KeyCite Red Flag - Severe Negative Treatment

Certiorari Granted, Judgment Vacated by Medtronic Sofamor Danek USA, Inc. v. NuVasive, Inc., U.S., January 19, 2016

778 F.3d 1365 United States Court of Appeals, Federal Circuit.

WARSAW ORTHOPEDIC, INC., Plaintiff/Counterclaim Defendant—Appellant
Medtronic Sofamor Danek USA, Inc., Counterclaim Defendant—Appellant
Medtronic Puerto Rico Operations Co., Medtronic Sofamor
Danek Deggendorf, GMBH, Counterclaim Defendants

NuVASIVE, INC., Defendant/Counterclaimant-Cross Appellant.

Nos. 2013–1576, 2013–1577. | | March 2, 2015.

#### **Synopsis**

**Background:** Patentee commenced action against competitor, alleging infringement of **patent** claims directed to oversized spinal implants capable of lateral insertion, and **patent** claims directed to instruments and methods for minimally invasive tissue retraction during surgery. Competitor counterclaimed alleging infringement of **patent** claims directed to a method for detecting the presence of and measuring the distance to a nerve during surgery. The United States District Court for the Southern District of California, Cathy Ann Bencivengo, J., granted judgment for each party after jury verdict finding infringement of each **patent**. Parties appealed.

Holdings: The Court of Appeals, Dyk, Circuit Judge, held that:

- [1] conclusion by jury that prior art references did not teach implant capable of lateral insertion was supported by substantial evidence;
- [2] claim in **patent** that was directed to oversized spinal implants capable of lateral insertion was not indefinite on basis of requirement to select spinal implant according to need of each particular patient;
- [3] conclusion by jury that differences between accused device and **patent** were insubstantial was supported by substantial evidence:
- [4] substantial evidence supported jury's finding of infringement of stopping step in patent;
- [5] Court could not conclude on appeal based on prosecution history of **patent** that interpretation of stopping step, as a "restart," was barred on basis that "stop" had been added to overcome prior art reference;
- [6] patentee did not establish functional relationship between **patented** technology and fixations that was necessary to support jury verdict awarding lost profits for convoyed sales; and
- [7] evidence was not sufficient for recovery of "true-up" payments; and

[8] remand was warranted for a new trial to determine a reasonable royalty.

Affirmed in part, vacated in part, and remanded.

West Headnotes (25)

# [1] Federal Courts - Taking case or question from jury; judgment as a matter of law

Denials of motions for judgment as a matter of law are reviewed de novo.

Cases that cite this headnote

## [2] Patents • Construction and Operation of Patents

When appealing a district court's **patent** claim construction, the underlying factual determinations concerning extrinsic evidence are reviewed for clear error, and intrinsic evidence and the ultimate construction of the claim is reviewed de novo.

1 Cases that cite this headnote

# [3] Patents • Infringement or noninfringement

**Patent** infringement is a question of fact that is reviewed for substantial evidence.

1 Cases that cite this headnote

# [4] Federal Courts - Damages or Other Monetary Relief

Court of Appeals reviews damages determinations by the court for an erroneous conclusion of law, clearly erroneous factual findings, or a clear error of judgment amounting to an abuse of discretion.

Cases that cite this headnote

#### [5] Patents Particular products or processes

# **Patents** Particular products or processes

Conclusion by jury that prior art references did not teach implant capable of lateral insertion was supported by substantial evidence, and thus jury was entitled to find that those references did not anticipate or render asserted claims of **patent** obvious that had been directed to oversized spinal implants capable of lateral insertion, where Food and Drug Administration had not approved implant for lateral insertion, ridges, grooves, and tool holes of references suggested they were intended for anterior or posterior insertion, not lateral insertion, and lack of tapering or rounding on prior art implant made it ill-suited for lateral insertion.

Cases that cite this headnote

# [6] Patents Particular products or processes

Claim in **patent** that was directed to oversized spinal implants capable of lateral insertion was not indefinite on basis of requirement to select spinal implant according to need of each particular patient, since human anatomy

did not vary significantly; average dimensions of human vertebrae were well-known, easily ascertainable, and well-documented in literature.

#### Cases that cite this headnote

# [7] Patents • Ambiguity, Uncertainty, or Indefiniteness

A patent claim is indefinite if viewed in light of the specification and prosecution history, it does not inform those skilled in the art about the scope of the invention with reasonable clarity.

#### 3 Cases that cite this headnote

## [8] Patents • Particular fields of invention

Conclusion by jury that differences were insubstantial between accused device with three enclosing prongs, two of which were capable of lateral movement and pivoting, and **patent** directed to instruments and methods for minimally invasive tissue retraction during surgery with two enclosing prongs, both of which were capable of lateral movement and pivoting, was supported by substantial evidence, and thus jury could find infringement under equivalents doctrine, where competitor's own witnesses admitted that working channel enclosed by three prongs "i[s] the same working channel as with only two [prongs]" and that "when the working channel is in the closed position, two and three [prongs] are equivalent."

## Cases that cite this headnote

# [9] Patents Particular fields of invention

Substantial evidence supported jury's finding of infringement of stopping step, in **patent** directed to method for detecting presence of nerve during surgery and measuring distance to nerve, by accused product that continued to emit pulses, just at a lower level of power, since decreased pulse was not part of previous series of increasing pulses, but instead was first pulse of new signal, and treating "restart" as type of stop was clearly envisioned by claims.

#### Cases that cite this headnote

## [10] Patents Participation, intent, and contributory infringement

Evidence was sufficient to support jury finding of induced infringement of **patent** directed to a method for detecting the presence of and measuring the distance to a nerve during surgery, where there was evidence that competitor was aware of **patent** prior to litigation and that competitor specifically taught doctors to use the product during the surgical procedures in an infringing manner.

## Cases that cite this headnote

## [11] Patents & Particular patents and claims

Court could not conclude on appeal based on prosecution history of **patent** directed to method for detecting presence of nerve during surgery and measuring distance to nerve, that interpretation of stopping step, as a "restart," was barred on basis that "stop" had been added to overcome prior art reference, since construction of "stopping" step had not been presented to jury, and competitor did not request construction beyond its plain and ordinary meaning.

#### Cases that cite this headnote

# [12] Patents • Reasonable royalty; hypothetical negotiation

With respect to any particular sale, a patentee is entitled to either a reasonable royalty or lost profits, but not both.

6 Cases that cite this headnote

## [13] Patents > Profits

Lost profits as a measure of damages is intended to make the party whole, i.e., to compensate the **patent** holder for profits lost as a result of the infringement; it is not solely a "but for" test.

5 Cases that cite this headnote

## [14] Patents - Reasonable royalty; hypothetical negotiation

A reasonable royalty is intended to compensate the patentee for the value of what was taken from him, i.e., the patented technology.

1 Cases that cite this headnote

## [15] Patents Profits

A patentee may not claim, as its own damages, the lost profits of a related company.

13 Cases that cite this headnote

## [16] Patents \( \bigcup \) Elements, measure, and amount in general

A "convoyed sale" is a sale of a product that is not **patented**, but is sufficiently related to the **patented** product such that the patentee may recover lost profits for lost sales.

13 Cases that cite this headnote

## [17] Patents • Profits and damages

Evidence of marketing material touting kits' comprehensive set of instruments and implants including fully integrated neuromonitoring, streamlined access instrumentation, anatomically designed implants, and percutaneous fixation systems did not establish functional relationship between **patent** directed to oversized spinal implants capable of lateral insertion and fixations that was necessary to support jury verdict awarding lost profits for convoyed sales, since patentee did not present testimony that fixations that it sold did not have any independent function, i.e., that they would not work as well in other surgeries not involving the **patented** technologies.

Cases that cite this headnote

## [18] Patents $\leftarrow$ Elements, measure, and amount in general

To be entitled to lost profits for convoyed sales, the related products, e.g., the fixations, must be functionally related to the **patented** product and losses must be reasonably foreseeable; being sold together merely for convenience or business advantage is not enough, and if the convoyed sale has a use independent of the **patented** device, that suggests a non-functional relationship.

## 4 Cases that cite this headnote

## [19] Patents Profits and damages

Evidence was not sufficient for recovery of "true-up" payments that would have been made from other related companies, as post hoc transfers to ensure that patentee received fair-market-value of product or service exchanged to comply with relevant tax and accounting laws, but for infringement of **patent** directed to oversized spinal implants capable of lateral insertion; even if "true-up" payments contained, in part, royalty payments from related company to patentee for sales of **patented** products to surgeons and hospitals, percentage of true-ups that was attributable to those payments had not been distinguished from payments on unrelated transactions.

## 1 Cases that cite this headnote

## [20] Patents $\leftarrow$ Remand; mandate

Remand was warranted for a new trial to determine a reasonable royalty on the **patented** technologies, where it was impossible to determine from the verdict form what portion of the verdict was attributable to lost profits and what portion was attributable to a reasonable royalty; although jury verdict did state reasonable royalty rate, the period for which that reasonable royalty was determined and whether the jury impermissibly relied on evidence not probative of the value of the **patented** technology was not entirely clear.

#### 2 Cases that cite this headnote

# [21] Patents • Reasonable royalty; hypothetical negotiation

Evidence of a number of existing royalty agreements entered into at arms-length can be evidence of the value of a **patent**.

2 Cases that cite this headnote

# [22] Patents $\leftarrow$ Reasonable royalty; hypothetical negotiation

Royalties paid by related parties have little probative value as to a patent's value.

1 Cases that cite this headnote

#### [23] Patents Patents Reasonable royalty; hypothetical negotiation

When computing damages, the impact in the United States that granting a license might have on sales of the **patented** inventions by patentee's related companies can be relevant to the hypothetical royalty negotiation, even if the amounts of intercorporate transfers are not.

Cases that cite this headnote

## [24] Patents 🕪 In general; utility

US Patent 5,192,327. Cited as Prior Art.

Cases that cite this headnote

[25] Patents • In general; utility

US Patent 5,860,973, US Patent 6,945,933, US Patent 7,470,236. Valid and Infringed.

Cases that cite this headnote

#### **Attorneys and Law Firms**

\*1368 Luke Dauchot, Kirkland & Ellis LLP, Los Angeles, CA, argued for plaintiff/counterclaim defendant-appellant, counterclaim defendant-appellant. Also represented by Alexander Fraser MacKinnon, Nimalka R. Wickramasekera, Sharre Lotfollahi; John C. O'Quinn, Liam Patrick Hardy, Washington, DC.

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Before LOURIE, DYK, and REYNA, Circuit Judges.

#### **Opinion**

DYK, Circuit Judge.

Warsaw Orthopedic ("Warsaw") brought suit against NuVasive, Inc. ("NuVasive") for infringement of U.S. Patent Nos. 5,860,973 ("the #973 patent") and 6,945,933 ("the #933 patent"). NuVasive counterclaimed for infringement of U.S. Patent No. 7,470,236 ("the #236 patent") against Warsaw and its related company, Medtronic Sofamor Danek USA, Inc. ("MSD"). For each of the three patents, the district court sustained jury findings of infringement, awarded damages for past infringement, and awarded an ongoing royalty rate. Both parties appealed. We affirm the district court with respect to invalidity and infringement of all three patents, but we remand for a new trial on damages with respect to the #973 and #933 patents.

#### **BACKGROUND**

We limit our discussion to the **patents** relevant to this appeal: the #973 **patent**, the #933 **patent**, and the #236 **patent**. Warsaw owns the #973 **patent** and the #933 **patent**. The #973 **patent** claims oversized spinal implants. The #933 **patent** claims methods and devices for retracting tissue to create a working channel for minimally invasive spinal surgery. NuVasive owns \*1369 the #236 **patent**, which relates to neuromonitoring during surgery.

On October 6, 2008, Warsaw and MSD filed a complaint against NuVasive, alleging infringement of the #973 and #933 patents. NuVasive counterclaimed, asserting infringement of the #236 patent. At trial, Warsaw asserted claims 24, 41, 42, 57, and 61 of the #973 patent and claims 21, 57, and 66 of the #933 patent. NuVasive asserted claims 1, 5, and 9 of the # 236 patent. On September 20, 2011, the jury found that the asserted claims of the #973 patent were not invalid (infringement was not in dispute), that the asserted claims of the #933 patent were infringed under the doctrine of equivalents (validity was not in dispute), and that the asserted claims of the #236 patent were infringed (validity was not in dispute). The jury awarded damages for each.

After trial, Warsaw filed motions seeking supplemental damages and a permanent injunction with respect to the #973 and #933 patents, and a motion for judgment as a matter of law ("JMOL") or a new trial with respect to the jury's finding

of infringement of the asserted claims of the #236 **patent**. NuVasive also moved for JMOL or a new trial, challenging the jury's finding of no invalidity of the asserted claims of the #973 **patent**, infringement of the asserted claims of the #933 **patent**, and Warsaw's entitlement to lost profits. The district court denied the motions for JMOL or a new trial and denied Warsaw's requests for supplemental damages and a permanent injunction for infringement of the #973 and #933 **patents**. The court set ongoing royalty rates.

Warsaw appealed, arguing that the district court erred in denying supplemental damages to compensate for NuVasive's infringement between the close of discovery and trial and in declining to award a higher ongoing royalty rate. Warsaw also argues that the district court erred in determining that MSD infringed the #236 patent. NuVasive cross-appealed, challenging the determinations that the asserted claims of the #973 patent were not invalid, the determination that NuVasive infringed the asserted claims of the #933 patent, and the damages calculation for infringement of the asserted claims of the #973 and #933 patents.

[1] [2] [3] [4] We have jurisdiction pursuant to 28 U.S.C. § 1295. We review denials of motions for judgment as a matter of law de novo. See Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 563 F.3d 1358, 1370 (Fed.Cir.2009); Janes v. Wal-Mart Stores, Inc., 279 F.3d 883, 886 (9th Cir.2002). We review the district court's claim construction under the standard set forth in Teva Pharm. USA, Inc. v. Sandoz, Inc., — U.S. —, 135 S.Ct. 831, 841, — L.Ed.2d — (2015). We review underlying factual determinations concerning extrinsic evidence for clear error. Id. at 841. We review intrinsic evidence and the ultimate construction of the claim de novo. Id. Infringement is a question of fact, DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1013 (Fed.Cir.2006), reviewed for substantial evidence. Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1356–57 (Fed.Cir.2012). We review damages determinations by the court for "an erroneous conclusion of law, clearly erroneous factual findings, or a clear error of judgment amounting to an abuse of discretion." Micro Chem., Inc. v. Lextron, Inc., 318 F.3d 1119, 1122 (Fed.Cir.2003) (internal quotation marks, citation omitted).

## **DISCUSSION**

# I. Invalidity and Infringement

We address first the arguments with respect to the district court's liability determinations as to the asserted claims of the #973, #933, and #236 patents.

## \*1370 A. #973 Patent Invalidity

The #973 patent claims are directed to oversized spinal implants capable of lateral insertion. The human spine has a series of stacked vertebrae. In between each vertebrae is a disk, which is composed of spongy material and provides flexibility to the spine. Prior to the invention, implants were typically smaller than the size of the corresponding vertebrae and were inserted either anteriorly or posteriorly, i.e., from the front or back, rather than the side. The claims of the #973 patent disclosed an oversized spinal implant capable of lateral insertion. The oversized implant arguably provided more stability than the smaller implants, and the lateral directionality of the insertion arguably made the surgery safer. Although claim 35 is not asserted, most of the asserted claims depend from claim 35, <sup>1</sup> and NuVasive appears to argue that the invalidity of the asserted claims turns on the invalidity of claim 35 covers:

A translateral spinal implant for insertion from the lateral aspect of the spine in the disc space between two adjacent vertebrae, said implant having

- a length that is greater than one half the transverse width of the vertebrae,
- said length being substantially greater than the depth of the vertebrae,
- a height for contacting each of the two adjacent vertebrae, and
- a width that is at least as great as the height.

#973 patent, col. 13 ll. 1–7 (line breaks added). NuVasive argues that the claim is anticipated and obvious in light of two prior art references: spinal implants used by surgeon Dr. John Brantigan before the critical date and U.S. Patent No. 5,192,327 to Brantigan (collectively, the "Brantigan references").

[5] The district court construed the preamble of claim 35 not to be limiting, but nonetheless instructed the jury that "said implant" refers to "a spinal implant capable of being inserted translaterally," and that "capable" should be given its plain meaning. *See* J.A. 206. We see no error in the court's determination that the claims require lateral insertion, and NuVasive therefore fails to show its entitlement to a new trial on that issue.

Warsaw also presented substantial evidence to the jury distinguishing the # 973 patent from the Brantigan references. Warsaw argued that the Brantigan references were not "capable" of lateral insertion because (1) the FDA had not approved the implant for lateral insertion, (2) the ridges, grooves, and tool holes of the Brantigan references suggested they were intended for anterior or posterior insertion, not lateral insertion, and (3) the lack of tapering or rounding on the Brantigan implant made it ill-suited for lateral insertion. Because there was substantial evidence for the jury to conclude that the Brantigan references did not teach an implant capable of lateral insertion, the jury was entitled to find that the Brantigan references did not anticipate or render obvious the asserted claims of the #973 patent.

[6] [7] NuVasive also argues that the asserted claims of the #973 patent are indefinite because, given the relative nature of the claim limitations, one cannot know whether an implant infringes until it is selected for a particular patient. Under the Supreme Court's decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, — U.S. —, 134 S.Ct. 2120, 189 L.Ed.2d 37 (2014), a claim is indefinite if "viewed in light of the specification and prosecution \*1371 history," it does not "inform those skilled in the art about the scope of the invention with reasonable clarity." *Id.* at 2129. The relative nature of the claim does not itself make it indefinite, and NuVasive failed to establish, by clear and convincing evidence, that human anatomy varies so significantly that reliance on the well-known dimensions of human vertebrae makes the claims indefinite. *See Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd.*, 401 F.3d 1367, 1371–73 (Fed.Cir.2005). Indeed, the parties stipulated that "[t]he average dimensions of the human vertebrae are well-known, easily ascertainable, and well-documented in the literature." J.A. 2882.

# B. #933 Patent Infringement

[8] The #933 patent is directed to instruments and methods for minimally invasive tissue retraction during surgery. It discloses a two-pronged device in which each prong forms one-half of a hollow cylinder. In combination, the two prongs form a working channel through the cylinder, through which the surgeon can pass instruments for spinal surgery. Neither prong is fixed—both can be moved away from each other and pivoted to adjust the size of the channel. Although claim 1 is not asserted, one of the asserted claims depends from claim 1, <sup>2</sup> and NuVasive appears to argue that the infringement of the asserted claims turns on the infringement of claim 1. Claim 1 provides:

A tissue retractor for percutaneous surgery in a patient, comprising:

a first portion having a proximal end and a distal end; and

a second portion having a proximal end and a distal end, said second portion forming with said first portion a working channel in communication with an exterior of said first and second portions at said proximal ends and said distal ends with said working channel being enclosed by said first portion and said second portion between said distal and proximal ends, wherein said working channel is enlargeable by laterally moving each of said first and second portions away from one another and pivoting each of said distal ends of said first and second portions away from one another such that only a portion of said working channel is enclosed by said first and second portions.

#### #933 patent, col. 13 ll 32–48.

As NuVasive identifies, the accused product has three, not two, portions. Moreover, one of the portions is fixed—incapable of lateral movement or pivoting. Thus, although NuVasive does not dispute that the other claim limitations are met, NuVasive argues that the accused device does not literally infringe the asserted claims of the #933 patent because there are three, not two, prongs, and the third prong is not capable of lateral movement or pivoting. Warsaw argues that the jury did not err in finding infringement under the doctrine of equivalents. NuVasive disagrees.

Warsaw submitted substantial evidence that the differences between the accused device and the **patented** technology are insubstantial. For example, there are admissions by NuVasive's own witnesses that a working channel enclosed by three prongs "i[s] the same working channel as with only two [prongs]" and that "when the working channel is in the closed position, two and three [prongs] are equivalent." J.A. 10735, 11755–56. Thus, substantial evidence exists to support a finding of infringement under the doctrine of equivalents because a jury could find that two enclosing prongs capable of \*1372 lateral movement and pivoting was equivalent to three enclosing prongs, two of which were capable of lateral movement and pivoting. <sup>3</sup>

## C. #236 Patent Infringement

[9] The #236 patent is directed to a method for detecting the presence of and measuring the distance to a nerve during surgery. During surgery, surgeons want to avoid contact with or damage to any nerves, as doing so could result in patient paralysis. The patented monitoring device sends a series of signals in increasing strength. When a nerve fires after receiving a signal, the device can predict its proximity to the nearest nerve based on the signal strength most recently sent by the device. The farther away it is from a nerve, the stronger the signal must be to trigger a response. Claim 1 is representative. It provides:

A method for assessing the proximity of a spinal nerve relative to a distal end of at least one probe or surgical tool being introduced towards at least one of a lumbar region and thoracic region of a patient's spine, said lumbar region and said thoracic region of said spine having a ventral column and a dorsal column, said ventral column including a plurality of vertebral bodies and a plurality of intervertebral discs disposed in between said vertebral bodies, said vertebral bodies and intervertebral discs each having an anterior aspect, a posterior aspect opposite from said anterior aspect, and a lateral aspect extending between said anterior and posterior aspects, said dorsal column including a plurality of bone elements extending from said vertebral bodies to form a spinal canal that contains and protects the spinal chord, said spinal nerve exiting from said spinal canal and disposed generally parallel to a longitudinal axis of said spine along said lateral aspect, the method comprising:

- (a) emitting a stimulus signal from an electrode disposed on a probe or surgical tool as said probe or tool is introduced towards a lateral aspect of at least one of a vertebral body and an intervertebral disc of at least one of a lumbar region and thoracic region of a patient's spine;
- (b) electromyographically monitoring muscles coupled to said spinal nerve to determine if a predetermined neuromuscular response is elicited by the stimulus signal;

- (c) increasing the intensity level of said stimulus signal until said predetermined neuro-muscular response is elicited by said stimulus pulse and stopping the emission of said stimulus signal immediately after said predetermined neuromuscular response is detected; and
- (d) communicating to an operator said intensity level of said stimulus signal required to elicit said predetermined neuro-muscular response, wherein said intensity level required to elicit said predetermined neuro-muscular response represents the proximity of said spinal nerve to said probe or surgical tool.

#236 patent, col. 17 l. 47—col. 18 l. 6. The court construed "stimulus signal" to mean "an electrical signal for eliciting a neuromuscular response." J.A. 208.

\*1373 MSD argues that its product, the NIM-Eclipse, does not infringe because, contrary to step (c), the NIM-Eclipse does not "stop[] the emission of said stimulus signal immediately after said predetermined neuromuscular response is detected." #236 patent, col. 17 ll. 58-60. According to MSD, "stopping" requires the termination of subsequent pulses, whereas the accused product continues to emit pulses, just at a lower level of power. MSD also argues that there is insufficient evidence to prove induced infringement.

NuVasive urges that the NIM-Eclipse signal does "stop." According to NuVasive, a "signal" is a series of increasing pulses. Signal strength decreases when a neuromuscular response is elicited. By decreasing the signal strength, the old signal terminates and a new one begins. This understanding is consistent with the claim construction presented to the jury. The district court defined "stimulus signal" in functional terms, to mean "an electrical signal for eliciting a neuromuscular response." J.A. 208. Thus, according to NuVasive and consistent with the claim construction, the old signal successfully elicited a response, and the decreased pulse is not part of the previous series of increasing pulses. Instead, it is the first pulse of a new signal. This "restart" involves a stop followed by a start.

There was substantial evidence to support a finding of infringement. Treating a "restart" as a type of stop was clearly envisioned by the claims. For example, dependent claims 4, 5, 6, 8, 9, and 10 all claim methods in which the method of claim 1 is repeated. And, NuVasive's expert testified that a "stimulus signal," which he interpreted to be a series of continually increasing pulses, stopped after eliciting a response because the pulse strength dropped and the gradual increase in pulse strength started over.

- [10] Additionally, NuVasive put forth enough evidence to support a jury finding of induced infringement. There was evidence that MSD was aware of the **patent** prior to the litigation and that MSD specifically taught doctors to use the product during the surgical procedures in an infringing manner.
- [11] In rebuttal, MSD argues that interpreting the stopping step in such a way is barred by the prosecution history, in which "stop" was added to overcome a prior art reference. But, no construction of the "stopping" step was presented to the jury, nor did Warsaw request a construction beyond its plain and ordinary meaning. We have previously explained that, "where the parties and the district court elect to provide the jury only with the claim language itself, and do not provide an interpretation of the language in the light of the specification and the prosecution history, it is too late at the JMOL stage to argue for or adopt a new and more detailed interpretation of the claim language and test the jury verdict by that new and more detailed interpretation." *Hewlett–Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1321 (Fed.Cir.2003).

II. #973 and #933 Damages Issues

Having sustained the district court's determinations with respect to liability under the three asserted **patents**, we consider Warsaw's and NuVasive's appeals from the damages awards for the #973 and #933 **patents**. Warsaw does not appeal the denial of injunctive relief.

Although Warsaw owns the #933 and #973 patents, it does not practice the patented technologies. Rather, it (1) licenses the technologies to related companies Medtronic Sofamor Danek Deggendorf, GMBH ("Deggendorf") and Medtronic Puerto Rico Operations Co. ("M Proc"), which manufacture and sell the patented \*1374 products to MSD and pay royalties to Warsaw on those sales and (2) manufactures "fixations," 4 which it sells to MSD for profit. MSD packages the fixations and the patented products together into medical kits, which it sells to hospitals and surgeons.

Warsaw asserts it has three sources of income related to the **patented** technologies. First, it receives revenue from the sale of fixations to MSD, which it argues should be treated as convoyed sales; second, it receives royalty payments from M Proc and Deggendorf; third, it receives payments from MSD resulting from an inter-company transfer pricing agreement, which are characterized by Warsaw as "true-up" payments.

At trial, Warsaw characterized all three sources of income as representing potential lost profits to Warsaw and sought to recover revenue declines allegedly the result of infringement by NuVasive. Warsaw also sought to recover a reasonable royalty. The jury awarded Warsaw \$101,196,000 in total damages. The verdict form indicated that the \$101 million award was for "Lost Profit Damages (with royalty remainder)" and provided royalty rates for each **patent**. It is impossible to determine from the verdict form what portion of the verdict is attributable to lost profits and what portion is attributable to a reasonable royalty, much less how much of the lost profits portion is attributable to each of the three different revenue streams.

After trial, the district court denied Warsaw's request for supplemental damages, and it set the ongoing royalty rate for the #973 patent at 13.75% of sales of infringing implants and set the ongoing royalty rate for the # 933 patent at 8.25% of sales of infringing retractors. NuVasive challenges the award of lost profits. Warsaw challenges the district court's refusal to award supplemental damages and the ongoing royalty rate.

Our treatment of damages is guided by the statute, which provides in part: "the court shall award the claimant damages adequate to compensate for infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer." 35 U.S.C. § 284. Our case law recognizes two measures of damages: lost profits and reasonable royalties. As we have previously explained:

Through section 284, Congress sought to ensure that the **patent** owner would in fact receive full compensation for any damages he suffered as a result of the infringement. Damages is the amount of loss to a patentee. A patentee may seek to recover actual damages, usually, the amounts of profits actually lost, or if unable to prove actual damages, the patentee is entitled to a reasonable royalty.

SmithKline Diagnostics, Inc. v. Helena Labs. Corp., 926 F.2d 1161, 1164 (Fed.Cir.1991) (internal quotation marks, citations omitted).

- [12] At least with respect to any particular sale, a patentee is entitled to either a reasonable royalty or lost profits—not both. *See id.* at 1164. At oral argument, counsel for Warsaw admitted it was not entitled to both a reasonable royalty and lost profits on a single sale, nor was it seeking both.
- [13] Lost profits and reasonable royalties measure damages differently. Lost profits as a measure of damages is intended to make the party whole—to compensate the **patent** holder for profits lost as a result of the infringement. It is not solely a "but for" test. *Rite—Hite Corp. v. Kelley* \*1375 *Co., Inc.*, 56 F.3d 1538, 1546 (Fed.Cir.1995) (en banc).

[14] A reasonable royalty, on the other hand, is intended to compensate the patentee for the value of what was taken from him—the **patented** technology. *See Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 770 (Fed.Cir.2014) ( "The 'value of what was taken'—the value of the use of the **patented** technology—measures the royalty." (quoting *Dowagiac Mfg. Co. v. Minn. Moline Plow Co.*, 235 U.S. 641, 648, 35 S.Ct. 221, 59 L.Ed. 398 (1915))).

[15] Under our case law a patentee may not claim, as its own damages, the lost profits of a related company. See Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1311 (Fed.Cir.2004) (explaining that related companies "may not enjoy the advantages of their separate corporate structure and, at the same time, avoid the consequential limitations of that structure—in this case, the inability of the patent holder to claim the lost profits of its non-exclusive licensee"); see also Mars, Inc. v. Coin Acceptors, Inc., 527 F.3d 1359, 1365 (Fed.Cir.2008) (refusing to award "lost profits" to the patent holder when its subsidiary corporation lost sales due to infringement), mandate recalled and amended on other grounds, 557 F.3d 1377 (Fed.Cir.2009). Indeed, Warsaw admits it is not entitled to the lost profits of Deggendorf, M Proc, or MSD.

## A. Convoyed Sales

[16] [17] NuVasive challenges treating decreases in revenue from the sale of fixations (e.g., rods and screws for holding the implant and vertebrae in place) as "lost profits." At trial, Warsaw's damages expert testified that NuVasive's infringement of the **patented** technologies resulted in Warsaw's making fewer sales of fixations to MSD, because MSD itself lost sales of the **patented** medical kits as a result of NuVasive's infringement. The expert calculated that Warsaw lost \$27.8 million in lost sales, \$24.5 million of which was lost profits (the remaining \$3.3 million was recouped in cost savings). Such a claim is based on the theory that the sales were convoyed sales. A convoyed sale is a sale of a product that is not **patented**, but is sufficiently related to the **patented** product such that the patentee may recover lost profits for lost sales. See Am. Seating Co. v. USSC Grp., Inc., 514 F.3d 1262, 1268 (Fed.Cir.2008).

[18] To be entitled to lost profits for convoyed sales, the related products (e.g., the fixations) must be functionally related to the **patented** product and losses must be reasonably foreseeable. *See Rite-Hite*, 56 F.3d at 1546–50. Being sold together merely for "convenience or business advantage" is not enough. *Am. Seating*, 514 F.3d at 1268. If the convoyed sale has a use independent of the **patented** device, that suggests a non-functional relationship. *See*, *e.g.*, *DePuy Spine*, *Inc. v. Medtronic Sofamor Danek*, *Inc.*, 567 F.3d 1314, 1333 (Fed.Cir.2009).

On appeal, NuVasive argues that the sale of fixations to MSD are not recoverable as "convoyed sales" because there is no functional relationship between the alleged convoyed sales and the **patented** products. That is, according to NuVasive, the unpatented components "can be and are frequently used independently of the **patented** implants and retractors." NuVasive's Opening Br. 48. In rebuttal, Warsaw argues that these sales are recoverable as convoyed sales because the unpatented components are part of comprehensive medical kits that "contain everything necessary for a fusion procedure." Warsaw's Reply Br. 48.

The fixations here are not convoyed sales recoverable as lost profits. Warsaw failed to prove a functional relationship necessary to support a jury verdict awarding \*1376 lost profits for convoyed sales. Warsaw points to its marketing material, in which it touted the kits' "comprehensive set of instruments and implants including fully integrated neuromonitoring, streamlined access instrumentation, anatomically designed implants and percutaneous fixation systems." J.A. 20587. This does not establish a functional relationship. This is the precise sort of convenience or business strategy excluded by *American Seating. See Am. Seating*, 514 F.3d at 1268 ("Our precedent has not extended liability to include 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." (quoting *Rite—Hite*, 56 F.3d at 1538)). Warsaw never presented testimony that the fixations it sold to MSD had no independent function—that is, that they

would not work as well in other surgeries not involving the **patented** technologies. Therefore, the district court erred in denying NuVasive's JMOL motion on this issue.

## B. Royalty Payments from M Proc and Deggendorf

NuVasive next challenges the inclusion of lost royalty payments from M Proc and Deggendorf in the lost profits award. At trial, Warsaw explained that, under its business model, it would license the **patented** technologies to related companies such as Deggendorf and M Proc, who would manufacture the **patented** devices. NuVasive's infringement detrimentally affected those manufacturers' sales, which in turn negatively affected the royalty payments they made to Warsaw.

On appeal, NuVasive argues that Warsaw is effectively claiming as "lost profits" the lost profits of its related companies. That is, that Deggendorf and M Proc are the companies actually harmed by NuVasive, and that by claiming "lost profits," Warsaw is seeking to recover the lost profits of those companies. Warsaw recognizes that *Poly–America* prohibits it from claiming its related companies' lost profits as its own, but it argues that it is not seeking damages that other companies suffered. Rather, because those companies would remit money back to Warsaw, Warsaw argues it is asking for that money—the money it would have received but-for NuVasive's infringement.

To be entitled to lost profits, we have long recognized that the lost profits must come from the lost sales of a product or service the patentee itself was selling. As we explained in *Rite–Hite*, "[n]ormally, if the patentee is not selling a product, by definition there can be no lost profits." 56 F.3d at 1548. Similarly, in *Poly–America* we noted, "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." 383 F.3d at 1311. Here, there is a failure of proof and as a result the revenue stream is not recoverable. <sup>5</sup>

## C. True-Up Payments

[19] NuVasive's final challenge is to the inclusion of the "true-up" payments from MSD to Warsaw. At trial, Warsaw's accounting witness explained that Warsaw engages in various transactions with related companies throughout the year. But, those initial transactions do not necessarily reflect the fair market value of the product or service exchanged. To comply with relevant tax and accounting laws, a transfer pricing agreement is used to require those related companies to transfer funds \*1377 back and forth to compensate each other for the fair market value of the property previously exchanged. The "true-up" payments are post hoc transfers to ensure that Warsaw receives fair-market-value. The number is substantial; MSD remits back 95% of the profit it made from the sale of patented technologies, and that accounts for the majority of the total lost profits requested by Warsaw.

It is not immediately clear from Warsaw's accounting witness' testimony what the underlying transactions were that made the 95% true-up payments necessary. The true-up payments from MSD to Warsaw appear to result from a variety of transactions. Some are for royalty payments, suggesting an implied licensing agreement between MSD and Warsaw for the sale of various **patented** technologies. Others, as suggested by spreadsheets in the record, are for other transactions—for example, management fees or implied licenses on other **patents**. *See* J.A. 23556–637; *see also Medtronic Sofamor Danek USA, Inc. v. Globus Med., Inc.*, 637 F.Supp.2d 290, 309 (E.D.Pa.2009).

Warsaw apparently contends that the true-up payments are recoverable because they contain, in part, royalty payments from MSD to Warsaw for sales of the **patented** products to surgeons and hospitals. But Warsaw makes no effort to distinguish what percentage of the true-ups was attributable to those payments as opposed to payments on unrelated transactions. Indeed, the transfer pricing policies indicate that the true-ups are established on a company-by-company, not a technology-by-technology or even a product-by-product, basis.

The district court erred in denying JMOL as to these payments. Just as the payments from M Proc and Deggendorf are not recoverable as lost profit, so too are the true-up payments not recoverable as lost profit.

# D. Reasonable Royalty

Qur rejection of Warsaw's claims for lost profits does not mean that Warsaw is precluded from any recovery. Warsaw is entitled to a reasonable royalty sufficient to compensate it for the value of what was taken from it—the value of the **patented** technology. As we recently explained, a reasonable royalty compensates the owner not for the damage he suffered, but for the value of what was taken. *See Aqua Shield*, 774 F.3d at 770 ("The 'value of what was taken'—the value of the use of the **patented** technology—measures the royalty." (quoting *Dowagiac*, 235 U.S. at 648, 35 S.Ct. 221)). Neither party argues it is possible to parse out and compute a reasonable royalty based on the jury verdict. Although the jury verdict did state a reasonable royalty rate, it is not entirely clear the period for which that reasonable royalty was determined or whether the jury impermissibly relied on evidence not probative of the value of the **patented** technology. We therefore remand for a new trial to determine a reasonable royalty on the **patented** technologies.

[21] Evidence of a number of existing royalty agreements entered into at arms-length can be evidence of the value of the patent. See Georgia—Pacific Corp. v. U.S. Plywood Corp., 318 F.Supp. 1116, 1120 (S.D.N.Y.1970) (listing "[t]he royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty" as the first factor in determining a reasonable royalty); Monsanto Co. v. McFarling, 488 F.3d 973, 978—79 (Fed.Cir.2007) ("An established royalty is usually the best measure of a 'reasonable' royalty for a given use of an invention because it removes the need to guess at the terms to which parties would hypothetically agree."). But, royalties paid by related parties have little probative value as to the patent's value. See \*1378 Allen Archery, Inc. v. Browning Mfg. Co., 898 F.2d 787, 790 (Fed.Cir.1990) (rejecting agreements between related parties as establishing a royalty rate because the transactions were not arms-length).

[23] Here, the parties are related. As we discussed above, the true-up payments have no relevance to the calculation of the reasonable royalty because Warsaw made no effort to determine what percentage of these payments represented royalties for the asserted **patents**. At this juncture, we do not decide whether royalty payments by Deggendorf and M Proc have any relevance in determining a reasonable royalty. We leave that question to the district court on remand to determine in the trial proceedings. 7

## E. Supplemental Damages

Warsaw challenges the district court's denial of supplemental damages. Discovery closed in June of 2010, but the jury did not render its verdict until September of 2011. Neither the court's instructions nor the verdict form specified the period of infringement during which the jury should award damages. The district court held that whether damages for the gap period were awarded was within the province of the jury. Because the court lacked "critical information about the jury's calculations, the court would ... be unable to formulate a supplement[al] damages award that would be consistent with the jury's verdict." J.A. 30259. Any attempt to do so, the court explained, "would be an improper invasion of the provi[]nce of the jury." *Id.* Warsaw contends on appeal that the district court erred in not awarding supplemental damages.

We need not resolve this issue because, as noted above, we are remanding for a new trial on damages. At the new trial, Warsaw may appropriately assert a claim for supplemental damages limited to a reasonable royalty. But, the time period of the claim must be presented to the jury with clarity so as to avoid the ambiguity that existed at the first trial. The jury instruction and jury verdict forms should make clear the period for which the jury is supposed to determine damages.

If that period ends before the date of the jury verdict, the district court may award supplemental damages in light of that gap period.

# F. Ongoing Royalty

Finally, Warsaw challenges the district court's determination of an ongoing royalty. Warsaw argues that the award is too low because it does not fully compensate Warsaw for lost profits, fails to account for the fact that validity and infringement \*1379 must be assumed when determining ongoing royalties, and fails to account for the fact that some kits were used multiple times, thus resulting in multiple acts of infringement of the method claims. NuVasive argues that that the ongoing royalty determination should be redone because it includes a lost profits component. Because the ongoing royalty impermissibly includes a lost profits component, we vacate the award and remand for the district court to determine an appropriate ongoing royalty rate in light of this opinion and the jury verdict after a new trial.

#### **CONCLUSION**

We affirm the district court with respect to invalidity and infringement for the #973, #933, and #236 patents. We vacate Warsaw's damages award and remand for a new trial on damages consistent with this opinion. At the new trial, Warsaw will be limited to a reasonable royalty and cannot recover lost profits.

## AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED-IN-PART

# **COSTS**

Costs to neither party.

#### **All Citations**

778 F.3d 1365, 113 U.S.P.Q.2d 1873

#### Footnotes

- Claim 24 depends from independent claim 1; claims 41, 42, and 57 depend from independent claim 35; and claim 61 is an independent claim.
- 2 Claim 21 depends from independent claim 1, claim 57 depends from independent claim 56, and claim 61 depends from independent claim 63.
- NuVasive argues that application of the doctrine of equivalents would result in claim vitiation. As we recently explained, vitiation is not a separate argument from insubstantiality. *See Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1347 (Fed.Cir.2013) ( "'Vitiation' is not an exception to the doctrine of equivalents, but instead a legal determination that the evidence is such that no reasonable jury could determine two elements to be equivalent." (quoting *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356 (Fed.Cir.2012))).
- 4 "Fixations" are medical products such as surgical rods and screws that are used in connection with the **patented** devices during surgery.
- Warsaw also argues that Warsaw, not its related manufacturers, was the one that really made the sales because the manufacturers were nothing more than Warsaw's contractual agents. The evidence does not support this characterization.
- We note that Judge Shapiro in *Medtronic Sofamor* described the relationship between Warsaw and its related companies as follows:

Warsaw, the patentee, is entitled to royalties under its license agreements with [M Proc] and Deggendorf. Under those agreements, Warsaw receives royalties of 23% of net sales by the licensee. However, since [M Proc] and Deggendorf are corporate entities related to Warsaw, the royalty rates provided under the license agreements do not prove a royalty rate established by an arms-length transaction. There is no evidence that Warsaw licensed the **patents** to unrelated parties (although it retained the right to do so), so there is no established royalty rate for the **patents** in suit. This factor has no effect on the royalty rate.

637 F.Supp.2d at 309.

We note that it is established that the impact in the United States that granting a license might have on sales of the patented inventions by Warsaw's related companies can be relevant to the hypothetical negotiation, even if the amounts of intercorporate transfers are not. See Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366, 1378 (Fed.Cir.2005), overruled on other grounds, Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 576 F.3d 1348 (Fed.Cir.2009) (en banc).

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