

Keywords: **obviousness; written description; claim construction; lost profits; willfulness; permanent injunction.**

General: **Evidence of uncertainty and extensive testing can be useful to show nonobviousness, even if a claimed element was known to be possible and considered at a prior time.**

Spine Solutions Inc. v. Medtronic Sofamor Danek USA Inc.
96 U.S.P.Q.2d 1640 (Fed. Cir. 2010)
Decided September 9, 2010

I. Facts

Spine Solutions, Inc. (“SSI”) is the assignee of U.S. Patent No. 6,936,071 (“the ‘071 patent”) directed to intervertebral implants. Intervertebral implants are artificial intervertebral discs used to replace discs between vertebrae in the spinal column that have degenerated or become diseased. The ‘071 patent discloses an intervertebral implant with two parts, wherein each part has a support face and each support face has a single anchor centrally positioned on the support face.

SSI sued Medtronic, alleging that Medtronic’s Maverick, A-Maverick, and O-Maverick devices infringe independent claim 1 and various dependent claims of the ‘071 patent. Medtronic raised defenses including noninfringement, invalidity for obviousness, and failure to comply with the written description requirement. The parties stipulated that the Maverick and A-Maverick devices infringe SSI’s asserted claims. Regarding the O-Maverick device, Medtronic filed a motion for summary judgment of noninfringement and SSI filed a cross-motion for partial summary judgment that the O-Maverick device infringed claims 1 and 2. The district court granted SSI’s motion that the O-Maverick device infringed claims 1 and 2 literally and under the doctrine of equivalents.

Medtronic filed a motion to preclude SSI from introducing evidence regarding lost profits because SSI does not make or sell any device covered by the patent. However, SSI’s sister company Synthes Spine Co., L.P. (“Synthes Spine”) makes and sells the ProDisc II implant, which is the commercial embodiment of the ‘071 patent. SSI opposed Medtronic’s motion and tried to add Synthes Spine as a co-plaintiff. Medtronic argued that the combination of SSI and Synthes Spine had no standing. The court allowed SSI to add Synthes Spine in addition to its parent company Synthes, Inc. as co-plaintiffs.

The case went to trial on Medtronic’s obviousness defense, SSI’s willful infringement claim, and damages. The court found that Medtronic did not prove that the ‘071 patent was invalid for obviousness. Therefore, the jury awarded lost profits and a reasonable royalty. The jury also found willful infringement, thereby doubling damages and the court awarded attorney fees. The court also entered a permanent injunction forbidding Medtronic from using, selling, or transferring any accused device already outside the U.S.

II. Issues

- A. Did the district court err in denying the Medtronic motion that the asserted claims of the ‘071 patent would have been obvious to one of skill in the art?
- B. Did the district court err in granting summary judgment that the ‘071 patent contains adequate written description to support the limitation “single anchor . . . adapted to enter a groove?”
- C. Did the district court err in construing the claim term “operative engagement?”
- D. Did the district court err in granting summary judgment that the O-Maverick implant infringes claims 1 and 2 of the ‘071 patent both literally and under the doctrine of equivalents?

-
- E. Did the district court abuse its discretion in allowing SSI to amend its complaint and add Synthes Spine and Synthes, Inc. as co-plaintiffs?
 - F. Did the district court err in denying the Medtronic motion for no willfulness by an SSI failure to establish that Medtronic's manufacture of the Maverick products was objectively reckless?
 - G. Did the district court err in permanently enjoining sales of Maverick devices that were already outside the U.S.?

III. Discussion

- A. No. The Federal Circuit found that even though U.S. Patent No. 5,314,477 (the '477 patent) disclosed every element of claim 1 except for the "single anchor" limitation, and Japanese Patent Application No. H2-261446 ("Nobuo") disclosed an artificial vertebra with a single, central projection at each end, the combination of the '477 patent and Nobuo was not obvious. The court further stated that although both references combine to disclose all limitations of claim 1, the parties themselves did not believe that a "single anchor" could be combined with the '477 patent. Further, it was through extensive testing of the "single anchor" that the '071 patent was developed.
- B. No. Claim 1 recites that the "single anchor" is "adapted to enter a groove in the adjacent vertebrae." Medtronic argued that the written description does not disclose the "adapted to enter a groove" limitation. The court stated that because the claims relate to the implant, applicants were not required to disclose grooves or how grooves should be formed or cut. Furthermore, even though the specification never mentions the word groove, it does disclose that the end face of each vertebrae "rests . . . on the support face" of the corresponding part of the implant. Thus, the court reasoned that the implants are inserted into a "groove" of some type in order for the end face of the vertebrae to rest on the support face.
- C. No. Claim 1 recites the limitation of "a lower part having a lower surface for engaging a vertebrae and an upper surface portion in *operative engagement* with the rounded portion of the upper part." The court construed "operative engagement" as "permitting movement," with or without a pivot insert. Medtronic asserted that the only "engagement" disclosed in the specification occurs between the upper part and the pivot insert, not between the upper and lower parts. However, the court looked at the plain language of the claim, in addition to figures that illustrate the pivot imbedded in the lower part to conclude that "operative engagement" does not require a separate pivot insert.
- D. Yes. The O-Maverick device has top and bottom pieces having an anchoring structure with two tabs separated by a one-millimeter wide gap. The Federal Circuit found that the O-Maverick includes two anchors on each end. The one-millimeter wide gap extends all the way to the base of the implant and separates the two anchors, therefore there is no literal infringement. Furthermore, the prosecution history of the '071 patent distinguished the claimed invention over the '477 reference where SSI stated: "a reference disclosing two anchors does not disclose a device affirmatively claiming a single anchor . . . a *single* element is not disclosed by prior art which teaches more than one element."
- E. Yes. The Federal Circuit stated that only a patent owner or an exclusive licensee can bring an infringement suit. SSI is the sole owner of the '071 patent. There is no evidence that Synthes, Inc. is a licensee of the '071 patent, so they did not have standing to bring suit. Regarding Synthes Spine, SSI did not have an agreement with Synthes Spine with respect to the '071 patent, but only had an "understanding." The court concluded that at most, SSI granted a bare license to Synthes

Spine. A bare license does not provide standing without the grant of a right to exclude others. Therefore, the district court abused its discretion by allowing Synthes, Inc. and Synthes Spine as co-plaintiffs and SSI is not entitled to recover lost profits.

- F. Yes. The Federal Circuit stated that Medtronic raised a substantial question as to the obviousness of the '071 patent. Therefore, Medtronic was not objectively reckless in relying on this defense.
- G. Yes. The Federal Circuit stated that an injunction is only proper to prevent future infringement, not to remedy past infringement. Medtronic's overseas sales of Maverick products cannot infringe any U.S. patent, so the district court abused its discretion in issuing the extraterritorial portion of the injunction.