United States District Court,
N.D. California.

**TARGET THERAPEUTICS, INC,**
Plaintiff.
v.
**SCIMED LIFE SYSTEMS, INC., and Cordis Endovascular,**
Defendants.

No. C-94-20775 RPA

**May 2, 1996.**

Jack W. Londen, Michael Dicke, Morrison & Foerster, San Francisco, CA.

Jeffrey R. Chanin, Michelle K. Lee, Keker & Van Nest, San Francisco, CA.

Gary H. Levin, Woodcock, Washburn, Kurtz, Mackiewicz & Norris, Philadelphia, PA.

**ORDER DENYING DEFENDANTS' MOTIONS FOR SUMMARY ADJUDICATION AS TO INVALIDITY; DENYING DEFENDANTS' MOTION FOR NONINFRINGEMENT; GRANTING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION; DENYING DEFENDANT'S MOTION FOR RELATED CASE; DENYING DEFENDANT'S MOTION FOR LEAVE TO AMEND ANSWER TO ADD CLAIMS; DENYING DEFENDANT'S MOTION TO JOIN ADDITIONAL DEFENDANT; DENYING VARIOUS PARTIES MOTIONS TO STRIKE DECLARATIONS**

**AGUILAR, Senior District Judge.**

Target Therapeutics, Inc. ("Target") brings a patent infringement suit against Defendants SciMed Life Systems, Inc. ("SciMed") and Cordis Endovascular Systems, Inc. ("Cordis"). The suit involves Target's patent no. 4,739,768 ("the '768 patent") for a microcatheter. Target's commercial embodiments of the patent are the Target Tracker and the Target FastTracker. Defendants' alleged infringing catheters are the SciMed Venture and Venture II and the Cordis Transit and RapidTransit.

## I. Background

A catheter is a tubular device which can be inserted into the canals, vessels or passageways of the body in order to insert or withdraw fluids or keep the passage open. The catheters at issue in the present case are used to travel deep into the human vasculature or blood vessels.

In 1986, Doctor Erik Engelson developed a new type of microcatheter. The Engelson catheter was designed to travel deep in the human vasculature to access sites which previous catheters could not. The new catheter could be effectively guided over a guide wire into some of the smallest regions of the vasculature in the

brain or liver. Accessing the smallest blood vessels in the brain or liver requires a catheter to be guided through small, intricate, tortuous vessels. Previous catheters were unable to effectively navigate the turns in the vasculature on their own. These catheters were also not effective with a guide wire, as they would force the guide wire out of the blood vessel because they were not sufficiently flexible.

Engelson's catheter was designed with multiple segments. The proximal end of the catheter was the stiffest and the distal end was extremely flexible. The flexibility of the catheter increased incrementally from the proximal end to the distal end. The extreme flexibility of the distal end allowed the catheter to track a guide wire through the small tortuous vasculature. The relative stiffness of the proximal end allowed the catheter to be pushed effectively into the vasculature from an external site.

The Patent and Trademark Office ("PTO") issued Engelson the '768 patent in 1988 which Engelson assigned to Target. In June 1993, Target initiated reexamination proceedings with the PTO. Any person, including the patent holder, can seek reexamination on the grounds that substantial new questions of patentability have been raised by prior cited art. In this proceeding, Target voluntarily dismissed the claims of its patent and submitted new substantially similar claims. The PTO accepted Target's new claims and issued a reexamination certificate in November 1994.

In addition, SciMed brought three separate reexamination requests to the PTO on the Target patent in August 1994, March 1995, and April 1995. The PTO consolidated all of the requests. A second reexamination certificate was issued on October 24, 1995 upholding the validity of the '768 patent.

Under the '768 patent, Target has developed the Tracker line of microcatheters. These catheters have been commercially successful and have vaulted Target from a small company into the leader of the field of interventional neuroradiology. The reason for the Tracker's commercial success is the significant advancement over the prior art catheters. In 1987, Doctor Grant Hieshima, an interventional neuroradiologist at the University of California San Francisco ("UCSF") and current expert for Cordis Endovascular, called the Target Tracker a catheter "unlike any other catheter manufactured today." He further stated that by using the Tracker he had been able to "complete embolizations that [he] would be unable to attempt with other catheters." Medical textbooks called the new variable stiffness microcatheters a "major revolution." A. Berenstein & P. Lasjaunias, 4 Endovascular Treatment of Cerebral Lesions in *Surgical Neuroangiography* at 197.

Defendants Cordis and SciMed have recently entered into the interventional neuroradiology field. Cordis's Transit line and SciMed's Venture line perform substantially the same function as the Target Tracker line in that they are able to successfully navigate small tortuous vasculature over a guide wire to reach a target site.

**II. Procedural History**

Target brought the present infringement action in 1994 charging that both the Transit and Venture lines infringed the '768 patent. The action was stayed by this Court pending the reexamination by the PTO of the '768 patent. That stay was lifted after the PTO issued its reexamination certificate in October 1995. Target immediately brought the present Motion for Preliminary Injunction asking the Court to enjoin the sale of the Transit and Venture lines during the suit. SciMed countered by bringing the present Motion for Summary Adjudication of Invalidity of the '768 patent in which Cordis joins. Cordis also brings its own Countermotion for Summary Adjudication of Non-Infringement. SciMed next brought a Motion for Severance in which Cordis joins. Target has filed a Counter-Motion to the Motion for Severance. Cordis

has sought Leave to Amend its Answer and Add Counterclaims. Cordis filed a Notice of Related Cases. Lastly all parties have filed motions seeking to strike portions of each others declarations.

**III. Motions for Summary Adjudication of Invalidity**

Summary Judgment or Summary Adjudication is appropriate where "there is no genuine issue as to any material fact and ... the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears "the initial responsibility of informing the district court of the basis for its motion." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). To satisfy this burden, the moving party must demonstrate that no genuine issue of material fact exists for trial. Id. at 322. However, the moving party is not required to negate those portions of the nonmoving party's claim on which the nonmoving party bears the burden of proof. Id. at 323.

Once the moving party demonstrates that there is no genuine issue of material fact, the nonmoving part must designate "specific facts showing that there is a genuine issue for trial." Id. at 324 (quoting Fed. R. Civ. P. 56(e)). The nonmoving party must "make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322.

However, there may be no genuine issue of material fact if "the evidence is of insufficient caliber or quantity to allow a rational finder of fact" to find for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 254 (1986). In some circumstances the factual context may render the nonmoving party's claim implausible, and the nonmoving party must come forward with "more persuasive evidence" to support the claim "than would otherwise be necessary." *Matsushita,* 475 U.S. at 587.

Both Defendants SciMed and Cordis ask the Court to find as a matter of law that the '768 patent is invalid. The courts have the power to declare a patent issued by the PTO invalid. However, the PTO is given deference due a qualified government agency and is presumed to have done its job correctly. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983). Therefore, a patent is presumed valid. 35 U.S.C. s. 282. The burden is on the party challenging validity to show by clear and convincing evidence, that the patent is invalid. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986), *cert. denied,* 480 U.S. 947 (1987). Because the patent is presumed valid, the patent holder need not prove the patent is valid, rather the onus is on the challenger to prove invalidity, failure to do so results in the patent being upheld. Stratoflex, 713 F.2d at 1534. If the patent challenger comes forward with evidence which was previously reviewed by the PTO in the patent application, then the burden on the challenger is high. American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984), *cert. denied,* 469 U.S. 821 (1984). Similarly, when a patent has been reexamined by the PTO, the burden on a party challenging the validity of a patent is more difficult to satisfy. E.I. du Pont de Nemours & Co. v. Poloroid Graphics Imaging. Inc., 706 F. Supp 1135, 1141 (D. Del. 1989).

Accordingly, "there runs this common core of thought and truth, that one otherwise an infringer who assails the validity of a patent fair upon its face bears a heavy burden of persuasion, and fails unless his evidence has more than a dubious preponderance." Radio Corp. v. Radio Engineering Laboratories, 293 U.S. 1, 8, 55 S.Ct. 928, 931 (1934).

**A. SciMed's Allegations**

**1. Indefiniteness:**

Under 35 U.S.C. s. 112, patent specifications must contain one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his or her invention. The Court must examine the claims to determine whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. Morton Int'l, Inc. v. Cardinal Chemical Co., 5 F.3d 1464, 1470 (Fed. Cir. 1993). "When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree" looking at whether one skilled in the art would understand what is claimed. Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826 (Fed. Cir. 1984). However, claims need only be "as precise as the subject matter permits." Hybritech, 802 F.2d at 1385; *see also* Georgia-Pacific Corp. v. United States Plywood Corp., 258 F.2d 124, 136 (2d Cir.) *cert. denied* 358 U.S. 884 (1958) ("If the claims, read in light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more") Whether or not a claim is indefinite is a determination for the trial court. Markman v. Westview Instruments, Inc., 116 S.Ct. 1384, 64 U.S.L.W. 4263 (1996).

SciMed claims that the patent language, "sufficiently flexible that ... [the catheter] must be guided with a guide wire" is indefinite. Specifically SciMed argues that whether or not a catheter is sufficiently flexible such that it must be passed over a guide wire depends on a variety of factors such as the path length, the number of turns and branches in the vasculature, the blood flow, and the type of disease encountered. SciMed argues that certain types of vasculature that fit within the definition of tortuous vasculature, as per the patent, are negotiable without a guide wire while others will require one. Further, whether a guide wire is required will also depend on the dexterity of the individual doctor. Therefore, SciMed asserts that the language "sufficiently flexible" as to require a guide wire is not objective enough for those with ordinary skill in the art to understand.

Target counters by first pointing out that the definition of tortuous path, as per the patent, necessarily includes vasculature which is small enough to be accessed only by guide wires under 18 mil. Thus, vasculature, which can be accessed by larger guide wires or without a guide wire, do not fit within the definition of "tortuous path". FN1 Target states that there is an acceptable standard of practice within the medical community such that a reasonable, prudent doctor would not attempt to enter these types of tortuous vasculature without a guide wire because of issues of safety and unnecessary risk to the patient. Target flatly asserts that neither the Transit nor the Venture can be guided into a tortuous vasculature without a guide wire, whether or not the tip has been steam shaped. Thus, according to Target, what is critical to the definition is what is proper procedure as understood by those in the art, not what is physically possible.

The Court accepts this analysis. A catheter which is sufficiently flexible that it must be guided with a guide wire is one which a prudent doctor, following acceptable standards of safety, would not insert without a guide wire because of dangers to his or her patient. While not a perfect definition, following *Hybritech,* the Court accepts that "sufficiently flexible" is as precise as the subject matter permits. Therefore, the Court determines as a matter of law that this claim is sufficiently definite to fall within the requirements of Section 112. Summary Adjudication is DENIED.

**2. Written Description:**

SciMed argues that the written description included in the original patent application does not describe the invention as per the claims issued after the reexamination. The law underlying their assertions states that the description of the invention in the specification must describe the invention as described in the claims. The

problem arises when, as here, the claims are changed in a reexamination proceeding. If the new claims do not fit within the ambit of the original description then the claims are invalid. In re Wilder, 736 F.2d 1516 (Fed. Cir. 1984) *cert. denied,* 469 U.S. 1209 (1985). Whether or not claims fit within the original patent's description requires claim construction and is a function of the trial court. Markman, 116 S.Ct. 1384, 64 U.S.L.W. 4263 (1996).

Here, the Examiner added the restriction "must be guided" to the new patent claims. The new claims teach an invention that is sufficiently flexible at its distal tip that it must be guided over a guide wire. SciMed argues that neither the specification nor the claims of the original application contained this "must be guided" restriction and thus that the new claims do not fit within the written description of the original patent.

This allegation is without merit. The original '768 patent is replete with references to a catheter which is to be used with a guide wire. The limitation that it "must be used" with a guide wire was adopted by the Examiner to distinguish this catheter from prior art catheters.

The Court finds as a matter of law that a claim for a catheter that "must be guided" over a guide wire fits within the description of a catheter that is "for use with a guide wire." The PTO Examiner inevitably agreed with this finding as it was the Examiner who reviewed this language and adopted it during the reexamination proceeding. The new claims fit within the original written description. Summary Adjudication is DENIED.

**B. Cordis's Allegations**

**1. Broadening of Claims**

It is improper to broaden claims during a reexamination proceeding. 35 U.S.C. s. 305. Whether claims have been enlarged during reexaminations is a matter of law for the court. Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1580 (Fed. Cir. 1995) *cert. denied* --- S.Ct. ---- (1996). If claims are broadened during reexamination, then the whole claim is invalid. Id. at 1582-83. Construing patent claims is the function of the trial court. Markman, 116 S.Ct. 1384, 64 U.S.L.W. 4263 (1996).

Cordis alleges that by removing the means language of a means-plus-function limitation in Target's patent claims, that the claims were broadened. Means-plus-function limitations are allowed under 35 U.S.C. s. 112, paragraph 6, which states that limitations, "may be expressed as a means or step for performing a specified function without the recital of structure, material or acts in support thereof and such claim shall be construed to cover the corresponding structure, material or acts described in the specification and equivalents thereof."

Target originally used "means" language in its patent, but dropped the word "means" from its description of the proximal and distal segments of the catheter after reexamination. The original '768 patent described "a relatively stiff proximal segment means for tracking the wire from the access site to a region adjacent the internal tissue." The claim, after reexamination, dropped the "means" language, but remained substantially similar. Target removed the "means" language for its description of the distal segment as well. Paragraph 6 acts as a limit to claims of a means-plus-function claim where the "claim sets forth a means for performing a specific function without reciting any specific structure for performing that function." Jonsson v. Stanley Works, 903 F.2d 812, 819 (Fed. Cir. 1990). Cordis asserts that removing the language expanded the patent to cover a relatively stiff proximal or distal segment of any type regardless of whether the structure or an equivalent was disclosed in the specification.

The Court disagrees with this interpretation. First, the means language only acts as a limitation where no structure is recited. *Id*. In the '768 patent in Claim 12, however, the catheter's structure is described as an "elongated tubular member having proximal and distal ends, an outer surface and an inner surface defining an inner lumen extending between those ends." Because the structure is disclosed, the means language does not operate as a limitation on the claim. Therefore removing that language did not change the scope of the claim.

Second, the Court accepts the determination of the PTO Examiner. In the reexamination proceedings by SciMed, SciMed brought up this exact point -- that removal of the means language necessarily broadened the claims. The PTO Examiner rejected that argument then and this Court rejects it now.

Cordis has failed to make a showing that removal of the "means" language broadened the claims of the patent. The Court rules as a matter of law that the patent claims have not been broadened. Summary Adjudication is DENIED.

**2. Fraud on the PTO**

Next, Cordis alleges that Target perpetrated fraud on the PTO. "A person sued for infringement may challenge the validity of the patent on various grounds, including fraudulent procurement." Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 176, 86 S.Ct 347, 350 (1965).

To show a prima facie case of inequitable conduct a party must produce "clear and convincing proof of: (1) prior art or information that is material; (2) knowledge chargeable to applicant of that prior art or information and of its materiality; and (3) failure of the applicant to disclose the information resulting from and an intent to mislead the PTO." FMC Corp. v. Manitowoc Co., Inc., 835 F.2d 1411, 1415 (Fed. Cir. 1987). Thus, the crux of the test for inequitable conduct is materiality. Information is material if a "substantial likelihood exists that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." Fox Indus., Inc. v. Structural Preservation Systems, Inc., 922 F.2d 801 (Fed. Cir. 1990).

The ultimate decision as to whether inequitable conduct has occurred is equitable in nature and thus given to the discretion of the trial court. Kingstown Med. Consultants v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988), *cert. denied* 490 U.S. 1067 (1989). However, summary judgment on the issue of inequitable conduct is "rarely" granted because of the difficulty in determining the intent of the parties at this level. KangaROOS U.S.A., Inc. v. Caldor, Inc., 778 F.2d 1571, 1573-74 (Fed. Cir. 1985). The record must demonstrate clear and convincing evidence of culpable intent in order to grant summary judgment. Demaco Corp. v. F. Von Langshoft Licensing Ltd., 851 F.2d 1387, 7 U.S.P.Q.2d 1222, 1228 (Fed. Cir.), *cert. denied* 488 U.S. 956 (1988).

Cordis charges that a demonstration to the PTO whereby Target was unable to pass a Tracker catheter through a 90 degree turn in a Lucite block without a guide wire was a fraud on the PTO. Cordis argues that Target was attempting to show that the Tracker was so flexible that a guide wire was required in order to pass it through a 90 degree turn. In fact, the turn could be negotiated without a guide wire by steam shaping the distal tip of the catheter. Cordis believes this demonstration to be a sham in which Target purports to show that the Tracker "must be guided with a guide wire" when, in fact, it does not require one.

Target, on the other hand, asserts that the test was merely to demonstrate to the Examiner how the guide wire could be used with a catheter, not to prove that a guide wire was required in order to negotiate a 90 degree turn in a Lucite block. In addition, Target points out that there is no proof that the Examiner used this demonstration in her consideration of whether to issue the patent. She makes no mention of the demonstration in her Notice of Intent to Issue Reexamination Certificate filed less than two weeks after the demonstration.

In order to obtain Summary Adjudication on Inequitable Conduct, Cordis is charged with demonstrating a material misrepresentation of information and the intent of Target to misrepresent. Cordis has failed on both counts to overcome the heavy burden of demonstrating clear and convincing evidence of inequitable conduct on the PTO. First, no evidence exists that the PTO Examiner relied on this demonstration in order to issue the patent. Second, Cordis has not shown that Target intended to mislead the PTO by virtue of the Lucite block demonstration. Summary Adjudication as to Inequitable Conduct is DENIED.

### 3. Obviousness and Anticipation

Lastly Cordis asserts that the patent is invalid as the invention was obvious or anticipated in light of the prior art.

In order to find, in summary judgment, that a patent was anticipated, the court must find that all the elements and limitations of the patent's claims are found in a single prior art reference. Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991). Cordis has failed to point the Court to any prior art which contained all the elements of the '768 patent. This allegation is without merit. Summary Adjudication is DENIED.

Whether or not an invention was obvious at the time of patenting involves a determination whether the invention would have been obvious to one with ordinary skill in the art to which the subject matter of the invention pertains at the time of the invention and in light of the teachings of the prior art. Bonito Boats Inc. v. Thunder Craft Boats Inc., 489 U.S. 141 (1989). The party supporting validity has no initial burden to prove validity, which is presumed by statute. The burden is on the challenger to the patent to demonstrate a prima-facie case of invalidity based on obviousness. Stratoflex, 713 F.2d 1530. Cordis has come forward with proffers of prior-art references which, Cordis alleges, make the '768 patent obvious. However, many of these references were already analyzed by the PTO Examiner during the patent prosecution and its various reexaminations. The Defendant is charged with producing prior art which is more relevant than that which was analyzed by the examiner in order to overcome the high burden on the challenger. American Hoist, 725 F.2d at 1359. E.I. du Pont de Nemours, 706 F. Supp at 1141.

In addition, the Court is suspect of a claim of obviousness when, as discussed above, the Tracker catheter was hailed by objective experts as a major revolution in the catheter field. The Tracker catheter has also enjoyed significant financial success. In light of these considerations, Target has amply proven a material factual dispute as to whether the '768 patent was obvious. Summary Adjudication on the issue of obviousness is DENIED.

## IV. Motions for Summary Adjudication of Noninfringement and Motion for Preliminary Injunction

Target moves for a Preliminary Injunction against the further sale of the alleged infringing Cordis and SciMed catheters. Cordis has moved for Summary Adjudication of Noninfringement on their Transit line of catheters. Cordis alleges that their catheters do not infringe the '768 patent as a matter of law. Because

infringement is a central issue in the determination whether to issue a preliminary injunction, the Court examines the issues of preliminary injunction and noninfringement together.

Target's '768 patent, in Claim 12, describes a catheter with three central elements: a) a catheter with three or more segments, b) a catheter with increased flexibility as one moves from the proximal end to the distal end, and c) a distal end which is so flexible that it must be used with a guide wire to access tortuous vasculature. The Defendants do not dispute that their products fit within the first two elements. However, both Defendants argue that their products do not meet the third element of the patent. According to Defendants, their products are capable of accessing tortuous vasculature *without* the use of a guide wire.

**A) Definition of a tortuous path**

The central inquiry in determining whether the products can access a tortuous path without a guide wire is: What is a tortuous path? Interpreting the language of the claims in a patent is within the exclusive province of the Court. Markman, 116 S.Ct. 1384, 64 U.S.L.W. 4263 (1996). The Court therefore looks to Column 6 of the '768 patent for a definition of a tortuous path. Column 6 defines a tortuous path as having the following characteristics: a) a path with a number of bends which may be 90 degrees or more; b) a path of small vessels typically less than about 3 mm. lumen diameters; c) a path length within the target tissue of at least 5 cm.; d) paths which branch off the proceeding vessel at angles greater than a right angle (as shown in patent figure 5); and e) paths consisting of vessels which are too delicate or tortuous for accessing by a guide wire significantly larger than 18 mil. Any vessel paths which do not contain all of these elements are not tortuous paths for purposes of the patent interpretation.

Target argues that because the patent's definition of tortuous paths includes the requirement that such vessels be too delicate to access with a larger than 18 mm. diameter guide wire that even if it may be physically possible to reach these vessels without a guide wire it may not mean that it is safe or reasonable to do so.

The Court finds this argument persuasive and agrees that the definition of "tortuous paths" necessarily includes issues of safety and reasonableness. Because of the delicate nature of the catheterization of a human being, safety issues are of the utmost importance. Therefore, a catheter which may be physically capable of limited catheterization of a path of less than three mm. lumen diameter over a path length of over five cm. without a guide wire will still infringe the '768 patent if it cannot be done in a medically safe and prudent manner. Target asserts that even if it is physically possible to use Defendants' catheters to reach tortuous sites without a guide wire that it would not be safe to do so under existing medical standards of practice.

With respect to the relevant standards of practice, Target points the Court to the testimony of specialists in the field of interventional neuroradiology. Doctor Fernando Vinuela, President of the American Society of Interventional Neuroradiology states that to access the tortuous vessels as defined in the patent a guide wire is required. He declares that he has not seen "one single institution or senior neuroradiologist utilizing these microcatheters in the brain in arteries of smaller than 3 millimeters without the use of a micro guide wire." Declaration of Dr. Fernando Vinuela, Regarding Reply Declaration and Videotape by Dr. Randall Higashida and Cordis at 2. He further states that for safety purposes that the use of a guide wire in connection with the catheters is required in order to decrease the possibility of dissection or damage to the arteries or blood vessels. Id.

Cordis and SciMed both counter that it is safe to navigate tortuous vasculature with their catheters without a

guide wire. Cordis has submitted evidence in the form of declarations and videos that purport to show their catheters accessing tortuous paths of small vessels of less than 3 mm. lumen diameter with lengths, within the target tissue, of at least 5 cm. and bends of greater than 90 degrees *without* a guide wire. Thus, Cordis asserts that because their products can access these vessels without a guide wire they do not infringe the patent.

In examining Cordis's claim, the Court looks to a videotape, submitted by Cordis, of two catheterization procedures of the brain which took place in March of 1996 at UCSF. In the video, Dr. Hieshima accesses sites in the brain using Cordis microcatheters without a guide wire. Said sites are purported to be accessed in vessels over five cm. long, involving turns of greater than 90 degrees in vessels less than three mm. in lumen diameter.

Target responds to Cordis's videotape with the videotape declaration of Dr. Vinuela. In the Target videotape Dr. Vinuela analyzes Dr. Hieshima's catheterization. Dr. Vinuela asserts that the vessels accessed by Dr. Hieshima were larger than 3 mm. lumen diameter because they were enlarged moments before by angioplastyFN2. He claims that the catheritization involved no selection of branch vessels because the microcatheter followed the natural pathway of the middle cerebral artery. These arguments bring into serious question whether these vessels fit within the definition of a tortuous vessel in the patent.

The Court finds two other points regarding these procedures which weigh against Cordis. First, in one of the procedures Dr. Hieshima resorted to the use of a guide wire with the Cordis catheter in order to access vessels beyond the area which had been embolized moments before. Second, the Court finds persuasive the declarations of Dr. Vinuela when he states that there was no reason not to use a guide wire in these procedures. He argues that by not using a guide wire, Dr. Hieshima is taking an unnecessary risk of significant damage to the cerebral artery. Even assuming, *arguendo,* that Dr. Hieshima had accessed a tortuous path without a guide wire (which has not been shown), Cordis has come forth with no convincing reasons why a reasonable, prudent doctor would want to access these vessels without a guide wire. The declarations have shown that accessing tortuous paths is made easier and safer with the use of a guide wire.

SciMed offers in its defense the declaration of Dr. Daniel Rufenacht which purports to demonstrate that the Venture catheter can access tortuous paths without a guide wire. Dr. Rufenacht claims that, in his procedures, he was able to steam-shape the tip of a Venture catheter to access "a tortuous path of at least 5 cm. through vessels of less than 3 mm. inner lumen diameter" without a guide wire. Declaration of Dr. Daniel A Rufenacht in Support of SciMed's Opposition to Target's Renewed Motion for Preliminary Injunction at 2. However, the definition of tortuous path under the '768 patent also includes the requirement that the vessels accessed must be too delicate to be accessed by a significantly larger-diameter guide wire than 18 mil. Target counters by arguing that the vessels accessed by SciMed's expert were vessels which are commonly safely accessed by guide wires of greater than 18 mil. If true, these vessels do not fit within the definition of "tortuous" under the patent.

Additionally, both Cordis and SciMed are hard pressed to escape from their own written words regarding the safe usage of their product. Despite their insistence to the contrary for purposes of this litigation, both Defendants have represented publicly that their products are for use only *with* a guide wire. Included with SciMed's Venture II catheter's instructions is the following passage: "The catheter is intended to be coaxially tracked over a steerable guide wire in order to access distal, tortuous vasculature." Cordis's RapidTransit catheters are "designed to be used with a steerable guide wire" according to the instructions included with the catheter.

Cordis and SciMed used much the same language in their written communications to the Food and Drug Administration ("FDA"). SciMed, in a response to questions from the FDA regarding their catheter, stated that the Venture is "intended to be tracked over a steerable guide wire" and that "[t]he infusion catheter is not torqued during the procedure, but rather is pushed over the guide wire." Cordis states even more bluntly in their 510(k) premarket notification to the FDA that "an infusion catheter is always advanced over a guide wire."

The Court is suspect of Defendants' current representations to the contrary. For now, despite the plain language Cordis and SciMed used before this litigation stating that their catheters are to be used with a guide wire in any procedure, Defendants wish the Court to find that their products can be used without a guide wire in the most delicate and tortuous paths of the human vasculature.

The Court finds that Cordis and SciMed have failed to show here that their products can safely and prudently access a tortuous path as defined in the patent.

**B) Preliminary Injunction**

The Court looks at four factors when determining whether to issue a preliminary injunction: (1) whether the movant has sufficiently established a reasonable likelihood of success on the merits; (2) whether the movant would suffer irreparable harm if the injunction were not granted; (3) whether the balance of hardships tips in the movant's favor; and (4) what impact, if any, will the injunction have on the public interest. Intel Corp. v. ULSI Sys. Technology, Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993) *cert. denied* 114 S.Ct. 923 (1994). This Court is required to make findings of fact to support the granting or denial of a preliminary injunction. Nutrition 21 v. U.S., 930 F.2d 867, 869 (Fed. Cir. 1991).

Examining the first factor, it is incumbent upon the patentee to show reasonable likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement. *Id.* As to validity, the patent owner needs to make a "clear showing that the patent is valid and enforceable." Atlas Powder Co. v. Ireco Chemicals, 773 F.2d 1230, 1233 (Fed. Cir. 1985). Target has made such a showing. Above, the Court found that none of the Defendants' attacks on the '768 patent's validity were strong. Given the presumption of validity given to patents under federal law, the failure of Defendants to successfully attack that presumption here, and the numerous reexamination proceedings before the PTO, the Court finds that the patent's validity and enforceability are likely to be upheld on the merits.

As to infringement, the Court finds that Cordis and SciMed have failed to show that their products can safely access a tortuous path (as defined in the patent) without a guide wire. Cordis and SciMed admit that their products can access these sites with a guide wire. It follows that a jury looking at infringement could find that the Defendants' catheters cannot access tortuous sites without a guide wire, yet can access them with a guide wire. If true, the Defendants' catheters *must* be guided with a guide wire, a central element of the '768 patent. Plaintiff Target has therefore made a clear showing that Defendants' catheters meet all three of the elements of Target's patent, described above. Accordingly, the Plaintiffs have demonstrated a high probability of success on the merits as to the issue of infringement. This finding does not foreclose Cordis or SciMed from demonstrating at trial that their product can in fact safely traverse a tortuous path without a guide wire. However, Target has shown a high likelihood of success on the merits.

Second, the Court looks to see whether there is irreparable harm to the patent holder by virtue of the

infringing product being on the market. The Federal Circuit has stated that where there has been a strong showing of validity of the patent and a continuing infringement of that patent that immediate irreparable harm is presumed. Smith Int'l., Inc., v. Hughs Tool Co., 718 F.2d 1573, 1581 (Fed. Cir. 1983) *cert. denied* 104 S.Ct. 493 (1983). The right granted by a patent is the right to exclude others. If there is a strong showing of validity and continuing infringement, that right is being subrogated and immediate injury is found. *Id.* Again, there has been a strong showing of validity of the patent and Defendants continue to sell products which seem to infringe Target's catheters. Accordingly, per *Smith,* immediate irreparable infringement is presumed.

Third, the Court balances the comparative hardships which would accrue to the patent holder or the alleged infringers if the injunction was or was not issued. The courts will normally grant relief against the alleged infringer when there is a high probability of success on the merits unless the balance of hardships tips decidedly in favor of the defendant. Hybritech Inc. v. Abbott Laboratories, 849 F. 2d 1446, 1457-58 (Fed. Cir. 1988). Here, Cordis and SciMed believe that the balance of hardships tips decisively in their favor because an injunction will bar them from competing in this lucrative market and destroy their substantial investment of time and resources. However, SciMed and Cordis entered into this market with full knowledge of the Target catheters and the '768 patent. Internal SciMed documents demonstrate that the design of the Venture catheter was completed at least in part by copying certain traits and aspects of Plaintiff's Tracker catheter. Cordis was aware of the Target Tracker and '768 patent while designing their catheter. The Federal Circuit has stated that "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 n.12 (Fed. Cir.) *cert. denied* 106 S.Ct. 3275 (1986). *see also* Laitram Corp. v. Rexnord, Inc., 15 U.S.P.Q.2d 1161, 1175 (E.D. Wis. 1990) *rev'd on other grounds* 939 F.2d 1533 (Fed. Cir. 1991) ("The loss of customers of business built upon the sale and use of infringing products does not amount, in the context of a patent infringement suit, to irreparable harm"). In the instant case, the balance of hardships does not tip heavily, if at all, in Defendants' favor.

Lastly, the Court looks at whether the public interest will be harmed if the Defendants are enjoined from selling their products. Defendants urge the Court to find that if their products are removed from the market that the public safety will be jeopardized because their life-saving products will be unavailable. There is case law stating that a preliminary injunction might be improper, as against the public interest, if it is shown that the infringing life-saving medical devices are clearly superior to the patented medical device. Datascope Corp. v. Kontron Inc., 786 F.2d 398 (Fed. Cir. 1986). However, no such showing has been made here. It is not sufficient for the Defendants to allege that some doctors prefer their devices over the plaintiff's devices. All parties submit declarations which purport to demonstrate that their products are superior to each others catheters. However, no party has shown that their product is *clearly* superior to the other parties' products.

Microcatheters will still be available should an injunction issue. Target was able to fill all of the demand for catheters before the Defendants entered the market. There is nothing to suggest that they will be unable to meet the demands of the market if the Defendants are enjoined from marketing their products. These microcatheters are important life-saving devices and the Court does not enjoin the sale of some of these devices without good cause. However, Defendants have failed to show that their catheters are superior to Plaintiff's catheters. Therefore, the public interest tips in favor of protecting the patent holder from infringing products. Hybritech, 849 F.2d at 1458.

Good cause appearing therefore, the Court makes the following orders:

1) Plaintiff Target's Motion for Preliminary Injunction is GRANTED.

2) Defendant Cordis is ENJOINED from selling or marketing their Transit or RapidTransit catheters during the pendency of this litigation.

3) Defendant SciMed is ENJOINED from selling or marketing their Venture or Venture II catheters during the pendency of this litigation.

4) Pursuant to Rule 65(c), Plaintiff Target is ORDERED to file a bond with the Clerk of this Court in the sum of One Million Dollars ($1,000,000) for the payment of such costs and damages as may be incurred or suffered by either Defendant who is found to have been wrongfully enjoined or restrained. The amount of this bond represents significantly less than 10% of Target's gross annual revenue for the sales of microcatheters based on the '768 patent. This Temporary Restraining Order shall not become effective until such time as this security is filed.

5) Cordis's Motion for Summary Adjudication of Non-Infringement is DENIED.

**V. Cordis's Motion to Join Cordis Corporation**

Cordis moves to join Cordis Corporation, its parent company, pursuant Fed. R. Civ. P. 19(a). Cordis argues that the presence of Cordis Corp. is necessary to just adjudication.

Federal Rule of Civil Procedure 19(a) allows joinder of persons if 1) in the person's absence complete relief cannot be accorded among those already parties, 2) that person has such an interest that to not join that person would impede protection of his interests, or leave the present parties open to the possibility of multiple liability.

Cordis seeks to join Cordis Corporation based on Cordis Corporation's ownership of patents in another action against Target, *Cordis Endovascular Systems v. Target Therapeutics, Inc.,* C 95-03516. However, Cordis Corporation does not own the '768 patent at issue in the instant case. Nor has Cordis shown that Cordis Corporation has any other relevance to the present case. The Court DENIES Cordis's motion to join Cordis Corporation.

**VI. Cordis's Motion to Relate Case**

Cordis files an Amended Notice of Related Case pursuant to Civil L.R. 3-12(a). Cordis wishes to relate *Cordis Endovascular Systems v. Target Therapeutics, Inc.,* C 95-03516, to the instant case. In C 95-03516, Cordis alleges that Target has infringed three of Cordis's microcatheter patents.

Target opposes relation of these cases. It argues that the parties differ, as C 95-03516 involves Cordis Corporation, parent of Cordis Endovascular, which is not a party to this action. Target further argues that the technology at issue in the cases differs. C 95-03516 deals with cardiological catheters, which are of a different construction than the microcatheters involved in the instant case.

Two or more actions can be related when all concern: 1) some of the same parties and similar claims; 2) some of the same property or events; 3) the same facts and questions of law; or 4) when both would likely duplicate labor, or create conflicts and unnecessary expense, if heard by different judges. Civil L.R. 3-12(b).

While some of the parties in the instant case are the same as the parties in the C 95-03516 action, the other action involves parties not present here. The catheters at issue in the present case are significantly different from the catheters at issue in the other action. Lastly, there is no evidence that judicial effort would be duplicated or conflicts would be created if the cases are heard by different judges. The Court DENIES the relation of these cases.

**VII. Cordis's Motion to File Supplemental Answer and Counterclaims**

Cordis has moved to add claims and counterclaims in a supplemental answer. The claims are: A) for declaratory judgment that the Engelson Patent is invalid; B) for antitrust violations; and C) three counterclaims for infringement of Cordis's patents by Target.

**A. Declaratory Judgment**

"In the case of actual controversy within its jurisdiction ... any court of the United States ... may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. s. 2201(a). If the controversy falls within the subject matter jurisdiction requirements of the federal courts, relief may be granted. However, there is nothing automatic or obligatory requiring a federal court to hear a declaratory judgment action. Wilton v. Seven Falls Co., 115 S.Ct 2137, 2143 (1995). The "district court is authorized, in the sound exercise of its discretion, to stay or to dismiss an action seeking a declaratory judgment before trial" *Id*. "By the Declaratory Judgment Act, Congress sought to place a remedial arrow in the district court's quiver; it created an opportunity, rather than a duty, to grant a new form of relief to qualifying litigants." *Id*. As discussed above, the Court finds that there is a strong showing of validity of the patent. Entertaining a declaratory judgment motion as to invalidity would serve no purpose at this point in the litigation. The Court DENIES the motion to add a claim for declaratory judgment as to invalidity.

**B. Sherman Act Violation**

Cordis accuses Target of violation of section 2 of the Sherman Act. Cordis claims that Target is attempting to monopolize the microcatheter market by the enforcement of the patent. The Court has found that the likelihood of success on the merits as to validity is strong. If the validity of the patent is upheld at the trial, Cordis's allegations of monopolization by Target under the patent will be moot. Adding antitrust claims at this time would only serve to confuse the jury. The Court considers these counterclaims as permissive counterclaims under Fed. R. Civ. P. 13(b). Leave to amend the answer to add these claims is DENIED.

**C. Counterclaims for infringement of Cordis's patents**

Cordis wishes to add three counterclaims against Target, for infringement of Cordis's own patents by Target. These counterclaims are presently the subject of C-95-03516 before Judge Orrick, which Cordis has moved to relate to the instant case. Relation has been denied above. In the alternative Cordis argues that they should be allowed to add these claims to the current action. Cordis argues that its parent, Cordis Corporation, only granted it the patents on September 27, 1995. At that time the Court had stayed the instant case. As Cordis could not then add the claims, it filed a separate action. Cordis will dismiss that action if granted leave to supplement its answer. Cordis further argues that allowing the additional claims will serve judicial efficiency. It states that all the claims will involve similar evidence, as both cases involve the patent infringement of catheters.

Target objects. Target counters that the claims are unrelated to the instant action. The catheters involved in

C-95-03516 are cardiological catheters, which involve a different construction than microcatheters for the brain. Expert evidence on each will therefore vary greatly. Target also argues that these patent counterclaims were obvious at the outset of this action, and so should have been brought at that time.

As these claims are the subject of another pending lawsuit and involve different types of catheters, the Court DENIES Cordis's motion for leave to add these additional counterclaims.

**VIII. Target's Countermotion to Stay Discovery**

Target has moved to stay discovery for Cordis's antitrust claim against Target. As the Court has denied Cordis leave to add these claims, this issue is moot. Cordis shall not conduct discovery as to antitrust claims in connection with this action. A limitation of discovery in this area does not restrict discovery of evidence of the patent's invalidity for issues not decided here.

**IX. Motions to Strike Declarations**

All parties have filed motions to strike certain declarations as contrary to the Federal Rules of Evidence and Federal Rules of Civil Procedure. The Court DENIES all Motions to Strike Declarations. The Court has considered only those Declarations which were relevant and which complied with the Federal Rules of Evidence and Federal Rules of Civil Procedure.

**X. Motions to Sever and Consolidate.**

An order on SciMed's and Cordis's Motions to Sever and Target's Motion to Consolidate will be forthcoming from the Court.

IT IS SO ORDERED.

FN1. The patent's definition of tortuous path is delineated below in section IV. This definition includes the issues of safety.

FN2. Angioplasty is a procedure whereby a catheter is inserted into a blood vessel with a small balloon attached to the distal end. The balloon is inflated to embolize the vessel and increase blood flow.

N.D.Cal.,1996.
Target Therapeutics, Inc. v. SciMed Life Systems, Inc.