UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

WARSAW ORTHOPEDIC, INC., MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC PUERTO RICO OPERATIONS COMPANY, and OSTEOTECH, INC., Plaintiffs, vs. NUVASIVE, INC., Defendant.	CASE NO. 12-cv-2738-CAB SECOND CLAIM CONSTRUCTION ORDER

I. Introduction

On November 7, 2013, the Court held a hearing to construe claims of four patents asserted by NuVasive, Inc., against Warsaw Orthopedic, Inc., Medtronic Sofamor Danek U.S.A., Inc., Medtronic Puerto Rico Operations Co., and Osteotech, Inc. (hereinafter collectively "Warsaw") – U.S. Patent Nos. 8,005,535 ("the '535 patent") and 8,000,782 ("the '782 patent"), which share a common specification; U.S. Patent No. 8,016,767 ("the '767 patent"); and U.S. Patent No. 8,192,356 ("the '356 patent"). The parties filed briefs and claim construction charts in accordance with the local rules of this District. [Doc. Nos. 109, 121, 123, 124 and related exhibits.] Luke Dauchot, Esq., Alexander MacKinnon, Esq., Nimalka Wickeramasekera, Esq., and Sharre Lotfollahi, Esq., appeared for Warsaw. Frank Scherkenbach, Esq., Michael Kane, Esq., and John Lamberson, Esq., appeared for NuVasive. Having considered the submissions of the

parties and the arguments of counsel, the Court construes the disputed terms addressed at argument[1] as follows.

II. Legal Standard

The Court construes the claim language when the parties dispute what a person of skill in the art would understand the term to mean. Claims are not read in a vacuum but in the context of the entire patent including the specification. *See Phillips v. AWH Corp*., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). The claims, the specification and the prosecution history are the most significant source of the legally operative meaning of disputed claims language. *See SmithKline Beecham Corp. v. Apotex Corp*., 403 F.3d 1331, 1338 (Fed Cir. 2005). The words of a claim are generally given the ordinary and customary meaning that a person of ordinary skill would have applied at the time of the invention. *Phillips*, 415 F.3d at 1313.

III. The '535 and '782 Patents

The '535 patent and '782 patent [Doc. Nos. 102-5 and 102-4, respectively] are directed at a method and system for performing surgical procedures involving the use of neurophysiology. [Doc. No. 102-5, Col. 1:22-26.] They share a common specification. The invention of the '535 patent claims methods for creating a working corridor through the patient's psoas muscle to insert a spinal implant while monitoring the relationship between the surgical instruments and the patient's nerves to avoid damaging nerves during the procedure. The fundamental method steps of the invention include: (a) stimulating one or more electrodes provided on a surgical accessory; (b) measuring the response of nerves innervated by the stimulation of step (a); (c) determining a relationship between the surgical accessory and the nerve based upon the response measured in step (b); and communicating this relationship to the surgeon in an easy-to-interpret fashion. [*Id.*, Col. 3:27-34.] The invention of the '782 patent

[1] At the hearing counsel represented that the parties had reached agreement as to the construction of certain terms of these patents previously submitted as disputed. Any terms not addressed in this order are therefore deemed withdrawn from the Court's consideration without prejudice to a request for construction upon a showing of good cause.

claims a surgical system for creating and using the corridor while monitoring the relationship between the instruments and the patient's nerves. The system is capable of performing one or more of the following functions: (1) determination of nerve proximity and/or nerve direction relative to the sequential dilation access system during and following the creation of an operative corridor to surgical target site; (2) assessment of pedicle integrity after hole formation and/or after pedicle screw placement via the pedicle testing assembly; and/or (3) assessment of nerve pathology (health or status) before, during, and/or after a surgical procedure via the nerve root retraction assembly. [Doc. No. 102-4, Col. 10:49-59.]

A. The '535 Patent Constructions for Claim 1

The terms and phrases of the '535 patent's only independent claim, Claim 1, set forth in bold italics, are presented by the parties for construction. These constructions apply to the asserted dependent claims (Claims 3, 11 and 12), as well.

> Claim 1. A method of inserting a spinal implant through a trans-psoas operative corridor to an intervertebral disc, comprising:
> mounting a plurality of EMG electrodes proximate to selected leg muscles;
> activating a control unit operable to provide a stimulation signal and including a graphical user interface to receive user input and to display neuromuscular response information in response to signals from the EMG electrodes;
> inserting an ***initial dilator cannula*** in a trans-psoas path through bodily tissue toward a lateral aspect of a spine while an elongate stimulation instrument is disposed within an inner lumen of the initial dilator cannula;
> activating the elongate stimulation instrument to deliver the stimulation signal proximate to a distal end of the initial dilator cannula ***when the initial dilator cannula is inserted into the trans-psoas path toward the spine***;
> monitoring the neuromuscular response information displayed by the control unit in response to delivery of the stimulation signal when the initial dilator cannula is inserted into the trans-psoas path toward the spine;
> advancing two or more sequential dilator cannulas of increasing diameter in the trans-psoas path toward the spine,
> advancing a working corridor instrument over the two or more sequential dilator cannulas in the trans-psoas path toward the spine;
> establishing a trans-psoas operative corridor to an intervertebral disc of the spine using the working corridor instrument; and
> delivering a spinal fusion implant through the trans-psoas operative corridor toward the spine.

[Doc. No. 102-5, Col. 27:21-51.]

1. *initial dilator cannula*

Based on a plain reading of the claim language the initial dilator cannula is the first tube inserted to expand an opening or passage through bodily tissue. This is not disputed. Warsaw however contends that this claim element must be interpreted in conjunction with the later step of advancing two or more sequential dilator cannulas of increasing diameter, such that the initial dilator should be construed to be the first tube in a series that includes the later claimed sequential tubes of increasing diameter.

The patent specification suggests the claimed invention encompasses a variety of systems for accomplishing the method steps, [Doc. No. 102-5, Col. 5:4-52], however the only method claimed is specific to the use of a sequential dilation access system that employs an initial dilator cannula, two or more sequential dilator cannulas and a working corridor instrument to accomplish the steps of establishing the trans-psoas operative corridor. [*Id.*, Col. 27:21-51.]

The specification identifies Figs. 16-19 as the illustration of "the sequential dilation access system 34 of the present invention in use creating an operative corridor." [*Id.*, Col. 19:62-67; Col. 18:52-57 (emphasis added)]. By referring to the disclosed system as the system of the present invention used to accomplish certain steps of the claimed method, and claiming and disclosing no other system to achieve these steps, Warsaw argues the patent is limited to the disclosed embodiment.

In the specification, the initial dilator cannula 48 is shown as part of a series of cannulae of increasing diameter and the specification instructs that the cannulae of increasing diameter are guided over the previously installed cannula, illustrated in Fig. 17. [*Id.*, Col. 20:31-35.] Once the working cannula 50 is in place, the sequential cannulae may be removed to establish the working corridor. [*Id.*, Col. 20:43-47.] Warsaw contends that this description, identified as "the system of the present invention," dictates that the initial dilator cannula be construed as part of the sequential dilation access system and further requires that in use, the two or more sequential dilator cannulas be advanced over the initial dilator cannula. This is the sequential

dilation access system described in the specification as "the system of the present invention" and the language of Claim 1 is limited to the use of a sequential dilation access system.

The Court agrees that the claim itself limits the method to the use of a sequential dilation access system, the specification discloses the sequential dilation access system of the invention, and in that disclosed system the two or more sequential dilator cannulas are advanced over the initial dilator cannula. No other sequential dilation access system is disclosed. The Court therefore construes the *initial dilator cannula* to be the first tube in a series of sequential tubes of increasing diameter.

2. *when the initial dilator cannula is inserted into the trans-psoas path toward the spine*

This phrase defines the method step of when the elongate stimulation instrument, disposed within the initial dilator cannula, is activated to deliver a stimulation signal. Based on the plain language of the claim, in the context of the entire claim and the specification, the Court construes this phrase as the continuous or selective delivery of the stimulation signal while the initial cannula is advanced from the point of insertion into the patient through the psoas muscle to the target spinal area. [*Id.*, Col. 20:18-20 (the electrode may be stimulated continuously or step-wise).]

B. The '535 Patent Construction for Claim 11

The following term of Claim 11, set forth in bold italics, was presented by the parties for construction.[2]

> Claim 11. A method of claim 10, wherein the ***numeric stimulation threshold current level***, displayed by the control unit indicates an amplitude of the stimulation current pulses that evokes an EMG response having an amplitude value greater than a predetermined voltage value.

[*Id.*, Col. 28:39-43.]

1. *numeric stimulation threshold current level*

[2] At the claim construction hearing the parties withdrew this term to allow them to further meet and confer on a joint construction. Supplemental briefs regarding the unresolved issues were submitted by each party on December 9, 2013 [Doc. Nos. 147 and 149] for the Court's consideration.

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