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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 WILLIAM D. SMITH M.D. IN SUPPORT OF DEFENDANT'S MOTION FOR STAY OF PERMANENT INJUNCTION PENDING APPEAL

I, William D. Smith, M.D., state and declare:

1. I am a Board-certified neurological surgeon associated with Western Regional Center for Brain & Spine Surgery with offices located in Kingman, Arizona and Las Vegas, Nevada. 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.

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- 2. I attended Georgetown University Medical Center. For seven years, I also did my residency at Georgetown University Medical Center in neurological surgery. I completed my residency in 1994 and have since worked continuously as a neurological surgeon in Arizona and Nevada. My specialty is neurological surgery, including surgery of the spine.
- 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. I typically perform 6-12 surgeries per week using NuVasive's XLIF® procedure and NuVasive's NEUROVISION® nerve monitoring system.
- 4. When I first started my neurosurgery practice, all lower spine surgery was "open surgery" wherein the spine was accessed from either the front (anterior) or the back (posterior). Such open spinal surgery involved significant risks, including significant blood loss, high morbidity rates, and lengthy recovery periods. The NEUROVISION® nerve monitor system was a groundbreaking development that allowed neurosurgeons to access the spine from the side (laterally) in a minimally invasive procedure. In accessing the spine from the side, there is little muscle dissection, less bone work and smaller incisions, which results in less blood loss, less operative time, and less pain to the patient as compared to standard open spine surgery. NuVasive's XLIF® procedure takes advantage of the

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advances provided by the NEUROVISION® nerve monitoring technology and allows safer and less invasive surgeries in the lower spinal region.

- 5. Not only are NuVasive's XLIF® procedure and NEUROVISION® nerve monitor used to address many common back problems, including, for example, degenerative disc disease, scoliosis, slipped discs, and disc herniation, they are also used in life threatening cases, such as in the case of a tumor or acute trauma.
- 6. XLIF® surgeries are in high demand, and they cannot be performed without NuVasive's NEUROVISION® nerve monitoring system. No other company manufactures a nerve monitoring system that can be used in connection with the XLIF® procedure. The inability to use the NEUROVISION® nerve monitor system to perform XLIF® procedures in life threatening cases involving acute trauma or tumors could worsen neurological injuries, or cause irreversible injury and possible death in cases that cannot be delayed.
- 7. The inability to use NuVasive's NEUROVISION® nerve monitoring system in cases that are not life threatening will also have serious repercussions for my patients. In the best case scenario, my patients' surgeries will be delayed until NuVasive is able to provide a NEUROVISION® nerve monitoring system, or until I am able to find an appropriate, safe, and reliable alternative surgical procedure, which may be more invasive than NuVasive's XLIF® procedure. In some cases,

however, it will mean that my patients will not be able to receive any surgical treatments at all because there is no suitable alternative to the XLIF® procedure. This is especially so for my elderly patients, for whom the morbidity rate and high risk of blood loss in traditional open surgeries is too great a risk. For these elderly patients, there is no alternative to NuVasive's XLIF® procedure, which requires the use of NuVasive's NEUROVISION® nerve monitor systems.

As a surgeon, I will fight any order that proscribes use of NuVasive nerve monitoring systems as it would threaten the well being of patients whose lives and limbs are under my care.

I declare under penalty of perjury under the laws of the United States of

America that the foregoing is true and correct. Executed on January //, 2011, in

Las Vegas, Nevada

William D. Smith, M.D.