

Artificial Disc Patent Case Could Define Shape Of The Market

Pending patent litigation between Medtronic and Spine Solutions could shape the artificial disc replacement market for years to come, according to Tram Anh Nguyen, VP of intellectual property at orthopedic consulting firm MCRA.

In its suit filed in the Memphis U.S. District Court in March 2007, Spine Solutions alleges that certain Medtronic Sofamor Danek intervertebral implants, including the *Maverick* lumbar disc, infringe Spine Solutions' '071 patent for components in its *ProDisc* artificial lumbar disc.

Spine Solutions is asking for damages and a sales injunction on the Medtronic products. The case is scheduled for trial Nov. 21.

"The stakes are very high here," Nguyen told "The Gray Sheet." "The ability to set boundaries that would eliminate a directly competing device in this very limited market is huge."

The case is "a seminal situation for total artificial disc technology" that will impact all manufacturers' design decisions in the artificial disc field, she said.

Spine Solutions says the '071 patent should be interpreted to cover spine implants with a single anchor at the lower part of the artificial disc, including *Maverick*, Nguyen explained.

Medtronic argues *Maverick* does not infringe the '071 patent because that patent should be interpreted to only cover artificial discs with a two-piece bottom part that is inserted in two steps, she said. Medtronic has also filed counterclaims alleging that one or more of the 32 claims of the '071 patent are invalid.

Spine Solutions was purchased by Swiss firm Synthes in 2003 from venture capital firm Viscogliosi Bros., which also owns MCRA. In addition, Viscogliosi Bros. owns Paradigm Spine and Raymedica, which are also developers of devices to treat degenerative disc disease with non-fusion interventions.

Maverick is pending FDA approval and is available in the United States in clinical trials under

continued access protocol. FDA approved *ProDisc* in 2006. The only other artificial lumbar disc currently on the U.S. market is Johnson & Johnson/DePuy's *Charité*, approved in 2004.

ProDisc/Maverick Suit May Affect Cervical Discs

Although the *Maverick* lumbar disc is the only Medtronic product specifically cited in the court filing, the patent in the case may also be applicable to other types of intervertebral implants, including cervical discs, Nguyen said.

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Some analysts believe cervical discs have greater commercial potential than lumbar replacements. The lumbar disc market has been hindered by the lack of long-term data on the devices and limited third-party payer reimbursement.

The only cervical discs on the U.S. market are Synthes *ProDisc-C*, approved in January, and Medtronic's *Prestige*, approved last July. An FDA advisory panel endorsed Medtronic's *Bryan* cervical disc last July ("The Gray Sheet" Aug. 27, 2007, p. 4).

The *Spine Solutions v. Medtronic* case is significant because it could bar one of only three current disc manufacturers from the U.S. market, but it could also create barriers for other disc developers trying to bring new devices to market, Nguyen said.

There has been a "tremendous boom of activity" in total artificial disc patent filings. As the field gets more crowded, it will be more difficult for new entrants to create a design that has not already been patented, she said.

"The more you sort of diverge from your original design with a second generation, the more challenges you have with clinical, regulatory hurdles," Nguyen explained.

"On the flip side, it's much easier to get IP protection for a newer and more radical design. So it's a constant struggle here to find the right balance."

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