United States Court of Appeals for the Federal Circuit

05-1043

CROSS MEDICAL PRODUCTS, INC.,

Plaintiff-Appellee,

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MEDTRONIC SOFAMOR DANEK, INC. and MEDTRONIC SOFAMOR DANEK USA, INC.,

Defendants-Appellants.

Bruce D. Kuyper, Latham & Watkins, LLP, of Los Angeles, California, argued for plaintiff-appellee. With him on the brief were Brian F. McMahon; Mark A. Finkelstein, Allan Z. Litovsky, and Jordan B. Kushner of Costa Mesa, California.

<u>Dirk D. Thomas</u>, Robins, Kaplan, Miller & Ciresi L.L.P., of Washington, DC, argued for defendants-appellants. With him on the brief were <u>Robert A. Auchter</u>; <u>Jan M.</u> <u>Conlin</u> and <u>Munir R. Meghjee</u>, of Minneapolis, Minnesota.

Appealed from: United States District Court for the Central District of California

Senior Judge Gary L. Taylor

United States Court of Appeals for the Federal Circuit

05-1043

CROSS MEDICAL PRODUCTS, INC.,

Plaintiff-Appellee,

v.

MEDTRONIC SOFAMOR DANEK, INC. and MEDTRONIC SOFAMOR DANEK USA, INC.,

Defendants-Appellants.

DECIDED: September 30, 2005

Before SCHALL, GAJARSA, and LINN, Circuit Judges.

LINN, Circuit Judge.

Medtronic Sofamor Danek, Inc. et al. ("Medtronic") appeals from an order of the United States District Court for the Central District of California ("district court") permanently enjoining Medtronic from infringing claim 5 of U.S. Patent No. 5,474,555 ("the '555 patent") owned by Cross Medical Products, Inc. ("Cross Medical"). <u>See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.</u>, No. SA CV 03-110-GLT(ANx) (C.D. Cal. Sept. 28, 2004). The permanent injunction was issued following the grant of Cross Medical's motions for partial summary judgment of validity and infringement. <u>See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.</u>, No. SA CV 03-110-GLT(ANx) (C.D. Cal. Aug. 19, 2004) ("<u>Invalidity Opinion</u>"); <u>Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.</u>, No. SA CV 03-110-GLT(ANx) (C.D. Cal. Aug. 19, 2004) ("<u>Invalidity Opinion</u>"); <u>Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.</u>, No. SA CV 03-110-GLT(ANx) (C.D. Cal. Aug. 19, 2004) ("<u>Invalidity Opinion</u>"); <u>Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.</u>, No. SA CV 03-110-GLT(ANx) (C.D. Cal. May 20, 2004) ("<u>Infringement</u>

<u>Opinion</u>"). As a threshold matter, we conclude, over Cross Medical's objection, that we have jurisdiction over this appeal. On Medtronic's challenge to the district court's claim construction rulings, we affirm the district court's construction of the "anchoring means," "securing means," and "bear against said channel" limitations, but modify the district court's construction of the "anchor seat means" and "operatively joined" limitations. Because we find genuine issues of material fact regarding infringement, we reverse the grant of Cross Medical's motion for partial summary judgment of infringement and find no abuse of discretion in the denial of Medtronic's cross-motion for partial summary judgment of non-infringement. We also reverse the grant of Cross Medical's motion. We further conclude that the district court did not abuse its discretion in denying Medtronic's cross-motion for summary judgment as to these invalidity issues. Consequently, we vacate the permanent injunction. Thus, we affirm-in-part, reverse-in-part, vacate-in-part, and remand.

I. BACKGROUND

This appeal involves orthopedic surgical implants used to stabilize and align the bones of a patient's spine. A common problem with spinal fixation is determining how to secure the fixation device to the spine without damaging the spinal cord. Methods of fixation have developed which utilize wires that extend through the spinal canal and hold a rod against the lamina,¹ or that utilize pedicular screws which extend into the pedicle²

¹ The "lamina" is part of the neural arch of a vertebra extending from the pedicle to the median line.

² The "pedicle" is the basal part of each side of the neural arch of a vertebra connecting the laminae with the centrum.

and secure a plate which extends across vertebral segments. The system taught in U.S. Patent No. 4,805,602 ("the '602 patent"), which is also assigned to Cross Medical and is part of the case against Medtronic but not involved in this appeal, exemplifies the advantages of both methods. The screw and rod system of the '602 patent provides a rigidity which is intermediate between wired implant and plate systems. Several screw and rod systems are known in the art. Those which feature an anchor secured to the bone by a separate screw are termed "polyaxial." Polyaxial screws have a capability of pivoting in the anchor. Devices in which the anchor and the bone screw form a unitary body are deemed "monoaxial." Monoaxial screws have no ability to pivot relative to the anchor.

Cross Medical's '555 patent discloses a device, an embodiment of which is illustrated in Figures 1, 2, and 3 below:



The '555 device allows a surgeon to place a series of bone screws 21, each carrying an anchor seat 23, into the bones of a patient. A stabilization rod 18 thereafter may be positioned in the channels 51, 52 of the anchor seats. The '555 device allows

surgeons to secure the rod to the anchor seats with top-tightening nuts 27. By connecting the rod in this fashion to the anchors on adjacent spinal bones, the position of the patient's spine may be fixed as desired by the surgeon.

On February 4, 2003, Cross Medical filed suit alleging that certain of Medtronic's polyaxial screws—MAS, Vertex, M8, Sextant, M10, Legacy 4.5, and Legacy 5.5 infringe the '555 patent and U.S. Patent No. 5,466,237 ("the '237 patent"). The accused devices employ a "set screw," which features external threads to mate with the receiver member's internal threads, to hold the rod in the receiver member. The accused devices also include a "crown member" that lies between the rod and the bone screw. An illustration of the accused device follows, with explanatory text added.



Medtronic denied infringement and counterclaimed seeking a declaratory judgment of non-infringement and invalidity. Subsequent to the initial pleading, responses and amended pleadings added claims and counterclaims relating to several additional patents, including the '602 patent. The district court resolved several issues through summary adjudication. Of importance to this appeal, the district court

separately entertained motions for partial summary judgment of infringement and

validity of claim 5 of the '555 patent.

Claim 5 recites:

A fixation device for the posterior stabilization of one or more bone segments of the spine, comprising:

at least two anchors and an elongated stabilizer comprising a rod having a diameter and a longitudinal axis, said anchors each comprising <u>anchoring means</u> which secure said anchors to said bone segment and an <u>anchor seat means</u> which has a lower bone interface <u>operatively joined</u> to said bone segment and an anchor seat portion spaced apart from said bone interface including a channel to receive said rod; and

<u>securing means</u> which cooperate with each of said anchor seat portions spaced apart from said bone interface and exterior to the bone relative to said elongated rod, said seat means including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel, and said securing means including second threads which cooperate with the first threads of the seat means to cause said rod to <u>bear against said channel</u> through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel.

'555 patent, col. 8, II. 33-57 (emphases added).

On May 29, 2004, the district court construed the "operatively joined," "securing means," and "bear against said channel" limitations of claim 5 of the '555 patent. Based on these constructions, the court granted Cross Medical's motion for partial summary judgment of infringement, and denied Medtronic's cross-motion for partial summary judgment of non-infringement. On August 19, 2004, the district court additionally construed the "anchor seat means" and "anchoring means" limitations of claim 5 of the '555 patent. The court then denied Medtronic's motion for partial summary judgment that claim 5 was anticipated, obvious, and indefinite, and granted Cross Medical's

cross-motion for partial summary judgment that claim 5 was neither anticipated, obvious, nor indefinite.

On September 28, 2004, with proceedings still on-going with respect to the '555 patent and other patents-in-suit, the district court granted Cross Medical's motion for a permanent injunction to preclude Medtronic's infringement of claim 5 of the '555 patent. The district court presumed irreparable harm because Cross Medical had prevailed on the merits at the summary judgment stage. Medtronic argued that there could be no harm because it withdrew all of the asserted infringing devices from the market; however, the district court found that some of the infringing products remained available and that Medtronic had the capacity to bring infringing product back to market. On October 4, 2004, the district court stayed the injunction for 90 days to allow Medtronic time to appeal.

On October 13, 2004, Medtronic appealed from the order granting the injunction, asserting jurisdiction under 28 U.S.C. § 1292(a)(1), (c)(1). Medtronic asks this court to review the district court's claim construction rulings, reverse or vacate the district court's partial summary judgment orders on infringement, indefiniteness, anticipation, and obviousness with respect to claim 5 of the '555 patent, and vacate the permanent injunction. On November 19, 2004, Cross Medical filed a motion to dismiss this appeal for lack of jurisdiction.

II. DISCUSSION

A. Jurisdiction

"Whether this court has jurisdiction over an appeal taken from a district court judgment is a question of law which we address in the first instance." <u>Pause Tech. LLC v. TiVo Inc.</u>, 401 F.3d 1290, 1292 (Fed. Cir. 2005). Section 1292(a)(1) provides that the court of appeals has jurisdiction over appeals from interlocutory orders "granting, continuing, modifying, refusing or dissolving injunctions, or refusing to dissolve or modify injunctions." 28 U.S.C. § 1292(a)(1) (2000). Section 1292(c)(1) provides this court exclusive jurisdiction over an appeal of an interlocutory order granting an injunction if we would otherwise have jurisdiction under § 1295. <u>Id.</u> § 1292(c)(1). Medtronic appeals from an order permanently enjoining Medtronic from infringing the '555 patent. On its face, the order falls within the scope of § 1292(a)(1), (c)(1).

Cross Medical argues that under <u>Woodard v. Sage Products, Inc.</u>, 818 F.2d 841 (Fed. Cir. 1987) (en banc), this court does not possess jurisdiction because the injunction is one in form but not substance. Cross Medical asserts that the injunction is not coercive because it enjoins Medtronic from engaging in activities it had abandoned before the injunction issued. Cross Medical asserts that Medtronic simply should have sought a stay of the injunction pending appeal under Federal Rule of Appellate Procedure 8(a). Alternatively, Cross Medical argues that even if the court has jurisdiction to review the order, it has no jurisdiction to reverse or vacate the partial summary judgment rulings because no final judgment on the '555 patent has been entered, and the orders were not certified for appeal.

Medtronic counters that the order falls under § 1292(a)(1), (c)(1). Medtronic asserts that <u>Sage Products</u> is inapposite and that no case has denied jurisdiction in an appeal from the grant of an injunction. Medtronic states that Cross Medical argued below that the injunction was necessary to prevent irreparable harm, that Medtronic pulled products from the market to avoid a willfulness finding, that the district court entered the injunction with full knowledge of Medtronic's actions, and that it would be unfair to deny Medtronic its statutory right of appeal.

Cross Medical's reliance on <u>Sage Products</u> is misplaced. In <u>Sage Products</u>, plaintiff's amended complaint included a prayer for injunctive relief, and the issue was whether plaintiff could lodge an appeal under § 1292(a)(1) from an order granting defendant's motion for summary judgment of non-infringement. 818 F.2d at 843-44. There was no order specifically denying injunctive relief. <u>Id.</u> Instead, plaintiff argued that the adverse summary judgment ruling had the effect of denying injunctive relief. <u>Id.</u> at 844. This court sitting en banc considered the impact of the Supreme Court's then recent decision in <u>Carson v. American Brands, Inc.</u>, 450 U.S. 79 (1981). We explained that <u>Carson</u> "instructed that an interlocutory appeal under section 1292(a)(1) requires (a) that the order be injunctive in nature, (b) that it cause a serious, if not irreparable, consequence, and (c) that the order can be effectively challenged only by immediate appeal." <u>Sage Products</u>, 818 F.2d at 849. We held that Woodard failed to establish that the order met the <u>Carson</u> requirements. <u>Id.</u> at 855.

However, in reporting on how other courts interpreted <u>Carson</u>, we criticized the Seventh Circuit for applying "the <u>Carson</u> requirements to an order <u>explicitly</u> granting an injunction," observing that "the Supreme Court in <u>Carson</u> expressly limited its holding to

orders that have 'the practical effect of refusing an injunction." Id. at 850 n.6 (quoting Carson, 450 U.S. at 84). We explained that "as a rule of general applicability to orders deemed to deny injunctions, the Carson rule is workable and sensibly balances the statutory provisions of sections 1291 and 1292(a)(1) in light of their respective purposes." Id. at 853. The Supreme Court subsequently confirmed our reading of <u>Carson</u> as applying only to orders that have "the practical effect of granting or denying injunctions." Gulfstream Aerospace Corp. v. Mayacamas Corp., 485 U.S. 271, 287-88 (1988) ("Section 1292(a)(1) will, of course, continue to provide appellate jurisdiction over orders that grant or deny injunctions and orders that have the practical effect of granting or denying injunctions and have "serious, perhaps irreparable, consequence."" (quoting Carson, 450 U.S. at 84 (quoting Baltimore Contractors, Inc. v. Bodinger, 348 U.S. 176, 181 (1955)))); see also 19 James Wm. Moore et al., Moore's Federal Practice ¶ 203.10[2][a], at 12 (3d ed. 2005) ("Moore's") ("While the statute clearly applies to orders that formally grant injunctive relief, it also authorizes interlocutory appeals from orders that have the practical effect of granting an injunction."). Therefore, "if the district court's order expressly grants an injunction, the order is appealable under § 1292(a)(1), without regard to whether the appellant is able to demonstrate serious or irreparable consequences." Moore's ¶ 203.10[2][a], at 14.

In this case, the district court entered an order expressly enjoining Medtronic from infringing claim 5 of the '555 patent. Thus, <u>Carson</u> is inapplicable. <u>See PIN/NIP</u>, <u>Inc. v. Platte Chem. Co.</u>, 304 F.3d 1235, 1242 (Fed. Cir. 2002) (finding jurisdiction without referring to the <u>Carson</u> test because "[t]he district court's grant of a permanent injunction . . . [brought the] appeal squarely within the confines of § 1292(a)(1)"). On

appeal from the district court's grant of the injunction, we have jurisdiction under 28 U.S.C. § 1292(a)(1).

Moreover, we may review the underlying partial summary judgment orders because they are inseparably connected to the merits of the permanent injunction. See id. at 1242-48 (reviewing a summary judgment ruling that a claim was not anticipated by the prior art where jurisdiction was based on § 1292(a)(1), (c)(1)); Katz v. Lear Siegler, Inc., 909 F.2d 1459, 1461 (Fed. Cir. 1990) (reviewing propriety of joinder of counterdefendant on appeal from injunction); Moore's ¶ 203.10[7][b], at 45-47 ("[An interlocutory appeal under § 1292(a)(1)] enable[s] the circuit court to review other orders that are inseparably or very closely connected with the merits of the injunctive order"). The district court presumed irreparable harm based on Cross Medical's success on the merits, which manifested itself in the summary judgment orders concerning claim 5. Because Cross Medical's success on the merits turns on the propriety of the summary judgment rulings, our review of the grant of the permanent injunction requires that we rule on the summary judgment orders. See Mendenhall v. Barber-Green Co., 26 F.3d 1573, 1581 n.12 (Fed. Cir. 1994) (noting "that an interlocutory appeal from a permanent injunction, to the extent that it considers questions of validity and infringement . . . is identical in substance to an appeal brought under § 1292(c)(2)"). The cases cited by Cross Medical are not germane.

For these reasons, Cross Medical's motion to dismiss the appeal for lack of jurisdiction is denied.

B. Standard of Review

"We review the grant of a permanent injunction for an abuse of discretion which requires plenary review of the correctness of ... rulings on matters of law." Stratos Mobile Networks USA, LLC v. United States, 213 F.3d 1375, 1379 (Fed. Cir. 2000) (internal quotations omitted). We review the grant of a motion for summary judgment de novo. Id. However, we review the denial of a motion for summary judgment for abuse of discretion. Gart v. Logitech, Inc., 254 F.3d 1334, 1338 (Fed. Cir. 2001). Summary judgment should only be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). In applying this standard, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in [the non-movant's] favor." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). "The fact that both the parties have moved for summary judgment does not mean that the court must grant summary judgment to one party or the other. ... Crossmotions are no more than a claim by each party that it alone is entitled to summary judgment, and the court must evaluate each motion on its own merits, taking care in each instance to view the evidence in favor of the nonmoving party." Bubble Room, Inc. v. United States, 159 F.3d 553, 561 (Fed. Cir. 1998) (internal citation omitted); accord Gart, 254 F.3d at 1338-39.

Claim construction is a question of law reviewed <u>de novo</u>. <u>See Phillips v. AWH</u> <u>Corp.</u>, 415 F.3d 1303, 1328 (Fed. Cir. 2005) (en banc). Determination of infringement is a factual question. <u>Bai v. L & L Wings, Inc.</u>, 160 F.3d 1350, 1353 (Fed. Cir. 1998).

"Indefiniteness, . . . like claim construction, is a question of law that we review <u>de novo</u>." <u>Atmel Corp. v. Info. Storage Devices</u>, 198 F.3d 1374, 1378 (Fed. Cir. 1999). Anticipation is a question of fact. <u>Advanced Display Sys.</u>, Inc. v. Kent State Univ.</u>, 212 F.3d 1272, 1281 (Fed. Cir. 2000). "Obviousness is a question of law based on underlying facts." <u>Group One Ltd. v. Hallmark Cards, Inc.</u>, 407 F.3d 1297, 1303 (Fed. Cir. 2005).

C. Claim Construction

In the course of its rulings on partial summary judgment for both infringement and validity, the district court construed the "anchoring means," "anchor seat means," "operatively joined," "securing means," and "bear against said channel" limitations of claim 5. Medtronic challenges each construction.

1. "anchors each comprising anchoring means . . . and anchor seat means"

In the district court, the parties disputed whether either the "anchoring means" limitation or "anchor seat means" limitation imposed a requirement that the bone screws be polyaxial. The district court did not construe each limitation separately. Instead, the district court referred to its prior ruling in <u>Cross Medical Products, Inc. v. DePuy</u> <u>AcroMed, Inc.</u>, No. SA CV 00-876-GLT(ANx), (C.D. Cal. Jan. 9, 2003), and explained that both the "anchoring means" and "anchor seat means" limitations were in § 112, ¶ 6 form and "must be construed by referring to the specification." <u>Invalidity Opinion</u> at 3-4. The district court held that "although the claim language itself does not indicate whether the screws are polyaxial or monoaxial, the specifications and the drawings establish that the claims are limited to polyaxial screws." <u>Id.</u> at 3.

Medtronic asserts that although the preferred embodiment describes a polyaxial screw, there is no basis to read this feature into claim 5 because neither "anchoring means" nor "anchor seat means" are § 112, ¶ 6 limitations. Medtronic argues that even if these are § 112, ¶ 6 limitations, a monoaxial screw is an alternative embodiment and, thus, should be considered corresponding structure, citing <u>Micro Chemical, Inc. v. Great</u> <u>Plains Chemical Co.</u>, 194 F.3d 1250 (Fed. Cir. 1999). Medtronic also relies on the doctrine of claim differentiation, arguing that the recitation in claim 1 of a polyaxial screw limitation implies that claim 5 does not possess that limitation. Finally, Medtronic adds that Cross Medical is estopped from denying that claim 5 covers monoaxial screws because Cross Medical marked its monoaxial screws with the '555 patent number.

Cross Medical counters that both "anchoring means" and "anchor seat means" are § 112, ¶ 6 limitations and their corresponding structure is a polyaxial screw. Cross Medical argues that claim differentiation must give way to a proper § 112, ¶ 6 analysis and that the court should not consider "marking estoppel" in construing claim 5 because marking is extrinsic evidence. Cross Medical adds that claims should be construed to preserve their validity.

The limitations at issue are contained in the following text of claim 5:

said anchors each compris[e] <u>anchoring means</u> which secure said anchors to said bone segment and an <u>anchor seat means</u> which has a lower bone interface operatively joined to said bone segment and an anchor seat portion spaced apart from said bone interface including a channel to receive said rod.... ... said <u>seat means</u> including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel

'555 patent, col. 8, II. 36-43, 46-51 (emphases added).

a. "anchoring means"

The limitation recites the word "means," which gives rise to the presumption that § 112, ¶ 6 applies. <u>See Rodime PLC v. Seagate Tech., Inc.</u>, 174 F.3d 1294, 1302 (Fed. Cir. 1999). The claimed function of the "anchoring means" is to "secure said anchors to said bone segment." '555 patent, col. 8, II. 38-39. No structure is recited in the claim to perform this function. <u>See id.</u>, II. 35-56. Thus, § 112, ¶ 6 applies and the "claim shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6 (2000); <u>AI-Site Corp. v. VSI Int'l, Inc.</u>, 174 F.3d 1308, 1320 (Fed. Cir. 1999).

The specification discloses only one embodiment. That embodiment contains a screw which carries a separate anchor such that "when the screw 21 engages the anchor seat 23, a limited ball-and-socket joint is formed which permits freedom of movement between the rod support 23 and the screw 21." '555 patent, col. 5, ll. 4-47. The specification unambiguously states that a feature of the "present invention" is that "[e]ach anchor seat is secured by a cancellous screw which cooperates through a sloped bore in the anchor seat so as to provide a limited ball and socket motion." Id., col. 1, l. 65–col. 2, l. 21. It continues:

The present invention utilizes a rod and vertebral anchors which holds [sic] the rod in position. Each anchor is secured to the vertebrae by a transpedicular screw member.

. . . .

... [T]he present design utilizes two implant sets on either side of the spinous processes. Each implant set includes a ... rod Generally, an implant set is used on each side of the spinous process The rod is held in position by a stainless steel vertebral anchor which captures the rods. The anchor has a seat member which is secured to the vertebrae by a stainless steel transpedicular screw. The screw is separate from the anchor seat and thus provides for limited motion between the anchor seat and the vertebrae.

<u>Id.</u>, col. 3, II. 26-67 (emphasis added). The patent discloses no other structure for securing the anchor to the bone. The patent states that the polyaxial 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." <u>Id.</u>, II. 63-67. Thus, the district court was correct both in linking the recited function to the structure disclosed in the specification and in concluding that the corresponding structure was polyaxial. Medtronic argues that even if the limitation is a means-plus-function limitation linked to the disclosed polyaxial structure, the claim nonetheless should be construed to include alternative structures like monoaxial screws. However, because there is only one embodiment described in the specification to secure the anchor to the bone—a polyaxial screw and anchor structure—there is no basis on which to extend the limitation to cover alternative, non-disclosed structure not shown to be structurally equivalent. <u>See</u> 35 U.S.C. § 112, ¶ 6; Al-Site, 174 F.3d at 1320.

We reject the parties' remaining arguments. First, although the doctrine of claim differentiation suggests that claim 5 should be broader than claim 1, any presumption that the claims differ with respect to this feature may be overcome by a contrary construction mandated by the application of § 112, ¶ 6. <u>See Laitram Corp. v. Rexnord,</u> <u>Inc.</u>, 939 F.2d 1533, 1538 (Fed. Cir. 1991) (holding that the doctrine of claim differentiation yields to an interpretation mandated by § 112, ¶ 6). Second, Medtronic's

assertion that "marking estoppel" applies is incorrect. Even if Cross Medical marked monoaxial screws with the '555 patent number, such evidence conflicts with the intrinsic record and has no bearing on our construction. See Phillips, 415 F.3d at 1318 ("[A] court should discount [extrinsic evidence] that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." (internal quotation omitted)); cf. SmithKline Diagnostics v. Helena Labs. Corp., 859 F.2d 878, 890-91 (Fed. Cir. 1988) (holding that an accused infringer's mis-marking of a product could not convert by estoppel an admittedly non-infringing product into an infringing product). Finally, Cross Medical's argument that we should consider the validity of claim 5 in construing the limitation misses the mark. Because the other claim construction tools unambiguously resolve the claim construction dispute, considering validity would be improper. Phillips, 415 F.3d at 1327 ("[W]e have limited the maxim [of construing a claim to preserve its validity] to cases in which 'the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.").

b. "anchor seat means"

While the limitation recites the word "means," thus giving rise to the presumption that § 112, ¶ 6 applies, see Rodime, 174 F.3d at 1302, the claim language is sufficiently structural as to take the limitation out of the ambit of § 112, ¶ 6. Thus, the district court erred in treating "anchor seat means" as a means-plus-function limitation; however, that error is harmless with respect to the conclusion that the claim covers polyaxial structures, based on the district court's correct construction of the "anchoring means" limitation, discussed supra.

2. "operatively joined"

The district court construed "lower bone interface operatively joined to said bone segment" to mean "connect[ed] during a surgical procedure." <u>Infringement Opinion</u> at 5. The district court interpreted "connect" to mean "in contact." <u>See id.</u> & n.2. The district court reasoned that because the claim involves a surgical procedure, "operatively" means "involving surgical operations." <u>Id.</u> The district court explained that construing "operatively" to mean "to produce an appropriate effect" would improperly import a limitation from the specification. <u>Id.</u> at 4-5.

Medtronic argues that the "bone interface" language surrounding the phrase "operatively joined" requires that there be contact between the bone segment and the anchor seat. Medtronic asserts that "operatively" means to produce an effect and that effect is micro-motion, which Medtronic describes as "limited motion" between the anchor and the bone. Medtronic argues that it would be inconsistent to construe claim 5 to require a polyaxial screw which enables polyaxial movement, but not to require a micro-motion effect. Medtronic adds that the district court's construction renders "operatively" superfluous because the only way to attach the screw to bone is via surgery.

Cross Medical counters that the "bone interface" is the portion of the anchor seat that comes into contact with the bone when there is contact, but that "bone interface" does not require contact. Cross Medical argues that the district court correctly construed "operatively" to mean "surgically." Cross Medical asserts that even if we construe "operatively" to mean "effectively," the effect is posterior stabilization, not

micro-motion. Cross Medical adds that "polyaxial" and "micro-motion" are not synonymous.

The claim recites an "anchor seat means which has a lower bone interface operatively joined to said bone segment." '555 patent, col. 8, II. 39-42. The claim does not state explicitly whether the "bone interface" and the "bone segment" must be in contact. However, we may refer to the dictionary to begin understanding the ordinary meaning of these claim terms, "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." <u>Phillips</u>, 415 F.3d at 1322-23 (internal quotations omitted). "[B]one" modifies "interface," indicating that the anchor seat has a "lower" portion that may share a "common boundary" with "bone." <u>See Webster's Third New Int'l Dictionary</u> 1178 (2002) (defining "interface"). The term "joined" describes the relationship between the "bone interface" and the "bone segment." Use of the word "joined" indicates that the "interface" and the "bone" must be brought together or connected to form a single unit, a whole, or a continuity, and thus that the interface and the bone are in contact. <u>See id.</u> at 1218 (defining "join").

The written description confirms that the interface must contact the bone. 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." <u>Id.</u>, col. 3, II. 19-22, II. 64-67. This use of the term "interface" is consistent with its meaning a "common boundary" between two parts. Moreover, the patent refers to the "anchor" as being held, '555 patent, Abstract, or "secured" to the bone, <u>id.</u>, col. 3, II. 59-60, and to the point of attachment as a "fusion bed," <u>id.</u>, col. 7,

I. 15. These references suggest contact between the anchor seat and the bone. Furthermore, to adjust the height of the anchor posterior to the bone, the patent teaches the addition of washers that are the same diameter as the anchor seat. Id., col. 5, II. 50-57. The washers co-act with the anchor seat to function as the bone interface while elevating the seat. If contact with bone were not contemplated, then there would be little need to add washers to elevate the seat. The drawings show contact between the anchor and bone, which is consistent with the description. Id., Figures 3, 14, 17-20. Because the ordinary meaning of "interface" and "joined," as reflected in dictionary definitions and in the overall context of the intrinsic record, leads to the conclusion that a person of ordinary skill in the art would have understood these terms to require "contact" between the interface and the bone, the district court's construction in this regard was correct. It would be improper to construe "joined" more broadly to mean "connected" without requiring contact.

As to "operatively," the term is often used descriptively in patent drafting to mean "effectively" in describing the functional relationship between claimed components. <u>See, e.g., Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.</u>, 381 F.3d 1111, 1118 (Fed. Cir. 2004) ("[Operatively connected] is a general descriptive term frequently used in patent drafting to reflect a functional relationship between claimed components."). Here, the preamble of the claim recites that the invention is operative when it effects posterior stabilization of one or more bone segments of the spine. '555 patent, col. 8, II. 33-34; <u>see Innova</u>, 381 F.3d at 1118 (declining to decide whether preamble was an affirmative limitation, but recognizing that preamble recited the intended use corresponding to "operatively"). The body of the claim is consistent as it

calls for anchors and a stabilizer rod, and provides detail on how these structures interrelate to stabilize the bone segment. See '555 patent, col. 8, II. 35-57; Innova, 381 F.3d at 1118-19 (looking to the body of the claim to understand the purpose). Although the written description does not define "operatively," it consistently describes the purpose of the device to be for posterior stabilization. See '555 patent, col. 1, II. 9-12 ("This invention relates generally to an apparatus for immobilization of the spine, and more particularly, to an apparatus for posterior internal fixation of the spine"); Innova, 381 F.3d at 1118-19 (looking to the written description to understand the purpose). It discusses disadvantages of prior art spinal fixation methods and apparatuses, '555 patent, col. 1, ll. 13-64; col. 2, l. 36-col. 3, l. 25, details how the invention's features provide an advantageous fixation system, id., col. 3, I. 26-col. 6, I. 44, and provides a method of spinal fixation therapy for use with the device, id., col. 6, l. 45-col. 7, l. 50. Therefore, from the context of the written description, it is clear that one of ordinary skill in the art would have understood "operatively" to mean effective to produce posterior stabilization. The district court erred in construing "operatively" to mean "surgically." Because the only way a "fixation device" can provide "posterior stabilization" is through a surgical procedure, construing "operatively" to mean "surgically" renders the word superfluous, as used in the claim.

For all of these reasons, we modify the district court's claim construction and conclude that, in claim 5, the "lower bone interface [is] operatively joined to said bone segment" when the interface and the bone segment are connected and in contact such that the device is effective to perform posterior stabilization.

3. "securing means"

The district court considered the "securing means" limitation to be in § 112, ¶ 6 form, and described its function as "appl[ying] a force to the rod, which compresses the rod against the anchor seats and secures the rod in place." Infringement Opinion at 6. The district court explained that compression must be applied on "either side"—either inside or outside—of the rod-receiving channel. Id. at 7. The district court identified the corresponding structure as an "outer nut." Id. at 6.

Medtronic argues that the district court's interpretation of the function of the "securing means" somehow ignores the claim language: "through the application of substantially equal compressive forces . . . <u>applied on either side along said longitudinal axis of said channel</u>." '555 patent, col. 8, II. 54-57 (emphasis added). Medtronic asserts that this language mandates that forces be applied along the longitudinal axis of the rod on "either side" of the channel and not on "either side" of the vertical axis. Medtronic interprets "either side" of the channel to be on the "outside" of the channel. Although Medtronic does not dispute that the corresponding structure is an external nut, Medtronic argues that the written description and prosecution history show a disavowal of equivalents to an external nut.

Cross Medical responds that the district court did not ignore the "either side" limitation, and that, in any event, "either side" can mean that the forces are applied "inside" the channel. Cross Medical provides the illustration that standing on "either side" of the room would connote standing inside the room. Cross Medical adds that the specification and prosecution history do not evince a disavowal, and that claim differentiation doctrine supports structural equivalents.

The claim requires:

at least two anchors and an elongated stabilizer comprising a rod having a diameter and a longitudinal axis

securing means which cooperate with each of said anchor seat portions...said securing means including second threads which cooperate with the first threads of the seat means to cause said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel.

'555 patent, col. 8, ll. 36-37, 44-57.

We agree with the parties that the limitation is in § 112, ¶ 6 format. See Rodime, 174 F.3d at 1302 (noting that a concession by the parties that the claim is in § 112, ¶ 6 form does not relieve the court of its duty to examine whether § 112, ¶ 6 applies). The claim recites "securing means," which gives rise to the presumption that § 112, ¶ 6 applies. See id. The function is "to cause said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel." '555 patent, col. 8, II. 53-57.

"[E]ither side" does not refer to "either side" of the rod on the vertical axis of the channel perpendicular to the rod, because that interpretation would render the "in the direction of the vertical axis" language redundant. The "and" in the phrase "in the direction of the vertical axis <u>and</u> applied on either side" makes that clear. Therefore, the function is to cause the rod to bear against the rod-receiving channel by applying a compressive force in the direction of the vertical axis while ensuring that substantially equal forces are applied along the longitudinal axis of the rod on opposite sides—either inside or outside—of the rod-receiving channel.

We must now determine whether the claim recites structure to carry out that function. The claim states that the "securing means . . . cooperate with each of said anchor seat portions," <u>id.</u>, II. 44-45, in that the "securing means include[s] second threads which cooperate with the first threads of the seat means to cause [the desired function]," <u>id.</u>, II. 51-57. Although it is the operation of the threads that causes the rod to bear against the channel by applying a compressive force in the direction of the vertical axis, a naked incantation of threads alone does not ensure that substantially equal forces are applied along the longitudinal axis of the rod on opposite sides of the rod-receiving channel. Because there is insufficient structure recited for performing the specified function, § 112, ¶ 6 applies. Thus, we construe the claim "to cover the corresponding structure . . . described in the specification and equivalents thereof."

The structure for performing the recited function is described as follows:

The nut 27 includes internal threads 83 which engage the external threaded area 76 on the anchor seat. The nut 27 is a hex nut which can be tightened relative to the seat 25.

As the nut 27 is rotated about the anchor seat 25, it cooperates with the top side of the flange 46,47 to tighten the clamp 25 in relation to the rod support 23. The rod 18 is grasped in the tunnel 84 formed between the rod-receiving channel 54 of the anchor seat 23 and the arch 72 of the cap 25.

The threads 76 on the anchor seat 23 extend downwardly on the seat below the top of the cylindrical surface of the rod 18 as is shown in FIG. 2 and the nut 27 has a relatively constant diameter through the bore as is shown in FIGS. 2 and 4. Accordingly, the nut 27 can be screwed directly onto the anchor seat 23 to compressively hold the rod without the cap 25.

'555 patent, col. 6, II. 9-24. Figures 5 and 7 depict the rod 18 in the channel created by

the anchor seat 23, with the nut 27 securing the rod in place. Thus, the structure that

corresponds to the claimed function is a nut with internal threads cooperating with the

external threads of the anchor seat (an "external nut"). The claim covers that structure and equivalents thereof.

We are not persuaded by Medtronic's argument that the written description shows a disavowal of equivalents. Although we need not decide that there can never be a disavowal of § 112, ¶ 6 equivalents, "§ 112-6 was written precisely to avoid a holding that a means-plus-function limitation must be read as covering only the means disclosed in the specification." <u>D.M.I., Inc. v. Deere & Co.</u>, 755 F.2d 1570, 1574 (Fed. Cir. 1985). In this case, the inventors were merely describing the structure that performs the claimed function.

Nor are we persuaded that the prosecution history shows a disavowal. In an August 4, 1994 Office Action ("<u>Office Action</u>"), the Examiner rejected the apparatus claims, in part, under § 112, ¶ 1, because "[t]he specification fail[ed] to provide an enabling description of the embodiment of the action device excluding the cap/cap means," and because "language directed toward the 'securing means' cooperating with the seat means through application of compressive forces by the securing means" failed to have support in the specification. <u>Office Action</u> at 4. Subsequent to that rejection, an interview was held with the Examiner and the Examiner Interview Summary referred to "securing means" as "i.e., the nut." In addition, Remarks in the April 27, 1995 Amendment ("<u>Amendment</u>") stated that Applicant amended the claims "to define the anchor seat means having a channel and threads which cooperate with the securing means." <u>Amendment</u> at 4. However, Applicant did not add language in claim 5 that limited securing means to a nut. The statements referring to "securing means" as

"i.e., the nut" simply help to provide the requisite linkage between the function recited in the claim and the "corresponding" structure. <u>See Default Proof Credit Card Sys., Inc. v.</u> <u>Home Depot U.S.A., Inc.</u>, 412 F.3d 1291, 1298 (Fed. Cir. 2005) ("A structure disclosed in the specification qualifies as "corresponding" structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim."). Applicant did not disclaim all structural equivalents.

Therefore, the district court correctly construed the "securing means" limitation to refer to the external nut described in the written description. Under § 112, ¶ 6, the claim also covers equivalents thereof.

4. "bear against said channel"

The parties dispute whether the language of claim 5 reciting that the "rod . . . bear[s] against said channel" precludes the presence of any intervening structure between the rod and the channel. The district court held that "[t]here is nothing in the [language of claim 5] which excludes an anchor channel composed of more than one component part." <u>Infringement Opinion</u> at 8. Medtronic argues that the district court's construction is erroneous, and that by placing a separable crown member over the anchor seat, Medtronic has prevented the rod from "bear[ing] against [the] channel" as a matter of law. Medtronic asserts that the anchor seat must form the channel and the crown is not part of the anchor seat. Cross Medical responds that claim 5 does not require that the channel of the anchor seat be a unitary component and thus does not preclude a finding that the crown is part of the anchor seat.

The dispute reduces to whether the "channel" must be formed in a unitary structure. The claim requires that the anchor seat means have "an anchor seat portion

spaced apart from said bone interface including a channel to receive said rod," '555 patent, col. 8, II. 41-42, and that the "securing means...cause[s] said rod to bear against said channel," <u>id.</u>, II. 51-54. The claim does not state that the anchor seat portion forming the channel is unitary. Although the sole embodiment described in the specification depicts a unitary structure, <u>id.</u>, col. 5, II. 20-21, the mere depiction of a structural claim feature as unitary in an embodiment, without more, does not mandate that the structural limitation be unitary. <u>See CCS Fitness, Inc. v. Brunswick Corp.</u>, 288 F.3d 1359, 1367 (Fed. Cir. 2002) (holding that "member" encompassed a multi-component structure where the preferred embodiment showed a single-component structure, but the specification did not otherwise require a certain number of components). There is nothing in the written description or prosecution history that limits the channel to being formed in a single-component structure. Thus, the district court correctly concluded that the "bear against said channel" language of claim 5 does not exclude an "anchor seat portion" composed of multiple components.

D. Infringement

The district court ruled as a matter of law that the accused devices met the "operatively joined," "securing means," and "bear against said channel" limitations, that Medtronic was a direct infringer, and that alternatively, Medtronic either contributed to infringement or induced infringement. <u>Infringement Opinion</u> at 4-9. Medtronic appeals.

1. "operatively joined"

The district court held that the accused devices met the "operatively joined" limitation as a matter of law because "the accused device, to be infringing, need only be capable of operating in the [infringing] mode . . . actual [infringing] operation in the accused device is not required." Id. at 5-6 (quoting Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 832 (Fed. Cir. 1991)). The district court cited <u>Hilgraeve Corp. v.</u> <u>Symantec Corp.</u>, 265 F.3d 1336, 1343 (Fed. Cir. 2001), for the proposition that "an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation." <u>Infringement Opinion</u> at 5. The court explained that Medtronic's devices "are capable of operative joinder to the bone segment, and are sometimes used in this way." Id. at 5-6. In response to Medtronic's argument that it could not directly infringe because it did not perform surgery, the district court held that "under 35 U.S.C. § 271 Defendants can be liable for inducing the infringement or for selling a device which constitutes part of the invention." Id. at 8.

Medtronic argues that it does not itself make an anchor seat which contacts bone and it does not perform surgery. Medtronic asserts that <u>Intel</u> and <u>Hilgraeve</u> are inapposite and that it cannot be a direct infringer simply because its accused devices are capable of being made into infringing devices by surgeons. Medtronic adds that it does not induce or contribute to infringement because there is no evidence of physicians bringing the receiver member into contact with the bone segment to make the claimed apparatus; because Medtronic does not design the receiver member to

contact the bone segment; and because Medtronic instructs surgeons not to place the device into contact with the bone.

Cross Medical counters that to directly infringe, Medtronic need only make devices that are capable of being converted into infringing devices, citing Intel, Hilgraeve, and Bell Com. Research Inc. v. Vitalink Com. Corp., 55 F.3d 615 (Fed. Cir. 1995). Cross Medical asserts that Medtronic's argument that it does not directly infringe because it does not perform surgery is as superficial as the non-infringement argument concerning the "Commissioner.com" product in Fantasy Sports Props., Inc. v. SportsLine.com, Inc., 287 F.3d 1108 (Fed. Cir. 2002), and therefore must fail. Furthermore, Cross Medical argues that Medtronic's representatives are present in the operating room and thus that Medtronic performs surgery. Alternatively, Cross Medical argues that Medtronic induces infringement because it sells devices to surgeons, designs its anchors to function when in contact with bone, and intends that surgeons bring the anchor seat into contact with bone; and because surgeons actually bring the anchor seat into contact with bone. Cross Medical asserts that Medtronic is a contributory infringer because it has not proven that there are substantial non-infringing uses.

"[W]hoever without authorization makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor [directly] infringes the patent." 35 U.S.C. § 271(a) (2000). To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents. <u>Advanced Cardiovascular</u>

<u>Sys., Inc. v. SciMed Life Sys., Inc.</u>, 261 F.3d 1329, 1336 (Fed. Cir. 2001). "Literal infringement requires that each and every limitation set forth in a claim appear in an accused product." <u>Franks Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.</u>, 389 F.3d 1370, 1378 (Fed. Cir. 2004) (internal citation omitted). Claim 5 of the '555 patent is an apparatus claim. <u>See</u> '555 patent, col. 8, II. 34-57. We held in Part II.C.2 <u>supra</u> that the "operatively joined" limitation requires that "the interface and the bone segment are connected and in contact such that the device is effective to perform posterior stabilization."

In support of its argument that Medtronic directly infringes, Cross Medical cites evidence that Medtronic's representatives appear in the operating room, identify instruments used by surgeons, and thus in effect "join" the anchor seat to the bone. Cross Medical argues that the situation is analogous to those in which courts have found a party to directly infringe a method claim when a step of the claim is performed at the direction of, but not by, that party. <u>See, e.g.</u>, <u>Shields v. Halliburton Co.</u>, 493 F. Supp. 1376, 1389 (W.D. La. 1980). However, if anyone makes the claimed apparatus, it is the surgeons, who are, as far as we can tell, not agents of Medtronic. Because Medtronic does not itself make an apparatus with the "interface" portion in contact with bone, Medtronic does not directly infringe.

Nor does <u>Intel</u> support a finding of direct infringement. The claim at issue in <u>Intel</u> called for a "programmable selection means" and thus required only that an accused device be capable of operating in the enumerated mode. 946 F.2d at 832; <u>see Fantasy</u> <u>Sports</u>, 287 F.3d at 1117-18; <u>High Tech Med. Instrumentation Inc. v. New Image Indus.</u>, Inc., 49 F.3d 1551, 1555-56 (Fed. Cir. 1995). Here, the claim does not require that the

interface be merely "capable" of contacting bone; the claim has a structural limitation that the anchor seat be in contact with bone. <u>See Fantasy Sports</u>, 287 F.3d at 1117-18 (stressing the "programmable" language of the claim at issue in <u>Intel</u> and holding that <u>Intel</u> "does not stand for the proposition . . . that infringement may be based upon a finding that an accused product is merely capable of being modified in a manner that infringes the claims of a patent"); <u>High Tech</u>, 49 F.3d at 1555-56 (distinguishing <u>Intel</u> based on the permissive language of the claim at issue). Cross Medical would distinguish <u>High Tech</u> by asserting that the device in that case had to be physically altered to become infringing, while Medtronic's device need not be altered. However, Cross Medical again fails to recognize that the limitation—the anchor seat being in contact with bone—is absent until the screw and anchor are put in place during surgery.

Bell Communications and Hilgraeve inapposite. are also In Bell Communications, plaintiff asserted that defendant's product embodied a claimed method, but the district court granted summary judgment of non-infringement reasoning that the product had non-infringing modes of operation. 55 F.3d at 618-19. In Hilgraeve, plaintiff asserted that defendant sold software that, when in operation, infringed plaintiff's method claim, but the district court granted summary judgment of non-infringement based on rationale similar to that in Bell Communications. See Hilgraeve, 265 F.3d at 1339-40. In both cases on appeal, this court held that the district court had erred by overlooking the rule that "an accused product that sometimes, but not always, embodies a claimed method nonetheless infringes." Bell, 55 F.3d at 622-23; accord Hilgraeve, 265 F.3d at 1343 ("[S]o too the sale of a device may induce infringement of a method claim even if the accused device is capable of non-infringing

modes of operation in unusual circumstances."). However, a rule that governs infringement of a method claim may not always govern infringement of an apparatus claim. <u>See, e.g., NTP, Inc. v. Research in Motion, Ltd.</u>, 418 F.3d 1282, 1317-18 (Fed. Cir. 2005) (distinguishing between method claims and apparatus claims for the purpose of determining infringement under section 271(a)). To infringe an apparatus claim, the device must meet all of the structural limitations. <u>See Hewlett-Packard Co. v. Bausch & Lomb, Inc.</u>, 909 F.2d 1464, 1468 (Fed. Cir. 1990) ("[A]pparatus claims cover what a device <u>is</u>, not what a device <u>does</u>."); <u>In re Michlin</u>, 256 F.2d 317, 320 (C.C.P.A. 1958) ("It is well settled that patentability of apparatus claims must depend upon structural limitations and not upon statements of function."). In this case, claim 5 is an apparatus claim which contains the structural limitation that the anchor seat contact bone. Cross Medical has not proven that Medtronic makes an apparatus with an anchor seat in contact with bone.

Cross Medical's reliance on Fantasy Sports is also misplaced. In Fantasy Sports, the apparatus claim called for "[a] computer for playing football." 287 F.3d at 1111. The district court found that the accused "Commissioner.com" product did not infringe because it was a "modifiable software tool," not a computer for playing football. See id. at 1118. We disagreed, holding that Sportsline directly infringed by making or juror could using the apparatus because no reasonable find that the "Commissioner.com" product was not software installed on a computer. See id. at 1118-19. Cross Medical argues that the theory that Medtronic does not directly infringe because it does not itself contact the anchor seat to the bone is as superficial as Sportsline's theory that its product was software but not a computer. However, unlike in

<u>Fantasy Sports</u>, in this case, no reasonable juror could find that the accused infringer itself makes or uses the entire claimed apparatus. The anchor seat of the device does not contact bone until the surgeon implants it.

Because Medtronic is not a direct infringer, we next consider whether Medtronic induces or contributes to infringement. Under § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "In order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement,' and 'second, that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1378 (Fed Cir. 2005) (quoting Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1304-05 (Fed. Cir. 2002)). Under § 271(c), "[w]hoever offers to sell or sells within the United States ... a component of a patented machine, manufacture, combination or composition . . . constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C. § 271(b). In order to succeed on a claim of contributory infringement, in addition to proving an act of direct infringement, plaintiff must show that defendant "knew that the combination for which its components were especially made was both patented and infringing" and that defendant's components have "no substantial non-infringing uses." Golden Blount, Inc. v. Robert H. Peterson Co., 365 F.3d 1054, 1061 (Fed. Cir. 2004) (internal quotations omitted).

As to the predicate act of direct infringement, we conclude that there is a genuine

issue of material fact as to whether surgeons infringe by making the claimed apparatus.

The only evidence that Cross Medical cites suggesting that the anchor seat contacts

bone is the statement of Medtronic's employee, Michael Sherman, during his January

29, 2004 deposition:

Q. How far down do you screw the screw initially?

A. Well, it depends. Because if you screw these screws all the way down, they stop rotating. And the rotating around the ball is a feature of the screw. So you lose some of your ability to rotate, or your freedom.

Because the reason these screws have multiple angles is to make it easier to assemble the system in the patient. So if you screw these things down super-tight, you may have – you know, you've eliminated the multiaxial capability of the screw.

So the surgeon in his judgment gets it down, and I like to tell them, as far as they feel comfortable doing and still have some rotation. Because the further in the instrumentation is into the patient, the lower – the closer the instrumentation is to the loads, and thus the lower the bending moments are on the instrumentation and the less likelihood of metal failure.

Q. In practice, in some instances the screw is screwed down such that the receiver touches the bone; is that right?

A. I'm sure some surgeons do that. And it can touch the bone and still move a little because the bone is elastic. And the tissue right on top of the bone isn't necessarily bone. It's periosteum. It's deformable.

Medtronic counters with an April 22, 2004, declaration from Kevin Foley, M.D., a board

certified neurosurgeon, who has performed over 500 operations using Medtronic's

allegedly infringing products. Dr. Foley states, in pertinent part, that:

[i]n all of the surgeries I perform using Medtronic Products, I try to minimize or avoid contact of any part of the receiver member to the patient's spinal anatomy to ease the eventual implantation of the rod. I do not count on any type of direct connection between the receiver member and the patient's spine to impart any stability to the spine or to the implant construct...

When implanting the Medtronic Products in a patient's spine, any contact between the receiver member and any portion of the patient's anatomy is incidental to the surgery and not intended to impart any stability to the spine. In fact, when I instruct other spine surgeons in how to implant the Medtronic Products, I tell them that if they tighten down on the bone screw enough to bring the receiver member into engagement with the spine, they should back off the bone screw by one-quarter to onehalf turn so as to better enable alignment of the receiver members with the rod.

Thus, Sherman—who is not testifying that he witnessed contact—speculates that some surgeons may bring the receiver member into contact with bone. Dr. Foley confirms that from time to time, "incidental to the surgery," the receiver member comes into contact with bone. However, Dr. Foley also suggests that he "tr[ies] to minimize or avoid contact" and instructs others to "back off the bone screw by one quarter to onehalf turn" "if they tighten down on the bone screw enough to bring the receiver member into engagement with the spine."

On the one hand, drawing inferences in favor of Medtronic, a reasonable juror could conclude that the apparatus is not made because, more likely than not, there is no contact between the receiver member and the bone. On the other hand, drawing inferences in favor of Cross Medical, a reasonable juror could conclude that the apparatus is made by surgeons. Sherman's statements suggest that the device is capable of posterior stabilization when the receiver member contacts bone, and the statements of both Sherman and Dr. Foley suggest that there may be some contact between the receiver member and the spine. We leave it to the fact finder to decide whether surgeons directly infringe.

As to inducement, there is a genuine issue of material fact both as to whether Medtronic "knowingly induced infringement" and as to whether Medtronic "possessed specific intent to encourage [the surgeons'] infringement." On the one hand, in the record are Medtronic's "Field Bulletins" instructing surgeons that the proper technique

for installation of the Medtronic device is with the receiver member not in contact with the bone. Medtronic asserts that these materials, together with Dr. Foley's statement, show that it had no knowledge that the surgeons made the claimed apparatus and that it had no specific intent to encourage infringement. On the other hand, Cross Medical points to Sherman's statements—that he would instruct surgeons to screw the receiver member down "as far as they feel comfortable doing and still have some rotation" and that "[the receiver member] can touch the bone and still move a little because the bone is elastic"-as evidence that Medtronic anticipated that surgeons would contact bone and intended that the device function when in contact with bone. Drawing inferences in favor of Medtronic, a reasonable juror could find that Medtronic did not know that surgeons make the claimed apparatus and, moreover, did not specifically intend for surgeons to contact bone with the anchor seat. Drawing inferences in favor of Cross Medical, a reasonable juror could find that Medtronic designed its device to function when the anchor seat contacted bone, anticipated that surgeons would contact the anchor seat to bone, and thus intended for the surgeon to make or use the apparatus as claimed.

As to contributory infringement, there is a genuine issue of material fact as to whether there are substantial non-infringing uses of Medtronic's devices, specifically, uses of the devices with no receiver member-to-bone contact. Drawing inferences in favor of Medtronic, a reasonable juror could conclude, based on Dr. Foley's statements, that a substantial number of surgeries occur in which the claimed apparatus is not made or used, as surgeons are able to avoid contact between the seat and bone. Drawing inferences in favor of Cross Medical, a reasonable juror might also conclude that in

almost every surgery, the claimed apparatus is made or used, as some contact between the receiver member and the bone is incidental.

Therefore, the district court erred in ruling both that there were no genuine issues of material fact as to infringement and that Medtronic infringed as a matter of law.

2. "securing means"

The district court ruled that Medtronic's "set screw" is equivalent to the external nut as a matter of law because it performs compression in "substantially the same way" to achieve "substantially the same result" as the "external nut." <u>Infringement Opinion</u> at 6. The district court cited testimony that the set screw has opposite points of contact on the rod 180 degrees apart, noted that the screw is intended to be coaxial with the anchor means, and explained that "[a]lthough Plaintiff does not provide tests showing the magnitude of the force on either side, everything before the Court supports the conclusion the forces are substantially equal." <u>Id.</u> at 7. The district court added that "[d]efendants submit[ed] no evidence to show the forces are not equal." <u>Id.</u> The district court reasoned: "[v]iewing the devices themselves and the testimony, it appears Defendants' inner screw meets the limitation applying substantially equal compressive forces on either side of the channel." <u>Id.</u>

Medtronic argues that a set screw is not equivalent to an external nut as a matter of law, citing <u>Chiuminatta Concrete Concepts Inc. v. Cardinal Industries, Inc.</u>, 145 F.3d 1303 (Fed. Cir. 1998). Medtronic notes that the '555 patent's express reference to the use of a set screw to attach a cross-link to the rod, but lack of a reference to a set screw to lock the rod to the anchor seat, is compelling evidence of non-equivalents. In addition, Medtronic asserts that set screws and external nuts are not interchangeable

because set screws apply a "splaying" force to the side walls of the anchor seat while external nuts do not; an external nut applies compressive forces to the rod in a way that bows or bends the rod upwardly in the anchor seat channel while the set screw minimizes this type of load on the rod; and bowing creates a problem in Medtronic's devices. Medtronic adds that Dr. Puno, an inventor of the '555 patent, testified that a set screw and an external nut were not interchangeable. Medtronic portrays as unsupported the views of Dr. Villarraga, Cross Medical's expert, who opined that the set screw and external nut are interchangeable. Medtronic argues that Cross Medical has offered no evidence that the set screw applies "substantially equal compressive forces" to the rod; and asserts that Michael Sherman offered convincing testimony that they do not. Medtronic asserts that at the least, there is a genuine issue of material fact as to whether the set screw is an equivalent.

Cross Medical argues that a set screw and external nut perform the function of compression in substantially the same way—applying a downward force on a rod achieved by engaging threads of the receiver—to achieve the identical result—securing the rod in the channel; and that <u>Chiuminatta</u> is distinguishable. Cross Medical cites evidence that the set screw applies force to opposite sides of the channel. Cross Medical asserts that, because the compression being applied from the set screw to the rod would be through absolutely equal forces applied on either side of the channel absent machining imperfections and patient physiology, if one were to account for these factors, the forces would be substantially equal. Cross Medical argues that "splaying" and "bowing" do not affect equivalents and that Dr. Villarraga's opinion on interchangeability is properly based on her knowledge of mechanical engineering and

her examination of the devices. Cross Medical asserts that Dr. Puno's testimony on interchangeability is irrelevant. Cross Medical argues that Medtronic admitted in U.S. Patent No. 6,660,004 ("the '004 patent") that the set screw and external nut were interchangeable. Cross Medical additionally asserts that because Medtronic argued that a set screw and external nut are equivalent to invalidate claims of another patent, Medtronic is estopped from asserting that they are not equivalent.

"Literal infringement of a § 112, ¶ 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." <u>Frank's Casing</u>, 389 F.3d at 1378 (quoting <u>Odetics</u>, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1267 (Fed. Cir. 1999)). "Because structural equivalents under § 112, ¶ 6 are included within literal infringement of means-plus-function claims, 'the court must compare the accused structure with the disclosed structure, and must find equivalent structure as well as identity of claimed function for the structure." <u>Id.</u> (quoting <u>Pennwalt Corp. v. Durand-Wayland, Inc.</u>, 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc) (emphasis omitted)). "This inquiry for equivalent structure under § 112, ¶ 6 examines whether 'the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result" <u>Id.</u> (quoting <u>Odetics</u>, 185 F.3d at 1267).

At the outset, we conclude that Medtronic is not estopped from challenging interchangeability. In this case, Medtronic argued that a set screw and external nut are functionally equivalent for purposes of invalidating claim 10 of the '237 patent. However, that argument has no bearing on Medtronic's challenge to the interchangeability of a set screw and an external nut with respect to claim 5 of the '555

patent because the functions of the "securing means" in claim 5 of the '555 patent and claim 10 of the '237 patent are different. Claim 10 does not require the application of substantially equal compressive forces to the rod on either side of the channel. <u>See</u> '237 patent, col. 4, II. 42-58, II. 61-63; col. 5, II. 14-22. Because the positions are not entirely inconsistent, judicial estoppel does not apply. <u>See Interactive Gift Express, Inc.</u> <u>v. Compuserve Inc.</u>, 256 F.3d 1323, 1345 (Fed. Cir. 2001) ("[A] party will be judicially estopped from asserting a position on appeal that is directly opposed to a position that the party successfully urged at trial." (internal citations omitted)).

As to the merits, the claimed function has two parts: (1) causing the rod to bear against the channel by applying a compressive force in the direction of the vertical axis; and (2) ensuring that substantially equal forces are applied along the longitudinal axis of the rod on opposite sides—either inside or outside—of the rod-receiving channel. There is no dispute that the set screw applies a compressive force in the direction of the vertical axis. However, there is a genuine issue of material fact as to whether the set screw applies substantially equal forces on opposite sides of the channel, and thus whether there is identity of function.

On the one hand, Cross Medical cites testimony stating that the v-ring on the bottom of the internal set screws creates two points of contact when the set screws are compressed against the rod; that the two points of contact between the set screw and the rod are 180 degrees apart, separated by the drive in the set screw; and that the set screw is intended to be co-axial with the receiver (but because of manufacturing tolerances is not co-axial). (Sherman Dep. of Jan. 29, 2004, at 137-41; Sherman Dep. of Jan. 30, 2004, at 283-84.) On the other hand, Medtronic cites testimony stating that

Sherman did not know if the load on the points of contact on either side of the v-ring were equal; that when the implant is functioning in a patient, the screw takes on additional load from the rod; and that anytime the screw is loaded, load will increase on one side of the plug such that forces on the two sides would be unequal. (Id. at 365-66.) Sherman further testified that he did not know if forces would be equal before the screw and anchor seat were implanted, because manufacturing tolerances might impact the forces. (Id. at 366-67.) Drawing inferences in favor of Medtronic, a reasonable juror could find that the forces are not substantially equal on each side of the channel because of manufacturing tolerances and the additional load placed on the screw by the rod when implanted. Crediting Cross Medical's evidence, a reasonable juror could draw an inference based on Sherman's testimony that the forces applied to the rod on either side of the channel are substantially equal.

Moreover, there is a genuine issue of material fact as to whether the set screw accomplishes the claimed function in substantially the same way as the external nut. Medtronic has cited the testimony of Dr. Puno stating that he considered using a set screw in 1990 to hold the rod in place but decided against the set screw because of splaying concerns. (Puno Dep. of April 9, 2004, at 32, I. 10-36, I. 24.) Dr. Puno stated that having the side walls of the anchor seat spread apart when the screw was tightened down would be "a bad thing" and "could end up loosening the connection on the rod." (Id. at 35, II. 7-14.) Although Dr. Puno testified that he thought a set screw and external nut were interchangeable, he qualified his statement when confronted with prior deposition testimony to the opposite effect. (Id. at 37, I. 3–41, I. 23.) Dr. Villarraga stated that the structures were interchangeable because they both could compress a

rod into a channel, and because other polyaxial devices utilized set screws. (Villarraga Decl. of April 12, 2004, at 2.) However, Dr. Villarraga neither explained with any specificity why one of ordinary skill in the art at the time the '555 patent issued would believe the structures to be interchangeable, nor did she refer to any testing. (See id.) Drawing inferences in favor of Medtronic, a reasonable juror could find that the set screw does not compress the rod in substantially the same way based on Dr. Puno's testimony about the potential for splaying and his conscious decision to avoid the set-screw design. Drawing inferences in favor of Cross Medical, a reasonable juror could find that the set screw does as a compresses the rod in substantially the same way because both employ threads as a compression mechanism, and some statements of Drs. Puno and Villarraga support a finding of interchangeability.

We thus disagree with Medtronic that the equivalents question should be removed from the trier of fact under <u>Chiuminatta</u>. In that case, we held that no reasonable juror could conclude that the differences between "soft round wheels" and a "skid plate" were insubstantial. <u>Chiuminatta</u>, 145 F.3d at 1310. One of the many reasons that we found no equivalents as a matter of law was that the patent at issue discussed the use of wheels for another function, but never disclosed that wheels could perform the same function as the skid plate. <u>Id.</u> In this case, although Medtronic may argue that the fact finder should draw an inference of no interchangeability based on the inventors' explicit reference to set screws to form a cross-link, <u>see</u> '555 patent, col. 6, II. 25-44, and their failure to explicitly recognize set screws as a means for securing the anchor to the bone, we must draw inferences in favor of Cross Medical in evaluating

Medtronic's cross-motion for summary judgment. As discussed <u>supra</u>, we believe that the issue of interchangeability should be left for the trier of fact.

We also reject the other arguments that both sides make in attempting to prevail on equivalents as a matter of law. First, we reject Cross Medical's argument that the '004 patent serves as an admission on interchangeability. Even though the '004 patent, which is assigned to an entity related to Medtronic, suggests that an "internally-threaded nut" is interchangeable with "a set screw or internal plug," '004 patent, col. 8, ll. 10-32, that patent issued in 2003 and is irrelevant to known interchangeability in 1995, when the '555 patent issued. See Al-Site, 174 F.3d at 1320 ("[A] structural equivalent under § 112 must have been available at the time of the issuance of the claim."). Second, we reject Medtronic's contentions that the lack of "bowing" with the set screw and the evidence that the external nut does not function to cause "bowing" in Medtronic's device are relevant to interchangeability. Even if the external nut causes "bowing" in Medtronic's device, it is immaterial to the equivalents analysis because "prevention of bowing" is not a limitation of claim 5. See Micro Chem., 194 F.3d at 1258 (cautioning against adopting a function different from that explicitly recited in the claim). Furthermore, although Medtronic argues that the external nut may not work well in Medtronic's products, any impact this might have on the interchangeability analysis is undercut by a lack of evidentiary support.

In summary, we conclude that there is a genuine issue of material fact with respect to whether a set screw is equivalent to an external nut. Thus, the district court erred in deciding equivalents as a matter of law.

3. "bear against said channel"

Relying on its holding that the channel of the anchor seat could comprise more than one component, the district court ruled that, even if the crown is free-floating and not physically joined to the anchor seat because there is no lock between the crown and the screw, Medtronic's devices met the "bear against said channel" limitation as a matter of law. <u>Infringement Opinion</u> at 7-8. The district court considered evidence that the crown member is physically joined to the anchor seat because it cannot be removed without breaking the screw. <u>Id.</u> The district court analogized the crown in Medtronic's devices to a "pressure disk"—which was physically between the rod and the anchor seat—that the district court previously had held met the "bear against the channel" limitation in <u>Cross Medical Products, Inc. v. DePuy Acromed, Inc.</u>, No. SA CV 00-876-GLT (ANx), (C.D. Cal. Feb. 11, 2002). <u>Infringement Opinion</u> at 7.

Medtronic argues that even if the anchor seat can be comprised of multiple components, as a matter of fact, the crown member in its accused devices is not part of the channel formed by the anchor seat and, thus, the rod does not bear against the channel as recited in the claim. Medtronic asserts that the crown is free floating and not physically or otherwise joined to the receiver; that the crown is either screwed or slid into the receiver; and that the crown is retained either by a snap ring or by interrupting the threads on the receiver after the crown is screwed into the receiver. Medtronic adds that the presence of the crown between the rod and the bone screw causes the receiver member to become rigidly locked to the screw, which serves a different function than a channel absent a crown member.

Cross Medical counters that there is nothing to preclude a finding that the crown is part of the anchor seat. Cross Medical argues that the crown member is part of the channel formed by the anchor seat because the crown is assembled into the device before it is sold, and cannot be removed without damaging the device. Cross Medical asserts that the crown is physically joined to the receiver, and adds that any difference in function is irrelevant because claim 5 has no functional limitation.

There is a genuine issue of material fact as to whether the "bear against [the] channel" limitation is met by the accused products. Sherman testified that in one product, "the crown member is threaded and screws down into the receiver member until it passes the threads of the receiver member and then floats freely until locked down by the rod." (Sherman Decl. of April 23, 2004, at 3.) Sherman stated that in other products, "the crown member is maintained in the receiver member by a snap ring that is designed to allow the crown 'member' to float or move freely within a limited range" before being locked down by the rod. (Id.) Sherman added that the rod touches only the crown member in each of Medtronic's products. (Id. at 3-4.) Viewing this evidence in the light most favorable to Medtronic, a reasonable juror could conclude that the rod bears only against the crown member, which is separate from the channel in the anchor seat, and thus the rod does not "bear against" the channel of the anchor seat.

However, a reasonable juror could also find that the crown member is a part of the channel, and thus that the rod bears against the channel. Cross Medical cites to evidence that the screw, crown, snap ring, and receiver are assembled as one unit before the implant arrives to the surgeon. (Sherman Dep. of Jan. 29, 2004, at 123.) Cross Medical also cites evidence that the snap ring, which holds the crown member

loosely in place, is damaged if the implant is disassembled. (<u>Id.</u> at 247.) And we agree with Cross Medical that the function served by the crown member is irrelevant to finding that this structural limitation is met. <u>See Amstar Corp. v. Envirotech Corp.</u>, 730 F.2d 1476, 1482 (Fed. Cir. 1984) ("[M]odifications by mere <u>addition</u> of elements of function . . . cannot negate infringement").

Because there is a genuine issue of material fact as to whether the "bear against [the] channel" limitation is met, the district court erred in ruling that the accused devices met this limitation as a matter of law.

E. Invalidity

The district court granted Cross Medical's cross-motion for partial summary judgment on all invalidity defenses raised by Medtronic with respect to claim 5 of the '555 patent, including indefiniteness, anticipation, and obviousness. Medtronic appeals each of these rulings.

1. Indefiniteness

As noted in Part II.C.3 <u>supra</u>, Medtronic argued that the district court erroneously interpreted the function of the "securing means" to require that equal forces be applied along the longitudinal axis of the channel on "either side" of the vertical axis. Medtronic asserted that the district court's interpretation would leave "said longitudinal axis" without a sufficient antecedent basis and render claim 5 indefinite. We construed the function of the "securing means" limitation as "to cause the rod to bear against the rod-receiving channel by applying a compressive force in the direction of the vertical axis, while ensuring that substantially equal forces are applied along the longitudinal axis of the rod-receiving channel." We

agreed with Medtronic that the antecedent basis for "said longitudinal axis" was by implication the longitudinal axis of the rod. <u>See Slimfold Mfg. Co. v. Kinkead Indus.</u>, <u>Inc.</u>, 810 F.2d 1113, 1116 (Fed. Cir. 1987) (noting that an antecedent basis can be present by implication). Because the "said longitudinal axis" limitation is not lacking in antecedent basis, we conclude that the district court did not err in granting Cross Medical's motion for summary judgment that claim 5 is not indefinite.

2. Anticipation

The district court held that claim 5 was not anticipated as a matter of law because claim 5 covers only polyaxial screws and the two prior art references asserted to be anticipating—U.S. Patent No. 4,763,644 to Webb ("the '644 patent") and the "Bryd-Transpedicular Spinal Fixator"—disclose only monoaxial screws. <u>Invalidity Opinion</u> at 5. Medtronic's arguments on anticipation turn entirely upon whether claim 5 covers monoaxial screws. Because we determined in Part II.C.1 <u>supra</u> that claim 5 does not cover monoaxial screws, we conclude that the district court did not err in granting Cross Medical's motion for partial summary judgment that claim 5 is not anticipated.

3. Obviousness

In the district court, Medtronic contended that claim 5 was obvious in view of the '602 patent, the '644 patent, and the Byrd device. <u>Invalidity Opinion</u> at 6. The parties agreed that the '602 and '644 patents were prior art, but the district court held that because Dr. Puno, an inventor on the '555 patent, also invented the closure mechanism of the Bryd device, the Bryd device was not prior art. <u>Id.</u> at 6. Focusing on the '602 and '644 patents that the '602 patent and the '555 patent are

both polyaxial spinal implant devices. <u>Id.</u> The district court noted that "[t]he only major difference between the '602 patent and the '555 is the '602 device is tightened from the bottom and the '555 is a top-loading nut," but that "[t]he '644 patent covers a top-loading monoaxial spinal implant device." <u>Id.</u> at 7. However, the district court held that there was no motivation to combine the '602 and '644 references, relying on its prior ruling in <u>Cross Medical Products, Inc. v. DePuy AcroMed, Inc.</u>, No. SA CV 00-876-GLT(ANx) (C.D. Cal. Jan. 9, 2003).

In <u>AcroMed</u>, the defendant had argued that "the top-loading nut would have been obvious in light of the problem to be solved, i.e., surgeons having difficulty tightening the bottom-loading nuts during implantation." <u>Invalidity Opinion</u> at 7. The district court "found AcroMed failed to show motivation to combine because 'the problem was not discovered by looking at the prior art or the patent itself.... It was only discovered when doctors tried to use the product." <u>Id.</u> The court cited <u>In re Sponnoble</u>, 405 F.2d 578, 585 (C.C.P.A. 1969), for the proposition that "a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified." <u>Invalidity Opinion</u> at 7.

The district court found that Medtronic offered no evidence that the problem was disclosed in the prior art. <u>Id.</u> The district court noted that "Defendants cite only the '555 patent to describe the problem the '555 patent sought to fix." <u>Id.</u> The district court explained that "[a]lthough Defendants argue the clinical investigators identified the problem with the bottom-loading nut, the investigators' letters are not prior art." <u>Id.</u> The district court acknowledged that "motivation to combine need not be explicit in the prior art; 'it can be implicit in the knowledge of one of skill in the art," <u>id.</u> (quoting <u>Nat'l Steel</u>

<u>Car, Ltd. v. Canadian Pac. Ry., Ltd.</u>, 357 F.3d 1319, 1337 (Fed. Cir. 2004)), but reasoned that "[t]his rule does not change the result in this case because it does not relate to identification of the problem," <u>id.</u> at 7. The district court then denied Medtronic's motion for summary judgment on obviousness and granted Cross Medical's cross motion. <u>Id.</u> at 7-8.

Medtronic argues that it presented sufficient evidence that the bottom-tighteningnut problem was known to those of ordinary skill in the art and that this provides a motivation to combine the '644 and '602 references. Medtronic cites communications from clinical investigators as evidence of recognition of the problem by those of ordinary skill in the art, and argues that the district court's analysis and adoption of the reasoning in <u>Sponnoble</u> were in error. In addition, Medtronic cites: (a) the '644 patent as evidence that bottom-tightening devices then available were problematic to assemble in situ; (b) U.S. Patent No. 5,261,913 ("the '913 patent") as evidence that it was within the knowledge of one of ordinary skill to use a top-tightening nut; and (c) the '555 patent as evidence that prior art polyaxial screws designed with bottom-tightening nuts were awkward.³ Medtronic argues that even if the '913 patent does not qualify as prior art, it

³ In a footnote in its opening brief, Medtronic asserts that the district court erroneously resolved a fact question as to whether Dr. Puno was an inventor of the Bryd device but never requests relief or provides record cites for its assertions. Medtronic makes no other reference to the Bryd device with respect to obviousness in its opening brief. In its response brief, Medtronic asserts that even if Dr. Puno is a joint inventor of the Bryd device, there is a different set of joint inventors on the Bryd device—Drs. Puno and Bryd—than on the '555 patent—Dr. Puno and Mellinger. Medtronic argues that the two sets of inventors are separate legal entities under In re Kaplan, 789 F.2d 1574, 1575 (Fed. Cir. 1986), and that the Bryd device may be prior art under §§ 102(f) and 103. Medtronic adds that even if the Bryd device is confidential, it evidences knowledge of those of ordinary skill.

Medtronic has not properly raised the inventorship issue in its opening brief to warrant relief from this court. See Fuji Photo Film Co. v. Jazz Photo Corp., 394 F.3d

evidences knowledge of one of ordinary skill in the art. Medtronic asserts that, at the least, this evidence is enough to create a genuine issue of material fact on motivation to combine.

Cross Medical counters that Dr. Puno was one of the clinical investigators who recognized the problem with the '602 device, that Dr. Puno discovered the problem as part of his inventive process, and thus that the clinical investigators' recognition of the problem is not evidence of a motivation to combine. Cross Medical argues that the '644 patent does not itself provide reason to apply its teachings to modify the '602 device because it discusses prior art assembly problems related to use of a locking nut and threaded rod to hold the screw. Cross Medical argues that the '602 device did not use a threaded rod with a locking nut, and thus the inventors did not confront the same problem as confronted by the inventors of the '644 device. Cross Medical asserts that the '913 patent cannot evidence knowledge of ordinary skill in the art at the time of the invention because the application that matured into the '913 patent was filed two months after the invention date of the '555 patent, and that application was not published for 18 months. Cross Medical cites differences between the '602 and '555 patents in addition to the bottom-tightening nut, and asserts that Medtronic submitted no evidence explaining how the particular structural elements of the '602 device could be modified to achieve the structure disclosed in claim 5 as a whole. Cross Medical argues that Medtronic failed to discuss "trade-offs" to the use of the top-tightening device, and neglected to discuss secondary considerations.

^{1368, 1375} n.4 (Fed. Cir. 2005) (holding that this court will not address arguments that are not properly raised in the opening brief). Nor will this court consider Medtronic's new arguments raised for the first time in its reply brief. <u>Id.</u>

"A claimed invention is unpatentable if the differences between it 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." In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000); see 35 U.S.C. § 103. An invention may be a combination of old elements disclosed in multiple prior art references. Kotzab, 217 F.3d at 1369. In determining whether a combination of old elements is non-obvious, the court must assess whether, in fact, an artisan of ordinary skill in the art at the time of invention, with no knowledge of the claimed invention, would have some motivation to combine the teachings of one reference with the teachings of another reference. See In re Fulton, 391 F.3d 1195, 1200-02 (Fed. Cir. 2004). Motivation to combine references "may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved." Kotzab, 217 F.3d at 1370. "The test for an implicit teaching is what the combined references, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." Id.

The sole issue before us is whether the district court erred in ruling that there is no genuine issue of material fact as to whether the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time of the invention based on the absence of any evidence of a motivation to combine the '602 and '644 references. We conclude that a genuine issue of material fact exists with respect to motivation to combine. Cross Medical designated the screw disclosed in the '602 patent as the "PWB I" and performed a pilot study testing its use in humans. A paper, entitled "The Puno-Winter-Bird (PWB) Spinal System for Transpedicular Fixation of the Lumbar Spine,"

recounted that surgeons participating in the pilot study found the implant design "tedious," and that it was "technically difficult to position the wrench when the nut was tightened, since it required that the nut be advanced from under the rod." The paper explained that "[a]lthough [the PWB I] provided satisfactory fixation of the rod, the design was not 'user friendly." The paper noted that "[a] design improvement was in order and led to the development of the PWB II." Other evidence in the record confirms that surgeons in the pilot study recognized the problem and requested changes. The surgeons who participated in the pilot included investigators other than inventors of the '555 patent.

From this evidence, a reasonable juror could conclude that at the time of the invention, one of ordinary skill in the art could have been motivated to modify the PWB I in light of the problem to be solved. Giving credit to Medtronic's evidence, the clinical investigators recognized the bottom-tightening problem with the '602 device and proposed changes. The problem was within the general knowledge of those of ordinary skill in the art, and thus provided sufficient motivation to navigate the prior art in the spinal implant field in search of a teaching on how one might modify the '602 device away from a bottom-tightening assembly.

The district court erred in discounting the clinical investigators' recognition of the problem. "It has long been the law that the motivation to combine need not be found in prior art references, but equally can be found 'in the knowledge generally available to one of ordinary skill in the art." <u>Nat'l Steel</u>, 357 F.3d at 1337 (quoting <u>In re Jones</u>, 958 F.2d 347, 351 (Fed. Cir. 1992)). Evidence of a motivation to combine references need not be in the form of prior art. <u>See id.</u> at 1338-39. Evidence that a person of ordinary

skill in the art recognized the same problem to be solved as the inventor and suggested a solution is, at the least, probative of a person of ordinary skill in the art's willingness to search the prior art in the same field for a suggestion on how to solve that problem. See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573 (Fed. Cir. 1996) (Motivation to combine "may also come from the nature of a problem to be solved, leading inventors to look to references relating to possible solutions to that problem." (citing Application of Rinehart, 531 F.2d 1048, 1054 (C.C.P.A. 1976))); In re Huang, 100 F.3d 135, 139 n.5 (Fed Cir. 1996) (stating that problem well-known to a person of ordinary skill in the art would have directed that person of ordinary skill to the reference teaching the missing elements); see also, e.g., In re Gartside, 203 F.3d 1305, 1320-21 (Fed. Cir. 2000) (recognizing that motivation to combine can come from the nature of the problem to be solved); In re Rouffet, 149 F.3d 1350, 1355 (Fed. Cir. 1998) (same). To the extent that the district court determined that the only investigators who recognized the problem of the bottom-tightening assembly were inventors on the '555 patent, that conclusion has no basis in the record.

Furthermore, the district court's reliance on <u>Sponnoble</u> is misplaced. In that case, those of ordinary skill in the art of packaging pharmaceutical products recognized a moisture-transfer problem with "structure[s] for temporarily isolating a compartment containing a solid pharmaceutical product from a compartment containing an aqueous solution." <u>Sponnoble</u>, 405 F.2d at 585. The industry believed that moisture was transmitted <u>around</u> the plug separating the two compartments. <u>Id.</u> at 586. Sponnoble discovered that moisture traveled <u>through</u> the plug and remedied that problem with a solution available in the prior art. <u>Id.</u> Our predecessor court held that the invention was

non-obvious because one of ordinary skill in the art would not have chosen the solution without recognizing the true cause of the problem, and "the cause of the problem [was] not suggested by the prior art." <u>Id.</u> In this case, however, the problem was known to the clinical investigators at the time of the invention, and thus, unlike <u>Sponnoble</u>, the problem was within the general knowledge of one of ordinary skill in the art. <u>See Nat'l Steel</u>, 357 F.3d at 1338 ("Something that has already been rendered obvious to a newcomer in the field is probative of what would be obvious to someone who has been around for a longer period of time."). If the problem is within the knowledge of one of ordinary skill in the art, then it is irrelevant that the prior art does not disclose the problem. <u>See id.</u> at 1337-39.

Moreover, we conclude—after drawing inferences in favor of Medtronic—that the '644 patent itself may have provided sufficient motivation for one of ordinary skill to have considered its teachings and altered the '602 device. The '644 invention was an improvement over prior art spinal implant devices which used a threaded rod with locking nuts. In characterizing the prior art, the patent states that "[t]he need to thread the nut along the rod results in the device being rather slow to assemble and can result in damage to soft tissue if carried out in situ." '644 patent, col. 2, II. 10-12. The solution was, in part, a top-tightening nut. <u>See id.</u>, col. 3, II. 16-23; <u>id.</u>, Figure 2. Thus, the '644 patent discusses a problem posed by the assembly of certain spinal stabilization devices in situ and a solution. Confronted with the implantation problem of the '602 device, one of ordinary skill might have found the problem solved by the '644 patent sufficiently analogous to have been motivated to apply its teachings. In turn, we reject Cross Medical's contention that the '644 device cannot provide the requisite motivation

because the problem it addressed may have differed slightly from the problem encountered by surgeons using the '602 device. One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings. <u>See In re Oetiker</u>, 977 F.2d 1443, 1448 (Fed. Cir. 1992) (Nies, C.J., concurring) ("Such suggestion or motivation to combine prior art teachings can derive solely from the existence of a teaching, which one of ordinary skill in the art would be presumed to know, and the use of that teaching to solve <u>the same or similar problem</u> which it addresses." (citing <u>In re Wood</u>, 599 F.2d 1032, 1037 (C.C.P.A. 1979)) (emphasis added)); <u>cf. In re Dillon</u>, 919 F.2d 688, 694 (Fed. Cir. 1990) (en banc) (""[A reference is not from a non-analogous art if] the reference is reasonably pertinent to the particular problem with which the inventor was involved."" (quoting <u>In re Deminski</u>, 796 F.2d 436, 442 (Fed. Cir. 1986) (quoting in turn from <u>Wood</u>, 599 F.2d at 1036))).

As to the other evidence cited by Medtronic, the '555 patent suggests that the inventor recognized the problem of bottom-tightening. However, the patent does not provide evidence that the problem was within the knowledge of those of ordinary skill in the art at the time of the invention; or that the problem was disclosed in the prior art. The '913 patent is also of limited relevance because it issued after the invention date. <u>See Mahurkar v. C.R. Bard, Inc.</u>, 79 F.3d 1572, 1576-77 (Fed. Cir. 1996).

Thus, we conclude that, because there are genuine issues of material fact on the underlying facts related to obviousness, the grant of summary judgment was in error.

III. CONCLUSION

We conclude that we have jurisdiction over this appeal. We affirm the district court's construction of the "anchoring means," "securing means," and "bear against said

channel" limitations, but modify the district court's construction of the "operatively joined" and the "anchor seat means" limitations. Because we find genuine issues of material fact regarding infringement, we reverse the grant of Cross Medical's motion for partial summary judgment of infringement and find no abuse of discretion in the denial of Medtronic's cross-motion for partial summary judgment of non-infringement. We also reverse the grant of Cross Medical's motion for partial summary judgment that claim 5 is not obvious but affirm the grant of that motion as to indefiniteness and anticipation. We further conclude that the district court did not abuse its discretion in denying Medtronic's cross-motion for summary judgment as to these invalidity issues. As a result, we vacate the permanent injunction. We remand for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED.

COSTS

Costs to Medtronic.