Abstract
The international filing date is considered the U.S. national filing date with 35 USC 102(e) exceptions (circa. 1994).

SCHNEIDER (EUROPE) AG and SCHNEIDER (USA) INC., Plaintiffs, v. SCIMED LIFE SYSTEMS, INC., Defendant.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA, THIRD DIVISION

March 4, 1994, Decided

COUNSEL:

For Plaintiffs: SHEA & GOULD by John E. Kidd, John B. Grant, Jr., Leora Ben-Ami, Annette M. McGarry, and Arthur M. Peslak, and PENNIE & EDMONDS by Gidon D. Stern, and MASLON, EDELMAN, BORMAN, & BRAND by Gary J. Haugen.

For Defendant: FISH & NEAVE by Robert C. Morgan, Thomas L. Giannetti, Mark H. Bloomberg, Kristin H. Neuman, and Brenda J. Panichi, and POPHAM, HAIK, SCHNOBRICH, & KAUFMAN, LTD. by Wayne G. Popham.

JUDGES: ALSOP

OPINIONBY: DONALD D. ALSOP

OPINION:

FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER

Based on the evidence presented at trial, the oral and written arguments of counsel, and all the files, records, and proceedings herein, the Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

I. Background Facts

A. Nature of the Action and the Parties

1. This is a patent infringement action with federal jurisdiction based upon 28 U.S.C. § 1338(a) (1988 & Supp. 1993). Venue is proper pursuant to 28 U.S.C. § 1400(b) (1988 & Supp. 1993).

2. Plaintiff Schneider (USA) Inc. is a corporation organized and existing under the laws of the State of Minnesota and having its principal place of business in Plymouth, Minnesota. Plaintiff Schneider (Europe) AG is a corporation organized and existing under the laws of Switzerland and having its principal place of business in Bulach, Switzerland.[1]

3. Defendant SciMed Life Systems, Inc. ("SciMed") is a corporation organized and existing under the laws of the State of Minnesota and having its principal place of business in Maple Grove, Minnesota.

4. U.S. Patent No. 4,762,129 originally issued on August 9, 1988 (" '129 patent"). Subsequently, the '129 patent was subject to a reexamination proceeding in the Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. § 304 (1981 & Supp. 1993). At the conclusion of the proceeding, Reexamination Certificate BI 4,762,129 (" '129 reexamination certificate" or "reexamination certificate") was issued on July 2, 1991.[2]

5. Plaintiff Schneider (Europe) AG is the exclusive licensee of the '129 patent and the '129 reexamination certificate under a license agreement with the patentee, Dr. Tassilo Bonzel. Plaintiff Schneider (USA) Inc. is a licensee of Schneider (Europe) AG under the '129 patent and the '129 reexamination certificate. See Schneider (Europe) AG and Schneider (USA) Inc. v. SciMed Life Systems, Inc., No. 3-91 CIV 241, slip op. at 11 (D. Minn. May 14, 1993) (Alsop, J.) (setting forth relationship and rights between Schneider (Europe) and Schneider (USA) under the license agreement).

6. Schneider filed suit against SciMed on April 23, 1991, alleging that, by making, using, and selling its EXPRESS TM dilatation catheter, SciMed wilfully infringed the '129 patent. Schneider seeks damages, increased damages, and attorney fees. Schneider also seeks a permanent injunction enjoining SciMed from manufacturing and selling the EXPRESS TM.

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[1] The Court will refer to the Plaintiffs jointly as "Schneider."

[2] For convenience, the Court will refer to the '129 patent and the '129 reexamination certificate collectively as "the '129 patent" in this Order. Schneider's claim for infringement is actually based on the claims in the reexamination certificate.

7. Schneider amended its complaint on October 16, 1992 to specifically allege that SciMed's actions in connection with its new dilatation catheter, the RALLY TM, infringe the '129 patent.

8. On June 11, 1993, Schneider moved for a preliminary injunction to prevent SciMed from making, using, or selling the RALLY TM in the United States. That motion was subsequently withdrawn and then renewed at trial. Schneider now seeks a permanent injunction enjoining SciMed from manufacturing and selling the RALLY TM. B. Background of the Invention.

9. The '129 patent relates to a medical device, referred to as a "balloon dilatation catheter," which is used for treating coronary artery disease. A balloon dilatation catheter is a long, thin, plastic tube with an expandable balloon near its tip. The end of the catheter where the balloon is located is referred to as the "distal" end, while the opposite end is called the "proximal" end. During use, the proximal end of the catheter is adjacent the physician and the distal end is inside the patient's body near the heart.

10. The coronary arteries supply blood to the heart, carrying nutrients and oxygen to heart muscle tissue. Coronary artery disease results from fatty plaque deposits on the interior surfaces of the artery. These deposits (or "lesions") cause a reduction in the area available for blood to flow through the artery. The areas where these deposits form are referred to as "stenoses."

11. A procedure, known as "angioplasty," is used to open up the lesions with a guiding catheter, a guide wire, and a balloon dilatation catheter. A Percutaneous Transluminal Coronary Angioplasty ("PTCA") procedure is a special angioplasty procedure that is a less invasive alternative to coronary artery bypass surgery. PTCA procedures are performed by specialists known as "interventional cardiologists." Interventional cardiology is a medical specialty dealing with interventional procedures in the heart. This speciality is distinct from radiology or vascular surgery.

12. PTCA was first performed in a human by Dr. Andreas Gruntzig in 1977. Dr. Gruntzig was the first person to discover that a balloon dilatation catheter could be used for angioplasty in the coronary arteries if the balloon is constructed from inelastic material.

13. A PTCA procedure is begun by inserting a guiding catheter into the femoral artery in the patient's groin area. The guiding catheter is a long, hollow, plastic tube that serves as a tunnel from the patient's groin to the coronary arteries. The guiding catheter is passed through the vasculature from the groin area up

through the aorta to the entrance of the coronary arteries. The entrance to the coronary arteries is called the "ostium."

14. Dr. Gruntzig developed the first balloon dilatation catheter, which became known as a "fixed-wire" catheter ("FWC"). When a FWC is used in a PTCA procedure, the catheter is inserted directly through the guiding catheter up to the entrance to the coronary arteries. The dilatation catheter is then pushed beyond the end of the guiding catheter and into the coronary arteries. During this time, an X-ray device called a "fluoroscope" is used by the cardiologist to monitor the position of the dilatation catheter. The dilatation catheter is then positioned so that the deflated balloon is located at the stenosis. At that point, liquid is injected into the catheter and the balloon is inflated. Inflation of the balloon causes a compression force on the stenosis that cracks the stenosis and stretches the artery. Normal blood flow through the artery is thereby restored.

15. The next major advance in PTCA occurred in 1978 with the development of what became known as the "over-the-wire" catheter ("OTW"). This advance has been generally attributed to Dr. John Simpson and Dr. Edward Robert. In an OTW catheter, the dilatation catheter contains two internal tubes that run the length of the catheter. One tube, the "inflation lumen" (or "inflation tube"), is connected to the interior of the balloon and is used to inflate the balloon. The second tube, known as the "guide wire lumen" (or "guide wire tube"), receives an independently moveable guide wire.

16. In November 1984, there were three predominant manufacturers of OTW catheters. Advanced Cardiovascular Systems ("ACS") made the catheter originally designed by Drs. Simpson and Robert. In the ACS OTW catheter, the guide wire tube is located inside the inflation tube in a "coaxial" construction. The other two major manufacturers of OTW catheters in 1984 were Schneider Medintag (a predecessor company to Plaintiff Schneider (Europe)) and the USCI division of C.R. Bard ("Bard"). Both Schneider Medintag and Bard sold OTW catheters in which the guide wire tube was laterally displaced from the inflation tube. This design is referred to as a "dual-lumen" construction.

17. The standard-length guide wire used with OTW catheters in November 1984 was about 175 centimeters. The typical length of OTW catheters available in November 1984 was about 135 centimeters.

18. When a cardiologist uses an OTW catheter, the guide wire is placed into the guide wire lumen of the OTW catheter prior to insertion into the guiding catheter. The OTW catheter and guide wire are inserted together and advanced to the tip of the guiding catheter. Next, the guide wire is advanced independently and located at the stenosis. This part of the procedure is difficult and time-

consuming. As a result, the majority of cardiologists in November 1984 believed that, once proper guide wire placement was achieved, it was highly desirable to maintain the guide wire in place, across the stenosis. After the guide wire is located at the stenosis, the OTW catheter is advanced along the guide wire until the balloon is located at the stenosis. If the balloon is the correct outside diameter to fit through the stenosis, the balloon is expanded by injecting inflation fluid through the inflation lumen. The stenosis is thereby expanded and normal blood flow is restored through the artery.

19. During a PTCA procedure, it is sometimes necessary to exchange the dilatation catheter for a second catheter with a different diameter balloon. For example, exchange is necessary if the balloon on the original catheter is either too large to fit through the stenosis in its uninflated state or its inflated diameter is too small to properly expand the stenosis.

20. Due to the difficult and time-consuming procedure of locating the guide wire at the stenosis, the typical interventional cardiologist in 1984 preferred to leave the guide wire in place during a catheter exchange. In order to do so, the operator needed to hold the end of the guide wire that extended from the patient throughout the exchange process. Because of the length of the standard guide wire compared to the OTW catheter, a cardiologist who tried to withdraw the OTW catheter would lose the end of the standard-length guide wire.

21. Prior to November 1984, the typical interventional cardiologist faced with the problem of exchanging an OTW catheter had three basic options. First, the dilatation catheter and guide wire could both be withdrawn together. Then, the entire procedure described above could be repeated with the second OTW catheter and guide wire. The second option was for the cardiologist to use an exchange wire. The standard wire is removed before the exchange wire is used. The typical exchange wire is 300 centimeters long and is inserted into the OTW catheter that needs to be exchanged. The old OTW catheter is withdrawn and a new OTW catheter is inserted over the exchange wire. The proximal end of the exchange wire typically extends to the ankles of the patient. Therefore, a second operator is needed to hold the end of the wire while the dilatation catheters are exchanged. In addition to being awkward and time-consuming, this option is problematic because the end of the wire sometimes falls off the table and becomes contaminated. Another problem is that the exchange wire can injure the operators if it "springs up" during the procedure. The third option involves starting the procedure with a 300 centimeter wire, as described by Kaltenbach, rather than with a standard-length wire. The benefit of this option is that, should an exchange become necessary, a long wire is immediately available. The third option, however, suffers from the same disadvantages as the second option. Beginning in 1986, a fourth option was practiced, which involved using an

"extension" or "docking" wire. These are wires which are attached to the proximal end of the standard-length guide wire when an exchange becomes necessary. The total length of the extension and standard-length guide wire is about 300 centimeters. Balloon catheter exchange over the extension wire created difficulties. The second, third, and fourth options discussed above involve modifying the guide wire. They do not involve modifying the configuration of the OTW dilatation catheters, which had full-length inflation and guide wire lumens.

22. The conventional, prevalent view among the majority of cardiologists in November 1984 was that it was necessary for an OTW catheter to have a full-length guide wire lumen. The full-length lumen provided advantages which were considered important. First, the full-length guide wire lumen was used to measure blood pressure through the distal end of the catheter after a PTCA procedure to determine if the procedure was successful. Second, the full-length guide wire lumen was used to inject dye into the coronary artery through the distal end of the catheter to view the stenosis on an X-ray. Third, the cardiologist preferred to have the ability to leave the dilatation catheter in place while withdrawing the guide wire, reshaping its tip, and reinserting the guide wire. None of these capabilities were available on a catheter without a full-length guide wire lumen.

C. The '129 Patent

23. The '129 patent is entitled to a priority date of November 23, 1984. On that date, Dr. Tassilo Bonzel filed his priority patent application in the Federal Republic of Germany. Subsequently, on November 15, 1985, a Patent Cooperation Treaty application was filed designating the United States. Under 35 U.S.C. § 363 (1981 & Supp. 1993), this date is deemed to be the filing date of the '129 patent in the United States. The United States application was perfected on July 14, 1986 and assigned application number 893,558. The '129 patent issued on August 9, 1988.

24. The claims of the '129 patent cover a dilatation catheter and the method of using that catheter. The dilatation catheter claimed in the '129 patent represents a major improvement over the conventional OTW catheters that were available in November 1984. It allows for rapid exchange of the catheter by a single cardiologist using a standard-length guide wire, while the guide wire remains in place with its distal end across the stenosis.

25. The '129 patented device is within a distinct market segment. This segment is called interchangeably, "SOE", "rapid-exchange," "monorail," and "monorail-type." "Monorail" is the trade name of the original Schneider rapid-exchange

catheter, but it is also used generically to describe all catheters within the rapid-exchange segment of the PTCA market.

26. Dr. Bonzel realized that, by making the guide wire tube relatively short compared to the inflation tube, a single cardiologist could easily and rapidly exchange one dilatation catheter for another over a stationary standard-length guide wire. Since the guide wire tube is relatively short compared to the inflation tube, the guide wire is not enclosed within the entire length of the dilatation catheter. As a result, the cardiologist can hold the end of the guide wire during the entire exchange procedure without using an exchange wire.

27. Other important advantages of the invention listed in Dr. Bonzel's patent specification include the ability to achieve bare wire or "wire first" access to the stenosis with a standard-length guide wire (the physician can place the standard-length wire across the stenosis before loading the dilatation catheter onto the wire) and reduced friction between the guide wire and dilatation catheter. The Bonzel invention is also advantageous in that it reduces the amount of exposure to radiation during a PTCA procedure. The primary feature, however, of the '129 patented device, is its rapid-exchange capability.

D. Reexamination of the '129 Patent.

28. On November 25, 1988, Bard filed a Request for Reexamination of the '129 patent with the PTO. Bard filed two additional Requests for Reexamination of the '129 patent on October 25, 1989 and on May 1, 1990. In addition, Advanced Cardiovascular Systems, Inc. ("ACS") filed a Request for Reexamination of the '129 patent on March 16, 1990. All four Requests for Reexamination were granted and merged into a single proceeding before the PTO. SciMed did not file a Request.

29. Each Request for Reexamination is considered by a primary examiner in the PTO. The examiner in the '129 patent reexamination proceedings was Michael H. Thaler.

30. During the reexamination proceedings, the examiner considered an extensive list of prior art references, including, but not limited to, the following: the Leary reference; the Samson '181 patent; the British Journal of Surgery article ("Erlem"); the Dotter reference; the Kaltenbach article; the Seldinger Technique article; the Nordenstrom 1962, 1965, and 1966 articles; the Borisenko patented device; various Fogarty references; and the Cardiospasm article by Moersch, which refers to an esophagus dilator. The examiner determined that the claims in the '129 reexamination certificate were patentable after considering these and many other references. See Reexamination Certificate B1 4,762,129 (Plaintiffs'

Trial Exhibit 1). Perfusion prior art, such as Erbel, was not before the examiner, but was presented by SciMed at trial.

31. On March 4, 1991, the PTO issued an Office Action in which it indicated that certain pending claims were allowed and certain claims were rejected. The allowed claims ultimately became the claims of the '129 reexamination certificate. On April 19, 1991, the PTO issued a Notice of Intent to Issue a Reexamination Certificate.

32. On July 2, 1991, the PTO issued Reexamination Certificate B1 4,762,129. As of that date, the claims in the reexamination certificate replaced those in the original '129 patent. Thus, Schneider's claim for infringement against SciMed is based on the claims in the reexamination certificate.

II. Infringement

A. Claim Construction of the '129 Patent

33. Schneider contends that the SciMed EXPRESS TM and the SciMed RALLY TM catheters infringe apparatus and method claims 1, 3-11, 13, 14 and 16-27.

34. Reexamination Claim 5 includes all of the elements in dispute in this case. The disputed elements are italicized and in bold:

> (a) providing an elongated guide wire having distal and proximal ends and a dilatation catheter comprising an expandable balloon having distal and proximal ends, *a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into interior of the expandable balloo*n, the first tube being sealingly connected to the proximal end of the balloon, and *a second, relatively short,* [3] *elongated hollow tube integral with said first tub*e, having distal and proximal ends, and adapted to receive said guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, and *the second tube terminating at its proximal end substantially distally of the proximal end of the first tube* in an aperture open to the exterior of the catheter, *said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tub*e. . . .

[3] SciMed does not contest the fact that the guide wire tube on the RALLY TM is "relatively short" and "substantially distal."

Reexamination Certificate B1 4,762,129, Claim 5, Col. 2, Lines 40-65.

35. SciMed also takes issue with the "stabilizing wire" limitation recited in Claims 3, 7, and 10 with respect to the RALLY TM.

36. Thus, the claim construction issues identified by the parties regarding infringement relate to:

a) The meaning of "integral" in relation to the first and second tubes (inflation and guide wire tubes). SciMed claims that "integral" should be narrowly defined to mean a dual-lumen catheter where the tubes are laterally displaced from each other and made of one-piece;

b) The limits on the length of the guide wire tube due to the claim terms "substantially distally" and "relatively short." SciMed claims that the length of the guide wire tube can be only about as long as the balloon;

c) Whether the EXPRESS TM and the RALLY TM catheters possess a "first tube" (inflation tube) that both i) opens adjacent its distal end into the interior of the balloon and ii) alone possesses "sufficient stiffness" to advance the distal end of the catheter (the balloon and the guide wire tube); and

d) Whether the RALLY<TM> catheter possesses the "stabilizing means" of reexamination claims 3, 7, and 10.

(a) The "Integral" Limitation

37. SciMed's assertion that the term "integral" is limited to a one-piece, dual-lumen construction is contrary to the understanding of those of ordinary skill in the art in November 1984. The ordinary meaning of "integral" within the catheter industry supports a broader definition than that advocated by Defendant.

38. A person of ordinary skill in the art would have looked to the specification, the prosecution history, and the reexamination history and concluded that "integral" refers to components that are attached together or joined in some manner, forming a unit so that the two pieces move together. It does not only refer to a structure that is made in one piece, laterally displaced, or arranged side-by-side in a "dual-lumen" formation. There is no language in the claims or in the prosecution history that precludes a coaxial construction.

39. During the reexamination proceedings, the examiner cited the Simpson-Robert article and the Leary patient interchangeably in discussing the scope of the prior art. The examiner therefore treated the '129 patent claims as commensurate in scope with either a coaxial or dual-lumen construction.

40. The examiner referred to a tube construction where two tubes are glued together as an "integral" construction. The examiner stated, "Turning now to a discussion of the cited patent to Rusch. Note the first tube (6-9) integral with a second short tube 1 having a balloon 3 mounted thereon." Reexamination File History, Information Disclosure Statement and Notice of Concurrent Proceedings (April 10, 1989) (Defendant's Trial Exhibit 2, Tab 4, at 3). In the Rusch patent, the two tubes are glued together.

41. The Detailed Description of the Invention describes a "one piece" construction of the claimed catheter. It states, "The tube 3 [the inflation tube] with its inner lumen 17 and the segment of tubing 7 [the guide wire tube] with balloon passage 8 are made in one piece in the region shown in FIG. 3." However, nothing in the actual claims of the '129 suggests that integral means "made in one piece." In addition, while figures 1 and 3 of the '129 patent and reexamination certificate show a laterally displaced, one-piece, dual-lumen construction of the inflation tube and guide wire tube, the Court notes that patented claims are not necessarily limited to the specification or drawings.

42. The '129 patent Summary of the Invention describes the claimed catheter as having an inflation tube "laterally displaced" from the guide tube. It also states that the inflation tube "no longer encloses the guide wire and the guide tubing enclosing it. . . ." SciMed argues that this language precludes a co-axial construction. Again, however, nothing in the claims suggests that the patent is limited to a co-axial construction. During the second preliminary amendment of the original prosecution history, in proposed Claims 9 and 10, Schneider used "integral" in the independent claim to indicate a construction broader than "laterally displaced and molded," which appeared in the dependent claim.

43. In the drawing of the '129 patented invention, a marker band goes around the stabilizing wire. A reasonable interpretation of the drawing is that the wire is held onto the tube by the clamping of the marker band. In claim 3 of the patent, this stabilizing wire is called "integral."

44. In the reexamination file history, the examiner stated "Although the patentee also adds stiffness by stabilizing member [four], this stabilizing member is an integral part of the tube, while mandrin [sixteen] of Borisenko is not part of the tube [twelve]." Reexamination File History, Office Action in Merged Reexamination (Oct. 26, 1990) (Defendant's Trial Exhibit 2, tab 24, at 18). This

portion of the file history indicates that the stabilizing means disclosed in the Bonzel patent is integral.

45. According to Dr. Solar, an expert witness at trial, "integral" has a broader ordinary meaning within the catheter industry than that advocated by SciMed. In accordance with his expert testimony, the Court finds that "integral" in the claims of the '129 patent necessarily includes co-axial catheters and catheters not made in one piece, as long as the elements of the catheter are somehow attached or bonded together.

46. The Court finds other evidence that the ordinary meaning of "integral" is consistent with Schneider's definition. SciMed's attorney, James Young, received advice from a German translator that, in the original German text of the priority application, the two tubes did not have to be manufactured as one piece. The translator indicated that the German word "angeformt," which was used in the original text, means "could be made in one pass or by subsequent assembly" and "indicates some assembly (not one piece)." (Plaintiffs' Trial Exhibit 607).

47. The term "integral" has a fundamentally different meaning than "formed integral," which is illustrated by U.S. Patent 4,582,181 to Samson for the Hartzler catheter (" '181 patent"). In describing the construction of the shaft and balloon from one piece of material, the '181 patent at Column 2, lines 30-31, states that "the balloon is formed as an integral part of the tubular member by distending a portion of the wall of the member." This catheter also contains a guide wire adhesively bonded to the tubular member. Such an arrangement is referred to as an "integral" guide wire in the patent.

48. During the prosecution of ACS's Simpson-Robert patent, U.S. Patent No. 4,323,071, the PTO initially construed the term "integral" to mean "attached" in rejecting the claims over the Gruntzig patent. ACS was able to distinguish its invention over this reference by drawing a distinction between the term "integral" (meaning "attached") and the term "formed integral" (meaning "made in one piece").

49. The ordinary meaning of "integral" within the catheter industry, as well as the way in which the term was used in the reexamination proceedings, convinces the Court that one of ordinary skill in the art would not limit "integral" in the '129 patent to a dual-lumen, one-piece construction.

(b) The "Relatively Short"/"Substantially Distal" Limitations

50. A person of ordinary skill in the art would have looked to the '129 patent specification, the reexamination history, and the prosecution history and

concluded that the catheter claimed in the '129 patent and reexamination certificate as having a "relatively short" guide lumen with its proximal opening "substantially distally of the proximal end" of the inflation tube does not limit the guide lumen to "about the length of the balloon."

51. The '129 patent covers various guide wire lumen lengths. It does not contain a narrow definition of the term "relatively short." Rather, the patent refers to various relative distances. The language, "about as long as the balloon," appears in the Summary of the Invention, but it does not appear in any of the claims of the '129 patent. Similarly, the figures of the '129 patent and reexamination certificate show the guide wire lumen as being about the length of the balloon. Again, however, the figures are merely examples of the Bonzel invention.

52. The claim language suggests that "relatively short" covers any guide wire tube that is at least about as long as the balloon, but is limited to a length less than the full length of the catheter. The second tube (guide wire tube) must be "relatively short" compared to the "relatively long" first tube (inflation tube). As long as the dilatation catheter can be rapidly exchanged over a standard-length guide wire, the guide wire tube is "relatively short." This interpretation of the '129 patent is consistent with the primary object of the invention, which is rapid exchange over a standard-length guide wire. To further the purpose of the invention, the guide wire lumen must be short enough so that one person can hold both ends of the wire. As long as the guide wire is equal to or less than approximately 55 or 50 centimeters, the guide wire lumen is sufficiently short to facilitate a rapid exchange.

53. In determining whether the '129 patent limits the guide wire lumen to "about the length of the balloon," Judge Ingram stated, "Plaintiff argues that the second tube is positioned substantially distally to the first tube because the second tube does not begin until 110 centimeters away from the proximal end of the first tube. The court agrees with Plaintiff." Schneider (Europe v. Advanced Cardiovascular Systems, Inc., No. C-88-20742-WAI at 7 (N.D. Cal. 1990). Judge Ingram's order is included in the file history of the reexamination. See Reexamination File History, Exhibit 10 Accompanying Response to Final Office Action of December 26, 1989 (Feb. 20, 1990) (Defendant's Trial Exhibit 2, Tab 13A, Exhibit 10, at 7).

54. One of the objects of the '129 patent is to reduce friction. SciMed claims that "relatively short" must mean "only about as long as the balloon" because, at that length, the friction in the system is reduced to the maximum extent. The '129 patent specification, however, does not state that the invention completely reduces friction. It merely states that friction is reduced to some extent.

(c) The "First Tube" and "Sufficient Stiffness" Limitations

55. Each of the asserted '129 patent and reexamination certificate claims requires that the inflation tube have "sufficient stiffness that the [guide wire] tube and expandable balloon can readily be advanced or withdrawn in use along the guide wire by exerting a pushing or pulling force upon the [inflation tube]."

56. A person of ordinary skill in the art would have looked to the specification, prosecution history, and the reexamination history and concluded that a tube can have "sufficient stiffness"even if it is constructed of several materials and pieces to achieve the requisite "sufficient stiffness."

57. The claim language in the '129 patent does not limit how the first tube is made as long as it has "sufficient stiffness" to advance the second tube (guide wire tube) and the expandable balloon. The inflation tube can be of "sufficient stiffness" even if it is constructed of several pieces. This is true even if the individual pieces making up the first tube do not, by themselves, perform the required functions of the claimed "first tube."

(d) The "Stabilizing Wire" Limitation

58. Claims 3, 7, and 10 of the '129 patent and reexamination certificate require that the inflation tube be reinforced by means of a "longitudinally-extending stabilizing means." Claims 3 and 10 further require that the "longitudinally-extending stabilizing means" be "integral" and "non-removable." The stabilizing wire stiffens the inflation tube.

59. There is no limitation in the '129 patent regarding how the "stabilizing wire" is connected to the inflation tube. One of ordinary skill in the art in November 1984 would have looked to the specification, the prosecution history and the reexamination history and concluded that the wire can be "integral" if it is glued, forced into a tight hold, or extruded.

(e) Scope of Coverage of the '129 Patent Claims

60. SciMed argues that Schneider's own rapid-exchange catheters are not within the scope of the '129 patent because they contain elements not covered by the '129 patented claims. For example, some of Schneider's rapid-exchange catheters have guide wire lumens longer than "about the length of the balloon." The Court rejects this argument based on the claim construction set forth above.

61. The length of the guide wire lumen on Schneider's rapid-exchange catheters has varied in length from 5 centimeters to 17 centimeters. SciMed alleges that

any catheter, including Schneider's own products, with a guide wire lumen longer than the length of the balloon, is not covered by the '129 patent.

62. Mr. Kagan testified that the ACS RX<TM> catheter does not infringe the '129 patent because of the length of its guide wire tube (25 centimeters). In a report Mr. Kagan wrote in 1990, however, he stated, "ACS RX catheter. First filed in 1986. RX as currently marketed appears to infringe on Bonzel." Novel Biomedical, Inc. and TFX Medical, "Percutaneous Transluminal Coronary Angioplasty Patent Search and Evaluation Overview," March 27, 1990, at 7 (Plaintiffs' Trial Exhibit 1052). Mr. Kagan wrote this report before he was hired by SciMed as an expert.

63. The '129 patent covers the Schneider MONORAIL<TM> products, the ACS RX,<TM> and the SYNERGY<TM> catheters because the claims of the '129 patent are not limited to guide wire lumens that are "about the length of the balloon." Nor are the claims of the '129 patent limited to a dual-lumen construction.

B. The Structure of the EXPRESS<TM> and the RALLY <TM>

(i) The EXPRESS<TM>

64. The SciMed EXPRESS<TM> is a balloon dilatation catheter designed by SciMed for use in PTCA procedures. The overall length of the EXPRESS<TM> is 135 centimeters. The EXPRESS<TM> catheter incorporates a stainless steel hypotube segment approximately 105 centimeters long. The guide wire lumen is 35 centimeters long. The distal end of the hypotube is soldered to the proximal end of a stainless steel crimp segment. The crimp segment is glued to a polyethylene outer distal shaft, a polyethylene inner distal shaft, a sheath, and an approximately 5 centimeter push coil. The inner distal shaft and outer distal shaft are glued as part of this assembly for a length of about .5 centimeters at their proximal ends.

65. The distal end of the outer distal shaft is glued to the proximal end of the balloon. The guide wire tube traverses the interior of the balloon from the proximal end to the distal end of the balloon. The guide wire tube is sealed to the balloon by an adhesive bond on the distal end of the balloon. The distal outer shaft and the guide wire tube are coaxial for their entire length, except for the approximately .5 centimeter exit port where the guide tube exits the catheter.

66. The EXPRESS<TM> balloon is made of Polyolefin Copolymer (or "POC"), which is a compliant material that stretches to defined diameters upon inflation to specified pressures. The balloon is elongated in the longitudinal direction and

exhibits a substantially cylindrical central working surface between distal and proximal conical sections when inflated.

(ii) The RALLY<TM>

67. The SciMed RALLY<TM> is a balloon dilatation catheter designed by SciMed for use in PTCA procedures. The overall length of the RALLY<TM> is 135 centimeters. The length of the guide wire tube is 35 centimeters. The guide wire tube, which is made from polyethylene, traverses the interior of the balloon from the distal end to the proximal end of the balloon.

68. The inflation tube on the RALLY TM incorporates a stainless steel hypotube segment approximately 105 centimeters long and a polyethylene outer distal shaft bonded to the distal end of the hypotube. The inflation medium used to inflate the balloon is passed through the hypotube and the outer polyethylene tube to the balloon. The polyethylene outer distal shaft of the RALLY TM is crimped at its distal- most end. The polyethylene outer distal shaft is glued to both the guide wire tube and the proximal end of the balloon.

69. A stainless steel core wire is brazed to the distal end of the hypotube and extends through the polyethylene outer distal shaft and into the middle of the balloon, where it is glued to the marker band on the guide wire tube.

70. The RALLY TM balloon is made of the same POC material as the EXPRESS TM balloon. The balloon is elongated in the longitudinal direction and exhibits a substantially cylindrical central working surface between distal and proximal conical sections when inflated.

C. Literal Infringement

(i) The EXPRESS TM

71. The EXPRESS TM meets every element of the '129 patent claims in dispute.

72. All of the claims of the '129 patent and the '129 reexamination certificate require that the guide wire tube be "integral" with the inflation tube of the catheter. "Integral" refers to components which are attached together or joined in some manner, forming a unit so that the two pieces move together. The EXPRESS TM has a guide wire tube that is integral with its inflation tube because its components are attached or joined in a manner such that the pieces of the unit move together. The two tubes on the EXPRESS TM are bonded together such that pushing on the inflation tube moves the guide wire tube.

73. The guide wire tube is not "about the length of the balloon" since the balloon is approximately 30 millimeters long. The '129 reexamination certificate at Column 1, Lines 35-45, however, refers to a "second, relatively short, elongated hollow tube . . . terminating at its proximal end substantially distally of the proximal end of the [inflation] tube. . . ." The critical question, therefore, is whether the guide wire tube on the EXPRESS TM is relatively short compared to the length of the inflation tube, as opposed to whether the guide wire tube is about the length of the balloon. The Court finds that the guide wire tube on the EXPRESS TM (35 centimeters) is relatively short compared to the length of the relatively long (135 centimeters) inflation tube.

74. The EXPRESS TM has an inflation tube that is a combination of several elements. The inflation tube opens at its distal end into the interior of the balloon. The outer distal polyethylene shaft does not alone possess sufficient stiffness to advance the distal end of the catheter. However, when the combination of elements that form the inflation tube receive a pushing or pulling force, the balloon and guide wire tube are readily advanced or withdrawn together, in use, along the guide wire. The EXPRESS TM brochure actually states that the plastic or polyethylene distal shaft transmits push to the lesion.

75. The SciMed marketing brochure for the EXPRESS TM instructs the cardiologist to use the EXPRESS TM with the wire first technique. In this technique, the guide wire is first inserted into the patient and located at the stenosis. The EXPRESS TM is then backloaded onto the guide wire and advanced to the stenosis. This procedure literally infringes the steps in method Claims 5, 6, 9, 10, 22, 23, 24, 25, and 26.

76. SciMed's brochure for the EXPRESS TM also teaches rapid exchange over a standard-length guide wire. This procedure literally infringes method Claims 17, 18, 19, 20, and 21.

(ii) The RALLY TM

77. The RALLY TM meets all of the disputed elements of the claims of the '129 patent and reexamination certificate as construed above.

78. The RALLY's TM guide wire tube is integral with its inflation tube. The two tubes are bonded together such that when a pushing or pulling force is applied to the inflation tube, the guide wire tube moves in response. A combination of elements creates an inflation tube in the RALLY TM.

79. Specifically, the inflation tube is a combination of a stainless steel hypotube shaft and a distal polyethylene shaft. It opens at its distal end into the interior of

the balloon and possesses sufficient stiffness, when actually used, to advance the distal end of the catheter.

80. The guide wire tube (3.5 centimeters) is relatively short compared to the relatively long (135 centimeters) inflation tube. As SciMed concedes, even under its definition of "relatively short," which is "about the length of the balloon," this element of the claim is met.

81. The inflation tube of the RALLY TM catheter is "reinforced by means of longitudinally extending stabilizing means." The stabilizing means is an "integral non-removable stabilizing means" within the meaning of the '129 patent.

82. The instructions for use for the SciMed RALLY TM instruct the cardiologist to use the RALLY TM with the wire first technique. In this technique, the guide wire is first inserted into the patient and located at the stenosis. The RALLY TM is then backloaded onto the guide wire and advanced to the stenosis. This procedure literally infringes the steps of method claims 5, 6, 7, 9, 10, 22, 23, 24, 25, and 26. SciMed's instructions for use for the RALLY TM also teaches rapid exchange of the RALLY TM over a standard-length guide wire. This procedure literally infringes method claims 17, 18, 19, 20, and 21.

D. The Doctrine of Equivalents[4]

(i) The "Integral" Limitation

83. Dual-lumen and coaxial rapid exchange catheters perform the same function in a similar manner to produce the same result. Thus, the coaxial structures in the EXPRESS TM and RALLY TM are substantially equivalent to the dual-lumen construction disclosed in the '129 patent.

84. The inflation tube and the guide wire tube of the EXPRESS TM and the RALLY TM are bonded or attached together to form a unit. As in the one-piece construction in the example in the '129 patent, the bonded tubes of the EXPRESS TM and RALLY TM allow an operator to push on the first tube to move the second tube. Thus, the bonded nature of the EXPRESS TM and RALLY TM is substantially equivalent to the structure shown in the '129 patent.

(ii) The "Relatively Short"/"Substantially Distal" Limitations

[4] The Court addresses this doctrine only as an alternative to its finding of literal infringement

85. To perform the same function (single operator exchange) and obtain the same result (more efficient, faster PTCA procedure) as the catheter claimed in the '129 patent, the EXPRESS TM and the RALLY TM catheters have a relatively short guide wire tube compared to the inflation tube. This structure allows a cardiologist to easily and rapidly exchange catheters during a PTCA procedure. It is substantially the same, if not identical, to that used in the claimed invention of the '129 patent.

(iii) The "First Tube" Limitation

86. In both the EXPRESS TM and RALLY TM catheters, the function of the inflation tube is to receive inflation fluid and discharge the fluid into the interior of the catheter balloon. Passing inflation fluid through the inflation tube expands the catheter balloon to clear the artery. The function performed and result accomplished by the inflation tube in the EXPRESS TM and RALLY TM catheters are the same as in the claimed invention of the '129 patent.

87. The '129 patent invention performs the inflation function with a hollow tube that extends from the proximal end to the distal end, terminating at the interior of the catheter balloon. Similarly, the aggregated segments of the EXPRESS TM catheter are bound together to form a hollow structure that receives inflation fluid and discharges the fluid into the interior of the catheter balloon. The RALLY TM catheter is also functionally equivalent to the '129 patent because the hypotube segment and the tubing shaft segment are bound together to form a hollow, tubular structure, through which the catheter balloon is inflated.

(iv) The "Sufficient Stiffness" Limitation

88. The EXPRESS TM and RALLY TM catheters perform the same function to obtain the same result as the catheter claimed in the '129 patent. In the '129 patent, the guide wire tube and expandable balloon advance or withdraw when the inflation tube receives a pushing or pulling force. Scimed catheters work in substantially the same way. The combination of elements forming the first tube, when receiving a pushing or pulling force, readily advance or withdraw the guide wire tube and the expandable balloon along the guide wire in the same way as the catheter claimed in the '129 patent.

(v) "Integral Stabilizing Means"

89. Relying on the expert testimony of Dr. Solar, the Court finds that the core wire of the RALLY TM catheter performs substantially the same function as the "stabilizing means" requirement of Claims 3, 7, and 10 of the '129 patent and reexamination certificate.

III. Validity

A. One of Ordinary Skill in the Art

90. One of ordinary skill in the art on November 23, 1984 (the '129 patent's effective filing date) was a practicing interventional cardiologist who performed dilation or coronary angioplasty dilatation procedures. Persons of ordinary skill in the art included knowledgeable PTCA practitioners, such as Dr. Robert Meier and Dr. Robert Van Tassel, who offered credible testimony at trial in support of Schneider's definition.

91. SciMed argued throughout trial that one of ordinary skill in the art was an engineer working in the area of dilatation catheter design or a physician who had an understanding of and skill in the design of dilatation catheters. The Court expressly rejects SciMed's proffered definition.

B. Scope and Content of Prior Art/Differences Between the Prior Art and the Claims at Issue

(i) Scope of the Relevant Prior Art

92. The '129 patent specification defines a dilatation catheter as a catheter "employed to enlarge constrictions in vessels and body cavities, in particular coronary arteries." During the reexamination proceedings, Schneider (Europe) acknowledged that some claims in the '129 patent were broadly directed to "dilatation catheters," while others were specific to vascular and coronary dilatation catheters.

93. The subject matter of the '129 patent invention relates to balloon dilatation catheters. As the patent examiner found, PTA and PTCA practitioners in 1984 would have had little, if any, exposure to non-dilatation medical devices, such as embolectomy, esophageal, thrombectomy, and urology catheters. The scope of relevant prior art is therefore limited to balloon dilatation catheters.

94. SciMed argued at trial that various prior art references, both inside and outside the balloon dilatation catheter field, are relevant and render the Bonzel invention obvious. The most arguably relevant of these references, which are identified below, were before the patent examiner during the reexamination. The only devices listed below that were not before the patent examiner are the perfusion catheter references.

(ii) Content of the Alleged Prior Art/Differences Between the Prior Art and the Claims at Issue

(a) Borisenko

95. The Borisenko Russian Inventor's Certificate No. 627,828 (1978) ("Borisenko") describes a thrombectomy catheter for removing occluded blood clots from main vessels, such as veins. Thrombectomy catheters, such as the Borisenko device, cannot not be used in the coronary arteries or in PTCA procedures.

96. PTCA catheters have balloons made of inelastic materials that assume a controlled, cylindrical shape when inflated. They are not performed with catheters having elastic balloon material because elastic balloons do not inflate to a predetermined size and shape. Instead, they tend to assume the shape of the vessel upon inflation. The soft elastic balloon disclosed in Borisenko does not hold a high enough pressure to compress a stenosis against the coronary artery wall. The occlusion balloon on the tip of the Borisenko catheter, if used in the coronary arteries, would be dangerous to the patient because it would stop blood from flowing through the artery to the heart muscle tissue downstream. In addition, the balloon in Borisenko has a reinforcing ring on its outer circumference, which is not used on PTCA catheter balloons.

97. The Borisenko device, like other thrombectomy devices, does not use a PTCA guide wire or PTCA guide wire lumen. Thus, Borisenko does not disclose a first relatively short tube for receiving a guide wire in a sliding fit, which is a required feature of the '129 patent. It does, however, possess a short guide lumen.

98. The Borisenko reference does not disclose a method for exchanging catheters. Any effort to exchange Borisenko's slider, balloon, and connecting tube would require the deflation of the balloon and the dismantling of the entire device during the procedure. Because the exchange could result in thrombus particles entering the circulatory system, such an exchange is not performed.

99. The Borisenko reference is a two-operator system. According to Borisenko, "By drawing up the guide tube 1, the mouth of the vena iliaca is closed off, and the tube is secured by the hand of the assistant." Borisenko et al., Russian Inventor's Certificate No. 627,828, at 2.

100. Modifying the Borisenko device into a PTCA catheter would involve changing the balloon material and the guide wire, inserting a guide wire lumen, removing the reinforcing ring on the balloon, and changing the balloon's shape. The Court finds that the Borisenko reference would not motivate one of ordinary skill in the art to invent the claimed invention.

(b) Nordenstrom

101. The Nordenstrom articles, "Balloon Catheters For Percutaneous Insertion Into the Vascular System" and "New Instruments For Catheterization And Angiocardiography," published in 1962 and 1965 respectively, describe a single lumen angiography catheter for diagnostic investigation of blood vessels and heart cavities. The Nordenstrom catheters were not designed for dilatation in a PTCA procedure or for any other therapeutic purpose.

102. Figure 1 of the 1962 Nordenstrom article discloses a series of occlusion balloon catheters with soft elastic balloons for percutaneous insertion into vessels for diagnostic occlusion. The main advantage taught by Nordenstrom is the ability to introduce the catheter percutaneously into a vessel with a guide wire. The article contains no disclosure of catheter exchange or rapid exchange. The 1962 Nordenstrom device is not used in the coronary arteries.

103. Prior to the 1962 and 1965 articles, the ability to inject a large amount of contrast dye into a cavity using a catheter that was blocked at the distal end was important. This function improved the visibility of the cavity on an X-ray machine. A catheter with a blocked distal end is not capable of receiving a guide wire to maintain the catheter access in the vessel. Dr. Nordenstrom solved this problem, as discussed in his 1962 and 1965 articles, by adding a short segment to the end of the catheter distal to the balloon, thereby allowing the use of a guide wire. Thus, Nordenstrom's catheters possessed a short guide lumen.

104. The problem that motivated Dr. Nordenstrom to design the catheter described in his articles was not the same problem encountered by PTCA practitioners in 1984. A PTCA procedure in 1984 used a guiding catheter to maintain access to the puncture site. Doctors already knew how to introduce balloon catheters percutaneously, as Dr. Wholey and Mr. Kagan conceded. The percutaneous access method taught by Nordenstrom, therefore, was not needed in 1984.

105. Nordenstrom does not teach that the guide wire lumen should be moved into the interior of the balloon or that the catheter should be used with a guiding catheter, which are features required by the '129 patent. In addition, as disclosed in the 1965 Nordenstrom article, the guide wire is removed prior to injection of contrast medium.

106. The "exchange" procedure set forth in the 1965 Nordenstrom article includes the following steps: (1) the catheter is pulled back; (2) a wire is placed next to the catheter; (3) the catheter is completely removed; and (4) a new

catheter is inserted. This procedure is followed to keep the puncture-site open and thereby maintain access to the artery. This motivation was irrelevant in PTCA in 1984 because guiding catheters were used, which eliminated the problem of keeping the entrance to the artery open.

107. The 1966 Nordenstrom article discloses a device comprised of two catheters -- an angiography catheter with no balloon or inflation tube and a balloon occlusion catheter.

108. The Court concludes that Nordenstrom would not have motivated one of ordinary skill in the art in 1984 to invent the rapid-exchange catheter disclosed in the '129 patent.

(c) Morton

109. A 1912 book by Dr. Henry H. Morton discloses a device called a "tunneled sound." This type of device is not a balloon catheter, but a device referred to as a "dilator." It was designed for dilating strictures in the urethra, not for use in the coronary or peripheral arteries. The instrument has a short lumen at its distal end for receiving a guide. In use, a guide is first passed through the stricture into the bladder. The instrument is passed over the guide and through the stricture to dilate it. While the guide is in place, the first catheter is withdrawn and a second, longer catheter is inserted over the same guide to further dilate the stricture. See Dr. Henry H. Morton, Genitourinary Diseases and Syphilis (3d ed. 1912).

110. The device disclosed in Morton is a surgical device that must be used with a knife, unlike a PTCA procedure, which in non-invasive. The procedure takes 18 months to complete. In 1984, a PTCA procedure took approximately 25-35 minutes.

111. None of the devices shown in the Morton reference have balloons or tubes for inflating balloons. In addition, dilating by placing increasingly large solid dilators through a constriction was rejected as a technique in PTCA in 1984. The stenosis treated in Morton is a different type of stenosis than the type treated in PTCA. Using the technique shown by Morton in a PTCA procedure would cause the stenosis to be pushed forward, producing a "snowplow" effect.

112. The tunnelled sounds illustrated in Figures 93, 97 and 98 of Morton's book are used in combination with a device referred to as a "filiform whalebone guide." There is no separate tube or lumen inside these tunnelled sounds through which the guide slides. In fact, there is no lumen at all inside the tunnelled sound. Rather, the sounds contain grooves on their exterior surfaces, over which the guide passes.

113. Morton would not have motivated one of ordinary skill in the art to invent the monorail-type catheter.

(d) Esophagal Devices

114. The Jameson reference, dated 1822, discloses a device having a metal dilator for dilation in the esophagus. See Dr. H.G. Jameson, "An Account of a Case of Stricture of the Esophagus," The Medical Recorder, January 1822. The device does not have a balloon or a hollow inflation tube. The procedure shown in the Jameson reference takes over two months, which is much longer than that required for a PTCA procedure in 1984.

115. An article by Dr. Keshishian discloses a device referred to as a "Jackson-Plummer metal olive dilator" for dilation in the esophagus. The device did not have a hollow inflation tube or a balloon. See Dr. John M. Keshishian, "Dilatation of Difficult Strictures of the Esophagus," 1984.

116. Both of these devices teach the use of a short guide wire lumen for guide wire first operation and exchange. However, neither of these references would have motivated one of ordinary skill in the art to invent a rapid-exchange catheter. (e) Hartzler

117. The Hartzler catheter had a guide wire fixed in the catheter running the length of the catheter (FWC). There was no separate guide wire lumen. Testimony at trial suggested that the Hartzler catheter was a catheter of "last resort," to be used when no other catheter could cross a lesion. It was not used routinely because distal pressure measurement and distal dye injection could not be performed. Knowledge of the Hartzler catheter would not have motivated one of ordinary skill in the art to create a monorail catheter. (f) Perfusion Catheters

118. A perfusion catheter, such as that disclosed by Erbel, is an OTW dilatation catheter that contains a series of small holes on either side of the balloon. See Erbel, "A Newly Developed Balloon Catheter for Reduction of Myocardial Ischemia During Transluminal Angioplasty," September 1984. The balloon is located at a stenosis and then inflated. The guide wire is partially withdrawn to uncover the holes, which goes against Bonzel's teachings that the guide wire should remain in place. Blood then flows through the guide wire lumen. The guide wire remains inside the full-length guide wire lumen throughout the procedure. The Erbel article does not mention exchange of catheters or use of the wire-first technique.

119. The Erbel perfusion catheter has a full-length guide wire lumen, but it does

not provide distal pressure measurement or distal dye injection. Erbel sacrificed these features to achieve perfusion capability. Modifying the catheter by placing the guide wire through the perfusion holes to create a short guide wire lumen would have destroyed the purpose of Erbel's device, which is to perfuse blood during a PTCA procedure. As a result, Erbel would not have motivated one of ordinary skill in the art in 1984 to invent the rapid-exchange catheter.

(g) Kaltenbach

120. The December 1984 Kaltenbach article, "The Long Wire Technique -- A New Technique For Steerable Balloon Dilatation Of Coronary Artery Stenosis," teaches a wire first technique using a 300 centimeter guide wire and a conventional OTW catheter. It does not teach this technique using a standard-length guide wire. Rather than shortening the guide wire lumen to effectuate an exchange, Kaltenbach taught using a longer guide wire, which is why it is called the "long wire technique." The Court finds that Kaltenbach would not have motivated one of ordinary skill in the art to invent the patented catheter.

(h) Leary

121. When references having a short guide wire lumen are combined with conventional OTW catheters in the PTCA field, such as the U.S. Patent Number 4,545,390 to Leary, teachings of distal dye injection and distal pressure measurement must be discarded because the full-length guide wire lumen is eliminated. Since none of the references cited by SciMed specifically teach how Leary can be modified to include a short guide lumen without destroying its intended function, and since the conventional wisdom among those of ordinary skill in the art in 1984 was that distal dye injection and distal pressure measurement were necessary, a PTA or PTCA practitioner would not have been motivated to make such a combination. See Finding of Fact 125.

C. The Claimed Catheter Would not have been Obvious to One of Ordinary Skill in the Art.

122. In the early 1980's, prior to Dr. Bonzel's invention, the PTCA field was in its infancy. There were only about 200 physicians performing angioplasty procedures in the United States by 1984. Only about 300 were performing them worldwide. The two primary types of PTCA catheters were FWC and OTW catheters. Both types employed full-length guide wire lumens, primarily because the prevalent view of those of ordinary skill in the art was that distal dye injection and distal pressure measurement were necessary in PTCA.

123. Dr. Bonzel's invention was motivated by problems associated with existing PTCA balloon dilatation catheters, such as the following: 1) not wanting to take the guide wire out for an exchange of catheters; 2) being able to position the catheter over the guide wire without jeopardizing the wire positioning; and 3) the desire to eliminate the extension wire.

124. SciMed argues that prior art that teaches the use of a short guide wire lumen, especially Borisenko, renders the Bonzel invention obvious in light of Erbel and Leary-type dual-lumen PTCA catheters. Borisenko and Nordenstrom are clearly the most relevant non-balloon dilatation devices offered by SciMed, especially in view of Erbel or Leary. However, they are not reasonably pertinent to the particular problem with which Dr. Bonzel was involved because the Borisenko, Nordenstrom, Morton, Wholey, Jameson, and Keshishian references do not address balloon dilatation catheters. As a result, they are outside the scope of relevant prior art.

125. Even if they were within the scope of prior art, none of them would suggest or motivate one of ordinary skill in the art to combine them with a balloon dilatation catheter, such as the perfusion or Leary-type catheters, which teach use of a full-length guide wire lumen. Moreover, such a combination would destroy the intended functions of Leary and Erbel.

126. Dr. Bonzel's invention went against the prevalent view of the majority of PTA and PTCA practitioners in 1984, which was that it was necessary for an OTW catheter to have a full-length guide wire lumen. A full-length guide wire lumen was considered necessary because it permitted distal pressure measurements and distal dye delivery through the guide wire lumen. One of ordinary skill in the art in 1984 would not have considered the Bonzel invention obvious.

D. Secondary Considerations

(i) Background -- Development of Schneider's Catheters

127. Schneider made a variety of prototypes with varying guide wire tube lengths during 1985 and early 1986. The first commercial product was referred to as the "Monorail Bonzel" catheter. This catheter had a guide wire tube length of about 5 centimeters and was publicly introduced by Dr. Bonzel and Schneider at a PTCA course sponsored by Dr. Bernhard Meier in March, 1986 in Geneva, Switzerland.

128. In 1986, Schneider modified the material used for the distal end of the catheter. This catheter was referred to as the "Monorail Snake" and had a guide wire tube about 9 centimeters long.

129. Schneider developed a new balloon material referred to as polyethylene terephthalate (or "PET"). Balloons made out of PET are thinner than those made out of polyvinylchloride (or "PVC"). The smaller outer diameter allows the catheter to pass through tighter stenoses. Schneider incorporated the PET balloon into its next generation of catheters, called the MONORAIL PICCOLINO <TM>. This catheter has a guide wire tube 17 centimeters long. Schneider (USA)'s version of the Piccolino was introduced in the United States in September 1989 after FDA approval.

130. The various catheter models developed and introduced by Schneider (Europe) and Schneider (USA) after the 1986 launch of the original Monorail Bonzel catheter represent a natural evolution in technology in a competitive market. There were no major clinical performance problems with any of these catheters that caused Schneider to abandon them. SciMed's documents verify the success and quality of Schneider's Monorail catheters.

(ii) Commercial Success of Schneider's Catheters

131. PTCA catheters that have a short guide wire lumen traversing through the balloon (rapid-exchange catheters) are a commercial success. The trial record as a whole clearly establishes that Schneider created a new, distinct segment of the PTCA balloon catheter market with the introduction of the rapid-exchange line of catheters, which incorporated a relatively short guide wire tube. See Findings of Fact 199-200.

132. Commercial success is indicated by the volume of Monorail sales by Schneider. The following indicate the approximate volume of Schneider's sales:

Year	**Schneider Units**
1986	3,171
1987	10,234
1988	21,136
1989	31,250
1990	47,364
1991	68,911
1992	72,611

See (Plaintiffs' Trial Exhibit 1098).

(iii) Commercial Success of Infringing Catheters

133. The ACS RX line of catheters is covered by the claims of the '129 patent and the reexamination certificate. Its success is indicative of the commercial success of the rapid-exchange-type catheter.

134. The approximate volume of sales of the ACS RX line of catheters is as follows:

Year	**ACS Units**
1991	68,127
1992	79,872

See (Plaintiffs' Trial Exhibit 1098).

135. SciMed's sales of the EXPRESS <TM> and the RALLY <TM> are also indicative of the commercial success of the rapid-exchange catheter. SciMed's sales of the EXPRESS <TM> are as follows:

Year	**SciMed EXPRESS <TM> Units**
1991	42,693
1992	44,191

See (Plaintiffs' Trial Exhibit 1098).

(iv) Other Secondary Considerations

136. The commercial success of Schneider's monorail catheter is minimally attributable, if at all, to the use of the PET balloon. In 1989, Schneider sold over four times as many MONORAIL PICCOLINO <TM> catheters than other Schneider PET catheters.

137. The Court expressly rejects testimony such as that offered by Mr. Richard L. Myers, SciMed's expert, who testified that the Schneider Monorail's commercial success is primarily attributable to something other than the rapid-exchange capability.

138. Dr. John Simpson first developed the conventional OTW catheter in 1978. Despite the obvious problems involved with exchanging OTW catheters over a standard-length guide wire, it was not until 1984 that the problem of how to rapidly exchange an OTW catheter over a standard guide wire was solved by Dr. Bonzel.

139. The record establishes that ACS and Bard had both identified exchange as a problem, but had not identified a method by which to solve the problem as of 1984. Nor did any other catheter-manufacturing companies invent the Bonzel catheter before 1984. In addition, the record establishes that in 1984, Mr. John Kagan, one of SciMed's experts at trial, accidentally punched a hole through the side of an OTW catheter, such that it resembled what it is now the rapid-exchange catheter. Although Mr. Kagan was a catheter designer, he did not find the accidental "monorail" useful or desirable.

140. Upon hearing of Dr. Bonzel's new catheter, people were initially skeptical of its ability to perform a successful PTCA procedure due to its lack of a full-length lumen.

141. Both ACS and Bard, the two Requestors in the '129 Patent Reexamination, sought and paid for licenses under the '129 Patent after the conclusion of the reexamination proceedings.

142. Dr. Yock's alleged "contemporaneous" developments are not evidence of the level of ordinary skill in the art in November 1984 because Dr. Yock's work cannot be corroborated earlier than April 15, 1986, the date on which he filed his patent application for a short guide wire lumen catheter.

E. Inequitable Conduct

143. The Court finds that SciMed has not proven that any factual statement made by Schneider was untrue. Nor has SciMed proven that Schneider intentionally misled the PTO.

144. Examiner Thaler thoroughly analyzed the materials submitted by Schneider and made his own judgment as to which arguments to accept and which to reject. Examiner Thaler was very experienced, as evidenced by the large number of patents he has examined. His analysis in the March 4, 1991 Office Action was cogent and there is no indication that the amount of information submitted by Schneider with the January 28, 1991 Amendment "steam-rolled" the examiner or prevented him from properly deciding the issue of patentability. The Reexamination Proceeding was detailed and complete. See (Defendant's Trial Exhibit 2).

145. The Court finds that the declarations submitted in support of Schneider's position regarding the definition of one of ordinary skill in the art were material because a reasonable patent examiner would certainly consider this definition important, if not critical, to this case. However, Schneider did not mislead or intend to mislead the patent examiner with its definition.

146. Schneider's declarations regarding the level of one of ordinary skill in the art were not the only definitions before the examiner. Declarations were filed and considered in the Reexamination Proceeding that supported the proposition that a person of ordinary skill in the art was an engineer or technician rather than a cardiologist or interventional radiologist. The Crittenden declaration was submitted by Bard in one of its Requests for Reexamination, and the Chin affidavit was submitted by ACS in a civil action between Schneider and ACS. Thus, the examiner had the benefit of Schneider's view of one of ordinary skill in the art, as well as the view of two of Schneider's competitors. See (Defendant's Trial Exhibit 2). Nonetheless, the Court finds that Schneider's representations were material.

147. Schneider represented to the patent examiner that those of ordinary skill in the art would not consider the teachings of short guide wire lumens from fields of medicine that did not involve angioplasty dilatation catheters. The Court finds that such representations, although arguably material, were not misleading or intentionally misleading. As Patent Examiner Thaler stated:

> [T]he field of angioplasty dilatation catheters exemplified by Simpson et al and Leary was widely recognized as being distinct from the field of thrombectomy catheters exemplified by Borisenko since the problems and solutions to those problems in the angioplasty dilatation catheter art were completely different from the problems and solutions in the thrombectomy catheter field. Thus, an artisan, when faced with the problems associated with the over-the-wire angioplasty dilation catheters of Simpson et al or Leary would not have been led to the thrombectomy catheter art for solutions.

Reexamination File History, Office Action in Reexamination (March 4, 1991) (Defendant's Trial Exhibit 2, Tab 31, at 11). In addition, the examiner stated:

> [S]uch a double modification would not have been obvious since the three references are located in three distinct fields of medicine: angioplasty dilatation of coronary arteries (Leary), contrast medium injection using a balloon for occlusion (Nordenstrom), and emboli removal from veins by traction (Borisenko).

Id. at 15.

148. The declarations Schneider submitted regarding the necessity of a full-length lumen were material. However, nothing in the record establishes that the declarations of Drs. Bonan, Cumberland, Foale, Meier, Persson and Schnitzler,

which support Schneider's view regarding the necessity of full-length guide wire lumen, were incorrect or intentionally misleading.

149. These doctors have a tremendous amount of experience and respect in the angioplasty field and clearly submitted their declarations in good faith. As of January 1991, Drs. Bonan, Cumberland, Meier, Schnitzler had performed around 2,000 or more PTCA procedures. Dr. Meier was a credible and straight-forward witness at trial and the Court expressly rejects SciMed's argument that his, or any other declarant's testimony, was intentionally misleading. In addition, Drs. Solar and Van Tassel confirmed Schneider's definition of one of ordinary skill in the art at trial.

150. Patent Examiner Thaler properly relied on these declarations and stated:

> In fact, the Patent Owner . . . has pointed out that there are reasons for maintaining the guidewire lumen length the full length of the catheter. Shortening the guidewire lumen would result in the loss of the important benefits which are dependent on the full length of the guidewire lumen.

Id. at 12. Schneider truthfully represented that the conventional wisdom was that a full-length guide wire lumen was necessary.

151. Some physicians did not consider a full-length guide wire lumen and the ability to perform distal dye injection and distal pressure measurements particularly important features. In addition, some PTCA catheters did not have such capabilities in 1984. For example, the Hartzler (or "low profile steerable") FWC, which was introduced by ACS in 1983, could not measure distal pressure or provide dye delivery. Nor could the Erbel and CPC Mainz perfusion catheters provide distal pressure measurement or distal dye injection. While it is undoubtedly true that some physicians used these catheters and believed that distal dye and distal pressure were unnecessary, the conventional view of the majority of cardiologists in 1984 was that a full-length guide wire lumen was necessary for distal dye injection and pressure measurement.

152. Schneider's declarants' representations regarding the definition of one of ordinary skill in the art, the necessity of a full-length guide wire lumen, and the scope of relevant prior art, were not untrue or misleading. Schneider did not intentionally mislead Examiner Thaler.

153. Perfusion prior art was arguably material and non-cumulative, but there is no compelling evidence that Schneider intended to deceive the PTO when it failed to cite perfusion prior art.

IV. Willfulness

154. SciMed has a corporate policy that it will not infringe any valid patent rights of others. In carrying out this policy, SciMed involves outside patent counsel early in its product development. Counsel's consideration of patent issues then continues as the project evolves.

155. While it is possible to postulate additional steps that SciMed could have taken to ensure that it did not infringe Schneider's valid patent rights, SciMed's infringement cannot be called "willful." SciMed acted affirmatively to determine the scope and validity/invalidity of the '129 patent before launching the EXPRESS <TM> and the RALLY <TM>.

156. SciMed first became aware of the '129 patent in August 1988. At that time, SciMed asked its patent attorneys at Kinney & Lange to review the '129 patent in connection with development projects then underway.

157. On December 12, 1988, David Fairbairn ("Fairbairn") of Kinney & Lange informed Thomas R. Hektner ("Hektner"), Vice President of Research and Development at SciMed, that, in his opinion, the project that SciMed was pursuing was not covered by the '129 patent.

158. On February 7, 1989, Fairbairn informed Hektner that a Request for Reexamination of the '129 patent had been filed by attorneys representing Bard. On February 18, 1989, Fairbairn sent Hektner a copy of the Request and informed Hektner that he would arrange to have the reexamination file monitored on a periodic basis.

159. In September 1989, James L. Young ("Young"), a partner at Kinney & Lange, assumed the work relating to the '129 patent. Young had the '129 reexamination file history monitored on a regular basis by a Washington, D.C. associate. Young first had discussions with SciMed relating to the '129 patent in June 1989. Peter Keith, a SciMed engineer, showed Young drawings of a new catheter design on which he was working. Mr. Young told him that there were distinctions between the design (which was to become the EXPRESS <TM>) and the '129 patent and that he did not believe the design infringed the '129.

160. On September 12, 1989, Young provided Hektner with an update of the status of the reexamination, indicating that apparatus Claims 1-4 had been rejected, while method Claims 5-7 had been allowed.

161. Young had a discussion with SciMed in November 1989. He explained that, while he did not think the proposed SciMed design possessed the "integral" structure set forth in the '129 patent, he felt uncomfortable hinging the launch of the product on his interpretation of "integral." He accordingly refused to give an opinion that the EXPRESS <TM> did not infringe the '129 patent. Schneider asserts that SciMed requested or pressured Young for an invalidity opinion on numerous occasions. The Court notes, however, that Mr. Young's refusal to render an opinion actually supports the independent and therefore reliable nature of counsel's opinion on the issue of validity.

162. On March 15, 1990, Young informed Hektner that a revocation action had been filed with the German Federal Patent Court by ACS, seeking to nullify the German counterpart to the '129 patent. This strengthened SciMed's belief that the '129 patent would be found invalid.

163. On April 18, 1990, the examiner issued an Office Action rejecting all '129 patent claims over the prior art, including Leary and Borisenko. See Reexamination File History, Office Action (April 18, 1990) (Defendant's Trial Exhibit 2, Tab 15).

164. In May, 1990, Young told SciMed management that, based on his own study of the '129 patent, its file history, and the prior art, it was his opinion that all claims of the '129 patent were invalid. SciMed management believed then, as it did when it later launched the EXPRESS <TM>, that the '129 patent was invalid.

165. On July 18, 1990, Young provided Spencer and Hektner with a letter setting forth his opinion that the '129 patent was invalid. Young noted that the patent examiner was of the same opinion. He further stated, "It is our belief, based upon the prior art which has been developed after the original prosecution of Bonzel, that Patent Examiner Thaler should not and will not change his mind regarding allowance of the claims of Bonzel, nor will Examiner Thaler's decision be overturned on appeal." See (Plaintiffs' Trial Exhibit 192, at 3). Young reached his opinion of invalidity expressed in his July 18, 1990 opinion letter, in part, by comparing the claims of the '129 reexamination to the prior art. SciMed management reasonably understood the opinion to be Mr. Young's independent analysis.

166. In a letter dated November 5, 1990, Young provided Hektner with a copy of the October 26, 1990 Office Action that again rejected all claims, informing him that he continued to hold the opinion set forth in his July 18, 1990 letter. Young further opined that the Bonzel patent "will not survive the reexamination process. . . ." and that "the Bonzel patent is not valid and will not be validly reissued after reexamination." See (Plaintiffs' Trial Exhibit 602, at 2). In other portions of his opinion letters, Young speaks in terms of probabilities rather than certainties, which lends to their credibility.

167. On December 26, 1990, Young sent Hektner a copy of the Interview Summary Record of the interview, held on November 13, 1990, at which new Claims 9-24 were proposed. Young informed Hektner that, as of the date of the interview, no claims had been allowed. In his December 26, 1990 letter, Young analyzed the claims and concluded that the examiner should not allow them. Mr. Young testified at trial that he would have told Mr. Hektner if the new claims impacted on his previous opinions of invalidity.

168. The examiner received new proposed claims on December 23, 1990. SciMed became aware of these claims in the December 26, 1990 letter from Kinney & Lange. On January 28, 1991, the new claims proposed on December 23, 1990 were made final. The final claims were not identical to the claims proposed on December 23, 1990. Young and SciMed did not learn about the January 28, 1991 final proposed claims for several months.

169. On January 7, 1991, Young reported to Spencer and Hektner that the German Federal Patent Court had revoked the German counterpart to the '129 patent. This strengthened SciMed's belief that the claimed invention was obvious in light of the prior art because it corroborated Young's opinion of invalidity.

170. At the EXPRESS <TM> pre-launch review meeting held on February 14, 1991, EXPRESS <TM> project engineer Peter Keith informed the other EXPRESS <TM> team members that, in Young's opinion, there were no patent issues that would impact launch.

171. On February 18, 1991, SciMed launched the EXPRESS TM catheter. At the time of launch, therefore, SciMed had received several written and oral opinions from Mr. Young at Kinney & Lange regarding the invalidity of the '129 patent.

172. On March 4, 1991, a claims allowance was issued by the PTO.

173. On March 22, 1991, Young learned about the final proposed amendment that was filed in the PTO on January 28, 1991. He also learned that some claims had been allowed by the examiner on March 4, 1991. He received a copy of the amendment a few days later in March.

174. On April 1, 1991, Young had a meeting with Spencer and Hektner, at which time Young reported that some claims had been allowed. Young informed them that he was trying to obtain all of the materials that had been filed with the January 28, 1991 Amendment so that he could determine why they were allowed and whether their allowance would affect his earlier opinion. Young wrote to his Washington associate, requesting that she send him the missing material.

175. On April 23, 1991, the present action was filed. Young did not receive all of the missing materials that had been submitted with the January 28, 1991 Amendment until May 1, 1991.

176. In June, 1991, Young reported to SciMed that he had studied the effect of the allowance of claims upon his earlier opinion of invalidity and that he disagreed with the examiner's allowance. Young reaffirmed his July 18, 1990 opinion of invalidity. He explained that he believed all claims of the '129 reexamination were obvious in view of Leary and Borisenko. He also explained that he believed the '129 reexamination claims had been allowed because the examiner had been misled concerning the definition and skill of one of ordinary skill in the art.

177. On July 2, 1991, reexamination certificate B1 4,762,129 issued.

178. In October 1992, a meeting was held at SciMed between Young, Cecily Hines (SciMed's General Counsel), Spencer, and Hektner to discuss the RALLY TM catheter, which had not yet received FDA approval, in relation to the '129 patent and the '129 reexamination certificate. Young orally gave his opinion, based on his further review of the '129 patent, the '129 reexamination file, and the prior art, that he believed the patent was invalid.

179. On November 13, 1992, Young provided Spencer and Hektner with a written opinion reconfirming the oral opinions that he had given regarding the invalidity of the '129 reexamination certificate.

180. In June 1993, SciMed commercially launched the RALLY TM catheter.

181. The Court finds that from the beginning of the development project leading to the EXPRESS TM and RALLY TM catheters, SciMed took precautions to

give effect to its policy not to infringe the valid patent rights of others. SciMed reasonably relied on the opinions of its counsel that the '129 patent and reexamination certificate were invalid as obvious.

V. Damages A. Background

182. In a "direct sales country," Schneider (Europe) controls the sales force and includes its profit or loss on consolidated financial statements. Schneider (Europe) sells directly in France, United Kingdom, Belgium, Holland, Canada, Switzerland, and Austria. In a "distributor country," Schneider (Europe) sells its products to a distributor, which has its own sales force. Schneider sells through distributors in Germany, Spain, Austria, "Other Europe", Japan, "Far East Other", Middle East, Latin America, and Africa.

183. SciMed argues that none of the claims of the original Bonzel '129 patent emerged substantively the same in the reexamination certificate and that Plaintiffs are therefore not entitled to damages on the reexamined claim before the date of the reexamination certificate. SciMed also argues that Plaintiffs are not entitled to damages after the date of the reexamination pursuant to the doctrine of intervening rights.

184. Specifically, SciMed contends that reexamination claims 5-7: 1) exclude a procedure in which the guide wire and the catheter are put in together; 2) exclude a procedure where the balloon is pulled out while inflated; and 3) exclude the use of the catheter in valvuloplasty procedures.

185. Schneider contends that Claims 5-7 were not substantively changed in the Reexamination Certificate. While word changes were made to the claim, Schneider contends that the amendments merely clarified that which was already implicit in the original Claims 5-7.

186. The Court finds that the original and reexamined Claims 5-7 are substantively identical. In the reexamination, Dr. Bonzel stated, "In order to advance the prosecution and to alleviate the examiner's apparent concerns regarding certain of the method claims 5-7 as issued, patentee has now made minimal changes by substituting words of identical meaning and by making explicit that which was already implicit in the claims. It is patentee's firm conviction that the scope of amended claims 5-7 is identical to the scope of issued claims 5-7 of the '129 patent." Reexamination File History, Amendment (Jan. 28, 1991) (Defendant's Trial Exhibit 2, Tab 26, at 21). Moreover, Bonzel stated in a subsequent amendment, "For the record, patentee also wishes to respectfully reiterate his position that each of claims 5-7 is identical in scope and without substantive change in respect to issued claims 5-7 of the '129 patent."

Reexamination File History, Amendment (March 12, 1991) (Defendant's Trial Exhibit 2, Tab 32, at 5).

187. The Court finds that one of ordinary skill in the art would read both original and reexamination Claims 5-7 as excluding valvuloplasty because by their language, both are limited to the "vascular" system.

188. The specification supports Schneider's position that the reexamination certificate is substantively identical. The specification states:

> First the guide wire 1 is introduced through the guide catheter into the proper coronary artery. . . . When the guide wire 1 has passed the constriction in the coronary artery, the tip of the guide wire 1 remains on the far side of the stenosis in the coronary vessel. At this point, and not until, the dilatation catheter according to the invention is thrust onto the guide 1 outside the body and advanced through the guide catheter along the track formed by guide wire 1. . . .

'129 Patent Specification, Col. 3, lines 9-22. After considering the reexamination file history, the specification, the claim language, and expert testimony, the Court finds that Claims 5-7 in the reexamination certificate are substantively identical to Claims 5-7 in the original '129 patent.

B. Lost Profits

189. The Schneider rapid-exchange catheters and SciMed's infringing catheters compete within the same market segment at similar prices. Prices on Schneider and SciMed's catheters ranged from $ 600 - $ 700 between 1991 and 1993 domestically. Both companies' prices were several hundred dollars less internationally.

(i) Demand for the Patented Product

190. The Schneider monorail catheter has had commercial success in both the domestic United States and the international markets. The number of units sold by Schneider and Schneider's competitors, including SciMed, is evidence of the monorail-type catheter's success. See Findings of Fact 131-135.

191. The most important feature of a SOE monorail-type catheter is the short guide wire lumen, which allows for rapid exchange of the catheter during a PTCA procedure. This feature is primarily responsible for the commercial success of the product. See Finding of Fact 136.

192. There are distinct segments within the PTCA market. Those segments include over-the-wire ("OTW"), fixed wire ("FWC"), and single operator exchange ("SOE"). Prior to the '129 patent and introduction of Schneider's monorail catheter, there was no SOE market segment. Upon introduction of the monorail, the SOE market segment grew rapidly in both the international and domestic markets.

193. The high demand for the rapid-exchange-type catheter is established in a SciMed internal memorandum dated 9/1/89, which states, "The monorail is a must. Dale [Spencer] is pressing this issue. . . . Be aware, and be alert to allocating priority resources." (Plaintiffs' Trial Exhibit 46). This element of the Panduit test is clearly met.

194. When the EXPRESS TM entered the market, the rapid-exchange market was already expanding at a rapid rate. SciMed estimated that the SOE catheter market in February 1991 was growing at an annual rate of 40%. It grew from 0% in 1988 to 6% in 1989; 15% in 1990; 26% in 1991; and 31% in 1992.

(ii) Absence of Non-Infringing Alternatives

195. The MAGNET TM was not a non-infringing alternative until it entered the market in September 1993. In January 1992, Bard was granted a non-exclusive worldwide license under the '129 patent.

196. The TRAPPER TM was not available on the market before January 1992. The TRAPPER TM is not a non-infringing alternative because it is intended for use with an OTW catheter and it does not have a guide wire lumen. In addition, the TRAPPER TM costs $ 75-$ 80 per unit. It does not compete with SOE catheters, which cost approximately $ 650 per unit.

197. ACS's monorail catheters infringed the Bonzel '129 patent and reexamination certificate and therefore do not qualify as a non-infringing alternative. However, as of December 17, 1991, which is the date that Schneider licensed the ACS RX as part of a settlement agreement, the ACS monorail catheters became a non-infringing alternative. After December 17, 1991, therefore, market share analysis is necessary to establish lost profits.

198. Schneider is entitled to lost profits on 100% of SciMed EXPRESS TM sales from introduction of the EXPRESS TM in February 1991 until December 17, 1991. From December 17, 1991 until the entry of final judgment, Schneider is entitled to lost profits on each SciMed sale allocated to Schneider pursuant to the market share allocation set forth by Dr. Dugan.

199. The Court finds that the market share allocation set forth by Dr. Dugan in Plaintiffs' Trial Exhibit 1098 is reasonable. SciMed argues that "but for" the introduction of the EXPRESS TM and RALLY TM, every sale that went to the EXPRESS TM and RALLY TM would not have necessarily been an SOE sale because the SOE market is not a distinct segment of the PTCA market. The Court expressly rejects this argument based on the totality of credible evidence, which establishes that the SOE market segment is a "special niche" market for PTCA catheters.

200. The evidence presented at trial establishes that SciMed itself consistently identified SOE as a distinct and rapidly growing market segment. In a Project Evaluation Request, SciMed stated, "the rapid-exchange or monorail segment is expected to be approximately 15% of the balloon catheter market. . . ." (Plaintiffs' Trial Exhibit 728) (emphasis added).

201. In defining the market segments, Dr. Dugan analyzed ACS, SciMed, and Schneider market segment shares by country and ascertained market segment share allocation damages on a period-by-period and country-by-country basis. This approach is reasonable and is supported by the testimony and evidence submitted at trial. Dr. Dugan testified, and the Court finds, that there was a reasonable probability that without the EXPRESS TM and RALLY TM, people would buy another type of rapid-exchange catheter rather than a SciMed OTW catheter.

202. It is reasonable to use the 1992 market share percentages for 1993 and beyond. More precise 1993 percentages could not be calculated because ACS data was not available for 1993. (iii) Ability to Meet Demand

203. The record, reviewed as a whole, establishes that Schneider (Europe) had the manufacturing capacity to make all of the monorail-type catheters that SciMed sold internationally. Schneider (Europe) has not had backorders that affected its ability to make and sell catheters. In addition, Schneider (USA) had the manufacturing capacity to make all the monorail-type catheters that SciMed sold in the United States. Schneider (USA) has not had backorders that affected its ability to make and sell catheters.

204. Schneider (Europe) and Schneider (USA) have distribution, sales, and marketing systems in all geographic areas in the United States and international markets in which SciMed sold infringing catheters from 1991 through the present. Schneider (Europe) and Schneider (USA) had sufficient capacity to make all of SciMed's sales in those areas. Schneider (Europe) and Schneider (USA) also had sufficient capacity to hire and train sales and marketing staff to meet the additional sales demand within the necessary time frame.

205. SciMed and Schneider have virtually identical sales force coverage throughout the United States and the world. The Court finds that Schneider could have added sales force and representatives to meet the increased demand. In addition, in 1991 - 1992, the market was ripe for hiring, so Schneider would not have had trouble finding persons to employ.

206. Dr. Dugan testified that between 1989 and 1990, Schneider demonstrated the ability to increase productive capacity by 400% in a one year period. Between 1991 and 1992, production at the Schneider Plymouth plant increased by 165%.

207. The Plymouth, Minnesota operating plant has a substantial amount of under-utilized capacity. Schneider's new plant in Bulach, Switzerland provides Schneider (Europe) with the capacity to produce substantially increased amounts of catheters to meet demand.

(iv) The Amount of Loss

208. The market share analysis conducted by Dr. Dugan, as set forth in Plaintiffs' Trial Exhibit 1098, provides a reasonable calculation of the number of lost Schneider sales. It also reasonably establishes the number of SciMed sales on which a royalty is due. The lost profit margins and supporting analysis, set forth by Dr. Nantell in Defendant's Trial Exhibit 1137, applied within the framework of Dr. Dugan's market share analysis, results in a reasonable calculation of Schneider's total damages. Several damage tables, which are included in these Findings, set forth the Court's calculation of damages based on a combination of Dr. Dugan and Dr. Nantell's analyses.

209. The Court finds that Dr. Dugan's incremental profit margins overestimate Schneider's actual profit margins. His analysis assumes that the variable cost per unit is the same regardless of the level of additional units. His profit margins are too high because he did not fully account for changes in the nature of fixed costs that occur as production greatly increases. Fixed costs are only fixed within certain ranges of production. For large changes in production, fixed costs often become variable.

210. In addition, the Court finds that the fixed nature of costs for large changes in volume, as contemplated by Dr. Dugan, is inconsistent with non-litigation analyses done by both Schneider and SciMed. The profit margins set forth by Dr. Dugan are much higher than those contemplated by Schneider in a non-litigation context. For example, in Plaintiffs' Trial Exhibit 714, Schneider estimated a profit margin of between 26% and 40% on its sales.

211. Dr. Nantell's analysis results in a reasonable calculation of Schneider's actual profit margins. He determined how fixed costs would change with volume by performing a regression analysis of the Plaintiffs' historic cost data to determine how Plaintiffs' costs varied with sales. The Court adopts his lost profit percentage figures.

212. Schneider is entitled to reasonable royalties on all SciMed sales of EXPRESS<TM> and RALLY<TM> catheters for which lost profits are not awarded.

213. From February 1991 through June 1993, all SciMed infringing catheters were made in the United States. Therefore, Schneider (Europe) may recover lost profits for the damages resulting from lost sales in foreign countries. See Schneider (Europe) AG and Schneider (USA) Inc. v. SciMed Life Systems, Inc., No. 3-91 CIV 241, slip op. at 15-16 (D. Minn. May 14, 1993) (Alsop, J.). Schneider (USA) may recover lost profit damages in the United States.

214. The damage tables incorporated in Findings do not include damage calculations after June 30, 1993 because the calculations presented by the parties at trial ended on that date. In addition to the total amount of damages set forth in the damage tables, Plaintiffs are entitled to lost profit damages or a reasonable royalty on all infringing catheters made and sold by SciMed between June 30, 1993 and March 4, 1994.

215. The damage tables set forth damages owed on free goods through October 1992. Schneider is also entitled to reasonable royalties on any free Express<TM> and Rally<TM> catheters that SciMed has distributed between October 31, 1992 and March 4, 1994.

C. Reasonable Royalty

216. The reasonable royalty rate for the Bonzel patent under the facts of this case is 15% of SciMed sales. In reaching this rate, the Court has considered the Georgia-Pacific factors set forth below. Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116 (S.D.N.Y. 1970), aff'd in part, modified in part, 446 F.2d 295 (2d Cir.), cert. denied, 404 U.S. 870 (1971).

217. The reasonable royalty rate is determined by a hypothetical negotiation. A hypothetical negotiation in this case would have taken place on or about February 1991, just prior to SciMed's first sale of the EXPRESS<TM>. The parties to the hypothetical negotiation would have included SciMed and Schneider. At the hypothetical negotiation, the Bonzel patent is presumed to be valid and infringed.

(i) Georgia-Pacific Factors

(a) Factor One: Established Royalty Rate for the '129 Patent

218. The Court finds that there was no established royalty rate for the Bonzel patent. The license agreement between Dr. Bonzel and Schneider (Europe) that provides for a 5% royalty payment to Dr. Bonzel is not evidence of an established royalty rate for the Bonzel patent for the following reasons: 1) Dr. Bonzel and Schneider (Europe) were not competitors and, therefore, Dr. Bonzel would not lose market share by licensing Schneider; 2) Dr. Bonzel was merely a physician seeking someone to promote his unproven invention at that time; 3) there was no patent at the time of the license; and 4) no market existed yet for monorail-type catheters.

219. Neither does the Schneider (Europe) and Schneider (USA) sublicense establish a royalty for the Bonzel patent because Schneider (Europe) and Schneider (USA) are not competitors. They are sister companies that do not sell in each other's territory. As a result, the sublicense cannot be considered an arm's-length agreement.

220. The Schneider/ACS settlement agreement includes a fully paid-up cross-license of the '129 patent to ACS and the Yock patents to Plaintiffs. The agreement also includes a $ 22 million payment from ACS to Plaintiffs. Mr. Smith testified at trial, and the Court agrees, that this agreement indicates that the '129 patent is valuable. Insufficient evidence was presented, however, to show that this or any other agreement established a royalty rate for the '129 patent.

(b) Factor Two: Rates Paid by SciMed for Patents Comparable to the '129 Patent

221. SciMed paid ACS a royalty rate of 20% under the ACS Yock patents in settlement of litigation. SciMed received the right to continue selling the EXPRESS<TM> catheter for a period of about two years. The Yock patents are for monorail-type catheters and are therefore comparable to the Bonzel patent. SciMed paid a considerably smaller royalty rate in a settlement agreement with Bard.

222. The Court notes that these royalty rates were reached in settlement of litigation, which detracts from their usefulness in arriving at a royalty rate in this case. However, A royalty rate of 15% does fall between the various royalty rates paid by SciMed in these settlement agreements.

(c) Factor Three: The Nature and Scope of the License

223. The license granted to SciMed under the Bonzel patent, while non-exclusive, would not be restricted to any particular territory of the United States. It would allow SciMed to sell throughout the world and would not contain restrictions regarding to whom SciMed could sell its products.

(d) Factor Four: Plaintiffs' Patent Licensing Policy

224. Schneider has an established policy and practice of not licensing the Bonzel patent, primarily because licensing it would not be profitable. In February 1991, it would not have licensed the Bonzel patent to SciMed.

225. Schneider conducted studies in response to various requests for a license under the '129 patent. Each study resulted in the conclusion that it would require royalty rates substantially higher than 15%.

(e) Factor Five: The Commercial Relationship Between the Parties

226. Schneider and SciMed are competitors in the same geographic territories and in the same line of business. Their rapid-exchange products directly compete within the rapid-exchange segment of the PTCA market.

227. SciMed's infringement interfered with the patent monopoly that the '129 enjoyed prior to the entrance of the EXPRESS<TM> into the market.

(f) Factor Six: Derivative or Convoyed Sales

228. In part, SciMed's business strategy was to increase sales of other SciMed products with sales of the EXPRESS<TM>. The ability of the EXPRESS<TM> to increase other SciMed product sales increases the reasonable royalty rate.

(g) Factor Seven: The Duration of the Patent and the Term of the License

229. The license would have been coextensive with the remaining term of the patent. At the time of the hypothetical negotiation, the Bonzel patent still had fourteen years left. This factor tends to favor SciMed and decreases the reasonable royalty rate slightly.

(h) Factor Eight: Established Profitability, Commercial Success, and Popularity of Products Made Under the '129 Patent

230. Schneider's Monorail sales may be used as a basis for evaluating the established profitability, commercial success, and popularity of products made under the '129 patent. The profitability, success, and popularity of Schneider's monorail products is primarily due to the rapid-exchange capability, which is the monorail's patented feature. The record establishes that Schneider's rapid-exchange catheters were highly profitable, popular, and successful in February 1991.

231. SciMed's infringing sales may also be used as a basis for evaluating these factors. In February 1991, SciMed anticipated extremely high profits from the sale of the EXPRESS<TM> based on the rate at which the rapid-exchange segment of the PTCA market was growing. SciMed expected to share in the success of the Schneider monorail products, which is evidence of the strength of the Bonzel patent.

(i) Factor Nine: Utility and Advantages of the '129 Patent Over Old Modes or Devices

232. The Bonzel patent has many advantages over the old devices, the most important of which is its rapid-exchange capability. Other advantages include: friction is reduced; fewer personnel are necessary to perform an exchange; less exposure to x-ray is required; and physicians are able to use the wire first technique with a standard-length guide wire.

(j) Factor Ten: The Nature of the Invention, Character of the Commercial Embodiment, and Benefits of the Invention

233. Schneider sold monorail-type catheters before February 1991, which means that at the time of the hypothetical negotiation, Schneider already knew that the monorail could be manufactured and sold successfully.

(k) Factor Eleven: The Extent to Which SciMed Made Use of the '129 Patent Prior to the Hypothetical Negotiation

234. At the time of the hypothetical negotiation, there had been no use by SciMed of the '129 patent.

(l) Factor Twelve: Customary Royalty Rates in the Hypothetical Negotiation

235. It was not established at trial that there is a customary royalty rate in the catheter industry. On the contrary, evidence and testimony suggests that royalty rates have varied considerably.

(m) Factor Thirteen: The Portion of the Profit That Should be Credited to the '129 Patent

236. The portion of profit that should be credited to the '129 patent is an important factor in determining royalty rates for catheter licenses. SciMed claims that the EXPRESS<TM> and RALLY<TM> catheters have many features that produce sales that are wholly unrelated to the '129 patent. The Court finds, however, that the critical feature of SciMed's rapid-exchange catheters is the ability to perform rapid-exchange. This finding is supported by the testimony contained in the record. Because that is the patented feature of the Bonzel invention, almost all of the realizable profit made by SciMed on its sales of Express catheters is attributable to the Bonzel patent.

237. SciMed was able to enter the rapid-exchange segment of the PTCA market with minimal business risk because the Schneider rapid-exchange products opened the market.

(n) The Opinion of Qualified Experts

238. Schneider's expert, Mr. Dudley Smith, opined that a reasonable royalty rate in this case is 30%. By virtue of his knowledge, training, and experience, Mr. Smith is qualified to offer his opinion as to a reasonable royalty in this case and to assist the Court in determining what royalty rate would be reasonable under the circumstances. However, the Court finds that consideration of the Georgia-Pacific factors, based on the record as a whole, renders 30% an excessively high figure.

239. SciMed's expert, Mr. Richard Myers, has extensive experience in negotiating royalty rates in the catheter industry. He testified that a reasonable royalty rate in this case is 6%. Mr. Myers is well-qualified to offer his opinion regarding a reasonable royalty in this case. However, the Court finds that his rate of 6% is excessively low.

(o) The Rate Which the Parties Would Have Agreed Upon, Leaving Each with a Reasonable Profit

240. The Court finds that, assuming that the '129 patent is valid and infringed, a reasonable royalty negotiated in February 1991 between Schneider and SciMed would have been 15%. A reasonable royalty rate of 15% is well within the royalty rates advocated by Mr. Smith and Mr. Myers and is an equitable, reasonable rate based on careful consideration of the record as a whole.

241. A reasonable royalty rate of 15% is supported by application of the Georgia-Pacific factors to the facts in this case.

242. The parties dispute the royalty SciMed could have paid and still maintained a profit. The Court finds that the record establishes that SciMed's anticipated profit for the EXPRESS<TM> would have been sufficient to pay a royalty rate of 15%. Such a rate would have also allowed SciMed to retain a reasonable profit on its EXPRESS<TM> sales.

D. Pre-judgment Interest

243. Plaintiffs' are entitled to pre-judgment interest on all damages, calculated to the date on which final judgment is entered. Pre-judgment interest shall be compounded for time. The Court finds that Dr. Nantell's calculation of pre-judgment interest, based on interest rates for government securities, is reasonable and reliable.

244. The damage tables incorporated in these Findings follow Dr. Natell's reasonable pre-judgment interest rates and compounding factors. Pre-judgment interest shall be based on the interest rates set forth in the tables. In addition to pre-judgment interest on the $ 45,132,427 in damages arrived at by the Court, calculated to entry of final judgment, Plaintiffs are entitled to pre-judgment interest on royalty damages for distribution by SciMed of infringing free goods, calculated to entry of final judgment. Plaintiffs are also entitled to pre-judgment interest on damages after June 30, 1993, calculated to final entry of judgment, at rates consistent with these Findings.

V. Attorney Fees and Costs

245. Schneider claims that this is an exceptional case under 35 U.S.C. § 285 such that it should be awarded attorney fees and costs. The Court concludes that this is not an exceptional case within the meaning of 35 U.S.C. § 285

VI. Permanent Injunction

246. Schneider requests that the Court enjoin SciMed from manufacturing or selling the RALLY<TM> catheter. SciMed argues that the RALLY<TM> catheter should not be enjoined for public policy reasons.

247. Pursuant to an agreement with ACS, SciMed stopped selling the EXPRESS<TM> catheter in November 1993. In anticipation of the possibility that SciMed could breach or renegotiate its agreement with ACS, Schneider also requests a permanent injunction against the EXPRESS<TM>.

248. SciMed argues that public interest justifies denying the injunction of the RALLY<TM>. The evidence and expert testimony presented at trial suggests that commercial rapid-exchange catheters are generally interchangeable. SciMed presented the testimony of four physicians, Dr. Randall Hundley, Dr. L. Stephen Endsley, Dr. Arthur Muller, and Dr. Charles Wilkins, all of whom testified that they prefer the RALLY<TM> to other rapid-exchange catheters. Each also testified to a certain small percentage of procedures that could not be done at all without the RALLY<TM>. They believe that without the RALLY<TM>, those patients will be forced to undergo coronary bypass surgery, which is far costlier and more traumatic than PTCA.

249. While it is undoubtedly true that some physicians strongly prefer the RALLY<TM> to other rapid-exchange catheters, and it may be the catheter of choice among physicians, but mere personal preference alone does not justify denying an injunction. No credible evidence in the trial record supports a finding that the RALLY<TM> is significantly objectively superior to other catheters in performance or that all other catheters are defective, unsafe, or incapable of performing as intended and required during a PTCA procedure.

250. To the extent that the Court's Conclusions of Law include what may be considered Findings of Fact, they are incorporated herein by reference.

CONCLUSIONS OF LAW

I. Infringement

251. Plaintiffs bear the burden of proof to establish infringement by a preponderance of the evidence. ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1582 (Fed. Cir. 1988). See 35 U.S.C. § 271 (1981 & Supp. 1993).

252. Determination of the issue of infringement requires a two-step analysis. First, each claim must be properly construed. Second, each properly construed claim is compared with the EXPRESS<TM> and RALLY<TM> to determine whether the claims cover the allegedly infringing products. Charles Greiner & Co., Inc. v. Mari-Med Mfg., Inc., 962 F.2d 1031, 1034 (Fed. Cir. 1992); Minnesota Mining and Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1570 (Fed. Cir. 1992).

A. Claim Construction

253. The scope of a claim is generally a question of law, although claim construction may require resolution of fact issues. Charles Greiner, 962 F.2d at

1034; Moeller v. Ionetics, Inc., 794 F.2d 653, 656 (Fed. Cir. 1986). The threshold requirement in claim construction is an examination of the claim at issue. ZMI Corp., 844 F.2d at 1579. It is the wording of the claim which sets forth the subject matter of the invention. Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 22 USPQ 1401, 1406 (D. Minn. 1991), aff'd 976 F.2d 1559 (Fed. Cir. 1992). The terms of a claim "will be given their ordinary meaning, unless it appears that the inventor used them differently." ZMI Corp., 844 F.2d at 1579.

254. Claims are normally construed as they would be by those of ordinary skill in the art. Fromson v. Offset Plate, Inc., 720 F.2d 1565, 1571 (Fed. Cir. 1983). One of ordinary skill in the art is a hypothetical person "who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights. . . ." Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985). In November 1984, one of ordinary skill in the art was a practicing interventional cardiologist who performed dilation or coronary angioplasty dilatation procedures See Findings of Fact 90-91.

255. The Court finds that the ordinary meaning of the elements of the '129 patent claims is helpful in construing the claims, but is not dispositive. Thus, extrinsic evidence, such as the specification, prosecution history, other claims in the patent, and expert testimony, is necessary to interpret claims of the '129 patent that are in dispute. Arachnid, Inc. v. Medalist Mktg. Corp., 972 F.2d 1300, 1302 (Fed. Cir. 1992); Howes v. Medical Components, Inc., 814 F.2d 638, 643 (Fed. Cir. 1987); Moeller, 794 F.2d at 656.

256. The specification "aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification." ZMI Corp., 844 F.2d at 1580 (quoting Autogiro Co. of Am. v. United States, 384 F.2d 391, 397 (Fed. Cir. 1967)). The Court must not, however, read into a claim a limitation appearing in the specification, but not in the claim. Minnesota Mining, 976 F.2d at 1566.

257. The claimed invention is not limited to the preferred embodiments or specific examples in the specification. Lemelson v. United States, 752 F.2d 1538, 1552 (Fed. Cir. 1985); Fromson, 720 F.2d at 1569.

258. The Court finds that consideration of the claim language, the specification, prosecution history, and expert testimony favors Schneider's interpretation of the claim elements in issue, as set forth in the Findings of Fact.

B. Infringement by the SciMed EXPRESS<TM> and RALLY<TM>

(i) Literal Infringement

259. Infringement requires that each limitation of a claim be met literally or by a substantial equivalent. Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 879 (Fed. Cir. 1991). A claim is literally infringed if the accused device embodies every element of the patent claim as properly construed. Id. Literal infringement is a question of fact. ZMI Corp., 844 F.2d at 1578.

260. The Court concludes that the EXPRESS<TM> and RALLY<TM> catheters embody every element of the '129 patent claim as properly construed, for the reasons set forth in the Findings of Fact. Because each claim element of the '129 patent is literally met, the Court finds that the EXPRESS<TM> and RALLY<TM> catheters literally infringe the '129 patent claims.

(ii) Doctrine of Equivalents

261. The doctrine only comes into play when there is no literal infringement. Seattle Box Co. Inc. v. Indus. Crating & Packing Inc., 731 F.2d 818, 828 (Fed. Cir. 1984). Thus, the Court considers the doctrine only as an alternative grounds for finding infringement of the '129 patent.

262. A claim that is not literally infringed may still be infringed under the Doctrine of Equivalents. Equivalence is a question of fact for which the burden of proof rests on Plaintiffs. Lemelson, 752 F.2d at 1550. This doctrine permits recovery if an allegedly infringing device performs substantially the same function, in substantially the same way, to achieve substantially the same result. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950).

263. To support an infringement determination under the Doctrine of Equivalents, the accused catheter must embody each claim limitation or its equivalent. Key Mfg. Group, Inc. v. Microdot, Inc., 925 F.2d 1444, 1449 (Fed. Cir. 1991).

264. For the reasons set forth in the Findings of Fact, the Court finds that the EXPRESS<TM> and RALLY<TM> catheters perform substantially the same function as the '129 patented catheters, in substantially the same way, to achieve substantially the same result. Graver Tank, 339 U.S. at 605. Even if they did not literally infringe the '129 patent, the Court would conclude that they infringe the '129 patent under the Doctrine of Equivalents.

II. Validity

265. The '129 patent is presumed valid pursuant to 35 U.S.C. § 282 (1981 & Supp. 1993). See American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir.), cert. denied, 469 U.S. 821 (1984). SciMed has the burden of proving, by clear and convincing evidence, that the '129 patent claims are invalid. American Hoist & Derrick, 725 F.2d at 1359.

266. The burden is difficult to meet where the prior art was before the patent examiner during the prosecution of the application because "a government agency such as the . . . Patent Office [is] presumed to do its job." American Hoist & Derrick, 725 F.2d at 1359. See Hewlett-Packard, 909 F.2d at 1467. The burden may be more easily met where the challenger produces prior art that is more pertinent than that considered by the Patent and Trademark Office. Ryco, Inc. v. Ag-Bag Corp., 857 F.2d 1418, 1423 (Fed. Cir. 1988). While Defendant produced perfusion catheter prior art at trial that was not considered by the PTO, and while the Court finds merit in SciMed's argument that it is not cumulative, the Court nonetheless concludes that Defendant has not met its burden of proving invalidity for the reasons discussed below.

A. Obviousness

267. A patent is invalid where the differences between the subject matter of the patent and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art . . ." to which the patent pertains. 35 U.S.C. § 103 (1981 & Supp. 1993). The relevant time in this case is November 1984.

268. One of ordinary skill in the art is a hypothetical person "who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights. . . ." Standard Oil, 774 F.2d at 454. Furthermore, "Inventors, as a class, . . . possess something . . . which sets them apart from workers of ordinary skill, and one should not go about determining obviousness under § 103 by inquiring into what patentees (i.e., inventors) would have known or would likely have done, faced with the revelations of references." Id. (emphasis in original). Schneider's definition of one of ordinary skill in the art is consistent with Standard Oil.

269. Obviousness is a question of law to be determined by the court based upon several factual determinations, including: 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) objective evidence of nonobviousness.

Graham v. John Deere Co., 383 U.S. 1, 17 (1966); Standard Oil, 774 F.2d at 454.

270. A prior art reference is within the scope of applicable prior art if that reference is within the field of the inventor's endeavor or is reasonably pertinent to the particular problem with which the patentee is involved. Ryco, 857 F.2d at 1423; Cable Elec. Prods., Inc. v. Genmark, Inc., 770 F.2d 1015, 1025 (Fed. Cir. 1985); Union Carbide Corp. v. American Can Co., 724 F.2d 1567, 1572 (Fed. Cir. 1984).

271. Combining devices that have a short guide wire lumen, but are not used in dilatation or coronary dilatation, with PTA and PTCA devices that have a long guide wire lumen, would not have been obvious to one of ordinary skill because they would not have been reasonably pertinent to the particular problem with which Dr. Bonzel was concerned. Such references, therefore, are not clear and convincing evidence of the obviousness of the '129 patent claims. See Ryco, 857 F.2d at 1423.

272. Even if devices outside the field of PTA and PTCA are pertinent to the particular problem to which the claimed invention is directed, see Cable Elec. Prods., 770 F.2d 1025, those devices, as a whole, would not render the claimed invention obvious to one of ordinary skill in the art in 1984. The Court reaches this conclusion having considered the additional prior art that was not before the PTO during the reexamination proceedings.

273. The combination of elements "from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a prima facie case of obviousness." In re Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992). There must be "some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination." Id.

274. It is insufficient that "the prior art disclosed the components of the patented device, either separately or used in other combinations. . . ." Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934 (Fed. Cir.), cert. denied, 498 U.S. 920 (1990). Individual references cannot be "employed as a mosaic to recreate a facsimile of the claimed invention." Id. (quoting W.L Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1551 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)).

275. Where obviousness is based upon a modification of a reference that destroys the intended purpose or function disclosed in a reference, there is no motivation for engaging in the modification. See In re Gordon, 733 F.2d 900,

902 (Fed. Cir. 1984). Modifying Leary or Erbel in the manner suggested by SciMed would destroy their intended purpose and would not have been obvious. See, e.g., Texas Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1178 (Fed. Cir. 1993) ("Absent such suggestion to combine the references, respondents can do no more than piece the invention together using the patented invention as a template. Such hindsight reasoning is impermissible."). To reach a contrary conclusion would require engaging in hindsight reconstruction, which the Court declines to do. Id.

B. Secondary Considerations

276. Factors such as commercial success, solving a long-felt, but unsolved need, the failure of others, inventing contrary to the teachings of the art, and producing an unexpected or synergistic result are relevant as indicia of non-obviousness. Graham, 383 U.S. at 17.

277. For commercial success to be relevant to the obviousness determination, Plaintiff must establish a nexus between the claimed invention and the commercial success. Sjolund v. Musland, 847 F.2d 1573, 1582 (Fed. Cir. 1988).A "nexus" is a "legally and factually sufficient connection between the proven success and the patented invention. . . ." Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir.), cert. denied, 488 U.S. 956 (1988). Plaintiffs have established a prima facie case that it is the patented features of their monorail catheters that have resulted in the catheters' success. The burden therefore falls on Defendants to show that the commercial success was due to extraneous factors other than the patented invention, which Defendants have failed to do in this case. Id. at 1393. The great weight of evidence presented at trial suggests that the success of SOE-type catheters is due to their rapid-exchange capability, as opposed to any other feature. Thus, the Court finds a positive inference that the claimed catheter would not have been obvious at the time the invention was made to one of ordinary skill in the art. Id. at 1394.

278. Long-felt need for the patented invention is analyzed "as of the date of an articulated identified problem and evidence of efforts to solve that problem." Texas Instruments, 988 F.2d at 1178. Testimony at trial established that between 1978 (when the first OTW catheter was invented) and 1984 (the date of Dr. Bonzel's invention), exchanging OTW catheters was generally regarded as highly problematic. It was not until 1984, however, that Dr. Bonzel discovered a way to rapidly exchange an OTW catheter over a standard-length guide wire. Thus, there is evidence of long-felt need for a rapid-exchange catheter in the record. Id.

279. The failure of others to find a solution to the problem addressed by the patentee is also evidence of nonobviousness. Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1578-79 (Fed. Cir. 1991). There is ample evidence in the record that there were persons of ordinary skill in the art who might have, but did not, conceive of Bonzel's invention. In fact, early attempts to design products which facilitated exchange of catheters resulted in awkward and time-consuming procedures, such as the extension wire.

280. Contemporaneous developments occurring after the priority date of the '129 patent are not evidence of obviousness of the claimed invention. See Lindemann Maschinenfabrik v. American Hoist and Derrick Co., 730 F.2d 1452, 1460 (Fed. Cir. 1984); 35 U.S.C. § 135 (1981 & Supp. 1993). Dr. Yock's invention does not indicate that the '129 patent is obvious because his invention cannot be corroborated before the date on which he filed a patent application (April 15, 1986), which is significantly later than the filing date of the '129 patent. See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); Lindemann, 730 F.2d at 1460-61.

281. Thus, upon careful review of the facts under 35 U.S.C. § 103 (1981 & Supp. 1993) as required by Graham, and upon full consideration of all prior art and other relevant evidence, the Court concludes that the invention claimed in the '129 patent would not have been obvious to a person of ordinary skill in the art at the time of the invention. See Graham, 383 U.S. at 1.

C. Inequitable Conduct

282. SciMed has the burden of proving inequitable conduct by clear and convincing evidence. Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1189 (Fed. Cir. 1993). Applicants for patents owe an uncompromising duty of candor to the Patent and Trademark Office. Precision Co. v. Automotive Co., 324 U.S. 806, 818 (1945). A patent is rendered unenforceable when the applicant fails to live up to the duty of candor toward the PTO. See Paragon, 984 F.2d at 1190-91.

283. The doctrine of inequitable conduct requires a trial court to undertake a two-step analysis. First, it "must discern whether the withheld references satisfy a threshold level of materiality. . . ." Halliburton Co. v.Schlumberger Technology Corp., 925 F.2d 1435, 1439 (Fed. Cir. 1991). Second, the court must "determine whether the applicant's conduct satisfies a threshold showing of intent to mislead." Id. These are both questions of fact. Id. Next, assuming satisfaction of the thresholds, the trial court must balance materiality and intent. Id. The more material the omission, the less culpable the intent required. Id.

284. Inequitable conduct "includes failure to disclose material information, or submission of false material information, with an intent to mislead." Minnesota Mining, 22 USPQ at 1410 (quoting J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559 (Fed. Cir. 1984), cert. denied, 474 U.S. 822 (1985)).

285. Information is "material" if there is "'substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.'" Id. at 1440 (quoting 37 C.F.R. § 1.56 (1989)). However, "a patentee has no obligation to disclose an otherwise material reference if the reference is cumulative or less material than those already before the examiner." If references found by Examiner Thaler are more closely related to the '129 patent than the uncited art, the reference is not material. Id.

286. The threshold of intent is not met by a finding of negligence or recklessness alone, absent culpable intent. See Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft, 945 F.2d 1546, 1554 (Fed. Cir. 1991). There must be not only a misrepresentation, but also actual knowledge of falsity, or an obligation to know it, before the threshold intent is met. Jaskiewicz v. Mossinghoff, 822 F.2d 1053, 1058 (Fed. Cir. 1987). An applicant's conduct must manifest a sufficiently culpable state of mind to warrant a determination that conduct was inequitable. Halliburton, 925 F.2d at 1443.

287. The perfusion prior art that SciMed suggests Schneider should have submitted to the PTO is arguably material and non-cumulative. While the perfusion prior art is similar to Leary, it contains elements (perfusion holes) not found in Leary, which SciMed argues renders the '129 patent obvious in light of short guide-lumen prior art.

288. However, the record lacks any credible evidence that Schneider intended to deceive the PTO in failing to submit perfusion prior art. Because inequitable conduct does not exist absent culpable intent, the Court finds that careful balancing of materiality and lack of intent clearly tips the scale toward the conclusion that inequitable conduct did not occur regarding the alleged omission of prior art. Tol-O-Matic, 945 F.2d at 1554.

289. The submission of false affidavits or declarations is necessarily material. Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556, 1571 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Furthermore, an inference of intent to deceive the PTO would be strongly supported by the submission of deceptive affidavits. Paragon Podiatry, 984 F.2d at 1191. The declarations Schneider submitted in support of its position regarding the definition of one of ordinary skill in the art and the necessity of a full-length guide wire lumen were material, but because

they were not misleading or intentionally misleading, the scale again tips against a finding of inequitable conduct. For the same reason, SciMed has failed to prove inequitable conduct regarding Schneider's representation that one of ordinary skill in the art would not reasonably consider art that was outside the field of arterial dilatation.

290. After careful review of the record as a whole, the Court concludes that SciMed has failed to meet its burden of showing, by clear and convincing evidence, that Schneider engaged in inequitable conduct during the original prosecution of the '129 patent or during the reexamination of the '129 patent.

III. Willfulness

291. Schneider requests increased damages pursuant to 35 U.S.C. § 284 (1981 & Supp. 1993) based on SciMed's alleged willful infringement.

292. Plaintiffs bear the burden of proving willfulness by clear and convincing evidence. Braun Inc. v. Dynamics Corp. of Am., 975 F.2d 815, 822 (Fed. Cir. 1992). Willfulness is a question of fact. Uniroyal, Inc. v. Rudkin-Wiley Corp., 939 F.2d 1540, 1546 (Fed. Cir. 1991). It is determined from a consideration of a totality of the circumstances. Ortho Pharmaceutical Corp. v. Smith, 959 F.2d 936, 944 (Fed. Cir. 1992); Gustafson, Inc. v. Intersystems Indus. Prods., Inc., 897 F.2d 508, 510 (Fed. Cir. 1990).

It is well-recognized that a potential infringer has "an affirmative duty to exercise due care to determine whether or not he is infringing" when has has actual notice of another's patent rights. Underwater Devices, Inc. v. Morrison Knudsen Co. Inc., 717 F.2d 1380, 1389-90 (Fed. Cir. 1983).

293. Willfulness is not present if SciMed formed a good faith belief that the '129 patent and the claims subject to reexamination were either invalid or not infringed. State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1581 (Fed. Cir. 1989), cert. denied, 493 U.S. 1022 (1990). Reliance on opinions of counsel is strong evidence of SciMed's good faith if the opinion justified a good faith belief that the claims were invalid or not infringed. Read Corp. v. Portec, Inc., 970 F.2d 816, 827 (Fed. Cir. 1992). Where opinions consist of merely conclusory statements, they do not constitute authoritative opinions "upon which a good faith reliance on invalidity may be founded." Bott v. Four Star Corp., 807 F.2d 1567, 1572 (Fed. Cir. 1986), cert. denied, 474 U.S. 802 (1985), partially overruled on other grounds by A.C. Aukerman Co. v. R.L. Chaides Constr., 960 F.2d 1020, 1038 (Fed. Cir. 1993) (quoting Kori Corp. v. Wilco Marsh Buggies & Draglines, 761 F.2d 649, 656 (Fed. Cir. 1985)). Oral opinions are not favored. Minnesota Mining, 976 F.2d at 1580.

294. Upon learning of a patent or a filing of suit, a potentially infringing party may exercise due care by continuing to manufacture and presenting what in good faith it believes to be legitimate defenses without risk that, on that basis alone, it will be found a willful infringer. Minnesota Mining, 22 USPQ at 1413. Cases where willful infringement is found, dispite the opinion of counsel, usually involve situations where opinion of counsel was ignored or found to be incompetent. Read, 970 F.2d at 829.

295. After careful consideration of the record, the Court concludes that Plaintiffs have failed to meet their burden of proving willfulness. The record establishes that SciMed received several written (July 18 and November 5, 1990) and verbal opinions from Kinney & Lange prior to launching the EXPRESS<TM> in February 1991. It was SciMed's reasonable belief, based on the opinion of counsel, that the '129 patent was invalid and would not survive reexamination.

296. The Court finds that Schneider's assertion that Mr. Young's opinion letters are "conclusory" and therefore unreliable is without merit. Mr. Young analyzed and reported on the reexamination proceedings and rendered his opinion that the '129 patent is invalid and would not reissue in his letters dated July 18, 1990 and November 5, 1990, before the launch of the EXPRESS<TM> in February 1991.

297. Mr. Young's opinion letters were thorough enough to instill a reasonable belief in SciMed that a court might reasonably hold the patent invalid or unenforceable. See Ortho Pharmaceutical, 959 F.2d at 944. This is especially true in light of other factors, such as the invalidation of the German '129 patent. See BIC Leisure Prod. v. Windsurfing International, 1 F.3d 1214, 1223 (Fed. Cir. 1993). Moreover, Mr. Young refused to give a non-infringement opinion, which supports the independent and reliable nature of his invalidity opinion. See Westvaco Corp. v. Int'l Paper Co., 991 F.2d at 735, 774 (Fed. Cir. 1993). Under the totality of the circumstances, "a reasonable person would prudently conduct himself with . . . confidence that a court might hold the patent invalid or infringed." Minnesota Mining, 976 F.2d at 1580. The Court therefore concludes, based on the totality of the circumstances, that SciMed's infringement cannot fairly be called "willful."

IV. Damages

A. Background

298. Schneider (USA) is entitled to recover lost profit damages for EXPRESS<TM> and RALLY<TM> sales it would have made in the United

States. Schneider (Europe) AG and Schneider (USA) Inc. v. SciMed Life Systems, Inc.,
3-91 CIV 241, slip op. at 16 (May 14, 1993) (Alsop, J.). Schneider (Europe) is entitled to recover lost profit damages for EXPRESS TM and RALLY TM sales that it would have made in Europe because all of SciMed's infringing actions took place within the United States. Id. See 35 U.S.C. § 271 (1981 & Supp. 1993).

299. Schneider (USA) is not precluded from collecting damages for infringement of the licensed patent under the licensing agreement between Schneider (Europe) and Schneider (USA). Schneider (Europe) AG and Schneider (USA) Inc. v. SciMed Life Systems, Inc., 3-91 CIV 241, slip op. at 11 (May 14, 1993) (Alsop, J.) See Waterman v. Mackenzie, 138 U.S. 252, 256 (1891).

300. To the extent that a reexamination certificate's "claims are identical with the original patent, [it] shall constitute a continuation thereof and have effect continuously from the date of the original patent." 35 U.S.C. § 252, 307(b) (1981 & Supp. 1993). The term "identical" means "at most, 'without substantive change.'" Westvaco, 991 F.2d at 741 (emphasis in original) (quoting Seattle Box, 731 F.2d at 828). A substantive change is any change where the scope of the claims is no longer identical to the original claims, which is a question of law. Seattle Box Co. v. Indus. Crating & Packing, 731 F.2d 818, 828 (Fed. Cir. 1984). If a reexamined claim is not identical to the original claims in terms of scope, the patentee is not entitled to damages on the reexamined claim before the date of the reexamination certificate. Westvaco, 991 F.2d at 742.

301. Pursuant to the doctrine of intervening rights, SciMed also argues that, because "substantial preparation was made before the grant of the reissue, . . ." the Court should protect the "investments [SciMed] made or business commenced [launch of the Express] before the grant of the reissue." 35 U.S.C. § 252 (1981 & Supp. 1993). The doctrine of intervening rights is properly raised only if valid claims in the original patent are altered in the reissued patent. If they are altered, the court must consider whether to fashion appropriate relief "to the extent and under such terms as the court deems equitable. . . ." Id. See Westvaco, 991 F.2d at 743 (quoting 35 U.S.C. § 252). See Seattle Box, 731 F.2d at 829-30.

302. Because the Court finds that the reexamination certificate is without substantial change to the original '129 patent, the Court accordingly denies Defendant such relief. See Seattle Box, 731 F.2d at 828.

303. Pursuant to 35 U.S.C. § 284 (1981 & Supp. 1993), a patent owner's claim for damages may be based upon a reasonable royalty for the license or profits lost by the patent owner as a result of the alleged infringement. Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075, 1078 (Fed. Cir. 1983). Computation of damages under 35 U.S.C. § 284 "is a matter within the sound discretion of the trial court." Trell v. Marlee Elec. Corp., 912 F.2d 1443, 1445 (Fed. Cir. 1993) (quoting Fromson, 853 F.2d at 1576). It is permissible to award damages containing a combination of lost profits and a reasonable royalty. State Indus., 883 F.2d at 1577.

304. Plaintiffs have the burden of proof, by a preponderance of the evidence, on all issues relating to damages. Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991). The finding of an amount of damages is a factual question. BIC Leisure Products, 1 F.3d at 1217.

B. Lost Profits

305. An award of lost profits requires proof of "a causal relation between the infringement and its loss of profits. The patent owner must show that 'but for' the infringement, it would have made the infringer's sales." BIC Leisure, 1 F.3d at 1218. The Panduit test is an appropriate "but for" test. The Panduit test assumes that the patent owner and the infringer sell products sufficiently similar to compete against each other in the same market segment at similar prices. Id.

306. The question of whether Schneider would have made SciMed's sales can be resolved by showing: 1) demand for the patented product; 2) absence of non-infringing alternatives; 3) ability to meet demand; and 4) the amount of profit Schneider would have made. Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978). See Gyromat Corp. v. Champion Spark Plug Co., 735 F.2d 549, 552 (Fed. Cir. 1984). Lost profits must be established to a "reasonable probability." BIC Leisure Products, 1 F.3d at 1218.

(i) Demand for the Patented Product 307. Demand for the patented product can be established by a substantial number of sales by SciMed or Schneider of a product containing the patented features. BIC Leisure Products, 1 F.3d at 1219; see, e.g., Gyromat, 735 F.2d at 552 (evidence of sales by infringing product as evidence of demand). Evidence and testimony presented at trial showed a extremely high demand for SciMed and Schneider products containing the patented features.

(ii) Absence of Non-Infringing Alternatives

308. Absence of a non-infringing alternative is shown when purchasers in the marketplace are willing to buy the patented product for its advantages or when specific purchasers of the infringing product base their purchases on those advantages. Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1373 (Fed. Cir. 1991), cert. denied, 113 S. Ct. 60 (1992). Absence of a non-infringing alternative can be established where the patentee and the infringer are the sole suppliers of a "special niche" or "mini-market" within a generic product market. Yarway Corp. v. Eur-Control USA, Inc., 775 F.2d 268, 276 (Fed. Cir. 1985). Because no other non-infringing rapid-exchange catheters were available before December 17, 1991, Plaintiffs have established the absence of non-infringing alternatives during that time frame.

309. A product is an acceptable non-infringing substitute if it competes in the same market for the same customers as the infringer's product. BIC Leisure Products, 1 F.3d at 1218. A licensed product is an acceptable non-infringing alternative as of the time that it is licensed. Id.

310. This element of the Panduit test also be met by substituting proof of market share for proof of the absence of acceptable substitutes. Id. at 1219. See State Indus., 883 F.2d at 1578. Thus, where there are competitors other than the defendant in a product market, and all of the competitors are likely infringers of the subject patent, the patentee is entitled to lost profits of a percentage of the defendant's sales corresponding to the market shares of all the infringing competitors in addition to the market share of the patentee. Id. After December 17, 1991, which is the date on which a non-infringing alternative became available, it is reasonable to apply Dr. Dugan's market share analysis to determine what percentage of SciMed sales were Schneider lost sales. Id.

311. Schneider is not required to negate every possibility that a purchaser might have bought another product, or that the purchaser would have purchased the product from someone else absent the infringement. Kaufman Co., Inc. v. Lantech, Inc., 926 F.2d 1136, 1141 (Fed. Cir. 1991). SciMed argued throughout trial that, had the EXPRESS <TM> not been introduced, a majority of EXPRESS <TM> sales would have been OTW and FWC sales ("cannibalization"). While it is probably true that not all infringing SciMed sales would have gone to another rapid-exchange catheter, the Court finds that Schneider has adequately proven a reasonable probability that it (or ACS) would have made the vast majority of SciMed's infringing sales after December 17, 1991 and that Schneider would have made SciMed's infringing sales before that date. See Standard Havens, 953 F.2d at 1372.

(iii) Ability to Meet Demand

312. If the patentee and the infringer are the only suppliers in the market, it is reasonable to assume that the patentee would have made the infringer's sales, provided that the patentee had the capacity to make such sales. State Indus., 883 F.2d at 1578.

313. Ability to meet demand for the rapid exchange catheter is measured by Schneider's capacity to meet the total sales made by Schneider and SciMed of the patented product. Datascope Corp. v. SMEC, Inc., 879 F.2d 820, 825 (Fed. Cir. 1989), cert. denied 493 U.S. 1024 (1990). The capacity can be shown by establishing that Schneider had an adequate distribution system and adequate sales personnel. Polaroid Corp. v. Eastman Kodak Co., 16 U.S.P.Q. 2d 1481, 1492 (D. Mass. 1990). Schneider has established with reasonable probability that it had the capacity to manufacture and sell the increased number of products and therefore this element of the Panduit test is met.

(iv) The Amount of Loss 314. The "amount of lost profits awarded cannot be speculative but the amount need not be proven with unerring precision." Bio-Rad Labs., Inc. v. Nicolet Inst. Corp., 739 F.2d 604, 616 (Fed. Cir.), cert. denied, 469 U.S. 1038 (1984). Any doubts regarding the precision of the calculation are resolved against SciMed as the infringer. Ryco, 857 F.2d at 1427.

315. The Court is "not restricted from choosing a figure other than that advocated by either party and may substitute an intermediate figure as a matter of judgment from all the evidence." Minnesota Mining, 976 F.2d at 1579 (citing SmithKline Diagnostics, Inc. v. Helena Lab., Corp., 926 F.2d 1161, 1168 (Fed. Cir. 1991)).

316. SciMed's damages expert, Dr. Timothy Nantell, challenged Dr. Dugan's lost profit calculations at trial. Because the Court agrees with SciMed's argument and Dr. Nantell's testimony that the lost profit percentages calculated by Dr. Dugan are excessive, the Court concludes that Schneider has failed to meet its burden of proving the amount of loss under the fourth element of the Panduit test.

317. The Court instead adopts the lost profit percentages suggested by Defendants as an alternative to Dr. Dugan's profit margins. Whereas Dr. Dugan used an incremental profit analysis, Dr. Timothy Nantell, SciMed's damages expert, primarily used a regression analysis. The Court finds that Dr. Nantell's percentages of profit are more reasonable than Dr. Dugan's and that they will adequately and fairly compensate Plaintiffs for their lost profits. Minnesota Mining, 976 F.2d at 1579.

318. Plaintiffs criticize Dr. Nantell's regression analysis, arguing that it produces "wildly unrealistic results." (Schneider's Post-Trial Brief at 23). The Court finds, however, that the margins at which Dr. Nantell arrived more closely reflect Schneider's own calculations of its profit margin, at which Schneider arrived in a non-litigation setting. See (Plaintiffs' Trial Exhibit 714). It therefore adopts Dr. Nantell's profit margins.

C. Reasonable Royalty

319. A successful patentee in an infringement action is entitled to recover "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284 (1981 & Supp. 1993). The reasonable royalty measure of patent damages is "merely the floor below which damages shall not fall." Lindemann, 895 F.2d at 1406; Fromson v. Western Litho Plate and Supply Co., 853 F.2d 1568, 1574 (Fed. Cir. 1988), cert. denied, 111 S. Ct. 1109 (1991); Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc., 750 F.2d 1552, 1568 (Fed. Cir. 1984).

320. The factors to be considered in determining a reasonable royalty rate and upon which this Court based its determination of a reasonable royalty rate are set forth in Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), aff'd in part, modified in part, 446 F.2d 295 (2d Cir.),cert. denied, 404 U.S. 870 (1971). See Smithkline Diagnostics, 926 F.2d at 1168.

321. A reasonable royalty should be based upon the amount that a willing licensor and a willing licensee would have agreed upon during a hypothetical negotiation at the time the infringement began, if both parties had been reasonably and voluntarily trying to reach an agreement. Id. at 1120. See Fromson, 853 F.2d at 1575. In a hypothetical negotiation, the patent is assumed to be valid and infringed. Trio Process Corp. v. L. Goldstein's Sons, Inc., 533 F.2d 126, 129 (3d Cir. 1976), cert. denied, 449 U.S. 827 (1980).

322. Evidence of a reasonable royalty can be presented in various ways, including: a) defendant's anticipated profits, as indicated by actual profits made; b) expert testimony regarding reasonableness under the circumstances; and c) the rate the patentee would have required to grant a license. Trell, 912 F.2d at 1446.

323. The trial court "is not limited to selecting one or the other of the specific royalty figures urged by counsel as reasonable." SmithKline Diagnostics, 926 F.2d at 1168 (emphasis in original) (citing Radio Steel & Mfg. Co. v. MTD

products, Inc., 788 F.2d 1554, 1556-57 (Fed. Cir. 1986)). "On the contrary, the determination of a reasonable royalty must be based upon the entirety of the evidence and the court is free to, indeed, must reject the royalty figures proffered by the litigants . . . where the record as a whole leads the court to a different figure." Id.

324. Based on careful review of the record as a whole, including consideration of evidence and testimony presented at trial, the Court concludes that application of the Georgia-Pacific factors to the facts of this case favors a reasonable royalty rate of 15% for the reasons set forth in the Findings of Fact. 15% is a fair, equitable rate that will adequately compensate Plaintiffs and that will allow Defendant to maintain a profit on its sales.

D. Pre-judgment Interest

325. Pre-judgment interest should ordinarily be awarded, absent some justification for withholding such award. General Motors Corp. v. Devex Corp., 461 U.S. 648, 657 (1983). A trial court is afforded wide latitude in the selecting the interest rate. Uniroyal, 939 F.2d at 154; Bio-Rad Laboratories v. Nicolet Instrument Corp., 807 F.2d 964, 969 (Fed. Cir. 1986), cert. denied, 482 U.S. 915 (1987). The purpose of pre-judgment interest is "to ensure that the patent owner is placed in as good a position as he would have been had the infringer entered into a reasonable royalty agreement." Bio-Rad, 807 F.2d at 969 (quoting Devex v. General Motors Corp., 461 U.S. 648, 655 (1983)).

326. The Court concludes that Plaintiffs are entitled to pre-judgment interest compounded for time as set forth in these Findings. V. Attorney Fees and Costs

327. In "exceptional cases," the trial court may award attorneys fees to the prevailing party pursuant to 35 U.S.C. § 285 (1981 & Supp. 1993). BIC Leisure, 1 F.3d at 1222. Exceptional cases involve willful infringement, misconduct during litigation, vexatious or unjustified litigation, or a frivolous defense. Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989). Because the Court finds that there is no evidence in the record supporting such a finding, the Court declines to award Plaintiff fees and costs.

VI. Permanent Injunction

328. Pursuant to 35 U.S.C. § 283, the court may "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." A patent is a property right to which the patent owner is entitled exclusivity. 35 U.S.C. § 261; 35 U.S.C. § 154 (1981 & Supp. 1993).

329. The standards of public interest measure the propriety and need for injunctive relief. Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858, 865-66 (Fed. Cir. 1984). Although the court's denial or grant of an injunction is discretionary, "injunctive relief against an adjudged infringer is usually granted." W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1281 (Fed. Cir. 1988). This is because "the right to exclude recognized in a patent is but the essence of the concept of property." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1246-47 (Fed. Cir.), cert. denied, 493 U.S. 853 (1989) (quoting Connell v. Sears Roebuck Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983)). Thus, it is the "general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it." Id.

330. In a patent infringement case, where the infringing device will continue to infringe and thus damage Plaintiffs in the future, "monetary damages are generally considered to be inadequate." See Shiley, Inc. v. Bentley Labs., Inc., 601 F. Supp. 964, 970 (C.D. Cal. 1985), cert. denied, 479 U.S. 1087 (1987). In Eli Lilly & Co. v. Medtronic, Inc., 7 USPQ 2d 1439, 1445 (E.D. Pa. 1988), rev'd on other grounds, 872 F.2d 402 (Fed. Cir. 1989), the trial court held:

> While the public interest is unquestionably advanced through the marketing of potentially lifesaving devices such as Medtronic's, Congress has determined it better for the nation in the long run to afford the inventors of novel, useful and non-obvious products short-term exclusivity on such products rather than to permit free competition in the goods. Congress has not seen fit to differentiate between what might be referred to as lifesaving devices and those of a more trivial or less important nature.
>
> The public interest is served by granting injunctions to effectuate patent rights.

Id. at 1445.

331. The fact that SciMed has ceased production of the EXPRESS <TM> does not prevent issuance of an injunction against any further infringement. Id. at 1446.

332. While it is proper to consider the public interest in patent injunction cases, the facts in this case do not support denying the injunction on such grounds. Shiley, 601 F. Supp. at 970.

333. SciMed argues that an injunction is not warranted because the products in issue are life-saving medical devices for which there are no adequate substitutes.

Other courts have entered preliminary and permanent injunctions in cases involving medical devices. See Minnesota Mining, 22 USPQ 2d 1401, 1415 (D. Minn. 1991), aff'd, 976 F.2d 1559 (Fed. Cir. 1992); Medtronic, 221 USPQ 595, 613-14 (D. Minn. 1983, aff'd, 789 F.2d 903 (Fed. Cir.), cert. denied, 479 U.S. 931 (1986); Shiley, 801 F. Supp. at 964.

334. The public interest will not be disserved by the issuance of an injunction in this case. It is generally held that "protecting patents from would-be infringers is always acting in the public interest." Pittway v. Black & Decker, 667 F. Supp. 585, 593 (N.D. Ill. 1987).

335. The Court is convinced, based on a review of the record as a whole, that SOE catheters are generally interchangeable. Furthermore, "mere expression of preference" is not adequate grounds for denying an injunction. Because any continued manufacture, use or sale of the EXPRESS <TM> and RALLY <TM> would infringe the '129 patent, Plaintiffs are entitled to a permanent injunction against the EXPRESS <TM> and the RALLY <TM>. See Shiley, 601 F. Supp. at 970.

336. The permanent injunction against the RALLY<TM> shall contain a one-year transition period to allow an efficient and non-disruptive changeover for those institutions and physicians who now employ the SciMed RALLY<TM> exclusively. See Shiley, 601 F. Supp. at 971. Defendant shall pay Plaintiffs a 15% royalty rate on Defendant's sales of the RALLY<TM> during that time. After the transition period ends, the permanent injunction against the RALLY<TM> shall take effect.

337. There is no just reason for delaying the entry of judgment as to all issues other than the amount of damages. Judgment on the amount of damages shall be entered after the parties update the damage award as directed in the Court's Findings and Order. Fed. R. Civ. P. 54(b).

338. To the extent that the Findings of Fact contain Conclusions of Law, they are incorporated herein by reference.

SUMMARY TABLE

	UNITED STATES	**OUTSIDE U.S. (Direct)**	**OUTSIDE U.S. (Distributor)**
	TO JUNE 30, 1993		
DAMAGES WITHOUT PREJUDGEMENT INTEREST	$ 27,030,141	$ 5,054,649	$ 12,574,719

PREJUDGMENT INTEREST
DAMAGES INCLUDING
PREJUDGMENT INTEREST

	FREE GOODS		**ALL MODELS & AREAS**	**TOTAL**
	2/91-10/92	**11/92-3/4/94**		
DAMAGES WITHOUT PREJUDGMENT INTEREST	$ 472,918		(7/1/93-3/4/94	$ 45,132,427 (Incomplete Total)
PREJUDGMENT INTEREST			(7/1/93-Final Judgment)	
DAMAGES INCLUDING REJUDGMENT INTEREST				(GRAND TOTAL)

UNITED STATES DAMAGES

	EXPRESS PERIOD #1 1/91-6/91	**EXPRESS PERIOD #2 7/91-12/16/91**
1. SCIMED INFRINGING UNIT SALES	14,111	29,054
SCHNEIDER LOST PROFITS		
2. % OF LINE 1 = SCHNEIDER	100%	100%
LOST UNIT SALES		
3. SCHNEIDER LOST UNIT SALES	14,107	29,054
4. SCHNEIDER $ PRICE PER UNIT	$ 684	$ 621
5. SCHNEIDER LOST SALES	$ 9,298,261	$ 18,932,327
6. % OF LINE 10 = SCHNEIDER	36%	44%
LOST PROFITS		
7. SCHNEIDER LOST PROFITS	$ 3,388,759	$ 8,291,136
ROYALTY DUE SCHNEIDER		
8. % OF LINE 1 = ROYALTY	0%	0%

UNIT SALES		
9. ROYALTY UNIT SALES	4	0
10. SCIMED $ PRICE PER UNIT	$ 674	$ 687
11. SCIMED ROYALTY $ SALES	$ 0	$ 0
12. % REASONABLE ROYALTY RATE	15%	15%
13. ROYALTY DUE SCHNEIDER	$ 0	$ 0

DAMAGES

14. DAMAGES	$ 3,388,759	$ 8,291,136
15. PREJUDGMENT INTEREST RATE	7%	7%
16. PREJUDGMENT COMPOUNDING FACTOR	19%	11%
17. PREJUDGMENT INTEREST		
18. TOTAL U.S. DAMAGES		

	EXPRESS PERIOD #3 12/17/91-12/92	**EXPRESS PERIOD #4 1/93-6/93**
1. SCIMED INFRINGING UNIT SALES	78,689	33,921

SCHNEIDER LOST PROFITS

2. % OF LINE 1 = SCHNEIDER	23%	23%

LOST UNIT SALES

3. SCHNEIDER LOST UNIT SALES	18,006	7,762
4. SCHNEIDER $ PRICE PER UNIT	$ 595	$ 680
5. SCHNEIDER LOST SALES	$ 10,863,586	$ 5,269,470
6. % OF LINE 10 = SCHNEIDER LOST PROFITS	33%	35%
7. SCHNEIDER LOST PROFITS	$ 3,564,647	$ 1,826,917

ROYALTY DUE SCHNEIDER

8. % OF LINE 1 = ROYALTY UNIT SALES	77%	77%
9. ROYALTY UNIT SALES	60,684	26,159
10. SCIMED $ PRICE PER UNIT	$ 699	$ 698
11. SCIMED ROYALTY $ SALES	$ 42,388,365	$ 18,260,802
12. % REASONABLE ROYALTY RATE	15%	15%

13. ROYALTY DUE SCHNEIDER	$ 6,358,255	$ 2,739,120
	DAMAGES	
14. DAMAGES	$ 9,922,902	$ 4,566,037
15. PREJUDGMENT INTEREST RATE	5%	3%
16. PREJUDGMENT COMPOUNDING FACTOR	7%	3%
17. PREJUDGMENT INTEREST		
18. TOTAL U.S. DAMAGES		

	RALLY PERIOD #4 1/93-6/93	**ALL PERIODS AND MODELS**
1. SCIMED INFRINGING UNIT SALES	6,272	162,047
	SCHNEIDER LOST PROFITS	
2. % OF LINE 1 = SCHNEIDER LOST UNIT SALES	23%	43%
3. SCHNEIDER LOST UNIT SALES	1,435	70,363
4.SCHNEIDER $ PRICE PER UNIT	$ 680	$ 644
5. SCHNEIDER LOST SALES	$ 980,532	$ 45,344,175
6. % OF LINE 10 = SCHNEIDER LOST PROFITS	35%	38%
7. SCHNEIDER LOST PROFITS	$ 341,160 $	17,412,620
	ROYALTY DUE SCHNEIDER	
8. % OF LINE 1 = ROYALTY UNIT SALES	77%	57%
9. ROYALTY UNIT SALES	4,837	91,684
10. SCIMED $ PRICE PER UNIT	$ 717	$ 699
11. SCIMED ROYALTY $ SALES	$ 3,467,641	$ 64,116,808
12. % REASONABLE ROYALTY RATE	15%	15%
13. ROYALTY DUE SCHNEIDER	$ 520,146	$ 9,617,521
	DAMAGES	
14. DAMAGES	$ 861,306	$ 27,030,141
15.PREJUDGMENT INTEREST RATE	3%	6%
16. PREJUDGMENT COMPOUNDING	2%	10%

FACTOR
17. PREJUDGMENT INTEREST
18. TOTAL U.S. DAMAGES

OUTSIDE UNITED STATES DAMAGES (DIRECT)

	EXPRESS PERIOD #1 1/91-6/91	**EXPRESS PERIOD #2 7/91-12/16/91**
1. SCIMED INFRINGING UNIT SALES	979	3,458
SCHNEIDER LOST PROFITS		
2. % OF LINE 1 = SCHNEIDER LOST UNIT SALES	99%	99%
3. SCHNEIDER LOST UNIT SALES	972	3,414
4. SCHNEIDER $ PRICE PER UNIT	$ 631	$ 631
5. SCHNEIDER LOST SALES	$ 613,113	$ 2,153,199
6. % OF LINE 10 = SCHNEIDER LOST PROFITS	57%	71%
7. SCHNEIDER LOST PROFITS	$ 347,151	$ 1,524,061
ROYALTY DUE SCHNEIDER		
8. % OF LINE 1 = ROYALTY UNIT SALES	1%	1%
9. ROYALTY UNIT SALES	7	44
10. SCIMED $ PRICE PER UNIT	$ 493	$ 481
11. SCIMED ROYALTY $ SALES	$ 3,333 $	21,127
12. % REASONABLE ROYALTY RATE	15%	15%
13. ROYALTY DUE SCHNEIDER	$ 500	$ 3,169
DAMAGES		
14. DAMAGES	$ 347,651	$ 1,527,230
15. PREJUDGMENT INTEREST RATE	7%	7%
16. PREJUDGMENT COMPOUNDING FACTOR	19%	8%
17. PREJUDGMENT INTEREST		
18. TOTAL U.S. DAMAGES		

	EXPRESS PERIOD #3 12/17/91-12/92	**EXPRESS PERIOD #4 1/93-6/93**
1. SCIMED INFRINGING UNIT SALES	6,135	3,737
SCHNEIDER LOST PROFITS		
2. % OF LINE 1 = SCHNEIDER LOST UNIT SALES	75%	75%
3. SCHNEIDER LOST UNIT SALES	4,573	2,785
4. SCHNEIDER $ PRICE PER UNIT	$ 596	$ 606
5. SCHNEIDER LOST SALES	$ 2,724,278	$ 1,687,228
6. % OF LINE 10 = SCHNEIDER LOST PROFITS	67%	67%
7. SCHNEIDER LOST PROFITS	$ 1,815,128	$ 1,133,134
ROYALTY DUE SCHNEIDER		
8. % OF LINE 1 = ROYALTY UNIT SALES	25%	25%
9. ROYALTY UNIT SALES	1,563	952
10. SCIMED $ PRICE PER UNIT	$ 499	$ 618
11. SCIMED ROYALTY $ SALES	$ 759,465	$ 587,805
12. % REASONABLE ROYALTY RATE	15%	15%
13. ROYALTY DUE SCHNEIDER	$ 113,920	$ 88,171
DAMAGES		
14. DAMAGES	$ 1,929,048	$ 1,221,305
15. PREJUDGMENT INTEREST RATE	5%	3%
16. PREJUDGMENT COMPOUNDING FACTOR	7%	2%
17. PREJUDGMENT INTEREST		
18. TOTAL U.S. DAMAGES		

	RALLY PERIOD #4 1/93-6/93	**ALL PERIODS AND MODELS**
1. SCIMED INFRINGING UNIT SALES	92	14,401
SCHNEIDER LOST PROFITS		
2. % OF LINE 1 = SCHNEIDER LOST UNIT SALES	75%	82%
3. SCHNEIDER LOST UNIT SALES	69	11,812
4. SCHNEIDER $ PRICE PER UNIT	$ 606	$ 611
5. SCHNEIDER LOST SALES	$ 41,656	$ 7,219,473
6. % OF LINE 10 = SCHNEIDER LOST PROFITS	67%	67%
7. SCHNEIDER LOST PROFITS	$ 27,976	$ 4,847,449
ROYALTY DUE SCHNEIDER		
8. % OF LINE 1 = ROYALTY UNIT SALES	25%	18%
9. ROYALTY UNIT SALES	23	2,589
10. SCIMED $ PRICE PER UNIT	$ 409	$ 534
11. SCIMED ROYALTY $ SALES	$ 9,601	$ 1,381,331
12. % REASONABLE ROYALTY RATE	15%	15%
13. ROYALTY DUE SCHNEIDER	$ 1,440	$ 207,200
DAMAGES		
14. DAMAGES	$ 29,416	$ 5,054,649
15. PREJUDGMENT INTEREST RATE	3%	6%
16. PREJUDGMENT COMPOUNDING FACTOR	2	%
17. PREJUDGMENT INTEREST		
18. TOTAL U.S.DAMAGES		

OUTSIDE UNITED STATES DAMAGES (DISTRIBUTORS)

	EXPRESS PERIOD #1 1/91-6/91	EXPRESS PERIOD #2 7/91-12/16/91
1. SCIMED INFRINGING UNIT SALES	2,546	11,479
SCHNEIDER LOST PROFITS		
2. % OF LINE 1 = SCHNEIDER LOST UNIT SALES	98%	99%
3. SCHNEIDER LOST UNIT SALES	2,505	11,369
4. SCHNEIDER $ PRICE PER UNIT	$ 564	$ 564
5. SCHNEIDER LOST SALES	$ 1,412,667	$ 6,411,639
6. %OF LINE 10 = SCHNEIDER LOST PROFITS	51%	70%
7. SCHNEIDER LOST PROFITS	$ 716,208 $	4,458,733
ROYALTY DUE SCHNEIDER		
8. % OF LINE 1 = ROYALTY UNIT SALES	2%	1%
9. ROYALTY UNIT SALES	41	109
10. SCIMED $ PRICE PER UNIT	$ 465	$ 473
11. SCIMED ROYALTY $ SALES	$ 19,052	$ 52,923
12. % REASONABLE ROYALTY RATE	15%	15%
13. ROYALTY DUE SCHNEIDER	$ 2,858	$ 7,938
DAMAGES		
14. DAMAGES	$ 719,066	$ 4,466,671
15. PREJUDGMENT INTEREST RATE	7%	7%
16. PREJUDGMENT COMPOUNDING FACTOR	19%	8%
17. PREJUDGMENT INTEREST		
18. TOTAL O.U.S. DISTRIBUTOR DAMAGES		

	EXPRESS PERIOD #3 12/17/91-12/92	EXPRESS PERIOD #4 1/93-6/93
1. SCIMED INFRINGING UNIT SALES	18,437	11,210
SCHNEIDER LOST PROFITS		

2. % OF LINE 1 = SCHNIDER LOST UNIT SALES	59%	59%
3. SCHNEIDER LOST UNIT SALES	10,953	6,659
4. SCHNEIDER $ PRICE PER UNIT	$ 585	$ 493
5. SCHNEIDER LOST SALES	$ 6,413,014	$ 3,283,801
6. % OF LINE 10 = SCHNEIDER LOST PROFITS	66%	64%
7. SCHNEIDER LOST PROFITS	$ 4,257,466	$ 2,095,897

ROYALTY DUE SCHNEIDER

8. % OF LINE 1 = ROYALTY UNIT SALES	41%	41%
9. ROYALTY UNIT SALES	7,485	4,550
10. SCIMED $ PRICE PER UNIT	$ 492	$ 618
11. SCIMED ROYALTY $ SALES	$ 3,677,167	$ 2,810,392
12. % REASONABLE ROYALTY RATE	15%	15%
13. ROYALTY DUE SCHNEIDER	$ 551,575	$ 421,559

DAMAGES

14. DAMAGES	$ 4,809,041	$ 2,517,456
15. PREJUDGMENT INTEREST RATE	5%	3%
16. PREJUDGMENT COMPOUNDING FACTOR	7%	2%
17. PREJUDGMENT INTEREST		
18. TOTAL O.U.S. DISTRIBUTOR DAMAGES		

	RALLY PERIOD #4 1/93-6/93	**ALL PERIODS AND MODELS**
1. SCIMED INFRINGING UNIT SALES	277	43,948

SCHNEIDER LOST PROFITS

2. % OF LINE 1 = SCHNEIDER LOST UNIT SALES	59%	72%
3. SCHNEIDER LOST UNIT SALES	164	31,651
4. SCHNEIDER $ PRICE PER UNIT	$ 493	$ 556
5. SCHNEIDER LOST SALES	$ 81,073	$ 17,602,195
6. % OF LINE 10 = SCHNEIDER	69%	66%

LOST PROFITS		
7. SCHNEIDER LOST PROFITS	$ 55,599	$ 11,583,903
ROYALTY DUE SCHNEIDER		
8. % OF LINE 1 = ROYALTY	41%	28%
UNIT SALES		
9. ROYALTY UNIT SALES	112	12,298
10. SCIMED $ PRICE PER UNIT	$ 409	$ 537
11. SCIMED ROYALTY $ SALES	$ 45,905	$ 6,605,440
12. % REASONABLE ROYALTY RATE	15%	15%
13. ROYALTY DUE SCHNEIDER	$ 6,886	$ 990,816
DAMAGES		
14. DAMAGES	$ 62,485	$ 12,574,719
15. PREJUDGMENT INTEREST RATE	3%	6%
16. PREJUDGMENT COMPOUNDING FACTOR	2%	7%
17. PREJUDGMENT INTEREST		
18. TOTAL O.U.S. DISTRIBUTOR DAMAGES FREE GOODS		

	PERIOD #1 2/91 - 10/92	**PERIOD #2 11/92 - 3/4/94**	**TOTAL DAMAGES FOR FREE GOODS**
SCIMED UNITS	4,580		
VALUE	$ 3,152,787		
REASONABLE ROYALTY RATE	15%		
DAMAGES	$ 472,918		
PREJUDGMENT INTEREST RATE			
PREJUDGMENT COMPOUNDING FACTOR			
PREJUDGMENT INTEREST			
TOTAL DAMAGES FOR FREE GOODS			

Upon all files, records, proceedings herein, and the Court's Findings of Fact and Conclusions of Law,

IT IS ORDERED That the Clerk of Court enter judgment as follows:

IT IS ORDERED, ADJUDGED, AND DECREED that:

1. Reexamination Certificate B1 4,762,129 is valid and enforceable;

2. Plaintiffs Schneider (Europe) AG and Schneider (USA) did not engage in inequitable conduct at any time during the prosecution of the reexamination certificate or during the prosecution of the original patent, U.S. Patent No. 4,762,129;

3. Defendant SciMed Life Systems, Inc. has infringed the claims of U.S. Patent No. 4,762,129 and Reexamination Certificate No. B1 4,762,129 by its manufacture and sale of the EXPRESS TM and RALLY TM catheters.

4. Defendant SciMed Life Systems, Inc.'s infringement of the above-listed patent and reexamination certificate was not willful.

5. Defendant SciMed Life Systems, Inc. is liable in damages to Plaintiffs Schneider (Europe) AG and Schneider (USA) for its infringement in the amount of Forty-Five Million, One Hundred Thirty-Two Thousand, Four Hundred Twenty-Seven Dollars ($ 45,132,427).

6. Plaintiffs are entitled to an additional award of prejudgment interest to the date of the entry of final judgment on the damages assessed against Defendant (paragraph 5), which amount the parties shall jointly calculate at rates consistent with the Court's Order of March 4, 1994.

7. Plaintiffs are entitled to additional damages on infringing free goods distributed by SciMed Life Systems, Inc. between October 31, 1992 and March 4, 1994, and prejudgment interest thereon, to the date of the entry of final judgment, which amounts the parties shall jointly calculate at rates consistent with the Court's Order of March 4, 1994.

8. Plaintiffs are entitled to additional damages on SciMed Life Systems, Inc.'s infringing sales of the EXPRESS TM and RALLY TM for the period between June 30, 1993 and March 4, 1994, and prejudgment interest thereon to the date of entry of final judgment, which amounts the parties shall jointly calculate at rates consistent with the Court's Order of March 4, 1994.

9. In the event that the parties are unable to jointly agree on calculations of additional damages or prejudgment interest, the Court shall conduct further hearings as may be necessary to make such calculations and order entry of final judgment.

IT IS FURTHER ORDERED That a writ of Permanent Injunction in the form attached to this Order shall issue forthwith.
DATED: March 4, 1994.

DONALD D. ALSOP, Senior Judge, United States District Court

PERMANENT INJUNCTION Pursuant to the Court's March 4, 1994 Order in this action,

IT IS ORDERED That:

1. Defendant SciMed Life Systems, Inc., its officers, agents, servants, employees, successors or assigns, and those persons in active concert with it who receive notice of this injunction, are enjoined from directly infringing, contributorily infringing, and/or actively inducing the infringement of U.S. Patent No. 4,762,129 and Reexamination Certificate B1 4,762,129, including, but not limited to, the further manufacture, use, or sale of infringing products, including the SciMed EXPRESS TM and the SciMed RALLY TM.

2. This injunction against the EXPRESS TM is effective immediately. The injunction against the RALLY TM shall take effect one year from this date. During that one year period, SciMed shall provide monthly written reports to Schneider of all sales of RALLY TM catheters manufactured in the United States and shall pay monthly to Schneider a 15% royalty on sales of all such units.

3. Defendant SciMed Life Systems, Inc. shall forthwith provide written notice of this injunction to its officers, agents, servants, employees, and those persons in active concert with it. This Order shall be binding on SciMed Life Systems, Inc. and its officers, agents, servants, employees, successors or assigns, and those persons in active concert or participation with it who receive actual notice of this Order by personal service or otherwise.

DATED: March , 1994.

DONALD D. ALSOP, Senior Judge, United States District Court