Abstract
Attempting to invalidate and deem unenforceable several patents held by Plaintiff, Defendant makes reference to a PCT application as a prior art document for application against the patents. This attempt was unsuccessful as the court held the PCT application was only effective as prior art on its publication (date).

ADVANCED CARDIOVASCULAR SYSTEMS, INC., Plaintiff, v. MEDTRONIC, INC., Defendant.

Nos. C-95-3577 DLJ, C-96-0942 DLJ

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

August 25, 1999, Decided
August 25, 1999, Filed

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JUDGES: D. Lowell Jensen, United States District Judge.

OPINIONBY: D. Lowell Jensen

ORDER

On August 11, 1999, the Court heard argument on plaintiff Advanced Cardiovascular Systems, Inc.'s ("ACS") motions for summary judgment of infringement and for summary judgment that the Yock patents are not invalid and are not unenforceable. Edward A. Mas appeared on behalf of ACS; Earnest Reveal appeared for defendant Medtronic, Inc. Having considered the arguments of counsel, the papers submitted, the applicable law, and the record in this case, the Court hereby GRANTS the motions.

I. BACKGROUND

A. Factual Background

ACS and Medtronic are companies engaged in developing, manufacturing, promoting, and selling medical devices, including catheters used in percutaneous transluminal coronary angioplasty ("PTCA"). These parties and others are currently involved in a complex series of patent infringement suits involving the treatment of heart disease with catheters.

Coronary artery disease is a disease of the heart in which a deposit, called a "stenosis," builds up in a coronary artery and restricts blood flow through the artery. Reduced blood flow can result in chest pain or heart attack. Coronary artery disease can be treated in one of two typical ways. In the first, a surgeon opens the patient's chest and grafts a vein or artery, usually taken from the patient's leg, onto the coronary artery, to provide a detour for blood to flow around a stenosis.

The less invasive PTCA procedure involves the insertion of a balloon dilatation catheter through an opening in the femoral artery. The catheter is then threaded through the aorta to a coronary artery, positioned across a stenosis, and inflated to compress the stenosis and stretch the artery wall thereby widening the path for blood flow through the coronary artery. A guide wire is used to navigate the twisting path through the arteries and to guide the balloon across the stenosis.

The patents-in-suit relate to rapid exchange catheters and a method for performing coronary angioplasty using such catheters. ACS has charged defendant with infringing four patents, all of which are licensed to ACS. The Yock patents (so named after the inventor, Paul G. Yock) consist of United States Patent No. 5,040,548 entitled "Angioplasty Method" (the " '548 patent"); United States Patent No. 5,061,273 entitled "Angioplasty Apparatus Facilitating Rapid Exchanges" (the " '273 patent"); and United States Patent No. 5,451,233 entitled "Angioplasty Apparatus Facilitating Rapid Exchanges" (the " '233 patent"). These patents claim their priority date from an original single parent patent application filed April 15, 1986. The fourth patent, the Horzewski-Yock Patent, United States Patent No. 5,496,346 (the " '346 patent"), is an improvement on the Yock rapid exchange catheter.

B. Procedural History

On October 10, 1995 plaintiff ACS filed its complaint against defendant Medtronic (C-95-3577). Plaintiff alleges that Medtronic's PTCA catheters willfully infringe the Yock patents, either directly or contributorily. ACS seeks injunctive and monetary relief, including treble damages and attorney's fees. On March 12, 1996, ACS filed an additional suit (C-96-0942) alleging willful infringement by Medtronic of the '346 patent. By the end of March that case had been related to the litigation pending in this Court. On March 16, 1999, the Court issued its claim construction for the patents at issue. On March 17, 1999, plaintiff filed a motion for summary judgment on Medtronic's affirmative defenses of invalidity. The Court denied the motion and granted Medtronic's cross-motion for leave to supplement its Response Chart. The Court subsequently struck part of the amended Response Chart as not in compliance with the Court's order.

ACS now moves for summary judgment of infringement with respect to claim 3 of the '233 patent. Medtronic has filed a notice of non-opposition to this motion. ACS has also moved for summary judgment that the Yock patents are not invalid and not unenforceable. Medtronic opposes this motion.

C. Legal Standard

Procedural matters not unique to patent law are decided by applying the law of the relevant regional circuit. See Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1278 (Fed. Cir. 1995).

The Federal Rules of Civil Procedure provide for summary adjudication when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(e).

In a motion for summary judgment, initially it is the moving party's burden to establish that there is "no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56 (c); British Airways Bd. v. Boeing Co., 585 F.2d 946, 951 (9th Cir. 1978). Subsequently, "if the party moving for summary judgment meets its initial burden of identifying for the court those portions of the materials on file that it believes demonstrate the absence of any genuine issues of material fact," the burden of production then shifts so that "the non-moving party must set forth, by affidavit or as otherwise provided in Rule 56, 'specific facts showing that there is a genuine issue for trial.'" T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n, 809 F.2d 626, 630 (9th Cir. 1987) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986)).

II. DISCUSSION

A. Infringement of Claim 3 of the '233 Patent

ACS has moved for partial summary judgment of infringement with respect to claim 3 of the '233 patent. ACS bears the burden of establishing infringement by a preponderance of the evidence. See Kegel Co., Inc. v. AMF Bowling, Inc., 127 F.3d 1420, 1425 (Fed. Cir. 1997). Literal infringement is shown where all the limitations of a claim are literally present in the accused device. See Jurgens v. McKasy, 927 F.2d 1552, 1560 (Fed. Cir. 1991).

Medtronic has filed a statement of non-opposition to the motion. Given the Court's claim construction, Medtronic believes that it cannot successfully oppose summary judgment at this time and wishes to have summary judgment entered to preserve its rights on appeal. ACS has met its burden of showing that the accused device contains each element of the claim. Accordingly, the Court grants summary judgement of infringement of claim 3 of the '233 patent.

B. Validity—Obviousness

ACS moves for summary judgment that Medtronic has failed to establish a prima facie case of obviousness and thus may not present an affirmative defense of invalidity on this ground at trial. This defense has been asserted against claim 3 of the '273 patent, claim 6 of the '548 patent, and claims 1-3 of the '233 patent.

1. Legal standard

Once issued, a patent is entitled to a presumption of validity. See 35 U.S.C. § 282. The party challenging the validity of an issued patent must come forth with clear and convincing evidence of invalidity. See Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1375 (Fed. Cir. 1986). The patent holder has no duty to come forward with evidence of validity until after the challenger has established a prima facie case of invalidity. See Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983). If "materials facts are disputed, and testimonial, documentary, and expert evidence are needed for their resolution, summary adjudication is not indicated." See Quad Envtl. Techs. Corp. v. Union Sanitary Dist., 946 F.2d 870, 872 (Fed. Cir. 1991)

A patent is invalid as obvious at the time of patenting where the subject matter would have been obvious to one with ordinary skill in the art familiar with the teachings of the relevant prior art. See Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151, 103 L. Ed. 2d 118, 109 S. Ct. 971 (1989).

Obviousness is a question of law, which is to be based on underlying factual findings. See Specialty Composites v. Cabot Corp., 845 F.2d 981, 989 (Fed. Cir. 1988). In Graham v. John Deere, 383 U.S. 1, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966), the Supreme Court set forth four factors to guide courts in evaluating the obviousness of a claimed invention. These factors are: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) whatever objective evidence may be present, such as commercial success, failure of others, and long-felt need. See id. at 17-18; see also Avia Group Int'l, Inc. v. L.A. Gear Cal., 853 F.2d 1557 (Fed. Cir. 1988).

2. Discussion

Medtronic alleges that there is a genuine issue of fact as to obviousness. Medtronic offers in opposition to summary judgment the references of Nordenstrom, Leary, Simpson, and Borisenko. However, the Court has previously ruled that Medtronic could not rely on the Simpson-Robert, Uthmann, Leary, or Borisenko references. Order of July 6, 1999 at 5.

Accordingly, Medtronic may not rely on these references in opposing summary judgment.

Although Medtronic makes repeated mention of the Bonzel references with respect to obviousness, implying that they are prior art, Medtronic also recognizes that under the U.S. Patent Code, the Bonzel references are not prior art against the Yock patents for the purposes of obviousness because of the rules governing the effective date as prior art of inventions developed outside the United States. The Yock patents have an effective date of April 15, 1986 for the purposes of determining prior art. The Bonzel '129 patent is not effective as prior art until its filing date, July 14, 1986. See 35 U.S.C. § 102(d); In re Hilmer, 57 C.C.P.A. 985, 424 F.2d 1108 (C.C.P.A. 1970). The Bonzel PCT application is not effective as prior art until its publication date of June 5, 1986. See id. The Bonzel Abstract was published in March 24, 1986. Medtronic concedes that the Yock patent was developed no later than early 1985. Thus none of the Bonzel references are effective as prior art over the Yock patents. Accordingly, the Court has not addressed the Bonzel references in context of the obviousness discussion. All that remains are the Nordenstrom references.

The Nordenstrom references consist of a series of articles published in 1962, 1964 and 1965. Art is prior if it was available before the claimed date of invention. See 35 U.S.C. § 103. ACS does not dispute that the Nordenstrom references pre-date the Yock patents.

Relevant art is that art "reasonably pertinent to the particular problem with which the inventor was involved," which "necessarily encompasses not only the field of the inventor's endeavor but also any analogous arts." In re GPAC, Inc., 57 F.3d 1573, 1577-78 (Fed. Cir. 1995). ACS contends that Nordenstrom is not relevant because the references are not pertinent to the problem of effective rapid exchange as addressed by the Yock patents. Medtronic contends that the Nordenstrom references are relevant prior art with respect to the issue of the use of a short tube to facilitate the exchange of one catheter for another.

ACS argues that this Court should be guided by the decision in Schneider (Europe) AG v. Scimed Life Systems, Inc., 852 F. Supp. 813, 835 (D. Minn. 1994), in which the trial court ruled that the Nordenstrom references were not prior art over the Bonzel '129 patent, which is a rapid exchange patent similar to the Yock patents. That court found that Nordenstrom did not teach the moving of the guide wire lumen into the interior of the balloon or the use of a guiding catheter. See id. at 836. These findings are persuasive.

In addition, the Nordenstrom references were before the patent examiner during prosecution of the Yock patents. Deference is due the examiner's decisions with

respect to prior art where the art was before the examiner when a decision as to validity was made. See American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir. 1984). After an initial rejection of the Yock claims as obvious over Nordenstrom with respect to the element of a guide wire lumen of at least 10 cm, the examiner was later persuaded by Yock's arguments that Nordenstrom did not suggest a lumen of such a minimum length that the proximal guide wire port remains within the guiding catheter throughout the procedure. Hansen Decl., Ex. 29 at A-217, A-245; Hansen Decl., Ex. 28 at B-62. Consistent with the examiner's decision is the acknowledgment of defendant's expert, Dr. Schwartz, that the element of having a longer guide wire lumen has certain benefits over a device with a lumen length shorter than about 10 cm. Hansen Decl., Ex. 42 at 116, 120.

It is not necessary to determine whether the Court should reject the patent examiner's conclusion that Nordenstrom was relevant, because even if the Court were to accept that Nordenstrom is relevant, Nordenstrom alone is insufficient to invalidate the Yock patents. As recognized by the District of Minnesota and the examiner, Nordenstrom does not teach the use of a guiding catheter or the moving of the guide wire lumen into the interior of the balloon, both of which are features of the Yock and Bonzel patents. Nor do the Nordenstrom references teach the use of a guide wire lumen of such a length that the proximal guide wire port remains in the guiding catheter during the procedure, a feature of the Yock patents.

At oral argument Medtronic argued at length that had the examiner been aware of arguments regarding the obviousness of the Bonzel patent in light of Nordenstrom made by ACS in patent litigation in Europe, the examiner would have evaluated the significance of Nordenstrom differently. This is an inequitable conduct argument, not an obviousness one. As discussed at greater length in the inequitable conduct portion of this order below, it is also an argument based on speculation about what the examiner might or might not have done and is not supported by the evidence. In addition, it relies on documents that the Court in its Order of July 6, 1999 specifically barred Medtronic from relying on in context of its obviousness defense. Finally, this argument does nothing to aid Medtronic in meeting its burden of establishing a prima facie case that all the elements of the Yock patents would have been obvious to a person of ordinary skill of the art conversant in the teachings of Nordenstrom alone.

Medtronic cannot establish invalidity by clear and convincing evidence. The new combination as a whole must have been obvious in light of the prior art. Medtronic cannot point to prior art references that address the entire combination of inventive elements, instead it is able to only address one sub-element of the inventive combination. With only the Nordenstrom references

available to make its claim of invalidity, Medtronic is not able to establish a prima facie case of the obviousness of the entire combination of elements and thus may not proceed to trial with this defense. Because Medtronic cannot meet its burden of establishing obviousness by clear and convincing evidence, summary judgment is granted as to Medtronic's affirmative defense of obviousness. This grant of summary judgment for ACS is applicable only in this case brought against Medtronic.

C. Validity--Inequitable Conduct

ACS moves for summary judgment on grounds that Medtronic cannot present a genuine issue of fact as to its claim that the '233 patent is not enforceable. Medtronic has pled inequitable conduct as both an affirmative defense and as a counterclaim for declaratory relief. In arguing that it has met its burden for establishing a genuine issue of fact, Medtronic sets forth four alleged acts that constitute the basis for its inequitable conduct claims:

(a) the failure to disclose the use of stiffened catheters in an interview with the Examiner, Fourth Am. Ans., P 52;

(b) the failure to disclose ACS's belief that the use of a short tube in the distal portion of the catheter to allow for exchange capabilities is obvious in light of the prior art, Fourth Am. Ans., P 58;

(c) the failure to disclose that the subject matter claimed in the '233 patent is the same as that claimed in the Bonzel '129 Patent, Fourth Am. Ans., P 55-58;

(d) the failure to disclose the fact and terms of the settlement agreement reached with ACS's competitor, Schneider (Europe) AG, Fourth Am. Ans., P 45-51, 55-58.

1. Legal Standard

An applicant for a patent owes a duty of candor and good faith to the Patent and Trademark Office ("PTO"). See 37 C.F.R. § 1.56. A patent may be found unenforceable as the result of inequitable conduct before the PTO where there was a misrepresentation or omission material to a determination of patentability with an intent to deceive or mislead the examiner. See Hebert v. Lisle Corp., 99 F.3d 1109, 1115 (Fed. Cir. 1996); Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 872 (Fed. Cir. 1988). Inequitable conduct must be proven by clear and convincing evidence. See id. Materiality and intent must be proven separately. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995).

Carelessness alone is not sufficient to establish an intent to deceive. See 863 F.2d at 873. The conduct, when viewed in light of all the facts, must be such as to indicate a level of culpability that warrants a finding of intent to deceive. See id. at 876.

Once the threshold showing of intent and materiality has been made, the district court must weigh the findings of materiality and intent in light of all the circumstances to determine whether they warrant a conclusion that inequitable conduct occurred. See Refac Int'l Ltd. v. Lotus Development Corp., 81 F.3d 1576, 1581 (Fed Cir. 1996) (citing Molins, 48 F.3d at 1178). As a general matter, "the more material the omission, the less evidence of intent will be required in order to find that inequitable conduct has occurred." Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). The ultimate determination of inequitable conduct is a matter for the Court to decide in the exercise of its equitable discretion. See Kingsdown Med. Consultants, 863 F.2d at 876.

2. Factual Background

In mid-1983 Dr. Bonzel conceived of a balloon dilatation catheter in which the guide wire lumen was comparatively short relative to the length of the inflation lumen to facilitate a rapid exchange of one catheter for another. DeMeules Decl., Ex. 3 at 9-10. On November 23, 1984, Bonzel filed a patent application on his design in Germany and shortly thereafter he disclosed the invention to Schneider (Europe) AG. DeMeules Decl., Ex. 5 at 2. In November of 1995, Bonzel filed an application under the Patent Cooperation Treaty, thereby preserving his right to claim priority internationally as of November 23, 1984. DeMeules Decl., Ex. 3 at 11. An application for a United States patent was not filed until July 14, 1986. Hansen Decl., Ex. 4.

Meanwhile, Dr. Yock conceived of his rapid exchange catheter design in early 1985. DeMeules Decl., Ex. 2 at 99-100; Ex. 38 at P 4. On January 9, 1986, Yock disclosed his invention to ACS. DeMeules Decl., Ex. 38 at P 4. Three months later, on April 15, 1986, Yock filed a patent application in the United States on his design. See id. at P 5. 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. See id. at P 4.

On August 9, 1988, Bonzel's patent issued as U.S. Patent No. 4,762,129 (the '129 patent). Hansen Decl., Ex. 4. Schneider subsequently sued ACS for infringement of the '129 patent. DeMeules Decl., Ex. 59. ACS filed a Notice of

Opposition with the European Patent Office in February of 1990. DeMeules Decl., Ex. 24. The opposition contended that Bonzel was not patentable in light of the Borisenko, Weikl, Nordenstrom, Dotter, and Gruntzig references. See id. ACS argued that the subject matter disclosed by Bonzel was limited to guide wire lumens which were only about as long as the balloon. See id. at 39-47.

On March 16, 1990, ACS filed a request for reexamination of Bonzel's '129 patent with the United States PTO. DeMeules Decl., Ex. 44. The request contended that the Bonzel patent was not valid in light of the prior art, citing to the Borisenko, Weikl, Fogarty, Dotter, Zeitler, Nordenstrom, Samson, and Hawkins references. Among other contentions, ACS argued that the key inventive element of Bonzel's catheter was the use of a short guide wire lumen to perform an exchange and that that element was taught by Nordenstrom. See id. at 16, 35. In affirming the '129 patent, the examiner noted that even though it might have been obvious in light of Nordenstrom to shorten the guide wire lumen, the combination would have led to the location of the lumen distal of the balloon. DeMeules Decl., Ex. 21 at 14-15. Instead the Bonzel patent ran the lumen through the balloon. See id. at 15. ACS had argued that it would have been obvious to move the guide wire lumen to the interior of the balloon and the proximal port proximal to the balloon. See id

Meanwhile Examiner Thaler was considering the Yock application in light of the Nordenstrom references. The examiner found the Yock claims obvious in light of Nordenstrom only with respect to the claim for a guide wire lumen of at least 10 cm. Hansen Decl., Ex. 29 at A-217. In distinguishing Nordenstrom, Yock argued that it did not suggest a relatively short guide wire lumen of at least 10 cm such that the proximal guide wire port remains within the guiding catheter throughout the procedure. See id. at A-245; Hansen Decl. Ex. 28 at B-62.

At an interview conducted in March of 1991, Yock demonstrated how the guide wire port remained in the guiding catheter when the guide wire lumen was at least 10 cm. DeMeules Decl., Ex. 12 at 272. One of the claimed advantages of this design was the reduction in the risk that a blood clot might form in the coronary artery on the exposed guide wire during the procedure. He also demonstrated the concept of push and argued that the longer guide wire lumen contributed to the patentability of the Yock design by improving pushability. See id. Among other benefits, the longer lumen reduced the potential for kinking, looping, and/or bowing of the guide wire, all of which negatively impacted the ability to maneuver the catheter through the arteries. The examiner reserved judgment on how critical the longer guide wire lumen was to the patentability of the design. Hansen Decl., Ex. 29 at A-224. He later allowed the claims.

On May 3, 1991, an infringement action filed by Schneider against ACS and its distributors in the United Kingdom was decided against ACS. Hansen Decl., Ex. 20. In finding infringement, that court noted that the inventive element of the Bonzel patent was in part the shortened guide wire lumen. See id. at 19. The court further ruled that the extension of the guide wire lumen from a length of approximately 5 centimeters to 17 to 25 centimeters was an improvement within the scope of the Bonzel patent. See id. The court found that the basis on which ACS sought to distinguish its catheter was an improvement not a variation. The specific improvement noted was the use in the ACS RX catheter of a guide wire lumen of such length that the proximal guide wire port remained in the guiding catheter and thus avoided problems of the kinking of the guide wire. See id. at 18.

Experts for ACS have admitted that the catheter design set forth in the Bonzel patent would permit a rapid exchange, although they contend that the short length could result in difficulty because of kinking, bowing, or looping of the wire. DeMeules Decl., Ex. 17 at 139-40. Yock has also conceded that there are similarities in that both patents have the guide wire exit the side of the catheter. DeMeules Decl., Ex. 18.

The Yock '548 patent issued on August 20, 1991. The claims stated that the guide wire lumen was at least 10 centimeters in length and was disposed inside the balloon or catheter walls. Hansen Decl. Ex 1; Order of March 16, 1991 at 25-27. The '273 patent was issued on October 29, 1991 with similar limitations.

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. DeMeules Decl., Ex. 52. ACS paid Schneider $ 22 million for a license under the Bonzel patent. Schneider and ACS also relinquished all right to continue pursuing claims of infringement with respect to the Yock and Bonzel patents against each other. See id.

On January 7, 1993, Bonzel asked the examiner to cancel certain claims previously made that read upon the Yock applications. DeMeules Decl., Ex. 64 & 55. In March 1994, Yock filed the application that become the '233 patent. Hansen Decl., Ex. 30. The Court has interpreted the '233 patent as disclosing a guide wire lumen that is short relative to the inflation lumen, which permits the performance of a rapid exchange. Order of March 16, 1999 at 23-24. Further, the Court held that the disclosure included at its "shortest extremity only those lengths that both (1) permit a rapid exchange over a guide wire that is of the standard length for use with the device during a particular procedure and (2)

ensure that the proximal guide wire port remains in the guiding catheter and outside the coronary artery during the procedure." Id.

During prosecution of the Yock application, Yock brought the Bonzel application to the examiner's attention. DeMeules Decl., Ex. 29 at A-71. Yock distinguished his design from the Bonzel application on grounds that the Bonzel application did not teach the step of "extending the [guide wire] sleeve at least 10 cm from the distal tip of the catheter or a substantial distance proximal from the balloon." Hansen Decl., Ex. 29 at A101-02. Yock acknowledged that both his design and the Bonzel design featured a relatively short guide wire lumen that extended through the interior of the balloon. DeMeules Decl., Ex. 29 at A-226. However, Yock argued that the 3 to 5 cm lumen of the Bonzel patent had fundamental problems and that commercial success was not achieved until the lumen was extended to a length of at least 10 cm. See id. at A-226-27.

3. Discussion

a. The Settlement Agreement and the Overlap of Bonzel '129 and Yock '233

Medtronic contends that the failure to inform the examiner of the settlement between Schneider and ACS constitutes inequitable conduct. Medtronic first claims that the failure to disclose the settlement is material because the settlement resulted in the avoidance of an "inevitable interference proceeding," which allegedly would have established the Bonzel patent's priority over the Yock claims. An interference is a proceeding for which the purpose is to determine which inventor has priority where more than one applicant seeks a patent on substantially the same subject matter. See 35 U.S.C. § 135; Minnesota Mining & Manufacturing Co. v. Norton Co., 929 F.2d 670, 674 (Fed. Cir. 1991). There is no basis in the record to support Medtronic's contention that an interference proceeding was on the horizon. Nor is there any basis on which a reasonable fact finder could conclude that disclosure of the terms of the settlement would have been material to the question of patentability.

What the evidence does show is that Yock continuously distinguished his design from the Bonzel claims on the basis that a longer guide wire lumen such that it remained inside the guiding catheter during the procedure had substantial benefits over the Bonzel structure. At some point, Bonzel attempted to redraft his claims to cover the design set forth in Yock's application. However those redrafted claims were withdrawn after the settlement. Medtronic contends this withdrawal was the result of a secret agreement to settle an "inevitable interference." This is sheer speculation. There is no evidentiary support for this proposition; however, there is substantial evidentiary support for the proposition that the settlement had nothing to do with an interference to establish priority.

The settlement came about after a United Kingdom court ruled that the ACS product infringed on the Bonzel patent and that the ACS product constituted an improvement on the Bonzel patent. The law of improvement patents is long and well-established. See Temco Elec. Motor Co. v. Apco Mfg. Co., 275 U.S. 319, 328, 72 L. Ed. 298, 48 S. Ct. 170 (1928). "[A] valid patent may issue for a nonobvious improvement on a prior patented invention, even though the improvement falls within the claims of that prior patent." Donald S. Chisum, Chisum on Patents, § 3.02[2] at 3-21 (1991), see also Rohm & Haas Co. v. Crystal Chem Co., 722 F.2d 1556 (Fed. Cir. 1983). "It is well established that an improver cannot appropriate the basic patent of another and that the improver without a license is an infringer and may be sued as such." Id.; see also Rolls-Royce Ltd. v. GTE Valeron Corp. 800 F.2d 1101 (Fed. Cir. 1986). Furthermore, "where an original machine and an improvement on it are both patented, neither patentee can use what does not belong to him, without the requisite authority from the owner." Blake v. Robertson, 94 U.S. 728, 733, 24 L. Ed. 245 (1876); see also Studiengesellschaft Kohle mb H v. Dart Indus., 549 F. Supp. 716, 746 (D. Del. 1982), aff'd 726 F.2d 724 (Fed. Cir. 1984).

The record supports the inference that the settlement came about upon a recognition that the Yock patents would be interpreted as an improvement on the Bonzel design and thus the two patents would block each other. This is distinct from a situation in which one patent entirely anticipates the other such that the two applications claim the same subject matter. There is no evidence in the record from which a reasonable inference could be drawn that Bonzel, or the patent examiner, believed or would be likely to believe, that the Bonzel design anticipated the ACS design and therefore rendered it unpatentable. Under the principles of improvement patents, the examiner was entitled to allow a patent whose claims were an improvement over a previously patented design, even if the older design might block the new design from being practiced.

Furthermore, this Court previously dismissed an identical theory of materiality for failure to state a claim upon which relief may be granted. Order of July 24, 1996. At that time, Medtronic alleged that ACS had acted inequitably when it failed to file a copy of the settlement agreement with the PTO. First, Medtronic contended that this failure violated 35 U.S.C. § 135(c), which requires that any settlement of an interference be disclosed to the PTO. The Court found that section 135(c) was not violated because the settlement was for a patent infringement suit, not a patent interference, and thus was not within the ambit of section 135 (c). Order of July 24, 1996 at 23-25. At summary judgment, Medtronic attempts to characterize the settlement as a global settlement of all disputes between Schneider (Europe) AG and ACS, including an alleged "inevitable interference." There is no evidence an interference was likely to have

occurred. Nor does the settlement, which is detailed with respect to which litigation it settles, mention an interference anywhere or contain language that indicates an interference was the subject matter of the settlement. Without such evidence, Medtronic's theory of materiality at summary judgment is identical to that previously rejected by the Court in the earlier motion to dismissIn the prior proceeding, Medtronic also argued that the failure to disclose the settlement violated the general duty of candor. At that time the Court ruled that the duty of candor was a generalized one that does not create a specific duty to disclose the settlement agreement. See id. at 24. As discussed above, there are no facts to support the conclusion that the settlement agreement was anything other than a valid settlement of a patent infringement action involving the Bonzel '129 patent. There is nothing in the terms of the settlement that would have caused the examiner to believe that the Bonzel reference rendered the Yock patent not patentable. The Bonzel reference was before the patent examiner, as was the fact that ACS had been sued for infringement of the '129 patent. DeMeules Decl., Ex. 28 at A-71, A-101-102, A-226, A-233. Disclosure of the terms of the settlement, which merely recite the litigation to be settled, the license terms, and the covenant not to sue each other, see DeMeules Decl., Ex. 52, would merely have been cumulative to information already before the examiner. Medtronic has not been able to present any facts that would support an inference that disclosure of the actual terms of the settlement would have materially affected the patentability determinations made by the examiner as to the Yock patents.

Medtronic also argues that the examiner would not have permitted Yock to broaden his claims, eliminating the specific lower bound of at least 10 cm in the '233 patent, had the settlement been disclosed. There is no support in the record for the contention that the specific length of 10 cm was the sole basis on which Yock had been distinguishing his design from Nordenstrom or Bonzel. Rather, as this Court found, the distinction was made functionally: thus, the Yock design featured a guide wire lumen of such a length that the proximal guide wire port remained in the guiding catheter during the procedure. Yock specifically argued to the examiner that of the catheters marketed by Schneider only its model with a guide wire lumen of longer than 10 cm had been commercially successful, largely because the proximal guide wire port remained inside the guiding catheter. Hansen Decl. Ex. 29 at A-251. Furthermore, when Yock did finally swear behind the Bonzel reference, the purpose was to overcome a rejection that was not addressed to the length of the guide wire lumen. Hansen Decl. Ex. 30, D-74. Rather the rejection was concerned with the procedure described and the claiming of an inflation lumen. See id. This record does not support an inference that the examiner considered Bonzel material to the issue of the guide wire lumen length. There is nothing about the terms of the settlement that would support an inference that their disclosure would have changed the examiner's view of Bonzel's relevance.

Related to this argument is Medtronic's contention that had ACS revealed to the examiner the fact that the '233 patent application's claims substantially overlapped the Bonzel '129 patent, the examiner's conclusions would have been materially altered. There is no support in the record for this argument. First, it ignores the fact that the length of the guide wire lumen in the '233 patent is functionally limited by the requirement that the proximal guide wire port remain in the guiding catheter, a limitation missing from Bonzel. Second, this argument is completely inconsistent with the law of improvement patents. Most importantly, the patent examiner had the Bonzel references before him during prosecution of the '233 patent and specifically made rejections based on those references. There is no basis on which to find an omission, much less a material one.

Medtronic cannot establish materiality with respect to the failure to disclose the specific terms of the settlement or the alleged overlap of the '129 and '233 patents. Nor is there any evidence that would support an inference that any such omission was intentional. Accordingly, summary judgment is granted as to these theories of inequitable conduct.

b. Inconsistent Positions Regarding Obviousness

Medtronic next contends that ACS acted inequitably by failing to disclose its view that Nordenstrom was prior art in the field of balloon catheters and that the Bonzel modifications to Nordenstrom of placing the proximal guide wire port proximal of the balloon and the guide wire lumen inside the balloon were obvious.

The first problem with Medtronic's argument is that it creates alleged inconsistencies by reading out of the record ACS's practice of distinguishing the Yock design from the Bonzel claims by reference to the fact that in the Yock design the guide wire lumen is of such a length that the proximal guide wire port remains inside the guiding catheter during the procedure. In the Bonzel design the guide wire lumen runs inside the balloon and exits proximally at the proximal end of the balloon, resulting in a lumen of 3-5 cm in length. DeMeules Decl., Ex. 24. In the Yock patent, the guide wire lumen extends for some distance proximal of the balloon before exiting the catheter body, resulting in a lumen of 10 or more cm in length.

ACS repeatedly contended, both in the U.S. and in foreign venues, that the Bonzel design was obvious over the prior art to the extent it moved the guide wire lumen inside the balloon. DeMeules Decl., Ex. 21 at 14-15. In making these arguments, ACS distinguished the Yock patent on grounds that extending

the guide wire lumen to such a length that the proximal guide wire port remained in the guiding catheter during the procedure resulted in significant therapeutic benefits over and reduced certain risks associated with the Bonzel structure with its shorter lumen. When the record is read in context, no inconsistency exists.

Furthermore, the examiner was fully aware that Yock considered his design to be patentable over Bonzel because of the guide wire lumen length specification of the Yock design. As discussed above, under the principle of improvement patents, Yock was entitled to distinguish his invention as an improvement over Bonzel, even if the two designs had strong similarities. Thus the fact that ACS argued that Bonzel was obvious does not support an inference of intent to deceive. The motion for summary judgement with respect to this claim of inequitable conduct is granted.

c. Interview with Examiner Thaler

Finally, Medtronic contends that Yock omitted a material fact during the March 1991 interview when he did not disclose that the demonstration catheter attained its greater pushability in part from the fact that it had been stiffened by its design construction. The catheter used in the demonstration was the same as that disclosed in the invention. There is nothing in the record to establish whether the examiner was or was not informed of the stiffened nature of the demonstration catheter. Medtronic bears the burden of establishing the facts that would support a defense of inequitable conduct on such a theory by clear and convincing evidence. An inference of intent cannot be generated from the absence of evidence. There is no evidence in support of this theory. Accordingly, summary judgment is granted.

4. Conclusion

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. ACS thus is entitled to summary judgment as to this affirmative defense and counterclaim. Accordingly, summary judgment that the Yock patents are not unenforceable is granted in the case against Medtronic.

III. CONCLUSION

For the foregoing reasons, the Court GRANTS summary judgment for ACS that claim 3 of the '233 patent is infringed. The Court also GRANTS summary

judgment against Medtronic that the Yock patents are not invalid and are not unenforceable.

IT IS SO ORDERED

Dated: August 25, 1999
D. Lowell Jensen United States District