United States Court of Appeals for the Federal Circuit

00-1417

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Plaintiff-Appellee,

v.

MEDTRONIC, INC.,

Defendant-Appellant.

Edward A. Mas, II, McAndrews, Held & Malloy, Ltd., of Chicago, Illinois, argued for plaintiff-appellee. With him on the brief were Timothy J. Malloy, Leland G. Hansen, and James M. Hafertepe.

Ernest I. Reveal, Robins, Kaplan, Miller & Ciresi L.L.P., of Minneapolis, Minnesota, argued for defendant-appellant. With him on the brief were Kevin D. Conneely, Rita Coyle DeMeules, and Susan L. Dunbar.

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

Senior Judge D. Lowell Jensen

United States Court of Appeals for the Federal Circuit

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ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Plaintiff-Appellee,

v.

MEDTRONIC, INC.,

Defendant-Appellant.

DECIDED: September 10, 2001

Before BRYSON, GAJARSA, and LINN, Circuit Judges.

LINN, Circuit Judge.

Medtronic, Inc. ("Medtronic") appeals a final judgment from the United States District Court for the Northern District of California. Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., No. C-95-3577 (N.D. Cal. May 17, 2000) (judgment). The district court decided, on summary judgment, that claim 3 of United States Patent No. 5,451,233 ("'233 patent"), owned by Advanced Cardiovascular Systems, Inc. ("ACS"), was not invalid, not unenforceable, and was infringed. Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., No. C-95-3577, slip op. at 13 (N.D. Cal. Aug. 25, 1999) ("Summary Judgment Opinion"). A jury then found that Medtronic's infringement was willful. On post-trial motion filed by ACS, the district court enhanced damages by thirty percent for a total of $7,086,311. Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., No. C-95-3577 (N.D. Cal. Mar. 31, 2000) ("Enhanced Damages Opinion").

Medtronic appeals: (1) the summary judgment, challenging the conclusion that claim 3 was not

unenforceable and challenging the claim construction that resulted in infringement; (2) the enhancement of damages; and (3) the district court's denial of two of its motions. The first motion, denied before summary judgment, was for leave to assert invalidity under 35 U.S.C. § 112, paragraph 1. The second motion was for a new trial based on various evidentiary preclusions at trial. Because Medtronic has not shown any reversible error, we affirm.

BACKGROUND

A. The Technology and the Relevant Patents

The technology involved relates to rapid exchange catheters for performing coronary angioplasty. In addition to the '233 patent, ACS has three other patents on this technology that were originally part of the present lawsuit. The '233 patent and two of ACS's other patents are referred to collectively by the parties as "the Yock patents," in reference to their common inventor. The two other Yock patents are United States Patent No. 5,040,548 ("'548 patent") and United States Patent No. 5,061,273 ("'273 patent"). The fourth ACS patent originally part of this lawsuit is United States Patent No. 5,496,346 ("'346 patent"). The last of these to issue was the '233 patent, which issued on September 19, 1995. Medtronic also has at least one patent in this field that is relevant to the present suit. That patent is United States Patent No. 5,549,556 ("'556 patent").

The '233 patent relates to rapid exchange catheters for use in coronary angioplasty. Coronary angioplasty refers to the use of a balloon to increase the blood flow through a stenosis, which is a partially blocked section of a blood vessel feeding the heart. As described in the '233 patent and the briefs, a typical coronary angioplasty consists of the following three steps. First, a physician inserts a guiding catheter, a tubular structure, into a patient's blood vessel beginning at the top of the patient's leg. The guiding catheter is advanced toward the heart through the patient's blood vessel, stopping short of the coronary arteries, and is then fixed in place. Second, the physician

inserts a guidewire into the guiding catheter until the distal end of the guidewire exits the guiding catheter, which is still inside the patient's blood vessel, and enters the coronary arteries. The physician then positions the guidewire across the stenosis to be treated in the coronary arteries, and the guidewire is fixed in place. Third, the physician advances a balloon catheter along the guidewire until the balloon, which is on the end of the balloon catheter closest to the heart, exits the guiding catheter and is positioned across the stenosis. The physician then inflates the balloon to treat the stenosis, deflates the balloon, and removes the balloon catheter without disturbing the placement of either the guidewire or the guiding catheter.

Physicians frequently need to exchange balloon catheters during a single coronary angioplasty. For example, if a stenosis blocks most of the blood flow through a vessel, the physician may first need to use a small balloon to increase the size of the opening through the stenosis, and then use a larger balloon to further increase the opening.

The physical connection between the balloon catheter and the guidewire is central to the present dispute. In the relevant prior art systems, the balloon catheter contained an internal channel, referred to as a guidewire lumen, along its entire length and an opening to the lumen at each end of the catheter. The balloon catheter also contained an inflating lumen that connected to, and provided the channel for inflating, the balloon. The guidewire lumen enabled the balloon catheter to travel over the guidewire, completely enclosing the guidewire, as the balloon catheter was inserted into the guiding catheter positioned in the blood vessel. The drawback of this design was that it was cumbersome to exchange balloon catheters because the guidewire was approximately ten feet long and, thus, changing the balloon catheter that rode along the guidewire was a two-person job.

The '233 patent describes a solution to this problem, providing a design that allows one person to exchange balloon catheters. The guidewire lumen in the balloon catheter is shortened considerably so that it no longer runs the entire length of the balloon catheter. Rather, the

guidewire lumen begins at the far end of the balloon catheter, that is, the end near the balloon, but extends back through the balloon catheter only about 10-15 cm. This length is selected so as to ensure that the proximal end of the guidewire lumen, that is, the end nearer the physician, is retained within the guiding catheter when the balloon catheter is in place across a stenosis. This retention is important because if the guidewire lumen of the balloon catheter protrudes entirely from the guiding catheter, problems can occur in positioning, moving, or withdrawing the balloon catheter.

A preferred embodiment of the ’233 patent has the guidewire lumen running through the inside of the balloon, giving the balloon a cylindrical shape. This is termed a coaxial design and is illustrated in the figures below from the ’233 patent.

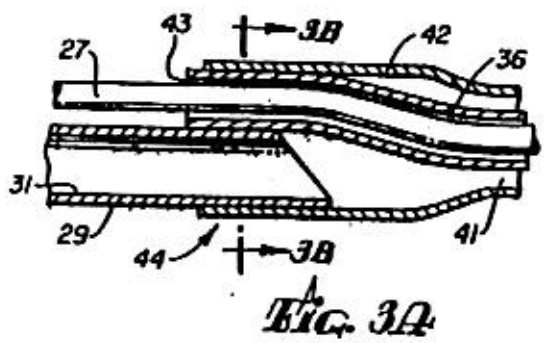

FIG. 3A

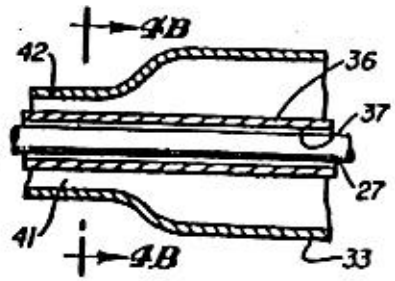

FIG. 4A

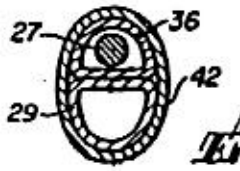

FIG. 3B

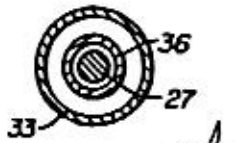

FIG. 4B

lumen, that is, also, therefore, 3A shows the does not occur end nearer the uidewire lumen ransition region uidewire lumen ens up into the balloon 33.

Although five patents are relevant to the present suit, only claim 3 of the ’233 patent is at issue, as explained below in the section describing the procedural history. Claim 3 recites:

> 3. An elongated balloon dilatation catheter for performing an angioplasty procedure within a human patient's coronary artery which has means for the rapid exchange of the catheter over a guidewire without the utilization of an exchange wire or an extension wire, comprising:
> a) an elongated catheter shaft having proximal and distal ends and being configured for percutaneous introduction into the patient's femoral artery;
> b) a distal guidewire opening in the distal end of the catheter shaft;
> c) a proximal guidewire opening in the catheter shaft spaced a short distance of at least 10 cm proximally from the distal guidewire opening and a substantial distance from the proximal end of the catheter shaft;
> d) a flexible distal shaft section configured to be advanceable within the patient's coronary arteries having a guidewire-receiving lumen extending proximally from the distal guidewire opening to the proximal guidewire opening and having an inflation lumen coextensive at least in part with the guidewire-receiving lumen,
> e) an inflatable dilatation balloon on the distal shaft section having proximal and distal ends, having an interior which is in fluid communication with the inflation lumen and being spaced closer to the distal end of the catheter shaft than the proximal guidewire opening; and
> f) a proximal shaft section much longer than the distal shaft section which is an elongated tubular member with an inner lumen extending therein in fluid communication with the inflation lumen in the distal section and which is suitable to advance the distal shaft section within a patient's coronary artery over a guidewire slidably disposed within the guidewire receiving lumen.

’233 patent, col. 12, l. 42 - col. 13, l. 10.

B. The Accused Product

The accused infringing device is Medtronic’s Falcon catheter. The Falcon catheter operates in the same manner as that described above and contains a shortened guidewire lumen at the far, or distal, end of the catheter, that is, the end with the balloon. However, the guidewire lumen of the Falcon catheter runs along the outside of the balloon, as opposed to running through the inside of the balloon. This is termed a side-by-side design. Medtronic’s opening brief uses Figure 10 from Medtronic’s ’556 patent, reproduced below, to illustrate the side-by-side design of the Falcon catheter.

In Figure 10, the balloon 25 is side-

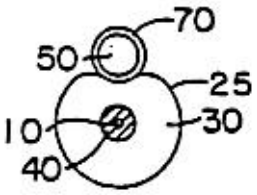

FIG. 10

xial, with guidewire lumen 50. Note that although Figure 3B from the '2 de-by-side design, it only illustrates the transition region and not the re , which is shown in Figures 4A and 4B.

One point of dispute in this appeal is whether claim 3 of the '233 patent reads on a side-by-side design or requires that the guidewire lumen be inside of the balloon. ACS alleges, and the district court determined, that claim 3 of the '233 patent does not require a coaxial design.

C. Events Related to Inequitable Conduct Allegation

A competing inventor named Bonzel, who assigned all of his inventions relevant to the present dispute to Schneider AG ("Schneider"), conceived of an invention in mid-1983 that is similar to that described in the '233 patent. Summary Judgment Opinion, slip op. at 13. Bonzel filed a patent application in Germany on November 23, 1984. Id. As is customary in Germany, this application presumably was published eighteen months later, on May 23, 1986. On November 15, 1985, Bonzel filed an application under the Patent Cooperation Treaty ("PCT"), thereby preserving his right to claim priority internationally as of November 23, 1984. Id. The PCT application was published on June 5, 1986. Bonzel filed a related United States patent application on July 14, 1986, which issued as United States Patent No. 4,762,129 ("'129 patent") on August 9, 1988. Id.

Yock conceived his invention in early 1985, disclosed it to ACS on January 9, 1986, and filed a United States application on April 15, 1986. Id. According to Yock, five days later he learned of the Bonzel design from an ACS employee who forwarded a report to him of a presentation given by Bonzel in Switzerland in March 1986 ("presentation report"). Id. The Yock application eventually gave rise to the '548, '273, and '233 patents.

Schneider and ACS became embroiled in numerous disputes, two of which are noted here. After the '129 patent issued, Schneider sued ACS in 1988 for infringement of the '129 patent. Id. ACS responded, in part, by filing a notice of opposition with the European Patent Office in February 1990. Id. at 14. Schneider also sued in the United Kingdom, presumably on a United Kingdom patent stemming from the PCT application. See id. at 19. On March 16, 1990, ACS responded, in part, by filing a request for reexamination of Bonzel's '129 patent with the United States Patent & Trademark Office ("PTO"). Id. According to the district court, Yock repeatedly stressed that the Bonzel patents did not disclose and were not limited to a shortened guidewire lumen that also remained within the guiding catheter. Id. at 13-17, 19. Yock also argued that the Bonzel patents were not patentable over a prior art reference of Nordenstrom.

On May 3, 1991, the infringement action filed by Schneider against ACS and its distributors in the United Kingdom was decided against ACS. Id. at 15. In December of 1991, ACS and Schneider entered into a settlement agreement to resolve litigation pending in the United States and Europe between ACS and Schneider alleging infringement of the Bonzel and Yock patents. Id. at 16-17. ACS paid Schneider $22 million for a license under the Bonzel patent, and both parties relinquished all right to continue pursuing claims of infringement against each other with respect to the Yock and Bonzel patents. Id. at 17.

In the meantime, Bonzel had filed a continuation of the '129 patent and added claims that largely copied claims from Yock's '273 patent. These added claims, however, each omitted a substantive limitation requiring that the guidewire lumen be at least approximately 10 cm in length. On January 7, 1993, over a year after the settlement and after these "copied" claims were rejected by the examiner over prior art, Bonzel cancelled the claims.

On March 9, 1994, Yock filed the application that became the '233 patent. Id. During prosecution, the examiner had the Bonzel presentation report before him. Id. at 23. Yock again distinguished his design from that of Bonzel. He also swore behind the Bonzel presentation

report.

D. Procedural History

On October 10, 1995, ACS filed a complaint against Medtronic alleging that Medtronic's Falcon catheter willfully infringed the Yock patents, either by direct or contributory infringement. Enhanced Damages Opinion, slip op. at 2. Medtronic began selling the Falcon catheter prior to the issuance of the '233 patent and stopped selling it in the beginning of 1999. Id. at 29. On March 12, 1996, ACS filed an additional suit alleging willful infringement by Medtronic of the '346 patent. Id. These actions were combined and the suit thus encompassed four patents. Id. at 2-3.

On March 16, 1999, the district court issued its claim construction ruling for the four patents then at issue. Id. at 3. After the district court's claim construction, Medtronic moved for leave to supplement the response chart it had filed and to amend its answer and counterclaim. Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., No. C-95-3577, slip op. at 5 (N.D. Cal. May 7, 1999) ("Denial of Motion to Amend"). The district court granted Medtronic leave to amend with respect to defenses asserted under 35 U.S.C. § 102 and § 103, but not with respect to § 112, paragraph 1.

ACS also moved for summary judgment that the Falcon catheter infringed claim 3 of the '233 patent and summary judgment that the claims of the Yock patents were not invalid and not unenforceable. Enhanced Damages Opinion, slip op. at 3. Medtronic filed a notice of non-opposition as to infringement of claim 3 of the '233 patent but opposed the rest of the summary judgment motion. Id.

On August 25, 1999, the district court granted summary judgment for ACS and held claim 3 of the '233 patent to be infringed. Summary Judgment Opinion, slip op. at 5. The district court also granted summary judgment for ACS finding the claims of the Yock patents not invalid and not unenforceable. Id. at 11, 26.

Trial on the issue of damages was scheduled for October 25, 1999. Enhanced Damages Opinion, slip op. at 3. A hearing was conducted on October 6, 1999 on the parties' motions in limine related to the trial. Id. At the hearing, ACS proffered to the court that ACS would file an amended complaint limited to an allegation of infringement of claim 3 of the '233 patent by the Medtronic Falcon catheter. Id. In addition to proffering to submit the amended complaint, ACS's counsel informed the court, on the record, that ACS would not assert any other patent infringement claims against Medtronic's Falcon catheter. Id. at 3-4. The court accepted ACS's proffer, and trial was limited to the question of damages for infringement of claim 3 of the '233 patent and the question of whether Medtronic willfully infringed claim 3 of the '233 patent. Id. ACS's amended complaint was filed, after trial, on December 8, 1999. Id. at 5.

On October 12, 1999, the district court issued an order regarding the various motions in limine. Id. at 4. The court ruled that Medtronic was precluded from showing that features of the Falcon are covered by Medtronic's '556 patent. Id. Medtronic had also decided to assert its attorney-client privilege with respect to its legal consultations on the '233 patent. Id. at 9. Based in part on that fact, the court ruled that Medtronic was precluded from introducing at trial and relying on opinion letters concerning the '548 and '273 patents, but reserved for trial the issue of whether to exclude evidence of Medtronic's efforts to design around the '548 and '273 patents. Id. at 4.

At trial, the court allowed Medtronic to introduce design-around evidence related to the '548 and '273 patents, but did not allow Medtronic to present evidence of its consultation with legal counsel in those efforts. Id. at 7-9. At trial, the court also precluded Medtronic from telling the jury about the procedural history of this case, including the timing of the court's claim construction ruling and the fact that four patents were at issue for most of the litigation. Id. at 7.

A jury trial on the issue of damages, limited to claim 3 of the '233 patent, was held on October 25,

26, 28, and 29, 1999 and on November 1 and 2, 1999. Id. at 4. The jury awarded ACS $3,418,508 in lost profits and $2,032,500 in reasonable royalty rate damages, for a total of $5,451,008. Id. The jury also found that Medtronic had willfully infringed claim 3 of the '233 patent. Id.

On November 24, 1999, the parties filed several post-trial motions, two of which are relevant to this appeal. Id. Medtronic moved for a new trial on the issue of willfulness pursuant to Rule 59 of the Federal Rules of Civil Procedure. Id. at 4-5. Medtronic's new trial motion alleged that the court's evidentiary preclusions prevented the jury from examining all of the relevant circumstances in determining if infringement was willful. Id. at 6-7. The district court denied Medtronic's motion for a new trial. Id. at 14. ACS moved for enhanced damages and attorney fees and for a permanent injunction prohibiting patent infringement. Id. at 4. The district court granted ACS's motion for enhanced damages, enhancing damages by thirty percent, or $1,635,303, and denied ACS's motion for attorney fees. Id. at 33, 36.

Medtronic appeals: (1) the denial of leave to assert invalidity under 35 U.S.C. § 112, paragraph 1; (2) the summary judgment of infringement of claim 3 of the '233 patent, alleging error in the claim construction; (3) the summary judgment that claim 3 of the '233 patent was not unenforceable; (4) the denial of its motion for a new trial based on the evidentiary preclusions at trial; and (5) the enhancement of damages. We have exclusive appellate jurisdiction over the issues appealed. 28 U.S.C. § 1295(a)(1) (1994).

DISCUSSION

A. Invalidity under 35 U.S.C. § 112, Paragraph 1

After the district court's claim construction in March 1999, Medtronic moved for leave to supplement its response chart and amend its answer and counterclaim. Denial of Motion to Amend, slip op. at 5. The district court observed that at claim construction it was clear what prior art Medtronic was relying on for its § 102 and § 103 defenses, but Medtronic had not provided

sufficient notice for any § 112, paragraph 1 defense. Id. at 13-14. Accordingly, the district court granted Medtronic leave to amend with respect to the § 102 and § 103 defenses, but not with respect to the § 112, paragraph 1 defense. Id. at 15.

We are faced with the question of which law to apply to our review of the district court's refusal to permit amendment of the pleadings. On this question, we apply the law of the regional circuit to which the district court appeal normally lies unless "the issue pertains to or is unique to patent law," in which case we will apply our own law to both substantive and procedural issues "intimately involved in the substance of enforcement of the patent right." Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1365, 57 USPQ2d 1635, 1637 (Fed. Cir. 2001) (citing Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855-56, 50 USPQ2d 1304, 1307 (Fed. Cir. 1999) (citations omitted)). Determining the sufficiency of notice regarding defenses asserted under specific statutory provisions of the patent laws clearly implicates the jurisprudential responsibilities of this court within its exclusive jurisdiction. Accordingly, we review the district court's refusal to allow Medtronic's amendment to the pleadings under Federal Circuit law. Decisions concerning the amendment of pleadings are reviewed by this court under the abuse of discretion standard. E.W. Bliss Co. v. United States, 77 F.3d 445, 450 (Fed. Cir. 1996).

By the time the district court construed the claims, approximately three and one-half years after ACS's complaint had been filed, Medtronic had provided only the barest allegation of invalidity under § 112, paragraph 1. Medtronic's position consisted essentially of a conclusory statement that if the claims of the '233 patent were not construed to include a "coaxial" limitation, then they would be invalid because nothing broader was disclosed. Clearly ACS would have been hard pressed to respond meaningfully to such a bare allegation. Accordingly, we cannot say that the district court abused its discretion in concluding that sufficient notice of Medtronic's § 112, paragraph 1 defense had not been provided to ACS, or in deciding to deny Medtronic leave to amend.

B. Summary Judgment Decisions

1. Standard of Review

We review a district court's grant of summary judgment de novo, reapplying the standard applicable at the district court. Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1301, 50 USPQ2d 1429, 1434 (Fed. Cir. 1999) (citing Conroy v. Reebok Int'l, Ltd., 14 F.3d 1570, 1575, 29 USPQ2d 1373, 1377 (Fed. Cir. 1994)). Summary judgment is only appropriate when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). We draw all reasonable inferences in favor of the non-movant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

2. Infringement and Claim Construction

The district court's construction of claim 3 of the '233 patent does not require that the guidewire lumen pass through, or inside of, the balloon. Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., No. C-95-3577, slip op. at 26-28 (N.D. Cal. Mar. 16, 2000) (claim construction). Medtronic challenges this construction on appeal. Medtronic does not independently contest the finding of infringement. That is, if we agree with the district court's construction of claim 3 of the '233 patent, then Medtronic concedes infringement. Claim construction is a matter of law and is reviewed de novo on appeal. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998) (en banc).

As always, we begin our construction with the words of the claim. Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331, 59 USPQ2d 1401, 1406-07 (Fed. Cir. 2001). After looking to the claim language we consider the rest of the intrinsic evidence, that is, the written description and the prosecution history if in evidence. Id. Accordingly, we proceed first to examine the claim language.

The preamble informs us that the claim is for an "elongated balloon dilatation catheter," also referred to in the preamble as a "catheter." The preamble notes that the catheter can be exchanged "over a guidewire," but the preamble does not restrict the claim to either a coaxial or a side-by-side design.

Parts a) through c) of the claim inform us that the catheter includes an "elongated catheter shaft," also referred to as a "catheter shaft," that includes two guidewire lumen openings. Parts b) and c) state that these openings are "in" the catheter shaft. Part d) informs us that the catheter includes a "flexible distal shaft section," also referred to as a "distal shaft section" in parts e) and f). Part d) also reveals that the distal shaft section contains the guidewire lumen extending between the two guidewire lumen openings. From this it is clear that the distal shaft section is a part of the catheter shaft, as the names themselves suggest. Part e) further informs us that an "inflatable dilatation balloon" is "on" the distal shaft section.

In summary, the language of the claim does not restrict the guidewire lumen to being either coaxial or side-by-side with the balloon. Further, the claim makes sense with either configuration, requiring only that: (1) there be two guidewire lumen openings in the catheter shaft, per parts b) and c); and (2) the balloon be located on the catheter shaft, per part e). These conditions can be met with either the coaxial or the side-by-side design. Thus, the words of the claim do not contain a coaxial limitation.

Medtronic places heavy emphasis on the claim's use of the words "in" and "on." The claim states that the guidewire openings are "in" the catheter shaft and that the balloon is "on" the catheter shaft. '233 patent, col. 12, ll. 51, 53, 65. Medtronic notes that the words "in" and "on" have different meanings and must be construed accordingly. So far, we are in agreement. However, Medtronic's opening brief alleges that in a side-by-side design, the guidewire lumen openings would be "on" the catheter and not "in" the catheter as the claim requires, "thereby erasing the difference between 'in' and 'on' by making those terms interchangeable." Medtronic attempts to

explain its logic, asserting that "there would be no need for two openings 'in' the catheter if the structure between those openings was not inside the claimed balloon catheter." (Emphasis Medtronic's).

Medtronic's argument assumes that because the guidewire lumen openings are "in" the catheter, the guidewire lumen must not only go through the catheter but also go through the balloon. We disagree. As part d) states, the claim only requires that the guidewire lumen go through the catheter shaft, and this is consistent with the common understanding of there being openings "in" the catheter shaft as required in parts b) and c). Further, the claim's requirement that the balloon be "on" the catheter shaft can be met either by the balloon being wrapped around the catheter shaft, as in a coaxial design, or simply being in contact with part of the circumference of the catheter shaft, as in a side-by-side design.

Medtronic points to various parts of the written description as supporting Medtronic's position. However, the written description does not support Medtronic. The written description does not define any claim terms to require a coaxial limitation and does not restrict the claimed invention to coaxial designs. To the contrary, the written description explicitly states that "[a]lthough the present invention has been described principally in conjunction with catheters having coaxial lumens, it should be appreciated that the invention is as applicable, if not more applicable, to catheters having side-by-side lumens." '233 patent, col. 11, ll. 28-32.

Medtronic next argues that the prosecution history compels the introduction of a coaxial limitation into claim 3 of the '233 patent. However, Medtronic argues exclusively from the prosecution history of the '273 and '548 patents—not the '233 patent. The prosecution history of a related patent can be relevant if, for example, it addresses a limitation in common with the patent in suit. Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc., 248 F.3d 1303, 1315, 58 USPQ2d 1607, 1617 (Fed. Cir. 2001); Watts v. XL Sys., Inc., 232 F.3d 877, 884, 56 USPQ2d 1836, 1841 (Fed. Cir. 2000); Jonsson v. Stanley Works, 903 F.2d 812, 818, 14 USPQ2d 1863, 1869 (Fed. Cir. 1990); cf.

Wang Labs., Inc. v. Am. Online, Inc., 197 F.3d 1377, 1383-84, 53 USPQ2d 1161, 1165-66 (Fed. Cir. 1999) (considering prosecution history of a parent application, in construing claims of a child application, when the specification of the child limited the claimed invention to the preferred embodiment and the subject matter of the parent was the same). Medtronic provides no plausible reason why the prosecution histories of either the '273 or '548 patents are relevant to the construction of claim 3 of the '233 patent. Notably, there are no common claim terms in dispute. Indeed, the present case involves the absence of a claim term. The patentee's whole point in filing the application that resulted in the '233 patent was to secure broader claims. As Medtronic admits in its opening brief, "none of the '233 Patent claims explicitly state the guidewire tube runs inside a balloon catheter."

Accordingly, we construe claim 3 of the '233 patent to read on both side-by-side and coaxial designs. We find no basis to read into claim 3 any requirement that the balloon be coaxial with the guidewire lumen. Infringement under this claim construction is not contested by Medtronic.

3. No Inequitable Conduct

On summary judgment, the district court found that "Medtronic has been unable, for any of its theories of inequitable conduct, to muster the evidence necessary to establish genuine issues of fact with respect to materiality and intent to deceive." Summary Judgment Opinion, slip op. at 26. Accordingly, the court entered summary judgment for ACS on the inequitable conduct issues.

On appeal, Medtronic asserts a variety of theories. Regarding materiality, Medtronic's principal argument is that the ACS-Schneider settlement was material to securing the broadened claims of the '233 patent because it allegedly also settled an imminent interference between the parties. In pressing this argument, Medtronic also asserts that the district court improperly resolved a variety of factual disputes and failed to make a variety of inferences in favor of Medtronic. Regarding an intent to deceive, Medtronic asserts that if inferences were properly drawn in its favor, then the

evidence regarding the settlement, the possibility of an interference, and ACS's allegedly inconsistent positions, reveals such an intent.

We agree with the district court that Medtronic has not carried its burden in establishing a genuine issue of material fact with respect to either materiality or intent. We separately address below the settlement agreement, the allegedly imminent interference, ACS's positions regarding the cited references, and intent.

The settlement agreement did not cover an interference. The agreement states its purpose in the last "Whereas" clause as "desir[ing] to effect a settlement of the litigations enumerated above, as well as settlement of certain other actual or potential disputes between them, defined with particularity in this Agreement." Nowhere in the agreement is an interference—actual, potential, threatened, imminent, or otherwise—even mentioned, much less "enumerated" or "defined with particularity." Further, the agreement specifically reserves the rights of the parties "to challenge the validity or enforceability of any United States patent or any foreign patent which is the subject of this Agreement." Thus, the parties actually preserved their right to provoke a possible interference should one become necessary.

Medtronic's allegations of an imminent or threatened interference are likewise completely unsubstantiated. At all times relevant to the present dispute, the Code of Federal Regulations has defined an interference as a proceeding between parties that are claiming the "same patentable invention." 37 C.F.R. §§ 1.601(i), 1.601(n) (2000). Medtronic introduced no credible evidence that the parties were claiming the same patentable invention. The evidence actually suggests the contrary. As explained earlier, Schneider added claims to a continuation of the '129 patent that were largely copied from Yock's '273 patent. These added claims did not include at least one substantive limitation from the claims in the '273 patent, and so it is questionable whether the claims were for the same patentable invention. Ignoring that potential infirmity, we observe that the examiner rejected these claims over the prior art, and Bonzel subsequently

cancelled the claims. Medtronic presents no argument that, after the cancellation of the "copied" claims, the parties were claiming the same patentable invention. We also note that the examiner responsible for the Yock applications was well aware of the Bonzel '129 patent and the other Bonzel references and could have declared an interference if one was justified.

Pressing its imminent interference theory further, Medtronic alleges that ACS was trying to evade the one-year window of 35 U.S.C. § 135(b), and thus prevent an interference from being declared. Section 135(b) requires that "[a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made . . . unless such claim is made prior to one year from the date on which the patent was granted." 35 U.S.C. § 135(b)(1) (Supp. V 1999). Medtronic argues that ACS delayed prosecution of the application that led to its '233 patent until after the settlement and after Bonzel withdrew the claims he "copied" from Yock's '273 patent. By doing so, Medtronic argues, ACS evaded the one-year period in which an interference can be declared between a pending application and an issued patent. Medtronic's logic escapes us. Even if ACS did delay, such delay would only have prejudiced ACS. The delay would have prevented ACS from copying claims from an issued patent in order to force an interference and, assuming that there was an interfering issued patent, the PTO would have been forced to reject ACS's claims. In re McGrew, 120 F.3d 1236, 1237-39, 43 USPQ2d 1632, 1634-35 (Fed. Cir. 1997) (explaining that 35 U.S.C. § 135(b) does not override the basic tenet that the PTO cannot allow two patents to issue for the same invention). Accordingly, we reject Medtronic's argument.

Medtronic's allegation that ACS took inconsistent positions regarding the effect of various references is also unsubstantiated. We have reviewed the record and agree with the district court that ACS's positions regarding the Bonzel references and the Nordenstrom reference were not inconsistent. Yock's position was, consistently, that neither the Bonzel references nor Nordenstrom disclosed a shortened guidewire lumen that also remained within the guiding

catheter.

Regarding an intent to deceive, Medtronic argues that ACS's intent should be inferred based on the alleged materiality of ACS's alleged misconduct. As noted, we have already determined that Medtronic failed to make a showing that ACS engaged in material misconduct. As a result, the basis for the inference Medtronic wishes us to draw is missing. And Medtronic provides no independent showing of intent. Accordingly, Medtronic has failed to carry its burden with regard to intent.

Medtronic also makes a collateral attack on the finding of no inequitable conduct, alleging that the district court abused its discretion by not permitting discovery into the negotiations surrounding the settlement agreement between ACS and Schneider. As to discovery matters, we have held that Federal Circuit law applies when deciding whether particular written or other materials are discoverable in a patent case, if those materials relate to an issue of substantive patent law. In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 803, 53 USPQ2d 1747, 1750 (Fed. Cir. 2000); Truswal Sys. Corp. v. Hydro-Air Eng'g, Inc., 813 F.2d 1207, 1212, 2 USPQ2d 1034, 1038 (Fed. Cir. 1987). In the present case, a determination of the materiality of the settlement agreement implicates the substantive patent issue of inequitable conduct. We therefore review the district court's refusal to permit discovery into the settlement negotiations under Federal Circuit law. Decisions concerning discovery matters are reviewed by this court under the abuse of discretion standard. Heat & Control, Inc. v. Hester Industries, Inc., 785 F.2d 1017, 1022, 228 USPQ 926, 930 (Fed. Cir. 1986); Cygnus Therapeutic Sys. v. Alza Corp., 92 F.3d 1153, 1161 n.2, 39 USPQ2d 1666, 1672 n.2 (Fed. Cir. 1996). In light of Medtronic's failure to show the materiality of the settlement agreement and, hence, the relevance of the evidence it would be seeking in discovery, we discern no abuse of discretion. Additionally, we are mindful, as was the district court, of the policy in favor of protecting settlement negotiations from being admitted as evidence, thus serving to encourage settlements. See Fed. R. Evid. 408; 23 Charles Alan Wright

& Kenneth W. Graham Jr., Federal Practice and Procedure § 5302 (1980) (discussing Rule 408 and the policies it promotes).

C. Denial of the Motion for New Trial

1.

As stated earlier, the district court precluded Medtronic from introducing various types of evidence at trial. These exclusions had the effect of precluding Medtronic from: (1) showing that features of the Falcon catheter are covered by Medtronic's '556 patent; (2) using legal opinion letters prepared for the '548 and '273 patents; (3) discussing Medtronic's consultation with legal counsel in its effort to design around the '548 and '273 patents; and (4) discussing the procedural history of the case. Medtronic argues that the district court erred and a new trial is warranted under the Federal Rules of Civil Procedure. Fed. R. Civ. Proc. 59, 61.

Evidentiary rulings and the denial of a new trial motion are not unique to our jurisdiction and, accordingly, we review them under the law of the Ninth Circuit. Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1574, 37 USPQ2d 1626, 1631 (Fed. Cir. 1996). The Ninth Circuit reviews evidentiary rulings of the type here involved, as well as the denial of a motion for a new trial, for an abuse of discretion. Wendt v. Host Int'l, Inc., 125 F.3d 806, 810 (9th Cir. 1997). Additionally, the Ninth Circuit will only grant a new trial "on the basis of an incorrect evidentiary ruling if the ruling substantially prejudiced a party." United States v. 99.66 Acres of Land, 970 F.2d 651, 658 (9th Cir. 1992). Medtronic must therefore prove that the evidentiary preclusions were an abuse of discretion and that it suffered substantial prejudice. Id.

Medtronic correctly notes that a willfulness finding must be based on all relevant circumstances, also referred to as the totality of the circumstances. Cent. Soya Co. v. Geo. A. Hormel & Co., 723 F.2d 1573, 1577, 220 USPQ 490, 492 (Fed. Cir. 1983). The thrust of Medtronic's argument is that the court's evidentiary preclusions prevented the jury from examining all relevant circumstances in

determining if infringement was willful. We find Medtronic's framing of the issue in this manner to be misguided.

Medtronic seems to argue that "all relevant circumstances" should include anything that Medtronic considers relevant. The decision on relevance, however, is not Medtronic's and is squarely within the discretion of the district court, subject to review for an abuse of that discretion. By establishing in our precedent that all relevant circumstances must be considered, we have not changed the foundational rules that the trial judge determines whether to admit evidence and that the trier of fact is only required to weigh and to consider all of the admitted evidence. The issue for our review is more properly framed, then, in accordance with our standard of review, as whether the district court abused its discretion in excluding evidence and, if so, whether Medtronic was substantially prejudiced thereby. With this framework in mind, we proceed to address the various exclusions by the district court.

2.

Medtronic's first assertion is that the district court abused its discretion by refusing to allow Medtronic to show that certain features of the Falcon catheter are covered by Medtronic's '556 patent. This assertion is wholly without merit. The fact that Medtronic's '556 patent might read on the Falcon catheter is totally irrelevant to the question of whether Medtronic willfully infringed another patent.

Medtronic's second assertion is that the district court abused its discretion by refusing to allow Medtronic to introduce legal opinion letters prepared for the '548 and '273 patents. Medtronic argues that the earlier opinions show Medtronic's diligent efforts to evaluate the '548 and '273 patents. Medtronic further argues that because those two patents were at issue for over three years, Medtronic's efforts to evaluate them must be relevant to the other patents at issue. We disagree. "Whether an act is 'willful' is by definition a question of the actor's intent . . . ."

Gustafson, Inc. v. Intersystems Indus. Prods., Inc., 897 F.2d 508, 510, 13 USPQ2d 1972, 1974 (Fed. Cir. 1990). Medtronic alleges absolutely no logical connection between its receipt of the earlier opinions and its intent with regard to the '233 patent. The only connection, which Medtronic does not argue, would be that the patents are all related. However, that relationship is an insufficient connection in this case because the claims are different, with claim 3 of the '233 patent omitting the crucial "coaxial" limitation that Medtronic alleges the claims of the earlier two patents all included. Further, Medtronic introduced no evidence that its intent with regard to the '233 patent was affected by the earlier opinions.

Medtronic's third assertion is that the district court abused its discretion by refusing to allow Medtronic witnesses either to offer legal opinions or to discuss Medtronic's consultation with legal counsel in its effort to design around the '548 and '273 patents. We reject this assertion for the same reasons that we rejected Medtronic's second assertion.

In addition to the lack of probative value of the challenged evidence, we agree with the district court that admitting evidence of Medtronic's legal activities regarding the '548 and '273 patents would have been potentially prejudicial to ACS. Enhanced Damages Opinion, slip op. at 9. As we have noted, Medtronic asserted its attorney-client privilege with respect to its legal consultations on the '233 patent, thus precluding discovery and evidence into Medtronic's legal consultations regarding the '233 patent. Id. A party asserting its attorney-client privilege runs the risk of having the fact-finder draw a negative inference. L.A. Gear, Inc. v. Thom McAn Shoe Co., 988 F.2d 1117, 1126, 25 USPQ2d 1913, 1919 (Fed. Cir. 1993) (noting that although a party to litigation may withhold disclosure of the advice given by its counsel, this assertion of privilege with respect to infringement and validity opinions of counsel may support the drawing of adverse inferences). Admitting the evidence in question, however, would potentially have allowed Medtronic, in addition to asserting privilege, to establish an inference that it acted in a legally reasonable manner with respect to the '233 patent. This would have prejudiced ACS.

Finally, Medtronic's assertion that the district court abused its discretion by refusing to allow Medtronic to tell the jury about the procedural history of the case is also unpersuasive. Medtronic has a variety of spins on this theme, three of which we consider.

First, Medtronic asserts that the jury needed to know that the suit involved four patents that Medtronic defended against for approximately four years. These other patents were settled, however, and were no longer in dispute or relevant.

Second, Medtronic notes that ACS did not allege willfulness with respect to the infringement of the '233 patent until after the 1999 claim construction. Thus, Medtronic argues, Medtronic defended the case in good faith. However, good faith defenses are not dispositive. See Gustafson, 897 F.2d at 511, 13 USPQ2d at 1974-75 ("Exercising due care, a party may continue to manufacture and may present what in good faith it believes to be a legitimate defense without risk of being found on that basis alone a willful infringer." (emphasis added, citation omitted)). Further, Medtronic controlled its own destiny because the suit was filed only one month after the '233 patent was issued. Medtronic could have virtually precluded any possibility that willful infringement would be alleged by taking appropriate steps with regard to the '233 patent. However, Medtronic chose to continue sales of the Falcon catheter for over three years after suit was filed and to assert its attorney-client privilege, thus precluding any possibility of relying upon an opinion of counsel.

Third, Medtronic alleges that it followed its corporate policies and it was prejudiced by not being able to provide the jury that information. What Medtronic means, however, is that it followed its corporate policies with regard to the '548 and '273 patents, for which it obtained legal opinions that it disclosed. Medtronic, however, asserted its attorney-client privilege with regard to the '233 patent and, therefore, neither disclosed nor relied upon any opinion of counsel.

Accordingly, we hold that the district court did not abuse its discretion in excluding the evidence in

question. As a result, "no grounds for a new trial exist" and we need not consider whether Medtronic also suffered substantial prejudice. 99.66 Acres of Land , 970 F.2d at 658.

D. Enhanced Damages

The district court, on motion from ACS, addressed enhanced damages under 35 U.S.C. § 284. The district court analyzed all of the relevant factors laid out in Read Corp. v. Portec, Inc., 970 F.2d 816, 826-27, 23 USPQ2d 1426, 1435-36 (Fed. Cir. 1992), abrogated on other grounds by Markman v. Westview Instruments, Inc. , 52 F.3d 967, 34 USPQ2d 1321 (Fed. Cir. 1995) (en banc). The district court noted that its analysis was to be based on all relevant circumstances known to the court, and that it was not limited to the circumstances known to the jury. Enhanced Damages Opinion, slip op. at 32. After a complete analysis, the district court enhanced damages by thirty percent. Id. at 33. The district court's decision is reviewed for an abuse of discretion. Nat'l Presto Indus., Inc. v. West Bend Co., 76 F.3d 1185, 1193, 37 USPQ2d 1685, 1690 (Fed. Cir. 1996).

Medtronic argues that the court abused its discretion by, allegedly, revisiting the willfulness decision and "substituting its own equitable determination for the jury's fact-finding role." Certainly a judge cannot substitute his or her factual determination for a jury's willfulness finding. However, such a substitution did not occur in this case. The district court merely assessed the circumstances known to the court and made a discretionary decision on whether, and how much, to enhance damages. The judge noted in passing that the relevant circumstances known to the court also indicated willful infringement, but the judge in no way substituted that decision for the jury's. Enhanced Damages Opinion, slip op. at 33.

Although far from clear, Medtronic may also be asserting error in the district court's consideration of evidence that was not available to the jury. We note that, at least in general, Read itself implicitly endorses this practice by including several factors that a jury is not in the best position to

assess, such as the "infringer's behavior as a party to the litigation" and the "[c]loseness of the case." Read Corp., 970 F.2d at 827, 23 USPQ2d at 1435; see Amsted Indus. Inc. v. Buckeye Steel Castings Co., 24 F.3d 178, 184, 30 USPQ2d 1462, 1466 (Fed. Cir. 1994) (noting that the "trial judge is in the best position to weigh considerations such as the closeness of the case, the tactics of counsel, the conduct of the parties, and any other factors that may contribute to a fair allocation of the burdens of litigation as between winner and loser"). Further, the additional evidence considered by the district court all favored Medtronic. Thus, any potential error was harmless, as it tended to exculpate Medtronic and limit the amount by which the damages were enhanced. 28 U.S.C. § 2111 (1994); Giove v. Dep't of Transp., 230 F.3d 1333, 1338-39 (Fed. Cir. 2000).

CONCLUSION

We affirm the judgment below in all respects. In particular, Medtronic has directed us to no error in: (1) the denial of leave to assert invalidity under 35 U.S.C. § 112, paragraph 1; (2) the summary judgment of infringement of claim 3 of the '233 patent; (3) the summary judgment that claim 3 of the '233 patent was not unenforceable; (4) the denial of Medtronic's motion for a new trial based on the evidentiary preclusions at trial; or (5) the enhancement of damages.

AFFIRMED