No. 11-55120

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NEUROVISION MEDICAL PRODUCTS, INC.,

Plaintiff,

v.

NUVASIVE, INC.,

Defendant.

On Appeal from the United States District Court
for the Central District of California,
Case No. 2-09-CV-6988 R (JEMx)

DECLARATION OF MARK D. PETERSON M.D. IN SUPPORT OF DEFENDANT'S MOTION FOR STAY OF PERMANENT INJUNCTION PENDING APPEAL

I, Mark D. Peterson, M.D., state and declare:

1. I am an orthopedic surgeon associated with Southern Oregon Orthopedics located in Medford, Oregon. I have personal knowledge of the matters stated herein, except where stated based on information and belief, and if called upon to do so, I would testify competently to them.

2. I attended medical school at Oregon Health Sciences University, graduating in 1988. Subsequently, I did my residency and internship in the Department of Orthopedic Surgery at Akron City Hospital. I completed my residency in 1993 and therefore had three fellowships in orthopedic and spinal surgery at the Royal Adelaide Hospital (in Adelaide, South Australia), Queens Medical Center (in Nottingham, England), and North Kansas City Hospital (in Kansas City, Missouri). I have worked continuously since 1994 as an orthopedic surgeon in Medford, Oregon, specializing in spinal surgery.

3. I regularly use NuVasive's XLIF® procedure in the course of my surgical practice, and am readily familiar with the XLIF® procedure and NuVasive's NEUROVISION® nerve monitoring system.

4. When I first started my orthopedic surgery practice, all lower spine surgery was "open surgery" wherein the spine was accessed from either the front (anterior) or the back (posterior). The NEUROVISION® nerve monitor system was a groundbreaking development that allowed spinal surgeons to access the spine from the side (laterally) in a minimally invasive procedure (NuVasive's XLIF® procedure), with little muscle dissection, less bone work and smaller incisions. This resulted in less blood loss, less operative time, and less pain to the patient as compared to standard open spine surgery.

5. Chronic lower back and leg pain often is a result of the deterioration of the flexible discs between the vertebrae in the lower back. The loss of disc height creates pressure upon the nerve roots and/or spinal cord – resulting in chronic lower back pain and/or pain, numbness, or weakness in the legs. This condition is known as degenerative disc disease ("DDD").

6. Until now, NuVasive could only treat patients suffering from DDD by fusing the adjacent vertebrae on either side of the degenerated disc. This involves removing the affected disc and implanting a generally rectangular, hollow plastic device that allows bone to grow from one adjacent vertebrae through the implant to the other adjacent vertebrae. While a dramatic improvement over the traditional anterior and posterior approaches to accomplish spinal fusion, there remains a significant unmet need for patients who may not need fusion yet and who would otherwise benefit from a restoration of disc height while preserving motion between the adjacent vertebrae.

7. A small number of companies offer motion preservation implants; however, they are implanted via an anterior approach to the lumbar spine. Approaching the lumbar (lower) spine in this manner (from the front of the patient) is necessarily an "open" procedure based on the need to move the bowels out of the way, and is routinely associated with greater blood loss, longer operative times, longer post-operative recovery, and inherent challenges based on the need to pass

by vital anatomical structures (e.g., the great vessels which lie in front of the spinal column) to reach the spine.

8. NuVasive has developed the answer to this unmet need: a total disc replacement device that we are currently studying for use via its minimally invasive (XLIF) technique. I am currently the lead investigator on a clinical trial that NuVasive is conducting for the device, called the "XL-TDR" (for "extreme lateral – total disc replacement). The NEUROVISION® nerve monitoring system is critical to the clinical trials because it is the only nerve monitoring system on the market that allows for safe and reproducible lateral access to the spine.

9. The trials are being conducted at 17 sites and will require a total of 252 surgeries on patients. Surgeons participating in the clinical trials have enrolled and performed surgeries on 60% of those patients, which means that an additional 150 patients still need to be enrolled. On average, approximately 8-10 patients are enrolled in the study each month. At this rate, full enrollment is anticipated to be complete in October 2011.

10. The XL – TDR device is particularly exciting for spinal surgeons because it will provide patients with a device that is designed to relieve the painful symptoms of DDD, *while preserving motion in the back*. Once implanted between the vertebrae, the disc is designed to restore height and to replicate the motion characteristics of an intact healthy disc. The ability to maintain motion is

important in that it will allow patients more freedom of movement to perform their activities of daily living. It may also minimize the number of patients who will ultimately need fusion surgery, which can cause a degenerative cascade at adjacent discs above and below the site of the original fusion surgery.

11. The clinical trials for NuVasive's new XL – TDR device require lateral access to the spine, which requires use of NuVasive's NEUROVISION® nerve monitoring system. I have already seen the benefits of the XL – TDR device in the clinical trials in which I have been involved, and believe that this device holds great promise for patients who suffer from lower back pain. Their pain will be prolonged if NuVasive is required to stop lending or circulating the NEUROVISION® nerve monitoring system to hospitals, surgical centers and research institutions because the clinical trials cannot be completed with using the NEUROVISION® nerve monitor. The trials would come to a complete halt.

12. If the trials are halted, Food and Drug Administration clearance of a promising new medical device would be delayed, resulting in prolonged pain for patients for whom a minimally invasive surgery implanting the XL – TDR device is the best option. As an orthopedic surgeon responsible for patient safety and comfort, it is untenable to me that the legal system would disrupt such important work because of an issue with the name of a product.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.