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 1056:	U.S. Patent No. 5,978,704, filed on June 3, 1997 and issued to Ideker et al. on Nov. 2, 1999 ("'704 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.

In addition, on March 23, 2015, Petitioner filed a Petition for *Inter Partes* Review (Case No. IPR2015-00918), also requesting review of claims 1-20 of the '563 Patent. IPR2015-00918 is a proceeding which may affect or be affected by a decision in this proceeding. This Petition does not present the "same or

substantially the same prior art or arguments" presented by Petitioner in IPR2015-00918. *See* 35 U.S.C. § 325(d). In IPR2015-00918, Petitioner seeks *inter partes* review and cancellation of claims 1-20 of the '563 Patent based on different prior art and a different ground than this Petition. More specifically, in IPR2015-00918, Petitioner asserts that the challenged claims are anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,797,967, whereas this Petition challenges claims 1-20 as obvious under 35 U.S.C. § 103 based on U.S. Patent No. 5,181,511 ("Nickolls"), U.S. Patent No. 5,433,729 ("Adams"), and the knowledge of a person of ordinary skill in the art. Furthermore, IPR2015-00918 depends on a determination that the '563 Patent is not allowed to rely on a filing date earlier than September 7, 1999. In contrast, the obviousness ground set forth in this Petition applies regardless of whether the '563 Patent is entitled to the benefit of either of the earlier filing dates of its ancestral applications.

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."[1] (Ex. 1001 at cls. 1, 7,

[1] Dr. Benditt's declaration provides relevant background information on the anatomy of the heart and antitachycardia pacing. (Ex. 1006, ¶¶ 21-109.)

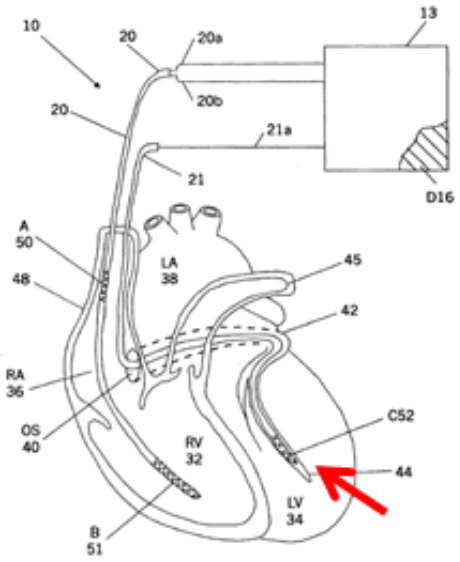
14, Abstract.) Each of the '563 Patent's independent claims also requires an electrode "configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart." (*Id.*) Independent claim 1 is representative of the claimed invention and claims:

> 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, ¶ 114.) 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.* ¶ 115.)

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 references set forth in the following table:

Claims	Basis	References
1-20	35 U.S.C. § 103	U.S. Patent No. 5,181,511 ("Nickolls") (Ex. 1009), U.S. Patent No. 5,433,729 ("Adams") (Ex. 1010), and the knowledge of a person of ordinary skill in the art

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 VIII.

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, ¶¶ 62-71, 219, 221-223.)
"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, ¶¶ 219, 252-254.)

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, ¶ 17.) 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.* ¶ 20.)

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

A detailed explanation of how construed claims 1-20 of the '563 Patent are unpatentable under 35 U.S.C. § 103, including identification of where each limitation of claims 1-20 is taught by the prior art references relied upon, as well as the rationale for combining those teachings, is provided in Section VIII 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, ¶¶ 21-109), level of skill in the art (*id.* ¶¶ 17-20), description and priority date of the '563 Patent (*id.* ¶¶ 110-190), scope and content of the prior art references (*id.* ¶¶ 191-217), and a detailed explanation of why all claims of the '563 Patent would have been obvious to a person of ordinary skill in the art as of the date of invention (*id.* ¶¶ 220-376).

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

Although Nickolls and Adams qualify as prior art under § 102(b) even if the challenged claims were somehow entitled to rely on the filing date of the earliest ancestral application (*see* Ex. 1006, ¶¶ 192, 198), the claims of the '563 Patent include new subject matter and are therefore not entitled to rely on a filing date earlier than September 7, 1999. 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, which 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.

The ’563 Patent is 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 require “antitachycardia pacing” and a “control circuit configured for delivering antitachycardia pacing.” (Ex. 1001 at cls. 1-20.) As set forth in detail in Dr. Benditt’s declaration, 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 application for the ’563 Patent, which was filed on September 7, 1999. (Ex. 1006, ¶¶ 123-190.) The previous ’261 Application (Ex. 1002) and ’705 Patent (Ex. 1004) would not have disclosed to a person of ordinary skill the concept of either “antitachycardia pacing” or a “control circuit configured for delivering antitachycardia pacing,” as required by the claims of the ’563 Patent. (*Id.* ¶¶ 123-182, 190.) The claims of the ’563 Patent are therefore not entitled to rely on any filing date earlier than September 7, 1999.

In any event, as explained in Dr. Benditt’s declaration, claims 1-20 of the ’563 Patent would have been obvious in view of Nickolls and Adams and the

knowledge of one of ordinary skill in the art as of March 13, 1998, or March 14, 1997, for the same reasons they would have been obvious as of September 7, 1999. Accordingly, even if claims 1-20 were somehow entitled to rely on the filing date of one of the earlier ancestral applications—*i.e.*, March 13, 1998, or March 14, 1997—all of the claims would have been obvious. (*Id*. ¶ 19.)

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). As described below, this Petition meets that threshold because the differences between the alleged invention and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art as of the date of the invention.[2] 35 U.S.C. § 103(a). For example, the Nickolls and Adams references and the common knowledge of a person of ordinary skill in the art disclose all of the limitations of

[2] As explained in Dr. Benditt's declaration, claims 1-20 of the '563 Patent would have been obvious to a person of ordinary skill in the art regardless of whether the '563 Patent is entitled to rely on the filing dates of any of its ancestral applications. (Ex. 1006, ¶ 19.) Accordingly, for purposes of this Petition, "date of invention" refers to any time period within the 1997-1999 timeframe.

claims 1-20 of the '563 Patent. A person of ordinary skill in the art also would have found all of the challenged claims to be a "predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007). (*See* Ex. 1006, ¶ 220.) Petitioner, therefore, respectfully submits that claims 1-20 are unpatentable under 35 U.S.C. § 103.

VII. SPECIFIC GROUNDS FOR UNPATENTABILITY

Pursuant to Rule 42.104(b)(4)-(5), the challenged claims are unpatentable because they are obvious in view of Nickolls, Adams, and the knowledge of one of ordinary skill in the art, 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, respectively. (*See* Ex. 1001, cls. 2, 8, 15; cls. 3, 9, 16; cls. 10, 17; cls. 4, 11, 18; cls. 6, 13, 20.) For efficiency, such dependent claims are addressed as a group.

VIII. SPECIFIC GROUNDS FOR UNPATENTABILITY BASED ON OBVIOUSNESS

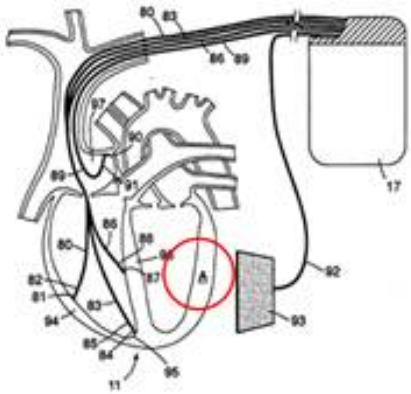
A. Overview of Obviousness Based on Nickolls and Adams

Nickolls issued on January 26, 1993, more than a year before the earliest potential priority date of the '563 Patent, and is prior art under 35 U.S.C. § 102(b).

(Ex. 1006, ¶ 192.) Like the claimed invention in the '563 Patent, Nickolls discloses an implantable system for delivery of antitachycardia pacing to the heart. (*See* Ex. 1009 at Abstract, Fig. 5; Ex. 1006, ¶ 193.) Nickolls is pertinent art because it discloses "[a]n implantable device . . . for treating cardiac arrhythmias in a patient's heart" and "[a] source of antitachycardia pacing therapy and an electrode system including at least three electrodes for delivering the antitachycardia pacing therapy to the heart." (Ex. 1009 at Abstract; Ex. 1006, ¶ 193.)

An exemplary embodiment from Nickolls is shown in Figure 5. (Ex. 1009, Fig. 5; Ex. 1006, ¶ 193.) As shown in Figure 5, the implantable system of Nickolls delivers ATP to the right and left ventricles. For the right ventricle, Nickolls delivers ATP via endocardial electrodes—*i.e.*, electrodes positioned inside the right ventricle. (*See* Ex. 1009 at 10:66-11:3 (leads 80, 83, and 86); Ex. 1006, ¶ 194.) The system of Nickolls also delivers ATP to the left ventricle and uses a patch electrode positioned on or near the surface of the left ventricle to focus the electrical energy of ATP to the epicardial surface of the left ventricle. (*See* Ex. 1009 at 5:59-63 ("It is another object of the invention to provide active electrodes strategically positioned around the focus of the VT, for example in

FIG. 5.



the right ventricle, subcutaneously over the heart and on the left epicardial surface of the heart[.]"), 10:63-65 ("lead 92 is provided with a conventional subcutaneous patch electrode 93"), 11:6-15 (when the sensing circuitry "has determined that a VT focus exists at point 'A' in the FIG. 5 embodiment" the circuitry determines the appropriate electrode orientation for applying ATP); Ex. 1006, ¶ 194.)

The implantable system disclosed by Nickolls includes almost all of the components of the implantable system claimed by the independent claims of the '563 Patent. Referring to representative claim 1, the Nickolls system discloses "a plurality of primary stimulation electrodes configured for" sensing cardiac signals and delivering antitachycardia pacing to the heart, including a patch electrode used for delivering antitachycardia pacing to the left ventricle, where the patch electrode is placed on the surface of the left ventricle or subcutaneously over the left ventricle. (Ex. 1009 at 5:59-64 ("It is another object of the invention to provide active electrodes strategically positioned around the focus of the VT, for example in the right ventricle, **subcutaneously over the heart and on the left epicardial surface of the heart**, with a reference electrode placed at a distance.") (emphasis added), Abstract (referring to "an electrode system including at least three electrodes for delivering the antitachycardia pacing therapy to the heart" and "[c]ircuitry and software for detecting a tachycardia"), Fig. 5; Ex. 1006, ¶ 195.) Figures 1 through 4 and the corresponding text of Nickolls disclose circuitry and

programming for delivering ATP through the electrodes of the system. (Ex. 1009 at Figs. 1-4, 6:59-10:34.) As discussed in detail below, the implantable system of Nickolls also includes "a power supply" and "a control circuit" as claimed by the independent claims of the '563 Patent.

The only limitation of representative claim 1 that Nickolls does not fully disclose is the one requiring that an electrode is "configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle[.]" Rather, in Nickolls, the electrode on or over the left ventricle is a patch electrode, which is not positioned transvenously but instead through an incision in the chest. (*See* Ex. 1009 at 5:59-63, 10:63-65; Ex. 1006, ¶ 195.) Thus, Nickolls does not disclose an electrode "configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle." (*See* Ex. 1001 at cl. 1).

Although Nickolls does not teach an electrode "configured for positioning through the coronary sinus ostium and within a vein," it does teach the importance of delivering ATP to the left ventricle. (Ex. 1006, ¶ 203.) Nickolls, for example, explains that it is important to deliver ATP to the left ventricle due to the fact that "many tachycardias arise in the left ventricle" and "if a rapid tachycardia develops at this site, it will not be possible to terminate it by ATP therapy delivered through a single electrode in the right ventricle due to the distance of the stimulating

electrode from the site of origin of the VT [Ventricular Tachycardia]." (Ex. 1009 at 5:18-25; *see also id.* at Abstract, 5:8-12 (emphasizing the importance of "the distance between the pacing site and the site of origin of a tachycardia").) Nickolls further explains that "only rarely can stimulation from the right ventricle be more effective than that from the left ventricle in terminating ventricular tachycardia." (*Id.* at 5:33-35; *see also* Ex. 1006, ¶ 203.) These statements in Nickolls are consistent with the knowledge in the art that delivery of antitachycardia pacing in close proximity to the site of origin of tachycardia maximizes its potential effectiveness. (*See* Ex. 1006, ¶ 204.)

Nickolls also explains that while it is important to deliver ATP to the left ventricle, "[i]t is not possible to place electrodes in the left ventricle permanently." (Ex. 1009 at 5:19-20.) A person of ordinary skill in the art would have understood this statement in Nickolls to refer to the dangers associated with placing an endocardial lead inside the left ventricle (*i.e.*, a lead in the endocardium or innermost layer of the heart tissue lining the chambers). (Ex. 1006, ¶ 205.) This cautionary point in Nickolls is because, while it was common in the late 1980s and early 1990s to place electrodes inside the right ventricle (as shown in Nickolls), it was well-known that placement of an endocardial lead inside the left ventricle placed a patient at significant risk of arterial thrombosis and/or the formation of a blood clot within the left ventricle. (*Id.*) And if a blood clot forms in the left

ventricle, the heart may pump the clot from the left ventricle directly into the arterial circulation of the body, leading to serious complications, such as stroke or death. (*Id*.) To avoid the dangers of placing an electrode inside the left ventricle, Nickolls used a patch electrode, placed either on the surface of the left ventricle or subcutaneously over the left ventricle. (*Id.* ¶ 206.)

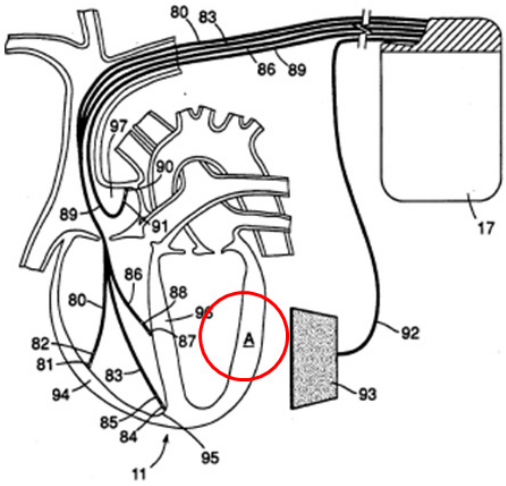
With respect to the location of the electrodes, Nickolls's placement of a patch electrode delivers ATP to a comparable location as the '563 Patent's electrodes placed on the surface of the left ventricle. (*Id*.) The main difference is that in Nickolls the electrode is a patch on or over the left ventricle, whereas in the '563 Patent the electrode is positioned through the coronary sinus and its tributaries to a vein on the surface of the left ventricle. (*Id*.) Thus, again, with respect to claim 1 of the '563 Patent, the only limitation not disclosed in Nickolls is an electrode "configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle[.]"

Adams, however, expressly discloses this missing limitation—*i.e.*, an electrode "configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle." Adams issued on July 18, 1995, more than a year before the earliest potential priority date of the '563 Patent, and is therefore prior art under 35 U.S.C. § 102(b). (*Id*. ¶ 198.) Adams is pertinent art to the '563 Patent because it discloses an implantable device (Ex. 1010 at Abstract)

with transvenous leads to position electrodes in or on both the right and left sides of the heart (*id*. at 15:47-16:7; *see also id.* at 16:40-49; Ex. 1006, ¶ 199). As shown in Figure 9 of Adams, below, and stated in the associated text, Adams teaches that an electrode can be positioned through the coronary sinus and into a coronary vein, such as the great cardiac vein, on the left ventricle. (Ex. 1010 at Fig. 9, 15:62-16:7; Ex. 1006, ¶ 200.) The lead carrying the electrodes in Adams is a transvenous epicardial lead implanted without the need for a surgical incision in the patient's chest. (Ex. 1006, ¶ 200.) Comparing Figure 5 of Nickolls with Figure 9 of Adams shows that Adams's electrodes are positioned to deliver ATP to a comparable location on the surface of the left ventricle as the system of Nickolls:

Nickolls

FIG. 5.



Adams

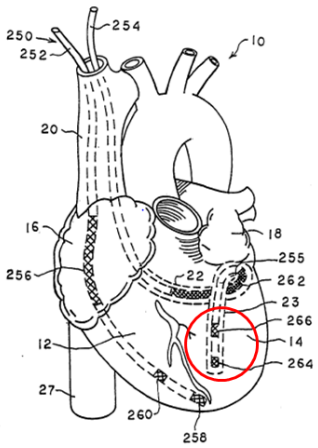


FIG. 9

One of ordinary skill in the art would have been motivated to combine the teachings of Nickolls and Adams in the manner claimed by the '563 Patent. (*Id.* ¶¶

201-217.) In particular, a person of ordinary skill in the art would have been motivated to replace the lead (92) and patch electrode of the implantable system in Nickolls with the transvenous lead (254) and electrode(s) in Adams. (*Id.* ¶ 209.) It would also have been well within the knowledge of a person of ordinary skill in the art and, indeed, would have been considered routine, to then configure the electrode(s) with appropriate circuitry for sensing and pacing. (*Id*.) A person of ordinary skill in the art would have recognized that modifying the system of Nickolls with the transvenous lead and electrode(s) from Adams would have the benefit of providing pacing close to the origin of tachyarrhythmias in the left ventricle while at the same time using a less invasive procedure. (*Id*.)

A person of ordinary skill reviewing Nickolls would have fully appreciated the known disadvantages of using a patch electrode relative to a transvenous electrode. For example, placement of a patch, as shown in Nickolls, requires a surgical incision in the chest. (*Id.* ¶ 210.) In addition, patch electrodes (both surface epicardial patches and subcutaneous patches) also have additional respective disadvantages, including a greater tendency to cause inflammation for surface epicardial patches and greater patient discomfort for subcutaneous patches. (*Id.* ¶¶ 210-211.) A subcutaneous patch is also farther away from the source of the tachycardia, because it is not placed directly on the surface of the left ventricle. (*Id.* ¶ 211.)

A person of ordinary skill in the art would have recognized that Adams's positioning of an electrode on the left ventricle transvenously through the coronary sinus and its tributaries would overcome the disadvantages associated with Nickolls's patch electrode. (*Id*. ¶ 212.) For example, positioning the electrode through the coronary sinus ostium and within a vein on the surface of the left ventricle, as taught by Adams, is a relatively less invasive procedure (*i.e.*, there is no need for an incision in the chest) and results in placement of an electrode in a vein directly on the surface of the left ventricle—*i.e.*, close to the site of the tachycardia. (*Id.*) This would have motivated a person of ordinary skill in the art to combine Nickolls and Adams in a manner that renders obvious the claimed invention of the '563 Patent. (*Id*. ¶ 213.)

A person of ordinary skill in the art also would have had a reasonable expectation of success in combining Nickolls and Adams in the manner discussed above. A person of ordinary skill would have already been familiar with placing electrodes transvenously—indeed, in Nickolls, the right ventricle electrodes are placed transvenously—and Adams shows how to position an electrode transvenously through the coronary sinus and its tributaries. (*See id.* ¶ 215.) Nickolls also discloses circuitry for configuring electrodes for sensing and delivering ATP, all of which was also within the common knowledge of a person of ordinary skill. (*Id*.) Moreover, as discussed by Dr. Benditt, advances in lead

technology and lead delivery systems in the early and mid-1990s improved the safety and reliability of introducing leads transvenously into smaller distal reaches of coronary sinus veins and tributaries to provide pacing to the left ventricle. (*Id.* ¶ 214.) Thus, it would have been obvious to replace the patch electrode of Nickolls with the transvenous lead (254) and electrode(s) of Adams and to configure the circuitry of the Nickolls system for applying ATP through the electrode(s). (*Id*. at ¶ 214.) The claimed invention, therefore, is no more than an "advance[] that would [have] occur[red] in the ordinary course without real innovation." *KSR Int'l Co.*, 550 U.S. at 419.

B. Claims 1-20 of the '563 Patent Would Have Been Obvious Based on Nickolls, Adams, and the Knowledge of a Person of Ordinary Skill

As discussed below, a person of ordinary skill in the art as of the date of the invention of the '563 Patent would have found it obvious to combine Nickolls and Adams in the manner of claims 1, 7, and 14 of the '563 Patent, as well as all of the dependent claims. Accordingly, claims 1-20 of the '563 Patent are obvious.

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, ¶¶ 221-223; *see also* Ex. 1001 at 3:63-4:3,

7:23-30, Fig. 2.) To the extent the preamble of claim 1 is a limitation, Nickolls teaches this limitation. Nickolls discloses "[a]n implantable device and method for treating cardiac arrhythmias in a patient's heart. A source of antitachycardia pacing therapy and an electrode system including at least three electrodes for delivering the antitachycardia pacing therapy to the heart are provided." (Ex. 1009 at Abstract; *see also id.* at 1:8-30 (stating that the invention relates to "implantable medical devices" which sense "atrial and ventricular tachycardia" and "deliver therapy in the form of electrical energy to cardiac tissue" and "an apparatus and method for antitachycardia pacing in a dual chamber arrhythmia control system"), Fig. 1, Fig. 5, 6:40-43, 1:50-57, 4:62-68.) Accordingly, a person of ordinary skill in the art would have found that Nickolls teaches this limitation. (Ex. 1006, ¶¶ 224-228.)

a. **First Limitation:** "a plurality of primary stimulation electrodes configured for sensing cardice[3] signals and delivering antitachycardia pacing to said heart;"

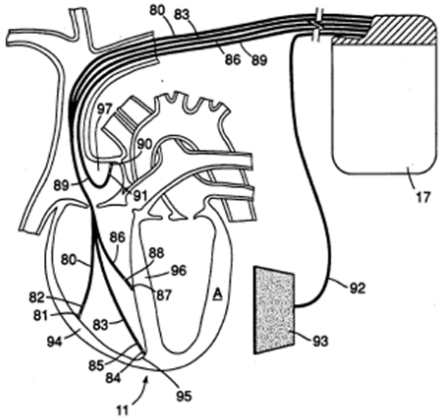
The broadest reasonable construction of this limitation in light of the specification is: multiple stimulation electrodes configured for sensing cardiac

[3] 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, ¶ 116 n.2.)

signals and delivering pacing pulses in response to tachycardia. (Ex. 1006, ¶ 229; *see also* Ex. 1001 at cls. 1-3, 7-9, 14-16, Abstract, 3:66-4:10.) Nickolls teaches this limitation.

The Abstract of Nickolls refers to both sensing of cardiac signals and delivering ATP to the heart using at least three electrodes. (Ex. 1009, Abstract (referring to "an electrode system including at least three electrodes for delivering the antitachycardia pacing therapy to the heart" and "[c]ircuitry and software for detecting a tachycardia"); *see also id*. at 10:46-65, 6:15-29, 11:6-15.) Figure 5 of Nickolls shows an example of the implantable device with multiple electrodes in the right ventricle and a patch electrode on or over the surface of the left ventricle. (Ex. 1006, ¶ 231.)

FIG. 5.



Nickolls teaches the use of "conventional" electrodes and provides a disclosure of the circuitry and microprocessor programming used to configure the electrodes for sensing of cardiac signals and delivering ATP. (Ex. 1009 at Figs. 1-4, 6:59-10:34, 10:57-65; Ex. 1006, ¶ 232.) Figure 2 of Nickolls depicts a block diagram of the pacemaker of the system, which shows circuitry, including "for atrial pacing 24, ventricular pacing 34, atrial sensing 25, ventricular sensing 35." (Ex. 1009 at 7:53-56.) Nickolls explains that the "sensing circuits 25 and 35 detect

respective atrial and ventricular analog signals 23 and 33 from the heart." (*Id.* at 7:59-61.) The pacing circuits receive "pace control input" and "pacing energy control input," which determine the type of pacing and the magnitudes of pulse energy to apply. (*Id*. at 8:7-23.) The pacing circuitry generates the "pacing pulses (or bursts of pulses for antitachycardia pacing)" delivered to the patient's heart. (*See id*. at 8:24-30.) Figure 3 of Nickolls depicts the microprocessor of its system. (*Id*. at 8:36-37.) The microprocessor includes programming for implementing the logic of the pacemaker's circuitry. (*See id.* at 8:44-50.) Nickolls thus discloses the use of multiple stimulation electrodes and provides configuration details needed for the system to enable the plurality of primary stimulation electrodes to sense cardiac signals and to deliver ATP, and a person of ordinary skill in the art would have found that Nickolls teaches this limitation. (Ex. 1006, ¶¶ 234-235.)

b. **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, ¶¶ 236-238; *see also* Ex. 1001 at 6:5-9, Abstract, 6:62-7:22.) This limitation would have been obvious in

view of the implantable device disclosed in Nickolls in combination with the teachings of Adams. (Ex. 1006, ¶ 239.)

As discussed above, Nickolls teaches the importance of delivering ATP to the left ventricle and discloses a patch electrode positioned to focus the electrical energy of ATP to the epicardial surface of the left ventricle. (Ex. 1009 at 10:63-65, 5:59-63.) Nickolls teaches that the patch electrode may be located on the surface of the left ventricle or subcutaneously over the left ventricle. (Ex. 1009 at 5:59-64; Ex. 1006, ¶ 240.) As also discussed above, in light of the known disadvantages of patch electrodes, including invasive surgery, a person of ordinary skill in the art would have been motivated to find a better option for placing an electrode on the left ventricle—a location that Nickolls teaches is important for delivery of ATP. (Ex. 1006, ¶ 241; Ex. 1009 at Abstract, 5:8-12, 5:18-25, 5:33-35.)

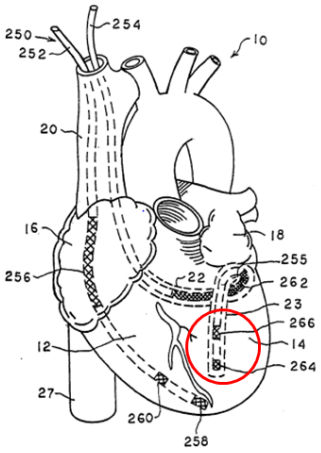


FIG. 9

Adams discloses and teaches a transvenous epicardial lead and electrode to deliver pacing to a comparable location as that of the electrode of Nickolls, without an invasive surgical procedure or the other disadvantages of a patch electrode. (Ex. 1006, ¶ 242; Ex. 1010 at Fig. 9.) Adams specifically teaches that an electrode can be positioned through the coronary sinus and in the great cardiac vein to

position the electrode in the epicardium of the left ventricle. Adams explains that "lead 254" with electrodes 264 and 266 "is fed into the superior vena cava 20 and into a coronary vein, such as the great vein 23 through the right atrium 16 and the coronary sinus 22 with electrodes 264 and 266 being adjacent the left ventricle within the great vein" and confirms that "[s]ince the coronary sinus 22 is in close proximity to the left ventricle 14, electrodes 264 and 266 will be in electrical contact with the left ventricle[.]" (Ex. 1010 at 15:62-16:7.) While the cited passage does not explicitly refer to "ostium," the coronary sinus ostium is the opening to the coronary sinus in the right atrium, and thus an electrode being fed "into a coronary vein . . . through the right atrium[] and the coronary sinus" is of anatomic necessity being fed through the coronary sinus ostium. (Ex. 1006, ¶ 244; *see also* Ex. 1010 at 5:28-34 (explicitly referring to passing of the lead "into the coronary sinus ostium"), 4:67-68 (showing "the coronary sinus ostium or opening 24"), Fig. 1.) A person of ordinary skill in the art would thus have understood Adams to disclose an electrode "configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart."

As explained above in Section VIII.A, in view of the comparative advantages relative to a patch electrode of positioning a lead and electrodes transvenously in a vein on the surface of the left ventricle as disclosed in Adams, one of ordinary skill in the art would have been motivated to apply this teaching to

the implantable system of Nickolls. (Ex. 1006, ¶ 245; *see also id*. ¶¶ 201-216.) In particular, a person of ordinary skill in the art would have been motivated to replace the lead (92) and patch electrode of the implantable system in Nickolls with the transvenous lead (254) and electrode(s) in Adams and to configure the circuitry of the Nickolls system for applying ATP through the electrode(s), so as to create a device in which a left ventricle electrode is positioned transvenously through the coronary sinus and its tributaries instead of through an incision in the patient's chest. (*See id.* ¶ 245.) It would have been well within the knowledge of a person of ordinary skill in the art and, indeed, would have been considered routine, to configure the electrode(s) with appropriate circuitry for sensing and pacing. (*Id.*) One of ordinary skill in the art would have also recognized that modifying Nickolls with the transvenous lead and electrode(s) from Adams would result in those electrodes being configured for sensing cardiac signals and delivering antitachycardia pacing. (*Id.* ¶ 246.)

Accordingly, a person of ordinary skill in the art would have been motivated to and found it obvious to replace the patch electrode in Nickolls with the lead and associated electrode(s) of Adams, which are configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of the heart, and to configure the electrode(s) for sensing cardiac signals and delivering antitachycardia pacing. (*Id.* ¶ 247.) Thus, a person of ordinary skill in the art

would have found this limitation obvious in light of the combination of Nickolls, Adams, and the knowledge of one of ordinary skill in the art. (*Id.* ¶ 248.)

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

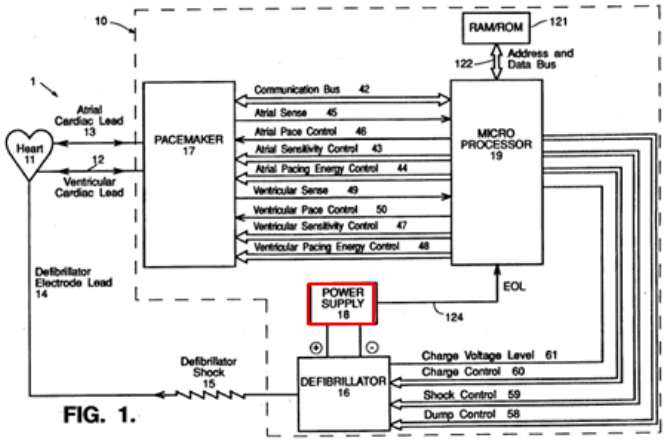


FIG. 1.

A person of ordinary skill in the art would have understood Nickolls to disclose a power supply, shown in Figure 1. (*Id.* ¶ 249.) Nickolls discloses that its system includes "a power supply 18 for the provision of a reliable voltage level to pacemaker 17, microprocessor 19, and a defibrillator 16." (Ex. 1009 at 7:11-13, Fig. 1). Pacemaker 17 delivers antitachycardia pacing. (*Id.* at 7:2-6 ("System 1 generally also includes a pacemaker 17 for the detection of analog signals representing cardiac electrical activity and for the delivery of bradycardia or antitachycardia pacing pulses.").) Thus Nickolls teaches this third limitation of claim 1. (Ex. 1006, ¶¶ 250-251.)

d. 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[4] 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 the stimulation electrodes. (Ex. 1006, ¶¶ 252-255; *see also* Ex. 1001 at 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 (shown to the right) "schematically illustrates the control circuitry employed in an apparatus of the present invention" (Ex. 1001 at 5:22-24) "and illustrates one example of an implantable housing 13 containing an **electronic circuit 15**" (*id.* at 7:23-24 (emphasis added)), 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

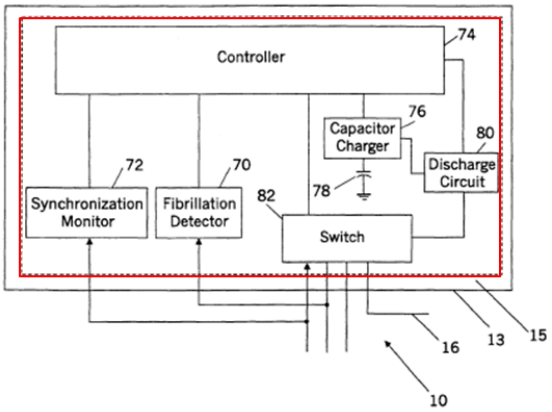


FIG. 2

[4] 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, ¶ 255.)

('synchronization monitor')" (*id.* at 7:23-56, Fig. 2).

A person of ordinary skill in the art would have understood Nickolls to disclose this limitation. Nickolls discloses a group of electrically connected components that includes a controller.

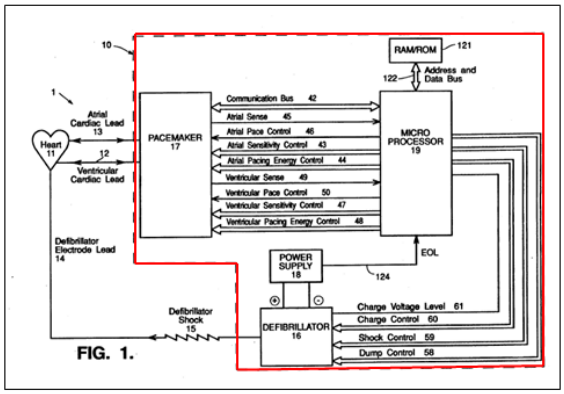


Figure 1 of Nickolls (shown right) "is a block diagram of a dual chamber arrhythmia control system (ACS)[.]" (Ex. 1009 at 6:40-42.) Figure 1 depicts the dual chamber arrhythmia control system, which "is designed to be implantable in a patient and includes a **cardioverter/defibrillator pacemaker or pulse module, shown generally at 10**, and appropriate leads for connecting module 10 to a patient's heart 11." (*Id.* at 6:59-65 (emphasis added).)

A person of ordinary skill in the art would have understood that cardioverter/defibrillator pacemaker or pulse module 10 is a group of electrically connected components that comprises a "control circuit," where microprocessor 19 is a "controller." (Ex. 1006, ¶ 257.) Nickolls states that microprocessor 19 of pulse module 10 generates control outputs, including outputs that control pacemaker 17. (Ex. 1009 at 7:2-13 ("[M]icroprocessor 19 … generate[s] different control and data outputs to both the pacemaker 17 and the defibrillator 16."), 9:3-14 (explaining that "[m]icroprocessor 19" performs arrhythmia detection and

produces control outputs that "determine the type of pacing to take place" and "the magnitude of the pulse energy" to be delivered); *see also id*. at 7:56-58 (confirming that "pacemaker 17 includes a control block 39 which includes an interface to microprocessor 19").) Microprocessor 19 is therefore a "controller," and cardioverter/defibrillator pacemaker or pulse module 10 is a group of electrically connected components that comprises a "control circuit." (Ex. 1006, ¶ 257.)

Nickolls also discloses that the electrically connected components of module 10 are operatively associated with a power supply (Ex. 1009 at 7:11-13 ("power supply 18 for the provision of a reliable voltage level to pacemaker 17, microprocessor 19, and defibrillator 16")) as shown in Figure 1 above. (Ex. 1006, ¶ 258.) Nickolls further discloses that pacemaker 17 is in turn operatively associated with stimulation electrodes, and therefore the control circuit of Nickolls (module 10) is configured for delivering pacing pulses in response to tachycardia through the stimulation electrodes. (Ex. 1006, ¶ 259; Ex. 1009 at 10:12-42 (describing the network of circuits and noting that "ventricular ATP pacing circuits" are connected to "appropriate electrodes" and can "deliver any type of currently used ATP therapy" once "a tachycardia is detected by the pacemaker"), 9:3-9 (referring to the arrhythmia detection and pacing determination made by the microprocessor); *see also id*. at Fig. 4.) Therefore Nickolls teaches all the

requirements of this limitation of claim 1 of the '563 Patent. (Ex. 1006, ¶ 260.)

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

A person of ordinary skill in the art would have understood Nickolls to disclose a group of electrically connected components that includes a controller (microprocessor 19) and also a capacitor. (Ex. 1006, ¶ 261.) A capacitor is a component used to store an electrical charge and is often utilized to output energy at the direction of a controller. (*Id*.) Nickolls explicitly discloses that its control circuit (pulse module 10) includes a capacitor, stating "[d]efibrillator 16 produces a high voltage **to charge its capacitors** and then optionally discharges them in response to control signals from microprocessor 19." (Ex. 1009 at 7:13-16 (emphasis added), Fig. 1.) Nickolls thus discloses this fifth limitation of claim 1.

Moreover, a control circuit that includes a capacitor was a common and well-known element of an implantable system for the delivery of antitachycardia pacing. (Ex. 1006, ¶ 263.) Nickolls discloses ATP pacing circuit 78, which outputs energy to electrodes to deliver antitachycardia pacing. (*Id.*; Ex. 1009 at Fig. 4, 6:47-50, 10:12-42.) A person of ordinary skill in the art would have known that one or more capacitors were commonly used in a pacing circuit to perform the function of delivering pacing pulses. (Ex. 1006, ¶ 263.) Thus, at a minimum, it would have been obvious to a person of ordinary skill in the art to include in the control circuit one or more capacitors in connection with pacemaker 17 to output

energy to the electrodes. (*Id*.) Accordingly, at a minimum, a control circuit including a capacitor was a well-known electronic design since at least the beginning of the use of implanted pacemakers and as such would have been an obvious and "predictable use of prior art elements according to their established functions" yielding "predictable results." *KSR*, 550 U.S. at 417. (Ex. 1006, ¶ 263.) Thus, Nickolls, in view of the knowledge of a person of ordinary skill in the art, teaches this fifth limitation of claim 1 of the '563 Patent. (*Id*. ¶ 264.)

Because Nickolls in view of Adams and the knowledge of a person of ordinary skill in the art teaches all of the limitations of claim 1, a person of ordinary skill in the art would have found claim 1 obvious in view of this combination as of the date of invention of the '563 Patent. (*Id.* ¶ 265.)

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, a person of ordinary skill in the art would have found that Nickolls teaches this limitation. (Ex. 1006, ¶ 266.)

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."[5] 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.* ¶ 267.) As discussed above with respect to claim 1, a person of ordinary skill in the art would have understood Nickolls to teach and disclose this limitation. (*See id.* ¶ 269.)

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 identical to that of claim 1, addressed above, except that as with the first limitation it recites "said primary electrodes" rather than "said primary stimulation electrodes" as in the second limitation of claim 1. For the reasons discussed above regarding the second limitation of claim 1, this limitation would have been obvious in view of the implantable device disclosed in Nickolls combined with the teachings of Adams. (*Id.* ¶ 272.)

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

This limitation of claim 7 is identical to that of claim 1, addressed above.

[5] For purposes of this Petition, there is no material difference under the broadest reasonable interpretation between "primary electrodes" and "primary stimulation electrodes." (Ex. 1006, ¶ 271.)

Accordingly, a person of ordinary skill in the art would have found that Nickolls teaches this limitation. (*Id.* ¶ 273.)

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. Accordingly, a person of ordinary skill in the art would have found that Nickolls teaches this limitation for the reasons stated in connection with the fourth limitation of claim 1. (*Id.* ¶ 277.)

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."

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. (Ex. 1006, ¶ 278.) 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 in the epicardium

of the left ventricle of the heart, such as the coronary sinus tributaries. (*Id*. ¶ 279.) The '563 Patent does not provide a more detailed description or definition of this term. (*Id*.)

As explained above in Section XII.A, due to the known advantages of transvenous epicardial lead placement, one of skill in the art would have been motivated to replace the lead and patch electrode on or over the left ventricle of the system in Nickolls with the electrode(s) of Adams configured for transvenous lead placement through the coronary sinus and into the great cardiac vein. A person of ordinary skill in the art would have understood the disclosure in Adams of the electrode configured for such placement as teaching this fifth limitation. In Figure 9, for example, Adams discloses an electrode 264 positioned on the surface or epicardium of the left ventricle. (*Id.* ¶ 281; Ex. 1010 at Fig. 9.) Adams further discloses that electrode 264 is placed in this position by passing it through the coronary sinus and into the great cardiac vein. (Ex. 1010 at 15:62-67 ("The electrodes 264, 266, and 262 are spaced apart on the second lead 254 so that when the lead 254 is fed into the superior vena cava 20 and into a coronary vein, such as the great vein 23 through the right atrium 16 and the coronary sinus 22 with electrodes 264 and 266 being adjacent the left ventricle

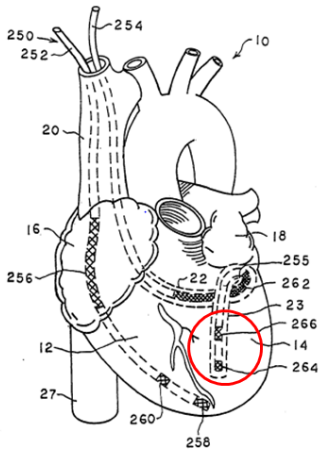


FIG. 9

within the great vein[.]"); Ex. 1006, ¶ 282.) Based on this disclosure and Figure 9 of Adams, a person of ordinary skill in the art would have understood Adams to disclose an electrode configured for positioning through the coronary sinus and within a tributary vein of the coronary sinus on the surface or epicardium of the left ventricle, including a tributary on the antero-lateral surface of the left ventricle. (Ex. 1006, ¶ 282.)

Furthermore, to the extent that Adams does not explicitly depict an electrode placed within a vein on the antero-lateral surface of the left ventricle of the heart, a person of ordinary skill in the art would have understood Adams to disclose an electrode "configured for" such placement. (*Id.* ¶ 283.) The disclosure in Adams of an electrode configured for positioning through the coronary sinus and great cardiac vein (a tributary of the coronary sinus) and on the surface or epicardium of the left ventricle, would have conveyed to one of ordinary skill in the art that the same electrode was also configured for positioning into other tributaries of the coronary sinus, *i.e.* into other veins on the left ventricle, including on its antero-lateral surface. (*Id.* ¶ 284.)

Indeed, a person of ordinary skill in the art would have understood that there are many tributary veins of the coronary sinus and that several of them could be used to access the antero-lateral surface of the left ventricle. (*Id.* ¶ 285.) In fact, because individual anatomies differ, the accessibility or usability of a particular

vein in a particular patient is not necessarily known with certainty until during the actual implantation procedure. (*Id*.) A person of ordinary skill in the art would therefore have understood that an electrode configured for placement transvenously on the left ventricle is configured for positioning into any one of the variety of existing cardiac veins, including those on the antero-lateral surface of the left ventricle. (*Id*.) Accordingly, a person of ordinary skill in the art would have understood that an electrode configured for positioning as taught in Adams within the great cardiac vein so that it is "adjacent the left ventricle" (Ex. 1010 at 15:62-67) as shown in Figure 9, is configured for positioning within a variety of cardiac veins on the left ventricle, including in veins on the antero-lateral surface of the left ventricle of the heart. (Ex. 1006, ¶ 285.)

Alternatively, at a minimum, placement of an electrode in a vein on the antero-lateral surface of the left ventricle would have been obvious based on Adams's disclosure of an electrode configured for positioning within the great cardiac vein (a tributary of the coronary sinus) and on the surface or epicardium of the left ventricle. (*Id.* ¶ 286.) A person of ordinary skill in the art would have recognized that an electrode configured for positioning or placement in one tributary would also be configured for positioning or placement in another tributary. (*Id*.) There are many tributary veins of the coronary sinus, and a person of ordinary skill in the art would have understood that, depending on the specific

location to be targeted, including on the antero-lateral surface of the left ventricle, a number of the veins could be used. (*Id*.) Thus, based on the disclosure of Adams of an electrode configured for placement through the coronary sinus and great cardiac vein, as well as the knowledge of a person of ordinary skill in the art, a person of ordinary skill in the art would have found an electrode "configured for positioning through the coronary sinus and within a vein on the antero-lateral surface of the left ventricle" of the heart to be an obvious and "predictable use of prior art elements according to their established functions" yielding "predictable results." *KSR,* 550 U.S. at 417. (Ex. 1006, ¶ 286.)

Therefore, this fifth limitation of claim 7 of the '563 Patent is taught, or at a minimum rendered obvious to a person of ordinary skill in the art, in view of Nickolls, Adams, and the knowledge of a person of ordinary skill. (*Id.* ¶ 287.)

Because Nickolls in view of Adams and the knowledge of a person of ordinary skill in the art teaches all of the limitations of claim 7, a person of ordinary skill in the art would have found claim 7 obvious in view of this combination as of the date of invention of the '563 Patent. (*Id.* ¶ 288.)

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, a person of ordinary skill in the art would have found that Nickolls teaches this limitation. (Ex. 1006, ¶ 289.)

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, a person of ordinary skill in the art would have found that Nickolls teaches this limitation. (*Id.* ¶¶ 290-291.)

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, a person of ordinary skill in the art would have found that Nickolls teaches this limitation. (*Id.* ¶¶ 292-293.)

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

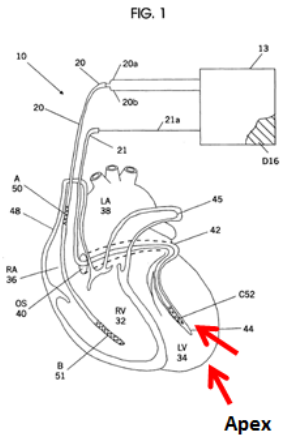
This limitation of claim 14 is identical to that of claims 1 and 7, addressed above. Accordingly, a person of ordinary skill in the art would have found that Nickolls teaches this limitation. (*Id.* ¶¶ 294-295.)

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, a person of ordinary skill in the art would have found that Nickolls teaches all of the requirements of this fourth limitation of claim 14 of the '563 Patent. (*Id.* ¶¶ 296-297.)

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."

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. (Ex. 1006, ¶¶ 298-299.) 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 in the epicardium of the left ventricle of the heart, such as the coronary sinus tributaries. (*Id.* ¶ 300.) The '563 Patent states the following regarding an electrode configured for positioning in a vein on the postero-lateral surface of the heart: "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). . . . 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)." (Ex. 1001 at 6:62-7:13.) Figure 1 is annotated above to indicate the locations of electrode C52 and the apex of the heart. (*Id*. at Fig. 1; Ex. 1006, ¶ 301.)

As explained above in Section VIII.A, due to the known advantages of transvenous epicardial lead placement, one of skill in the art would have been motivated to replace the patch electrode on or over the left ventricle of the system in Nickolls with the electrode(s) of Adams configured for transvenous lead placement through the coronary sinus and into the great cardiac vein. A person of ordinary skill in the art would have understood the disclosure in Adams of the electrode configured for such placement as teaching this fifth limitation. (Ex. 1006, ¶ 304.) In Figure 9, for example, Adams discloses that electrode 264 is placed in this position by passing it through the coronary sinus and into the great cardiac vein. (*Id.* ¶ 305; Ex. 1010 at Fig. 9.) Adams further discloses an electrode that is fed through the coronary sinus and into the great cardiac vein. (Ex. 1010 at 15:62-67 ("The

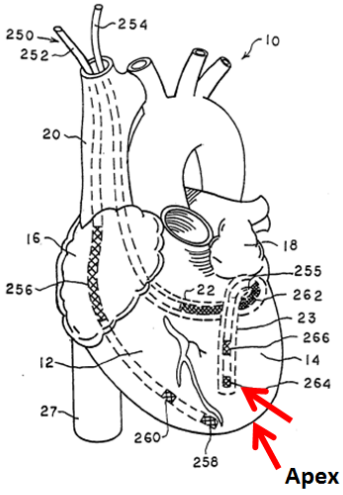


FIG. 9

electrodes 264, 266, and 262 are spaced apart on the second lead 254 so that when the lead 254 is fed into the superior vena cava 20 and into a coronary vein, such as the great vein 23 through the right atrium 16 and the coronary sinus 22 with electrodes 264 and 266 being adjacent the left ventricle within the great vein[.]"); Ex. 1006, ¶ 305.) Based on this disclosure and Figure 9 of Adams, a person of ordinary skill in the art would have understood Adams to disclose an electrode configured for positioning through the coronary sinus and within a tributary vein of the coronary sinus on the surface or epicardium of the left ventricle, including a tributary on the postero-lateral surface of the left ventricle. (Ex. 1006, ¶ 306.)

Furthermore, to the extent that Adams does not explicitly depict an electrode placed within a vein on the postero-lateral surface of the left ventricle of the heart, a person of ordinary skill in the art would nonetheless have understood Adams to disclose an electrode "configured for" such placement. (*Id.* ¶ 307.) The disclosure in Adams of an electrode configured for positioning through the coronary sinus and great cardiac vein (a tributary of the coronary sinus) and on the surface or epicardium of the left ventricle, would have conveyed to one of ordinary skill in the art that the same electrode was also configured for positioning into other tributaries of the coronary sinus, *i.e.* into other veins on the left ventricle, including on its postero-lateral surface. (*Id.* ¶ 308.)

Indeed, a person of ordinary skill in the art would have understood that there

are many tributary veins of the coronary sinus, and that several of them could be used to access various locations of the cardiac epicardial surface, including the postero-lateral surface of the left ventricle. (*Id.* ¶ 309.) In fact, individual anatomies differ, and the accessibility or usability of a particular vein in a particular patient is not necessarily known with certainty until during the implantation procedure. (*Id*.) A person of ordinary skill in the art would therefore have understood that an electrode configured for placement transvenously on the left ventricle is configured for positioning into any one of the variety of cardiac veins, including those on the postero-lateral surface. (*Id*.) Accordingly, a person of ordinary skill in the art would have understood that an electrode configured for positioning as taught in Adams within the great cardiac vein so that it is "adjacent the left ventricle" (Ex. 1010 at 15:62-67) as shown in Figure 9, is configured for positioning within a variety of cardiac veins on the left ventricle, including in veins on the postero-lateral surface of the left ventricle of the heart. (*Id*.)

Alternatively, at a minimum, the placement of an electrode in a vein on the postero-lateral surface of the left ventricle would have been obvious based on Adams's disclosure of an electrode configured for positioning within the great cardiac vein (a tributary of the coronary sinus) and on the surface or epicardium of the left ventricle. (Ex. 1006 ¶ 310.) A person of ordinary skill in the art would have recognized that an electrode configured for positioning or placement in one

tributary would also be configured for positioning or placement in another. (*Id*.) There are many tributary veins of the coronary sinus, and a person of ordinary skill in the art would have understood that, depending on the location to be targeted, including on the postero-lateral surface of the left ventricle, a number of the veins could be used. (*Id*.) Thus, based on the disclosure of Adams of an electrode configured for placement through the coronary sinus and great cardiac vein, as well as the knowledge of a person of ordinary skill in the art, a person of ordinary skill would have found an electrode "configured for positioning through the coronary sinus and within a vein on the postero-lateral surface of the left ventricle" of the heart to be an obvious and "predictable use of prior art elements according to their established functions" yielding "predictable results." *KSR,* 550 U.S. at 417. (Ex. 1006, ¶ 310.) Therefore, this fifth limitation of claim 14 of the '563 Patent is taught, or at a minimum rendered obvious, in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. (Ex. 1006 ¶ 311.)

Because Nickolls in view of Adams and the knowledge of a person of ordinary skill in the art teaches all of the limitations of claim 14, a person of ordinary skill in the art would have found claim 14 obvious in view of this combination as of the date of invention of the '563 Patent. (*Id.* ¶ 312.)

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 in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. 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. (Ex. 1006, ¶ 314.) The only additional term 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 a left ventricle and a right ventricle. (*Id.* ¶ 22.) Nickolls discloses this limitation, as its system has electrodes configured for delivering antitachycardia pacing to both ventricles.

As discussed in Section VIII.A, Nickolls discloses a system with electrodes configured for delivering pacing pulses in response to tachycardia to the ventricles. (*Id.* ¶ 316.) Nickolls discloses a "dual chamber antitachycardia pacing device, . . . including a pacemaker and a plurality of electrodes, in which the electrodes are used as sensors to determine which of the electrodes are nearest to the site of the tachycardia" and then the selected electrodes are used "to provide ATP therapy" to the tissue in the area of the tachycardia focus site. (Ex. 1009 at 6:15-29; *see also*

id. at Abstract.) Figure 5 of Nickolls shows electrodes positioned in the right ventricle and on or over the left ventricle and discloses that the electrodes are configured for delivering pacing pulses in response to tachycardia to the ventricles. (Ex. 1006, ¶¶ 317-318; Ex. 1009 at 10:46-65 ("a number of possible electrode orientations that may be selected by the sensing circuitry . . . to establish a virtual electrode and apply appropriate ATP therapy"), 9:27-38, 11:6-15.)

As discussed above in Section VIII.A, while the electrode in Nickolls on or over the left ventricle is a patch electrode, it would have been obvious to modify the implantable device disclosed in Nickolls by replacing the patch electrode of Nickolls with the transvenous lead and electrode(s) of Adams and configuring the circuitry of the Nickolls system for applying ATP through the electrode(s), and one of ordinary skill in the art would have been motivated to make this replacement. (Ex. 1006, ¶ 320.) The modified system would therefore include electrodes in the right ventricle and electrode(s) on the left ventricle, allowing the system to deliver ATP to both ventricles. (*Id.* ¶¶ 320-321.) Accordingly, the modified Nickolls system also renders obvious the additional limitation of claims 2, 8, and 15, as the electrodes of that modified system are configured for delivering ATP to the ventricles of the heart.

Because the other limitations of claims 2, 8, and 15 would have been obvious for the reasons explained above for claims 1, 7, and 14, claims 2, 8 and 15

also would have been obvious to a person of ordinary skill in the art, as of the date of invention of the '563 Patent, in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. (*Id.* ¶ 322.)

3. Dependent Claims 3, 9, and 16

Claims 3, 9, and 16 depend from claims 1, 7, and 14, which as discussed above are unpatentable in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. Claims 3, 9, and 16 add the following limitation:

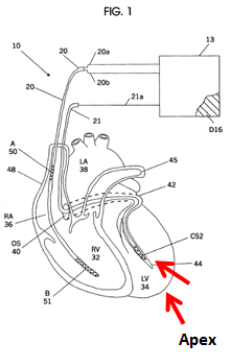
> **a. Additional Limitation:** "a system according to claim [1, 7, or 14], wherein a first one of said primary electrodes is configured for positioning through the coronary sinus and in either the apical third of the posterior cardiac vein or the apical half of the great cardiac vein."

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. (Ex. 1006, ¶ 324.) 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.* ¶ 325.) Regarding the preferred embodiment of Figure 1, the '563 Patent states that it 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 at 6:62-7:1.)

As explained above in Section VIII.A, one of ordinary skill in the art would have been motivated to modify the Nickolls implantable system to use a lead and electrode(s) positioned in a vein on the surface of the left ventricle, as disclosed in Adams, so as to create a device in which the left ventricle electrode(s) are positioned transvenously through the coronary sinus and its tributaries instead of through an incision in the patient's chest. (*See* Ex. 1006, ¶ 327.)

The Nickolls system, when modified to use the positioning of an electrode in a vein on the left ventricle in the manner disclosed by Adams, teaches the additional limitation of claims 3, 9, and 16. A comparison of Figure 1 of the '563 Patent and Figure 9 of Adams shows that the electrodes in Figure 1 of the '563 Patent and Figure 9 of Adams are both positioned in a similar location in a vein on the left ventricle and near the apex of the heart:

'563 Patent



Adams

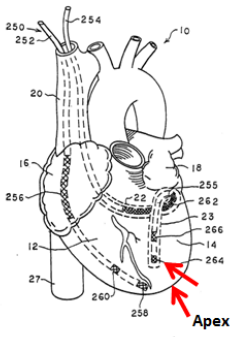


FIG. 9

As shown above, Figure 9 in Adams discloses an electrode, for example electrode 264, positioned at a very similar location as electrode C52 in the preferred embodiment shown in Figure 1 of the '563 Patent. (*Id*. ¶ 329; Ex. 1010

at Fig. 9.) A person of ordinary skill in the art would have understood Figure 9 to show an electrode positioned in the "apical half of the great cardiac vein," or the half of the great cardiac vein nearest the apex of the heart. (Ex. 1006, ¶ 329.) Adams states that this electrode is fed through the coronary sinus and into the great cardiac vein: "The electrodes 264, 266, and 262 are spaced apart on the second lead 254 so that when the lead 254 is fed into the superior vena cava 20 and into a coronary vein, such as the great vein 23 through the right atrium 16 and the coronary sinus 22 with electrodes 264 and 266 being adjacent the left ventricle within the great vein[.]" (Ex. 1010 at 15:62-67.) A person of ordinary skill in the art therefore would have found Adams to teach an electrode 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, ¶ 330.) Thus, the implantable device disclosed in Nickolls, when modified to use a transvenous epicardial lead and electrode(s) configured for positioning in a vein on the surface of the left ventricle as disclosed in Adams, meets this limitation. (*Id.* ¶ 331.)

In the alternative, to the extent that Adams does not explicitly disclose an electrode positioned through the coronary sinus and in either the apical third of the posterior cardiac vein or the apical half of the great cardiac vein, a person of ordinary skill in the art would have found this additional limitation obvious in light of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. (*Id.*

¶ 332.) Adams discloses electrode(s) configured for positioning within the coronary sinus and great cardiac vein, and it would have been obvious to one of ordinary skill in the art based on this disclosure to position an electrode in, for example, the apical half of the great cardiac vein or the apical third of the posterior cardiac vein depending on the target site for delivery of ATP and accessibility or usability of a particular vein in a particular patient. (*Id*.)

Because the other limitations of claims 3, 9, and 16 would have been obvious for the reasons explained above for claims 1,7, and 14, claims 3, 9, and 16 also would have been obvious to a person of ordinary skill in the art, as of the date of invention of the '563 Patent, in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. (*Id.* ¶ 333.)

4. 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 in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art, and add the following limitations:

a. **Claim 4 Additional Limitation:** "a system according to claim 1, wherein said capacitor is a 20 to 400 microfarad capacitor."

b. **Claims 11 and 18 Additional Limitation:** "a system according to claim [7 or 14], wherein said power supply includes a 20 to 400 microfarad capacitor."

The only limitation added to these claims specifies that the capacitor is a "20

to 400 microfarad capacitor." The '563 Patent does not provide any reasoning for using a 20 to 400 microfarad capacitor. A person of ordinary skill would have found this additional limitation to be well-known and obvious for capacitors that may be used in pacemakers and/or defibrillators. (*See* Ex. 1006, ¶ 335.)

Both Nickolls and Adams disclose inclusion of capacitors in their respective implantable systems for treatment of cardiac arrhythmias. (Ex. 1009 at 7:13-16, Fig. 1; Ex. 1010 at 7:17-25.) It was well-known to one of ordinary skill that the particular capacitor(s) selected for a pacemaker and/or defibrillator would depend on the device's intended application and requirements, and that there are a variety of capacitors with different capacitance value ranges that may be used in an implantable pacemaker and/or defibrillator, including capacitors with capacitance values of 20-400 microfarads. (*See* Ex. 1006, ¶ 337.) A person of ordinary skill in the art also would have known that it was common to combine pacing and defibrillation circuitry in a single device, and that such combined devices should include capacitors with higher capacitance values for the defibrillation capabilities. (*Id.* ¶ 338.) For example, the device in Nickolls is capable of delivering a defibrillation shock using its capacitors. (*See, e.g.*, Ex. 1009 at 7:13-19.) It would have been within the common knowledge of a person of ordinary skill to select capacitors with a variety of capacitance values, including within the range of 20 to 400 microfarads, for a device such as that of Nickolls. (Ex. 1006, ¶¶ 342-348

(discussing examples of capacitance value ranges between 20 to 400 microfarads that could be selected for use in an implantable device depending on its intended application).)

Because the other limitations of claims 4, 11, and 18 would have been obvious for the reasons explained above for claims 1, 7, and 14, and the additional limitations of claims 4, 11, and 18 would have been obvious to a person of ordinary skill in the art based on Nickolls, Adams, and common knowledge, claims 4, 11, and 18 would have been obvious based on Nickolls, Adams, and the knowledge of one of ordinary skill in the art. (*Id.* ¶ 349.)

5. Dependent Claims 10 and 17

Claims 10 and 17 depend from claims 7 and 14, which as discussed above are unpatentable in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. 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. (Ex. 1006, ¶ 351.) 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 at 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, ¶ 352.) 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.* ¶ 353.)

A person of ordinary skill would have understood Nickolls to disclose a power supply used in conjunction with a capacitor. Nickolls explicitly refers to a power supply and capacitors as part of the same circuit. More specifically, Nickolls discloses "a **power supply 18** for the provision of a reliable voltage level to pacemaker 17, microprocessor 19, and a defibrillator 16. Defibrillator 16 produces a high voltage **to charge its capacitors** and then optionally discharges

them in response to control signals from microprocessor 19." (Ex. 1009 at 7:11-16 (emphasis added), Fig. 1). Thus Nickolls discloses this additional limitation of claims 10 and 17.

Moreover, a person of ordinary skill in the art would have understood that it was common for power supplies in implantable devices to include capacitors to modify output voltage and adjust pulse configuration as needed. (Ex. 1006, ¶ 356.) A person of ordinary skill in the art would have known that a capacitor is used in conjunction with a power supply because a capacitor is used to store an electrical charge that originates from a power supply, such as a battery. (*Id*.) Thus, a power supply that "includes" a capacitor would have been a "predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417. Therefore, at a minimum, it would have been obvious to a person of ordinary skill in the art based on Nickolls's disclosure that a system for delivering ATP would have a power supply that "includes a capacitor." (Ex. 1006, ¶ 356.)

Because the other limitations of claims 10 and 17 would have been obvious for the reasons explained above for claims 7 and 14, claims 10 and 17 also would have been obvious in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. (*Id.* ¶ 357.)

6. Dependent Claims 5, 12, and 19

Claims 5, 12, and 19 depend from claims 1, 7, and 14, which as discussed

above are unpatentable in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. 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."

The implantable device disclosed in Nickolls, when modified to use an electrode configured for transvenous epicardial placement on the left ventricle as disclosed in Adams, teaches this additional limitation. (Ex. 1006, ¶ 359.) A person of ordinary skill in the art would have understood all of the electrodes disclosed in Nickolls, except the surface epicardial patch electrode for the left ventricle, to be carried by transvenous leads. (*Id.* ¶ 360; Ex. 1009 at Fig. 5, 10:46-65, 11:6-15.) As explained above in Section VIII.A, a person of ordinary skill would have been motivated to modify the implantable system of Nickolls to use the lead and electrode positioning from Adams. (Ex. 1006, ¶ 363.) When the device in Nickolls is modified to use a lead and electrode(s) configured for transvenous epicardial placement in a vein on the left ventricle as disclosed in Adams, the electrode(s) introduced into the left ventricle would also be carried by a transvenous lead, as called for by the additional limitation of claims 5, 12, and 19. (*Id.* ¶ 364.) In particular, Adams discloses multiple electrodes carried by a transvenous lead for positioning in a vein on the surface of the left ventricle. (*See* Ex. 1010 at 15:47-16:7 (referring to a "second lead 254" with "electrodes 264 and

266" being fed through the coronary sinus and into a coronary vein like the great cardiac vein), Fig. 9.) A person of ordinary skill in the art thus would have understood that the electrodes disclosed in Adams are carried by a transvenous lead, and that in the implantable device disclosed in Nickolls, when modified using the transvenous epicardial electrode placement for the left ventricle disclosed in Adams, each electrode would be carried by a transvenous lead. (Ex. 1006, ¶ 364.)

Because the other limitations of claims 5, 12, and 19 would have been obvious for the reasons explained above for claims 1, 7, and 14, claims 5, 12, and 19 also would have been obvious to a person of ordinary skill in the art, as of the date of invention of the '563 Patent, in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. (*Id.* ¶ 366.)

7. Dependent Claims 6, 13, and 20

Claims 6, 13, and 20 depend from claims 1, 7, and 14, which as discussed above are unpatentable in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. 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. (Ex. 1006, ¶ 368.) As shown by both

Nickolls and Adams, the concept of multiple electrodes being carried by the same transvenous lead was well known to a person of ordinary skill in the art. (*Id*. ¶ 369.) Nickolls discloses a system where multiple electrodes configured for sensing and delivering pacing pulses in response to tachycardia are carried by the same transvenous lead. (Ex. 1009 at 10:46-65, Fig. 5; Ex. 1006, ¶ 369.) Adams also discloses multiple electrodes on the same transvenous lead. (*See* Ex. 1010 at 15:47-16:7 (referring to a "first lead 252" that "carries or includes" electrodes 256, 258, and 260 and a "second lead 254" that includes electrodes 262, 264, and 266).)

A person of ordinary skill in the art would have found the additional limitation of claims 6, 13, and 20 obvious in view of the combination of the Nickolls system with the teaching from Adams of positioning a transvenous lead with electrodes through the coronary sinus and in a vein on the surface of the left ventricle. Adams discloses multiple electrodes on the lead carrying the electrodes positioned in a vein on the left ventricle. (*See* Ex. 1010 at 15:47-16:7 (referring to a "second lead 254" with "electrodes 264 and 266" being fed through the coronary sinus and into a coronary vein like the great cardiac vein such that the electrodes are in electrical contact with the left ventricle), Fig. 9; Ex. 1006, ¶ 371.) As explained above in Section VIII.A, a person of ordinary skill would have been motivated to replace the lead (92) and patch electrode of Nickolls with the transvenous lead (254) and electrode(s) in Adams and to configure the electrode(s)

for pacing, so as to create a device in which the left ventricle electrode(s) are positioned transvenously through the coronary sinus and its tributaries instead of through an incision in the patient's chest. (*See* Ex. 1006 ¶ 372.) Therefore, the combination of Nickolls and Adams teaches the additional limitation.

Because the other limitations of claims 6, 13, and 20 would have been obvious for the reasons explained above for claims 1 and 7, and 14, claims 6, 13, and 20 also would have been obvious to a person of ordinary skill in the art, as of the date of invention of the '563 Patent, in view of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. (*Id.* ¶ 375.)

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: April 10, 2015

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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 – 1056 to be served via United States Postal Service Priority Mail on April 10, 2015, on the following:

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