

United States District Court,
S.D. Indiana, Indianapolis Division.

CARDIAC PACEMAKERS, INC, Guidant Sales Corporation, Eli Lilly & Company,
Plaintiffs.

v.

ST JUDE MEDICAL, INC-Counterclaimant 10/2/00, Pacesetter, Inc-Counterclaimant 10/2/00,
Ventritex, Inc-Counterclaimant 10/2/00, John Does 1-10,
Defendants.

No. IP96-1718-C-H/G

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ENTRY ON CLAIM CONSTRUCTION ISSUES

HAMILTON.

Introduction

Plaintiffs Cardiac Pacemakers, Inc. ("CPI"), Guidant Sales Corporation, and Eli Lilly and Company allege that defendants St. Jude Medical, Inc., Pacesetter, Inc., and Ventritex, Inc. have infringed three patents for medical devices and methods used to evaluate and treat abnormal conditions in a patient's heart. The three patents in suit are United States Patent No. 4,316,472 (issued Feb. 23, 1982), No. 4,572,191 (issued Feb. 25, 1986), and No. 4,407,288 (issued Oct. 4, 1983). All three patents address an implantable cardiac stimulator

that delivers electrical shocks to return a heart to its normal rhythm if it is beating too quickly, too slowly, or erratically. The implantable cardiac stimulation devices are referred to variously as "pacemakers," "cardioverters," or "defibrillators" depending on the exact functions performed by the particular device.

To prevail in this action, plaintiffs must prove that the defendants have infringed their patents. Patent infringement occurs when a device or method that is literally covered by the claims (or is equivalent to the claimed subject matter) is made, used, or sold without authorization of the patent holder during the term of the patent. See 35 U.S.C. s. 271; *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1476 (Fed.Cir.1998).

The claims in a patent are "concise statements of the subject matter for which the statutory right to exclude is secured by the grant of the patent." 133 F.3d at 1476. Thus, the specific claims that appear in the patent establish the scope of the protection offered by the patent laws. Where the language used in the claims is ambiguous, it may become necessary for a court to interpret the meaning of the claims. It is the court's role, and the purpose of this Entry, to interpret the disputed language used in the claims of the '472, '191, and '288 patents.

Background

Plaintiff CPI owns the three patents in suit and has brought this infringement action against the three defendants. Guidant Sales Corporation and Eli Lilly and Company also claim an interest in the patents. The court refers to the plaintiffs collectively as "CPI" and to the defendants collectively as "St. Jude." FN1

FN1. Plaintiffs have also named "John Does" 1 through 10 as defendants, but that action has no legal significance or effect.

To begin at the beginning with the claimed inventions, the human heart is a muscular pump consisting of four chambers: the left atrium and the right atrium, and the left and right ventricles. The pumping action of the heart results when the heart muscle tissue contracts, which is caused by electrical stimulation. Arrhythmias are heart diseases which result from disturbances in the natural electrical conduction mechanism of the heart. Three broad classes of arrhythmias are relevant here: (1) bradycardia, where the heart tends to beat too slowly all or part of the time; (2) tachycardia, where the heart beats too quickly all or part of the time, and (3) fibrillation, where the heart beats in an erratic, disorganized, or quivering fashion. See generally Kadish Decl. at para. para. 3-11 (defense expert providing background on heart structure and heart disease).

An arrhythmia can affect either the atria or the ventricles. It is important not only to distinguish among the three types of arrhythmia, but also to identify the location of the arrhythmia. Ventricular fibrillation, for example, poses an immediate threat to a patient's life. Atrial fibrillation may need medical attention, but it is not such a great and immediate threat. A therapy intended for treating ventricular fibrillation must account for the fact that a patient experiencing ventricular fibrillation loses consciousness in a matter of seconds. See *id.*

The patents in suit cover various devices and methods for detecting and treating various arrhythmias using an implantable cardiac stimulator. A given device may treat only a single type of arrhythmia, or it may be capable of treating multiple types of arrhythmia. To be effective, the device must be capable of delivering

the proper electrical therapy to the right location in the heart at the right time. Further discussion of both the structures of the devices and the processes for treating cardiac arrhythmias follows in the discussion of the particular claim construction issues.

Patent Claim Construction

I. Claim Construction Standards

The parties have called upon the court to interpret arguable (or at least argued) ambiguities in some of the patent claims at issue. The court must construe the terms in the patent as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). In *Markman* the Supreme Court explained that the "construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis." 517 U.S. at 388. The interpretation process does not involve questions of infringement.

Construing the claims of a patent is closely akin to construing other written documents like contracts or statutes. Some special considerations apply, however, based on the public's interest in the patent system and the need for other inventors to know as precisely as possible the scope of a patentee's claimed invention. Thus, in *Markman* the Federal Circuit emphasized the need to focus on publicly available documents in construing patent claims. 52 F.3d at 978-79, 987. In interpreting an asserted claim, "the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996).

In considering the intrinsic evidence, the court must first look to the words of the claims themselves. These words are "generally given their ordinary and customary meaning." *Id.* The words "in a patent claim are construed as they would be understood by a reader skilled in the relevant art unless it appears that the inventor used the words differently." *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed.Cir.1996). The patentee may use words in any manner he or she wishes in defining the invention as long as any special definitions are clear in the patent specification. *Vitronics*, 90 F.3d at 1582.

In addition to the language of the claims themselves, the Federal Circuit has stressed the importance of using the patent specification in defining the terms in claims: "the specification is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* The court may also consider the prosecution history of the patent, in which the applicant may have made specific statements about the scope of claims in dispute. *Id.* Both the specification and the prosecution history are forms of intrinsic evidence.

"Extrinsic evidence is that evidence which is external to the patent and file history, such as expert testimony, inventor testimony, dictionaries, and technical treatises and articles." *Id.* at 1584. Courts should not rely on extrinsic evidence in claim construction to contradict the meaning of claims discernible from thoughtful examination of the claims. However, courts are not prohibited from examining extrinsic evidence even in cases where the patent is itself clear. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed.Cir.1999). As the Federal Circuit has explained:

[I]t is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field.

Id. at 1309.

The parties here have asked the court to construe twenty-five phrases used in the disputed patent claims. Several of the phrases overlap with one another, so resolving the meaning of the language in one claim will often resolve the same issues as presented in another claim. Having considered the claim language, the specification of each patent, the documents from prosecution histories, other exhibits, and the parties' briefs and oral arguments from the *Markman* hearing, the court provides the following claim construction, which the court intends to provide to the jury in its instructions.FN2

FN2. This entry does not resolve the parties' dispute over the meaning of the "third monitoring means" element of Claim 1 of the '191 patent. By separate order today, the court is setting a hearing for further argument on that element.

II. Claim Construction of the '472 Patent

In general, the '472 patent describes an implantable cardioverting device for the treatment of high rate arrhythmias such as atrial fibrillation, flutter, or tachycardia. During those times when the patient is suffering such an arrhythmia and cardioversion is in order, a command given by the patient or the patient's physician brings the invented device out of its standby condition to administer a pulse of energy directly to the heart. ' 472 Patent, col. 1, *ll.* 46-59.

The patent specification discloses two embodiments of the claimed invention. The first embodiment is designed for operation by a physician. From an external console, the physician programs the desired level of cardioverting energy. Then both the power to charge the device and a set of control signals are transmitted through the skin of the patient and into the implanted unit. The invention contemplates that the timing of the release of the charge can be synchronized with the QRS complex.FN3 The physician-operated embodiment includes a display unit that allows the physician to monitor the patient's electrocardiograph (ECG) signals. ' 472 Patent, col. 1, *l.* 60 to col. 2, *l.* 12; Figs. 1 & 2.

FN3. The QRS complex (also known as the R-Wave) is a particular point in the heart's ventricular cycle that can be observed by tracking the electrocardiograph (ECG) signal. See Pl. Br. at 5. Timing the delivery of a shock to the atrium to occur right after the QRS complex will prevent the shock from inducing (fatal) ventricular fibrillation. See Def. Br. at 38-39.

The second embodiment allows the patient to cardiovert his or her heart without the intervention of a physician. The patient is taught to recognize the symptoms of a cardiovertible arrhythmia and then accomplishes cardioversion when appropriate by placing a magnet over the skin close to the implanted device. The magnet closes a switch that initiates the electrical discharge cycle. By leaving the magnet in place over the skin, the patient can deliver the cardioverting shocks in sequentially increasing energy levels. Thus, if low energy level cardioversion does not correct the arrhythmia, the patient leaves the magnet in place to trigger cardioversion at higher energy levels. In this embodiment, the energy source—a battery—is incorporated directly into the implanted cardioverting device. Because there is an implanted battery, energy need not be transmitted through the skin at the time of cardioversion. Like the physician-operated embodiment, the patient-operated embodiment can be equipped with circuitry for synchronizing the cardioverting shocks with the QRS complex. '472 Patent, col. 2, *ll.* 13-58; Fig. 3.

The parties dispute the meaning of language used in both Claim 1 and Claim 18 of the '472 patent. Claim 1 is an apparatus claim, which states:

1. In a cardioverting device, comprising:

storage means for storing energy to convert an abnormal cardiac rhythm to normal sinus rhythm,

delivery electrode means for discharging the stored energy into the heart of a wearer of the device, and

switch means for controlling the discharge of the stored energy into the heart of the wearer;

said device further comprising:

charging means for delivering to said storage means said energy to convert said abnormal cardiac rhythm,

determining means for determining when the stored energy has reached a predetermined magnitude for converting said abnormal cardiac rhythm, and

initiating means for initiating the discharge of converting energy into the heart of the wearer after the stored energy has reached said predetermined magnitude;

the improvement wherein said device is an implantable externally programmable cardioverting device, and includes receiving means for receiving commands from external to the skin of the wearer of the device, said programming commands designating a predetermined magnitude of stored energy for converting said abnormal cardiac rhythm, said device also including selecting means responsive to said programming commands received by said receiving means for selecting said predetermined magnitude, from among a plurality of selectable magnitudes, of stored energy, for converting said abnormal cardiac rhythm.

'472 Patent, col. 8, l. 64 to col. 9, l. 26.

A. '472 Claim 1: "cardioverting device"

The principal dispute over the term "cardioverting device" in Claim 1 of the '472 patent is whether the term is limited to atrial cardioverting devices, as St. Jude contends, or whether the term includes both ventricular and atrial devices, as CPI argues. The court agrees with CPI that the term "cardioverting device" as used in the claim without limitation includes both atrial and ventricular devices.

The claim construction process begins with the claim language itself. As a starting point, the court gives claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the field of invention. *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 955 (Fed.Cir.2000). Neither Claim 1 of the '472 patent nor any of the other '472 claims uses the word "atrium" or "atrial." Looking exclusively at the claim itself, there is no basis for adding the limiting adjective "atrial" to the construction of the more general term "cardioverting device." FN4

FN4. The parties have submitted extrinsic evidence on this issue, with experts in the field arguing that the term "cardioverting device" in the '472 patent claims either is or is not limited to atrial devices. See Pitney

Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d at 1309 (stating that it is appropriate to consult extrinsic evidence to ensure that the court's construction of technical terms is not inconsistent with the widely held understandings in the pertinent technical field). However, even the defense experts do not claim that one skilled in the art would ordinarily understand the term "cardioverting device," *unless otherwise qualified*, as limited to only atrial devices. The defense experts instead argue from other intrinsic evidence that the term should be given the limited reading when it is read in context in the '472 patent. See Kadish Decl. para. 12 (opining that "in the context of the '472 patent," the term "cardioverting device" describes atrial cardioverters, but not suggesting in any way that the term is generally understood to be so limited); Kroll Rebuttal Decl. para. 6 (opining that the claim should be understood to cover only atrial devices because "the entire specification of the '472 patent is directed solely to atrial devices").

The claim term's ordinary and accustomed meaning in the art, however, serves initially only as a default meaning. The Federal Circuit has explained:

[T]he patentee may act as a lexicographer and ascribe a different, or modified, meaning to the term. *See* Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed.Cir.1998) (observing that an inventor, acting as a lexicographer, may bestow "a special meaning to a term in order to convey a character or property or nuance relevant to the particular invention"); Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388, 21 USPQ2d 1383, 1386 [(Fed.Cir.1992)]. The court, therefore, must examine a patent's specification and prosecution history to determine whether the patentee has given the term an unconventional meaning. *See* Vitronics, 90 F.3d at 1582, 39 USPQ2d at 1577 (holding that "it is *always* necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning [because the specification] acts as a dictionary when it expressly defines terms ... or when it defines terms by implication" (emphasis added)); Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 USPQ2d 1673, 1676 (Fed.Cir.1995) (determining that "[a]rguments and amendments made during the prosecution of a patent application ... as well as the specification and other claims *must* be examined to determine the meaning of terms in a claim" (emphasis added)). If the patentee has not done so, the term's ordinary and accustomed meaning controls. *See* York Prods., Inc. v. Central Tractor Farm Family Ctr., 99 F.3d 1568, 1572, 40 USPQ2d 1619, 1622 (Fed.Cir.1996) ("Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning.").

Id. Under these rules of claim construction, the court must examine the specification and the prosecution history to determine whether the patentee explicitly or implicitly defined "cardioverting device" to refer only to atrial devices.

The specification does not explicitly limit the phrase "cardioverting device" to atrial devices. St. Jude argues that the '472 patent specification nevertheless at least implicitly defines the term "cardioverting device" to include only atrial devices. There are several examples of potentially limiting language in the written description of the '472 patent. For example, the Abstract describes "An externally controlled implantable electronic device for delivering a cardioverting pulse of energy to the atrium of an ailing heart." The specification also states that the invention "relates to an atrial device designed to be implanted under the skin of patients who frequently suffer from bouts of atrial fibrillation, flutter or tachycardia," '472 Patent, col. 1, *ll.* 46-49; that "it is one object of the present invention to provide a device which will enable to [sic] cardioversion of a heart undergoing atrial fibrillation, flutter or tachycardia, without hospitalization," '472 Patent, col. 2, *ll.* 59-62; that "Yet another object of the present invention is to provide a method for

cardioverting a heart suffering from an atrial malfunctioning, wherein cardioversion is initiated by a physician or by the wearer while in a state of consciousness," '472 Patent, col. 3, *ll.* 18-22; and "Now, with reference to FIG. 3, the totally implantable embodiment of the invention elective atrial device will be described." '472 Patent, col. 7, *ll.* 3-5.

Beyond the repeated use of the words "atrial" and "atrium" in the specification, there is no doubt that the two disclosed embodiments (shown in Figures 1 through 3 and discussed in detail in the specification) are designed to treat only atrial arrhythmias. The specification does not describe an embodiment of the invention that is designed to function as a ventricular defibrillator.

There is obviously some tension between the narrower '472 specification language and the broader '472 claim language. The Federal Circuit, however, has repeatedly cautioned against limiting the scope of a claim to a preferred embodiment or to specific examples disclosed in the specification. See, *e.g.*, *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1302-03 (Fed.Cir.1997) (holding that the district court erred in interpreting the phrase "conductive liquid-like medium" as being limited to liquids having a conductivity similar to the examples listed in the specification). The fact that the written description focuses on characteristics and functions of the disclosed embodiments does not prevent the patentee from claiming an invention broader than the disclosed embodiments. See *Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed.Cir.1994) ("claims are not to be interpreted by adding limitations appearing only in the specification"); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed.Cir.1985) (*en banc*) ("If everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims.").

In this case, the difference between the broad term "heart" and more specific references to only the atria or to only the ventricles is clear to anyone skilled in the art. The deliberate use of the broader terms "heart" and "cardioverting device" in the claims, when contrasted with the narrower language in the specification, indicates an intentional choice by the patentee to reach beyond the embodiments discussed in the specification. In this respect, the language of Claim 1 itself is broad, but it is not ambiguous. Cf. *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499 (1985) (rejecting attempt to narrow deliberately broad language in civil RICO statute: "[T]he fact that RICO has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth."), quoting *Haroco, Inc. v. American National Bank & Trust Co.*, 747 F.2d 384, 398 (7th Cir.1984), *aff'd*, 473 U.S. 606 (1985). Construing the term "cardioverting device" to reach both atrial and ventricular devices is consistent with the rest of the language in Claim 1 of the '472 patent. As explained by CPI: "The invention of [Claim 1 of] the '472 patent is the ability to externally program the amount of energy to be delivered by a cardioverting device. Whether the device treats the atrium or the ventricle has no bearing on the external programmability of energy levels that the inventors had invented." Pl. Reply Br. at 29.

The prosecution history of the '472 patent also indicates that both the patentee and the patent examiner were fully aware of the differences between atrial and ventricular devices and that the claim language was intentionally drafted to reach beyond atrial cardioverting devices. First, the claims of the '750 patent, a related "parent" application cited in the '472 patent, distinguished between atrial cardioverters (claims 1-25, 29) and cardioverting devices generally (claim 26). Ex. 110, '750 Patent, col. 8, *l.* 58 to col. 14, *l.* 22. The claims of the '472 patent contain no similar limit. Second, during the prosecution of the claims in the '472 patent application, the examiner applied ventricular prior art. Ex. 14, '472 Pros. Hist., at CPI 005590-92. These examples from the prosecution history show that the drafters were fully aware of the differences

between atrial cardioverters, ventricular cardioverters, and cardioverters generally, and that the examiner did not consider ventricular devices irrelevant to the '472 claims.

CPI contends that the court should also consider as relevant intrinsic evidence (1) an amendment that was made to the '472 patent title during claims prosecution which eliminated the word "atrial," and (2) the granting of a term extension for the '472 patent based on a ventricular device in 1992. During prosecution of the '472 patent, the drafters changed the patent title from "Command Atrial Cardioverter" to "Cardioverting Device with Stored Energy Selecting Means and Discharge Initiating Means, and Related Method." Pl. Br. at 31-32. This change was made after the patent examiner raised an objection that the original title and statements of invention were "not commensurate with the claimed subject matter." Ex. 14, '472 Pros. Hist., at CPI 005590.

The court is reluctant to give much weight to the title change because the Federal Circuit has noted the "near irrelevancy of the patent title to claim construction" and has stated that "an amendment of the patent title during prosecution should not be regarded as having the same or similar effect as an amendment of the claims themselves by the applicant." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d at 1312 (concluding that the district court attached too much weight in its claim construction to the patent title and to the amendment of that title). In any event, the title change certainly does not support defendants' effort to construe the claim language narrowly to exclude devices that treat ventricular conditions.

The application for an extension of the '472 patent term explicitly stated that the approved product treated ventricular tachycardia and ventricular fibrillation and that Claim 1 covered the product. Plaintiffs contend that the extension could not have been granted unless the Patent Office agreed that the '472 patent claims could reach ventricular cardioverters. Pl. Reply Br. at 36; Ex. 14, '472 Pros. Hist., Request for Extension of Patent Term. However, it is not clear where an application for a patent term extension fits in the interpretive hierarchy. Certainly the device descriptions in a patent extension application cannot be read to amend the claims or specification of the original patent document. The patent term extension is consistent with the clear language of Claim 1, but the claim language itself is by far the most important evidence that supports plaintiffs' interpretation of "cardioverting device." FN5

FN5. CPI also contends the court should consider evidence of licenses and royalty payments among manufacturers of cardioverting devices. CPI believes this evidence will show that defendants have construed the claims of CPI's patents as covering the defendants' devices. CPI has not offered any specific case support for using such evidence in construing ambiguous claim language, and the court has not considered such evidence for two principal reasons. First, under *Markman*, it is clear that evidence relevant to claim construction should be publicly available evidence. See 52 F.3d at 978-79, 987 (discussing the importance of the public record). Other inventors are entitled to know the scope of the claims and may try to design around those claims. See *Vitronics*, 90 F.3d at 1583. If evidence of licensing agreements and royalty payments (which are often confidential) were deemed relevant to claim construction, the scope of claims could not be known without access to private, often highly confidential information from multiple sources in an industry. Second, as the evidence in this case suggests, an industry may operate on the basis of a complex web of cross-licensing agreements negotiated on the basis of a complicated matrix of business considerations and legal risks. The fact that licenses have been negotiated and royalties paid offers little or nothing of probative value as to how claim language should be construed when a court is finally called upon to provide a definitive construction.

Defendants have cited several statements made by the inventors and patentees during the prosecution of a parent application to the continuation application that actually resulted in the '472 patent. Defendants argue that these statements, like the language of the '472 specification, limit the scope of the '472 patent claims to atrial cardioverting devices. Def. Br. at 23-24. The cited statements include the following:

The broad invention disclosed in the parent and instant applications relates to an implanted electronic device which is manually operable from external to the skin of the wearer, for accomplishing atrial cardioversion. Never before has such a device been conceived, and it is therefore the firm belief and opinion of the applicants that their broad invention is patentable over the prior art.

Ex. 118 at 8 (remarks supporting an amendment to the claims and description in patent application Serial No. 641,381, dated December 17, 1975) (emphasis added).FN6 Similarly:

FN6. The continuation application that resulted in the '472 patent was filed on August 9, 1979.

Because these two types of fibrillation are so different, ventricular defibrillation and atrial defibrillation are not suited for indiscriminate comparison. It is on this basis that the application of the Schuder et al article is deemed improper.

In the February 23, 1977 Action, it is alleged that an obvious step would be to combine the teachings of a Schuder et al article, admittedly directed to ventricular defibrillation, with a Charms patent, which suggested atrial defibrillation. This combination is untenable for two basic reasons. First, even if the references were to be combined, the man having ordinary skill in the art would have evolved a *fully automatic* implantable atrial defibrillator; based upon his awareness of ventricular defibrillation technology, he would not have considered a non-automatic approach.

Ex. 119 at 2 (response to patent examiner, dated June 22, 1977) (emphasis in original).

The above-identified application relates to a non-automatic atrial defibrillator. This device is in every way practical and realistic. The wearer is able to recognize when he is experiencing atrial fibrillation; and he, himself, can initiate a defibrillating procedure. Or, if he chooses, the individual can consult with his physician, discuss his suspected arrhythmia, and decide either to, or not to, initiate a defibrillating procedure. While ventricular defibrillation is a necessity to save a life, and while a reaction to ventricular fibrillation must be immediate, atrial defibrillation is an elective procedure.

Accordingly, the invention described in the above-identified application involves far more than merely borrowing from the art of ventricular defibrillation. The concept of a fully-implantable non-automatic atrial defibrillator can be thought of as an accommodation to a heart patient; with such a device, defibrillation can be accomplished at home, without the inconvenience of repeated visits to a physician.

Ex. 111, para. 11 (Declaration of Mieczyslaw Mirowski, dated June 8, 1977).

For the reasons set forth in my October 28, 1976 Declaration and those set forth in the foregoing paragraphs, I am of the firm belief that an implantable non-automatic ventricular defibrillator is unrealistic and totally impractical, because not useful by the suffering individual himself, and because the suffering individual is not likely to experience ventricular fibrillation in the presence of one skilled in medicine and aware that the individual wears an implanted defibrillator.

Ex. 112, para. 5 (Declaration of Morton M. Mower, dated June 8, 1977).

While statements made during the prosecution of a parent application are part of the prosecution history and relevant to interpreting claims in a subsequent daughter application, see *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377, 1383-84 (Fed.Cir.1999), they form only part of the interpretive backdrop. In this case, the parent application, Serial No. 641,381, was abandoned. Significantly, at least some of the claims in the abandoned parent application referred explicitly to the "atrium" and to devices for converting "supra-ventricular" cardiac arrhythmias. Ex. 118 at 3-7.

Defendants are correct to point out through the inventors' statements that the devices disclosed in the abandoned parent application (as well as the devices in Figure 1 and Figure 3 of the '472 patent) are not suited for ventricular defibrillation. However, the removal of all references to the words "atrium," "atrial," and "supra-ventricular" in the claims of the '472 patent indicates a deliberate intent to broaden the claims over those in the abandoned parent application. The statements made in support of the abandoned parent application do not limit the unambiguous language in the claims of the '472 patent. FN7

FN7. In contrast to the claims in the abandoned parent application, the claims in the '472 patent also make no explicit reference to a "non-automatic" or "manually operated" device. In fact, the claims of the '472 patent were specifically amended during prosecution to replace the phrase "implantable non-automatic converting device" with the more general term "cardioverting device." Ex. 14, '472 Pros. Hist., at CPI 005600-07.

Nevertheless, defendants have cited Federal Circuit decisions that are difficult to reconcile with the cases suggesting that a claim may be broader than the specific embodiment disclosed in a specification. For example, in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1480 (Fed.Cir.1998), the court wrote that "claims may be no broader than the supporting disclosure, and therefore ... a narrow disclosure will limit claim breadth." In *Gentry Gallery*, however, the court was deciding an issue of validity and held invalid broad claims that reached beyond the disclosure. In *Laitrum Corp. v. Morehouse Industries, Inc.*, 143 F.3d 1456, 1462-63 (Fed.Cir.1998), the court rejected a number of arguments by a patentee who sought a broad claim interpretation: "It is entirely proper to 'use the specification in order to determine what the inventor meant by terms and phrases in the claims.' * * * While claims are not necessarily limited by the written description, it is relevant that nothing in the written description suggests that the driving surfaces can be anything but flat." In *North American Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1576-77 (Fed.Cir.1993), the court noted that the written description requirement of 35 U.S.C. s. 112, para. 1 warranted a claim construction limited to the disclosures in the specification. See also *Modine Manufacturing Co. v. United States Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed.Cir.1996) ("when the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment").

In the present case, however, both the deliberate use of broad language in the claims and the prosecution history show a clear choice to write claims that would apply to the entire heart, including the ventricles. To the extent that the broad claim language raises issues of validity, those issues may be addressed later in the case. They would not support an artificially narrowed reading of the deliberately broad claim language applying to the entire heart. The court therefore intends to define "cardioverting device" for the jury as "a device capable of correcting high-rate arrhythmic heart conditions by applying non-pacing electrical shocks to the heart. Such heart conditions include atrial arrhythmias and/or ventricular arrhythmias." For essentially the same reasons, the terms (1) "cardioverting a heart" and "cardioverting the heart" in Claim 18 of the '472 patent, and (2) "cardioverting device" in Claim 1 of the '191 patent will be defined to include both atrial and

ventricular cardioversion. See '472 Patent, col. 10, ll. 62-63; col. 12, ll. 6-8; '191 Patent, col. 8, l. 56.

B. '472 Claim 1: "storage means for storing"

The second disputed phrase in Claim 1 of the '472 patent is "storage means for storing." In addition to the standard hierarchy of intrinsic and extrinsic interpretive resources, this phrase is the first of several elements in the '472 patent that potentially brings into play a special subset of interpretive rules under paragraph 6 of 35 U.S.C. s. 112 ("s. 112 para. 6"). Section 112 para. 6 provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Claims phrased under s. 112 para. 6 are often called "means-plus-function" or "step-plus-function" claims. In operation, s. 112 para. 6 allows a patentee to state claims in broad, general language by stating the "functions" of the invention, rather than by repeating the detailed structures or materials (in apparatus claims) or detailed acts (in method claims) that perform the claimed functions. A "means-plus-function" or "step-plus-function" statement in a claim may be an economical way of expressing the more complex structure or acts covered by the claim. The patentee may use s. 112 para. 6 function statements so long as the "missing" detail appears in the specification. See *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1360 (Fed.Cir.2000) (the duty to link structure to function is the "statutory quid pro quo" for the convenience of employing s. 112 para. 6). The relevant structural details or relevant acts from the specification are then essentially incorporated into the function claims. See *Multiform Desiccants*, 133 F.3d at 1479 (discussing the form and purpose of claims containing functional limitations written in the s. 112 para. 6 "means-for" form).

The "cost" of using a s. 112 para. 6 function statement, especially if done unintentionally, is that the scope of the claim is restricted to the particular structures or acts disclosed in the specification, as well as their equivalents. See *Personalized Media Communications, LLC v. International Trade Comm'n*, 161 F.3d 696, 703 (Fed.Cir.1998) ("s. 112, para. 6 operates to restrict claim limitations drafted in such functional language to those structures, materials, or acts disclosed in the specification (and their equivalents) that perform the claimed function.").FN8

FN8. Structure in an accused device will be a s. 112 para. 6 "equivalent" if (1) it performs the identical function as the function stated in the claim, and (2) it is otherwise insubstantially different with respect to structure as the disclosed structure. See *Kemco Sales*, 208 F.3d at 1364, citing *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed.Cir.1999); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed.Cir.1987) (*en banc*). Significantly, the test developed for the doctrine of equivalents is not wholly transferable to the s. 112 para. 6 statutory equivalence context due to the functional identity requirement. See *Odetics*, 185 F.3d at 1267.

The word "means" is a generic description of an apparatus element, and the implementation of such a concept is by structure or material. See *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1582-83 (Fed.Cir.1997). The term "steps" refers to the generic description of elements of a process, and the term "acts" refers to the implementation of such steps. Thus, for apparatus claims, means-plus-function interpretation rules apply if

the claim is expressed as a means for performing a specified function without also identifying in the claim itself the specific material or structure that accomplishes that function. For method claims, step-plus-function rules apply if the claim element is expressed as a step for performing a specified function without stating in the claim itself the more specific acts that explain how to accomplish the function. See *id.*

If s. 112 para. 6 applies to a claim, a court construing the claim must then (1) "construe the function recited in that claim," and (2) "determine what structures [or acts] have been disclosed in the specification that correspond to the means [or steps] for performing that function." *Kemco Sales*, 208 F.3d at 1361. Sometimes, however, the threshold issue is whether s. 112 para. 6 applies at all. The Federal Circuit has established some general rules of thumb.

First, the specific language of the claim can create a presumption that s. 112 para. 6 either does or does not apply:

[U]se of the word "means" creates a presumption that s. 112, para. 6 applies, *see York Prods., Inc. v. Central Tractor*, 99 F.3d 1568, 1574 (Fed.Cir.1996) ("In determining whether to apply the statutory procedures of [s. 112, para. 6], the use of the word 'means' triggers a presumption that the inventor used this term advisedly to invoke the statutory mandates for means-plus-function clauses."), and ... the failure to use the word "means" creates a presumption that s. 112, para. 6 does not apply, *see [Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1213 (Fed.Cir.1998)]*. These presumptions can be rebutted if the evidence intrinsic to the patent and any relevant extrinsic evidence so warrant.

Personalized Media, 161 F.3d at 703-04 (footnotes omitted); *see also Kemco Sales*, 208 F.3d at 1361 (discussing the quoted language from *Personalized Media* with approval; "plastic envelop closing means" limitation invokes the presumption and is in means-plus-function format). Similarly, if a claim drafter uses "steps for" to express a method claim element, it is a signal that the drafter intended to invoke s. 112 para. 6. *See Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed.Cir.1996).

Second, if an apparatus claim element itself arguably identifies some structure, the test is whether one of skill in the art would understand the term at issue to connote sufficiently definite structure. *See Personalized Media*, 161 F.3d at 703-05 (finding that the term "digital detector" recited sufficient structure to avoid s. 112 para. 6; "Even though the term 'detector' does not specifically evoke a particular structure, it does convey to one knowledgeable in the art a variety of structures known as 'detectors.' "); *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d at 1583 (stating that the inquiry is whether the term used as the name for structure "has a reasonably well understood meaning in the art"). Where a claim recites a function but the claim itself also sets forth sufficient structure or material to perform entirely the recited function, the claim is not a means-plus-function claim even if it uses the term "means." *See Personalized Media*, 161 F.3d at 704, citing *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 1427-28 (Fed.Cir.1997).

Third, in method claims, merely claiming a step without recital of a function is not analogous to a means plus a function. *See O.I. Corp. v. Tekmar Co.*, 115 F.3d at 1583 (holding that the step of "passing the analyte slug through a passage ..." was not subject to s. 112 para. 6). Thus, claiming a "step" by itself, or even a series of steps, does not invoke s. 112 para. 6. *See id.* Under this rule, a patentee can define a method or process claim containing steps that begin with a gerund such as passing, heating, reacting, transferring, etc. without necessarily subjecting the claim to s. 112 para. 6 limitations. *See id.*

Applying these rules to Claim 1 of the '472 patent, the parties disagree as to whether s. 112 para. 6 controls

the element "storage means for storing." St. Jude contends that "storage means for storing" is a means-plus-function recital and that "storage means" therefore should be limited to "a capacitor"-the structure disclosed in the specification that performs the stated function. CPI initially asserts that s. 112 para. 6 does not apply and that there is no need for further interpretation of the phrase. Pl. Reply Br. at 37. Arguing in the alternative, and assuming that s. 112 para. 6 does apply, CPI offers the following construction: "The corresponding structure is a capacitor and equivalents thereof. A combination of capacitors is the equivalent of a single capacitor." Pl. Amd. Prop. Conc. of Law at 5.

The phrase "storage means for storing" is subject to s. 112 para. 6. As written in the claim, some unidentified "storage means" performs the function of "storing energy to convert an abnormal cardiac rhythm to normal sinus rhythm." '472 Patent, col. 8, ll. 65-66. The claim is stated in means-plus-function form. Because the claim uses the key phrase "means for," it is presumed that the claim falls under s. 112 para. 6. CPI has not shown any basis for departing from the presumption in this instance. One skilled in the art would not understand the broad term "storage means" to connote sufficiently definite structure.

Because s. 112 para. 6 applies, the court must identify the structure disclosed in the specification that performs the function of "storing energy to convert an abnormal cardiac rhythm to normal sinus rhythm." See *Kemco Sales*, 208 F.3d at 1361. The court agrees with St. Jude that the capacitors disclosed in the two embodiments of the device are the only structures that perform the function at issue. See '472 Patent, Figs. 1 & 3; col. 7, ll. 44-64.

CPI has asked the court to include in the claim construction the statement that a combination of capacitors is the equivalent of a single capacitor. It is not appropriate to define as a matter of law at the stage of claim construction the structures that may be "equivalents" of the disclosed means. "Whether an accused device or method infringes a claim either literally or under the doctrine of equivalents is a question of fact. Literal infringement of a s. 112, para. 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 1379 (Fed.Cir.2000) (internal quotation and citation omitted); accord, *IMS Technology, Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1430 (Fed.Cir.2000) ("Whether an accused device or method infringes a claim with a s. 112, para. 6 limitation, *i.e.*, whether it performs the identical function with the same structure, materials, or acts described in the specification or an equivalent thereof, is a question of fact."). The court therefore will not adopt the portion of CPI's proposed construction stating that a "combination of capacitors is the equivalent of a single capacitor." It is not possible to say at this point that a reasonable jury would be required to conclude that multiple capacitors are the equivalent of a single capacitor. The term "storage means" in Claim 1 of the '472 patent will be defined as "a capacitor and equivalents thereof."

C. '472 Claim 1: "delivery electrode means for discharging"

The third disputed phrase in Claim 1 identifies "delivery electrode means for discharging the stored energy into the heart of a wearer of the device." '472 Patent, col. 8, ll. 67-68. CPI asserts that s. 112 para. 6 does not apply to "delivery electrode means for discharging," while St. Jude contends that the phrase is a means-plus-function statement and that the disclosed structure is "an electrode that is implanted in the atrium of the patient's heart." Def. Prop. Conc. of Law at 2.

The claim element is stated in means-plus-function form with "means for" language, so the presumption is that s. 112 para. 6 applies. CPI argues that there is a basis for departing from the presumption in this

instance because one skilled in the art would understand the term "delivery electrode" to connote sufficiently definite structure (*i.e.*, an electrode) to perform the stated function. See, *e.g.*, *Personalized Media*, 161 F.3d at 703-05 (holding that the term "digital detector" recited sufficient structure to avoid s. 112 para. 6; claim did not use word "means"); *MediaCom Corp. v. Rates Technology, Inc.*, 2 F.Supp.2d 17, 27 (D.Mass.1998) (holding that "switch means operatively connected to said first jack means for disconnecting said first telephone from said network" was not a s. 112 para. 6 means-plus-function statement "because it describes the structure that supports the disconnecting function (*i.e.* a switch or switches).").

The court disagrees that the "delivery electrode means" element recites sufficient structural detail to overcome the presumption that s. 112 para. 6 controls. In cases where the Federal Circuit has departed from the presumption established by the use of "means for," the court has emphasized that the claim language provided detail beyond some minimal statement of structure. See, *e.g.*, *Envirco Corp. v. Clestra Cleanroom, Inc.*, 209 F.3d 1360, 1365 (Fed. Cir.2000) (finding that "second baffle means" rebuts the presumption that s. 112 para. 6 applies because the term "baffle" itself imparted structure and because the claim gave further location and formational details); *Rodime PLC v. Seagate Technology, Inc.*, 174 F.3d 1294, 1303-04 (Fed.Cir.1999) ("The claim also recites the specific location and interconnection of each of these structural sub-elements.... This detailed recitation of structure for performing the moving function takes this claim element out of the scope of s. 112, para. 6."); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed.Cir.1996) (finding that the claim language described definite structure as well as the location and extent of the structure). Further, in *Unidynamics Corp. v. Automatic Products Int'l, Ltd.*, the Federal Circuit adhered to the presumption established by use of the term "means" and found that the claim element "spring means tending to keep the door closed" invoked s. 112 para. 6. 157 F.3d 1311, 1319 (Fed.Cir.1998). The court distinguished *Cole v. Kimberly-Clark* on the basis that the claim in *Cole* had not only described definite structure but also described the location and extent of the structure. See *id.*

St. Jude's proposed construction, which requires the electrode to be implanted in the atrium of the patient's heart, is also faulty. The function to be performed-"discharging the stored energy into the heart of a wearer of the device"-is stated in terms broad enough to include both atrial and ventricular therapies. A limitation requiring the discharging end of the electrode to be implanted in the atrium would import structural detail of the disclosed devices beyond what is required to perform the recited function. See *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.*, 145 F.3d 1303, 1308 (Fed.Cir.1998) (claim construction properly omitted details of the embodiment that defined structure unrelated to the recited function).

The use of an atrial catheter electrode is necessary to the disclosed embodiments, but not necessary to the function recited in the claim. The claim element is concerned more broadly with a means by which to transfer energy from the device to any point in the heart where the electrical therapy is to be delivered. See '472 Patent, col. 7, ll. 39-43 ("AND gate 82 switches the discharge switch 84 to its conductive state, thereby discharging the storage and discharge capacitor 78 through the heart 76 by way of a catheter 72 implanted in or about the heart, as in the right atrium 74.").

The court intends to define "delivery electrode means" as "structure identical or equivalent to a catheter-type electrode extending from the implanted device to the heart, such that the point of discharge is located at the point where the electrical therapy is to be delivered."

D. '472 Claim 1: "charging means for delivering"

The fourth disputed phrase in Claim 1 indicates that a "charging means" performs the function of

"delivering to said storage means said energy to convert said abnormal cardiac rhythm." '472 Patent, col. 9, ll. 4-6. St. Jude contends that this element is controlled by s. 112 para. 6 and proposes the following construction: "The 'charging means'... requires energy to be transmitted from the physician's external console through the skin of the patient to the implanted device." CPI responds that the word "charging" in the claim language adds the structural limitation of a "charging circuit" and that s. 112 para. 6 therefore does not apply. In the alternative, CPI argues that, even if s. 112 para. 6 does apply, power inverter 52 in Figures 1 and 3 is the structure that performs the stated function, or that, at the very least, the court should adopt a claim construction that "identifies an external source and an implanted battery as interchangeable energy sources for the physician-operated embodiment specifically disclosed in the '472 patent." Pl. Reply Br. at 41.

The s. 112 para. 6 interpretive rules apply to the element "charging means for delivering." The adjective "charging" does not identify sufficient structure to defeat the presumption raised by the use of the "means for" language. The next step is to identify the disclosed structure that performs the function of delivering energy to the storage means.

Both parties seem to agree that the "charging means" generally is responsible for transferring energy from one location (an energy source) to the storage means (*i.e.*, the capacitor). The patent specification supports this general construction. In the physician-operated embodiment shown in Figure 1, energy is transferred from an energy source that is external to the skin to the capacitor via a series of steps. The patent specification, discussing Figure 1, states that "power inverter 52 and the associated circuitry ... serves the purpose of charging the storage capacitor at a predetermined energy level." '472 Patent, col. 5, ll. 56-60. In the patient-operated embodiment in Figure 3, however, energy is transferred from an internal battery to the capacitor via switch 118 and power inverter 52.

The real dispute over the "charging means" language centers on whether the language of Claim 1, viewed in its entirety, limits the supporting structure for the "charging means" solely to the charging structure identified in the physician-operated embodiment. St. Jude contends that the claim language applies only to the "charging means" used in the physician-operated embodiment because (1) the claim later states that *programming commands* designate the energy magnitude that is to be used to treat the arrhythmia, and (2) only the physician-operated embodiment uses external *programming commands* to designate the energy level. The specification does not state that an internal battery is interchangeable with the disclosed external energy source in Figure 1, so St. Jude asserts that "the patent teaches that the type of energy source is not optional." Def. Br. at 34 n. 17.FN9

FN9. St. Jude's argument supposes that the patient-operated embodiment (Fig.3) has no direct application to Claim 1 because the cardioverting device described in the claim is expressly stated to be an "an implantable externally programmable cardioverting device." St. Jude is correct that Figure 3 does not disclose an "externally *programmable* " device and that, therefore, Figure 3 does not disclose a device as described in Claim 1. The energy levels for cardioversion in the patient-operated embodiment cannot be changed once the device is implanted. The same is true for Claim 18, which indicates that "a receiver for receiving *control information* " is an essential component of the implanted "package ." The patientoperated embodiment has no such receiver.

CPI's response is that one of ordinary skill in the field of implanted cardioverters "would recognize that the implanted battery is interchangeable with the external console as sources of energy for the physician-operated embodiment covered by claim 1." Pl. Reply Br. at 41. Thus, according to CPI, the charging circuit

in Figure 1 and the charging circuit in Figure 3 are interchangeable, disclosed structures which correspond to the "charging means" recited in Claim 1.

CPI's argument about the "charging means" is more persuasive. Nothing in the specification indicates that the *particular* source of energy used to cardiovert the heart is essential to the operation of an externally programmable cardioverting device. In addition, the principle of claim differentiation supports this view. Under the doctrine of claim differentiation, the general rule is that "limitations stated in dependent claims are not to be read into the independent claim from which they depend." *Karlin Technology, Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 972 (Fed.Cir.1999); see also *Tandon Corp. v. United States Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed.Cir.1987) ("To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant."). Dependent Claim 6 of the '472 patent reads: "In the device of claim 1, wherein said receiver means receives power signals generated from external to the skin of the wearer; said device including utilizing means for utilizing said power signals as electrical power necessary for the operation of the device." '472 Patent, col. 9, *ll.* 44-48. The added limit in Claim 6 of using power from outside the patient's skin further indicates that Claim 1 should be construed more broadly to include devices that do *not* have "means for utilizing said power signals as electrical power necessary for the operation of the device."

The court intends to construe "charging means" as follows: "a power inverter and the associated charging circuitry necessary to perform the function of transferring energy from a power source to the storage means. The charging means must be identical or equivalent to the power inverter and associated circuitry disclosed and described in either (a) the physician-operated embodiment described in the '472 patent (Figure 1), or (b) the patient-operated embodiment described in the '472 patent (Figure 3)."

E. '472 Claim 1: "*initiating means for initiating the discharge of converting energy*"

Claim 1 of the '472 patent states that the cardioverting device must include "initiating means for initiating the discharge of converting energy into the heart of the wearer after the stored energy has reached said predetermined magnitude." '472 Patent, col. 9, *ll.* 10-13. The parties agree that the "initiating means" claim element is subject to s. 112 para. 6, but they disagree on the structure to be associated with the stated function.

CPI contends that the specification teaches two different methods for initiating the discharge of energy into the heart. First, the physician-operated embodiment discloses a button located on the physician-controlled console. '472 Patent, Fig. 2, element 40. The physician presses the button to initiate the discharge of the capacitor once the capacitor has been charged to the desired level. '472 Patent, col. 4, *ll.* 43-45; col. 5, *ll.* 1-4. Second, the patient-operated embodiment discloses a mechanism by which the implanted device itself initiates the discharge of the stored energy when the capacitor is fully charged and the heart is in the proper stage of the ventricular cycle. '472 Patent, Fig. 3, element 82. CPI claims that the initiating means in the physician-operated device involves a manual procedure, while the initiating means in the patient-operated device is structure that performs the function automatically.

St. Jude's proposed construction of "initiating means" limits the associated structure to a "manually operated triggering device, such as a button." According to St. Jude, the specification clearly ties the push button in Figure 2 to the stated function of initiating the discharge of energy. See '472 Patent, col. 4, *ll.* 43-45. As far as the patient-operated embodiment, St. Jude contends: "At most, the patient-initiated embodiment disclosed

in the patent teaches a system for continued operation with limited patient participation after an initial trigger." Def. Surreply Br. at 12. Thus, according to St. Jude, nowhere does the '472 patent teach "automatic" initiation.

The language of the recited function is the key to the construction of this element. The initiating structure must initiate "the discharge of converting energy into the heart of the wearer *after the stored energy has reached said predetermined magnitude.*" '472 Patent, col. 9, *ll.* 10-13 (emphasis added). Thus, the focus is on what happens *after* the capacitor has been charged to a predetermined level. In the patient-operated device, the patient's magnet is already in place at the point the capacitor reaches its full charge. In fact, the magnet initiates the charging process. The structure that later initiates the discharge, however, is not the magnet. The specification explains the structure involved in the initiating process as follows:

[W]hen discharge capacitor 78 reaches the proper level of charging, a "ready" signal is issued and is passed to AND gate 82 via line 80. At the same time, the ventricular catheter 126 or another appropriate sensing lead senses the heart function, and a set of QRS synchronization pulses is produced by circuit 132 and fed to AND gate 82 via line 56.

Upon the simultaneous occurrence of a "ready" signal and a QRS pulse, AND gate 82 switches discharge switch 84 to its conductive state and the discharge capacitor 78 discharges through the heart 76 of the patient via atrial catheter 72.

'472 Patent, col. 7, *l.* 61 to col. 8, *l.* 5. This description indicates that "AND gate 82" performs the function of initiating the discharge process upon receiving signals from discharge capacitor 78 and the QRS circuit. The presence of the magnet over the device is a necessary condition that must be fulfilled before the "initiating" function is performed in the patient-operated embodiment, but the magnet is not structure that accomplishes the stated function. Therefore, the court rejects St. Jude's proposed construction, which would limit the definition of "initiating means" to manually-operated triggering devices.

The court intends to define "initiating means" as follows: The accused device contains "initiating means" as stated in Claim 1 of the '472 patent if it contains structures identical or equivalent to (1) AND gate 82 as shown in Figure 3 and described in the specification, or (2) the manually operated discharge button 40 as shown in Figure 2 and described in the specification. FN10

FN10. By adopting a construction of the term "initiating means" that does not include a limitation to manually-operated devices, the court does not intend to suggest that Claim 1 necessarily reaches a completely automatic device in the sense that the device automatically *detects and treats* an arrhythmia without, for example, a patient placing a magnet near the device or a physician using an external console to control the delivery of shocks to the heart.

F. '472 Claim 1: "*stored energy for converting said abnormal cardiac rhythm*"

The final paragraph of Claim 1 of the '472 patent states that the cardioverting device must be capable of receiving programming commands from external to the skin of the wearer. The programming commands received by the device designate "a predetermined magnitude of stored energy for converting said abnormal cardiac rhythm...." '472 Patent, col. 9, *ll.* 16-20. St. Jude contends that the source for the "stored energy" mentioned in the claim must be external to the patient because only the physician-operated embodiment

allows programming of the amplitude of the shock.

As stated above in interpreting the term "charging means," the court agrees with CPI that the '472 patent discloses that an external power source and an internal battery are interchangeable sources of power for cardioversion. The court does not anticipate defining "stored energy" or "programming commands" for the jury beyond what is already stated in the claim.

G. '472 Claim 18: Disputed Terms Similar to Terms in Claim 1

Claim 18 defines a method for electrically cardioverting a patient's heart, although it has apparatus elements. The claim reads:

18. A method for electrically cardioverting a heart, the method comprising the steps of:

implanting an electronic package beneath the skin of a wearer, said electronic package including a storage element for storing electrical energy to convert an abnormal cardiac rhythm to normal sinus rhythm, delivery electrodes for discharging said stored energy into the heart of the wearer, a receiver for receiving control information from external to the skin of the wearer, said control information designating a selected magnitude of energy to be discharged through said delivery electrodes into the heart of the wearer, and charge control means responsive to said control information for storing said selected magnitude of stored energy in said storage element;

sensing an abnormal cardiac rhythm, wherein cardioversion is required;

delivering said control information through the skin of the wearer to cause the storage element to store said selected magnitude of energy; and

electrically cardioverting the heart by discharging said selected magnitude of stored energy through said delivery electrodes into the heart of the wearer.

'472 Patent, col. 10, *l.* 62 to col. 12, *l.* 8.

Several of the disputed terms in the method claim are identical to or very similar to the disputed terms in apparatus Claim 1. However, even where the language used in the method and apparatus claims is identical, the method claims must be considered independently. It is possible that the same language will have a different meaning, especially where, as is true here, some claim elements are subject to s. 112 para. 6:

We understand that the steps in the method claim are essentially in the same language as the limitations in the apparatus claim, albeit without the "means for" qualification. However, even if we were to hold that the word "passage" in the apparatus claims meets the section 112, para. 6, tests, we would not agree with Tekmar that the "parallelism" of the claims means that the method claims should be subject to the requirements of section 112, para. 6. Each claim must be independently reviewed in order to determine if it is subject to the requirements of section 112, para. 6. Interpretation of claims would be confusing indeed if claims that are not means-or step-plus-function claims were to be interpreted as if they were, only because they use language similar to that used in other claims that are subject to this provision.

O.I. Corp. v. Tekmar Co., 115 F.3d at 1583-84. The court will dispose of Claim 18 issues by reference to the

disposition of Claim 1 issues only where it is appropriate to do so.

1. '472 Claim 18: "A method for electrically cardioverting a heart"

St. Jude contends that the method for "electrically cardioverting a heart" defined in Claim 18 is limited to atrial cardioversion. CPI proposes a construction that would include ventricular cardioversion. The parties agree that the issues presented in interpreting the term "cardioverting" in Claim 1 and Claim 18 are substantially identical, and they cite identical evidence in support of their arguments.

As explained above with reference to Claim 1, the language of the claims is not ambiguous. The patentees used the word "cardioverting" to include both atrial and ventricular devices and processes despite the fact that the two disclosed embodiments are atrial devices. The term "electrically cardioverting a heart" for purposes of Claim 18 of the '472 patent means "applying non-pacing electrical shocks to the heart to correct high-rate arrhythmic heart conditions. Such heart conditions include atrial arrhythmias and/or ventricular arrhythmias."

2. '472 Claim 18: "a storage element for storing electrical energy"

The first step defined in Claim 18 of the '472 patent is the step of "implanting an electronic package beneath the skin of a wearer." The claim then identifies various components of the electronic package, several of which are nearly identical to the components identified in the apparatus Claim 1 and will be interpreted similarly.

The "implanting" step of Claim 18 states that the electronic package must include "a storage element for storing electrical energy to convert an abnormal cardiac rhythm to normal sinus rhythm." '472 Patent, col. 10, ll. 65-67. The significant difference between this statement and the similar statement in Claim 1 is the substitution of the word "element" for the word "means." Because the claim language does not use the word "means" there is no presumption that s. 112 para. 6 applies. However, the element is stated in purely functional terms, so s. 112 para. 6 still controls. See *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1213-15 (Fed.Cir.1998) (interpreting "lever moving element" and "movable link member" under s. 112 para. 6); accord, *Al- Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1318 (Fed.Cir.1999) ("[W]hen it is apparent that the element invokes purely functional terms, without the additional recital of specific structure or material for performing that function, the claim element may be a means-plus-function element despite the lack of express means-plus-function language.").

The proper construction of "storage element" in Claim 18 is identical to the construction provided for "storage means" in Claim 1 above. The term "storage element" in Claim 18 will be defined as "a capacitor and equivalents thereof."

3. '472 Claim 18: "delivery electrodes for discharging said stored energy into the heart of the wearer"

The element "delivery electrodes for discharging said stored energy into the heart of the wearer" in Claim 18 recites another structural element that must be included in the implanted "electronic package." As was the case for the term "delivery electrode means" in Claim 1, St. Jude contends that the "delivery electrodes" element in Claim 18 is a means-plus-function element and that the specification limits the scope of the claim to electrodes implanted in the atrium.

Although the phrase in Claim 18 omits the word "means," the element is otherwise not different from the

"delivery electrode means" element in Claim 1. The phrase in Claim 18 also identifies a function, and it provides no more illumination than the parallel element of Claim 1. The court sees no valid basis for finding that "delivery electrode means" discloses less structure than the phrase "delivery electrodes." The court finds that the element is subject to s. 112 para. 6 and intends to define "delivery electrodes" as "structure identical or equivalent to a catheter-type electrode extending from the implanted device to the heart, such that the point of discharge is located at the point where the electrical therapy is to be delivered."

H. '472 Claim 18: "receiver for receiving control information from external to the skin of the wearer, said control information designating a selected magnitude of energy to be discharged through said delivery electrodes into the heart of the wearer"

The parties appear to agree that s. 112 para. 6 applies to the phrase "receiver for receiving." The unresolved issue is whether, as St. Jude contends, the energy source must be external to the skin of the patient, or whether the energy source may also be an internal battery.

The claim language and the specification both clearly indicate that the "control information designating a selected magnitude of energy" comes from an external source (e.g., the physician's console), but the *energy source* for cardioversion may be either external or internal. The "receiver" claim language does not imply any limit on where the energy source must be located. As discussed above in relation to Claim 1, the disclosed embodiments teach two interchangeable sources for the energy that will be discharged into the patient's heart. The physician-operated embodiment discloses an external source. The patient-operated embodiment discloses an internal battery. One skilled in the art would readily understand that an internal battery could be used in a device that receives external "control information designating a selected magnitude of energy."

The court intends to adopt CPI's proposed construction of this disputed claim element. Therefore, "a receiver for receiving control information" is the circuitry inside the implanted cardioverter that receives the information sent to the device for programming the energy level.

I. '472 Claim 18: "charge control means responsive to said control information for storing said selected magnitude of energy in said storage element."

The final disputed claim element in the "electronic package" defined in Claim 18 identifies "charge control means responsive to said control information for storing said selected magnitude of energy in said storage element." '472 Patent, col. 11, ll. 6-8. St. Jude contends that s. 112 para. 6 controls, and it proposes that: "The 'charge control means' requires energy to be transmitted from the physician external console through the skin of the patient to the implanted device." Def. Br. at 37. CPI contends that s. 112 para. 6 does not apply and that "charge control means" should be interpreted identically to "charging means" in Claim 1 of the '472 patent.

The court finds that s. 112 para. 6 applies to the "charge control means" claim element. The element uses the key word "means," and the claim element recites a function without identifying sufficiently definite structure for performing that function. The stated function is to control the charging of the storage element (i.e., the capacitor) in a manner that is responsive to the control information. The claim earlier defines the "control information" as information received by the device from an external source that designates a selected magnitude of energy for cardioversion. '472 Patent, col. 11, ll. 2-5.

Thus, the stated function is to charge the capacitor to the energy level indicated by the programming

commands received by the device. Essentially, the function to be accomplished by the "charge control means" in Claim 18 is a combination of the functions recited in two Claim 1 elements: (1) the "charging means" element, and (2) the "determining means" element. However, the function recited in the "charge control means" element of Claim 18 is even more specific than the "determining means" element in Claim 1 because it explicitly references the "control information" received from external to the skin of the wearer that designates a selected magnitude of energy.

The structure associated with the function stated in the claim must be capable of performing entirely the recited function. Only the physician-operated embodiment is responsive to "control information" that selects the magnitude of energy to be used for cardioversion. The cardioverting energy levels in the patient-operated device are hard-wired and cannot be altered non-invasively after the device is implanted. In other words, the patient cannot designate a particular magnitude of energy prior to attempting cardioversion. The patient can only progress through a series of predetermined energy levels during repeated attempts at cardioversion. It is neither obvious to one skilled in the art nor explained in the patent document how the "charge control means" of the patient-operated device could be "responsive" to the external control information described in Claim 18. For this reason, the structure associated with "charge control means" is limited exclusively to the structure identified and described in reference to the physician-operated embodiment and its equivalents.

The structure associated with the function of the "charge control means" in the physician-operated embodiment includes the power inverter (element 52), the comparator (element 100), and the associated circuitry. '472 Patent, Fig. 1. When switched on, the power inverter delivers energy to the capacitor. The comparator balances the charge building in the capacitor with the energy control command. When the voltage across the capacitor equals the voltage indicated by the energy control command, the comparator produces a "ready" signal which is sent to the power inverter and turns the power inverter off. At this point, the charging operation is complete. '472 Patent, col. 6, *ll.* 26-57. The power inverter delivers energy to the capacitor, but the comparator ensures that the power inverter stops charging the capacitor when the voltage reaches the selected magnitude. In this way, the disclosed structure of the device is "responsive" to the external control information.

Contrary to St. Jude's proposed construction, however, the ultimate source of the energy used to charge the capacitor is in no way critical to accomplishing the function of controlling the charging process to ensure that the capacitor is charged to the voltage designated in the energy control command. Again, the external energy source used in the physician-operated embodiment and the internal battery used in the patient-operated embodiment are interchangeable sources of the energy for cardioversion disclosed in the patent document.

The court intends to define "charge control means" as used in Claim 18 of the '472 patent as follows: The "charge control means" are the power inverter, comparator, and associated circuitry as disclosed in Figure 1 and the written description of the '472 patent. The accused device infringes this element of Claim 18 if it uses identical or equivalent structures to ensure that the capacitor is charged to the magnitude of energy designated in the programming commands received by the implanted device.

J. '472 Claim 18: "*sensing an abnormal cardiac rhythm, wherein cardioversion is required.*"

In contrast to the first several disputed elements in Claim 18, the recited step of "sensing an abnormal cardiac rhythm, wherein cardioversion is required" is actually a step in the method claim rather than a

recitation of components. The parties dispute whether "sensing an abnormal cardiac rhythm" is a step-plus-function element subject to s. 112 para. 6. St. Jude argues that s. 112 para. 6 controls and that the sensing step is performed by human intervention in both disclosed embodiments of the invention. Def. Br. at 38. CPI contends that the element recites an act, not subject to s. 112 para. 6 and that the element should not be confined to "sensing" that involves human judgment. Pl. Reply Br. at 47-48.

The s. 112 para. 6 limitations apply to an element in a method claim "only when steps *plus function* without acts are present." *O. I. Corp. v. Tekmar Co.*, 115 F.3d at 1583 (emphasis in original). Thus, the initial task is to determine whether the contested element recites an act or a function. Judge Rader has provided extensive comments on the often difficult-to-draw distinction between acts and functions:

[C]laim elements without express step-plus-function language may nevertheless fall within s. 112, para. 6 if they merely claim the underlying function without recitation of acts for performing that function. Unfortunately, method claim elements often recite phrases susceptible to interpretation as either a function or as an act for performing a function. Both acts and functions are often stated using verbs ending in "ing." For instance, if the method claim element at issue in this case had merely recited the "step of" "spreading an adhesive tack coating," it would not have been clear solely from this hypothetical claim language whether "spreading" was a function or an act. In such circumstances, claim interpretation requires careful analysis of the limitation in the context of the overall claim and the specification.

In general terms, the "underlying function" of a method claim element corresponds to *what* that element ultimately accomplishes in relationship to what the other elements of the claim and the claim as a whole accomplish. "Acts," on the other hand, correspond to *how* the function is accomplished. Therefore, claim interpretation focuses on what the claim limitation accomplishes, *i.e.*, it's [sic] underlying function, in relation to what is accomplished by the other limitations and the claim as a whole. If a claim element recites only an underlying function without acts for performing it, then s. 112, para. 6 applies even without express step-plus-function language.

Seal-Flex, Inc. v. Athletic Track and Court Constr., 172 F.3d 836, 849-50 (Fed.Cir.1999) (Rader, J., concurring) (emphasis in original).

The preamble of Claim 18 recites the overall purpose of the claimed method and introduces a series of steps for accomplishing that purpose with the words "steps of." Such a general statement of purpose in the preamble does not constitute an associated function for each of the method steps that follow. See *O.I. Corp. v. Tekmar Co.*, 115 F.3d at 1583. In addition, functions are more likely to be introduced by the phrase "steps for" rather than "steps of." See *Seal-Flex*, 172 F.3d at 850 (Rader, J., concurring). Thus, the language in the preamble of Claim 18 suggests that s. 112 para. 6 does not apply. However, the language of the specific claim element in question-"sensing an abnormal cardiac rhythm"-recites a step at a very abstract level. Upon encountering the step of "sensing an abnormal cardiac rhythm," even one skilled in the art could reasonably ask *how* does the device sense the abnormal cardiac rhythm? The language of the disputed "sensing" element in this claim provides nowhere near as much detail as the "passing" steps found to be acts in *O.I. Corp. v. Tekmar Co.* See 115 F.3d at 1579, 1583 ("passing the analyte slug through a passage heated to a first temperature higher than ambient, as the analyte slug passes from the sparge vessel to the trap" is not a step-plus-function limitation). In *Serrano v. Telular Corp.*, the Federal Circuit found that the step of "automatically determining the last-dialed number of the telephone number dialed on the telephone communications-type device" was an act and not a function. 111 F.3d 1578, 1583 (Fed.Cir.1997). The "determining" step in *Serrano* was actually a sub-step to a more general step stated in the claim and

explains a detailed point in the claimed method that is simply not comparable to the generic step of "sensing an abnormal cardiac rhythm."

Analyzing the "sensing" limitation in the context of the overall claim and the specification, the court concludes that the step recites a function rather than an act, even though the element is not introduced by "step for" language. First, the "sensing" step obviously is critical to the overall process. Second, the rest of the language in Claim 18 does not aid construction of the "sensing" step" by filling in details that would answer the critical "how" question. Third, the specification discloses specific acts for accomplishing the sensing function. In light of the need to answer the critical question of *how* the patentee intended to accomplish the step of "sensing an abnormal cardiac rhythm," the court concludes that the "sensing" step in Claim 18 is a step-plus-function element controlled by s. 112 para. 6.

The specification expressly teaches two manual "sensing" methods. In the physician-operated embodiment of Figure 1 and Figure 2, the external display and control console receives an ECG signal through an input device. The physician views a display of the ECG signal and determines the presence of an abnormal cardiac rhythm. In the patient-operated embodiment, the patient is taught to recognize the symptoms of arrhythmia based on sensing his or her heartbeat. Once the patient senses an arrhythmia, he or she places the magnet over the proper switch on the implanted device.FN11

FN11. CPI claims that a second "automatic" sensing process takes place in the patient-operated device. According to CPI, the circuitry in the device "automatically" senses that an abnormal cardiac rhythm is present "due to the expiration of the time out period of timer 116 before the magnet is removed by the patient." Pl. Reply Br. at 47. The court disagrees. The "sensing" done by the timer, if anything, is sensing the elapse of the time delay and sensing that the magnet is still in place. If the first shock to the heart corrects the arrhythmia, but the magnet is left in place and the timer expires, another shock will be delivered to the heart even though the patient is no longer experiencing arrhythmia.

The court intends to define "sensing an abnormal cardiac rhythm" as limited to the disclosed sensing methods of (1) displaying an ECG signal for observation and interpretation by a physician, or (2) direct observation of the heartbeat by the physician or patient, or (3) sensing methods equivalent to method (1) or (2).

K. '472 Claim 18: "*electrically cardioverting the heart by discharging said selected magnitude of stored energy through said delivery electrodes into the heart of the wearer.*"

The step of "electrically cardioverting the heart by discharging said selected magnitude of stored energy through said delivery electrodes into the heart of the wearer" is another disputed element of the method stated in Claim 18. However, unlike the step of "sensing an abnormal cardiac rhythm," the "cardioverting" element recites the acts that accomplish the cardioverting function. The clause "by discharging said selected magnitude of stored energy through said delivery electrodes into the heart of the wearer" sufficiently describes how the heart is cardioverted. Thus, s. 112 para. 6 does not control this element and there is no basis for limiting the scope of the claim to the disclosures in the specification. Nonetheless, St. Jude renews its argument that the patentee has at least implicitly limited the definition of the word "cardioverting" to the treatment of atrial, and not ventricular, arrhythmias.

To support the contention that "cardioverting," as used in a step of the method claim, should be limited to

atrial cardioversion, St. Jude cites the same intrinsic evidence discussed above in Section II-A of this entry. St. Jude also points out a few additional instances in the specification where the description discusses atrial arrhythmias or the discharge of cardioverting energy "in or about the heart, as in the right atrium." '472 Patent, col. 7, ll. 42-43; see also, *e.g.*, col. 6, ll. 2-5 ("the discharge capacitor feeds directly to a catheter 72 implanted in or about the atrium 74 of a heart"); col. 8, ll. 1-7 ("the discharge capacitor 78 discharges through the heart 76 of the patient via atrial catheter 72.").

For the reasons discussed in detail above regarding Claim 1, the court finds that the step of "cardioverting the heart" as used in Claim 18 is not limited to atrial cardioversion.

III. Claim Construction of the '191 Patent

The '191 patent was issued on February 25, 1986, and is closely related to the '472 patent. The two patents disclose identical embodiments, and the written descriptions track one another word-for-word with the exception of the titles, the abstracts, and two statements of purpose that appear only in the '472 patent. The claims in the two patents differ substantially, of course. CPI asserts that the '191 patent is "directed to the synchronization of a cardioversion pulse with a repeatable characteristic of the ECG signal (such as the R-wave)." Pl. Br. at 5. St. Jude describes the scope of the claimed invention more narrowly: "The invention claimed here has to do with what is called QRS synchronization, which is a treatment function that is only applicable to atrial defibrillation." Def. Br. at 38.

The apparatus Claim 1 of the '191 patent reads:

1. A cardioverting device comprising:

detecting means for issuing an electrical signal representing the actual ECG activity of the heart of a wearer of the device;

storage means for storing energy to convert an abnormal cardiac rhythm to normal sinus rhythm;

delivery electrode means for discharging the stored energy into the heart of the wearer;

switch means for controlling the discharge of the stored energy into the heart of the wearer;

charging means for delivering to said storage means said energy to convert the abnormal cardiac rhythm;

first monitoring means for monitoring the operation of said storage means and issuing a first signal when said storage means has stored a predetermined amount of energy;

second monitoring means for monitoring the ECG signal produced by said detecting means and for detecting a preselected repeatable characteristic of the ECG signal, said monitoring means further including means for issuing a second signal each time said second monitoring means detects said preselected repeatable characteristic of the ECG signal;

third monitoring means for monitoring the ECG signal produced by said detecting means for activating said charging means in the presence of abnormal cardiac rhythm in need of correction; and

actuating means connected to said first and second monitoring means and requiring the simultaneous presence of said first and second signals at the time the stored energy is to be delivered to the heart of the wearer, said actuating means for actuating said switching means.

'191 Patent, col. 8, l. 56 to col. 9, l. 23.

A. '191 Claim 1: Disputed Language Similar to the Language in Claim 1 of the '472 Patent

1. '191 Claim 1: "A cardioverting device"

The dispute over the scope of the word "cardioverting" reappears in Claim 1 of the '191 patent. As discussed above in Section II-A, the court rejects St. Jude's proposed construction, which would limit the claim to an atrial device.

2. '191 Claim 1: Other Elements Construed Identically to their '472 Claim 1 Counterparts

The parties generally agree that the following elements appearing in Claim 1 of the '191 patent present interpretation issues identical, or nearly identical to those presented in the construction of disputed terms in Claim 1 of the '472 patent: (1) "storage means for storing;" (2) "delivery electrode means for discharging;" and (3) "charging means for delivering to said storage means said energy." The court has independently considered the claim language, relevant intrinsic evidence, and arguments of the parties in reaching a conclusion with respect to construction of these elements in the '191 patent. The court intends to define each of these elements in a manner identical to the manner in which the corresponding elements in Claim 1 of the '472 patent have been defined above. Thus, for the sake of simplicity, the court simply refers back to the reasoning and claim construction as stated in Sections II-B, II-C, and II-D.

B. '191 Claim 1: "third monitoring means"

The final dispute over the language in Claim 1 of the '191 patent concerns the element that identifies a "third monitoring means for monitoring the ECG signal produced by said detecting means for activating said charging means in the presence of abnormal cardiac rhythm in need of correction." Both sides agree that the element is in means-plus-function format, but they disagree as to the proper interpretation of the element under s. 112 para. 6. By separate order today, the court is scheduling a further hearing on this element.

IV. Claim Construction of the '288 Patent

The third patent in suit, the '288 patent, was issued October 4, 1983. It relates to a device capable of detecting abnormal heart activity, selecting the appropriate therapy, and then executing the therapy so as to treat the determined condition. Operations carried out by the implantable heart stimulator include cardiac pacing, cardioversion, and automatic defibrillation. '288 Patent, Abstract.

The parties' claim construction disputes relate to Claim 1, a method claim, and Claim 10, an apparatus claim. The claims read:

1. A method of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising the steps of:

- (a) determining a condition of the heart from among a plurality of conditions of the heart;
- (b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition; and
- (c) executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.

'288 Patent, col. 21, ll. 9-23.

10. An implantable heart stimulator capable of monitoring and detecting a plurality of arrhythmias, and capable of being programmed to undergo a single or multi-mode of operation corresponding to a respective arrhythmia to treat automatically the detected arrhythmia, said stimulator comprising:

determining means for determining the occurrence of one of a plurality of conditions of the heart;

selecting means responsive to said determining means for selecting at least one mode of operation of said implantable heart stimulator corresponding to a respective one of said plurality of conditions for automatically treating said determined conditions; and

executing means for executing a sequence of events defined by said at least one mode of operation, whereby to treat said determined condition.

'288 Patent, col. 22, ll. 10-26. The terms and phrases used in these two claims overlap. The court first analyzes a disputed phrase that appears in the preambles of both Claim 1 and Claim 10, then proceeds to the apparatus elements of Claim 10, and then returns to Claim 1 to construe disputed terms in the method steps.

A. '288 Claim 1 & '288 Claim 10: "*single or multi-mode operation*"

Claim 1 of the '288 patent refers to an implantable heart stimulator "capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia." CPI proposes that the term "multi-mode operation to treat a detected arrhythmia" be construed to mean: "two or more different modes of therapy (e.g., antitachy pacing and cardioversion) capable of being used in sequence to treat a single arrhythmia (e.g., tachycardia)." Pl. Amd. Prop. Conc. of Law at 1. St. Jude objects to CPI's definition because it includes unnecessary examples and because the phrase "capable of being used in sequence" is claimed to be inaccurate, or at least imprecise. St. Jude offers the following as the proper construction:

The phrase "multi-mode operation to treat a detected arrhythmia" as used in claims 1 and 10 of the '288 patent means two or more different modes of therapy capable of being used individually to treat a single arrhythmia.

Def. Prop. Conc. of Law at 8.

To begin by defining the term "mode" as used in Claim 1, the patent specification reveals that the operating modes of the device include various treatment modes, or therapies, that can be applied to the heart in the event of an arrhythmia.FN12 Each type of therapy, or mode, involves some form of electrical stimulation of the heart. The specification identifies the following treatment modes: ventricular fixed-rate pacing, atrial

fixed-rate pacing, ventricular demand pacing, bifocal pacing, automatic defibrillation, cardioversion, and various automatic ventricular tachycardia control operations. '288 Patent, col. 4, ll. 21-27; col. 4, l. 65 to col. 5, l. 3.

FN12. Besides the various treatment modes, other operating modes include the "automatic patient warning" feature and the "direct memory access" mode. '288 Patent, col. 4, ll. 67-68; col. 5, ll. 5-8.

Referring again to the claim language itself, the device is said to be "capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia." The plain meaning of this language is that the device can be programmed to treat any particular arrhythmia using either *one* mode of operation, or *more than one* mode of operation. If the device is programmed to treat an arrhythmia using one mode of operation, it will "undergo a single ... mode operation." If the device is programmed to treat an arrhythmia using more than one mode of operation, it will "undergo a ... multi-mode operation."

The specification provides a clear example of "multi-mode operation" in explaining the automatic ventricular tachycardia control operations:

In this mode, any combination and/or sequence of the following sub-modes can non-invasively be selected (programmed) by the attending physician: ventricular overdrive pacing, ventricular coupled pacing, automatic cardioversion, and rapid atrial pacing. Any or all of these can be selected, so that, if the first response is not effective in controlling ventricular tachycardia, the next response is activated. That is, initially, a list associated with the various modes can be developed; then, the doctor can revise the list depending on the patient's reaction to treatment.

'288 Patent, col. 5, ll. 33-43. FN13 The specification further explains that in executing such automatic ventricular tachycardia control operations, the device automatically proceeds from one response mode to the next. '288 Patent, col. 5, ll. 50-52. This specific example is consistent with the more general description of the invention that appears in the patent document. See '288 Patent, col. 7, ll. 7-12 ("The implantable heart stimulator and method involve ... the choosing of *at least one* mode of treatment for treating the condition.") (emphasis added). Together, the claim language and the specification provide strong support for CPI's proposed construction of "multi-mode operation to treat a detected arrhythmia."

FN13. Another example of "multi-mode operation," closely associated with dependent Claim 8, involves a method for treating the heart when the device detects the absence of a natural R-wave. '288 Patent, col. 21, l. 55 to col. 22, l. 6. The absence of an R-wave could indicate either an asystole (treatable by pacing), or life-threatening ventricular fibrillation. Under such conditions, the device first executes a pacing treatment. If the pacing therapy does not restore a forced R-wave, the device then attempts defibrillation. '288 Patent, col. 2, l. 66 to col. 3, l. 5.

St. Jude's characterization of CPI's proposed construction as an improper "limitation" on the claim has no merit. According to St. Jude, the specification and the prosecution history provide no support for claiming that "multiple modes" could be used only in sequence. Def. Br. at 44. Under this view, which is reflected in St. Jude's preferred construction, the device has more than one treatment mode that could be used to treat each specific heart condition (thus, multiple modes), but a single mode is selected from among the multiple possibilities and programmed as the individual mode that will treat a given arrhythmia. Such individually

selected modes, defendants argue, would not be executed in sequence and, thus, an "in sequence" limitation would be improper. *Id.* at 44-45 & n. 22.

St. Jude may well be correct that a single mode of treatment can be programmed to treat a given arrhythmia even though the device is capable of executing different modes to treat that same arrhythmia. However, this possibility is already accounted for in the claim language that refers to programming a device to undergo a "single" mode operation. Multi-mode operation, as taught by both the claim language and the specification, is different. It involves programming the device to *undertake* more than one treatment mode to treat a single arrhythmia, especially if the first mode is not successful. St. Jude's preferred construction would effectively re-write the language of the claim to read "a heart stimulator providing at least one treatment mode for each specific heart condition and capable of being programmed to undergo the single available mode, or, if applicable, one of the multiple available modes to treat the detected arrhythmia." That interpretation is contrary to the claim language and the written description.

St. Jude offers a proposed alternate construction in an attempt to save at least part of its preferred construction:

The phrase "multi-mode operation to treat a detected arrhythmia" as used in claim 1 of the '288 patent means two or more different modes of therapy capable of being used individually or together in sequence to treat a single arrhythmia.

Def. Br. at 41. The court rejects this construction because it is unnecessarily complex and confusing. The possibility that a device may offer more than one treatment mode for a single arrhythmia but may be programmed to undertake only one of those modes is accounted for by the fact that the claim language already allows a device to be programmed for single mode operation. Thus, St. Jude's construction of "multi-mode operation" to encompass two or more modes "capable of being used individually" repeats what is already stated in the claim.

St. Jude's final argument on this language is that it would be improper for the court to include the examples of treatment modes and heart conditions that plaintiffs have selected and included in their claim construction. The court agrees that using examples is unlikely to be necessary. By the end of the trial, the jurors should be able to identify for themselves (at least with the help of counsel) appropriate examples of treatment modes and different types of arrhythmia. The court, therefore, intends to adopt plaintiffs' proposed construction of "multi-mode operation" with the exception of the parenthetical examples. This interpretation of the language in the preamble of Claim 1 of the '288 patent will also apply to the disputed parallel language in the preamble of Claim 10 of the '288 patent.

B. '288 Claim 10: "determining means for determining the occurrence of one of a plurality of conditions of the heart"

The first apparatus element in Claim 10 identifies "determining means for determining the occurrence of one of a plurality of conditions of the heart." The parties agree that s. 112 para. 6 governs this language. They do not agree on the structures that perform the functions of detecting various heart conditions (*e.g.*, normal heart rhythm, ventricular fibrillation, low-rate tachycardia, and super-ventricular tachycardia) and distinguishing them from one another.

An understanding of two types of detection circuitry is essential background information to the parties'

dispute over the "determining means" element of the '288 patent. First, there is rate detection circuitry. A rate detector is capable of determining whether the heart rate is above or below a set threshold rate. Thus, if the threshold rate is set at 50 beats per minute, a rate circuit's output tells the device that the heart rate is either less than 50 beats per minute or greater than 50 beats per minute. It does not return an exact measurement of the heart rate. In other words, if the threshold rate is 50 beats per minute, the rate circuit cannot differentiate between 75, 100, or 200 beats per minute. It can only tell that the rate is greater than 50 beats per minute. Kroll Decl. para. 6. However, by using a combination of two or more rate detectors, a device can differentiate among various ranges of heart rates. For example, if one rate detector were set at 50 beats per minute and another at 150 beats per minute, one could determine when the heart rate is (1) less than 50 beats per minute, (2) between 50 and 150 beats per minute, or (3) greater than 150 beats per minute. The greater number of rate detectors used, the greater number of heart rate ranges that can be distinguished.

A second type of detection circuitry is based on probability density function (PDF) analysis of the ECG voltage. PDF circuitry determines the fraction of time, on the average, that the ECG signal spends between two amplitude limits. For a normal heart condition, the voltage stays near zero most of the time and jumps up only at the start of the heartbeat (seen as a blip on the patient monitor). When a heart is fibrillating, however, the voltage fluctuates chaotically between positive and negative extremes. The PDF circuitry essentially uses the PDF measurements to "profile" the condition of the heart. See Ex. 121, '493 Patent, col. 3, *ll.* 14-24 (discussed below); Kroll Decl. para. 4-6.

The diagrams and the written description of the '288 patent identify a "dedicated cardiac state evaluation circuit 34." '288 Patent, Fig. 2A, element 34; col. 9, *l.* 59 to col. 10, *l.* 18. Circuit 34 generates binary outputs which are then analyzed to determine the condition of the heart. Each combination and permutation of binary outputs corresponds to a particular heart condition. The device is programmed to associate each particular heart condition with a treatment regimen. It is possible to generate the binary outputs described in the specification using a combination of rate and PDF circuitry in circuit block 34. However, it is also possible to use multiple rate circuits, without any PDF circuitry, to detect the various heart arrhythmias. These alternative possible means for detecting the condition of the heart give rise to the parties' dispute over the "determining means" element.

St. Jude argues that the "determining means" of Claim 10 "requires a structure that utilizes, at least in part, a PDF analysis of the ECG signal for performing the function of determining the occurrence of one of a number of possible conditions of the patient's heart." Def. Br. at 53. This construction would exclude "determining means" based on the use of multiple rate detectors *without* PDF circuitry. St. Jude claims that this is the proper construction because the patent specification does not disclose that heart rate alone could be used. CPI contends that the structure corresponding to "determining means" is *either* rate detection circuitry *or* PDF circuitry. In CPI's view, the fact that the specification refers to each type of detection circuitry is more important than the fact that it also discloses them as being used together.

Under s. 112 para. 6, of course, the court or other readers must turn to the specification to learn what structure performs the function of determining the heart's condition. The critical section of the specification describes both the function and structure of the dedicated cardiac state evaluation circuit 34:

Dedicated cardiac state evaluation circuit 34 also generates, in response to detection of particular cardiac states, corresponding outputs indicating the occurrence of the particular state, that is to say, output FIB (indicating fibrillation), output TACHY (indicating tachycardia), and output BRADY (indicating bradycardia). The latter three outputs are provided to input selector 36.

More specifically, the dedicated cardiac state evaluation circuit 34 comprises *circuitry similar to the heart rate circuitry contained in the arrhythmia detection system disclosed in copending application Ser. No. 175,670 filed on Aug. 5, 1980 and fibrillation detection circuitry as in Pat. No. 4,184,493 of Langer et al.*

'288 Patent, col. 9, *l.* 59 to col. 10, *l.* 8 (emphasis added). The quoted excerpt, read in light of the two public documents incorporated by reference, shows that circuit block 34, the disclosed "determining means," uses both rate and PDF detection circuitry.

Patent application Ser. No. 175,670 was a parent application to Pat. No. 4,475,551 ("the '551 patent") and is incorporated by reference into the written description of circuit 34. The '551 patent discloses an arrhythmia detection system that uses rate detection circuitry in conjunction with PDF analysis to eliminate a problem with "false positives" that occurred when PDF analysis, used alone, failed to distinguish between fibrillation and high rate tachycardia, on the one hand, and low rate tachycardia, on the other hand. Ex. 122, '551 Patent, col. 2, *ll.* 24-40, 43-60. The false positives caused devices to deliver a defibrillating shock to the heart when it was not appropriate to do so. *Id.* The '551 patent discloses two specific types of rate detecting circuits. '551 Patent, Figs. 2 & 5. Used in conjunction with PDF circuitry, these rate circuits are designed to distinguish more accurately among various arrhythmias.

The second document incorporated by reference into the '288 description of circuit block 34 describes how PDF analysis is a superior means of detecting ventricular fibrillation. '493 Patent, col. 2, *l.* 67 to col. 3, *l.* 16 ("The inventive detector enjoys operation independent from the concepts of QRS detection and heart rate calculations to maximize accuracy.... The inventive [ventricular fibrillation] detector depends ... upon ... the principle of probability density function."). The '493 patent describes solely the use of PDF circuitry as a means of detecting ventricular fibrillation.

The significant point to draw from the '551 and '493 patents is that both documents disclose means for detecting arrhythmias that include the use of PDF circuitry. Neither discloses structure for detecting and differentiating among abnormal heart conditions *without* the use of PDF circuitry. That fact weighs in favor of a construction of "determining means" that requires PDF analysis, as St. Jude contends.

CPI counters with two arguments to bolster its favored construction of "determining means," which would allow for solely rate-based detection. CPI first contends that the '288 patent's reference to the rate detection circuitry disclosed in the '551 patent indicates that the inventors "disclosed multiple ways for achieving the results." However, the '551 patent contains no language suggesting either that PDF analysis is an optional component of the disclosed arrhythmia detection system, or that heart rate analysis is independently sufficient to perform the determining function. In fact, the '551 patent document refers to the inventive use of rate detection as "a 'backup' technique by means of which high rate tachycardia is treated by issuance of a defibrillating shock to the patient." '551 Patent, col. 2, *ll.* 37-40. In the two disclosed embodiments of the '551 patent, the rate circuits are shown to "backup" PDF circuits. '551 Patent, Figs. 1 & 4. Moreover, in describing the structure of dedicated cardiac state evaluation circuit 34, the '288 specification uses the conjunction "and" to state that circuit 34 comprises circuitry similar to both the '551 patent *and* the '493 patent. This language gives no indication that rate circuitry and PDF circuitry are interchangeable alternatives.

CPI's second argument is based on the prosecution history, including the fact that the patent examiner cited prior art that used rate detection circuitry and the fact that a patent term extension was granted based on a

device that uses rate-based detection. While the prosecution history supports CPI's argument that rate-based detection is part of the '288 patent's disclosed arrhythmia detection system, it is not sufficient to overcome the fact that the only structures disclosed in the '288 patent document also use PDF analysis. Having elected to phrase the claim in means-plus-function form, CPI cannot use the prosecution history to broaden the claim beyond what is disclosed in the specification.

The court intends to define the term "determining means," as used in Claim 10 of the '288 patent, as follows:

The '288 patent specification discloses a "dedicated cardiac state evaluation circuit 34" to perform the function of determining the occurrence of one of a plurality of conditions of the heart. The dedicated cardiac state evaluation circuit, in turn, is comprised of both heart rate circuitry and probability density function (PDF) circuitry. Therefore, "determining means" requires an arrhythmia detection structure that is identical or equivalent to the disclosed use of both heart rate circuitry and PDF circuitry.

The parties' dispute as to whether the disclosed structure either forecloses or allows an arrhythmia detection system that uses only rate-based circuits is an equivalency argument they will have to make to the finder of fact.

C. '288 Claim 10: "executing means for executing a sequence of events defined by said at least one mode of operation, whereby to treat said determined condition"

Both parties agree that s. 112 para. 6 controls this claim. The parties' dispute over "executing means" requires the court to identify the disclosed structure that performs the stated function of "executing a sequence of events defined by said at least one mode of operation, whereby to treat said determined condition."

The "executing" function occurs after the device has identified the arrhythmia that is present in the heart and after it has matched the arrhythmia to the appropriate treatment sequence. The various treatment sequences are stored as programs in program memory 44 and may involve a single-mode operation or a multi-mode operation. The patent specification indicates that microprocessor 40 "responds to successive op codes from the program memory 44 so as to execute the program corresponding to the desired treatment (pacing, cardioversion, defibrillation, and so forth)." '288 Patent, col. 12, ll. 61-65.

CPI argues that because microprocessor 40 executes the program corresponding to the desired treatment, microprocessor 40 is the structure associated with the "executing means" element. However, the claim language indicates that the structure executes a sequence of events "whereby to treat said determined condition." '288 Patent, col. 22, ll. 24-26. Thus, after the device has completed the executing function, the claim indicates that the heart should have received the treatment (if appropriate). Microprocessor 40 alone cannot perform the entire "executing" function as stated in the claim. It is part of the executing process, but additional structure is involved in executing the sequence of events defined by the selected mode (or modes) of operation.

"Output stage 22" is further structure disclosed in the specification that is essential to the "executing" function. '288 Patent, Figs. 1 & 5. Output stage 22 includes the following structure: inverter 62, pulse generator 64, atrial pacer drive circuit 66, ventricular pacer drive circuit 68, and patient warning circuit 70. '288 Patent, col. 17, ll. 12-16. Output stage 22 receives control outputs generated by, for example,

microprocessor 40, and responds by performing the tasks indicated by the control outputs. See, *e.g.*, '288 Patent, col. 17, *ll.* 17-32 (explaining how the output stage responds when it receives the "START DEFIB" signal generated by microprocessor 40); col. 10, *ll.* 36-54 (describing the sequence of events that is initiated in response to detection of a ventricular fibrillation condition). Because output stage 22 is structure necessary to perform the "executing" function stated in the claim, the court rejects CPI's proposed construction of this claim language.FN14

FN14. CPI's proposed construction is also faulty because it identifies only one of two microprocessors responsible for generating control outputs that control the release of energy into a patient's heart. The specification teaches a preference for the use of dual processors for executing various treatment programs. '288 Patent, col. 4, *l.* 3 to col. 5, *l.* 9. Thus, microprocessor 40 has a counterpart, microprocessor 56. Microprocessor 40 generates control outputs such as "START DEFIB" (indicating the need for defibrillation), "AP1" (indicating the need for atrial pacing), and "VEP1" (indicating the need for ventricular pacing). '288 Patent, col. 14, *l.* 59 to col. 15, *l.* 10. Microprocessor 56 generates outputs including "AP2" (indicating the need for atrial pacing) and "VP2" (indicating the need for ventricular pacing). '288 Patent, col. 15, *ll.* 61-68. Which element controls the atrial or ventricular pacing depends on the particular type of pacing to be performed. As explained in the specification:
[T]he microprocessor 40 (FIG.3A) operates in conjunction with the output latch 52 to implement atrial and ventricular pacing involving long-term, relatively simple procedures. Conversely, the microprocessor 56 (FIG.4) handles atrial and ventricular pacing involving short-term, relatively more complicated procedures.

'288 Patent, col. 17, *l.* 59 to col. 18, *l.* 5.

St. Jude's proposed construction of this element reads as follows:

The "executing means" of claim 10 of the '288 patent requires the execution of a sequence of events defined by the selected mode of operation without regard to the patient's history and includes the acts of charging a capacitor from an energy source, such as a battery, and applying the accumulated charge to the patient's heart in order to treat the determined heart condition.

Def. Br. at 54. The court rejects this construction for three reasons. First, it fails to link the function stated in the claim with its associated structure as disclosed in the specification, which is the point of interpretation under s. 112 para. 6. Rather than defining the structure, St. Jude's construction focuses on acts-a construction more appropriate for a method claim. Second, the phrase "without regard to the patient's history" adds a limitation that is unrelated to the "executing means" element. As the claim language itself indicates, selecting the appropriate treatment and the criteria upon which that decision is based is a function separate from executing the treatment thereby selected. Third, the claim language does not limit the "sequence of events" performed in the executing stage to the steps of charging a capacitor and applying the charge to the heart. Executing the mode (or modes) of operation identified with a particular detected heart condition may involve more than the ultimate event of applying a charge to the heart. For example, the specification indicates that when the device detects ventricular fibrillation, one of the events that is performed prior to applying a defibrillating shock to the heart is that the pacing circuits are shut down. '288 Patent, col. 10, *ll.* 36-54.

The court intends to define the "executing means" element of Claim 10 by explaining the recited function and by identifying the structure that the specification associates with that function:

The function of the "executing means" in Claim 10 of the '288 patent is to perform the sequence of events associated with each mode of operation that has been selected to treat the identified arrhythmia.

The "executing means" disclosed in the '288 patent are the following structures: (1) the microprocessors and associated circuitry that translate programming associated with the desired treatment into output command signals, and (2) the structures comprising output stage 22 that respond to the command signals and perform the desired treatment, as diagramed in Figure 5 of the '288 patent and described in the specification.

The accused devices infringe the "executing means" element if they include identical or equivalent structure for performing the stated function.

D. '288 Claim 1: "determining a condition of the heart from among a plurality of conditions of the heart"

Returning now to Claim 1 of the '288 patent, the first method step recited is the step of "determining a condition of the heart from among a plurality of conditions of the heart." The court must determine whether s. 112 para. 6 applies to this method step, and if so, whether the specification limits the claim to determining the condition of the heart by using, at least in part, probability density function (PDF) analysis of the ECG signal. The court finds that s. 112 para. 6 controls this claim element and that the element is limited to detecting and distinguishing among arrhythmias by analyzing the outputs of rate circuitry and PDF circuitry.

CPI argues that because Claim 1 of the '288 patent uses "steps of" rather than "steps for" to introduce the three recited method steps, there is a presumption that s. 112 para. 6 does not apply. See *SealFlex*, 172 F.3d at 850 (Rader, J., concurring). CPI further contends that the language of the "determining" claim element recites an act and not a function. The court does not agree.

The claim element uses extremely broad language. A simple question arises: If the step of "determining a condition of the heart" is not limited by the disclosures, how is it limited at all? CPI asserts in its brief: "The step of 'determining a condition of the heart' carries no limitations in the claim language as to the manner or way in which the condition is detected, and none can be properly read into the claim language." Pl. Br. at 22. However, allowing CPI to claim all possible methods of detecting heart arrhythmia sweeps too broadly. The court is mindful that not all claims using gerunds should be construed as functions. Nonetheless, comparing the "determining step" at issue here to the claim elements that avoided s. 112 para. 6 in *O.I. Corp. v. Tekmar Co.* and *Serrano v. Telular Corp.*, the court finds that CPI needed to remove at least one level of abstraction from its claim. For example, if the step were phrased in terms of "determining a condition of the heart by analyzing the output signals generated by heart status detection circuitry to distinguish among various conditions of the heart," the element would come much closer to stating *how* the function of determining a condition of the heart is performed. Although patentees may wish to state claims as broadly as possible, they run the danger of reaching the boundaries established by s. 112 para. 6. "Determining a condition of the heart" crosses the line.

The court intends to construe the claim element as follows: " 'Determining a condition of the heart from among a plurality of conditions of the heart' means detecting the current condition of the heart and differentiating among various arrhythmias by analyzing the outputs generated by a cardiac state evaluation circuit comprising heart rate circuitry and PDF circuitry." CPI is free to pursue as an equivalency argument its contention that a person of skill in the art would "know that evaluation circuit 34, broadly described in the '288 patent, could be configured to provide the FIB, TACHY and BRADY outputs without using PDF."

See Pl. Reply Br. at 17.

E. '288 Claim 1: "*selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition*"

The second step recited in Claim 1 is the step of "selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition." St. Jude contends that the claim language dictates the following limitation:

The step of "selecting at least one mode ... [corresponding] to said determined condition" of claim 1 of the '288 patent requires that the selection of a mode of operation be based on the currently determined condition of the heart without regard to any previously determined condition of the heart.

Def. Prop. Conc. of Law at 9. CPI contends that the "selecting step" is an act, not a function, and that St. Jude's proposed narrowing limitation is not warranted by the language of the claim.

St. Jude's proposed construction of the claim language is derived from the decision criteria involved in "selecting at least one mode of operation." According to St. Jude, the '288 patent "discloses a system in which the treatment mode is totally independent of history and is a function only of the current detected condition." Def. Br. at 52.FN15 The court agrees with St. Jude's contention that the currently determined condition of the heart is the only variable that affects the step of "selecting."

FN15. St. Jude bases its construction of the "selecting" element primarily on an amendment to the claim language made during the prosecution of the patent that added the phrase "unique sequence of events." See Def. Br. at 51-52, citing Ex. 123, '288 Pros. Hist., at 2, 8-9. The court does not fully agree with St. Jude's analysis of the prosecution history. Had the claim language or the written description suggested that the step of "selecting at least one mode" was a function of a variable in addition to the determined condition of the heart, the phrase "unique sequence of events" would not limit the claim as suggested by St. Jude.

The language of the "selecting" step states that the device selects an operation (consisting of at least one mode) "corresponding to said determined condition" of the heart. The phrase "corresponding to" does not by itself foreclose the possibility that the device considers variables in addition to the currently determined condition of the heart. However, the remainder of the claim language and the written description indicate that "corresponding to" should be interpreted to indicate that the selection of an operation is based solely on the currently determined condition of the heart.

First, the claim language states that the selected operation corresponds to "said determined condition." The determined condition, as defined through the determining step in Claim 1, is the result of an evaluation of the current condition of the heart. The evaluation process involves using rate and PDF circuitry to detect the presence of various arrhythmias and to differentiate those arrhythmias from one another. Nothing other than assessing the current condition of the heart is involved in the determining step.

Second, the written description explains how the selecting step is accomplished without ever suggesting that any additional variable affects the selection process. The "at least one mode of operation" is selected by matching the output of the "determining" step (*i.e.*, a current heart condition in need of treatment) to the corresponding treatment. In greater detail, the matching process involves programming the device so that a

particular treatment, consisting of one or more modes, is associated with each detected heart condition. A section of program memory contains the instructions for carrying out the sequence of events necessary to execute each treatment operation. Then, when a particular heart condition is detected, the device selects the proper set of instructions (*i.e.*, the unique sequence of events of the treatment operation) by matching the determined heart condition to the area of the program memory that contains the program for treating that heart condition. ' 288 Patent, col. 12, *ll.* 11-65; Fig. 3B. At the step of selecting the treatment mode, the only relevant variable is the currently determined heart condition.

In summary, if the patentee intended to claim a method of selection involving criteria other than the currently determined condition of the heart, the claim language and the patent specification fail to provide adequate notice of this intent. See *Athletic Alternatives, Inc. v. Prince Manufacturing, Inc.*, 73 F.3d 1573, 1581 (Fed.Cir.1996) ("Where there is an equal choice between a broader and narrower meaning of a claim, ... we consider the notice function of the claim to be best served by adopting the narrower meaning."). The court intends to define the "selecting" step in method Claim 1 as follows:

The step of "selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition" involves matching the currently determined heart condition to the unique set of instructions that have been programmed to treat the detected condition. The treatment operation selected by the device is determined exclusively by the currently determined condition of the heart.FN16

FN16. The court acknowledges that the physician may consider factors other than the currently determined condition of the heart when programming a device. However, at the point where a device *itself* detects an arrhythmia and selects a treatment mode to execute, no other variables are at work.

F. '288 Claim 1: "*executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.*"

The last claim element in need of construction is the step of "executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition." St. Jude asserts that the claim is stated in functional language subject to s. 112 para. 6 and provides the following proposed construction:

The step of "executing said at least one mode ... [to] treat said determined heart condition" of claim 1 of the '288 patent requires that a capacitor be charged from an energy source, such as a battery, with the accumulated charge then applied to the patient's heart in order to treat the determined heart condition.

Def. Prop. Conc. of Law at 9. CPI contends that the "executing" element of Claim 1 is not subject to the step-plus-function rules of construction and that the step should be construed to mean "performing the programmed operation for the particular detected heart arrhythmia in order to treat it." Pl. Prop. Conc. of Law at 3.

Regardless of whether this claim element is treated as an act or a function, the court finds that defendants' proposed construction portrays an incomplete picture of the executing process by placing undue emphasis on the acts of charging a capacitor and applying the charge to the heart. As explained in the discussion of Claim 10, the executing process involves executing the program corresponding to the desired treatment.

Several discrete events often make up the entire treatment operation. For example, the specification explains in detail all of the steps involved in executing the treatment associated with ventricular fibrillation. In addition to building up a charge and issuing a shock to the patient's heart, the device shuts down the pacing circuits, checks the treatment parameters stored in a parameter memory, and determines whether or not the pulse generator is synchronized. See '288 Patent, col. 10, ll. 37-63.

Because the step of "executing said at least one mode of operation" involves performing multiple events which differ from one treatment mode to the next, the court does not find it appropriate to catalogue all possible events, or some subset of events, that are part of the "executing" process. Neither the claim language nor the specification emphasizes particular events over others. The material aspect of the executing step is that the device performs the programmed operation that was specifically selected to treat the determined condition of the heart. By executing the appropriate programmed operation, the device treats the heart.

Assuming that s. 112 para. 6 governs this element, the court is required to specify the disclosed act (or acts) that performs the step of "executing said at least one mode of operation." CPI's proposed construction adequately defines the disclosed act. Therefore, the court intends to interpret the executing step as follows:

"Executing said at least one mode of operation" means performing the programmed operation that has been designated to correspond to the particular heart arrhythmia in order to treat it.

This construction adequately indicates that "said at least one mode of operation" is executed by performing the programmed sequence of events associated with the selected operation.

Conclusion

The court intends to interpret the disputed elements of the '472, '191, and ' 288 patents as indicated in this Entry. Date: November 29, 2000

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