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Paper 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION,
Petitioner,

v.

UAB RESEARCH FOUNDATION,
Patent Owner.

Case IPR2015-00918
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 9, "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.

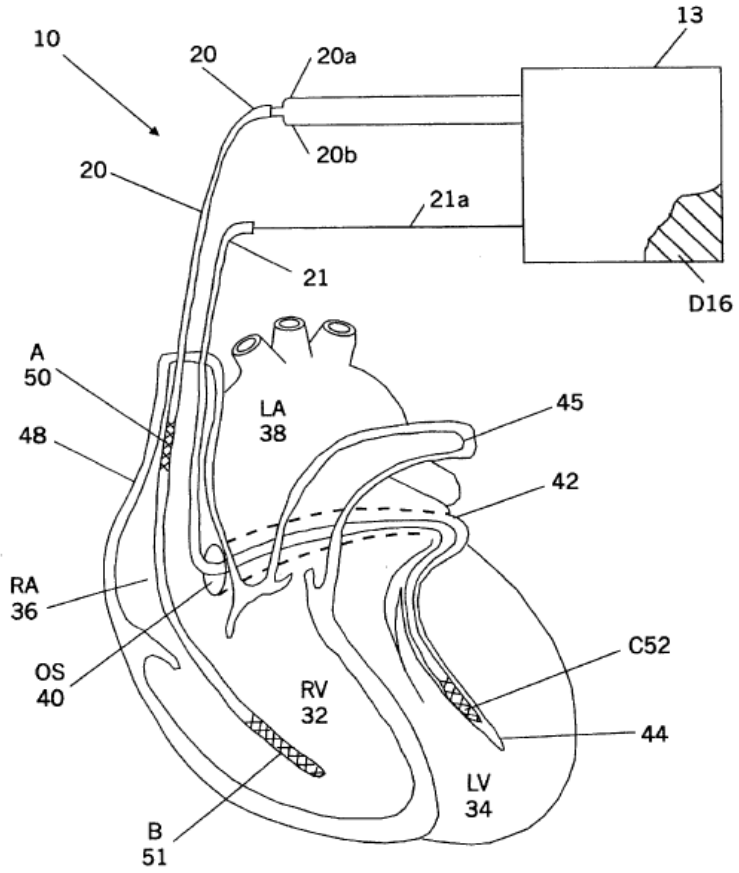
A. Related Matters

Petitioner identifies the following district court proceeding as a related matter: (1) *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. Related Applications

The '563 patent issued on July 24, 2001 from Application No. 09/391,026 (filed Sept. 7, 1999), which is a continuation-in-part of Application No. 09/039,143, now U.S. Patent No. 5,978,705 ("the '705 patent"), which in turn is a continuation-in-part of Application No. 08/818,261 (filed Mar. 14, 1997) ("the '261 Application," Ex. 1002), now abandoned. Ex. 1001, at [63].

E. The Alleged Grounds of Unpatentability

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

Reference	Basis	Claims challenged
KenKnight '967[1]	§ 102(b)	1–20

II. ANALYSIS

A. Claim Construction

We determine that none of the terms in the challenged claims requires express construction at this time, as neither of the parties has requested construction of claim language for institution.

[1] KenKnight, U.S. Patent No. 5,797,967, iss. Aug. 25, 1998 (Ex. 1008).

B. Anticipation over KenKnight '967 (Ex. 1008)

Relying on the Declaration of David G. Benditt (Ex. 1006), Petitioner contends that KenKnight '967 anticipates claims 1–20. Pet. 25–58. Petitioner contends that KenKnight '967 is prior art to the '563 patent based on Petitioner's argument that the '563 patent does not derive priority from the '261 Application. *Id.* at 14–19. Patent Owner disagrees. Prelim. Resp. 11–37.

For the reasons that follow, we determine that KenKnight '967 is not prior art to the '563 patent, and therefore does not anticipate the claims of the '563 patent.

1. Overview of KenKnight '967

KenKnight '967 discloses a hybrid antitacharrhythmia therapy of pacing therapy (optionally followed by reduced-strength defibrillation) and defibrillation therapy. Ex. 1008, at [57]. The two therapies are applied in either a temporally coincident, or an immediately sequential fashion. *Id.* According to KenKnight '967, "slow, monomorphic, hemodynamically stable ventricular tachyarrhythmia (VT) may be treated with pacing (~40 microjoule) therapies, e.g., antitachyarrhythmia pacing (ATP), while fast, polymorphic, hemodynamically unstable rhythms may be treated with low strength (0.05–2 Joules) shocks followed by higher strength (2–40 Joules) shocks if earlier interventions fail." *Id.* at 1:54–60.

2. The '261 Application

As with the '563 patent, the '261 Application contains the following statement of use:

> The present invention may be used to treat all forms of cardiac tachyarrythmias, including ventricular fibrillation, with defibrillation (including cardioversion) shocks or pulses. The

> treatment of polymorphic ventricular tachycardia and ventricular fibrillation are particularly preferred.

Ex. 1002, 7:4–9; *accord* Ex. 1001, 1:14–16. As with the '563 patent, the '261 Application sets forth the positioning of the electrodes as follows:

> As illustrated in Figure 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 postero lateral surface of the left ventricle. The active external portion of the housing 16 serves as a fourth electrode D.

Ex. 1002 at 9:3–9; *accord* Ex. 1001, 6:62–7:2. As with the '563 patent, the '261 Application discloses that "[t]he energy of the auxiliary pulse may be from .01 or .05 to 1 or 2 Joules. The energy of the defibrillation pulse may be from 5 or 10 Joules to 30, 40 or 50 Joules." Ex. 1002, 12:30–32; *accord* Ex. 1001, 4:21–23, 6:5–15, 8:57–60, 13:51–60.

3. Analysis

A patent that arises from an application that is a continuation-in-part of a parent application may benefit from the filing date of the earlier application so long as the disclosure of the earlier application meets the requirements of 35 U.S.C. § 112, ¶ 1, including the written description requirement. *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326 (Fed. Cir. 2008). To meet the requirements thereof, the disclosure of the earlier application must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention, as of the filing date sought. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991). "[W]hile the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in*

haec verba, a description that merely renders the invention obvious does not satisfy the requirement." *Ariad Pharma., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc) (internal citations omitted).

Petitioner argues that the '563 patent added new subject matter directed to antitachycardia pacing and is not entitled to a filing date earlier than its September 7, 1999 filing date. Pet. 14–19. In support thereof, Petitioner includes a chart setting forth certain differences between the '705 patent (which issued from the '261 Application) and the '563 patent. *Id.* at 14–18. Petitioner also relies on the Declaration of Dr. Benditt in support of its assertion that the '563 patent "constituted the first time the inventors described and disclosed using antitachycardia pacing, including a control circuit configured for delivering antitachycardia pacing." *Id.* at 17–18 (citing Ex. 1006 ¶¶ 178–185). Petitioner does not add further argument with respect thereto.

Patent Owner asserts that "[a]s a whole, the '261 application discloses a device for the treatment of cardiac tachyarrhythmias via multiple therapies, including defibrillation, auxiliary pulsing, and pacing." Prelim. Resp. 13. Patent Owner further asserts that by treating tachyarrhythmias, the device disclosed in the '261 Application "by definition could treat both tachycardia and fibrillation." *Id.* Patent Owner relates that it was understood such an implantable device would provide "tiered therapy," and that the "use of these 'tiered therapy' devices was well known in the art." *Id.* (citing Ex. 2004; Ex. 1006 ¶ 46; Ex. 2002, 2038).

We agree with Patent Owner, and we determine that the '261 Application sets forth a device "configured for" "delivering antitachycardia pacing to said heart," as recited by independent claims 1, 7, and 14.

Petitioner has not persuaded us that the '261 Application fails to disclose the claimed structure. Indeed, the '261 Application discloses the same configuration of electrodes that deliver electrical impulses of the same energy and characteristics as the '563 patent. Ex. 1002, 9:3–9, 12:30–32, Fig. 1. As noted by Patent Owner, the '261 Application makes plain that it is directed to the treatment of "all forms of cardiac tachyarrythmias," including "ventricular tachycardia." *See id.* at 7:4–9.[2]

Petitioner further observes that the '563 patent contains additional language, not contained in the '261 Application, which states 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 [sic] to an additional electrode, such as an electrode positioned in the right ventricle." Pet. 17–18 and Table (quoting Ex. 1001, 6:5–15). However, written description support need not be *in haec verba*. As set forth above, the examples provided in the '261 Application and '563 patent describe primary and auxiliary pulses, where the energy of the auxiliary pulse may be from .01 or .05 to 1 or 2 Joules. Ex. 1001, 12:30–32. As explained by Petitioner's declarant, it was understood in 1996 that a typical pacing pulse would have been .025 Joules (25 μJ), whereas cardioversion pulses would be 1–15 Joules, and defibrillation pulses would be even higher energies. Ex. 1006 (Benditt Decl.) ¶¶ 66–67 (citing Ex. 1011; Ex. 1015). Thus, the auxiliary pulses of the '261 Application have the same energy as pacing pulses (.01 or .05

[2] Page 11 (original page number) of the '261 Application appears to be missing from Ex. 1002.

Joules) or cardioversion pulses (1 or 2 Joules), and the device is configured to deliver either.[3]

The claims at issue recite "a plurality of primary stimulation electrodes," and do not differentiate among those electrodes as to the delivery of primary pulses or auxiliary pulses. Indeed, as explained above, the same electrodes (A, B, C, or D) may be used to deliver auxiliary or primary pulses depending on the instance. *See* Ex. 1002, Tables 1–4; Ex. 1001, Tables 1–4. In this connection, the '261 Application describes "a plurality of primary stimulation electrodes" that are configured to deliver pulses having the same energy as antitachycardia pacing pulses, as recited by claims 1–20 of the '563 patent.

Further, we agree with Patent Owner (Prelim. Resp. 14) that the '261 Application also discloses the use of "pace/sense" electrode 54, which can be located proximal or distal to primary electrode 53 on lead 23. *See* Ex. 1002, 15:17–20, 27–29, Fig. 6. The '261 Application describes the placement of electrode 53 [electrode E] as follows:

> the beneficial effects are augmented by placing an additional electrode E; 53 on endocardial transvenous elongate lead 23 in the area of the heart experiencing the weakest electric field when electrode C; 52 is present. The weak field area in this location is in the region of the right ventricular conus.

[3] We note, in this regard, the 1990 scientific article relied on by Patent Owner for the knowledge of a person of ordinary skill in the art at the time of the invention (*see* Prelim. Resp. 13), which explains that "[t]he ideal implantable antitachycardia device should be capable of several modes of therapy including antitachycardia pacing, low-energy cardioversion, and high-energy defibrillation," and that the device would deliver a particular therapy based upon the device's ability to detect and differentiate ventricular tachycardia from ventricular fibrillation. Ex. 2002, 2038–39.

> Specifically, the electrode E can be located within the right atrial appendage or the right ventricular outflow track.

Ex. 1002, 15:1–9. Thus, the '261 Application uses the term "pace" with respect to electrode E, indicating that the disclosed system was intended to provide "[p]acing and sensing capability" when the system is "configured to monitor electrical rhythm activity in both atrial and ventricular chambers." *Id.* at 16:1–5. For all of these reasons, we determine that Petitioner has not demonstrated that it is reasonably likely to prevail in showing that the '261 Application fails to provide adequate written-description support for the '563 patent claims.

III. CONCLUSION

We determine that the '563 patent may benefit from the filing date of the '261 Application, and that KenKnight '967 is not prior art to the '563 patent.

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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