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Paper 9
Entered: October 19, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION,
Petitioner,

v.

UAB RESEARCH FOUNDATION,
Patent Owner.

Case IPR2015-01038
Patent 6,266,563 B1

Before PHILLIP J. KAUFFMAN, BENJAMIN D. M. WOOD, and JAMES A. WORTH, *Administrative Patent Judges*.

WORTH, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, Boston Scientific Corporation ("Boston Scientific"), filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–20 of U.S. Patent No. 6,266,563 B1 ("the '563 patent," Ex. 1001). Patent Owner, UAB Research Foundation ("UAB"), filed a Preliminary Response (Paper 8, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

To institute an *inter partes* review, we must determine that the argument and evidence presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, we do not institute an *inter partes* review for the challenged claims.

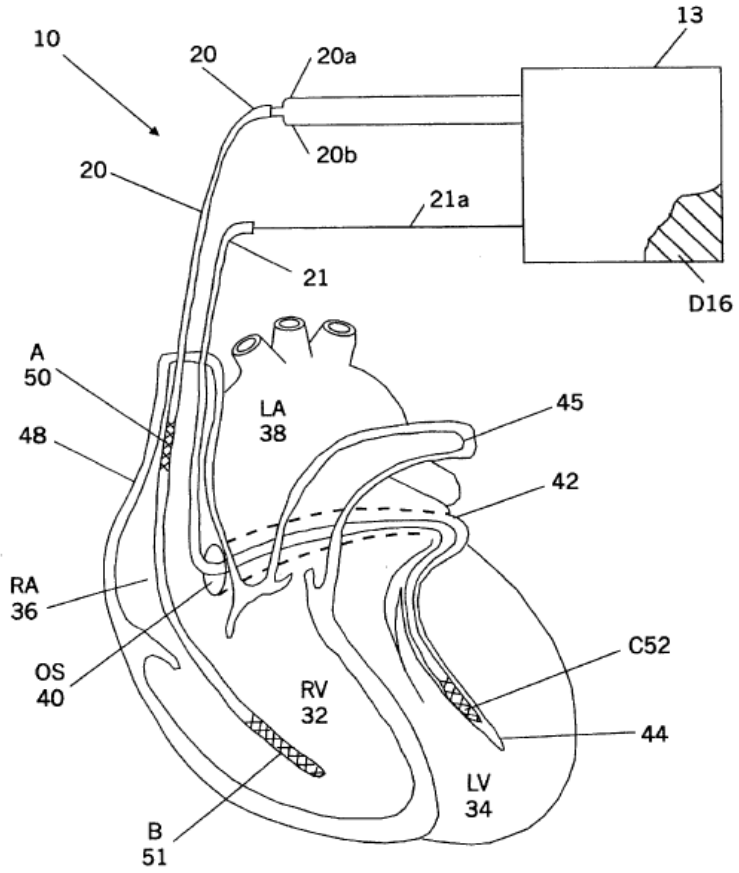
A. Related Matters

Petitioner identifies the following district court proceeding as a related matter: *The Board of Trustees of the University of Alabama at Birmingham v. Boston Scientific Corp.*, No. 2:14-cv-01800 (N.D. Ala.) (filed Sept. 22, 2014). Pet. 1; Paper 4, 2.

B. The '563 Patent (Ex. 1001)

The '563 patent is titled "Method and Apparatus for Treating Cardiac Arrhythmia," and relates to an implantable system for the antitachycardia pacing of the heart of a patient in need of such treatment. Ex. 1001, at [54], [57]. One of the problems in the art of implantable defibrillators is that conversion thresholds increase with time, such that therapy is terminated after four separate attempts at defibrillation. *Id.* at 1:37–40. At the same time, it is desirable to lower shock strength in order to reduce the size of the implantable device and of its capacitor. *Id.* at 1:19–22.

The ’563 patent discloses an implantable defibrillator comprising “a plurality of primary electrodes, at least one auxiliary electrode, a power supply, and a control circuit.” *Id.* at 4:12–15. The power supply may include a 20–400 microfarad capacitor. *Id.* at 8:5–6. The electrodes are depicted in Figure 1, below:



As shown in Figure 1, Electrode A (50) is positioned in the superior vena cava or innominate vein, electrode B (51) is positioned in the right ventricle, electrode C (52) is positioned within a vein on the posterolateral surface of the left ventricle (e.g., the posterior cardiac vein or great cardiac vein), and the external portion of the device’s housing (16) serves as electrode D. *Id.* at Fig. 1, 6:62–7:2.

The electrodes are configured for delivering a defibrillation pulse or primary pulse that may be from 5 or 10 Joules to 30, 40, or 50 Joules. *See id.* at 6:5–15, 8:58–60. The electrodes also are configured for delivering an auxiliary pulse from 0.01 or 0.05 to 1 or 2 Joules, simultaneous with or in sequential relationship to the defibrillation pulse. *Id.* at 4:21–23, 8:57–58, 13:51–60. Although the Specification refers to pulses as "primary" or "auxiliary," this distinction appears to refer to function and not structure in that each of the electrodes may deliver either primary or auxiliary pulses. Ex. 1001, Tables 1–4. The '563 patent discloses that certain dual shock treatments lowered the defibrillation threshold. *Id.* at 18:24–26. Various pairings of electrodes may be employed for the primary and auxiliary pulses. *See id.*, Tables 1–5.

The '563 patent also discloses that "[t]he antitachycardia pacing may be delivered from the primary electrode placed through the coronary sinus ostium and within a vein on the surface of the left ventricle alone, or may be coupled to or yolked to an additional electrode, such as an electrode positioned in the right ventricle." *Id.* at 6:5–15.

C. Illustrative Claims

Claims 1, 7, and 14 are independent claims. Claim 1, reproduced below, is illustrative of the subject matter at issue.

> 1. An implantable system for the delivery of antitachycardia pacing to a patient's heart, comprising:
>
> a plurality of primary stimulation electrodes configured for sensing cardice [sic] signals and delivering antitachycardia pacing to said heart;
>
> 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;

a power supply; and

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;

wherein said control circuit includes a capacitor.

D. The Alleged Grounds of Unpatentability

Petitioner contends that claims 1–20 are unpatentable on the following grounds:

Reference	Basis	Claims challenged
Nickolls[1], Adams[2], and the knowledge of a person of ordinary skill in the art	§ 103	1–20

II. ANALYSIS

A. Claim Construction

Petitioner proposed constructions of "antitachycardia pacing" and "control circuit." Pet. 8. Patent Owner disputes the construction of "antitachycardia pacing." Prelim. Resp. 4–5.

We determine that none of the terms in the challenged claims requires express construction for purposes of this Decision in order to resolve the issues presented by the Petition. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

[1] Nickolls, U.S. Patent No. 5,181,511, iss. Jan. 26, 1993 (Ex. 1009).

[2] Adams, U.S. Patent No. 5,433,729, iss. July 18, 1995 (Ex. 1010).

B. Obviousness over Nickolls (Ex. 1009), Adams (Ex. 1010), and the Knowledge of a Person of Ordinary Skill in the Art

Relying on the Declaration of David G. Benditt (Ex. 1006), Petitioner contends that Nickolls, Adams, and the knowledge of a person of ordinary skill in the art at the time of the invention would have rendered obvious claims 1–20. Pet. 22–60. Patent Owner disagrees. Prelim. Resp. 11–19.

For the reasons that follow, we determine that Petitioner has not established a reasonable likelihood of prevailing on its assertion with respect to claims 1–20.

1. Overview of Nickolls

Nickolls discloses an apparatus and method for antitachycardia pacing ("ATP") using a virtual electrode, in which three or more electrodes are connected to create a virtual electrode at the focus site upon delivery of the therapy to the heart based on the relative distances of the electrodes from the focus site. Ex. 1009, at [54], [57]. The disclosure states "the term 'virtual electrode' refers to an electric field the strength of which is above the stimulation threshold of adjacent cardiac tissue," and is "created by applying suitable voltages to two or more electrodes, and a zero voltage to a reference electrode." *Id.* at 5:52–58.

A determination is made as to which sensing electrodes are nearest the site of the tachycardia by identifying which electrodes register the earliest fiducial points on an electrocardiogram, i.e., peaks, points of maximum slope, and inflections. *Id.* at 6:29–38. The ATP therapy is in the form of simultaneous pacing waves which approach the focus site from different directions, effectively from all sides if the selected electrodes surround the site, otherwise from a point or line or area near the site. *Id.* at 6:25–30. The system delivers therapy to the atria or the ventricles. *Id.* at 6:65–7:2.

The leads are preferably anchored to the right free wall of the heart, the apex or the right ventricle of the heart, the right septal wall of the heart, and the high right atrium of the heart. *Id.* at 10:66–11:5. In addition, leads may be epicardial or subcutaneous patches. *Id.* at 11:61–65.

2. Overview of Adams

Adams, titled "Atrial Defibrillator, Lead Systems, and Method," discloses a fully automated implantable atrial defibrillator for delivering a pulse of defibrillating electrical energy to the atria of a human heart, cardioversion, and bradycardia pacing. Ex. 1010, 1:1–3, 1:12–27. The system conserves battery power by activating the atrial fibrillation detector only when the ventricular rate indicates a probability of atrial fibrillation. *Id.* at 2:41–45.

The atrial defibrillator uses an endocardial lead "at locations which minimize the energy which must be delivered to the atria for cardioverting or defibrillating" the atria. *Id.* at 2:55–59. The system and method "assures that the delivered electrical energy is confined to the atria and little of the electrical energy is passed through the ventricles." *Id.* at 2:45–50.

An exemplary embodiment is depicted below in Figure 9:

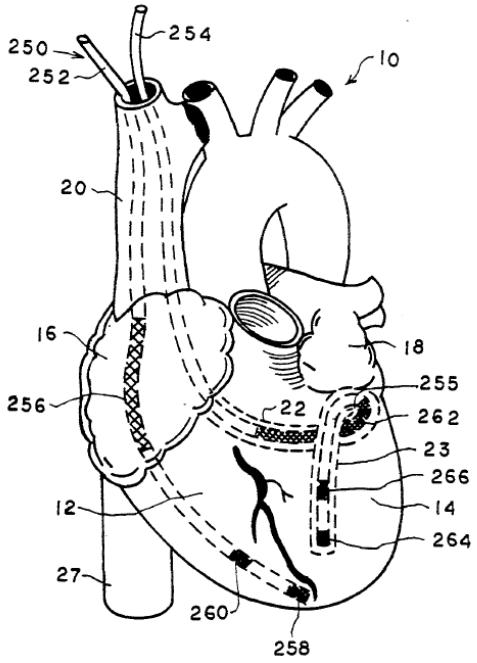


FIG. 9

Figure 9 illustrates the placement of the leads with electrodes. As relevant to this proceeding, the system is composed of sense electrodes and electrodes capable of providing defibrillation placed in specific locations after being fed through specific veins:

> The first lead 252 carries or includes a first elongated, large surface area, electrode 256, a distal or tip sense electrode 258, and a ring or proximal sense electrode 260. The electrodes 258, 260, and 256 are spaced apart on the lead 252 so that, when lead 252 is fed into the superior vena cava 20 and into the right ventricle 12 through the right atrium 16 to a position where electrode 258 is at the apex of the right ventricle, the first elongated electrode 256 will be disposed in and in electrical contact with the right atrium 16 of the heart 10. Also, electrodes 258 and 260 will be in electrical contact with the right ventricle of the heart 10.
>
> The second lead 254 includes a second elongated, large surface area, electrode 262, a tip or distal sense electrode 264,

> and a ring or proximal sense electrode 266. 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 as illustrated, the second elongated electrode 262 will be disposed within the coronary sinus 22 just beneath the left atrium 18 and adjacent to the left ventricle 14. Since the coronary sinus 22 is in close proximity to the left atrium 18 and the left ventricle 14, electrodes 264 and 266 will be in electrical contact with the left ventricle and electrode 262 will be in electrical contact with the left atrium 18.

Id. at 15:47–16:7.

3. Analysis

Petitioner contends that claims 1–20 are obvious over Nickolls, Adams, and the knowledge of a person of ordinary skill in the art. In the Petition, Petitioner alleges how each limitation of the claims would be understood to be disclosed by the combination of Nickolls, Adams, and the knowledge of a person of ordinary skill in the art, and that such a combination would have been obvious to a person of ordinary skill in the art. Pet. 22–60.

As with the parties, we focus our analysis on the following 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," as recited by independent claims 1, 7, and 14, where the electrodes are "configured for . . . delivering antitachycardia pacing." Petitioner relies on a combination of teachings for this limitation. Pet. 25–29, 35, 41. Specifically, Petitioner asserts that Nickolls discloses the delivery of antitachycardia pacing to the left ventricle

via a patch electrode on the epicardial surface of the left ventricle or subcutaneously over the left ventricle. Pet. 26 (citing Ex. 1009, 10:63–65, 5:59–64; Ex. 1006 ¶ 240). Petitioner further asserts that Adams discloses a transvenous epicardial lead to deliver pacing to a comparable location as that of the electrode of Nickolls, and contends that a person of ordinary skill in the art would have been motivated to apply this teaching to the implantable system of Nickolls to avoid an invasive surgical procedure or the other disadvantages of a patch electrode. *Id.* at 26–28 (citing Ex. 1006 ¶¶ 201–16, 242, 245–247; Ex. 1010, 4:67–68, 5:28–34, 15:62–16:7, Fig. 9).

Patent Owner argues that Adams "explicitly discourages" placement of a stimulation electrode on the surface of the left ventricle when Adams "explains that the disclosed defibrillator is specifically designed to confine the delivery of electrical energy to the atria and avoid the delivery of electrical energy to the ventricles." Prelim. Resp. 14–16 (citing Ex. 1010, 2:45–50, 2:17–23, 5:48–61, 14:27–31, 17:61–64). On this basis, Patent Owner urges that Adams teaches away from the invention of the '563 patent. *Id.* at 15–16 (citing *Optivus Tech., Inc. v. Ion Beam Applications S.A.*, 469 F.3d 978, 989 (Fed. Cir. 2006) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference. . . .")).

We disagree with Patent Owner's assertion that Adams broadly teaches away from providing electrical energy to the ventricles inasmuch as Adams explicitly discloses providing bradycardia pacing to the right ventricle. Ex. 1010, 7:12–17, 7:39–46, 8:7–19. However, we agree with Patent Owner that Adams discloses that the delivery of atrial defibrillation is directed to the atria in such a manner as to minimize delivery of electrical

energy to the ventricles during the atrial defibrillation, i.e., in order to reduce the risk of inducing ventricular fibrillation. Ex. 1010, 1:21–24, 2:17–23.

Whether or not there is a teaching away, Patent Owner argues that Adams does not suggest placement of an electrode on the left ventricle for the purpose of delivering ATP, and that the reason advanced by Petitioner for the combination of Nickolls and Adams is conclusory. Prelim. Resp. 16–17.[3] Indeed, we agree with Patent Owner that Adams's electrodes [264 and 266] which are adjacent, and in contact with, the left ventricle are sense electrodes. *See* Prelim. Resp. 14 (citing Ex. 1005, 119); Ex. 1010, 15:60–62, 16:4–6. Petitioner contends that "[o]ne 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

[3] Patent Owner also requests assignor estoppel against Petitioner for arguing during prosecution that Adams does not render obvious the claims of the '563 patent. *See* Prelim. Resp. 1–2, 17–19 (relying on *TorPharm, Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1329 (Fed. Cir. 2003)). However, we understand *TorPharm* to encourage the reviewing tribunal to make a finding as to the patentability of the claims despite previous contrary positions taken by a patentee. *See id.* ("a court's responsibility is not to speculate what a particular examiner would or would not have done in light of the new information, but rather to assess independently the validity of the claim against the prior art under section 102 or section 103."). Further, the USPTO as a creature of statute does not have a provision for considering such an equitable estoppel. *See, e.g., Esselte Corp. v. Dymo B.V.B.A.*, Case IPR2015-00766, slip. op. at 19–20 (PTAB Aug. 28, 2015) (Paper 14); *see also Esselte Corp. v. Dymo*, Case IPR2015-00779, slip op. at 4–7 (PTAB Aug. 28, 2015) (Paper 13), Case IPR2015-00781, slip op. at 4–7 (PTAB Aug. 28, 2015) (Paper 13); *Dot Hill Systems Corp. v. Crossroads Systems, Inc.*, Case IPR2015-00822, slip op. at 7–8 (PTAB Sept. 17, 2015) (Paper 18).

for sensing cardiac signals and delivering antitachycardia pacing." Pet. 28 (citing Ex. 1006 ¶ 246).

We agree with the Patent Owner that Petitioner does not explain why a person of ordinary skill in the art would have looked to the atrial defibrillator of Adams for placement of leads for antitachycardia pacing to the left ventricle. Although Adams discloses pacing to the right ventricle in the context of bradycardia, and discloses sense electrodes on the left ventricle, that does not necessarily suggest the placement of leads for delivery of energy to the left ventricle. The fact that sense electrodes were known in the art does not explain why a person of ordinary skill in the art would have performed the combination of electrodes in this manner for the delivery of energy to the left ventricle, or would have looked to Adams for the placement of leads to deliver energy to that location.

Relying on the Declaration of Dr. Benditt, Petitioner contends that Nickolls would have informed the placement of electrodes for the delivery of energy to the left ventricle (Pet. 28 (citing Ex. 1006 ¶¶ 201–216, 245–47)), but that again begs the question as to why a person of ordinary skill would then have looked to Adams for the placement of electrodes for delivering energy. Further, Petitioner does not present sufficient evidence that it would have been predictable to substitute the transvenously-placed lead and electrode of Adams for the lead and patch electrode of Nickolls. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions."). Having reviewed the Declaration, we agree with Patent Owner that Petitioner's reasoning for the

combination of references is conclusory and does not state a reasonable likelihood of prevailing on its assertion of obviousness.

III. CONCLUSION

We determine that Petitioner has not established a reasonable likelihood of prevailing on its assertion with respect to claims 1–20.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is not instituted.

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