

2013-1576, -1577

**United States Court Of Appeals
for the Federal Circuit**

WARSAW ORTHOPEDIC, INC.,
Plaintiff/Counterclaim Defendant-Appellant,

and

MEDTRONIC SOFAMOR DANEK USA, INC.,
Counterclaim Defendant-Appellant,

and

**MEDTRONIC PUERTO RICO OPERATIONS CO. and MEDTRONIC
SOFAMOR DANEK DEGGENDORF, GMBH,**
Counterclaim Defendants,

v.

NUVASIVE, INC,
Defendant/Counterclaimant-Cross-Appellant,

APPEALS FROM THE U.S. DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA IN CASE
NO. 08-CV-1512, JUDGES CATHY ANN BENCIVENGO AND MICHAEL M. ANELLO

NUVASIVE'S OPENING BRIEF

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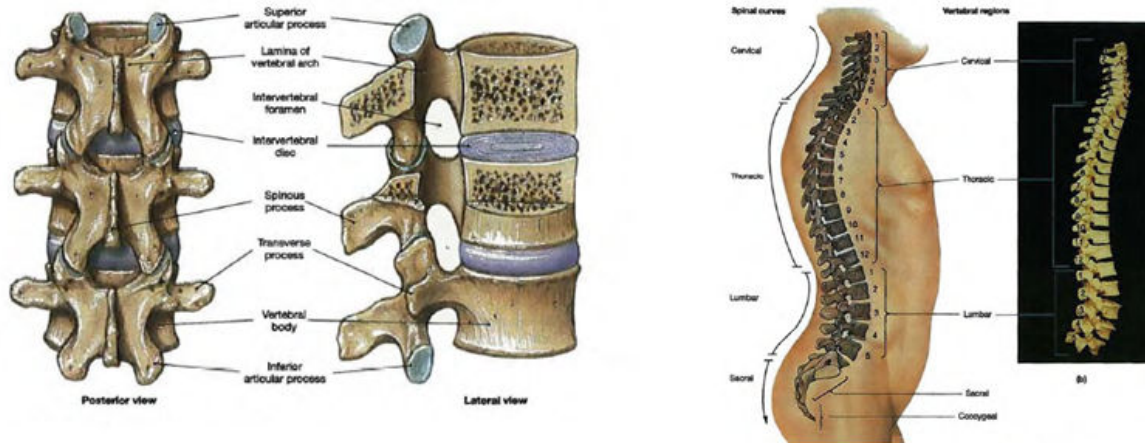
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February 3, 2014

STATEMENT OF THE FACTS

I. Technology Background on Spinal Fusion Surgery.

The patents-in-suit relate to various spinal surgery components. The spine includes a vertebral column that is composed of a series of bony vertebral bodies separated by spongy discs. (A1998-99.)



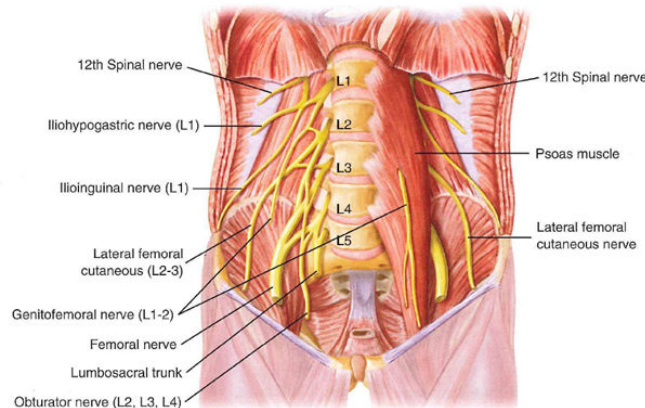
The discs can deteriorate, bulging into surrounding tissue or irritating nearby nerves. One treatment is fusion surgery, in which all or part of the disc is removed and replaced with an implant (which maintains proper separation between the vertebrae) and bone growth material (which promotes fusion between vertebrae). (A10131-32.) Surgeons can optionally install fixation equipment (*e.g.*, rods and screws) separately in patients to further stabilize the spine. (A11186-87.)

There are multiple ways to access the disc space to perform a fusion, including through the patient's front (anterior), back (posterior), or side (lateral). Several references in the 1980s and early 1990s disclosed lateral insertion, (A17429-41 at

A17436, A17438, A17440; A11835-37; A12186-87; A17450-59 at 2:55-59), and the lateral approach had the known benefit of avoiding the aorta or the spinal cord.

(A252-53.) But the lateral approach had a major challenge that prevented its widespread use, particularly for the lower, lumbar, spine. (A10367-70, A10470-72.)

The lumbar spine is surrounded by the psoas, a nerve-packed muscle:



(A17546.) A surgeon trying to access the disc space through the psoas without guidance has an 80-90% chance of hitting a nerve. (A17634-35, A10472-73.)

NuVasive solved this problem by introducing eXtreme Lateral Interbody Fusion (XLIF) in 2003—the first safe and reproducible lateral procedure that included a nerve-monitoring system. (A10403-04, A10413, A10470-72.) Nerve-monitoring made lateral procedures accessible to all properly trained spine surgeons, not just the few, highly skilled ones who had successfully performed a lateral fusion in the past. (*Id.*) NuVasive’s U.S. Patent 7,470,236 covers its first nerve-monitoring algorithm. (A279-300, A10468-71.) NuVasive has other patents on various aspects of XLIF, several of which it currently asserts against Medtronic in another suit.