Calse 3:18-cv-00347-CAB-MDD Document 281 Filed 04/10/20 PageID.26346 Page 1 of 15



<sup>2</sup> At Doc. Nos. 1-8; 1-6; and 1-12, respectively.

28

9,833,227; U.S. Patent No. 8,753,270; U.S. Patent No. 9,924,859; and U.S. Patent No. 9,974,531.

adjudication of the validity of all seven of the asserted patents. Finally, NuVasive moves for summary adjudication of Alphatec's inequitable conduct affirmative defense. [Doc. No. 250.] Alphatec opposed. [Doc. No. 260.] NuVasive filed a reply. [Doc. No. 262.] The Court held oral argument on March 13, 2020. Having considered the submissions of the parties and the arguments of counsel, the motion is GRANTED IN PART and DENIED IN PART.

The patents-at-issue generally claim a surgical access system including a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optimally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor to a surgical target site.<sup>3</sup> In particular, the systems are designed for use in creating an operative corridor in a lateral, trans-psoas path to the lumbar spine.

NuVasive accuses Alphatec's Battalion Lateral Lumbar Spacer System ("Battalion System") of infringing various claims of the patents at issue and moves for summary judgment of infringement of claims 1, 3, 9 and 10 of the '832 patent, claims 21, 22, 24 and 27 of the '780 patent, and claims 1, 2, 3, 6 and 12 of the '270 patent.

## I. Summary Judgment of Infringement

Pursuant of Fed. R. Civ. P. 56(a), summary judgment is appropriate when "there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." To prove direct infringement a patentee must establish, by a preponderance of the evidence, that one or more claims of the patent read on the accused device literally or under the doctrine of equivalence. *See Adv. Cardiovascular Sys., Inc., v. Scimed Life Sys., Inc.* 261 F.3d 1329, 1336 (Fed Cir. 2001). Summary judgment for the plaintiff on the issue of infringement is proper when no reasonable jury could not find that every limitation recited in a properly construed claim is found in the accused device either literally or under

<sup>&</sup>lt;sup>3</sup> See Abstract, '832 Patent; Abstract '780 Patent; Abstract '270 patent.



the doctrine of equivalents. *See PC Connector Solutions LLC v. Smartdisk Corp.*, 406 F.3d 1359, 1364 (Fed. Cir. 2005).

Determining whether a claim has been infringed requires a two-step analysis. First the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device. *Id.* at 1362.

#### A. The '832 Patent

The '832 patent is for a "Surgical Access System and Related Methods." The system is designed to establish an operative corridor through or near any of a variety of tissues having neural structures which, if contacted or impinged, may result in neural impairment for the patient. [Doc. No. 1-8, at Col. 2:65- Col. 3:3.] A specific intended use of the system of the '832 patent, as set forth in claim 1, is to create an operative corridor in a lateral, trans-psoas path to the lumbar spine. NuVasive alleges Alphatec's Battalion System literally infringes the following claims.

Claim 1. A system for forming an operating corridor to a lumber spine, comprising:

a distraction assembly to create a tissue distraction corridor in a lateral, transpsoas path to a lumbar spine, wherein said distraction assembly includes an elongate inner element and a plurality of dilators, the plurality of dilators being configured to sequentially advance along the lateral, trans-psoas path to the lumbar spine, the elongate inner element being positionable in a lumen of an initial dilator of the plurality of dilators, wherein at least one instrument from the group consisting of said elongate inner element and said dilators includes a stimulation electrode that outputs electrical stimulation for nerve monitoring when the at least one instrument is positioned in the psoas muscle;

a three-bladed retractor tool slidable over an exterior of an outermost sequential dilator of the dilator system toward the targeted spinal disc along the lateral, trans-psoas path, the three-bladed retractor assembly including:

a blade-holder assembly, and

a posterior-most retractor blade, a cephalad-most retractor blade, and a caudal-most retractor blade that extend from the blade-holder assembly, wherein the posterior-most, cephalad-most, and caudal-most retractor blades are slidably advanced over the exterior of the outermost sequential dilator while in a first position, wherein the blade-holder assembly is adjustable to



move the posterior-most, cephalad-most, and caudal-most retractor blades to a second position in which the cephalad-most and caudal-most retractor blades are spaced apart from the posterior-most retractor blade to define an operative corridor,

wherein three-bladed retractor tool is configured to define the operative corridor along the lateral, trans-psoas path to the lumbar spine in which a space extending to the targeted spinal disc between the posterior-most, cephalad-most, and caudal-most refractor [sic] blades is dimensioned so as to pass an implant through the operative corridor along the lateral, trans-psoas path to the lumbar spine.

Claim 3. The system of claim 1, wherein the elongate inner member is advanced along the lateral, trans-psoas path to the targeted spinal discs such that a distal tip portion of the elongate inner member penetrates into an annulus of the targeted spinal disc.

Claim 9. The system of claim 1, further comprising a fourth retractor blade that couples with the blade-holder assembly only after the blade-holder assembly moves the posterior-most, cephalad-most and caudal-most retractor blades to the second position.

Claim 10. The system of claim 1, further comprising a fixation element to releasably engage with one of said retractor blades so that at least a portion of the fixation element extends distally into the lumbar spine, wherein the fixation element is configured to releasably engage with the posterior-most retractor blade after the posterior-most retractor blade is advanced along the lateral, trans-psoas path to the lumbar spine.

[Doc. No. 1-8 at Col. 14:31- Col.15:45.] NuVasive contends that all the elements of claims 1, 3, 9 and 10 of the '832 patent are present in the Battalion System.

Alphatec's Surgical Technique Guide describes the Battalion System as including: (1) sequential dilators used to split and advance through the psoas muscle until flush to the disc space; (2) the dilators having neuromonitoring capability; (3) a K-wire (i.e., an elongate inner element) introduced through the dilators and inserted half-way into the target disc; and (4) a three-blade retractor system introduced over the second dilator flush with the disc space, the blades of which can be adjusted to define an operative corridor. [Doc. No. 250-42.] The Squadron Retractor, as described in the surgical guide, includes

an intradiscal shim (i.e., fixation element) to stabilize the retractor and an optional fourth blade.

### 1. Distraction Assembly Limitation

Alphatec contends that the Battalion System does not meet the limitations of claim 1 because it teaches a lateral, trans-psoas approach in which the surgeon is instructed to first use blunt scissors and/or a finger to "dissect the subcutaneous tissue" to reach the "retroperitoneal space" and then use a finger as a guide to insert an initial dilator to the psoas muscle. [Doc. No. 250-42 at 5-7.] The initial dilator is then used to traverse the psoas muscle to a position flush with the disc space. Alphatec argues that the "distraction assembly" of the accused Battalion System therefore does not meet the distraction assembly claim limitation as the system employs the use of scissors and/or the surgeon's finger to distract the tissues in the lateral path between the skin of the patient and the psoas muscle, not just the use of sequential dilators.

To meet the limitations of claim 1, the distraction assembly must include sequential dilators, an elongate element, and the retractor in accordance with the claim limitations. "Includes" is the equivalent of "comprising" and is therefore not limiting. *See Lucent Technologies, Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1214 (Fed. Cir. 2008) ("including" and "comprising" have the same meaning namely, that the listed elements are essential but other elements may be added). The distraction assembly of claim 1 does not preclude the addition of a scissor or finger to assist in the creation of the distraction corridor, provided the distraction assembly also utilizes the elongate inner element and the plurality of dilators. It is undisputed that the Battalion System includes the essential elements. It is also undisputed that these elements of the accused system are capable of creating a distraction corridor in a lateral, trans-psoas path to the patient's spinal target, with or without the addition of the scissors or a finger to dissect the subcutaneous tissue. Accordingly, the Court finds that the Battalion System meets the distraction assembly limitation.

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