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Attorneys for Plaintiff NuVasive, Inc.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SAN DIEGO DIVISION

NUVASIVE, INC., a Delaware corporation,

Plaintiff,

v.

ALPHATEC HOLDINGS, INC., a Delaware corporation, and ALPHATEC SPINE, INC., a California corporation,

Defendants.

CASE NO. 3:18-cv-0347-CAB-MDD

DECLARATION OF JIM A. YOUSSEF, M.D. IN SUPPORT OF NUVASIVE'S MOTION FOR PRELIMINARY INJUNCTION

Judge: Hon. Cathy Ann Bencivengo
Courtroom: 4C
Hearing Date: May 10, 2018

JURY TRIAL DEMANDED

TABLE OF CONTENTS

Page

I. BACKGROUND 1

II. EXPERT QUALIFICATIONS 1

III. LEGAL STANDARDS PROVIDED BY COUNSEL 3

IV. SUMMARY OF OPINIONS 4

V. BACKGROUND 5

A. History of Spinal Fusion Procedures Prior to XLIF 5

B. XLIF Solves the Problems Associated With Other Procedures 14

i. Access Tools 16

ii. Implant 19

iii. Neuromonitoring 20

iv. NuVasive's Patents 21

VI. ALPHATEC'S PRODUCTS 22

VII. PERSON OF ORDINARY SKILL IN THE ART 23

VIII. CLAIM CONSTRUCTION 24

A. Lateral, Trans-Psoas Path 25

B. Pivoting First And Second Pivotable Arm Members Relative To One Another 25

C. Rigidly Coupled 26

D. Closed Position 26

E. Opened 27

F. Groove 27

IX. U.S. PATENT NO. 7,819,801 28

A. Claim 1 29

i. A system for accessing a surgical target site, comprising 29

ii. a dilator system comprising a plurality of sequential dilators deliverable along a lateral, trans-psoas path to a targeted spinal site to create a distraction corridor; 30

iii. a handle assembly including a first pivotable arm member, a second pivotable arm member that pivots relative to said first arm member in response to manual adjustment of a component of the handle assembly, and a translating member adapted to move longitudinally relative to said first and second arm members;..... 31

iv. a first retractor blade having a generally concave inner facing surface and being rigidly coupled to said first pivotable arm member prior to introduction toward the targeted spinal site, a second retractor blade having a generally concave inner-facing surface and being rigidly coupled to said second pivotable arm member prior to introduction toward the targeted spinal site, and a third retractor blade rigidly coupled to said translating member prior to introduction toward the targeted spinal site; 33

v. an intradiscal shim element that releasably mounts to the third retractor blade such that a maximum length of the intradiscal shim element extends generally parallel to a maximum length of the third retractor blade and a distal tip portion of the intradiscal shim element extends distally of the distal end of the third retractor blade, wherein the intradiscal shim element engages with a groove defined by the third retractor blade to penetrate into a spinal disc at the targeted spinal site when the intradiscal shim element is releasably mounted to the third retractor blade; and 35

vi. said handle assembly being configured to simultaneously introduce said first, second and third retractor blades along the lateral, trans-psoas path toward the targeted spinal site in a closed position while the generally concave inner-facing surfaces of said first and second retractor blades engage with an outermost dilator of the dilator system and thereafter opened by pivoting said first and second pivotable arm members relative to one another to create an operative corridor to said surgical target site. 36

B. Claim 2: The system of claim 1, further comprising a K-wire configured to be advance along the lateral, trans-psoas path to the targeted spinal site and engage an annulus of said spinal disc, the K-wire further configured to extend entirely through a dilator of said dilator system from the annulus of the spinal disc to a position beyond a proximal most end of the dilator system. 38

C. Claim 6: The system of claim 1, wherein at least one of said plurality of sequential dilators is equipped with at least one stimulation electrode. 38

D. Claim 15: The system of claim 1, wherein each of the plurality of sequential dilators includes a stimulation electrode at a distal region. 39

E. Claim 16: The system of claim 15, further comprising a K-wire configured to be advanced to the targeted spinal site and to engage an annulus of said spinal disc at the targeted spinal site, wherein at least one of the plurality of sequential dilators are deliverable over the K-wire. 39

F. Claim 19: The system of claim 1, wherein the third retractor blade includes a generally concave inner-facing surface and the groove of the third retractor blade is formed along the generally concave inner-facing surface. 40

G. Claim 20: The system of claim 19, wherein the intradiscal shim element includes at least one dovetail element to mate with the groove of the third retractor blade. 40

H. Claim 23: The system of claim 1, wherein said handle is configured to simultaneously move said first arm member and said second arm member. 40

I. Claim 26: The system of claim 1, further comprising a shim insertion tool that releasably attaches to the intradiscal shim element during introduction of the intradiscal shim element toward the targeted spinal site. 41

J. Claim 28: The system of claim 1, wherein the handle assembly further includes a locking mechanism to selectively lock at least the first arm member in a retracted position such that the first retractor blade is spaced apart from the second retractor blade..... 41

K. Claim 29: The system of claim 1, wherein the first, second, and third retractor blades define an operative corridor to the targeted spinal site when moved to the opened position such that an implant is deliverable through the operative corridor to the targeted spinal site. 41

X. U.S. PATENT NO. 8,355,780 42

A. Claim 21 43

i. A system for forming an operating corridor to a lumbar spine, comprising: 43

ii. a dilator system to create a distraction corridor along a lateral, trans-psoas path to the lumbar spine, wherein said dilator system comprises at least two dilators of sequentially larger widths deliverable to a spinal disc along the lateral, trans-psoas path to the lumbar spine, a second dilator of said at least two dilators being slidably engageable with an exterior of a first of said at least two dilators, at least one of the first and second dilators including a stimulation electrode to deliver electrical stimulation for nerve monitoring when the stimulation electrode is positioned along the lateral, trans-psoas path to the lumbar spine; 44

iii. a three-bladed retractor assembly slidable over the dilator system toward the spinal disc along the lateral, trans-psoas path, the three-bladed retractor assembly including: 45

iv. a blade holder assembly and first, second, and third retractor blades that extend generally perpendicularly relative to arm members of the blade holder assembly, ... 45

v. wherein the three-bladed retractor assembly is adjustable from a first position in which the first, second, and third retractor blades are adjacent to one another and slidable over the dilator system to a second position in which the second and third retractor blades are moved away from the first retractor blade to enlarge the distraction corridor and thereby form an operative corridor along the lateral, trans-psoas path to the lumbar spine, ... 46

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