

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALPHATEC HOLDINGS, INC. and ALPHATEC SPINE, INC.
Petitioners,

v.

NUVASIVE, INC.,
Patent Owner.

Case No. IPR2019-00362
Patent No. 8,361,156

DECLARATION OF MATTHEW LINK

I, Matthew Link, declare as follows:

1. PERSONAL BACKGROUND

1. I am currently President of NuVasive, Inc. (“NuVasive”), a position I have held since January 2019. My responsibilities include overseeing NuVasive’s product and systems development, global marketing, surgeon education, clinical research, corporate development, and short- and long-term corporate and product strategy.

2. I have been employed by NuVasive since June 2006. Prior to my current position, I served as Executive Vice President of Strategy, Technology, and Corporate Development from August 2017 to January 2019. I also served as President of U.S. Commercial from July 2015 to July 2017, President of U.S. Sales and Service from January 2015 to July 2015, Executive Vice President of U.S. Sales from January 2013 to December 2014, Senior Vice President of Sales, East from January 2012 to December 2012, Area Vice President of Sales, South from April 2010 to December 2011, Sales Director, Atlantic from January 2008 to April 2010, and Area Business Manager, Virginia from June 2006 to January 2008.

3. While employed at NuVasive, I have been involved to varying degrees in the development, sales, and marketing of NuVasive’s eXtreme Lateral Interbody Fusion (“XLIF”) products and systems. My work requires me to be knowledgeable about the development history and technical features of XLIF, as

well as NuVasive's sales teams, marketing, distribution, position in the marketplace, customer feedback, customer pricing and demand requirements, and corporate and product strategy.

VIII. NUVASIVE/XLIF HISTORY

4. NuVasive was established in 1997. In the beginning, it was a struggling start-up company, operating essentially out of the garage of its cofounder. Since then, it has grown into a leading medical device company at the forefront of transforming spine surgery with minimally invasive, procedurally-integrated solutions. When NuVasive began development of XLIF, it had revenues of only \$2.6 million. Today, NuVasive generates total revenues of approximately \$1 billion, driven to a great extent from widespread adoption of its XLIF product line.

5. XLIF is a minimally invasive surgical approach to spinal fusion surgery that, unlike the traditional approaches, accesses the disc space from the lateral aspect of the patient. Specifically, the XLIF surgical procedure accesses the disc space by creating an operative corridor through the psoas muscle. Because damage to the nerves of the psoas could lead to serious and potentially irreversible consequences, specialized nerve monitoring is employed during placement and removal of the instruments used to access the disc space. NuVasive built and tested an array of specialized instruments and surgical components (*e.g.*, MaXcess®

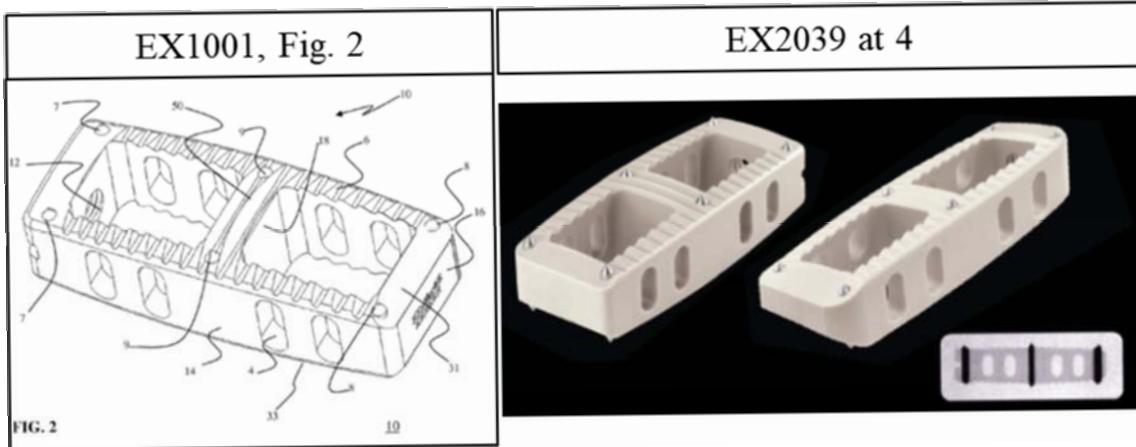
retractor, neuromonitoring equipped dilators, specially constructed implants) to enable the XLIF surgical approach. *See generally* EX2038.

6. Prior to XLIF, there were different procedures available for treating patients in need of spinal fusion that suffered from their own drawbacks. Most involved approaching the lumbar spine either from the back (the posterior approach) or from the abdomen (the anterior approach), removing the diseased or damaged vertebral disc(s), and inserting an implant in the disc space to restore it to its proper height.

7. NuVasive recognized the unmet need for an effective spinal fusion surgery without the disadvantages of these earlier procedures. Before XLIF, lateral approaches to the spine were avoided because they required traversing the nerve-rich psoas muscle, and thus carried a high risk of nerve damage that can lead to a host of medical issues for a patient. That changed, however, when NuVasive invented XLIF: the first safe and reproducible minimally invasive lateral trans-psoas approach to the spine.

8. Developing XLIF required NuVasive to spend significant resources. NuVasive's initial expenditures for the development of XLIF were approximately \$20 to \$30 million. The CoRoent® XL implant was built to meet the demands of the XLIF surgical approach innovated by NuVasive.

9. I understand that Dr. Jim Youssef has, based on his own review, determined that NuVasive's CoRoent® XL implants fall within the scope of the claims of the '334 and '156 patents. The figures below depict the CoRoent® XL implant.



IX. SKEPTICISM REGARDING XLIF AND COROENT® XL IMPLANT

10. Despite the extraordinary time, effort, and resources NuVasive invested in development of the XLIF surgical 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.

11. Members of the spinal community published their doubts regarding the safety and efficacy of XLIF in the literature. Among these concerns, was the large width—18 mm—of the CoRoent® XL implants. For example, Patrick Miles, formerly of NuVasive and now Chairman and CEO of Alphatec, testified regarding

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