United States Court of Appeals for the Federal Circuit

2008-1240, -1253, -1401

DEPUY SPINE, INC. (formerly known as Depuy Acromed, Inc.),

Plaintiff-Cross Appellant,

and

BIEDERMANN MOTECH GMBH,

Plaintiff-Cross Appellant,

v.

MEDTRONIC SOFAMOR DANEK, INC.
(formerly known as Sofamor Danek Group, Inc.)
and MEDTRONIC SOFAMOR DANEK USA, INC.,

Defendants-Appellants.

Calvin P. Griffith, Jones Day, of Cleveland, Ohio, argued for all plaintiffs-cross appellants. With him on the brief for Depuy Spine, Inc. (formerly know as Depuy Acromed, Inc.), were Patrick J. Norton; and Gregory A. Castanias, of Washington, DC. On the brief for Biedermann Motech GmbH were Luke L. Dauchot and Greer N. Shaw, Kirkland & Ellis LLP, of Los Angeles, California.

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; and Mark C. Fleming, Richard W. O'Neill, Timothy R. Shannon, Lauren B. Fletcher, and Sydenham B. Alexander, III, of Boston, Massachusetts. Of counsel on the brief were Dirk D. Thomas, André J. Bahou, and John K. Warren, Dewey & LeBoeuf LLP, of Washington, DC.

Appealed from: United States District Court for the District of Massachusetts

Senior Judge Edward F. Harrington

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Defendants-Appellants.

Appeals from the United States District Court for the District of Massachusetts in case no. 01-CV-10165, Senior Judge Edward F. Harrington.

DECIDED: June 1, 2009

Before NEWMAN, BRYSON, and LINN, Circuit Judges.

LINN, Circuit Judge.

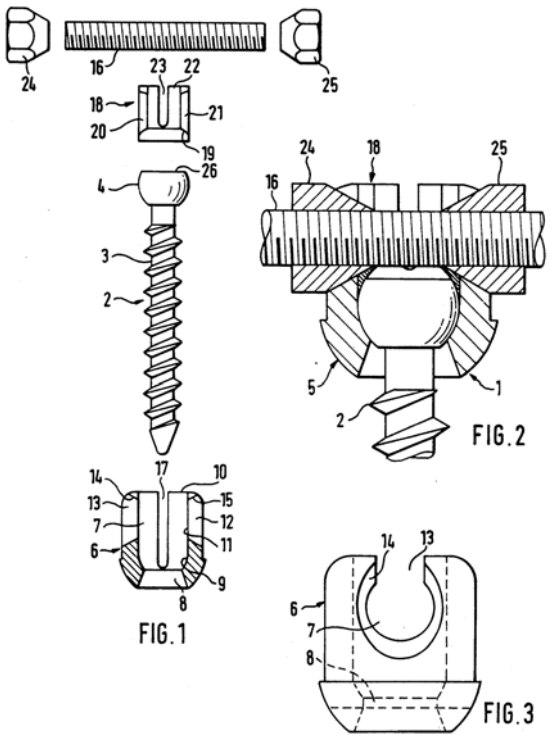
Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively "Medtronic") appeal from a final judgment of the United States District Court for the District of Massachusetts. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-CV-10165 (D. Mass. Dec. 11, 2007). The district court denied Medtronic's ensnarement defense after a jury found that Medtronic had infringed U.S. Patent

No. 5,207,678 ("the '678 patent") under the doctrine of equivalents and awarded $226.3 million in lost-profit damages to DePuy Spine, Inc. and Biedermann Motech GmbH (collectively "DePuy"). DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 526 F. Supp. 2d 162 (D. Mass. 2007) ("Ensnarement Order"). The district court also found that Medtronic had engaged in litigation misconduct, for which the court awarded DePuy $425,375 in attorney fees under 35 U.S.C. § 285 and imposed a further $10 million sanction against Medtronic under the court's inherent authority. Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 534 F. Supp. 2d 224 (D. Mass. 2007) ("Sanctions Order"). DePuy cross-appeals from the grant of Medtronic's motion for judgment as a matter of law ("JMOL") of no willful infringement and from the denial of DePuy's motion for new trial on reasonable royalty damages.

Because the district court correctly denied Medtronic's ensnarement defense and correctly denied Medtronic's motion for JMOL on lost profits of patented pedicle screws, we affirm the damages award as to those products. However, we reduce the damages award insofar as the lost profits were based partly on lost sales of unpatented "pull-through" products, which neither compete nor function with the patented invention. We also reverse the award of attorney fees and the imposition of sanctions, which were predicated on a legal error involving the application of the reverse doctrine of equivalents. Finally, we conclude that the district court correctly determined that Medtronic was entitled to JMOL of no willfulness, and that it did not abuse its discretion in denying DePuy's motion for new trial on royalty damages. Thus, we affirm-in-part, reverse-in-part, and remand for calculation of post-judgment interest.

BACKGROUND

This appeal involves Medtronic's Vertex® model of polyaxial pedicle screws used in spinal surgeries. In a prior appeal, we affirmed the district court's grant of summary judgment of no literal infringement of the '678 patent by the Vertex® model, but reversed the grant of summary judgment of noninfringement under the doctrine of equivalents. DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-CV-10165 (D. Mass. Feb. 24, 2004), aff'd in part, rev'd in part sub nom. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1026 (Fed. Cir. 2006) ("DePuy Spine I"). We held that the Vertex® model, which contains a receiver member having an inner hollow space that is conical in shape, does not literally infringe because it does not meet the "spherically-shaped" limitation of claim 1. 469 F.3d at 1016. However, we concluded that a question of fact existed as to whether the Vertex® model's conical shape was insubstantially different from the claimed "spherically-shaped portion" under the doctrine of equivalents, and remanded for resolution of that issue. Id. at 1020. The patented device, as shown below in figures 1 through 3 of the '678 patent, includes a pedicle screw **1** having a screw head **4** that is surrounded by the spherically-shaped portion **9** of the receiver member **5**:



On remand, Medtronic raised an "ensnarement" defense against the doctrine of equivalents, arguing that the asserted scope of equivalency would encompass, or "ensnare," the prior art. Specifically, Medtronic argued that the combination of U.S. Patent No. 5,474,555 ("Puno") and U.S. Patent No. 2,346,346 ("Anderson") would have rendered obvious a "hypothetical" version of claim 1 of the '678 patent, in which the phrase "conically-shaped" is substituted for the actual claim term "spherically-shaped." The district court took the question from the jury and held that ensnarement, like prosecution history estoppel, is a legal limitation on the doctrine of equivalents that would be decided by the court at the conclusion of the infringement proceeding. Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 515 F. Supp. 2d 206 (D. Mass. 2007).

A two-week jury trial was held on the issues of infringement, willfulness, and damages. At the close of evidence, the district court granted Medtronic's motion for JMOL of no willfulness. The case then went to the jury on infringement and damages.

The jury, using a special verdict form, found that the Vertex® model infringed independent claim 1 and dependent claims 3, 5, and 6 of the '678 patent under the doctrine of equivalents, and awarded DePuy a total of $226.3 million in damages consisting of $149.1 million in lost profits on pedicle screws and $77.2 million in lost profits on "pull-through" products. But the jury awarded DePuy a 0% royalty rate on $237.2 million worth of infringing sales that were not subject to DePuy's claim for lost profits, even though Medtronic itself had argued for no less than a 6% royalty rate if its products were found to infringe. After the jury was dismissed, the district court denied Medtronic's post-trial motions for a new trial on infringement and for JMOL on lost profits. Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 533 F. Supp. 2d 243 (D. Mass. 2008) ("Feb. 6 Order"). DePuy also filed a post-trial motion seeking a new trial on royalty damages. The district court denied that motion, noting that DePuy had failed to timely object to the inconsistency in the verdict before the jury was discharged. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-CV-10165 (D. Mass. Feb. 14, 2007) ("Feb. 14 Order").

After the jury trial, the district court conducted a separate bench trial on Medtronic's ensnarement defense. In a memorandum and order dated December 11, 2007, the district court held that the combination of Puno and Anderson did not render the hypothetical claim obvious. Ensnarement Order, 526 F. Supp. 2d at 176. As part of that order, the district court directed entry of judgment on the jury verdict, including the jury determination of $226.3 million in damages. Id. at 177. Several months later, in a concurrent reexamination of the '678 patent requested by Medtronic (Control No. 90/008,589), the U.S. Patent & Trademark Office issued a Notice of Intent to Issue an

Ex Parte Reexamination Certificate, indicating that all (actual) claims under reexamination were being confirmed over Puno and Anderson without change. A reexamination certificate issued on June 24, 2008.

DePuy next moved for enhanced damages under 35 U.S.C. § 284 and attorney fees under § 285, alleging a "litany" of litigation misconduct on the part of Medtronic. Sanctions Order, 534 F. Supp. 2d at 225. The district court denied enhanced damages because willful infringement had not been shown. But, because the court perceived Medtronic to have attempted to relitigate at trial its argument from the first appeal regarding the construction of the "pressed against" limitation, in the guise of a reverse doctrine of equivalents defense, the court awarded DePuy 15% of its attorney fees, totaling $425,375. The court stated that Medtronic's reverse doctrine of equivalents defense "threatened to mislead and confuse the jury" and "flouted the governing claim construction as set forth by the Federal Circuit." Id. at 226-27. Based on this misconduct, the district court sua sponte imposed a further $10 million sanction under the court's inherent authority, remarking in a footnote that "[w]here the amount in controversy in a case is large (as was the case here), the prospective penalty for litigation misconduct, if it is to serve the purpose of deterring that conduct, should also be large." Id. at 227 n.3.

Both parties appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Ensnarement

Ensnarement bars a patentee from asserting a scope of equivalency that would encompass, or "ensnare," the prior art. See Wilson Sporting Goods Co. v. David

Geoffrey & Assoc., 904 F.2d 677, 683 (Fed. Cir. 1990), overruled in part on other grounds, Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 92 n.12 (1993). On appeal, Medtronic challenges the district court's denial of its ensnarement defense on the merits. Alternatively, Medtronic argues that it was entitled to present its defense to a jury rather than to the district court. We first address the jury issue and hold that ensnarement, like prosecution history estoppel, is a legal limitation on the doctrine of equivalents to be decided by the court, not a jury. We then conclude that Medtronic's ensnarement defense was properly denied on the merits.

A. The Jury Issue

"The constitutional question of whether a party is entitled to a jury trial is a question of law that this court reviews de novo." Tegal Corp. v. Tokyo Electron Am., Inc., 257 F.3d 1331, 1339 (Fed. Cir. 2001). Medtronic argues that ensnarement, like infringement, must be tried to a jury when requested by a defendant. Although Medtronic acknowledges that ensnarement is ultimately a question of law, see Wilson Sporting Goods, 904 F.2d at 683, Medtronic argues that ensnarement's underlying factual issues must be resolved by a jury if one is requested.

Notwithstanding the jury's proper fact-finding role in assessing the equivalence of each limitation of a claim, the Supreme Court has recognized "various legal limitations on the application of the doctrine of equivalents." Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 39 n.8 (1997). These "legal limitations . . . are to be determined by the court either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict." Id. (emphasis added). In Warner-Jenkinson, the Supreme Court identified two

such "legal limitations": (1) the "all-elements rule," which bars a patentee from asserting "a theory of equivalence [that] would entirely vitiate a particular claim element," and (2) prosecution history estoppel, which bars a patentee from asserting a scope of equivalency surrendered during prosecution. Id. On the issue of prosecution history estoppel, our second en banc Festo decision held that "the determinations concerning whether the presumption of surrender has arisen and whether it has been rebutted are questions of law for the court, not a jury, to decide." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 344 F.3d 1359, 1368 (Fed. Cir. 2003) (en banc) (emphasis added).

Although Warner-Jenkinson did not explicitly mention "ensnarement" as one of the "various legal limitations on the application of the doctrine of equivalents" to be decided by a court, we have consistently treated it as such. We have called ensnarement and prosecution history estoppel, collectively, "two policy oriented limitations" on the doctrine of equivalents, both of which are "applied as questions of law." Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 870 (Fed. Cir. 1985), overruled in part on other grounds, Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998) (en banc). Ensnarement, like prosecution history estoppel, limits the scope of equivalency that a patentee is allowed to assert. This limitation is imposed even if a jury has found equivalence as to each claim element. See Wilson Sporting Goods, 904 F.2d at 683 ("Even if this [function-way-result] test is met, however, there can be no infringement if the asserted scope of equivalency of what is literally claimed would encompass the prior art."); id. at 687 (deciding ensnarement "as a matter of law" after jury found infringement). The ensnarement inquiry is separate and distinct from

the jury's element-by-element equivalence analysis, and it has no bearing on the validity of the actual claims. See id. at 685 ("Wilson's claims will remain valid whether or not Wilson persuades us that it is entitled to the range of equivalents sought here.").

We see no reason why ensnarement should be treated differently, for procedural purposes, than prosecution history estoppel. As mentioned, both are "legal limitation[s] on the application of the doctrine of equivalents," decided as questions of law, and reviewed de novo. Festo, 344 F.3d at 1368; Wilson Sporting Goods, 904 F.2d at 683. In both analyses, the burden of persuasion is on the patentee to establish either that the reason for the amendment was unrelated to patentability, Warner-Jenkinson, 520 U.S at 33 (prosecution history estoppel), or that the asserted scope of equivalency would not ensnare the prior art, Wilson Sporting Goods, 904 F.2d at 685 (ensnarement). Although both analyses "may be subject to underlying facts," we have recognized that "the resolution of factual issues underlying a legal question may properly be decided by the court," Festo, 344 F.3d at 1368 n.3 (prosecution history estoppel), and we review the district court's resolution of those factual issues for clear error, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 493 F.3d 1368, 1376 (Fed. Cir. 2007) (prosecution history estoppel). Accordingly, we hold that ensnarement, like prosecution history estoppel, is "to be determined by the court, either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict." Warner-Jenkinson, 520 U.S at 39 n.8. As a practical matter, both legal limitations may be readily addressed in the same set of motions.

For guidance on resolving ensnarement's factual issues, we again draw analogy to prosecution history estoppel, particularly in the context of rebutting the presumption of surrender under the "foreseeability" criterion. See Festo, 344 F.3d at 1369 ("This criterion presents an objective inquiry, asking whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment."). In that context, when deciding whether an equivalent would have been unforeseeable, "a district court may hear expert testimony and consider other extrinsic evidence relating to the relevant factual inquiries," including "the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment." Id. So too, in the ensnarement context, a district court may hear expert testimony and consider other extrinsic evidence regarding: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). If a district court believes that an advisory verdict would be helpful, and that a "hypothetical claim" construct would not unduly confuse the jury as to equivalence and validity, then one may be obtained under Federal Rule of Civil Procedure 39(c). See, e.g., Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1375 (Fed. Cir. 2001) (ensnarement submitted to jury with parties' consent). Ultimately, however, ensnarement is a question of law for the court, not the jury, to decide.

B. The Ensnarement Defense

Medtronic argues that the district court erred in holding that hypothetical claim 1 would not have been obvious over a combination of Puno and Anderson. The district

court found that Puno "teaches away" from the proposed combination and that various "secondary considerations" support a conclusion of nonobviousness. Ensnarement Order, 526 F. Supp. 2d at 172-76. We review de novo the district court's conclusion that a hypothetical claim does not ensnare the prior art. Wilson Sporting Goods, 904 F.2d at 683. We review a district court's resolution of underlying factual issues in the ensnarement context for clear error. Cf. Festo, 493 F.3d at 1376 (applying clear error standard to review of fact-finding underlying "foreseeability" criterion).

A helpful first step in an ensnarement analysis is to construct a hypothetical claim that literally covers the accused device. Interactive Pictures, 274 F.3d at 1380. Here, both parties agree that the following hypothetical claim literally covers the Vertex® model:

> Device for stabilizing spinal column segments, comprising a pedicle screw (1) having a threaded shaft portion (3) and a spherically-shaped head (4) at the end of said threaded shaft portion, a receiver member (5) flexibly connected to said head (4), said receiver member being provided with two holes for receiving a rod 916) [sic:(16)], a receiver chamber (7) being provided within said receiver member (5), the receiver chamber (7) having at one end thereof a bore (8) for passing the threaded shaft portion (3) therethrough and an inner hollow conically-shaped portion (9) for receiving the head (4) of said screw (1), an opening (10) being provided opposite said bore (8) for inserting said screw (1), said device further comprising a compression member (18) for exerting a force onto said head (4) such that said head is pressed against the hollow conically-shaped portion (9).

'678 patent, cl.1 (emphases added to denote substitution of "conically" for "spherically").

Next, the district court must assess the prior art introduced by the accused infringer and determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art. Interactive Pictures,

274 F.3d at 1380. Ultimately, "[i]f such a claim would be unpatentable under 35 U.S.C. §§ 102 or 103, then the patentee has overreached, and the accused device is noninfringing as a matter of law." Id.

Medtronic produced two references, Puno and Anderson, that it believes renders the hypothetical claim obvious under § 103. Puno discloses a polyaxial pedicle screw assembly, illustrated in figure 7 of Puno, reproduced below left, which the parties agree contains all elements of the claim other than a "compression member" for pressing the screw head against the receiver member. Because Puno's design lacks a compression member, the screw head **30** is separated from the receiver member, depicted in figure 7 as anchor seat **23**, and achieves what Puno calls a "shock absorber" effect, allowing for some motion between the anchor seat and the vertebrae. Puno col.3 ll.60-63. This shock absorber effect "prevent[s] direct transfer of load from the rod to the bone-screw interface prior to achieving bony fusion, thereby decreasing the chance of failure of the screw or the bone-screw interface." Id. col.3 ll.64-67. Medtronic asserts that Puno's missing compression member is readily found in Anderson. Anderson discloses an external fracture immobilization splint for immobilizing long bones, such as arm or leg bones, with a swivel clamp that is capable of polyaxial movement until it is rigidly secured by a compression member. The compression member is depicted in figure 4 of Anderson, reproduced below right, as sleeve **15** having a spherically-curved seat **15′**. Anderson pg.2 col.2 ll.30-37.

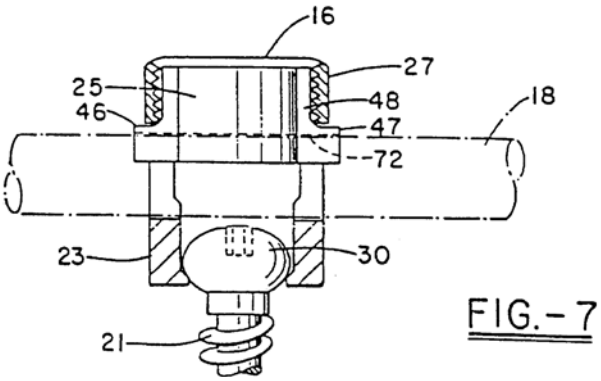
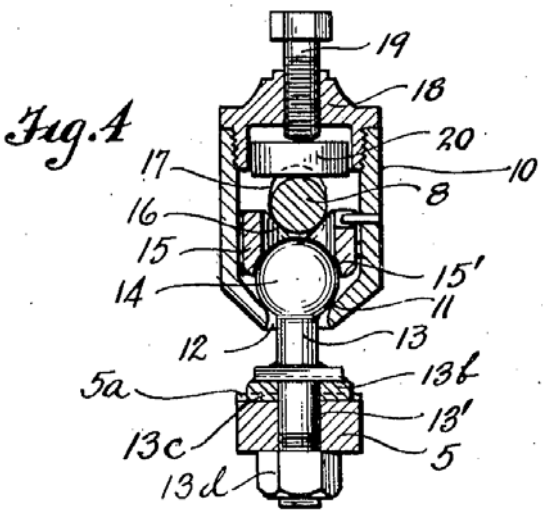


FIG.-7



When asked on cross-examination at the ensnarement hearing whether a person of ordinary skill would have recognized that the addition of Anderson's compression member to Puno's device would have achieved a rigidly-locked polyaxial pedicle screw covered by the hypothetical claim, DePuy's expert answered "I think so." J.A. 5557. Medtronic argues that this admission alone is sufficient to render the hypothetical claim obvious. We disagree.

Although predictability is a touchstone of obviousness, the "predictable result" discussed in KSR refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose. KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739-40 (2007). As the Supreme Court explained, "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." Id. at 1739 (emphasis added). The Supreme Court went on to state that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." Id. at 1740 (quoting Sakraida v. Ag Pro, Inc.,

425 U.S. 273, 282 (1976)) (emphasis added). The opposite conclusion would follow, however, if the prior art indicated that the invention would not have worked for its intended purpose or otherwise taught away from the invention. See United States v. Adams, 383 U.S. 39, 52 (1966) (upholding nonobviousness where references teaching away from the claimed combination would "deter any investigation into such a combination"); In re ICON Health & Fitness, Inc., 496 F.3d 1374, 1382 (Fed. Cir. 2007) ("[A] reference teaches away from a combination when using it in that combination would produce an inoperative result."). An inference of nonobviousness is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.

Here, Medtronic asserts that achieving a rigid pedicle screw was itself the reason to combine Puno and Anderson. In rebuttal, DePuy argues, and the district court found, that Puno "teaches away" from a rigid screw because Puno warns that rigidity increases the likelihood that the screw will fail within the human body, rendering the device inoperative for its intended purpose. Ensnarement Order, 526 F. Supp. 2d at 172. The district court thus found that Puno's teachings undermine the very reason Medtronic proffers as to why it would have been obvious to combine Puno and Anderson, viz., the creation of a rigid screw.

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." Ricoh Co., Ltd. v. Quanta Computer Inc., 550 F.3d 1325, 1332 (Fed. Cir. 2008) (quoting In re Kahn, 441 F.3d 977, 990 (Fed. Cir. 2006)). A reference does not

teach away, however, if it merely expresses a general preference for an alternative invention but does not "criticize, discredit, or otherwise discourage" investigation into the invention claimed. In re Fulton, 391 F.3d 1195, 1201 (Fed. Cir. 2004). In this case, we agree with the district court that Puno does not merely express a general preference for pedicle screws having a "shock absorber" effect. Rather, Puno expresses concern for failure and states that the shock absorber feature "decrease[s] the chance of failure of the screw or the bone-screw interface" because "it prevent[s] direct transfer of load from the rod to the bone-screw interface." Puno col.3 ll.64-67 (emphasis added).

The district court found that the addition of Anderson's compression member to Puno's device would have eliminated or reduced the device's desired "shock absorber" effect, which then "would increase the chance that screw and bone-screw interface failure would occur." Ensnarement Order, 526 F. Supp. 2d at 172. The causal relationship between rigidity and screw failure described in Puno is supported by the testimony of DePuy's expert, Dr. Erik Karl Antonsson, see J.A. 5546-47, 5555 (testifying that rigidity increases the likelihood of "screw breakage" or failure). Medtronic does not specifically challenge that testimony on appeal. Rather, Medtronic's challenge to the conclusion that Puno teaches away from a rigid screw is directed at other teachings in the prior art, which, in Medtronic's view, would have motivated a person of ordinary skill to look past Puno's warning regarding screw failure.

First, Medtronic directs us to an opinion of this court in a different case, in which we construed the word "operatively" in the phrase "lower bone interface operatively joined to said bone segment" in Puno's claim 5 to mean effective to perform "posterior stabilization" of the spine rather than "micro-motion," proffered by Medtronic in that case

to mean "'limited motion' between the anchor and the bone." Cross Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1305 (Fed. Cir. 2005). According to Medtronic in the present appeal, our claim construction in Cross Medical shows that Puno's screws are not limited to "micro" or "limited" motion and that Puno's screws can therefore be rigid. The district court rejected this argument, noting that it was not clear that "posterior stabilization" and "micro-motion" were mutually exclusive, and regardless of the construction of the claims, that Puno's specification taught away from a rigid screw. Ensnarement Order, 526 F. Supp. 2d at 172 n.13. We agree with the district court. Nothing in our construction of the word "operatively" in Cross Medical specifies what degree of rigidity is needed between Puno's anchor seat and vertebrae to achieve posterior stabilization, or that Puno's "shock absorber" effect—a stated advantage of the patent—is incompatible with achieving posterior stabilization. The claim construction of the word "operatively" in no way overshadows the specification's warning against increased rigidity.

Second, Medtronic points to U.S. Patent No. 4,946,458 ("Harms patent"), which lists the same inventors as those on the '678 patent and discloses how certain fasteners may be tightened or loosened "as desired" to achieve either "a substantially stiff connection" or "a desired dampening movement." Harms patent col.5 ll.8-16. The Harms patent is silent, however, as to why a person of ordinary skill would have "desired" either of these rigidity levels, much less why a rigid connection would have been selected in the face of Puno's warning against such rigidity.

Finally, Medtronic submits that a third patent, which lists Dr. Rolando Puno as a co-inventor, teaches a screw-and-rod system with an "intermediate" amount of rigidity.

U.S. Patent No. 4,805,602 col.1 ll.58-60 ("Puno '602 patent"). This teaching, in Medtronic's view, would have motivated the creation of a rigid screw. But the Puno '602 patent explains that this "intermediate" amount of rigidity represents a trade-off between the advantages and disadvantages of "wired implant" and "plate systems." Id. Whereas "wired implants have the advantages of . . . decreasing rigidity," id. col.2 ll.55-58 (emphases added), "the use of plates with the screws is more rigid than the wired implants and . . . can cause dislocation or even shearing of the screw," id. col.2 ll.64-67 (emphases added). The Puno '602 patent consistently views low rigidity as an advantage and high rigidity as a disadvantage, one that should be avoided whenever possible. The Puno '602 patent thus bolsters, rather than undermines, the district court's finding that the prior art teaches away from rigid pedicle screws.

For the foregoing reasons, we conclude that the district court correctly found that Puno, viewed against the backdrop of the collective teachings of the prior art, teaches away from a rigid pedicle screw encompassed by the hypothetical claim, such that a person of ordinary skill would have been deterred from combining Puno and Anderson in the manner that Medtronic proposes.

We also believe that certain secondary considerations—"failure by others" and "copying"—support the view that this combination would not have been obvious at the time of invention. The district court found that when Medtronic set out to design a rigid pedicle screw in 1991—after the '678 patent's 1989 priority date but before it was issued and published in May 1993—Medtronic's engineers initially settled on a design that involved using a rod, not a compression member, to exert pressure on the screw head. Ensnarement Order, 526 F. Supp. 2d at 174-75. Medtronic's engineers were

focused on solving the same problem as the '678 patent—making Puno's device more rigid—and were also aware of compression members analogous to those found in Anderson. Id. at 174; J.A. 5532. As late as April 1993, Dr. Kevin Foley, a member of the Medtronic team that had been working to develop a rigid pedicle screw, considered their alternate design (with no compression member) to be the "best solution" for making Puno's device more rigid.[1] J.A. 5534. When the '678 patent issued the following month, however, Medtronic's team suddenly changed direction and decided to insert a compression member between the rod and the screw head, in the manner disclosed in the '678 patent. Id. This new design eventually became what is now the accused Vertex® model. The district court inferred from these facts that Medtronic relied on and copied the patent's "compression member" limitation. Ensnarement Order, 526 F. Supp. 2d at 175. On appeal, Medtronic argues that it did not copy the patent but tried, albeit unsuccessfully, to design around the patent's "spherically-shaped" limitation to avoid infringement. But Medtronic does not allege that it independently conceived the idea of adding a compression member to a pedicle screw; indeed, Medtronic does not specifically deny copying the patent's "compression member" concept. Because the addition of a compression member to a pedicle screw is what Medtronic argues would have been obvious, we agree with the the district court that Medtronic's initial attempt at making a rigid pedicle screw without a compression member, together with Medtronic's prompt adoption of the claimed feature soon after the patent issued, are relevant indicia of nonobviousness. See Graham, 383 U.S. at 17-

[1] The district court found that Dr. Foley is "a person highly skilled in the relevant art," a finding that Medtronic does not dispute. Ensnarement Order, 526 F. Supp. 2d at 174.

18 (stating that secondary considerations may "give light to the circumstances surrounding the origin of the subject matter sought to be patented").

For the foregoing reasons, we hold that the hypothetical claim would not have been obvious in view of Puno and Anderson and, therefore, the district court properly denied Medtronic's ensnarement defense.[2]

II. Lost Profits

Medtronic challenges the jury's award of $149.1 million in lost profits on patented pedicle screws and $77.2 million in lost profits on unpatented, so-called "pull-through" products. We review the district court's denial of Medtronic's motion for JMOL under the law of the regional circuit in which an appeal from the district court would usually lie. Summit Tech., Inc. v. Nidek Co., 363 F.3d 1219, 1223 (Fed. Cir. 2004). In the First Circuit, "[t]he district court's decision to grant or deny a motion for judgment as a matter of law is reviewed de novo." Soto-Lebron v. Fed. Express Corp., 538 F.3d 45, 56 (1st Cir. 2008). JMOL is warranted when "the presentation of the party's case reveals 'no legally sufficient evidentiary basis' for a reasonable jury to find for that party." Mag Jewelry Co. v. Cherokee, Inc., 496 F.3d 108, 117 (1st Cir. 2007) (quoting Fed. R. Civ. P. 50(a)(1)).

A. Pedicle Screws

At trial, DePuy argued that Medtronic's infringing sales of Vertex® pedicle screws caused DePuy to lose $149.1 million in profits that DePuy would have made by selling its own pedicle screw system, marketed as Summit™ and Mountaineer™. DePuy

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[2] We reach this conclusion even assuming, but without deciding, that Puno constitutes prior art and that Anderson is analogous.

advanced a lost-profits theory under the four-factor Panduit test, which requires a showing of (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) manufacturing and marketing capability to exploit the demand, and (4) the amount of profit that would have been made. Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978). The district court instructed the jury on each of these four factors, and the jury found in favor of DePuy. On appeal, Medtronic challenges the sufficiency of the first two Panduit factors.

1. Demand for the Patented Product

Medtronic argues that the verdict cannot be upheld because DePuy failed to show, under the first Panduit factor, that the demand for DePuy's Summit™ and Mountaineer™ pedicle screws was driven by the screws' "top-loading" feature. It is this top-loading feature, in Medtronic's view, that distinguishes DePuy's patented screws and Medtronic's infringing Vertex® screws from Medtronic's bottom-loading screws, which do not infringe the '678 patent and which are not at issue in the present appeal. See DePuy Spine I, 469 F.3d at 1022 (holding that Medtronic's bottom-loading screws, unlike its top-loading Vertex® screws, do not possess claim 1's "opening" limitation). Accordingly, Medtronic asks us to hold that the requisite demand under the first Panduit factor is demand for the specific feature (i.e., claim limitation) that distinguishes the patented product from a noninfringing substitute, not simply demand for the patented product.

We decline Medtronic's request. Medtronic's argument unnecessarily conflates the first and second Panduit factors. All that the first factor states, and thus requires, is "demand for the patented product." Panduit, 575 F.2d at 1156. This factor does not

require any allocation of consumer demand among the various limitations recited in a patent claim. Instead, the first Panduit factor simply asks whether demand existed for the "patented product," i.e., a product that is "covered by the patent in suit" or that "directly competes with the infringing device." Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1548-49 (Fed. Cir. 1995) (en banc).

In this case, Medtronic does not dispute that demand generally existed for the Summit™ and Mountaineer™ pedicle screws and that those screws are covered by the '678 patent. Medtronic also concedes that demand for those screws was driven primarily by their polyaxial capability, a feature inherent in both Medtronic's accused Vertex® screws and DePuy's Summit™ and Mountaineer™ screws. Because the jury heard testimony as to this fact, an evidentiary basis was thus presented from which the jury could have found "demand for the patented product" under the first Panduit factor.

Medtronic argues that our prior decisions in Grain Processing, Slimfold, and Ferguson compel a different result. We disagree. In Grain Processing, the district court found that certain claim limitations could easily be omitted from the accused product in a manner that was perfectly acceptable to consumers. In particular, the court found that there was no specific demand for the features corresponding to the omitted claim limitations and that an acceptable noninfringing substitute was readily available. Grain Processing Corp. v. Am. Maize-Products Co., 979 F. Supp. 1233, 1237 (N.D. Ind. 1997) (Easterbrook, J.), aff'd, 185 F.3d 1341 (Fed. Cir. 1999). On appeal, we affirmed the denial of lost profits, not because demand was absent under the first Panduit factor, but because acceptable noninfringing substitutes were available under the second Panduit

factor. 185 F.3d at 1354-55 (holding that a noninfringing substitute was both "available" and "acceptable" during the accounting period, thus failing Panduit's second factor).

Like our decision in Grain Processing, our decision in Slimfold affirmed a denial of lost profits, not because demand was lacking under the first Panduit factor, but because acceptable noninfringing substitutes were available under the second. Slimfold Mfg. Co., Inc. v. Kinkead Indus., Inc., 932 F.2d 1453, 1458 (Fed. Cir. 1991). In that case, "[w]ith respect to the availability of acceptable non-infringing substitutes"—i.e., the second Panduit factor—the district court found that certain "old hardware," previously used by the accused infringer, did not infringe the patent-in-suit and was both available and acceptable to consumers. Id. On appeal, the patentee argued that the old hardware was not "acceptable" to customers because it lacked features corresponding to claim limitations that were supposed "advantages" of the patented product. Id. We rejected that argument because the evidence showed that the supposed "advantages" of the patented product were not at all important to consumers, thus indicating that the old hardware was an acceptable noninfringing substitute under the second Panduit factor.

Medtronic's reliance on Ferguson fares no better. Ferguson dealt with lost profits under the "entire market value" rule, which permits a patentee to recover the entire value of an apparatus that contains both patented and unpatented components, so long as the patented component is the basis for customer demand. Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1346 (Fed. Cir. 2003) (vacating and remanding lost profits award for entire value of a device containing a first component embodying a first patent, found infringed, as well as

a second component embodying a second patent, found not infringed, where profits could fairly be allocated to customer demand for second component); see Rite-Hite, 56 F.3d at 1549 ("[T]he entire market value rule permits recovery of damages based on the value of a patentee's entire apparatus containing several features when the patent-related feature is the 'basis for customer demand.'") (quoting State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1580 (Fed. Cir. 1989)). In the present case, Medtronic challenges the lost-profits award for Summit™ and Mountaineer™ pedicle screws under the Panduit factors, not under the "entire market value" rule. Ferguson is also factually distinguishable. As previously noted, the polyaxial capability of the patented pedicle screws—the capability that Medtronic admits drove sales of Summit™ and Mountaineer™ pedicle screws—is itself an inherent feature of the patented screws, not a feature of some other, unpatented device that may also be used in the surgery.

As we have held, the focus on particular features corresponding to individual claim limitations is unnecessary when considering whether demand exists for a patented product under the first Panduit factor. Rather, the elimination or substitution of particular features corresponding to one or more claim limitations goes to the availability of acceptable noninfringing substitutes under the second Panduit factor, to which we now turn.

2. Noninfringing Substitutes

Medtronic asserts that DePuy failed to establish the second Panduit factor because it contends that noninfringing, bottom-loading pedicle screws were available

during the relevant accounting period (2000-2003).[3] However, because Medtronic did not actually have a noninfringing substitute "on the market" during the relevant accounting period, it was Medtronic that bore the burden of overcoming the inference of unavailability. Grain Processing, 185 F.3d at 1353 ("When an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time."). Medtronic had to show that the substitute was "available" during this period based on alternative actions that Medtronic reasonably could have taken to avoid infringement. Id. In this regard, Medtronic asserts that it could have made a noninfringing, bottom-loading version of Vertex® screws in 2000-2003 and that it did in fact provide such screws for use in a surgery in 2007. Alternatively, Medtronic argues that it was unfairly precluded from introducing into evidence the district court's 2004 summary judgment ruling that the top-loading Vertex® model did not infringe the '678 patent. Medtronic believes that this evidence would have helped the jury to understand why Medtronic did not switch to a noninfringing, bottom-loading design until 2007. We address these arguments in turn.

First, substantial evidence supports the jury's factual finding under the second Panduit factor that no acceptable noninfringing alternative was available between 2000 and 2003. DePuy presented evidence of Medtronic's three unsuccessful attempts (in 2000, 2003-2004, and 2006-2007) to develop a noninfringing, bottom-loading design. For example, the jury heard testimony that Medtronic's various bottom-loading

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[3] DePuy admits that in "late 2003, acceptable noninfringing alternatives from third parties became available" and states that its expert accounted for these alternatives using a market-share analysis. DePuy's Principal Br. at 42. Medtronic does not specifically contest the market-share analysis but challenges the availability of lost profits generally.

prototypes were deemed "too large" by surgeons, were "substantially weaker" in pull-out strength than the infringing, top-loading Vertex® model, and had never been submitted to the Food & Drug Administration for the necessary marketing approval. J.A. 5214. Based on this evidence, a reasonable jury could have concluded, as it apparently did, that even if Medtronic had pursued a bottom-loading design rather than the infringing, top-loading Vertex® model, the bottom-loading design would not have been available or acceptable to consumers before the end of 2003.

Second, we discern no abuse of discretion in the district court's exclusion of its 2004 summary judgment ruling that the top-loading Vertex® model did not infringe, which we reversed in 2006 as to equivalents, and which Medtronic contends is the reason why it did not switch to a bottom-loading design until 2007. See Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1267 (Fed. Cir. 2008) (applying First Circuit's abuse of discretion standard to review of evidentiary rulings) (citing Cavallaro v. United States, 284 F.3d 236, 245 (1st Cir. 2002)). In excluding this evidence, the district court stated that the relevance of its prior ruling was "almost insignificant" in view of the "plethora of evidence that's gone in" and that the substance of the ruling was "erroneous" in view of our subsequent reversal. J.A. 5253. We agree that the probative value of this evidence was low compared to the risk of jury confusion. Although the district court's favorable 2004 ruling might have been the reason that Medtronic felt content to wait until after our 2006 decision to actually develop a noninfringing, bottom-loading version of Vertex®, the theory of available substitutes that Medtronic pressed at trial assumed a hypothetical "but-for world" in which Medtronic focused exclusively on developing a bottom-loading design. In this "but-for world," a

legal ruling in 2004 would have had little bearing on the technical feasibility of Medtronic's redesign efforts in the critical timeframe of 2000-2003. The summary judgment ruling would not have addressed why Medtronic had failed three times prior to 2007 to overcome the various technical and regulatory hurdles in achieving a noninfringing design. If the district court had admitted the 2004 ruling into evidence, however, it would have had to explain to the jury that the court had previously decided the infringement issue, that the decision was overruled in part with regard to equivalence but not literal infringement, and that the jury must ignore this evidence when deciding equivalence for itself but may later consider it when assessing damages. The risk of jury confusion is apparent. The decision to exclude this evidence was not an abuse of discretion.

For the foregoing reasons, we affirm the award of lost-profits damages as to the patented pedicle screws.

B. "Pull-Through" Products

The jury also awarded DePuy $77.2 million in profits that DePuy believes it would have made from selling so-called "pull-through" products but that were purportedly lost when Medtronic sold its infringing Vertex® pedicle screws. DePuy's damages expert could not identify specifically what products he included in his lost-profits analysis, but speculated that pull-through products included such things as head braces, vests, and other products not used in spinal surgeries. J.A. 5246. He admitted that these products are not covered by the '678 patent, do not compete with the patented pedicle screws, have no functional relationship with the patented pedicle screws, and can be used independently of the patented pedicle screws. Id. Instead, these products are related

only by virtue of the business relationship that is created when a customer first buys a patented Summit™ or Mountaineer™ device. Id. at 5235 ("The advanced product serves as . . . a door-opener. It gets you in. It gets you working with the surgeon, subsequently you have the opportunity to makes sales that you might not otherwise have made."). It is this business relationship that gave rise to DePuy's characterization of these products as "pull-through" products. Medtronic argues that these lost-profit damages are foreclosed by our decisions in Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538 (Fed. Cir. 1995) (en banc), and American Seating Co. v. USSC Group, 514 F.3d 1262 (Fed. Cir. 2008).

"Whether lost profits are legally compensable in a particular situation is a question of law that we review de novo." Poly-Am., L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1311 (Fed. Cir. 2004) (citing Rite-Hite, 56 F.3d at 1544). "A patentee may recover lost profits on unpatented components sold with a patented item, a convoyed sale, if both the patented and unpatented products 'together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit.'" Am. Seating, 514 F.3d at 1268 (quoting Rite-Hite, 56 F.3d at 1550). In contrast to such functionally-integrated components that are properly subject to lost profits, "there is no basis for extending that recovery to include damages for [unpatented] items that are neither competitive with nor function with the patented invention." Rite-Hite, F.3d at 1551. For example, lost profits cannot be recovered on unpatented items "that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage." Id. at 1550. Because it is undisputed that

DePuy's unpatented pull-through products neither compete nor function with its patented Summit™ and Mountaineer™ devices and were sold (i.e., "pulled-through") only by virtue of DePuy's business relationship with surgeons, DePuy was not legally entitled to recover lost profits on those unpatented products.

DePuy attempts to distinguish Rite-Hite and American Seating on the ground that those cases dealt with "convoyed sales," in which the patented and unpatented products were sold together, whereas DePuy's pull-through products are sold in separate transactions following the initial sale of its patented Summit™ and Mountaineer™ devices. This is a distinction without a difference. To hold otherwise would be to allow a patentee to circumvent Rite-Hite and American Seating by simply executing separate sales contracts. Like DePuy's pull-through products, the unpatented dock levelers in Rite-Hite were sold with the patented vehicle restraints "only for marketing reasons, not because they essentially functioned together." 56 F.3d at 1551. Similarly, in American Seating, the patented tie-down system and unpatented passenger seats were sold together "for reasons of convenience and 'one-stop shopping,' not because of an absolute requirement that the two items function together." 514 F.3d at 1269. Because "the Rite-Hite 'functional unit' test set[s] forth the key criterion for lost profits of unpatented materials" that are sold with (or sold separately as a result of) a patented item, the jury had no legal basis to award lost profits on DePuy's unpatented pull-through products, which neither compete nor function with its patented pedicle screws. Juicy Whip, Inc. v. Orange Bang, Inc., 382 F.3d 1367, 1372 (Fed. Cir. 2004).

Accordingly, we reverse the award of lost-profit damages on pull-through products.

III. Royalty Damages

On cross-appeal, DePuy challenges the district court's denial of a motion for new trial on the issue of reasonable-royalty damages. At trial, DePuy argued for a 15% royalty rate on $237.2 million worth of infringing sales that were not subject to DePuy's claim for lost profits, for a total of $31.8 million in royalties. Medtronic disputed this royalty rate and argued instead that a 6% rate would give DePuy "full and fair compensation" if its products were found to infringe. J.A. 5473. DePuy therefore believes that the jury should have simply picked a number between 6% and 15%. The jury awarded 0%. Shortly after the jury was dismissed, DePuy indicated to the court that the jury "may have possibly misunderstood" that the reasonable royalty applied to a different set of infringing sales, but ultimately told the court that DePuy "will be investigating" the issue and "[m]aybe we will conclude that there is nothing." J.A. 5501-02. Several weeks later, DePuy filed a motion for new trial on royalty damages.

"We review decisions on . . . motions for a new trial under the law of the regional circuit." Lucent Tech., Inc. v. Gateway, Inc., 543 F.3d 710, 717 (Fed. Cir. 2008). The First Circuit reviews the denial of a motion for new trial for an abuse of discretion. Davignon v. Hodgson, 524 F.3d 91, 100 (1st Cir. 2008). Here, the district court cited the First Circuit's Wennik decision, which sets forth the circuit's "iron-clad rule that a party 'waives [the issue of] inconsistency if it fails to object after the verdict is read and before the jury is dismissed.'" Wennik v. Polygram Group Distrib., Inc., 304 F.3d 123, 130 (1st Cir. 2002) (alteration in original) (quoting Toucet v. Mar. Overseas Corp., 991 F.2d 5, 8

(1st Cir. 1993)). Under this precedent, the district court stated that it was unclear why the jury awarded a 0% royalty rate in light of "other aspects of the jury's verdict," but that any inconsistency in the verdict should have been resolved before the jury was discharged. Feb. 14 Order at 1. For that reason, the district court denied DePuy's motion.

DePuy resists characterizing the jury's award of a 0% royalty rate as an "inconsistency," arguing instead that the award lacks evidentiary support. We disagree and fail to see this as a question of evidence. The jury verdict, on its face, was inconsistent. A 0% royalty rate cannot be squared with: (1) the jury's finding that the subject sales constituted acts of infringement, and (2) the instruction that the jury choose a royalty rate between 6% and 15%—the sole form of compensation that DePuy requested on those sales. As the district court correctly observed, these "other aspects of the jury's verdict" should have resulted in a royalty rate between 6% and 15%. We therefore agree with the district court that the award of 0% rendered the verdict inconsistent.

The jury may well have been confused by the wording used in the special verdict form, which expressly instructs the jury to "answer Question Nos. 11 and 12" (calculation of royalty rate) if they found that DePuy is not entitled to lost profits, but to "answer Question No. 10" (calculation of lost profits) if they found that DePuy is entitled to lost profits. J.A. 9. In the latter event, if lost profits are available (as the jury found here), the form says nothing about answering Question Nos. 11 and 12 regarding the royalty rate. Those questions themselves ask for a royalty on "an infringement for which plaintiffs are not entitled to recover lost profits," without specifying which "infringement"

or sale was at issue. Id. (emphasis added).[4] Whatever the cause, the verdict was inconsistent, placing an obligation on DePuy to object. In view of the First Circuit's "iron-clad rule" barring untimely inconsistency objections, and given DePuy's awareness of the issue and its ability to have properly objected, we cannot say that the denial of DePuy's motion for new trial was an abuse of discretion.

Moreover, we need not decide in this case whether an otherwise untimely inconsistency objection can ever be saved by the statutory damages floor of 35 U.S.C. § 284 (setting a damages floor not "less than a reasonable royalty for the use made of the invention by the infringer"). DePuy's $149.1 million lost-profits award, which we have affirmed, exceeds DePuy's alternative request for $59.2 million in total damages based solely on royalties on all of Medtronic's accused sales—i.e., the entire "use made of the invention by the infringer" under § 284. J.A. 5520-21, 12263 (requesting, in the alternative if lost profits were found unavailable, $59.2 million in royalties on all $462 million in accused sales).

Accordingly, the denial of DePuy's motion for new trial is affirmed.

IV. Willfulness

The jury found that Medtronic's Vertex® model infringed the '678 patent under the doctrine of equivalents. DePuy argued that this infringement was willful. At the close of evidence, however, the district court granted Medtronic's motion for JMOL of no willfulness, applying the willfulness standard articulated in In re Seagate Technology,

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[4] A general instruction to answer all of Question Nos. 9, 10, 11 and 12 is found on the preceding page of the verdict form, J.A. 8, but is superseded on the next page by what appears to be more specific instructions, discussed supra.

LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). On cross-appeal, DePuy argues that the evidence was sufficient for willfulness to have gone to the jury.

We review the grant of JMOL under the law of the regional circuit. See Proveris Scientific, 536 F.3d at 1266. The First Circuit applies a de novo standard of review. See Soto-Lebron, 538 F.3d at 56. JMOL is appropriate when "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." Fed. R. Civ. P. 50(a)(1). In Seagate, we held that "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. . . . If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." 497 F.3d at 1371.

As to Seagate's first prong, DePuy argues that the jury could have concluded, as the district court later did at the ensnarement hearing, that Medtronic "copied" the invention directly out of the '678 patent. According to DePuy, "knowingly copying a competitor's patented invention is objectively risky behavior of the highest order." DePuy's Principal Br. at 70. Medtronic counters that DePuy's allegation of "knowingly copying" bears only on Medtronic's state of mind, which is not relevant to the objective inquiry under Seagate's first prong. Rather, the objective reasonableness of its conduct is confirmed, in Medtronic's view, by the result of the prior appeal in DePuy I, in which

we affirmed the grant of summary judgment of no literal infringement and remanded for a jury to resolve infringement under the doctrine of equivalents.

We agree with Medtronic and the district court that there was no legally sufficient evidentiary basis to find an objectively high likelihood under Seagate's first prong that the Vertex® model (which contains a conically-shaped portion) infringed the '678 patent (whose claims recite a "spherically-shaped portion"). Seagate's first prong is objective, and "[t]he state of mind of the accused infringer is not relevant to this objective inquiry." Seagate, 497 F.3d at 1371. Similarly, evidence of copying is "of no import on the question of whether the claims of an issued patent are infringed," either literally or by equivalents. Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1351 (Fed. Cir. 2002) (citing Warner-Jenkinson, 520 U.S. at 35-36)). Accordingly, evidence of copying in a case of direct infringement is relevant only to Seagate's second prong, as it may show what the accused infringer knew or should have known about the likelihood of its infringement.

In the prior appeal, we affirmed the district court's grant of summary judgment of no literal infringement, concluding that no reasonable jury could have found that the Vertex® model's conically-shaped portion literally meets the claimed "spherically-shaped" limitation. DePuy I, 469 F.3d at 1016. Moreover, in reversing the district court's grant of summary judgment of noninfringement under the doctrine of equivalents, we held that a question of material fact exists as to whether the difference between the two shapes is substantial. Id. at 1020. A jury was needed to resolve that question on remand. At the close of evidence at trial, the district court denied DePuy's motion for JMOL of infringement under the doctrine of equivalents.

Medtronic presented a substantial question of noninfringement under the doctrine of equivalents. The specification of the '678 patent explains that the screw head achieves a "rigid lock" when it is "completely surrounded" by the spherically-shaped surface of a receiver member whose radius of curvature is equal to that of the screw head. '678 patent col.2 ll.21-53, col.3 l.56-col.4 l.7 (emphasis added). By contrast, the screw head is only partially surrounded, along a circle in one plane, when a conical shape is used in the inner hollow space of the receiver member. This evidence tends to show a lack of equivalence, because it shows that a conical surface achieves a rigid lock in a different "way" than a spherical surface. See Warner-Jenkinson, 520 U.S. at 39 (acknowledging that there is "substantial agreement" that the function-way-result test for equivalence is particularly "suitable for analyzing mechanical devices"). On the other hand, DePuy submitted evidence tending to show that conical and spherical surfaces are interchangeable. But even accepting DePuy's view of the facts that conical and spherical surfaces are interchangeable, a finding of equivalence does not necessarily follow. See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1309 (Fed. Cir. 1998) ("[A] finding of known interchangeability, while an important factor in determining equivalence, is certainly not dispositive.") (emphasis added). The jury could have reasonably found for either party on the question of equivalence. While the fact that an issue was submitted to a jury does not automatically immunize an accused infringer from a finding of willful infringement, the record developed in the infringement proceeding in this case, viewed objectively, indisputably shows that the question of equivalence was a close one, particularly insofar as equivalence "requires an intensely factual inquiry." Vehicular Tech. Corp. v. Titan Wheel Int'l, Inc., 212 F.3d

1377, 1381 (Fed. Cir. 2000). The mere fact that the jury ultimately found equivalence does not diminish the difficulty of their task, which must be viewed objectively. Accordingly, the district court was correct to rule on JMOL that an objectively high likelihood of infringement could not have been found under Seagate's first prong.

Because we hold that DePuy failed as a matter of law to satisfy Seagate's first prong, we need not address DePuy's arguments concerning "copying" and Medtronic's rebuttal evidence concerning "designing around," both of which are relevant only to Medtronic's mental state regarding its direct infringement under Seagate's second prong. Moreover, because "an award of enhanced damages requires a showing of willful infringement," Seagate, 497 F.3d at 1368 (citing Beatrice Foods Co. v. New England Printing & Lithographing Co., 923 F.2d 1576, 1578 (Fed. Cir. 1991)), DePuy is not entitled to enhanced damages. See Cohesive Tech., Inc. v. Waters Corp., 543 F.3d 1351, 1374 (Fed. Cir. 2008) ("The majority of the en banc court in Seagate did not elect to overrule Beatrice Foods, and we therefore remain bound by that decision.").

Accordingly, we affirm the grant of JMOL of no willfulness.

V. Attorney Fees and Sanction

Medtronic challenges the district court's imposition of $425,375 in attorney fees under 35 U.S.C. § 285 and a further $10 million sanction under the court's inherent authority, based on what the court perceived to be Medtronic's litigation misconduct.

"Where a district court finds a case exceptional under 35 U.S.C. § 285, this court reviews the underlying factual findings for clear error and legal conclusions without deference. Once the district court has found a case to be exceptional, we review any award of attorney fees for an abuse of discretion." Frazier v. Roessel Cine Photo Tech,

Inc., 417 F.3d 1230, 1234 (Fed. Cir. 2005) (citing Rambus Inc. v. Infineon Tech. Ag, 318 F.3d 1081, 1088 (Fed. Cir. 2003)). "A court's exercise of its inherent powers is reviewed for an abuse of discretion." Pickholtz v. Rainbow Tech., Inc., 284 F.3d 1365, 1376 (Fed. Cir. 2002).

The district court found that Medtronic "fail[ed] to accept the claim construction governing this case" and that its infringement defense appeared to have been "wholly based on an attempt to obscure, evade, or minimize the Federal Circuit's construction of the patent-in-suit." Sanctions Order, 534 F. Supp. 2d at 225. Specifically, in the prior appeal, we construed the term "pressed against the hollow spherically-shaped portion" to be literally met whenever the screw head "presses against all or any part of that portion—including the edge." DePuy I, 469 F.3d at 1015. At trial, Medtronic did not dispute that the accused Vertex® model literally meets this limitation, given that the screw head "presses against . . . the edge" of the conically-shaped portion. Instead, Medtronic attempted to invoke the so-called "reverse doctrine of equivalents" as an infringement defense against this particular claim limitation, arguing that a screw head presses against a conically-shaped portion in a "substantially different way" than it does against a spherically-shaped portion—via an "interference fit" rather than a "mating fit." J.A. 5334-35.

We have explained that "[t]he reverse doctrine of equivalents is an equitable doctrine designed 'to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention.'" Roche Palo Alto LLC v. Apotex, Inc., 531 F.3d 1372, 1377 (Fed. Cir. 2008) (quoting Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1581 (Fed. Cir. 1991)). According to the Supreme Court:

> [W]here a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the [reverse] doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.

Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608-09 (1950) (emphasis added). Because the reverse doctrine of equivalents requires a fundamental change in the basic principle by which the device operates, the doctrine is rarely invoked and virtually never sustained. See Roche, 531 F.3d at 1378 ("[T]his court has never affirmed a finding of non-infringement under the reverse doctrine of equivalents."); Leesona Corp. v. United States, 530 F.2d 896, 906 (Ct. Cl. 1976) (predecessor court finding no infringement despite the fact that the accused structure, "in a very loose sense," could be said to fall within the literal words of the claim (emphasis added)).

In this case, the district court faulted Medtronic and its experts for arguing that the "pressed against" limitation of the patented device operates using "mating surfaces between the screw head and the receiver member, which . . . renders it substantially different from the accused products (which have non-mating surfaces that lock the screw by means of an interference fit)." Sanctions Order, 534 F. Supp. 2d at 225-26. In the district court's view, Medtronic's argument "flouted the governing claim construction as set forth by the Federal Circuit" and "threatened to mislead and confuse the jury." Id. at 226, 227.

The basis for the district court's conclusion that Medtronic's argument "flouted the governing claim construction" is revealed in a separate post-trial order, issued several weeks before the sanctions order. In the earlier order, the district court stated that "the [reverse] doctrine [of equivalents] (which requires literal infringement) does not apply to

the accused Vertex devices themselves because they do not literally infringe the '678 patent," emphasizing the fact that the case had been remanded by the Federal Circuit for a determination of infringement under the doctrine of equivalents only. Feb. 6 Order, 533 F. Supp. 2d at 245-46 ("[T]he reverse doctrine of equivalents was simply inapplicable in this case and served only to confuse the jury."). However, the district court's understanding of the circumstances in which the reverse doctrine of equivalents may be asserted is incorrect. The reverse doctrine of equivalents, like the doctrine of equivalents, is applied to individual limitations of a claim. See Warner-Jenkinson, 520 U.S. at 29 ("[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole."); Leesona, 530 F.2d at 906 (applying reverse doctrine of equivalents to "porous self-sustaining metal layer" limitation). Thus, the fact that DePuy argued the "spherically-shaped portion" limitation under a doctrine of equivalents theory of infringement did not prevent Medtronic from raising the reverse doctrine of equivalents against the literal scope of a different limitation, namely, the "pressed against" limitation.

As for the argument that the reverse doctrine of equivalents "threatened to mislead and confuse the jury," the unusual nature of the reverse doctrine of equivalents is not itself a reason to sanction a party for invoking it. The Supreme Court has recognized it to be a viable defense, even if it is rarely asserted.

Apart from Medtronic's mere assertion of the reverse doctrine of equivalents, there was no finding in this case that Medtronic litigated the defense in bad faith. Although the district court ultimately concluded that the underlying substance of Medtronic's defense "lacks merit," Sanctions Order, 534 F. Supp. 2d at 226, there is no

indication, much less a finding, that Medtronic's arguments were baseless, frivolous, or intended primarily to mislead the jury. Although the defense ultimately failed, Medtronic should not have been sanctioned for merely raising it, absent a finding of "vexatious or unjustified litigation," "frivolous suit," or other type of "bad faith." Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc., 549 F.3d 1381, 1387 (Fed. Cir. 2008); see Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1552 (Fed. Cir. 1989) (stating that a purpose of 35 U.S.C. § 285 is to prevent "'gross injustice' when the accused infringer has litigated in bad faith").

Because the district court's exceptionality finding was based on Medtronic's mere assertion of the reverse doctrine of equivalents, rather than the way in which Medtronic litigated it, the finding of exceptionality in this case was erroneous. The district court's imposition of $425,375 in attorney fees is, therefore, reversed. We also reverse the court's sua sponte imposition under its inherent authority of a $10 million sanction, which was premised on the same alleged misconduct and cannot be sustained.

VI. Post-Judgment Interest

In this appeal, we have reduced the amount of the district court's damages award by reversing the lost-profits award on pull-through products while affirming the lost-profits award on pedicle screws. Our decision therefore "modifies" the district court's judgment within the meaning of Federal Rule of Appellate Procedure 37(b), which, in turn, requires us, the appellate tribunal, to specify the allowance of post-judgment interest. See Mars, Inc. v. Coin Acceptors, Inc., 557 F.3d 1377, 1379 (Fed. Cir. 2009); Tronzo v. Biomet, Inc., 318 F.3d 1378, 1381 (Fed. Cir. 2003) ("[T]he responsibility and

authority for [determining whether a party to an appeal is entitled to post-judgment interest] is assigned to the appellate tribunal.").

"The application of Rule 37 is not unique to judgments in patent cases, and thus we look to the law of the regional circuit for guidance." Tronzo, 318 F.3d at 1381. In the First Circuit, post-judgment interest accrues from "the initial entry of the district court's judgment on the jury verdict," not from the denial of post-judgment motions. Marshall v. Perez-Arzuaga, 866 F.2d 521, 522 (1st Cir. 1989). Accordingly, we hold that DePuy is entitled to post-judgment interest at the applicable statutory rate under 28 U.S.C. § 1961 running from December 11, 2007—the date the district court denied Medtronic's ensnarement defense and entered judgment on the jury verdict. We remand for calculation of post-judgment interest consistent with this opinion.

CONCLUSION

We affirm the award of $149.1 million in lost profits on patented pedicle screws. We reverse the award of $77.2 million in lost profits on unpatented pull-through products. We also reverse the imposition of $425,375 in attorney fees and the $10 million sanction. We remand for calculation of post-judgment interest at the applicable statutory rate under 28 U.S.C. § 1961 running from December 11, 2007.

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

COSTS

Each party shall bear its own costs.