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**Datasheet for the decision
of 21 April 2015**

Case Number: T 0844/14 - 3.2.02

Application Number: 06773241.2

Publication Number: 1893115

IPC: A61B18/18

Language of the proceedings: EN

Title of invention:

TREATMENT AND DIAGNOSTIC CATHETERS WITH HYDROGEL ELECTRODES

Applicant:

St. Jude Medical,
Atrial Fibrillation Division, Inc.

Headword:

Relevant legal provisions:

EPC Art. 54(1), 54(2), 56, 82

Keyword:

Novelty - (yes)
Inventive step - (yes)
Unity of invention - after amendment

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 0844/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 April 2015

Appellant: St. Jude Medical
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 20 December 2013 refusing European patent application No. 06773241.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
C. Körber

Summary of Facts and Submissions

- I. The applicant has appealed the Examining Division's decision, dispatched on 20 December 2013, to refuse European patent application No. 06 773 241.2.
- II. For the application the Search Division had drawn up a supplementary European search report covering claims 1 to 19 as then pending. The remaining claims were not searched, as they related to different, non-unitary inventions. The Search Division based its reasoning concerning the finding of lack of unity on document:

D1: US-A-2004/0059327.

In its decision the Examining Division considered the following documents of the prior art:

D2: US-A-2004/0143253;

D4: US-A-2004/0215181.

It held that, as far as the main request was concerned, the subject-matter of independent claims 1 and 37 lacked novelty and that independent claims 1, 16 and 27 lacked unity of invention. Auxiliary requests I to VI were not admitted into the proceedings because they belonged "to the group of inventions for which no search fees [had] been paid" and hence, "in line with the decision of the Enlarged Board of Appeal G2/92", the applicant could not pursue that application for the subject-matter in respect of which no search fees had been paid.

- III. The notice of appeal was received on 20 February 2014 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was

received on 21 March 2014.

IV. The Board summoned the appellant to oral proceedings and set out its preliminary opinion in a communication dated 7 January 2015.

V. The appellant filed amended application documents by two letters dated 24 March 2015, following which the oral proceedings were cancelled.

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with letter received on 24 March 2015 at 16.40 hrs.

VII. Claim 1 of the main request, which corresponds in substance to claim 1 of the main request on which the impugned decision was based, reads as follows:

"A catheter for treatment of tissue, the catheter comprising at least one conductive hydrogel virtual electrode adapted to contact the tissue to be treated, wherein said catheter has a distal portion (10^I; 10^{II}; 10^{III}; 10^{IV}; 10^V; 10^{VI}; 10^{VII}) comprising
a straight section (12; 84);
a hoop-shaped section (14; 38; 52; 64; 78; 96; 110);
an offset (16; 82) that joins said straight section to said hoop-shaped section;
an active region (30; 44; 50; 62; 76; 94; 108) along said hoop-shaped section; and
a hydrogel delivery feature (34; 40; 42; 54; 58; 72; 90; 102, 104) along said active region, wherein said hydrogel delivery feature is adapted to be placed against the tissue to be treated and adapted to allow the hydrogel to be alternately forced from and

retracted back into the catheter using a hydrogel displacement device."

Claims 2 to 15 are dependent claims.

VIII. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows:

The main request only comprised 15 claims, which corresponded in substance to claims 1 to 15 of the main request on which the impugned decision was based.

The cited prior art neither disclosed nor rendered obvious a hydrogel delivery feature adapted to allow the hydrogel to be alternately forced from and retracted back into the catheter using a hydrogel displacement device. Hence the main request was allowable.

Reasons for the Decision

1. The appeal is admissible.
2. *The invention*

The invention as defined in claim 1 concerns a catheter comprising an electrode for the treatment of tissue, for example of the type used to treat cardiac arrhythmias by means of ablation. This type of treatment involves the introduction of a catheter into the vascular system of a patient until it reaches the heart, so that lesions can be produced in the tissue of the latter, resulting in scars that cut off the path for undesirable electrical signals.

More particularly, the invention proposes a catheter with a conductive hydrogel as the electrode and with a particular shape of its distal part. According to the application, such a catheter should make it possible to adjust the electrode to the region to be treated, making it particularly effective for treating the region around the opening of the pulmonary vein into the left atrium (paragraph [0007]).

3. *Basis in the original application*

The subject-matter of claim 1 derives from claims 1 and 5 and paragraph [0042], penultimate sentence, of the application as filed. The dependent claims correspond to respective dependent claims of the application as filed.

The Board is satisfied that Article 123(2) EPC is complied with.

4. *Novelty*

The most relevant documents revealed by the international and the supplementary European search reports are D1, D2 and D4.

Document D1 relates to an ablation catheter with a hoop-shaped distal part for creating circumferential lesions in body tissue, specifically adapted for treating the region around the opening of the pulmonary vein into the left atrium (paragraph [0011]). The catheter comprises electrodes (22 in the figures) that may be coated with a porous material, for example a hydrogel (paragraph [0126]). Document D1 does not disclose any hydrogel delivery feature adapted to allow the hydrogel to be alternately forced from and

retracted back into the catheter using a hydrogel displacement device. Moreover, the hydrogel coating of the electrodes, permanently affixed to the latter, cannot be considered as building up "virtual" electrodes within the meaning of claim 1. Hence document D1 is not novelty-destroying for the subject-matter of claim 1.

Document D2 also relates to an ablation catheter with a hoop-shaped distal part for creating circumferential lesions in body tissue, specifically adapted for treating the region around the opening of the pulmonary vein into the left atrium (paragraph [0048]). The catheter shape is similar to that claimed and disclosed in the present application. Furthermore, the catheter of document D2 comprises conductive virtual electrodes consisting of a fluid medium flowing out from portholes of an active region (paragraphs [0046] and [0047], last sentence). However, there is no disclosure of a conductive *hydrogel* virtual electrode, as required by claim 1. The fluid is simply defined as a "conductive fluid medium", e.g. "hypertonic saline" (paragraph [0046]). In its analysis of document D2 in the impugned decision, the Examining Division asserted that "neither the hydrogel nor the displacement device form part of the claimed catheter". However, claim 1 expressly defines a "conductive hydrogel virtual electrode" forming part of the subject-matter for which protection is sought. Hence, document D2 is not novelty-destroying for the subject-matter of claim 1 either.

Document D4 relates to an ablation catheter for creating lesions in body tissue, specifically adapted for treating prostate tissue (paragraph [0028]). The catheter comprises a virtual electrode in the form of a

fluid (paragraph [0033], last sentence), which could be a hydrogel (paragraph [0049]), delivered through openings in an active region (parts 52 and 54 in figure 3, as described in paragraph [0038]). Document D4 does not disclose a distal portion comprising a hoop-shaped section, wherein the active region is along the hoop-shaped section. Hence, document D4 is not novelty-destroying for the subject-matter of claim 1 either.

The Board therefore concludes that the subject-matter of claim 1 is novel within the meaning of Article 54(1) and (2) EPC.

5. *Inventive step*

In the Board's view, document D2 is the closest prior art, since, like the claimed invention, it specifically addresses the treatment of the region around the opening of the pulmonary vein into the left atrium with a catheter having a virtual electrode.

More particularly, document D2 discloses a catheter for treatment of tissue (abstract), the catheter comprising at least one conductive virtual electrode adapted to contact the tissue to be treated (paragraph [0046], second sentence), wherein said catheter has a distal portion (depicted for example in figure 2) comprising a straight section (section 32), a hoop-shaped section (section 38), an offset (sections 34 and 36) that joins said straight section to said hoop-shaped section, an active region (where portholes 40, 42 and 44 are located) along said hoop-shaped section and a fluid delivery feature (portholes 40, 42 and 44) along said active region, wherein said fluid delivery feature is adapted to be placed against the tissue to be treated and is adapted to allow the fluid to be alternately

forced from and retracted back into the catheter using a fluid displacement device (the mere presence of the openings connected with a catheter lumen makes this possible in view of the fact that the displacement device does not form part of the claimed subject-matter, as also convincingly argued by the Examining Division in the impugned decision).

The subject-matter of claim 1 differs from the disclosure of document D2 in that the conductive virtual electrode is in the form of a hydrogel electrode.

According to the description, this has the effect that during treatment no appreciable amount of treatment fluid, i.e. the hydrogel, enters the patient's bloodstream (paragraph [0042], fifth sentence). The introduction of a large amount of conductive fluid into bloodstream may have detrimental effects on the patient (paragraph [0008]).

Hence, also according to the present application, the problem to be solved is reducing detrimental side-effects of the treatment on the patient.

Document D2 does not recognise any side-effects caused by the introduction of conductive fluid into the patient. On the contrary, it stresses the advantages of having a flow of fluid in the treatment region (paragraph [0059]).

The only cited document disclosing a virtual electrode in the form of a hydrogel is document D4. However, the latter is concerned with delivering an anaesthetic during prostate ablation treatment (paragraph [0033]) and the reason why a hydrogel is proposed is to provide

a controllable flow out of the distal end of the catheter, apparently in order to correctly deliver the anaesthetic to the target region (paragraph [0034]). In any case, during prostate ablation of the kind disclosed in document D4 the problem of introducing fluid into the patient's bloodstream does not arise, since the ablation is performed from within the urethra (paragraph [0028]) and not within a blood vessel.

Therefore it has to be concluded that the skilled person would have no incentive to combine the teaching of documents D2 and D4.

Hence, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

6. *Unity of invention*

The main request comprises 15 claims, with a single independent claim defining novel and inventive subject-matter. These claims relate to the invention searched by the Search Division when it drew up the supplementary European search report.

It follows that the requirement of unity of invention under Article 82 EPC is fulfilled.

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:
 - claims 1 to 15 of the main request filed with letter received on 24 March 2015 at 16.40 hrs;
 - description pages 1 to 19 filed with letter received on 24 March 2015 at 14.39 hrs;
 - drawing sheets 1/11 to 11/11 of the application as originally filed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated