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Datasheet for the decision of 27 July 2011

Case Number: T 1565/09 - 3.2.02

Application Number: 04252451.2

Publication Number: 1472975

IPC: A61B 5/042

Language of the proceedings: EN

Title of invention:
Device for performing a medical procedure

Applicant:
Biosense Webster, Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1565/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 27 July 2011

Appellant: Biosense Webster, Inc.
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Diamond Bar, CA 91765 (US)

Representative: Mercer, Christopher Paul
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 27 February 2009 refusing European patent application No. 04252451.2 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: M. Noël
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 5 May 2009 against the decision of the Examining Division to refuse the European patent application, posted on 27 February 2009. The fee for appeal was paid on the same day and the statement setting out the grounds for appeal was received on 9 July 2009.

II. The application was refused on the ground that the subject-matter of claim 1 did not involve an inventive step having regard to the combination of documents:

D4: "Transseptal left heart catheterization: usefulness of the intracavitary electrocardiogram in the localisation of the fossa ovalis", Bidoggia H. et al., Catheterization and cardiovascular diagnosis, vol. 4, no. 3, November 1991, pp. 221-225, and

D1: WO-99/39624.

III. Following a provisional opinion of the Board, the appellant requested by letter dated 30 June 2011 that the decision under appeal be set aside and that a patent be granted on the basis of a main request according to the following version:

- description: pages 1 to 3, 3a, 4 to 22
- claims 1 to 9
- Drawings: sheets 1/17 to 17/17.

IV. Claim 1 of the main request reads as follows:

"A transseptal facilitation device (120) comprising:
a body (120a) having a lumen (122a) extending therethrough and an open end at a distal end (122) of the body, and the body (120a) having at least one electrode (124) at the distal end adapted to generate signals for determining an injury pattern on tissue (105) within a patient's heart (100) to enable identification of the location of the fossa ovalis (107); and
a penetrating device (150) removably received within the lumen (122a) of the body (120a) and extendable out of the distal end (122) thereof such that a distal tip of the penetrating device is able to make an aperture in the fossa ovalis (107) sufficient for the distal end (122) of the body to be passed into the left atrium (110), the penetrating device (150) being adapted to be removed from the lumen (122a) when the distal end (122) has passed into the left atrium (110), and the body (120a) being adapted to receive another device for extension out of the distal end (122) for performing a diagnostic and/or therapeutic procedure in the left atrium (110)."

V. The appellant argued essentially as follows.

In D4 a Brockenbrough needle was used as an electrode and as a penetrating element and was inserted through a catheter. D4 did not, however, disclose a body having a lumen with at least one electrode at the distal end. In the invention, on the other hand, the body was independent of the penetrating element or other device

which was inserted through it for carrying out treatment procedures.

D1 did not relate to transseptal heart catheterization but to drug delivery. Since the needle could not be removed from the catheter which was provided with electrodes, said catheter had no ability to receive different devices for performing different treatments, whilst remaining in place in the atrium.

The skilled person starting from D4, therefore, would not turn to D1 in order to provide more effective treatment.

Reasons for the Decision

1. The appeal is admissible.

2. Inventive step

2.1 D4 discloses a transseptal left heart catherization using a Brockenbrough needle as an exploratory electrode for performing an electrocardiographic mapping of the right arterial endocardium. While D4 generally discloses a method of catheterization through the interatrial septum, it also necessarily discloses the corresponding transseptal facilitation device comprising, using the words of claim 1 at issue, a catheter body having a lumen and an open end at the distal end thereof for removably receiving a penetrating device (Brockenbrough needle) extendable out of the distal end, such that a distal tip of the

penetrating device is able to make an aperture in the fossa ovalis.

The facilitation device of D4 further comprises an electrode (Brockenbrough needle) adapted to generate signals for determining an injury pattern on tissue within a patient's heart to enable identification of the location of the fossa ovalis (see the passage before "Introduction" on page 221 and the passages on page 222 and left column, third paragraph on page 225). The Brockenbrough needle, therefore, has a double function and is used both as an exploratory electrode and as a penetrating device for perforating the septum at the fossa ovalis.

2.2 The subject-matter of claim 1 at issue differs therefrom in that at least one electrode 124 is provided at the distal end of the body 120a (Figures 12A/12B), the penetrating device 150 being formed of an element independent of the electrode, and in that the aperture made in the fossa ovalis is sufficient for the distal end of the body to be passed into the left atrium. Contrary to that, in D4 the catheter is withdrawn from the right atrium whereas the needle alone is further advanced in order first to engage the fossa ovalis floor and then perforate the septum (see page 222).

2.3 The problem underlying the above distinguishing structural and functional features of claim 1 is to provide for more effectively performing a transseptal facilitation procedure, in accordance with paragraph [12] of the application as published.

Based on the signals generated at the distal tip electrodes 124a, the physician is able to determine more rapidly and efficiently the exact location of the fossa ovalis (see paragraphs [43], [44] and [49]). The claimed structural arrangement of the electrodes is neither disclosed nor suggested by D4.

2.4 D1 discloses a device principally used for intracardiac drug delivery to the myocardium, including (see Figures 1A/1B and 5) a catheter 20,64 and a hollow needle 24 inserted within the catheter for injection of the drug. However, the needle can be retracted but cannot be removed from the lumen of the catheter (see page 15, third paragraph).

The catheter further comprises a position sensor 32, which is used to locate the catheter near the site of administration, and physiological sensors or electrodes 38 for identifying ischemic areas to be treated, by measuring the electrical activity of the heart wall and producing a viability map of the heart tissue (see paragraph bridging pages 4 and 5 and page 16, lines 15 - 32). Other contact sensors 36 are used to confirm proper contact between the catheter and the heart wall before the extension of the needle 24 (see page 16, lines 24 - 27 and page 18, lines 16 - 17).

Unlike the embodiment of D4, the electrodes in D1 are independent of the needle and provided at the distal end of the catheter. However, all the sensors disclosed in D1 are used in conjunction so as to produce a viability map of the heart, in accordance with which the drug is administered, and to achieve accurate location and proper contact of the catheter.

In the present application, on the other hand, the electrodes 124a alone are sufficient to ensure accurate location of the point of interest (fossa ovalis) and may be used independently of the location sensor 128. Moreover, there is no mention in D1 of specifically identifying the location of the fossa ovalis with a view to subsequently making an aperture enabling the distal end of the catheter to be passed therethrough. Thus the two devices are hardly comparable.

Therefore, if only for these reasons, the combination of features according to claim 1 in suit represents a structural simplification over the teaching of D1 and the skilled person would not arrive at the subject-matter of claim 1 by merely combining the teachings of D4 and D1.

2.5 It follows from this that the subject-matter of claim 1 of the main request involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of the following version:
   - description: pages 1 to 3, 3a, 4 to 22, and
   - claims 1 to 9,

   filed with the appellant's letter of 30 June 2011;
   - Drawings: sheets 1/17 to 17/17 as originally filed.

The Registrar: The Chairman:

D. Sauter M. Noël