United States District Court,
N.D. Illinois, Eastern Division.

R2 MEDICAL SYSTEMS, INC,
Plaintiff.

and

Cardiotronics, Inc,
Plaintiff.
v.
KATECHO,
INC.

and

Cardiovascular Group of Oregon,
Inc.

and

Padeco, Inc,
Defendants.

July 19, 1996.

Holder of six patents relating to heart monitoring and resuscitation devices sued alleged infringers. Alleged infringers moved for summary judgment. The District Court, Gettleman, J., held that: (1) patentee's action was not barred by laches or equitable estoppel; (2) fact questions precluded summary judgment on issue of whether patents satisfied best mode requirement; (3) fact questions precluded summary judgment regarding direct infringement; (4) one alleged infringer was not liable for inducement of infringement or contributory infringement prior to date it had actual knowledge of existence of patents; and (5) fact questions precluded summary judgment regarding two alleged infringers' liability for inducement of infringement and contributory infringement.

Motion for summary judgment granted in part and denied in part.

4,419,998, 4,494,552, 4,848,345, 4,850,356, 4,852,585, 4,895,169. Cited.

Richard P. Steinken, Jenner & Block, Stephen J. Manich, Michael Laszlo Korniczky, Wood, Phillips, VanSanten, Hoffman & Ertel, Gomer Winston Walters, Lindenbaum, Coffman, Kurlander, Brisky & Hayes, Ltd., Chicago, IL, Robert C. Morgan, Frances M. Lynch, Gene W. Lee, Fish & Neave, New York City, for R2 Medical Systems, Inc.

James P. Ryther, Mary Spaulding Burns, Rockey, Rifkin and Ryther, Chicago, IL, Michael G. Voorhees, Daniel J. Cosgrove, Michael R. Crabb, Zarley, McKee, Thomte, Voorhees & Sease, Des Moines, IA, for Katecho Inc.

Joan I. Norek, Chicago, IL, for Cardiovascular Group of Oregon, Inc.

Jeffrey A. Sadowski, Steven L. Oberholtzer, Eric J. Sossenko, Harness, Dickey & Pierce, Troy, MI, Joan I. Norek, Chicago, IL, for Padeco, Inc.

MEMORANDUM OPINION AND ORDER

GETTLEMAN**, District Judge.**

Plaintiffs R2 Medical Systems, Inc. ("R2") and its parent corporation, Cardiotronics, Inc. FN1 claim that defendants have infringed or caused to be infringed certain patents R2 holds on heart monitoring and resuscitation devices. This memorandum opinion and order disposes of a number of summary judgment motions filed by defendants.

FN1. Both plaintiffs will be referred to herein as "R2."

Defendants Katecho, Inc. ("Katecho"), Cardiovascular Group of Oregon, Inc. ("Cardiovascular"), and Padeco, Inc. ("Padeco") have moved for summary judgment against all R2's claims for patent infringement. All defendants move for summary judgment based upon the affirmative defenses of laches and equitable estoppel. Katecho also moves for summary judgment arguing that each of the patents asserted against it are invalid because they allegedly failed to satisfy the best mode requirement under 35 U.S.C. s. 112. Finally, defendants move for summary judgment of the claims under the six patents asserted by R2, arguing that there is no genuine issue of material fact that defendants' products did not infringe the patents.

BACKGROUND

The patents at issue involve a system to monitor and treat heart irregularities through the use of disposable physiological electrodes and non-disposable cable systems that are used with ECG monitoring, defibrillation, and electrosurgical/ablation equipment. With traditional defibrillation, electrodes are attached to a patient's chest to monitor his heart beat for irregular behavior. Once heart problems are detected, medical personnel take a separate electronic device attached to two metal paddles, smear the paddles with a conductive gel and hold the paddles to the patient's chest to defibrillate the heart with bursts of electricity. Although life-saving, this system suffers from several difficulties, including the danger of electrical shock to the administering medical personnel and periods following defibrillation when it is impossible to monitor the patient's heart activity accurately.

The patented devices were intended to solve these difficulties by providing cheaper disposable electrodes that could perform a variety of functions and permit medical personnel to apply electric shocks from a safe distance. The first patent, U.S. patent 4,848,345 (" '345 patent"), covers a system of disposable adhesive steel electrodes and cables that replace the traditional paddles for defibrillation. This system permits medical personnel to defibrillate a patient at a safe distance through the adhesive electrodes that are attached to the

patient's chest. In addition, medical personnel may switch the electrodes back and forth between the monitoring and defibrillation functions.

U.S. patent 4,852,585 (" '585 patent") and U.S. patent 4,895,169 (" '169 patent") disclose electrodes intended to improve upon this system by better performing all three functions of monitoring, defibrillation and electrosurgical therapy for lower cost. These patents contemplate electrodes that have a surface of conductive metal, preferably tin, with a conductive medium of a saline gel located between the metal surface and the patient's skin. This medium improves the transfer of electricity between the electrode and the patient. The gel is held in a foam layer that covers the conductive metal surface. The primary distinctive feature of these electrodes is that a chloride of the conductive metal, preferably stannous (tin) chloride, be located between the electrode's surface of the conductive metal and the patient's skin. These patents reveal two alternative locations for the stannous chloride: (1) within the gel, or (2) directly "affixed" to the conductive metal surface. If it is "affixed" to the surface, the patent suggests that the stannous chloride may be sprayed onto the surface in a thin layer. The electrode patents' claims require that the stannous chloride be "affixed" to the electrode.

These electrodes, in turn, may be used with the remaining three patented systems. U.S. patent 4,850,356 (" '356 patent") provides a system of adapters and cable that permits the use of these disposable electrodes with traditional defibrillation systems. U.S. patent 4,494,552 (" '552 patent") provides a system that permits the use of two electrodes for ECG monitoring. ECG monitoring previously required the use of three electrodes. U.S. patent 4,419,998 (" '998 patent"), which includes a connector and cable system, permits the use of these multifunctional electrodes with all three of the pertinent cardiovascular treatment systems: monitoring, defibrillation, and electrosurgical therapy. With these patents, R2 manufactures and sells multifunctional electrodes and cable and adapter systems to various hospital-related clients.

The '998 patent was issued in 1983. The '552, '345 and '356 patents are collectively known as the "system patents." The '552 patent was issued on January 22, 1985. The '345 and '356 patents were issued respectively on July 18, 1989 and July 25, 1989. The '585 and '169 patents are known as the "electrode patents" and were issued respectively on August 1, 1989 and January 23, 1990.

All three defendants are or were suppliers of hospital-related products. Katecho manufactures and sells electrodes, including the electrodes accused of infringement. Cardiovascular and Padeco are suppliers of hospital-related products, including the electrodes at issue and related products. Cardiovascular purchased and Padeco purchases all of their allegedly infringing electrodes from Katecho.

R2 alleges that Katecho infringes three of the patents at issue. First, R2 asserts that Katecho's packaging, advertising and instructions on certain models of electrodes direct that they be used for either the monitoring, defibrillation or therapeutic function, thereby inducing and contributing to its customers' infringement of the '998 patent. Based upon discovery, R2 has determined that these models were first sold on January 1, 1989, but were not widely distributed until sometime in 1991. Second, R2 contends that Katecho sells electrodes that directly infringe the '585 and '169 patents.

In or about 1986, Katecho began to supply the electrodes at issue to a former customer of R2, the Laerdal Corporation. Sometime in 1986 or 1987, Buddy Rampersaud, procurement manager for Laerdal, informed R2 that his company would be purchasing their electrodes from Katecho instead of R2. In deposition testimony, William J. Smirles, director of R2's department of research and development, indicated that R2 was aware that Katecho was continuing to compete in the sale of electrodes in 1988. The present record also

reveals that sometime during the late 1980's, Smirles asked R2's management for additional resources in order to investigate infringement matters. At that time, R2 declined Smirles' request. It is unclear when this took place. Smirles also affirmed that, by April of 1989, he was aware that Katecho supplied Cardiovascular with its competing line of electrodes.

Following 1987, Katecho's overall sales grew steadily, requiring Katecho to invest in additional space, equipment and personnel. However, its sales of the electrodes at issue fluctuated, doubling some years, but then falling close to previous levels in other years. Consequently, while the sales of other electrodes were 60% higher than allegedly infringing sales in 1989, in 1994 such sales were four times higher than allegedly infringing sales. Overall, the allegedly infringing electrodes accounted for approximately 23% of Katecho's sales during the period of 1988 through 1994.

R2 alleges that Cardiovascular and, later, Padeco infringed all six of the patents at issue. First, R2 alleges that these defendants sell electrodes that directly infringe the '585 and '169 patents. Second, R2 charges these defendants with contributory infringement and inducement of infringement of the '998 patent through their packaging, advertising and instructions on certain packaged models of electrodes. R2 also alleges that these defendants manufacture and distribute switch boxes that permit their customers to selectively use the accused electrodes with any of the three devices. Third, R2 charges defendants with contributory infringementand inducement of infringement of the remaining three system patents through their sale of adapter cable systems and R2 switch control cables with multifunctional electrodes that allegedly infringe R2's electrode patents.

Cardiovascular originally began to sell the devices at issue in 1986 under the trade name, "Padeco." In 1991, Cardiovascular ceased selling its hospital-related products, including the electrodes at issue. At that time, a newly incorporated company, Padeco, began to sell the electrodes and related products under the same trade name. Joseph M. Mertz, sole owner of Cardiovascular, is also an owner and officer of Padeco. As noted, Cardiovascular and Padeco both purchased all of their allegedly infringing electrodes from Katecho.

By 1988, it is evident that R2 was aware that Cardiovascular was competing for R2's electrode market. In January and July of 1988, R2 or its agents asked third parties to obtain information on Cardiovascular by inquiring with them as prospective clients about their products. In July of 1988, R2 acquired samples of a Cardiovascular electrode and two adapters, at least one of which was intended for use with R2 systems. In addition, R2 has admitted that by July 1989 it was aware of at least one instance in which R2 cables had been modified to use with Cardiovascular electrodes. In February of 1988, R2 hired a consultant to instigate a Food and Drug Administration ("FDA") investigation of the effectiveness and safety of using Cardiovascular's products with R2 systems. At this time, R2 also hired legal counsel to confront Cardiovascular with respect to its safety concerns arising from Cardiovascular's alteration of the cables and connectors in R2 systems and the potential use of R2's systems for unintended functions. In this letter, R2 accused Cardiovascular of possible FDA violations and warned that it considered Cardiovascular liable for any injuries arising from the modifications and cross-use. Finally, Smirles testified that sometime prior to 1990, after looking at Padeco brand name electrodes and their labeling, he "may have rendered an opinion [to R2 management] that there is a possibility [of infringement]."

Cardiovascular initially sold a variety of hospital-related products. From 1986 until 1991, Cardiovascular's sales of electrodes gradually accounted for a larger proportion of its total sales. Testimony by Cardiovascular's president indicates that it discontinued carrying other hospital products when the manufacturers of those other products terminated their relationships. Cardiovascular asserts that it chose not

to replace manufacturers of such products because of its growing business associated with the electrodes at issue. Cardiovascular contends that it would not have concentrated on electrode sales had it been aware that its products infringed upon another's patent.

On May 24, 1994, R2 filed the instant suit against all defendants. Defendant Katecho and defendants Cardiovascular and Padeco raise similar motions for summary judgment. Defendants argue that, (1) R2's claims for patent infringement are barred by equitable estoppel, and (2) R2's claims for damages arising prior to suit are barred under the doctrine of laches. Defendants assert that R2 unreasonably delayed in raising all of its claims even though it reasonably should have been aware of its infringement claims by at latest February, 1988. With respect to the '998 patent and the '552 patent, defendants contend that R2 unreasonably delayed for more than six years, giving rise to a presumption of laches. With respect to the remaining patents, defendants argue that circumstances required R2 to raise its claims as soon as each patent was issued. Defendants also argue that R2 should be estopped from raising its claim because its inaction from the late 1980's until 1994 constituted misleading conduct which reasonably led defendants to continue to invest in the production and sales and the challenged devices.

In a separate motion for summary judgment, Katecho argues that the electrode patents are invalid because the inventor, Roger L. Heath ("Heath"), failed to disclose his contemplated best mode of electrodes. All defendants also move for summary judgment of R2's claims under the electrode patents arguing that R2 has failed to present an issue of material fact that the accused electrodes have stannous chloride "affixed" to their surface as required by the electrode patents. In a separate motion, all defendants move for summary judgment of R2's claims under the '998 patent, arguing that the '998 patent covers a system capable of the simultaneous connection of all three cardiac care devices to the electrodes. Finally, Cardiovascular and Padeco move for summary judgment of R2's claims under the system patents arguing that their customers' use of the accused electrodes with R2 systems is protected under the doctrine of permissible repair.

DISCUSSION

To succeed on a motion for summary judgment, the moving party bears the initial burden of identifying those portions of the record, pleadings, answers to interrogatories and affidavits that demonstrate an absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S.Ct. 2548, 2551, 91 L.Ed.2d 265 (1986). If the moving party satisfies this burden, then the nonmoving party must provide specific facts raising a genuine issue of fact for trial. Id. at 322, 106 S.Ct. at 2552. In determining summary judgment, the court must view all evidence and draw all reasonable inferences in the light most favorable to the nonmoving party. Lohorn v. Michal, 913 F.2d 327, 331 (7th Cir.1990).

I. *Laches*

[1] [2] [3] [4] [5] [6] [7] Laches provides an equitable bar where a patentee's neglect or delay in filing suit for alleged infringement results in material prejudice to the adverse party. A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1028-29 (Fed.Cir.1992) (en banc). Laches may bar only the award of damages incurred prior to suit. It does not bar prospective relief. Id. at 1041. To invoke the defense of laches successfully, an alleged infringer must demonstrate at least two factors: (1) the patentee delayed filing suit for an unreasonable and inexcusable length of time from the time the patentee knew or reasonably should have known of its claim against the defendant; and (2) the delay operated to the prejudice or injury of that defendant. Id. at 1032. Laches focuses upon the reasonableness of the patentee's conduct. Id. at 1034. The period of delay is measured from when the plaintiff knew or reasonably should have known of the alleged infringing activity until the time of suit. Id. at 1032. There are no mechanical rules to determine if the length

of delay was unreasonable. Rather, the reasonableness of any delay depends upon the circumstances of each case. *Id*. However, a delay exceeding six years creates a rebuttable presumption that the delay was unreasonable and that the defendant suffered material prejudice. In order to rebut this presumption, the patentee must produce some evidence that creates a genuine issue of fact as to at least one of the elements of laches. *Id*. at 1037-38.

[8] [9] [10] [11] In addition, the defendant must demonstrate that it suffered material prejudice as a result of any alleged delay. Such prejudice may be either evidentiary or economic. In considering economic prejudice, a court should require more than mere monetary loss attributable to a finding of liability. *Id*. at 1033. Rather, a court must look to the "change in the economic position of the alleged infringer during the period of delay." *Id*. The defendant must demonstrate a causal nexus between the patentee's delay and the defendant's expenditures or investment: "It is not enough that the alleged infringer changed its position-i.e., invested in production of the allegedly infringing device. The change must be because of and as a result of the delay, not simply a business decision to capitalize on a market opportunity." Hemstreet v. Computer Entry Sys. Corp., 972 F.2d 1290, 1294 (Fed.Cir.1992). Where more than one patent is asserted, laches must be shown separately for each such patent. Meyers v. Asics Corp., 974 F.2d 1304, 1309 (Fed.Cir.1992).

A. *Katecho*

1. *The* '998 Patent

As an initial matter, with respect to R2's action for inducement of infringement and contributory infringement of the '998 patent, Katecho has failed to demonstrate that R2 is presumptively barred because it delayed for more than six years in filing its suit. Under laches, the period of delay is measured backwards from the filing of suit until the patentee knew or, in the exercise of due diligence, should have known of the alleged infringing activity. Aukerman, 960 F.2d at 1035-36. R2 filed suit on May 23, 1994. Therefore, the six year deadline rests on May 23, 1988. Although the '998 patent was issued in 1983, R2 does not allege that Katecho's sale of its electrodes infringed this patent. Instead, R2 accuses Katecho of contributory infringement and inducement of infringement of its customers through the packaging, advertising and instructions of specified models of its products. A patentee could not have delayed in raising its claim until there was allegedly infringing activity of which it could have become aware. *See* id. Discovery by R2 has revealed that Katecho did not begin to package its products in the allegedly infringing manner until 1989, less than six years prior to the initiation of suit in May, 1994. Therefore, Katecho is not entitled to a presumption of laches with respect to R2's claim under the '988 patent.

[12] The record also fails to demonstrate uncontested facts showing that R2 unreasonably delayed in raising its claim under the '998 patent. Although R2 was aware that Katecho manufactured and sold competitive electrodes since 1986 or 1987, the critical question is when R2 should have become aware that the challenged packaging may have infringed upon its patent. Because the record does not indicate when R2 actually became of aware of this packaging, for purposes of this motion the period of delay begins when R2 reasonably should have become aware of the packaging. Id.

As a practical matter, R2 could not have discovered the allegedly infringing activity until it came into some contact with the packaging at issue. The present record indicates that neither Katecho nor the other defendants began to distribute this packaging widely until 1991, approximately two and half to three years before R2 filed suit. Consequently, the earliest that R2 could be expected to identify the challenged packaging was sometime in 1991, providing a maximum delay of two and a half to three years. The reasonableness of such a delay is generally not amenable to summary judgment. *See* Asics, 974 F.2d at 1309

(finding reasonableness of four year delay not amenable to summary judgment). Accordingly, Katecho has not proven laches with respect to R2's action for infringement under the '998 patent.

2. ***The Electrode Patents***

[13] [14] [15] Under the doctrine of laches, the period of delay may not begin prior the issuance of the patent. Aukerman, 960 F.2d at 1032. Where patents are closely related, it is generally reasonable for a patentee to delay filing suit under any of the patents until all have been issued. Asics, 974 F.2d at 1307; Meyers v. Brooks Shoe, Inc., 912 F.2d 1459, 1462 (Fed.Cir.1990), *overruled on other grounds,* Aukerman, 960 F.2d at 1028. The '585 and '169 patents are continuation patents that arose from the '998 patent, each disclosing similar multifunctional electrodes for use in the cardiac care system. In light of the close relationship of these patents, R2 was not required to bring suit under either patent until the issuance of the patent for the second electrode on January 23, 1990, approximately four years and four months prior to the filing of suit.

[16] The issuance of a patent necessary to the claim, however, determines only the maximum period of delay. The actual period of delay begins when the patentee knew or reasonably should have known of the alleged infringement. Aukerman, 960 F.2d at 1034. The record does not demonstrate when R2 had actual knowledge of its claims prior to the time of suit. Therefore, for purposes of this motion, the period of delay is determined by when R2 had constructive knowledge of each of their claims as a matter of law. In determining the date of constructive knowledge, a patentee is "charged with such knowledge as [it] might have obtained upon inquiry, provided the facts already known to [it] were such as to put upon a man of ordinary intelligence the duty of inquiry." Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc., 988 F.2d 1157, 1162 (Fed.Cir.1993) (citations omitted). R2 provides no reason why information obtained prior to the issuance of a patent is irrelevant to discerning whether it had constructive knowledge once the patent was issued. In fact, such a rule would be contrary to laches' equitable character. *See* Jamesbury Corp. v. Litton Indus. Prod., Inc., 839 F.2d 1544, 1551 (Fed.Cir.1988) ("Laches is an equitable defense which depends on consideration of all the facts in the particular case."), *overruled on other grounds,* Aukerman, 960 F.2d at 1042.

The record provides evidence of circumstances that, by 1990, could have suggested R2's current claims for infringement of the electrode patents. Since 1986, R2 was aware that Katecho sold competing electrodes to the same clients to be used for similar purposes as their own electrodes. Further, R2 remained aware of Katecho's competitive status throughout the late 1980's.

[17] [18] The fact that a competitor provides a similar product that is used as a substitute by common customers, however, does not necessarily suggest infringement. To find constructive knowledge on summary judgment, there must be evidence of the patentee's repeated contact with or actual examination of the challenged device or specifications of that device. *See* Haworth, Inc. v. Herman Miller, Inc., 856 F.Supp. 354, 357 (W.D.Mich.1994) (constructive knowledge where patentee's agent saw challenged device at several trade shows, obtained and examined samples and consulted with patent counsel); Teradyne, Inc. v. Hewlett-Packard Co., 1994 WL 327213 at *7-8 (N.D.Cal. June 24, 1994) (constructive knowledge where patentee's researcher attended conference on challenged device, composed memo, and sent memo with manuals on device to legal counsel); ABB Robotics, Inc. v. GMFanuc Robotics Corp., 828 F.Supp. 1386, 1391 (E.D.Wis.1993) (constructive knowledge where patentee saw challenged device at exhibition and later discussed with infringer possibility of infringement), *aff'd,* 52 F.3d 1062 (Fed.Cir.1993). R2's infringement claims rest upon the alleged similar structure between Katecho's and R2's electrodes and its assertion that

Katecho's electrodes use stannous chloride "affixed" to their tin surface. It is not clear when R2 concluded or can be charged with the conclusion that Katecho's electrodes also used stannous chloride.

In addition, Smirles' request from R2 management for resources for an investigation of infringement matters does not establish constructive knowledge. While Smirles' testimony in regard to this request appears to refer to Katecho, it not entirely clear whether his investigation had any particular potential infringer in mind. Assuming that the request was aimed at Katecho, it is unclear what basis Smirles offered for his request other than Katecho's competitive position. In addition, it is uncertain when Smirles presented this suggestion to R2 management. If he presented his suggestion long before the issuance of the electrode patents, R2 could not even be certain when or if they would obtain those patents to pursue a suit against Katecho.

Although evidence that Smirles had looked at samples of Cardiovascular's electrodes, and their labeling, suggests circumstances that might impose constructive knowledge, this evidence does not establish constructive knowledge as a matter of law. In his deposition testimony, Smirles stated that he was aware that Katecho was the manufacturing source of Cardiovascular's electrodes by April of 1989. Smirles also stated that had looked at Cardiovascular's electrodes for infringement sometime prior to 1990. Even if he did not realize that Cardiovascular's electrodes were produced by Katecho when looking at them, by 1990 he should have been aware of this fact. However, Smirles' ambiguous reference to having "looked at" the electrodes does not provide the more developed record of analysis of the challenged device generally relied upon to find constructive knowledge on summary judgment. For instance, in *Haworth,* the patentee had not only examined samples of the challenged device and concluded that they were a "knock-off," but also discussed his findings with patent counsel. Haworth, 856 F.Supp. at 357. In *Teradyne,* the court found constructive knowledge because the patentee had attended a conference on the challenged device, composed a memo concluding a possibility of infringement, and distributed the memo with manuals on the device to patent counsel. Teradyne, 1994 WL 327213 at *7-8; *see also* ABB Robotics, 828 F.Supp. at 1391 (constructive knowledge after patentee raised issue of device's infringement with defendant at a licensing negotiation).

In the instant suit, the record presents only a concession that Smirles had looked at Cardiovascular's electrodes for the possibility of infringement. However, as defendants argue in a related motion for summary judgment against R2's claims under the electrode patents, there is no obvious evidence of the critical infringing element, stannous chloride, on the surface of Katecho's electrodes. R2's only evidence of stannous chloride on the electrodes is based upon a method of atomic analysis, auger electron spectroscopy. In fact, defendants argue that even this atomic analysis does not reveal the presence of stannous chloride on the electrodes. Drawing all inferences in favor of R2, a reasonable fact-finder could conclude that Smirles' unspecified examination did not suggest infringement. Further, Smirles' vague recollection that he might have told management that there was a possibility of infringement fails to establish whether he passed on information that imposed a further duty of inquiry on R2. Consequently, a question remains whether R2 should have recognized its claim under the electrode patents when the second patent issued in 1990.

Moreover, even if R2 had constructive knowledge of Katecho's alleged infringement when the final electrode patent was issued, Katecho has not demonstrated that this constructive knowledge would render R2's subsequent delay unreasonable as a matter of law. Measuring backwards from R2's filing of this suit in May, 1994, R2 would have delayed raising its claims, at most, for four years and four months. The only precedent cited finding a similar period of time unreasonable reached this conclusion after trial. Rosemount v. Beckman Instruments, 727 F.2d 1540, 1550 (Fed.Cir.1984). Further, the alleged infringer had notified the patentee of the challenged device to discern if the patentee intended to raise suit. *Id*. No similar

circumstances are present here. Consequently, assuming a four year and four month delay due to constructive knowledge, the reasonableness of such a delay remains a question appropriately left to the trier of act.

In addition, the record does not demonstrate as a matter of law that Katecho was materially prejudiced as a result of R2's alleged delay in raising its infringement suit. Although Katecho invested in increased space, equipment and personnel during the period in question, R2 has raised a genuine issue whether this expansion was a result of the alleged delay. R2 submits evidence indicating that Katecho's sales of its unchallenged electrodes increased at a notably faster rate than its sales of the electrodes at issue. Therefore, whether Katecho's expansion was a result of the R2's alleged delay remains a genuine issue of fact.

Katecho contends that damages arising from its continuing sales of the challenged devices establish material prejudice as a matter of law. In contrast to Katecho's assertion, however, damages that would have been prevented by an earlier suit do not necessarily prove material prejudice. To demonstrate economic prejudice, it is not enough that the alleged infringer changed its economic position by investing in the production of the allegedly infringing device during the time of delay. Hemstreet, 972 F.2d at 1294. If such damages necessarily constituted prejudice, then practically every patent claim would establish material prejudice. *See* Aukerman, 960 F.2d at 1033. In granting summary judgment to the alleged infringer on laches, courts usually have relied upon evidence of considerable capital investment or substantially increased sales. *See* Adelberg Laboratories, Inc. v. Miles, Inc., 921 F.2d 1267, 1272 (Fed.Cir.1990) (during delay, defendant made considerable capital investments in expanding business); ABB Robotics, 828 F.Supp. at 1396 (granting summary judgment where alleged infringer enjoyed three-fold increase in sales of challenged device during period of delay). As noted, Katecho has not demonstrated any dramatic increase in sales during the alleged period of delay. In fact, the only cited precedent finding material prejudice based solely on increased sales also relied upon evidence affirmatively indicating that the alleged infringer would have modified its behavior if the patentee had acted earlier. *See* ABB Robotics, 828 F.Supp. at 1396-97 (defendant had halted production on similar device when it found possible infringement of patent at issue and sought license from patentee); *see also* ABB Robotics, 52 F.3d at 1064 (affirming decision on equitable estoppel grounds based upon this same evidence). Katecho provides only its bald assertion that it would have altered its behavior had it known of R2's claims. In addition, the *ABB Robotics* court granted summary judgment only after finding a legal presumption of laches. 828 F.Supp. at 1396. Katecho enjoys no such presumption here. Consequently, a genuine issue of fact remains whether Katecho suffered material prejudice as a result of any delay by R2.

Because Katecho has demonstrated neither an unreasonable delay nor material prejudice, its motion for summary judgment based on laches is denied.

B. *Cardiovascular and Padeco*

1. " *Tacking* "

Padeco did not incorporate and commence its allegedly infringing activity until 1991. However, Cardiovascular's and Padeco's motion for summary judgment presumes that Padeco may rely upon any alleged delay by R2 in raising its claims against Cardiovascular in determining Padeco's period of laches. Defendants argue that Padeco may "tack on" these years of delay because Padeco is Cardiovascular's "successor-in-interest" to its line of challenged products.

R2 responds that laches is a "personal defense" applicable only to the relationship between the plaintiff and

each particular defendant. Hughes Aircraft Co. v. General Instrument Corp., 275 F.Supp. 961, 972 (D.C.R.I.1967), *rev'd in part on other grounds,* 399 F.2d 373 (1st Cir.1968); Pierce v. American Communications Co., 111 F.Supp. 181, 190 (D.C.Mass.1953), *vacated on other grounds,* 208 F.2d 763 (1st Cir.1953). To support a defense of laches with a patentee's conduct toward another party, R2 argues that a defendant at least must have merged with the prior party or have purchased the assets of that party's business. *See, e.g.,* American Home Products Corp. v. Lockwood Mfg. Co., 483 F.2d 1120, 1124 (6th Cir.1973) (permitting alleged infringer to tack on period of delay of company from which it purchased all of its assets). Because the record does not reveal that Padeco is formally related to Cardiovascular or ever purchased any of its assets related to the challenged devices, R2 asserts that Padeco may not "tack on" any alleged delay with respect to Cardiovascular.

Without any citation to authority, defendants propose that an alleged infringer need not have any formal identity with a prior business in order to "tack on" a period of delay for purposes of laches. Defendants assert that an alleged infringer becomes a "successor-in-interest" where it carries an identical line of products, under an identical trade name and the previous party ceases to carry that challenged line of products. In such circumstances, defendants argue that the parties are analogous to a purchaser and seller of a line of business, with all its attendant technology and goodwill.

[19] [20] [21] [22] [23] Although the court agrees that an alleged infringer need not acquire the assets of another company in order to "tack on" a period of delay, some formal transfer of the technology and goodwill of the accused product is required. As a general matter, the defense of laches is personal to the defendant. Aukerman, 960 F.2d at 1032. Where the plaintiff is a transferee of a patent, however, that plaintiff must bear the consequences of any delay by the transferor. *See, e.g.,* Continental Coatings Corp. v. Metco, Inc., 464 F.2d 1375 (7th Cir.1972). Conversely, a defendant that is the transferee of an entire business or its assets may rely upon the patentee's delay in suing the transferor. *See, e.g.,* Autoclave Engineers, Inc. v. Duriron Co., 190 U.S.P.Q. 125 (E.D.Pa.1976); *see generally,* Donald S. Chisum, *Patents,* s. 19.05[2][a][ii] (1994). In such circumstances, the transferee effectively has assumed the transferor's identity, usually retaining the same machinery, customers and management. *See* Autoclave, 190 U.S.P.Q. at 132. Similarly, where the alleged infringer has purchased a business division or a line of business, it assumes the transferor's identity for purposes of a patent challenge to that line of business. *See* Raber v. Pittway Corp., 1994 WL 374542 at *2-3 (N.D.Cal. July 11, 1994).

[24] Defendants have not presented evidence establishing that any formal transfer of the challenged product line took place. The record suggests that Padeco may have acquired Cardiovascular's goodwill in the challenged product line. Padeco sells identical devices under an identical trade name used by the transferee. In fact, Padeco incorporated under this trade name. In addition, Cardiovascular discontinued its sales of the Padeco line of products that same year. However, these circumstances do not establish that Padeco assumed Cardiovascular's identity with respect to the challenged line of business. Defendants have presented no evidence of any agreement between Cardiovascular and Padeco either transferring Cardiovascular's technology and goodwill to Padeco or restraining Cardiovascular's right to resume sales of the challenged devices. *Cf.* Tandy Corp. v. Malone & Hyde, Inc., 769 F.2d 362, 367 (6th Cir.1985) (to assume laches of previous trademark owner, defendant must acquire goodwill of business associated with that trademark); Greenlon, Inc. of Cincinnati v. Greenlawn, Inc., 542 F.Supp. 890, 894-95 (S.D.Ohio 1982) (requiring transferor to give up some right to the business for transferee of trademark to assume transferor's period of laches). Consequently, Padeco has not presented adequate evidence to permit it, as a matter of law, to rely upon any delay by the R2 against Cardiovascular.

2. ***The*** '998 Patent

R2 accuses Cardiovascular and Padeco of contributing to infringement and inducement of infringement of the '998 patent through their packaging, advertising and instructions on certain models of electrodes. As explained with respect to Katecho, the record does not indicate that defendants used the packaging alleged to have infringed the '998 patent until 1989, at the earliest, less than six years prior to the filing of the instant suit. Consequently, defendants are not entitled to a legal presumption of laches with respect to R2's infringement claims under the '998 patent.

Defendants respond that R2 did not originally pursue a claim for contributory infringement. In support of this argument, defendants point to R2's answer to an early interrogatory requesting R2 to characterize its specific claims for infringement of the '346, '356, '552 and '998 patents. In its answer to this interrogatory, R2 indicated that defendants' electrodes, adapters and converted cables "directly infringed" all of these patents. Defendants ask the court to prevent R2 from avoiding a potential bar of laches by narrowing its suit to activity that occurred later.

[25] [26] Answers to interrogatories, however, do not bind parties as do allegations or admissions in a pleading. Donovan v. Crisostomo, 689 F.2d 869, 875 (9th Cir.1982); Marcoin, Inc. v. Edwin K. Williams & Co., 605 F.2d 1325, 1328 (4th Cir.1979). R2's answer reveals that the parties were still early in the discovery process and R2 had not yet determined the scope of its suit. In fact, prior to its characterization of the infringement, the answer formally objects to the interrogatory under Federal Rule of Civil Procedure 33(b). In addition, R2's answer may contemplate both a contributory claim and a claim based upon the packaging and its instructions. In each paragraph identifying alleged infringements, R2's answer indicates that the combined use of the defendants' adapters, modified R2 cables and electrodes "directly infringed" the patents at issue. Thus, R2's theory focused on the simultaneous use of Padeco components as directly infringing, an event more likely to occur with defendants' customers than with defendants, themselves. In explaining how defendants' goods "directly infringed," R2's answer also refers to Padeco's packaging, advertising and instructions on their electrodes. Assuming that R2's delay in asserting a claim for direct infringement of the '998 patent would be relevant to determining a delay of laches in the instant claim, the record does not demonstrate that a cause of action for direct infringement in fact exists. R2 does not raise such a claim. On defendants' motion for summary judgment, it would be inappropriate to infer one. Consequently, for purposes of this motion, there is no presumption that R2's claim for infringement of the '998 patent is subject to laches.

Defendants provide no further evidence suggesting why R2 should have been aware of the alleged infringement of the '998 patent until 1991, when the record indicates that the challenged packaging was first widely distributed. As noted with respect to Katecho, such a delay is not necessarily unreasonable. Therefore, the court denies Cardiovascular's and Padeco's motion for summary judgment on the issue of laches with respect to the '998 patent.

3. ***The System and Electrode Patents***

[27] R2 argues that Cardiovascular and, later, Padeco contributed to the infringement and induced the infringement of the system patents, '552, '345 and '356, by manufacturing and selling adapters, modified R2 cables and multifunctional electrodes that infringed upon the electrode patents, '585 and '169. R2 asserts that by providing all of these components for use with its cable systems, defendants contributed to their customers' direct infringement of the patents allegedly protecting those systems. However, under the doctrine of permissible repair, a party is permitted to replace used or worn parts of a patented system

without infringing any patent protecting that system. *See, e.g.,* Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 344, 81 S.Ct. 599, 603-04, 5 L.Ed.2d 592 (1961) (" *Aro I* "). To overcome this defense, R2 proposes that replacement with components that infringe upon other patents held by the owner of the system patent infringes both the component patent and the system patent, regardless of the reason for the replacement. *See* Warner and Swasey Co. v. Held, 256 F.Supp. 303, 311 (E.D.Wis.1966). Based upon this theory, R2 argues that use of infringing electrodes in the R2 systems constitutes a direct infringement of the patents protecting those systems.

[28] As explained above, in determining laches, the period of delay cannot begin until the issuance of the underlying patent. Aukerman, 960 F.2d at 1033. Where the party had no cause of action for infringement to pursue, it could not yet have delayed. *See* Watkins v. Northwestern Ohio Tractor Pullers Ass'n, 630 F.2d 1155, 1161 (6th Cir.1980). Under R2's theory of liability, defendants did not infringe upon any of the system patents until the electrode patents were issued in 1989 and 1990. Therefore, the allegedly infringing activity-the sale of patented electrodes with the other components-did not occur until 1989, at the earliest, after the first electrode patent issued.

In response, defendants repeat their argument that R2 originally raised its claims under the system patents as direct infringement. As noted above, however, R2 is not bound by its references to Padeco's direct infringement in their answer to an early interrogatory. *See* Donovan, 689 F.2d at 875. Neither R2 nor defendants assert that there is a cause of action for direct infringement. At this stage in the proceedings, it would be improper to infer that such a hypothetical cause of action exists. Because R2's claim for infringement depends upon the issuance of the electrode patents, for purposes of this motion, R2's period of delay does not begin until 1989, at the earliest. In light of the related nature of the two electrode patents, at this stage in the case, the court will infer, as it did with respect to Katecho, that R2 reasonably delayed until at least the issuance of the second electrode patent on January 23, 1990. With respect to Padeco, the period of delay could not begin until it commenced its own allegedly infringing activity in 1991.

Like Katecho, Cardiovascular and Padeco argue that R2 had constructive knowledge of their claims under these remaining claims immediately upon issuance of each of the patents. Consequently, they assert that R2's subsequent delay of four years and four months is unreasonable as a matter of law. Defendants rely upon much of the same evidence as Katecho: R2's ongoing awareness that Cardiovascular provided competing electrodes for cardiac care; R2's acquisition of samples of Cardiovascular's electrodes and adapters; and Smirles' examination of the electrodes. In addition, defendants point to R2's awareness of the use of Cardiovascular's devices in conjunction with R2 systems and its attempt to instigate an FDA investigation in February, 1988.

Although suggestive, the record does not establish as matter of law that R2 had constructive knowledge of their claims by 1990 under either the electrode patents or the system patents. Defendants' evidence of R2's concerns with the safety and effectiveness of the conjoined use of Cardiovascular devices with R2 systems does not necessarily establish that R2 reasonably should have been aware of its infringement claims. Drawing all reasonable inferences in R2's favor, the record only demonstrates R2's concerns over the incompatibility of the parties' products and possible unintended uses of R2 systems with Cardiovascular devices. The court cannot find as a matter of law that it would have been unreasonable for R2 to conclude at that time that Cardiovascular was not infringing the system patents. Regardless, as explained with respect to Katecho, it remains unclear when R2 reasonably should have recognized its claim that Cardiovascular's electrodes infringe its patents through the use of stannous chloride. The fact that R2 obtained samples of Cardiovascular's products as early as July 1988 does not alter this conclusion. The sale of patented

components is an essential element of R2's theory of infringement of the system patents. Therefore, the court cannot conclude on summary judgment that R2 had constructive knowledge of its system patent claims in 1990.

Further, even if the court were to conclude that R2 should have recognized its claims under the electrode and system patents in 1990, the record does not indicate that the subsequent four year and four month delay is unreasonable as a matter of law. The evidence does not demonstrate R2's actual knowledge of its claims. *Cf.* Rosemount, 727 F.2d at 1550 (finding three year delay unreasonable where defendant notified patentee of challenged device). Rather, the record indicates that R2 had significant difficulty in discerning whether Cardiovascular's electrodes used stannous chloride, a critical element to a claim under either of the electrode patents. In these circumstances, the reasonableness of a four year and four month delay is more appropriately determined at trial.

The record also does not clearly demonstrate that either Cardiovascular or Padeco suffered material prejudice as a result of R2's alleged delay. Because "economic prejudice is not a simple concept but rather is likely to be a slippery issue to resolve," Aukerman, 960 F.2d at 1033, it usually is not amenable to summary judgment. The fact that Cardiovascular's sales of the challenged devices increased during this time period or that it gradually relied more fully upon them does not establish the required causal nexus as matter of law. For purposes of this motion, the longest possible period of delay extends from January 1990 until May 1994. Based upon defendants' vague assertions of increased sales from 1986 until 1991, the extent of the growth in sales during these final two years remains unclear. *Cf.* ABB Robotics, 828 F.Supp. at 1396 (finding material prejudice from three-fold increase in sales during period of delay).

More importantly, deposition testimony by the sole owner of Cardiovascular, Joseph M. Mertz, indicates that the company exited the market for other hospital-related goods as its suppliers severed their relationships. While Cardiovascular asserts that it did not replace these suppliers because of a conscious decision to focus on the electrodes at issue, this testimony reveals a remaining genuine issue of fact as to the reason for Cardiovascular's increasing focus of the electrodes. Consequently, an issue of fact remains whether their increasing sales were caused by R2's delay.

Because Cardiovascular and Padeco have not established either that R2 unreasonably delayed raising any of its claims or that they suffered material prejudice as a result of the alleged delay, their motion for summary judgment with respect to laches is denied.

II. ***Equitable Estoppel***

[29] [30] [31] [32] [33] Equitable estoppel provides an affirmative defense to a patent claim which, if proven, may entirely bar a patentee's suit. Aukerman, 960 F.2d 1020, 1041 (Fed.Cir.1992). In contrast to laches, equitable estoppel focuses upon the reasonableness of the defendant's conduct. *See* id. at 1033 & 1043-44. To prove estoppel, a defendant must establish at least three factors: (1) the patentee engaged in misleading conduct that could reasonably lead the alleged infringer to infer that the patentee did not intend to pursue its claim; (2) the alleged infringer relied on the patentee's conduct; and (3) due to its reliance, the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim. Id. at 1041-43. Misleading conduct may include specific statements, action, inaction, or silence where there is a clear duty to speak. Id. at 1043. The patentee's conduct "must have supported an inference that the patentee did not intend to press an infringement claim against the alleged infringer." Id. at 1042. On a motion for summary judgment, "such an inference must be the only possible inference from the evidence." Id. at 1044.

[34] [35] Although silence or inaction may constitute misleading conduct, it must be combined with "other facts respecting the relationship or communication between the parties to give rise to a necessary inference" that the plaintiff would not enforce its patent rights. Id. at 1042. These facts surrounding the inaction must have imposed upon the patentee a clear duty to speak. Id. at 1043. While a patentee's awareness of the defendant's challenged activities may be a necessary factor, *see* id. at 1042, it is not sufficient to render its inaction misleading. Instead, courts have required communication between the parties either somehow encouraging the challenged activity, or indicating an intent to enforce the patent rights followed by inaction. *See, e.g.,* ABB Robotics, 52 F.3d at 1064 (patentee objection to challenged device as infringing rendered subsequent six years of inaction misleading); Adelberg, 921 F.2d at 1271 (eleven years of inaction after patentee threatened infringement suit misleading); Olympia Werke Aktiengesellschaft v. General Elec. Co., 712 F.2d 74, 78 (4th Cir.1983) (estoppel for years of inaction where defendant alerted patentee of product and patentee entered into negotiations to license from defendant).

[36] In contrast to laches, the defendant not only must demonstrate that it would suffer material prejudice as a result of the patentee's misleading conduct, but also must prove that it suffered this prejudice because it in fact relied upon this conduct. Reliance requires more than a showing of economic harm. The evidence must show that the defendant had a relationship or communication with the patentee which would have reasonably lulled the infringer into a sense of security in investing in the infringing product. Aukerman, 960 F.2d at 1042-43.

A. *Katecho*

[37] Katecho argues that it relied to its detriment upon R2's failure to raise suit from 1986, when Katecho first believed that R2 was aware of its competing electrodes, until 1994, when R2 filed suit. For misleading conduct, Katecho relies solely upon R2's inaction during this period. Katecho raises no evidence of any relationship between the parties other than their competitive posture and telephone conversations with a former customer of R2, Laerdal, in which Laerdal's procurement officer reported R2's frustration over the loss of its customer.

Because equitable estoppel imposes more drastic consequences than laches, it requires proof of more pernicious conduct by the patentee than mere delay. *See* Naxon Telesign Corp. v. Bunker Ramo Corp., 686 F.2d 1258, 1264 (7th Cir.1982). An alleged infringer must demonstrate that the plaintiff's conduct was so misleading as to reasonably lead the alleged infringer to conclude that the plaintiff would never raise a patent challenge. Aukerman, 960 F.2d at 1041-42. Where a patentee sleeps on its rights, laches redresses any injustice by barring retrospective relief. But to bar a patentee's entire suit because of silence or inaction, the patentee must have had some duty, distinct merely from its obligation under laches, to inform the defendant of its intent to enforce its patent rights. Otherwise, the distinction between laches and estoppel is blurred despite their different consequences for the patentee.

The fact that R2 and Katecho sold competing products to the same customers for the same purposes does not provide a relationship that imposes such a duty. Rather, to infer that a plaintiff did not intend to press a patent claim from a period of inaction, courts have required that the patentee had first notified the defendant of its intent to pursue its patent rights. *See* id. at 1042. In such circumstances, subsequent years of inaction may reasonably indicate abandonment of the claim. In the present suit, R2 neither encouraged nor threatened Katecho. In fact, there is no evidence that R2 communicated with Katecho at all. Katecho does not argue that Laerdal acted as an agent for R2. Instead, Katecho states that Laerdal's procurement manager

described to Katecho that R2 was angry about the loss of Laerdal's business. Even if this evidence was admissible for purposes of summary judgment, R2's inaction following this general expression of anger to a third party simply could not lead Katecho to reasonably conclude that R2 would not contemplate a patent suit some time in the future. Because Katecho has not demonstrated misleading conduct, the court need not address the remaining elements of reliance and material prejudice.

B. ***Cardiovascular and Padeco***

[38] Like Katecho, Cardiovascular and Padeco argue that they relied upon R2's years of inaction in continuing to invest in expanding sales of the challenged devices. However, in addition to the parties' competitive posture, these defendants contend that R2's direct confrontation with Cardiovascular in 1988 over alleged safety issues provided the necessary communication between the parties to render R2's subsequent years of inaction misleading conduct for purposes of equitable estoppel. As defendants concede, in contrast to precedent finding inaction misleading, R2's inaction was not preceded by a threat or any communication at all with regard to R2's patent rights. Instead, R2 accused Cardiovascular of potentially violating FDA regulations and warned that it would hold Cardiovascular liable for injuries arising from the conjoined use of their products or the unintended use of R2 products. Defendants contend that it was this conspicuous absence of any reference to patent rights in the context of a legal confrontation over the challenged activity that reasonably led them to presume that R2 did not hold a patent claim that covered their challenged activity.

[39] It is difficult to see how defendants could rely upon this communication to reach such a conclusion. In light of equitable estoppel's dramatic bar of relief, misleading inaction must have "encouraged the belief that the infringer's business would be unmolested." Continental Coatings, 464 F.2d 1375, 1380. The alleged infringer may not rely upon its "unilateral expectations or even reasonable hopes" in concluding that no possible patent challenge exists. *See* Stickle v. Heublein, Inc., 716 F.2d 1550, 1559 (Fed.Cir.1983). To create a reasonable inference that a party does not intend to assert a patent claim, courts have required that the patentee had notified the defendant that a potential patent claim exists. *See* Aukerman, 960 F.2d at 1042 (defendant must know of patent or patentee to render silence misleading conduct); *see also, e.g.,* ABB Robotics, 52 F.3d at 1064 (prior to years of inaction, parties negotiated over license and defendant asserted no infringement).

[40] If an alleged infringer is completely ignorant of any patent rights, the patentee's previous silence may be misleading where there is a clear duty for it to have spoken. Aukerman, 960 F.2d at 1043. For instance, such a duty may arise from a legal relationship between the parties or where the patentee's conduct encourages the subsequently challenged activity. *See* Wang Lab., Inc. v. Mitsubishi Electronics America, Inc., 30 U.S.P.Q.2d 1241, 1249-52 (C.D.Cal.1993) (potential misleading conduct where plaintiff strenuously lobbied defendant and others to adopt its technology as industry standard without disclosing pending patent); Potter Instrument Co. v. Storage Technology Corp., 207 U.S.P.Q. 763 (E.D.Va.1980) (misleading conduct where patentee who sat on industry standardization committee failed to raise patent rights despite official policy to contrary).

[41] R2's accusations against Cardiovascular of negligent modification of its products and suggestions of potential future liability, however, did not encourage defendants to continue their activities. Defendants present no legal authority implying a duty to raise a potential claim in the context of raising other legal concerns with respect to the ultimately challenged activity. There is no evidence that R2 actually pursued any legal action against Cardiovascular. At the most, the record reflects an effort move a federal agency to

conduct an investigation. In fact, R2's correspondence with Cardiovascular did not suggest imminent legal action. Even where a patentee had brought its patent to the alleged infringer's attention, mere suggestions of possible infringement do not create an adequately adversarial stance to render subsequent inaction misleading. *See* Hemstreet, 972 F.2d at 1295; Teradyne, 1994 WL 327213 at *5; *cf.* International Harvester Co. v. Deere & Co., 623 F.2d 1207, 1213 (7th Cir.1980) (patentee's request for samples of defendant's product to test for infringement did not raise reasonable apprehension of patent suit to warrant an action for declaratory judgment).

Accordingly, R2's oblique references to possible lawsuits unrelated to infringement, lawsuits that would not necessarily be raised by R2, itself, were not sufficiently misleading, as a matter of law, for Cardiovascular to reasonably conclude that R2 did not have a patent claim. Defendants could not presume that R2 would have recognized any potential patent claims. Even if defendants could rely upon such a presumption, they could not be certain whether R2 refrained from raising its patent claims because of a possible excuse under laches. *See* Aukerman, 960 F.2d at 1033 (providing nonexclusive list of potential excuses for delay).

Finally, defendants could not be certain that R2 harbored potential claims under patents that had not yet issued. In fact, in the instant case, four of the six patents in question had not issued at the time of this correspondence. The court is unaware of a legal obligation, in a case such as this, to alert potential future infringers of currently pending patents. *See* Bell Sports, Inc. v. Graber Products, Inc., 29 U.S.P.Q.2d 1211, 1215-16, 1993 WL 597383 (W.D.Wis.1993) (finding no duty to disclose pending patent in connection with dispute over another patent). Consequently, for purposes of summary judgment, the court cannot conclude that defendants' "only possible inference" from R2's correspondence was that R2 would never raise a patent suit against Cardiovascular's electrodes and related products. Aukerman, 960 F.2d at 1044.

Because defendants have failed to present sufficient evidence to establish that R2 engaged in misleading conduct toward either Cardiovascular or Padeco, the court need not reach the elements of reliance and material prejudice. Defendants' motion for summary judgment with respect to equitable estoppel is denied.

III. ***Best Mode***

[42] [43] Under 35 U.S.C. s. 112, a patent specification must "set forth the best mode contemplated by the inventor of carrying out his invention." Section 112 provides an alleged infringer with an affirmative defense that, if proven, invalidates the patent. The alleged infringer has the burden to demonstrate that the patent violated the best mode requirement by clear and convincing evidence. Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 560 (Fed.Cir.1994). Whether the patent satisfied the best mode requirement is a question of fact. Transco, 38 F.3d at 559.

[44] [45] The best mode requirement entails a two-step inquiry. In the first step, the alleged infringer must prove that the inventor in fact knew of a mode of practicing the invention that he considered better than any other at the time he filed the application. Id. at 560. This wholly subjective inquiry focuses solely upon the inventor's awareness of information as of the date of application, and not on any information or beliefs developed afterwards, to determine if there was any preferred mode to conceal. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535 (Fed.Cir.), *cert. denied,* 484 U.S. 954, 108 S.Ct. 346, 98 L.Ed.2d 372 (1987).

[46] [47] [48] [49] If a best mode is found, then the "second step is to compare what [the inventor] knew with what he disclosed to determine whether the disclosure is adequate to enable one skilled in the art to

practice the best mode." Transco, 38 F.3d at 560. This question of concealment presents a largely objective inquiry that depends upon the scope of the claimed invention and the skill of the prior art. *See* Chemcast Corp. v. Arco Industries Corp., 913 F.2d 923, 926-927 (Fed.Cir.1990). First, it must be determined whether the identified preferred mode is within the scope of the claimed invention. Id. at 927. Unclaimed subject matter is not subject to the disclosure requirements of s. 112. Engel Industries, Inc. v. Lockformer Co., 946 F.2d 1528, 1531 (Fed Cir.1991). If the preferred mode was within the scope of the claimed invention, then concealment is determined by whether one who is skilled in the art of the invention could practice the invention. Chemcast, 913 F.2d at 926-27. Section 112 does not require a patent to provide details that one of ordinary skill in the art would know. Cobraco Mfg. Co. v. Valley View Specialties Co., 1992 WL 77672 at (N.D.Ill. April 6, 1992).

A. ***Katecho's Claims***

[50] Although R2 currently owns all of the patents at issue, Heath was the named inventor as well as the founder and original chief executive officer of R2. The application for the '998 patent was filed on August 8, 1980. The '585 and '169 patents, describing the electrodes used in the system, were later filed as continuation applications of patent '998, and add no additional disclosure to the '998 patent. Heath was discharged by R2 in 1986.

Katecho moves for summary judgment, alleging that at the time of the original application, Heath did not disclose the best modes that he contemplated for manufacturing the electrodes. First, Katecho argues that Heath concealed a preferred method of affixing the stannous chloride to the electrodes' surface, including the materials used with the stannous chloride and an optimum amount of stannous chloride. Second, Katecho argues that Heath concealed the character and tradename identity of his preferred saline gel to use with the electrodes. In support of these allegations, Katecho's relies primarily upon Heath's deposition testimony. At his deposition, Heath indicated that he has experimented with various methods to affix the stannous chloride to the metal surface of the electrodes, but repeatedly declined to describe these methods, asserting that they were and are "trade secrets." His testimony referred to the existence of other materials that may be used to carry the stannous chloride to the metal, as well as the amount of stannous chloride used. In addition, Heath indicated that properties of the conductive gel could be important to protecting the patient from chemical burns, such as preventing migration of the stannous chloride to the skin during treatment. However, Katecho notes that none of these factors are discussed in either patent's specifications. In light of these statements, Katecho argues that the '998 patent and electrode patents are invalid.

B. ***Analysis***

1. ***Preferred Method to Apply Stannous Chloride***

Under the patents at issue, stannous chloride must be located between the conductive metal surface and the patient's skin. The stannous chloride may be located either in the gel that rests between the conductive metal surface of the electrode and the skin, or it may be applied directly onto the conductive metal surface. As an example, the patents explain that it may be applied "by spraying a thin layer thereon."

Katecho contends that Heath contemplated a preferred method of applying the stannous chloride to the metal surface that is not disclosed in the '998 patent. In particular, Katecho alleges that these methods possibly involve, (1) the use of unknown materials mixed with the stannous chloride, and (2) a preferred amount of stannous chloride in the solution. In support, Katecho points to Heath's testimony that he had experimented with various methods of applying the stannous chloride, but would not discuss the results because they were

"trade secrets." For example, Heath noted that the stannous chloride must be mixed with other materials to form it on the electrode's surface, but would not divulge those materials that he has tried because they are trade secrets. Similarly, Heath indicated that through experimentation he arrived at an optimum amount of stannous chloride to be applied. Katecho argues that, despite Heath's statements, the patents never indicate either any materials to mix with the stannous chloride, any amount of stannous chloride, or any method to apply the stannous chloride other than "spraying" it onto the surface.

R2 responds that Heath's testimony fails to establish that he contemplated any optimum method or solution mixture at the time of application. First, R2 argues that the testimony never reveals when Heath experimented or arrived at any preferred methods of applying the stannous chloride. Further, R2 contends that the testimony does not reveal whether Heath has ever contemplated a preferred method distinct from R2's current method of mixing the stannous chloride into a solution of alcohol. To the extent he may have contemplated this method as a preferred mode, R2 argues that the patents' references to "spraying" on the stannous chloride provides adequate disclosure for one skilled in the art to discern this method without undue experimentation.

In support of its motion, Katecho relies heavily on the fact that Heath repeatedly referred to the details of his method of applying stannous chloride as a "trade secret." In contrast to Katecho's implication, however, this does not necessarily establish that the information would violate the best mode requirement. First, a procedure or material considered to be a trade secret prior to application of the patent may have been subsequently disclosed in the patent. For instance, despite an inventor's claims of secrecy, his concealed methods may be apparent to those skilled in the art of the claimed invention, particularly in light of other information provided in the patent. Second, trade secrets may conceal information for a variety of reasons that do not necessarily relate directly to the performance or effectiveness of the manufactured device, such as cost-effective manufacturing or other merits outside of the scope of the claimed invention. *See* Wahl Instruments, Inc. v. Acvious, Inc., 950 F.2d 1575, 1581-82 (Fed.Cir.1991).

Katecho's strongest evidence that Heath contemplated a preferred mode arises from the following exchange with Heath:

Q. Getting back to my question now: At the time you filed your patent application-

A. Okay.

Q. -whatever your method for affixing it, was that a trade secret?

A. Yes.

Q. And you consciously decided not to include that in your patent?

A. You know, to answer your question completely, and I keep coming back to fixation, because that was- you know, I would say we applied it to the surface. Whether it was fixed, could be debated. I suppose some would stay on the surface, and you could interpret that as fixed, I don't know.

Q. So your method for applying it to the surface was the-

A. That would be more accurate. It was a trade secret, is a trade secret.

Q. At the time you filed your application?

A. Yes, that's correct.

Q. And you chose not to put that in the patent because you wanted to keep it as a trade secret?

A. I believe that was, that may have been discussed at the time. I don't know whether we decided at that point to do that. I don't know whether it was decided that it wasn't as significant or whether it was actually decided not to put it in the patent.

This testimony indicates that Heath contemplated some method of applying the stannous chloride at the time of the patent application. However, it does not establish any of the characteristics of this method. For instance, none of Heath's testimony demonstrates that Heath contemplated a solution using materials other than alcohol. Although Heath noted later in the deposition that the stannous chloride must be mixed with other materials to carry it onto the surface of the electrodes, he characteristically refused to identify these materials as "trade secrets." When asked if these materials were important to the functioning of the electrodes, he answered only that "[t]hey could be." Upon further questioning, Heath responded that some materials may be toxic to the patient. At the least, there is an issue of fact whether the importance of the attribute of toxicity would have been obvious to one skilled in the art.

Consequently, Heath's testimony, taken in either distinct sections or as a whole, fails to clarify whether his preferred method at the time he applied for the patent was distinct from R2's current method of spraying the stannous chloride in a solution mixed with alcohol. This was the method that Heath had provided in a separate document in 1980. Later in his deposition, after reviewing the patents, Heath stated that spraying was "likely the methodology used" at the time of the patent application. Alcohol is generally non-toxic when applied to the skin in an open air environment. Therefore, a genuine issue of fact remains whether in August of 1980 Heath's contemplated preferred method of applying the stannous chloride was in an alcohol solution.

If an alcohol solution was Heath's preferred method of application, then the current record would not establish Heath's concealment. FN2 As noted, the patents reveal that one method to apply the stannous chloride is by spraying it onto the surface of the conductive metal. It is not at all clear that one skilled in the art would not recognize that stannous chloride must be mixed into a solution for such an application. For example, Heath testified that "tin chloride is a powder, it can't be sprayed by itself." Evidence indicates that the data sheets available upon purchase of stannous chloride provide a list of preferred solvents for use, including alcohol, along with their proper mixing ratios. R2's expert witness, John G. Webster, has stated in an affidavit that one skilled in art would recognize alcohol as an easy, non-toxic and inexpensive solvent to use with stannous chloride.

FN2. In fact, even if Heath was referring to a preferred material other than alcohol, the record does not demonstrate necessarily that he chose that material for reasons related to the operation or effectiveness of the electrodes. *See* Wahl, 950 F.2d at 1581-82 (no violation of best mode where inventor concealed more cost-effective method to manufacture claimed device); Christianson v. Colt Indus. Oper. Corp., 870 F.2d 1292, 1301-02 (7th Cir.1989) (concealment of modes to make patented rifle parts interchangeable with other rifles unrelated to scope of claimed patent). Outside of toxicity to the skin, Heath never revealed his standard of choosing the proper materials to apply the stannous chloride. The record indicates that there are

other solvents that may be mixed with stannous chloride to apply it successfully to the electrode's surface. Consequently, it would be unclear if Heath chose any hidden materials because of their effect of the electrode's performance or for reasons associated with non-best mode factors such as cost or ease of manufacturing. *See* Wahl, 950 F.2d at 1581.

With respect to a preferred measure of stannous chloride, Heath's testimony does not establish that he contemplated a preferred amount at the time of application. Rather, Heath stated that too much stannous chloride "could have deleterious effects on the electrode" and that too little may affect functioning. This statement does not necessarily indicate a preferred measure to improve the electrode's performance, but only broad parameters. Although Heath indicated that he experimented with amounts and arrived at an "approximation" of a proper amount, he specifically noted that he did not "know when that particular time occurred." Therefore, the testimony does not establish whether Heath contemplated any optimum measure of stannous chloride in 1980. While the court need not reach the issue, it also notes that the basis of this proper amount and its relationship to the effectiveness of the electrodes also remain ambiguous.

For the reasons stated above, Katecho has not demonstrated as a matter of uncontested fact, by clear and convincing evidence, that any of the patents concealed a preferred mode of applying the stannous chloride to the electrodes that he contemplated in August of 1980.

2. *Preferred Gel*

The '998 patent and the electrode patents require that a conductive medium, a saline gel, be located between the metal surface of the electrode and the patient's skin. The patents state that this gel is necessary for proper functioning of the electrodes by improving the flow of electricity with the patient. In addition, the patents contemplate that instead of affixing the stannous chloride to the surface of the electrode, the stannous chloride may be located in the gel itself. However, R2 has not commercially distributed electrodes using stannous chloride in the gel. Apparently, stannous chloride may irritate and even burn the patient's skin if it is not bonded with the tin surface.

Katecho alleges that Heath contemplated a preferred gel compound at the time of his patent application. Specifically, Katecho alleges that: (1) Heath had identified a manufacturer that provided a preferred gel; (2) Heath contemplated a preferred level of viscosity for the gel which prevented the migration of the stannous chloride to the patient's skin; and (3) Heath had preferred a specific measure of a (non-stannous) chloride compound in the gel. FN3 In support, Katecho relies on testimony indicating that Heath had experimented with gels from various suppliers, and that the supplier that he used at the time of the patent application provided the gel he preferred. In addition, Heath testified that he ultimately chose a gel with high viscosity that better protected the patient's skin from exposure to the irritating stannous chloride. Katecho also points to testimony indicating that acid and chloride levels in the gel may irritate the patient's skin. In light of evidence that R2 unsuccessfully attempted to reverse engineer its preferred gel, Katecho argues that their preferred gel could not have been obvious to one skilled in the art. Because the patents never mention a preferred supplier of gel or the viscosity, chloride content or acidity of the gel, Katecho argues that they conceal Heath's best mode.

FN3. In their briefs and statements of facts, the parties also allude to a potential claim that Heath contemplated a preferred amount of stannous chloride in the gel. The court does not read Heath's references to chloride in the gel as referring to stannous chloride content. Heath indicated that the use of stannous

chloride in the gel was not a preferred method.

As an initial matter, Heath's testimony fails to establish that he had identified a preferred gel at the time of the patent application. In support of its motion, Katecho relies upon Heath's statements indicating that he experimented with different gels to determine their ability to protect patients. Although Heath affirmed that his ultimate supplier of saline gel provided him with gel prior to the date of application, Heath also specifically stated that he did not know if he had yet determined that this gel was best. Further, Heath stated that the performance of the various suppliers were all similar, and that the chemistry of the gel did not change much among these suppliers. This raises a question whether his original preference related to the gel's effect on the operation of the electrodes versus non-best mode reasons such as cost. Continuing to use a supplier because of satisfactory performance does not necessarily reflect a preferred mode for purposes of Section 112. *See* Wahl, 950 F.2d at 1581.

Heath's testimony with regard to the viscosity level of the gel does not resolve these ambiguities. In his testimony, Heath stated that a higher viscosity gel prevented the stannous chloride from migrating from the electrode's surface to the patient's skin where its could cause injury. However, it is unclear if Heath had recognized this fact at the time of the patent application. Heath's testimony establishes only that he experimented with a variety of suppliers of gels.

In addition, Heath's testimony does not necessarily demonstrate that he has ever contemplated either a preferred amount of chloride or a preferred level of acidity in the gel, let alone preferred measures of either attribute in 1980. Heath states that a gel used as a conductive medium with medical electrodes may injure the patient's skin if it has high levels of acidity. Katecho has not established that one skilled in the art or, for that matter, one unskilled in the art would not deduce this general fact from the gel's position on the patient's body. Regardless, Heath never indicated that he contemplated a preferred level of acidity. Similarly, Heath's testimony with respect to the level of sodium or potassium chloride in the gel does not indicate a contemplated preferred measure. Heath stated that the level of chloride in the gel could affect both the performance of the heart monitor or defibrillator functions and at high enough levels could irritate or injure the skin. But he did not indicate any preferred level or that he ever experimented with those levels.

Because it has not demonstrated that Heath had determined a supplier of a superior performing gel prior to the patent application, Katecho has not established concealment. Each of the patents explains that:

Any suitable type of conductive medium or gel may be utilized that meets the requirements of the various functions to be performed through the electrode elements. Particular attention, however, must be directed to the selection of conductive medium or gel that provides the desired results during application of defibrillation pulses.

R2's expert witness, Webster, attests that one of ordinary skill in the art in 1980 would have known to use highly conductive commercial gel for purposes of defibrillation, and that a standard reference text specifically describes the required characteristics of a conductive medium for defibrillation, including trade names. Webster also attests that one ordinarily skilled in the art would know that high acid levels or chloride content could potentially injure the patient. As explained above, the record does not establish that in August of 1980 Heath was aware of either the significance of the viscosity of the gel or the relative viscosity of the gel from each supplier. Therefore, there is at least a genuine issue whether the relevance of these factors to performance was adequately disclosed to one skilled in the art in 1980. The fact that R2 could not

successfully replicate its preferred gel two years later does not establish inadequate disclosure, but only that one skilled in the art of electrode manufacturer may have to resort to commercial gel suppliers. Where a patent's generic description sufficiently apprises a skilled artisan of what is needed to practice the best mode of the invention, and where there are a limited number of sources of the industrial products of the type required, "then it is an entirely defensible position, if not an ultimately convincing one, that a skilled artisan could easily have procured the necessary material to practice the invention." Transco, 38 F.3d at 562. Consequently, Katecho has failed to demonstrate as a matter of law, by clear and convincing evidence, that Heath concealed a preferred saline gel for use in the '998, '585 or '169 patents.

IV. *The Electrode Patents*

A. *Asserted Claims*

The '585 and '169 patents each describe disposable multifunctional physiological electrodes for cardiac care. These electrodes utilize an electrically conductive plate, preferably constructed of tin. In addition, the electrodes use an electrically conductive medium, such as a saline gel, located between the plate and the patient's skin in order to improve the transfer of electrical energy between the plate and the patient. At issue in this motion is the limitation in each of the asserted claims that a portion of stannous (tin) chloride be "affixed" to the conductive plate. According to the patents and R2's expert, the use of a tin plate and stannous chloride are important to the electrode's multifunctional capabilities, particularly by allowing its "quick recovery" from the electrical bursts of defibrillation to resume accurate monitoring of the patient. In addition, the specifications explain that tin and stannous chloride are able to conduct high energy currents produced by defibrillation without deterioration.

The specifications of each patent provide two alternative locations for the stannous chloride between the tin plate of the electrode and the patient: (1) in the saline gel, or (2) by "forming a layer of chloride directly on the metal." R2 alleges that the accused electrodes infringe claims 1, 2 and 4 of the '585 patent. These claims each describe a "disposable physiological electrode element for use in monitoring or stimulating the heart." The critical limitation of all three claims requires:

a quantity of stannous chloride affixed to at least a portion of said tin between said tin and the skin of a patient.

R2 also alleges that the accused electrodes infringe claims 1 and 2 of patent '169. The critical limitation for each of these claims similarly requires:

a chloride of said electrically conductive metal being affixed to said outer surface of said metal to provide enhanced monitoring capability through the same electrode used for stimulation.

In sum, R2 asserts that the defendants' electrodes infringe the '585 and '169 patents because (1) the electrodes use stannous chloride, and that (2) this stannous chloride is "affixed" to the surface of the tin conductive plate of the electrodes.

R2 does not argue that stannous chloride is sprayed onto the surface of the accused electrodes. Like R2's electrodes, the accused electrodes use a conductive tin surface. During the manufacturing process, Katecho places the tin in contact with either a conductive adhesive or a wet gel, both of which contain potassium chloride and/or sodium chloride. Relying on the deductions of their expert witness, R2 argues that these chloride compounds then react with the tin from the surface, breaking apart to form stannous chloride

directly "affixed" to the electrode's tin surface.

Defendants move for summary judgment, arguing that, (1) there is no genuine issue showing that stannous chloride is present on the Katecho electrodes, and (2) even if there were an issue, any stannous chloride could not be "affixed" to the electrodes' conductive plate as required by the patents' claims. Defendants contend that R2 provides no evidence directly revealing the presence of stannous chloride on the tin plate of their electrodes, but only present a speculative theory that it may form from the combination of sodium chloride and tin. Assuming *arguendo* that stannous chloride is present, defendants argue that it could not have been "affixed" as required by the asserted claims. Defendants propose that the specifications, prosecution history and prior art of the electrode patents all indicate that to have stannous chloride "affixed" to the conductive plate can only mean that it is separately applied and not formed by chemical reaction.

B. ***Analysis***

[51] [52] [53] There are two steps to infringement analysis. First, the court must determine the meaning and scope of the patent claims asserted. Second, the court must compare the construed claims to the accused device. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The first step, claim construction, is a question of law. Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The second step, determining whether the accused device infringes, is a question of fact. Texas Instruments Inc. v. U.S. Int'l Trade Comm'n, 988 F.2d 1165, 1172 (Fed.Cir.1993).

1. ***Claim Construction***

[54] [55] [56] [57] In the recent *Markman* decision, the Federal Circuit clarified the proper methodology for construing a patent claim. To interpret a claim, a court must consider the terms of the claims themselves, the specifications, and the prosecution history. Markman, 52 F.3d at 979. Claim construction begins with the language of the claim itself. North American Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1575 (Fed.Cir.1993). These terms are read in light of the specification, which may act as a sort of dictionary providing clues to how specific terms are used. Markman, 52 F.3d at 979-80; *see* Autogiro Co. of Am. v. U.S., 384 F.2d 391, 397 (Ct.Cl.1967) ("words must be used in the same way in both the claims and the specification"). The prosecution history similarly may present the patentee's understanding of specific claims as well as limit the meaning of the claims' terms to exclude any interpretation that was disavowed by the inventor in his or her effort to obtain the patent. Markman, 52 F.3d at 980. In addition, the court may consider extrinsic evidence to better understand the patent and the embodied art, but not for the purpose of varying or contradicting the terms of the claims. Id. at 980-81.

Defendants' first argument in their motion turns on the legal construction of the claim language requiring "a quantity of stannous chloride affixed to at least a portion of said tin." Defendants propose that the term "affixed" excludes stannous chloride that forms as a result of a chemical reaction between the electrode's surface and an applied substance. Specifically, defendants define "affixed" as requiring that the stannous chloride be directly deposited or sprayed onto the surface of the conductive plate. In support, they point to the distinction in each patent's specificationbetween locating the stannous chloride in the gel and locating it directly on the electrode's conductive plate.FN4 Defendants contend that this distinction indicates that the second alternative is limited to the separately placing stannous chloride onto the surface.

FN4. Although distinct in some aspects, the specifications of the '585 and '169 present essentially identical descriptions of the electrodes with respect to the stannous chloride.

Defendants also argue that the prosecution history requires that "affixed" exclude stannous chloride that is somehow derived from the gel. In response to the patent examiner's ("Examiner") rejection of his application, Heath amended the asserted claims to replace the original limitation, that the stannous chloride be "coated on" the conductive surface, with the limitation that it be "affixed to" that surface. The Examiner had rejected the application in light of the prior art reference of a physiological electrode patented by Kado, et al ("Kado patent"). The Kado patent disclosed an electrode using a tin wire submerged in a solution of stannous chloride contained in a ceramic container. In his remarks to his amendment, Heath distinguished the Kado electrode by noting that its stannous chloride merely "contacted" the tin surface of the electrode, but was not "affixed" to it. The remarks further explained that:

the affixation of the stannous chloride to the tin, as described and shown in this application, is of more significance than originally anticipated. It was thought that the stannous chloride could be located in the saline gel, but subsequent work has shown that the stannous chloride rapidly migrates to the skin of the patient, where it causes skin irritation.

Defendants contend that Heath's efforts to distinguish his electrodes by emphasizing that the stannous chloride is not located in the gel indicate that "affixed" cannot refer to stannous chloride that is derived from the gel through a chemical reaction.

[58] [59] [60] Words in patent claims are given their ordinary and accustomed meanings unless the specifications or prosecution history indicate otherwise. In re Paulsen, 30 F.3d 1475, 1480 (Fed.Cir.1994). In general usage, "affixed" means "to be attached physically." *See* Webster's New Third International Dictionary (1963). As used in the limitation, "affixed" describes the location and state of the stannous chloride in relation to the remainder of the electrode. The terms of the claims do not indicate that "affixed" refers to a process by which the stannous chloride is bound to the conductive plate, but only that it refers to the result of that process. *See* CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc., 893 F.Supp. 508, 519 (D.Md.1995) (limitation that element be in "work-hardened pseudoelastic metallurgic state" speaks to the structure, not the process, of manufacture). The asserted claims are all product claims, specifically apparatus claims, and not method or process claims.FN5 None of the other limitations in any of these claims appear to refer to a process of manufacture. The parties present no evidence revealing a contrary technical definition of "affixed." Therefore, the claims' use of the term "affixed" indicates a structural relationship between the stannous chloride and the electrode's tin plate.

FN5. Even where terms are amenable to interpretation as a procedure of manufacture, apparent "process" terms should be interpreted as structural limitations when used in an adjective non-process sense and define a physical characteristic of the apparatus. *See* 2 Donald S. Chisum, *Patents* s. 8.05[5], at 8-96 (1994); *see also* Application of Garnero, 412 F.2d 276, 279 (C.C.P.A.1969) (reading "interbonded one to another by interfusion" as a structural limitation).

[61] [62] The specifications further confirm that "affixed" is not limited to stannous chloride separately applied to the conductive plate. As defendants argue, the specifications distinguish between two possible locations for the stannous chloride: on the surface of the conductive plate or in the saline gel. However, this distinction does not refer to the manner in which the stannous chloride is located. Neither specification states that the only alternative to locating the stannous chloride in the gel is to spray it onto the surface.

Instead, they repeatedly describe the alternative location of the stannous chloridein broad terms such as "forming a layer of the chloride directly on the metal" or refer to stannous chloride as "associated" with the conductive plate. Although they both disclose that the stannous chloride may be "sprayed" onto the surface, this method is clearly suggested as an example:

The stannous chloride may be directly applied to the tin surface, *such as* by spraying a thin layer thereon. (emphasis added).

A chloride of the conductive metal is located between the conductive metal and the skin of the patient, *such as* by spraying a layer [ ] thereof on the metal conductive plate. (emphasis added).

It has been noted that the stannous chloride may be associated with the tin plate 71 by spraying a layer 72 of the stannous chloride on the plate.

Of these three references, two are located in the section revealing the preferred embodiment and the third is contained in an earlier paragraph referring to this preferred embodiment. An applicant is not required to describe every conceivable embodiment of his or her invention, but only the best contemplated mode. *See* SRI Int'l v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1121 (Fed.Cir.1985). Describing this best mode will often require the applicant to include a description of a preferred process for manufacturing the claimed apparatus. But this does not transform a structural limitation into a process limitation. *See* Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed.Cir.1988) ("examples in the specifications will not generally be read into the claims").

The specifications of each patent describe apparatuses-multifunctional electrodes. Outside of their description of the preferred embodiment, there is no reference to the method of manufacture. The patents allude only to the structure of the electrodes as important to their utility: the use of stannous chloride in conjunction with tin within electrodes designed for both monitoring and defibrillation. They do not imply that the method of production or applying the stannous chloride will have any important impact on the electrode's utility.

The prosecution history is no more helpful to the defendants' proposed construction. In his remarks, Heath explained that the "affixation" of the stannous chloride distinguished the Kado reference because the Kado electrode's tin surface was merely "in contact" with the stannous chloride. These remarks argued that the significance of the bonded state of the stannous chloride, in contrast to placing in the conductive medium between the electrode and the patient, is that unbonded stannous chloride may reach and irritate the patient's skin. This argument does not look to the manner of applying the stannous chloride, but only to its structural relationship with the conductive plate and the importance of that relationship to protecting the patient from injury.

Defendants contend that an electrode produced according to the limitations of the Kado patent must also have stannous chloride attached to the tin surface of the wire. In particular, defendants propose that if the wire in the Kado patent were removed from the solution and dried, some stannous chloride would remain "affixed" to the tin. Therefore, to distinguish the claims from Kado, defendants argue that Heath must have added "affixed" as a process limitation describing stannous chloride that was not derived from the gel. But the Kado patent does not contemplate an electrode where stannous chloride has been dried onto the tin wire. Instead, the Kado patent describes an electrode using a wire immersed in a stannous chloride solution.

In fact, the Examiner raised a similar objection in response to the inventor's use of the term "affixed." He stated that while Kado's stannous chloride may be located in the conductive medium, some stannous chloride was also "affixed by the chamber to at least a portion of the tin surface": The container held some stannous chloride in the solution against the tin. This objection indicates that the Examiner similarly interpreted "affixed" to refer to the structural relationship between the tin and stannous chloride, not to the source of the stannous chloride. The record does not reveal that Heath ever narrowed his interpretation of "affixed" to refer to a method of applying the stannous chloride. Neither does it indicate that the Examiner imposed or argued for a narrower interpretation of "affixed." FN6 Consequently, the prosecution history does not indicate that "affixed" is limited to a process by which the stannous chloride becomes attached to the conductive surface.

FN6. Heath submitted several subsequent amendments to the claims before the electrode patents were granted. Defendants have not identified any subsequent changes to the use of the term "affixed." But Heath subsequently added a limitation that the electrodes must be constructed for monitoring or defibrillation. The record reveals that the Examiner agreed that the prior art did not teach the use of tin and tin chloride for use with defibrillation, and that a publication in fact indicated that tin was not a favored material for that purpose.

Defendants confuse R2's allegation that a chemical reaction derives an element from the gel to form stannous chloride with their own position that the stannous chloride may not be located within the gel. In their briefs, defendants repeatedly refer to deposition testimony and documents distinguishing stannous chloride that is "affixed" to the electrode versus that which is placed in a solution or gel in contact with the electrode. R2 does not contend that the stannous chloride allegedly "affixed" to the accused electrodes is applied from stannous chloride in the gel. Rather, it asserts that the gel reacts with the tin surface to create stannous chloride attached to the electrode's tin surface. R2 never asserts that stannous chloride is located within the gel.

In a final argument, defendants contend that "affixed" must be construed to exclude stannous chloride that is formed by an electrochemical reaction in order to avoid rendering the asserted claims invalid in light of the prior art. Assuming *arguendo* the presence of stannous chloride on their accused electrodes, defendants argue that their electrodes are obvious in light of five presented prior art references. In particular, defendants assert that the Muir patent, Ruben patent, Allison patent and Frances patent each reveal physiological electrodes using a tin surface in contact with a sodium chloride solution.FN7 If R2's alleged chemical reaction occurs on the accused electrodes, defendants argue that it would also have occurred on electrodes constructed according to these prior references. Thus, these prior references unwittingly taught the use of stannous chloride "affixed" to the conductive tin surface of a physiological electrode. If the asserted claims are read to include stannous chloride formed by this reaction, then defendants conclude that these claims would be obvious in light of the prior art and, consequently, invalid.

FN7. Defendants also point to the '345 patent as a prior reference that renders the electrode patents obvious. Although it does not disclose the use of either tin or stannous chloride, the '345 patent discloses a defibrillation system using physiological electrodes.

R2 responds that the defendants' analysis is inappropriate, and that neither the electrode patents nor the accused electrodes are obvious in light of the cited prior art. First, R2 argues that infringement is not

determined by whether the accused device adopts the combined teaching of the prior art. *See* Baxter Healthcare Corp. v. Spectramed, Inc., 49 F.3d 1575, 1583 (Fed.Cir.1995) (finding no requirement that an accused be obvious in light of the prior art). Rather, such claims go to an affirmative defense of validity that defendants must prove by clear and convincing evidence. Second, R2 argues that the accused electrodes are not obvious in light of the prior art. In particular, R2 notes that none of the cited references describe electrodes used or constructed for defibrillation, let alone multifunctional use of either monitoring or defibrillation. Because the prior art allegedly taught away from using tin for defibrillation, R2 contends that using tin and stannous chloride within an electrode constructed for this purpose was nonobvious.

[63] [64] The Supreme Court has mandated that claim construction is a question of law to be resolved by the court. Markman, 517 U.S. 370, 116 S.Ct. 1384. As explained above, claim construction is determined by the terms of the claim, the specifications, the prosecution history and, when appropriate, extrinsic evidence. Markman, 52 F.3d at 979. Arising either in the prosecution history or separately submitted as extrinsic evidence, the prior art may be relevant to interpretingthe scope of an asserted claim. As part of the file wrapper, prior art presents a legislative history to help determine the proper scope of a claim. *See* Autogiro, 384 F.2d 391, 399. As extrinsic evidence, it may provide important clues to understanding the definition of technical terms of art. Markman, 52 F.3d at 980.

[65] [66] [67] Where the terms of a claim are susceptible to two reasonable interpretations, a court may look to the prior art in order to adopt the interpretation that preserves the validity of the claim. Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 871 F.2d 1054, 1065 (Fed.Cir.1989); *see* Whittaker Corp. v. UNR Industries, Inc., 911 F.2d 709, 712 (Fed.Cir.1990). However, a court may not use evidence extrinsic to the patent and prosecution history in order to change the meaning of a claim when that interpretation is made clear by these documents. Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed.Cir.1995); *see also* Texas Instruments, 871 F.2d at 1065 (court may not read a limitation disavowed during prosecution history back into claim in order to sustain its validity). Although a court may refer to the prosecution history and prior art in interpreting key terms of a claim, it may not use them to impose a limitation from the specifications or any other source. Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1566 (Fed.Cir.1992). Extrinsic evidence should be used only to assist "the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." Markman, 52 F.3d at 981.

As explained above, the patent and prosecution history demonstrate that "affixed" does not exclude electrodes that have stannous chloride formed on their tin surface through a chemical reaction rather than separately applied to the surface. The '585 and '169 patents each present apparatus claims describing multifunctional physiological electrodes. Accordingly, the adjective "affixed" describes the structural relationship of the stannous chloride to the tin plate, and not the method by which the manufacturer places the compound there. Nothing in the patent or file history indicates that "affixed" was limited to stannous chloride that had been sprayed or separably applied onto the surface. Defendants ask this court to interpret "affixed" as an adjective describing a process of manufacture of the apparatus: bonded onto the surface by any manner other than created by a chemical reaction with the conductive plate. But such an interpretation would vary the meaning of "affixed" by reading in a limitation from the prior art or the specification's preferred embodiment. *See* Minnesota Mining, 976 F.2d at 1566.

Because the meaning of "affixed" is clear from the patent and prosecution history, neither defendants nor the plaintiffs may use the prior art in order to circumscribe its meaning. *See* Kearns v. Chrysler Corp., 32 F.3d 1541, 1547 (Fed.Cir.1994) (no error in refusing to consider prior art evidence where plain meaning of

terms resolved proper interpretation of patent claim). The court does not doubt that patentees will assert patent claims defined by limitations that the patent and prosecution history leave ambiguous. In such circumstances, it may be appropriate to interpret a critical term in a manner that would sustain the validity of the patent. But where the alleged infringer raises an alternative interpretation belied by the document and file history, it cannot avoid the required factual analysis of obviousness by presenting its challenge as one of claim construction. If defendants wish to challenge the validity of the asserted patents, they may do so directly. The court concludes, however, that "affixed" as used in the asserted claims describes stannous chloride that attached or bonded with the tin plate, and does not describe only stannous chloride separably applied onto the tin surface.

2. *Infringement*

[68] [69] In the alternative, defendants argue that R2 has failed to present a genuine issue of fact whether stannous chloride in fact forms on the surface of the accused electrodes. To show literal infringement, R2 must demonstrate by a preponderance of the evidence that the accused device embodies each of the properly construed limitations of the asserted claim. Carroll Touch, Inc. v. Electro Mechanical Systems, Inc., 15 F.3d 1573, 1576 (Fed.Cir.1993). Whether the accused device embodies the limitations is a question of fact. Texas Instruments, 988 F.2d 1165, 1172. Therefore, the court asks whether R2 has set forth evidence creating a genuine issue of fact that stannous chloride is "affixed" to the surface of the accused electrodes.

[70] R2 does not present evidence that directly reveals stannous chloride on the surface of the accused electrodes. Instead, it relies upon the conclusions of its expert witness, Dr. Stephen H. Carr.FN8 Dr. Carr applied a technique called Auger Electro Spectroscopy ("AES") to analyze the top atomic layers of the tin surface of Katecho's electrodes. AES provides an analysis of an extremely thin sample layer, only two to three atoms thick. This makes AES an important tool for identifying the composition of the surface of a test sample. To remove the saline gel from the surface of the accused electrodes prior to testing, Dr. Carr first used a steel spatula. After applying the spatula, Dr. Carr used a technique called "sputtering," in which Argon ions are exposed to the test surface and cause the loss of an atomic layer about every minute. AES does not directly reveal the compounds that compose the tested surface. Instead, AES provides a non-quantitative analysis of the atomic elements from which the researcher must deduce the compounds present.FN9

FN8. Dr. Stephen H. Carr has received a B.S. degree in Chemical Engineering, a M.S. degree in Polymer Science and a Ph.D. degree in Polymer Science. Dr. Carr has worked as an assistant professor, associate professor and professor in the Departments of Material Science and Engineering, Chemical Engineering and Biomedical Engineering at Northwestern University. He has also served as a consultant to the polymer industry.

FN9. Although AES does not provide a precise quantitative analysis of the composition of the test surface, it may reveal an approximation of the relative abundance of the atoms present. For instance, it may show that oxygen, carbon and nitrogen exist on the test sample in a ratio of roughly 3:2:1.

Dr. Carr's AES analysis revealed the presence of the elements of tin, chlorine, and sodium,FN10 as well as oxygen and carbon. From these results, Dr. Carr concluded that stannous chloride is affixed to the tested surfaces from these electrodes. Dr. Carr postulates that sodium chloride dissolved in the applied gel reacts

with ionized tin from the surface of the electrode to form stannous chloride within the outer metal oxide layer of the conductive plate. Although his report is silent on the matter, Dr. Carr apparently bases his deductions upon the behavior of tin and chlorine in light of their ionic charges. For further support, R2 also point to tests conducted by another expert witness, Dr. John Webster, revealing that at least two of the six groups of accused models of electrodes have "quick recovery" capability from defibrillation to monitoring functions.FN11 In light of Dr. Carr's analysis, Dr. Webster concludes that the chlorine from the gel and the tin surface form stannous chloride "affixed" to the electrode's plate that provides the accused electrodes with this alleged capability.

FN10. Although his report does not state that sodium is present, Dr. Carr conceded at deposition that at least some of his test results indicate sodium on the accused electrodes.

FN11. Dr. Webster believed that the poor recovery evidenced by two of the models reflected poor construction of the particular samples. Dr. Webster did not perform tests on the two remaining models. Dr. Webster concludes that each of these models also embody the asserted patent claims based upon defendants' representations in their advertising and labeling.

Defendants argue that Dr. Carr's deductions from the AES results are mere speculation with no foundation in science, and consequently fail to create a genuine issue of fact. As a general matter, defendants assert that neither R2 nor Dr. Carr present any direct evidence that the alleged electrochemical reaction occurs. More specifically, defendants argue that there is no evidence that the tin from the conductive plate ever entered into an ionic state, presumably necessary to permit the tin to react with the chloride to form stannous chloride. Rather, defendants contend that the sodium and chloride revealed by the AES merely reflect sodium chloride left over in residue from the removed gel. Because Dr. Carr provides no "objective" evidence of the presence of stannouschloride, but only his speculative theory, defendants propose that he has not created a genuine issue of fact that stannous chloride exists on the surface of the accused electrodes. *See* Morton Int'l, Inc. v. Cardinal Chemical Co., 959 F.2d 948, 951 (Fed.Cir.1992) (affirming holding that expert's speculation that critical compound existed in accused device was insufficient to prove infringement), *vacated on other grounds,* Cardinal Chemical Co. v. Morton Int'l, Inc., 508 U.S. 83, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993).

Although somewhat vague, Dr. Carr's affidavits and deposition testimony concerning his conclusions provide a genuine issue of material fact at this stage in the proceedings. The parties do not dispute that AES is a recognized method of analysis that reveals elements that constitute a surface. Rather, defendants contest Dr. Carr's deductions from the results of his AES analysis. But defendants' contention that these results merely reflect tin from the electrode's plate and chloride in remnant sodium chloride from the gel does not necessarily defeat Dr. Carr's theory. In their brief, defendants repeat their assertion that Dr. Carr's removal of the gel with the spatula and "sputtering" must have left some residue of the gel on the conductive plate. But they point to no evidence in support of this critique. While they may prove correct, there is nothing so obvious about their position as to eliminate any genuine issue whether Dr. Carr's analysis reflects remnants of sodium chloride rather than stannous chloride.

Further, Dr. Carr attests that stannous chloride would form despite the presence of sodium, including sodium in an ionic state. When the chloride originally comes into contact with the tin surface, it is ionically bound with sodium as sodium chloride (salt). In his rebuttal report, however, Dr. Carr explains that when dissolved

in the gel, the sodium and chloride ions that compose the sodium chloride separate and become available to react with other elements. At his deposition, Dr. Carr admitted that if none of the tin were in an ionic state, and the sodium and chloride each had an ionic charge, then the tin would not react with the chloride. But defendants point to no evidence of either the existence or probability of this hypothetical circumstance. Dr. Carr, on the other hand, testified that tin virtually always forms an adjoining layer such as tin oxide. His declarations further attest that the AES results of oxygen on the surface verify this presumption. Finally Dr. Carr stated that tin oxide requires the constituent tin to enter into an ionic state, rendering them available to react with the chloride ions to form stannous chloride.

Defendants rely only upon *Morton International,* in which the Federal Circuit held that a district court's factual finding rejecting the patentee's expert witness' testimony to the existence of critical compound was not clearly erroneous. Morton, 959 F.2d at 951. Examining the post-trial evidence, the *Morton* court concluded that the defendant's expert provided more credible testimony than the speculative theory of the patentee's expert. *Id*. Thus, the adequacy of the expert's theory was an issue of fact determined after trial, not on summary judgment. At his deposition, Dr. Carr explained that the tin would form a tin oxide layer, and that this requires some tin to enter an ionic state. In his rebuttal report, Dr. Carr explained that, in solution, the chloride and sodium ions separate and become available to react with other elements. At this point in the proceedings, the court presumes that Dr. Carr may develop his testimony to reveal the reasons that the availability of tin and chloride ions demonstrate the subsequent formation of stannous chloride. Although Dr. Carr's AES does not directly reveal stannous chloride, his hypothesis that the AES results demonstrate that stannous chloride exists on the accused electrodes presents a genuine issue of fact. Therefore, Dr. Carr's report and testimony raise a genuine issue of fact as to the presence of stannous chloride on the defendants' electrodes.

In the alternative, defendants also argue that there is no evidence that any such stannous chloride would be "affixed" to the conductive plate rather than located in the gel. Dr. Carr's theory requires that the chloride ions dissolved in the saline gel combine chemically with tin ions from the electrode's tin oxide layer to form stannous chloride. Defendants respond that his theory does not demonstrate that the subsequent stannous chloride would not also be dissolved. By entering this chemical state, defendants reason that the stannous chloride could not be "affixed" or attached with the electrode's surface but must remain disassociated in the gel. Defendants propose that any stannous chloride became "affixed" to the surface only after Dr. Carr removed the gel and dried the electrode's surface in preparation for his AES analysis.

However, defendants present no evidence to support their position. No evidence before the court indicates that stannous chloride exists in the removed gel. Dr. Carr attests that the alleged chemical reaction creating the stannous chloride occurs in a tin oxide layer on the conductive plate, and so forms "affixed" to that layer when the gel is still present. In fact, his AES test results indicate that chloride exists several atomic layers into the surface of the conductive plate. Therefore, Dr. Carr's report and testimony create a genuine issue of fact whether the alleged stannous chloride is "affixed" with the surface.

V. *The* '998 Patent

R2 also accuses Katecho, Cardiovascular and Padeco of inducement of infringement and contributory infringement of claims 34, 35, 36 and 37 of the '998 patent. The '998 patent discloses a physiological electrode and cable system to permit a pair of multifunctional electrodes to be connected to any of three cardiac care devices: a monitoring device, a therapeutic device, or a stimulating device. The system includes a connecting means and plug to join the electrodes with three types of cables that each, in turn, connect to

the three types of devices. Each of the asserted patent claims are dependant upon the limitations set forth in claim 34, the independent claim that is the focus of defendants' motion.

R2 alleges that all defendants induce and contribute to their end customers' direct infringement of the asserted claims through their products and labeling on their products. R2 argues that defendants' electrodes are designed for use with multifunctional cable systems protected under the '998 patent, and that past labeling on these electrodes advertises that the electrodes are intended for all three uses of monitoring, stimulating or ablation (therapeutic) as referred to in the asserted patent claims. R2 also argues that Padeco has sold its customers an 1150 switch box, which it alleges is advertised to connect defendants' electrodes to cables for either a monitoring device, stimulating device or a therapeutic device. In addition, R2 submits declarations by witnesses attesting to have seen two of defendants' customers select an appropriate cable and use the switch box to connect defendants' electrodes to a therapeutic device and to a combination monitoring and stimulating device. R2 contends that the use of these electrodes, switch box and cables directly infringe the asserted claims under the '998 patent.

Defendants FN12 move for summary judgment, asserting that there is no genuine issue of material fact that their customers use their electrodes in a manner that directly infringes the '998 patent. Defendants' motion focuses on their interpretation of claim 34 to protect only cable systems simultaneously connected to all three devices, or at least require a cable system embodying the cables and circuits necessary for such simultaneous connection. Assuming that this is the case, defendants argue that R2's evidence indicates only that defendants' customers have used their electrodes in conjunction with cable systems incapable of simultaneously connecting to all three devices. In the alternative, Katecho moves for partial summary judgment of R2's claims for any violations occurring prior to October 4, 1993, when it claims that it first learned of the asserted patent.

FN12. Cardiovascular and Padeco have moved for leave to join in Katecho's motion for summary judgment of noninfringement of the '998 patent.

A. *Claim Construction*

[71] To dispose of R2's claims under the '998 patent, defendants rely upon an interpretation limiting claim 34 to a system capable of simultaneous connection to all three cardiac care devices. Direct infringement is an essential element of both inducement of infringement and contributory infringement. *See* Aro I, 365 U.S. 336, 341, 81 S.Ct. 599, 602. If there is no evidence that defendants' customers directly infringe the '998 patent through their use of defendants' products, then R2 has failed to raise a genuine issue as to an essential element of defendants' liability. Id.

[72] [73] [74] As noted above, claim construction is a question of law. Markman, 52 F.3d 967, 979. First, a court must look to the terms of the claim itself, including the surrounding claims contained in the patent. North American Vaccine, 7 F.3d 1571, 1575. In addition, the court should look to the descriptions and illustrations contained in the specification to interpret the terms of the claims. Markman, 52 F.3d at 979-80. Finally, the prosecution history is relevant where the inventor asserted, or disavowed, an interpretation of the claim in order to obtain allowance of the patent claim. Zenith Lab., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1421 (Fed.Cir.1994).

1. *Claim 34*

[75] The critical claim in the '998 patent to defendants' motion is claim 34,FN13 set forth below:

FN13. Claims 35, 36 and 37 each depend on the limitations set forth in claim 34. Therefore, if there is no infringement of these limitations, either literally or under the doctrine of equivalents, then the dependant claims also are not infringed. Teledyne McCormick Selph v. U.S., 558 F.2d 1000, 1004 (Ct.Cl.1977).

A physiological electrode system providing for the connection of a monitoring device, a therapeutic device or a stimulating device to a patient through a single common instrument-to-body interface and comprising:

first and second electrode elements to be attached to the patients body, said electrode elements constructed to have the characteristic required for monitoring, stimulating and therapeutic applications, including the capability of handling relatively large energy requirements for stimulating and therapeutic applications and the sensitivity to low level signals required for monitoring applications;

standardized connecting plug means;

first and second electrically conducting lines connected from said electrode elements to said connecting plug means, said electrode elements, said connecting plug means and said conducting lines constituting a disposable electrode set;

connector means to engage said connecting plug means; and

cable means electrically joined to said connector means for selectively connecting the monitoring device, the therapeutic device or the stimulating device to said electrode elements by engagement of said connector means and said connecting plug means.

Figures 1 and 28 of the '998 patent illustrate a system simultaneously connecting the electrode set through three types of cables to all three devices. Figure 28 reveals the system in its entirety, with the connectors and protective circuitry to permit all three of the cables to connect the electrodes simultaneously to the three devices.FN14

FN14. In particular, the specification describes a "low pass filter network" and "high voltage protection circuit" to protect the ECG monitor from damage and undue interference from the employment of simultaneously attached defibrillation and therapeutic devices.

The parties' dispute focuses on the meanings of a "single common instrument-to-body interface" and "cable means." Defendants contend that "single common interface" must refer to a system capable of simultaneous connection to all three devices in light of the plain language, the specification, and the file history. First, because the claim requires the devices attach to a "single common instruments-to-body interface," defendants argue that claim 34 must refer to one apparatus actually hooked to all three devices. Otherwise, defendants question what meaning the adjectives, "single common," add to the description. Consequently, defendants contend that the claim must refer to a cable system constructed with all components necessary, such as the connecting cables and protective circuitry, to permit the simultaneous connection to all three devices.

Defendants also point to the specification and its drawings as limiting claim 34 to a system simultaneously attached to all three devices. Without dispute from R2, defendants argue that the cable component of the invention, the "cable means," is presented as a "means-plus-function" limitation. 35 U.S.C. section 112, paragraph 6 restricts a "means-plus-function" limitation to equivalents of the structures provided in the specification to carry out the function. *See* Valmont Industries, Inc. v. Reinke Mfg. Co., Inc., 983 F.2d 1039, 1043 (Fed.Cir.1993). Defendants contend that these specifications only set forth a structure capable of simultaneous connection to all three devices.

Third, defendants argue that the prosecution history reveals that the inventor disavowed a system incapable of simultaneous connection in order to obtain the patent grant from the Patent Examiner. The inventor, Heath, originally submitted 117 claims and 28 figures in relation to the '998 patent. In response, the Examiner issued a requirement for restriction asserting that these claims were "specific to more than one species of the generic invention," and identified the species by reference to the drawings. Pursuant to 35 U.S.C. section 121, the Examiner directed Heath to elect a single species. Heath elected the species disclosed by figures 1 and 28, depicting the system simultaneously connected to all three devices, and 45 of the 117 claims that Heath asserted read on the species. Defendants argue that, through this election, Heath abandoned any claims covering systems incapable of connection to all three devices as depicted in figures 1 and 28.

R2 responds that the "single common interface" refers to the multifunctional electrodes, connector plugs and sets of cables that may be combined in various permutations to permit attachment to any of the three devices, but not necessarily to two or three devices at once. In support, R2 argues that defendants' interpretation would render claim 34 redundant of the '998 patent's other independent claim that expressly provides for the "simultaneous" connection to two or more devices. With respect to "cable means," R2 argues that the specification discloses an embodiment that includes a system that only selectively attaches to any of three devices. Finally, R2 contends that Heath abandoned only claims related to the electrodes alone, the cables alone, or to systems using only the electrodes and one or two types of devices irrespective or their ability to selectively connect to the other devices. Accordingly, R2 interprets the inventor's remarks to elect claims related to a species that contemplates both the selective connection of the multifunctional electrodes with the three devices as well as one including the connectors and circuitry necessary for simultaneous connection.

2. ***Interpretation of Claim 34***

a. ***The Claims Themselves***

In contrast to defendants' reading, the plain language of claim 34 does not indicate a cardiac system including cables and protective circuitry permitting simultaneous connection to all three cardiac care devices. Claim 34 describes an "interface" capable of connecting "a monitoring device, therapeutic device *or* a stimulating device" to the patient. This interface is comprised of a disposable electrode set, a connector plug, connector means and cables. Neither the monitoring device, therapeutic device nor stimulating device, themselves, are presented as elements of the invention. Rather, electrodes, connectors and cables constructed for connection to these devices comprise the invention. The "cable means" is defined as intended for "selectively connecting the monitoring device, therapeutic device or stimulating device" to the electrode sets. None of the limitations refer to simultaneous connection or use. Thus, the "selective" character indicates that the "cable means" refers to any of three cables that may be attached at any one time to employ the desired device.

In contrast, another independent claim of the '998 patent, claim 1, specifically describes a system using connectors and protective circuitry for "simultaneous" connection. Claim 1 and claim 34 read substantially similar in providing the fundamental limitations on invention. Instead of calling for a "cable means," however, claim 1 requires the use of an "interrelating means" that provides for "the simultaneous connection of said electrode elements to at least two said devices." Claim 1 also requires the additional element of a "protective means associated with said interrelating means for selectively permitting desired combinations of ... [the three devices] ... to be simultaneously connected to the patient solely through first and second said electrode elements." Thus, in contrast to claim 34, claim 1 explicitly refers to a system using cables and circuitry that permit the simultaneous connection of two or more devices.FN15

FN15. In fact, there are a total of seven independent claims in the '998 patent; claims 1, 20, 25, 27, 31, 32 and 34. Claims 20, 25, 27 and 31 all require an "interrelating means" as well as the attachment of a "protective means" for "permitting the desired combination" of devices to be "simultaneously connected to the patient." Claim 32 appears to require the actual connection of all three types of devices to the system.

[76] [77] Under the interpretive doctrine of "claim differentiation," an interpretation of a claim should be avoided if it would make that claim read identically to another claim in the same patent. Autogiro, 384 F.2d 391, 404; *see* Tandon Corp. v. U.S. Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed.Cir.1987); DMI, Inc. v. Deere & Co., 755 F.2d 1570, 1574 (Fed.Cir.1985). Defendants respond that "claim differentiation" only restricts the reading of express limitations from a dependant claim into an independent claim, and is not applicable to the comparison of two independent claims in the same patent. As defendants note, the doctrine has greater argumentative force when an interpretation would render an independent claim identical to its own dependant claim. *See* Hormone Research Foundation, Inc. v. Genentech, Inc., 904 F.2d 1558, 1567 n. 15 (Fed.Cir.1990) ("It is not unusual that separate claims may define the invention using different terminology, especially where ... independent claims are involved"). Dependant claims are generally used to narrow an independent claim by describing the disclosed invention with greater detail, and so, stricter scope.

However, defendants cite no precedent limiting "claim differentiation" to this context. *Cf. id.* (interpreting independent claims as identical where specification and file history require that interpretation). More importantly, the Federal Circuit has applied the doctrine to interpret one independent claim in light of another independent claim. *See* Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1055 (Fed.Cir.1988); Caterpillar Tractor Co. v. Berco, SPA, 714 F.2d 1110, 1116 (Fed.Cir.1983). Defendants have not pointed to any distinction between claim 1 and claim 34 other than claim 1's limitations describing an "interrelating means" and "protective means" and claim 34's "cable means." Therefore, the redundant character of defendants' interpretation of "cable means" further supports R2's more natural interpretation of "cable means."

This interpretation of claim 34 does not render the terms "single common," modifying the "instrument-to-body interface," superfluous. As a general matter, the fact that "single common instrument-to-body interface" appears in the preamble of claim 34 does not necessarily indicate that it imposes a structural limitation on the claim. *See* Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 688 (Fed.Cir.1990) (description in preamble constitutes limitation only if necessary to precisely define and give meaning to the invention set forth in the formal limitations). Regardless, the "single common interface" refers to the fact that the same disposable electrode set, connector plug and set of cables are used regardless of the device selected. The fact that the specific cable connected at any one time is different does not contradict the description of a "single common" interface between the patient and the device chosen. The

other elements of the actual entity used, the disposable electrode set, remain the same. Only the final element of the cable used at any one time is altered.

b. ***Mean-Plus-Function Analysis***

[78] Defendants argue that 35 U.S.C. section 112, paragraph 6, restricts claim 34 to devices capable of simultaneous connection. Instead of reciting a particular structure, a "means-plus-function" limitation describes an element of a product claim as "a means or step for performing a specified function." 35 U.S.C. s. 112 para. 6. In contrast to the usual interpretive rule against reading limitations from the specification into the patent claims, *see* Constant, 848 F.2d 1560, 1571, a "means-plus-function" limitation is restricted to the description, and equivalents thereof, of structures set forth in the specification intended to carry out the function described in the limitation. Valmont, 983 F.2d 1039, 1043-44. The parties do not dispute that the "cable means" constitutes a "means-plus-function" limitation. Claim 34 never describes the structure of its "cable means" other than to note its connection to the connector means and the cardiac care devices. If the specification only presents the structure of a "cable means" that is capable of simultaneous connection, then this limitation must be read into claim 34 regardless of the tenant of the "claim differentiation." Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538 (Fed.Cir.1991).

Defendants point to the specification's description of "the preferred approach disclosed" with the utilizing of a cable "electrically joined to the desired instrument or instruments," where "[t]hese cables may then be relatively permanent, with only the electrode sets being replaced for each usage." In the subsequent more detailed section on the preferred embodiment, the specification describes cable structures for each of the three devices, as well as connectors and circuits to be attached with each cable that protect the devices from damage when employing another simultaneously connected device. In addition, the drawings in figures 1 and 28 depict a system using a "cable means" with protective circuitry that simultaneously hooks the electrodes to a monitor, a defibrillator and an electrosurgical device. As these drawings in the specification illustrate a configuration of the cables and connectors permitting simultaneous connection, defendants argue that the "cable means" must be limited to equivalents of such a configuration.

[79] As defendants argue, the specification presents a preferred embodiment where all three devices are simultaneously attached to the electrode set. In setting forth the system in structural detail, the specification further describes connectors and circuitry attached to each of the cables for various permutations of simultaneous connection to the devices. But a "means-plus-function" limitation is not limited to the equivalents of a single preferred structure. Rather, it is limited to the equivalents of any structures described therein necessary for carrying out the function. *See* United States v. Telectronics, Inc., 857 F.2d 778, 782 (Fed.Cir.1988) (defining means-plus-function limitation as including structural alternative presented in specification).

[80] [81] In addition, a "means-plus-function" limitation incorporates only the disclosed structure necessary to perform the specified function. *See* General Elec. Co. v. U.S., 572 F.2d 745, 776 (Ct.Cl.1978) (refusing to incorporate elements into limitation from the specification not necessary for performing function); *see also* Lockheed Aircraft Corp. v. U.S., 553 F.2d 69, 81 (Ct.Cl.1977) ("a 'means-plus-function' claim covers the structure necessary to perform the specified function"). The function which defines the limitation is determined by the terms of the claim, not the specification. *See* DMI, 755 F.2d 1570, 1573. As explained above, claim 34 does not indicate that the "cable means" is for the function of simultaneous connection of the devices, but rather that it is for the function of "selectively connecting the monitoring device, the therapeutic device or the stimulating device" to the connector means and electrode sets.

In the preferred embodiment, the specification details the structure of a cable for each device, and the necessary connector means so that the cable may attach to a standardized connector plug. Although the specification further describes connectors and protective circuitry to connect the devices together and the disposable electrode set, these additional structures are only required for the preferred embodiment. Accordingly, the preferred embodiment presents an "interrelating arrangement" depicted in figures 1 and 28 that includes the attachment of the protective circuitry and connectormeans for the simultaneous connection of all of three cables and devices.

But the specification never limits the "cables means" to either figure 1 or 28. *Cf.* Hormone Research Foundation, 904 F.2d at 1563 (specification and prosecution history explicitly limited claimed invention to single accompanying figure). Instead, the specification provides that in addition to the preferred embodiment the invention includes sub-systems using many of the same elements:

Each of these instruments be connected to the patient's body through the electrode elements by itself or in combination with one or more of the other instruments by means of an appropriate interrelating arrangement.

After presenting the preferred embodiment, the specification explains that the invention includes the separate connection of each of the devices to the electrode elements:

In addition to the provision of a multiplicity of functions through a single pair of electrode elements, this invention also provides for the separate connection of each of the instruments to that pair of electrode elements ... Therefore this invention not only relates to the unique system, but it also relates to a number of novel and unobvious sub-systems and components of that physiological electrode system.

The specification details the structures of all the elements necessary for a system capable of only selective connection to the cardiac care devices. Therefore, the specification presents an embodiment of the "cable means" where only one device is connected at a time as well as one in which a number of devices are connected.

c. *Prosecution History*

Under 35 U.S.C. section 121, and regulations promulgated thereunder, the patent examiner has the discretion to restrict a patent application to one invention if "two or more independent and distinct inventions are claimed in one application." A species of an invention is a particular embodiment of the invention disclosed in a patent application. Manual of Patent Examining Procedure (MPEP) s. 806.04(e) (6th ed. 1995). A species claim, in turn, reads on that embodiment. *Id.* If there is no disclosed relationship between different species, the patent examiner generally will consider them "independent" inventions. MPEP s. 808.01(a); *see* s. 806.04(b). A generic claim, in contrast, is defined as a claim with limitations that both include the primary organizational structure of more than one disclosed species and whose limitations read on each of the pertinent species. MPEP s. 806.04(d).

Where an application contains a generic claim for all of the disclosed species, a restriction usually is not proper.FN16 *See* MPEP s. 809.02(d). But if an application contains no generic claim that covers separate species disclosed in that application, then the patent examiner may issue a restriction requiring the applicant to elect a single disclosed species and those claims that read upon that species. 37 C.F.R. s. 1.141. Although

the applicant may contest ("traverse") the restriction and try to convince the patent examiner that the identified separate species does not reflect independent and distinct inventions, the applicant must provisionally elect one of the species. If the patent examiner concludes that the species are independent and distinct, he or she may make the requirement final. Subsequently, the patent examiner has the authority to restrict, and so refuse to consider, any submitted claims that are not directed to the elected species. FN17 At the time of the final action on the application, the patent examiner may compel the applicant to either cancel the unelected, and unreviewed, claims or petition the restriction to the Commissioner of Patents. *See* MPEP s. 821.01. If not appealed through the petition process, the applicant may either pursue the unelected claims in a divisional application for a separate patent or abandon them. Studiengesellschaft Kohle mbH v. N. Petrochemical Co., 784 F.2d 351, 360 (Fed.Cir.1986) (Newman, J., concurring).

FN16. It also is improper to issue a restriction if the separate species are not "mutually distinctive"-if either species would be clearly obvious in light of the other species. MPEP s. 806.04(h). Because contesting a restriction on this basis involves arguing for the obviousness of the invention, it is unlikely that applicants would contest a restriction on this basis.

FN17. To restrict a claim from a species thereafter, it must contain "mutually exclusive" limitations with those claims considered to read upon the species-each claim must contain an element that is not contained in the other claim. MPEP s. 806.04(f).

Heath originally submitted 117 claims in relation to the '998 patent, along with the 28 figures currently set forth in the specification. Considering these claims to disclose several distinct inventions, the Examiner issued a requirement for a restriction in his first office action:

This application contains claims specific to more than one species of the generic invention, as for example, the species of Figs. 1-4 and 28; Figs. 5-7; Figs 8-9; Figs. 10-13; Figs. 14-17; Figs. 18-20; Figs. 21-25 and Figs. 26-27, respectively. Applicant is required under 35 USC 121(1) to elect a single disclosed species of and the preferred embodiment to which the examiner's action will be limited until a generic claim is finally held allowable, and (2) to *list* all claims readable on such elected species includes any claims subsequently added.

In his response, Heath attempted to traverse the restriction requirement, arguing that the figures and claims disclosed the related embodiments of a single invention of a system combination, sub-systems, sub-combinations and related components and functions. In explaining the claims, Heath stated in the response:

Turning now to the claims, it should be understood that the relating of the claims to particular portions of the drawing is for purposes of identification and it is not for intended to limit the scope of the claims to which the applicant is entitled in any way. Thus, [the ultimately elected claims] are directed to a system able to selectively obtain a multiplicity of functions through a single pair of electrodes. These claims relate to the overall system, and its equivalents, depicted Figures 1-4 and 28, but many of the features of the system, as claimed in these claims are included in the various portions of the system illustrated more fully in other figures of the drawing.

After reviewing all of the claims and arguing that they presented a single invention, Heath provisionally elected to prosecute 45 claims that he described were "basically directed to the subject matter, and its

equivalents, illustrated in figures 1-4 and 28, with other features of the dependent claims shown in various other figures of the drawing." FN18 This list included the claim currently designated as claim 34. Ultimately, the Examiner made his restriction final:

FN18. Apparently, Heath did not abandon all of the remaining 72 claims, but pursued and obtained a number of them, in altered or identical form, in the related electrode patents, the '356 patent or the '552 patent. These include claims covering the electrode elements, a monitoring system, a defibrillation system, and various cable constructions for use with ECG and defibrillation devices.

The requirement for restriction is repeated and made final. Applicant argues that only one invention is disclosed. It would appear that the combined units is only one way the individual units can be used separately or in various combinations. Therefore, the alleged system combination represents one species.

Defendants contend that this prosecution history demonstrates that Heath limited his invention under the '998 patent to the system capable of simultaneous connection to all three devices ("simultaneous system"). Regardless of Heath's intent, defendants interpret the Examiner's restriction to require Heath to exclude any claims that did not disclose a simultaneous system. When the Examiner made his restriction final, defendants argue that his action acted as collateral estoppel to prohibit Heath thereafter from asserting that any of the claims under the '998 patent that do not disclose a simultaneous system.

[82] The prosecution history informs the interpretation of a patent claim "by excluding any interpretation of the claim language that would permit the patentee to assert a meaning for the claim that was disclaimed or disavowed during prosecution in order to obtain claim allowance." Zenith, 19 F.3d 1418, 1421. As a general matter, the claim is construed in light of the applicant's arguments and remarks seeking to establish the patentability of the invention by distinguishing references to the prior art. *See, e.g.,* Carroll Touch, 15 F.3d 1573, 1577. Narrowed language or discarded broader claims may indicate surrendered subject matter. Similarly, applicant's explanations of why the new or previous language is nonobvious often assert specific interpretations of the limitations and thereby disavows subject matter.

[83] In contrast to this standard usage of prosecution history, defendants interpret claim 34 in light of the administrative matter of a requirement for a restriction. In a restriction, an applicant and patent examiner do not dispute what subject matter is included in the invention versus the public domain, or even if the application employs adequately descriptive language to satisfy the requirements of 35 U.S.C. section 112. Rather, for the purposes of case management and control of filing and search fees, the patent examiner requires the applicant to divide his or her claims among distinct, though related, patent applications. *See* Application of Weber, 580 F.2d 455, 458 (C.C.P.A.1978) (purpose of restriction power is to permit Patent and Trademark Office control over research filing fees and caseload management). Neither an applicant's traverse nor his election of species attempts to induce the grant of patent protection. A restriction is not a rejection. *See id.* The applicant is free to pursue withdrawn claims in divisional applications, usually enjoying the same priority date and scope of prior art as the original patent. 35 U.S.C. s. 121; *see* 37 C.F.R. s. 1.147. Consequently, there is some question whether an applicant's response to a restriction has the same preclusive effect as a response to a rejection. In fact, the court has not identified any precedent using prosecution history of the election of a species in order to restrict or otherwise interpret the scope of a patent claim.

[84] However, "[t]he court has broad power to look as a matter of law to the prosecution history of the

patent in order to ascertain the true meaning of the language used in the patent claims." Markman, 52 F.3d 967, 980. The "avowed understanding of the patentee, expressed by him, or on his half," may confirm the construction of the patent. *See id*. (quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L.Ed. 149 (1880)). Although this record may aid in understanding the terms of the claim, "it too cannot 'enlarge, diminish, or vary' the limitations in the claims." *Id*. (citations omitted). Accordingly, the court will review the prosecution history in order to discern if it reveals an "avowed understanding" that claim 34 discloses a system capable of simultaneous connection.

As an initial matter, the prosecution history does not reveal that Heath expressly abandoned from the '998 application subject matter relating to a system capable of selective but not simultaneous connection to the three devices from his patent application ("selective system"). None of the unelected claims require an electrode system capable of connecting any of the three devices. Some of these unelected claims disclose specific components, such as cables or electrodes. Others disclose an electrode system for attachment to only one or two of the devices. But even these do not require the cables or connectors necessary for selective connection to all of the three devices. Similarly, none of the figures depicting the ultimately unelected species, as identified by the Examiner, illustrated a selective system. Rather, some figures illustrate a system connected to a single specific device while others illustrate a system connected to two devices. As no single unelected group of figures depicts all three types of cables, it is questionable whether claim 34, as interpreted to disclose a selective system, would read upon any one group of these unelected figures. Therefore, none of the explicitly unelected species or claims embody a selective system.

Neither does the record reveal that Heath clearly expressed an understanding of his elected claims as limited to a system capable of simultaneous connection. Although he stated in his response that the elected claims, including claim 34, "relate to the overall system" depicted in figures 1 and 28, it is not clear that this "overall system" does not embody a system capable only of selective connection as well as one capable of simultaneous connection. *See* Lemelson v. TRW, Inc., 760 F.2d 1254, 1263 (Fed.Cir.1985) (noting that "the enumeration of figures in which an elected species is illustrated cannot always be interpreted as meaning that everything in those figures is part of the elected species"). The preferred embodiment of the invention illustrated in figures 1 and 28 contain all of the essential elements in the selective system that R2 proposes is disclosed by claim 34. As noted, none of the figures in the unelected groups depicted all of the elements necessary for such a selective system. Thus, of the figures in the drawings, only figures 1 and 28 illustrated all three cables and connectors as required for each device under either a selective system or a simultaneous system. Further, interpreting Heath's reference to figures 1 and 28 as limiting the scope of the claims to a simultaneous system would ignore his immediately preceding caution that the use of figures was for identification only and "not intended to limit the scope of the claims." In sum, Heath's response does not indicate that he interpreted the elected species or claims to disclose only a simultaneous system.

[85] Defendants argue that Heath's statements and intent are irrelevant to determining what subject matter he abandoned. Defendants contend that it only matters what subject matter the Examiner required Heath to surrender. Arguing that the Examiner required the '998 patent to be restricted to an invention capable of simultaneous connection to three devices, defendants propose that Heath may not assert subsequently granted claims beyond the scope of that subject matter. In construing the meaning of the claim, neither the applicant's nor the patent examiner's subjective intentions is determinative. *See* Markman, 52 F.3d at 985-87. Rather, the meaning of the claim is affected by what the written record of the file wrapper confirms. Id. at 980. If the record demonstrates that the Examiner restricted the species elected by Heath to a simultaneous system, then Heath's subsequent election of claims may constitute an avowed understanding that those claims were directed to that subject matter. Therefore, if the Examiner identified the elected species as

directed to a simultaneous system, then Heath's response that the elected claims, including claim 34, were directed to that species may constitute an avowal that claim 34 is directed only to a simultaneous system.

The problem with defendants' position is that the prosecution history does not reveal that the Examiner ever clearly identified the elected species as restricted to a simultaneous system. Because the restriction occurred in the first office action before any review of the merits of the claims, it is not entirely surprising that the exact boundaries of these species were vague. In issuing the restriction, the Examiner only identified the alternative species through reference to groups of figures. As noted, none of the unelected groups of figures illustrate a selective system. Figures 1 and 28, in contrast, illustrate an embodiment that contains all of the principle components of a selective system. Therefore, these references do not reveal whether the Examiner perceived the elected species as requiring simultaneous connection.

The Examiner's only other characterization of the elected species occurred after Heath had provisionally elected his claims and the restriction was made final. The Examiner concluded that "the alleged system combination represents one species." However, the language of the claims and specification indicate that Heath's "alleged system combination" involves both the combination system for simultaneous connection and the combination system for only selective connection. Further, both a simultaneous system and selective system involve all of the cables and the selective use among any of the three cardiac care devices. This scant prosecution history on the scope of the elected species does not demonstrate that it excluded systems capable of only selective connection to all three devices. In light of the plain language of claim 34 and the specification, the court finds that the Examiner's restriction requirement did not circumscribe the identified elected species to only simultaneous systems. *See* Intervet Am. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1054 (Fed.Cir.1989) (ambiguous prosecution history may not vary unambiguous claim language).

For the reasons set forth above, claim 34 discloses a cable system capable of selective connection to either a monitoring device, a stimulating device, or a therapeutic device. It does not require that the system protected is capable of simultaneous connection to all three devices.

B. ***Infringement***

[86] Whether an accused apparatus infringes an asserted claim is a question of fact. Texas Instruments, 988 F.2d 1165, 1172. According to R2's allegations, defendants have sold electrodes with labeling representing that they are suitable for all three cardiac care functions. R2 also alleges that defendants have sold these electrodes to hospitals that own all three types of devices and the appropriate cables. In addition, R2 alleges that defendant Padeco sells the 1150 switch box that advertises the ability to selectively connect to all three devices. R2 has submitted a declaration attesting that these hospitals have used defendants' electrodes with cable systems capable of selective connection to any of the three devices.

Because defendants have not specifically contested in their motion that Padeco's switch box satisfies the "standardized connector plug" and "connector means" limitations of claim 34, the court assumes, for purposes of this motion, that these limitations are met. Therefore, R2 has created a genuine issue of fact that defendants' customers directly infringe the asserted claims of the '998 patent.

C. ***Katecho's Intent and Knowledge of the Alleged Direct Infringement***

[87] [88] In the alternative, Katecho moves for partial summary judgment on the issue of inducement of infringement, as well as its liability under either inducement of infringement or contributory infringement for any acts prior to October 4, 1993. *See* 35 U.S.C. s. 271(b) & (c).FN19 To show either inducement of

infringement or contributory infringement, R2 must demonstrate that Katecho sold its components "knowing the same to be especially made or especially adapted for use in an infringement of such [combination] patent." Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 488, 84 S.Ct. 1526, 1533, 12 L.Ed.2d 457 (1964) (contributory infringement) (" *Aro II* "); *see* Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed.Cir.1990) (inducement). Contributory infringement requires that the defendant know that the "combination for which his component was especially designed was both patented and infringed." Aro II, 377 U.S. at 488, 84 S.Ct. at 1533. In addition to this knowledge requirement, inducement of infringement requires that the defendant specifically intended that its sale or other challenged acts induce its customers to engage in the conduct that allegedly directly infringes. Hewlett-Packard Co., 909 F.2d at 1469.

FN19. Section 271(b) provides:

"Whoever actively induces infringement of a patent shall be liable as an infringer."Section 271(c) provides:

"Whoever sells a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer."

[89] First, Katecho argues that R2 has failed to raise a genuine issue of fact that Katecho ever intended its ultimate customers to infringe the asserted claims under the '998 patent. *See* H.B. Fuller Co. v. Nat'l Starch & Chemical Corp., 689 F.Supp. 923, 945 (D.Minn.1988). There indubitably is sufficient evidence for a fact finder to rationally infer that Katecho was aware of its customers' allegedly infringing activity.

Katecho designs multifunctional physiological electrodes. Its principle retailer of its electrodes to its end customer hospitals, Padeco, manufactures and distributes a switch box for use with Katecho's electrodes to use in the allegedly infringing manner. Of course, mere knowledge that its customers use its products in the infringing manner does not demonstrate the requisite intent. *See* Oak Industries Inc. v. Zenith Electronics Corp., 697 F.Supp. 988, 992-94 (N.D.Ill.1988). However, R2 argues that inducement occurs in light of Katecho's labeling on the electrodes indicating their use with either monitoring, defibrillation or therapeutic devices. *See* Rexnord Inc. v. Laitram Corp., 6 U.S.P.Q.2d 1817, 1842, 1988 WL 141526 (E.D.Wis.1988) (inducement of infringement can be established through the defendant's advertising or provision of instructions). Although these allegations may not necessarily demonstrate Katecho's intent that its customers use its electrodes in a selective system, they raise a triable issue of fact. *See* Allen Organ Co. v. Kimball Int'l, Inc., 839 F.2d 1556, 1567 (Fed.Cir.1988) (intent is factual determination particularly within the province of the trier of fact).

Katecho also contends that R2 has failed to raise a genuine issue of fact that Katecho satisfied the knowledge requirement of both inducement of infringement and contributory infringement, which requires that it had actual knowledge that the allegedly infringed systems were protected by patent prior to R2's letter in October, 1993. In response, R2 asserts that it has marked its electrodes and cable systems since the mid 1980s. In light of this fact, R2 argues that Katecho knew or should have known of a patent protecting a selective system. *See* Manville Sales Corp. v. Paramount Systems, Inc., 917 F.2d 544, 553 (Fed.Cir.1990) (inducement of infringement requires that the defendant "knew or should have known" that his activities

would induce actual infringement); Drexelbrook Controls, Inc. v. Magnetrol Int'l, Inc., 720 F.Supp. 397, 407 (D.Del.1989) (finding sufficient evidence of culpability under sections 271(b) and 271(c) where the plaintiff marked products), *aff'd,* 904 F.2d 45 (Fed.Cir.1990).

Assuming that R2 has marked its products since the mid 1980s, this fact still would not provide sufficient evidence, in itself, that Katecho was aware of a patent protecting a selective cable system. In support of this position, R2 only cites *Drexelbrook,* where a Delaware district court found that the plaintiff who had marked its products had presented sufficient evidence of culpability to support liability for either inducement of infringement or contributory infringement. 720 F.Supp. at 407. In *Drexelbrook,* however, the court also noted that the defendant designed its accused product from the plaintiff's specifications, indicating actual contact between the defendant and the product or official design. *Id*. R2 points to no similar evidence indicating that Katecho actually had obtained components or specifications indicating a patent protecting a cable system.FN20

FN20. There is evidence in the record indicating that Padeco may have obtained R2 components, and particularly R2 cables that it converted. However, R2 has not pointed to any similar evidence in the record implicating Katecho's contact with R2 products.

[90] Further, R2 fails to cite any precedent stating that constructive knowledge of the patent is sufficient to impose liability under either theory. Both the Federal Circuit and the Supreme Court have indicated that actual knowledge of patent protection is required to impose liability under contributory infringement. Dynamis, Inc. v. Leepoxy Plastics, Inc., 831 F.Supp. 651, 655 (N.D.Ind.1993); *see* Hewlett-Packard, 909 F.2d at 1469 n. 4; *see also* Aro II, 377 U.S. at 514, 84 S.Ct. at 1546-47 (White, J., concurring) (knowledge requirement generally construed as knowledge of an infringement controversy over the combination). Reaching an even broader range of conduct than contributory infringement, inducement requires a showing of culpability similar, if not greater, than section 271(c). For instance, in addition to the knowledge of infringement required for contributory infringement, inducement also requires specific intent to cause the actual challenged conduct. Hewlett-Packard, 909 F.2d at 1469. Every court that has addressed the issue has required the plaintiff to prove actual knowledge in order to impose liability for inducement of infringement. L.A. Gear, Inc. v. E.S. Originals, Inc., 859 F.Supp. 1294, 1300 (C.D.Cal.1994); *see* Young Dental Mfg. Co. v. Q3 Special Prod., Inc., 891 F.Supp. 1345, 1348 (E.D.Mo.1995); Dynamics, 831 F.Supp. at 657. Accordingly, to impose liability under either sections 271(b) or 271(c), a patentee must demonstrate that the defendant had actual knowledge of the asserted patent.

Because R2 has failed to point to any evidence in the record raising a genuine issue of fact that Katecho had actual knowledge of the '998 patent prior to October 4, 1993, Katecho's motion for summary judgment on the issue of liability for infringement of the '998 patent for its conduct prior to that date is granted. The remainder of defendants' motion for summary judgment on the '998 patent is denied.

VI. ***System Patents***

R2 accuses defendants Cardiovascular and Padeco of inducement of infringement and contributory infringement of the '552, '356, and '345 patents ("system patents") under 35 U.S.C. sections 271(b) and 271(c). These patents each cover a combination of multifunctional electrodes, connectors and cables for use with cardiac care devices. The '356 patent discloses an adapter and cable system that permits the use of electrodes with a defibrillation device constructed with the traditional paddles. The '552 patent discloses a

physiological monitoring electrode system that permits the use of two electrodes with an ECG monitor (ECG monitoring units usually require the use of three electrodes). The '345 patent discloses a circuit for connecting a monitoring device and defibrillator device to a single pair of flexible, self-adhesive disposable electrodes that carry out both functions. The '552 and '356 patents, as well as R2's electrode patents, all originated from the same application for the '998 patent.FN21 R2 sells cables and connectors ("R2 cable systems") as well as disposable multifunctional electrodes that, when combined, embody the claims of the system patents.

FN21. A separate inventor, Ilias R. Zenkich, previously applied for the '345 patent on January 30, 1978. R2 subsequently obtained ownership of this patent.

R2 does not accuse Cardiovascular and Padeco of direct infringement of the system patents. Rather, R2 alleges that defendants' infringement arises from their supplying multifunctional electrodes to purchasers of R2 cable systems and adapters to use those electrodes with the cable systems.FN22 When these customers place defendants' multifunctional electrodes into R2 cable systems, R2 contends that the resulting combination directly infringes the asserted system patent claims. By supplying these components for use with R2 systems, R2 alleges that defendants' sales, in turn, induce and contribute to the customers' alleged direct infringement.

FN22. R2 also alleges that defendants have converted R2 cables to mate with defendants' electrodes.

Cardiovascular and Padeco's instant motion relates solely to R2's claims under these three patents.FN23 Because the electrodes used with R2 cable systems are disposable and expected to be regularly replaced, defendants argue that their customers' placement of the accused electrodes and adapters into R2 cable systems does not directly infringe the system patents, but is protected under the doctrine of permissible repair.

FN23. In this motion, defendants do not argue for summary judgment of the '998 patent.

Direct infringement is an essential element of both contributory infringement and inducement of infringement. Aro I, 365 U.S. 336, 341, 81 S.Ct. 599, 602 (contributory infringement). Therefore, if the parties' mutual customers do not directly infringe the system patents through their use of the defendants' electrodes with R2 cable systems, then R2's system claims must fail. *Id.*

[91] [92] [93] In its briefs, R2 does not contest that its customers' use of a non-infringing electrode as a replacement in an R2 cable system would not violate the system patents. Once a patent owner sells a patented article, the purchaser also acquires an implied right to use and maintain that article continually. While there is no right to "rebuild" the article, the right of continued use implies an attendant right to make repairs or replace worn-out, unpatented parts as necessary to restore the article for its original use. Aro I, 365 U.S. at 346, 81 S.Ct. at 605; *see* Aro II, 377 U.S. 476, 497, 84 S.Ct. 1526, 1538. The right to repair extends to the replacement of perishable components whose useful life is regularly exhausted by the proper use of the article. *See, e.g.,* Heyer v. Duplicator Mfg. Co., 263 U.S. 100, 101-02, 44 S.Ct. 31, 32, 68 L.Ed. 189 (1923); Everpure, Inc. v. Cuno Inc., 875 F.2d 300, 303 (Fed.Cir.1989). The purchaser does exactly what the patent owner intended he should do-replace a necessary but periodically perishable component "without

the replacement of which the remainder of the device is of no value." Morgan Envelope Co. v. Albany Perforated Wrapping Paper Co., 152 U.S. 425, 434, 14 S.Ct. 627, 631, 38 L.Ed. 500 (1894). However, the right of repair does not extend to replacement or reconditioning of the article that is tantamount to "reconstruction" of the patented article. *See* Aro I, 365 U.S. at 342 & 346, 81 S.Ct. at 602-03 & 605. Such a reconditioning is analogous to a second construction of the article that infringes the right to exclude its manufacture. Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 709 (Fed.Cir.1992).

The R2 cable systems at issue employ disposable electrodes that are discarded after each use. Because these cable systems are intended to endure beyond a single use of the electrode, the structure of the electrodes and cable systems imply R2's intent that its customers will regularly replace these electrodes in normal use of the machine. Assuming that the new electrodes, themselves, do not infringe any of R2's patents, R2's customers are implicitly authorized to replace spent electrodes with the accused electrodes in R2 cable systems under the doctrine of permissible repair.FN24 *See* Kendall Co. v. Progressive Medical Technology, Inc., 85 F.3d 1570 (Fed.Cir.1996).

FN24. The fact that defendants' customers must purchase and use adapters to mate the accused electrodes with R2's cable systems does not render the replacement a reconstruction or otherwise impermissible. *See* Everpure, 875 F.2d at 303; Surgical Laser Technologies Inc. v. Surgical Laser Products Inc., 25 U.S.P.Q.2d 1806, 1807-09, 1992 WL 245892 (E.D.Pa.1992).

Rather, R2's claim depends upon its allegation that defendants' electrodes used as replacements in R2 cable systems infringe R2's separate electrode patents. R2 argues that the doctrine of permissible repair is limited to permitting "one lawfully using a patented combination to preserve and maintain the combination by making repairs or replacing *unpatented* component parts necessary for continued use." *E.g.,* Everpure, 875 F.2d at 302-03 (emphasis added); *see,* Aro I, 365 U.S. at 346, 81 S.Ct. at 605 (the "maintenance of the 'use of the whole' of the patented combination through replacement of a spent, *unpatented* element does not constitute reconstruction") (emphasis added). Conversely, R2 infers that the right of repair excludes the replacement with components that infringe a commonly owned patent. R2 contends that lawful purchasers of its cable systems do not hold the *authority under the system patents* to use infringing electrodes because R2's ownership of separate patents covering those electrodes partially negates the customers' implied license of repair. *See* Warner and Swasey Co. v. Held, 256 F.Supp. 303, 311 (E.D.Wis.1966); *see also* Hensley Equipment Co. v. Esco Corp., 383 F.2d 252 (5th Cir.1967) (rejecting defendants' position that repair with infringing elements did not also infringe combination patent).

Because "the combination patent covers only the totality of the elements in the claim and [ ] no element, separately viewed, is within the grant," Aro I, 365 U.S. at 344, 81 S.Ct. at 604, defendants respond that their customers' use of electrodes that infringe R2's separate patents would not also infringe the system patents.FN25 Defendants argue that to hold otherwise would extend the monopoly under the system patents beyond the grant over the combination to the use of one of its component parts. *See* id. at 341, 81 S.Ct. at 602. According to defendants' position, the monopoly granted a patentee under its component patent is irrelevant to the patentee's monopoly under the separate combination patent. The only issue under the combination patent is whether the replacement is tantamount to a "reconstruction" of the patented article. *See* id. at 342 & 345-46, 81 S.Ct. at 602 & 604-05. Defendants interpret precedent restricting the right of repair to the replacement of unpatented components to emphasize merely that the purchaser of the patented combination obtains no license against the separate patent protecting the new component.

FN25. For purposes of this motion, defendants assume *arguendo* that their electrodes infringe R2's electrode patents, and that the parties' customers have used defendants' electrodes with defendants' adapters or converted R2 cables and R2 cable systems.

In the alternative, defendants attempt to distinguish the *Hensley* and *Warner* decisions relied upon by R2 by arguing that the patent claims covering the combination patents at issue in those decisions were defined by the critical limitations of the patent claims protecting the individual components. Although each of the asserted claims under the system patents requires the use of a physiological electrode, none of these claims requires the use of an electrode built according to the limitations of either electrode patent. Most notably, the system patents do not require an electrode with stannous chloride "affixed" to a tin conductive surface. Here, defendants argue that the replacement with a separately patented component may infringe a combination patent only if the entire element of the combination patent is protected by the separate patent-if the specific limitations describing the element of the combination patent are essentially identical to the limitations of the separately patented component.

The right of repair arises from the implied license to a lawful purchaser to use a lawfully purchased patented article continually. Standard Havens Products, Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1375-76 (Fed.Cir.1991). The "license to use a patented combination includes the right 'to preserve its fitness for use so far as it may be affected by wear or breakage.' " Aro I, 365 U.S. at 345, 81 S.Ct. at 604 (quoting Leeds & Catlin Co. v. Victor Talking Machine Co., 213 U.S. 325, 336, 29 S.Ct. 503, 507, 53 L.Ed. 816 (1909)). The patent owner so arranged the components "as a part of its combination, that the [article] could not be continued in use without a succession of [the components] at short intervals." Wilson v. Simpson, 50 U.S. 109, 126, 9 How. 109, 13 L.Ed. 66 (1850). In replacing these components as they wear, "the purchaser uses [the combination] in the way the inventor meant it to be used, and in the only way the machine can be used." *Id*. As long as the replacement is not tantamount to a "second creation" of the article, replacing the unpatented component does not infringe the patent owner's right to exclude others from manufacturing its invention. Mallinckrodt, 976 F.2d at 709.

[94] But if the patent owner also acquires a separate patent on an individual component of the combination, it is no longer appropriate to imply a license to replace that component with a part that infringes on the patent owner's separate patent. "[T]he very fact that the patentee of a patented combination bothers to secure a patent upon a component part of that combination negates any inference that in selling the combination he contemplates or intends licensing such purchaser to replace the patented part from any source other than himself." Warner, 256 F.Supp. at 311.

By obtaining a patent over a construction of the disposable electrode component, R2 has indicated that it withholds the authority to replace spent electrodes with electrodes that infringe upon the separate electrode patents. Replacement with such electrodes is not considered merely the preservation of continued use. Instead, R2 expects its customers to obtain like-constructed electrodes from R2, or locate and use non-infringing substitutes. Because the customers are not authorized to connect infringing electrodes to R2 cable systems, such conduct would directly infringe the systems patents.

"Of course, if the [component] itself is the subject of a valid patent, it would be an infringement of that patent to purchase such [component] of another than the patentee." Morgan, 152 U.S. at 433, 14 S.Ct. at 632. FN26 Looking to the Supreme Court's reasoning in the seminal decision on the repair doctrine, *Aro I,* defendants contend that only the component patent may be infringed by its use in the patented combination.

Aro I addressed whether the replacement of a worn unpatented component, a fabric covering, in a patented combination, a convertible folding top for an automobile, infringed the combination patent: was the replacement by the car owner infringing "reconstruction" or permissible "repair." 365 U.S. at 342, 81 S.Ct. at 602. The Court explained that "reconstruction" occurred only upon a "second creation" after "the entity, viewed as a whole, has become spent." Id. at 346, at 605. It did not matter whether the fabric was an "essential" element of the entire invention. Id. at 343-44, at 603-04. Finding "reconstruction" because a component was "essential" would ascribe to it the status of the patented invention:

FN26. Relying upon this dicta, defendants argue that the Supreme Court already has addressed this issue and concluded that the use of an infringing component infringes *only* the component patent. In *Morgan,* however, the Court already had determined that the components sold by the alleged infringer were not protected by a separate patent. *Id*. at 428, at 629. More importantly, in neither the statement above nor the remainder of the decision did the Court address whether the use of an infringing component in the combination also infringed the patent on the combination. Therefore, *Morgan* 's dicta did not resolve this issue.

The fact that an unpatented part of a combination patent may distinguish the invention does not draw to it the privileges of the patent. That may be done only in the manner provided by law. However worthy it may be, however essential to the patent, an unpatented part of a combination patent is no more entitled to monopolistic protection than any other unpatented device.

Id. at 344, at 604 (quoting Mercoid Corp. v. Minneapolis-Honeywell Regulator Co., 320 U.S. 680, 684, 64 S.Ct. 278, 280, 88 L.Ed. 396 (1944)).

But this analysis of infringing reconstruction applied only to the effect of the replacement of an unpatented component in the patented combination: "We hold that maintenance of the 'use of the whole' of the patented combination through replacement of a spent, *unpatented* element does not constitute reconstruction." *Id*. at 346, at 605 (emphasis added). Precedent requires that the "reconstruction of a patented entity, *comprised of unpatented elements,* is limited to such a true reconstruction of the entity as to 'in fact make a new article.' " *Id*. (emphasis added). But replacement with an independently infringing component is not a reconditioning of the combination necessary to preserve the combination's continued use. Therefore, the replacement with patented components may infringe the combination patent regardless of whether the entire combination is considered exhausted. *See id*. at 370, at 616 (Harlan, J., dissenting) ("[T]he Court holds that there can be no direct infringement ... of a combination patent by replacement of any of the components of the patented entity unless (1) such component is itself separately patented or (2) the entire entity is rebuilt at one time").

Contrary to defendants' assertion, this restriction on the repair doctrine does not extend the monopoly under the combination patent beyond its grant. If the purchaser uses an unpatented part as a replacement, its use of the patented combination with that part is authorized unless the entire combination is deemed exhausted. *Id*. In determining whether the replacement constitutes repair or reconstruction, it is inappropriate to ask if the replaced part is the "heart" or "gist" of the invention of the combination. *Id*. at 344, at 604. Such inquiry ascribes to the component the status of the patented combination by looking to the inventive character and contribution of the separate component to discern if it warrants the protection of the combination patent. *See id*. Where the part is unpatented, the Supreme Court has emphasized that the critical question is whether the entire combination is exhausted.

But if the new part is protected under separate patent, the court does not inquire whether the entire combination is exhausted upon the replacement of the worn part. Replacement with the patented part does not infringe the combination patent because that separate patent ascribes the status of the combination to that part. The separate patent does not render the inventiveness of the component an "essential" element of the invention of the combination. *Aro I* clearly rejected this analysis. Rather, replacement infringes the combination patent because the purchaser engages in an unauthorized use of the combination by configuring it with an element that infringes another patent of the patent owner. Whether considered a form of unauthorized use or reconstruction, the purchaser has no license to maintain the "use of the whole" through elements that infringe the combination patent owner's separate patent.FN27 Thus, in contrast to the repair and reconstruction inquiry, R2's legal action under the system patents does not challenge the use of the electrode elements, "separately viewed." It challenges a particular use of the combination with the infringing electrodes.

FN27. Similarly, the Federal Circuit has indicated that the right of repair does not extend to the replacement of unspent parts of a patented combination even though the combination, in its entirety, is not exhausted. Universal Electronics, Inc. v. Zenith Electronics Corp., 846 F.Supp. 641, 650 (N.D.Ill.1994); *see* Everpure, 875 F.2d at 303 (affirming plaintiff's position that only replacement of spent parts constitutes repair and not reconstruction); King Instrument Corp. v. Otari Corp., 814 F.2d 1560, 1564 (Fed.Cir.1987); *see also,* Aro I, 365 U.S. at 342 & 346, 81 S.Ct. at 602 & 605 (holding that "replacement of *unspent,* unpatented element does not constitute reconstruction") (emphasis added).

In an alternative argument, defendants propose that the replacement with a component that infringes a commonly owned patent may infringe the combination patent only if the combination patent requires limitations identical to those defining the separately patented component. According to defendant's position, in order for a component to infringe a combination because it infringes a separate commonly owned patent, the entire element of the combination must be protected under the separate patent and not merely the component used as that element.

In *Hensley,* for instance, the Fifth Circuit addressed a patent related to a tooth used in excavating equipment comprising an adapter and a wear point. 383 F.2d 252, 255. The patent contained claims individually covering the wear point and adapter as well as their combination. The court held that the customers' use of wear points sold by the defendant violated both the patent claims covering that component *and* the patent claims covering the combination. Id. at 260. Although the Fifth Circuit did not allude to this fact, the combination claims were not limited by the use of any wear point, but were limited to the use of a wear point defined by the essential limitations of the claim protecting the individual wear point.FN28 *See* Esco Corp v. Hensley Equipment Co., 251 F.Supp. 631, 632 (N.D.Tex.1966). In contrast, none of the claims that R2 asserts under the system patents defines the electrode element as specifically constructed according to the critical limitations under R2's electrode patents. Based upon this distinction, defendants argue that the patent owner may assert a combination patent over separately patented components only if the combination claim comprises the limitations of the component patent.

FN28. The *Warner* decision does not reveal whether the combination patent at issue was defined by the use of component embodying the limitations of the plaintiff's distinct component patent.

Defendants never explain, however, why the incorporation of the terms of the separate component patent is

critical to infringement. Defendants imply that including the limitations of the component patent would incorporate the inventive essence of the component into the inventive essence of the combination. But as explained above, the replacement with a separately infringing component does not infringe the combination patent because the separate patent somehow renders that component an inventive "heart" or "gist" of the combination. It is because the patent owner's common ownership of the component patent negates the presumption that his sale of the patented combination also includes a license to preserve the entire combination through the use of the infringing device as an element of the patented combination. Consequently, the critical issue is whether the replacement component is used as an element in the combination and whether it infringes a commonly owned patent.

[95] R2 alleges that its customers use defendants' electrodes with cable systems that embody the limitations of the system patents. For the reasons set forth above, if defendants' electrodes infringe the electrode patents, the customers' use of these electrodes in the cable systems would infringe the system patents. Therefore, R2 has presented a genuine issue of fact that its customers directly infringe the system patents and that defendants are liable for contributory infringement and inducement of infringement. Cardiovascular and Padeco's motion for summary judgment of the system patent claims is therefore denied.

CONCLUSION

For the reasons set forth above, defendants' motions for summary judgment based on laches and equitable estoppel are denied, Katecho's motion for summary judgment because of concealment of best mode is denied, defendants' motion for summary judgment on R2's claims under the electrode patents is denied, defendants' motion for summary judgment on R2's claims under the '998 patent is denied, and Cardiovascular and Padeco's motion for summary judgment of R2's claims under the system patents is denied. However, Katecho's motion for partial summary judgment with respect to its liability for inducement of infringement and contributory infringement of the '998 patent prior to October 4, 1993, is granted.