IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION

Petitioner

v.

UAB RESEARCH FOUNDATION

Patent Owner

Patent No. 6,266,563
Filing Date: September 7, 1999
Issue Date: July 24, 2001

Title: METHOD AND APPARATUS FOR TREATING CARDIAC ARRHYTHMIA

Inter Partes Review No.: Unassigned

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.*

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Exhibit 1051:	C. Leclercq et al., *A Pilot Experience with Permanent Biventricular Pacing to Treat Advanced Heart Failure*, Am. Heart J. 140:862–870 (2000)
Exhibit 1052:	U.S. Patent No. 6,240,313, filed on April 19, 1999, and issued to Esler et al. on May 29, 2001 ("'313 Patent")

Boston Scientific Corporation ("Boston Scientific" or "Petitioner") hereby petitions for *inter partes* review pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.* of claims 1-20 of U.S. Patent No. 6,266,563 ("the '563 Patent"), attached hereto as Exhibit 1001.

I. MANDATORY NOTICES PURSUANT TO 37 C.F.R. § 42.8(a)(1)

A. 37 C.F.R. § 42.8(b)(1): Real Parties in Interest

Boston Scientific Corporation and Cardiac Pacemakers Inc. are the real parties-in-interest for this Petition ("Petition").

B. 37 C.F.R. § 42.8(b)(2): Related Matters

The '563 Patent is currently the subject of a patent infringement lawsuit against Petitioner, captioned *The Board of Trustees of the University of Alabama at Birmingham & UAB Research Foundation v. Boston Scientific Corp. & Cardiac Pacemakers Inc.*, U.S. District Court for the Northern District of Alabama, Case No. 2:14-cv-01800, which was filed on September 22, 2014. Boston Scientific was served with the Complaint on September 29, 2014. This judicial matter may affect, or be affected by, decisions made in this proceeding.

C. 37 C.F.R. § 42.8(b)(3) and (4) and § 42.10(b): Lead and Back-Up Counsel, Service Information, Request to File Motion to Admit Counsel *Pro Hac Vice*, and Power of Attorney

Petitioner designates the following counsel at the addresses shown below and consents to electronic service at the email addresses below. A power of

attorney designating counsel is being filed with this Petition. Petitioner requests authorization to file a motion for additional Back-Up Counsel, who are substantially involved in and familiar with the matters in this Petition, to appear *pro hac vice*. Petitioner will file such a motion upon the granting of this request.

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II. COMPLIANCE WITH THE REQUIREMENTS FOR A PETITION FOR *INTER PARTES* REVIEW

A. Payment of Fees Pursuant to 37 C.F.R. § 42.103

The undersigned authorizes the Commissioner to charge the $9,000 request fee, $14,000 post-institution fee, and $2,000 excess claim fee (total of $25,000) to Deposit Account No. 060029 for the fee required for this Petition as set forth in 37 C.F.R. § 42.15(a) along with any additional fees that may be required.

B. Grounds for Standing Pursuant to 37 C.F.R. § 42.104(a)

Petitioner hereby certifies that the '563 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging claims 1-20 on the grounds identified in this Petition. Petitioner also states that, to the extent Patent Owner tries to raise an issue of assignor estoppel, the doctrine of assignor estoppel does not apply or otherwise preclude Petitioner from requesting *inter partes* review. *See, e.g.*, *Ariosa Diagnostics, Inc. v. Illumina, Inc.*, IPR2014-01093, slip op. at 11-12 (PTAB Jan. 8, 2015) (Paper 14) ("35 U.S.C. § 311(a) states that 'a person *who is not the owner of a patent* may file with the Office a petition to institute inter partes review of the patent.'") (citing *Redline Detection, LLC v. STAR EnviroTech, Inc.*, IPR2013-00106, slip. op. at 4-5 (PTAB Aug. 27, 2013) (Paper 31) (emphasis in original)); *Synopsys, Inc. v. Mentor Graphics Corp.*, IPR2012-00042, slip op. at 16-17 (PTAB Feb. 19, 2014) (Paper No. 60) ("[A]ssignor estoppel is not a basis for denying a petition requesting *inter partes* review."); *Athena Automation Ltd. v. Husky Injection Molding Sys. Ltd.*, IPR2013-00290, slip op. at 12-13 (PTAB Oct. 25, 2013) (Paper No. 18) ("[A]n assignor of a patent, who is no longer an owner of the patent at the time of filing, may file a petition requesting *inter partes* review.").

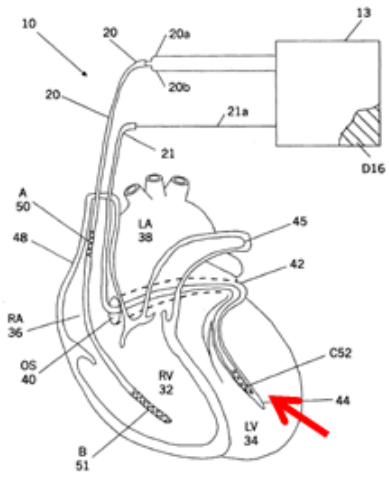
III. THE ’563 PATENT

The claims of the ’563 Patent are directed to “[a]n implantable system for the delivery of antitachycardia pacing to a patient’s heart.” (Ex. 1001, cls. 1, 7, 14; *see also* Abstract.) Each of the ’563 Patent’s independent claims also requires an electrode “configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart.” (*Id.*) Independent claim 1 is representative of the claimed invention and claims:

> An implantable system for the delivery of antitachycardia pacing to a patient’s heart, comprising:
>
> [1] a plurality of primary stimulation electrodes configured for sensing cardice [sic] signals and delivering antitachycardia pacing to said heart;
>
> [2] a first one of said primary stimulation electrodes configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart;
>
> [3] a power supply; and
>
> [4] a control circuit operatively associated with said power supply and said primary stimulation electrodes, said control circuit configured for delivering antitachycardia pacing through said primary stimulation electrodes;
>
> [5] wherein said control circuit includes a capacitor.

"Various embodiments of the present invention can be illustrated with reference to FIG. 1." (*Id.* at 6:42-43.) Figure 1 from the '563 Patent "illustrates a preferred set of electrode placements in an apparatus for carrying out the present invention." (*Id.* at 5:19-20.) "The system includes a first catheter 20 and a second catheter 21, both of which are insertable into the heart (typically through the superior or inferior vena cava) without the need for surgical incision into the heart." (*Id.* at 6:55-61.) The preferred embodiment illustrated in Figure 1 is a system with multiple electrode placements: "As illustrated in FIG. 1, the system includes an electrode A [50] that resides in the superior vena cava or innominate vein, an electrode B [51] positioned in the right ventricle, and an electrode C [52] positioned within a vein on the posterolateral surface of the left ventricle (e.g., in the apical third of the posterior cardiac vein or the apical half of the great cardiac vein)." (*Id.* at 6:62-7:1.) Figure 1 is shown on the right, with an arrow pointing to electrode C positioned within a vein on the surface of the left ventricle.

FIG. 1



As explained by the '563 Patent, this preferred embodiment allows for delivery of antitachycardia pacing ("ATP"), including to the left ventricle, without "requir[ing] invasion of the chest cavity for the placement of epicardial

electrodes." (*Id.* at 3:47-51.) The '563 Patent does not define antitachycardia pacing, describe specific methods of antitachycardia pacing, or describe how to deliver antitachycardia pacing. (Ex. 1006, ¶ 108.) The '563 Patent also does not provide any details on how to position a transvenous lead and electrodes through the coronary sinus to its tributaries on the left ventricle of the heart. (*Id.*, ¶ 109.)

IV. IDENTIFICATION OF CHALLENGE PURSUANT TO 37 C.F.R. § 42.104(b) AND STATEMENT OF THE RELIEF REQUESTED

A. 37 C.F.R. § 42.104(b)(1) and (2): Claims for Which Review Is Requested and Ground(s) on Which the Challenge Is Based

Petitioner respectfully requests *inter partes* review and cancellation of claims 1-20 of the '563 Patent based on the statutory ground and prior art reference set forth in the following table:

Claim(s)	Basis	Reference
1-20	35 U.S.C. § 102(b)	U.S. Patent No. 5,797,967 (KenKnight '967)

B. 37 C.F.R. § 42.104(b)(3): How the Challenged Claims Are to Be Construed and the Level of Ordinary Skill in the Art

1. How the Challenged Claims Are to Be Construed

An unexpired claim subject to *inter partes* review "shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). For purposes of this proceeding, claim terms are presumed to have their broadest reasonable constructions. The specific claim

constructions proposed by Petitioner are listed in the table below and addressed in detail in Section VII.

Limitation	Proposed Construction
"antitachycardia pacing" (Claims 1, 2, 7, 8, 14, 15)	pacing pulses in response to tachycardia (*See, e.g.*, Ex. 1001, 3:63-4:3; 7:23-30; Ex. 1006, ¶¶ 56-65, 199, 201-203)
"control circuit" (Claims 1, 7, 14)	a group of electrically connected components that includes a controller (*See, e.g.*, Ex. 1001, Fig. 2; 5:22-24; 7:23-56; 7:57-58; 9:23-27; Ex. 1006, ¶¶ 199, 234-236)

2. The Level of Ordinary Skill in the Art

The relevant field of the invention of the '563 Patent is the field of cardiac pacing systems. (Ex. 1006, ¶ 12.) A person of ordinary skill in this field would have been either:

- A physician or surgeon trained in cardiology or cardiovascular surgery, who has implanted a substantial number (*e.g.*, at least 20) of cardiac pacemakers or defibrillators, and who, as a part of his or her regular medical practice, studied pacemaker technology and was familiar with the implantation of pacemakers and the placement of leads; or

- An engineer or scientist who has designed and been associated with the building of implantable cardiac pacing or defibrillator systems and leads, and who has participated in or attended the implantation of at least 5 cardiac pacing systems (including pacemakers and/or defibrillators and leads), and who was familiar with cardiac ventricular and venous anatomy as a result of this clinical exposure and anatomical study. (*Id.,* ¶¶ 13-14.)

C. 37 C.F.R. § 42.104(b)(4): How the Construed Claims Are Unpatentable Under the Statutory Grounds Identified

Claims 1-20 of the '563 Patent are unpatentable under 35 U.S.C. § 102(b) because each claim is anticipated by U.S. Patent No. 5,797,967 ("KenKnight '967"). A detailed explanation of the reasons KenKnight '967 anticipates each claim, including identification of where each limitation of claims 1-20 is disclosed by the reference, is provided in Section VII below.

D. 37 C.F.R. § 42.104(b)(5): Evidence Supporting Petitioner's Challenge

A List of Exhibits supporting this Petition is included after the table of authorities. This includes a Declaration of Dr. David G. Benditt in support of this Petition in accordance with 37 C.F.R. § 1.68 (Ex. 1006). Dr. Benditt has over 35 years of experience in the field of cardiac pacing systems. (Ex. 1006, ¶¶ 3-6, Ex. 1007.) His declaration provides evidence of, among other things, relevant technical background (Ex. 1006, ¶¶ 15-103), level of skill in the art (*id.*, ¶¶ 12-14),

description and priority date of the '563 Patent (*id.*, ¶¶ 104-185), scope and content of the prior art reference (*id.*, ¶¶ 186-199), and a detailed explanation of why all claims of the '563 Patent are anticipated by KenKnight '967 (*id.*, ¶¶ 200-326).

V. ALL OF THE CHALLENGED CLAIMS INCLUDE NEW SUBJECT MATTER AND ARE THEREFORE NOT ENTITLED TO RELY ON ANY FILING DATE EARLIER THAN SEPTEMBER 7, 1999

The claims of the '563 Patent all require "antitachycardia pacing." The patentee disclosed "antitachycardia pacing" as part of the invention for the first time in the Application for the '563 Patent, which was filed on September 7, 1999, as a continuation-in-part of U.S. Patent No. 5,978,705 ("the '705 Patent" (Ex. 1004)), filed on March 13, 1998, and U.S. Application No. 08/818,261 ("the '261 Application" (Ex. 1002)), filed on March 14, 1997. The claims of the '563 Patent are not entitled to rely on the filing dates of these ancestral applications.

Under 35 U.S.C. § 120, for a claim in a later application to be entitled to rely on the filing date of an earlier application, the earlier application must contain a disclosure that complies with 35 U.S.C. § 112, ¶ 1. Section 112, paragraph 1 requires that the specification "contain a written description of the invention, including the manner and process of making and using it." A priority application must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). "Obviousness simply is not

enough; the subject matter must be disclosed to establish possession." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1310 (Fed. Cir. 2008). Thus, subject matter that appears for the first time in a continuation-in-part cannot rely on the filing date of an earlier application. *Id.* at 1306.

Here, the '563 Patent is directed to "[a]n implantable system for the delivery of antitachycardia pacing to a patient's heart." (Ex. 1001, cls. 1, 7, 14; *see also* Abstract.) Each claim of the '563 Patent requires a "control circuit configured for delivering antitachycardia pacing." (*Id.* at cls. 1-20.) "Antitachycardia pacing" is the delivery of pacing pulses in response to tachycardia. (*See supra* Part IV(B)(1); *see also* Ex. 1006, ¶¶ 56-65, 199, 201-203.) Pacing pulses used in antitachycardia pacing have a well-understood meaning in the art and deliver energy on the order of microjoules, or 10^{-6} (0.000001) Joules. (*See* Ex. 1006, ¶¶ 66-67.)

The first time the inventors described or otherwise disclosed a system for "delivery of antitachycardia pacing" or a "control circuit configured for delivering antitachycardia pacing" was in the '563 Patent filed on September 7, 1999. (Ex. 1006, ¶¶ 118-185.) Indeed, the previous '261 Application and '705 Patent do not so much as mention "antitachycardia pacing" or a "control circuit configured for delivering antitachycardia pacing," as required by every claim of the '563 Patent. (*See, e.g.*, Ex. 1001, cls. 1, 7, 14.) The '563 Patent is therefore not entitled to any filing date earlier than September 7, 1999.

A. The ’261 Application—Filed on March 14, 1997—Is Directed to Defibrillation and Cardioversion and Does Not Disclose Antitachycardia Pacing

As explained by Dr. Benditt, the ’261 Application does not even mention the term “antitachycardia pacing” and does not disclose a “control circuit configured for delivering antitachycardia pacing.” (Ex. 1006, ¶¶ 118-185.) A person of ordinary skill in the art would have understood the ’261 Application to disclose a device for delivering only defibrillation pulses and auxiliary pulses for the purpose of cardioversion or defibrillation. (*Id.*, ¶¶ 125-156.) Cardioversion and defibrillation therapies require much higher energy than antitachycardia pacing therapies. (*Id.*, ¶ 123.) In addition, one of ordinary skill would not have attempted antitachycardia pacing with a cardioversion or defibrillation pulse, as the energy delivered by cardioversion and defibrillation pulses are orders of magnitude higher than the energy delivered by pacing pulses. (*See id.*, ¶ 124.) In short, a person of ordinary skill would have understood that cardioversion and defibrillation therapies are distinct from antitachycardia pacing therapy. (*Id.*, ¶¶ 42, 66-67, 123-124.)

The ’261 Application distinguishes “defibrillation” pulses and “auxiliary” pulses from “pacing” pulses. (*Id.*, ¶¶ 130-133.) The ’261 Application explains that “the auxiliary pulse . . . is of a magnitude greater than pacing pulses, but less than a defibrillation pulse.” (Ex. 1002, 12:35-37.) Dr. Benditt also explains that the smallest defibrillation pulse disclosed in the ’261 Application (5 Joules) is many

magnitudes stronger than the pacing pulses used in antitachycardia pacing therapy. (Ex. 1006, ¶ 131; *see also* Ex. 1002, 12:31-32 ("The energy of the defibrillation pulse may be from 5 to 10 Joules or 30, 40 or 50 Joules.").) And the smallest auxiliary pulse disclosed in the '261 Application (.01 Joules) is still approximately ten thousand times stronger than the pacing pulses used in antitachycardia pacing therapy. (Ex. 1006, ¶ 132; *see also* Ex. 1002, 12:29-31 ("The energy of the auxiliary pulse may be from .01 or .05 Joules to 1 or 2 Joules.").) No one of skill in the art, therefore, would have understood the disclosure of defibrillation pulses or auxiliary pulses to include the delivery of pacing pulses in response to tachycardia—*i.e.*, antitachycardia pacing. (*See* Ex. 1006, ¶¶ 133, 156.)

As explained by Dr. Benditt, all of the embodiments and examples in the '261 Application are for defibrillation/cardioversion using defibrillation and auxiliary pulses. (*See id.*, ¶¶ 125-156.) All of the embodiments in the '261 Application describe the use of a "primary electrode" for delivering "defibrillation pulses" (also referred to in the Application as "primary pulses") and an "auxiliary electrode" for delivering "auxiliary pulses." (*See id.*; Ex. 1002, Tbls. 1-4.)

In connection with Table 3, the '261 Application discloses a "pace/sense electrode" positioned in the right atrial appendage or the right ventricular outflow track to "sens[e]" and "monitor" atrial activity. (Ex. 1002, 15:3-9; 15:19-20; 15:23-27; 16:2-3; *see also id.* at Figs. 5 & 6.) Pace/sense electrodes were well-

known and common electrical components used in many implantable cardiac systems. (Ex. 1006, ¶ 149.) The '261 Application states that the pace/sense electrodes are for "monitor[ing] electrical rhythm activity in both atrial and ventricular chambers." (Ex. 1002, 16:1-4; Ex. 1006, ¶¶ 147-149.) The '261 Application does not suggest that antitachycardia pacing is applied using the pace/sense electrode or that a control circuit is configured for delivering antitachycardia pacing. (Ex. 1002, 16:1-4; Ex. 1006, ¶¶ 147-149.) Accordingly, a person of ordinary skill in the art would not have understood this general disclosure of a common electrical component used for the purpose of sensing or monitoring cardiac rhythm to disclose a device for delivering pacing pulses in response to tachycardia—*i.e.*, antitachycardia pacing. (Ex. 1006, ¶ 149.)

B. The '705 Patent and Its Application—Filed on March 13, 1998—Are Also Directed to Defibrillation and Cardioversion and Do Not Disclose Antitachycardia Pacing

The disclosures of the '705 Patent and its associated application are similar to that of the '261 Application, and none mentions the term "antitachycardia pacing" or disclose a "control circuit configured for delivering antitachycardia pacing." (*See* Ex. 1006, ¶ 158.) Like the '261 Application, the '705 Patent and its Application disclose only defibrillation pulses and auxiliary pulses. (*See id.*, ¶¶ 157-177.) Accordingly, for the same reasons discussed above, a person of ordinary skill in the art would not have understood the '705 Patent or its Application to

include antitachycardia pacing. (*See id.*, ¶ 177.)

C. The '563 Patent Added New Subject Matter Directed to Antitachycardia Pacing and Is Not Entitled to Rely on a Filing Date Earlier than Its September 7, 1999 Filing Date

The '563 Patent, as a continuation in part of the '705 Patent and '261 Application, is the first time the inventors introduced the concept of an invention using "antitachycardia pacing " and a "control circuit configured for delivering antitachycardia pacing." (*See id.*, ¶¶ 178-185.) All of the new matter in the '563 Patent is directed to antitachycardia pacing.

The following table compares the relevant excerpts from the '705 Patent with the new matter added in the '563 Patent. Any subject matter from the '705 Patent that was removed in the '563 Patent is shown with a strikethrough and any new subject matter in the '563 Patent is shown with underlining (*see id.,* ¶ 180):

Language in '705 Patent	New Subject Matter in '563 Patent
"Method and Apparatus for Treating Cardiac Arrhythmia Using Auxiliary Pulse." (Ex. 1004, Title)	"Method and Apparatus for Treating Cardiac Arrhythmia ~~Using Auxiliary Pulse~~." (Ex. 1001, Title)
"An implantable system for the defibrillation or cardioversion of the heart of a patient in need of such	"An implantable system for the ~~defibrillation or cardioversion~~ antitachycardia pacing of the heart of a

treatment comprises a plurality of primary electrodes, a power supply, and a control circuit. Preferably, at least one auxiliary electrode is also included. The plurality of primary electrodes are configured for delivering a defibrillation pulse along a predetermined current pathway in a first portion of the heart, the current pathway defining a weak field area in a second portion of the heart. The at least one auxiliary electrode is configured for delivering an auxiliary pulse to the a [sic] portion of the heart where the primary shock field intensity is at or near a minimum. The control circuit is operatively associated with the primary electrodes, the auxiliary electrode, and the power supply,	patient in need of such treatment comprises a plurality of primary electrodes, a power supply, and a control circuit. ~~Preferably,~~ At least one ~~auxiliary electrode is also included. The plurality~~ of the primary electrodes ~~are~~ is configured for positioning through the coronary sinus ostium and in a vein on the left surface of the patient's heart. ~~delivering a defibrillation pulse along a predetermined current pathway in a first portion of the heart, the current pathway defining a weak field area in a second portion of the heart. The at least one auxiliary electrode is configured for delivering an auxiliary pulse to the a [sic] portion of the heart where the primary shock field intensity is at or near a minimum. The control circuit is operatively associated with the primary~~

with the control circuit configured for delivering a cardioversion sequence comprising an auxiliary pulse sufficient to induce a cessation of the propagation in the weak field area through the auxiliary electrode, followed by a defibrillation pulse through the primary electrodes delivered during the cessation of propagation in the weak field area." (Ex. 1004, Abstract.)	~~electrodes, the auxiliary electrode, and the power supply, with the control circuit configured for delivering a cardioversion sequence comprising an auxiliary pulse sufficient to induce a cessation of the propagation in the weak field area through the auxiliary electrode, followed by a defibrillation pulse through the primary electrodes delivered during the cessation of propagation in the weak field area.~~" (Ex. 1001, Abstract.)
"A first aspect of the present invention is an implantable system for the defibrillation or cardioversion of a patient's heart." (Ex. 1004, 3:62-64.)	"A first aspect of the present invention is an implantable system for the defibrillation or cardioversion of a patient's heart<u>, or the administration of antitachycardia pacing to a patient's heart</u>." (Ex. 1001, 3:63-66.)
"The plurality of primary electrodes are configured for delivering a	"The plurality of primary electrodes are configured for delivering a defibrillation

defibrillation pulse along a predetermined current pathway in a first portion of the heart, with a first one of the primary electrodes configured for positioning through the coronary sinus and within a vein on the surface of the left ventricle of the heart." (Ex. 1004, 3:65-4:4.)	pulse, cardioversion pulse, or antitachycardia pacing along a predetermined current pathway in a first portion of the heart, with a first one of the primary electrodes configured for positioning through the coronary sinus and within a vein on the surface of the left ventricle of the heart." (Ex. 1001, 3:67-4:6.)
"The present invention may be used to treat all forms of cardiac tachyarrhythmias, including ventricular fibrillation, with defibrillation (including cardioversion) shocks or pulses." (Ex. 1004, 5:63-66.)	"The present invention may be used to treat all forms of cardiac tachyarrhythmias, including ventricular fibrillation, with defibrillation (including cardioversion) shocks or pulses, including antitachycardia pacing." (Ex. 1001, 5:66-6:2.)
No disclosure	"The antitachycardia pacing may be delivered from the primary electrode placed through the coronary sinus ostium

	and within a vein on the surface of the left ventricle alone, or may be coupled to or yolked [sic] to an additional electrode, such as an electrode positioned in the right ventricle. An independent right ventricle may be provided as an alternate source of antitachycardiapacing [sic], based on the origin of the trigger and cross-channel syntactic patterns. Antitachycardia pacing may be delivered from the right ventricle and then the left ventricle electrode, or may be delivered from the left ventricle and then the right ventricle electrode." (Ex.1001, 6:5-15.)

As described in Dr. Benditt's declaration, after reading the '261 Application, the '705 Patent and its application, and the '563 Patent, a person of ordinary skill in the art would have understood that the September 7, 1999, Application for the '563 Patent constituted the first time the inventors described and disclosed using antitachycardia pacing, including a control circuit configured for delivering antitachycardia pacing. (Ex. 1006, ¶¶ 178-185.) Accordingly, none of the claims

of the ’563 Patent are entitled to rely on a filing date earlier than September 7, 1999. (*See id.*, ¶¶ 118-185.)

VI. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A Petition for *inter partes* review must demonstrate “a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition.” 35 U.S.C. § 314(a). This Petition meets that threshold because, as detailed in Section VII below, each and every limitation of the ’563 Patent is found in U.S. Patent No. 5,797,967 (“KenKnight ’967”). 35 U.S.C. § 102(b).

KenKnight ’967 was filed on September 27, 1996, and issued on August 25, 1998, more than a year before the September 7, 1999 filing date of the ’563 Patent. The sole inventor is Bruce KenKnight, who is also a named inventor on the ’563 Patent. Because KenKnight ’967 issued on August 25, 1998, more than a year before the filing date of ‘563 Patent, and because the ’563 Patent is not entitled to rely on the filing dates of ancestral applications, KenKnight ’967 is § 102(b) prior art. KenKnight ’967 was also not disclosed to or considered by the Examiner during prosecution of the ’563 Patent. (*See* Ex. 1005.)

Petitioner respectfully submits that claims 1-20 are unpatentable under 35 U.S.C. § 102(b) because they are anticipated by KenKnight ’967.

VII. SPECIFIC GROUNDS FOR UNPATENTABILITY

Pursuant to Rule 42.104(b)(4)-(5), the challenged claims are unpatentable because they are anticipated by KenKnight '967, as discussed below and in the Benditt Declaration. (Ex. 1006.) The analysis for independent claim 1 covers the same limitations found in independent claims 7 and 14. Differences between the independent claims are analyzed as distinct limitations in the sections regarding claims 7 and 14 following the discussion of claim 1. There are also multiple dependent claims that add the same or similar limitations to independent claims 1, 7, and 14. (*See* Ex. 1001, cls. 2, 8, 15; cls. 3, 9, 16; cls. 10, 17; cls. 4, 11, 18; cls. 6, 13, 20.) For efficiency, each set of dependent claims is addressed as a group.

A. Overview of KenKnight '967

Like the '563 Patent, KenKnight '967 discloses an implantable system for delivering antitachycardia pacing to a patient's heart. KenKnight '967 discloses a "System and Method to Reduce Defibrillation Requirements" by utilizing "[a] hybrid tachyarrhythmia therapy" that includes "pacing therapy." (Ex. 1008, Abstract; *see also* Ex. 1006, ¶ 187.) KenKnight '967 describes its invention as "a single electrical therapy applied to a selected region of selected cardiac tissue, comprising the combination of two **discrete** therapies: **pacing level therapy** applied to a localized portion of a region of the selected cardiac tissue having relatively low susceptibility to defibrillation-level shock field strengths; followed

by (or occurring simultaneously with) defibrillation therapy applied to portions of the tissue having regions of fibrillating myocardium over which the sub-defibrillation level shocks exert control." (Ex. 1008, 3:38-47 (emphasis added).) With respect to the "pacing pulses" or "pacing shocks" (*see id.* 1:18-21 (using "pulses" and "shocks" interchangeably), KenKnight '967 explains that the "preferred embodiment is a series of pacing level shocks, which is readily provided by known pacing techniques." (*Id.* at 4:52-54.) KenKnight '967 also explains that "pacing pulses of the type used for . . . antitachycardia pacing are those which have energies on the order of microjoules, and thus are well below the energy level of defibrillation or cardioversion shocks." (*Id.* at 1:31-34.)

KenKnight '967 uses electrodes that are configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of the heart. (*See* Ex. 1006, ¶ 189.) Figure 1 of KenKnight '967 discloses an embodiment in which "pacing pulses are administered from a transvenous lead (10) residing in or near the coronary sinus along the postero-basal region of the left ventricle (LV) or in the right ventricle (RV) outflow tract[.]" (Ex. 1008, 6:12-16.) Thus, as shown in Figure 1, KenKnight '967 expressly discloses a transvenous lead 10 configured for passing through the coronary sinus ostium and into a vein on the

surface of the left ventricle of the heart. [1]

In discussing Figure 1 (reproduced to the right), KenKnight '967 does not specifically identify or describe any electrodes. (Ex. 1006, ¶ 190.) Instead of identifying or describing the electrode system in Figure 1, KenKnight relies on a different drawing—Figure 10 (reproduced below)—to illustrate how the electrode system of lead 10 in Figure 1 is implemented. KenKnight '967 notes that Figure 10 "illustrates schematically one of the possible system embodiments of the invention, **implementing** again, for illustrative purposes only, **the electrode configuration of FIG. 1** and employing the **pacing-level shocks** described above." (*Id.*; Ex. 1008, 9:53-57 (emphasis added).)

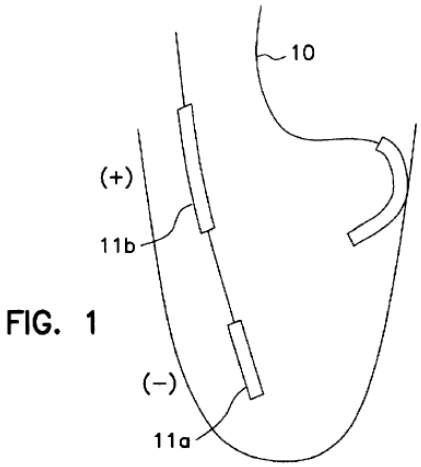


FIG. 1

In "implementing" the "electrode configuration of FIG. 1," Figure 10 (reproduced below) provides two separate lead lines and two separate reference

[1] Reference number 10 points generally to a lead. KenKnight '967 refers to reference number 10 in Figure 1 as "transvenous lead 10" (Ex. 1008, 6:13-14) and later as "coronary sinus electrode 10" (*id.* at 10:28-29) and as part of "electrode systems (10, etc.)" (*id.* at 10:32-34).

characters that identify two individual electrodes (18a and 18b) on the coronary sinus lead 10. (Ex. 1006, ¶ 191.) KenKnight '967 makes clear that the "coronary sinus electrode system comprises two electrodes (18a, 18b)." (Ex. 1008, 9:61-64; Ex. 1006, ¶ 192.) These two electrodes (18a and 18b) on the coronary sinus lead monitor the cardiac rhythms and "each provide bipolar electrograms." (Ex. 1008, 9:61-64.) The two electrodes (18a and 18b) on the coronary sinus lead (10) are then used to apply pacing pulses in response to detected tachycardia: "The pacing output circuit (160) and capacitor network charge/discharge controller (170) provide the **pacing-level shocks** (S_P) and defibrillation-level shocks (S_D) through appropriate **electrode systems** to the **coronary sinus electrode (10)** and defibrillation electrodes (11a, 11b)." (Ex. 1008, 10:25-29 (emphasis added); Ex. 1006, ¶¶ 192-193.)

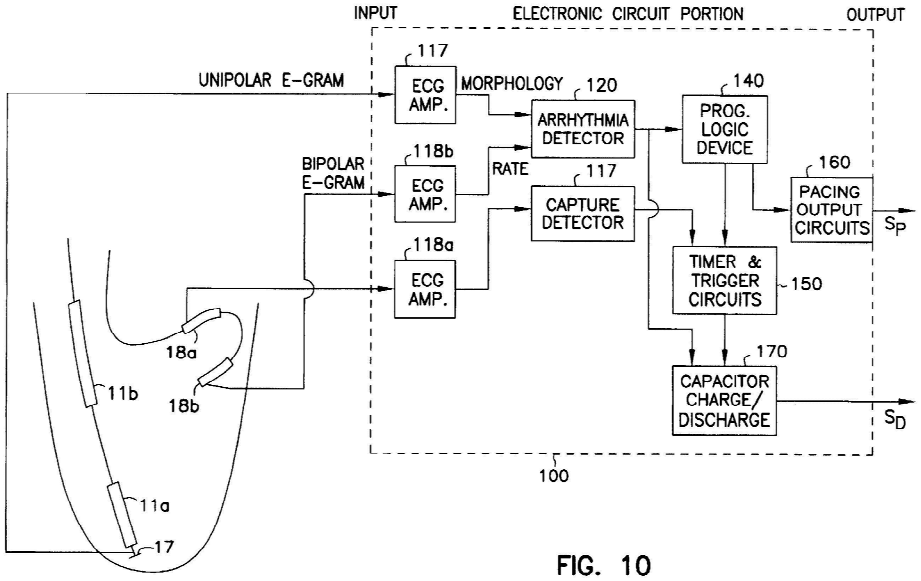


FIG. 10

Thus, when implemented according to Figure 10, what KenKnight '967 refers to interchangeably as "transvenous lead (10)" (Ex. 1008 at 6:13-14), "electrode systems (10, etc.)" (*id.* at 10:33), and "coronary sinus electrode (10)" (*id.* at 10:28-29), includes a system of two specific electrodes (18a, 18b) located on a transvenous lead for applying pacing pulses in response to tachycardia—*i.e.*, antitachycardia pacing. (*See* Ex. 1006, ¶ 193.)

KenKnight '967 also discloses that the electrode system of Figure 10 is configured for positioning in a variety of locations, including within the coronary sinus and its tributaries as well as in the right ventricle. For example, KenKnight '967 states that "pacing pulses are administered from a transvenous lead (10) residing in or near the coronary sinus along the postero-basal region of the left ventricle (LV) or in the right ventricle (RV) outflow tract[.]" (*Id.*, ¶¶ 194-196; Ex. 1008 at 6:12-16.) KenKnight '967 also states that the electrode system of Figure 10 is configured for positioning in the manner shown in Figures 2-4: "The principles described above regarding use of alternate electrode configurations (such as those shown in **Figs. 2-4**) . . . can all be incorporated (in whatever combination is required) by the skilled artisan into system embodiments, **like that of Fig. 10**, without undue experimentation." (Ex. 1008 at 10:35-40 (emphasis added); Ex. 1006, ¶ 194.) Figure 4, in turn, discloses positioning the transvenous lead in tributaries of the coronary sinus: "FIG. 4 shows a preferred location for a

transvenous pacing electrode (15) which has been introduced into the coronary sinus, then into the great cardiac vein, and then into the ascending limb of either the anterior cardiac vein or the posterior cardiac vein, into the vasculature of the left ventricle." (Ex. 1008 at 6:40-45.) Accordingly, a person of ordinary skill in the art would have understood that in the system of Figure 10, the transvenous coronary sinus lead and its associated electrodes 18a and 18b are configured for positioning in a variety of locations, including through the coronary sinus and into its tributaries as well as in the right ventricle outflow tract. (*See* Ex. 1006, ¶ 195.)

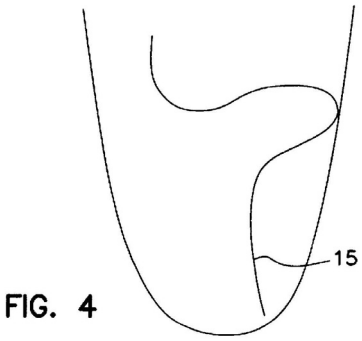


FIG. 4

B. KenKnight '967 Anticipates Claims 1-20

As described below, KenKnight '967 discloses each and every limitation of claims 1-20 of the '563 Patent.

1. Independent Claim 1

a. Preamble Language: "An implantable system for the delivery of antitachycardia pacing to a patient's heart, comprising:"

The broadest reasonable construction of this term in light of the specification is: an implantable system for the delivery of pacing pulses to a patient's heart in response to tachycardia. (Ex. 1006, ¶¶ 201-203; *see also* Ex. 1001, 3:63-4:3; 7:23-30; Fig. 2.) To the extent the preamble of claim 1 is a

limitation, KenKnight ’967 discloses this limitation.

KenKnight ’967 discloses an implantable system: “While any portion of the system other than the shocking and sensing electrodes may be external on the patient, a fully-implantable system is preferred.” (Ex. 1008, 5:18-20; *see also id.* at 5:14-17 (“[D]evices combining these two functions into a single implantable pulse generator are preferred.”); Ex. 1006 ¶ 205.) Moreover, the specification additionally describes “an implantable housing.” (Ex. 1008, 10:30-32.) An implantable device is thus disclosed. (Ex. 1006, ¶ 205.)

KenKnight ’967 additionally discloses the delivery of pacing pulses in response to tachycardia—*i.e.*, the delivery of antitachycardia pacing. The Abstract discloses “[a] hybrid tachyarrhythmia therapy utiliz[ing] a combination of two therapies: pacing therapy . . . and defibrillation (including cardioversion) therapy.” (Ex. 1008, Abstract; *see also id.* at 5:40-45; 4:52-54; 5:14-17; Figs. 5, 10; Ex. 1006, ¶ 206). Figure 5 provides the “details of a scheme employing pacing-level pulses.” (Ex.1008, 6:59.) In Figure 5, “the series of **pacing-level pulses**, denoted $\mathbf{S_P}$, is delivered during a period of

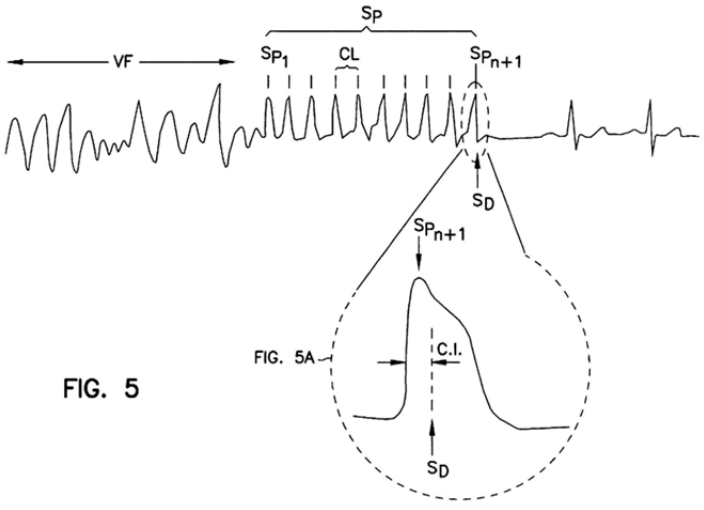


FIG. 5

hemodynamically unstable tachyarrhythmia, denoted schematically as VF (the tachyarrhythmia need not be only ventricular fibrillation, though that is a common condition)." (Ex.1008, 6:61-65 (emphasis added); *see also id.* Fig 5; Ex. 1006, ¶ 207.) KenKnight '967 also discloses that the system delivers pacing-level pulses in response to tachycardia. (*See, e.g.*, Ex. 1008 at 9:67-10:17; 10:25-29; Fig. 10; Ex. 1006, ¶ 208.)

Accordingly, KenKnight '967 discloses an implantable system for delivery of pacing pulses in response to tachycardia—*i.e.*, "an implantable system for the delivery of antitachycardia pacing to a patient's heart." (*See* Ex. 1006, ¶¶ 201-209.)

b. First Limitation: "a plurality of primary stimulation electrodes configured for sensing cardice[2] signals and delivering antitachycardia pacing to said heart;"

The broadest reasonable construction of this limitation in light of the specification is: multiple stimulation electrodes configured for sensing cardiac signals and delivering pacing pulses in response to tachycardia to said heart. (Ex. 1006, ¶ 210; *see also* Ex. 1001, cls. 1-3, 7-9, 14-16; Abstract.) KenKnight '967

[2] This is the language of claim 1 of the '563 Patent, and is a typographical error. A person of ordinary skill in the art would readily have understood "cardice" to mean "cardiac." (Ex. 1006, ¶ 210.)

discloses this limitation.

KenKnight '967 discloses multiple stimulation electrodes configured for sensing cardiac signals and delivering pacing pulses in response to tachycardia. KenKnight '967 explains that the pacing pulses are applied in "regions of weak field intensity" by "introduction and fixation of pacing electrodes." (Ex. 1008, 5:58-65; Ex. 1006, ¶ 212.) Figure 1 shows an example of a transvenous lead placed through the coronary sinus and explains that "pacing pulses are administered from a transvenous lead (10) residing in or near the coronary sinus along the postero-basal region of the left ventricle (LV) or in the right ventricle (RV) outflow tract, while the defibrillation-level pulse is applied between endocardial electrodes (11a, 11b) residing in the RV apex (electrode 11a) and in the superior vena cava (SVC) (electrode 11b) just proximal to or partially in the right atrium." (Ex. 1008 at 6:12-20.) Thus, as shown in Figure 1, the pacing pulses are applied through the transvenous cardiac sinus lead (10) while the defibrillation pulses are applied through the endocardial lead with electrodes 11a and 11b. (*See* Ex. 1006, ¶ 213.)

As noted above in Section VII(A), Figure 1 does not include any lead lines or reference characters for the particular electrode configuration on coronary sinus lead 10. KenKnight '967 relies instead on Figure 10 to identify and describe the two pacing electrodes that **implement** the electrode configuration of Figure 1:

"FIG. 10 illustrates schematically one of the possible system embodiments of the invention, **implementing** again, for illustrative purposes only, the **electrode configuration of FIG. 1** and employing the **pacing-level shocks** described above." (Ex. 1008 at 9:53-57 (emphasis added); *see also* 5:37-38; Ex. 1006, ¶ 214.)

Figure 10 (reproduced below) separately identifies a plurality of pacing electrodes: electrodes 18a and 18b. Both of these electrodes are part of the coronary sinus electrode system on transvenous lead 10. (*See, e.g.*, Ex. 1008, 9:61-64 ("The coronary sinus electrode system comprises two electrodes (18a, 18b) which each provide bipolar electrograms as described below."); *id.* at 10:25-29 ("provide the pacing-level shocks . . . through appropriate electrode systems"); *id.* at 10:33 ("electrode systems (10, etc."); *see also id.* at 6:12-13 ("pacing pulses are administered from a transvenous lead (10)"); Ex. 1006, ¶ 214.)

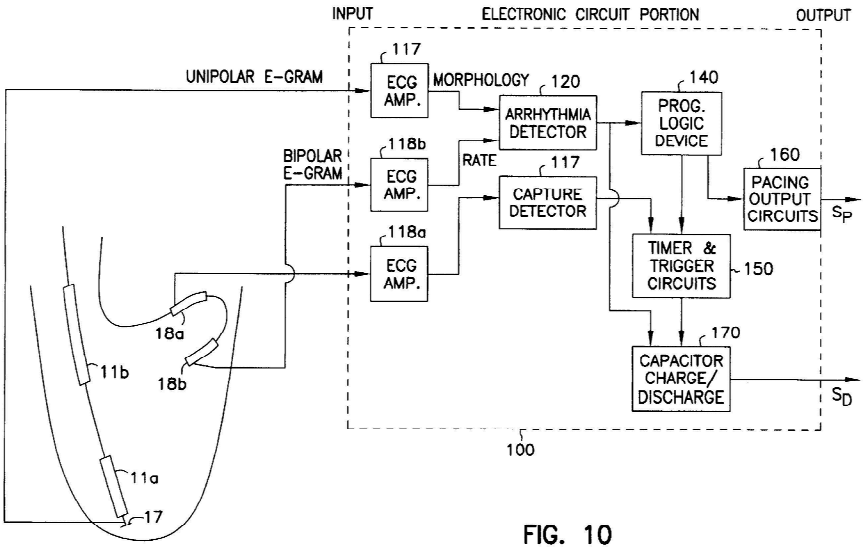


FIG. 10

The electrodes 18a and 18b on the cardiac sinus electrode system are configured for sensing cardiac signals and delivering antitachycardia pacing (*i.e.*, pacing pulses in response to tachycardia) to the heart. KenKnight '967, for example, explains that electrodes 18a and 18b "each provide bipolar electrograms" by, among other things, providing "inputs" to "their respective ECG amplifiers," which in turn produce "outputs . . . used for additional processing." (Ex. 1008, 9:61-10:3; Ex. 1006, ¶¶ 216-17.) KenKnight '967 then provides further details of how the output signals from coronary sinus electrode 18a and coronary sinus electrode 18b are directed to an arrhythmia detector and capture detector, respectively, in order to determine the appropriate pacing-level shocks to apply. (Ex. 1008, 10:4-24; Fig. 10; Ex. 1006, ¶¶ 216-17.) If the system detects tachycardia, pacing pulses are applied through the coronary sinus electrode system of 18a and 18b. (Ex. 1008, 10:25-29 ("[P]acing output circuit (160) and capacitor network charge/discharge controller (170) provide the pacing-level shocks (S_P) and defibrillation-level shocks (S_D) through appropriate electrode systems to the coronary sinus electrode (10) and defibrillation electrodes (11a, 11b)."); 6:59-65 ("The details of a scheme employing pacing-level pulses, applicable to any of the embodiments of FIGS. 1-4, are shown schematically in FIGS. 5 and 5A."); Ex. 1006, ¶ 218.) Accordingly, KenKnight '967 discloses "a plurality of primary stimulation electrodes"—electrodes 18a and 18b—that are "configured for sensing

cardiac signals and delivering antitachycardia pacing to said heart." (Ex. 1006, ¶¶ 210-19.)

c. Second Limitation: "a first one of said primary stimulation electrodes configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart;"

The broadest reasonable construction of this limitation in light of the specification is: one of said stimulation electrodes (which are configured for sensing cardiac signals and delivering pacing pulses in response to tachycardia) is configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart. (Ex. 1006, ¶ 220; *see also* Ex. 1001, 6:5-9; Abstract; 6:62-7:22.) This limitation is disclosed by KenKnight '967.

As explained above, KenKnight '967 discloses that the coronary sinus lead and its associated electrodes may be positioned in a variety of locations, one example of which is the tributaries of the great cardiac vein, as shown in Figure 4. KenKnight '967 specifically states: "The principles described above regarding use of alternate electrode configurations (such as those shown in **Figs. 2-4**) multiple defibrillation-level shocks, etc., can all be incorporated (in whatever combination is required) by the skilled artisan into system embodiments, **like that of Fig. 10**, without undue experimentation." (Ex. 1008, 10:35-40 (emphasis added); Ex. 1006, ¶ 224.) Figure 4, in turn, "shows a preferred location for a transvenous pacing electrode (15) which has been introduced into the coronary sinus, then into the

great cardiac vein, and then into the ascending limb of either the anterior cardiac vein or the posterior cardiac vein, into the vasculature of the left ventricle." (Ex. 1008 at 6:40-52; Ex. 1006, ¶ 225.) KenKnight '967 further explains: "Because the courses of these veins are near the surface of the heart, this location gives performance very similar to that of the epicardial electrode discussed below, even though the location is within the cardiac vasculature. This embodiment places the pacing electrode (15) as close as possible to the apex of the left ventricle via a transvenous procedure, which is desirable to avoid a thoracotomy, median sternotomy, or other extensive surgical procedure." (Ex. 1008 at 6:40-52, Fig. 4; Ex. 1006, ¶ 226.)

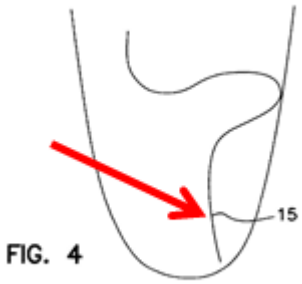


FIG. 4

Accordingly, a person of ordinary skill in the art would have understood that electrodes 18a and 18b, the "coronary sinus electrode system" of Figure 10, are configured for positioning through the coronary sinus and into the tributaries of the great cardiac vein. (*See* Ex. 1006, ¶ 227.) Thus, a person of ordinary skill in the art would have understood that the electrodes 18a and 18b in the coronary sinus electrode system of Figure 10 are configured for "positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of [the] heart," for example as illustrated in Figure 4. (*See* Ex. 1006, ¶ 227.)

KenKnight '967 therefore discloses "a first one of said primary stimulation

electrodes configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart." (Ex. 1006, ¶¶ 220-229.)

d. Third Limitation: "a power supply; and"

A person of ordinary skill in the art would have understood KenKnight '967 to disclose a "power supply." KenKnight '967 discloses that "power supplies" are "[o]f course, not shown in FIG. 10 but well within the skill of the art to supply." (Ex. 1008, 10:30-34.) A person of ordinary skill in the art would have further understood that a power supply (such as a battery) is necessary to, for example, allow "[t]he pacing output circuit (160) and capacitor network charge/discharge controller (170) [to] provide the pacing-level shocks (S_p) and defibrillation-level shocks (S_D) through appropriate electrode systems" (*id.* at 10:25-29) because a source of electrical energy would be required to output electrical energy to the electrode systems. (Ex. 1006, ¶ 231.) KenKnight '967 thus discloses a "power supply." (*Id.*, ¶¶ 230-232.)

e. Fourth Limitation: "a control circuit operatively associated with said power supply and said primary stimulation electrodes, said control circuit configured for delivering antitachycardia pacing through said primary stimulation electrodes;"

The broadest reasonable construction of this fourth limitation in light of the specification is: a group of electrically connected components that includes a

controller[3] operatively associated with a power supply and stimulation electrodes, said group of electrically connected components that includes a controller configured for delivering pacing pulses in response to tachycardia through said stimulation electrodes. (Ex. 1006, ¶¶ 233-236; *see also* Ex. 1001, 5:22-24; 7:23-56; 7:57-58; 9:23-27; Fig. 2.) The preferred embodiment shown in Figure 2 of the '563 Patent (reproduced below) "schematically illustrates the control circuitry employed in an apparatus of the present invention" (Ex. 1001, 5:22-24) and "illustrates one example of an implantable housing 13 containing an electronic circuit 15" (*id.* at 7:23-24), which includes controller 74 and other components including "one or more amplifiers (not shown) for amplifying sensed cardiac signals," "an [sic] detector which determines if ventricular fibrillation . . . is present," and "a cardiac cycle monitor ('synchronization monitor')" (*id.* at 7:23-56; Fig 2).

[3] One of ordinary skill in the art would have generally understood that a "controller" is usually a component or group of components used to control the manner in which electrical power is delivered to the apparatus to which it is connected. (Ex. 1006, ¶ 236.)

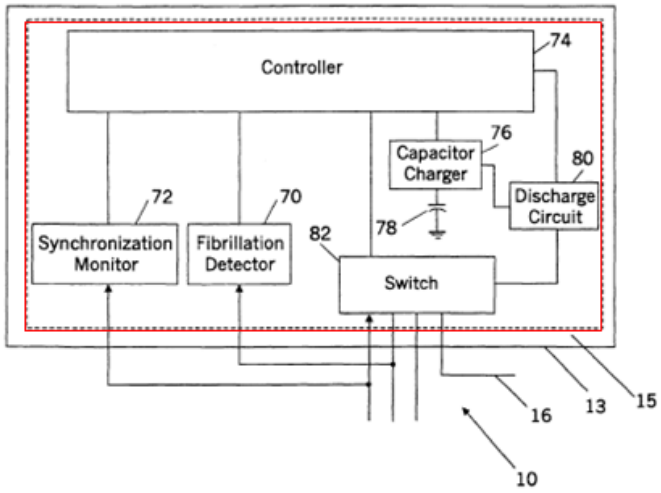


FIG. 2

KenKnight '967 discloses this limitation. A person of ordinary skill in the art would have understood that the group of electrically connected components of pulse generator system (100) of Figure 10 (which includes the "arrhythmia detector" (120), "preferred programmable logic device" (140), and "pacing output circuit" (160)) comprises a "control circuit" under its broadest reasonable construction. (Ex. 1006, ¶¶ 238-239.) Figure 10 even titles (100) as the "Electronic Circuit Portion."

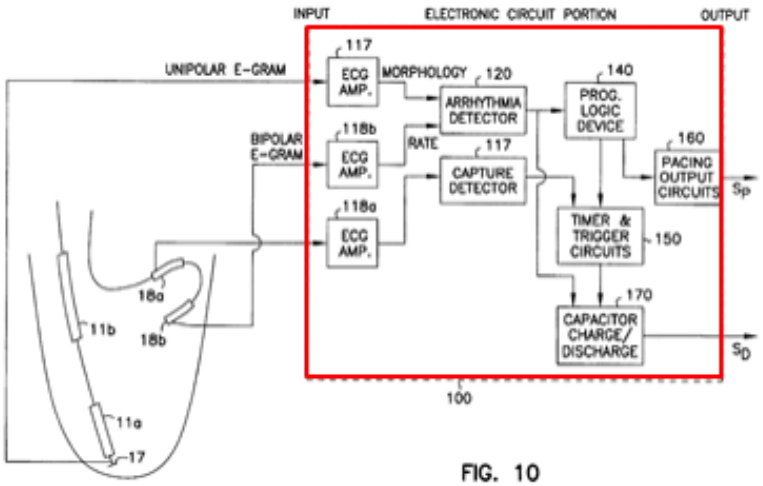


FIG. 10

A person of ordinary skill in the art would have understood the "preferred programmable logic device" (140) to be a "controller" because it is used to control the manner in which electrical power is delivered to the pacing output circuit (160) and in turn to the electrode systems. (*See* Ex. 1008, 10:13-29 ("The arrhythmia detector (120) output goes in parallel to a preferred programmable logic device (140) which produces the pacing-level signal logic required; and additionally to the capacitor network charge/discharge controller (170) which produces the defibrillation-level signal logic required. The programmable logic device (140) also drives timing/trigger circuitry (150), as does the output of the capture detector (130). The output of the timing/trigger circuitry (150) is another input to the capacitor network charge/discharge controller (170). The pacing output circuit (160) and capacitor network charge/discharge controller (170) provide the pacing-level shocks (S_p) and defibrillation-level shocks (S_D) through appropriate electrode systems to the coronary sinus electrode (10) and defibrillation electrodes (11a, 11b)."); Ex. 1006, ¶¶ 240-241.)

KenKnight '967 discloses that the pulse generator (100) is operatively associated with a power supply, which would have been necessary to allow the system to output energy to, for example, "provide the pacing-level shocks (S_p)." KenKnight '967 states: "Of course, not shown in FIG. 10 but well within the skill of the art to supply, are power supplies[.]" (Ex. 1008, 10:30-34; *see also id.* at

10:25-29; Ex. 1006, ¶ 242.)

KenKnight ’967 also discloses that the pulse generator (100), which includes the “arrhythmia detector” (120), “preferred programmable logic device” (140) and “pacing output circuit” (160), is configured for delivering pacing pulses in response to tachycardia because it is configured to detect tachycardia and deliver pacing pulses in response thereto. (Ex. 1006, ¶ 243.) Arrhythmia detector (120) processes inputs from the electrodes, and provides input to the preferred programmable logic device (140), or controller. (Ex. 1008, 9:67-10:17; Ex. 1006, ¶ 243.) The control circuit of KenKnight ’967 uses the inputs to determine if a tachycardia exists and the appropriate pacing pulses to apply in response. (*See* Ex. 1006, ¶ 243.)

The pulse generator (100) is operatively associated with stimulation electrodes and configured for delivering pacing pulses in response to tachycardia through the stimulation electrodes of coronary sinus electrode system 10 (*i.e.*, electrodes 18a, 18b). (Ex. 1008, 9:61-64 (“coronary sinus electrode system comprises two electrodes (18a, 18b)”); 10:25-29 (“The pacing output circuit (160) and capacitor network charge/discharge controller (170) provide the pacing-level shocks (S_P) and defibrillation level shocks (S_D) through the appropriate electrode systems to the coronary sinus electrode (10) and defibrillation electrodes (11a, 11b).”); 9:53-56 (“FIG. 10 illustrates . . . implementing . . . the electrode

configuration of FIG. 1 and employing the pacing-level shocks described above."); Ex. 1006, ¶ 244.)

Accordingly, KenKnight '967 discloses each requirement of this fourth limitation of claim 1 of the '563 Patent. (Ex. 1006, ¶¶ 233-245.)

f. Fifth Limitation: "wherein said control circuit includes a capacitor."

KenKnight '967 discloses that the control circuit (pulse generator (100)) includes a "capacitor network charge/discharge controller (170)": "The pacing output circuit (160) and capacitor network charge/discharge controller (170) provide the pacing-level shocks (S_p) and defibrillation-level shocks (S_D) through appropriate electrode systems to the coronary sinus electrode (10) and defibrillation electrodes (11a, 11b)." (Ex. 1008, 10:25-29; Fig. 10; *see also* Ex. 1006, ¶ 246.) KenKnight '967 explains that defibrillation "shocks are preferably produced by terminating the discharge waveform of a capacitor network," which may include "[a] single capacitor, or multiple capacitors, as dictated by morphology, available pulse generator volume, and other considerations." (Ex. 1008, 7:4-15; Ex. 1006, ¶ 246.) A person of ordinary skill in the art would have understood that the control circuit (pulse generator (100)) would also necessarily include one or more capacitors in connection with pacing output circuit (160) in order for it to output energy to electrodes. (Ex. 1006, ¶ 247.) KenKnight '967 therefore discloses this fifth limitation of claim 1. (*Id.*, ¶¶ 246-248.)

Because KenKnight '967 fully discloses all of the limitations of claim 1, KenKnight '967 anticipates claim 1 of the '563 patent. (*Id.*, ¶ 249.)

2. Independent Claim 7

a. Preamble Language: "An implantable system for the delivery of antitachycardia pacing to a patient's heart, comprising:"

The preamble of claim 7 is identical to that of claim 1, addressed above. Accordingly, KenKnight '967 fully discloses this limitation for the same reasons discussed above in connection with claim 1. (*See Id.*, ¶ 250.)

b. First Limitation: "a plurality of primary electrodes configured for delivering antitachycardia pacing to said heart;"

This limitation is the same as the first limitation of claim 1, except it refers to "primary electrodes" instead of "primary stimulation electrodes."[4] The broadest reasonable construction of this limitation in light of the specification is: multiple electrodes configured for delivering pacing pulses in response to tachycardia. (*Id.*, ¶ 251.) As discussed above with respect to claim 1, KenKnight '967 fully discloses this limitation. (*Id.*, ¶¶ 253-254; *see, e.g.*, Ex. 1008, 6:40-42; *see also id.*

[4] For purposes of this Petition, there is no material difference under the broadest reasonable interpretation between "primary electrodes" and "primary stimulation electrodes." (Ex. 1006, ¶ 252.)

at 10:35-40, Figs. 1-4.)

c. Second Limitation: "a first one of said primary electrodes configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart;"

This limitation of claim 7 is the same as the second limitation of claim 1, except it refers to "one of said primary electrodes" instead of "one of said primary stimulation electrodes." The broadest reasonable construction of this limitation in light of the specification is: one of said electrodes (which are configured for delivering pacing pulses in response to tachycardia) is configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart. (Ex. 1006, ¶ 255.) Accordingly, for the reasons discussed above with respect to the second limitation of claim 1, this limitation is fully disclosed by KenKnight '967. (*Id.*, ¶¶ 255-257; *see, e.g.*, Ex. 1008, 6:40-52; 10:35-40; Fig. 4.)

d. Third Limitation: "a power supply; and"

This limitation of claim 7 is identical to that of claim 1, addressed above. Accordingly, KenKnight '967 fully discloses this limitation. (Ex. 1006, ¶¶ 258-259.)

e. Fourth Limitation: "a control circuit operatively associated with said power supply and said primary electrodes, said control circuit configured for delivering antitachycardia pacing through said primary electrodes;"

This limitation of claim 7 is identical to that of claim 1, addressed above, except that it recites "said primary electrodes" rather than "said primary stimulation electrodes" as in the fourth limitation of claim 1. The broadest reasonable construction of this limitation in light of the specification is: a group of electrically connected components that includes a controller operatively associated with a power supply and electrodes, said group of electrically connected components that includes a controller configured for delivering pacing pulses in response to tachycardia through said electrodes. (*Id.*, ¶ 260.) Accordingly, for the reasons discussed above with respect to the fourth limitation of claim 1, this limitation is fully disclosed by KenKnight '967. (*Id.*, ¶¶ 260-262.)

f. Fifth Limitation: "wherein a first one of said primary electrodes is configured for positioning through the coronary sinus and within a vein on the antero-lateral surface of the left ventricle of said heart."

This limitation is similar to the second limitation of claims 1 and 7, but it adds an additional requirement that a first one of the primary electrodes is not only positioned through the coronary sinus and within a vein on the surface of the left ventricle, but that it is within a vein "on the antero-lateral surface of the left ventricle" of the heart. The broadest reasonable construction of this limitation in

light of the specification is: one of said electrodes is configured for positioning through the coronary sinus and within a vein on the antero-lateral surface of the left ventricle of the heart. (*Id.*, ¶ 263.) A person of ordinary skill in the art would have understood "on the antero-lateral surface of the left ventricle" to mean on the front and away from the midline, or on the front and left surface of the left ventricle, and would have understood this to include a vein on the "surface" or on the epicardium of the left ventricle of the heart, such as the great cardiac vein and its tributaries. (*Id.*, ¶ 264.) The '563 Patent does not provide a more detailed description or definition of this term. (*Id.*)

KenKnight '967 discloses this limitation. (*Id.*, ¶ 265.) As discussed above, KenKnight '967 explains that the coronary sinus electrode system of Figure 10, which includes electrodes 18a and 18b, is configured to position the lead and electrodes as shown in Figure 4. (Ex. 1008, 10:35-40 (explaining that the system of Figure 10 may be implemented using the configuration of Figure 4).) Figure 4, in turn, shows positioning the electrode system through the "coronary sinus, then into the great cardiac vein, and then into the ascending limb of either the anterior cardiac vein or the posterior cardiac vein, into the vasculature of the left ventricle." (*Id.*, 6:40-45.) Thus, given that the electrode system of Figure 10 of KenKnight '967 may be positioned as shown in Figure 4, the electrode system of Figure 10 is configured for positioning "into the coronary sinus, then into the great cardiac

vein, and then into the ascending limb of either the anterior cardiac vein or the posterior cardiac vein, into the vasculature of the left ventricle." (*Id.* at 6:40-45; Fig. 4; Ex. 1006, ¶ 266.)

A person of ordinary skill in the art would have understood this to disclose an electrode configured for positioning through the coronary sinus and within a vein on the surface of the left ventricle of the heart. (*See* Ex. 1008, 6:40-52 (electrode is introduced "into the vasculature of the left ventricle" and "[b]ecause the courses of these veins are near the surface of the heart, this location gives performance very similar to that of [an] epicardial electrode"); Ex. 1006, ¶ 267.) In addition, a person of ordinary skill in the art would have understood that positioning an electrode "into the ascending limb of [] the anterior cardiac vein . . . into the vasculature of the left ventricle" discloses a lead configured for positioning within a vein on the antero-lateral surface of the left ventricle of the heart. (*Id.*) Accordingly, KenKnight '967 fully discloses all of the requirements of the fifth limitation of independent claim 7. (Ex. 1006, ¶¶ 263-268.)

Because KenKnight '967 discloses all of the limitations of claim 7, KenKnight '963 anticipates claim 7 of the '563 Patent. (*Id.*, ¶¶ 250-269.)

3. Independent Claim 14

a. Preamble Language: "An implantable system for the delivery of antitachycardia pacing to a patient's heart, comprising:"

The preamble of claim 14 is identical to that of claims 1 and 7, addressed above. Accordingly, KenKnight '967 fully discloses this limitation. (Ex. 1006, ¶ 270.)

b. First Limitation: "a plurality of primary electrodes configured for delivering antitachycardia pacing to said heart;"

This limitation of claim 14 is identical to that of claim 7, addressed above. Accordingly, KenKnight '963 fully discloses this limitation. (*Id.*, ¶¶ 271-272.)

c. Second Limitation: "a first one of said primary electrodes configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart;"

This limitation of claim 14 is identical to that of claim 7, addressed above. Accordingly, KenKnight '967 fully discloses this limitation. (*Id.*, ¶¶ 273-274.)

d. Third Limitation: "a power supply; and"

This limitation of claim 14 is identical to that of claims 1 and 7, addressed above. Accordingly, KenKnight '967 fully discloses this limitation. (*Id.*, ¶¶ 275-276.)

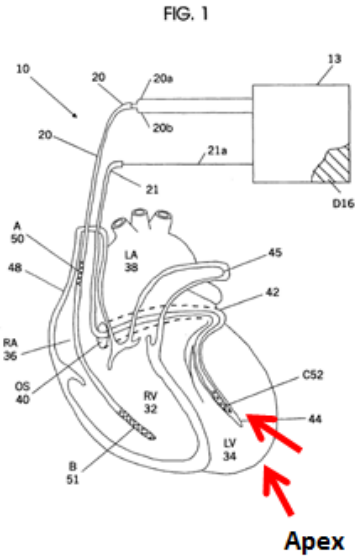
e. **Fourth Limitation:** "a control circuit operatively associated with said power supply and said primary electrodes, said control circuit configured for delivering antitachycardia pacing through said primary electrodes;"

This limitation of claim 14 is identical to that of claim 7, addressed above. Accordingly, KenKnight '967 fully discloses all of the requirements of this fourth limitation of claim 14 of the '563 Patent. (*Id.*, ¶¶ 277-278.)

f. **Fifth Limitation:** "wherein a first one of said primary electrodes is configured for positioning through the coronary sinus and within a vein on the postero-lateral surface of the left ventricle of said heart."

This limitation is similar to the fifth limitation of claim 7, except instead of specifying placement on the "antero-lateral surface of the left ventricle of the heart" as in claim 7, this limitation specifies placement on the "postero-lateral surface of the left ventricle of the heart." The broadest reasonable construction of this limitation in light of the specification is: one of said electrodes is configured for positioning through the coronary sinus and within a vein on the postero-lateral surface of the left ventricle of the heart. (*Id.*, ¶ 279.) The '563 Patent states that an electrode is "within a vein on the postero lateral surface of the left ventricle" when it is "in the apical third of the posterior cardiac vein or the apical half of the great cardiac vein": "As illustrated in FIG. 1, the system includes . . . an electrode C [52] positioned within a vein on the postero lateral surface of the left ventricle (e.g., in the apical third of the posterior cardiac vein or the apical half of the great cardiac

vein)." (Ex. 1001, 6:62-7:1.) The '563 Patent further explains in reference to Figure 1 that "Electrode C may be positioned entirely within a vein on the postero-lateral surface of the left ventricle, or may also extend into the coronary sinus (as in the case of an elongate electrode)." (*Id.* at 7:9-13.) Figure 1 is shown on the right, with annotations to indicate the locations of electrode C52 and the apex of the heart. (*Id.*, Fig. 1; Ex. 1006, ¶ 281.) A person of ordinary skill in the art would have understood "on the postero-lateral surface of the left ventricle" to mean on the back and away from the midline, or on the back and left surface of the left ventricle, and would have understood this to include a vein on the "surface" or on the epicardium of the left ventricle of the heart. (Ex. 1006, ¶¶ 280-282.)



KenKnight '967 discloses this limitation. (*Id.*, ¶ 283.) As discussed above in connection with the fifth limitation of claim 7, KenKnight '967 explains that the coronary sinus electrode system of Figure 10, which includes electrodes 18a and 18b, is configured for positioning the electrodes as shown in Figure 4—namely, through the "coronary sinus, then into the great cardiac vein, and then into the ascending limb of either the anterior cardiac vein **or the posterior cardiac vein**,

into the vasculature of the left ventricle." (Ex. 1008, 6:40-45 (emphasis added).) In particular, KenKnight '967 explains that the coronary sinus electrode system of Figure 10 may be implemented using the particular configuration illustrated in Figure 4 (*id.* at 10:35-40), which includes introducing the electrodes "into the coronary sinus, then into the great cardiac vein, and **then into the ascending limb of** either the anterior cardiac vein or the **posterior cardiac vein**, **into the vasculature of the left ventricle**" (*id.* at 6:40-52 (emphasis added); *see also id.* at Fig. 4; Ex. 1006, ¶ 284). KenKnight '967 explains that "[b]ecause the courses of these veins are near the surface of the heart, this location gives performance very similar to that of the epicardial electrode discussed below, even though the location is within the cardiac vasculature." (Ex. 1008, 6:40-52; *see also id.* at Fig. 4.)

A person of ordinary skill in the art would have understood this to disclose an electrode configured for positioning through the coronary sinus and within a vein on the surface of the left ventricle of the heart. (*See id.*; Ex. 1006, ¶ 285.) A person of ordinary skill in the art also would have understood that placement of an electrode "into the ascending limb of . . . the **posterior cardiac vein**, into the vasculature of the left ventricle" to disclose a lead configured for positioning within a vein on the postero-lateral surface of the left ventricle of the heart. (*See* Ex. 1006 ¶ 285.) Accordingly, KenKnight '967 fully discloses all of the requirements of the fifth limitation of independent claim 14. (*Id.*, ¶¶ 279-286.)

Because KenKnight ’967 discloses all of the limitations of claim 14, KenKnight ’967 anticipates claim 14 of the ’563 Patent. (*Id.*, ¶ 287.)

4. Dependent Claims 2, 8, and 15

Claims 2, 8, and 15 depend from independent claims 1, 7, and 14, respectively, which, as discussed above, are unpatentable as anticipated by KenKnight ’967. Claims 2, 8, and 15 add the following limitation:

> **a. Additional Limitation:** “a system according to claim [1, 7, or 14], wherein said primary electrodes are configured for delivering antitachycardia pacing to the ventricles of said heart.”

The broadest reasonable construction of this limitation in light of the specification is: a system where said electrodes [of claims 1, 7, and 14] are configured for delivering pacing pulses in response to tachycardia to the ventricles of the heart. (*Id.*, ¶ 289.) This limitation is fully disclosed by KenKnight ’967. (*Id.*, ¶ 290.)

The only additional term that is added to these dependent claims is that the primary electrodes are configured for delivering antitachycardia pacing to “the ventricles of [the] heart.” The heart contains two ventricles: a left ventricle and a right ventricle. The transvenous lead (10) and its associated electrodes in KenKnight ’967 are configured for delivering antitachycardia pacing to the left ventricle as well as the right ventricle. (Ex. 1008, 6:13-17; Ex. 1006, ¶ 290; *see also* Section VII(A) above.) In fact, KenKnight ’967 explicitly states that “pacing

pulses are administered from a transvenous lead (10) residing in or near the coronary sinus along the postero-basal region of the **left ventricle** (LV) or in the **right ventricle** (RV) outflow tract." (Ex. 1008, 6:13-17 (emphasis added); Ex. 1006, ¶ 290.) A person of ordinary skill in the art would have understood based on the disclosure in KenKnight '967 that transvenous lead (10) and its associated electrodes 18a and 18b are therefore configured for delivering pacing pulses in response to tachycardia to the ventricles of the heart, and KenKnight '967 therefore meets the limitation of these dependent claims. (*See* Ex. 1006, ¶¶ 288-292.)

5. Dependent Claims 3, 9, and 16

Claims 3, 9, and 16 depend from claims 1, 7, and 14, respectively, which, as discussed above are unpatentable as anticipated by KenKnight '967. Claims 3, 9, and 16 add the following additional limitation:

> **a.** **Additional Limitation:** "a system according to claim [1, 7, or 14], wherein a first one of said primary electrodes is configured for positioning through the coronary sinus and in either the apical third of the posterior cardiac vein or the apical half of the great cardiac vein."

The broadest reasonable construction of this limitation in light of the specification is: a system where one of said electrodes [of claims 1, 7, and 14] is configured for positioning through the coronary sinus and in either the apical third of the posterior cardiac vein or the apical half of the great cardiac vein. (*Id.*, ¶ 294.) A person of ordinary skill in the art would have understood the "apical

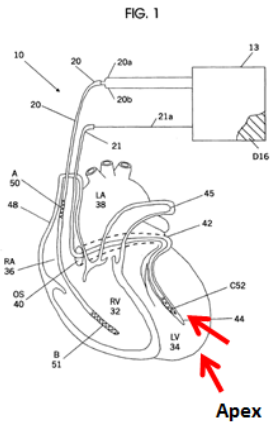
third" or "apical half" to mean the third or half of the vein closest to the apex of the heart. (*Id.*, ¶ 295.)

As explained above, KenKnight '967 explains that transvenous lead 10 and its associated electrodes (18a and 18b) are configured for positioning in a variety of configurations, including as shown in Figure 4. (*See* Ex. 1008, 10:35-40; Ex. 1006, ¶ 296.) Figure 4, in turn, shows a configuration that allows positioning of electrodes in the "apical third" or "apical half" of the left ventricle—i.e., the third or half of the vein closest to the apex of the heart. (*See* Ex. 1006, ¶ 297.) Thus, a person of ordinary skill in the art would have understood that the electrodes of Figure 10 of KenKnight '967 are configured "for positioning through the coronary sinus and in either the apical third of the posterior cardiac vein or the apical half of the great cardiac vein."

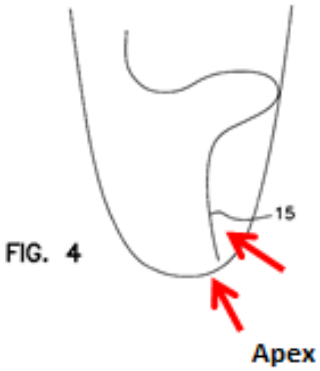
This is further shown by comparing Figure 1 of the '563 Patent with Figure 4 of KenKnight '967. Regarding Figure 1 of the '563 Patent, the '563 Patent states: "As illustrated in FIG. 1, the system includes . . . an electrode C 52 positioned within a vein on the postero lateral surface of the left ventricle (e.g., in the **apical third** of the posterior cardiac vein or the **apical half** of the great cardiac vein)." (Ex. 1001, 6:62-7:1 (emphasis added).) As illustrated below, a comparison of Figure 1 of the '563 Patent and Figure 4 of KenKnight '967, shows that the pacing electrodes of KenKnight '967 are configured for positioning in a

comparable location as electrode C [52] in Figure 1 of the ’563 Patent. This further shows that electrodes 18a and 18b in Figure 10 of KenKnight ’967, which may be positioned in accordance with Figure 4, are configured for “positioning through the coronary sinus and in either the apical third of the posterior cardiac vein or the apical half of the great cardiac vein,” as required by dependent claims 3, 9, and 16. (Ex. 1006, ¶¶ 297-298.)

’563 Patent



KenKnight ’967



KenKnight ’967 also explains that a “preferred location for a transvenous pacing electrode (15) which has been introduced into the coronary sinus, then into the great cardiac vein, and then into the ascending limb of either the anterior cardiac vein or the **posterior cardiac vein**, into the vasculature of the left ventricle.” (Ex. 1008, 6:40-50 (emphasis added); *see also id.* at Fig. 4; Ex. 1006, ¶ 299.) The specification also specifies that “[t]his embodiment places the pacing electrode (15) **as close as possible to the apex of the left ventricle** via a

transvenous procedure." (Ex. 1008, 6:48-50 (emphasis added); *see also id.* at Fig. 4; Ex. 1006, ¶ 299.)

Accordingly, a person of ordinary skill in the art would have understood that the coronary sinus electrode system of Figure 10 includes a primary electrode that is "configured for positioning through the coronary sinus and in either the apical third of the posterior cardiac vein or the apical half of the great cardiac vein." (Ex. 1006, ¶¶ 293-300.) Thus, because the other limitations of claims 3, 9, and 16 are anticipated for the reasons explained above for claims 1 and 7, and 14, claims 3, 9, and 16 are also unpatentable as anticipated by KenKnight '967. (*Id.*, ¶ 301.)

6. Dependent Claims 10 and 17

Claims 10 and 17 depend from claims 7, and 14, respectively, which as discussed above are unpatentable as anticipated by KenKnight '967. Claims 10 and 17 add the following limitation:

a. Additional Limitation: "a system according to claim [7 or 14], wherein said power supply includes a capacitor."

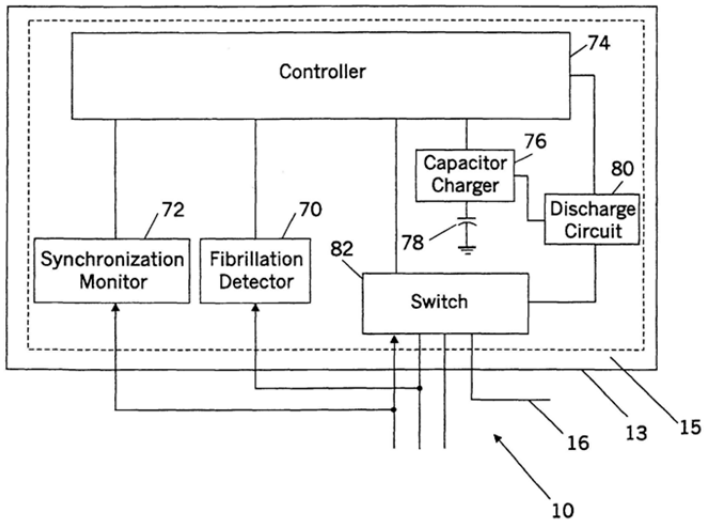
The '563 Patent does not teach or require any particular implementation of a power supply that "includes" a capacitor. (*Id.*, ¶ 303.) The specification states:

> Numerous configurations of capacitor and control circuitry may be employed. The power supply may include a single capacitor, and the control circuit may be configured so that both the auxiliary pulse and the defibrillation pulse are generated by the discharge of the single capacitor. The power supply may include a first and second capacitor,

with the control circuit configured so that the auxiliary pulse is generated by the discharge of the first capacitor and the defibrillation pulse is generated by the discharge of the second capacitor. In still another embodiment, the power supply includes a first and second capacitor, and the control circuit may be configured so that the auxiliary pulse is generated by the discharge (simultaneous or sequential) of both the first and second capacitors, and the defibrillation pulse likewise generated by the discharge of the first and second capacitors. The controller's power supply may include a 20 to 400 microfarad capacitor.

(Ex. 1001, 7:57-8:6.)

Figure 2 of the '563 Patent illustrates a "capacitor/charger (76)" component as part of electronic circuit 15; Figure 2 does not show a power supply. (Ex. 1006, ¶ 304.)



A person of ordinary skill would have understood the '563 Patent's disclosure of a "power supply includ[ing] a capacitor" to refer to a power supply used in

conjunction with a capacitor. (*Id.*, ¶ 305.)

A person of ordinary skill in the art reading KenKnight '967 would have understood it to disclose a power supply in conjunction with a capacitor. (*Id.*, ¶ 306.) KenKnight '967 discloses that the device includes a capacitor, referring to the "capacitor network charge/discharge controller (170)" (Ex. 1008, 10:18-20; *see also id.* at Fig. 10), specifying that the "capacitor network [has] capacitance in the range of 200-400 μF" (*id.* at 7:8-10), and disclosing that the invention can utilize "a single capacitor, or multiple capacitors, as dictated by morphology, available pulse generator volume, and other considerations" (*id.* at 7:14-15). (*See* Ex. 1006, ¶ 306.)

In association with the pulse generator (100), which includes "capacitor network charge/discharge controller (170)," KenKnight '967 also discloses a power supply: "[o]f course, not shown in FIG. 10 but well within the skill of the art to supply, are **power supplies**, implantable housings and other materials for the pulse generator (100) and electrode systems (10, etc.), general timing, memory, and support circuitry, and the like." (Ex. 1008, 10:30-34 (emphasis added); Ex. 1006 ¶ 307.) A person of ordinary skill in the art also would have understood that a capacitor is necessarily used in conjunction with a power supply. (Ex. 1006, ¶ 307.)

The power supply and capacitor(s) disclosed in KenKnight '967 appear to

perform the same functions as the "power supply includ[ing] a capacitor" disclosed in the '563 Patent, described above. (*Id.*, ¶ 308.) Specifically, "[t]he pacing output circuit (160) and capacitor network charge/discharge controller (170) provide the pacing-level shocks (S_p) and defibrillation-level shocks (S_D) through appropriate electrode systems." (Ex. 1008, 10:25-28; Ex. 1006, ¶ 308.) KenKnight '967 therefore discloses a power supply that includes a capacitor. (Ex. 1006, ¶ 308.)

Because the other limitations of claims 10 and 17 are anticipated for the reasons explained above for claims 7 and 14, claims 10 and 17 are also anticipated by KenKnight '967. (*Id.*, ¶¶ 302-310.)

7. Dependent Claims 4, 11, and 18

Claims 4, 11, and 18 depend from claims 1, 7, and 14, respectively, which as discussed above are unpatentable an anticipated by KenKnight '967. Claim 4 adds the following limitation:

a. **Additional Limitation:** "a system according to claim 1, wherein said capacitor is a 20 to 400 microfarad capacitor."

Claims 11 and 18 add the following similar limitation:

b. **Additional Limitation:** "a system according to claim [7 or 14], wherein said power supply includes a 20 to 400 microfarad capacitor."

KenKnight '967 discloses a capacitor of 20 to 400 microfarads: "a capacitor network having capacitance in the range of 20 to 400 μF." (Ex. 1008, 7:8-10.)

The specification goes on to explain that the capacitor network may be a single capacitor or multiple capacitors. (*Id.* at 7:14-15.) These limitations are therefore disclosed by KenKnight '967. (Ex. 1006, ¶ 312.)

Because the other limitations of claims 4, 11, and 18 are anticipated for the reasons explained above for claims 1 and 7, and 14, claims 4, 11, and 18 are also unpatentable as anticipated by KenKnight '967. (*Id.*, ¶¶ 312-314.)

8. Dependent Claims 5, 12, and 19

Claims 5, 12, and 19 depend from claims 1, 7, and 14, respectively, which as discussed above are unpatentable as anticipated by KenKnight '967. Claims 5, 12, and 19 add the following limitation:

a. **Additional Limitation:** "a system according to claim [1, 7 or 14], wherein each one of said primary electrodes is carried by a transvenous lead."

KenKnight '967 fully discloses this limitation. KenKnight '967 states that "pacing pulses are administered from **a transvenous lead** (10)." (Ex. 1008, 6:12-13 (emphasis added).) Figure 10, in turn, "implement[s] . . . the electrode configuration of FIG. 1." (*Id.* at 9:53-56.) It is clear that electrodes 18a and 18b in Figure 10 are carried by transvenous lead (10)—KenKnight expressly notes that the "coronary sinus electrode system comprises two electrodes (18a, 18b)." (*Id.* at 9:61-63). In addition, even from visual inspection of Figures 1 and 10, a person of ordinary skill in the art would have concluded that electrodes 18a and 18b are

"carried by" transvenous lead 10. (*See* Ex. 1006, ¶ 316.) Accordingly, KenKnight '967 discloses a system where "one of [the] primary electrodes is carried by a transvenous lead." (*Id.*, ¶¶ 315-320.)

Because the other limitations of claims 5, 12, and 19 are anticipated for the reasons explained above for claims 1 and 7, and 14, claims 5, 12, and 19 are also anticipated by KenKnight '967. (*Id.*, ¶ 320.)

9. Dependent Claims 6, 13, and 20

Claims 6, 13, and 20 depend from claims 1, 7, and 14, respectively, which as discussed above are unpatentable as anticipated by KenKnight '967. Claims 6, 13, and 20 add the following limitation:

a. **Additional Limitation:** "a system according to claim [1, 7 or 14], wherein said plurality of primary electrodes are carried by a common transvenous lead."

The broadest reasonable construction of this limitation in light of the specification is: a system where said multiple electrodes [of claims 1, 7, and 14] are carried by the same transvenous lead. (*Id.*, ¶ 322.) Figure 10 discloses "[t]he coronary sinus electrode system comprises two electrodes (18a, 18b)" (Ex. 1008, 9:61-62), which are illustrated as carried on a single transvenous lead. (*Id.* at Fig. 10; Ex. 1006, ¶ 323.) Figure 10 below shows a single transvenous lead carrying electrodes 18a and 18b:

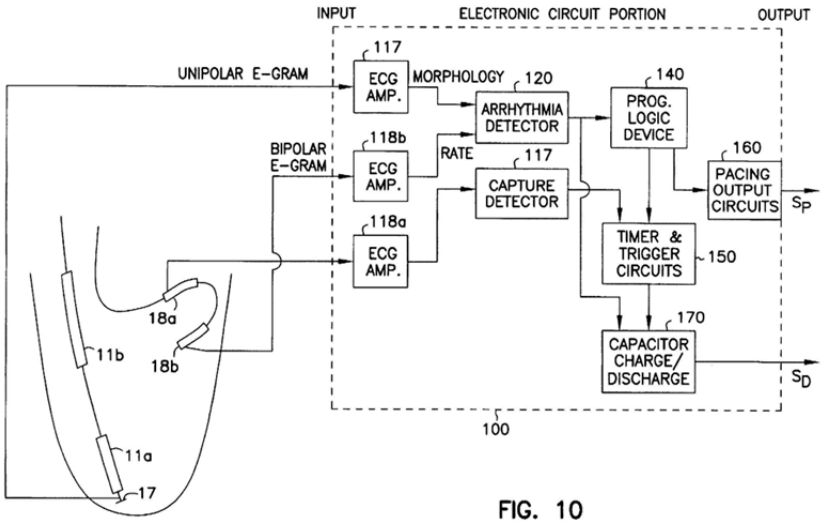


FIG. 10

KenKnight '967 states that Figure 10 "implement[s] . . . the electrode configuration of FIG. 1[.]" (Ex. 1008, 9:53-10:15; Ex. 1006, ¶ 324.) Thus, electrodes 18a and 18b, which meet the claim limitation of "said plurality of primary electrodes" as discussed above, are carried by the same transvenous lead (10). (*See* Ex. 1006, ¶ 324.) Accordingly, a person of ordinary skill in the art would have understood KenKnight '967 to disclose multiple electrodes carried by a single transvenous lead. (*Id.*, ¶¶ 321-325.)

Because the other limitations of claims 6, 13, and 20 are anticipated for the reasons explained above for claims 1 and 7, and 14, claims 6, 13, and 20 are also unpatentable as anticipated by KenKnight '967. (*Id.*, ¶ 326.)

VIII. CONCLUSION

Petitioner respectfully submits that *inter partes* review of claims 1-20 of U.S. Patent No. 6,266,563 should be instituted on the grounds set forth herein.

FAEGRE BAKER DANIELS LLP

Dated: March 23, 2015

By: /Jason Kraus/
Jason Kraus
Reg. No. 42,765

Faegre Baker Daniels LLP
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.105, I hereby certify that I caused a true and correct copy of the Petition for *Inter Partes* Review in connection with U.S. Patent No. 6,266,563 and Exhibits 1001 – 1052 to be served via United States Postal Service Priority Mail on March 23, 2015, on the following:

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