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ALPHATEC HOLDINGS, INC. AND ALPHATEC SPINE, 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. 18-CV-00347-CAB-MDD

DEFENDANTS' BENCH MEMORANDUM REGARDING SECONDARY CONSIDERATIONS

Judge: Hon. Cathy Ann Bencivengo
Courtroom: 4C

Alphatec respectfully submits that there is no nexus between the asserted claims and NuVasive's proffered evidence of secondary considerations of non-obviousness relating to the XLIF platform and procedure as a whole. A "patent claim is not coextensive with a product that includes a 'critical' unclaimed feature that is claimed by a different patent and that materially impacts the product's functionality." *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349, 1361 (Fed. Cir. 2021). The undisputed evidence in this case—and governing Federal Circuit law—establishes that XLIF includes an unclaimed feature—***neuromonitoring***—that NuVasive and its witnesses have admitted is critical and required to perform XLIF, that materially impacts the product's functionality, and that is claimed by other patents in NuVasive's portfolio. Thus, the Court should (1) preclude NuVasive from presenting any evidence of secondary considerations, including commercial success, skepticism, industry praise, long-felt but unmet need, failure of others, teaching away, and unexpected results, and (2) limit NuVasive's evidence of copying to the patented features. To hold otherwise would apply different standards to proving infringement and invalidity. By the language of the asserted claims, NuVasive is not required to show that Alphatec's accused system includes all the components of XLIF for a finding of infringement. Yet permitting NuVasive to argue that XLIF is the claimed invention forces Alphatec to argue the invalidity of XLIF as a whole, as opposed to the asserted claims.

I. ARGUMENT

The Court cautioned NuVasive that it "cannot establish secondary considerations of non-obviousness by talking about the neuromonitoring system [that is part of XLIF] but is not part of the claim." 2/28/2022 Hr'g at 9:20–23; *see also id.* at 10:14-17 ("[NuVasive] can't get over any hump there by saying oh, and then with this neuromonitoring, which is not a claim that is asserted here, we have demonstrated that this is an advancement in the surgical art."). Yet NuVasive presented this exact argument to the jury during its opening statement, and the Court should preclude further attempts to attribute secondary indicia ***regarding XLIF*** to the asserted claims. Further,

NuVasive should not be permitted to disguise evidence regarding XLIF simply by calling it NuVasive's "lateral system."

A. The asserted claims do not require neuromonitoring

NuVasive asserts three patents against Alphatec: the '531 patent, the '801 patent, and the '832 patent. ***None*** of the asserted claims require neuromonitoring, a necessary component of NuVasive's XLIF platform and procedure. *See* '531 patent at claims 1, 39; '801 patent at claims 1, 2, 15, 16, 26; '832 patent at claims 1, 3, 9, 10. There is only one independent claim remaining in the case that remotely relates to neuromonitoring, and even that only requires conventional sequential dilators equipped with stimulation electrodes untied to any system with functionality that stimulates the electrodes, receives feedback, and actually monitors the nerves in the psoas muscle. *See* '832 patent, claim 1 ("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"). One dependent claim of the '801 patent requires the same. *See* '801 patent, claim 15 ("each of the plurality of sequential dilators includes ***a stimulation electrode*** at a distal region"). Notably, the asserted claims of the '531 patent simply recite a collection of known instruments without any capability of connecting to a neuromonitoring system.

The lack of neuromonitoring in the asserted claims is further highlighted by the fact that there are other claims in the asserted patents that ***do*** require neuromonitoring. *See*, *e.g.*, '801 patent, claim 7 ("further comprising ***a control unit capable of electrically stimulating said at least one stimulation electrode***, sensing a response of a nerve depolarized by said stimulation, determining at least one of ***proximity and direction*** between said at least one stimulation electrode and said depolarized nerve based upon the sensed response, and communicating said at least one of proximity and direction to a user"), '832 patent, claim 11 ("further comprising ***a monitoring system*** that delivers an electrical stimulation signal to the stimulation electrode of the initial dilator, monitors

electromyographic activity detected by a set of sensor electrodes in leg muscle myotomes associated with nerves in the vicinity of the targeted spinal disc, and displays information on a display screen in response to the detection of said electromyographic activity via said set of sensor electrodes in said leg muscle myotomes"). None of these claims are asserted in this case.

B. There is no nexus between the asserted claims and XLIF

The Federal Circuit has previously concluded that NuVasive's XLIF Surgical Technique ***requires*** the NeuroVision® System:

> [***T]he Guide specifically identifies*** the MaXcess® II Access System, MaXcess® XLIF System, and ***NeuroVision® System as part of the required instruments*** to successfully complete the technique… While the Guide does list the components of the 'XLIF Instrument System,' ***it is very clear that the actual XLIF surgical technique requires more than just these instruments***; ***it utilizes*** the MaXcess® II Access, MaXcess® XLIF, and ***NeuroVision® Systems in addition to general surgical tools*** such as nerve retractors, disc cutters, and curettes that are traditionally employed in interbody fusion procedures.

NuVasive, Inc. v. Iancu, 752 F. App'x 985, 995–996 (Fed. Cir. 2018) (emphasis added).

NeuroVision® is NuVasive's proprietary neuromonitoring system that "allows surgeons to monitor the placement of the surgical instruments relative to nearby neural structures." *Id.* at 989. The trial record reflects the same: NuVasive's XLIF Surgical Technique (PTX-2763) expressly states that "[t]o successfully complete this technique, the following patient positioning supplies, instruments, implants, and fixation options are ***required*** . . . NVM5® . . . NVM5 EMG Module." *Id.* at 4 (emphasis added). Step 5 of the XLIF Surgical Technique stresses the "importance of neuromonitoring." *Id.* at 12. It confirms that neuromonitoring is "***critical to the safety and reproducibility of any lateral transpsoas approach*** due to the lumbar plexus' positioning within the psoas." *Id.* at 13 (emphasis added). "The XLIF® Procedure relies on the clinically validated dynamic EMG nerve avoidance mode of NVM5® to identify a safer docking position and working area." *Id.* at 12; *see also* PTX-59 at 17.

NuVasive's documents confirm that "the primary benefits of XLIF compared to conventional surgical approaches" and the "critical, differentiating factors that help to make XLIF reproducible" include the "use of automated, directionality stimulated electromyography (NVJJB®/M5®) with discrete threshold responses which provide information on the location and distance of instrumentation to motor nerves." PTX-2879 at 1. As confirmed by NuVasive's witness, Kyle Malone, this system includes a separately "patented Hunting Algorithm." PTX-2535 at 2; *see also* https://www.nuvasive.com/resources/virtual-patent-marking/.

Dr. Youssef has also told the jury that the "XLIF procedure has a very rote approach to the system, meaning you do each step, like I just described, which is very specific to that procedure." Trial Day 3 Rough Tr. (Youssef) at 101:2–4. Indeed, his demonstration to the jury on the XLIF procedure specifically referenced neuromonitoring using directional stimulated dilators. Trial Day 3 Rough Tr. at 31:9–18 ("that line is then emitting an impulse and you can hook up neuromonitoring … so I'm looking at the X-ray machine and I'm responding to the information I'm getting from the EMG machine."), 32:5–10 ("I'm placing the second dilator on and turning this on, once again, 360 degrees, confirming that no nerve is in the way… using the same neuromonitoring, I'm confirming I'm not near a nerve or on a nerve.").

In *NuVasive, Inc. v. Iancu*, the Federal Circuit found that nexus existed between the invention in U.S. Patent No. 7,691,057 and NuVasive's XLIF. However, unlike the asserted claims in this case, the '057 patent expressly claimed "neuromonitoring" (*i.e.*, "monitoring for resulting electromygraphic (EMG) activity after emission of each stimulation signal") by coupling the dilators equipped with stimulation electrode "to a control unit of a neuromonitoring system":

> ***performing neuromonitoring … wherein the neuromonitoring comprises*** causing the emission of a plurality of electrical stimulation signals from a stimulation electrode provided on a distal portion of at least one component of the distraction assembly and ***monitoring for resulting electromyographic (EMG) activity after the emission of***

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