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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
SAN DIEGO DIVISION

NUVASIVE, INC., a Delaware corporation, Plaintiff, v. ALPHATEC HOLDINGS, INC. and ALPHATEC SPINE, INC., a Delaware corporation, Defendants.	CASE NO. 3:18-cv-00347-CAB-MDD **DECLARATION OF MATTHEW LINK IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION** **Judge:** Hon. Cathy Ann Bencivengo **Courtroom:** 4C **Hearing Date:** April 30, 2018 **Jury Trial Demanded** REDACTED VERSION

18. Each of the above described components – neuromonitoring capabilities, specialized access tools, and specialized implants – were essential in enabling NuVasive to become the first company to provide a safe, effective, and reproducible minimally invasive lateral trans-psoas approach to the lumbar spine.

19. NuVasive debuted the XLIF procedure in October 2003 at the North American Spine Society ("NASS") Annual Meeting. Doc. No. 1-2 (IPR2014-00075, July 8, 2014, Declaration of Patrick Miles) at 9. Despite the time, effort, and cost NuVasive had put into developing the XLIF procedure, the majority of the spinal surgery community was immediately skeptical. From the beginning, and even during my first few years at the company, many surgeons did not believe that spinal fusion surgery via a lateral, trans-psoas approach could be done safely and reproducibly.

20. Members of the spinal community published their doubts regarding the safety and efficacy of XLIF in the literature. For example, a 2003 article explained that while surgeons recognized advantages to a lateral approach through the psoas muscle, they "have not felt comfortable with dissecting the psoas because of the presence of the lumbar plexus." Ex. 5 (T. Moro, M.D., et al., *An Anatomic Study of the Lumbar Plexus with Respect to Retroperitoneal Endoscopic Surgery*, Spine Vol. 28, No. 5, pp. 423-428 (2003)) at 428. These misgivings regarding the safety of traversing the psoas persisted through at least the 2009 timeframe, when NuVasive's internal market research demonstrated that some surgeons were still concerned about "the perceived complications associated with XLIF (e.g., psoas pain/weakness, dysthesias, numbness, and quad weaknesses)." Ex. 6 (S. Craig Meyer, M.D., *From the Proctor's Perspective,* SOLAS News, Issue 10 (Apr. 2010)) at 3.

21. Other factors also hampered the initial adoption of XLIF, including the fact that surgeons are generally reluctant to adopt new surgical techniques,

especially those for which they have had little training and require tools they are not used to using.

22. NuVasive undertook considerable efforts to overcome these hurdles, establishing a new lateral market in the process.

23. NuVasive initially focused on educating the spinal community that XLIF was actually safe and effective, and training inexperienced surgeons how to perform the XLIF procedure. At first, NuVasive partnered with the pioneers and early adopters of XLIF to have them demonstrate the procedure and specialized equipment in their own operating rooms to various inexperienced and skeptical surgeons. One such surgeon was Dr. Luiz Pimenta in Brazil. Dr. Pimenta was the surgeon who initially demonstrated a minimally invasive endoscopic lateral, trans-psoas approach for spinal fusion to NuVasive in Brazil. He then worked with NuVasive to develop its unique surgical tools and neuromonitoring that enabled *reproducible* minimally invasive lateral, trans-psoas fusion surgery. Once the inexperienced surgeons saw the XLIF technology in action, including in the operating room of Dr. Pimenta himself, they felt far more comfortable using XLIF in their own practices.

24. NuVasive also began utilizing the cadaver lab in its San Diego, California headquarters as an XLIF surgeon training center. This facility, which had been used to develop and clinically validate the viability of the XLIF solution, now allowed NuVasive to demonstrate the benefits of XLIF to surgeons in a hands-on environment. Facilitated by a team of experts, since 2005 through today, the six-suite operating room and training facility is available for surgeons on virtually a "24/7" basis. NuVasive also implemented the "Marquis Visit Program," or "MVP," at the training center, where visiting surgeons have the opportunity to be trained in the XLIF technique by proctors. Having a central facility for demonstrating and teaching the XLIF technique to surgeons has been instrumental

in allowing for the safe and reproducible execution of the XLIF procedure by surgeons across the country. NuVasive also began to provide local lab training for surgeons without convenient access to the San Diego facilities and began to facilitate peer-to-peer interaction through many different venues for surgeons to discuss and observe the XLIF technique.

25. NuVasive also came to recognize that surgeons would be far more likely to adopt XLIF if their interface with the company came from personnel that not only had exhaustive knowledge of the XLIF procedure and its benefits, but were also highly attuned to the unique needs and preferences of individual surgeons. NuVasive first instituted a culture of "absolute responsiveness" and innovation at "cheetah speed" at all levels of the company, which is still in place today. This culture led to NuVasive's unique sales representative model.

26. When I joined NuVasive in 2006, the company utilized mostly (if not entirely) third-party, non-exclusive distributors to sell its XLIF offerings. This model was widely followed by most small players in the spinal market whose business was based on a limited number of customers and surgical offerings. However, as more and more surgeons began seeing XLIF's proven results and adopting the procedure, NuVasive realized that it needed a different approach aligned with its corporate culture of innovation and responsiveness to interface with these new surgeon customers. Thus, NuVasive began using direct sales representatives in conjunction with third-party sales representatives employed by *exclusive* distributors; each was exhaustively trained regarding XLIF products and procedure. From the beginning, this training has been intensive, and [redacted]. In fact,

NuVasive requires each and every member of the on-the-ground sales team (including third party sales representatives) to demonstrate their clinical capability and fluency by scoring at least 90% in a comprehensive exam. Each individual trainee representative requires NuVasive to spend [redacted]. Since the beginning of its intensive sales representative training efforts, NuVasive has made sure to provide surgeons with easy and comprehensive access to these knowledgeable and highly-trained sales people, resulting in deep relationships between surgeons in the lateral market and NuVasive.

27. In addition, NuVasive realized it could even more effectively address surgeons' skepticism if it also collected and produced data showing XLIF's superiority to previous surgical procedures. To that end, NuVasive invested substantial time and cost in quantifying exactly how XLIF was better than previous procedures. The data showed XLIF obtained equally effective results as previous procedures, but resulted in minimal loss of blood, shorter hospital stays (in some cases going from three or four days in the hospital to outpatient surgery), fewer and less severe complications, less post-operative pain, and quicker recovery times for the patient; hospitals also incurred significantly fewer costs.

28. NuVasive then, and still today, made sure these results were published in academic journals, presented at industry conferences, included in public filings, and incorporated in marketing materials to hospitals, surgeons, and patients. Ex. 7 (Excerpt from 2013 NuVasive Investor Morning Transcript, Nov. 14, 2013) at 6 ("I think there is no doubt that we have committed a ton of time and effort with regard to clinical evidence, and so if you look at the volume of effort that has been put into this, 142 journal articles, greater than 60 book chapters, 26 white papers, I would tell you through – we have made a market through the publication of clinical evidence that suggests that what we are doing is real."). The following are

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