# United States Court of Appeals for the Federal Circuit

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**SPINE SOLUTIONS, INC.,**
**SYNTHES SPINE COMPANY, L.P.**
**AND SYNTHES, INC.,**
*Plaintiffs-Appellees,*

**v.**

**MEDTRONIC SOFAMOR DANEK USA, INC.,**
**AND MEDTRONIC SOFAMOR DANEK, INC.,**
*Defendants-Appellants.*

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2009-1538

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Appeal from the United States District Court for the Western District of Tennessee in case No. 07-CV-02175, Judge Jon P. McCalla.

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Decided: September 9, 2010

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JEFFREY M. OLSON, Sidley Austin LLP, of Los Angeles, California, argued for plaintiffs-appellees. With him on the brief were PAUL H. MEIER, ROBERT A. HOLLAND, SEAN A. COMMONS, SAMUEL N. TIU and MATTHEW S. JORGENSON.

SETH P. WAXMAN, Wilmer Cutler Pickering Hale and Dorr LLP, of Washington, DC, argued for defendants-appellants. With him on the brief were WILLIAM G. MCELWAIN, JAMAICA P. SZELIGA and JASON A. SKINDER; and MARK C. FLEMING of Boston, Massachusetts. Of counsel on the brief were JAN M. CONLIN, MUNIR R. MEGHJEE and CYRUS A. MORTON, Robins, Kaplan, Miller & Ciresi LLP, of Minneapolis, Minnesota.

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Before DYK, FRIEDMAN, and MOORE, *Circuit Judges*.

MOORE, *Circuit Judge*.

Medtronic Sofamor Danek USA, Inc. and Medtronic Sofamor Danek, Inc. (collectively, Medtronic) appeal the decision of the United States District Court for the Western District of Tennessee granting summary judgment that Medtronic infringes the asserted claims of U.S. Patent No. 6,936,071 (the '071 patent). Medtronic also appeals the court's grant of summary judgment that the asserted claims are not invalid for failure to satisfy the written description requirement and the court's denial of its motions for judgment as a matter of law (JMOL) of obviousness, no willfulness, and no entitlement to lost profits. Further, Medtronic appeals the court's order permanently enjoining Medtronic from using or selling any of the accused devices that are currently outside the U.S. For the following reasons, we affirm-in-part, reverse-in-part, vacate-in-part, and remand.

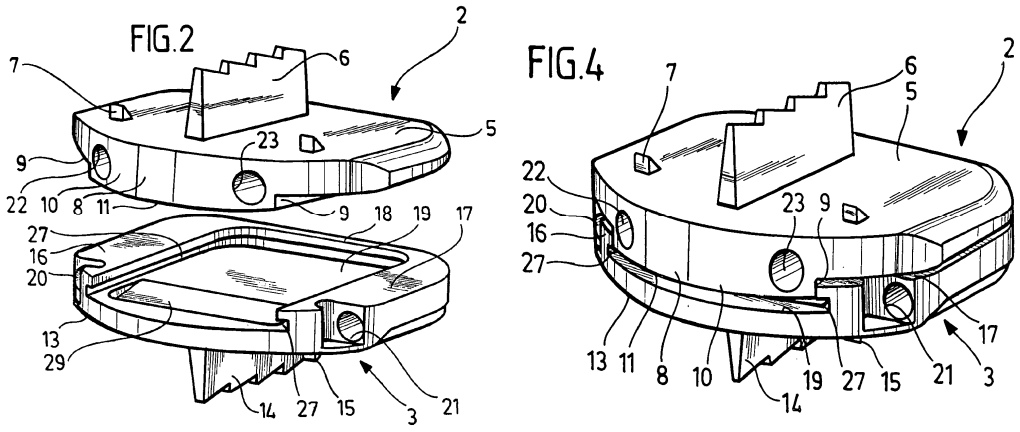
## I. BACKGROUND

This patent case relates to intervertebral implants, which are also known as artificial intervertebral discs or total disc replacement devices. Intervertebral implants

are used to replace discs between vertebrae in the spinal column that have degenerated or become diseased.

Spine Solutions, Inc. (SSI) is the assignee of the '071 patent. The '071 patent discloses an intervertebral implant that includes an upper part and a lower part, each of which has a "support face" for an adjacent vertebra. '071 patent col.1 ll.3-5. Each of the upper and lower parts has a single anchor, or keel, that is centrally positioned on the support face. *Id.* figs.1-7 (nos. 6, 14). The anchors affix the upper and lower parts into the adjacent vertebrae. *Id.* col.5 ll.59-64.

The '071 patent discloses that the upper and lower parts of the implant each have "protrusions and recesses . . . which are offset laterally from one another in such a way that . . . they mesh with each other" when the two parts are brought close together. *Id.* col.1 ll.56-62. This orientation allows the implant's structural height to be minimized during insertion, making it easier to insert the implant into the intervertebral space. *Id.* col.1 ll.52-55, col.4 ll.30-32. Figures 2 and 4 of the '071 patent depict a view of the implant's upper and lower parts when brought into maximum proximity with each other:




The '071 patent discloses that "in a preferred embodiment, the lower part and the upper part each have a respective receptacle for a pivot insert." *Id.* col.3 ll.1-2. This pivot insert is placed between the upper and lower parts after the implant is inserted. *Id.* col.5 ll.1-8. The insert "supports the upper part and lower part against one another" and "leads to a certain pivotability of the two parts . . . relative to one another, so that a pivotability of the adjacent vertebra is thus attainable as well." *Id.* col.3 ll.2-9.

SSI sued Medtronic, alleging that Medtronic's Maverick, A-Maverick, and O-Maverick intervertebral implants infringe independent claim 1 and dependent claims 2, 6, 7, 10, 11, and 13 of the '071 patent. Medtronic raised various defenses, including noninfringement and invalidity for obviousness and failure to comply with the written description requirement. After claim construction, Medtronic filed a motion for summary judgment of noninfringement with respect to O-Maverick; SSI filed a cross-motion for partial summary judgment that O-Maverick infringes claims 1 and 2. The district court granted SSI's

motion, ruling that O-Maverick infringes claims 1 and 2 both literally and under the doctrine of equivalents. The court then denied Medtronic's motion for summary judgment that claim 1 is invalid for lack of written description and granted SSI's cross-motion to dismiss all of Medtronic's 35 U.S.C. § 112 defenses. The parties then stipulated that the accused products infringed all of the asserted claims.

A few weeks before trial, Medtronic filed a motion in limine to preclude SSI from offering any evidence relating to lost profits. There is no dispute that SSI, the assignee of the '071 patent, 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 sought to amend its complaint to add as co-plaintiffs Synthes Spine and Synthes, Inc., SSI's parent corporation. Medtronic objected, arguing that Synthes Spine and Synthes, Inc. had no standing to bring an infringement suit on the '071 patent. As SSI was the sole owner, Medtronic argued that SSI alone could bring suit. The parties ultimately agreed that Medtronic could submit an offer of proof (outside the presence of the jury) as to the standing issue, and the court allowed SSI to amend its complaint to name SSI, Synthes Spine, and Synthes, Inc. (collectively, SSI) as co-plaintiffs.

The case went to trial on Medtronic's obviousness defense, SSI's willful infringement claim, and damages. At trial, the jury rendered a verdict in favor of SSI. The jury found that Medtronic did not prove that the '071 patent was invalid for obviousness. The jury also found that Medtronic's infringement was willful. The jury awarded SSI $5.7 million in lost profits for the 2005-2007 time-

frame and an 18% reasonable royalty on the remaining $9.1 million in revenue from infringing sales of the accused O-Maverick, A-Maverick, and Maverick products. The court then denied Medtronic's motions for JMOL of obviousness and no willfulness. The court also found that Medtronic waived its standing argument and therefore denied Medtronic's motion for JMOL that SSI was not entitled to lost profits. The court doubled the damages award pursuant to 35 U.S.C. § 284 and awarded attorney fees under 35 U.S.C. § 285. Finally, the court entered a permanent injunction that forbids Medtronic from, among other things, using, selling, or transferring any accused devices that are already outside the U.S. This extraterritorial portion of the injunction is stayed pending this appeal.

Medtronic appeals, raising numerous issues. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

## II. DISCUSSION

### A. Obviousness

Medtronic argues that the district court erred in denying its motion for JMOL that the asserted claims of the '071 patent would have been obvious to one of skill in the art. We review denials of JMOL under the law of the regional circuit, here the Sixth Circuit. *Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1379 (Fed. Cir. 2009). The Sixth Circuit reviews a denial of a motion for JMOL *de novo*. *Imwalle v. Reliance Med. Prods.*, 515 F.3d 531, 543 (6th Cir. 2008). JMOL will be granted only where "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." *Id.* "The grant is

appropriate only if, in viewing the evidence in the light most favorable to the nonmoving party, reasonable minds could come to but one conclusion, in favor of the moving party." *Id.* (citation omitted).

Claim 1 of the '071 patent, the only independent claim at issue, reads as follows:

> An intervertebral implant insertable between adjacent vertebrae, comprising,
>
> an upper part having an upper surface for engaging a vertebrae and a lower surface which includes a rounded portion,
>
> 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,
>
> said implant being constructed to be the sole implant in its intervertebral space,
>
> the implant having a lead end which leads as the implant is inserted along a path into the intervertebral space and a trailing end opposite the lead end, and lateral planes which pass through the outermost boundaries of the implant and parallel to the said path, and
>
> *a single anchor on each of the upper surface of the upper part and the lower surface of the lower part*, each said anchor being elongated, having a height greater than its width, and located along a line parallel to said path, the two anchors lying essentially in the same vertical plane, which plane is essentially midway between said lateral planes,

> each said anchor being adapted to enter a groove in the adjacent vertebrae as the implant moves along said path into the intervertebral space, to anchor its respective part to the vertebrae which its surface engages.

'071 patent col.6 l.54-col.7 l.13 (emphasis added).

It is undisputed that U.S. Pat. No. 5,314,477 (the '477 patent) discloses every element of claim 1 except for the "single anchor" limitation. The '477 patent discloses an intervertebral implant that includes a top plate and a bottom plate, with the bottom plate having a "joint piece" embedded by force. '477 patent col.2 ll.26-32. Each plate is equipped with *two* "anchoring flaps" positioned near the outside edges of the plate that affix the implant into the adjacent vertebrae. *Id.* col.4 ll.7-10. The named inventor of the '477 patent is Dr. Thierry Marnay, one of the named inventors of the '071 patent.

Medtronic asserts that several prior art references disclose the claimed "single anchor" limitation. In particular, Medtronic focuses on Japanese Patent Application No. H2-261446 (Nobuo), which discloses an artificial vertebra with a single, central projection at each end. Medtronic argues that because a "single anchor" was known from various references, such as Nobuo, the combination of Nobuo and the '477 patent is "the product not of innovation but of . . . common sense." *KSR v. Teleflex*, 550 U.S. 398, 421 (2007). Indeed, Medtronic asserts, Dr. Marnay knew about the possibility of using a single anchor: Dr. Marnay testified that although he ultimately decided on a dual-anchor design for the '477 patent, he knew about and considered single anchor designs as early as 1989, ten years before the priority date of the '071 patent. Therefore, Medtronic argues, the asserted claims

of the '071 patent would have been obvious to one of skill in the art over the '477 patent in view of Nobuo.

SSI responds that Nobuo does not disclose a "single anchor." SSI also asserts that the record evidence shows that a person of skill in the art would not have been prompted to combine Nobuo's single anchor with the implant of the '477 patent because he would not have expected a single, centrally-placed keel to provide sufficient fixation for an intervertebral implant.

We agree with Medtronic that Nobuo discloses the claimed "single anchor." The district court construed "single anchor" as meaning, in relevant part, "[t]he upper and lower surfaces of the implant each have one anchor having the characteristics recited in the last paragraph of [claim 1] (elongated, height greater than width, parallel to an insertion path, lying essentially in a vertical plan[e] essentially between lateral planes, and adapted to enter a groove in the adjacent vertebrae)." *Spine Solutions, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 07-2175, 2008 U.S. Dist. LEXIS 116648, at *43 (W.D. Tenn. July 2, 2008) (*Claim Construction Order*). Figure 6 of Nobuo depicts an artificial vertebra with a single projection on each of its top and bottom ends. J.A. 18665. Each projection is elongated, with a height greater than its width, and is centrally placed between the "lateral planes" defined by the sides of the vertebra. Further, Nobuo discloses that the projections are mounted in grooves formed in the adjacent vertebrae. J.A. 18659 ("grooves 25 for mounting the projections 13 and 17 are made in the removed vertebra 2 and the healthy vertebrae 1"). The projections of Nobuo meet the limitation of a "single anchor," as construed by the court.

The combination of the '477 patent and Nobuo plainly discloses every limitation of claim 1; the question remains whether the combination of those references would have been obvious to a person of skill in the art. We agree with the district court that the record contains substantial evidence to support the jury's fact finding, implicit in its verdict of nonobviousness, that it would not have been obvious to a person of skill in the art to use a single anchor with the implant of the '477 patent. In particular, the record contains substantial evidence showing that a person of skill in the art would not have viewed a single keel as being stable enough for a disc replacement device. The record contains evidence showing that the center of a vertebra—the location of the '071 patent's single anchor—is typically the weakest part of a diseased or degenerated disc. J.A. 15306. Dr. Marnay testified that he decided not to use a single keel for the implant of the '477 patent because he did not think a single keel would provide sufficient stability. *Id.* Instead, Dr. Marnay chose to use a dual-keel design that anchored the parts of the implant into the stronger, outside portions of the vertebral bone. J.A. 15297-99. Dr. Marnay testified that he performed extensive testing of his single keel design prior to filing the application that issued as the '071 patent, due to his uncertainty regarding the stability of the single keel. J.A. 15324-25. The record also contains deposition testimony showing that Medtronic's own engineers were unsure as to whether a single keel would provide sufficient fixation during the development of Maverick. J.A. 15416, 15470**.**

Viewing this evidence most favorably to SSI, we cannot say that "reasonable minds could come to but one conclusion," in favor of Medtronic. *See Imwalle*, 515 F.3d at 543. Rather, the record contains substantial evidence to support the jury's implicit findings underlying its determination that it would not have been obvious to use

a single keel, such as that disclosed by Nobuo, with the implant of the '477 patent. Therefore, substantial evidence exists to support the jury's verdict of nonobviousness, and we affirm the court's denial of Medtronic's motion for JMOL of obviousness.

### B. Written Description

Medtronic asserts that the district court erred in granting summary judgment that the '071 patent contains adequate written description to support the limitation "single anchor . . . adapted to enter a groove." We review a grant of summary judgment *de novo*, reapplying the standard applicable at the district court. *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1345 (Fed. Cir. 2007). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008).

Claim 1 recites that the "single anchor" is "*adapted to enter a groove* in the adjacent vertebrae." '071 patent col.7 ll.3-10 (emphasis added). Medtronic argued that the written description does not disclose the "adapted to enter a groove" limitation. SSI argues that the '071 patent necessarily discloses anchors that are "adapted to enter a groove" because it discloses that the adjacent vertebrae rest on the support faces of the intervertebral implant after insertion. The district court granted summary

judgment holding that the claim was adequately supported by the written description. We see no error in this judgment.

Medtronic is correct that the '477 patent disclosure was not incorporated by reference and therefore cannot provide the disclosure of the "adapted to enter a groove" limitation. In the two pages Medtronic devotes to this issue, it argues that the patent makes no mention of grooves. *See*, *e.g.*, Medtronic's Br. at 37 ("patent's failure to disclose any information concerning the grooves located in the vertebrae and their interaction with the anchor is a prime example of SSI's attempt to expand its claims beyond its disclosures"); Medtronic's Reply Br. at 8 (arguing that the patent diagrams do not show any grooves). Because the claims at issue relate to the implant and do not cover the groove itself, applicants were not required to disclose grooves or how grooves should be formed or cut. The limitation at issue does not recite cutting a groove into vertebrae, or even inserting an anchor into a groove; rather, it recites "a single anchor . . . adapted to enter a groove." The issue for written description purposes is whether a person of skill in the art would understand the '071 patent to describe a single anchor that is adapted to enter a groove. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) ("the test for sufficiency [of the written description requirement] is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date").

We see no error in the district court's determination that there is no genuine dispute of material fact; the specification describes the claimed "single anchor" as necessarily being "adapted to enter a groove." The disclo-

sure of the shape of the anchor in combination with its placement adequately describes an anchor adapted to enter a groove. The specification discloses that each of the top and bottom parts of the implant has a support face that includes a single anchor. '071 patent col.3 ll.56-58, col.4 ll.9-12, figs. 1-7. These anchors affix the upper and lower parts into the adjacent vertebrae such that the end face of each vertebrae "rests . . . on the support face" of the corresponding part of the implant. *Id.* col.3 ll.58-60, col.5 ll.59-64. Thus, the specification discloses that the single anchor enters the adjacent vertebrae in such a way that the vertebrae "rest" on the support faces of the top and bottom parts of the implant. For such direct contact between the implant and vertebrae to occur, the single anchor must be entirely inserted into the adjacent vertebrae: that is, the anchors must be fully inserted into a "groove" of some type, whether that groove is pre-cut or formed by the anchor itself (e.g., by a "self-cutting" anchor). The specification, therefore, discloses that the single anchor is inserted into a vertebral groove. The record lacks adequate evidence to create a genuine dispute over whether the specification discloses that the anchors are "adapted to enter a groove." The fact that the specification never mentions the word groove is not sufficient to create a genuine dispute of material fact.

We agree with the district court that the specification of the '071 patent provides adequate written description to support the "single anchor . . . adapted to enter a groove" limitation. Therefore, we affirm the court's grant of SSI's motion for partial summary judgment dismissing Medtronic's 35 U.S.C. § 112 defenses.

## C. Claim Construction

Medtronic asserts that the district court erred in construing the claim term "operative engagement." Claim construction is a matter of law, and we review the court's claim construction without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1451 (Fed. Cir. 1998) (en banc). In doing so, we are mindful of the principle that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). We read the claims "in view of the specification," which is "the single best guide to the meaning of a disputed term." *Id.* at 1315.

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." '071 patent col.6 ll.60-62 (emphasis added). At claim construction, Medtronic proposed construing "operative engagement" to mean "the interaction between the pivot insert and the rounded portion of the upper part." *Claim Construction Order*, 2008 U.S. Dist. LEXIS 116648, at *18. The court observed that although the preferred embodiment of the '071 patent has a pivot, claim 1 does not recite such a limitation: rather, claim 1 recites only an upper and a lower part that are "in operative engagement" with each other. The court also found that claim differentiation weighed against reading a pivot limitation into claim 1, because various dependent claims add limitations relating to a two-piece lower part with a pivot insert. Therefore, the court adopted SSI's proposed construction, construing "operative engagement" as "permitting movement (for example pivotability)." *Id.* at *23.

Medtronic asserts that the court erred in construing "operative engagement" as not incorporating a pivot insert. According to Medtronic, the only "engagement" disclosed by the specification occurs between the upper part and the pivot insert, not between the upper and lower parts. SSI asserts that the court's construction is correct because the plain language of the claim does not limit the invention to the preferred three-piece embodiment.

We agree with SSI that the court correctly construed "operative engagement." The language of the limitation is straightforward: the lower part of the implant engages "operatively" with the rounded portion of the upper part. Given that the claimed invention is an intervertebral implant designed to replace a disc in a spinal column, "operative engagement" must be engagement such that the upper and lower parts of the implant can move relative to each other; otherwise, the implant would be rigid and would inhibit movement of the adjacent vertebrae. Thus, the court correctly determined that "operative engagement" relates to permitting movement. The court also did not err in identifying pivotability as an example type of movement; the '071 patent specifically discloses pivotability in association with the preferred embodiment. However, nothing in the claim suggests that the upper part of the implant must be specifically engaged with a pivot insert, as opposed to the lower part of the implant. To the contrary, the claim indicates that the upper and lower parts are engaged with each other directly. '071 patent col.6 ll.60-62 ("a lower part having . . . an upper surface portion in operative engagement with the rounded portion of the upper part"). Therefore, the court did not err in construing "operative engagement" as "permitting movement (for example pivotability)."

Medtronic asserts, in the alternative, that under the court's construction claim 1 is invalid for failure to comply with the written description requirement. Therefore, Medtronic argues, the court erred in granting summary judgment that the '071 patent contains adequate written description to support the limitation "lower part having . . . an upper surface portion in operative engagement with the rounded portion of the upper part." Medtronic argues that the '071 patent only describes a three-piece device with a separate pivot insert, not a two-piece device that permits movement between the top and bottom parts. However, Figures 3 and 6 of the '071 patent illustrate the implant outside the intervertebral space (i.e., prior to insertion) and show the pivot insert as embedded in the lower part. Additionally, the evidence at summary judgment included deposition testimony from Medtronic's expert that a person of skill in the art would have known that an implant having a lower plate with an embeddable pivot insert—such as that disclosed by the '071 patent—could have been assembled prior to insertion and inserted into the patient as a two-piece device. Medtronic does not point to any evidence rebutting this testimony. Therefore, we agree with the district court that a person of skill in the art would have understood the '071 patent to describe an implant that could be pre-assembled prior to insertion, such that the upper surface of the lower part is "operatively engaged" with the lower surface of the upper part.

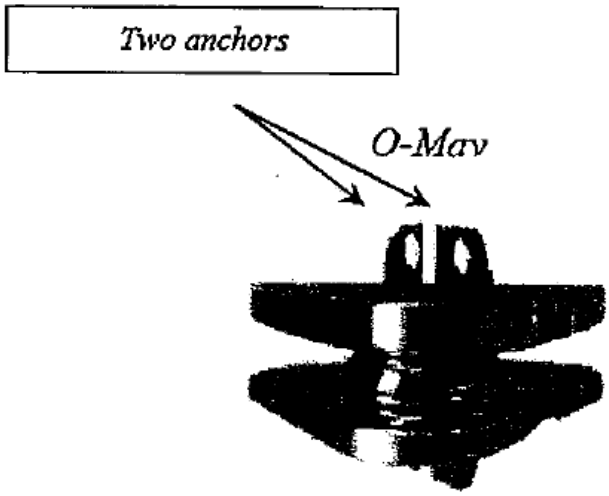
Medtronic contends that the '071 patent does not describe a two-piece implant because the '071 patent actively disparages the two-piece design of the '477 patent. In discussing the two-piece design of the '477 patent, the '071 patent notes that it is "particularly difficult" to achieve a minimum structural height for an implant if the pivot is embedded prior to insertion. *Id.* col.1 ll.11-19. However, this does not rise to the level of an express

disclaimer sufficient to limit the scope of the claims; "[d]isavowal requires expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Epistar Corp. v. ITC*, 566 F.3d 1321, 1335 (Fed. Cir. 2009). Further, claim 1 is not directed to the height-minimizing embodiment. The originally-filed claims recited limitations directed to "protrusions and recesses . . . which are offset laterally from one another in such a way that . . . [the upper and lower parts] mesh with one another," *see* J.A. 17167; claim 1 as issued recites no such limitation.

## D. Noninfringement

Medtronic asserts that the district court erred 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. Although "infringement is a question of fact, we review a district court's grant of summary judgment without deference." *Schindler Elevator Corp. v. Otis Elevator Co.*, 593 F.3d 1275, 1281 (Fed. Cir. 2010). "Prosecution history estoppel is a legal question subject to de novo review on appeal." *Cybor Corp.*, 138 F.3d at 1460.

O-Maverick is a two-piece implant arranged as an articulating ball-and-socket joint. As shown below, each of the top and bottom pieces includes an anchoring structure that consists of two tabs separated by a one-millimeter wide gap:




Medtronic moved for summary judgment that O-Maverick does not infringe claims 1 and 2, arguing that O-Maverick has two anchors on each piece and therefore does not meet the "single anchor" limitation. SSI cross-moved for summary judgment of infringement, arguing that O-Maverick has a single, "slotted" keel and infringes both literally and under the doctrine of equivalents.

The district court determined on summary judgment that the O-Maverick anchoring structure meets the claimed "single anchor" limitation. The court acknowledged that the issue of infringement turned on whether the O-Maverick anchoring structure was properly deemed to be one or two anchors. The court held, effectively as a matter of law, that the O-Maverick anchoring structure qualified as a "single anchor." The court characterized the gap between the tabs as "a diagonal slot" and stated that its construction of "single anchor" did not exclude such a feature. J.A. 57. Therefore, the court held that O-Maverick literally infringed claims 1 and 2 as a matter of law. The court also held as a matter of law that the anchoring structure met the "single anchor" limitation

under the doctrine of equivalents. Medtronic argued that prosecution history estoppel barred SSI from arguing equivalence because applicants disavowed the use of dual anchors during prosecution of the '071 patent; the court rejected this argument, concluding that applicants' disavowal was not "a clear and unmistakable surrender of the type of keel structure on the [O-Maverick]." J.A. 61. The court therefore granted SSI's motion for summary judgment of infringement with respect to O-Maverick, both literally and under the doctrine of equivalents, and denied Medtronic's motion for summary judgment of noninfringement.

We agree with Medtronic that the court erred in determining that O-Maverick literally infringes claims 1 and 2. The court construed "single anchor" to mean, in relevant part, that "[t]he upper and lower surfaces of the implant each have *one anchor* having the characteristics recited in the last paragraph of [claim 1]." *Claim Construction Order*, 2008 U.S. Dist. LEXIS 116648, at *43 (emphasis added). A simple observation of O-Maverick confirms that the implant has two anchors on each of the upper and lower pieces, not one. The anchors are separated by a one-millimeter gap that extends all the way to the base of the implant; at no point are the two anchors joined or connected in any way. O-Maverick clearly has two anchors on each piece, not a "single anchor" as recited by claims 1 and 2. Therefore, we hold as a matter of law that O-Maverick does not literally infringe claims 1 and 2.

With respect to the doctrine of equivalents, Medtronic argues that applicants made a clear surrender of any designs containing more than one anchor during prosecution of the '071 patent. We agree. During prosecution, applicants expressly distinguished the claimed invention over the '477 patent by asserting that "a reference disclos-

ing two anchors does not disclose a device affirmatively claiming a single anchor . . . reciting a negative limitation in the form of a *single* element is not disclosed by prior art which teaches more than one element." J.A. 17524. This is a clear disclaimer of claim scope, and prosecution history estoppel therefore bars SSI from arguing that a two-anchor device is equivalent to the claimed implant. Because we hold that O-Maverick is a two-anchor device, SSI cannot argue that O-Maverick infringes claims 1 and 2 under the doctrine of equivalents.

Because O-Maverick has two anchors, we hold as a matter of law that it does not literally infringe claims 1 and 2 of the '071 patent. Further, because prosecution history estoppel bars SSI from arguing that O-Maverick's two anchors are equivalent to the claimed "single anchor," we hold as a matter of law that O-Maverick does not infringe claims 1 and 2 under the doctrine of equivalents. Therefore, we reverse the district court's grant of summary judgment of infringement and denial of summary judgment of noninfingement, and we remand for the court to enter judgment of noninfringement with respect to O-Maverick.[1]

## E. Standing and Lost Profits

Medtronic asserts that the court abused its discretion in allowing SSI to amend its complaint to add Synthes Spine and Synthes, Inc. as co-plaintiffs. Medtronic argues that Synthes Spine and Synthes, Inc. lack standing to sue

[1] As it appears to be undisputed that Maverick and A-Maverick are both single-anchor implants, our holding of noninfringement with respect to O-Maverick does not disturb the parties' stipulation that Maverick and A-Maverick infringe the asserted claims.

for infringement of the '071 patent because they are neither owners nor exclusive licensees of the patent. "The question of standing to sue is a jurisdictional one, which we review *de novo*." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1551 (Fed. Cir. 1995) (en banc). "The party bringing the action bears the burden of establishing that it has standing." *Sicom Sys. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005).

It is well-settled that "[o]nly a patent owner or an exclusive licensee can have constitutional standing to bring an infringement suit; a non-exclusive licensee does not." *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008). To be an exclusive licensee for standing purposes, "a party must have received, not only the right to practice the invention within a given territory, but also the patentee's express or implied promise that others shall be excluded from practicing the invention within that territory as well." *Id.* (citing *Rite-Hite*, 56 F.3d at 1552). "If the party has not received an express or implied promise of exclusivity under the patent, i.e., the right to exclude others from making, using, or selling the patented invention," the party has only a "bare license"—and a "bare license to sell an invention in a specified territory, even if it is the only license granted by the patentee, does not provide standing without the grant of a right to exclude others." *Rite-Hite*, 56 F.3d at 1552, 1553.

It is undisputed that SSI is the sole owner of the '071 patent. With respect to Synthes, Inc., SSI's parent corporation, the record contains no evidence that Synthes, Inc. is an exclusive licensee of the '071 patent. In fact, the amended complaint does not even allege that Synthes, Inc. *licenses* the '071 patent. Given that nothing in the record indicates that Synthes, Inc. is an owner or exclusive licensee of the '071 patent, we agree with Medtronic

that SSI failed to show that Synthes, Inc. had standing to bring this suit. Therefore, the district court abused its discretion in allowing SSI to amend its complaint to add Synthes, Inc. as a co-plaintiff.

The question remains whether Synthes Spine, SSI's sister corporation that makes and sells ProDisc II, is an exclusive licensee for purposes of standing. Medtronic argues that the record does not contain sufficient evidence to establish that Synthes Spine has an exclusive license to the '071 patent. SSI acknowledges that there is no agreement, either oral or written, between SSI and Synthes Spine with respect to the '071 patent. However, SSI asserts that an "understanding" exists within the Synthes family that Synthes Spine has the exclusive right to practice the '071 patent. SSI points to deposition testimony from its corporate representative—Robert Donohue, the Chairman of SSI and Chief Financial Officer of Synthes, Inc.—that this "understanding" is "based on the fact that [Synthes Spine] has the exclusive right to market and distribute all spine-related products in the U.S. . . . I'm not aware of an expressed agreement that is oral or written. I believe it's an agreement between the parties based on the way Synthes is organized." J.A. 13588. SSI also relies on Mr. Donohue's testimony that "based on the way Synthes is organized and operates," SSI would not be able to license the '071 patent to any party other than Synthes Spine. J.A. 14101. SSI asserts that the only reasonable conclusion to be drawn from Synthes' organizational structure is that SSI has made an implied promise to exclude entities other than Synthes Spine from practicing the '071 patent.

We agree with Medtronic that SSI failed to establish that Synthes Spine had standing to join SSI's infringement suit. The evidence of record shows that SSI owns

and enforces the '071 patent and that Synthes Spine is the only entity that makes and sells products practicing the patent. Based solely on this "organization," SSI asks us to infer that it made an implied promise to exclude all entities other than Synthes Spine from practicing the '071 patent. However, the fact that Synthes Spine is currently the only entity practicing the '071 patent does not mean that SSI has promised to exclude all others from doing so. Nothing in the record shows that SSI would be prohibited from licensing the '071 patent to a third party, should it so desire. Indeed, Mr. Donohue's testimony shows that the "understanding" regarding the '071 patent is based on nothing more than the way in which the various Synthes entities presently operate. This indicates that by allowing Synthes Spine to practice the claimed invention, SSI has granted it at most a bare license.

If we were to find standing on these facts, this would mean that any company related to a patent owner could be treated as an exclusive licensee, so long as the patent owner allows only that company to practice the patent, regardless of any actual agreement as to exclusivity. This is plainly contrary to our case law, which specifies that a "bare license . . . even if it is the only license granted by the patentee, does not provide standing without the grant of a right to exclude others." *Rite-Hite*, 56 F.3d at 1553. Given that SSI fails to point to any evidence other than its current "organization" to show that Synthes Spine is an exclusive licensee, we conclude that SSI failed to meet its burden of establishing that Synthes Spine has standing to bring suit. Therefore, the district court abused its discretion in allowing SSI to amend its complaint to add Synthes Spine as a co-plaintiff.

SSI asserts that Medtronic waived the right to challenge the availability of lost profits through reliance on

any "corporate distinctions" between the Synthes entities because Medtronic allegedly treated the various Synthes entities as one throughout discovery. Regardless of how SSI characterizes Medtronic's position, however, Medtronic is challenging the standing of Synthes, Inc. and Synthes Spine to bring suit on the '071 patent. Under Article III of the Constitution, "standing . . . is jurisdictional and not subject to waiver." *Pandrol USA, LP v. Airboss Ry. Prods.*, 320 F.3d 1354, 1367 (Fed. Cir. 2003) (citation omitted).

Because we conclude that neither Synthes Spine nor Synthes, Inc. has standing to sue on the '071 patent, SSI is not entitled to recover for any lost profits suffered by Synthes Spine or Synthes, Inc. It is undisputed that SSI does not itself sell any products. Therefore, SSI is not entitled to any lost profits damages. *See Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004) ("the patentee needs to have been selling some item, the profits of which have been lost due to infringing sales, in order to claim damages consisting of lost profits"). We reverse the district court's denial of Medtronic's motion for JMOL of no lost profits and vacate the jury's award of lost profits damages. We remand to the court for a determination of the proper reasonable royalty to which SSI might be entitled on the infringing sales of Maverick and A-Maverick for which the jury awarded lost profits.

## F. Willfulness

Medtronic asserts that the court erred in denying its motion for JMOL of no willfulness because SSI failed to establish that Medtronic's manufacture of the Maverick products was objectively reckless. Medtronic argues that its infringement defenses, and its reliance on those defenses, were reasonable. Willfulness is a question of fact,

and our review on appeal is "limited to asking whether [the jury's] verdict is supported by substantial evidence." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 859 (Fed. Cir. 2010).

To establish willful infringement, "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007). This "objective" prong of *Seagate* tends not to be met where an accused infringer relies on a reasonable defense to a charge of infringement. *E.g.*, *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1336-37 (Fed. Cir. 2009) (holding that the district court correctly granted JMOL of no willfulness where defendant "presented a substantial question" of noninfringement under the doctrine of equivalents, even though the jury found equivalence); *cf. i4i*, 598 F.3d at 860 (affirming the district court's denial of JMOL of no willfulness because "the jury was free to decide for itself whether Microsoft reasonably believed there were any substantial defenses to a claim of infringement"). If *Seagate*'s objective prong is met, "the patentee must also demonstrate that this objectively-defined risk . . . was either known or so obvious that it should have been known to the accused infringer." *Id.*

Medtronic raised a substantial question as to the obviousness of the '071 patent. The combination of the '477 patent and Nobuo plainly discloses all of the claimed limitations. Although we hold that the record contains substantial evidence to support the jury's implicit finding that one of skill in the art would not have found the combination obvious, Medtronic was not objectively reckless in relying on this defense. *Seagate*, 497 F.3d at 1371 ("proof of willful infringement permitting enhanced

damages requires at least a showing of objective recklessness"). Indeed, the district court expressly noted in the context of its enhanced damages analysis that Medtronic's obviousness arguments were "reasonable." J.A. 198. We conclude that substantial evidence does not support the jury's finding that Medtronic acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. Therefore, we reverse the district court's denial of Medtronic's motion for JMOL of no willfulness.

Because we reverse the denial of JMOL of no willfulness, we also vacate the award of enhanced damages. *i4i*, 598 F.3d at 858 ("A finding of willful infringement is a prerequisite to the award of enhanced damages."). Further, as the court's finding of exceptionality was based solely on "evidence of Medtronic's willful infringement," we also vacate the award of attorney fees under 35 U.S.C. § 285. J.A. 202.

### G. Permanent Injunction

Finally, Medtronic argues that the court abused its discretion in permanently enjoining sales of Maverick devices that are already outside of the U.S. "We review the decision to grant an injunction, as well as the scope of that injunction, for abuse of discretion." *i4i*, 598 F.3d at 861.

The court's injunction prohibits Medtronic from, among other things, "using, selling, offering for sale, or otherwise transferring" any of the accused devices that have already been exported. J.A. 232. Medtronic asserts, citing 35 U.S.C. § 283, that an injunction is only proper to prevent *future* infringement. Medtronic contends that future sales of its Maverick devices outside the U.S.

cannot infringe any U.S. patent. Medtronic also contends that there is no risk that the accused devices will be re-imported because the Maverick devices are not sold within the U.S.

A district court "may grant injunctions in accordance with the principles of equity *to prevent the violation of any right secured by patent*, on such terms as the court deems reasonable." 35 U.S.C. § 283 (emphasis added). An injunction is only proper to prevent future infringement of a patent, not to remedy past infringement. *See also Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1365 (Fed. Cir. 1998) ("[A]n injunction is only proper to the extent it is 'to prevent the violation of any right secured by patent.'") (quoting 35 U.S.C. § 283). As we noted in *CellPro*, a patentee must seek compensation for past infringement under 35 U.S.C. § 284; the purpose of an injunction is to prevent future violations of the patent. *Id.* at 1367.

Medtronic's overseas sales of the Maverick products cannot infringe any U.S. patent, and there is little risk that the infringing devices will be imported.[2] Thus, the extraterritorial portion of the injunction appears to be premised solely on Medtronic's past infringement, not on the prevention of future infringement. This is contrary to the plain language of 35 U.S.C. § 283. Therefore, the court abused its discretion in imposing the extraterritorial restraints on Medtronic. On remand, the court is directed to vacate the extraterritorial portion of the injunction.

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[2] At oral argument, SSI's counsel represented that SSI agrees the injunction should be modified to delete the extraterritorial portion. Trans. of Oral Arg. at 29:39-30:08.

## CONCLUSION

For the foregoing reasons, we affirm the district court's denial of Medtronic's motion for JMOL that the asserted claims of the '071 patent are invalid for obviousness. We also affirm the court's denial of Medtronic's motion for summary judgment of invalidity for failure to comply with the written description requirement; its grant of SSI's motion for partial summary judgment dismissing Medtronic's 35 U.S.C. § 112 defenses; and its construction of the term "operative engagement." We reverse the court's denial of Medtronic's motion for summary judgment of noninfringement and its grant of summary judgment of infringement with respect to O-Maverick, and we remand for the court to enter judgment of noninfringement with respect to O-Maverick. We also reverse the court's denial of Medtronic's motion for JMOL of no lost profits, and we therefore vacate the jury's award of lost profits damages and remand for the court to determine any additional reasonable royalty to which SSI might be entitled. We reverse the court's denial of Medtronic's motion for JMOL of no willfulness and consequently vacate the enhanced damages and attorney fee awards. Finally, we remand for the court to modify the terms of the permanent injunction by deleting the extraterritorial portion.

AFFIRMED-IN-PART, REVERSED-IN-PART,
VACATED-IN-PART and REMANDED

## COSTS

No costs.