United States Court of Appeals for the Federal Circuit

2007-1297, -1343

JAN K. VODA, M.D.,

Plaintiff-Cross Appellant,

v.

CORDIS CORPORATION,

Defendant-Appellant.

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Appealed from: United States District Court for the Western District of Oklahoma

Senior Judge Tim Leonard

United States Court of Appeals for the Federal Circuit

2007-1297, -1343

JAN K. VODA, M.D.,

Plaintiff-Cross Appellant,

v.

CORDIS CORPORATION,

Defendant-Appellant.

Appeals from the United States District Court for the Western District of Oklahoma in case no. 03-CV-1512, Senior Judge Tim Leonard.

DECIDED: August 18, 2008

Before MAYER, BRYSON, and GAJARSA, Circuit Judges.

GAJARSA, Circuit Judge.

This is a patent infringement case involving catheters used in interventional cardiology. The issues on appeal and cross-appeal include claim construction, patent validity, infringement, willfulness, and the district court's denial of a permanent injunction. Because we find no reversible error in the decision below with respect to the issues of claim construction, patent validity, and the denial of a permanent injunction, we affirm those aspects of the judgment. The judgment of infringement, however, is affirmed-in-part and reversed-in-part. Lastly, because the willfulness finding was based on a jury instruction that is erroneous under our intervening decision in In re Seagate

Technology, LLC, 497 F.3d 1360 (Fed. Cir. 2007) (en banc), we vacate the judgment with respect to willfulness and remand for reconsideration under the Seagate standard.

PROCEDURAL HISTORY

Dr. Jan K. Voda, M.D., ("Voda") sued Cordis Corporation ("Cordis") for infringement of U.S. Patent Nos. 5,445,625 ("the '625 patent"), 6,083,213 ("the '213 patent"), and 6,475,195 ("the '195 patent") in the United States District Court for the Western District of Oklahoma.[1] Specifically, Voda alleged that Cordis's "XB" catheters infringe claim 1 of the '625 patent, claims 1 through 5 of the '213 patent, and claims 1 through 6 of the '195 patent. The parties tried the case to a jury, and it returned a verdict finding that Cordis willfully infringed all asserted claims of the patents-in-suit and that claims 1 through 3 of the '213 patent are not invalid. The jury also determined that Voda was entitled to a reasonable royalty of 7.5% of Cordis's gross sales of the infringing XB catheters. Following the jury verdict, the district court denied Cordis's motion for judgment as a matter of law ("JMOL") that claims 1 through 3 of the '213 patent are invalid and that Cordis's XB catheters do not infringe any of the asserted claims of the patents-in-suit. The district court also granted Voda's motion for enhanced damages and attorneys' fees but denied Voda's request for a permanent injunction.

On appeal, Cordis challenges the district court's construction of the term "along a line" in claims 1 through 3 of the '213 patent. Cordis also challenges the district court's denial of JMOL that claims 1 through 3 of the '213 patent are invalid and that Cordis's XB catheters do not infringe any of the asserted claims of the patents-in-suit. Finally,

[1] This is the second time that this case has been before the court. The first appeal involved a procedural matter. See Voda v. Cordis Corp., 476 F.3d 887 (Fed. Cir. 2007).

Cordis argues that the finding of willfulness should be vacated on the ground that the jury instruction on willfulness was erroneous under our recent Seagate decision. On cross-appeal, Voda argues that the district court abused its discretion in denying Voda's request for a permanent injunction. Voda also argues that the district court erred in construing the "substantially straight leg" limitation in claims 4 and 5 of the '213 patent and claims 1 through 6 of the '195 patent.

This court has jurisdiction over this appeal and cross-appeal pursuant to 28 U.S.C. § 1295(a)(1).

BACKGROUND

Cardiac guide catheters have been used to diagnose and treat heart disease since the late 1960s. A cardiac guide catheter is a long thin plastic tube with a preformed tip that comes in a variety of sizes and configurations. The method of using a cardiac guide catheter involves first inserting a wire into the catheter to straighten the preformed tip. Once the wire is inside the catheter, the catheter is inserted into the femoral artery and advanced to the aorta of the heart. The catheter is further advanced up the descending aorta, over the aortic arch, and down the ascending aorta until the tip of the catheter reaches a position at or near the opening (i.e., "ostium") of the coronary artery. The wire is then removed from the catheter, which allows the tip of the catheter to return to its preformed shape. As the catheter tip returns to its shape, it moves into the desired position: specifically, the tip of the catheter is inserted into the coronary ostium while another portion of the catheter rests against the opposing wall of the aorta to provide support. Hereinafter, the portion of a guide catheter that rests against the opposing wall of the aorta is referred to as the "contact portion" of the guide catheter.

1. Voda's Patents

The three patents-in-suit are all directed to an "advantageous orientation of the guide catheter in the aortic complex." '625 patent col.8 ll.51-52; '213 patent col.8 ll.21-22; '195 patent col.8 ll.25-26. All three patents issued from continuation-in-part applications of a common parent application, namely, U.S. Patent App. No. 07/622,873.

The '625 patent claims guide catheters with "a significant change in the overall shape/configuration" of the catheter in order to "maximize backup support for distal advancement of a balloon catheter through the guide catheter." '625 patent col.7 ll.60-67. Claim 1 of the '625 patent reads as follows:

> 1. A femoral approach angioplasty guide catheter adapted for selective catheterization of a left main coronary artery within a cardiovascular system comprising:
>
> an elongate flexible tubular member in a relaxed state prior to insertion in the cardiovascular system further comprising in consecutive arrangement:
>
> a first straight proximal portion extending distally from a proximal end of the tubular member;
>
> a second straight portion joined to the first straight portion and having a length of about 1.5 to 2.5 centimeters;
>
> a tertiary curved portion defining a junction of the first straight portion and the second straight portion and defining a vertex of an obtuse angle of 130° to 150° between the first and second straight portions;
>
> a secondary curved portion joined to the second straight portion and having an arcuate curvature of about 150° to 180° and a radius of curvature of about 1 centimeter;
>
> a third straight portion joined to the secondary curved portion;
>
> a fourth straight portion joined to the third straight portion and having a distal end defining a terminal distal tip of the tubular member; and
>
> a primary curved portion a junction of the third straight portion and the fourth straight portion and defining a vertex of an obtuse angle of 140° to 160° between the third and fourth straight portions,
>
> wherein the interiors of the tertiary curved portion and every curve portion distal thereof, including the secondary curved portion and the primary curved portion, all generally face each other,
>
> wherein the first straight portion, second straight portion, third straight portion, and fourth straight portion all lie in generally the same

> plane, the third straight portion and the fourth straight portion extending slightly out of plane to the extent that the fourth straight portion overlaps the first straight portion, and
>
> wherein the length of the fourth straight portion is approximately equal to the sum of the length of the third straight portion and the radius of curvature of the secondary curved portion.

'625 patent cols.32-33 (emphasis added). In the written description of the '625 patent, the "second straight portion" is identified as the portion of the catheter that engages the wall of the aorta opposite the coronary ostium during use (along with a proximal portion of the secondary curve portion). Id. at col.9 l.50-col.10 l.4. The engagement of the second straight portion with the wall of the aorta is described as providing "a large area of general backup support . . . which makes it quite difficult to dislodge the guide catheter from its desired orientation" during use. Id. Cordis argues that its XB catheters do not infringe claim 1 of the '625 patent because they do not meet the "second straight portion" limitation. For discussion purposes, this opinion will refer to claim 1 of the '625 patent as the "straight claim."

Claims 1 through 3 of the '213 patent are method claims. Claim 1 is representative:

> 1. A method for advancing a catheter through the aorta and into a coronary ostium, the aorta having an arch and an inner wall opposite the ostium, comprising the steps of:
>
> providing a catheter including an elongate catheter body having a proximal end and a distal end and having a central lumen from the proximal end to the distal end adapted to slidably receive a therapeutic catheter, the catheter body including a tip at the distal end of the catheter body adapted to removably lodge in the coronary artery ostium;
>
> advancing the catheter body distal end through the aortic arch; and
>
> engaging the aorta inner wall with a portion of the catheter body such that when the distal end of the catheter is positioned in the ostium, the catheter body engages the opposite wall of the aorta along a line having a length of about 1.5 cm or greater.

’213 patent col.30 ll.49-67 (emphasis added). With respect to claims 1 through 3 of the ’213 patent, Cordis argues (1) that the district court misconstrued “along a line”; (2) that Cordis does not infringe claims 1 through 3 under a proper construction of “along a line”; and (3) that under the district court’s construction of “along a line,” claims 1 through 3 of the ’213 patent are invalid for obviousness or anticipation.

The ’195 patent includes both apparatus and method claims. For purposes of this discussion, claim 1 is representative of both the method and apparatus claims:

> 1. An assembly for guiding the path of a therapeutic catheter, comprising:
>
> an elongate tubular member including a proximal shaft portion, a profiled portion, and a substantially straight tip portion;
>
> the profiled portion comprising, in order from the proximal shaft portion to the tip portion, a first bend, a first substantially straight leg, a second bend, a second substantially straight leg, and a third bend;
>
> the first bend, the first substantially straight leg, the second bend, the second substantially straight leg, and the third bend being disposed within a chamber of an aorta;
>
> a distal end of the tip portion being disposed within an ostium defined by the aorta;
>
> the first substantially straight leg seating against a wall of the aorta opposite the ostium of the coronary artery; and
>
> the elongate tubular member defining a lumen extending from a distal end of the elongate tubular member to a proximal end of the elongate tubular member, wherein the lumen is constructed and arranged to receive the therapeutic catheter.

’195 patent cols.28-29 (emphases added). Here, the “first substantially straight leg” corresponds to the “second straight portion” of the ’625 patent (as well as the “second straight portion” of the ’195 patent’s written description). Cordis argues that its XB catheters do not infringe the ’195 patent because the XB catheters do not meet the “first substantially straight leg” limitation, which appears in all the claims of the ’195 patent. In addition, as with the claims of the ’195 patent, claims 4 and 5 of the ’213 patent contain a “first substantially straight leg” limitation. Thus, Cordis also argues that its XB

catheters do not infringe claims 4 and 5 of the ’213 patent for failure to meet the “first substantially straight leg” limitation. For the sake of discussion, this opinion will refer to all claims of the ’195 patent and claims 4 and 5 of the ’213 patent as the “substantially straight claims.”

2. Cordis’s XB Catheter

The accused product in this case is Cordis’s XB catheter. The original version of Cordis’s XB catheter, which was made and sold prior to the issuance of Voda’s patents, included a “second straight portion” as claimed in the ’625 patent. However, before the Voda patents issued, Cordis redesigned its XB catheter by replacing the second straight portion with a curved portion. For discussion purposes, this opinion will refer to this curved portion as the “redesigned curve portion.” The only aspects of the infringement judgment that Cordis challenges are whether the redesigned curve portion of the XB catheter meets the “along a line” limitation of claims 1 through 3 of the ’213 patent under a proper claim construction and whether it meets the straight and substantially straight limitations of the ’625, ’213, and ’195 patents under the doctrine of equivalents.

DISCUSSION

1. Standards of Review

Claim construction is a question of law that is reviewed de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc); Markman v. Westview Instruments, Inc., 52 F.3d 967, 981 (Fed. Cir. 1995) (en banc).

This court reviews the denial of a motion for JMOL or a new trial under the law of the regional circuit where the district court sits—here, the Tenth Circuit. Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1328 (Fed. Cir. 2008). The Tenth Circuit reviews a

denial of a motion for JMOL de novo, applying the same legal standard as the district court. Equal Employment Opportunity Comm'n v. Heartway Corp., 466 F.3d 1156, 1160 (10th Cir. 2006). JMOL is appropriate when "a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1); Century 21 Real Estate Corp. v. Meraj Int'l Inv. Corp., 315 F.3d 1271, 1278 (10th Cir. 2003). The Tenth Circuit has explained that "[w]hen a jury verdict is challenged on appeal, our review is limited to determining whether the record—viewed in the light most favorable to the prevailing party—contains substantial evidence to support the jury's decision." United Int'l Holdings, Inc. v. Wharf (Holdings) Ltd., 210 F.3d 1207, 1227 (10th Cir. 2000) (quotation omitted); see also Dawn Equip. Co. v. Ky. Farms, Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998) ("In reviewing factual issues for substantial evidence, the inquiry is whether a reasonable jury, given the record before it viewed as a whole, could have arrived at the conclusion it did."). In addition, the Tenth Circuit reviews a denial of a motion for a new trial for abuse of discretion. United States v. Lamy, 521 F.3d 1257, 1265-66 (10th Cir. 2008).

Finally, this court reviews a denial of a permanent injunction in a patent case for abuse of discretion, applying Federal Circuit law. Int'l Rectifier Corp. v. Samsung Elecs. Co., 361 F.3d 1355, 1359 (Fed. Cir. 2004). "An abuse of discretion may be established under Federal Circuit law by showing that the court made a clear error of judgment in weighing the relevant factors or exercised its discretion based on an error of law or clearly erroneous fact finding." Id.

2. Claim Construction of the ’213 Patent

Claim terms must be given “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). That meaning is determined by reference to several sources, including “‘the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.’” Id. at 1314 (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004)). This court has further explained that “Phillips teaches that these sources should be accorded relative weights depending on the circumstances of the case, with intrinsic sources being the most relevant.” Microprocessor Enhancement Corp. v. Tex. Instruments Inc., 520 F.3d 1367, 1378 (Fed. Cir. 2008) (citing Phillips, 415 F.3d at 1314-19).

Here, Cordis challenges the district court’s construction of “along a line” in claims 1 through 3 of the ’213 patent. The district court construed “along a line” as:

> Contacting the aorta inner wall with a portion of the tube body such that when the end of the catheter lodges within the opening in the coronary artery, an about 1.5 cm or greater length of the tube body bears upon the wall of the aorta opposite the opening.

Voda v. Cordis Corp., No. 03-CV-1512 (W.D. Okla. Sept. 15, 2005) (Claim Construction Order). Cordis argues that the district court’s construction of “along a line” is erroneous because it does not require “that a straight portion of the catheter engage the wall of the aorta.” Appellant Br. at 34-39. Cordis further argues that the claims, the specification, and the prosecution history of the ’213 patent support its proposed construction of

"along a line." We disagree. The following discussion will address each of Cordis's arguments in turn.

a. The Words of the Claims Themselves

Cordis argues that the use of the words "along a line" in claim 1 of the '213 patent requires the contact portion of the catheter to be straight in its rest state because "'straight' is inherent in the word 'line.'" However, Cordis's argument ignores the context in which the phrase "along a line" is used in claim 1. See Phillips, 415 F.3d at 1314 ("[T]he context in which a term is used in the asserted claim can be highly instructive."). As the district court observed, Cordis's argument fails to recognize that claim 1 refers to the position of the catheter as it is being used in the human body rather than the shape of the catheter in its rest state. Because "along a line" describes the contact portion of the catheter in its engaged state, claim 1 does not inherently require the contact portion of the catheter to be straight in its rest state.

In addition, Cordis concedes that "claim 1 does not expressly recite a 'straight portion.'" Appellant Reply Br. at 6. By contrast, claims 4 and 5 of the '213 patent specifically require that the contact portion of the catheter be a "substantially straight leg" in its rest state. '213 patent col.32 ll.1-2. Therefore, the fact that claim 1—and dependent claims 2 and 3—does not expressly recite a "straight" or "substantially straight" portion strongly implies that claims 1 through 3 do not require the contact portion of the catheter to be straight in its rest state. See Phillips, 415 F.3d at 1314 ("Differences among claims can also be a useful guide in understanding the meaning of particular claim terms."); see also Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438

F.3d 1374, 1380-81 (Fed. Cir. 2006) (discussing the doctrine of claim differentiation as applied to independent claims).

In sum, the use of the words "along a line" in claims 1 through 3 does not, by itself, limit the claimed methods to those in which the contact portion of the catheter is straight in its rest state.

b. The Specification

Although the use of "along a line" does not by itself support Cordis's construction, the words of the claims "must be read in view of the specification, of which they are a part." Phillips, 415 F.3d at 1315 (quotation omitted). Indeed, "the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." Id. at 1316. However, any such disclaimer "must be clear." Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1357 (Fed. Cir. 2006); see also Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002) ("The patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.") However, this court has cautioned against importing limitations from the specification into the claims. Phillips, 415 F.3d at 1323. Moreover, this court has recognized that "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice." Id.; see also Comark Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed. Cir. 1998).

Here, Cordis argues that the '213 patent's written description limits the scope of claims 1 through 3 to methods in which the contact portion of the catheter is straight in

its rest state. To support its argument, Cordis cites to portions of the written description that describe the contact portion "of the catheter of the present invention" as a "straight portion." Appellant Br. at 34-35 (citing '213 patent cols.9-10). Cordis also states that "nowhere does the patent suggest that the claimed invention can only use a curved portion to engage the wall." Id. at 34.

We do not agree with Cordis that the written description provides "a clear disavowal of claim scope," Teleflex, 299 F.3d at 1325. Although the written description often discusses "providing a straight portion . . . that contacts the aortic wall," e.g. '213 patent col.7 ll.55-58 (emphasis added), the specification also discusses the contact portion without requiring that it be straight in its rest state. For example, the specification provides that:

> The primary feature of the superior (i.e., better) orientation of the guide catheters of the present invention is that, when disposed in the aortic complex, a contact portion of the guide catheter is established in a substantially contiguous manner against the aortic wall for a substantial length (at least about 1.5 centimeters).

'213 patent col.8 ll.53-58 (emphasis added). Other portions of the written description also discuss the contact portion without requiring that it be straight in its rest state. See, e.g., '213 patent col.7 ll.49-52 ("The factors determining the support provided by the guide catheter include . . . a large supportive segment of the guide catheter that rests against the wall of the ascending aorta to increase stability of the guide catheter within the aortic complex." (emphasis added)); '213 patent col.8 ll.6-12 ("The guide catheter has a distal end portion such that with the distal tip of the distal end portion . . . fully disposed within the cardiovascular system[], a portion of the distal end portion contacts

and rests against and is substantially contiguous with a wall of the ascending aorta . . . ." (emphasis added)).

Accordingly, the written description of the '213 patent does not clearly limit the scope of claims 1 through 3 to methods in which the contact portion of the catheter is straight in its rest state.

c. The Prosecution History

In construing patent claims, a court may consult the patent's prosecution history, if it is in evidence. Phillips, 415 F.3d at 1317. The prosecution history can assist the court in understanding how an inventor understood and described his invention and whether the inventor disclaimed or disavowed certain subject matter from the scope of his claims. Id. This court has emphasized, however, that in order to disavow claim scope during prosecution "a patent applicant must clearly and unambiguously express surrender of subject matter." Sorensen v. Int'l Trade Comm'n, 427 F.3d 1375, 1378-79 (Fed. Cir. 2005); see also Omega Eng'g, Inc., v. Raytek Corp., 334 F.3d 1314, 1325-26 (Fed. Cir. 2003) ("[F]or prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.").

In this case, claim 1 of the '213 patent was amended during prosecution to overcome a rejection under 35 U.S.C. § 102 for anticipation by U.S. Patent No. 5,163,921 ("the Feiring reference"), U.S. Patent No. 5,299,574 ("the Bower reference"), and U.S. Patent No. 4,822,345 ("the Danforth reference"). The amendment changed the third step of the method of claim 1 as follows:

> engaging the aorta inner wall with a portion of the catheter body such that when the distal end of the catheter is positioned in the ostium, the catheter

> body engages the opposite wall of the aorta along a line [wherein the line is proximate of the ostium of the coronary artery] having a length of about 1.5 cm or greater.

Amdt. to U.S. Patent App. No. 08/854,996 at *2 (Filed May 13, 1997) (deletion bracketed; insertion underlined). In the remarks accompanying this amendment, the applicant stated:

> Applicant respectfully submits that his invention, unlike the catheters disclosed by Feiring, Bower and Danforth engages the wall of the aorta, opposite the distal end of the catheter when the distal end of the catheter is positioned in the ostium, along a line having a length of about 1.5 cm or greater. Each of the catheters disclosed by Feiring, Bower and Danforth engage the ascending aorta at a bend or curve along the catheter. None provide support along a line of about 1.5 cm or greater.

Id. at *3.

Cordis argues that the amendment to claims 1 through 3 and the accompanying remarks demonstrate Voda's intent to limit the claimed methods to those in which the contact portion of the catheter is straight in its rest state. We disagree. Although Voda's amendment specifically limited his claims to methods where the catheter engages the wall of the aorta for "a length of about 1.5 cm or greater," the amendment makes no reference to the shape of the contact portion of the catheter in its rest state. Id. at *2. The remarks accompanying this amendment also make no reference to the shape of the contact portion of the catheter in its rest state. Rather, the remarks distinguish the prior art catheters based on the shape and length of the contact portion of the catheter during use. For instance, Voda explained that his claimed methods were "unlike" the Feiring, Bower, and Danforth methods because the claimed methods require "engage[ing] the wall of the aorta, opposite the . . . ostium, along a line having a

length of about 1.5 cm or greater." Id. In addition, Voda states that "[n]one [of the prior art methods] provide support along a line of about 1.5 cm or greater." Id.

Accordingly, we read the amendment and the accompanying remarks to distinguish the prior art based on the length of the engagement with the ascending aorta during use, rather than the shape of the contact portion of the catheter in its rest state. The '213 patent's prosecution history thus does not clearly and unmistakably limit the scope of claims 1 through 3 to methods in which the contact portion of the catheter is straight in its rest state.

* * *

In sum, we affirm the district court's construction of "along a line" with respect to claims 1 through 3 of the '213 patent. In addition, because Cordis has waived any argument that its XB catheters do not infringe claims 1 through 3 of the '213 patent under the district court's claim construction, we affirm the judgment of infringement with respect to these claims.

3. Validity of Claims 1 through 3 of the '213 Patent

Patents are presumed to be valid. 35 U.S.C. § 282. A party challenging the validity of a patent bears the burden of proving invalidity by clear and convincing evidence. Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1359 (Fed. Cir. 2007).

Cordis argues that under the district court's construction of "along a line," claims 1 through 3 of the '213 patent are invalid for anticipation under 35 U.S.C. § 102 or invalid for obviousness under 35 U.S.C. § 103. Specifically, Cordis argues that, under the district court's claim construction, claims 1 through 3 are anticipated by the "Amplatz

references"[2] and are anticipated or obvious in view of the "Bourassa reference."[3] Despite Cordis's arguments, we find that a reasonable jury could conclude that claims 1 through 3 are not invalid based upon the evidence adduced at trial. Accordingly, we affirm the finding that claims 1 through 3 are not invalid.

a. Anticipation

Anticipation is a question of fact that is reviewed for substantial evidence when tried to a jury. Finisar, 523 F.3d at 1334. "Anticipation requires disclosure of each and every claim limitation in a single prior art reference, either explicitly or inherently." In re Omeprazole Patent Litig., 483 F.3d 1364, 1371 (Fed. Cir. 2007).

Here, the parties only dispute whether a reasonable jury could have found that neither the Amplatz nor the Bourassa references disclose the third limitation of claims 1 through 3 of the '213 patent. The third limitation of representative claim 1 requires "engaging the aorta inner wall with a portion of the catheter body such that when the distal end of the catheter is positioned in the ostium, the catheter body engages the opposite wall of the aorta along a line having a length of about 1.5 cm or greater." '213 patent col.30 ll.63-67.

In arguing for anticipation by the Amplatz references, Cordis notes Voda's concession that "in one of the working positions of the Amplatz catheter . . . a significant

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[2] The Amplatz references are: Kurt Amplatz et al., Mechanics of Selective Coronary Artery Catheterization via Femoral Approach, 89 Radiology 1040 (1967); United States Catheter and Instrument Co., PTCA in Perspective, USCI Technical Perspective 23-42 (1986); and United States Catheter and Instrument Co., USCI Positrol II® and Nycore™ Cardiovascular Catheters . . . A Discernible Difference, Brochure 1-20 (1990).

[3] The Bourassa reference is: Martial G. Bourassa et al., Selective Coronary Arteriography by the Percutaneous Femoral Artery Approach, 107 American Journal of Roentgenology 377 (1969).

segment is leaning on the opposite side of the aorta." J.A. 14265. This concession, however, fails to establish that any of the Amplatz references disclose the third limitation of claim 1. First, Voda did not concede that the contact portion of the Amplatz catheter was "1.5 cm or greater." Second, Voda did not concede that the Amplatz catheter leans against the wall of the aorta opposite the ostium "when the distal end of the catheter is positioned in the ostium." Rather, Voda testified that the prior art method of positioning the end of the Amplatz catheter in the ostium required pulling back on the catheter such that the catheter lost contact with the wall of the aorta. Given this record, a reasonable jury could conclude that Cordis failed to show that the Amplatz references disclosed the third limitation of claims 1 through 3 by clear and convincing evidence. Accordingly, the district court did not err in denying Cordis's motion for JMOL that claims 1 through 3 of the '213 patent were anticipated by the Amplatz references.

In arguing for anticipation by the Bourassa reference, Cordis places substantial reliance on the testimony of Mr. Thomas Trotta, one of its experts, regarding the method of using the Bourassa catheter. However, as the district court observed, Mr. Trotta is a catheter engineer, not an interventional cardiologist. Accordingly, the district court instructed the jury that Mr. Trotter has no education or training in the proper use of guiding catheters in the human body and has never used a catheter in a human. This instruction was not an abuse of discretion. Cordis also relies on the testimony of Dr. Frank Hildner, another one of its experts, that the length of contact between the Bourassa catheter and the wall of the aorta opposite the coronary ostium was 1.5 cm or more. However, on cross-examination Dr. Hildner admitted that his estimates as to the length of contact between the Bourassa catheter and the aortic wall were "very

inaccurate," and that he did not represent his estimates "to be accurate in any way." In addition, Voda testified that the images in the Bourassa reference did not clearly depict whether there was any contact between the Bourassa catheter and the wall of the aorta opposite the ostium during use. Given this record, a reasonable jury could conclude that Cordis failed to show that the Bourassa reference disclosed the third limitation of claims 1 through 3 by clear and convincing evidence. Accordingly, the district court did not err in denying Cordis's motion for JMOL that claims 1 through 3 of the '213 patent were anticipated by the Bourassa reference.

b. Obviousness

Section 103 of Title 35 of the U.S. Code "forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.'" KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1729 (2007) (quoting 35 U.S.C. § 103). "When reviewing a district court's JMOL determination as to obviousness, '[t]his court reviews a jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence.'" Finisar, 523 F.3d at 1338 (quoting Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (quotation omitted)).

Cordis offers only a perfunctory argument that it would have been obvious at the time of Voda's invention to increase the length of the contact portion of prior art catheters to 1.5 cm or more to provide additional support during use. Appellant Br. at 46. Cordis makes no argument and cites no evidence to support this conclusion.

Accordingly, Cordis has failed to show any reason to reverse the jury findings of obviousness nor any reason to grant a new trial on obviousness in light of the Supreme Court's recent decision in KSR. See SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1320-21 (Fed. Cir. 2006) (treating insufficiently developed arguments as waived).

* * *

In sum, we find that a reasonable jury could conclude that claims 1 through 3 are not invalid based upon the evidence adduced at trial. Accordingly, we affirm the district court's denial of JMOL that claims 1 through 3 are invalid.

4. Infringement of the Straight and Substantially Straight Claims under the Doctrine of Equivalents[4]

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950)); see also Dawn Equip. Co. v. Ky. Farms, Inc., 140 F.3d 1009, 1015 (Fed. Cir. 1998) (explaining that to prove infringement under the

[4] On cross-appeal, Voda also argues that the Cordis literally infringes the substantially straight claims. However, where an argument is merely an alternative basis to support a judgment of infringement, it is not a proper basis for cross-appeal and should be dismissed. Nautilus Group, Inc. v. Icon Health & Fitness, Inc., 437 F.3d 1376, 1377-78 (Fed. Cir. 2006); Elan Corp. v. Andrx Pharms., Inc., 366 F.3d 1336, 1340 (Fed. Cir. 2004) (dismissing a cross-appeal as improper where it merely raised an alternative ground for affirmance); Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1252 (Fed. Cir. 2004) (treating appellee's claim construction argument as an alternative ground for affirmance, and not an issue properly raised on cross-appeal). Accordingly, we dismiss Voda's argument with respect to literal infringement of the substantially straight claims as improperly raised on cross-appeal.

doctrine of equivalents, "the accused device must be shown to include an equivalent for each literally absent claim limitation"). However, the use of the doctrine of equivalents to establish infringement is limited by the doctrine of prosecution history estoppel. Warner-Jenkinson, 520 U.S. at 30. In particular, "prosecution history estoppel limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relinquished when a patent claim is narrowed during prosecution." Conoco, 460 F.3d at 1363 (citations omitted).

Here, the parties dispute whether Cordis's accused XB catheters have a portion that is equivalent to the "second straight portion" limitation of claim 1 of the '625 patent (i.e., the straight claim) or the "first substantially straight leg" limitation of claims 4 and 5 of the '213 patent and all claims of the '195 patent (i.e., the substantially straight claims). Cordis makes two arguments in support of noninfringement. First, Cordis argues that prosecution history estoppel bars Voda from arguing that the "redesigned curve portion," see discussion supra Background Section 3, of the XB catheter meets the straight and substantially straight limitations. Second, Cordis argues that the finding of infringement should be overturned because no reasonable jury could find that the redesigned curve portion of its XB catheter is equivalent to the straight or substantially straight limitations.[5] We will address each argument in turn.

[5] More precisely, Cordis argues that treating the redesigned curve portion "as an equivalent to the claims' 'straight' or 'substantially straight' portion would vitiate that limitation." Appellant Br. at 48 (emphasis added). However, this court has explained that claim vitiation arguments are nothing more than arguments "that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency." DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1018-19 (Fed. Cir. 2006).

a. Prosecution History Estoppel

This court has explained that "prosecution history estoppel can occur during prosecution in one of two ways, either (1) [when the applicant makes] a narrowing amendment to the claim ('amendment-based estoppel') or (2) [when the applicant surrenders] claim scope through argument to the patent examiner ('argument-based estoppel')." Conoco, 460 F.3d at 1363 (citations omitted). Here, Cordis argues that both amendment-based estoppel and argument-based estoppel apply to the substantially straight claims of the '213 patent.[6]

Under amendment-based estoppel, "[a] patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 740-41 (2002) (citations omitted). However, "the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence" by showing: (1) that the equivalent was unforeseeable at the time of the patent application; (2) that the rationale underlying the amendment bore "no more than a tangential relation to the equivalent in question"; or (3) "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." Id.

During prosecution of claim 4 of the '213 patent, Voda amended claim 4 as follows:

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[6] Cordis also argues that prosecution history estoppel applies to the straight and substantially straight claims of the '625 and '195 patents. However, the district court correctly found that Cordis waived those arguments by failing to raise them in its post-trial motion for JMOL. Because those arguments were waived below, we decline to address them here in the first instance. See Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1426 (Fed. Cir. 1997).

> 4. A method for advancing a catheter through an aorta and into a branch artery, the aorta having an arch and an inner wall opposite the branch artery, comprising the steps of:
>
> providing a catheter including a tubular member having a shaft, an integral profiled portion, and an integral, substantially straight tip portion, the tip portion being adapted to axially engage the branch artery;
>
> wherein the catheter profiled portion comprises, in order from the shaft portion to the tip portion, a first bend, a first substantially straight leg, a second bend, a second substantially straight leg, and a third bend;
>
> advancing the catheter tip portion through the aorta; and
>
> engaging the branch artery with the tip portion, such that when the tip portion is engaged with the branch artery, the profiled portion engages the aorta wall opposite the branch artery along a line.

Amdt. to U.S. Patent App. No. 08/854,996 at *2 (Filed May 13, 1997) (insertions underlined). Thus, this amendment added, among other things, a requirement that the claimed methods must be performed with catheters having a "first substantially straight leg."[7] Under amendment-based estoppel, Voda is presumed to have disclaimed methods that do not involve catheters with a first substantially straight leg. See Festo, 535 U.S. at 740-41. Moreover, Voda has failed to make any argument to overcome this presumption. Accordingly, the prosecution history of claims 4 and 5 of the '213 patent bars a finding of equivalence between the redesigned curve portion of the Cordis catheters and "first substantially straight leg" limitation.[8] The district court therefore erred in denying Cordis's post-trial motion for JMOL that it does not infringe claims 4 and 5 of the '213 patent under the doctrine of equivalents. We therefore reverse the finding of infringement with respect to these claims.

[7] As noted earlier, the first substantially straight leg engages the wall of the aorta opposite the coronary ostium.

[8] Because we find that Voda's doctrine of equivalents argument with respect to claims 4 and 5 of the '213 patent is barred by amendment-based estoppel, we need not address argument-based estoppel with respect to these claims.

b. Application of the Doctrine of Equivalents

This court applies two articulations of the test for equivalence. See Warner-Jenkinson, 520 U.S. at 40 (explaining that different phrasings of the test for equivalence may be "more suitable to different cases, depending on their particular facts"). Under the insubstantial differences test, "[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial." Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1139 (Fed. Cir 2004). Alternatively, under the function-way-result test, an element in the accused device is equivalent to a claim limitation if it "performs substantially the same function in substantially the same way to obtain substantially the same result." Schoell v. Regal Marine Indus., Inc., 247 F.3d 1202, 1209-10 (Fed. Cir. 2001).

As discussed, the only limitations that Cordis argues have no equivalent in its XB catheters are the second straight portion limitation of claim 1 of the '625 patent and the first substantially straight leg limitation of all claims of the '195 patent.[9] However, we conclude that Voda introduced substantial evidence establishing that the redesigned curve portion of the XB catheter meets the straight and substantially straight limitations under the doctrine of equivalents. One of Voda's experts testified that the difference in shape between the redesigned curve portion and a straight portion was so insubstantial that cardiologists would have difficulty distinguishing the two during use. There was also testimony that the redesigned curve portion performed the same function as a straight portion, in the same way, to achieve the same result. First, one of Voda's

[9] Because we find that Voda's doctrine of equivalents argument with respect to claims 4 and 5 of the '213 patent is barred by amendment-based estoppel, we need not address the application of the doctrine of equivalents to these claims.

experts explained that the redesigned curve portion of the XB catheter provides the same function as the straight and substantially straight portions in Voda's claims because it provides extra backup support for the catheter during use. Indeed, the name "XB" stands for "extra backup." There was also testimony that Cordis's substitution of the redesigned curve portion in the accused XB catheter made the product easier to manufacture, but did not alter the XB catheter's functionality. Second, one of Voda's experts testified that the redesigned curve portion of the XB catheter functions in the same way as the straight and substantially straight portions in Voda's claims because it engages the wall of the aorta opposite the coronary ostium for a substantial length during use. The length of engagement by the redesigned curve portion during use was explained to be indistinguishable from the length of engagement in Voda's claims. Third, there was testimony that the redesigned curve portion achieves the same result as the straight or substantially straight elements by making it "difficult to dislodge the guide catheter from its desired orientation" during use.

Given this record, we find that substantial evidence supports the jury's findings that Cordis's XB catheters infringe the straight and substantially straight claims of the '625 and '195 patents under the doctrine of equivalents. Accordingly, we affirm the jury's findings of infringement with respect to these claims.

5. Willfulness

In In re Seagate, 497 F.3d 1360 (Fed. Cir. 2007) (en banc), this court overruled the standard of willfulness adopted in Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380 (Fed. Cir. 1983). The Underwater Devices standard for willfulness imposed an affirmative duty of care on potential infringers to determine whether their

conduct was infringing if they had notice of another party's patent rights. 717 F.2d at 1389-90. Under the new Seagate standard for willfulness, "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness." 497 F.3d at 1371. "[T]o establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." Id. "If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." Id. The Seagate decision also clarified that there is "no affirmative obligation to obtain opinion of counsel" in order to avoid liability for willful infringement. Id.

In this case, the district court issued its jury instruction on the standard for willful infringement prior to the issuance of Seagate. The district court instructed the jury, inter alia, that "[w]hen a person becomes aware that a patent may have relevance to his or her activities, that person has a duty to exercise due care and to investigate whether or not his or her activities or proposed activities infringe any valid, enforceable claim of the patent." Voda v. Cordis Corp., No. 03-CV-1512, slip op. at *46 (W.D. Okla. May 25, 2006) (Jury Instructions). Cordis did not object to this jury instruction at trial. However, on appeal, Cordis seeks a new trial on willfulness under the new standard for willfulness adopted in Seagate.

This court reviews challenges to jury instructions under the law of the regional circuit where the district court sits. Eli Lilly and Co. v. Aradigm Corp., 376 F.3d 1352, 1359 (Fed. Cir. 2004). Generally, if the defendant fails to object to a jury instruction at

trial, the Tenth Circuit reviews the district court's decision to administer the jury instruction for plain error. Fed. R. Civ. P. 51(d)(2); Williams v. W.D. Sports, N.M., Inc., 497 F.3d 1079, 1094 (10th Cir. 2007). Under the plain error standard, the Tenth Circuit "will affirm unless the instructions were patently, plainly erroneous and prejudicial." Id. However, where, as here, the claimed error in the jury instruction is based on a change in the law that arose after trial, the Tenth Circuit reviews the jury instruction de novo. Anixter v. Home-Stake Prod. Co., 77 F.3d 1215, 1231 (10th Cir. 1996); Key v. Rutherford, 645 F.2d 880, 883 (10th Cir. 1981). If the jury instruction is erroneous, the Tenth Circuit will nevertheless affirm if the error is "harmless in the context of the trial as a whole." World Wide Ass'n of Specialty Programs v. Pure, Inc., 450 F.3d 1132, 1139 (10th Cir. 2006). An error in a jury instruction is harmless when it "could not have changed the result of the case." Id. (quoting Lusby v. T.G. & Y. Stores, Inc., 796 F.2d 1307, 1310 (10th Cir. 1986)); see also CytoLogix Corp. v. Ventana Med. Sys., Inc., 424 F.3d 1168, 1174 (Fed. Cir. 2005).

The parties agree that the jury instruction on willfulness was erroneous under Seagate. Nonetheless, Voda argues that the willfulness finding should be upheld because the error in the jury instruction was harmless.[10] Specifically, Voda argues that the instructional error was harmless because the evidence showed that Cordis's XB

[10] Voda also argues that Seagate should not be applied retroactively in this case. This argument is without merit. See Rivers v. Roadway Express, Inc., 511 U.S. 298, 311-12 (1994) ("The principle that statutes operate only prospectively, while judicial decisions operate retrospectively, is familiar to every law student . . . ."); Harper v. Virginia Dep't of Taxation, 509 U.S. 86, 97 (1993) ("When this Court applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law and must be given full retroactive effect in all cases still open on direct review and as to all events, regardless of whether such events predate or postdate our announcement of the rule.").

catheters were intentional copies of the Voda catheters. However, Voda points to no evidence that shows that the accused Cordis XB catheters are literal copies of Voda's patented catheters. Indeed, Voda admits that Cordis redesigned its XB catheters before the issuance of the patents-in-suit, making "slight changes" to the original XB catheter that had copied Voda's catheters. Cross-Appellant Br. at 7. In addition, Cordis points to evidence showing that it obtained several opinions of counsel regarding whether its redesigned XB catheters infringed Voda's patents. Given this record, we find that a jury instruction in accord with the Seagate objective recklessness standard may have changed the result of the jury verdict on willfulness. Accordingly, we vacate the finding of willfulness and remand for a determination of whether Cordis's infringement was willful under the objective recklessness standard of Seagate. On remand, the district court may at its discretion assess Voda's evidence of willful infringement under the Seagate standard to determine whether a new trial on willfulness is necessary or whether Voda's evidence is insufficient as a matter of law to support a finding of willfulness. See Hilton Davis Chem. Co. v. Warner-Jenkinson Co., Inc., 114 F.3d 1161, 1164 (Fed. Cir. 1997) (remanding case to district court based on intervening change in the law). Additionally, we reject Cordis's argument that, under the Seventh Amendment, a new trial on willfulness would require a new trial on infringement.

6. The Denial of a Permanent Injunction

In eBay Inc. v. MercExchange, L.L.C., the Supreme Court held that a plaintiff seeking a permanent injunction in a patent case must demonstrate:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff

> and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

547 U.S. 388, 391 (2006).

In this case, the district court found that Voda had not identified any irreparable injury to himself due to Cordis's infringement of his patents and also failed to show that monetary damages are inadequate to compensate for Cordis's infringement. The district court explained that Voda had attempted to prove irreparable injury by alleging irreparable harm to his exclusive licensee, rather than himself.

Voda argues that the district court erred in adopting a categorical rule that precludes a patent owner from proving its entitlement to an injunction by showing irreparable harm to its exclusive licensee. Specifically, Voda argues that such a categorical rule conflicts with eBay. In eBay, the Court explained that:

> [S]ome patent holders, such as university researchers or self-made inventors, might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to bring their works to market themselves. Such patent holders may be able to satisfy the traditional four-factor test, and we see no basis for categorically denying them the opportunity to do so. To the extent that the District Court adopted such a categorical rule, then, its analysis cannot be squared with the principles of equity adopted by Congress.

Id. at 393. We disagree with Voda that the denial of a permanent injunction in this case conflicts with eBay. The Supreme Court held only that patent owners that license their patents rather than practice them "may be able to satisfy the traditional four-factor test" for a permanent injunction. Id. (emphasis added). Nothing in eBay eliminates the requirement that the party seeking a permanent injunction must show that "it has suffered an irreparable injury." Id. (emphasis added). Moreover, we conclude that the district court did not clearly err in finding that Voda failed to show that Cordis's

infringement caused him irreparable injury. In addition, we find that the district court did not clearly err or abuse its discretion in finding that monetary damages were adequate to compensate Voda. Accordingly, we affirm the district court's denial of Voda's request for a permanent injunction.

CONCLUSION

For the foregoing reasons, we affirm the judgment of infringement with respect to claims 1 through 3 of the '213 patent as well as the judgment that those claims are not invalid. In addition, we affirm the judgment of infringement with respect to claim 1 of the '625 patent and all claims of the '195 patent. We also affirm the district court's denial of a permanent injunction. However, we reverse the finding of infringement with respect to claims 4 and 5 of the '213 patent. Lastly, we vacate the judgment of willfulness with respect to all claims and remand for a determination of willfulness under the standard recently adopted in Seagate.

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

No costs.