proposed rejections are numbered (9)-(15) in this opinion.

At the outset, we observe that the Examiner's basis for declining to adopt any of the involved rejections of claim 6 is premised on a single required feature of the claim. In particular, the feature concerns the establishment of an operative corridor at a spinal target site "via a lateral, trans-psoas approach." (App. Br., Claims App'x, ii.) According to the Examiner, each of the proposed rejections of claim 6 relies on the disclosure of Schick, Michelson, or Mathews '826 for disclosing the application of a "lateral trans-psoas approach to the spine" in connection with spinal surgery. (RAN, 5.) In reaching that conclusion, the Examiner credited the testimony of NuVasive's expert witness, Dr. Garfin, over the testimony of Medtronic's expert, Dr. Mathews. (*Id.*)

i. Claim Construction (Claim 6)

In resolving the involved appeal, we find it necessary to construe the term “lateral, trans-psoas approach” as appears in claim 6. Claims terms are usually given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the underlying patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). The written description underlying a claim usually provides authoritative guidance in determining claim meaning. *See id.*

Turning to the specification of the ’058 Patent, we take note of the following passages (’058 Patent, 1:52-62; 2:30-39; 15:3-8):

One drawback associated with prior art surgical access systems relates to the ease with which the operative corridor can be created as well as maintained over time, depending upon the particular surgical target site. For example, when accessing surgical target sites located beneath or behind musculature or other relatively strong tissue (such as, by way of example only, the psoas muscle adjacent to the spine), it has been found that advancing an operative corridor-establishing instrument directly through such tissues can be challenging and/or lead to unwanted or undesirable effects (such as stressing or tearing the tissues).

This can be seen, by way of example only, in the spinal arts, where the exiting nerve roots and neural plexus structure in the psoas muscle have rendered a lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine virtually impossible. Instead, spine surgeons are largely restricted to accessing the spine from the posterior (to perform, among other procedures, posterior lumbar interbody fusion (PLIF)) or from the anterior (to perform, among other procedures, anterior lumbar interbody fusion (ALIF)).

This is to prevent the unnecessary distraction of the psoas muscle **304** (which must be passed through in order to approach the surgical target site in the lateral or far-lateral approach shown) in the instance significant nerves or neural structures are encountered in the initial advancement of the K-wire **44**.

From the content of the '058 Patent, including the above-quoted passages, one with ordinary skill in the art would understand that the claimed “lateral, trans-psoas approach” describes a spinal surgery technique in which the target area of the spine is accessed laterally, or from the side of a patient’s spine, as opposed to a posterior or anterior approach, and which passes through the psoas muscle.

ii. Each of Schick, Michelson, and Mathews '826

Each of Schick, Michelson and Mathews '826 describes surgical techniques directed to regions of a patient’s spine. In particular, Schick describes the recognition in the art that “percutaneous treatment of lumbar disc herniations” may be accomplished through practices expressed as “[l]ateral percutaneous techniques.” (Schick, Introduction.)

In Michelson, the inventive spinal surgery techniques disclosed are characterized in the following manner (Michelson, 3:46-56):

The present invention is directed to methods and instrumentation for performing surgery on the spine along its lateral aspect (side) and generally by a lateral or an anterolateral surgical approach, from a position anterior to the transverse processes of adjacent vertebrae of the spine, such that the instruments enter the body from an approach that is other than posterior and make contact with the spine along its lateral aspect. The present invention provides for the entire surgical procedure to be performed through a relatively small incision and may be performed in either the thoracic or lumbar spine.

Mathews '826 discloses that its invention is directed to “techniques for percutaneous, minimally invasive spinal surgery.” (Mathews '826, 1:11-15.) The invention is further explained as being applicable “at various levels of the spine including the cervical, thoracic and lumbar spine,” and may be “used in various approaches to the spine.” (*Id.* at 12:62-66.) In describing one particular embodiment directed to the thoracic region of the spine, Mathews '826 explains that one such approach that is envisioned is a “translateral approach.” (*Id.* at 13:9-11.)

Thus, the prior art, specifically each of Schick, Michelson, and Mathews '826, reasonably conveys that either a “lateral” approach or a “translateral” approach may be employed in areas of the spine which include the lumbar region and the thoracic region. With that in mind, we consider the declaration testimony of NuVasive’s and Medtronic’s expert witnesses, Dr. Garfin and Dr. Mathews, respectively.

Regarding the location of the psoas muscle in a patient’s spine, Dr. Garfin testifies (Garfin Decl., ¶ 4):

It is well known that the psoas muscle originates at the lower-most thoracic vertebral bone (T12) and, in some patients, originates at the upper-most lumbar vertebra (L1). In either case, the psoas muscle originates as a very narrow connection located toward the posterior aspect of the vertebra (T12 or L1).

Dr. Mathews does not disagree with Dr. Garfin’s testimony in that regard. Indeed, Dr. Mathews also testifies that the psoas muscle is located in the “lumbar” region of the spine. (Mathews Decl., ¶ 5.) The record thus reflects that the psoas muscle is generally understood as being located in

areas adjacent the lumbar region and portions of the thoracic region alongside a patient's spine.

In light of the above, including the teachings of the prior art and the expert testimony, it is evident that in the spinal surgery art those with ordinary skill would have readily recognized that a "lateral" or "translateral" surgical approach in the area of the spine in which the psoas muscle resides were known and viable techniques. Both Dr. Garfin and Dr. Mathews testify that it was known in the art that such a lateral approach may be accomplished in a manner in which the psoas muscle is either avoided or retracted such that the approach is not a "trans-psoas" lateral approach, *i.e.*, the psoas muscle is not passed through. (*See* Garfin Decl., ¶ 3; Mathews Decl., ¶ 5.) However, that a "trans-psoas" approach may not "necessarily" occur, as is testified by Dr. Garfin (Garfin Decl., ¶ 3), provides little meaningful guidance in evaluating the obviousness of such an approach, which is the inquiry before us.

We observe that Dr. Mathews testifies that a surgeon would have recognized that a "lateral approach" may involve a procedure which passes through the psoas muscle. (Mathew Decl., ¶ 5.) Dr. Garfin does not dispute that testimony. Indeed, as support for that testimony, Dr. Mathews makes reference to other extrinsic evidence including U.S. Patent 5,313,962 (the "'962 Patent"). The '962 Patent is directed to a method of performing surgery characterized as laparoscopic lumbar discectomy (Abstract) and clearly conveys that when taking a "lateral" approach "the surgery may traverse through the psoas muscle." ('962 Patent, 6:14-32.) We credit Dr. Mathews' testimony and conclude that those of ordinary skill in the art

would have generally recognized that a lateral surgical approach to the spine may traverse through the psoas muscle.

References are available for all of their specific teachings, as well as the inferences one of ordinary skill in this art would have reasonably been expected to draw therefrom. *In re Fritch*, 972 F.2d 1260, 1264-65 (Fed. Cir. 1992). One of ordinary skill in the art is also presumed to have knowledge apart from what the prior art references explicitly state. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Here, although each of Schick, Michelson, and Mathews '826 do not make explicit that their disclosure of "lateral" or "translateral" approaches encompasses "trans-psoas lateral" approaches, the record suitably conveys that one of ordinary skill in the art of spinal surgery would have known that traversing the psoas muscle is an available and viable option when performing such surgery. We thus reject NuVasive's argument to the contrary.

After due consideration of the record, we are of the opinion that the Examiner was incorrect in not adopting the rejections proposed by Medtronic which incorporate the teachings of either Schick, Michelson, or Mathews '826 based on the position that none of those references teach a "lateral trans-psoas approach." (RAN, 5-6.) In our view, such a position does not fully consider what a skilled artisan would have understood about a "lateral" or "translateral" surgical approach from the teachings in those references. We conclude, therefore, that the Examiner has not adequately explained why the rejections proposed by Medtronic, and numbered in this opinion as (9)-(15), do not demonstrate the obviousness of claim 6. We

observe that the claim charts filed October 14, 2009 and labeled A-F and I appropriately inform the basis of the rejections of claim 6 which were proposed by Medtronic, but not adopted by the Examiner.

Claims 57-64 ultimately depend from claim 6. Medtronic's proposed rejections of claims 57-64 are laid out in the claim charts designated "Claim Chart A – Continued," "Claim Chart B – Continued," and "Claim Chart D – Continued" filed March 19, 2010.

For the foregoing reasons, we reverse the Examiner's decision not to adopt the rejections of claims 6 and 57-64¹⁴ numbered in this opinion as (9)-(15). **Pursuant to 37 C.F.R. § 41.77(b), our reversal in that regard, and our entry of the rejections herein as proposed by Medtronic, constitutes a new ground of rejection.**

d. Claim 10

Also at issue in this appeal are three proposed rejections of claim 10, numbered (16)-(18) in this opinion. Those rejections are as follows:

- (16) Mathews '826, Michelson, Kelleher, and Finneran
- (17) Koros, Michelson, Foley '871, Kelleher, and NIM Guide
- (18) Smith, Michelson, Koros, Marino, and NIM Guide

Claim 10, like claim 6, is directed to a method of accessing a surgical target site and includes a requirement that an operative corridor is formed "along a lateral, trans-psoas path." NuVasive makes essentially the same

¹⁴ As noted *supra* Medtronic has proposed no rejection of dependent claim 65 which depends from claim 6. Claim 65 specifies that the "secondary instrument" introduced in claim 6 is a "speculum assembly." (App. Br. Claims App'x, xiii.)

argument with respect to that requirement as it did with claim 6. Namely, according to NuVasive, the prior art does not disclose a spinal surgical path or approach that is a “lateral, trans-psoas” one. We disagree.

Each of the above-noted rejections includes the teachings of either Mathews '826 or Michelson. As discussed above in connection with claim 6, those references describe a “lateral” or “translateral” path for accessing a targeted surgical area of the spine. For the same reasons noted above with respect to claim 6, we conclude that a person of ordinary skill in the art would have recognized that traversing the psoas muscle, *i.e.*, a lateral trans-psoas path, would have been a recognized option when undertaking a lateral or translateral approach. We reject NuVasive’s contention which conflicts with that conclusion.

NuVasive, however, also offers additional reasons as to why the Examiner’s refusal to adopt the involved rejections of claim 10 was correct. In that regard, NuVasive contends that the prior art does not account for the feature in claim 10 directed to a “locking member” that is “releasably received *within a passageway of the first retractor blade*” of the retractor assembly. (Resp. Br., 22.) Medtronic takes the position that the above-quoted requirement is accounted for in each of Mathews '826 and Koros.

In particular, Medtronic relies on component 115 in Mathews '826 as forming the “locking member” required by claim 10. (App. Br., 38-39.) Mathews '826’s component 115 is described as “a pair of guide pins” or “fixation pin[s]” which extend through “pin bores **60, 61**” provided in the outer wall 51 and inner wall 54 of ring member 50 and anchor the ring member to the surgical cite. (Mathews '826, 7:24-46; 9:38-42.) Medtronic

also relies on Koros as disclosing “screws 83” acting as the required locking members. (App. Br., 39-41.) Koros’ screws 83 are described as “fixation screws” which extend through tubular guides 82 and 86 associated with Koros’ distractor blades 32. (Koros, 6:53-67.)

After careful review of Medtronic’s position, we are not persuaded that it has suitably accounted for the locking members configured as required by NuVasive’s claim 10. In particular, while we agree that Mathews ’826’s pins 115 and Koros’ screws 83 are themselves locking members, it is not evident how those members are “received within a passageway of the first retractor blade.” In Mathews ’826, the pin bores 60 and 61 are located in ring member 50 and are not passageways “within” any retractor blade. In Koros, the tubular guides 82 and 86 are associated with Koros’ distractor blades 32 and not the separate retractor blades 30 of its assembly. Although Medtronic generally contends that the locking components of Mathews’826 and Koros are within a “passageway” (App. Br., 38-39), lacking from those contentions is a suitable explanation as to how the referenced passageways are “a passageway *of the first retractor blade.*” (App. Br. Claims App’x, iv) (emphasis added).

Accordingly, for the foregoing reasons, we are not persuaded that Medtronic has appropriately accounted for all the requirements of NuVasive’s claim 10 in the rejections numbered (16)-(18) in this opinion. Accordingly, we do not discern error in the Examiner’s decisions declining to adopt those rejections of claim 10 of the claims 11-29 which ultimately depend therefrom. The Examiner’s decisions are affirmed.

e. Claim 30

Medtronic's appeal in connection with claim 30 involves the following rejections:

- (19) Mathews '826, Michelson, and Kelleher
- (20) Koros, Foley '871, Michelson, and Kelleher
- (21) Smith, Michelson, Marino, and NIM Guide

Claim 30 is drawn to a method of accessing a surgical target site. Similar to claims 6 and 10, claim 30 includes recitation of a corridor formed "along a lateral trans-psoas path." Claim 30, like claims 1 and 4, also requires steps directed to nerve monitoring including sensing, determining, and communicating nerve proximity. With respect to the above-noted features, NuVasive relies on the same arguments that were advanced in conjunction with claims 6 and 10 and also claims 1 and 4.

As discussed *supra*, we are persuaded that the prior art of Mathews '826 and Michelson suitably accounts for "a lateral trans-psoas path" with respect to targeting a surgical site of the spine. We also are persuaded that it would have been obvious to one with ordinary skill in the art to combine Kelleher's teachings directed to nerve monitoring to a variety of types of spinal surgery, including the prior art associated with rejections (19)-(21) noted above. The teachings of NIM guide, which is titled "Nerve Integrity Monitor," are similar in nature to those of Kelleher in so far as nerve proximity sensing, determining, and communicating is concerned.

In connection with rejection (21) involving Smith, NuVasive also takes a position that the reference lacks disclosure of retractor blade portions which are "similarly sized." (Resp. Br., 24.) Pointing to Smith's Figures 1

and 7 and column 3, lines 53-56, NuVasive urges that Smith's retractor blades must be different sizes. (*Id.*) We do not agree with NuVasive.

The cited portion of Smith at column 3 does not require that the retractor blades have different sizes, and instead simply sets forth that in one embodiment of Smith's invention, one of the blades is greater in length than the other. It is not apparent that the blades of Smith, even if having different lengths or some variation in their respective sizes, are nevertheless not understood as being "similarly" sized. Moreover, as argued by Medtronic (Reb. Br., 17), it is clear from the disclosures of other involved references, such as Koros, that it is understood in the art that retractor blades may have the same size.

We have considered NuVasive's arguments but are not persuaded that they point out deficiencies in the prior art in accounting for the features required by claim 30. We are in agreement with Medtronic that the Examiner should have adopted the proposed rejections of claim 30, numbered in this opinion as (19)-(21). Accordingly, we reverse the Examiner decision not to adopt the rejections of claim 30 and dependent claims 31-47, 49, and 50 that are set forth in Medtronic's Claim Charts J, K, and L filed March 19, 2010.¹⁵ **Pursuant to 37 C.F.R. § 41.77(b), our reversal of the Examiner's decision with respect to claims 30-47, 49, and 50, and our entry of the rejections herein as proposed by Medtronic, constitutes a new ground of rejection.**

¹⁵ Upon review of the record, including the noted claim charts, it is evident that Medtronic proposed no prior art rejection of claim 48 which depends from claim 30. Claim 48 requires that a "secondary instrument" introduced in claim 30 be a "speculum assembly." (App. Br. Claims App'x, x.)

D. CONCLUSION

1. The Examiner should have rejected claims 10-50 as being impermissibly enlarged in scope under 35 U.S.C. § 314.
2. The Examiner was correct in not rejecting claims 10-16, 19-27, 30-36, 38-43, 45-50, and 57 as lacking adequate written description in the specification of the '058 patent for any recited claim features. The Examiner was not correct in declining to so reject claims 17, 18, 28, 29, 37, and 44.
3. The record does not show that a person of ordinary skill in the art would have regarded a tubular type working cannula as a retractor blade or a plurality of retractor blades.
4. The record shows that a person of ordinary skill in the art would have understood from the prior art that a surgical target site in a patient's spine may be reached via a "lateral trans-psoas" approach or path.
5. Medtronic has adequately shown that the Examiner was not correct in concluding that none of NuVasive's claims would have been obvious in light of the teachings of prior art.

The ORDER appearing below sets forth our reversals and affirmances of the Examiner's decisions in light of the above-noted conclusions. We observe that, based on those conclusions, at least one rejection should have been applied to each of the claims 1, 2, 4-8, 10-55, and 57-64 involved in this appeal. No rejection has been proposed for either claim 56 or claim 65, nor do we enter any rejection of those claims.

E. ORDER

REVERSALS

35 U.S.C. § 314

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The Examiner's decision not to adopt Medtronic's proposed rejection of claims 10-50 under 35 U.S.C. § 314 as being improperly broadened (numbered as rejection (23) in this opinion) is **reversed**.

35 U.S.C. § 112

The Examiner's decision not to adopt Medtronic's proposed rejection of claims 28, 29, and 44 under 35 U.S.C. § 112, first paragraph (*see* section II.d. of this opinion) is **reversed**.

The Examiner's decision not to adopt Medtronic's proposed rejection of and claims 17 and 37 under 35 U.S.C. § 112, first paragraph (*see* section II.e. of this opinion) is **reversed**.

We also **enter** a new ground of rejection of claim 18 on the same basis.

Prior Art Rejections

The Examiner's decision not to adopt Rejection (3) based on Smith and Rose and involving claims 1, 2, 4, 5, 7, 8, and 51-55 is **reversed**.

The Examiner's decision not to adopt Rejection (5) based on Mathews '279 and Neubardt involving claims 1, 2, 4, 5, 7, and 8 is **reversed**.

The Examiner's decision not to adopt Rejection (8) based on Mathews '826 and Kelleher and involving claims 4, 5, 7, and 8 is **reversed**.

The Examiner's decision not to adopt Rejections (9)-(15)¹⁶ involving claims 6 and 57-64 is **reversed**.

The Examiner's decision not to adopt Rejections (19)-(21)¹⁷ involving claims 30-50 is **reversed**.

AFFIRMANCES

35 U.S.C. § 112

The Examiner's decision not to adopt Medtronic's proposed rejection of claims 10-29 and 57 under 35 U.S.C. § 112, first paragraph (*see* section II.a. of this opinion) is **affirmed**.

The Examiner's decision not to adopt Medtronic's proposed rejections of claims 30-50 under 35 U.S.C. § 112, first paragraph (*see* section II.b. of this opinion) is **affirmed**.

¹⁶ (9) Foley Article, Kelleher, and Schick;
(10) Foley '871, Marino, and Michelson;
(11) Mathews Article, Kelleher, and Michelson;
(12) Smith, Rose, and Schick;
(13) Foley Article, Epoch 2000, and Schick;
(14) Mathews '279, Neubardt, and Michelson; and
(15) Mathews '826 and Kelleher.

¹⁷ (19) Mathews '826, Michelson, and Kelleher;
(20) Koros, Foley '871, Michelson, and Kelleher; and
(21) Smith, Michelson, Marino, and NIM Guide.

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The Examiner's decision not to adopt Medtronic's proposed rejections of claims 10-29 under 35 U.S.C. § 112, first paragraph (*see* section II.c. of this opinion) is **affirmed**.

Prior Art Rejections

The Examiner's decision not to adopt Rejection (1) based on Foley Article and Kelleher and involving claims 1, 2, 4, 5, 7, 8, and 51-55 is **affirmed**.

The Examiner's decision not to adopt Rejection (2) based on Foley '871 and Marino and involving claims 1, 2, 4, 5, 7, 8, and 51-55 is **affirmed**.

The Examiner's decision not to adopt Rejection (4) based on Foley Article and Epoch 2000 and involving claims 1, 2, 4, 5, 7, 8, and 51-55 is **affirmed**.

The Examiner's decision not to adopt Rejection (6) based on Mathews Article and Kelleher and involving claims 4, 5, 7, and 8 is **affirmed**.

The Examiner's decision not to adopt Rejection (7) based on Mamo and Foley '871 and involving claims 4, 5, 7, and 8 is **affirmed**.

The Examiner's decision not to adopt Rejections (16)-(18)¹⁸ involving claims 10-29 is **affirmed**.

¹⁸ (16) Mathews '826, Michelson, Kelleher, and Finneran;
(17) Koros, Michelson, Foley '871, Kelleher, and NIM Guide; and
(18) Smith, Michelson, Koros, Marino, and NIM Guide.

This opinion, including the above-noted reversals, contains new grounds of rejection pursuant to 37 C.F.R. § 41.77(b) which provides that “[a]ny decision which includes a new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.” 37 C.F.R. § 41.77(b) also provides that the Patent Owner, WITHIN ONE MONTH FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

- (1) *Reopen prosecution.* The owner may file a response requesting reopening of prosecution before the examiner. Such a response must be either an amendment of the claims so rejected or new evidence relating to the claims so rejected, or both.
- (2) *Request rehearing.* The owner may request that the proceeding be reheard under § 41.79 by the Board upon the same record. ...

Any request to reopen prosecution before the examiner under 37 C.F.R. § 41.77(b)(1) shall be limited in scope to the “claims so rejected.” Accordingly, a request to reopen is limited to issues raised by the new ground(s) of rejection entered by the Board. A request to reopen prosecution that is directed to issues other than those raised by the new ground(s) is unlikely to be granted. Likewise, comments of the requester under 37 C.F.R. § 41.77(c) shall be limited in scope to the issues raised by the Board's opinion reflecting its decision to reject the claims and the owner's response under paragraph (b)(1). New proposed rejections are not permitted unless presented in response to an amendment and/or new evidence submitted by the owner which is properly limited to issues raised by the new ground(s) of

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rejection entered by the Board. The Examiner will issue a determination under 37 C.F.R. § 41.77(d) as to whether the Board's rejection is maintained or has been overcome, and return the proceeding to the Board together with any comments and reply submitted by the owner and/or requester under 37 C.F.R. § 41.77(e) for reconsideration and issuance of a new decision by the Board as provided by 37 C.F.R. § 41.77(f).

AFFIRMED-IN-PART; REVERSED-IN-PART

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