

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

DEPUY SPINE, INC., f/k/a DEPUY
ACROMED, INC. and
BIEDERMANN MOTTECH GMBH

Plaintiffs

v.

CIVIL ACTION NO.:
01-10165-EFH

MEDTRONIC SOFAMOR
DANEK, INC., f/k/a SOFAMOR
DANEK GROUP, INC., and
MEDTRONIC SOFAMOR
DANEK USA, INC.,

Defendants.

MEMORANDUM AND ORDER

December 11, 2007

HARRINGTON, S.D.J.

I. BACKGROUND

A. Procedural History

The plaintiffs, DePuy Spine, Inc. and Biedermann Motech GMBH, brought this action against the defendants, Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc., contending, *inter alia*, that several of the defendants’ products infringe various claims of U.S. Patent No. 5,207,678 (the “‘678 patent”), which Biedermann, the patentee, has licensed to

DePuy. This Court determined that two of the accused devices, the defendants' Vertex and Vertex MAX products, did not infringe the '678 patent, either literally or under the doctrine of equivalents, and granted summary judgment to the defendants. The Court also granted summary judgment on a third product, the bottom-loaded screw model, but denied summary judgment with respect to the defendants' MAS model. The case proceeded to trial on the MAS model, resulting in a jury verdict in favor of the plaintiffs and damages in the amount of 21 million dollars.

The plaintiffs appealed the Court's order granting summary judgment on the Vertex devices.¹ The Federal Circuit affirmed the Court's order with regard to literal infringement, DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1016 (Fed. Cir. 2006), *cert. denied* 128 S. Ct. 58 (2007), but reversed its order granting summary judgment of non-infringement under the doctrine of equivalents, and remanded the case for further proceedings. Id. at 1026. Specifically, the Federal Circuit held that the "hollow spherically-shaped portion" of the '678 patent includes the edge of that portion and that "[b]ecause the screw head in the Vertex [products] presses against an edge of a hollow conically-shaped portion argued to be an equivalent of the 'spherically-shaped' limitation, a question of fact exists as to whether the difference in the equivalent is substantial." Id. at 1020.

Prior to trial on the Vertex devices, the defendants informed the Court that they intended to assert the ensnarement doctrine as a defense to infringement.² After briefing by the parties, the

¹The plaintiffs also contested the order granting summary judgment on the bottom-loading screw model. The defendants cross-appealed, raising various issues.

²The defendants did not assert an invalidity defense in the trial on the MAS model and thus cannot assert on remand that the '678 patent is invalid. Although the plaintiffs correctly point out that the defendants' ensnarement argument covers much the same ground as would an invalidity defense, they are distinct doctrines, for the ensnarement defense relates to a finding that the

Court determined that ensnarement was a question of law to be determined by the Court in a supplemental proceeding. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 2007 U.S. Dist. LEXIS 73893 at *7 (D. Mass. October 3, 2007). The case went to trial and, after a 13 day jury trial, the jury returned a verdict of infringement under the doctrine of equivalents and assessed damages in excess of 226 million dollars. On October 9, 2007, an evidentiary hearing was held on the ensnarement defense.

B. Ensnarement

“[A] patentee should not be able to obtain, under the doctrine of equivalents, coverage which he could not lawfully have obtained from the PTO by literal claims.” Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 684 (Fed. Cir. 1990). Accordingly, a patentee cannot claim infringement based on an equivalent that would have been anticipated or rendered obvious by the prior art. Id. at 683-84. In determining whether the prior art would have “ensnared” the alleged equivalent, it is useful to craft a hypothetical claim that covers the infringing device. Id. at 684. Once an appropriately crafted hypothetical is devised, the inquiry turns to “whether that hypothetical claim could have been allowed by the PTO over the prior art.” Id. “If such a claim would have been 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.” Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1380 (Fed. Cir. 2001) (citing Wilson

Vertex devices infringed the ‘678 patent under the doctrine of equivalents. Since summary judgment had been granted in favor of the defendants prior to trial on the doctrine of equivalents infringement claim, the defendants had no reason or opportunity to raise the ensnarement defense as to the Vertex devices during the first trial. Accordingly, the Court concludes that the defendants did not waive ensnarement and that, because ensnarement functions as a limitation on the doctrine of equivalents, the ensnarement defense falls within the scope of the Federal Circuit’s mandate.

Sporting Goods Co., 904 F.2d at 683-84). “The burden of producing evidence of prior art to challenge a hypothetical claim rests with an accused infringer, but the burden of proving patentability of the hypothetical claim rests with the patentee.” Id. (citation omitted). The parties agree that the plaintiffs must meet their burden of persuasion by a preponderance of the evidence.

The defendants contend that the plaintiffs could not have patented a hypothetical claim covering the accused product because such a claim would have been anticipated or rendered obvious by two prior art references: U.S. Patent No. 2,346,346 (the “Anderson” patent), and U.S. Patent No. 5,474,555 (the “Puno” patent).³

C. The ‘678 Patent, the Accused Devices, and the Hypothetical Claim

1. The ‘678 patent

Claim 1 of the ‘678 patent⁴ reads as follows:

Device for stabilizing spinal column segments, comprising a pedicle screw having a threaded shaft portion and a spherically-shaped head at the end of said threaded shaft portion, a receiver member flexibly connected to said head, said receiver member being provided with two holes for receiving a rod, a receiver chamber being provided within said receiver member, the receiver chamber having at one end thereof a bore for passing the threaded shaft portion therethrough and an inner hollow spherically-shaped portion for receiving the head of said screw, an opening

³The plaintiffs, citing the invention date on the face of the Puno patent, argue that Puno is not prior art to the ‘678 patent. The defendants contend that the plaintiffs are collaterally estopped from contesting Puno’s status as prior art. The Court will assume for the sake of this memorandum that Puno is prior art.

⁴There are a number dependent claims at issue in this case as well. Only claim 1, however, has been litigated in the ensnarement proceedings. Accordingly, the Court will focus exclusively on claim 1.

being provided opposite said bore for inserting said screw, said device further comprising a compression member for exerting a force onto said head such that said head is pressed against the hollow spherically-shaped portion.

(‘678 patent, Col. 4, ll. 9-24). Claim 1 discloses a pedicle screw, a receiver member, and a compression member. Pedicle screws are implanted in human vertebra during surgery. The head of each pedicle screw rests in a receiver member. The receiver members of the several screws are connected via threaded rods. Surgeons use this network of screws, receiver members, and rods to stabilize spinal column segments.

The connection between the pedicle screw and the receiver is “polyaxial,” meaning that the receiver can rotate and angulate relative to the screw. This polyaxial capacity is a useful feature. Because of variation in the spine, the various screws need to be implanted at assorted angles dictated by the patient’s anatomy. This makes it difficult to line up the screws with the rod. The polyaxial connection in the ‘678 patent reduces this problem by enabling a surgeon to bring the receiver to the rod. In other words, regardless of the angle at which the pedicle screw is inserted, the receiver member can be angulated in such a manner that it is better aligned with the rod. Once a desirable angle is achieved, each screw is locked into place by a compression member, which, as its name implies, exerts force onto the screw head and presses it against the receiver member.⁵ Rods then connect the several receiver members.

⁵Another way of responding to the variation in the spine is to bend the rod so that it accommodates the various angles at which the screws are placed. Bending the rod, however, has a number of undesirable consequences.

2. The accused devices

The only relevant difference between claim 1 of the '678 patent and the accused devices is that the receiver chamber in the '678 patent has spherically-shaped portion for receiving the screw head, whereas the receiver chambers in the accused products have conically-shaped portions for receiving the screw head. The jury, applying the doctrine of equivalents, determined that despite this difference, the accused devices infringe the patent claims because they perform substantially the same function, in substantially the same way, to achieve substantially the same result as the patent claims. Cf. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39-40 (1997) (describing the function-way-result standard).

3. The hypothetical claim

The parties agree that an accurate hypothetical claim covering the accused devices would be identical to claim 1 of the '678 patent, except that the term "spherically-shaped portion" would be replaced with the term "conically-shaped portion." The following hypothetical claim would literally read on the accused device:

Device for stabilizing spinal column segments, comprising a pedicle screw having a threaded shaft portion and a spherically-shaped head at the end of said threaded shaft portion, a receiver member flexibly connected to said head, said receiver member being provided with two holes for receiving a rod, a receiver chamber being provided within said receiver member, the receiver chamber having at one end thereof a bore for passing the threaded shaft portion therethrough and an inner hollow **conically-shaped portion** for receiving the head of said screw, an opening being provided opposite said bore for inserting said screw, said device further comprising a compression member for exerting a force onto said head such that said head is pressed against the hollow **conically-shaped portion**.

D. The Prior Art

1. Anderson

The Anderson reference discloses an external fracture immobilization splint for immobilizing long bones, such as arm or leg bones. The Anderson device works by first applying pins to a fractured bone on opposite sides of the fracture. Each pin is attached to a metal bar or plate. Affixed to each bar is a swivel clamp, consisting of a receiver member capable of accommodating a rod, and bolt whose head rests in the receiver member. The swivel-clamp is capable of polyaxial movement until it is locked into place by a compression member. The swivel-clamps are then connected to one another via a rod. This assembly of pins, plates, and rods act as a splint, immobilizing the fractured bone.

2. Puno

The Puno reference discloses a polyaxial spinal screw. It consists of a receiver member capable of accommodating a rod, and a screw whose head rests in a receiver member. The screw is capable of polyaxial movement. Unlike the '678 patent, Puno does not have a compression member.

II. ANTICIPATION

A patent claim is anticipated if “a single, prior art document describe[s] every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.” Advanced Displays Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000). The defendants argue that the Anderson reference anticipates the hypothetical claim because it describes every element of the claim. The plaintiffs acknowledge that the Anderson swivel-clamp describes most of the elements found in

the hypothetical claim, but contend that Anderson fails to disclose a “pedicle screw,” a phrase that is found in the body of the claim and thus serves as a claim limitation. Cf. 3 Chisum on Patents § 8.06[1][b] (stating that a claim typically has three components: 1) a preamble; 2) a transitional phrase, such as “comprising”; and 3) the body, which recites the claim’s limitations). A pedicle screw is a screw that is suitable for use in the narrow portion of an individual vertebra (one of the bony segments that constitute the human spinal column) called the “pedicle.” The plaintiffs argue that the Anderson reference does not disclose a “pedicle screw” because Anderson fails to describe a screw and because the Anderson swivel-clamp is not suitable for use in the human spine.

A. Screw

The plaintiffs contend that the Anderson reference cannot anticipate the hypothetical claim because the reference fails to disclose a screw. In the hypothetical claim, a screw enters the receiver member and its head rests in the receiver member’s hollow conically-shaped receiver portion. According to Anderson’s specification, the object that rests in the receiver member of the Anderson swivel-clamp is a bolt.⁶

The defendants argue that the term “screw” encompasses the bolt disclosed in Anderson. In support of this contention, they note that a medical dictionary available at the time the hypothetical patent would have been filed defines the term “screw” as “[a] helically grooved cylinder for fastening two objects together or for adjusting the position of an object resting on one end.” (Tr. 2014). The defendants’ expert, Dr. Foley, testified that this definition includes the bolt

⁶Both the defendants’ expert, Dr. Kevin Foley, and the plaintiffs’ expert, Mr. Erik Antonsson, characterize the object resting in the receiver member of the Anderson swivel-clamp as a “bolt.”

described in the Anderson specification. Dr. Foley also testified, however, that there are differences between bolts and screws, namely, that a “bolt typically has a flattened end to it, and a screw typically has more of a tapered or sharpened end to it.” (Tr. 1946-47). Mr. Antonsson, the plaintiffs’ expert, relying upon the definition provided by the National Standards Institute, testified that the difference between screws and bolts lies in how they are tightened: a bolt is tightened by means of a nut, whereas a screw is tightened by the turning of the screw itself.⁷ The Anderson reference itself appears to confirm a difference between screws and bolts: it uses both terms in the specification, with a bolt being fastened by means of a nut, and a screw being tightened by means of torque applied to the screw head. In light of the foregoing, the Court concludes that bolts and screws are distinct and, therefore, that Anderson does not disclose a screw.

B. Pedicle

Even if Anderson disclosed a screw, however, the Court also agrees with the plaintiffs that the Anderson swivel-clamp is not suitable for use in the human spine (or any other bones) and thus does not meet the hypothetical claim limitation that the screw at issue be a “pedicle” screw. There is little dispute that the Anderson swivel-clamp is not suitable for use in the human spine, or in any other bones.

The defendants argue, however, that the term “pedicle” lacks patentable significance. In other words, the defendants contend that it does not matter that the swivel-clamp cannot be used in the spine. In support of their argument, the defendants draw the Court’s attention to a

⁷Dr. Foley also alluded to this distinction in his testimony: “Your Honor, think of bolting two plates of metal together, and screwing two plates of metal together. If I put a bolt in, I would drill two holes through those two pieces of metal, and put a nut potentially on the other side of that bolt to hold the thing together. If I put a threaded screw in, I would drill the holes and I could drive the screw in through the two holes.” (Tr. 1947).

determination by the PTO that the term “pedicle screw” does not “structurally define over any other screw which is capable of being inserted into a bone.” (Defendants’ Bench Brief Regarding the “Ensnarement” Defense, Exhibit 10). This determination does not materially assist the defendants. First, the PTO’s determination relates to the prosecution of a different patent — the Harms and Biedermann ‘458 patent. The Court is not convinced that a determination regarding a term used in one patent – which is prosecuted at a different time and is evaluated in light of different prior art – will necessarily be applicable to another patent, even if the two patents describe fairly similar devices.⁸ Although there may be circumstances where a determination regarding one proposed invention will inform the interpretation of another, specific argumentation detailing this nexus is required. Second, contrary to the defendants’ characterization, the PTO did not determine that the term “pedicle screw” had no patentable significance. Instead, it merely noted that the term “pedicle screw” in the ‘458 patent did not “define over” other bone screws. (See Defendants’ Bench Brief Regarding the “Ensnarement” Defense, Exhibit 10). In other words, the term “pedicle screw,” according to the PTO’s determination, would include other bone screws. This does not assist the defendants, however, because the Anderson swivel-clamp does not disclose a bone screw. (Tr. 2142). The Anderson swivel-clamp is applied to a metal plate, not to bone.

Because Anderson does not disclose a screw and is unsuitable for use in the human spine or any other human bones, the Court concludes that the plaintiffs have demonstrated by a

⁸The ‘458 patent, like the hypothetical claim, describes a polyaxial screw.

preponderance of the evidence that Anderson would not have anticipated the hypothetical claim.⁹

III. OBVIOUSNESS

The defendants contend that the hypothetical claim would have been obvious because a person of ordinary skill in the art could have predicted that adding the compression member from Anderson to the Puno polyaxial screw would result in a device reading on the hypothetical claim. The plaintiffs acknowledge that a person of ordinary skill in the art could have predicted that combining the two prior art references would result in a device covered by the hypothetical claim, but argue that there would have been no motivation to combine the two references because the Puno patent “teaches away” from making the proposed combination and because a person of ordinary skill in the art would not have thought to resort to Anderson to make a rigid polyaxial screw.

A claimed invention is obvious “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” Dystar Textilfarben GmbH v. C.H. Patrick Co., 464 F.3d 1356, 1360 (Fed. Cir. 2006) (quoting 35 U.S.C. § 103(a)), *cert. denied* 127 S. Ct. 2937. “[O]bviousness depends on

⁹The Court need not reach the plaintiffs’ contention that the preamble to the hypothetical claim is a claim limitation. The Court does note, however, that either the claim term “pedicle screw” or the expression “[d]evice for stabilizing spinal column segments” (from the preamble), or some other comparable limitation, would probably be necessary to “give life, meaning, and vitality to the claim.” MBO Laboratories, Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1330 (Fed. Cir. 2007) (describing the circumstances in which the preamble may be used to limit a patent claim) (citation omitted). Otherwise, as the plaintiffs point out, the hypothetical claim would likely encompass too broad a range of screw assemblies (those in automobiles, for example). If the preamble is considered a claim limitation, Anderson would not anticipate the hypothetical claim because Anderson does not disclose a “[d]evice for stabilizing spinal column segments.”

(1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; (4) and any relevant secondary considerations, including commercial success, long felt but unresolved needs, and failure of others.” Id. (citing Graham v. John Deere Co., 383 U.S. 1, 17 (1966)).

The Supreme Court has recently observed that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739 (2007). The Court also noted, however, that

[a]lthough common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

Id. at 1741. Accordingly, one must inquire whether “a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so.” Dystar Textilfarben GmbH, 464 F.3d at 1360 (citation omitted). A prior art reference “that ‘teaches away’ from a given combination may negate a motivation to modify the prior art to meet the claimed invention.” Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1308 (Fed. Cir. 2006). “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.” Id. (quoting In re Kahn, 441 F.3d 977, 990 (Fed. Cir. 1990)). If the proposed invention would “defeat the purpose” of a reference, for example, that reference teaches away from the invention. In re Haruna, 249 F.3d 1327, 1336 (Fed. Cir. 2001) (where purpose of design patent reference is to conceal defects, it teaches away from a design in which defects are more readily apparent). To teach away, the reference must “criticize, discredit, or otherwise discourage the solution” reached by the proposed invention. In re Fulton, 391 F.3d 1195, 1201 (Fed. Cir. 2004); see also C.R. Bard v. Medtronic, Inc., 2000 U.S. App. LEXIS 15316 at *18-19 (Fed. Cir. June 29, 2000) (where prior art reference relating to a filter for removing gas bubbles from blood states that surface contact with blood should be minimized, the reference teaches away from filter shapes that increase surface contact).

The defendants suggest that under the Supreme Court’s decision in KSR, an invention comprised of elements found in the prior art will necessarily be obvious if a person of ordinary skill in the art would have been able to predict that the proposed combination of prior art elements would be successful. (Defendant’s Bench Brief Regarding the Ensnarement Defense at 12). In other words, the defendants appear to contend that predictability of success is the sole criterion of the obviousness inquiry and that it is irrelevant whether a person of ordinary skill would be motivated to make the proposed combination in the first place. The Court disagrees with the defendants’ interpretation of KSR.

The defendants’ argument is based primarily upon three passages from the KSR opinion.¹⁰

¹⁰The first passage reads, “The Court recognized [in United States v. Adams] that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable

The Court acknowledges that the wording of two of these passages supports the defendants' interpretation, as they suggest that a predictable result makes a proposed combination obvious. KSR, 127 S. Ct. at 1740 (citing United States v. Adams, 383 U.S. 39, 50-51 (1966) and Sakraida v. Ag Pro, Inc., 425 U.S. 273, 282 (1976)). These two passages, however, merely summarize the holdings of prior cases. The third passage, which appears to represent KSR's actual holding on this subject, is less absolute: it merely states that a combination of known elements that yields predictable results "is *likely* to be obvious." Id. at 1739 (emphasis supplied). Moreover, KSR reaffirms the relevance of motivation, noting that the Court of Customs and Patent Appeal "captured a helpful insight" when it "first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements." Id. at 1741. Although the Court stated that this requirement should not be applied with undue rigidity, identifying the reason for combining prior art references in the first place remains "important." Id. This Court also notes that the bright-lined standard the defendants appear to be promoting is not consonant with KSR's broader teaching, which suggests that flexibility and common sense, rather than rigidity and formalism, should drive the obviousness determination. Cf. Id. at 1742-43 ("Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.").

In light of the foregoing, this Court rejects the defendants' argument that "[u]nder KSR a

result." KSR, 127 S. Ct. at 1740 (citing United States v. Adams, 383 U.S. 39, 50-51 (1966)). The second passage notes that in Sakraida v. Ag Pro, Inc., 425 U.S. 273 (1976), "the Court derived from the precedents the conclusion 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. (quoting Sakraida, 425 U.S. at 282). The third passage reads: "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." Id.

combination of old elements must produce some new or unexpected results to be patentable.” (Defendants’ Bench Brief Regarding the “Ensnarement” Defense at 6).¹¹ Accordingly, the Court also rejects defendants’ contention that the predictable consequences of combining Puno and Anderson rendered the hypothetical claim obvious.

A. Puno

1. Teaching Away

The plaintiffs contend that the Puno reference teaches away from the hypothetical claim because Puno discourages the rigidity that would result from adding a compression member to the Puno polyaxial screw. Puno’s specification states that

[t]he screw is separate from the anchor seat and thus provides for limited motion between the anchor seat and the vertebrae. In addition, this aspect of the design acts as a “shock-absorber” to prevent 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 prior to achieving bony-fusion. This greatly facilitates the surgical procedure and therapy incorporating this device.

(Puno patent, col. 3, l. 60 - col. 4, l. 1).¹² Puno thus teaches a polyaxial screw that provides for limited motion between the vertebra and the anchor seat. This feature decreases “the

¹¹The Court also rejects the defendants’ contention that teaching away is “only relevant to the question of whether one of ordinary skill could have predicted that a prior art device could be successfully modified or combined with features of another prior art device.” (Defendants’ Bench Brief Regarding the “Ensnarement” Defense at 12). Teaching away is not so restricted in the pre-KSR case law, and the Court is not persuaded that KSR altered the standard. Moreover, the Court notes that it is not clear that any witness testified that a person of ordinary skill in the art would have predicted that the proposed combination would be “successful.” (Meaning, a combination that would result in a screw that performs its task satisfactorily.)

¹²The parties appear to agree that the Puno anchor seat is essentially the same as the receiver member in the hypothetical claim.

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.” The limited motion Puno discloses would be reduced or eliminated if a compression member were added to the Puno device because the compression member would press the screw-head against the receiver member. This would undermine one of the stated benefits of the Puno design and would increase the chance that screw and bone-screw interface failure would occur. Because adding a compression member to the Puno device would defeat one of the stated purposes of the invention and because Puno discourages the creation of a rigid screw, the Court agrees with the plaintiffs that the Puno reference teaches away from adding a compression member.¹³

¹³The defendants suggest that Puno does not teach away from rigid screws because one of its claims covers rigidly locking screws. In support of this contention, the defendants cite a decision from the Federal Circuit construing the phrase “operatively joined” (which pertains to the connection between the bone and the screw) in claim 5 of the Puno patent. Cross Med. Prods. Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1305 (Fed. Cir. 2005). For the reasons set forth in the plaintiffs’ bench brief on this topic, the Court agrees with the plaintiffs that Puno discloses a screw with limited motion between the bone and the anchor seat, even if Puno’s claims are construed to encompass rigid screws. Cf. In re Benno, 768 F.2d 1340, 1346 (Fed. Cir. 1985) (“The scope of a patent’s claims determines what infringes the patent; it is no measure of what it discloses.”). It is the prior art’s disclosure that informs the obviousness inquiry. See In re Young, 927 F.2d 588, 591 (Fed. Cir. 1991) (observing that in an obviousness inquiry, courts consider a prior art “reference for what it disclose[s] in relation to the claimed invention.”). The patent teaches that limited motion is beneficial, and thus teaches away from rigidity. The Court notes, moreover, that it is not entirely clear from the Federal Circuit’s opinion that claim 5 encompasses rigid screws. The Federal Circuit stated only that there must be contact between the “bone segment” and the “interface” and that they must be connected in manner that will make them “effective to perform posterior stabilization.” Cross Med. Prods., 424 F.3d at 1306. In so doing, the Federal Circuit cited, *inter alia*, the same language from the specification upon which the plaintiffs rely. See id. at 1305 (citing Puno patent, col. 3, ll. 19-22, ll. 64-67) (“The screw is separate from the anchor seat, which prevents the direct transfer of load from the rod to the ‘bone-screw interface,’ and decreases the chance of failure of the ‘bone screw-interface.’”). It is thus not clear to the Court that the Federal Circuit has construed Puno’s claims in quite the manner alleged by the defendants, an uncertainty compounded by the absence of specific argumentation supporting their interpretation.

2. The Defendants' Arguments

Although the defendants' principal argument is that obviousness pertains to the predictability of success rather than a motivation to combine, the defendants also argue that a person of ordinary skill in the art would have been motivated to add a compression member to Puno because it was understood in the field that some practitioners considered greater rigidity desirable. This argument is unavailing. Even if a general motivation existed to create a rigid screw, a person of ordinary skill in the art would nevertheless understand that Puno teaches that the addition of a compression member to the Puno device would lead to undesirable results (such as an increased chance of screw-failure) and thus discourages the proposed combination.¹⁴ Whatever a skilled artisan might think about rigid screws in general, therefore, the Puno reference teaches away from the specific combination at issue in this case: turning Puno into a rigid screw.

The defendants contend next that the hypothetical claim does not necessarily require a rigid screw (and thus would not run afoul of Puno's teaching). The whole point of adding a compression member, however, is to make the screw more rigid. Indeed, the defendants' principal argument is that a skilled practitioner could predict that the addition of the Anderson compression member to the Puno device would result in a rigidly locking screw.

B. Anderson

The plaintiffs contend that it was not obvious to combine Anderson and Puno because "the Anderson reference is not pertinent to the field of spinal implants." (Plaintiffs' Proposed

¹⁴It bears mention that Dr. Foley himself acknowledged that a certain amount of looseness "might" be beneficial. (Tr. at 1908).

Findings of Fact and Rulings of Law at 19). The defendants respond that Anderson is relevant to the field of spinal implants and has, in fact, been cited in several patents for spinal implant devices. The Court concludes that even if the Anderson reference was reasonably pertinent prior art with respect to some spinal implant devices, Anderson was not reasonably pertinent in this case because a person of ordinary skill in the art would not look to the Anderson swivel-clamp if he or she sought guidance in creating a rigidly locking polyaxial screw.

“Analogous art is that which is relevant to a consideration of obviousness under section 103.” Wang Lab. v. Toshiba Corp., 993 F.2d 858, 864 (Fed. Cir. 1993). In determining whether a prior art reference is analogous, courts consider “(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the art is not within the same field of endeavor, whether it is still reasonably pertinent to the particular problem to be solved.” Id. (citation omitted). “A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” Id. (quotation omitted).

As the plaintiffs note, the Anderson device is quite different from both the hypothetical claim and the Puno polyaxial screw. Anderson discloses an external fixation device, whereas the screws at issue in this case are placed in the human body. Anderson is applied to long bones; the hypothetical claim and the Puno screw are applied to spinal bones. Anderson is a temporary fixation device that uses pins to secure the bone to the device; the hypothetical claim and the Puno reference use screws and, because they are implanted in the human body, are not temporary fixation devices comparable to the Anderson device. Despite these differences, the defendants

argue that Anderson “would have been applicable to the field of spinal implants ” at the time the hypothetical claim would have been prosecuted (Defendant’s Bench Brief Regarding the “Ensnarement” Defense at 9-10), pointing out that Anderson has been cited in several spinal implant patents and that external fixation devices have been cited in various spinal implant patents.

Even if Anderson was reasonably pertinent to some *other* spinal implant devices, however,¹⁵ the crucial question in this case is whether a skilled artisan who wished to turn Puno into a rigid polyaxial screw would turn his or her attention to the Anderson reference, look past the most conspicuous aspects of the device (its bulk, the fact that it is an external fixation device, *etc.*), and focus on one mechanical detail (the swivel-clamp). Apart from the fact that Anderson has been considered relevant to some other spinal implant devices, there is little indication that Anderson “logically would have commended itself,” Wang Lab., 993 F.2d at 864, to an inventor seeking to make the Puno screw more rigid.

This is confirmed by the conduct of actual persons skilled in the art of spinal implants who were interested in creating rigid polyaxial pedicle screws. When the defendants sought to patent Vertex, a polyaxial pedicle screw encompassed by the hypothetical claim, they decided not to cite Anderson as prior art — despite the fact that they were aware of the Anderson reference. This is a telling omission. If Anderson was reasonably pertinent, the defendants neglected to cite a prior art reference that is, if their various arguments before this Court are credited, of the utmost significance. The defendants’ witness on this topic, Dr. Foley, could not explain the defendants’

¹⁵The Court will assume for the sake of argument that Anderson was reasonably pertinent to those patents in which it was cited. The Court notes, however, that the defendants have not explained why and how Anderson was pertinent to these other spinal implant devices.

decision not to cite Anderson. The Court draws the inference that the individuals making decisions about the Vertex patent did not cite Anderson, despite its many conspicuous structural similarities to Vertex (which, to reiterate, is encompassed by the hypothetical claim), because they did not consider the Anderson reference to be analogous art, an assessment that tends to belie the defendants' contention in these proceedings that a person of ordinary skill in the art would have considered Anderson when seeking to create a rigid polyaxial screw.¹⁶

The Court also observes that, in 1991, when Dr. Foley, a person highly skilled in the relevant art, wanted to make Puno more rigid, his preferred solution was a design that involved using the rod, rather than a compression member, to exert pressure on the screw-head. The defendants argue that this is immaterial because Dr. Foley did not know about the Anderson reference in 1991.¹⁷ In 1991, however, Dr. Foley apparently did know about compression members analogous to those found in the Anderson swivel-clamp.¹⁸ Nevertheless, Dr. Foley,

¹⁶At oral argument, several days after the evidentiary hearing, the defendants suggested that they neglected to cite Anderson during the prosecution of the Vertex patent, because an Anderson reference would have been cumulative of the defendants' reference to the '678 patent, which, like Anderson, describes the means by which one locks a polyaxial screw. (Oral Argument Tr. at 63). This explanation, proffered for the first time at oral argument, is unsupported by record evidence or witness testimony.

¹⁷For purposes of this Memorandum and Order, the Court will credit Dr. Foley's testimony that he did not know of the Anderson reference. The Court does have doubts, however, about Dr. Foley's general credibility. Although Dr. Foley is undoubtedly an excellent surgeon and a fine inventor, the jury evidently did not credit his trial testimony. The Court concurs in this assessment. Dr. Foley is not an independent expert and his testimony at the ensnarement hearing was evasive, coy, and — occasionally — somewhat misleading. He appeared far more interested in sparring with the plaintiffs' counsel than forthrightly and honestly answering the questions.

¹⁸Dr. Foley's testimony on this point is difficult to pin down with precision. Nevertheless, the most straightforward interpretation of his deposition and hearing testimony is that he had considered applying a compression member to the Puno screw in 1991.

working with the defendants' engineers, came up with a design that did not involve adding an Anderson-style compression member to the Puno screw. (Plaintiffs' Exhibit 4579). In April 1993, Dr. Foley considered this alternate design to be the "best solution" for creating a rigid screw. (Tr. at 1998). Their design, which later became Vertex, did not incorporate a compression member until later in 1993, after the Vertex patent had issued. In other words, although Dr. Foley and others were motivated to create a rigid screw, it took them some time to eventually settle on a design that they now contend was obvious. The Court concludes that even if a person of ordinary skill in the art were motivated to make Puno more rigid (contrary to Puno's teaching), it would not have been obvious to add the Anderson compression member to the Puno screw.

C. Secondary considerations

The so-called "secondary considerations" confirm that it was not obvious to combine Anderson and Puno to create a device encompassed by the hypothetical claim. In determining whether a patent claim is obvious in light of the prior art, courts may consider "secondary considerations [such] as commercial success, long felt but unresolved needs, failure of others, etc., [that can] be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." KSR, 127 S. Ct. at 1734 (quoting Graham, 383 U.S. at 17-18). In this case, of course, it is a hypothetical claim that is at issue, not the plaintiffs' '678 patent. Nevertheless, in light of the substantial equivalence between the hypothetical claim and claim 1 of the '678 patent, the Court will consider evidence pertaining to the '678 patent.

1. Long felt need and failure of others

As set forth above, Dr. Foley and the defendants sought to create a rigid polyaxial screw

and entertained a design that was dissimilar to both the hypothetical claim and the '678 patent. This design was evidently unsatisfactory. There was thus a recognized need for a rigidly locking polyaxial screw and an initial failure by the defendants — for some period of time, at least — to arrive at a suitable design.

2. Copying

Evidence that the defendants copied the '678 patent, after failing to come up with a satisfactory design, supports a finding of nonobviousness. See *Advanced Display Sys.*, 212 F.3d at 1285-86 (highlighting the significance of evidence that an alleged infringer failed to develop the claimed invention independently and then copied the plaintiff's device). The defendants initially pursued a design that was very different from the one eventually employed by the Vertex device. They settled upon a design with a compression member only after the '678 patent had issued. Dr. Foley could not explain this change of plans, and the defendants never asked one of their other witnesses, Mr. Farris (who was Dr. Foley's co-inventor on Vertex), how he came up with the compression member design that was later incorporated into the Vertex device. This evidence, coupled with other evidence introduced at trial, indicates that the defendants relied upon the '678 patent and tried, unsuccessfully, to design around it. The Court also notes that Dr. Foley's testimony on the development of the Vertex product was particularly evasive. The Court cannot but draw the inference that the defendants' case would have been ill-served by a full and accurate picture of Vertex's development.

3. Commercial success

There was also evidence that the hypothetical claim, if patented, would have been commercially successful. "When a patentee can demonstrate commercial success, usually shown

by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention.” J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997) (citation omitted). Once the nexus between commercial success and the patented invention is shown, “the burden shifts to the challenger to prove that the commercial success is instead due to other factors extraneous to the patented invention, such as advertising or superior workmanship.”

Id.

The jury in this case awarded damages to the plaintiffs in the amount of 226.3 million dollars. A jury in a prior case involving the ‘678 patent and the defendants’ screws awarded the plaintiffs 21 million dollars. Two juries, therefore, concluded that devices featuring the ‘678 patent were very commercially successful. In light of the similarities between claim 1 of the ‘678 patent and the hypothetical claim, the Court concludes that devices featuring the hypothetical claim would have experienced comparable success.

The defendants argue that because the plaintiffs’ products reflect other patents, in addition to the ‘678 patent, the plaintiffs cannot prove that these devices’ commercial success is attributable to the ‘678 patent. The Court disagrees. First, the defendants’ argument does not account for the sales of devices that were found to infringe the ‘678 patent. Second, in light of the evidence that the defendants tried to work around the ‘678 patent while developing their polyaxial screw and the evidence that they copied the ‘678 design, the Court simply cannot believe that the ‘678 patent made no contribution to the success of the various devices containing

it.¹⁹

C. The hypothetical claim would not have been obvious in light of prior art.

Considering the evidence as a whole, and viewing it through the lens of common sense, as KSR instructs, the Court concludes that the plaintiffs have shown by a preponderance of the evidence that it would not have been obvious for a person of ordinary skill in the art to combine the compression member of the Anderson swivel-clamp with the Puno polyaxial screw.²⁰

IV. ENTRY OF JUDGMENT

¹⁹The defendants also suggest that witnesses associated with the plaintiffs “admitted that it is possible to have an equivalently commercially successful polyaxial screw without the ‘678 patent.” (Defendants’ Bench Brief on the “Ensnarement” Defense at 19 (citing Tr. at 1373-75)). One witness testified that surgeons would not care whether a screw is inserted into a “saddle” from the top or the bottom during the *manufacturing process*. The other witness testified that one could have a successful polyaxial screw without the ‘678 patent (a conclusion echoed by the next witness called by the defendants). This testimony does not suggest that the ‘678 patent lacks value or that “equivalent” commercial success could be attained without it. Even if surgeons do not care about the manufacturing process, they may very well care about the products’ features. Moreover, even if there were other, competitive screws available on the market that did not contain the ‘678 patent, that does not mean that devices containing the ‘678 patent were not commercially successful or that the ‘678 patent made no contribution to their success.

²⁰In the defendants’ bench brief, filed after the evidentiary hearing, they suggest that Anderson, by itself, would have made the hypothetical claim obvious. The defendants never raised this contention at the evidentiary hearing and, when specifically asked what their contentions were, informed the Court that they were asserting 1) anticipation based on Anderson; and 2) obviousness based on Anderson combined with Puno. Moreover, no witness testified that Anderson, considered alone, would have rendered the hypothetical claim obvious. The Court therefore declines to consider the defendants’ late-raised assertion that the hypothetical claim would have been obvious in light of Anderson alone.

The jury's verdict in favor of the plaintiffs and its award of 226.3 million dollars plus interest is hereby entered.

SO ORDERED.

/s/ Edward F. Harrington
EDWARD F. HARRINGTON
United States Senior District Judge

Publisher Information

Note* This page is not part of the opinion as entered by the court.

**The docket information provided on this page is for the benefit
of publishers of these opinions.**

1:01-cv-10165-EFH DePuy Spine, Inc., et al v. Medtronic Sofamor Da, et al

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